

Urgent Field Safety Notice

April 08, 2019

CyberKnife® M6™ and CyberKnife® VSI™ Secondary Collimation Subsystem Drop Recall

Issue Summary

Accuray Incorporated has found an issue within the CyberKnife® M6™ and CyberKnife® VSI™ Treatment Delivery System related to the unintended drop of a secondary collimator housing that can occur during housing Xchange™ workflows. Specifically, during an automated housing Xchange™, an interlock may interrupt this operation causing the collimator housing to partially attach. The user is notified of an interlock. If the operator attempts to manually drive the robot back to the “perch” (home) position after the interlock, then the partial attachment can lead to the secondary collimator unexpectedly dropping from the LINAC head. No automatic robot motion commands, including treatment, can occur while the secondary collimator is partially attached; this condition only relates to manual commands after the interlock occurs. No patient or clinicians have been harmed by this issue.

Cause

CyberKnife® M6™ and CyberKnife® VSI™ System software version 11.x introduced a failure mode where any incomplete pickup or drop-off of a secondary collimator housing during Xchange™ operations will immediately cause a system interlock. If this partial collimator attachment occurs and there is a gap between the LINAC head and the secondary collimator housing, then the unintended drop of a secondary collimator housing may occur when manually commanding the robot to move from the Xchange™ Table.

One contributing factor for this gap is debris located on the LINAC head connection plate of the secondary collimator housing during Xchange™ operation.

Affected Product

Accuray CyberKnife® M6™ and CyberKnife® VSI™ System models at software version 11.x when using any secondary collimator may potentially be affected by this issue.

Safety Instructions

If Xchange™ operation fails and an interlock occurs when the robot is in the Xchange™ housing bucket, do not manually command the robot to “perch” (home) and contact Accuray Customer Support immediately. In addition, keep the Xchange™ Table secondary collimator connection surfaces clean and clear of debris, as normally specified.

Product Correction

All impacted customers with affected systems will be contacted to arrange for a software upgrade.

Accuray is committed to providing our customers and their patients with products that deliver safe and effective radiation treatments. If an issue is identified, Accuray will work with the customer to address the situation with minimal impact to their patients' treatment schedules.

For questions about this Field Safety Notice, please contact Accuray Customer Support using the Service Request form available at www accuray.com/service-requests or by phoning one of our regional support lines (North America +1.877.668.8667 and follow prompts to reach CyberKnife® M6™ and CyberKnife® VSI™ Technical Support, other regional phone numbers are listed at www accuray.com/service-requests).

Sincerely,



Darl Moreland
Senior Vice President Regulatory, Quality, Compliance
Accuray Incorporated
One Erdman Place
Madison, WI 53717

Acknowledgement Form

Urgent Field Safety Notice

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

Urgent Field Safety Notice concerning the CyberKnife® M6™ and CyberKnife® VSI™ Secondary Collimation Subsystem Drop Recall

I confirm that I understand the content of this Urgent Field Safety Notice dated 08-Apr-2019 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:
FANotification@Accuray.com

Or send hard copy to:
FA Notification (Product Surveillance)
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Madison, WI 53717