



QuikRead go® Instrument software 7.5.1 release note

QuikRead go Instrument new software version 7.5.1 will be released in July 2018. The new version includes new features as well as improvements to existing features.

The new software version has been developed in compliance with IEC 62304:2006+AMD1:2015 Medical device software -- Software life cycle processes sekä General Principles of Software. It has been validated according to Final Guidance for Industry and FDA Staff Jan 11 2002. Testing included measurement of 33 samples with both software versions, new 7.5.1 and previous 7.2.5. All results passed.

Updating to this software version works from all previous software versions. Update does not delete old results from memory.

New features

New analytes

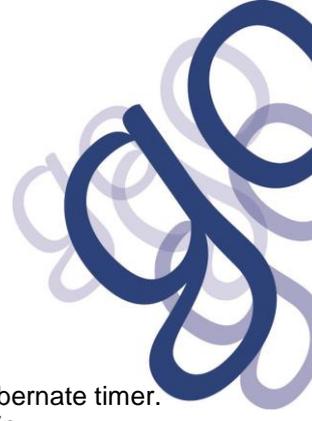
- QuikRead go wrCRP and wrCRP+Hb.

Security settings: User authentication

- A new feature **Security settings** is available at *Settings > Measurement flow > Maintenance > Admin settings > Security settings*.
- When the Security settings is set ON, users need to have a user account created with Operator ID, full name and password.
- Three user levels are in use:
 - Admin:
 - o only one per instrument, operator ID is ADMIN. The name is not modifiable.
 - o when starting Set-up wizard, QuikRead go will ask an admin password to be created.
 - Supervisor
 - o has access to all except for performing factory reset and deleting security logs.
 - Normal User
 - o can set user specific settings.
 - o can see QC and LIS offline results and optionally old patient results.
 - o can add new QC lots locally when doing Quality control measurement and if QC checking is set ON.
 - o can see error log and transfer the log to a USB storage.
 - o features not accessible are greyed out.
- See table below for user roles and rights.
- All users have a username and an own password. Nobody can see others' passwords.
- Profiles will not be in use when the Security settings is enabled.
- Factory reset removes all normal user and supervisor accounts, erases security logs, and resets admin password to the default QRG0SET. The admin password can be changed in the set-up wizard starting automatically after a factory reset.

A temporary admin password for a lost one can be requested at the net site <http://www.softwareupdate.quikread.com/>. An instrument serial number is needed when requesting a password. The temporary password can only be used once and is valid for one week. This procedure does not remove user accounts, nor erase security logs.





Security settings: Login functionality

- Session inactivity timer is a separate and independent setting from the *Power save* hibernate timer. The inactivity timer is set at *Security settings: Logout timeout*. Time range is 5 – 60 min.
- When the session inactivity timer expires, the user will be logged out.
- If the *Full standby option* in *Power save* is in use, the user will be logged out when QuikRead go enters sleep mode.
- The user can also log out manually.
- Emergency measurement is possible by logging in only with an Operator ID, password will not be needed.

Delete QC lots

- Admin (and Supervisor, if Security settings ON) can edit or delete QC lots onsite. Requires password.
- This is not possible with POCT1-A2 connected QuikRead go instruments.

Power save

- Lid closing time & Full standby time can be set down to 1 minute.
- All options are 1, 5, 10, 15, and 20 minutes.

New languages

- Latvian language has been added.

LIS related issues

- Local user management and POCT1-A2 can be simultaneously used, but when POCT1-A2 user login is enabled, local user management will not be in use.

Availability of new software

- The new software version 7.5.1 will be available at the net site <http://www.softwareupdate.quikread.com/> or on a QuikRead go Software USB storage, cat. no 137540

Instrument logs

- Separate files for error logs (*Settings / Measurement flow / Maintenance / Error log*), instrument logs (*Settings / Measurement flow / Maintenance / Maintenance logs / Instrument logs*) and security logs (*Settings / Measurement flow / Maintenance / Maintenance logs / Security logs*).
- When *Security settings* is set ON, Admin can erase the security logs, needed for example when sending an instrument to service. The security logs contain traffic data between QR go and LIS. With *Security settings* set OFF, the security logs cannot be deleted.
- Instrument logs cannot be deleted. They contain important information needed in case an instrument needs to be sent to service.





Instrument manuals

- QuikRead go instrument manuals have been updated to include these new features.

TABLE OF USER ROLES AND RIGHTS WHEN SECURITY SETTINGS 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

* Optional right, by default disabled in the US region, by default enabled in the rest of the world, setting will also affect POCT1-A2 use.

