

## Urgent Field Safety Notice

**Commercial name of the affected product:** FlexLab

**FSCA-identifier:** FSCA – FLX - 202303 – 01

**FSN-identifier:** FSN – FLX – 202303 – 01 v.2

Date: March 10<sup>th</sup>, 2023

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 modules may be impacted by the issue:

| Module                                  | Hardware versions   | Firmware versions                                    |
|---|---|--|
| Input Output Module (IOM)               | All versions, complete list below:<br>FLX-201-00, FLX-201-10, FLX-253-10, FLX-253-11,<br>FLX-253-12                                     | GWC board: prior to 2-3-0<br>DDT board: all versions |
| Storage and Retrieval Module (SRM)      | All versions, complete list below:<br>FLX-207-00, FLX-207-01, FLX-207-02, FLX-230-00,<br>FLX-230-01, FLX-207-10, FLX-207-11, FLX-230-10 | All versions   |
| PVT Interface Module (PVT)              | All versions, complete list below:<br>72147000.A  | All versions   |
| Vesmatic Cube 80 Interface Module (VMC) | All versions, complete list below:<br>FLX-067-00  | All versions   |
| Alinity h Interface Module (HSQ)        | All versions, complete list below:<br>FLX-274-20  | All versions   |

### Description of the problem:

The firmware of the modules listed above has the potential to mis-associate sample IDs leading to incorrect results or delayed results.

The event may happen only if all the following conditions occurs in few milliseconds' timeframe:

- The module is releasing a sample tube (Tube A) just placed into the carrier
- Another sample tube (Tube B) is erroneously not diverted into the module buffer lane

Only in this specific scenario, the Tube A may be released by the module as Tube B due to a miscommunication between the module firmware and the Automation software without any error message.

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The Automation System loses the traceability of Tube A. It manages both Tube A (incorrectly identified as Tube B) and the real Tube B according to the test orders not performed yet on Tube B.

### Risk to Health

| The potential risks associated with this issue   | Potential impact to results |
|--|-----------------------------|
| If Tube A has still pending tests, these tests are not performed since the traceability of Tube A is lost  | Delay of results            |
| If Tube B has pending tests on modules or interface modules without barcode readers for positive sample identification, these tests might be performed on Tube A (wrongly identified as Tube B) or on the real Tube B  | Incorrect results           |
| If Tube A (wrongly identified as Tube B) is processed by Aliquoter Module, the secondary sample tubes are labeled as Tube B secondary tubes. If these tubes are further processed, the sample ID mismatch cannot be detected by any downstream module or interface module. | Incorrect results           |

Inpeco has evidence about only one occurrence of this issue happened on the field. The probability of occurrence of delayed/incorrect results has been evaluated as rare considering the specific sequence of events which may lead to the issue.

### Actions to be taken by the user:

The scenario occurs in the case of a divert malfunction.

To avoid the occurrence of the described issue Inpeco recommends to visually check every day the gates at the buffer lane entry of the impacted modules (refer to Image 1.a and Image 1.b) to verify that:

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

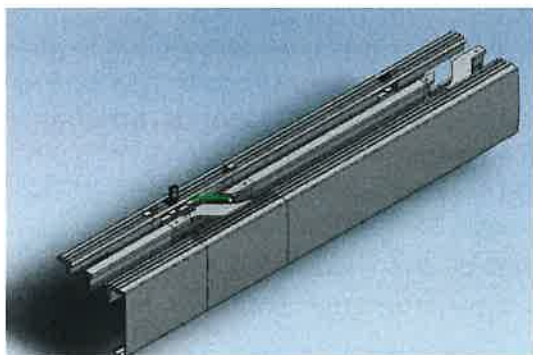


Image 1.a: Divert gate position

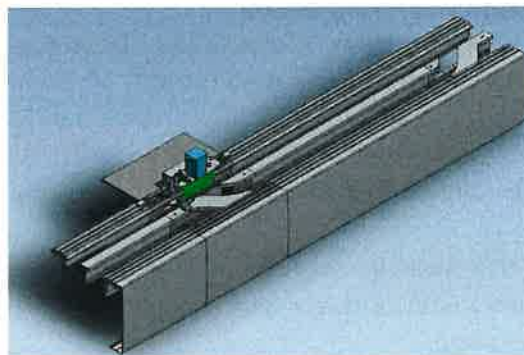
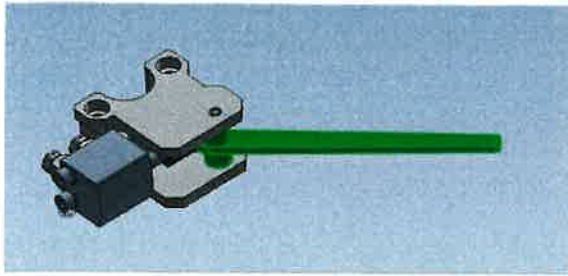


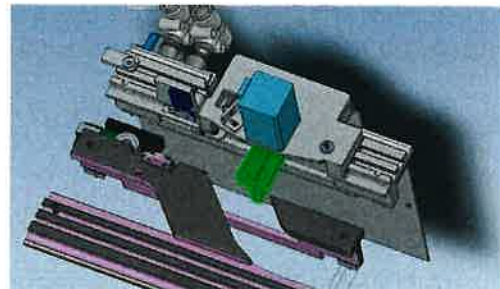
Image 1.b: No Stop Divert position

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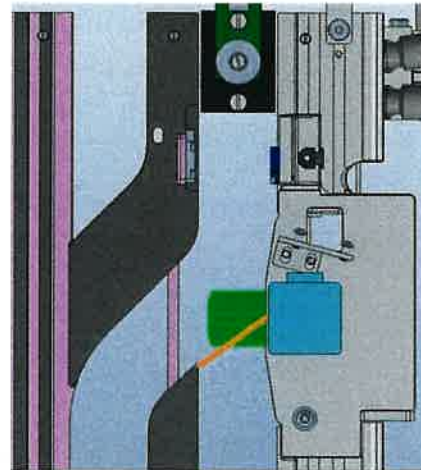
*Image 2.a: Divert appearance*



*Image 2.b: No Stop Divert appearance*



*Image 3.a: Divert alignment*



*Image 3.b: No Stop Divert alignment (in orange)*

If the visual check is not passed, contact your local technical support for assistance before using the Automation System impacted modules to process samples.

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 "Field Safety Notice Receipt Confirmation and Implementation Check" form attached to this letter within **30 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](mailto:regulatory.affairs@inpeco.com)

Phone: (+41) 91 9118 224

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MOD-FSN.03



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

Kind Regards,

A handwritten signature in blue ink that reads "Eva Balzarotti".

Eva Balzarotti - Regulatory Affairs Manager

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## FIELD SAFETY NOTICE RECEIPT CONFIRMATION and IMPLEMENTATION CHECK

FSCA- FLX - 202303 - 01

This response form is to confirm receipt of the enclosed Field Safety Notice dated March 10<sup>th</sup>, 2023 regarding FSCA- FLX - 202303 - 01.

Please read each question and indicate the appropriate answer.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter.  
 YES       NO
2. I have applied all the actions required in 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 \_\_\_\_\_

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