ABL90 FLEX reference manual

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reference
manual

RADIOMETER

Reference manual

Note to the operators of the ABL90 FLEX analyzer

Introduction

This note outlines the improvements in software version 2.8.

Instructions to operators

Put the Note to the operators in the binder of your manual and replace the corresponding front and date of issue pages with the new pages in this update kit.

Setup

You can now enter an operator-defined offset correction for *c*tHb.

For instructions on how to enter operator-defined offset corrections, see *Parameter setup* in section *Parameters and input setup* in chapter 1 in the ABL90 FLEX reference manual.

Performance specifications

Radiometer has tested and verified the performance of pO_2, cNa^+ and *c*Glu at these extended lower levels:

Sensor	Level
pO_2	15 mmHg
Na	100 mmol/L
Glu	0.3 mmol/L

Due to the extended lower levels, the reportable ranges for pO_2 and cNa^+ are now:

Parameter	Unit	Range of indication	Reportable range (default)
pO_2	mmHg; Torr	0-800	10-550
	kPa	0-107	1.33-73.3
cNa^+	mmol/L; meq/L	7-350	95-190

The performance test results of pO_2, cNa^+ and *c*Glu, with the extended lower levels, are now:

Performance test results – pO_2

$Bias_{Prim.ref}$ and Repeatability – blood samples

pO_2 (mmHg)	$Bias_{Prim.ref}$	S_0	S_X	CV_X%	TE_A	TE_A (%)
15.0	-3.0	0.13	0.83	5.6	4.63	30.8
30.0	0.0	0.21	0.60	2.0	1.18	3.9
75.0	0.7	0.31	0.84	1.1	2.35	3.1
125	0.7	0.37	1.19	1.0	3.03	2.4
250	-2.0	1.54	2.93	1.2	7.74	3.1
500	-6.1	2.47	5.95	1.2	17.76	3.6

Performance test results – cNa$^+$

Bias$_{Prim.ref}$ and Repeatability – blood samples

cNa$^+$ (mmol/L)	Bias$_{Prim.ref}$ *)	S_0	S_X	CV_X%	TE_A	TE_A (%)
100	-0.1	0.2	0.8	0.8	1.67	1.7
120	0.0	0.1	0.9	0.8	1.76	1.5
130	0.3	0.2	1.1	0.8	2.46	1.9
140	0.5	0.1	1.1	0.8	2.66	1.9
160	0.6	0.3	1.2	0.8	2.95	1.8
180	0.9	0.1	1.6	0.9	4.04	2.2

*) ABL735 analyzer corr. to NIST through:

Na(ABL735, corr) = 1.055 * Na(ABL735, meas) – 6.8966 (mM)

Performance test results – cGlu

Bias$_{Prim.ref}$ and Repeatability – blood samples

Blood, $pO_2 \geq 90$ mmHg

cGlu (mmol/L)	Bias$_{Prim.ref}$	S_0	S_X	CV_X%	TE_A	TE_A (%)
0.3	0.03	0.01	0.08	26.7	0.20	65.6
2.0	-0.09	0.02	0.09	4.5	0.27	13.3
6.0	-0.07	0.06	0.16	2.7	0.38	6.4
10.0	0.23	0.09	0.24	2.4	0.70	7.0
25.0	-0.87	0.18	0.83	3.3	2.5	10.0
40	-1.58	0.52	2.33	5.8	6.2	15.4

Blood, 25 mmHg$\leq pO_2 <$90 mmHg

cGlu (mmol/L)	Bias$_{Prim.ref}$	S_0	S_X	CV_X%	TE_A	TE_A (%)
0.3	-0.04	0.01	0.11	36.7	0.26	86.17
2.0	0.14	0.01	0.10	5.0	0.33	16.34
6.0	0.22	0.05	0.22	3.7	0.66	10.95
10.0	0.27	0.10	0.41	4.1	1.1	10.84
25.0	-0.35	0.25	1.38	5.5	3.1	12.43
40	-2.63	0.74	3.15	7.9	8.9	22.35

Blood, 10 mmHg$\leq pO_2 <$25 mmHg

cGlu (mmol/L)	Bias$_{Prim.ref}$	S_0	S_X	CV_X%	TE_A	TE_A (%)
0.3	-0.04	0.01	0.07	23.3	0.17	58.3
2.0	0.14	0.01	0.09	4.5	0.32	16.2
6.0	0.22	0.04	0.28	4.6	0.78	13.0
10.0	0.27	0.08	0.63	6.3	1.52	15.2
25.0	-1.60	0.22	2.23	8.9	6.05	24.2

Serum pool, pO_2≥90 mmHg

*c*Glu (mmol/L)	$Bias_{Prim.ref}$	S_0	S_X	CV_X%	TE_A	TE_A (%)
0.3	-0.04	0.01	0.06	20	0.17	55.51
2.0	0.14	0.02	0.09	4.5	0.32	16.11
6.0	0.22	0.03	0.21	3.5	0.63	10.51
10.0	0.27	0.04	0.35	3.5	0.98	9.76
25.0	0.68	0.18	0.82	3.3	2.3	9.28
40	0.53	0.59	1.61	4.0	3.7	9.37

Impact of the pO_2 level on Glucose linearity and specifications of the ABL90 FLEX analyzer

CAUTION – *Risk of incorrect results*

Low pO_2 levels can influence the linearity of glucose measurements, and can therefore result in falsely low glucose results. Please note that glucose performance is not specified when the pO_2 is less than 10 mmHg (1.3 kPa).

The linearity of the glucose is dependent on the oxygen tension of the sample. This dependence is due to the co-reaction of glucose and oxygen by the enzyme glucose oxidase. Low pO_2 levels can influence the linearity of the glucose sensor. The following table outlines the glucose linearity as a function of the pO_2.

Impact of the pO_2 level on Glucose	
If the pO_2 level in a sample is:	**Then** *c*Glu linearity specifications only apply to *c*Glu values between:
<10 mmHg (<1.3 kPa)	Linearity not specified. The *c*Glu value is not usable.
10≤pO_2<25 mmHg (1.3≤pO_2<3.3 kPa)	0-25 mmol/L If *c*Glu>25 mmol/L, the linearity is not specified and the *c*Glu value not usable.
≥25 mmHg (≥3.3 kPa)	0-40 mmol/L

If pO_2<10 mmHg (<1.3 kPa), the *c*Glu value is not usable and no value is shown. Analyzer message no. 1387 informs you that the *c*Glu value is not usable.

Analyzer messages

These messages are new or changed:

No.	Message	Interpretation	Operator action
1230	Inlet Gasket Holder replaced	Shown in the activity log at the time of a replacement.	– No action required.
1232	Inlet Connector Gasket replaced	Shown in the activity log at the time of a replacement.	– No action required.

1234	Demonstration software - not for clinical purposes	Demonstration software - not for clinical purposes	– No action required.
1362	Inlet gasket cleaning has been started	Guided troubleshooting step has been started by operator	– No action required
1363	Inlet gasket cleaning has been skipped	Guided troubleshooting step has been skipped by operator	– No action required
1364	Inlet gasket cleaning test ok	Test after action by operator is ok	– No action required
1365	Inlet gasket cleaning test failed	Test after action by operator has failed	– No action required
1366	Inlet gasket holder replacement has been started	Guided troubleshooting step has been started by operator	– No action required
1367	Inlet gasket holder replacement has been skipped	Guided troubleshooting step has been skipped by operator	– No action required
1369	Inlet gasket holder replacement test failed	Test after action by operator has failed	– No action required
1371	Solution pack replacement skipped	Guided troubleshooting step has been skipped by operator	– No action required
1372	Solution pack replacement test ok	Test after action by operator is ok	– No action required
1373	Solution pack replacement test failed	Test after action by operator has failed	– No action required
1374	Inlet connector gasket replacement started	Guided troubleshooting step has been started by operator	– No action required
1375	Inlet connector gasket replacement skipped	Guided troubleshooting step has been skipped by operator	– No action required
1376	Inlet connector gasket replacement test ok	Test after action by operator is ok	– No action required
1377	Inlet connector gasket replacement test failed	Test after action by operator has failed	– No action required
1378	Inlet gasket holder replacement test ok	Test after action by operator is ok	– No action required
1379	Solution pack replacement started	Guided troubleshooting step has been started by operator	– No action required
1380	Manual flush started	Guided troubleshooting step has been started by operator	– No action required
1381	Manual flush skipped	Guided troubleshooting step has been skipped by operator	– No action required
1382	Manual flush test ok	Test after manual flush is ok	– No action required
1383	Manual flush test failed	Test after manual flush has failed	– No action required

1384	Replace inlet gasket holder	The inlet gasket holder needs to be replaced.	– Replace inlet gasket holder
1386	System time adjusted more than 2 hours	No action	– No action
1387	Glu not usable	pO_2 too low for reliable *c*Glucose measurement	N/A

The contents of this document will be added to the manual the next time the manual is updated.

CE IVD

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ABL90 FLEX

Reference manual

From software version 2.8xx

CE

RADIOMETER

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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.

Radiometer cannot provide or verify system performance characteristics if the system is not installed, used and maintained in accordance with Radiometer procedures or if accessories not meeting the specifications provided by Radiometer are used.

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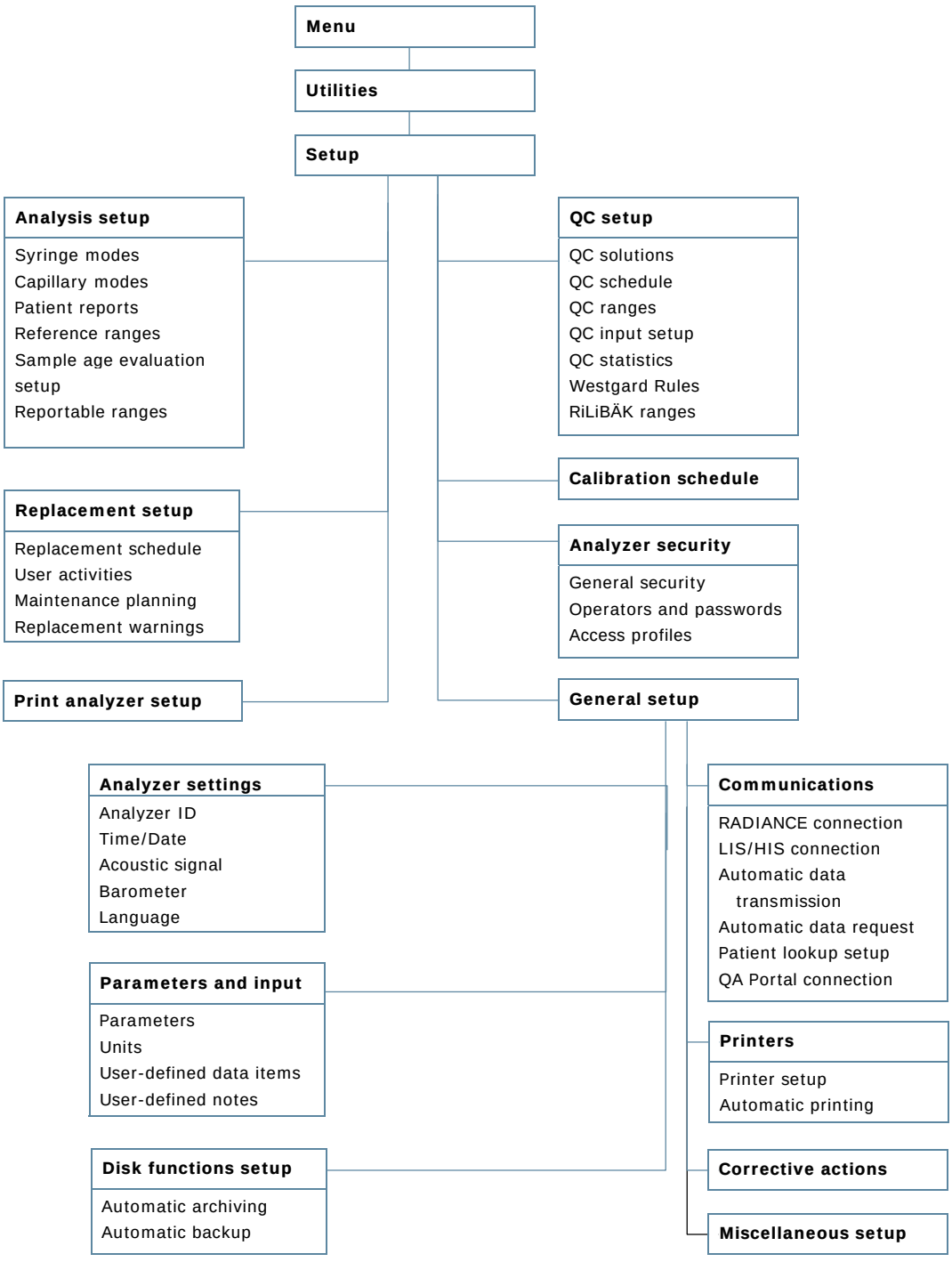
Contents

1. Setup

Setup menu structure



Analyzer security

Programs

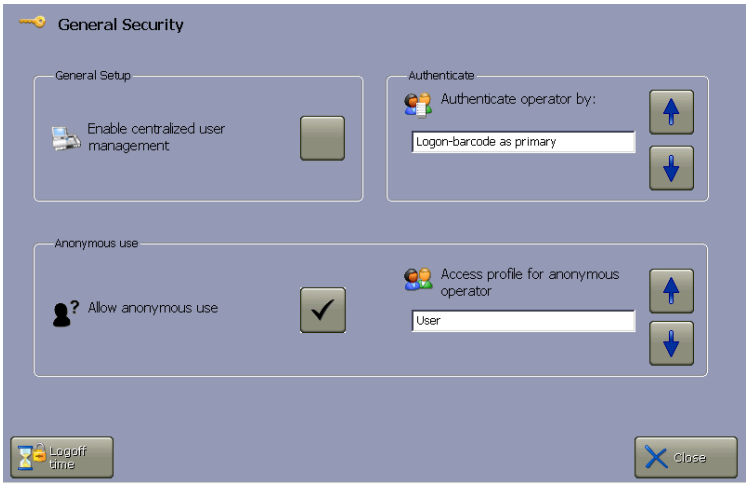
The Analyzer security program allows you to do the following:

- Set up the general security (set automatic logoff time)
- Add/remove operators from the operator list
- Assign and define access profiles (assign an anonymous operator, i.e. allow the use of the analyzer without a password, define access to menus for each access profile, Select configuration of six buttons on the main screen)

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 and to define the logoff time of an operator.

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 next to "Enable centralized User Management".

With this option enabled you can only view the operators, not add, edit or remove any of them. All users defined on the ABL90 FLEX analyzer are deleted and the list of users in the RADIANCE system is copied to the ABL90 FLEX analyzer.

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

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:

- User ID/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.
- User ID/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 section for information on how to define the access profiles.

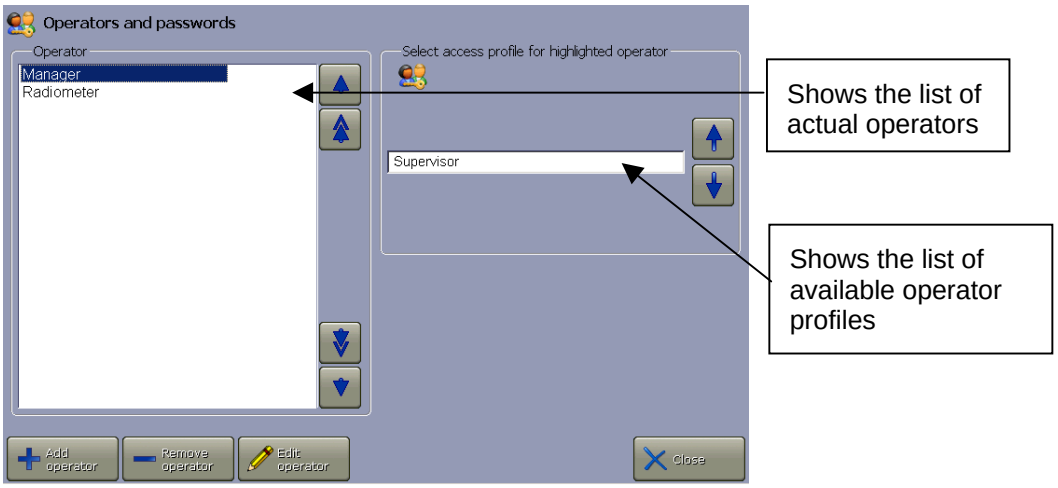
To set the time interval to elapse, before an operator is automatically logged off, press the ***Logoff time*** button. Select the logoff time in minutes (from 0 to 60) and seconds (from 0 to 50 in 10-second intervals). The default logoff time is three minutes. Press ***Back*** to return to the **General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

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***.

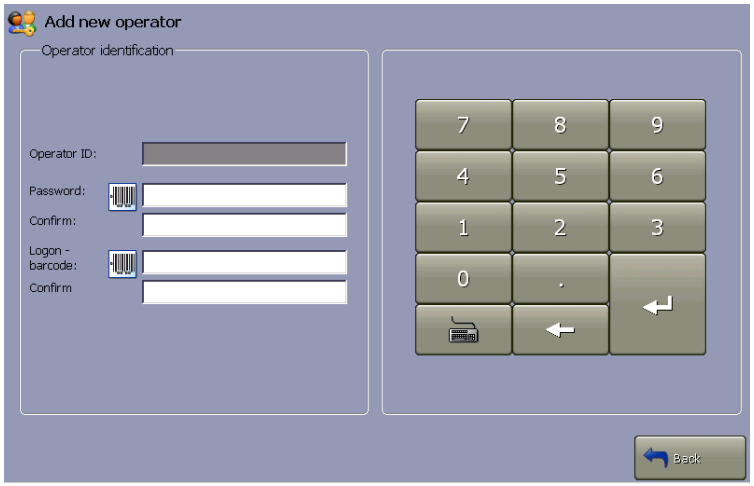


When the analyzer is taken into use, the following default operators are available:

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	All menu items and programs (user and service) on the analyzer, if this is given to the Remote operator.

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

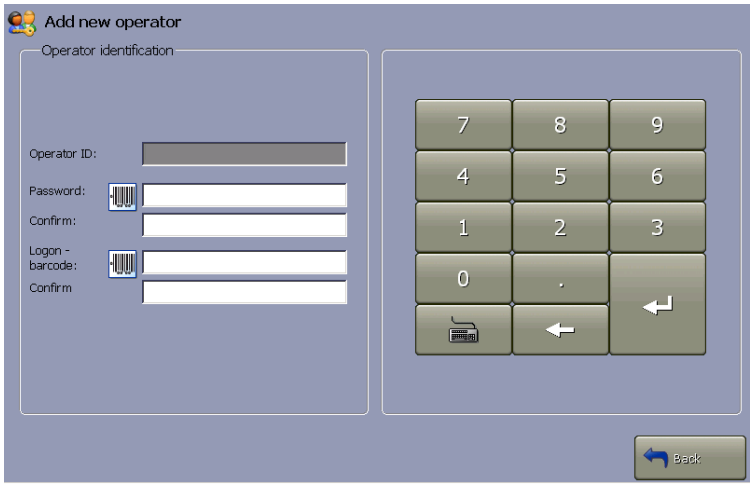
Step	Action
1.	Press the ***Add Operator*** button to display the **Add New Operator** screen.



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 password 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.

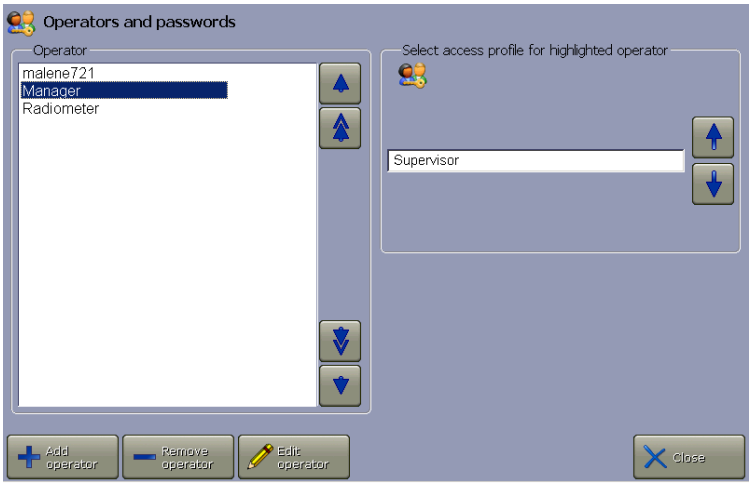
To edit the operator identifications of an operator, do the following:

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



2.	Touch and highlight the box to be changed. Enter the change. If you change the passwords, confirm them again. The password must be at least four characters long. The logon barcode and the password can be identical.
3.	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.
4.	In the **Operators and Passwords** screen, select the desired access profile of the new operator.

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***.

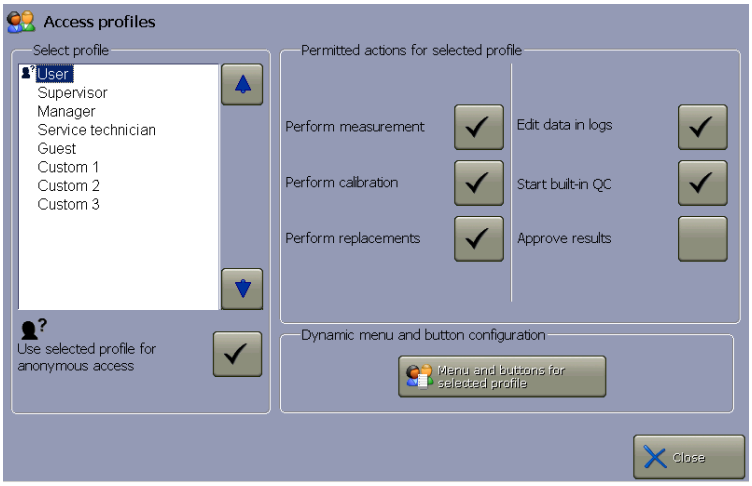


NOTICE: If the Centralized User Management option is enabled in the General Security screen you cannot add, remove or edit the operators, but only view the access profiles of the individual operators.

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***.

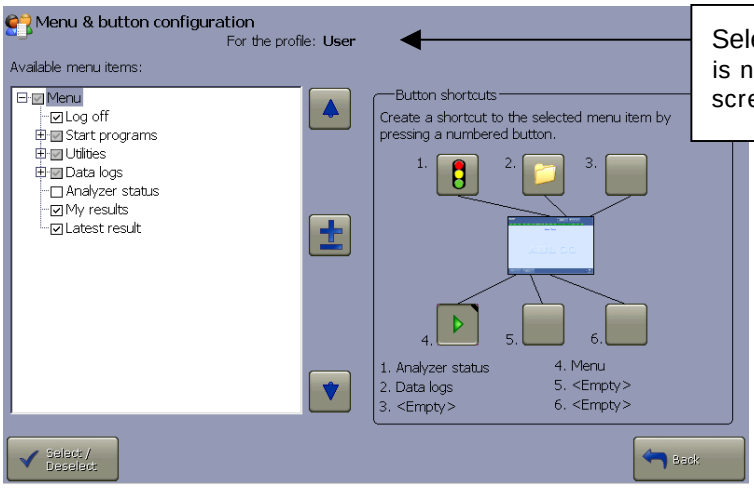


To define the permitted actions of an access profile, select the desired profile in the "Profile names" box and activate the desired check buttons in the "Permitted actions" box.

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

To define the available menu items and button shortcuts of an access profile do 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.



Selected profile is named on the screen.

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

The buttons allows you to do the following:

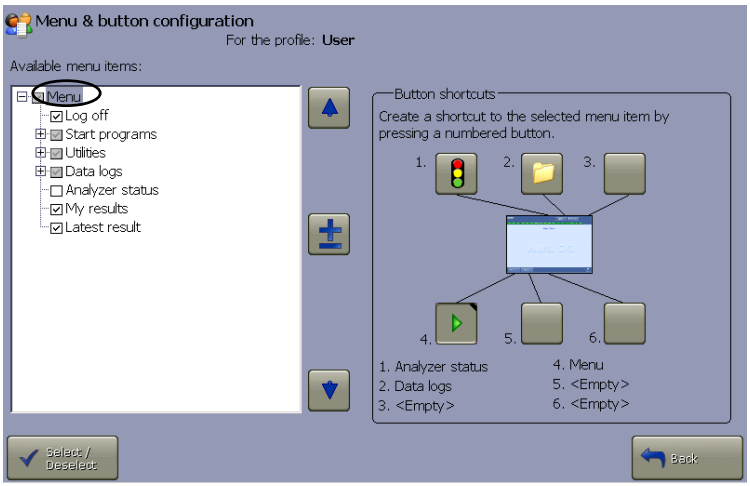


Highlight menu items


Open/close submenus

Select/deselect a menu item.

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.



4. Select other five buttons in the same manner, if desired.

5. To deselect a button, press it once again.

6. 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

Program

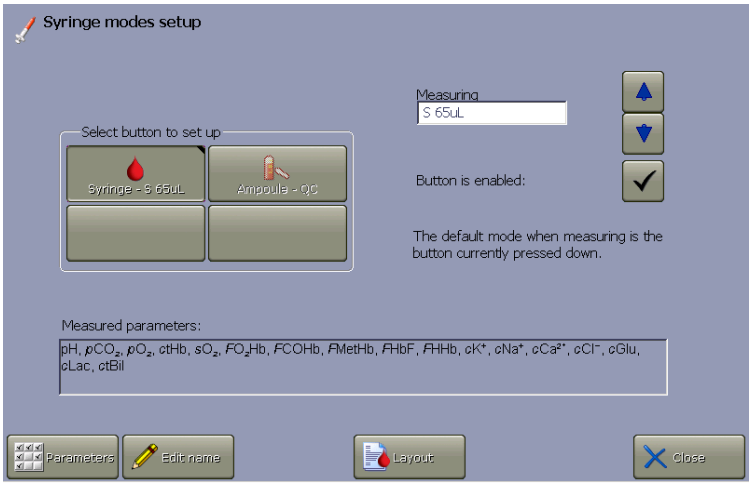
Press ***Menu> Utilities > Setup > Analysis setup*** and activate a button to enter a program.

The following programs are available:

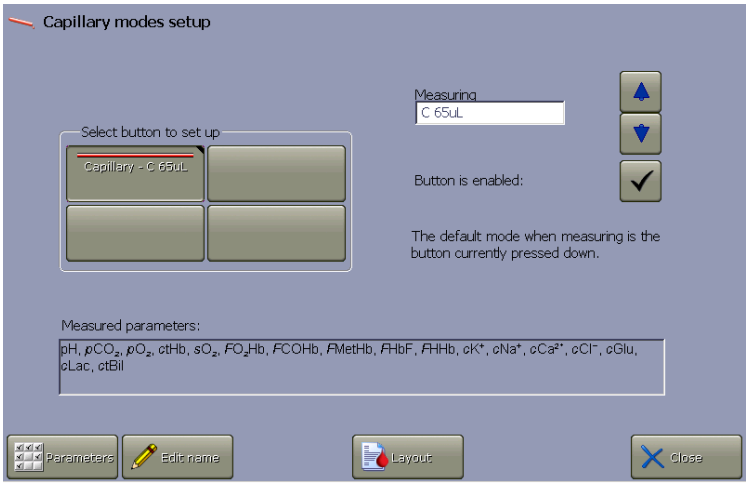
- Syringe mode
- Capillary mode
- Patient reports
- Reference ranges
- Sample age evaluation setup
- Reportable ranges
- Sample pre-registration

Syringe / capillary modes

The **Syringe modes setup** screen is shown below:



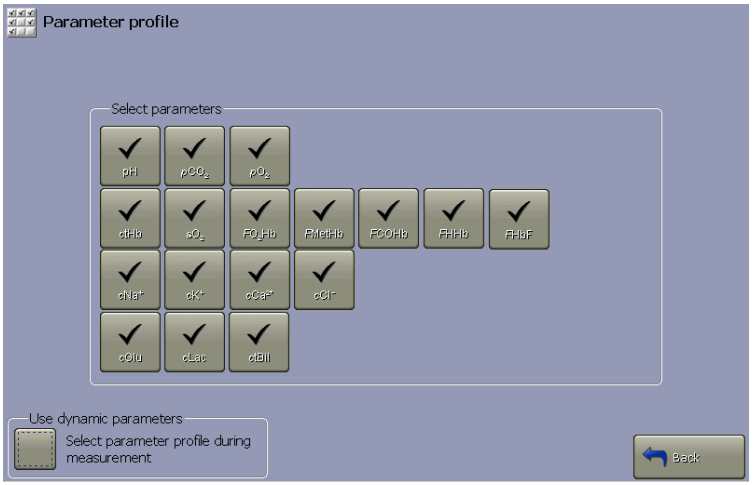
The **Capillary modes setup** screen is shown below:



Setting up a new measuring mode

Step	Action
1.	Select an unoccupied button in the "Select button to set up" field on the **Syringe modes setup** or **Capillary modes setup** screen.
2.	Enable the button by activating the "Button is enabled" check button.
3.	Select the desired measuring program with the arrow buttons and select the desired parameter profile (see *Selecting a parameter profile* below).

Selecting a parameter profile



Step	Action
1.	Press ***Parameters*** on the **Syringe modes setup** or **Capillary modes setup** screen.
2.	Select parameters for a given measuring mode by activating a parameter check button (see *Screen elements* in section *Software*, chapter 2 in the ABL90 FLEX operator's manual).
3.	Activate the check button in the "Use dynamic parameters" box to select parameters during a sample measurement.

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.**

A parameter that has been deselected for the given syringe or capillary mode 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 measurement* in the ABL90 FLEX operator's manual.

Editing name of button

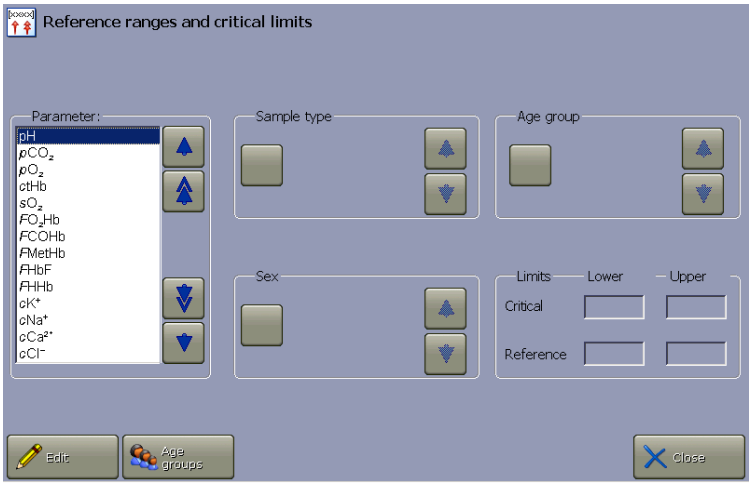
Step	Action
1.	Press ***Edit*** on the **Syringe modes setup** or **Capillary modes setup** screen.
2.	Enter the new name on the keyboard and confirm the entry with ***Enter***. The screen returns to the **Syringe modes setup** or **Capillary modes setup** screen.

Selecting a default layout

Step	Action
1.	Press ***Layout*** on one of the **Modes setup** screens.
2.	Select the layout from the list (made in the Patient report setup – see *Patient report setup* further in this section). The selected layout will be the default layout for the given measuring mode.
3.	Press ***Back*** to confirm the settings.

Reference ranges and critical limits

In this program you can 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.



Selecting sample type

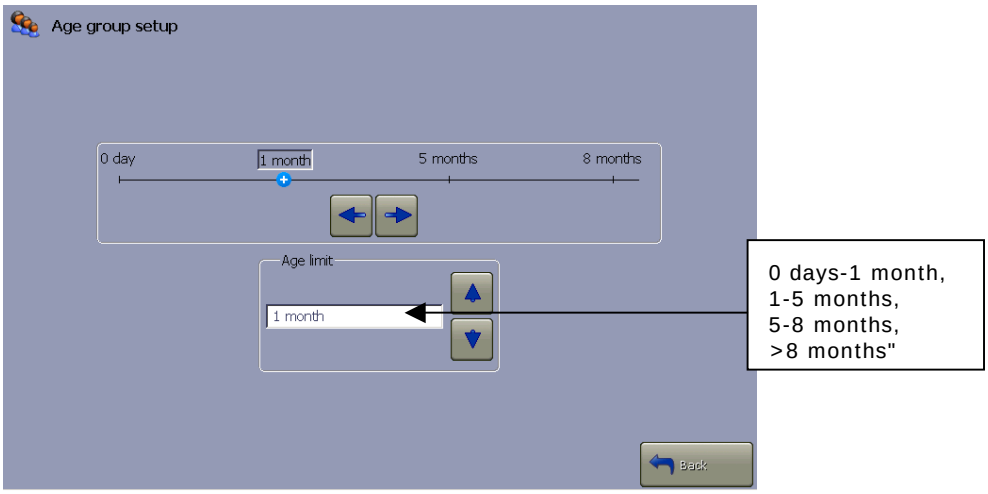
Step	Action
1.	Highlight a parameter in the "Parameter" box, using the up/down arrows.
2.	Press the check button in the "Sample type" box and select a sample type, using the up/down arrows in the box.

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

Selecting sex

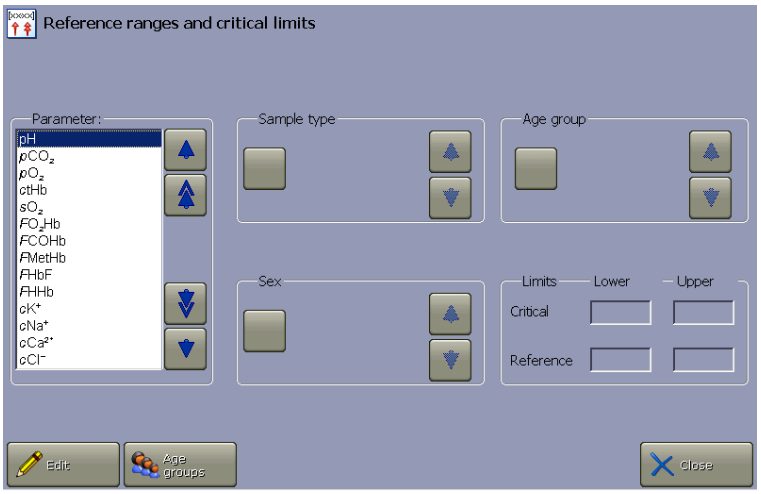
Step	Action
1.	Highlight a parameter.
2.	Press the check button in the "Sex" box and select sex type, using the up/down arrows in the box.

Setting age group limits

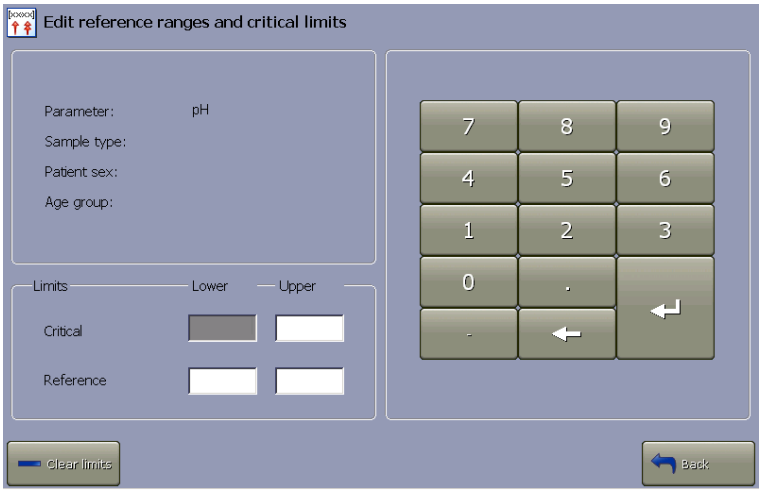


Step	Action
1.	Press the ***Age groups*** button on the **Reference ranges and critical limits** screen.
2.	Use the following to set/change the age groups: • Left/right arrows to choose the age group limit you want to change (indicated by a blue circle with a white cross) • Up/down arrows to scroll through 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 in the **Reference ranges and critical limits** screen and select the desired age group.

Setting reference and critical limits for each parameter

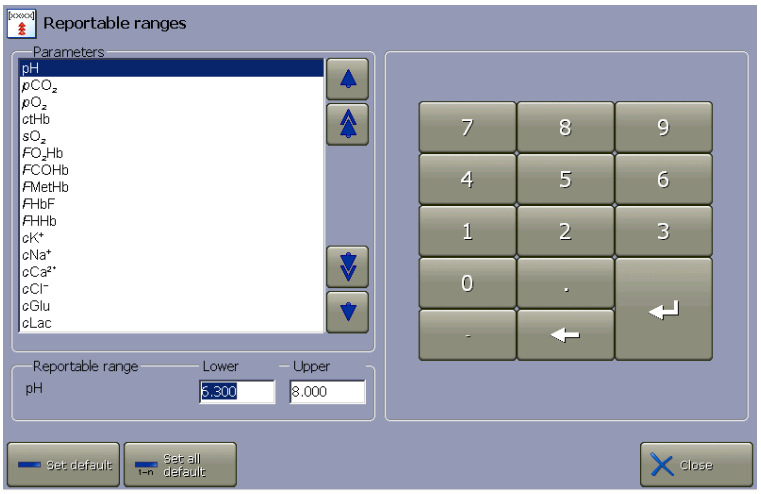


Step	Action
1.	Highlight a parameter on the **Reference ranges and critical limits** screen, using the up/down arrows.
2.	Enter sample type, sex and age group, if required.
3.	Press ***Edit*** to edit entries for a highlighted parameter.



4.	If any entries are present and you cannot use any of them, press ***Clear limits***. Then enter new critical and reference limits, using the keypad and confirming each entry with ***Enter***.
5.	To change a value, touch and highlight it. Then enter the limit and confirm with ***Enter***.
6.	Press ***Back*** to return to the **Reference ranges and critical limits** screen.
7.	Highlight a parameter in the "Parameter list" box to view the limits on the **Reference ranges and critical limits** screen.

Reportable ranges



Step	Action
1.	Scroll to the desired parameter, using the up/down arrows or the 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***.
5.	To change all parameters to the default values, press ***Set all default***. Press ***Continue*** to change the reportable ranges of all parameters to the default ones. Press ***Cancel*** to keep the user-defined reportable ranges and return to the previous screen.
6.	Press ***Close*** to exit and confirm the selected settings.

NOTICES:

- A reportable range must be smaller than or equal to the range of indication
- Measured parameters show the reportable ranges. Derived parameters show "....."
- See also *Calibration verification,* chapter 6 in the ABL90 FLEX operator's manual.

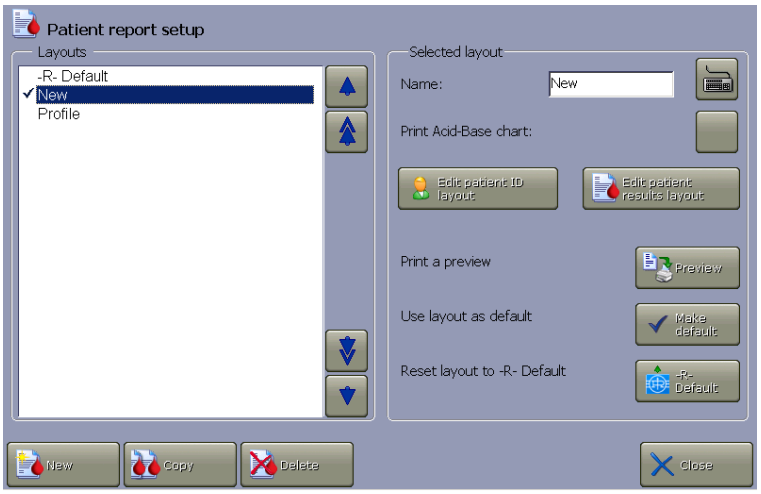
Patient report setup

Program

In this program you can create a number of new layouts for patient reports or modify the existing ones.

Press ***Menu > Utilities > Setup > Analysis setup > Patient reports*** to access the program.

Creating a layout

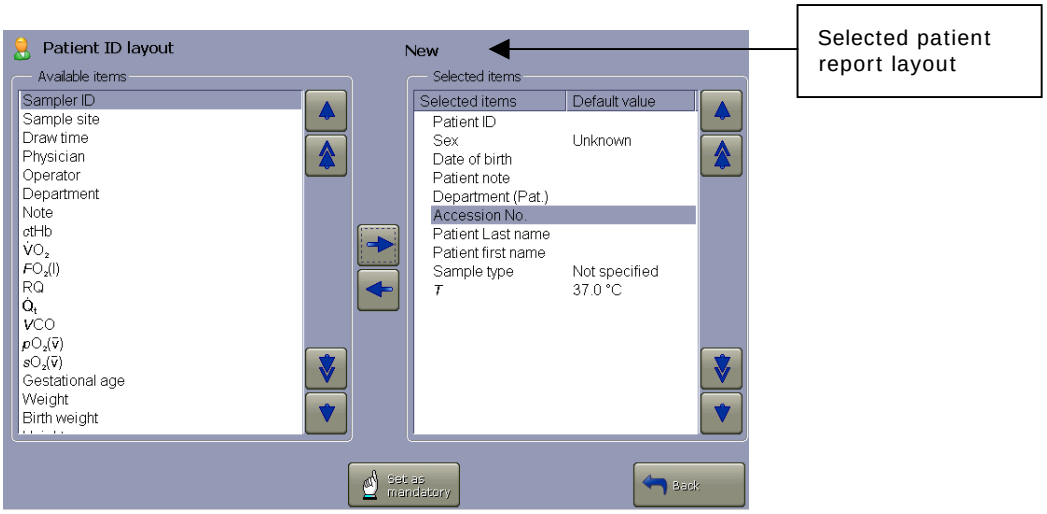


Step	Action
1.	Press ***New*** to make a new layout (marked "New") or ***Copy*** to make a copy of a highlighted layout.
2.	Press the ***Keyboard*** button next to the "Name" box, type in a new name for your layout and confirm with ***Enter*** to return to the **Patient report setup** screen.
3.	Enforce, if desired, the Radiometer default settings on the highlighted layout by pressing ***-R- default***. This will give you a starting point for designing your own layout.
4.	Edit your layout as described in *Editing a layout* further in this section.
5.	If desired, make the highlighted layout a default for your analyzer by pressing ***Make default***. It will be marked with (✓) in the list of layouts.
6.	Make a test printout, if desired, of the highlighted layout (patient ID items and selected parameter groups with the parameters/units for each parameter group) by pressing ***Preview***. This test print will be labeled "Preview".
7.	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

Step	Action
1.	Highlight a layout in the list by touching it on the screen.
2.	Press ***Edit patient ID layout*** to edit the patient ID items or press ***Edit patient results layout*** to edit the parameter groups – see the description further in this section.
3.	Activate ***Print Acid-Base chart*** if an automatic printout of the Acid-Base chart for this layout is desired.

Patient ID layout



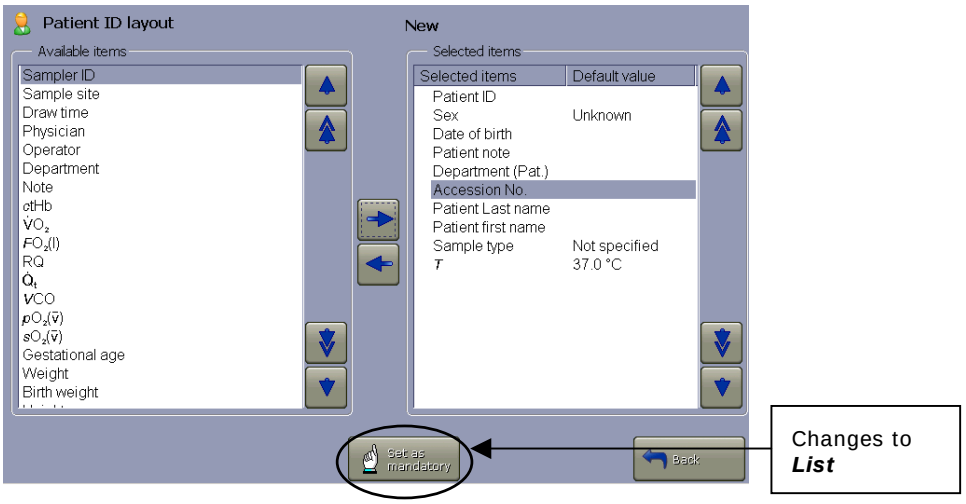
Editing a patient ID for a selected patient report layout:

Step	Action
1.	• Add a highlighted item in the "Available items" box to the list of selected items by pressing the  button Or • Remove a highlighted item from the "Selected items" box by pressing the  button
2.	Press ***Set as mandatory*** to make a highlighted item in the list of selected items mandatory. 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.
3.	To remove the mandatory mark, highlight the item in the "Selected items" box and press ***Set as mandatory*** again.

NOTICES:

- To use the Patient lookup function, Department (Pat.) should be selected for the **Patient identification** screen.
- To use the Request function, Accession number and/or Patient ID should be selected for the **Patient identification** screen.

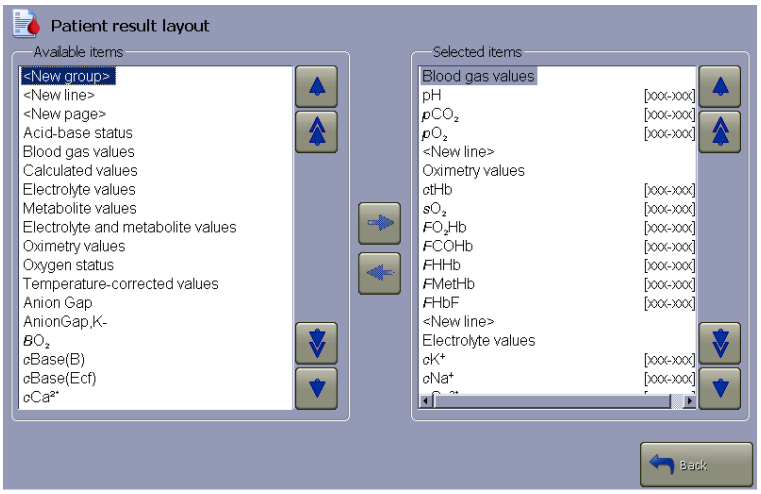
Default values



Step	Action
1.	Highlight the desired item in the "Selected items" box with the arrow buttons.
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 a similar manner.

NOTICE:
- 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

Editing patient result layout



Step	Action
1.	Highlight a patient report layout on the **Patient report setup** screen and press ***Edit patient results layout***.
2.	• Add a highlighted item in the "Available items" box to the list of selected items by pressing the button Or • Remove a highlighted item from the "Selected items" box by pressing the button
3.	Select parameters for this parameter group by highlighting them one by one and pressing . (To exclude an item from the selected parameter list, highlight it and press .)
4.	Select another parameter group along with parameters for this group in the same manner.
5.	Use layout commands: • <New group> (items following this command are placed at the top of the next half of the screen) • <New Line> (a line is inserted between items) • <New Page> (items following this command appear on next screen page) as desired and press .

To show the range of a selected item, do the following:

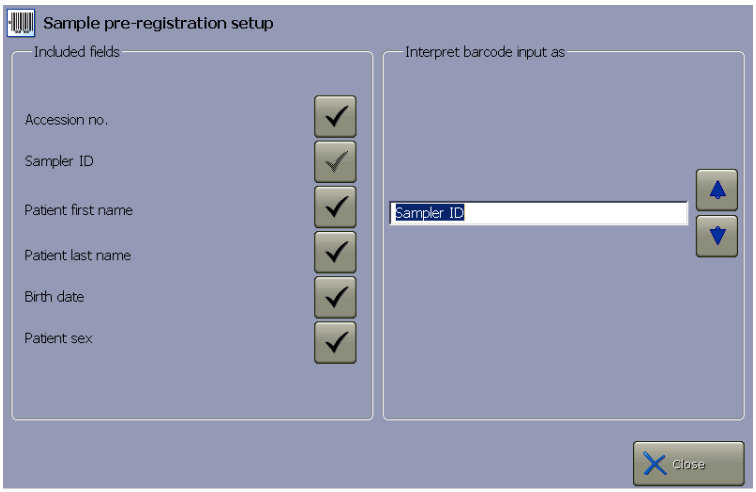
Step	Action
1.	Highlight the desired item in the "Selected items" box.
2.	Press ***Show ranges*** to indicate it by "[xxx-xxx]".
3.	Repeat for other items in the same matter.

Refer to chapter 8: *Parameters* in this manual, for information on parameters and their groups.

Sample pre-registration setup

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

Press ***Menu > Utilities > Setup > Analysis setup > Sample pre-registration*** to access the program.



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: • Patient ID • Accession Number • Sampler ID. Note that choosing the Accession Number or Sampler ID will gray out its check button (Sampler ID on the screen above).
2.	Select the barcode entry.
3.	Activate the relevant check buttons in the" Included fields" box: Accession no., Patient first name, Patient last name, Birth date, Patient Sex.
4.	Press ***Close*** to confirm the settings and return to the main screen.

Sample age evaluation setup

This program allows you to set up a maximum sample age for the individual parameters to enable an automatical sample age evaluation.

Press ***Menu > Utilities > Setup > Analysis setup > Sample age evaluation setup***.

To enable the sample age evaluation of the individual parameters, do the following:

Step	Action
1.	Press the check button in the "Enable sample age evaluation" box.
2.	Select the maximum sample age in minutes for pH, using the arrow buttons.
3.	To enable the same number of minutes for all parameters, press the check button next to "Same rule for all the parameters".
4.	Press ***Close*** to return to the main screen.

To edit the maximum sample age, do the following:

Step	Action
1.	In the Parameter/Aging timetable select the desired parameter.
2.	In the "Maximum sample age in minutes" box select the desired number of minutes, using the arrow buttons.
3.	Press ***Close*** to return to the main screen.

Calibration schedule setup

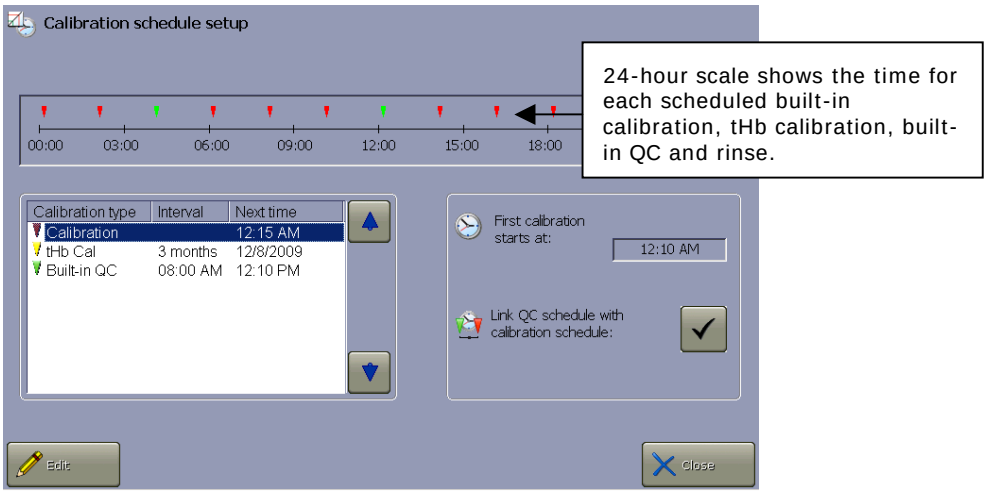
Program

Press ***Menu > Utilities > Setup > Calibration schedule*** to access the Calibration schedule setup program.

In the program you can do the following:

- Set the time for the first calibration each day. This is only an option, and if the time is not set, the first calibration will by default start at 00:00 (12 midnight).
- Set the time for tHb calibrations

For more detailed information on calibration, see chapter 6: *Calibration* in the ABL90 FLEX operator's manual.



Editing the settings

Step	Action
1.	Highlight the desired calibration on the screen and press ***Edit***.
	NOTICE: The ***Edit*** button is not available for Built-in QC.
2.	Use the arrow buttons to select start time for calibrations and the interval between each calibration.

As illustrated above, it is possible to link the QC schedule to the calibration schedule and in this way minimize the number of activities and ensure the most optimum utilization of the solution pack.

When the QC schedule is linked to the calibration schedule, the built-in QC will by default run at the following times: 04:00, 12:00 and 20:00 (04 am, 12 midday, 8 pm). If, however, calibration is set to start at a different time than 00:00 (e.g. 00:30), the built-in QC will run correspondingly later.

If the QC schedule is not linked to the calibration schedule, you will have to set the QC schedule yourself – see further in this chapter.

If the QC schedule is not linked to the calibration schedule, a rinse will be run at the predefined times instead.

Available calibration schedule options

Option	Interval
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.

Quality control setup

Program

Press ***Menu > Utilities > Setup > QC*** to access the Quality control solutions setup and activate a button to enter a program.

The following programs are available:

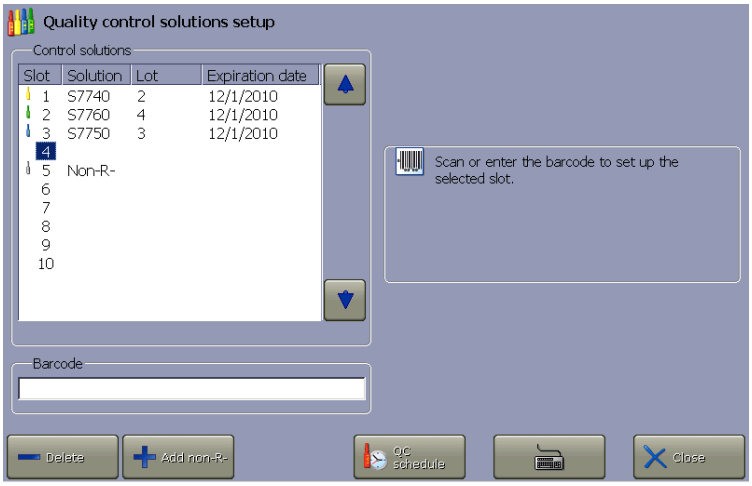
- QC solutions
- QC schedule
- QC ranges
- QC input setup
- QC statistics
- Westgard Rules
- RiLiBÄK ranges

Built-in QC solution is set up together with the Calibration schedule (see earlier in this chapter)

Manual quality control (QC) solutions

In this program you can assign or change a QC solution to a specific slot – manual QC measurements only.

Built-in QC results are assigned to the slots A, B and C.



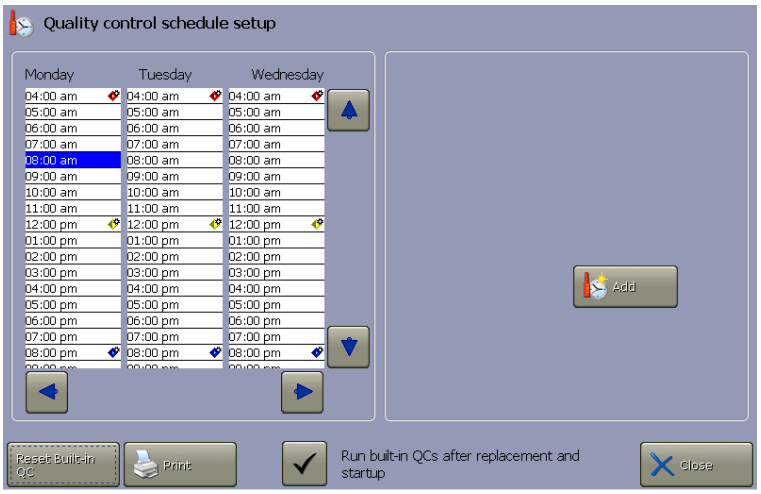
Step	Action
1.	Highlight a slot, using the arrow buttons.
2.	• Solutions from Radiometer (the QUALICHECK5+ control solution): scan the barcode or press ***Keyboard*** to enter the barcode information (see *Barcode reader* in section *Hardware*, chapter 2: *What is what* in the ABL90 FLEX operator's manual) • Non-Radiometer control solutions: press ***Add Non-R-***.
3.	To delete a control solution, highlight the desired slot and press ***Delete*** to cancel the operation. A warning that this will irreversibly delete all statistical data related to the selected slot appears. Press ***Delete*** to delete the control solution.

CAUTION – *Changing QC*

Changing a QC assigned to a slot will delete all current QC statistics obtained on that slot. If you want a copy of the statistics for the last QC month, create a WDC Report disk – see chapter 2: *Disk functions setup programs*.

Quality control schedule setup

In this program you schedule QC measurements, both built-in and manual, for your analyzer for all days of the week.



Navigation:

 and  Use to select time during a day.

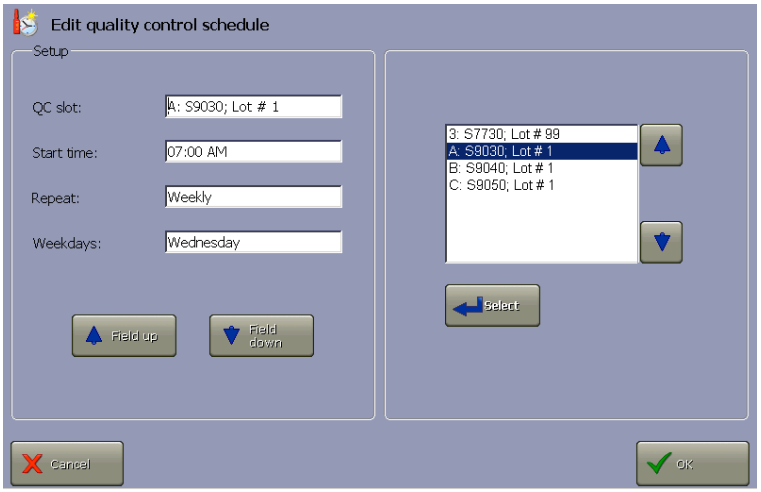
 and  Use to display other weekdays.

Symbols for manual and built-in QC:

 Measurement(s) on the manual QC.

 Measurement(s) on the built-in QC performed automatically.

Adding a new QC solution to a schedule:



Step	Action
1.	Select the desired time and press ***Add*** to display the screen above.
2.	Touch the "QC slot" box to activate it, if not already activated. Select the desired slot/quality control solution, using the up/down arrows in the box. Confirm with ***Select***. Built-in QC results are assigned to the slots A, B and C.
3.	Highlight the "Week days" box using ***Field down*** and activate the relevant check buttons to select the days of the week on which this measurement should be performed.
4.	Highlight the "Start time" box, using ***Field up***, and key in the time to perform a measurement and confirm with ***Enter*** on the keypad.
5.	Highlight the "Repeat" box and select the interval with which the measurement should be repeated, using the up/down arrows in the box. The QC schedule reminder "Lock analyzer when QC overdue" (selected in Corrective actions – see further in this chapter) will work on the basis of the setting selected in this box. The symbols for the built-in or manual quality control will automatically appear in the schedule.
6.	Press ***OK*** to return to the **Quality control schedule setup** screen.

Editing the QC schedule:

Press ***Edit*** and follow the procedure above.

Deleting items from the QC schedule:

Step	Action
1.	Highlight the desired item (i.e. QC measurement) and press ***Delete***.
2.	Press ***Event for this day***, ***Event for all days*** or ***All entries for QC slot*** to remove the QC measurement from the schedule. When changes have been made to the QC schedule the Please confirm screen appears when leaving the Quality control schedule setup screen.

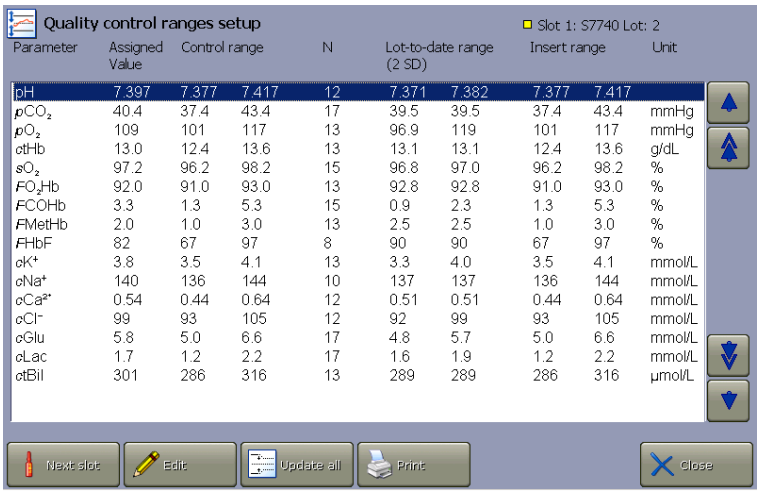
By default the analyzer is set up to run Built-in QCs after replacement and startup. To deactivate this function deactivate the check button next to the "Run Built-in QCs after replacement and startup".

QC ranges

In this program you can do the following:

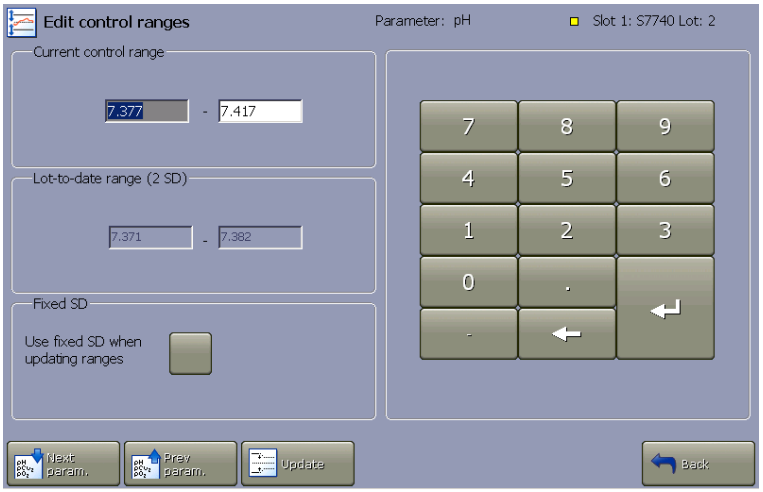
- Globally update all control ranges of a slot to a calculated lot-to-date range
- Individually edit parameter control ranges by entering your own ranges or updating to a calculated lot-to-date range
- Define a minimum allowed control range by entering a Fixed SD (standard deviation)

For Built-in QC the ***Edit*** and ***Update all*** buttons are grayed-out.



Step	Action

1. Press ***Next slot*** to display the desired slot and then 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).

4. Press the check button to activate or deactivate the Fixed SD (i.e. a minimum allowed control range is defined by setting a Fixed SD).

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

5. Highlight the limit by touching it on the screen and enter your own value(s), using the keypad. Confirm with ***Enter***.

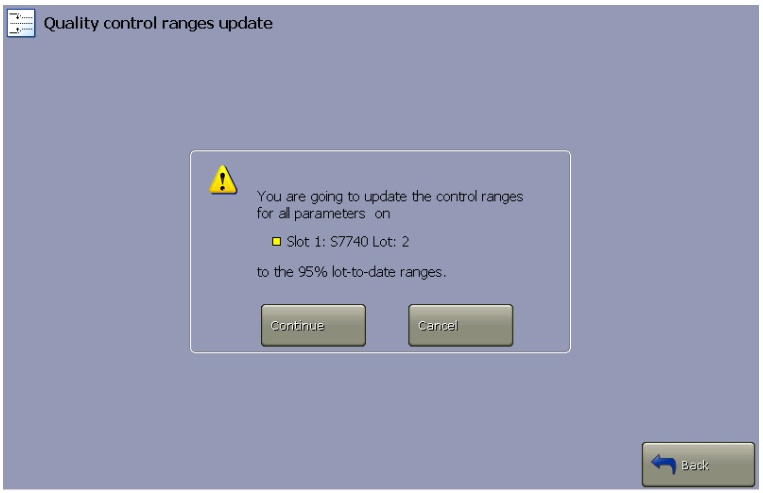
6. Repeat the procedure for other parameters in the same manner.

NOTICES:

- See *I Appendix - Quality control* in this manual for detailed information on statistics and its parameters
- "Lot-to-date range (2 SD)" is the range calculated over the course of the lot, represented mathematically by the mean value ± 2 SD; this is the range within which 95 % of the measurements are found.

Updating control ranges for all parameters of the displayed level:

Step	Action
1.	Display the desired slot, using ***Next slot***.
2.	Press ***Update all***.
3.	Press ***Continue*** to update the control ranges for all parameters under the specified slot, or press ***Cancel*** to cancel updating.

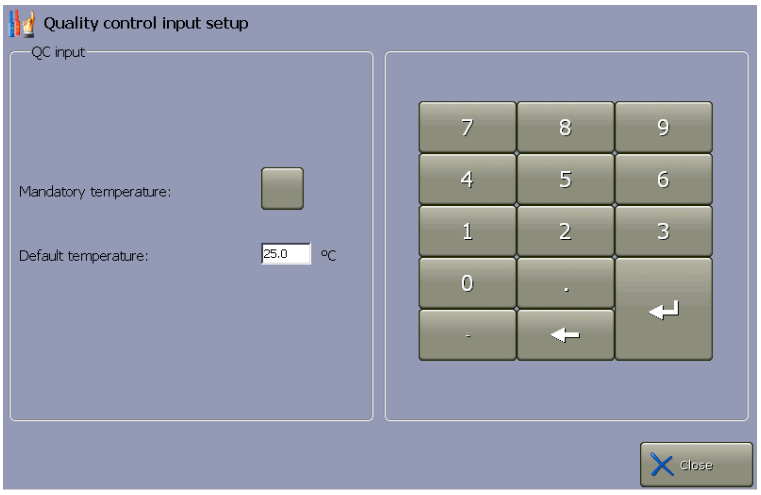


NOTICE: Once the Fixed SD has been activated, you cannot update the control ranges to limits that are narrower than those determined by the Fixed SD, for both single-parameter and multiple-parameter updates.

QC input setup

In this program you can select the following for the **Quality control identification** screen during a manual QC measurement:

- Mandatory temperature entry by the operator
- The default temperature always displayed (unless changed by the operator)



Step	Action
1.	Activate the ***Mandatory temperature*** check button
2.	Or highlight the default temperature in the "Default temperature" box, enter a default temperature on the keypad and confirm with ***Enter.***

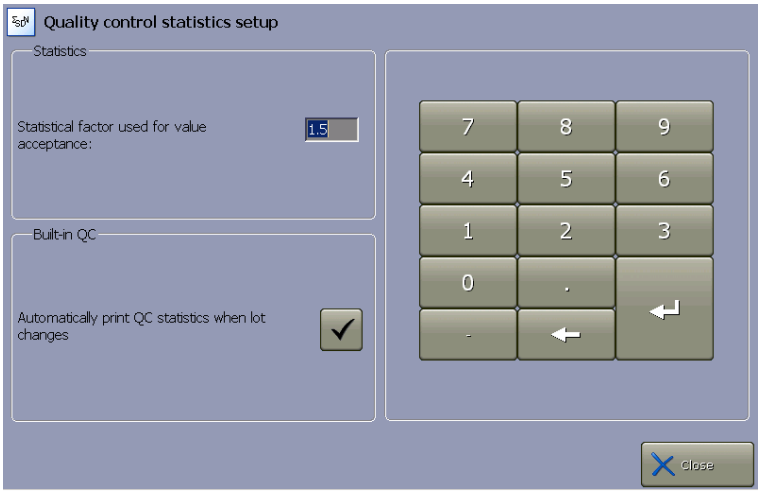
NOTICES:

- A ☞ will appear next to an empty temperature box on the **Quality control identification** screen during each QC measurement; otherwise the result cannot be retrieved.
- The value in °C or °F is automatically entered on the **Quality control identification** screen during measurement. The temperature can be changed for a particular measurement but will return to the default setting for future measurements.

QC statistics

In this program you can select the following:

- The statistics factor
- Automatic printing of QC statistics when the lot changes

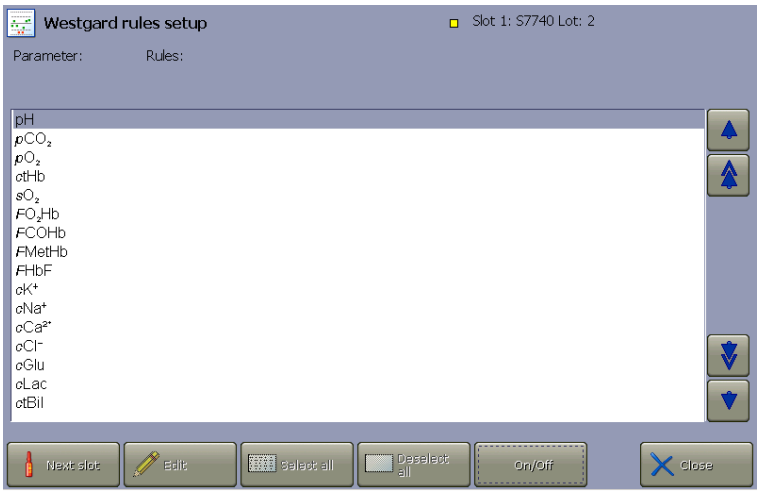


Step	Action
1.	Key in the desired statistics factor (from 1.0 to 9.9) on the keypad and confirm with ***Enter***. The default value is 1.5.
2.	Activate the check button in the “Built-in QC” field to automatically make a printout of the QC statistics if the lot is changed.
3.	Press ***Close*** to exit.

NOTICE: Statistics factor expands the control range to the statistics range (it is the range within which QC results must fall in order to be included in the QC statistics).

Westgard Rules setup

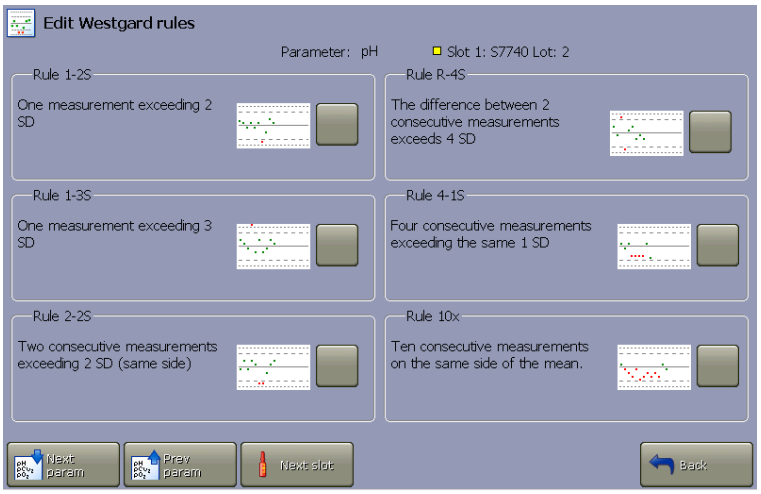
In this program you can select Westgard Rules for all slots or for specific parameters.



Step	Action
1.	Select the desired slot, using ***Next slot***.
2.	Press ***On/Off*** to activate the assigned Westgard Rules for the slot or press this button again to deactivate them.

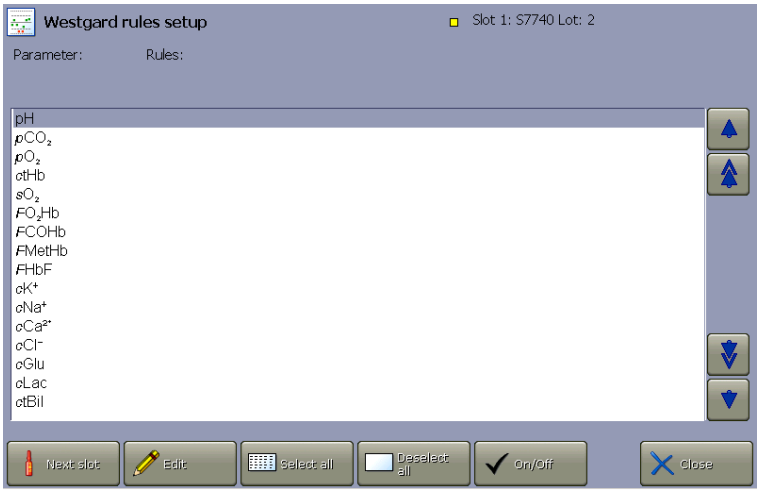
NOTICE: The Westgard Rules are a set of statistical rules. When applied to the QC results, they can increase the probability of detecting an error in the sampling procedure or in the analyzer itself, or they can help detect a shift or trend in your QC results by comparing current measurement values of a QC solution with previous values.

Activating Westgard Rules for a specific parameter:



Step	Action
1.	Display the desired slot, using ***Next slot*** and press ***Edit***.
2.	Display the desired parameter using ***Next param*** or ***Prev param***.
3.	Activate the desired Westgard Rule(s) by pressing the corresponding check button. (All future quality control data for the given slot/parameter will be evaluated according to the selected Westgard Rule(s).)
4.	Select Westgard Rules for other parameters or levels in the same manner.
5.	Press ***Back*** to return to the **Westgard Rules setup** screen.

Selecting / deselecting all Westgard Rules:



Step	Action
1.	Display the desired slot, using ***Next slot***.

2. Press ***Select All*** or ***Deselect all*** and verify the information on the screen.

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

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

NOTICES:

- When a QC measurement violates an applied Westgard Rule, a W is added to the parameter in the result. For interpretation/evaluation of the results with respect to Westgard Rules, see *I Appendix - Quality control* in this manual.
- Use ***On/Off*** to restore the previous settings.

Reference

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

RiLiBÄK ranges

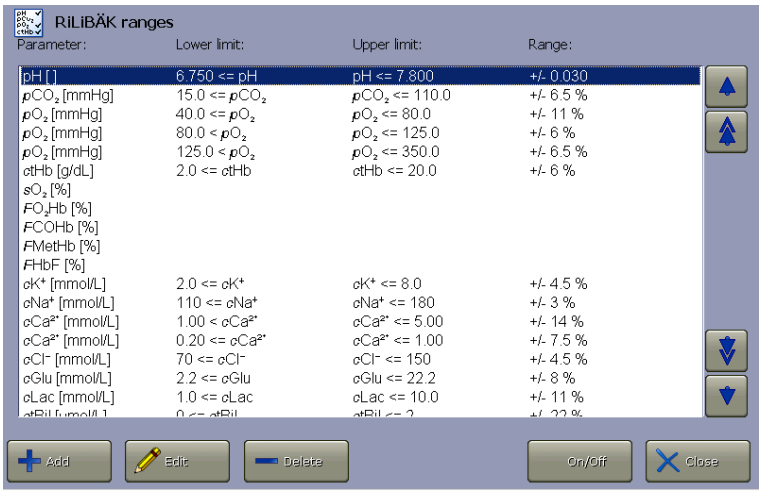
The RiLiBÄK ranges program allows you to define a set of rules to control the maximum deviation of any parameter from the assigned target value.

The assigned target values are given on the QC insert.

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

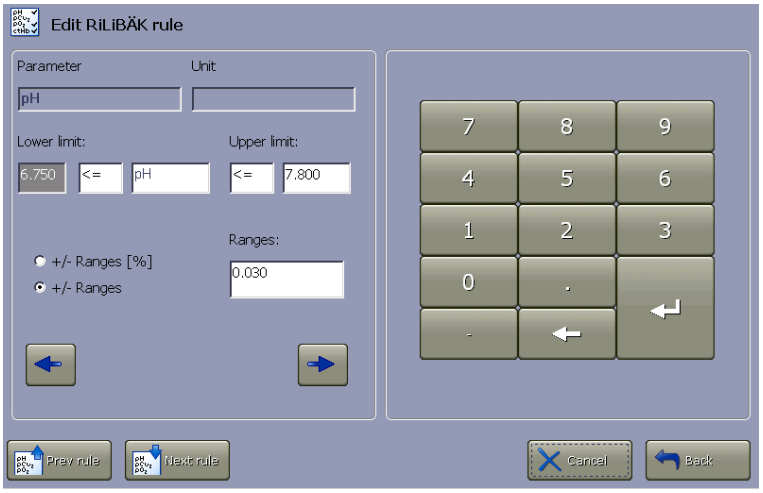
To activate or deactivate the RiLiBÄK rules, do the following:

Step	Action
1.	Press the ***On/Off*** button to activate/deactivate the assigned RiLiBÄK rules.



To add a new RiLiBÄK rule, do the following:

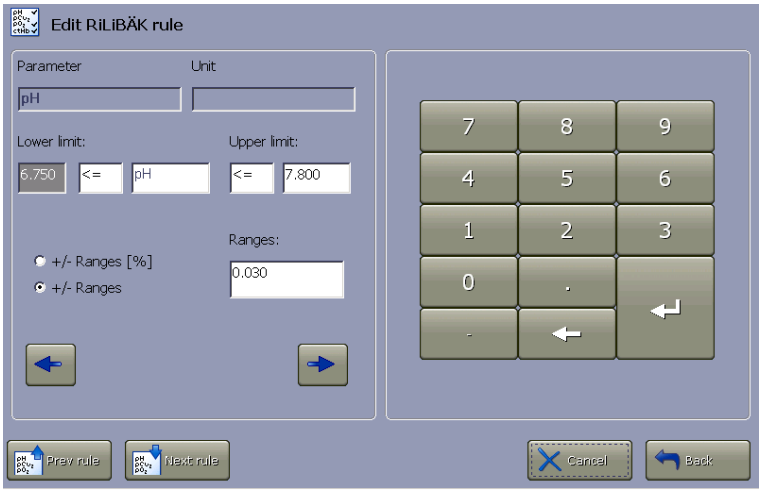
Step	Action
1.	Press the ***Add*** button to display the screen below:



2.	Select the desired parameter from the parameter list shown in the right side of the screen.
3.	Press  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 lower limit.
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:



2.	Use  or  to jump between the input boxes and edit the desired values.
3.	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 QC measurement violates an applied RiLiBÄK rule, a red R is shown in front of the parameter name in the result.

Replacement setup

Program

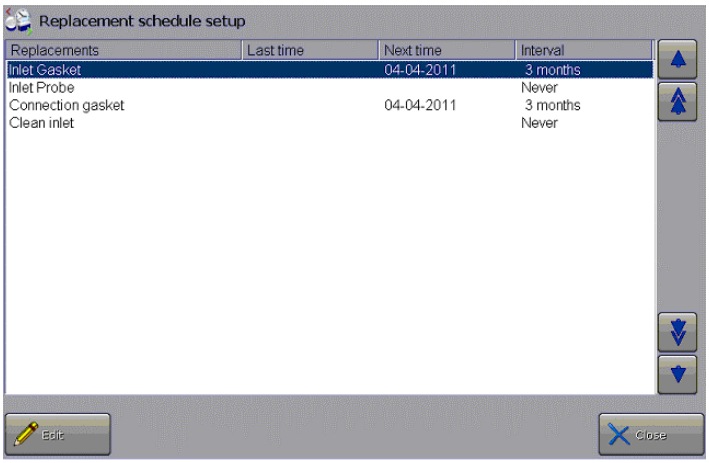
Press ***Menu > Utilities > Setup > Replacement setup*** to access the Replacement setup and activate a button to enter a program.

The following programs are available:

- Replacement schedule
- User activities
- Maintenance planning
- Replacement warning

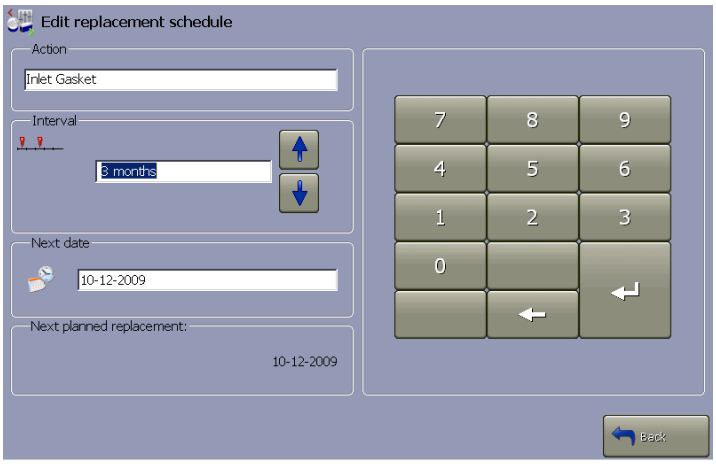
Replacement schedule setup

In this program you can schedule routine replacements along with the current scheduled date and interval for replacement. The settings selected here are then used in Replacement on the **Analyzer status** screen.



Step	Action

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



2. Change the interval for the selected replacement action (displayed in the "Action" box), using the up/down arrows (see *Recommended replacement intervals* below).

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 the screen keypad. Confirm with ***Enter***.

4. Press ***Back*** to return to the **Replacement schedule setup** screen.

5. Repeat steps **1-4** for each replacement action to be scheduled.

Recommended replacement intervals

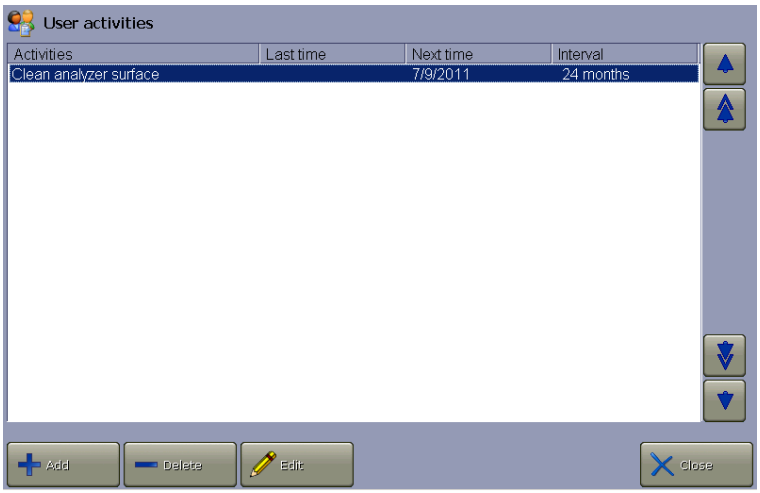
Action	Interval	
Replacing solution pack	When the number of available activities has reached zero or after max. 30 days in the instrument	
Replacing sensor cassette	When the number of available tests has reached zero or after max. 30 days in the instrument	
Replacing connection gasket	Every 3 months	
Replacing inlet gasket	**Tests/day**	**Interval**
	10	3 months
	20	1½ month
	30	1 month
	60	14 days
	>120	7 days

NOTICE: The replacement intervals are guidelines only and based on the average use of the analyzer (10 samples per day); 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.

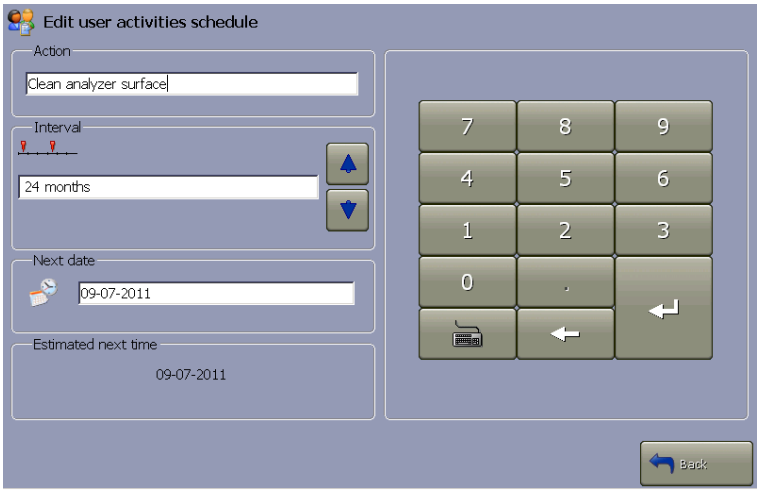
It is possible to set the time for a warning to appear before a replacement – see *Replacement warnings* later in this section.

User activities

In this program you can 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



Step	Action
1.	Press ***Add*** to display the **Edit user activities schedule** screen.
2.	Press the ***Keyboard*** button and type a new activity. Confirm with the ***Enter*** button on the keyboard.
3.	Select the interval, using the up/down arrows in the "Interval" box.
4.	Type in the "Next date", using the screen keypad. Confirm with ***Enter***.
5.	Press ***Back*** to return to the **User activities** screen and repeat steps **1-4** for each activity to be scheduled.

Editing a user activity

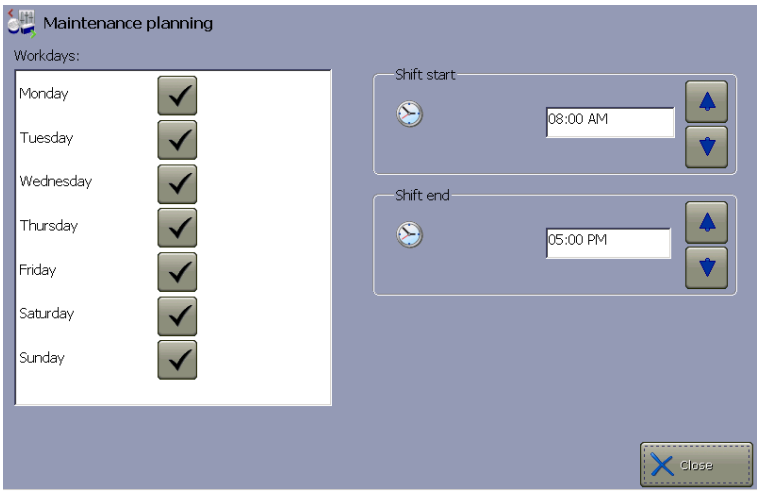
Step	Action
1.	Highlight the desired user activity on the **User activities** screen and press ***Edit***.
2.	Press the ***Keyboard*** button to edit the text. Confirm the text with ***Enter***. Change, if desired, the interval or next date (confirm the date with ***Enter***).
3.	Press ***Back*** to return to the **User activities** screen and edit other user activities in the same manner.

Deleting a user activity

Step	Action
1.	On the **User activities** screen, highlight the action to be deleted and press ***Delete***.
2.	Press ***Continue*** to delete the activity or press ***Cancel*** to return to the **User activities** screen.

Maintenance planning

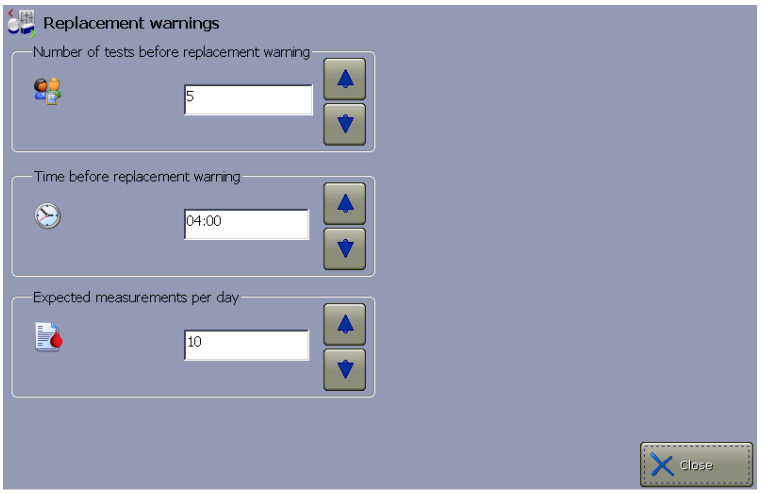
In this program you can plan replacements during a week and the shift.



Step	Action
1.	Activate the check buttons for the days on which maintenance is to be performed.
2.	Select the time at the beginning or the end of the shift, using the up/down arrows.
3.	Press ***Close*** to confirm the settings.

Replacement warnings

In this program you can set the time for a warning to appear before a replacement. This will affect the status of the traffic light on the main screen.



Step	Action
1.	Select the number of remaining tests before the warning should be given, using the up/down arrows.
2.	Select the time before a replacement warning, using the up/down arrows.
3.	Select the expected measurements per day, using the up/down arrows.
4.	Press ***Close*** to confirm the settings.

Parameters and input setup

Program

Press ***Menu > Utilities > Setup > General setup > Parameters and input setup*** and activate a button to enter a program.

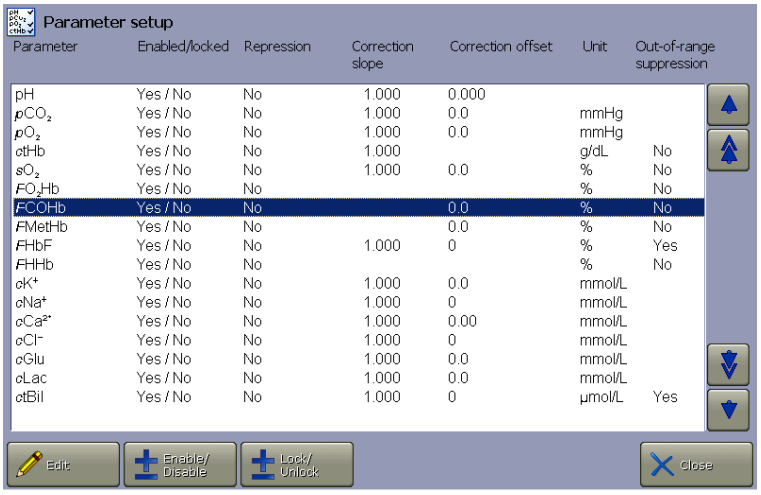
The following programs are available:

- Parameters
- Units
- User-defined data items
- User-defined notes

Parameter setup

In this program you can do the following:

- Disable or enable a parameter
- Repress parameters if problems are detected
- Lock a parameter
- Make user-defined corrections for each measured parameter
- Make out-of-range suppression of oximetry parameters and bilirubin



Disabling / enabling a parameter:

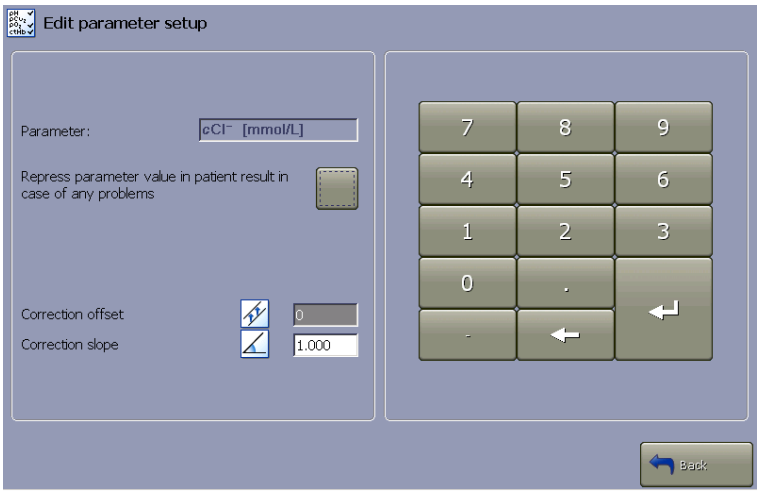
Step	Action
1.	Highlight a parameter on the screen, using the scroll facilities.
2.	Press ***Enable / Disable*** to include/exclude the parameter from a parameter profile and the parameter bar. Note that pH, pCO_2 and pO_2 cannot be excluded.

Locking / unlocking a parameter:

Step	Action
1.	Ensure that the analyzer is not connected to the RADIANCE system, as parameters can be locked/unlocked from the RADIANCE system.
2.	Highlight a parameter on the screen, using the scroll facilities.
3.	Press ***Lock / Unlock***. (This button is grayed-out if the analyzer is connected to the RADIANCE system.)
4.	To unlock a parameter, highlight it and press ***Lock / Unlock***. The traffic light on ***Analyzer status*** will change from YELLOW to a color corresponding to the analyzer's overall status.

NOTICE: A locked parameter will show YELLOW on the parameter bar and will change the overall analyzer status traffic light on the **Analyzer status** screen to YELLOW. The parameter value will be absent from the printout; however, the locked parameter will be calibrated.

Editing the parameter setup:



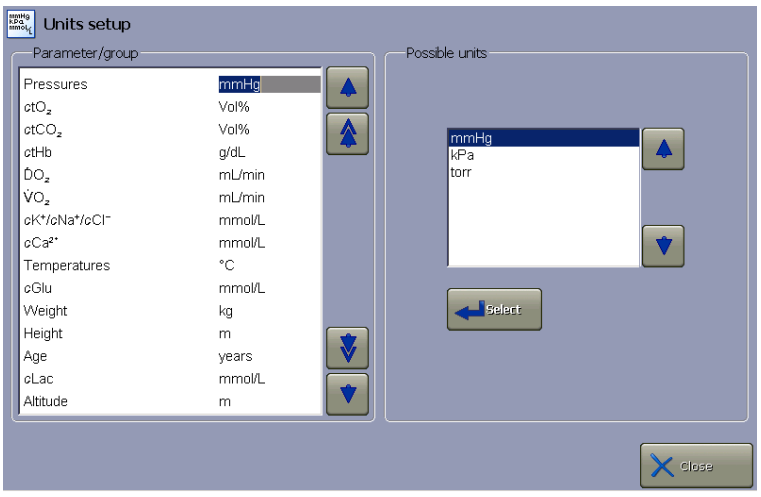
Step	Action
1.	Highlight the desired parameter in the **Parameter setup** screen and press ***Edit***.
2.	Activate (or deactivate) the following check buttons to select (or deselect) the following functions: • Repression (repress parameter value in patient result in case of any problems) • Out-of-range suppression for oximetry parameters or *c*tBil. When activated, this function is applied to the oximetry/ctBil results (including those obtained in the past) as follows: o *c*tHb values lower than "0 g/dL", but inside the range of indication will be shown as "0 g/dL" o Oximetry parameter values (exclusive *c*tHb) inside the range of indication, but lower than "0" or higher than "100 %" will be shown as "0" or "100 %", respectively o *c*tBil values lower than "0 µmol/L", but inside the range of indication will be shown as "0 µmol/L".
3.	Enter correction offset and correction slope. Confirm each entry with ***Enter***.
4.	Press ***Back*** to return to the **Parameter setup** screen and repeat steps **1-3** for another parameter, if desired.

CAUTION – *User-defined corrections affect measurement results*

User-defined corrections for blood measurements will affect 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 setup

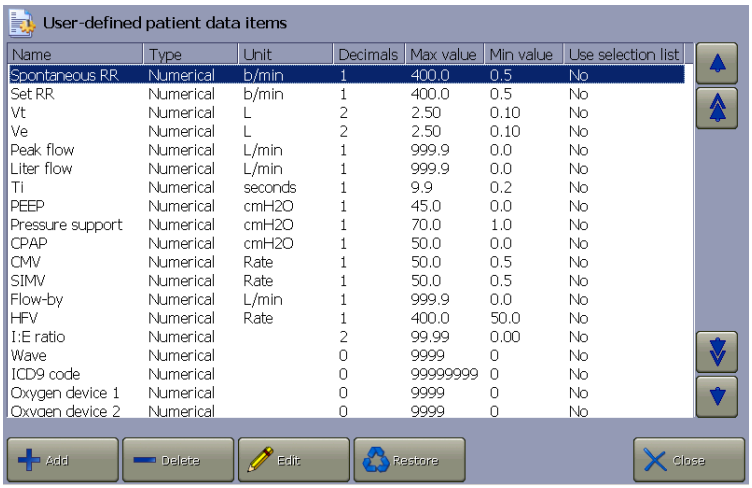
In this program you can select the unit for each parameter or group of parameters.



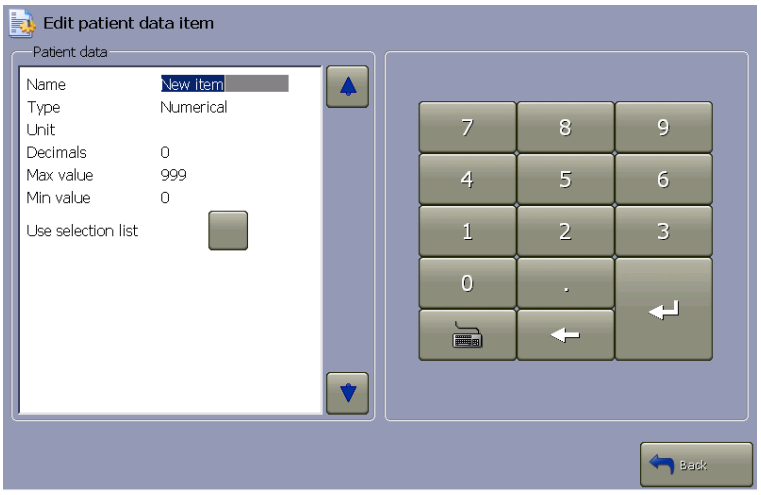
Step	Action
1.	Highlight a parameter or a group of parameters, using the arrow buttons.
2.	Select the unit, using the arrow buttons, and confirm with ***Select***.
3.	Change units for other parameters in a similar manner.
4.	Press ***Close*** to return to the main screen.

User-defined patient data items

In this program you can include other patient data in the Patient ID layout than those already available there.



Editing an item in the list:



Step	Action
1.	Highlight an item on the **User-defined patient data items** screen and press ***Edit***.

2. Press the ***Keyboard*** button 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 arrows and press ***Select***.
   - For "Text" entry, go to step **8**
   - For "Numerical" entry, go to step **4**
4. Highlight "Unit" and press the ***Keyboard*** button on the keypad. Type in the new name of up to 20 characters and confirm with ***Enter***.
5. Highlight "Decimals" (if not already done) and the box with "0", "1", "2","3" is displayed. Choose the number of decimals with the up/down arrows and press ***Select*** to confirm.
6. Highlight "Max. value". Type in the value and confirm with ***Enter*** on the keypad.
7. "Min. value" is now highlighted. Type in the value and confirm with ***Enter*** on the keypad.
8. Press the check button to activate the "Use selection list" function.

   To make a list:
   - Press ***Add***
   - Type in the item on the displayed keyboard (up to 20 characters)
   - Confirm with ***Enter***

   Add as many items as you wish in the same manner.
9. Press ***Back*** to return to the **User-defined patient data items** screen. The new entry will be included in the list

NOTICE: The check button in the "Use selection list" can be activated only if the list contains two or more items.

Including a new item in a patient ID layout:

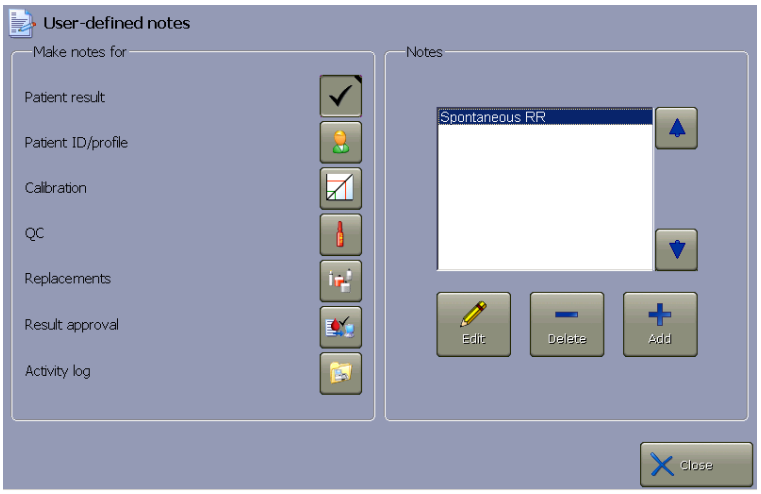
Step	Action
1.	Press ***Menu*** > ***Utilities*** > ***Setup*** > ***Analysis setup*** > ***Patient reports*** > ***Edit patient ID layout.***
2.	Follow the procedure described in *Patient reports* in this chapter.

Restore default:

To restore the default settings press ***Restore***.

User-defined notes

Press ***Utilities > Setup > General setup > Parameters and input > User-defined notes.***



Adding a Note:

Step	Action
1.	Activate one of the check buttons on the screen.
2.	Press ***Add.***
3.	Type the text for the Note, using the screen keyboard. Confirm with ***Enter*** to save the text and return to the previous screen.

Editing a Note:

Step	Action
1.	Highlight a Note in the "Notes" box, using the up/down arrows, and press ***Edit***.
2.	Edit the text and confirm with ***Enter***.

Deleting a Note:

Step	Action
1.	Highlight a Note in the "Notes" box.
2.	Press ***Delete***.

NOTICE: A list of Notes made for a given option will be marked with a pencil icon on the relevant screen(s).

Analyzer settings

Program

Press ***Menu > Utilities > Setup > General setup > Analyzer settings*** and activate a button to enter a program.

The following programs are available:

- Analyzer ID
- Time/Date
- Acoustic signal
- Barometer
- Language

Analyzer identification

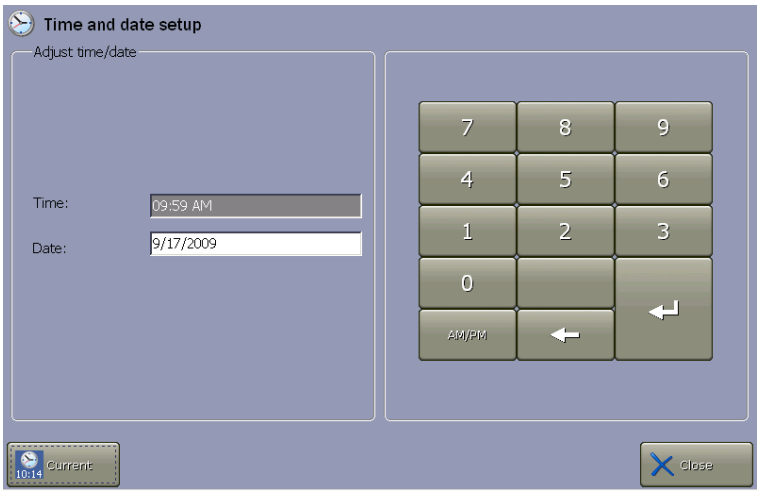
In this program you can change the analyzer's identification.

Step	Action
1.	Touch and highlight the "Analyzer name" box if not already highlighted.
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: The installation number cannot be changed. Quote this number in any technical inquiries you may have to Radiometer.

Time/date setup

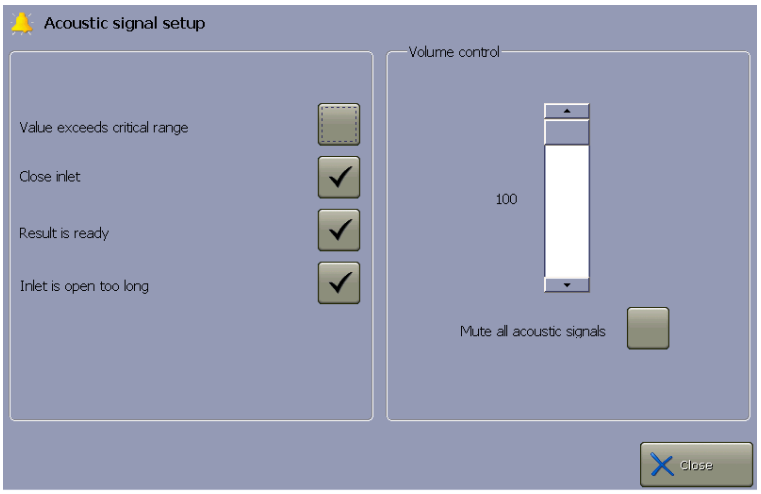
In this program you can change the current time and date setting.



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***.
	Separators are automatically added between hours, minutes and seconds.
3.	Repeat steps **1-2** to set the date.
4.	To revert to the previous settings, press ***Current***.

Acoustic signal setup

In this program you can set up a short beep to sound after certain events.

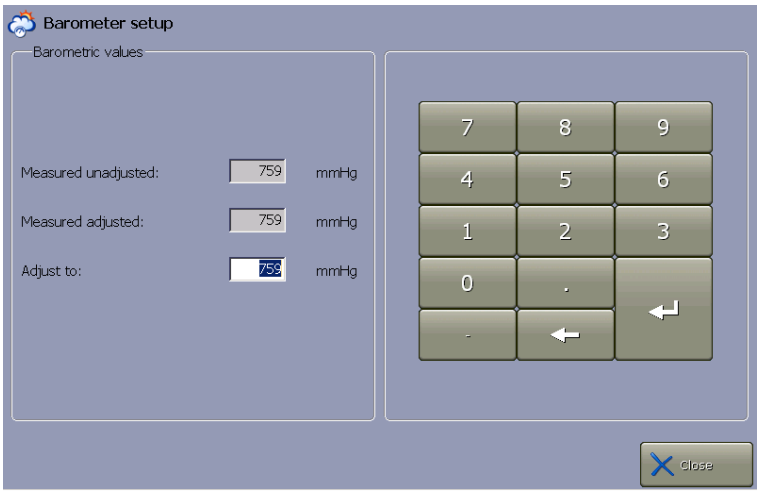


Step	Action
1.	Activate the desired check button(s).
2.	Select volume for the acoustic signal *or* activate the "Mute all acoustic signals" check button.

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.

Barometer setup

In this program you can adjust the automatic barometer in accordance with the reference barometer in your laboratory.



Step	Action
1.	Key in the desired pressure value on the keypad.
2.	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). 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.

Languages

In this program you can select or change a language of your choice from the list of languages on your analyzer.

NOTICE: It is only possible to select or change languages if they have been installed. Not all listed languages may be available.

Step	Action
1.	In the “Select a language from the list” box, select the desired language with the arrows and press ***Set language***. To choose a special regional setting, e.g. English (US), select the desired regional setting in the “Regional language” box and press ***Set regional settings***.
2.	Press ***Continue*** to restart the analyzer. Press ***Cancel*** to continue operating the analyzer with the language unchanged.

Communications setup

Program

Press ***Menu > Utilities > Setup > General setup > Communications*** and activate a button to enter a program.

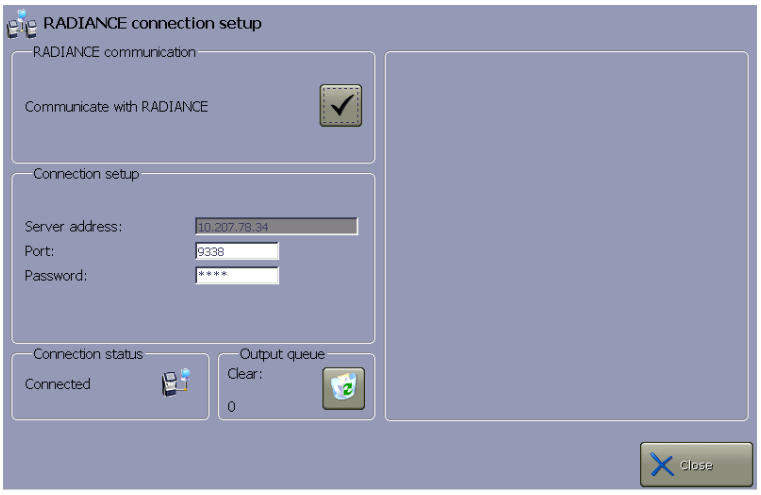
The following programs are available:

- RADIANCE connection
- LIS/HIS connection
- Automatic data transmission
- Automatic data request
- Patient lookup setup
- QA Portal connection

See *Rear* in section *Hardware*, chapter 2 in the ABL90 FLEX operator's manual for the identification and location of the serial RS-232 interface connection (COM) and the network (TCP/IP) RJ45 Ethernet connection.

RADIANCE connection setup

In this program you can connect the analyzer to the RADIANCE system.



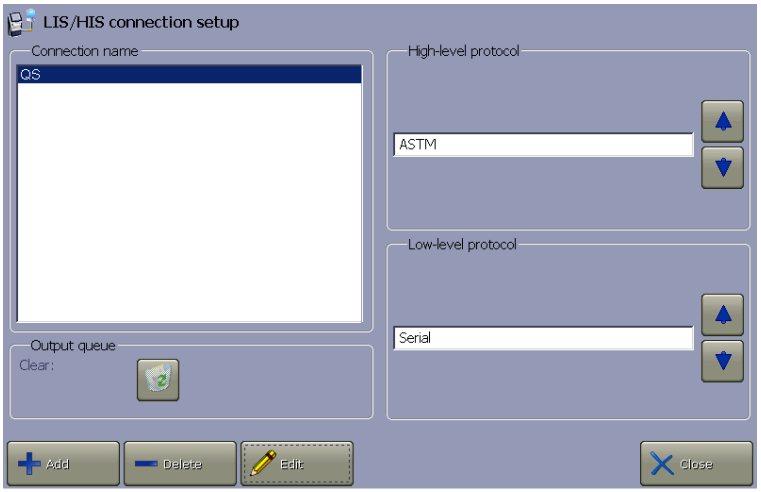
NOTICE: Connecting the analyzer to the RADIANCE system should be performed by the RADIANCE administrator of your institution.

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

Step	Action
4.	Press the check button in the "RADIANCE communication" box to activate connection.
5.	The "Connection status" box with the handshake indicates an established connection to the RADIANCE system.
6.	The Icon in the "Connection status" box indicates the state of the RADIANCE connection. "Connected" indicates an established connection to the RADIANCE system. A RADIANCE icon in the Information bar will indicate the established connection as well.
7.	Clear the queue by activating the recycle bin icon. (The "Output queue" box shows the number of data queued up for transfer. It will be sent to the RADIANCE system.)
8.	Press ***Close*** to exit.

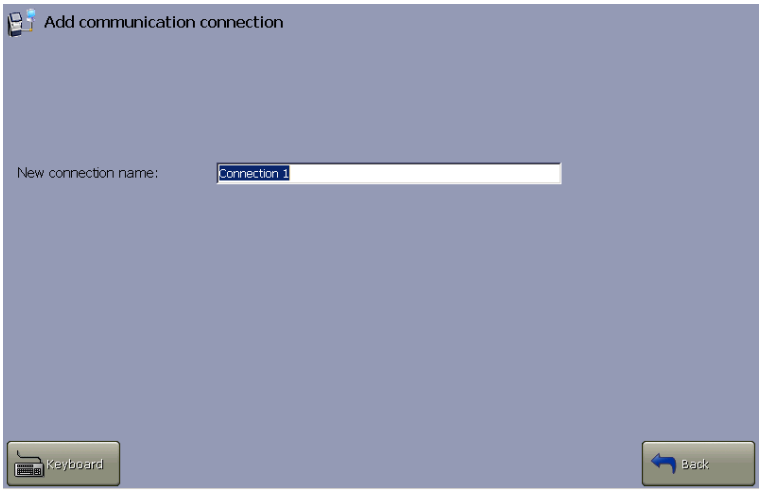
LIS/HIS connection setup

In this program you can select the communication protocol for a connected device.



The "Output queue" box shows the number of data queued up for transfer to LIS/HIS. Clear, if necessary, the queue by activating the recycle bin icon.

Step	Action
1.	Press ***Add.***

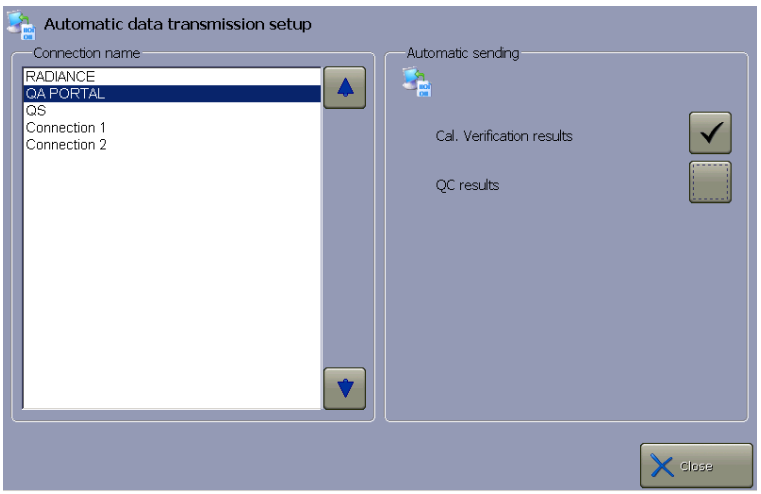


2.	Press ***Keyboard,*** type in the name of the connection instead of the default one, and press ***Enter***. Press ***Back*** to return to the **LIS/HIS connection setup** screen.
3.	Select the high-level protocol according to the requirements of the connected device, using the up/down arrows in the box. Available protocols: ASTM, ASTM6xx, HL7 ver. 2.2, HL7 version 2.5 or POCTDML1A.
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)

Step	Action
5.	Connection specifications for serial low-level protocol:
	Press ***Edit*** to display the **Connection specifications** screen.
	Press ***Edit*** to enter the options screen and use the up/down arrows in each box to select baud rate, Com port and port configuration.
	• Baud rate: 1200, 2400, 4800, 9600, 14400, 19200, 38400 – default is 9600
	• Com Port: COM1, COM2 – default is COM1
	• Port configuration:
	- Data bits: 5, 6, 7, 8, – default is 8 - Stop bits: 1, 1.5, 2 – default is 1 - Parity: None, Even, Odd – default is None
6.	Connection specifications for network low-level protocol:
	Press ***Edit*** to display the **Connection Specifications** screen.
	Touch the screen to highlight the following boxes one after another:
	• Server Address
	• Com Port
	• Reconnect interval
	Use the keypad/keyboard to enter the relevant information.
7.	Connection specifications for POCTDML1A low-level protocol:
	Touch the screen to highlight the following boxes one after another:
	Server Address – Port – Reconnect Interval.
	Use the keypad/keyboard to enter the relevant information.

Automatic data transmission setup

In this program you can set up automatic transmission of data to a connected LIS/HIS computer system or to the RADIANCE system.

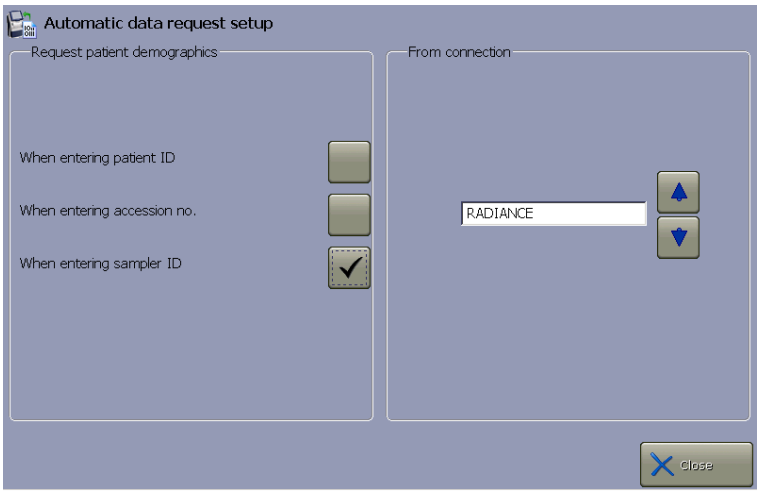


Step	Action
1.	Highlight a desired connection device on the screen, using the up/down arrows.
2.	Activate the relevant check button(s) to select the data to be sent to the highlighted connection.

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

Automatic data request setup

In this program you can select the conditions for requesting patient demographics automatically from the connected RADIANCE system or from the LIS/HIS computer system when entering patient ID, accession number or sampler ID.

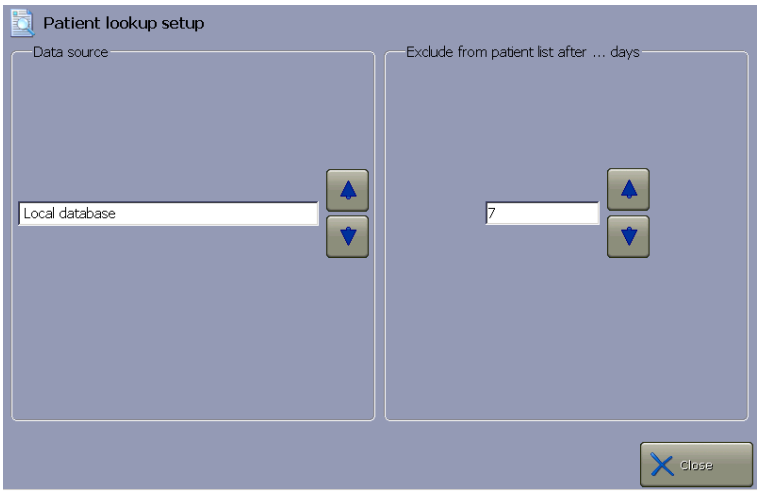


Step	Action
1.	Select a connected device in the "From connection" box, using the up/down arrows.
2.	Activate the relevant check button(s) to request patient demographics when entering: • Patient ID • Accession number • Sampler ID
3.	Press ***Close*** when completed.

NOTICE: If the requested patient data (e.g. Patient Last Name) was received after leaving the **Patient identification** screen, the patient report will be stored without the 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.

Patient lookup setup

In this program you can select the data source from which to obtain the patient information on the **Patient identification** screen.

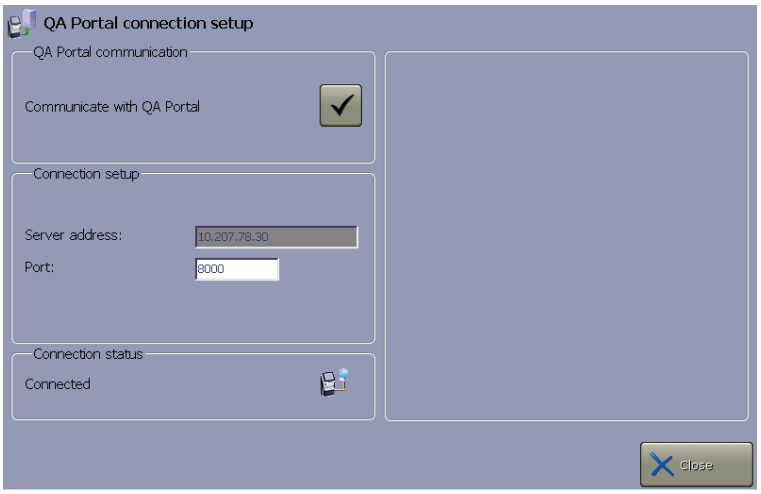


Step	Action
1.	Select a data source from the established connections (local database, RADIANCE or LIS/HIS connections).
2.	Select the number of days you want each patient to be kept in the list, using the up/down arrows in the box.
3.	Press ***Close***.

QA Portal connection setup

This program allows you to connect the analyzer to a QA Portal.

If the QA 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.	Touch and highlight the "Server address" box. Type in the TCP/IP address of your QA Portal, using the screen keypad or keyboard.
2.	Touch and highlight the "Port" box. Type in port number, using the keypad.
3.	Press the check button in the " QA Portal communication" box to activate the connection. The icon in the "Connection status" box indicates the state of the QA Portal connection. "Connected" indicates an established connection to the QA Portal.
4.	Press ***Close*** to exit the screen.

Disk functions setup

Program

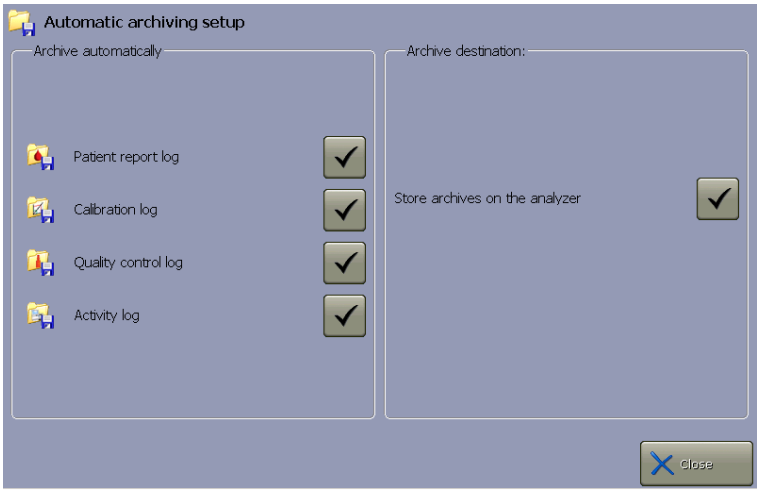
Press ***Menu > Utilities > Setup > General setup > Disk functions setup*** and activate a button to enter a program.

The following programs are available:

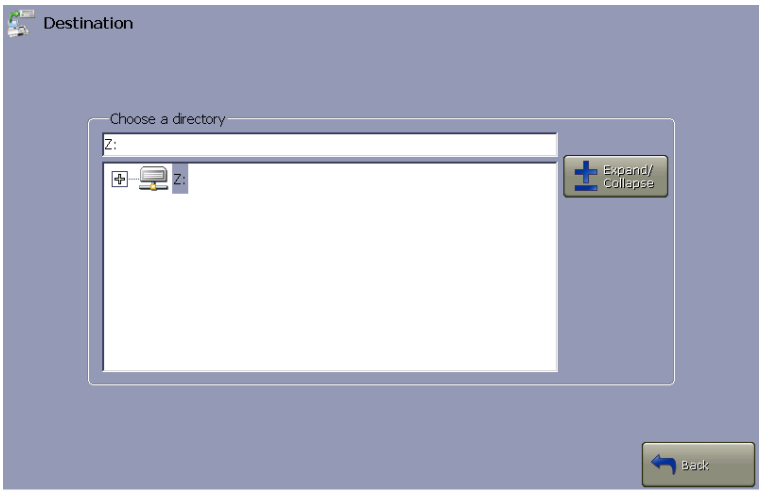
- Automatic archiving
- Automatic backup

Automatic archiving setup

In this program you can select automatic archiving of the data logs by activating the relevant check buttons.



Step	Action
1.	Activate the check button to select automatic archiving on the analyzer's disk.
2.	To select another destination, deactivate the check button in the "Archive destination" box and press the drive icon that appears.



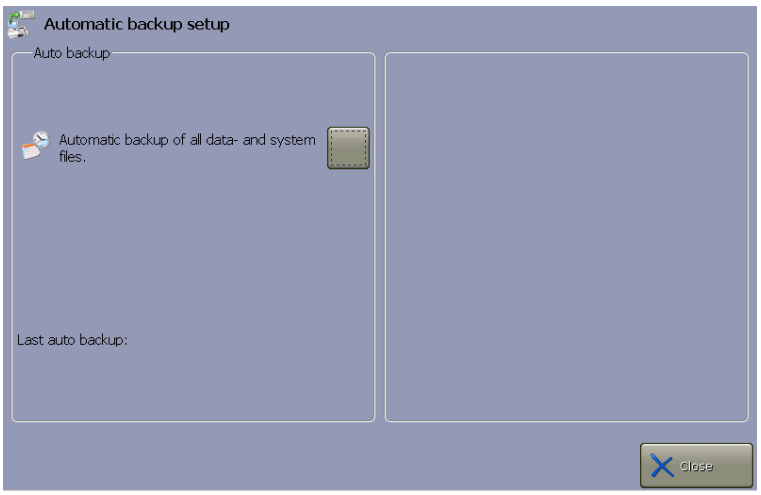
3.	Highlight the drive or folder and press ***Expand/Collapse*** to open a folder in a directory or within a folder. When completed, the correct destination appears in the upper part of the box.
4.	Press ***Back*** to return to the **Automatic archiving setup** screen.
5.	Press ***Close*** to return to the main screen.

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

For detailed information on archiving the old data, please refer to chapter 2: *Disk functions setup program* in this manual.

Automatic backup setup

In this program you can select automatic backup of all data and system files.



Step	Action
1.	Activate the check button.
2.	Select time for automatic backup by highlighting the "Time" box and typing in the time, using the screen keypad. Confirm with ***Enter***.
3.	Enter the interval between subsequent backups in the "Interval (days)" box and type in the number of days, using the screen keypad. Confirm with ***Enter***.
4.	Press the drive icon next to the "Destination" box to select destination.
5.	Highlight the drive or folder and press ***Expand/Collapse*** to open a folder in a directory or within a folder. Note that automatic backup can be selected for the internal disk or the network. When completed, the correct destination appears in the upper part of the box.
5.	Press ***Back*** to return to the **Automatic backup setup** screen.
6.	Press ***Close*** to return to the main screen.

Printers

Program

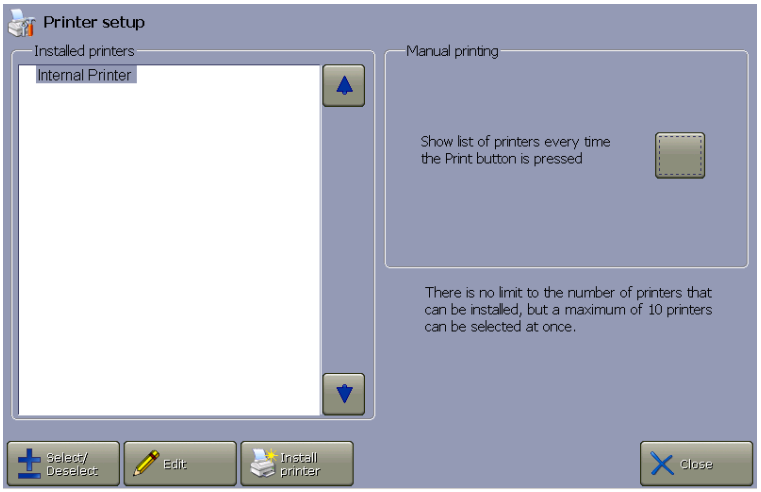
Press ***Menu > Utilities > Setup > General setup > Printers*** and activate a button to enter the program.

The following programs are available:

- Printer setup
- Automatic printing

Printer setup

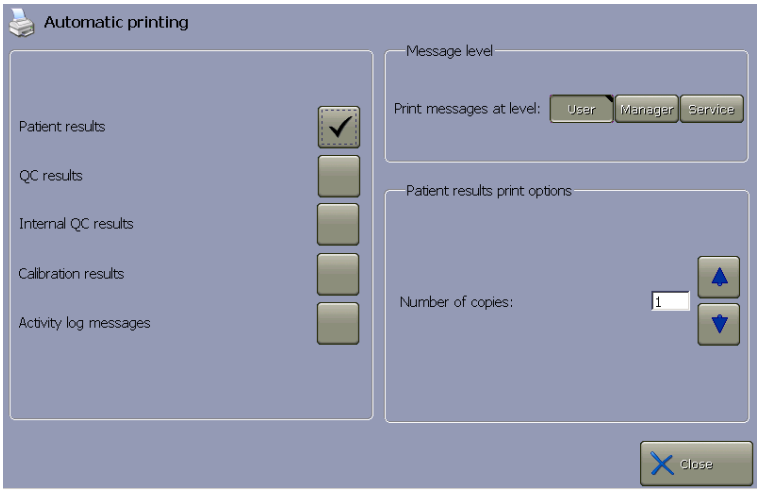
In this program you can set up other printers than the analyzer's printer for making printouts.



Step	Action
1.	Highlight a printer from the list, using the up/down arrows.
2.	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 at a time.
3.	Activate the check button in the "Manual printing" box to display the list of printers every time the ***Print*** button has been pressed. If not activated, all selected printers will make a printout every time the ***Print*** button is pressed.
4.	Press ***Edit*** to display the keyboard to change the highlighted printer's name, Type a name and confirm with ***Enter***.
5.	To install a new printer, press ***Install printer***. The Add Printer Wizard program appears. This function can be used by a Radiometer service representative or a person with network knowledge. To get the desired printer installed the analyzer will run a restart.

Automatic printing

In this program you can select automatic printout of patient, QC (both manually and built-in) and calibration results plus Activity log messages.



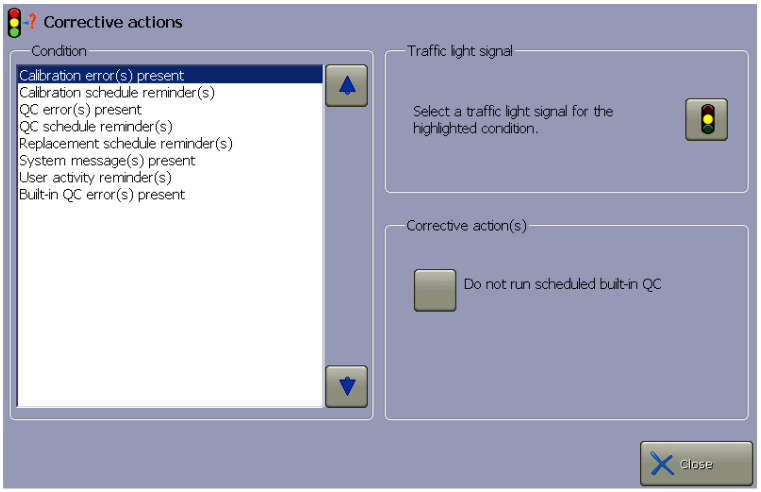
Step	Action
1.	Activate the desired check buttons for automatic printout.
2.	Select automatic printout of several copies (1-5) of patient results, using the up/down arrows in the "Patient results print options" box.
3.	Press ***User***, ***Manager*** or ***Service*** in the "Message level" box to select the level for the messages in the Activity log.
4.	Press ***Close*** to return to the main screen.

Corrective actions

Program

In this program you can select the following:

- Corrective actions for the events listed in the "Conditions" box
- Traffic light signal, if available, for an event
- Analyzer action for the subsequent measurements



Step	Action
1.	Highlight the desired condition, using the up/down arrows in the box.
2.	Select an action for this condition from the options 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 corrective actions

Conditions and corresponding corrective action options are as follows:

Condition	Corrective action	Traffic light
Calibration error(s) present	• Do not run scheduled built-in QC	GREEN or YELLOW
Calibration schedule reminder(s)	• Message on next patient result	GREEN or YELLOW
QC error(s) present	• "?" on specific parameters	YELLOW
QC schedule reminder(s)	• Message on next patient result	GREEN or YELLOW
	• Lock analyzer when QC overdue	GREEN or YELLOW

Replacement schedule reminder(s)	• Message on next patient result • Lock analyzer when 10 % overdue	GREEN or YELLOW GREEN or YELLOW
System message(s) present	• Message on next patient result	GREEN or YELLOW
User activity reminder(s)		GREEN or YELLOW
Built-in QC error(s) present	Rerun same level once (default OFF)	

NOTICE: Critical system messages will always result in a RED traffic light signal.

The specified traffic light signal and the messages will continue to appear until the condition no longer exists.

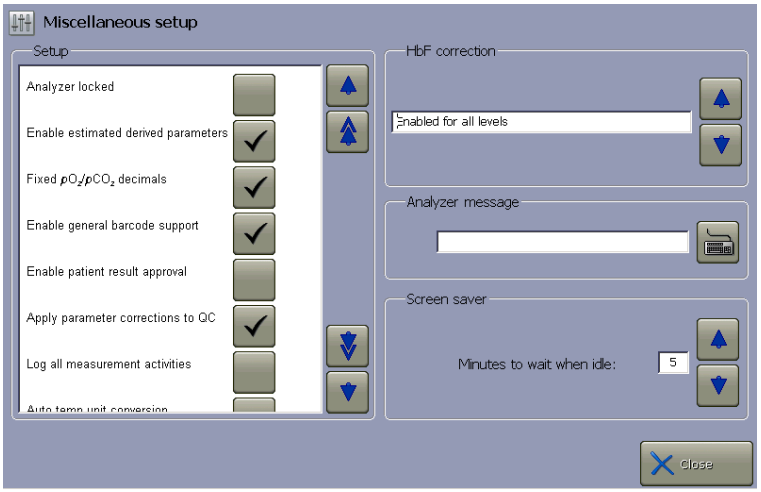
Explanation of corrective actions

Corrective action	Explanation
"?" on specific parameters	The affected parameter(s) will be marked with "?" in subsequent patient results.
Message on next patient result	The subsequent patient results will be marked on the **Message** screen.
Lock analyzer when QC overdue	If a scheduled quality control measurement is more than 0 % overdue compared with its scheduled time, the analyzer will be locked.
Lock analyzer when 10 % overdue	If a scheduled replacement procedure is more than 10 % overdue compared with its scheduled time, the analyzer will be locked.

Miscellaneous setup

Program

In this program you can select the following options (use the arrow buttons to display the rest of the options):



List of options

Option	Function
Analyzer locked	Suspends all measurements on the analyzer; 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 RADIANCE.
Enable estimated derived parameters	Enables estimation of the derived parameters based on default values and parameters that 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** and **Quality control identification** 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 results. For detailed information, refer to chapter 4: *Sample measurement* in the ABL90 FLEX operator's manual.
Apply parameter corrections to QC	If enabled, the user-defined corrections (slope and offset) will be applied to the QC results.
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 log. This option aims to avoid too many entries in the log.
Auto temp unit conversion	°C will be automatically changed to °F if the entered temperature is over the value of 45.
Enable screen saver	The screen saver will appear if the analyzer has been idle for 5 minutes.

Option	Function
Show parameter bar	If disabled, the parameter bar will not appear on the main screen.

Activating/ deactivating an option

Step	Action
1.	Scroll the list of options with the up/down arrows.
2.	Highlight the option and press the check button next to it. To deactivate the option, press the check button again.
3.	Press ***Close*** to confirm the settings and return to the main screen.

Selecting HbF correction

This option disables HbF correction for all levels, or enables it for all levels or for HbF levels higher than 20 %.

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

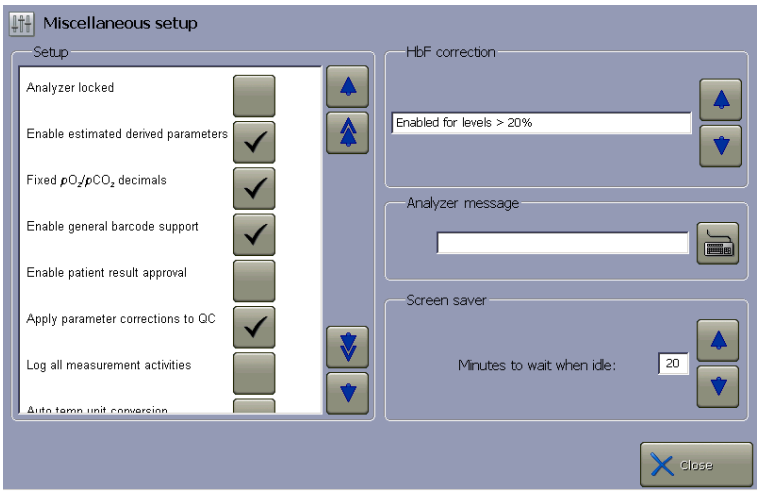
Guidelines for selecting/deselecting HbF correction:

For neonatal samples:	Use "Enabled for all levels". It is important to enable HbF correction to obtain correct results for *c*tBil, sO_2, FO_2Hb, *F*MetHb, *F*COHb and *F*HHb.
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 the measurement of sO_2, FO_2Hb, *F*MetHb, *F*COHb and *F*HHb, and will cause a marginal number of adult samples reported with HbF present.

Analyzer messages

A message, sent from the RADIANCE system to the connected analyzer and displayed on the main screen, can be changed or deleted in this program.



Step	Action
1.	Press the ***Keyboard*** button, type the message (up to 40 characters long) 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.
2.	Confirm the change with ***Enter*** to return to the **Miscellaneous setup** screen.

Setting the time for the screen saver to appear

Step	Action
1.	Check that the “Enable screen saver” check button is activated in the “Setup” box.
2.	In the “Screen saver” box, select the time with the arrow buttons.

Setup default settings

Access to Radiometer default setup

Press ***Menu*** > ***Utilities*** > ***Disk functions*** > ***Restore default setup***.

You can select the parts of the Setup to be set back to Radiometer defaults.

Operators and passwords

Item	Setting
User password	123456
Logoff time	3 minutes

Default settings for **Access profiles** are as follows:

	A	B	C	D	E	F	G	H	I
User	X	X	X		(X)	X			
Supervisor	X	X	X	X	X	X	X		X
Manager	X	X	X	X	X	X	X		X
Service techn.	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	

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 = 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

Analysis setup

Analysis setup	Default setting	
Syringe modes	S65 µL; ampoule QC. All user-defined modes are deleted.	
Capillary modes	C65 µL. All user-defined modes are deleted.	
Parameter profile	All parameters (except *F*HbF) are selected. Dynamic Parameters: Off	
Sample pre-registration	• Interpret barcode input as: Sampler ID • Confirm pre-registered data: On • Included fields: All fields On	
Sample logistics setup	Sample age: On (30 minutes for all parameters)	
Patient reports	• Layouts: -R- 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	
	*c*tHb	[xxx – xxx]
	sO_2	[xxx – xxx]
	FO_2Hb	[xxx – xxx]
	*F*COHb	[xxx – xxx]
	*F*HHb	[xxx – xxx]
	*F*MetHb	[xxx – xxx]
	*F*HbF	[xxx – xxx]
	< New Line >	

Analysis setup	Default setting	
Patient reports (*continued*)	**Electrolyte values**	
	cK^+	[xxx – xxx]
	cNa^+	[xxx – xxx]
	cCa^{2+}	[xxx – xxx]
	cCl^-	[xxx – xxx]
	< New Line >	
	Metabolite values	
	*c*Glu	[xxx – xxx]
	*c*Lac	[xxx – xxx]
	*c*tBil	[xxx – xxx]
	< New Page >	
	Temperature-corrected values	
	pH(*T*)	
	$pCO_2(T)$	
	$pO_2(T)$	
	< New Group >	
	Oxygen Status	
	ctO_2	
	*p*50	
	< New Line >	
	Acid-Base status	
	*c*Base(Ecf)	
	$cHCO_3^-$(P,st)	

Calibration schedule

Activity	Default setting
tHb calibration	3 months
Start time of first calibration	00:00
Link QC schedule to calibration schedule	On

Quality control setup

Program	Item	Default setting
QC statistics	Statistics factor	1.5
	Cut-off date for month-to-date statistics	1
	Remind to print statistics each month	No
	Remind to export WDC data each month	No

QC input setup	Mandatory temperature	No
	Default temperature	25 °C
QC schedule	Built-in QC (S9030, S9040, S9050)	04:00, 12:00, 20:00
Westgard Rules		All rules are "Off"
Run QC after replacement		On

Replacement setup

Program	Item	Default setting
Replacement schedule	Inlet gasket	3 months
	Inlet probe	Never
	Connection gasket	3 months
	Clean inlet	Never
User activities	None	–
Maintenance planning	None	–
Replacement warnings	Number of activities before replacement warning	5
	Time before replacement warning	4 hours
	Expected measurements per day	–

General setup

Parameter setup default settings:

Parameter	Enabled / Locked	Repression	Offset	Slope	Units	Out-of-range suppression
pH	Not altered	No	0.000	1.000		N/A
pCO_2	Not altered	No	0.0	1.000	mmHg	N/A
pO_2	Not altered	No	0.0	1.000	mmHg	N/A
*c*tHb	Not altered	No	N/A	1.000	g/dL	No
sO_2	Not altered	No	0.0	1.000	%	No
FO_2Hb	Not altered	No	N/A	N/A	%	No
*F*COHb	Not altered	No	0.0	N/A	%	No
*F*MetHb	Not altered	No	0.0	N/A	%	No
*F*HbF	Not altered	No	0	1.000	%	Yes
*F*HHb	Not altered	No	N/A	N/A	%	No
cK^+	Not altered	No	0.0	1.000	mmol/L	N/A
cNa^+	Not altered	No	0	1.000	mmol/L	N/A
cCa^{2+}	Not altered	No	0.00	1.000	mmol/L	N/A
cCl^-	Not altered	No	0	1.000	mmol/L	N/A
*c*Glu	Not altered	No	0.0	1.000	mmol/L	N/A
*c*Lac	Not altered	No	0.0	1.000	mmol/L	N/A

*c*tBil	Not altered	No	0	1.000	µmol/L	Yes

Units default settings:

Parameter	Unit
Pressures	mmHg
*c*tBil	µmol/L
*c*tHb	g/dL
*F*COHb	%
*F*HbF	%
*F*HHb	%
*F*MetHb	%
FO_2Hb	%
sO_2	%
Gas fractions	%
$FO_2(I)$	%
Hct	%
$pO_2(a/A)$	%
*F*Shunt	%
RI	%
$cK^+/cNa^+/cCl^-$	mmol/L
cCa^{2+}	mmol/L
*c*Glu	mmol/L
*c*Lac	mmol/L
Temperatures	°C
ctO_2	Vol %
$ctCO_2$	Vol %
$\dot{D}O_2$	mL/min
$\dot{V}O_2$	mL/min
Age	years
Weight	kg
Height	m
Altitude	m
Birth weight	g

User-defined patient data items default settings:

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	2
Ti	Numerical	seconds	1
PEEP	Numerical	cmH_2O	1
Pressure support	Numerical	cmH_2O	1
CPAP	Numerical	cmH_2O	1
CMV	Numerical	Rate	1
SIMV	Numerical	Rate	1
Flow-by	Numerical	L/min	1
HFV	Numerical	Rate	1
I:E ratio	Numerical	None	2
Wave	Numerical	None	None
ICD9 code	Numerical	None	None
Oxygen device 1	Numerical	None	None
Oxygen device 2	Numerical	None	None
Diagnostic code	Numerical	None	None

User-defined notes default settings: No notes defined.

Language default setting: English.

Acoustic signals default settings:

Event	Default setting
Value exceeds critical limits	No
Close inlet	Yes
Result is ready	Yes
Inlet is open too long	Yes

Corrective actions default settings:

Event	Default setting	Traffic light
Calibration error(s) present	Do not run QC	YELLOW
Calibration schedule reminder(s)	No setting	YELLOW
QC error(s) present	? on specific parameters	YELLOW
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
Built-in QC error(s) present	No setting	YELLOW

Miscellaneous setup default settings:

Event	Default setting
Analyzer locked	Not set
Enable estimated derived parameters	Off
Fixed pO_2/pCO_2 decimals	Off
Enable general barcode support	On
Enable patient result approval	Off
Apply parameter corrections to QC	On
Log all measurement activities	Off
Auto temp unit conversion	On
Enable screen saver	On
Show parameter bar	On
HbF correction	"Enabled for levels > 20 %"
Analyzer message	(Blank)
Screen saver	5 minutes to wait when idle

Automatic printing default settings:

Item	Default setting
Patient results	On
QC results	Off
Calibration results	Off
Activity log message	Off
Message level	User
Number of copies	1

Printer setup default settings:

Item	Default setting
Installed printers	Internal Printer (added printers are not deleted)
Select printer dialogue	Off

Automatic archiving default settings:

Item	Default setting
Patient report log	On
Calibration log	On
Quality control log	On
Activity log	On
Store archives on the analyzer	On

Automatic backup default settings:

Item	Default setting
Auto backup	on

Communication setup default settings:

Item	**Default setting**
RADIANCE system	Off
LIS/HIS	None
Automatic data request	"When entering sampler ID" – on
Automatic data transmission	Patient results, Calibration results, QC results, Activity log messages
Patient lookup	Local database
Remote control	Enable remote access

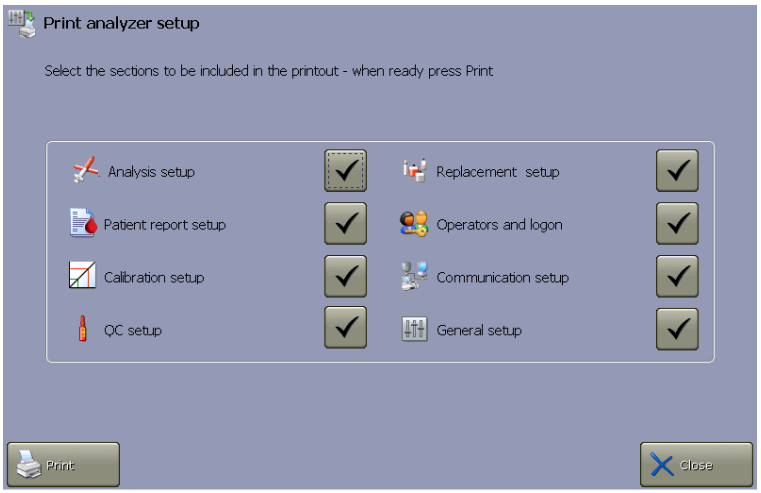
Setups without Radiometer settings

The following setups have no Radiometer settings:

- Barometer setup
- Time and date setup
- Analyzer identification setup

Print setup

With this program you can print out all or part of your analyzer setup.



Step	Action
1.	Press ***Menu*** > ***Utilities*** > ***Setup*** > ***Print analyzer setup***.
2.	All check buttons are activated. Deactivate relevant check buttons to deselect those setups that you do not wish to be printed out.
3.	Press ***Print*** to start printing the selected setups or press ***Close*** to return to the main screen.

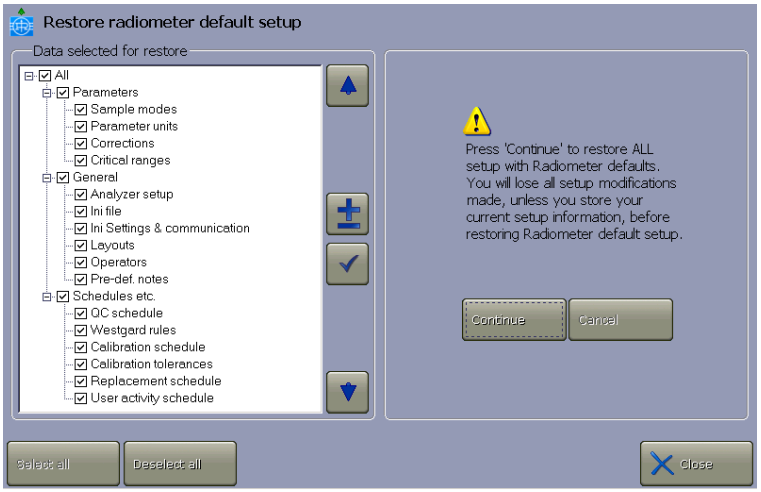
Contents of setup settings

Press ***Menu > Utilities > Disk functions > Restore default setup*** to access the **Restore radiometer default setup** program.

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*, chapter 2: Disk functions setup programs.

Each setup group of settings is described in this section.

Parameters group

The following settings (i.e. screens and their data) will be restored in the Parameters group:

Item	Setup (screens)
Sample modes	• 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	• Reference ranges • Critical limits • Age groups

General group The following settings (i.e. screens and their data) will be restored in the General group:

Item	Setup (screens)
Analyzer setup	• Corrective actions • Acoustic signals • Low level warning
Ini file	• Selected language • Printer path
Ini settings and communications	• RADIANCE connection • LIS/HIS connection • 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 • Westgard Rules (enable Westgard Rules) • Printer setup (show list of printers)
Layouts	• 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	• Operators and passwords • Access profiles
Pre-def. notes	• 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).
Wet section setup	• Calibration schedule (minus tHb Cal and the start time)
Westgard rules	• Westgard rules settings
Replacement schedule	• Replacement schedule
User activities schedule	• User activities • Edit user activities

Interfacing facilities

Connecting a mouse

A mouse connected to the analyzer may be used to activate all the analyzer's screen functions instead of the operator touching the screen.

A standard PS/2 port mouse or a USB mouse is the sole item that is required for connection to the analyzer.

Connecting a mouse:

Step	Action
1.	For a standard PS/2 port mouse only: Switch off the analyzer.
2.	Connect the mouse to the mouse port at the rear of the analyzer.
3.	For a standard PS/2 port mouse only: Switch on the analyzer. After restart the mouse is ready for use. A USB mouse can be used right after it has been connected.

Connecting an alpha-numeric keyboard

An external alphanumeric keyboard may be used to enter data instead of the on-screen keyboard. However, to select individual buttons on the analyzer screen, you must use a mouse or must touch the screen.

An IBM enhanced personal computer keyboard or a USB keyboard is the sole item that is required for connection to the analyzer. The keyboard layout must correspond to the language version used by the analyzer.

Connecting a keyboard:

Step	Action
1.	For an IBM enhanced personal computer keyboard only: Shut down the analyzer.
2.	Connect the keyboard to the keyboard port at the rear of the analyzer.
3.	For an IBM enhanced personal computer keyboard only: Turn on the analyzer. After restart the keyboard is ready for use. A USB keyboard can be used right after it has been connected.

Connecting to a network

Many hospitals are equipped with 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

Step	Action
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 two of the protocols stated below is used for communication with the central computer. • ASTM • HL7 • POCTDML1A

For further information, refer to the *Communication protocol specifications for Radiometer products* (code no. 989-329).

Radiometer recommends that a qualified service technician carry out connection of the analyzer to a network.

External barcode reader

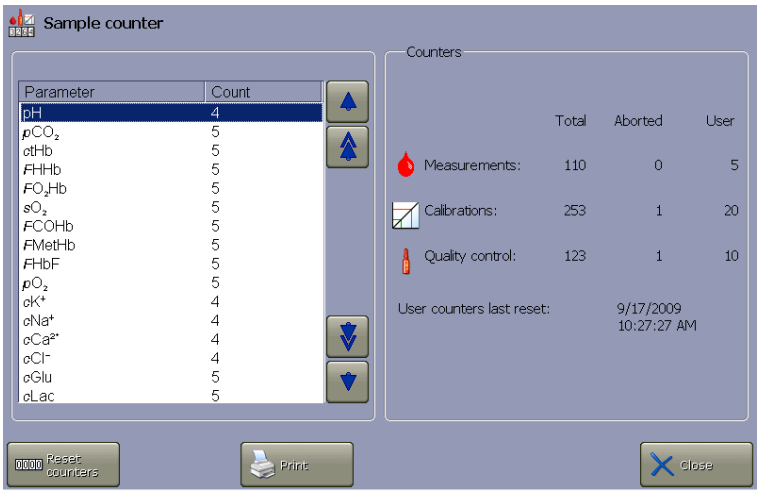
An external barcode reader can be connected and used side by side with the built-in barcode reader – contact your Radiometer service representative.

Sample counter

Purpose

The sample counter lets you keep track of measurements, calibrations and QC. Press ***Utilities > Sample counter*** to enter the program.

Description



Element	Function	
Parameter and Count	List the parameters and how many times each has been measured by the analyzer. Normally the count is the same as the total number of measurements if the parameters have not been 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:	
	Activity	**Number of...**
	Total	Completed sample/QC measurements/ calibrations only. Interrupted or aborted activities are excluded.
	Aborted	Aborted sample/QC measurements/calibrations due to sample errors, wet-section errors, etc. – interrupted activities excluded.
	User	All completed sample/QC 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.	
Buttons	• ***Reset counters*** resets the counters in the "User" column (on analyzers with no logon protection of the Setup programs). • ***Print*** prints out information in Counters and in Parameter.	

2. Disk functions setup programs

General information

Disk functions programs

To access the Disk functions programs, press ***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 at a designated location.
Restore all data	To restore a backup of all data files to the analyzer's internal disk from a designated location.
Export data logs	To export selected records from selected data logs.
Import / Export archives	To import externally archived data logs. To export or delete 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.

Definitions

Setup data refers to information or files that configure the analyzer to operate according to settings defined in the Setup programs.

All data refers to data in the analyzer's internal database, including but not limited to data logs, setup and system files.

Data storage options

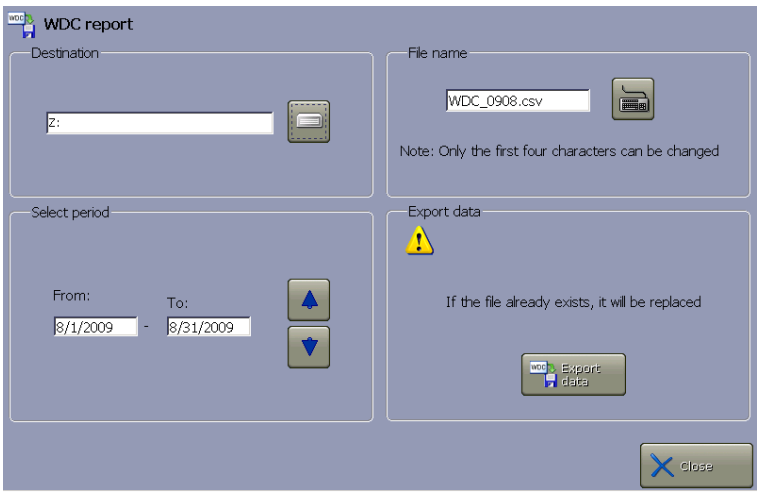
Information is stored on or retrieved from the internal disk, a network, a connected CD-drive (CD-RW, CD-R/RW) or a removable drive (USB mass storage device).

Disk handling rules

The CD-drive and removable drive (USB mass storage device) should be handled according to the instructions on the packaging.

Creating a WDC report

Purpose With this function you can make a Worldwide DATACHECK (WDC) file for reporting monthly quality control data. For information on Worldwide DATACHECK reporting, see the *Worldwide DATACHECK manual*.



Step	Action
1.	Touch the "From:" box in the “Select period” box and set the dates for the desired month, using the up/down arrows. The date in the "To:" box will change automatically.
2.	Highlight the desired drive or folder (another directory, removable or externally connected CD-drive) by pressing the ***Disk drive*** button on the screen, and touching it on the screen. Press ***Expand/Collapse*** to open a folder in a directory or within a folder. When completed, the correct destination appears in the upper part of the box. Press ***Back*** to return to the previous screen.
3.	In the "File name" box (the **WDC report** screen), press the ***Keyboard*** button to type the file name: you can change the four characters "WDC_". Confirm with ***Enter*** on the keyboard and return to the **WDC report** screen.
4.	Send the file to the selected destination by pressing ***Export data*** in the "Export data" box. Wait until the WDC report screen appears and remove the disk, if any, with the WDC report.

NOTICES:

- "Could not create output file" appears if the destination is not accessible.
- "No statistical data found. WDC data not generated" appears if no data is available for the selected month

Backing up all data

Purpose

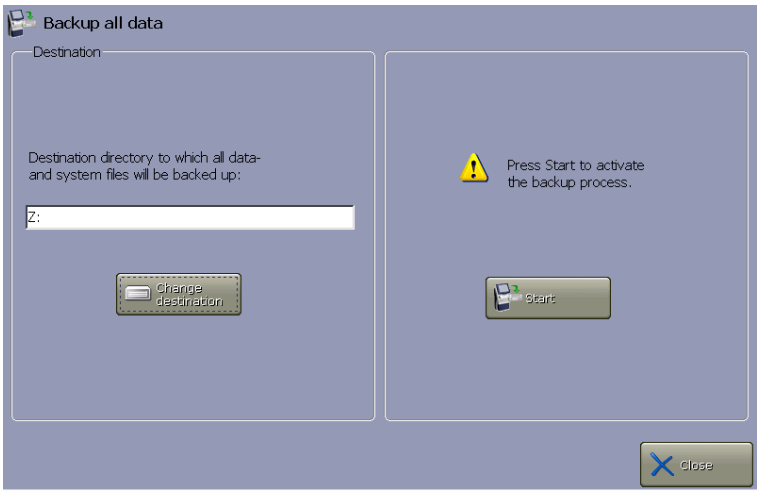
This function is intended as a protection or security against the loss of data or system files that include, but are not limited to, the following:

- 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 a network, a connected CD-drive or a removable drive.

Automatic backup (can be selected – see *Automatic backup setup* in section *Disk functions setup,* chapter 1 in this manual): Data can be stored on the internal 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.

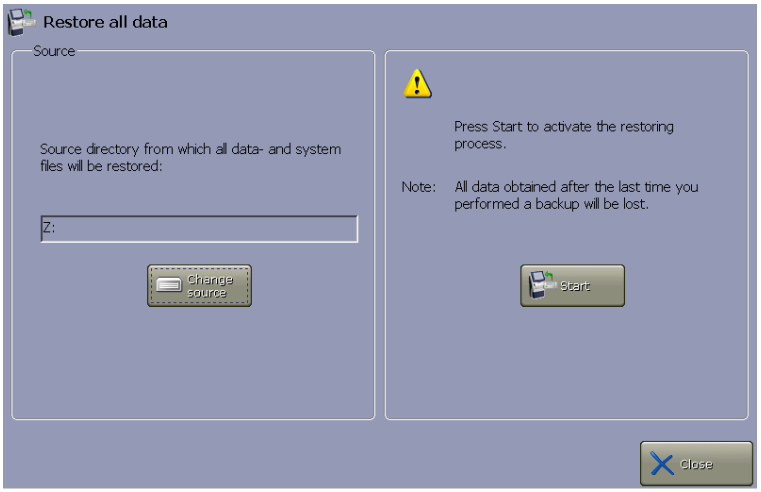


NOTICE: It is the user's responsibility to ensure that all valuable data is regularly backed up. During the analyzer warranty period Radiometer accepts warranty responsibility only for the original storage hardware and installed software.

Step	Action
1.	Press ***Change destination*** to choose the destination.
2.	Highlight the drive or folder by touching it on the screen. Press ***Expand/Collapse*** to open a folder in a directory or within a folder. When completed, the correct destination appears in the upper part of the box. If a removable drive is used, connect it to the USB port Press ***Back*** to return to the previous screen.
3.	On the **Backup all data** screen press ***Start*** to continue.
4.	The backup process begins. • Network drive or internal disk: Backup continues without any further action from the operator • Removable drive: Wait for the data to be prepared (see the timer in the current task field located next to 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 main 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.



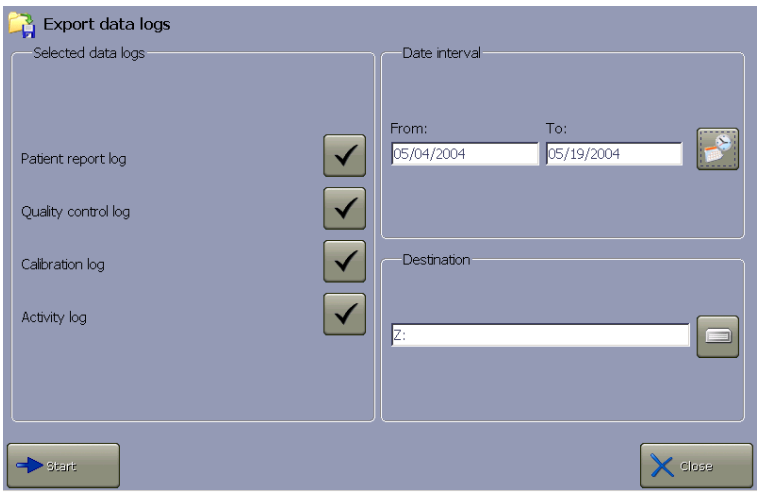
Step	Action
1.	Press ***Change source*** to choose the source drive/directory.
2.	Highlight the drive or folder by touching it on the screen. Press ***Expand/Collapse*** to open a folder in a directory or within a folder. When completed, the correct destination appears in the upper part of the box. If a removable drive is used, connect it to the USB port. 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 main screen.)
4.	The restore process begins. • Network: Restoring does not require any further action • Removable drive: Press ***Start***
5.	Complete restoring all data. When restoring is complete, the analyzer shuts down and 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 or 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.



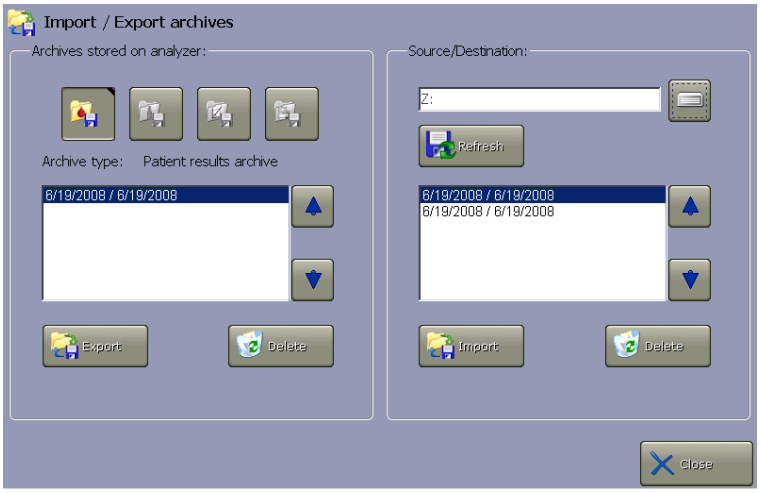
Step	Action
1.	Activate the check buttons next to the data logs to be exported.
2.	Activate the calendar icon, the Choose date screen appears. Type the "From:" date and confirm with ***Enter***. Repeat the same for the "To:" date. Press ***Back*** to return to the **Export data logs** screen.
3.	Activate the ***Disk drive*** button on the **Export data logs** screen. Activate the desired drive by touching it on the screen. Press ***Expand/Collapse*** to open a folder in a directory or within a folder. When completed, the correct destination appears in the upper part of the box. Press ***Back*** to return to the **Export data logs** screen.
4.	On the **Export data logs** screen press ***Start***. The ***Save Data Logs*** screen, showing the data logs to be exported, the amount of saves and the From-To export dates, appears. Press ***Start*** to begin the export of data to the selected destination.
5.	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:

- Export (or delete) archived data logs stored onto any drive
- Import externally archived data logs into the analyzer's archive directory from any location



Exporting an archive

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 arrows.
3.	To export the highlighted archive, select the location by pressing the ***Disk drive*** button. Touch and highlight the desired location on the **Source/Destination** screen. Press ***Expand/Collapse*** to open a folder in a directory or within a folder. When completed, the correct destination appears in the upper part of the box.
4.	Press ***Back*** to return to the **Import/Export archives** screen.
5.	On the **Import/Export archives** screen press ***Export***. 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 ***Import***.

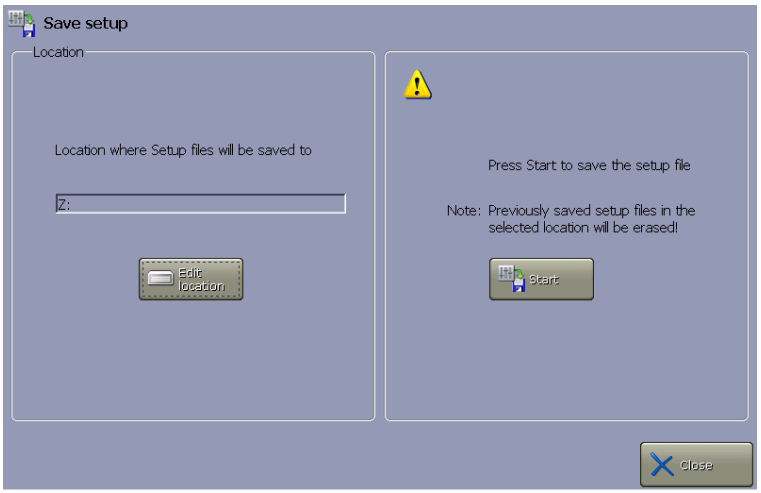
Deleting an archive

To delete an archive from a directory, highlight the desired archive and press ***Delete***.

Saving setup

Purpose

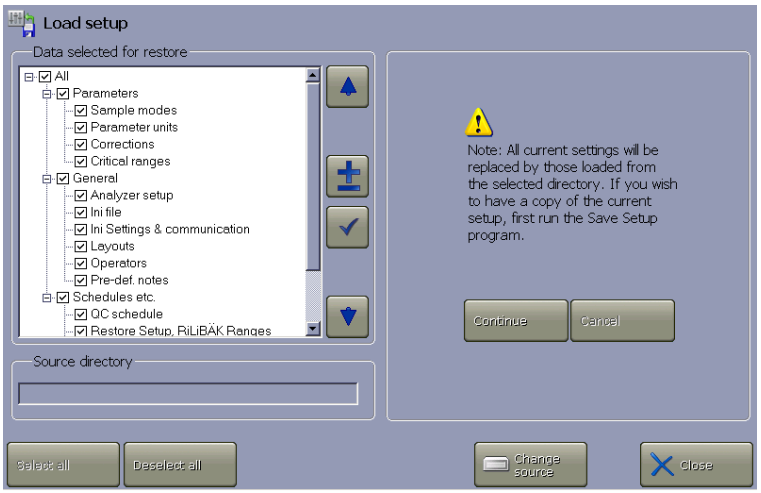
You can copy your analyzer's current setup configuration onto a CD-RW, removable drive, or network. It can be reloaded if the current setup is lost or damaged or if the same setup configuration should be loaded on other analyzers without performing all the Setup programs.



Step	Action
1.	Press ***Edit location*** to select destination.
2.	Select the required location by touching it on the screen. If a removable drive is used, connect it to the USB port Press ***Expand/Collapse*** to open a folder in a directory or within a folder. When completed, the correct destination appears in the upper part of the box.
3.	Press ***Back*** to return to the **Save setup** screen.
4.	On the **Save setup** screen press ***Start***.
5.	When saving is complete, press ***Close*** to return to the main screen.
6.	Remove the removable drive, if any.

Loading / restoring setup

Purpose You can reinstall a saved setup quickly and easily without performing the Setup programs. If desired, only part of the setup can be loaded, e.g. operators.



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, highlight the desired item, using the up/down arrows. 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. Removable disk: Connect it to the USB port.
5.	Select the required source by touching and highlighting it on the screen.
6.	Press ***Expand / Collapse*** to access the required folder. The chosen source appears in the "Choose a directory" box.
7.	Press ***Back*** to return to the **Load setup** screen.
8.	Press ***Continue***. The analyzer will shut down and then restart with reloaded setup configuration. Pressing ***Cancel*** will terminate loading the setup.

NOTICE: Contents of Setup settings – see *Setup default settings,* chapter 1 in this manual.

3. Wet section

Introduction

Definition

The wet section of the analyzer is where all samples and solutions are transported for measurement, calibration, rinse and quality control.

All solutions for the ABL90 FLEX analyzer are contained in the solution pack.

Gas tanks are not necessary with the ABL90 FLEX analyzer, as gas is included in the solution pack.

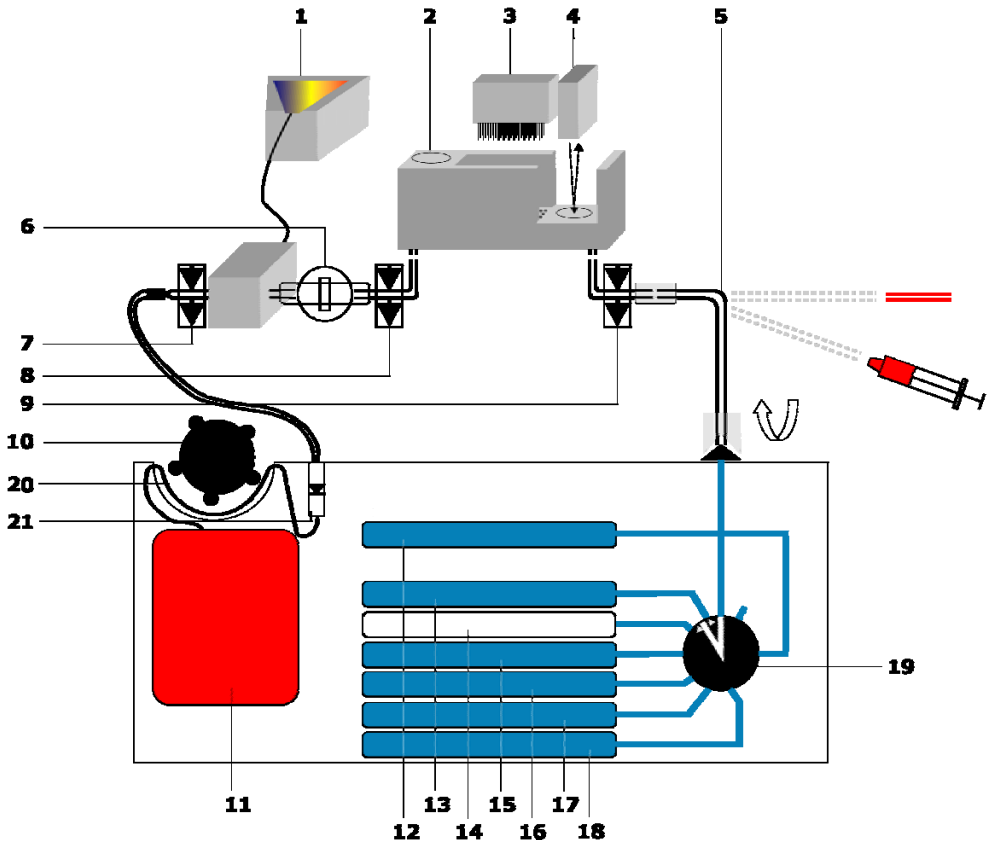
Contents of wet section

The main components of the wet section are:

- Inlet
- Sensor cassette
- Oximetry system
- Internal tubing
- Tube valve
- Peristaltic pump for solution and sample transport
- Liquid sensors
- Waste connector
- Solution pack containing three calibration solution pouches (one of them being for rinse), one gas mixture pouch, three quality control solution pouches, a flow selector, pump tubing and a waste pouch.

Wet section diagram

Diagram The following is a schematic diagram of the wet section of the ABL90 FLEX analyzer.



Item	Part
1	Oximetry module
2	Reference electrode
3	Sensor interface
4	Optical pO_2
5	Inlet
6	Valve
7	Liquid sensor 3
8	Liquid sensor 2
9	Liquid sensor 1
10	Peristaltic pump

Item	Part
11	Waste pouch
12	CAL 3 pouch
13	CAL 1 pouch/rinse
14	Gas mixture pouch
15	QC 1 solution pouch
16	CAL 2 pouch
17	QC 3 solution pouch
18	QC 2 solution pouch
19	Flow selector
20	Pump tube
21	Waste connector

Measuring processes

Introduction

The following pages describe the process that occurs within the analyzer during sample introduction, rinse, calibration and quality controls. The various types of sampling modes are discussed separately.

All processes refer to the wet section diagram earlier in this chapter.

General information

Prior to measurement

When the analyzer is in the Ready mode prior to a measurement, the sensor cassette contains CAL 1 from the solution pack.

Heating

The sensor cassette measurement chamber and the cuvette in the hemolyzer unit of the optical system is thermostatted to 37 °C to ensure correct measuring conditions.

Solutions

All necessary solutions contained in the solution pack are introduced automatically as required into the sensor cassette and oximetry module via the flow selector and inlet.

Waste removal

All waste liquids are transported to the waste pouch contained in the solution pack. This includes blood sample waste.

Patient samples

Measuring process

The following table describes the analytical process of a blood sample measurement with the ABL90 FLEX analyzer system.

Stage	Description
1.	The analyzer is ready to accept a patient sample. • "Ready" message is displayed • Traffic light is displaying a GREEN or YELLOW light • The desired parameters are available
2.	At the **Ready** screen, the user lifts the inlet handle to the syringe or capillary position. The sample (syringe or capillary tube) is pressed against the inlet gasket and the inlet probe extends into the sample, which is automatically aspirated. A 1-point calibration is performed by sampling on the CAL1 (rinse) solution.
3.	The sample is drawn into the sensor measuring chamber and the oximetry module. This process is controlled by liquid sensors that also check sample homogeneity with respect to air bubbles. A "?" appears in case of an inhomogeneous sample. In case of problems during the process or in case of insufficient sample, the measuring process is aborted, as the validity of the measuring result may be compromised.
4.	When the aspiration is finished, close the inlet.
5.	Measurement of the sample is performed as soon as the sample is positioned in the measuring chambers. The measurement takes 35 seconds. Concurrent with sample analysis, the user enters patient information as necessary.
6.	When the measurement is complete, the results are computed and then displayed on the screen and a rinse process starts. For further information on the rinse process see page 3-6.

Rinse process

After a measurement is complete a rinse is performed. The rinse process is the same, no matter what kind of measurement (patient measurement, QC and calibration) is performed. The following table describes this rinse process.

Stage	Description
1	After the measurement is complete the first part of the rinse is performed with a mixture of solutions and air.
2.	The next part of the rinse is performed with a mixture of solutions and gas.
3.	Thereafter the wet section is checked. The system is filled with gas to equilibrate the measuring chambers.
4.	The entire measuring path is filled with CAL 1 (rinse) solution. The calibration status is reestablished and the device is now ready for a new measurement.

Calibration

The calibration can be divided into four kinds of calibrations:

- pO_2 calibration
- pCO_2, *c*Glu, *c*Lac calibration
- pH, cK^+, cNa^+, cCa^{2+}, cCl^- calibration
- Oxi calibration

pO_2 calibration

pO_2 is sensitivity calibrated on ambient air and status checked on CAL1. For further information on the pO_2 calibration see *Calibration of the pO_2 sensor* in section *pO_2 sensor* in chapter 5 in this manual.

pO_2 is sensitivity calibrated once a day and status checked with every measurement.

pCO_2, *c*Glu, *c*Lac calibration

pCO_2, *c*Glu, *c*Lac are sensitivity calibrated on CAL3 and status calibrated on CAL1. For further information on the pCO_2, *c*Glu, *c*Lac calibration, see *Calibration of the pCO_2 sensor* in section *pCO_2 sensor* and *Calibration of the metabolite sensors* in section *Metabolite sensors* in chapter 5 in this manual.

pCO_2, *c*Glu, *c*Lac are sensitivity calibrated every four hour and status calibrated with every measurement.

pH, cK^+, cNa^+, cCa^{2+}, cCl^- calibration

pH, cK^+, cNa^+, cCa^{2+}, cCl^- are sensitivity calibrated on CAL2 and status calibrated on CAL1. For further information on the pH, cK^+, cNa^+, cCa^{2+}, cCl^- calibration, see *Calibration of the pH and electrolyte sensors* in section pH *and electrolyte sensors* in chapter 5 in this manual.

pH, cK^+, cNa^+, cCa^{2+}, cCl^- are sensitivity calibrated once a day and status calibrated with every measurement.

Oxi calibration

*c*tHb and *c*tBil are sensitivity calibrated on S7770 *c*tHb Calibration Solution and *c*tHb, *c*tBil and the oximetry parameters are status calibrated on a transparent solution (CAL3) from the solution pack. For further information on the oxi calibration, see *Calibration of the optical system* in section *c*tHb *and derivates* in chapter 5 in this manual.

It is recommended that *c*tHb and *c*tBil are sensitivity calibrated (cuvette factor) manually every three months by performing the tHb calibration. Also the wavelength is calibrated. For further information on the *c*tHb calibration, see section *tHb calibration* in chapter 6: *Calibration* in the ABL90 FLEX operator's manual.

*c*tHb and the oximetry parameters are status calibrated every four hours and if the temperature of the oximetry optical system changes to a temperature outside drift limits.

Automatic QC

Measuring process

The solution pack contains three levels of QC solution. The analyzer is designed to run each level once every 24 hours. However, it is possible to set up a schedule to run QC more often, if required, as described in section *QC Schedule* in chapter 1.

The QC solutions that come from pouches in the solution pack enter the sample path through the inlet as a normal blood sample. The only difference is the position of the inlet that remains in the closed position.

Stage	Description
1.	When an automatic QC is scheduled to be run, it will postpone measurements etc., unless the analyzer is busy measuring a blood sample. In this case, the scheduled QC will be run after the analyzer has completed the measurement.
2.	The QC measuring procedure begins: • For QC level B only: A measurement of high oxygen is performed on a gas from a pouch that is aspirated before the QC solution. • Measurement of the QC solution is performed as soon as it is positioned in the measuring chambers.
3.	The result is saved in the Quality Control log.
4.	The result is compared with the defined control range, measuring range and statistics range.
5.	The absence of any markings next to a parameter indicates that a parameter was measured without any fault.

Marking	Explanation
?	Error in the previous calibration, or analyzer malfunction.
W	A violated Westgard Rule.
R	A violated RiLiBÄK rule.
↑ ↓	Parameter value is outside the control range, but inside the statistics range. Only the values within the statistics range are considered accepted and are included in the QC statistics.
⇈ ⇊	Parameter value is outside the statistics range and is not included in the statistics.
⇈ ⇊	Parameter value is outside the range of indication. Measurement is not included in the statistics.
*	Parameter values with user-defined corrections – see section *Parameters and input setup,* chapter 1 for details
.....	Parameter value could not be calculated, most likely due to a system error or malfunction. These values will for the most part be accompanied by a "?". To obtain a possible explanation, press ***Message***.

6.	After the measurement is complete, it is followed by a rinse. For further information on the rinse process see page 3-6.

Manual QC samples

Measuring process

The following table describes the analytical process of a manual QC measurement using the manual QC option.

Stage	Description
1.	The analyzer is ready to accept a QC sample. • "Ready" message is displayed • Traffic light is GREEN or YELLOW. The desired parameters are available
2.	At the **Ready** screen, the user lifts the inlet handle to the syringe position. Press ***Ampoule – QC***.
3.	The adapter is pressed against the inlet gasket and the inlet probe extends into the sample, which is automatically aspirated. **NOTE:** It is mandatory to use the adapter to minimize the risk of possible glass pieces from the ampoule getting into the system of the analyzer.
4.	When the aspiration is finished, close the inlet. The screen is now ready to accept QC information.
5.	After the measurement is complete, it is followed by a rinse. For further information on the rinse process see page 3-6.

4. Electronics

General information

General information

The electronics of the ABL90 FLEX analyzer can be subdivided into the following modules:

- The user interface module which consists of a touch screen, a built-in barcode scanner and an embedded computer module
- An integrated thermal printer
- Electronics for control of the wet section pump, valve, sensor cassette, solution pack and flow selector
- Interface to electronic chip for solution pack identification
- Power supply unit
- Inlet positioning
- Sample mixer

Communication

Communication between an external data management computer and the analyzer may be achieved via a serial RS232 interface or Ethernet connection via the RJ45 interface port.

Electronic boards and components

Power supply

Universal power supply with input from 100-240 VAC, 50-60 Hz.

It includes three internal DC output levels, +5 VDC, +12 VDC, and +24 VDC, distributed to different parts of analyzer electronics.

Power supply is prepared for battery option.

Sensor Module

The Sensor module includes the Wet Section Control, Sensor Interface, Oximetry System, Selector Detector and Cassette/Instrument ID.

Wet Section Control:

The Wet Section Control PCB handles the measurement system and takes care of data collection and actuator controls.

It includes a microcontroller circuit, motor drivers, oximetry circuit and barometer.

It interfaces to User Interface Module, Sensor Interface PCB, Oximetry System (spectrophotometer and hemolyzer) and other peripheral sensor module PCB´s.

Sensor Interface:

The Sensor interface PCB handles data collection from electro-chemical and optical sensors.

It includes high-impedance amplifiers and integrated analog-to-digital converters to acquire sensor signals and transmit those data to Wet Section Control.

Selector Detector:

The Selector Detector PCB handles the position detection of the selector function in the liquid cassette.

It communicates with the Wet Section Control through an I2C interface.

Cassette / Instrument ID:

The Cassette/Instrument ID PCB handles data collection for the instrument- and liquid cassette.

It includes a unique instrument ID and a connector to collect data from the liquid cassette ID chip.

Oximetry System:

The oximetry system consists of a hemolyzer with cuvette and a 138-wavelength spectrophotometer with a measuring range of 467-672 nm. The spectrophotometer is connected via an optical fiber to a combined hemolyzer and measuring chamber.

Inlet positioning

The Inlet Position with guide plate handles the detection of inlet positions and signaling LED´s.

It includes Hall detectors and an input/output port that communicates with the Wet Section Control through an I2C interface.

User Interface Module

The User Interface Module includes the CPU Unit, display unit and barcode reader.

CPU Unit:

The CPU Unit runs the operating system and application software.

It includes a compact ETX-PC module mounted on a baseboard that interfaces signals to internal and external connectors.

It also includes a speaker, a fan and a solid-state disk (CF), in which all operating system and software files are stored, along with system database files.

Display Unit:

The display unit handles the Man Machine Interface.

It includes a 8,4" TFT display, resistive touch panel, and an Interface PCB for LVDS signal, backlight and touch control.

Barcode Reader:

The barcode reader acts as input device for consumables, user and patient barcodes.

It includes a laser scan engine, a proximity sensor, a buzzer, and a serial interface.

Printer unit

The 4" printer unit handles printouts of instrument and patient results.

The printer unit includes a 4" clamp shelf printer mechanism, a DC-DC converter and a printer controller with USB interface.

Sample mixer (for *safe*PICO only)

The sample mixer detects and mixes blood samples in *safe*PICO.

It includes a mixing motor, detectors and a micro-controller that communicates with the Wet Section Control through an I2C interface.

5. Sensors and measuring technologies

Overview

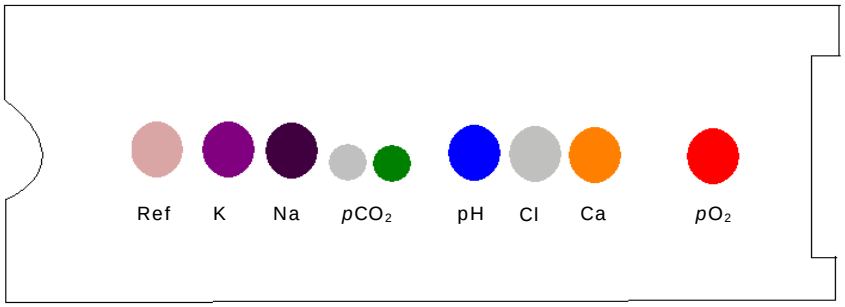
General construction

Sensors

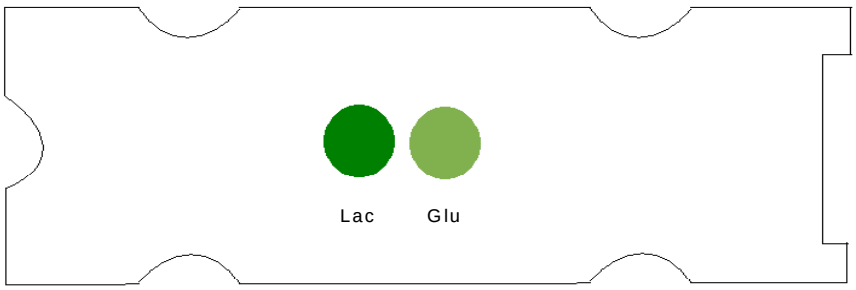
In this manual, the term sensor refers to an individual sensor as part of the sensing array within a sensor cassette. The electrical signal from each sensor is measured by proprietary analog electronics contained within the analyzer unit.

The sensors are located on sensor boards in the sensor cassette.

Top sensor board:



Bottom sensor board:



General measuring principles

Introduction

There are four different measuring principles employed in the sensors in the ABL90 FLEX analyzer.

- **Potentiometry:** The potential of a sensor chain is recorded using a voltmeter, and related to the concentration of the sample (the Nernst equation). The potentiometric measuring principle is applied in the pH, pCO_2, K^+, Na^+, Ca^{2+} and Cl^- sensors.
- **Amperometry:** The magnitude of an electrical current flowing through a sensor chain is proportional to the concentration of the substance being oxidized or reduced at an electrode in the chain. The Amperometric measuring principle is applied in the *c*Glu and *c*Lac sensors.
- **Optical pO_2:** The optical system for pO_2 is based on the ability of O_2 to reduce the intensity and time constant of the phosphorescence from a phosphorescent dye that is in contact with the sample. This measuring principle is applied in the pO_2 sensor.
- **Spectrophotometry:** Light passes through a cuvette containing a hemolyzed blood sample. The specific wavelengths absorbed and their intensity generates an absorption spectrum used to calculate oximetry parameters. This measuring principle is used for measuring *c*tHb, sO_2, FO_2Hb, *F*COHb, *F*HHb, *F*MetHb, *F*HbF and *c*tBil.

The first three measuring principles are described under the sensors, where they are applied. Spectrophotometry is described in the section titled *c*tHb *and derivates*.

Activity vs. concentration

Strictly speaking, in potentiometry the potential of a sensor chain is related to the activity of a substance, and not its concentration.

The activity of a substance can be considered the "effective concentration" of a species, taking non-ideality of the medium into account.

Activity and concentration are related by the following equation:

$a_x = \gamma\, c_x$

where:

a_x = the activity of the species x

γ = the activity coefficient of species x under the measurement conditions (for ideal systems $\gamma = 1$)

c_x = the concentration of species x (mol/L)

NOTICE: To be exact, activity is related to the molality of species x, i.e. the number of mol/kg of solvent. However molality is converted to concentration (molarity).

Conversion of activity to concentration

The analyzer automatically converts activities into concentrations. The term concentration is therefore used in explanations of the measuring principles for each of the sensors further on in this chapter.

Calibration

General information

Definition

Calibration is the process that relates the electrode signals during the calibration sequence to the values of the calibrating solutions and air. Calibration enables the electrode signals to be converted to the accurate values for an unknown sample.

Frequency

Calibration must be performed at regular intervals so that normal variations in sensor output can be compensated for after inevitable minor changes in the sensor's behavior.

Calibration solutions

Calibration of all sensors is performed using air, CAL 1 (also used for rinse), CAL 2 and CAL 3 (see chapter 9, *Solutions* for more information on the solutions).

The calibration solutions contain known concentrations of the substrates to be measured. These concentrations are vital in determining the measurement accuracy of the analyzer.

The concentration of each substance in the calibration solutions is programmed into the integrated smart chip of the solution pack. The information is automatically read by the analyzer when a solution pack is installed in the analyzer.

Traceability of calibration solutions

The traceability certificate for the solution pack is found in chapter 9 of this manual.

The calibration equation

Definition

The calibration equation expresses the relationship between the electrical measurement at a sensor and the concentration of the substrate specific to the sensor.

Use

The calibration line forms the basis of the scale used by the analyzer to convert electrical measurements to concentrations.

Deriving the calibration line

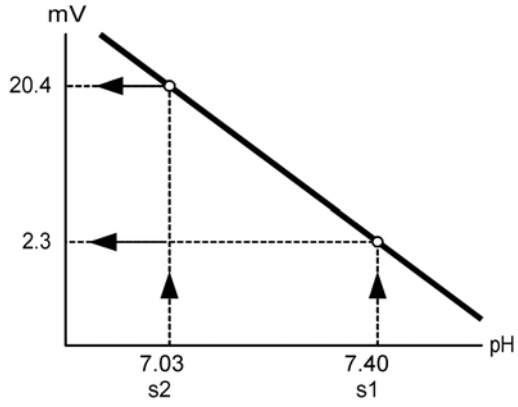
Each sensor has a unique calibration equation.

In the following example of a potentiometric sensor, the pH sensor is used to illustrate how this equation is derived from two solutions of known pH. The pH value as graphed is a linear scale. All other electrolyte values, if graphed, would be expressed as $\log_{10}(a_{ion})$.

- Solution 1 (s1) has a pH of **7.40**, which gives a potential reading of **2.3 mV**.
- Solution 2 (s2) has a pH of **7.03**, which gives a potential reading of **20.4 mV**.

These two values are plotted on a graph.

The relationship between potential and pH is linear so a line can be drawn between the two points, as shown in the diagram below:



Scale

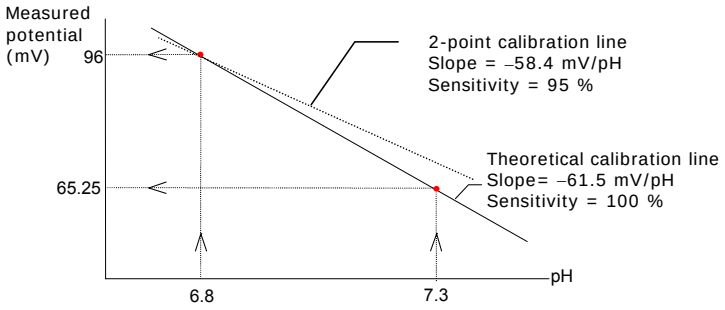
The calibration line now forms the scale used to convert the potential measured at the pH sensor during sample analysis to an actual pH value.

Sensitivity

Definition

The electrode sensitivity illustrates the slope of the calibration line compared to the slope of the theoretical electrode.

The sensitivity of the theoretical electrode is 100 % or 1.00.



If an electrode has a sensitivity of 95 % or 0.95, its sensitivity is 5 % lower than the sensitivity of the theoretical electrode.

The sensitivity of an electrode is calculated as:

$$\text{Sensitivity} = \frac{\text{Potential at } 6.8 - \text{Potential at } 7.3}{61.5 \times (7.3 - 6.8)} \quad (\%)$$

where 61.5 = sensitivity of theoretical electrode.

Each electrode has its own sensitivity limits.

The sensitivities are range checked:

	pH	pCO_2	pO_2	cK^+	cNa^+	cCa^{2+}	cCl^-	cGlu	cLac
	%	%	%	%	%	%	%	pA/mmol/L	pA/mmol/L
Min.	85	60	85	85	85	85	75	100	100
Max.	105	105	110	105	105	105	105	2000	2000

Updating

The calibration line slope is re-established with every calibration.

Sensitivity

The slope of the calibration line is described by the sensitivity value.

Status

The calibration status values are, in general, defined as the sensor signals of CAL 1, except for pO_2, which is only calibrated in one point (pO_2 status reflects the cal check):

	pH	pCO_2	pO_2	cK^+	cNa^+	cCa^{2+}	cCl^-	cGlu	cLac
	mV	mV	mmHg	mV	mV	mV	mV	pA	pA
Min.	-50	-50	-20	150	150	200	-50	0	0
Max.	250	250	20	350	350	400	100	3000	3000

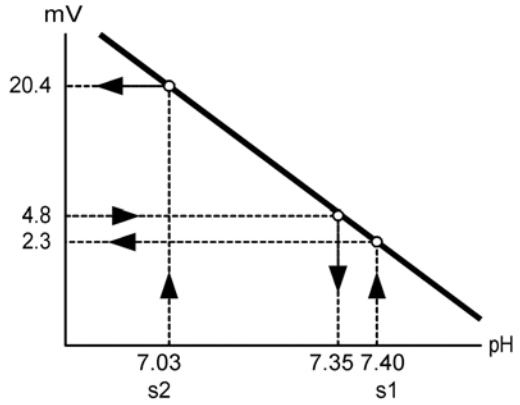
Drift

Drift describes the variation in location of the calibration line between consecutive calibrations. Typically, sensitivity drift is insignificant compared to status drift. The analyzer automatically compensates for this drift by performing a 1-point calibration with every measurement.

Measurement

Sample measurements

A blood sample gives a potential reading of 4.8 mV at the pH sensor. Reading off from the calibration line shown below, this potential corresponds to a pH of 7.35.



Corrections

To compensate for deviations from ideal behavior (ex. dilution of sample with residual rinse solution, and change in gas level by contact with the sample path), a correction is applied, to give the final value.

The correction is typically a linear correction, and is described for each sensor type in the following.

Quality Management

Introduction

This section describes the functionalities that the analyzer, apart from the built-in quality checks, applies to ensure the measurement quality.

System / analysis checks

System checks:

System checks are performed regularly and automatically consist of the following checks:

- Communication checks
  (to check the communication between the PC and embedded systems. Are performed after analyzer startup.)
- Software checks
  (to check the correct Data Management system (DMS) against the correct wet section software. Are performed after analyzer startup.)
- Mechanical checks
  (to check the calibration and the positioning of the flow selector and the solution pump volume and to check for leakages. Solution pump volume and leakage checks are performed once a day. Flow selector calibration checks are performed with every activity)
- Electronical checks
  (to check the wet section liquid transport, leak current and liquid sensor. Are performed once a day.)
- Temperature checks
  (to check the sensor array, spectrophotometer and the temperature inside the analyzer. Are performed continuously.)
- Consumable integrity checks on time of installation
  (Sensor cassette: To check the expiration date, lifetime, conditioning time and sensitivity of all the parameters. The activities mentioned under analysis check are also checked. These checks are performed after sensor cassette installation.
  Solution pack: To check the expiration date, lifetime and number of remaining tests along with the correct solution pack positioning and sample flow integrity. These checks are performed after solution pack installation.)

Analysis checks:

Analysis checks are performed in connection with analysis – be it patient sample analysis, calibration or a QC measurement – consist of the following checks:

- Status calibrations/checks
  (to check the status of the sensors a status calibration is performed on all the sensors except on the pO_2, where is status check is performed. A detailed description of the calibrations can be found further on in this chapter under the individual sensor types.)
- Sample integrity checks
  (to check for sensor response stability, air bubbles, insufficient sample volume and sample path obstructions. Blockages can indirect be revealed during these checks.)
- Temperature checks
  (to check the sensor array, spectrophotometer and the temperature inside the analyzer. Are performed continuously and with every measurement.)
- Mechanical checks
  (to check the pressure, solution pump and flow selector and to check for leakages.)

- Electronical checks
  (to check the sensor impedance and leak current.)
- Measurement preparation checks
  (to ensure that the analyzer, after each activity, is ready for a new measurement.)
- Consumable lifetime checks
  (To check the expiration date and lifetime of the sensor cassette. To check the expiration date, lifetime and number of remaining tests of the solution pack.)

Software checks:

During the software check, the correct version software in the DMS is checked against the correct version of the wet section. In case of software consistency errors the analyzer does not allow measurements.

Communication checks:

During the communication check, the communication between the PC and embedded systems is checked. In case of errors the analyzer automatically tries to re-establish the connection.

Temperature checks:

During temperature checks, the temperatures of the sensors, spectrophotometer, cuvette and barometer (internal temperature) are checked. If a check of the continuous temperature monitoring fails the analyzer enters the User intervention required mode that is automatically left again if the temperature check is ok. After power on or replacements the analyzer waits for the temperatures to be within limits. In case of temperature drift of the Oxi spectrophotometer, an Oxi calibration is set pending and performed in connection with a measurement, if no scheduled calibration has been performed, thus compensating for the drift. The temperature is monitored and logged during aspiration of sample, QC and Cal solutions.

Sensor checks:

During sensor response checks, the signal responses of the sensors are checked. Stability errors are reported by an error message and a "?" next to the parameter results.

During calibration checks, the calibration values of the sensors are checked to ensure that the analyzer is ready for measurement. In case of calibration errors (except severe fluid transport errors) the calibration is retried. The User intervention required mode is not entered if no other severe errors are encountered.

Mechanical checks:

During flow selector checks, the calibration/positioning of the flow selector in the solution pack is checked. If the flow selector calibration fails, the activity is stopped and retried. If the second calibration fails, the User intervention required mode is entered.

During pump checks, the volume of the pump flow is checked. If the pump calibration fails, the activity is stopped and retried. If the second calibration fails, the User intervention required mode is entered.

Electronical checks:

During leak current checks, the leak current between the reference electrode and the chassis is checked to detect liquid leaks in the solution pack. If the check fails, the check is repeated. If the second check fails, the User intervention required mode is entered.

During impedance checks, the impedance between each pH, $c\mathrm{K}^{+}$, $c\mathrm{Na}^{+}$, $c\mathrm{Ca}^{2+}$, $c\mathrm{Cl}^{-}$ sensor and the reference electrode is checked. The internal impedance of

the pCO_2 sensor is also checked. If the check fails, the check is repeated. If the second check fails, the User intervention required mode is entered.

During liquid sensor checks, the inlet, sensor and oxi liquid sensors check the liquid transport in the wet section. The calibration of the liquid sensors is also checked. In case a calibration fails, a rinse is performed and the system calibration repeated. If the second calibration fails the User intervention required mode is entered. If the solution is inhomogeneous, the refill program will perform three retries before aborting. If a rinse, as part of another program, fails, a new rinse is tried and the User intervention required mode is entered if the second attempt fails. During aspiration of a sample or internal solution, the liquid sensors check the liquid transport (both the air segments and the liquid are expected to trig off the sensors within certain time limits). In case of errors the activity will be aborted.

Measurement preparation checks:

A rinse is performed after each activity. With the rinse, the temperature and homogeneity of the rinse solution is checked. In case of rinse error, a rinse will be performed. If this rinse fails too, the User intervention required mode is entered.

Sample integrity checks:

The pO_2 check is used to check for any blockage or leak in the flow path, and, furthermore, the pO_2 sensor is checked for air in front of the pO_2 sensor. In case of any air the pO_2 parameter will be marked with a ? and a corresponding error message is given. During pO_2 checks, pressure tests are performed. In case the tests fail, the activity is retried. If this activity fails, the User intervention required mode is entered.

Consumables checks:

During consumables check, the sensor cassette and the solution pack lifetime and expiration date are checked by inspecting the smart chip data of the individual consumables. In case of chip data errors the User-intervention-required mode is entered. If the consumables are used up or have expired, the User-action-needed mode is entered. The user has the possibility to perform a replacement.

Apart from the checks mentioned above a flow selector check, pressure test, refill, pump calibration and a rinse are also performed during a solution pack replacement. Furthermore, it is checked whether the Solution pack has been used before. In case of errors, the User intervention required mode is entered. The user has the possibility to perform a replacement.

During a sensor cassette replacement it is also checked whether the sensor cassette has been used before and if the minimum/maximum conditioning time has been met. Thereafter, a pressure test, liquid sensor check, pump calibration, rinse and a calibration of all the sensors are performed. In case of any errors the sensor cassette is considered to be unconditioned, and the analyzer will perform an automatic conditioning and a new calibration that prolong the startup time to 30 minutes.

By default each of the three built-in QC will be run after replacements and startup. If this function has been deactivated it is recommended to perform QCs after replacements and startup.

If the solution pack and the sensor cassette have been replaced at the same time, all the above checks will be carried out. In case of errors the User-intervention-required or the User-action-needed mode is entered. The user has the possibility to perform a replacement.

Furthermore some system checks are also performed after the replacement of the solution pack and sensor cassette.

Calibration

The following additional parameters are checked:

- Sensitivity
- Status

In case of error in a scheduled calibration, a new calibration is automatically performed.

Measurement

A 1-point calibration is automatically performed with every measurement. For pO_2, which is only calibrated in one point, a calibration check is performed. If this check fails, a new calibration is automatically performed after measurement and used to calculate the pO_2 in the measurement, or, in other words, actually, to perform a calibration/to ensure a valid calibration.

After sensor replacement, the metabolite sensors have a significant drift in the sensitivity. The analyzer automatically compensates for this by performing a calibration, when needed, after every measurement that is used to calculate the measured metabolite values.

By performing the calibration with the measurement, instead of performing frequent calibrations, sensor drifts are reduced more effectively. As calibrations, furthermore, only are performed when needed, the uptime, where the analyzer is ready for measurement, is maximized.

Reference electrode

Background information about the reference electrode

Purpose

The purpose of the reference electrode is to provide a stable, fixed potential, against which other potential differences can be measured.

The potential at the reference electrode is not altered by the sample composition.

Fixed potential

A fixed potential is maintained at the reference electrode by the following equilibrium reactions:

$$AgCl \Leftrightarrow Ag^{+} + Cl^{-}$$

$$Ag^{+} + e^{-} \Leftrightarrow Ag$$

These reactions are possible because the electrode is made of an Ag rod coated with AgCl to provide the Ag/Ag^{+} equlibrium in a solution with constant Cl^{-} concentration and to determine the reference potential.

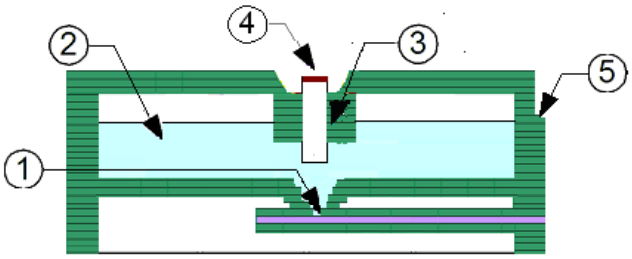
Use

The reference electrode is used in the measurement of pH and electrolyte concentrations.

Contact with the sample is made via a membrane junction between the reference electrode liquid chamber and the measuring chamber.

Construction of the reference electrode

Diagram



Parts and functions

Item	Part	Description / Function
1	Membrane	Interface to the sample.
2	Electrolyte solution	Acts as a salt-bridge solution that maintains an electrical contact between the electrode and the sample.
3	Electrode	Provides the contact between the Electrolyte solution and the electrical contact.
4	Electrical contact	The point of electrical contact between the electrode and the analyzer.
5	Housing	Sensor cassette housing with integrated reference electrode.

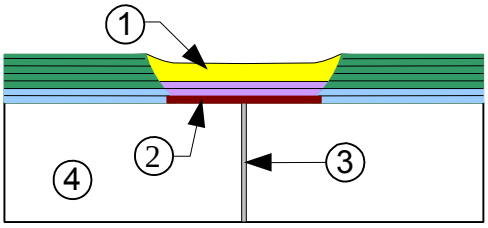
pH and electrolyte sensors

Construction of the pH and electrolyte sensors

Diagram

The pH and electrolyte sensors are of solid-state design with a H^+, K^+, Na^+ and Ca^{2+} sensitive PVC membrane. The Cl^- sensor is of solid-state design with a Cl^- sensitive epoxy membrane.

The pH sensor is used as an example:



Parts and description

Item	Part	Description
1	Membrane	Ion-selective membrane that is in direct contact with the sample or calibration solution and that is sensitive to a specific ion, e.g. the H^+ ions.
2	Solid-state contact	The point of electrical and ionic contact with the membrane.
3	Electrical contact	The point of electrical contact between the sensor and the analyzer.
4	Electrode base	The structural platform on which the electrode is formed.

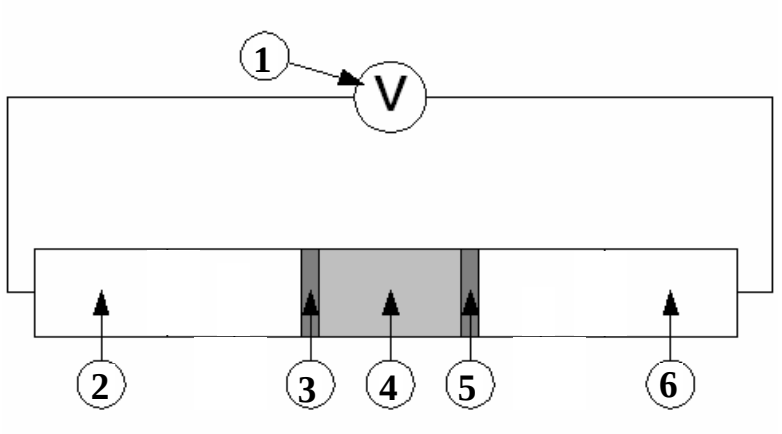
Measuring principle of the pH and electrolyte sensors

Potentiometric measuring principle

The pH and electrolyte sensors are measured according to the potentiometric measuring principle, where the potential of an electrode chain recorded at a voltmeter is related to the concentration of a substance via the Nernst equation.

Electrode chain

The electrode chain (or electrical circuit) set up to measure pH/electrolytes is illustrated in the following diagram:



Parts and description

The electrode chain describes an electrical circuit consisting of the following:

Item	Part	Function
1	Voltmeter	Measures the voltage potential in the circuit.
2	Reference electrode	Provides electrical connection to the voltmeter.
3	Liquid junction	Point of contact between the reference sensor and the sample.
4	Sample	The unknown liquid being measured.
5	Membrane	An ion-sensitive membrane, which is sensitive to H^+/electrolyte ions.
6	Solid-state contact	Provides electrical connection to the voltmeter.

Electrode chain potential

Every element in the electrode chain contributes a voltage to the total potential drop through the chain. Thus:

- When immersed in the appropriate electrolyte solution, both electrodes exhibit separate potentials
- The membrane junctions between the sample and electrolyte solutions also exhibit separate potentials

The total potential across the electrode chain, therefore, is the sum of these separate potentials, all but one of which are known and constant, as outlined in the table on next page.

Element	Potential	Symbol
Reference electrode	Known and constant when the Ag/AgCl is immersed in the electrolyte solution.	E_{ref}
Liquid junction between the electrolyte solution in the reference electrode and the sample	Known and constant. Independent of sample composition.	E_{LJ}
Ion-sensitive membrane separating the sample and the pH sensor	Unknown. Dependent on sample composition.	E_{Sample}
Solid-state contact	Known and constant.	E_E
Total potential	Measured by the voltmeter.	E_{tot}

Unknown potential

The unknown potential difference across the ion-sensitive PVC membrane is the difference between the measured total potential and the sum of the known potentials:

$$E_{sample} = E_{total} - (E_{ref} + E_{LJ} + E_E)$$

Ion-sensitive membrane

The potential difference across the membrane arises as a consequence of a change in the charge balance at the membrane.

The membrane is sensitive to H^+/electrolyte ions in that it has an ion exchange ability. Since the internal solid-state reference electrode fixes the internal potential, changes in the external charging of the membrane produce measurable changes in the overall potential.

Nernst equation

Having measured the unknown potential (E_{sample}), the potential difference across the membrane in the sensor can be expressed by the Nernst equation:

$$E_{sample} = E_0 + \frac{RT}{nF} \times \ln a_x$$

where:

E_0 = Standard electrode potential
R = Gas constant (8.3143 J/°K-mole)
T = Absolute temperature (°K)
n = Charge on the ion
F = Faraday constant (96487 C/mole)
a_x = Activity of the species x

Activity and concentration

As shown in the equation above, measuring the potential of each of the electrode chains gives a reading of the activity of the ions in the sample.

Activity expresses the "effective concentration" of a species and is explained in more detail in the section *General measuring principles* earlier in this section.

The activity of the ions is automatically converted to a concentration value by the analyzer.

The relationship between activity and concentration is explained in the section *General measuring principles* at the beginning of this chapter.

Calibration of the pH and electrolyte sensors

Introduction

The pH and electrolyte sensors are calibrated by determining the E_0 and sensitivity from 2-point calibrations. Slight variations in sensor performance between calibrations are addressed by performing a measurement of CAL 1 within every sample measurement process.

2-point calibration

A 2-point calibration is performed at preset intervals using two solutions from the solution pack. The precise values for these solutions are contained in the smart chip located on the solution pack.

Calibration levels

The pH and electrolyte values for CAL 1 and CAL 2 are as follows (approximate values):

		Level	
Substance	**Unit**	**CAL 1**	**CAL 2**
pH	-	7.3	6.8
$c\mathrm{Na}^+$	mmol/L	150	70
$c\mathrm{K}^+$	mmol/L	4	10
$c\mathrm{Cl}^-$	mmol/L	95	50
$c\mathrm{Ca}^{2+}$	mmol/L	0.5	2.3

The solution pH and electrolyte values are known and contained in the solution pack smart chip.

Calibration

The sensitivity is calculated in the following way and expressed as the percentage of the theoretical sensitivity, calculated from the sensor signal of the two calibration solutions (mV) and the nominal calibration values:

pH:

$$S = \frac{mV_{cal2} - mV_{cal1}}{-61,5mV \cdot (pH_{cal2} - pH_{cal1})}$$

Electrolyte sensors:

$$S = \frac{n(mV_{cal2} - mV_{cal1})}{61,5mV \cdot \log_{10}(\frac{c_{cal2}}{c_{cal1}})}$$

where n is the ionic charge.

Status is defined as the sensor signal of CAL 1 (rinse): mV1.

Measurement – pH and electrolytes

Measurement

The pH value measured from the sample is calculated as follows, from the sensor signal of the sample mV_{sample}:

$$pH = pH_{cal1} + \frac{mV_{sample} - mV_{cal1}}{-61,5mV \cdot S}$$

The electrolyte concentration in a sample is calculated from the following equations:

$$c = c_{cal1} \cdot 10^{\frac{n(E_{sample} - E_{cal1})}{61,5mV \times S}}$$

where n is the ionic charge.

The measured value is applied a linear correction:

$$c_{displayed} = k_1 \cdot c + k_2$$

NOTICE: *c*Cl^- is compensated for *c*HCO_3^- interference by using the measured pH and *p*CO_2, before the linear correction is applied.

Checks

The following parameters are range checked:

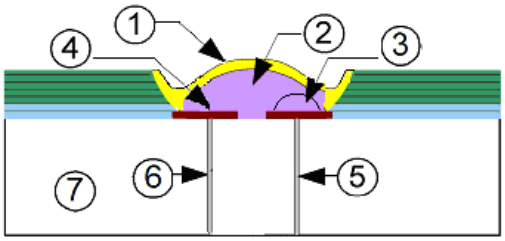
- Sensitivity
- Sensitivity drift
- Status
- Sensor response stability

The sensor response stability is defined as the standard deviation of the last 5 updatings of the response.

pCO_2 sensor

Construction of the pCO_2 sensor

Diagram

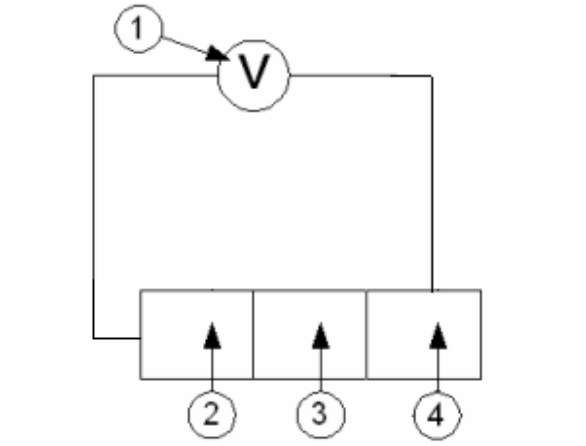


Parts and description

Item	Part	Description
1	Silicone membrane	A membrane separating the sample and the electrolyte solution. Is only permeable to CO_2.
2	Electrolyte solution	A solution separating the silicone membrane and the pH membrane, Ag/AgCl sensors. The electrolyte solution is vented by CO_2 whereby pH is changed.
3	pH membrane	H^+ sensitive membrane.
4	Reference	Ag/AgCl electrode
5	Solid-state contact for the pH system	The point of electrical contact between the pH membrane and the analyzer.
6	Solid-state contact for the Ag/AgCl system	The point of electrical contact between the reference electrode and the analyzer.
7	Electrode base	The structural platform on which the electrode is formed.

Measuring principle of the *p*CO_2 sensor

Electrode chain The electrode chain (or electrical circuit) set up to measure *p*CO_2 is illustrated in the following diagram:



Parts and description The electrode chain describes an electrical circuit consisting of the following:

Item	Part	Description
1	Voltmeter	Measures the voltage potential in the circuit.
2	pH electrode	Provides electrical connection to the voltmeter
3	Electrolyte solution	Medium for connection
4	Internal reference electrode (Ag/AgCl)	Provides electrical connection to the voltmeter

Electrode chain potential The potential differences at all the junctions in the electrode chain are known and constant, except that at the pH-sensitive membrane. (See the section *pH and electrolyte sensors* for a full explanation.)

The potential difference at the pH-sensitive membrane depends on the pH of the electrolyte solution, which in turn depends on the CO_2 content of the sample. This is explained in the measuring process below.

Measuring process

The following is an account of the measuring process in the pCO_2 sensor.

Part	Function
Transport of CO_2	CO_2 from the sample permeates the membrane.
Dissolution of CO_2	The CO_2 dissolves in the electrolyte solution. This produces carbonic acid: $H_2O + CO_2 \Leftrightarrow H_2CO_3$
Dissociation of carbonic acid	Carbonic acid dissociates according to the following equilibrium reaction: $H_2CO_3 \Leftrightarrow H^+ + HCO_3^-$
pH change	The release of H^+ ions changes the H^+ concentration, and thus the pH of the inner buffer solution on one side of the pH-sensitive membrane.
Measurement of potential	The concentration gradient of H^+ ions across the membrane creates a potential difference across the membrane. This change in potential across the membrane is measured by the voltmeter.
Relation of pH to pCO_2	The pH value is related to the partial pressure of CO_2 in the sample by the following equation: $pH = pK_a + \log \frac{[HCO_3^-]}{\alpha * pCO_2}$ where: $pK_a = -\log K_a$, the equilibrium constant for the dissociation of carbonic acid in water α = solubility coefficient for CO_2 in water The structure of the pCO_2 sensor is similar to the pH sensor, including the presence of a pH-sensitive membrane. The major difference is in the internal electrolyte solution present in the pCO_2 sensor which allows the dissolution and ultimate dissociation of carbonic acid mentioned above. If $[cHCO_3^-]$ and α in the electrolyte solution is constant this results in the following: $pH = K - \log pCO_2$ Where K contains the equilibrium constant pK_a, the solubility coefficient α and the concentration of bicarbonate $[cHCO_3^-]$. $E = E'_0 - 61.5 \times pH = E_0 + 61.5 \times \log pCO_2$

Calibration of the *p*CO_2 sensor

Introduction

The *p*CO_2 sensor is calibrated by determining the sensitivity from 2-point calibrations. Calibration measurements are performed on two levels of solution. Slight variations in sensor performance between calibrations are addressed by performing a measurement on CAL 1 within every sample measurement process.

Calibration levels

The ABL90 FLEX analyzer is equipped with a solution pack. This pack contains precision-tonometered fluids. The tonometry calibration gas mixture is of a known composition.

The partial pressure of CO_2 (*p*CO_2) and the solution pH values are known and contained in the solution pack smart chip.

Sensitivity

The sensitivity is calculated in the following way and expressed as the percentage of the theoretical sensitivity, calculated from the sensor signal of the two calibration solutions (mV) and the nominal calibration values:

$$S = \frac{mV_{cal2} - mV_{cal1}}{61,5mV \cdot \log_{10}\left(\frac{pCO_2(cal2)}{pCO_2(cal1)}\right)}$$

Status is defined as the sensor signal of CAL 1 (rinse): mV_1.

Measurement – pCO_2

Measurement

The pCO_2 value measured from the sample is calculated as follows, from the sensor signal of the sample mV_{sample}:

$$pCO_2 = pCO_2(cal1) \cdot 10^{\frac{E_{sample} - E_{cal1}}{61{,}5mV \cdot S}}$$

The measured value is applied a linear correction:

$$c_{displayed} = k_1 \cdot c + k_2$$

Checks

The following parameters are range checked:

- Sensitivity
- sensitivity drift
- status
- sensor response stability

The sensor response stability is defined as the standard deviation of the last 5 updatings of the response.

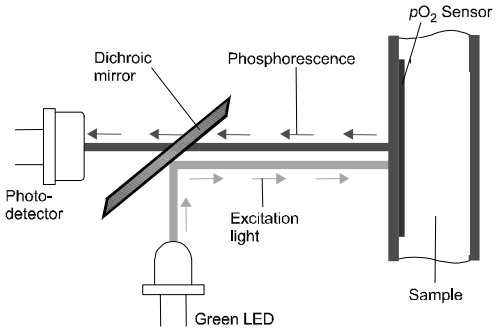
pO_2 sensor

Measuring principle of the pO_2 sensor

Optical system for pO_2

The optical system for pO_2 is based on the ability of O_2 to reduce the intensity and time constant of the phosphorescence from a phosphorescent dye that is in contact with the sample.

The optical system for measuring pO_2 is shown in the following diagram:



Measuring sequence

The green LED emits light, which is reflected by a dichroic mirror onto the pO_2 sensor. Due to the phosphorescence, red light is emitted back through the dichroic mirror and onto a photo detector. The photo detector sends the electrical signals, proportional to the light intensity, to the analog/digital converter and the data processing unit. The calculation of the pO_2 is performed.

Calculations

The pO_2 is calculated on the basis of the Stern-Volmer equation, which describes the relationship between the phosphorescence intensity/time constant (τ) and the pO_2 value in a sample:

$$pO_2(\tau) = k \cdot \left(\frac{\tau_0}{\tau} - 1 \right)$$

where k and τ_0 are constants.

Calibration of the pO_2 sensor

Introduction

The pO_2 sensor is calibrated to determine its sensitivity by measuring one calibration point during a sensitivity calibration process. Performance of the sensor from calibration to calibration is checked and during sample or quality control analysis any drift on sensitivity is checked. The pO_2 sensor is calibrated on ambient air.

Sensitivity

The sensitivity is defined as the percentage of the measured pO_2 on ambient air compared to the reference value:

$$S = \frac{pO_2(\text{meas})}{pO_2(\text{ref})}$$

where pO_2(ref) is the pO_2 tension in ambient air saturated with water vapor:

$$pO_2(\text{ref}) = FO_2 \cdot (p(\text{amb}) - pH_2O)$$

where FO_2 is the pO_2 fraction in ambient air, and pH_2O is the partial water vapor pressure of saturated air at 37 °C, and p(amb) is the barometric pressure.

Status

In connection with the sensitivity calibration performed on ambient air, also the CAL1 (rinse) solution is measured to obtain a status. This status aims to check the performed calibration. This is done by comparing the measured value of the CAL1 (rinse) solution to the reference value of CAL1, given by the smart chip):

$$pO_2(\text{status,cal}) = pO_2(\text{CAL1,cal}) - pO_2(\text{CAL1,ref})$$

For every measurement, the pO_2 calibration is checked by comparing the measured value of CAL1 (rinse) solution to the value obtained on the CAL1 solution of the last calibration ($CAL1_{CAL}$):

$$pO_2(\text{status,meas}) = pO_2(\text{CAL1,meas}) - pO_2(\text{CAL1,cal})$$

Measurement - pO_2

On whole blood, pO_2 is adjusted with the sensitivity value and the measured pO_2 is therefore determined as follows:

$$pO_2(\text{sens,adjusted}) = \frac{pO_2(\text{meas})}{S}$$

The measured value is applied a 2nd order blood correction, to compensate for the varying buffer value of blood, as a function of pO_2 tension. A second-order correction is applied:

$$pO_2(\text{display}) = k_1 pO_2^2 + k_2 pO_2 + k_3$$

NOTICE: During a measurement, the sensor technology used offers detection of any air bubble in front of the pO_2 sensor that could lead to significant errors.

Checks

The following parameters are range checked:

- Sensitivity
- Sensitivity drift
- Status

Metabolite sensors

Construction of the metabolite sensors

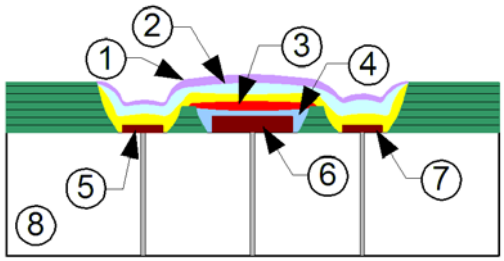
Basic description

The *c*Glu and *c*Lac sensors are three-electrode sensors consisting of an internal silver/silver chloride reference electrode, a platinum auxiliary electrode, and a platinum anode. The sensors are covered by a multi-layer membrane bound to the sensor board.

The membrane consists of four layers:

- The biocompatible layer
- The outer membrane – permeable to *c*Glu/*c*Lac
- The enzyme layer
- The inner membrane – permeable to H_2O_2

Diagram



Parts and description

Item	Part	Description
1	Biocompatible layer	Biocompatible layer
2	Outer membrane	Outer membrane permeable to glucose – diffusion control
3	Enzyme layer	Contains glucose/lactate oxidase.
4	Inner membrane	Cellulose acetate.
5	Reference	Ag/AgCl electrode.
6	Anode	Platinum electrode.
7	Cathode	Platinum electrode.
8	Electrode base	The structural platform on which the sensor is formed.

Zero current

The zero current is a small background current measured at the electrode when no *c*Glu/*c*Lac is present in a solution. As CAL 1 contains no *c*Glu/*c*Lac, a baseline representing the zero current, I_0 as a function of time ($I_0 = f(t)$), is obtained from continuous measurements on CAL 1.

This I_0 baseline is obtained as follows:

- At the end of a rinse, with CAL 1 in the measuring chamber, the zero current of the metabolite electrodes is measured periodically
- The previous N (N = 8) measurements on the CAL 1 – before a calibration or a sample measurement starts – are used to obtain a baseline representing the time function of I_0

- The baseline is extrapolated throughout the whole electrode calibration or sample measurement period, and represents the zero current time function
- The I_0 baseline is used in the determination of the sensitivity of the *c*Glu/*c*Lac sensor

Calibration of the metabolite sensors

Sensitivity

The sensitivity of the *c*Glu and *c*Lac sensors is calculated by measuring the current from CAL 3 then subtracting the zero current as measured from CAL 1. CAL 3 has a nominal glucose concentration of 10 mmol/L and a nominal lactate concentration of 10 mmol/L. The precise values are specific to the individual lot of the solution pack and are contained in the solution pack smart chip.

The current at the *c*Glu and *c*Lac sensors with CAL 3 in the measuring chamber is measured at regular intervals after the chamber is filled with solution. The current, when signal stability is reached, is used to determine the sensitivity of the cGlu or *c*Lac sensor.

The sensitivity of the *c*Glu or *c*Lac sensor is calculated as follows:

$$S = \frac{I_{cal3} - I_0}{c_{cal}}$$

where I_0 is the zero current estimated to the time of measurement from the 8 samples taken on CAL 1 (rinse).

Status is defined as I_0.

Measurement – metabolites

Measurement

The glucose or lactate concentration in a sample is calculated from the following equation, using the difference between the current in the sample and the extrapolated zero current from the rinse solution:

$$c = \frac{I_{sample} - I_0}{S}$$

The measured value is applied a linear correction:

$$c_{displayed} = k_1 \cdot c + k_2$$

NOTICE: *c*Lac is compensated for the dependence of the ionic composition by using the measured electrolyte values before the linear correction is applied. If the electrolytes are not measured, default values are used.

Checks

The following parameters are range checked:

- Sensitivity
- Sensitivity drift
- Sensor response stability

The sensor response stability is defined as the standard deviation of the last 5 updatings of the response for CAL 1 (rinse).

For CAL 3, it is defined as the standard deviation of a linear regression for the last 5 samples, normalized with the signal magnitude.

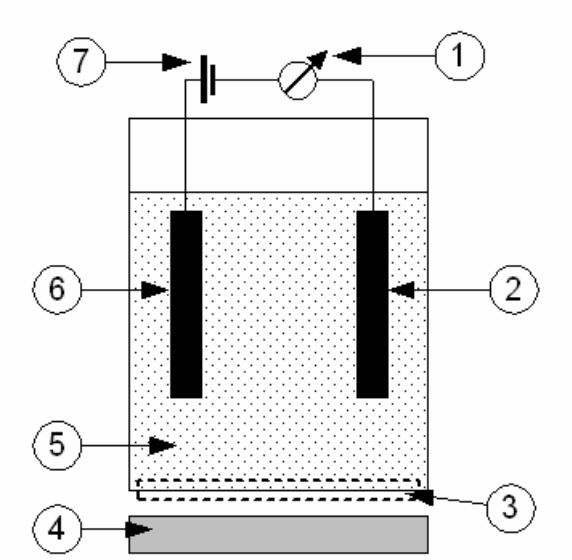
Measuring principle of the metabolite sensors

Amperometric measuring principle

The *c*Glu and *c*Lac sensors are measured according to the amperometric measuring principle, in which the magnitude of an electrical current flowing through an electrode chain is related to the concentration of a substance being oxidized or reduced at an electrode in the chain.

Electrode chain

The electrode chain set up to measure glucose/lactate is illustrated in the following diagram[1]:



Parts and functions

The electrode chain describes the electrical circuit consisting of the following:

Item	Part	Description
1	Amperemeter	Measures the current flowing through the circuit in nanoamperes.
2	Cathode	Negative electrode where a reduction reaction occurs and electrons are consumed.
3	Membrane	Allows the appropriate molecules to pass through from the sample.
4	Sample	Contacts the membrane.
5	Electrolyte	Provides electrical contact between the anode and cathode.
6	Anode	Positive electrode where an oxidation reaction occurs and electrons are released.
7	Applied voltage	Applies the necessary potential for the reduction or oxidation reaction under study.

[1] Note that polarization voltage is applied between the anode and the reference electrode (not shown). The current runs through the anode and cathode chain.

Measuring process

A constant polarization voltage is applied to the electrode chain. The current through this chain is measured by an amperemeter.

Glucose or lactate molecules, in solution, are transported across the outer layer of a multilayer membrane system. The enzymes glucose oxidase or lactate oxidase, immobilized between the outer and inner layers, converts glucose/lactate according to the following reactions:

Glucose: $\text{Glucose} + H_2O + O_2 \rightarrow \text{Gluconic Acid} + H_2O_2$

Lactate: $\text{Lactate} + H_2O + O_2 \rightarrow \text{pyruvate} + H_2O_2$

The oxygen for this reaction is supplied by the membrane system as well as by the oxidation of H_2O_2 at the platinum anode.

The H_2O_2 produced by the enzyme reaction is transported across the inner membrane to the platinum anode.

When a potential is applied to the electrode chain, the oxidation of H_2O_2 produces an electrical current proportional to the amount of H_2O_2, which in turn is directly related to the amount of glucose/lactate.

$H_2O_2 \rightarrow 2H^+ + O_2 + 2e^-$

At the counter electrode a reduction process, consuming electrons will occur:

1) $H_2O_2 + 2e^- \rightarrow 2OH^-$

   (This process consumes excess H_2O_2 not consumed in the reaction above.)

2) $½O_2 + H_2O + 2e^- \rightarrow 2OH^-$

   (This process consumes excess O_2 not consumed in the reaction above.)

3) $2H_2O + 2e^- \rightarrow H_2 + 2OH^-$

   (This process can also occur at the cathode.)

Any of these three reactions at the cathode will serve to neutralize the protons generated in the second reaction, so the total change in acidity is caused by the gluconic acid/pyruvate only.

*c*tHb and derivates

General information

Measured parameters

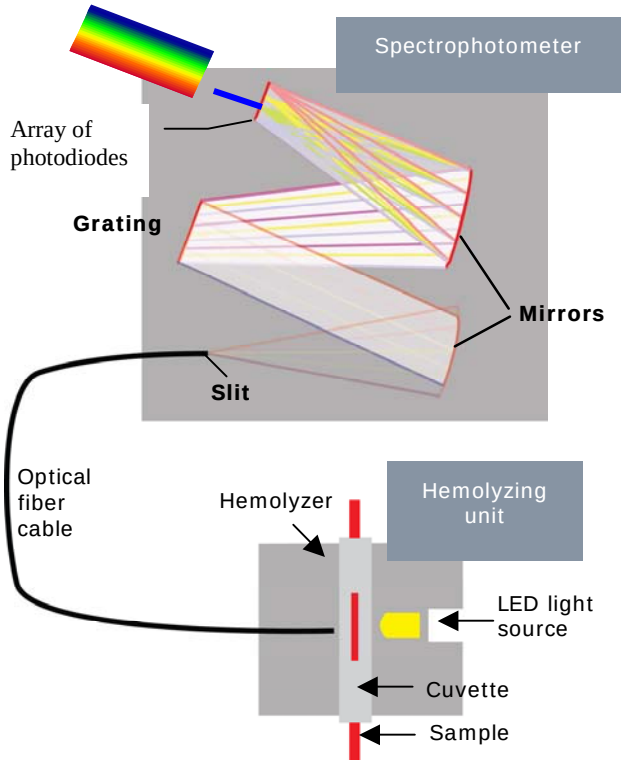
The optical system of the ABL90 FLEX analyzer is designed to measure the following parameters:

Parameter	Description
*c*tHb	Concentration of total hemoglobin
sO_2	Oxygen saturation
FO_2Hb	Fraction of oxyhemoglobin
*F*COHb	Fraction of carboxyhemoglobin
*F*HHb	Fraction of deoxyhemoglobin
*F*MetHb	Fraction of methemoglobin
*F*HbF	Fraction of fetal hemoglobin
*c*tBil	Concentration of total bilirubin (the sum of unconjugated and conjugated bilirubin) in plasma

NOTICE: *c*tBil can be measured on a whole-blood or plasma sample. Plasma samples provide the optimal measurement performance. To obtain optimal accuracy when following a patient trend in *c*tBil, use the same sample type and the same analyzer.

Construction

The optical system is based on a 138-wavelength spectrophotometer with a measuring range of 467-672 nm. The spectrophotometer is connected via an optical fiber to a combined hemolyzer and measuring chamber.



Measurement cycle

The method used in the analyzer's optical system is visible absorption spectroscopy. The measurement cycle consists of the following steps:

Step	Description
1	The blood sample is transported to the cuvette positioned in the hemolyzer unit. The temperature of the cuvette is regulated to 37 °C.
2	A back pressure is exerted on the sample. This one atmosphere over-pressurization is maintained throughout the hemolyzation and measurement to eliminate air bubbles in the sample and to enhance the hemolyzation process.
3	The one-µL sample in the cuvette is ultrasonically hemolyzed at a frequency of about 30 kHz. This hemolyzation process ruptures the walls of the red blood cells, evenly mixing the content of the red blood cells with the plasma and producing an optically clear solution.
4	Light from a white LED is emitted to the cuvette and the light transmitted through the cuvette is guided to the spectrophotometer via an optical fiber.
5	The light passes through a slit that directs it towards an arrangement of mirrors and a grating.
6	The grating separates the light into the colors of the rainbow and the mirror focuses the light on a photodiode array.
7	The photodiode array has 256 diodes or pixels, one for each wavelength, which convert the monochromatic light signals to currents.
8	The currents and therefore the intensity of the light signals are measured at each of the 256 diodes, which form the basis for the absorption spectrum for a particular sample.
9	The spectrum is sent to the analyzer's computer, where the calculations of the oximetry parameter values are made. The 256 channels are standardized into 138 selected wavelengths.

Lambert-Beer's law

Absorption spectroscopy is based on Lambert-Beer's law, which states that the measured absorbance for a single compound is directly proportional to the concentration of the compound and the length of the light path through the sample [2]:

$$A_y^\lambda = \varepsilon_y^\lambda \times c_y \times l$$

where:

A_y^λ = absorbance of compound y at wavelength λ

ε_y^λ = extinction coefficient of compound y at wavelength λ (a constant, characteristic of the compound)

c_y = concentration of compound y in sample

l = length of the light path

Absorbance

The absorbance (A) of a compound is defined as the logarithm of the ratio of the light intensity before and after transmission through the compound.

In practice it is the logarithm of the ratio of the light intensity transmitted through water to the light intensity transmitted through the compound.

$$A = \log \frac{I_0}{I}$$

where:

I_0 = intensity of light transmitted through water (I_0 is measured as the intensity of light transmitted through CAL 3 solution)

I = intensity of light transmitted through the compound

Total absorbance

For samples containing more than one optically active compound, the total absorbance (A_{total}) is the sum of the individual compounds' absorbance, since absorbance is an additive quantity.

For example, if a sample contains six compounds y_1, y_2, ….y_6, the total absorbance measured for that sample at wavelength λ_1 is:

$$A_{\text{total}}^{\lambda_1} = A_{y_1}^{\lambda_1} + A_{y_2}^{\lambda_1} + A_{y_3}^{\lambda_1} + A_{y_4}^{\lambda_1} + A_{y_5}^{\lambda_1} + A_{y_6}^{\lambda 1}$$

$$= I\left(\varepsilon_{y_1}^{\lambda_1} c_{y_1} + \varepsilon_{y_2}^{\lambda_1} c_{y_2} + \varepsilon_{y_3}^{\lambda_1} c_{y_3} + \varepsilon_{y_4}^{\lambda_1} c_{y_4} + \varepsilon_{y_5}^{\lambda_1} c_{y_5} + \varepsilon_{y_6}^{\lambda_1} c_{y_6}\right)$$

If there are Y compounds and measurements are taken at *n* wavelengths, a general expression can be written for A_{total} at the wavelength λ_n:

$$A_{\text{total}}^{\lambda_n} = \sum_{y=1}^{Y} \varepsilon_y^{\lambda_n} \times c_y \times I$$

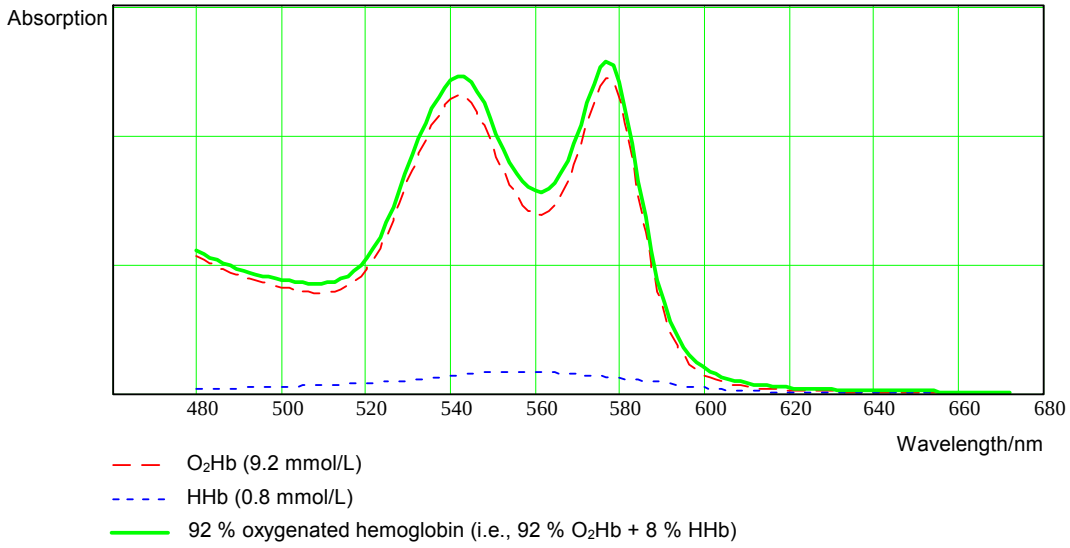
where:
λ_n = the individual wavelengths.

Continuous spectrum

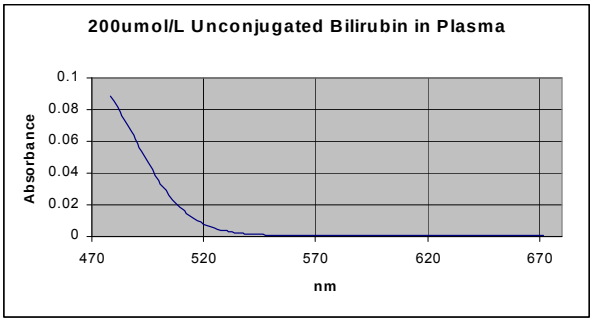
$A_{\text{total}}^{\lambda_n}$ can be depicted graphically as a function of wavelength, and if the differences between the wavelengths are small enough, a continuous spectrum is produced.

Spectrum examples

The figure below shows three spectra; pure O_2Hb, pure HHb in a low concentration, a spectrum of 92 % oxygenated hemoglobin obtained by adding the spectra of O_2Hb and HHb. The additivity of absorption and the continuity of the spectra can be seen.



Example of the spectrum obtained from unconjugated bilirubin at a concentration of 200 µmol/L.



The spectrum of conjugated bilirubin is slightly different.

Determining concentrations

In the spectrum taken of a sample, the absorption recorded at each wavelength contains contributions from each of the compounds in the sample. The task then is to determine the magnitude of that contribution and thereby the concentration of each compound in the sample.

The concentrations are determined using the following equation:

$$c_y = \sum_{n=1}^{138} K_y^{\lambda_n} A_{total}^{\lambda_n}$$

where:

$K_y^{\lambda_n}$ = a constant specific to compound y at wavelength λ_n.

Matrix of constants

The constants ($K_y^{\lambda_n}$) are determined using Multivariate Data Analysis [2] where the spectra of the calibration compounds are considered together with the reference values of the calibration compounds. The essential interfering substances (intralipids and sulfhemoglobin) were also taken into account.

Calibration of the optical system

Calibration materials

The optical system is calibrated at two points using the following:

- The S7770 ctHb Calibration Solution with a known dye concentration to determine the cuvette path length, *l*.
- A transparent solution from the solution pack in the analyzer to determine the zero point, I_o.

Zero point

The zero point, I_o, is the current (or intensity) measured by the photodiode array on the transparent solution in the cuvette. During this "blank calibration" the *c*tHb is calibrated to this zero point.

I_o is measured automatically during system start up and during calibrations.

Cuvette path length

The cuvette path length (i.e. the length of the light path) is determined from Lambert-Beer's Law by measuring the absorbance of the colored dye present in the tHb Calibration Solution (S7770), which has a known equivalent hemoglobin concentration.

Beer's Law: $A = \varepsilon \times C_{dye} \times l$

where:

A = absorbance

ε = extinction coefficient

C_{dye} = concentration of colored dye

l = length of light path

tHb calibration frequency

It is recommended that a tHb calibration is performed every three months. See section *tHb calibration* in chapter 6: *Calibration* in the ABL90 FLEX operator's manual for further information about the tHb calibration.

Correcting for interferences

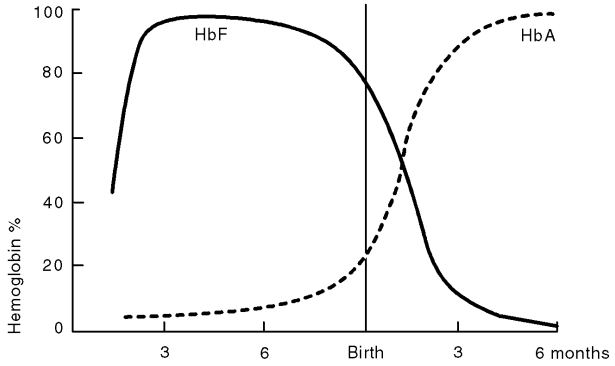
HbF versus HbA

Fetal hemoglobin (HbF) does not have the same spectrum as adult hemoglobin (HbA) due to a slight variation in molecular structure. The presence of HbF in a sample will interfere with the result if a correction is not performed.

It is thus important when measuring hemoglobin levels in premature neonates and neonates aged 0-3 months, as well as adults suffering from e.g. thalassemia, to take into account this difference [4], and the ABL90 FLEX analyzer automatically corrects for HbF.

NOTICE: Hb types other than HbA and HbF interfere with hemoglobin measurements and are not compensated for in the ABL90 FLEX analyzers.

The diagram below shows the transition from fetal hemoglobin to adult hemoglobin [5].



This graph is only schematic and cannot be used to determine *F*HbF.

Deviation of results

If the difference between the adult and fetal types of hemoglobin is not taken into account in measurements on samples containing HbF (e.g. from premature neonates and neonates aged 0-3 months) then a deviation in the measurement will arise.

The deviation is most important for measurements of oxygen saturation (sO_2 and FO_2Hb) and the fraction of carboxyhemoglobin (*F*COHb), since inaccurate measurements of these parameters can lead to incorrect diagnostic interpretation of the results, and consequent risk of inappropriate treatment.

Detecting HbF

The presence of HbF in a sample is detected from the difference spectrum between fetal and adult oxyhemoglobin. From the size of the difference spectrum the concentration of fetal oxyhemoglobin, cO_2HbF, can be determined.

Correcting for HbF

The amount of cO_2HbF exceeding a certain level indicates HbF interference. The analyzer automatically corrects for this interference by subtracting the difference spectrum of fetal oxyhemoglobin from the measured spectrum.

Repressing spectra

Repressing the spectra of the likely interfering substances is done in two ways depending on the substance:

- **Either** the substance is taken account of in the calculation of the matrix of constants, K. This applies to Intralipids and Sulfhemoglobin.
- **Or** the substance is detected, and the measured spectrum is corrected accordingly. This applies to HbF.

Residual spectrum

The measured spectrum is compared to a model spectrum calculated from the determined concentrations. The difference between these two spectra is called the residual spectrum. If this residual spectrum is too high, the oximetry module parameters *c*tHb, sO_2, FO_2Hb, *F*COHb, *F*MetHb, *F*HHb, *F*HbF and *c*tBil will be flagged with a warning.

In addition, a warning will accompany the results if any of the following conditions exist:

- *c*tHb < –0.1 mmol/L or *c*tHb > 25 mmol/L
- *F*Hb(deriv) < –2 % or *F*Hb(deriv) > 102 %

  where *F*Hb(deriv) is defined as sO_2, FO_2Hb, *F*COHb, *F*MetHb, *F*HHb
- SHb < –2 % or SHb > 10%
- Value of Turbidity < –0.5 % or > 5%

Measurement and corrections

Oximetry parameters

The oximetry parameters are calculated as follows:

Parameter	Equation
*c*tHb(meas)	$= cO_2Hb + cCOHb + cHHb + cMetHb$
sO_2	$= \frac{cO_2Hb}{ceHb}$ $ceHb = cHHb + cO_2Hb$ (effective hemoglobin)
FO_2Hb	$= \frac{cO_2Hb}{ctHb}$
*F*COHb	$= \frac{cCOHb}{ctHb}$
*F*HHb	$= \frac{cHHb}{ctHb}$
*F*MetHb	$= \frac{cMetHb}{ctHb}$
*F*HbF	$= \frac{cHbF}{ctHb}$

where:

cO_2Hb = concentration of oxyhemoglobin in the sample

*c*COHb = concentration of carboxyhemoglobin in the sample

*c*HHb = concentration of deoxyhemoglobin in the sample

*c*MetHb = concentration of methemoglobin in the sample

*c*HbF = concentration of fetal hemoglobin in the sample (is not measured directly, but determined on the basis of a definition equation)

Bilirubin

Bilirubin is calculated as follows:

$$ctBil(P) = \frac{ctBil(B)}{1 - Hct(calc)}$$

where:

*c*tBil(P) = concentration of total bilirubin in plasma

*c*tBil(B) = concentration of diluted plasma bilirubin after sample hemolyzation

Hct(calc) = calculated hematocrit (a fraction).

$$Hct(calc) = \frac{0.0301}{g/dL} \times ctHb$$

For further details on Hct(calc) please refer to *Interference Tests* and the explanation of MCHC (Mean Corpuscular Hemoglobin Concentration) in chapter 7 in this manual.

Restrictions The following parameters will not be calculated:

Parameter	Is not calculated if...
sO_2, *F*COHb, *F*MetHb, *F*HHb, FO_2Hb	*c*tHb < 1 mmol/L
sO_2	*c*eHb = *c*HHb + cO_2Hb < 0.75 mmol/L
*c*tBil	*c*tHb > 14.27 mmol/L

The following conditions are required to perform HbF suppression:

Parameter or Feature	Requirement
*c*tHb	> 5 mmol/L
*F*COHb	< 20 %
*F*MetHb	< 10 %
HbF correction – Enabled for levels >20%	cO_2HbF/*c*tHb should be more than 0.2.
HbF correction – Enabled for all levels	No lower limit value for cO_2HbF is required, i.e. even adult blood samples will be corrected for HbF. It may be of value when analyzing blood samples from newborns who have received adult blood transfusion. In these cases *F*HbF can be lower than 20 % and significant deviations of oximetry parameters and bilirubin can occur.
HbF correction – Disabled	No HbF corrections made.
HbF suppression has been activated	The *F*HbF value is normally, but not always, displayed by the analyzer. Message "Oxi compensated for HbF" is displayed.
sO_2 < 50 %	Message "*F*HbF measurement is not possible" is displayed by the analyzer, if a HbF suppression has been activated, and the *F*HbF estimation from cO_2HbF is too uncertain.

Corrections for *c*tHb

The uncorrected hemoglobin concentration, *c*tHb(sample), measured on capillary or syringe samples is corrected as follows:

$$c\text{tHb(sample,corr)} = \frac{c\text{tHb(sample)}}{F_{cuv}}$$

where:

*c*tHb(sample,corr)	=	corrected *c*tHb
F_{cuv}	=	analyzer-dependent cuvette path length constant determined at tHb calibrations and automatically stored by the analyzer

Corrections for *c*tBil

The uncorrected total bilirubin concentration, *c*tBil(sample), measured on capillary or syringe samples is corrected as follows:

$$c\text{tBil(sample,corr)} = \frac{c\text{tBil(sample)}}{F_{cuv}}$$

F_{cuv} is the same as for tHb.

References

1. CLSI/NCCSL document C12-A, Clinical and Laboratory Standards Institute, 940 West valley Road, Suite 1400, Wayne, PA 19087.
2. Ewing GW. Instrumental methods of chemical analysis. 5th ed. McGraw.Hill, 1985
3. Martens H. Multivariate calibration: quatitative interpretation of non-selective chemical data: Dr. Techn. Thesuis. NTH Univ. of Trondheim, 1986.
4. Krzeminski A. Why correct for fetal hemoglobin in blood oximetry measurements? Radiometer Publication Info. No. 1992-3. Copenhagen: Radiometer Medical A/S, 1992.
5. Huehns ER, Beanen GH. Developmental changes in human hemoglobins. Clin Dev Med 1971; 37: 175-203.

6. User-defined corrections

General information

Purpose of use

User-defined corrections are most commonly implemented in situations where the values measured for a particular parameter by two or more analyzers deviate consistently from each other.

NOTICE: Since the performance of all ABL90 FLEX analyzers is tested as described in chapter 7: *Performance characteristics* in this manual, and each instrument is assumed to operate accurately and optimally, the unnecessary correction of parameter values by the user can lead to inaccurate measurements being reported.

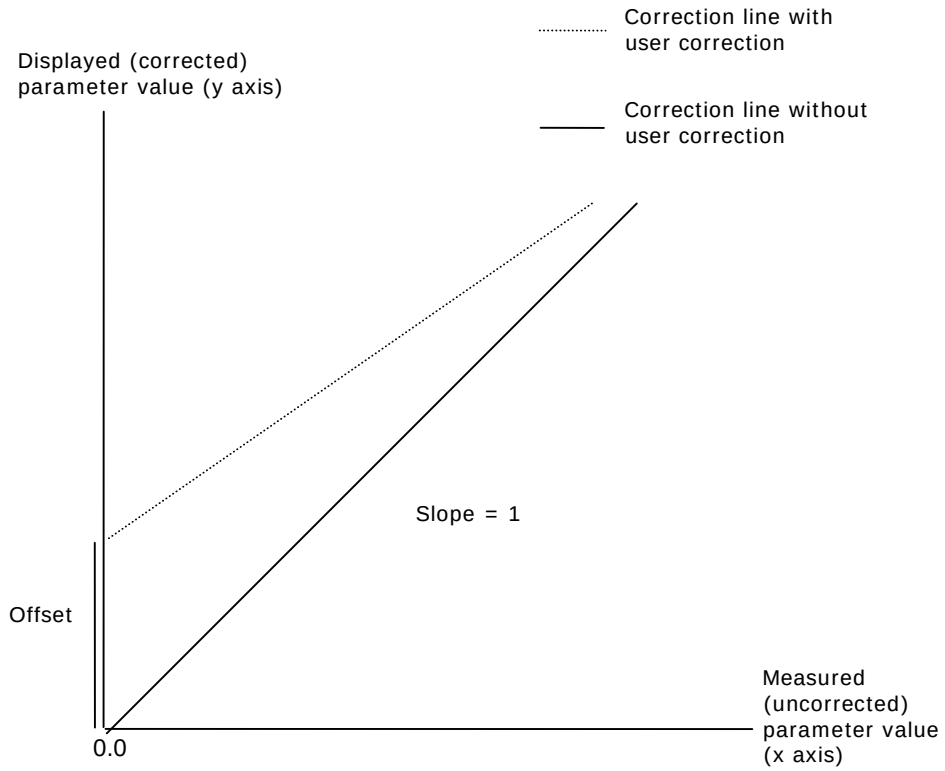
User-defined corrections

User-defined corrections are based on a linear correlation between the measured values (without user-defined corrections) and the displayed values (with user-defined corrections).

The correction factors for each measured parameter are the slope and the offset of the correction line. With user-defined corrections it is possible to change the values of either one or both of these correction factors, depending on the parameter type.

Corrected value = Slope × Uncorrected value + Offset

The diagram below is a schematic representation of the relationship between correction lines without and with user-defined correction.



Preparatory action

Prior to entering corrections for any parameter, the user must obtain the reference values for the chosen parameters, using the method accepted in his/her laboratory.

It should be noted that in order to define corrections:

- Measurements should be taken on the ABL90 FLEX analyzer without user-defined corrections, and on a single reference analyzer
- A series of measurements that cover the entire measuring range should be performed
- The measurements should be made simultaneously on the ABL90 FLEX and the reference analyzer, and samples must be handled correctly.
- The slope and the offset must be calculated. The user may, for example, make a linear correlation between the values measured on the ABL90 FLEX analyzer and the reference analyzer, using the ABL90 FLEX analyzer as an independent variable.
- The user must verify the corrections that are entered.

Details of these procedures may be found in the section *Test conditions* in chapter 7.

Entering user-defined corrections

The slope/offset for each parameter are configured in **General Setup** > **Parameters and Input** > **Parameters**. User-corrected values are marked with a "*" after the result.

NOTICE: The user-defined corrections will be applied to Quality Control measurements unless the "Apply parameter corrections to QC" option was deactivated in Miscellaneous setup as described in the section *Miscellaneous setup* in chapter 1.

For detailed instructions on how to enter user-defined corrections, refer to the section *Parameters and input setup* in chapter 1.

Correction factors for pH and blood gases

Correcting slope and offset

The following corrections to the slope and offset are possible within the stated limits for:

Arterial, venous, and a-$\bar{v}$ samples:

Parameter	Slope	Offset
pH	0.80-1.20	±0.05
pCO_2	0.80-1.20	±10 mmHg
pO_2	0.80-1.20	±20 mmHg

Correction factors for oximetry parameters

Allowed corrections

The following corrections can be user-defined for the oximetry parameters:

Parameter	Allowed user-defined corrections	
	Slope	Offset
*c*tHb	Yes	No
sO_2	Yes	Yes
*F*COHb	No	Yes
*F*MetHb	No	Yes
FO_2Hb	No	No
*F*HHb	No	No
*F*HbF	Yes	Yes
*c*tBil	Yes	Yes

NOTICE: In order to define the corrections accurately the measurements of the oximetry parameters on the ABL90 FLEX analyzers should be made without any entered corrections. To avoid truncation errors from an enabled "Out-of-range-suppression" function it is important to disable the function.

The following recommendations apply to the oximetry parameters:

ctHb

Item	Description
Units	g/dL; g/L; mmol/L
Sample	Set *c*tHb of a SAT100 sample to ≈15 g/dL (9.3 mmol/L) and pH ≈ 7.4
*c*tHb, maximum point	Uncorrected or corrected: ≈ 15 g/dL or 9.3 mmol/L
Slope	0.950-1.050

sO_2

Item	Description
Units	Fraction
Sample	Set *c*tHb of gas equilibrated SAT0 and SAT100 samples to ≈ 15 g/dL (9.3 mmol/L) and pH ≈ 7.4
Slope	0.900-1.100
Offset	±0.050

*F*COHb

Item	Description
Units	Fraction
Sample	The zero point (*F*COHb ≈ 0) is saturated to approximately SAT100, and *c*tHb is set to ≈ 15 g/dL (9.3 mmol/L) and pH ≈ 7.4.
Offset	±0.050

*F*MetHb

Item	Description
Units	Fraction
Sample	The zero point (*F*MetHb ≈ 0) is saturated to approximately SAT100, and *c*tHb is set to ≈ 15 g/dL (9.3 mmol/L) and pH ≈ 7.4.
Offset	±0.050

*F*HbF

Item	Description
Units	Fraction
Sample	Radiometer recommends that *c*tHb in the adult samples (with *F*HbF = 0) and fetal samples (with high *F*HbF) is set to ≈ 15 g/dL (9.3 mmol/L), sO_2 ≈ 100 % and pH ≈ 7.4. The "Enabled for all levels" HbF Correction function should be enabled in order to have the *F*HbF value displayed for the adult sample. Averaging repeated measurements on blood from different donors gives an optimized accuracy of the correction. Averaging repeated measurements on blood from the same donor also improves the accuracy.
Slope	0.800-1.200
Offset	±0.20

FO_2Hb and *F*HHb

The units for FO_2Hb and *F*HHb are [Fraction].

After the user-defined corrections of the parameters sO_2, *F*COHb and *F*MetHb have been carried out, FO_2Hb and *F*HHb are automatically calculated using the formulae stated below, since the sum of the fractions *F*COHb, *F*MetHb, FO_2Hb and *F*HHb as defined must be equal to 1.0:

FO_2Hb:

$$FO_2Hb = (1 - FCOHb - FMetHb) \times sO_2$$

FHHb:

$$FHHb = (1 - FCOHb - FMetHb) \times (1 - sO_2)$$

ctBil

The following recommendations apply to *c*tBil:

Item	Description
Units	μmol/L
Sample	Radiometer recommends that human plasma or serum is used with pH ≈ 7.4 (the analyzer reading). Zero point sample could be adult sample (*c*tBil ≈ 0 μmol/L) and maximum point could be an unconjugated bilirubin sample (neonatal) with *c*tBil ≈ 300-400 μmol/L. Averaging repeated measurements on samples from different donors gives an optimized accuracy of the correction. Averaging repeated measurements on samples from the same donor also improves the accuracy. Commercial bilirubin standards can interfere with bilirubin measurement because they may have an absorbance spectrum different from that of human plasma.
Slope	0.500-1.500
Offset	±100

Correction factors for electrolyte and metabolite parameters

Correcting slope and offset

The following corrections to the slope and the offset are possible within the stated limits for:

Blood samples:

Parameter	Slope	Offset
$c\mathrm{K}^+$	0.80-1.20	±1.0 mmol/L
$c\mathrm{Na}^+$	0.80-1.20	±10 mmol/L
$c\mathrm{Ca}^{2+}$	0.80-1.20	±1.00 mmol/L
$c\mathrm{Cl}^-$	0.80-1.20	±10 mmol/L
*c*Glu	0.750-1.250	±5.0 mmol/L
*c*Lac	0.750-1.250	±5.0 mmol/L

Resetting corrections to default values

The Radiometer default values for the electrolyte and metabolite parameters must be reset manually by the user on the **Parameter setup** screen to 1.000 for each parameter.

7. Performance characteristics

General information

Performance specifications are achieved by comparison between the ABL90 FLEX analyzer and the primary reference methods, and by comparison between the ABL90 FLEX analyzer and the ABL735 analyzer.

Performance specifications of the ABL90 FLEX analyzers are described, using the following:

- $Bias_{Prim.ref}$ = the mean difference between the ABL90 FLEX analyzer and the primary reference methods.
- $Bias_{Sec.ref}$ = the mean difference between the ABL90 FLEX analyzer and the ABL735 analyzer.
- Repeatability (imprecision estimate)
- Reproducibility (imprecision estimate)
- Total variation range.

Definition of terms

Bias

The bias of a quantity is defined as the mean difference between the measured value on a group of test instruments and the estimated true value (as assayed by the reference method or certified standard reference material). $Bias_{Prim.Ref}$ is determined as follows:

$$Bias_{Prim.ref} = \bar{X}_{ABL90\ FLEX} - \bar{X}_{Primary\ Reference\ method}$$

$Bias_{Sec.Ref}$ is a relative bias between the ABL90 FLEX analyzer and the ABL735 analyzer in macromode (C195 µL mode), and is determined as follows:

$$Bias_{Sec.ref} = \bar{X}_{ABL90\ FLEX} - \bar{X}_{ABL735}$$

Bias given in the tables in this chapter have been obtained experimentally.

Reference methods

Parameter	Primary Reference Method	Secondary Reference Method	Reference
pH	Capillary-type glass pH electrode with a saturated calomel reference electrode and a liquid junction saturated with KCl (BMS Mk2). The calibration standards are traceable to the Primary Reference Standards for pH.	ABL735	[Ref. 1,2]
pCO_2	Tonometry. The gases used for tonometry are traceable to NIST-certified Standard Reference Materials.	N/A	[Ref. 3]
pO_2	Tonometry. The gases used for tonometry are traceable to NIST-certified Standard Reference Materials.	N/A	[Ref. 3]
cCa^{2+}	Calcium transfer standards were used. These are traceable to NIST SRM 915 and SRM 956b and have an ionic strength of 160.0 mmol per kg of water and pH 7.40 at 37 °C, using 1 mmol/L (37 °C) HEPES buffer.	ABL735	The standards were produced as indicated in [Ref. 4]
cCl^-	NIST-certified Standard Reference Material SRM 909b (human serum) and SRM 956b.	ABL735	
cK^+	NIST-certified Standard Reference Material SRM 909b (human serum) and SRM 956b.	ABL735	
cNa^+	NIST-certified Standard Reference Material SRM 909b (human serum), NIST 956b and Radiometer-specified standard serum material (specified using flame photometry).	ABL735	

Parameter	Primary Reference Method	Secondary Reference Method	Reference
*c*Glu	Spectrophotometry, using the hexokinase (HK) method recommended by NCCLS, measured on serum.	N/A	[Ref. 5]
*c*Lac	Spectrophotometry using a lactate dehydrogenase (LDH) method, measured on serum.	N/A	[Ref. 8]
*c*tHb	HiCN method recommended by NCCLS.	ABL735	[Ref. 6]
sO_2	Tonometry: 100%: whole blood is tonometered with a gas mixture containing 94.4% O_2 and 5.6% CO_2. 0%: whole blood is tonometered with a gas mixture containing 94.4% N_2 and 5.6% CO_2 + dithionite.	ABL735	
FO_2Hb	Measured according to the following relation: $FO_2Hb = 1 - (FHHb + FCOHb + FMetHb)$	ABL735	
*F*HHb	0%: whole blood is tonometered with a gas mixture containing 94.4% N_2 and 5.6% CO_2 + dithionite.	ABL735	
*F*COHb	Gas chromatography: The Standards are carbon monoxide mixtures with atmospheric air, whose purity is validated in accordance with NIST SRM 1678 (50 ppm CO in N_2)	ABL735	
*F*MetHb	Spectrometry, modified Evelyn-Malloy method.	ABL735	[Ref. 7]
*c*tBil	The reference method for total bilirubin is a spectrophotometric method (wet chemistry based on a method from Bayer Healthcare, Tarrytown USA). The method is traceable to NIST SRM916a Bilirubin.	ABL735	
*F*HbF	The reference method is based on Cation Exchange HPLC.	ABL735	[Ref. 15]

General reference: [Ref. 10].

Coefficient of variation (CV%)

The coefficient of variation is reported as a percentage and calculated from the mean (or measuring level) and standard deviation as follows:

$$CV\% = \frac{\text{Standard deviation}}{\text{Measuring level}} \times 100$$

Confidence intervals

Confidence interval provides a range of values estimated from a study group that is highly likely to include the true, but unknown, value ("confidence interval" applies to the results of a statistical analysis). A 95% confidence interval means that there is only a 5% chance that the true value is not included in the interval.

Repeatability / Reproducibility

Repeated measurements using one analyzer on samples assumed to be identical will not necessarily yield identical results. The degree of variation in the results is a measure of the precision of the analyzer.

The table on the next page describes the parameters used to characterize precision obtained via the performance tests on the ABL90 FLEX analyzer. [Ref. 9]

Parameter	Description
S_0	**Repeatability** This is a standard deviation obtained from repeated measurements within a short interval of time using: • The same instrument and location • The same measurement procedure • Identical portions of the same sample • One operator per instrument S_0 for each level is pooled for all test instruments and test days.
S_x	**Reproducibility** is obtained from repeated measurements over several days using: • Random instrument • Random sample • Random operators Reproducibility for each level is pooled for all test instruments and test days.

Total analytical error

TE_A, total analytical error is a quality specification that sets a limit for both the random error (imprecision) and systematic error (inaccuracy) in a single measurement or single test result. In Radiometer reference manual the following expression for total analytical error is either expressed in an absolute number

$$TE_A = (|Bias| + 1.96 \times S_x)$$

or in %

$$TE_A = (|Bias\%| + 1.96 \times CV_x)\ \%$$

The formula we are using for total error allowable works at 95% probability to allow for 5% error.

Test conditions

Test conditions to determine $bias_{Prim.ref}$, $bias_{Sec.ref}$, repeatability, reproducibility and total variation for pH, pCO_2, pO_2, cCa^{2+}, cCl^-, cK^+, cNa^+, *c*Glu, *c*Lac, *c*tHb, sO_2, FO_2Hb, *F*COHb, *F*MetHb, *F*HHb, *c*tBil and *F*HbF were as follows:

Item	Description
Reference analyzers	Five ABL735 analyzers with AutoCheck module were used as a reference. The capillary mode was used for pCO_2 and pO_2, and the syringe mode for all the other parameters.
Primary/secondary reference methods	As specified for each parameter earlier in this chapter.
Analyzers and test modes	8-10 ABL90 FLEX analyzers were tested in syringe and capillary mode.
Blood samples	Heparinized blood samples from healthy, voluntary donors. The blood is prepared to obtain different concentration levels of each measured parameter.
Blood measurements	Measurements on every parameter are performed on all analyzers, with 5 measurements on every sample of each run, repeated for 3 days. The measurements were performed by different operators.
Solution pack	All calibration solutions and gases used for the tests are traceable to Primary Reference Standards. Traceability certificates for the ABL90 FLEX calibration solutions and gases are found at the end of chapter 9: *Solutions*.
Experimental conditions	Ambient temperature: 22-25 °C Relative humidity: 30-50 %. Barometric pressure: 730 - 780 mmHg

NOTICES:

- The solutions used in the performance tests are those recommended by Radiometer. Performances using other solutions cannot be guaranteed.
- The performance tests are performed under conditions where the analyzers are not influenced by electromagnetic fields.

Performance test results – chart description

General reference for the entire section: [Ref. 11].

Modes

Tests were performed in the following modes:

Mode	Volume
Syringe	65 µL
Capillary	65 µL

Number of measurements

The number of measurements during the test are listed below:

Parameter	Number of measurements	Test period, days	Number of Instruments
pH	786	30	8
pCO_2	691	25	10
pO_2	917	27	9
cK^+	800	13	10
cNa^+	799	30	8
cCa^{2+}	797	30	8
cCl^-	799	30	8
*c*Glu	Blood: 1268	23	9
	Serum pool: 408	23	9
*c*Lac	Blood: 1622	22	8
	Serum pool: 546	22	8
*c*tHb	1042	8	10
sO_2	1193	22	10
FO_2Hb	1193	22	10
*F*COHb	1041	12	10
*F*MetHb	1049	9	10
*F*HHb	1193	22	10
*F*HbF	864	24	10
*c*tBil	649	16	10

Performance test results – pH

Reference method

Capillary-type glass pH electrode with a saturated calomel reference electrode and a liquid junction saturated with KCl (BMS Mk2) [Ref. 1,2].

The calibration standards are traceable to the Primary Reference Standards for pH.

$Bias_{Prim.ref}$

pH	$Bias_{Prim.ref}$	N
7.0	0.008	45
7.4	-0.004	45
7.6	0.004	45

N = number of measurements employed

$Bias_{ABL90\text{-}Prim.ref} = Bias_{ABL90\text{-}ABL735} + Bias_{ABL735\text{-}Prim.ref}$

$Bias_{Sec.ref}$ and Repeatability – blood samples

pH	$Bias_{Sec.ref}$	S_0	S_X	TE_A
6.800	-0.007	0.0014	0.0076	0.022
7.000	-0.004	0.0012	0.0064	0.017
7.200	-0.002	0.0014	0.0064	0.015
7.400	-0.002	0.0014	0.0073	0.016
7.800	-0.006	0.0017	0.0113	0.028

Performance test results – *p*CO_2

Reference method

Tonometry [Ref. 3].

The gases used for tonometry are traceable to NIST-certified Standard Reference Materials.

$Bias_{Prim.ref}$ and Repeatability – blood samples

pCO_2 (mmHg)	$Bias_{Prim.ref}$	S_0	S_X	CV_X%	TE_A	TE_A (%)
15.0	0.13	0.16	0.70	4.7	1.50	10.0
40.0	0.18	0.25	0.55	1.4	1.26	3.2
60.0	-0.16	0.29	0.87	1.5	1.87	3.1
80.0	-0.36	0.23	1.45	1.8	3.20	4.0
100	-0.77	0.85	2.36	2.4	5.40	5.4

Performance test results – pO_2

Reference method

Tonometry [Ref. 3].

The gases used for tonometry are traceable to NIST-certified Standard Reference Materials.

$Bias_{Prim.ref}$ and Repeatability – blood samples

pO_2 (mmHg)	$Bias_{Prim.ref}$	S_0	S_X	CV_X %	TE_A	TE_A (%)
30.0	0.0	0.21	0.60	2.0	1.18	3.9
75.0	0.7	0.31	0.84	1.1	2.35	3.1
125	0.7	0.37	1.19	1.0	3.03	2.4
250	-2.0	1.54	2.93	1.2	7.74	3.1
500	-6.1	2.47	5.95	1.2	17.76	3.6

Performance test results – cK^+

Reference method

NIST-certified Standard Reference Material SRM 909b (human serum).

$Bias_{Prim.ref}$

cK^+ (mmol/L)	$Bias_{Prim.ref}$	N
5.973	0.065	45
3.983	0.067	45
1.987	0.108	45

N = number of measurements on several analyzers used for the test.

$Bias_{ABL90\text{-}Prim.ref} = Bias_{ABL90\text{-}ABL735} + Bias_{ABL735\text{-}Prim.ref}$

$Bias_{Sec.ref}$ and Repeatability – blood samples

cK^+ (mmol/L)	$Bias_{Sec.ref}$	S_0	S_X	CV_X %	TE_A	TE_A (%)
2.0	0.09	0.02	0.08	4.0	0.25	12.3
4.0	0.09	0.01	0.08	2.0	0.25	6.2
6.0	0.12	0.01	0.11	1.8	0.34	5.6
8.0	0.05	0.01	0.12	1.5	0.29	3.6
10.0	-0.01	0.02	0.12	1.2	0.25	2.5

Performance test results – *c*Na$^+$

Reference method

NIST-certified Standard Reference Material SRM 909b (human serum) and Radiometer-specified standard serum material (specified using flame photometry).

Bias$_{Prim.ref}$ and Repeatability – blood samples

*c*Na$^+$ (mmol/L)	Bias$_{Prim.ref}$ *)	S_0	S_X	CV_X %	TE_A	TE_A (%)
120	0.0	0.1	0.9	0.8	1.76	1.5
130	0.3	0.2	1.1	0.8	2.46	1.9
140	0.5	0.1	1.1	0.8	2.66	1.9
160	0.6	0.3	1.2	0.8	2.95	1.8
180	0.9	0.1	1.6	0.9	4.04	2.2

*) ABL735 corr. to NIST through:

Na(ABL735, corr) = 1.055 * Na(ABL735, meas) – 6.8966 (mM)

Performance test results – *c*Cl$^-$

Reference method

NIST-certified Standard Reference Material SRM 909b (human serum).

Bias$_{Prim.ref}$

*c*Cl$^-$ (mmol/L)	Bias$_{Prim.ref}$	N
89.11	-0.8	45
119.45	3.45	45

N = number of measurements on several analyzers used for the test.

$Bias_{ABL90\text{-}Prim.ref} = Bias_{ABL90\text{-}ABL735} + Bias_{ABL735\text{-}Prim.ref}$

Bias$_{Sec.ref}$ and Repeatability – blood samples

*c*Cl$^-$ (mmol/L)	Bias$_{Sec.ref}$	S_0	S_X	CV_X %	TE_A	TE_A (%)
80	0.8	0.1	0.9	1.1	2.56	3.2
100	0.8	0.1	1.1	1.1	2.96	3.0
120	1.1	0.1	1.5	1.3	4.04	3.4
140	0.8	0.1	1.6	1.1	3.94	2.8
150	0.7	0.1	1.7	1.1	4.03	2.7

Performance test results – *c*Ca^{2+}

Reference method

The calcium transfer standards were used. These are traceable to NIST SRM915 and have an ionic strength of 160.0 mmol per kg of water and pH 7.40 at 37 °C, using 1 mmol/L (37 °C) HEPES buffer.

The standards were produced as indicated in [4].

$Bias_{Prim.ref}$

cCa^{2+} (mmol/L)	$Bias_{Prim.ref}$	N
0.4903	0.063	45
1.2608	0.022	45
2.5111	-0.02	45

$$Bias_{ABL90\ FLEX\ -\ Prim.ref} = Bias_{ABL90\ FLEX\ -\ ABL735} + Bias_{ABL735\ –\ Prim.ref}$$

$Bias_{Sec.ref}$ and Repeatability – blood samples

cCa^{2+} (mmol/L)	$Bias_{Sec.ref}$	S_0	S_X	CV_X%	TE_A	TE_A (%)
0.5	-0.031	0.002	0.015	3.0	0.060	12.0
0.75	-0.011	0.002	0.014	1.9	0.038	5.1
1.25	0.013	0.003	0.017	1.4	0.046	3.7
1.75	0.044	0.005	0.024	1.4	0.091	5.2
2.50	0.063	0.010	0.037	1.5	0.136	5.4

Performance test results – *c*Glu

Reference method

Spectrophotometry, using the hexokinase (HK) method recommended by NCCLS/CLSI [Ref. 5], measured on serum.

$Bias_{Prim.ref}$ and Repeatability – blood samples

Blood, *p*O2>90 mmHg

*c*Glu (mmol/L)	$Bias_{Prim.ref}$	S_0	S_X	CV_X%	TE_A	TE_A (%)
2.0	-0.09	0.02	0.09	4.5	0.27	13.3
6.0	-0.07	0.06	0.16	2.7	0.38	6.4
10.0	0.23	0.09	0.24	2.4	0.70	7.0
25.0	-0.87	0.18	0.83	3.3	2.5	10.0
40	-1.58	0.52	2.33	5.8	6.2	15.4

Blood, pO_2<90 mmHg

*c*Glu (mmol/L)	$Bias_{Prim.ref}$	S_0	S_X	CV_X%	TE_A	TE_A (%)
2.0	-0.09	0.01	0.10	5.0	0.29	14.3
6.0	-0.12	0.05	0.18	3.0	0.47	7.9
10.0	0.08	0.06	0.27	2.7	0.61	6.1
25.0	-1.73	0.28	0.84	3.4	3.4	13.5
40	-3.28	0.62	1.92	4.8	7.0	17.6

Serum pool, pO_2>90 mmHg

*c*Glu (mmol/L)	$Bias_{Prim.ref}$	S_0	S_X	CV_X%	TE_A	TE_A (%)
2.0	-0.09	0.01	0.07	3.5	0.23	11.4
6.0	-0.07	0.03	0.13	2.2	0.32	5.4
10.0	0.23	0.04	0.24	2.4	0.70	7.0
25.0	-0.87	0.17	0.72	2.9	2.3	9.1
40	-1.58	0.45	1.36	3.4	4.3	10.6

Performance test results – *c*Lac

Reference method

Spectrophotometry using a lactate dehydrogenase (LDH) method, measured on serum [Ref 10].

$Bias_{Prim.ref}$ and Repeatability – blood samples

Blood, pO_2>90 mmHg

*c*Lac (mmol/L)	$Bias_{Prim.ref}$	S_0	S_X	CV_X%	TE_A	TE_A (%)
0.3	0.03	0.01	0.08	26.7	0.19	62.3
1.0	0.03	0.05	0.12	12.0	0.27	27.0
5.0	0.09	0.07	0.22	4.4	0.52	10.4
10.0	0.19	0.10	0.77	7.7	1.70	17.0
15.0	0.29	0.11	0.92	6.1	2.09	13.9
25	0.06	0.24	2.32	9.3	4.61	18.4

Blood, pO_2<90 mmHg

*c*Lac (mmol/L)	$Bias_{Prim.ref}$	S_0	S_X	CV_X%	TE_A	TE_A (%)
0.3	0.03	0.01	0.08	26.7	0.19	62.3
1.0	0.03	0.03	0.09	9.0	0.21	21.0
5.0	0.09	0.10	0.33	6.6	0.74	14.8
10.0	-0.05	0.08	0.78	7.8	1.58	15.8
15.0	-0.01	0.10	1.17	7.8	2.30	15.3
25	-1.26	0.21	2.70	10.8	6.55	26.2

Serum pool, pO_2>90 mmHg

*c*Lac (mmol/L)	$Bias_{Prim.ref}$	S_0	S_X	CV_X%	TE_A	TE_A (%)
0.3	0.03	0.01	0.07	23.3	0.17	56.7
1.0	0.03	0.01	0.07	7.0	0.17	17.0
5.0	0.09	0.04	0.17	3.4	0.42	8.4
10.0	0.19	0.04	0.45	4.5	1.07	10.7
15.0	0.29	0.06	0.78	5.2	1.82	12.1
25	0.06	0.16	1.92	7.7	3.82	15.3

Performance test results – *c*tHb

Reference method

HiCN method recommended by NCCLS [Ref. 6].

Setup:

Adult samples. HbF correction is not activated.

$Bias_{Prim.ref}$ and Repeatability – blood samples

*c*tHb (g/dL)	sO_2 (%)	$Bias_{Prim.ref}$ *)	S_0	S_X	CV_X%	TE_A	TE_A (%)
0.00	-	-0.02	0.01	0.02	-	0.06	-
3.5	100	0.02	0.04	0.08	2.3	0.18	5.1
7.0	100	0.05	0.08	0.16	2.3	0.36	5.1
10.0	100	0.06	0.07	0.20	2.0	0.45	4.5
15.0	100	0.06	0.07	0.24	1.6	0.53	3.5
20.0	100	0.00	0.09	0.29	1.5	0.57	2.9
25.0	100	0.08	0.11	0.37	1.5	0.81	3.2

*) ABL735 HICN-corr. through:

$$ctHb(ABL735),corr = -0.000707 * (ctHb(ABL735),meas)^2 + 0.9977 * ctHb(ABL735),meas$$

Performance test results – sO_2

Reference method

Tonometry:

100%: whole blood is tonometered with a gas mixture containing 94.4% O_2 and 5.6% CO_2.

0%: whole blood is tonometered with a gas mixture containing 94.4% N_2 and 5.6% CO_2 + dithionite.

$Bias_{Prim.ref}$

*c*tHb (g/dL)	sO_2 (%)	$Bias_{Prim.ref}$	N
15	0	0.07	150
15	100	-0.26	150
7	100	0.46	150
25	100	0	148

N = number of measurements on several analyzers used for the test.

Setup:

Adult samples. HbF correction not activated.

$Bias_{ABL90\text{-}Prim.ref} = Bias_{ABL90\text{-}ABL735} + Bias_{ABL735\text{-}Prim.ref}$

$Bias_{Sec.ref}$ and Repeatability – blood samples

*c*tHb (g/dL)	sO_2 (%)	$Bias_{Sec.ref}$	S_0	S_X	CV_X%	TE_A	TE_A (%)
15	0	0.09	0.07	0.25	-	0.58	-
15	50	-0.26	0.24	0.40	0.8	1.04	2.1
15	65	-0.20	0.27	0.46	0.7	1.10	1.7
15	75	-0.10	0.30	0.48	0.6	1.04	1.4
15	90	-0.10	0.19	0.35	0.4	0.79	0.9
15	100	-0.07	0.09	0.29	0.3	0.64	0.6
7	100	0.45	0.11	0.37	0.4	1.18	1.2
25	100	-0.53	0.09	0.28	0.3	1.08	1.1

Performance test results – *F*O_2Hb

Reference method

Measured according to the following relation:

FO_2Hb = 1 - (*F*HHb + *F*COHb + *F*MetHb)

Setup:

Adult samples. HbF correction is not activated.

$Bias_{Sec.ref}$ and Repeatability – blood samples

FO_2Hb (%)	*c*tHb (g/dL)	$Bias_{Sec.ref}$	S_0	S_x	CV_X%	TE_A	TE_A (%)
0.0	15	0.07	0.07	0.25	-	0.56	-
50.0	15	-0.25	0.27	0.58	1.2	1.39	2.8
65.0	15	-0.43	0.30	0.48	0.7	1.37	2.1
75.0	15	-0.27	0.35	0.55	0.7	1.35	1.8
90.0	15	-0.23	0.23	0.40	0.4	1.01	1.1
100.0	15	-0.10	0.16	0.38	0.4	0.84	0.8
100.0	7	-0.09	0.19	0.48	0.5	1.03	1.0
100.0	25	-0.45	0.18	0.53	0.5	1.49	1.5

Performance test results – *F*COHb

Reference method

Gas chromatography: The Standards are carbon monoxide mixtures with atmospheric air, whose purity is validated in accordance with NIST SRM 1678 (50 ppm CO in N_2).

Setup:

Adult samples. HbF correction is not activated.

$Bias_{Prim.ref}$

*c*tHb (g/dL)	*F*COHb (%)	$Bias_{Prim.ref}$	N
15	0	0.22	45
15	20	-1.01	45

N = number of measurements on several analyzers used for the test.

$Bias_{ABL90\text{-}Prim.ref} = Bias_{ABL90\text{-}ABL735} + Bias_{ABL735\text{-}Prim.ref}$

$Bias_{Sec.ref}$ and Repeatability – blood samples

*c*tHb (g/dL)	*F*COHb (%)	$Bias_{Sec.ref}$	S_0	S_X	CV_X %	TE_A	TE_A (%)
15	0.0	0.00	0.07	0.23	-	0.45	-
15	5.0	0.08	0.07	0.26	5.2	0.59	11.8
15	10.0	0.04	0.06	0.34	3.4	0.71	7.1
15	20.0	0.11	0.07	0.67	3.4	1.42	7.1
15	30.0	0.17	0.07	0.68	2.3	1.50	5.0
15	50.0	0.30	0.08	0.68	1.4	1.63	3.3
15	99.0	0.54	0.12	0.72	0.7	1.95	2.0

Performance test results – *F*MetHb

Reference method

Spectrometry, modified Evelyn-Malloy method [Ref. 7].

Setup:

Adult samples. HbF correction is not activated.

$Bias_{Prim.ref}$

*c*tHb (g/dL)	*F*MetHb (%)	$Bias_{Prim.ref}$	N
15	0	0.12	45
15	20	-0.76	45

N = number of measurements on several analyzers used for the test.

$Bias_{ABL90\text{-}Prim.ref} = Bias_{ABL90\text{-}ABL735} + Bias_{ABL735\text{-}Prim.ref}$

$Bias_{Sec.ref}$ and Repeatability – blood samples

*c*tHb (g/dL)	*F*MetHb (%)	$Bias_{Sec.ref}$	S_0	S_X	CV_X %	TE_A	TE_A (%)
15	0.0	-0.04	0.10	0.23	-	0.49	-
15	5.0	0.02	0.09	0.25	5.0	0.51	10.2
15	10.0	-0.04	0.12	0.33	3.3	0.69	6.9
15	20.0	-0.18	0.08	0.27	1.4	0.71	3.5
15	30.0	-0.26	0.08	0.34	1.1	0.93	3.1
15	50.0	-0.21	0.09	0.43	0.9	1.05	2.1
15	99.0	0.11	0.05	0.61	0.6	1.31	1.3

Performance test results – *F*HHb

Reference method

0%: whole blood is tonometered with a gas mixture containing 94.4% N_2 and 5.6% CO_2 + dithionite.

Setup:

Adult samples. HbF correction is not activated.

$Bias_{Sec.ref}$ and Repeatability – blood samples

*F*HHb (%)	*c*tHb (g/dL)	$Bias_{Sec.ref}$	S_0	S_x	CV_x%	TE_A	TE_A (%)
0.0	15	0.07	0.10	0.28	-	0.62	-
10.0	15	0.08	0.18	0.35	3.5	0.77	7.7
25.0	15	0.05	0.30	0.48	1.9	0.99	4.0
35.0	15	0.08	0.27	0.50	1.4	1.06	3.0
50.0	15	0.11	0.26	0.57	1.1	1.23	2.5
100.0	15	-0.14	0.16	0.40	0.4	0.92	0.9
0.0	7	-0.45	0.13	0.36	-	1.16	-
0.0	25	0.53	0.09	0.26	-	1.04	-

Performance test results – *F*HbF

Reference method

The reference method is based on Cation Exchange HPLC. The method is described in [Ref. 15]. The method is performed by the Hæmatology Laboratory at Herlev Hospital, Denmark.

Setup:

Mixed adult and Fetal samples. HbF correction enabled for all levels.

$Bias_{Prim.ref}$ and Repeatability – blood samples

*F*HbF (%)	*c*tHb (g/dL)	$Bias_{Prim.ref}$ *)	S_0	S_X	CV_x%	TE_A	TE_A (%)
0	15	1.6	1.8	3.0	-	7.48	-
5	15	3.2	1.8	3.3	66	9.67	193
10	15	0.9	1.7	3.2	32	7.17	71.7
20	15	1.1	1.8	3.6	18	8.16	40.8
30	15	-1.7	1.8	4.2	14	9.93	33.1
50	15	-3.1	1.6	3.9	7.8	10.74	21.5
80	15	-4.2	1.8	4.1	5.1	12.24	15.3

*) ABL735 corrected to HPLC through:

$$FHbF(ABL735),corr = FHbF(ABL735),meas - 0.9 * ctHb + 11.7$$

Performance test results – bilirubin

Reference method

The reference method for total bilirubin is a spectrofotometric method (wet chemistry based on a method from Bayer Healthcare, Tarrytown USA.

The method is calibrated using NIST SRM916a Bilirubin.

The method is performed by the Laboratory Unilabs AS., Denmark.

Setup:

HbF correction is not activated

$Bias_{Prim.ref}$

*c*tBil (µmol/L)	*c*tHb (g/dL)	$Bias_{Prim.ref}$	N
0	15	0.8	3
200	15	4.7	3
400	15	4.7	3

$Bias_{ABL90\text{-}Prim.ref} = Bias_{ABL90\text{-}ABL735} + Bias_{ABL735\text{-}Prim.ref}$

$Bias_{Sec.ref}$

*c*tBil (µmol/L)	*c*tHb (g/dL)	$Bias_{Sec.ref}$	S_0	S_X	CV_X%	TE_A	TE_A (%)
8	15	1.0	2.7	7.1	89	14.9	186
100	15	0.2	3.2	9.7	9.7	19.2	19.2
200	15	-4.8	3.6	12.7	6.4	29.7	14.9
400	15	-5.3	4.8	13.9	3.5	32.5	8.1
600	15	-11.7	5.9	18.0	3.0	47.0	7.8

NOTES:

a. Adult/fetal blood, pH = 7.4 ± 0.1, normal MCHC and albumin variation. Spiked with unconjugated bilirubin.

External test results

The purpose of the bilirubin external tests was to make a regression study of ABL90 bilirubin against reference hospital analyzers on hospital neonatal blood samples.

A limited study was performed on hospital adult samples [Ref. 13].

For neonatal use: The bilirubin method has been evaluated on whole blood. The allowed analytical error is ±10% to satisfy average clinical requirements for bilirubin measurement [16,17,18,19,20]. For whole blood the analytical error is slightly higher.

For adult use: *Adult samples within reference range:*

The uncertainty in the bilirubin measurement on whole blood can, in some cases, exceed the level required to measure normal bilirubin levels for children older than 3 months and adults (bilirubin reference range 4-22 µmol/L).

Adult samples with an increased bilirubin level:

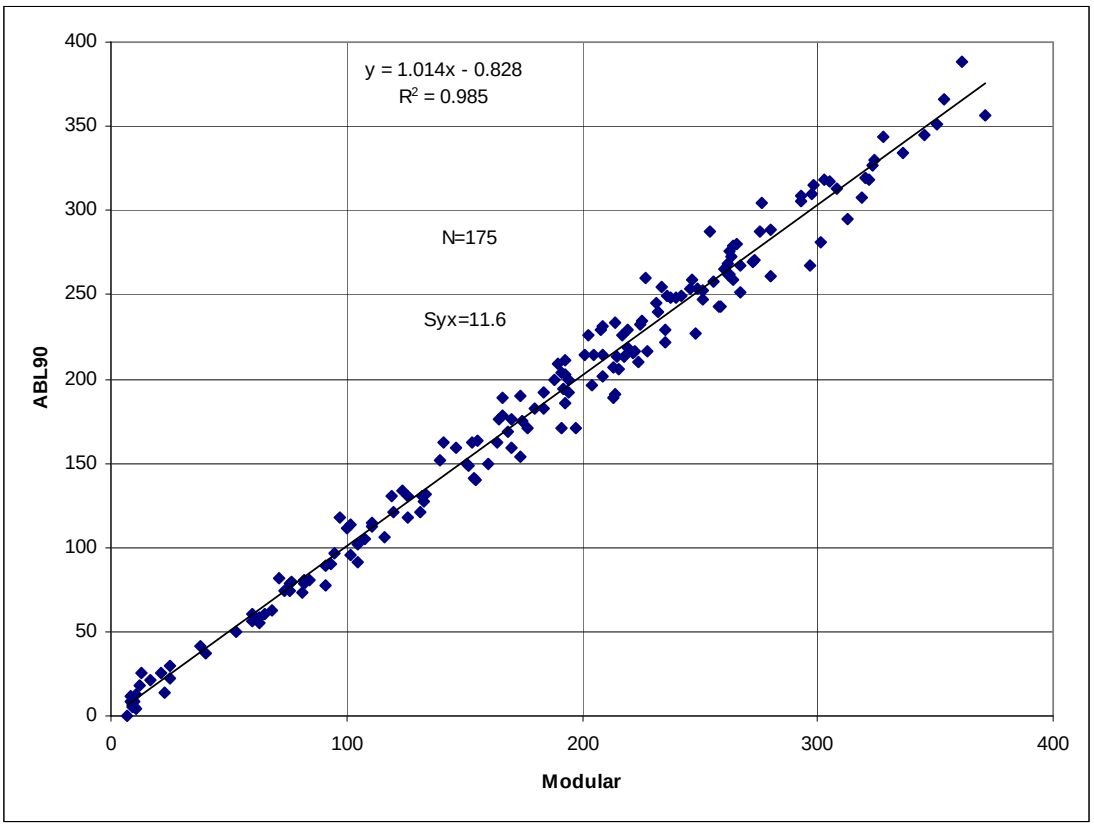
External tests using adult samples were performed on samples with typically 80 % of the total bilirubin in the conjugated form. For these highly conjugated samples the external tests showed a negative bias of 18% on whole-blood samples.

The patient samples represented typical variations in *c*tBil, *c*tHb, sO_2, pH and MCHC (Mean Corpuscular Hemoglobin Concentration) values.

Three external tests were carried out at two different sites. Each test had its own ABL90 analyzer – a total of three.

Wet Chemistry analyzer Roche Modular with Roche Calibrator was used as a reference [Ref. 21]**.** Each external test site had two Modulars – a total of four. *c*tBil was measured in µmol/L.

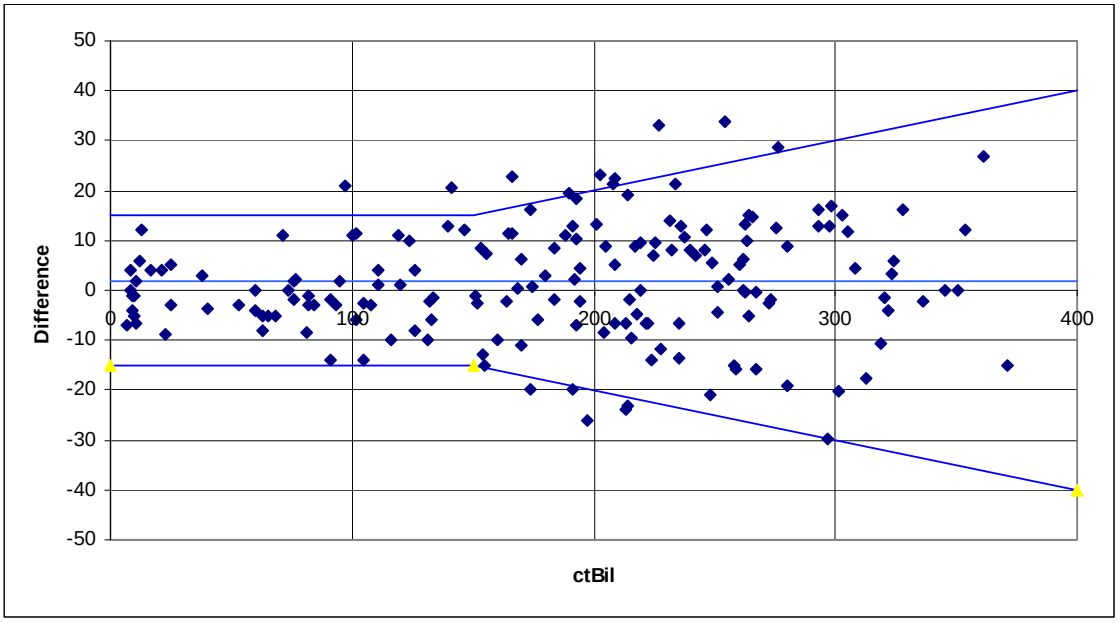
The field test results are given below:



S_{yx} is the spreading around the linear line.

Actual external test from neonatal critical care hospitals using whole blood. Data from three field tests are merged. Values are in µmol/L.

The same data as above but depicted in a Bland-Altman plot below.



Lines indicate “Mean” and +/- “15 umol or 10%”. Values are in µmol/L. Difference = ABL90 – Modular.

Interference tests

The results from the interference tests are given as the deviation from the correct result [Ref. 14].

pH / blood gas The following interference results are found for the pH and blood gas electrodes:

Substance	Test Concentration	Interference on ...			Test matrix
		pH (level 7.4)	pCO_2	pO_2 mmHg	
Intralipid	2%	< |0.010|	N/A	< |1|	Blood/Aqueous
	5%	< |0.010|	N/A	< |1|	Blood/Aqueous
Fluorescein	400 mg/L	N/A	N/A	< |1|	Blood
K^+	17 mM	< |0.010|	N/A	N/A	Blood
Na^+	190 mM	< |0.010|	N/A	N/A	Blood
Ca^{2+}	5.5 mM	< |0.010|	N/A	N/A	Blood

Electrolytes The following interference results are found for the electrolyte electrodes:

Substance	Test concentration	Interference on				Test matrix
		cK^+ (4 mM level)	*c*Na^+ (140 mM level)	*c*Ca^{2+} (1.25 mM level)	*c*Cl^- (105 mM level)	
Lithium (Li^+)	3.2 mM	<|0.1|	<|1|	<|0.02|	N/A	Plasma
Potassium (K^+)	12 mM	N/A	<|1|	<|0.02|	N/A	Plasma
Calcium (Ca^{2+})	3.4 mM	<|0.1|	**1.2**	N/A	N/A	Plasma
	2.2 mM	N/A	<|1|	N/A	N/A	Plasma
	1.8 mM	N/A	<|1|	N/A	N/A	Plasma
	1.6 mM	N/A	<|1|	N/A	N/A	Plasma
Sodium (Na^+)	180 mM	N/A	N/A	**0.029**	N/A	Plasma
Ammonium(NH_4^+)	1 mM	<|0.1|	<|1|	N/A	**1.1**	Plasma
	107 µM	<|0.1|	<|1|	N/A	<|1|	Plasma
Magnesium (Mg^{2+})	5 mM	N/A	<|1|	<|0.02|	N/A	Aqueous
Zinc (Zn^{2+})	170 µM	<|0.1|	<|1|	**0.024**	N/A	Plasma
Strontium (Sr^{2+})	150 µM	N/A	N/A	<|0.02|	N/A	Plasma
pH		N/A	N/A	**-0.037 mM/pH**	N/A	Aqueous/ buffer
	6.8 – 8	N/A	N/A	N/A	<|1|	Plasma
Bromide (Br^-)	37.5 mM	N/A	N/A	N/A	**76.6**	Plasma
	18.75 mM	N/A	N/A	N/A	**37.6**	Plasma
	10 mM	N/A	N/A	N/A	**19.5**	Plasma
	5 mM	N/A	N/A	N/A	**10.1**	Plasma
	1 mM	N/A	N/A	N/A	**1.8**	Plasma
Iodide (I^-)	2.99 mM	N/A	N/A	N/A	**12.4**	Plasma
	1.5 mM	N/A	N/A	N/A	**5.3**	Plasma
	1 mM	N/A	N/A	N/A	**3.5**	Plasma
	0.75 mM	N/A	N/A	N/A	**2.5**	Plasma
Fluoride (F^-)	107 µM	N/A	N/A	N/A	<|1|	Plasma
	1 mM	N/A	N/A	N/A	<|1|	Plasma
Perchlorate (ClO_4^-)	1.5 mM	–0.3	-	–0.27*	4-30	Plasma
Benzalkonium chloride	7.5 µg/mL	**0.27**	**8.7**	**0.138**	<|1|	Plasma
	10 µg/mL	**0.39**	**12.1**	**0.182**	<|1|	Plasma
	15 µg/mL	**0.60**	**18.8**	**0.269**	<|1|	Plasma
	30 µg/mL	**1.28**	**40.4**	**0.622**	<|1|	Plasma

* Depending on the pH level

A "-" indicates that interference has not been measured on the respective parameter.

Substance	Test concentration	Interference on …….				Test matrix
		cK^+ (4 mM level)	cNa^+ (140 mM level)	cCa^{2+} (1.25 mM level)	cCl^- (105 mM level)	
Acetylsalicylic acid	0.91 mM	N/A	N/A	N/A	<|1|	Plasma
	1.21 mM	N/A	N/A	N/A	<|1|	Plasma
	1.81 mM	N/A	N/A	N/A	**1.1**	Plasma
	3.62 mM	N/A	N/A	N/A	**3.0**	Plasma
Salicylic acid	1.09 mM	N/A	N/A	N/A	<|1|	Plasma
	1.45 mM	N/A	N/A	N/A	<|1|	Plasma
	2.17 mM	N/A	N/A	N/A	**1.7**	Plasma
	4.34 mM	N/A	N/A	N/A	**5.2**	Plasma
Thiocyanic acid	0.43 mM	N/A	N/A	N/A	**4.8**	Plasma
	0.57 mM	N/A	N/A	N/A	**5.5**	Plasma
	0.86 mM	N/A	N/A	N/A	**8.7**	Plasma
	1.72 mM	N/A	N/A	N/A	**17.2**	Plasma
Ascorbic acid	170 µM	N/A	N/A	N/A	<|1|	Plasma
	850 µM	N/A	N/A	N/A	<|1|	Plasma
Citrate	1 mM	N/A	N/A	N/A	<|1|	Plasma
	40 mM	N/A	N/A	N/A	**-4.9**	Plasma
Oxalate	1 mM	N/A	N/A	N/A	<|1|	Plasma
	10 mM	N/A	N/A	N/A	<|1|	Plasma
Lactate	25 mM	N/A	N/A	N/A	<|1|	Plasma
Caprylic acid	0.12 mM	N/A	N/A	N/A	<|1|	Plasma
Acetyl-tryptophane	0.12 mM	N/A	N/A	N/A	<|1|	Plasma

Number in **bold**: Exceeds specifications

Metabolites The following interference results are found for the metabolite electrodes:

Substance	Test Concentration	Interference on		Test matrix
		Glu mM	Lac mM	
Acetaminophen=paracetamol	2 mM	< |0.1|	< |0.1|	Whole blood
Acetylsalicylic acid	3.62 mM	< |0.1|	< |0.1|	Whole blood
Ibuprofen (sodium)	2.5 mM	< |0.1|	< |0.1|	Whole blood
Dopamine HCl	1 mM	< |0.1|	< |0.1|	Whole blood
Chlorpromazine HCl	0.2 mM	< |0.1|	< |0.1|	Whole blood
Ethanol	87 mM	< |0.1|	< |0.1|	Whole blood
Glucosamine HCl	2 mM	**0.12**	< |0.1|	Whole blood
Glycolic acid	0.25 mM	N/A	**0.31**	Whole blood
	0.33 mM	N/A	**0.39**	Whole blood
	0.5 mM	N/A	**0.48**	Whole blood
	1 mM	< |0.1|	**0.52**	Whole blood
Lactic acid	12 mM	< |0.1|	N/A	Whole blood
Maltose (monohydrate)	5 mM	< |0.1|	< |0.1|	Whole blood
Mannose	1 mM	**0.11**	< |0.1|	Whole blood
Salicylic acid	4.34 mM	< |0.1|	< |0.1|	Whole blood
Sodium thiocyanate	6 mM	**14.39**	**10.95**	Whole blood
	8 mM	**19.31**	**14.57**	Whole blood
	12 mM	**31.08**	**21.91**	Whole blood
	24 mM	**94.69**	**58.75**	Whole blood
Xylose	1 mM	< |0.1|	< |0.1|	Whole blood
Acetoacetate (Lithium acetacetoacetate)	2 mM	< |0.1|	**0.11**	Whole blood
Creatinine	3 mM	< |0.1|	< |0.1|	Whole blood
Galactose	3.3 mM	**0.14**	< |0.1|	Whole blood
D-Glucose	67 mM	N/A	**-0.21**	Whole blood
Pyruvate (pyruvic acid sodium salt)	2 mM	< |0.1|	< |0.1|	Whole blood
Urea	84 mM	< |0.1|	< |0.1|	Whole blood
Uric acid	1.5 mM	< |0.1|	< |0.1|	Whole blood
Heparin	8000 iu/dL	< |0.1|	< |0.1|	Whole blood
EDTA (Edetate disodium $2H_2O$)	3 mM	< |0.1|	< |0.1|	Whole blood
Citrate (sodium citrate $2H_2O$)	1 mM	< |0.1|	< |0.1|	Whole blood
Oxalate (sodium oxalate)	1 mM	< |0.1|	< |0.1|	Whole blood
Fluoride (Sodium fluoride)	50 mM	**-0.12**	**-0.13**	Whole blood
Pralidoxime chloride	0.045 mM	< |0.1|	< |0.1|	Whole blood

Substance	Test Concentration	Interference on		Test matrix
		Glu mM	Lac mM	
2-deoxy Glucose	2.5 mM	**2.25**	N/A	Whole blood
	3.33 mM	**2.88**	N/A	Whole blood
	5 mM	**4.58**	N/A	Whole blood
	10 mM	**9.58**	< |0.1|	Whole blood
Unconjugated Bilirubin	0.2 g/L	< |0.1|	< |0.1|	Whole blood
Conjugated Bilirubin	0.2 g/L	< |0.1|	< |0.1|	Whole blood
Ascorbic acid	170 µmol/L	< |0.1|	< |0.1|	Whole blood

Oximetry parameters

The substances against which the oximetry parameters (*c*tHb, sO_2, FO_2Hb, *F*COHb, *F*MetHb, *F*HHb, *F*HbF) and *c*tBil were tested for interference are given in the table below:

(SAT100 blood reference test sample: *c*tHb = 15 g/dL, sO_2 = 100 %, *F*COHb = 0.7%, *F*MetHb = 0.5%, *c*tBil = 0, pH = 7.4. Parameter sensitivity from the influence on the absorbance spectrum from various substances.)

	Level	***c*tHb g/dL**	***s*O₂ %**	***F*O₂Hb %**	***F*COHb %**	***F*MetHb %**	***F*HHb %**	***F*HbF %**	***c*tBil µmol/L**
		Limit for clinical relevance.....							
		0.5 g/dL	1%	1%	1%	1%	1%	20%	30 µmol/L
pH	6.85	<|0.5|	<|1%|	**-1.1**	<|1%|	<|1%|	<|1%|	**ND**	<|30|
	7.15	<|0.5|	<|1%|	<|1%|	<|1%|	<|1%|	<|1%|	**ND**	<|30|
	7.4	Reference pH							
	8	<|0.5|	<|1%|	<|1%|	<|1%|	<|1%|	<|1%|	**22**	<|30|
Fluorescein	250 mg/L	**1.34**	**-3.2**	**-9.6**	**-4.1**	**10.7**	**2.9**	**ND**	**-1115**
beta-carotene*)	3.7 µmol/L	<|0.5|	<|1%|	<|1%|	<|1%|	<|1%|	<|1%|	<|20%|	<|30|
Patent Blue V	10 mg/L	<|0.5|	<|1%|	**2.2**	<|1%|	<|1%|	<|1%|	**ND**	<|30|
Methylene Blue	10 mg/L	**-0.66**	<|1%|	**5.3**	<|1%|	**-4.5**	<|1%|	**ND**	**-57**
	30 mg/L	**-2.14**	**3.0**	**19.5**	<|1%|	**-16.0**	**-3.3**	**ND**	**-161**
	60 mg/L	**-3.99**	**4.8**	**40.5**	**-2.7**	**-31.5**	**-6.3**	**ND**	**-282**
Cardio Green	7 mg/L	<|0.5|	<|1%|	<|1%|	<|1%|	<|1%|	<|1%|	<|20%|	<|30|
	30 mg/L	<|0.5|	<|1%|	**2.2**	<|1%|	**-1.7**	<|1%|	**ND**	<|30|
Evans Blue	5 mg/L	<|0.5|	<|1%|	<|1%|	<|1%|	<|1%|	<|1%|	<|20%|	<|30|
Intralipid	2% (200 mg/dL)	<|0.5|	<|1%|	<|1%|	<|1%|	<|1%|	<|1%|	<|20%|	<|30|
	5% (1000 mg/dL)	<|0.5|	<|1%|	<|1%|	<|1%|	<|1%|	<|1%|	<|20%|	<|30|
HiCN	30%	**1.90**	**-14.1**	**-40.6**	**6.7**	**24.1**	**9.8**	**ND**	**895**
SHb	20%	**-2.17**	<|1%|	<|1%|	<|1%|	<|1%|	<|1%|	**ND**	<|30|
	50%	**-4.69**	**1.8**	**-4.6**	<|1%|	**6.4**	**-1.7**	**ND**	**119**
Bilirubin (unconj)	500 µmol/L	<|0.5|	<|1%|	<|1%|	<|1%|	<|1%|	<|1%|	<|20%|	**524**
Bilirubin (conj)	400 µmol/L	<|0.5|	<|1%|	<|1%|	<|1%|	<|1%|	<|1%|	<|20%|	**377**
Hydroxocoba-lamin	2 g/L	**2.43**	<|1%|	**-16.0**	**2.6**	**12.7**	<|1%|	**ND**	**-87**
	0.8 g/L	**1.10**	<|1%|	**-7.3**	**1.1**	**5.9**	<|1%|	<|20%|	**-37**
	0.4 g/L	**0.53**	<|1%|	**-4.0**	<|1%|	**3.4**	<|1%|	<|20%|	<|30|
	0.2 g/L	<|0.5|	<|1%|	**-2.4**	<|1%|	**1.8**	<|1%|	<|20%|	<|30|

	Level	*c*tHb g/dL	sO_2 %	FO_2Hb %	*F*COHb %	*F*MetHb %	*F*HHb %	*F*HbF %	*c*tBil µmol/L
		Limit for clinical relevance…..							
		0.5 g/dL	1%	1%	1%	1%	1%	20%	30 µmol/L
Cyanocobalamin	2 g/L	**2.35**	**-4.1**	**-16.4**	**2.9**	**9.9**	**3.5**	**ND**	<|30|
	0.8 g/L	**1.19**	**-2.1**	**-8.8**	**1.6**	**5.3**	**1.9**	<|20%|	<|30|
	0.4 g/L	**0.71**	**-1.2**	**-5.2**	<|1%|	**3.2**	**1.2**	<|20%|	<|30|
	0.2 g/L	<|0.5|	<|1%|	**-2.2**	<|1%|	**1.4**	<|1%|	<|20%|	<|30|

* Interference calculated from spectrum

ND: Not displayed

Numbers/text in **bold**: Exceeds limits for clinical relevance

_F_HbF sensitivity for pH changes

*F*HbF is sensitive to pH deviations from the nominal value of pH = 7.4. If pH is converted into cH^+ (hydrogen ion concentration), the relationship between the changes in cH^+ and *F*HbF is linear as seen from the following equation:

$$\Delta F\text{HbF} = -0.51\%/(\text{nmol/L}) \times (cH^+ - 40\ \text{nmol/L})$$

pH	Δ*F*HbF %
7.15	-15.8
7.25	-8.2
7.4	0
7.5	4.1
7.6	7.7

_c_tBil sensitivity for MCHC variations

MCHC (Mean Corpuscular Hemoglobin Concentration) is used to estimate hematocrit, Hct, which is used in the *c*tBil measurement. MCHC is an average Hb concentration in the red blood cell (RBC). If the RBC volume decreases, MCHC increases. If an RBC has iron deficit, MCHC decreases.

Hct is determined from *c*tHb as follows:

$$\text{Hct} = \frac{c\text{tHb}}{\text{MCHC}}$$

A standard value of 332 g/L is assumed for MCHC which gives

Hct = *c*tHb × 0.0301 if the unit for *c*tHb is g/dL.

MCHC can, however, deviate from this standard value as illustrated in the following table (see the next page).

Erythrocytometric values given for “apparently healthy” white and black subjects of different ages are taken from: “Geigy Scientific Tables, Physical Chemistry, Composition of Blood, Hematology, Somametric Data”, CIBA-GEIGY, 1984; 3, 207.

Subjects	Age	Hct mean	Hct 95 % range	MCHC mean, g/L	MCHC 95 % range, g/L
Men	Adults	0.47	0.39-0.55	340	310-370
Women	Adults	0.42	0.36-0.48	330	300-360
Boys	Newborn	0.59	0.53-0.65	330	320-340
	1 month	0.50	0.44-0.56	320	310-330
	3 months	0.45	0.39-0.52	330	320-340
	6 months	0.46	0.39-0.51	300	290-310
	9 months	0.45	0.39-0.52	280	270-300
	1 year	0.41	0.37-0.45	290	280-300
	2 years	0.40	0.36-0.47	300	280-310
	4 years	0.37	0.30-0.44	280	270-290
	8 years	0.41	0.37-0.45	290	280-300
	14 years	0.41	0.36-0.46	300	290-310
Girls	Newborn	0.58	0.51-0.65	340	330-350
	1 month	0.49	0.42-0.56	320	310-330
	3 months	0.44	0.39-0.51	330	320-340
	6 months	0.44	0.39-0.50	320	310-330
	9 months	0.43	0.37-0.50	300	290-310
	1 year	0.43	0.37-0.49	300	290-310
	2 years	0.43	0.36-0.50	300	290-310
	4 years	0.43	0.36-0.51	280	270-290
	8 years	0.40	0.36-0.46	280	270-290
	14 years	0.40	0.36-0.47	290	280-300

If ΔMCHC is defined as ΔMCHC = 332 g/L – MCHC, then the contribution to the relative error on the *c*tBil measurement is as follows:

$$\frac{\Delta c\text{tBil}}{c\text{tBil}} = -\frac{\text{Hct}}{1-\text{Hct}} \times \frac{\Delta\text{MCHC}}{\text{MCHC}}$$

A worst-case example, using 95 % confidence values:

A newborn girl with Hct = 0.58, MCHC = 350 g/L and *c*tBil = 400 μmol/L. *c*tHb may be derived as Hct × MCHC = 0.58 x 350 g/L = 20.3 g/dL (reference range is 18.0 – 21.0 g/dL).

$$\frac{\Delta c\text{tBil}}{c\text{tBil}} = -\frac{0.58}{1-0.58} \times \frac{-18}{350} = +0.071$$ And Δ*c*tBil = 0.071 x 400 = 28 μmol/L.

If the reference value for Hct is known, it is possible to correct the displayed *c*tBil value, using the following equation:

$$c\text{tBil(corrected)} = c\text{tBil(displayed)} \times \frac{1 - c\text{tHb(displayed)} \times 0.0301}{1 - \text{Hct(reference)}}$$

*c*tHb is measured in g/dL.

*c*tBil is slightly sensitive to pH deviations from the nominal value of pH = 7.4.

General reference: [Ref. 12]

Anticoagulants (sampling)

Anticoagulants containing sodium salts give erroneously high cNa^+ results. Sodium fluoride with or without EDTA and oxalate (disodium) affects *c*Glu results. Sodium fluoride gives erroneously high cNa^+ and low cCa^{2+}, *c*Glu and *c*Lac results. Trisodium citrate affects cNa^+, cK^+ and *c*Glu results.

Radiometer, therefore, recommends the use of heparin as the only anticoagulant.

⚠	**WARNING - *Risk of erroneous results*** 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.

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8. Parameters

General information

The Deep Picture

The Deep Picture developed by Radiometer [1] (visit our website www.deep-picture.com) expands traditional pH and blood gas analysis by evaluating the capability of arterial blood to carry sufficient oxygen to tissues and to release it. It simplifies interpretation by dividing the process into three stages:

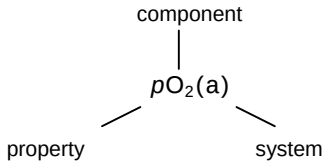
Stage	Description
Oxygen uptake	Oxygen uptake in the lungs indicates whether the pulmonary gas exchange is efficient enough to oxygenate arterial blood. The uptake of oxygen in the lungs can be described by parameters in combination, primarily the arterial oxygen tension (pO_2(a)), fraction of O_2 in dry inspired air (FO_2(I)) and shunt fraction of perfused blood ($\dot{Q}_s/\dot{Q}_t$) However, other parameters may also be used, such as the difference in alveolar air and arterial blood oxygen tension (pO_2(A-a)).
Oxygen transport	Oxygen transport reveals if arterial blood contains sufficient oxygen. The oxygen concentration of arterial blood (ctO_2(a)) also termed oxygen content is determined by the concentration of total hemoglobin (ctHb(a)), the fraction of oxygenated hemoglobin (FO_2Hb(a)) and the arterial oxygen tension (pO_2(a)). Other parameters that should be known are the oxygen saturation (sO_2 (a)) and the fractions of dyshemoglobins (FCOHb(a) and FMetHb(a)).
Oxygen release	Oxygen release describes the ability of arterial blood to release oxygen to the tissues. The release of oxygen from capillaries to tissues is determined by the oxygen tension gradient between the two. This release of oxygen is also influenced by the hemoglobin-oxygen affinity, which is indicated by the oxygen tension at 50 % saturation, p50.

Symbols

The symbols for the parameters are based on the principles described by Wandrup [2]. Each symbol consists of three parts, described below:

1. *Property*	A symbol in italics describing the quantity	*p* for pressure *c* for concentration *F* for fraction *V* for volume etc.
2. Component	An abbreviation of the component name	O_2 for oxygen CO_2 for carbon dioxide COHb for carboxyhemoglobin etc.
3. (System)	Specification of the system	B for blood P for plasma a for arterial blood $\bar{v}$ for mixed venous blood A for alveolar air *T* for patient temperature

Example:



The parameters are listed by symbol in three groups: measured, input and derived.

Ranges and limits

The following ranges are used:

Range	Description
Indication	The *range of indication* for a parameter is the range within which the analyzer is physically capable of measuring.
Reportable	Is user-defined; is equal to or narrower than the range of indication. Can be selected for all measured and derived parameters. Reportable range is the range of results from a testing system or method over which a specified analytical performance is claimed.
Reference	"Reference ranges are valuable guidelines for the clinician, but they should not be regarded as absolute indicators of health and disease. Reference ranges should be used with caution since values for 'healthy' individuals often overlap significantly with values for persons afflicted with disease. In addition, laboratory values may vary significantly due to methodological differences and mode of standardization" [10]. Ref. 10 has been the source for the reference ranges given in this section. In some cases the values are taken from other sources marked by their reference number. When possible, the reference ranges for arterial blood have been listed. Reference ranges must be used with caution as they depend on a number of factors, such as sex, age and normal physiological condition.

Critical limits are user-defined and can be entered into the analyzer software – see section *Reference ranges and critical limits* in chapter 1.

Derived parameters

Derived parameters are calculated according to the equations stated.

If...	Then...
the required measured or input values are unknown	default values are used, unless a measured parameter does not have a value or is outside the range of indication.
all values are known	the derived parameter is designated *calculated* and a "c" is added to the result.
a default value is used	the derived parameter is designated *estimated* and an "e" is added to the result.

If one or more default values have been used in the calculation, the result may deviate significantly from the true value. The deviation on "estimated" oxygen status parameters might become particularly significant if default values are used instead of measured blood oximetry data.

In some cases, however, the default value is not accepted as the input for the calculation. This is because the actual values of the missing parameter may deviate significantly from the default value, thus making the estimation clinically inappropriate. If sO_2 cannot be measured due to severe errors, it will be calculated.

Measured parameters Some of the listed parameters are measured, depending on the analyzer configuration. In these cases the equation given only applies if that parameter is *not* directly measured by the analyzer.

Sample type Unless otherwise stated, a parameter will be calculated or estimated irrespective of the choice on the **Patient Identification** screen: "Arterial", "Capillary", "Venous", "Mixed venous" or "Not specified". Some parameters, however, are defined for arterial samples only; they will be calculated only for sample types entered as "Arterial" or "Capillary".

The symbol for system (blood (B) or plasma (P)) is not stated in the equations unless it is important for the calculation.

Units The units given for each parameter refer to the units available on the analyzer for that parameter.

Default values The default values are listed in *Default values* at the end of this chapter.

Measured parameters

General information

The following is the used:

m =	male
f =	female
Reference range	For adult arterial blood
Reference	[10]
	(unless otherwise specified)

pH

Definition	Indicates the acidity or alkalinity of the sample.
Unit	-
Range of indication	6.300-8.000
Reference range	7.35-7.45 (m, f)

***c*H$^+$**

Definition	Concentration of hydrogen ions in blood.
Unit	nmol/L
Range of indication	10.0-501
Reference range	35.5-44.7 (m, f)

***p*CO$_2$**

Is used both for blood and expired-air samples.

Definition	Partial pressure (or tension) of carbon dioxide in blood. High and low pCO_2 values of arterial blood indicate blood hypercapnia and hypocapnia, respectively.
Unit	mmHg; kPa; Torr
Range of indication	mmHg; Torr: 5.0-250 kPa: 0.67-33.3
Reference range	mmHg: 35-48 (m); 32-45 (f) kPa: 4.67-6.40 (m); 4.27-6.00 (f)
Conversion of units	p(kPa) = 0.133322 × p(mmHg) = 0.133322 × p(Torr) p(mmHg) = p(Torr) = 7.500638 × p(kPa)

***p*O$_2$**	Is used for both blood and expired air samples.	
	Definition	Partial pressure (or tension) of oxygen in blood. High and low pO_2 values of arterial blood indicate blood hyperoxia and hypoxia, respectively.
	Unit	mmHg; kPa; Torr
	Range of indication	mmHg; Torr: 0.0-800 kPa: 0.00-107
	Reference range	mmHg: 83-108 (m, f) kPa: 11.07-14.40 (m, f)
	Conversion of units	p (kPa) = 0.133322 × p(mmHg) = 0.133322 × p(Torr) p(mmHg) = p(Torr) = 7.500638 × p(kPa)
Baro	Definition	Ambient barometric pressure (p(amb)).
	Unit	mmHg; kPa; Torr
	Range of indication	mmHg; Torr: 450-800 kPa: 60.0-106.7
	Reference range	-
	Conversion of units	p (kPa) = 0.133322 × p(mmHg) = 0.133322 × p(Torr) p(mmHg) = p(Torr) = 7.500638 × p(kPa)
***c*tHb**	Definition	Concentration of total hemoglobin in blood. Total hemoglobin includes all types of hemoglobin: deoxy-, oxy-, carboxy-, met-.
	Unit	g/dL; g/L; mmol/L
	Range of indication	g/dL: –0.48-27.7 g/L: –4.8-277 mmol/L: –0.30-17.2
	Reference range	g/dL: 13.5-17.5 (m); 12.0-16.0 (f) g/L: 135-175 (m); 120-160 (f) mmol/L: 8.4-10.9 (m); 7.4-9.9 (f)
	Conversion of units	*c*tHb (g/dL) = 1.61140 × *c*tHb (mmol/L); *c*tHb (g/L) = 16.1140 × *c*tHb (mmol/L); *c*tHb (mmol/L) = 0.62058 × *c*tHb (g/dL) = 0.062058 × *c*tHb (g/L)
	Default value	9.3087 mmol/L, (15.0 g/dL or 150 g/L)

sO_2 Can also be calculated: see *Derived parameters* eq. 39.

Definition	Oxygen saturation, the ratio between the concentrations of oxyhemoglobin and the hemoglobin minus the dyshemoglobins.
Unit	%; fraction
Range of indication	%: –2-102
	Fraction: –0.02-1.02
Reference range	%: 95-99 (m, f)
	Fraction: 0.95-0.99 (m, f)
Reference	[11]

FO_2Hb Can also be calculated: see *Derived parameters* eq. 40.

Definition	Fraction of oxyhemoglobin in total hemoglobin in blood.
Unit	%; fraction
Range of indication	%: –2-103
	Fraction: –0.02-1.03
Reference range	%: 94-98 (m, f)
	Fraction: 0.94-0.98 (m, f)

FCOHb

Definition	Fraction of carboxyhemoglobin in total hemoglobin in blood.
Unit	%; fraction
Range of indication	%: –2-103
	Fraction: –0.02-1.03
Reference range	%: 0.5-1.5 (m, f)
	Fraction: 0.005-0.015 (m, f)
Default value	0.004 (0.4 %)

FMetHb

Definition	Fraction of methemoglobin in total hemoglobin in blood.
Unit	%; fraction
Range of indication	%: –2-103
	Fraction: –0.02-1.03
Reference range	%: 0.0-1.5 (m, f)
	Fraction: 0.000-0.015 (m, f)
Default value	0.004 (0.4 %)

***F*HHb**	Can also be calculated: see *Derived parameters* eq. 41.	
	Definition	Fraction of deoxyhemoglobin in total hemoglobin in blood. Deoxyhemoglobin is the part of total hemoglobin which can bind oxygen forming oxyhemoglobin. It is also termed reduced hemoglobin, RHb.
	Unit	%; fraction
	Range of indication	%: –2-102 Fraction: –0.02-1.02
***F*HbF**	Definition	Fraction of fetal hemoglobin in total hemoglobin in blood.
	Unit	%; fraction
	Range of indication	%: –25-121 Fraction: –0.25-1.21
	Reference range (neonates)	%: ≈80 (m, f) Fraction: ≈0.80 (m, f)
***c*K^+**	Definition	Concentration of potassium ions in plasma.
	Unit	mmol/L; meq/L
	Range of indication	mmol/L; meq/L: 0.5-25.0
	Reference range	m, f: 3.4-4.5 mmol/L
	Conversion of units	mmol/L = meq/L
***c*Na^+**	Definition	Concentration of sodium ions in plasma.
	Unit	mmol/L; meq/L
	Range of indication	mmol/L; meq/L: 7-350
	Reference range	m, f; 136-146 mmol/L
	Conversion of units	mmol/L = meq/L
***c*Ca^{2+}**	Definition	Concentration of calcium ions in plasma.
	Unit	mmol/L; meq/L; mg/dL
	Range of indication	mmol/L: 0.2-9.99 meq/L: 0.4-19.98 mg/dL: 0.8-40.04
	Reference range	m, f: 1.15-1.29 mmol/L; 2.30-2.58 meq/L; 4.61-5.17 mg/dL
	Conversion of units	meq/L = 2 mmol/L mg/dL = 4.008 mmol/L
	Reference	[12]

***c*Cl$^-$**	Definition	Concentration of chloride ions in plasma.
	Unit	mmol/L; meq/L
	Range of indication	mmol/L; meq/L: 7-350
	Reference range	98-106 mmol/L (m, f)
	Conversion of units	mmol/L = meq/L
***c*Glu**	Definition	Concentration of D-glucose in plasma.
	Unit	mmol/L; mg/dL
	Range of indication	mmol/L: 0-60
		mg/dL: 0-1081
	Reference range	m, f: 3.89-5.83 mmol/L; 70-105 mg/dL
	Conversion of units	*c*Glucose (mg/dL) = 18.016 × *c*Glucose (mmol/L)
		*c*Glucose (mmol/L) = 0.055506 × *c*Glucose (mg/dL)
***c*Lac**	Definition	Concentration of L-lactate in plasma.
	Unit	mmol/L; meq/L; mg/dL
	Range of indication	mmol/L: –0.1-31
		meq/L: –0.1-31
		mg/dL: –1-279
	Reference range	m, f: 0.5-1.6 mmol/L; 4.5-14.4 mg/dL
	Conversion of units	*c*Lactate (mg/dL) = 9.008 × *c*Lactate (mmol/L)
		*c*Lactate (mmol/L) = 0.11101 × *c*Lactate (mg/dL)
		(conversion based on the molecular weight of lactic acid)
***c*tBil**	Definition	Concentration of total bilirubin in plasma.
		Total bilirubin includes its two forms: conjugated and unconjugated.
	Unit	µmol/L; mg/dL; mg/L
	Range of indication	µmol/L: –20-1000
		mg/dL: –1.2-58.5
		mg/L: –12-585
	Reference range	See the table on the next page.
	Conversion of units	*c*tBil (µmol/L) = 17.1 × *c*tBil (mg/dL)
		*c*tBil (µmol/L) = 1.71 × *c*tBil (mg/L)
		*c*tBil (mg/dL) = 0.0585 × *c*tBil (µmol/L)
		*c*tBil (mg/L) = 0.585 × *c*tBil (µmol/L)

The reference ranges are as follows:

Age	*c*tBil
≤24 hrs, premature	103-205 µmol/L 1.0-8.0 mg/dL 10-80 mg/L
≤24 hrs, full-term	34-103 µmol/L 2.0-6.0 mg/dL 20-60 mg/L
≤48 hrs, premature	103-205 µmol/L 6-12 mg/dL 60-120 mg/L
≤48 hrs	103-171 µmol/L 6-10 mg/dL 60-100 mg/L
3-5 days, premature	171-239 µmol/L 10-14 mg/dL 100-140 mg/L
3-5 days, full-term	68-137 µmol/L 4-8 mg/dL 40-80 mg/L
>1 month	3.4-17 µmol/L 0.2-1.0 mg/dL 2-10 mg/L

The following table shows the possible ranges and precision (number of decimals) of the measured parameters.

These ranges can be narrowed by calculation ranges, reportable ranges, range of indication, etc., but should be taken into consideration when external systems are interfaced to the analyzer.

Symbol	Unit	Numerical format within the following ranges:					
		Range				Range	
pH	-	4.000		11.000			
cH^+	nmol/L	-999999.0		199.9		200	9999999
pCO_2	mmHg	0.0		99.9		100	750
	kPa	0.00		9.99		10.0	100.0
pO_2	mmHg	0.0		99.9		100	2250
	kPa	0.0	9.99	10.0	99.9	100	300
Baro	mmHg	98		1500			
	kPa	13.0		200.0			
*c*tHb	g/dL	-0.81		0.99		1.0	80.6
	g/L	-8.1		9.9		10	806
	mmol/L	-0.50		0.99		1.0	50.0
sO_2	%	-1000.0		1000.0			
	fraction	-10.000		10.000			

Symbol	Unit	Numerical format within the following ranges:			
		Range		Range	
FO_2Hb	%	-1000.0	1000.0		
	fraction	-10.000	10.000		
*F*COHb	%	-1000.0	1000.0		
	fraction	-10.000	10.000		
*F*MetHb	%	-1000.0	1000.0		
	fraction	-10.000	10.000		
*F*HHb	%	-1000.0	1000.0		
	fraction	-10.000	10.000		
*F*HbF	%	-100	200		
	fraction	-1.00	2.00		
cK^+	mmol/L	0.0	100.0		
	meq/L	0.0	100.0		
cNa^+	mmol/L	0	1500		
	meq/L	0	1500		
cCa^{2+}	mmol/L	0.00	50.00		
	meq/L	0.00	100.00		
	mg/dL	0.00	200.40		
cCl^-	mmol/L	0	1000		
	meq/L	0	1000		
*c*Glu	mmol/L	-1.0	24.9	25	150
	mg/dL	-18	2702		
*c*Lac	mmol/L	-1.0	14.9	15	100
	meq/L	-1.0	14.9	15	100
	mg/dL	-9	901		
*c*tBil	mg/dL	-5.8	292.3		
	micromol/L	-100	5000		
	mg/L	-58	2923		

Input parameters

Definition Input parameters are the parameters keyed in by the operator on the **Patient Identification** screen or transferred from an interfaced database.

All input parameters are given in this section.

T	Definition	Patient temperature.
	Unit	°C; °F
	Input range	°C: 15.0-45.0 °F: 59-113
	Conversion	T °F = $\frac{9}{5}T\ ^{o}C + 32$; T °C = $\frac{5}{9}(T\ ^{o}F - 32)$
***F*O$_2$(I)**	Definition	Fraction of oxygen in dry inspired air.
	Unit	%; fraction
	Input range	%: 0-100 fraction: 0.000-1.000
	Reference range	35.5-44.7 (m, f)
***c*tHb**	Is used if the analyzer version does not include the oximetry measuring system.	
	Definition	Concentration of total hemoglobin in blood.
	Input range /Unit	g/dL: 0.0-33.0 g/L: 0-330 mmol/L: 0.0-20.5
	Conversion	*c*tHb (g/dL) = 1.61140 × *c*tHb (mmol/L); *c*tHb (g/L) = 16.1140 × *c*tHb (mmol/L); *c*tHb (mmol/L) = 0.62058 × *c*tHb (g/dL) = 0.062058 × *c*tHb (g/L)
RQ	Definition	Respiratory quotient, ratio between the CO_2 production and the O_2 consumption.
	Input range	0.00-2.00
***p*O$_2$($\bar{v}$)**	Definition	Oxygen tension of mixed venous blood.
	Input range/Unit	mmHg; Torr: 0.0-750.0 kPa: 0.00-100
	Conversion	*p*(kPa) = 0.133322 × *p*(mmHg) *p*(mmHg) = 7.500638 × *p*(kPa)

$sO_2(\bar{v})$	Definition	Oxygen saturation of mixed venous blood.
	Input range/Unit	%: 0.0-100.0 fraction: 0.000-1.000
$\dot{Q}_t$	Definition	Cardiac output; volume of blood delivered from the left ventricle into the aorta per unit of time. Also termed CO or C.O.
	Input range/Unit	0.0-100.0 L/min
$\dot{V}O_2$	Definition	Oxygen consumption; total amount of oxygen utilized by the whole organism per unit of time.
	Input range/Unit	mL/min: 0-21000 mmol/min: 0.0-937.1
	Conversion	mmol/min = (mL/min)/22.41
***V*CO**	Definition	Volume of carbon monoxide added to the patient for measurement and calculation of *V*(B) [5].
	Input range/Unit	0.0-1000.0 mL
***F*COHb(1)**	Definition	The fraction of COHb measured before the CO-injection.
	Input range/Unit	%: 0.0-100.0 fraction: 0.000-1.000
***F*COHb(2)**	Definition	The fraction of COHb measured after the CO-injection.
	Input range/Unit	%: 0.0-100.0 fraction: 0.000-1.000

Derived parameters

General information

In the **Type** column the following symbols are used:

- ms for measured parameters
- dv for derived parameters
- in for input parameters

Acid-base derived parameters

Symbol	Definition	Type	Eq.
pH(*T*)	pH of blood at patient temperature.	dv	**1**
$cH^+(T)$	Concentration of hydrogen ions in blood at patient temperature.	dv	**2**
$pCO_2(T)$	Partial pressure (or tension) of carbon dioxide at patient temperature.	dv	**3**
$cHCO_3^-$(P)	Concentration of hydrogen carbonate in plasma (also termed actual bicarbonate).	dv	**4**
*c*Base(B) or ABE	Actual Base Excess, the concentration of titrable base when the blood is titrated with a strong base or acid to a plasma pH of 7.40, at pCO_2 of 5.33 kPa (40 mmHg) and 37 °C, at the actual oxygen saturation [4,5,24]. Positive values (base excess) indicate a relative deficit of non-carbonic acids; negative values (base deficit) indicate a relative excess of non-carbonic acids.	dv	**5**
*c*Base(B,ox)	*c*Base(B) of fully oxygenated blood.	dv	**6**
*c*Base(Ecf) or SBE	Standard Base Excess, an *in vivo* expression of base excess [5,6,24]. It refers to a model of the extracellular fluid (one part of blood is diluted by two parts of its own plasma) and is calculated using a standard value for the hemoglobin concentration of the total extracellular fluid.	dv	**7**
*c*Base(Ecf,ox)	*c*Base(Ecf) of fully oxygenated blood.	dv	**8**
$cHCO_3^-$(P,st)	Standard Bicarbonate, the concentration of hydrogen carbonate in the plasma from blood that is equilibrated with a gas mixture with pCO_2 = 5.33 kPa (40 mmHg) and $pO_2 \geq$ 13.33 kPa (100 mmHg) at 37 °C [4,5].	dv	**9**
$ctCO_2$(P)	Concentration of total carbon dioxide, (free CO_2 + bound CO_2) in plasma.	dv	**10**
$ctCO_2$(B)	Concentration of total carbon dioxide in whole blood (also termed CO_2 content). Calculated based on the total CO_2 concentrations in the two phases: plasma and erythrocyte fluid [5].	dv	**11**

Symbol	Definition	Type	Eq.
pH(st)	Standard pH (or eucapnic pH), defined as the pH of plasma of blood equilibrated to pCO_2 = 5.33 kPa (40 mmHg). By ensuring the normal value of pCO_2, the respiratory influence from pH is removed, and pH(P,st) therefore reflects the metabolic status of the blood plasma.	dv	**12**
VCO_2/V(dry air)	The volume fraction of carbon dioxide in dry air.	dv	**51**

Oximetry derived parameters

Symbol	Definition	Type	Eq.
*F*HHb	Fraction of deoxyhemoglobin in total hemoglobin in blood. Deoxyhemoglobin is the part of total hemoglobin which can bind oxygen, forming oxyhemoglobin. It is also termed reduced hemoglobin, RHb.	ms/dv	**41**
FO_2Hb	Fraction of oxyhemoglobin in total hemoglobin in blood.	ms/dv	**40**
sO_2	Oxygen saturation, the ratio between the concentrations of oxyhemoglobin and the hemoglobin minus the dyshemoglobins.	ms/dv	**39**
Hct	Hematocrit, the ratio between the volume of erythrocytes and the volume of whole blood.	dv	**13**

Oxygen derived parameters

Symbol	Definition	Type	Eq.
$pO_2(T)$	Partial pressure (or tension) of oxygen at patient temperature.	dv	**14**
pO_2(A)	Partial pressure (or tension) of oxygen in alveolar air.	dv	**15**
pO_2 (A,*T*)	Partial pressure (or tension) of oxygen in alveolar air at patient temperature.	dv	**16**
pO_2(a)/ FO_2(I)	Oxygen tension ratio of arterial blood and the fraction of oxygen in dry inspired air	dv	**17**
pO_2(a,*T*)/ FO_2(I)	Oxygen tension ratio of arterial blood at patient temperature and the fraction of oxygen in dry inspired air	dv	**18**
*p*50	Partial pressure (or tension) of oxygen at half saturation (50 %) in blood. High and low values indicate decreased and increased affinity of oxygen to hemoglobin, respectively.	dv	**19**
*p*50(*T*)	Partial pressure (or tension) of oxygen at half saturation (50 %) in blood at patient temperature.	dv	**20**

Symbol	Definition	Type	Eq.
*p*50(st)	Partial pressure (or tension) of oxygen at half saturation (50 %) in blood at standard conditions: temperature = 37 °C pH = 7.40 pCO_2 = 5.33 kPa *F*COHb, *F*MetHb, *F*HbF set to 0 *p*50(st) may, however, vary due to variations in 2,3-DPG concentration or to the presence of abnormal hemoglobins.	dv	**21**
pO_2(A–a)	Difference in the partial pressure (or tension) of oxygen in alveolar air and arterial blood. Indicates the efficacy of the oxygenation process in the lungs.	dv	**22**
pO_2(A–a,*T*)	Difference in the partial pressure (or tension) of oxygen in alveolar air and arterial blood at patient temperature.	dv	**23**
pO_2(a/A)	Ratio of the partial pressure (or tension) of oxygen in arterial blood and alveolar air. Indicates the efficacy of the oxygenation process in the lungs.	dv	**24**
pO_2(a/A,*T*)	Ratio of the partial pressure (or tension) of oxygen in arterial blood and alveolar air at patient temperature.	dv	**25**
pO_2(x) or p_x	Oxygen extraction tension of arterial blood. Reflects the integrated effects of changes in the arterial pO_2(a), ctO_2 and *p*50 on the ability of arterial blood to release O_2 to the tissues [8].	dv	**26**
pO_2(x,*T*) or p_x(*T*)	Oxygen extraction tension of arterial blood at patient temperature.	dv	**50**
ctO_2(B)	Total oxygen concentration of blood. Also termed O_2 content.	dv	**27**
$ctO_2(a-\bar{v})$	Oxygen concentration difference between arterial and mixed venous blood.	dv	**28**
BO_2	Hemoglobin oxygen capacity; the maximum concentration of oxygen bound to hemoglobin in blood saturated, so that all deoxyhemoglobin is converted to oxyhemoglobin.	dv	**29**
ctO_2(x)	Extractable oxygen concentration of arterial blood. Defined as the amount of O_2 that can be extracted per liter of arterial blood at an oxygen tension of 5.0 kPa (38 mmHg), maintaining constant pH and pCO_2 [8].	dv	**30**
$\dot{D}O_2$	Oxygen delivery; the total amount of oxygen delivered to the whole organism per unit of time.	dv	**31**

Symbol	Definition	Type	Eq.
$\dot{Q}_t$	Cardiac output; volume of blood delivered from the left ventricle into the aorta per unit of time. Also termed CO or C.O.	dv/in	**32**
$\dot{V}O_2$	Oxygen consumption; total amount of oxygen utilized by the whole organism per unit of time.	dv/in	**33**
$FO_2(I)$	Fraction of oxygen in dry inspired air.	in	
*F*Shunt	Relative physiological shunt or concentration-based shunt [5,8,9]. • Calculated from the pulmonary shunt equation: $\frac{\dot{Q}_s}{\dot{Q}_t} = \frac{1}{1 + \frac{ctO_2(a-\bar{v})}{ctO_2(A) - ctO_2(a)}}$ if both arterial and mixed venous blood samples are used. • May be estimated from one arterial sample by assuming a constant difference in the concentrations of total oxygen in arterial and mixed venous blood: $ctO_2(a-\bar{v}) = 2.3$ mmol/L (5.15 mL/dL)	dv	**34**
*F*Shunt (*T*)	*F*Shunt at patient temperature.	dv	**35**
RI	Respiratory Index; ratio between the oxygen tension difference of alveolar air and arterial blood and the oxygen tension of arterial blood.	dv	**36**
RI(*T*)	Respiratory Index; ratio between the oxygen tension difference of alveolar air and arterial blood and the oxygen tension of arterial blood at patient temperature.	dv	**37**
VO_2/V(dry air)	Volume fraction of oxygen in dry air.	dv	**52**
Q_x	Cardiac oxygen compensation factor of arterial blood defined as the factor by which the cardiac output should increase to allow release of 2.3 mmol/L (5.1 mL/dL) oxygen at a mixed venous pO_2 of 5.0 kPa (38 mmHg) [5,8].	dv	**38**
V(B)	Volume of blood, calculated when *F*COHb and *V*(CO) values are keyed in [5].	dv	**42**

Units and numerical format of derived parameters

Calculated versus estimated parameters

Derived parameters are calculated or estimated on the basis of measured and keyed-in data. Calculations are made using equations programmed into the analyzer. The accuracy of the calculations depends on the input parameters keyed into the analyzer's computer.

If the calculation of a parameter requires input from the operator, but this input is not forthcoming, the analyzer will use certain default values (refer to the section *Default values* in this chapter).

Not all input parameters are stored as defaults. In these instances the dependent derived parameter will not be reported if the relevant input parameter(s) is/are *not* entered.

If the default values are used in the calculation of a parameter, then a parameter is considered *estimated* ("e") rather than *calculated* ("c").

Electrolyte parameters

The table below lists the electrolyte derived parameters for the analyzers.

Symbol	Unit	Analyzer	Input parameter	Sample type
Anion Gap, K^+	meq/L, mmol/L	c[2)]		
Anion Gap	meq/L, mmol/L	c[3)]		
$cCa^{2+}(7.4)$	meq/L, mg/dL, mmol/L	c[4)]		
*m*Osm	mmol/kg	c[5)]		

2) If the analyzer includes K^+, Na^+ and Cl^- measurements.

3) If the analyzer includes Na^+ and Cl^- measurements.

4) If the analyzer includes Ca^{2+} measurement.

5) If the analyzer includes Na^+ and Glucose measurements.

Possible ranges and precision (number of decimals)

The following table shows the possible ranges and precision (number of decimals) of the measured parameters. These ranges can be narrowed by calculation ranges, reportable ranges, range of indication, etc., but should be taken into consideration when external systems are interfaced to the analyzer.

Symbol	Unit	Numerical format within the following ranges:			
		Range		Range	
pH(*T*)	-	4.000	11.000		
$cH^+(T)$	nmol/L	-999999.0	199.9	200	9999999
$pCO_2(T)$	mmHg	0.0	99.9	100	750
	kPa	0.00	9.99	10.0	100.0
$cHCO_3^-$(P)	mmol/L	0.0	100.0		
*c*Base(B)	mmol/L	-50.0	50.0		
*c*Base(B,ox)	mmol/L	-100.0	100.0		
*c*Base(Ecf)	mmol/L	-50.0	50.0		
*c*Base(Ecf,ox)	mmol/L	-100.0	100.0		
$cHCO_3^-$(P,st)	mmol/L	0.0	150.0		
$ctCO_2$(P)	mmol/L	0.0	100.0		
	Vol %	0.0	224.1		
	mL/dL	0.0	224.1		
$ctCO_2$(B)	mmol/L	0.0	100.0		
	Vol %	0.0	224.1		
	mL/dL	0.0	224.1		
pH(st)	-	4.000	11.000		
VCO_2/V(dry air)	%	-10.0	110.0		
	fraction	-0.100	1.100		
Hct	%	-10.0	110.0		
	fraction	-0.100	1.100		
$pO_2(T)$	mmHg	0.0	99.9	100	750
	kPa	0.00	9.99	10.0	100.0
pO_2(A)	mmHg	0.0	750.1		
	kPa	0.00	100.00		
pO_2(A,*T*)	mmHg	0.0	750.1		
	kPa	0.00	100.00		
*p*50	mmHg	0.00	750.06		
	kPa	0.00	100.00		
*p*50(*T*)	mmHg	0.00	750.06		
	kPa	0.00	100.00		
*p*50(st)	mmHg	0.00	750.06		
	kPa	0.00	100.00		

Symbol	Unit	Numerical format within the following ranges			
		Range		Range	
pO_2(A–a)	mmHg	0.0	750.1		
	kPa	0.00	100.00		
pO_2(A–a,*T*)	mmHg	0.0	750.1		
	kPa	0.00	100.00		
pO_2(a/A)	%	0.0	10000.0		
	fraction	0.000	100.000		
pO_2(a/A, *T*)	%	0.0	10000.0		
	fraction	0.000	100.000		
pO_2(a)/FO_2(I)	mmHg	0.0	99.9	100	7501
	kPa	0.00	9.99	10.0	1000.0
pO_2(a,*T*)/ FO_2(I)	mmHg	0.0	99.9	100	7501
	kPa	0.00	9.99	10.0	1000.0
pO_2(x)	mmHg	0.0	750.1		
	kPa	0.00	100.00		
pO_2(x,*T*)	mmHg	0.0	750.1		
	kPa	0.00	100.00		
ctO_2(B)	mmol/L	0.0	100.0		
	Vol %	0.0	224.1		
	mL/dL	0.0	224.1		
ctO_2(a–$\bar{v}$)	mmol/L	0.0	100.0		
	Vol %	0.0	224.1		
	mL/dL	0.0	224.1		
BO_2	mmol/L	0.0	100.0		
	Vol %	0.0	224.1		
	mL/dL	0.0	224.1		
ctO_2(x)	mmol/L	0.0	100.0		
	Vol %	0.0	224.1		
	mL/dL	0.0	224.1		
$\dot{D}O_2$	mL/min	0	22414		
	mmol/min	0.0	1000.0		
$\dot{Q}_t$	L/min	0.0	100.0		
$\dot{V}O_2$	mL/min	0	22414		
	mmol/min	0.0	1000.0		

Symbol	Unit	Numerical format			
		Range		Range	
*F*Shunt	%	-10.0	110.0		
	fraction	-0.100	1.100		
*F*Shunt(*T*)	%	-10.0	110.0		
	fraction	-0.100	1.100		
RI	%	-10	999900		
	fraction	-0.10	9999.00		
RI(*T*)	%	-10	999900		
	fraction	-0.10	9999.00		
Q_x	fraction	-0.10	10.0		
VO_2/V(dry air)	%	-10.0	1.100		
	fraction	-0.100	1.100		
V(B)	L	0.0	20.0		
Anion Gap, K^+	mmol/L	-500.0	500.0		
	meq/L	-500.0	500.0		
Anion Gap	mmol/L	-500.0	500.0		
	meq/L	-500.0	500.0		
cCa^{2+}(7.4)	mmol/L	0.00	50.00		
	meq/L	0.00	100.00		
	mg/dL	0.00	200.40		
*m*Osm	mmol/kg	-0.7	3150.0		

List of equations

Units and symbols

All definitions and equations are based on SI units. If "T" for patient temperature is not stated, the calculation is based on a temperature of 37.0 °C.

The following SI units are used:

concentration in mmol/L

temperature in °C

pressure in kPa

fractions (not %)

The following symbols are used in the equations:

$\log(x) = \log_{10}(x)$

$\ln(x) = \log_e(x)$

pH(*T*)

Eq. 1 [13]:

$$pH(T) = pH(37) - \left[0.0147 + 0.0065 \times \left(pH(37) - 7.40\right)\right]\left[T - 37\right]$$

NOTICE: The formula is different from previous Radiometer analyzers. The constant 0.0146 is now changed to 0.0147, to be in accordance with NCCLS (CLSI)-approved guidelines [24].

The change corresponds to –0.1 mpH/°C.

$cH^+(T)$

Eq. 2:

$$cH^+(T) = 10^{(9 - pH\ (T))}$$

$pCO_2(T)$

Eq. 3 [4]:

$$pCO_2(T) = pCO_2(37) \times 10^{\left[0.019 \times (T - 37)\right]}$$

NOTICE: The formula is different from previous Radiometer analyzers. The constant 0.021 is now changed to 0.019, to be in accordance with NCCLS (CLSI)-approved guidelines [24].

The change corresponds to 2%/5 °C.

$cHCO_3^-(P)$

Eq. 4 [24]:

$$cHCO_3^-(P) = 0.23 \times pCO_2 \times 10^{(pH - pK_p)}$$

where

$pK_p = 6.095$

$cHCO_3^-(P)$ includes ions of hydrogen carbonate, carbonate and carbamate in the plasma.

NOTICE: The formula is different from previous Radiometer analyzers. The pK_p is now constant, to be in accordance with NCCLS (CLSI)-approved guidelines [24].

The change corresponds to 5% in the pH range 7-7.8.

cBase(B) **Eq. 5** [24]:

$$c\text{Base(B)} = (1 - 0.014c\text{tHb})(c\text{HCO}_3^-(\text{P}) - 24.8 + (1.43\ c\text{tHb} + 7.7)(\text{pH} - 7.4))$$

NOTICE: The formula is different from previous Radiometer analyzers. The calculation is done in accordance with NCCLS (CLSI)-approved guidelines [24].

However, since it is assumed that the previous method [14] is a better model, the previous range checks are retained (no values displayed outside ±50 mmol/L and values tagged with "?" outside the range of ±30 mmol/L).

The change corresponds to less than 0.6 mmol/L in the reference ranges for pH, $p\text{CO}_2$ and *c*tHb.

cBase(B,ox) **Eq. 6** [4]:

$$c\text{Base(B, ox)} = c\text{Base(B)} - 0.3062 \times c\text{tHb} \times (1 - s\text{O}_2)$$

If *c*tHb is not measured or keyed in, the default value will be used.

If $s\text{O}_2$ is not measured, it will be calculated from equation 39.

cBase(Ecf) **Eq. 7** [24]:

$$c\text{Base(Ecf)} = c\text{HCO}_3^-(\text{P}) - 24.8 + 16.2\ (\text{pH} - 7.4)$$

See NOTICE in Eq. 5

cBase(Ecf,ox) **Eq. 8**:

$$c\text{Base(Ecf,ox)} = c\text{Base(Ecf)} - 0.3062 \times 3 \times (1 - s\text{O}_2)$$

$c\text{HCO}_3^-$(P,st) **Eq. 9** [4,14]:

$$c\text{HCO}_3^-(\text{P,st}) = 24.47 + 0.919 \times Z + Z \times a' \times (Z - 8)$$

where

Eq.	Description
9.1	$a' = 4.04 \times 10^{-3} + 4.25 \times 10^{-4} \times c\text{tHb}$
9.2	$Z = c\text{Base(B)} - 0.3062 \times c\text{tHb} \times (1 - s\text{O}_2)$

$c\text{tCO}_2$(P) **Eq. 10** [4,5]:

$$c\text{tCO}_2(\text{P}) = 0.23 \times p\text{CO}_2 + c\text{HCO}_3^-(\text{P})$$

$ctCO_2(B)$ **Eq. 11** [5]:

$$ctCO_2(B) = 9.286 \times 10^{-3} \times pCO_2 \times ctHb \times \left[1 + 10^{(pH_{Ery} - pK_{Ery})}\right] + ctCO_2(P) \times \left(1 - \frac{ctHb}{21.0}\right)$$

where

Eq.	Description
11.1	$pH_{Ery} = 7.19 + 0.77 \times (pH - 7.40) + 0.035 \times (1 - sO_2)$
11.2	$pK_{Ery} = 6.095 - \log\left[1 + 10^{(pH_{Ery} - 7.84 - 0.06 \times sO_2)}\right]$

pH(st) **Eq. 12** [14]:

pH(st): see equations 5.3-5.5 below.

Eq.	Description
5.3	$pH(st) = pH + \log\left(\frac{5.33}{pCO_2}\right) \times \left(\frac{pH(Hb) - pH}{\log pCO_2(Hb) - \log(7.5006 pCO_2)}\right)$
5.4	$pH(Hb) = 4.06 \times 10^{-2} ctHb + 5.98 - 1.92 \times 10^{(-0.16169 ctHb)}$
5.5	$\log pCO_2(Hb) = -1.7674 \times 10^{-2} ctHb + 3.4046 + 2.12 \times 10^{(-0.15158 ctHb)}$

Hct **Eq. 13** [15]:

Hct = 0.04939×*c*tHb

Hct cannot be calculated on the basis of a default *c*tHb value.

NOTICE: The formula is different from the formula used in previous Radiometer analyzers. The previous formula Hct = 0.0485×*c*tHb+8.3×10^{-3} was changed to ensure that Hct=0 when *c*tHb=0. The slope was adjusted to make Hct identical for the two formulas when *c*tHb=9.3087 mmol/L.

The change corresponds to 1% in the *c*tHb range 6.3-12.3.

$pO_2(T)$ **Eq. 14** [16,17]:

The standard Oxygen Dissociation Curve (ODC) is used (i.e. *p*50(st) = 3.578 kPa) at actual values of pH, pCO_2, *F*COHb, *F*MetHb, *F*HbF (see equations 46-47 in the section *Oxyhemoglobin dissociation curve (ODC)* further in this chapter).

$pO_2(T)$ is calculated by a numerical method using:

$$t_i(T) = ctHb \times (1 - FCOHb - FMetHb) \times sO_{2,i}(T) + \alpha O_2(T) \times pO_{2,i}(T)$$

where

Eq.	Description	See...
14.1	S = ODC(P,A,*T*)	Eq. 47
14.2	$sO_{2,i}(T) = \frac{S \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$	Eq. 46.12
14.3	$pO_{2,i}(T) = \frac{P}{1 + \frac{FCOHb}{sO_{2,i}(T) \times (1 - FCOHb - FMetHb)}}$	Eq. 46.10
14.4	$\alpha O_2 = 0.0105 e^{\left[-1.15\times10^{-2}(T-37.0)+2.1\times10^{-4}\times(T-37.0)^2\right]}$	
14.5	P is the variable during iteration.	
14.6	$A = ac - 1.04 \times \frac{\partial pH}{\partial T} \times (T - 37.0)$	
14.7	*T*= patient temperature in °C (keyed-in).	
14.8	$\frac{\partial pH}{\partial (T)} = -1.47\times10^{-2} - 6.5\times10^{-3} \times (pH(37) - 7.40)$ When $t_i(T) = t_i(37.0)$, then $pO_{2,i}(T) = pO_2(T)$	

Changes in the equations for pH(*T*) and *c*tO_2 correspond to less than 0.5% of *p*O_2(*T*) in the reference range for pH, *p*CO_2, *p*O_2 and *c*tHb and *T* in the interval 32-42 °C, using *F*HbF = 0.5%.

***p*O₂(A)**

Eq. 15 [5]:

$$pO_2(A) = FO_2(I) \times (p(amb) - 6.275) - pCO_2 \times \left[RQ^{-1} - FO_2(I) \times (RQ^{-1} - 1)\right]$$

If *F*O_2(I) and RQ are not keyed in, they are set to the default values.

The calculation requires entering the sample type as "Arterial" or "Capillary".

***p*O₂(A,*T*)**

Eq. 16 [4,5,18]:

$$pO_2(A,T) = FO_2(I) \times [p(amb) - pH_2O(T)] - pCO_2(T) \times \left[RQ^{-1} - FO_2(I) \times (RQ^{-1} - 1)\right]$$

$$pH_2O(T) = 6.275 \times 10^{\left[2.36\times10^{-2}\times(T-37.0) - 9.6\times10^{-5}\times(T-37.0)^2\right]}$$

If *F*O_2(I) and RQ are not keyed in, they are set to the default values.

The calculation requires entering the sample type as "Arterial" or "Capillary".

***p*O₂(a)/*F*O₂(I)**

Eq. 17:

$$pO_2(a) / FO_2(I) = \frac{pO_2(a)}{FO_2(I)}$$

The calculation cannot be performed on the basis of the default *F*O_2(I) value, and the calculation requires entering the sample as "Arterial" or "Capillary".

***p*O$_2$(a,*T*) / *F*O$_2$(I)**

Eq. 18:

$$p\mathrm{O}_2(\mathrm{a},T) / F\mathrm{O}_2(\mathrm{I}) = \frac{p\mathrm{O}_2(\mathrm{a},T)}{F\mathrm{O}_2(\mathrm{I})}$$

The calculation cannot be performed on the basis of the default *F*O$_2$(I) value, and the calculation requires entering the sample as "Arterial" or "Capillary".

***p*50**

Eq. 19 Refer to Eq. 46.10:

The ODC is determined as described in equations 46-47 in the section *Oxyhemoglobin Dissociation Curve* further in this chapter.

$$p50 = \frac{\mathrm{P}}{1 + \frac{F\mathrm{COHb}}{0.5 \times (1 - F\mathrm{COHb} - F\mathrm{MetHb})}}$$

where

Description	See...
P = ODC(S,A,*T*)	Eq. 47
$S = \frac{0.5 \times (1 - F\mathrm{COHb} - F\mathrm{MetHb}) + F\mathrm{COHb}}{1 - F\mathrm{MetHb}}$	Eq. 46.11
A = a	
T = 37.0 °C	Eq. 46.13

***p*50(*T*)**

Eq. 20:

The ODC is determined as described in equations 46-47 in the section *Oxyhemoglobin Dissociation Curve* further in this chapter.

$$p50(T) = \frac{\mathrm{P}}{1 + \frac{F\mathrm{COHb}}{0.5 \times (1 - F\mathrm{COHb} - F\mathrm{MetHb})}}$$

where

Description	See...
P = ODC(S,A,*T*)	Eq. 47
$S = \frac{0.5 \times (1 - F\mathrm{COHb} - F\mathrm{MetHb}) + F\mathrm{COHb}}{1 - F\mathrm{MetHb}}$	Eq. 46.11
$A = \mathrm{a} - 1.04 \times \frac{\partial \mathrm{pH}}{\partial (T)} \times (T - 37.0)$	
$\frac{\partial \mathrm{pH}}{\partial (T)} = -1.47 \times 10^{-2} - 6.5 \times 10^{-3} \times (\mathrm{pH}(37) - 7.40)$	
T = patient temperature in °C (keyed-in)	

p50(st) **Eq. 21**:

p50 is calculated for pH = 7.40, $p\mathrm{CO_2}$ = 5.33 kPa, FCOHb = 0, FMetHb = 0, FHbF = 0.

The ODC is determined as described in equations 46-47 in the section *Oxyhemoglobin dissociation curve (ODC)*, see equation 47 further in this chapter.

p50(st) = ODC(S,A,T)

where

Description	See...
S = 0.5	Eq. 46.11
A = a6 corresponds to pH = 7.40, $p\mathrm{CO_2}$ = 5.33 kPa, FCOHb = 0, FMetHb = 0, FHbF = 0	Eq. 46.13
T = 37.0 °C	

$p\mathrm{O_2}$(A-a) **Eq. 22**:

$$p\mathrm{O_2}(\mathrm{A}-\mathrm{a}) = p\mathrm{O_2}(\mathrm{A}) - p\mathrm{O_2}(\mathrm{a})$$

The calculation requires entering the sample type as "Arterial" or "Capillary".

$p\mathrm{O_2}$(A-a,T) **Eq. 23**:

$$p\mathrm{O_2}(\mathrm{A}-\mathrm{a},T) = p\mathrm{O_2}(\mathrm{A},T) - p\mathrm{O_2}(\mathrm{a},T)$$

The calculation requires entering the sample type as "Arterial" or "Capillary".

$p\mathrm{O_2}$(a/A) **Eq. 24**:

$$p\mathrm{O_2}(\mathrm{a/A}) = \frac{p\mathrm{O_2}(\mathrm{a})}{p\mathrm{O_2}(\mathrm{A})}$$

The calculation requires entering the sample type as "Arterial" or "Capillary".

$p\mathrm{O_2}$(a/A,T) **Eq. 25**:

$$p\mathrm{O_2}(\mathrm{a/A},T) = \frac{p\mathrm{O_2}(\mathrm{a},T)}{p\mathrm{O_2}(\mathrm{A},T)}$$

The calculation requires entering the sample type as "Arterial" or "Capillary".

$pO_2(x)$ (or p_x)

Eq. 26 [8]:

The ODC is determined as described in equations 46-47 in the section *Oxyhemoglobin Dissociation Curve* further in this chapter.

$pO_2(x)$ is calculated by a numerical method, using:

Eq.	Description	See...
26.1	S = ODC(P,A,*T*)	Eq. 47
26.2	$sO_{2,i} = \frac{S \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$	Eq. 46.12
26.3	$pO_{2,i} = \frac{P}{1 + \frac{FCOHb}{sO_{2,i} \times (1 - FCOHb - FMetHb)}}$	Eq. 46.10
26.4	$t_i = ctHb \times (1 - FCOHb - FMetHb) \times sO_{2,i} + 0.0105 \times pO_{2,i}$	
26.5	A = a	
26.6	*T* = 37 °C	

When $t_i = ctO_2 - 2.3$ mmol/L, then $pO_{2,i} = pO_2(x)$, where ctO_2 is determined as described in equation 27.

$pO_2(x)$ cannot be calculated on the basis of a default *c*tHb value.

$pO_2(x)$ can only be calculated if the measured $sO_2(a) \leq 0.97$.

The calculation requires entering the sample type as "Arterial" or "Capillary".

ctO_2

Eq. 27 [5]:

$$ctO_2 = \alpha O_2 \times pO_2 + sO_2 \times (1 - FCOHb - FMetHb) \times ctHb$$

αO_2 is the concentrational solubility coefficient for O_2 in blood (here set to 0.0105 mmol/L/kPa at 37 °C [24].

ctO_2 cannot be calculated on the basis of a default *c*tHb value.

NOTICE: The formula is different from previous Radiometer analyzers. The oxygen solubility coefficient is now changed from 0.00983 to 0.0105 to be in accordance with NCCLS (CLSI)-approved guidelines [24].

The change corresponds to 0.00067 mmol/L/kPa.

$ctO_2(a-\bar{v})$

Eq. 28:

$ctO_2(a - \bar{v}) = ctO_2(a) - ctO_2(\bar{v})$
where $ctO_2(a)$ and
$ctO_2(\bar{v})$ are calculated from equation 27 for arterial and mixed venous blood, respectively. The calculation requires two measurements and input of both $pO_2(\bar{v})$ and $sO_2(\bar{v})$.

BO_2

Eq. 29 [7]:

$$BO_2 = ctHb \times (1 - FCOHb - FMetHb)$$

BO_2 cannot be calculated on the basis of a default *c*tHb value.

$ctO_2(x)$ (or c_x)

Eq. 30 [8]:

The ODC is determined, as described in equations 46-47 in the section *Oxyhemoglobin Dissociation Curve* further in this chapter.

$$ctO_2(x) = ctO_2(a) - t_i$$

where

Eq.	Description	See...
30.1	$t_i = ctHb \times (1 - FCOHb\text{-}FMetHb) \times sO_{2,i} + 0.0105 \times pO_2(5)$	
30.2	$pO_2(5)$ = 5.00 kPa	
30.3	S = ODC(P,A,*T*)	Eq. 47
30.4	$P = pO_2(5) \times \left[1 + \frac{FCOHb}{sO_{2,i} \times (1 - FCOHb - FMetHb)}\right]$	Eq. 46.9
30.5	$sO_{2,i} = \frac{S \times (1 - FMetHb) - FCOHb}{(1 - FCOHb - FMetHb)}$	Eq. 46.12
30.6	A = a	
30.7	*T* = 37.0 °C	

ctO_2(a) is determined as described in equation 27.

ctO_2(x) cannot be calculated on the basis of a default *c*tHb value.

ctO_2(x) can only be calculated if the measured $sO_2(a) \leq 0.97$.

The calculation requires entering the sample type as "Arterial" or "Capillary".

$\dot{D}O_2$

Eq. 31:

$$\dot{D}O_2 = ctO_2 \times \dot{Q}_t$$

$\dot{Q}_t$ is the cardiac output and is an input parameter for the calculation of $\dot{D}O_2$.

If $\dot{Q}_t$ is not keyed in, $\dot{D}O_2$ will not be calculated.

The calculation requires entering the sample type as "Arterial" or "Capillary".

$\dot{Q}_t$

Eq. 32:

$$\dot{Q}_t = \frac{\dot{V}O_2}{ctO_2(a\text{-}\bar{v})}$$

If $\dot{V}O_2$ is not keyed in, $\dot{Q}_t$ will not be calculated.

$\dot{V}O_2$

Eq. 33:

$$\dot{V}O_2 = \dot{Q}_t \times ctO_2(a\text{-}\bar{v})$$

If $\dot{Q}_t$ is not keyed in, $\dot{V}O_2$ will not be calculated.

***F*Shunt**

Eq. 34 [5]:

$$F\text{Shunt} = \frac{c\text{tO}_2(\text{c}) - c\text{tO}_2(\text{a})}{c\text{tO}_2(\text{c}) - c\text{tO}_2(\bar{\text{v}})}$$

and

Eq.	Description
34.1	$F\text{Shunt} \cong \frac{c\text{tO}_2(\text{A}) - c\text{tO}_2(\text{a})}{c\text{tO}_2(\text{A}) - c\text{tO}_2(\bar{\text{v}})}$
34.2	$F\text{Shunt} = \left[1 + \frac{c\text{tO}_2(\text{a}) - c\text{tO}_2(\bar{\text{v}})}{c\text{tO}_2(\text{A}) - c\text{tO}_2(\text{a})}\right]^{-1}$
	where
	$c\text{tO}_2(\text{c})$: total oxygen in pulmonary capillary blood
	$c\text{tO}_2(\text{a})$: total oxygen in arterial blood
	$c\text{tO}_2(\text{A})$: total oxygen in alveolar air. Oxygen tension = $p\text{O}_2(\text{A})$.
	$c\text{tO}_2(\bar{\text{v}})$: total oxygen in mixed venous blood
34.3	$c\text{tO}_2(\text{a}) = 0.0105 p\text{O}_2(\text{a}) + c\text{tHb} \times \left(1 - F\text{COHb} - F\text{MetHb}\right) \times s\text{O}_2(\text{a})$
34.4	$c\text{tO}_2(\text{A}) = 0.0105 p\text{O}_2(\text{A}) + c\text{tHb} \times \left(1 - F\text{COHb} - F\text{MetHb}\right) \times s\text{O}_2(\text{A})$
34.5	$c\text{tO}_2(\bar{\text{v}}) = 0.0105 p\text{O}_2(\bar{\text{v}}) + c\text{tHb} \times \left(1 - F\text{COHb} - F\text{MetHb}\right) \times s\text{O}_2(\bar{\text{v}})$
	where:
	$p\text{O}_2(\text{a})$: oxygen tension in arterial blood; measured
	$p\text{O}_2(\text{A})$: oxygen tension in alveolar blood. See equation 15.
	$p\text{O}_2(\bar{\text{v}})$: oxygen tension in mixed venous blood; measured and then entered
	$s\text{O}_2(\text{a})$: oxygen saturation in arterial blood; can be measured
	$s\text{O}_2(\text{A})$: oxygen saturation in (alveolar) blood calculated from equation 39 where P = $p\text{O}_2(\text{A})$
	$s\text{O}_2(\bar{\text{v}})$: oxygen saturation in mixed venous blood; measured and then entered
	The calculation requires entering the sample type as "Arterial" or "Capillary"
	If $s\text{O}_2(\text{a}) > 0.97$, the default value (3.578 kPa) will be used to estimate the ODC.
	If no venous sample is measured, *F*Shunt is estimated assuming:
	$c\text{tO}_2(\text{a}) - c\text{tO}_2(\bar{\text{v}})$ = 2.3 mmol/L in equation 34.2

***F*Shunt(*T*)** **Eq. 35** [5,16]:

$$F\text{Shunt}(T)=\left[1+\frac{c\text{tO}_2(\text{a},T)-c\text{tO}_2(\bar{\text{v}},T)}{c\text{tO}_2(\text{A},T)-c\text{tO}_2(\text{a},T)}\right]^{-1}$$

where

$c\text{tO}_2(\text{a},T)$: total oxygen in arterial blood at patient temperature

$c\text{tO}_2(\text{A},T)$: total oxygen in alveolar blood at patient temperature

$c\text{tO}_2(\bar{\text{v}},T)$: total oxygen in mixed venous blood at patient temperature

Eq.	Description	See...
35.1	$c\text{tO}_2(\text{a},T)$ = $c\text{tO}_2$ calculated from equation 25 for arterial $p\text{O}_2$ and $s\text{O}_2$ values at 37 °C	
35.2	$c\text{tO}_2(\text{A},T)=\alpha\text{O}_2(T)\times p\text{O}_2(\text{A},T)+c\text{tHb}\times\left(1\text{-}F\text{COHb-}F\text{MetHb}\right)\times s\text{O}_2(\text{A},T)$	
35.3	$\alpha\text{O}_2(T)=0.0105\text{e}^{\left[\text{-}1.15\times10^{-2}\times(T\text{-}37.0)+2.1\times10^{-4}\times(T-37.0)^2\right]}$	
35.4	$p\text{O}_2(\text{A},T)$ is calculated from equation 16	
35.5	$s\text{O}_2(\text{A},T)$ = S	
35.6	S = ODC(P,A,*T*)	Eq. 47
35.7	P = $p\text{O}_2(\text{A},T)$	
35.8	$\text{A}=\text{a}-1.04\times\frac{\partial\text{pH}}{\partial(T)}\times\left(T-37.0\right)$	
35.9	*T* = patient temperature (keyed-in)	
35.10	$\frac{\partial\text{pH}}{\partial(T)}=-1.47\times10^{-2}-6.5\times10^{-3}\left(\text{pH}(37)-7.40\right)$ If $s\text{O}_2(\text{a})$ > 0.97, the default *p*50(st) (3.578 kPa) will be used to determine the ODC.	
35.11	$c\text{tO}_2(\bar{\text{v}},T)=c\text{tO}_2(\bar{\text{v}})$ at 37 °C is calculated from equation 27 for mixed venous blood values of $p\text{O}_2$ and $s\text{O}_2$. If no mixed venous sample is measured, the *F*Shunt(*T*) is estimated assuming $c\text{tO}_2(\text{a},T)$ – $c\text{tO}_2(\bar{\text{v}},T)$ = 2.3 mmol/L in equation 35.	

RI **Eq. 36**:

$$\text{RI}=\frac{p\text{O}_2(\text{A})-p\text{O}_2(\text{a})}{p\text{O}_2(\text{a})}$$

The calculation requires entering the sample type as "Arterial" or "Capillary".

RI(*T*) **Eq. 37**:

$$\text{RI}(T)=\frac{p\text{O}_2(\text{A},T)-p\text{O}_2(\text{a},T)}{p\text{O}_2(\text{a},T)}$$

The calculation requires entering the sample type as "Arterial" or "Capillary".

Q_x

Eq. 38 [8]:

The ODC is determined as described in equations 46-47 in the section *Oxyhemoglobin Dissociation Curve* further in this chapter.

$$Q_x = \frac{2.3}{ctO_2(a) - t_i}$$

Eq.	Description	See...
38.1	$t_i = ctHb \times (1\text{-}FCOHb\text{-}FMetHb) \times sO_{2,i} + 0.0105 pO_2(5)$	
38.2	$pO_2(5)$ = 5.00 kPa	
38.3	S = ODC(P,A,*T*)	
38.4	$P = pO_2(5) \times \left[1 + \frac{FCOHb}{sO_{2,i} \times (1 - FCOHb - FMetHb)}\right]$	Eq. 46.9
38.5	$sO_{2,i} = \frac{S \times (1 - FMetHb) - FCOHb}{1\text{-}FCOHb\text{-}FMetHb}$	Eq. 46.12
38.6	A = a	
38.7	*T* = 37.0 °C	

$ctO_2(a)$ is determined as described in equation 27.

Q_x cannot be calculated on the basis of a default *c*tHb value.

Q_x can only be calculated if the measured $sO_2(a) \leq 0.97$.

The calculation requires entering the sample type as "Arterial" or "Capillary".

sO_2

Eq. 39:

The ODC is determined as described in equation 46 (points I and III). See the section *Oxyhemoglobin dissociation curve (ODC)* further in this chapter.

$$sO_2 = \frac{S \times (1 - FMetHb) - FCOHb}{1\text{-}FCOHb\text{-}FMetHb}$$

where

Description	See...
S = ODC(P,A,*T*)	
$P = pO_2 + \frac{pO_2 \times FCOHb}{sO_2 \times (1 - FCOHb - FMetHb)}$	Eq. 46.9
A = a	
T = 37.0 °C	

FO_2Hb

Eq. 40:

$$FO_2Hb = sO_2 \times (1 - FCOHb - FMetHb)$$

If sO_2 is not measured, it will be calculated from equation 39.

If dyshemoglobins (*F*COHb, *F*MetHb) are not known, they are set to the default values.

***F*HHb**

Eq. 41:

$$FHHb = 1 - sO_2 \times (1 - FCOHb - FMetHb) - FCOHb - FMetHb$$

If sO_2 is not measured, it will be calculated from equation 39.

If dyshemoglobins (*F*COHb, *F*MetHb) are not known, they are set to the default values.

***V*(B)**

Eq. 42 [5]:

$$V(B) = \frac{V(CO)}{24 \times (FCOHb(2) - FCOHb(1)) \times 0.91 \times ctHb}$$

Eq.	Description
42.1	$V(B) = \frac{V(CO)}{21.84 \times (FCOHb(2) - FCOHb(1)) \times ctHb}$
42.2	*V*(CO) = volume (in mL) of carbon monoxide injected according to the procedure and the value keyed in
42.3	*F*COHb(1) = fraction of COHb measured before the CO injection
42.4	*F*COHb(2) = fraction of COHb measured after the CO injection

Anion Gap,K^+

Eq. 43:

$$\text{Anion Gap},K^+ = cNa^+ + cK^+ - cCl^- - cHCO_3^-$$

Anion Gap

Eq. 44:

$$\text{Anion Gap} = cNa^+ - cCl^- - cHCO_3^-$$

***c*Ca^{2+}(7.4)**

Eq. 45 [12]:

$$cCa^{2+}(7.4) = cCa^{2+} \times 10^{-0.24(7.4-pH)}$$

Due to biological variations this equation can only be used for a pH value in the range 7.2-7.6.

NOTICE: The formula is different from previous Radiometer analyzers. The previous formula was an approximation of the current formula.

The change corresponds to 1% in the pH range 7.2-7-6.

Eq. 46-47

See *Oxyhemoglobin dissociation curve (ODC),* further in this chapter.

***m*Osm**

Eq. 48 [25]**:**

$$mOsm = 2cNa^+ + cGlu$$

***F*HbF**

Eq. 49:

An iterative method is used to calculate *F*HbF. The input parameters are sO_2, *c*eHb (effective hemoglobin concentration) and cO_2HbF (concentration of fetal oxyhemoglobin).

In the calculations the following are assumed: pH = 7.4, pCO_2 = 5.33 kPa, *F*COHb = 0, *F*MetHb = 0, *c*DPG = 5 mmol/L, and temp = 37 °C.

Eq.	Description	See...
49.1	An estimate of *F*HbF is made: $FHbF_{est}$ = 0.8	
49.2	$pO_{2,est}$ = ODC (sO_2,A,*T*);	Eq. 47
	where the constant A depends on *F*HbF = $FHbF_{est}$	
49.3	sO_2 (for fetal blood) = ODC ($pO_{2,est}$, A,*T*);	Eq.47
	where *F*HbF = 1	
49.4	cO_2HbF_{est} = sO_2 (fetal blood) × *c*eHb × $FHbF_{est}$	
49.5	$\Delta FHbF_{est} = \frac{cO_2HbF_{meas.} - cO_2HbF_{est}}{c\text{eHb}}$	
49.6	If $\lvert\Delta FHbF_{est}\rvert \geq 0.001$, proceed to **49.7**.	
	If $\lvert\Delta FHbF_{est}\rvert < 0.001$, proceed to **49.9**.	
49.7	$FHbF_{est,\,new} = FHbF_{est,\,old} + \Delta FHbF_{est}$	
49.8	Return to **49.2**.	
49.9	End of iteration. The value for *F*HbF has converged.	

$pO_2(x,T)$

Eq. 50 [8,18]:

The ODC is determined as described in equations 46-47 in *Oxyhemoglobin Dissociation Curve* further in this chapter.

$pO_2(x)$ is calculated by a numerical method, using:

Eq.	Description	See...
50.1	S = ODC(P,A,*T*)	Eq. 47
50.2	$sO_{2,i}(T) = \frac{S \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$	Eq. 46.12
50.3	$pO_{2,i}(T) = \frac{P}{1 + \frac{FCOHb}{sO_{2,i}(T) \times (1 - FCOHb - FMetHb)}}$	Eq. 46.10
50.4	$t_i(T) = ctHb \times (1 - FCOHb - FMetHb) \times sO_{2,i}(T) + \alpha O_2(T) \times pO_{2,i}(T)$	
50.5	$A = a - 1.04 \times \frac{\partial pH}{\partial (T)} \times (T - 37.0)$	Eq. 20
50.6	*T* = patient temperature	
50.7	$\alpha O_2(T) = 0.0105 \times e^{\left[-0.115 \times (T-37) + 21 \times 10^{-5} \times (T-37)^2\right]}$	
50.8	$pO_{2,i} = pO_2(x,T)$	
	when $t_i(T)$ = ctO_2(37 °C) – 2.3 mmol/L	

$pO_2(x,T)$ is calculated in accordance with OSA V3.0.

$pO_2(x,T)$ can only be calculated if the measured $sO_2(a) \leq 0.97$.

$pO_2(x,T)$ is tagged with "?" if any of the following parameters: sO_2, *F*MetHb, *F*COHb, pO_2, pCO_2, pH or *c*tHb is tagged with "?".

The calculation requires entering the sample type as "Arterial" or "Capillary".

VCO_2/V(dry air) **Eq. 51**:

$$VCO_2/V(\text{dry air}) = \frac{pCO_2}{p(\text{amb}) - 6.275}$$

VO_2/V(dry air) **Eq. 52**:

$$VO_2/V(\text{dry air}) = \frac{pO_2}{p(\text{amb}) - 6.275}$$

Oxyhemoglobin dissociation curve (ODC)

ODC equations

These equations account for the effect of *F*COHb on the shape of the Oxyhemoglobin Dissociation Curve (ODC) in accordance with the Haldane equation.

Eq. 46 [16,18]:

$$y - y^o = (x - x^o) + h \times \tanh\left[k^o\left(x - x^o\right)\right]$$

where $k^o = 0.5343$

Eq.	Description
46.1	$x = \ln p$
46.2	$y = \ln \frac{s}{1 - s}$
46.3	$y^o = \ln \frac{s^o}{1 - s^o}$ where $s^o = 0.867$
46.4	$x^0 = x^{00} + a + b = \ln(p^{00}) + a + b$ where $p^{oo} = 7$ kPa.

The actual position of the ODC in the coordinate system (ln(*s*/(1–*s*)) vs ln(*p*)) used in the mathematical model, is expressed by equations 46.3 and 46.4.

The symbols "a" and "b" reflect the ODC displacement from the reference position to its actual position in this coordinate system:

"a" describes the displacement at 37 °C.
"b" the additional displacement due to the patient temperature difference from 37 °C.

The ODC reference position

The reference position of the ODC was chosen to be the one that corresponds to the default value for *p*50(st) = 3.578 kPa, which is traditionally considered the most likely value of *p*50 for adult humans under standard conditions, namely:

pH = 7.40

pCO_2 = 5.33 kPa

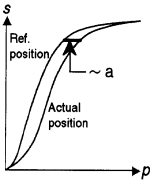
*F*COHb, *F*MetHb, *F*HbF = 0

*c*DPG = 5 mmol/L

The ODC displacement

The ODC displacement which is described by "a" and "b" in the coordinate system ($\ln(s/(1-s))$ vs $\ln(p)$), is given by the change in $p50$ from the default to its actual value in a more common coordinate system (sO_2, pO_2).

Eq.	Description
46.5	$x - x^o = \ln\frac{p}{7} - a - b$
46.6	$h = h^o + a$ where h^o = 3.5
46.7	$b = 0.055 \times (T - T^o)$ T^o = 37 °C
46.8	$p = pO_2 + M \times pCO$ where $M \times pCO$ is taken from the Haldane equation [20]: $\frac{pO_2}{cO_2Hb} = M \times \frac{pCO}{cCOHb}$, to give eq. 46.9
46.9	$p = pO_2 + \frac{pO_2}{sO_2} \times \left[\frac{FCOHb}{1 - FCOHb - FMetHb}\right]$ or equation 46.10
46.10	$pO_2 = \frac{p}{1 + \frac{FCOHb}{sO_2 \times (1 - FCOHb - FMetHb)}}$



The ordinate, *s*, may loosely be termed the combined oxygen/carbon monoxide saturation of hemoglobin and is described by equation 46.11 below:

Eq.	Description
46.11	$s = \frac{cO_2Hb + cCOHb}{cO_2Hb + cCOHb + cHHb}$ or $= \frac{sO_2 \times (1 - FCOHb - FMetHb) + FCOHb}{1 - FMetHb}$
46.12	$sO_2 = \frac{s \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$

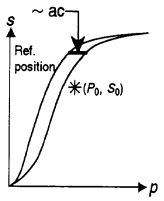
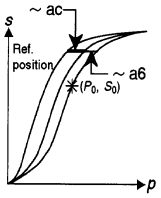
The actual ODC position

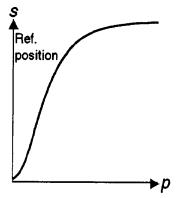
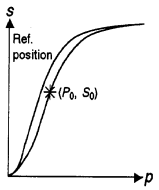
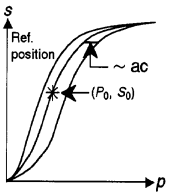
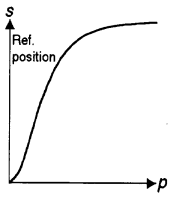
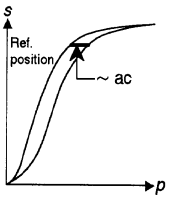
The actual position of the ODC at 37 °C for a given sample is, in principle, determined in two steps:

1. The calculation of the combined effect on the ODC position at 37 °C of all known causes for displacement (= ac in equation 46.13), and based on this position.
2. The computation by a numerical method of the actual position of the ODC curve by shifting it to pass through the known set of coordinates (P_0, S_0).

Eq.	Description
46.13	a = ac + a6
46.14	ac = a1 + a2 + a3 + a4 + a5
46.15	$a1 = -0.88 \times (pH - 7.40)$
46.16	$a2 = 0.048 \times \ln \frac{pCO_2}{5.33}$
46.17	$a3 = -0.7 \times FMetHb$
46.18	$a4 = (0.06 - 0.02FHbF) \times (cDPG - 5)$
46.19	$a5 = -0.25 \times FHbF$

Determining the actual displacement

Step	Description
I:  	pO_2, sO_2 can be used. If sO_2 > 0.97, the calculation is based on II or III – *see below*. Coordinates (P_0, S_0) are calculated from equations (46.9) and (46.11). If *F*COHb and *F*MetHb are not known, the default values are used. The ODC is shifted from the reference position to a position that corresponds to the effect of all measured parameters according to step I. The magnitude of the shift is "ac". The ODC is then further shifted to pass through the point (P_0, S_0). The magnitude of the shift is "a6".

Step	Description
II: 	sO_2 > 0.97 (or erroneous) and p50(st) is known. Coordinates (P_0, S_0) are calculated from (p50(st), 0.5) using equations 46.9 and 46.11. Reference position of the ODC.
	The ODC is shifted from the reference position to pass through the point (P_0, S_0). In this position, the ODC reflects the p50(st) of the patient, i.e., the particular patient but at standard conditions.
	The ODC is further shifted, as determined by the effect of the measured parameters ("ac"), to its actual position. This position reflects the p50(act) of the patient.
(III): 	sO_2 > 0.97 (or erroneous). Reference position of the ODC.
	The position of the actual ODC can now be approximated from the reference position, using the actual values of pH, pCO_2, FCOHb, FMetHb and FHbF to determine the shift "ac".

NOTICE: The curves are used only to illustrate the principles of the ODC determination.

Coordinates on the ODC

Calculation of a set of coordinates on the ODC is symbolized by:

Eq. 47:

S = ODC(P, A, *T*) or P = ODC(S, A, *T*)

These equations are symbolic representations of the relationship between saturation (S), tension (P), displacement (A) and temperature (*T*).

To calculate S or P and to further calculate sO_2 and pO_2, the other variables should be specified. S and P are calculated using numerical methods.

P is input to equation 46.1.

S is input to equation 46.2.

A is input to equation 46.5.

T is input to equation 46.7.

Conversion of units

SI units

The equations stated above are based on the SI-unit system. If parameters are known in other units, they must be converted into a SI unit before entering the equations. The result will be in an SI unit.

After the calculation the result may be converted to the desired unit. Conversion of units may be performed, using the equations stated below:

Temperature

$T\,°F = \frac{9}{5}(T\ {}^{o}C) + 32$

$T\,°C = \frac{5}{9}(T\ {}^{o}F - 32)$

cK^+, cNa^+, cCl^-

cX (meq/L) = cX (mmol/L) where X is K^+, Na^+ or Cl^-.

cCa^{2+}

cCa^{2+} (meq/L) = $2 \times cCa^{2+}$ (mmol/L) or

cCa^{2+} (mg/dL) = $4.008 \times cCa^{2+}$ (mmol/L)

cCa^{2+} (mmol/L) = $0.5 \times cCa^{2+}$ (meq/L)or

cCa^{2+} (mmol/L) = $0.2495 \times cCa^{2+}$ (mg/dL)

Pressure

p (mmHg) = $\underset{\text{(Torr)}}{p}$ = $7.500638 \times p$(kPa)

p (kPa) = $0.133322 \times p$(mmHg) = $0.133322 \times p$(Torr))

$ctHb$

[4]

$ctHb$ (g/dL) = $1.61140 \times ctHb$ (mmol/L)

$ctHb$ (g/L) = $16.1140 \times ctHb$ (mmol/L) or

$ctHb$ (mmol/L) = $0.62058 \times ctHb$ (g/dL)

$ctHb$ (mmol/L) = $0.062058 \times ctHb$ (g/L)

$ctCO_2$, ctO_2, $ctO_2(a–\bar{v})$, BO_2

Vol % = 2.241 × (mmol/L)

Vol % = mL/dL

mmol/L = 0.4462 × (mL/dL)

$\dot{V}O_2$

$\dot{V}O_2$ mmol/min = $\dot{V}O_2$/22.41 mL/min

cGlu [22]

*c*Glu (mg/dL)	=	18.016 × *c*Glu (mmol/L) or
*c*Glu (mmol/L)	=	0.055506 × *c*Glu (mg/dL)

cLac [22]

*c*Lac (mg/dL)	=	9.008 × *c*Lac (mmol/L) or
*c*Lac (mmol/L)	=	0.11101 × *c*Lac (mg/dL)
*c*Lac (meq/L)	=	*c*Lac (mmol/L)

(conversion based on the molecular weight of lactic acid)

ctBil

*c*tBil (µmol/L)	=	17.1 × *c*tBil (mg/dL)
*c*tBil (µmol/L)	=	1.71 × *c*tBil (mg/L) or
*c*tBil (mg/dL)	=	0.0585 × *c*tBil (µmol/L)
*c*tBil (mg/L)	=	0.585 × *c*tBil (µmol/L)

NOTICE: All conversions of units are made by the analyzer.

Default values

Values

The following default values are used in the analyzer, if other values are not keyed in.

T	=	37.0 °C
FO_2(I)	=	0.21 (21.0 %)
RQ	=	0.86
*c*tHb	=	9.3087 mmol/L, (15.00 g/dL or 150 g/L)
*F*COHb	=	0.004 (0.4 %)
*F*MetHb	=	0.004 (0.4 %)
*p*50(st)	=	3.578 kPa (26.84 mmHg)

In addition to the above default values, the analyzer uses the following default:

Ambient temperature = 25.0 °C.

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9. Solutions

General information

Introduction

The ABL90 FLEX analyzer utilizes a solution pack for all calibrations, QC and rinse procedures, and for the collection of waste fluids.

Solution pack

The solution pack contains eight foil pouches:

- Three with calibration solution
- One with a gas mixture
- Three with quality control solution
- One for waste

One of the calibration solutions (CAL 1) is also used for rinse.

Calibration solutions and QC solutions in the solution pack have a unique lot number. Assigned values for the QC solutions are unique for each individual solution pack because they are adjusted according to the lifetime of the solution pack when installed on the analyzer.

Lot

Each solution pack has a lot number, which identifies the solution packs assembled in one production lot.

***In vitro* diagnostic use**

All the solutions described in this chapter are for *in vitro* diagnostic use.

Expiration date

The expiration date of the solution pack is found on the solution pack barcode label. A solution pack can be used on the analyzer for up to 30 days (or until no more activities are left) but not after the expiration date. This means that if you install a solution pack 5 days before the expiration date, it can only be used for 5 days.

Storage

The solution pack storage temperature range is 2-25 °C. The storage altitude range is sea level to 4000 meters. The barometer pressure should lie between 450-800 mmHg, or 60.0-106.7 kPa, or 450-800 Torr.

Material safety Data Sheets

Material Safety Data Sheets (MSDS) for all solutions in the solution pack are available from your Radiometer distributor.

Solutions

Use

The solutions contained in the pouches of the solution pack are used for either calibration or quality control of all analytes. During sample analysis and quality control measurements CAL 1 also acts as a rinse solution, removing the sample from the sensor cassette measuring chamber.

Pouch volume

Solution	Volume (mL)
S1920 CAL 1	200
S1930 CAL 2	100
S1940 CAL 3	100
S9030 QC 1	200
S9040 QC 2	100
S9050 QC 3	100
Gas mixture	150 *)

*) at sea level

Composition

Solution compositions include organic buffers, inorganic salts, surfactant, metabolites, preservatives, anti-coagulant, enzyme and colorant which provide the following substances with approximate concentrations as given below:

		Concentration		
Substance	**Unit**	**CAL 1 S1920**	**CAL 2 S1930**	**CAL 3 S1940**
pH		7.30	6.8	NA
pCO_2	mmHg	35	NA	80
pO_2	mmHg	180	NA	NA
cNa^+	mmol/L	150	70	NA
cK^+	mmol/L	4	10	NA
cCl^-	mmol/L	95	50	NA
cCa^{2+}	mmol/L	0.5	2.3	NA
*c*Glu	mmol/L	0 (background)	NA	10
*c*Lac	mmol/L	0 (background)	NA	10
*c*tHb	g/dL	NA	NA	0

NOTICE: The actual analyte concentrations for each solution in a solution pack lot are included in the smart chip contained in each solution pack. The values are read into the analyzer when the solution pack is installed in an analyzer.

		Concentration			
Substance	**Unit**	**S9030 (QC 1)**	**S9040 (QC 2)**		**S9050 (QC 3)**
		Solution	**Solution**	**Gas pO_2 (at 760 mmHg)**	**Solution**
pH		7.2	6.8	NA	7.5
pCO_2	mmHg	30	67	NA	15
pO_2	mmHg	180		300 (42.07 %)	20
cNa^+	mmol/L	140	118	NA	175
cK^+	mmol/L	4	7	NA	1.8
cCl^-	mmol/L	105	95	NA	125
cCa^{2+}	mmol/L	0.8	1.65	NA	0.3
*c*Glu	mmol/L	0	15	NA	7
*c*Lac	mmol/L	0	8	NA	4
*c*tHb	mmol/L	0	8	NA	12
sO_2	%		97	NA	70
FO_2Hb	%		92	NA	49
*F*COHb	%		3	NA	20
*F*MetHb	%		2	NA	10
*F*HbF	%		80	NA	50
*c*tBil	µmol/L	0	300	NA	450

NOTICE: The actual analyte concentrations for each solution in a solution pack lot are included in the smart chip contained in each solution pack. The values are read into the analyzer when the solution pack is installed in an analyzer.

Certificate of traceability

Certificate of Traceability

Product name: ABL90 FLEX Solution pack

Type: Calibration solution 1, Calibration solution 2, Calibration solution 3, QC1, QC2, QC3, Gas mixture

Code: 944-157

Traceability of parameters:

Parameter	Unit	Traceable to	Solution	Expanded Uncertainty
pH		The IUPAC pH scale. Primary pH standards are certified by The Danish Primary Laboratory for Electrochemistry (DPLEC) at the Danish Institute of Fundamental Metrology (DFM) under DANAK accreditation no. 255. The system is validated by comparison with SRM produced by National Institute of Standards and Technology (NIST).	Cal 1 Cal 2 QC1 QC2 QC3	0.0072 0.009 0.0072 0.0072 0.0072
pCO_2	mmHg	Certified gasses, NIST SRM 1674b and SRM 2625a.	Cal 1 Cal 2 Cal 3 QC1 QC2 QC3	0.80 1.80 1.80 1.00 1.96 0.74
pO_2*	mmHg	Certified gasses, NIST SRM 2658a and NIST 2659a.	QC1 QC2 (gas) QC3	16.0 5.0 9.2
cK^+	mmol/L (37 °C)	Certified Reference Material. NIST SRM 999b. Potassium Chloride.	Cal 1 Cal 2 QC1 QC2 QC3	0.034 0.084 0.034 0.090 0.032
cNa^+	mmol/L (37 °C)	Certified Reference Material. NIST SRM 919b. Sodium Chloride.	Cal 1 Cal 2 QC1 QC2 QC3	0.76 0.56 1.12 1.10 1.18
cCa^{2+}	mmol/L (37 °C)	Certified Reference Material. NIST SRM 915. Calcium Carbonate.	Cal 1 Cal 2 QC1 QC2 QC3	0.052 0.049 0.022 0.048 0.012
cCl^-	mmol/L (37 °C)	Certified Reference Material. NIST SRM 999b. Potassium Chloride.	Cal 1 Cal 2 QC1 QC2 QC3	1.10 0.54 1.28 0.90 1.58
cGlu	mmol/L (37 °C)	Certified Reference Material. NIST SRM 917b. Glucose.	Cal 1 Cal 3 QC1 QC2 QC3	0.16 0.20 0.18 0.50 0.32
cLac	mmol/L (37 °C)	Pure Material. Lactic Acid, Lithium salt. SIGMA L-2250.	Cal 1 Cal 3 QC1 QC2 QC3	0.18 0.20 0.20 0.28 0.20
ctHb	(g/dL)	Haemiglobin Cyanide Standard. J.T. Baker, Product no. 3061. NIST SRM standard for absorbance, NIST SRM 930D. Optical filters. NIST SRM standard for wavelength, NIST SRM 2034, Holmium Oxide Solution.	Cal 1 QC1 QC2 QC3	0.04 0.04 0.32 0.36

* pO_2 sensor is calibrated on atmospheric air: O_2 = 20.946±0.14%

Certification: Each lot of this product has been tested, and the control limits specified on the insert included with this product have been established with the above traceability.

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The traceability of the above parameters is fully described in booklet AS 117: *Traceability to the Primary Reference Standards at Radiometer*, available from Radiometer.

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RADIOMETER

10. Messages

List of analyzer messages

Messages on user and manager levels

The following messages will be seen on the user and 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.

In case of analyzer error or malfunction, the error will be logged in the Activity log.

Do the following:

Step	Action
1.	Open the Activity log.
2.	Find the relevant error.
3.	Highlight it by touching the screen.
4.	Press ***Troubleshoot***.
5.	Follow the procedures given to remedy the error.

The following table describes possible errors and how to remedy them.

NOTICE: The list contains all possible errors and may thus list errors that will not be relevant for all analyzer variants. Furthermore, operator actions are in relation of the analyzer and may differ from local procedures in your institution. In that case, follow local procedures.

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	The 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	The parameter value is below the user-defined reference range. This is only a message, not an error.	- No action required.
85	Value below critical limit	The parameter value is below the user-defined critical limit. This is only a message, not an error	- No action required.
86	Value above critical limit	The parameter value is above the user-defined critical limit. This is only a message, not an error.	- No action required.
89	Measured QC value above control range	The measured parameter value is above the control range.	- Verify the procedure and repeat the measurement. - Refer to the ABL90 FLEX reference manual.*
90	Measured QC value below control range	The measured parameter value is below the control range.	- Verify the procedure and repeat the measurement. - Refer to the ABL90 FLEX reference manual.*
93	Value above reportable range	The parameter value is above the reportable range.	- 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.
* The ABL90 FLEX reference manual includes a quality control appendix for manual QC.			

No.	Message	Interpretation	Operator action
94	Value below reportable range	The parameter value is below the reportable range.	- 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 a measurement on new blood sample.
117	LIS/HIS: Invalid connection configuration	The communication configuration or the protocol definition was invalid.	- Check the communication parameters specified in Communications Setup.
128	LIS/HIS: Failed to open connection	The communication hardware was busy or the remote system did not respond.	- 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.	- Check that the remote system is running and responding. - Check the 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 massage.	- 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.	- Check that the remote system is running and responding. - Check cables.
134	LIS/HIS: Connection established	The connection was successfully established.	- No action required. For information only.

No.	Message	Interpretation	Operator action
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 +/- 2 SD range.	- Verify procedure and repeat measurement. - Check Replacement Status for pending replacements. - Refer to the ABL90 FLEX reference manual for detailed evaluation procedure.
202	Westgard Rule (1.3s) violation	Measured parameter value is outside the mean +/- 3 SD range.	- Verify procedure and repeat measurement. - Check Replacement Status for pending replacements including electrodes. - Refer to the ABL90 FLEX reference manual for detailed evaluation procedure.
203	Westgard Rule (2.2s) violation	Two consecutive measurements are outside the mean +/- 2 SD range on the same side of the mean. This may indicate a shift.	- Verify procedure and repeat measurement. - Check Replacement Status for pending replacements including electrodes. - Refer to the ABL90 FLEX reference manual for detailed evaluation procedure.
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.	- Verify procedure and repeat measurement. - Check Replacement Status for pending electrode replacements. - Refer to the ABL90 FLEX reference manual for detailed evaluation procedure.

No.	Message	Interpretation	Operator action
205	Westgard Rule (4.1s) violation	Four consecutive measurements are outside the mean +/- 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.	- Check for excessive electrode sensor calibration drift. - Check Replacement Status for pending electrode replacements. - Refer to ABL90 FLEX 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.	- Check the electrode drift during last calibration. - Check Replacement Status for pending electrode replacements. - Refer to ABL90 FLEX 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.
210	Calibration error(s) present	An error registered on one or more parameters during the last calibration.	- Check 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 were registered during last QC measurement on one of the installed QC levels.	- Check 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 corrective required action.
213	Automatic backup failed	An error occurred during the scheduled data backup.	- Check Automatic Backup Setup. - Check network and servers used for the backup. - Contact your IT engineer.

No.	Message	Interpretation	Operator action
214	Automatic backup succeeded	The scheduled automatic backup was completed successfully.	- No action required.
216	General printer error	A printer problem has occurred, e.g. the paper is jammed	- Check printer paper. Clear any jam. - 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.
290	Warning: SHb detected	*F*SHb detected in the range of 1-10 %.	- No action required. For information only.
291	SHb too high	Detected *F*SHb 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.	- 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	Oxi compensated for HbF	OXI parameters have been HbF compensated. Parameter FHbF may be shown or not shown.	- No action required. For information only.
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 sensor. Measurement is aborted.	- Ensure that adequate sample volume is used. - Check the sample for clots.

No.	Message	Interpretation	Operator action
357	Temp. error: Barometer	Temperature in the barometer on the Analyzer Control is outside 37 +/- 1.0 °C.	- Ensure that the ambient temperature is between 15 and 32 °C. - If the system has just performed a cold start, wait for the error to disappear. - Replace the fan filter, if dirty. - Shield the analyzer from direct sunlight and other heat sources. - Contact Radiometer service representative.
375	Calibration status out of limits	The status value is outside the range for the given parameter.	- Check for and remedy any system messages. - Repeat the calibration. - Check solution pack status and replace, if necessary. - Check sensor cassette status and replace, if necessary. Removal condition: - Successful calibration.
376	Calibration Drift 1 out of range	The Drift 1 value exceeds the tolerance.	- Check for and remedy any system messages. - Repeat the calibration. - Check solution pack status and replace, if necessary. - Check sensor cassette status and replace, if necessary. Removal condition: - Successful calibration.
377	Calibration Drift 2 out of range	The Drift 2 value exceeds the tolerance.	- Check for and remedy any system messages. - Repeat the calibration. - Check solution pack status and replace, if necessary. - Check sensor cassette status and replace, if necessary. Removal condition: - Successful calibration.

No.	Message	Interpretation	Operator action
378	Calibration sensitivity out of range	The sensitivity value is out of range for the given parameter.	- Check for and remedy any system messages. - Repeat the calibration. - Check solution pack status and replace, if necessary. - Check sensor cassette status and replace, if necessary. Removal condition: - Successful calibration.
379	Calibration unstable (response fault)	An electrode response fault occurred during calibration.	- Check for and remedy any system messages. - Repeat the calibration. - Check solution pack status and replace, if necessary. - Check sensor cassette status and replace, if necessary. Removal condition: - Successful calibration.
443	Ca(7.4) not usable	*c*Ca^{2+} at a pH of 7.4 is not usable as the actual pH is outside the 7.2-7.6 range.	- No action required.
452	Interference during measurement	Interference was detected during measurement.	- Check the patient record for medication containing possible interfering substances.
484	Today is last day in stat. 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.
494	Bilirubin too high	Detected bilirubin concentration, *c*tBil(blood), is greater than 2000 µmol/L. The corresponding plasma bilirubin concentration can be calculated as follows: *c*tBil(blood) = (1-Hct) × *c*tBil(plasma).	- No action required.

No.	Message	Interpretation	Operator action
508	Liquid transport error during rinse	Liquid transport of Rinse failed	- Check solution pack or sensor cassette status and replace, if necessary. Removal condition: - Successful Rinse.
512	Temperature error	The temperature was outside the required range during measurement or calibration. All results are marked with "?".	- Ensure that the ambient temperature is between 15 and 32 °C. - If the analyzer has recently performed a cold start, wait for the temperature error to disappear. - If the solution pack or sensor cassette has recently been replaced, wait for the temperature error to disappear. - Shield analyzer from direct sunlight or heat sources. - Contact Radiometer service representative.
521	Inhomogeneous sample	Air bubbles were detected in the sample. Results may have "?".	- Repeat the measurement.
522	Calibration error	One or more calibration values are erroneous.	- Check for and remedy any system messages. - Repeat the calibration. - Check solution pack status and replace, if necessary. - Check sensor cassette status and replace, if necessary. Removal condition: - Successful calibration
523	Calibration drift out of range	Calibration drift exceeds defined limits.	- 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: - Calibration drift within defined limits.

No.	Message	Interpretation	Operator action
529	Inlet LS failed to calibrate	Inlet liquid sensor failed to calibrate.	- Repeat the liquid sensor calibration. - Contact Radiometer service representative.
531	Sensors LS failed to calibrate	Liquid sensor near the sensor cassette failed to calibrate.	- Repeat the liquid sensor calibration. - Check solution pack status and replace if necessary. - Contact Radiometer service representative.
537	OXI LS failed to calibrate	OXI module liquid sensor failed to calibrate.	- Repeat the liquid sensor calibration. - Check solution pack status and replace, if necessary. - Contact Radiometer service representative.
581	OXI spectrum mismatch	Spectrum deviates from the expected blood or QC spectrum. Measurement may be unreliable.	- Check the patient record for medication containing possible interfering substances. - Start a calibration. - Contact Radiometer service representative.
582	tHb calibration cuvette factor outside limits	tHb calibration failed.	- Perform a calibration. - Repeat the tHb calibration. - Contact Radiometer service representative. Removal condition: - Successful tHb calibration.
584	tHb calibration wavelength outside limits	tHb calibration failed.	- Perform a calibration. - Repeat the tHb calibration. - Contact Radiometer service representative. Removal condition: - A successful tHb calibration
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.	- Verify the procedure and repeat the measurement. - Refer to the ABL90 FLEX reference manual for details on the evaluation of the results.

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.	- Verify the procedure and repeat the measurement. - Refer to the ABL90 FLEX 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 "?".	- Repeat the measurement, ensuring sufficient sample volume. - Contact Radiometer service representative.
595	Liquid sensor calibration error	One or more of the liquid sensors failed calibration.	- Repeat the liquid sensor calibration. - Check solution pack status and replace, if necessary. - Contact Radiometer service representative.
606	Cal expired (pH)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	- Perform a calibration. Removal condition: - Successful calibration.
608	Cal expired (pCO_2)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	- Perform a calibration. Removal condition: - Successful 2-point calibration.
609	Cal expired (pO_2)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	- Perform a calibration. Removal condition: - Successful 2-point calibration.
610	Cal expired (K)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	- Perform a calibration. Removal condition: - Successful 2-point calibration.
611	Cal expired (Na)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	- Perform a calibration. Removal condition: - Successful 2-point calibration.
612	Cal expired (Ca)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	- Perform a calibration. Removal condition: - Successful 2-point calibration.

No.	Message	Interpretation	Operator action
613	Cal expired (Cl)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	- Perform a calibration. Removal condition: - Successful 2-point calibration.
614	Cal expired (Glu)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	- Perform a calibration. Removal condition: - Successful 1- or 2-point calibration.
615	Cal expired (Lac)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as “.....”.	- Perform a calibration. Removal condition: - Successful 1- or 2-point calibration.
616	Cal expired (OXI)	Too long time elapsed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	- Perform a calibration. Removal condition: - Successful 1- or 2-point calibration.
641	ABL/DMS PC restarted	The analyzer was restarted from power off.	- No action required. For information only.
642	ABL/DMS PC connected to wet section	Added by DMS PC when connection to the wet section is obtained.	- No action required.
643	ABL/DMS PC disconnected from wet section	The connection from the DMS PC to the wet section is lost.	- Shut down and restart the analyzer. - Contact Radiometer service representative.
648	Calibration failed or not accepted	The last calibration was aborted or not accepted.	- Check solution pack status and replace, if necessary. - Check sensor cassette status and replace, if necessary. - Check for and remedy system messages. - Repeat the calibration. Removal condition: - Successful calibration.
662	Barometer out of range	Measured barometer value is outside the measuring range: 60-106.7 kPa.	- Contact Radiometer service representative.
669	QC value outside control range	Measured parameter value is outside control range.	- Verify the procedure and repeat measurement. - Refer to Quality Control Systems Reference Manual.

No.	Message	Interpretation	Operator action
679	Barometer error	The measured parameter may be unreliable due to barometer error.	- Contact Radiometer service representative.
682	OXI module not active	The OXI module is not responding due to an internal communication problem, or the 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: - OXI module ready, or software configured without OXI module support.
688	*c*tHb/*c*eHb too low for OXI calculation	*c*tHb < 1 mmol/L, or *c*eHb < 0.75 mmol/L. If *c*tHb is too low, *F*HHb, FO_2Hb, *F*COHb and *F*MetHb are not calculated. If *c*eHb = *c*HHb + cO_2Hb is too low, sO_2 is not calculated.	- If Oxi derivates are wanted, elevate tHb and/or sO_2.
692	ABL not connected to RADIANCE	The analyzer is not connected to RADIANCE.	- Contact your RADIANCE/IT engineer. - 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.
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.

No.	Message	Interpretation	Operator action
699	Built-in QC measurement started due to calibration error	The analyzer was set up to perform built-in QC measurements in case of calibration errors.	- Check Calibration Status and remedy any reported calibration errors.
700	Scheduled built-in QC not run due to errors in last calibration	Last calibration contained an error, and the analyzer was set up to suspend built-in QC measurements in case of calibration errors.	- Check Calibration Status and remedy calibration errors.
703	QC expired	QC measurement is 25 % overdue (corrective action "Lock analyzer" has been selected in the Setup program: Corrective Actions).	- Perform a quality control measurement. Removal condition: - No QC measurements are pending.
704	Built-in QC measurement is repeated	The scheduled QC measurement was not accepted; the measurement was repeated as requested in the Setup program: Corrective Actions.	- No action required.
705	Built-in QC measurement is repeated twice	The scheduled QC measurement was not accepted; the measurement was repeated twice as requested in the Setup program: Corrective Actions.	- No action required.
707	Replacement(s) overdue by 10 %. Analyzer locked.	Replacement is overdue by 10 % (corrective action "Lock analyzer" was selected in the 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 the Miscellaneous Setup program. Removal condition: - No replacement pending.
708	Corrective action not possible due to empty solution pack	Scheduled built-in QC measurement was requested, but the solution pack was empty.	- Insert a new solution pack.
712	*F*HbF measurement not possible	Composition of the blood sample makes *F*HbF measurement too inaccurate, but OXI parameters are compensated for HbF. See explanation in the ABL90 FLEX reference manual.	- If *F*HbF is wanted change sample composition. For example, elevate sO_2 and tHb.
713	*c*tBil measurement not possible	Blood sample *c*tHb is so high that hardly any plasma is left to measure plasma bilirubin on. *c*tHb > 15.5 mmol/L.	- If *c*tBil is wanted, lower the ctHb value.

No.	Message	Interpretation	Operator action
734	General WSM exception	The data management system establishes connection to the analyzing unit, or the connection is lost.	- Wait a few minutes for the connection to establish. - Restart the analyzer. - If the error persists, contact Radiometer service representative.
745	Low disk space	Free disk space is low.	- Move archive files to another storage device. Removal condition: - Sufficient free hard disk space.
766	ABL not connected to RADIANCE - no RADIANCE connection license	The analyzer has been refused connection to RADIANCE because there is no connection license 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.
769	ABL<>RADIANCE communication error - XML packet could not be parsed	Communication error between the analyzer and RADIANCE.	- Contact RADIANCE/IT engineer or Radiometer service representative.
770	Failed to restore Custom Setup	The setup could not be restored.	- Download the setup data from another floppy disk, hard disk or network drive. - 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.

No.	Message	Interpretation	Operator action
773	Remote operator logged on with user:	A remote operator has logged on the analyzer via NetOp.	- No action required.
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.
780	RADIANCE communication enabled	RADIANCE communication has been enabled as part of the RADIANCE Connection Setup.	- No action required. For information only.
781	RADIANCE communication disabled	RADIANCE communication has been disabled as part of the RADIANCE Connection Setup.	- No action required. For information only.
782	RADIANCE output queue cleared	The output queue was cleared in the RADIANCE Connection Setup.	- No action required. For information only.
783	Automatic backup started	Automatic backup (selected in Disk Functions Setup) has started.	- No action required. For information only.
785	Automatic archiving started	Automatic archiving (selected in Disk Functions Setup) has started.	- No action required. For information only.
786	Automatic archiving completed	Automatic archiving (selected in Disk Functions Setup) completed successfully.	- No action required. For information only.
787	Export of data logs started	Export of data logs was started by the user.	- No action required. For information only.
798	User logged on	User logged on successfully.	- No action required. For information only.
799	User logged off	User logged off.	- No action required. For information only.
800	Logon attempt failed	User tried to log on but did not provide a valid password.	- Provide a valid password to log on.
810	pH locked	The 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.

No.	Message	Interpretation	Operator action
811	pCO_2 locked	The 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.
812	pO_2 locked	The 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.
813	K locked	The 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.
814	Na locked	The 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.
815	Cl locked	The 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.
816	Ca locked	The 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.
818	Glu locked	The 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.

No.	Message	Interpretation	Operator action
819	Lac locked	The 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.
820	tHb locked	The 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.
821	MetHb locked	The 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.
822	COHb locked	The 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.
823	HHb locked	The 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.
824	O_2Hb locked	The 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.
825	sO_2 locked	The 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.

No.	Message	Interpretation	Operator action
826	HbF locked	The 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.
827	tBil locked	The 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	pH unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.
832	pCO_2 unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.
833	pO_2 unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.
834	K unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.
835	Na unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.
836	Cl unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.
837	Ca unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.
839	Glu unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.
840	Lac unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.

No.	Message	Interpretation	Operator action
841	tHb unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.
842	MetHb unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.
843	COHb unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.
844	HHb unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.
845	O_2Hb unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.
846	sO_2 unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.
847	HbF unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.
848	tBil unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	- No action required. For information only.
852	RADIANCE:	Message from RADIANCE.	- No action required. For information only.
855	Base Excess out of range	Base Excess exceeds the +/- 30 mmol/L range.	- For information only. No analyzer error was detected.
875	Sample aged	The specified limit for sample age has been exceeded.	- Draw and analyze new sample.
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. For information only.
886	LIS/HIS: No valid POCT1A DML Device ID file	A file with a valid Device ID does not exist. A valid Device ID is needed in order to use the POCT1A DML protocol.	- Contact Radiometer service representative to obtain a Device ID file. Removal condition: - Valid Device ID found.

No.	Message	Interpretation	Operator action
963	Leak current in analyzer detected	Leak currents were detected during system calibration and may distort measuring results.	- Replace inlet connector, sensor cassette or solution pack. - Contact Radiometer service representative.
964	Leak current in relation to solution pack detected	Leak currents were detected during system calibration and may distort measuring results.	- Replace solution pack. - Contact Radiometer service representative.
970	Replace solution pack	This message is shown when the solution pack needs to be replaced. The analyzer will enter "User-intervention required".	- Replace solution pack.
971	Replace sensor cassette	This message is shown when the sensor cassette needs to be replaced. The analyzer will enter "User-intervention required".	- Replace sensor cassette.
973	Printer paper must be replaced	No more paper in printer.	- Insert new printer paper.
978	Flow selector calibration error	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
979	Inhomogeneous rinse solution	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
983	Inhomogeneous cal 3 solution	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
984	The analyzer could not aspirate homogeneous calibration solution	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1000	Number of pO_2 hardware data fail	Can be shown on a result if unable to calculate oxygen due to an unexpected system error.	- Restart the analyzer. - Perform a calibration. - Contact Radiometer service representative.

No.	Message	Interpretation	Operator action
1001	Timeout while waiting for pO_2 hardware data	Can be shown on a result if unable to calculate oxygen due to an unexpected system error.	- Restart the analyzer. - Perform a calibration. - Contact Radiometer service representative.
1002	pO_2 dark data is out of range	Can be shown on a result if unable to calculate oxygen due to an unexpected system error.	- Restart the analyzer. - Perform a calibration. - Contact Radiometer service representative.
1004	Unable to calculate oxygen parameter	Can be shown on a result if unable to calculate oxygen due to an unexpected system error.	- Restart the analyzer. - Perform a calibration. - Contact Radiometer service representative.
1005	Unable to calculate oxygen parameter	Can be shown on a result if unable to calculate oxygen due to an unexpected system error.	- Restart the analyzer. - Perform a calibration. - Contact Radiometer service representative.
1006	Unable to calculate oxygen parameter	Can be shown on a result if unable to calculate oxygen due to an unexpected system error.	- Restart the analyzer. - Perform a calibration. - Contact Radiometer service representative.
1007	Missing oxygen calibration	No calibration data exists for oxygen.	- Perform a calibration.
1008	Unable to calculate oxygen parameter	Can be shown on a result if unable to calculate oxygen due to an unexpected system error.	- Restart the analyzer. - Perform a calibration. - Contact Radiometer service representative.
1009	Unable to calculate oxygen parameter	Can be shown on a result if unable to calculate oxygen due to an unexpected system error.	- Restart the analyzer. - Perform a calibration. - Contact Radiometer service representative.
1010	Oxi data collection error	Oxi hardware problem	- Restart the analyzer. - Perform a calibration. - Contact Radiometer service representative.
1011	Oxi has no Blank Cal	Missing Blank Cal. Not necessarily a hardware error.	- Perform a calibration. - Restart the analyzer. - Contact Radiometer service representative. Removal conditioning: - Successful Blank calibration
1012	Oxi has no sample spectrum	The system has not made a sample measurement yet, or there is a hardware problem.	- Repeat the measurement. - Restart the analyzer. - Contact Radiometer service representative.
1013	Oxi data collection error	Oxi hardware error	- Restart the analyzer. - Perform a calibration. - Contact Radiometer service representative.

No.	Message	Interpretation	Operator action
1014	Oxi Blank Cal. intensity too high	The spectrometer received too high light intensity during Blank Cal.	- Check solution pack. During Oxi Blank calibration, the cuvette must be filled with liquid. - Perform a calibration. - Restart the analyzer. - Contact Radiometer service representative.
1015	Oxi sample intensity too high	The spectrometer received too high light intensity during sample measurement.	- Check solution pack. During Oxi Blank calibration, the cuvette must be filled with liquid. - Perform a calibration. - Repeat the sample measurement.
1016	Oxi Blank Cal. intensity too low	The spectrometer received too low light intensity during Blank Cal.	- Perform a calibration. - Restart the analyzer. - Contact Radiometer service representative.
1017	Oxi sample intensity too low	The spectrometer received too low light intensity during sample measurement.	- Restart the analyzer. - Perform a calibration. - Contact Radiometer service representative.
1018	Oxi electronic adjustment error	Oxi hardware problem.	- Restart the analyzer. - Perform a calibration. - Contact Radiometer service representative.
1019	Oxi Blank Cal. outside limits	Peak value of Blank Cal. spectrum intensity is outside acceptance limits.	- Check solution pack. The cuvette must be filled with liquid during Blank calibration. - Perform a calibration. - Restart the analyzer. - Contact Radiometer service representative.
1020	Oxi neon intensity outside limits	Oxi hardware problem.	- Restart the analyzer. - Perform a calibration. - Contact Radiometer service representative.
1021	Oxi neon correction outside limits	Oxi hardware problem.	- Restart the analyzer. - Contact Radiometer service representative.
1022	Oxi background correction outside limits	Oxi hardware problem.	- Restart the analyzer. - Contact Radiometer service representative.
1023	Oxi spectrometer memory read problem	Oxi hardware problem.	- Restart the analyzer. - Contact Radiometer service representative.

No.	Message	Interpretation	Operator action
1024	Oxi spectrometer memory write problem	Oxi hardware problem.	- Restart the analyzer. - Contact Radiometer service representative.
1025	Oxi hemolyzer tuning problem	Oxi hardware problem.	- Restart the analyzer - Contact Radiometer service representative.
1026	Oxi hemolyzer frequency problem	Oxi hardware problem.	- Restart the analyzer. - Contact Radiometer service representative.
1027	Oxi hemolyzer temperature deviation too high	Oxi hardware problem.	- Restart the analyzer. - Contact Radiometer service representative.
1028	Oxi neon voltage outside limits	Oxi hardware problem.	- Restart the analyzer. - Contact Radiometer service representative.
1029	Oxi light source voltage outside limits	Oxi hardware problem.	- Restart the analyzer. - Contact Radiometer service representative.
1030	Oxi hemolyzer voltage outside limits	Oxi hardware problem.	- Restart the analyzer. - Contact Radiometer service representative.
1031	Oxi initialization in progress	Oxi initialization in progress.	- Please wait up to 50 minutes before restarting the analyzer. - Restart the analyzer. - Contact Radiometer service representative.
1032	Oxi data collection problem	Oxi hardware problem.	- Restart the analyzer. - Contact Radiometer service representative.
1033	Oxi task was not finished	Internal software problem.	- Restart the analyzer. - Contact Radiometer service representative.
1034	Oxi hardware problem	An Oxi hardware problem has occurred.	- Restart the analyzer. - Perform a calibration. - Contact Radiometer service representative.
1045	Unable to read consumable information	Unable to read information stored on either sensor cassette or solution pack.	- Reinstall the solution pack and sensor cassette. - Restart the analyzer. - Contact Radiometer service representative.
1061	Pressure test flow error	The sample transport through the analyzer is hindered.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.

No.	Message	Interpretation	Operator action
1062	Pressure test pressure error	A leak has been found in the solution transport.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1063	Pressure test vacuum error	A leak has been found in the solution transport.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1064	Temperature in sensor cassette top out of range	Hardware temperature error.	- Ensure that the ambient temperature is between 15 and 32 °C. - If the system has just performed a cold start, wait for the error to disappear. - Replace the fan filter, if dirty. - Shield the analyzer from direct sunlight and other heat sources. - Contact Radiometer service representative.
1065	Temperature in sensor cassette bottom out of range	Hardware temperature error.	- Ensure that the ambient temperature is between 15 and 32 °C. - If the system has just performed a cold start, wait for the error to disappear. - Replace the fan filter, if dirty. - Shield the analyzer from direct sunlight and other heat sources. - Contact Radiometer service representative.
1066	Temperature in sensor cassette substrate out of range	Hardware temperature error.	- Ensure that the ambient temperature is between 15 and 32 °C. - If the system has just performed a cold start, wait for the error to disappear. - Replace the fan filter, if dirty. - Shield the analyzer from direct sunlight and other heat sources. - Contact Radiometer service representative.

No.	Message	Interpretation	Operator action
1069	Temperature in Oxi cuvette out of range	Hardware temperature error.	- Ensure that the ambient temperature is between 15 and 32 °C. - If the system has just performed a cold start, wait for the error to disappear. - Replace the fan filter, if dirty. - Shield the analyzer from direct sunlight and other heat sources. - Contact Radiometer service representative.
1070	Sensor response error	Unstable signal from sensor.	- Repeat measurement
1071	Temperature in Oxi spectrometer out of range	Hardware temperature error.	- Ensure that the ambient temperature is between 15 and 32 °C. - If the system has just performed a cold start, wait for the error to disappear. - Replace the fan filter, if dirty. - Shield the analyzer from direct sunlight and other heat sources. - Contact Radiometer service representative.
1079	Sensor impedance error	Sensor impedance error	- Perform calibration - Replace sensor cassette
1081	Inhomogeneous rinse solution	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1083	Inhomogeneous cal 2 solution	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1084	Inhomogeneous cal 3 solution	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1085	Inhomogeneous QC1 solution	Bubbles were detected in the QC1 solution.	- Perform a refill from the auxiliary program. - Replace the solution pack.

No.	Message	Interpretation	Operator action
1086	Inhomogeneous QC2 solution	Bubbles were detected in the QC2 solution.	- Perform a refill from the auxiliary program. - Replace the solution pack.
1087	Inhomogeneous QC3 solution	Bubbles were detected in the QC3 solution.	- Perform a refill from the auxiliary program. - Replace the solution pack.
1089	Inhomogeneous gas	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1090	No rinse solution	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1092	No cal 2 solution	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1093	No cal 3 solution	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1094	No QC1 solution	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1095	No QC2 solution	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1096	No QC3 solution	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.

No.	Message	Interpretation	Operator action
1098	No gas	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1099	Pump calibration error	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1100	Outlet LS not empty during pump calibration	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1101	Outlet LS not full during pump calibration	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1111	Inhomogeneous air	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1112	LS inlet not empty	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1113	LS sensors not empty	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1114	LS outlet not empty	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1115	Ws communication error: wrong message format	Internal communication error.	- Restart the analyzer. - Contact Radiometer service representative.

No.	Message	Interpretation	Operator action
1116	Ws communication error: keep alive timeout	Internal communication error.	- Restart the analyzer. - Contact Radiometer service representative.
1117	Oxi spectrometer temperature drift	A large deviation in temperature has been observed. This is probably due to a change in the ambient environment.	- Perform a calibration
1120	Sensor replacement successful	This message is shown in the Activity Log following a successful replacement of the sensor cassette.	- No action required. For information only.
1121	The port did not open during sensor replacement	This message is shown in the Activity Log after a failed sensor cassette replacement.	- Reinstall the sensor cassette. - Restart the analyzer. - Contact Radiometer service representative.
1123	The sensor chip data could not be read or written during replacement	This message is shown in the Activity Log after a failed sensor cassette replacement.	- Reinstall the sensor cassette. - Restart the analyzer. - Contact Radiometer service representative.
1124	An unregistered sensor was installed during replacement	This message is shown in the Activity Log after a sensor cassette replacement that did not identify a previously conditioned cassette.	- No action required. For information only.
1125	An unregistered and used sensor was installed during replacement	This message is shown in the Activity Log after a sensor cassette replacement. It informs that the sensor cassette installed is already used and no information exists about the conditioning hereof.	- No action required. For information only.
1126	A registered sensor had been used before installation	This message is shown in the Activity Log after a sensor cassette replacement. It informs that the sensor cassette installed has been used before.	- No action required. For information only.
1134	The chip information for the solution pack cannot be read or written	This message is shown in the Activity Log after a failed solution pack replacement.	- Reinstall the solution pack. - Restart the analyzer. - Contact Radiometer service representative.
1135	The solution pack has been used before	This message is shown in the Activity Log after a failed solution pack replacement.	- Reinstall the solution pack.

No.	Message	Interpretation	Operator action
1140	The solution pack has used the maximum number of measurements at installation	This message is shown in the Activity Log after a failed solution pack replacement.	- Reinstall the solution pack.
1142	The printer door is open. Printing not possible	Printer door open.	- Ensure that the printer paper is properly installed. - Close the printer door.
1143	Internal printer is offline. Printing not possible	Printer hardware error.	- Ensure that the printer paper is properly installed. - Close the printer door.
1144	Check that printer door is closed and that paper is present	Printer hardware error.	- Ensure that the printer paper is properly installed. - Close the printer door.
1145	A printer error has occurred. Call service technician	Printer hardware error.	- Ensure that the printer paper is properly installed. - Close the printer door.
1146	Printer paper replaced	This message is shown in the Activity Log after replacement of printer paper.	- No action required. For information only.
1147	Inlet opened during rinse	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1148	Inlet open during calibration	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1149	Inlet open during wet section activity	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1150	Inlet closed without aspirating sample	This message is shown in the Activity Log when a measurement has been cancelled due to inlet being closed before aspiration could be completed.	- No action required. For information only.

No.	Message	Interpretation	Operator action
1151	Inlet not closed: no sample aspirated	This message is shown in the Activity Log when a measurement has been cancelled due to inlet being closed too late.	- No action required. For information only.
1152	The solution pack chip data could not be read or written during replacement	This message is shown in the Activity Log when a replacement of the sensor cassette or solution pack has failed. The reason was that it was impossible to communicate with the chip on the consumable.	- Repeat replacement operation.
1157	No valid FTC programs detected	System error.	- Contact Radiometer service representative.
1160	The top thermistor is not connected	The top thermistor is not connected	- Restart the analyzer - If still present, replace top thermistor
1161	The top thermistor short-circuited	The top thermistor short-circuited	- Restart the analyzer - If still present, replace top thermistor
1163	The sensor cassette thermistor is not connected	The sensor cassette thermistor is not connected	- Restart the analyzer - If still present, replace sensor cassette
1164	The sensor cassette thermistor is short-circuited	Sensor cassette thermistor is short-circuited	- Restart the analyzer - If still present, replace sensor cassette
1165	Solution pack not properly installed	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1166	Solution pack expired	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1167	Sensor cassette not properly installed	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.

No.	Message	Interpretation	Operator action
1168	Sensor cassette expired	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1169	Unable to pump solutions	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1170	Inlet has been open for too long	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1171	Inlet is missing or in unknown state	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1172	Sensor cassette damaged	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1173	Solution pack damaged	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1174	Inlet opened while the analyzer was busy	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.

No.	Message	Interpretation	Operator action
1175	Sensor temperature error	Hardware temperature error (Thermistor).	- Ensure that the ambient temperature is between 15 and 32 °C. - If the system has just performed a cold start, wait for the error to disappear. - Replace the fan filter, if dirty. - Shield the analyzer from direct sunlight and other heat sources. - Contact Radiometer service representative.
1176	A liquid sensor error was detected	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1177	A flow selector error was detected	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1178	A pump calibration error was detected	Shown on screen when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1180	An error occurred when trying to communicate with wet section	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1181	A software or hardware error exists in wet section	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1183	Valve malfunctioning	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.

No.	Message	Interpretation	Operator action
1184	Leak detected	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1185	Warning: Free memory is low	The internal memory is low.	- Restart the analyzer
1186	Free system memory is critically low	The internal memory is critically low.	- Restart the analyzer
1187	Disk shows signs of wear	The permanent memory is showing exhaustion signs and should probably be replaced soon.	- Contact Radiometer service representative.
1188	Disk shows serious signs of wear	The permanent memory is showing exhaustion signs and should be replaced soon.	- Contact Radiometer service representative.
1189	FTC aborted, LS state change error	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1190	Inlet open	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1191	QA Portal communication enabled	Shown in the Activity Log after enabling QA Portal communication	- No action required. For information only.
1192	QA Portal communication disabled	Shown in the Activity Log after disabling QA Portal communication	- No action required. For information only.
1193	QA Portal output queue cleared	Shown in the Activity Log when the QA Portal has been reset.	- No action required. For information only.
1194	ABL not connected to QA Portal	The analyzer is not connected to the QA Portal.	- Contact your IT engineer. - Check QA Portal Communication Setup, including TCP/IP address, port no. and password. - Check that QA Portal is responding. - Check network connections.

No.	Message	Interpretation	Operator action
1195	ABL not connected to QA Portal - incorrect password	The analyzer was refused connection to the QA Portal due to incorrect password.	- Enter the correct password in the analyzer's QA Portal Communication Setup.
1196	ABL connected to QA Portal	The analyzer is connected to the QA Portal.	- No action required. For information only.
1197	ABL disconnected form QA Portal	The analyzer is disconnected from the QA Portal.	- No action required. For information only.
1198	ABL<>QA Portal communication error - XML packet could not be parsed	Communication error between the analyzer and the QA Portal.	- Contact IT engineer or Radiometer service representative.
1199	FTC program has been retried	This message is found in the Activity Log when a measurement or calibration activity has been retried due to error.	- No action required. For information only.
1200	Solution pack empty	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1201	Solution pack lifetime expired	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1202	Expiration date reached	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1203	Lifetime in analyzer exceeded	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1204	No more activities left	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.

No.	Message	Interpretation	Operator action
1216	Lifetime in analyzer exceeded	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1217	No more tests left	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1218	Expiration date reached	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1219	RiLiBÄK Violation: Value above upper limit	The measured value lies above the upper RiLiBÄK range.	- No action required.
1220	RiLiBÄK Violation: Value below lower limit	The measured value lies below the lower RiLiBÄK range.	- No action required.
1221	System temperature out of range	Hardware temperature error (all).	- Ensure that the ambient temperature is between 15 and 32 °C. - If the system has just performed a cold start, wait for the error to disappear. - Replace the fan filter, if dirty. - Shield the analyzer from direct sunlight and other heat sources. - Contact Radiometer service representative.
1222	Temperature system error	Hardware temperature error (Top/bottom thermistor).	- Ensure that the ambient temperature is between 15 and 32 °C. - If the system has just performed a cold start, wait for the error to disappear. - Replace the fan filter, if dirty. - Shield the analyzer from direct sunlight and other heat sources. - Contact Radiometer service representative.

No.	Message	Interpretation	Operator action
1223	Analyzer did not connect at start-up	The analyzer DMS has not been able to establish contact to the WS(M) at start-up.	- Restart the analyzer. - Contact Radiometer service representative.
1224	Analyzer is temporarily shut down	Shown in the Activity Log after temporary shutdown of the analyzer.	- No action required.
1225	The sample is older than a day	The time between sampler draw time and aspiration is larger than 1 day.	- Either sampler draw time has been entered incorrectly or time of the analyzer is incorrect. Change either to correct the error.
1226	The sample age is negative	The time between sampler draw time and aspiration is less than zero.	- Either sampler draw time has been entered incorrectly or time of the analyzer is incorrect. Change either to correct the error.
1227	Correction for bicarbonate contains errors from pH, pCO_2	Chloride is corrected for bicarbonate, calculated from pH and pCO_2. Errors from pH, pCO_2 results in this error on chloride.	- No action required.
1228	Correction for lactate contains errors from K^+, Na^+, Ca^{2+}	Lactate is corrected for ion strength, calculated from K^+, Na^+, Ca^{2+}. Errors from K^+, Na^+, Ca^{2+} results in this error on lactate.	- No action required.
1230	Inlet gasket replaced	Shown in the activity log at the time of a replacement.	- No action required.
1231	Inlet probe replaced	Shown in the activity log at the time of a replacement.	- No action required.
1232	Inlet connection gasket replaced	Shown in the activity log at the time of a replacement.	- No action required.
1233	Inlet cleaned	Shown in the activity log at the time when an inlet cleaning was performed.	- No action required.
1234	Demonstration software - not for clinical purposes		
1235	Failed to aspirate sample	Aspiration failed	- Remove sampler. Retry aspiration
1236	Failed to aspirate sample	Aspiration failed, due to blocked inlet	- Remove sampler. Retry aspiration
1240	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1242	Liquid transport failed	Unstable aspiration from solution pack	- No action required

No.	Message	Interpretation	Operator action
1243	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1244	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1245	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1246	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1247	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1248	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1249	Liquid transport failed	Unstable aspiration from solution pack	No action required
1250	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1253	Failed to aspirate sample	Aspiration failed sample not detected	- Retry aspiration
1254	Failed to aspirate sample	Aspiration failed sample not detected	- Retry aspiration
1257	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1258	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1259	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1260	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1261	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1262	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1263	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1264	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1265	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1266	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1267	Liquid transport failed	Unstable aspiration from solution pack	- No action required

No.	Message	Interpretation	Operator action
1268	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1269	Failed to aspirate sample	Unstable aspiration from solution pack	- No action required
1270	Failed to aspirate sample	Unstable aspiration from solution pack	- No action required
1271	Failed to aspirate sample	Aspiration failed sample not detected	- Retry aspiration
1272	Failed to aspirate sample	Aspiration failed sample not detected	- Retry aspiration
1275	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1276	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1279	Liquid transport failed	Unstable aspiration from solution pack	No action required No action required
1280	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1281	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1282	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1283	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1284	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1285	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1286	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1290	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1292	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1294	Liquid transport failed	Unstable aspiration from solution pack	- No action required
1295	Activity has been repeated due to the following reason:	This message is shown in the activity log when an activity is repeated automatically. It lists the error and parameter id that was the cause of the repeat.	- No action required.
1296	Printer out of paper	The printer is out of paper. A new paper roll must be inserted	- Insert a new paper roll

No.	Message	Interpretation	Operator action
1297	Printer is offline	The printer is offline due to either a bad or missing power / USB connection	- Check the power connection - Check the USB connection - Contact Radiometer service representative.
1298	Printer lid open	The printer lid is open	- Close the printer lid
1299	Rinse activity repeated:	A rinse activity has been repeated. The following entries in the log explain the reason for the repeat.	- No action required.
1300	Calibration activity repeated:	A calibration activity has been repeated. The following entries in the log explain the reason for the repeat.	- No action required.
1301	QC activity repeated:	A QC activity has been repeated. The following entries in the log explain the reason for the repeat.	- No action required.
1302	Startup activity repeated:	A startup activity has been repeated. The following entries in the log explain the reason for the repeat.	- No action required.
1303	Activity repeated:	An activity has been repeated. The following entries in the log explain the reason for the repeat.	- No action required.
1304	Calibration activity repeated	A calibration activity has been repeated. The following entries in the log explain the reason for the repeat.	- No action required.
1305	End of repeat reason list	This message indicates the end of repeat reasons. See errors 1299-1304.	- No action required.
1306	Solution pack manually removed	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1307	Disk space less than fifteen percent	The disk space on the analyzer is low.	- Delete some archives to free up space on the drive.
1308	Disk space less than one percent	The disk space on the analyzer is less than 1 %	- Free disk space. E.g. deleting some archives
1309	Unable to start FTC activity - FTC activity in progress		

No.	Message	Interpretation	Operator action
1310	Response error	Sensor (Metabolite) does not work properly	- Replace sensor
1311	The analyzer chip data could not be read or written	It's not possible to read or write data to the analyzer chip	- Contact Radiometer service representative.
1312	Export data logs failed	The export data log operation has failed.	- Make sure the selected export path exists. - Make sure enough space is available.
1313	Export data logs done	The export data log operation has completed successfully.	- No action required.
1314	Sensor temperature error during rinse	Sensor temperature error (substrate) during rinse	- Check sensor status and replace, if necessary.
1315	Cal backlog error (pH)	Cal backlog error (pH), leaping signals on rinse	- Perform rinse
1316	Cal backlog error (pCO_2)	Backlog unstable, leaping signals on rinse	- Perform rinse
1317	Cal backlog error (pO_2)	Backlog unstable, leaping signals on rinse	- Perform rinse
1318	Cal backlog error (K)	Backlog unstable, leaping signals on rinse	- Perform rinse
1319	Cal backlog error (Na)	Backlog unstable, leaping signals on rinse	- Perform rinse
1320	Cal backlog error (Ca)	Backlog unstable, leaping signals on rinse	- Perform rinse
1321	Cal backlog error (Cl)	Backlog unstable, leaping signals on rinse	- Perform rinse
1322	Cal backlog error (Glu)	Backlog unstable, leaping signals on rinse	- Perform rinse
1323	Cal backlog error (Lac)	Backlog unstable, leaping signals on rinse	- Perform rinse
1324	Inhomogeneous rinse solution (LS sensors)	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1325	Sensor thermistor recalibrated	Show in activity log when a recalibration of the sensor thermistor has been performed	- Information only

No.	Message	Interpretation	Operator action
1326	Sensor thermistor recalibration failed - thermistor mal-functioning	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1327	Analyzer locked by user	User has locked the analyzer	- No action required.
1328	Analyzer locked on request from LIS	The analyzer was locked on request from LIS	- No action required.
1329	Analyzer locked on request from Radiance	The analyzer was locked on request from Radiance	- No action required.
1330	pO_2 substrate thickness	The thickness of the pO_2 substrate is outside the ranges	
1331	Intervention required entered	The analyzer enters UIR	- No action required.
1332	Intervention required exited	The analyzer exits UIR	- No action required.
1335	Solution pack replaced	This message is used in the Activity log to indicate replacement of solution pack	- No action required
1336	Sensor cassette replaced	This message is used in the Activity log to indicate replacement of sensor cassette	- No action required
1337	Printer paper replaced	This message is used in the Activity log to indicate replacement of printer paper	- No action required
1338	Demo mode enabled	This message is used in the Activity log to indicate that ABL 90 demo mode has been enabled	- No action required
1339	Demo mode disabled	This message is used in the Activity log to indicate that ABL 90 demo mode has been disabled	- No action required
1340	Sensor cassette maintenance by Analyzer has been interrupted	This message is used in the Activity log to indicate startup using a sensor cassette which has been left without an FTC activity for more than 2 hour.	- No action required

No.	Message	Interpretation	Operator action
1341	Leak detected	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1342	Leak detected	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1343	Unable to pump solutions	Shown in the Activity Log when "User-intervention required" has been entered due to this reason.	- The analyzer will automatically enter "User-intervention required". Follow the instructions shown on the screen.
1344	Solution pack removed	This message is used in the Activity log to indicate replacement of solution pack	- No action required
1345	Solution pack inserted	This message is used in the Activity log to indicate replacement of solution pack	- No action required
1346	Sensor cassette removed	This message is used in the Activity log to indicate replacement of sensor cassette	- No action required
1347	Sensor cassette inserted	This message is used in the Activity log to indicate replacement of sensor cassette	- No action required
1348	Warning - Battery low	This message is used in the Activity log to indicate low battery level	- Plug analyzer into mains
1349	Analyzer shutdown due to low battery	Analyzer shutdown due to low battery	- No action required
1350	Clot suspected in Inlet	Clot suspected in inlet	- No action required
1351	Clot suspected in sensor cassette	Clot suspected in sensor cassette	- No action required
1352	Clot suspected in OXI module	Clot suspected in OXI module	- No action required
1353	User Action Needed entered	The analyzer has entered User Action Needed	- User should perform action shown on screen
1354	User Action Needed exited	The analyzer has exited User Action Needed	- No action required

No.	Message	Interpretation	Operator action
1355	Conditioned Sensor Startup	Conditions for performing a conditioned sensor startup was fulfilled. The analyzer does not initially perform calibration with every measurement.	- No action required
1356	Non-Conditioned Sensor Startup	Conditions for performing a conditioned sensor startup was fulfilled. The analyzer does not initially perform calibration with every measurement.	- No action required
1357	Software upgrade initiated	This message is shown in the Activity log when a software upgrade has been initiated	- No action required
1358	Upgraded from	This message is shown in the Activity log when a software upgrade has been performed	- No action required
1359	Upgrade option:	This message is shown in the Activity log when a software upgrade has been performed	- No action required
1360	No clots detected in Analyzer	This message is shown in the Activity log when the clot detection program did not detect any clots	- No actions
1361	Internal reference electrode error in sensor cassette	The reference electrode is malfunctioning	- Replace sensor cassette

I Appendix - Quality control

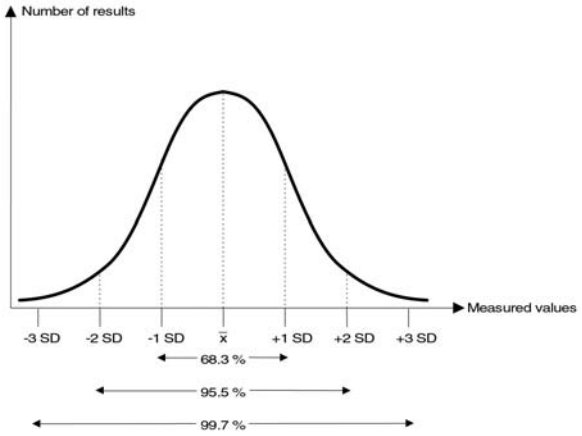
General information

This appendix includes general information about quality control/quality management that is relevant and in some case also specific for the ABL90 FLEX analyzer.

Some of the sections in this appendix contain information about both built-in and manual quality controls. Most of the information in this appendix is, however, only relevant for manual quality control and the appendix is, therefore, first and foremost thought as a supplement to the manual quality controls.

Statistical parameters

This section describes the terms and statistical parameters used in the topic quality control:

Parameter	Definition
Mean value, $\overline{X}$	The mean value is the average value as shown below: $\overline{X} = \frac{\sum X}{n}$ where X = single result $\sum X$ = the sum of single results n = number of single results
Standard Deviation, SD	The standard deviation describes the distribution about the mean value and is calculated as follows: $1\,SD = \sqrt{\frac{\sum (X - \overline{X})^2}{n-1}}$ and can be illustrated on the normal distribution curve:  1 SD includes 68.3 % of the results. 2 SD includes 95.5 % of the results and is normally used for clinical instruments.
Coefficient of variation, CV%	Coefficient of variation expresses the variation in the sampling results and is calculated as follows: $CV = \frac{SD}{\overline{X}} \times 100\ (\%)$ where SD = standard deviation and $\overline{X}$ = mean value from lot-to-date. CV% is used to compare the deviation from the absolute mean value from lot-to-date and can, therefore, be of limited use at low mean values with low precision.

Control ranges (for manual QC only)

About control ranges

The control ranges are the ranges within which the result of a quality control measurement should fall in order for the analyzer to be well functioning. Each package of quality control ampoules is supplied with an insert with control ranges for all parameters and analyzers which the given quality control system can evaluate.

As the control ranges determine whether an analyzer is judged to be well functioning or not, it is imperative that they are founded on well-established reference methods and certified reference standards, and in-depth knowledge of the correlation between an analyzer type and the quality control solution.

Blood gas analyzers are developed to analyze whole human blood, and different types of analyzers will measure identical values (within the specifications). The blood algorithm of the analyzers ensures this. When quality control solutions, which are not blood, are measured, the same corrections will be applied to the quality control result. Therefore, different types of analyzers will measure differently, and control ranges must be established separately for each type of analyzer.

The width of the control ranges is determined during the development phase by measuring on a number of analyzers. The measurements are performed by different persons, over several days, using different dispensers and with different lot numbers of calibration solutions – all this to ensure that all natural variations such as:

- person-to-person
- day-to-day
- analyzer-to-analyzer
- dispenser-to-dispenser
- lot-to-lot
- variation from calibration solutions, etc.

are included in the control ranges.

Definitions

The following terms are used by Radiometer in connection with control ranges:

Term	Explanation	At Radiometer
True value	The value of a parameter in a quality control solution, e.g. pH, is traceable to a primary reference standard. There is one true value for each parameter per lot of a quality control solution. The true value of a parameter is analyzer-independent.	The true value for each parameter included in the reference ampoules are determined by the Metrology Section at Radiometer Medical using NIST standards or standards traceable to the Danish primary laboratory for Electrochemistry (DPLEC) at the Danish Institute of Fundamental Metrology (DFM). This primary laboratory is accredited by Danish Accreditation.

Term	Explanation	At Radiometer
Assigned value	The center value of a control range. There is one assigned value for each parameter for each type of analyzer.	When a quality control system is developed, it is tested on 10 well-functioning analyzers of the type for which the quality control system has been designed. Measurements on level 1 – level 2 – level 3 – level 4 are performed two to five times during 24 hours. These measurements are repeated for 1–4 weeks in order to give 30 – 50 measurements per analyzer.
From true value to assigned value		The true value of a parameter is correlated to the assigned value by an algorithm for a particular type of analyzer and QC product. This is a one-time-only act.
Insert control ranges	The interval within which a quality control result of a well-functioning analyzer should fall with at least 95 % probability.	The insert control ranges are established by being centered around each parameter's assigned value. The width of the insert control ranges is determined using an uncertainty budget comprising contributions from the analyzer, the calibration solutions and the QCs. The uncertainty budget guarantees that only relevant contributions to the width of the insert control ranges are included.
User control ranges (analyzer-specific)	A range established by the user based on results obtained on one analyzer.	

The inserts have control ranges for all analyzers for which the quality control solution can be used. By using the data codes on the inserts, the information about the type and level of the quality control solution and control ranges for all parameters are transferred to the analyzer. The analyzer is then able to recognize the quality control solutions.

User control ranges (for manual QC only)

Introduction

The specified control ranges in the inserts, which are established by Radiometer, include all well-functioning analyzers, and the uncertainty budget will therefore include a contribution derived from the analyzer-to-analyzer variation. This means that results obtained on one specific analyzer should fall within control ranges that are narrower than the insert control ranges.

Before establishing analyzer-specific or so-called user-defined control ranges, you should ensure that your analyzer functions correctly and is properly maintained. The procedure below should be followed. User control ranges must be established and updated each time you start using a new lot of quality control solutions.

Establishing analyzer-specific control ranges

Perform 20 measurements on each level of quality control solution in order to take into account the following variations:

- sample-to-sample
- person-to-person by using two or more people to make measurements
- day-to-day by spreading measurements over a minimum of 4-5 days
- other variations such as uncertainty from calibration solutions, chemical decomposition of the quality control solutions, and inhomogeneity of the QC lot should be included in the user-defined control ranges (see procedure further in this chapter).

The following requirements should be fulfilled for analyzer-specific control ranges:

- The established mean value falls within the insert control ranges
- Worldwide DATACHECK participants: the established SD is not wider than 1.26 x Avg(SD) of the peer group of similar analyzers

To establish your own control ranges, do the following.

Step	Action
1.	Perform at least 20 measurements as described above.
2.	Enter the **QC** screen (press ***Menu > Utilities > Setup*** (if necessary, log on) ***> QC Setup > QC Ranges***). Select the desired control solution by pressing ***Next Slot***.
3.	Press ***Edit*** to change the lower/upper limit in the "Lot to date range (2SD)" column. Confirm each change with ***Enter*** on the keypad. Use ***Next*** or ***Prev. Param***. to change to another parameter.
4.	Press ***Close*** to exit the program.

To get full benefit from the evaluation procedure, Radiometer recommends the use of a statistics factor of 1.5 (default) to establish the statistics range (see section *Statistics factor and statistics range* further in this appendix.

Another option is to manually correct the 2 SD control ranges in order to include uncertainty contributions from:

- chemical decomposition of the QUALICHECK5+ solution
- inhomogeneity of QC lots
- calibration solutions

To correct the 2 SD control ranges for the above contributions, do the following:

Step	Action
1.	Find the mean ($\overline{X}$) and the two times standard deviation (2 SD) value in the Quality Control log (press: ***Data Logs > Quality Control Log > Statistics***) or calculate the values from the last 20 quality control measurements.
2.	Find SD_{total} in tables below.
3.	Determine $SD_{corrected}$ as follows: $SD_{corrected} = \sqrt{(2 \times SD)^2 + (2 \times SD_{total})^2}$
4.	Determine the user-defined control ranges as $\overline{X} \pm SD_{corrected}$.
5.	Enter the user-defined control ranges for each parameter in the Control Ranges setup program (press: ***Menu > Utilities > Setup > QC Setup Control Ranges > Edit***).

Table 1: **SD_{total} for QUALICHECK5+ solutions:**

Level 1	
Parameter:	**ABL90 FLEX analyzer**
pH	0.0041
pCO_2 kPa	0.14
pO_2 kPa	0.31
cK^+ mmol/L	0.035
cNa^+ mmol/L	0.7
cCa^{2+} mmol/L	0.021
cCl^- mmol/L	1.26
*c*Glu mmol/L	0.1
*c*Lac mmol/L	0.1
*c*tBil µmol/L	2.5
*c*tHb g/dL	0.11
*F*HbF %	1
Other Hb derivatives %	0.13

Level 2	
Parameter:	**ABL90 FLEX analyzer**
pH	0.0054
pCO_2 kPa	0.09
pO_2 kPa	0.26
cK^+ mmol/L	0.036
cNa^+ mmol/L	0.6

cCa^{2+} mmol/L	0.020
cCl^{-} mmol/L	1.16
*c*Glu mmol/L	0.1
*c*Lac mmol/L	0.1
*c*tBil µmol/L	3.0
*c*tHb g/dL	0.13
*F*HbF %	3.6
Other Hb derivatives %	0.36

Level 3	
Parameter:	**ABL90 FLEX analyzer**
pH	0.0074
pCO_2 kPa	0.07
pO_2 kPa	0.44
cK^{+} mmol/L	0.036
cNa^{+} mmol/L	0.6
cCa^{2+} mmol/L	0.019
cCl^{-} mmol/L	1.08
*c*Glu mmol/L	0.4
*c*Lac mmol/L	0.2
*c*tBil µmol/L	4.1
*c*tHb g/dL	0.18
*F*HbF %	2.6
Other Hb derivatives %	0.19

Level 4:	
Parameter:	**ABL90 FLEX analyzer**
pH	0.0046
pCO_2 kPa	0.26
pO_2 kPa	0.73
cK^{+} mmol/L	0.055
cNa^{+} mmol/L	0.5
cCa^{2+} mmol/L	0.023
cCl^{-} mmol/L	0.95
*c*Glu mmol/L	0.1
*c*Lac mmol/L	0.1
*c*tBil µmol/L	2.2

*c*tHb g/dL	0.06
*F*HbF %	0.4
Other Hb derivatives %	0.1

Statistics factor and statistics range

Definitions

Normal statistical variation implies that 95.5 % of all quality control results obtained on a well-functioning analyzer falls within ± 2 SD range, and 99.7 % falls within ± 3 SD range.

In order to include all results from a well-functioning analyzer, a statistics factor of 1.5 (default) is used to expand the control ranges. This also ensures that user control ranges do not become too narrow over time.

Using the recommended statistics factor of 1.5 will have the following effect:

User control ranges (2 SD):	The statistics range will correspond to $\bar{X}$ ± 3 SD.
Insert control ranges:	The statistics range will correspond to 1.5 × insert control range.

All results outside the statistics range will be excluded from the statistics and marked accordingly.

Example

The control range is: pH low = 6.986 and pH high = 7.016

To calculate the statistics range, do the following:

Step	Action
1.	Calculate the mean value: $\bar{X}$ = (6.986 + 7.016)/2 = 7.001.
2.	Calculate the 2 SD: pH high – $\bar{X}$ = 7.016 – 7.001 = 0.015.
3.	Calculate the 3 SD: (0.015 ×3)/2 = 0.0225 = 0.023.
4.	The statistics range will then be: pH low = 7.001 – 0.023 = 6.978. pH high = 7.001 + 0.023 = 7.024.

Temperature corrections (for manual QC only)

Purpose

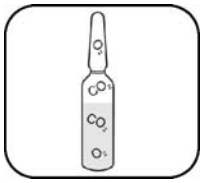
Temperature correction is done to ensure that the quality control results reflect the analyzer performance and are not influenced by fluctuations in the ambient temperature.

Parameters that require temperature correction

The insert control ranges are determined at a reference temperature of 25 °C. Deviations from this temperature will have an impact on the following parameters: pH, pCO_2 and pO_2.

The reason for temperature correction is as follows:

An unopened ampoule consists of two phases: a liquid and a gas phase. Both phases contain molecules of CO_2 and O_2, and equilibrium between the two phases is temperature dependent. As only the liquid phase is measured, it is important to temperature correct the result to the actual temperature.



To ensure that the QC result actually reflects the performance of the analyzer and not just fluctuates because of temperature variations, it is important to keep the ampoule at a stable and known temperature, so that variations can be corrected for in the correct way.

The default temperature of a QC measurement is automatically set at 25 °C unless otherwise specified by the user. If the ampoule temperature is not 25 °C, the equilibrium will be different. The lower the temperature, the more O_2 and CO_2 molecules will migrate to the liquid phase, and the pCO_2 and pO_2 will report too high values, and the pH a too low value, if the results are not temperature corrected. If the temperature is higher than 25°C, the pCO_2 and pO_2 values will be too low and the pH too high, if the results are not temperature corrected. The pH value will be affected, as an increase of the pCO_2 will make the quality control solution more acidic.

Temperature	Parameters		
	pH	pCO_2	pO_2
> 25 °C	↑	↓	↓
< 25 °C	↓	↑	↑

where ↑ = higher values, and ↓ = lower values.

Radiometer recommends that ampoules that have been stored in a cool place are conditioned at a known room temperature for at least 5 hours before a measurement, and we strongly advise not to keep ampoules on the top of an analyzer as the temperature there can vary.

In the ABL90 FLEX analyzers the software will automatically temperature correct the results on Radiometer QUALICHECK5+ solutions once the ambient temperature has been entered.

Radiometer uses a reference temperature of 25 °C.

Temperature corrections for pH, pCO_2 and pO_2

Range+ QUALICHECK solutions (usable for e.g. Calibration verification, see section *Calibration verification* in Chapter 6: *Calibration* in the ABL90 FLEX operator's manual).

Parameter	Equation for temperature correction
pH:	pH(corr. to 25 °C) = pH(meas.) – A(t – 25)
pCO_2:	pCO_2(corr. to 25 °C) = pCO_2(meas.) × [1 – A(t – 25)]
pO_2:	pO_2(corr. to 25 °C) = pO_2(meas.) × [1 – A(t – 25)]

where A = a temperature constant. The values are given in the table below.

Range+ QUALICHECK	Temperature constants, A	
	Level 1	Level 2
pH	0.0013	0.0026
pCO_2	–0.0056	–0.0071
pO_2	–0.0098	–0.0107

NOTICE: Temperature fluctuations for S7950 (level 3) are negligible so that no temperature corrections are required for this control solution.

Westgard rules

About Westgard rules

The Westgard rules are a set of statistical rules that, when applied to the quality control results, can aid the following:

- Increase the probability of detecting an error on the analyzer by analyzing the quality control measurements
- Help detecting a shift or trend in your quality control results by comparing current measurement values of a control solution to previous values, thus further enabling you to determine the quality and validity of your blood sample results

Westgard rules are based on the calculation of the mean and standard deviation (SD) of quality control measurement values for a particular parameter and a specific device, through modification of control ranges. They are best expressed in the form of plots.

Westgard rules are divided into two types:

Westgard rule types	Explanation
Warning rules	Indicate that the next measurement should be treated with care as the previous measurement was outside the established ranges. It is recommended to perform a second measurement on a new ampoule of the same level. Rule 1_{2s} is the only warning rule.
Rejection rules	Indicate an error and require troubleshooting your analyzer before analyzing blood samples. Rules 1_{3s}, 2_{2s}, R_{4s}, 4_{1s} and 10_{x} are rejection rules.

Plot lines

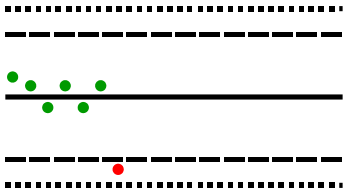
The following lines are used in the plots:

·····	Shows ±3 SD ranges
— — —	Shows control ranges (±2 SD)
———	Shows the mean value

The Westgard rules described in the following are selected for evaluation of quality control measurement results. All six rules are applicable to manual QC. Only four of the rules are applicable to built-in QC.

Rule 1_{2s} This rule is a warning rule.

Measurement value is outside the mean ± 2 SD.



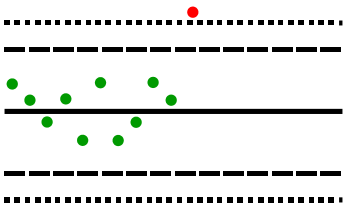
Corrective action: Perform another measurement on a new ampoule of the same level. If the second result falls within the control range, then the first result can be attributed to normal statistical variation.

If the second result is outside the established mean ±2 SD, see section *Quality control evaluation* further in this appendix.

This rule is applicable to both manual and built-in QC.

Rule 1_{3s} This rule is a rejection rule.

Measurement value is outside the mean ± 3 SD.



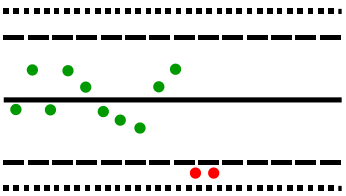
Corrective action: Perform another measurement on a new ampoule of the same level. If the second result falls within the control range, then the first result can be attributed to normal statistical variation.

If the second result is outside the established mean ±2 SD, see section *Quality control evaluation* further in this appendix.

This rule is applicable to both manual and built-in QC.

Rule 2_{2s} This rule is a rejection rule.

Two consecutive measurements are outside the mean ± 2 SD on the same side of the mean.

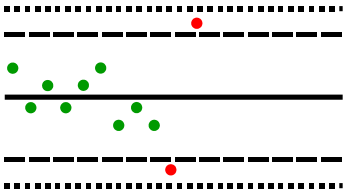


Corrective action: Perform steps described in section *Quality control evaluation* further in this appendix.

This rule is applicable to both manual and built-in QC.

Rule R_{4s} This rule is a rejection rule.

The difference between two consecutive measurements exceeds 4 SD.



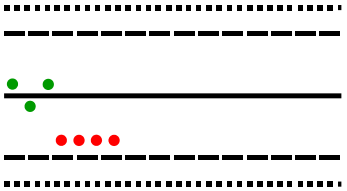
This indicates inconsistency in your procedures or an unstable analyzer.

Corrective action: Perform steps described in section *Quality control evaluation* further in this appendix.

This rule is applicable to both manual and built-in QC.

4_{1s} This rule is a rejection rule.

Four consecutive measurements outside the mean ±1 SD on the same side of the mean.



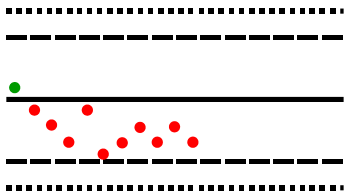
This indicates a trend or shift.

Corrective action: Perform steps described in section *Quality control evaluation* further in this appendix.

This rule is only applicable to manual QC and is only recommended when user-defined control ranges are established.

Rule 10_x This rule is a rejection rule.

10 consecutive measurements on the same side of the mean.



This indicates a trend or shift.

Corrective action: Perform steps described in section *Quality control evaluation* further in this appendix.

This rule is only applicable to manual QC and is only recommended when user-defined control ranges are established.

Quality control evaluation

Evaluation procedure

The QC evaluation procedure for analyzers is as follows:

- Check if the QC results are marked with a "?" (a "?" can be caused by an error in the previous calibration or by analyzer malfunctions). In case of "?", follow the troubleshooting instructions on the screen.
- Check the presence of any other markings in the QC result. In case of any markings, follow the troubleshooting instructions on the screen, and, if running manual QC, consider the questions below.

No.	Question
1.	Did you store the ampoules according to specifications?
2.	Did you condition the ampoules according to the specifications?
3.	Did you key in the correct ampoule conditioning temperature?
4.	Did you shake the ampoule vigorously for 15 seconds before using it?
5.	Did you remember to hold the ampoule between your thumb and index finger when you shook it? (This is done to avoid heating up the ampoule contents and thus change its temperature.)
6.	Did you analyze control solutions immediately after opening the ampoule? (Each QC ampoule must be used immediately after being opened, for **one** measurement on **one** analyzer only, in order to ensure the reliability of the measurement).
7.	Did you use Radiometer QUALICHECK adapter?
8.	If own user-defined limits were entered: Did you enter too narrow control ranges?
9.	If everything is OK – repeat the QC measurement.

II Appendix - Traceability to the primary standards at Radiometer

Introduction

The Metrology Section at Radiometer is responsible for establishing metrological traceability for the parameters pH, pCO_2, pO_2, cK^+, cNa^+, cCa^{2+}, cCl^-, *c*Glu, *c*Lac, sO_2, *F*COHb, *F*MetHb, *F*HbF, Hct, *c*tBil and *c*tHb. This booklet documents the traceability for each of these parameters.

Traceability

pH

The primary pH standards are traceable to the definitive method for pH. The definitive method is based on a Hydrogen Electrode System. The primary pH standards are obtained from the Danish primary laboratory for Electrochemistry (DPLEC) at the Danish Institute of Fundamental Metrology (DFM). This primary laboratory is accredited by Danish Accreditation (DANAK accreditation no. 255) Certification is done in accordance with the method recommended by the International Union of Pure and Applied Chemistry (IUPAC). The Hydrogen Electrode System of DLPEC is validated by comparison with Standard Reference Materials (SRMs) produced by the National Institute of Standards and Technology (NIST). The primary standards are therefore also traceable to NIST.

The IUPAC-recommended method is described in Ref. 1.

The NIST SRMs used are: 186I/II, 185, 187, 191-192.

Using the primary pH standards, the secondary pH standards are certified in the Metrology Section. These are normally of the same composition as the primary buffers, tapped into 2-mL glass ampoules and heat sterilized. The secondary buffers are stored at 5 °C. Measurements of the secondary buffers are done using a glass electrode with a saturated calomel reference electrode and a liquid junction of saturated KCl. The liquid junction is a vertical, cylindrical and open liquid junction. Measurement of a secondary buffer is done using a primary buffer together with a certified secondary buffer as standards for making a 2-point calibration of the glass electrode arrangement.

pCO_2 and pO_2

The primary gases used are Standard Reference Materials (SRMs) produced by NIST. The NIST SRMs used are: 1674b, 2625a, 2658a and 2659a. The NIST SRM gases are used to validate primary gravimetric working gas standards, certified by Scott Medical, Air Liquide or Air Products. The primary gravimetric working gas standards are validated using a computer-controlled gas chromatography system, introducing the NIST SRM gases as samples and comparing the obtained results with the certified values.

The primary gravimetric working gas standards are used as standards in the gas chromatography system, so that the composition of secondary working gas standards can be determined.

By using the secondary working gas standards in a tonometer together with an aqueous buffer solution, a solution with a known pCO_2 and pO_2 is produced. This aqueous buffer solution is then used to determine the pCO_2 and pO_2 of secondary working standards. These secondary working standards are aqueous buffer solutions kept in 2-mL ampoules.

cK^+ and cNa^+

The primary working standards used are gravimetric standards produced from KCl and NaCl Suprapur, produced by Merck. These primary working standards are validated using Standard Reference Materials (SRMs) produced by NIST, so that traceability to NIST is achieved. The NIST SRMs used are: 919a (NaCl) and 999 (KCl). Validation of the primary working standards is done using a flame photometer together with the NIST SRMs.

The flame photometer method of validating the primary working standards is described in Ref. 2.

The primary working standards are used to determine the sodium and potassium concentrations of the secondary working standards. The concentrations of the secondary working standards are measured using a flame photometer. The determination of the sodium and potassium concentrations of fluorocarbon-based secondary standards is done using ion-selective K and ion-selective Na electrodes on the ABL735 analyzer. The determination takes place using the primary working standards.

cCa^{2+}

The primary standards used are the so-called Ca^{2+} transfer standards, produced from $CaCO_3$ Urtitersubstanz®, produced by Merck. The transfer standards are pH-stabilized to pH = 7.4, with 1 mmol/L HEPES and an ionic strength of 160.0 mmol per kg. Validation of the Ca^{2+} transfer standards is done using similar standards produced from NIST SRM 915.

The transfer standards are used to determine the calcium concentrations of secondary standards. These measurements take place using ion-selective Ca electrodes on the ABL735 analyzer.

cCl^-

The primary working standards are gravimetric standards, prepared from KCl Suprapur, produced by Merck. The primary working standards are validated by making comparative titrations using similar standards prepared from NIST SRM 999 (KCl). The titrations are done using an $AgNO_3$ solution as the titrant, and potentiometric titration equipment.

The standardized $AgNO_3$ solution is used as the titrant for the determination of the chloride concentration of the secondary standards, using the potentiometric titrator (TitraLab 900 from Radiometer Analytical, France).

cGlu

The primary working standards are prepared from NIST SRM 917a (D-glucose). These primary standards are used to determine the glucose concentration of secondary standards. The measurements take place using the glucose reference method, which is the hexokinase/glucose-6-phosphate dehydrogenase method recommended by CLSI. This method is described in Ref. 3.

cLac

No certified standard reference material for lactate is available at present. The primary working standards are therefore prepared from a pure commercially available material, namely the Lithium salt of L ($^+$) Lactic Acid (Cat. No, L-2250) supplied by the Sigma Chemical Company.

These primary standards are used to determine the lactate concentration of secondary standards.

The measurements take place using a spectrophotometric method. The method is based on a reaction of lactate, catalyzed by L-Lactate Dehydrogenase (LDH). The reaction produces dihydronicotinamide (NADH), which is measured at 339 nm. The method is described in Ref. 4.

ctHb

The primary standard used is an oxygenated whole-blood sample. The ctHb value of this sample is determined by the use of the HiCN reference method. This method is described in Ref. 5. The HiCN reference method is a spectrophotometric method. The spectrophotometer used is calibrated using a NIST SRM 930D filter. This method is further validated using the certified reference material Hemoglobin-cyanide standard (product no. 3061) produced by J.T Baker, Holland.

The primary standard is used to calibrate the ABL735 reference instruments.

Saturation – sO_2 = 100 %

The primary working standard used is a whole-blood sample, with the *c*tHb value adjusted to between 13 and 15 g %. The blood sample is tonometered with 5.6 % CO_2 - 94.4% O_2, traceable to NIST SRM gases.

The primary standard is used to calibrate the ABL735 reference instruments.

Saturation – sO_2 = 0 %

The primary working standard used is a whole-blood sample. The blood sample is centrifuged and the resultant blood concentrate is deoxygenated using Argon and treated with a dithionite solution.

The primary working standard is used to calibrate the ABL735 reference instruments.

***F*COHb – normal value**

The primary standards used are CO with atmospheric air mixtures, produced in a container of known volume. The CO used for making these gas mixtures has a certified purity of 99.997 %. Validation of the mixing method is done by comparison with NIST SRM 1678 (50 ppm CO in N_2).

The produced mixtures are used as calibration standards in connection with a gas chromatography method. The gas sample, injected into the gas chromatograph, is the headspace of a blood sample which has been treated so that all the bound CO is released from the hemoglobin. The analyzed result is measured in % CO, and from this the *F*HbCO is calculated. The method is described in Ref. 6.

The measured blood sample is used as secondary standard and is used to calibrate the ABL735 reference instruments.

***F*COHb – 100 %**

The primary working standard used is a whole-blood sample. The blood sample is tonometered with 100 % CO, with a certified purity of 99.997 % CO. The primary working standard is used to calibrate the ABL735 reference instruments.

***F*MetHb**

The primary working standard is a whole-blood sample. The *F*MetHb is determined using the KCN addition method according to Evelyn and Malloy (Ref. 7). This method is a spectrophotometric method, where the absorbance measurements are done at 630 nm (local peak for MetHb) on two sets of solutions, prepared from the whole-blood sample. The first set allows determination of the relative MetHb content, whereas *c*tHb is determined from the second set. From these measurements, the *F*MetHb of the whole-blood sample can be calculated.

***F*HbF**

The primary working standard is a whole-blood sample. The *F*HbF of this sample is determined using the Cation Exchange HPLC reference method. The method is described in [Ref. 9]. The method is performed by the Hæmatology Laboratory at Herlev Hospital, Denmark.

Hct

Reference method

Radiometer uses a reference method based on the packed-cell-volume procedure described by the Clinical and Laboratory Standards Institute (Ref. 10). The packed-cell volume is the measure of the ratio of the volume occupied by the red cells to the volume of whole blood in a sample of capillary or venous blood. The ratio is measured after appropriate centrifugation.

Radiometer measurements

The Hct measurement is based on conductivity measured in a sample and then corrected for the presence of sodium ions. A Sigma 201 Micro hematocrit centrifuge with RCF of 12620*g, which fulfills most of the CLSI requirements, has been used for the test together with 75 mm Microhematocrit capillary tubes with an inner diameter between 1.1 and 1.2 mm. The centrifugation time has been 5 minutes.

The conductivity and sodium concentration has been measured on approximately 1000 blood samples with a sodium concentration varying from 80 mmol/L to 180 mmol/L. Hct measurements have then been correlated to the Hct measured by the reference method.

***c*tBil**

The primary working standard is a whole-blood sample. The total bilirubin is determined on a serum sample prepared from this. The determination is performed using a Hitachi 717 wet-chemistry analyzer, which uses the Boehringer Mannheim reagency kit, DPD method, given in Ref. 11. The reference instrument is calibrated using four levels of NIST SRM916a unconjugated bilirubin standard material.

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Date of issue

Radiometer representative:

Manufacturer:

RADIOMETER

If you have any questions
or need assistance,
please contact your local
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