SIEMENS

ADVIA® Chemistry XPT Systems

Multiple Issues Identified in Software Version 1.0.3

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

Table 1. Affected ADVIA Chemistry Products

Product	Siemens Material Number (SMN)
Software Version 1.0.3	11127538

Reason for Correction

Siemens Healthcare Diagnostics has identified the following issues with the ADVIA® Chemistry XPT systems (SMN: 10723034) with Software version 1.0.3 (SMN 11127538) that may affect the day to day behavior and/or workflow of the system.

Multiple Issues Identified in Software Version 1.0.3

Table 2. Description of Observed Issues

Issue Number	Observed Issue	Description of observed behavior
1	Auto Start-Up Failing	Intermittently, the auto-startup function fails requiring manual intervention to perform the start-up wash sequence.
2	Calibration Interval Resets when a Reagent Blank (RBL) is run	When an RBL is run the calibration interval resets as though a full calibration were performed. It should be noted that the On Board Stability (OBS) is unaffected. Assays that use an RBL only (Enzymes) are not affected.
3	Control Definition screen assumes that the range is defined is 2 SD (Standard Deviation)	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.
4	Laboratory Information System (LIS) communication / Laboratory Automation(LAS) issue	When a sample is rescanned and re-queried from the LIS before the initial reaction processing is complete, that sample will become stuck in a communication loop and all the tests associated with that sample will read as "inprocess" indefinitely. This occurs during front loading or when samples are routed from an Automation track. On the ADVIA Automation system, when a sample is retrieved from the Buffer Tray for a change order for a test on the ADVIA Chemistry XPT, other ADVIA Chemistry XPT tests may become unrouted and cause the sample tube to be returned to the system multiple times unnecessarily. If the tube is returned to the Chemistry XPT multiple times by the LAS then the sample may become depleted.

Multiple Issues Identified in Software Version 1.0.3

5	Printer Driver Resets	The printer stops printing if multiple printouts are requested in quick succession.
6	ISE Calibration Ranges are too conservative for Urine Sodium (Na)	The ISE calibration for Urine Sodium (Na) may fail unnecessarily due to the ranges being set conservatively during development.
7	Archiving and deletion may fail	The automatic, or manually started, archiving and deletion maintenance activity may fail preventing data from being permanently removed from the workstation. This may limit the amount of tests that can be run.
8	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.

All the issues above except (Issue #8) are corrected in software version 1.1 (SMN 11127561 which is now available for installation on your system. The actions defined in the 'Actions to be taken by the Customer' section do not need to be performed if your system has been upgraded to software version 1.1. The remaining issue will be corrected in future software version.

Risk to Health

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. Calibration and control issues are detectable through normal laboratory monitoring practices. Siemens recommends discussing the content of this letter with your laboratory director.

Actions to be taken by the Customer

If you are utilizing one of the workflows and/or performing a behavior described in Table 2, please perform the following actions:

1. **Auto Start Failing:** Manually perform the Startup Wash, run controls and any calibrations that are due.

2. **Calibration interval resets when an RBL is run:** Calibration should be run according to the recommendations in the Instructions for Use (IFU) for each assay. Keep a record of required calibrations and ensure that all assays are calibrated before use.

Multiple Issues Identified in Software Version 1.0.3

3. **Control definition screen assumes that the range is defined as 2 SD values:** When creating QC definitions, enter the values associated with a +/- 2 Standard Deviation (SD) range in the "+/- ranges" field.

4. **Laboratory Information System (LIS) communication / Laboratory Automation (LAS) issue**: Be aware of errors in the event log and take action as needed. Manual intervention and rerunning of the sample may be necessary. Wait to rescan samples until all pending tests have resulted. If using Chemistry XPT connected to ADVIA Automation, remove the Buffer Tray on all Sample Managers. The Partial Process Tray will perform excess sample tube management.

5. **Printer Driver Resets:** Reboot the printer and the workstation in the event of a failure to print.

6. **ISE calibration ranges are too conservative for Sodium (Na) Urine:** Perform an ISE wash from the "Maintenance > ISE Operations > Wash Electrode" screen before calibrating. If the calibration still fails, perform the "Wash Electrode" procedure and then perform the "Line Wash" procedure.

7. **Archiving and deletion may fail:** contact your local Siemens support center to optimize the database if the Archive/Delete process is failing.

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

- Do not run only an RBL calibrator on a method that requires more than one calibrator when running auto-calibration during pack switch on a new or previously uncalibrated lot of reagent.

- Ensure an LIS log file is displayed on the "Events > LIS Logs > Log Files dialog box" prior to selecting the date filter box .

- Do not select and accept a full page of samples (250) that are in the Inprocess status on the "Test Results > Filter Today's Samples > Select SID checkbox" screen while the system is processing samples. Reduce the number of records selected to less than a full page.

- Do not import the Maintenance log on the "Maintenance > Log > Select the Filter button" screen when importing a copied configuration in languages other than English. This may cause a blank row to appear in the log. When a blank row is present and the log is filtered the workstation will restart.

- Do not add a contamination set, probe or cuvette, to the parent of a test that has an alias on the "Setup > TDEF > Chemistry > Carryover Set button" screen. Delete the alias, update the parent and recreate the alias.

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

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Page 4 of 6

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Tarrytown, NY 10591
www.siemens.com/diagnostics

Urgent Field Safety Notice CHSW-15-05.A.OUS
– October 2015

Multiple Issues Identified in Software Version 1.0.3

In addition, please perform the following:

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

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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Page 5 of 6

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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CHSW-15-05.A.OUS dated October, 2015 regarding "Multiple Issues Identified in Software Version 1.0.3". 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 (xxx) xxx-xxxx. If you have any questions, contact your local Siemens technical support representative.

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Page 6 of 6

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