

URGENT FIELD SAFETY NOTICE

Date: 18 November 2014
Attention: TomoTherapy® System Medical Physicist
Affected Product: Software versions 2.0.1/2.0.2/2.0.3 (Hi-Art 5.0.1/5.0.2/5.0.3)

Accuray has become aware of a potential safety issue related to the TomoTherapy® Treatment System caused by a failure to monitor the jaw position after a jaw error occurs. This may result in an incorrect jaw position during treatment, without generating a system interruption.

Please review the following information with all applicable members of your staff.

Description of the Issue

On rare occasions, a jaw communication issue may occur and the jaws will not perform any further planned movement. If this occurs prior to beam-on during a delivery procedure, the jaw monitoring system will interlock appropriately. However, if this occurs at the beginning of beam-on, software anomaly #54148 can then cause the jaw monitoring system to stop monitoring the jaw position. The jaws will then remain stationary for the remainder of the procedure.

This issue is unlikely to have a dosimetric impact for procedures using static jaws, unless a separate additional error occurred during beam-on. Procedures using static jaws will start at the correct position, and then remain stationary. For TomoEDGE™ Dynamic Jaw procedures, the jaws will remain at the position specified at the beginning of the procedure, and the procedure will appear to finish normally, although the jaws remain stationary for the remainder of the procedure. By reviewing machine logs, the probability of the jaws remaining at a static position throughout the remainder of a TomoEDGE Dynamic Jaw Procedure has been determined to be approximately 0.03% (3 in 10,000).

Example: For a dynamic jaw procedure, the field width will start at 1.05cm. In normal operation, this field width will increase until the maximum planned field width has been achieved. In the event that the issue above occurs, the field width will stay at 1.05cm for the remainder of the procedure, with the jaws in their maximally asymmetric position, as shown in the screenshot from the Operator Station in Figure 1, below.

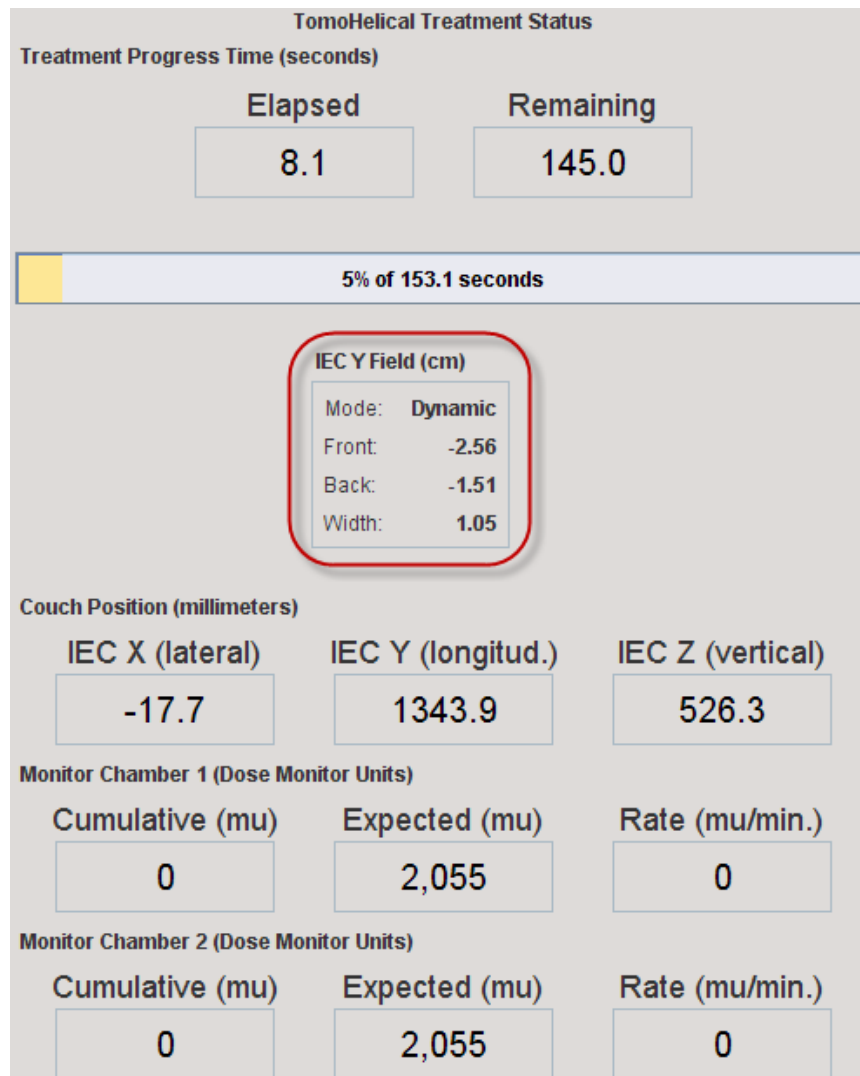


Figure 1. Screenshot from the Operator Station, showing the asymmetric 1.05cm beam that would be expected at the superior edge of the target.

If the issue described in this notice occurs, this field will not change during treatment.

Safety Instructions

For TomoEDGE™ Dynamic Jaw procedures, either:

- Replan these procedures using the static jaw delivery mode, or
- At the Operator Station (see Figure 1), monitor the **Width** for the **IEC Y Field (cm)** at the beginning of these procedures to ensure that it increases over time. If it does not increase, stop treatment and contact Accuray Customer Support for assistance.

We recommend you do not deliver TomoEDGE™ Dynamic Jaw completion procedures. If this error occurs during a completion procedure, the jaws are more likely to start at a wider opening, and fail to close properly at the end of the delivery, potentially causing extra radiation to be delivered to the area inferior to the target region. Instead, contact Accuray Customer Support.



Final Resolution

A software fix to the monitoring system has been implemented in version 2.0.4/5.0.4 software. You will be contacted by Accuray Customer Support to schedule a software upgrade to your system.

For more information or to ask any questions about this notification, please contact Accuray Customer Support at 1-877-668-8667 or visit the Accuray Technical Solutions Center at www.accuray.com > Services & Support or call: **North America:** +1.877.668.8667, **Europe:** +800.4141.9595, **Hong Kong:** +852.2247.8688, **Japan:** +81.3.6269.9556.

Please complete the attached acknowledgment for this notification and return to Accuray Regulatory Affairs.

Sincerely,

██████████
Vice President, Regulatory Affairs



ACKNOWLEDGMENT FORM

URGENT FIELD SAFETY NOTICE

TomoTherapy® Systems with software versions 2.0.1/2.0.2/2.0.3 (Hi·Art 5.0.1/5.0.2/5.0.3)

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

- Urgent Field Safety Notice Concerning Dynamic Jaw Field Widths during Treatment

I confirm that I understand the content of this Field Safety Advisory Notification dated November 18, 2014 and have distributed the information to all applicable members of my staff.

Name (print): _____

Signature: _____

Hospital Name: _____

Date: _____

Please keep this Field Safety Notice regarding Dynamic Jaw Field Widths during Treatment with your User Manual.

Send to:

Accuray International
REGULATORY AFFAIRS & QUALITY ASSURANCE EIMEA
e-mail: EIMEA-RAQA@accuray.com
subject line: FSCA 5.0.4