

ABL800 FLEX operator's manual

ABL800 FLEX
operator's
manual

What is new in this manual?

Update for software version 6.16

This manual has been updated with a new third-party software and trademarks statement.

Operator's manual

Note to users of ABL800 FLEX and ABL800 BASIC analyzers

| | |
|--|---|
| Introduction | This note tells about the changes in the operator's manual for software version 6.14. |
| Instructions to users | <p>Replace the date-of-issue page and the front page in your binder with the corresponding pages in this document. Place all the remaining pages of this document in the front of your binder.</p> <p>The contents of this document will be included in the manual the next time the manual is updated.</p> |
| New sample types | <p>The "Cord Blood" sample type has been split into two types: "Cord Blood Venous" and "Cord Blood Arterial". This was done to distinguish between arterial and venous cord blood.</p> <p>In previous versions of the software, the sample type "Cord Blood" was based on venous cord blood. The sample type for venous cord blood is now called "Cord Blood Venous" and cord blood measurements done before the installation of software version 6.14 will now be named "Cord Blood Venous".</p> |
| Change to how values that lie outside the reportable ranges are shown | <p>Results that lie outside the reportable ranges of the analyzer are by default shown without any values on the Patient Result screen and in printed results. These results are not transmitted to connected LIS/HIS systems.</p> <p>It is now possible to show values of results that are outside the reportable range as less than the lower limit of the reportable range or greater than the upper limit of the reportable range. For example, for pH with a reportable range of 6.300-8.000, the values can now be shown as <6.300 or >8.000.</p> <p>Contact your local Radiometer representative if you want to make use of this feature.</p> |
| Confirmation of requested demographics | <p>If your analyzer is set up to request data automatically from a LIS/HIS or data management system, you can now set up the analyzer to ask for confirmation of the requested data before it is included in the Patient Identification screen.</p> |

To set up confirmation of data

1. Press *Menu – Utilities – Setup – General Setup – Communications – Automatic Data Request*.
2. Press the check button in the "Confirmation of Demographics" box.
NOTICE: Make sure that a check mark is shown in the check button.
3. Press *Close*.

For more general information about the automatic data request, see *Automatic data*

request in chapter 3: *Installation and setup*.

Critical Limit Notification

In some countries it is required that physicians are notified when patient results lie outside critical limits. To meet this request, a new feature “Critical Limit Notification” has been implemented in the software.

If this feature is enabled, a notification procedure is necessary before results with values that lie outside critical limits can be transmitted to external systems and printed automatically. The results are pending until a notification procedure is done. The results can be seen in the ***Pending Results Log***.

To enable critical limit notification

1. Press ***Menu – Utilities – Setup – General Setup – Miscellaneous Setup***.
2. Highlight the option “Enable Critical Limit Notification” and press the check button beside it.
NOTICE: Make sure that a check mark is shown in the check button.
3. Press ***Close***.

If a print of the result is needed, you can make a print from the **Notification** screen. The printout will tell you that the notification is pending.

To use the critical limit notification feature

1. Choose an option and follow the steps for it.

| Option | Steps |
|--|---|
| If a pop-up window notifies the user that the result has values that lie outside critical limits. | Go to step 2. |
| If an exclamation mark is shown on the <i>Data Logs</i> button. NOTICE: For ABL800 FLEX analyzers with the FLEXQ module, an exclamation mark is also shown on the result button for samplers still in the tray. | <ol style="list-style-type: none">a. Press <i>Data Logs – Pending Results Log</i>.b. Highlight a result.c. Press <i>Result</i>. NOTICE: A pop-up window notifies the user that the result has values that lie outside critical limits. |

2. Press inside the message to close the pop-up window.
3. Press ***Notification***.
4. See the values that are outside critical limits.
NOTICE: If it is not necessary to notify about the values, for example if the measurement is calibration verification or a proficiency test, you can press ***Not Needed***.
5. Call the physician or person responsible for the treatment and tell them about the values.
6. Fill in the data fields on the screen.
7. Press ***Accept***.

Pending Results Log A new log called *Pending Results Log* has been added to the data logs. This log contains the following results:

- Results that need to be notified about
- Results that need to be approved
- Results that need mandatory input

Results in the *Pending Results Log* are filtered from the *Patient Results Log*. Results in the log are pending until they have been dealt with.

To access the Pending Results Log

Press *Data Logs – Pending Results Log*.

How to see if results are pending

If results are pending, an exclamation mark is shown on the *Data Logs* button. For ABL800 FLEX analyzers with the FLEXQ module, an exclamation mark is also shown on the result button in the **Ready** screen.

New input fields in patient report layout New notification-related fields can be added to the patient report layout:

- Notified Whom
- Notified Time
- Notified By
- Notification Status
- Notification Note

For information about how to include these items in a patient report layout, see *Editing patient ID layout* in chapter 3: *Installation and setup*.

Alignment of the acid-base chart with current standards Some of the explanations in the acid-base chart have been changed to be in alignment with current standards.

| Letter | Old text... | Changed to... |
|---------------|-----------------------------|-------------------------------|
| A | acute hypercapnia | acute respiratory acidosis |
| B | chronic hypercapnia | chronic respiratory acidosis |
| C | chronic metabolic alkalosis | Not changed |
| D | acute hypocapnia | acute respiratory alkalosis |
| E | chronic hypocapnia | chronic respiratory alkalosis |
| F | chronic metabolic acidosis | Not changed |
| G | acute metabolic acidosis | Not changed |
| N | normal area | Not changed |

For more general information about the acid-base chart, see section *Acid-Base Chart* in chapter 4: *Sample measurements*.

What to do if the electrode sealing ring falls off If the sealing ring at the bottom of the pH, $p\text{CO}_2$, $p\text{O}_2$, Glucose, Lactate and Crea electrode falls off, you must contact your Radiometer representative to get it mounted again.

Step 2 in the procedure *Remembraning an electrode* should, therefore, read:

2. All electrodes:

Rinse the electrode with tap water and shake to remove excess drops of water. Do not dry the electrode.

Further for $c\text{K}^+$, $c\text{Cl}^-$, $c\text{Ca}^{2+}$, $c\text{Na}^+$ and reference electrodes:

Remove any salt deposits, using tap water.

Further for pH, $p\text{CO}_2$, $p\text{O}_2$, Glucose, Lactate and Crea electrodes:

If the sealing ring at the bottom of the pH, $p\text{CO}_2$, $p\text{O}_2$, Glucose, Lactate or Crea electrode falls off, contact your Radiometer representative to get it mounted again.

The type of replacement done must be selected before you exit the Hold mode

When you do electrode replacements, you must select the type of replacement that you have done before you can exit the **Hold** mode.

If no replacement was done, you can select the option “No Replacements Done”.

Disposal of non-refillable gas cylinders

Non-refillable gas cylinders must be disposed of in accordance with local and national regulations.

Automatic backup to USB memory stick

The analyzer can be set up to automatically back up data and system files to a USB memory stick.

To set the analyzer up for automatic backups to USB memory sticks

1. Connect the USB memory stick to a USB port at the rear of the analyzer.
2. Press *Menu – Utilities – Setup – General Setup – Disk Functions Setup – Automatic Backup*.
3. Press the check button in the “Auto backup” box.
NOTICE: Make sure that a check mark is shown in the check button.
4. Select the time for the automatic backup and the interval between subsequent backups.
5. Press the drive icon in the “Destination:” box.
6. Select the USB memory stick drive.
7. Press *Back - Close*.

For more general information about the automatic backup, see *Automatic Backup* in chapter 3: *Installation and setup*.

Link to patent numbers

Patents have been updated.

See <http://www.radiometer.com/en/legal/patents> for patent information.

New symbols on the analyzer New symbols are shown on the analyzers.

| Symbol/icon | Explanation |
|---|---|
|  | Mark compliance with SJ/T 11363-2006 (China RoHS). The number in the symbol shows the environmentally friendly use period in years. |
|  | Marks compliance with SJ/T 11363-2006 (China RoHS). The product contains no restricted substances above the prescribed thresholds. |

Approval and patents In the section *Approvals and patents* in chapter 13: *Specifications*, the text in the topic *Approvals* should read:

The equipment complies with the following standards:

- UL 61010-1: Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements
- IEC 61010-2-81: Electrical Equipment for Laboratory Use; Particular requirements for automatic and semiautomatic laboratory equipment for analysis and other purposes
- IEC 61010-2-101: Electrical Equipment for Measurement, Control, and Laboratory Use; Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Laser specifications The ABL800 FLEX and BASIC analyzers contain 3 lasers which are in compliance with international standard (IEC 60825-1 Safety of laser products) and US requirements (21 CFR 1040.10 - LASER PRODUCTS).



Note to users of the ABL800 FLEX analyzers

Introduction

This note to users gathers changes from previous note to users in one document and outlines some new changes to the operator's manual of your ABL800 FLEX analyzer (from software version 6.10).

Instructions to user

Please remove the existing note to users from the binder of your manual and place this note to users in the binder instead.

Brief overview of the change

| Changes/Description | | | | | |
|--|--|--------------|--------------|--------------------------|---|
| Interference – new interference results for ClO_4^- | Limitations of use and known interfering substances:  CAUTION - Known interfering substances | | | | |
| | <table border="1"> <thead> <tr> <th>Substance</th> <th>Interference</th> </tr> </thead> <tbody> <tr> <td>ClO_4^- (drugs)</td> <td> For ClO_4^-, interference on $c\text{Ca}^{2+}$ (1.25 mmol/L level), $c\text{Cl}^-$ (110 mmol/L level), and $c\text{K}^+$ (4 mmol/L level) has been detected: $c\text{Ca}^{2+}$ (1.25 mmol/L level): -0.27* $c\text{Cl}^-$ (110 mmol/L level): 4-30 $c\text{K}^+$ (4 mmol/L level): -0.3. </td> </tr> </tbody> </table> | Substance | Interference | ClO_4^- (drugs) | For ClO_4^- , interference on $c\text{Ca}^{2+}$ (1.25 mmol/L level), $c\text{Cl}^-$ (110 mmol/L level), and $c\text{K}^+$ (4 mmol/L level) has been detected: $c\text{Ca}^{2+}$ (1.25 mmol/L level): -0.27* $c\text{Cl}^-$ (110 mmol/L level): 4-30 $c\text{K}^+$ (4 mmol/L level): -0.3. |
| | Substance | Interference | | | |
| ClO_4^- (drugs) | For ClO_4^- , interference on $c\text{Ca}^{2+}$ (1.25 mmol/L level), $c\text{Cl}^-$ (110 mmol/L level), and $c\text{K}^+$ (4 mmol/L level) has been detected: $c\text{Ca}^{2+}$ (1.25 mmol/L level): -0.27* $c\text{Cl}^-$ (110 mmol/L level): 4-30 $c\text{K}^+$ (4 mmol/L level): -0.3. | | | | |
| * Depending on the pH level | | | | | |
| USB connector | Instead of the CD-ROM drive, a USB connector may be available. <div style="display: flex; align-items: center;"> <div style="margin-right: 20px;"> USB connector or CD-ROM drive </div>  </div> <p>The USB connector can be used for storing data on a USB flash drive (memory stick) or for connecting USB devices. Can also be used for installation of software.</p> | | | | |

| | | | |
|----------------------------|---|-----------------|------------------------|
| Measured parameters | New table for pleural liquid: | | |
| | Parameter | Unit | Measuring Range |
| | pH | pH scale | 6.300-8.000 |
| | | | 7.0-7.5* |
| | * If the measured values obtained lie outside the test range, Radiometer advises you to repeat the measurement by means of another method. | | |
| Environmental requirements | Indoor use statement added according to CSA regulations: | | |
| | Location | Indoor use only | |
| Environmental ratings | Pollution degree 2 statement added according to CSA regulations: Installation category II. Pollution degree 2. | | |
| Clot detection | <p>A new feature is included in software version 6.06 of the following products:</p> <ul style="list-style-type: none"> • ABL7xx Series (XPE) analyzers • ABL800 FLEX analyzers • ABL800 BASIC analyzer. <p>The new feature enables the analyzer to detect clots caught in the measurement chamber under the pH electrode. This document describes it.</p> <p>When to activate the clot-detection feature</p> <p>It is especially beneficial to activate the clot detection feature in analyzers frequently used to analyze samples known to be prone to clotting, for example, samples drawn from umbilical cords. Once activated clot detection is active during all sample measurements.</p> <p>NOTICE: It is important to note that activating the feature will delay measurement results by approximately one minute, even though it only increases the measurement cycle time by five seconds. It also increases consumption of Rinse solution, but this is minimal.</p> | | |

| <p>To activate the clot-detection feature</p> <p>Contact a Radiometer representative and request that clot detection be enabled via the service program.</p> <p>Clot-detection process</p> <p>During calibration the measuring chamber is rinsed and the pH of the Rinse solution is measured. The value is stored in the analyzer.</p> <p>During a sample measurement the measuring chamber is also rinsed and the pH of the rinse solution is measured and compared with the pH value stored during the last calibration. If the difference between these values (the pH drift) exceeds a pre-determined maximum value, it could indicate the presence of a clot beneath the pH electrode.</p> <p>When enabled, the clot-detection feature can generate three new messages that are listed below.</p> <p>Analyzer messages</p> <p>NOTICE: Operator actions are listed in order of priority. Perform the first action in the list and the actions indicated in the "Removal condition(s) list. If the message persists, perform the next listed action and the actions indicated in the "Removal condition(s) list, and so on.</p> | | | |
|---|--------------------------------------|---|--|
| No. | Message | Interpretation | Operator action(s) |
| 1025 | Clot suspected beneath pH electrode* | <p>The difference between the pH of the rinse solution, measured during the sample measurement, and that stored after the last calibration exceeds the maximum allowable drift.</p> <p>This indicates the presence of a clot in the measuring chamber beneath the pH electrode.</p> | <ul style="list-style-type: none"> – Remove the pH electrode and check the measuring chamber for clots: clean the measuring chamber with a cotton stick moistened with distilled water. Make sure no cotton fibers are left in the measuring chamber – Clean pH electrode – Membrane Ref electrode – Replace pH electrode <p>Perform a 1- or 2-point calibration</p> <p>Removal condition(s):</p> <ul style="list-style-type: none"> – Acknowledge execution of the "Clot removal procedure" – Successful 1- or 2-point calibration |
| * NOTICE: This is a system message. | | | |

| | | | |
|------|-------------------------------------|--|--|
| 1026 | Clot (pH) detection not possible | The pH of the rinse solution - stored during the latest calibration - was invalidated when either the Rinse solution was replaced, or when maintenance was performed on an electrode. A new pH value needs to be established by performing a calibration. | <ul style="list-style-type: none"> – Perform a 1- or 2-point calibration. <p>Removal condition(s):</p> <ul style="list-style-type: none"> – Successful 1- or 2-point calibration. |
| 1027 | Clot suspected beneath pH electrode | The difference between the pH of the rinse solution, measured during the sample measurement, and that stored after the last calibration exceeds the maximum allowable drift. This indicates the presence of a clot in the measuring chamber beneath the pH electrode. | <ul style="list-style-type: none"> – Remove the pH electrode and check the measuring chamber for clots: clean the measuring chamber with a cotton stick moistened with distilled water. Make sure no cotton fibers are left in the measuring chamber – Clean pH electrode – Remembrane Ref electrode – Replace pH electrode <p>Perform a 1- or 2-point calibration</p> <p>Removal condition(s):</p> <ul style="list-style-type: none"> – Acknowledge execution of the "Clot removal procedure" – Successful 1- or 2-point calibration |

| | | |
|---|-------------|--|
| Acknowledging execution of a "Clot-removal procedure" | Step | Action |
| | 1. | Press <i>Analyzer status > Electrodes and others.</i> |
| | 2. | Press <i>Replace.</i> |
| | 3. | Press <i>Clots removed.</i> |

Technical documentation

Data in this document will be added to the manual next time it is updated.



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ABL800 FLEX

Operator's manual

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System performance

The procedures described in this manual must be observed in order to ensure proper system performance, and to avoid hazards.

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Date of issue

1. Introduction

Overview

| | | | | | | | | | |
|---|--|-----------------------------|-----|---|-----|-----------------------------------|-----|------------------------|-----|
| Introduction | <p>The chapter briefly describes the intended use of the analyzer, lists all measured parameters and the substances known to interfere with the measurements, and explains the different notices that appear in the manual.</p> <p>Throughout this manual, "ABL800 FLEX analyzer" is used for all ABL8xx FLEX analyzers, i.e.: ABL837/835/830/827/825/820/817/815/810/805 and ABL810 BG only.</p> <p>The abbreviation "ABL8x7 FLEX analyzer" is used for the ABL837/27/17 FLEX analyzers throughout this manual.</p> | | | | | | | | |
| Contents | <p>This chapter contains the following topics.</p> <table><tr><td>Names and intended use.....</td><td>1-2</td></tr><tr><td>Limitations of use and known interfering substances</td><td>1-4</td></tr><tr><td>Warning/Caution and Notices</td><td>1-7</td></tr><tr><td>Symbols overview</td><td>1-8</td></tr></table> | Names and intended use..... | 1-2 | Limitations of use and known interfering substances | 1-4 | Warning/Caution and Notices | 1-7 | Symbols overview | 1-8 |
| Names and intended use..... | 1-2 | | | | | | | | |
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Names and intended use

| | | |
|--------------|-------------------|---|
| Names | Proprietary name: | ABL800 FLEX blood gas, oximetry, electrolyte and metabolite analyzer. |
| | Common name: | Blood gas, oximetry, electrolyte and metabolite measuring system. |

Intended use The ABL800 FLEX analyzers are intended for:

- In Vitro testing of samples of whole blood for the parameters pH, pO_2 , pCO_2 , cK^+ , cNa^+ , cCa^{2+} , cCl^- , $cGlu$, $cLac$, $cCrea$, $ctBil$, and co-oximetry parameters ($ctHb$, sO_2 , and the hemoglobin fractions FO_2Hb , $FCOHb$, $FMetHb$, $FHHb$ and $FHbF$)
- in vitro testing of samples of expired air for the parameters pO_2 and pCO_2
- in vitro testing of pleura samples for the pH parameter.

The following parameters can be measured on blood:

| Parameter group | Parameters |
|-----------------|--|
| pH/blood gas: | pH (acidity) |
| | pCO_2 (carbon dioxide tension) |
| | pO_2 (oxygen tension) |
| Oximetry: | $ctHb$ (total hemoglobin concentration) |
| | sO_2 (oxygen saturation) |
| | FO_2Hb (fraction of oxyhemoglobin in total hemoglobin) |
| | $FCOHb$ (fraction of carboxyhemoglobin in total hemoglobin) |
| | $FHHb$ (fraction of deoxyhemoglobin in total hemoglobin) |
| | $FMetHb$ (fraction of methemoglobin in total hemoglobin) |
| | $FHbF$ (fraction of fetal hemoglobin) |
| Electrolytes: | cK^+ (potassium ion concentration) |
| | cNa^+ (sodium ion concentration) |
| | cCa^{2+} (calcium ion concentration) |
| | cCl^- (chloride ion concentration) |
| Metabolites: | $cGlu$ (D-glucose concentration) |
| | $cLac$ (L(+)-lactate concentration) |
| | $ctBil$ (concentration of total bilirubin, measurement in plasma is possible, see <i>Limitations of use</i> later in this chapter) |
| | $cCrea$ (concentration of creatinine, measurement on plasma and serum possible, see <i>Limitations of use</i> later in this chapter) |

Continued on next page

Names and intended use, *Continued*

Intended use (continued) The following parameters can be measured on pleura samples:

| Parameter group | Parameters |
|-----------------|--------------|
| Measured value | pH (acidity) |

The following parameters can be measured on expired air samples:

| Parameter group | Parameters |
|-----------------|---|
| Measured values | pCO ₂ (carbon dioxide tension) |
| | pO ₂ (oxygen tension) |

Derived parameters are listed in *chapter 13: Specifications* and described in detail in the Reference Manual, *chapter 6*.

Requirement to the operator The analyzer should be used by personnel who have received special education and training with regard to procedures utilizing in vitro diagnostic medical devices.

Measurements on animal blood Animal blood has not been tested on the ABL800 FLEX analyzer. Some components in animal blood differ from those in human blood, and variations in the composition of blood from different animal species may also exist.

FLEXMODE This mode allows you to analyze a blood sample of 35 µL and higher – up to the maximum volume accepted by your analyzer. Depending on the available sample volume, the FLEXMODE provides the highest number of parameters: from all available to as many as reliably possible.

This mode is not available in the ABL8x7 FLEX analyzers.

Measurements on pleural fluids Pleura pH can be measured on pleural fluids. Corrections are present in the device.

Other fluids mode All parameters available on your ABL800 FLEX analyzers can be measured on fluids other than heparinized human whole blood

NOTICE: Before using this mode you must establish "user-defined corrections" for each parameter used, on the fluid in question. The corrections assume a linear correlation between the measured value and the reference instrument. The data used for establishing "user-defined corrections" have to cover the desired measuring range. If no user-defined corrections are entered, you will measure in this mode as if on heparinized human whole blood.

FLEXQ module The FLEXQ module can accommodate up to three samplers simultaneously. It reads a sampler's barcode, mixes the sample and transports the sampler to the inlet for aspiration and analysis without any further assistance from the operator. Results can be delivered via FLEXLINK (for information refer to the *RADIANCE Installation and Setup Manual*).

NOTICE: The model ABL810 can also be ordered without oximetry parameters: as ABL810 BG only.

Limitations of use and known interfering substances

Limitations of use

The following limitations should be taken into consideration:

The ABL800 FLEX analyzers are designed for measurements of adult and fetal hemoglobin with normal spectrum characteristics. Some spectra deviate from the normal characteristics, e.g. for certain hemoglobinopathies and the ABL800 FLEX analyzers do not compensate for this.



CAUTION - Fulfillment of user-specific analytical needs

The user should review the analyzer performance data to assure that the performance fulfills the user-specific analytical needs.



WARNING – Clinical decisions

The validity of the test results from this instrument must be carefully examined by a clinician and related to the patient's clinical condition, before any clinical decisions are taken on the basis of the test results.



CAUTION - Risk of erroneous results

Always meticulously follow the sampling procedures described in *chapter 12: Sampling*. Failure to follow these procedures may introduce clots or air bubbles in the sample and yield erroneous results.

NOTICE: Bilirubin measurements on plasma and creatinine measurements on plasma and serum need to be measured in Other fluids mode, as the other modes are intended for measurement on human whole blood only. Corrections for Creatinine can be found in the Reference Manual.

FHbF measurement:

The uncertainty in *FHbF* measurements exceeds the level required to measure normal HbF levels in the adult range (*FHbF* reference range is 0-1 %).



CAUTION - Known interfering substances

The following substances are known to affect or interfere with measurements on the ABL800 FLEX analyzers.

| Substance | Interference |
|---|--|
| Halothane (anesthetic) | May give unreliable pO_2 results. |
| Lipid therapy (treatment) | In OXI measurements. After measurement on blood from a patient who has received lipid therapy it may be necessary to clean the analyzer using the Cleaning program. |
| Methylene Blue, HiCN (medication) | In OXI measurements. |
| Anions: Br^- , I^- , S^{2-} and ClO_4^- (drugs) | Erroneously high cCl^- results. |

Continued on next page

Limitations of use and known interfering substances, *Continued*



**CAUTION -
Known
interfering
substances
(continued)**

| Substance | Interference |
|---|---|
| Anticoagulants (sampling) | <p>Anticoagulants that contain sodium salts will give erroneously high cNa^+ results. Sodium fluoride with or without EDTA and oxalate (di Na) influence $cGlu$ results. Sodium fluoride gives erroneously high cNa^+ and low cCa^{2+}, $cGlu$ and $cLac$ results. Tri sodium citrate influences cNa^+, cK^+ and $cGlu$ results.</p> <p>Thus Radiometer recommends the exclusive use of heparin as anticoagulant. Solutions containing organic preservatives may damage the ion-selective membranes of the cK^+ and $cGlu$ electrodes when introduced into the analyzer.</p> <p>Do not use EDTA, as it leads to erroneous pH, pCO_2, cNa^+, cK^+ and cCa^{2+} results. Use of EDTA will also affect subsequent measurements on the Ca electrode and it will reduce the lifetime of this electrode.</p> |
| Thiocyanic acid (degradation product from treatment with nitroprussid. Also produced in thiosulphate treatment of cyanide poisoning) | Erroneously high $cGlu$ and $cLac$ measurements. |
| Glycolic acid (ethyleneglycol degradation product) | Erroneously high $cLac$ measurements. |
| <p>Insufficiently stabilized blood.</p> <p>Caustic fluids (e.g. strong acids or bases, detergents, etc.).</p> <p>Fluids that precipitate.</p> <p>Fluids that affect the sensor enzymes.</p> <p>Fluids that form complexes with the analyzer solutions (calcium).</p> <p>High viscosity fluids.</p> <p>Hydrophobic fluids.</p> <p>Reactive fluids.</p> | <p>Other fluids mode allows you to measure on fluids other than heparinized human blood.</p> <p>Be aware that some substances, such as listed in the left column, measured in the Other fluids mode may damage the instrument or the electrodes. This can affect the subsequent measurement on human blood or quality control solutions.</p> |

Continued on next page

Limitations of use and known interfering substances, *Continued*



**CAUTION -
Known
interfering
substances
(continued)**

| Substance | Interference |
|--|--|
| Carboxymethyl cellulose (CMC) | Some auto-venting arterial blood samplers contain carboxymethyl cellulose (CMC) in the porous vent. CMC can dissolve into the sample and give erroneously low cCa^{2+} results. Therefore we recommend Radiometer accessories together with our analyzers, e.g. the <i>safePICO</i> arterial blood sampler which is specifically designed to minimize sample contamination with CMC. |
| Galactose, glucosamine, maltose, mannose, xylose | Erroneously high $cGlu$ measurements. |

For detailed information – see *Interference Tests* in chapter 5 of the *ABL800 FLEX Reference Manual*.

Warning/Caution and Notices

Definitions

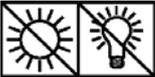
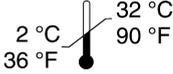
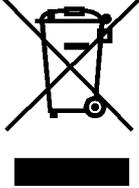
Throughout the manual, the various procedures may contain operational cautions and warnings, which are important and should be read carefully before performing the related procedures. The manual also contains a number of **NOTICES**.

The following table indicates the type of information given in Warnings, cautions and notes.

| Symbol | Explanation |
|---|--|
|  | <p>WARNING</p> <p>A warning alerts the reader about a situation, which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards. The designation of a hazard alert as a "warning" is reserved for the most significant problems. The term WARNING is generally used as signal word for this type of hazard alert.</p> |
|  | <p>CAUTION</p> <p>The term precaution is used for the statement of a hazard alert that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or the patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse. The word CAUTION is generally used as signal word for a precaution statement.</p> |
| | <p>NOTICE</p> <p>Notices give practical information.</p> |

Symbols overview

List of symbols The symbols below are used by Radiometer.

| Symbol | Explanation |
|---|---|
|  | Biohazard |
|  | Expiry date |
|  | See instructions for use |
|  | For In Vitro Diagnostic Use |
|  | Lot number |
|  | Sensitive to light. Store in a dark place. |
| REF | Code number |
|  | For single use only |
|  | Sterilized by ethylene oxide |
|  | Sterilized by irradiation |
|  | Storage temperature from 2 °C to 32 °C (36 °F to 90 °F) |
|  | <p>Waste of Electrical and Electronic Equipment (WEEE)</p> <p>The symbol indicates that:</p> <ul style="list-style-type: none"> • Radiometer Medical ApS and its distributors within the European Union (EU) and associated states have taken the necessary steps to comply with the directive, 2002/96/EC on waste electrical and electronic equipment (WEEE). • The instrument, when reaching its end of life, must be collected and recycled separately from other waste according to national requirements. Please contact your local Radiometer distributor for instructions. <p>Environmental implications: WEEE contains materials that are potentially hazardous to the environment and to human health.</p> |

2. What is what

Overview

Introduction The ABL800 FLEX analyzer is a complete unit comprised of several different modules each performing a specific function and controlled by comprehensive software. The modules are collected into well-defined sections according to their related function.

This chapter describes the basic parts of the ABL800 FLEX analyzer and its software.

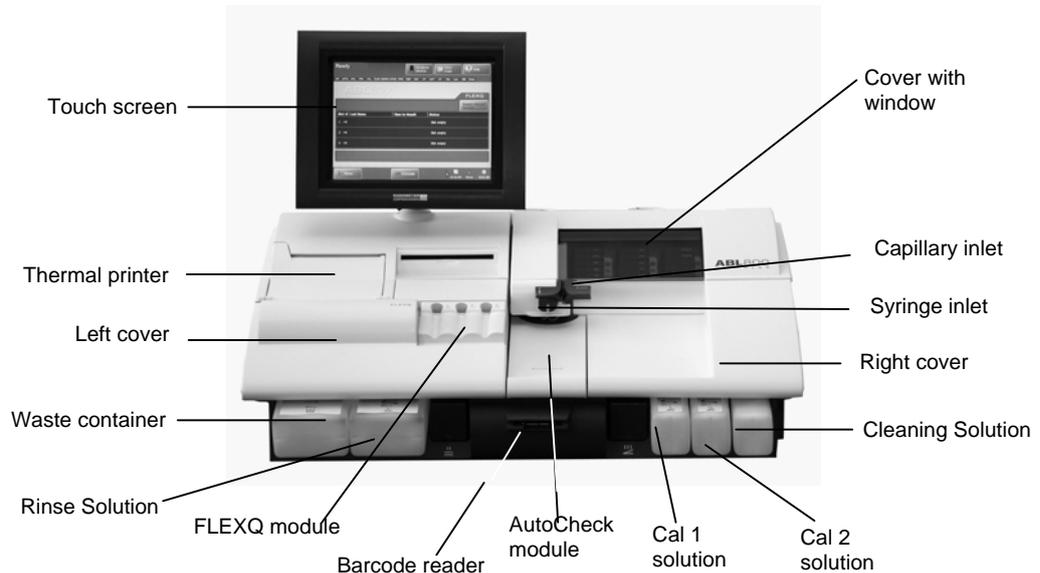
Contents This chapter contains the following topics.

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|-----------------------------|------|
| Analyzer - front | 2-2 |
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| Menu structure | 2-24 |
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Analyzer - front

Parts and functions

The components of the analyzer front (with covers) is shown below.



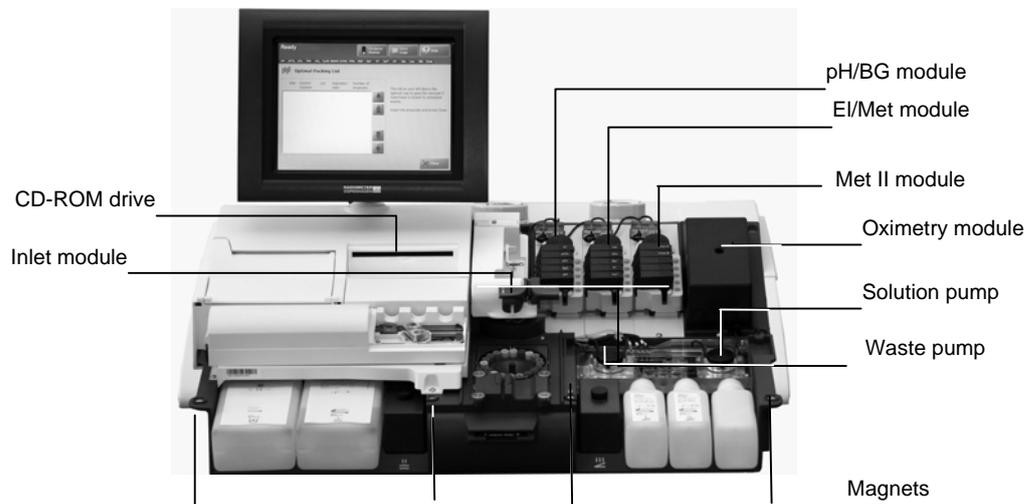
| Part | Function |
|----------------------|--|
| Color touch screen | 10.4" LCD for operation and management of the analyzer. |
| Thermal printer | For automatic printout of data. |
| Left cover | To access the waste container/Rinse Solution. |
| Waste container | For waste collection. A sensor detects when container is full, and a message is displayed on the screen. |
| Rinse Solution | For rinsing the liquid transport system after various analyzer activities. |
| FLEXQ module | See <i>FLEXQ module</i> in this chapter. |
| Barcode reader | See <i>Barcode reader</i> in this chapter. |
| AutoCheck module | See <i>AutoCheck module</i> in this chapter. |
| Cal 1 Solution | For performing 1- and 2-point calibrations. |
| Cal 2 Solution | For performing 2-point calibrations. |
| Cleaning Solution | For cleaning the liquid transport system of lipid deposits. |
| Right cover | To access solutions and pumps – see overleaf. |
| Syringe inlet flap | Lift to introduce syringe samples and quality control solutions. |
| Capillary inlet flap | Lift to introduce capillary samples. |
| Cover with window | See <i>Measuring Section</i> in this chapter. |

Continued on next page

Analyzer - front, *Continued*

Parts and functions (*continued*)

The components of the analyzer front (without covers) is shown below.



| Part | Function |
|---|--|
| Inlet module | Accepts samples from a syringe/test tube or a capillary – see <i>Inlet Module</i> in this chapter. |
| CD-ROM drive | For storing data on a CD-RW disk or retrieving data from a CD (e.g. installation software). |
| <p>⚠ CAUTION – <i>Installation of correct software</i></p> <p>Install only software which is strictly intended for use with the analyzer. Installation of other types may affect analyzer performance.</p> | |
| pH/Blood Gas (BG) module | Measures pH, pO_2 , pCO_2 and cCl^- . See measuring component detail. |
| Electrolyte/Metabolite (EI/Met) module | Measures cCa^{2+} , cK^+ , cNa^+ , $cGlu$ and $cLac$. See measuring section detail. |
| Met II module | Measures creatinine. (Only available for the ABL8x7 FLEX analyzers) |
| Oximetry (Oxi) module | Measures $ctHb$, sO_2 , $FHHb$, FO_2Hb , $FCOHb$, $FMetHb$, $FHbF$ and $ctBil$. See measuring component detail. |
| Solution pump | Transports solutions through the liquid transport system. |
| Waste pump | Transports liquid to the waste container. |
| Magnets | Hold the covers in place. |

Analyzer - rear

Parts and functions

The parts and components of the analyzer's rear panel are shown below.

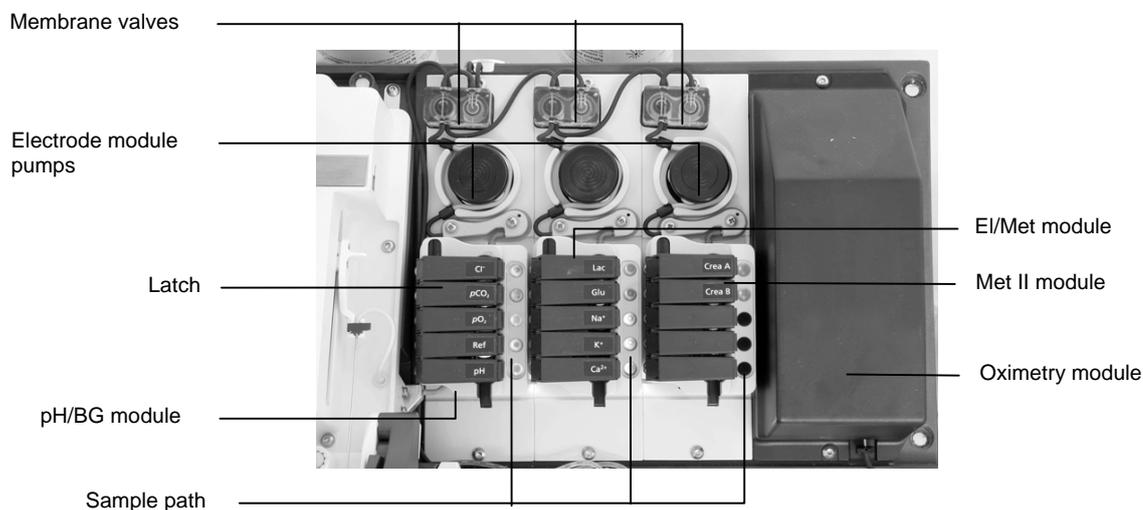


| Part | Function |
|---------------------|--|
| Gas 1 cylinder | Contains a gas mixture of 5.61 % CO ₂ , 19.76 % O ₂ ; balance 74.64 % N ₂ . |
| Gas 2 cylinder | Contains a gas mixture of 11.22 % CO ₂ , < 0.04 % O ₂ ; balance > 88.74 % N ₂ . |
| Fan | For cooling internal components. |
| Gas cylinder socket | For mounting the gas cylinders. |
| Communication ports | See section <i>Communication Ports</i> in this chapter. |
| Power switch | For turning the analyzer on (position I) and off (position O). |
| Power socket | For connecting the power cord. In USA: If source is 120 V, use Radiometer cord 615-403 with parallel blade attachment plug. If source is 240 V, use Radiometer cord 615-405 with tandem blade attachment plug. |

Measuring section

Parts and functions

The modules and components of the measuring section are shown below.



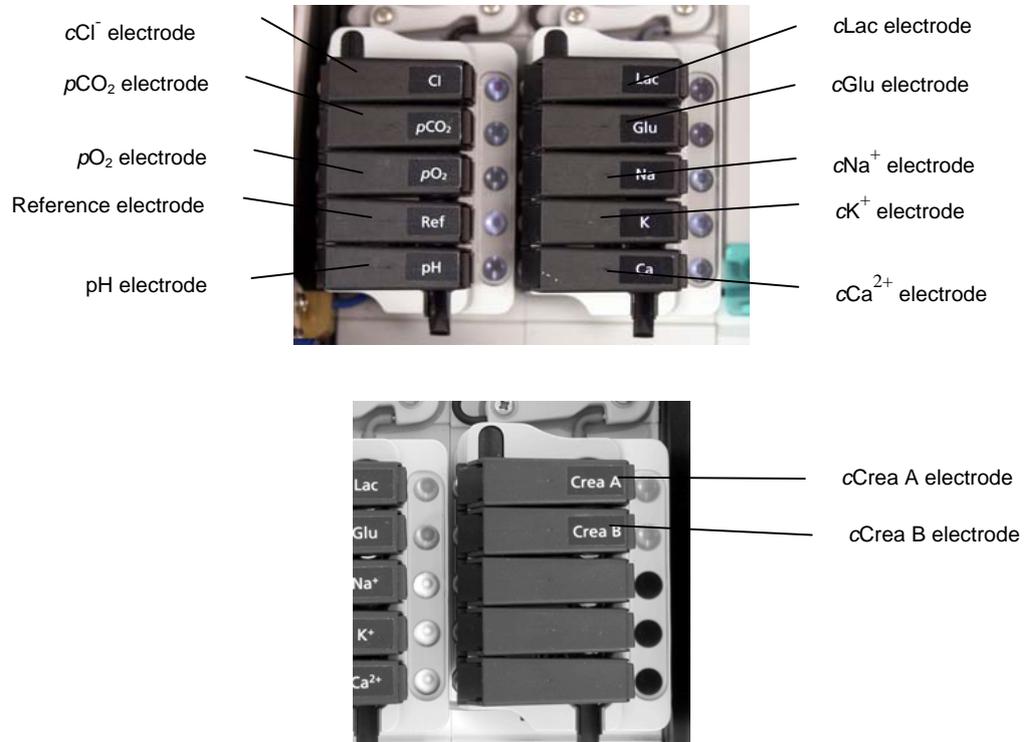
| Part | Function |
|------------------------|---|
| Membrane valves | Control the flow of gas and solutions into the measuring modules. |
| Electrode module pumps | Transport solutions and gas mixtures through the measuring modules. |
| Latch | Establishes electric contact between the electrode in the measuring chamber and the electrode amplifier. To access an electrode, push inwards on the upper portion of the latch, and lift upwards. |
| Sample path | Transports samples, solutions and gas mixtures. |
| pH/BG module | Contains the measuring chamber with the pH, reference, pCO_2 , pO_2 and cCl^- electrodes. |
| EI/Met module | Contains the measuring chamber with the cCa^{2+} , cK^+ , cNa^+ , $cGlu$, and $cLac$ electrodes (a filter is installed for the $cGlu$ and $cLac$ electrodes). |
| Met II module | Contains the measuring chamber with the $cCrea A$ and $cCrea B$ electrodes (Only available for the ABL8x7 FLEX analyzers) |
| Oximetry module | Contains the hemolyzer with glass cuvette, spectrophotometer for measuring $ctHb$, sO_2 , $FHHb$, FO_2Hb , $FCOHb$, $FMetHb$, $FHbF$, $ctBil$ on 128 wavelengths, and the lamp unit. |

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Measuring section, *Continued*

Electrode locations

The electrodes are located in the electrode modules as follows:



The table below describes each electrode.

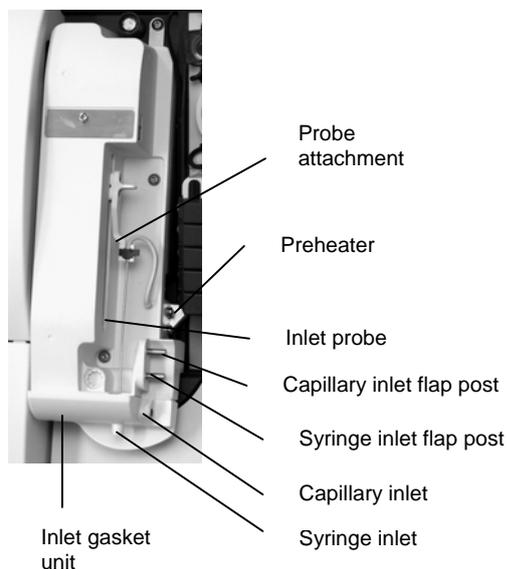
| Module | Electrode | Type |
|--------|-------------------------|-------|
| pH/BG | <i>cCl⁻</i> | E744 |
| | <i>pCO₂</i> | E788 |
| | <i>pO₂</i> | E799 |
| | Reference | E1001 |
| | pH | E777 |
| El/Met | <i>cLac</i> | E7077 |
| | <i>cGlu</i> | E7066 |
| | <i>cNa⁺</i> | E755 |
| | <i>cK⁺</i> | E722 |
| | <i>cCa²⁺</i> | E733 |
| Met II | <i>cCrea A</i> | E8088 |
| | <i>cCrea B</i> | E8089 |

NOTICE: An orange filter is placed in the measuring chambers for the *cGlu*, *cLac*, *cCrea A* and *B* electrodes.

Inlet module

Parts and functions

The inlet module accepts samples from a syringe/test tube or a capillary (the syringe and capillary inlet flaps are removed on the picture). Syringe and capillary inlet flaps are interlocked so that only one may be opened at a time.



| Part | Function |
|---------------------------|---|
| Probe attachment | Secures inlet probe. Open the clip to remove probe. |
| Preheater | Heats all samples and gases to 37 °C. |
| Inlet probe | Automatically moves into the syringe to aspirate the required sample. |
| Capillary inlet flap post | Holds the inlet flap for capillary samples. |
| Syringe inlet flap post | Holds the inlet flap for syringe samples. |
| Capillary inlet | Receives sample from a capillary. |
| Syringe inlet | Receives sample from a syringe and test tube. |
| Inlet gasket unit | Provides transfer of samples from a sampling device to the inlet probe; can be removed. |

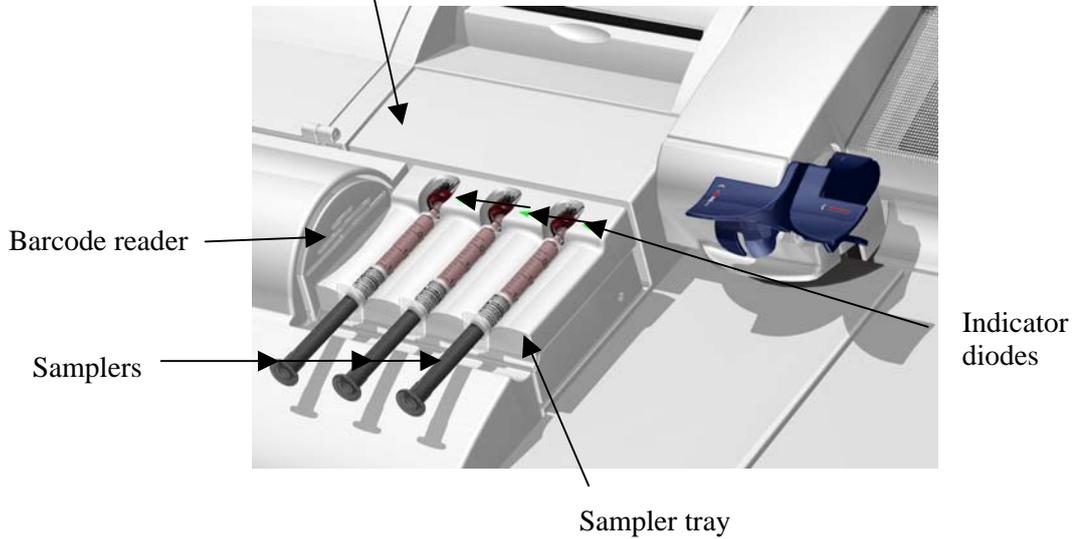
FLEXQ module

Parts and functions

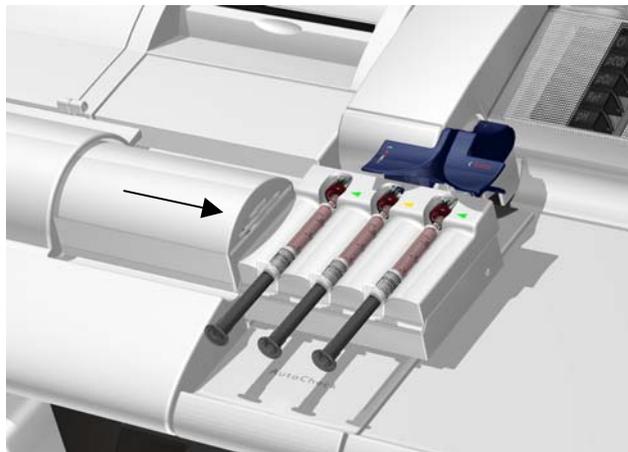
FLEXQ module for automatic transport of samplers to the inlet is shown below.



FLEXQ position before or after analysis:



FLEXQ position during analysis:

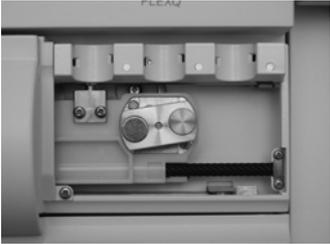


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FLEXQ module, *Continued*

Parts and functions
(continued)

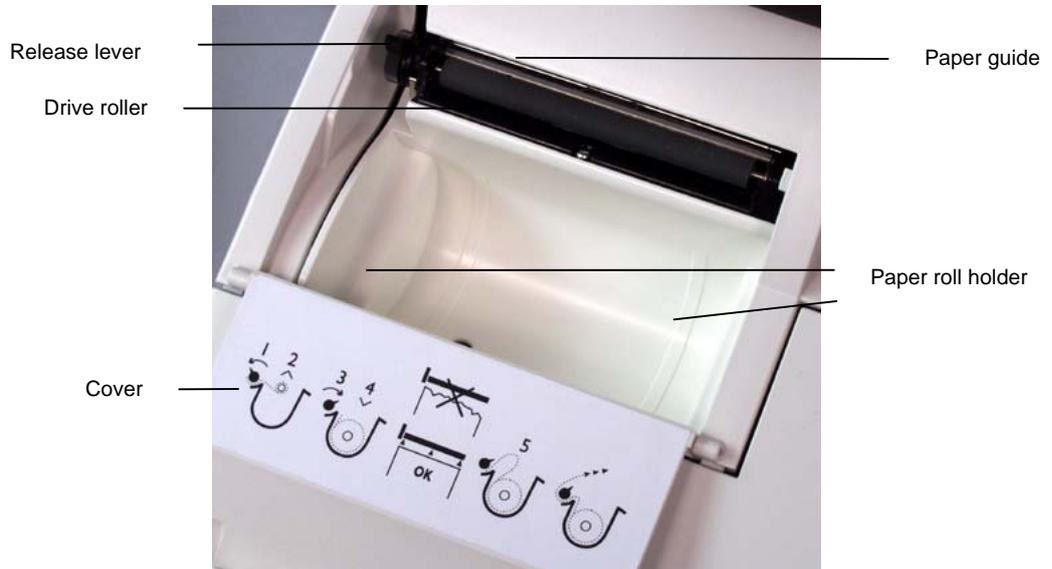
The components are as follows:

| Part | Function |
|---|---|
| FLEXQ sampler tray | <p>FLEXQ sampler tray moves to the position for measurement by means of a step motor (not shown).</p> <p>The samplers used in the sampler tray should be <i>safe</i>PICO sampler with the <i>safe</i>TIPCAP.</p> |
| Indicator diodes | <p>Change the color from green to yellow when the optical switch detects the sampler placed in the slot.</p> |
| Barcode reader | <p>Laser barcode reader reads the sampler barcode. A short beep indicates that the barcode has been read. You can scan the Sampler ID on the analyzer's scanner and then place it in the sample tray or you can place the sampler in the sampler tray and let the FLEXQ scanner read the sampler barcode.</p> |
| Sampler tray cover  | <p>The sampler tray cover has three slots for the samplers; the slots have optical switches for detecting the sampler. The cover can be removed (as shown) for cleaning.</p> |
| Mixer tray  | <p>The mixer rotates and moves the ball in the sampler in order to mix the blood sample. The sample is adequately mixed after 7 seconds.</p> <p>The mixer tray moves into position under the sampler immediately before the measurement.</p> |

Thermal printer

Parts and functions

The components of the thermal printer (with the cover open) are shown below.

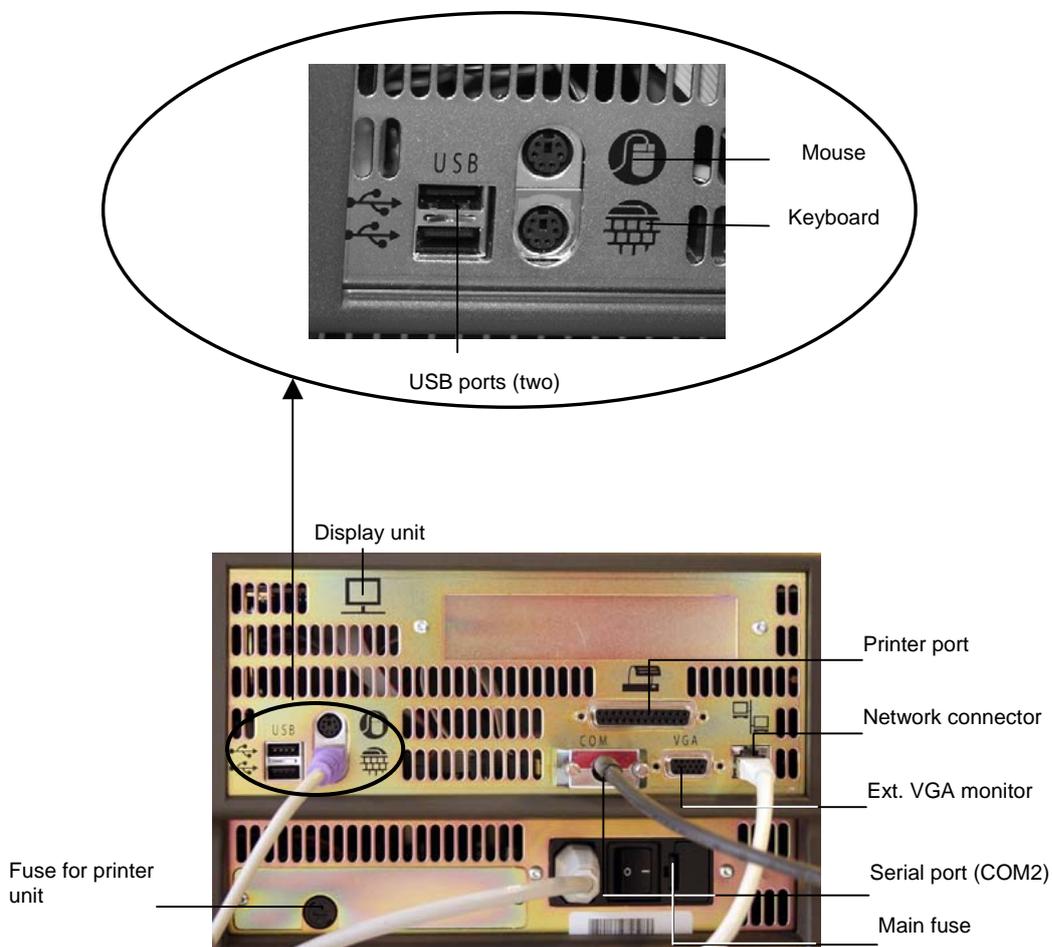


| Part | Function |
|-------------------|--|
| Release lever | <p>Push the lever fully back to lift the drive roller from the printer head and paper guide in order to adjust paper alignment.</p> <p>Remember to return the lever to its original position (as shown) in order to print.</p> |
| Drive roller | Feeds the thermal paper through the printer. |
| Paper guide | Located behind the drive roller, it is between this and the drive roller that paper is fed. |
| Paper roll holder | Holds the paper roll in place. |
| Cover | <p>Open to replace the paper roll. Contains instructions on how to make a replacement.</p> <p>Close the cover when a new paper roll has been mounted in the printer.</p> |

Communication ports

Ports and functions

The following communication ports are available:



The functions of the communication ports are as follows:

| Port | Function |
|--------------------|---|
| Display unit port | For connection to the analyzer's display |
| Mouse port | PS/2 connector used for the connection of a standard mouse (user supplied). |
| Keyboard port | PS/2 connector used for connection of a keyboard (user supplied). |
| Serial port (COM2) | 9-pin serial port used for HIS/LIS communication or connection of an external barcode reader. |
| Network | RJ45 ethernet interface connection to network. |
| Printer port | Parallel port for connection to a local printer |

Continued on next page

Communication ports, *Continued*

| Ports and functions (<i>continued</i>) | Port | Function |
|---|---------------------------|--|
| | External VGA monitor port | 15-pin connector for external monitor (optional; is enabled by Radiometer service representative). |
| | USB (2 ports) | For connecting USB devices, e.g. a removable drive. USB keyboard supported. Other USB devices need an approved XP driver (user-supplied mouse or modem, etc.). |
| | Fuse for printer unit | The compartment contains 1 protective fuse: 5 × 20 mm, 4 Amp, Slow blow (T4AL) (order code number 450-035). |
| | Main fuse | The compartment contains 2 protective fuses: 5 × 20 mm, 4 Amp, High break (T4AH). Type Shurter No. 0001.2510 (order code number 450-144). |



WARNING – Risk of fire

Fire hazard. Replace fuse as marked.

Barcode reader

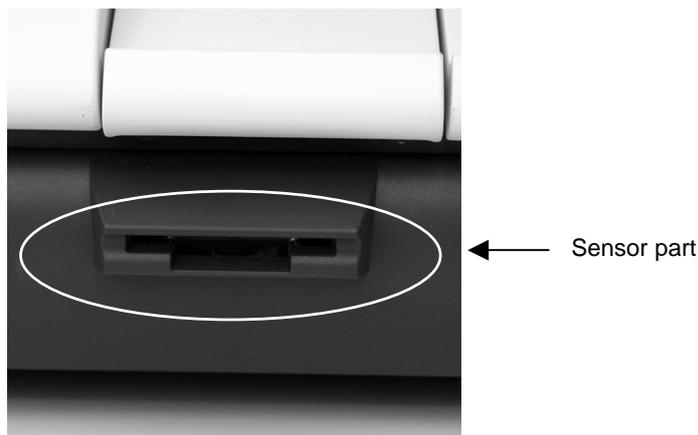
Barcoded items The following items have barcodes that can be read into the analyzer:

| Item | Location of barcode |
|--------------------------|---|
| All solution containers | Label on the container |
| QC ampoules | Insert in the box containing the ampoules |
| tHb calibration ampoules | Insert in the box containing the ampoules |
| Electrodes | Label on the box containing the electrode |
| Electrode membranes | Label on the box containing the membrane unit |
| Gas cylinders | Label on the cylinder |
| Pump tubing | Label on the tubing packaging |
| Fan filter | Label on the box containing the filter |
| Inlet gasket | Label on the box containing the inlet gasket |

In addition to the items above, you can enable every text box on the **Patient Profile, Patient ID, Patient Result, QC ID** and **Recording Fluid Replacement** screens where it is possible to enter a barcode – refer to *Miscellaneous Setup* in *chapter 3: Installation and setup*.

Reading in a barcode

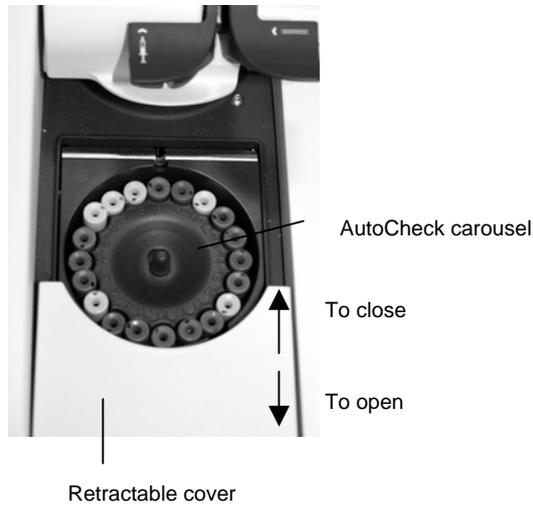
Hold the barcode of the item you wish to read in parallel to the sensor part of the barcode reader. A short beep from the barcode reader indicates that the information has been read in successfully.



AutoCheck module

Parts and functions

The AutoCheck module is shown below.



| Part | Function |
|--------------------|--|
| Retractable cover | <p>Gives access to the carousel.</p> <p>You can either slide the carousel cover open or press <i>Menu - Analyzer Status - AutoCheck - More - Open Module.</i></p> <p>Make sure that no objects prevent the cover from opening freely.</p> |
| AutoCheck carousel | <p>Contains the AutoCheck ampoules packed according to the optimal packing list – see <i>Refilling the AutoCheck carousel</i> in <i>chapter 7: Replacements.</i></p> |

Screen elements

Ready screen Operation and management of the ABL800 FLEX analyzers is performed via a touch screen. Almost all commands to the analyzer come from the touch of a button or area on the screen.

The touch screen is divided into three sections:



For the analyzers without the FLEXQ module, the **Ready** screen looks as follows:



The **Ready** screen appears automatically if the touch screen remains idle for more than 3 minutes. The screen intensity reduces by 50 % when the analyzer is not used.

Top section The **status bar** varies slightly, according to which screen you are in and the status of the analyzer.

Example:



The status describes the current task of the analyzer (e.g. calibration, measurement, etc.) or its status (e.g. ready for use, on hold, etc.).

Continued on next page

Screen elements, *Continued*

Top section (*continued*)

The **time bar** is present only when the analyzer is performing a task; it follows the progress of the current task. For example:



The **Stop** button is visible only when it is allowed to interrupt an activity in progress.

The **parameter bar** lists all measured parameters available and activated on your analyzer.



It allows you to judge the parameter status at a glance before you have to perform a measurement.

Green parameter: Parameter status is okay; no problem is detected on the given measuring channel.



Yellow parameter: Error associated with the given parameter during last calibration or quality control measurement. The parameter is unreliable and will have “?” (if requested in Corrective Actions) in front of the result.



Red parameter: Serious error associated with the given measuring channel. Parameter cannot be used at all and will be displayed as “.....”; or a parameter was repressed in the Parameter Setup program due to errors during last calibration or quality control measurement.



NOTICE: A parameter disabled in the Parameter Setup program will be removed from the parameter bar – see *Analysis Setup Programs (Disabled versus Deselected Parameters)* in chapter 3.

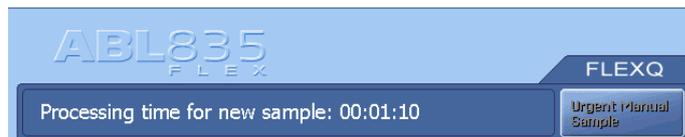
Continued on next page

Screen elements, *Continued*

Center section The center section is the main information and interaction area of which there are many different types.

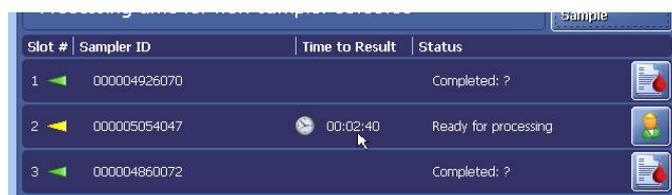
The center section of the **Ready** screen is described part by part, starting from the top (for the analyzers without FLEXQ module the center part contains the analyzer type and – if entered in Miscellaneous Setup (see *chapter 3*) – analyzer message).

This part of the **Ready** screen contains the following elements:



- Analyzer name
- The messages to the operator regarding the FLEXQ activities
- **Urgent Manual Sample** request button. The button allows you to book an inlet for an urgent measurement while the analyzer performs a task. The button is grayed out when the analyzer is ready for any measurement.

This part of the **Ready** screen contains the following elements:



- "Slot #": condition of each sampler tray slot (1, 2 and 3) is indicated with the arrows that reflect the indicator diodes in the sampler tray:

| | | | |
|----------------|---|-----------------|--|
| Green | Place the sampler into the slot or remove it from the slot. | Yellow | Do not remove the sampler from the slot. |
| Blinking green | Wait for the sampler to be identified. | Blinking yellow | Remove the sampler from the slot. |

- "Sampler ID": appears when the sampler is placed in the sampler tray slot and is registered. The name of this column can be changed in the Sample Logistics Setup (see *Analysis Setup* in *chapter 3* of this manual).
- "Time to Result": shows time left till a result will be ready; the clock indicates that the sample age has exceeded settings selected in Sample Logistics setup.
- "Status": gives information about a sampler in the slot:

| | |
|----------------------|--|
| Slot empty | A slot is ready to accept a sampler. |
| Ready for processing | Sampler has been registered in the slot. |
| Processing | Patient and sampler data are being processed. |
| Completed | Measurement is completed and the result can be viewed. |

Continued on next page

Screen elements, *Continued*

Center section
(*continued*)

| | |
|---|-----------------------------|
|  | Patient data can be edited. |
|  | Result can be viewed. |

This part of the **Ready** screen is reserved for the analyzer messages and is entered in the Miscellaneous Setup (see *chapter 3* in this manual):

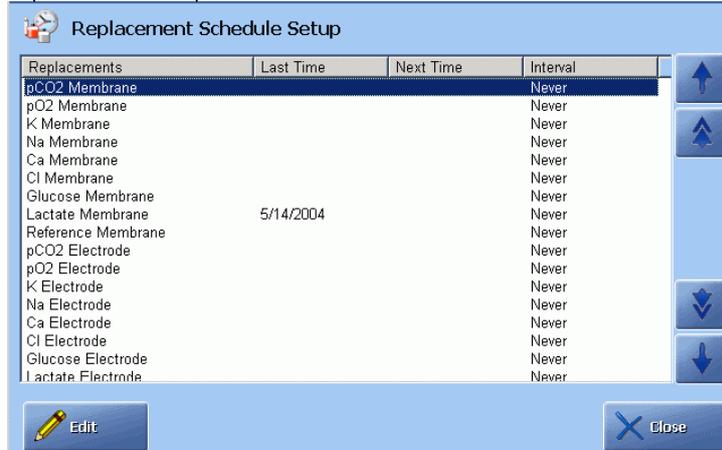


Other screen types and their elements are described on the following pages.

Icon and screen name identify each screen. Example:

Icon Screen name

↓ ↓



| Replacements | Last Time | Next Time | Interval |
|--------------------|-----------|-----------|----------|
| pCO2 Membrane | | | Never |
| pO2 Membrane | | | Never |
| K Membrane | | | Never |
| Na Membrane | | | Never |
| Ca Membrane | | | Never |
| Cl Membrane | | | Never |
| Glucose Membrane | | | Never |
| Lactate Membrane | 5/14/2004 | | Never |
| Reference Membrane | | | Never |
| pCO2 Electrode | | | Never |
| pO2 Electrode | | | Never |
| K Electrode | | | Never |
| Na Electrode | | | Never |
| Ca Electrode | | | Never |
| Cl Electrode | | | Never |
| Glucose Electrode | | | Never |
| Lactate Electrode | | | Never |

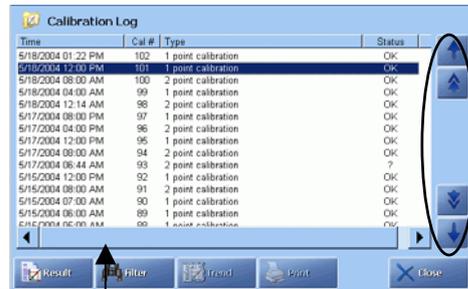
The icon and title of a screen are the same as the button that gives access to that screen.

Continued on next page

Screen elements, *Continued*

Center section (*continued*)

Text boxes show a text in the form of lists, items, tables, etc. Various types of text boxes and navigation in them are given on the next page.



Scroll bar

Scroll keys

The first line is highlighted. To highlight another line, touch it on the screen or use up and down arrow scroll keys displayed on the screen beside a relevant text box.

A **scroll bar** scrolls a text box horizontally when the text box extends beyond the area available on the screen.

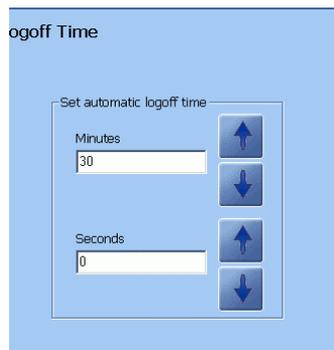
A **single-arrow scroll button** highlights one item at a time upward or downward.

A **double-arrow scroll button** highlights an item at the top or the bottom of the screen.



The first line is highlighted. To highlight another line, use the up and down arrow buttons or touch this line in the box.

Enter the data using the screen keypad or keyboard.



In this text box you can select one of the predefined options.

Use the up and down arrow buttons to select an item.

NOTICE: If the text box already contains an entry, it will be overwritten and cannot be retrieved.

Text boxes are designated in quotation marks, e.g. "Operator". The same applies to the other elements on the center section of the screen: names of the columns (e.g. "Status"), input fields (e.g. "Draw time"), etc.

Continued on next page

Screen elements, *Continued*

Center section (*continued*)

Check buttons allow you to enable/disable or select/deselect an item on the screen. For example:



A function is selected (e.g. acoustic signal if the inlet remains open) or activated (e.g. communication with the RADIANCE system)



A function is deselected or deactivated.

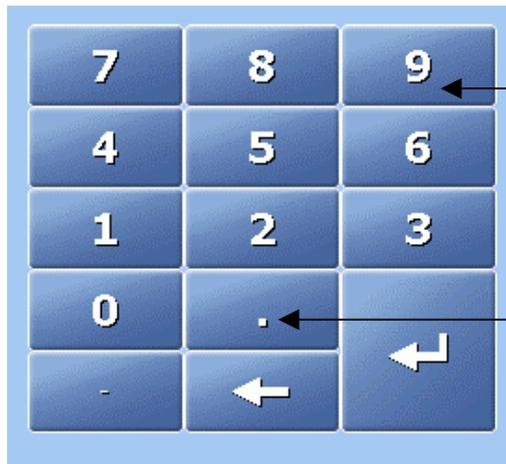


Parameter is selected.



Parameter is deselected.

Screen keypad allows the entry of numerical data on the screen.



Numerical keys from 0 to 9.

Decimal point.

The buttons listed below have the following functions:



Press to confirm a numerical entry and to highlight the next line in the text box.



Press to delete a character (from right to left) or to type in the new data (the box is cleared as soon as the first character is typed).



Press to display the full alphanumeric keyboard.

Continued on next page

Screen elements, *Continued*

Center section
(continued)

Screen keyboard is used for entering both alphabetical and numerical data – see the description on the next page.



The keyboard functions as a normal keyboard with alphabetical and numerical characters. The typed text appears in the activated text box.



Enter

Press to confirm the entry and to return to the previous screen.



Backspace

Press to delete characters from right to left.



Press to cancel any changes made in the activated text box and to return to the previous screen



Press to delete an entry in the activated text box.



Shift

Press to type a capital letter or symbol.



Press to lock the keyboard in order to type capital letters and symbols on the numerical keys. When activated, indicator is green.



Up/down/left/right arrows move the cursor in the activated text box in order to edit a text.

Continued on next page

Screen elements, *Continued*

Buttons

Each button has an icon and a name placed on it. When pressed, it opens a screen or a menu.



The buttons are designated in bold italics in this manual, e.g. *Menu*, *Utilities*, etc.

The buttons displayed in full color can be activated. A button in a weaker color, i.e. grayed-out, is temporarily inactive.

The buttons at the top and the bottom of the screen can be selected in the Setup program Access Profiles (in the Analyzer Security menu) together with the access profiles for each operator – for detailed information see the description in *chapter 3: Installation and setup*.

Note the functions of the following buttons:



Returns you to the previous screen in the same program, e.g. in the Patient Results log, it will return you from the **Patient Identification** screen to the **Patient Result** screen.



Returns you to the **Ready** screen.

Information bar and icons

The **information bar** is placed in the lower right corner of the screen.



Continued on next page

Screen elements, *Continued*

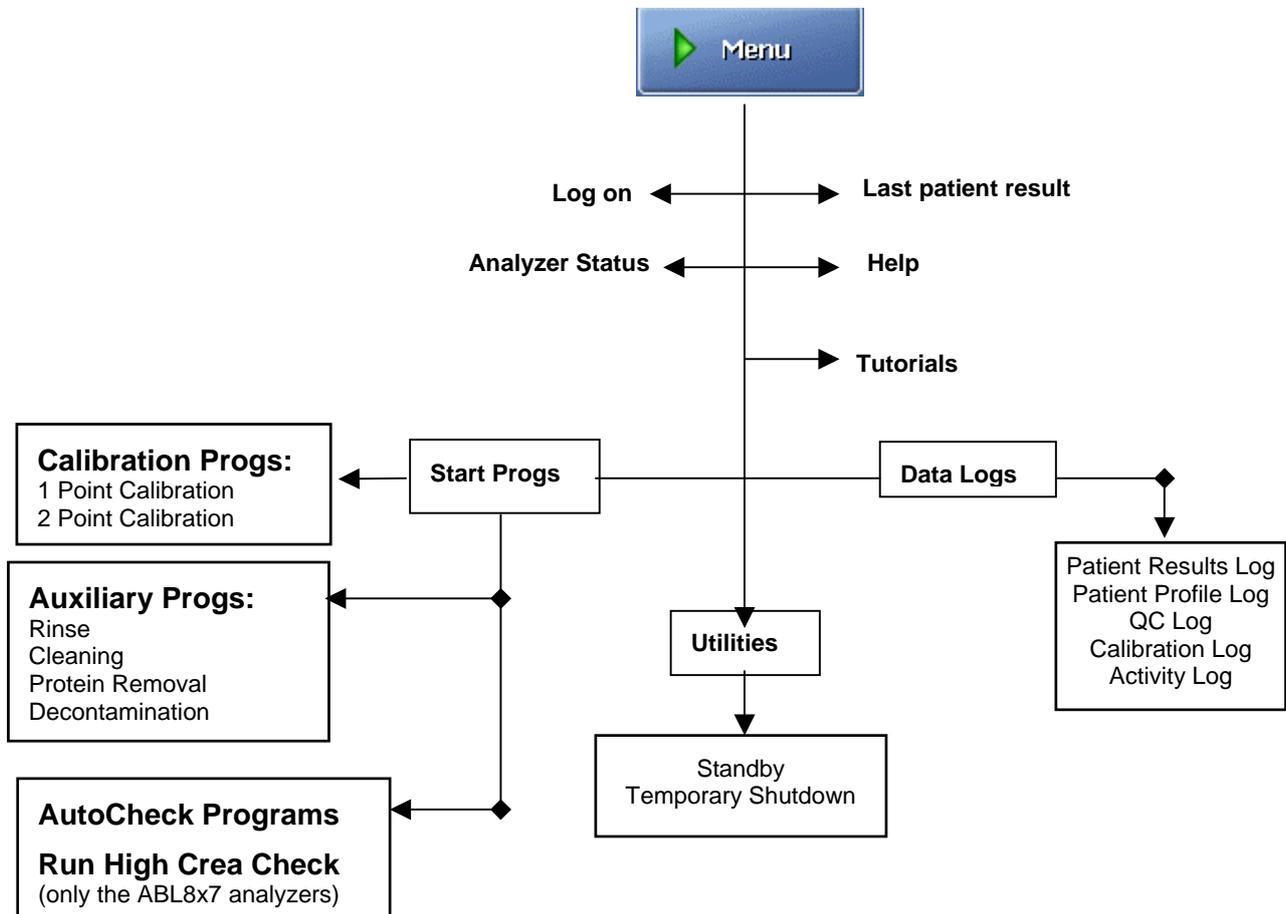
Information bar and icons The following **icons** are available on the information bar:
(*continued*)

| Icon | Function |
|---|---|
|  | Shows the current time in the selected format. |
|  | Shows that an analyzer is connected to the RADIANCE system. |
|  | Shows that an analyzer is connected to the QA Portal. |
|  | Shows the time of the next scheduled calibration. The time changes when a calibration has been completed. |
|  | Shows the time of the next scheduled QC measurement. The time changes when a QC measurement has been completed. |
|  | Shows that the remote operator is connected. |
|  | Click to make more icons visible. |
|  | Click to reduce the number of visible icons to a clock. |

Menu structure

Menu at analyzer startup When the analyzer is taken into use, only the following limited menu is available:

Press *Menu*.



Allowed actions at analyzer startup The following actions are allowed at analyzer startup:

- | | |
|--|---|
| <ul style="list-style-type: none"> • To perform a measurement • To call a calibration • To edit data in the data logs | <ul style="list-style-type: none"> • To perform a replacement • To start an AutoCheck measurement |
|--|---|

The menu above and the scope of actions are suitable for those users whose activities include performing measurements and occasional replacements.

Continued on next page

Menu structure, *Continued*

Entering standard password

To access the complete menu, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Press **Menu** on the **Ready** screen.
Then click on **Logon**.
2. Type in the standard password: 123456.



Standard password:
123456.

See *chapter 3: Installation and setup, Analyzer Security*, in this manual for further information about the logon possibilities.

Confirm with **Enter**.

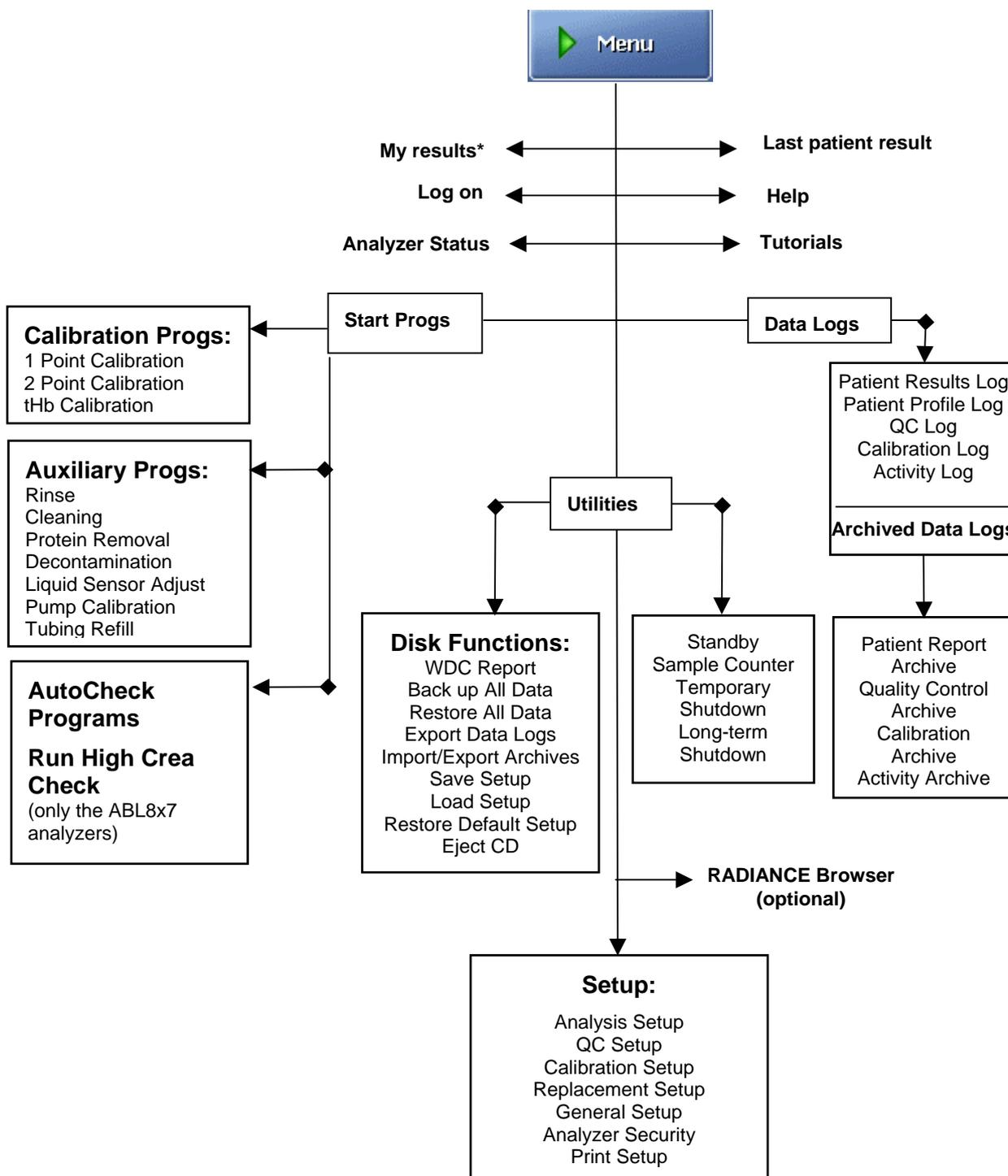
3. Press **Menu** to access the complete menu – see the next section.

The access possibilities for each user of the analyzer and their passwords are entered in Setup program Access Profiles – see *chapter 3: Installation and setup* in this manual.

Continued on next page

Menu structure, *Continued*

Complete menu Press *Menu*.



* Is selected in the Setup program Access Profiles (in the Analyzer Security menu) – see *chapter 3*.

Structure of the Setup programs – see *chapter 3: Installation and Setup*.

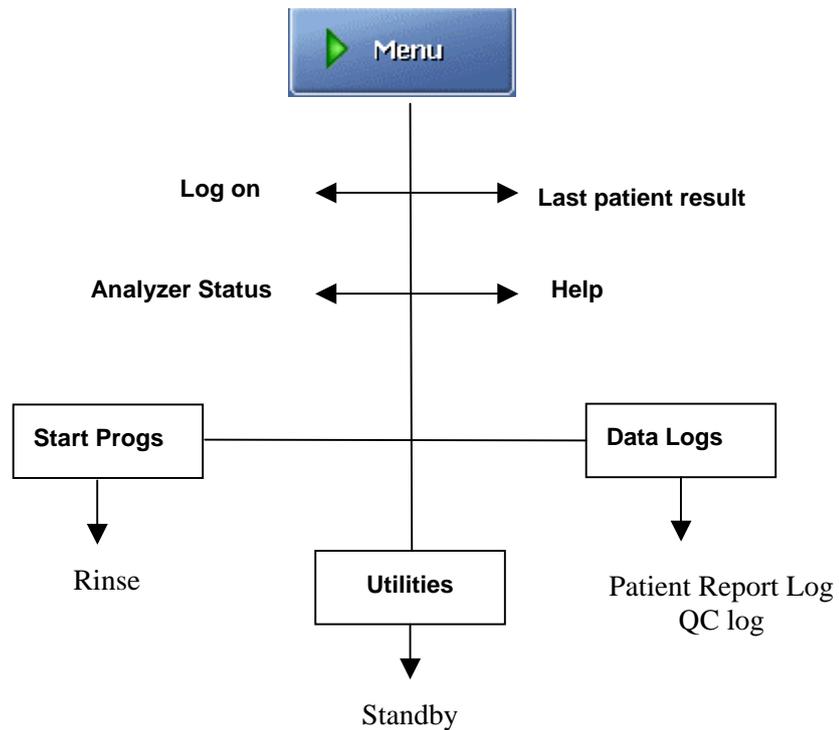
Continued on next page

Menu structure, *Continued*

Access to analyzer menu The access to various parts/functions of the analyzer menu is determined by the rights defined in the Setup program Access Profiles (in the Analyzer Security menu).

Example:

You as a user can enter the following: Rinse, Patient Report and QC logs, and Standby programs. Then your menu – after you have logged on – will look like this:



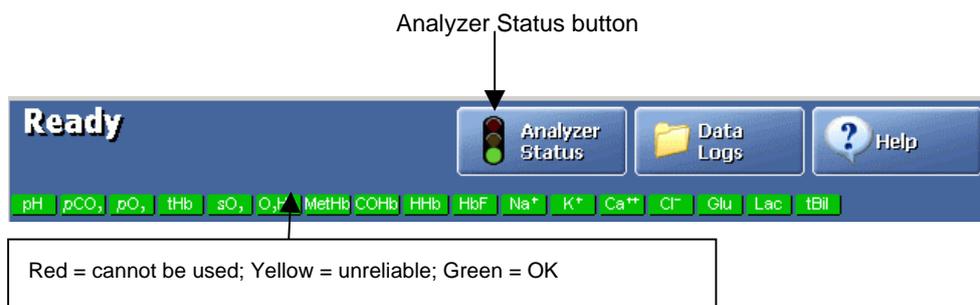
For details see the *chapter 3: Installation and setup* and *chapter 15: Radiometer Settings*.

Analyzer status

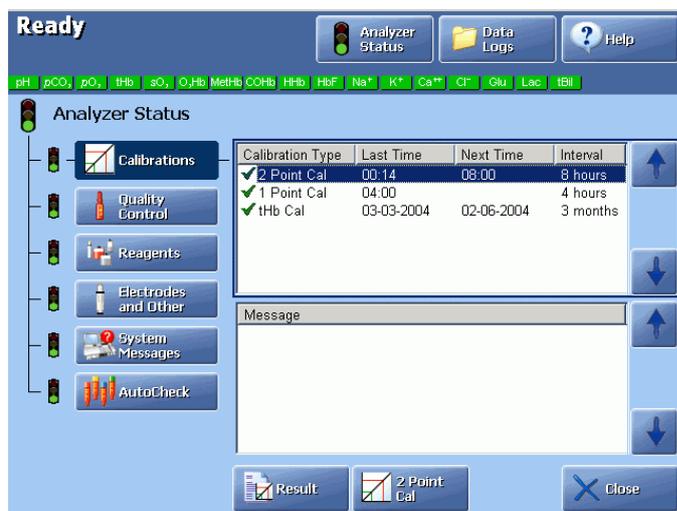
Analyzer status at a glance The working condition of the analyzer is continuously monitored during its operation.

To evaluate the analyzer status at a glance before a measurement, use the following facilities:

- parameter bar
- color of the traffic light on the *Analyzer Status* button.



Analyzer Status elements To enter the *Analyzer Status* screen, press *Menu - Analyzer Status*.



Traffic light color of the *Analyzer Status* button is determined by the traffic light colors of the following status elements:

| Status element | The colors indicate... |
|---------------------------|--|
| <i>Calibration Status</i> | GREEN – OK. |
| | YELLOW – error(s) in the last calibration and/or cal schedule reminders. |
| | RED – error-prone parameters are repressed. |

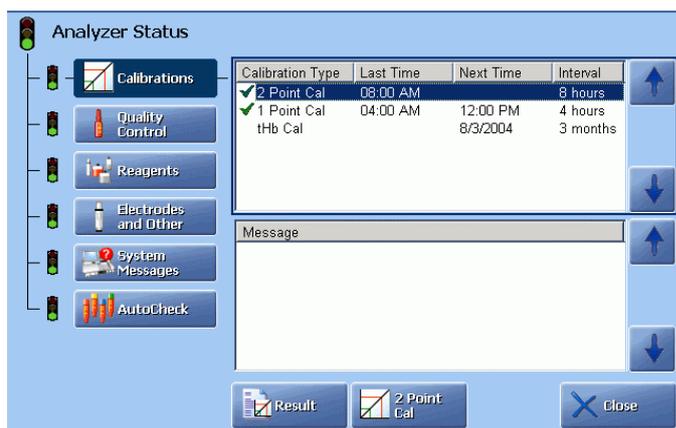
Continued on next page

Analyzer status, *Continued*

| Analyzer Status elements (<i>continued</i>) | Button | The colors indicate... |
|--|--------|---|
| <i>Quality Control Status</i> | | GREEN – OK. YELLOW – error(s) in the last QC measurement and/or QC schedule reminders. RED – error-prone parameters are repressed. |
| <i>Reagents Status</i> | | GREEN – no replacements due at the present time. YELLOW – a replacement is due, Calibration/Cleaning solutions expire soon or Calibration/Cleaning solutions have expired. |
| <i>Electrode and others</i> | | GREEN – no replacements due at the present time. YELLOW – a replacement is due. |
| <i>System Messages</i> | | GREEN – no (critical) messages. YELLOW – non-critical messages. RED – critical messages. The analyzer cannot calibrate or measure. |
| <i>AutoCheck Status</i> | | GREEN – no replacements due at the present time. YELLOW – a replacement is due. |

Calibrations status

The Calibrations status gives an overview of the status of the most recently performed calibration of each type and relevant messages.



The following information is available on the screen:

| | |
|---|--|
| Calibration Type | Lists each calibration type along with its status: |
| OK | Calibration was accepted. |
| ? | Error(s) detected during calibration. |
|  | Pending or overdue calibration. The last calibration was accepted. |

Continued on next page

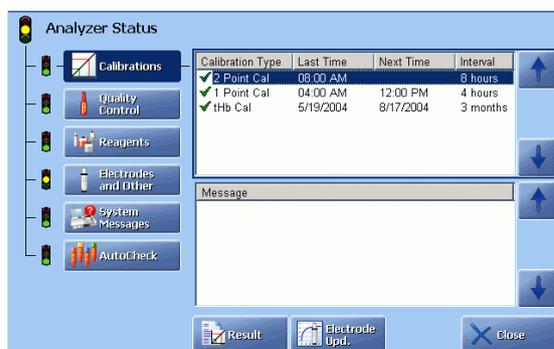
Analyzer status, *Continued*

Calibration status (*continued*)

| Calibration Type | Lists each calibration type along with its status: |
|------------------|--|
| ?+ |  Pending or overdue calibration. The last calibration was not accepted. |
| Last Time | The date and time the last calibration of the specified type was performed. |
| Next Time | The date and time the next calibration of the specified type is due according to the Calibration Schedule - see <i>Calibration Schedule, chapter 3</i> . |
| Interval | The time interval between calibrations as set up in the Calibration Schedule. |

The following buttons are available:

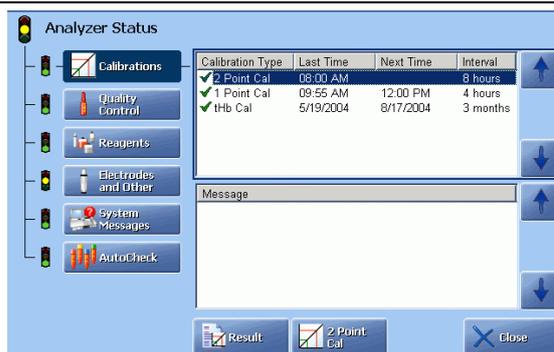
During a calibration:



Result Press to display the result of the highlighted calibration.

Electrode Upd. Press to display the electrode updatings for the ongoing calibration.

After a calibration:



Result Press to display the result of the highlighted calibration.

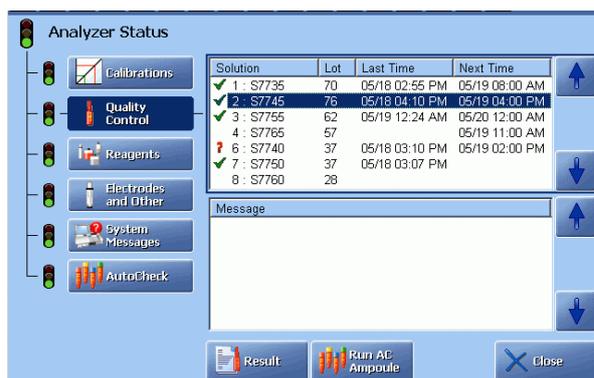
Start Calibration Is activated for the overdue calibrations or the calibrations with "?".

Continued on next page

Analyzer status, *Continued*

Quality Control status The Quality Control status provides the following information:

- status of the last measurement on each control solution type
- messages referring to quality control measurements.



For the ABL8x7 FLEX analyzers, please note that Slot 11 will be automatically installed when you scan the barcode for the Cleaning Met II Solution during replacement.

| Element | Function |
|-----------|--|
| Solution | <p>Lists the quality control slot and its solution type along with a status symbol.</p> <p>Cleaning Met II Solution (for ABL8x7 FLEX analyzers only) is used for quality control of high creatinine levels.</p> <p>OK The last measurement was accepted.</p> <p>? One or more of the following occurred:</p> <ul style="list-style-type: none"> • error in the last calibration. • analyzer error during last QC measurement. • a parameter measurement is outside the defined ranges or a Westgard Rule has been violated. <p> The next measurement is overdue, and the previous measurement, if any, was accepted.</p> <p>?  The last quality control measurement had errors present, and the next measurement is overdue.</p> |
| Lot | The solution lot number for the slot. |
| Last Time | Lists the time the last measurement was performed. |
| Next Time | Lists the next scheduled time to perform the measurement on the slot. See <i>Quality Control Schedule, chapter 3</i> . |

Continued on next page

Analyzer status, *Continued*

Quality Control Buttons:

status
(continued)

**Run AC
ampoule**

Press to start a measurement on the highlighted AutoCheck solution.

For ABL8x7 FLEX analyzers only: When Slot 11 is highlighted, this button changes to **Run High Crea Check** to start a measurement on the Cleaning Met II Solution.

Result

Press to display the last measurement result on the control solution.

Reagents status The Reagents status shows the following:

- status of the solutions and gas cylinders

When Calibration/Cleaning solutions are expired, the container in question is marked with a clock above it and the contents are colored orange.

- messages referring to solutions and gas cylinders.



Buttons:

Replace

Press to enter the screen for replacements of fluids – see *chapter 7: Replacements*.

Adjust Level

Press to enter the Solution Level Adjustment program to make adjustments – see *chapter 3* in this manual.

Troubleshoot

Press to view the error interpretation and operator actions – see the description in *chapter 11: Troubleshooting*.

Close

Press to exit to the **Ready** screen.

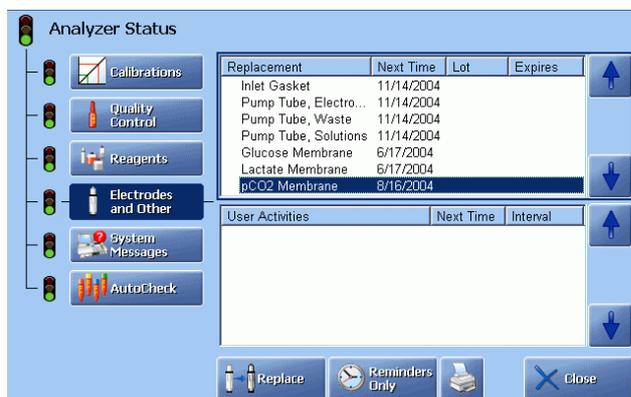
NOTICE: The Calibration and Cleaning Met II Solution containers are filled so that they provide up to 14-days of use in the ABL8x7 FLEX analyzer. This will be registered on the screen by percentages that are lower than 100 % (i.e. 87%, 75%, 50% for the Calibration Solution 1, Calibration Solution 2 and Cleaning Met II Solution, respectively). This has been made so that the solution warning function will not be impaired and you can select the warning values in the usual manner.

Continued on next page

Analyzer status, *Continued*

Electrodes and Other status The Electrodes and Other status shows the following:

- replacement schedule for items replaced in the Hold mode
- messages referring to replacements or user activities.



Buttons:

- Replace** Highlight the item and press this button to enter the screen for replacements of electrodes/membranes – see *Replacing membrane or electrode* in chapter 7.
- Log Activity** Activate “User Activities” part of the screen to make this button visible. When the button is visible, press it to enter the User Activity program to edit the user activities list – see chapter 3 in this manual.
- Close** Press to exit to the **Ready** screen.

System messages See chapter 11: *Troubleshooting*.

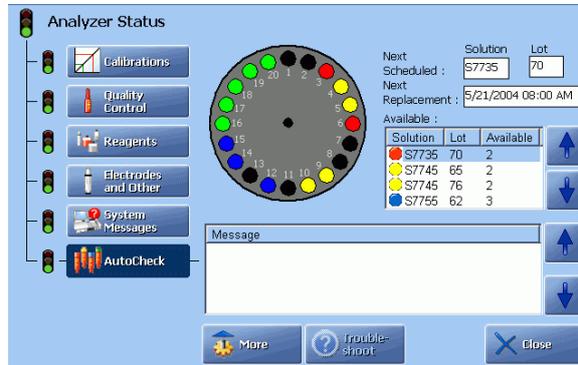
AutoCheck status AutoCheck Status is available only if the AutoCheck module has been installed. It shows the following:

- status of the carousel and the measurements scheduled in the QC Schedule program (see section *Quality control setup* in chapter 3).
- Messages referring to AutoCheck.

Continued on next page

Analyzer status, *Continued*

AutoCheck status (*continued*)



| Element | Function |
|------------------|--|
| Next Scheduled | To show the next AutoCheck solution/lot combination according to the scheduled setup. |
| Next Replacement | To show the date and time for refilling the carousel according to the scheduled setup. |
| Available | To show the presently available AutoCheck control solutions: type, lot and quantity of ampoules in the carousel. Use the up/down arrow buttons to highlight the desired solution. |

Continued on next page

Analyzer status, *Continued*

AutoCheck status (*continued*)

The carousel shows the number of ampoules available in it. The black spots indicate used ampoules.



Button unrolls to access the following buttons:

Packing List

Displays the **Optimal Packing List** screen.

Reset

- Cancels any pending quality control measurements.
- Interrupts ampoule conditioning in the carousel.
- Resets wet section programs.

Open Module

Opens the cover of the AutoCheck module.

AutoCheck Programs

Displays the **AutoCheck Programs** screen to start an AutoCheck measurement.

Online aid facilities

Online facilities The online aid facilities include the following:

- Online Help
- Tutorials
- Online troubleshooting (see *chapter 11* in this manual).

Help

This function assists you in using the analyzer.



Press the button in the Main menu (if not moved to the **Ready** screen – see Access Profiles (in the Analyzer Security menu) in *chapter 3*) or on the **Ready** screen.

The help text is available for practically every screen your analyzer shows during its operation.



The **Contents** screen displays all help topics. Each topic is hyper-linked to either the next topic level or to the appropriate help text screen.

Use the scroll bar or touch the text to search through the topics and access the relevant help information.

Press the **Previous Topic** button to display the help text of a previous screen.



The **Index** screen is an alphabetic list of subjects in the help program.

Each letter at the top of the screen is a hyperlink to that section in the index.

Touch the letter to display the list of entries under that letter.

Each index entry is displayed in bold, purple text (a hyperlink). Simply touch the text to display the relevant help text.

Continued on next page

Online aid facilities, *Continued*

Tutorials

Tutorials are short video sequences of commonly used procedures. Press the



button in the main menu or



button next to the

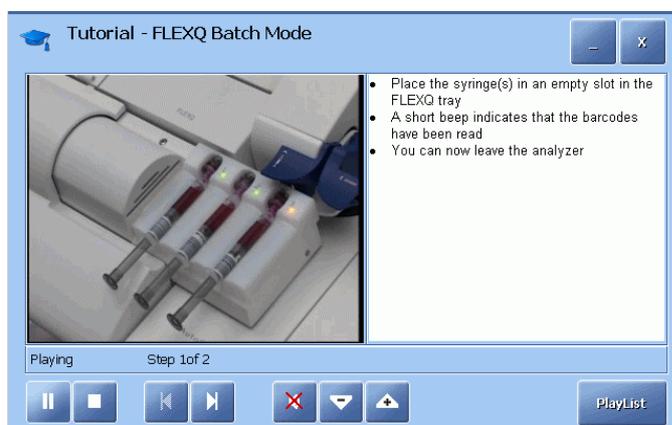
Troubleshooting button (when performing troubleshooting) to enter the **Tutorial Playlist** screen.



The Preview shows the highlighted sequence animation. To start a tutorial on full screen, highlight the topic of interest from the menu, using the arrows, and press the **Play** button.

| Topic | Contents |
|---------------|---|
| Blood Samples | Videos of a capillary, syringe or expired air sample introduction by highlighting it. |
| Quality Check | Videos of manual or AutoCheck quality control. |
| Replacement | Video sequences on various replacements. |

The buttons on the **Tutorial** screen during a sequence allow to do the following:



Continued on next page

Online aid facilities, *Continued*

Tutorials (*continued*)

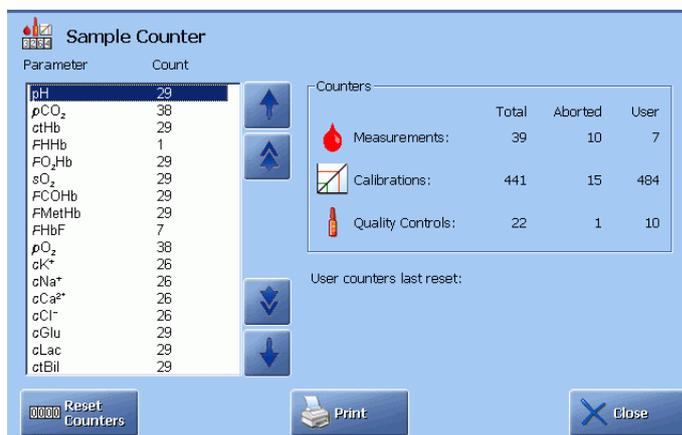
| Button | Function |
|---|---|
|  | Play. |
|  | Pause. |
|  | Stop. |
|  | Show previous picture – show next picture. |
|  | Switch on the sound (voice presentation of a sequence) with volume regulation. |
|  | Switch off the sound. |
|  | Show the list of video sequences. |
|  | The "-" button puts Tutorials in the background in order to perform an action and then to return to Tutorials again. The "x" button exits Tutorials. |

When a button is grayed out, it is not functional.

Sample counter

Purpose The sample counter allows you to keep track of the measurements, calibrations and quality control.

Description The screen elements are described below:



| Element | Function | | | | | | | | |
|--------------------------|--|----------|--------------|-------|--|---------|--|------|--|
| Parameter Count | Lists the parameters and how many times each of them was measured by the analyzer. Normally the count is the same as the total number of measurements provided the parameters were not excluded from the measurement(s). | | | | | | | | |
| Counters | Shows the number of sample measurements, calibrations and QC measurements made since the sample counter was last reset (User column). The following is registered: <table border="1" style="margin-left: 20px;"> <thead> <tr> <th>Activity</th> <th>Number of...</th> </tr> </thead> <tbody> <tr> <td>Total</td> <td>Completed sample/quality control measurements/calibrations only. Interrupted or aborted measurements are excluded.</td> </tr> <tr> <td>Aborted</td> <td>Aborted sample/quality control measurements/calibrations due to sample errors, wet section errors, etc. interrupted measurements excluded.</td> </tr> <tr> <td>User</td> <td>All completed sample/quality control measurements/calibrations performed by all operators since the sample counter was last reset.</td> </tr> </tbody> </table> | Activity | Number of... | Total | Completed sample/quality control measurements/calibrations only. Interrupted or aborted measurements are excluded. | Aborted | Aborted sample/quality control measurements/calibrations due to sample errors, wet section errors, etc. interrupted measurements excluded. | User | All completed sample/quality control measurements/calibrations performed by all operators since the sample counter was last reset. |
| Activity | Number of... | | | | | | | | |
| Total | Completed sample/quality control measurements/calibrations only. Interrupted or aborted measurements are excluded. | | | | | | | | |
| Aborted | Aborted sample/quality control measurements/calibrations due to sample errors, wet section errors, etc. interrupted measurements excluded. | | | | | | | | |
| User | All completed sample/quality control measurements/calibrations performed by all operators since the sample counter was last reset. | | | | | | | | |
| User counters last reset | Gives the date when the counters in the User column were last reset to zero. | | | | | | | | |

Continued on next page

Sample counter, *Continued*

Description
(*continued*)

| Element | Function |
|-----------------------|--|
| <i>Reset Counters</i> |  |
| <i>Print</i> | Press to start the printout of information in Counters and in Parameters. |
| <i>Close</i> | Press to return to the Ready screen. |

3. Installation and setup

Overview

| | |
|---------------------|---|
| Introduction | After the analyzer has been installed, you can define the settings on your ABL800 FLEX analyzer according to your own needs and requirements. |
| Contents | This chapter contains the following topics. |
| | Installation..... 3-2 |
| | Setup menu structure..... 3-3 |
| | Analyzer security 3-6 |
| | Analysis setup 3-13 |
| | Patient reports 3-26 |
| | Calibration setup 3-32 |
| | Quality control setup 3-35 |
| | Replacement setup 3-48 |
| | Parameters and input setup..... 3-55 |
| | Analyzer settings..... 3-62 |
| | Communications 3-68 |
| | Printers 3-77 |
| | Disk Functions setup..... 3-80 |
| | Corrective actions 3-83 |
| | Miscellaneous setup..... 3-86 |

Installation

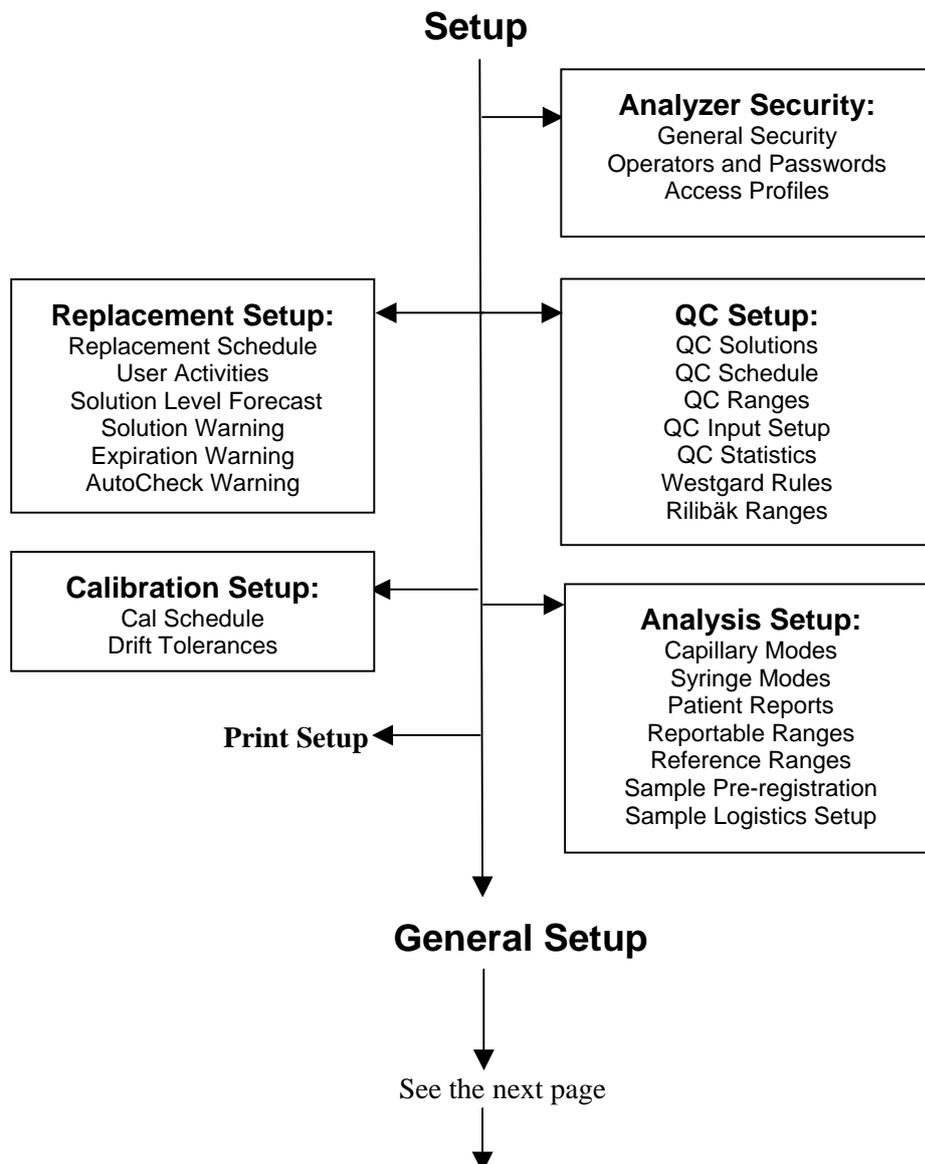
Information The ABL800 FLEX analyzers are installed and fully prepared for use by Radiometer representatives in your country. The reason for it is that – due to the analyzer's modular design – each user can select only those modules that cover his/her specific needs. These modules are installed and checked at the user's place. Installation of consumables and accessories are exactly the same as the procedures described in *chapter 7: Replacements*.

Setup menu structure

Accessing Setup programs To access the Setup programs, press the buttons:



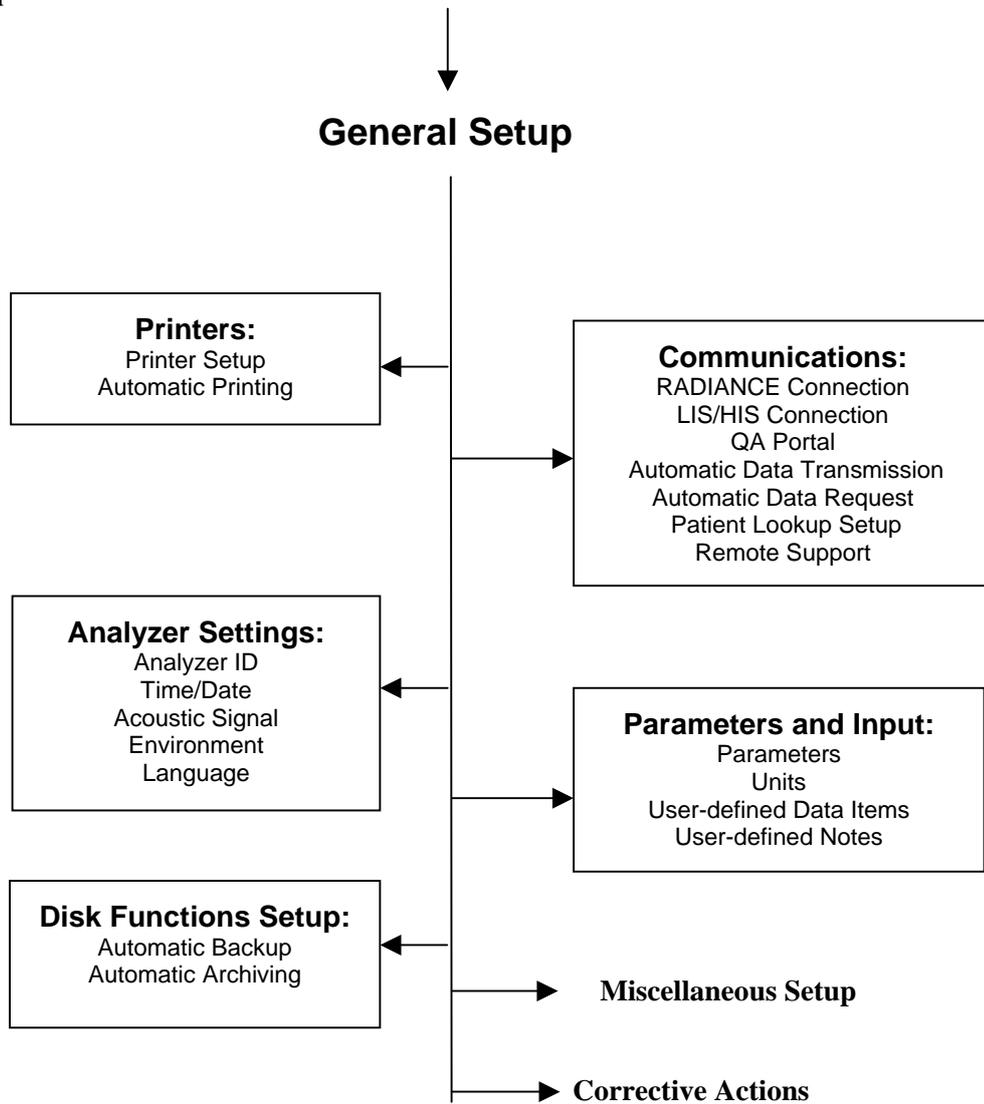
Setup menu structure



Continued on next page

Setup menu structure, *Continued*

Setup menu structure
(continued)



Note that the exit from a setup program returns you to the **Ready** screen. You will find it more convenient to place some buttons, e.g., *Utilities*, on the **Ready** screen to shortcut the entry to a desired setup program - refer to Access Profiles program (in the Analyzer Security menu) in *chapter 3*.

Continued on next page

Setup menu structure, *Continued*

Entering password

To enter the Setup programs, do the following.

- | Step | Action |
|------|---|
| 1. | Press Menu on the Ready screen. Then click on Logon . |
| 2. | Depending on the authentication setting chosen in the General Security screen, enter or scan your user name and password, or your logon-barcode. |

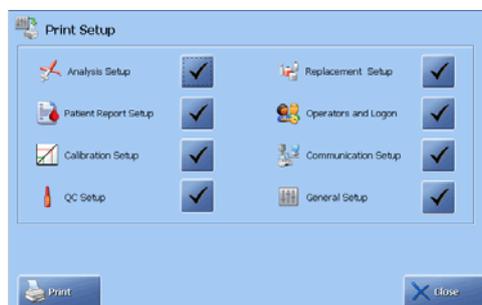


Confirm with **Enter**.

Print Setup

This program allows you to print parts of the setup.
To select the parts of the setup for printing, do the following:

- | Step | Action |
|------|---|
| 1. | Press Menu – Utilities – Setup – Print Setup . |
| 2. | All setups are selected as a default. Press the relevant check buttons to deselect the setup that you do not wish to be printed out. |

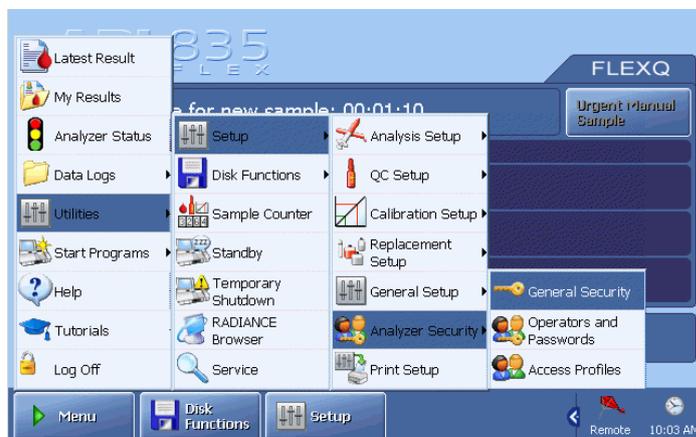


- Press **Print** to start printout of the selected setups or press **Close** to return to the **Ready** screen.

Analyzer security

Programs

Analyzer Security programs are described in this section.



General Security

This program allows you to hand over the control of the operators and passwords to the RADIANCE system and to allow an anonymous use of the analyzer.

To enter this program, press *Menu – Utilities – Setup – Analyzer Security – General Security*.



To hand over the control of the operators and passwords to the RADIANCE system activate the check button in the "Centralized User Management" box.

With this option enabled you can only view the operators, not add, edit or remove any of them. All users defined on the ABL are deleted and the list of users in the RADIANCE system is copied to the ABL.

NOTICE: This option can only be enabled if RADIANCE communication is enabled in the RADIANCE Connection Setup program.

Continued on next page

Analyzer security, *Continued*

General Security (*continued*)

To define, how the user should log on, use the up/down arrow buttons in the "Authenticate" box to select the desired logon option. The following options are available:

- UserId/Password as primary
This option allows you to enter or scan a User name and password in the **Logon** screen. By pressing the **Log On BC** button a Logon-barcode can be scanned.
- UserId/Password only
This option allows you to enter or scan the user name and password in the **Logon** screen.
- Logon-barcode as primary
This option allows you to enter or scan a Logon-barcode in the **Logon** screen. By pressing the **Extended Log On** button a user name and password can be scanned.
- Logon-barcode only
This option allows you to enter or scan a Logon-barcode in the **Logon** screen.

To allow an anonymous use of the analyzer, i.e. use without logon, use the up/down arrow buttons to select "Yes" in the "Anonymous use" box (default) and select the desired access profile of the anonymous operator, in the "Access profile for anonymous operator" box. The "Access profile for anonymous operator" box only appears, when "Yes" is chosen in the "Anonymous use" box. See *Access Profiles* further in this chapter for information on how to define the access profiles.

To set the time interval to elapse, before an operator is automatically logged off, press the **Logoff Time** button. Select the logoff time in minutes (from 0 to 60) and seconds (from 0 to 50 in 10-second intervals). The default logoff time is three minutes. Press **Back** to return to the **General Security** screen.

Continued on next page

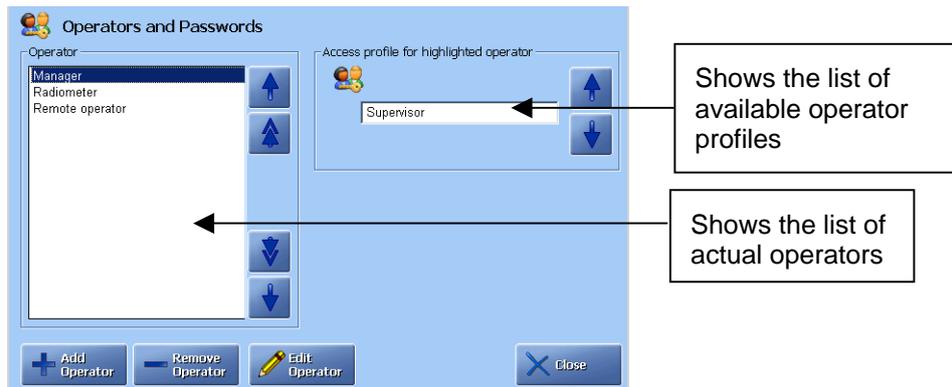
Analyzer security, *Continued*

Operators and Passwords

This program allows you to add, edit or remove operators and to assign an access profile to each operator.

NOTICE: If the Centralized User Management option is enabled in the **General Security** screen, you cannot add, remove or edit the operators, but only view the access profiles of the individual operators.

To enter the Operators and Passwords program, press **Menu – Utilities – Setup – Analyzer Security – Operators and Passwords**.



When the analyzer is taken into use, the following default operators are available:

| Operator | Has access to... |
|-----------------|---|
| Manager | All menu items and programs (not service programs). It is recommended to remove this operator with the standard password: 123456, and enter the actual users with their profiles and passwords. |
| Radiometer | All menu items and programs (user and service) on the analyzer. Note that "Radiometer" cannot be removed from the operator list. |
| Remote operator | Only if the Remote Support option key is installed. |

Continued on next page

Analyzer security, *Continued*

Operators and Passwords (*continued*)

To add an operator to the list, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Press the **Add Operator** button to display the **Add New Operator** screen.

2. Type the name of the operator or operator category in the "Operator ID" box, using the screen keyboard.
3. Enter or scan the password: in the "Password" box.
The password must be at least four characters long, and not more than 32.
4. Re-enter or re-scan the password in the "Confirm" box.
5. Enter or scan the logon barcode in the "Logon – barcode:" box
The logon barcode must be at least four characters long. The logon barcode and the password can be identical.
6. Re-enter or re-scan the logon barcode in the "Confirm" box.
7. Press **Back**.
If the password is not accepted, the **Add New Operator** screen remains open and a message, telling you what was wrong, appears.
If the password is accepted, the **Operators and Passwords** screen is displayed.
8. In the **Operators and Passwords** screen, select the desired access profile of the new operator.

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Analyzer security, *Continued*

Operators and Passwords (continued)

To remove an operator from the list, use the up/down arrow buttons in the "Operator" box to highlight the operator and press **Remove Operator**.

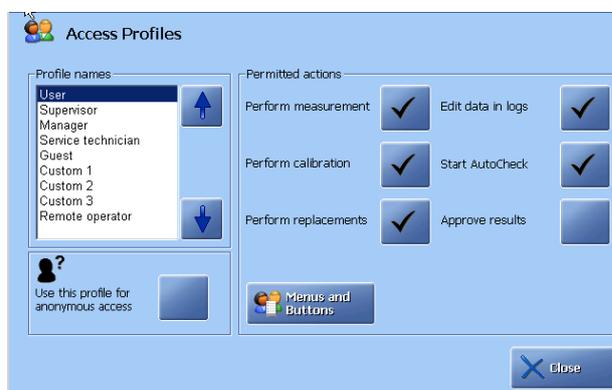


NOTICE: If the Centralized User Management option is enabled in the **General Security** screen you cannot add, remove or edit the operators, but only view the access profiles of the individual operators.

Access Profiles

This program allows you to define the permitted actions, the available menu items and button shortcuts of an access profile.

To enter this program, press **Menu – Utilities – Setup – Analyzer Security – Access Profiles**.



To define the permitted actions of an access profile, select the desired profile in the "Profile names" box and activate the desired check buttons in the "Permitted actions" box.

To deactivate an action, press the check buttons once again.

Continued on next page

Analyzer security, *Continued*

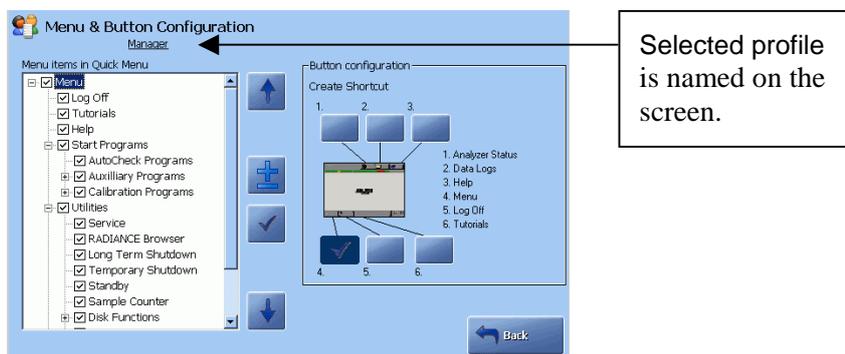
Access Profiles To define the available menu items and button shortcuts of an access profile do
(*continued*) the following:

| Step | Action |
|------|--------|
|------|--------|

- | | |
|----|---|
| 1. | In the Access Profiles screen highlight the desired access profile in the "Profile names" box and press Menus and Buttons . |
|----|---|

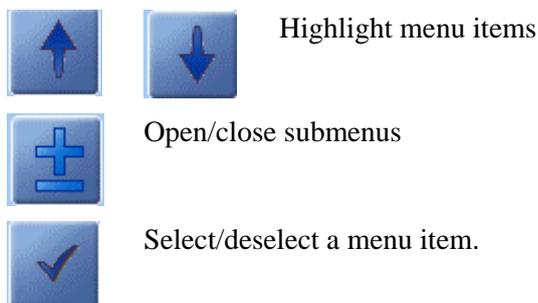
Note that this button is grayed-out for the service technician profile.

- | | |
|----|--|
| 2. | Select the desired menu items in the "Menu Items in Quick Menu" box. |
|----|--|



A grayed-out item in the **Menu & Button Configuration** screen indicates that only some subitems were selected in this group. Clear checked items indicate that all subitems have been selected.

The buttons allows you to do the following:

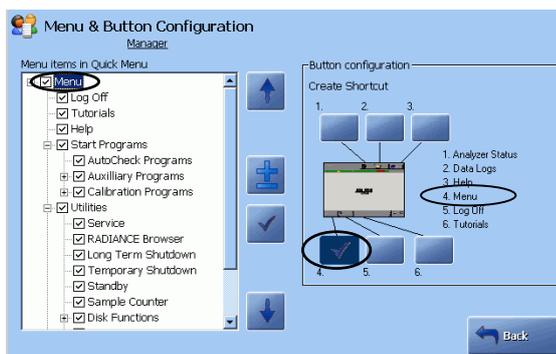


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Analyzer security, *Continued*

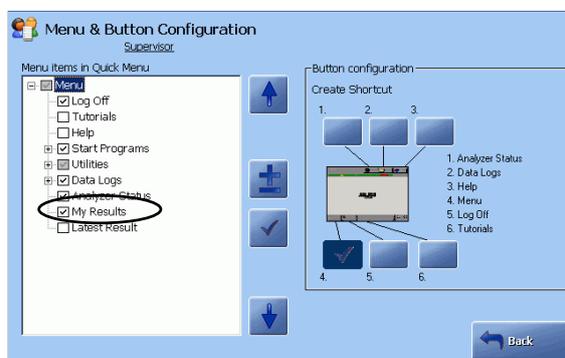
Access Profiles (*continued*)

- | Step | Action |
|------|---|
| 3. | To create a button shortcut for a specific item, highlight the desired item in the "Menu Items in Quick Menu" box and then, in the "Button configuration" box, press the button position that you wish to give the selected item. |



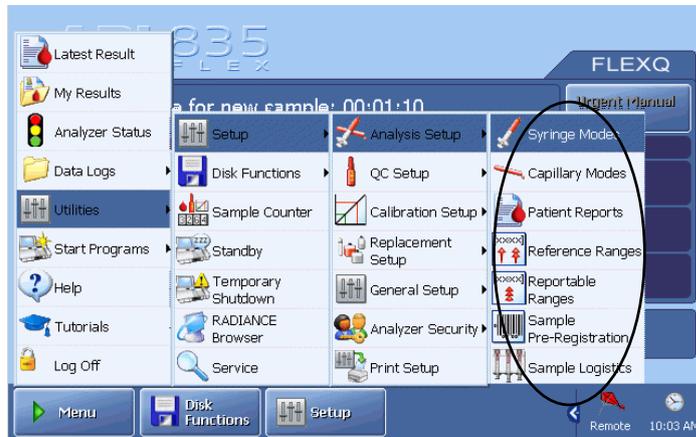
- Select other five buttons in the same manner, if desired.
- To deselect a button, press it once again.
- Press **Back** to return to the **Access Profiles** screen.

Enabling the "My Results" option will give the operator an easy access to all Patient Results made by that operator, by displaying the Patient Result Log, filtered on the operator name.



Analysis setup

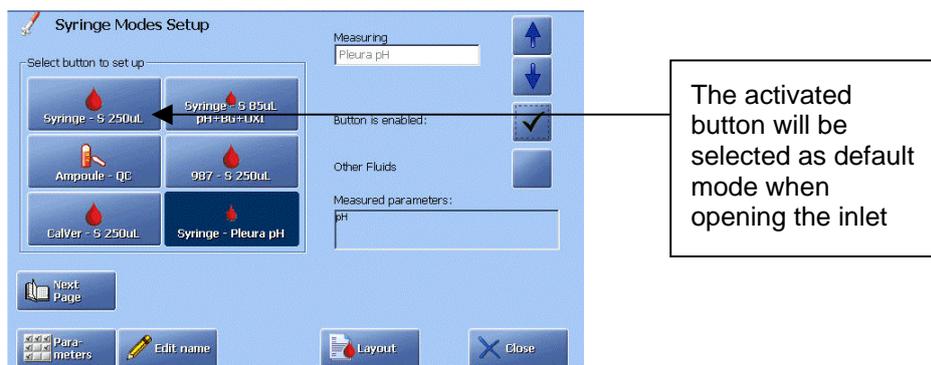
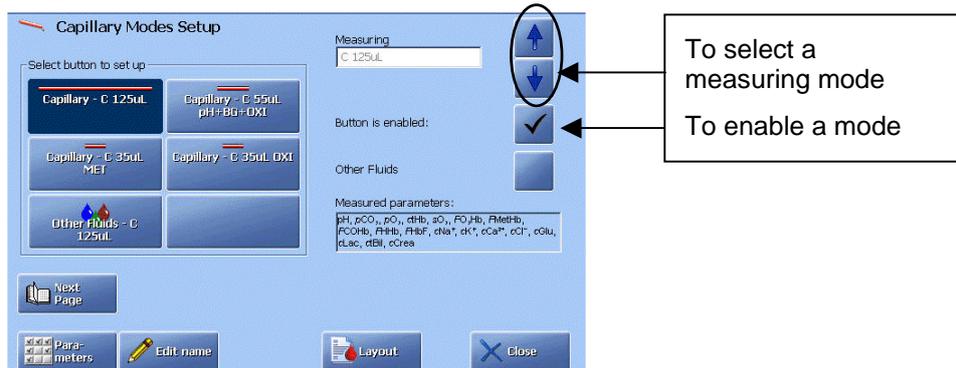
Programs Analysis Setup programs are described in this section.



Activate a button to enter the program.

Syringe Modes and Capillary Modes Setup

The **Syringe Modes Setup** and **Capillary Modes Setup** are shown below:



Continued on next page

Analysis setup, *Continued*

Selecting a measuring program

To select a measuring program, do the following:

| Step | Action |
|------|---|
| 1. | <p>Blood, pleura and expired air samples: Press the desired mode button, enable it and select the desired measuring program with the arrow buttons.</p> <p>Other fluids: Activate the desired mode button and enable the Other fluids check button.</p> |
| 2. | Press Parameters to select a parameter profile for a measuring program – see <i>Selecting parameter profile</i> below. |
| 3. | Edit, if desired, the left part of the button name for the mode by pressing Edit Name . |
| 4. | Enter corrections for the Other fluids mode by pressing Corrections – see <i>Entering corrections for Other Fluids Modes</i> further in this section. |
| 5. | Select the report layout for a measuring program by pressing Layout – see <i>Selecting a report layout</i> further in this section. |

- NOTICES:**
- You can use one of the syringe measuring modes for test tubes.
 - Use Capillary – 35 µL OXI for bilirubin analysis (ctHb = 0) on plasma. Deselect all other parameters for this mode in the Parameter Profile. Alternatively, you can use the Other Fluids mode for the bilirubin measurement on plasma (this is not relevant for the ABL8x7 FLEX analyzers).
 - In the *Syringe Modes Setup* and *Capillary Modes Setup* screens you can define up to 12 measuring programs. To get access to the last 6 mode buttons press **Next Page**.

Continued on next page

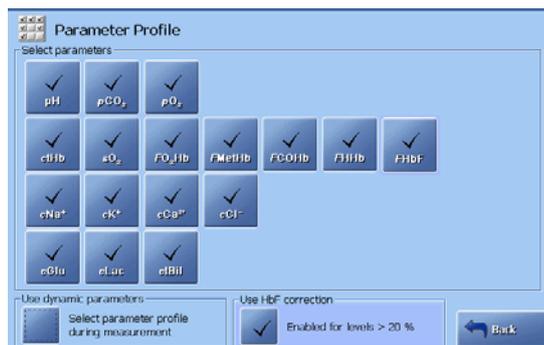
Analysis setup, *Continued*

Selecting parameter profile

To select parameter profile for each measuring program, do the following:

- | Step | Action |
|------|--|
| 1. | Select a measuring program and press Parameters on the Syringe Modes Setup or Capillary Modes Setup screen. |
| 2. | Select parameters for a given measuring mode by pressing a parameter check button (see <i>Screen elements</i> in chapter 2). |

The list of available parameters depends on your analyzer version.



3. Select the dynamic parameters option in the "Use dynamic parameters" box as follows:



Parameters can be selected **before** a measurement.



Parameters can be selected **after** a measurement.

4. Press the **Back** button to return to the **Syringe Modes Setup** or **Capillary Modes Setup** screen.

Disabled versus deselected parameter

A parameter is disabled, i.e. excluded from the **Parameter Profile** screen and the parameter bar, in General Setup – Parameters and Input – Parameters.

A parameter deselected for the given syringe or capillary measuring program will be measured, but excluded from the displayed and printed patient report.

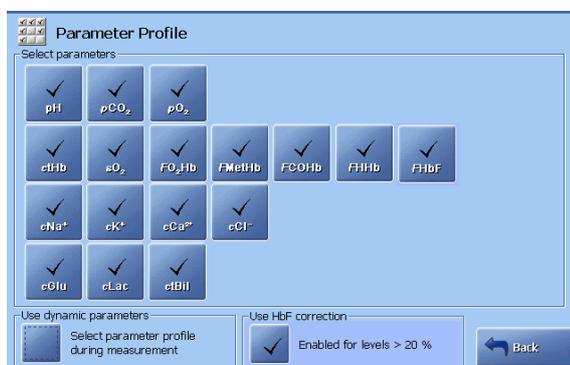
You can further select or deselect a parameter before or after a measurement – see *chapter 4: Sample measurements*.

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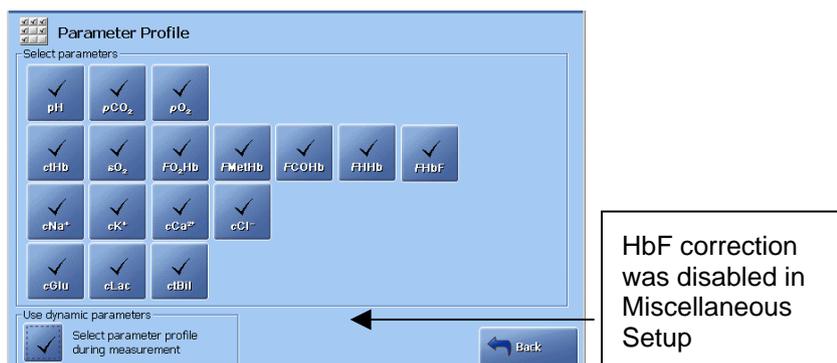
Analysis setup, *Continued*

Selecting HbF correction To give the user the possibility of selecting or deselecting HbF correction during a measurement, do the following:

- | Step | Action |
|------|--|
| 1. | Select HbF correction for all levels or for HbF levels higher than 20 % in Miscellaneous Setup (<i>Setup – General Setup – Miscellaneous Setup</i>) – see the description further in this chapter. |
| 2. | Return to the Analysis Setup, choose the desired syringe or capillary program and press the <i>Parameters</i> button to enter the Parameter Profile screen. |
| 3. | Activate the check button in the "Use HbF correction" box (if "Disabled for all levels" has been selected in Miscellaneous Setup, the text box and the check button in it will not be visible on this screen). |



4. Press the dynamic parameters check button in the "Use dynamic parameters" box in order to be able to exclude the HbF correction and other parameters during a sample measurement.



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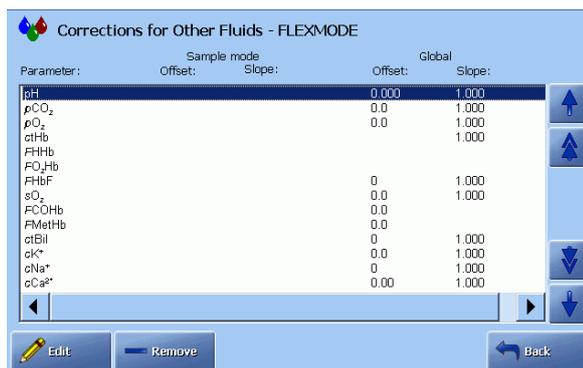
Analysis setup, *Continued*

Entering corrections for Other Fluids mode

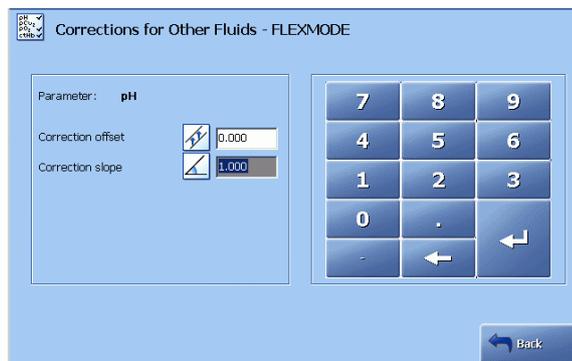
The Other Fluids mode allows measurement on samples other than heparinized whole human blood and, therefore, requires entering corrections (offset and slope).

| Step | Action |
|------|--------|
|------|--------|

1. Select the Other Fluids mode and press the **Corrections** button on one of the Modes Setup screens (Capillary or Syringe).
2. Highlight the parameter with the arrow buttons and press **Edit**.



3. Key in the slope and offset values. Confirm each entry with **Enter**.



Please note that only values within the range programmed into the software will be accepted.

4. Press **Back** to confirm the entries and return to the previous screen.
5. To delete a correction, highlight it and then press the **–Remove** button.

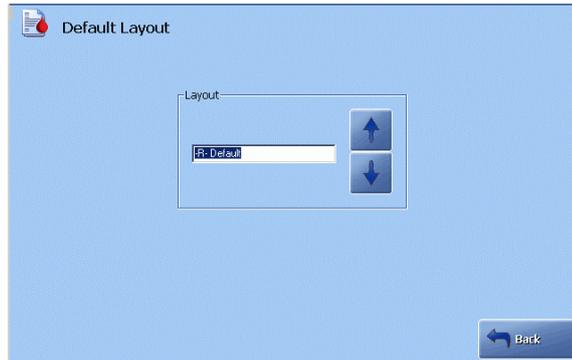
Continued on next page

Analysis setup, *Continued*

Selecting a report layout

To select a report layout for a measuring program, do the following:

- | Step | Action |
|------|--|
| 1. | Select a measuring program. |
| 2. | Press the Layout button on one of the Mode Setup screens. |



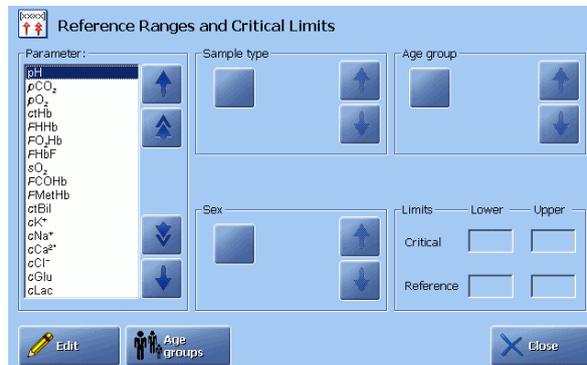
- | | |
|----|---|
| 3. | Select the layout for the measuring program from the list made in the Patient Report Setup – see <i>Patient report</i> further in this chapter. The selected layout will be the default layout for the given measuring program. |
| 4. | Press Back to confirm the settings. |

Continued on next page

Analysis setup, *Continued*

Reference ranges and critical limits

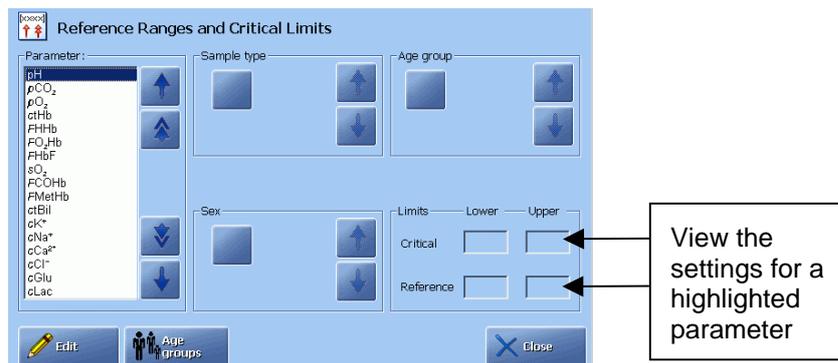
This program allows you to enter your own reference ranges and critical limits for all measured and calculated parameters. For each parameter, you can choose whether or not to differentiate between the categories of sample type, sex and age group.



Press the check button to activate a function; press the check button again to deactivate it.

Viewing the reference ranges and critical limits

To view the reference ranges and critical limits, highlight a parameter in the "Parameter list" box using the arrow buttons.



Selecting sample type

To select a sample type, highlight a parameter in the "Parameter" box, using the arrow buttons.

Press the check button in the "Sample type" box and select a sample type, using the arrow buttons in the box.

To deactivate sample type differentiation, press the check button again.

Selecting sex

To select sex, highlight a parameter.

Press the check button in the "Sex" box and select sex type, using the arrow buttons in the box.

To deactivate sex differentiation, press the check button again.

Continued on next page

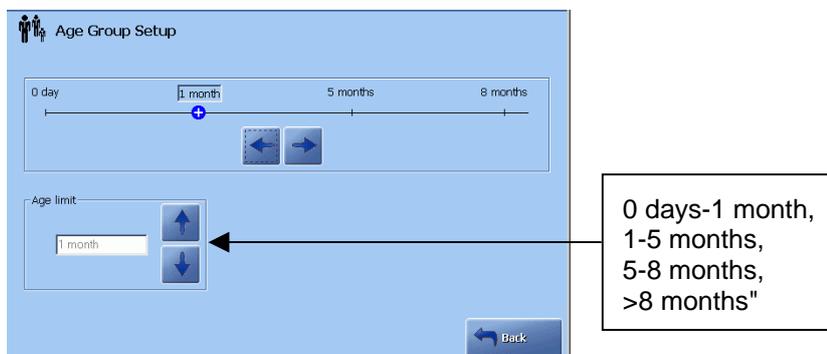
Analysis setup, *Continued*

Setting age group limits

To set the age group limits, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Press the **Age groups** button to display the following screen:



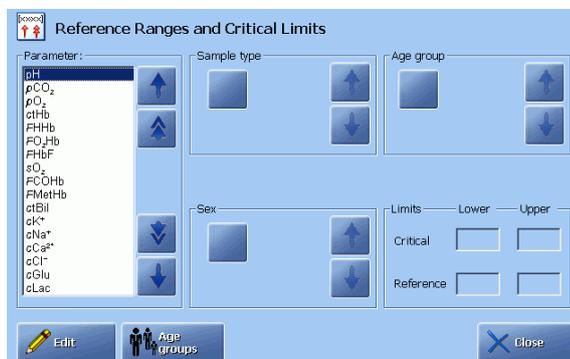
2. Use the following:
 - left/right arrows to choose the age group limit you want to alter (indicated by a blue circle containing a white cross).
 - up/down arrows to scroll through the list of possible age limits. As the list is scrolled the text on the age group bar changes accordingly.
3. Repeat step 2 for each limit to be changed.
4. Press **Back** when completed to return to the **Reference Ranges and Critical Limits** screen.
5. Activate the **Age group** check button.
To deactivate age group differentiation, press the check button again.

Setting reference and critical limits

To set the reference and critical limits for each parameter do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Highlight a parameter by using the up/down arrow buttons.



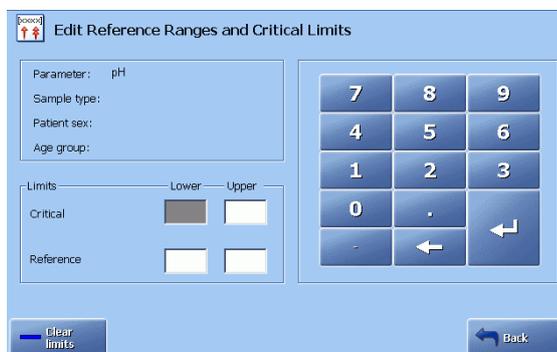
2. Choose the sample type, sex, age group and press the **Edit** button.

Continued on next page

Analysis setup, *Continued*

Setting reference and critical limits (*continued*)

- | Step | Action |
|------|---|
| 3. | To remove all current ranges, press the Clear limits button. |

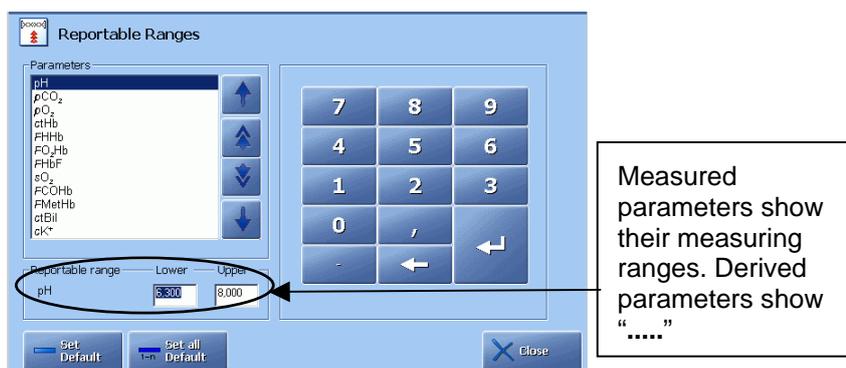


- | | |
|----|--|
| 4. | To change the value in a range limit, touch and highlight the range. Then enter the limit, using the screen keyboard and confirm with Enter . |
| 5. | Repeat for other limits in a similar way. |
| 6. | Press Back when completed. |

Reportable ranges

To change or enter a reportable range (must be selected smaller than or equal to the measuring range), do the following:

- | Step | Action |
|------|--|
| 1. | Scroll to the desired parameter, using the up/down arrows or scroll bar. |



- | | |
|----|---|
| 2. | Key in the desired lower limit and confirm with Enter on the keypad. |
| 3. | Key in the upper limit and confirm with Enter on the keypad. |
| 4. | To change the reportable range to the default (primary) setting, highlight the desired parameter and press Set Default . |

Continued on next page

Analysis setup, *Continued*

Reportable ranges (*continued*)

- | Step | Action |
|------|---|
| 5. | To change all parameters to the default values, press the <i>I-n Set All Default</i> button. |



Press ***Continue*** to change all parameters' reportable ranges to the default ones.

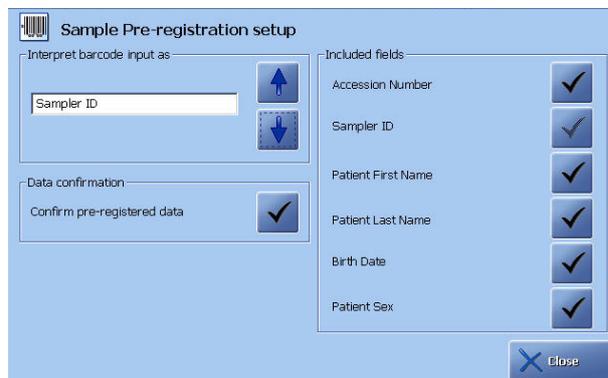
Press ***Cancel*** to keep the user-defined reportable ranges and return to the previous screen.

- | | |
|----|--|
| 6. | Press <i>Close</i> to exit the program and confirm the selected settings. |
|----|--|

See also *Calibration verification* in *chapter 15* in this manual.

Sample Pre-registration setup

This program allows you to select interpretation of the barcode and the patient data that can be confirmed before a sample measurement.



To select the settings, do the following:

- | Step | Action |
|------|--|
| 1. | Use the up/down arrow buttons to select the interpretation of the barcode setting in the "Interpret barcode input as" box. Choose one of the following: <ul style="list-style-type: none"> • Patient ID • Accession Number • Sampler ID. |

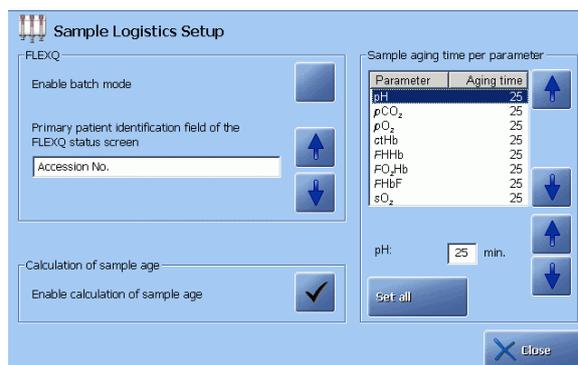
Continued on next page

Analysis setup, *Continued*

Sample Pre-registration setup (*continued*)

| Step | Action |
|--------------|--|
| 1 (cont.) | Note that choosing the Accession Number or Sampler ID will gray out its check button (Sampler ID on the screen above). Choosing the Accession Number or Sampler ID ensures that this data will be included in the "Data confirmation" box. |
| 2. | Select the barcode entry. |
| 3. | Activate the relevant check buttons in the "Included fields" box: Accession Number, Sampler ID, Patient First Name, Patient Last Name, Birth Date, Patient Sex. |
| 4. | Activate the check button in the "Data confirmation" box so that the patient data can be confirmed before the sample measurement. |
| 5. | Press <i>Close</i> to confirm the settings and return to the Ready screen. |

Sample Logistics Setup This program allows you to select the following: the batch mode (automatic sample handling), Patient Identification shown on the **Ready** screen and to define maximum allowed sample age for each measured parameter.



Batch mode (automatic sample handling)

The batch mode allows you to place your sampler in an empty slot in the FLEXQ sampler tray and leave the analyzer. The sampler will be registered, sample analyzed and the results sent to the required person.

To achieve this the following is required:

- Analyzer has live connection to the RADIANCE system
- Barcode interpretation is set to Sampler ID in the Sample Pre-registration
- "When entering Sampler ID" in "Request patient demographics" box is selected and "From connection" must be set to RADIANCE in the Automatic Data Request setup
- All sample/patient information is present on the RADIANCE system

Continued on next page

Analysis setup, *Continued*

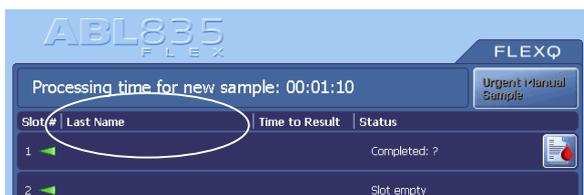
Batch mode (automatic sample handling) (*continued*)

If the above requirements are fulfilled, activate the check button in the "FLEXQ" box. This box is not available for the analyzers without the FLEXQ module.

If a live RADIANCE connection is detected, the analyzer will automatically set the connect option when activating the **Enable batch mode** button.

Patient identification on the Ready screen

To select the information in the second column on the **Ready** screen, use the up/down arrow buttons in the "FLEXQ" box.



The choices are: Patient Last Name, Accession No. or Sampler ID.

Sample age

Sample age is the time within which the sample should be analyzed. It can be defined for each measured parameter individually or for all parameters.

Patient Report Layout (described further in this chapter) offers the following time registration items in the Patient ID:

- "Draw time", i.e. when the sample was obtained from the patient; is entered by the operator on the **Patient Identification** screen on the analyzer or obtained from the RADIANCE system.
- "Sample registration", i.e. when the sample was registered by the analyzer; is automatically registered by the analyzer.
- "Time before FLEXQ", i.e. sample transport time to the analyzer; is obtained if the "Draw time" has been entered; is automatically registered by the analyzer.
- "Time in the FLEXQ", i.e. waiting time; is automatically registered by the analyzer.
- Max. sample age (is entered on the RADIANCE system). This setting, if used, will overrule the settings selected on the analyzer.

The sample age is calculated, using the following:

| | |
|--------------------|--|
| Manual measurement | "Sample age " = "Sample registration" – "Draw time". Sample age = 0 if "Draw time" is not entered. |
| FLEXQ measurement | "Sample age" = "Time before FLEXQ" + "Time in FLEXQ" where: "Time before FLEXQ" = "Sample registration" – "Draw time"; Time in FLEXQ = "Time the sample aspiration begins" – "Sample registration" |

Continued on next page

Analysis setup, *Continued*

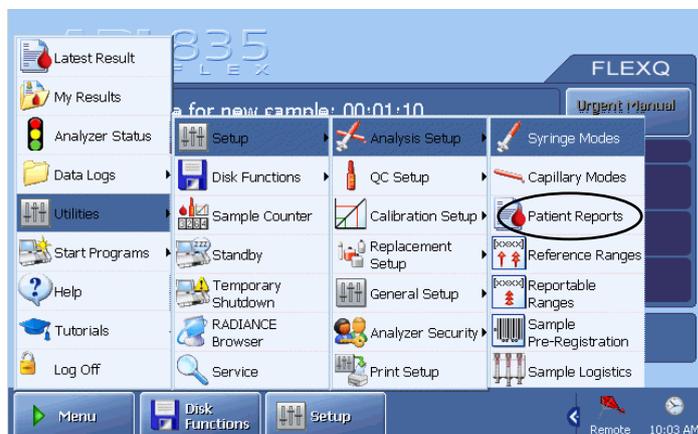
Sample age (*continued*)

To define maximum allowed sample age, do the following:

| Step | Action |
|------|--|
| 1. | Activate the check button in the "Calculation of sample age" box. |
| 2. | To select the same age for all parameters, press <i>Set all</i> . To select the sample age for each parameter individually, highlight a parameter in the "Sample aging time per parameter" box, using the up/down arrow buttons. |
| 3. | Select sample age for the highlighted parameter, using up/down arrow buttons. |

Patient reports

Purpose This program allows you to create a number of new layouts for patient reports or to modify the existing ones.



The screen accommodates two main functions: creating a layout and editing a layout.

Creating a layout

To create a new layout, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Press **New** to make a new blank layout with the name "New" displayed on the right side of the screen in the "Name" box.

If you wish to make a copy of an existing layout and use it as a basis for a new layout, select the desired layout and press **Copy**. "Copy" will be added to the name in the "Name" box (i.e. "-R- default Copy").



Press the keyboard icon beside the "Name" box

Type in a new name for your layout.

Confirm with **Enter** to return to the **Patient Report Setup** screen.

The newly named layout will be added to the list of layouts.

2. Edit your layout as described in *Editing a layout* further in this section.

Continued on next page

Patient reports, *Continued*

Creating a layout (*continued*)

To make the highlighted layout a default for your analyzer press ***Make Default***. The default layout will be marked with (✓) in the list of layouts.

To make a test printout of the highlighted layout (patient ID items and selected parameter groups with the parameters/units for each parameter group) press ***Preview***. This test print will be labeled "Preview".

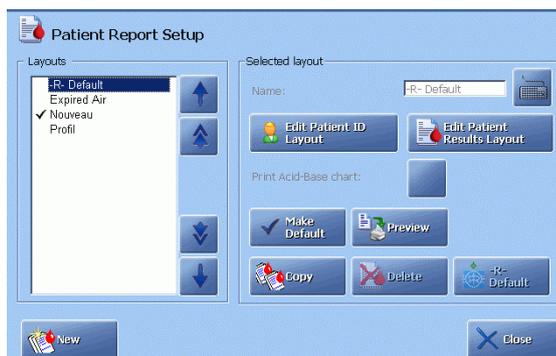
To reset any user defined layout to the –R- Default layout, select the desired layout and press ***–R- Default***.

To delete a highlighted layout, press ***Delete***.

Note that the Radiometer default layout cannot be deleted. The button is disabled if only the Radiometer default layout is available.

Editing a layout To edit a layout, do the following:

| Step | Action |
|------|--|
| 1. | Highlight a layout in the list by touching it on the screen. |
| 2. | Press the <i>Edit Patient ID Layout</i> button to edit the patient ID items – see description on the next page. |
| 3. | Press the <i>Edit Patient Results Layout</i> button to edit the parameter groups – see description further in this section. |
| 4. | If an automatic printout of the Acid-Base chart for this layout is desired, activate the <i>Print Acid-Base Chart</i> button. |

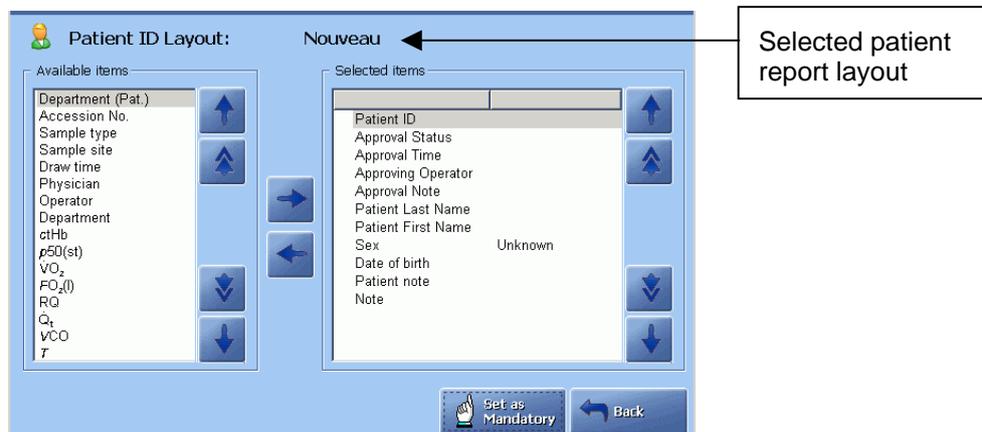


Continued on next page

Patient reports, *Continued*

Editing patient ID layout You can customize the patient identification (Patient ID) information as follows:

- select the items to be included in the Patient ID.
- set Patient ID entries as mandatory.
- define default values for Patient ID.



To edit a patient ID for a selected patient report layout, do the following:

- | Step | Action |
|------|---|
| 1. | To add a highlighted (by touching it on the screen) item in the "Available items" box, to the list of selected items, press the "→" button. |
| 2. | To remove a highlighted (by touching it on the screen) item from the "Selected items" box, press the "←" button. |
| 3. | To make a highlighted item in the list of selected items mandatory, press the Set as Mandatory button. The item will be indicated by a  on the Patient ID screen and must be entered during a measurement before a patient result can be viewed. |

To remove the mandatory mark, highlight the item in the "Selected items" box and press the **Set as Mandatory** button again.

NOTICE: If you are using mandatory input fields, you are not allowed to change the report layout during measurement, unless the mandatory fields have been filled out.

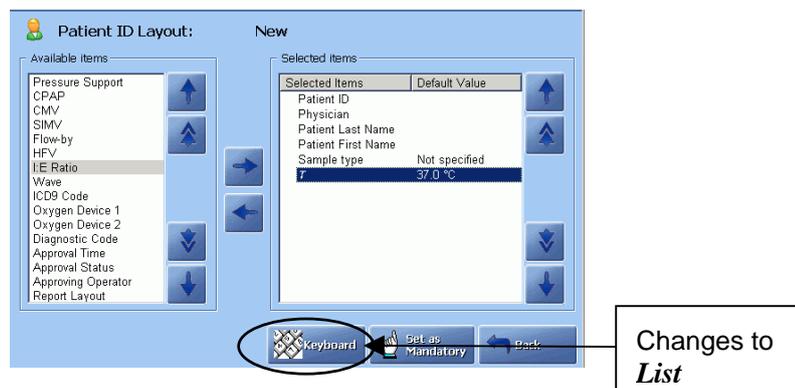
- | | |
|----|---------------------------------------|
| 4. | Press Back to exit the screen. |
|----|---------------------------------------|

Continued on next page

Patient reports, *Continued*

Entering default values To enter default values for patient identification items, do the following:

- | Step | Action |
|------|---|
| 1. | Use the arrow buttons on the right to highlight the desired item in the "Selected items" box. |



2. Set the default:
 - If the item has a value, press **Keyboard**, enter the value and press **Enter** on the keyboard to confirm.
 - If the item has a list of options, press **List**, highlight the option using the arrow buttons and press **Enter** to confirm.
3. Set or change other default values in the similar manner.
4. Press **Back** to exit and confirm changes.

NOTICES:

- It is not possible to set default values for all items.
- The values can be changed on a result-by-result basis on the **Patient Identification** screen.
- An item placed in the *Selected items* list does not appear in the *Available items* list.
- To use the Patient Lookup function, Department (Pat.) should be selected for the **Patient Identification** screen.
- To use the Request function, Accession number, Sampler ID and/or Patient ID should be selected for the **Patient Identification** screen.

Continued on next page

Patient reports, *Continued*

Editing patient result layout

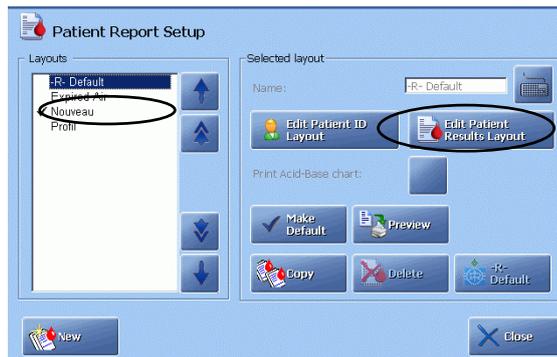
You can do the following:

- select parameter groups and the parameters in each group, and
- make report layout by using layout commands.

To edit a patient result layout, do the following:

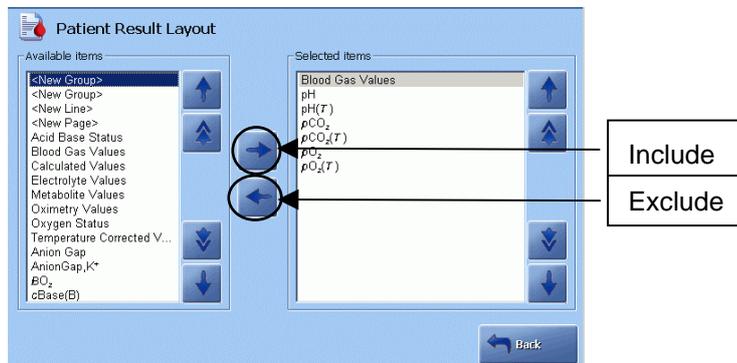
| Step | Action |
|------|--------|
|------|--------|

1. Select the patient report layout by highlighting it on the screen and



press *Edit Patient Results Layout*.

2. Use the arrow buttons to highlight a parameter group and press “→”



to include the group in the patient result. It will be shown in the "Selected items" box.

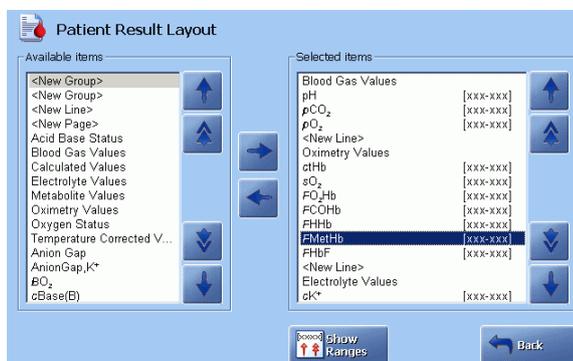
3. Select parameters for this parameter group by highlighting them one by one and pressing “→” (*Include*).
4. Select another parameter group and parameters for this group in the same manner.
5. Use layout commands <New group> (items following this command are placed on the top of the next half of the screen), <New Line> (a line is inserted between items) or <New Page> (items following this command appear on next screen page) as desired and press “→”.

Continued on next page

Patient reports, *Continued*

Editing patient result layout (*continued*)

- | Step | Action |
|------|---|
| 6. | To exclude an item from the selected parameter list, highlight it and |



press “←”

- If you wish to display parameters with their reference ranges and have them checked against reference ranges/critical limits, do the following:
 - Highlight a parameter.
 - Press **Show Ranges** to indicate it by “[xxx-xxx]”.
 - Repeat for other parameters in the same manner.

If the “[xxx-xxx]” is not included for a parameter, checking against reference ranges/critical limits is disabled for this parameter.

However, checking against the reportable ranges is always performed.

NOTICE: Refer to the Reference Manual, *chapter 6: Parameters*, for information on parameters and their groups.

Calibration setup

Programs Calibration Setup programs are described in this section.



Activate a button to enter the program.

Calibration drift tolerances This program allows you to change the default drift tolerances for the pH, $p\text{CO}_2$, $p\text{O}_2$, electrolyte and metabolite electrodes – see *Radiometer default settings* in *chapter 15* in this manual.

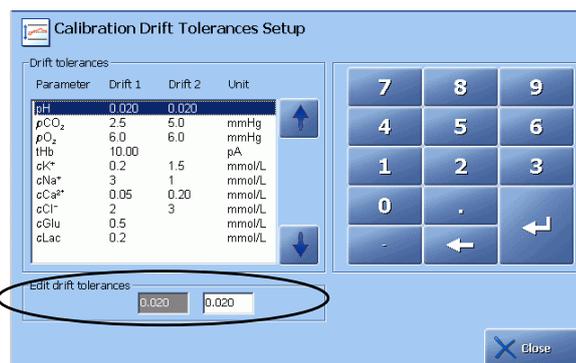
NOTICE: Radiometer recommends the use of the default drift tolerances. Too narrow drift tolerances will cause electrode drift errors even for normal electrode fluctuations. If the drift tolerances are made wider, no warning will be given if the electrode should become unstable. Significant measurement errors could result.

To define your own drift tolerances, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Highlight the desired parameter by touching it on the screen.

The list of available parameters depends on your analyzer version.



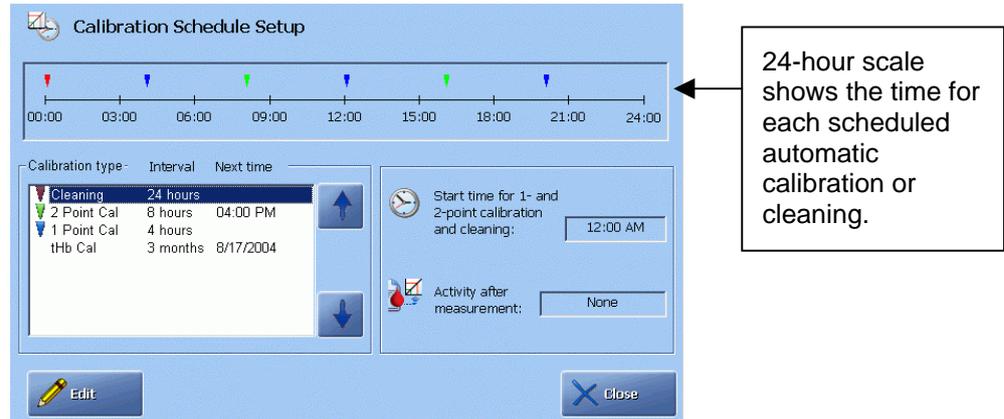
2. Type in your own value and confirm with **Enter**.
3. Change other drift tolerances in the same manner.
4. Press **Close** to confirm the changes.

Continued on next page

Calibration setup, *Continued*

Calibration schedule

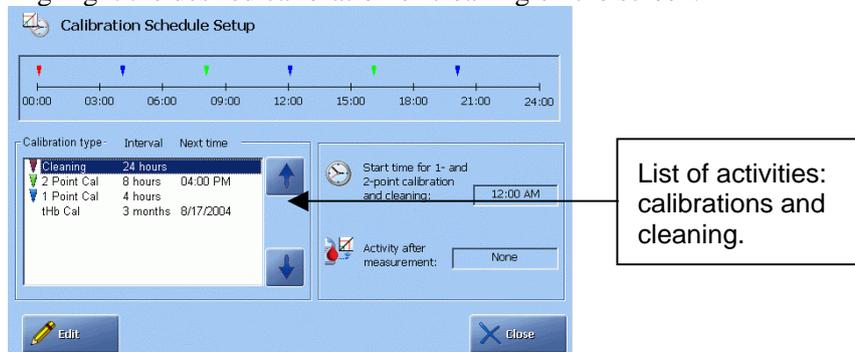
This program allows you to schedule automatic calibrations, manual tHb calibration and automatic cleaning (the first automatic cleaning also includes quality control of the Crea A and B electrodes for high creatinine values on the ABL8x7 FLEX analyzers), and select a calibration to be performed after a sample measurement.



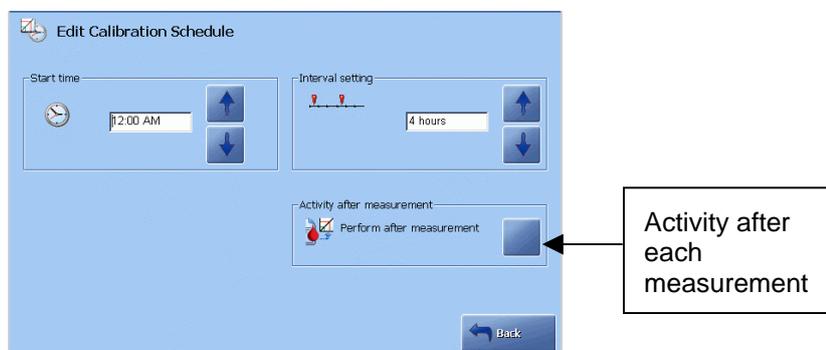
To edit the schedule for automatic calibrations/cleaning and tHb calibration, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Highlight the desired calibration or cleaning on the screen.



2. Press the *Edit* button.



Use the arrow buttons to select start time for calibrations and cleaning and the intervals between each activity.

Continued on next page

Calibration setup, *Continued*

Calibration schedule (*continued*)

| Step | Action |
|------|--|
| 3. | Select activity after each measurement by activating the check button for the desired calibration. |

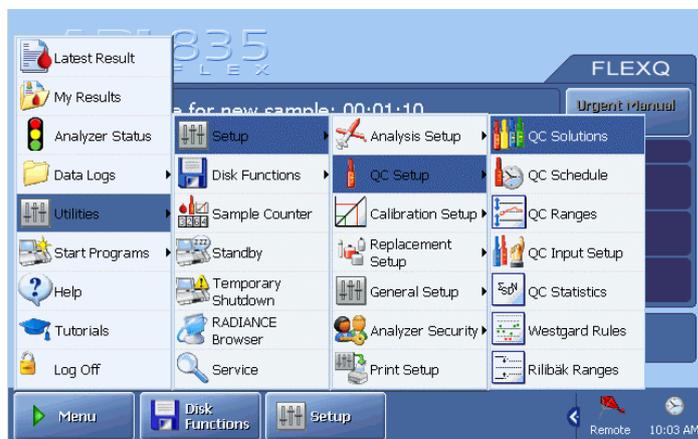
Available calibration schedule options

The following options are available.

| Option | Interval |
|---|--|
| 1 Point calibration | 30 min, 1 hour, 2, or 4 hours. |
| 2 Point calibration | 1 hour, 2, 4 or 8 hours. |
| 1 Point pH/BG calibration (for the USA only) | 30 min, 1 hour, 2 hours. |
| tHb calibration | Never, 7 days, 1 month, 2, 3, 4 or 6 months |
| Start time | 00:00, 00:15, 00:30, 00:45..... 23:45. or 12 midnight, 12:15 am, 12:30 am, 12:45 am.....12 midday, 12:15 pm.....11:45 pm. |
| Activity after measurement | none, 1 Point pH/BG calibration (for the USA only), 1 Point calibration, 2 Point calibration. |
| Cleaning intervals | 8, 24 hours. |

Quality control setup

Programs The quality control setup programs are described in this section.



Activate a button to enter the program.

QC solutions This program allows you to assign or change a quality control solution to a specific slot.

NOTICE: Changing a control solution assigned to a slot will delete all current quality control statistics obtained on that slot. If you want a copy of the statistics for the last QC month, create a WDC Report – see *chapter 8: Disk Functions*.



NOTICE: (for the ABL8x7 FLEX analyzers only) Slot 11 is assigned to the Cleaning Met II Solution used for high Crea check.

Continued on next page

Quality control setup, *Continued*

QC solutions (continued)

To assign a control solution to a slot, do the following:

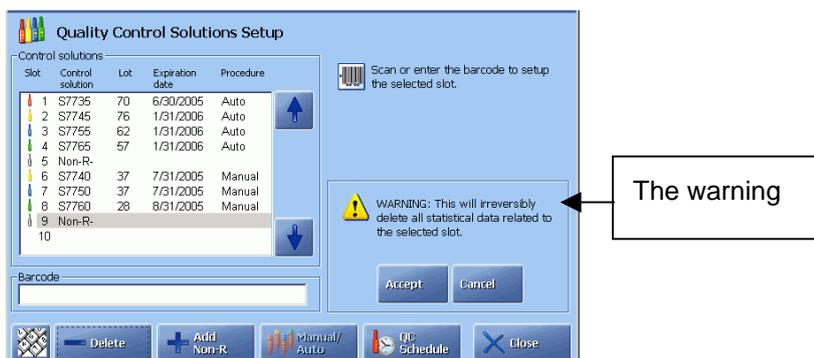
| Step | Action |
|------|--------|
|------|--------|

1. Highlight a slot, using the arrow buttons.
2. For control solutions from Radiometer, scan the bar code or press the



keypad button to enter the barcode.

3. For non-Radiometer control solutions, press **Add Non-R-**.



Press **Accept** to continue with the installation of the control solution.

Press **Cancel** to cancel installation of the control solution.

4. To delete a control solution, highlight the desired slot and press **Delete**. The warning as in step 3 above appears.

Press **Accept** to continue with the removal of the control solution.

Press **Cancel** to cancel.

5. To define whether an AutoCheck quality control measurement is to be run manually or automatically, press the **Manual/Auto** button. Useful if the AutoCheck module is out of order.

The following quality control solutions can be used with the ABL800 FLEX analyzers:

| Quality control system | Analyzer |
|--|--------------|
| QUALICHECK5+; AutoCheck5+ | ABL805 |
| QUALICHECK3+; QUALICHECK5+; AutoCheck3+; AutoCheck5+ | ABL830/20/10 |
| QUALICHECK5+; AutoCheck5+ | ABL835/25/15 |
| AutoCheck6+, S8377 Cleaning Met II Solution | ABL837/27/17 |

For the solution types for each quality control system, please refer to *chapter 14: Ordering information* in this manual.

You can also use a suitable non-Radiometer quality control system for your analyzer.

Continued on next page

Quality control setup, *Continued*

QC ranges

This program allows you to do the following:

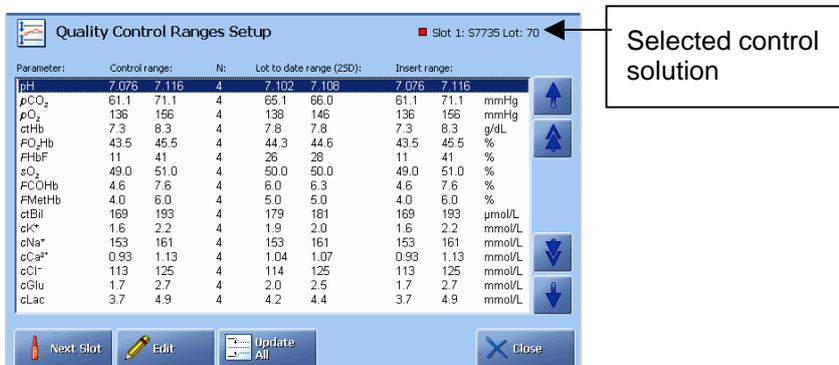
- globally update all control ranges of a slot to a calculated lot-to-date range.
- individually edit parameter control ranges by entering your own ranges or updating to a calculated lot-to-date range.
- define a minimum allowed control range by entering a Fixed SD (standard deviation).

See the *Quality Control Systems Reference Manual* for detailed information on statistics and its parameters.

To edit data for the control solution, do the following:

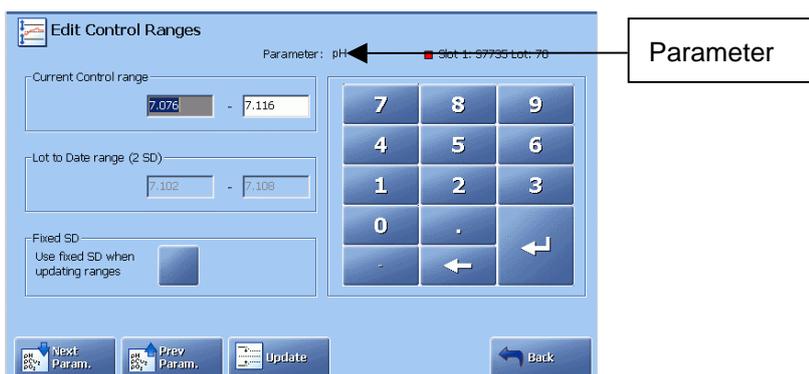
| Step | Action |
|------|--------|
|------|--------|

1. Use *Next Slot* to display the desired slot.



Press *Edit*.

2. Select the parameter to be edited, using *Next Param.* or *Prev Param.*



3. Press *Update* to change the range to the one shown in the "Lot-to-Date range (2 SD)" box - if available (i.e. the range calculated over the course of the lot, represented mathematically by: mean value ± 2 SD. This is the range within which 95 % of the measurements taken are found).

Continued on next page

Quality control setup, *Continued*

QC ranges (*continued*)

- | Step | Action |
|------|---|
| 4. | Highlight the limit by touching it on the screen and enter your own value(s), using the keypad. |
| 5. | To activate or deactivate the Fixed SD (i.e. a minimum allowed control range is defined by setting a Fixed SD), press the check button. |



To change the SD value, touch the **SD** field to highlight it and enter the value, using the keypad. Confirm the entry with **Enter**.

- | | |
|----|--|
| 6. | Repeat the procedure for other parameters in the same manner. |
| 7. | To update the control ranges for all parameters of a displayed level to the corresponding lot-to-date (2 SD) range shown, display the desired slot, using Next Slot . |

| Parameter: | Control range: | Ni: | Lot to date range (2SD): | Insert range: | |
|---------------------|----------------|-----|--------------------------|---------------|--------|
| pH | 7.070 7.116 | 4 | 7.102 7.169 | 7.070 7.116 | |
| pCO ₂ | 51.1 71.1 | 4 | 65.1 88.0 | 51.1 71.1 | mmHg |
| pO ₂ | 136 156 | 4 | 138 146 | 136 156 | mmHg |
| ctHb | 7.3 8.3 | 4 | 7.8 7.8 | 7.3 8.3 | g/dL |
| FO ₂ Hb | 43.5 45.5 | 4 | 44.3 44.6 | 43.5 45.5 | % |
| FlHbF | 11 41 | 4 | 26 28 | 11 41 | % |
| sO ₂ | 49.0 51.0 | 4 | 50.0 50.0 | 49.0 51.0 | % |
| FCO ₂ Hb | 4.6 7.6 | 4 | 6.0 6.3 | 4.6 7.6 | % |
| FlMetHb | 4.0 6.0 | 4 | 5.0 5.0 | 4.0 6.0 | % |
| ctBil | 169 193 | 4 | 179 161 | 169 193 | μmol/L |
| ctK ⁺ | 1.6 2.2 | 4 | 1.9 2.0 | 1.6 2.2 | mmol/L |
| ctNa ⁺ | 153 161 | 4 | 153 161 | 153 161 | mmol/L |
| ctCa ²⁺ | 0.93 1.13 | 4 | 1.04 1.07 | 0.93 1.13 | mmol/L |
| ctCl ⁻ | 113 125 | 4 | 114 125 | 113 125 | mmol/L |
| ctGlu | 1.7 2.7 | 4 | 2.0 2.5 | 1.7 2.7 | mmol/L |
| ctLac | 3.7 4.9 | 4 | 4.2 4.4 | 3.7 4.9 | mmol/L |

Press **Update All**.

- | | |
|----|--|
| 8. | Press Continue to update the control ranges for all parameters under the specified solution slot. |
|----|--|



Press **Cancel** to cancel updating.

Continued on next page

Quality control setup, *Continued*

QC ranges (continued) **NOTICE:** Once the Fixed SD is activated, you cannot update the control ranges to the limits that are narrower than those determined by the Fixed SD, for both single-parameter and multiple-parameter updates.

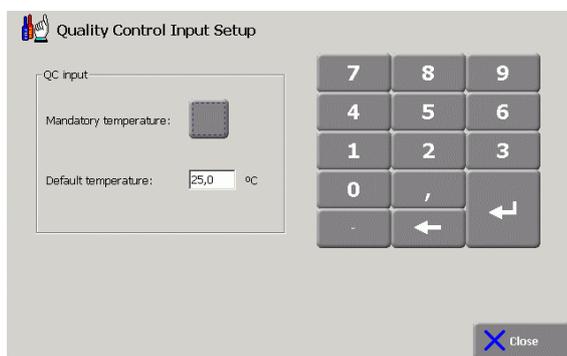
QC input setup This program allows you to select the following for the **Quality Control Identification** screen during a measurement:

- mandatory temperature entry by the operator
- the default temperature always displayed (unless altered by the operator).

To select the settings, do the following:

| Step | Action |
|------|--------|
|------|--------|

- | | |
|----|---|
| 1. | Activate the <i>Mandatory temperature</i> check button. |
|----|---|



A  will appear next to an empty temperature box on the **Quality Control Identification** screen during each quality control measurement and a temperature must be entered, otherwise the result cannot be retrieved.

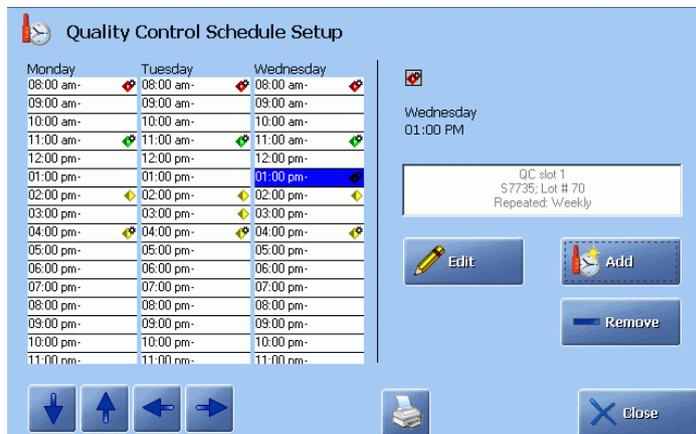
2. Highlight the default temperature in the "Default temperature" box and enter a default temperature on the keypad; confirm with **Enter**.

The value in °C or °F is automatically entered on the **Quality Control Identification** screen during measurement. The temperature can be altered for a particular measurement but will return to the default setting for future measurements.

Continued on next page

Quality control setup, *Continued*

QC schedule This program allows you to schedule quality control measurements for your analyzer.



The screen shows the timetable for all days of the week and time during a day.

| Step | Action |
|------|--------|
|------|--------|

1. To select time during a day, use the ↑ and ↓ buttons.
2. To display other weekdays, use the ← and → buttons.

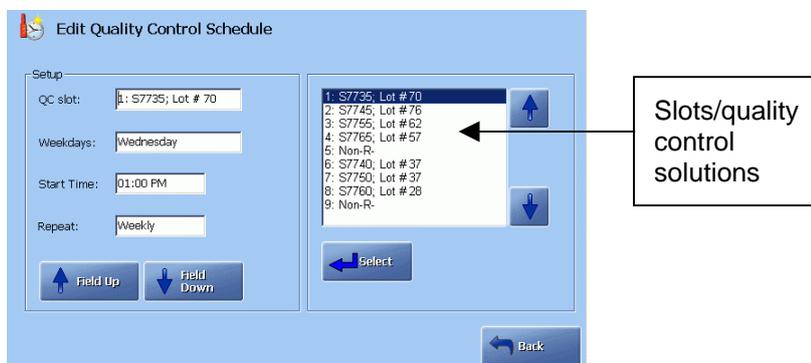
Symbols for manual and automatic quality control are as follows:

-   measurement(s) on the control solution **manually** performed.
-   measurement(s) on the control solution **automatically** performed.

To add a new quality control solution to a schedule, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Select the desired time.
2. Press the **Add** button to display the screen below.



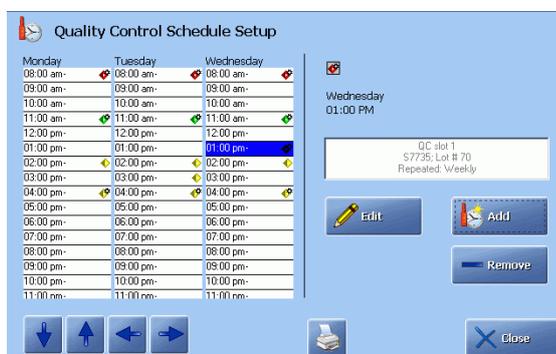
Touch the “QC slot” box to activate it.

Continued on next page

Quality control setup, *Continued*

QC schedule (*continued*)

- | Step | Action |
|------|--|
| 3. | Select the slot/quality control solution (entered in the Quality Control Solutions program), using the up/down arrow buttons in the box. Confirm with Select . |
| 4. | Highlight the "Weekdays" box using the Field down button. Activate the relevant check buttons to select the days of the week this measurement should be performed. |
| 5. | Highlight the "Start time" box. Key in the time to perform a measurement and confirm with Enter on the keypad. NOTICE: The symbols for the automatic or manual quality control (given on the previous page) will automatically appear in the schedule. |
| 6. | Highlight the "Repeat" box. Select the interval the measurement should be repeated, using the up/down arrow buttons in the box. |
| 7. | Press Back to return to the Quality Control Schedule Setup screen. If more than one quality control solution was scheduled, the schedule screen will look like this: |



To edit the schedule, press **Edit** and follow the procedure above.

Continued on next page

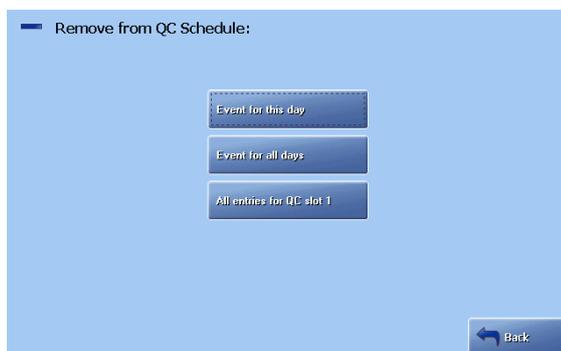
Quality control setup, *Continued*

QC schedule (*continued*)

To remove a quality control measurement from the schedule do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Highlight the desired quality control measurement and press **Remove**.



2. Press the desired button to remove the quality control measurement from the schedule: **For this day**, **For all days** or **All entries for QC slot** (number).
3. Press **Back** to return to the **QC Schedule** screen.

QC Statistics

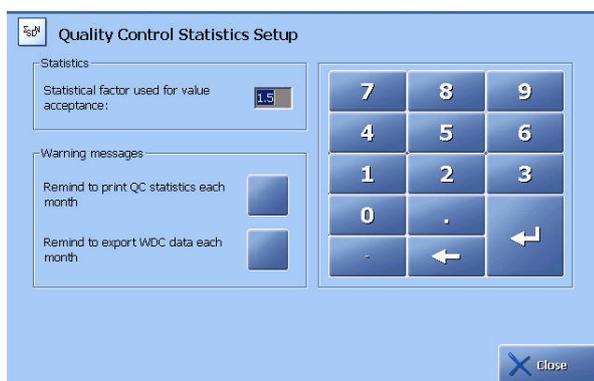
This program allows you to select the following:

- the statistics factor
- the initiation of warning messages at the end of the statistical month.

To select the settings, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Statistics factor expands the control range to the statistics range (it is a range within which quality control results must fall in order to be included in the quality control statistics).



1. Key in the desired statistics factor (from 1.0 to 9.9) on the keypad and confirm with **Enter**. The default value is 1.5.

Continued on next page

Quality control setup, *Continued*

QC Statistics (*continued*)

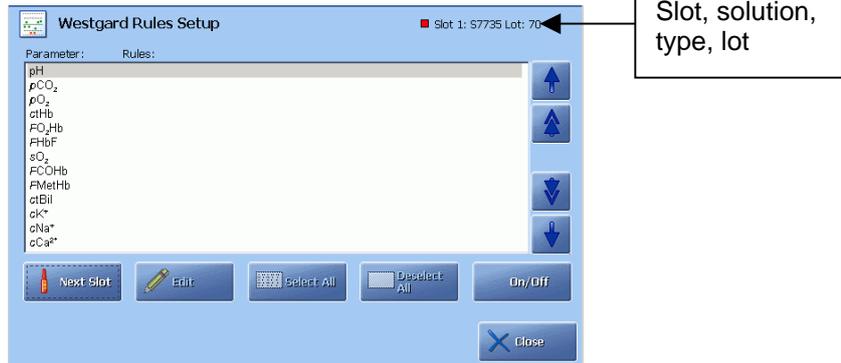
- | Step | Action |
|------|--|
| 2. | To set up the analyzer to send reminders to print or export the monthly statistics, activate the appropriate check button (or both) for the message(s) to appear in System Messages upon occurrence. |
| 3. | Press <i>Close</i> to exit the program. |

Westgard Rules The Westgard Rules are a set of statistical rules that, when applied to the quality control results, can increase the probability of detecting an error in the sampling procedure or in the analyzer itself, or help detecting a shift or trend in your quality control results by comparing current measurement values of a control solution with previous values.

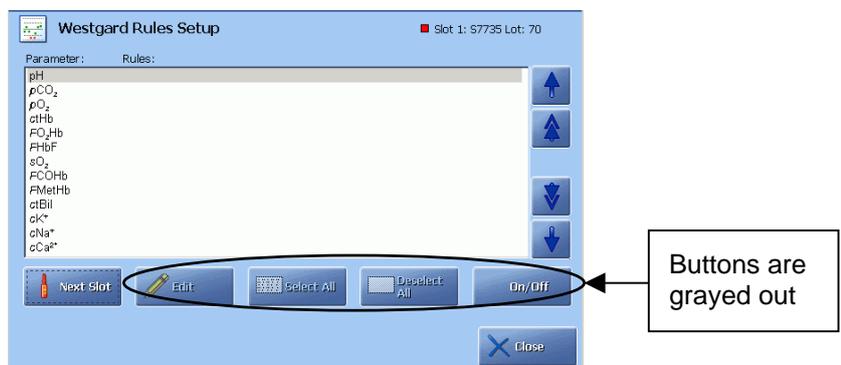
This program allows you to select Westgard Rules for all slots or for specific parameters.

To activate or deactivate the assigned Westgard Rules, do the following.

- | Step | Action |
|------|--|
| 1. | Press <i>On/Off</i> button to activate the assigned Westgard Rules for the slot. |



Press *On/Off* again to deactivate the assigned Westgard Rules.

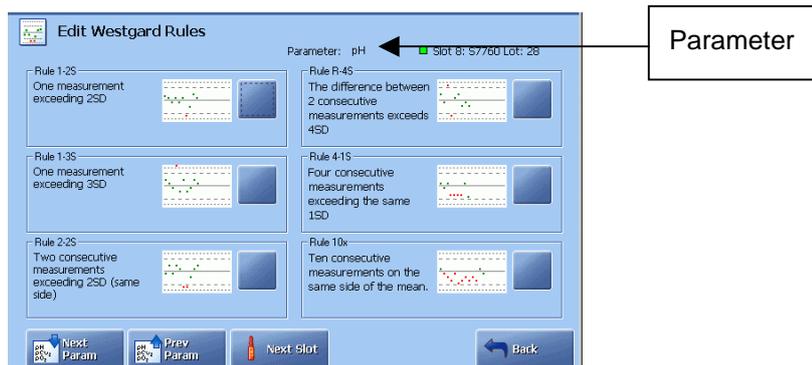


Continued on next page

Quality control setup, *Continued*

Westgard Rules (*continued*)

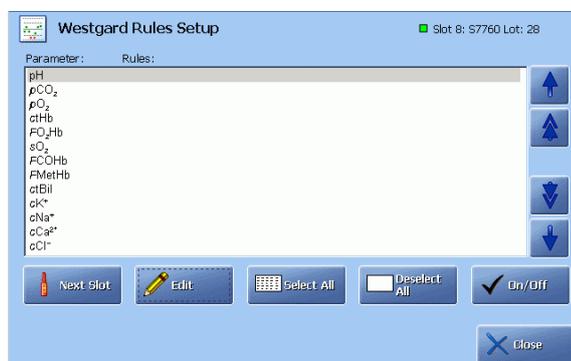
- | Step | Action |
|------|---|
| 2. | Press Next Slot and activate/deactivate the Westgard Rules for the other slots in the same manner. |
| 3. | To activate the Westgard rules for specific parameters in a slot, display the desired slots by using Next Slot . |
| 4. | Press the Edit button. The screen shows all the Westgard Rules and their current settings for the parameter. |



5. Display the desired parameter using the **Next Param** or **Prev Param** buttons.
6. Activate the desired Westgard Rule(s) by pressing the corresponding check button.

Once edited, all future quality control measurements on the parameter for the given slot will be evaluated according to the selected Westgard Rule(s).

7. Select Westgard Rules for other parameters or levels in the same manner.
8. To select/deselect all six Westgard Rules for every parameter of a displayed control solution slot, select the desired slot by pressing the **Next Slot** button.



Continued on next page

Quality control setup, *Continued*

Westgard Rules (*continued*)

- | Step | Action |
|------|--|
| 9. | Press Select All or Deselect All . |
| 10. | Verify information on the screen. |



Press **Continue**. Changes are made and shown in the Westgard Rules Setup.

Press **Cancel**. No changes are made.

- | | |
|-----|---|
| 11. | Select or deselect the Westgard Rules for other slots in the same manner. |
|-----|---|

NOTICES:

- All future measurements taken on the slot will be evaluated with respect to the Westgard Rules if the Select All function was activated
- Settings will be removed under Deselect All. To have the possibility to return to the settings as they were, use the **On/Off** button.
- When a quality control measurement violates an applied Westgard Rule, a W is added to the parameter in the result. For a detailed explanation of how to interpret and evaluate results with respect to Westgard Rules, see *chapter 7* of the *Quality Control Reference Manual*.

Reference:

Westgard JO, Barry PLL. Cost effective quality control: managing the quality and productivity of analytical processes. Washington: AACC Press, 1992.

Rilibäk Ranges

The **Rilibäk Ranges** program allows you to define a set of rules to control the maximum deviation of any parameter from the assigned target value.

The target values are given on the QC insert.

It is possible to define more than one rule for the individual parameters.

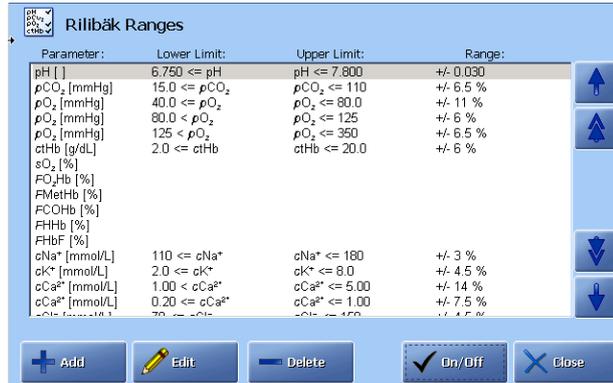
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Quality control setup, *Continued*

Rilibäk Ranges To activate or deactivate the Rilibäk Rules, do the following.
(*continued*)

Step Action

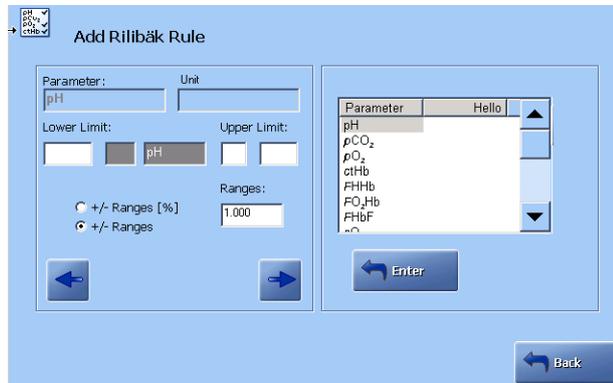
1. Press the **On/Off** button to activate/deactivate the assigned Rilibäk rules.



To add a new Rilibäk rule, do the following:

Step Action

1. Press the **Add** button to display the screen below:



2. Select the desired parameter from the parameter list shown in the right side of the screen.
3. Press the **Left** arrow button until the first "Lower Limit" box is highlighted and enter the desired lower limit.
4. Highlight the next box and select "<" or "<=".
5. Highlight the first "Upper Limit" box and select "<" or "<=".
6. Highlight the next "Upper Limit" box and enter the desired upper limit.

Continued on next page

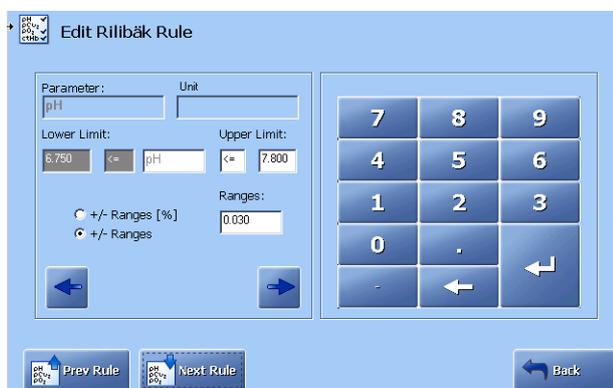
Quality control setup, *Continued*

Rilibäk Ranges (*continued*)

| Step | Action |
|------|---|
| 7. | To select the desired +/- range press the desired radio button. |
| 8. | Enter the desired +/- range in the "Ranges" box. |
| 9. | Press Back to return to the Rilibäk Ranges screen. The added Rilibäk rule is now shown in the screen. |

To edit a Rilibäk rule, do the following:

| Step | Action |
|------|--|
| 1. | Select the desired rule in the Rilibäk Ranges screen and press Edit to display the screen below: |



- Use the **Right** or **Left** arrows to jump between the input boxes and edit the desired values.
- Press **Back** to return to the **Rilibäk Ranges** screen.

To remove a Rilibäk rule, do the following:

| Step | Action |
|------|--|
| 1. | Highlight the desired rule in the Rilibäk Ranges screen and press Delete . |

NOTICE: When a quality control measurement violates an applied Rilibäk Rule, a red R is shown in front of the parameter name in the result.

Replacement setup

Programs

Replacement Setup includes the programs described in this section.



Activate a button to enter the program.

Replacement schedule

This program allows you to schedule routine replacements along with the current scheduled date and interval for replacement. The settings selected here are then used in the Replacements on the **Analyzer Status** screen.

To edit the schedule of replacement actions, do the following:

Step Action

1. Highlight the replacement action to be scheduled and press **Edit**.

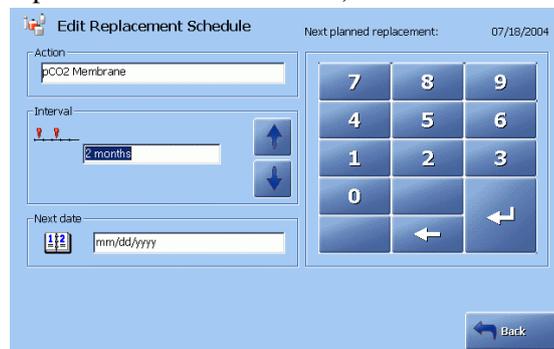


Continued on next page

Replacement setup, *Continued*

Replacement schedule (continued)

- | Step | Action |
|------|---|
| 2. | Change the interval for the selected replacement action (displayed in the "Action" box) with the up/down arrow buttons (see recommended replacement intervals below). |



NOTICE: The replacement schedule reminder "Lock analyzer when 10 % overdue" (selected in Corrective Actions – see further in this chapter) will work on the basis of the setting selected in the "Action" box.

3. Touch to highlight the "Next date" box and change the date using screen keypad. Confirm with **Enter**.
4. Press **Back** to return to the **Replacement Setup** screen.
5. Repeat steps **1-4** for each replacement action to be scheduled.

Recommended replacement intervals

The following replacement intervals are recommended by Radiometer.

NOTICE: The replacement intervals below are guidelines only. Under no circumstances do they guarantee the lifetime of the replacement items. For analyzers with high throughput the replacement intervals should be adjusted accordingly in the Replacement schedule.

For an average of 40 samples per day:

| Action | Interval |
|---|-------------|
| Replacing Crea A and Crea B electrode membranes | 14 days |
| Replacing metabolite membranes | 1 month |
| Replacing blood gas and electrolyte electrode membranes | 3 months |
| Replacing pump tubing | 6 months |
| Replacing inlet gasket | 6 months |
| Replacing fan filter | as required |
| Replacing electrodes | as required |

Replacing reference electrode membranes:

| | | |
|----------------------|---|---------|
| 40 samples per day: | All analyzers, except ABL8x7 FLEX analyzers | 1 month |
| ≤40 samples per day: | ABL8x7 FLEX analyzers only | 14 days |
| >40 samples per day: | ABL8x7 FLEX analyzers only | 1 week |

The status of solutions, waste container and gas cylinders are not scheduled and can be viewed in the Replacements on the **Analyzer Status** screen.

Continued on next page

Replacement setup, *Continued*

User Activities This program allows you to formulate and schedule your own activities (e.g. cleaning analyzer, replacing printer paper, etc.) along with the current scheduled date and interval. The settings selected here are then used in the Replacement Status.

Adding a user activity To add the user activity, do the following:

- | Step | Action |
|------|--|
| 1. | Press Add to display the Edit User Activities Schedule screen. |



2. To add text, press the keyboard icon and type the activity. Confirm with **Enter** on the keyboard.



Choose the Interval with the up and down arrow keys in the "Interval" box:

1-2-3-4-5-6-7-10-14-20-30 days or 2-3-4-6-8-12-18-24 months.

3. Type the "Next date" using screen keypad. Confirm with **Enter**.
4. Press **Back** to return to the **User Activities** screen.
5. Repeat steps **1-4** for each activity to be scheduled.

Continued on next page

Replacement setup, *Continued*

Editing a user activity To edit a user activity, do the following:

- | Step | Action |
|------|---|
| 1. | Highlight the desired user activity on the User Activities screen. Press Edit . |
| 2. | Press the keyboard icon to edit the text. Confirm the text with ENTER. |



Change, if desired, the interval or next date (confirm the date with **Enter**).

- | | |
|----|---|
| 3. | Press Back to return to the User Activities screen. |
| 4. | Edit other user activities in the same manner. |

Deleting a user activity To delete a user activity from the list, do the following:

- | Step | Action |
|------|---|
| 1. | Press Delete on the User Activities screen. |
| 2. | Press Continue to delete the activity. |



Press **Cancel** to return to the **User Activities** screen.

Continued on next page

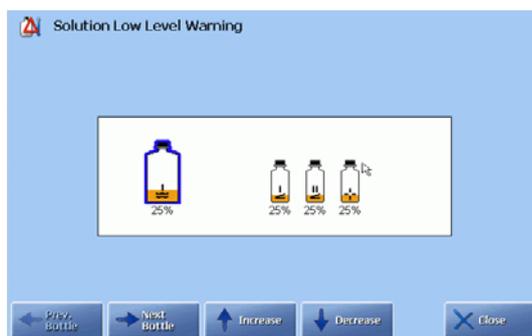
Replacement setup, *Continued*

Solution warning

This program allows you to select a solution level value in % below which a warning will be given.

To select the solution level value for the warning to be activated (default value is 25 %), do the following:

- | Step | Action |
|------|--|
| 1. | Highlight the desired solution bottle: touch the bottle on the screen or use <i>Next Bottle</i> or <i>Prev. Bottle</i> . |



- | | |
|----|--|
| 2. | Select the solution warning level (in %), using <i>Increase</i> or <i>Decrease</i> . |
| 3. | Select warning values for solution levels in other bottles in the same manner. |
| 4. | Press <i>Close</i> to confirm the settings. |

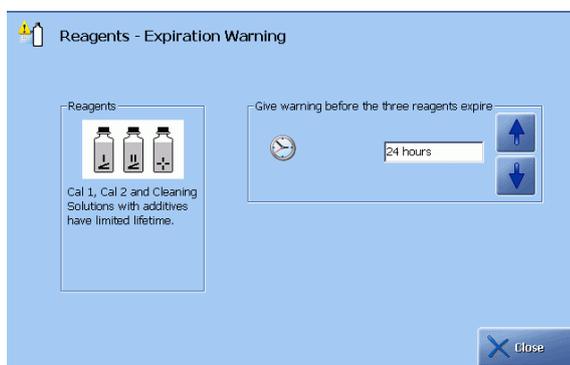
Reagents – Expiration Warning

This program allows you to set the time for the analyzer to give a warning before the calibration and cleaning solutions with additives will expire.

To set the time for the warning, do the following:

- | Step | Action |
|------|--|
| 1. | Select time, using the up/down arrow buttons in the "Give warning before reagents expire" box. |

The actual bottles of the analyzer depend on the analyzer type.



- | | |
|----|--|
| 2. | Press <i>Close</i> to exit the program and confirm the settings. |
|----|--|

Continued on next page

Replacement setup, *Continued*

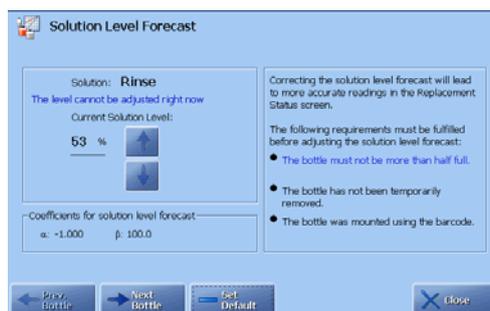
Solution Level Forecast This program allows you to change the solution level forecast so that the analyzer will predict the solution levels in the bottles more precisely.

It will improve both the graphical presentation on the **Replacement Status** screen and the accuracy of the solution low level warning.

To change solution level forecast, do the following:

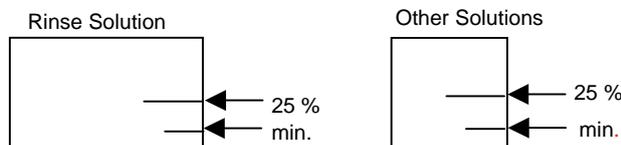
| Step | Action |
|------|--------|
|------|--------|

1. Select the solution bottle, using the *Next bottle* or *Prev. bottle* button (the Rinse solution has been selected on the screen).



2. Select the true level (in %) with the up and down arrow buttons on the screen.

The bottom of each solution bottle has markings for solution levels.



You can also remove the solution bottle to check the level, and the analyzer will not enter Hold mode. However, the Refill will be performed as soon as the bottle has been mounted back again.

The selected setting will be displayed on the **Analyzer Status** screen. The screen below is an example.



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Replacement setup, *Continued*

Solution Level Forecast (*continued*)

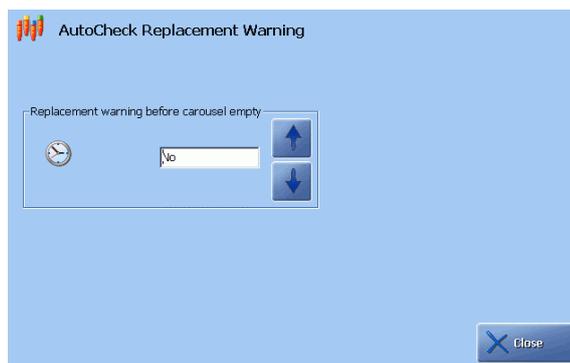
| Step | Action |
|------|---|
| 3. | Select solution level forecasts for other solutions in the same manner. |
| 4. | To reset all solution level forecasts to the default values: $\alpha = -1.00$ and $\beta = 100.0$, press the –Set Default button. |
| 5. | Press Close to confirm the settings. |

AutoCheck Replacement Warning

This program allows you to select the time for a reminder to appear in the System Messages in order to fill up the carousel.

To select time for the reminder, do the following:

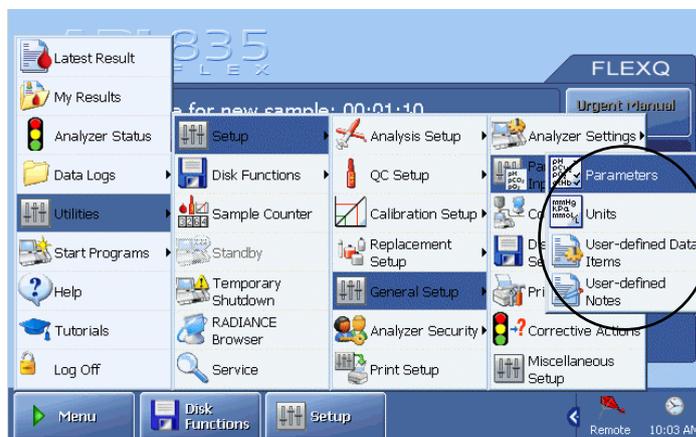
| Step | Action |
|------|--|
| 1. | Use the up/down arrow buttons to select one of the settings: No, 1 hour, 2 hours, 4, 8, 12, 24, 48 hours. |



2. Press **Close** to exit the program.

Parameters and input setup

Programs Parameters and Input Setup includes the programs described in this section.



Activate a button to enter the program.

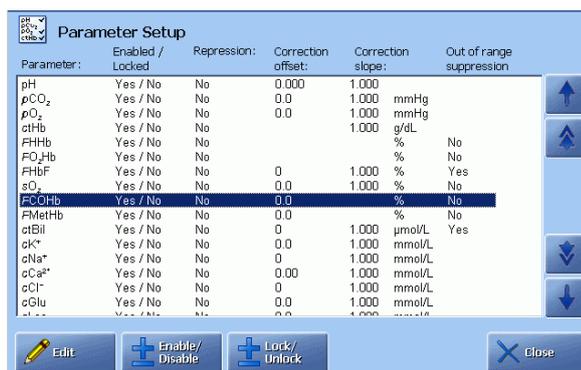
Parameters This program allows you to do the following:

- disable or enable a parameter
- repress parameters if any problems are detected
- lock a parameter
- make user-defined corrections for each measured parameter
- make out-of-range suppression of oximetry parameters and bilirubin.

To disable/enable a parameter, do the following:

Step Action

1. Highlight a parameter on the screen, using the scroll facilities.



2. Press **Enable/Disable** to include or exclude the parameter from a parameter profile and the parameter bar. Note that pH, pCO₂ and pO₂ cannot be excluded.

Continued on next page

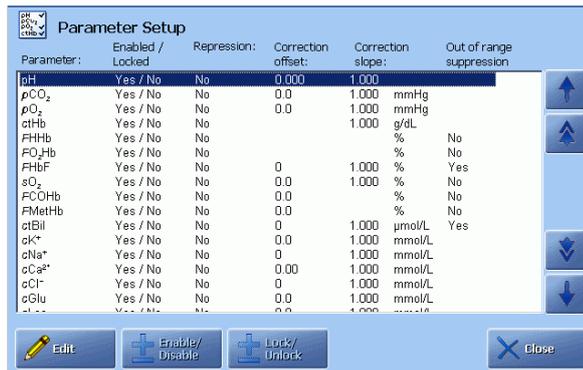
Parameters and input setup, *Continued*

Parameters
(continued)

Parameters can be **locked/unlocked** from the RADIANCE system. To lock or unlock a parameter from the analyzer, do the following:

Step Action

1. Make sure the analyzer is not connected to the RADIANCE system. Highlight a parameter on the screen, using the scroll facilities.



2. Press **Lock/Unlock**. (This button is grayed out if the analyzer is connected to the RADIANCE system.)

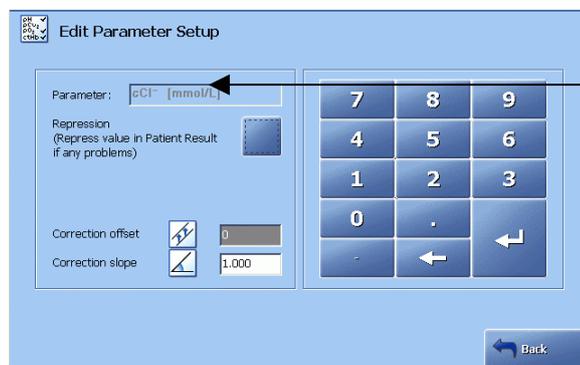
The locked parameter will show red on the parameter bar and will change the overall analyzer status traffic light on the **Analyzer Status** button to red. The parameter value will be absent from the printout. However, the locked parameter will be calibrated.

3. To unlock a parameter, highlight it and press **Lock/Unlock**. The traffic light on the **Analyzer Status** button will change from red to a color corresponding to the analyzer's overall status.

To **edit** the parameter setup, do the following.

Step Action

1. Highlight the desired parameter and press **Edit**.
2. Activate (or deactivate) the following check buttons to select (or deselect) the following functions:



Highlighted parameter

Continued on next page

Parameters and input setup, *Continued*

Parameters (*continued*)

| Step | Action |
|------------------------|---|
| 2. (cont.) | <ul style="list-style-type: none"> • Repression (Repress value in patient result, if the parameter is marked with a question mark, either because there is a calibration problem or QC problem). • Out of range suppression – for oximetry parameters or ctBil only. When activated, this function is applied to the oximetry/ctBil results (including those obtained in the past) as follows: <ul style="list-style-type: none"> – Oximetry parameters and ctBil values inside the measuring range but lower than “0” or higher than "100 %" will be shown as “0” or "100 %", respectively. – ctBil values higher than "1000 µmol/L" but inside the measuring range will be shown as "1000 µmol/L". |
| 3. | Use the keypad to enter the following for the highlighted parameter: <ul style="list-style-type: none"> • Correction offset. Confirm the entry with Enter. • Correction slope. Confirm the entry with Enter. |
| 4. | Press Back to return to the previous screen and repeat steps 1-3 for another parameter, if desired. |

NOTICE: User-defined corrections for blood measurements will influence the measurement results from blood and QC analyses and change the specific performance characteristics unless “Apply parameter corrections to QC” was disabled in Miscellaneous Setup.

Units

This program allows you to select the unit for each parameter or group of parameters.

To select the unit for a group or for a single parameter, do the following:

| Step | Action |
|------|--|
| 1. | Highlight the group (i.e. parameters which use the same unit as "pressures" = ($p\text{CO}_2$, $p\text{O}_2$, Baro, etc) or a parameter, using the arrow buttons. |
| 2. | Select the desired unit, using the arrow buttons. |

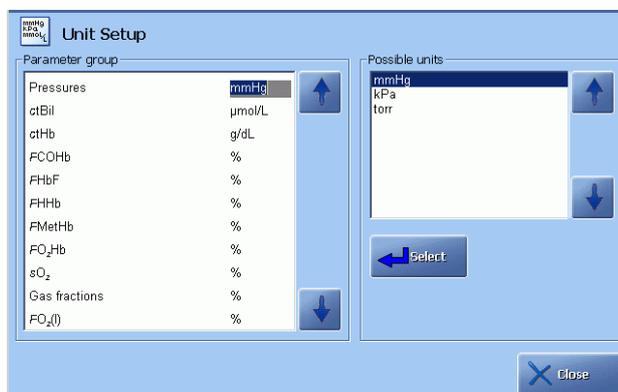
Continued on next page

Parameters and input setup, *Continued*

Units (*continued*)

| Step | Action |
|------|--------|
|------|--------|

3. Confirm the selected unit with *Select*.



4. Change units for other parameters in a similar manner.
5. Press *Close* to return to the **Ready** screen.

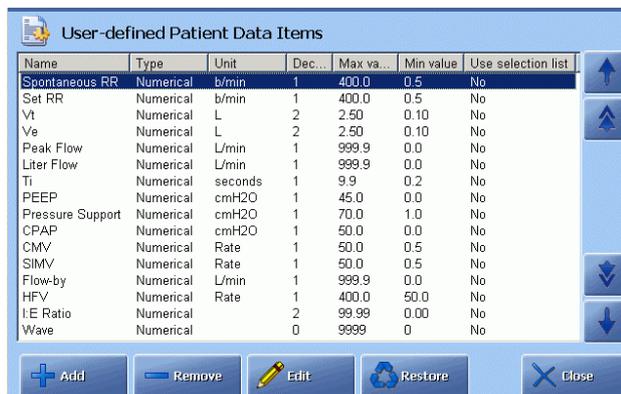
User-defined Patient Data Items

This program allows you to include other patient data in the Patient ID layout than those already available there.

To add a new item to the list, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Press *Add*.



2. Follow the procedure for editing an item from step 2 – see the next page.

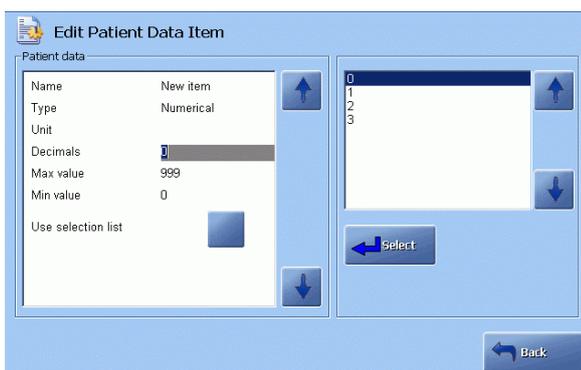
Continued on next page

Parameters and input setup, *Continued*

User-defined Patient Data Items (*continued*)

To edit an item in the list, do the following:

- | Step | Action |
|------|---|
| 1. | Highlight an item in the list and press Edit . |
| 2. | To change the name, press the keyboard icon on the keypad and type in the new name of up to 20 characters. Confirm with Enter on the keyboard. |
| 3. | Select the data type with the up/down arrow buttons and press Select . |



For "Text" entry proceed to step 8.

For "Numerical" entry proceed to step 4.

- Highlight "Unit". The keypad is now displayed. Press the keyboard icon on the keypad and type in the new name of up to 20 characters. Confirm with **Enter**.
- "Decimals" is now highlighted and the box with "None", "1", "2", "3" is displayed. Choose the number of decimals with the up/down arrow keys and press **Select** to confirm.
- Highlight "Max. value". Type in the value and confirm with **Enter** on the keypad.
- "Min. value" is now highlighted. Type in the value and confirm with **Enter** on the keypad.

Continued on next page

Parameters and input setup, *Continued*

User-defined Patient Data Items (*continued*)

- | Step | Action |
|------|--------------------------------|
| 8. | "Use selection list" function: |

Press the check button.

To make a list, press **Add**, type in the item on the displayed keyboard (up to 20 characters) and confirm with **Enter**. Add as many items as you wish in the same manner.

The check button can be activated only if the selection list contains two or more items.

- | | |
|----|---|
| 9. | Press Back to return to the User-defined Patient Data Items screen. The new entry will be included in the list. |
|----|---|

To include the new items in a Patient ID Layout, press **Menu - Utilities - Setup - Analysis Setup - Patient Reports - Patient Report ID** and follow the procedure described under *Including an Item into Patient ID in Patient reports* in this chapter.

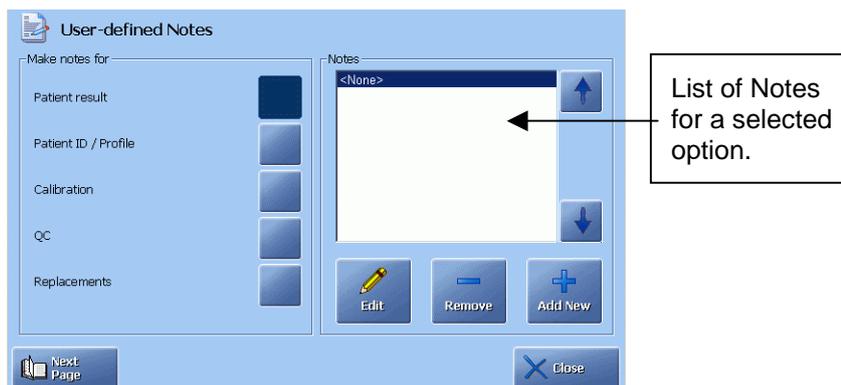
Continued on next page

Parameters and input setup, *Continued*

User-defined Notes This program allows you to formulate and store notes.
To make a Note text, do the following.

| Step | Action |
|------|--------|
|------|--------|

1. Activate one of the check buttons (e.g. Patient Result, Replacements, etc.). See also the remaining options by pressing *Next Page*.

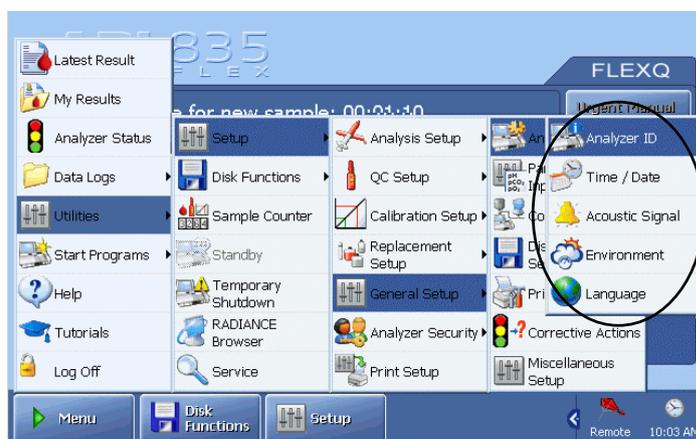


2. Press *Add New* and type the text for the Note, using the screen keyboard. Confirm with *Enter* to save the text and return to the previous screen. Your Note is now included in the list.
3. To edit a Note, highlight it in the Notes box, using the up and down arrow buttons, and press *Edit*.
The keyboard will be displayed with the Note text on it. Edit the text and confirm with *Enter*.
4. To delete a Note, highlight it in the Notes box, using the up and down arrow buttons, and press *Remove*.
5. Make notes for other options in the same manner.
6. Press *Back* to exit to the **Ready** screen.

If a list of Notes has been made for a given option, it will be marked with a pencil icon on the relevant screen(s).

Analyzer settings

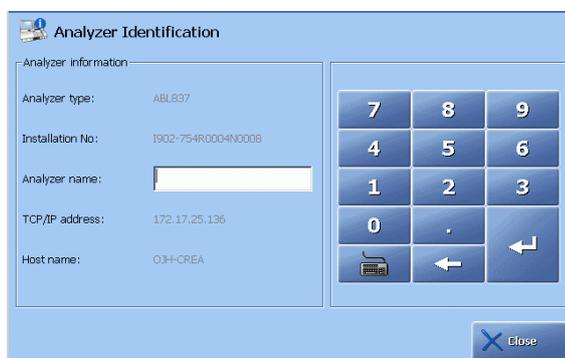
Programs The Analyzer Settings includes the programs described in this section.



Activate a button to enter the program.

Analyzer ID This program allows you to change the analyzer's identification. To enter analyzer ID do the following:

- | Step | Action |
|------|--|
| 1. | Touch and highlight the "Analyzer name" box. |



- | | |
|----|---|
| 2. | Type in an identification name and/or number for the analyzer (up to 32 characters), using the screen keypad or keyboard. Confirm with Enter . |
|----|---|

NOTICE: Installation number cannot be changed. Quote this number in any technical inquiries you have to Radiometer.

Continued on next page

Analyzer settings, *Continued*

Environment Setup

This program allows you to enter altitude above sea level, to adjust the built-in barometer in accordance with the reference barometer in your laboratory and to enter the ambient temperature required for the Crea reagents.

To enter the altitude at which your analyzer is placed (this is generally used for analyzers at particularly high altitudes), do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Touch the "Altitude above sea level" box to activate.
2. Type in the height above sea level in meters, using the keypad. Confirm with **Enter**.

At high altitudes, the difference between $p\text{CO}_2$ values in blood and in the QC solutions is very small due to the high buffer capacity of blood and the QC solutions, and is considered to be negligible. However, the aqueous QC solutions have a different capacity than blood to take up oxygen, and correcting for different $p\text{O}_2$ QC values at high altitudes is imperative as deviations from the respective values at sea level are significant. To correct for the different $p\text{O}_2$ values, the QC control ranges are modified according to the altitude. For detailed information, please refer to the *Quality Control Systems Reference Manual, chapter 4*.

NOTICE: To make altitude corrections operative for the installed QC solutions, re-enter the QC solutions in their slots and re-scan their barcodes.

To adjust the internal barometer, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Touch the "Adjust to:" in the "Barometer values" box to activate.
2. Key in the desired pressure value on the keypad and confirm with **Enter**. The value will be shown in the "Measured adjusted" box.
Maximum accepted correction is ± 19 mmHg (i.e. the difference between the "Measured unadjusted" and "Measured adjusted" settings).

Continued on next page

Analyzer settings, *Continued*

Environment Setup (*continued*)

| Step | Action |
|--------------|--|
| 2 (cont). | Barometer pressure limits are 450-800 mmHg, or 60.0-106.7 kPa, or 450-800 torr. The units are selected in the Setup program: Units. |

Check the barometer of the ABL800 FLEX analyzer against a known calibrated barometer at least once a month. See ranges in *chapter 13* in this manual.

To enter the ambient temperature, do the following:

| Step | Action |
|------|--|
| 1. | Touch the "Ambient temperature" box to activate. |
| 2. | Key in the new temperature, using the keypad. Confirm with Enter . |

The concentrations of creatinine and creatine in calibration solutions depend on the ambient temperature. This dependency is well-known and taken into account as follows: the analyzer calculates the correct concentrations, using the equilibration constants, time and the ambient temperature entered by user in the Environment Setup (*Menu > Utilities > Setup > General Setup > Analyzer settings*).

- For ambient temperatures between 15 °C and 28 °C or temperatures fluctuating through the entire operating range 15-32 °C of the analyzer, enter 23.5 °C. For ambient temperatures constantly above 28 °C and up to 32 °C enter 30 °C. Using these settings will provide analyzer performance according to the performance characteristics specified in the *ABL800 Reference manual, chapter 5*.
- In the temperature-controlled environment with constant temperature enter the average ambient temperature in the Environment Setup in order to improve the creatinine performance.
- If an error in the keyed-in ambient temperature is about 5 %, the bias in the reported *cCrea* results will be < 0.5 % unless creatine concentration in a sample is \geq *cCrea* concentration.

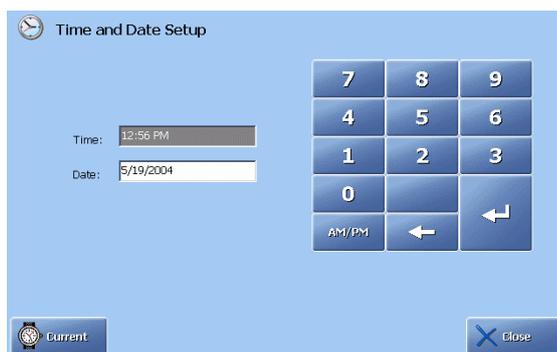
Continued on next page

Analyzer settings, *Continued*

Time/Date setup This program allows you to change the current time and date setting.
To reset the time and date, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Highlight the "Time" box by touching it on the screen.

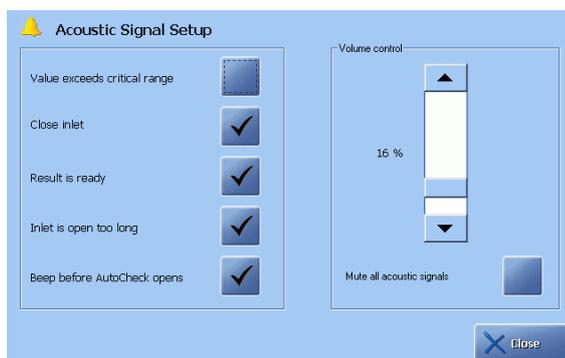


2. Key in the time on the screen keypad. Confirm with **Enter**.
A separator is automatically added between hours, minutes and seconds.
3. Repeat steps 1-2 to reset the Date.
4. To revert to the previous settings, press **Current**.

Acoustic signal setup This program allows you to set up a short beep to sound after certain events.
To activate the acoustic signal, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Activate the desired check button(s).



2. Select volume for the acoustic signal or activate the "Mute all acoustic signals" check button.

Continued on next page

Analyzer settings, *Continued*

Acoustic signal setup (continued) The following events are available:

| Event | Explanation |
|------------------------------|--|
| Value exceeds critical range | One of the measured values exceeds the specified critical limits for that parameter. |
| Close inlet | The inlet should be closed. |
| Result is ready | A sample has been analyzed and the results are ready for viewing. |
| Inlet is open too long | The inlet should be closed. |
| Beep before AutoCheck opens | A beep sounds to indicate that an AutoCheck measurement is about to take place. |

Language This program allows you to select a language of your choice from the list of languages available on your analyzer.

To change to another language do the following:

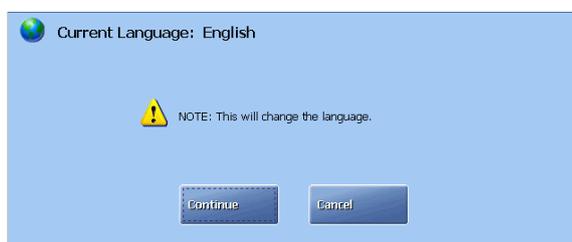
| Step | Action |
|------|--------|
|------|--------|

1. Select the desired language with the arrow buttons.



Press **Set Language**.

2. Press **Continue** to continue or press **Cancel** to continue operating the analyzer with the language unchanged.



Continued on next page

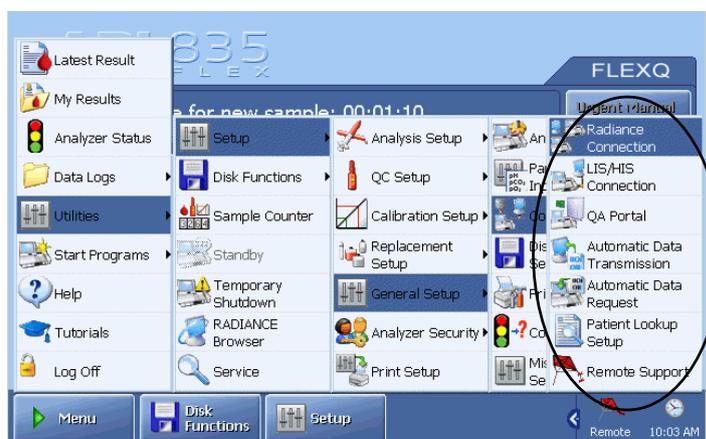
Analyzer settings, *Continued*

Language (*continued*)

| Step | Action |
|------|--|
| 3. | <p><u>If you pressed <i>Continue</i>:</u></p> <p>Press <i>Continue</i> once again to restart the analyzer right away and to use the new selected language right away or</p> <p>Press <i>Cancel</i> to continue operating the analyzer with the current language until the next restart, where the language then will be changed.</p> |

Communications

Programs The Communications Setup programs are described in this section.



Activate a button to enter the program.

Refer to *Chapter 2, Communication Ports* for the identification and location of a serial RS232 interface connection (COM2) and a network (TCP/IP) RJ45 ethernet connection.

RADIANCE Communication Setup

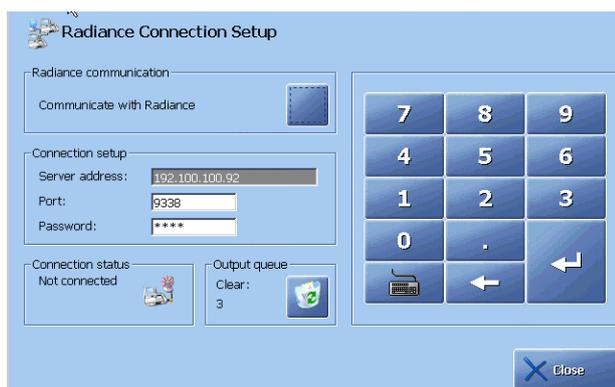
This program allows you to connect the analyzer to the RADIANCE system.

NOTICE: Connecting the analyzer to the RADIANCE system should be performed by the RADIANCE administrator in your institution.

To enable communication with the RADIANCE system, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Touch and highlight the "Server address" box.



Type in the TCP/IP address of your RADIANCE PC, using the screen keypad or keyboard.

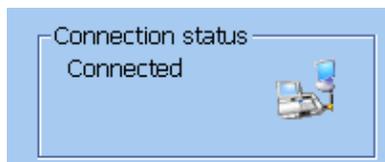
2. Touch and highlight the "Port" box. Type in port number, using the keyboard.
3. Touch and highlight the "Password" box. Type in your RADIANCE password, using the keyboard.

Continued on next page

Communications, *Continued*

RADIANCE Communication Setup (*continued*)

- | Step | Action |
|------|--|
| 4. | Press the check button in the "Radiance Communication" box to activate connection. |



The Icon in the "Connection status" box indicates the state of the RADIANCE connection. "Connected" indicates an established connection to the RADIANCE system.



The  icon will indicate the established connection as well.

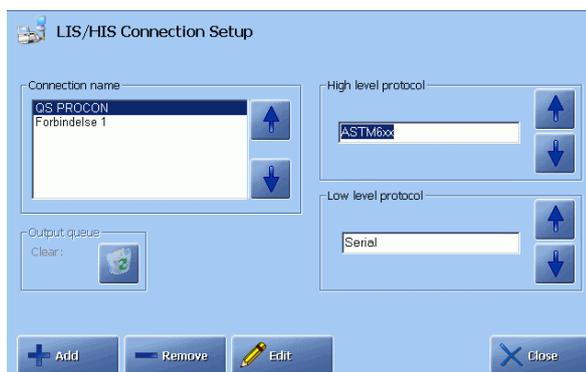
- | | |
|----|--|
| 5. | The "Output queue" box shows the number of data queued up for transfer. It will be sent to the RADIANCE system. Otherwise clear the queue by activating the recycle bin icon. |
| 6. | Press <i>Close</i> to exit the screen. |

LIS/HIS Connection Setup

This program allows you to select the communication protocol for a connected device.

To select the communication protocol, do the following:

- | Step | Action |
|------|---------------------------------|
| 1. | Press <i>Add</i> on the screen. |



The "Output queue" box shows the number of data queued up for transfer. It will be sent to LIS/HIS.

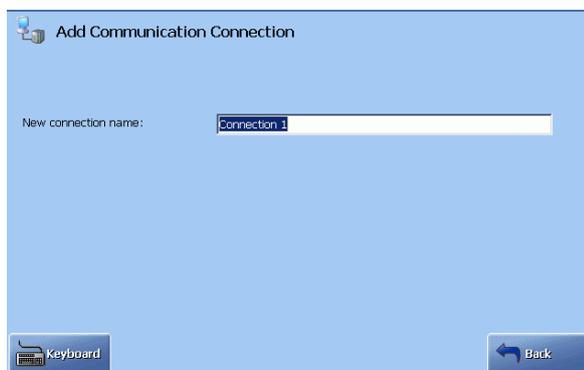
Otherwise clear the queue by activating the recycle bin icon.

Continued on next page

Communications, *Continued*

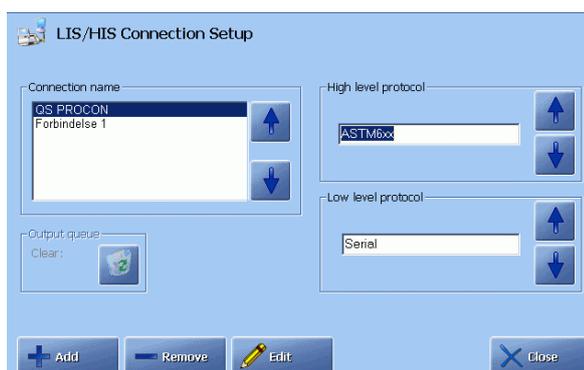
LIS/HIS Connection Setup (*continued*)

- | Step | Action |
|------|--|
| 2. | Press Keyboard , type the name of the connection instead of the default one, and press Enter . |



Press **Back** to return to **LIS/HIS Connection Setup** screen.

3. Select the high-level protocol according to the requirements of the connected device.



Select between: ASTM, ASTM6xx, HL7 version 2.2, HL7 version 2.5 or POCT1-A DML, using the up/down arrows in the box.

4. Select the low-level protocol as follows:
- Use “Serial” or “Serial (RAW)” for the serial connection.
 - Use “Network (TCP/IP)” for the network connection.
 - Use “Network (TCP/IP)ASTM” for additional serial connection (not all combinations of high-level protocols and low-level protocols are possible).

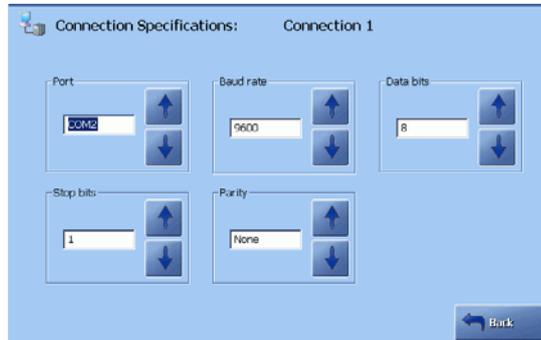
Continued on next page

Communications, *Continued*

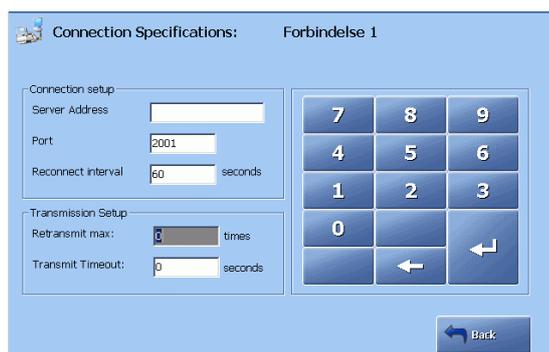
**LIS/HIS
Connection
setup
(continued)**

Step Action

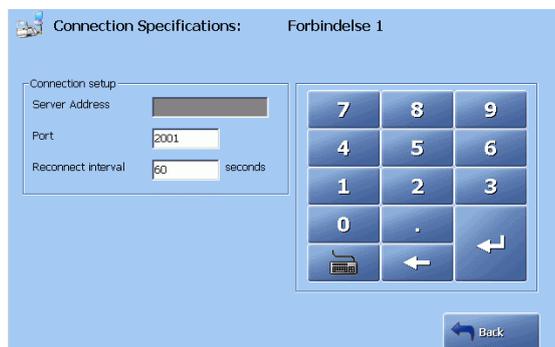
5. a. Connection specifications for serial low-level protocol:
Press *Edit* to display the **Connection Specifications** screen below.



- b. Connection specifications for network low-level protocol:
Press *Edit* to display the **Connection Specifications** screen below (HL 7 version 2.5 is used as an example).



- c. Connection specifications for POCT1-A DML low-level protocol:



Continued on next page

Communications, *Continued*

LIS/HIS Connection Setup (*continued*)

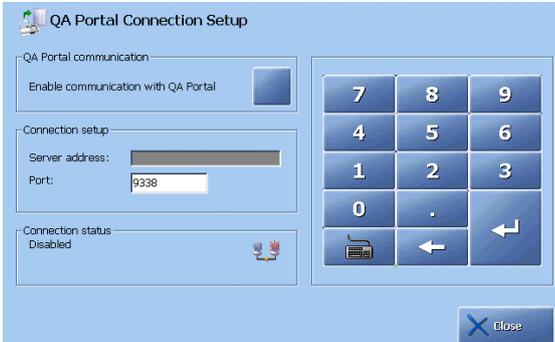
| Step | Action | | | | | | | | | | |
|-----------|---|-----|--------|-----------|---|-----------|------------|-----------|-----------|--------|------------------|
| 6. | <p>a. <u>Connection specifications for serial low-level protocol:</u> Use the up and down arrows in each box to select baud rate, stop bits, data bits and parity. Port number should be COM2.</p> <table border="1"> <thead> <tr> <th>Box</th> <th>Option</th> </tr> </thead> <tbody> <tr> <td>Baud rate</td> <td>1200, 2400, 4800, 9600, 14400, 19200, 38400, 115200</td> </tr> <tr> <td>Data bits</td> <td>5, 6, 7, 8</td> </tr> <tr> <td>Stop bits</td> <td>1, 1.5, 2</td> </tr> <tr> <td>Parity</td> <td>Even, odd, none.</td> </tr> </tbody> </table> <p>b. <u>Connection specifications for network low-level protocol:</u> Touch the screen to highlight the following boxes one after another: Server address – Port number – Reconnect Interval (time interval in seconds to attempt re-connection if connection failed) – Retransmit max – Transmit timeout. Use the keypad/keyboard to enter the relevant information.</p> <p>c. <u>Connection specifications for POCT1-A DML low-level protocol:</u> Touch the screen to highlight the following boxes one after another: Server address – Port number – Reconnect Interval. Use the keypad/keyboard to enter the relevant information.</p> | Box | Option | Baud rate | 1200, 2400, 4800, 9600, 14400, 19200, 38400, 115200 | Data bits | 5, 6, 7, 8 | Stop bits | 1, 1.5, 2 | Parity | Even, odd, none. |
| Box | Option | | | | | | | | | | |
| Baud rate | 1200, 2400, 4800, 9600, 14400, 19200, 38400, 115200 | | | | | | | | | | |
| Data bits | 5, 6, 7, 8 | | | | | | | | | | |
| Stop bits | 1, 1.5, 2 | | | | | | | | | | |
| Parity | Even, odd, none. | | | | | | | | | | |

QA Portal

This program allows you to connect the analyzer to the QA portal.

If the QC Portal communication is enabled, the analyzer will automatically send QC results and Cal Verification measurements to the QA portal.

To enable communication with the QA portal, do the following:

| Step | Action |
|------|---|
| 1. | <p>Touch and highlight the "Server address" box.</p>  |

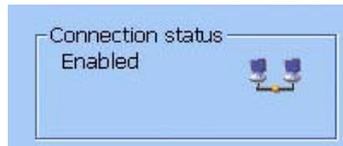
Type in the TCP/IP address of your QA portal, using the screen keypad or keyboard.

Continued on next page

Communications, *Continued*

QA Portal (*continued*)

| Step | Action |
|------|---|
| 2. | Touch and highlight the "Port" box. Type in port number, using the keyboard. |
| 3. | Press the check button in the "Enable communication with QA Portal" box to activate connection. |



The Icon in the "Connection status" box indicates the state of the QA portal connection. "Enabled" indicates an established connection to the QA portal.



The QA Portal icon in the information bar will indicate the established connection as well.

4. Press **Close** to exit the screen.

Communications, *Continued*

Automatic data request This program allows you to select the conditions for requesting patient demographics automatically from the connected the RADIANCE system or from LIS/HIS computer system when entering Patient ID, Accession Number or Sampler ID.

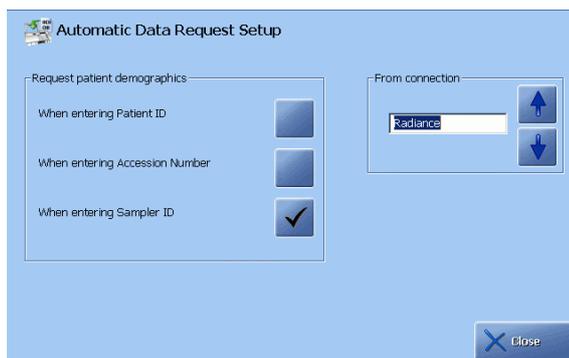
FLEXQ: The request will be made during scanning the sampler.

Manual measurement: The request will be made when the corresponding data is entered on the **Patient Identification** screen during or after analysis.

To select the settings, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Select a connected device in the "From connection" box, using the up/down arrows buttons.



2. Activate the relevant check button(s) to request patient demographics from the connected RADIANCE system or LIS/HIS when:
 - entering Patient ID
 - entering Accession Number
 - entering Sampler ID.
3. Press *Close* when completed.

NOTICE: If the requested patient data (e.g. Patient Last Name) was received after exiting the **Patient Identification** screen, the patient report will be stored without the requested data in the Patient Report log. The requested patient data will be stored as a patient profile in the analyzer's database without, however, being attached to any patient report.

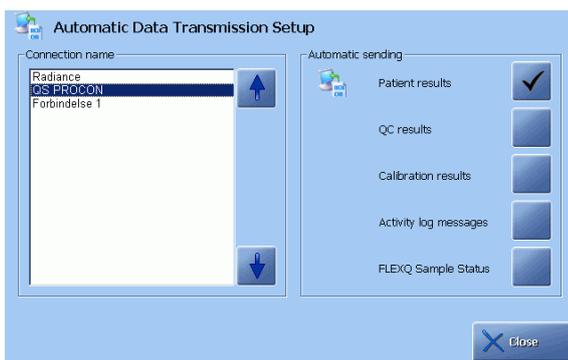
Continued on next page

Communications, *Continued*

Automatic Data Transmission Setup This program allows you to set up automatic sending of data to a connected LIS/HIS computer system or to the RADIANCE system.
To select the settings, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Highlight a desired connection device on the screen, using the up/down arrows (note that the "FLEXQ Sample Status" is not available if connection to the RADIANCE system has been selected).



2. Activate the relevant check button(s) to select the data to be sent to the highlighted connection.

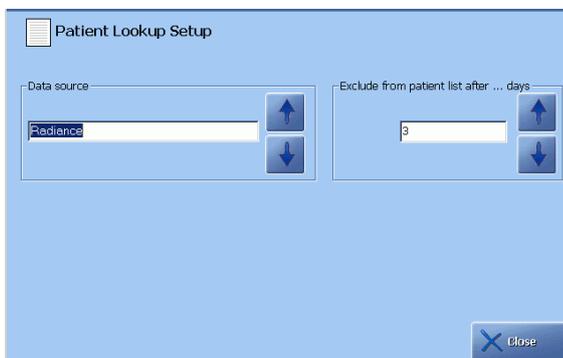
NOTICE: If the requested patient data (e.g. Patient Last Name) was received after exiting the **Patient Identification** screen, the patient report will be transmitted without the requested data. To prevent this, select one of the patient data items transferred from LIS/HIS as mandatory.

Patient Lookup Setup This program allows you to select the data source in order to obtain the patient information on the **Patient Identification** screen.

To select the settings, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Select a data source from the established connections (local database, RADIANCE or LIS/HIS).



Continued on next page

Communications, *Continued*

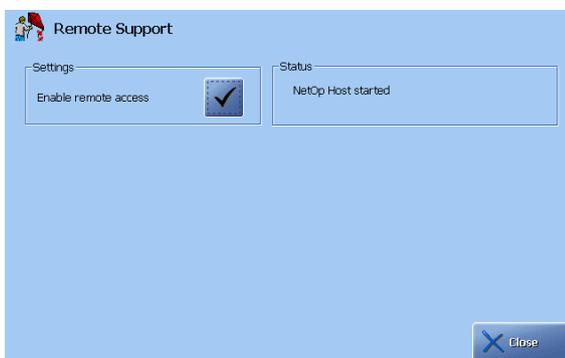
Patient Lookup Setup (*continued*)

| Step | Action |
|------|---|
| 2. | Select the number of days you want each patient to be kept in the list, using the up and down arrow buttons in the box. |

Remote Support This program allows a remote operator, e.g. a service technician, to log onto your analyzer and monitor its functions.

To select access, do the following:

| Step | Action |
|------|---|
| 1. | Press the "Enable remote access" check button to allow a remote operator to log onto your analyzer. |



When connected (logged on), the "Remote operator" appears on the analyzer status bar.

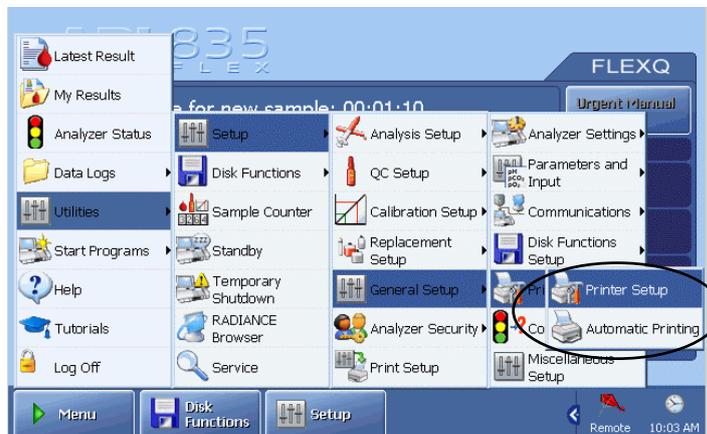
2. Deactivate the check button to prevent a remote operator logging onto your analyzer.

NOTICE: To select the access profile for the remote operator – see description in *General Security* in *Analyzer Security* earlier in this chapter.

Printers

Programs

The Printers programs are described in this section. Activate a button to enter the program.



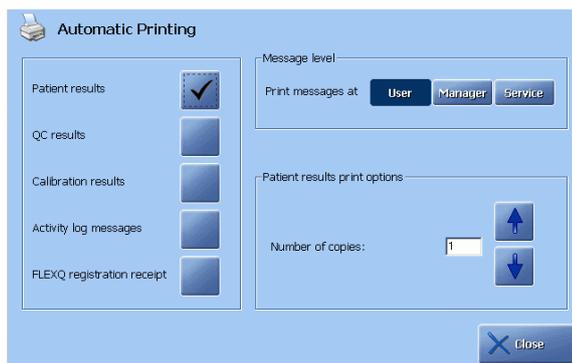
Automatic Printing

This program allows you to select automatic printout of patient, QC and calibration results, activity log messages, and registration receipts.

A registration receipt contains patient data and the barcode with the analyzer ID and the sampler number. Scanning the barcode will display the corresponding result.

To select options available on the screen, do the following:

- | Step | Action |
|------|---|
| 1. | Activate the desired check buttons for the automatic printout of the patient results, QC results, calibration results, activity log messages and registration receipts for FLEXQ. |



The last line will not be visible on the analyzers without the FLEXQ module.

- Select automatic printout of several copies of patient results (from 1 to 5), using the up/down arrow buttons in the "Patient results print options" box.

Continued on next page

Printers, *Continued*

Automatic Printing (*continued*)

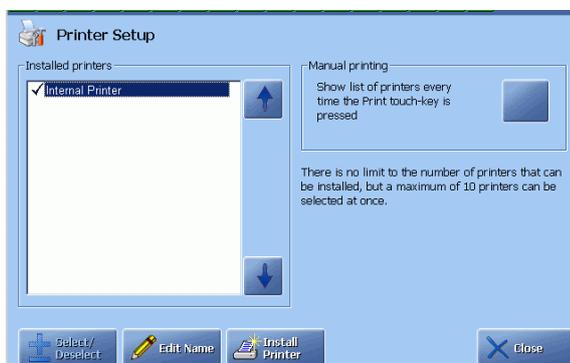
- | Step | Action |
|------|---|
| 3. | Press "User", "Manager" or "Service" in the "Message level" box to select the level for the messages in the Activity log. |

Printer Setup

This program allows you to set up other printers than the analyzer's printer for making printouts.

To select a printer for the analyzer, do the following:

- | Step | Action |
|------|---|
| 1. | Highlight a printer from the list by using the arrow buttons. |



- Press **Select/Deselect** to select the highlighted printer for printing. You can install any number of printers, but only up to 10 printers can be selected.
- To display the list of printers every time the **Print** button is pressed, activate the check button in the "Manual printing" box.
If not activated, all the selected printers will make a printout every time the **Print** button is pressed.
- To change the highlighted printer's name, press **Edit Name** to display the keyboard. Type a name and confirm the entry with **Enter**.

Continued on next page

Printers, *Continued*

Printer Setup (*continued*)

| Step | Action |
|------|--------|
|------|--------|

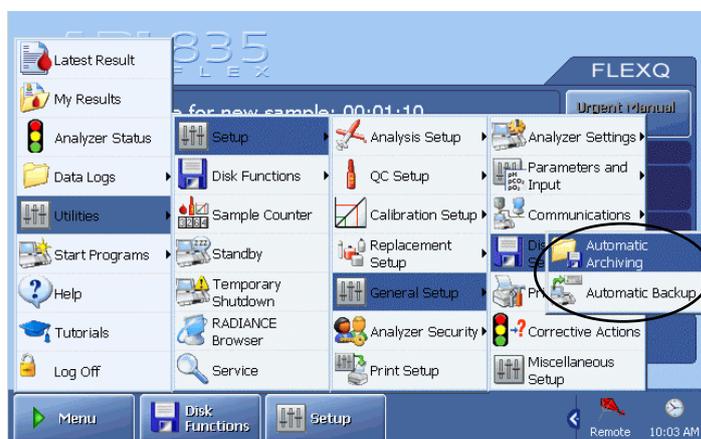
5. To install a new printer, press the ***Install Printer*** button.



This function can be used by Radiometer service engineer or a person with network knowledge.

Disk Functions setup

Programs The Disk Functions Setup programs are described in this section.

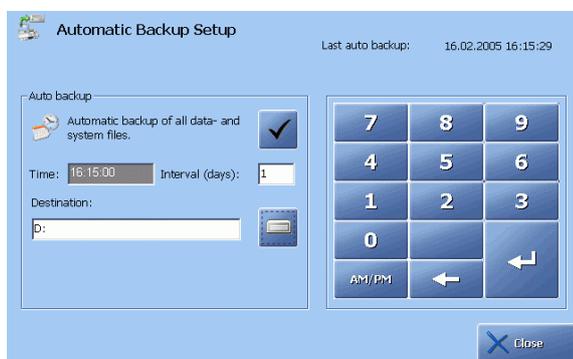


The programs are Automatic Backup and Automatic Archiving.

Automatic Backup Setup This program allows you to select automatic backup of all data and system files. Do the following:

| Step | Action |
|------|--------|
|------|--------|

- | | |
|----|---|
| 1. | To select automatic backup of all data and system files, activate the check button. |
|----|---|



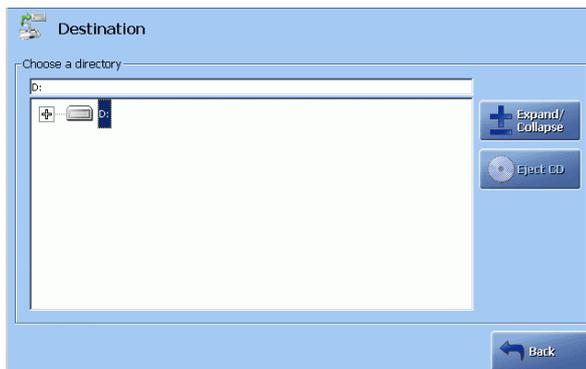
- | | |
|----|---|
| 2. | Select time for auto backup by highlighting the "Time" box and typing the time, using the screen keypad. Confirm the entry with Enter . |
| 3. | Enter the interval between subsequent backups in the "Interval" box and type the number of days, using the screen keypad. Confirm with Enter . |

Continued on next page

Disk Functions setup, *Continued*

Automatic Backup Setup (*continued*)

- | Step | Action |
|------|---|
| 4. | Press the drive icon in the “Destination” box to select destination. |
| 5. | Highlight the drive or folder and press the <i>Expand/Collapse</i> button to open a folder in a directory or within a folder. |



Note that automatic backup can be selected for the internal hard disk or the network.

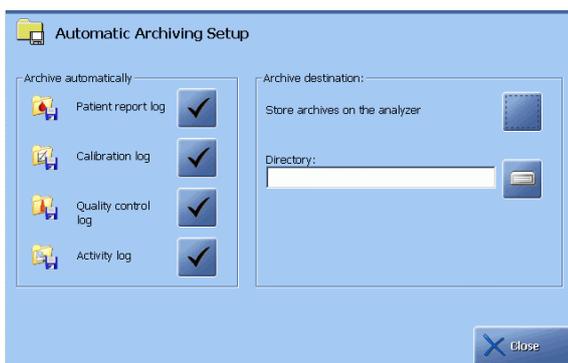
When completed, the correct destination should appear in the upper part of the box.

Automatic Archiving Setup

This program allows you to select automatic archiving of the data logs by activating the relevant check button.

Do the following:

- | Step | Action |
|------|---|
| 1. | To select automatic archiving on the analyzer's hard disk, activate the check button. |



- To select another destination, press the drive icon to select a directory as described in step 5 for *Automatic Backup Setup* above.

Continued on next page

Disk Functions setup, *Continued*

Automatic Archiving Setup (continued) The oldest records (500 patient reports, quality control or calibration results, or 2000 entries in the Activity log) will be automatically removed from a data log and placed into the relevant archive. The archives can be stored on the analyzer's hard disk and viewed in "Archived Data logs" or at a remote location.

For detailed information on archiving the old data, please refer to *chapter 8: Disk functions* in this manual.

Corrective actions

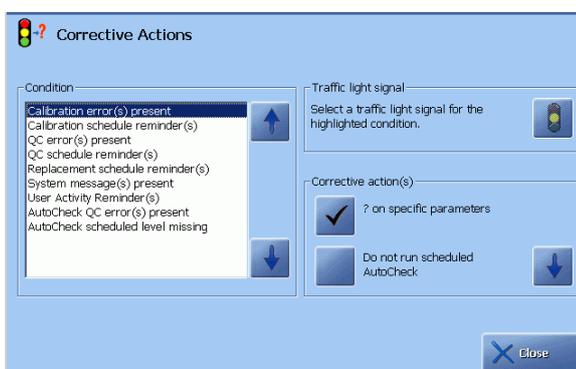
Purpose This program allows you to do the following:

- to select corrective actions for the events listed in this program,
- to select the traffic light indication, if available, for an event,
- to select analyzer action for the subsequent measurements.

To specify the corrective action and traffic light signal (if available) for each condition listed in the "Condition" box, do the following:

Step Action

1. Highlight the desired condition using the up/down arrows in the box.



2. Select an action for this condition, using the arrow buttons in the "Corrective action(s)" box – see the table below.
3. Select the desired traffic light signal (yellow or green, if available) for the specified event by pressing the traffic light in the "Traffic light signal" box – see the table below.
4. Select corrective actions/traffic light signal for the other conditions in a similar way.

Conditions and correction actions Conditions and corresponding corrective action choices are as follows:

| Condition | Corrective action | Traffic light |
|----------------------------------|---|-----------------|
| Calibration error(s) present | ? on specific parameters Perform AutoCheck measurement Do not run scheduled AutoCheck | – |
| Calibration schedule reminder(s) | Message on next Patient Result | Green or yellow |
| QC error(s) present | ? on specific parameters | – |

Continued on next page

Corrective actions, *Continued*

Conditions and corrective actions (*continued*)

| Condition | Corrective action | Traffic light |
|-----------------------------------|--|-----------------|
| QC schedule reminder(s) | Message on next Patient Result | Green or yellow |
| | Lock analyzer immediately when overdue | – |
| Replacement schedule reminder(s) | Message on next Patient Result | Green or yellow |
| | Lock analyzer when 10 % overdue | – |
| System message(s) present | Message on next Patient Result | Green or yellow |
| User activity reminder(s) | | Green or yellow |
| AutoCheck QC error(s) present | Re-run same level once | – |
| | Re-run same level twice | – |
| AutoCheck scheduled level missing | Use ampoule last in schedule | Green or yellow |

Explanation of corrective actions

The explanation of the corrective actions is given below.

| Corrective action | Explanation |
|--|---|
| ? on specific parameters | The affected parameter(s) will be marked with “?” in subsequent patient results. |
| Message on next Patient Result | To mark the subsequent patient results on the Message screen |
| Lock analyzer immediately when overdue | If a quality control measurement is not run 1 minute after the scheduled time for it, the analyzer will be locked. As a QC takes more than 1 minute to complete, the analyzer will enter the "Locked" state during measurement. It will, however, automatically leave the "Locked" mode again, if the quality control measurement results are valid. |
| Lock analyzer when 10 % overdue | If a scheduled replacement procedure is more than 10 % overdue compared with the scheduled time for it, the analyzer will be locked. |
| Re-run same level once | If an error has been registered during a scheduled AutoCheck measurement, it will be re-run provided the control solution is available in the carousel. |

Continued on next page

Corrective actions, *Continued*

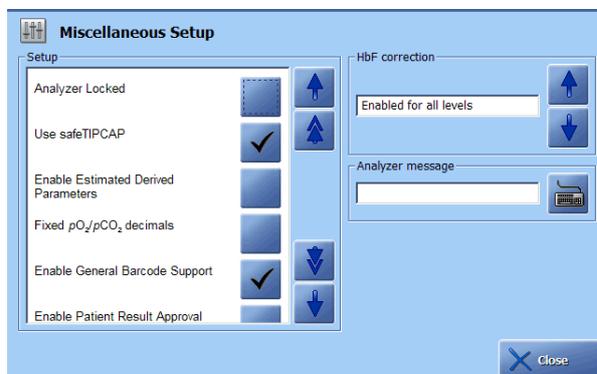
| Explanation of corrective actions (<i>continued</i>) | Corrective action | Explanation |
|---|------------------------------|---|
| | Re-run same level twice | If an error has been registered during a scheduled AutoCheck measurement, it will be repeated twice provided the control solution is available in the carousel. |
| | Use ampoule last in schedule | If a control solution scheduled for AutoCheck is missing in the carousel, the measurement will be on the control solution type scheduled before this one. |

NOTICES:

- The critical system messages will always result in a red traffic light signal.
- If the analyzer locks due to QC or replacement schedule reminders, a critical system message will be generated and the traffic light signal will be red
- The specified traffic light signal and the messages will continue to appear until the condition no longer exists.

Miscellaneous setup

Purpose This program allows you to select the following options (use the arrow buttons to display the rest of the options):



List of options The options are as follows:

| Option | Function |
|-------------------------------------|--|
| Analyzer locked | Suspends all measurements on the analyzer; the other functions such as calibrations and service programs are still enabled. The analyzer can be locked via this program or via a “lock” command from an externally connected system, e.g. LIS or the RADIANCE system. |
| Use <i>safe</i> TIPCAP | After the syringe inlet has been opened, two Start buttons will be displayed: one for the samplers without a <i>safe</i> TIPCAP and the other for samplers with a <i>safe</i> TIPCAP. If the check button is disabled, only the Start button for samplers without a <i>safe</i> TIPCAP will be available. |
| Enable estimated derived parameters | Enables estimation of the derived parameters based on default values even though the measured parameters have been deselected or are not available. |
| Fixed pO_2/pCO_2 decimals | If enabled, these parameters will be reported with a fixed number of decimals. |
| Enable general barcode support | Enables every text box on the Patient Profile, Patient Identification, Patient Result, QC ID and Recording Fluid Replacement screens where it is possible to enter a barcode. |
| Enable patient result approval | Enables the additional buttons on the Patient Result screen used for approval of the result. For detailed information please refer to <i>chapter 4: Sample measurements</i> . |
| Apply parameter corrections to QC | If enabled, the user-defined corrections (slope and offset) will be applied to the quality control results. |

Continued on next page

Miscellaneous setup, *Continued*

List of options (*continued*)

| Option | Function |
|--------------------------------|---|
| Log all measurement activities | If enabled, "Ready", "Rinse", "Aspirating" and "Measurement" will be registered in the Activity log. Otherwise these activities will not be registered in the Activity log. This option aims to avoid too many entries in the Activity log. |
| Auto temp. unit conversion | °C will be automatically changed to °F if the entered temperature is over the value of 45. |
| Show screen saver | The screen saver will show up if the analyzer was idle for 10 minutes. |
| Show parameter bar | If disabled, the parameter bar will not be shown on the Ready screen. |

To activate/deactivate an option, do the following:

| Step | Action |
|------|--|
| 1. | Scroll the list of options with the up/down arrow keys. |
| 2. | Highlight the option and press the check button (✓) beside it. To deactivate the option, press the check button again. |
| 3. | Press <i>Close</i> to confirm the settings and return to the Ready screen. |

Selecting HbF correction option

This option disables HbF correction for all levels, or enables it for all levels or for HbF levels higher than 20 % (HbF correction will be automatically disabled if $FCO_{Hb} < -0.5\%$ in order to decrease a false HbF detection on adult blood samples and to ensure non-biased oximetry results).

The guidelines for selecting/deselecting HbF correction are as follows:

For neonatal samples: Use "Enabled for all levels".
It is important to enable HbF correction in order to obtain correct results for $ctBil$, sO_2 , FO_2Hb , $FMetHb$, FCO_{Hb} and $FHHb$.

For adult samples: Use "Disabled" or "Enabled for levels > 20 %".

NOTICE: When an adult sample is measured with HbF correction "Enabled for all levels" or "Enabled for levels > 20 %", it will slightly affect measurement of sO_2 , FO_2Hb , $FMetHb$, FCO_{Hb} and $FHHb$, and will cause a marginal number of adult samples reported with HbF present.

If this is not acceptable, the HbF correction for adult samples can be turned off before a measurement – see *Selecting HbF Correction* in the Analysis Setup in this chapter.

To select the desired option, use the arrow buttons in the box.

Continued on next page

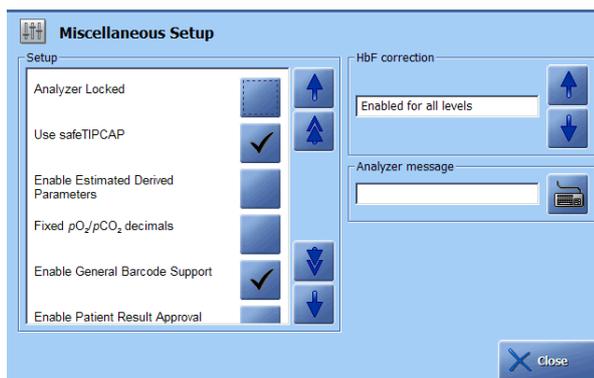
Miscellaneous setup, *Continued*

Analyzer message

A message, sent from the RADIANCE system to the connected analyzer and displayed on the **Ready** screen, can be changed or deleted in this program as follows:

| Step | Action |
|------|--------|
|------|--------|

1. Press the keyboard icon to display the keyboard.



Type the message and confirm with **Enter**.

To delete the current message, press **Delete** on the keyboard, or delete a message and type a new one if desired.

NOTICE: The analyzer message can be up to 40 characters long.

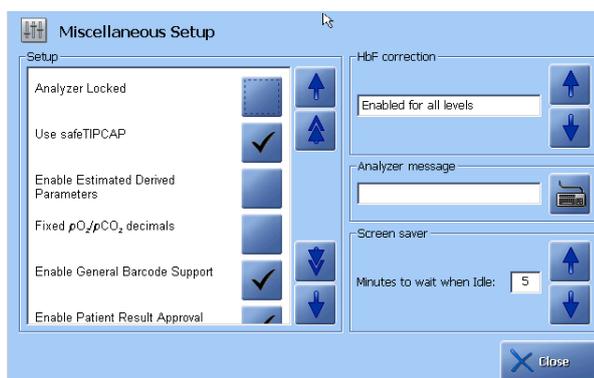
2. Confirm the change with **Enter** on the keyboard to return to the **Miscellaneous Setup** screen.

Screen saver

To set the time for the screen saver to appear, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Check that the screen saver check button is activated.



2. In the "Screen saver" box select the desired time with the arrow buttons.

4. Sample measurements

Overview

Introduction This chapter describes how to perform measurements on patient samples and how to interpret the results.

Contents This chapter contains the following topics.

| | |
|---|------|
| General information | 4-2 |
| Immediately before analysis | 4-9 |
| Measurements with FLEXQ | 4-10 |
| Introducing a blood sample | 4-12 |
| Introducing an expired air sample | 4-15 |
| Patient identification | 4-17 |
| Patient result | 4-21 |
| Calculation of F_{Shunt} and $ctO_2(a-\bar{v})$ | 4-25 |
| Patient result messages | 4-26 |

General information

Measuring modes with FLEXQ

With the FLEXQ module installed, it is possible to make the measuring process automatic (i.e. just place up to three samples in the sampler tray and go), or to place a single sampler in the sampler tray and perform a single measurement.

The following rules apply to the **batch mode**:

- The analyzer is connected to the RADIANCE system
- All information is entered on the RADIANCE system via FLEXLINK
- Automatic data request is based on Sampler ID
- Measuring mode will always be the largest syringe mode, and it will be marked "Flex"
- Default layout is always used.

The following rules apply to a **single measurement**:

| Parameter profile received from the RADIANCE system | Parameter profile not received from the RADIANCE system |
|---|---|
| <ul style="list-style-type: none"> • Measuring modes will be those syringe modes that can provide the requested parameter profile; these modes will be marked "Flex" • Default layout is always used. | <ul style="list-style-type: none"> • The measuring modes are those that can be selected on the analyzer (see <i>Available modes and parameters</i> below) • The layout will be the one assigned to the selected measuring mode. |

Available modes and parameters

The modes and the measured parameters available on the ABL800 FLEX analyzers are listed below.

| Analyzer | Measuring modes | Measured parameters |
|----------|--|--|
| 805 | Syringe – S165 µL | pH, $p\text{CO}_2$, $p\text{O}_2$, $c\text{K}^+$, $c\text{Na}^+$, $c\text{Ca}^{2+}$, $c\text{Cl}^-$, $c\text{Glu}$, $c\text{Lac}$ |
| | Syringe – S95 µL Capillary – C95 µL | pH, $p\text{CO}_2$, $p\text{O}_2$, $c\text{K}^+$, $c\text{Na}^+$, $c\text{Ca}^{2+}$, $c\text{Cl}^-$, $c\text{Glu}$, $c\text{Lac}$ |
| | Syringe – S85 µL pH+BG Capillary – C55 µL pH+BG | pH, $p\text{CO}_2$, $p\text{O}_2$ |
| | Capillary – C35 µL MET | $c\text{Glu}$, $c\text{Lac}$ |
| | Capillary – FLEXMODE | See below |
| | Syringe – Pleura pH* | pH |
| | Other fluids (any mode) | Depends on the selected mode |
| | Expired air | $p\text{CO}_2$, $p\text{O}_2$ |

* See page 4-5

Continued on next page

General information, *Continued*

Available modes and parameters
(*continued*)

| Analyzer | Measuring modes | Measured parameters |
|-------------|--|---|
| 805 (cont.) | Ampoule QC | All available |
| 810 BG only | Syringe – S85 µL Capillary – C55 µL | pH, $p\text{CO}_2$, $p\text{O}_2$ |
| | Capillary – FLEXMODE | See below |
| | Syringe – Pleura pH* | pH |
| | Other fluids (any mode) | Depends on the selected mode |
| | Expired air | $p\text{CO}_2$, $p\text{O}_2$ |
| | Ampoule QC | All available |
| 810/20/30 | Syringe – S85 µL Capillary – C55 µL | pH, $p\text{CO}_2$, $p\text{O}_2$ and 810: ctHb, $s\text{O}_2$ 820: ctHb, $s\text{O}_2$, FO_2Hb , FCOHb , FMetHb 830: ctHb, $s\text{O}_2$, FO_2Hb , FCOHb , FMetHb , ctBil, FHbF |
| | Capillary – C35 µL OXI | 810: ctHb, $s\text{O}_2$ 820: ctHb, $s\text{O}_2$, FO_2Hb , FCOHb , FMetHb 830: ctHb, $s\text{O}_2$, FO_2Hb , FCOHb , FMetHb , ctBil, FHbF |
| | Capillary – FLEXMODE | See below |
| | Syringe – Pleura pH* | pH |
| | Other fluids (any mode) | Depends on the selected mode |
| | Expired air | $p\text{CO}_2$, $p\text{O}_2$ |
| | Ampoule QC | All available |

* See page 4-5

Continued on next page

General information, *Continued*

Available modes
and parameters
(*continued*)

| Analyzer | Measuring modes | Measured parameters |
|------------|--|--|
| 815/25/35 | Syringe – S195/95 µL Capillary – C95 µL | pH, $p\text{CO}_2$, $p\text{O}_2$, $c\text{K}^+$, $c\text{Na}^+$, $c\text{Ca}^{2+}$, $c\text{Cl}^-$, $c\text{Glu}$, $c\text{Lac}$ and 815: $ct\text{Hb}$, $s\text{O}_2$ 825: $ct\text{Hb}$, $s\text{O}_2$, $FO_2\text{Hb}$, $FCO\text{Hb}$, $F\text{MetHb}$ 835: $ct\text{Hb}$, $s\text{O}_2$, $FO_2\text{Hb}$, $FCO\text{Hb}$, $F\text{MetHb}$, $ct\text{Bil}$, $F\text{HbF}$ |
| | Syringe – S85 µL pH+BG + OXI Capillary – C55 µL pH+BG+OXI | pH, $p\text{CO}_2$, $p\text{O}_2$ and 815: $ct\text{Hb}$, $s\text{O}_2$ 825: $ct\text{Hb}$, $s\text{O}_2$, $FO_2\text{Hb}$, $FCO\text{Hb}$, $F\text{MetHb}$ 835: $ct\text{Hb}$, $s\text{O}_2$, $FO_2\text{Hb}$, $FCO\text{Hb}$, $F\text{MetHb}$, $ct\text{Bil}$, $F\text{HbF}$ |
| | Capillary – C35 µL MET | $c\text{Glu}$, $c\text{Lac}$ |
| | Capillary – C35 µL OXI | 815: $ct\text{Hb}$, $s\text{O}_2$ 825: $ct\text{Hb}$, $s\text{O}_2$, $FO_2\text{Hb}$, $FCO\text{Hb}$, $F\text{MetHb}$ 835: $ct\text{Hb}$, $s\text{O}_2$, $FO_2\text{Hb}$, $FCO\text{Hb}$, $F\text{MetHb}$, $ct\text{Bil}$, $F\text{HbF}$ |
| | Capillary – FLEXMODE | See below |
| | Syringe – Pleura pH* | pH |
| | Other fluids (any mode) | Depends on the selected mode |
| | Expired air | $p\text{CO}_2$, $p\text{O}_2$ |
| Ampoule QC | All available | |

* See page 4-5

Continued on next page

General information, *Continued*

Available modes and parameters
(*continued*)

| Analyzer | Measuring modes | Measured parameters |
|-----------|--|---|
| 837/27/17 | Syringe – S250 µL Capillary – C125 µL | pH, $p\text{CO}_2$, $p\text{O}_2$, $c\text{K}^+$, $c\text{Na}^+$, $c\text{Ca}^{2+}$, $c\text{Cl}^-$, $c\text{Glu}$, $c\text{Lac}$, $c\text{Crea}$ and 817: $ct\text{Hb}$, $s\text{O}_2$ 827: $ct\text{Hb}$, $s\text{O}_2$, $FO_2\text{Hb}$, $FC\text{OHb}$, $FM\text{etHb}$ 837: $ct\text{Hb}$, $s\text{O}_2$, $FO_2\text{Hb}$, $FC\text{OHb}$, $FM\text{etHb}$, $ct\text{Bil}$, $F\text{HbF}$ |
| | Syringe – S85 µL pH + BG + OXI | pH, $p\text{CO}_2$, $p\text{O}_2$ and 817: $ct\text{Hb}$, $s\text{O}_2$ 827: $ct\text{Hb}$, $s\text{O}_2$, $FO_2\text{Hb}$, $FC\text{OHb}$, $FM\text{etHb}$ 837: $ct\text{Hb}$, $s\text{O}_2$, $FO_2\text{Hb}$, $FC\text{OHb}$, $FM\text{etHb}$, $ct\text{Bil}$, $F\text{HbF}$ |
| | Capillary – C55 µL pH + BG + OXI | pH, $p\text{CO}_2$, $p\text{O}_2$ and 817: $ct\text{Hb}$, $s\text{O}_2$ 827: $ct\text{Hb}$, $s\text{O}_2$, $FO_2\text{Hb}$, $FC\text{OHb}$, $FM\text{etHb}$ 837: $ct\text{Hb}$, $s\text{O}_2$, $FO_2\text{Hb}$, $FC\text{OHb}$, $FM\text{etHb}$, $ct\text{Bil}$, $F\text{HbF}$ |
| | Capillary – C35 µL MET | $c\text{Glu}$, $c\text{Lac}$ |
| | Capillary – C35 µL OXI | 817: $ct\text{Hb}$, $s\text{O}_2$ 827: $ct\text{Hb}$, $s\text{O}_2$, $FO_2\text{Hb}$, $FC\text{OHb}$, $FM\text{etHb}$ 837: $ct\text{Hb}$, $s\text{O}_2$, $FO_2\text{Hb}$, $FC\text{OHb}$, $FM\text{etHb}$, $ct\text{Bil}$, $F\text{HbF}$ |
| | Syringe – Pleura pH* | pH only |
| | Other fluids (any mode) | Depends on the selected mode |
| | Expired air | $p\text{CO}_2$, $p\text{O}_2$ |
| | Ampoule QC | All available |

* **NOTICE:** The *safe*TIPCAP cannot be used with pleura fluids, and as a consequence of this the Pleura pH measuring mode is not available when placing a sampler in the FLEXQ module. The *safe*TipCap start button is also not available as an option when starting a manual pleura pH measurement

NOTICE: In order to perform measurements in the 35 µL mode in accordance with performance specifications it is highly recommended to use 35 µL capillaries with mixing wire and a clot catcher.

Continued on next page

General information, *Continued*

FLEXMODE This mode allows you to analyze a blood sample of 35 μL and higher – up to the maximum volume accepted by your analyzer. Depending on the available sample volume, the FLEXMODE provides the highest number of parameters: from all available to as many as reliably possible.

The following parameters can be obtained depending on the available sample volume (for the ABL835):

| Volume | Parameter profiles | Message No. ** |
|------------------------|----------------------------------|----------------|
| 35-40 μL * | pH + OXI | 869 |
| 40-55 μL * | pH + OXI | 870 |
| 50-70 μL * | pH + OXI + BG | 871, 872 |
| 65-100 μL * | pH + OXI + BG + MET | 873 |
| > 90 μL * | pH + OXI + BG + MET + EL | 874 |
| 195 μL | pH + OXI + BG + MET + EL + ctBil | No message |

* All volumes are approximate volumes at ctHb = 15 g/dL.

** The messages will accompany the obtained result – see *Patient result messages* at the end of this chapter. For interpretation of the messages – see *Troubleshooting messages* in *chapter 11* in this manual.



CAUTION notices

- CAUTION – Presence of glucolic acid**
 Never use analyzer for lactate measurements if there is any suspicion of presence of glycolic acid in blood as e.g. in case of ethylene glycol poisoning or xylitol infusion. Glycolic acid interferes with the lactate sensor resulting in erroneously high lactate readings
- CAUTION – Risk of incorrect result**
 Visually inspect the measuring chambers for blockages when lifting the inlet flap prior to performing a measurement. If there is a blockage, close the flap and the analyzer will perform a rinse. If repeated visual inspection shows blockages in the measuring chamber, clean the electrodes and the measuring chamber according to step 7 in *chapter 11: Troubleshooting*, section "*Fluid transport troubleshooting procedure*" in this manual.
- CAUTION - Risk of incorrect result**
 Always remove air bubbles from a sample before introducing it into the analyzer. Air bubbles may result in erroneous $p\text{O}_2$ values.
- CAUTION - Risk of incorrect result**
 During measurement, use the sample path view to observe the sample in the measuring chambers. If any bubbles are seen, disregard the result and repeat the measurement.

Continued on next page

General information, *Continued*



CAUTION notices
(*continued*)

5.  **CAUTION - Risk of incorrect result**
When measurements are flagged always conduct the operator actions required by the troubleshooting program to prevent possible clots from remaining in the sample path. Fluid path clots may cause erroneous measurement results.

6.  **CAUTION - Risk of erroneous results**
Always meticulously follow the sampling procedures described in *chapter 12: Sampling*. Failure to follow these procedures may introduce clots or air bubbles in the sample and yield erroneous results.

When the FLEXQ is in use, the **CAUTION** notices 2 and 4 above do not apply.

Interrupting a measurement

To interrupt a measurement, press  (Stop) button.

Before using the FLEXQ

To use the FLEXQ efficiently, the setup should be made thoroughly.

| Program | Recommendations |
|--|---|
| Analysis Setup – Syringe Modes | <ul style="list-style-type: none"> • Make the report layout for each measuring program you are going to use, including the Patient ID items and parameter profile • Select the default layout for each selected measuring program. <p>This will define the number of measuring programs to select from before each measurement.</p> |
| Analysis Setup – Sample Pre-registration | Select interpretation of the barcode entry. |
| Analysis Setup – Sample Logistics | <ul style="list-style-type: none"> • Select batch mode for automatic measuring process or deselect it if single measurements are to be performed • Select sample age for each measured parameter |

Continued on next page

General information, *Continued*

Before using the FLEXQ (*continued*)

| Program | Recommendations |
|-------------------------------|---|
| Connections | <ul style="list-style-type: none"> • Select connection to the RADIANCE system, LIS/HIS • Select conditions for automatic patient data request • Select data to be transmitted to the RADIANCE system, LIS/HIS • Select patient data source (Patient Lookup) |
| Printers – Automatic Printing | <ul style="list-style-type: none"> • Select printing of the registration receipt for FLEXQ measurements |

To make the measuring process automatic, the following is required:

- Batch mode selected in the Sample Logistics Setup
- Barcode interpretation (patient ID, Accession number, Sampler ID) selected in Sample Pre-registration and corresponds to that on the RADIANCE system
- Analyzer connected to the RADIANCE system
- Patient information entered on the RADIANCE system via FLEXLINK.

Sampling See *chapter 12* in this manual.

Immediately before analysis

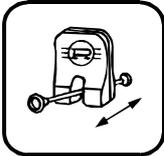
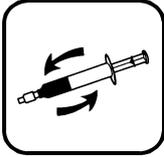
Purpose It is necessary to mix a blood sample before introducing it into the system to ensure its homogeneity. If a sample is transferred from a syringe to an analyzer without being properly mixed, either the plasma phase or packed red blood cells may be analyzed, rendering the oximetry results meaningless.

 **CAUTION - Risk of incorrect result**
Always remove air bubbles from a sample before introducing it into the analyzer. Air bubbles may result in erroneous pO_2 values.

 **CAUTION - Risk of erroneous results**
Always meticulously follow the sampling procedures described in *chapter 12: Sampling*. Failure to follow these procedures may introduce clots or air bubbles in the sample and yield erroneous results.

FLEXQ module Place a *safePICO* sampler in the FLEXQ sampler tray. The sample will be automatically mixed before the measurement.

Mixing a sample For the analyzers without FLEXQ module, mix a blood sample in a sampling device as follows:

| Sampling device | Description |
|---|--|
|  | Mix a capillary sample with a magnet. Then move the mixing wire to the end of the capillary opposite to that from which the blood is to be aspirated. Remove both capillary caps. |
|  | <i>safePICO</i> sampler or another syringe: Invert the syringe repeatedly and roll it between the palms of your hands. |
|  | Invert the test tube repeatedly. Then remove the cap. |

 **CAUTION - Risk of incorrect result**
Use capillary tubes with a volume relevant for the selected measuring mode. Too small a volume will give the “Insufficient sample” error. Too large a volume will render the internal analyzer corrections invalid and the results inaccurate.

Guidelines for handling capillary blood samples See *chapter 12* in this manual.

Measurements with FLEXQ

Single measurement from the FLEXQ sampler tray

To make a single measurement, do the following:

- | Step | Action |
|------|--|
| 1. | Place the sampler in a slot on the tray. A short beep indicates that the barcode has been accepted. |
| 2. | The available measuring modes are shown; the selected mode is highlighted. Change a measuring mode if desired. Press <i>Proceed</i> . |
| 3. | Enter, if required, additional patient data or mandatory data. |

Press *Accept* to accept all the data (patient data, measuring mode, selected parameters, layout, etc.).

- Remember to take the registration receipt printed out on the analyzer's printer.
- Repeat steps 1-4 for another sampler.
- The measurement starts. The patient name and the time left till the result is ready are displayed on the **Ready** screen.

If further editing of the patient data has to be made, press the  button on the **Ready** screen to return to the **Sample Registration** screen.

- When the result is ready, it will be automatically transmitted to its destination (the RADIANCE system or LIS/HIS).

Batch measurement

To make a batch measurement, do the following:

- | Step | Action |
|------|---|
| 1. | Make sure that a slot indicator is green and ready to accept a sampler. |
| 2. | Place the sampler in an empty FLEXQ sampler tray slot. A short beep indicates that the barcode has been accepted. |
| 3. | Make sure that your sampler is ready for processing. If not, check analyzer connection to FLEXLINK. |
| 4. | Proceed with the next sampler in the same manner as described above. |

Continued on next page

Measurements with FLEXQ, *Continued*

An urgent measurement To bypass a queued measurement while the analyzer processes the samplers in the sampler tray, do the following:

- | Step | Action |
|------|---|
| 1. | Check that <i>Urgent Manual Sample</i> is active on the Ready screen and press it. |



- | | |
|----|--|
| 2. | If the urgent measurement violates parameter lifetime of one or more queued samples, accept violation and book the inlet for manual measurement by pressing <i>Yes</i> or abort booking of the inlet by pressing <i>No</i> . |
| 3. | When allowed on the screen, open the inlet flap, insert the sampling device in the inlet and press <i>Start</i> – see <i>Introducing a blood sample</i> in this chapter. |

Note that if the *Urgent Manual Sample* button is grayed out, the inlets are free and the sample can be analyzed immediately.

Editing sample registration To change or add information to sample registration, do the following:

- | Step | Action |
|------|---|
| 1. | Locate the required sample in the "FLEXQ Status" on the Ready screen and press the  button to proceed to the Sample Registration screen. |
| 2. | Change the patient data on the Sample Registration screen. |
| 3. | Press <i>Accept</i> to confirm the patient data. |

Introducing a blood sample

Syringe samples To analyze a blood or other fluid sample without the use of the FLEXQ sampler tray, do the following.

| Step | Action |
|------|--------|
|------|--------|

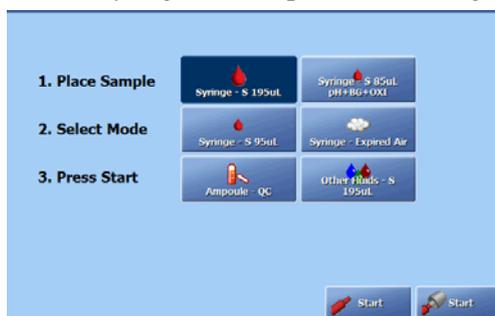
1. Check that the analyzer is in the Ready mode and scan the sample barcode.



Accept or cancel the displayed patient data (selected in Sample Pre-registration setup program – see *chapter 3* in this manual).

If no sample pre-registration was selected, proceed to step 2 below.

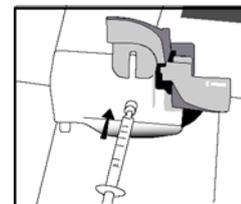
2. Lift the syringe inlet flap. The following screen appears:



If sample pre-registration was selected (see *Analysis Setup* in *chapter 3*), press **Accept** to accept displayed patient data or **Cancel** to cancel the patient data.

3.  **CAUTION - Risk of incorrect result**

Always remove air bubbles from a sample before introducing it into the analyzer. Air bubbles may result in erroneous pO_2 values.



Place the syringe tip firmly in the inlet as shown.

SafePICO sampler: Do not remove the *safeTIPCAP*.

4. Select the desired mode by pressing the appropriate button.

Continued on next page

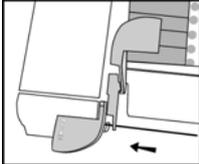
Introducing a blood sample, *Continued*

Syringe samples (*continued*)

| Step | Action |
|------|---|
| 5. | Press Start with the <i>safe</i> TIPCAP for <i>safe</i> PICO samplers or press Start without <i>safe</i> TIPCAP for other samplers (two Start buttons will be available only if "Use <i>safe</i> TIPCAP" check button is enabled in the Miscellaneous Setup). |
| 6. | Check the selection of parameters depending on their status (green, yellow, red) and your needs (if the "Dynamic Parameters" check button has been activated for the given measuring mode). Deselect any parameters or the HbF correction for this mode by pressing the parameters or the "HbF correction" check button. |
| 7. | Press Aspirate to start the measurement. |
| 8. | When prompted by the analyzer, remove the sampling device and close the inlet flap. <i>safe</i> PICO sampler: remove the sampler by holding the <i>safe</i> TIPCAP. |
| 9. | Enter the information on the Patient Identification screen. |

Capillary samples

To analyze a blood or other fluid sample from a capillary do the following:

| Step | Action |
|------|--|
| 1. | Check that the analyzer is in the Ready mode and scan the sample barcode. Accept or cancel the displayed patient data (selected in Sample Pre-registration setup program – see <i>chapter 3</i> in this manual). If no sample pre-registration was selected, proceed to step 2 below. |
| 2. | Lift the capillary inlet flap.  CAUTION - Risk of incorrect result Always remove air bubbles from a sample before introducing it into the analyzer. Air bubbles may result in erroneous pO_2 values. |
| 3. | Remove the capillary end caps and insert the capillary into the inlet as shown.  |
| 4. | Select the desired mode by pressing the appropriate button. |
| 5. | Press the Start button. |
| 6-9. | See steps 6-9 for the syringe mode. |

NOTICE: If the capillary breaks in the inlet, do not attempt to remove it, but replace the inlet gasket as described in *chapter 7: Replacements*.

Continued on next page

Introducing a blood sample, *Continued*

Test tube samples

To analyze a blood or other fluid sample, do the following.

| Step | Action |
|------|--------|
|------|--------|

1. Check that the analyzer is in the Ready mode and scan the sample barcode.

Accept or cancel the displayed patient data (selected in Sample Pre-registration setup program – see *chapter 3* in this manual).

If no sample pre-registration was selected, proceed to step 2 below.

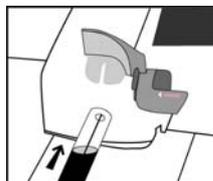
2. Lift the syringe inlet flap.



CAUTION - Risk of incorrect result

Always remove air bubbles from a sample before introducing it into the analyzer. Air bubbles may result in erroneous pO_2 values.

3. Hold the test tube at the syringe inlet.



4. Select the desired mode by pressing the appropriate button.
5. Press **Start**.

The probe will move out of the syringe inlet into the test tube.

- 6-9. See steps 6-9 for the syringe mode.



CAUTION – Risk of erroneous results

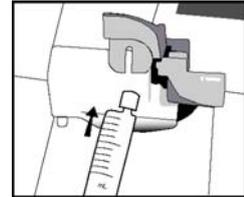
Always meticulously follow the sampling procedures described in *chapter 12: Sampling*. Failure to follow these procedures may introduce clots or air bubbles in the sample and yield erroneous results.

NOTICE: After measurement on blood from a patient who has received protamine sulphate it may be necessary to clean the analyzer using the Cleaning program to avoid clots.

Introducing a pleura sample

Procedure To analyze a pleura sample, do the following:

| Step | Action |
|------|--|
| 1. | Open the syringe inlet flap and select the Pleura pH mode. NOTICE: The Pleura pH measuring program has to be selected in the Analysis Setup for syringe samples in order to obtain the button on the screen. |
| 2. | Place the syringe tip in the inlet. NOTICE: Radiometer recommends always to use heparinized samplers for pleural liquids to avoid introducing clots in the analyzer. |
| 3. | Press <i>Start</i> . |
| 4. | When prompted by the analyzer status, remove the syringe and close the inlet flap. |
| 5. | Enter the patient information on the Patient Identification screen. |



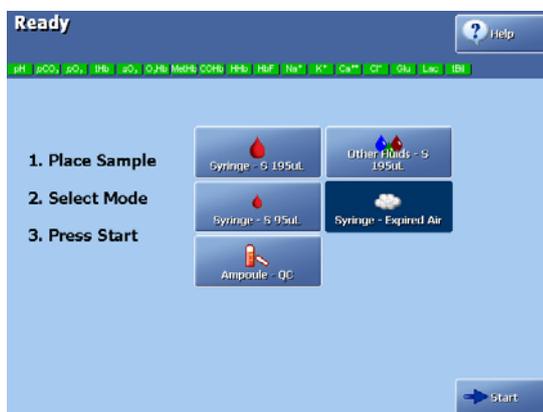
NOTICE: If pleura samples with identified bacterial infections are introduced into the analyzer, it is recommended to run a Decontamination.

Introducing an expired air sample

Procedure To analyze an expired air sample, do the following:

| Step | Action |
|------|--------|
|------|--------|

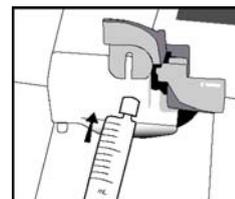
1. Open the syringe inlet flap and select the Expired Air mode.



NOTICE: The Expired Air measuring program has to be selected in the Analysis Setup for syringe samples in order to obtain the button on the screen.

2. Place the syringe tip in the inlet.

NOTICE: The Expired Air mode is exclusively used for samples of expired air. Injection of blood or other liquid in this mode may cause damage to the analyzer.



3. Press *Start*.
4. Inject the sample slowly, following the volume bar on the screen. Make sure to continue injecting the expired air sample as long as the volume is higher than 0 mL.
5. When prompted by the analyzer status, remove the syringe and close the inlet flap.
6. Enter the patient information on the **Patient Identification** screen.

Patient identification

Entering information with barcode reader

Unless the Batch mode is used, the **Patient Identification** screen is displayed while the sample is being aspirated.

To enter information with a barcode reader (the "Enable General Barcode Support" must be activated in Miscellaneous Setup) in the item boxes, which have barcode support, do the following:

| Step | Action |
|------|--------|
|------|--------|

- | | |
|----|---|
| 1. | <p>Scan the barcode with the barcode reader.</p> <p>Primarily, Operator, Accession No., Patient ID and Sampler ID are scanned.</p> <p>If the operator is scanned from the ID-card, and the operator is not included in the list of the analyzer's registered users, the barcode will be read directly from the ID-card.</p> |
|----|---|

Entering information manually

To enter patient information manually, do the following:

| Step | Action |
|------|--------|
|------|--------|

- | | |
|----|--|
| 1. | If desired, select another report layout by selecting the "Report layout" item/box on the screen and choosing the desired layout in the appearing list |
| 2. | <p>Highlight the desired text boxes and use the keyboard to type the desired data and press <i>Enter</i>.</p> <ul style="list-style-type: none"> • Sample demographics on the basis of an entered/scanned Sampler ID, i.e. all information about the sample (measuring mode, parameters, all input values and patient demographics). Data based on the Sampler ID is transferred from the RADIANCE system. • Patient demographics on the basis of an entered/scanned Accession No., Patient ID or Department (Pat.), i.e. all information about Patient ID, Patient Last Name, Patient First Name, Sex, Date of birth, Department (Pat.), Patient Note, Birth weight and Gestational Age. Data based on Accession No., Patient ID or Department (Pat.) can be transferred from all connections |

Mandatory text boxes (with a  next to it) must be filled in order to view the measurement results.

Continued on next page

Patient identification, *Continued*

Entering information manually (*continued*)

NOTICES:

- If the requested patient data (e.g. Patient Last Name) was received after the **Patient Identification** screen was exited, the patient report will be stored without the requested data in the Patient Report log. The requested patient data will be stored as a patient profile in the analyzer's database without, however, being attached to any patient report.
- If the requested patient data (e.g. Patient Last Name) was received after the **Patient Identification** screen was exited, the patient report will be transmitted without the requested data. To prevent this, select one of the patient ID items transferred from LIS/HIS as mandatory.

Patient Lookup

The Patient Lookup function allows you to transfer the patient information from a department's specific list to the **Patient Identification** screen.

Department (Pat.) must be included in the report layout and filled in on the **Patient Identification** screen.

To use the Patient Lookup function, do the following:

| Step | Action |
|------|---|
| 1. | Highlight and fill in the Department (Pat.) in the Patient Identification screen. Press Patient Lookup . |
| 2. | Select your patient from the list by highlighting the line on the screen. Press the Update button to update the Patient List. |
| 3. | Press Select to transfer the specific patient information to the Patient Identification screen and return to the previous screen. Press Back to return to the previous screen without updating the patient information. |

Continued on next page

Patient identification, *Continued*

Selecting a report layout

To select a report layout, do the following:

| Step | Action |
|------|---|
| 1. | Highlight "Report Layout" with the up/down arrows on the Patient Identification screen. |
| 2. | <p>If "Report Layout" is included in the Patient ID, select a layout from the list displayed on the right side of the screen, using the up/down arrows. (The list of report layouts has been made in the Patient Report Setup - see <i>chapter 3: Installation and setup</i> in this manual.)</p> <p>If "Report Layout" is not included in the Patient ID, the text box is separated from the rest of the items on the Patient Identification screen.</p> <p>You can select another report layout by highlighting the line on the screen and selecting the desired layout. The patient report will be saved in this layout.</p> <p>NOTICE: If you are using mandatory input fields you are not allowed to change the report layout during measurement unless the mandatory fields have been filled.</p> |

Electrode updatings

It is possible to see updatings of the pH, $p\text{CO}_2$, $p\text{O}_2$, $c\text{K}^+$, $c\text{Na}^+$, $c\text{Ca}^{2+}$, $c\text{Cl}^-$, $c\text{Glu}$, $c\text{Lac}$ and $c\text{Crea}$ electrodes (the number of electrodes depends on the type of your analyzer) during a measurement.

To display the Electrode Updatings screen, press the ***Electrode Upd.*** button on the **Patient Identification** screen.

Press ***Back*** to return to the on the **Patient Identification** screen.

Continued on next page

Patient identification, *Continued*

Selecting parameters after a measurement

To change the parameter profile after a given measurement, do the following:

- | Step | Action |
|------|--|
| 1. | Press <i>Parameters</i> on the Patient Identification screen. |
| 2. | To exclude a parameter, deactivate the relevant button. To include a parameter, activate the relevant button. |
| 3. | Press <i>Back</i> to return to the Patient Identification screen and press <i>Result</i> to display the changed result. |
| 4. | Press <i>Print</i> to print out the changed patient report. |

NOTICE: The **Selected Parameters** screen displays all the parameters selected in the Parameter Profile for a given measuring mode, depending on the analyzer version.

Patient result

Retrieving patient result

The FLEXQ module is installed:

The measurement result will not be displayed automatically. You can do one of the following:



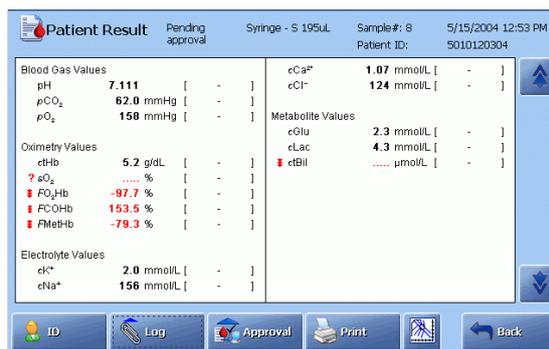
- Press the  button on the **Ready** screen
- Scan the registration receipt
- Press **Menu – Latest Result**
- Press **Menu – My Results**
- Press **Menu – Data Logs – Patient Results Log**, highlight the desired result and press **Result**.

The FLEXQ module is not installed:

The **Patient Result** screen will be displayed automatically when the measurement has been completed. However, if the patient identification information took longer time to enter than the measurement, you can do one of the following:

- Press the **Result** button on the **Ready** screen
- Press **Menu – Latest Result**
- Press **Menu – My Results**

Press **Menu – Data Logs – Patient Results Log**, highlight the desired result and press **Result**.



Press **Print** to print out the patient report.

Parameter status

The absence of any markings next to a parameter indicates that the parameter was measured without any fault.

The following markings may appear next to a parameter:

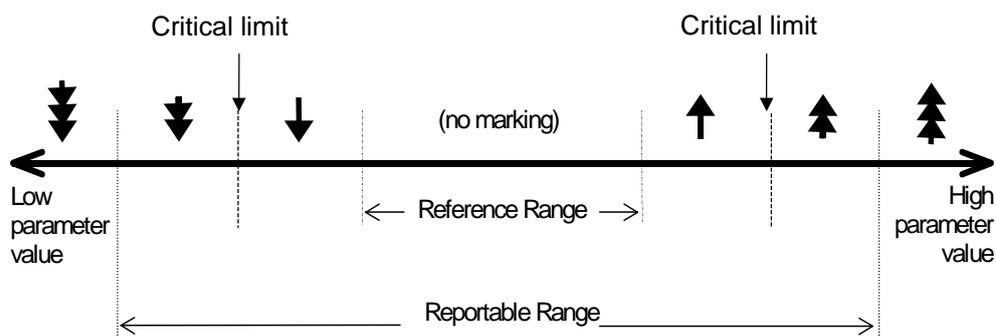
| Marking | Explanation |
|---------|--|
| ? | <ul style="list-style-type: none"> • Error in the last quality control measurement or calibration, or due to sample problems • Parameter has violated the sample age. |
| ↑ ↓ | Parameter value is outside the reference range (the range within which the parameter value is considered normal, for the specific type of sample being measured), but inside the critical limits. |

Continued on next page

Patient result, *Continued*

Parameter status (*continued*)

| Marking | Explanation |
|-----------------------------|--|
| ↑ ↓ | Parameter value is outside the upper or lower critical limit (the limits outside of which a parameter value is dangerously high or low, for the specific type of sample being measured), but inside the reportable range. |
| ↑↑ ↓↓ | Parameter value is outside the reportable range (user-defined and equal to or narrower than the measuring range). These markings will be printed together with the result and a verbal explanation. |
| "...." instead of the value | A parameter cannot be calculated or exceeds the numerical limit of the analyzer. |
| * next to the value | Values with user-defined correction factors. |



Patient result approval

Result approval is possible if the "Enable Result Approval" check button has been activated (✓) in the Miscellaneous Setup program.

To use this function, do the following:

| Step | Action |
|------|---|
| 1. | Press Approval on the Patient Result screen. |
| 2. | The following buttons become available when you press the button: Approve Press Accept to accept the result and to send it to the connected RADIANCE system or LIS/HIS. Press the keyboard icon to write a note. Press Cancel to return to the previous screen. |

Continued on next page

Patient result, *Continued*

Patient result approval (*continued*)

| Step | Action |
|---------------|--|
| Reject | <p>Press Accept to reject the result and to send it to the connected RADIANCE system or LIS/HIS.</p> <p>Press the keyboard icon to write a note.</p> <p>Press Cancel to return to the previous screen.</p> |
| Rerun | <p>Press Accept to mark that the measurement should be repeated, and to send it to the connected RADIANCE system or LIS/HIS.</p> <p>Press the keyboard icon to write a note.</p> <p>Press Cancel to return to the previous screen.</p> |
| Note | <p>Press the keyboard icon to type a note prior to the approval or to edit a highlighted note.</p> <p>To delete a highlighted note, press the keyboard icon and delete the note.</p> |

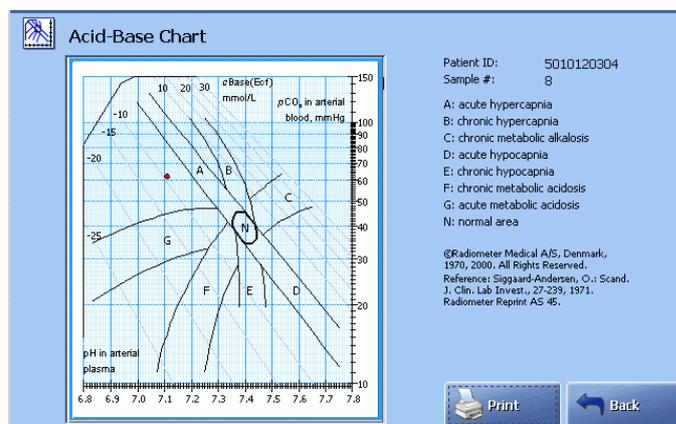
Once the result has been approved/rejected/rerun, the ID data can only be viewed, not changed (grayed-out input boxes). The **Parameters**, **Patient Lookup** and **Request** buttons will not be available either.

In the Patient Report log you can filter patient reports according to the approval status.

The **Approval** button changes to **Send** (if an external connection is used) after the approval of the patient result has been made.

If result approval is used, data will not be transmitted to a LIS/HIS connection before the approval has been made.

Acid-Base Chart Press **Acid-Base Chart** to view the acid-base chart for the selected patient result (the button will not be available if pH and $p\text{CO}_2$ were deselected in the Parameter setup. The sample type should be either “Arterial” or “Capillary”).



The chart illustrates the patient result according to the Siggard-Andersen nomogram. The clinical conditions corresponding to each of the 8 zones listed to the right of the screen.

Continued on next page

Patient result, *Continued*

Acid-Base Chart (continued) The point position is determined by the pH and $p\text{CO}_2$ values from the patient result. If the pH and $p\text{CO}_2$ values are outside the defined limits of the acid-base chart, the message “Measurement out of range” will appear on the chart in red and the **Print** button will disappear.

Available buttons:

Print = to print out the displayed acid-base chart and the corresponding patient result, if available - see above.

Back = to return to the **Patient Result** screen.

NOTICE: The information provided by the acid-base chart should only be used as a guideline for interpreting the patient’s condition. The patient results must always be examined carefully by a clinician before a proper diagnosis is made.

Recalling patient ID

To recall the **Patient Identification** screen, press the **ID** button.

For detailed information, refer to the topic *Patient Identification* in this chapter.

Patient result audit trail

Any changes made to an existing result will be registered in the Audit Trail.

The **Messages** button is substituted with the **Log** button to indicate that changes were made.

To see the audit trail, do the following:

| Step | Action |
|------|---|
| 1. | Press Log on the Patient Result screen to display the following buttons: Audit Trail and Messages . |
| 2. | Press Audit Trail . The audit trail contains information about the operator who made the change, time of change and new/old values. The changes made at the same time are indicated with “–” in Time and User columns. |
| 3. | Use the up/down arrow buttons to scroll the list of changes. Press Back to return to the Patient Result screen. |

Calculation of $FShunt$ and $ctO_2(a - \bar{v})$

Calculation of $FShunt$ and $ctO_2(a - \bar{v})$

To obtain the calculated values of $FShunt$ and $ctO_2(a - \bar{v})$, it is necessary to analyze a mixed-venous and an arterial (or capillary) blood sample from the patient.

Do the following:

| Step | Action |
|------|---|
| 1. | <p>Make, if required, a new patient report layout (see <i>Patient Reports</i> in <i>chapter 3</i>) with the following parameters included:</p> <ul style="list-style-type: none"> • $FShunt$ and/or $ctO_2(a - \bar{v})$ into the Patient Result • $pO_2(\bar{v})$, $sO_2(\bar{v})$, $FO_2(I)$, RQ and T (patient temperature) into the Patient ID |
| 2. | Analyze the mixed-venous sample and record the $pO_2(\bar{v})$ and $sO_2(\bar{v})$. |
| 3. | Analyze the arterial sample. |
| 4. | <p>On the Patient Identification screen, select the sample type as “Arterial“ or “Capillary“ and key in the following values:</p> <ul style="list-style-type: none"> • $pO_2(\bar{v})$ and $sO_2(\bar{v})$ from the mixed-venous sample (step 2 above) • $FO_2(I)$ if it differs from the default value of 0.21 (for $Fshunt$) • RQ if it differs from the default value of 0.86 (for $Fshunt$) • T if it differs from the default value of 37 °C (for $Fshunt$). • $p50(st)$ from the mixed-venous sample if $sO_2(a) > 97\%$. |

NOTICE: The $FShunt$ value will be available as an estimated value even without the data obtained from the mixed-venous sample.

Patient result messages

Screen messages The **Patient Result Messages** screen is displayed after the **Messages** button has been pressed.

The screen gives the erroneous parameter(s) and the message(s) with number(s) referring to the message described in *Troubleshooting Messages, chapter 11*.

Messages can be seen on the following three information levels:

| Level | Explanation |
|---------|--|
| User | Messages for the user familiar with the basic daily operation of the analyzer and primarily responsible for performing measurements. |
| Manager | Messages for the user with deeper knowledge of the analyzer functions and responsible for the analyzer's proper operation. |
| Service | Messages for the service technician with thorough knowledge of the operation and construction of the analyzer. |

Buttons and functions

The following buttons are available:

| Button | Function |
|---------------------|---|
| Result | Press to return to the Patient Result screen. |
| Troubleshoot | Press to display the error description and operator actions – see <i>Troubleshooting Messages, chapter 11</i> for detailed information. |
| Print | Press to print the screen message(s). |
| Back | Press to return to the previous screen. |
| Note | Press to display the keyboard, type the note and confirm with Enter . If Notes for patient result were entered in the User-defined Notes program (see <i>chapter 3: Installation and Setup</i>), select a Note from the list with the up/down arrow buttons. To edit a note use Edit Note and type the note on the keyboard. Remember to confirm it with Enter on the keyboard. To delete a note use Delete Note and delete it. |

5. Quality control

Overview

Introduction Quality control is used to evaluate the performance of the analyzer to ensure the reliability, accuracy and precision of patient sample results.

This chapter describes how to perform a quality control measurement and the subsequent presentation of results.

Contents This chapter contains the following topics.

| | |
|---|------|
| General information | 5-2 |
| Preparing a control solution | 5-4 |
| Manual quality control measurement..... | 5-6 |
| AutoCheck measurement | 5-7 |
| Quality control identification | 5-8 |
| Quality control result..... | 5-10 |
| Quality control result messages | 5-15 |

General information

- Purpose** The purpose of quality control is to validate the analyzer's performance by evaluating accuracy and precision. Performing quality control routinely will help to ensure that results from actual patient samples are accurate.
- Solutions** Each quality control system includes four types of control solutions in order to provide control of analyzer performance when measuring parameters at low, normal and high levels – refer to the *Quality control setup* in *chapter 3*.
It is possible to use non-Radiometer solutions although the accuracy and validity of the results cannot be guaranteed.
- Inserts** Control solutions are packed in ampoule boxes. Each ampoule box contains an insert with the Radiometer-determined assigned values and control limits valid for that particular lot of control solutions. The solution type, lot number, assigned value and expiration date is barcoded for easy entry.
- Quality control frequency** Quality control solutions are solutions with predetermined values that cover the clinically relevant ranges for the measured parameters, the objective being to simulate a patient sample. Each quality control system from Radiometer includes four levels of quality control solutions in order to cover the whole clinically significant range: low, normal and high. The number of levels should cover the analytical measuring range.
Special country, state and local regulations must be complied with. Additional quality control should be run after any troubleshooting or preventive maintenance which might alter performance and whenever the technician has questions about the performance of the analyzer.

An example of daily routine with the 4-level quality control system is given below:

| Shifts per day | Quality control routine |
|----------------|--|
| 3 | One level tested at the beginning of each shift. The 4th level is tested in the 8-hour shift with the highest volume of patient samples. |
| 2 | Two levels at the beginning of each shift. |
| 1 | All levels are tested at the beginning of each shift. |

Continued on next page

General information, *Continued*

Glossary of terms

The following terms are used in the quality control:

| Term | Explanation |
|-------------------|---|
| Accepted result | A measurement value which falls within the statistics range. |
| Control range | The range within which a measurement should fall. Typically the control range is set to be the mean \pm 2 SD (see <i>Quality control setup</i> in <i>chapter 3</i>). This range can be set using the lot-to-date range (2 SD) calculated by the analyzer, or it may be user-defined. |
| Insert limits | Upper and lower control limits, established by Radiometer, printed in the insert provided with each box of control solutions. |
| Lot-to-date range | A range calculated by the analyzer from measurements taken on a lot of a particular control solution. It is represented by mean \pm 2 SD. |
| Measuring range | The range for each parameter the analyzer is capable of measuring. Refer to <i>Measured parameters</i> in <i>chapter 13</i> for the analyzer measuring range for each parameter. |
| Statistics factor | The factor by which the control range is expanded (multiplied by) to determine the statistics range. The recommended statistics factor is 1.5. |
| Statistics range | The range within which a measurement must fall in order to be included in the quality control statistics. It is determined by multiplying the control range limits by the entered statistics factor. It is typical that the statistics range is set to the mean \pm 3 SD. |

For detailed information on terminology and principles for the quality control systems, please refer to the *Quality Control Systems Reference Manual*.

NOTICE:

In cases where the first blood sample measurement after a measurement on a QUALICHEK3+/5+ or AutoCheck3+/5+/6+ control solution is to be performed with HbF correction (either set up for all levels or for FHbF > 20 %), a rinse must be called prior to the blood measurement to ensure accurate oximetry results.

Preparing a control solution

About control solutions Brief information is given below:

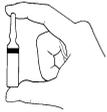
| Item | Description |
|---------------------------------|--|
| Quantity | <ul style="list-style-type: none"> Each QC ampoule of QUALICHECK+ contains 2 mL of QC solution. Each QC ampoule of AutoCheck contains 0.7 mL of QC solution. |
| Conditioning before measurement | Store the ampoules for five hours at 18-32 °C. Control solutions are sensitive to light, so always keep the ampoule box closed. |
| Open ampoule stability | In order to ensure the reliability of the measurement, each QC ampoule must be used immediately after opening, for one measurement on one analyzer only. |

Required materials

The following materials are required to make a manual measurement on a control solution:

| Quality control system | Materials required |
|---|--|
| QUALICHECK3+ QUALICHECK5+ | <ul style="list-style-type: none"> Four levels of control solutions H700 Ampoule adapter Ampoule opener Rubber gloves |
| AutoCheck3+ AutoCheck5+ AutoCheck6+ | <ul style="list-style-type: none"> Four levels of control solutions H700 Ampoule adapter H705 Ampoule holder Rubber gloves |

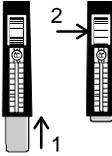
Before measurement on QUALICHECK+ control solution Do the following:

| Step | Action |
|------|--|
| 1. |  Holding the ampoule between two fingers as shown, shake it vigorously for at least 15 seconds. |
| 2. | Tap the top of the ampoule until all of the solution collects at the bottom. |

Continued on next page

Preparing a control solution, *Continued*

Before measurement on QUALICHECK+ control solution
(continued)

| Step | Action |
|------|--|
| 3. |  <p>Place the ampoule in the ampoule opener and break off the ampoule neck.</p> |
| 4. |  <p>Place the ampoule fully into the H700 adapter.</p> |

Before manual measurement on AutoCheck control solution

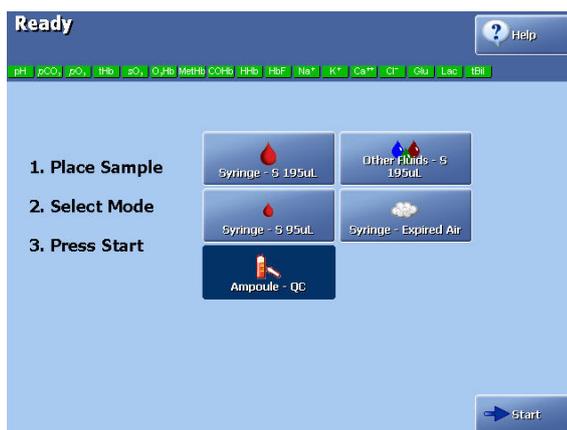
Do the following:

| Step | Action |
|------|---|
| 1. | Place the ampoule in the H705 Ampoule holder. |
| 2. | Holding the ampoule in its holder between two fingers, shake it vigorously for at least 15 seconds. |
| 3. | Place the H700 Ampoule adapter over the ampoule and press it down to open the ampoule. |

Manual quality control measurement

Procedure To make a manual measurement on a QUALICHECK+ or AutoCheck control solution, do the following:

- | Step | Action |
|------|--|
| 1. | Open the syringe inlet flap. |
| 2. | Place the adapter tip up into the syringe inlet. |
| 3. | Press <i>Ampoule-QC</i> to select the measuring program. |



- Press *Start*.
The sample is aspirated and the **Quality Control Identification** screen appears. Refer to the next section, for information on entering data.
- When prompted by the analyzer, remove the adapter and close the syringe inlet flap.
- Dispose of the used ampoules as infectious waste*.

* **Reference:** Clinical laboratory waste management. CLSI document GP5-A2.

High Crea Check

S8377 Cleaning Met II Solution is used to check the analyzer performance at a high creatinine level. The check up is made automatically during the system alignment procedure.

To call an unscheduled High Crea Check, do one of the following:

- Press *Menu > Start Programs > Run High Crea Check*
- On the **Analyzer Status** screen highlight the line for Slot 11 and press **Run High Crea Check** to start a measurement.

AutoCheck measurement

Scheduled AutoCheck measurement

A scheduled AutoCheck measurement will start on time provided that no calibrations are pending. A pending calibration will be performed before the scheduled AutoCheck measurement.

On the screen that appears when an AutoCheck measurement is about to run (scheduled either from QC Schedule or from the RADIANCE system), select one of the three possibilities:

- **No action taken:** the AutoCheck measurement starts after 20 seconds (see counter on the screen)
- ***Proceed*** pressed: the AutoCheck measurement starts immediately.
- ***Postpone*** pressed: the AutoCheck measurement will be delayed by five minutes.

Unscheduled AutoCheck measurement

To start an unscheduled AutoCheck measurement, do the following:

| Step | Action |
|------|--|
| 1. | Press <i>Analyzer Status – Quality Control</i> . |
| 2. | Highlight the solution to run an unscheduled measurement on. |
| 3. | Press <i>Run AC Ampoule</i> to start the measurement. |

The Quality Control Result is shown after the measurement is completed.

NOTICE: It is only possible to choose ampoules that are packed in the carousel. If an ampoule is not available, the *Run AC Ampoule* button is inactive.

Quality control identification

Entering information with barcode reader

To enter the information with the barcode reader, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Scan "Operator" from your ID-card.

If the name is included in the list of the analyzer's registered users, the barcode will identify the person and fill in the name automatically.

Entering information manually

To enter information manually, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Highlight the item to be edited, using the arrow buttons.
 Solution and Lot Are automatically detected and entered if only one quality control system is used. Otherwise highlight the desired solution from the screen and confirm with **Enter**.
 If the same type of QUALICHECK+/AutoCheck+ solution is used, then only the solution type will be identified. Choose the specific slot from the screen.
2. For manual QC measurements only: Enter the temperature (default: 25 °C) on the keypad and confirm with **Enter**.
 Mandatory entry is indicated by a .

Continued on next page

Quality control identification, *Continued*

Entering information manually (*continued*)

| Step | Action |
|------|--|
| 3. | Enter "Department" on the keypad and confirm with <i>Enter</i> . |
| 4. | Enter "Operator" on the keypad or keyboard and confirm with <i>Enter</i> (filled in automatically when operator is logged on). |

"Scheduled: Yes" indicates that a QC is performed according to a planned QC in the Quality Control Schedule.

"Scheduled: No" indicates that a QC is performed on behalf of the user.

Electrode Updatings

To display the electrode updatings during measurement, press the *Electrode Upd.* button.

Quality control result

Quality Control Result screen In most cases the **Quality Control Result** screen will be displayed automatically when the measurement has been completed. However, if the quality control identification took longer time to enter than the measurement, you can:

Press **Result** from on the **Quality Control Identification** screen;
 from the **Menu > Analyzer status > Quality Control**;
 from the Quality Control log.

| Quality Control Result | | | |
|-------------------------|---------------------------|---------------------------|-----------------------------|
| Slot: 1 | S7735 | Lot #: 70 | QC# 1 |
| | | 5/18/2004 01:22 PM | |
| Blood Gas Values | | Electrolyte Values | |
| pH | 7.103 [7.076 - 7.116] | cK ⁺ | 1.9 mmol/L [1.6 - 2.2] |
| pCO ₂ | 65.4 mmHg [61.1 - 71.1] | cNa ⁺ | 154 mmol/L [153 - 161] |
| pO ₂ | 143 mmHg [136 - 156] | cCa ²⁺ | 1.06 mmol/L [0.93 - 1.13] |
| Oximetry Values | | Metabolite Values | |
| ctHb | 7.8 g/dL [7.3 - 8.3] | cGlu | 2.2 mmol/L [1.7 - 2.7] |
| sO ₂ | 50.0 % [49.0 - 51.0] | cLac | 4.2 mmol/L [3.7 - 4.9] |
| FO ₂ Hb | 44.5 % [43.5 - 45.5] | ctBil | 180 μmol/L [169 - 193] |
| FCOHb | 6.1 % [4.6 - 7.6] | | |
| FMethHb | 5.0 % [4.0 - 6.0] | | |
| FHbF | 27 % [11 - 41] | | |

The measured values are compared with the defined control range, measuring range and statistics range, then given a status mark accordingly.

NOTICE: The user-defined corrections (slope and offset) do not influence the quality control results, unless the "Apply parameter corrections to QC" function has been activated in the Miscellaneous Setup.

Parameter status

The absence of any markings next to a parameter indicates that the parameter was measured without any fault.

The following markings may appear next to a parameter:

| Marking | Explanation |
|---------|--|
| ? | Error in the previous calibration, or analyzer malfunction. |
| W | A violated Westgard Rule. |
| R | A violated Rilibäk Rule. |
| ↑ ↓ | Parameter value outside the control range, but inside the statistics range. Only the values within the statistics range are considered accepted and are included in the quality control statistics. |
| ↑ ↓ | Parameter value outside the statistics range and not included into statistics |
| ↑ ↓ | Parameter value outside the measuring range. Measurement is not included into statistics. |

Continued on next page

Quality control result, *Continued*

| Parameter status (<i>continued</i>) | Marking | Explanation |
|---|---------|--|
| | “*” | Parameter values with user-defined corrections – see <i>Parameters and input, chapter 3</i> for details. |
| | “....” | Parameter value could not be calculated, most likely due to a system error or malfunction. These values for the most part will be accompanied with a “?”. To obtain a possible explanation, press the Message button. |
| Unknown solutions | | Quality control on a solution identified as unknown is not compared with any previous measurements or statistics, and therefore does not receive a status marking. The parameter results for unknown levels cannot be plotted and are not included in any statistical data unless later changed to a defined slot. |
| Temperature corrections | | <ul style="list-style-type: none"> • For control solutions from Radiometer temperature corrections are made automatically by using the measured or typed-in temperature. • For non-Radiometer control solutions, temperature corrections must be made manually. Refer to manufacturer’s literature for procedure. |
| Reference | | For a detailed explanation of the evaluation of results, refer to <i>chapter 6</i> of the <i>Quality Control Systems Reference Manual</i> . |
| Recalling quality control identification | | <p>To change data that can be edited (non-grey lettered) on the screen, press QC ID. For detailed information, refer to previous section <i>Quality Control Identification</i> in this chapter.</p> <p>NOTICES (for manual QC measurements only):</p> <ul style="list-style-type: none"> • Changing the temperature will initiate recalculation of the last result. It will be substituted by the recalculated result, and the statistics will also be recalculated. In case the temperature is mandatory, the result cannot be viewed until it has been entered. • Exiting the QC ID screen without entering a temperature, the previous temperature will be recalled. |

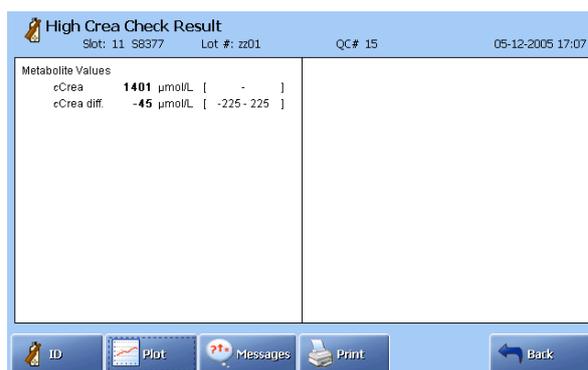
Continued on next page

Quality control result, *Continued*

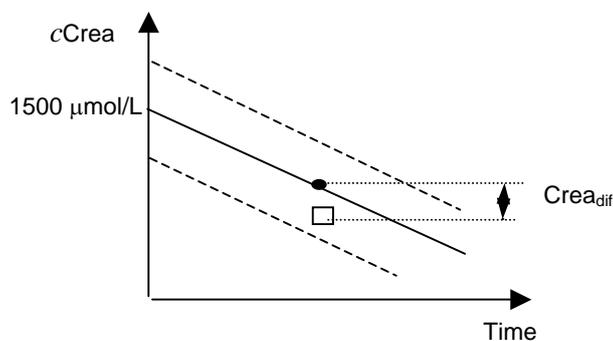
High Crea Check
(for the ABL8x7 FLEX analyzers only)

The high Crea check result of the ABL8x7 FLEX analyzers can be retrieved as follows:

Press **Result** on the **Quality Control Identification** screen
from the **Menu > Analyzer status > Quality Control**
from the Quality Control log



The initial *cCrea* concentration in the Cleaning Met II Solution is approximately 1500 µmol/L when the container is installed in the analyzer. The exact concentration is entered from the barcode when the solution is installed in the analyzer (the value shown as *cCrea* on the **High cCrea Check** screen above). With time, creatinine in the solution transforms into creatine, the speed of this transformation depends on the ambient temperature.



| | |
|-------|--|
| ———— | Expected <i>cCrea</i> concentration in the Cleaning Met II Solution |
| ----- | The upper/lower drift limits for <i>cCrea</i> is ± 225 µmol/L, i.e. if the initial <i>cCrea</i> is 1500 µmol/L, the corresponding control ranges will be 1275-1725 µmol/L. |
| • | Expected <i>cCrea</i> concentration in the Cleaning Met II Solution at the time of the High Crea check has been performed |
| □ | Measured <i>cCrea</i> concentration in the Cleaning Met II Solution at the time of the High Crea check has been performed |

Continued on next page

Quality control result, *Continued*

High Crea Check (for the ABL8x7 FLEX analyzers only) *(continued)*

Crea_{diff.} is the difference between the expected creatinine value in the Cleaning Met II Solution and the measured value. It is shown on the plot – see page 5-14.

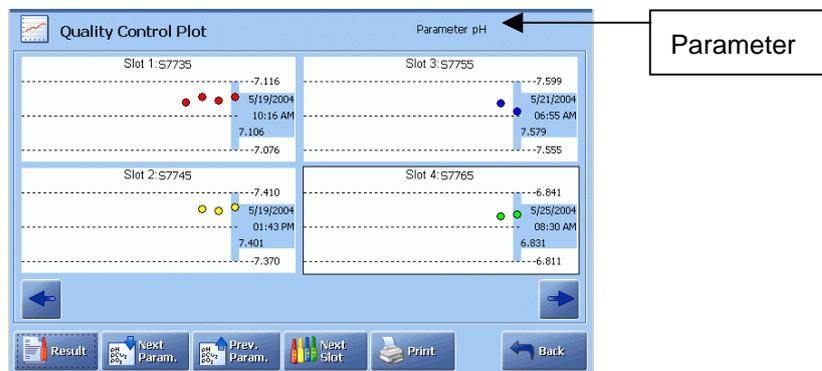
To evaluate the Crea_{diff.} accurately, it is required to enter the expected ambient temperature for the 14-day period in the Environment Setup – see *Analyzer settings* in *chapter 3*.



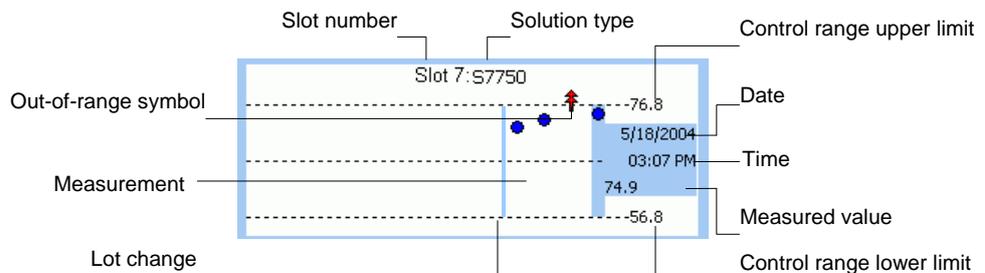
The ambient temperature on the **High Crea Check ID** screen is grayed out, i.e. it can only be viewed. The ambient temperature setting can be changed in the Environment Setup.

Quality control plot

The **Quality Control Plot** screen appears once the *Plot* button is pressed.



The following diagram shows the details of a typical plot.



Continued on next page

Quality control result, *Continued*

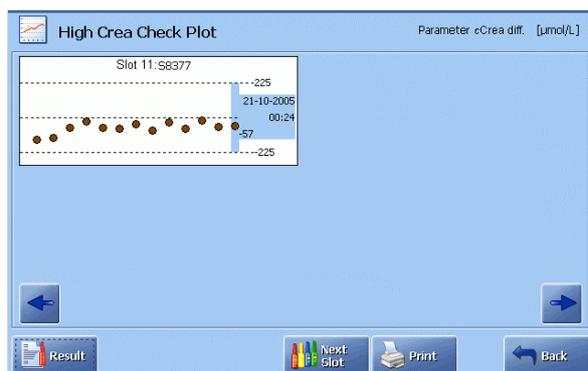
| Quality control plot (<i>continued</i>) | Plot element | Function |
|---|----------------------|--|
| | Shaded block | Date, time and measured value for the highlighted measurement. Use the arrow buttons to scroll the plot and view other measurements. |
| | Control range limits | Show the upper and the lower limits of the control range for the highlighted measurement. |
| | Dots | Show the number of measurements for the selected parameter. To view a measurement result, highlight a dot on the screen and press Result . |
| | Out-of-range symbols | <p>↑ ↓ Measurement outside the control range and inside the statistical range.</p> <p>↑↑ ↓↓ Measurement outside both the control and statistical ranges.</p> |

Use the following buttons to do the following:

| | |
|---------------------|--|
| Next Param. | Display the quality control plots for the requested parameter. |
| Prev. Param. | Display the quality control plots for the requested parameter. |
| Next Slot | Display plots of the next control solution slot. |
| Result | View quality control result for the highlighted measurement of the highlighted plot. |
| Print | Print out the plot. |
| Back | Return to the previous screen. |

(For the ABL8x7 FLEX analyzers only):

The plot for the High Crea Check of the ABL8x7 FLEX analyzers presents Crea_{diff}.



The screen is similar to the quality control solution plot, but the **Next Param.** and **Prev Param.** buttons are absent.

Quality control result messages

Quality control result messages To see the quality control result and check the messages, do the following:

| Step | Action |
|------|---|
| 1. | Press Menu - Analyzer Status - Quality Control . |
| 2. | Highlight the desired quality control measurement and press Result . |
| 3. | Press Messages to see the messages in connection with the given quality control result. The erring parameter(s) and the message(s) with number(s) referring to the message are described in <i>Troubleshooting Messages, chapter 11</i> . |
| 4. | Troubleshoot, if required, by highlighting the message (the first message is already highlighted) and pressing Troubleshoot . Follow instructions on the screen to remedy the error. Use Tutorials for assistance. When it is done, press Troubleshooting completed . |
| 5. | Press Back to return to the list of messages screen. Press Print to print out the list of messages. Press Note to display the keyboard, type the note and confirm with enter. If Notes for quality control result were entered in User-defined Notes program (see <i>chapter 3: Installation and Setup</i>), select a Note from the list with the up/down arrow buttons. To edit a note, use Edit Note . To delete a note, use Delete Note . |
| 6. | Press Back to close the Note popup window. Press Back to return to the Quality Control Result screen. |

AutoCheck status See *Refilling the AutoCheck carousel* in *chapter 7: Replacements*.

6. Calibration

Overview

Introduction This chapter describes the available calibration programs and the calibration results.

A short glossary of terms used in the chapter is also given.

Contents This chapter contains the following topics.

| | |
|--|------|
| General information | 6-2 |
| Unscheduled calibrations | 6-4 |
| Interrupted, pending or expired calibrations | 6-5 |
| tHb calibration..... | 6-6 |
| Calibration result..... | 6-8 |
| Calibration result messages..... | 6-10 |

General information

Purpose The calibration process determines and checks the accuracy with which the analyzer measures its parameters. The process is therefore important in ensuring the reliability of results.

Calibrations are performed using solutions and gases of known concentration, for each of the measured parameters.

Calibration programs The following calibrations performed on the analyzer are briefly described below. (For detailed explanation please refer to the *Reference Manual, chapters 1,2,3.*)

| Calibration | Description |
|------------------------------|---|
| 1 point | Measures each parameter on one solution and/or gas of known composition, giving one value per parameter. Relates the measured values to the theoretical values of a solution and/or gas of the same composition. Gives the Drift 1 and status values of the electrode. |
| 2 point | Measures each parameter on two different solutions and/or gases both of known composition, giving two values per parameter. Relates the measured values to the theoretical values of solutions and/or gases of the same composition. Gives the Drift 1, Drift 2 values and the status or zero point, sensitivity of the electrodes (two sensitivity values are given for the Crea B electrode and one for the Crea A electrode of the ABL8x7 FLEX analyzers). |
| 1 point pH/BG (the USA only) | Measures $p\text{CO}_2$ and $p\text{O}_2$ on one gas mixture of known composition and pH on a known solution, giving one value per parameter Relates the measured values to the theoretical values of a mixture/solution of the same composition. Gives the Drift 1 of the electrodes. |
| tHb | Calibrates the spectrophotometer. See <i>tHb calibration</i> in this chapter. |

Calibrations performed automatically at specific intervals selected in the Calibration Schedule setup (see *Calibration Setup* in *chapter 3*) are called **scheduled** calibrations.

All calibration results are automatically recorded in the Calibration Log from which they can be viewed and printed. Refer to *chapter 9: Data Management* for details.

The calibration process and a detailed explanation of the terms are described in the *Reference Manual*.

Continued on next page

General information, *Continued*

NOTICE: Additional 1-point calibrations are performed on the analyzers with the metabolite electrodes:

- after 11 measurements made one after another, no more than 10 minutes apart and
- 30 minutes after the last measurement was made.

The additional 1-point calibration does not change the intervals selected for the scheduled calibrations.

In cases when a scheduled 2-point calibration is imminent, the additional 1-point calibration will be substituted with the 2-point calibration.

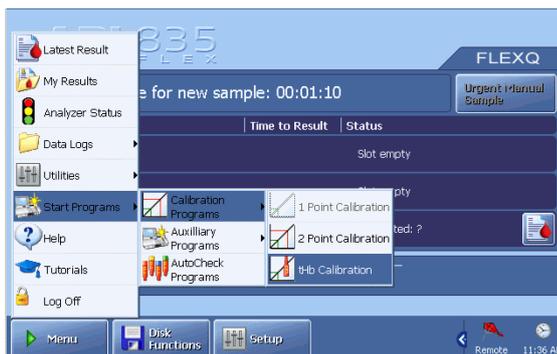
NOTICE: (for the USA only) If an unacceptable pH drift is detected during a 1 point pH/BG calibration, the ongoing calibration is aborted and a normal 1-point calibration is performed.

Unscheduled calibrations

Calling an unscheduled calibration

Calibrations called by the operator at any time are called **unscheduled** calibrations. To call an unscheduled calibration, do the following:

- | Step | Action |
|------|---|
| 1. | Check that the analyzer is in the Ready mode. |
| 2. | Press <i>Menu – Start Programs – Calibration Programs</i> . |



Call a calibration.

If a button is grayed out, a calibration cannot be called (as 1-point calibration on the screen).

- | | |
|----|--|
| 3. | To see the electrode updatings during a calibration, go to the Analyzer Status screen and press the <i>Electrode Upd.</i> button. |
|----|--|

Calibrations during 24 hours after restart

The 24-hour calibration period is only necessary after the replacement of electrodes and/or electrode membranes.

The calibration intervals for the first 24 hours after restart are as follows:

| Time after restart | Calibration intervals | |
|--------------------|-----------------------|------------------|
| First 4 hours | 1-point calibration | Every 30 minutes |
| | 2-point calibration | Every hour |
| Remaining 20 hours | 1-point calibration | Every hour |
| | 2-point calibration | Every 4 hours |

NOTICE: If the restart is caused by cGlu/cLac electrode/membrane maintenance 1-point calibrations will be performed every 30 minutes for the first 4 hours and every hour for the following 20 hours. 2-point calibrations will follow the normal schedule.

NOTICE: If the calibration schedule is set up to perform calibrations at intervals less frequent than those programmed for the 24-hour calibration period, the calibration schedule is overridden.

Interrupted, pending or expired calibrations

Interrupted calibrations

A calibration is interrupted when the operator presses the *Stop* button during the calibration process. The analyzer performs a rinse before returning to the Ready mode.

If the interrupted calibration was a scheduled calibration, it will be automatically performed after the analyzer has been in the Ready mode for three minutes without any activity, i.e. measurements. The scheduled calibration becomes pending if interrupted.

Pending calibrations

A calibration is pending when a **scheduled** calibration cannot be performed at its scheduled time because the analyzer is occupied with another function, e.g. measurement.

A pending calibration is indicated by a clock symbol next to it on the **Analyzer Status – Calibrations** screen as a warning.

A pending calibration will be performed three minutes after the analyzer has returned to the Ready mode without any activity. If more than one type of calibration is pending, the highest-priority calibration is performed. The calibrations are given in descending order of priority, the 2-point calibration having the highest priority.

If a calibration is pending, a scheduled AutoCheck measurement will be postponed until after the calibration has been performed.

Expired calibrations

A full calibration means that all parameters are calibrated. Normally, a full calibration is a 2-point calibration, but in the case of glucose and lactate electrodes it is a 1-point calibration.

A calibration is expired and considered to be invalid when:

- an electrode or electrode membrane is replaced.
- the time interval since the last accepted full calibration exceeds the time interval between two full calibrations **plus** a 1-point calibration.

Under these conditions a “Cal expired (parameter)” message appears in the Activity and System Messages logs, and the replaced item is also recorded in the Activity log.

An expired calibration can be remedied by performing a successful full calibration after a replacement.

Upgraded calibrations

Whenever a 2-point calibration contains an error, the next calibration will be upgraded to a 2-point calibration. If a 2-point calibration contains errors on Glu, Lac and oximetry parameters only, the errors can be remedied by a 1-point calibration. Thus the next calibration will not be updated to a 2-point calibration. A 1-point pH/BG calibration (the USA only) will, however, be updated to a 1-point calibration.

tHb calibration

Purpose The calibration is used to calibrate the analyzer's spectrophotometer and is performed once every three months on S7770 tHb Calibrating Solution. The calibration can be included in the Calibration Schedule.

Preparation

- It is recommended to perform the **Protein Removal Program** before a tHb calibration in order to remove protein deposits – see *Decontamination and Protein Removal program, chapter 7*.
- Check that the analyzer is in the Ready mode.
- Prepare an ampoule of S7770 Calibrating Solution, an H700 Ampoule adapter and an ampoule opener.

Performing a tHb calibration To perform a tHb calibration, do the following.

| Step | Action |
|------|---|
| 1. | Perform Cal 1 or Cal 2, if not done after the Protein Removal. |
| 2. | Press the Menu - Start Programs - Calibration Programs - tHb Calibration . Enter the barcode from the tHb Calibration Solution insert, using the barcode reader or the keyboard. To cancel the program, press Close . |
| 3. | When the barcode has been accepted, a screen with requirements appears. Requirements 1-3 should be fulfilled before you press Start . |
| 4. | Tap the top of the tHb Calibration Solution ampoule to collect the liquid at the bottom and break off the ampoule neck, using the ampoule opener. |
| 5. | Put the ampoule in the H700 Ampoule adapter. |
| 6. | Open the syringe inlet flap and place the adapter tip into the inlet. |
| 7. | Press Start to aspirate the calibrating solution. |
| 8. | When prompted by the analyzer, remove the adapter and close the syringe inlet flap. Do not discard the S7770 ampoule, as it will be used for the tHb Calibration verification. After the measurement a rinse is performed and then the analyzer returns to the Ready mode. |
| 9. | If the calibration results are accepted, perform the tHb calibration check immediately – see below. Otherwise remedy the error and perform a new tHb calibration. |

Continued on next page

tHb calibration, *Continued*

tHb calibration check To verify the validity of the tHb calibration, do the following.

| Step | Action |
|------|--|
| 1. | Open the syringe inlet flap and place the adapter with the S7770 solution in the inlet. |
| 2. | Select the mode: Syringe – S195 µL or Syringe – S85 µL or Syringe – S250 µL depending on the ABL800 FLEX version. |
| 3. | Press the Start button. Remove the ampoule when prompted and close the inlet. |
| 4a. | If the calibration check value* is within the insert limits, the tHb calibration is accepted. |
| 4b. | If the calibration check value* is outside the insert limits, repeat the tHb calibration and then the calibration check immediately after it. If the second tHb calibration and the calibration check fail again, contact a service technician. |

* Can be ctHb, or ctHb and ctBil, or ctBil.

NOTICE: If the tHb calibration check has not been performed immediately after the tHb calibration, repeat the calibration and the calibration check immediately after it.

Calibration result

Viewing a calibration result

The result can be viewed as soon as the calibration is completed. Results from the most recent calibrations can be viewed via the **Analyzer Status – Calibration** screen or via the Calibration Log.

To recall the result, highlight the desired calibration and press the **Result** button to display the **Calibration Result** screen.

| Calibration Result | | | | | | Scheduled: Yes |
|---------------------------|-------------|-------|----------|----------|-----------------|----------------|
| Type: 2 point calibration | | | Cal # 44 | | 6/30/2009 14:00 | |
| pH | 7.402 | Drift | -0.000 | Status | 7.571 | |
| | 6.860 | Drift | -0.000 | Sens. | 98.1 % | |
| | | | | Status 0 | 7.174 | |
| pCO ₂ | 40.3 mmHg | Drift | -0.1 | Status | 38.7 mmHg | |
| | 80.6 mmHg | Drift | -0.2 | Sens. | 86.8 % | |
| | | | | | | |
| pO ₂ | 141.7 mmHg | Drift | 0.2 | Sens. | 11.9 pA/mmHg | |
| | 0.0 mmHg | Drift | -0.1 | Zero | 0.6 mmHg | |
| | | | | | | |
| ck* | 4.1 mmol/L | Drift | -0.0 | Status | 2.5 mmol/L | |
| | 10.0 mmol/L | Drift | -0.0 | Sens. | 94.7 % | |
| | | | | | | |
| eNa* | 146 mmol/L | Drift | -0 | Status | 13 mmol/L | |
| | 50 mmol/L | Drift | -0 | Sens. | 96.6 % | |
| | | | | | | |

Press button:



To display the remainder of the calibration result.

Messages

To display interpretation of any detected errors.

Print

To print out the result.

(Send)

To send the result to a connected LIS/HIS system.

"Scheduled: Yes" indicates that a QC is performed according to a planned QC in the Quality Control Schedule.

"Scheduled: No" indicates that a QC is performed on behalf of the user.

1- or 2-point calibration results

The calibration data is grouped together by parameter:

Bold characters Indicate data updated during this calibration.

Grey characters Indicate data taken from the previous calibration and not included in this calibration.

"?" Indicates an error or the value outside the recommended range, such as:

Drift value = outside the drift tolerances – see *Calibration Setup* in chapter 3.

Status = outside the default limits.

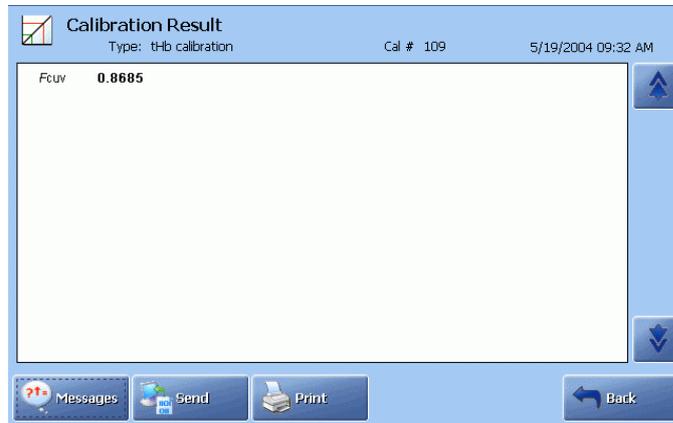
Sensitivity = outside the default limits.
(Two sensitivity values are given for the Crea B electrode and one for the Crea A electrode of the ABL8x7 FLEX analyzers.)

"....." Indicates the value could not be calculated, most likely due to a system error or malfunction. These values for the most part will be accompanied by a "?". Press the **Messages** button for an explanation of the error.

Continued on next page

Calibration result, *Continued*

tHb calibration result An example of a successfully performed tHb calibration is shown below:



F_{CUV} is a factor which expresses the ratio of the effective light path of the analyzer cuvette to that of a reference cuvette determined by Radiometer.

The value should be between 0.80-1.20 and have no errors, i.e. no "?" in it.

Calibration result messages

Access to the screen Press the *Messages* button on the **Calibration Result** screen to display the **Calibration Result Messages** screen.

The following buttons are available:

| | |
|---------------------|--|
| Result | To return to the Calibration Result screen. |
| Troubleshoot | To display the interpretation and operator actions – see <i>Troubleshooting Messages, chapter 11</i> . |
| Note | A Note can be selected from a list of Notes (made in the User-defined Notes program), typed by pressing the keyboard icon, edited by pressing the <i>Edit Note</i> button, or deleted by pressing the <i>Delete Note</i> button. |
| Print | To print out the messages. |
| Back | To return to the previous screen. |

Message levels The message levels can be considered as a type of filter in which the messages displayed are based on the following:

| Level | Explanation |
|--------------|--|
| User | Messages for the user familiar with the basic daily operation of the analyzer and primarily responsible for performing measurements. |
| Manager | Messages for the user with deeper understanding the analyzer functions and responsible for the analyzer's proper operation. |
| Service | Messages for the service technician with thorough knowledge of the operation and construction of the analyzer. |

7. Replacements

Overview

Introduction This chapter describes the replacement procedures that ensure proper functioning of your analyzer.

Remember to perform Decontamination before replacing the parts that were in direct contact with blood.

Contents This chapter contains the following topics.

| | |
|--|------|
| General information | 7-2 |
| Replacing membranes or electrodes..... | 7-6 |
| Replacing pump tubes | 7-9 |
| Replacing inlet gasket and inlet probe | 7-12 |
| Replacing waste container, fan filter, printer paper | 7-14 |
| Replacing solutions and gases..... | 7-16 |
| Refilling the AutoCheck carousel | 7-19 |
| Automatic auxiliary programs..... | 7-20 |
| Decontamination and Protein Removal programs | 7-21 |
| Cleaning the analyzer..... | 7-23 |
| List of references..... | 7-25 |

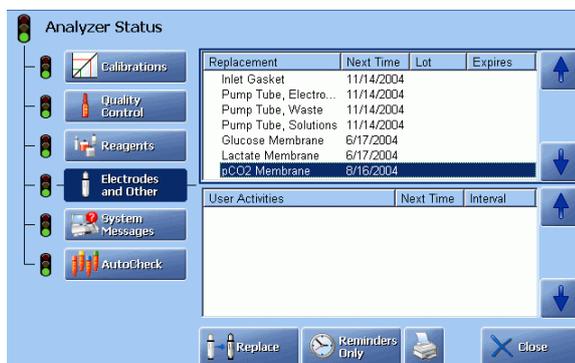
General information

Viewing replacement requirements

To view the replacements that are due, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Check the following on the **Analyzer Status** screen:



- Replacement schedule for the electrode membranes and the electrodes
 - Messages referring to the membranes/electrodes or user activities
 - Traffic light color (GREEN = No replacements are due at the present time; YELLOW = A replacement is due)
2. Highlight the item to enter the screen for replacements of electrodes/membranes – see the next page.
 3. Press **Log Activity** to enter the User Activity program to view user activities list – see *chapter 3* in this manual.
 4. Press **Close** to exit to the **Ready** screen.

Entering the Hold mode

The Hold mode ensures that all wet section activities are suspended and that the proper restart sequence will follow the exit from the Hold mode.

To enter the Hold mode, do one of the following:

- Go to **Menu – Analyzer Status – Electrodes and Other**. Press **Replace**.
- Remove the cover to the measuring modules.
- Open the window to the electrode module and wait for draining to complete.
- Remove both inlet flaps.
- Remove a solution container.

Continued on next page

General information, *Continued*

Recording replacements in Hold mode

To record replacements in the Hold mode, do the following:

- | Step | Action |
|------|--|
| 1. | Enter the Hold mode as described earlier. |
| 2. | Remove the component to be replaced according to the recommended procedure. |
| 3. | Preferably scan the barcode of the new item before mounting it in the analyzer. Otherwise highlight the item in the list and press Replaced in order to have it appear in “Recorded replacements” box on the right of the screen. |
| 4. | Repeat step 2 for another replacement in the similar manner. |



To remove an item from the list of recorded replacements, highlight it (with the up/down arrow buttons) and press **Undo**.

- If desired, enter the operator initials and a note for the Activity Log by pressing the keyboard icon in the “Operator:” box (or the keyboard) in the “Note:” box.
 - Select a Note from the list with the up/down arrow buttons.
 - Edit, if desired, a highlighted Note by pressing **Edit** and displaying the keyboard. Remember to confirm a change with **Enter**.
 - Delete, if desired, a highlighted Note by pressing **Delete Note**.
- When all replacement actions are completed, mount all components and the covers, and close the inlets.
- Press **Restart** to begin the proper restart sequence.

For the ABL8x7 FLEX analyzers only:

In case the Crea A and Crea B electrode membranes or electrodes have been replaced, pressing **Restart** will display the following screen (see the next page):

Continued on next page

General information, *Continued*

Recording replacements in Hold mode (*continued*)

| Step | Action |
|------|--------|
|------|--------|

| | |
|----------------------------|--|
| 7. (<i>continued</i>) | |
|----------------------------|--|



(In case only the Crea electrodes were remembraned or replaced, the **Confirm Membrane Replacement** screen will be used.)

Press **Accept** to start the restarting sequence or press **Back** to return to the previous screen.

After the required action is completed, press **Restart** and then **Accept**.

Entering Fluid Replacements mode

The Fluid Replacements mode ensures that the proper restart sequence will follow the exit from this mode.

To enter the Fluid Replacements mode, do one of the following:

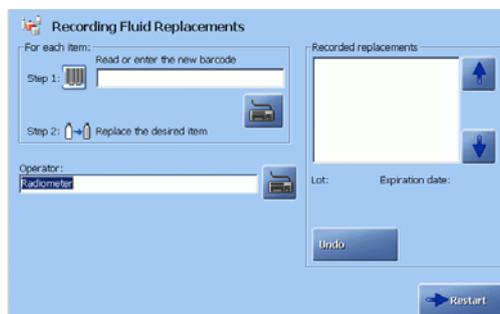
- Press **Analyzer Status – Reagents – Replace**.
- Remove a solution container

Recording replacements in the Fluid Replacements mode

To record replacements in the Fluid Replacements mode, do the following:

| Step | Action |
|------|--------|
|------|--------|

| | |
|----|---|
| 1. | Press Analyzer Status – Reagents – Replace . |
|----|---|



| | |
|----|---|
| 2. | Remove the component to be replaced according to recommended procedure. |
|----|---|

Continued on next page

General information, *Continued*

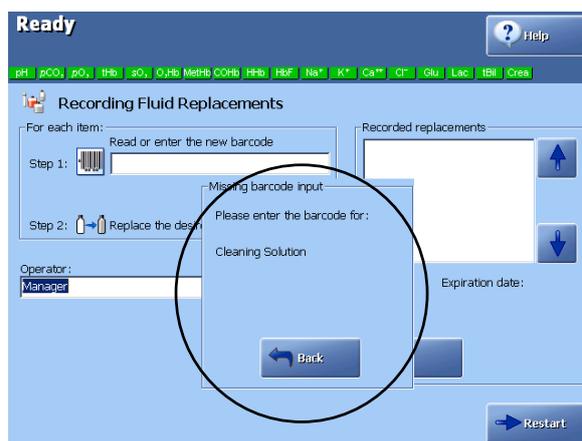
Recording replacements in the Fluid Replacements mode (*continued*)

| Step | Action |
|------|--|
| 3. | Scan the barcode on a new component, or press the keyboard icon in the "For each item" box, type in the barcode and confirm with Enter . The replaced items appear in the "Recorded replacements" box as soon as the code has been scanned or typed. |
| 4. | Install a new component according to recommended procedure. |
| 5. | Repeat steps 1-4 for another replacement in a similar manner. |
| 6. | To remove an item from the recorded replacements list, highlight it with the up/down arrow buttons in the box and press Undo . |

If desired, enter the operator initials and a note for the Activity Log.

Restart after replacements

Press **Restart** and then **Accept** on the **Confirm Replacement** screen.



If the barcode for the new Rinse, Calibration or Cleaning solution has not been entered, the analyzer will not restart and the pop-up window appears with the message to enter the solution barcode. Press **Back** to return to the **Recording Fluid Replacements** screen and to scan the barcode.

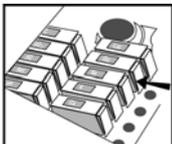
Press **Restart** and then **Accept**. The analyzer performs a restart sequence, depending on the replaced item.

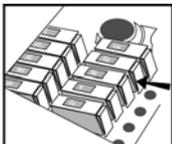
After electrode and electrode membrane replacements, calibrations are performed more frequently during the first 24 hours – see *Unscheduled Calibrations* in *chapter 6* of this manual.

Replacing membranes or electrodes

Removing an electrode from measuring chamber

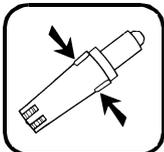
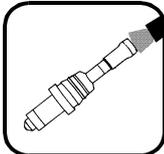
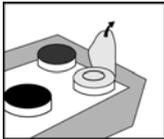
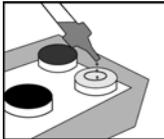
To remove an electrode from the measuring chamber, do the following:

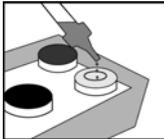
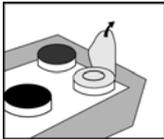
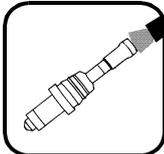
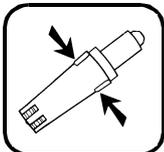
| Step | Action |
|------|---|
| 1. | Enter the Hold mode and record the replacement action. |
| 2. |  Press the electrode connector latch, and lift the electrode connector open and lift the electrode out of the measuring chamber. |



Remembraning an electrode

To remembrane an electrode, do the following:

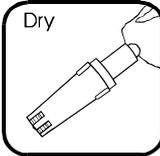
| Step | Action |
|------|---|
| 1. |  <p><u>All electrodes:</u> Remove the electrode jacket by pressing the tabs on the sides and pulling.</p> <p><u>Further for the reference electrode:</u> Remove the electrode jacket by pulling it off. If the O-ring remains on the electrode, remove it. If the electrode is stuck in its jacket due to salt crystals around the top of the jacket, soak it in water until the crystals dissolve.</p>  <p><u>Further for the pO₂ electrode:</u> Brush the electrode tip with the supplied brush.</p> |
| 2. | <p><u>All electrodes:</u> Rinse the electrode with tap water and shake to remove excess drops of water. <i>Do not dry the electrode.</i></p> <p><u>Further for cK⁺, cCl⁻, cCa²⁺, cNa⁺ and reference electrodes:</u> Remove any salt deposits, using tap water.</p> |
| 3. |  <p><u>All electrodes:</u> Remove the protective foil of a sealed electrode jacket in the membrane box.</p>  <p><u>Further for cGlu, cLac or cCrea A + cCrea B electrodes:</u> Open a capsule of the electrolyte solution supplied and empty it into the electrode jacket.</p> <p>NOTICE: Always remembrane both cCrea A and cCrea B electrodes at the same time.</p> |



Continued on next page

Replacing membranes or electrodes, *Continued*

Remembraning an electrode (*continued*)

- | Step | Action |
|------|---|
| 4. | <p><u>All electrodes:</u> Press the electrode firmly into the jacket until a click is heard.</p> <p><u>Further for the reference electrode:</u> Check that the old O-ring has been removed and press the electrode through the protective film covering the electrode jacket.</p> <p> CAUTION – Safety precautions Solution is irritating to eyes, respiratory system and skin. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.</p> |
| 5. | <p><u>All electrodes:</u> Remove the membraned electrode from the membrane box.</p> <p><u>Further for the reference electrode:</u> Rinse the electrode with tap water and dry with a lint-free tissue.</p> <p><u>Further for $p\text{CO}_2$ and $p\text{O}_2$ electrodes:</u> Remove any air bubbles trapped between the electrode tip and the membrane by pressing the tabs on the electrode jacket and moving the electrode up and down slightly in the electrolyte until the bubble disappears.</p> |
| 6. | <p> <u>All electrodes:</u> Dry the electrode contact.</p> |
| 7. | <p><u>All electrodes:</u> Place the electrode into the measuring chamber and close the electrode connector, pushing on its top until it clicks shut.</p> |
| 8. | <p>If no more replacement actions are to be made, mount all covers and parts, and press Restart.</p> |

Replacing an electrode

To replace an electrode, do the following:

- | Step | Action |
|------|---|
| 1. | <p><u>All electrodes:</u> Remove the old electrode from the measuring chamber.</p> |
| 2. | <p><u>For the new pH, $p\text{CO}_2$ and $p\text{O}_2$ electrodes only:</u></p> <p>2a. Rinse the electrode under tap water.</p> <p>2b. Shake it to remove excess drops of water. Do not dry the electrode.</p> |
| 4. | <p><u>All electrodes, except the pH electrode:</u> Membrane the electrode at once.</p> |

Continued on next page

Replacing membranes or electrodes, *Continued*

Replacing an electrode (*continued*)

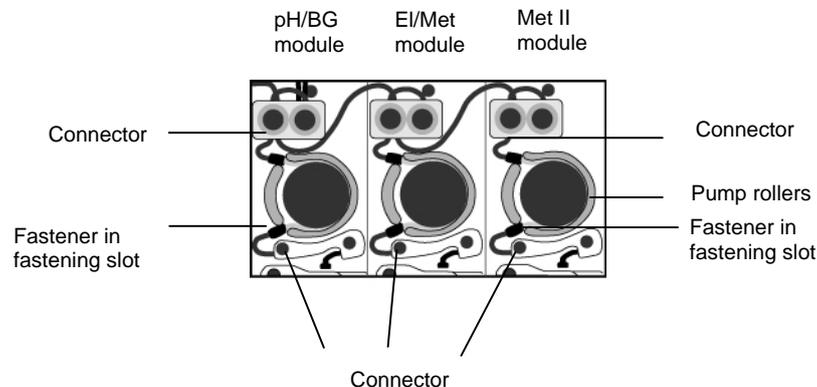
| Step | Action |
|------|--------|
|------|--------|

5. All electrodes:
Dry the electrode contact and place the new electrode in the measuring chamber.
6. If no more replacement actions are to be made, mount all covers and parts, and press ***Restart***.

Replacing pump tubes

Replacing the electrode pump tubes

The following diagram identifies the parts of the electrode module pumps to aid you in performing the replacement procedure.



To replace an electrode module pump tube, do the following:

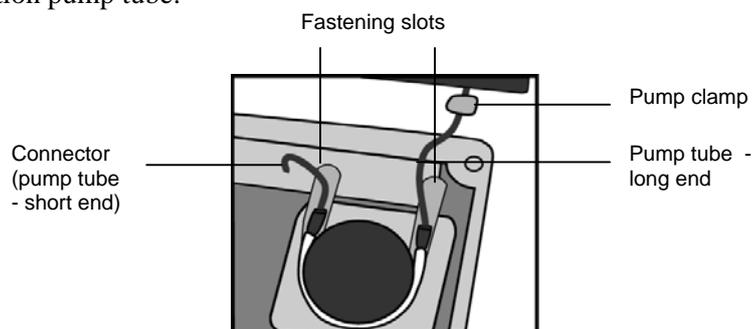
| Step | Action |
|------|---|
| 1. | Enter the Hold mode and record the replacement action. |
| 2. | Disconnect the ends of the tube from connectors. |
| 3. | Gripping one end of the tube, free the fastener from the fastening slot by pulling upward. |
| 4. | Pull upward to free the remainder of the tube from around the pump rotor and the other fastening slot. |
| 5. | Place a new pump tube around the pump rotor. |
| 6. | Secure the upper fastener of the end of the tube in the fastening slot. |
| 7. | Gripping the other fastener, wrap the tube around the pump rotor, laying the tube along the top of the rollers. Secure the fastener in the other fastening slot. |
| 8. | Press the Rotate Pumps button to turn the pump and seat the tube. This can also be done manually by turning the rotor a few rotations in the both directions. |
| | NOTICE: If seated correctly, the tube should begin to be drawn downwards onto the rollers. The tubing is correctly drawn onto the rollers by the pump rotation during restart. |
| 9. | Attach the ends of the tube to the connectors, pushing the tube onto the connector as far as possible. |
| 10. | If no more actions are to be performed, remount all covers and restart the analyzer by pressing Restart . |

Continued on next page

Replacing pump tubes, *Continued*

Replacing the solution pump tube

The solution pump tube:



To replace the solution pump tube, do the following:

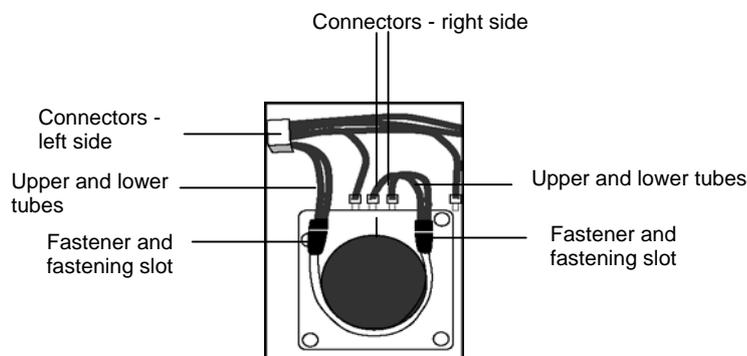
- | Step | Action |
|------|--|
| 1. | Enter the Hold mode and record the replacement action. |
| 2. | Remove the pump clamp and disconnect the ends of the old tube from the connectors. |
| 3. | Gripping the end of the tube, free the right fastener from the fastening slot by first pulling outward and then lifting upward. |
| 4. | Pull upward to free the remainder of the old tube from around the pump rotor and out of the other fastening slot. |
| 5. | Secure the fastener of the left – short – end of the new tube in the fastening slot. The short end of the tube is to be on the left, the long end on the right. |
| 6. | Gripping the longer fastener, wrap the new tube around the pump rotor, laying the tube along the top of the rollers. Secure the fastener in the other fastening slot. |
| 7. | Press the Rotate Pumps button to turn the pump and seat the tube. This can also be done manually by turning the rotor a few rotations in both directions. NOTICE: If seated correctly, the tube should begin to be drawn downwards onto the rollers by the pump rotation during restart. |
| 8. | Attach the ends of the tube to the connectors, pushing the tube onto the connector as far as possible. |
| 9. | Slide a new pump clamp (supplied with the pump tubes) over the right-side connector so that it is seated over the enlarged portion of the tube end, then clamp it shut. |
| 10. | If no more actions are to be performed, remount all covers and restart the analyzer by pressing Restart . |

Continued on next page

Replacing pump tubes, *Continued*

Replacing the waste pump tubes

When replacing the waste pump tubes, use the **yellow** tubes with black ends. These have a greater capacity than the other pump tubes, and leakage of fluid from the inlet due to a smaller capacity tube will be avoided.



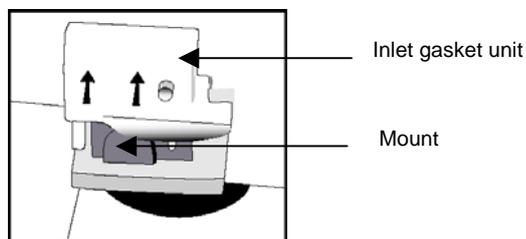
To replace the waste pump tubes, do the following:

| Step | Action |
|------|---|
| 1. | Enter the Hold mode and record the replacement action. |
| 2. | Gripping the left end of the upper tube, free the fastener from the fastening slot by first pulling outward, then lifting upward. Pull upward to free the remainder of the tube from around the pump rotor, sliding the right fastener out of the fastening slot. |
| 3. | Remove the lower tube in the same manner. |
| 4. | Take the short end of one of the new yellow tubes and place the fastener into the lower right-side fastening slot. Gripping the other fastener, wrap the tube around the pump rotor, laying the tube along the top of the rollers. Secure the fastener in the lower left-side fastening slot. |
| 5. | Press the Rotate Pumps button to turn the pumps and seat the tube. This can also be done manually by turning the rotor a few rotations in the counterclockwise direction. If seated correctly, the tube should begin to be drawn downwards onto the rollers by the pump rotation during restart. |
| 6. | Connect the right end of the new tube to one of the right-side connectors and the left end of the tube to one of the left-side connectors. Ensure that tube ends are pressed completely onto the connectors. |
| 7. | Repeat steps 4-6 with the other yellow tube except securing the tube fasteners in the upper fastening slots. |
| 8. | If no more replacement actions are to be performed, remount all covers and restart the analyzer by pressing Restart . |

Replacing inlet gasket unit and inlet probe

Replacing the inlet gasket unit

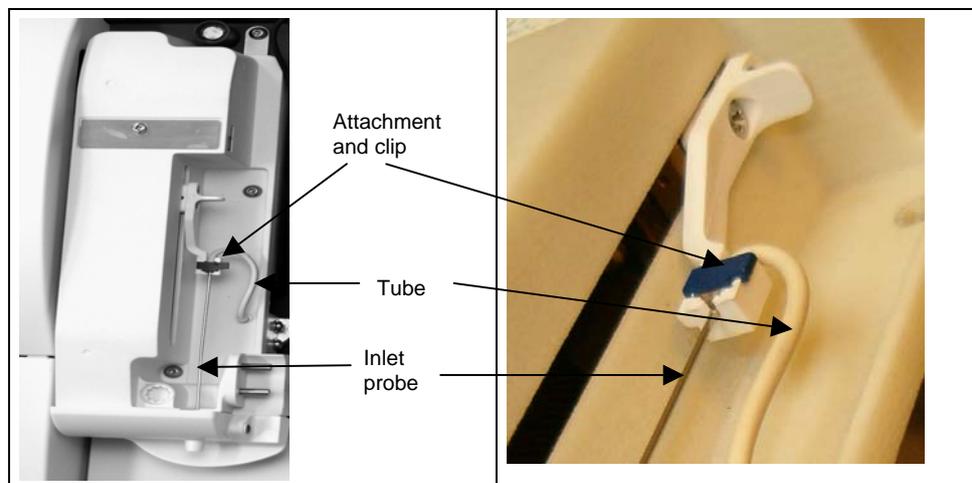
To replace the inlet gasket, do the following:



| Step | Action |
|------|--|
| 1. | Remove the capillary and then the syringe inlet flaps and record the action in the Hold mode. |
| 2. | Remove the old inlet gasket unit by grabbing it on either side and lifting it upward. |
| 3. | Slide the new inlet gasket unit onto the mount and press down the top of the unit to secure it in place. Mount the syringe inlet flap and then the capillary inlet flap. |
| 4. | Press Restart . |

Replacing the inlet probe

To replace the inlet probe, do the following:



| Step | Action |
|------|--|
| 1. | Remove the inlet flaps to enter the Hold mode. |
| 2. | Remove the gasket unit – see <i>Replacing the inlet gasket unit</i> above. |
| 3. | Lift the clip to open it. |
| 4. | Lift the inlet probe out of the attachment. |

Continued on next page

Replacing inlet gasket unit and inlet probe, *Continued*

Replacing the inlet probe (*continued*)

| Step | Action |
|------|---|
| 5. | Disconnect the tube from the inlet probe and the nipple on the inlet module. |
| 6. | Connect the new tube to the nipple on the inlet module and to the new probe. Then insert the inlet probe with the tube into the groove of the attachment and seat it properly. Close the clip. |
| 7. | Mount the inlet gasket unit and inlet flaps, then press <i>Restart</i> . |

Replacing waste container, fan filter, printer paper

Replacing the waste container

To replace the waste container, do the following:

| Step | Action |
|------|---|
| 1. | Remove the existing container by gripping its sides and pulling it off the connector. |
| 2. | Place a new waste container onto the connector with the waste label facing upwards. Use an empty rinse solution container as waste container. Prior to use, remove the rinse label to reveal the underlying waste label. |
| 3. | Close the filled waste container with a cap immediately. |

To monitor the volume of fluid in the waste container:

- look at the waste bottle in the *Analyzer Status – Reagents*.
- check the waste bottle under the analyzer's cover with the naked eye.

If the waste container is critically full, the analyzer will enter the Forced Standby mode.

If required by local authorities, a concentrated disinfectant can be added to the waste container before use or disposal. The final concentration of disinfectant in a filled container should be 20 % household bleach (1 % sodium hypochlorite), 10 % formalin (3.7 % formaldehyde) or 20 % glutaraldehyde[1].

NOTICE: Always handle a used waste container with care. Keep the waste container standing at all times in order to prevent any leaks from it.

Replacing the fan filter

If the filter is noticeably dirty, replace it to avoid unnecessary heating of the analyzer. To replace the fan filter (at the rear of the analyzer), do the following:

| Step | Action |
|------|--|
| 1. | Remove the existing filter from the fan compartment. |
| 2. | Place the new filter in position on top of the fan. |

To have this replacement recorded, replace the fan filter in the Hold mode.

Replacing the printer paper

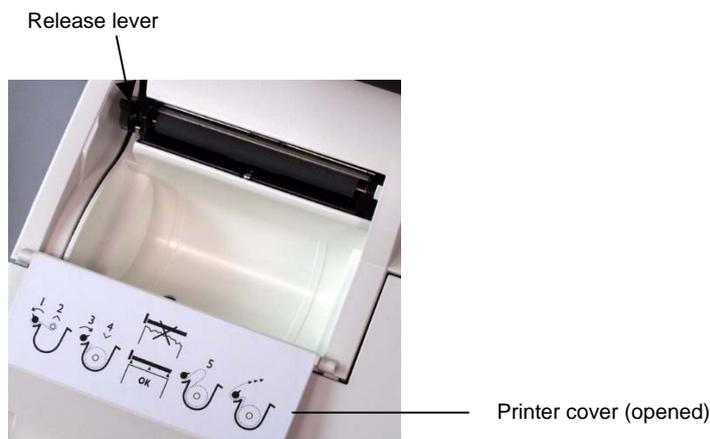
NOTICE: Avoid contact of paper with direct sunlight, water, high temperature and humidity, alcoholic and organic solvents, PVC-containing materials, freshly developed diazo copy sheets, extensive pressure and scratching. For storage, use folders and cases made of polyethylene, polypropylene, polyester, etc.

Continued on next page

Replacing waste container, fan filter, printer paper, *Continued*

Replacing the printer paper (*continued*)

To prepare the new roll, tear off and discard approximately the first 25 cm of paper and cut the leading edge of the paper straight.



To replace the printer paper, do the following:

| Step | Action |
|------|---|
| 1. | Move the release lever fully back to the nearly horizontal position. |
| 2. | Remove any leftover paper from the printer. |
| 3. | Move the release lever forward. |
| 4. | Make sure that the paper edge is cleanly cut. Place the new roll into position in the printer so that the paper unreels from underneath the roll. The thermal side of the paper is on the outside of the roll. |
| 5. | Aligning the leading edge of paper straight, feed it behind the drive roller. The paper will feed through the printer automatically once the internal sensor detects the edge of the paper. Check that alignment is satisfactory. Realign as required. |
| 6. | Close the printer cover, making sure the paper feeds out of the printer. |

To realign the paper or to remove a paper jam, do the following:

| Step | Action |
|------|--|
| 1. | Place the release lever in the down position. |
| 2. | Grip the paper edges close to the printer and gently pull the paper through the printer until alignment is satisfactory. Draw enough paper through the printer so that all damaged paper is removed. |
| 3. | Place the release lever in the upright position. |
| 4. | Close the printer cover making sure the paper feeds out of the printer through the provided slot. |

Replacing solutions and gases

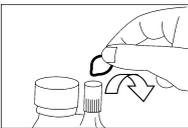
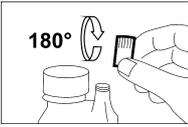
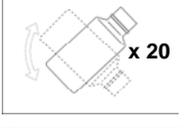
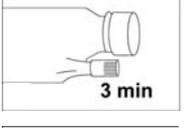
Preparing the Calibration and Cleaning Solution



CAUTION – Risk of allergic reaction

Contains streptokinase. May cause allergic reaction.

Prepare S1827 Calibration Solution 1, S1837 Calibration Solution 2 or S8375 Cleaning Solution, S8377 Cleaning Met II Solution as follows:

| Step | Action |
|------|---|
| 1. |  <p>Remove the foil from the DosiCapZip and unscrew it.</p>  |
| 2. |  <p>Turn the DosiCapZip upside down and screw it onto the container again.</p> <p>NOTICE: If the contents of the DosiCapZip or the container have been spilt by accident, both the container and the DosiCapZip should be discarded to prevent incorrect concentrations in the solution.</p>  |
| 3. |  <p>Invert the container at least 20 times to dissolve the additive.</p> |
| 4. |  <p>Place the container horizontally so that the solution may enter the DosiCapZip and leave it for 3 minutes.</p> |
| 5. |  <p>Invert the container again at least 20 times to fully dissolve the additive.</p> |
| 6. | Unscrew the lid from the new solution container. |
| 7. | Remove the used solution container by holding it on the sides and pulling. |
| 8. | Scan the barcode of the new solution, using the barcode reader. |
| 9. | Place the new solution container in position on the analyzer and push it firmly onto the connector as far as possible. |
| 10. | Press Restart and Accept to restart the analyzer. |

Continued on next page

Replacing solutions and gases, *Continued*

Replacing solutions

To replace a solution container, do the following:

- | Step | Action |
|------|--|
| 1. | Remove the solution container by gripping its sides and pulling it off the connector. The Recording Fluid Replacements screen is displayed. |
| 2. | Remove the cap from the new bottle. |
| 3. | Scan the barcode on the new solution container <i>Always scan the barcode for each new solution container to provide precise concentration of the installed solution.</i> |
| 4. |  Place the new bottle in position label upward, and push it firmly and completely onto the connector. |
| 5. | Repeat steps 1-4 for the other solutions if required. |
| 6. | <i>For ABL8x7 FLEX analyzers only:</i> Press Accept to confirm that the additive has been added and to start the proper restarting sequence or press Back to prepare the Calibration or Cleaning Solution properly. |
| 7. | Press Restart to start the proper restarting sequence. |

Replacing gas cylinders

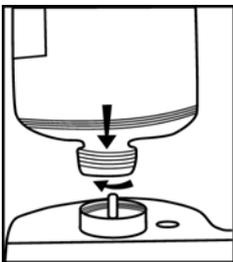
To replace a gas cylinder, do the following:

- | Step | Action |
|------|---|
| 1. | Press Analyzer Status – Reagents – Replace . The Recording Fluid Replacements screen is displayed. |
| 2. | Remove the gas cylinder by turning it counterclockwise until it becomes free.  CAUTION – Removal of safety valve Before discarding an empty cylinder remove the safety valve using the Valve Key (code number 922-509). |
| 3. | Remove the cap covering the valve on the new gas cylinder. Check that the valve is clear of any debris. |

Continued on next page

Replacing solutions and gases, *Continued*

Replacing gas cylinders (*continued*)

| Step | Action |
|------|--|
| 4. | Scan the barcode on a new gas cylinder. |
| 5. |  <p>Place the gas cylinder valve into position on the socket of the regulator. To ease alignment, use the analyzer enclosure as a guide.</p> |
| 6. | <p>The replaced items appear in the “Recorded replacements” box as soon as the code has been scanned or typed.</p> <p>To remove an item from the recorded replacements list, highlight it with the up/down arrow buttons in the box and press Undo.</p> |
| 7. | Press Restart to start the proper restarting sequence. |



CAUTION – Risk of personal injury

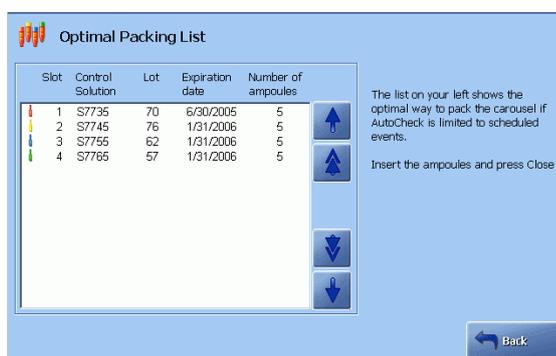
Pressurized container. Non-flammable compressed gas. Do not breathe gas. Gas mixtures containing less than 19.5 % oxygen may cause suffocation. Protect from sunlight and do not expose to temperatures exceeding 50 °C. Store and use with adequate ventilation. Keep away from oil and grease. Do not refill.

Refilling the AutoCheck carousel

Refilling AutoCheck carousel

To refill the AutoCheck carousel, do the following:

- | Step | Action |
|------|--|
| 1. | Open the retractable cover or go to the Analyzer Status screen and press AutoCheck - More - Open Module . |
| 2. | Remove the carousel. Dispose of the used ampoules as infectious waste*. |
| 3. | Fill the carousel with the control solutions according to the Optimal Packing List screen (the packing list is based on the selected quality control schedule). |



- Place the packed carousel in the module and check that it sits properly in the module.
NOTICE: Do not refill the carousel when it sits in the AutoCheck module as the analyzer will not register the action and will not scan the carousel contents.
- Close the cover either from the screen or on the module.

* **Reference:** Clinical laboratory waste management. CLSI document GP5-A2.

Messages after refilling AutoCheck carousel

After a packed carousel has been placed in the AutoCheck module and scanned, the following messages can be observed:

| Message | Explanation |
|------------------------------------|---|
| "AutoCheck Packing list confirmed" | Appears for 10 seconds in the status field if the carousel has been packed according to the list. This message can, however, be overwritten in case of an activity that updates the status field. |
| "Carousel packing not optimal" | Appears at the bottom of the status field if the carousel has not been packed according to the list. |

If, however, you have exited the screen and, for example, started a sample measurement, no message will be displayed in the status field.

Automatic auxiliary programs

Purpose The following programs might be requested:

| Program... | Is used... |
|--------------------------|---|
| Rinse | To remove traces of a sample, calibrating solution or a quality control solution from the liquid transport system. |
| Cleaning | To remove lipid deposits from the liquid transport system and the electrodes by using the Cleaning Solution. The program is followed by a rinse. To make the cleaning start automatically – see section <i>Calibration schedule</i> in <i>Calibration setup</i> in <i>chapter 3</i> for details. |
| Tubing refill | To fill the liquid transport system with solution (is performed automatically during restart after replacement of any solution container). |
| Liquid sensor adjustment | To adjust the liquid sensors in the Wet Section. |
| Pump calibration | To calibrate the rotation of the analyzer's pumps (is performed automatically during restart after replacement of the pump tubes). |

Starting a program To start one of the above programs, do the following:

- | Step | Action |
|------|--|
| 1. | Go to the Auxiliary programs menu: Menu - Start Programs - Auxiliary Programs . |



- | | |
|----|--------------------------------------|
| 2. | Press the button to start a program. |
|----|--------------------------------------|

Interrupting a program The following programs can be interrupted by pressing the **Stop** button:

- Cleaning
- Tubing refill
- Liquid sensor adjustment
- Pump calibration.

The Rinse program, once started, cannot be interrupted.

Decontamination and Protein Removal programs

Decontamination program

The Decontamination program disinfects the liquid transport system and items in direct contact with blood such as electrodes, pump tubing, etc.



CAUTION – Replacements before decontaminations

Do not perform the Decontamination Program without first replacing the *cCl⁻*, *cGlu*, *cLac*, *cCrea A* and *cCrea B* electrodes with dummy electrodes, unless the membranes are to be replaced at this time. The Hypochlorite Solution used in decontamination will damage the membranes.

It is recommended to perform Decontamination program once a month.

To perform Decontamination, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Replace the *cCl⁻*, *cGlu*, *cLac*, *cCrea A* and *cCrea B* electrodes with dummy electrodes, code 945-626.
2. Fill a syringe with 0.5 mL of S5362 Hypochlorite Solution.
3. Press **Menu – Start Programs – Auxiliary Programs – Decontamination**.
(To cancel the program at this time, press **Close**.)
4. Open the syringe inlet flap and place the syringe tip in the inlet.
5. Press **Start** to start aspiration of the solution and the program to begin.
6. Remove the syringe and close the inlet flap as prompted on the screen.
7. When the program is completed, the analyzer returns to the **Ready** screen.
8. Replace the dummy electrodes with the *cGlu*, *cLac*, *cCl⁻*, *cCrea A* and *cCrea B* electrodes.
9. Perform a 2-point calibration.

Protein Removal program

The Protein Removal program is a shorter version of the Decontamination program and is used when required to clean the pH/BG and oximetry modules, pump tubings and the inlets. Replacement of the *cGlu*, *cLac*, *cCrea* and *cCl⁻* electrodes with dummy electrodes is not required.

The Protein Removal program must be performed once a week in order to maintain the performance of the reference electrode membrane.

To perform Protein Removal, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Fill a syringe with 0.5 mL of S5362 Hypochlorite Solution.
2. Press **Menu – Start Programs – Auxiliary Programs – Protein Removal**.
(To cancel the program at this time, press **Close**.)

Continued on next page

Decontamination and Protein Removal programs, *Continued*

Protein Removal program (*continued*)

| Step | Action |
|------|--|
| 3. | Open the syringe inlet flap and place the syringe tip in the inlet. |
| 4. | Press Start to start aspiration of the solution and the program to begin. |
| 5. | Remove the syringe and close the inlet flap as prompted on the screen. |
| 6. | When the program is completed, the analyzer returns to the Ready screen. |

NOTICE: The program can be terminated at any time by pressing the **STOP** button.

Cleaning the analyzer

Introduction

The analyzer surfaces should always be kept clean of blood and/or other liquids. Immediately clean all surfaces if they become contaminated with blood or other liquids.



CAUTION – *Safety precautions*

The use of rubber gloves is recommended when cleaning the analyzer

Cleaning the measuring chambers

To clean the measuring chamber, do the following.

| Step | Action |
|------|--|
| 1. | Lift the window to the measuring modules to enter the Hold mode automatically. |
| 2. | Remove the electrode from the measuring chamber. |
| 3. | Clean the measuring chamber using a cotton swab moistened in distilled water. Check that no cotton fibers are left in the chamber. |
| 4. | Clean the electrode contact with a dry tissue if dirty or wet. |
| 5. | Remount the electrode in the measuring chamber. |
| 6. | Remount cover and press Restart to restart the analyzer. |

Cleaning the inlet flaps and inlet gasket

To clean the syringe or capillary inlet, do the following.

| Step | Action |
|------|--|
| 1. | Remove the capillary inlet flap by sliding it off to the right. |
| 2. | Remove the syringe inlet flap by sliding it to the right. |
| 3. | The analyzer is placed in the Hold mode after draining. |
| 4. | Remove the inlet gasket by pulling it vertically upwards. |
| 5. | Clean the flaps and inlet area as required. |
| 6. | Soak the inlet gasket in Deconex™ or a similar detergent. (Deconex is used in soaking baths and ultrasonic cleaning systems for cleaning laboratory utensils and precision components to remove moderate to most resilient contamination of organic nature.) |
| 7. | Slide the inlet gasket onto the inlet mount, the syringe inlet flap onto the mounting post, followed by the capillary inlet flap. Check that the inlet probe is in the correct position. |
| 8. | Ensure that both flaps are closed and press Restart to restart the analyzer. |

Continued on next page

Cleaning the analyzer, *Continued*

Cleaning the analyzer exterior When cleaning the analyzer covers and outer case, use soapy water or a mild detergent.
Do not use abrasive cleansers or pads, ethanol-based substances or aggressive detergents for cleaning.

Cleaning the analyzer touch screen Use a dry or lightly dampened soft lint-free cloth to clean the analyzer's touch screen. Wipe the screen gently to remove fingerprints and/or dirt. To avoid streaking, an approved screen cleaner is recommended.

Cleaning the FLEXQ sampler tray cover Use a tissue lightly dampened in mild soapy water.
If you wish to clean the sampler tray cover separately, do the following:

| Step | Action |
|------|---|
| 1. |  Carefully lift the empty sampler tray cover as shown. |
| 2. | Use a tissue lightly dampened in mild soapy water to clean it. |
| 3. | Remount the sampler tray cover |



Disinfection of outer surfaces Disinfection of outer surfaces is performed when appropriate. Disinfection frequency depends on local requirements and the use of the analyzer.
Prior to disinfection always ensure that that analyzer surfaces are clean and without residues from blood and/or liquids.



CAUTION – Safety precautions

Follow legal and local rules for safe work practices with chemicals.

Use the following disinfectants:

- 70 % isopropyl alcohol
- 70 % ethanol
- 4 % Diversol BX

Wipe the outer surfaces of the analyzer and the touch screen, using disinfectant on a paper towel or tissue.

List of references

1. Protection of laboratory workers from occupationally acquired infections; Approved Guideline – Second edition. CLSI (former NCCLS) document M29-A2. Wayne, Pa: CLSI (former NCCLS), 2001.

8. Disk Functions

Overview

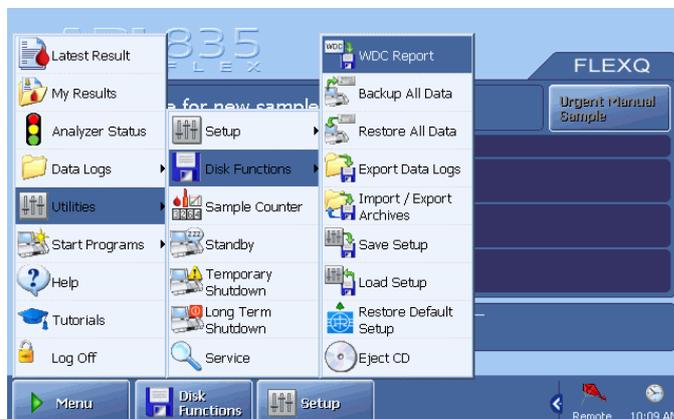
Introduction This chapter describes the disk functions available on your analyzer. The Disk Functions programs are a data management tool for storing and retrieving data logs, analyzer setup configurations, and other data and system files.

Contents This chapter contains the following topics.

| | |
|------------------------------------|------|
| General information | 8-2 |
| Creating a WDC report | 8-4 |
| Backing up all data..... | 8-6 |
| Restoring all data | 8-8 |
| Exporting data logs | 8-9 |
| Importing/exporting archives | 8-11 |
| Saving setup | 8-13 |
| Loading/restoring setup..... | 8-14 |

General information

Disk Functions programs Press the following buttons to access the Disk Functions programs: **Menu - Utilities - Disk Functions**.



The following programs are available by pressing a corresponding button:

| Button | Function |
|-------------------------------|---|
| WDC Report | To make a Worldwide DATACHECK report. |
| Backup All Data | To make a backup of all data. Data is stored as a backup on a designated location. |
| Restore All Data | To restore a backup of all data files to the analyzer hard drive from a designated location. |
| Export Data Logs | To export selected records from selected data logs. |
| Import/Export Archives | To export or delete archived data logs. To import externally archived data logs. |
| Save Setup | To save the current setup of your analyzer. |
| Load Setup | To load a previously saved setup. |
| Restore Default Setup | To restore all or only some Radiometer default settings. |
| Eject CD | To eject a CD from the CD-drive. Similar buttons will be on the Source and Destination screens. |

Continued on next page

General information, *Continued*

- Definitions** **Setup data** refers to information or files that configure the analyzer to operate according to settings entered through the Setup programs.
- All data** refers to data contained in the analyzer's internal database, including but not limited to data logs, setup and system files.
- Data storage options** Information is stored on or retrieved from an internal hard disk, a network, CD-RW, CD-R/RW or a removable drive (USB mass storage device).
- Disk handling rules** The CD-RW, CD-R/RW and a removable drive (USB mass storage device) should be handled according to the instructions printed on the packaging.

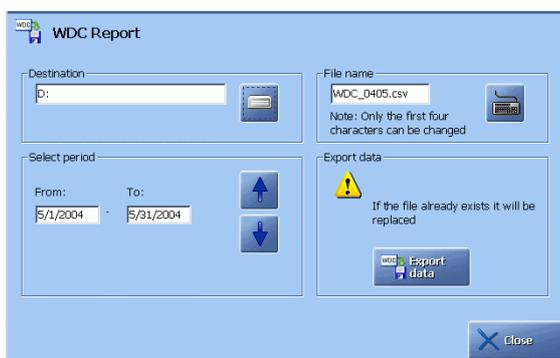
Creating a WDC report

Purpose This function allows you to make a Worldwide DATACHECK (WDC) file for reporting monthly quality control data.

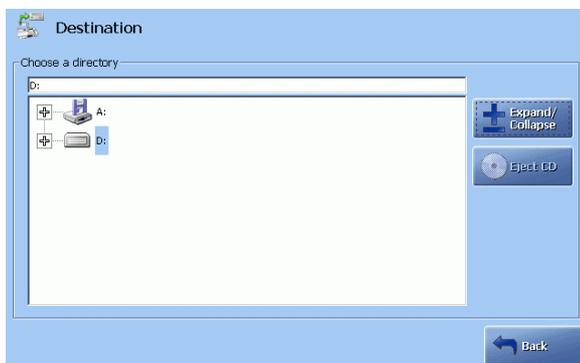
For information regarding Worldwide DATACHECK reporting, refer to the *Worldwide DATACHECK Manual*.

Storing a WDC report To make a WDC report, do the following:

- | Step | Action |
|------|--|
| 1. | Select the desired month in the "Select period" box, using the up/down arrows. |



2. Select destination by pressing the destination icon .



Highlight the desired destination (removable or CD-RW drive, or another directory) by touching it on the screen.

Use the *Expand/Collapse* button to choose a source directory/drive.

Press the *Back* button to return to the previous screen.

Continued on next page

Creating a WDC report, *Continued*

Storing a WDC report (*continued*)

| Step | Action |
|------|---|
| 3. | In the "File name box (the WDC Report screen), press the keyboard icon to type the file name. You can change the four characters "WDC_". Confirm the entry on the keyboard and return to the WDC Report screen. |
| 4. | Send the file to the selected destination by pressing <i>Export data</i> . Or insert a disk and press <i>Export data</i> in the "Export data" box. Wait until the WDC Report screen appears and remove the disk with the WDC report. |

Error messages The following error messages may appear in the analyzer status:

| | |
|---|--|
| "Could not create output file" | if the wrong disk type (e.g. filled or read-only) is inserted. |
| "No statistical data found. WDC data not generated" | if no data is available for the selected month. |

Backing up all data

Purpose This function is intended as a protection or security against the loss of data or system files that includes, but is not limited to, the following:

- Patient report data
- Patient profile data
- Setup data
- Quality control data (i.e. results, statistics, plots)
- Calibration results and setup (i.e. schedule)
- Activity data (i.e. replacement actions, system messages)

Manually performed backup: data can be stored on the internal hard disk, the network, CD-RW or removable drive.

Automatic backup (can be selected – see *Disk Functions Setup* in chapter 3): data can be stored on the internal hard disk or the network.

In case of data loss or similar problem, the loss can be minimized by using the backup file and the Restore All Data function.

NOTICE: It is the user's responsibility to ensure that all valuable data is regularly backed up. During the warranty period of the ABL800 FLEX analyzers Radiometer accepts warranty responsibility for the original storage hardware and installed software only.

Creating a backup of all data

To make a backup of all data, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Press **Change Destination** to choose the destination.



2. Select the drive/directory by touching it on the screen.
If a CD-RW is used, place it in the CD-drive.
If a removable drive is used, connect it to the USB port.

Use the **Expand/Collapse** button to choose a destination directory, then press **Back** to return to the previous screen.

Continued on next page

Backing up all data, *Continued*

Creating a backup of all data (*continued*)

| Step | Action |
|------|--|
| 3. | On the Backup All Data screen press Start to continue. (Or press Back to cancel and return to the Ready screen.) |
| 4. | The backup process begins. <ul style="list-style-type: none">• Network drive or internal hard disk drive: backup continues without any further action from the operator.• CD- or removable drive: wait for the data to be prepared (see the timer in the current task field located beside the status indicator in the upper left corner of the screen) and press Start. |
| 5. | If the analyzer status shows a “Backup done” message, the process is complete. Press Close to return to the Ready screen. |

Restoring all data

Purpose You can restore all data in case of loss or damage, provided the backup of all your data is available.

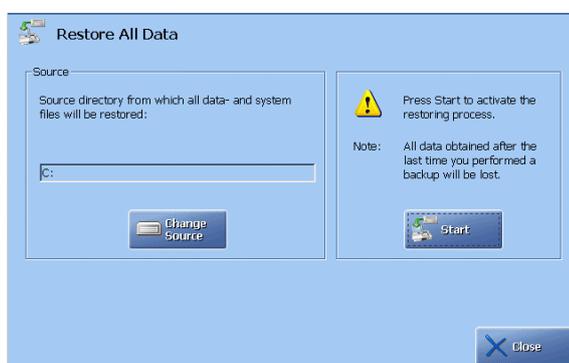
NOTICES:

- When restoring all data, any existing data will be overwritten by the data obtained from the backup files.
- When restoring all data is complete, the analyzer will automatically and without warning shut down and restart.

Restoring all data To restore a backup of data files, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Press **Change Source** to choose the source drive/directory.



2. Select the drive/directory by touching it on the screen.
If a CD-RW is used, place it in the CD-drive.
If a removable drive is used, connect it to the USB port.
Use **Expand/Collapse** to choose a source directory, then press **Back** to return to the previous screen.
3. On the **Restore All Data** screen press **Start** to continue.
(Or press **Close** to cancel and return to the **Ready** screen.)
4. The restore process begins.
 - Network drive or internal hard disk drive: restoring does not require any further action.
 - CD or removable drive: press **Start**.
5. Complete restoring all data.

When restoring is complete, the analyzer shuts down and then restarts automatically, configured to the information obtained from the backup file.

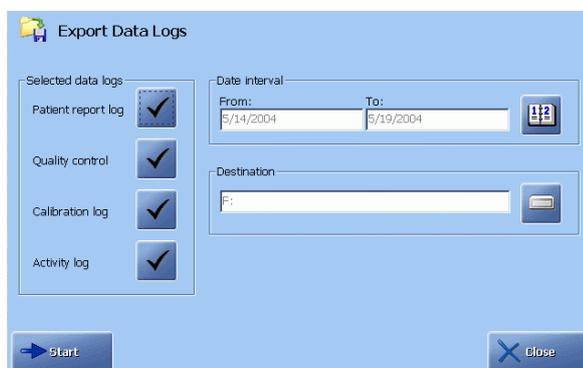
Exporting data logs

Purpose You can export data from the data logs to a CD-RW, removable disk, network. The exported files are made in a form of a compressed "comma separated value (CSV)" file which can be read using a number of standard database and spreadsheet programs, e.g. Microsoft Excel®, Access®, Lotus 123®, etc.

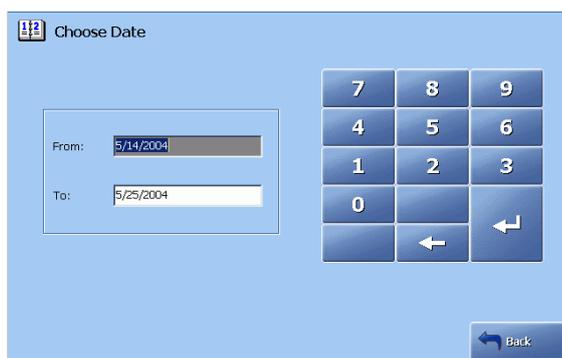
NOTICE: It is important that the disk to which data is being exported is not ejected from the disk drive during the process.

Exporting data logs To export data logs, do the following:

- | Step | Action |
|------|--|
| 1. | Activate the check buttons beside the data logs that are to be exported. |



2. Activate the calendar icon.



Type the "From:" date; confirm with **Enter**. Type the "To:" date; confirm with **Enter**.

Press **Back** to return to the **Export Data Logs** screen.

Continued on next page

Exporting data logs, *Continued*

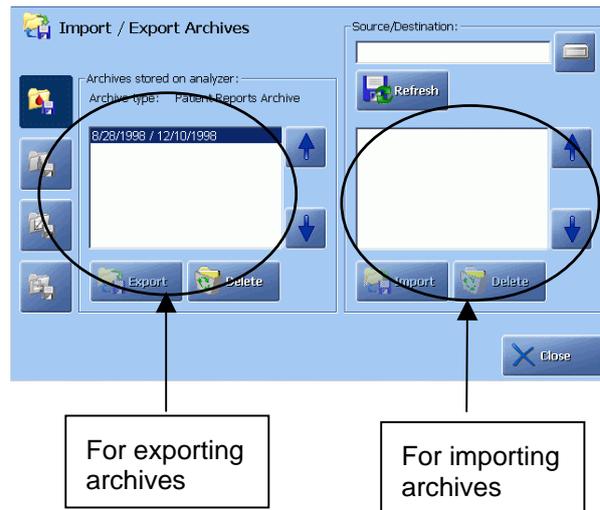
| Exporting data logs (<i>continued</i>) | Step | Action |
|--|------|--|
| | 3. | On the Export Data Logs screen press the drive icon. Activate the desired drive by touching it on the screen. Press <i>Expand/Collapse</i> to select the destination directory. Press <i>Back</i> to return to the Export Data Logs screen. |
| | 5. | On the Export Data Logs screen press <i>Start</i> to begin the export of data to the selected destination. |
| | 6. | If the dates are different for each exported data log, repeat steps 2-5 for each data log. |

Importing/exporting archives

Purpose

This function allows you to do the following:

1. To export archived data logs onto any media.
2. To delete archived data logs.
3. To import externally archived data logs into the analyzer's archive directory from any location.



For exporting archives

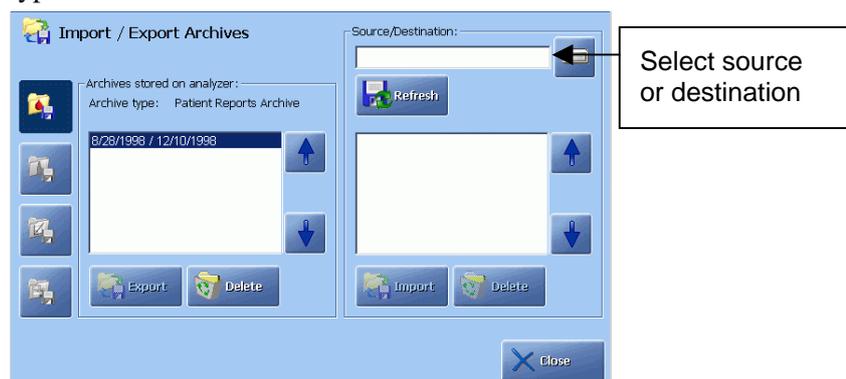
For importing archives

Exporting an archive

To export an archive, do the following:

| Step | Action |
|------|--------|
|------|--------|

- | | |
|----|---|
| 1. | Select the desired archive type by activating one of the four archive type buttons. |
|----|---|



- | | |
|----|---|
| 2. | Highlight the desired archive with the up/down arrow buttons. |
|----|---|

Continued on next page

Importing/exporting archives, *Continued*

Exporting an archive (*continued*)

| Step | Action |
|------|--|
| 3. | To export the highlighted archive, select the location by pressing the |



icon.

Touch and highlight the desired location on the **Source/Destination** screen.

To open a folder contained in a drive or within a folder, highlight the drive or folder, then press **Expand/Collapse**.

Press **Back** to return to the **Import/Export Archives** screen.

4. On the **Import/Export Archives** press the **Export** button.

Press **Refresh** to update the contents of a drive or directory.

Importing an archive

To import an archive, follow the procedure for exporting an archive, using the right-hand section of the screen and the **Import** button.

Deleting an archive

To delete an archive from a directory, use the **Delete** button.

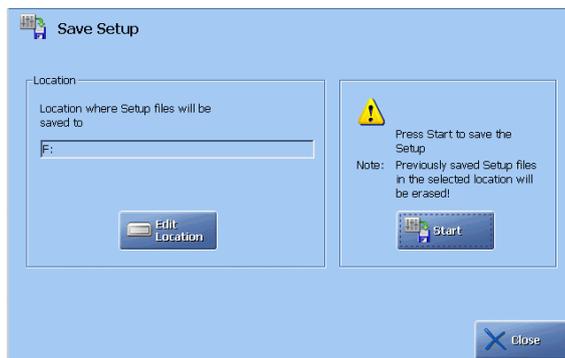
Saving setup

Purpose You can copy your analyzer's current setup configuration onto a CD-RW, removable drive, hard disk or network. It can be reloaded in the event the current setup is lost or damaged or the same setup configuration should be loaded on other analyzers without performing all the Setup programs.

Storing the setup To store the current analyzer setup, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Press **Edit Location** to select destination.



2. Select required location by touching and highlighting it on the screen. If a CD-RW is used, place a CD-RW in the CD-drive. If a removable drive is used, connect it to the USB port. Press **Expand/Collapse** to select the destination directory. Press **Back** to return to the **Save Setup** screen.
3. On the **Save Setup** screen press **Start**. When saving is complete, the **Ready** screen is displayed.
4. Remove CD-RW (use the **Eject CD** button) or removable drive.

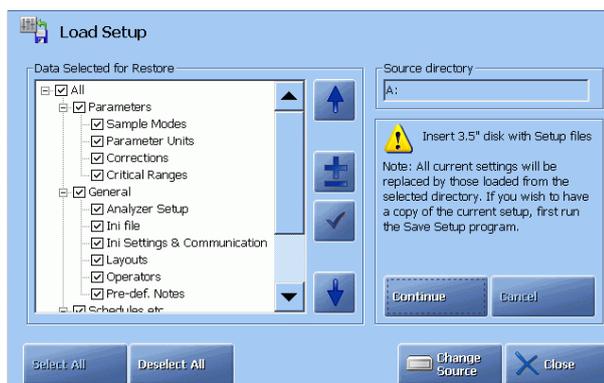
Loading/restoring setup

Purpose You can re-install a saved setup quickly and easily without performing the Setup programs. If desired, only part of the setup can be loaded, e.g. operators.

Loading a setup To load a setup, do the following:

| Step | Action |
|------|--------|
|------|--------|

- | | |
|----|---|
| 1. | Press Select All to include all items from the list on the screen. Or press Deselect All to exclude all items from the list. |
|----|---|



- | | |
|----|--|
| 2. | To select single items, do the following: <ul style="list-style-type: none"> • Highlight the desired item, using the up and down arrow buttons. • Press the check button (✓) to include an item. |
| 3. | To open or close a group of items, highlight the group title (e.g. General) and press the ± button. |
| 4. | Press the Change Source button to select the source. If a CD-RW is used, place it in the CD-drive. If a removable disk is used, connect it to the USB port. Select required source by touching and highlighting it on the screen. Press the Expand/Collapse button to access the required folder. The chosen source appears in the “Choose a directory” box. |
| 5. | Press the Back button to return to the Load Setup screen. |
| 6. | Press Continue . The analyzer will shut down and then restart with reloaded setup configuration. Pressing Cancel will terminate loading the setup. |

Contents of Setup settings

See *chapter 15: Radiometer settings* in this manual.

9. Data management

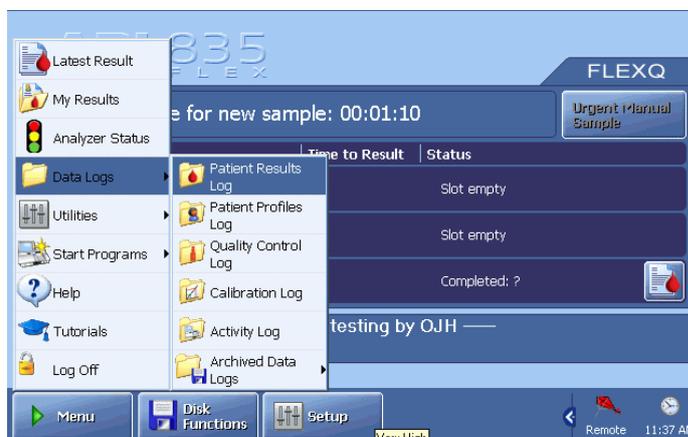
Overview

Introduction This chapter describes the functions of the Patient Results log, Patient Profile log, Quality Control log, Calibration log and Activity log. It also describes the archiving of data logs and the optional feature: RADIANCE browser.

| | | |
|-----------------|---|------|
| Contents | This chapter contains the following topics. | |
| | General information | 9-2 |
| | Patient Results Log | 9-4 |
| | Patient Profiles Log..... | 9-7 |
| | Quality Control Log | 9-11 |
| | Calibration Log | 9-17 |
| | Activity Log | 9-20 |
| | Replacement Log | 9-23 |
| | Archived Data Logs | 9-24 |
| | RADIANCE Browser (optional)..... | 9-26 |

General information

Access to data logs To access Data Logs, press *Menu - Data Logs*.



The following data logs are available:

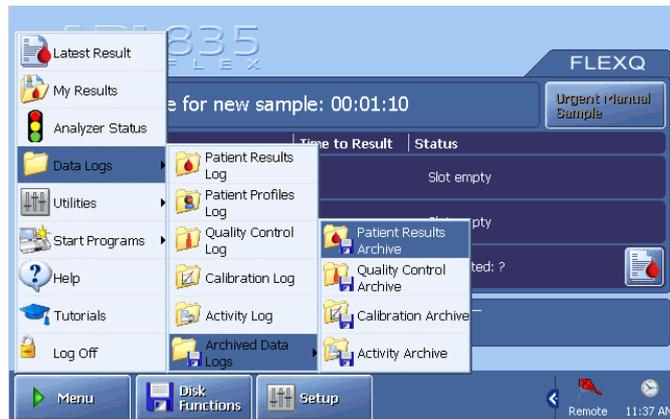
| Log | Description |
|----------------------|--|
| Patient Results Log | Contains up to 2000 patient reports from which you can view patient report, edit Patient ID, print and/or send patient report, search for a patient report, and make a parameter trend for the selected patient reports. |
| Patient Profiles Log | Provides a list of patient profiles containing general information about patients, from which you can find and view patient profiles, add, edit or remove a patient profile. |
| Quality Control Log | Contains up to 1500 quality control results from which you can view a quality control result, view statistics and plots of results, print and/or send result, search for a particular result, and make a parameter trend for the selected quality control results. |
| Calibration Log | Contains up to 1000 calibration results from which you can find and view result, make a parameter trend for the selected calibrations, print and/or send result. |
| Activity Log | Contains up to 5000 records of all measurements, replacements, system messages and operator messages. From the log, you can search an activity, add an operator message, print and/or send records. |

Continued on next page

General information, *Continued*

Archived data logs To keep the database clean and responsive, data can be archived into respective archived data logs.

If a need to examine the old archived data should arise, the archived data can be reloaded.



Press **Menu - Data Logs - Archived Data Logs** to access the archived Patient Results Log, Quality Control Log, Calibration Log and Activity Log.

Patient Results Log

Purpose The Patient Results Log is a historical file of patient reports automatically saved in the Patient Results Log after a measurement.

| Time | Sample # | Sample type | Status | Patient Id | Last Name |
|--------------------|----------|---------------|-------------|------------|-----------|
| 5/18/2004 03:04 PM | 31 | Not specified | Interrupted | | |
| 5/18/2004 02:33 PM | 30 | Venous | ? | 7020150304 | White |
| 5/18/2004 01:43 PM | 29 | Not specified | ? | 7020150304 | White |
| 5/18/2004 01:40 PM | 28 | Capillary | ? | 7020150304 | White |
| 5/18/2004 01:35 PM | 27 | Not specified | ? | 7200130504 | Patrick |
| 5/18/2004 01:30 PM | 26 | Not specified | ? | 7200130504 | Patrick |
| 5/18/2004 12:59 PM | 25 | Expired Air | ? | 5010100404 | White |
| 5/18/2004 12:55 PM | 24 | Not specified | ? | 7020150304 | White |
| 5/18/2004 12:51 PM | 23 | Not specified | ? | 7020150304 | White |
| 5/18/2004 12:48 PM | 22 | Not specified | ? | 7410260204 | Green |
| 5/18/2004 12:44 PM | 21 | Not specified | ? | 5010120304 | Black |
| 5/18/2004 12:42 PM | 20 | Not specified | ? | 7020150304 | White |
| 5/18/2004 12:37 PM | 19 | Not specified | ? | 7020150304 | White |
| 5/18/2004 12:34 PM | 18 | Not specified | ? | 7410260204 | Green |
| 5/18/2004 11:52 AM | 17 | Not specified | ? | 7020150304 | White |

Each patient report contained in the log is listed as an individual record. The reports are listed chronologically, the latest report being at the top of the screen.

Each report is identified as follows:

| Item | Description |
|-------------|---|
| Sample # | Indicates the number of the sample. |
| Time | Date and time sample measurement was performed. |
| Sample type | Shows the type of blood sample specified in Patient ID. |
| Status | Indicates the status of the sample measurement: <ul style="list-style-type: none"> OK a successful measurement ? an error detected or a parameter exceeded the reportable range Interrupted a measurement stopped by the operator Aborted a measurement stopped by the analyzer most likely due to insufficient sample. |
| Patient ID | Patient identification number, up to 20 characters. |
| Last Name | Patient's last name, up to 50 characters. |

NOTICE: The columns displayed in the log and their positions can be changed. Contact a qualified service technician.

Continued on next page

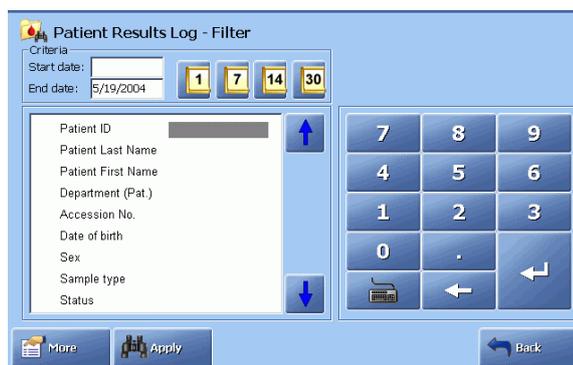
Patient Results Log, *Continued*

Button functions The following functions are available by activating a button:

| Button | Function |
|-------------------------------|---|
| Result | Displays the highlighted patient report – see <i>chapter 4: Sample measurements</i> for the detailed information. |
| Filter | Sets conditions for finding a patient report or for trend function – see below. |
| Close | Returns to the Ready screen. |
| Trend and Print | Are inactive until the filter criteria are chosen and applied. |

Filter function To set the filter criteria in order to find a patient report or to select a number of patient reports, do the following:

- | Step | Action |
|------|--|
| 1. | Set the start date by using the 1-day, 7-day, 14-day or 30-day icons in the “Criteria” box. Or type in the date, using the keypad and confirming the entry with Enter . |



- Change if necessary the end date by highlighting it and typing date other than the current date. Confirm with **Enter**.
- Use the arrow buttons to highlight the desired search criteria. Press **More** to display more filter criteria.
Note that the right side of the screen changes to show choices for the highlighted search criterion.
- Select the desired choice and confirm each entry with **Enter**. Or use the keyboard to enter the desired data and confirm each entry with **Enter**.
- When all the criteria have been selected, press **Apply** to start the search.

Continued on next page

Patient Results Log, *Continued*

Trend function To make a parameter trend for the selected patient reports, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Set up search criteria as described under *Filter function* and apply them. The screen of the selected patient reports will be displayed.

| Time | Sample # | Sample type | Status | Patient Id | Last Name |
|--------------------|----------|---------------|-------------|------------|-----------|
| 5/18/2004 03:04 PM | 31 | Not specified | Interrupted | | |
| 5/18/2004 01:43 PM | 29 | Not specified | ? | 7020150304 | White |
| 5/18/2004 01:35 PM | 27 | Not specified | ? | 7200130504 | Patrick |
| 5/18/2004 01:30 PM | 26 | Not specified | ? | 7200130504 | Patrick |
| 5/18/2004 12:55 PM | 24 | Not specified | ? | 7020150304 | White |
| 5/18/2004 12:51 PM | 23 | Not specified | ? | 7020150304 | White |
| 5/18/2004 12:48 PM | 22 | Not specified | ? | 7410260204 | Green |
| 5/18/2004 12:44 PM | 21 | Not specified | ? | 5010120304 | Black |
| 5/18/2004 12:42 PM | 20 | Not specified | ? | 7020150304 | White |
| 5/18/2004 12:37 PM | 19 | Not specified | ? | 7020150304 | White |
| 5/18/2004 12:34 PM | 18 | Not specified | ? | 7410260204 | Green |
| 5/18/2004 11:52 AM | 17 | Not specified | ? | 7020150304 | White |
| 5/18/2004 11:36 AM | 16 | Not specified | OK | 7020150304 | White |
| 5/18/2004 11:32 AM | 15 | Not specified | OK | 7410260204 | Green |
| 5/18/2004 11:28 AM | 14 | Not specified | OK | 7410260204 | Green |

The **Trend** and **Print** buttons are now active.

2. Press **Trend** to select the parameter(s).
3. Press **View Trend** to display the trend of the selected parameter(s) for the selected patient reports.
4. To view the selected filter criteria, press **View Filter**.

The criteria can only be viewed, not changed.

To apply new criteria, repeat the Filter function procedure described in this topic and the procedure for the Trend function.

5. Press **Back** to return to the previous screen.

Patient Profiles Log

About a patient profile A patient profile is a record containing general information about a particular patient. It is created automatically whenever a new patient ID number is entered **during measurement** and recorded in the Patient Profiles log. Alternatively, a patient profile can be added to the log.

The given patient data recorded in a patient profile will be automatically used as soon as patient ID number is entered on the **Patient Identification** screen during a measurement.

NOTICE: If the analyzer is set up to request data from a LIS/HIS or the RADIANCE system, this patient information will always override that from the Patient Profiles log.

Patient Profiles log The patient profiles are listed in the order they were created.



The following data can be entered in a patient profile (use the left/right scroll bar to see the items):

| Item | Description |
|-------------------|--|
| Patient ID | Lists the patient ID number |
| Last Name | Provides the patient's surname. |
| First Name | Provides the patient's first name. |
| Sex | Identifies the patient's sex. |
| Date of birth | Identifies the patient's date of birth. |
| Department (Pat.) | Identifies the department in which the patient is located. |
| Patient note | Lists a note regarding the patient. |
| Birth weight | Gives the weight at birth. |
| Gestational age | Gives the duration of pregnancy. |

The functions available on the **Patient Profiles** screen are described in this section.

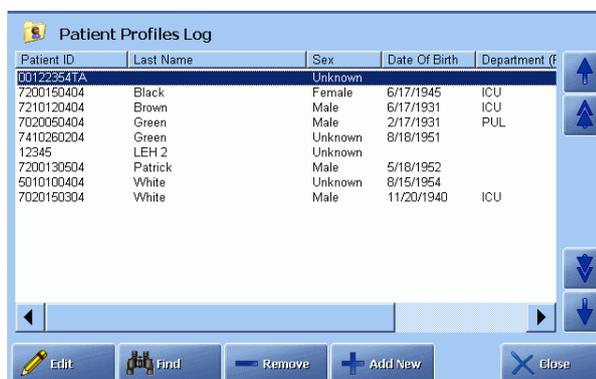
Continued on next page

Patient Profiles Log, *Continued*

Editing a patient profile To edit a patient profile, do the following:

Step Action

1. Highlight the patient profile and press **Edit**.



2. Use a barcode reader to scan the patient data supported by the barcode (the "Enable General Barcode Support" should be activated in the Miscellaneous Setup) – see the procedure in *Entering information with barcode reader* in chapter 4, section *Patient identification*.
Or request (if connected) the data from LIS/HIS by verifying the patient ID and pressing the **Request** button.
3. To edit data on the screen, highlight an item, using the arrow buttons, and type in the data, using the screen keyboard or keypad. Confirm each entry with **Enter**.



4. When completed, press **Back** to return to the previous screen.

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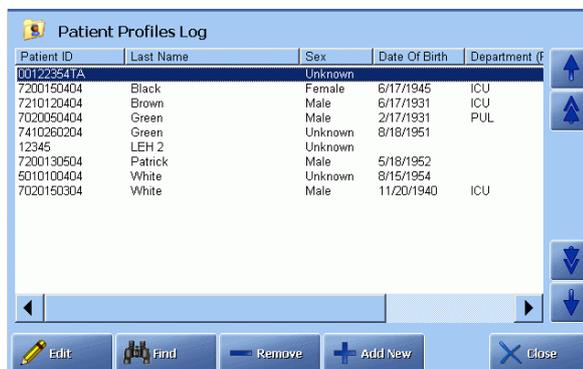
Patient Profiles Log, *Continued*

Adding a new patient profile

To add a new patient profile, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Press **Add New** to display the screen below.



2. Use a barcode reader to scan the patient data supported by the barcode (the "Enable General Barcode Support" should be activated in the Miscellaneous Setup) – see the procedure in *Entering information with barcode reader* in chapter 4, section *Patient identification*.
Or request (if connected) the data from LIS/HIS by verifying the patient ID and pressing the **Request** button.
3. To edit data on the screen, highlight an item, using the arrow buttons and type in the data, using the screen keypad or keypad.
Confirm each entry with **Enter**.
4. When completed, press **Back** to return to the previous screen.

Deleting a patient profile

To delete a patient profile from the log, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Highlight the desired patient profile.
2. Press **Remove**.

Continued on next page

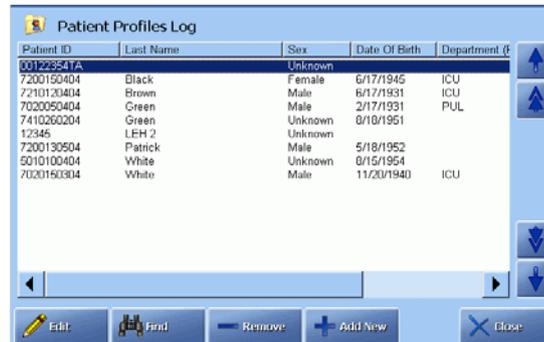
Patient Profiles Log, *Continued*

Finding a patient profile

To find a patient profile, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Press **Find** on the screen.



2. Using the arrow buttons, highlight the search criterion and enter the data using the screen keypad or keyboard.

Or use a barcode reader to scan the Patient ID barcode.

3. Press **Find**.

If a patient profile is found, it will be highlighted on the **Patient Profile Log** screen.

If a patient profile is not found, "No item found that matches search criteria" message appears in analyzer status. Repeat step 2 or press **Back** to cancel.

Quality Control Log

Purpose

The Quality Control Log is a historical file of all quality control results automatically saved in the Quality Control Log after a measurement.

Each quality control result is listed chronologically as an individual record.

Each result is identified as follows (use the left/right scroll bar to see the items):

| Item | Description |
|----------|---|
| Time | Date and time the measurement was performed. |
| QC# | The ID number of a quality control measurement. |
| Slot | Control solution slot as defined in setup. |
| Solution | Control solution type as defined in setup. |
| Lot | Lot number of the control solution. |
| Status | Indicates the status of the quality control measurement: <ul style="list-style-type: none"> OK a successful measurement ? an error detected or a measured value exceeded a control, statistical or measuring range. Interrupted a measurement stopped by the operator Aborted a measurement stopped by the analyzer most likely due to insufficient sample. |

NOTICE: The columns displayed in the log and their positions can be changed. Contact a qualified service technician.

The functions of the buttons available on the **Quality Control Log** screen are described in this section.

Continued on next page

Quality Control Log, *Continued*

Viewing a result To view a result, do the following:

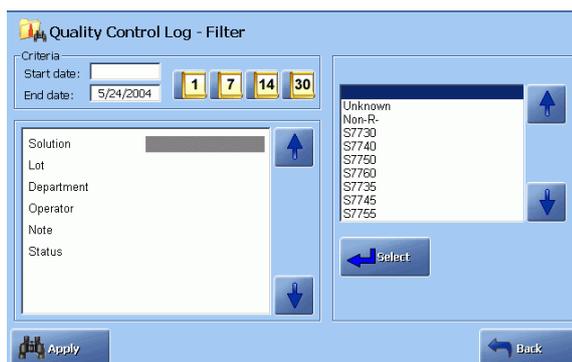
- | Step | Action |
|------|---|
| 1. | Highlight the desired quality control result using scroll facilities. |
| 2. | Press the Result button. For details – see <i>Quality Control Result</i> in chapter 5. |

Filter/trend function

This function allows you to find a quality control result or to select a number of results in order to make a trend.

To set the filter criteria, do the following:

- | Step | Action |
|------|---|
| 1. | Press the Filter button on the Quality Control Log screen. |
| 2. | Set the start date by using the 1-day, 7-day, 14-day or 30-day icons in the “Criteria” box. |



Or type in the date using the keypad and confirming the entry with **Enter**.

Change if necessary the end date by highlighting it and typing a date other than the current date. Confirm with **Enter**.

- | | |
|----|---|
| 3. | Use the up and down arrow buttons to highlight the desired search criteria. |
| 4. | Select the desired choice and confirm each entry with Enter . |

Or use the keyboard to enter the desired data and confirm each entry with **Enter**.

Continued on next page

Quality Control Log, *Continued*

Filter/trend function (*continued*)

- | Step | Action |
|------|--|
| 5. | When all the criteria have been selected, press Apply to make the search. Press Trend to select the parameters. |
| 6. | Select the desired parameter(s) by activating the check buttons (e.g. pH, pCO_2 , pO_2). Press View Trend . |
| 7. | The trend of the selected parameter(s) is displayed. To view the filter criteria, press the View Filter (the criteria cannot be changed, only viewed). To print the displayed trend, press Print . To return to the screen in step 5, press Back . |

Viewing quality control statistics Only those measurement values that fall within the statistical range are included in the statistical data. Therefore parameters outside the measuring range or with a "?" are not included.

| Slot | Solution | Lot | N | Mean | 2SD | CV | Control range |
|------|----------|-----|---|-------|-------|-------|---------------|
| 1 | S7735 | 70 | 2 | 7.105 | 0.005 | 0.033 | 7.076 7.116 |
| 2 | S7745 | 76 | 1 | 7.400 | 0.000 | 0.000 | 7.370 7.410 |
| 3 | S7755 | 62 | 1 | 7.584 | 0.000 | 0.000 | 7.555 7.599 |
| 4 | S7765 | 57 | 0 | 0.000 | 0.000 | 0.000 | 6.811 6.841 |
| 5 | | | | | | | |
| 6 | S7740 | 37 | 4 | 7.406 | 0.008 | 0.055 | 7.371 7.411 |
| 7 | S7750 | 37 | 4 | 7.589 | 0.006 | 0.042 | 7.557 7.601 |
| 8 | S7760 | 28 | 0 | 0.000 | 0.000 | 0.000 | 6.809 6.839 |
| 9 | | | | | | | |
| 10 | | | | | | | |

- The screen shows statistics for each control solution (identified by its slot, type and lot number) for a single parameter.
Press **Next param..** or **Prev. param..** to view other parameters.
- Press **WDC Report** to create a WDC Report – see *Creating a WDC Report* in *chapter 8*.

Continued on next page

Quality Control Log, *Continued*

Viewing quality control statistics (continued) **Month-to-date** statistics are obtained from all measurements taken on the current lot of a control solution over the course of the month – see *QC Statistics in Quality control setup* in *chapter 3* for information.

Lot-to-date statistics are obtained from all measurements taken over the entire course of the current lot of the control solution.

The **Month-to-date** and **Lot-to-date** statistics give the following information:

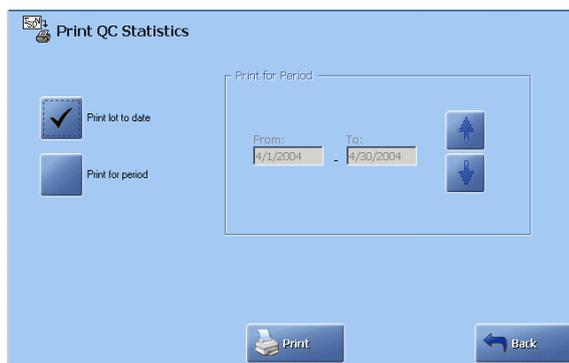
| Item | Description |
|---------------|--|
| N | Number of measurements included in statistics for the slot. |
| Mean | Calculated mean of the measurement values*. |
| 2 SD | Calculated $2 \times$ standard deviation of measurement values*. |
| CV | Coefficient of variation*. |
| Control Range | Current control range for the control solution level. |

* See *Quality Control Systems Reference Manual* for detailed information.

Printing QC statistics

To print QC statistics, do the following:

- | Step | Action |
|------|---|
| 1. | Press Print on the Quality Control Statistics screen. |
| 2. | To print QC statistics for an entire lot, activate Print lot to date button and press Print . |

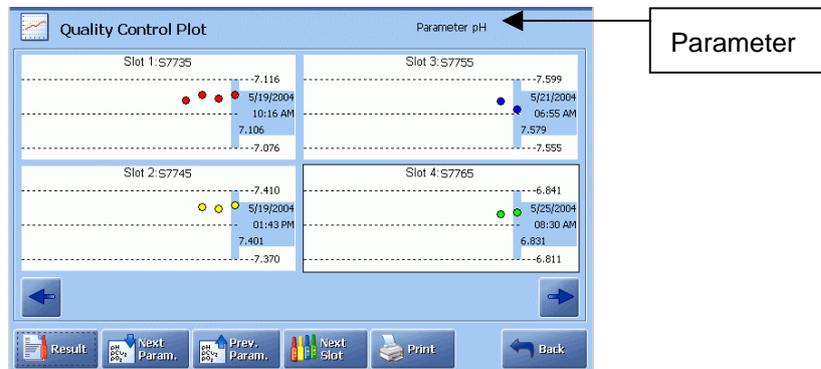


- | | |
|----|--|
| 3. | To print monthly QC statistics, activate Print for period . Select the month, using up and down buttons. Then press Print . |
| 4. | Press Back to return to the Quality Control Statistics screen. |

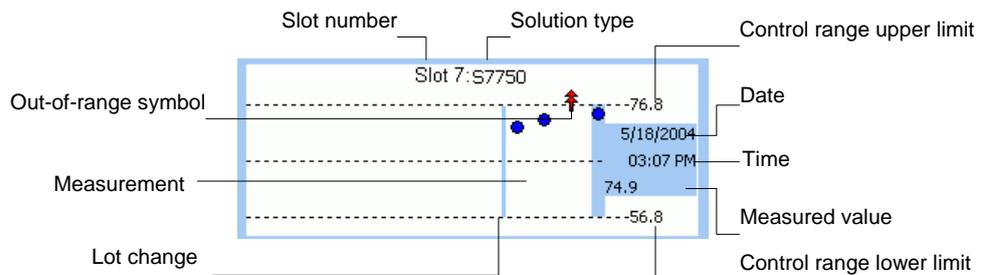
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Quality Control Log, *Continued*

Quality control plot To view the **Quality Control Plot** screen press **Plot** on the **Quality Control Log** screen.



The following diagram shows the details of a typical plot.



| Plot element | Function |
|----------------------|--|
| Shaded block | Date, time and measured value for the highlighted measurement. Use the arrow buttons to scroll the plot and view other measurements. |
| Control range limits | Show the upper and the lower limits of the control range for the highlighted measurement. |
| Dots | Show the number of measurements for the selected parameter. To view a measurement result, highlight a dot on the screen and press Result . |
| Out-of-range symbols | <p>↑ ↓ Measurement outside the control range and inside the statistical range.</p> <p>↑↑ ↓↓ Measurement outside both the control and statistical ranges.</p> |

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Quality Control Log, *Continued*

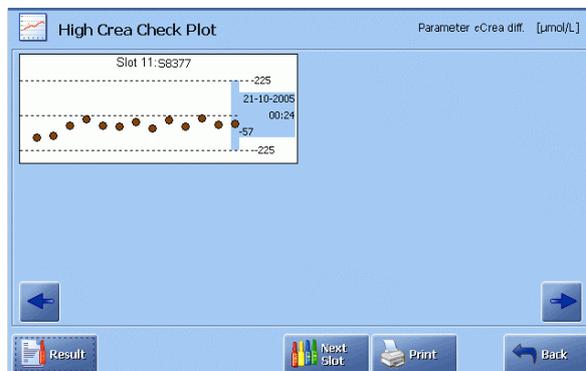
Quality control plot (*continued*)

Use the following buttons to do the following:

- Next Param.*** Display the quality control plots for the requested parameter.
- Prev. Param.***
- Next Slot*** Display plots of the next control solution slot.
- Result*** View quality control result for the highlighted measurement of the highlighted plot.
- Print*** Print out the plot.
- Back*** Return to the previous screen.

(For the ABL8x7 FLEX analyzers only):

The plot for the High Crea Check of the ABL8x7 FLEX analyzers presents Crea_{diff}.



The screen is similar to the quality control solution plot, but the ***Next Param.*** and ***Prev Param.*** buttons are absent.

Calibration Log

Purpose The Calibration Log is a historical file of calibrations automatically saved in the Calibration Log after a calibration.

| Time | Cal # | Type | Status |
|--------------------|-------|---------------------|-------------|
| 5/19/2004 08:00 AM | 108 | 2 point calibration | OK |
| 5/19/2004 04:00 AM | 107 | 1 point calibration | OK |
| 5/19/2004 12:14 AM | 106 | 2 point calibration | OK |
| 5/18/2004 08:00 PM | 105 | 1 point calibration | OK |
| 5/18/2004 04:00 PM | 104 | 2 point calibration | OK |
| 5/18/2004 02:46 PM | 103 | 1 point calibration | Interrupted |
| 5/18/2004 01:22 PM | 102 | 1 point calibration | OK |
| 5/18/2004 12:00 PM | 101 | 1 point calibration | OK |
| 5/18/2004 08:00 AM | 100 | 2 point calibration | OK |
| 5/18/2004 04:00 AM | 99 | 1 point calibration | OK |
| 5/18/2004 12:14 AM | 98 | 2 point calibration | OK |
| 5/17/2004 08:00 PM | 97 | 1 point calibration | OK |
| 5/17/2004 04:00 PM | 96 | 2 point calibration | OK |
| 5/17/2004 12:00 PM | 95 | 1 point calibration | OK |
| 5/17/2004 08:00 AM | 94 | 2 point calibration | OK |

Each calibration report is listed as an individual record. The reports are listed chronologically, the latest report being at the top of the screen.

Each report is identified as follows (use the left/right scroll bar to see the items):

| Item | Description |
|--------|---|
| Time | Date and time the calibration was performed. |
| Cal # | The ID number of a performed calibration. |
| Type | Indicates the calibration type: 1-point, 2-point or tHb. |
| Status | Indicates the calibration status: <ul style="list-style-type: none"> OK a successful calibration ? an error detected or a parameter exceeded the measuring range Interrupted a calibration stopped by the operator Aborted a calibration stopped by the analyzer most likely due to missing calibration solution. |

NOTICE: The columns displayed in the log and their positions can be changed. Contact a qualified service technician.

Continued on next page

Calibration Log, *Continued*

Viewing a calibration result

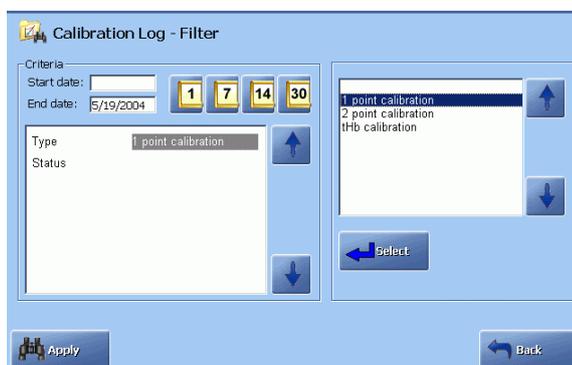
To view a calibration result, do the following:

- | Step | Action |
|------|---|
| 1. | Highlight the desired calibration. |
| 2. | Press Result – see <i>chapter 6</i> for details about calibration results. |

Filter function

This function allows you to find a calibration or to select a number of calibrations. To set the filter criteria, do the following:

- | Step | Action |
|------|---|
| 1. | Press the Filter button on the Calibration Log screen. |
| 2. | Set the start date by using the 1-day, 7-day, 14-day or 30-day icons. |



Or type in the date using the keypad and confirm with **Enter**.

Change if necessary the end date by highlighting it and typing the date other than the current date. Confirm with **Enter** or **Select**.

- | | |
|----|--|
| 3. | Select the desired calibration type and status, using the relevant arrow buttons. Confirm each entry with Enter or Select . |
| 4. | When the criteria have been selected, press Apply to start the filter. |

Continued on next page

Calibration Log, *Continued*

Trend function This function allows you to make a parameter trend for the selected calibrations. To make a trend, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Set up the search criteria as described above and apply them.

| Time | Cal # | Type | Status |
|--------------------|-------|---------------------|-------------|
| 5/19/2004 04:00 AM | 107 | 1 point calibration | OK |
| 5/18/2004 08:00 PM | 105 | 1 point calibration | OK |
| 5/18/2004 02:46 PM | 103 | 1 point calibration | Interrupted |
| 5/18/2004 01:22 PM | 102 | 1 point calibration | OK |
| 5/18/2004 12:00 PM | 101 | 1 point calibration | OK |
| 5/18/2004 04:00 AM | 99 | 1 point calibration | OK |
| 5/17/2004 09:00 PM | 97 | 1 point calibration | OK |
| 5/17/2004 12:00 PM | 95 | 1 point calibration | OK |
| 5/15/2004 12:00 PM | 92 | 1 point calibration | OK |
| 5/15/2004 07:00 AM | 90 | 1 point calibration | OK |
| 5/15/2004 06:00 AM | 89 | 1 point calibration | OK |
| 5/15/2004 05:00 AM | 88 | 1 point calibration | OK |
| 5/15/2004 03:00 AM | 86 | 1 point calibration | OK |
| 5/15/2004 02:00 AM | 85 | 1 point calibration | OK |
| 5/15/2004 01:00 AM | 84 | 1 point calibration | OK |

Press **Trend** to select a parameter.

2. Select a parameter (only one for calibrations) and press **View Trend**.
3. To view the filter criteria, press the **View Filter** (the criteria cannot be changed, only viewed).

To print the displayed trend, press **Print**.

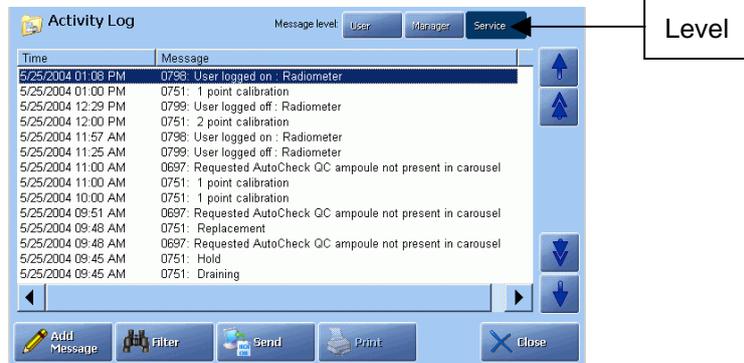
To return to the screen in step 5, press **Back**

4. To apply the new criteria, repeat the Filter function procedure described in this topic and the procedure for the Trend function.

Activity Log

Purpose

The Activity Log provides a historical record of all replacements, system messages and errors during operation. It also lists any operator messages and allows the entry of additional notes.



The records are listed chronologically and can be displayed at user, manager or service level.

The record is identified as follows (use the left/right scroll bar to see the items):

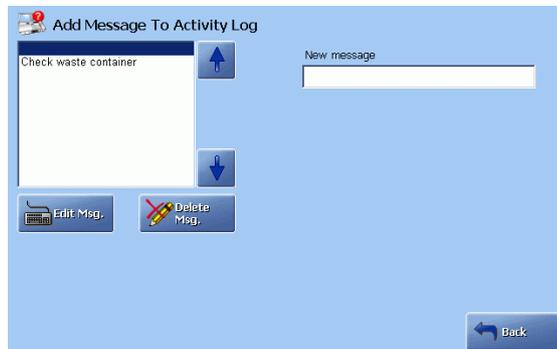
| Item | Description |
|---------|---|
| Time | Shows the date and time when the activity occurred. |
| Message | Gives a message number and an explanation of the activity. Operator note text appears as written. |

NOTICE: The columns displayed in the log and their positions can be changed. Contact a qualified service technician.

Adding a message

To add a message to the log, do the following:

- | Step | Action |
|------|---|
| 1. | Press Add Message on the Activity Log screen. |
| 2. | <u>If Notes were entered in Setup program User-defined Notes</u> (see <i>Parameters and Input setup</i> in chapter 3: <i>Installation and Setup</i>), then you can edit a highlighted message by pressing Edit Msg. to display the keyboard and make the changes. |

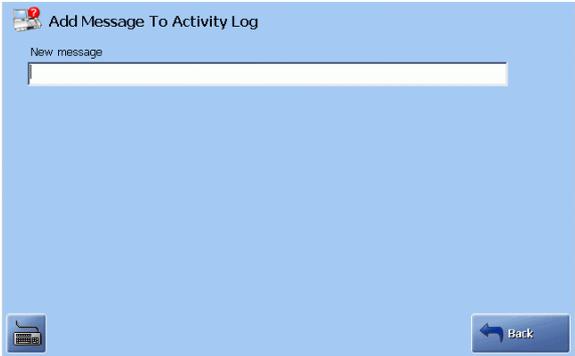


To delete a message, highlight it and press **Delete Msg.**

Continued on next page

Activity Log, Continued

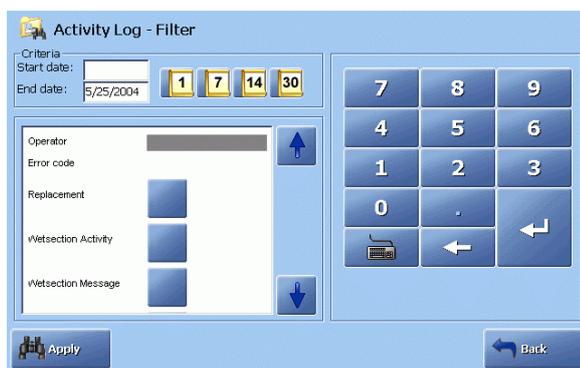
Adding a message (continued)

| Step | Action |
|---------------|--|
| 2 (cont.). | <p>If Notes were not entered in Setup program User-defined Notes</p>  <p>To key in a note, press the keyboard touch-key to display the keyboard, type a message and press Enter to confirm and return to the Activity Log screen</p> |
| 3. | Press Back to return to the Activity Log screen |

Filter function

This function allows you to find an activity or to select a number of activities. To set the filter criteria, do the following:

| Step | Action |
|------|---|
| 1. | Press the Filter button on the Activity Log screen. |
| 2. | Set the start date by using the 1-day, 7-day, 14-day or 30-day icons. |



Or type in the date using the keypad and confirm with **Enter**.

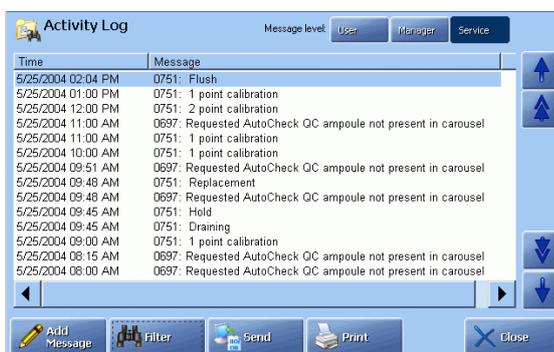
Change if necessary the end date by highlighting it and typing the date other than the current date. Confirm with **Enter**.

Continued on next page

Activity Log, *Continued*

Filter function (*continued*)

- | Step | Action |
|------|--|
| 3. | Use the arrow buttons to highlight the desired search criterion or criteria. NOTICE: If you filter the Activity Log for "Replacement" only and set the message level to Manager or Service, the "Activity Log" changes to "Replacement Log". |
| 4. | When all the criteria have been selected, press Apply to start. |
| 5. | The Activity Log displays the list of selected activities. |



By selecting the message level, you can see messages on the user, manager or service levels.

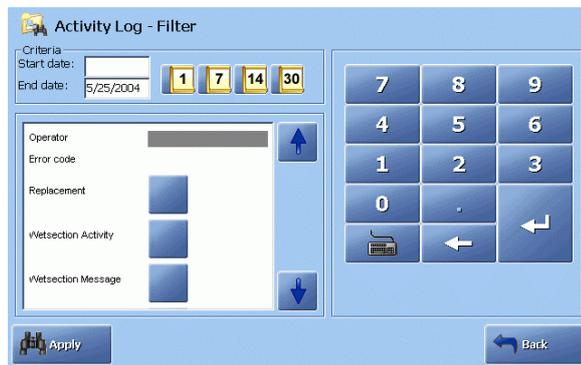
The **Add Message** button is available on all levels.

6. Press **Filter** to set other search criteria if desired.
Press **Close** to return to the **Ready** screen.

Replacement Log

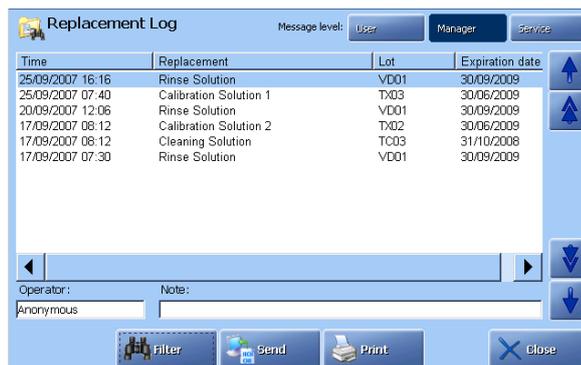
Replacement Log The Replacement Log provides a historical record of replacements only.
To get a list of all the replacements, do the following:

- | Step | Action |
|------|---|
| 1. | Enter the Activity Log screen. |
| 2. | Select the Manager or Service message level. |
| 3. | Press the Filter button. |
| 4. | Set the start date by using the 1-day, 7-day, 14-day or 30-day icons. |



Or type in the date using the keypad and confirm with **Enter**.

- Highlight the criteria **Replacement** and press **Apply**.
- The Replacement Log appears with all the replacements and an Operator and Note field.



- Press **Close** to return to the **Ready** screen.

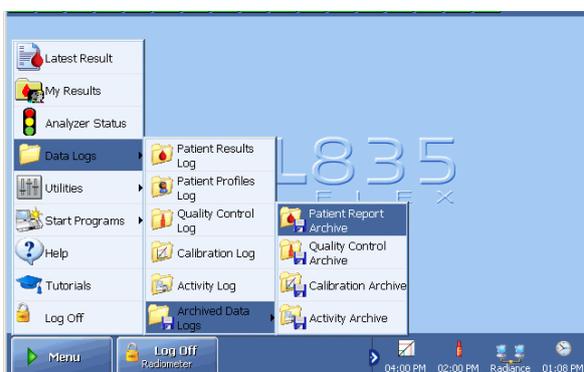
Archived data logs

Purpose You can view the old patient reports, quality control results, calibration results and activities which have been archived automatically when maximum log size (2000 patient reports, 1500 quality control results, 1000 calibration results, and 5000 activity log entries) has been reached.

The archives are located on the analyzer's hard disk and can be exported to a CD-RW, removable disk, network, etc. – see *Importing/exporting archives* in *chapter 8: Disk functions*.

The archives are archived after date: 500 reports from each log, and 2000 entries from the Activity log.

Press **Menu - Data Logs - Archived Data Logs** and select the log archives.

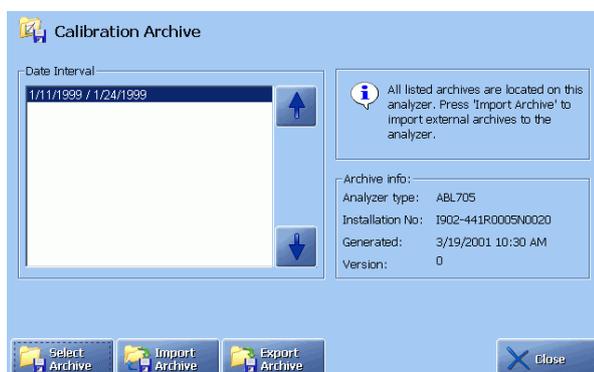


Press the button on the screen to select the log archives. As the functions are similar for all archives, the Calibration Archive is used as an example.

Selecting archive stored on the analyzer

To select an archive saved on the analyzer, do the following:

- | Step | Action |
|------|---|
| 1. | Highlight the desired archive with the up/down arrow buttons (if a few archives are present). |



Information about analyzer type, installation number and the date this archive was generated is on the screen.

Continued on next page

Archived data logs, *Continued*

Selecting archive stored on the analyzer (*continued*)

| Step | Action |
|------|--|
| 2. | Press Select Archive to obtain it for viewing. |
| 3. | Press, if desired, Filter to enter the search criteria and apply the filter. |
| 4. | Highlight the desired report by touching it on the screen and press Result to display the result. |
| 5. | Press Close to exit to the Ready screen. |

Moving an archive

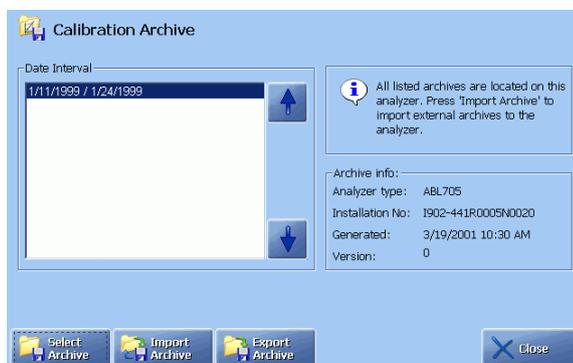
To move an archive to another media (e.g. computer) or from another media to the analyzer, do the following:

| Step | Action |
|------|---|
| 1. | Press Import Archive to move it. The Import/Export Archives screen will be displayed. |
| 2. | Proceed as described in <i>Importing/exporting archives, chapter 8: Disk functions</i> . |

Converting an archive into .csv format

To convert an archive into .csv format, do the following:

| Step | Action |
|------|--|
| 1. | Highlight an archive and press Export Archive . |



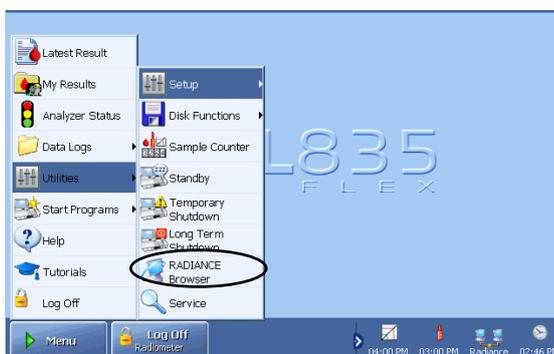
2. Press **Start** to start conversion.
Press **Back** to cancel and return to the previous screen.
3. Export the converted archive to a disk as described in *Importing/exporting archives, chapter 8: Disk functions*.

RADIANCE browser (optional)

Purpose This option allows you to get in touch with the RADIANCE system in order to find information on patients, quality control, calibrations, from all analyzers connected to the RADIANCE network.

Access to the RADIANCE system To get access to the RADIANCE system, do the following:

- | Step | Action |
|------|--|
| 1. | Make sure that a connection to the RADIANCE server is established in the RADIANCE Communication Setup program. |
| 2. | Press <i>Menu - Utilities - RADIANCE Browser</i> . |



The analyzer will exchange information with the RADIANCE system about your access profile, and the contents of the RADIANCE main page will reflect the scope of your privileges.



3. Refer to the *RADIANCE Operator's Manual* on how to browse on the RADIANCE system.

10. Analyzer shutdown

Overview

Introduction This chapter describes the Standby mode, Temporary Shutdown, Long Term Shutdown programs and the Forced Standby mode.

Contents This chapter contains the following topics.

| | |
|----------------------------|------|
| General information | 10-2 |
| Standby mode..... | 10-3 |
| Full waste container | 10-5 |
| Temporary Sutdown..... | 10-6 |
| Long Term Sutdown | 10-8 |

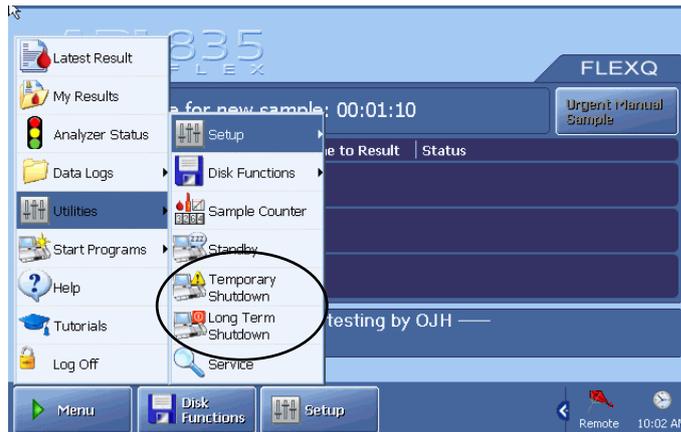
General information

Shutdown programs

The following programs are available:

- Standby
- Temporary Shutdown
- Long Term Shutdown.

To access the programs, press *Menu - Utilities*.



Then press the desired button to enter the program.

When the waste container becomes critically full, the analyzer automatically enters Forced Standby mode.

Standby mode

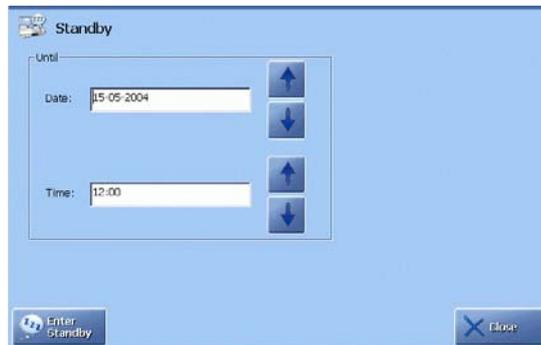
Purpose The Standby mode is used for the following:

- to keep the analyzer ready for measurements (the electrodes conditioned and solutions thermostatted) during short-term time periods such as weekends or holidays.
- to prevent spillage from the waste container when it gets critically full.

By placing the analyzer on standby the consumption of solutions is reduced, as the scheduled calibrations are suspended.

Entering Standby To put the analyzer into Standby mode, do the following:

- | Step | Action |
|------|---|
| 1. | Enter date and time for the analyzer to automatically exit the Standby mode, using the arrow buttons. |

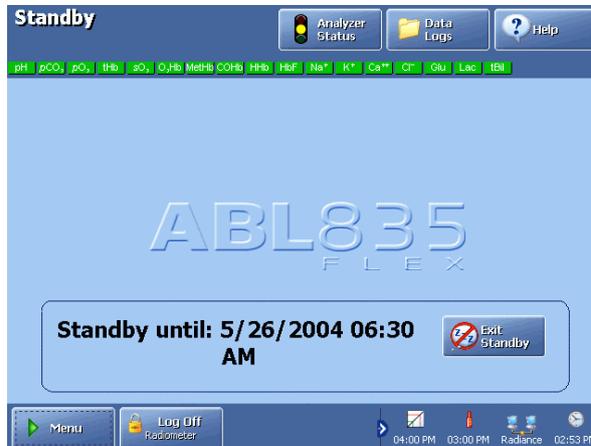


- | | |
|----|---|
| 2. | Press <i>Enter Standby</i> to enter the Standby mode. The button changes to <i>Exit Standby</i> . |
|----|---|

Continued on next page

Standby mode, *Continued*

Exiting Standby The analyzer automatically exits the Standby mode on the selected day and time.



Press **Exit Standby** to exit standby before the scheduled date/time. If the **Exit Standby** button is not shown, you have to logon to the analyzer as a user with permission to exit standby.

The analyzer will return to the Ready mode upon exit from Standby, unless:

- all parameters are marked "Cal Expired"
- analyzer is locked due to "QC Expired".
- Analyzer is locked due to "Replacement overdue".

Pending calibrations and/or QC measurements will be performed when possible.

Full waste container

Forced Standby When the waste container gets critically full, the analyzer enters the Forced Standby mode.



To return the analyzer to the Ready mode, do the following:

- | Step | Action |
|------|---------------------------------------|
| 1. | Replace the waste container. |
| 2. | Press the <i>Exit Standby</i> button. |

For users with limited access (selected in the Access Profiles program – see *chapter 3*), this button may not be visible. Press **Menu – Log on** and type in your password.

If your access profile allows the exit from the Standby mode, the *Exit Standby* button will be visible.

Temporary Shutdown

Purpose This program prepares the analyzer software for switching off power, and is used for temporary (short-term) shutdown of the analyzer.

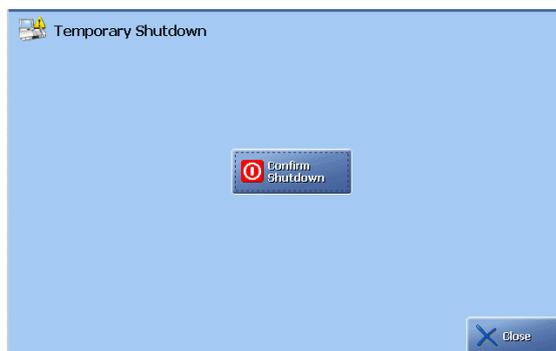
This program differs from the Long Term Shutdown used for a long-term storage of an analyzer that requires removal of system components.

Executing Temporary Shutdown program

To switch the analyzer off for a short time, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Enter the program.



2. Press *Confirm Shutdown* to continue.
Press *Close* to cancel.
3. Follow the instructions on the screen to complete the temporary shutdown.

Restarting the analyzer

To restart the analyzer after Temporary Shutdown, do the following:

| Step | Action |
|------|--------|
|------|--------|

1. Verify that the system requirements are met and all components are installed.
2. Place the power switch in the ON or I position.
The startup procedure begins. When completed, the analyzer's **Ready** screen appears

Depending on the length of the shutdown, the analyzer performs either a cold start or a warm start.

Continued on next page

Temporary Shutdown, *Continued*

Restarting the analyzer (*continued*)

| Start | Is performed if... |
|-------|---|
| Cold | <p>The thermostating temperature is outside predefined limits. It lasts approximately 25 minutes and includes:</p> <ul style="list-style-type: none"> • Loading of software • Inlet calibration (not shown in status) • Leak test • Initializing • Liquid sensor adjustment • Pump Calibration • Rinse • Startup (conditioning of the electrodes) • 2-point calibration. |
| Warm | <p>The thermostating temperature is within the predefined limits. It lasts approximately 5 minutes and includes:</p> <ul style="list-style-type: none"> • Loading of software • Inlet calibration (not shown in status) • Leak test • Rinse |

Over the first 24 hours after the cold start, the analyzer will automatically perform a number of calibrations at specific intervals as follows:

- The first four hours: 1-point calibration every 30 minutes
 2-point calibration every hour
- remaining 20 hours: 1-point calibration every hour
 2-point calibration every four hours.

During the startup, available analyzer functions are indicated by the appearance of the buttons. A greyed-out button indicates that the function is not available.

NOTICE: Message 962 "Ambient temperature not specified" will be present after the ABL837/27/17 cold startup in the System messages on the **Analyzer Status** screen. To remedy it, enter the ambient temperature in the Environment Setup (press *Menu – Utilities – Setup – General Setup – Analyzer Settings – Environment*).

Long Term Shutdown

Purpose This program gives the procedure for emptying the analyzer of solutions before transport or storage for an extended period of time.

The Shutdown procedure takes approximately 15 minutes.

Before shutdown You will need the following:

- Four ~50 cm long tubes with an internal diameter capable of fitting onto the solution connectors.
- One large glass beaker filled with distilled water

The shutdown procedure Enter the Long Term Shutdown program and follow the prompts on the screen.

| Screen | Prompts and operator actions |
|--------|---|
| 1 | <p>Perform Decontamination (use the button on the screen to enter the program).</p>  <p>Press Confirm Shutdown to continue, or Close to cancel the procedure. After this point there is no opportunity to cancel the shutdown.</p> |
| 2 | Remove the Rinse, Cal 1, Cal 2 and Cleaning Solution containers. Press Continue . |
| 3 | Wait for the fluid transport path to drain. |
| 4 | Place tubes on the Rinse, Cal 1, Cal 2 and Cleaning solution connectors and the free ends in a beaker filled with distilled water. Press Continue . |
| 5 | Wait while the fluid transport path is rinsed with distilled water. |
| 6 | Remove beaker with distilled water and disconnect the tubes. Press Continue . |
| 7 | Wait for the fluid transport path to drain. |

Continued on next page

Long Term Shutdown, *Continued*

The shutdown procedure
(*continued*)

| Screen | Prompts and operator actions |
|--------|---|
| 8 | <p>Read the steps below prior to performing any actions.</p> <ul style="list-style-type: none"> • Remove Gas 1 and Gas 2 cylinders. • Remove all electrodes and place them in their respective protective jackets. • Remove waste container. • Place covers on all solution connectors and gas inlets. • Press <i>Finish</i> to power down. When the message "You can now turn off your PC" appears, turn off the power (the power switch at the back of the analyzer). • Remove pump tubings. • Remove paper from printer, and network and power cables from the back of the unit. <p>Shutdown is now complete.</p> |

Storing the analyzer

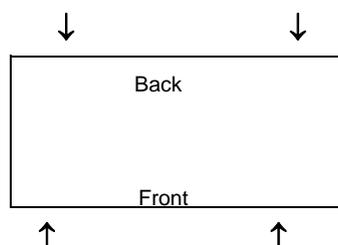
Radiometer recommends to place the analyzer on a trolley in its normal position, and protect it from dust using a plastic cover.

Transporting the analyzer

To transport the analyzer from one location to another, put it back in its original packaging and seal.

To transport the analyzer without its original packaging, follow the recommendations below:

- A minimum of two persons is recommended.
- Remove all solutions and gas containers; disconnect power and peripheral devices prior to lifting.
- The analyzer can be lifted and carried from any position along the base apart from the gas regulator. As a recommendation, see the diagram below outlining the analyzer base. Hand positions are indicated by the arrows.



NOTICE: Do not lift analyzer by the gas regulator. Damage to the analyzer can occur.

11. Troubleshooting

Overview

Introduction This chapter describes Hold causes and standard troubleshooting procedures.

Contents This chapter contains the following topics.

| | |
|---|-------|
| General information | 11-2 |
| Forced Hold causes | 11-5 |
| Analyzer messages | 11-7 |
| Fluid transport troubleshooting procedure | 11-74 |
| Inlet probe troubleshooting procedure | 11-75 |
| Inlet troubleshooting procedure | 11-76 |
| Leak troubleshooting procedure..... | 11-77 |
| Electrode troubleshooting procedures | 11-78 |
| Pump troubleshooting procedure | 11-80 |
| Fluid transport system description | 11-81 |

General information

Analyzer action in case of error Depending on the severity of the error the analyzer will do one of the following:

- continue its activity, but mark relevant parameter results with a “?”
- interrupt and abort its activity
- enter the Hold mode
- deny measurements and calibrations.

FLEXQ – sampler messages

- If a sampler was accidentally removed from the slot, the following screen appears:

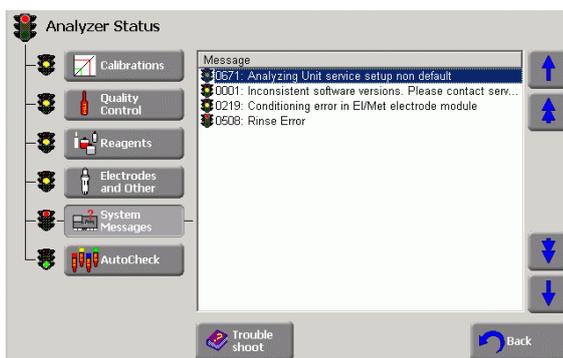


- If the batch mode was selected, but the analyzer is not connected to the RADIANCE system, the message “Remove sampler” will appear on the screen
- If two samplers were placed in the sampler tray one immediately after the other so that the FLEXQ had no time to register the first sampler, the message “Remove sampler” will appear on the screen.

Operator actions in case of error

To locate and remedy messages/errors, do the following:

| Step | Action |
|------|--|
| 1. | Check which of the status button indicators is red or yellow on the Analyzer Status screen. |
| 2. | Press the relevant button (example: <i>System Messages</i> was pressed). |



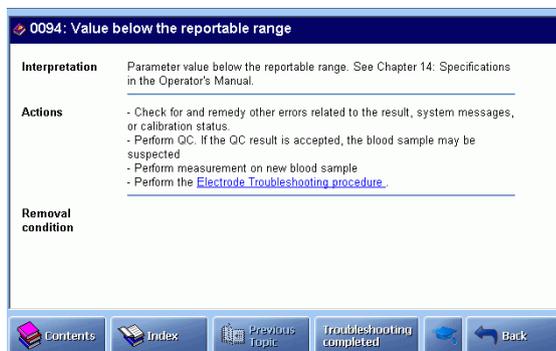
Highlight the error (the first line is automatically highlighted).

Continued on next page

General information, *Continued*

Operator actions in case of error
(*continued*)

- | Step | Action |
|------|--|
| 3. | Press Troubleshoot for error description and operator action. |



Is placed in the top right corner of the screen so that you can continue troubleshooting.



Use Tutorials to assist in the troubleshooting procedure.



Online Help at the bottom of the screen.



Returns to the previous help topic.



Press to return to the **Analyzer Status** screen when all messages have been remedied.



Press to return to the **Analyzer Status** screen.

- Remedy the error as described in the Actions on the screen.
- Remedy other error(s) if present.
- Press **Troubleshooting completed** after all errors have been remedied. (The **Help** button will then reappear in the top right corner of the screen).

NOTICE: For description of analyzer messages and operator actions see *Analyzer messages*.

Continued on next page

General information, *Continued*

Logging system messages All system messages are automatically recorded in the Activity Log at the time of their occurrence. The items in the Activity Log are listed in chronological order and form a permanent record for the user of all system messages that have taken place.

Using the filter function (see description in *Activity Log, chapter 9* in this manual), you can select the desired type of messages and view them at the user, manager and service levels.

Forced Hold causes

Purpose Forced Hold mode suspends all the wet section activities in case certain analyzer conditions occur. Until the condition has been corrected the analyzer cannot be restarted.



The causes for the Forced Hold mode are as follows:

| Condition | Screen message | Corrective action |
|--|--------------------------------|---|
| Forced Standby | Replace waste container | Replace the waste container. Press the <i>Exit Standby</i> button. |
| Rinse error | Rinse Error | Replace the Rinse Solution bottle – see the procedure in <i>chapter 7: Replacements</i> . |
| Operator intervention required | Intervention Required | Check Analyzer Status and remedy the condition/error. |
| Cover to the measuring modules removed or the window opened. | Cover removed or window opened | Verify the cover is properly mounted and the window shut prior to restart. |
| Both inlet flaps removed. | Inlet flaps removed | Verify the inlet flaps are properly mounted prior to restart. |
| The inlet cannot obtain proper position. | Inlet positioning error | Contact service representative. |
| Inlet calibration failed | Inlet calibration error | Perform the procedure described on the next page. |
| Leakage test failed | Leak detected | Perform the procedure described on the next page. |

Inlet calibration error This condition occurs when the calibration of the inlet fails, most likely caused by a problem with the inlet components.

To correct the error, do the following:

| Step | Action |
|------|--|
| 1. | Remove the analyzer cover and the inlet flaps. |
| 2. | Check that the inlet probe and gasket are mounted properly. |
| 3. | Remove the inlet gasket and check for wear or damage. Replace as required. |

Continued on next page

Forced Hold causes, *Continued*

Inlet calibration error (*continued*)

| Step | Action |
|------|--|
| 4. | Check the condition of the inlet probe. If it appears bent or damaged, replace it. |
| 5. | Mount all components, then restart the analyzer by pressing Restart . If the error has been corrected, the analyzer performs an inlet calibration during restart and enters the Ready mode. If the Hold mode remains, contact a service representative. |

Leak Detected error

This condition occurs when a leakage test has failed, indicating a leak in the fluid transport system.

To correct the error, do the following:

| Step | Action |
|------|---|
| 1. | Remove the analyzer covers and inspect the fluid transport system for leaks. |
| 2. | Check for poor tube connections or worn tubes. Repair as required. |
| 3. | Check the inlet gasket; change if required. |
| 4. | Ensure that electrodes are properly mounted in the measuring chamber and the electrode connector is latched shut. |
| 5. | Mount all items, restart the analyzer by pressing Restart . If the error has been corrected, the analyzer performs a restart sequence (includes a leakage test) and enters the Ready mode. If the Hold mode remains, contact a service representative. |

Analyzer messages

Messages at manager level

The following messages will be seen at the manager levels. The messages are listed in numerical order.

Operator actions are listed in order of priority. Perform the first action in the list; if unsuccessful, try the next action, etc.

| No. | Message | Interpretation | Operator action |
|-----|--|--|--|
| 1 | Inconsistent software versions. Please contact service. | Inconsistent software versions for different modules. May appear after replacing a complete module or as a result of an incomplete software upgrade. | Contact Radiometer service representative. Removal condition: Successful software consistency check. |
| 83 | Value above reference range | Parameter value is above the user-defined reference range. This is only a message, not an error. | No action required. |
| 84 | Value below reference range | Parameter value is below the user-defined reference range. This is only a message, not an error. | No action required. |
| 85 | Value is below the critical limit | Parameter value is below the user-defined critical limit. This is only a message, not an error. | No action required. |
| 86 | Value is above the critical limit | Parameter value is above the user-defined critical limit. This is only a message, not an error. | No action required. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|--|--|
| 89 | Measured QC value above the control range | Measured parameter value is above the control range. | <ul style="list-style-type: none"> - Verify procedure and repeat measurement. - Refer to Quality Control Systems Reference Manual. Crea: <ul style="list-style-type: none"> - Mount a new Cleaning Met II Solution. - Remembrane both Crea A and Crea B electrodes |
| 90 | Measured QC value below control range | Measured parameter value is below the control range. | <ul style="list-style-type: none"> - Verify procedure and repeat measurement. - Refer to Quality Control Systems Reference Manual. Crea: <ul style="list-style-type: none"> - Mount a new Cleaning Met II Solution. - Remembrane both Crea A and Crea B electrodes |
| 93 | Value above the reportable range | Parameter value is above the reportable range. See chapter 13: Specifications in the Operator's Manual | <ul style="list-style-type: none"> - Check for and remedy other errors related to the result, system messages, or calibration status. - Perform QC. If the QC result is accepted, the blood sample may be suspected. |
| 94 | Value below the reportable range | Parameter value below the reportable range. See chapter 13: Specifications in the Operator's Manual. | <ul style="list-style-type: none"> - Repeat measurement on a new blood sample. - Perform the Electrode Troubleshooting procedure. |
| 117 | LIS/HIS: Invalid connection configuration | The communication configuration or the protocol definition was invalid. | Check the communication parameters specified in Communications setup. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|---|---|
| 128 | LIS/HIS: Failed to open connection | The communication hardware was busy or the remote system did not respond. | <ul style="list-style-type: none"> - Check that the remote system is running, correctly configured and responding. - Check communication parameters, e.g. baud rate, parity, IP address, etc., as defined in Communication setup. - Reboot the analyzer. |
| 129 | LIS/HIS: Failed to close connection | Messages were queued when the communication channel was closed. Results and other messages sent by the analyzer to a remote system may be lost. | If the problem persists, check the communication hardware. The remote system may lack buffer capacity. |
| 131 | LIS/HIS: Failed to send packet | A communication error occurred while sending a message. The message was not sent. | <ul style="list-style-type: none"> - Check that the remote system is running and responding. - Check communication hardware including cables. - Repeat sending. |
| 132 | LIS/HIS: Failed to receive packet | An error occurred while receiving a message. The analyzer was not able to recognize the received message. | <ul style="list-style-type: none"> - Check that protocol types are correctly configured on both the analyzer and the remote system. - Contact Radiometer service representative. |
| 133 | LIS/HIS: Connection lost | A previously established LIS/HIS connection has been lost. | <ul style="list-style-type: none"> - Check that the remote system is running and responding. - Check cables. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|---|--|
| 134 | LIS/HIS: Connection established | The connection was successfully established. | No action required. The message is informative. |
| 165 | LIS/HIS: High level protocol could not generate high level packet | An error occurred while formatting a message. | - Check protocol configurations. - Contact Radiometer service representative. |
| 166 | LIS/HIS: General communication error | An internal error occurred in the LIS/HIS communication module. | Contact Radiometer service representative if the problem persists. |
| 167 | LIS/HIS: High level protocol received packet in wrong format | An error occurred while parsing (interpreting) a message. | - Check protocol configurations. - Contact Radiometer service representative. |
| 200 | User msg: | This is only a message. An operator has entered a note in the log. | No action required. |
| 201 | Westgard Rule (1.2s) violation | Measured parameter value is outside the mean \pm 2 SD range. | - Verify procedure and repeat measurement. |
| 202 | Westgard Rule (1.3s) violation | Measured parameter value is outside the mean \pm 3 SD range. | - Check Replacement Status for pending replacements (including electrodes). |
| 203 | Westgard Rule (2.2s) violation | Two consecutive measurements are outside the mean \pm 2 SD range on the same side of the mean. This may indicate a shift. | - Refer to the Quality Control Systems Reference Manual for detailed evaluation procedure. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|---|---|
| 204 | Westgard Rule (R.4s) violation | The difference between two consecutive measurements exceeds 4 SD. This may indicate an inconsistency in your procedure or an unstable analyzer. | <ul style="list-style-type: none"> - Verify procedure and repeat measurement. - Check Replacement Status for pending electrode replacements. - Refer to the <i>Quality Control Systems Reference Manual</i> for detailed evaluation procedure. |
| 205 | Westgard Rule (4.1s) violation | Four consecutive measurements are outside the mean \pm 1 SD range on the same side of the mean. A trend or shift is indicated. Patient results should be considered unreliable until the problem is remedied. | <ul style="list-style-type: none"> - Check for excessive electrode sensor calibration drift. - Check Replacement Status for pending electrode replacements. - Refer to Quality Control Systems Reference Manual for evaluation procedure. |
| 206 | Westgard Rule (10.x) violation | Ten consecutive measurements are on the same side of the mean. A trend or shift is indicated. Patient results should be considered unreliable until the problem is remedied. | <ul style="list-style-type: none"> - Check the electrode drift during last calibration. - Check Replacement Status for pending electrode replacements. - Refer to Quality Control Systems Reference Manual for evaluation procedure. |
| 207 | Calibration schedule reminder(s) present | One or more scheduled calibrations are overdue. | Check the Calibration Status and perform any pending calibrations. |
| 208 | Quality control schedule reminder(s) present | One or more scheduled QC measurements are overdue. | Check the Quality Control Status and perform the pending quality control. |
| 209 | Replacement schedule reminder(s) present | One or more scheduled replacements are overdue. | Check the Replacement Status and perform any pending replacement actions. |

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|----------------------------------|---|---|
| 210 | Calibration error(s) present | An error registered on one or more parameters during the last calibration. | Check the Calibration Status for errors in latest calibration results for the given parameter. View calibration error messages and take required corrective action. |
| 211 | Quality control error(s) present | One or more errors registered during last QC measurement in one of the installed QC levels. | Check the Quality Control Status for errors. View QC error messages and take required corrective action. |
| 212 | System message(s) present | One or more systems errors are present. | Check the System Messages Status for errors. Take required corrective action. |
| 213 | Automatic backup failed | An error occurred during the scheduled data backup. | <ul style="list-style-type: none"> - Check Automatic Backup Setup. - Check network and servers used for the backup. - Contact your IT engineer. |
| 214 | Automatic backup succeeded | The scheduled automatic backup was completed successfully. | No action required. |
| 216 | Printer error | The printer is out of paper, paper is jammed, or some other printer problem has occurred. | <ul style="list-style-type: none"> - Check printer paper. Clear any jam or mount a roll. - Power down and restart the analyzer. - Contact Radiometer Service Representative. |
| 217 | Replacement: | The message is used in the Activity Log to indicate a performed replacement. | No action required. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|---|---|--|---|
| 218 | Inlet positioning error | Inlet probe was not positioned properly within required time frame. Causes the activity to abort. | Perform the Inlet Troubleshooting Procedure Removal condition: Successful inlet calibration. |
| 219 | Conditioning error in El/Met electrode module | Rinse Solution was not detected in El/Met electrode module. The glucose and lactate results will be reported as "....." in the next measurement. | - Check Rinse Solution for adequate volume, proper installation or obstructions in container opening. Replace as necessary. - Perform the Fluid transport troubleshooting procedure. Removal condition: Successful Rinse. |
| 232 | Oximetry calibration error | Water spectrum intensity was too low or too high during absorbance calculation. OXI measurements cannot be performed. | - Perform a 2-point calibration. - Contact Radiometer Service Representative if the problem persists. Removal condition: Successful 2-point calibration. |
| 234-238, 245-252, 254-258, 269, 314-316 | Oximetry hardware error | The Oxi module has a hardware error. | - Perform a 2-point calibration. - Contact Radiometer Service Representative if the problem persists. |
| 259, 270, 354-357 | Temperature error | Analyzer temperature is outside 37.0 ± 0.2 degrees Celsius. | - Ensure the ambient temperature is between 15 and 32 degrees Celsius. - If the system has just performed a cold start, wait for error to disappear. - Replace the fan filter if dirty. - Shield analyzer from direct sunlight and other heat sources. - Contact Radiometer service representative. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|--|--|
| 290 | Warning: SHb detected | F _S Hb detected in the range of 1-10 %. | No action required. For information only. |
| 291 | SHb too high | Detected F _S Hb is greater than 10 %. Measurement accuracy is affected. | Repeat the measurement. |
| 292 | Turbidity too high | Turbidity is greater than 5 %: too high for reliable measurements. | <ul style="list-style-type: none"> - Check pump tubes and inlet tube for leaks. Repair as necessary. - Hyperlipemic sample; decrease the lipemic content by, e.g. centrifuge or extraction. - Perform the measurement on a blood sample from a healthy donor. - Contact Radiometer service representative. |
| 293 | Warning: HbF detected and compensated for | Detected F _H bF is greater than 20 % of ctHb. Oxi parameters are automatically corrected. | No action required. For information only. |
| 326 | Empty Gas 1 cylinder | Gas 1 cylinder is detected as empty. | - Enter Replacement mode via Replacement Status. |
| 327 | Empty Gas 2 cylinder | Gas 2 cylinder is detected as empty. | <ul style="list-style-type: none"> - Scan the barcode of a new Gas 1 or 2 cylinder. - Replace Gas 1 cylinder. (See chapter 7: <i>Replacements</i> for detailed information.) Removal condition: Gas pressure in Gas 1 or 2 cylinder. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|---------------------------|---|---|---|
| 328 | No leading air segment in inlet's liquid sensor within time frame | Air segment in front of sample is too small or missing during sample aspiration, possibly due to obstructions in inlet or problems with liquid sensors. Measurement is aborted. | <ul style="list-style-type: none"> - Check inlet for obstructions and clean as required. - Perform liquid sensor adjustment. - Perform the Fluid Transport Troubleshooting procedure. |
| 329 | QC expiration date exceeded | The quality control measurement was performed on an expired control solution. | Discontinue the use of the lot and set up a valid lot for the control solution. |
| 331 | No sample detected during sample aspiration | No sample detected in the pH/BG module. Measurement is aborted. | <ul style="list-style-type: none"> - Ensure that adequate sample volume is used. - Check the sample for clots. - Perform the Fluid Transport Troubleshooting procedure. |
| 332, 333 | pH/BG module not filled | Sample did not fill the pH/BG module properly during aspiration. Measurement is aborted. | <ul style="list-style-type: none"> - Ensure that adequate sample volume is used. - Check the sample for clots. - Perform the Fluid Transport Troubleshooting procedure. |
| 339-340, 342-343, 345-346 | Pump calibration error | The pump calibration failed for one or more pumps. The previous pump calibration is used. A successful pump calibration should be attempted as soon as possible. | <ul style="list-style-type: none"> - Check rinse solution for sufficient volume. Replace as necessary. - Repeat pump calibration. - Perform the Pump Troubleshooting procedure. <p>Removal condition: Successful pump calibration.</p> |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--------------------------------------|--|---|
| 369 | El/Met not filled within time frame | El/Met module did not fill properly with calibration solution. Calibration is aborted. | <ul style="list-style-type: none"> - Check the solution containers. Replace as required. - Perform the Fluid transport troubleshooting procedure. Removal condition: Successful calibration. |
| 374 | Inhomogeneous sample at pH/BG module | pH/BG lower liquid sensor detected air bubbles in the sample; they might affect the measurement. All parameters are marked with "?". | <ul style="list-style-type: none"> - Ensure the sample is free of air bubbles and that sufficient volume is used. - Check the condition of the inlet gasket. Replace as necessary. |
| 375 | Calibration status out of limits | The status value is outside the range for the given parameter: pH: 6.7-8.1 $p\text{CO}_2$: 6.2-260 mmHg or 0.83-34.66 kPa $c\text{K}^+$: 0.5-12 mmol/L $c\text{Na}^+$: 10-250 mmol/L $c\text{Ca}^{2+}$: 0.1-20 mmol/L $c\text{Cl}^-$: 30-900 mmol/L | <ul style="list-style-type: none"> - Check for and remedy any System Messages. - Perform any pending electrode replacements. - Check that electrodes are properly installed. - Verify that proper solutions and gases are being used. - Perform the Electrode Troubleshooting procedure. Removal condition: Successful 1- or 2-point calibration. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--------------------------------------|---|---|
| 376 | Calibration Drift 1 out of range | The Drift 1 value exceeds the user-defined tolerance. | - Check for and remedy any System Messages. - Perform any pending electrode replacements. |
| 377 | Calibration Drift 2 out of range | The Drift 2 value exceeds the user-defined tolerance. | - Check that electrodes are properly installed. - Verify that proper solutions (all additives are added) and gases are used. - Perform the Electrode Troubleshooting procedure. Removal condition: Successful 1- or 2-point calibration. |
| 378 | Calibration sensitivity out of range | The sensitivity value is out of range for the given parameter: pH: 92-103 % $p\text{CO}_2$: 85-100 % $p\text{O}_2$: 5-40 pA/mmHg or 37.5-300 pA/kPa $c\text{K}^+$: 92-105 % $c\text{Na}^+$: 90-105 % $c\text{Ca}^{++}$: 90-105 % $c\text{Cl}^-$: 85-100 % $c\text{Glu}$: 100-1800 pA/mM $c\text{Lac}$: 150-2000 pA/mM $c\text{Crea}$: 5-15 pA/ μM (1) $c\text{Crea}$: 65-85 % (2) $c\text{Crea}$: 50-200 % or 3.5-20 pA/ μM (3) Affected parameters and measurements are marked with "?". | - Check for and remedy any System Messages. - Check that electrodes are properly installed. - Verify that proper solutions (all additives are added) and gases are used. - Perform the Electrode Troubleshooting procedure. Removal condition: Successful 1- or 2-point calibration. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|---|--|
| 379 | Calibration unstable. (response fault) | An electrode response fault occurred during calibration. Affected parameters and measurements (only creatinine) are marked with "?". | <ul style="list-style-type: none"> - Check for and remedy any System Messages. - Perform any pending replacements including electrodes. - Check that electrodes are properly installed. - Verify that proper solutions and gases are used. - Perform the Electrode Troubleshooting procedure. Removal condition: Successful 1- or 2-point calibration. |
| 386 | Barometer out of range | The barometer reading is out of the range: 450-800 mmHg or 60.0-106.7 kPa. Measurement results are marked with "?". | <ul style="list-style-type: none"> - Check the measured pressure in Barometer Setup program and compare it to that of an external barometer. Adjust the analyzer pressure accordingly. - Contact Radiometer service representative. |
| 408 | Zero current error | Zero current was too high during calibration. Affected parameters and measurements are marked with "?". | <ul style="list-style-type: none"> - Check for and remedy System Messages. - Perform any pending replacements, including electrodes. - Perform the Electrode troubleshooting procedure. - Contact Radiometer service representative. |
| 443 | Ca(7.4) not usable | cCa ⁺⁺ at a pH of 7.4 is not usable as the actual pH is out of the range 7.2-7.6. | No action required. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|---|---|
| 452 | Interference during measurement | Interference was detected during measurement. | Check the patient record for medication containing possible interfering substances. |
| 467 | Inhomogeneous sample at EI/Met module | Lower liquid sensor at EI/Met module detected air bubbles. The affected parameters are marked with "?". | <ul style="list-style-type: none"> - Repeat the measurement ensuring that the sample is free of air bubbles and that proper sample volume is used. - Replace Pump Tubing in pH/BG and EI/Met modules and solution pump. - Contact Radiometer Service Representative. |
| 468 | Inhomogeneous sample in Met II module | Lower liquid sensor at Met II module detected air bubbles. The affected parameters are marked with "?". | <ul style="list-style-type: none"> - Repeat the measurement ensuring that the sample is free of air bubbles and that proper sample volume is used. - Replace Pump Tubing in pH/BG, EI/Met and Met II modules and solution pump. - Contact Radiometer Service Representative. |
| 474 | No sample in EI/Met upper liquid sensor within time limit | The sample did not fill the EI/Met module properly. | <ul style="list-style-type: none"> - Check the sample for clots. - Ensure sample volume matches the selected sample mode. - Perform the Fluid Transport Troubleshooting procedure. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|--|--|
| 475 | No sample in Oxi liquid sensor within time limit | The sample did not fill the oximetry module properly. | <ul style="list-style-type: none"> - Check the sample for clots. - Ensure sample volume matches the selected sample mode. - Perform the Fluid Transport Troubleshooting procedure. |
| 476 | Measurement unstable | The electrode response fault occurred during measurement. | <ul style="list-style-type: none"> - Check for and remedy other errors in System Message or Calibration Status. - Repeat the measurement. - Perform any pending replacements, including electrodes. - Ensure the electrode is properly installed. - Ensure the analyzer is properly grounded. - Perform QC. If the QC result value is within the control range, the blood sample may be suspected. Continue troubleshooting. - Perform the Electrode Troubleshooting procedure. |
| 478 | $p\text{CO}_2$ drifting | The $p\text{CO}_2$ drift value exceeds the user-defined limits + 0.3 kPa during flush. | <ul style="list-style-type: none"> - Call 1-point calibration. - Check for and remedy any specific errors in the last calibration result, then call another 1-point calibration. |
| 480 | $p\text{O}_2$ drifting | The $p\text{O}_2$ drift value exceeds the user defined limits + 0.3 kPa during flush. | <ul style="list-style-type: none"> - Contact Radiometer service representative. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|---------|--|---|--|
| 481-482 | Conditioning error | Indicates a fluid transport problem of pH/BG module during Flush. | |
| 484 | Today is last day in current statistical month – remember to print QC statistics | After the current day, quality control statistics obtained over the month will be deleted and new statistics started. | Print the QC statistics if a copy is required. |
| 487 | A new statistical month has begun – remember to export WDC data | A new statistical month has begun. | Make a WDC report disk. Removal condition: A WDC report disk has been made. |
| 493 | Warning: Bilirubin detected and compensated for | Detected bilirubin concentration is greater than 50 umol/L. The corresponding plasma bilirubin concentration can be calculated as follows: $ctBil(blood) = (1-Hct) \times ctBil(plasma)$. | No action required. |
| 494 | Bilirubin too high | Detected bilirubin concentration, $ctBil(blood)$, is greater than 2000umol/L. The corresponding plasma bilirubin concentration can be calculated as follows: $ctBil(blood) = (1-Hct) \times ctBil(plasma)$. | No action required. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|--|--|
| 499 | Sample too early in Oxi liquid sensor. | The Oxi module detected liquid prematurely during sample aspiration. The activity is aborted. | <ul style="list-style-type: none"> - Check the sample for clots. - Repeat measurement. - Replace inlet gasket. - Perform the Fluid transport troubleshooting procedure. |
| 500 | Rinse detected by pH/BG module when not expected | The pH/BG module detected liquid unexpectedly. | Perform the Fluid transport troubleshooting procedure. |
| 501 | Rinse not aspirated into the pH/BG module within time limit | The pH/BG module was not filled properly with Rinse Solution. | <ul style="list-style-type: none"> - Check the Rinse Solution for sufficient volume and proper mounting. Replace as necessary. - Perform the Fluid transport troubleshooting procedure. |
| 503 | Unable to fill inlet with continuous rinse segment during Pump Calibration | Three attempts to fill the inlet probe with a continuous rinse segment have failed; the Pump Calibration program aborts. | <ul style="list-style-type: none"> - Check Rinse Solution for sufficient volume. Replace as necessary. - Perform the Pump troubleshooting procedure. |
| 504 | No sample in EI/Met lower liquid sensor within time limit | The sample did not fill EI/Met module properly. The activity is aborted. | <ul style="list-style-type: none"> - Check the sample for clots. - Ensure that sample volume matches selected sample mode. - Perform the Fluid transport troubleshooting procedure. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|--|---|
| 505 | Met II upper liquid sensor did not detect Cleaning Solution | The Met II module was not filled properly during Cleaning program. The activity is aborted. | - Check the Cleaning solution for sufficient volume. Replace as required. |
| 506 | El/Met upper liquid sensor did not detect Cleaning Solution | The El/Met module was not filled properly during Cleaning program. The activity is aborted. | - Perform Fluid transport troubleshooting procedure. Removal condition: Successful Cleaning. |
| 507 | pH/BG upper liquid sensor did not detect Cleaning solution | The pH/BG module was not filled properly during Cleaning program. Cleaning is aborted. | |
| 508 | Rinse error | Rinse Solution was not detected during Rinse program. Measurements and calibrations cannot be performed until the condition is removed. | - Check the rinse solution for sufficient volume. Replace as required. - If the message "Inlet flow impeded" (765) has been reported, replace or clean inlet probe. - Perform Fluid transport troubleshooting procedure. Removal condition: Successful Rinse. |
| 509 | pH/BG upper liquid sensor did not receive Rinse from above | The pH/BG module was not filled properly during Rinse program; automatic Refill is attempted. | - Check the Rinse Solution for sufficient volume. Replace as required. - Perform Fluid transport troubleshooting procedure. |
| 510 | El/Met upper liquid sensor did not receive Rinse from above | The El/Met module was not filled properly during Rinse program; automatic Refill is attempted. | Removal condition: Successful Rinse. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----------------------|---------------------------------|---|---|
| 512 | Temperature error | The temperature was outside the required range during measurement or calibration. All results are marked with "?". | Ensure ambient temperature is between 15 and 32 °C. - If the analyzer has recently performed a Cold start, wait for temperature error to disappear. - Shield analyzer from direct sunlight or heat sources. - Contact Radiometer service representative. |
| 513 | No gas | Measurement or calibration was performed with Gas error present. Activity is aborted. | - Check pressure in gas cylinders. Replace as required. - Verify that cylinders are properly installed. - Enter the Replacement screen (via Replacement Status) and re-scan the barcode labels of the gas cylinders. |
| 521 | Inhomogeneous sample | Air bubbles were detected in the sample. Results may have "?". | - Ensure sampler and sample volume match the selected sample mode. - Repeat measurement. - Check pump tubes and inlet for leaks. Replace tubing and inlet gasket as required. |
| 529, 531-532, 534-537 | Liquid sensor calibration error | One or more of the liquid sensors failed to calibrate. | - Repeat liquid sensor calibration. - Perform Fluid transport troubleshooting procedure. - Contact Radiometer Service Representative. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|--|--|
| 538 | pH/BG pump error | The pH/BG module pump failed to calibrate. Previous calibration is used until a successful pump calibration is performed. | <ul style="list-style-type: none"> - Perform Pump troubleshooting procedure. - Contact Radiometer service representative. |
| 539 | El/Met pump error | The El/Met module pump failed to calibrate. Previous calibration is used until a successful pump calibration is performed. | <ul style="list-style-type: none"> - Perform Pump troubleshooting procedure. - Contact Radiometer service representative. |
| 540 | Met II pump error | The Met II module pump failed to calibrate. Previous calibration is used until a successful pump calibration is performed. | <ul style="list-style-type: none"> - Perform Pump troubleshooting procedure. - Contact Radiometer service representative. |
| 541 | Solution pump error | The solution pump failed to calibrate. Previous calibration is used until a successful pump calibration is performed. | <ul style="list-style-type: none"> - Perform Pump Troubleshooting procedure. - Contact Radiometer service representative. |
| 564 | No Cleaning Solution detected by Oxi liquid sensor during initializing. | No Cleaning Solution was detected by Oxi module during Startup. | <ul style="list-style-type: none"> - Check the Cleaning solution for sufficient volume. Replace as necessary. - Perform Fluid transport troubleshooting procedure. |
| 567 | No Cal 2 Solution detected by Oxi liquid sensor during initializing | No Cal 2 Solution was detected by Oxi module during Startup. | <ul style="list-style-type: none"> - Check the Cal 2 solution for sufficient volume. Replace as necessary. - Perform Fluid transport troubleshooting procedure. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|---------|---|---|---|
| 569 | No Cal 1 Solution detected by Oxi liquid sensor during initializing | No Cal 1 Solution was detected by the Oxi module during Startup. | Check the Cal 1 solution for sufficient volume. Replace as necessary. - Perform Fluid transport troubleshooting procedure. |
| 571 | No Rinse Solution detected by OXI liquid sensor during initializing | No Rinse Solution was detected by the OXI module during Startup. | - Check the Rinse solution for sufficient volume. Replace as necessary. - Perform Fluid transport troubleshooting procedure. |
| 573 | Oximetry hardware error | The OXI module has a hardware error. | - Perform a 2-point calibration. - Contact Radiometer Service Representative if the problem persists. |
| 574 | Oximetry calibration error | The measuring system has no calibration data. It is not possible to make a measurement. | - Perform a 2-point calibration. - Contact Radiometer Service Representative. Removal condition: Successful 2-point calibration. |
| 577-578 | Option key error | An error occurred in the analyzer protection system. The analyzer cannot be used. | - Shut down the analyzer using the Temporary Shutdown function, then restart it. - Contact Radiometer Service Representative. Removal condition: Key installed correctly and accepted by analyzer. |
| 579 | Oximetry hardware problem. Not possible to measure. | Parameter cannot be reliably measured because of a hardware problem. | Perform a 2-point calibration. - Contact Radiometer service representative. Removal condition: No errors detected by oximetry hardware. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|--|---|
| 580 | Oximetry hardware problem. Possible to measure. | A hardware problem exists in the OXI module. Parameter can be measured. | <ul style="list-style-type: none"> - Perform a 2-point calibration. - Contact Radiometer service representative. <p>Removal condition: No errors detected by oximetry hardware.</p> |
| 581 | Oximetry measuring error | Spectrum deviates from expected blood or QC spectrum. Measurement may be unreliable. | <ul style="list-style-type: none"> - Check patient record for medication containing possible interfering substances. - Call a 2-point calibration. - Contact Radiometer Service Representative. |
| 582 | tHb calibration outside limits | tHb calibration failed. | <p>Repeat tHb calibration.</p> <p>Removal condition: Successful tHb calibration.</p> |
| 583 | Measured value outside reportable range for the parameter | The parameter value is outside the defined reportable range or the analyzer measurement range. | <ul style="list-style-type: none"> - Check for and remedy other errors in the result, and any errors in System Messages or Calibration Status. - Perform QC. If the QC result value lies within the measuring range, the blood sample may be suspected. - Perform the Electrode Troubleshooting procedure. |
| 588 | Measured QC value lower than statistical range | The parameter value is below the lower limit of the user-defined statistical range. Measurement is not included in statistics. | <ul style="list-style-type: none"> - Verify procedure and repeat the measurement. - Refer to the Quality Control Systems Reference Manual for details on the evaluation of the results. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|---|--|
| 589 | Measured QC value higher than statistical range | The parameter value is above the upper limit of the user-defined statistical range. Measurement not included into statistics. | <ul style="list-style-type: none"> - Verify procedure and repeat the measurement. - Refer to the Quality Control Systems Reference Manual for details on the evaluation of the results. |
| 593 | Insufficient sample | Sample volume is too small for the selected measuring mode. Affected parameters will be marked with "?". | <ul style="list-style-type: none"> - Make sure sample volume matches the selected measuring mode. - Repeat the measurement, ensuring sufficient sample volume. - Contact Radiometer service representative. |
| 597 | Liquid detected in pH/BG module during Gas Calibration | Unexpected liquid is detected by the pH/BG module during calibration. Calibration is aborted. | <ul style="list-style-type: none"> - Repeat calibration. - Perform Fluid transport troubleshooting procedure. |
| 600 | Demo option will expire soon | One or more currently installed demo options will expire and be removed within the next 7 days. | <p>To have the option permanently, contact a Radiometer sales or service representative.</p> <p>Removal condition: Options expired or permanent options installed.</p> |
| 604 | Parameter not installed | Parameter was not installed or is corrupted. Parameter cannot be measured. | Contact Radiometer service representative. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---------------------------------|---|---|
| 605 | Cal expired | Too long time passed since the last successful calibration of the parameter. Calibrations of the parameter are considered invalid and values reported as ".....". | Perform 1- or 2-point calibration. Removal condition: Successful 1- or 2-point calibration. |
| 606 | Cal expired (pH) | | |
| 608 | Cal expired (pCO ₂) | | |
| 609 | Cal expired (pO ₂) | | |
| 610 | Cal expired (K) | | |
| 611 | Cal expired (Na) | | |
| 612 | Cal expired (Ca) | | |
| 613 | Cal expired (Cl) | | |
| 614 | Cal expired (Glu) | | |
| 615 | Cal expired (Lac) | | |
| 616 | Cal expired (OXI) | | |
| 618 | Waste detector error | The waste detector may be faulty or damaged. | Contact Radiometer service representative. Removal condition: Functioning waste detector installed. |
| 619 | Waste container missing | The waste container is missing or improperly mounted. | Mount the waste container properly. Removal condition: Waste container properly mounted. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---------------------------------|--|--|
| 620 | Waste container full | Waste container is filled to near-maximum capacity. Unless replaced soon, the analyzer will enter Standby until the container is replaced. | Replace waste container. Removal condition: Empty Waste container installed. |
| 621 | Waste container critically full | The waste container is filled to maximum capacity. The analyzer enters Standby mode; no measurements or calibrations can be performed. | Replace waste container. Removal condition: Empty Waste container installed. |
| 622 | Expected liquid level below 0 | One or more of the solution barcodes was entered incorrectly during replacement. The analyzer cannot monitor solution consumption. | Check the solution containers and replace as necessary. Remember to scan barcodes. Removal condition: Solution containers correctly installed and solution barcodes correctly recorded by the analyzer. |
| 623 | Solution empty | Wet section activities are suspended due to one or more empty solution containers. | Check the solution levels and replace containers as necessary. Removal condition: Sufficient level of all solutions. |
| 624 | Solution missing | One or more solution containers is missing or improperly mounted. | Check that all solution containers are mounted properly. Removal condition: All solution containers are mounted correctly. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|---|---|
| 628 | No Cleaning Solution detected by Oxi liquid sensor during Refill | OXI module was not filled correctly with Cleaning Solution. | <ul style="list-style-type: none"> - Check Cleaning solution level in the container. Replace as necessary. - Perform Fluid transport troubleshooting procedure. |
| 630 | No Cal 2 Solution detected by Oxi liquid sensor during Refill | OXI module was not filled correctly with Cal 2 Solution. | <ul style="list-style-type: none"> - Check Cal 2 Solution level in the container. Replace as necessary. - Perform Fluid transport troubleshooting procedure. |
| 632 | No Cal 1 Solution detected by Oxi liquid sensor during Refill | OXI module was not filled with Cal 1 Solution. | <ul style="list-style-type: none"> - Check Cal 1 Solution level in the container. Replace as necessary. - Perform Fluid transport troubleshooting procedure. |
| 634 | No Rinse Solution detected by Oxi liquid sensor during Refill | OXI module was not filled with Rinse Solution. | <ul style="list-style-type: none"> - Check Rinse Solution level in the container. Replace as necessary. - Perform Fluid transport troubleshooting procedure. |
| 636 | Gas 1 cylinder low pressure | Low pressure level is detected in Gas 1 cylinder. | <p>Replace the Gas 1 cylinder within a few days.</p> <p>Removal condition: Sufficient pressure in Gas 1 cylinder.</p> |
| 637 | Gas 2 cylinder low pressure | Low pressure level is detected in Gas 2 cylinder. | <p>Replace the Gas 2 cylinder within a few days.</p> <p>Removal condition: Sufficient pressure in Gas 2 cylinder.</p> |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|--|--|
| 641 | ABL/DMS PC restarted | The analyzer was restarted from power off. | No action required. For information only. |
| 644 | Missing sample at EI/Met module in C95 uL mode | The EI/Met module was not filled properly with sample. Measurement is aborted. | - Check pump tubing in EI/Met module and solution pump. Replace as necessary. - Contact Radiometer service representative. |
| 648 | Calibration failed or not accepted | The last calibration was aborted or not accepted. | - Check solution levels and replace containers as necessary. - Check for and remedy System Messages. - Repeat the calibration. Removal condition: Successful calibration. |
| 652 | Oxi liquid sensor did not receive Rinse from the Fluidic module | Rinse solution was not detected by the OXI module. | - Check Rinse Solution for sufficient volume and proper mounting. Replace as necessary. - Perform Fluid transport troubleshooting procedure. Removal condition: Successful Rinse. |
| 653 | Sample in pH/BG upper liquid sensor detected prematurely during aspiration | pH/BG module was not filled correctly during sample aspiration. | - Ensure sample is free of clots. - Repeat measurement. - Perform Fluid transport troubleshooting procedure. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|--|--|
| 654 | Sample in EI/Met upper liquid sensor detected prematurely during aspiration | EI/Met module was not filled correctly during sample aspiration. | <ul style="list-style-type: none"> - Ensure sample is free of clots. - Repeat measurement. - Perform Fluid transport troubleshooting procedure. |
| 655 | Sample in pH/BG upper liquid sensor detected prematurely during aspiration | pH/BG module was not filled correctly during sample aspiration. | <ul style="list-style-type: none"> - Ensure sample is free of clots. - Repeat measurement. - Perform Fluid transport troubleshooting procedure. |
| 656 | Sample in OXI liquid sensor detected prematurely during aspiration | OXI module was not filled correctly during sample aspiration. | <ul style="list-style-type: none"> - Ensure sample is free of clots. - Repeat measurement. - Perform the Fluid Transport Troubleshooting procedure. |
| 658 | Inlet flaps removed | The analyzer entered HOLD because both inlet flaps were removed. | <p>Ensure the inlet flaps are properly mounted prior to restart.</p> <p>Removal condition: Inlet flaps properly mounted.</p> |
| 659 | Cover removed or window opened | The analyzer entered HOLD because the cover was removed or the window to the electrode modules opened. | <p>Position the cover and close the window prior to restart.</p> <p>Removal condition: Cover in position and window closed.</p> |
| 660 | Inlet calibration error | An error occurred during Inlet calibration. Analyzer entered HOLD mode. | <ul style="list-style-type: none"> - Remove the inlet gasket. - Inspect the gasket and inlet probe. Replace as necessary. - Press Restart. <p>Removal condition: Successful Inlet calibration</p> |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|------------------------|--|---|
| 661 | Leak detected | A leak was detected. The analyzer entered HOLD mode. | <ul style="list-style-type: none"> - Remove the analyzer covers and inspect the fluid transport system for leaks. - Check the inlet gasket, pump tubes and ensure electrodes are mounted correctly. Repair as necessary - Restart the analyzer. During restart the analyzer performs a leak detection. <p>Removal condition: Leak test completed without any leaks detected.</p> |
| 662 | Barometer out of range | Measured barometer value is outside the measuring range: 60-106.7 kPa. | Contact Radiometer service representative. |
| 663 | Leakage | A leak was detected in the fluid transport system. | <ul style="list-style-type: none"> Remove the analyzer covers and inspect the fluid transport system for leaks. - Check the inlet gasket, pump tubes and ensure electrodes are mounted correctly. Repair as necessary. - Restart the analyzer. During restart the analyzer performs a leak detection. <p>Removal condition: Leak test completed without any leaks detected.</p> |
| 664 | Sample problem | A problem was detected during sample transport through the analyzer. | <ul style="list-style-type: none"> - Check the sample for clots. - Ensure sample volume matches selected sample mode. - Perform the Fluid Transport Troubleshooting procedure. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|--|---|
| 671 | Analyzing Unit service setup non-default | An option in the service setup was changed from default setting. | Contact Radiometer service representative. Removal condition: Options restored to default values. |
| 677 | Unreliable | A measurement or calibration was attempted during "Conditioning error in EI/Met electrode module". | - Check whether Conditioning error (525) was reported during the last analyzer activity. If not, repeat measurement/calibration. - Check Rinse Solution level in the container. - Perform Rinse. Removal condition: Rinse without Conditioning error. |
| 678 | Heater error | One or more measuring modules are over-heated. | - Ensure the ambient temperature is between 15 and 32 degrees Celsius. - Shut down the analyzer using the Temporary Shutdown function, then restart the analyzer. - Replace fan filter if dirty. - Shield analyzer from direct sunlight and other heat sources. - Contact Radiometer Service Representative. Removal condition: Analyzer temperature within required range. |
| 679 | Barometer error | Measured parameter may be unreliable due to barometer error. | Contact Radiometer service representative. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--------------------------|--|--|
| 680 | pH/BG module not active | The pH/BG module is not responding due to internal communication problem. | <ul style="list-style-type: none"> - Shut down the analyzer using the Temporary Shutdown function, then restart it. - Contact Radiometer Service Representative. Removal condition: pH/BG module ready. |
| 681 | El/Met module not active | The El/Met module is not responding due to internal communication problem, or software configuration does not match the analyzer type. | <ul style="list-style-type: none"> - Shut down the analyzer using the Temporary Shutdown function, then restart it. - Contact Radiometer Service Representative. Removal condition: El/Met module ready, or software configured without El/Met module support. |
| 682 | Oxi module not active | The Oxi module is not responding due to internal communication problem, or software configuration does not match the analyzer type. | <ul style="list-style-type: none"> - Shut down the analyzer using the Temporary Shutdown function, then restart it. - Contact Radiometer Service Representative. Removal condition: OXI module ready, or software configured without OXI module support. |
| 683 | Inlet module not active | The inlet module is not responding due to internal communication problem. | <ul style="list-style-type: none"> - Shut down power using the Temporary Shutdown function, then restart the analyzer. - Contact Radiometer Service Representative. Removal condition: Inlet module ready. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|--|---|
| 688 | ctHb/ceHb too low for OXI calculation | ctHb < 1 mmol/L or ceHb < 0.75 mmol/L. If ctHb is too low FHHb, FO ₂ Hb, FCOHb and FmetHb are not calculated. If ceHb = cHHb + cO ₂ Hb is too low sO ₂ is not calculated. | Informative message. No analyzer error detected. |
| 689 | Gas pressure offset voltage out of range. | The gas pressure offset voltage measured by the transducer is out of range: 0.07-0.35 V. | <ul style="list-style-type: none"> - Restart analyzer. - Contact Radiometer service representative. Removal condition: Gas pressure transducer offset within the required range. |
| 692 | ABL not connected to RADIANCE | The analyzer is not connected to RADIANCE. | Contact your RADIANCE /IT engineer. <ul style="list-style-type: none"> - Check RADIANCE communication setup including TCP/IP address, port No. and password. - Check that RADIANCE is responding. - Check network connections. Removal condition: RADIANCE connection established or disabled. |
| 693 | ABL not connected to RADIANCE - incorrect password. | The analyzer was refused connection to RADIANCE due to incorrect password. | Enter the correct password in the analyzer's RADIANCE Communication setup. Removal condition: RADIANCE connection established or disabled. |
| 694 | ABL connected to RADIANCE | The analyzer is connected to RADIANCE. | No action required. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|---|--|
| 695 | ABL disconnected from RADIANCE | The analyzer was disconnected from RADIANCE. | No action required. |
| 696 | ABL <> RADIANCE communication error | Communication error between the analyzer and RADIANCE. | Contact Radiometer service representative. |
| 697 | Requested AutoCheck QC ampoule not present in carousel | A scheduled QC ampoule was absent in the carousel. | Refill AutoCheck carousel according to the packing list. |
| 698 | Performing AutoCheck on last ampoule in schedule instead of non-present | If the scheduled QC ampoule was absent in the carousel, the analyzer performs QC measurement on the ampoule scheduled previously. | Refill AutoCheck carousel according to the packing list. |
| 699 | AutoCheck QC measurement started due to calibration error | The analyzer was set up to perform AutoCheck measurements in case of 1- or 2-point calibration errors. | Check Calibration Status and remedy any reported calibration errors. |
| 700 | Scheduled AutoCheck not run due to errors in last calibration | Last calibration contained an error, and the analyzer was set up to suspend AutoCheck measurements in case of calibration errors. | Check Calibration Status and remedy calibration errors. |
| 703 | QC expired | QC measurement is overdue (corrective action "Lock analyzer" has been selected in Setup program Corrective Actions). | Perform a quality control measurement. Removal condition: No QC measurements are pending. |
| 704 | AutoCheck QC measurement is repeated | The scheduled QC measurement was not accepted; the measurement was repeated as requested in Setup program Corrective Actions. | No action required. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|--|--|
| 705 | AutoCheck QC measurement is repeated twice | The scheduled QC measurement was not accepted; the measurement was repeated twice as requested in Setup program: Corrective Actions. | No action required. |
| 707 | Replacement overdue by 10%. Analyzer locked | Replacement is overdue by 10% (corrective action "Lock analyzer" was selected in Setup program: Corrective Actions). When the analyzer is locked, scheduled calibrations are performed, but no patient samples or QC measurements are allowed. | - Check Replacement Status and replace as required. - Unlock analyzer in Miscellaneous Setup program. Removal condition: No replacement pending. |
| 708 | Corrective action not possible due to empty AutoCheck carousel | Scheduled AutoCheck measurement was requested, but the carousel was empty. | Refill AutoCheck carousel. |
| 709 | El/Met module not expected | Software configuration does not match analyzer type. | Contact Radiometer service representative. Removal condition: Matching software and hardware configuration. |
| 710 | OXI module not expected. | Software configuration does not match analyzer type. | Contact Radiometer service representative. Removal condition: Matching software and hardware configuration. |
| 711 | Warning: DysHb high | Blood sample has a high level of DysHb. $FCO_{Hb} + FMetHb > 5\%$. | Informative message. No analyzer error was detected. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|--------------|--------------------------------|---|--|
| 712 | FHbF measurement not possible | Composition of blood sample makes FHbF measurement too inaccurate, but OXI parameters are corrected for HbF. See explanation in the <i>Reference Manual</i> . | Informative message. No analyzer error was detected. |
| 713 | ctBil measurement not possible | Blood sample ctHb is so high that nearly no plasma is left to measure plasma bilirubin on. ctHb > 15.5mmol/L. | Informative message. No analyzer error was detected. |
| 714, 740-743 | AutoCheck mechanical error | A mechanical error occurred in one of the AutoCheck sub-modules. | - Check the AutoCheck module cover. Close if opened. - If error persists, contact Radiometer service representative. |
| 715 | AutoCheck communication error | Communication error between AutoCheck submodules. | - Shut down the analyzer using the Temporary Shutdown function, then restart the analyzer. - Contact Radiometer Service Representative. |
| 716 | AutoCheck cover missing | The cover was removed from the AutoCheck module. | Mount the AutoCheck cover. Removal condition: AutoCheck cover is mounted correctly. |
| 717 | Carousel packing not optimal | The AutoCheck carousel was not packed according to the schedule. | Repack AutoCheck carousel according to the packing list. Removal condition: AutoCheck carousel packed according to Packing list. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|--|---|
| 718 | AutoCheck carousel will need refilling soon | AutoCheck ampoule stock is low. | Refill AutoCheck carousel when convenient. Removal condition: AutoCheck refilled. |
| 719 | Insufficient sample in pH/BG module | Air bubbles were detected in the sample with possible implications on measurement accuracy. All parameters are marked with "?". | - Ensure that sample is free of air bubbles. - Ensure that sample volume matches the selected sample mode. - Check inlet tube. Replace if necessary. - Repeat the measurement. |
| 720 | Insufficient sample at El/Met module | Air bubbles were detected in the sample with possible implications on measurement accuracy. All affected parameters are marked with "?". | - Ensure that sample is free of air bubbles. - Ensure that sample volume matches the selected sample mode. - Check inlet tube. Replace if necessary. |
| 721 | Insufficient sample in Met II module | Air bubbles were detected in the sample with possible implications on measurement accuracy. All affected parameters are marked with "?". | - Repeat measurement. |
| 722 | Sample error | Insufficient or inhomogeneous sample during measurement. | - Check and remedy other fluid transport errors. - Repeat the measurement. |
| 723 | No Cleaning Solution detected by inlet during Startup | pH/BG module was not filled correctly with Cleaning Solution during Startup. | - Check Cleaning solution level. Replace container as necessary. - Perform Fluid transport troubleshooting procedure. |
| 724 | No Cal 2 Solution detected by inlet during Startup | pH/BG module was not filled correctly with Cal 2 Solution during Startup. | - Check Cal 2 solution level. Replace container as necessary. - Perform Fluid transport troubleshooting procedure. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|---|--|
| 725 | No Cal 1 Solution detected by inlet during Startup | pH/BG module was not filled correctly with Cal 1 Solution during Startup. | - Check Cal 1 solution level. Replace container as necessary. - Perform Fluid transport troubleshooting procedure. |
| 726 | No Rinse Solution detected by inlet during Startup | pH/BG module was not filled correctly with Rinse Solution during Startup. | - Check Rinse solution level. Replace container as necessary. - Perform Fluid transport troubleshooting procedure. |
| 727 | No Cleaning Solution detected by inlet during Refill | pH/BG module was not filled correctly with Cleaning Solution during Refill. | - Check Cleaning solution level. Replace container as necessary. - Perform Fluid transport troubleshooting procedure. |
| 728 | No Cal 2 Solution detected by inlet during Refill | pH/BG module was not filled correctly with Cal 2 Solution during Refill. | - Check Cal 2 solution level. Replace container as necessary. - Perform Fluid transport troubleshooting procedure. |
| 729 | No Cal 1 Solution detected by inlet during Refill | pH/BG module was not filled correctly with Cal 1 Solution during Refill. | - Check Cal 1 solution level. Replace container as necessary. - Perform Fluid transport troubleshooting procedure. |
| 730 | No Rinse Solution detected by inlet during Refill | pH/BG module was not filled correctly with Rinse Solution during Refill. | - Check Rinse solution level. Replace container as necessary. - Perform Fluid transport troubleshooting procedure. |
| 731 | Met II upper liquid sensor did not receive Rinse from above | Met II module was not filled correctly during Rinse program; automatic Refill is attempted. | - Check the Rinse Solution for sufficient volume. Replace as required. - Perform Fluid transport troubleshooting procedure. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|---|---|
| 734 | DMS not connected to Analyzing Unit | Data management system establishes connection to the Analyzing Unit, or the connection is lost. | <ul style="list-style-type: none"> - Wait a few minutes for the connection to establish. - Restart the analyzer. - If the error persists, contact Radiometer service representative. |
| 738 | Ampoule(s) in AutoCheck carousel not installed | AutoCheck carousel contains an ampoule which was not selected in Control Solutions Setup program. | <p>Read in the barcodes for all ampoules present in AutoCheck carousel – use inserts.</p> <p>Removal condition: Barcodes read in for all ampoules present in the AutoCheck carousel.</p> |
| 739 | Solution's composition not identifiable | AutoCheck ampoule solutions do not match labeling. | <ul style="list-style-type: none"> - Repeat measurement. - Contact Radiometer service representative if the problem persists. |
| 744 | AutoCheck Laser Setup Error | AutoCheck barcode reader has failed. | <ul style="list-style-type: none"> - Restart analyzer. - If the error persists, contact Radiometer service representative. |
| 745 | Low hard disk space | Free hard disk space is below 100 Mb. | <p>Move archive files to another storage device.</p> <p>Removal condition: More than 100 Mb of free hard disk space.</p> |
| 746 | Rinse Solution low warning | Rinse Solution level is below the defined warning level. | <p>Replace container as required.</p> <p>Removal condition: Solution level above warning level.</p> |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|---|--|
| 747 | Cal 1 solution low warning | Cal 1 Solution level is below the defined warning level. | Replace container as required. Removal condition: Solution level above warning level. |
| 748 | Cal 2 Solution low warning | Cal 2 Solution level is below the defined warning level. | Replace container as required. Removal condition: Solution level above warning level. |
| 749 | Cleaning Solution low warning | Cleaning Solution level is below the defined warning level. | Replace container as required. Removal condition: Solution level above warning level. |
| 750 | Solution projection adjusted | The estimated solution level was adjusted by the operator. | No action required. |
| 751 | <p>Message 751 is only found in the Activity Log to inform the user about activities that have taken place. The message is blank (empty) in the database, and when an activity occurs the actual status information is appended to it resulting in the logged 751-message.</p> <p>If the setting "Log All Measuring Activities" is enabled in Miscellaneous Setup, all wet section activities will be logged in the Activity Log as 751-messages.</p> | | |
| 753 | Service Electrode Updatings enabled | Logging of sensor signals was enabled. This may be due to ongoing technical service activities on the analyzer. The condition does not affect analyzer functions. | Contact Radiometer service representative if logging was not enabled on purpose. Removal condition: Electrode signal logging disabled by Radiometer service representative. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|---|--|
| 763 | AutoCheck temperature out of required range | The QC temperature was outside the range valid for the temperature correction algorithms. | <ul style="list-style-type: none"> - Ensure the ambient temperature is between 15 and 32 degrees Celsius. - If the system has just performed a cold start, wait for error to disappear. - Replace fan filter if dirty. - Shield analyzer from direct sunlight and other heat sources. - Contact Radiometer Service Representative. Removal condition: AutoCheck temperature within the required range. |
| 764 | Liquid detected in pH/BG module during Expired Air sample | Liquid sample detected during aspiration in the Expired Air mode. | Do not use the Expired Air mode for liquid samples. |
| 765 | Inlet flow impeded | Inlet flow is impeded by some foreign matter. | <ul style="list-style-type: none"> - Perform Inlet troubleshooting procedure. - Perform the Protein Removal program. Removal condition: Inlet has no obstructions. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|---|---|
| 766 | ABL not connected to RADIANCE – no RADIANCE connection license | The analyzer has been refused connection to RADIANCE because there is no connection licence available on RADIANCE. | Contact RADIANCE /IT engineer or Radiometer service representative. Removal condition: Connection to RADIANCE established. |
| 767 | ABL not connected to RADIANCE – ABL StatLink version too high | The analyzer has been refused connection to RADIANCE because the ABL StatLink version is higher than the RADIANCE StatLink version. | Contact RADIANCE /IT engineer or Radiometer service representative. Removal condition: RADIANCE connection established. |
| 768 | ABL not connected to RADIANCE – ABL StatLink version too low | The analyzer has been refused connection to RADIANCE because the ABL StatLink version is lower than the RADIANCE StatLink version. | Contact RADIANCE /IT engineer or Radiometer service representative. Removal condition: RADIANCE connection established. |
| 770 | Failed to restore Custom Setup | The setup could not be restored. | - Download the setup data from another floppy disk, hard disk or network. - Contact Radiometer service representative if the error persists. |
| 771 | Succeeded to restore Custom Setup | Restoring of setup is completed. | No action required. |
| 772 | User Activity: | User activity logged by operator. | No action required. |
| 773 | Remote operator logged on with user: | A remote operator has logged on the analyzer via NetOp | No action required. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--------------------------------------|---|--|
| 774 | Remote operator logged off with user | An operator, remotely logged on via NetOp, has logged off or has been logged off by a local operator. | No action required. |
| 775 | Failed to restore Default Setup | Restoring analyzer setup to default values has failed. | Contact Radiometer service representative. |
| 776 | Succeeded to restore Default Setup | Restoring setup to default values is completed. | No action required. |
| 778 | Inlet gasket should be replaced soon | Inlet gasket is nearly worn out and should be replaced soon. | Replace inlet gasket. |
| 779 | Cleaning failed | The last Cleaning was aborted or interrupted. | <ul style="list-style-type: none"> - Check solution level and replace container as necessary. - Check for and remedy System Messages. - Repeat Cleaning. Removal condition: Successful Cleaning. |
| 780 | RADIANCE communication enabled | RADIANCE communication has been enabled as part of the RADIANCE Connection Setup. | Informative message. No action required. |
| 781 | RADIANCE communication disabled | RADIANCE communication has been disabled as part of the RADIANCE Connection Setup. | Informative message. No action required. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|--|---|
| 782 | RADI- ANCE output queue cleared | The output queue was cleared in RADIANCE Connection Setup. | Informative message. No action required. |
| 783 | Automatic backup started | Automatic backup (selected in Disk Functions Setup) has started. | Informative message. No action required. |
| 785 | Automatic archiving started | Automatic archiving (selected in Disk Functions Setup) has started. | Informative message. No action required. |
| 786 | Automatic archiving completed | Automatic archiving (selected in Disk Functions Setup) completed successfully. | Informative message. No action required. |
| 787 | Export of data logs started | Export of data logs was started by the user. | Informative message. No action required. |
| 788 | Hypochlorite detected - remembrane Glu, Lac, Cl and both Crea electrodes | <p>Measurement on a substance resembling hypochlorite has been performed.</p> <p>Any installed Glu, Lac, Cl and Crea electrodes have been damaged and must be remembraned before blood measurements can be performed.</p> <p>As a precaution all parameters are marked with 'Calibration Expired'.</p> | <p>- Remembrane any installed Glu, Lac, Cl and Crea (A and B) electrodes.</p> <p>- Perform a 2-point calibration.</p> <p>Removal condition: Successful 2-point calibration.</p> |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---------------------------------|--|---|
| 790 | Adaptive measuring mode applied | Due to insufficient or inhomogeneous sample, the analyzer has automatically chosen an adaptive sample handling in order to report as many of the desired parameters as possible. | If missing parameters are needed, repeat the measurement with sufficient sample free of clots and air bubbles. |
| 791 | Parameter could not be measured | Due to insufficient or inhomogeneous sample, the parameter in question could not be measured. | If missing parameters are needed, repeat the measurement with sufficient sample free of clots and air bubbles. |
| 792 | Liquid sensor calibration error | Inlet lower liquid sensor failed to calibrate. | <ul style="list-style-type: none"> - Repeat liquid sensor calibration. - Perform the Fluid Transport Troubleshooting procedure. - Contact Radiometer service representative. |
| 793 | pH/BG pump asymmetry error | The pH/BG module pump failed to calibrate pump asymmetry. The same calibration values will be used for both directions until a successful calibration of pump asymmetry is performed. | <ul style="list-style-type: none"> - Perform the Pump troubleshooting procedure. - Contact Radiometer service representative. |
| 794 | El/Met pump asymmetry error | The El/Met module pump failed to calibrate pump asymmetry. The same calibration values will be used for both directions until a successful calibration of pump asymmetry is performed. | <ul style="list-style-type: none"> - Perform the Pump troubleshooting procedure. - Contact Radiometer service representative. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|---|---|
| 795 | Met II pump asymmetry error | The Met II module pump failed to calibrate pump asymmetry. The same calibration values will be used for both directions until a successful calibration of pump asymmetry has been performed. | - Perform the Pump troubleshooting procedure. - Contact Radiometer service representative. |
| 796 | Solution pump asymmetry error | The Solution module pump failed to calibrate pump asymmetry. The same calibration values will be used for both directions until a successful calibration of pump asymmetry is performed. | - Perform the Pump Troubleshooting procedure. - Contact Radiometer service representative. |
| 797 | Waste pump asymmetry error | The Waste pump in the Solution module failed to calibrate pump asymmetry. The same calibration values will be used for both directions until a successful calibration of pump asymmetry is performed. | - Perform the Pump Troubleshooting procedure. - Contact Radiometer service representative. |
| 798 | User logged on | User logged on successfully. | No action required. Informative message. |
| 799 | User logged off | User logged off. | Informative message. No action required. |
| 800 | Logon attempt failed | User tried to log on but did not provide a valid password. | Provide a valid password to log on. |
| 801 | Hard disk S.M.A.R.T. threshold(s) exceeded | The analyzer's hard disk drive has given a warning. This may mean imminent hard disk drive failure. | Contact Radiometer service representative. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|---|--|
| 805 | Adaptive measuring mode applied (decay to pH/BG/Met/Oxi) | Due to insufficient or inhomogeneous sample, the analyzer has automatically chosen an adaptive sample handling in order to report as many of the desired parameters as possible. | - If missing parameters are needed, repeat the measurement with sufficient sample free from clots and air bubbles. |
| 806 | Adaptive measuring mode applied (decay to all micro mode) | | |
| 807 | Unauthorized software | Software option key is not installed. Analyzer cannot be used. | Contact Radiometer service representative. |
| 808 | Calibration drift not available | <p>A calibration drift value could not be calculated, since this is the first calibration result after calibration drift monitoring was started.</p> <p>This message may appear on the first calibration result after the analyzer has been turned on or after the parameter in question has been enabled.</p> <p>A drift value will be calculated for the next calibration result.</p> | No action required. The message is informative. |
| 809 | Service Electrode Updatings disabled | The message is used in the Activity Log to indicate that Service Electrode Updatings have been disabled. | No action required. The message is for information only. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|----------------------|--|---|--|
| 810-827 829, 830 | Parameter locked (pH, pCO ₂ , pO ₂ , cK ⁺ , etc.) | Parameter has been locked by a RADIANCE operator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results. | Await corrective actions initiated by the RADIANCE operator. Removal condition: Determined by the RADIANCE operator. |
| 831-848, 850, 851 | Parameter unlocked (pH, pCO ₂ , pO ₂ , cK ⁺ , etc.) | The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked. | Informative message. No action required. |
| 852 | Radiance: | Message from RADIANCE | Informative message. No action required. |
| 853 | LIS/HIS: Missing Communication Option key | No valid option key for LIS/HIS communication is installed on the analyzer. | Contact Radiometer service representative. |
| 854 | No leading air segment in inlet's lower liquid sensor within time frame | Air segment in front of sample is too small or missing during sample aspiration, possibly due to obstructions in inlet or problems with liquid sensor. Measurement is aborted. | <ul style="list-style-type: none"> - Check inlet for obstructions and clean as required. - Perform liquid sensor adjustment. - Perform the Fluid Transport Troubleshooting procedure. |
| 855 | Base Excess out of range | Base Excess exceeds +/- 30 mmol/L range | Informative message. No analyzer error was detected. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|---|--|
| 862 | pH-only sample handling adapted to 35uL range | To counteract insufficient or inhomogeneous sample, the analyzer has automatically adjusted the sample handling to the sample volume. | None. |
| 864 | pH-only sample handling adapted to 55uL range | | |
| 865 | pH/BG sample handling adapted to 35uL range (decay to pH only) | Due to insufficient or inhomogeneous sample, the analyzer has automatically chosen an adaptive measuring mode in order to report as many of the desired parameters as possible. | If missing parameters are needed, repeat the measurement with sufficient sample free from clots and air bubbles. |
| 867 | pH/BG sample handling adapted to 55uL range | To counteract insufficient or inhomogeneous sample, the analyzer has automatically adjusted the sample handling to the sample volume. | None. |
| 868 | pH/BG/Oxi sample handling adapted to 55uL range | | |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|---|--|
| 869 | Adaptive sample handling applied (decay to pH/Oxi without Bil) | Due to insufficient or inhomogeneous sample, the analyzer has automatically chosen an adaptive measuring mode in order to report as many of the desired parameters as possible. | If missing parameters are needed, repeat the measurement with sufficient sample free from clots and air bubbles. |
| 870 | Adaptive sample handling applied (decay to pH/Oxi) | | |
| 871 | Adaptive sample handling applied (decay to pH/BG/Oxi) | | |
| 872 | Adaptive measuring mode applied (pH/BG/Oxi [2]) | | |
| 873 | Adaptive measuring mode applied (pH/BG/Met/Oxi) | | |
| 874 | Adaptive measuring mode applied (decay to all micro mode) | | |
| 875 | Sample aged | | |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---------------------------|---|---|
| 876 | FLEXQ positioning warning | A problem was detected during positioning of the sampler tray | The message is informative and intended for service use only Removal condition: No FLEXQ positioning problems observed for 24 hours. |
| 877 | FLEXQ positioning error | A sampler in the sampler tray could not be aligned with the syringe inlet; aspiration of the sample was not possible. | <ul style="list-style-type: none"> - Remove all the samplers from the sampler tray (the sampler registration is lost). - If the sampler tray is blocking the syringe inlet or AutoCheck module, try to push it gently to its home position. - If the syringe inlet is not blocked, scan the sampler barcode, using the analyzer's barcode reader and perform a manual measurement. - To get the FLEXQ operational again, restart the analyzer, using Temporary Shutdown and power off/on. - If the error persists, contact Radiometer service representative. - Removal condition: Successful FLEXQ sampler tray calibration. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|--|--|
| 878 | No Rinse solution during calibration | The analyzer was not able to retrieve Rinse solution during calibration. | Check level in Rinse Solution bottle. Replace bottle as necessary. |
| 879 | No Cal1 solution during calibration | The analyzer was unable to retrieve Cal1 solution during calibration. | Check level in Cal1 solution bottle. Replace bottle as necessary. |
| 880 | No Cal2 solution during calibration | The analyzer was unable to retrieve Cal2 solution during calibration. | Check level in Cal2 solution bottle. Replace bottle as necessary. |
| 881 | LIS/HIS: Missing CIC Communication Option Key | No valid Option Key for CIC communication is installed on the analyzer. | Contact Radiometer service representative. |
| 882 | Mixer tray slip detected | A small positioning problem of the mixer tray has been detected and corrected. | <ul style="list-style-type: none"> - Lift the sampler tray cover and check for obstructions in the mixer tray area. - Remove any foreign objects. - Remount the sampler tray cover. Removal condition: Alignment operation performed without slip. |
| 883 | Mixer error | The sample may not have been adequately mixed. | <ul style="list-style-type: none"> - Lift the sampler tray cover and check for obstructions in the mixer tray area. - Remove any foreign objects. - Remount the sampler tray cover. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|--------------|--|---|--|
| 884 | Sampler tray adjustment needed | It was not possible to position one or more samplers directly below the syringe inlet. The affected sampler tray positions in the sampler tray must be adjusted. | Contact your service engineer to perform the Sampler Tray Adjustment procedure. Removal condition: All sampler tray positions are adjusted. |
| 885 | Cyclic QC schedule reset from RADIANCE | The cyclic QC schedule has been reset and all related reminders have been removed as a result of a RADIANCE command. | No action required. Informative message only. |
| 887 | Adaptive measuring mode disabled | Due to insufficient or inhomogeneous sample, the analyzer would normally have chosen an adaptive measuring mode but this option has been disabled. Measurement is aborted. | Repeat the measurement with sufficient sample free from clots and air bubbles. |
| 888-889, 891 | Pump calibration error | The pump calibration failed for one or more pumps. The previous pump calibration is used. A successful pump calibration should be attempted as soon as possible. | - Repeat Pump calibration. - Perform the Pump Troubleshooting procedure. Removal condition: Successful pump calibration. |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|--|--|
| 890 | Error measuring Inlet's liquid sensor to Oxi's liquid sensor volume | During pump calibration, measurement of internal volume part failed. Causes the Fluid Transport Control program to abort. | - Check Rinse Solution for sufficient volume. Replace as necessary. - Perform Pump Calibration. |
| 892 | Inlet not filled properly during pump calibration using reagent as backup | During pump calibration measurement of internal volume part failed. Causes the Fluid Transport Control program to abort. | - Perform the Fluid Transport Troubleshooting procedure. Removal condition: Successful pump calibration. |
| 893 | Sample in Met II's upper liquid sensor detected prematurely during aspiration | Met II module was not filled correctly during sample aspiration. | - Ensure sample is free of clots. - Repeat measurement. - Perform the Fluid Transport Troubleshooting procedure. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|---|--|
| 894 | Adaptive measuring mode applied (pH/BG/Met/Oxi [2]) | Due to insufficient or inhomogeneous sample, the analyzer has automatically chosen an adaptive measuring mode in order to report as many of the desired parameters as possible. | If missing parameters are needed, repeat the measurement with sufficient sample free from clots and air bubbles. |
| 895 | Adaptive measuring mode applied (pH/BG/Met/El/Oxi) | | |
| 896 | Adaptive measuring mode applied (pH/BG/Met/El/Oxi [2]) | | |
| 897 | Adaptive measuring mode applied (pH/BG/Met/El/Oxi [3]) | | |
| 898 | Adaptive measuring mode applied (pH/BG/Met/El/Crea/Oxi) | | |
| 899 | Adaptive measuring mode applied (pH/BG/Met/El/Crea/Oxi [2]) | | |

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Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|---|---|
| 900 | Adaptive measuring mode applied (pH/BG/Met/El/Crea/Oxi [3]) | Due to insufficient or inhomogeneous sample, the analyzer has automatically chosen an adaptive measuring mode in order to report as many of the desired parameters as possible. | If missing parameters are needed, repeat the measurement with sufficient sample free from clots and air bubbles. |
| 901 | Adaptive measuring mode applied (pH/BG/Met/El/Crea/Oxi [4]) | Due to insufficient or inhomogeneous sample, the analyzer has automatically chosen an adaptive measuring mode in order to report as many of the desired parameters as possible. | If missing parameters are needed, repeat the measurement with sufficient sample free from clots and air bubbles. |
| 909 | Met II not filled within time limit | Met II module did not fill properly with calibration solution. Causes the calibration program to abort. | - Check the solution containers for adequate volume. Replace as required. - Perform the Fluid Transport Troubleshooting procedure. Removal condition: Successful calibration. |
| 919 | Inlet not in CONE3 position before timeout prior to wash with cleaning | Inlet was not in proper position within required time frame. The activity is aborted. | - Remove the inlet gasket and inspect the condition of inlet probe and gasket. Replace as necessary. Install all parts. - Restart the analyzer. - Contact Radiometer Service Representative. Removal condition: Successful inlet calibration. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|---------|--|--|---|
| 920-922 | Module not filled within time limit in wash with cleaning | Module did not fill properly with cleaning solution. | <ul style="list-style-type: none"> - Check the solution containers for adequate volume. Replace as required. - Perform the Fluid Transport Troubleshooting procedure. Removal condition: Successful Rinse |
| 923 | Inlet not refilled properly during bi-directional pump calibration | The inlet module was not filled properly during bi-directional pump calibration. | <ul style="list-style-type: none"> - Check Rinse Solution for sufficient volume. Replace as necessary. - Perform Pump Calibration. - Perform the Fluid Transport Troubleshooting procedure. Removal condition: Successful pump calibration. |
| 924 | Inlet's liquid sensor to Oxi's liquid sensor volume could not be confirmed 1 | During pump calibration, measurement of internal volume part failed. Causes the Fluid Transport Control program to abort. | <ul style="list-style-type: none"> - Check Rinse Solution for sufficient volume. Replace as necessary. - Perform Pump Calibration. - Perform the Fluid Transport Troubleshooting procedure. Removal condition: Successful pump calibration. |
| 925 | Inlet's liquid sensor to Oxi's liquid sensor volume could not be confirmed 2 | During pump calibration, measurement of internal volume part failed. Causes the Fluid Transport Control program to abort. | <ul style="list-style-type: none"> - Check Rinse Solution for sufficient volume. Replace as necessary. - Perform Pump Calibration. - Perform the Fluid Transport Troubleshooting procedure Removal condition: Successful pump calibration. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|--|--|
| 926 | Inlet's liquid sensor to Oxi's liquid sensor volume could not be confirmed 3 | During pump calibration, measurement of internal volume part failed. Causes the Fluid Transport Control program to abort. | - Check Rinse Solution for sufficient volume. Replace as necessary. - Perform Pump Calibration. - Perform the Fluid Transport Troubleshooting procedure. Removal condition: Successful pump calibration. |
| 927 | Inlet's liquid sensor to Oxi's liquid sensor volume could not be confirmed 4 | | |
| 928 | Unable to fill Inlet with continuous rinse during pump calibration | | |
| 929 | TIPCAP conflict detected 1 | The detection of the TIPCAP failed. The activity is aborted. | - Remove the inlet flaps and the inlet gasket. Inspect the condition of the inlet probe and gasket. Look for obstructions that may hinder probe movement. Replace as necessary. Install all parts. - Perform the Inlet Probe Troubleshooting Procedure. - Restart the analyzer. - Contact Radiometer Service Representative. Removal condition: Successful inlet calibration. |
| 930 | TIPCAP conflict detected 2 | | |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|---|--|
| 931 | No sample in Met II's lower liquid sensor within time limit | The sample did not fill Met II module properly. The activity is aborted. | <ul style="list-style-type: none"> - Check the sample for clots. - Ensure that sample volume matches selected sample mode. - Perform the Fluid Transport Troubleshooting procedure. |
| 932 | No sample in Met II's upper liquid sensor within time limit | | |
| 934 | Inlet not in CONE3 position before timeout prior to wash with MetCal1 | Inlet probe was not in proper position within the required time limit. | <ul style="list-style-type: none"> - Remove the inlet gasket and inspect the condition of inlet probe and gasket. Replace as necessary. Install all parts. - Restart analyzer. - Contact Radiometer Service Representative. <p>Removal condition: Successful inlet calibration.</p> |
| 935 | Cal1 Solution - Crea will expire soon | <p>The additive used in the Calibration Solution 1 to calibrate Crea will expire soon.</p> <p>This is a warning - the solution lifetime is 14 days.</p> | Replace the solution before the lifetime is actually exceeded. |
| 936 | Cal2 Solution - Crea will expire soon | <p>The additive used in the Calibration Solution 2 to calibrate Crea will expire soon.</p> <p>This is a warning - the solution lifetime is 14 days.</p> | Replace the solution before the lifetime is actually exceeded. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|---|--|
| 937 | Cleaning Solution - Crea will expire soon | The additive used in the Cleaning Solution to measure the High Crea Check will expire soon. This is a warning - the solution lifetime is 14 days. | Replace the solution before the lifetime is actually exceeded. |
| 938 | Cal1 Solution - Crea is expired | The additive used in the Calibration Solution 1 to calibrate Crea is expired. The solution is more than 14 days old. It is no longer possible to calibrate Crea. | Replace the Calibration Solution 1 bottle - remember to add the additive. Removal condition: Fresh bottle installed. |
| 939 | Cal2 Solution - Crea is expired | The additive used in the Calibration Solution 2 to calibrate Crea is expired. The solution is more than 14 days old. It is no longer possible to calibrate Crea. | Replace the Calibration Solution 2 bottle - remember to add the additive. Removal condition: Fresh bottle installed. |
| 940 | Cleaning Solution - Crea is expired | The additive used in the Cleaning Solution to measure the High Crea Check is expired. The solution is more than 14 days old. It is no longer possible to perform the High Crea Check. | Replace the Cleaning Solution bottle - remember to add the additive. Removal condition: Fresh bottle installed. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|---|--|
| 941 | Cal expired (Crea) | Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....". | Perform a 2-point calibration. |
| 942 | Cal expired (Creatine) | | Removal condition: Successful 2-point calibration. |
| 944 | Met II module not expected | Software configuration does not match analyzer type. | Contact Radiometer Service Representative. Removal condition: Matching software and hardware configuration. |
| 945 | Met II module not active | The Met II module is not responding due to internal communication problems, or software configuration does not match the analyzer type. | - Shut down the analyzer using the Temporary Shutdown function, then restart it. - Contact Radiometer Service Representative. Removal condition: Met II module ready, or software configured without Met II module support. |
| 946 | Conditioning error in Met II electrode module | Rinse Solution was not detected in Met II electrode module. The Crea results will be reported as "....." in the next measurement. | - Check Rinse Solution for adequate volume, proper installation or obstructions in bottle opening. - Replace as necessary. - Perform the Fluid Transport Troubleshooting procedure. Removal condition: Successful Rinse. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|---|---|
| 951 | Creatine is below the reportable range | Creatine is below the reportable range. See chapter 14: Specifications in the Operator's Manual. | <ul style="list-style-type: none"> - Check for and remedy other errors related to the result, system messages or calibration status. - Perform QC. If the QC result is accepted, the blood sample may be suspected. - Perform measurement on new blood sample. - Perform the Electrode Troubleshooting procedure. |
| 952 | Creatine is above the reportable range | Creatine is above the reportable range. See chapter 14: Specifications in the Operator's Manual. | <ul style="list-style-type: none"> - Check for and remedy other errors related to the result, system messages or calibration status. - Perform QC. If the QC result is accepted, the blood sample may be suspected. - Perform measurement on new blood sample. - Perform the Electrode Troubleshooting procedure. |
| 953 | Measured QC value above the control range (Crea A) | Creatine value is above the control range. Error on the Creatine measurement is possible. | <ul style="list-style-type: none"> - Verify procedure and repeat measurement. - Refer to Quality Control Systems Reference Manual. |
| 954 | Measured QC value below the control range (Crea A) | Creatine value is below the control range. Error on the Creatine measurement is possible. | <ul style="list-style-type: none"> - Verify procedure and repeat measurement. - Refer to the Quality Control Systems Reference Manual. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|--|---|
| 955 | Measured QC value lower than statistical range (Crea A) | The parameter value is below the lower limit of the user-defined statistical range. Measurement is not included in the statistics. | <ul style="list-style-type: none"> - Verify procedure and repeat the measurement. - Refer to the Quality Control Systems Reference Manual for details on the evaluation of the results. |
| 956 | Measured QC value higher than statistical range (Crea A) | The parameter value is above the upper limit of the user-defined statistical range. Measurement is not included in the statistics. | <ul style="list-style-type: none"> - Verify procedure and repeat the measurement. - Refer to the Quality Control Systems Reference Manual for details on the evaluation of the results. |
| 958 | Solution lifetime exceeded | <p>A solution is more than 14 days old and cannot be used for Crea calibration or High Crea Check.</p> <p>Calibration Solutions:</p> <ul style="list-style-type: none"> - Crea is no longer reported during measurements and is marked red on the parameter bar. <p>Cleaning Solution:</p> <ul style="list-style-type: none"> - It is no longer possible to perform a High Crea Check. | <p>Replace required solution bottle - remember to add the additive.</p> <p>Removal condition: Fresh bottle installed.</p> |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|--|---|--|
| 959 | Crea Calibration Check failed. Possible mix-up. | During a 2-point calibration, the Crea A electrode detects too high a signal in Cal 1. This situation indicates a possible mix-up of either the electrodes or the Calibration Solutions. | <ul style="list-style-type: none"> - Check that the Crea A and Crea B electrodes are placed in the correct measuring chambers. - Check that the Calibration Solutions are placed in the correct positions on the analyzer. - Replace Calibration Solutions and perform a 2-point calibration. - Remembrane both Crea A and Crea B electrodes. <p>Removal condition: Successful 2-point calibration.</p> |
| 960 | Measurement unstable (Crea A) | An electrode response fault occurred during measurement on the Crea A electrode. | <ul style="list-style-type: none"> - Check for and remedy other errors in System Message or Calibration Status. - Repeat the measurement. - Perform any pending replacements, including electrodes. - Ensure the electrode is properly installed. - Ensure the analyzer is properly grounded. - Perform QC. If the QC result value is within the control range, the blood sample may be suspected. Continue troubleshooting. - Perform the Electrode Troubleshooting procedure. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|----------|---|---|---|
| 961 | Total concentration outside measuring range | The total concentration of Crea + Creatine is above the measuring range and the analyzer is not able to measure Crea within the specifications. See chapter 14: Specifications in the Operator's Manual. | - Check for and remedy other errors related to the result, system messages or calibration status. - Perform a High Crea Check. If the High Crea Check result is accepted, the blood sample may be suspected. - Perform measurement on new blood sample. - Perform the Electrode Troubleshooting procedure. |
| 962 | Ambient temperature not defined | Ambient temperature has not been defined by the user in Environment Setup. Until the ambient temperature has been defined, a default value of 25 °C is used during High Crea Check and the internal Crea calibration calculations. Please maintain an ambient temperature between 18 °C and 29 °C | Enter ambient temperature in Environment Setup - see Operator's Manual chapter 3. Removal condition: Ambient temperature entered. |
| 963, 964 | Leak currents detected | Leak currents are detected during calibration and may distort the measuring results. The affected parameters are marked with "?". | Contact Radiometer service representative. |
| 965 | Cleaning – Additive is expired | The Cleaning additive is too old and the Cleaning Solution cannot be used anymore. | Replace Cleaning Solution bottle – remember to add the additive. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|-----|---|--|--|
| 966 | Cleaning – Additive will expire soon | The Cleaning additive will expire soon. | Replace the solution before the lifetime is actually exceeded. |
| 967 | Creatine high. Unable to perform Crea measurement | The Creatine concentration is too high compared to the Crea concentration and the analyzer is not able to measure Crea within the specifications. See chapter 14: Specifications in the Operator's Manual | <ul style="list-style-type: none"> - Check for and remedy other errors related to the result, system messages or calibration status. - Perform a High Crea Check. If the High Crea Check result is accepted, the blood sample may be suspected. - Perform measurement on a new blood sample. - Perform the Electrode Troubleshooting procedure |
| 969 | FLEXQ module not expected | Software configuration does not match analyzer type. | Contact Radiometer Service Representative. Removal condition: Matching software and hardware configuration. |
| 970 | Rilibäk violation: Value above upper limit | | |
| 971 | Rilibäk violation: Value below lower limit | | |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|------|--|---|--|
| 975 | No Cleaning solution | The analyzer was unable to retrieve Cleaning solution during calibration or High Crea Check | Check level in Cleaning solution bottle. Replace bottle as necessary. |
| 977 | Error reading QA Portal configuration file | The file QAPortalSetup.xml was not found or was corrupted. | Check if the file QAPortalSetup.xml is missing in the Abl700 directory (root) and that the file is not empty or corrupted. |
| 978 | pH of Rinse Solution outside range of pH/BG Calibration | | |
| 979 | 1 point pH/BG Calibration upgraded due to large pH drift | | |
| 1010 | Discrepancy between pO_2 and sO_2 | <p>The pO_2 and sO_2 deviates so much from the standard Oxygen Dissociation Curve that an error is assumed. Causes may be:</p> <ul style="list-style-type: none"> - The pO_2 electrode may have measured the pO_2 of a bubble of atmospheric air. - The patient may be treated with Oxygen enriched air yet still have a low oxygenation. - Your ABL is working at high altitude (low atmospheric pressure). | <p>If air bubble is suspected:</p> <ul style="list-style-type: none"> - Make sure, that all air is expelled from the sample prior to mixing. - This includes 'tapping' the sampler to loosen any air adhering to the walls of the sampler. - Repeat sampling and measurement. <p>If the problem occurs repeatedly:</p> <ul style="list-style-type: none"> - Contact your service technician. |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|------|---|----------------|-----------------|
| 1012 | Error writing to QA Portal configuration file | | |
| 1013 | Volume Calibration Failed (Wet Section internal Volume Measurement) | | |
| 1014 | Volume measurement failed: pH/BG module to Oxi's LS | | |
| 1015 | Volume measurement failed: EI/Met module to Oxi's LS | | |
| 1016 | Volume measurement failed: Met II module to Oxi's LS | | |
| 1017 | Volume measurement below limit: pH/BG module to Oxi's LS | | |

Continued on next page

Analyzer messages, *Continued*

Messages at manager level (*continued*)

| No. | Message | Interpretation | Operator action |
|------|--|----------------|-----------------|
| 1018 | Volume measurement below limit: EI/Met module to Oxi's LS | | |
| 1019 | Volume measurement below limit: Met II module to Oxi's LS | | |
| 1020 | Volume measurement above limit: pH/BG module to Oxi's LS | | |
| 1021 | Volume measurement above limit: EI/Met module to Oxi's LS | | |
| 1022 | Volume measurement above limit: Met II module to Oxi's LS | | |
| 1023 | Software Upgrade Initiated | | |
| 1024 | Upgraded From | | |

Fluid transport troubleshooting procedure

Using the troubleshooting procedure The actions are listed in order of priority. It is recommended to perform a step in the procedure below and verify whether or not the error has been remedied. If the error persists, proceed to the next step of the procedure.

- NOTICES:**
- For specific instructions on the replacement of components, refer to the relevant sections of *chapter 7*.
 - Record all replacement actions.

Fluid transport troubleshooting procedure Use the table of solutions below to identify and correct errors in the fluid transport system.

| Step | Action |
|------|---|
| 1. | Remove the analyzer cover to the solutions and call the Rinse program. Observe the flow of solution through the fluid transport system as this may help to identify the problem – see <i>Fluid transport system description</i> for details. And check the fluid transport system for clots. |
| 2. | Remove the cover to the measuring modules and check the following: <ul style="list-style-type: none"> • The electrodes are properly mounted in the measuring chamber and the electrode connector is latched shut. • The pump tubings and connectors have no leaks or damage. • The pump rotor seatings. • The inlet module has no leaks or damaged parts. |
| 3. | Make any necessary repairs. |
| 4. | Mount all the parts and press Restart . |
| 5. | Call the Liquid Sensor Adjustment program (in the Auxiliary Programs). |
| 6. | Call the Pump Calibration program (in the Auxiliary Programs). |
| 7. | Clean the electrodes and the measuring chambers, using distilled water and a cotton swab. |
| 8. | Check the inlet probe and gasket unit for obstructions – see the <i>Inlet probe troubleshooting procedure</i> further in this chapter. |
| 9. | If the error persists, contact a service representative. |

Inlet probe troubleshooting procedure

Causes of error The following conditions are the causes of error:

| Condition | Explanation |
|-------------------------|---|
| Inlet positioning error | This condition occurs when the inlet probe cannot obtain the proper position within a defined time limit. |
| Inlet calibration error | This condition occurs when the calibration of the inlet fails, most likely caused by a problem with the inlet components. |

Procedure To correct the error, do the following:

| Step | Action |
|------|---|
| 1. | Remove the analyzer cover and the inlet flaps. |
| 2. | Check that the inlet probe and gasket are mounted properly. |
| 3. | Remove the inlet gasket and check for wear or damage. Replace as required. If the inlet probe has not retracted, move it in by pressing the probe attachment back. Note that you will feel resistance while moving the probe in. |
| 4. | Check the condition of the inlet probe. If it appears bent or damaged, replace it. |
| 5. | Mount all parts and press Restart . The inlet calibration is performed automatically during restart. The error has been corrected when the analyzer enters the Ready mode. If the error persists, the analyzer remains in the Hold mode. Contact a service representative. |

Inlet troubleshooting procedure

Indication of obstructions in the inlet

The following conditions may indicate an obstruction somewhere in the inlet system.

- No sample flow through the fluid transport system.
- Solution dripping from the inlet.
- Excessive suction noise coming from inlet when waste pump is activated.
- Fluid flowing upwards in the electrode measuring modules during the wrong stage of a rinse.
- Erratic flow of fluid through all three modules and/or excessive air bubbles flowing through the system.
- Lack of fluid movement through the small canals off the waste pump tubes, just above the pump rotor.

If one or more of the above conditions are present, perform the following Inlet troubleshooting procedure.

Procedure

To troubleshoot possible obstructions in the inlet, do the following:

| Step | Action |
|------|---|
| 1. | Remove the inlet gasket unit and inspect its condition. If it appears worn or damaged, replace it. Rinse the gasket and its openings by filling a syringe with distilled water and injecting the water through both the syringe and capillary openings. |
| 2. | Remove the inlet probe and tube. |
| 3. | <ul style="list-style-type: none"> • Fill a syringe with distilled water. • Take the end of the inlet tube, press it firmly against the tip of the syringe and inject the distilled water. The water should stream freely out of the opening at the end of the probe. If not, replace the inlet probe and tube. |
| 4. | Install all parts and press Restart . |

For detailed instructions on removal and/or replacement of parts, refer to *chapter 7: Replacements*.

NOTICE:

The spillage of liquid from the inlet may be caused by damaged waste pump tubes, improper mounting of the inlet gasket unit, clots, etc, so all these factors should be inspected, then corrected or replaced.

Leak troubleshooting procedure

Leak error This condition occurs when a leak detection program has failed, possibly indicating a leak in the fluid transport system.

Procedure To correct the error, do the following:

| Step | Action |
|-------------|---------------|
|-------------|---------------|

-
1. Remove the analyzer covers and inspect the fluid transport system for poor tube connections or worn tubes. Repair as required.
 2. Ensure that electrodes are properly mounted in the measuring chamber and the electrode connector is latched shut.
 3. Mount all parts and press ***Restart***.

The leak detection is performed automatically during the restart. The error is corrected when the analyzer enters the Ready mode.

If the error persists, the analyzer remains in the Hold mode. Contact a service representative.

Electrode troubleshooting procedures

Using the procedures

The actions are listed in order of priority. It is recommended to perform each action and verify whether or not the error has been remedied. If not, proceed to the next step.

pH, cK^+ , cNa^+ , cCa^{2+} , and cCl^- troubleshooting procedure

To troubleshoot pH, cK^+ , cNa^+ , cCa^{2+} , and cCl^- electrodes, do the following:

| Step | Action |
|------|---|
| 1. | <u>The pH electrode only:</u> Clean the electrode, using a cotton swab moistened with Cleaning Solution. |
| 2. | Check the measuring chamber for clots: clean the measuring chamber with a cotton stick moistened with distilled water. Make sure that no cotton fibers are left in the measuring chamber. |
| 3. | Replace the electrode membrane (not the pH electrode). |
| 4. | Call a 2-point calibration. If the error persists, replace the electrode. |

If an error has occurred on two or more parameters, troubleshoot the reference electrode.

Reference electrode troubleshooting procedure

To troubleshoot the reference electrode, do the following:

| Step | Action |
|------|--|
| 1. | Remove the electrode and check the measuring chamber for clots: clean the measuring chamber with a cotton stick moistened with distilled water. Make sure that no cotton fibers are left in the measuring chamber. |
| 2. | Replace the electrode membrane. |
| 3. | Call a 2-point calibration. If the error persists, replace the electrode. |

pCO_2 and pO_2 troubleshooting procedure

To troubleshoot the pCO_2 and pO_2 electrodes, do the following:

| Step | Action |
|------|--|
| 1. | Remove the electrode and check for air bubble(s) trapped between the electrode tip and the membrane. If any air bubbles exist, remove them by pressing the tabs on the electrode jacket and moving the electrode slightly up and down until they dissipate. |
| 2. | Replace the electrode membrane. The pO_2 electrode: brush the electrode tip with the supplied brush before remembraning the electrode. |
| 3. | Call a 2-point calibration. If the error persists, replace the electrode. |

Continued on next page

Electrode troubleshooting procedures, *Continued*

cGlu and cLac troubleshooting procedure To troubleshoot the cGlu and cLac electrodes, do the following:

| Step | Action |
|------|--|
| 1. | Remove the electrode and check the measuring chamber for clots; clean the measuring chamber with a cotton stick moistened with distilled water. Make sure that no cotton fibers are left in the measuring chamber. |
| 2. | Replace the electrode membrane. |
| 3. | Call a 1-point calibration. If the error persists, replace the electrode. |

cCrea electrodes troubleshooting procedure To troubleshoot the cCrea-A and cCrea-B electrodes, do the following:

| Step | Action |
|------|---|
| 1. | Remove the electrodes and check the measuring chamber for clots; clean the measuring chamber with a cotton stick moistened with distilled water. Make sure that no cotton fibers are left in the measuring chamber. |
| 2. | Replace the membranes of both electrodes. |
| 3. | Call a 2-point calibration. If the error persists, replace the electrodes. |

NOTICE: Refer to *chapter 7* for specific instructions on replacing electrodes and membranes. Remember to record all replacements.

Pump troubleshooting procedure

Procedure To troubleshoot pumps, do the following:

| Step | Action |
|-------------|--|
| 1. | Check the Rinse Solution container for sufficient volume and proper mounting. Replace as required. |
| 2. | Inspect the pump tube(s) for leaks, wear and proper seating. Replace as required. |
| 3. | Call the Liquid Sensor Adjustment program. |
| 4. | Call the Pump Calibration program. This program is performed automatically after any replacements made in step 2 above. |
| 5. | If the error persists, contact a service representative. |

Fluid transport system description

Diagram of fluid transport system The description of the fluid transport system and a detailed explanation of the rinse process aim to help troubleshooting.

The fluid transport system of the analyzer is shown below.

The available moduls depends on the analyzer version.

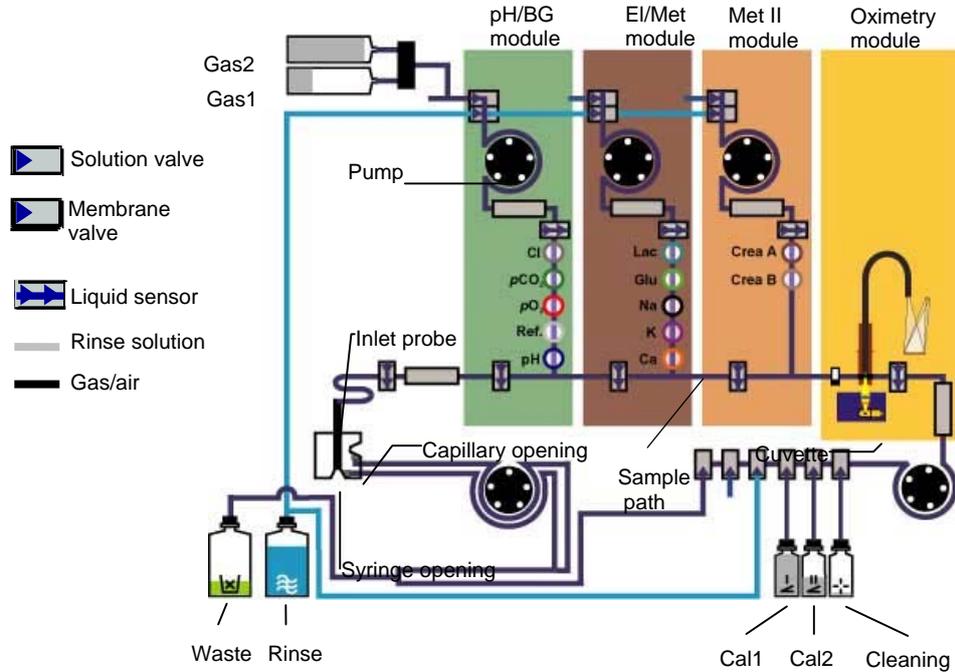
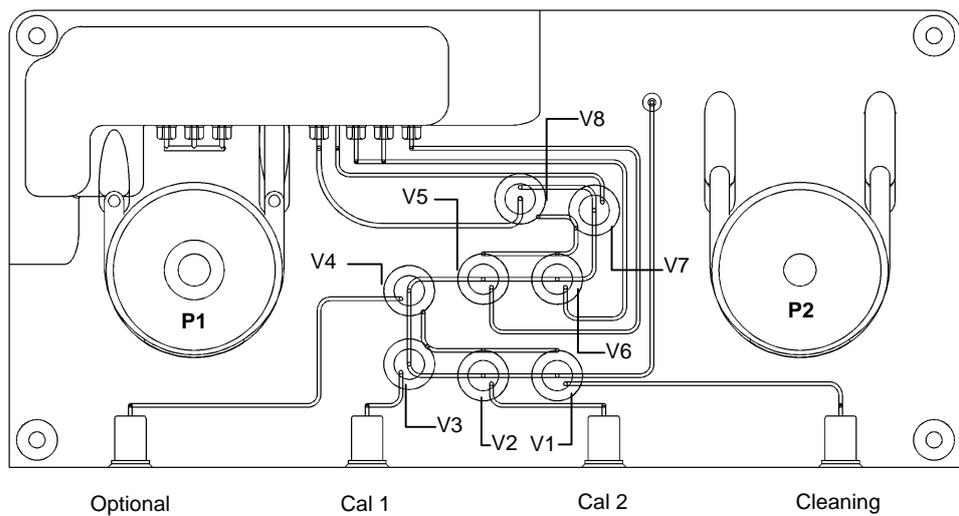


Diagram of the fluidic module

A detailed illustration of the fluidic module is given below.



Continued on next page

Fluid transport system description, *Continued*

Description of the fluidic module

The function of the fluidic module is to transport solutions from the containers to the measuring modules, and to transport samples from the inlet and measuring modules to the waste container.

The right fluidic module consists of a transparent fluid unit including all flow lines and four solution connectors. Eight membrane valves and two pumps select the flow path and control the flow.

The functions of the principal parts are given below.

| Part | Function |
|------|---|
| V1 | Pulled to enable supply of cleaning solution to the wet section. |
| V2 | Pulled to enable supply of Cal 2 solution to the wet section. |
| V3 | Pulled to enable supply of Cal 1 solution to the wet section. |
| V4 | Not used. |
| V5 | Not used. |
| V6 | Pulled to enable supply of rinse solution to the wet section. |
| V7 | Pulled to enable supply of air to the wet section. |
| V8 | Pulled to enable flow to the waste container (used when the sample is transported into the measuring modules). |
| P1 | Waste pump. Includes two tubes with larger inner diameter than the other pump tubes. It aspirates from the inlet and transports solutions and sample to the waste container. The pump rotation is always counterclockwise. |
| P2 | Solution pump. Includes one tube. Transports solutions from the containers to the measuring modules, and solutions from the measuring modules to the waste container (when sample is transported into the measuring modules). Rotates in both directions. |

Rinse process

The basic stages of the rinse process are described below.

| Stage | Description |
|-------|---|
| 1 | The measuring modules are drained of fluid flowing through the inlet and out to the waste container. The pH/BG, El/Met and Met II measuring chambers drain from the top down. Fluid from the Oxi module (cuvette) flows from right to left through the sample path. |
| 2 | The system is washed with alternating segments of air and rinse solution. The flow should be similar to that of Stage 1. |

Continued on next page

Fluid transport system description, *Continued*

Rinse process (*continued*)

| Stage | Description |
|-------|--|
| 3 | The measuring modules are filled with rinse solution flowing through the measuring chambers from the bottom up. |
| 4 | The pH/BG module is filled with gas containing CO ₂ . The gas is filled from the top, expelling the rinse solution from the measuring chambers. |
| 5 | The outer portion of the inlet system is filled with air drawn from the exterior (not shown). |

Evaluating the rinse

Carefully observe the flow of fluid through the system during the rinse. Use the table below to help identify possible sources of error.

| Possible cause | Indication | Recommended action |
|--|---|---|
| Obstruction in inlet | <ul style="list-style-type: none"> Fluid flowing upwards through pH/BG, El/Met and Met II modules during Stage 1. Erratic flow of fluid through all three modules that contains excessive air bubbles. Fluid does not move through the small canals off the waste pump tubes, just above the pump rotor. Excessive suction noise coming from inlet. | Perform inlet troubleshooting procedure. |
| Improper electrode installation | <ul style="list-style-type: none"> Fluid and air bubbles rising up into a measuring chamber. Leakage from electrode compartment. | Ensure the electrodes are properly installed. |
| Obstruction in the measuring chamber of a measuring module | Fluid does not flow freely through all measuring chambers of a particular measuring module. | Clean the measuring chambers of the measuring module. |

12. Sampling

Overview

Introduction This chapter provides guidelines and recommendations for blood, pleura and expired air sample collection prior to analysis, i.e. the preanalytical phase, in order to avoid errors and obtain the most accurate results.

For more comprehensive information regarding blood sampling, see the references at the end of this chapter.

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Causes of errors in preanalytical phase



WARNING – Risk of infection

Blood sampling should be performed by authorized personnel only. Always handle blood and the collection devices with care. Avoid direct contact with the sample by using certified rubber gloves. Sterile techniques are required at all times to avoid infection.

Introduction

The major source of errors in blood sample analysis is the preanalytical phase, i.e. sample collection and handling prior to transfer into the analyzer. In order to avoid errors, it is necessary to observe certain guidelines during:

- preparation prior to sampling
- sampling
- transport
- storage
- preparation prior to transfer of the sample into the analyzer

Causes of error

The possible causes of errors during the preanalytical phase and preventative measures are given below.

| Cause of error | Major affected parameters | Preventative measures |
|-----------------------|--------------------------------|---|
| Air bubbles in sample | pO_2^* | Remove air bubbles immediately. |
| Clot in sample** | pH | <ul style="list-style-type: none"> • Use correct pre-analytical handling • Use Cleaning additive • Capillaries: Use the mixing wire • Use clot catcher. |
| Sedimented samples | $ctHb, pO_2, pCO_2$ | Mix sample prior to transfer into analyzer. |
| Hemolysis | $cK^+, cCa^{2+}, cCl^-, cNa^+$ | <ul style="list-style-type: none"> • Sampling device construction, narrow needle diameter causes hemolysis – choose a proper device for sampling. • Avoid squeezing the tissue during sample collection into a capillary • Avoid mixing too vigorously • See section <i>Storage and preparation prior to analysis</i> further in this chapter |

Continued on next page

Causes of errors in preanalytical phase, *Continued*

Causes of error (*continued*)

| Cause of error | Major affected parameters | Preventative measures |
|---|--|--|
| Dilution from liquid heparin | Electrolytes and metabolites, $c\text{HCO}_3^-$, $p\text{CO}_2$, $ct\text{Hb}$, | Use preheparinized devices with dry heparin. |
| Heparin interference | Electrolytes, especially $c\text{Ca}^{2+}$ | Use electrolyte-balanced heparin. |
| Arterial blood mixed with venous blood | pH, $p\text{O}_2$, $s\text{O}_2$ | Use proper sampling technique. |
| Instability of patient | pH and blood gases | <ul style="list-style-type: none"> • Sample at least 20 minutes after ventilatory adjustment • Inform patient of procedure |
| Leakage from red blood cells | $c\text{K}^+$ | Store glass capillary samples for maximum 30 minutes in cold (0- 4 °C) condition. |
| Exposure to artificial light or sunlight | $ct\text{Bil}$ | For patients receiving phototherapy, lights should be extinguished prior to drawing the sample. |
| Inappropriate amount of flush solution is discarded from the catheter | Electrolytes and metabolites | Discard sufficient volume from the catheter before taking a blood sample. |
| Infusion solution given in the same arm | Electrolytes and metabolites | Stop infusion for a period or use another sampling site. |



*** CAUTION – Risk of incorrect results**

Always remove air bubbles from a sample before introducing it into the analyzer. Air bubbles may result in erroneous $p\text{O}_2$ values.



**** CAUTION – Risk of clots**

When measurements are flagged always conduct the operator actions required by the troubleshooting program to prevent possible clots from remaining in the sample path. Fluid path clots may cause erroneous measurement results.

See also *Recommended literature* at the end of this chapter.

Continued on next page

Causes of errors in preanalytical phase, *Continued*

Selection of anticoagulant

To avoid introduction of clotted blood samples into the analyzer which may give inaccurate measurement results and cause analyzer damage, Radiometer recommends the following:

- Exclusive use of preheparinized sampling devices
- Exclusive use of dry heparin, preferably of sodium or lithium
- Do not use liquid heparin as this causes dilution of the sample [1]
- Use heparin in sufficient concentration. The recommended concentration depends on the sampling device and specific blood sample – please refer to documentation for specific sampling devices.
- Use electrolyte-balanced heparin to minimize bias from heparin on electrolyte values



CAUTION – *Risk of erroneously high results*

Do not add sodium fluoride to the blood samples, as it gives erroneously high $c\text{Na}^+$ and low $c\text{Ca}^{2+}$, $c\text{Glucose}$ and $c\text{Lactate}$ results. Sodium fluoride also damages the Glucose and Lactate electrodes.

Preparing the patient

The respiratory condition of the patient should be stable.

- The patient should preferably be in a steady state of ventilation before and during the collection of blood sample
- The patient should be informed about the procedure in order to avoid unnecessary anxiety. If the patient hyperventilates due to anxiety, for example, pH and blood gases may be affected.

Preparation prior to arterial/venous sampling

Sample types The recommendations and considerations for the sample type are as follows:

| Sample type | Recommendations and considerations |
|-------------|---|
| Arterial | <p>The most preferred and recommended type of blood for pH/blood gas analysis.</p> <ul style="list-style-type: none"> • Gives the best information about oxygen uptake in the lungs and oxygen transport • Information is basically the same regardless of the sampling site |
| Venous | <p>Not generally recommended for blood gas analysis.</p> <ul style="list-style-type: none"> • Affected by peripheral circulatory efficiency and cellular metabolic needs • Should not be used to evaluate oxygen status • Can be used to reflect acid-base status (pH, $p\text{CO}_2$, $c\text{Base(Ecf)}$), $ct\text{Hb}$, $F\text{COHb}$, $F\text{MetHb}$, $F\text{HbF}$ and $ct\text{Bil}$ |

Arterial and venous sampling sites The recommendations and considerations for selecting a sampling site are as follows:

| Sample | Site | Advantages/disadvantages |
|---------------|-----------------|--|
| Arterial | Radial artery | <ul style="list-style-type: none"> • Good collateral circulation • Easy access <p>Prior to sampling from the radial artery, perform a Modified Allen's Test to confirm adequate collateral circulation.</p> |
| | Brachial artery | <ul style="list-style-type: none"> • Difficult to puncture due to location • Greater risk of damage to surrounding structures |
| | Femoral artery | <ul style="list-style-type: none"> • Large and easy to puncture • Poor collateral circulation • Should be avoided on newborns and elderly |
| Arterial line | | Remove the flush solutions used in A-lines completely from the system to avoid dilution of the blood sample. It is recommended to withdraw a volume equal to three to six times the "dead space" of the catheter. |
| Venous | Brachial vein | <p>Convenient site.</p> <p>For sampling on venous blood, use the standard procedure of your institution.</p> |

Continued on next page

Preparation prior to arterial/venous sampling, *Continued*

Arterial sampling guidelines

The following are guidelines for sampling by arterial puncture:

| Sampling method | Guidelines |
|-----------------|--|
| Puncture | <ul style="list-style-type: none"> • Be careful not to mix venous blood with the arterial sample. This can occur if a vein is punctured before locating the artery. Arterial blood (due to the higher pressure) will generally fill faster than venous blood, and is lighter in color. • It is important to expel any air bubbles immediately without prior agitation. An air bubble with a relative volume of 0.5 % or more of the blood volume in the syringe is a potential source of significant error [2, 3]. The effect of such an air bubble increases with the storage time and agitation of the sample. • Mix sample thoroughly with heparin immediately after sampling by inverting the sampler several times and then rolling the sample between your palms. |
| A-line | <ul style="list-style-type: none"> • If aspirating the sample, do so slowly in order to avoid hemolization of the sample • Expel any air bubbles immediately (see above) • Mix the sample thoroughly with heparin immediately after sampling by inverting the sampler several times and then rolling the sample between your palms. |

Disposal of used sampling devices



WARNING – Risk of infection

Discard the waste as infectious waste [4].

Preparation prior to capillary sampling

Capillary sampling sites

The following are recommended capillary sampling sites:

- Earlobe
- Fetal scalp
- Finger tip
- Heel*
- Big toe*

* The heel and big toe should not be used on patients older than six months.

NOTICE: In general, results obtained from capillary samples, particularly pO_2 values, should be interpreted with caution.

Capillary sampling guidelines

The guidelines for capillary sampling are as follows:

- Arterialize the puncture site by warming it up to approximately 42 °C for 5 to 10 minutes prior to actual sampling. Failure to do so will make the blood sample only representative of the local tissue, and not the general status of the patient.
- Make a puncture using a lancet or the like, so that blood flows freely. Do not squeeze the area.
- Remove the first drop of blood, since it may be diluted with tissue fluid. Take the sample from the center of the second blood drop. To prevent air from entering the capillary, take the sample from the center of the drop.
- Squeezing or milking the puncture site is to be avoided as this will result in an admixture of blood and tissue fluid, resulting in faulty measurements. It can also cause hemolysis of the blood sample (or part of the sample), resulting in cK^+ readings being too high.
- Mix the sample with heparin immediately after collection to prevent blood from clotting. (Clots can clog the analyzer and cause unnecessary downtime.) Use a mixing wire and magnet when mixing a capillary sample.

Disposal of used sampling devices



WARNING – Risk of infection

Discard the waste as infectious waste [4].

Sampling devices

Introduction Radiometer has an assortment of specialized blood gas sampling devices. The PICO product line is used for puncture and A-line sampling, and CLINITUBES product line are used for capillary sampling.

For ordering information on sampling devices, see *chapter 14: Ordering Information* or contact your local distributor of Radiometer products.

Arterial blood samplers The following arterial blood samplers available from Radiometer are recommended:

- PICO70: Self-filling arterial blood sampler for arterial puncture or A-line sampling
- PICO50 (2 mL): Arterial blood sampler for the aspiration of arterial blood from A-lines
- *Safe*PICO: Self-filling arterial blood sampler for arterial puncture or A-line sampling (contains a ball for automatic sample mixing in the FLEXQ sampler tray)

CLINITUBES The following CLINITUBES for capillary blood sampling available from Radiometer are recommended:

- D956G-70-210
- D956G-70-100
- D957P-70-100
- D941G-240-55 (do not use for measuring electrolytes)
- D956G-70-35

(G = glass; P = plastic; the last figure designates volume in μL)



CAUTION - Risk of erroneous results

Do not use 85 μL CLINITUBES sampling device with high heparin concentration in FLEXMODE.

Storage and preparation prior to analysis

Storage recommendation Radiometer recommends the following for samples obtained in plastic and glass syringes:

| Material | Storage recommendation |
|-----------------|---|
| Plastic syringe | <ul style="list-style-type: none"> Storage should be avoided whenever possible or, at least, kept to a minimum If it is not possible to analyze the sample immediately, analyze it within 30 minutes after collection [5, 6, 7, 8, 9, 10, 11] Recommended sample storage temperature: room temperature [5, 6, 8] Samples with expected high pO_2 values or for special studies like shunt studies should be analyzed immediately or within 5 minutes. The use of glass syringes can also be considered [5, 7, 8] |
| Glass syringe | <ul style="list-style-type: none"> Storage should be avoided whenever possible or, at least, kept to a minimum If it is not possible to analyze the sample immediately, analyze it within 30 minutes after collection when stored at room temperature [5, 12] Alternatively, store the sample in ice-water (0-4 °C). The storage time should not exceed 1 hour [13] Samples with expected high pO_2 values or for special studies like shunt studies should be analyzed immediately or within 5 minutes [13] |

Radiometer recommends the following for samples obtained in plastic and glass capillaries:

| Material | Storage recommendation |
|-------------------|---|
| Plastic capillary | Analyze the sample within 10 minutes. Note that for samples with $pO_2 > 80$ mmHg (10.7 kPa) a positive bias from 1 to 9 % is observed. The bias depends on the pO_2 , pH and time. |
| Glass capillary | Analyze the sample within 10 minutes. If storage is unavoidable, store the sample horizontally at 0-4 °C for maximum 30 minutes. |

Continued on next page

Storage and preparation prior to analysis, *Continued*

Pay attention to the following:

- For some samples the recommendation above does not apply and individual guidelines should be used or developed. Examples of these samples are samples with an increased leukocyte or platelet count, fetal scalp samples, samples with atypical metabolism, fast-clotting samples, etc. [9, 14].
- Typical metabolic activity in blood samples causes an increase in the lactate concentration and a decrease in the glucose concentration. For samples within the typical reference range this corresponds to an average change in the lactate concentration of 0.25 mmol/L and of -0.2 mmol/L for glucose over 30 minutes at room temperature [15].

Preparation prior to analysis

Arterial puncture and A-line samples:

- If there is an air bubble in a sample that has been stored, pH and blood gas values should not be reported
- Thoroughly mix the sample by inverting the sampler several times and rolling it between the palms of your hands.

Capillary samples:

- Thoroughly mix the sample with heparin using a mixing wire and magnet.

Capillary blood sample measurements

In order to perform in accordance with the analyzer performance specifications, Radiometer highly recommends to follow the recommendations below.

| | |
|---|--|
| <p>Capillary blood sample measurements:</p> | <ul style="list-style-type: none"> • When performing capillary blood sample measurements, use the mixing wire in order to ensure appropriate mixing of the sample and thereby prevent clots from being introduced into the analyzer. The sample should be mixed immediately after collection, moving the mixing wire with a magnet 20 times along the full length of the capillary. This procedure should be repeated immediately before analyzing the sample. • When performing capillary blood sample measurements and clots are suspected, use a clot catcher in order to prevent blockage of the measuring chamber. • Do not remove the mixing wire before the sample is aspirated for measurement. Slide the mixing wire to the end of the capillary opposite to that from which the blood is to be aspirated. <p>Remove both capillary end caps.</p> |
|---|--|

Continued on next page

Storage and preparation prior to analysis, *Continued*

Capillary blood sample measurements (*continued*)

Capillary blood sample measurements on fetal scalp blood:

- When performing capillary blood sample measurements on fetal scalp blood, insert the mixing wire into the capillary tube **after** the sample has been collected.
- When performing measurements on fetal scalp blood, introduce the capillary sample into the analyzer from the cap end free from Vaseline smear. In case both capillary ends are smeared, dry one of the ends with a lint-free tissue before measurement.
- Due to their inherent characteristics fetal scalp blood samples are generally regarded as potentially difficult to work with. An important prerequisite for successfully analyzing fetal scalp blood samples is the sample quality and that the preanalytical precautions listed above are followed very closely.

Sampling procedures

NOTICE: This section describes non-Radiometer sampling devices. For information on use and handling Radiometer sampling devices, please refer to the inserts supplied with the sampling devices.

Sampling with a standard syringe Prepare the following together with a standard syringe (dead space 2-6 %):

- Anticoagulant: lithium or sodium heparin (1000 IU per mL sample)
- Two needles, 20-25 gauge
- Tourniquet – for venous samples
- Skin antiseptic, e.g. 70 % alcohol
- Sterile gauze sponge or cotton wool
- Rubber stopper or syringe end cap (stainless steel)
- Adhesive tape and pressure dressing

| Step | Action |
|------|--|
| 1. | Mount a needle on the syringe and draw the heparin into the syringe. |
| 2. | Change the needle and flush the barrel walls, then expel air and heparin through the needle. |
| 3. | Extend the patient's arm. Apply the tourniquet for a venous puncture. |
| 4. | Locate the blood vessel with the finger tip and clean the skin area with antiseptic and a sterile gauze sponge or cotton wool. |
| 5. | Insert the needle in the vessel with the bevel upward. Withdraw the syringe plunger gently to collect blood. |
| 6. | Release the tourniquet (if used), remove the needle and immediately apply dry gauze or cotton wool over the puncture site. Maintain pressure on an arterial puncture for at least 5 minutes. |
| 7. | Apply a pressure dressing over the puncture site and elevate the site for at least 2-3 minutes, if possible. |
| 8. | Expel any air bubbles from the syringe and remove the needle according to your standard procedure. |
| 9. | Mix the sample by inverting the syringe several times and then rolling it between your palms. |
| 10. | Mix the sample immediately before analysis. Analyze the sample immediately. |

Continued on next page

Sampling procedures, *Continued*

Sampling with a test tube Prepare the following items:

- A test tube and cap
- Anticoagulant: lithium or sodium heparin (1000 IU per mL sample)
- Pipette or syringe and a needle for heparin dosage
- One hypodermic needle, 20-25 gauge
- Tourniquet
- Skin antiseptic, e.g. 70 % alcohol
- Sterile gauze sponge or cotton wool
- Adhesive tape and pressure dressing

| Step | Action |
|------|--|
| 1. | Transfer the heparin to the test tube using a syringe or a pipette: 50 µL heparin per 5 mL blood. |
| 2. | Extend the patient's arm. Apply the tourniquet for a venous puncture. |
| 3. | Locate the vein with the fingertip. Clean the skin area with antiseptic and a sterile gauze sponge or cotton wool. |
| 4. | Collect the sample according to the procedure in your institution. |
| 5. | Apply dry gauze or cotton wool over the puncture site. |
| 6. | Close the test tube with a cap, then mix the contents by inverting it or rolling it between your palms about 20 times. |
| 7. | Apply a pressure dressing over the puncture site and elevate the site for at least 2-3 minutes, if possible. |
| 8. | Mix the sample immediately before analysis. Analyze the sample immediately. |

Pleural liquid sampling

To collect a pleural liquid sample, do the following:

| Step | Action |
|------|---|
| 1. | Collect the sample directly from the patient or from a drain. |
| | NOTICE: Radiometer recommends always to use heparinized samplers for pleural liquids to avoid introducing clots in the analyzer. |

Continued on next page

Sampling procedures, *Continued*

Expired air sampling

To collect an expired air sample, do the following:

| Step | Action |
|-------------|--|
| 1. | Collect the patient's expired air in the Douglas bag. |
| 2. | Connect a syringe (minimum 20 mL, with a rubber cap) to the bag. |
| 3. | Fill and empty the syringe twice, then fill it with the sample. Close the syringe with the rubber cap. |

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13. Specifications

Overview

Introduction This chapter lists specifications for the ABL800 FLEX analyzers.

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Measured parameters

Definitions The **measuring range** for a parameter is the range within which the analyzer is physically capable of measuring. The measuring range corresponds to the "range of indication" as defined in the "International vocabulary of basic and general terms in metrology" (VIM).

The **test range** for a parameter is the range within which accuracy and precision of a measured parameter has been specified and intended to lie within specified limits. The test range corresponds to the "measuring range" as defined in the "International vocabulary of basic and general terms in metrology" (VIM).

Blood The following measured parameters are available, independent of analyzer configuration.

| Parameter | Unit | Measuring range | Test range |
|--------------------|------------|-----------------|------------|
| pH | pH scale | 6.300-8.000 | 6.85-7.55 |
| cH ⁺ | nmol/L | 10.0-501 | 28-141 |
| pCO ₂ | mmHg; Torr | 5.0-250 | 17-160 |
| | kPa | 0.67-33.3 | 2.27-21.3 |
| pO ₂ | mmHg; Torr | 0.0-800 | 20-580 |
| | kPa | 0.00-107 | 2.67-77.3 |
| ctHb | g/dL | 0.00-27.7 | 2.5-23 |
| | g/L | 0.0-277 | 25-230 |
| | mmol/L | 0.00-17.2 | 1.55-14.2 |
| sO ₂ | % | 0.0-100.0* | 0-100 |
| | fraction | 0.00-1.000* | 0-1 |
| FO ₂ Hb | % | 0.0-100.0* | 0-100 |
| | fraction | 0.00-1.000* | 0-1 |
| FCOHb | % | 0.0-100.0* | 0-20 |
| | fraction | 0.00-1.000* | 0.0-0.2 |
| FMetHb | % | 0.0-100.0* | 0-20 |
| | fraction | 0.00-1.000* | 0.0-0.2 |
| FHHb | % | 0.0-100.0* | 0-100 |
| | fraction | 0.00-1.000* | 0-1 |

For (*) see explanation on the next page.

Continued on next page

Measured parameters, *Continued*

Blood (*continued*)

| Parameter | Unit | Measuring range | Test range |
|-------------------|---------------|-----------------|------------|
| FHbF | % | 0.0-100.0* | 0-80 |
| | fraction | 0.00-1.000* | 0.0-0.8 |
| cK ⁺ | mmol/L; meq/L | 0.5-25.0 | 2-8 |
| cNa ⁺ | mmol/L; meq/L | 7-350 | 120-180 |
| cCa ²⁺ | mmol/L | 0.20-9.99 | 0.51-2.2 |
| | meq/L | 0.40-19.98 | 1.0-4.4 |
| | mg/dL | 0.80-40.04 | 2.0-8.8 |
| cCl ⁻ | mmol/L; meq/L | 7-350 | 95-150 |
| cGlu | mmol/L | 0.0-60 | 0.5-15 |
| | mg/dL | 0-1081 | 9.0-270 |
| cLac | mmol/L; meq/L | 0.0-30 | 0.5-15 |
| | mg/dL | 0-270 | 4.5-135 |
| cCrea | μmol/L | 10-1800 | 50-1500 |
| | mg/dL | 0.11-20.4 | 0.57-17.0 |
| ctBil | μmol/L | 1-1000* | 0-400 |
| | mg/dL | 0.0-58.5* | 0.0-23.4 |
| | mg/L | 0-585* | 0-234 |

* The values are for the analyzer with the activated "Out of range suppression" function. In case this function has not been activated, the measuring ranges will be as follows:

| Parameter | Unit | Measuring range |
|--|----------|-------------------|
| sO ₂ , FO ₂ Hb, FCOHb, FMetHb | % | -2.0 % to 102.0 % |
| | fraction | -0.020 to 1.020 |
| FHbF | % | -15 % to 102 % |
| | fraction | -0.15 to 1.02 |
| ctBil | μmol/L | -20 to 1000 |
| | mg/dL | -1.2 to 58.5 |
| | mg/L | -12 to 585 |

Continued on next page

Measured parameters, *Continued*

Pleural liquid

| Parameter | Unit | Measuring Range | Test range |
|-----------|----------|-----------------|------------|
| pH | pH scale | 6.300-8.000 | 7.0-7.5* |

* If the measured values obtained lie outside the test range, Radiometer advises you to repeat the measurement by means of another method.

Expired air

| Parameter | Unit | Measuring Range | Test range |
|----------------|------|-----------------|------------|
| $p\text{CO}_2$ | mmHg | 5.0-250 | 15-150 |
| | kPa | 0.67-33.3 | 2.00-20.00 |
| $p\text{O}_2$ | mmHg | 0.0-800 | 15-530 |
| | kPa | 0.00-107 | 2-70 |

Baro

| Parameter | Unit | Measuring Range | Test range |
|-----------------|------------|-----------------|------------|
| $p(\text{amb})$ | mmHg; Torr | 450-800 | 450-800 |
| | kPa | 60.0 -106.7 | 60.0-106.7 |

Other fluids All parameters available on the analyzer.

Input parameters

List of parameters

All the input parameters available on the ABL800 FLEX analyzers, independent of configuration, are listed below.

| Symbol | Parameter | Unit | Input range | Defaults |
|-----------------|--|----------|--------------|----------|
| T | Patient temperature | °C | 15.0-45.0 | 37 |
| | | °F | 59.0-113.0 | 98.6 |
| | QUALICHECK+/AutoCheck+ ampoule temperature | °C | 18.0-32.0 | 25 |
| | | °F | 64.4-89.6 | 77 |
| $FO_2(I)$ | Fraction of oxygen in dry inspired air | % | 0.0-100.0 | 21.0 |
| | | fraction | 0.000-1.000 | 0.210 |
| ctHb | Total hemoglobin concentration (if not measured) | g/dL | 0.0-33.0 | - |
| | | g/L | 0.0-330 | - |
| | | mmol/L | 0.0-20.5 | - |
| RQ | Respiratory quotient – ratio of carbon dioxide production and oxygen consumption | - | 0.00-2.00 | 0.86 |
| $pO_2(\bar{v})$ | Oxygen tension in mixed venous blood | mmHg | 0.0-xxx.x* | - |
| | | kPa | 0.00-xx.xx* | - |
| $sO_2(\bar{v})$ | Oxygen saturation in mixed venous blood | % | 0.0-100.0 | - |
| | | fraction | 0.000-1.000 | - |
| \dot{Q}_t | Cardiac output | L/min | 0.0-xxx.x* | - |
| $\dot{V}O_2$ | Total oxygen consumption | mL/min | 0-xxxx* | - |
| | | mmol/min | 0.0-xxx.x* | - |
| VCO | Volume of carbon monoxide | mL | 0.0-xxx.x* | - |
| $p50(st)$ | Half saturation tension of oxygen in blood at standard conditions | mmHg | 0.01-100.00 | 26.84 |
| | | kPa | 0.001-13.332 | 3.578 |
| $FCOHb(1)$ | The fraction of COHb measured before the CO-injection | % | 0.0 -100.0 | - |
| | | fraction | 0.000-1.000 | - |
| $FCOHb(2)$ | The fraction of COHb measured after the CO-injection | % | 0.0 -100.0 | - |
| | | fraction | 0.000-1.000 | - |

* numerical format

Derived parameters

List of parameters

All derived parameters of the ABL800 FLEX analyzers are listed below.

| Symbol | Input parameter required (if not determined by analyzer) |
|---|---|
| $\text{pH}(T)$ | T |
| $c\text{H}^+(T)$ | T |
| $p\text{CO}_2(T)$ | T |
| $c\text{HCO}_3^-(P)$ | - |
| $c\text{Base}(B)$ | ctHb |
| $c\text{Base}(B,\text{ox})$ | ctHb |
| $c\text{Base}(Ecf)$ | - |
| $c\text{Base}(Ecf,\text{ox})$ | - |
| $c\text{HCO}_3^-(P,\text{st})$ | ctHb |
| $ct\text{CO}_2(P)$ | - |
| $ct\text{CO}_2(B)$ | - |
| $\text{VCO}_2/\text{V}(\text{dry air})$ | |
| $\text{pH}(\text{st})$ | - |
| Hct | ctHb |
| $p\text{O}_2(T)$ | T |
| $p\text{O}_2(A)$ | $\text{FO}_2(I) + \text{RQ}$ |
| $p\text{O}_2(A,T)$ | $\text{FO}_2(I) + \text{RQ} + T$ |
| $p\text{O}_2(a)/\text{FO}_2(I)$ | $\text{FO}_2(I)$ |
| $p\text{O}_2(a,T)/\text{FO}_2(I)$ | $\text{FO}_2(I) + T$ |
| $p50$ | - |
| $p50(T)$ | T |
| $p50(\text{st})$ | - |
| $p\text{O}_2(A-a)$ | $\text{FO}_2(I) + \text{RQ}$ |
| $p\text{O}_2(A-a,T)$ | $\text{FO}_2(I) + \text{RQ} + T$ |
| $p\text{O}_2(a/A)$ | $\text{FO}_2(I) + \text{RQ}$ |
| $p\text{O}_2(a/A,T)$ | $\text{FO}_2(I) + \text{RQ} + T$ |

Continued on next page

Derived parameters, *Continued*

List of parameters (*continued*)

| Symbol | Input parameter required (if not determined by analyzer) |
|----------------------------------|---|
| $pO_2(x)$ | ctHb, p50(st) |
| $pO_2(x, T)$ | ctHb, p50(st), T |
| ctO ₂ (B) | ctHb |
| ctO ₂ (a- \bar{v}) | ctHb |
| BO ₂ | ctHb |
| ctO ₂ (x) | ctHb, p50(st) |
| $\dot{D}O_2$ | \dot{Q} |
| \dot{Q}_t | $\dot{V}O_2$ |
| $\dot{V}O_2$ | \dot{Q} |
| FShunt | ctHb + FO ₂ (I) + RQ |
| FShunt(T) | ctHb + FO ₂ (I) + RQ + T |
| RI | FO ₂ (I) + RQ |
| RI(T) | FO ₂ (I) + RQ + T |
| Qx | ctHb, p50(st) |
| VO ₂ /V(dry air) | |
| sO ₂ | - |
| FO ₂ Hb | - |
| FHHb | |
| V(B) | ctHb, VCO, FCOHb(1), FCOHb(2) |
| Anion Gap(K ⁺) | |
| Anion Gap | |
| cCa ²⁺ (pH=7.4) | |
| mOsm | |
| GFR, if non AA | Crea, Sex, Age |
| GFR, if AA | Crea, Sex, Age |

NOTICE: All parameters are calculated in SI units. If other units are selected, the results are obtained by converting the SI units into those selected. For detailed information please refer to the Reference Manual, *chapter 6*.

Sample handling

ABL837/27/17

| Mode | Sample volume | Measuring time (sec)* | Cycle time (sec) | Samples per hour |
|---|---------------|-----------------------|------------------|------------------|
| Syringe – S250 Other fluids – S250 Ampoule - QC | 250 µL | 100 | 170 | 21 |
| Syringe – S85 pH + BG + OXI | 85 µL | 80 | 170 | 21 |
| Capillary – C125 | 125 µL | 150 | 225 | 16 |
| Capillary – C55 | 55 µL | 100 | 80 | 20 |
| Capillary – C35 Met | 35 µL | 80 | 145 | 24 |
| Capillary – C35 OXI | 35 µL | 80 | 145 | 24 |
| Syringe – Pleura pH | 85 µL | 80 | 170 | 21 |
| Expired air | 15 mL | 80 | 170 | 21 |

ABL835/25/15

| Mode | Sample volume | Measuring time (sec)* | Cycle time (sec) | Samples per hour |
|---|-------------------------|-----------------------|------------------|------------------|
| Syringe – S195 Other fluids – S195 Ampoule - QC | 195 µL | 80 | 150 | 24 |
| Capillary – FLEXMODE Other fluids – FLEXMODE (no message) | 195 µL | 80 | 150 | 24 |
| Capillary – FLEXMODE Other fluids – FLEXMODE (message 869 or 870) | 30-40 µL or 40-55 µL | 100 | 170 | 21 |
| Capillary – FLEXMODE Other fluids – FLEXMODE (message 871 or 872) | 50-70 µL | 100 | 170 | 21 |
| Capillary – FLEXMODE Other fluids – FLEXMODE (message 873) | 65-100 µL | 135 | 200 | 18 |
| Capillary – FLEXMODE Other fluids – FLEXMODE (message 874) | > 90 µL | 135 | 200 | 18 |
| Syringe – S95 Capillary – C95 | 95 µL | 135 | 200 | 18 |

* From the moment the inlet flap is lifted until the results are displayed.

Continued on next page

Sample handling, *Continued*

ABL835/25/15 (continued)

| Mode | Sample volume | Measuring time (sec)* | Cycle time (sec) | Samples per hour |
|---------------------|---------------|-----------------------|------------------|------------------|
| Syringe – S85 | 85 µL | 80 | 170 | 21 |
| Capillary – C55 | 55 µL | 100 | 170 | 21 |
| Capillary – C35 Met | 35 µL | 80 | 145 | 25 |
| Capillary – C35 Oxi | 35 µL | 80 | 145 | 25 |
| Syringe – Pleura pH | 85 µL | 80 | 170 | 21 |
| Expired air | 15 mL | 80 | 170 | 21 |

ABL830/20/10/ 10 BG only

| Mode | Sample volume | Measuring time (sec)* | Cycle time (sec) | Samples per hour |
|---|-------------------------|-----------------------|------------------|------------------|
| Syringe – S85 Other fluids – S85 Ampoule - QC | 85 µL | 80 | 170 | 25 |
| Capillary – FLEXMODE Other fluids – FLEXMODE (no message) | 85 µL | 80 | 145 | 25 |
| Capillary – FLEXMODE Other fluids – FLEXMODE (message 869 or 870) | 30-40 µL or 40-55 µL | 100 | 170 | 21 |
| Capillary – FLEXMODE Other fluids – FLEXMODE (message 871 or 872) | 50-70 µL | 100 | 170 | 21 |
| Capillary – C55 | 55 µL | 100 | 170 | 21 |
| Capillary – C35 Oxi (not active on the ABL810 BG only) | 35 µL | 80 | 145 | 25 |
| Syringe – Pleura pH | 85 | 80 | 170 | 21 |
| Expired air | 15 mL | 80 | 170 | 21 |

* From the moment the inlet flap is lifted until the results are displayed.

Continued on next page

Sample handling, *Continued*

ABL805

| Mode | Sample volume | Measuring time (sec)* | Cycle time (sec) | Samples per hour |
|---|-------------------------|-----------------------|------------------|------------------|
| Syringe – S165 Other fluids – S165 Ampoule - QC | 165 µL | 80 | 170 | 21 |
| Capillary – FLEXMODE Other fluids – FLEXMODE (no message) | 165 µL | 80 | 150 | 24 |
| Capillary – FLEXMODE Other fluids – FLEXMODE (message 869 or 870) | 30-40 µL or 40-55 µL | 80 | 145 | 25 |
| Capillary – FLEXMODE Other fluids – FLEXMODE (message 871 or 872) | 50-70 µL | 80 | 145 | 25 |
| Capillary – FLEXMODE Other fluids – FLEXMODE (message 873) | 65-100 µL | 80 | 170 | 21 |
| Capillary – FLEXMODE Other fluids – FLEXMODE (message 874) | > 90 µL | 100 | 170 | 21 |
| Syringe – S95 Capillary – C95 | 95 µL | 100 | 170 | 19 |
| Syringe – S85 | 85 µL | 80 | 170 | 21 |
| Capillary – C55 | 55 µL | 80 | 145 | 25 |
| Capillary – C35 Met | 35 µL | 80 | 145 | 25 |
| Syringe – Pleura pH | 85 µL | 80 | 170 | 21 |
| Expired air | 15 mL | 65 | 170 | 21 |

* From the moment the inlet flap is lifted until the results are displayed.

Calibration and maintenance programs

Calibrations

| Calibration type | Adjustable frequency (hours) | Duration, min | | | |
|----------------------------------|------------------------------|---------------|---------------|--------------|--------|
| | | ABL837/27/17 | ABL835/ 25/15 | ABL830/20/10 | ABL805 |
| Cal 1 | ½, 1, 2, 4 | 5 | 4¾ | 3¾ | 4¾ |
| Cal 2 | 1, 2, 4, 8 | 10 | 9½ | 8 | 9½ |
| 1 Point pH/BG (for the USA only) | ½, 1, 2 | 2¼ | 2 | 2 | 2 |
| tHb | Manual | 2¾ | 2¼ | 2¼ | - |

High Crea Check

Duration: 3½ min.

Auxiliary programs

| Program | Started... | Duration, min | | | |
|--------------------------|---|---------------|--------------|--------------|--------|
| | | ABL837/27/17 | ABL835/25/15 | ABL830/20/10 | ABL805 |
| Cleaning | Every 8 or 24 hours, or called by operator | 4 | 4¼ | 4¼ | 4¼ |
| Tubing Refill | After changing all solution bottles or called by operator | 4¼ | 4 | 4 | 4¼ |
| Decontamination | Called by operator | 4¼ | 2¾ | 2¾ | 2¾ |
| Protein Remover | Called by operator | 3¾ | 2½ | 2½ | 2½ |
| Liquid Sensor Adjustment | Called by operator | 3¼ | 3 | 3 | 3 |

Fortsættes på næste side

Calibration and maintenance programs, *Continued*

Auxiliary programs (*continued*)

| Program | Started... | Duration, min | | | |
|------------------|---|------------------|------------------|------------------|--------|
| | | ABL837/27/ 17 | ABL835/25 /15 | ABL830/20 /10 | ABL805 |
| Pump Calibration | Called by operator | 4¾ | 4 | 3½ | 4 |
| Rinse | After each measurement, calibration or called by operator | 1½ | 80 sec | 80 sec | 80 sec |
| Flush | Automatically | 1 | 50 sec | 50 sec | 50 sec |
| Draining | Automatically | ½ | 21 sec | 21 sec | 21 sec |

System alignment

ABL830: approximately 21 min.

ABL835/05: approximately 24 min.

ABL837/27/17: Approximately 26 min.

Analyzer requirements

| | | |
|------------------------------|--|---|
| Analyzer requirements | Power | Rated voltage: 100-240 V; 50/60 Hz; 270 VA. Maximum voltage fluctuations: $\pm 10\%$. Leakage current measured at 230 V and 50 Hz: Normal condition (ground connected): < 0.005 mA Single fault condition (ground disconnected): < 0.5 mA |
| | Fuses | Printer unit has 1 protective fuse: 5 × 20 mm, 4 Amp, Slow blow (T4AL). Main fuse includes 2 protective fuses: 5 × 20 mm, 4 Amp, High break (T4AH). Type Shurter No. 0001.2510.  WARNING – Risk of fire Fire hazard. Replace fuse as marked. |
| | Start up | Cold start: typically 25 minutes Warm start: 5 minutes |
| | Gas pressure | Operating pressure: 1.0-38 bar Maximum pressure: 38 bar |
| | Environmental requirements | Location Indoor use only Relative humidity 20 to 80 % Operating temperature 15 °C to 32 °C Storage temperature –20 °C to 60 °C Altitude correction Up to 3000 meters above sea level at standard barometric pressure of 760 mmHg. Baro 450-800 mmHg 60.0-106.7 kPa 0.600-1.067 bar 450-800 Torr |
| Environmental ratings | Installation category II. Pollution degree 2. | |

Analyzer specifications

| | | |
|-----------------------|--|--|
| Specifications | Thermostating | Solid state, 37.0 ± 0.15 °C |
| | Spectrophometer | Wavelength range: 478-672 nm |
| | Hemolyzer | Hemolyzation: at approximately 30 kHz cuvette light path: approximately 0.01 cm |
| | External serial ports | 1 x RS-232 (9-pin) connector. Baud rate: 1200, 2400, 4800, 9600, 14400, 19200, 38400, 115200 |
| | USB ports | Pin header for two USB (Universal Serial Bus) ports |
| | Ethernet | 1 x RJ45 connector, 32-bit PCI bus interface, Novell NE 2000 compatible, onboard 10-Base T, fully compliant with IEEE 802.3 10 Mbps CSMA/CD standards. |
| | External printer port | Bi-directional parallel (ECP/EPP/SPP) port (25-pin) connector |
| | Keyboard/Mouse | Keyboard/PS/2 mouse interface |
| | External VGA Screen | Connector for VGA screen |
| | Printer | Built-in thermal; paper 11 cm wide |
| | Barcode reader | Built-in. Reading distance: contact – 70 mm. Barcode length: max. 65 mm Bar width: ≥127 µm (5 mil) Number of characters: <62 Code types: 128, 39, I 2 of 5 Class 1 laser product Codabar barcode support |
| | Dimensions (basic module, without accessories) | Height: 548 mm(21.95 in.) with the vertical screen Width: 700 mm (27.6 in.) Depth: 476 mm(18.5 in.) |
| | Weight (kg) (with AutoCheck) | ABL805: 32.9 ABL830/20/10: 32.9 ABL835/25/15: 33.9 ABL837/27/17 36.2 |

Continued on next page

Analyzer specifications, *Continued*

| | | |
|---|---|---|
| AutoCheck module specifications | Number of ampoules in the carousel | 0 to 20 |
| | Positioning of ampoules in the carousel | Random |
| | Lot change | 2 Lots of the same level at the same time possible |
| | Ampoule volume, liquid | 0.7 mL |
| | Expiration of ampoules | 24 months at 25 °C (including 15 days at up to 32 °C) |
| | Conditioning time (from room temperature) | < 15 min. with filled carousel |
| | Scanning time | < 60 sec with filled carousel |
| | Manual quality control measurement possible | Yes |
| | Remote control | Remote monitoring and start of measurement via the RADIANCE system. |
| | FLEXQ module specifications | The specifications for the FLEXQ module are as follows: |
| Number of samplers in the sampler tray | | up to 3 |
| Sampler type | | <i>safe</i> PICO with <i>safe</i> TIPCAP |
| Positioning of samplers in the sampler tray | | Random |
| Sample mixing time | | 7 sec |
| Scanning time per sample | | Typically <1 sec |
| Warning signal for missing sampler ID | | < 5 sec |
| Barcode scanner reads | | Code 128 between 5-10 mil. |

Approvals and patents

| | |
|---------------------|---|
| Approvals | <p>The equipment complies with the following standards:</p> <ul style="list-style-type: none"> • UL 61010-1: Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements • IEC 61010-2-81: Electrical Equipment for Laboratory Use; Particular requirements for automatic and semiautomatic laboratory equipment for analysis and other purposes • IEC 61010-2-101: Electrical Equipment for Measurement, Control, and Laboratory Use; Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment |
| CE-mark | The equipment complies with the requirements in 98/79/EC on in vitro diagnostic medical devices |
| EMC emission | The equipment complies with the emission requirements for Class A equipment in EN 61326-1: Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements. |
| EMC immunity | The equipment complies with the immunity requirements in EN 61326-2-6: Electrical equipment for measurement, control and laboratory use – EMC requirements - Part 2-6 Particular requirements - <i>In vitro</i> diagnostic (IVD) medical equipment |
| Patents | <p>One or more of the following patents and patent applications may apply:</p> <p>US Patent Nos.: US6051389, US6099804, US6551480, US6689318, US6880384, US6980285</p> <p>European Patent Nos.: EP889951, EP944731, EP1084398</p> <p>Japanese Patent Nos.: JP2972351, JP3285879, JP3369547, JP4229912</p> <p>German Patent Nos.: DE69729185, DE69735127, DE69938550</p> <p>US Patent Application Nos.: US2005-0130285, US2006-0275857, US2006-0275859, US2006-0275860</p> <p>European Patent Application Nos.: EP1086366, EP1273920, EP1583952, EP1692522, EP1885871, EP1889075</p> <p>Japanese Patent Application Nos.: JP2007-512519, JP2008-541103, JP2008-541104, JP2008-545952</p> <p>Chinese Patent Application Nos.: CN101175999, CN101184851, CN101223284</p> |

14. Ordering information

Overview

Introduction This chapter lists accessories used for the analyzer.

Contents This chapter contains the following topics.

| | |
|----------------------------|------|
| Analyzer accessories | 14-2 |
| Quality control | 14-5 |
| Sampling devices | 14-7 |

Analyzer accessories

Introduction The following accessories are available on order for the ABL800 FLEX analyzer depending on analyzer configuration.

| Electrodes | Item | Code No. | Type |
|-------------------|----------------------------|-----------------|-------------|
| | Reference Electrode | 945-603 | E1001 |
| | pH Electrode | 945-614 | E777 |
| | pO ₂ Electrode | 945-613 | E799 |
| | pCO ₂ Electrode | 945-612 | E788 |
| | K Electrode | 945-615 | E722 |
| | Na Electrode | 945-618 | E755 |
| | Cl Electrode | 945-617 | E744 |
| | Ca Electrode | 945-616 | E733 |
| | Glucose Electrode | 945-620 | E7066 |
| | Lactate Electrode | 945-619 | E7077 |
| | Crea A electrode | 945-662 | E8088 |
| | Crea B electrode | 945-663 | E8089 |
| | Dummy Electrode | 945-626 | - |

| Membrane boxes | Item | Code No. | Type |
|-----------------------|--|-----------------|--------------------|
| | Reference Membrane Box (4 units) | 942-058 | D711 |
| | pO ₂ Membrane Box (4 units) | 942-064 | D799 |
| | pCO ₂ Membrane Box (4 units) | 942-063 | D788 |
| | K Membrane Box (4 units) | 942-059 | D722 |
| | Na Membrane Box (4 units) | 942-062 | D755 |
| | Cl Membrane Box (4 units) | 942-061 | D744 |
| | Ca Membrane Box (4 units) | 942-060 | D733 |
| | Glucose Membrane Box (4 units) | 942-065 | D7066 |
| | Lactate Membrane Box (4 units) | 942-066 | D7077 |
| | Membrane Box for Crea A and Crea B electrodes (2 × 2 units) | 942-073 | D8088 and D8089 |

Continued on next page

Analyzer accessories, *Continued*

Solutions

ABL835/830/825/820/815/810/810 BG only/805:

| Item | Code No. | Type |
|--|----------|-------|
| Waste Container 600 mL | 905-802 | D513 |
| ctHb Calibration Solution (4 ampoules) | 944-021 | S7770 |
| Cleaning Solution 175 mL | 944-126 | S8375 |
| Calibration Solution 1 200 mL | 944-128 | S1820 |
| Calibration Solution 2 200 mL | 944-129 | S1830 |
| Rinse Solution 600 mL | 944-132 | S4980 |

ABL837/27/17:

| Item | Code No. | Type |
|--|----------|-------|
| Waste Container 600 mL | 905-802 | D513 |
| ctHb Calibration Solution (4 ampoules) | 944-021 | S7770 |
| Cleaning Met II Solution, 100 mL × 6 | 944-136 | S8377 |
| Calibration Solution 1, 175 mL × 6 | 944-133 | S1827 |
| Calibration Solution 2, 150 mL × 6 | 944-134 | S1837 |
| Rinse Solution, 600 mL | 944-159 | S4987 |

Gas accessories

| Item | Code No. | Type |
|---|----------|------|
| Gas Cal 1 (10 bar) Onboard gas bottle | 962-169 | - |
| Gas Cal 2 (10 bar) Onboard gas bottle | 962-170 | - |
| Gas Cal 1 (34 bar) Onboard gas bottle for non-EU countries | 962-183 | - |
| Gas Cal 2 (34 bar) Onboard gas bottle for non-EU countries | 962-184 | - |
| Gas Cal 1 (34 bar), Onboard gas bottle for the USA and Canada | 962-174 | - |
| Gas Cal 2 (10 bar), Onboard gas bottle for the USA and Canada | 962-175 | - |
| Gas Cal 1 (26 bar), Onboard gas bottle for Japan | 962-176 | - |
| Gas Cal 2 (10 bar), Onboard gas bottle for Japan | 962-177 | - |
| Valve Key | 922-509 | - |

Continued on next page

Analyzer accessories, *Continued*

Power cords

| Item | Code No. | Type |
|--|----------|------|
| Line Cord 120 V, USA and Japan | 615-403 | - |
| Line Cord 230 V, UK | 615-312 | - |
| Line Cord 230 V, ITA | 615-313 | - |
| Line Cord 230 V, DK | 615-314 | - |
| Line Cord 230 V, ISR | 615-315 | - |
| Line Cord 230 V, CHE | 615-316 | - |
| Line Cord 230 V, other 230 V countries | 615-303 | - |
| Line Cord 230 V, AUS and NZA | 615-317 | - |
| Line Cord 230 V, ZAF and IND | 615-318 | - |

Other accessories

| Item | Code No. | Type |
|--|----------|-------|
| Thermal Paper (8 rolls) | 984-070 | - |
| Hypochlorite Solution | 943-906 | S5362 |
| Inlet Gasket | 902-668 | - |
| Inlet Probe | 902-797 | - |
| Inlet Probe Tube | 841-780 | - |
| Inlet Syringe Handle | 902-669 | - |
| Inlet Capillary Handle | 902-670 | - |
| Pump Tube for electrode modules | 842-328 | - |
| Waste Pump Tube, yellow (2 pcs.) | 842-326 | - |
| Pump Tube for solutions | 842-327 | - |
| Fan Filter | 924-073 | - |
| Clot Catcher for the ABL800 FLEX analyzer, 250 units | 906-020 | - |

Documentation

| Item | Code No. | Type |
|---|----------|------|
| Communication Protocol Specifications, English | 989-329 | - |
| ABL800 FLEX Operator's manual, English | 994-908 | - |
| ABL800 FLEX Reference manual, English | 989-963 | - |
| ABL800 FLEX Reference manual on CD-ROM, English | 990-449 | - |

Quality control

Quality control accessories

| Item | Code No. | Type |
|----------------|----------|------|
| Ampoule Opener | 920-712 | - |
| QC Adapter | 924-036 | H700 |

Automatic quality control accessories

| Item | Code No. | Type |
|----------------|----------|------|
| Carousel | 887-865 | - |
| Ampoule Holder | 924-185 | H705 |

QUALICHECK3+ The QUALICHECK3+ quality control system contains the following solutions:

| Type | Description | Code |
|-------|------------------|---------|
| S7330 | Level 1 – RED | 944-049 |
| S7340 | Level 2 – YELLOW | 944-050 |
| S7350 | Level 3 – BLUE | 944-051 |
| S7360 | Level 4 – GREEN | 944-052 |

QUALICHECK5+ The QUALICHECK5+ quality control system contains the following solutions:

| Type | Description | Code |
|-------|------------------|---------|
| S7730 | Level 1 – RED | 944-017 |
| S7740 | Level 2 – YELLOW | 944-018 |
| S7750 | Level 3 – BLUE | 944-019 |
| S7760 | Level 4 – GREEN | 944-020 |

AutoCheck3+ The AutoCheck3+ quality control system contains the following solutions:

| Type | Description | Code |
|-------|------------------|---------|
| S7335 | Level 1 – RED | 944-082 |
| S7345 | Level 2 – YELLOW | 944-083 |
| S7355 | Level 3 – BLUE | 944-084 |
| S7365 | Level 4 – GREEN | 944-085 |

Continued on next page

Quality control, *Continued*

AutoCheck5+ The AutoCheck5+ quality control system contains the following solutions:

| Type | Description | Code |
|-------|------------------|---------|
| S7735 | Level 1 – RED | 944-074 |
| S7745 | Level 2 – YELLOW | 944-075 |
| S7755 | Level 3 – BLUE | 944-076 |
| S7765 | Level 4 – GREEN | 944-077 |

AutoCheck6+ The AutoCheck6+ quality control system contains the following solutions:

| Type | Description | Code |
|-------|------------------|---------|
| S7835 | Level 1 – RED | 944-094 |
| S7845 | Level 2 – YELLOW | 944-095 |
| S7855 | Level 3 – BLUE | 944-096 |
| S7865 | Level 4 – GREEN | 944-097 |

Range+ QUALICHECK The Range+ QUALICHECK quality control system contains the following items:

| Type | Description | Code |
|-------|-----------------------------|---------|
| S7930 | Level 1, box of 30 ampoules | 944-151 |
| S7940 | Level 2, box of 30 ampoules | 944-152 |
| S7950 | Level 3, box of 30 ampoules | 944-153 |
| H700 | ABL700 QC Adaptor | 924-036 |
| | Ampoule Opener | 920-712 |

Quality Control Documentation

| Type | Description | Code |
|------|--|---------|
| | Quality Control Systems Reference Manual | 989-046 |
| | QUALICHECK Short-form Instructions | 983-313 |
| | Logbook Control Binder, QUALICHECK+ | 984-129 |
| | Logbook Control Charts, Blood Gas | 989-417 |
| | Logbook Control Charts, Electrolytes and Metabolites | 989-418 |
| | Control Charts – Oximetry | 989-419 |

Sampling devices

Arterial blood gas samplers

The following sampling devices are available:

| Item | Code no. | Type |
|---|----------|--------|
| PICO50, 2 mL aspirator (100 units) | 956-552 | PICO50 |
| PICO70 w/o needle (100 units) | 956-518 | PICO70 |
| PICO70 w/o needle (w/o needle cube) (100 units) | 956-519 | PICO70 |
| PICO70 22G × 1" (100 units) | 956-522 | PICO70 |
| PICO70 22G × 1 1/4" (100 units) | 956-525 | PICO70 |
| PICO70 23G × 5/8" (100 units) | 956-529 | PICO70 |
| PICO70 23G × 1" (100 units) | 956-533 | PICO70 |
| PICO70 23G × 1 1/4" (100 units) | 956-534 | PICO70 |
| PICO70 23G × 5/8" (w/o needle cube) (100 units) | 956-546 | PICO70 |
| PICO70 25G × 5/8" (100 units) | 956-547 | PICO70 |
| PICO70 22G × 1" (w/o needle cube) (100 units) | 956-563 | PICO70 |
| <i>safe</i> PICO70 22G × 1/4" with needle shield device (100 units) | 956-608 | PICO70 |
| <i>safe</i> PICO70 23G × 5/8" with needle shield device (100 units) | 956-609 | PICO70 |
| <i>safe</i> PICO70 22G × 1" with needle shield device (100 units) | 956-624 | PICO70 |

Capillary samplers, glass

| Item | Code no. | Type |
|--|----------|----------------|
| CLINITUBES with balanced heparin, 125 µL including mixing wire and capillary caps (5 × 50 units) | 942-880 | D957G-70-125x5 |
| CLINITUBES with balanced heparin, 100 µL including mixing wire and capillary caps (5×75 units) | 942-878 | D957G-70-100x5 |
| CLINITUBES with sodium heparin, 55 µL including mixing wire and capillary caps (5×75 units) | 942-885 | D941G-240-55x5 |

Continued on next page

Sampling devices, *Continued*

Capillary samplers, plastic

| Item | Code no. | Type |
|---|----------|----------------|
| CLINITUBES with balanced heparin, 125 µL including mixing wire and capillary caps (500 units) | 942-893 | D957P-70-125x1 |
| CLINITUBES with balanced heparin, 100 µL including mixing wire and capillary caps (1 × 250 units) | 942-892 | D957P-70-100x1 |
| CLINITUBES with balanced heparin, 70 µL including mixing wire and capillary caps (1×250 units) | 942-898 | D957P-70-70x1 |

Sampling devices for FLEXQ

The following sampling devices are available on order for the ABL800 FLEX analyzers with FLEXQ module:

| Item | Code No. |
|---|----------|
| * <i>safe</i> PICO Self-fill without needle with <i>safe</i> TIPCAP, 0.7-1.5 mL (100 units) | 956-610 |
| <i>safe</i> PICO Self-fill with <i>safe</i> TIPCAP, without needle shield device, 22G x 32 mm, 0.7-1.5 mL (100 units) | 956-611 |
| <i>safe</i> PICO Self-fill with <i>safe</i> TIPCAP, without needle shield device, 23G x 16 mm, 0.7-1.5 mL (100 units) | 956-612 |
| <i>safe</i> PICO Self-fill with <i>safe</i> TIPCAP, without needle shield device, 22G x 25 mm, 0.7-1.5 mL (100 units) | 956-613 |
| * <i>safe</i> PICO Self-fill with needle shield device and <i>safe</i> TIPCAP, 22G x 32 mm, 0.7-1.5 mL (100 units) | 956-614 |
| * <i>safe</i> PICO Self-fill with needle shield device and <i>safe</i> TIPCAP, 23G x 16 mm, 0.7-1.5 mL (100 units) | 956-615 |
| * <i>safe</i> PICO Self-fill with needle shield device and <i>safe</i> TIPCAP, 23G x 25 mm, 0.7-1.5 mL (100 units) | 956-616 |
| * <i>safe</i> PICO Self-fill with needle shield device and <i>safe</i> TIPCAP, 22G x 25 mm, 0.7-1.5 mL (100 units) | 956-620 |
| * <i>safe</i> PICO Aspirating without needle with <i>safe</i> TIPCAP, 0.7-1.7 mL (100 units) | 956-622 |
| * <i>safe</i> PICO Self-fill with needle shield device and <i>safe</i> TIPCAP, 25G x 16 mm, 0.7-1.5 mL (100 units) | 956-623 |

* Without a needle cube.

15. Radiometer settings

Overview

Introduction This chapter describes Radiometer settings, contents of various Ini files and calibration verification procedure.

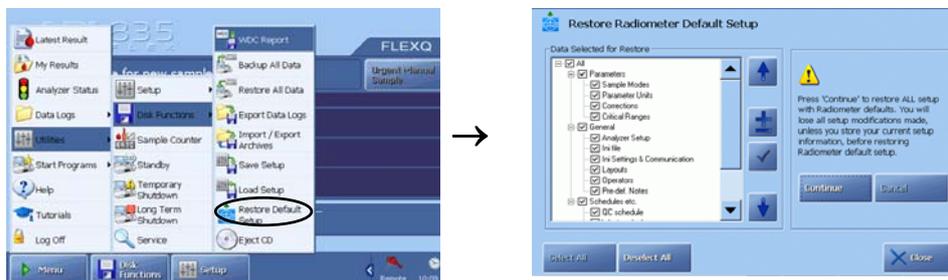
Contents This chapter contains the following topics.

| | |
|----------------------------------|-------|
| Radiometer default settings..... | 15-2 |
| Contents of setup settings..... | 15-15 |
| Calibration verification | 15-18 |
| Interfacing facilities | 15-20 |

Radiometer default settings

Radiometer default setup screen

Press *Menu - Utilities - Disk Functions - Restore Default Setup*:



You can select the parts of the Setup to be set back to Radiometer defaults.

Analyzer Security

Default settings for **General Security** are as follows:

| Item | Default setting |
|------------------------------------|--------------------------|
| Enable Centralized User Management | Off |
| Authenticate operator by | Logon-barcode as primary |
| Allow anonymous use | Yes |
| Logoff Time | 3 min |
| Profile for anonymous user | User |

Continued on next page

Radiometer default settings, *Continued*

Default settings for **Access Profiles** are as follows:

| | A | B | C | D | E | F | G | H | I | J |
|-----------------|---|---|---|---|-----|---|---|---|---|---|
| User | X | X | X | | (X) | X | | | X | |
| Supervisor | X | X | X | X | X | X | X | | X | X |
| Manager | X | X | X | X | X | X | X | | X | X |
| Service techn. | X | X | X | X | X | X | X | X | X | X |
| Guest | X | | | | (X) | | | | | |
| Custom 1 | | | | | (X) | | | | | |
| Custom 2 | | | | | (X) | | | | | |
| Custom 3 | | | | | (X) | | | | | |
| Remote operator | X | X | X | X | X | X | X | X | X | |

A = Perform measurement

B = Perform calibration

C = Perform replacements

D = Perform Disk Functions

E = View Data Logs

F = Edit data in logs

G = Enter Setup Programs

H = Enter Service Programs

I = Start AutoCheck

J = Approve results

Columns D, E, G and H are controlled via the **Menu and Button Configuration** screen settings, not via the check buttons on the **Access Profiles** screen.

(X) means restricted access to data logs:

- User can view the logs, but there is no access to the archived data logs.
- Guest and Custom can view Patient Results Log and Quality Control Log.

Continued on next page

Radiometer default settings, *Continued*

Analysis Setup defaults The following default measuring modes are available:

| Analyzer | Modes | Default button |
|--------------------------------|----------------------------|---|
| ABL837/27 /17 | Syringe Capillary | Syringe – S250 µL; Syringe – S85 µL; Syringe – Pleura pH Ampoule – QC; Expired air Capillary – C125 µL; Capillary – C55 µL; Capillary – C35 µL MET; Capillary – C35 µL OXI |
| ABL835/25 /15 | Syringe: Capillary: | Syringe – S195 µL; Syringe – S95 µL; Syringe – Pleura pH Ampoule-QC Capillary – FLEXMODE; Capillary – C95 µL; Capillary – C55 µL pH+BG+OXI; Capillary – C35 µL MET Capillary – C35 µL OXI |
| ABL830/20 /10/10 BG only | Syringe: Capillary: | Syringe – S85 µL; Syringe – Pleura pH Ampoule-QC Capillary – FLEXMODE; Capillary – C55 µL Capillary – C35 µL OXI |
| ABL805 | Syringe: Capillary: | Syringe – S165 µL; Syringe – S95 µL; Syringe – Pleura pH Ampoule-QC Capillary – FLEXMODE; Capillary – C95 µL; Capillary – C55 µL pH+BG; Capillary – C35 µL MET |
| ABL800* | N/A | N/A |

* Not available at the time of the release.

- All user-defined modes and Other Fluids mode are deleted. All modes are set to Radiometer default layout.
- Reference ranges and critical limits are deleted.
- **Parameter profile:** All parameters are selected.
- Dynamic Parameters: Off.
- **Sample Pre-registration** settings:
 - Interpret barcode input as: Sampler ID
 - Confirm pre-registered data : On.
 - Included fields: All fields On.
- **Sample Logistics Setup** settings:
 - Batch mode: Off
 - Sample age: On (30 min for all parameters)
 - Primary patient ID field in "FLEXQ" box: Patient Last Name.

Continued on next page

Radiometer default settings, *Continued*

Analysis Setup defaults
(*continued*)

- Available **layouts**: -R- Default (Default)
- GFR not activated by default.
- **Patient ID layout** settings included in the -R- Default Layout:
 - Patient ID
 - Patient Last Name
 - Patient First Name
 - Sample type
 - Temp. °C
- **Patient Result** settings included in the -R- Default Layout (bold text = a new title; [xxx-xxx] = the reference range for a parameter):

| | |
|---------------------------|-----------|
| Blood Gas Values | |
| pH | [xxx-xxx] |
| pCO ₂ | [xxx-xxx] |
| pO ₂ | [xxx-xxx] |
| < New Line > | |
| Oximetry Values | |
| ctHb | [xxx-xxx] |
| sO ₂ | [xxx-xxx] |
| FO ₂ Hb | [xxx-xxx] |
| FCOHb | [xxx-xxx] |
| FHHb | [xxx-xxx] |
| FMetHb | [xxx-xxx] |
| FHbF | [xxx-xxx] |
| < New Line > | |
| Electrolyte Values | |
| cK ⁺ | [xxx-xxx] |
| cNa ⁺ | [xxx-xxx] |
| cCa ²⁺ | [xxx-xxx] |
| cCl ⁻ | [xxx-xxx] |
| < New Line > | |
| Metabolite Values | |
| cGlu | [xxx-xxx] |
| cLac | [xxx-xxx] |
| cCrea | [xxx-xxx] |
| ctBil | [xxx-xxx] |
| < New Page > | |

Continued on next page

Radiometer default settings, *Continued*

Analysis Setup defaults (*continued*)

| |
|--|
| Temperature Corrected Values |
| pH(<i>T</i>) |
| <i>p</i> CO ₂ (<i>T</i>) |
| <i>p</i> O ₂ (<i>T</i>) |
| < New Group > |
| Oxygen Status |
| ctO ₂ |
| <i>p</i> 50 |
| < New Line > |
| Acid Base Status |
| <i>c</i> Base(Ecf) |
| <i>c</i> HCO ₃ ⁻ (P, st) |

Calibration Setup defaults

Default settings for **Drift tolerances** are as follows:

| Parameter | Drift 1 | Drift 2 | Units |
|---------------------------|---------|---------|--------|
| pH | 0.020 | 0.020 | |
| <i>p</i> CO ₂ | 2.5 | 5 | mmHg |
| <i>p</i> O ₂ | 6 | 6 | mmHg |
| ctHb | 10 | N/A | pA |
| <i>c</i> K ⁺ | 0.2 | 1.5 | mmol/L |
| <i>c</i> Na ⁺ | 3 | 1 | mmol/L |
| <i>c</i> Ca ²⁺ | 0.05 | 0.2 | mmol/L |
| <i>c</i> Cl ⁻ | 2 | 3 | mmol/L |
| <i>c</i> Glu | 0.5 | N/A | mmol/L |
| <i>c</i> Lac | 0.2 | N/A | mmol/L |
| <i>c</i> Crea | 15 | 15 | μmol/L |

Continued on next page

Radiometer default settings, *Continued*

Calibration Setup defaults (continued)

Default settings for **Calibration Schedule** are as follows:

| Activity | Default setting |
|--|-----------------|
| 2 Point Cal | 8 hours |
| 1 Point Cal | 4 hours |
| 1 Point pH/BG calibration (for the USA only) | 2 hours |
| tHb Cal | 3 months |
| Cleaning | 8 hours |
| Start time for 1- and 2-point calibration and cleaning | 00:00 |
| Activity after measurement | None |

Quality Control Setup defaults

Default settings for **Quality Control Statistics** are as follows:

| Item | Default setting |
|---------------------------------------|-----------------|
| Statistics factor | 1.5 |
| Remind to print statistics each month | No |
| Remind to export WDC data each month | No |

Default settings for **Quality Control Mandatory Input** are as follows:

| Item | Default Setting |
|-----------------------|-----------------|
| Mandatory temperature | No |
| Default temperature | 25 °C |

- **QC Schedule** settings are deleted.
- **AutoCheck Setup**: replacement warning before carousel empty: No.
- **Westgard Rules**: all rules are 'Off' and the use of Westgard Rules is disabled.
- **Rilibäk Ranges**: the use of Rilibäk rules is disabled.

Continued on next page

Radiometer default settings, *Continued*

Replacement Setup defaults

The default settings for **Replacements** are as follows:

| Item | Default setting |
|---------------------------------------|-----------------|
| pCO ₂ Electrode Membrane | Never |
| pO ₂ Electrode Membrane | Never |
| K Electrode Membrane | Never |
| Na Electrode Membrane | Never |
| Ca Electrode Membrane | Never |
| Cl Electrode Membrane | Never |
| Glucose Electrode Membrane | Never |
| Lactate Electrode Membrane | Never |
| Crea A and Crea B Electrode Membranes | Never |
| Reference Electrode Membrane | Never |
| K Electrode | Never |
| Na Electrode | Never |
| Ca Electrode | Never |
| Cl Electrode | Never |
| Glucose Electrode | Never |
| Lactate Electrode | Never |
| Crea A Electrode | Never |
| Crea B Electrode | Never |
| Reference Electrode | Never |
| pH Electrode | Never |
| pCO ₂ Electrode | Never |
| pO ₂ Electrode | Never |
| Inlet Gasket | Never |
| Rubber Tube for Inlet | Never |
| Pump Tube, Electrode Modules | Never |
| Pump Tube, Waste | Never |
| Pump Tube, Solutions | Never |
| Fan Filter | Never |

Continued on next page

Radiometer default settings, *Continued*

Replacement Setup defaults (*continued*)

Solution warning settings are 25 %.

Reagents Expiration warning setting: 24 hours.

User Activities settings are blank.

AutoCheck Warning: No.

General Setup defaults

The default settings for **Parameter Setup** are as follows:

| Parameter | Enabled/ Locked | Repress- ion | Offset | Slope | Units | Out of Range Suppression |
|--------------------|--------------------|-----------------|--------|-------|--------|--------------------------------|
| pH | Yes/No | No | 0.000 | 1.000 | | |
| pCO ₂ | Yes/No | No | 0.0 | 1.000 | mmHg | |
| pO ₂ | Yes/No | No | 0.0 | 1.000 | mmHg | |
| ctHb | Yes/No | No | N/A | 1.000 | g/dL | |
| FHHb | Yes/No | No | N/A | N/A | % | No |
| FO ₂ Hb | Yes/No | No | N/A | N/A | % | No |
| FHbF | Yes/No | No | 0 | 1.000 | % | Yes |
| sO ₂ | Yes/No | No | 0.0 | 1.000 | % | No |
| FCOHb | Yes/No | No | 0.0 | N/A | % | No |
| FMetHb | Yes/No | No | 0.0 | N/A | % | No |
| ctBil | Yes/No | No | 0 | 1.000 | μmol/L | Yes |
| cK ⁺ | Yes/No | No | 0.0 | 1.000 | mmol/L | |
| cNa ⁺ | Yes/No | No | 0 | 1.000 | mmol/L | |
| cCa ²⁺ | Yes/No | No | 0.00 | 1.000 | mmol/L | |
| cCl ⁻ | Yes/No | No | 0 | 1.000 | mmol/L | |
| cGlu | Yes/No | No | 0.0 | 1.000 | mmol/L | |
| CLac | Yes/No | No | 0.0 | 1.000 | mmol/L | |
| cCrea | Yes/No | No | 0.0 | 1.000 | μmol/L | |

Continued on next page

Radiometer default settings, *Continued*

General Setup defaults (*continued*)

Default settings for **Units** are as follows:

| Parameter | Unit |
|---|---------|
| Pressures | mmHg |
| cCrea | μmol/L |
| ctBil | μmol/L |
| ctHb | g/dL |
| Oximetry fractions | % |
| Saturation | % |
| Gas fractions | % |
| FO ₂ (I) | % |
| Sensitivity pH/cK ⁺ /cNa ⁺ /cCa ²⁺ /cCl ⁻ | % |
| Hct | % |
| pO ₂ (a/A) | % |
| FShunt | % |
| RI | % |
| cK ⁺ /cNa ⁺ /cCa ²⁺ /cCl ⁻ | mmol/L |
| cGlu/cLac | mmol/L |
| Temperatures | °C |
| ctO ₂ /ctCO ₂ | Vol % |
| ḐO ₂ | mL/min |
| ḐO ₂ | mL/min |
| Age | years |
| Weight | kg |
| Height | m |
| Altitude | m |
| Birth weight | g |
| pO ₂ sensitivity | PA/mmHg |
| cCrea sensitivity 1 | pA/μM |
| cCrea sensitivity 2 and 3 | % |

Continued on next page

Radiometer default settings, *Continued*

General Setup defaults (*continued*)

Default settings for **User-defined Patient Data Items** are as follows:

| Name | Type | Unit | Decimals |
|------------------|-----------|--------------------|----------|
| Spontaneous RR | Numerical | b/min | 1 |
| Set RR | Numerical | b/min | 1 |
| Vt | Numerical | L | 2 |
| Ve | Numerical | L | 2 |
| Peak Flow | Numerical | L/min | 1 |
| Liter Flow | Numerical | L/min | 1 |
| Ti | Numerical | seconds | 1 |
| PEEP | Numerical | cmH ₂ O | 1 |
| Pressure Support | Numerical | cmH ₂ O | 1 |
| CPAP | Numerical | cmH ₂ O | 1 |
| CMV | Numerical | Rate | 1 |
| SIMV | Numerical | Rate | 1 |
| Flow-by | Numerical | L/min | 1 |
| HFV | Numerical | Rate | 1 |
| I:E Ratio | Numerical | | 2 |
| Wave | Numerical | | None |
| ICD9 Code | Numerical | | None |
| Oxygen Device 1 | Numerical | | None |
| Oxygen Device 2 | Numerical | | None |
| Diagnostic Code | Numerical | | None |

Default settings for **User-defined Notes**: No notes defined.

Default settings for **Language**: English.

Default settings for **Acoustic Signals** are as follows:

| Event | Default setting |
|-------------------------------|-----------------|
| Value exceeds critical limits | No |
| Close inlet | Yes |
| Result is ready | Yes |
| Inlet is open too long | Yes |
| Beep before AutoCheck opens | Yes |

Continued on next page

Radiometer default settings, *Continued*

General Setup defaults (*continued*)

Default settings for **Corrective Actions** are as follows:

| Event | Default setting | Traffic light |
|-----------------------------------|----------------------------|---------------|
| Calibration error(s) present | "? on specific parameters" | Yellow |
| Calibration schedule reminder(s) | No setting | Yellow |
| QC error(s) present | No setting | Green |
| QC schedule reminders | No setting | Yellow |
| Replacement schedule reminders | No setting | Yellow |
| System message(s) present | No setting | Yellow |
| User Activity Reminder(s) | No setting | Yellow |
| AutoCheck QC error(s) present | No setting | N/A |
| AutoCheck scheduled level missing | No setting | Green |

Default settings for **Miscellaneous Setup** are as follows:

| Event | Default setting |
|-------------------------------------|-----------------------------------|
| Analyzer locked | Not set |
| Use <i>safe</i> TIPCAP | Yes |
| Enable Estimated Derived Parameters | No |
| Fixed pO_2/pCO_2 decimals | No |
| Enable General Barcode Support | Yes |
| Enable Patient Result Approval | No |
| Apply Parameter Corrections to QC | Yes |
| Log All Measurement Activities | No |
| Show Parameter Bar | Yes |
| Auto temp unit conversion | No |
| HbF correction | "Enabled for levels > 20 %" |
| Analyzer Message | (Blank) |
| Screen saver | Yes, Minutes to wait when idle: 5 |

Default settings for **Automatic Printing** are as follows:

| Item | Default setting |
|----------------------------|-----------------|
| Patient results | On |
| QC results | Off |
| Calibration results | Off |
| Activity log messages | Off |
| FLEXQ registration receipt | Off |
| Message level | User |
| Number of copies | 1 |

Continued on next page

Radiometer default settings, *Continued*

General Setup defaults (*continued*)

Default settings for **Printer Setup** are as follows:

| Item | Default setting |
|-------------------------|--|
| Installed printers | Internal Printer (added printers are not deleted) |
| Select printer dialogue | Off |

Default settings for **Automatic Backup** are as follows:

| Item | Default setting |
|-------------|-----------------|
| Auto Backup | Off |

Default settings for **Automatic Archiving** are as follows:

| Item | Default setting |
|--------------------------------|-----------------|
| Patient report log | On |
| Calibration log | On |
| Quality control log | On |
| Activity log | On |
| Store archives on the analyzer | On |

Default settings for **Communication Setup** are as follows:

| Item | Default setting |
|-----------------------------|---|
| RADIANCE Connection | Off |
| LIS/HIS Connection | None |
| QA Portal | Off |
| Automatic Data Request | "When entering sampler ID" – on |
| Automatic Data Transmission | Patient results, Calibration results, QC results, Activity log messages |
| Patient Lookup Setup | Local database |
| Remote Support | Enable remote access |

Continued on next page

Radiometer default settings, *Continued*

- Setups without Radiometer settings** The following setups have no Radiometer settings:
- Environment setup
 - time and date setup
 - analyzer identification setup

Contents of setup settings

Groups of Setup settings The setup is divided in the following groups of settings:

- Parameters
- General
- Schedules, etc.



You can restore the Radiometer Default Setup or a setup you have customized (Customer Setup) and saved.

Selecting or deselecting items in the setup – see *Loading/restoring Setup* in chapter 8.

Each setup group of settings is described in this section.

Parameters

The following settings (i.e. screens and their data) will be restored in the Parameters group:

| Item | Setup (screens) |
|-----------------|---|
| Sample Modes | <ul style="list-style-type: none"> • Syringe Mode • Capillary mode • Parameter Setup (Offset and slope only) |
| Parameter Units | Units Setup |
| Corrections | Parameter Setup (Repression and Out-of-range suppression only) |
| Critical Ranges | <ul style="list-style-type: none"> • Reference ranges, Critical limits • Age groups |

Continued on next page

Contents of setup settings, *Continued*

General

The following settings (i.e. screens and their data) will be restored in the General group:

| Item | Setup (screens) |
|---------------------------------|---|
| Analyzer Setup | <ul style="list-style-type: none"> • Corrective Actions • Acoustic Signals • Low Level Warning |
| Ini File | <ul style="list-style-type: none"> • Selected Language • Printer path • Reagents Expiration Warning |
| Ini Settings and Communications | <ul style="list-style-type: none"> • RADIANCE Connection • LIS/HIS Connection • QA Portal • Automatic Data Transmission • Automatic Data Request • Patient Lookup Setup • Operators and Passwords (Logon Protection Level and Logoff Time only) • Miscellaneous Setup (All, except Analyzer Locked) • Automatic Printing • Automatic Archiving • Automatic Backup • Save Setup (Destination) • Load Setup (Source) • Backup All Data (Destination) • Export Data Logs (Destination) • Function: External keyboard enabling • Function: Enable remote access when operator is logged on • QC Statistics Setup • QC Input Setup • AutoCheck Setup • Westgard Rules (enable Westgard Rules) • Rilibäk Ranges (enable Rilibäk rules) • Printer Setup (Show list of printers) |

Continued on next page

Contents of setup settings, *Continued*

General (*continued*)

| Item | Setup (screens) |
|----------------|--|
| Layouts | <ul style="list-style-type: none"> • Patient Report Setup • Patient ID Layout • Patient Result Layout • User-defined Data Items • The width of the following column setups: Patient Results Log; Patient Lookup; Patient Profiles Log; QC Log; Calibration Log; System Messages; Replacement Schedule |
| Operators | <ul style="list-style-type: none"> • General Security • Operators and Passwords • Access Profiles |
| Pre-def. Notes | <ul style="list-style-type: none"> • User-defined Notes |

Schedules, etc. The following ini files (i.e. screens and their data) will be restored in the Schedules, etc. group:

| Item | Setup (screens) |
|--------------------------|--|
| QC Schedule | QC Schedule (QC schedule is restored for the slots with the control solutions installed in them. The schedule follows the slots, not the QC levels). |
| Rilibäk Ranges | Rilibäk rules are restored |
| Wetsection Setup | <ul style="list-style-type: none"> • Calibration Schedule (minus tHb Cal and the start time) • Calibration Drift Tolerances |
| Replacement Schedule | Replacement Schedule |
| User Activities Schedule | <ul style="list-style-type: none"> • User Activities • Edit User Activities |

Calibration verification

Purpose Regulations in some countries require verification of the reportable ranges selected for the measured parameters, and a special feature described below is provided to assist in the collection of this data.

Once the reportable ranges for the measured parameters are established, the limits may be entered in the Reportable Ranges program described in *Analysis Setup*, chapter 3.

Preparatory steps The procedure given below is only a suggestion to easily identify your specific layout and measuring mode.

| Step | Action |
|------|--------|
|------|--------|

1. Make a new report layout called, e.g. "Cal. Verification", based on the Radiometer default layout – see *Patient Report Setup* in chapter 3.
2. Press *Patient ID layout* and deselect all items except for the Patient ID and Sample type. Set default sample type to Cal. Verification.



3. Press *Edit Patient Results Layout* and deselect all parameters except for the measured parameters. Deselect range checks for all parameters.
4. In the *Analysis Setup - Syringe Mode Setup* dedicate one unoccupied button to this specific mode (call it, e.g. Cal. Verification) using *Edit name*.



Select desired parameters (press *Parameters*) and layout (press *Layout*) that you have made in step 1 above.

Continued on next page

Calibration verification, *Continued*

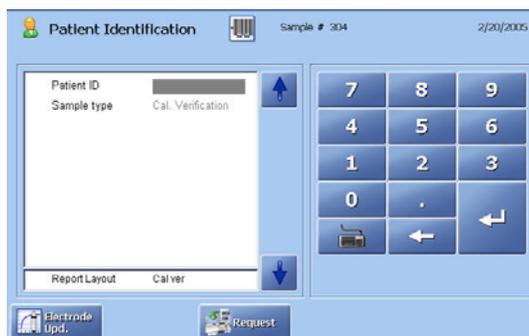
Preparatory steps (*continued*)

- | Step | Action |
|------|--|
| 5. | Condition calibration verification kit – see <i>Preparing a control solution</i> in <i>chapter 5</i> of this manual. |
| 6. | Place the ampoule in the ampoule opener and break off the ampoule neck. Place the ampoule fully into the H700 Adapter. |

Verification procedure

To perform a verification measurement, do the following:

- | Step | Action |
|------|---|
| 1. | Check that the analyzer is in the Ready mode. |
| 2. | Open the syringe inlet flap and place the adapter tip into the syringe inlet. |
| 3. | Select the Cal. verification mode on the screen and press Start . |
| 4. | Press Aspirate to start sample aspiration. |
| 5. | When prompted by the analyzer, remove the sampling device and close the inlet flap. |
| 6. | Enter the information on the Patient Identification screen. |



- Use a dedicated identifier for each solution (e.g. Level 1) as Patient ID.
- | | |
|----|---|
| 7. | After all measurements on the calibration verification solutions have been completed, review the data by filtering it in the Patient Results log or transfer the data to a data analysis program – see <i>Exporting Data Logs</i> in <i>chapter 8: Disk Functions</i> . |
| 8. | After the new reportable ranges have been determined, enter any changes in Setup program: Reportable Ranges. |

Once the first measurement in this mode has been performed, the mode is available for the next seven days. During this time you can verify your reportable ranges according to the procedure used in your institution. After seven days the mode will not be available for the next 14 days.

Interfacing facilities

Connecting a mouse

A mouse connected to the analyzer may be used to activate all the analyzer's screen functions instead of touching the screen. This mouse facility is first and foremost intended for service technicians and not for the daily use of the analyzer.

A standard PS/2 port mouse is the sole item that is required for connection to the analyzer.

To connect the mouse to the analyzer, do the following:

| Step | Action |
|------|--|
| 1. | Switch off the analyzer. |
| 2. | Connect the mouse to the mouse port at the rear of the analyzer. |
| 3. | Switch on the analyzer. |

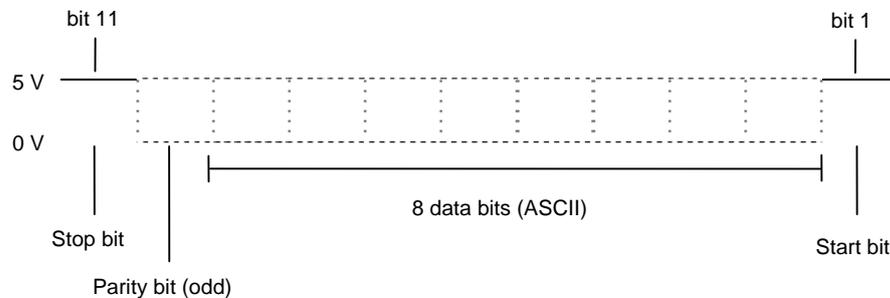
Connecting an alphanumeric keyboard

An external alphanumeric keyboard may be used instead of the on-screen keyboard to enter data. However, to select individual buttons on the analyzer's screen, a mouse must be used or the operator must touch the screen.

An IBM enhanced personal computer keyboard is the sole item that is required for connection to the analyzer.

NOTICE: The keyboard layout must correspond to the language version used by the analyzer.

The transmission format for an alphanumeric keyboard is as follows:



Pin designation on the cable connector are as follows:

Pin 1 – Clock in/out

Pin 2 – Data in/out

Pin 3 – Not connected

Pin 4 – Ground

Pin 5 – +5 V

Pin 6 – Not connected

Continued on next page

Interfacing facilities, *Continued*

Connecting an alphanumeric keyboard (*continued*)

To connect the keyboard to the analyzer, do the following:

| Step | Action |
|------|--|
| 1. | Switch off the analyzer. |
| 2. | Connect the keyboard to the keyboard port at the rear of the analyzer. |
| 3. | Switch on the analyzer. |

Connecting to a network

Many hospitals utilize a computer-controlled information system such as the Hospital Information System (HIS) or the Laboratory Information System (LIS). Connecting the analyzer to such an information system via a network enables the user to exercise greater control over the amount of patient data circulating within the hospital.

The types of information that can be communicated via a network between the central computer controlling the information system and the analyzer are:

- Patient results
- Quality control results
- Calibration data
- System messages

Recommendations:

1. Use a shielded data cable with an RJ45 connector to connect the analyzer to a network.
2. The analyzer is first connected to the computer controlling the information system via one of the following two interfaces:
 - A serial line (RS232 Interface)
 - An Ethernet interface (TCP/IP)
3. Once the analyzer has been physically connected to the network, one of the protocols stated below is used for communication with the central computer.
 - ASTM
 - HL7
 - POCT1-A

For further information refer to the *Communication Protocol Specifications for Radiometer Products* (code 989-329).

Radiometer recommends that a qualified service technician carries out connection of the analyzer to a network.

External barcode reader

An external barcode reader can be connected and used side by side with the built-in barcode reader – contact your Radiometer service representative.

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Date of issue

Radiometer representative:

Manufacturer:

RADIOMETER 

If you have any questions
or need assistance,
please contact your local
Radiometer representative.



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