

Urgent Field Safety Notice

Follow-up Information

ASW21-02.B.OUS

December, 2020

Atellica® IM 1300 Analyzer
Atellica® IM 1600 Analyzer
Atellica® CH 930 Analyzer

Follow-up Communication for:

Multiple issues in Software v1.23.2 and lower.

In version A (ASW21-02.A.OUS) of this Urgent Field Safety Notice (UFSN) you were informed of multiple issues that could occur when using Atellica Solution system software V1.23.2 or lower. The affected products are listed below in Table 1.

Our records indicate that your facility may have received one or more of the following products:

Table 1. Atellica® Solution Affected Product(s):

Product	Siemens Material Number (SMN)
Atellica CH 930 Analyzer	11067000
Atellica IM 1300 Analyzer	11066001
Atellica IM 1600 Analyzer	11066000

Reason for Urgent Field Safety Notice

The purpose of this follow-up is to communicate additional details regarding Issue #1.

Siemens Healthcare Diagnostics has identified the following issues with the Atellica Solution products listed in Table 1, which are installed with Atellica Solution software (SW) versions V1.23.2 (SMN 11469032) or lower and provide instructions on actions your laboratory must take.

These issues will be corrected in software version 1.24 or higher, which will be available soon.

Description of Observed Behaviors

Issue Number	Observed Behavior	Description of Observed Behavior
1	<p>Atellica CH 930 or IM 1300 and IM 1600 analyzers</p> <p>Patient orders may be run on an Analyzer where the assay has been disabled.</p>	<p>A patient order may sporadically be processed at an analyzer where the assay has been disabled by the user for any reason (e.g. if QC is out of range). A potentially discrepant result may be reported from the analyzer where the assay was disabled depending on the reason for it being disabled.</p> <p>This issue only occurs if the following conditions are met:</p> <ul style="list-style-type: none"> - A Cal/QC workorder is not able to be run on an analyzer because the targeted analyzer was down. - The Analyzer is then put back into service but patient processing for the assay was disabled by the user and at the same time patient samples were loaded from the sample handler drawer. <p>Note: If the Atellica Solution has multiple analyzers connected, then it is possible that the patient order may be processed at an analyzer where the assay has not been disabled. In this case the issue will not occur.</p> <p>Any assay on the CH or IM analyzers may be affected if it was disabled on one of the analyzers.</p> <p>Please refer to Addendum 1 for additional details regarding this issue.</p>
2	<p>Atellica IM 1300 and Atellica IM 1600</p> <p>Analyzers may operate and report results in a service 'bypass' mode.</p>	<p>On the Atellica IM 1300 and Atellica IM 1600 Analyzers, a 'bypass' mode is available for service personnel to operate the system during servicing. This mode requires use of a service interlock override tool to bypass the top covers. The tool is required to be removed from the system before it can be used for routine sample processing. An unlikely but possible software logic error can cause the system to start operating in 'bypass' mode (without use of the service tool) when the analyzer covers are opened and closed in a sequence.</p> <p>When running in this mode, the analyzer will not stop processing results when vacuum, pressure or thermal issues arise on the system and may result in potentially discrepant results being reported without appropriate flags.</p> <p>Any assay on the IM analyzers may be affected after both the front and back covers have been opened and closed.</p>

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3	Atellica CH 930 Analyzer Manual entry of Atellica A1c_E - Calibrator bottle values.	On the Atellica CH 930 Analyzer, when manually entering calibrator bottle values for the Atellica A1c_E assay from the keyboard, the system may use default bottle values instead of the entered values until a system reboot occurs. The use of default calibrator bottle values can result in up to a -7% relative bias in the A1c_E result. The system uses the correct calibrator bottle values if the assay barcode is scanned. No other assays are affected.
4	Atellica CH 930 Analyzer Incorrect Lot Calibration Interval for Ammonia assay in Test Definition Parameters	The test definition for the Ammonia assay incorrectly allows for a 60-day lot calibration interval. The correct calibration interval for the Ammonia assay is 30 days as indicated in the Instructions for Use (IFU). Based on Siemens Healthineers' investigation, there is no statistically significant drift observed at clinically relevant concentrations of ammonia, including values approximating the reference interval (19-54 ug/dL or 11-32 µmol/L) when results are generated using a calibration that is >30 days. A worst-case bias of negative 17% was observed at an ammonia concentration of approximately 700 ug/dL (410 µmol/L) at 62 days post lot calibration. No other assays are affected.

Risk to Health

Issue Number	Risk to Health
1	Worst case, the potential exists for a sample to be tested using an assay that has been disabled, which may lead to the reporting of discrepant patient results. Mitigations include correlation to clinical information such as clinical presentation, other laboratory and diagnostic results and patient history, operator investigation or analyzer having no reagents or running out of reagents due to continuous testing. Due to the remote probability of this event, Siemens is not recommending a review of previously generated results.
2	Worst case, the unlikely but possible potential exists that this issue may lead to the reporting of discrepant patient results in the presence of instrument errors. Mitigations include correlation to clinical information such as clinical presentation, other laboratory and diagnostic results and patient history, manual QC result review, operator investigation and event log review that indicates that the system is in 'bypass' mode setting. Due to the remote probability of this event, Siemens is not recommending a review of previously generated results.

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3	The management of patients with hyperglycemia is dependent upon the monitoring of diet, lifestyle, glucose concentrations, HbA1c, and the adjustment of therapy to glycemic control. A negative bias of up to 7.0% (relative percent) may be considered clinically significant at clinically relevant HbA1c values and may result in the modification of the therapy for hyperglycemia. The modification of hyperglycemic therapy can increase the risk of occurrence of hyperglycemia, which may be observed through personal glucose monitoring and/or patient symptoms. Siemens is not recommending a review of previously generated results.
4	When ammonia results are generated using a calibration that exceeds 30 days the observed differences are negligible and would not lead to a clinically significant difference in patient management. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

The following actions must be taken until your system has been updated to software version 1.24 or higher which resolves the issues listed below. Siemens Healthineers will notify you when an updated software version is available.

Issue Number 1: Patient orders may be run on an Analyzer where the assay has been disabled.

1. When reporting results, ensure that the result for the assay that is disabled on one analyzer, came from an analyzer where the assay had not been disabled and all QC results are within the laboratory acceptable range.
2. To check if an assay is enabled or disabled, navigate to Setup > Test Definition > Assay List > CH or IM tab. An assay is enabled if the box is checked in the column for an analyzer.
3. The Audit Trail screen (System->Logs->Audit Trail.Log) can be checked to see if an assay had been disabled in the past.

Ways to avoid the problem until the software (v1.24 or higher) upgrade is installed:

Before resolving a Yellow glyph on Cal/QC, ensure that no patient orders are being processed by doing the following steps in the sequence below:

1. Stop sample tube processing by clicking on 'Pause VMM'.
2. After the system is in the 'Stop state'
3. THEN Resolve the Cal/QC 'yellow glyph' condition.
4. Resume sample processing by clicking on 'Resume VMM'.

Additional options:

1. Don't load patient samples until QC/Cal has passed on all modules.
2. Check patient samples after checking on a QC/Cal blocked issue (yellow glyph) and check that the assay was not disabled on any module.
3. Click the 'Going offline' Button on the Aptio Automation (SMS). This will stop routing tubes but allows all tube processing to finish. After tube processing has completed, resolve the Cal/QC yellow glyph issue, then go back 'online'.

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Issue Number 2: Analyzers may operate and report results in a service 'bypass' mode.

1. Always ensure that the system covers are properly physically closed and latched. The lock glyph on the System > Status screen for an analyzer indicates whether the cover is locked or unlocked. Ensure that there are no 'yellow' unlocked glyphs displayed.
2. Before starting sample processing, check the Operator Event log and ensure that the following error code is not present:

"03 600 00 44: A cover is open with the Service Bypass Tools in place. Ensure all operators are clear of moving subassemblies to avoid personal injury or system damage. Corrective Action: Contact the local technical support provider for assistance."

Refer to the online help Alerts section 03 IM Event Troubleshooting if the error code is present.

Issue Number 3: Manual entry of Atellica A1c_E - Calibrator bottle values.

1. It is recommended to always scan the calibrator bottle values via the barcode on the A1c_E CAL Table of Assigned Values (TAV) sheet received with the calibrator bottles. If the bottle values are scanned, the issue does not occur.
2. If the calibrator bottle values are entered manually, restart the CH Analyzer by following the directions in the online help: "Starting Analyzers within the System".

Issue Number 4: Ammonia Lot Calibration

1. Navigate to **Calibration > Calibration Results** and select the Ammonia Assay.
 2. Record the date and time of the Ammonia Lot calibration. A lot calibration will need to be performed 30 days from the recorded date.
 3. Ensure the Ammonia assay has a lot calibration performed every 30 days.
- 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 Technical Support representative.

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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 technical support provider.

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Addendum 1: Issue #1 Details and actions available

There is a 10-millisecond timing window where a patient order may be incorrectly run. The following conditions must be true:

1. The assay or module must be in a non-patient processing state but able to process calibrators and QC – See Description 2 below to understand how an assay or module may be set to a non-patient processing state.
2. A calibrator or QC order that was blocked becomes unblocked – See Description 3 for possible causes of blocked QC or Calibration orders.
3. A patient order is processed within a 10-millisecond window immediately following the unblocking of the QC/Calibration order.

Description 2: Actions that can activate a ‘Non-Patient Processing’ State.

1. The Assay is set to ‘Troubleshoot’ from the Assay List screen – Either on an Assay basis or ‘Assay by Specimen type’.
2. The analyzer is set to ‘Disable’ from Analyzer status screen by removing the check mark in the “Patient Sample Processing” checkbox for that analyzer. This action will render the whole analyzer in a state that does not process patient samples.
3. The assay has been disabled from the Laboratory Information System (LIS). Atellica internally sets the assay to ‘troubleshoot mode’ for that assay when an assay disable command is received from the LIS. This instruction can be done from the following connections: Centralink, Atellica Data Manager and the Aptio – Data Management System (DMS Version R20). DMS vR19 does not allow this action.
4. The assay has been disabled by the system because the ‘QC Statistics Violation: Patient Test action’ setting was activated. Using this feature will place the assay in a ‘Troubleshoot’ mode if a QC measurement produces results outside of defined ranges and configurations. In this case, Automation systems may send samples for processing to the Atellica Solution. The Atellica Solution will send an Inventory status of Zero to the Automation system (e.g. Aptio) which will stop Aptio from sending the test to the Atellica Solution. However, in a multi- module setup (e.g. an SCII configuration), the zero inventory may not be sent if one of the modules can run tests (the status of all available inventory will be sent to the automation system instead). In this case the test may be run on the module that has the test disabled.

Note: Disabling Calibrations – e.g. a ‘Cal invalid’ status or expired status will not cause the problem.

Description 3: Possible Causes of Blocked QC or Calibration Orders

1. The analyzer state is not an ‘operating’ state e.g. (Maintenance/Diagnostics), therefore a Cal/QC order cannot run.
2. Primary or Ancillary reagents issues that prevent sample processing.
3. System problems where samples cannot be processed.

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If the above conditions exist and the Calibration or QC orders are blocked, after removing the block of the Cal/QC order, the next patient order may have the issue due to a 10-millisecond timing window.

How to tell if Cal/QC was blocked:

- For Calibrations - on the Calibration Results screen – the order will have flags that indicate why it is blocked (e.g. no primary, module not available etc.). A yellow glyph will show.
- For QC - On the Worklist screen – the QC order will have flags (No primary or Module not available, Cal Invalid) – A yellow glyph will show.

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FIELD CORRECTION EFFECTIVENESS CHECK

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This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) ASW21-02.B.OUS dated December 2020 titled "Multiple issues in Software v1.23.2 and lower". Please read each question 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 UFSN instructions provided in this letter. Yes No

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Please send a scanned copy of the completed form via email to the following e-mail address: XXXX@XXXX,

Or fax this completed form to the Customer Care Center at (xxx) xxx-xxxx.

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

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