Urgent Field Safety Notice

Follow-Up Information

POC 20-001.B.OUS

July 2020

CLINITEK Status® Connect System

Follow-Up Communication for:
Incorrect Results Potentially Transmitted to LIS

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

Table 1. Affected Products

Product	Siemens Material Number (SMN)	Software Version
All CLINITEK Status®+ Analyzers, including:		
CLINITEK Status®+ Analyzer USA	10379675	V2.620
CLINITEK Status®+ Analyzer UK	10379676	
CLINITEK Status®+ Analyzer European	10379677	
CLINITEK Status®+ Analyzer French	10379678	
CLINITEK Status®+ Analyzer German	10379679	
CLINITEK Status®+ Analyzer Japanese	10379680	
CLINITEK Status®+ Analyzer Chinese	10379681	
CLINITEK Status®+ Analyzer Canada	10376324	

The issue is limited to customers using the CLINITEK Status® Connect System with the CLINITEK Status®+ Analyzer at software version 2.620, as listed in Table 1, and the Connect Platform at software version 2.4.2.0. as listed in Table 2.

Standalone CLINITEK Status®+ Analyzers and CLINITEK Status® Connect Systems on other software versions are not affected.

Table 2. Affected Connect Platform

Product	Siemens Material Number (SMN)	Software Version
CLINITEK Status Connect Platform (World Wide)	10376322	V2.4.2.0
CLINITEK Status Connect Platform (USA)	10376323	

2 Edgewater Drive
Norwood, MA 02062

Reason for Urgent Field Safety Notice

Siemens Healthcare Diagnostics previously communicated that the CLINITEK Status® Connect System could transmit incorrect results to the laboratory information system (LIS) in Urgent Field Safety Notice POC 20-001.A.OUS dated January 2020. The results sent to the LIS via a data manager could be corrupt and be presented as multiple entries of the same reagent results (for example, all LEU results) or unexpected text (for example, text LARGE instead of a pH reading of numeric figure 7.0).

UFSN POC 20-001.B Update:

In the previous letter, Siemens Healthcare Diagnostics communicated that this transmission of incorrect results to the laboratory information system (LIS) was limited to certain conditions and to address the issue, Siemens Healthcare Diagnostics recommended resetting the option "*Automatically send results to Laboratory Information System*" to Enabled as described in the Operator's Guide.

Siemens Healthcare Diagnostics has now determined that setting this option will not necessarily prevent the transmission of incorrect results to the LIS.

The results reported on the instrument screen and on the result printouts are always correct. Albumin:Creatinine (A:C) and Protein:Creatinine (P:C) ratio results are not affected. CLINITEST® hCG pregnancy test results are not affected.

Risk to Health

The risk to health depends on the test strip utilized, the affected analyte and reported result. In many scenarios, the erroneous results would be obviously discordant or clinically equivalent or would be flagged if the LIS checks for unit mismatch. Worst case, falsely depressed protein, albumin or ketone results may be obtained, which could delay differential diagnosis of kidney dysfunction or metabolic disorders. Urine analysis results would be used in conjunction with the patient's medical history, clinical examination and other findings including but not limited to other kidney and metabolic biomarkers such as urine albumin or protein to creatinine ratio, serum creatinine, quantitative urine protein, blood glucose, serum ketones.

Siemens Healthineers is not recommending a review of previously generated results.

Actions to be Taken by the Customer

1. Please complete and return the Field Correction Effectiveness Check form attached to this letter within 30 days.
2. If your site has one or more CLINITEK Status®+ Analyzers at software version 2.620 connected to a CLINITEK Status® Connect Platform at software version 2.4.2.0, you can request a software update by contacting your local Technical Solutions Center. **Before you call, please ensure you have the affected CLINITEK Status+ Analyzer Serial Numbers to provide to the Technical Solution Center.**
3. Please review this letter with your Medical Director.
4. Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

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This issue is due to a software issue with CLINITEK Status®+ software version 2.620, and it is addressed in CLINITEK Status®+ software version 2.630. Customers who indicate their system(s) are affected in the Field Correction Effectiveness Check form will receive the CLINITEK Status® Connect System software version 2.630/2.4.2.0 Update Kit at no cost.

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

Additional Information

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

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FIELD CORRECTION EFFECTIVENESS CHECK FORM

CLINITEK Status® Connect System Incorrect Results Potentially Transmitted to LIS

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice POC 20-001.B.OUS dated July 2020 regarding an issue whereby CLINITEK Status® Connect Systems may potentially transmit incorrect results to the LIS. Please read the questions below and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions 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. I have one or more affected CLINITEK Status®+ Analyzers at software version 2.620, connected to a CLINITEK Status® Connect Platforms at software version 2.4.2.0. I will follow the instruction below to request the software update. Upon receipt of the software update I will proceed to upgrade the affected systems. Yes ☐ No ☐

    - If “Yes” box is checked,
        - please call your local Siemens Technical Solutions Center at xxx-xxx-xxx to provide your affected product information (serial# of **all** affected CLINITEK Status®+ Analyzers) to receive software update kits. Please reference UFSN POC 20-001B and SKB #0114786.

Name of person completing questionnaire:

Title:	
Institution:	Instrument Serial Number*:
Street:	
City:	State:
Phone:	Country:
Customer Sold To #:	Customer Ship To #:

**If additional space is required for the serial numbers, you may attach a separate sheet.*

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