SIEMENS

Urgent Field Safety Notice

CSW16-04.A.OUS

May 2016

ADVIA® Centaur XPT

Issues related to Results Processing

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) and V1.1 (Bundle 1.1.243 SMN 11221979). These issues may affect the results generated by the system.

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

Risk to Health

For Table 2 (Issue #1)

- There is potential for discrepant QC and patient results. Stop running the system until it is serviced if the conditions occur. The probability of this failure occurring is extremely unlikely.

For Table 2 (Issue #2)

- If the Daily Cleaning Procedure (DCP) fails to complete there is potential for discrepant QC and patient results. The probability of this failure occurring is unlikely but possible if bulk fluids are not filled prior to starting the DCP.

For all remaining issues:

- There is potential for delayed results noticeable to the user as either absence of results or an error posted for the sample. No erroneous results will be reported.

Siemens is not recommending a look back.

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

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Table 2. Description of Observed Issues

Issue Number	Observed Issue	Description of observed behaviour
1	Sample Tip Error	If a horizontal move error occurs while the sample probe is picking up the 119th tip from a tip tray (2nd to last tip in the tray), the instrument will recover from this error and use the remaining two tips in the tray. However, after performing a tray exchange, the next aspiration of a sample (third aspiration after this sequence of errors) can occur without a sample tip being picked up by the probe. This can potentially lead to improper sample dispense and can potentially lead to contamination of the probe causing discrepant results to be generated on a future sample.
2	Daily Maintenance	If the Daily Maintenance fails due to a bulk consumable or bulk waste problem and a fluid prime is performed, the instrument can go to Ready state and allow processing of samples even though the daily maintenance procedure failed.
3	Result Reporting for High/Low Linearity samples.	Results are not reported if all of the following conditions are present at the same time: • Only one end of the linearity range is setup on the system (either low or high, but not both). • The linearity limit is within the concentration limit • The sample result is between the linearity limit and the concentration limit (set by the Test Definition) • There is no automatic dilution set for samples higher than the linearity range.

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Issue Number	Observed Issue	Description of observed behaviour
4	Auto-repeat Conditions	• When a result gets a Signal 3 error it is not automatically repeated. • Results that should be held for review due to 'signal 3' flags or 'no calculation' flags will not be held for repeat. A result of 'ERROR' is sent to the LIS for results with these flags. • Tests will not auto-repeat due to “dilution point” or “linearity” ranges if the result had any of the following errors: o Consumable Error (e.g. No primary reagent available) o Sample Integrity Error o Signal related error o System related error o Dilution permission error o Reagent usage error
5	Barcode Misreads in Rack ID mode	When running in Rack order mode, the system will not aspirate samples if no SID is defined in the order and a barcode mis-read occurs.
6	Low Probe Wash	If the system does not have Probe Wash 2 (PW2) available on board during a run with tests requiring this probe wash, the system will not run this test as expected. However once PW2 is replenished, the system will run the test, but will report the result as Error with the following flags "Low probe Wash, No Calculation, Omitted Rep".

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Issue Number	Observed Issue	Description of observed behaviour
7	LAS Communication	• Error code details of 0x47, 0x48 and 0x2B for sampling error, are sent to the LAS under certain error conditions by the instrument. However, the LAS might not be able to process them as they are not defined in the Interface Specifications Guide. • When running with an automation system and an auto-dilution reflex test is required, the "resend tube request" is not sent to the LAS to bring the tube back for processing.
8	System Status Unknown	The system may display an “Unknown status” under certain conditions, if the cuvette bin runs out of cuvettes or an internal error related to cuvette handling occurs while processing samples.

Actions to be Taken by the Customer

Please perform the following actions:

1. Sample Tips Issue: Stop running samples and call Siemens service if the following scenario occurs while processing samples:

   - The tip tray loader is jammed while ejecting a sample tip tray and the tip tray which is ejected is a full tip tray.

     AND

   - The following error codes are displayed in the Event log in this exact order.

     i. 01 100 01 08 - Motor home is not known for the sample probe horizontal move with the details: Move to Tip Position = 119
     ii. 01 600 03 06 - Sample probe tip detection failure.
     iii. 01 600 02 02 – Sample inprocess queue cycle failure
     iv. 01 600 02 06 - Tip tray exchange failure because of a subassembly error

   o All the error messages will be displayed within a two minute time frame.
   o Stop running samples until Siemens has verified proper operation of the sample probe.

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2. Daily Maintenance:
    - Prior to starting the Daily Maintenance (DCP), ensure that the bulk consumables have been filled and all bulk waste has been emptied.
    - If DCP fails, address any fluid needs on the system and run the appropriate bulk fluid prime if needed.
    - Repeat the DCP again after the appropriate prime has completed.
    - After the DCP has been performed, check the Maintenance log (Maintenance –> Log tab) to ensure that DCP passed before running samples.
    - Otherwise, perform further troubleshooting and run DCP again until it has passed

3. Result Reporting for High/Low Linearity samples: On the configuration screen- Setup / Test Definitions / Ranges / Linearity tab, either define none or both the low and high linearity limits to ensure results are reported.

4. Auto-repeat Conditions:
    - Manually re-run results with 'signal 3' flags or 'no calculation' flags.
    - Sample results above dilution point or outside linearity range: Ensure that all reagents required for the tests being ordered are on board the system. Manually rerun tests that have integrity errors if a repeat is required.

5. RackID mode: Eject the rack with samples that have not resulted. Check the barcodes and replace if needed. Re-introduce the rack for processing.

6. Low Probe Wash: Make sure PW2 is present and in sufficient quantity before starting to process samples requiring this probe wash.

7. LAS Communication:

    - Inform the LAS vendor of the meaning of the following error codes:
        - 0x47 (System Cancel)
        - 0x48 (temperature out of range)
        - 0x2B (Cancel sampling). It means that the sample had errors during aspiration and could not be processed. Check the sample.

    - Manually move tubes from the automation system to the instrument if auto-dilution tests are required.

8. System Status Unknown: Ensure that the cuvette bulk bin is full before starting sample processing to ensure that all samples will be processed successfully. If "Unknown Status" is displayed, restart the system and refill the cuvette bin before re-starting of sample processing.

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In addition, please perform the following:

- Complete and return the Field Correction Effectiveness Check attached to this letter within 14 days.
- Please review this letter with your Medical Director.

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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 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.

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FIELD CORRECTION EFFECTIVENESS CHECK

Issues related to Results Processing

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CSW-16-04.A.OUS dated May 2016 regarding Issues related to Results Processing. Please read each question and indicate the appropriate answer. Please return this completed form to Siemens Healthcare Diagnostics within 14 days of receipt.

Ref: CSW 16-04 [C/3525]

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:	Post Code:
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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