

epoc® Blood Analysis System

iQC Sample Delivery (E49) error limit conflicts with the measurement range of Calculated Bicarbonate (cHCO₃⁻)

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)	Software Version
epoc Host 2 (Model: MC550)	10736387	00809708052898	ALL software versions since epoc System (ES) 3.16.0 with Sensor Configuration 22.0 (including all NXS software versions)
	10736388	00809708069117	
	10736389	00809708097219	
	10736390	00809708075576	
	10736393	00809708053901	
	10736394	00809708069124	
	10736395	00809708075583	
	10736433	00809708097226	
epoc Host 2 (Model: MC55X)	11413524	00630414606460	
	11413528	00630414606378	
	11413541	00630414608617	
	11413543	00630414608532	
	11413601	00630414615004	
	11413602	00630414614885	
	11413603	00630414614762	
	11413604	00630414614892	
epoc NXS Host	11413497	00630414605760	
	11413475	00860414606095	
	11413506	00630414605821	
	11413517	00630414605838	
	11413518	00630414605678	
	11413498	00630414605814	
	11413583	00630414612447	
	11413879	00630414631028	

Reason for Customer Notification

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

Siemens Healthcare Diagnostics Inc. has confirmed an issue on the epoc Blood Analysis System in which calculated bicarbonate (cHCO_3^-) results between 75 mmol/L and 85 mmol/L will falsely report an iQC Sample Delivery (E49) error due to the fact the limit for bicarbonate concentration is incorrectly set at 75 mmol/L. Any blood sample with a calculated bicarbonate (cHCO_3^-) concentration above 75 mmol/L is reported as an incomplete test, labeled as iQC Sample Delivery (E49), with all analyte results suppressed. Sample Delivery iQC (E49) flags for irregularities detected with sample injection, so only repeated E49 errors may be due to the issue described in this notice.

The measurement range for calculated bicarbonate (cHCO_3^-) on the epoc System is 1 – 85 regardless of the units, mmol/L or mEq/L. Patient bicarbonate (cHCO_3^-) results between 75 and 85 should be reported as a numerical value.

Actions to be Taken by the Customer

- Please review this letter with your medical director.
- Please retain this letter for your laboratory records and forward this letter to those who may have received this product.

This issue is corrected in the next epoc release due in the Spring of 2024, with Sensor Configuration 44.n (Host2 version 3.40.x and NXS version 4.13.x). The current epoc software version expires on June 11, 2024.

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.