

Urgent Field Safety Notice

POC 25-007.A.OUS

epoc® Blood Analysis System

Title	Discrepant High pH Results with Sensor Configuration 45.n
Date Issued	March 2025
Issue Description	The purpose of this communication is to inform you of a potential issue with the products indicated in the table below and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed the occurrence of discrepant high pH results in samples introduced with higher injection volumes (beyond the epoc Reader beep or after the "Analyzing Sample" message is displayed) with epoc sensor configuration 45.n (software version: epoc Host v3.41.2 and epoc NXS v4.14.9 & 4.14.11).

The observed maximum bias, average bias and probability of occurrence (PO) at **higher injection volumes** for the affected products are detailed in the table below.

pH level	Maximum Bias	Average Bias	PO of Bias > 0.04
7.00	+0.043	-0.0125	0.55%
7.35	+0.126	+0.0290	5.84%
7.45	+0.103	+0.0378	10.82%

It should be noted that Total Carbon Dioxide (TCO₂) is a measured value that uses the pH result. The maximum bias, average bias and probability of occurrence for measured TCO₂ is detailed below:

TCO ₂ range tested (mmol/L)	Maximum bias (mmol/L)	Average bias (mmol/L)	PO of Bias ≥ 8 mmol/L
19 to 31	+9	+2	0.29%

Discrepant high pH results may affect the following calculated values:

- Anion Gap (AGap) (through cHCO₃ or TCO₂)
- Base Excess (blood) (BE(b))
- Base Excess (extra cellular fluid) (BE (ecf))
- Calculated Bicarbonate (cHCO₃-)
- Calculated Oxygen Saturation (cSO₂)
- Calculated Total Carbon Dioxide (cTCO₂)

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

Siemens Healthcare Diagnostics determined the root cause of the pH bias to be caused by sensor configuration 45.n.

Product

Product Description	Siemens Material Number (SMN)	Unique Device Identification (UDI-DI)	Lot Number (xx-nnnnnn-nn)	epoc Software Version & Sensor Configuration	SW expiration (yyyy-mm-dd)
epoc BGEM BUN Test Card	10736515	00809708121860	All lot numbers with prefix (xx) 02 or 12	epoc Host SW v3.41.2 epoc NXS SW v4.14.9 & 4.14.11 Sensor Configuration 45.n	2025-06-10
epoc BGEM Crea Test Card	10736382	00809708072254	All lot numbers with prefix (xx) 00 or 06		

Impact to Results

The epoc Host2 and NXS Host were confirmed to report discrepant high pH values. Falsely elevated pH values may lead to unrecognized acidosis and/or the misinterpretation of acid-base disorders which could result in suboptimal management decisions. For example, if acidosis is unrecognized due to the false elevation of pH, a clinician may opt not to initiate vasopressors and/or optimize ventilator settings which could increase the likelihood of clinical deterioration of the patient. The impact of this issue could include the following:

- The erroneous pH is not recognized by the provider despite discordance from historical results, other test results, and the patient's clinical presentation.
- The likelihood a patient's pH is in a range where if the clinician did not question the erroneously elevated result the patient would be at greater risk of injury.
- The likelihood of the extent of positive bias of the reported result being clinically significant.
- The likelihood that a patient is significantly harmed due to the falsely elevated pH.

The potential for injury based on a calculated parameter or the measured TCO₂ is not significantly increased when the pH is erroneous because these would not be used in isolation to guide clinical decisions.

Customer Actions

- Please review this letter with your Medical Director determine the appropriate course of action, including for any previously generated results, if applicable.
- If you are a distributor, please ensure your customers receive this UFSN letter.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 7 days.
- This issue is isolated for samples introduced with higher injection volumes (beyond the Reader beep or after the "Analyzing Sample" message is displayed). It is recommended to stop injecting the sample as soon as the audio/visual cues are presented to minimize the potential for erroneous pH results. The current affected software version/sensor configuration expires on June 10, 2025. Once the next software version is available, install the upgrade as soon as possible.

Siemens Healthineers

Siemens Healthcare Diagnostics Inc.
POC HQ
333 Coney Street
Walpole, MA 02062, USA
siemens-healthineers.com

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- Please retain this letter with your epoc System Manual with NXS Host or place the letter near the affected instrument for reference. Please also forward this letter to those who may have received this product at your site.
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Resolution

A new sensor configuration will be released in the April/May 2025 software update, resolving the issue with discrepant high pH results on epoc systems running sensor configuration 45.n.

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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice POC 25-007.A.OUS dated March 2025. 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 for on Page 2 immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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

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|-----------------------------------------------------------------------------------------|------------------------------|-----------------------------|
| 1. I have read and understood the instructions provided in this letter. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2. All affected Site Personnel have been notified. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3. A copy of the letter has been retained and posted with our current product labeling. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Name of person completing questionnaire:			
Title:			
Institution:			
Street:			
City:		State:	
Phone:		Country:	

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

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 Healthineers

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Walpole, MA 02062, USA
siemens-healthineers.com