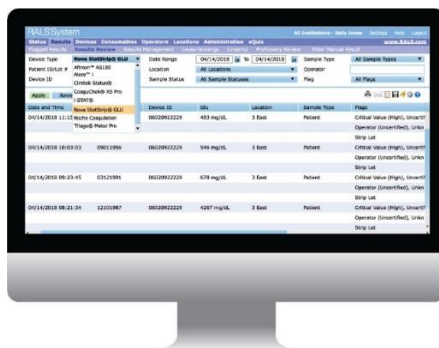




# Customer Release Notes



## Version 6.0 SP7

Contents	Page
<a href="#">RALs™ System Updates</a>	2
• Lightweight Directory Access Protocol (LDAP) Support (Active Directory)	2
• Roche cobas® Liat® System Module Update	3
• Roche ACCU-CHEK® Inform II Module Update	4
• Roche CoaguChek® XS Plus / CoaguChek® XS Pro Module Update	4
• Siemens epoc® Blood Analysis System Module Update	5
• NOVA Biomedical Device Manual Test Entry (MTE) Configuration Update	5
• Quidel® Sofia® Module Update	6
• RALs™ New User Interface Updates	6
• Result Purge	8
• Interfacing Update	8
<a href="#">RALs™ System Corrections</a>	9



## RALS™ System Updates

### Lightweight Directory Access Protocol (LDAP) Support (Active Directory)

The RALS™ LDAP Interface, also known as Active Directory, provides the ability to sync RALS™ operators with a hospital's directory system using the industry-standard Lightweight Directory Access Protocol (LDAP). When the RALS™ LDAP Interface syncs with a hospital's LDAP system, it can automatically add and update operators in RALS™. A RALS™ LDAP sync can be performed manually or automatically; automatic synchronization happens once every 24 hours.

When an LDAP configuration is synced, the RALS™ LDAP Interface will independently process the following sync options (as specified in the configuration):

- Add Operators
- Edit Operators
- Deactivate Operators
- Activate Operators

Each time an LDAP configuration is synced, either manually or automatically, that sync is recorded. This history of sync sessions, along with details of added, edited, activated and deactivated operators, can be viewed for all LDAP configurations (in the RALS™ navigation under the Logs menu) or for an individual LDAP configuration (from the configuration's details page).

KEY	LDAP CONFIGURATION	SYNCED BY	SESSION TIME	STATUS	ADDED OPERATORS	EDITED OPERATORS	ACTIVATED OPERATORS
28	AlereAD (10.91.32.16)	Automated Process	12/4/2020 1:33:40 PM	Successful	0	5	0
27	AlereAD (10.91.32.16)	MASSupport (MAS)	12/3/2020 7:56:36 PM	Successful	0	5	0

For more information about Active Directory please contact your Informatics Executive.



## Roche cobas® Liat® System Module Update

The screenshot displays the RALS web application interface. At the top, there is a navigation bar with tabs: Status, Results, Devices, Consumables, Operators, Locations, Tasks, Administration, and eQuiz. Below this, a secondary bar contains links: Flagged Results, Results Review, Results Management, Results (New), Levey-Jennings, Linearity, Proficiency Review, Enter Manual Result, and View Orders. The main area features several filter sections: 'Device Type' (cobas® Liat), 'Date Range' (07/27/2020 to 07/27/2020), 'Location' (All Locations), 'Sample Status' (All Sample Statuses), 'Test Type' (All Test Types), 'Sample Type' (All Sample Types), 'Operator', and 'Flag' (All Flags). Below these filters is a row of action buttons: Apply, Review, Saved Notes, Resend, Add Notification, Notification Actions, Reassign, and Recall. At the bottom, a table header lists columns: Date and Time, Patient ID / Lot #, Test Type, Location, Operator, Flags, Sample Status, Sample Type, Cartridge Lot #, Profile Name, Accession #, LIS Comment, Device ID, Device Name, Last Review Note, and Last.

RALS™ 6.0 SP7 adds support for firmware version 3.3 including:

- Added support for Patient Verification, allowing Liat to query RALS for patient information

Additional Enhancements including:

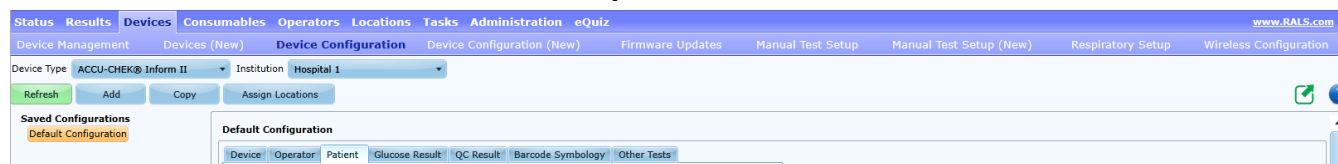
- Add support to request a complete list of users from the device
- Updated user list management:
  - Handling of user “ADMIN” – password may be changed in RALS and updated on the device. This user cannot be removed.
  - Handling of “reserved” users: MANUF, SERVICE. These cannot be updated or removed
  - Create Device Events, viewable on Device Management page, for Users that cannot be sent because they do not meet device requirements
  - Full List is sent only if the number of change entries  $\geq$  the number of full list entries or a Sync is requested, or a user change occurs on the device.
- Updated material list management:
  - Device Material List is requested only when an event that could potentially change the list occurs (material change on the device, change to the list of assigned materials in RALS, review of a material in RALS, delete/restore of a material in RALS, or Sync Requested)
  - Full list is sent only if the number of change entries is  $\geq$  the number of full list entries or a Sync is requested.

Added the following columns to the Device Management page

- IP Address
- Status



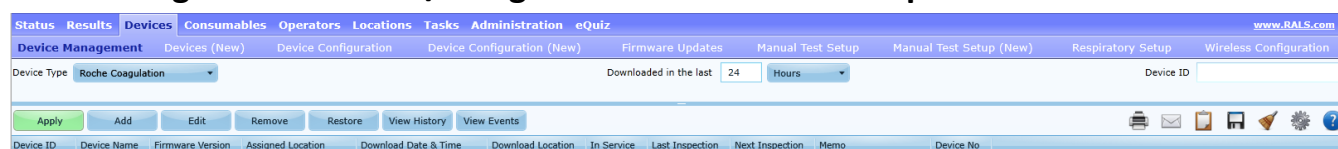
## Roche ACCU-CHEK® Inform II Module Update



RALS™ 6.0 SP7 adds support for the following firmware versions:

- 03.07.00 New configuration options:
  - QC Lockout After Strip Lot Switch
  - Extended Patient ID Validation by Length Check
  - TLS encryption
- 04.03.00 New configuration options:
  - Data Compression
  - Add Barcode to result
  - Barcode separators
  - Auto Power off
  - Power off Reconnect
  - Order Strip Lot
  - OTS QC Enabled
- 04.03.00 New Features:
  - New device statuses with data compression
  - Overserved test sequence for QC
- 04.04.00:
  - New device events
  - Operator Password hashing

## Roche CoaguChek® XS Plus / CoaguChek® XS Pro Module Update

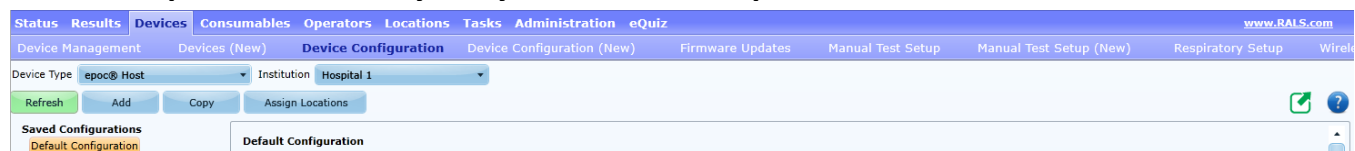


RALS™ 6.0 SP7 adds support for the following firmware versions: 03.05.00 and 03.05.01

- 03.05.00 New Feature:
  - Hashing of operator passwords
- 03.05.01 New Feature:
  - TLS encryption support - 03.05.01
- Added support for device Request of Configuration



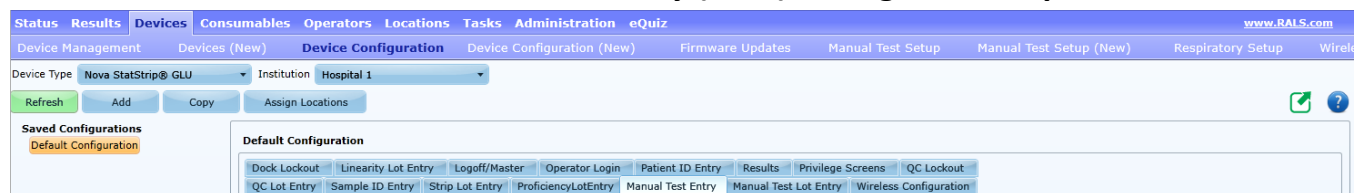
## Siemens epoc® Blood Analysis System Module Update



RALS™ 6.0 SP7 adds support for the new epoc NXS host hardware model with firmware version 4.4 and for legacy host firmware versions 3.31, 3.32 and 3.33

- Ability to identify NXS host
  - For Firmware Version starting with '3', the Hardware Version will be "Zebra"
  - For Firmware Version starting with '4', the Hardware Version will be "NXS"
- "NXS" New value types:
  - Flow
  - OS Version
  - OS Security Patch Level
- 3.31 New Device Configuration option:
  - Automatic log out after inactivity timer changed from list of options to numeric input field
- 3.32 New Device Configuration option:
  - Administrator password encryption
- 3.33 New Device Configuration option:
  - BUN and TCO2 analytes in test selection settings are now enabled by default
- Updates to CSV export file output:
  - Support for current epoc CSV file format (Version 4 – 51011256 Rev: 04, 2020-06)
- Updated Analyte definitions for AGap and AGapK calculations when using test cards that report measured TCO2 (Orange card) vs. using test cards (Green cards) that use calculated  $\text{CHCO}_3^-$  (which requires pH,  $\text{pCO}_2$ )

## NOVA Biomedical Device Manual Test Entry (MTE) Configuration Update



RALS™ 6.0 SP7 updated support for NOVA Biomedical Device MTE

- RALS™ will now handle result value names that are longer than 20 characters from a NOVA Biomedical device with the result value name truncated to 20 characters, RALS™ now maps the result value to the result value with the full name
  - Specific Result Values for COVID-19 Manual Tests that are over 20 Characters:



- SARS-CoV-2 Viral Load
- Employed in healthcare?
- Symptomatic as defined by CDC?
- Date of Symptom Onset mm/dd/yy
- Resident in a congregate care setting?

## Quidel® Sofia®

RALS™ 6.0 SP7 adds support for Flu+SARS test type to support the Sofia® 2 Flu + SARS Antigen FIA (Fluorescent Immunoassay) test cassette.

## RALS™ New User Interface Updates

### Device Configuration

RALS™ 6.0 SP7 adds support for existing Silverlight Device Configurations:

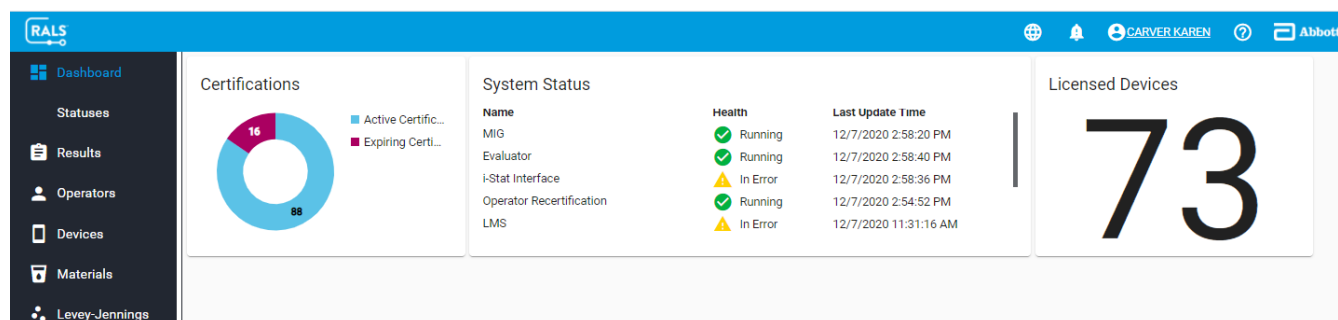
- Abbott DIGIVAL™
- Roche CoaguChek® XS Plus / CoaguChek® XS Pro
- Instrumentation Laboratory Hemochron Signature Elite®
- Instrumentation Laboratory Hemochron Signature+®
- LifeHealth™ IRMA TruPoint®
- HemoCue® 201 DM Glucose
- HemoCue® 201 DM HB
- NOVA Biomedical StatStrip® GLU
- NOVA Biomedical StatStrip® LAC
- NOVA Biomedical StatSensor® CREAT

All device types that currently have Device Configuration in RALS™ are now supported in 6.0 Sp7.



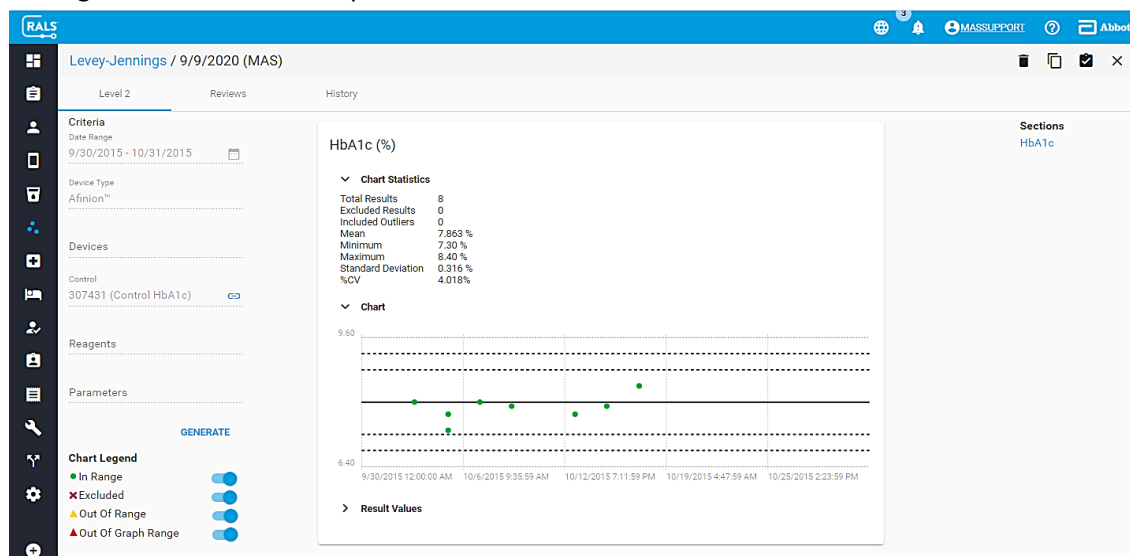
## Dashboard

RALS™ 6.0 SP7 adds support for a dashboard. A dashboard is a collection of one or more widgets configured to display summarized RALS information. A dashboard can display a variety of customized widgets. These widgets display data as charts or counts and are derived from a user's saved views. Every user has a dashboard which is only visible to the operator that owns it and cannot be shared with other users. The dashboard can also be used to display the Statuses, indicating the health of RALS components and processes.



## Levey-Jennings

RALS™ 6.0 SP7 provides the initial implementation of Levey-Jennings in the New UI. The Levey-Jennings page allows the ability to generate, view, and review Levey-Jennings charts for Quality Control results. Levey-Jennings allows users to designate specific devices, material lots, and parameters for which results are charted using the associated ranges within the charted period.





## Roles

RALS™ 6.0 SP7 provides the initial implementation of Roles in the New UI. The Roles feature controls what data and actions are available to operators in RALS™. A role is a collection of permissions that is used to control operators' access within RALS. Every RALS operator has a role. There are 5 System default roles (POCC, POCC Assistant, Devices Operator, Test Station Operator, and WLAN Configuration) which can be edited and deactivated. A RALS™ User with proper permissions can Add, Edit, Deactivate and Clone a Role.

ACTIVE	NAME	NOTES	PERMISSIONS
✓	Nurse Educators		Display Views Manage, Display Views Read, Operators Manage, Operators Read, Results Read, ...
✓	Nursing Educator		Display Views Manage, Display Views Read, Operators Manage, Operators Read, Roles Read
✓	Op Management		Display Views Manage, Display Views Read, Operators Manage, Operators Read, Recertification...
✓	Operator Management		Display Views Manage, Display Views Read, Operators Manage, Operators Read, Roles Manage,...
✓	OperatorOnly		Display Views Manage, Display Views Read, Operators Manage, Operators Read, Roles Manage,...
✓	Ops read only		Operators Read, Roles Read
✓	Permissions Test Role		Devices Manage, Devices Read
✓	POCC		Comments Manage, Comments Read, Device Configurations Manage, Device Configurations Re...
✓	POCC Assistant		Comments Manage, Comments Read, Device Configurations Manage, Device Configurations Re...
✓	POCC2		Comments Manage, Comments Read, Devices Manage, Devices Read, Display Views Manage, ...

## Result Purge

RALS™ 6.0 SP7 adds a new result purge feature that provides a mechanism that can be optionally enabled to delete results older than a configured number of months. This will allow RALS™ to be configured to match data retention policies.

## Interfacing Update

RALS™ 6.0 SP7 adds support to the outbound results interface for the following additional information:

- Result Notification's Operator ID
- Result Notification's Operator Name





## RALS™ System Corrections

---

**Incorrect UOM/Decimal Place Data that is currently identified in the database with 0 num decimals exists for multiple device types.**

The data affects reports that RALS™ generates for these device types and now has corrected the UOM/Decimal Place Data for the following device types:

Radiometer® 800 Series	Siemens Rapidpoint® 400/405/500	Roche cobas b® 221 (Omni-S)
Radiometer ABL® 80 FLEX	Instrumentation Laboratory GEM® Premier™ 3000	NOVA Biomedical Stat Profile® Prime Analyzer
Radiometer ABL® 90 FLEX	Instrumentation Laboratory GEM® Premier™ 4000	Abaxis Piccolo Xpress™
Sysmex XP-300™	Instrumentation Laboratory GEM® Premier™ 5000	Abbott i-STAT®
Siemens DCA Vantage®	HemoSonics Quantra®	

### **Abbott i-STAT® results not flagging for “Outside AMR (High)” or “Outside AMR (Low)”**

Starting in RALS™ 6.0 SP5 results were no longer flagging with values outside AMR high or AMR Low. Updates to the RALS™ disabled flags functionality now accounts for Abbott i-STAT® multiple value types with the same flags, therefore correctly flagging results outside of AMR in RALS™ Results Review and Flagged Results pages.

### **NOVA Biomedical Wireless Operator Query Supporting IDs containing apostrophes**

Previously, NOVA Biomedical StatStrip® GLU (Glucose) devices querying RALS™ for operator IDs that contained an apostrophe, while in wireless mode, would create a SQL exception. RALS™ now supports queries for operator ID that contain an apostrophe while in wireless mode.

### **Roche CoaguChek® XS Plus / CoaguChek® XS Pro Reagent Update Failure**

Reduced the max number of Roche CoaguChek® XS Plus / CoaguChek® XS Pro reagents sent in each communication message from 10 to 5 to prevent download failures.

### **Operator List Update via NovaNet Failures**

RALS™ 6.0 SP7 contains updates to the handling of operator list messages with NOVA Biomedical devices connected via NovaNet.

### **Abbott FreeStyle Precision Pro® KF Meter Extended Sample Type Display**

Abbott FreeStyle Precision Pro® KF meter extended sample types were previously being displayed differently in RALS™ than on the meter. RALS™ now sends the correct extended sample types to the meter, therefore allowing the sample types to match between RALS™ and what is displayed on the meter: Arterial, Capillary Fingerstick, Capillary Heel stick and Venous.



### **Roche ACCU-CHEK® Inform II Firmware LQC Ranges Changed to Abnormal Range**

Previously, Roche ACCU-CHEK® Inform II LQC Level 1 and Level 2 ranges were automatically changed to abnormal range when LQC results were out of any defined range with device firmware version 04.03.00.

### **Roche ACCU-CHEK® Inform II LQC Strip Lot Range Changes**

Previously, when a range was received as part of a Roche ACCU-CHEK® Inform II LQC result, RALS™ would update the corresponding level range for the associated Strip Lot. This may overwrite changes a RALS™ User had made to the range. Now, once Roche ACCU-CHEK® Inform II ranges have been edited in RALS™, ranges sent from the device with results will not change the associated Strip Lot ranges.

### **Instrumentation Laboratory Hemochron Signature Elite® Auto Download**

Instrumentation Laboratory Hemochron Signature Elite® devices were not auto downloading results when connected to RALS™ via a Data Port. RALS™ 6.0 SP7 introduces a system configuration setting Instrumentation Laboratory Hemochron Signature Elite® device to modify the baud rate and support auto downloading.

### **Siemens Clinitek Status® Results Display**

Previously, results were displayed differently in RALS™ compared to the display on the device. RALS™ now recognizes all Siemens Clinitek Status® results as qualitative and therefore displays what the device displays and sends.

### **Abbott ID NOW™**

Previously, RALS™ did not update the operator entry on the ID NOW™ device when the operator's certification expiration date changed. RALS™ now automatically sends the operator to the ID NOW™ when the certification expiration date is updated.