Field Corrective Action Reference: **FCA-NU-0006**

This notice reference: 806-01-BTD-001

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Flexitron internal cable guides inspection

Product: Flexitron

Scope: Flexitron HDR/PDR and Flexitron Co-60 systems

Notification Released: November 2019

Description of Problem:
In case of a component failure of the Flexitron internal check cable or source cable guide mechanism, a treatment interruption or incorrect source positioning can occur.

Details:
One customer complaint has been reported from the field concerning a system in which the internal check cable guide mechanism failed. Due to an obstruction during the check cable out drive, the internal guiding tube became displaced and the check cable became damaged.

A highly unlikely chain of events has been identified in which the internal source cable guide displacement can cause incorrect source cable positioning.
For this to occur, all of the following conditions need to be met simultaneously:

1. Both internal guiding tubes for the check cable and source cable are defective.
2. The obstruction in the cable path is not detected by the check cable.
3. The obstruction in the cable path occurs after all channels passed the check cable checks.

In addition, it is improbable that this error condition would not have been noticed during the mandatory safety, performance and functional tests that are performed during each source exchange or planned maintenance:

- The cable obstructions detection circuits tests.
- Transfer tube connection test.
- Cable alignment verification done after these tests.

Nevertheless, as a precautionary measure, Elekta has decided to inspect all Flexitron systems to ensure your system performs as intended.

Clinical Impact:
This issue can cause treatment interruption or in a very unlikely chain of event, incorrect source positioning.

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Recommended User Action:
If you have experienced any issues with source obstructions or source position displacement during treatment or QA, please notify your Elekta service representative and have the system inspected as soon as possible. If no issues have been observed, the system can continue to be used clinically and your system will be inspected during a regular source exchange or maintenance visit.

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, on the content of this letter.

Elekta Corrective Actions:
Your system will be inspected by an Elekta service representative during the source exchange or planned maintenance.

This notice has been submitted 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 either acknowledge receipt of this notification via the Elekta Care Community or complete this form and return it to Elekta immediately upon receipt, but no later than within 30 days.

Classification:	Important Field Safety Notification	FCO Reference Number:	806-01-BTD-001
Description	Flexitron internal cable guides inspection		

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

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

Name: Title:

Customer Signature: Date:

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

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

Name: Title:

Signature: Date: