

Urgent Field Safety Notice

POC 25-002.A.US.OUS

epoc® Blood Analysis System

Title NXS Host Potential Patient Demographic Error Due to Connectivity Issue

Date Issued November 2024

Issue Description The purpose of this communication is to inform you of a potential issue with the products indicated in the table below and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed a rare scenario in which the demographic information of a previously analyzed patient is displayed with the current Patient ID on the epoc NXS Host screen during Positive Patient Identification (PPID) Lookup. The issue occurs only when all of the following conditions are met:

- The customer uses PPID; and
- The user performs consecutive tests on patients (i.e., removes a test card and inserts a new one) without logging out or returning to the home page; and
- The connection between the epoc NXS Host and Data Manager (DM) is lost during the PPID Lookup process; and
- The user inadvertently accepts the previous patient’s demographics displayed on the epoc NXS Host screen for the current patient and proceeds with testing.

When these conditions are met, the current patient’s results may be listed with the previous patient’s name and demographic information. Therefore, calculated analytes that rely on patient demographic data, like eGFR (Glomerular Filtration Rate), could be affected.

Siemens Healthineers has confirmed two external complaints associated with this issue.

Product

Product	Siemens Material Number	Unique Device Identification	Software Version
epoc NXS Host	11413475 (US)	00630414606095	4.14.9
	11413497 (EU)	00630414605760	
	11413498 (JP)	00630414605814	
	11413506 (CA)	00630414605821	
	11413517 (MX)	00630414605838	
	11413518 (ROW)	00630414605678	
	11413583 (CN, KR)	00630414612447	
	11413879 (IN)	00630414631028	

Impact to Results	<p>The EPOC NXS Host was confirmed to display mismatched patient identifiers (name and date of birth) under a rare use-case and was only observed if the connection with DM was lost during the PPID Lookup process. This could result in a clinician treating a patient using data from a different patient which could be harmful. The chance of this occurring is very low due to the sequence of events necessary to create this situation including:</p> <ul style="list-style-type: none">• Not positively identifying the patient as required by Good Clinical Practice and as specified in the ePoc System Manual with NXS Host.• The rare occurrence of the loss of DM connectivity at a specific time.• Not confirming the abnormal lab result prior to initiating treatment.• Discordance from prior test results and the clinical presentation of the current patient not being recognized by the clinician.• Management of the prior patient's results would be deleterious to the current patient.
Customer Actions	<ul style="list-style-type: none">• Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.• If you are a distributor, please ensure your customers receive this UFSN letter.• To avoid the issue, please follow one of the options below:<ul style="list-style-type: none">○ Option 1: After completing a patient test, either log out or return to the home page before proceeding to the next patient test by pressing "Close and Transmit" button.○ Option 2: Before starting a new test, follow the steps outlined in Section 6.19 "Patient ID Lookup" of the ePoc System Manual with NXS Host and confirm the correct patient demographics. It is important to verify the demographics, as some of this data may be used for calculated analytes. If the demographics are incorrect, delete and re-enter the Patient ID and perform the PPID Lookup again.• Complete and return the Field Correction Effectiveness Check Form attached to this letter within 10 days.• Please retain this letter with your ePoc System Manual with NXS Host or place the letter near the affected instrument for reference. Please also forward this letter to those who may have received this product.
Resolution	<p>The issue will be resolved in the next planned release of the ePoc NXS Host software, scheduled for April 2025.</p>

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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice POC 25-002.A.OUS dated November 2024. Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1 immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Return this completed form as per the instructions provided at the bottom of this page.

- 1. I have read and understood the instructions provided in this letter. Yes No
- 2. All affected Site Personnel have been notified. Yes No
- 3. A copy of the letter has been retained and posted with our current product labeling. Yes No

Name of person completing questionnaire:			
Title:			
Institution:			
Street:			
City:		State:	
Phone:		Country:	

Please send a scanned copy of the completed form via email to fscreportingunit.my@siemens-healthineers.com.

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.