

2 November 2016

ATTN: Risk Manager Biomedical Engineering, Chief Medical Physicist

cc: Chairman Medical Board and relevant Head of Departments

Dear Valued Customer,

Please kindly refer to the relevant Urgent Important Field Safety Notification with

Notice reference: 382-01-MON-007

Subject:

Contours Are Not Handled Correctly for Some CT Datasets

Description of Problem:

Contours are not handled correctly if the CT dataset contains slices with DICOM Z coordinates of xx.x50mm.

The attached Urgent Important Field Safety Notification contains important information for the continued safe and proper use of your equipment. The details and impact of the problem have been clearly described. The recommended user action has been provided. Please kindly return the acknowledgement form in the Urgent Important Field Safety Notification in order to represent your understanding and awareness.

By signing the acknowledgment form, the customer representative confirms that this notice has been read and understood and communicated to the appropriate employees within the organization. If you have any questions, please feel free to contact our Elekta Application Specialist to provide you with additional information and/or guidelines if necessary.

Tel. 62212322 e-mail: Fareast.Support@elekta.com.

Sincerely,



Henry Hou
Regulatory Affairs Manager
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Field Corrective Action Reference: **FCA-IMS-0019**

This notice reference: 382-01-MON-007
HPQC 3883

URGENT IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Contours Are Not Handled Correctly for Some CT Datasets

Product: Monaco®

Scope: Sites affected will be those:

1. Running Monaco® V 5.00 and higher, and
2. Importing CT slice data with DICOM Z coordinates occurring at xx.x50mm

Notification Released: October, 2016

Description of Problem:

Contours are not handled correctly if the CT dataset contains slices with DICOM Z coordinates of xx.x50mm.

Details:

If the CT data contain slices that occur at positions of xx.x50mm, there can be portions of the volume where there is a mismatch between the contour graphics shown on the screen and the contour data used during the optimization and calculation of dose. Unloading and reloading the patient data corrects the problem.

Clinical Impact:

Incorrect structure volumes can be used during optimization. Incorrect electron densities can be assigned to some regions of the patient. This can result in incorrect dose calculations. Dose errors of greater than 5% can occur.

Recommended User Action:

The problem can be avoided if the user takes the following action:

- Following contour edits, perform an "Unload All" and reload the plan prior to performing dose calculation.

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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URGENT IMPORTANT FIELD SAFETY NOTIFICATION

Elekta Corrective Actions:

This problem will be resolved in Monaco® release 5.30 and in patches to Monaco releases 5.10 and 5.11.

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.



URGENT IMPORTANT FIELD SAFETY NOTIFICATION

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: 382-01-MON-007
Description: Contours Are Not Handled Correctly for Some CT Datasets	

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:

cc: Chairman Medical Board and relevant Head of Departments