

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	Siemens Material Number (SMN)
Aptio Automation Interface Module to the ADVIA Centaur XP/XPT Instrument	10703038

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. 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 when 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. In 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 a specific sequence of rare and consecutive events.

The Actions to be Taken by the Customer section below describes the actions to be taken to prevent this issue from occurring.

Risk to Health

When this issue occurs, the potential exists for an incorrect association of test results which could impact clinical interpretations and clinical decisions. Mitigations include cross-checking samples that have been flagged and sent to the input/output rack, retesting of samples, correlation of patient results with clinical signs and symptoms or historical results, and/or even serial testing of patient samples.

Siemens Healthineers is not recommending a review of previously generated reports due to the remote probability of the event.

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.

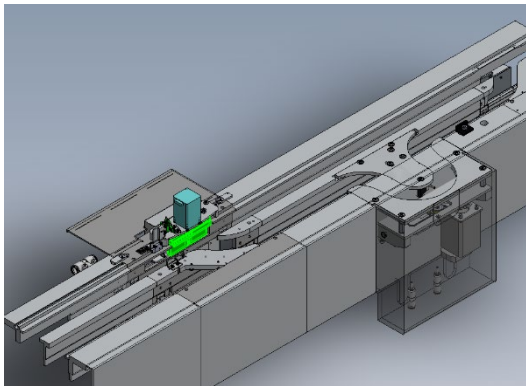


Image 1.a: ADVIA Centaur XP/XPT Interface Module (SMN 10703038)

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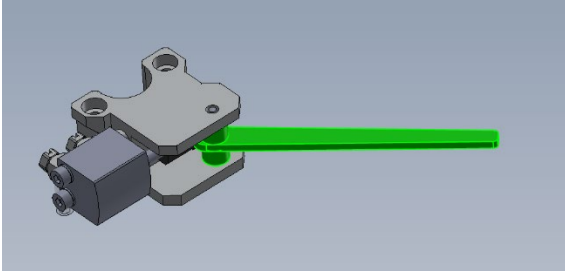


Image 2.a: Divert appearance

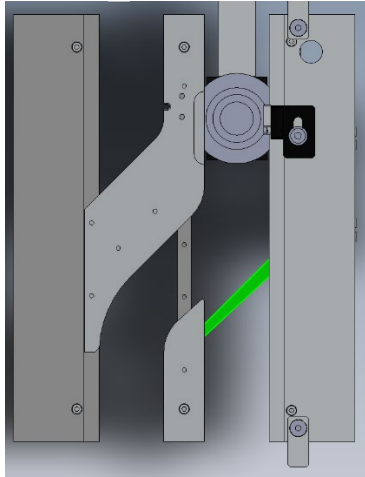


Image 3.a: Divert alignment

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

In the event that an 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 by an ADVIA Centaur XP/XPT	Manually or automatically reload the sample tube on an ADVIA Centaur XP/XPT to perform the test(s).

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<p>If the tube is flagged with an error and has test result(s) performed by ADVIA Centaur XP/XPT</p>	<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 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.
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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.
- 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.

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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.

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) LASW21-01.A.OUS dated October 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 Diagnostics 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 XXXX@XXXX.

Or to fax this completed form to the Customer Care Center at XXXXXXXX.

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