



Urgent Field Safety Notice

VSW-15-01/03.A.OUS

May 2015

Dimension Vista[®] 500 Intelligent Lab System
Dimension Vista[®] 1500 Intelligent Lab System

Information Regarding Vista Software Issues

Our records indicate that your laboratory has either the Dimension Vista[®] 500 Intelligent Lab System or Dimension Vista[®] 1500 Intelligent Lab System using 3.6.1 software versions.

Dimension Vista[®] Affected Products

Product	Siemens Material Number (SMN)
Dimension Vista 500 Intelligent Lab System	US: 10284473 Outside US: 10488224
Dimension Vista 1500 Intelligent Lab System	US: 10444801 Outside US: 10444802

Reason for Correction

Siemens Healthcare Diagnostics has identified the following two issues using Dimension Vista[®] Intelligent Lab System software versions 3.6.1, 3.6.1_MU3p, and 3.6.1SP1.

Issue 1:

Samples may stop processing without notification on the Dimension Vista 500 or Dimension Vista 1500. This issue is due to a failure to exchange aliquot plates, causing the lane to become unavailable.

The issue can be observed on all Dimension Vista configurations by navigating to the Sidebar Sample Option view where the samples remain in a "Not Started" status. When Dimension Vista instruments are connected to Automation systems, the issue may also be detected when sample tubes are not aliquoted from the diverter lane.

Issue 2:

The following issue does not pertain to the Dimension Vista 500 systems as they do not have Reagent Server 2 hardware.

Complaints were received on the Dimension Vista 1500 for a series of unexpected results, some of which were not flagged with errors or results that were flagged with errors. It has been determined that under a rare set of conditions, a timing issue may cause a Reagent Server to temporarily lose synchronization during the automatic removal of reagent cartridges from Reagent Server 2 to Waste A Container.

Until the Reagent Server automatically restores synchronization, the software gives no indication that there is a problem and may cause either wrong reagent or no reagent delivery to occur. The Vista system incorporates a number of reaction quality checks, designed to evaluate expected results with conditional error flags. However it is possible, although extremely unlikely, for unflagged erroneous results to be generated until synchronization is automatically restored.

In the extremely unlikely circumstance that this issue occurs, a flag will be generated for the majority of assays. However, there is the potential to produce unflagged erroneous but believable results for the following assays: Albumin, Cholesterol, Enzymatic Creatinine, HDLC, Creatine Kinase, Direct Bilirubin, Lactate Dehydrogenase, Alkaline Phosphatase, Iron, TIBC, Ethanol, Urine/Cerebral Spinal Fluid Protein, Phosphorous, IgM, IgG, Folate, Salicylate, Thyronine Uptake, and Digitoxin. QC may not detect this issue.

To prevent the Reagent Servers from temporarily losing synchronization, see Actions to be Taken by Customer.

Risk to Health

Issue 1:

When samples stop processing without notification, the potential for clinical impact is limited to a delay in test results in emergent clinical situations until the delay becomes apparent. This could affect any assay on the Dimension Vista platform running software versions 3.6.1. There is no risk of producing erroneous results. Siemens is not recommending a review of previously generated results due to this issue.

Issue 2:

Under the extremely unlikely circumstance that a Reagent Server loses synchronization, the potential exists for generating erroneous but believable results. The clinical impact is limited to the assays listed in the section above. Error flags are expected to be generated for all other assays, preventing the reporting of erroneous results. Siemens is not recommending a review of previously generated results due to this issue.

Actions to be Taken by the Customer

For the corresponding issues listed above, please perform the following:

Issue 1:

If you experience this situation, sample processing can be resumed using the step(s) below:

Step 1: From the Operation Icon select PAUSE, then immediately return to the Operation Icon and select Cancel PAUSE. Sample aliquotting should immediately resume.

Step 2: If sample processing does not resume after Step 1, wait until the instrument displays System Ready, then restart the system software per the Vista Operator Guide, Section 2, Controlled Shutdown-Restart procedure.

Issue 2:

To prevent the Reagent Servers from temporarily losing synchronization, Siemens recommends setting the Auto Dispose option to “No” for methods assigned to Reagent Server 2 (see instructions below). These empty or expired reagent cartridges will now remain on the instrument and require the operator to unload them.

Please consult your Vista Operator’s Guide or method Instructions for Use when results with flags and/or errors occur.

Turning Off the Auto Dispose Option

Step 1: Navigate to the Advance>Configuration>Reagent Server Configuration screen and Print the Reagent Server Map to identify the Reagent Server 2 methods.

Step 2: Navigate to the Advance>Configuration>Reagent Flex Configuration screen.

Step 3: Using the Reagent Server Map printout, reconfigure each method listed on Reagent Server 2 as follows:

- a. Select the method by clicking on it in the table.
- b. On the Action Sidebar select Edit Configuration.
- c. At the bottom of the screen locate the Auto Dispose drop down box and select “No”.
- d. Save the change by pressing the Save Changes option in the Action Sidebar.

Step 4: Repeat step 3 for all methods listed on Reagent Server 2 or anytime you move a method to Reagent Server 2.

Step 5: When completed, restart the Vista application by selecting the Operation Icon and SHUTDOWN. Once at the Vista console menu restart the Vista application.

Removing Empty/Expired Reagent Cartridge Inventory from the Instrument

Note: Siemens recommends removing empty or expired reagent cartridges from inventory at a routine time each day, for example just prior to loading reagent cartridges before Off Peak Activities or before daily QC.

Step 1: Navigate to Setup>Inventory screen.

Step 2: Click on the word “Status” to sort the reagent cartridge inventory. Find and select each empty or expired reagent cartridge and select “Unload”.

Step 3: Empty or expired reagent cartridges will be moved to the instrument bulk loader for removal.

Siemens will be providing corrections for these issues in a future Vista software version.

Please review this letter with your Medical Director.

Complete and return the Field Correction Effectiveness Check Form attached to this letter.

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

Information Regarding Vista Software Issues

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

Dimension Vista is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Information Regarding Vista Software Issues

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice VSW-15-01/03.A.OUS, May 2015 regarding Information Regarding Vista Software Issues. 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.

Ref: VSW 15-01 – VSW 15-03 [C/3140]

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2. Signed.	Date:	

Name of person completing questionnaire: Block capitals	
Title:	
Institution:	Instrument Serial Number:
Street:	
City:	State:
Phone:	Email:

It is important that your organisation takes the actions detailed in the UFSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to this UFSN. Your organisations reply is evidence which, Siemens Healthcare, and subsequently the MHRA, needs to monitor the progress of the UFSN. Without your reply Siemens Healthcare cannot verify the completeness of the UFSN and the MHRA may need to issue a Medical Device Alert.

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