

## Urgent Field Safety Notice

August 23, 2018

### CyberKnife Calibration Film Variation Affecting Positional Accuracy

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#### Issue Summary

Accuray Incorporated (Accuray) has discovered an issue related to specific batches of calibration film used with the Ball-Cube II phantom in calibrating the CyberKnife® Treatment Delivery System (CyberKnife® System). You are receiving this notice if Accuray has previously provided you with the affected film. The Ball-Cube II phantom calibration film (Ball-Cube II film) was not manufactured within necessary dimensions and may introduce up to 0.5 mm of positional inaccuracy to the CyberKnife® System. This inaccuracy is within the 0.95 mm specification for overall delivery accuracy of the CyberKnife® System. However, it is an additional source of error that when added to other sources of error may exceed the expected positional tolerance of the system.

Please ensure that all necessary personnel in your facility are made aware of this notification and the appropriate steps to assess and correct the matter.

#### Cause

Specific batches of Ball-Cube II film were manufactured with physical dimension and geometry variations that do not support the testing of CyberKnife® system accuracy and the associated calibration activity.

#### Affected Product

Only Accuray customers who received the **Ball-Cube II film supplied from August 1, 2017 to July 31, 2018**, are affected by this action. Most systems calibrated using the affected Ball-Cube II film will still operate within the 0.95 mm overall delivery accuracy. A small portion of systems may have up to a 1.45 mm error in positional accuracy. Only Ball-Cube II film labeled with “Ashland” is affected. Calibration films for the Ball-Cube I and other ball cube (e.g. mini and XLT) phantoms are not affected. Also, calibration film provided by Accuray and labeled with “Hayes” is not affected.

#### Safety Instructions

Accuray recommends taking the following actions to ensure CyberKnife® System positional accuracy is within specifications:

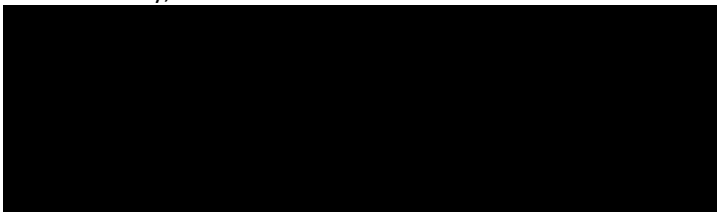
- Please stop using and quarantine Ball-Cube II film manufactured between August 1, 2017 to July 31, 2018 and labeled “Ashland”. An Accuray representative will recover and replace all affected film from your site as part of this action.
- The new Ball-Cube II film provided with this letter can be used to perform both a 6D Skull and Fiducial End-to-End test to preliminarily assess the positional inaccuracy.
- If the results do not meet your acceptance criteria, please contact Accuray Customer Support to schedule Service.

#### Product Correction

Accuray is committed to providing our customers and their patients with products that deliver safe and effective radiation treatments. Accuray will remove and replace all affected calibration film provided by Accuray. An Accuray representative will contact you to recover the affected calibration film and provide new replacement film. Accuray will arrange a time to evaluate your system to determine the existing calibration error and confirm that the system is operating within specification after any adjustments.

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](http://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](http://www accuray.com/locations)).

Sincerely,



# Acknowledgement Form

## Urgent Field Safety Notice

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

Urgent Field Safety Notice concerning the Ball-Cube II phantom calibration film.

I confirm that I understand the content of this Urgent Field Safety Notice dated August 23, 2018 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:

Accuray International  
REGULATORY AFFAIRS & QUALITY ASSURANCE EIMEA :  
E-mail : [EIMEA-RAQA@accuray.com](mailto:EIMEA-RAQA@accuray.com)