Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 61 **dated** 28/3/2023 **Regarding NCMDR Field Safety Corrective Action of Accelerator a3600 from (mfr: Inpeco S.A).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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Circular No. 61 **/ 2023**

06-09-1444 H

28-03-2023

Field Safety Corrective Action of Accelerator a3600 from Inpeco S.A.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19485
Product	Accelerator a3600.
Description	IVD.
Manufacturer	Inpeco S.A.
The affected products	Module: Input Output Module (IOM) Hardware versions: All versions, complete list below: ACP-201 00 Firmware versions: prior to 2-3-0 Module: Storage and Retrieval Module (SRM) Hardware versions: All versions, complete list below: ACP-207-00, ACP-207-01, ACP-230-00, ACP-230-01, FLX-207-01, FLX-207-02, FLX-230-01, FLX-230-02 Firmware versions: All versions Module: Alinity h Interface Module (HSQ) Hardware versions: All versions, complete list below: FLX-274-20 Firmware versions: All versions
Reason	The firmware of the modules listed above has the potential to mis-associate sample IDs leading to incorrect results or delayed results.
Action	1. Visually check every day the gates at the buffer lane entry of the impacted modules. (Refer to Actions to be taken by the user). 2. Your service provider will contact you to schedule the firmware upgrade. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

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ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Urgent Field Safety Notice

Commercial name of the affected product: Accelerator a3600
FSCA-identifier: FSCA – ACP – 202303 – 02
FSN-identifier: FSN – ACP – 202303 – 02 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: ACP-201-00	prior to 2-3-0
Storage and Retrieval Module (SRM)	All versions, complete list below: ACP-207-00, ACP-207-01, ACP-230-00, ACP-230-01 FLX-207-01, FLX-207-02, FLX-230-01, FLX-230-02	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 of this 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 1) 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;
- the position of the divert is aligned to the profiles when it is diverting a tube, refer to Image 3; tubes that need to be routed by the module are diverted fluidly, without any missing or partial block of the carrier.

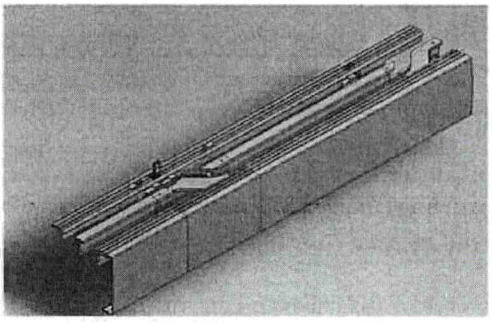

Image 1: Divert gate position

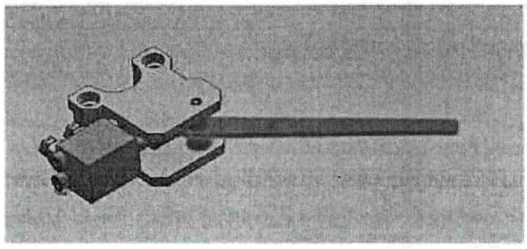

Image 2: Divert appearance

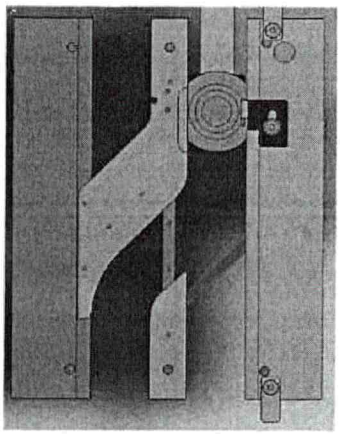

Image 3: Divert alignment

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: (+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