

10 December 2020

Urgent Field Safety Notice

“MLC tickle error” issue during TomoHelical™ delivery

Issue Summary

Accuray® Incorporated (Accuray) has discovered an issue related to an “MLC tickle error”. When this error is presented at the end of treatment, it indicates that the MLC leaf-open pattern timing slightly lagged behind the expected planned timing for part of the procedure, without causing the system to interrupt. For TomoHelical™ deliveries, this causes the delivered dose to effectively rotate from the planned dose, with the amount of rotation increasing from the time the original error occurred through the end of treatment. There is no clinically relevant impact to TomoDirect™ deliveries. Please ensure that all necessary personnel in your facility are made aware of this issue.

Reason for Urgent Field Safety Notice

While the overall dosimetric impact on the course of treatment is typically well within a 3%/3mm passing gamma specification, based upon investigation of clinical cases to date, TomoHelical™ treatments with fast rotation periods, long treatment volumes, and hypofractionated courses of treatment may experience a larger overall impact. This could result in either more or less dose than intended to the target volume or volumes of interest, compared to the original plan. In addition, users will not know if the error has occurred until the end of the treatment delivery, when the error message appears on the treatment delivery console. Accuray recommends that clinical personnel review the TomoHelical™ treatments with the characteristics described above to assess the potential dosimetric impact.

Affected Product

This issue affects TomoTherapy Systems at software version 5.1.5, and TomoTherapy Systems with iDMS® at software version 1.2.0.

Next Steps

Accuray is committed to providing our customers and their patients with products that deliver safe and effective radiation treatments. Accuray is planning software releases (TomoTherapy v5.1.6, and TomoTherapy with iDMS v1.2.0.1) that will address this issue. All TomoTherapy systems at affected software versions will be upgraded to these versions once released.

Contact Information

For questions about this Urgent Field Safety Notice, please contact Accuray Customer Support by phone or email, using the Service Request form available at <http://www accuray.com/service-requests>.

Sincerely,

Daniel Biank
Vice President, Regulatory Affairs

Accuray Incorporated
1209 Deming Way
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 "MLC Tickle error" issue during TomoHelical™ delivery.

I confirm that I understand the content of this Urgent Field Safety Notice dated 10 December 2020 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 Urgent Field Safety Notice document with your User Manual and forward a copy to:

Email to:

FANotification@Accuray.com

Or send hard copy to:

FA Notification (Product Surveillance)
Accuray Incorporated
1209 Deming Way
Madison, WI 53717