Customer Notification

POC 26-008.A.OUS

epoc® Blood Analysis System

Title Positive bias on creatinine and other parameters calculated using creatinine

Date Issued **JUL-2026**

Product Description	Siemens Material Number	GTIN	Software Version
Epoc Host2 (MC55/x)	10736387	00809708052898	epoc Host2 v3.44.0 epoc NXS v4.17.6 Sensor Configuration 48.0
	10736388	00809708069117	
	10736389	00809708097219	
	10736390	00809708075576	
	10736393	00809708053901	
	10736394	00809708069124	
	10736395	00809708075583	
	11413528	00630414606378	
	11413541	00630414608617	
	11413542	00630414608624	
	11413543	00630414608532	
NXS Host	11413497	00630414605760	
	11413498	00630414605814	
	11413506	00630414605821	
	11413517	00630414605838	
	11413518	00630414605678	
	11413583	00630414612447	
	11413879	00630414631028	

Issue Description Siemens Healthineers has confirmed that discrepantly high creatinine results may occur in arterial, venous, and capillary patient samples with epoc sensor configuration 48.0 (epoc Host v3.44.0 and epoc NXS v4.17.6) when samples with creatinine concentrations between 4.0 and 8.0 mg/dL (354 and 707 µmol/L) are introduced more than 40 seconds after initiation of the "Inject Sample" stage. Test cards stored at the top end of allowable temperatures range (30°C) may contribute to this issue.

Discrepant high creatinine results may cause the following calculated values to have a low bias:

- GFRmdr, GFRmdr-a, GFRckd, GFRckd-a, GFRckd21, GFRswz
- BUN/Crea ratio, Urea/Crea ratio

For more information about calculated values or the specific equations, refer to section 12.16 ‘Calculated Values’ of the epoc System Manual.

SIEMENS Healthineers

Quality control does not detect this issue and aqueous fluids are unaffected.

The root cause of the creatinine bias was determined to be caused by sensor configuration 48.0. No complaints have been received related to this issue.

Impact to results

Erroneously elevated creatinine results may occur, related to injection time and elevated storage temperature. The positive bias observed was up to approximately +2.0 mg/dL at 4.0 mg/dL (+177 µmol/L at 354 µmol/L) and +4.0 mg/dL at 6.0-8.0 mg/dL (+ 354 µmol/L at 530-707 µmol/L). Mitigations include injection timeliness, discordance from historical results, other test results, repeat testing, and the patient's clinical presentation.

Customer Actions

Perform the instructions provided below:

- Customers should inject samples within the first 40 seconds after the "Inject Sample" message appears on screen or prior to 240 seconds from inserting the test card to minimize the potential of erroneous results.
- Please review this letter with your Medical Director/POC Coordinator to determine the appropriate course of action, including any previously generated results, if applicable.
- For customers reporting creatinine: An interim software update with sensor configuration 48.1 is available and corrects the issue. Customers should upgrade to the new software to mitigate the issue.
- Customers not reporting creatinine may continue to use the current software version.
- Please complete and return the Field Correction Effectiveness Check Form attached to this letter.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

Resolution

An interim software update with sensor configuration 48.1 is available and corrects the issue. Customers should upgrade to the new software to mitigate the issue if reporting creatinine. Both the interim and the current software version/sensor configuration 48.0 will expire December 9, 2026. Customers may continue to use current software version if they do not report creatinine.

Single Registration Number

CA-MF-000017182

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.

Siemens Healthcare Sdn. Bhd.
Registration No: 201501001338 (1126670-U)

Management: Siow Ai Li, Managing Director;
Jan Henning Tiedermann, Finance Director

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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers POC 26-008.A.OUS dated JUL-2026. Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1 immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Please return this completed form as per the instructions provided at the bottom of this page.

1.	Have you read and understood the instructions provided in this letter?	Yes ☐	No ☐
2.	Were affected Site Personnel notified?	Yes ☐	No ☐
3.	Was a copy of the letter retained and posted with the current product labeling?	Yes ☐	No ☐
4.	Do you perform creatinine testing on patients?	Yes ☐	No ☐
5.	By selecting Yes, you confirm impacted devices have been upgraded to the interim software if performing creatinine testing on patients.	Yes ☐	

Please complete the information requested below if your institution performs creatinine testing on patients.

Name of person completing questionnaire:		
Title:		
Institution:		
Street:		
City:	**State:**	**Zip Code:**
Phone:	**Country:**	
Customer Sold To #	**Customer Ship To #**	
Product Description **Product Catalog #/SMN #/Lot #**	**List of Serial Numbers in inventory upgraded**	
Host2		

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NXS Host	

Please send a scanned copy of the completed form via email to fscareportingunit.my@siemens-healthineers.com.

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