

Urgent Field Safety Notice

11-21

December 2011

Dimension Vista® Systems

Vista Software Version 3.4 - Invalid Below Manufacturer Assay Range Flags

Our records indicate that your laboratory has the Dimension Vista® System.

Siemens has confirmed customer complaints on Vista® software version 3.4 for Below Manufacturer Assay Range error flags associated with QC and patient test results that are within the assay range as defined in the Instructions For Use for the respective method. This issue is isolated to Vista® software version 3.4. Customers who have not made any changes to the default method configurations are not affected. Other versions of Vista® software are also not affected.

Invalid Below Manufacturer Assay Range flags are generated when any change is made to the method configuration for multiple methods and then not saved before moving on to the next method. When this occurs, results for any affected method will be assessed against an invalid extended assay range.

Invalid Below Manufacturer Assay Range flags are temporary. This issue will automatically be resolved after restart of the Vista® Application Software. To prevent this issue from occurring it is important to edit and save one method at a time.

We recommend discussing the content of this letter with your laboratory director and assessing the potential impact on any rules affecting the transmission of test results.

If you have any technical questions regarding this information, please contact the Siemens Technical Solutions Center.

We apologize for any inconvenience that this situation has caused. Thank you for your patience and continuing support of Siemens Healthcare Diagnostics.

If you are currently using Dimension Vista® software version 3.4 on the Dimension Vista® System, please complete the attached FIELD CORRECTION EFFECTIVENESS CHECK form return it using the details below.

Siemens Healthcare Diagnostics

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Newark, DE 19714-6101

800-441-9250
www.siemens.com/diagnostics

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Example: How are invalid Below Manufacturer Assay Range errors generated?

The operator has made changes to the method configuration(s) for four different methods in the following order BUN, CTNI, PHNO, CA and only saves the changes after CA. Changes were not saved for each individual method.

Since changes were not saved for each individual method, BUN, CTNI and PHNO will implement an invalid extended assay range based on the assay range of 5 – 15 for CA, and convert the range using the appropriate units of the individual method affected. If this occurs, the test result will be correct but the result will be flagged with an invalid Below Manufacturer Assay Range.

	BUN	CTNI	PHNO	CA
Assay Range	1 - 150	0.015 - 40	2.1 - 80.0	5 - 15
Units	mg/dL	ng/mL	µg/mL	mg/dL
Method Configuration Change Made By Operator	Enabled Out of Assay Range Rerun	Enabled Method	Changed Calibrations Acceptance Criteria	Changed Calibrations Acceptance Criteria Conifugred "I" Indices
Invalid Extended Assay Range	5 - 15	5M - 15M	0.5M - 1.5M	NA

The invalid Below Manufacturer Assay Range that is implemented will not be visible to the operator. The only indicator of the issue is that QC or patient test results that are within the assay range are flagged with Below Manufacturer Assay Range.

If the assay range is extended for a linear method and a result is generated that is below the assay range as defined in the respective method’s Instructions For Use, a flag for Below Manufacturer Assay Range is expected. In this case the flag is not an invalid flag.

When modifying the method configuration for multiple methods using Vista® software version 3.4, changes should be saved before moving on to the next method in order to avoid occurrence of invalid Below Manufacturer Assay Range.

In order to correct this situation, please do the following:

1. Select the method that is generating invalid Below Manufacturer Assay Range flags in **ADVANCED > CONFIGURATION > METHOD CONFIGURATION** and **press the ALT P keys together to obtain a screen print**
2. Select **Modify**
3. Make any change to the Method Configuration (except for the units, as this will trigger a calibration)
4. **Save** the changes for this method
5. Select **Modify** and revert the value changed in Step 3 back to the original value (refer to screen print obtained in Step 1) and select **Save**
6. Repeat this procedure for all affected methods

OR

Restart the Dimension Vista® Application Software.

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 dated December 2011 regarding Vista® software version 3.4 - Invalid Below Manufacturer Assay Range Flags. Please read the question below and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics using the details indicated at the bottom of this page.

1. Do you intend to take the recommended action as requested? Yes No

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

PLEASE FAX THIS COMPLETED FORM TO:

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