

Aptio® Automation StreamLAB® Automation

Some modules missing pacemaker warning labels

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

Table 1. Aptio Automation (SMN 10713760) - Affected Product(s)

MODULE	Siemens Material Number (SMN)
APTIO INPUT/OUTPUT MODULE	10703031, 10713760, 10713775, 10713772
APTIO RACK INPUT MODULE	10703037, 10711144
APTIO CENTRIFUGE MODULE	10703032, 10713761
APTIO 15000 REFRIGERATED STORAGE MODULE	10703036, 10713762
APTIO 9000 REFRIGERATED STORAGE MODULE	10703049, 10715227
APTIO RACK OUTPUT MODULE	10715432, 10715434

Table 2. StreamLAB Automation (SMN 10444806) - Affected Product(s)

MODULE	Siemens Material Number (SMN)
STREAMLAB – CORE UNIT / LYNX WITH IOM	10444806
STREAMLAB - REFRIGERATED STORAGE MODULE 9000	10482426, 10464532, 10635930
STREAMLAB - REFRIGERATED STORAGE MODULE 15000	10482428

Reason for Correction

Siemens Healthcare Diagnostics has confirmed that some modules listed in Table 1 and manufactured prior to December 13, 2017 may have been shipped without a warning label for potential risk of interference to pacemaker functionality. In addition, new information specified for the transport mechanism components now require the warning label on the modules listed in Table 2.

- In the modules listed in Table 1 and 2, 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 indicates the potential risk of interference to pacemaker functionality. On some modules, this label may be missing.



- The current safety distance specified in the Operator's Guide is being updated. The following is new information regarding the safety label which shall be added to the Operator's Guide for all the modules listed in Table 1 and 2 :
 - 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 Table 1 and 2.
 - 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).

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.

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 and Table 2 even if the warning label is missing.
2. Verify that the modules listed in Table 1 and 2 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 last page 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 save this letter with the Operator's Guide for your automation system 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 within 30 days.
- 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.

Additional Information

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

FIELD CORRECTION EFFECTIVENESS CHECK

Modules missing pacemaker warning labels

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics, Urgent Field Safety Notice LAI18-04.A.US dated August 2018 – Some modules missing pacemaker warning labels. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the Urgent Medical Device Correction instructions provided in this letter. Yes No
2. I found missing labels on the following modules. 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.

Tape this sheet to any module listed in Table 1 or Table 2 that is missing a warning label:

