SIEMENS

Urgent Field Safety Notice

CSW-15-04.OUS

November 2015

ADVIA® Centaur XPT

Multiple Software Issues (V1.0.1, V1.0.2, V1.0.3)

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 and Table 3 with the ADVIA® Centaur XPT system software V1.0.1 (Bundle 1.0.912 SMN 10819704), V1.0.2 (Bundle 1.0.1086 SMN 11219806) and V1.0.3 (Bundle 1.0.1108 SMN 11220781) that may affect the operation and workflow of the system.

The issues listed in Table 2 (Issues 1-12) will be corrected in software version 1.1 (Bundle 1.1.243 SMN: 11221979), which will soon be available for installation on your system. The Actions to Be Taken section indicates if the specific issue is corrected in V1.1. For issues corrected in software version 1.1, the actions do not need to be performed after your system has been upgraded to software version 1.1.

The issues listed in Table 3 (Issues 13-20) will be corrected in future software versions.

Risk to Health

For Table 2 (Issue #1)

- Using multiple replicates with the listed assays will generate averaged results for the assay that may lead to incorrect diagnosis.
- If you are running samples as described in Table 2 (Issue #1) with Replicates set to any value greater than 1, Siemens recommends a lookback of all results that may be affected.

For all remaining issues:

- With the alerts generated by the instrument for the scenarios impacting samples, the operator will be aware that a sample may not have been processed and can take action.

Siemens recommends discussing the content of this letter with your laboratory director.

Unrestricted

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Table 2. Description of Observed Issues (Issues 1-12)

Issue Number	Observed Issue	Description of observed behaviour
1	Using the Replicates Option with the Final Result Rule (FRR).	If the assay is being run with multiple replicates defined, the Centaur XPT reports the test result as a mean value of all replicate results. The individual replicate results are not reported on the Results screen or to the LIS. This behaviour applies to the following assays (RubG, RubM, ToxG,ToxM). The same behaviour of averaging all replicates for each test ordered also applies to the following assays: (HBcM,aHBcM, aHAVM, aHBs, aHBs2, aHCV, CHIV, EHIV, HBcT, aHBe, HBeAg, HBs, HBsII, SYPH) ONLY if the Final Result Rule (FRR) option in the TDEF is disabled. Note: In all cases, If only one replicate is defined for each test ordered, the correct result is displayed with the correct interpretation on the Results screen and sent to the LIS.
2	Delta Check units	If there was a unit change in the Test Definition for an assay and the Delta check functionality is enabled for this assay, the Delta Check functionality assesses the delta check range for a new result (with new units) against historical results (with the previous units). This could lead to incorrect flagging of the new result for failure of the delta check evaluation.
3	Units on the Calibration Data Details Report	In the Calibration Data Details Report, the unit assigned to the calibrator high and low dosage is always printed as ng/mL. Depending on the assay, the printed unit might not match the actual unit of the assay that is displayed on the workstation screen. The numerical result printed is correct, even though the unit printed might not match the actual unit of the assay.

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4	Using the Copy Configuration Utility	The Copy Configuration utility, used to transfer the configuration from one instrument to another can only be used before TDEF's have been installed on a system. This utility does not transfer the Test Definition (TDef) Conversion Factor Field and the Patient/Control Acceptable CV % Field correctly. When the copied configuration is loaded on another instrument, these values will round off to the nearest whole number (i.e. 1.54 become 2.00). This behaviour affects only assays that have been modified from the default TDEF settings for the above mentioned fields. In addition, the Online Help documentation erroneously indicates that the system must be in the Inprocess status for the Copy Configuration Utility to be used, instead of Mechanics Off status. **Note:** This tool is used primarily during system installation by Siemens personnel. Any discrepancies would already have been corrected during the system verification process.
5	Printer Driver Resets	Automatic printing of the Runtime report might not resume following printer related errors such as, Out of paper, Paper Jam, etc.. After resolution of the problem on the printer itself, the UIW workstation might not resume printing automatically even though the printer is online.
6	Calibrating TSTO	It is not possible to calibrate the Testosterone assay (TSTO) if the Assign Cal option is not checked in the Test Definition (TDef). This behaviour is specific to TSTO and is due to the presence of the mitigation wash within the reagent pack.
7	Laboratory Automation(LAS) offline due to Vacuum error	If a physical low vacuum pressure condition exists at Startup of the ADVIA Centaur XPT and is resolved by the user, an updated status is not communicated to the LAS. This will cause the instrument to remain offline at the LAS.
8	Monitoring the Laboratory Automation (LAS) communication	The current version of Centaur XPT software does not display messaging to or from the LAS in the Events / LAS Logs tab even though the Capture setting is selected as 'On'. Alternate screens must be used when monitoring the LAS communication.

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9	Priming Needed error reported to Laboratory Automation (LAS)	Under certain scenarios, a “System Error” flag is generated when processing a sample. In these cases, there will be no corresponding message in the Operator Event Log and a “Priming needed” error is reported to the LAS.
10	Sample Status reported to Laboratory Automation (LAS)	If a sample aspiration error occurs at the LAS sampling position, the Sample Status message transmitted by the Centaur XPT instrument to the LAS may not be accurate. Under certain scenarios, the system will incorrectly report the sample aspiration as successful to the LAS. This can result in an incorrect display of the sample and test order status at the LAS user interface.
11	Non-Siemens Laboratory Automation(LAS) – General Status message	When connected to Non-Siemens LAS systems, if the instrument is already in the Inprocess state, it will incorrectly report an error status to the LAS General Status Message request. This will cause the instrument to remain offline at the LAS. Note: The LAS General Status Message request is not used when connecting to a Siemens LAS system.
12	Non-Siemens Laboratory Automation(LAS) – Immediate index	When connected to Non-Siemens LAS systems, under certain scenarios of sampling failures, the sample with the error may not be immediately indexed out of the sampling position. In addition, a delay in the release of the sample can occur if the LAS system setting “Immediate Index When No Order” is enabled. Note: This setting is not used when connecting to a Siemens LAS system.

Table 3 - **Description of Observed Issues (Issues 13-20)**

Issue Number	**Observed Issue**	**Description of observed behaviour**
13	Using dilution for automated repeats	The current software does not allow selection of the dilution option when setting up ‘Out of Concentration/Index’ range automated repeats. The system only allows selection of the number of replicates.

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14	Printing of results for Replicates	The printed reports for Lab Results by Sample and Lab Results by Test do not print replicate data in the same order as displayed on the Test Results Overview -> Replicate Data workstation screen. The workstation screen displays replicates in the chronological order, whereas the printed report is printed in the reverse replicate order. The numerical values of the results are correctly associated with all the other data for each result.
15	Workstation services may restart	A Workstation Services restart screen may appear under multiple scenarios causing the user interface to be temporarily inaccessible. The user will be prompted to login once the services restart. In some cases, a black screen may appear with two icons on the bottom of the screen.
16	Rinse System Maintenance task	The Rinse System maintenance task does not complete successfully and leaves the system in a frozen Cleaning status. This task is an “as needed” maintenance task that could be used to flush the system with water if required.
17	On Board Stability(OBS) for HBsll	The Instructions for use (IFU) for the HBsII ancillary reagent define the On Board Stability (OBS) as 60 days. However if the Confirmatory assay is enabled on the system, scanning its Master Curve Card will change the OBS of the HBsII ancillary reagent to 42 days in accordance with the requirements for the Confirmatory assay IFU.
18	Enhanced Liver Fibrosis (ELF) test results	The interpretation result for the multi-component Enhanced Liver Fibrosis (ELF) test is not printed on the Runtime report. The interpretation result is displayed properly on the system screen.

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19	Archiving and deletion may fail	The Archive / Delete maintenance task might not complete under certain circumstances and the following event message is displayed:“Archiving and deletion is canceled because a partially transferred Archive database could not be deleted”. This issue occurs only when there are duplicate records present in the database and calibration results are enabled for the Archive / Delete maintenance task.
20	Processing repeats with multiple reagent lots	The system will not successfully process a repeat request for a test if the original lot of the reagent lot used to process the initial test is not available on the system. The “No Primary / No Lot Match” flag displays in the Test Results / Overview screen even though there is a reagent pack for the same test available from a different lot.

Actions to be Taken by the Customer

If you are utilizing one of the workflows described in Table 2 and your system has not yet been upgraded to V1.1, please perform the following actions:

1. **Using the Replicates Option with the Final Result Rule (FRR**): Do not define replicates as greater than 1 for the assays defined. If multiple replicates are required for these assays, in order to receive individual values for every test replicate, orders must be created for each test individually.

   This issue is corrected in Software V1.1

2. **Delta Check units**: If results are flagged due to a delta check failure, verify that the units of the two results are the same. If the units of the historical result and the new result do not match, the delta check will need to be manually calculated.

   This issue is corrected in Software V1.1.

3. **Units on the Calibration Data Details Report:** Refer to Calibration Data Details Report on the Calibration results overview -> Replicate Data workstation screen to verify the actual unit for the assay.

   This issue is corrected in Software V1.1

4. **Using the Copy Configuration Utility:** The Copy Configuration Utility should not be used to transfer system configurations between two instruments or to restore the configurations of an instrument. This tool is used primarily during system installation by Siemens personnel. Any discrepancies would already have been corrected during the system verification process. If the tool was used by non-Siemens

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personnel in your laboratory, please contact your Siemens Customer Service Engineer to schedule time to check and correct any parameters if needed.

This issue is corrected in Software V1.1. When using V1.1, the system must be in the mechanics Off State in order to use this feature (this is incorrect in the online help for this feature). The online help will be updated with the correct information in a future update.

5. **Printer Driver Resets:** If the workstation does not automatically resume printing following printer errors, after resolving the errors, restart the printer and the workstation using the System State button.

   This issue is corrected in Software V1.1.

6. **Calibrating TSTO:** To Calibrate TSTO, verify that the Assign Cal option is selected in the TDef main screen.

   Note: The Assign Cal function must be deselected once there is a valid calibration.

   This issue is corrected in Software V1.1.

7. **Laboratory Automation (LAS) offline due to Vacuum error:** Always check that the LAS system is online after resolving errors that cause the system to stop processing samples.

   After resolving a low vacuum pressure error, press the Start button at the Centaur XPT to send an updated system status to the LAS.

   This issue is corrected in Software V1.1.

8. **Monitoring the Laboratory Automation (LAS) communication:** The LAS related communication messages can be viewed in the Diagnostics / Lab Automation tab which displays LAS communication messages for as long as the window remains open. Other events that can be used to determine system status are found in the Events / Operator Event Log.

   This issue is corrected in Software V1.1

9. **Priming Needed error reported to Laboratory Automation (LAS):** If a sample has not been processed and displays a “System Error” message in the event log, there will be a corresponding “Priming needed” message displayed on the LAS side user interface, re-introduce the sample via the LAS to re-process it.

   This issue is corrected in Software V1.1

10. **Sample Status reported to Laboratory Automation (LAS):** If sample aspiration errors occur, tubes will be indexed automatically out of the sampling position. If other errors are generated due to the delay in the release of a tube from the sampling position, re-introduce any un-processed samples via the LAS.

    This issue is corrected in Software V1.1

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11. **Non-Siemens Laboratory Automation (LAS) – General Status message**: If connected to a Siemens LAS system, no action is required as the General Status Message is not used in the Siemens LAS interface.

    When connected to a Non-Siemens LAS system, if the General Status Message is in use, initiate an LAS connection only when the Centaur XPT is in Ready state.

    This issue is corrected in Software V1.1.

12. **Non-Siemens Laboratory Automation (LAS) – Immediate index**: This setting is not used when connecting to a Siemens LAS system. When connected to a Siemens automation system, the LAS system setting "Immediate Index When No Order" must be set to disabled. Verify that this setting is disabled.

    For Non-Siemens LAS connections, if a sample has not been processed due to a sample aspiration error, verify the quality of the sample and repeat the sample by front-loading it at the Centaur XPT or via the LAS. The operator should review the Centaur XPT Test Results / Overview screen for the status of any samples and test orders where the status is in question at the LAS.

    This issue is corrected in Software V1.1.

If you are utilizing one of the workflows described in Table 3, please perform the following actions (regardless of the software version installed on your system):

13. **Using dilution for automated repeats:** To run a repeat for a test that is out of the concentration range, manually order the test with the required dilution factor.

14. **Printing of results for Replicates**: Refer to the information displayed on the Test Results Overview -> Replicate Data workstation screen to verify the correct chronologic order of the results for tests that are run with replicates.

15. **Workstation services may restart:** In order to avoid Workstation Service restarts, avoid doing the following:

    - Do not close the Maintenance screen during the DCP.

      Remove the Warning window for the auto-scheduled maintenance task. Use the *Set Warning* button located in the bottom right corner of the Maintenance Task window and deselect the "*Confirm Prior to an Automatically Started Activity*" toggle.

    If the workstation is not displaying the user interface, perform the following steps to reboot:

    - Do not power down the entire instrument
    - Press Ctrl – Alt – Del
    - Select the red power button on the bottom right of the screen

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- Select Restart. The UIW will reboot.
- Log back in the instrument as usual

16. **Rinse System Maintenance task:** The Rinse System maintenance task should not be used. Either the Daily Cleaning Procedure (DCP) or another available Prime function should be used depending on the need.
    If the maintenance procedure was started and the system is left in the *Cleaning* state, follow the steps below:
    - Turn off the UIW workstation by pressing Ctrl-Alt-Del to obtain the Windows screen
    - Select the red Off button in the bottom right corner of the screen
    - Once the workstation is off, power the system down using the breaker switch at the back of the instrument.
    - Wait for 2 minutes
    - Power the instrument back up normally
    - Once Mechanics are turned on, the instrument will be in ready, however, the Rinse System maintenance will be in a fail status.
17. **On Board Stability (OBS) for HBsII:** The reagent Onboard Stability (OBS) is controlled by the system and therefore cannot be changed. If the Confirmatory assay is being used, the OBS for the HBSII ancillary reagent will be 42 days.
18. **Enhanced Liver Fibrosis (ELF) test results**: The interpretation for ELF can be obtained from the Results Summary screen on the workstation. Please use the 'print screen' function on this screen if a printout is needed.
19. **Archiving and deletion may fail:** Perform the following steps to prevent failure of the Archive / Delete maintenance task:
    - In the Maintenance task window, select the Database Archive / Delete task.
    - Click on the Edit / View button on the right side.
    - Select Default value from the dropdown list.
    - Edit the value for Historical Calibration Orders to Do Not Delete / Archive
    - Select Save.
20. **Processing repeats with multiple reagent lots:** When possible, move the initial results for a test to historical before processing a sample repeat in order to avoid a No Primary / No Lot flag.

    Perform the following steps if a sample repeat is not being processed:

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- Verify that there is reagent available for that test.
- Edit the Test order to assign the current lot of reagent available on the system to the order.

In addition, please perform the following:

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

Your Siemens Customer Service Engineer will contact you to schedule time for installation of the V1.1 software when it is available.

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.

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FIELD CORRECTION EFFECTIVENESS CHECK

Multiple Software Issues (V1.0.1, V1.0.2, V1.0.3)

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CSW-15-04.A.OUS dated November 2015 regarding Multiple Software Issues (V1.0.1, V1.0.2, V1.0.3). 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 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 (###) ###-####. If you have any questions, contact your local Siemens technical support representative.

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