

epoc® Blood Analysis System

Possible Incorrect Decoding of BGEM Test Card Lot Number by epoc Reader

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

Table 1. Affected Products

Product Description	Siemens Material Number (SMN)	Unique Device Identification (UDI-DI)
epoc Reader	10736398	00809708016685
epoc Reader	11413750	00630414619903
epoc Reader	11413815	00630414624723
epoc Reader, Refurb	10736404	00809708116712
epoc Reader Refurb	11413817	00630414624792
epoc Reader Refurb	11413816	00630414624686
epoc Reader Refurb	10736401	00809708032333

Reason for Customer Notification

The purpose of this communication is to inform you of a possible problem with the products indicated in **Table 1** above and to provide you with instructions on actions that your facility should take.

Siemens Healthcare Diagnostics Inc. has confirmed that, **in rare instances**, the epoc reader may incorrectly decode the barcode of a BGEM Test Card lot number to a different BGEM lot number. For example, BGEM Test Card with lot number A is inserted into the epoc Reader and the barcode is then incorrectly decoded as BGEM Test Card lot number B.

When the BGEM test card is incorrectly decoded, two situations can occur.

1. The barcode is incorrectly decoded to another valid lot number (ie. a lot number that meets the manufacturing lot format and has a valid expiration date) but does not match the inserted card lot number. A patient test will be permitted with the incorrect/different lot number. In this situation, analytes will perform within the BGEM Test Card Specifications as listed in Section 12 of epoc System Manual, except creatinine at high concentrations (≥ 4 mg/dL). In a worst-case scenario, patient samples with creatinine at high concentrations (≥ 4 mg/dL) could produce a -15% difference in results due to the incorrect decoding.

The probability of occurrence of this situation is estimated to be **0.0016%**.

2. The barcode is incorrectly decoded to an invalid lot number and the operator will receive error messages and/or error codes on the instrument. These error messages and/or error codes will prevent the patient tests from proceeding. These error messages and responses are described

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in Section 14 of the epoc System Manual.

Risk to Health

When the incorrect decoding to a valid card lot number occurs, **the risk to health is negligible** because the magnitude of the error (-15%) at high levels of creatinine (i.e., ≥ 4 mg/dL) would not change the interpretation of the test result (i.e., an elevated level of creatinine would still be correctly classified as elevated).

Siemens Healthcare Diagnostics is not recommending a retrospective review of test results because the problem is not expected to lead to clinical misclassification of patients with already high levels of creatinine.

Actions to be Taken by the Customer

- If you are a distributor, please ensure your customers receive this customer notification letter.
- If your device displays an error code/message, follow the instructions in Section 14 of the epoc System Manual to repeat the insertion of the card or to insert a new card.
- To reduce the likelihood of the incorrect decoding problem in the future, customers are reminded to follow manufacturer's instructions as outlined in epoc System Manual, Section 3.10 Inserting the Test Card:
 - Insert the Test Card into the Reader's Card Insertion Slot at the front of the Reader with a smooth, swift, single motion to enable the Barcode on the Card Label to be correctly read by the Reader during insertion.
 - Avoid any abrupt stops or unevenness in speed during Test Card insertion.
- Please review this letter with your Medical Director.
- Please retain this letter with your laboratory records in case there are questions about QC and test results.
- Forward this letter to those who may have received the affected product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Technical Solution Center 1800-815-508 or your local Siemens Healthineers technical support representative.

Additional Information

epoc® is a trademark of Siemens Healthcare Diagnostics Inc.