



**Urgent Field Safety Notice**  
**Resolution Update**

**POC 19-014.C.OUS**

**September 2021**

**Stratus® CS & CS 200 Acute Care™ Diagnostic Systems**

**Resolution Update for:**  
**False Positive cTnI Results for Acute Care™ cTnI TestPak**

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

**Table 1. Affected Product**

<b>Product</b>	<b>Siemens Material Number (SMN)</b>
Stratus® CS Acute Care™ cTnI TestPak	10445071

**Reason for this Resolution Communication**

This is a resolution update to POC 19-014.OUS. The purpose of this communication is to inform you of the resolution of an issue with the product indicated in Table1 above and provide instructions on actions that your laboratory should take.

As notified in POC 19-014.OUS, issues with positive bias and non-repeatable false positive cTnI results were identified. Since then, through subsequent complaint analysis and investigation, Siemens Healthineers has implemented corrective actions and determined that these issues are now resolved.

All the corrective actions have been implemented on lots beginning with cTnI TestPak Lot # 231172002.

**Actions to be Taken by the Customer**

- For the cTnI TestPak lots listed below in Table 2, please continue using precautions by repeating tests for positive result verification.

**Table 2. Lots Manufactured Prior to Lot # 231172002**

<b>Lot#</b>	<b>Expiration Date</b>
231158002	2021-10-05
231165002	2021-10-12

- Starting with Lot # 231172002 and forward, repeating tests for positive result verification is no longer required. All corrective actions have been implemented allowing these lots to be used as originally instructed via the IFU.
- Please complete and return the Field Correction Effectiveness Check form attached to this letter within 30 days to indicate that you have received this information. Please acknowledge receipt of this letter and return the response form even if you do not have product on hand.
- Please review this letter with your medical director or laboratory director.
- Retain this letter with your laboratory records, and we also ask that you please forward this notification to anyone to whom you may have distributed this product.

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

### **Additional Information**

Stratus® CS & CS 200 are trademarks of Siemens Healthcare Diagnostics Inc.

## FIELD CORRECTION EFFECTIVENESS CHECK

### Resolution Update for False Positive cTnI Results for Acute Care™ cTnI TestPak

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice Resolution Update POC 19-014.C.OUS dated September 2021 regarding False Positive cTnI Results for Acute Care™ cTnI TestPak. Please read the question below and indicate the appropriate answer.

Please 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 Resolution Update instructions provided in this letter. Yes  No

Name of person completing questionnaire: \_\_\_\_\_

Title: \_\_\_\_\_

Institution: \_\_\_\_\_ Instrument Serial Number: \_\_\_\_\_

Street: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_

Phone: \_\_\_\_\_ Country: \_\_\_\_\_

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.