

Siemens Healthcare Diagnostics GmbH, HC CEMEA CEE QT, Siemensstrasse 90,
1210 Vienna

Name	M.A. Roland Ertl
Department	HC CEMEA CEE QT
Telephone	+43 51707-38274
Mobile	+43 (664) 8011738274
E-mail	roland.re.ertl@siemens.com
Date	August 28, 2018
Document Ref#	LAI 18-04.A.OUS

Urgent Field Safety Notice:

Aptio® Automation StreamLAB® Automation

Some modules missing pacemaker warning labels

Dear Sirs,

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

Siemens Healthcare Diagnostics GmbH
Management: Wolfgang Koepl, Stefan Scheidler

Siemensstrasse 90
1210 Vienna
Austria

Tel.: +43 51707 0
healthcare.siemens.com

Rechtsform: Gesellschaft mit beschränkter Haftung; Firmensitz: Wien; Firmenbuchnummer: FN 135042 t; Firmenbuchgericht: Handelsgericht Wien; DVR: 0816540

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.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH



i.V. Dipl. Ing. Franz Schwarz
Head of RAQS Austria & SEE



i.A. Dr.ⁱⁿ Brigitte Gassner
Product Manager Austria & SEE