

## Urgent Field Safety Notice

30982 Rev. A

December 2013

### RAPIDPoint® 500 Systems

#### pO2 Out of Box Failures with RAPIDPoint® 500 Lactate Measurement Cartridges

This communication is to advise you of an Out of Box Failure issue with pO2 on RAPIDPoint® 500 Measurement Cartridges. The cartridge generates a D3 failure for pO2 that prevents the cartridge from calibrating, and no patient results are generated.

This issue affects RAPIDPoint 500 Measurement Cartridge P/Ns 10491447, 10491448, and 10491449.

RAPIDPoint 500 Cartridges within the following ranges of serial numbers have this defect:

**2330201012 through 2330901917**

**and**

**2332300913 through 2333004925**

**Please Note: This issue only impacts RAPIDPoint 500 Measurement Cartridges. It does not impact RAPIDPoint 400 or RAPIDPoint 405 Measurement Cartridges.**

Until Siemens is able to provide RAPIDPoint 500 cartridge inventory to meet demand, the immediate resolution for customers is to use a RAPIDPoint® 405 Measurement Cartridge. The RAPIDPoint 405 cartridge is available in three sizes.

Measurement Cartridge P/N	Description
10310469	RAPIDPoint 405 system (750 samples) Full Blood Gas and CO-ox
10313971	RAPIDPoint 405 system (400 samples) Full Blood Gas and CO-ox
10283222	RAPIDPoint 405 system (250 samples) Full Blood Gas and CO-ox

Since the Lactate parameter is not available on the RAPIDPoint 405 cartridge, you will need to make arrangements to get your lactate results from instruments in your central laboratory.

The Siemens manufacturing plant is increasing cartridge production in order to meet demand.

If you have unused RAPIDPoint 500 Measurement Cartridges at your facility that fall within the affected serial number range, please discard and contact your local Siemens Customer Service Center at xxx-xxx-xxxx to obtain a full credit.

Please forward this notification to anyone to whom you may have distributed this product.

We apologize for the inconvenience that this situation has caused. Thank you for your patience and continued support.

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### Siemens Healthcare Diagnostics Inc.

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Tarrytown, NY 10591

914-631-8000  
[www.siemens.com/diagnostics](http://www.siemens.com/diagnostics)

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**FIELD CORRECTION EFFECTIVENESS CHECK**

pO2 Out of Box Failures with RAPIDPoint 500 Lactate Measurement Cartridges

This response form is to confirm receipt of the Siemens Healthcare Diagnostics Urgent Field Safety Notice dated December 2013 regarding pO2 Out of Box Failures with RAPIDPoint 500 Lactate Measurement Cartridges. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated 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 (please print name):

\_\_\_\_\_

Title: \_\_\_\_\_

Institution: \_\_\_\_\_

Street: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Phone: \_\_\_\_\_

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT  
XXX-XXX-XXXX