

Urgent Field Safety Notice

LAI18-05.FLX.A.OUS

September 2018

FlexLab Automation

Some modules missing pacemaker warning labels

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

Table 1. Affected Products

System	Siemens Material Number (SMN)
FlexLab Automation System	10628151

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 – FLX – 201808 – 01 (attached), indicating that specific modules of the FlexLab Automation system may have been shipped without a warning label for potential risk of interference to pacemaker functionality. In addition, the Inpeco UFSN indicates 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 making our customers aware of the missing label and updated safety information. Please see the attached Urgent Field Safety Notice from Inpeco and take appropriate action.

Actions to be taken by the Customer

1. Personnel fitted with a pacemaker must not be at distances less than 200 mm (7.87 inches) of the modules axes (transport mechanisms) for the modules listed in Table 1 of the Inpeco UFSN (Page 4 of this document) even if the warning label is missing.

2. Verify that the modules listed in Table 1 of the Inpeco UFSN (Page 4 of this document) all have a pacemaker safety label attached either on the cover or inside the cover of the module. If there is no safety label on the module, please remove the page 7 of this letter and tape a copy of the safety label to the cover of the module until an official Siemens product label is available.
3. Please review the attached OM Errata Corrige and save it with the Operations Manual you currently have for future reference regarding the "safety distance" required for pacemakers.

In addition:

- 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.
- Customer Service Engineers will schedule a visit and apply the correct label to any module that is missing a label when the replacement labels are available.

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.

FlexLab is a trademark of Inpeco.

FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice LAI18-05.FLX.A.OUS dated September 2018 FlexLab Automation - Some modules missing pacemaker warning labels. 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.