
Urgent Field Safety Notice

Commercial name of the affected product: Aptio® Automation

FSCA-identifier: FSCA – AP2 - 202008 - 03

FSN-identifier: FSN – AP2 – 202008 – 03 v.1

Date: August 7th, 2020

At the kind attention of:
To whom it may concern

According to our records your System may be affected by the issue described below.

Details on affected devices:

The following Automation System module may be impacted by the issue:

Module	Part Number
Sysmex XN-9000/XN-9100 Interface Module (dual robot)	FLX-290-10; FLX-290-20

Description of the problem:

The firmware of the Sysmex XN-9000/XN-9100 Interface Module (IM) has the potential to mis-associate sample IDs leading to incorrect results or delayed results.

The issue occurs when:

- there are at least 2 carriers at the Barcode Reader gate at the exit of the XN-9000/XN-9100 Interface Module. *Example: Tube a on carrier A followed by Tube b on carrier B.*
- *carrier A* is released from the Barcode Reader Gate before the Barcode Reader scans the *Tube a* sample ID.
- The Barcode Reader is able to read the sample ID of *Tube b* instead of *Tube a*.

In this scenario:

- The firmware of the Sysmex XN-9000/XN-9100 Interface Module associates the sample ID of *Tube b* to *carrier A* without any error message;
- The Automation System loses the traceability of *Tube a* and manages *Tube a* according to the test orders not performed yet on *Tube b*;
- *Carrier B* is released as an empty carrier: when *Tube b* on *carrier B* is detected by downstream tube presence sensors, it is automatically routed to the Input/Output Module to be reidentified, flagged as Duplicate Sample ID (error code SC00E) and sent to the Priority Output rack of the Input/Output Module to be manually managed by the Operators.

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Risk to Health

The potential risks associated with this issue	Potential impact to results
If <i>Tube a</i> has pending tests downstream of XN 9000/9100 IM, these tests are not performed since the traceability of <i>Tube a</i> is lost	Delay of results
If <i>Tube b</i> has pending tests downstream of XN 9000/9100 IM on modules or interface modules without barcode readers for positive sample identification, these tests are performed on <i>Tube a</i> actually present on <i>carrier A</i> and the test results are associated to the patient of <i>Tube b</i>	Incorrect results
If <i>Tube b</i> downstream of XN 9000/9100 IM: <ul style="list-style-type: none"> - is routed to a Storage Module and then retrieved for additional tests, there is a delay in the execution of these tests since the retrieved tube is <i>Tube a</i> instead of <i>Tube b</i> (mismatch detected by the Barcode Reader at the Storage Module exit) - is routed to an Output Module for additional tests off-track, there is a delay in the execution of these tests since the retrieved tube is <i>Tube a</i> instead of <i>Tube b</i> (mismatch should be detected by Operators who manually manage the Tube or by the Third Party Analyzer where the Tube is loaded) 	Delay of results

Actions to be taken by the user:

For all tubes with error SC00E (Duplicate Sample ID) in the IOM Priority Output racks, identify if the tube has been processed by XN9000/XN9100 Interface Module:

If	Then
Tube associated with error SC00E was NOT processed by XN9000/XN9100 Interface Module	No further action is required
Tube associated with error SC00E was processed by XN9000/XN9100 Interface Module	<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 SC00E received after Sysmex XN9000/XN9100 processing. b. Perform a delivery process for the sample ID associated with error SC00E to remove it from the Automation System. This action should return the mis-identified sample <i>Tube a</i> unless the sample tube was sorted and removed from the Automation system. <p>In case the tube was sorted out to be processed off-track search for the tube in the specific rack.</p>

	<p>c. Check work list for any remaining tests on sample <i>Tube a</i>.</p> <p>d. Order a rerun from the Middleware/Host LIS for the missing tests ordered for the sample ID associated with error SC00E.</p> <p>e. Reload sample tubes on the Automation System to perform any remaining tests.</p> <p>Note: Contact your Middleware/Host LIS vendor if you need further information on how to perform the actions a. and d. above.</p>
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To assist the user on identifying tubes with error SC00E, it is recommended to configure a dedicated sort lane to collect sample tubes with error SC00E 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 = #SC00E
 - 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” of Automation System Operations Manual for additional Sorting Lanes configuration options.

Contact your local technical support provider if you need assistance in implementing these actions.

Your service provider will contact you to schedule the firmware upgrade.

Until the service visit please maintain awareness on this notice and apply the actions recommended above.

Please transfer this notice to whom it might concern.

Please complete and return the “Urgent Field Safety Notice Receipt Confirmation and Implementation Check” form attached to this letter within **15 days** directly to the email address specified in the email communication.

Contact reference person:

For any clarification you may need, do not hesitate to contact:

Eva Balzarotti - Regulatory Affairs Manager

E-mail: Regulatory.Affairs@inpeco.com

Phone: (+41) 91 9118 224



We apologize for the inconvenience this situation may cause. Thank you for your cooperation. The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.

Kind Regards,

Eva Balzarotti - Regulatory Affairs Manager



URGENT FIELD SAFETY NOTICE RECEIPT CONFIRMATION and IMPLEMENTATION CHECK
FSCA- AP2- 202008 - 03

This response form is to confirm receipt of the enclosed Urgent Field Safety Notice dated 08/07/2020 regarding FSCA - AP2 - 202008 - 03.

Please read each question and indicate the appropriate answer.

1. I have read and understood the instructions provided in this letter.
 YES NO

2. I have applied all the actions required in this letter.
 YES NO

Please fill in the form and send a scan copy to the email address specified in the email communication

Name of person filling in the form: _____

Title: _____

Institution: _____

Automation Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Signature _____