



Urgent Field Safety Notice

LASW21-02.A.AP2.OUS

September 2021

Aptio Automation

Interface Module to the ADVIA® Centaur XP/XPT

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

Table 1. Aptio Automation Interface Module to the ADVIA Centaur XP/XPT

Module	Part Numbers
Aptio Automation Interface Module to the ADVIA Centaur XP/XPT Instrument	FLX-021-00, APT-021-00

Reason for Correction

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

Siemens Healthcare Diagnostics Inc. is issuing an Urgent Field Safety Notice on behalf of Inpeco SA, the legal manufacturer.

The manufacturer (Inpeco) has informed Siemens of the following:

- Urgent Field Safety Notice FSN – AP2 – 202109 – 03 v.1. Refer to Attachment 1 LASW21-02.A.AP2.OUS.

Inpeco has confirmed that the Aptio Automation Firmware (FW) for the ADVIA Centaur XP/XPT Interface Module may lead, in specific and rare cases, to an incorrect association of test result(s) to sample ID. The problem was detected through the investigation of a customer complaint.

The issue occurs as a consequence of a sample tube that is to be processed by the ADVIA Centaur XP/XPT is not diverted into the Interface Module due to a mechanical issue or due to an obstruction. Upon this scenario, one of the following sample tube(s) that is diverted into the Interface Module in order to be processed by the ADVIA Centaur XP/XPT may be released from the Interface Module and flagged with the error code 3160 “Sampling Not Successful” and with test results obtained from another sample tube. According to the default Automation System configuration, the sample tube is flagged with error code 3160 and is sent into an Input/Output Module (IOM) Priority Output rack.

This Software (SW) level of protection supports the detection of the issue described in this letter, nevertheless you can contact your Service Assistance to perform a look back to identify still detectable previous occurrences, if any happened, to verify they were properly managed. Note: this issue does not occur upon every divert error, but according to the specific sequence of events.

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Risk to Health

The potential risk associated with this issue is related to an incorrect patient result that may lead to wrong patient treatment.

The scenario occurs only in the case of a divert malfunctioning, that is mitigated by the execution of routine Service Maintenance.

In addition, the evaluation of clinical coherence with previous results obtained for the same analytical test and with other test results obtained for the same patient and the evaluation of the overall medical case may contribute to detect the possible incorrect result and mitigate the effective impact on patient.

Actions to be Taken by the Customer

To avoid the occurrence of this issue, take the following precautions:

A daily visual check on the divert of the Aptio Automation Interface Module to the ADVIA Centaur XP/XPT is required to verify that:

- there are no obstructions that prevent the correct activation and movement of the divert, refer to Image 1.a.
- the divert looks to be intact, refer to Image 2.a.
- the position of the diverter is aligned to the profiles when it is diverting a tube, refer to Image 3.a; tubes that need to be routed by the Analyzer are diverted fluidly, without any missing or partial block of the carrier.

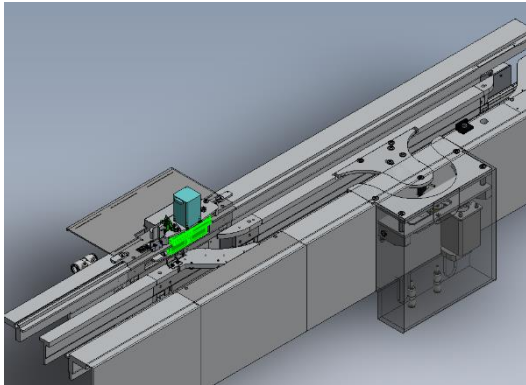


Image 1.a: ADVIA Centaur XP/XPT Interface Module
(Part number FLX-021-00, APT-021-00)

Aptio Automation Interface Module to the ADVIA® Centaur XP/XPT

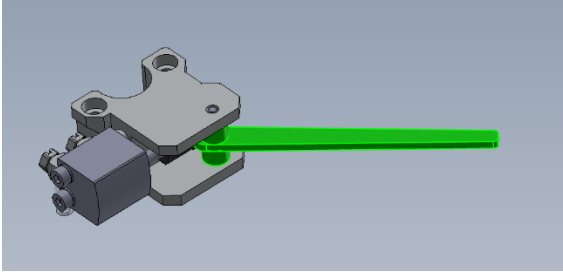


Image 2.a: Divert appearance

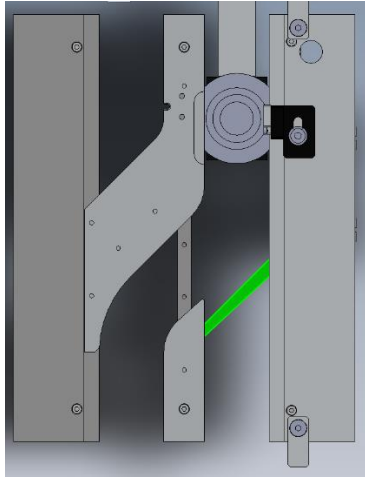


Image 3.a: Divert alignment

If the visual check does not pass, contact your local technical support for assistance.

In case of error code 3160 has occurred take the following precautions to manage the impacted sample tube and avoid risk for patient:

- For all tubes flagged with the error code 3160 that, according to the default Automation System configuration, are unloaded in the IOM Priority Output racks wait at least 60 minutes from the moment the sample tube has been unloaded in order to allow the ADVIA Centaur XP/XPT Analyzer to complete the analysis and to release the tests result to the Data Management System (DMS).
- Then refer to Table 2 Condition and Action.

Table 2. Condition and Action

Condition	Action
If the tube is flagged with an error has no test result(s) performed	Manually or automatically reload the sample tube on an ADVIA Centaur XP/XPT to perform the test(s).

Aptio Automation Interface Module to the ADVIA® Centaur XP/XPT

by an ADVIA Centaur XP/XPT	
If the tube is flagged with an error and has test result(s) performed by ADVIA Centaur XP/XPT	<ol style="list-style-type: none"> a. Perform the necessary steps on the Middleware and/or Host LIS to prevent the automatic or manual release of erroneous test results for the sample ID associated with error 3160 code received from ADVIA Centaur XP/XPT processing. b. Order a rerun from the Middleware/Host LIS for the tests to be performed on ADVIA Centaur XP/XPT for the sample ID associated with error code 3160. <p>Note: Contact your Middleware/Host LIS vendor if you need further information on how to perform the steps a. and b. above</p> <ol style="list-style-type: none"> c. Put the Interface Module Off-line. d. Manually load the sample tube on ADVIA Centaur XP/XPT to do the test/tests. e. Contact your local technical support for assistance.

In addition:

To assist the user on identifying tubes with error code 3160, it is recommended to configure a dedicated sort lane at IOM to collect sample tubes with the specific errors instead of unloading them in the generic Priority Output rack:

- a. To configure the sorting test, log-in as Supervisor and access Automation Test screen on the IUI (path: Setup/Configurator/Automation Tests)
- b. Select Sorting Tests tab.
- c. Click on the Add button.
- d. Fill in the fields with the following values:
 - i. ASTM Code/Test Code = #3160.
 - ii. Description = (Sorting for Unexpected Duplicate Tube detected on Track).
 - iii. Sorting Lanes = (enter IOM lanes that are available to be used for sample tube sorting).
 - iv. Tube Processing = P.
- e. Click on the Save button.

Refer to paragraph "Sorting tests" in the Aptio Automation Operations Manual for additional Sorting Lane configuration options.

- Please review this letter with your Medical Director.
- Perform the instructions provided in Additional Information.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Aptio Automation Interface Module to the ADVIA® Centaur XP/XPT

- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 10 working 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 at 1800-888-872.

Additional Information

A new version of Firmware for the Aptio Automation Interface Module to the ADVIA Centaur XP/XPT will correct the issue. Your service provider will contact you to schedule the firmware upgrade.

FIELD CORRECTION EFFECTIVENESS CHECK

Aptio Automation Interface Module to the ADVIA® Centaur XP/XPT

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) LASW21-02.A.AP2.OUS dated September 2021 regarding the Aptio Automation Interface Module to the ADVIA® Centaur XP/XPT. Please read the statement below and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Sdn Bhd as per the instructions provided at the bottom of this page.

1. I have read and understood the UFSN instructions provided in this letter. Yes No

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Please send a scanned copy of the completed form via email to fscareportingunit.my@siemens-healthineers.com

If you have any questions, contact your local Siemens Healthineers technical support representative.