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**Urgent Field Safety Notice:**

**ADVIA Chemistry XPT - Mix Sensing**

Dear Sirs,

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

**Table 1. ADVIA Chemistry System and Software**

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

**Reason for Correction**

The purpose of this communication is to inform you of an issue with the products indicated in Table 1 above and provide instructions on actions that your laboratory must take.

- Siemens Healthcare Diagnostics Inc. has confirmed that the system behavior in all commercially available software versions (V1.4 SMN 11314625 and V1.4 China SMN 11316885) for the ADVIA Chemistry XPT system may not be aligned with customer expectations for the current default mixer failure detection setting of “2: Warning+STOP” (option 2 in System Parameters) for the Reagent 1 and Reagent 2 mixer assemblies.
- Customers who have chosen to use the mix verification setting of 0: Ignore, 1: Warning or 3: Warning+WAIT are not impacted by this issue.

Table 2 below provides a comparison of the expected behavior and the observed behavior.

**Table 2. Expected and Observed Software Behavior During a Mix Failure**

Case	Mixer Assembly	Expected Behavior	Observed Behavior
1	Reagent 1 Mixer Or Reagent 2 Mixer	A failure of the rotation motor generates error messages in the alarm log, flags all impacted test results and stops further sampling.	A failure of the rotation motor generates a single mix failure message in the alarm log, flags only the initial test result of the 1 <sup>st</sup> sample where the failure occurred and produces test results for subsequent tests without a test result flag, until the instrument stops processing samples. The instrument will complete the in-process tests in approximately 12 minutes and then stop.

## Risk to Health

If this issue occurs, the potential exists for an erroneously elevated or depressed patient result to be reported without alert on the test result. Mitigations would include review of the alarm log and flag on the first sample result, correlation to the clinical information such as clinical presentation, other laboratory and diagnostic results and patient history. Siemens is not recommending a review of previously generated results due to the remote probability of a clinically significant impact on patient results and the remote probability of this issue.

## Actions to be Taken by the Customer

Until the next version of instrument software is available Siemens recommends changing the software behavior from the current default of "2: Warning+STOP" to "1: Warning".

The behavior for the Warning setting is to display the test result as "ERROR" with a Safety(S) flag and generate a yellow warning in the Operator's event log for each test result encountering a mix error. The instrument will continue to process samples. The flagged test must be repeated to obtain a valid result.

Use the following steps to change the system configuration settings for Reagent Mixer 1 and Reagent Mixer 2

1. Login to the ADVIA Chemistry XPT instrument software using the Lab Manager account.
  - 1.1. Bring the system to READY STATE.
  - 1.2. NOTE: allow samples that are in process to complete. Do not process any new samples.
2. Navigate to Setup -> System Configuration -> System Parameters screen.
3. Under Section dropdown, select "Controller 2" option.
4. Select line **199 - MIX1 Verification Alarm** row and click on the value field.
  - 4.1. Change the value to 1.
5. Select line **201 - MIX2 Verification Alarm** row and click on the value field.
  - 5.1. Change the value to 1.
6. Click on Save button.
  - 6.1. A message will be displayed stating – "Change will take effect after initialize".
  - 6.2. Click OK.
7. Verify values of MIX1 Verification Alarm and MIX2 Verification Alarm are set to 1.
8. Navigate to System Operations and click on Initialize.
9. Wait for Initialize operation to complete.
  - 9.1. System will return to READY state after initialize operation completes.
10. Run the laboratory's quality control material to verify instrument performance.

Letter of May 28, 2021  
to



Please review this letter with your Medical Director.

Complete and return the Field Correction Effectiveness Check Form 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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Sincerely yours,

— Siemens Healthcare Diagnostics GmbH

**Signature:**

Handwritten signature of Roland Ertl in blue ink.

*Electronically signed by: Roland Ertl  
Reason: I am approving this document  
Date: May 25, 2021 11:54 GMT+2*

**Email:** roland.re.ertl@siemens-healthineers.com

i.A. Roland Ertl, MA

**Signature:**

Handwritten signature of Brigitte Gassner in blue ink.

*Electronically signed by: Brigitte Gassner  
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