

Atellica[®] Solution

Potential for Erroneous Results on Atellica Solution Systems with Multiple Atellica IM Analyzers

Our records indicate that your facility has an Atellica Solution System with two or more connected Atellica IM Analyzers:

Table 1.

Product	Siemens Material Number (SMN)
Atellica Solution System with two or more Atellica IM 1300 Analyzers	SMN 11066001
Atellica Solution System with two or more Atellica IM 1600 Analyzers	SMN 11066000

Reason for Correction

Siemens Healthcare Diagnostics is conducting a field correction for Atellica Solution configurations with more than one IM Analyzer connected. When changing IM Test Definition (TDef) Units with an Atellica Solution configuration containing two or more Atellica IM Analyzers, the change to units of measure may not be applied correctly to results from multiple analyzers. Although all results will display the desired unit of measurement, the results from a specific analyzer may have been calculated with the original unit conversion factor.

This issue only occurs during the following scenarios:

- a) If an Atellica Solution is initially installed with one IM Analyzer and a second IM Analyzer is installed at a later time, then a manual unit change requiring a conversion factor is made to the TDef, the manual changes may not be applied successfully to all of the IM Analyzers on the Atellica Solution.
- b) If an IM Analyzer in an Atellica Solution is offline and additional TDefs are added to the online IM Analyzer, then a manual unit change requiring a conversion factor is made to the TDef after all IM Analyzers are online, the manual changes may not be applied successfully to all of the IM Analyzers on the Atellica Solution.

Unit changes are not saved by both IM Analyzers under the scenarios listed above. One IM Analyzer will save the unit change and apply the conversion factor correctly to all results, but additional IM Analyzers may not save the change and will display the results with the new units but will not apply the correct conversion factor to the result. Therefore, there is a potential for an erroneous result.

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When multiple IM Analyzers are installed and configured at the same time all changes are applied to all IM Analyzers simultaneously and this behavior is not present and all results are correct.

This issue only impacts unit changes which require a conversion factor. Unit changes with a 1:1 relationship are not impacted.

This issue does not apply to Atellica Solution systems with only one Atellica IM Analyzer.

This issue has been corrected in software v1.12.1 which is now available.

Risk to Health

The probability of misinterpretation of results due to this issue is remote. Mitigations include correlation to clinical history and presentation as well as to other diagnostic laboratory testing, serial testing, and/or concomitant imaging studies depending on the analyte. Siemens is not recommending a lookback as a result of this issue.

Actions to be Taken by the Customer

1. No action is needed if you are using Atellica Solution Software Version 1.12.1 or higher.
2. No action is needed if your Atellica Solution system has only one Atellica IM Analyzer.
3. If you are using Atellica Solution Software Version 1.12 or below and your system configuration contains more than one IM Analyzer:
 - Do not change the IM Test Definition Units on Atellica Solution systems with multiple Atellica IM Analyzers.
 - Contact your local Siemens technical support representative to request the installation software version 1.12.1 on your system.

In addition please perform the following:

- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 7 days.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

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We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Atellica is a trademark of Siemens Healthcare Diagnostics Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

Changing IM Test Definition Units on Atellica Solution Systems
with Multiple Atellica IM Analyzers

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice ASW18.01.A.OUS dated February 2018, regarding Potential for Erroneous Results on Atellica Solution Systems with Multiple Atellica IM Analyzers.

Please read each question and indicate the appropriate answer.

Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the [Letter Type] instructions provided in this letter. Yes No

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

To fax this completed form please send it to the Customer Care Center at (XXX) XXX-XXXX. If you have any questions, contact your local Siemens technical support representative.