Field Corrective Action Reference: **FCA-EL-0004 & FCA-EL-0005**

This notice reference: **200-01-502-053**

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Potential for positional errors following automatic table movement (ATM)

Product: **Integrity™**

Scope: All Integrity™ R1.2 and Integrity™ R3.2 systems with a Precise Treatment Table™ for ATM license option

Notification Released: November, 2017

Description of Problem:
Elekta have identified that it is possible to get a positional error with the Precise Treatment Table™ following automatic table movement. This can occur if there is an undetected failure of the positional sensors. This has been previously communicated through notification 200-01-204-011.

Details:
The Precise treatment table is equipped with sensors that achieve a high degree of reliability in the readout of the table position.
In case of an undetected failure of one of these sensors, it is possible to get a positional error with the Precise Treatment Table™ following automatic table movement when using XVI and MOSAIQ™.

The system has a software check which is intended to detect large positional errors resulting from a fault in the sensors. In those cases, it is possible to position the treatment table with errors over 5 mm and no inhibits are displayed. This can occur using automatic table movement.

If the automatic table movement is done by iGUIDE, the positional error will be detected.

Clinical Impact:
It is possible to deliver treatment with the patient in an incorrect position, if this fault were to occur and go undetected.

Recommended User Action:
Elekta will release Integrity™ R4.0.0, which will identify positional errors over 5 mm if a sensor has failed. Upgrades in the field are expected to start in the first half of 2018. If necessary, arrange with your local service representative for a free of charge upgrade to Integrity™ R4.0.0.

This document contains important information for the continued safe and proper use of your equipment.

- Please post this notice in a place accessible to all users, e.g. Instructions for Use, until this action is closed.
- Advise the appropriate personnel working with this product the content of this letter

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Elekta Corrective Actions:
This notice has been provided to the appropriate Regulatory Authorities.

We sincerely apologize for any inconvenience this action may cause and thank you in advance for your cooperation.

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Acknowledgement Form

In order to meet regulatory requirements, you are required to complete this form and return it to Elekta immediately upon receipt but no later than 30 days.

Classification:	Important Field Safety Notification	FCO Reference Number:	200-01-502-053
Description	Potential for positional errors following automatic table movement (ATM)		

Hospital:	
Device Serial No(s): (if applicable)	Location or Site:

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

Name: Title:

Customer Signature: Date:

New installation confirmation to be signed by the installing Elekta engineer or Representative employee when the installed product has a physical IFU/manual:

I acknowledge that the customer is informed on the content of this notice and that it has been inserted into the applicable copy of the User Manual or added to the record with the applicable User Manual:

Name: Title:

Signature: Date:

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