



Urgent Field Safety Notice

POC 16-019.A.OUS

June 2016

Stratus[®] CS Acute Care[™] Diagnostics System
Stratus[®] CS 200 Acute Care[™] Diagnostics System

Potential Reporting Errors with TestPaks that Are Due to Expire within 48 Hours

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

Table 1. Affected Product

Analyzer	Siemens Material Number (SMN)	Software Versions	Analyzer Serial Numbers
Stratus [®] CS 200 Acute Care [™] Diagnostics System	10714016	2.0.1 and 2.0.2	All serial numbers
Stratus [®] CS Acute Care [™] Diagnostics System	10444834 10453531 10453570 10453571 10470384	All software versions	All serial numbers

Reason for the Urgent Field Safety Notice

Siemens Healthcare has confirmed a software defect in the Stratus CS Acute Care Diagnostics System and Stratus CS 200 Acute Care Diagnostics System regarding TestPak calibration and quality control (QC) status when a TestPak is due to expire within 48 hours.

Depending on the calibration status, either an Above Assay Range (AAR) or an inaccurate value could potentially be reported when running a TestPak that is due to expire within 48 hours.

Risk to Health

The risk to health is limited to potentially generating an AAR flag or inaccurate result when a TestPak is due to expire within 48 hours and the calibration has expired, not been performed, or failed prior to the TestPak being installed on the analyzer. In all cases, the probability of occurrence is extremely unlikely and other factors such as previous results, patient presentation, and other diagnostic testing would initiate clinical questioning and reduce the potential for injury.

Actions to be Taken by the Customer

- Do not use TestPaks that are due to expire within 48 hours, OR
- Check Reagent Status to ensure all TestPaks in use have valid calibration expiry dates beyond the TestPak lot expiry date, AND
- If your laboratory performs routine QC and if using a TestPak that is due to expire within 48 hours, ensure that scheduled QC is performed before running a test.

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

Please review this letter with your Medical Director.

If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

We apologize for any inconvenience this situation may cause.

Additional Information

Siemens Healthcare is currently developing software updates to address this issue and will be providing new information as it becomes available.

Stratus CS and Stratus CS 200 are trademarks of Siemens Healthcare Diagnostics.

It is important that your organisation takes the actions detailed in the UFSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to this UFSN. Your organisations reply is evidence which, Siemens Healthcare, and subsequently the MHRA, needs to monitor the progress of the UFSN. Without your reply Siemens Healthcare cannot verify the completeness of the UFSN.

Fax: 0845 605 6800

Email: robert.davies@siemens.com

FIELD CORRECTION EFFECTIVENESS CHECK

Potential Reporting Errors with TestPaks that Are Due to Expire within 48 Hours

Ref: POC 16-019 [C/3546]

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice POC 16-019.A.OUS dated June 2016, regarding Potential Reporting Errors with TestPaks that Are Due to Expire within 48 Hours. Please read each question and indicate the appropriate answer.

Please return this completed form to Siemens Healthcare Diagnostics within 14 days of receipt.

I have read and understood the Urgent Field Safety Notice instructions provided in this letter.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Name of person completing questionnaire:		
Title:		
Institution:	Instrument Serial Number:	
Street:		
City:	Post Code:	
Phone:	Email:	
Signed:	Date:	

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