Urgent Field Safety Notice

Commercial name of the affected product: FlexLab X
FSCA-identifier: FSCA - FXX - 202610 – 01
Document Version: 2

Date: October 13th, 2026

At the kind attention of:
To whom it may concern

The purpose of this letter is to advise you that Inpeco SA is voluntarily conducting a Field Safety Corrective Action to correct an issue identified with a specific power cable installed on FlexLab X.

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

Details on affected devices:
The following components installed within FlexLab X automation systems are subject to this Field Safety Corrective Action:

Component	Description
MEE0074	Power Cable End Plug at the Automation Track Head, at T Turn Module and L Turn Module
MEE0075	Power Cable End Socket at the Automation Track Head, at T Turn Module and L Turn Module
MEE0082	Power Cable Central Power Junction Box at the Automation Track and Track T Module

Description of the problem:
The electrical terminal connections of the above specified power cables, used to connect the main distribution cabinet to the bus bar and distribute electrical power within the FlexLab X automation system, may not have been properly torqued (refer to picture 1.b below). Note: the following pictures relate to the lower portion of the FlexLab X track modules, with and without the protection panels (refer to picture 1.a and picture 1.b respectively). Operators are not allowed to remove the panels unless specified in the FlexLab X operations manual for specific maintenance procedures.



1.a 1.b

Picture 1.a: Track portion with the protection panels in place.
Picture 1.b: Track portion without the protection panels in place. MEE0082 is the component highlighted with the red square, MEE0074 and MEE0075 are both inside the component highlighted with the yellow square.

The issue may affect the phase conductors, the neutral conductor, the protective earth conductor, or a combination of these conductors, potentially leading to delayed sample processing due to product malfunction or possible injury to personnel in the laboratory.

Risk to Health:

The identified issue could give rise to three hazardous scenarios. Each scenario has a different potential harm and is assessed as a separate risk.

1. Delayed reporting of diagnostic results due to the automation system malfunctioning.
2. Respiratory irritation to users or people in the vicinity of the automation system, due to smoke caused by overheating components.
3. Pain, tissue damage or arrhythmia (which may lead to death) due to stray electrical current.

Harm 1. This harm could occur if the automation system malfunctions. Third-party instruments that perform the analytical measurement are separately powered and are therefore not impacted. Users are alerted in case of anomalous system behaviour, and they can retrieve sample tubes from automation system and process them manually. Any delay in processing the sample may delay the reporting of results and, consequently, patient treatment. Appropriate clinical monitoring of the patient reduces risk of related harms. The risk severity is limited/transient, and the probability of consequent adverse events is remote, resulting in a low risk level.

Harm 2. This harm could occur if components overheat during operation due to voltage redistribution. Smoke generation can be expected to be limited in duration and extent, since the automation system is certified in accordance with the applicable safety standards, which include requirements intended to minimize the risk of fire and ignition under the specified conditions of use. Other warning signs (e.g. system malfunction, burning smell) would likely appear before smoke is generated, reducing the risk of harm to user. The risk severity is moderate/temporary, and the probability of consequent adverse events is improbable, resulting in a low risk level.

Harm 3. This harm requires a secondary failure, where another wire, cable or element is independently damaged and comes into contact with an accessible metallic part. If the user touches that part, the residual current device (RCD) would be expected to trip. If the RCD also failed (a tertiary failure), a hazardous current could flow through the user. This sequence of failures could result in an electrical shock. The risk severity is major/ serious, and the probability of consequent adverse events is improbable, resulting in a low risk level.

Advise on action to be taken by the user:

Users must not open, access, inspect, adjust, repair or perform any other activity involving the power cable and bus bar electrical distribution, including the power cable end plugs, power cable end sockets and power cable central power junction boxes. Such activities must exclusively be performed by qualified and authorized service personnel.
As a precautionary measure, users should avoid contact with the external housing of the bus bar: refer to Picture 1, specifically the white boxes highlighted in the yellow and red squares.
During normal operation, laboratory personnel should watch for any indication of an electrical abnormality, including:

- Unexpected shutdown or loss of power to modules or interface modules.
- Repeated tripping of circuit breakers or other electrical protection devices.
- Abnormal behavior of connected modules or analyzers, including any unexpected power interruptions should be treated as malfunctions and the system should be taken out of service.
- Unusual noise, smell, heat, smoke or visible signs of overheating in the area where the power cables and the bus bar electrical distribution are located within the automation system.

The User is advised to apply a notice on/around the FlexLab X product in order to be sure that all personnel who operate or service the automation system are aware about the issue and the action listed above.

These precautions do not correct the potentially loose terminal connection.
Your service provider will contact you to schedule the corrective intervention needed to inspect the affected components and, if required, replace them.

Transmission of this Field Safety Notice:

Until the service visit takes place, users are requested to follow the recommendations in this notice.

Please forward this notice to all personnel who operate or service the affected automation system. Inpeco recommends that all personnel are made aware of this notice and follow the instruction reported in the “Action to be taken by the user” paragraph.

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 in the accompanying email.

Contact reference person:
For additional information or clarification, contact:

- Inpeco Regulatory Affairs Department, e-mail: regulatory.affairs@inpeco.com
- Inpeco Service Team, e-mail: support.inpeco@inpeco.com

We apologize for the inconvenience this situation may cause. Thank you for your cooperation.

FIELD SAFETY NOTICE RECEIPT CONFIRMATION and IMPLEMENTATION CHECK

FSCA- FXX - 202610 – 01

This response form is to confirm receipt of the enclosed Field Safety Notice dated October 7th, 2026 regarding FSCA- FXX - 202610 – 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 _____