

Urgent Field Safety Notice

LAI18-05.AP2.A.OUS

September 2018

Aptio® Automation

Updated safety instructions for pacemakers

Our records indicate that your facility may have received the following product:

Table 1. Affected Products

| System | Siemens Material Number (SMN) |
|-------------------------|-------------------------------|
| Aptio Automation System | 11266636 |

Reason for Correction

Siemens Healthineers is issuing an Urgent Field Safety Notice on behalf of Inpeco, the legal manufacturer.

The manufacturer (Inpeco) has informed Siemens of Urgent Field Safety Notice (UFSN) # FSCA - AP2 - 201808 - 03 (attached), indicating that the current safety distance specified in the Operations Manual is being updated. The following is new information regarding the safety label which is included with the Inpeco UFSN:

- The risk of pacemaker malfunction due to magnetic interference applies to all personnel with a pacemaker who are in close proximity to the modules listed in the Inpeco UFSN.
- The minimum safety distance has been increased to 200 mm (7.87 inches) from the transport mechanisms located inside the safety covers. Any person with a pacemaker must not get closer than this distance from the modules axes (transport mechanisms).

As the distributor of the product, Siemens is informing our customers of the updated safety information from Inpeco. Please see the attached Urgent Field Safety Notice from Inpeco and take appropriate action.

Actions to be taken by the Customer

- Please review the attached OM Errata Corrigé and save it with the Operations Manual you currently have for future reference regarding the "safety distance" required for pacemakers.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter on page 3 within 7 days. Do not send this information to Inpeco.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Aptio is a trademark of Siemens Healthcare Diagnostics. All other trademarks and brands are the property of their respective owners.

FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice LAI18-05.AP2.A.OUS dated September 2018 Aptio Automation - Updated safety instructions for pacemakers. Please read each question and indicate the appropriate answer.

Fax this completed form to Siemens Healthineers at the fax number provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes No
2. I understand that the new safety distance for pacemakers is 200mm and have applied all the actions required in the letter from Inpeco. Yes No

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Please send a scanned copy of the completed form via email to xxx@yyy.com,

Or to fax this completed form to the Customer Care Center at XXXXXX.

If you have any questions, contact your local Siemens technical support representative.

Urgent Field Safety Notice

Commercial name of the affected product: Aptio Automation

FSCA-identifier: FSCA – AP2 – 201808 – 03

FSN-identifier: FSN – AP2 – 201808

Date: August, 2018

At the kind attention of:
To whom it may concern

Details on affected devices:

The following Automation System modules can be impacted by the issue:

| Module | Part Number | |
|---------------------------|---------------------|-------------------------------------------------|
| | Current module PN | Previous module PN (also impacted by the issue) |
| Input/Output Module | FLX-201 | 510; 509; F3.6-001 |
| Storage Retrieve Module | FLX-207 and FLX-230 | 617; 517; F3.6-007 and F3.6-030 |
| Rack Input Module | FLX-214 | 523; F3.6-014 |
| Rack Output Module | FLX-216 | F3.6-016 |
| BNII Interface Module | FLX-287 | n.a. |
| AU5800 Interface Module | FLX-275 | n.a. |
| Sapphire Interface Module | FLX-264 | n.a. |
| XN-9000 Interface Module | FLX-263 and FLX-290 | n.a. |

Table 1

According to our records in your facility at least one of these modules is present.

Description of the problem:

In the modules listed in Table 1, the transport mechanism that moves the robot along the axes generates a magnetic field which may interfere with pacemaker functionality at close distances.

The pacemaker safety label shown below is applied on the modules cover to warn who have a pacemaker about the risk in case they operate on these modules.



The information regarding the label included in the Operations Manual has been updated to specify that:

- the risk of a pacemaker malfunction applies to anyone with a pacemaker who may work on these modules;
- the minimum safety distance has been increased to 200 mm (7.87") from the transport mechanisms. Any person with a pacemaker must not get closer than this distance from the modules axes.

Refer to the attached OM Errata Corrige for the updated instructions.

Risk to Health:

Exposure to an electromagnetic field may interfere with pacemaker device functionality potentially leading to asynchronous pacing. Normal function typically resumes once the pacemaker is removed from the electromagnetic field. Symptomology related to electromagnetic interference may include palpitations, syncope, and/or difficulty breathing. Persons with pacemakers are generally aware of the potential adverse effects of magnetic fields and have been educated to avoid leaning on or near any potential source of electromagnetic interference.

Advise on action to be taken by the user:

1. Please be aware that personnel fitted with a pacemaker must not handle or work on these modules at distances lower than 200 mm.
2. Please review the attached OM Errata Corrige and save it with the Operations Manual you currently have available for future references regarding the "safety distance" required for pacemakers.

In addition:

- [Redacted]
- Please transfer this notice to whom it might concern.






We apologize for the inconvenience this situation may cause. Thank you for your cooperation. The undersign confirms that this notice has been/will be notified the appropriate Regulatory Agency.
Kind regards,



Georgia Amabile - Quality & Regulatory Manager

Errata Sheet

This document amends the Operations Manual.

| Icon | Description |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>This symbol indicates that the area access can cause risks to persons wearing a pace-maker.</p> <p>Any person with a pace-maker must keep a safety distance of at least 200 mm from the module axes.</p> |