IMPORTANT USER NOTICE

We are providing the information in this Notice to notify you of an important 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 CT to ED When Using Focal Image Statistics Tool

Product: Focal

Reference number (Field Change Order, FCO): FCO 382-03-FCL-001
Field Corrective Action (FCA) number (if applicable): FCA-IMS-0005a

Scope:	Sites affected will be those meeting ALL three criteria below: 1. Running Focal Release 4.80.00 2. Using a CT Slice Spacing not equal to the CT Slice Thickness 3. Using the Image Statistics Tool to quantify CT phantom densities which are then used to populate the CT to ED file.
Description:	When a CT phantom is scanned and the images are transferred to Focal, it is possible to sample the densities using the Image Statistics tool in Focal. In the case where CT slice thickness is not the same as CT slice spacing the Image Statistics tool will report an incorrect HU. If the user bases their CT to ED file on this incorrect density information, dose calculation errors will result. The magnitude of the dose calculation error will be dependent on the magnitude of the HU error. The problem occurs when the CT Slice Spacing does not equal the CT Slice Thickness, and information from the Image Statistics tool is used to populate the CT to ED file. Workaround: The problem can be avoided by using a CT Slice Spacing equal to the CT Slice Thickness.

IMPAC Medical Systems, Inc.
13723 Riverport Drive, Suite 100
Maryland Heights, Missouri 63043
Tel: 314 993 0003 Toll-Free: 800 878 4267
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Clinical impact:	If the user bases their CT to ED file on the incorrect density information from the Image Statistics tool, Focal will assign an incorrect density leading to dose errors that may result in non-serious adverse health consequences.
Solution:	The problem will be resolved in a patch to the following release: Focal 4.80
Technical Reference:	None
Contact:	If you have any queries about this Notice, please contact your local Elekta office.

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IMPORTANT USER NOTICE ACKNOWLEDGEMENT

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 an 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.**

Classification:	Important User Notice	FCO Ref:	382-03-FCL-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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