SIEMENS

Urgent Field Safety Notice

34002 Rev. A

January 2016

CLINITEK Status®+ Connect Systems

Possible Delay in Read Times for Urinalysis Results

Our records indicate that your facility may have received the following products:

Table 1. CLINITEK Status®+ Connect System Affected Products

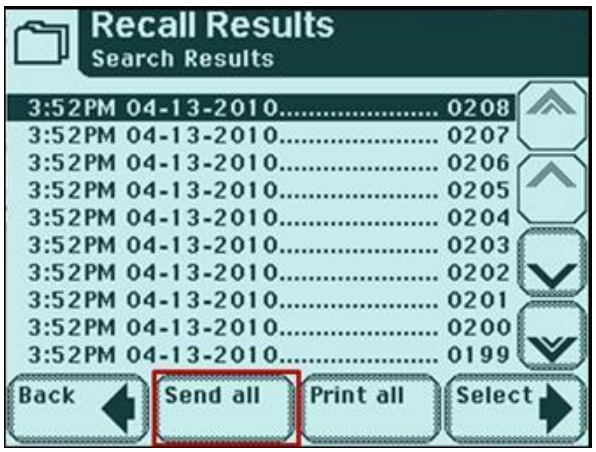
Siemens Material Number (SMN)	Product Description
10844420	CLINITEK Status+ Connect System 2.60/2.4.0.0 (2.61/2.4.1.0) SW Upgrade Kit (OUS)
10719594	CLINITEK Status+ Connect System 2.60/2.4.0.0 (2.61/2.4.1.0) SW Upgrade Kit (US)

Reason for Urgent Field Safety Notice

During an internal product review, Siemens Healthcare Diagnostics determined that there is an issue in software versions 2.60/2.4.0.0 and 2.61/2.4.1.0 for the CLINITEK Status+ Connect systems that could potentially affect patient results.

In the case that an operator transmits all of the data stored in the instrument to an LIS or data manager by selecting the **Send All** function (Figure 1), the software will allow the operator to perform a urinalysis strip or cassette test while data is still being transferred. In this case, the instrument may be slow to respond. Depending on the amount of data being transferred and the speed at which it is transferred, there may be a delay in timing when the urinalysis reagents are read by the analyzer. This delay in read time can potentially affect patient results.

Figure 1. Location of Send All Button on Recall Results Screen



2 Edgewater Drive
Norwood, MA 02062
www.siemens.com/diagnostics

DQSP-00003-T1V1.0 Effective: 2016-Jan.-25
Related Procedure: DQSP-00003 Field Action

Risk to Health

The probability of occurrence of this issue is extremely unlikely due to the low frequency of usage for this software function. Therefore, the overall risk to health is negligible. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

Please perform the following steps:

- Enable “Authorized Operators” on all instruments that are running v2.60/2.4.0.0 or v2.61/2.4.1.0 to ensure the “Send all” feature is not inadvertently used by your institution's regular operators. Refer to “Setting up the Authorized Operators” in the System Configuration section of your *CLINITEK Status+ Operator's Guide* for specific steps on how to set this up.
- Instruct the individuals with administrative rights to the "Instrument Settings" and the "Send all" function on your CLINITEK Status+ Connect system that this function should not be used.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter.

You may continue to run your instrument and report patient results, as long as the “Send all” function is not being utilized.

Please retain this letter with your laboratory records, and forward it to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Service Center or your local Siemens technical support representative.

CLINITEK Status+ and CLINITEK Status Connect are trademarks of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

Possible Delay in Read Times for Urinalysis Results

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 34002 Rev. A, dated January 2016, regarding Possible Delays in Read Times for Urinalysis Results. 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.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes ☐ No ☐
2. Do you now have any of the noted products on hand? Please check inventories before answering. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Please fax this completed form to the Customer Care Center at (XXX-XX-XXXX)

If you have any questions, contact your local Siemens technical support representative.

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