SIEMENS

Urgent Field Safety Notice

11220241, Rev. A

March 2015

ADVIA Centaur® XPT

System Workflow Optimization

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

Table 1. ADVIA Centaur XPT Affected Products

Product	Siemens Material Number (SMN)
ADVIA Centaur XPT System	10711433

Reason for Correction

Siemens Healthcare Diagnostics has identified the following workflow issues with the ADVIA Centaur® XPT system software V1.0.1 (SMN 10819704) and V1.0.2 (Bundle 1.0.1086.0 SMN 11219806):

1. The system does not display any indication of a missing required Probe Wash pack on the results screen. Furthermore the event log message for a missing required Probe Wash pack will only refer to the first sample that encounters this issue and not the subsequent ones.
2. The data shown on the “Utilities->Assay Utilization” screen is incorrect for the totals of calibrators run on the instrument.
3. The data shown on the “Utilities->Assay Utilization”screen and the printout report for the Assay Utilization screen may not match. The printed version of the report will show multiple rows of data for the same assay if the Print Name of the assay is defined to be a different name than the assay/display name. In addition, the sum of all tests at the bottom of the report will be incorrect when this occurs.

The following issues are related only to instruments connected to a Lab Automation System (LAS).

1. Under certain circumstances, if the instrument receives new work orders while transitioning from the In-Process state to the Ready state, the sample will be routed to the instrument but will not be processed. The instrument will stop processing all further orders from the LAS.
2. Under certain circumstances, the system may stop processing samples from the LAS and hold a tube at the LAS sampling position. For this problem to occur, samples must

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be processed simultaneously from the front loading queue and the LAS position and a sample aspiration error must occur.

All five issues outlined above will be corrected in a future version of software.

Risk to Health

The operator will be aware that a sample may not have been processed as the samples will not be processed and display a 'pending' status. Siemens recommends discussing the content of this letter with your laboratory director.

Actions to be Taken by the Customer

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

1. Probe Wash: When running victim and aggressor assays on an instrument, ensure that all possibly required probe wash materials are on-board. See table below for victim assays which may require probe wash material.
   Contact your TAS for more information about victim and aggressor assays.

Table 2. Probe Wash Materials

Assay	Probe Wash Material	SMN
GENT	PW2	Included in ReadyPack
TNIUltra, TSTO	PW4	10321290
HBcT, HBe, CHIV	PW3	10334314
aHAVT, FolateBA, HAVT, HBcT, HBsII, PRGE, SYPH, TSTO	APW1	10309060
VB12	T3/T4/VB12 Ancillary Reagent	10309954 10319315

2. Assay Utilization: A typical Calibration Event consists of 3 replicates of the low level calibrator and 3 replicates of the high level calibrator however, when a calibration is performed for an assay, the Assay Utilization Report only records 3 tests. When assessing assay utilization make sure that this is factored into the assessment.

3. Assay Utilization Print Report: To avoid multiple rows of data for the same test, ensure that the Print Name for all assay test definitions (Tdefs) match the assay/display name for each TDef. In addition, when printing the assay utilization report, check the count of each assay in order to avoid duplicate reporting of the same test.

For issues related to instruments connected to an LAS system:

1. When it is observed that samples are not being processed correctly from the LAS position, perform the Reset Queue command from the LAS.

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2. Whenever possible, avoid processing samples from the In-Process Queue and the LAS at the same time. When it is observed that samples are not being processed correctly from the LAS position, perform the Reset Queue command from the LAS.

In addition, 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.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

Centaur XPT System Workflow Optimization

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 11220241, Rev. A dated March 2015 regarding Centaur XPT System Workflow Optimization. Please read the 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.

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.

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