ELEKTA

URGENT
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 Notice by signing and returning the statement on the Acknowledgement page.

We advise you to insert this Notice in the applicable copy of the User Manual.

Incorrect Treatment When DICOM Exporting Arcs Using Composite Field Sequencing

Product: Monaco

Reference number (Field Change Order, FCO): FCO 382-01-MON-001
Field Corrective Action (FCA) number (if applicable): FCA-IMS-001

Scope:	Sites affected will be those: 1. Running Monaco Release 3.20 and higher, and 2. With Elekta or Siemens linacs, and 3. With any of the following licenses: VMAT or Dynamic Conformal or 3D (static arcs), and 4. Using Composite Field Sequencing (CFS) when DICOM exporting plans. Customers with Focal Releases 4.70 and 4.80 are also affected by this issue when Focal is used with Monaco and meet the criteria above.
Description:	When DICOM exporting an arc plan (VMAT, Dynamic Conformal or 3D Static Arcs) and using the Composite Field Sequencing (CFS) feature, the DICOM exported plan will not match the approved treatment plan. The problem occurs when the starting gantry angle of the second arc is exactly 180 degrees and the stop angle of first beam is greater than 180 degrees away from the start position of the second arc. CFS is designed to combine arcs into a single beam to streamline delivery. However, under these specific circumstances, the start and stop points for the arcs become corrupted. To avoid the problem, do not use 180 degrees for the starting gantry angle of the second arc. Using 180.1 or 179.9 degrees as the starting gantry angle will completely avoid this issue.

This Notice has been notified to the appropriate Regulatory Authorities

IMPAC Medical Systems, Inc.
13723 Riverport Drive, Suite 100
Maryland Heights, Missouri 63043
Tel: 314 993 0003 Toll-Free: 800 878 4267
Fax: 314 993 0075

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Clinical impact:	Areas that should receive no dose may be treated and areas that are supposed to be treated may receive more or less dose than they should. The DICOM exported plan and subsequent treatment delivery will not match the approved treatment plan. There is a remote probability of the issue resulting in serious adverse health consequences.
Solution:	The problem will be resolved in patches to the following releases: Focal 4.80 Monaco 3.30 Monaco 5.00
Technical Reference:	None
Contact:	If you have any queries about this Notice, please contact your local Elekta office.

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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 Notice 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: 382-01-MON-001
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Hospital:		
Device Serial No: (e.g. linac - if applicable)		Location or Site No:
Acknowledgement to be signed by customer*: I acknowledge that I have read and understood this Notice and accept implementation of any given recommendations: Name:		Title:
Signature:		Date:

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