

epoc® Blood Analysis System

NXS Host – Potential for Test Record to Include Unselected Analytes

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) | Software Version |
|---------------------|-------------------------------|---------------------------------------|---|
| epoc NXS Host | 11413497 (EU) | 00630414605760 | From 4.9.4 to the current version 4.11.11 |
| | 11413475 (US) | 00630414606095 | |
| | 11413506 (CA) | 00630414605821 | |
| | 11413517 (MX) | 00630414605838 | |
| | 11413518 (ROW) | 00630414605678 | |
| | 11413498 (JP) | 00630414605814 | |
| | 11413583 (CN, KR) * | 00630414612447 | |
| | 11413879 (IN) | 00630414631028 | |

* Currently only for sale in South Korea

Reason for Urgent Field Safety Notice

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

Siemens Healthcare Diagnostics Inc. has confirmed a potential issue that could occur under specific conditions when the (automatic) Delete Blood Tests feature is enabled.

When the results are run on the epoc NXS Host and Delete Blood Tests feature is enabled, the results that are generated at the time of testing are correct; however, when this issue occurs, results that are printed, saved and/or transferred to a data manager, may include unselected analytes.

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This potential issue can be observed ONLY when the following conditions are met:

| If | Then |
|--|-------------------------------|
| <ul style="list-style-type: none"> • The Delete Blood Tests setting is NOT set to NEVER; AND • The Automatic test record deletion is executed and all test records are deleted, leaving no test records in NXS Host; AND • The NXS Host is rebooted | <p>This issue COULD OCCUR</p> |

For example, the following may be observed when the conditions above are met, and this issue occurs. If a test is run for only gases (i.e., pH, pCO₂, and pO₂) the results for the selected analytes (i.e., pH, pCO₂, and pO₂) are correct. Then, if the conditions above are met, then, an additional analyte result (e.g., sodium (Na⁺)) may be reported even though this analyte (e.g., sodium (Na⁺)) was not part of the selected analytes. Please note that this additional result is not from the test run but rather from a previous test record.

This potential issue is NOT observed when:

| If | Then |
|--|--------------------------------------|
| <ul style="list-style-type: none"> • Delete Blood Tests is set to NEVER, OR <p><i>Note - "NEVER" is the default setting and the system uses the First in First Out (FIFO) method to remove/replace tests. This FIFO method does not result in the issue.</i></p> <ul style="list-style-type: none"> • The test records are deleted manually by an operator/user. | <p>This issue is NEVER Observed.</p> |

Siemens Healthcare Diagnostics Inc. has received customer complaints associated with this issue and the probability of the occurrence of the issue is very low at **0.003%**.

Risk to Health

The epoc NXS Host was confirmed to display incorrect results in Test History, after printing, or when viewed on a Data Manager after synchronization given certain criteria. Erroneous results of tests not selected could potentially lead to incorrect diagnoses and/or delay of diagnosis of multiple conditions (including electrolyte abnormalities, hypoxia, and acid/base disorders) and inappropriate management decisions.

Mitigations to these issues include that several sequential conditions would need to be met for the malfunction to occur, limited likelihood of results varying between patients that would cause a change in clinical interpretation, recognition that results were received on an analyte that was not selected, deviation from historical results, and discordance from the clinical presentation of the patient. Finally, when analyte abnormalities are identified, especially those discordant with clinical presentation, confirmatory testing is often completed prior to acute management.

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Actions to be Taken by the Customer

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- To mitigate this issue, follow the instructions below to set Delete Blood Test settings to NEVER and continue using device as normal. To change the device setting:
 - Log in as Administrator
 - Select Settings
 - Select General Settings - scroll to the bottom and select Delete Blood Tests
 - Set Delete Blood Tests to Never.
- If a Data Manager is in use, the Delete Blood Tests option must be changed on the Data Manager. Do NOT make the change on the epoc Host as the setting will be overwritten on the next synchronization. The Delete Blood Tests option may have a different name depending on the Data Manager in use. Please contact the Data Manager customer service for additional support, if needed.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you are a distributor, please ensure your customers receive this UFSN letter.

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

This issue will be corrected with the next NXS software version (4.12.XX) which must be installed by December 12, 2023, when current software version (4.11.11) expires.

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 is a trademark of Siemens Healthcare Diagnostics Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

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This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice POC 24-001.A.OUS dated October 2023 regarding epoc NXS Host Potential for Test Record to Include Unselected Analytes. Please read the below 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 UFSN instructions provided in this letter. Yes No

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.