SIEMENS
Healthineers
Siemens Healthcare Diagnostics Inc.

Urgent Field Corrective Action

POC 18-021.A.OUS

September 2018

RAPIDPoint® 500 Blood Gas Systems

Optional Custom Demographic Field Incorrectly Retrieved

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

Table 1.   RAPIDPoint® 500 Blood Gas Systems

System	Impacted Software Versions	Siemens Material Number (SMN)
RAPIDPoint® 500 Blood Gas Analyzer	V2.2, V2.3 and V2.3.1	10492730, 10696855, 10696857, 10697306

Reason for this Urgent Field Corrective Action Notice

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 above.

Siemens Healthcare Diagnostics has identified an issue with the optional Custom Demographics software feature. This optional feature enables you to define up to 10 free text fields. The issue impacts the Custom Demographics fields sent to the LIS and viewed/printed from the data recall screen. These fields may get mixed up with Custom Demographics from another patient. See Figure 1 on the next page. The sample printout obtained at the time the sample was run is not impacted.

Patient test results, Patient Demographics (i.e., patient ID, last name, first name, etc.), and Sample Demographics (i.e., operator ID, Physician ID, draw date, etc.) are not affected.

Software versions 2.4.1 and 3.0 are not affected.

Risk to Health

Patient results, Patient Demographics and Sample Demographics are not affected; therefore, the risk to health is negligible.

Original Printout	**Recalled Printout**

```
DEMONSTRATION ONLY
ARTERIAL SAMPLE
06 / 13 / 2018          11:18
System ID              0500-33783
Patient ID             33-16
Lst Name               L16

ACID/BASE 37.0 °C
  pH              7.149
  pCO₂            70.6      mmHg
  pO₂             155.6     mmHg
  HCO₃⁻act        24.0      mmol / L
  BE(B)           – 6.9     mmol / L
```

```
DEMONSTRATION ONLY
ARTERIAL SAMPLE
06 / 13 / 2018          11:18
System ID              0500-33783
Patient ID             33-16
Lst Name               L16

ACID/BASE 37.0 °C
  pH              7.149
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  pO₂             155.6     mmHg
  HCO₃⁻act        24.0      mmol / L
  BE(B)           – 6.9     mmol / L
```

```
CUSTOM DEMOGRAPHICS
  Comment                COM16
  Mode                   MODE16
  Mode2nd                CD3-016
  CD4                    CD4-016
  CD5                    CD5-016
  CD6                    CD6-016
  CD7                    CD7-016
  CD8                    CD8-016
  CD9                    CD9-016
  CD10                   CD10-016
```

```
CUSTOM DEMOGRAPHICS
  Comment                COM16
  Mode                   MODE8
  Mode2nd                CD3-008
  CD4                    CD4-008
  CD5                    CD5-008
  CD6                    CD6-008
  CD7                    CD7-008
  CD8                    CD8-008
  CD9                    CD9-008
  CD10                   CD10-008
```

Figure 1. Example Printout

Actions to be Taken by the Customer

- If the Custom Demographic feature is not enabled, no further action is required.

- If the Custom Demographic feature is in use, or if you plan to use it, please contact your Siemens representative for updated software.

Complete and return the Field Correction Effectiveness Check form attached to this letter.

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.

RAPIDPoint is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Optional Custom Demographic Field Incorrectly Retrieved

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Corrective Action Notice POC 18-021.A.OUS dated September 2018 regarding Optional Custom Demographic Field Incorrectly Retrieved. Please read the question below and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

I have read and understood the Urgent Field Corrective Notice instructions provided in this letter.   Yes ☐   No ☐

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Please send a scanned copy of the completed form via email to (XXXX@XXXX) or fax this completed form to the Customer Care Center at (XXX-XXX-XXXX).