

Urgent Field Safety Notice

32536 Rev. A

March 2015

RAPIDPoint® 405 Analyzer

Discontinue Reporting Neonatal Bilirubin Results on the RAPIDPoint 405 Analyzer

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

Table 1. Systems Affected

System	Siemens Material Number (SMN)
RAPIDPoint® 405 Blood Gas Analyzer	10310464, 10314817, 10317193, 10318999, 10320055, 10321238, 10322347, 10328278, 10328302, 10336784, 10338281

Reason for Urgent Field Safety Notice

This letter is a follow up to Urgent Field Safety Notice Document Number 32258 titled “*Neonatal Bilirubin Reporting When tHb Is Out-of-Range High*” (Siemens FSCA reference number POC 15-003).

This letter applies only to RAPIDPoint 405 customers who report nBili results. It does not apply to customers using the RAPIDPoint 500, RAPIDLab® 1245, or RAPIDLab 1265 analyzers.

Siemens Healthcare Diagnostics requests that you discontinue reporting all nBili results on your RAPIDPoint 405 analyzer. Currently, there is no plan to update the RAPIDPoint 405 software.

Risk to Health

The risk to health is the same as indicated in the initial Urgent Field Safety Notice document number 32258.

Actions to be Taken by the Customer

- Please discontinue reporting nBili results on the RAPIDPoint 405 analyzer.
- To disable the nBili parameter, please do the following (this requires Level 1 security):
 1. From the Status Screen, touch **Setup**. Enter password if prompted.
 2. Touch **Secured Options** and navigate to the second set of options to locate the **Activate Feature** button.
 3. Touch **Activate Feature**.
 4. Delete the nBili key by clearing the numbers in the box to the right of nBili.
 5. When you are finished, touch the **Continue** button to return to the Analysis Screen.
- Please 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 this letter to those who may have received this product.

We apologize for the inconvenience that this situation has caused. Thank you for your understanding.

If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

RAPIDPoint and RAPIDLab are trademarks of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Discontinue Reporting Neonatal Bilirubin Results on the RAPIDPoint 405 Analyzer

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 32536 Rev. A, dated March 2015 titled, Discontinue Reporting Neonatal Bilirubin Results on the RAPIDPoint 405 Analyzer. Please read the question 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 Urgent Field Safety Notice instructions provided in this letter.

Yes ☐

No ☐

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Please fax this completed form to the Customer Care Center at (XXX) – XXX - XXXX

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