RADIOMETER

AQT90 FLEX

Instructions for use

from software version 8.4

Contents

1 Introduction

Intended use

For *in vitro* diagnostic use.

The AQT90 FLEX analyzer is an immunoassay instrument based on the quantitative determination of time-resolved fluorescence to estimate the concentrations of clinically relevant markers on whole-blood and plasma specimens to which a relevant anticoagulant has been added. It is intended for use in point-of-care and laboratory settings.

Note: The *AQT90 FLEX parameter-specific Test Kit* inserts tell you whether both types of sample can be used and list the anticoagulants that can be used for each assay/test.

Limitations of use

Operators must read the performance data of the analyzer to make sure that it satisfies their analytical needs.

A clinician must always interpret patient test results in the relevant clinical context.

⚠ **WARNING – *Risk of incorrect results on subsequent samples***
Only analyze human blood and plasma samples or dedicated quality control material.

⚠ **CAUTION – *Risk of equipment damage***
Only analyze human blood and plasma samples or dedicated quality control material.

Operator requirements

Operators must be trained to use this analyzer.

Documentation

⚠ **CAUTION – *Risk of equipment damage***
The documents in the table give instructions for the safe and proper operation of the analyzer. Radiometer does not accept warranty claims or product liability if operators do not obey the instructions.

Document	Description
Instructions for use	How to install and set up the analyzer, instructions for daily use and reference information
Inserts	Instructions and information about consumables supplied for use with the analyzer

Document	Description
Short-form instructions	A summary of key instructions showing how to do daily procedures
Ordering information	Name and reference ordering number (REF) of products used with the analyzer

Hazards

A hazard symbol shows which instructions an operator must obey to prevent risk to persons or equipment. There are two types of hazard.

Hazard type	Hazard symbol	Risk
WARNING		Death or injury to persons
CAUTION		Equipment damage

General warnings, cautions and notes

WARNING – *Risk of electric shock*
Make sure the analyzer is a minimum of 1.5 m from patient beds.

WARNING – *Risk of infection*
Dispose of all used sample tubes, quality control (QC) tubes and Solution Packs as biohazardous waste. Follow your local regulations.

CAUTION – *Risk of equipment damage*
Instructions for use documents are provided with the analyzer. Use them to find out how to operate the analyzer. Radiometer will not accept warranty claims or product liability claims if procedures are not followed.

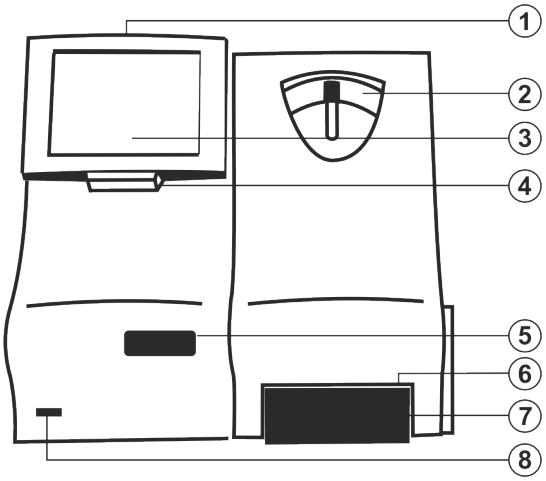
Note: Do not put paper or other objects underneath the analyzer as it will decrease the volume of air that can be drawn through the analyzer to cool it.

Getting to know the analyzer

2

Overview of the analyzer

Front view

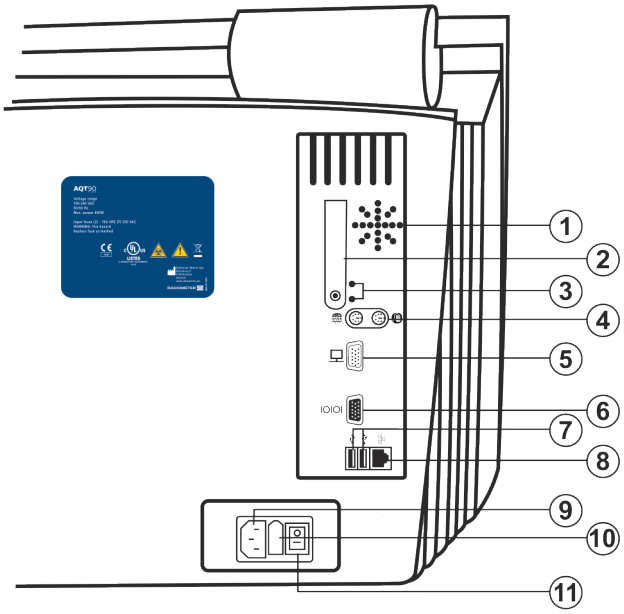


1 Thermal printer
2 Sample inlet
3 Touch screen
4 Barcode reader
5 Compartment for cartridges
6 Solution Pack compartment
7 Solution Pack
8 USB port

Use of the barcode reader

The barcode reader is used to read data in barcodes supplied with consumables and barcodes that identify personnel, patients and patient samples.

Back view



1	Speaker	7	USB ports
2	Memory card	8	Network cable port
3	Reset buttons	9	Mains power socket
4	External keyboard and mouse ports	10	Mains power fuse
5	External monitor port	11	Power switch ON (—) and OFF (O)
6	Barcode reader port		

Consumables

Consumables are products that are used up during operation of the analyzer. See the *AQT90 FLEX ordering information* document for details.

Consumbles	Description
Cartridges	Cartridges for calibration adjustment, tests and maintenance activities
Solution Pack	Contains buffer material and closed containers that hold used test cups and liquid waste
Thermal printer paper	Paper for the thermal printer
LQC solutions	Liquid quality control solutions
Cleaning Solution Tubes	Contain cleaning solution for system clean and maintenance activities
Empty Tube Kit	Used for non-Radiometer LQC solutions
Sample tubes	Used to hold samples for analysis. The tubes contain anticoagulants.

Related Information

- Tubes approved for use with the analyzer, page 132

To see details about installed consumables

1. Tap **Menu** > **Analyzer status** > **Consumables**.
   Some data is shown.
2. Tap the **Detailed inventory** button to see more data about the installed cartridges.

Data about installed consumables

The **Consumables** part of the **Analyzer status** screen shows data about the installed Solution Pack and some data about the installed cartridges. More data about each installed cartridge is shown in the **Detailed inventory** screen.

Consumable	Screen	Details
Solution Pack	**Consumables**	• Lot number • Installation date • On-board expiry date • Remaining cup capacity. This is the estimated number of used test cups the Solution Pack still has space for.
Cartridges	**Consumables**	• Total number of remaining tests for each parameter • Total number of used/expired cartridges for each parameter
Cartridges	**Detailed inventory**	• Number of remaining tests • Lot number • On-board expiry date • Cartridge type • Status - valid or invalid. Cartridges are valid until their expiry date or on-board expiry date. • Calibration adjusted? - yes or no

Is the analyzer ready for use?

Three important conditions

The analyzer is ready for use when three conditions are present.

1. The analyzer is in one of three **Ready** modes: **Ready**, **Ready for sample registration**, or **Ready for sample registration and cartridge replacement**.
2. The color of the tab of the parameters you want to measure must be green or yellow.
3. The color of the traffic light in the **Analyzer status** button is green or yellow.

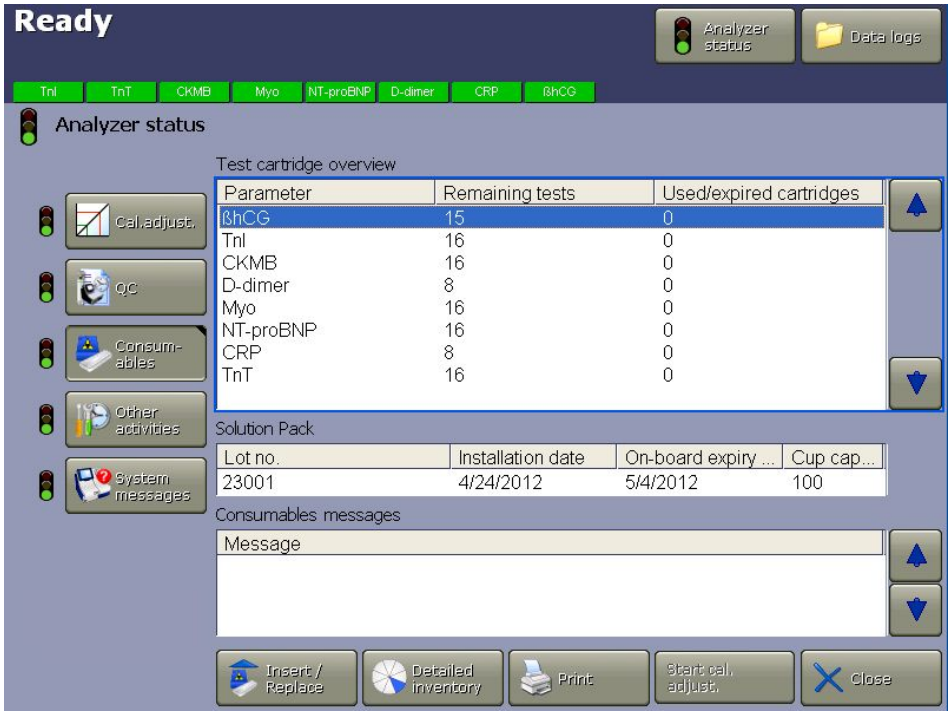
Parameter tab colors

Parameter tab color	Indication
Green	The parameter can be measured
Yellow (with one line crossing)	An LQC error was found but the parameter can be measured
Red (with two lines crossing)	The parameter cannot be measured. The conditions that may cause a tab to be red are shown below. • No Test Cartridge is installed for the parameter • Installed Test Cartridges for the parameter have not been calibration adjusted, or no tests are available on them, or they are not valid • An operator has locked the parameter • A scheduled LQC measurement of the parameter is overdue • An LQC error was found. Corrective action has locked the parameter. • A scheduled system clean is overdue **Note**: A cartridge is not valid after its on-board expiry date or expiry date.

Related Information

- To set up corrective action for errors in LQC results, page 104

The Analyzer status screen



The traffic light shown on the left side of the buttons in the **Analyzer status** screen shows the status of:

- Calibration adjustment
- Quality control
- Consumables
- Other activities (for example, maintenance activities)

- System messages

A green traffic light shows that there are no issues. A yellow traffic light shows that there is a non-critical issue. A red traffic light shows that there is critical issue.

The color of the traffic light on the **Analyzer status** button shows the most critical issue shown by these five traffic lights.

Analyzer status - Traffic light colors

Traffic light color	Indication	Consequences
Green	No issues were found	All operations are possible
Yellow	A non-critical issue was found	Measurements and other activities are possible, but one or more issues need attention
Red	A critical issue was found	LQC measurements can be done if the analyzer operating mode is **Locked - LQC pending**. No other type of measurement and no calibration adjustments are possible.

Messages

The analyzer uses messages to tell operators something. There are different types of messages.

Message type	Where messages are shown
Status	In **Analyzer status** screens
Feedback	In the space above the parameter bar. **Note**: Feedback messages tell operators something about an action that they have just done. Feedback messages are shown for a short period of time.
Pop-up	In pop-up windows. **Note**: Operators have to tap a button in pop-up windows to close them.
Result	In result message screens
Activity	In the **Activity log** screen

Issues

Issues are messages that tell you about conditions that require some action.

To find and troubleshoot issues

Prerequisite: The traffic light in the **Analyzer status** button is yellow or red.

1. Tap **Menu** > **Analyzer status**.
2. Tap the button on the right side of a yellow or red traffic light.
3. Read and note the message numbers.
4. Troubleshoot the messages.
5. Do steps 2 to 4 again for each button with a yellow or red traffic light.
6. Tap the **Close** button.

Related Information

- To troubleshoot messages that require some action, page 50

Ready modes

Normally, the analyzer operates in one of the three **Ready** modes shown in the table.

Mode	Indication
Ready	You can use the analyzer for any operation
Ready for sample registration	You can put a new sample in the sample inlet and register it, while another sample is being analyzed
Ready for sample registration and cartridge replacement	You can put a new sample in the sample inlet and register it or insert/replace cartridges, while another sample is being analyzed

Non-Ready modes

Normally, the analyzer operates in one of its three **Ready** modes. However, conditions will sometimes cause the analyzer to operate in non-Ready modes. The table shows the conditions that may cause each mode.

Mode	Indication
Busy	• The inlet wheel is rotating to mix a sample. • Two samples are in the inlet wheel. One is being analyzed. The other sample is registered and waits to be analyzed.
Error	No operations can be done
Locked	In-progress analyses will be completed, but no new analyses will be started
Locked - QC pending	A scheduled LQC measurement is overdue
Maintenance	A maintenance activity is overdue. The set critical limit was exceeded.
Not operational	The incubation temperature is outside its specified range
Not operational Automatic recovery in progress. Please wait.	An automatic shutdown and restart procedure is in progress. The procedure may remove a condition that would cause the analyzer to go into “Error” mode.
Replacement	• A consumable is being inserted/replaced • No valid test cups are available • Installed Test Cartridges are not calibration adjusted • The installed Solution Pack has either passed its on-board expiry date or its expiry date
Service	The **Service** menu of the analyzer is open
Shutdown	A shutdown procedure was either started by an operator, or automatically started by the analyzer
Startup	The mains power switch has been put in the ON (—) position

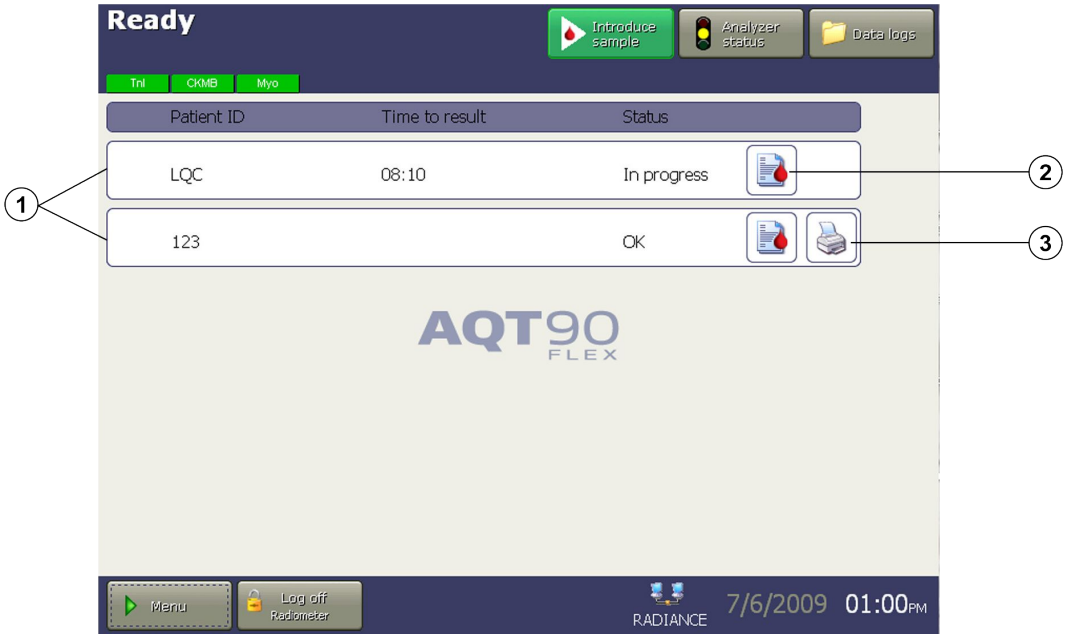
Related Information

- To get back to a "Ready" mode, page 49

User interface

Result links

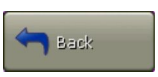
Result links (1) show the **Time to result** of in-progress measurements, the **Status** of the current and previous measurement results, and buttons you can tap to see results (2) and to print results (3).



Status in result links

Status	Explanation
In progress	A measurement or activity is being done
OK	The measurement was successfully completed
Not reviewed	The patient result has not been approved or rejected
?	An error was found during the measurement
Interrupted	The measurement was stopped by an operator
Aborted	The measurement was stopped by the analyzer

Back and Close buttons

	This button saves changes and goes to the previous screen
	The button saves changes and closes the screen

Check buttons

Deselected check button	Selected check button
	

Basic tasks

To scan a barcode

1. Hold the barcode parallel to the barcode reader and no more than 7 cm below it.

To enter text

1. Tap where you want to enter text.
2. Tap the **On-board keyboard** button  .
3. Enter the text and tap the **Enter** button  .

To log on

1. Tap **Menu** > **Log on**.
2. Enter or scan data into the fields.
   Note: If that is not possible, tap the **Alternate logon** button and enter or scan data into the fields.

To save changes

1. Tap the **Back** button or the **Close** button.

Menu

Menu structure

Introduce sample	
Remove tube	
Analyzer status	
Data logs	• **Patient results log** • **Patient profiles log** • **Cal.adjustment log** • **Activity log** • **Event log** • **System-clean log**

	• **QC logs**	• **LQC log** • **System-check log**	
	• **Archived data logs**	• **Patient results archive** • **Cal.adjustment archive** • **Activity archive** • **Event archive** • **System-clean archive**	
		• **QC archives**	• **LQC archive** • **System-check archive**
Utilities	• **Setup**	See the related topic.	
	• **Disk functions**	• **Backup all data** • **Restore all data** • **Export data logs** • **Import / export archives** • **Save setup** • **Load setup** • **Restore default setup**	
	• **Sample counter**		
	• **Shutdown**		
	• **RADIANCE browser** (not applicable in the USA)		
	• **Service**		
Log off			

Related Information

- Setup menu structure, page 77

Data logs

Overview of data logs

Data logs are where results of measurements and activities are kept.

Data logs	Content
Patient results log	• Results of patient sample analyses • Results of linearity, calibration-verification and reportable range measurements (referred to as LCR measurements)
Patient profiles log	The **Patient ID**, **First name** and **Last name** of patients whose blood has been analyzed
Cal.adjustment log	Results of calibration adjustments
Activity log	Activities done on or by the analyzer
Event log	Activities done by specified operators
System-clean log	Date and status (successful or not) of system cleans

Data logs	Content
LQC log	• Results of LQC measurements • Results of LQC measurements done after calibration adjustments (referred to as calibration-verification measurements)
System-check log	Results of system check tests
Archived data logs	The oldest results/activities from the data logs. **Note**: Automatic archiving must be set up.

Patient profiles log

Patient profiles log

The **Patient ID**, **First name** and **Last name** entered in the **Patient identification** screen for a patient sample is automatically recorded in the **Patient profiles log**.

When an operator enters data in the **Patient ID** field of the **Patient identification** screen, the analyzer looks in the **Patient profiles log**. If the **Patient ID** is in the log, the **First name** and **Last name** of the patient is downloaded automatically to the screen. However, this will not occur if the analyzer is set up to automatically request patient data from a LIS/HIS/data management system.

To access data logs

1. Tap **Menu** > **Data logs**.
2. Tap the data log you want.

To edit a patient profile

1. Tap **Menu** > **Data logs** > **Patient profiles log**.
2. Tap a patient profile.
3. Tap the **Edit** button.
4. Edit the values you want to edit.
5. Tap **Back** > **Close**.

To add a new patient profile

1. Tap **Menu** > **Data logs** > **Patient profiles log**.
2. Tap the **Add new** button.
3. Enter data in the **Patient ID** field.
4. Enter data in other fields that help to identify the patient.
5. Tap the **Back** > **Close** buttons.

To remove a patient profile

1. Tap **Menu** > **Data logs** > **Patient profiles log**.
2. Select the patient profile.
3. Tap the **Remove** button.
4. Tap the **Close** button.

To find a patient profile

1. Tap **Menu** > **Data logs** > **Patient profiles log**.
2. Tap the **Find** button.
3. Select in the field of the criterion you want to use to find the patient profile. For example **Patient ID**.
4. Enter data in the field.
5. Tap in the field you selected in step 3.
6. Tap the **Find** button.
7. Tap the **Close** button.

Activity logs

To see activities in the Activity log

1. Tap **Menu** > **Data logs** > **Activity log**.
2. Tap the **Close** button.

To add a message to the Activity log

1. Tap **Menu** > **Data logs** > **Activity log**.
2. Tap the **Add message** button.
3. Enter the message.
4. Tap the **Close** button.

To filter activities from the Activity log

1. Tap **Menu** > **Data logs** > **Activity log**.
2. Tap the **Filter** button.
3. In the **Criteria** frame, choose an option and follow the steps for it.

Option	Steps
To select a time period prior to today's date	Tap the number button for the number of days you want
To select a start and end date	Enter data in the **Start date** and **End date** fields

4. Select the next criterion. If necessary, enter or select a value for it.
5. Do step 4 again for each criterion.
6. Tap the **Apply** button.
7. Tap the **Close** button.

Patient sample analysis 3

General warnings and cautions

⚠ **WARNING – *Risk of infection***
Only let authorized personnel draw and work with blood samples. Make sure they wear approved gloves.

⚠ **WARNING – *Risk of incorrect results on subsequent samples***
Only analyze human blood and plasma samples or dedicated quality control material.

⚠ **CAUTION – *Risk of equipment damage***
Only analyze human blood or plasma samples or dedicated quality control material on the analyzer.

⚠ **WARNING – *Risk of infection***
Dispose of all used sample tubes, quality control (QC) tubes and Solution Packs as biohazardous waste. Follow your local regulations.

⚠ **WARNING – *Risk of temporary disturbance of vision***
Do not stare into the laser beam in the sample inlet.

To get good results

Prerequisite: Use an approved sample tube.

Good results come from good samples. Here are five points to remember.

1. Label the sample. Use more than one patient identifier.
2. Draw the sample from a suitable site.
3. ⚠ **WARNING – *Risk of incorrect results***
   Let the tube fill to its predetermined volume. Follow sample tube manufacturer's instructions.
4. ⚠ **WARNING – *Risk of incorrect results***
   Mix the sample immediately after it is drawn. For example: Gently turn the tube upside down 5 times. Follow sample tube manufacturer's instructions.
5. Analyze the sample as soon as possible within the maximum sample age.

Maximum sample age

Maximum sample age is the maximum period of time a parameter stays stable in whole-blood samples kept between 18-25 °C. Samples must therefore be analyzed within this time period.

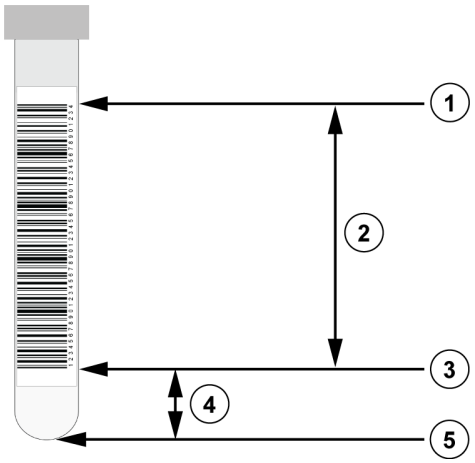
See the *AQT90 FLEX parameter-specific Test Kit* inserts for details.

Sample tubes

Only use approved sample tubes that contain a recommended anticoagulant for the parameters to be measured. For approved anticoagulants, see the *AQT90 FLEX parameter-specific Test Kit* inserts.

Barcode labels on sample tubes

The diagram shows you where to put a barcode label on a sample tube.



1 Top of the barcode
2 Maximum 66 mm
3 Bottom of the barcode
4 Minimum 10 mm
5 Bottom of the sample tube

Sample types

To find out what type of sample (whole-blood or plasma) can be used for each test, see the *AQT90 FLEX parameter-specific Test Kit* inserts.

Analyzing patient samples

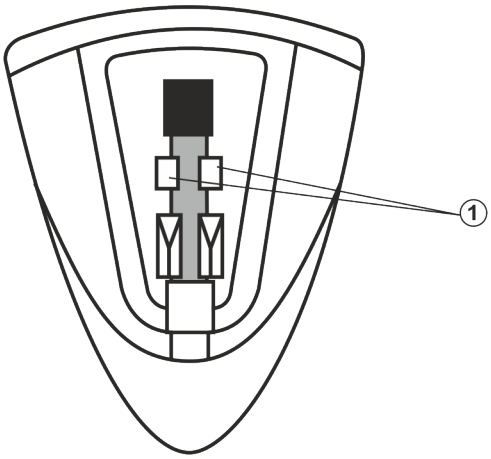
To analyze a sample

Prerequisites:

- A good sample
- The analyzer is in one of three **Ready** modes: **Ready**, **Ready for sample registration** or **Ready for sample registration and cartridge replacement**.

1. Tap the **Introduce sample** button.
Note: If there is a tube in the tube holder, remove it.

2. Put the tube in the tube holder with its cap side upwards and barcode pointing inwards. Press the tube down between the tabs (1).



Note: If necessary change the **Report layout**.

3. Enter the necessary data in the **Patient identification** screen.

Note: You must enter data in fields with this icon: .

4. Tap the **Accept** button.
5. **WARNING – *Risk of incorrect results***
Select the type of tube you put in the tube holder.
6. Select the tests you want.
7. Tap the **Start** button.

WARNING – *Risk of incorrect results*
Do not remove or replace the tube immediately after you tapped the **Start** button.

You can read the **Time to result** in the result link.

To request patient data manually

Prerequisites:

- The analyzer is connected to a LIS/HIS/data management system
- The analyzer is set up to enable patient data to be requested manually
- A patient sample is in the tube holder

1. In the **Patient identification** screen, choose an option and follow the steps for it.

Option	Steps
If there is a **Request** button in the screen.	**a)** Tap the **Request** button.
If there is a **Patient lookup** button in the screen.	**a)** Enter data in the **Patient department field**. **b)** Tap the **Patient lookup** button. **c)** Tap the **Update** button. **d)** Select the patient in the list. **e)** Tap the **Select** button.

To change the report layout

Prerequisite: A patient sample is in the tube holder.

When you change the report layout, data fields in the **Patient identificatIon** screen will change.

1. Tap the current **Report layout**.
2. Select a new layout.
3. Tap the **Select** button.

To edit patient identification data

Prerequisites:

- A result link to the measurement
- The result is not approved or rejected

1. Tap the  button in the result link of the analysis.
2. Tap the **Patient ID** button or tap the **Edit** > **Patient ID** buttons.
3. Edit the necessary data.
4. Tap the **Back** > **Close** buttons.

To add a test to an analysis in progress

1. Tap the  button in the result link of the analysis in progress.
2. Tap the **Edit** > **Parameters** buttons.
3. Select test types.
   Note: A total of five tests can be done on a sample.
4. Tap the **Start** button.

To stop a patient sample analysis

1. Tap the  button in the result link of the analysis in progress.
2. Tap the **Stop** button.
3. Tap the **OK** button.

To remove a sample tube

1. Tap **Menu** > **Remove tube**.
2. When the analyzer tells you, remove the sample tube from the inlet.

   WARNING – *Risk of incorrect results*
   If the tube you are told to remove was used for a coagulation assay, a message tells you that the sample must NOT be used again.
3. Tap the **OK** button.

Patient results

To use a Registration Ticket

Prerequisite: The analyzer is set up to automatically print a Registration Ticket when a patient sample analysis is started.

1. Scan the barcode on the Registration Ticket.
   Results of the analysis are either automatically printed or they appear on the analyzer screen.

To find a patient result

1. Tap the  button in the result link of the analysis.
   Note: If there is no link to the analysis, go the next step.
2. Tap **Menu** > **Data logs** > **Patient results log**.
3. Select the measurement.
4. Tap the **Result** button.
5. Tap the **Back** > **Close** buttons.

To edit Patient identification data

Prerequisite: Patient results are not approved or rejected.

1. Tap the  button in the result link of the analysis.
2. Tap the **Patient ID** button.
3. Edit the necessary data.
4. Tap the **Back** > **Close** buttons.

Symbols on patient results

Symbol	Description
	An error occurred. No result is available. The message attached to the result describes the error.
	Result is above the reference range but below the upper critical limit
	Result is below the reference range but above the lower critical limit
	Result is above the upper critical limit but below the upper limit of the reportable range
	Result is below the lower critical limit but above the lower limit of the reportable range
> "value"	Result is above the "value", which is the upper limit of the reportable range
< "value"	Result is below the "value", which is the lower limit of the reportable range

Symbol	Description
 and > "value"	Result is above the upper limit of the reportable range. It may indicate that the patient needs immediate attention. **Note**: The  symbol is not used to mark parameters whose concentration at this level is considered to be normal, e.g. the pregnancy indicator ßhCG.
 and < "value"	Result is below the lower limit of the reportable range. It may indicate that the patient needs attention immediately. **Note**: The  symbol is not used to mark parameters whose concentration at this level is considered to be normal.
*	User-defined correction factors were used to calculate the result

To see messages on patient results

Prerequisite: There are messages on the patient result.

1. Tap **Menu** > **Data logs** > **Patient results log**.
2. Select the measurement.
3. Tap the **Result** button.
4. Tap the **Messages** button or tap the **Log** > **Messages** buttons.
5. Tap the **Back** > **Back** > **Close** buttons.

Reviewing and editing patient results

To approve a patient result

1. Tap **Menu** > **Data logs** > **Patient results log**.
2. Select the measurement.
3. Tap the **Result** button.
4. Tap the **Review** > **Approve** buttons.
5. If necessary, enter a note.
6. Tap the **Accept** button.
7. Tap the **Back** > **Close** buttons.

To reject a patient result

1. Tap **Menu** > **Data logs** > **Patient results log**.
2. Select the measurement.
3. Tap the **Result** button.
4. Tap the **Review** > **Reject** buttons.
5. If necessary, enter a note.
6. Tap the **Accept** button.
7. Tap the **Back** > **Close** buttons.

To remove a test result from a patient result

Prerequisites:

- The patient result contains more than one test result
- The result is not approved or rejected.

1. Tap **Menu** > **Data logs** > **Patient results log**.
2. Select the measurement.
3. Tap the **Result** > **Review** > **Deselect test** buttons.
4. Deselect the check button for the parameter.
5. Tap the **Back** > **Back** > **Close** buttons.
   Note: The result of the test is removed from the **Patient results** screen and from printed results.

To see the audit trail on a patient result

Prerequisite: Changes were made to the patient result.

An audit trail shows the changes made to a patient result.

1. Tap **Menu** > **Data logs** > **Patient results log**.
2. Select the measurement.
3. Tap the **Result** button.
4. Tap the **Log** > **Audit trail** buttons.
   Note: The **Log** button will only be available if changes were made to the patient result.
5. Tap the **Back** > **Back** > **Close** buttons.

To filter data from the Patient results log

1. Tap **Menu** > **Data logs** > **Patient results log**.
2. Tap the **Filter** button.
3. In the **Criteria** frame, choose an option and follow the steps for it.

Option	Steps
To select a time period prior to today's date	Tap the number button for the number of days you want
To select a start and end date	Enter data in the **Start date** and **End date** fields

4. Select the next criterion. If necessary, enter or select a value for it.
5. If more criteria are necessary, tap the **More criteria** button.
6. Do step 4 again for each criterion.
7. Tap the **Apply** button.
8. Tap the **Close** button.

To see trends in a patient's results

Prerequisite: You have filtered data from the **Patient results log**.

1. Tap the **Trend** button.
2. Select the parameters.
3. Tap the **View trend** button.
4. Tap the **Back** > **Back** > **Close** buttons.

Maintenance 4

To order consumables

1. See the *AQT90 FLEX ordering information* document for details.
2. Contact your local Radiometer representative to order products for use with your analyzer.

Cartridges

To see the status of installed cartridges

1. Tap **Menu** > **Analyzer status** > **Consumables** > **Detailed inventory**.
2. Tap the **Back** > **Close** buttons.

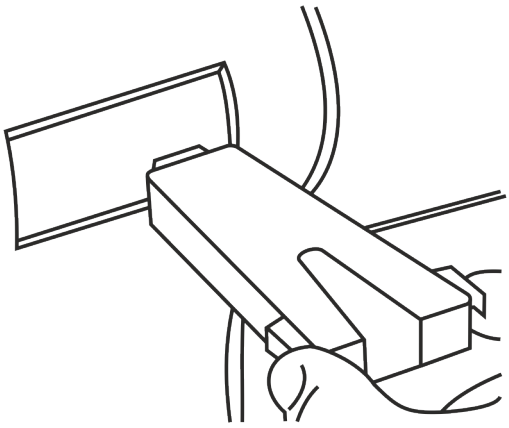
To insert a cartridge

⚠ **WARNING – *Risk of incorrect results***
Do not insert a cartridge that has been used on another analyzer.

⚠ **WARNING – *Risk of incorrect results***
Cartridges are sensitive to humidity and must not be removed from their sealed pouches until just before use. Only use cartridges that have been kept according to storage specifications and are not damaged.

1. Tap **Menu** > **Analyzer status** > **Consumables** > **Insert/Replace** > **Insert/Replace cartridge**.
2. If a cartridge is ejected, remove it and dispose of it as potentially infectious waste. **Note**: Cartridges are only ejected if they are used up or have passed their expiry date or on-board expiry date.
3. Remove the new cartridge from its sealed pouch.

4. Hold the cartridge with its barcode pointing downwards and its narrow end in front.



5. Push the cartridge into the cartridge compartment until it clicks in place.
6. Tap the **Accept** button.
7. Tap the **Back** > **Close** buttons.

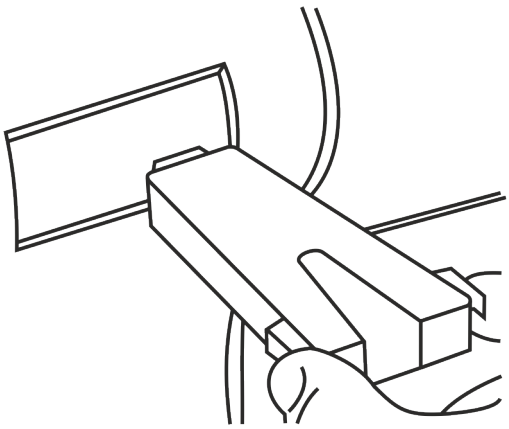
To select and replace a cartridge

When you want to insert a cartridge and there is no space for it because the maximum number (15) of cartridges are installed and are all valid, the analyzer will tell you to do this procedure.

⚠ **WARNING – *Risk of incorrect results***
Do not insert a cartridge that has been used on another analyzer.

⚠ **WARNING – *Risk of incorrect results***
Cartridges are sensitive to humidity and must not be removed from their sealed pouches until just before use. Only use cartridges that have been kept according to storage specifications and are not damaged.

1. Tap **Menu** > **Analyzer status** > **Consumables** > **Detailed inventory**.
2. Select the cartridge you want to replace.
3. Tap the **Insert/replace cartridge** button.
4. Remove the ejected cartridge.
   Note: The cartridge may be used again on the SAME analyzer.
5. Remove the new cartridge from its sealed pouch.
6. Hold the cartridge with its barcode pointing downwards and its narrow end in front.



7. Push the cartridge into the cartridge compartment until it clicks in place.

8. Tap the **Accept** button.
9. Tap the **Back** > **Close** buttons.

Solution Pack

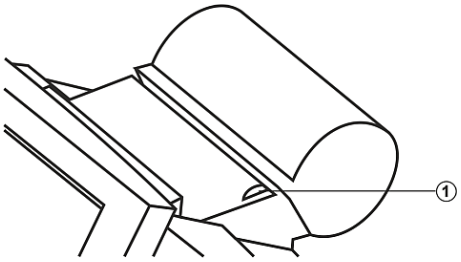
To replace the Solution Pack

1. Tap **Menu** > **Analyzer status** > **Consumables** > **Insert/Replace** > **Replace Solution Pack**. Wait until the analyzer ejects the Solution Pack.
2. ⚠ **WARNING – *Risk of infection***
   Remove the used Solution Pack and dispose of it as biohazardous waste.
3. Remove the new Solution Pack from its box.
4. Remove the top label to show the biohazard symbol.
5. Push the new Solution Pack into the Solution Pack compartment until it clicks in place.
6. Tap the **Accept** button.
   Note: If you cannot see an **Accept** button, tap the **Eject** button and do steps 5 and 6 again.

Thermal printer paper

To replace the thermal printer paper

1. Press the release button (1).



2. Open the cover and remove the used paper roll.
3. Put in the new paper roll. Make sure it unwinds from below.
4. Make sure some paper extends out of the printer.
5. Close the cover. It must click in place.

Protection of printed data

Note: Do not expose data printed on the thermal printer paper of the analyzer to pressure, high temperatures, high humidity, direct sunlight, water, alcoholic or organic solvents, freshly-developed diazo copy sheets or materials that contain polyvinyl-chloride (PVC), and do not scratch them. Keep the printed data in polyethylene, poly-propylene or polyester folders or boxes.

System clean

System clean

System clean is a procedure that cleans the section of the analyzer that transports samples through the system.

System clean frequency

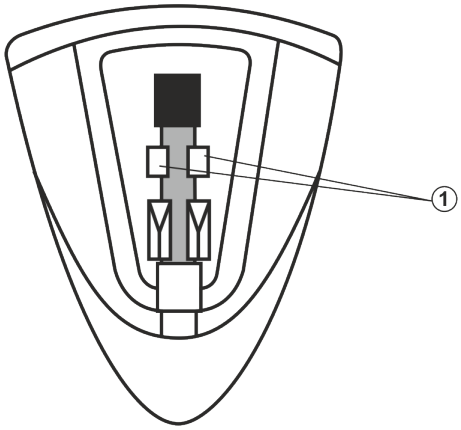
Radiometer recommends that a system clean is done after 200 tests.

To do a system clean

Prerequisites:

- One Radiometer Cleaning Solution Tube
- An installed Blank Test Cartridge with a minimum of one **Remaining tests**
- Solution Pack with a minimum **Cup capacity** of two
- The analyzer is in a **Ready**, **Ready for sample registration**, or **Ready for sample registration and cartridge replacement** mode

1. Tap **Menu** > **Analyzer status**.
2. Tap the **Other activities** > **Other activities details** buttons.
3. Tap the **Service/System clean** > **System clean** buttons.
4. Put the Cleaning Solution Tube in the tube holder with its cap side upwards and barcode pointing inwards. Press the tube down between the tabs (1)



5. Tap the **Start** button.
   You can read the **Time to result** in the result link.

Related Information

• To see details about installed consumables, page 5

To find a system-clean record

1. Tap **Menu** > **Data logs** > **System-clean log**.
2. Tap the **Close** button.

To add a note to a system-clean record

1. Tap **Menu** > **Data logs** > **System-clean log**.
2. Select the record.
3. Tap the **Note** button.
4. Enter the note.
5. Tap the **Close** button.

Cleaning

Blood spillage inside the analyzer

⚠ **WARNING – *Risk of electrical shock***
Do not open the analyzer for any reason. If blood is spilled inside the analyzer, contact your local Radiometer representative to get a service technician to clean it.

To clean the touch screen

Prerequisite: A lint-free cloth

⚠ **CAUTION – *Risk of damage to the touch screen***
Do not use liquid or aerosol cleaners to clean the touch screen.

1. Lightly dampen a lint-free cloth with water.
2. Wipe the screen carefully.

To clean the analyzer exterior

Prerequisites:

- A lint-free cloth
- A mild soap or detergent

Note: Do not use abrasive cleaning materials, or strong detergents.

1. Lightly dampen a lint-free cloth with soapy water or a mild detergent.
2. Gently wipe the analyzer exterior.

Disinfecting

To disinfect the touch screen

Prerequisites:

- A lint-free cloth
- A 70 % solution of iso-propyl alcohol (2-propanol)

⚠ **CAUTION – *Risk of damage to the touch screen***
Do not use liquid or aerosol cleaners to clean the touch screen.

1. Lightly dampen a lint-free cloth with a 70 % solution of iso-propyl alcohol.

2. Wipe the screen carefully.

To disinfect the analyzer exterior

Prerequisites:

- A lint-free cloth
- A 70 % solution of iso-propyl alcohol (2-propanol)

1. Lightly dampen a lint-free cloth with a 70 % solution of isopropyl alcohol (2-propanol).
2. Gently wipe the analyzer exterior.

Recording an operator activity

To record an operator activity

Prerequisite: The analyzer is in one of three **Ready** modes: **Ready**, **Ready for sample registration** or **Ready for sample registration and cartridge replacement**.

This procedure lets you record an operator maintenance activity in the **Activity log**.

1. Tap **Menu** > **Analyzer status** > **Other activities** > **Other activities details**.
2. Tap in the **Operator-activities schedule** field.
3. Tap the **Log operator activity** button.
4. Select the activity you want to record.
5. Tap the **Done** button.
6. If necessary, enter other data in the **Recording operator activities** screen.
7. Tap the **Back** > **Close** buttons.

Analyzer service

For service

For service, contact your local Radiometer representative. You may have to supply the installation number of the analyzer and the version number of the installed software.

To find the installation number of the analyzer

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Analyzer settings** > **Analyzer ID**.
2. Read the installation number on the screen.
3. Tap the **Close** button.

To find the version of software installed

1. Tap **Menu** > **Analyzer status**.

2. Read the software version in the lower left corner of the screen.
3. Tap the **Close** button.

To see an overview of measurements and tests done on the analyzer

1. **Menu** > **Utilities** > **Sample counter**.
2. Tap the **Close** button.

Sample counter

The **Sample counter** screen gives an overview of the measurements and tests done on the analyzer.

Data	Description
Parameter, **Patient samples** and **LQCs** on the left side of the screen	Shows the number of tests done for each parameter on patient samples and LQC solutions.
Completed column	Shows the number of completed patient sample analyses, calibration adjustments and LQC measurements. **Note**: Because a measurement can include more than one test, the total number of completed measurements will not be equal to the total number of tests.
Aborted column	Shows the number of measurements stopped by the analyzer because it found an error.
Operator column	The number of measurements done since the operator counters were last set to zero.

Note: The analyzer does not count the number of measurements with an "Interrupted" status. That is, measurements stopped by operators.

Needle replacement

Needle replacement is a mandatory maintenance activity. The **Critical limit** for needle replacement cannot be edited. The needle must be replaced before it gets to the critical limit. The critical limit is a measure of the total number of times the needle has aspirated samples from tubes since the needle was last replaced.

The needle must be replaced by a Radiometer service representative.

To find the number of times the needle has been used

1. Tap **Menu** > **Analyzer status**.
2. Tap the **Other activities** button.
3. Tap the **Other activities details** button.
4. In the **Maintenance counters** field, find the value in the **Current count** column for the "Needle replacement" activity. The value is the number of times the needle was used since the activity was last done.
5. Tap the **Close** > **Close** buttons.

To record a service inspection

Prerequisite: The analyzer is in **Ready** mode.

This procedure lets you record a service inspection in the **Activity log**.

1. Tap **Menu** > **Analyzer status** > **Other activities** > **Other activities details**.
2. Tap in the **Maintenance schedule** field.
3. Tap the **Log service inspection** button.
4. Select the activity you want to record.
5. Tap the **Done** button.
6. If necessary, enter other data in the **Recording maintenance activities** screen.
7. Tap the **Back** > **Close** buttons.

Battery on the printed circuit (PC) board

WARNING – *Risk of electrical shock*
Only let a trained technician service the battery circuit and replace the lithium battery on the PC board and only use the battery for this purpose.

Quality control 5

Quality control (QC)

QC evaluates the performance of the analyzer to make sure that the patient results are accurate and precise.

Quality control (QC) management

Quality control is managed by the analyzer and by operators.

QC manager	Name of the QC procedure	Description
The analyzer	Automatic test sequences (frequently referred to as built-in QC)	Tests done at regular intervals to make sure that all parts of the analyzer operate within specifications.
	Setup and apply statistical rules to LQC results. For example: Westgard Rules and RiLiBÄK rules (used in Germany). **Note**: The analyzer has to be set up to do this.	Finds unexpected shifts, trends or increased imprecision in results. Symbols on results show those that have not obeyed the rules.
Operators	Liquid quality control (LQC) measurements	Measurements done with LQC solutions
	LQC after calibration adjustment	Measurements done to verify the calibration adjustment of a test lot. **Note**: These measurements are referred to as calibration verification measurements.
	System checks	Results of test sequences are recorded
	Linearity, calibration-verification and reportable range (LCR) measurements	Measurements that let you verify the linearity and reportable range of measured parameters

Frequency of liquid quality control (LQC) measurements

Do a LQC measurement.

- After a calibration adjustment
- After maintenance that may have an effect on test performance
- When internal quality assessment procedures recommend that it is done

- When local, state and federal regulations recommend that it is done

LQC solutions

Radiometer recommends that Radiometer liquid quality control products are used. See the *AQT90 FLEX ordering information* document for details.

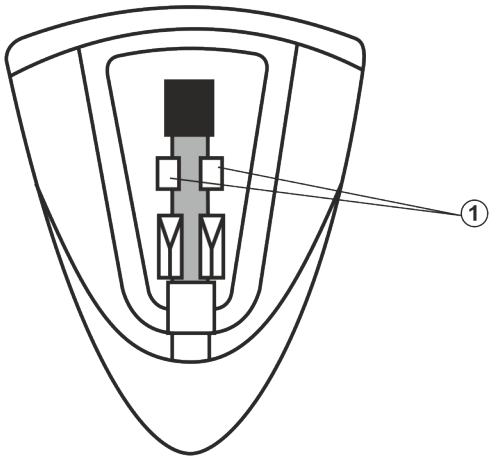
LQC measurements

To analyze a Radiometer LQC solution

Pre-requisites:

- The LQC solution is registered on the analyzer
- The analyzer is in one of three **Ready** modes: **Ready**, **Ready for sample registration** or **Ready for sample registration and cartridge replacement**

1. ⚠ **WARNING – *Risk of incorrect results***
   Follow manufacturer's instructions to prepare the LQC solution for use.
2. Tap the **Introduce sample** button.
   Note: If there is a tube in the inlet, remove it.
3. Put the tube in the tube holder with its cap side upwards and barcode pointing inwards. Press the tube down between the tabs (1).



4. Tap the **Accept** button.
5. Tap the **Start** button.
   You can read the **Time to result** in the result link.

Related Information

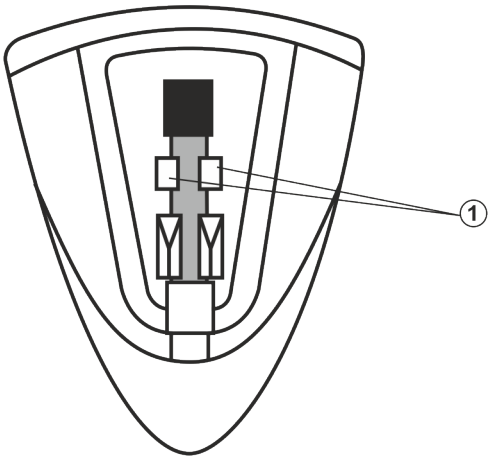
- To register a Radiometer LQC solution, page 99

To analyze a non-Radiometer LQC solution

Prerequisites:

- A tube from the Radiometer Empty Tube Kit
- The non-Radiometer LQC solution is registered on the analyzer
- The analyzer is in one of three **Ready** modes: **Ready**, **Ready for sample registration** or **Ready for sample registration and cartridge replacement**

1. ⚠ **WARNING – *Risk of incorrect results***
   Prepare the LQC solution for use. Follow the instructions in the *Empty Tube Kit* insert.
2. Tap the **Introduce sample** button.
   Note: If there is a tube in the inlet, remove it.
3. Tap the **LQC ID** button.
4. Put the tube in the tube holder with its cap side upwards. Press the tube down between the tabs (1).



5. Select the "Position: Solution / Lot number" that identifies the LQC solution in the tube holder.
6. Tap the **Select** button.
7. If necessary, enter a note.
8. Tap the **Accept** button.
9. Tap the **Start** button.
   You can read the **Time to result** in the result link.

Related Information

- To register a non-Radiometer LQC solution, page 99

To stop an LQC measurement

1. Tap the  button in the result link of the LQC measurement in progress.
2. Tap the **Stop** button.
3. Tap the **OK** button.

LQC results

To find an LQC result

1. Tap **Menu** > **Data logs** > **QC logs** > **LQC log**.
2. Select the measurement.
3. Tap the **Result** button.
4. Tap the **Back** > **Close** buttons.

Symbols on LQC results

Symbol	Description
	An error occurred. No result is available.
	The result is outside the user-defined control range, but inside the statistical range. Results inside the statistical range are included in statistics.
	The result is outside the statistical range. The result is not included in statistics.
	The result is outside the reportable range. The result is not included in statistics.
*	User-defined slope/offset corrections were used to calculate the result
W	The result violates a Westgard rule
R	The result violates a RiliBÄK rule

To see messages on an LQC result

1. Tap **Menu** > **Data logs** > **QC log** > **LQC log**.
2. Select the measurement.
3. Tap **Result** > **Messages**.
4. Tap the **Back** > **Back** > **Close** buttons.

Reviewing LQC results

To filter data from the LQC log

1. Tap **Menu** > **Data logs** > **QC logs** > **LQC log**.
2. Tap the **Filter** button.
3. In the **Criteria** frame, choose an option and follow the steps for it.

Option	Steps
To select a time period prior to today's date	Tap the number button for the number of days you want.
To select a start and end date	Enter data in the **Start date** and **End date** fields.

4. Select the next criterion. If necessary, enter or select a value for it.
5. Do step 4 again for each criterion.
6. Tap the **Apply** button.
7. Tap the **Close** button.

To see trends in LQC results

Prerequisite: You have filtered data from the **LQC log**.

1. Tap the **Trend** button.
2. Select the parameters.
3. Tap the **View trend** button.

4. Tap the **Back** > **Close** buttons.

LQC statistics

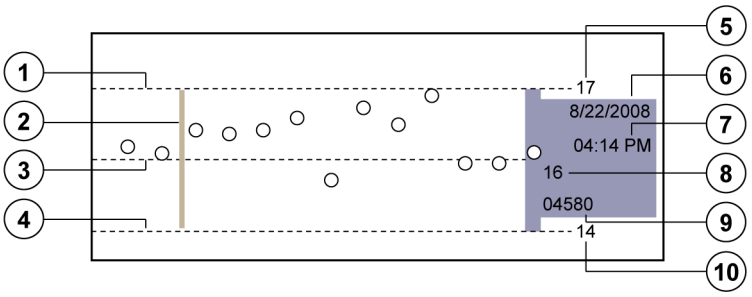
To find and print LQC statistics

LQC results are within the statistical ranges.

1. Tap **Menu** > **Data logs** > **QC logs** > **LQC log**.
2. Tap the **Statistics** button.
3. Tap the **Next param.** or **Prev. param.** button to see statistics for other parameters.
4. Tap the **Print** button.
5. Tap either the **Print lot-to-date** or the **Print for monthly period** button.
6. Tap the **Print** button.
7. Tap the **Back** > **Back** > **Close** buttons.

LQC plots

LQC plots are Levey-Jennings plots that show LQC results done with registered LQC solutions. The results are shown on a horizontal axis that represents the time they were done.



1	2 SD (standard deviations) above the mean value	6	Date
2	Lot number of the LQC solution or the user-defined control range was changed	7	Time
3	Mean value	8	LQC measurement result
4	2 SD (standard deviations) below the mean value	9	Lot number of the LQC solution used
5	Upper limit of the user-defined control range	10	Lower limit of the user-defined control range

To find an LQC plot

1. Tap **Menu** > **Data logs** > **QC logs** > **LQC log**.
2. Tap a measurement with the **Test type** "LQC".

3. Tap the **Plot** button.
4. If necessary, tap the **Next position** button to see plots for other registered LQC solutions.
5. Tap the **Next Param.** or **Prev. Param.** button to see the plots for other parameters.
6. To see other measurements in a plot, do as follows:
   a) Tap in the field of the plot.
   b) Use the left and right arrow buttons to select other measurements in the plot.
7. Tap the **Back** > **Close** buttons.

Symbols on LQC plots

Symbol	Description
	The result is outside the user-defined control range, but inside the statistical range.
	The result is outside the user-defined control range and the statistical range.
	The result is outside the reportable range.

LQC after calibration adjustments

LQC after calibration adjustments

LQC after a calibration adjustment lets you verify that the calibration adjustment of a test lot gives results that are equivalent to those measured with previous test lots.
Note: These measurements are referred to as calibration-verification measurements.

Frequency of LQC after calibration adjustments

LQC must be done after each calibration adjustment of a test lot.

To verify the calibration adjustment of a test lot

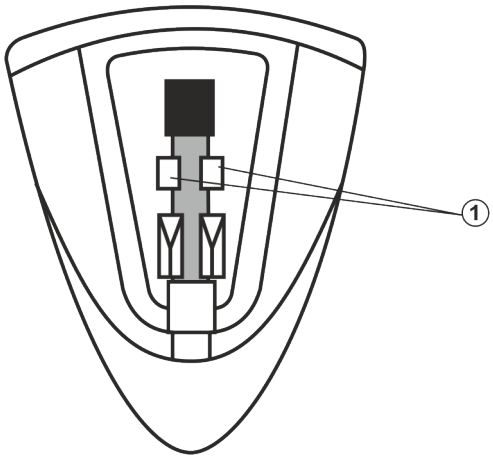
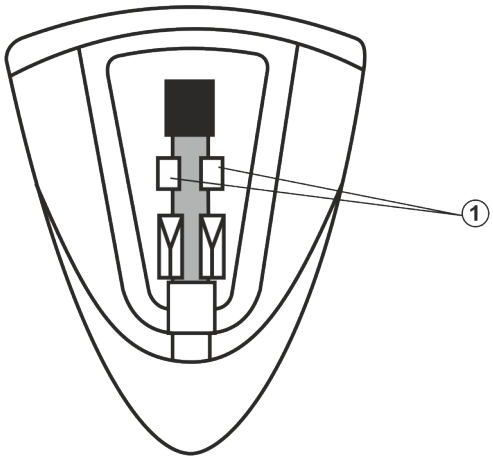
Prerequisites:

- An LQC solution
- The LQC solution is registered for use
- The analyzer is in one of three **Ready** modes: **Ready**, **Ready for sample registration** or **Ready for sample registration and cartridge replacement**

Note: The measurement done during this procedure is referred to as calibration-verification measurement.

1. **WARNING – *Risk of incorrect results***
   Follow manufacturer's instructions to prepare the LQC solution for use.
2. Tap the **Introduce sample** button.
   Note: If there is a tube in the inlet, remove it.

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

Option	Steps
For a Radiometer LQC solution	**a)** Put the tube in the tube holder with its cap side upwards and barcode pointing inwards. Press the tube down between the tabs (1). 
For a non-Radiometer LQC solution	**a)** Tap the **LQC ID** button. **b)** Put the tube in the tube holder with its cap side upwards. Press the tube down between the tabs (1).  **c)** Select the "Position: Solution / Lot number" that identifies the LQC solution in the tube holder.

4. For **Test type**, select "Cal.verification".
5. Enter the necessary data on the **LQC identification** screen.
6. Tap the **Accept** button.
7. Select the test lots you want to use for the measurement.
8. Tap the **Start** button.
   You can read the **Time to result** in the result link.

Related Information

- To register a Radiometer LQC solution, page 99
- To register a non-Radiometer LQC solution, page 99

To find results of an LQC done after a calibration adjustment

Note: LQCs done after calibration adjustment are referred to as calibration-verification measurements.

1. Tap **Menu** > **Data logs** > **QC logs** > **LQC log**.
2. Tap the **Filter** button.
3. In the **Criteria** frame, choose an option and follow the steps for it.

Option	Steps
To select a time period prior to today's date	Tap the number button for the number of days you want
To select a start and end date	Enter data in the **Start date** and **End date** fields

4. For **Test type**, select **Cal.verification**.
5. Tap the **Apply** button.
6. Select the measurement.
7. Tap the **Result** button.
8. Tap the **Print** button.
9. Tap the **Back** > **Close** buttons.

Symbols on results of an LQC done after a calibration adjustment

Note: LQCs done after calibration adjustment are referred to as calibration-verification measurements.

Symbol	Description
	An error occurred. No result is available.
	The result is outside the user-defined control range. The result is not included in the statistics.
	The result is outside the statistical range. The result is not included in statistics.
	The result is outside the reportable range. The result is not included in the statistics.

System checks

System checks

System checks make sure that the analyzer operates at the high level of precision necessary for good test results. System checks make sure that all parts of the analyzer operate within specifications. Results of the tests are recorded and can be printed. If a test in a system check fails, it will not stop use of the analyzer. However, the automatic test sequences done at regular intervals by the analyzer will find the same issue and stop use of the analyzer until the issue is resolved.

System checks can be done manually and they can also be scheduled to be done automatically. System-check results are saved in the **System-check log**.

To do a manual system check

Prerequisite: The analyzer is in one of three **Ready** modes: **Ready**, **Ready for sample registration** or **Ready for sample registration and cartridge replacement**.

1. Tap **Menu** > **Analyzer status**.
2. Tap the **QC** button.
3. Tap the **Start system check** button.
4. Tap the **Close** button.

To find system-check results

1. Tap **Menu** > **Data logs** > **QC logs** > **System-check log**.
2. Select the system check.
3. Tap the **Result** button.
   Note: If a test fails, a message is attached to the result.
4. Tap the **Back** > **Close** buttons.

To see messages on a system-check result

1. Tap **Menu** > **Data logs** > **QC logs** > **System-check logs**.
2. Select the system check.
3. Tap the **Result** > **Messages** buttons.
4. Tap the **Back** > **Back** > **Close** buttons.

Calibration verification (in the USA)

Calibration verification

In the USA and some other countries, regulations require calibration verification. Calibration verification is a process that lets you verify the linearity and reportable range of the parameters measured by the analyzer.

The calibration verification process includes these activities:

- Analyze as patient samples a minimum of three different levels of LQC solution. One level must be near the lower limit of the reportable range, one near the upper limit of the reportable range, and one in between.
  Note: On the analyzer, these measurements are referred to as linearity, calibration-verification and reportable range (LCR) measurements.
- Use the LCR measurement results to verify the linearity and reportable range of the measured parameters. Follow your local, state and federal guidelines.
  Note: If it is necessary to change the reportable range it can be done.

Related Information

• To set up reportable ranges, page 90

Frequency of calibration verification

Calibration verification is usually done every six months and when one or more of these conditions apply:

- After maintenance or an activity that may have an effect on test performance

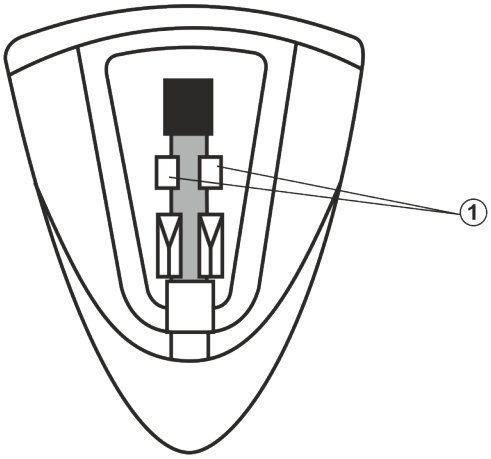
- If daily LQC measurements show unusual trends and shifts or results are outside acceptable limits
- If your laboratory rules that calibration verification must be done more frequently.

To do an LCR measurement

Prerequisites:

- A report layout that includes "Measurement type"
- A minimum of three levels of LQC solution.
  Note: One level must be near the lower limit of the reportable range, one near the upper limit of the reportable range, and one in between.
- The analyzer is in one of three **Ready** modes: **Ready**, **Ready for sample registration** or **Ready for sample registration and cartridge replacement**.

1. **WARNING – *Risk of incorrect results***
   Follow manufacturer's instructions to prepare the LQC solution for use.
2. Tap the **Introduce sample** button.
   Note: If there is a tube in the inlet, remove it.
3. Put the tube in the tube holder with its cap side upwards and barcode pointing inwards. Press the tube down between the tabs (1).



4. Tap the current **Report layout**.
5. Select a report layout that includes “Measurement type”.
6. For **Measurement type**, select “LCR sample”.
7. Enter the name and level of the LQC solution. If no special field is available, enter this data in the **Patient ID** field.
8. If necessary, enter other data in the **Patient identification** screen.
   Note: You must enter data in fields with this icon: 
9. Tap the **Accept** button.
10. Select the lot numbers of the Test Cartridges to use.
11. Tap the **Start** button.
    You can read the **Time to result** in the result link.

Related Information

- Report layout for LCR measurements, page 95

To find an LCR measurement result

1. Tap **Menu** > **Data logs** > **Patient results log**.
2. Tap the **Filter** button.

3. In the **Criteria** frame, choose an option and follow the steps for it.

Option	Steps
To select a time period prior to today's date	Tap the number button for the number of days you want
To select a start and end date	Enter data in the **Start date** and **End date** fields

4. For **Measurement type**, select "LCR sample".
5. Tap the **Apply** button.
6. Select the measurement.
7. Tap the **Result** button.
8. Tap the **Back** > **Close** buttons.

Symbols on LCR measurement results

The symbols used on LCR results are the same as the symbols used on patient results.

Calibration adjustment 6

Calibration adjustment

A calibration adjustment adjusts factory-defined calibration data to a specific analyzer. The calibration adjustment makes sure that measurement results are accurate and reliable.

Frequency of calibration adjustment

Do a calibration adjustment when:

- Test Cartridges with a new lot number are used
- Local, state and federal regulations recommend that it is done

Pending and active calibration adjustments

Status of calibration adjustments

Status of a calibration adjustment	Explanation
Pending	Calibration adjustment of the test lot has not been done. **Note**: If the **Status** value is "in queue" it shows that the CAL Cartridge is installed but the calibration adjustment procedure was not started.
Active	Calibration adjustment was done for this test lot

To find the status of calibration adjustments

1. Tap **Menu** > **Analyzer status**.
2. Tap the **Cal.adjust.** button.
   The screen shows the test lots with a "Pending" status.
3. To see test lots with an "Active" status, tap the **Active cal. adjust.** button.
4. To see the details of an active calibration adjustment:
   a) Select an active test lot.
   b) Tap the **Cal. adjust. details** button.
5. Tap the **Back** > **Back** > **Close** buttons.

To see and print active calibration adjustments

1. Tap **Analyzer status** > **Cal.adjust.**.
2. Tap the **Active Cal. adjust.** button.
3. Tap the **Print** button.

Doing calibration adjustments

To do a calibration adjustment

Prerequisites:

- A Solution Pack with a minimum **Cup capacity** of 16
- A CAL Cartridge in a sealed pouch
- The *Factory-defined calibration data* sheet in the Test Kit or CAL Cartridge box
- A Cleaning Solution Tube (for coagulation assays only)

⚠ **WARNING – *Risk of incorrect results***
Do not insert a cartridge that has been used on another analyzer.

⚠ **WARNING – *Risk of incorrect results***
Cartridges are sensitive to humidity and must not be removed from their sealed pouches until just before use. Only use cartridges that have been kept according to storage specifications and are not damaged.

1. Tap **Menu** > **Analyzer status** > **Consumables**.
2. Tap the **Insert/Replace** > **Insert/replace cartridge** buttons.
3. Remove the new CAL Cartridge from the sealed pouch.
4. Hold the cartridge with its barcode pointing downwards. Push the cartridge into the cartridge compartment until it clicks in place.
5. Scan the barcode on the *Factory-defined calibration data* sheet.
   Note: This step is not necessary if calibration adjustment of the test lot has been done before.
6. If the analyzer tells you, put a Cleaning Solution Tube in the tube holder.
   Note: This step is only required for coagulation assays.
7. Tap the **Accept** button.
8. Tap the **Start cal. adjust.** button.
9. Tap the **OK** button to start the calibration adjustment or tap the **Cancel** button to delay the start by 30 minutes.
   You can read the **Time to result** in the result link.

Post-requisite: Do LQC after calibration adjustment for this test lot. Follow the local, state and federal guidelines.

Related Information

- To see details about installed consumables, page 5

To invalidate an active calibration adjustment

Prerequisite: A test lot that is calibration adjusted.

It is necessary to do this procedure before you do calibration adjustment of a test lot again.
Note: The procedure permanently removes the active calibration adjustment data for the selected test lot.

1. Tap **Menu** > **Analyzer status** > **Cal.adjust.**.

2. Tap the **Active Cal. adjust** button.
3. In the **Test type** column, select the test type of the cartridge lot.
4. Tap the **Invalidate cal.adjust.** button.
5. Tap the **OK** button.
6. Tap the **Back** > **Close** buttons.

To do the calibration adjustment of a test lot again

Pre-requisite: The test lot is calibration adjusted.

1. Invalidate the active calibration adjustment for the test lot.
2. Do a calibration adjustment of the test lot.

To do an "in queue" calibration adjustment

Prerequisite: The installed CAL Cartridge has an “in queue” pending status.

1. Tap **Menu** > **Analyzer status** > **Consumables**.
2. Tap the **Start cal. adjust**. button.
3. Tap the **OK** button to start the calibration adjustment or tap the **Cancel** button to delay the start by 30 minutes.
   You can read the **Time to result** in the result link. If the procedure fails, do the procedure again.

Post-requisite: Do LQC after calibration adjustment for this test lot. Follow the local, state and federal guidelines.

To do a pending calibration adjustment

Prerequisites:

- A Solution Pack with a minimum **Cup capacity** of 16
- A CAL Cartridge in a sealed pouch

⚠ **WARNING – *Risk of incorrect results***
Do not insert a cartridge that has been used on another analyzer.

⚠ **WARNING – *Risk of incorrect results***
Cartridges are sensitive to humidity and must not be removed from their sealed pouches until just before use. Only use cartridges that have been kept according to storage specifications and are not damaged.

1. Tap **Menu** > **Analyzer status** > **Cal.adjust**.
2. In the **Pending calibration adjustments** field, select the parameter you want.
3. Tap the **Cal.adjust. details** button.
4. Tap the **Consumables** button.
5. Tap the **Start cal. adjust** button.
6. Tap the **OK** button to start the calibration adjustment or tap the **Cancel** button to delay the start by 30 minutes.
   You can read the **Time to result** in the result link.

Post-requisite: Do LQC after calibration adjustment for this test lot. Follow the local, state and federal guidelines.

Related Information

• To see details about installed consumables, page 5

To do a number of calibration adjustments

Prerequisites:

- A Solution Pack with a minimum **Cup capacity** of 16 for each calibration adjustment
- A CAL Cartridge in a sealed pouch for each test lot
- The *Factory-defined calibration data* sheet for each test lot
- Active calibration adjustments are invalidated for each test lot

⚠ **WARNING – *Risk of incorrect results***
Do not insert a cartridge that has been used on another analyzer.

⚠ **WARNING – *Risk of incorrect results***
Cartridges are sensitive to humidity and must not be removed from their sealed pouches until just before use. Only use cartridges that have been kept according to storage specifications and are not damaged.

This procedure explains how to do a number of calibration adjustments one after the other.

1. Tap **Menu** > **Analyzer status** > **Consumables**.
2. Tap **Insert/Replace** > **Insert/replace cartridge**.
3. Remove a CAL Cartridge from its pouch.
4. Hold the cartridge with its barcode pointing downwards. Push the cartridge into the cartridge compartment until it clicks in place.
5. Scan the barcode on the *Factory-defined calibration data* sheet.
   Note: You can find the sheet in the Test Kit or CAL Cartridge box.
6. If the analyzer tells you, put a Cleaning Solution Tube in the tube holder.
   Note: This step is only necessary for coagulation assays.
7. Tap the **Accept** button.
8. Do steps 2 to 7 for each CAL Cartridge.
9. Tap the **Start cal. adjust.** button.
10. Tap the **Close** button.
11. Tap the **OK** button to start the procedure or tap the **Cancel** button to delay the start by 30 minutes.
    You can read the **Time to result** for each test lot in the result link.

Post-requisite: Do LQC after calibration adjustment for this test lot. Follow the local, state and federal guidelines.

Related Information

- To see details about installed consumables, page 5

To stop a calibration adjustment

1. Tap the  button in the result link to the calibration adjustment that is in progress.
2. Tap the **Stop** button.
3. Tap the **OK** button.

Calibration adjustment results

To find results of a calibration adjustment

1. Tap **Menu** > **Data logs** > **Cal.adjustment log**.

2. Select the calibration adjustment.
3. Tap the **Result** button.
4. Tap the **Back** > **Close** buttons.

To see messages on a calibration adjustment result

1. Tap **Menu** > **Data logs** > **Cal.adjustment log**.
2. Select the calibration adjustment.
3. Tap the **Result** button.
4. Tap the **Messages** button.
5. Tap the **Back** > **Back** > **Close** buttons.

Reviewing calibration adjustment results

To filter data from the Cal.adjustment log

1. Tap **Menu** > **Data logs** > **Cal.adjustment log**.
2. Tap the **Filter** button.
3. In the **Criteria** frame, choose an option and follow the steps for it.

Option	Steps
To select a time period prior to today's date	Tap the number button for the number of days you want
To select a start and end date	Enter data in the **Start date** and **End date** fields

4. Select the next criterion. If necessary, enter or select a value for it.
5. Do step 4 again for each criterion.
6. Tap the **Apply** button.
7. Tap the **Close** button.

To see trends in the calibration adjustment log

Prerequisite: You have filtered data from the **Cal.adjust. log**.

1. Tap the **Trend** button.
2. Tap the **Back** > **Close** buttons.

Troubleshooting 7

To get back to a "Ready" mode

Operating mode	To get back to a “Ready” mode
Busy	**1.** Wait 10 to 120 minutes.
Error	**1.** Read the system messages in the **Analyzer status** screen. **2.** Troubleshoot the messages. **3.** Restart the analyzer. **4.** If the mode does not change, contact your local Radiometer service representative.
Locked	**1.** Read the messages in the **Analyzer status** screen. **2.** Troubleshoot the message.
Locked - QC pending	**1.** Do the scheduled LQC measurements.
Maintenance	**1.** Do the scheduled maintenance activities.
Not operational	**1.** Wait.
Not operational Automatic recovery in progress. Please wait.	**1.** Wait 2 to 6 minutes.
Replacement	**1.** Read the **Consumables** messages in the **Analyzer status** screen to find the root cause. **2.** Replace the consumables.
Service	**1.** Contact your local Radiometer representative.

Operating mode	To get back to a “Ready” mode
Shutdown	**1.** Wait until Windows shuts down. **2.** Push the power switch to the *On* (—) position. **3.** If the mode does not change to **Ready**, contact your local Radiometer representative.
Startup	**1.** Wait. The mode changes to **Not operational** before it changes to a **Ready** mode.

Message types

The analyzer makes two types of message.

- Messages that tell you about conditions that require some action.
- Messages that supply information, but do not require any action.

To troubleshoot messages that require some action

1. Note the message number.
2. Find the message in the topic about messages that require some action.
3. Follow the actions given in the **Operator actions** column.

Messages that require some action

Messages in the table are sorted by number. An explanation is given for each. Operator actions tell you how to troubleshoot each message.

No.	Message	Explanation	Operator actions
1	Inconsistent software versions	The versions of the installed software modules are inconsistent.	Contact your local Radiometer service representative.
2	Inconsistent analyzer system software	The versions of the installed software modules are inconsistent.	Contact your local Radiometer service representative.
89	Measured value above upper limit of the user-defined control range	The LQC or calibration-verification result is above the upper limit of the user-defined control range.	Follow local procedures to troubleshoot this type of error.
90	Measured value below lower limit of the user-defined control range	The LQC or calibration-verification result is below the lower limit of the user-defined control range.	Follow local procedures to troubleshoot this type of error.

No.	Message	Explanation	Operator actions
117	Invalid connection configuration	Either the communication configuration or the protocol definition is invalid for the data management system.	Make sure the values set in the communication setup are correct.
118	LIS/HIS: Connection manager could not open high-level protocol	Either the communication setup or the protocol definition is not valid.	**1.** Make sure the values set in the communication setup are correct. **2.** Restart the analyzer.
128	Failed to open connection	Either the communication hardware was busy or the remote system did not respond.	**1.** Try to open the connection again. **2.** Make sure that there is enough buffer capacity on the remote system. **3.** If the message stays, check the communication hardware.
129	Failed to close connection	The connection between the analyzer and the remote system failed. Some data may be missing.	**1.** Make sure that the remote system is running and responding. **2.** Check the communication cables and other hardware. **3.** Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Communications** > **LIS/HIS connection**. **4.** Tap the button in the **Output queue** frame. **Note**: This will delete messages in the queue. **5.** Tap the **Close** button.
131	Failed to send packet	Data from the analyzer was not sent because of a communication error.	
132	Failed to receive packet	Data from the remote system was not received because of a communication error.	**1.** Check that protocol types are correctly configured on both the analyzer and the remote system. **2.** If the message stays, contact your local Radiometer service representative.

No.	Message	Explanation	Operator actions
133	Connection lost	The connection between the analyzer and the LIS/HIS system failed.	**1.** Make sure that the remote system is running and responding. **2.** Check the communication cables.
165	High-level protocol could not generate high-level packet	An error occurred while formatting a message.	**1.** Check that protocol configurations. **2.** If the message stays, contact your local Radiometer service representative.
166	General communication error	An internal error occurred in the LIS/HIS communication module.	If the message stays, contact your local Radiometer service representative.
167	LIS/HIS: High-level protocol received packet in wrong format	An error occurred while parsing (interpreting) a message.	**1.** Check that protocol configurations. **2.** If the message stays, contact your local Radiometer service representative.
201	Westgard Rule (1-2s) violation	One measurement exceeds 2 SDs.	Follow local procedures to troubleshoot this type of error.
202	Westgard Rule (1-3s) violation	One measurement exceeds 3 SDs.	Follow local procedures to troubleshoot this type of error.
203	Westgard Rule (2-2s) violation	Two consecutive measurements exceed 2 SDs (same side).	Follow local procedures to troubleshoot this type of error.
204	Westgard Rule (R-4s) violation	The difference between two consecutive measurements exceeds 4 SDs.	Follow local procedures to troubleshoot this type of error.
205	Westgard Rule (4-1s) violation	Four consecutive measurements exceed the same 1 SD.	Follow local procedures to troubleshoot this type of error.
206	Westgard Rule (10-x) violation	Ten consecutive measurements lie on the same side of the mean.	Follow local procedures to troubleshoot this type of error.
208	LQC schedule reminder(s) present for solution <*Solution name*>	A scheduled LQC measurement (with the named QC material) is pending.	Do the pending LQC measurement.

No.	Message	Explanation	Operator actions
209	Replacement schedule reminder(s) present	One or more scheduled maintenance or user activity is pending.	**1.** Tap **Menu** > **Analyzer status** > **Maintenance** > **Maintenance details**. **2.** Do the pending activity.
210	Calibration adjustment error(s) present	An error was registered during the last calibration adjustment of a parameter.	**1.** Tap **Menu** > **Data logs** > **Cal.adjust log**. **2.** Tap the measurement with the **Status** "Failed". **3.** Tap **Result** > **Messages**. **4.** Do the calibration adjustment again.
211	Error present in measurement made with LQC solution setup in position <"number">	A process check failed during the LQC measurement.	Do the LQC measurement again.
212	System message(s) present	One or more system errors are present.	**1.** Tap **Menu** > **Analyzer status** > **System messages**. **2.** Find the message in this table and follow the operator actions to troubleshoot it.
213	Automatic backup failed	An error occurred during the scheduled data backup.	**1.** Make sure the values selected in the **Automatic backup** screen are correct. **2.** Check the network and servers used for the backup. **3.** If the message stays, contact your IT engineer.

No.	Message	Explanation	Operator actions
216	Printer error	Some paper is caught in the printer, or the printer is out of paper, or some other printer error has occurred.	**1.** Make sure no paper is caught in the printer. **2.** If necessary, replace the thermal printer paper. **3.** If the message stays, shutdown and restart the analyzer. **4.** If the message stays, contact your Radiometer service representative.
484	Today is the last day of the month - remember to print out LQC statistics	This is a reminder to print the LQC statistics before the end of the month.	Print the LQC statistics for the month.
588	Measured value is less than the lower limit of the defined statistical range	The measured value of the parameter is below the lower limit of the statistical range.	**1.** Do the LQC or calibration-verification measurement again. **2.** If the message stays, follow local procedures to troubleshoot this type of error.
589	Measured value is higher than the upper limit of the defined statistical range	The measured value of the parameter is above the upper limit of the statistical range.	**1.** Do the LQC or calibration-verification measurement again. **2.** If the message stays, follow local procedures to troubleshoot this type of error.
604	Parameter not installed	Parameter was not installed or is corrupted. Parameter cannot be measured.	Contact your local Radiometer service representative.
703	LQC lot in <*position*> has expired.	The QC material registered in the given position has passed its expiry date.	**1.** Register a new lot of LQC solution on the analyzer. **2.** Do an LQC measurement with the LQC solution.

No.	Message	Explanation	Operator actions
707	Replacement overdue by 10 %. Analyzer locked	A scheduled maintenance or user activity is overdue.	**1.** Tap **Menu** > **Utilities** > **Setup** > **Maintenance details** > **General setup** > **Miscellaneous setup**. **2.** Deselect the **Analyzer locked** check button. **3.** Tap **Menu** > **Analyzer status** > **Maintenance** > **Maintenance details**. **4.** Do the pending activity.
745	Low hard disk space	Low hard disk space.	Take appropriate action.
769	AQT90 FLEX <> RADIANCE system communication error	Communication error between the analyzer and the RADIANCE system.	Contact your local Radiometer service representative.
770	Failed to restore the selected setup	The setup could not be restored.	**1.** Download the setup data from another floppy disk, hard disk or network. **2.** If the message stays, contact your local Radiometer service representative.
775	Failed to restore Default setup	Restoring analyzer setup to default values has failed.	Contact your local Radiometer service representative.
800	Logon attempt failed	An operator could not log on because an invalid password was used.	Enter or scan a valid password.
875	Sample aged	The sample has passed the specified age limit.	Draw and analyze a new sample.
886	LIS/HIS: No valid POCT1A DML device ID file	No valid devices ID file for the POCT1A DML protocol can be found. Therefore no connection can be made to the LIS/HIS system.	Check the communication parameters.
896	Calibration adjustment job submission failed	Calibration adjustment failed.	Do the calibration adjustment again.

No.	Message	Explanation	Operator actions
901	Less than 5 % free disk space remaining	Less than 5 % disk space is available to store data on the analyzer.	Back up data to an external storage device. **Note**: If this action is not done, the analyzer will go into *Error* mode.
902	Less than 15 % free disk space remaining	Less than 15 % disk space is available to store data on the analyzer.	Back up data to an external storage device.
1003	Warning limit exceeded for maximum tests between system-clean procedures	The maximum number of tests between system cleans has passed the warning limit set in the **Maintenance schedule setup** screen.	Do a system clean.
1004	Critical limit exceeded for maximum tests between system-clean procedures	The maximum number of tests between system cleans has passed the critical limit set in the **Maintenance schedule setup** screen.	Do a system clean.
1005	Needle replacement counter has exceeded the warning limit	The total number of needle piercings between needle-replacement procedures has passed the warning limit set in the **Maintenance schedule setup** screen.	Contact your local Radiometer representative to get a service technician to replace the needle. **Note**: If this action is not done before the analyzer gets to the critical limit, it will go into *Error* mode.
1006	Needle replacement counter has exceeded the critical limit	The total number of needle piercings between needle-replacement procedures has passed the critical limit set in the **Maintenance schedule setup** screen.	Contact your local Radiometer representative to get a service technician to replace the needle.
1007	Scheduled system-clean procedure is overdue	A scheduled system clean is overdue.	Do a system clean.
1008	Service inspection scheduled time has been exceeded	A scheduled service inspection is overdue.	Contact your local Radiometer representative to get a service technician to do a service inspection.

No.	Message	Explanation	Operator actions
1009	Scheduled time for an operator activity has been exceeded	A scheduled user activity is overdue.	**1.** Tap **Menu** > **Analyzer status** > **Maintenance** > **Maintenance details**. **2.** Do the user activity that is overdue.
1010	System-clean procedure not successfully completed (aborted)	The analyzer stopped the system clean because it found an error.	**1.** Do a new system clean. **2.** If the message stays, contact your local Radiometer service representative.
1012	Scheduled maintenance activity is overdue	A scheduled maintenance activity is overdue.	**1.** Tap **Menu** > **Analyzer status** > **Maintenance** > **Maintenance details**. **2.** Do the maintenance activity that is overdue.
1020	Incubation temperature out of range	The incubation temperature was outside the specified range.	Wait until the analyzer goes into one of its **Ready** modes.
1024	Calibration adjustment blank outliers check failed	During calibration adjustment the blank outliers check failed.	Do the calibration adjustment again.
1025	Calibration adjustment analyte outliers check failed	During calibration adjustment the analyte outliers check failed.	Do the calibration adjustment again.
1026	Counts measured per cycle are above the valid limit	Process check. During sample analysis, the counts measured per cycle were outside the specified range.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.
1027	Incubation time out of range	Process check. During sample analysis, the incubation time for a test was outside the specified range.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.
1028	Maximum dark measurement difference out of range	Process check. During sample analysis, the maximum dark measurement was outside the specified range.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.

No.	Message	Explanation	Operator actions
1029	Optical sensitivity out of range	Process check. During sample analysis, the optical sensitivity was outside the specified range.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.
1030	Drying temperature out of range	Process check. During sample analysis, the drying temperature was outside the specified range.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.
1031	Optical intensity out of range	Process check. During sample analysis, the optical intensity was outside the specified range.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.
1032	Shake time out of range	Process check. During sample analysis, the shake time was outside the specified range.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.
1033	Incubation temperature standard deviation out of range	Process check. During sample analysis, the standard deviation of the incubation temperature was outside the specified range.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.
1034	System software validity check failed	Process check. During sample analysis, the software consistency check failed.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.
1035	Maximum dark measurements failed	Process check. During sample analysis, the maximum dark measurements check failed.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.
1036	Volume in the test cup out of range	Process check. During sample analysis, the volume in the test cup was outside the specified range.	**1.** If necessary, draw a new patient sample. **2.** Analyze the sample.

No.	Message	Explanation	Operator actions
1037	Optical reference check out of range	Process check. During sample analysis, the optical reference check was outside the specified range.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.
1038	Mean incubation temperature out of range	Process check. During sample analysis, the average incubation temperature was outside the specified range.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.
1051	No test available for measurement	Either no Test Cartridges are installed, or the installed cartridges contain no valid tests.	**1.** Insert Test Cartridges for the necessary tests. **2.** Do the tests again.
1052	Solution Pack not accessible	The installed Solution Pack has either passed its on-board expiry date or its expiry date.	Replace the installed Solution Pack with a new one.
1054	Calibration adjustment failed for <*parameter*> with lot no. <*n*>	Calibration adjustment of the given lot of Test Cartridges failed.	Do the calibration adjustment again.
1055	Calibration adjustment interrupted for <*parameter*> with lot no. <*n*>	An operator stopped calibration adjustment of the given lot of Test Cartridges.	Do the calibration adjustment again.
1056	Calibration adjustment aborted for <*parameter*> with lot no. <*n*>	The analyzer found an error and stopped calibration adjustment of the given lot for the given parameter.	Do the calibration adjustment again.
1057	Needle pierce count exceeded	Process check. The needle pierce count was above the threshold value of 10,000.	Contact your local Radiometer service representative.
1058	Dilution cup volume out of range	Process check. During sample analysis, the volume in the dilution cup was outside the specified range.	Do the test again.
1059	Calibration adjustment process failed	The calibration adjustment failed.	Do the calibration adjustment again.
1060	Calibration adjustment process interrupted	The calibration adjustment was stopped by an operator.	Do the calibration adjustment again.

No.	Message	Explanation	Operator actions
1061	Calibration adjustment process aborted	The analyzer found an error and stopped the calibration adjustment.	Do the calibration adjustment again.
1063	Solution Pack capacity insufficient to do a calibration adjustment	The Solution Pack does not have enough space to hold the cups that are discarded during calibration adjustment.	Replace the installed Solution Pack with a new one.
1065	Parameter measurement aborted	The analyzer found an error and stopped measurement of the parameter.	**1.** If necessary, draw a new patient sample. **2.** Do the test again.
1067	Sample measurement aborted	The analyzer found an error and stopped the sample analysis.	Analyze the sample again.
1068	Temperature out of range before drying	Before the start of a measurement cycle, the temperature of the air in the dryer was outside the specified range.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.
1069	Temperature out of range after drying	After the start of a measurement cycle, the temperature of the air in the dryer was outside the specified range.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.
1070	Air flow temperature out of range	The air flow in the dryer was outside the specified range.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.
1071	Maximum sample age exceeded	The sample is too old and therefore will not be analyzed	**1.** Draw a new patient sample. **2.** Analyze the sample within the maximum sample age.
1075 to 1088	*<Messages from installed printers>*		Follow the printer-manufacturer's instructions.
1089	LQC measurement aborted	The analyzer found some error and stopped the measurement.	Do the LQC measurement again.

No.	Message	Explanation	Operator actions
1090	LQC measurement was interrupted	An operator stopped the measurement.	Do the LQC measurement again.
1091	Parameter locked - LQC pending	Either a scheduled LQC measurement is overdue, or an error was found during an LQC measurement.	Do the scheduled LQC measurement.
1092	LQC warning present for LQC in position <*n*>	Either a scheduled LQC measurement is overdue, or an error was found during an LQC measurement with the QC material that is registered in the given position.	Do the scheduled LQC measurement.
1093	All available parameters locked - LQC pending	Either all scheduled LQC measurements are overdue, or errors were found during all previous scheduled LQC measurements.	Do all scheduled LQC measurements.
1187	This operation may affect Analyzer's status. An LQC measurement is advised.	The requested operation may change the status of the analyzer.	**1.** Do the operation. **2.** Do LQC measurements.
1189	Parameter requested by RADIANCE system not measured	A test requested via the RADIANCE system could not be done.	**1.** Tap **Menu** > **Analyzer status** > **Consumables**. **2.** Insert a Test Cartridge for parameters that have zero **Remaining tests**. **3.** If necessary, replace the installed Solution Pack. **4.** Analyze the patient sample again.
1190	The analyzer is locked	The analyzer was locked via the RADIANCE system.	**1.** Remove the condition that caused the operator to lock the analyzer. **2.** Unlock the analyzer via the RADIANCE system.
1199	The in-progress calibration-verification measurement was aborted by analyzer	The analyzer found an error and stopped the calibration-verification measurement.	Do the calibration-verification measurement again.

No.	Message	Explanation	Operator actions
1204	System check failed	Errors were found during the system check.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.
1205	The temperature inside the analyzer lies outside the specified limits.	The ambient temperature in the room where the analyzer is placed has changed. This could occur if the analyzer is put in direct sunlight, or an air-conditioning unit is started.	**1.** Adjust the ambient temperature to 15-32 °C. **2.** If the message stays, contact your local Radiometer service representative.
1206	+12V power supply lies outside specified limits	The system check failed.	Contact your local Radiometer service representative.
1207	+24V power supply "A" lies outside specified limits	The system check failed.	Contact your local Radiometer service representative.
1208	+24V power supply "B" lies outside specified limits	The system check failed.	Contact your local Radiometer service representative.
1209	+24V power supply "C" lies outside specified limits	The system check failed.	Contact your local Radiometer service representative.
1210	User-defined date and time settings do not match those in the operating system of the analyzer	The values entered for date and time are out of range with the values on the analyzer.	Enter the correct values for date and time.
1211	Three-minute average temperature at incubation wheel is out of range	The system check failed.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.
1212	System check was aborted by the analyzer	The analyzer found an error and stopped the system check.	**1.** Do a system check. **2.** If the message stays, contact your local Radiometer service representative.

No.	Message	Explanation	Operator actions
1213	The LCR measurement was aborted by the analyzer	The analyzer found an error and stopped the LCR measurement.	**1.** Do the LCR measurement again. **2.** If the message stays, contact your local Radiometer service representative.
1218	Insufficient sample available for measurement	There was not enough sample to do a measurement.	• If the measurement was a patient sample analysis, draw a new sample and analyze it. • For all other types of measurement, do the measurement again with a new sample.
1222	Error in system determining Hct values	There is an error in the system that determines hematocrit values.	Contact your local Radiometer service representative.
1223	Hct value cannot be correctly determined	The hematocrit value could not be correctly determined.	**1.** Centrifuge the sample. **2.** Analyze the resultant plasma. **Note**: If message 1222 is received at the same time as this one, contact your local Radiometer service representative.
1224	Hct value determined to be > 62 %	Hct value was found to be > 62 %.	**1.** Centrifuge the sample. **2.** Analyze the resultant plasma.
1225	Voltage measured in optical unit is outside specifications	The voltage measured in optical unit is outside the specified range.	Contact your local Radiometer service representative.
1226	The following operators setup via the RADIANCE system could not be added to the analyzer: *<Operator ID>*	The given operator could not be added via the RADIANCE system because either the password or the operator ID was not unique.	In the RADIANCE system, enter a unique password and operator ID for the given operator.
1238	Error found: <"error number">. Automatic recovery was started.	The analyzer shuts down and restarts.	**1.** If the analyzer goes into "Error" mode, contact your local Radiometer service representative.

No.	Message	Explanation	Operator actions
1542	The external storage device is either inaccessible, or non-writable/full	Either no disc is installed, or the disc is read-only.	Insert a writable compact disc (CD).
1996	Restart the analyzer. If the message remains, contact your local Radiometer service representative.	Restart analyzer. If problem persists contact service.	**1.** Restart the analyzer. **2.** If the message stays, contact your local Radiometer service representative.
1997	Unknown error logged with error code: <*number*>	An error was found that has not been specified.	**1.** Restart the analyzer. **2.** If the message stays, contact your local Radiometer service representative.
1999	UNDEFINED_LOOKUP_STRING		**1.** Restart the analyzer. **2.** If the message stays, contact your local Radiometer service representative.

Messages that do not require action

Messages in the table are sorted by number. An explanation is given for each.

No.	Message	Explanation
83	Value above reference range	The result is above the user-defined reference range.
84	Value below reference range	The result is below the user-defined reference range.
85	Value is below the critical limit	The result is below the user-defined critical limit.
86	Value is above the critical limit	The result is above the user-defined critical limit.
93	Value above the reportable range	The result is above the reportable range of the parameter.
94	Value below the reportable range	The result is below the reportable range of the parameter.
134	Connection established	The connection was successfully established.
200	Operator message:	An operator entered a note in the activity log.
214	Automatic backup succeeded	A scheduled automatic backup was completed successfully.

No.	Message	Explanation
217	Replacement performed:	A maintenance or user activity was recorded in the **Activity log** screen.
641	AQT90 FLEX restarted	The analyzer was restarted from power off.
733	New part installed	A new part was successfully installed on the analyzer.
771	Succeeded to restore Custom setup	The procedure to load a saved setup is completed.
772	Operator activity: <*operator message*>	An operator added the given message in the **Activity log** screen.
773	Remote operator logged on with Operator ID:	An operator used the given ID to log on to the analyzer via NetOp*.
774	Remote operator logged off with Operator ID:	An operator with the given ID logged off the remote operator.
776	Default setup was restored successfully	The procedure to restore the Radiometer default setup is completed.
780	RADIANCE system communication enabled	Communication with the RADIANCE system was started from the **RADIANCE connection** screen.
781	RADIANCE system communication disabled	Communication with the RADIANCE system was stopped from the **RADIANCE connection** screen.
782	RADIANCE system data queue emptied	Queued data was sent to the RADIANCE system from the **RADIANCE connection** screen.
783	Automatic backup started	An automatic backup procedure was started.
785	Automatic archiving started	An automatic archiving procedure was started.
786	Automatic archiving completed	The automatic archiving procedure was completed without error.
787	Export of data logs started	An export data logs procedure was started.
798	Operator logged on	An operator logged on to the analyzer with the given operator ID.
799	Operator logged off	An operator logged off the analyzer.
852	Message from RADIANCE system: <*message*>	The given message was received from the RADIANCE system.
887	Solution Pack buffer level low	The level of buffer in the Solution Pack is low.
889 to 895	<*Parameter name*> capacity low	The number of remaining tests for the given parameter is below the value set in the **Replacement warning setup** screen.

No.	Message	Explanation
897	Calibration adjustment verified	The calibration adjustment was verified.
898	An active calibration adjustment was invalidated	An operator invalidated the active calibration.
903	Automatic backup setup changed	Some values were changed in the **Automatic backup** screen.
1000	System-clean procedure successfully completed	The system clean was completed without error.
1001	Needle replacement activity completed	The needle was replaced.
1002	Service inspection activity completed	A service inspection maintenance activity was recorded in the **Activity log**.
1011	System-clean procedure started	A system clean was started.
1039 to 1044	<*Parameter name*> locked	An operator locked the given parameter.
1045 to 1050	<*Parameter name*> unlocked	An operator unlocked the given parameter.
1053	Expiry date of the Solution Pack is within the replacement warning period	The **Cup capacity** in the installed Solution Pack is below the value set in the **Replacement warning setup** screen.
1062	Sample registration interrupted	An operator stopped registration of a sample.
1066	Parameter measurement interrupted	An operator stopped the given test.
1163	Warning and/or critical limit for a system clean activity was updated	An operator changed the warning and/or critical limit for the system clean activity.
1164	Warning limit for a needle replacement activity was updated.	An operator changed the warning limit for the needle replacement activity.
1170	Reference range/critical limits changed for <*parameter*>	An operator changed the limits of either the **Reference** and/or **Critical** ranges for the given parameter.
1172	Analyzer unit accessed	An operator opened a **Service** menu.
1173 to 1176	<*Parameter* > capacity low	The number of valid remaining tests for the given parameter is below the value set in the **Replacement warning setup** screen.
1177 to 1181	<*Parameter name*> locked	An operator locked the given parameter.
1182 to 1186	<*Parameter name*> unlocked	An operator unlocked the given parameter.
1188	Restore-all-data operation requested	A restore-all-data operation was requested.

No.	Message	Explanation
1191	Analyzer unlocked	The analyzer was unlocked via the RADIANCE system.
1192	A "Lock parameter" command from the RADIANCE system was ignored	A parameter could not be locked because the analyzer status shown in the RADIANCE system did not agree with the actual status of the analyzer.
1193	An "Unlock parameter" command from the RADIANCE system was ignored	A parameter could not be unlocked because the analyzer status shown in the RADIANCE system did not agree with the actual status of the analyzer.
1194	The <*command*> received from the RADIANCE system was ignored	The given instruction could not be done because the analyzer status shown in the RADIANCE system did not agree with the actual status of the analyzer.
1200	In-progress calibration-verification measurement was manually stopped	An operator stopped the calibration-verification measurement.
1201	Parameter value measured during cal.verification above user-defined control range	The value of a parameter measured during calibration-verification was above the user-defined control range.
1202	Parameter value measured during cal. verification below user-defined control range	The value of a parameter measured during calibration-verification was below the user-defined control range.
1203	The next scheduled system check is due.	The next scheduled system check is due.
1214	The LCR measurement was interrupted an operator	An operator stopped the LCR measurement
1215	Measured LCR value above the upper limit of the reference range	The value measured during an LCR measurement was above the upper limit of the reference range of the parameter.
1216	Measured LCR value below the lower limit of the reference range	The value measured during an LCR measurement was below the lower limit of the reference range of the parameter.
1220	Measured LQC value below RiLiBÄK range [<RiLiBÄK range>]	The measured value is below the lower limit of the RiLiBÄK range.
1221	Measured LQC value above RiLiBÄK range [<RiLiBÄK range>]	The measured value is above the upper limit of the RiLiBÄK range.
1227	Operator list received from the RADIANCE system	Operator data from the RADIANCE system has overwritten the operator data in the analyzer database.
1228	Blank Cartridge cup capacity low	The number of remaining tests for the given “Demo” parameter is below the value set in the **Replacement warning setup** screen.

No.	Message	Explanation
1229	Demo parameter locked	An operator locked the “Demo” parameter.
1230	Demo parameter unlocked	An operator unlocked the “Demo” parameter.
1231	Result must not be used for clinical purposes. Test was run with a demo parameter.	Do not use the result for clinical purposes. The test was done with a “Demo” parameter.

*A software product that gives secure access to the analyzer from a remote location.

Shutting down, moving and restarting the analyzer

8

Shutting down the analyzer

When to shut down the analyzer

The analyzer is kept switched on so that it is ready to use at any time. However, there are a few situations that require an operator to shut down the analyzer.

- Before the analyzer is moved to a new location
- When it is an action in a troubleshooting procedure
- After a PS/2 keyboard or mouse is connected to an analyzer that is switched on

To do a temporary shutdown

A temporary shutdown is necessary if the analyzer needs to moved, or is not going to be used for a period of less than 6 days.

1. If there are sample tubes in the sample inlet, remove them.
2. Tap **Menu** > **Utilities** > **Shutdown**.
3. Tap the **Confirm shutdown** button.
4. Wait until the **Shutdown** screen closes and the message **Windows is shutting down** is shown.
5. When Windows has shut down, push the analyzer power switch to the "Off" position (O).

Long-term shutdown of the analyzer

A long-term shutdown is necessary if the analyzer is not used for a week or more. Contact your local Radiometer representative.

Moving the analyzer

To move the analyzer on a trolley

Prerequisites:

- Two persons

- A trolley that can support the analyzer

1. Do a temporary shutdown of the analyzer.
2. Disconnect the power supply cord and peripheral devices.
3. Put the trolley near the analyzer.
4. With another person at the opposite end of the analyzer, put your fingers under the corners of the analyzer.
5. **WARNING – *Risk of back and hand injury***
   At the same time as the other person, lift the analyzer and put it on to the trolley.
6. Move the trolley near the new position for the analyzer.
7. **WARNING – *Risk of back and hand injury***
   At the same time as the other person, lift the analyzer and put it in its new position.
8. Connect the power supply cord and peripheral devices.

Restarting the analyzer

To restart the analyzer after a temporary shutdown

1. Push the power switch to the "On" (—) position.
2. Wait until the analyzer goes into a **Ready** mode.
   You may only have to wait 10 minutes, but you may have to wait 2 hours.

To restart the analyzer after a long-term shutdown

1. **CAUTION – *Risk of equipment damage***
   Use a power supply cord that meets the required specifications to connect the analyzer to the mains power supply.
2. Push power switch to the "On" (—) position.
3. When the analyzer tells you, insert a Solution Pack.
4. The analyzer goes into a **Not operational** mode while it warms up. It can last one hour.
5. Wait until the analyzer changes mode.
   Note: The analyzer will go into the mode it was in before it was shutdown.
6. Do what is necessary to get the analyzer back to **Ready** mode.

Installation 9

Installing the analyzer

Delivery of the analyzer

Make sure that the analyzer and all the products that were ordered with it are delivered are not damaged.

Preparing the location for the analyzer

Make sure that the location meets these environmental requirements:

- It is indoors
- Altitude: Not more than 2000 m (6 562 feet)
- Ambient temperature: 15-32 °C (59-89.6 °F)
- Relative humidity: 20-80 %
- Mains power supply: 100/110/120/220/230/240 V ±10 %; 50/60 Hz ±5 %
- Transient over-voltage: Impulse withstand: category II of IEC 60364-4-443
- Pollution degree: 2 (occasional/temporary conductivity caused by condensation)

Make sure that these space requirements are met:

- There is sufficient space in front of the analyzer
- There is sufficient space on the sides for good air flow
- ⚠ **WARNING – *Risk of electric shock***
  Make sure the analyzer is a minimum of 1.5 m from patient beds.
- Easy access to the mains power supply switch

To unpack and move the analyzer

Prerequisites:

- Two persons
- A trolley that can support the analyzer

1. Put the analyzer box on a horizontal surface with the topside up. Arrows on the box point to the topside.
2. Use a Torx 20 screwdriver to remove the screws in the lower part of the box. Screwdrivers on the box point to the screws.
   Note: These screws attach the top and bottom of the box to the sidewalls.
3. Remove the top and sidewalls.

4. Remove the foam and plastic.
   Note: The packaging material can be used as protection when the analyzer is moved to a different location. The material can withstand temperatures from –20 °C to 60 °C.
5. Put the trolley near the analyzer.
6. With another person at the opposite end of the analyzer, put your fingers under the corners of the analyzer.
7. ⚠ **WARNING – *Risk of back and hand injury***
   At the same time as the other person, lift the analyzer and put it on to the trolley.
8. Move the trolley near the new position for the analyzer.
9. ⚠ **WARNING – *Risk of back and hand injury***
   At the same time as the other person, lift the analyzer and put it in its new position.
10. ⚠ **WARNING – *Risk of damage to electronic and mechanical components***
    Do not connect the analyzer to the mains power supply until the temperature of the analyzer is the same as the temperature of the room. You may have to wait a maximum of 2 hours.
11. Follow the installation procedure.

To install the analyzer

Prerequisites:

- The supplied power supply cord

  ⚠ **CAUTION – *Risk of equipment damage***
  Use a power supply cord that meets the required specifications to connect the analyzer to the mains power supply.
- An AQT90 FLEX Solution Pack
- CAL and Test Cartridges for each parameter the analyzer is to measure

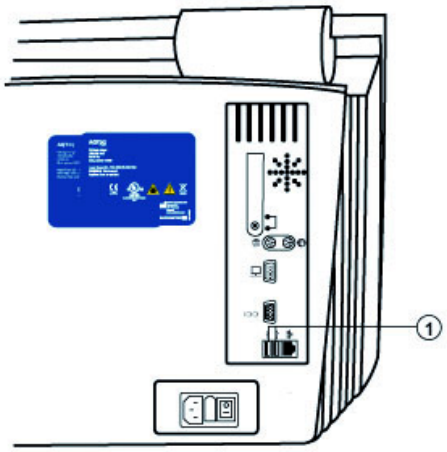
When the analyzer has been installed, keep it connected to the mains power supply so it can be used at all times.

1. Connect the power supply cord to the analyzer and the mains power supply.
2. Push the power switch to the "On" (—) position.
3. When the analyzer tells you, insert the Solution Pack.
   Note: The analyzer goes into **Not operational** mode while it warms up. It can last one hour.
4. Wait until the analyzer goes into **Replacement** mode.
5. Do calibration adjustment for each parameter the analyzer is to measure.
6. Insert a Test Cartridge for the parameters that are calibration adjusted.

Installing peripheral devices

To install a USB external keyboard / mouse

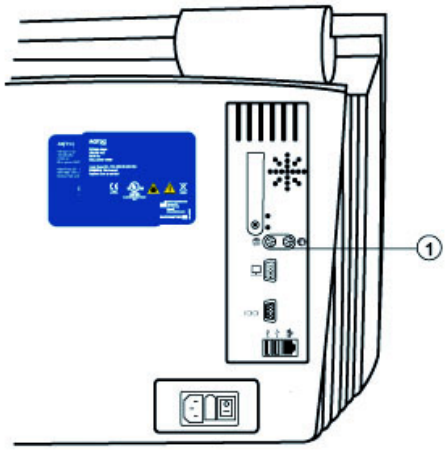
1. Connect the external keyboard / mouse cable to one of the USB ports (1) on the analyzer.



Note: The analyzer will find the connection to the external keyboard / mouse immediately.

To install a PS/2 external keyboard / mouse

1. Do a temporary shutdown of the analyzer.
2. Connect the external keyboard / mouse cable to one of the external keyboard and mouse ports (1) of the analyzer.



3. Restart the analyzer.

Related Information

- To do a temporary shutdown, page 69
- To restart the analyzer after a temporary shutdown, page 70

To do a temporary shutdown

A temporary shutdown is necessary if the analyzer needs to moved, or is not going to be used for a period of less than 6 days.

1. If there are sample tubes in the sample inlet, remove them.
2. Tap **Menu** > **Utilities** > **Shutdown**.
3. Tap the **Confirm shutdown** button.
4. Wait until the **Shutdown** screen closes and the message **Windows is shutting down** is shown.
5. When Windows has shut down, push the analyzer power switch to the "Off" position (O).

To restart the analyzer after a temporary shutdown

1. Push the power switch to the “On” (—) position.
2. Wait until the analyzer goes into a **Ready** mode.
   You may only have to wait 10 minutes, but you may have to wait 2 hours.

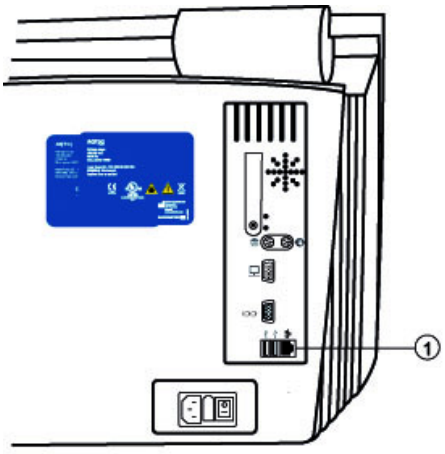
To install an external barcode reader

1. Connect the cable of the barcode reader to the external barcode reader port (1) of the analyzer.

Note: The analyzer will find the connection to the barcode reader immediately.

To connect the analyzer to a network

1. Connect your network cable to the network cable port of the analyzer (1).



Note: If the analyzer is set up for connection to a LIS/HIS or data management system, the analyzer will find the network immediately.

Setup 10

Setup menu structure

Analysis setup	• **Tube setup** • **Patient reports** • **Reference ranges** • **Reportable ranges** • **Sample registration setup**	
LQC setup	• **LQC** • **LQC statistics** • **Westgard Rules** • **RiLiBÄK Ranges**	
Other activities setup	• **Other activities schedule** • **Operator activities** • **Replacement warning**	
General setup	**Analyzer settings**	• **Analyzer ID** • **Time/date** • **Acoustic signal** • **Language** • **Calibrate touch screen**
	Parameters and input	• **Parameters** • **Units** • **User-defined patient data items** • **User-defined notes**
	Communications	• **RADIANCE connection** (not applicable in the USA) • **LIS/HIS connection** • **Automatic data transmission** • **Automatic data request** • **Patient lookup setup**
	Disk functions setup	• **Automatic archiving** • **Automatic backup**
	Printers	• **Printer setup** • **Automatic printing**
	Corrective actions	
	Miscellaneous setup	

System-check schedule	
Analyzer security	• **General security** • **Operators and passwords** • **Access profiles**
Print setup	

To print setups

1. Tap **Menu** > **Utilities** > **Setup** > **Print setup**.
2. Deselect the check buttons for the setups you do not want to print.
3. Tap the **Print** button.
4. If necessary, select the printer and tap the **Select printer** button.
5. Tap the **Close** button.

Managing operators

To select the logon procedure

1. Tap **Menu** > **Utilities** > **Setup** > **Analyzer security** > **General security**.
2. In the **Authenticate operator by** field, select the option you want.

Option	Action
To let most operators log on with an **Operator ID** and **Password**, but let some operators log on with a **Logon barcode**	Select "Operator ID and password as primary"
To let most operators to log on with a **Logon barcode**, but let some operators log on with an **Operator ID** and **Password**	Select "Logon barcode as primary"
To only let operators log on with an **Operator ID** and **Password**	Select "Operator ID and password only"
To only let operators log on with a **Logon barcode**	Select "Logon barcode only"

3. Tap the **Close** button.

Access profiles

An access profile specifies what an operator with the given profile can do on the analyzer.

- The operations that can be done
- The menus and screens that can be opened
- The shortcut buttons that are available to operators

Seven access profiles are available. Access profiles may be edited, but their names cannot be changed. No new access profiles can be created. An access profile must be selected for each operator.

To edit an access profile

Note: All access profiles may be edited, but some only in part.

⚠ **WARNING – *Risk of incorrect results***
Radiometer recommends that an access profile is selected and edited for each type of operator. The access profile given to each operator must match their qualifications and experience.

1. Tap **Menu** > **Utilities** > **Setup** > **Analyzer security** > **Access profiles**.
2. Select the access profile.
3. Select the check buttons in the **Permitted actions** field.
   Note: To permit LCR measurements, select the **Perform cal.adjustment** check button. To permit LQC after calibration adjustments, select the **Perform cal.adjustment** and the **Perform LQC measurements** check buttons.
   Note: The **Perform other activities** button, permits mandatory maintenance activities and operator activities.
4. Tap the **Menus and buttons** button.
5. To create a shortcut button.
   Note: You can create a shortcut button to six menus.
   - **a)** In the **Menu items in quick menu** field, select the menu you want a shortcut button for.
   - **b)** In the **Main screen button configuration** field, select a button position for the shortcut.
   - **c)** Do steps "a" and "b" again for each shortcut button you want to create.
6. To create access to menus.
   - **a)** In the **Menu items in quick menu** field, select the menu that you want to create access to.
   - **b)** Tap the button with a checkmark. 
     Note: Make sure a checkmark is shown in the selected check box.
   - **c)** Do steps "a" and "b" again for each menu you want to create access to.
7. Tap the **Back** > **Close** buttons.

To prevent patient sample analysis

You must edit an access profile as follows:

1. Do not create a shortcut button for the **Introduce sample** button.
2. Do not create access to the **Introduce sample** menu.

Anonymous use

Operators do not have to log on to an analyzer that is set up for anonymous use. The access profile selected for anonymous use specifies the shortcut buttons and menus that anonymous operators can use.

To set up anonymous use

1. Tap **Menu** > **Utilities** > **Setup** > **Analyzer security** > **General security**.
2. Select the **Allow anonymous use** check button.
3. Select an access profile for anonymous use.
4. Tap the **Close** button.

Default operators

Some operators are set up by default and cannot be removed.

Operator	Access
Radiometer	All operator and service menus.
Remote operator	All operator and service menus. **Note**: This operator is only shown when you have the "remote support" option. Contact your local Radiometer service representative for details.

To add an operator

1. Tap **Menu** > **Utilities** > **Setup** > **Analyzer security** > **Operators & passwords**.
2. Tap the **Add operator** button.
3. Choose an option and follow the steps for it.

Option	Steps
To make the operator log on with an **Operator ID** and a **Password**:	**a)** Enter a unique ID for the operator. **Note**: Do not include characters such as apostrophes (') and slashes (/). **Note**: Only enter 26 characters, so that the complete ID is seen in the **Logon** screen. **b)** Enter or scan in the password for the operator. **Note**: The password must contain a minimum of 4 characters. **c)** Enter or scan in the password again in the **Confirm password** field.
To make the operator log on with a **Logon barcode**:	**a)** Enter or scan in the logon barcode for the operator. **Note**: The logon barcode must be unique and contain a minimum of 4 characters. **b)** Enter or scan in the logon barcode again in the **Confirm logon barcode** field.
To make the operator log on with an **Operator ID** and a **Password** or with a **Logon barcode**:	**a)** Enter a unique ID for the operator. **Note**: Do not include characters such as apostrophes (') and slashes (/). **Note**: Only enter 26 characters, so that the complete ID is seen in the **Logon** screen. **b)** Enter or scan in the password for the operator. **Note**: The password must contain a minimum of 4 characters. **c)** Enter or scan in the password again in the **Confirm password** field. **d)** Enter or scan in the logon barcode for the operator. **Note**: The logon barcode must be unique and contain a minimum of 4 characters. **e)** Enter or scan in the logon barcode again in the **Confirm logon barcode** field.

4. Tap the **Back** button.
   Note: If data is not valid, the analyzer sends an acoustic signal and a feedback message.
5. Make sure that the operator is selected.
6. ⚠ **WARNING – *Risk of incorrect results***
   Select an access profile that matches the qualifications and experience of the operator.
7. To record events while the operator is logged on, select the **Enable event logging** check button.
   Note: Only operators with the access profile of "Manager" or "Supervisor" can see and select this check button.
8. Tap the **Close** button.

To remove an operator

1. Tap **Menu** > **Setup** > **Operators and passwords**.
2. Select the operator.
3. Tap the **Remove operator** button.
4. Tap the **Close** button.

To set a logoff time for all operators

1. Tap **Menu** > **Utilities** > **Setup** > **Analyzer security** > **General Security**.
2. Tap the **Logoff time** button.
3. Set a logoff time in minutes and seconds.
   Note: If no time is set operators will be automatically logged off after 3 minutes. The maximum logoff time that can be set is 60 minutes and 59 seconds.
4. Tap the **Back** > **Close** buttons.

Centralized user management

Centralized user management lets a connected RADIANCE system do some of the management procedures usually done on the analyzer. The table shows which procedures will have to be done on the connected RADIANCE system if centralized user management is set up.

Procedures	Done on the RADIANCE system	Done on the analyzer
Add new operator	X	
Select an access profile for a new operator	X	
Remove operators	X	
Select the logon procedure		X
Set up anonymous use of the analyzer		X
Edit an access profile		X
Set the logoff time for all operators		X

To set up centralized user management

Note: We recommend that you use the same set of rules to add analyzer operators to the RADIANCE system as you use to add operators to the analyzer. If centralized user management is then disabled, operators can continue to log on.

1. In the connected RADIANCE system, add present operators of the analyzer as present operators in the RADIANCE system.
   Note: This is important because when centralized user management is set up, all operator data in the analyzer is overwritten by data received from the RADIANCE system. Only present operators in the RADIANCE system can log on to the analyzer.
2. Tap **Menu** > **Utilities** > **Setup** > **Analyzer security** > **General security**.
3. Select the **Enable centralized user management** check button.
4. Select the **Close** button.
   Note: This will have no effect on the activities in progress.

Event logging

Logged events

The event log keeps a record of these events.

- Registration of patient samples
- Analysis of patient samples
- Registration of LQC solution
- LQC measurements
- Calibration adjustments
- Maintenance activities
- Replacement of consumables

Event log

An event log records events that occur when some operators are logged on. Events are recorded in sequence.

The log can be used to examine the competency of operators and identify the need for more training.

To enable event logging

Prerequisite: The operator who does this procedure must have a "Manager" or "Supervisor" access profile.

The procedure tells you how to set up the analyzer to log events for an operator.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Miscellaneous setup**.
2. Select the **Enable event logging** check button.
3. Tap the **Close** button.
4. Tap **Menu** > **Utilities** > **Setup** > **Analyzer security** > **Operators and passwords**.
5. Select the operator.
6. Select the **Enable event logging for the selected operator** check button.
7. Tap the **Close** button.

To examine the competency of an operator

Prerequisite: Events logging was enabled for the operator.

1. Tap **Menu** > **Data logs** > **Event log**.
2. Tap the **Filter** button.
3. Enter the start and end dates.
4. Enter the ID of the operator in the **Operator ID** field.
5. Tap the **Apply** button.
   The competency of the operator can be examined from the sequence of recorded events.
   Note: The event log can be printed.
6. Tap the **Close** button.

Compliance training

Compliance training

Regulations in some countries require compliance training of operators and records to show that training is in compliance. This is possible on the analyzer. The “Demo” parameter and Blank Cartridges are necessary.

To get the 'Demo' parameter

Compliance training requires the use of the 'Demo' parameter.

1. Contact you local Radiometer service representative.

To set up and do compliance training

These are the necessary procedures:

1. Enable event logging for the operators who are to be trained.
2. Set up the analyzer for compliance training.
3. Train the operators to analyze samples.
4. Examine the competency of the operators.

Blank Cartridges

Blank Cartridges contain empty cups and no reagents. The cartridge can be used in the place of Test Cartridges in training sessions to reduce analysis time. The Blank Cartridge measures a "training" parameter named "Demo".

Demo parameter

Facts about the “Demo” parameter:

- The value for a 'Demo' parameter result is always “90”
- The unit for a parameter result is “AQT”
- 'Demo' parameter results must never be used for clinical purposes
- 'Demo' parameter results cannot be sent to a connected LIS/HIS/management system
- Calibration adjustment of the 'Demo' parameter is not necessary

- Liquid quality control (LQC) measurements cannot be done for the 'Demo' parameter.

To set up the analyzer for compliance training

Prerequisites:

- The “Demo” parameter is available
- Event logging is enabled for operators
- If necessary, a report layout for compliance training

1. Tap **Menu** > **Analyzer status** > **Consumables**.
2. Make sure that the “Blank cups” parameter has some remaining tests. If necessary, insert a new Blank Cartridge.
3. Tap the **Close** button.
4. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Parameters and input** > **Parameters**.
5. To enable the “Demo” parameter.
   a) Select “Demo” in the **Parameter** column.
   b) Make sure that **Enabled/locked** value for the “Demo” parameter is “Yes/No”.
   c) If the “Demo” parameter is not “Yes/No”, tap the **Enable/disable** button.
6. Tap the **Close** button.
   A number of setups are automatically created.
   Note: A green “Demo” parameter tab is shown. It changes to a red color when the Blank Cartridge is empty.

Related Information

• To create a Patient ID / Report layout, page 93

Setups created for the "Demo" parameter

When the parameter “Demo” is enabled, a number of setups are automatically created.

- A test panel named “Demo” is created
- A tube type named “Demo” (with a black cap color) is created
- Default values are given to the critical and reference range limits of the “Demo” parameter. The values may be edited.

Note: These setups are automatically deleted when the “Demo” parameter is disabled.

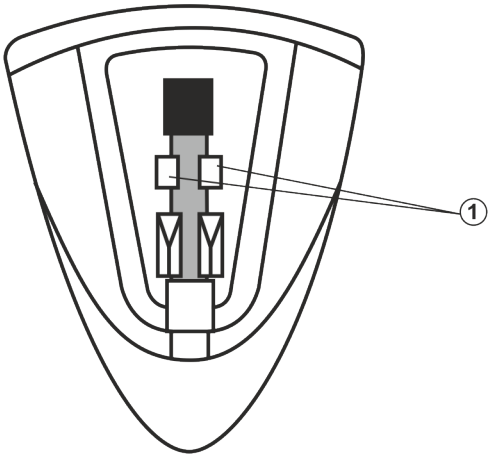
To train operators to analyze samples

Prerequisites:

- An installed Blank Cartridge with some **Remaining tests**
- Sample tubes (approved for use with the analyzer) that contain a minimum volume of 2 mL of a 0.9 % (w/v) saline solution (sodium chloride in water), or a whole-blood sample or a plasma sample
- The analyzer is in one of three **Ready** modes: **Ready**, **Ready for sample registration** or **Ready for sample registration and cartridge replacement**.

1. Tap the **Introduce sample** button.
   Note: If there is a tube in the tube holder, remove it.

2. Put the tube in the tube holder with its cap side upwards and barcode pointing inwards. Press the tube down between the tabs (1).



3. Enter "Training sample" or equivalent text in the **Patient ID** field to show that the sample is not a patient sample.
4. Enter the necessary data in **Patient identification** screen.

   Note: You must enter data in fields with this icon: 
5. Tap the **Accept** button.
6. Select "Demo" for the **Tube type**.
7. Select "Demo" for the **Test type**.
8. Tap the **Start** button.
   You can read the **Time to result** in the result link.

Analyzer operations

To lock the analyzer

When the analyzer is locked, operations that are in progress will be completed. No new operations can be started.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Miscellaneous setup**.
2. Select the **Lock the analyzer** check button.
3. Tap the **Close** button.

To unlock the analyzer

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Miscellaneous setup**.
2. Deselect the **Analyzer locked** check button.
3. Tap the **Close** button.

To lock/unlock parameters for measurement

A locked parameter cannot be measured.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Parameters and input** > **Parameters**.
2. Select the parameter.

3. Tap the **Lock/unlock** button.
   Note: The last value in the **Enabled/locked** column must be "Yes" to lock the parameter, and "No" to unlock it.
4. Tap the **Close** button.

To show a message on the analyzer screen

The message is shown below the result links.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Miscellaneous setup**.
2. Enter a message in the **Analyzer message** frame.
3. Tap the **Close** button.

To calibrate the touch screen

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Analyzer settings** > **Calibrate touch screen**.
2. Touch the tip of each arrow when they are shown on the screen.
   Note: If you cannot use the touch screen, use a mouse or keyboard to access the menus and start the procedure again.

Analyzer settings

To enable the screen saver

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Miscellaneous setup**.
2. Select the **Show screen saver** check button.
3. In the **Screen saver** frame, select the number of minutes the analyzer must not be in use before the screen saver is shown.
4. Tap the **Close** button.

To create a heading for printed data

Note: The text you enter in this procedure is the heading that will be shown on all data printed by the analyzer.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Analyzer settings** > **Analyzer ID**.
2. Enter the text for the heading (up to 25 characters). For example, a hospital or department name.
3. Tap the **Close** button.

To set the time and date

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Analyzer settings** > **Time/date**.
2. Enter the time.
3. Enter the date.
   Note: The **Previous** button cancels entered values.

4. Tap the **Close** button.
   Note: The analyzer goes into **Error** mode if the difference between your settings and the system settings is more then 100 hours.

To set the acoustic signals

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Analyzer settings** > **Acoustic signal**.
2. Select when you want an acoustic signal to be given.
3. Use the scroll buttons to select the volume level.
4. Tap the **Close** button.

To mute all acoustic signals

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Analyzer settings** > **Acoustic signal**.
2. Select the **Mute all acoustic signals** check button.
3. Tap the **Close** button.

To change the language on the screens

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Analyzer settings** > **Language**.
2. Select the language.
3. Tap the **Save language** button.
4. Tap the **Continue** button.
5. Choose an option and follow the steps for it:

Option	Steps
To change the language immediately	Tap the **Continue** button. **Note**: This will shut down and restart the analyzer.
To change the language later	**a)** Tap the **Cancel** button. **b)** Shut down and restart the analyzer later.

Analysis setup

Test panels

Test panels

A test panel contains one or more tests. The tests are intended for use as an aid in the diagnosis of medical conditions. For example, a "Cardiac risk" test panel could include tests for troponin I, myoglobin and CKMB as an aid in the diagnosis of heart conditions.

To set up test panels

1. Tap **Menu** > **Utilities** > **Setup** > **Analysis setup** > **Tube setup**.
2. Tap the **Define panels** button.
3. Tap the **New** button.
   Note: A maximum of 8 panels can be set up.
4. In the **Selected panel** frame, enter a name for the new panel.
5. In the **Available test types** frame, select a test for the panel.
6. Tap the right arrow button. 
7. Do steps 5 and 6 again for each test for the panel.
   Note: A maximum of 5 tests can be added to a panel.
8. Tap the **Back** > **Close** buttons.

Tube types

Tube types

It is necessary to set up a tube type for each type of sample tube approved for use on the analyzer. Usually, three types of sample tube are used.

- Tubes with EDTA anticoagulant
- Tubes with lithium heparin anticoagulant
- Tubes with citrate anticoagulant

Related Information

- Tubes approved for use with the analyzer, page 132

To set up a tube type

Prerequisite: Test panels are set up.

Note: In this procedure, it is important to select the correct color for the tube cap and enter a name that lets operators easily and correctly identify the tube.

1. Tap **Menu** > **Utilities** > **Setup** > **Analysis setup** > **Tube setup**.
2. Tap the **New** button.
3. In the **Selected tube type** frame, enter a name for the new tube type.
4. In the **Color:** field, select the color of the cap.
5. In the **Blood fraction:** field: select "1" for tubes with Heparin or EDTA anticoagulants and "0.9" for tubes with citrate anticoagulant.
   Note: The blood fraction is used for the citrate correction.
6. In the **Available panels** frame, select a panel that contains tests that can be done with the tube.
7. Tap the right arrow button. 
8. Make sure the selected panel is shown in the **Selected panels** frame.
9. Do steps 6 to 8 again for each panel you want to include.
   Note: A maximum of four panels can be selected.
10. Tap the **Close** button.

Citrate correction

Blood samples collected in tubes with citrate anticoagulant are diluted by the liquid anticoagulant. Test results are therefore corrected. This formula is used:

[1/(Blood fraction value)] x [Uncorrected result] = [1/0.9] x [Uncorrected result] = Corrected result.

Test order codes

Test order codes

Test order codes are unique codes that can be set up in LIS/HIS systems and the analyzer. When test order codes are set up, tests and patient identification data are automatically downloaded to the analyzer. Test order codes also make it possible to see if the correct tube type has been used before a sample analysis is started.

To set up test order codes

Prerequisites:

- Test panels are set up
- Tube types are set up
- LIS/HIS test order codes are available

Note: Only one tube type can be selected for a test order code.

1. Tap **Menu** > **Utilities** > **Setup** > **Analysis setup** > **Tube setup**.
2. Select a **Tube type** with an anticoagulant that can be used for the tests in the test order code.
3. Tap the **Define test order code** button.
4. Tap the **New** button.
5. Enter the LIS/HIS test order code in the **Code:** field.
6. Select the tests to select when the test order code is used.
7. Do steps 2 to 6 for each test order code you want to set up.
8. Tap the **Back** > **Close** buttons.

Reference ranges and critical limits

Reference ranges

Reference range is the range of test values expected for a healthy population of individuals or some other defined group. Patient results that lie outside the limits will be marked with a symbol.

"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." (Tietz NW, Logan NM. Reference ranges. In: Tietz NW, ed. Fundamentals of clinical chemistry. 3rd ed. Philadelphia: WB Saunders Company, 1987: 944-75).

Critical limits

Critical limits are user-defined and can be entered into the analyzer software. If critical limits are entered, patient results that lie outside the limits will be marked with a symbol. The symbol may be used to indicate when a patient requires immediate attention.

To set up reference ranges and critical limits

1. Tap **Menu** > **Utilities** > **Setup** > **Analysis setup** > **Reference ranges**.
2. Select a parameter in the **Parameter** field.
3. Tap the **Edit** button.
4. Enter values for the reference range and the critical limits.

   If the entered values are not accepted, a feedback message will be shown above the parameter tabs on the left of the screen.

   Note: If values below the lower limit of the reportable range are thought to be normal for the parameter, you must enter the same value for the lower limit of the reference range and the lower critical limit. The lower limit of the reportable range must also be given the same value. This makes sure that the correct symbols are used on patient results.
5. Do steps 2 to 4 again for each parameter.
6. Tap the **Close** button.

Reportable ranges

Reportable ranges

Reportable range is the range of results from a testing system or method over which analytical performance is claimed. Patient results that lie outside the limits will be marked with a symbol.

See the *AQT90 FLEX parameter-specific Test Kit* inserts for details.

To set up reportable ranges

Note: A symbol is shown on a test result that falls outside the reportable range of the measured parameter.

1. Tap **Menu** > **Utilities** > **Setup** > **Analysis setup** > **Reportable ranges**.

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

Option	Steps
To set the reportable range of all parameters to the default values	Tap the **Set default value to all** button.
To set the reportable range for a parameter to the default value	**a)** Select a parameter in the **Parameter** field. **b)** Tap the **Set default value** button.
To set the reportable range for a parameter	**a)** Select the parameter in the **Parameter** field. **b)** Enter new values for the upper and lower limits of the reportable range. **Note**: New values must be within the reportable range specified in the *AQT90 FLEX parameter-specific Test Kit* inserts. **Note**: If the entered values are not accepted, a feedback message will be shown above the parameter tabs on the left of the screen. **Note**: If values below the lower limit of the reportable range are thought to be normal for the parameter, the lower limit of the reportable range must be given the same value as the lower limit of the reference range and the lower critical limit. This makes sure that the correct symbols are used on patient results.

3. Tap the **Close** button.

Registration Tickets

Registration Tickets

Registration Tickets are printed by the analyzer. The tickets contain data about patient samples, the ID of the analyzer and a barcode. Operators can scan the barcode on the tickets to show the patient results on screen.

You can set up the analyzer to automatically print registration tickets after patient sample analyses are started.

To select data in Registration Tickets

1. Tap **Menu** > **Utilities** > **Setup** > **Analysis setup** > **Sample registration setup**.
2. Select the check buttons for the data you want to include in Registration Tickets.
3. Tap the **Close** button.

To set up automatic printing of Registration Tickets

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Printers** > **Automatic printing**.
2. Select the **Registration ticket** check button.
3. Tap the **Close** button.

Result links

To set up result links

1. Tap **Menu** > **Utilities** > **Setup** > **Analysis setup** > **Sample registration setup**.
2. Enter the number of result links to let operators use.
   Note: The screen can show 5 links at a time.
3. In the **Patient identification** field, select the data item to identify patient samples in result links.
4. Tap the **Close** button.

Sample registration

Sample age calculation

- If a **Draw time** is entered for the sample:

  [Sample age] = [Time the sample analysis was completed] – [Time the sample was drawn]
- If no **Draw time** is entered for the sample:

  [Sample age] = [Time the sample analysis was completed] – [Time the **Introduce sample** button was tapped (prior to the sample being placed in the analyzer)]

Maximum sample age

Maximum sample age is the maximum period of time a parameter stays stable in whole-blood samples kept between 18-25 °C. Samples must therefore be analyzed within this time period.

See the *AQT90 FLEX parameter-specific Test Kit* inserts for details.

To set a maximum sample age

Prerequisites: An *AQT90 FLEX parameter-specific Test Kit* insert for each parameter to be measured on the analyzer.

1. Find the maximum sample age for each parameter.
2. Tap **Menu** > **Utilities** > **Setup** > **Analysis setup** > **Sample registration setup**.
3. Enter the lowest value in the **Maximum sample age** field.
4. Tap the **Close** button.

To interpret barcodes on sample tubes

1. Tap **Menu** > **Utilities** > **Setup** > **Analysis setup** > **Sample registration setup**.
2. In the **Interpret barcode as** field, select a value.
   Note: If you want to use the FLEXLINK module, you must select "Accession number".
3. Tap the **Close** button.

Related Information

- To enable the use of FLEXLINK modules*, page 116

Patient ID / Report layouts

Patient ID / Report layouts

A patient ID / report layout contains the set of data fields shown in the **Patient identification** screen. It is possible to make data fields mandatory and enter default values for some of them. A patient ID / report layout may also be selected as a default. Layouts must contain data fields that let samples be correctly identified.

To create a Patient ID / Report layout

1. Tap **Menu** > **Utilities** > **Setup** > **Analysis setup** > **Patient reports**.
2. Tap the **New** button.
3. To add data items to the layout:
   - **a)** Select a data item In the **Available items** frame.
   - **b)** Tap the right arrow button.
     Note: Data items are shown in the layout as you add them.
   - **c)** Do steps "a" and "b" again for each data item you want to add.
     Note: If patient data is to be automatically requested from a LIS/HIS/ management system: add the data item selected to interpret barcodes on sample tubes.
     Note: If patient data is to be looked up, found and requested manually: Add the "Patient department" data item.
     Note: If patient data is to be requested manually, but directly: Add the "Accession number" or "Patient ID" field data item.
4. To make a data item mandatory:
   - **a)** Select the data item in the **Selected items** frame.
   - **b)** Tap the **Set as mandatory** button.
     Note: The mandatory icon is shown adjacent to the data item. 
5. To set a default value for a data item:
   - **a)** Select the data item in the **Selected items** frame.
   - **b)** Enter a value, or: (1) Tap the **List** button. (2) Select a value. (3) Tap the **Select** button.
6. Tap the **Back** button.
7. Enter a name for the report in the **Name** field.
8. Tap the **Close** button.

To select a Patient ID / Report layout as default

The patient ID / report layout you select as default is the one shown in the **Patient identification** screen when it opens.

1. Tap **Menu** --> **Utilities** --> **Setup** --> **Analysis setup** --> **Patient report**.
2. Select the patient ID layout.
3. Tap the **Make default** button.
4. Tap the **Close** button.

To edit a Patient ID / Report layout

1. Tap **Menu** > **Utilities** > **Setup** > **Analysis setup** > **Patient report**.
2. Select the layout.

3. Tap the **Edit patient ID layout** button.
4. To add a data item to the layout:
   a) Select a data item In the **Available items** field.
   b) Tap the right arrow button.
5. To remove a data item from the layout:
   a) Select a data item In the **Available items** field.
   b) Tap the left arrow button.
6. To make a data item mandatory:
   a) Select the data item in the **Selected items** field.
   b) Tap the **Set as mandatory** button.
7. To set a default value for a data item:
   a) Select the data item in the **Selected items** field.
   b) Enter a value, or: (1) Tap the **List** button. (2) Select a value. (3) Tap the **Select** button.
8. Tap the **Back** button.
9. If necessary, enter a new name for the report in the **Name** field.
10. Tap the **Close** button.

To create extra items for use in Patient ID / Report layouts

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Parameters and input** > **User-defined patient data items**.
2. Tap the **Add** button.
3. Enter the name of the item.
   Note: Only enter 20 characters, so that the complete name is seen in the **Patient Identification** screen.

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

Option	Steps
To create an alphanumeric item with no selection list.	**a)** Select "Alphanumeric" in the **Type** field.
To create an alphanumeric item with a selection list. **Note**: A minimum of 2 items must be added to create a list.	**a)** Select "Alphanumeric" in the **Type** field. **b)** Select the **Use selection list** check button. **c)** Tap the **Add** button. **d)** Enter a text. **e)** Do steps "a" to "d" again for each item you want in the selection list.
To create a numerical item with no selection list.	**a)** Select "Numerical" in the **Type** field. **b)** If entered numbers must have a fixed number of decimals to be accepted, select the number of decimals. **c)** If entered numbers must fall within a range to be accepted, enter the maximum and minimum values of the range.
To create a numerical item with a selection list. **Note**: A minimum of 2 items must be added to create a list.	**a)** In the **Type** field, select "Numerical". **b)** Select the **Use selection list** check button. **c)** Tap the **Add** button. **d)** Enter a text. **e)** Do steps "a" to "d" again for each item you want in the selection list.

5. Tap the **Back** > **Close** buttons.

Report layout for LCR measurements

Measurements done in connection with calibration verification in the USA are referred to as a linearity, calibration-verification and reportable range (LCR) measurements.

It is necessary to select a report layout that contains the "Measurement type" data item before you can do an LCR measurement. An alternative is to create a special layout for LCR measurements that contains the "Measurement type" data field. We recommend that the layout also contains a data field for the name and level of the LQC solution.

Patient result settings

To create a layout for patient results

This procedure tells you how to create a layout for patient results for a selected patient ID / report layout.

1. Tap **Menu** > **Utilities** > **Setup** > **Analysis setup** > **Patient reports**.
2. Select a patient ID / report layout.

3. Tap the **Edit patient results layout** button.
4. In the **Available items** field, select a parameter.
   Note: Parameters will be shown in the results as they are shown in the **Selected items** field.
5. Tap the right arrow button.
6. Do steps 4 and 5 again for each parameter.
7. To change the position of a parameter in the **Selected items** field:
   a) Select the parameter.
   b) Tap the left arrow button.
   c) In the **Selected items** field, select the parameter you want the selected parameter to follow.
   d) Tap the right arrow button.
8. To show the reference range of a parameter with patient results:
   a) In the **Selected items** field, select a parameter.
   b) Tap the **Show ranges** button.
   c) If necessary, do steps "a" and "b" again for other parameters.
9. If necessary, do steps 2 to 8 again for other patient ID / report layouts.
10. Tap the **Back** > **Close** buttons.

To enable patient result approval

When you enable the **Enable patient result approval** option, patient results can be approved or rejected.
Note: Only complete patient results can be approved and/or rejected and sent to a connected RADIANCE system.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Miscellaneous setup**.
2. Select the **Enable patient result approval** check button.
3. Tap the **Close** button.

Parameter settings

To show the parameter bar

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Miscellaneous setup**.
2. Select the **Show parameter bar** check button.
3. Tap the **Close** button.

To show/hide parameter tabs in the parameter bar

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Parameters and input** > **Parameters**.
2. Select the parameter.
3. Tap the **Enable/disable** button.
   Note: The first value in the **Enabled/locked** column must be "Yes" to show the parameter tab, and "No" to hide it.
4. Tap the **Close** button.

To hide the parameter bar

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Miscellaneous setup**.
2. Deselect the **Show parameter bar** check button.
3. Tap the **Close** button.

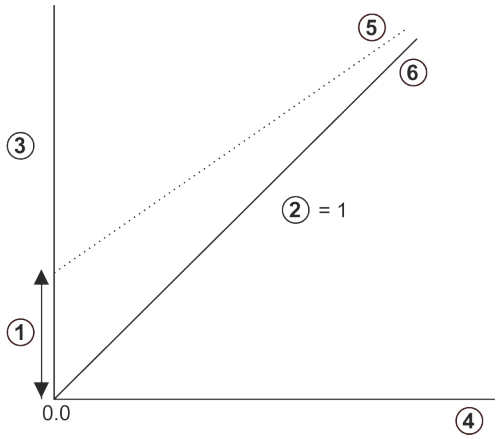
To set up measurement units for parameters

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Parameters and input** > **Units**.
2. Use the scroll buttons to select the field adjacent to the parameter.
3. In the **Possible units** frame, select the unit.
4. Tap the **Close** button.

Calibration adjustment settings

User-defined corrections (offset and slope)

User-defined corrections refer to corrections made to the offset and slope of parameters.



1	Offset	4	Measured (uncorrected) parameter value (x axis)
2	Slope	5	Correction line with user-defined corrections
3	Displayed (corrected) parameter value (y axis)	6	Correction line without user-defined corrections

The diagram shows the relation between correction lines without and with user-defined corrections.

User-defined corrections are most commonly applied when the values measured for a parameter by two or more analyzers deviate consistently from each other.

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

slope and offset or only change the value of only one of them. This depends on the parameter.

Corrected value = Slope × Uncorrected value + Offset

Before you enter corrections for a parameter, you must have the reference value for the parameter. Use a procedure accepted in your laboratory to get the reference value.

Here are some more prerequisites.

- Analyses must be done on the analyzer without the use of user-defined corrections and on one reference analyzer.
- Analyses must be done over the full measuring range
- Analyses must be done on the analyzer and on the reference analyzer at the same time, and the 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 analyzer and the reference analyzer. The analyzer is then used as an independent variable.
- The user must verify the corrections entered.

To edit the offset and slope for a parameter

Note: Changes made to the offset and slope for a parameter are only applied to patient results. If you want to apply the corrections to LQC results too, you must set it up as a corrective action on LQC results.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Parameters and input** > **Parameters**.
2. Select the parameter.
3. Tap the **Edit** button.
4. If necessary, enter a new value for **Correction offset**.
5. If necessary, enter a new value for **Correction slope**.
6. Tap the **Back** > **Close** buttons.

Related Information

- To apply user-defined corrections to LQC results, page 104

To limit when calibration adjustments can be stopped

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Miscellaneous setup**.
2. In the **Calibration adjustment** frame, set the time in minutes.
   Note: If you select zero minutes, calibration adjustments in progress cannot be stopped.
3. Tap the **Close** button.

Quality control

Liquid quality control (LQC) solutions

Registration of LQC solutions

Each lot of liquid quality control (LQC) solution must be registered for use on the analyzer.

When a Radiometer LQC solution is registered, the analyzer reads data from the barcode on the tube and saves it. When a non-Radiometer LQC solution is registered

all data must be entered manually. The saved/entered data is used to make sure LQC results are within user-defined control ranges and put symbols on results that are not. The data is also shown in LQC plots.

Data saved during registration of LQC solutions

Data about a Radiometer LQC solution that is saved during registration:

- Generic name – **Solution** name
- Lot number
- Expiry date
- Parameters to measure
- Assigned control range of each parameter
- User-defined control range of each parameter
  Note: During registration, the user-defined range is set by default to be the same as the assigned control range. However, the limits of user-defined ranges can be edited.
- A user-defined name – **LQC name** – this is set by default to be the same as the generic name. However, the user-defined name can be edited.

All the data entered during registration of non-Radiometer LQC solutions is saved.
Note: Non-Radiometer LQC solutions are given a generic name **Non-R** followed by a number.

To register a Radiometer LQC solution

Prerequisite: The *Specification* insert supplied with the LQC solution.

You must register each lot of LQC solution before you can use it.

1. Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **LQC**.
2. Make sure the number selected in the **Position** column contains no data.
   Note: The number can be thought of as a registration number.
3. Scan or enter the barcodes on the *Specifications* insert.
4. Tap the **Accept** button.
5. Choose an option and follow the steps for it.

Option	Steps
If the LQC solution is a LQC Multi-CHECK solution	**a)** Select the check button of each parameter to be measured. **b)** Tap the **Confirm** button.
If the LQC solution is not a LQC Multi-CHECK solution	Go to the next step.

6. Tap the **Close** button.

To register a non-Radiometer LQC solution

Prerequisite: For the LQC solution, this data must be available:

- Name
- Lot number
- Expiry date
- The parameters to be measured
- Limits of the assigned control range for each parameter to be measured

1. Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **LQC**.
2. Make sure the number selected in the **Position** column contains no data.
   Note: This number can be thought of as a registration number.

3. Tap the **Add Non-R-** button.
4. Enter a name for the LQC solution.
5. Enter the lot number of the LQC solution.
6. Enter the expiry date of the LQC solution as follows:
   a) Tap the button with the calendar icon adjacent to the **Expiry date** field.
   b) Use the format shown to type in the date.
   c) Tap the **Back** button.
7. Select the parameter to measure.
8. Tap the **Edit (2)** button.
9. Enter the assigned and user-defined control ranges for the parameter as follows:
   a) Enter values for the lower and/or upper limits of the assigned range for the parameter.
   Note: The values must be within the reportable range for the parameter.
   b) Enter values for the lower and/or upper limits of the user-defined range for the parameter.
   Note: The values must be within the assigned control range for the parameter.
10. Set the standard deviation value for the parameter as follows:
    a) Select the **Use fixed SD when updating ranges** check button.
    b) Tap in the **SD** field.
    c) Enter a value in the **SD** field.
    Note: When the standard deviation is set, the limits of the user-defined control range cannot be changed to values that are within the range determined by the standard deviation.
11. Deselect the **Exclude parameter** check button.
12. If necessary, tap the **Next Param.** or **Prev. Param.** button to select a new parameter and do steps 7 to 11 again.
13. Tap the **Back** > **Back** > **Close** buttons.

Edit data about registered LQC solutions

To edit data about a registered LQC solution

You can change the name of the LQC solution, and for each parameter you can change these items:

- The user-defined control range
- The user-defined control range to lot-to-date values
- The standard deviation value
- The parameters to be measured when the LQC solution is used

1. Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **LQC**.
2. Select the LQC solution you want to edit.
3. Tap the **Edit LQC setup** button.
4. If necessary, edit the name.
5. If necessary, change the user-defined control range of all parameters to lot-to-date values, tap the **Update all** button.

6. If necessary, change the assigned and user-defined control ranges of one parameter as follows:
   a) Select the parameter.
   b) Tap the **Edit (2)** button.
   c) Enter a new value for the lower and/or upper limits of the assigned control range for the parameter.
   Note: The values must be within the reportable range for the parameter.
   d) Enter a new value for the lower and/or upper limits of the user-defined control range for the parameter.
   Note: The values must be within the assigned control range for the parameter.
7. If necessary, edit the standard deviation value for the parameter as follows:
   a) Tap in the **SD** field.
   b) Enter a value in the **SD** field.
   Note: When the standard deviation is set, the limits of the user-defined control range cannot be changed to values that are within the range determined by the standard deviation.
8. If necessary, exclude the parameter from the measurement as follows:
   a) Select the **Exclude parameter** check button.
9. If necessary, tap the **Next Param.** or **Prev. Param.** button to select a new parameter and do steps "6b" to "6d" and steps 7 to 8 again.
10. Tap the **Back** > **Back** > **Close** buttons.

To change the user-defined control range of a parameter

1. Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **LQC**.
2. Select the LQC solution you want to edit.
3. Tap the **Edit LQC setup** button.
4. Select the parameter.
5. Tap the **Edit (2)** button.
6. Enter a new value for lower and/or upper limits of the user-defined control range for the parameter.
   Note: Values must be within the assigned control range for the parameter.
7. If necessary, tap the **Next Param.** or **Prev. Param.** button to select a new parameter.
8. Do steps 5 and 6 again.
9. Tap the **Back** > **Back** > **Close** buttons.

To change user-defined control ranges to lot-to-date ranges

1. Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **LQC**.
2. Select the LQC solution you want to edit.
3. Tap the **Edit LQC setup** button.
4. To change the user-defined control range of all parameters to lot-to-date values, tap the **Update all** button.

5. To change the user-defined control range of one parameter to lot-to-date values:
   a) Select the parameter.
   b) Tap the **Edit (2)** button.
   c) Tap the **Update** button.
   d) If necessary, tap the **Next Param.** or **Prev. Param.** button to select a new parameter.
   e) Do steps "5c" and "5d" again.
6. Tap the **Back** > **Back** > **Close** buttons.

To edit the standard deviation for parameters

1. Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **LQC**.
2. Select the LQC solution you want to edit.
3. Tap the **Edit LQC setup** button.
4. To fix the standard deviation for a parameter:
   a) Select the parameter.
   b) Tap the **Edit (2)** button.
   c) Select the **Use fixed SD when updating ranges** check button.
   d) Tap in the **SD** field.
   e) Enter a value in the **SD** field.
   Note: When the standard deviation is set, the limits of the user-defined control range cannot be changed to values that are within the range determined by the standard deviation.
   f) If necessary, tap the **Next Param.** or **Prev. Param.** button to select a new parameter and do steps "4c" to "4d" again.
5. Tap the **Back** > **Back** > **Close** buttons.

To select the parameters to be measured

1. Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **LQC**.
2. Select the LQC solution you want to edit.
3. Tap the **Edit LQC setup** button.
4. Select a parameter that can be measured when the selected LQC solution is used.
5. Tap the **Edit (2)** button.
6. Choose an option and follow the steps for it.

Option	Steps
To include measurement of the parameter	Deselect the **Exclude parameter** check button.
To not include measurement of the parameter	Select the **Exclude parameter** check button.

7. If necessary, tap the **Next Param.** or **Prev. Param.** button to select a new parameter.
8. Do steps 6 and 7 again.
9. Tap the **Back** > **Back** > **Close** buttons.

Scheduled LQC measurements

To schedule LQC measurements

Prerequisite: The LQC solution is registered.

1. Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **LQC**.
2. Select the LQC solution to use for scheduled measurements.
3. Tap the **LQC schedule** button.
4. Select the day and the time to start scheduled measurements.
5. Tap the **Add** button.
6. Select how often the measurements must be done as follows:
   a) Tap the **Repeat** field.
   b) Select a value from the field on the right of the screen.
   c) Tap the **Select** button.
7. Tap the **Back** > **Back** > **Close** buttons.

To edit an LQC measurement schedule

1. Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **LQC**.
2. Select the LQC solution to be used for scheduled measurements.
3. Tap the **LQC schedule** button.
4. Select the scheduled measurement you want to edit.
5. Tap the **Edit** button.
6. Choose an option and follow the steps for it.

Option	Steps
To change the days of the week measurements must be done	**a)** Tap in the **Weekdays** field. **b)** Select check buttons for the days, in the field on the right of the screen.
To change the start time for measurements	**a)** Tap in the **Start time** field. **b)** Enter a new start time.
To change how frequently measurements must be done	**a)** Tap in the **Repeat** field. **b)** Select a value from the field on the right of the screen.

7. Tap the **Back** > **Back** > **Close** buttons.

To set up corrective actions for overdue scheduled LQC measurements

This procedure lets you set up the analyzer to lock parameters that have not been measured because scheduled LQC measurements are overdue. The procedure also lets you select the traffic light color to show when LQC measurements are overdue.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Corrective actions**.
2. Select the condition "LQC schedule reminder(s)".
3. Make sure the check button in the **Corrective action** frame is deselected.

4. Tap the traffic light button to select the color you want.
5. Select the **Lock parameter(s) when a scheduled LQC activity is XX % overdue** check button.
6. Select a value for XX %.
7. Tap the **Close** button.

Corrective actions on LQC results

To set up corrective action for errors in LQC results

This procedure lets you set up the analyzer to lock parameters with errors in LQC results.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Corrective actions**.
2. Select the condition "LQC error(s) present".
3. Select the **Lock parameter(s)** check button.
   Note: If the condition occurs, the traffic light color changes to yellow.
4. Tap the **Close** button.

To apply user-defined corrections to LQC results

User-defined corrections refer to corrections made to the offset and slope for parameters.

Note: Radiometer recommends that corrections are NOT applied to LQC results. If corrections are applied, assigned control ranges will have to be calculated again and it will not be easy to compare LQC results with peer laboratories.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Miscellaneous setup**.
2. Select the **Apply user-defined parameter-corrections to LQC results** check button.
3. Tap the **Close** button.

Related Information

- To edit the offset and slope for a parameter, page 98

LQC statistics

To set the statistical factor and a reminder to print

1. Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **LQC statistics**.
2. If necessary, enter a new value In the **Statistical factor used for value acceptance** field.
   Note: The value is set by default to 1.5, but can be changed to a value between 1.0 and 9.9.
3. If you want the analyzer to send a reminder to print LQC statistics at the end of each month, select the check button.
4. Tap the **Close** button.

To enable Levey-Jennings plots to be viewed

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Miscellaneous setup**.
2. Select the **Enable viewing of Levey-Jennings plot** check button.

3. Tap the **Close** button.

Westgard Rules

Westgard Rules

Westgard Rules are a set of control rules that can be applied to LQC results to help you do two things:

- Find errors in LQC results. The symbol "W" is used to show when LQC results have violated applied Westgard Rules.
- Find shifts or trends in LQC results. This helps you assess the quality and validity of patient sample analyses.

Types of Westgard Rule

There are two types of rule.

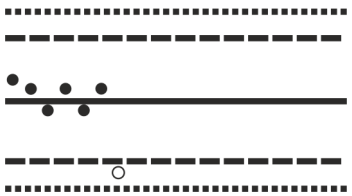
- Warning rules. Rule 1_{2s} is the only warning rule.
- Rejection rules. Rules 1_{3s}, 2_{2s}, R_{4s}, $R4_{1S}$ and 10_{x} are rejection rules.

Description of the lines used in Westgard rule illustrations

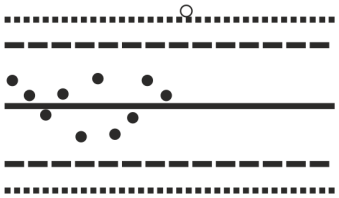
Line type	Description
.....	Shows ±3 SD ranges
_ _ _	Show control ranges (±2 SD)
_____	Shows the mean value

Westgard rules and corrective actions

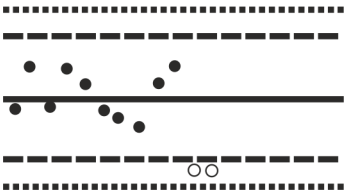
Rule 1:2s (also written 1_{2s}) is the only warning rule.

Westgard rule 1_{2s}		Corrective action
The LQC result exceeds the mean ±2 SD		Do a new measurement with QC material of the same type, level and lot number. • If the new result does not exceed the mean ±2 SD, the original QC result can be attributed to normal statistical variation. • If the new result exceeds the mean ±2 SD, do what is necessary to comply with your local QC regulations.

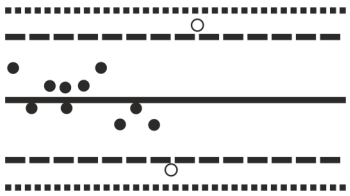
Rule 1:3s (also written 1_{3s}) is a rejection rule.

Westgard rule 1_{3s}		Corrective action
The LQC result exceeds the mean ±3 SD		Do a new measurement with QC material of the same type, level and lot number. • If the new result does not exceed the mean ±3 SD, the original QC result can be attributed to normal statistical variation. • If the new result exceeds the mean ±3 SD, do what is necessary to comply with your local QC regulations.

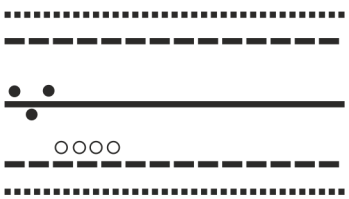
Rule 2:2s (also written 2_{2s}) is a rejection rule.

Westgard rule 2_{2s}		Corrective action
Two consecutive LQC results exceed and are on the same side of the mean ±2 SD		Do what is necessary to comply with your local QC regulations.

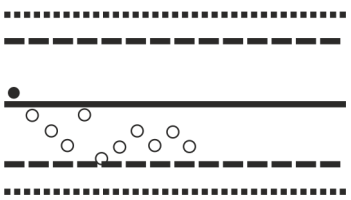
Rule R:4s (also written R_{4s}) is a rejection rule.

Westgard rule R_{4s}		Corrective action
The difference between two consecutive LQC results exceeds 4 SD	 This indicates inconsistency in your QC procedures or an unstable analyzer.	Do what is necessary to comply with your local QC regulations.

Rule 4:1s (also written 4_{1s}) is a rejection rule.

Westgard rule 4_{1s}		Corrective action
Four consecutive LQC results exceed, and are on the same side of the mean ±1 SD	 This indicates a trend or shift.	Do what is necessary to comply with your local QC regulations.

Rule 10:x (also written 10_x) is a rejection rule.

Westgard rule 10_x		Corrective action
Ten consecutive LQC results are on the same side of the mean	 This indicates a trend or shift.	Do what is necessary to comply with your local QC regulations.

To set up Westgard rules

1. Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **Westgard Rules**.
2. Tap the **Next position** button to select the LQC solution.
3. Make sure that there is a checkmark on the **Apply WR** button.
4. Tap the **Select all** button to apply all the Westgard rules to the LQC results for all parameters.
5. Tap the **Continue** button.
6. If you only want to apply some Westgard rules to the LQC results of some parameters, do as follows:
   - **a)** Select the parameter you do not want to apply some Westgard rules to.
   - **b)** Tap the **Edit** button.
   - **c)** Deselect the check buttons of the rules you do not want to apply.
   - **d)** If necessary, tap the **Next param.** or **Prev. param.** button to select a new parameter and do step "6c" again.
7. Tap the **Back** > **Close** buttons.

To apply Westgard Rules to LQC results

1. Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **Westgard Rules**.
2. Make sure that there is a checkmark on the **Apply WR** button. If there is no checkmark, tap the button.
3. Tap the **Close** button.

RiLiBÄK rules

RiLiBÄK rules

RiLiBÄK rules are guidelines of the German Federal Medical Council. The rules provide minimum requirements for the quality of quantitative test results in medical laboratories.

To access the RiLiBÄK ranges setup screen

In the **RiLiBÄK ranges setup** screen you can add, edit or remove RiLiBÄK rules.

This procedure gives you access to the **RiLiBÄK ranges setup** screen. The procedure also applies rules for the parameters that have the value "On" in the **On/Off** column of the **RiLiBÄK ranges setup** screen.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Miscellaneous setup**.

2. Select the **Enable RiLiBÄK ranges** check button.
3. Tap the **Close** button.

To apply RiLiBÄK rules that are “On”

This procedure lets you apply rules for the parameters that have the value “On” in the **On/Off** column of the **RiLiBÄK ranges setup** screen. The procedure also gives you access to the **RiLiBÄK ranges setup** screen.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Miscellaneous setup**.
2. Select the **Enable RiLiBÄK Ranges** check button.
3. Tap the **Close** button.

To add a new RiLiBÄK rule

Prerequisite: The **RiLiBÄK ranges setup** screen can be accessed.

This procedure adds a new rule and sets its **On/Off** value to “On”.

1. Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **RiLiBÄK Ranges**.
2. Tap the **Add** button.
3. Select the parameter you want.
4. Tap in the first field in the **Lower limit (Valid range)**.
5. Enter the value of the lower limit.
6. Tap in the second field in the **Lower limit (Valid range)**.
7. Tap “<” or “<=”.
8. Tap in the first field in the **Upper limit (Valid range)**.
9. Tap “<” or “<=”.
10. Tap in the second field in the **Upper limit (Valid range)**.
11. Enter the value of the upper limit.
12. Choose an option and follow the steps for it.

Option	Steps
To use a percentage to calculate the acceptable deviation from the assigned value. **Note**: This is most frequently used.	• Select the **+/- Ranges [%]** button. • Enter the percentage value in the **Ranges** field.
To use an absolute value to calculate the acceptable deviation from the assigned value	• Select the **+/- Ranges** button. • Enter the absolute value in the **Ranges** field.

13. Tap the **Back** button.
    Note: The rule is shown in the screen. The **On/Off** value is set by default to “On”.
14. Do steps 2 to 13 again for each rule you want to add.
    Note: More than one rule can be added for a parameter as long as the valid ranges of each rule do not overlap.
15. Tap the **Close** button.

To edit a RiLiBÄK rule

Prerequisite: The **RiLiBÄK ranges setup** screen can be accessed.

1. Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **RiLiBÄK Ranges**.
2. Select the rule you want to edit.
3. Tap the **Edit** button.

4. Edit the values.
5. If necessary, choose an option and follow the steps for it.

Option	Steps
To use a percentage to calculate the acceptable deviation from the assigned value. **Note**: This is most frequently used.	• Select the **+/- Ranges [%]** button. • Enter the percentage value in the **Ranges** field.
To use an absolute value to calculate the acceptable deviation from the assigned value	• Select the **+/- Ranges** button. • Enter the absolute value in the **Ranges** field.

6. Tap the **Back** > **Close** buttons.

To remove a RiLiBÄK rule

Prerequisite: The **RiLiBÄK ranges setup** screen can be accessed.

1. Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **RiLiBÄK Ranges**.
2. Select the rule you want to remove.
3. Tap the **Delete** button.
4. Tap the **OK** button.
5. Tap the **Close** button.

To set the On/Off value of a RiLiBÄK rule to "Off"

Prerequisite: The **RiLiBÄK ranges setup** screen can be accessed.

1. Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **RiLiBÄK Ranges**.
2. Select the rule you want to disable.
3. Tap the **On/Off** button to deselect the selected rule.
4. Make sure that the value in the **On/Off** column has changed to “Off”.
5. Tap the **Close** button.

System check

System check

System checks make sure that the analyzer operates at the high level of precision necessary for good test results. System checks make sure that all parts of the analyzer operate within specifications. Results of the tests are recorded and can be printed. If a test in a system check fails, it will not stop use of the analyzer. However, the automatic test sequences done at regular intervals by the analyzer will find the same issue and stop use of the analyzer until the issue is resolved.

System checks can be done manually and they can also be scheduled to be done automatically. System-check results are saved in the **System-check log**.

To schedule automatic system checks

1. Tap **Menu** > **Utilities** > **Setup** > **System-check schedule**.
2. Select the **Automatic system-check** check button.
3. Tap in the **Start time** field.
4. Enter the time you want the first system check to start.

5. Tap in the **Repeat interval** field.
6. Select how frequently you want system checks to be done.
   Note: Radiometer strongly recommends that a system check is scheduled to be done every day.
7. Tap the **Close** button.

Maintenance setup

Mandatory maintenance activities

Maintenance activities

Mandatory maintenance activities are scheduled activities that must be done. The activities are set up with default counter values that determine how frequently the activities must be done. The counter value is the number of times the analyzer needle is used to aspirate samples from tubes since the activity was last done. Two counter values are set, a **Warning limit**, and a **Critical limit**. You can change the values set for warning limits and some of the values set for critical limits. You can also schedule activities to be done with a frequency determined by time.

If an activity is not done before the counter value gets to the warning limit, a message is sent as a reminder to do the activity. If the activity is not done before the counter value gets to the critical limit, the analyzer goes into "Maintenance" mode until the activity is successfully completed.

To edit the warning/critical limits for mandatory maintenance activities

You can change the values set for warning limits and some of the values set for critical limits.

1. Tap **Menu** > **Utilities** > **Setup** > **Other activities setup** > **Other activities schedule**.
2. In the lower part of the screen, select the activity you want to change the limits of.
3. Tap the **Edit** button.
4. If necessary, enter a new warning limit.
5. If necessary, enter a new critical limit.
   Note: For the “System clean” activity, Radiometer recommends this value is set to 200.
   Note: This value cannot be edited for the "Needle replacement" activity.
6. Tap the **Back** > **Close** buttons.

To schedule mandatory maintenance activities by time

1. Tap **Menu** > **Utilities** > **Setup** > **Other activities setup** > **Other activities schedule**.
2. In the top part of the screen, select the activity.
3. Tap the **Edit** button.
4. Select the frequency for the activity in the **Interval** field.
   Note: The next activity is planned to be done immediately.
5. Tap in the **Days** field.

6. Select the days of the week you want the activity to be done.
   Note: This field is not available if you selected "Never" or "Daily" in the **Interval** frame.
7. Tap the **Back** > **Close** buttons.

To set up corrective action for overdue mandatory maintenance activities

This procedure lets you set up the analyzer to lock when a scheduled maintenance activity is more than 10 % overdue.

For example: If an activity is scheduled to be done every 10 days and the activity is not done [10 days + (10 % of 10 = 1) day] = 11 days after the activity was last done, the analyzer locks.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Corrective actions**.
2. Select the condition "Maintenance schedule reminder(s)".
3. Select the **Lock analyzer when 10 % overdue** check button.
   Note: If the condition occurs, it is recorded as a critical issue and the color of the traffic light in the **Analyzer status** button changes to red.
4. Tap the **Close** button.

To set up corrective action for overdue scheduled system cleans

Pre-requisite: Scheduled system-clean procedures are set up.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Corrective actions**.
2. Select "System clean schedule reminder".
3. Select the **Lock the analyzer when the selected condition is XX% overdue** check button.
4. Select a value for XX %.

   This is a percentage of the **Warning limit** set in the **Edit maintenance schedule** screen for system clean.

   For example, if the warning limit was set to 180 measurements, and XX is set to 10 %, the analyzer will lock if a system clean is not successfully done [180 + (10 % x 180)] = 198 measurements after a system clean was last done.
5. Tap the **Close** button.

Related Information

- To edit the warning/critical limits for mandatory maintenance activities, page 110

Operator-defined activities

Operator activities

Operator activities are activities you can set up and schedule to be done at regular intervals of time. For example, to clean the touch screen and analyzer exterior. When a scheduled activity is due, a message is sent as a reminder to do the activity.

To set up an operator activity

1. Tap **Menu** > **Utilities** > **Setup** > **Other activities setup** > **Operator activities**.
2. Tap the **Add** button.
3. Enter a name for the activity.

4. Select the frequency for the activity in the **Interval** field.
   Note: The selected interval is used to calculate the next planned date = [current date] + [selected interval]. If you want to use another date to calculate the next planned date, do steps 5 and 6, otherwise go to step 7.
5. Tap the **Next date** field.
6. Enter a date.
7. Tap the **Back** > **Close** buttons.

To set up corrective action for pending operator activities

This procedure lets you set up the analyzer to change the color of the traffic light in the **Analyzer status** button to remind operators about pending operator activities.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Corrective actions**.
2. Select the condition "Operator-activity reminder(s)".
3. Tap the button with the traffic light icon to select the color you want to show.
4. Tap the **Close** button.

To delete an operator activity

1. Tap **Menu** > **Utilities** > **Setup** > **Other activities setup** > **Operator activities**.
2. Select the activity.
3. Tap the **Delete** button.
4. Tap the **Continue** button.
5. Tap the **Close** button.

Replacement warnings

To set up replacement warnings

- For installed Test Cartridges: You can set up the analyzer to send a replacement warning message some days before the number of valid tests fall below a specified value.
- For the installed Solution Pack: You can set up the analyzer to send a replacement warning message some days before the Solution Pack expires and/or when the remaining cup capacity of the Solution Pack falls below a specified value.

Note: Cartridges and Solution Packs are valid until their expiry date or on-board expiry date.

1. Tap **Menu** > **Utilities** > **Setup** > **Other activities setup** > **Replacement warning**.
2. To set up a replacement warning message for installed Test Cartridges:

   a) In the **if remaining tests will fall below** field, select the number of valid tests you want to be available in X days' time.

   b) In the **in:** field, select a value for X.
   Note: When the number of valid tests fall below this value, a replacement warning message is sent.

3. To set up a replacement warning messages for the installed Solution Pack:
   a) In the **if Solution Pack cup capacity falls below** field, select the minimum number of cups the Solution Pack must have the capacity for before a replacement warning message is sent.
   b) In the **in:** field, select how many days before the Solution Pack expires you want a replacement warning message to be sent.
4. Tap the **Close** button.

Note fields

To create standard texts for use in Note fields

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Parameters and input** > **User-defined notes**.
2. Select the check button for the screen where standard text is necessary for the **Note** field.
   Note: The **Next page** button lets you select check buttons for other screens.
3. Make sure that the top right corner of the selected check button is black.
4. Tap the **Add new** button.
5. Enter the standard text.
6. Do steps 3 and 4 again for each standard text you want to add.
7. Tap the **Close** button.

Communications

Patient data saved on the analyzer

The **Patient ID**, **First name** and **Last name** entered in the **Patient identification** screen for a patient sample is automatically recorded in the **Patient profiles log**.

When an operator enters data in the **Patient ID** field of the **Patient identification** screen, the analyzer looks in the **Patient profiles log**. If the **Patient ID** is in the log, the **First name** and **Last name** of the patient is downloaded automatically to the screen. However, if the analyzer is set up to automatically request patient data from a LIS/HIS/data management system, this will not occur.

Patient data from LIS/HIS/data management systems

Patient data can be downloaded to the analyzer from a connected LIS/HIS/data management system.

You can set up the analyzer to request patient data automatically from the system, or let operators request patient data manually. There are 2 options for manual requests:

1. Fill in the **Patient department** field in the **Patient identification** screen, lookup, find and request the patient data.
2. Fill in the **Accession number** or **Patient ID** field in the **Patient identification** screen and request the patient data.

You must enable patient lookup and set up a connection to a LIS/HIS/data management system to use the first option. To use the second option, it is only necessary to set up a connection to a LIS/HIS/data management system.

To set up a LIS/HIS connection

Prerequisite: The analyzer is connected by cable to the LIS/HIS system.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Communications** > **LIS/HIS connection**.
2. Tap the **Add** button.
3. Enter a name for the connection.
4. Tap the **Back** button.
5. Select the high-level protocol used by the LIS/HIS system.
6. Select the low-level protocol.
7. Tap the **Edit** button.
8. Make sure the settings shown in the **Connection setup** frame are correct for the LIS/HIS system.
9. If the settings are not correct, tap the **Edit** button.
10. Select the correct settings.
    Note: For serial low-level protocols, the **Port number** must be "COM2".
11. Tap the **Back** > **Back** > **Close** buttons.

To set up a RADIANCE connection

The analyzer is connected by cable to the RADIANCE* system via a server.
Note: *Not applicable in the USA.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Communications** > **RADIANCE connection**.
2. Enter the address of the RADIANCE server the analyzer is connected to.
3. Enter the number of the RADIANCE server port the analyzer is connected to.
4. Enter the password the analyzer was given to access the RADIANCE system.
5. Select the **Communicate with the RADIANCE system** checkbox.
6. Tap the **Close** button.
   The RADIANCE system icon is shown at the bottom of the analyzer screen. When there is a connection between the analyzer and the RADIANCE system, this icon is shown: 

   When there is no connection between the analyzer and the RADIANCE system, this icon is shown: 

To set up automatic requests for patient data

Prerequisite: A connection is set up to the LIS/HIS/data management system that patient data is to be requested from.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Communications** > **Automatic data request**.
2. Select the connection to the system that patient data is to be requested from.

3. In the **Request patient demographics** frame, select the check buttons for the data fields that must be filled in before patient data is automatically requested from the system.
4. Tap the **Close** button.

To set up automatic transmission of patient results to a system

Prerequisite: A connection is set up to the LIS/HIS/data management system that data is to be sent to.

Note: If the analyzer is connected to a RADIANCE* system, software version > 15 or equal to 15.0 must be installed.
Note: *Not applicable in the USA.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Communications** > **Automatic data transmission**.
2. Select the name of the connection.
3. Select the check buttons for the data to be automatically sent.
   Note: For a LIS/HIS connection: You can select **Patient results (complete)** or **Patient result (single)**, but not both. If you select **Patient results (complete)**, test results are only sent when the result of all ordered tests are available. You can approve or reject complete patient results. If you select **Patient result (single)**, each test result is sent when it is available. You cannot approve or reject single test results.
   Note: For a RADIANCE* connection: You can only select **Patient results (complete)** and **LQC results**.
4. Tap the **Close** button.

To enable patient data to be requested manually

Prerequisite: A connection is set up to the LIS/HIS/data management system the data is to be requested from.

This procedure lets operators request patient data manually after they have filled in the **Patient department** field of the **Patient identification** screen.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Communications** > **Patient lookup setup**.
2. Select the name of the connection.
   Note: The local database of the analyzer may also be selected. Patient data is saved in the **Patient profiles log**.
3. Select the number of days patient data must be available in the **Patient profiles log**. After this time period, patient data is deleted.
4. Tap the **Close** screen.

FLEXLINK modules*

The FLEXLINK module is a PC- and PDA-compatible RADIANCE* software module. The module is used at point of care to enter patient data and order tests on patient samples. The data is automatically sent to a connected RADIANCE* system. The analyzer reads the barcode on the patient sample tube when it is put in the tube holder and automatically requests data from the RADIANCE* system. The data is used to fill in data fields in the **Patient identification** screen and select the tests to be done. This decreases the time used to identify samples and decreases errors that can occur when data is filled in manually.
Note: *Not applicable in the USA.

To enable the use of FLEXLINK modules*

Note: *Not applicable in the USA.

1. Set up a connection to a RADIANCE* system.
2. Set up automatic requests for patient data as follows:
   a) Select a "RADIANCE" in the **Connection** field.
   b) Select check buttons for the data that must be entered before patient data can be requested from the connected RADIANCE* system.
3. Make sure that the barcode on sample tubes is set up to be interpreted as an "Accession number".
4. Set up automatic transmission of patient data as follows:
   a) If you want patient results to be automatically sent to the RADIANCE* system, make sure that " RADIANCE"* is selected as the connection.

To access the RADIANCE system from the analyzer

Prerequisite: A connection is set up to the RADIANCE* system.
Note: Not applicable in the USA.

Access to the RADIANCE* system is available on request. Contact your local Radiometer service representative.

1. Make sure the RADIANCE* icon shows there is connection between the analyzer and the RADIANCE* system. 

2. Tap **Menu** > **Utilities** > **Radiance browser**.
   Note: See the *RADIANCE system, User's manual* for instructions.

Printers

To set up automatic printing

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Printers** > **Automatic printing**.
2. Select the check buttons for the data you want to be printed automatically.
3. Select the number of copies of patient results that must be printed.
4. Make sure that **User** button is selected.
5. Tap the **Close** button.

To enable test results to be printed immediately

This procedure lets you print patient test results when they become available.

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Printers** > **Automatic printing**.
2. Make sure that the **Patient results** check button is selected.
3. Select the **Enable immediate reporting** check button.
4. Tap the **Close** button.

To install a new printer for the analyzer

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Printers** > **Printer setup**.
2. Tap the **Install printer** button and follow the instructions shown on the screen.
3. If necessary, tap the **Edit name** button and enter the new name.
4. Do step 3 again for each printer you want to install.
   Note: Radiometer recommends that a maximum of 10 printers are installed.
5. Choose an option and follow the steps for it.

Option	Steps
To print data on the same printers each time	**a)** Select the printer. **b)** Tap the **Select/deselect** button. **c)** Make sure a check mark is shown adjacent to the printer name. **d)** Do steps "a" to "c" again for each printer.
To get a list of the installed printers before you print data	Select the check button in the **Manual printing** frame.
To print data on all installed printers	Make sure that the check button in the **Manual printing** frame is deselected.

6. Tap the **Close** button.

To remove a printer from the setup

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Printers** > **Printer setup**.
2. Select the printer.
3. Tap the **Remove** button.
4. Tap the **Close** button.

To edit the name of a printer

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Printers** > **Printer setup**.
2. Select the printer.
3. Tap the **Edit name** button, and enter the new name.
4. Tap the **Close** button.

Data logs and archives

Data logs and archived data logs

The analyzer can be set up to automatically save data logs to archives on the analyzer or on an external device. Data is moved to the archives when the data logs are full.

You can export data logs and archived data logs manually and save them on an external device. You can also import archives from other AQT90 FLEX analyzers.

To set up automatic archiving

1. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Disk functions setup** > **Automatic archiving**.
2. Select the check buttons for the data logs that you want to be archived.
3. Choose an option and follow the steps for it:

Option	Steps
To archive the data logs on the D:\ drive of the analyzer	**a)** Select the **Store archives on the analyzer** check button. **b)** Tap the **Close** button.
To archive the data logs to a different destination	**a)** Tap the button with the folder icon. **b)** Select the folder where the data logs must be archived. **c)** Tap the **Back** > **Close** buttons.

File format of exported data logs

The format of exported data logs is a compressed Comma Separated Value (CSV) file. The CSV file can be read by database and spreadsheet programs. For example: Microsoft Excel, Access and Lotus 1-2-3.

To export data logs

Note: Data logs are not removed from the analyzer during this procedure. The exported data logs are only copies.

1. Make sure that there is a connection between the analyzer and the device to which the logs are to be exported.
2. Tap **Menu** > **Utilities** > **Disk functions** > **Export data logs**.
3. Deselect the check buttons for the data logs that you do not want to export.
4. Tap the button with the calendar icon in the **Date interval** frame.
5. Enter a date in the **From** and **To** fields.
6. Tap the **Back** button.
7. Tap the button with the folder icon in the **Destination** frame.
8. Select the folder to export data logs to.
9. Tap the **Back** button.
10. Tap the **Accept** button.
11. Tap the **Start** button.

To export a whole archive

1. Make sure that there is a connection between the analyzer and the device to which the archive is to be exported.
2. Tap **Menu** > **Data logs** > **Archived data logs**.
3. Select the archive type.
4. Tap the **Export archive** button.
5. Tap the button with the folder icon in the **Destination** frame.
6. Select the folder to export the archive to.
7. Tap the **Back** button.

8. Tap the **Accept** button.
9. Tap the **Start** button.
10. Tap the **Close** button.

To export parts of an archive

1. Make sure that there is a connection between the analyzer and the device to which the archive parts are to be exported.
2. Tap **Menu** > **Utilities** > **Disk functions** > **Import/export archives**.
3. Select the archive type.
4. Choose an option and follow the steps for it.

Option	Steps
To export all parts of the archive	Go to step 5
To export one or more parts of the archive	**a)** Select the archive part you do not want to export. **b)** Tap the **Delete** button. **c)** If necessary, do steps "a" and "b" again.

5. Tap the button with the folder icon in the **Source/destination** frame.
6. Select the folder to export the archive parts to.
7. Tap the **Back** button.
8. Select an archive in the **Archives stored on this analyzer** frame.
9. Tap the **Export** button.
10. Tap the **Refresh** button.
11. Do steps 8 to 10 again for all the archive parts.
12. Tap the **Close** button.

To import an archive

1. Make sure that there is a connection between the analyzer and the device that contains the archives.
2. Tap **Menu** > **Utilities** > **Disk functions** > **Import/export archives**.
3. Select the archive type.
4. Tap the button with the folder icon in the **Source/destination** frame.
5. Select the folder that contains the archives you want to import.
6. Tap the **Back** button.
7. Select one of the archives in the **Source/destination** frame.
8. Tap the **Import** button.
9. Tap the **Close** button.

Data backup and restoration

Backup

Note: The customer must make sure that a backup is done regularly.

A backup includes all data logs and system files. Backup can be set up to be done automatically. The backup can also be done manually.

If data is lost or damaged, the backup will restore most of the data and keep data loss to a minimum.

Destinations for backup data

A backup can be saved to these destinations.

- The D:\ drive on the analyzer. This is where data is saved by default. The data on this drive cannot be overwritten.
- A USB
- An external CD drive
- A folder on an external network drive

Note: Radiometer recommends that backup data is saved to an external device.

To schedule automatic backups

1. Create a folder for the backup on the device on which the backup is to be saved.
2. Make sure that there is a connection between the analyzer and the device.
3. Tap **Menu** > **Utilities** > **Setup** > **General setup** > **Disk functions setup** > **Automatic backup**.
4. Select the **Automatic backup of all data and system files** check button.
5. Enter the time.
6. Enter the number of days between subsequent backups.
7. Tap the button with the folder icon.
8. Select the folder where the backup is to be saved.
9. Tap the **Back** > **Close** buttons.

To do a manual backup

1. Create a folder for the backup on the device on which the backup is to be saved.
2. Make sure that there is a connection between the analyzer and the device.
3. Tap **Menu** > **Utilities** > **Disk functions** > **Back up all data**.
4. Tap the **Change destination** button.
5. Select the folder where the backup is to be saved.
6. Tap the **Back** button.
7. Tap the **Start** button.
8. Look at the feedback message above the parameter tabs. The message will tell you when the backup is done.
   Note: A message is shown on the screen if the backup cannot be done.
9. Tap the **Close** button.

To restore data from a backup

Note: A backup is used to restore data.

1. Make sure that there is a connection between the analyzer and the device that contains the backup.
2. Tap **Menu** > **Utilities** > **Disk functions** > **Restore all data**.
3. Tap the **Change source** button.
4. Select the folder that contains the backup.
5. Tap the **Back** button.
6. Tap the **Start** button.

7. Tap the **OK** button.
   Note: The analyzer will shut down and restart.

Saving and loading setups

To save the setup

1. Make sure that there is a connection between the analyzer and the device on which the setup is to be saved.
2. Tap **Menu** > **Utilities** > **Disk functions** > **Save setup**.
3. Tap the **Edit location** button.
4. Select the folder where the setup is to be saved.
5. Tap the **Back** button.
6. Tap the **Start** button.
7. Tap the **Close** button.

To load a setup

Note: The **IP address** and the **Port number** of the LIS/HIS server are not included in the setup that is loaded. If you have to connect the analyzer to a LIS/HIS system, you must enter these values again after the setup is loaded. Values are entered on the **LIS/HIS connection setup** screen.

1. Make sure that there is a connection between the analyzer and the device from which the setup is to be loaded.
2. Tap **Menu** > **Utilities** > **Disk functions** > **Load setup**.
3. Choose an option and follow the steps for it.

Option	Steps
To load all parts of the setup	Tap the **Select all** button
To load one or more parts of the setup	**a)** Tap the **Deselect all** button. **b)** Select the part you want in the **Data selected for restore** field. **c)** Tap the  button. **d)** Make sure a check mark is shown in the checkbox. **e)** Do steps “a” to “d” for each part you want.

4. Tap the **Change source** button.
5. Select the folder from which the setup is to be loaded.
6. Tap the **Back** button.
7. Tap the **Continue** button.
   Note: The analyzer will shut down and restart with the new setup.

To restore Radiometer default settings

1. Tap **Menu** > **Utilities** > **Disk functions** > **Restore default setup**.

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

Option	Steps
To restore all parts of the setup	Tap the **Select all** button
To restore one or more parts of the setup	**a)** Tap the **Deselect all** button. **b)** Select the part you want In the **Data selected for restore** field. **c)** Tap the  button. **d)** Make sure a check mark is shown in the checkbox. **e)** Do steps "a" to "d" for each part you want.

3. Tap the **Continue** button.
Note: The analyzer will shut down and restart with the new setup.

Principles of operation

11

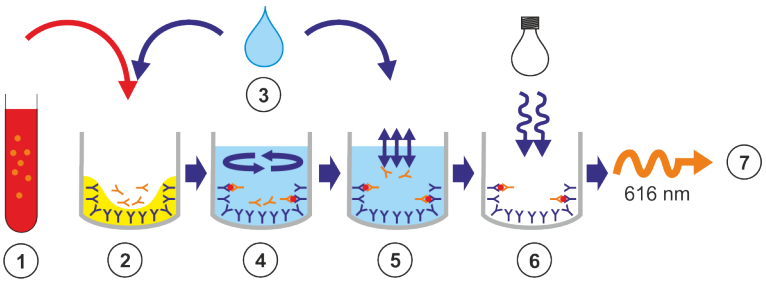
Immunoassays

The dry-chemistry concept for immunoassays

AQT90 FLEX immunoassays are based on a chemistry in which all the reagents are provided in a dry, stable form within an assay test cup. Biotinylated antibodies (Ab) have been immobilized on the streptavidin surface of the cup and a separating layer and europium-labeled tracer antibodies have been added on top of the biotinylated capture antibodies. The separating layer prevents the direct contact of the capture and tracer antibodies in storage.

The sample analysis process for immunoassays

The illustration shows the principles of the immunoassay process.



1	Whole blood	5	Washing
2	Ready to use test cup	6	Drying
3	Buffer solution	7	Quantitative result
4	Complex formation		

1. The sample wheel rotates to re-mix the sample in the sample tube.
2. A test cup for the selected parameter is punched out of a Test Cartridge and put into the incubator wheel.
3. A pre-determined volume of generic buffer solution (from the Solution Pack) is automatically added to the test cup containing the assay-specific reagents.
4. A volume of sample is aspirated from the sample tube.

5. The volume is checked to make sure that is correct (short sample detection).
6. A pre-determined volume of the aspirated sample is dispensed into the test cup.
7. The hematocrit value is determined on the rest of the sample.
8. The test cup and its contents are incubated at 37 °C and shaken for a period of time. The tracer and capture antibodies form a sandwich complex with the analyte (the parameter to be measured) present in the sample.
9. Buffer solution is then used to wash away excess free tracer antibodies, unreactive sample components and other material present in the cup leaving only the sandwich complex in the cup.
10. The cup is dried.
11. The time-resolved fluorescence of the europium-labeled sandwich complex from the dry surface of the assay cup is then measured.

    The concentration of the analyte/parameter is directly proportional to the measured europium signal. The measured signal is converted to a concentration using the instrument-adjusted, lot-specific calibration curves stored in the memory of the analyzer [11,12]. A quantitative result is shown on the screen a few minutes after starting the analysis.

There are small differences between the tests, for example how much sample is dispensed, how much buffer solution is added, and how long each test is incubated, but the principle is the same in each case. Some tests require the sample to be diluted before incubation. Test Cartridges for these tests contain the necessary dilution cups.

Coagulation assays

The dry-chemistry concept for coagulation assays

AQT90 FLEX coagulation assays are based on a chemistry in which all the reagents are provided in a dry, stable form within two types of cup, a reaction cup and a detection cup. The reaction cup contains activators and a europium-labeled biotinylated substrate for thrombin. The detector cup is coated with streptavidin to capture the substrate.

The sample analysis process for coagulation assays

1. The sample wheel rotates to re-mix the sample in the sample tube
2. A reaction cup for the selected coagulation test is punched out of a Test Cartridge and put into the incubator wheel.
3. A pre-determined volume of generic buffer solution (from the Solution Pack) is automatically added to the reaction cup, which contains the assay-specific reagents.
4. A volume of sample is aspirated from the sample tube.
5. The volume is checked to make sure that is correct (short sample detection).
6. A pre-determined volume of the aspirated sample is dispensed into the reaction cup.

7. The hematocrit value of the remaining sample is determined.
8. The cup and its contents are incubated at 37 °C and shaken for a period of time. This activates the coagulation process and thrombin is created. Thrombin cleaves the substrate and europium-label is released from the substrate.
9. A pre-determined volume is aspirated from the reaction cup to a detection cup. **Note**: The sample that remains in the tube is flushed through the aspirating needle to clean it. The process contaminates the sample. When it is necessary to remove the tube, a warning is shown on the screen. The warning tells operators not to use the sample again because it is contaminated.
10. The detection cup and its contents are incubated at 37 °C and shaken for a period of time. Both the cleaved and non-cleaved thrombin substrate is captured by the streptavidin in the detection cup.
11. Buffer solution is then used to wash away free europium label, unreactive sample components and other material present in the cup leaving only the captured substrate in the cup.
12. The cup is dried.
13. The time-resolved fluorescence of the europium-labeled substrate from the dry surface of the test cup is then measured. The measured signal is converted to a coagulation test result using the instrument-adjusted, lot-specific calibration curves stored in the memory of the analyzer. A quantitative result is shown on the screen a few minutes after starting the analysis.

Built-in hematocrit (Hct) determination

Built-in hematocrit determination

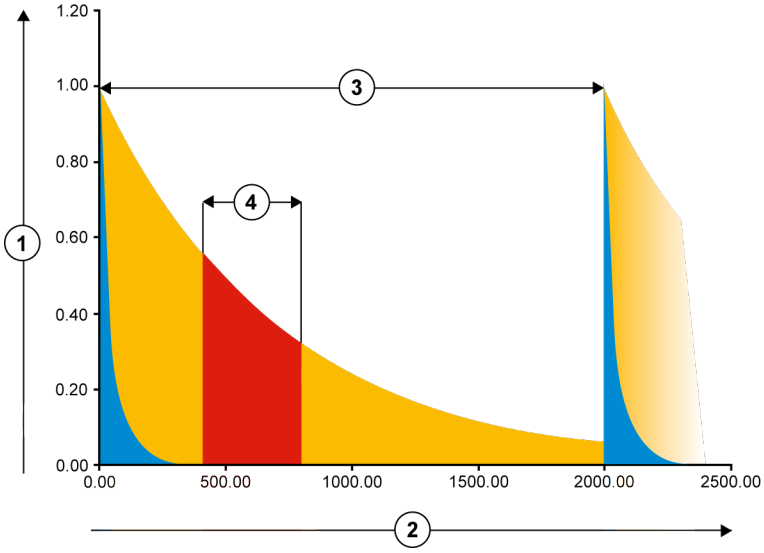
The analyzer has a built-in system to determine the hematocrit value of the sample aspirated at the start of a test. This value is necessary to calculate the accurate analyte concentration in plasma. If the hematocrit value is determined to be less than 15 %, the value is set to zero. If the value is determined to be greater than 62 %, no test results will be available and an error message attached to the result will explain why.

Determined hematocrit values will not appear on the analyzer screen, in printed results, or in exported patient results.

Method of detection (TRF)

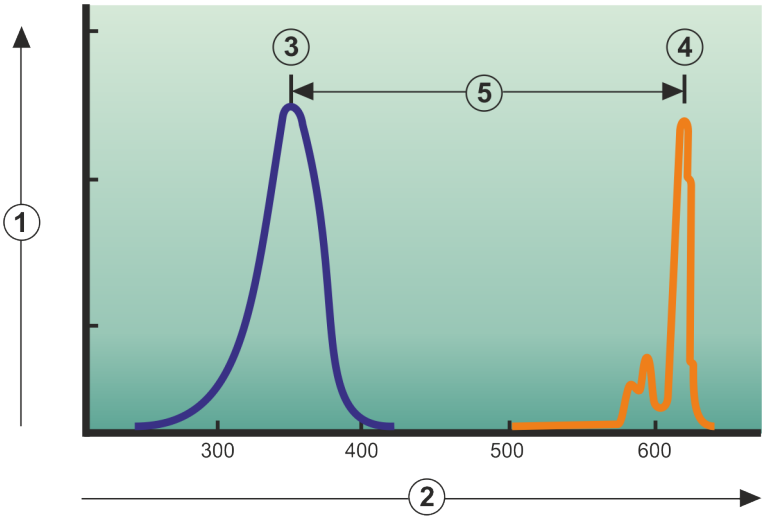
Time-resolved fluorometry

The detection methodology used in all AQT90 FLEX assays is based on time-resolved fluorometry (TRF). TRF has several unique features that make it a very suitable detection technology for assays requiring high sensitivity and wide dynamic range. For example in immunoassay techniques using conventional fluorescence detection, high non-specific background caused by light scattering, e.g. from the biological components of the sample, is a severe limitation to the sensitivity of the assay. However, in TRF used in AQT90 FLEX assays, this problem is avoided by using lanthanide chelate labels with unique fluorescence properties.



1 y-axis: Fluorescence
2 x-axis: Time (µs)
3 Cycle duration
4 Counting time

Lanthanides (such as europium) are rare earth metals with fluorescence lifetimes several orders of magnitude longer than the non-specific background fluorescence. The sample is pulsed from 1000 to 2500 times with excitation light of 340 nm. Between the repeated pulses, the sample fluorescence is measured after a delay time of 400 µs. At this measurement point, the non-specific background fluorescence has declined to a minimum. This gives an increased range in the low concentration area.



1 y-axis: Fluorescence
2 x-axis: Wavelength (nm)
3 Excitation
4 Emission
5 Stokes shift

Other unique features of lanthanide chelate labels are the large Stokes shift, i.e. the difference between excitation and emission wavelengths, and the narrow emission peak. The wavelength of the emitted light is almost 300 nm longer than that of the excitation light used and may be measured at its own characteristic wavelength. Both of these properties significantly increase the signal-to-noise ratio.

A special characteristic of AQT90 FLEX chemistry is also the way the TRF measurement is performed: TRF is measured directly from the dry surface of the well, and an additional enhancement or special label development step is not required.

12 Specifications

Product specifications

Specification	Value	
Height	450 mm (17.72 inches)	
Width	460 mm (18.11 inches)	
Depth	480 mm (18.9 inches)	
Weight	35 kg (77.2 pounds)	
Measurement methodology	Time-resolved fluorescence	
Incubator temperature	36.5 °C to 37.5 °C (97.7 °F to 99.5 °F)	
Noise levels	Values measured according to ISO-3746: • Weighted average value (during operation) <70 dBA • Peak impulse value (excluding alarms) <80 dBA	
Measurement cycle time	• Up to 18.5 min (Undiluted assays) • Up to 20.5 min (Diluted assays)	
Hematocrit range	0-62 %	
Throughput	Up to 30 samples per hour	
Data storage capacity	Patient profiles log	1000 patient profiles
	Patient results log	2500 patient results
	Activity log	7000 records
	Cal.adjustment log	5500 results
	LQC log	2000 results
	System-clean log	2000 records
	Event log	5000 records
External serial port	RS232, 9-pin subD connector. 5V is available at pin 9 for supply of external barcode reader	
USB ports	3 USB 2.0 (1 in front and 2 in the back of the analyzer)	
Ethernet	RJ45 connector, 10/100Mbit/sec	
Keyboard/mouse port	PS/2	

Specification	Value
External VGA screen port	VGA connector
External communication protocols	High level protocols: • ASTM 1381-91, E1394-91 • ASTM6xx • HL7 ver. 2.2 • HL7 ver. 2.5 • POCTDML1A
	Low level protocols: • Serial • Serial (Raw) • Network (TCP/IP) • Network (TCP/IP) (RAW) • Network (TCP/IP) (ASTM)
Display	• 8" TFT-LCD, resolution 800 x 600 VGA • Resistive touch screen
Built-in printer	Thermal printer (paper width 112 mm)
Built-in barcode reader (under the screen)	• Auto scan by proximity sensor • Reading distance: 0-70 mm (0-2.75 inches) • Resolution: ≥5 mil • Accepted codes: Code 128, Code 39, Code 93, Interleaved 2 of 5 Codabar
Available items in the **Patient ID layout** screen	• Patient ID* • Accession number* • Patient last name* • Patient first name* • Sex • Date of birth • Patient note • Patient department • Sample site • Draw time • Physician • Operator • Department • Note • Measurement type • Age • Weight • Height • Approval status • Sample tube type • Approval time • Report layout • Sample age • Max. sample age • Patient account number • Test order code *These items are included in the Radiometer (-R-) default Patient ID layout.

Specification	Value
Sample tube barcode reader	• The barcode label should have at least 2 mm of white space before the first line and after the last line of the barcode • The resolution must be ≥7.5 mil • Accepted codes: Code 128, Code 39, Code 93, Interleaved 2 of 5, Codabar
Battery on the PC board	The battery on the PC board can be purchased from the manufacturer or their representatives (Lithium battery type CR2032, manufactured by "Matsushita Electric", "Panasonic", "MH12210").
Maximum power consumption	400 W (typical consumption 100 W)
Transient over-voltage	Impulse withstand: category II of IEC 60364-4-443
Operating temperature	15 °C to 32 °C (59 °F to 89.6 °F)

Environmental specifications

Specification	Value
Location	Indoor use only
Altitude	0-2000 m (6562 feet)
Ambient temperature	15-32 °C (59-89.6 °F)
Relative humidity	20-80 %
Mains supply	100/110/120/220/230/240 V ±10 %; 50/60 Hz ±5 %
Pollution degree	2 (occasional/temporary conductivity caused by condensation)
Startup	3 hours
Ventilation	Unobstructed
Electrical construction	Double insulation (as defined in IEC 61010-1)
EMC construction	Class A (other than domestic use)
Space requirement	Ample working space in front and space on the sides for cooling. The analyzer should not be kept within an enclosure. Mains should always be easily accessible to switch off the analyzer in emergency situations.
Storage temperature	-20 °C to 60 °C (-4 °F to 140 °F)

WARNING – *Risk of electric shock*
Make sure the analyzer is a minimum of 1.5 m from patient beds.

Detachable power supply cord

Country	Power-supply cord specifications
For USA and Japan (125 VAC)	UL listed and KAM cord, min. type SV, min. 18 AWG, 3 conductors. Rated min. 60 C. Provided with a molded grounding-type (NEMA 5-15P) attachment plug rated 125 VAC, min. 2.5 A. Opposite end terminates in IEC 320 style connector rated 250 VAC, min. 10 A.
For Europe (250 VAC)	Cord type min. H05RR-F or min. H05VV-F or min. H05VVH2-F, rated min. 60 C, 2 × 0.75 mm^2. Provided with a molded grounding-type attachment plug rated min. 250 VAC, min. 2.5 A. Opposite end terminates in molded IEC 320 style connector rated min. 250 VAC, min. 2.5 A.

Tubes approved for use with the analyzer

Evacuated tubes to contain blood samples for use with the AQT90 FLEX analyzer must fulfill the following requirements:

- contain an appropriate anticoagulant for the parameter(s) to be measured (see the *AQT90 FLEX Parameter-specific Test Kit* inserts for details)
- not contain any gel

Sarstedt evacuated tubes approved for use with the analyzer			
Size **diameter (mm) x length (mm)**	**Tube type**	**Anticoagulant**	**Material**
13x65	Monovette	Lithium heparin	Plastic
11x66	Monovette	Lithium heparin	Plastic
13x65	Monovette	Di-potassium EDTA	Plastic
11x66	Monovette	Di-potassium EDTA	Plastic
13x65	Monovette	Citrate 3.2 %	Plastic
11x66	Monovette	Citrate 3.2 %	Plastic

Becton Dickinson evacuated tubes approved for use with the analyzer			
Size **diameter (mm) x length (mm)**	**Tube type**	**Anticoagulant**	**Material**
13x75	Conventional	Di-potassium EDTA	Plastic
13x75	Hemogard Safety Closure	Di-potassium EDTA	Plastic
13x75	Hemogard Safety Closure	Lithium heparin	Plastic
13x75	Conventional	Lithium heparin	Plastic
13x75	Hemogard Safety Closure	Citrate 3.2 %	Plastic

Terumo evacuated tubes approved for use with the analyzer			
Size diameter (mm) x length (mm)	**Tube type**	**Anticoagulant**	**Material**
13x75	Conventional	Tri-potassium EDTA	Glass
13x75	Conventional	Lithium heparin	Glass
13x75	Venosafe	Citrate 3.2 %	Plastic
13x75	Venosafe	Di-potassium EDTA	Plastic
13x75	Venosafe	Tri-potassium EDTA	Plastic
13x75	Venosafe	Lithium heparin	Plastic
13x78	Venoject II	Di-potassium EDTA	Plastic
13x78	Venoject II	Citrate 3.2 %	Plastic
13x78	Venoject II	Heparin	Plastic

Greiner International evacuated tubes approved for use with the analyzer			
Size diameter (mm) x length (mm)	**Cap type**	**Anticoagulant**	**Material**
13x75	Safety cap	Lithium heparin	Plastic
13x75	Pull cap[1)]	Lithium heparin	Plastic
13x75	Safety cap	Di-potassium EDTA	Plastic
13x75	Safety cap	Tri-potassium EDTA (dry)	Plastic
13x75	Safety cap	Tri-potassium EDTA (liq)	Plastic
13x75	Safety cap	Tri-potassium EDTA	Plastic
13x75	Pull cap	Di-potassium EDTA	Plastic
13x75	Pull cap	Tri-potassium EDTA (dry)	Plastic
13x75	Safety cap	Citrate 3.2 %	Plastic
13x75	Pull cap	Citrate 3.2 %	Plastic

[1)] Pull cap ~non-ridged. The non-ridged tubes are also fitted with a Safety Screw Cap. However, because of the absence of ridges on the tubes, the cap can be removed by a simple pull action.

Graphical symbols 13

Explanation of graphical symbols

These are the symbols you may find on the analyzer and the consumable products used with it.

Symbol	Explanation
	Keep dry
	Do not use if package is damaged
	For single use
	Expiry date
	Contents
	Storage temperature range
	Lot no.
	Catalog no.
	Consult instructions for use
	On-board stability in days
	Manufacturer
	For *in vitro* diagnostic use
	Biohazard
	Keyboard

Symbol	Explanation
	Mark of compliance with the EU Directives
	COM gate (scanner/barcode reader)
	VGA (monitor)
	Mouse
	Network
	Off
	On
	UL certification
	USB
	Warning
	**Waste of Electrical and Electronic Equipment (WEEE)** The symbol indicates that: • Radiometer Medical ApS and its distributors within the European Union (EU) and associated states have taken the necessary steps to comply with the directive, 2002/96/EC on waste electrical and electronic equipment (WEEE). • The instrument, when reaching its end of life, must be collected and recycled separately from other waste according to national requirements. Please contact your local Radiometer distributor for instructions. Environmental implications: WEEE contains materials that are potentially hazardous to the environment and to human health.

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If you have any questions or need assistance, please contact your local Radiometer representative.

Radiometer representative:

Code number: 995-235
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