Urgent Field Safety Notice

Commercial name of the affected product: Flexlab
FSCA-identifier: FSCA - FLX - 202303 - 07
FSN-identifier: FSN - FLX - 202303 - 07 v.2

Date: March 10th, 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: FLX-207-00, FLX-207-70, FLX-253-70, FLX-253-77, FLX-253-72	GWC board: prior to 2-3-0 DDT board: all versions
Storage and Retrieval Module (SRM)	All versions, complete list below: FLX-207-00, FLX-207-07, FLX-207-02, FLX-230-00, FLX-230-07, FLX-207-70, FLX-207-77, FLX-230-70	All versions
PVT Interface Module {PVT)	All versions, complete list below: 72747000.A	All versions
Vesmatic Cube 80 Interface Module {VMC)	All versions, complete list below: FLX-067-00	All versions
Alinity h Interface Module {HSQ)	All versions, complete list below: 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.

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 ofthis 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 la and Image l.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 anymissing or partial black of the carrier.

Image 7.a: Divert gate position

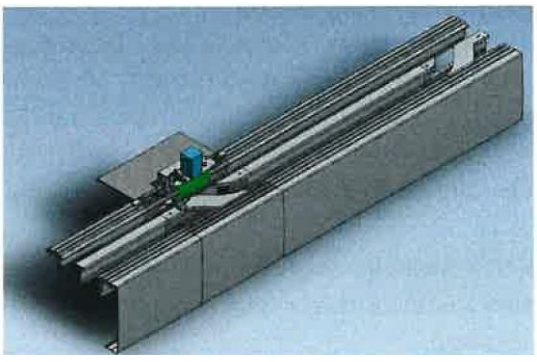

Image 7.b: No Stop Divert position

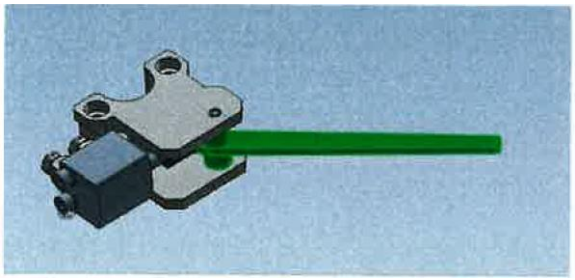

Image 2.a: Divert appearance

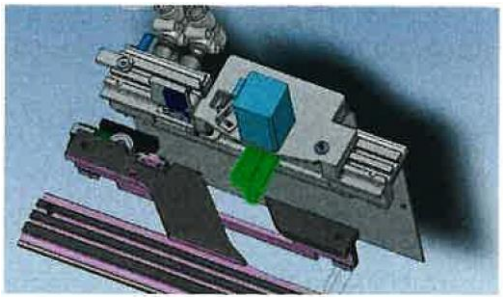

Image 2.b: No Stop Divert appearance

Image 3.a: Divert alignment

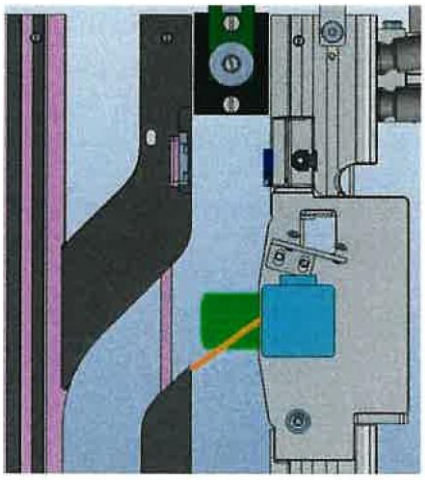

Image 3.b: No Stop Divert alignment (in orange)

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
Phone: (+47) 97 9778 224

We apologize forthe inconvenience this situation maycause. Thankyou foryour cooperation. The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

Kind Regards,

Inpeco SA
Via Torraccia 26, 6883 Novazzano - Switzerland
Partita IVA: CHE-774538 298
Tel +4197 9778200

FIELD SAFETY NOTICE RECEIPT CONFIRMATION and IMPLEMENTATION CHECK

FSCA- FLX - 202303 - Ol

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

Please read each question and indicate the appropriate answer.

1. ı have read and understood the Urgent Field Safety Notice instructions provided in this letter.
   [] YES [] **NO**

2. ı 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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