

ADVIA Centaur® XPT

Information Regarding Additional Software Issues

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 following issues with the ADVIA Centaur® XPT system software V1.0.1 (Bundle 1.0.912 SMN 10819704) and V1.0.2 (Bundle 1.0.1086 SMN 11219806).

1. The “Reset Ranges” button in the Ranges window of a TDef currently does not properly reset predefined Overdilution points. This impacts the assay ThCG which has a predefined Overdilution point. If the “Reset Ranges” button is pressed for ThCG, the assay will lose its predefined Overdilution point and diluted results which are below the overdilution point will not be flagged as overdiluted.
2. If the system is set up to process samples with the settings for Rack ID, Positions mode and Rack Order mode activated at the same time, the system will not process test orders, if there are no Sample Identifiers (SID's) defined for the tubes. In addition, when processing samples with these settings and a second rack is received for processing within 15-30 seconds of the ejection of the 1st rack, the system may incorrectly use the orders of the 1st rack when processing the 2nd rack. This will cause transposition of patient results.
3. The Maintenance operation to automatically move completed test data to Historical does not move SIDs associated with multiple assays to the historical database. For example, if SID “XYZ” had been run for tests AFP and TSH, that SID would not be moved to the historical database by the “Move to Historical” maintenance activity.
4. The Visual Status light currently does not light up for certain scenarios. The Visual Status light will not light up for unacknowledged warnings or errors associated with the following tabs: Samples, Reagents, Calibrations, and Supplies.

5. The system may incorrectly use a primary reagent pack with a lower priority when a primary reagent pack with a higher priority is available. This may also result in the instrument using an uncalibrated primary pack if the assay has the “Assign Cal” parameter enabled within the TDef. Since the reagent pack was un-calibrated, the system will not generate results and will only report a Relative Light Unit (RLU) value.
6. In the QC definition screen, the system has a field for “+/- Range”. The system considers this parameter to be the 2 Standard Deviation (SD) range value. The QC definition fields are all handled by the system under the assumption that the values being entered are for a +/- 2SD range. If users are unaware of this, they could enter in values associated with either a wider or smaller range and the instrument would be unaware. This can cause QC flagging to be incorrect.
7. When the system is configured to a date/time format other than English (United States), the date/time information for Calibration events is not displayed in the Quality Control windows.

The Actions to Be Taken section indicates the two issues (issue 2 and issue 6) that are corrected in software version 1.0.3 (Bundle 1.0.1108 SMN 11220781), which is now available for installation on your system. For issues corrected in software version 1.0.3, the actions do not need to be performed if your system has been upgraded to software version 1.0.3. The remaining issues will be corrected in future software versions.

Risk to Health

When running ThCG samples, with an initial dilution of 1 to 200, without processing neat specimens, it is potentially possible to miss a positive ThCG value where the neat value is less than 1000. A lookback of 48 hours is recommended for negative ThCG samples if neat values were not initially run for ThCG and large dilutions were employed.

There is the extremely unlikely potential to transpose patient results when running in rack order mode without positive sample identification. A lookback of 48 hours for any instruments running in this mode is recommended.

Actions to be Taken by the Customer

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

1. Avoid pressing the “Reset Ranges” button for the ThCG assay. If you need to use the “Reset Ranges” button for ThCG, perform the following steps:
 - Select Reset Ranges.
 - Navigate to the Definition tab of ThCG on this screen.
 - Select Disable and then select Enable.
 - Click Save. After saving the TDef, the predefined overdilution point will be refreshed and will be active.

2. Avoid configuring the system to be in both Rack ID and Position mode and Rack Order mode at the same time. When using these settings, define the SID for all samples presented to the instrument. Furthermore, it is strongly recommended to use SID's for all patient samples.

This issue is corrected in ADVIA Centaur XPT software version 1.0.3.

3. Manually move SIDs associated with multiple assays to the historical database. This can be done by navigating to the Results tab and selecting the relevant SIDs. Once the relevant SIDs have been selected, the Move to Historical button on the right side of the screen can be selected.
4. Do not rely solely on the visual status indicator light for assessing system status. Periodically check the status screen on the instrument. Warnings or errors will flash in yellow or red and must be checked. If connected to a Lab Automation System (LAS), the system status should be requested periodically through the LAS.
5. When placing new reagent packs on the instrument, place new packs to the left of older reagent packs of the same assay. In order to avoid having the instrument perform tests without a valid calibration, the Test Definition (Tdef) for tests should be configured to disable the Assign Cal parameter by deselecting the 'Assign Cal' checkbox in the Test Definition / Calibration tab. In addition, avoid having uncalibrated and calibrated lots onboard at the same time and order the calibration for a new lot of reagent at the time the pack is placed onboard.

If tests were run from an uncalibrated reagent pack:

- Calibrate the reagent lot.
- When a valid calibration is available, it can be assigned to the previously run tests and the system will calculate a value which will be displayed with the assigned cal flag.

6. When creating QC definitions, enter the values associated with a +/- 2 Standard Deviation (SD) range in the "+/- ranges" field.

This issue is corrected in ADVIA Centaur XPT software version 1.0.3.

7. The date/time for Calibration Events can be checked by navigating to the Calibration tab. The Calibration tab will correctly show this information.

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 V1.0.3 software.

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

Information Regarding Additional Software Issues

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

Information Regarding Multiple Software Issues

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CSW-15-03.A.OUS dated July 2015 regarding Information Regarding Additional 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.

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.