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Urgent Field Safety Notice:

Atellica® IM 1300 Analyzer
Atellica® IM 1600 Analyzer
Atellica® Sample Handler Prime

Multiple Issues Identified in Atellica Solution System Software in V 1.17SP2 and lower.

Dear Sirs,

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

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

Product	Siemens Material Number (SMN)
Atellica IM 1300 Analyzer	11066001
Atellica IM 1600 Analyzer	11066000
Atellica Sample Handler Prime	11069001

Reason for Urgent Field Safety Notice

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 V1.17SP2 (SMN 11469659) or lower.

These behaviors are corrected in software version v1.18, which will be available soon.

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Description of Observed Behaviors

Issue Number	Observed Behavior	Description of Observed Behavior
1	For specific configurations of the Atellica Solution, the back cover on the Atellica Magline ™ Transport for the Atellica CH 930 Analyzer, IM 1300 Analyzer, and IM 1600 Analyzer may not be detected as being open when the cover is open or removed.	The following scenarios may occur: • On systems with a right turn or left turn located anywhere after the 2nd analyzer, the back cover may not be detected as open when the cover is open or removed. This will prevent the Atellica Magline from initializing and carriers will not move. • On systems with a linear configuration and only one analyzer, the back cover may not be detected as open when the cover is open or removed. Carrier motion may continue on the Magline, and the operator may not be alerted that a cover is open.
2	Scanning new versions of IM Test Definitions (TDef) resets the customer defined settings to default values in the TDef.	When a new kit lot of reagent that includes an update to the Test Definition is introduced to the system by scanning the 2D Master Curve and TDef barcodes included in the reagent package, the customer defined settings for that assay, may reset to default values. Numerical results are reported using default settings including units and conversion factors. The effects of resetting the customized fields to default values may include but are not limited to incorrect units or conversion factor, missing or additional flags, etc. (see full list of affected fields on pages 3-5 below). The issue only occurs if one or more of the assay TDef settings (e.g. Units, LIS code) have been customized and the assay was subsequently disabled and re-enabled before a new version of the 2D Test Definition barcode is scanned. This issue does not apply to Atellica CH Analyzer assays.

Risk to Health

Issue Number	Risk to Health
1	The potential exists, though remote, for the operator to be hit by moving carriers when reaching into the Atellica Magline Transport. This may occur only if the cover has been removed and the Magline Transport has not been put into standby mode. In addition, there is a potential for loss of sample and an apparent delay in testing.
2	This issue only affects user customized TDef settings. Depending on the field affected and the difference between the customized and default settings, there is a potential for an effect on the reporting of patient or QC results. Worst case, this effect may include but is not limited to erroneous results (example: conversion factor effect) or delayed reporting.

Actions to be Taken by the Customer

The following actions must be taken until your system has been updated to software version v1.18 which resolves the issues listed above.

1. The system must be safely stopped prior to opening the Atellica Magline Transport covers. Please follow the procedure "Removing Atellica Magline Transport Covers" by searching the Atellica Solution online help or refer to the Operator's guide (December 2018). To replace the covers and resume operation, follow the procedure "Installing Atellica Magline Transport Covers" as detailed in the Atellica Solution online help or Operator's Guide (December 2018).

2. After scanning a new version of the 2D Master Curve and Test Definition barcodes included in the reagent package, verify the settings of the customized fields, if applicable, on the Setup/Test Definition/IM Test Definition screen listed below. Verify that QC results are not affected, and that results and all associated customized parameters (units, flags, etc.) are reported correctly.

Definition Tab
Display Name
Print Name
LIS Code
Enable/Disable
LOINC
Automatic Result Review
Patient Replicates
Patient Acceptable CV
Control Replicates
Control Acceptable CV
Anonymous
Reuse Result
Result Time Limit (hours)
First Aspiration Timeout (Min)
Advanced Dilution Option
QC on Pack Change
Centrifuge for Repeat
Control Bracketed Test
Apply Final Result Rule (Only displayed if test type is ID Auto FRR)
Automatic Repeat Dilution (Only displayed when test type Combination is selected.)
Result Calculation Tab
Concentration Decimal
Index Decimal
Displayed Result Type
Master Curve Units (continued)
Units
Conversion Factor
Slope
Intercept
Hemolysis Threshold
Icteric Threshold
Lipemic Threshold

Calibration Tab
New Lot Replicates
Current Lot Replicates
Lot Calibration Interval (Days)
Lot Calibration Interval (Hours)
Extend Cal
Accept Cal
Retain Cal
Autoexclude Cal Replicates
Order QC with Cal
Automatic Acceptance
Pack Calibration Interval (Days)
Pack Calibration Interval (Hours)
Auto Cal Expiration Trigger
Auto Cal (Lot) Expiration Time
Auto Cal (Pack) Expiration Time
Auto Call Pack Expiration Trigger
Auto Cal New Lot Trigger
Auto Cal IFU Change Trigger
Cal OBS Refrigerated
Cal OBS Unrefrigerated

- Please contact your Siemens Customer Care Center or your local Siemens Technical Support representative to schedule a visit to upgrade your system to software version v1.18.
- 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 Customer Care Center or your local 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 Customer Care Center or your local technical support provider.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

i.V. Dipl. Ing. Franz Schwarz
Head of RAQS Austria & SEE

i.A. Dr.in Brigitte Gassner
Product Manager Austria & SEE