



## Customer Notification

CHSW-16-01.A. OUS

April 2016

### ADVIA® Chemistry XPT Systems

#### Multiple Issues Identified in Software Version 1.0.3 and Version 1.1

---

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

**Table 1. Affected ADVIA Chemistry Products**

Product	Siemens Material Number (SMN)
ADVIA Chemistry XPT System	10723034

#### 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) and software version 1.1 (SMN 11127561) that may affect the day-to-day behavior and/or workflow of the system.

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

#### Risk to Health

The risk to health due to these issues is negligible.

**Table 2. Description of Observed Issues**

Issue Number	Observed Issue	Description of observed behavior
1	All levels of QC run when only 1 is selected in Start/Restart window	When the system is attempting to run a single level of QC on a method, multiple levels of QC will autorun regardless of whether or not they are selected
2	QC selection error	Changing the display name of an assay deselects that method in its associated QC panel, therefore QC for the renamed assay will not run as part of the panel.
3	Workstation services may restart	<p>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.</p> <p>a. Workstation services may restart if a user defined filter is created in the Test Results Overview screen that includes the 31<sup>st</sup> day of the month, but is run in a month that does not have 31 days.</p> <p>b. Workstation services may also restart when all items are removed from the Watchlist.</p>
4	Assay Utilization is not updating for ISE tests	The Chemistry XPT software does not update assay utilization counters for ISE tests when patient samples and QC samples are run in version v1.1.

### **Actions to be taken by the Customer**

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

1. **All levels of QC run when only 1 is selected in start/restart:** if a test is defined with multiple controls and the instrument is configured to auto-calibrate when switching packs, but only one level of control is selected from the Start/Restart window, all levels of controls defined for that assay will be ordered by the instrument. Users should ensure all controls for the assay selected are onboard the system.

## Multiple Issues Identified in Software Version 1.0.3 and Version 1.1

2. **QC selection error:** Change the method display name back to default or manually select the method when running the QC panel.
3. **Workstation services may restart:** Two scenarios have been identified that can cause workstation services to restart;
  - a. Users can avoid this issue by selecting "Today's Samples", instead of selecting "Today" in the Operator-defined filter.
  - b. The Watchlist is a new feature that was introduced with the ADVIA Chemistry XPT, to enable tracking of specific samples. Samples are added to the Watchlist from the Results Tab. Deleting all samples or controls from the Watchlist may cause the Workstation services to restart. Items in the Watchlist can be deleted individually.

**NOTE:** If either scenario described above occurs the user can log back in to the operational software and all tests in progress will resume as expected.

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

4. **Assay Utilization not updating for ISE tests:** The Assay Utilization counter is working for all colorimetric methods. Continue to monitor ISE performance through running calibrations and controls as per your laboratories standard operating procedures.

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 is a trademark of Siemens Healthcare Diagnostics.