Revision History

Version and publication date	Change classification	Section of change
136852-10 05/2023	Technical change	Turning power on
		Audio volume
		Printing result
		Settings
		LIS transfer
		Saving measurement flow and Personal settings to Profiles for further use
		Basic settings
		Maintenance logs
		Security settings
		POCT1-A2 features
		TCP/IP settings
		WLAN settings
		Cleaning the instrument
		Changing the clock battery
		Troubleshooting / Fehlerdiagnose / Depannage / Risoluzione dei problemi
		Dimensions and power requirements
		Disposal
136852-10 05/2023	Regulatory change	Explanation of symbols
		Intended purpose
		QuikRead go Instrument
		Safety information
		Precautions and limitations
		During use
		Declaration of conformity
		Revision history
136852-10 05/2023	Correction	Accessories
		Connectors and cables
		Software update
		Security settings
		LIS connection

Change classification/ Klassifizierung ändern/ Classification de la modification/ Variazione della classificazione/ Klasifikace změny/ Klasifikácia zmeny/ Besorolás módosítása/ Zmiana klasyfikacji/ Muutoksen luokitus/ Ändringsklassificering/ Endringsklassifisering/ Ændring af klassifikation/ Clasificación de cambio/ Alterar classificaçã/ Classificatie wijzigen/ Spremeni klasifikacijo/ Promenite klasifikaciju/ Promjena klasifikacije/ Αλλαγή ταξινόμησης	Description/ Beschreibung/ Description/ Descrizione/ Popis/ Popis/ Leírás/ Opis/ Kuvaus/ Beskrivning/ Beskrivelse / Beskrivelse/ Descripción/ Descrição/ Beschrijving/ Opis/ Opis/ Opis/ Περιγραφή
New instructions for use/ Neue Anwendungshinweise/ Nouveau mode d'emploi/ Nuove istruzioni per l'uso/ Nový návod k použití/ Nový návod na použitie/ Nowa instrukcja użycia/ Új használati utasítás/ Uusi käyttöohje/ Ny bruksanvisning/ Ny brugsanvisning/ Ny bruksanvisning/ Nieuwe gebruiksinstructies/ Nuevas instrucciones de uso/ Novas instruções de utilização/ Νέες οδηγίες χρήσης/ Nova navodila za uporabo/ Novo uputstvo za upotrebu/ Nove upute za uporabu	First version of a new instructions for use/ Erste Version der neuen Anwendungshinweise/ Première version d'un nouveau mode d'emploi/ Prima versione delle nuove istruzioni per l'uso/ První verze nového návodu k použití/ Prvá verzia nového návodu na použitie/ Pierwsza wersja nowej instrukcji użycia/ Új használati utasítás első verziója/ Käyttöohjeen ensimmäinen versio/ Första version av ny bruksanvisning/ Første version af ny brugsanvisning/ Første versjon av ny bruksanvisning/ Eerste versie van nieuwe gebruiksinstructies/ Primera versión de unas instrucciones de uso nuevas
Correction/ Korrektur/ Correction/ Correzione/ Oprava/ Oprava/ Poprawka/ Javítás/ Korjaus/ Korrigering/ Rettelse/ Retting/ Correctie/ Corrección/ Correção/ Διόρθωση/ Popravek/ Ispravka/ Ispravak	Correction of documentation anomalies (minor typographical, grammar, and formatting changes are not included)/ Korrektur von Anomalien in der Dokumentierung (kleinere typografische, grammatikalische und Formatierungsänderungen sind nicht eingeschlossen)/ Correction d'anomalies dans la documentation (les modifications typographiques, grammaticales et de formatage mineures ne sont pas incluses)/ Correzione delle anomalie della documentazione (i piccoli refusi, la grammatica e le variazioni di formattazione non sono inclusi)/ Oprava odchylek v dokumentaci (drobné typografické, gramatické a formátové změny nejsou zahrnuty)/ Oprava odchýlok v dokumentácii (drobné typografické zmeny, gramatické zmeny a zmeny formátovania nie sú zahrnuté)/ Poprawka nieprawidłowości dokumentacji (drobne poprawki typograficzne, gramatyczne i zmiany formatowania nie są uwzględnione)/ A dokumentáció hibáinak javítása (kivéve a kisebb tipográfiai, nyelvtani és formázási módosításokat)/ Dokumentaatiovirheiden korjaus (ei sisällä pienten kirjoitusvirheiden, kielioppi- tai muotoiluvirheiden korjauksia)/ Korrigering av dokumentationsavvikelser (mindre typografiska, grammatiska och formateringsändringar ingår inte)/ Rettelse af uregelmæssigheder i dokumentation af afvigelser (mindre typografiske ændringer og grammatik- og formateringsændringer er ikke inkluderet)/ Retting av uregelmessigheter i dokumentasjon (mindre typografiske, grammatiske og formateringsrelaterte endringer er ikke inkludert)/ Correctie van fouten in de documentatie (wijzigingen in de typografie, grammatica en opmaak niet inbegrepen)/ Corrección de anomalías en la documentación (no se incluyen pequeños cambios tipográficos, gramaticales y de formato)
Technical change/ Technische Änderungen/ Modification technique/ Variazione tecnica/ Technická změna/ Technická zmena/ Zmiana techniczna/ Műszaki módosítás/ Tekninen muutos/ Teknisk ändring/ Teknisk ændring/ Teknisk endring/ Technische wijziging/ Cambio técnico/ Alteração técnica/ Τεχνική αλλαγή/ Tehnična sprememba/ Tehnička promena/ Tehnička promjena	Addition, revision and/or removal of information related to the product/ Hinzufügung, Änderung und/oder Entfernung von Informationen über das Produkt/ Ajout, révision et/ou suppression d'informations liées au produit/ Aggiunta, revisione e/o rimozione delle informazioni relative al prodotto/ Přidání, změna a/nebo odebrání informací souvisejících s produktem/ Pridanie, revízia a/alebo odstránenie informácií súvisiacich s produktom/ Ponadto redakcja i/lub usuwanie informacji związanych z produktem/ A termékkel kapcsolatos információ hozzáadása, felülvizsgálata és/vagy eltávolítása/ Tuotteeseen liittyvien tietojen lisäys ja/tai poisto/ Tillägg, omarbetning och/eller borttagning av information relaterad till produkten/ Tilføjelse, ændring og/eller fjernelse af oplysninger vedrørende produktet/ Tillegg, revisjon og/eller fjerning av informasjon knyttet til produktet/ Toevoeging, herziening en/of verwijdering van informatie over het product/ Adición, revisión o eliminación de información relativa al producto
Regulatory change/ Regulatorische Änderungen/ Modification réglementaire/ Variazione normativa/ Regulační změna/ Regulačná zmena/ Zmiana regulacyjna/ Szabályozási változás/ Sääntelyn muutos/ Regulatorisk ändring/ Regulatorisk ændring/ Regulatorisk endring/ Regulatieve wijziging/ Cambio normativo/ Alteração de regulamentação/ Κανονιστική αλλαγή/ Sprememba regulative/ Regulatorna promena/ Regulatorna promjena	Changes due to regulations, directives, laws and/or registration/ Änderungen aufgrund von Verordnungen, Richtlinien, Gesetzen und/oder Registrierung/ Modifications dues aux réglementations, directives, lois et/ou à l'enregistrement/ Variazioni dovute a normative, direttive, leggi e/o registrazione/ Změny z důvodu předpisů, směrnic, zákonů a/nebo registrace/ Zmeny z dôvodu predpisov, smerníc, zákonov a/alebo registrácie/ Zmiany z powodu przepisów, dyrektyw i/lub rejestracji/ Módosítások határozatok, irányelvek, jogszabályok és/vagy rendeletek miatt/ Asetuksista, direktiiveistä, laeista ja/tai rekisteröinneistä johtuvat muutokset/ Ändringar på grund av bestämmelser, direktiv, lagar och/eller registrering/ Ændringer som følge af regulativer, direktiver, love og/eller registrering/ Endringer på grunn av forskrifter, direktiver, lover og/eller registrering, Wijzigingen in voorschriften, richtlijnen, wetten en/of registratie/ Cambios debidos a normativas, directivas, legislación o registro/ Määrustest, käskkirjadest, seadustest ja
General change/ Allgemeine Änderungen/ Modification générale/ Variazione generale/ Obecná změna/ Všeobecná zmena/ Zmiana ogólna/ Általános módosítás/ Yleinen muutos/ Allmän ändring/ Generel ændring/ Generell endring/ Algemene wijziging/ Cambio general/ Alteração geral/ Γενική αλλαγή/ Splošna sprememba/ Opšta promena/ Opća promjena	Implementation of non-technical changes/ Implementierung von nichttechnischen Änderungen/ Mise en œuvre de modifications non technique/ Implementazione di variazioni non tecniche/ Implementace netechnických změn/ Implementácia netechnických zmien/ Wdrożenie widocznych dla użytkownika zmian/ Nem technikai jellegű módosítások végrehajtása/ Ei-tekniset muutokset/ Implementering av icke-tekniska ändringar/ Implementering af ikke-tekniske ændringer/ Implementering av ikke-tekniske endringer/ Implementatie van niet-technische wijzigingen/ Implementación de cambios no técnicos que

AIDIAN

QuikRead go®
Instrument

免疫浊度分析仪使用说明书

Explanation of symbols • 医疗器械标签所用的图形、符号、缩写等内容的解释

IVD	*In vitro* diagnostic medical device 体外诊断医疗器械		Mains cable 电源线
	Device for near-patient testing 用于床旁检测的器械		Consult instructions for use 使用说明书
SN	Serial number 系列号		Caution (See Precautions and limitations) 注意事项
REF	Catalogue number 货号		Temperature limitation 储存温度
	Manufacturer 生产企业		Fragile, handle with care 易碎，小心轻放
	Date of manufacture 生产日期		Keep dry 保持干燥
CONT	Contents 组件		China RoHS GB/T 26572 中国 RoHS GB/T 26572
	Instrument 仪器		Waste electrical and electronic equipment 废弃电子电机设备
	Power supply 电源适配器	**CH REP**	Authorised representative in Switzerland 在瑞士的授权代表

QuikRead *go* ®

Cat. No. 136196
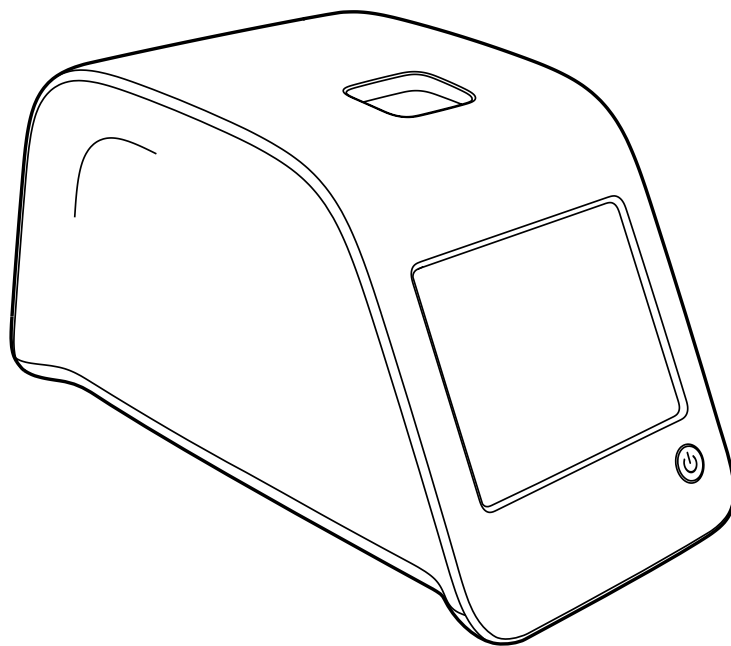
CONTENTS

1 INTRODUCTION

Intended purpose

QuikRead go® Instrument is an automated instrument designed and calibrated for both photometric and turbidimetric measurements. The instrument is intended for quantitative and qualitative determination of various QuikRead go® reagent kit analytes from human samples such as whole blood, serum, plasma, throat swabs and faecal samples to be used as an aid in diagnosis and treatment monitoring. QuikRead go Instrument is intended to be used by healthcare professionals in clinical laboratory and near patient testing settings.

Intended use

QuikRead go is an easy to use *in vitro* diagnostic test system. It has been designed to measure various analytes from patient samples needed as an aid in diagnosis and treatment monitoring. The system consists of QuikRead go Instrument and QuikRead go reagent kits.

QuikRead go Instrument

The instrument will guide you through the assay procedure by means of a series of messages and animations shown on the screen. In every start-up the instrument goes through a self-check routine assuring functionality of the instrument. QuikRead go Instrument measures the absorbance of the cuvette contents and converts the absorbance value into a concentration value or positive/negative result on the basis of preset test calibration data. The calibration data defining the overall assay curve or cut-off value for each test is encoded on each cuvette label. This information is transferred to QuikRead go Instrument automatically during the measurement.

The assays are performed according to the user instructions accompanying each QuikRead go reagent kit. The results are available in minutes.

The instrument can be operated on the mains power or with an accumulator, it has USB connections for an external printer or keyboard, or barcode reader.

QuikRead go Instrument can be connected to a remote Laboratory and Hospital Information System (LIS/HIS). The instrument uses a standardised data transfer protocol. Contact your local supplier for more details.

Safety information

For your own safety, comply with all warning and caution statements. To alert you to potential electrical or operational hazards, warning and caution statements are provided where applicable.

Before taking QuikRead go Instrument into use, please read the instrument's instructions for use, the following precautions and limitations carefully. In case of a serious incident, please report it to the manufacturer or its representative and/or national authority.

Precautions and limitations

- For *in vitro* diagnostic use only.
- Do not spill any liquids or drop any objects onto or into the instrument.
- Spillage 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 (see Section "Cleaning the instrument"). Material used to clean spills, including gloves, should be disposed of as biohazardous waste.
- Read beforehand and carefully follow QuikRead go reagent instructions for use supplied with each reagent kit.
- Only QuikRead go reagents can be used.
- Materials required but not provided are listed in QuikRead go reagent kit instructions for use.
- Do not mix components with different lot numbers or different assays.
- Never place a cuvette without a tightly placed cap into QuikRead go Instrument.
- 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 placed so that it is removable.
- Use only the official QuikRead go Instrument accumulator supplied by Aidian.
- The electromagnetic environment should be evaluated prior to operation of the instrument.
- Do not put your fingers or any external devices into QuikRead go Instrument during measurement.
- Do not remove or shut down a USB-device during data transfer.
- Do not open the instrument's covers by opening any screws. If the warranty seal is broken, the instrument warranty is not valid (see **Picture 3**).
- Use a secure internal network or Virtual Private Network (VPN) when connecting the QuikRead go Instrument to a LIS/HIS using LAN.
- Do not use or connect the instrument to LAN if the warranty seal is broken.

2 GETTING STARTED

Unpacking
Open the packaging box and check that it contains all the necessary items:
- Instrument
- Instructions for use
- Power supply
- Mains 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 local supplier.

Accessories
Printer
The instrument can be connected to an external printer. A list of compatible printers and configuration parameters can be found at **quikread.com**. Connect the compatible printer to a USB port and follow the instructions on the screen.

Barcode reader
An external barcode reader can be connected to QuikRead go Instrument. A list of compatible barcode readers can be found at **quikread.com**. Connect the compatible barcode reader to a USB-port and follow the instructions on the screen.

WLAN adapter
For a wireless network connection. Use only an adapter supplied by Aidian. Insert the adapter to any free USB port.

QuikRead go Instrument parts
The components of QuikRead go Instrument are shown in **Picture 1** (instrument from above), **Picture 2** (instrument from the rear) and **Picture 3** (instrument from below).
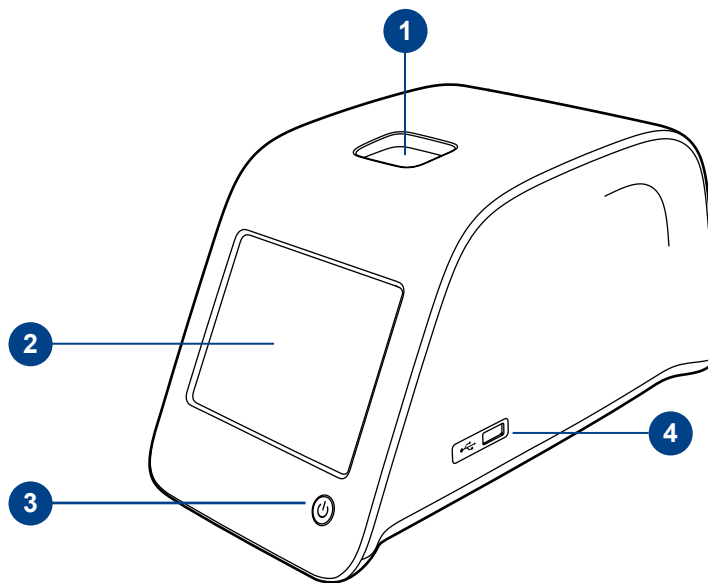
Picture 1
1. Measurement well for cuvette
2. Touch screen
3. Power button
4. USB-port 1 (type A)
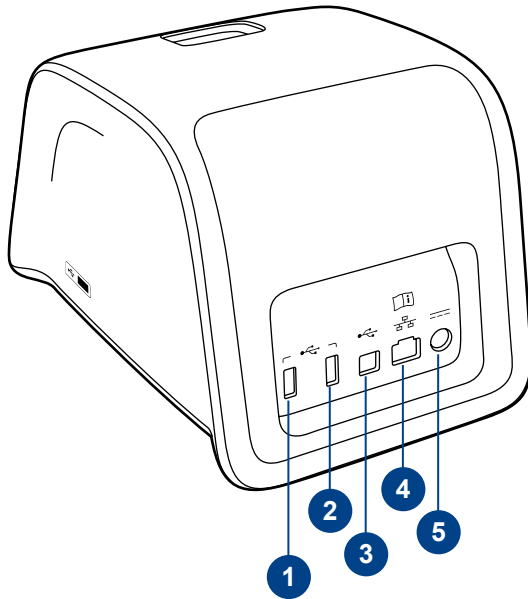
Picture 2
1. USB-port 2 (Type A)
2. USB-port 3 (type A)
3. USB-port 4 (Type B)
4. RJ-45 port
5. Connector for power supply
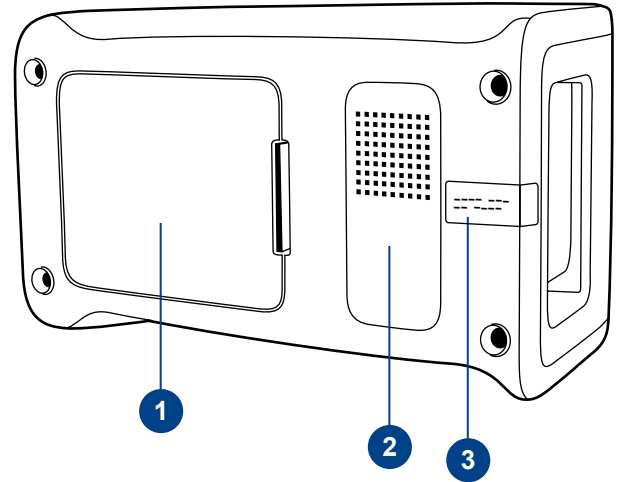
Picture 3
1. Accumulator unit cover
2. Instrument label with serial number
3. Warranty seal

Lifting/transporting the instrument

When lifting or transporting QuikRead go Instrument, always handle it carefully. In the back of the instrument there is a handle to enable lifting it by one hand (**Picture 4**).

A recess is added to the instrument side surfaces to help the grasp (**Picture 5**).
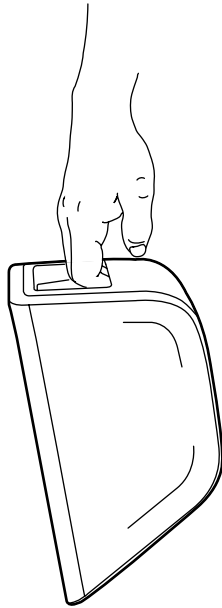
Picture 4
Lifting the instrument by one hand.

Picture 5
Lifting the instrument by two hands.

Location and environment

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

- Indoor use
- Altitude up to 2000 m
- The ambient temperature must be between 15°C and 35°C.
- Maximum relative humidity 80 % for temperatures up to 31°C decreasing linearly to 67 % relative humidity at 35°C (non-condensing).
- Mains supply voltage fluctuations up to ±10 % of the nominal voltage.
- Installation category II (2500 V transient).
- Do not place the instrument in direct sunlight.
- Place the instrument in such way that it is easy to turn power off and unplug the power supply cable.
- Do not place the instrument into a strong magnetic or electric field.
- Do not use this instrument in proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with proper operation.
- Do not move the instrument while a test is being measured.
- Do not measure in a moving vehicle.
- Pollution degree 2.

During transport and storage
- The ambient temperature must be between 2°C and 35°C.
- Protect from rain and humidity.
- Handle the instrument with care.

Power supply cable & accumulator

QuikRead go Instrument can be used either by the power supply cable or the accumulator.
The accumulator is charged automatically when the power cable is plugged in.

Connectors and cables

In the back of the instrument there are five connectors with symbols describing their use. One USB connector is placed on the right side of the instrument. All symbols are described in **Picture 6**.

The RJ-45 connector can be used for serial and LAN connections. Wiring diagram of the cable is described at **quikread.com.**

Plugging the power supply cable

Plug the power supply cable into the back of the instrument (see **Picture 7**). Plug the power supply into a power outlet.

Symbol	Description
USB	USB
RJ-45	RJ-45
Please consult instructions for use	Please consult instructions for use
Power	Power
On-Off switch	On-Off switch

Picture 6
Symbols on QuikRead go Instrument
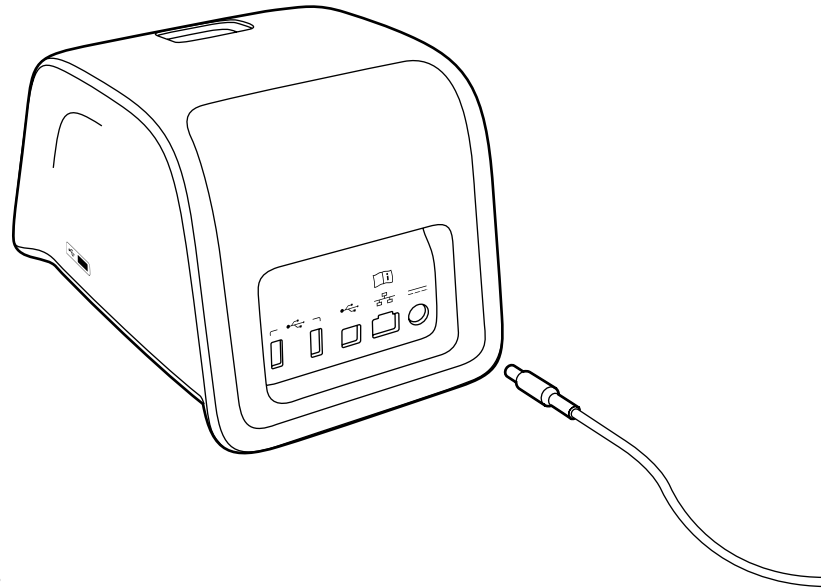
Picture 7
Connecting Power Supply Cable

Inserting the accumulator

Please follow carefully the steps below for inserting the accumulator to QuikRead go Instrument (see **Picture 8)**.

1. Turn off the instrument (if on).
2. Unplug the power supply cable.
3. Turn the instrument onto its side on a table.
4. Open the accumulator cover.
5. Attach the accumulator connector to the accumulator.
6. Press the accumulator into its place and ensure that it is placed properly.
7. Close the accumulator unit cover.
8. Turn the instrument back to a standing position.
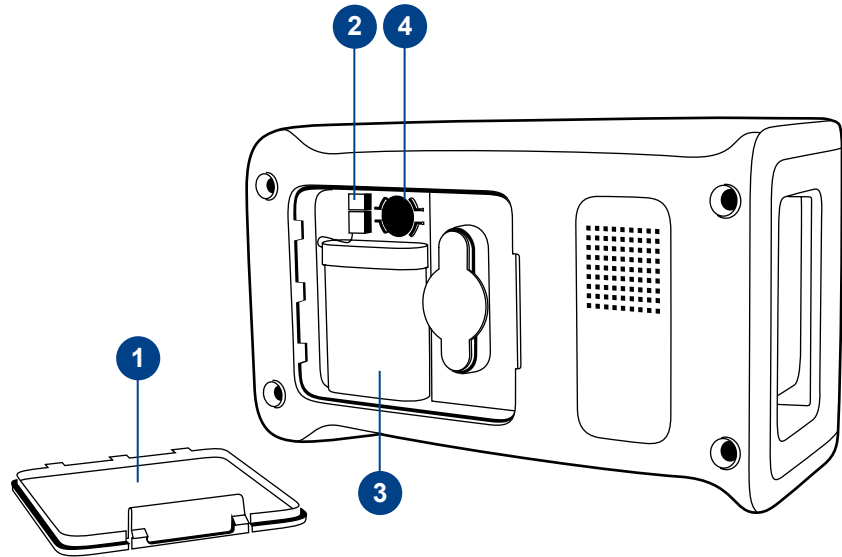
Picture 8

1. Accumulator unit cover
2. Accumulator connector
3. Accumulator unit
4. Clock battery

Power (on, off, sleep mode)

QuikRead go Instrument can be in three modes: on, off or sleep mode.

Turning power on

To turn the instrument on, press *Power* button on the front panel. The light on *Power* button will indicate that the instrument is powered on.

If nothing happens, ensure that the power outlet is connected, or if the instrument is on accumulator usage, that the accumulator is charged.

After pressing *Power* button, the backlight of the screen will light up, the instrument will start and proper function of the instrument is checked by the self-check procedure. After the successful self-check, the main menu will appear.

Starting QuikRead go Instrument for the first time will open Set-up wizard (see Section "Set-up wizard").

Turning power off

To turn the instrument off, press *Power* button for approx. two seconds. The instrument will ask you to confirm the shut down by asking "Do you want to shut down?". If Yes is chosen on the touch screen, the instrument will turn off. In case a cuvette was inside the instrument while shutdown, the cuvette will be lifted up and the instrument will ask you to remove it.

Sleep mode

The purpose of the sleep mode is to save accumulator charge in accumulator usage. The sleep mode will activate automatically when the instrument has been inactive for longer than the time chosen in Set-up wizard (see more Section "Set-up wizard"). The sleep mode functionality can be "Full standby" or "Close lid only".

The instrument indicates the sleep mode by blinking *Power* button light.

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

Use of the touch screen

QuikRead go Instrument has a colour touch screen. It is operated by touching the virtual buttons by fingers. The screen can be used both with bare fingers and with gloves on (see **Picture 9**). The touch screen does not require much pressure, and pressing too hard or using sharp items may damage the screen.

There is always a multisensorial feedback to touching a button: the button will indicate the touching both visually by changing appearance and with an audible sound.

A command is registered when the finger is released from the button touched. If the release happens outside the initial button area, no command is given.
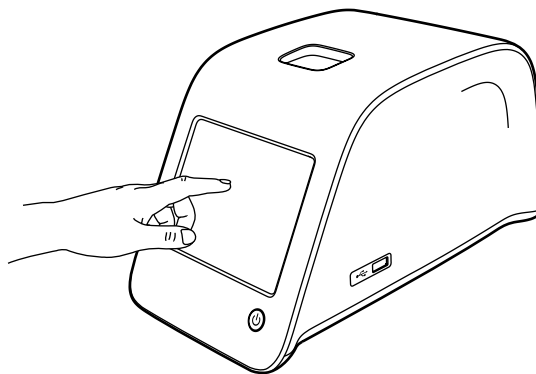
Picture 9
Using the touch screen by pressing the screen gently using a finger.

Set-up wizard

When starting QuikRead go Instrument for the first time, you will be asked to complete Set-up wizard. During Set-up wizard you will be asked to select e.g., the language, and to set the date and time. The default language is English. The language can be changed on the first step on Set-up wizard. Start Set-up wizard by choosing *Start* (see **Picture 10**).

Note: Set-up wizard can be started also manually from *Settings → Measurement flow → Maintenance → Basic Settings*.

```
┌─────────────────────────────────────────────────────────────┐
│              ▭  ▦  ║║║  🖨   L↓S  ▬▬▶ 10:30                    │
│  ┌────────────────────────────────────────────────────────┐  │
│  │ Set-up                                        WELCOME   │  │
│  │ ┌──────────────────────────────────────────────────┐   │  │
│  │ │                                                    │   │  │
│  │ │    Welcome to QuikRead go!                         │   │  │
│  │ │                                                    │   │  │
│  │ │    To start using the instrument we kindly ask     │   │  │
│  │ │    you to complete the following setup. This will  │   │  │
│  │ │    take only a few minutes.                        │   │  │
│  │ │                                                    │   │  │
│  │ │    On the next screen you are asked to choose the  │   │  │
│  │ │    language for the instrument.                    │   │  │
│  │ │                                                    │   │  │
│  │ │    Please choose *Start* below to start the set-up.│   │  │
│  │ │                                                    │   │  │
│  │ └──────────────────────────────────────────────────┘   │  │
│  │                                    ┌──────────────────┐  │  │
│  │                                    │      Start       │  │  │
│  │                                    └──────────────────┘  │  │
│  └────────────────────────────────────────────────────────┘  │
└─────────────────────────────────────────────────────────────┘
```
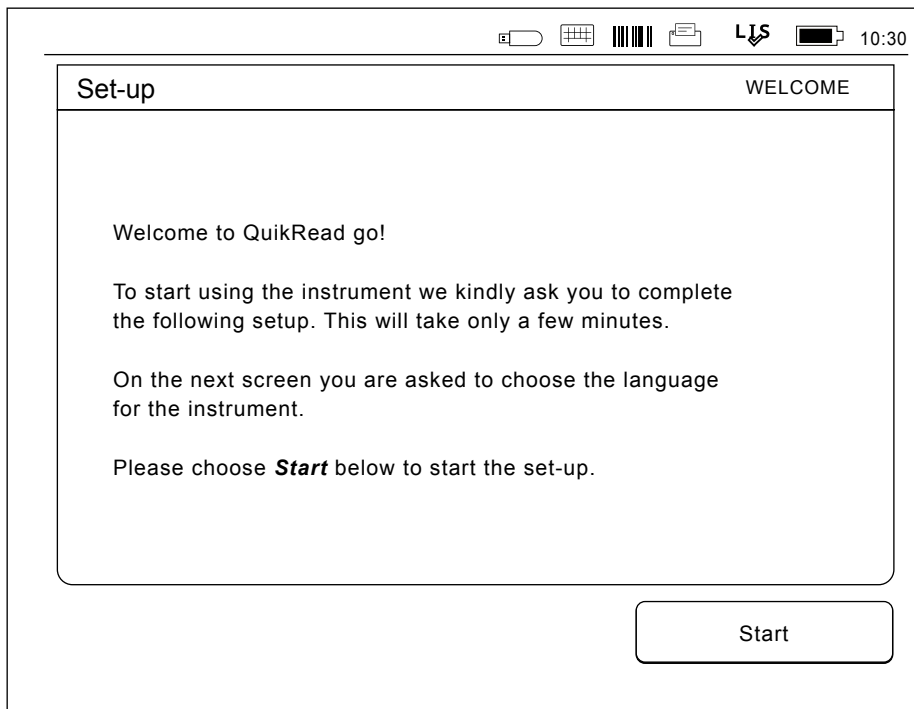
Picture 10
To start Set-up wizard, choose *Start* in Set-up screen.

Language

Choose the language you wish to use on the instrument. If you cannot see the desired language on the list, choose *More languages* for more options. Select the language by touching the corresponding button (see **Picture 11**).

You will then be asked to confirm your language choice. You will see the confirmation request both in English and in the chosen language. If the chosen language is correct choose *Yes,* if not, choose *No*.

Note: The chosen language can be changed any time from *Settings → Measurement flow → Maintenace → Basic settings*.

Set-up   LANGUAGE

SL	SR	HR	EL
FR	EN	DE	IT
NO	FI	SV	DA
CZ	SK	HU	PL
ES	PT	NL	

Back   More languages
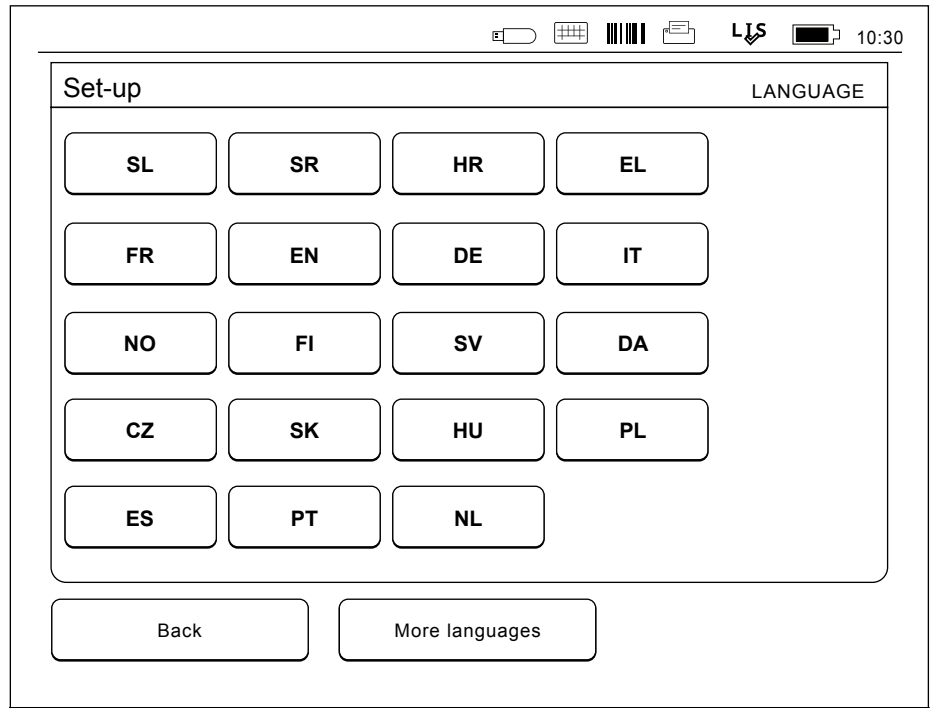
Picture 11
The first step in Set-up wizard is to choose the operating language for QuikRead go Instrument.

Date and time

The second step in Set-up wizard is to adjust the date and time (see **Picture 12**). To do this follow the instructions below:

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

Screen brightness

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

1. Adjust screen brightness with the arrow buttons.
2. Accept by choosing *Next*.
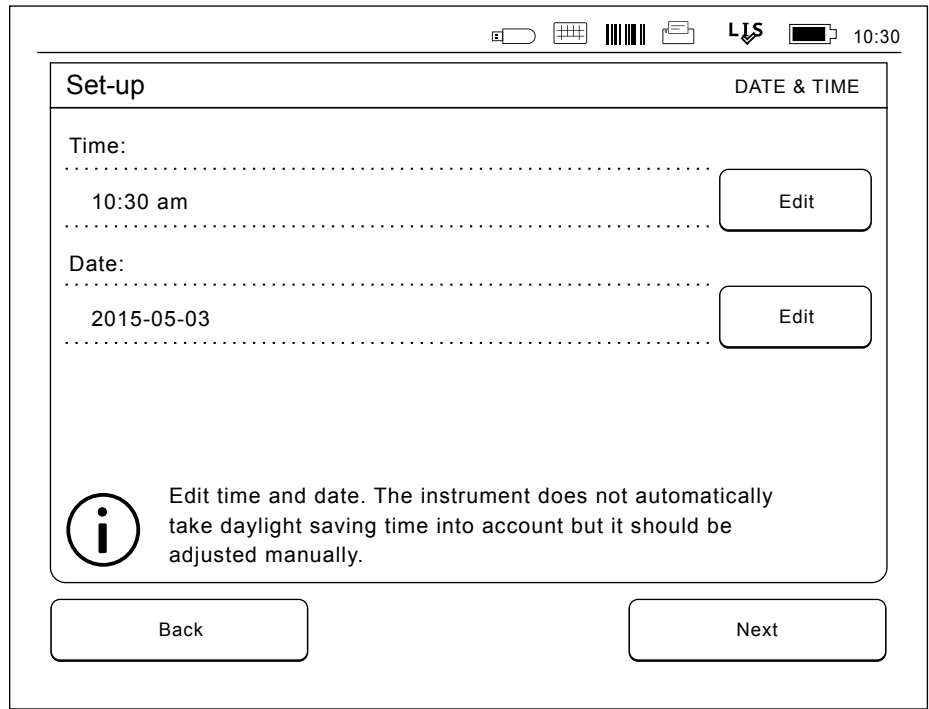
Picture 12

The second step in Set-up wizard is to adjust the time and date for the instrument.

Audio volume

The fourth step in Set-up wizard is to adjust audio volumes (see **Picture 13**):

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

Power save

Adjust the power save time to reduce power consumption when the instrument is being powered from the battery pack (see **Picture 14**). A lower time increases the operation time.

1. Choose the time after which QuikRead go Instrument will enter sleep mode (hibernate).
2. Choose the functionality of the sleep mode. In *Full standby* QuikRead go Instrument will enter the sleep mode and turn off the backlight of the screen after the time specified. In the *Close lid only* mode only the lid will be closed.
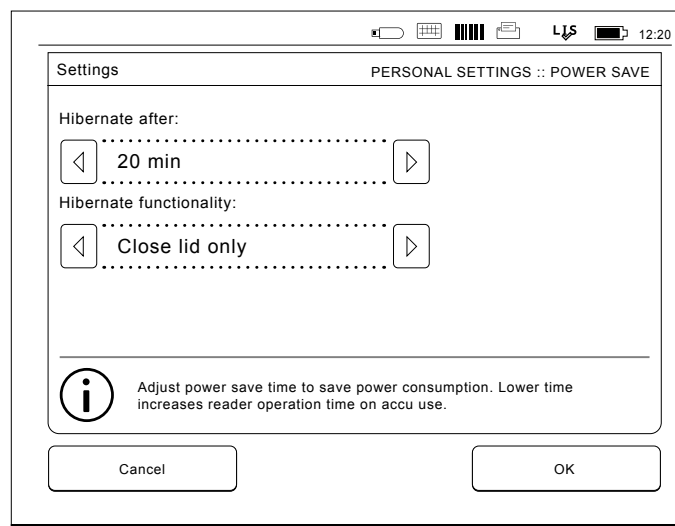
Finishing the Set-up wizard

You have now completed Set-up wizard. You may start using the instrument or continue making additional settings in *Advanced Set-up*, which takes you to *Measurement flow* where you can adjust laboratory- or work-routine oriented settings (see Section "Measurement flow").

Picture 13 The fourth step in Set-up wizard is to adjust audio volumes.

Picture 14 Power save

User interface in general

QuikRead go Instrument is used via a graphical user interface. In this section the main principles of the user interface are explained.

Main menu

All the features of the user interface can be accessed via the main menu (see **Picture 15**).

Status area symbols

The status area may contain the following symbols (see **Picture 16**):

Picture 15

	Measure	
Quality control		Results
Settings		Profiles
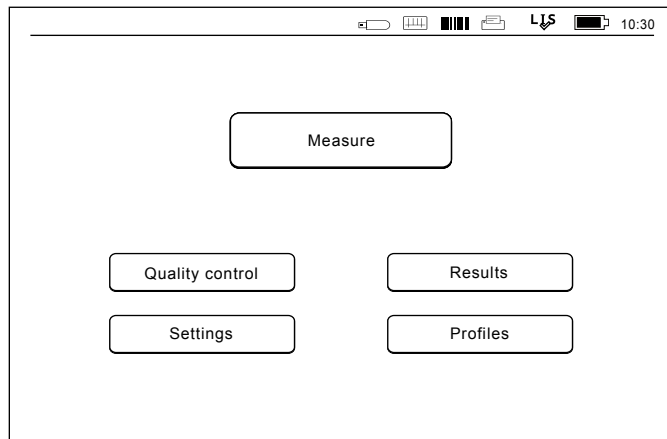
LIS Connection state:

LIS ✓ LIS online

LIS ⚠ LIS offline

LIS ? LIS pending

POCT state:

LIS ✉ Messages in queue

🔒 Instrument locked

Power state:

⌁ Mains condition ok

⌁ Mains condition disorder (symbol red)

▬ Accumulator power condition ok

▭ Accumulator power condition low (symbol red)

🕐 Real-time clock battery power condition low (symbol red)

Others:

‖‖‖ Barcode

🖶 Printer

▭ USB storage

⌗ Keyboard

Feeder Connected to QR go Feeder

Picture 16
Status area symbols

Layout

The screen area of the user interface is divided into five functional areas (see **Picture 17a and 17b**):

1. Status area
   Indicates the status of QuikRead go Instrument via symbols.

2. Notification area
   Indicates the current stage of the process via colour. The default colour is grey, while green means that something is currently being performed, yellow means that a user action is needed and red indicates an error.

3. Content area
   The actual data is at the centre of the screen.

4. Information area
   On most screens there is additional information for guidance.

5. Navigation area
   Standard buttons for navigation can be found at the bottom of the screen.
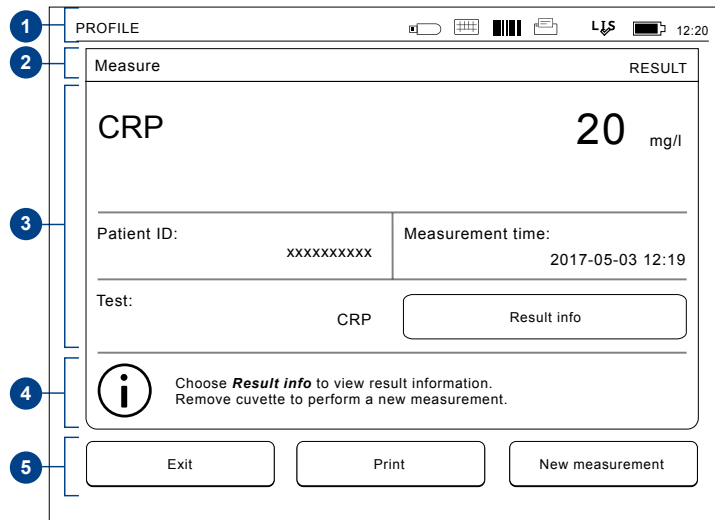
Picture 17a Result screen
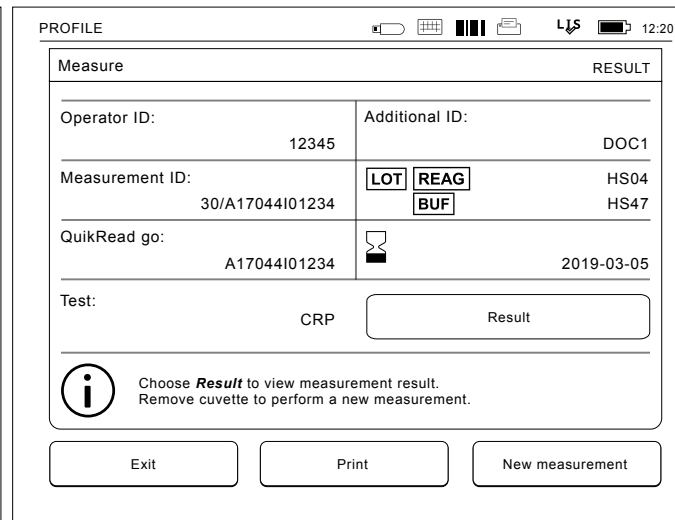
Picture 17b Result info screen

Structure of the user interface

The structure is different depending on whether the Security login is enabled in *Settings → Measurement flow → Maintenance → Admin settings → Security settings*. (see **Picture 18a and 18b**):

Their functionality is described in the next chapter.

User interface structure without Security login feature:

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

User interface structure with Security login enabled:

1. Measurement
2. Quality control
3. Results
4. Settings
5. Logout
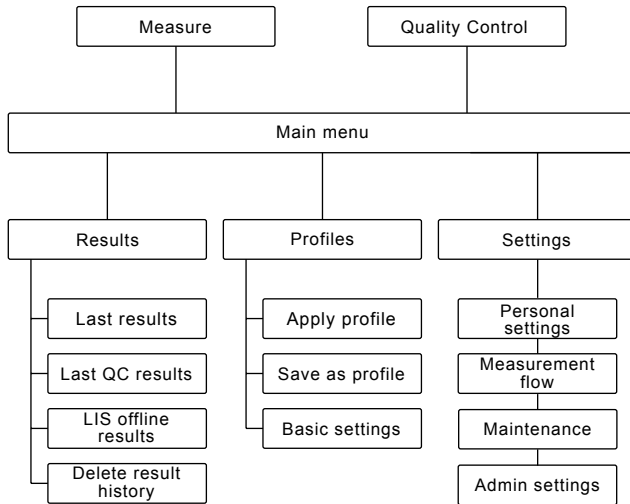
Picture 18a
The user interface structure without the Security login feature.
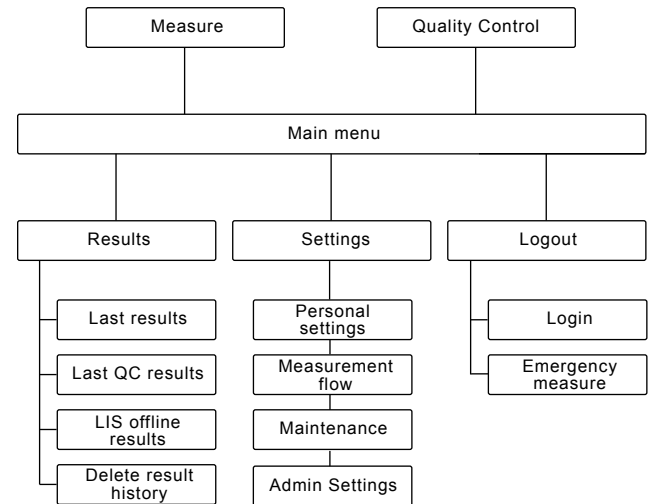
Picture 18b
The user interface structure with Security login enabled.

3 USAGE

The usage of QuikRead go Instrument can be divided into 3 main operations:

- Performing an assay
- Viewing results
- Changing instrument settings

Performing an assay

The instrument can be set to different measuring modes as needed. The basic measuring mode uses the simplest measuring protocol and is set as default in a new instrument if settings have not been changed when taking the instrument into use (see **Picture 19**).

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.
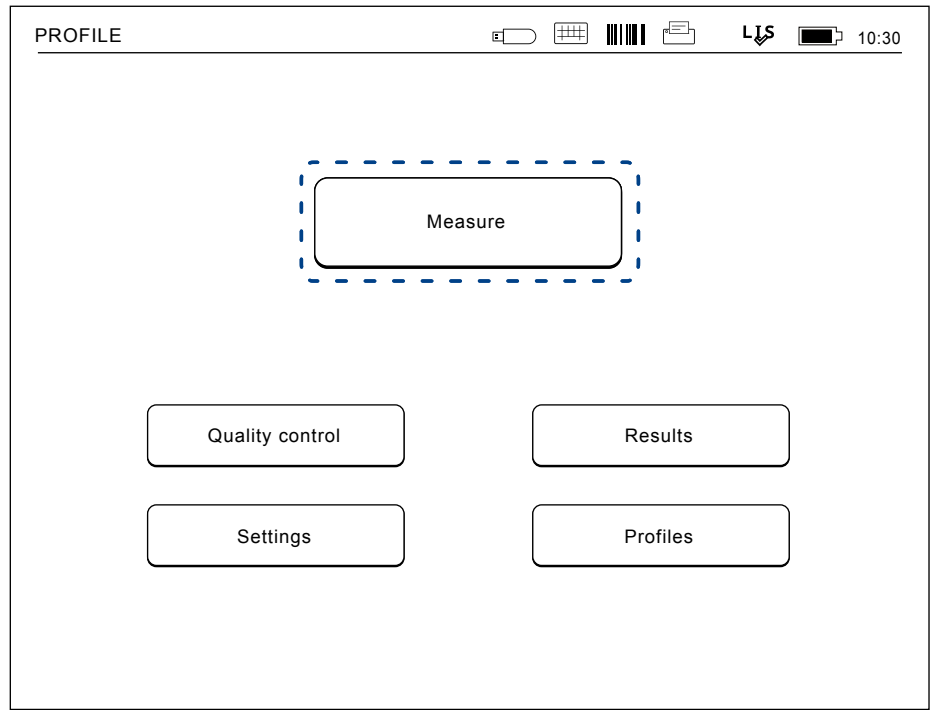
Picture 19
Start a basic measurement by choosing *Measure* on the main menu.

Performing an assay in basic measuring mode

In the basic measuring mode QuikRead go Instrument performs an assay measurement and shows the result on the screen with reagent lot data.

To perform a measurement do the following:

1. Choose *Measure* on the main menu and follow the instructions on the screen (see **Picture 19**).
2. Drop a cuvette into the measurement well in the right position. The barcode of the cuvette must be facing towards you (see **Picture 20**).
   Note: Do not place a finger or any other object 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 screen and the cuvette lifted up for removal. Choose *Result info* to see additional information of the test (see **Picture 17b**).
5. Remove the cuvette. The result disappears from the screen. It can be displayed again by choosing *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 measuring mode

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

Other measuring modes

The instrument can be used in different measuring modes in addition to the basic measuring mode. The optional protocols include the use of Patient ID, Operator ID, printing the results or sending the results to an LIS (Laboratory Information System). The measurement protocol is defined in the settings menu where these features can be enabled or disabled. If Security login is enabled, it replaces Operator ID.

Operator and Patient IDs can be given via a barcode reader or written with the instrument's virtual keyboard or an external keyboard. The user feeds Operator and Patient IDs before the measurement. Optionally, either or both IDs can be disabled in configurations.

Operator ID can also be configured to propose the last input value. The user may change Operator ID before a measurement by overwriting the last ID with a new one.

The measurement results can be sent to a printer and/or to an LIS by enabling printer and/or LIS transfer.

Picture 20
Drop a cuvette into the measurement well so that the barcode is facing towards you.

Results

The results are stored in *Results* file, where they can be viewed, printed or transferred to USB storage. *Results* file consists of the following submenu items: *Last results, Last Quality Control results, LIS offline results* and *Delete result history*.

LIS offline results are stored in the memory of QuikRead go Instrument which is normally connected to an LIS but has temporarily been in LIS offline mode, e.g. during a home or a ward visit.

Viewing results

To view the results choose *Results* in the main menu. You can select *Last results* or *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*, *Test* or *Patient ID* by choosing the relevant buttons. Touching a result line gives detailed information of a single measurement.

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

To print results, choose *Last results*. By touching a result line it is possible to print a single result. The results can also be print sorted by *Time*, *Test* or *Patient ID*. Touch the desired sorting criterion and then touch *Print* button. Select the results to be printed through ▥ buttons (see **Picture 21**). Choose *OK* to start printing.

Transferring results to USB storage

The results can be transferred to a USB storage. Connect a USB-storage to a USB port. Choose *Transfer to USB*, select the results to be transferred and choose *OK (*see Section "Printing results")*. Don't remove the USB storage until the transfer is completed. After completion of the transfer a message "Transferring completed. You can now safely remove the USB storage." will be shown.

Sending offline results to LIS/HIS

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

QuikRead go Instrument checks the LIS connection automatically during start-up, when entering the main menu and after every measurement. If a connection is available and there is data in the LIS offline result history, QuikRead go Instrument automatically proposes sending the offline results to the LIS.
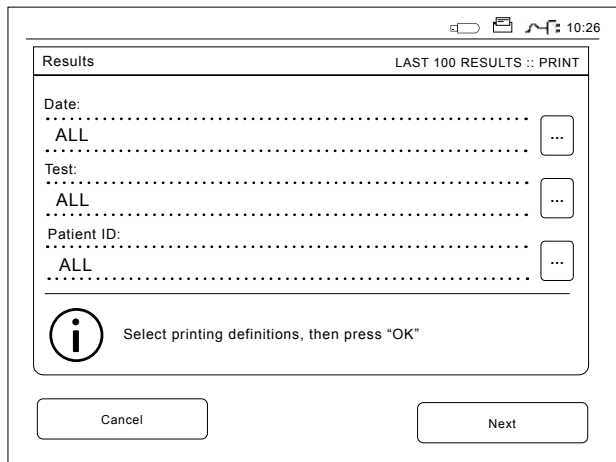
Picture 21
Pringting results

Settings

QuikRead go Instrument settings can be configured through the touch screen. The settings are divided into 4 main categories.

- Personal settings
- Measurement flow
- Maintenance
- Admin settings

Saving changes into Personal settings and Measurement flow settings is done by saving them as profiles and can be taken into use later on by applying a profile after start-up. Otherwise, the changes will only take effect until the instrument is shut down.

Changing the factory settings is done with the Set-up wizard. When started for the first time the instrument uses the factory settings. If Security login is enabled, there will be different user roles with different user rights in use, see the table User roles and rights on page 34.

Personal settings

In Personal settings the operator can adjust or choose user oriented settings (see **Picture 22**). These settings can be selected for temporary use until shut down of the instrument. For further use these settings need to be saved to *Profile* (see Section "Profilies"). For continuous use the settings should be configured with the Set-up wizard: *Settings → Measurement flow → Maintenance → Basic settings.*

Language

The language has been selected with Set-up wizard. Here it is possible to change the language by choosing *Language* and selecting desired language. Accept by *YES* or reject by *NO*.

Screen

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

Volume

Sound volume can be adjusted by choosing *Volume*. Adjust the keypad tone volume and the alert tone volume by touching the *arrow*-buttons. Accept by *OK* or reject by *Cancel*.

Power save

The time after which QuikRead go Instrument closes the lid – without entering sleep mode – can be adjusted from *Power save → Close lid only*. Adjust the delay value using the arrow buttons.

The instrument will close the lid without entering the sleep mode (activating the hibernation function) if it has not been used for the amount of time specified. This mode does not disrupt any LIS/HIS connection.

The time after which QuikRead go Instrument enters sleep mode can be adjusted from *Power save → Full standby*. Adjust the delay value using the arrow buttons. The instrument goes from idle
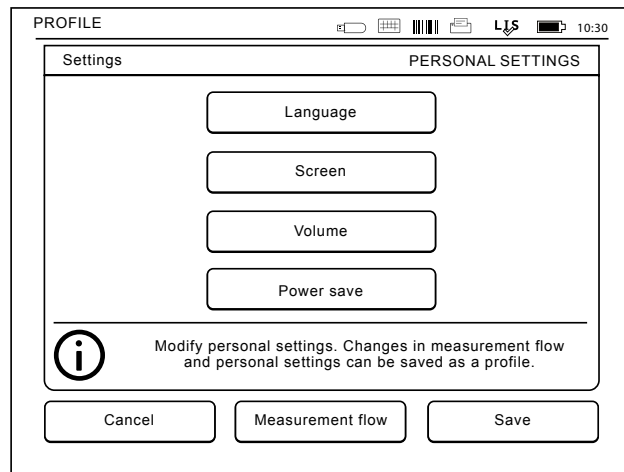
Picture 22
Personal settings menu

mode into sleep mode if it has not been used for the amount of time indicated. Entering the sleep mode closes any active LIS/HIS connection. Accept the settings by *OK*, or reject by *Cancel*.

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

Saving setting to profiles for further use
On the main menu screen choose *Profiles*. Choose *Save as profile*, select an empty profile and name it or select a profile you'd like to modify, give the profile a new name if needed and accept by *OK*.

Measurement flow
In Measurement flow settings the operator can adjust or choose laboratory/work routine oriented settings like Operator and Patient IDs, printing, LIS transfer and some test specific parameters (see **Picture 23**).
These settings can be selected for temporary use by choosing *Save* after making the changes.
For further use the settings need to be saved to a Profile. For continuous use the settings should be configured with Set-up wizard: *Settings → Measurement flow → Maintenance → Basic settings*.

Operator ID
is an identification 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, and the ID is coupled with the test result.
- *Operator ID ON + Propose previous*: The in-

strument suggests a previous ID to be used, but it can also be changed.

Patient ID
is an 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 given before every measurement, and the ID is coupled with the test result.

Test parameters
Some test specific parameters can be changed. Changes require giving the ADMIN password, which is QRGOSET. Choose ⬛ / Test parameters and the corresponding Test. A list of parameters to be configured will be shown.

Quality control (QC) checking
These settings are for quality controls. Quality control lots can be used to automate QC checking. Enter and edit information of quality control lots here. If POCT1-A2 is in use, information of a new lot to be sent to LIS/HIS can be entered here, but cannot be edited manually.
QC checking can be configured to give a warning only or it can be configured to disable patient measurements if the quality control measurement is outside the critical limits. A successful quality control measurement will re-enable patient measurements. Setting QC checking OFF and ON again will also reset QC lock and re-enable patient measurements.
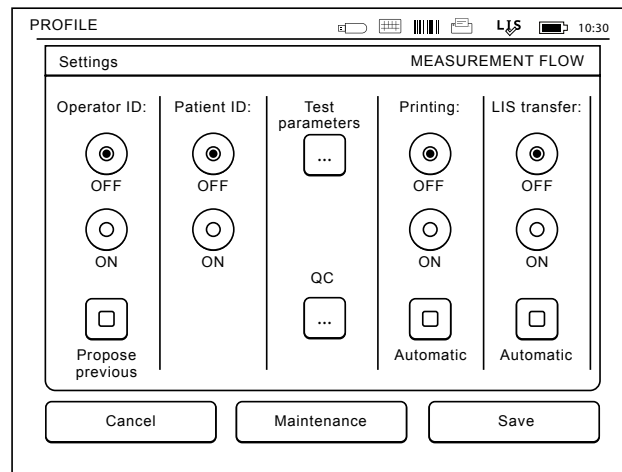
Picture 23
Measurement flow menu

To turn QC checking on, choose ▦ / QC and enter the ADMIN password, QRGOSET (see **Picture 24**).

- QC *checking OFF*: Quality control checking is not in use.
- QC *checking ON*: Quality control checking is in use.
- *QC lock*: If this is chosen, the instrument will be locked if a quality control result is outside the critical limits.

To set a new quality control sample, follow the instructions below:
1. Choose *Settings → Measurement flow → QC*. Give the administrator password.
2. Choose *New lot*.
3. Select the test from *Test* list.
4. Enter *QC lot ID* (mandatory).

5. Select the unit from *Units* list (mandatory).
6. Set *Warning range* limits (optional).
Note: Decimals must be marked with a decimal point rather than a comma.
7. Set *Critical range* limits (mandatory).
8. Set T*arget valu*e (mandatory).
9. Choose *Next*.
10. Enter the expiration date (mandatory).
11. Accept twice by pressing *OK*.
12. Choose *Back*.
13. Choose *Save*.

The quality control lot has now been defined.The parameters of a lot can be edited or the lot deleted by choosing the line and selecting *Edit* or *Delete*. When starting a Quality control measurement, the quality control lot can be chosen from the list by choosing ▦

Picture 24
QC lot properties

Printing
- *Printing OFF*: The instrument does not suggest printing. It is nevertheless possible to print the result by choosing *Print* on 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*. On the result card, select *Comment* to add a comment to the result before transferring the result.
- *LIS transfer ON + Automatic*: The instrument sends the measurement result automatically to the LIS.

Contact your supplier for more details about LIS connection.

Saving Measurement flow and Personal settings to Profiles for further use
The above settings can be saved to *Profiles* if desired (see more Section "Profiles"): On the main menu screen choose *Profiles*. Choose *Save as profile*, select an empty profile and name it or select a profile you'd like to modify, give the profile a new name if needed and choose *OK*.

Maintenance settings

The instrument specific settings can be configured in the Maintenance menu: *Settings → Measurement flow → Maintenance.*

Basic settings

When wanted to make permanent setting changes, they are made through *Basic settings*. The basic settings contain all the same settings as Set-up wizard.

Date & time

Date & time can be adjusted by choosing *Date & Time*. To do this follow the instructions below:

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

Error log

The instrument error codes are stored in the memory. Error codes can be scrolled with the up and down arrows on the right or they can be sorted by choosing *Time* or *Error* code.
Error codes can be transferred to a USB storage.

1. Choose *Transfer to USB*.
2. Connect a USB storage to a USB port. Wait until the screen shows: "Transferring completed. You can now safely remove USB storage."

3. Choose *OK* and remove the USB stick.
4. Choose *Back* to return to Maintenance menu. *Delete Error log* button deletes all error codes from the memory. Before deleting a confirmation text is shown.

1. Accept by *Yes* or cancel by *No*.
2. Choose *OK* on the Error log deleted screen.
3. Choose *Back* and *Cancel* and return to the main menu.

Self-diagnostics

The instrument performs operational checks to ensure proper functioning. Perform a 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 available via the website softwareupdate.quikread.com or it can be ordered to be delivered on a USB storage device. Choose *Settings → Measurement flow → Maintenance → Software update*.

Note: If the instrument has an accumalator, remove it before starting updating.

Connect the storage to a USB port. The version numbers of current and new software will be shown on the screen. 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 touch screen can be calibrated to optimise the usability of buttons. Start the calibration by choosing *Touch screen calibration*. Calibrate the touch screen by touching each of the black circles in turn. After "Touch display calibration succeeded" choose *OK*.

Product information

About screen shows instrument-specific details:
• Instrument serial number
• Software version number
• LIS connection details

Maintenance logs

Instrument logs and Security logs can be transferred to USB storage. For Security logs set LIS logging ON (*Admin settings → LIS features*), restart the instrument and use the instrument normally for the time required. Security logs can also be deleted. Transferring to USB storage does not empty the log files.

Admin settings

The administrative settings (*Settings → Measurement flow → Maintenance → Admin settings*) allow administrative personnel to adjust instrument-specific settings regarding LIS connection, GMT value, Security settings and QuikRead go Feeder settings. *Factory reset* can also be started from here.

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

GMT

GMT is a universal time against which the instrument's time is set. GMT is not visible to the user but is an internal clock for the instrument.

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

Internal clock

• Date and time have been adjusted to GMT at the factory.
• Date and time are stored in the memory once a day at start up.
• If the clock battery runs out, the clock stops. When the battery has been replaced, the clock continues from the last saved time. The time is adjusted in the Admin settings and requires a password. A new adjusted time cannot be before the last saved time. Giving too old a time will create an error message.

Local time

• Adjust the time according to the local time (*Set-tings → Measurement flow → Maintenance: Date & time*). The local time is saved to the memory as an offset to GMT.
• When changing the clock battery, adjust the time and date. The time cannot be adjusted to more than 24 hours before the last saved GMT. Giving too old a time prompts an error message "Setting of date failed. Date is in the past."

Security settings

When *Security settings* is set ON, user must always log in to QuikRead go Instrument with Operator ID and password before starting to use the instrument. Only emergency measurements can be measured just with Operator ID, without a password. All users have a role and need a user account with Operator ID, full name and password. User roles are

Admin:
• only one per instrument, Operator ID is ADMIN. The ID is not modifiable.

Supervisor:
• has access to all except for performing factory reset and deleting security logs.

Normal User:
• can set user specific settings.
• can see QC and LIS offline results, and optionally old patient results.
• can add new QC lots locally when doing a Quality control measurement. QC checking needs to be ON.
• can see error log and transfer the log to a USB storage device.
• features not accessible are greyed out.

See table on page 34 of user roles and rights.

Picture 25
Security settings
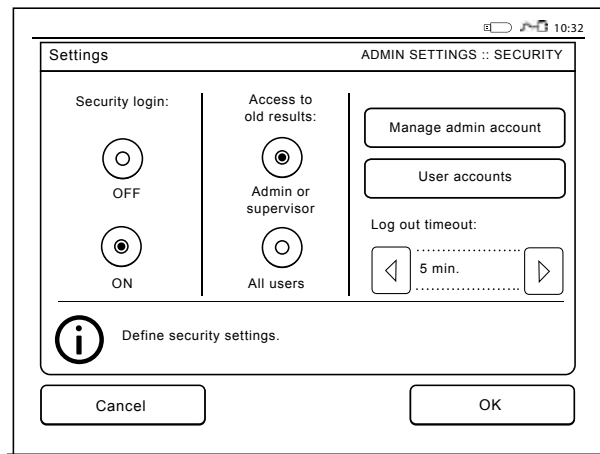
To take Security settings into use, go to *Settings → Measurement flow → Maintenance → Admin settings → Security settings* (see **Picture 25**).

- Select *Security login ON*.
- Define access to old results.
- Admin password can be changed in *Manage admin account*. Default admin password is QRGOSET.
- Set up user and supervisor accounts in *User accounts*.
- Adjust time after a user will be logged out. This is different to the hibernate settings in *Power save*. If Full standby option in Power save is in use, the user will be logged out when QuikRead go Instrument enters sleep mode. The user can also log out manually.

In case of a lost or forgotten Admin password, request a temporary password at **softwareupdate. quikread.com**. You will need an instrument serial number to proceed. The temporary password is valid for one week and can only be used once to reset the instrument to factory settings.

LIS settings

From LIS settings option (*Settings → Measurement flow → Maintenance → Admin settings*), 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 about LIS connection.

LIS features

Select the following features OFF or ON.

- *LIS logging*. When set ON, LIS traffic will be logged.

- *Identify QC result*. When set ON, QC results will have a special identification in LIS communication.
- *LIS delay*. When set ON, there will be a short delay between consecutive results sent to LIS. A delay can be useful in solving congestion issues with older serial-type connections.
- *Additional ID*. When set ON, on top of Patient ID and Operator ID a third sample ID can be added, e.g. patient birthdate or Doctor ID. Additional ID can be taken into use also with QuikRead go instruments not connected to LIS.

POCT1-A2 features

Select the following features OFF or ON.

- *Operator login*. When set ON in POCT1-A2 features settings, all users need to log in always before starting to use QuikRead go Instrument. User information has to be provided by the POCT1-A2 server.
- *Patient ID validation*. When set ON, Patient IDs will be checked against a downloaded patient list before sending results to the LIS.
- *Patient data shown*. When set ON, patient data will be shown before a measurement starts.
- *Emergency button shown*. When set OFF, emergency measurement is disabled in login screen. The emergency measurement can be taken into use also with QuikRead go instruments not connected to LIS.

TCP/IP settings

Select the type of LIS connection used. The correct settings should be asked from an administrative person responsible for the LIS-system.

WLAN settings

Select the type of WLAN connection used by choosing *Scan* or *Manual setup*. Use only an adapter supplied by Aidian. You can insert the adapter to any free USB port. **Note:** Use only the strongest available security policy.

Character encoding

Select the type of character encoding used for LIS01-A2 protocol.

Factory reset

The user interface can be restored to factory settings. Factory reset deletes all profiles and results, and empties the error log. In instruments where Security login is enabled, the Factory reset deletes security logs as well. After a Factory reset all user accounts need to be recreated.

Manufacturer settings

This section is only for the manufacturer's use.

Profiles

User adjusted settings can be saved as profiles for later use. Four different user profiles can be saved to the instrument's memory. Profiles are not in use, if Security login is enabled.

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 an (empty) 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* sets the instrument to work according to basic settings set by Set-up wizard.

4   MAINTENANCE

QuikRead go Instrument has been designed to be as user-friendly as possible with no need for regular maintenance. For any repair requirement, contact your local supplier.

Instrument calibration

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

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

Cleaning the instrument

Periodically clean the exterior of the instrument using a lint-free cloth dampened with water. Pay special attention to cleaning the screen. Take care that no liquid runs onto the edges of the screen, the measurement well or the connectors.

If necessary, a mild detergent may be used. Do not use organic solvents or corrosive substances. Spillage of potentially infectious material should be wiped off immediately with absorbent paper tissue and the contaminated areas swabbed with 70% ethyl alcohol, Desicton (Kiilto), 0.5% sodium hypochlorite or Super Sani-Cloth® Germicidal Disposable Wipe. For safety, use chemical resistant gloves and follow the instructions in the safety data sheet. Materials used to clean spills, including gloves, should be disposed of as biohazardous waste.

Software update

New software can be uploaded to the instrument with a USB storage, see page 25. Ask your local supplier for more information.

Changing the clock battery

The instrument has a battery which gives power to the internal clock. If the clock battery charge is empty a warning is displayed. The clock battery can be replaced with a same type of battery (type CR 2032 3V).

1. Turn off the instrument (if on).
2. Unplug the power supply cable.
3. Place the instrument onto its side on a table.
4. Open the accumulator unit cover.
5. If an accumulator is in place disconnect the accumulator connector from the accumulator and remove the accumulator.
6. Take the clock battery out of the battery holder.
7. Place new clock battery (type CR 2032 3V) into the battery holder on the plus side facing you.
8. If an accumulator is used, attach the accumulator connector to the accumulator and press the accumulator into place and ensure that it is placed properly. Close the accumulator unit cover.
9. Turn the instrument back to a standing position and plug the power supply cable.
10. Start the instrument by pressing the *Power* button.
11. Adjust the date and time (*Settings → Personal settings → Measurement flow → Maintenance → Date and Time*).

5 TROUBLESHOOTING

QuikRead go Instrument displays error messages and guides the user in case it detects errors. Follow the instruction displayed and see the troubleshooting table in this instruction for use and in QuikRead go kit instruction for use.

Contact your local supplier in case of needed support or a repair requirement.

Error message / Troubleshooting	Possible cause	Corrective action
Error code with the message "Please restart QuikRead go" is displayed.	Temporary malfunction of the instrument.	Restart the instrument. If this error message is displayed frequently, contact customer service.
Error code with the message "Please contact customer service" is displayed.	Permanent malfunction of the instrument.	Contact customer service.
"Accumulator level is low. Please connect to the mains cable in order to continue operation" error message is displayed.	Charge in accumulator is low.	Connect the power unit into QuikRead go Instrument power connector.
"Cuvette position not correct. Remove cuvette." error message is displayed.	Remnants of cuvette sealing foil is left on the cuvette collar.	Remove cuvette when the instrument has lifted it up. Make sure that all remnants are removed when doing the next measurement.
	The instrument has a mechanical malfunction.	Check the item above. If it does not apply, restart the instrument. If the problem persists, contact customer service.

Error message / Troubleshooting	Possible cause	Corrective action
"Measurement prohibited."	Reagent cap is missing or cuvette is used.	Check that the cuvette has a reagent cap and the inner coloured part of the cap is not pressed down.
	Reading lot data from the barcode failed.	Try again. If the problem persists, cancel the test.
	Kit lot expired.	Discard expired kit lot. Use a new one.
	Cuvette temperature too low.	Let the cuvette warm up to room temperature. Test the same cuvette again.
	Cuvette temperature too high.	Let the cuvette cool down to room temperature. Test the same cuvette again.
"Test cancelled."	Blank too high.	Test the same cuvette again. The blanking process has not been completed or the sample may contain interfering substances. 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.
QuikRead go Instrument does not start.	Power unit is not connected.	Connect power unit and retry.
	The instrument has an electronic malfunction.	Contact customer service.

Error message / Troubleshooting	Possible cause	Corrective action
Touch panel on screen is not functioning properly.	Touch calibration is not correct i.e. the active area is not under the button.	Calibrate the touch screen according to the procedure described in the Maintenance chapter.
	Touch panel is not responding at all.	Contact customer service.
Instrument alarm sounds cannot be heard.	Volume is set at a low level.	Set volume according to the procedure described in the Section "Personal settings".
	Instrument sound system has a malfunction.	Restart QuikRead go Instrument. If the problem persists, please contact customer service.
Printer is not printing.	The printer is off or the printer cable is not connected or the printer has malfunction or the settings are not correct.	Make sure that the printer is connected and its power is on. Check the settings. If the problem continues start-up the instrument and printer and retry printing from the Results menu. If problem continues, contact customer service.
Barcode reader is not functioning.	The barcode reader is not connected or the barcode reader has a malfunction or the settings are not correct.	Make sure that the barcode reader is connected. Check the settings. If the problem continues start-up the instrument and retry the barcode reading. If problem continues, contact customer service.
Accumulator must be re-charged frequently.	Accumulator storage capacity decreases during its life time.	Replace the old accumulator with a new one according to the procedure described in the Section "Inserting accumulator".
Clock battery warning is displayed.	Internal clock battery is empty.	Replace the clock battery according to the procedure described in the Section "Changing the clock battery".

6 INSTRUMENT SPECIFICATION

Declaration of conformity

QuikRead go Instrument complies with the regulation (EU) 2017/746 on *in vitro* diagnostic medical devices, the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment together with the delegated directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU and the directive 2012/19/EU on waste electrical and electronic equipment (WEEE).

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

Technical specification

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

Photometer

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

Touch screen display

The user interface is based on an easy-to-use touch screen display. It is used by touch buttons that appear on the screen. It also provides the user with messages and prompts for performing each assay step, and gives test results and error messages.

- Resistive touch screen
- Display size: 116.16 x 87.12 mm
- Pixels: 640 x 480

Dimensions & power requirements

- Weight: 1.7 kg without power supply
- Size: 27 x 15.5 x 14.5 cm
- Power requirements
  Voltage: 100–240 V AC
  Frequency: 50–60 Hz
  Power consumption: Max 26 W

Software update

New software can be uploaded with a USB-memory storage. Ask your local supplier for more details.

Instrument identifier

Each QuikRead go Instrument has a unique serial number which can be found on the label on the bottom of the instrument.

Memory

QuikRead go Instrument has an internal memory for results history. See the Section "Results".

Power supply

The instrument is powered by a power supply supplied with the instrument. In addition to the power supply, the instrument can use an accumulator as a power source. An internal switch inside the cable connector will switch automatically from accumulator-powered use to mains-powered use. For instructions on installing an accumulator, see the Section "Inserting accumulator".

LIS connection

The connection can be made using:

- An RJ-45 connector as a serial port with a special cable. Specification for wiring the cable can be found at **quikread**.com.
- An RJ-45 connector and a supported 10BASE-T/100BASE-TX Ethernet connection. Cat 5 / Cat 5e UTP (unshielded twisted pair) cable should be used.
- A WLAN connection. An external WLAN USB-stick is needed.
- Power over Ethernet (PoE) is not supported.
- Contact your supplier for more details.

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.

Service

QuikRead go Instrument is designed to be free of regular maintenance with build-in self-check operations. In case of instrument malfunction or a repair requirement, please contact your local supplier. Before shipping the instrument to service, delete all patient results from Result history and clean the exterior of the instrument. See Section "Cleaning the instrument" for detailed instructions.

Warranty

The manufacturer's warranty for QuikRead go Instrument covers defects in materials or manufacturing for a period of two years from the date of purchase. For the warranty to be valid, the warranty seal (see **Picture 3**) needs to be untouched. The manufacturer agrees to repair or replace the instrument if it becomes inoperative due to the failure of any internal part of the instrument. The warranty does not cover damage caused by use not in accordance with 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 an instrument malfunction, please contact your local supplier.

Disposal

QuikRead go Instrument is a low-voltage electronic device. A used QuikRead go Instrument must be treated as potentially biohazardous waste. The instrument should be disposed of as Used Medical Equipment according to national and local law. Be sure to delete all patient data before disposing of the instrument.

The packaging materials are recyclable materials. The accumulator should be disposed of according to national and local accumulator collection rules based on Directive 2006/66/EC.

Revision History

Revision history can be found from aidian.eu.

Removed: *It is designed in compliance with the RoHS directive (Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment: Directive 2011/65/EU).*

Found in: *Declaration of conformity*

QuikRead go Instrument user levels and rights when Security login is enabled

Action	Normal user	Supervisor	Administrator
Patient measurement	x	x	x
QC measurement	x	x	x
See all QC results	x	x	x
Add new QC lot	x	x	x
See old patient results	– / x*	x	x
See LIS offline results	x	x	x
Transfer old results to USB	–	x	x
Personal settings (Language, Power save)	–	x	x
Personal settings (Screen brightness, Audio volume)	x	x	x
Measurement flow	–	x	x
Test parameters	–	x	x
QC parameters	–	x	x
Maintenance (Error log, Self-diagnostics, About)	x	x	x
Maintenance (Basic settings, Date & Time, Software update, Touch calibration, Maintenance logs: transfer)	–	x	x
Maintenance logs: Delete security logs	–	–	x
Admin settings (all except Factory reset)	–	x	x
Admin settings (Factory reset)	–	–	x
Change own password	x	x	x
Create / Edit / Remove a User	–	x	x
Create a new Supervisor	–	x	x

*Depending on settings in *Settings → Measurement flow → Maintenance → Admin settings → Security settings*.

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说明书的编制或者修订日期
05/2023