

### epoc® Blood Analysis System

### epoc Discrepant High Glucose Results on Multiple Test Card Lots

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

**Table 1. Affected Products**

Product Description	Siemens Material Number (SMN)	Unique Device Identification (UDI-DI)	Lot Number	epoc Software (SW) Version and Sensor Configuration
epoc BGEM BUN Test Card	10736515	00809708121860	04-23003-60	epoc Host SW v3.37.3 epoc NXS SW v4.10.6 Sensor Configuration 41.1*
			11-22337-60	
			04-23034-40	
			04-23059-50	
			04-23059-60	
			04-23069-40	
epoc BGEM Crea Test Card	10736382	00809708072254	03-23002-60	
			03-23056-50	

\* epoc Host SW v3.37.3/ epoc NXS SW v4.10.6/Sensor Configuration 41.1 expires June 13, 2023.

### Reason for Urgent Field Safety Notice

The purpose of this communication is to inform you of an issue with the products indicated above in Table 1 and provide instructions on actions that your facility must take.

Siemens Healthcare Diagnostics Inc. has confirmed the occurrence of discrepant high glucose results in samples with glucose results on the lower end of the reportable range (at or below 54 mg/dL) when using the above listed lots of BGEM test cards in conjunction with sensor configuration 41.1 (software version: epoc Host v3.37.3 and epoc NXS v4.10.6). The observed maximum bias for the affected lots are detailed in Table 2 below.

**For card lot 04-23003-60:** At a medical decision level of less than or equal to 54 mg/dL, the maximum positive bias is +21 mg/dL.

**For all other card lots listed:** At a medical decision level of less than or equal to 54 mg/dL, the maximum positive bias is +13 mg/dL or +14 mg/dL.

epoc BGEM Test Cards perform within specifications at all other medical decision levels.

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**Table 2. Maximum Bias of Affected Lots**

Product SMN	Card Lot Number	Expiration Date	Maximum Bias At $\leq 54$ mg/dL
10736515	04-23003-60	20-Jun-2023	+21
10736515	11-22337-60	20-May-2023	+14
10736515	04-23034-40	21-Jul-2023	+13
10736515	04-23059-50	15-Aug-2023	
10736515	04-23059-60	15-Aug-2023	
10736515	04-23069-40	25-Aug-2023	
10736382	03-23002-60	19-Jun-2023	
10736382	03-23056-50	12-Aug-2023	

This issue also affects external quality control (QC) results. QC testing may or may not detect the issue.

Siemens Healthcare Diagnostics has not received any customer complaints associated with this issue. There have been no reports of adverse events.

Siemens Healthcare Diagnostics has determined the preliminary root cause to be not attributable to software. The next sensor configuration, 42.1, mitigates the issue.

### Risk to Health

This situation may lead to an increase in the misclassification of patients with Level 2 hypoglycemia (i.e. blood glucose level  $< 54$  mg/dL [3 mmol/L]), thereby delaying the recognition and management of severe hypoglycemia. At normal and high levels of glucose and at Level 1 hypoglycemia (i.e. blood glucose level at  $< 70$  mg/dL (3.9 mmol/L) but  $\geq 54$  mg/dL [3 mmol/L]), epoc BGEM Test Cards perform within specification and would not be expected to alter management of a patient or to result in any harm.

### Actions to be Taken by the Customer

- Complete and return the Field Correction Effectiveness Check attached to this letter within 7 days.
- If you are a distributor, please ensure your customers receive this UFSN letter.
- Update all epoc Systems to epoc Host SW v3.38.2 / epoc NXS SW v4.11.11 (sensor configuration 42.1). Once updated, all impacted lots can be used as normal. This planned software update is available in Siemens Healthineers Document Library or the epoc Live Update Service (eLUS). The affected SW /configuration version will expire June 13, 2023.
- If you have already updated to epoc Host SW v3.38.2 / epoc NXS SW v4.11.11 (sensor configuration 42.1), no further action is required.
- You may also choose to dispose any inventory of epoc BGEM test card lots listed in Table 2 that are currently in your possession in accordance with your local and state disposal requirements. You may request free of charge replacement product from your local Siemens or distributor office. Please review your inventory of this product and assess your laboratory's replacement needs.

## **epoc Discrepant High Glucose Results on Multiple Test Card Lots**

- Please review this letter with your Medical Director.

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

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.

### **Additional Information**

epoc® Blood Analysis System is a trademark of Siemens Healthcare Diagnostics Inc.

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### FIELD CORRECTION EFFECTIVENESS CHECK

#### epoc Discrepant High Glucose Results on Multiple Test Card Lots

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice POC 23-014.A.OUS dated June 2023 regarding epoc Discrepant High Glucose Results on Multiple Test Card Lots. Please read each question and indicate the appropriate answer.

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 instructions provided in this letter. Yes ☐ No ☐
2. Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes ☐ No ☐

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

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory Discarded/ Replacement Quantity Required
epoc BGEM Crea Test Card, SMN #10736382, Lot# 03-23002-60, 03-23056-50	
epoc BGEM BUN Test Card, SMN #10736515, Lot# 04-23003-60, 11-22337-60, 04-23034-40, 04-23059-50, 04-23059-60, 04-23069-40	

Name of person completing questionnaire:	
Title:	
Institution:	Instrument Serial Number:
Street:	
City:	State:
Phone:	Country:
Customer Sold To #:	Customer Ship To #:

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.

If you have any questions, contact your local Siemens Healthineers technical support representative.