SIEMENS

Urgent Field Safety Notice

POC 16-021.A.US-OUS

August 2016

RAPIDPoint® 400/405/500 Systems
RAPIDLab® 1200 Systems

Potential Patient Demographic Error

Our records indicate that your facility may have received the following product(s):

Table 1. Affected Products

System	Siemens Material Number (SMN)
RAPIDPoint® 400 Blood Gas Analyzer	10291507, 10314585, 10318899, 10321239, 10322654, 10324081, 10328803, 10331381, 10339634
RAPIDPoint® 405 Blood Gas Analyzer	10282093, 10310464, 10314817, 10317193, 10318999, 10320055, 10321238, 10322347, 10328278, 10328302, 10336784
RAPIDPoint® 500 Blood Gas Analyzer	10492730, 10696855, 10696857, 10697306
RAPIDLab® 1240 Blood Gas Analyzer	10321840, 10491392
RAPIDLab® 1245 Blood Gas Analyzer	10321844, 10337179, 10491393
RAPIDLab® 1260 Blood Gas Analyzer	10321846, 10491394
RAPIDLab® 1265 Blood Gas Analyzer	10321852, 10470366, 10491395

Reason for this Urgent Field Safety Notice

Siemens Healthcare Diagnostics has determined that when all the following steps occur there is a potential for the first and/or last name of one patient to be printed with Patient ID and result data from a different patient, even though those fields have been turned Off for the system.

1. The blood gas analyzer is configured with the patient demographics (last name, first name) turned Off, and the Rapid Sample Identification Option (host query used to retrieve these patient demographics fields from data management systems) is turned On.
2. An incorrect patient ID barcode is scanned at the Analysis screen prior to the sample being analyzed; i.e., it is not the barcode for the patient sample being tested.
3. The incorrect Patient ID and Last Name displayed at the Analysis screen are not confirmed and corrected.
4. The sample is analyzed and the correct Patient ID is scanned or entered at the Demographics screen by the operator.

2 Edgewater Drive
Norwood, MA 02062

DQSP-00003-T1 V2.0 Effective: June 28, 2016
Related Procedure: DQSP-00003 Field Action

The patient ID and patient test result data, however, are correct on the analyzer screen and the LIS. Only the printout may contain the incorrect First or Last Name data, which should not have been printed because those fields were turned Off in Setup.

Risk to Health

An incorrect patient name on the blood gas printout has the potential to lead to patient mismanagement. However, the correct patient test results are on the analyzer and the LIS, and the probability for this error to occur is extremely unlikely. Other factors such as previous results, patient presentation, and other diagnostic testing would initiate clinical questioning and reduce the potential for injury. The overall risk to health, therefore, is low.

Actions to be Taken by the Customer

- Do not configure your Siemens Blood Gas Analyzer with the patient demographics (last name, first name) turned Off and the Rapid Sample Identification Option turned On.
- If sample IDs are scanned at the analysis screen, confirm that the patient ID is correct on the screen prior to analyzing the sample.
- If the patient ID is not correct, correct it at the analysis screen.
- 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.

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

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice POC 16-021.A.US-OUS dated August 2016 regarding a Potential Patient Demographic Error. 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.

I have read and understood the instructions provided in this Urgent Field Safety Notice. 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 6366-3376. If you have any questions, contact your local Siemens technical support representative.

Signature	
Company Stamp	

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