ORION DIAGNOSTICA

QuikRead go® Instrument

145841-6
- English
- Español

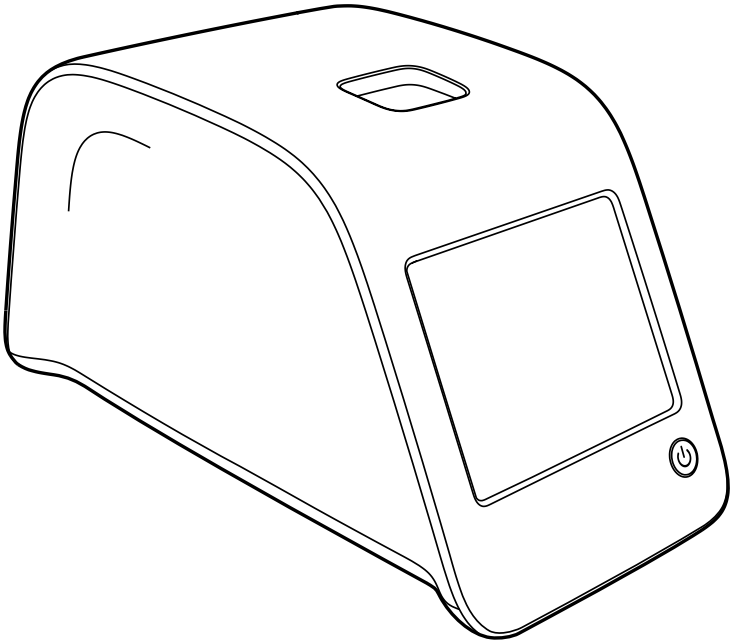
	Explanation of symbols	Explicación de los símbolos
IVD	In vitro diagnostic medical device	Producto sanitario para diagnóstico in vitro
REF	Catalogue number	Número de catalogo
	Manufacturer	Fabricante
	Date of manufacture	Fecha de fabricación
CONT	Contents	Contenido
	Instrument	Equipo
	Power supply	Fuente de alimentación
	Power cable / Mains cable	Cable de poder
	Consult instructions for use	Consultar las instrucciones de uso
	Caution	Precaución
	Biological risks	Riesgos biológicos
	Temperature limit	Límite de temperatura
	Fragile, handle with care	Frágil, manejar con cuidado
	Keep dry	Manténgase seco
	China RoHS GB/T 26572	China RoHS GB/T 26572
Rx only	For prescription only	Solamente para uso con receta

QuikRead go®

Cat. No. 145218

Rx only

English



English

CONTENTS

1 INTENDED USE

Orion Diagnostica **QuikRead go®** is an *in vitro* diagnostic test system. The QuikRead go instrument has been designed to measure quantitative test results from patient samples using QuikRead go reagent kits. Not for point-of-care use.

2 FUNCTION OF THE QUIKREAD GO INSTRUMENT

QuikRead go is a photometer capable of reporting quantitative measurements. The instrument has been designed and calibrated for both photometric and turbidimetric measurements. It guides the user through the assay procedure by means of a series of messages and animations shown on the display.

3 INSTALLATION PROCEDURES AND REQUIREMENTS

Safety information

For your own safety, comply with all warning and caution statements. To alert you to potential electrical or operation-related hazards, warning and caution statements are provided where applicable.
Before beginning to use QuikRead go, please read the **Precautions and restrictions on operation** in Chapter 8 carefully.

Unpacking

Open the packaging box and check that it contains all the necessary items:

- Instrument
- Instructions for use
- Power supply
- Power cable
- Certificate of analysis

Carefully examine the instrument to ascertain that it has not been damaged during shipment.
If damage has occurred or any parts are missing, immediately notify your supplier.

Parts of the QuikRead go instrument

The QuikRead go components are shown below, in **Image 1** (instrument from above), **Image 2** (instrument from the rear), and **Image 3** (instrument from below).

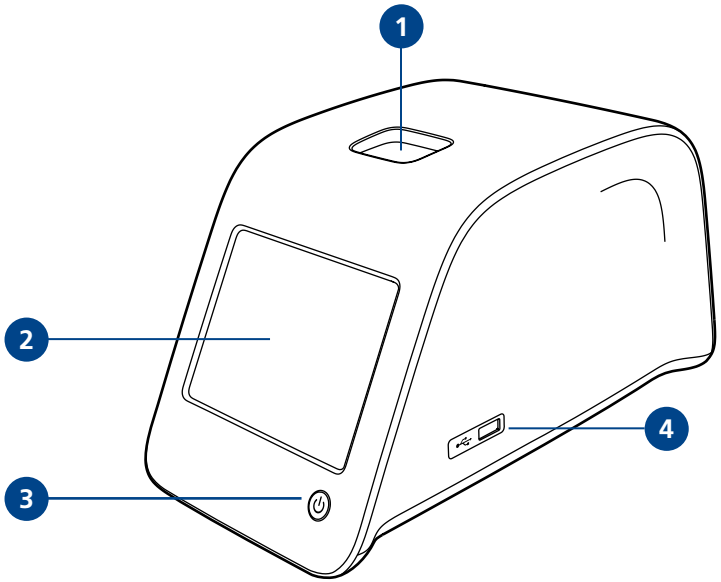


Image 1

1. Measurement well for cuvette
2. Touchscreen display
3. Power button
4. USB port 1 (Type A)

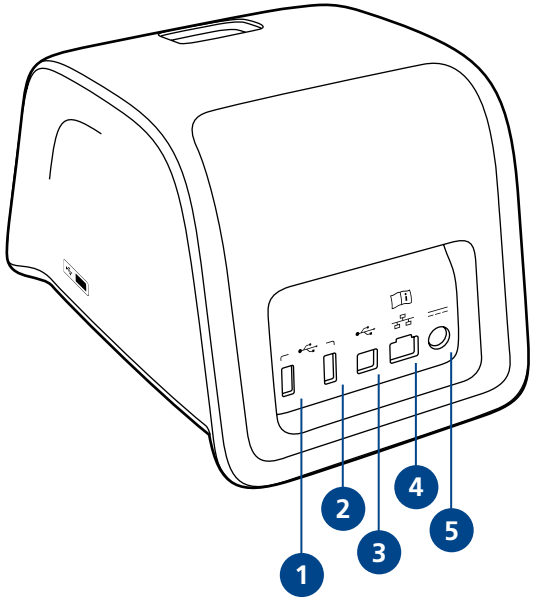


Image 2
1. USB port 2 (Type A)
2. USB port 3 (Type A)
3. USB port 4 (Type B)
4. RJ45 port
5. Connector for power supply

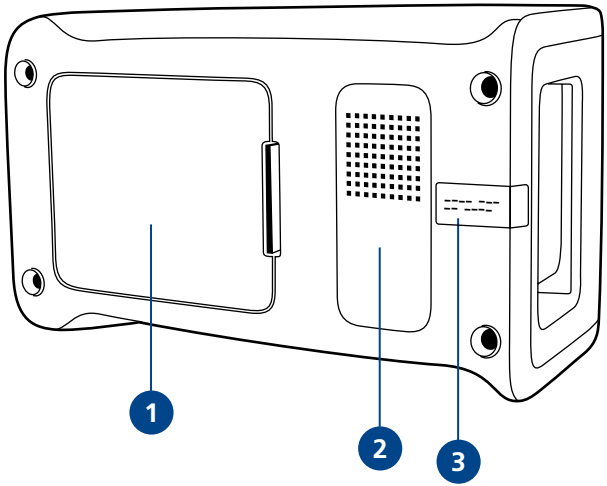


Image 3
1. Battery unit cover
2. Instrument label, with serial number
3. Warranty seal

Lifting/transporting the instrument

When lifting or transporting the QuikRead go instrument, always handle it carefully. At the back of the instrument is a handle, enabling lifting with one hand (**Image 4**).

A recess is added to the instrument side surfaces to help the grasp (**Image 5**).

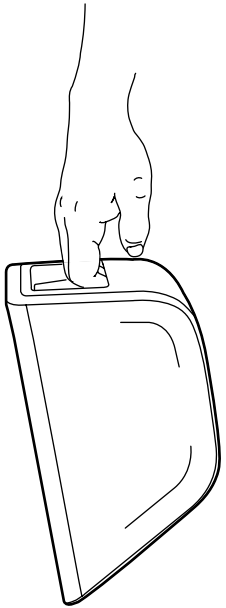


Image 4
Lifting the instrument with one hand.

Image 5
Lifting the instrument with two hands.

Location and environment

During use

The instrument should be placed on a flat, clean, horizontal surface, and the following restrictions should be observed:

- Altitude up to 6,500 feet (2,000 m)
- Ambient temperature between 59 °F (15 °C) and 95 °F (35 °C)
- Maximum relative humidity 80% for temperatures up to 87 °F (31 °C), decreasing linearly to 67% at 95 °F (35 °C)
- Power-supply voltage fluctuations of no more than ±10% of the nominal voltage
- Installation category II (2,500 V transient)
- Do not expose the instrument to direct sunlight
- Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation
- Do not move the instrument while it is performing measurements
- Noise level generated is <85 dB (A)
- Environmental limit of Pollution Degree 2

During transport and storage

- The ambient temperature must be between 36 °F (2 °C) and 95 F (35 °C)
- Protect from rain and humidity
- Handle the instrument with care

Power cable and battery pack

The QuikRead go instrument can be used with either the power-supply cable or an optional battery pack. The battery pack is charged automatically when the power cable is plugged in.

Connectors and cables

On the back of the instrument are five connection slots, with symbols describing their use. One USB port can be found on the right side of the instrument. All of the symbols are described in **Image 6**. The RJ45 connector can be used for serial and LAN connections.

Plugging in the power supply cable

Plug in the power-supply cable, using the marked connection at the back of the instrument. Plug in the other end of the cable to a power outlet.

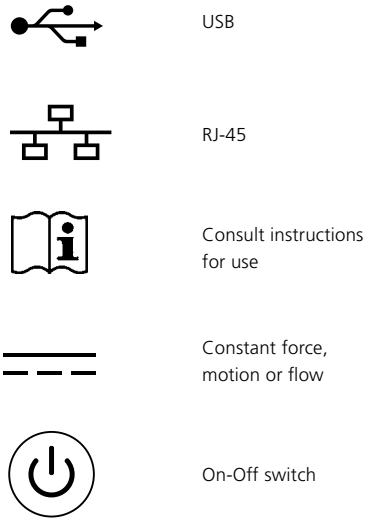


Image 6
Symbols on QuikRead go

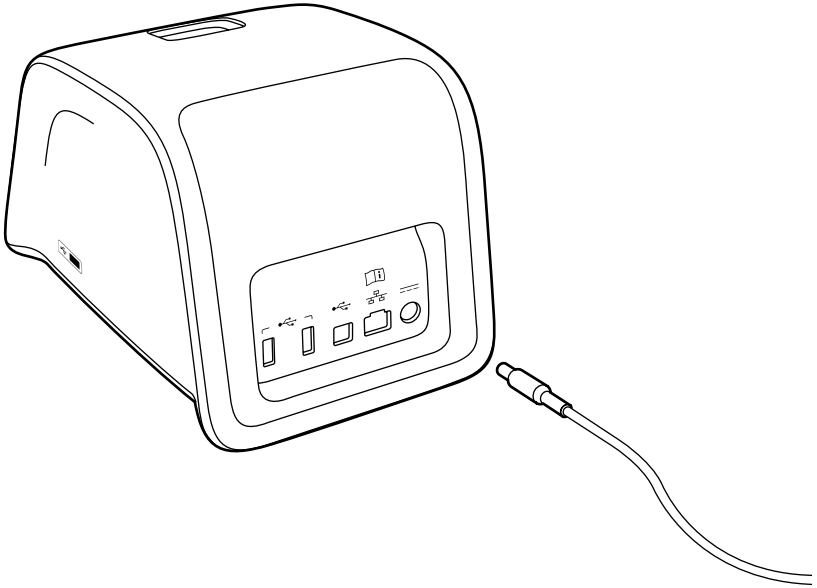


Image 7
Connection of the power supply cable

Inserting a battery pack

Follow the steps below to insert a battery pack into the QuikRead go instrument.

1. Make sure the instrument is turned off
2. Unplug the power-supply cable
3. Place the instrument on its side on a table
4. Open the battery compartment, removing the cover
5. Attach the battery connector to the battery pack
6. Press the battery pack into place and ensure that it is positioned properly
7. Attach the battery-compartment cover
8. Place the instrument back in the upright, operation position

External devices

Barcode reader

An external barcode reader can be connected to the QuikRead go instrument. A list of compatible barcode reader devices can be found via **www.quikread.com.**

Connect the compatible barcode reader to a USB port and follow the instructions on the display.

Printer

The instrument can be connected to an external printer. A list of compatible printers and configuration parameters can be found on the QuikRead website, **www.quikread.com**.

Connect the compatible printer to a USB port and follow the instructions on the display.

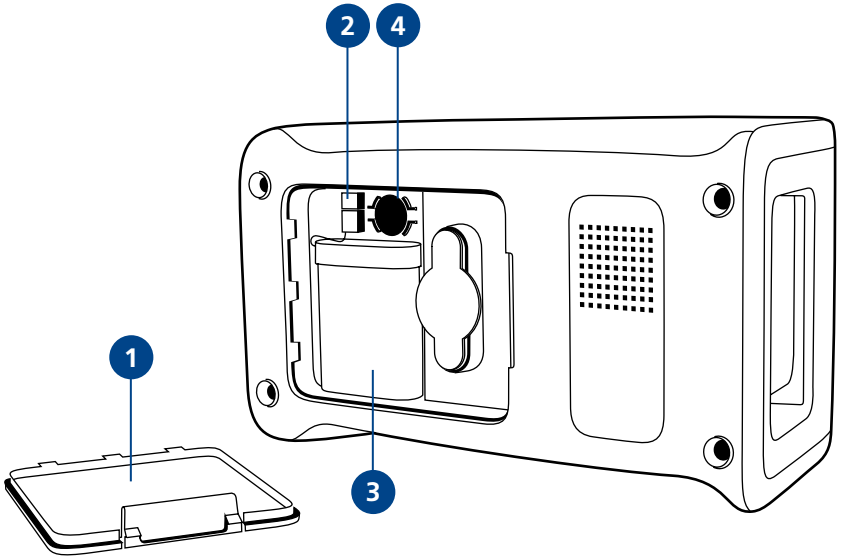


Image 8

1. Battery-compartment cover
2. Battery-pack connector
3. Battery pack
4. Clock battery

Use of the touchscreen

The QuikRead go instrument has a color touchscreen. The user operates it by touching the virtual buttons with the fingers. The screen can be used either with bare fingers or with gloves. The touchscreen does not require much pressure, and pressing too hard or operating it with sharp items could damage the screen.

There is always multimodal feedback to touching a button: the button press is indicated both with a change in appearance and via an audible signal.

A command is registered when the finger is released from the button touched. If the release occurs outside the initial button area, no command is issued.

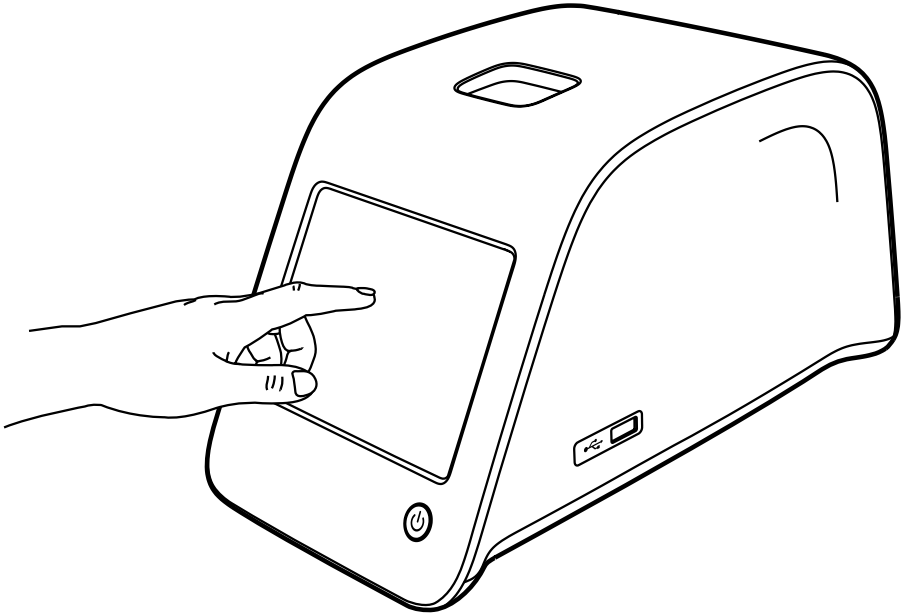


Image 9

Using the touchscreen by pressing gently with a finger.

Set-up wizard

When starting up the QuikRead go instrument for the first time, you will be asked to follow a set-up wizard. During the set-up process, you will be asked to select the language and to set the date and time. The default language is English. The interface language can be changed in the first step presented by the set-up wizard.

The wizard is activated by choosing *Start* (see **Image 10**).

Note

The set-up wizard can be started also manually, from *Settings –> Measurement flow –> Maintenance –> Basic Settings*.

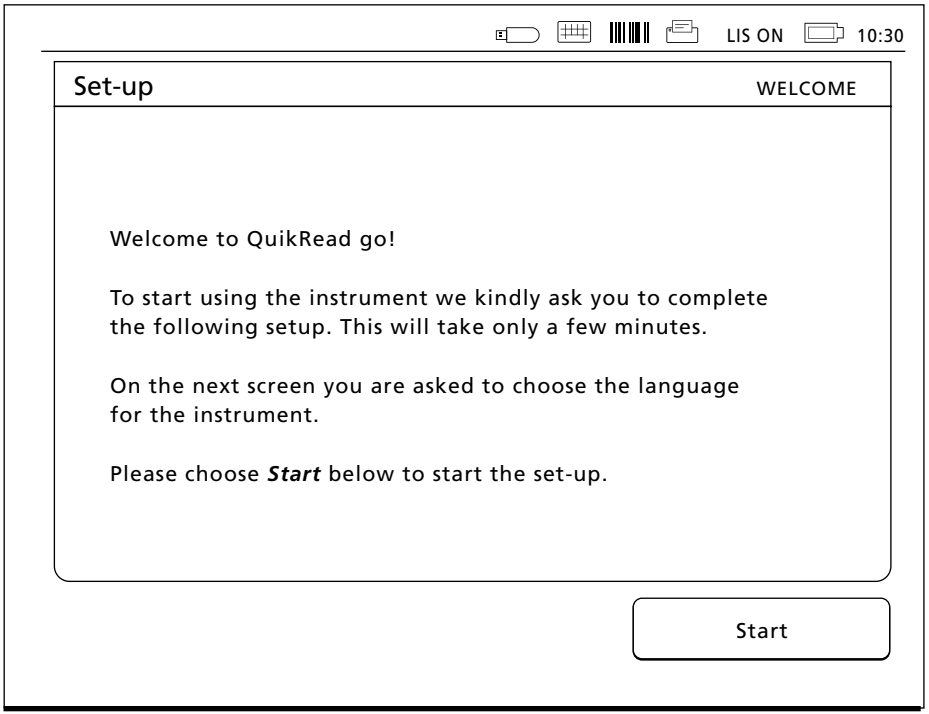


Image 10
To start the set-up wizard, choose *Start* from the set-up screen.

Language

Choose the language you wish to use with the instrument.

You will then be asked to confirm your language choice. The confirmation request is shown in the chosen language and, if that is not English, in English also.

If the chosen language is desired, choose *Yes*, if not, choose *No*.

The chosen language can be changed later, at any time.

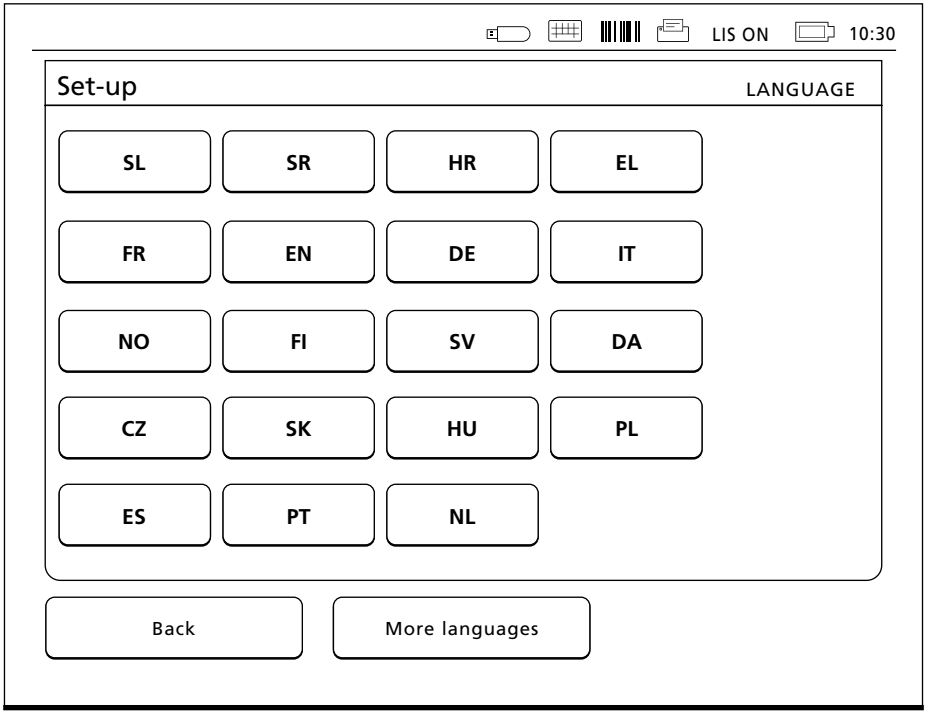


Image 11

The first step in the set-up process is to choose the interface language for the QuikRead go instrument.

Date and time

The second step presented by the set-up wizard is to adjust the date and time. To do this, follow the instructions below:

1. Choose *Edit* on the *Time* row
2. Adjust the time with the arrow buttons
3. Choose between a 12-hour and 24-hour clock
4. Accept the selection by choosing *OK*
5. Choose *Edit* on the *Date* row
6. Indicate the date with the arrow buttons
7. Select a date format
8. Accept by selecting *OK*
9. Select *Next* to continue
10. Choose *Next*

Screen brightness

The third step in the set-up process is to adjust screen brightness. To do this, follow the instructions below:

1. Adjust the screen's brightness level with the arrow buttons.
2. Accept the selection by choosing *Next*.

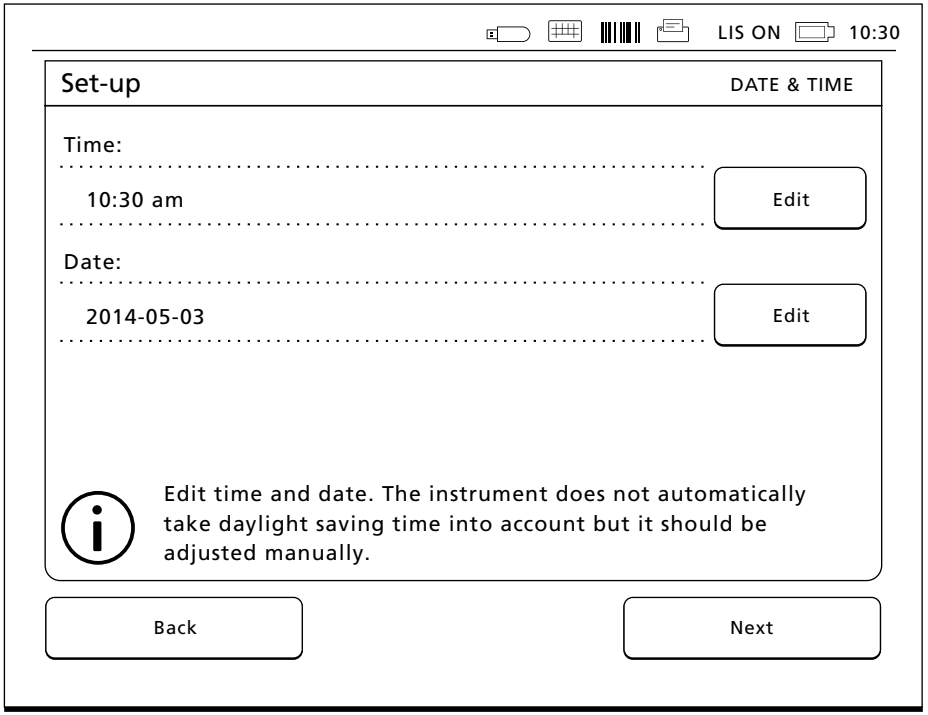


Image 12
The second step presented by the set-up wizard is to adjust a time and date for the instrument.

Audio volume

The fourth step presented by the set-up wizard is to adjust the volume levels:

1. Adjust the keypad tone volume with the arrow buttons.
2. The volume of these sounds can be tested with the *Test* button.
3. Adjust the volume for the alert tones by using the arrow buttons.
4. The sound volume can be tested by means of the *Test* button.
5. Accept the selection by choosing *Next*.

Power save

Adjust the power save time to reduce power consumption when the instrument is being powered from the battery pack. A lower time increases the operation time.

1. Choose the time after which the QuikRead go instrument will enter sleep mode (hibernate)
2. Choose the functionality of the sleep mode.

Finishing the set-up process

You have now completed the set-up process. You may start using the instrument or make additional settings from *Advanced set-up* which takes you to *Measurement flow* where you can adjust laboratory or work-routine settings.

4 PRINCIPLES OF OPERATION

The QuikRead go instrument measures the absorbance of the cuvette contents and converts the resulting figure into a concentration value on the basis of pre-set test-calibration data. The calibration data defining the overall assay curve are encoded on each cuvette label. This information is transferred to the QuikRead go instrument automatically during the measurement.

Assays are performed in accordance with the user instructions accompanying the QuikRead go reagent kit. The results are available within minutes.

The instrument can be operated using a mains power supply or a battery pack. It has USB sockets for an external printer or barcode reader.

The QuikRead go instrument can be connected to a remote laboratory or hospital information system (LIS/HIS). The instrument uses a standards-compliant data-transfer protocol. Contact your supplier for more details.

Power (on, off or sleep mode)

The QuikRead go instrument can be in any of the three modes: on, off or sleep mode.

Turning the power on

To turn on the instrument, press the *Power* button on the front panel. A light on the button is illuminated when the instrument is powered on.

If nothing happens, ensure that the power is connected or, if the instrument is operating from a battery pack, that the battery pack is charged.

After the *Power* button is pressed, the backlight of the display comes on, the instrument starts up, and the main menu appears.

Starting the QuikRead go instrument for the first time opens a set-up wizard (see the "Set-up wizard" section).

Turning the power off

To turn the instrument off, press the *Power* button and hold for approximately two seconds. The instrument requests you to confirm the shutdown, asking, "Do you want to shut down?" If *Yes* is chosen on the touchscreen display, the instrument will turn off. If a cuvette was inside the instrument when the shutdown command was given, the cuvette will be raised and the instrument will ask you to remove it.

Sleep mode

The purpose of sleep mode is to prolong the battery life while the unit is being powered from the battery pack (available separately). Sleep mode is activated when the instrument has been inactive for longer than the time indicated in the personal settings (see the section on *Settings* > *Power save*). The sleep mode's functionality can be "Full standby" or "Close lid only".

The instrument indicates that it is in sleep mode via blinking of the *Power* button light.

To wake the instrument up, press the *Power* button.

User interface in general

The QuikRead go instrument is used via a graphical user interface. This section of the manual explains the main principles of the user interface.

Main menu

All the features of the user interface can be accessed via the main menu (see **Image 13**).

Status area symbols

The status area may contain the following symbols or indicators (see **Image 13**):

1. Profile name
2. USB storage
3. External keyboard
4. Barcode reader
5. Printer
6. LIS status
7. Battery level
8. Time

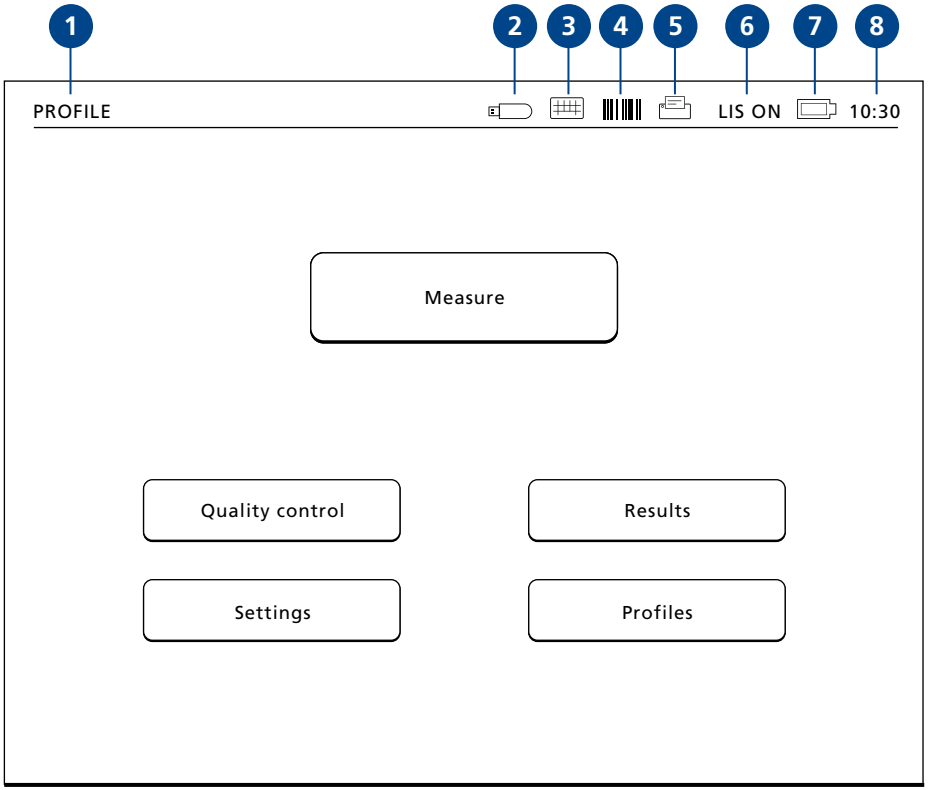


Image 13
The main menu and the symbols used by the system.

Layout

The screen area of the user interface is divided into five sections by function (see **Image 14**):

1. Status area
   This indicates the status of the QuikRead go instrument via symbols.

2. Notification area
   Here, information is given, with the color indicating the current stage of the process. The default color is gray, while green means that something is currently being done, yellow means that a user action is required, and red indicates an error.

3. Content area
   The actual data are at the center of the screen.

4. Information area
   Most views provide the user with additional information or guidance.

5. Navigation area
   Standard buttons for navigation can be found at the bottom of the screen.

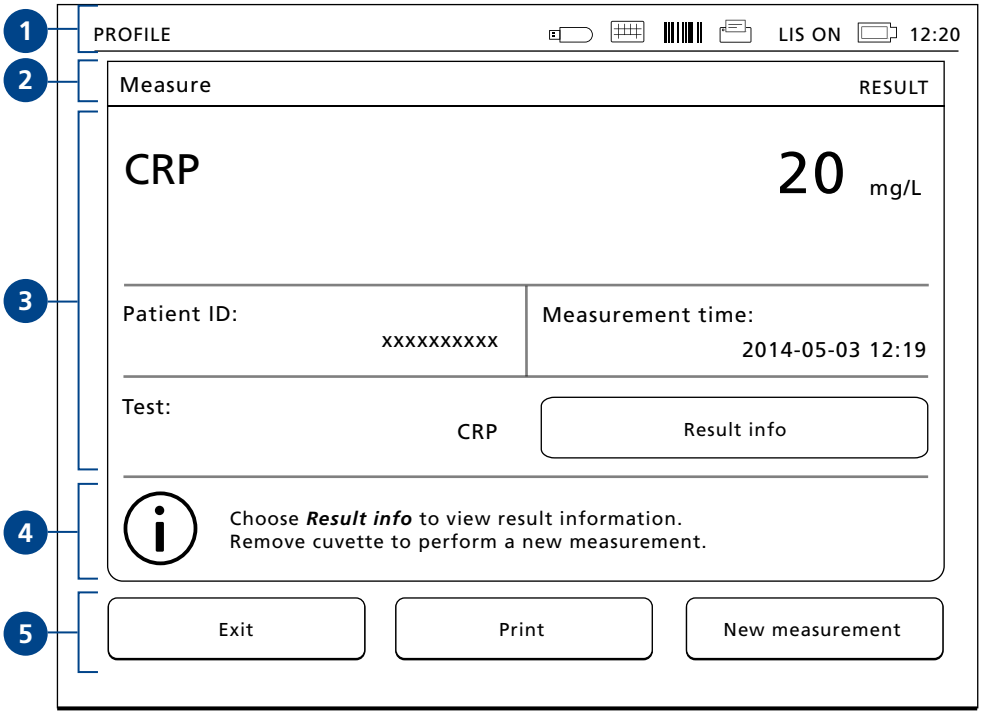


Image 14

Structure of the user interface

The user interface features a menu system with five main sections under the main menu (see **Image 15**):

1. Measurement
2. Quality control
3. Results
4. Profiles
5. Settings

Settings

QuikRead go system settings can be configured from the touchscreen display. The settings are divided into five main categories:

- Personal settings
- Measurement flow
- Maintenance
- Admin settings
- Manufacturer settings (for manufacturer use only)

Saving changes to the personal settings and measurement flow settings is done by saving them as profiles, which can be brought into use later on through application of the desired profile after start-up.
Changes from the factory settings are made with the set-up wizard. When started for the first time, the instrument uses the factory settings.

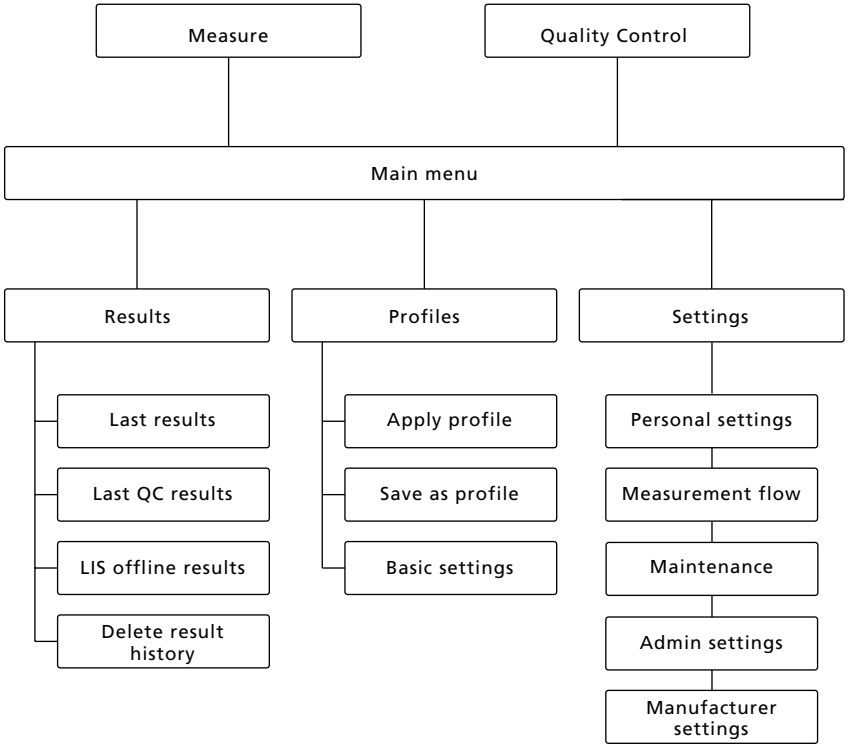


Image 15
The user interface's menu system.
Directly under the main manu are *Measurement*, *Quality control*, *Results*, *Profiles* and *Settings*.

Personal settings

From *Personal settings*, the operator can set language, screen, volume, and power-saving options. These can be chosen for temporary use (that is, until powering down of the instrument) or for further use, in which case the settings need to be saved to a profile. Settings for continuous use should be configured with the set-up wizard: *Settings > Measurement flow > Maintenance > Basic settings*.

Language

The language is selected with the set-up wizard. From here, it is possible to change the language by choosing *Language* and then selecting the desired language. Accept the selection with *Yes*, or reject it with *No*.

Screen

Screen brightness can be adjusted from *Screen*. To increase or decrease the brightness of the screen, use the arrow buttons. Accept with *OK*, or reject by selecting *Cancel*.

Volume

Sound volume can be adjusted from *Volume*. Adjust the keypad tone volume and the alert tone volume by using the arrow buttons. Accept the selection with *OK*, or reject it with *Cancel*.

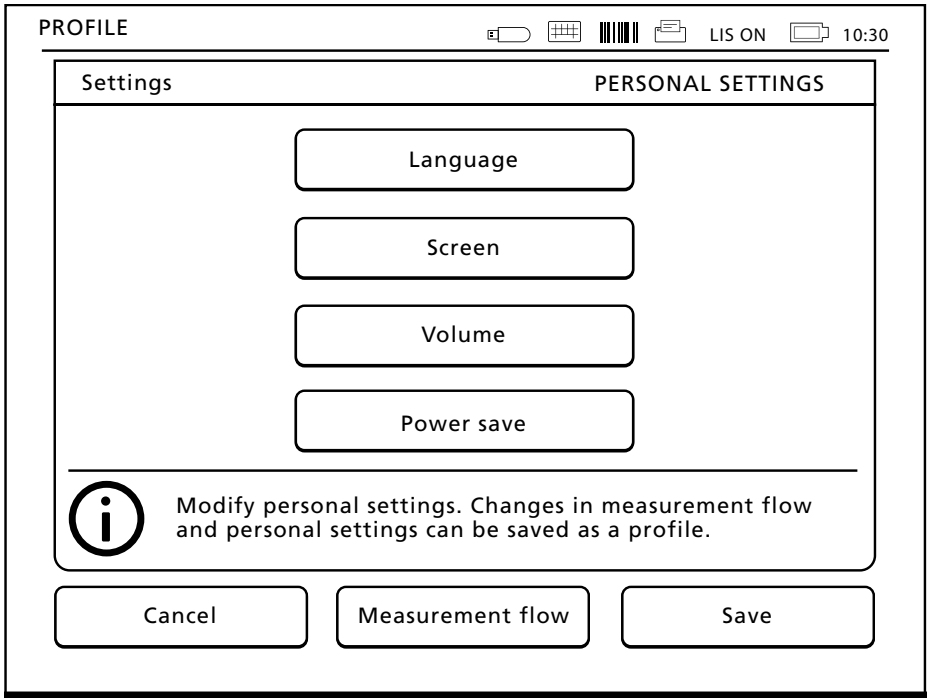


Image 16
The *Personal settings* menu

Power-save operation
The time after which the QuikRead go instrument closes the lid – without entering sleep mode – can be adjusted from *Power save* > *Close lid only*; adjust the delay value with the arrow buttons. The instrument will close the lid if it hasn't been used for the amount of time specified, without entering sleep mode (activating the hibernation function). This mode does not disrupt any LIS/HIS connection.
The time after which the QuikRead go instrument enters sleep mode can be adjusted from *Power save* > *Full standby*; adjust the delay value with the arrow buttons. The instrument goes from idle mode into sleep mode if it hasn't been used for the amount of time indicated. Entering sleep mode breaks any active LIS/HIS connection.
Accept the settings with *OK*, or reject with *Cancel*.

Saving changes to personal settings
After all desired adjustments to personal settings have been made, choose *Save*.

Saving setting to profiles for further use
From the main menu screen, choose *Profiles*. Choose *Save as profile*, and select either use of a new profile or a profile you'd like to copy and then modify. Supply a name for the profile, and accept with *OK*.

Measurement flow
With the measurement flow settings, the operator can adjust laboratory- or work-routine-oriented settings such as operator and patient IDs, printing, LIS transfer, and some test-specific parameters.
These settings can be selected for temporary use (use until power-down) with *Save* after you make the desired changes.
For further use, the settings need to be saved to a profile. Settings for continuous use should be configured with the set-up wizard.

Operator ID
... is an identifier of the user.
- *Operator ID OFF*: The instrument does not request an Operator ID.
- *Operator ID ON*: An Operator ID has to be given before every sample measurement. That ID is paired with the test result.
- *Operator ID ON + Propose previous*: The instrument suggests a previous ID for use, but a different ID can be supplied.

Patient ID
... provides identification of the patient sample.
- *Patient ID OFF*: The instrument does not request a Patient ID.
- *Patient ID ON*: A patient ID has to be supplied before every measurement, and that ID is presented with the test result.

Test parameters
The unit of results can be chosen here. The change requires the administrator's password, which is QRGOSET. Choose ••• and the options will be shown. To make settings permanent, they should be configured with the set-up wizard.

Printing
- *Printing OFF*: The instrument does not prompt for printing. It is nevertheless possible to print the result if one chooses *Print* from the *Measure / Result* screen.
- *Printing ON:* After lifting the cuvette, the instrument asks "Print current result?". Accept printing by choosing *Yes*. Cancel printing by choosing *No*.
- *Printing ON + Automatic:* The instrument prints every measurement result automatically.

LIS transfer
- *LIS transfer OFF:* The instrument does not send the results to the Laboratory Information System.
- *LIS transfer ON:* After printing, if activated, the instrument asks: "Send result to LIS?" Accept sending by choosing *Accept*. Reject by choosing *Reject*.
- *LIS transfer ON + Automatic:* The instrument sends the measurement result automatically to the LIS.

Saving measurement flow settings to a profile for further use

On the main menu screen choose *Profiles*. Then choose *Save as profile*. Select a new profile and supply a name for it, or select a profile you'd like to modify and supply a name for the profile (if the existing profile is no longer needed), and choose *OK*.

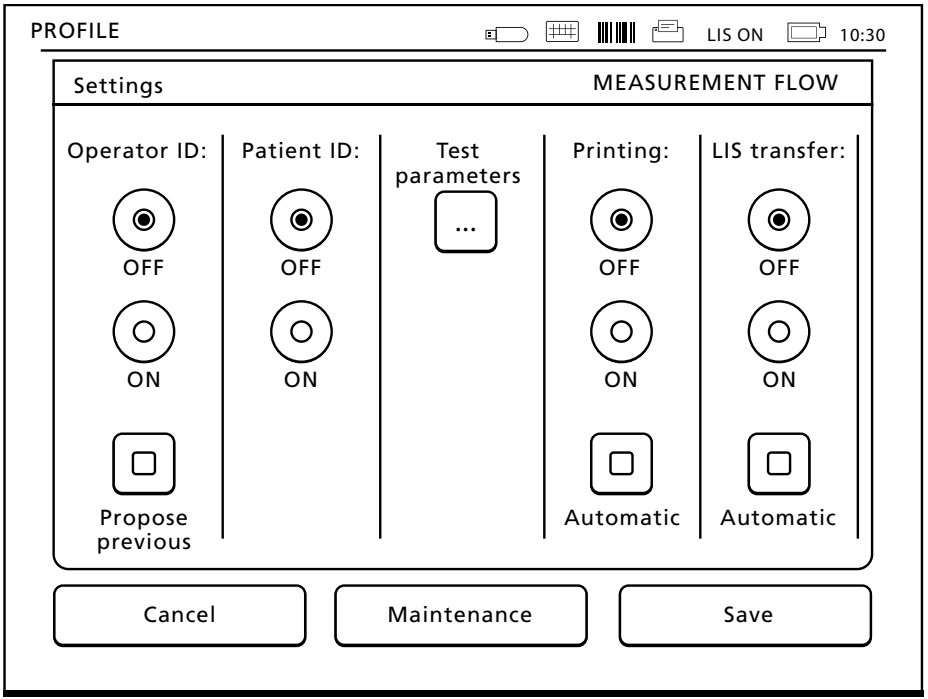


Image 17
Measurement flow menu

Maintenance settings

The instrument-specific settings can be configured from the *Maintenance* menu.

Date and time

The date and time can be adjusted by choosing *Date and Time*. To do this, follow the instructions below:

1. Choose *Edit* on the *Time* row
2. Adjust the time with the arrow buttons
3. Choose between a 12-hour and 24-hour clock
4. Accept the selection with *OK*
5. Choose *Edit* on the *Date* row
6. Adjust the date with the arrow buttons
7. Select the format for the date
8. Accept with *OK*, and confirm by choosing *OK* on the next screen
9. Choose *OK* to continue working with the settings

Error log

The instrument's error log is saved in its memory. Error records can be scrolled from the log screen with the up and down arrows on the right. The user can sort them by choosing *Time* or *Error* code as the sort key.

The error log can be copied to USB storage.

1. Choose *Transfer to USB*.
2. Connect a USB storage device to a USB port. Wait until the screen shows "Transferring completed. You can now safely remove USB storage."
3. Choose *O*K and remove the USB device.
4. Choose *Back* to return to the Maintenance menu.

The *Delete Error log* button deletes all error records from the memory. Before deletion, confirmation is requested.

1. Accept with *Yes*, or cancel with *No*.
2. Choose *OK* when the Error log deleted screen appears.
3. Choose *Back* and then *Cancel* to return to the main menu.

Self diagnostics

The instrument performs operation checks to ensure its proper functioning. Start its self-diagnostics by selecting *OK*. Return to *Maintenance* by choosing *OK*.

Software update

QuikRead go software defines the instrument operations. Software can be updated to the newest available version if desired. New software will be delivered on a USB storage. Connect the storage to a USB port. The version numbers of current and new software will be shown on the display. Confirm the updating by choosing *Yes*. After completion of the software update, the following message is shown: "*You can now safely remove the USB storage. After restart, update will continue and the screen will be blank for about 30 seconds. Do not switch the power off until update is complete. Press OK to restart*." Press *OK*. Next, the following message will be shown: "*Instrument needs to be restarted to complete software update.*" Press *Restart*. QuikRead go will restart and returns to the Main menu.

You can now safely remove the USB storage.

Touch screen calibration

The touchscreen can be calibrated to optimize the buttons' usability. Start the calibration by choosing *Touchscreen calibration*. Calibrate the touchscreen by touching each of the black circles in turn. After "Touch display calibration succeeded" is shown, choose *OK*.

Product information

On the About screen, instrument-specific details are shown:

- Instrument serial number
- Software version number
- LIS connection details

Admin settings

The administrative settings allow instrument-specific settings for the LIS connection and GMT value to be adjusted. A *Factory reset* can also be performed from here.

The following password is needed to change the admin settings: QRGOSET. The password is used as a confirmation step to ensure that the user does not access this page inadvertently.

GMT

GMT (Greenwich Mean Time) is a universal reference time in relation to which the instrument's time is stored. The GMT value is not visible to the user; it is used internally for the instrument.

To set the GMT value, adjust the date and time appropriately with the arrow buttons.

Internal clock

The date and time have been adjusted (in GMT) at the factory.

Once a day, the date and time values are recorded in the memory, on start-up.

If the clock battery runs out, the clock stops. Once that battery has been replaced, the clock continues from the last time value saved. The time can be adjusted from the admin settings. This operation requires a password. The new time entered cannot be before the last time value saved; supplying a time too far in the past results in an error message.

Local time

Adjust the time in accordance with the local time. The local time is saved to the memory as an offset from GMT.

When changing the clock battery, adjust the date and time appropriately. The time supplied cannot be more than 24 hours before the last saved (GMT) value. Giving a time too far in the past results in an error message: "Setting of date failed. Date is in the past."

LIS settings

From the *LIS settings* option, the LIS settings for data transfer can be adjusted. The data are transferred via a serial or a LAN connection. TCP/IP settings must be supplied before a LAN connection can function. Contact your supplier for more details.

Factory reset

The factory settings of the user interface can be restored. The factory reset deletes all profiles and results, and empties the error log.

Manufacturer settings

The *Manufacturer settings* section of the menu system is only for the manufacturer's use.

Profiles

User-adjusted settings can be saved as profiles for later use. Up to four user profiles can be saved in the instrument's memory.

Creating a profile

When the instrument has been set to work as desired, the settings can be saved as a profile:

1. Choose *Save as profile*.
2. Select a profile (you may choose a new profile).
3. Give the profile a name.
4. Choose *OK*.

Applying a profile

Choose *Apply a profile*. Select the desired profile.

Basic settings

Choosing *Basic settings* starts the instrument operating in accordance with the basic settings made with the set-up wizard.

5 PERFORMANCE CHARACTERISTICS AND SPECIFICATIONS

Declaration of Conformity

The QuikRead go instrument complies with the electromagnetic emission and immunity requirements described in the standard IEC 61326-2-6.

Technical specification

The instrument has a pre-programmed microprocessor that controls the assay steps and data processing. Test identification, timing, and the calibration curve are stored in a barcode on each cuvette. Once activated by the cuvette label, the microprocessor controls and guides all steps in the assay and converts the absorbance values from the samples into concentration units.

Photometer

The QuikRead go photometer features a measurement well, three LEDs, and light-detectors. The photometer has been designed and calibrated for both photometric and turbidimetric measurements.

Touchscreen display

The user interface consists of an easy-to-use touchscreen display. It is used by means of touch-sensitive buttons presented on the screen. It also provides the user with messages and prompts for performing each step in the assay, and it reports the test results and any error messages.

- 4-wire resistive
- Display size: 116.16 × 87.12 mm
- Pixels: 640 × 480

Dimensions and power requirements

- Weight: 1.7 kg without power supply
- Size: 27 x 15.5 x 14.5 cm
- Power requirements:
  100–240 V AC
  50–60 Hz power supply or battery pack
  8 W power consumption
- Power supply: supplied with the instrument
- Battery pack: supplied separately (only a battery pack supplied for QuikRead go use can be used)

Instrument software

New software can be uploaded via USB. Ask your local supplier for more details.

Instrument identifier

Each QuikRead go instrument has its own serial number, which can be found on the label on the bottom of the instrument.

Memory

The QuikRead go instrument has an internal memory for result history. See the section "Results".

Power supply

The instrument is powered by a power supply supplied with the instrument. Additionally, the instrument can use a battery pack as a power source. An internal switch within the cable connector switches the instrument automatically from battery-powered to mains current use. For instructions on installing a battery pack, see the section "Inserting a battery pack."

Serial connection

The RJ45 socket can be used for a serial-type connection with a special cable. Specifications for wiring of the cable can be found on the website **www.quikread.com**.

LAN connection

The RJ45 interface supports a 10BASE-T/ 100BASE-TX Ethernet connection. Cat 5 / Cat 5e UTP (unshielded twisted pair) cable should be used.
Power over Ethernet (PoE) is not supported.

USB connection

The instrument has three A-type USB connectors. These connectors can be used for the printer, barcode reader and memory stick. The instrument can be connected as a virtual com-port to a PC or computer via a B-type USB connector.

6 OPERATING INSTRUCTIONS

Usage of the QuikRead go instrument can be characterized as involving three main operations:

- Performing an assay
- Viewing results
- Changing the instrument's settings

Performing an assay

The instrument can be placed in various measurement modes, as needed. The basic mode uses the simplest measurement protocol and is set to be the default for a new instrument.

Only QuikRead go reagent kits can be used to perform an assay. Read the instructions for use of the corresponding QuikRead go reagent kit before use. The instructions provide more detailed information on carrying out tests and handling samples.

Performing an assay in basic measuring mode

In the basic measuring mode, the QuikRead go instrument performs an assay measurement and shows the result on the display, along with reagent lot data.

To perform a measurement, do the following:

1. Choose *Measure* in the main menu, and follow the instructions on the display (see **Image 18**).

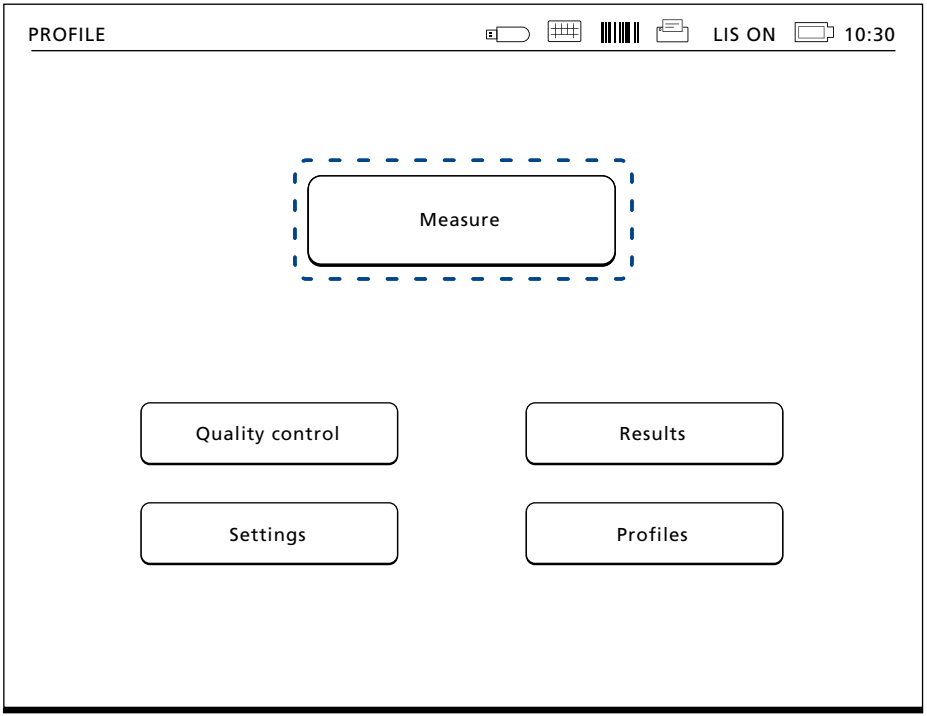


Image 18
Start a basic measurement by choosing *Measure* in the main menu

2. Drop a cuvette into the measurement well in the right position. The barcode of the cuvette must be facing towards you (see **Image 19**).
   Note: do not insert your finger or anything else into the measurement well.
3. The lid closes, and the instrument starts the measurement.
4. After the test is completed, the result is shown on the display and the cuvette is raised for removal.
5. Remove the cuvette. The result disappears from the display. It can be displayed again via *See previous result*.
6. If you wish to make another measurement, insert a new cuvette into the measurement well. Choosing *Cancel* takes you to the main menu.

Quality control

QuikRead go has a separate result history file for quality-control samples. Quality-control samples are measured in the same way as normal samples, but the results are stored in a separate result file. To start a quality control measurement, choose *Quality control* in the main menu and follow the instructions on the screen.

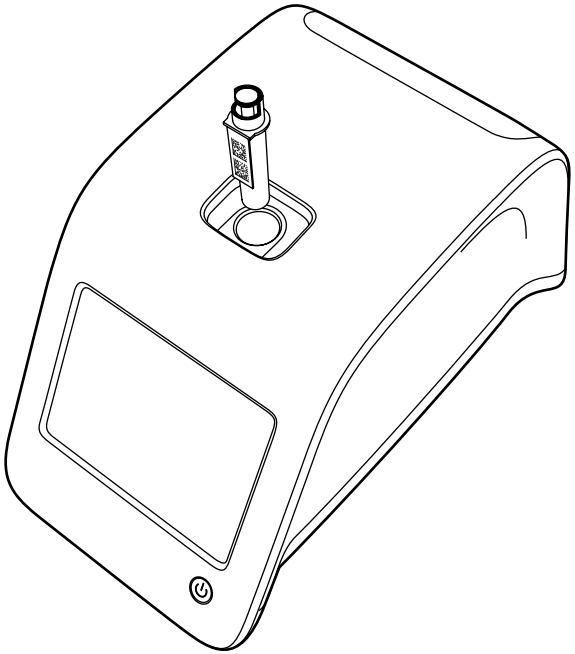


Image 19
Drop a cuvette into the measurement well with the barcode facing towards you.

Other measuring modes

The instrument can be used in other measurement modes besides its basic mode. The optional protocols include use of a patient ID and/or an operator ID, printing of the results, and sending of the results to a laboratory information system (LIS). The measurement protocol is specified in the settings menu, where these features can be enabled or disabled.

Operator and patient IDs can be supplied via a barcode reader or entered with the instrument's virtual keyboard or an external keyboard. The user supplies the operator and patient IDs before the measurement. Optionally, use of either or both types of ID can be disabled in the configuration settings.

Also, the operator ID function can be configured to propose the last input value. The user may change the operator ID from the suggested value before making a measurement, typing the new ID over the previous, suggested one.

The measurement results can be sent to a printer and/or to an LIS when printer and/or LIS transfer is enabled.

Results

The results are stored in the *Results* file, from which they can be viewed, printed, or transferred to USB storage. The file's content is divided into the following: the last results, the last quality-control results, and the last LIS offline results.

LIS offline results are results stored in the memory of a QuikRead go instrument that is normally connected to an LIS but has temporarily been in LIS offline mode.

Viewing results

To view the results, choose *Results* from the main menu. You can select *Last results*, *Last QC results*, or *LIS offline results*. The results can be scrolled with the up and down buttons on the right.

The results can be sorted by time, analyte, or patient ID by means of the corresponding buttons. Tapping a result line gives detailed information on the individual measurement in question.

Deleting result history

Choosing *Delete result history* permanently deletes all results from the history file. The instrument will ask for confirmation before deletion.

Printing results

Choosing *Print* gives an option of printing the results, sorted by date, analyte, or patient ID.

Tap the  button, and select the results to be printed. Choose *OK* to start printing.

Transferring results to USB storage

The results can be transferred to USB storage. Connect a USB drive to a USB port. Choose *Transfer to USB*, then select the results to be transferred and choose *OK*. Do not remove the USB device until the transfer is complete. After completion of the transfer, the message "Transferring completed. You can now safely remove the USB storage." will be shown.

Sending offline results to LIS/HIS

All results not yet sent to the LIS can be viewed via *LIS offline results*. Choosing *Send to LIS* sends them to the LIS, and the results are deleted from the LIS offline memory after successful transfer. Choosing *Delete offline results* deletes the results without sending them to the LIS.

The QuikRead go instrument checks the LIS connection automatically during start-up, when the user enters the main menu, and after every measurement. If a connection is available and there are results in the LIS offline result history, the QuikRead go instrument automatically proposes sending the offline results to the LIS.

7 CALIBRATION PROCEDURES

Instrument calibration

The instrument is factory-calibrated. Proper functioning of the instrument is checked by the self-check procedure during every measurement. In the event of malfunction, an error message is displayed.

Test calibration

The calibration data defining the overall assay curve for each test are encoded on the cuvette label. This information is transferred automatically to the instrument during every measurement.

8 PRECAUTIONS AND RESTRICTIONS ON OPERATION

Precautions and restrictions

- Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- Do not spill any liquids or drop any objects on or into the instrument.
- For prescription only.
- Any spills of potentially infectious material should be wiped off immediately with absorbent paper tissue and the contaminated areas swabbed with a standard disinfectant or 70% ethyl alcohol. Material used to clean spills, including gloves, should be disposed of as hazardous biological waste.
- Before use, carefully read the QuikRead go reagent instructions for use supplied with each reagent kit. Follow these directions with care.
- Only QuikRead go reagents may be used.
- Do not mix components with different lot numbers.
- Never place a cuvette without a tightly attached cap into QuikRead go.
- Ensure that the cuvette sealing foil is totally removed.
- Use only the power supply supplied with the instrument, and make sure that the plug is positioned such that it is readily removable.
- Use only the official QuikRead go battery pack supplied by Orion Diagnostica.
- Do not put fingers or any external devices into the QuikRead go instrument while measurements are in progress.
- Do not remove or shut down a USB device during data transfer.
- Do not open the instrument covers by turning any screws. If the warranty seal is broken, the instrument warranty is not valid.
- Use a secure internal network or Virtual Private Network (VPN) when connecting QuikRead go to LIS/HIS using LAN.
- Do not use or connect the instrument to a LAN if the warranty seal is broken.

Warranty

The manufacturer's warranty for the QuikRead go instrument covers defects in materials or manufacturing for a period of two years from the date of purchase.
The manufacturer agrees to repair or replace the instrument if it becomes inoperative in consequence of the failure of any internal part of the instrument. The warranty does not cover damage caused by use not in accordance with the instructions. This warranty is valid for two years. The manufacturer is under no obligation to modify or update the instrument once it has been manufactured, unless a manufacturing defect is identified.
In the event of instrument malfunction, please contact your local supplier.

Recycling

The QuikRead go instrument is a low-voltage electronic device, and it should be recycled as electrical equipment waste. The packaging materials are recyclable.

9 TROUBLESHOOTING

The QuikRead go instrument displays error messages and guides the user if it detects errors. Follow the instructions displayed, and consult the troubleshooting table in this manual and also the QuikRead go kit instructions for use.

Contact your local supplier in the event that support is needed or repair requirements arise.

Error message / symptom	Possible cause	Corrective action
QuikRead go does not start.	The power is not connected.	Connect to the power supply and retry.
	The instrument has an electronic malfunction.	Contact Customer Service.
The touch panel is not functioning correctly.	The touchscreen calibration is not correct (the active area is not under the button).	Calibrate the touchscreen, following the procedure described under "Maintenance settings".
	The touchscreen panel does not respond at all.	Contact Customer Service.
Instrument alarm sounds cannot be heard.	The volume is set at too low a level.	Set volume according to the procedure described in the chapter on personal settings.
	The instrument's sound system is not functioning correctly.	Restart QuikRead go. If the problem persists, contact Customer Service.

Error message / symptom	Possible cause	Corrective action
Printer does not print.	The printer is off. The printer cable is not properly connected. The printer has a malfunction. The settings are not correct.	Make sure that the printer is connected and its power is on. Check the settings. If the problem is not solved, restart the instrument and printer, and try printing again, from the Results menu. If the problem persists, contact Customer Service.
Barcode reader is not functioning.	The barcode reader is not connected or has a malfunction. The settings are not correct.	Make sure that the barcode reader is connected. Check the settings. If the problem is not solved, restart the instrument and retry the barcode reading. If the problem persists, contact Customer Service.
"Error code XXX. Please restart QuikRead go" message is displayed.	Humidity has accumulated on optical surfaces.	Move the instrument to a dry environment, and restart.
	The instrument has a temporary malfunction.	Restart the instrument. If this error message is displayed frequently, contact Customer Service.
"Error code XXX. Please contact customer service" is displayed.	Permanent malfunctioning of the instrument.	Contact Customer Service.
Battery pack (optional) needs charging frequently.	The battery pack's storage capacity decreases as its service life progresses.	Replace the old battery pack with a new one, in accordance with the procedure described in the section "Inserting a battery pack."
"Battery level is low. Please connect to the mains cable in order to continue operation" error message is displayed.	The battery pack's level of charge is low.	Connect power via the QuikRead go power connector.
Clock battery warning is displayed.	The internal clock's battery is empty.	Replace the clock battery, in line with the procedure described under "Changing the clock battery."

Error message / symptom	Possible cause	Corrective action
"Cuvette position not correct. Remove cuvette." error message is displayed.	Remnants of cuvette sealing foil remain on the cuvette collar.	Remove the cuvette when the instrument has raised it. Make sure that all foil remnants are removed before the next measurement.
	The instrument has a mechanical malfunction.	See the item above. If it does not apply, restart the instrument. If the problem persists, contact Customer Service.
Measurement noted as prohibited.	The reagent cap is missing, or the cuvette is used.	Check that the cuvette has a reagent cap and that the inner colored part of the cap is not pressed down.
	Reading of lot data from the barcode failed.	Try again. If the problem persists, cancel the test.
	The reagent-kit lot has expired.	Discard the expired lot. Use a new one.
	Cuvette temperature is too low.	Let the cuvette warm up to room temperature. Test the same cuvette again.
	Cuvette temperature is too high.	Let the cuvette cool down to room temperature. Test the same cuvette again.
Test cancelled.	Blank too high.	Test the cuvette again. The blanking process has not been completed, or the sample may contain substances that create interference. In the latter case, the test cannot be completed.
	Unstable blank.	
	Error in reagent addition.	Perform a new test. There has been some problem during reagent addition. Make sure that the cap is properly closed.
	Instrument failure.	Perform a new test. If this message appears often, contact customer service.

10 SERVICE AND MAINTENANCE INFORMATION

The QuikRead go instrument has been designed to be as user-friendly as possible, with no need for regular maintenance. In the event of any repair requirements, please contact your local supplier.

Cleaning the instrument

Periodically clean the exterior of the instrument using a lint-free cloth dampened with water. Pay special attention to cleaning the display. Take care that no liquid comes in contact with the edges of the display, the measurement well, or the connectors.
If necessary, a mild detergent may be used. Do not use organic solvents or corrosive substances. Spills of potentially infectious material should be wiped off immediately with absorbent paper tissue and the contaminated areas swabbed with a standard disinfectant or 70% ethyl alcohol. Materials used to clean spills, including gloves, should be disposed of as hazardous biowaste.

Software updates

New software can be uploaded to the instrument via a USB drive, in line with the instructions presented on the screen. Ask your local supplier for more information.

Changing the clock battery

The instrument has a battery that supplies power to the internal clock. If the clock battery runs out, a warning is displayed. The clock battery can be replaced with a battery of the same type (CR 2032 3V).

1. Turn off the instrument (if it is on).
2. Unplug the power-supply cable.
3. Place the instrument on its side on a table.
4. Open the battery-compartment cover.
5. If a battery pack is inserted, unplug the battery-pack connector from it, and remove the battery pack.
6. Remove the clock battery from the battery-holder.
7. Place a new clock battery (type CR 2032 3V) in the battery-holder, text side down.
8. If a battery pack is being used, reattach the battery-pack connector to the battery pack, press the battery pack back into place, and ensure that it is positioned properly. Close the battery-compartment cover.
9. Place the instrument back in an upright position and plug in the power-supply cable.
10. Start the instrument by pressing the *Power* button.
11. Adjust the date and time (*Settings* > P*ersonal settings* > *Measurement flow* > *Maintenance* > *Date and Time*).

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