SIEMENS

cc Chairman Medical Board and
Relevant Head of Departments

Urgent Field Safety Notice

POC 17-008.A.OUS

April 2017

RAPIDPoint® 500 Systems

Potential Patient Demographic Error with Blank Patient ID Field

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

Table 1. Affected Products

System	RP500 Siemens Material Number (SMN)
RAPIDPoint® 500 Blood Gas Analyzer with V2.4 Software	10492730, 10696857, 10697306

Only analyzers with V2.4 software are affected. Other software versions are not affected.

Reason for this Urgent Field Safety Notice

Siemens Healthcare Diagnostics has identified an issue with RAPIDPoint 500 Blood Gas Analyzers with V2.4 software. There is a potential to misassign patient demographic information (Last Name, First Name, Gender, or Date of Birth) when the Patient ID field is left "blank" on multiple patient samples and a recall of the patient information is initiated. For example:

- Patient sample #1 is run with a blank patient ID field and Demographics are assigned (Last Name, First Name, Gender, or DOB).
- Patient sample #2 is run with a blank patient ID field and different Demographics are assigned (Last Name, First Name, Gender, or DOB).
- An attempt is made to recall patient sample #1 results but sample #2 demographics are displayed, not sample #1 demographics (results are for patient sample #1).

This issue does not affect RAPIDPoint 400/405 or RAPIDLab blood gas analyzers.

Risk to Health

There is a risk to health based upon the potential misclassification of a patient as having falsely abnormal test results receiving additional diagnostic testing and treatment, as well as the risk of a patient who has abnormal results being incorrectly identified as having normal results based upon incorrect sample identification.

As stated in the RAPIDPoint 500 Operators Guide, the Patient ID field is a "required" field, and the Patient ID field is set as "required" when the RAPIDPoint 500 analyzer is shipped from Siemens. Standard laboratory procedures and regulations require a two-step procedure to confirm the correct patient identification for sample processing. Therefore, the probability for this mismatch to occur is extremely unlikely, and other factors such as patient presentation and

2 Edgewater Drive
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other diagnostic testing would initiate clinical questioning to reduce the potential for injury. The overall risk to health is low.

If you have run samples from multiple patients with the Patient ID field blank, Siemens recommends a review of those previously generated results.

Actions to be taken by the Customer

- **Maintain the Patient ID field as enabled and a "required" Patient Demographic entry on your RAPIDPoint 500 analyzer.** To confirm that the Patient ID field is set as a "required" field on your RAPIDPoint 500 analyzer, verify that there is a black triangle " ▶" next to the Patient ID field. This black triangle indicates that data is required in that field.
- If the Patient ID field on your RAPIDPoint 500 analyzer is not set as "required," reset it to "required" by following these steps:
    - Access **Setup > Sample > Patient Demographics**.
      NOTE: Depending on the security setting selected, you may need to log in to access Setup.
    - If "Patient ID" option is unselected (unchecked), first touch the "Patient ID" button to make it selected (checked).
    - To the left of the "Patient ID" button is another button (triangular in shape) that indicates whether the field is required. Touch this button so that the triangle is selected (checked).
    - Exit Setup screens by pressing "=>" (Continue) buttons until the Status screen is displayed.
- Review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 7 days.

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

Siemens Healthcare is currently developing a software update to address this issue and will be providing new information as it becomes available.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

RAPIDLab and RAPIDPoint are trademarks of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

Potential Patient Demographic Error with Blank Patient ID field

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice POC 17-008.A.OUS dated April 2017 regarding a Potential Patient Demographic Error with a Blank Patient ID field. Please read the question below and indicate the appropriate answer.

Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes o No o

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

To fax this completed form, please send it to the Customer Care Center at (XXX) XXX-XXXX. If you have any questions, contact your local Siemens technical support representative.

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