

QuikRead go® connection to LIS/HIS system
Version 5.5 April - 2021

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For further information please contact Aidian Product Support
product.support@aidian.eu

1: General information

1.1 Background

The QuikRead go instrument can be connected to an external data handling systems such as

- Laboratory Information System (LIS)
- Hospital Information System (HIS)
- Middleware data handling system (MW)

The connection can be done using a serial (see chapter 2) or a TCP/IP LAN or WLAN network connection (see chapter 3).

The QuikRead go instrument can be connected to any data handling system which is capable of communicating with the QuikRead go instrument using the ASTM protocol (LIS01-A2) or POCT1-A2 protocol. The data handling system needs to have a driver for QuikRead go. This document gives guidance how to connect the QuikRead go instrument to a data handling system using the ASTM or POCT1-A2 protocol.

In an ASTM message QuikRead go sends the following data:

- Patient ID (in case patient ID is set ON)
- Running measurement number
- Analyte information / analyte name
- Result and result unit
- Operator ID (in case Operator ID is set ON)
- Measurement date and time
- System name and serial number information

Detailed description of ASTM protocol is in QuikRead go LIS01-A2 Interface Specification.

Detailed description of POCT1-A2 messaging is in QuikRead go POCT1-A2 Interface Specification.

Note: As neither LIS01-A2 or POCT1-A2 has any standardized way of encrypting the traffic, connecting the instrument to Internet is not recommended unless separate VPN solution is used.

Note: If you are using POCT1-A2 to send iFOBT results please see attachment 2.

Note: If you are using POCT1-A2, Date & Time need to be in default format, that is, date as yyyy-mm-dd and time as hh:mm in 24 hour clock.

1.2 Purpose

This document describes QuikRead go data connectivity settings and features for laboratory information systems and hospital information systems. This information is intended for health care instrument connectivity specialists and information technology specialists.

1.3 Scope

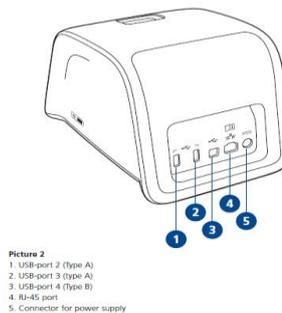
The following sections describe QuikRead go instrument hardware and software connectivity features as well as instructions for related instrument settings and configurations.

This document does not cover messaging layer between QuikRead go and an observation reviewer. It is separately available for software developers and system integrators.

2: QuikRead go® ASTM (LIS01-A2) connection using serial connection via RJ-45 serial port

2.1 QuikRead go® instrument serial port and cable layout

For a serial ASTM connection the QuikRead go instrument uses an RJ-45 connector in the back of the instrument (see connector 4 in the picture below)



For a serial connection a special QuikRead go serial cable (Aidian prod.no. 141060) is needed. The cable can be ordered from Aidian. In case another cable is used, please see Attachment 1.

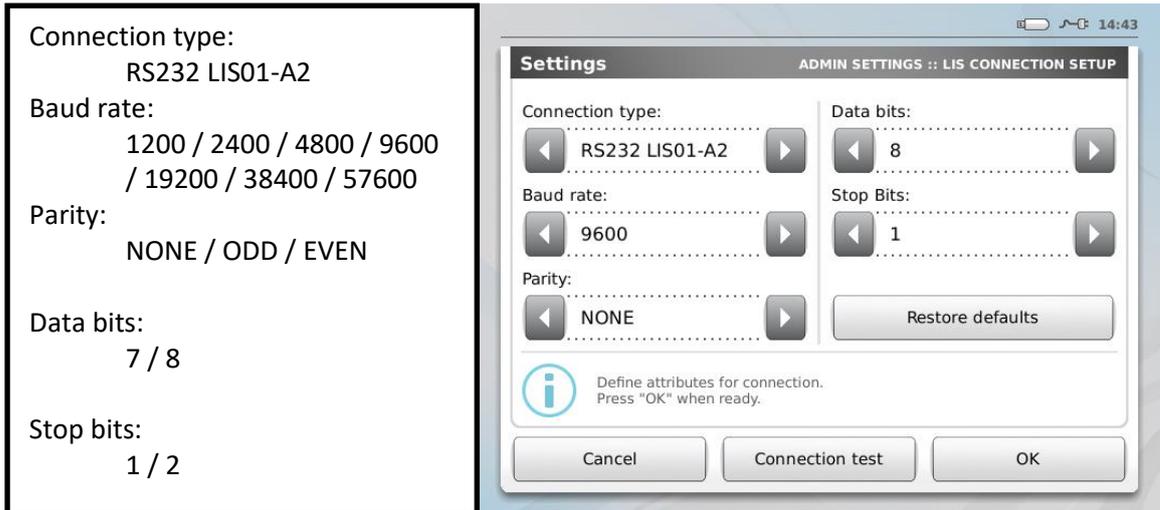
2.2: LIS configuration in Admin settings

LIS connection settings depend on the LIS system. Correct settings should be asked from a person responsible for the LIS system.

Go to LIS settings using the following route:

Settings => Measurement flow settings => Maintenance => Admin settings => (give password: QRGOSSET) => LIS settings

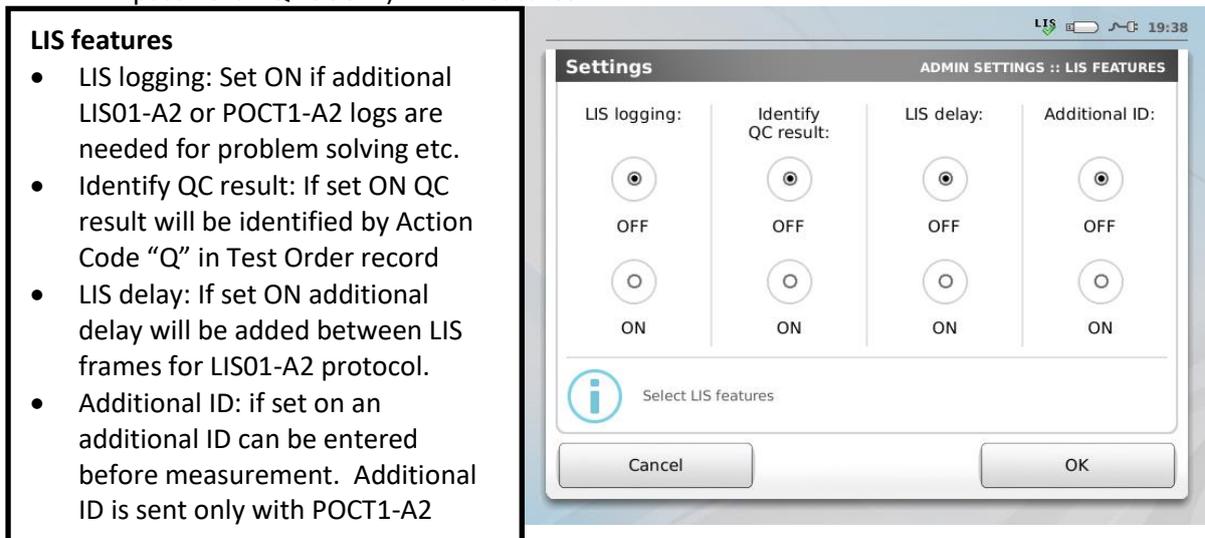
Choose the right settings for the system



The Connection test button can be used to send a simple connection check message.

Note: If your system has a Flow control setting it should be set to None.

For additional LIS settings go to LIS Features using the following route:
 Settings => Measurement flow settings => Maintenance => Admin settings => (give password: QRGASET) => LIS features



LIS features

- LIS logging: Set ON if additional LIS01-A2 or POCT1-A2 logs are needed for problem solving etc.
- Identify QC result: If set ON QC result will be identified by Action Code "Q" in Test Order record
- LIS delay: If set ON additional delay will be added between LIS frames for LIS01-A2 protocol.
- Additional ID: if set on an additional ID can be entered before measurement. Additional ID is sent only with POCT1-A2

2.3: LIS configuration in Measurement flow settings

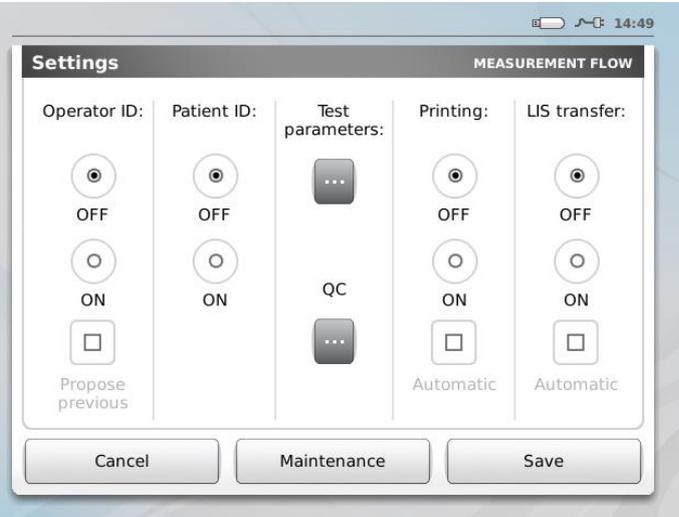
LIS sending and Operator ID and/or Patient ID are taken into use on Measurement flow. (Before using LIS transfer choose the right LIS settings, see section 2.2).

If Patient ID and Operator ID are set ON QuikRead go requests them before starting a measurement. They can be given with a barcode reader or written manually on the touch display.

To make Measurement flow settings permanent they have to be set via Set-up wizard which can be started from Maintenance settings ->Basic settings or which is automatically started after performing Factory reset (Admin settings->Factory reset).

Measurement flow settings

- LIS transfer: ON and automatic in case a manual confirmation is not needed before sending.
- Operator ID: ON if Operator ID is needed. Propose previous means that the previous operator is as default. ID will be coupled with the result.
- Patient ID (Sample ID): ON. ID will be requested before every measurement and sent to the LIS coupled with the result.



3: QuikRead go TCP/IP LAN connection via RJ-45

3.1: QuikRead go® instrument TCP/IP port and cable

For a TCP/IP connection (Ethernet) the QuikRead go instrument uses an RJ-45 connector in the back of the instrument (see connector 4 in the picture below)



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

Please use a standard 10/100 Cat 5/5e UTP (Unshielded twisted pair) Ethernet cable for the TCP/IP connection.

NOTE: Power-over-Ethernet (PoE) is not supported. QuikRead go must not be connected to a PoE network.

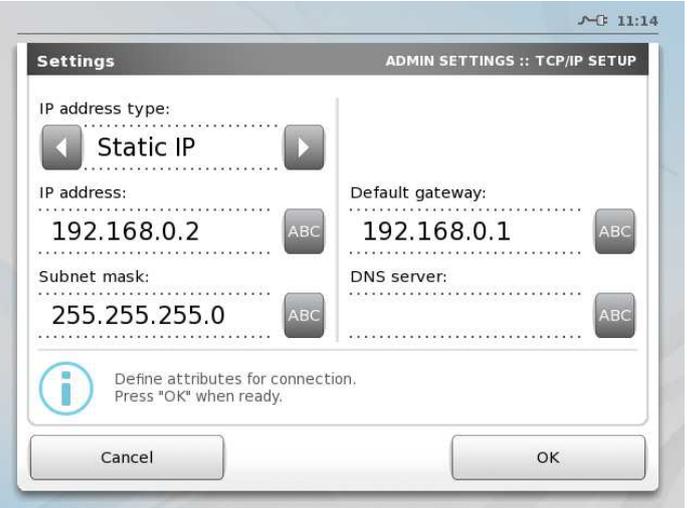
3.2: TCP/IP configuration in Admin settings

An IP address is information which is used for instrument identification in the network. The IP address type can be Static or Dynamic.

A static IP address type is used when the IP-address is defined by the network admin and it is not changing. In case the Dynamic IP address type is chosen, the instrument automatically gets the IP-address from a DHCP-server every time the instrument is powered on.

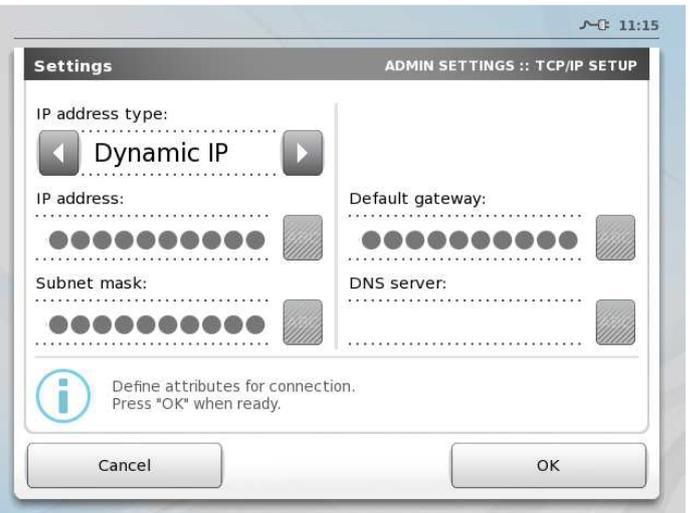
TCP/IP settings – Static IP

- IP address type:
Static IP
- IP address:
Give IP address of the device
- Subnet mask :
Give Subnet mask information
- Default gateway
Give default gateway information.
- DNS server:
Optional, can be left empty



TCP/IP settings – Dynamic IP

In this case the IP address, Default gateway and Subnet mask information will not be given in the settings but the QuikRead go instrument will automatically detect these.



4: QuikRead go TCP/IP WLAN connection via USB WLAN adapter

4.1: QuikRead go WLAN USB adapter

Use only adapter supplier by Aidian. Insert adapter to any free USB port.

4.2: TCP/IP configuration in Admin settings

Usually dynamic IP is used with WLAN. For TCP/IP settings see section 3.2.

4.3: WLAN configuration in Admin settings

WLAN connection settings depend on the available WLAN network. For security reasons LAN will be disabled if WLAN is in use and vice versa.

Go to WLAN settings using the following route:

Settings => Measurement flow settings => Maintenance => Admin settings => (give password: QRG0SET) => WLAN settings

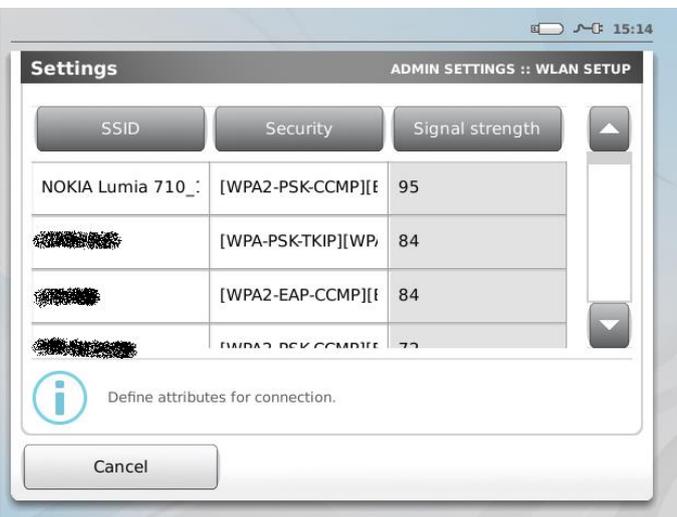


To start scanning available networks press Scan. For manual setup press Manual setup. Pressing either of the buttons will automatically turn on WLAN. To switch WLAN on/off choose OFF/ON and press OK.

WLAN settings – Scan

- SSID: Network identifier, can be empty if network is hidden
- Security: Lists the security policies of the WLAN network
- Signal strength: 0-100

Note: Use strongest available security policy.



Press anywhere on the row to choose one of the networks:

WLAN settings – Scan – WLAN setup

Security settings depend on the network. Fill in the requested (active) settings and press OK. In the above example only the passkey (PSK) needs to be filled in.

The screenshot shows the 'Settings ADMIN SETTINGS :: WLAN SETUP' interface. It features two columns of settings. The left column includes 'SSID:' with the value 'NOKIA Lumia 710_1495' and 'PSK:' with the value 'ABC'. The right column includes 'WLAN security type:' with the value 'WPA2-PSK'. At the bottom, there is an information icon and the text 'Define attributes for connection. Press "OK" when ready.' along with 'Cancel' and 'OK' buttons.

If settings are correct and network is available connection will be established.

WLAN settings – Manual setup

In manual setup the available settings will change depending which WLAN security type is selected. Press OK after all settings are complete.

The screenshot shows the 'Settings ADMIN SETTINGS :: WLAN SETUP' interface for manual setup. It features two columns of settings. The left column includes 'SSID:' with the value 'ABC', 'EAP:' with the value 'PEAP', and 'Phase 2:' with the value 'MSCHAPV2'. The right column includes 'WLAN security type:' with the value 'WPA-EAP', 'PEAP version:' with the value '0', and 'Identity' with the value 'ABC'. At the bottom, there is an information icon and the text 'Define attributes for connection. Press "OK" when ready.' along with 'Cancel' and 'OK' buttons.

If settings are correct and network is available, connection will be established.

4.4: Supported WLAN security policies

QuikRead go supports the following WLAN security policies:

WPA-PSK

WPA2-PSK

WPA-EAP (Enterprise) and WPA2-EAP (Enterprise)

- EAP-PEAP with phase 2 methods:

- GTC

- MD5

- MSCHAPv2

- TLS

- EAP-TLS

- EAP-TTLS with phase 2 methods:

- EAP-GTC

- EAP-MD5

- EAP-MSCHAPv2

- EAP-TLS

- CHAP

- MSCHAP

- MSCHAPv2

- PAP

5: QuikRead go TCP/IP ASTM (LIS01-A2) connection (LAN or WLAN)

5.1 Network configuration

Configure network according to instructions in chapter 3 (LAN) or chapter 4 (WLAN).

5.2 LIS configuration in Admin settings

LIS settings - TCP/IP ASTM

- Connection type TCP/IP LIS01-A2
- Connection mode:
Client or Server
- LIS server (in case of Client mode)
Give LIS server info
- TCP port
Give TCP port information

The Connection test button can be used to send a simple connection check message. In Server-mode the instrument cannot initiate a connection, so the Connection test button is disabled.

5.3: LIS configuration in measurement flow settings

LIS sending is taken into use on the measurement flow settings (set also Patient ID and Operator ID ON if needed).

If Patient ID and Operator ID are set ON, QuikRead go requests them before starting a measurement. They can be given with a barcode reader, external keyboard or written manually on the touch display.

Measurement flow settings

- LIS transfer: ON and automatic in case a manual confirmation is not needed before sending.
- Operator ID: ON if Operator ID is needed. Propose previous means that the previous operator is as default. ID will be coupled with the result.
- Patient ID (Sample ID): ON. ID will be requested before every measurement and sent to the LIS coupled with the result.

6: QuikRead go TCP/IP POCT1-A2 connection (LAN or WLAN)

6.1: Recommended order to setup POCT1-A2 connection

To make settings permanent the Set-up wizard should be used. There are two ways to start Set-up wizard:

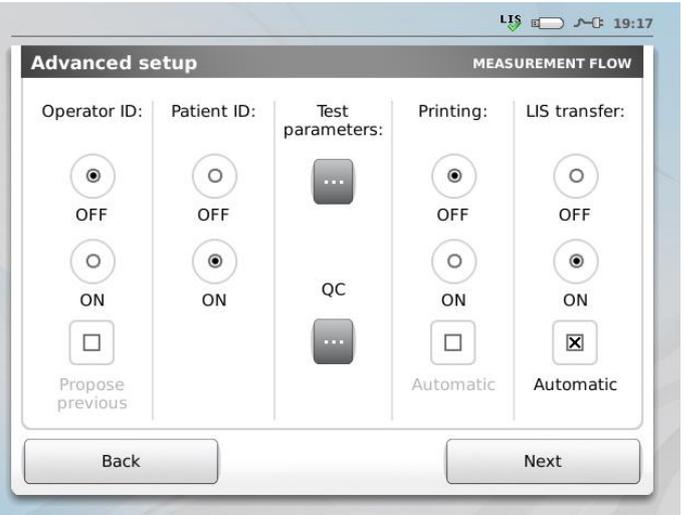
1. If there is no need to keep result history the recommended way is to perform factory reset from Admin settings (or if new instrument is used Set-up wizard starts up at first boot automatically). After restart the Set-up wizard starts up automatically.
2. To preserve result history and keep current network and other settings select Basic settings from Maintenance settings. This will start the Set-up wizard.

Complete Set-up wizard according to QuikRead go instructions until you reach the screen with Advanced setup button. Select Advanced setup and set up Measurement flow settings as instructed in the next chapter.

6.2: POCT1-A2 configuration in Measurement flow settings

Measurement flow settings - POCT1-A2

- Operator ID: ON if Operator ID is needed. Propose previous means that the previous operator is as default. ID will be coupled with the result.
- Patient ID: Mandatory to set ON in POCT1-A2 (if POCT1-A2 already selected in LIS settings this will be ON automatic and cannot be changed)
- LIS transfer: Needs to be ON and Automatic for POCT1-A2 to be active.



6.3 Network configuration

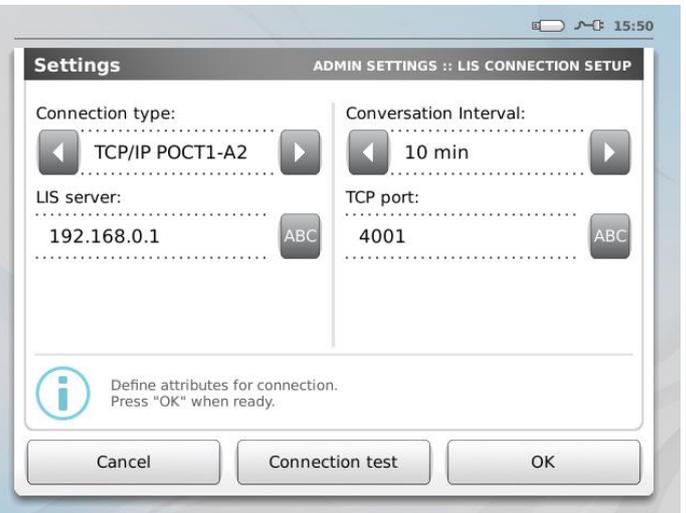
Configure network according to instructions in chapter 3 (LAN) or chapter 4 (WLAN). POCT1-A2 cannot be used with RS232 connection.

6.4: POCT1-A2 connection configuration in Admin settings

POCT1-A2 connection settings are set from LIS settings in Admin settings:

LIS settings – TCP/IP POCT1-A2

- Connection type
TCP/IP POCT1-A2
- Conversation Interval
Define how often QuikRead go initiates conversation
- POCT server
Give POCT server info
- TCP port
Give TCP port information



The Connection test button can be used to start a conversation. This conversation is used only for testing the connection and it is terminated by QuikRead go after Hello and Device capability topics.

6.5: POCT1-A2 features

There are POCT1-A2 specific features that can be set from Admin Settings
 ->POCT1-A2 feature:

<p>POCT1-A2 features</p> <ul style="list-style-type: none"> • Operator login: Set ON if operator login is required • Patient ID validation: Set ON if entered patient ID validity should be checked from Patient list. • Patient data shown: Set ON if patient name and birthdate (if available in patient list) should be shown for positive patient identification before measurement is started 	
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Note: If you are using POCT1-A2 to send iFOBT results please see attachment 2.

After POCT1-A2 setup is complete (Network settings and LIS settings done and saved, and LIS transfer set ON in Measurement flow) QuikRead go will try to start POCT1-A2 conversation according to the Conversation interval setting. Conversation is also started after each measurement.

7: QuikRead go POCT1-A2 usage

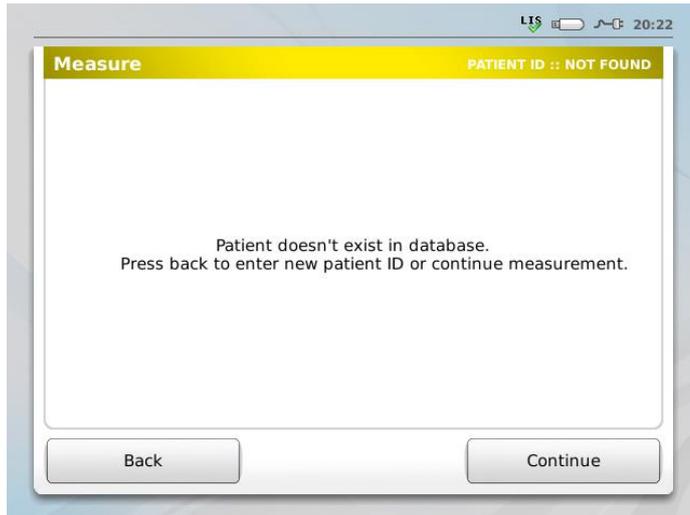
7.1: Observations (patient and QC measurements)

After POCT1-A2 has been configured successfully the patient and QC measurements are delivered automatically after the measurement (if Observation reviewer requests observations).

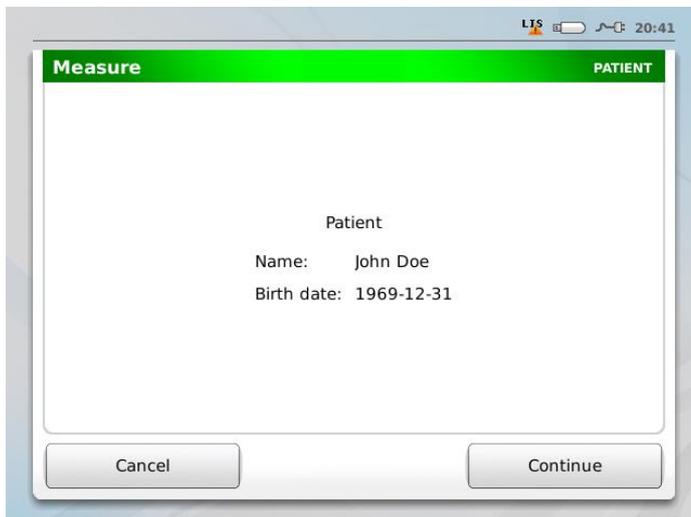
If after start-up there are unsent POCT1-A2 observations or events, QuikRead go will show message "Please wait". This message will be shown during the time the messages are being queued and sent to LIS/HIS.

Entering Patient ID or Control ID is mandatory when POCT1-A2 is used.

If *Patient ID validation* is ON (see 6.4) there will be warning if entered patient ID is not found from the patient list downloaded from the Observation Reviewer. Patient list is an optional feature.



If *Patient data shown* is ON, additional information about the patient is shown for positive patient identification:



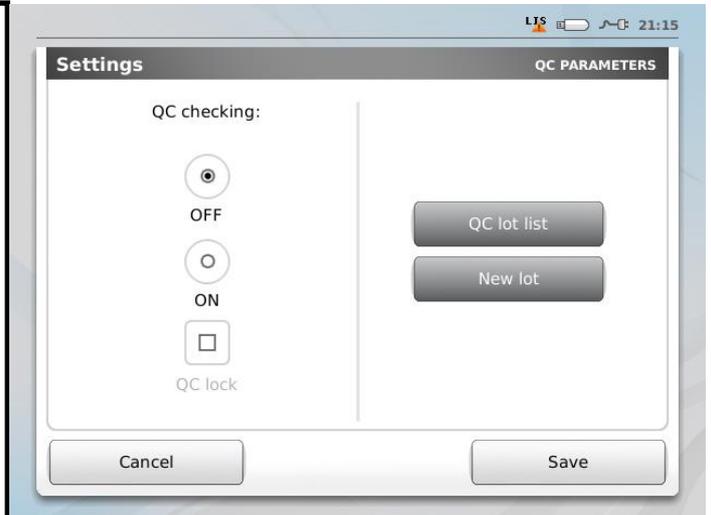
On top of Patient ID and Operator ID a third sample ID can be added, e.g. patient birthdate or Doctor ID. If the additional ID is given with a barcode reader, first delete the previous ID by tapping the Abc button. When the additional ID is in use and a new QC lot is created manually on site, QuikRead go needs to be shut down and restarted after creating the new QC lot.

7.2: QC lots

QC lots are an optional feature. QC lots can be used locally even if POCT1-A2 is not in use.

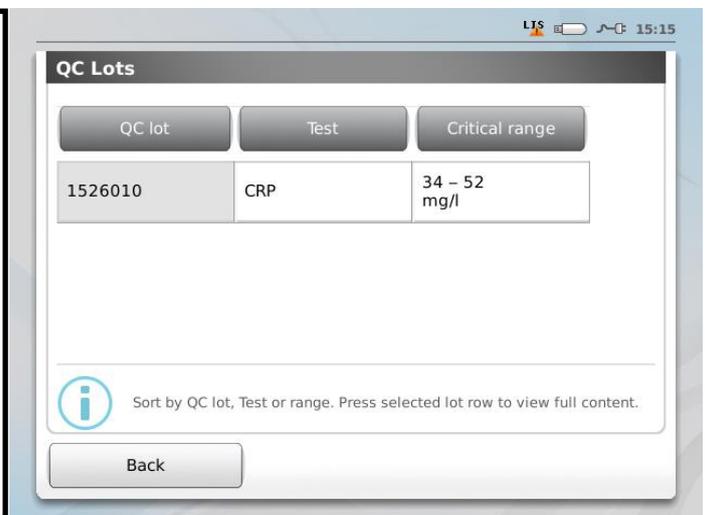
QC parameters - POCT1-A2

- QC checking: If set ON the Control ID for QC measurement will be checked against QC lot list. If matching lot is not found QC measurement is not allowed.
- QC lock: If this is checked a failed QC measurement will lock the device so that normal patient measurements cannot be done until successful QC measurement has been done. **Switching QC lock off and on again will also remove the QC lock.**
- QC lot list: Press to browse the active QC lots
- New lot: Create a new lot. Lots can also be downloaded from the Observation reviewer.



QC lots - POCT1-A2

- QC lots can be browsed and sorted according to QC lot, Test or Critical range
- Details view is not available when POCT1-A2 is in use



QC lot properties

New QC lots can be added both in POCT1-A2 and local use, but existing lots can be modified and details viewed only in local use.

First screen is for QC lot ID, Test, Units and ranges.

Press Next when details have been added.

Note: Critical range is used for checking the QC measurement, Warn range is optional.

The screenshot shows a settings screen titled 'Settings' with the subtitle 'MEASUREMENT FLOW :: QC LOT PROPERTIES'. The screen contains several input fields with navigation arrows:

- Test: CRP
- QC lot ID: 1526010
- Units: mg/l
- Warning range: 38 to 48
- Critical range: 34 to 52
- Target value: 43

At the bottom, there are 'Cancel' and 'Next' buttons.

QC lot expiration date

This screen is used for editing the QC lot expiry date.

Press OK to Save QC lot.

The screenshot shows a settings screen titled 'Settings' with the subtitle 'MEASUREMENT FLOW :: QC LOT EXPIRATION DATE'. The screen contains three date input fields with navigation arrows:

- Year: 2015
- Month: 4
- Day: 16

At the bottom, there are 'Cancel' and 'OK' buttons. An information icon and text at the bottom left state: 'Set QC lot expiration date. Press "OK" when ready.'

7.3: Operators and user levels

Operator lists are an optional feature. Operator lists can be downloaded from the Observation reviewer for user validation and authorization.

Every instrument has one ADMIN user. Default password is QRGASET. The password can be changed at Settings => Measurement flow settings => Maintenance => Admin settings => Security settings => Manage admin account.

Security settings

- Set Security login ON (local)
- Define access to old results
- Change admin password
- Add user accounts (local)
- Define logout timeout

Each operator can be assigned one of the following user levels :

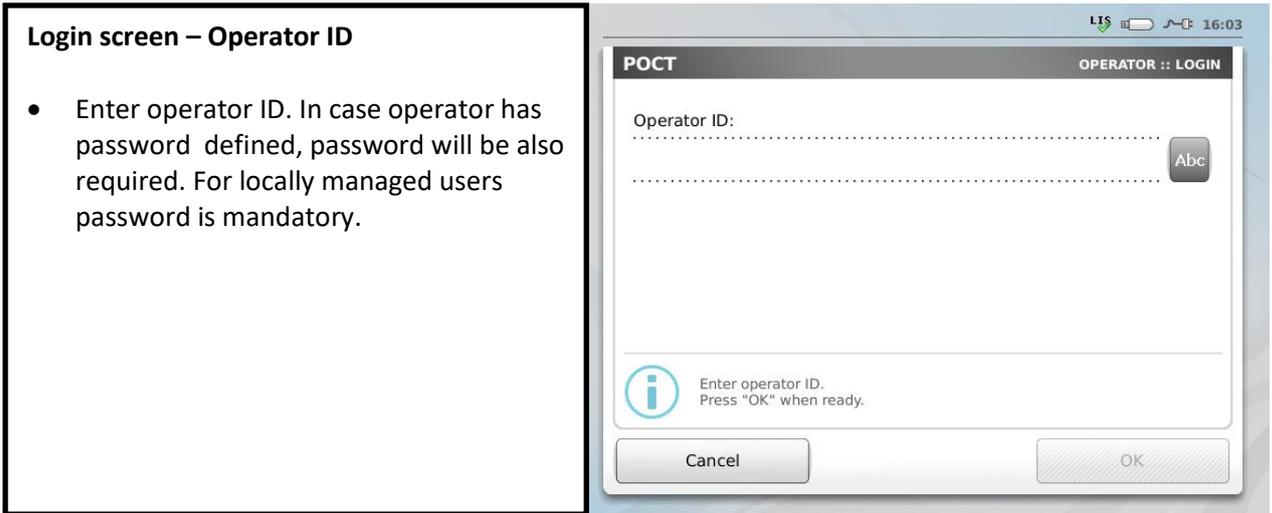
- **SUPERVISOR:** Full access to the system (Admin)
- **USER:** Can operate system to produce test results

If *POCT1-A2 features* => *Operator login* or *Security login* is set OFF in *POCT1-A2 features* (see 3.2) the operator ID is entered for each measurement.

If *Operator login* is set ON user must login to the instrument. When nobody is logged in Login screen is shown.

Login screen

- Login: press this to log in to system
- Emergency measure: press this to bypass login to perform an emergency measurement



Login screen – Operator ID

- Enter operator ID. In case operator has password defined, password will be also required. For locally managed users password is mandatory.

Notes to the operator are shown after login. Note is shown only once.

Operator will be automatically logged out when logout timer expires or power save activates. Operator can manually log out from the idle screen. Logout time can be adjusted from Security settings or using the remote setting "logout_timeout".

7.4: User comment list

Comments can be added to the results after the measurement or even later from the result history. Predefined comments can be downloaded from the Observation Reviewer. See the POCT1-A2 interface specification for details. Free text comments are also supported.

7.5 Emergency measurements

Emergency patient measurements are allowed in some cases in POCT1-A2 use. Emergency measurements have special status_cd defined, so they can have special processing in Observation Reviewer.

If instrument is remotely locked from the Observation Reviewer, an emergency measurement is possible as long as remote setting *lock_stat_tests* is larger than zero. Each emergency measurement will decrease the *lock_stat_tests* by one. It is possible to adjust *lock_stat_tests* remotely from Observation Reviewer.

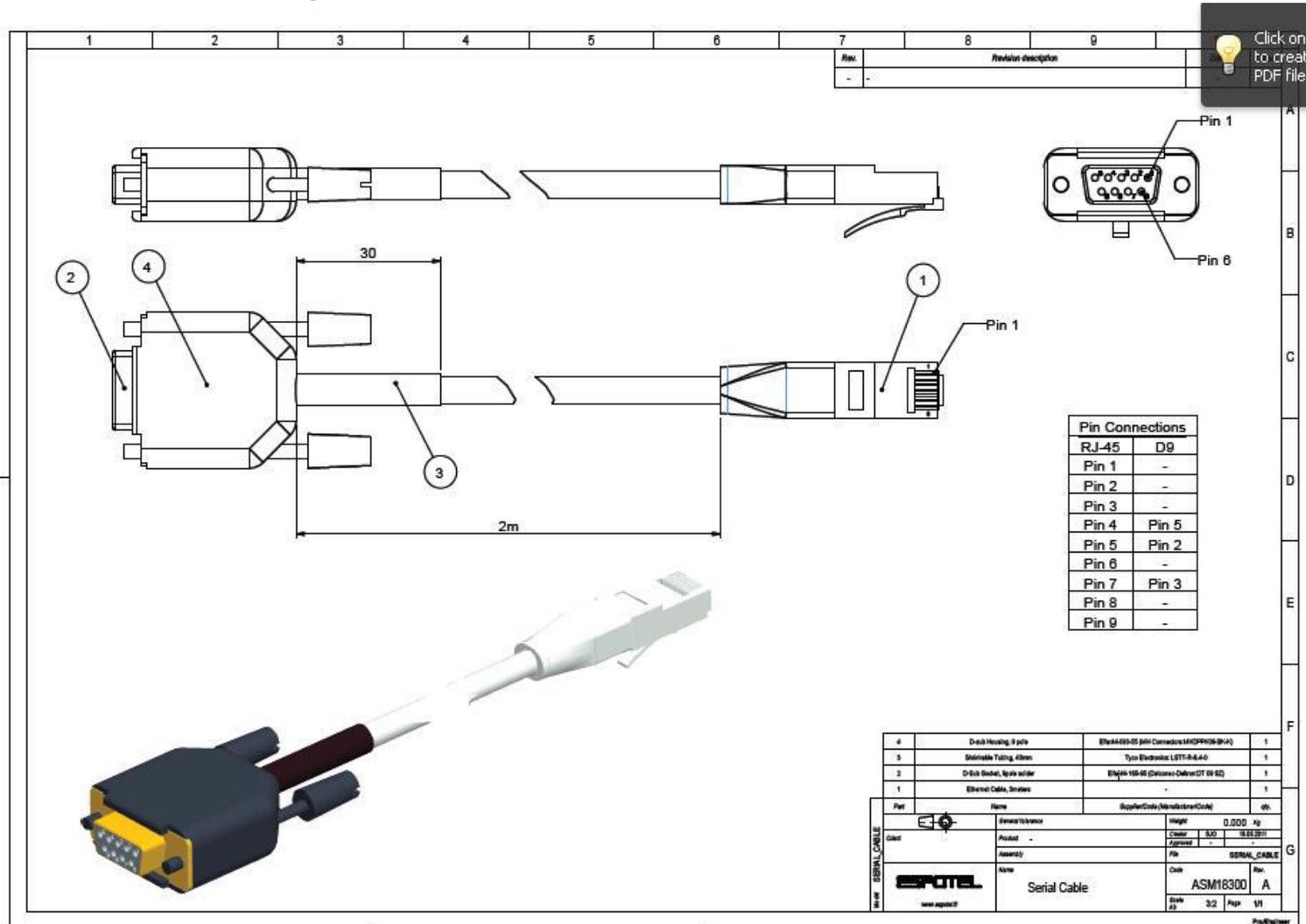
If operator is not authorized to perform some test, emergency measurement is always possible (*lock_stat_tests* is not used).

In case of QC locked instrument, emergency measurements are not allowed as local QC lots can be used also with LIS01-A2 and there is no standard way to indicate emergency measurement with LIS01-A2.

8: Change history

Version	Date	Changes
5.5	1.4.2021	Company name and contact detail changed

Attachment 1: QuikRead go serial cable



Attachment 2. Notice concerning the use of POCT1-A2 protocol to transfer iFOBT results

In case the QuikRead go instrument with software 7.1.10 connected bi-directionally (POCT1-A2) to a LIS/HIS is used for measuring the QuikRead go iFOBT test in quantitative mode do not use these settings:

- a. *iFOBT units selection set to Both*
- b. LIS units selection set to $\mu\text{g/g}$**
- c. *iFOBT type selection set to Quantitative*

the test result unit connected to a test value when sent to LIS/HIS will be wrong.

Results sent to LIS/HIS will always be correct, if the settings are as below:

- a. *iFOBT units selection set to Both*
- b. *LIS units selection set to ng/ml*
- c. *iFOBT type selection set to Quantitative*

or

- a. *iFOBT units selection set to $\mu\text{g/g}$*
- b. *iFOBT type selection set to Quantitative*

or

- a. *iFOBT units selection set to ng/ml*
- b. *iFOBT type selection set to Quantitative*

Customers having their LIS connection based on LIS01-A2 are not affected.