Abbott Laboratories
Diagnostics Division
Abbott Park, IL 60064-6081



# Urgent Field Safety Notice
# Product Correction

**Immediate Action Required**

**Date Issued** September 7, 2018

**Product**

| Product | List Number | Serial Numbers | UDI |
|---|---|---|---|
| Accelerator APS | 07L01 | All | N/A |

**Explanation**

Abbott has identified an issue in the modules listed below. The transport mechanism that moves the robot along the axes generates a magnetic field which may interfere with pacemaker/implanted heart defibrillator functionality at close distances. This affects all APS system serial numbers.

The table below lists modules that contain this transport mechanism.

| Module |
|---|
| Input/Output Module |
| Centrifuge Module |
| Storage Retrieve Module |

Abbott has identified that the required pacemaker/implanted heart defibrillator safety label shown below was not applied to the module covers to warn laboratory technicians who have a pacemaker/implanted heart defibrillator about the risk in case they operate these modules.

The information regarding the label was not included in the Operations Manual to identify:

- the risk of a pacemaker/implanted heart defibrillator malfunction, which applies to anyone with a pacemaker/implanted heart defibrillator who may work on these modules.
- the minimum safety distance of 200 mm (7.87'') from the transport mechanisms. Any person with a pacemaker/implanted heart defibrillator must not get closer than this distance from the modules axes.

Refer to the attached Errata Sheet for the updated instructions.

| | |
|---|---|
| **Patient Impact** | Due to exposure to the electromagnetic field, there is a potential impact to the system operator or other users of the system if he/she has a pacemaker/implanted heart defibrillator. Exposure to an electromagnetic field may interfere with pacemaker/defibrillator device functionality, leading to asynchronous pacing or interfere with arrhythmia detection and/or defibrillation. |
| **Necessary Actions** | Please be aware that personnel fitted with a pacemaker/implanted heart defibrillator must not handle or work on these modules at distances less than 200 mm even if the warning label is missing.<br><br>Your Abbott representative will be contacting you to schedule time to place a new hazard label on the APS modules. In the interim, please remove the last page of this letter and affix a copy of the label on the cover of these modules until the official pacemaker label is available.<br><br>Please review the attached Errata Sheet and save it with the Operations Manual for future reference regarding the “safety distance” required for pacemakers/implanted heart defibrillator.<br><br>Please retain this letter for your laboratory records. |
| **Contact Information** | We sincerely regret any inconvenience this may have caused your laboratory. If you or any of the health care providers you serve have any questions regarding this information, U.S. Customers please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service.<br><br>Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA’s MedWatch Adverse Event Reporting program either online (http://www.fda.gov/MedWatch/report.htm), by mail (http://www.fda.gov/MedWatch/getforms.htm), by phone (1-800-332-1088), or by fax (1-800-FDA-0178). |

Affix this sheet to any product listed above that is missing a warning label: