Automation in Healthcare

Urgent Field Safety Notice

Commercial name of the affected product: Accelerator a3600
FSCA-identifier: FSCA- ACP - 202003 - 02
FSN-identifier: FSN – ACP – 202003 – 02 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 Accelerator a3600 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: • CM_1-7-0.H86 • CM_1-7-1.H86 The Centrifuge Module firmware version can be displayed on Accelerator a3600 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. 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 - c8000/c16000 Interface Module Total Timeout expired Error Recovery	
Details on affected devices	The impacted Interface Module is the ARCHITECT cSystem (c8000/c16000) Interface Module (Inpeco Part Number FLX-208-00 and ACP-208-00).
Description of the problem	Total Timeout expired errors (code 7083) can be generated if a sample tube is at the sampling gate of the ARCHITECT cSystems Interface Module (IM) and one of the following scenarios occurs: • Sample carousel lid of ARCHITECT cSystems is left open for more than 20 minutes without putting the cSystem Interface Module offline • Running multiple tubes or QC in the sample carousel of an ARCHITECT cSystems for more than 20 minutes without putting the ARCHITECT cSystems IM Offline The current step-by-step error recovery of Total Timeout expired error displayed on Automation System IUI is not appropriate since it allows the release of the sample tubes present in the Secondary Lane of the ARCHITECT cSystem Interface Module, while the Analyzer may perfom additional aspirations foreseen for the sample tube present at the sampling position when the processing of sample tubes on the Automation System was interrupted. It is possible that the probe aspirates from other tubes in the IM queue while they are passing through the sampling position.
Risk to Health	The identified risks are cross contamination of the tubes wrongly sampled by the probe and incorrect results due to the association of test results obtained from other tubes in the IM queue to the tube flagged with 7083 error. Moreover the Analyzer probe may cause the fall of one of the passing-through sample tubes leading to the sample processing delay.
Action to be taken by the user	To avoid the occurrence of the described issue take the following precautions: 1) Before loading samples in the ARCHITECT cSystem carousel, change the ARCHITECT cSystem IM status to **Offline** or **Going to Offline** on the IUI of the Automation System (refer to *Changing the status of Automation Module and Interface Modules* procedure in Section 5 of the Automation System Operations Manual). 2) Verify that all sample tubes in the ARCHITECT cSystem IM have completed sampling and that the Interface Module is Offline.

	3) Load the sample tubes in the ARCHITECT cSystem carousel (refer to *Sample management* procedure in Section 5 of the ARCHITECT Operations Manual) and close the lid. 4) On the IUI of the Automation System, select the **Online** button for the ARCHITECT cSystem IM. The ARCHITECT c8000/c16000 Interface Module section of the Automation System Operations Manual has been reviewed accordingly (refer to attachment 1). Please save it with the Automtion System Operations Manual you currently have available for future references. In case a "Total Timeout Expired" error has occurred take the following precautions that were agreed with ARCHITECT cSystem Manufacturer: 1) Ensure that there are no test in "running" status in the cSystem Software User Interface. 2) Perform the "Total Timeout Expired" error Recovery procedure displayed on Automation System IUI: NOTE: step 1.4 "Refer to Analyzer Operations Manual to recover the error condition" includes all the following operations on ARCHITECT cSystem Software User Interface: A. Put the cSystem processing module in STOP status using F6-STOP button in the cSystem Software User Interface, refer to the System statuses, in Section 1 of the ARCHITECT cSystem Operations Manual. B. Perform As-needed maintenance procedure 6052 Wash Cuvettes, in the Service and maintenance in Section 9 of the ARCHITECT cSystem Operations Manual. C. Put the cSystem processing module in RUNNING status after cuvette wash complete. NOTE: Do not set the ARCHITECT cSystem Interface Module back online (step 1.5 of the error recovery) before all the operations of step 1.4 are completed 3) Reload sample tube flagged with 7083 error on an input module of the Automation System if needed.

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Issue 3 – ImmunoCAP 1000 Interface Module offline command	
Details on affected devices	The impacted Interface Module (IM) is the following: **Module** / **Part Number** ImmunoCAP 1000 IM (also called Phadia 1000 IM) / FLX-226-01 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 impacted Interface Module and the Automation software. This problem can occur only when this Interface Module 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: 1) Visually check that the secondary lane of the impacted Interface Module is empty before sending the Off-line command; or 2) Select the "Going to Off-line" command for the impacted Interface Module. This ensures that the Module completes processing samples already inside the Module, releases the tubes and then passes to Off-line status.

Issue 4 – 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: • AQMb_3-3-0.H86 • AQMa_3-1-1-8.H86 and AQMb_3-1-1-8.H86 The Aliquoter Module firmware version can be displayed on Accelerator a3600 IUI following the path: Automation/ System/ Software/Firmware
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: 1) Discard the Primary Tube flagged with Clot Detection error or manage it according to your laboratory guidelines considering that it may be diluted. 2) Call Service Assistance in case the frequency of the Clot Detection Error increases (more than 5 consecutive Clot Detection Errors).

Issue 5 - Defective Safety Sensors STR-1 type	
Details on affected devices	The following Automation System module can be impacted by the issue: **Module** / **Part Number**: HSQ Interface Module / FLX-274 Table 5.1
Description of the problem	In the impacted module, the safety switches of type STR-1 (Inpeco Part Number STM0027 and STM0028) are installed in order to interrupt the power supply of the moving parts, and as a consequence, to avoid their movement (e.g. robotic loading and unloading of sample tubes), when the sensors are activated. The sensors are activated when the module cover is removed. Inpeco became aware that some sensors of the type STR-1 with serial numbers of 2018 are affected by delayed activation. In 1% of the cases, the response delay can be up to a maximum delay of 2 seconds, instead of 40ms expected by design.
Risk to Health	In case the safety switch activates with delay, the laboratory operator and Service Personnel (FSE) can be exposed to moving parts that can lead to physical injury.
Action to be taken by the user	After module protection removal, wait at least 2 seconds before accessing the impacted module.

Issues #1, #2, #3 and #4 have been addressed by new software releases.
Issue #5 will be addressed with hardware component replacement.
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.

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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 - Regulatory Affairs Manager

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URGENT FIELD SAFETY NOTICE RECEIPT CONFIRMATION and IMPLEMENTATION CHECK
FSCA- ACP - 202003 - 02

This response form is to confirm receipt of the enclosed Urgent Field Safety Notice dated 03/23/2020 regarding FSCA- ACP - 202003 - 02.

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 _____