SIEMENS

Urgent Field Safety Notice

VSW16-01.A.OUS

March 2016

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

Dimension Vista System May Not Perform Aliquot Probe Rinse

Our records indicate that your laboratory has the Dimension Vista® 500 Intelligent Lab System or Dimension Vista® 1500 Intelligent Lab System running on software versions V. 3.6.1 SP1 or V. 3.6.2.

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 received customer complaints of discrepant patient results on Dimension Vista Intelligent Lab Systems. Siemens Healthcare Diagnostics has confirmed a software defect which, in a very specific set of circumstances, results in the Dimension Vista System omitting an aliquot probe rinse between sample aspirations when processing tubes in Sample Racks that are front loaded on the Dimension Vista System. Omission of the aliquot probe rinse may result in carryover of residual sample estimated up to 10% when the sample is dispensed into the aliquot well. Carryover of residual sample from the outside of the aliquot probe into the sample tube is estimated at less than 0.1%.

Tubes processed directly from an automation system track are not impacted.

Samples processed using Dimension Vista Small Sample Container (SSC) or Dimension® Sample Cups are not impacted.

Hemoglobin A1c (HbA1c) whole blood samples processed from primary tubes are not impacted.

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This issue only occurs during the initial level sensing of a sample tube if the Dimension Vista System detects a “Bad Sample Detect (False Transition)” error and a second sample with a specific timing condition interrupts processing before the level sensing retry of the first sample is complete.

The frequency of “Bad Sample Detect (False Transition)” errors may be impacted by the following:

- laboratory environmental conditions (i.e., humidity and temperature outside specifications)
- sample integrity (i.e., foaming, bubbles)
- instrument mechanics (i.e., Probe vibration, Loose or pinch grounding wire, Fluid detection malfunction, Defective e-chain, and Pinched coaxial cable)

As designed, when the Dimension Vista System generates a “Bad Sample Detect (False Transition)” error, the system records the first incident on the Process Error screen, and automatically attempts a retry of the sample aspiration without posting an Alert. After two “Bad Sample Detect (False Transition)” errors on the same sample, the instrument posts a “Problem Sample Alert” on the instrument display to notify the operator that the sample did not process. These samples are not impacted by this issue. For guidance with “Problem Sample Alerts”, see the Dimension Vista Operator’s Guide: Sample Processing and Test Report Messages.

Siemens has identified a software correction to address this issue and is working to provide this updated software to all affected customers. Until the updated software is available, please refer to the “Actions to be Taken by the Customer” in this letter. **Upon installation of Dimension Vista System software Version V. 3.6.2 SP1 or Version V. 3.7 by a Siemens Service Representative, the “Actions to be Taken by the Customer” in this letter are no longer required.**

Risk to Health

There are two possibilities for carryover of residual sample to impact a test result. The most likely scenario is carryover of residual sample from the aliquot probe. This can contaminate the aliquot well of another sample potentially leading to inaccurate results. The less likely scenario is carryover of residual sample from the outside of the aliquot probe into a sample tube, which is subsequently used, for infectious disease testing. This second scenario is less likely as the level of contamination is slight.
While there is potential for the instrument to create inaccurate results, the potential for this to occur with significant impact is reduced based on the alignment of specific sample types when the error occurs.

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Although many possible scenarios exist for the potential of clinical assays to be affected, the following have been considered for risk to health if this software defect occurs.

1. Residual fluid from a urine specimen carries over into a serum aliquot well. In this circumstance, an elevation of BUN, creatinine or potassium is possible. Unexpected elevated BUN and or creatinine either will likely be considered unbelievable or will typically be followed up with further testing. Under rare circumstances, a potassium result could either be normalized in a hypokalemic sample or elevated in a normokalemic sample.

2. A reduction of serum sodium is also possible if the urine specimen has reduced sodium, as is a normalization of a hyponatremic sample if under rare circumstances a urine specimen with elevated sodium contaminates a serum specimen with reduced sodium. Normalization of phosphate in a patient with reduced serum phosphate could also occur.

3. There is also the potential to contaminate and cause a false positive BHCG in a serum sample with urine or serum of a pregnant woman. This could lead to reconsideration of optimal care under emergent situations (avoidance of certain drugs or radiography). Contamination of a serum specimen with troponin from another specimen with elevated troponin post-infarction is also possible.

4. Contamination of the outside of the aliquot probe with an HIV or HBsAg positive sample could carryover to another sample. If that sample is subsequently taken to another instrument and tested for HIV or HBsAg there is the potential for a false positive result which would likely not confirm due to dissipation of the very small volume of sample carried over in this circumstance.

Siemens is recommending a look back under specific circumstances. Please review the Process Error log for “Bad Sample Detect (False Transition)” errors with an exclamation point inside a WHITE triangle for the period of time available to you and do the following:

- If no “Bad Sample Detect (False Transition)” errors are logged, no further action is required for the look back.
- If “Bad Sample Detect (False Transition)” errors are observed and Sample Rack information is available, refer to Step 4 in “Actions to be Taken by Customer” in this letter.
- If in the past 48 hours, “Bad Sample Detect (False Transition)” errors are observed and Sample Rack information is available, please repeat all BHCG on any samples processed in the two Sample Racks following the error. If in the past 24 hours, “Bad Sample Detect (False Transition)” errors are observed and Sample Rack information is available, please repeat all CTNI, LYTES, BUN, CREA, CRE2, ECREA, PHOS, TSH, TPSA, and FPSA tests on any samples processed in the two Sample Racks following the error.

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Actions to be Taken by the Customer

There are various causes of ''Bad Sample Detect (False Transition)'' errors. Siemens recommends that laboratories should coordinate a combination of the following steps to minimize or eliminate the impact of this specific software defect.

- To minimize the impact of the software defect due to ''Bad Sample Detect (False Transition)'' errors when processing front loaded samples, please follow Steps 1-4.

- To eliminate the impact of the software defect when processing front loaded samples, please follow Step 5.

Step 1: To reduce the frequency of "Bad Sample Detect (False Transition)" errors, please verify that your laboratory meets the humidity and temperature specifications for the Dimension Vista Systems. If your laboratory is operating outside the specifications listed in Section 2, Safety and Specifications in the Dimension Vista System Operator's Guide, please contact your hospital maintenance department. If you need assistance or have questions regarding your laboratory environmental conditions, please contact Siemens Customer Care Center or your local Siemens technical support representative.

Step 2: Process Sample Racks with urine tubes separately from all other fluid types until further notice. Wait until the urine tube racks exit from the instrument before introducing racks of any other fluid type onto the Dimension Vista System.

Step 3: Turn off the "Panic Rerun" feature for any methods and all fluid types in which you have this feature enabled until further notice.

- Select Advanced → Configuration → Method Configuration
- Make list of methods and fluid types where you are using this feature
- Select a method
- Select Modify Method Configuration
- Under Panic Range, uncheck the Panic Rerun option for all fluid types
- Save changes
- Repeat these steps for all methods where the Panic Rerun feature is used

NOTE: With this feature turned off, if a panic repeat is required, the test must be repeated as an add-on and "Run From Sample Rack" only at the Dimension Vista System.

For additional guidance, see the Dimension Vista Operator's Guide: Advanced Functions; Section 9, Method Configuration.

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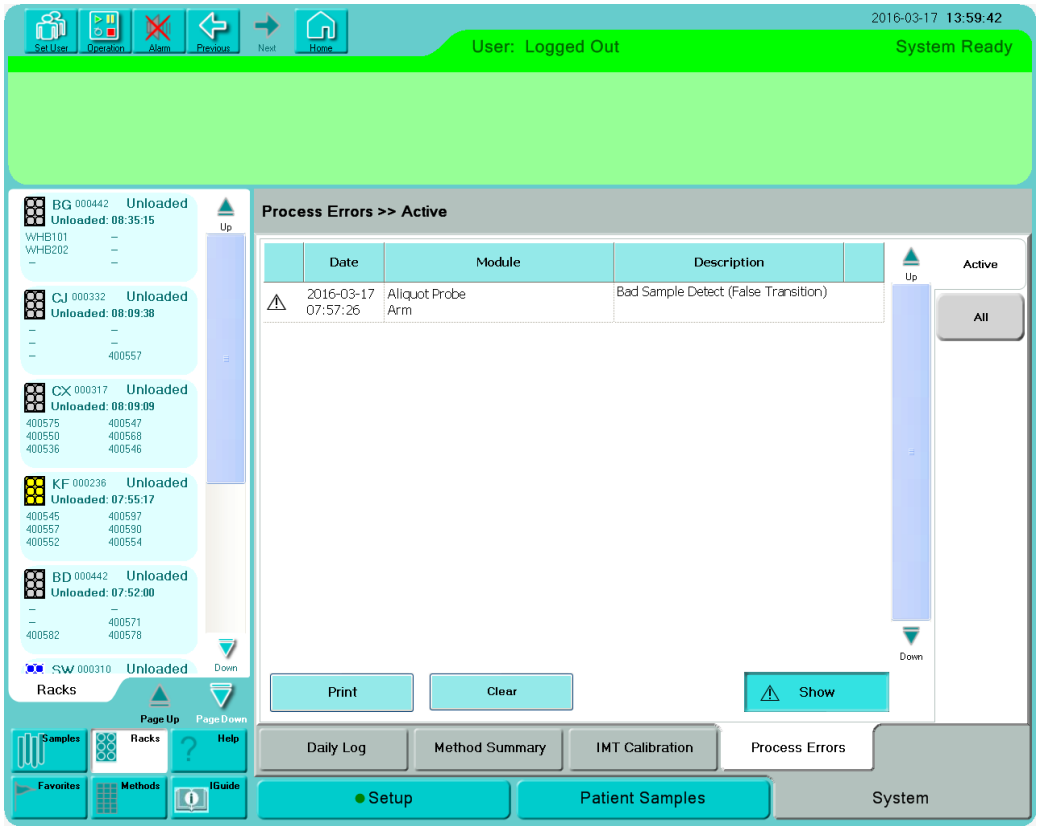
Step 4: If processing via front loaded Sample Racks with tubes on your Dimension Vista System, use the following steps to identify if a ''Bad Sample Detect (False Transition)'' error has occurred which may have impacted a sample.
NOTE: Before re-using Sample Racks complete all of Step 4.

4a) Select System button → Process Errors → All → Show



4b) Review the log for "Bad Sample Detect (False Transition)" in the column titled "Description". A “Bad Sample Detect (False Transition)” error with an exclamation point inside a WHITE triangle requires evaluation.

NOTE: If you see a Problem Sample Alert with “Bad Sample Detect”, select the alert to identify sample(s) that could not be processed. These samples are not at risk of contamination. For additional guidance, see the Dimension Vista Operator’s Guide: Sample Processing and Test Report Messages.

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4c) For those errors that require evaluation, under the “Date” column for the error, note the time of the error.

4d) Select the “Racks” sidebar button to show information about each sample rack. Identify the **first two Sample Racks** that were unloaded at least one minute after the “Bad Sample Detect (False Transition)” error occurred. The potentially impacted primary tube sample, if any will be located on one of the two identified Sample Racks. For example, in the screenshot above, the potentially impacted sample for the error time stamped 07:57:26 will be contained within Sample Racks CX000317 or CJ000332 which were unloaded at 08:09:09 and 08:09:38, respectively (the other Sample Racks were unloaded either prior to the error or were not one of the first two Sample Racks unloaded at least one minute after the error).

4e) The BHCG, CTNI, LYTES, BUN, CREA, CRE2, ECREA, PHOS, TSH, TPSA and FPSA samples in the two Sample Racks identified in Step 4d should be repeated as an add-on and “Run From Sample Rack” only at the Dimension Vista System. Confirm results against the original results. If results are discrepant, follow your laboratory procedures.

4f) Until further notice, repeat Step 4 at regular intervals and before reusing Sample Racks.

4g) If you need assistance with Step 4, please contact Siemens Customer Care Center or your local Siemens technical support representative.

Step 5: To eliminate the impact of the software defect on your Dimension Vista System when processing front loaded samples, process all front loaded samples using Dimension Vista Small Sample Container (SSC) (KS860, SMN 10472099) or Dimension® Sample Cups (DSC4, SMN 10445041) until further notice. This requires the operator to follow appropriate fill guidelines as instructed in the Dimension Vista Operator’s Guide: Sample Containers and Racks, Section 5, Sample Processing and Test Reports.

Please review this letter with your Medical Director.

Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

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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 has caused. If you have any questions, please contact Siemens Customer Care Center or your local Siemens technical support representative.

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Customer Frequently Asked Questions

1. **How can I currently assess if my results may have been impacted by this issue?**
   If your laboratory is experiencing unexplained discrepant results which upon repeat testing from a new aliquot recover within limits, then this issue may have occurred. Please see "Actions to be Taken by the Customer" in this letter to determine if "Bad Sample Detect (False Transition)" errors are occurring on your Dimension Vista System.

2. **When can I stop performing the "Actions to be Taken by the Customer"?**
   Upon installation of Dimension Vista System software Version 3.6.2 SP1 or Version 3.7 by a Siemens Service Representative, the "Actions to be Taken by the Customer" in this letter are no longer required.

3. **What should I do if I believe my Dimension Vista Systems are having a high frequency of** "Bad Sample Detect (**False Transition)"errors listed in the Process Error screen?**
   The frequency of "Bad Sample Detect (False Transition)" errors may be impacted by the following:
   - laboratory environmental conditions (i.e., humidity and temperature outside specifications)
   - sample integrity (i.e., foaming, bubbles)
   - instrument mechanics (i.e., Probe vibration, Loose or pinch grounding wire, Fluid detection malfunction, Defective e-chain, and Pinched coaxial cable)

   To view false transition errors, select System button, select Process Errors button, select All button, select Show button, and review the log. If you're Dimension Vista System is posting routine "Bad Sample Detect (False Transition)" errors, please contact Siemens Customer Care Center or your local Siemens technical support representative to review and address possible environmental or mechanical issues with your instruments.

4. **Why are Dimension Vista SSC and Dimension Sample Cups not impacted?**
   The Dimension Vista® System does not utilize level sensing for SSC and Sample Cups therefore the software defect identified does not impact the processing of samples in these containers.

5. **What impact does this issue have on processing tubes from an Automation track?**
   If you are processing all of your tubes from an automation track, this software issue has no impact on processing these samples. Continue to operate in this mode. See #6 - 7 below.

6. **How do I manage a <u>single</u> routine/stat sample with my Automation system?**

If you have a single routine/stat sample that must be front loaded onto your Dimension Vista System which is also processing tubes from an automation track, one single tube may be front loaded in a rack without experiencing this issue. No additional samples may be front loaded until that sample tube exits the instrument.

7. **How do I manage multiple routine/stat samples with my Automation system?**
   If you have a multiple routine/stat samples that need to be front loaded onto your Dimension Vista System which is also processing tubes from an automation track, Siemens recommends processing those samples in Dimension Vista SSC or Dimension® Sample Cups as described in the "Actions to be Taken by the Customer" section in this letter.

8. **What impact does this issue have on processing whole blood?**
   Processing Hemoglobin A1c (HbA1c) whole blood samples from primary tubes or sample cups are not impacted. All other whole blood samples processed using sample cups are not impacted.

9. **What specific sample fluid type is impacted by this aliquot sampling issue?**
   All samples have the potential of being impacted by this specific issue. However, processing urine samples separately from other sample fluid types minimizes the impact of this issue.

10. **Which SSC is recommended for use on the Dimension Vista System?**
    It is recommended that you use the Dimension Vista SSC due to the workflow of the Dimension Vista System and the setup of the vision system.
    - If you are currently set up to use Dimension SSCs you can continue to do so.
    - If you choose to change from Dimension Vista SSC to Dimension SSC or from Dimension SSC to Dimension Vista SSC , a Siemens service representative must reconfigure your instrument.
    - DO NOT intermix the Dimension SSC with the Dimension Vista SSC
    - Please contact Siemens Customer Care Center or your local Siemens technical support representative to reconfigure your instruments.

11. **What actions are Siemens taking to correct this issue?**
    Siemens has identified a software correction to address this issue and is working to finalize and provide this updated software to all affected customers. Upon installation of Dimension Vista System software Version V. 3.6.2 SP1 or Version V. 3.7 by a Siemens Service Representative, the "Actions to be Taken by the Customer" in this letter are no longer required.

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FIELD CORRECTION EFFECTIVENESS CHECK

Dimension Vista System May Not Perform Aliquot Probe Rinse

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice VSW16-01.A.OUS dated March 2016 regarding Dimension Vista System May Not Perform Aliquot Probe Rinse. Please read and indicate the appropriate answer to the question below. 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 Urgent Medical Device Correction instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution:

Street:

City: State:

Phone: Country

Customer Sold To #: Customer Ship To #:

Please fax this completed form to the Customer Care Center. If you have any questions, contact your local Siemens technical support representative.

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