Automation in Healthcare

# Urgent Field Safety Notice

**Commercial name of the affected product:** Aptio® Automation
**FSCA-identifier:** FSCA- AP2 - 202003 - 03
**FSN-identifier:** FSN – AP2 – 202003 – 03 v.1

Date: 03/23/2020

At the kind attention of:
To whom it may concern

Inpeco is sending this letter regarding the following issues for the Aptio® Automation System.
According to our records your System may be affected by at least one of the issues described below.

| Issue 1 - Centrifuge Module loading algorithm | |
|---|---|
| **Details on affected devices** | The impacted modules are the Centrifuge Modules (Inpeco Part Number FLX-202) with one of the following firmware versions:<br>• CM_1-7-0.H86<br>• CM_1-7-1.H86<br>The Centrifuge Module firmware version can be displayed on Aptio® Automation IUI following the path: Automation/ System/ Software/Firmware. |
| **Description of the problem** | The Centrifuge Module tube loading algorithm included in the firmware versions mentioned above is not in compliance with the Hettich Centrifuge balancing instructions.<br><br>The Centrifuge is able to detect unbalanced loading. With the above Centrifuge Module firmware versions, the loading algorithm may lead to an unbalanced load with an imbalance degree lower than the one detectable by the Centrifuge. In the worst case scenario, such as repeated unbalanced loads, this may lead to the damage of the Centrifuge. |

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|---|---|
| **Risk to Health** | Risk of injury to operators in proximity of the Centrifuge in event of Centrifuge crash. |
| **Action to be taken by the user** | None. At present there is not a risk to the user as the impact to the hardware would be cumulative over time. Your service provider will contact you to schedule the firmware upgrade. |

| Issue 2 – Advia 2120LAS and ImmunoCAP 1000 Interface Modules offline command | |
|---|---|
| **Details on affected devices** | The impacted Interface Modules (IM) are the followings:<br><br>**Module** / **Part Number**<br>Advia2120LAS IM (also called Advia2120i LAS IM) / FLX-219-00<br>ImmunoCAP 1000 IM (also called Phadia 1000 IM) / FLX-226-01<br>Table 3.1 |
| **Description of the problem** | The identified problem is an erroneous association between the carrier and the sample tube caused by a communication error between the firmware of the Interface Modules (listed in Table 3.1) and the Automation software. This problem can occur only when one of these Interface Modules is put off-line after a carrier in their secondary lane is physically returned on the main track and then put back on-line when the carrier is used to transport another tube. |
| **Risk to Health** | The potential hazard associated to this event is the execution of the tests order on the wrong tube and, consequently, the delivery of erroneous results to the patient. |
| **Action to be taken by the user** | To avoid the occurrence of the described issue take one of the following precautions:<br>1) Visually check that the secondary lane of the Interface Modules listed in Table 3.1 is empty before sending the Off-line command; or<br>2) Select the "Going to Off-line" command for the modules listed in Table 3.1. This ensures that the Module completes processing samples already inside the Module, releases the tubes and then passes to Off-line status. |

| Issue 3 – Aliquoter Module primary tube dilution | |
|---|---|
| **Details on affected devices** | The impacted modules are the Aliquoter Modules (Inpeco Part Number FLX-212) with a firmware version prior to the followings:<br><br>• AQMb_3-3-0.H86<br>• AQMa_3-1-1-8.H86 and AQMb_3-1-1-8.H86<br><br>The Aliquoter Module firmware version can be displayed on Aptio® Automation IUI following the path: Automation/ System/ Software/Firmware |

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| **Description of the problem** | In the firmware versions prior to the ones listed above, in case a Clot Detection error (error code E0E0) is generated during the sample aspiration the current error recovery procedure dispenses 2/3 of sample volume back into the Primary Tube. Evidence from the field showed that in case of Clot Detection error, this management may lead to the dilution of the Primary Tube with the distilled water of the hydraulic circuit of the Aliquoter Module. |
| **Risk to Health** | The potential hazard associated with this event is the contamination of the Primary Tube with water from the hydraulic circuit of the Aliquoter Module. |
| **Action to be taken by the user** | To avoid the risk of contamination take the following precaution:<br>1) Discard the Primary Tube flagged with Clot Detection error or manage it according to your laboratory guidelines considering that it may be diluted.<br>2) Call Service Assistance in case the frequency of the Clot Detection Error increases (more than 5 consecutive Clot Detection Errors). |

Issues #1, #2 and #3 have been addressed by new software releases.
Inpeco Service or their representatives will contact you to arrange a visit to fix the problems present in your site. Until the service visit please maintain awareness on this notice.

Please transfer this notice to whom it might concern.

Please complete and return the Field Safety Notice Receipt Confirmation 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 undersign confirms that this notice has been notified the appropriate Regulatory Agency.

Kind Regards,

Eva Balzarotti

Eva Balzarotti - Regulatory Affairs Manager

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**URGENT FIELD SAFETY NOTICE RECEIPT CONFIRMATION and IMPLEMENTATION CHECK**
FSCA- AP2 - 202003 - 03

This response form is to confirm receipt of the enclosed Urgent Field Safety Notice dated 03/23/2020 regarding FSCA- AP2 - 202003 - 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 for the issues that impact my System.
   [ ] 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 _____