SIEMENS Healthineers

Urgent Field Safety Notice

POC 20-001.A.OUS

January 2020

CLINITEK Status® Connect System

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	

Reason for Urgent Field Safety Notice

Siemens Healthcare Diagnostics has confirmed that the CLINITEK Status® Connect System could transmit incorrect results to the laboratory information system (LIS) under the following conditions:

2 Edgewater Drive
Norwood, MA 02062

- The instrument setup option "*Automatically send results to Laboratory Information System*" has been set to Disabled (the default is Enabled).
- A user runs a second strip test immediately after completion of the first test.

Results reported on the instrument screen and on the result printouts are always correct, however 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). This unexpected text may be apparent (for example a numeric figure replaced with text; LIS unit mismatch detection) or unapparent (for example a numeric figure replacing another numeric figure). The exact result presentation at the LIS will depend on how the LIS handles the received data.

Albumin:Creatinine (A:C) and Protein:Creatinine (P:C) ratio results are not affected.

Risk to Health

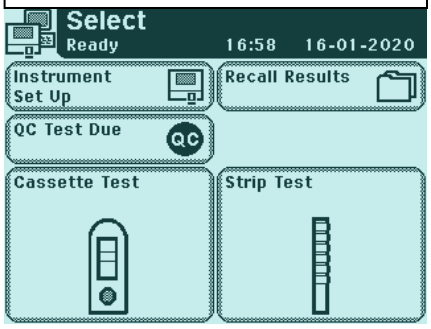
The risk to health depends on the test strip utilized, the affected analyte and reported result. In many scenarios, the erroneous results would be obviously discordant or clinically equivalent or would be flagged if the LIS checks for unit mismatch. Worst case, falsely depressed protein, albumin or ketone 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.

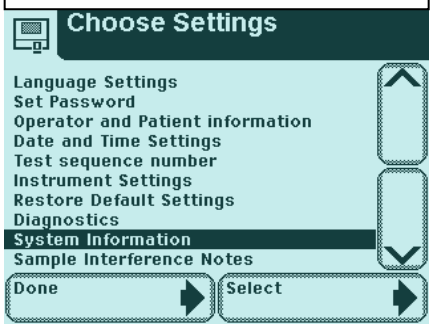
Actions to be Taken by the Customer

- Check which version of software your CLINITEK Status® Connect System is on by following these steps:

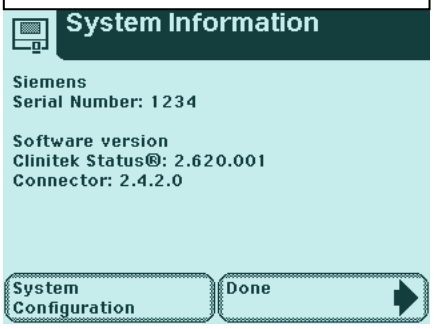
1. On the Select screen select ***Instrument Set Up***



2. Select ***System Information***



3. Check software versions

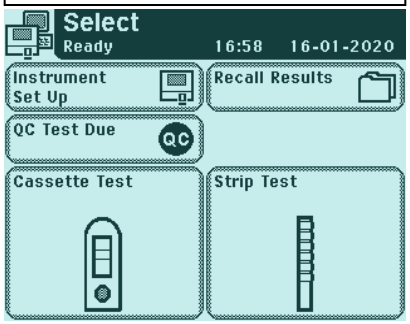


- If your CLINITEK Status®+ Analyzer is on software version 2.620 and the Connect Platform is on software version 2.4.2.0, Siemens Healthineers advises that the option "Automatically send results to Laboratory Information System" is set to Enabled in the instrument settings

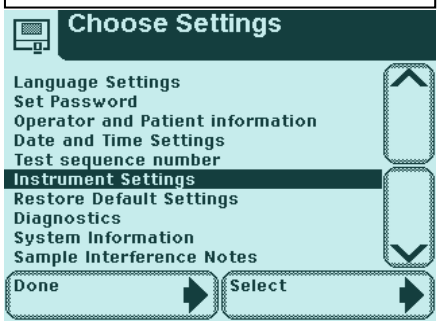
2 Edgewater Drive
Norwood, MA 02062

by following the steps below. This is the default setting and should not be changed unless the instrument is not connected to the network.

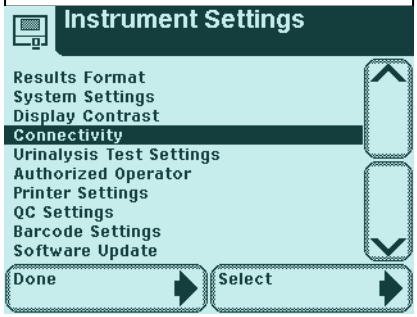
1. On the Select screen select ***Instrument Set Up***



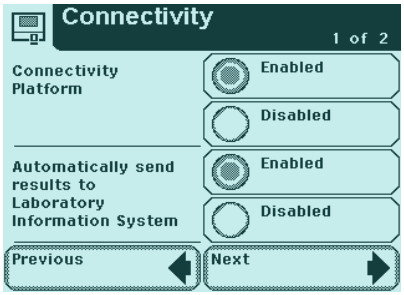
2. Select ***Instrument Settings***



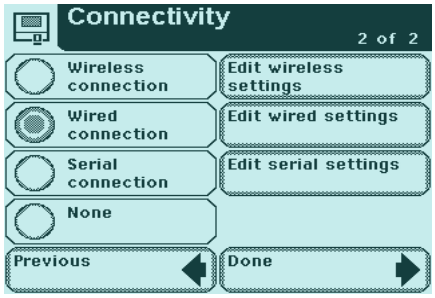
3. Select ***Connectivity***



4. Set the option ***Automatically send results to Laboratory Information***



5. Select ***Next***. Select ***Done*** three times to return to the Ready Select screen



- Please complete and return the attached Field Correction Effectiveness Check form attached to this letter within 30 days.
- Please review this letter with your Medical Director.

Please retain this letter with your laboratory records and forward this letter 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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Additional Information

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

2 Edgewater Drive
Norwood, MA 02062

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.A.OUS dated January 2020 regarding an issue that CLINITEK Status® Connect System incorrect results may potentially be transmitted to 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 read and understood the Urgent Field Safety Notice. Our system(s) is affected. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Customer Sold To #: Customer Ship To #:

Please send a scanned copy of the completed form via email to XXXX@XXXX or fax this completed form to the Customer Care Center at XXXXXX.

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

2 Edgewater Drive
Norwood, MA 02062