

Urgent Field Safety Notice

POC 25-014.A.OUS

epoc® Blood Analysis System

Title Negative Sodium Bias on Multiple Test Card Lots

Date Issued July 2025

Products

Product	Siemens Material Number	GTIN	Lot Number / Expiration
epoc BGEM BUN Test Card [25pk]	10736515	00809708121860	Refer to the Appendix for the complete list of affected lots

Issue Description

The purpose of this communication is to inform you of a potential issue with the product indicated in the table above and provide instructions on actions that your facility must take.

Siemens Healthcare Diagnostics Inc. has confirmed that a negative sodium bias may exist in some epoc test card lots. All other analytes are performing as intended.

The observed average bias for sodium was -4.4 mmol/L. The maximum bias observed was -14 mmol/L, which occurred at a higher sodium concentration around 150 mmol/L. No positive bias has been observed. Quality Control (QC) fluid may or may not detect the issue depending on the bias magnitude and the frequency of QC testing.

Impact to Results

Erroneous sodium test results could lead to a delayed diagnosis of hypernatremia or unnecessary treatment for hyponatremia. An example of the worst-case scenario would be an erroneously depressed sodium level resulting in the incorrect decision to withhold treatment from a patient with hypernatremia leading to worsening electrolyte abnormalities.

Mitigations include deviation from historical results, the likelihood of repeat testing prior to initiating treatment, discordance from the clinical presentation of the patient, and the unlikely event the patient is significantly harmed due to a falsely depressed sodium.

Customer Actions

- Please review this Urgent Field Safety Notice letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- You may discard and request a replacement of any affected lots. Alternatively, if your institution does not need to report sodium, you can turn off sodium following the instruction of the owner's manual and use the cards to test other analytes.
- If you are a distributor, please ensure your customers receive this UFSN letter.
- Complete and return the Field Correction Effectiveness Check Form and if applicable, product replacement form attached to this letter within 30 days.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

Single Registration Number (SRN) CA-MF-000017182

We apologize for any 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.

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Siemens Healthineers

Siemens Healthcare Diagnostics Inc.

POC HQ

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[siemens-healthineers.com](https://www.siemens-healthineers.com)

Appendix: epoc Test Card Lots Impacted

**All lots pertain to epoc BGEM BUN Test Cards (SMN 10736515) with expiration dates from 20-Sept-2025 to 20-Oct-2025.*

Lots ending-30	Lots ending-40	Lots ending-50	Lots ending-60	Lots ending-70
02-25095-30	02-25096-40	02-25096-50	12-25096-60	02-25099-70
02-25096-30	02-25097-40	02-25098-50	12-25097-60	02-25101-70
02-25098-30	02-25098-40	02-25099-50	12-25098-60	02-25104-70
02-25099-30	02-25099-40	02-25100-50	12-25100-60	02-25105-70
02-25100-30	02-25101-40	02-25102-50	12-25101-60	02-25107-70
02-25101-30	02-25102-40	02-25103-50	12-25102-60	02-25108-70
02-25102-30	02-25105-40	02-25105-50	12-25103-60	02-25110-70
02-25103-30	02-25106-40	02-25107-50	12-25111-60	02-25111-70
02-25105-30	02-25121-40	02-25108-50	02-25112-60	02-25112-70
02-25111-30	02-25122-40	02-25111-50	02-25113-60	02-25113-70
02-25112-30	02-25124-40	02-25112-50	02-25114-60	02-25115-70
02-25114-30	02-25125-40	02-25113-50	02-25115-60	02-25116-70
02-25115-30		02-25114-50	02-25116-60	02-25118-70
02-25116-30		02-25115-50	02-25117-60	02-25120-70
02-25117-30		02-25119-50	02-25118-60	
02-25119-30		02-25120-50	02-25120-60	
02-25121-30			02-25121-60	
02-25122-30			02-25122-60	
02-25123-30			02-25123-60	
02-25124-30			02-25124-60	

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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 25-014.A.OUS dated July-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 on Page 1 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.

1. Have you read and understood the instructions provided in this letter? Yes ☐ No ☐
2. Do you have the affected product(s) on hand? Please check inventories before answering. Yes ☐ No ☐
3. Were affected Site Personnel notified? Yes ☐ No ☐
4. Was a copy of the letter retained and posted with the current product labeling? Yes ☐ No ☐

If the answer to question #2 above is yes, please complete the table below to indicate the quantity of affected product in your facility and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory Discarded/Replacement Quantity Required	
epoc BGEM BUN Test Card [25pk] (SMN 10736515)		
Lot #(s):		
Name of person completing questionnaire:		
Title:		
Institution:		
Street:		
City:	State:	Zip Code:
Phone:	Country:	

Please send a scanned copy of the completed form via email to cruinnfsngroup@cruinn.ie. Or fax this completed form to the Customer Care Center at 01 629 7401.

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