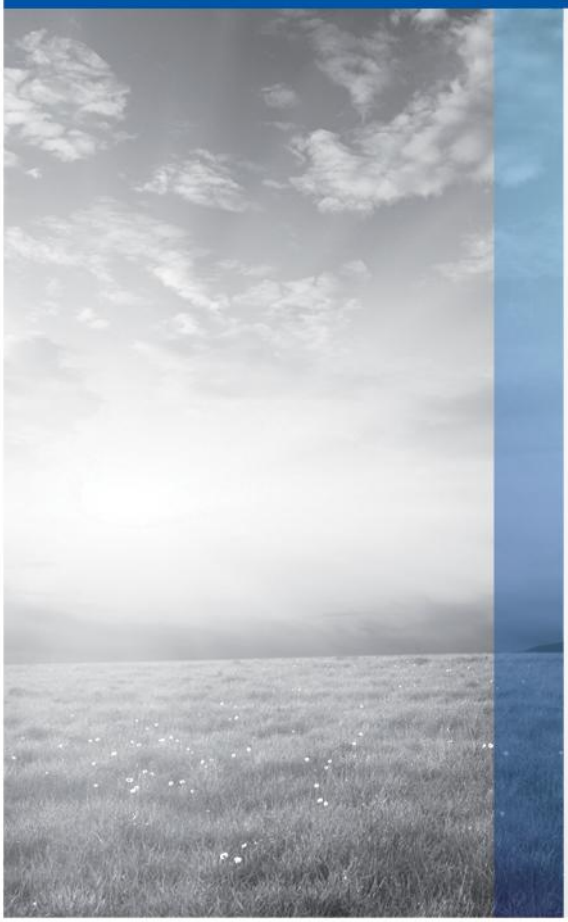
Important Field Safety Notice



Recommended quality assurance after a calibration procedure

Product: Integrity™

Date: November 2013
FCO: 200 01 502 043

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Important Field Safety Notice

We are providing the information in this Notice to notify you of an important safety issue that may exist on your equipment, and to inform you of any actions needed to safeguard both your staff and your patients. We ask that you please read and understand the content of this notice and implement any recommendations provided.
We also need you to acknowledge and accept this FCO by signing and returning the statement on the FCO Action Notification Report.
We advise you to insert this Notice in the applicable copy of the User Manual.

Recommended quality assurance after a calibration procedure

Product: Integrity™

Date: November 2013
FCO: 200 01 502 043

Scope:	Integrity™ R1.1, R3.0, and R3.1
Description:	During the treatment table, gantry, and collimator calibration procedures, it is possible to type incorrect values. If you do not do the quality assurance (QA) procedures after the calibration, it is possible that you will not find the error made during the calibration. For example: 1. The Service User types the minimum and maximum lateral values for the treatment table in the incorrect sequence. 2. You do not do the post-calibration QA checks, or you do the QA checks incorrectly. 3. You use the machine for clinical operation. 4. You do not do the daily QA checks, or you do the QA checks incorrectly. 5. When you do a remote automatic table movement during an online XVI workflow, you do not see that the treatment table moves in the opposite lateral direction. 6. You deliver the treatment with the patient in the incorrect position.
Clinical impact:	If the treatment table, gantry, or collimator calibration is incorrect, and you do not do the recommended QA procedures, it can cause clinical mistreatment.

This Notice has been notified to the appropriate Regulatory Authorities

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Solution:	Elekta recommends that: • You do the daily QA procedures in the *Precise Table Instructions for Use (IFU) and Integrity™ IFU*. • You do a daily QA check to make sure that the magnitude and direction of the treatment table movements are correct. • If you have XVI, you do the QA procedures in the *XVI IFU* and the procedure in this Notice to do the daily phantom scan.
Technical Reference:	CLM 01681502
Contact:	If you have any queries about this Notice, please contact your local Elekta office.

Recommended QA for XVI

The XVI system is a precision instrument, and it is necessary to do regular planned maintenance, user maintenance, safety checks, and QA checks. These maintenance tasks and checks help to give safe and satisfactory system operation with the necessary reliability.

It is the responsibility of the Clinical User to make sure that the QA checks are completed before clinical operation.

It is the responsibility of the authority that has the control of the equipment to:

- Set up a QA program to make sure that the image quality is satisfactory, the equipment aligns correctly, and the calibration is correct.
- Make sure that the QA program obeys applicable laws and regulations in the jurisdiction of the equipment.
- Make sure that the QA checks are completed.
- Keep the necessary QA records.

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Elekta recommends that the authority that has the control of the equipment uses these documents to help set up a QA program:

- Klein et al., 2009. 'Task Group 142 report: Quality assurance of medical accelerators.' Medical Physics, 36(nine), pp. 4197-4212.
- Bissonnette et al., 2008. 'Quality assurance for the geometric accuracy of cone-beam CT guidance in radiation therapy.' Int. J. Radiat. Oncol. Biol. Phys., 71(1), pp.S57-S61.
- Bissonnette et al., 2008. 'A quality assurance program for image quality of cone-beam CT guidance in radiation therapy.' Med. Phys., 35(5), pp.1807-1815.
- Sykes et al., 2008. 'Measurement of cone beam CT coincidence with megavoltage isocentre and image sharpness using the QUASAR™ Penta-Guide phantom.' Phys. Med. Biol., 53, pp.5275-5293.
- Cho et al., 2005. 'Accurate technique for complete geometric calibration of cone-beam computed tomography systems.' Med. Phys., 32(4), pp.968-983.

Doing the daily phantom scan

This is a procedure to make sure that the communication between the Table Move Assistant and the treatment table is active.

Elekta recommends that you do a daily phantom scan before the daily treatment cycle. This will make sure that communication between the Table Move Assistant and the treatment table is active for the radiation treatments.

1. Do the daily phantom scan, see the documents that follow for more information:

- The AAPM TG-179 report, Bissonnette J-P et al, Quality assurance for image-guided radiation therapy utilizing CT-based technologies: A report of the AAPM TG-179. This is available at http://www.aapm.org.
- Kurt Stump, Elekta XVI Volumetric Imaging and Registration QA With the MIMI Phantom. This is available at http://www.standardimaging.com.

This procedure also identifies an incorrect calibration of the treatment table.

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Safety reference

The following warnings and cautions are associated with this notice:

WARNING

Do not use the equipment unless the user maintenance, safety checks, and QA checks are satisfactorily completed, and the planned maintenance program is completed to the current date. If you ignore this warning, it can cause fatal injury, clinical mistreatment, and damage to the equipment.

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FCO Action Notification Report

Please complete the details below and sign the appropriate acknowledgement section:

- Existing installations; Acknowledgement by the customer
- New installations: New installation confirmation by the installing Elekta or Representative employee

Please return this report to your local Elekta Office or Representative, as soon as possible and within 30 days at the latest.

***The information in this FCO has been provided to address a safety issue and therefore the customer is expected to acknowledge and accept the recommendations given, and ensure they are implemented. By refusing to implement the recommendations, the customer assumes full responsibility and liability for all matters (including costs, losses, claims, and expenses) resulting, whether directly or indirectly from not implementing such recommendations. Further the customer will hold Elekta harmless from all matters (including costs, losses, claims and expenses) resulting, whether directly or indirectly from not implementing such recommendations.**
Failure to sign and return the acknowledgement may affect any follow-up actions necessary for us to take, and may require Elekta to report to the Regulatory Authorities in your country.

Classification:	Important Field Safety Notice	FCO Ref:	200 01 502 043
FCO description:	Recommended quality assurance after a calibration procedure		
Scope:	Integrity™ R1.1, R3.0, and R3.1		

Hospital:	
Device Serial No: (e.g. linac - if applicable)	Location or Site No:

Acknowledgement by customer*:
This notification to be signed by the customer

I acknowledge that I have read and understood this Notice and accept implementation of any given recommendations:

Name: Title:

Signature: Date:

New installation confirmation:
This notification to be signed by the installing Elekta or Representative employee

Name: Title:

Signature: Date:

This Notice has been notified to the appropriate Regulatory Authorities

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