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 Field Size When DICOM Exporting Monaco 3D Plan with Composite Field Sequencing

Product: Monaco

Reference number (Field Change Order, FCO): FCO 382-01-MON-004

Field Corrective Action (FCA) number (if applicable): FCA-IMS-0013

Monaco HPQC: 3653

Scope:	Sites running Monaco V 5.10.00 and higher are affected by this NOTICE.
Description:	When DICOM exporting a 3D Monaco plan and the "Composite Field Sequencing" (CFS) checkbox is selected, the Y jaws will snap to the port shape when they should remain where they were defined. This occurs when the port shape used to define or edit the MLC positions extends beyond or inside the actual jaw positions. The defect is triggered when using a workflow for Forward Planning IMRT that involves creating multiple beams for the same gantry angle with a single MLC shape defined for each beam. These beams are then exported using CFS to combine the individual 3D beams into a single IMRT beam sequence.
Clinical impact:	The planned and approved dose distribution will not agree with the dose delivered. This deviation is considered a geometric miss and the patient can be overdosed or underdosed depending on whether the MLC shape is drawn outside or inside of the collimator jaws. There is a remote probability that serious injury could occur.
Workaround:	The problem can be avoided by not using the CFS option for any 3D delivery mode plan including Forward IMRT based plans.

This Notice has been submitted 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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Solution:	This problem will be resolved in patches to the following Monaco Releases: 5.11 5.20
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 one 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-004
Description:	Incorrect Field Size When DICOM Exporting Monaco 3D Plan with Composite Field Sequencing		
Scope:	Sites running Monaco V 5.10.00 and higher are affected		
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:	

This Notice has been submitted to the appropriate Regulatory Authorities

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