Urgent Field Safety Notice

Commercial name of the affected product: FlexLab
FSCA-identifier: FSCA- FLX – 202311 – 01
FSN-identifier: FSN – FLX – 202311 – 01 v.1

Date: November 3rd, 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 module may be impacted by the issue:

Module	Hardware versions	Firmware versions*
Roche Cobas 8000 and Cobas PRO Interface Module (CO8 IM)	FLX-247-00 F3.6-029-00 F3.6-047-00	COBASa_2.2.0 COBASa_2.3.0

(*) The Cobas 8000 IM firmware version can be displayed on FlexLab IUI following the path: Automation/ System/ Software/Firmware.

Description of the problem:
The firmware of the Interface Module with Roche Cobas 8000 and Cobas PRO (CO8 IM) may lead to a delayed sample tube processing.
Specifically, it may happen that the CO8 IM physically returns the sample tube to the Automation system main Track and later, the firmware of the CO8 IM erroneously sends a message to the Automation system software leading the Automation System software to update the sample location back to the CO8 IM while the sample tube is physically located elsewhere.

Risk to Health:
The issue leads to sample traceability loss and potential delay of tests results if there are still test orders to be performed on the sample tube (such as a rerun or add-on test or tests previously received but not yet performed). If there are no additional test to be performed, the loss of traceability does not lead to any injury for the patient.
The specific risk depends on the physical location of the sample tube at the time the delayed (and thus incorrect) message is sent.

Inpeco has evidence about only three occurrences of this issue happened on the field that lead to a delayed sample processing.

Below are reported the three different scenarios with different potential risk associated to the issue.

Scenario	The potential risks associated with this issue
If the sample tube has been already put in the Inpeco Storage and Retrieval Module (SRM), the Automation SW does not retrieve the sample tube from the SRM in the event subsequent tests are added to the sample tube. The sample tube is not loaded from the SRM back to the Automation System.	Delay of results since the automatic retrieve of sample tube is not performed and the sample tube location displayed on IUI is incorrect.
If the sample tube has been already unloaded into an Output Module such as IOM and ROM by design the Operator is supposed to manually retrieve the sample tube in order to proceed with its process.	Delay of results since the location displayed on IUI is incorrect and the Operator may have difficulty to retrieve the specific sample tube.
If the tube is in other Modules/Interface Modules or on the Track it may be incorrectly flagged with SC00E "Duplicate Sample ID".	Delay of results since the sample tube is not a real duplicate Sample ID and need to be manually managed by Operator.

The probability of occurrence of delayed results has been evaluated as rare for all scenarios since the hazard situation, indeed, could occur only in case of the above-mentioned conditions happen for the three different scenarios and plus, the involved sample tubes have test orders still to be performed.

Advise on action to be taken by the user:
Please apply the following instructions to detect the sample tubes potentially impacted by the issue (Step 1) and to manage them according to the specific occurred scenario (Step 2).
If Step 1 leads to determine that the issue has not occurred, Step 2 is not to be performed.

Note: The test orders status displayed on the IUI is not overwritten neither changed in any way due to the issue: it would be possible to monitor the turn-around time of sample tubes processed by the CO8 IM in order to identify any overdue sample tube with tests still to be executed.

Step 1:
In order to detect the sample tubes potentially impacted by the issue apply steps described in option 1 or 2. Note that the two options are interchangeable, there is no preferred action.
Option 1 can be applied while the CO8 IM is On-line, so without interrupting the sample tubes processing. Option 2 requires to temporarily interrupt sample tubes processing.
Apply option 1 or option 2 at least twice a day.

Option 1:
1. Access the IUI and click on "Routine – Search" to open the search panel.

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2. Click on "Clear Filter" to remove any filter.
3. Uncheck box "Include Disposed Samples".
4. Select "Received" option in the "Order Status" field.
5. Select "On-Track" option in "Status" field.
6. Select the "Node" corresponding to the CO8 IM you want to check.
7. Click "Snapshot" button. Listed sample tubes could be impacted by the issue.
8. Access the CO8 IM and check if the sample tubes identified through the above steps are actually present in the Interface Module or into the Analyzer. If necessary, access the Analyzer Software User Interface and double check which sample tube the Analyzer is processing.
9. If there are sample tubes not present in the Interface Module or into the Analyzer, the issue has occurred. The sample tubes not physically present in the Interface Module or into the Analyzer are impacted by the issue: the process of these sample tubes is delayed.
   On the contrary, if all the sample tubes reported in the list are physically present in the Interface Module or into the Analyzer, the issue has not occurred: if this is the case, no further action is required. Skip to step 10 to double check other CO8 Interface Modules.
10. Repeat steps above for all other CO8 Interface Modules.

Option 2:
1. Access the IUI and set the CO8 IM to Going Offline. This command leads the Module to complete processing samples currently inside the Module and then change to Offline status. If the Module status does not change in Offline when all the sample tubes have been released from the Interface Module, the issue has occurred.
   On the contrary, if the Module status changes in Off-line when all the sample tubes have been released, the issue has not occurred: if this is the case, the Module can be set to On-line and no further action is required. Skip to step 9 to double check other CO8 Interface Modules.
2. Access the IUI and click on "Routine – Search" to open the search panel.
3. Click on "Clear Filter" to remove any filter.
4. Uncheck box "Include Disposed Samples".
5. Select "Received" option in the "Order Status" field.
6. Select "On-Track" option in "Status" field.
7. Select the "Node" corresponding to the CO8 IM you want to check.
8. Click "Snapshot" button. Listed sample tubes are impacted by the issue: the process of these sample tubes is delayed.
9. Repeat steps above for all other CO8 Interface Modules.

Step 2
Apply Step 2 only if the issue has occurred as determined from Step 1.
Step 2 provides instruction to manage the sample tubes impacted by the issue with orders in status "Received" (i.e., test orders still to be performed) in order to mitigate delay in samples processing.
1. Access the Automation Software User Interface (IUI).
2. Search the ID of the sample tubes.
3. On the sample panel, click on the Trace icon ( ) in order to display the trace pop-up window.

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4. Look for the Event code "S001" logged before the S001 message received for the CO8 IM: refer to the details reported in "Description" column. This is the tube physical location.
5. Manage the sample tube as suggested in the following steps:
    a. If the sample tube is physically located in the Storage and Retrieval Module (SRM): the sample tube cannot be manually retrieved by Lab personnel. Contact Service Assistance or manage the patient according to Good Lab Practice considering the sample tube as lost.
    b. If the sample tube is at Input/Output Module (IOM) or at Rack Output Module (ROM): access the Module and manually retrieve the sample tube. Access the IUI, Remove the sample tube from Automation Software and (if needed) reload the sample tube on the Automation System to complete the processing. As an alternative, manually load the sample tube directly on the Analyzers required to complete the process.
    c. If the sample tube is flagged with error SC00E "Duplicate Sample ID": wait until the sample tube has been unloaded into a Priority Output rack at IOM and repeat step b.
6. In order to allow the CO8 IM affected by the issue to change the status in Off-line upon the Going to Offline command, Remove from the Automation Software all the sample tubes impacted by the issue without any additional test orders, so not managed through the previous steps.

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.

Transmission of this Field Safety Notice:
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: (+41) 91 9118 224
Inpeco SA EU SRN (if applicable): CH-MF-000017833

We apologize for the inconvenience this situation may cause. Thank you for your cooperation. This notice is notified the appropriate Regulatory Agency.

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FIELD SAFETY NOTICE RECEIPT CONFIRMATION and IMPLEMENTATION CHECK

FSCA – FLX – 202311 - 01

This response form is to confirm receipt of the enclosed Field Safety Notice dated November 3rd, 2023 regarding FSCA – FLX – 202311 - 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
   If NO, explain the reason: _____

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: FlexLab Serial Number:

Street:

City: State:

Phone: Country:

Signature

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