20 November 2017
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-006

Subject:
Incorrect Dose When Using the Reset Function

Scope:
Sites affected will be those:
1. Running Monaco® V 5.11, and
2. Creating 3D plans, and
3. Using Elekta Motorized Wedges

Description of Problem:
Dose can be incorrectly calculated when using the Reset function in Monaco®.

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
Elekta Limited
henry.hou@elekta.com
Tel: +852 2892 4359

Field Corrective Action Reference: **FCA-IMS-0018**
This notice reference: 382-01-MON-006
HPQC 3840

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Incorrect Dose When Using the Reset Function

Product: Monaco®

Scope: Sites affected will be those:
1. Running Monaco® V 5.11, and
2. Creating 3D plans, and
3. Using Elekta Motorized Wedges

Notification Released: October, 2016

Description of Problem:
Dose can be incorrectly calculated when using the Reset function in Monaco®.

Details:
When creating 3D plans using Dose weighting mode, if the user rescales the plan, selects “Reset”, and then changes the wedge angle, the plan dose and monitor units (MU) should be returned to the original values before the rescale. Instead, the system correctly restores the edited wedge field but incorrectly applies the scale reset value again to all other beams in the plan.

Clinical Impact:
The MUs are correct for the non-wedged beams but the dose being presented on the screen is incorrect. Therefore the dose displayed will not be what is delivered.

Recommended User Action:
The problem can be avoided by forcing a Monaco® recalculation (change dose calculation grid spacing and change back) when any wedge angle change is made.

Prior to treatment, independent dose calculation checks and secondary MU checks should always be done. Both should be standards of practice in radiation therapy clinics and will detect the problem.

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

IMPAC Medical Systems, Inc.
Tel: 314 993 0003 Toll Free: 800 878 4267
FAX: 314 993 0075

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Elekta Corrective Actions:
This problem will be resolved a patch to Monaco® release 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.

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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-006
Description	Incorrect Dose When Using the Reset Function		

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

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