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Urgent Field Safety Notice:

Atellica® CH 930 Analyzer - Issues with setting Open Channel Assay parameters

To whom it may concern,

In version A (ASW22-01.A.OUS) of this Urgent Field Safety Notice (UFSN), issued November 2021, you were informed of issues that could occur when using Atellica CH 930 Analyzer software (SW) v1.25.1 and lower. The affected product is listed below in Table 1.

Our records indicate that your facility has received one or more of the following product:

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

Product		Siemens Material Number (SMN)
Atellica CH 930 Analyzer		11067000

Reason for Urgent Medical Device Correction

The purpose of this follow-up is to communicate final information regarding affected software versions and resolution. Specifically, Atellica Solution SW v1.25.X (and lower as previously stated) have since been identified with the previously communicated issues listed in Table 2, only when using Open Channel Assays. Siemens Healthineers Assays are not impacted.

These behaviors are corrected in SW v1.26.0 and higher. In the interim, please continue to follow the previously identified work around in the “Action to be Taken by the Customer” section until all Atellica CH930 Analyzers in your laboratory are updated to SW v1.26.0 or higher.

Table 2. Description of Observed Behaviors

Issue Number	Observed Behavior	Description of Observed Behavior
1	TDef (Test Definition) Parameters for Open Channel Assays reverting to Default Values	If TDef parameters have been edited for an Open Channel Assay under the CH Test Definition screen, the next time an Open Channel configuration screen is edited, it may overwrite the previously edited Open Channel TDef parameters on the CH Test Definition screen with default values. The following issues may occur if parameters are reset to default values: • If an Open Channel Assay uses an Assay Correlation factor, reversion to default would shift test results by the magnitude of the implemented Assay Correlation factor. A significant shift in results due to this issue would be reflected in the QC results. • If an Open Channel Assay was using HIL settings, reversion to default would disable the HIL alert. No samples will be flagged for HIL. • Refer to Table 3 below for the complete list of parameters that can be affected.
2	On Board Stability (OBS) Not Updating with Manual Changes	When the customer manually changes the onboard stability (OBS) for reagent packs for Open Channel Assays, the operator will only see a change for Reagent 1-Well-1 with no change to R1-Well-2, R2-Well-1, and R2-Well-2. The system may continue to use the reagent past its OBS date leading to potential erroneous patient sample results.

Table 3. Affected CH Test Definition Settings

The following parameters cannot be edited on the Open Channel screen but can be edited on the CH Test Definition screen and can be overwritten when saving from the Open Channel screen.

#	CH Test Definition Setting	Sub-settings
1	Definition Tab (General)	a. Result Review Mode b. Result Time Limit c. Analyte Stability
2	Definition Tab (Measuring Intervals)	Repeat when outside Measuring Interval check box
3	Calculation (General)	Fixed digits after decimal
4	Calculation (HIL Alert Indices)	All Parameters
5	Calculation (Assay Comparison Correlation Factor)	All Parameters
6	Calibration	All Parameters (Under 'Acceptance' and 'Measuring Interval Verification Acceptance' sub tab)

Table 4. Risk to Health

No records of injuries have been reported for this issue.

Issue Number	Risk to Health
1	This issue may cause no HIL flagging of Open Channel Assay results, depending on the scenario, which could potentially lead to the generation of erroneous results. Worst case, patient results may not be flagged as appropriate. Siemens Healthineers is not recommending a review of previously generated results as the likelihood of a subsequent clinically significant effect is remote.
2	The potential exists for the system to continue using a reagent beyond its OBS expiry date. The potential gradual impact on results would be detected by QC testing and alert the operator. Siemens Healthineers is not recommending a review of previously generated results due to the apparent nature of the issue.

Table 5. Actions to be Taken by the Customer

The following actions must be taken until your system has been updated to software version 1.26.0 or higher which resolves the issues described in Table 2 above.

Issue Number	Actions to be Taken
1	When saving changes in the Open Channel configuration screen, saving the screen will reset TDef parameter to default settings. To correct this behavior, navigate back to the TDef screen (Setup>Test Definition>CH Test Definition) and ensure that all TDef parameters are correct (refer to Table 3): • Definition Tab (General) • Definition Tab (Measuring Intervals) • Calculation (General) • Calculation (HIL Alert Indices) • Calculation (Assay Comparison Correlation Factor) • Calibration There is no need to go back to the Open Channel configuration screen after the TDef parameters have been confirmed to be correct or corrected. If navigating back to the Open Channel configuration screen and saving, please repeat above steps.
2	After making manual edits on the Open Channel screen, select the affected assay again in the 'Open Channel' screen. Once there, click the "Modify Existing" button and use the "Save Changes" button to update the OBS on all Reagents and Wells.

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.

Sincerely yours,
Siemens Healthcare Diagnostics GmbH

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