Abbott Laboratories
Diagnostics Division
Abbott Park, IL 60064-6081

Product Correction

Urgent - Immediate Action Required

Date Issued

September 07, 2018

Product

Product	List number	Serial Numbers	UDI
Accelerator a3600	06P33	All	N/A

Explanation

Abbott Diagnostics has received the attached Urgent Field Safety Notice from Inpeco, the manufacturer of ACCELERATOR a3600. The transport mechanism component that allows the movement of the robot along the axes generates a magnetic field which at close distance may interfere with the pacemaker/implanted heart defibrillator functionality.

The table below lists modules that contain this transport mechanism.

Module
Input/Output Module
Centrifuge Module
Storage Retrieve Module
Rack Input Module
Rack Output Module
AU5800 Interface Module
Sapphire Interface Module
XN-9000 Interface Module

The Inpeco letter describes two issues that are associated with transport mechanism.

1. Some modules are missing a pacemaker/implanted heart defibrillator label. See Appendix A.
2. The Operations Manual description of the hazard requires an update.

See attached Inpeco Urgent Field Safety Notice for more details.

Patient Impact

See attached Inpeco Urgent Field Safety Notice.

Necessary Actions

Refer to necessary action section in the attached Inpeco Urgent Field Safety Notice.

Your Abbott representative will be contacting you to schedule time to place a new hazard label on the a3600.

Please complete the included Abbott Customer Reply Form. It is not necessary to complete the Inpeco Customer Reply as Abbott will provide Abbott response to Inpeco.

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. 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).

Appendix A: a3600 modules missing the pacemaker warning label.

A3600 Systems	Rack Input Module	Rack output Module	Sapphire Interface Module
ACP001	X		
ACP002	X		
ACP004	X		
ACP013	X		
ACP018		X	
ACP019		X	
ACP032	X		
ACP036	X		
ACP038	X		
ACP043	X	X	
ACP044			X
ACP046	X		
ACP047			X
ACP049	X		
ACP050	X	1	
ACP057	X		
ACP062	X		
ACP063	X		
ACP064	X		
ACP065	X		
ACP073	X		
ACP076	X		
ACP077	X		
ACP083	X		
ACP084	X		
ACP085	X		
ACP086	X		
ACP093	X		
ACP095	X	X	X
ACP096	X		
ACP097	X	X	
ACP101	X		
ACP106	X	X	
ACP107	X		
ACP110	X		
ACP112	X	X	
ACP118		X	
ACP124	X		
ACP126	X	X	
ACP128	X		
ACP130	X		
ACP138		X	