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.

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Norwood, MA 02062

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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.

PLEASE NOTE THAT SIEMENS HEALTHCARE DIAGNOSTICS IS INTRODUCING AN IMPROVED PROCESS FOR INFORMING CUSTOMERS OF URGENT FIELD SAFETY NOTIFICATIONS INCLUDING A MORE EFFECTIVE WAY FOR CUSTOMERS TO ACKNOWLEDGE RECEIPT.

It is important that your organisation takes the actions detailed in the UFSN and replies immediately clicking on **this link** at the **bottom of the email**. Your organisations reply is evidence which, Siemens Healthcare, and subsequently the MHRA, needs to monitor the progress of the UFSN. Without your reply Siemens Healthcare cannot verify the completeness of the UFSN to the MHRA.

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 or enquiries regarding this UFSN, please do not hesitate to contact the Siemens Healthcare Diagnostics

Helpdesk:RAPIDLab and RAPIDPoint are trademarks of Siemens Healthcare Diagnostics.

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