SIEMENS Healthineers

Urgent Field Safety Notice

PP-22-002-A OUS

June 2022

Protis® software 2.x

Possible incorrect sample assignment by Protis 2.x software

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

Table 1. Affected Product(s)

Software	Software Version	Siemens Material Number (SMN)
Protis software	2.x	10454765 10461541 10482083

Reason for Urgent Field Safety Notice

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

Siemens Healthcare Diagnostics Products GmbH has confirmed a potential risk of incorrect assignment of results and patient names by Protis 2.x software. In very specific cases, sample results from their original patient's name will be miss-assigned to another patient's name. The affected samples and their assessments will be finally shown with an incorrect patient name in the software.

The issue only occurs if the following conditions are given:

1. The instrument is connected to Protis 2.x software via ASTM protocol.
2. Protis 2.x software has already assigned one or more samples to the corresponding patients.
3. Additional measurements for different patient samples are requested **manually** at the instrument **without** a patient name. The issue will not occur if requests are ordered by host query.
4. Results of these measurements are released together (en bloc) at the instrument. The issue will not occur if results of manually requested measurements from different patients are released one by one.

The incorrectly assigned patient name will be transmitted in the ASTM header record if these results are transferred from Protis 2.x software to a LIS.

The root cause of this issue is a software bug within the Protis 2.x software. However, the successor software *aurelio/lab Edition for SIEMENS Protis Assessments* is not affected by the issue.

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D – 35041 Marburg, Germany

Actions to be Taken by the Customer

- Based on our findings the following recommendations should be implemented to avoid this issue:

1. Order requests should only be generated by host query (especially if the instrument is connected to Protis 2.x software by using the ASTM protocol).
2. If a manual request is necessary, results from different patients must not be released together (en bloc), but instead one by one.
3. As an alternative, it should be considered to change the connection between the instrument and Protis 2.x software from ASTM to Autohost protocol because the problem will not occur on Autohost protocol.

- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Sincerely yours,

This letter was created electronically and is valid without signature

[redacted]
Director
Quality Systems & Compliance

[redacted]
Marketing Manager
Global Marketing

Protis is a trademark of Siemens Healthcare Diagnostics.

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