

Urgent Field Safety Notice

CSW17-02.A.OUS

February 2017

ADVIA[®] Centaur XPT

Multiple Software Issues – V1.0 to V1.2

Our records indicate that your facility may have received the following product:

Table 1. ADVIA Centaur XPT Affected Product

Product	Siemens Material Number (SMN)
ADVIA Centaur XPT System	10711433

Reason for Correction

Siemens Healthcare Diagnostics has identified the issues described in Table 2 for all the ADVIA[®] Centaur XPT system software versions V1.0.1 (Bundle 1.0.912 SMN 10819704), V1.0.2 (Bundle 1.0.1086 SMN 11219806), V1.0.3 (Bundle 1.0.1108 SMN 11220781, 11219656), V1.1 (Bundle 1.1.243 SMN 11221979, 11222064) and V1.2 (Bundle: 1.2.223.0 SMN: 11222258, 11223813)). These issues may affect the operation and workflow of the system.

The issues listed in Table 2 will be corrected in future software versions.

Risk to Health

The potential exists for an apparent delay to testing when these issues occur. The risk to health is negligible from these issues. Siemens is not recommending a laboratory look back of previously generated results.

Table 2. Description of Observed Issues

Issue Number	Observed Issue	Description of observed behaviour
1	System Status Unknown	<p>The system may display an “Unknown status”, if a software error occurs due to:</p> <ul style="list-style-type: none"> • Reagent barcode processing • Missing wash packs for mitigations • Sample processing if the aHAVM assay is ordered. • During the Daily Cleaning or Rinse operation. • Software processing errors.
2	LAS Communication	<p>Tubes received from the LAS may not be processed if the following conditions occur:</p> <ul style="list-style-type: none"> • If the LAS is setup using custom test names, in software v1.2, the reagent status is not sent to the LAS. The LAS may not route tubes to the system for processing if the reagent status is not known. • Due to an internal system timing error, samples may stop processing from the LAS if there is only one tube in the LAS queue and it is in the process of being indexed out just as another tube is being added.
3	QC Profiles	<p>If a new test is added to an existing QC profile, the new test is not added into all levels of the QC material that exist in the QC profile, the display will not show all control levels of the new test. Therefore, all controls may not be run for a new test.</p>

<p>4</p>	<p>'No Primary' Error</p>	<p>A 'No Primary' error is generated and tests are aborted under the following scenarios:</p> <ul style="list-style-type: none"> • If any bulk consumable container is removed while a test already has a No Primary error, all tests for that tube will be flagged with a No Primary flag. The tests will need to be re-ordered. • If an "immediate unload" of a primary reagent pack is requested by the user and the user then requests a "cancel unload" of the same pack. When the pack is depleted, any tests scheduled for the reagent pack will be aborted and will need to be re-ordered. • If an auto-repeat is triggered and requires an auto-dilution, an error in the calculation of the reagent volume required for the dilution may determine that there is insufficient reagent volume in any of the remaining onboard packs.
<p>5</p>	<p>LIS Specification</p>	<p>The software does not operate according to the published LIS specification. The following are corrections to the specification:</p> <ul style="list-style-type: none"> • The Order Record does not follow the specification. The '^' symbol is not transmitted between the rack number and the position number under the following conditions: <ul style="list-style-type: none"> • 'Send Rack IDs with Results' is enabled in LIS Configuration. • The QC order has Rack & Position. • The QC Sample is loaded using automation track or loaded on a RackID whose rack number is less than 1000 (Ex: '1A', '20B', '999A'). • The Rack ID and position number in the query record are always sent to the LIS regardless of which mode is being used on the system.

Actions to be Taken by the Customer

Please perform the following actions:

1. System Status Unknown: Ensure that all wash mitigation packs are loaded on the system before starting sample processing to ensure that all samples will be processed successfully. If “Unknown Status” is displayed, shutdown and restart the system before re-starting of sample processing.
 - It is recommended that the system be re-started at least once a week to improve system performance.

Summary of instructions to shutdown and re-start the system:

Note: Please follow all cautions and warnings as detailed in the operating instructions Chapter 8 called ‘Turning the System Off and Restarting the System’.

1. On the status bar, select System State.
 2. Select Turn System Off.
 3. At the prompt, select Yes to continue.
 4. Wait while the system powers down.
 5. Check for obstructions before restarting the system.
 6. Press the system computer power button.
 7. Sign in with your user ID and password.
 8. On the status bar, select System State.
 9. Select Turn Mechanics On.
 10. Select OK and then select Yes at the confirmation window.
 11. When the system state is Ready resume operation.
- It is recommended to run the system prime every 4 hours to avoid the Unknown state when running aHAVM.
 - If the “Unknown Status” message is displayed during a DCP or Rinse operation, restart the system and repeat the DCP or Rinse.
2. LAS Communication:
 - Reagent Status: This issue only occurs If the system is running V1.2. The default test names must be used for the LIS Name in the Test Definition setup screen in order for the reagent status to be sent to the LAS. Your Siemens service personnel can check if this is setup correctly for V1.2.
 - Sampling stop at LAS: Sampling may stop if the tubes to be processed arrive sporadically at the system for processing. Optimize the delivery of tubes so that there is a steady stream of tubes arriving at the system to be processed.
 3. QC Profiles – To add a new test into an existing QC profile, delete all levels of the control material in the QC profile (using the ‘Remove Control’ button) and recreate the entire QC profile once again with all the tests including the new one.

4. 'No Primary' Flags: The following procedures should be followed to minimize interruption of test processing and "no primary" errors.
 - Ensure that all reagents and bulk consumables are available prior to starting sample processing. If a 'No Primary' flag is received on a test, resolve that condition prior to replenishing any bulk consumables.
 - When removing reagent packs using the "immediate unload" command, do not request a "cancel unload". If a "cancel unload" is requested, then the pack must be physically removed from the reagent compartment and the compartment door must be closed in order for the system to scan all the reagent packs and resume normal test processing. The pack can be reloaded after the reagent compartment scanning has completed.
 - When running tests that may require auto-repeats with auto-dilutions, ensure that the packs have sufficient reagent volume so that they do not go low or deplete while running.
 - If a 'No Primary' flag is received on a test, it will need to be re-ordered.

5. LIS Specification: Please communicate the information regarding the changes in LIS Specification stated in issue #5 in Table 2 to your LIS vendor and implement as defined in this communication. Note: The Centralink and syngo LIS interfaces are designed to work with this specification and do not need any changes.

In addition, please perform the following:

- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.
- Please review this letter with your Medical Director.

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 Siemens Technical Support Representative.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.

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 CSW-17-02.A.OUS dated February 2017 regarding Multiple Software Issues – V1.0 to V1.2. Please read the 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 Urgent Field Safety Notice instructions provided in this letter. Yes No

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

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