SIEMENS

RAPIDComm® Data Management System

Urgent Field Safety Notice

31484 Rev. A

May 2014

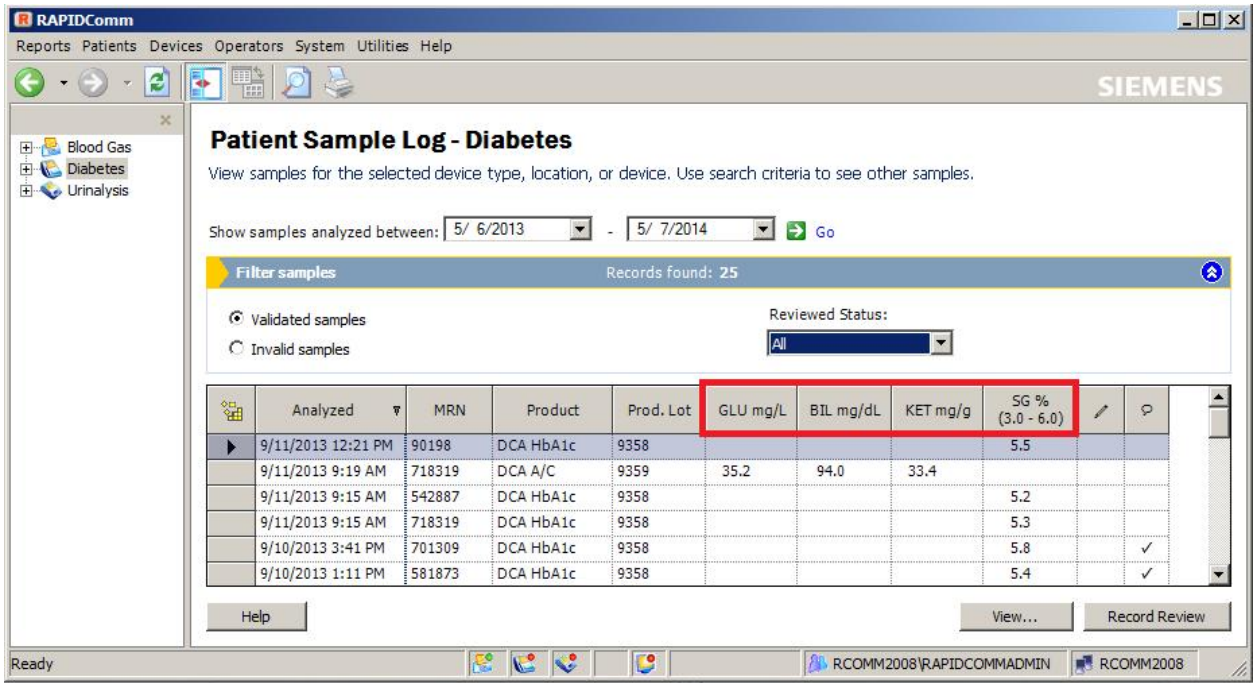
RAPIDComm® 5.0 Screen Layout Customization Defect

Our records indicate that you have received RAPIDComm® Data Management System version 5.0 software.

A defect in this version of software was identified by Siemens Healthcare Diagnostics that could potentially impact customers using RAPIDComm 5.0 to manage both CLINITEK Status® Connect urinalysis instruments and DCA Vantage® diabetes instruments. The defect occurs when a very specific sequence of configuration steps is intentionally performed to first customize the layout of the "Validate Patient Sample" screen for Urinalysis or Diabetes, immediately followed by layout customization of the other modality (Diabetes or Urinalysis).

The resulting issue is that the column headers for patient sample reports and QC reports within RAPIDComm will display incorrect test names. However, patient results transmitted to the HIS/LIS system are not affected and continue to be reported with the correct test names. If the issue were to occur, it can be resolved by reconfiguring the test names within RAPIDComm.

The image below shows an example of how the incorrect test names would be displayed within the column header of the Patient Sample Log for Diabetes. When the defect occurs, (GLU replaces ALB, BIL replaces CRE, KET replaces A/C, and SG replaces HbA1C).



Unless the screen customization is intentionally performed, the issue will not occur. The defect does not impact customers using RAPIDComm 5.0 to manage blood gas instruments only.

Siemens is developing a software update to correct the problem, which will be required for customers who use RAPIDComm 5.0 to manage Urinalysis and Diabetes instruments. We will update you when the software is available.

Because results continue to be reported to the LIS with the correct test names, and results remain correct on the analyzer, there is no risk to health and no repeat testing of patient samples is necessary.

Please retain this letter with your laboratory records. Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

If you are using RAPIDComm version 5.0 to manage both CLINITEK Status Connect Urinalysis instruments and DCA Vantage Diabetes instruments and would like to customize the screen layouts within RAPIDComm, please contact your local support representative who will assist you in configuring this layout.

We apologize for the inconvenience this situation has caused. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative at +45 2912 5734

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FIELD CORRECTION EFFECTIVENESS CHECK

RAPIDComm 5.0 Screen Layout Customization Defect

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 31484 Rev. A dated May 2014 regarding RAPIDComm 5.0 Screen Layout Customization Defect. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Serial Number*:

Street:

City: State:

Phone: Country

Please send this completed form to helle.schultz@siemens.com. If you have any questions, contact your local Siemens technical support representative.

* The serial number can be found by navigating to Help > About within the RAPIDComm 5.0 software application.