

**epoc® Blood Analysis System**

**Delay of Results and Potential Loss of Patient Sample When Using the Positive Patient ID (PPID) Lookup**

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

**Table 1. Affected Products**


| Product Description      | Siemens Material Number (SMN) | Unique Device Identification (UDI-DI) | epoc Host2 Software Version |
|--------------------------|-------------------------------|---------------------------------------|-----------------------------|
| epoc Host2 (Model MC55A) | 10736387                      | 00809708052898                        | 3.38.2                      |
|                          | 10736388 (CA)                 | 00809708069117                        |                             |
|                          | 10736389 (CN)                 | 00809708097219                        |                             |
|                          | 10736390 (JP)                 | 00809708075576                        |                             |
|                          | 10736393 (Refurb)             | 00809708053901                        |                             |
|                          | 10736395 (JP Refurb)          | 00809708075583                        |                             |
| epoc Host2 (Model MC55X) | 11413524 (US)                 | 00630414606460                        |                             |
|                          | 11413528 (W)                  | 00630414606378                        |                             |
|                          | 11413541 (IN)                 | 00630414608617                        |                             |
|                          | 11413543 (JP)                 | 00630414608532                        |                             |
|                          | 11413542 (CN)                 | 00630414608624                        |                             |
|                          | 11413601 (US Refurb)          | 00630414615004                        |                             |

*Note: All epoc host2 devices are affected.*

**Reason for Customer Notification**

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

Siemens Healthcare Diagnostics Inc. has confirmed an occurrence of the epoc Host2 device freezing during analysis when the “Use this ID” button is pressed while the system is performing test result calculations. This issue only occurs when the epoc Host2 is used with the PPID feature during calculations. The Positive Patient Identification (PPID) Lookup feature is only available when used with an epoc compatible data manager and relies on admission, discharge, and transfer (ADT) information supplied by the data manager.

When the PPID Lookup feature is enabled, the Lookup icon  will appear next to the patient ID field.

## Delay of Results and Potential Loss of Patient Sample When Using the Positive Patient ID (PPID) Lookup

The normal workflow is to insert a test card and during the calibration period, scan the patient ID and perform the PPID Lookup. This issue occurs if PPID is selected when the Host2 displays "Test Completed - Calculating" and the "Use This ID" button is pressed (shown in Figure 1). The "Use this ID" button should have been disabled but is prematurely enabled for the last 8 seconds of calculation. If the "Use this ID" button is pressed during this 8 second period, Host2 freezes causing results and the patient sample to be lost and sample re-collection may be potentially required.



Figure 1: epoc Host2 "Use this ID" Button

### Risk to Health

The epoc Host2 was confirmed to freeze if the Positive Patient ID feature is enabled and the "Use this ID" button is pressed during a specific 8 second window which leads to an apparent delay of reporting results. This issue is mitigated by specimen re-application to the same or alternate device and may require specimen re-collection. As the device is commonly used near the patient location, the time delay caused by this issue is expected to be short and clinically acceptable.

### Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- If you are not using the **Positive Patient ID (PPID) Look-up** feature, no action is required.
- To mitigate this issue when using the PPID feature, scan the patient ID and perform the PPID Lookup either before injection or after the test calculation completes. Do not use PPID when the Host2 displays "Test Completed – Calculating".
- If the "Use this ID" button is pressed during "Test Completed – Calculating" and the Host2 screen freezes, restart the device and repeat analysis.
- If you are a distributor, please ensure your customers receive this letter.

## **Delay of Results and Potential Loss of Patient Sample When Using the Positive Patient ID (PPID) Lookup**

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

This issue will be corrected in the next epoc Host2 software release (3.39.x) which must be installed by December 12, 2023, when current software (3.38.x) expires.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

### **Additional Information**

epoc® Blood Analysis System is a trademark of Siemens Healthcare Diagnostics Inc.