

RAPIDPoint® 500e Blood Gas Systems

Handheld Barcode Scanner Code 39 Check Digit Checking Failure

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

Table 1. Affected Product

Siemens Material Number (SMN)	Product Description	Model
11416778	RP500e Handheld Barcode Scanner	Zebra Model: DS4308 - HC0062BZZWW

Reason for this Urgent Field Safety Notice

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 above and provide instructions on actions that your laboratory should take.

The optional handheld barcode scanner used for the RAPIDPoint 500e Blood Gas System allows scanning of Operator ID, Patient ID and Accession number. The scanner supports multiple 1D & 2D barcode symbologies, including Code 39 with or without check-digit. Barcodes with check-digit have an additional digit at the end of the unique alpha/numeric string, providing an extra functionality that reduces the frequency of erroneous scans.

Siemens Healthcare Diagnostics has confirmed an issue with reading of Code 39 barcodes using handheld barcode scanner DS4308. The scanner is not confirming the integrity of read barcode data using the check-digit. As a result of the issue, three scenarios can occur when RAPIDPoint 500e Blood Gas System is configured with Code 39 check-digit selected, and the operator scans a Code 39 barcode:

1. The scanner might allow misinterpretation of barcode data which may lead to incorrect data entry for Patient ID or Accession Number because it matches an existing Patient ID or Accession Number values. This can cause the results of a particular sample to be mis-identified and potentially assigned to a different patient.

In order for this unlikely event to occur, incorrect decoding of the barcode by the scanner must occur (~0.01% probability), and the incorrect patient ID must match a different existing patient ID (~0.01% probability).

2. The scanner might allow misinterpretation of barcode data which may lead to incorrect data entry for Patient ID or Accession Number that does not match any existing Patient

ID or Accession Number values. This may lead to the sample being unmatched until the correct Patient ID or Accession Number is entered.

3. The scanner might allow misinterpretation of barcode data which may lead to incorrect data entry for Operator ID or Password. If this occurs, it may prevent the user from being immediately authenticated. This issue can be mitigated by rescanning the barcode.

Please note, if code 39 without check-digit is selected on the RAPIDPoint 500e Blood Gas System, this issue is not applicable.

This issue does not impact the functionality of the onboard barcode scanner.

Risk to Health

Scenario 1: The potential exists, though remote, for misidentification of a patient sample due to this issue, which depending on the analyte results may lead to an effect on diagnosis or treatment. This only will occur if the misread barcode matches the sample ID of another sample with pending orders. Siemens is not recommending a laboratory look back of previously generated results due to the remote possibility of this event.

Scenarios 2 and 3: The potential exists for an apparent delay in testing. The potential for injury is negligible.

Actions to be Taken by the Customer

Complete and return the Field Correction Effectiveness Check form attached to this letter within 30 days.

If your system is not configured to use code 39 with check-digit, no further action is required.

If your system is configured to use code 39 with check-digit, you may take the following workaround actions:

- Use the integrated on-board barcode scanner, or
- Re-configure the handheld barcode scanner following the instructions below:
 1. Scan barcode to enable “check digit” using the following barcode:



Enable Code 39 Check Digit

2. Scan barcode to enable “transmit check digit” using the following barcode:



Transmit Code 39 Check Digit (Enable)

3. Confirm the effectiveness of the “workaround” as follows:
 - A. Access Setup -> Printer and Devices -> Bar Code Setup -> Bar Code Mask Setup screen
 - B. Select Patient Data option under the “Multi-Field Mask” heading
 - C. Press the continue button on the “Select Demographics contained in Multi-Field Barcode” screen to access the “Multi-Field Patient Data Barcode Mask Setup” screen.
 - D. Scan this code 39 with check-digit barcode



The screen should display “39CHECKDIGIT” (the “9” is the check-digit, which was correctly removed. The scan is good.)

- E. Scan this code 39 without check-digit barcode



NOTE: If this barcode scans and “CODE39NOCHEC” is displayed on the screen, the workaround steps have not been performed correctly, please try the above steps again.

F. The re-configuration is complete now. Please exit the Setup screen by pressing the back arrow twice and continue forward arrow three times to return to the Status screen.

Note if at any time, the “RETURN TO FACTORY DEFAULT” barcode is scanned, please repeat the above re-configuration steps.

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

Additional Information

RAPIDPoint 500e is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

RAPIDPoint® 500e Blood Gas Systems Handheld Barcode Scanner Code 39 Check Digit Checking Failure

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice POC 20-008.A.OUS dated May 2020 regarding RAPIDPoint® 500e Blood Gas Systems Handheld Barcode Scanner Code 39 Check Digit Checking Failure. 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.

1. 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:

Customer Sold To #:

Customer Ship To #:

Please send a scanned copy of the completed form via email to XXXX@XXXX. Or to fax this completed form to the Siemens Customer Care Center at XXXXXX.

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