Urgent Field Safety Notice
POC 24-004.A.OUS
October 2023

RAPIDPoint® 500 Blood Gas System
RAPIDPoint® 500e Blood Gas System

Potential for Low Na^+ Values and Question Result Error flags

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

Table 1. Affected Products

Siemens Material Number (SMN)	Description	Unique Device Identifier (UDI)
10844813	RAPIDPoint 500 Systems Measurement Cartridge (with Lactate) – 100	00630414947556
10491447	RAPIDPoint 500 Systems Measurement Cartridge (with Lactate) – 250	00630414589756
10491448	RAPIDPoint 500 Systems Measurement Cartridge (with Lactate) – 400	00630414589763
10491449	RAPIDPoint 500 Systems Measurement Cartridge (with Lactate) – 750	00630414589770

Reason for Urgent Field Safety Notice

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

Siemens Healthcare Diagnostics Inc. has confirmed an issue with RAPIDPoint 500 Systems Measurement Cartridges (with lactate). This issue has the potential to affect the Sodium (Na^+) sensor, as well as cause a *Question Result "-----?" error flag* for multiple electrolytes on patient samples and quality control.

When the Na^+ sensor is affected, Na^+ slope calibration errors (D3) will be seen in the Recall events log during cartridge initialization, resulting in low Na^+ values. The maximum sodium bias on internal testing and reported by customers comparing results to other direct method analyzers was <10 mM. To date, the impact to Na^+ results has been observed in less than 1% of the RAPIDPoint 500 Systems Measurement Cartridges (with lactate).

The *Question Result "-----?" error flag* has been observed on electrolytes. This may occur at any time over the life of the cartridge.

Based on our investigation thus far, these issues are due to an electronic noise that is observed on RAPIDPoint 500 Systems Measurement Cartridges (with lactate). Measurement cartridges without lactate are not affected.

Siemens is continuing to investigate and monitor the issue.

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2 Edgewater Drive
Norwood, MA 02062

Recommended Workarounds

Workaround: Na^+ Sensor issue

Siemens is recommending the following actions to address the Na^+ Sensor issue for customers using RAPIDPoint 500 Systems Measurement Cartridges (with lactate):

Option 1.

- Turn off Na^+ if your institution does not need to report this analyte or use alternate methods to report Na^+. Once Na^+ is turned off, run other analytes as normal. Please refer to the RAPIDPoint 500/500e Operator's Guide for instructions on how to turn off an analyte.

Option 2.

- If your institution would like to continue reporting Na^+ on a measurement cartridge with lactate, you must follow this action below to mitigate the probability of occurrence of this issue:
  a. When installing a new RAPIDPoint 500 Systems Measurement Cartridge (with lactate), allow the system to complete its initialization period in approximately 24 minutes.
  b. Review the Recall events log for Na^+ D3 slope errors.
  c. If there are
     - No Na^+ D3 slope errors, proceed with using the cartridge.
     - any Na^+ D3 slope errors, DO NOT USE. Replace the cartridge (repeat steps a-b).

Option 3.

- If your institution does not report lactate or you choose not to follow Options 1 or 2, please contact Siemens to inquire about getting a non-lactate measurement cartridge.

Workaround: Repeated *Question Result "-----?"* error flag

Siemens is recommending customers who are experiencing repeated *Question Result "-----?" error flag* for electrolytes follow the instructions stated in the RAPIDPoint 500/500e Operator's Guide. If the *Question Result "-----?" error flag* persists, please replace the cartridge.

Risk to Health

The RAPIDPoint 500 and RAPIDPoint 500e Benchtop Blood Gas Analyzers were confirmed to display a Q*uestion Result "-----?" error flag* for multiple analytes resulting in an apparent delay and/or a negative sodium bias which may not be apparent to the operator.

A negative sodium bias could result in serious injury due to a delayed diagnosis of hypernatremia or unnecessary intervention for hyponatremia especially if the true sodium result is near the thresholds of severe alterations. This issue is mitigated by deviation from historical results and discordance from the clinical presentation of the patient. When analyte abnormalities are identified,

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especially those discordant with clinical presentation, confirmatory testing is often completed prior to acute management.

If a Q*uestion Result "-----?" error flag* is obtained, this issue is mitigated by the presence of an error flag and specimen re-application to the same or alternate device, possibly requiring specimen re-collection. As the device is commonly used near the patient, the delay is expected to be short.

As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test but must be made by the physician after all clinical and laboratory findings are evaluated.

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.
- If you experience this issue, you may request a no-charge replacement or receive a credit from your local Siemens Healthineers representative.
- Complete and return the Field Correction Effectiveness Check 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.

We apologize for the inconvenience this situation may cause. Siemens Healthineers is conducting a comprehensive evaluation with a cross-functional team to promptly resolve the issue with utmost priority. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Additional Information

RAPIDPoint is a trademark of Siemens Healthcare Diagnostics Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice POC 24-004.A.OUS dated October 2023 regarding. 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 [INSERT] or to fax this completed form to the Customer Care Center at [INSERT].

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

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