

Urgent Field Safety Notice

November 8, 2017

Unintended Descent Issue for High Performance Patient Table

Issue Summary

An issue has been discovered that relates to the TomoTherapy High-Performance Patient Couch at your facility. Under certain circumstances when the user initiates patient couch motion in the Z-direction (up or down) for patient setup or patient unload using the keypad or PCP, it can exhibit an unintended descent. The probability of this issue resulting in injury to the patient is extremely low.

Please ensure that all necessary personnel in your facility are made aware of this notification and how the matter will be corrected.

Cause

The root cause of the issue is the control system's handling of the motion feedback loss with in vertical drive actuator.

Affected Product

This issue affects all TomoTherapy High-Performance Patient Couches that are currently in use. It does not impact the Legacy patient couches or the patient couch that is currently manufactured as part of the Radixact System.

Safety Instructions


Please review your manual for proper patient handling. This failure mode is extremely rare. In the unusual circumstance that it does occur, risk to the patient can be minimized by following existing instructions for monitoring and attending patients during couch motion.

Product Correction

Accuray® will correct all affected High-Performance Patient Couches. An Accuray representative will contact you to arrange a time to update your system. The update includes the installation of TomoTherapy® H™ Series software version 2.1.2 (Hi-Art® v5.1.2) on your system, as well as the replacement of cables within the couch subsystem.

For more information, to request documentation or if you have a service issue, please contact Accuray Customer Support using the Service Request form available at www accuray.com/service-request or by phoning one of our regional support lines (North America +866.368.4807, other regional phone numbers are listed at www accuray.com/locations).

Sincerely,


Darl Moreland
Senior Vice President, Regulatory, Quality, and Compliance
Accuray Incorporated
1310 Chesapeake Terrace
Sunnyvale, CA 94089

Acknowledgement Form

Urgent Safety Advisory Notification

I acknowledge that I have received the following document from Accuray:

Urgent Field Safety Notice concerning a potential issue involving an unintended descent of the HP Patient Couch.

I confirm that I understand the content of this Field Safety Notice dated October 24, 2017 and have distributed the information to all applicable members of my staff.

Hospital Name: _____

System Serial Number(s): _____

Signature: _____

Name (print): _____

Date: _____

Please keep this Field Safety Notice with your User Manual and forward a copy to:

Email to:
astsauver@accuray.com

Or send hard copy to:
Adam St. Sauver
Accuray Incorporated
One Erdman Place
Madison, WI 53719

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Appendix I - List of affected products in Singapore.

Device Name: TOMOTHERAPY Hi●Art® System

Identifier: H-0000-0003

Serial number: 110295

Software version number: all software versions before Hi Art v5.1.2.

cc Chairman Medical Board and relevant Head of Departments