



17 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-003

Subject:

Unintended Update of Dose and MU / Incorrect Assignment of Bolus

Scope:

Sites affected will be those running Monaco 5.10.00 or Monaco 5.10.01

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



URGENT

IMPORTANT FIELD SAFETY NOTICE

We are providing the information in this Notice to notify you of two important safety issues 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.

Unintended Update of Dose and MU

Incorrect Assignment of Bolus

Product: Monaco

Reference number (Field Change Order, FCO): FCO 382-01-MON-003

Field Corrective Action (FCA) number (if applicable): FCA-IMS-0010

Unintended Update of Dose and MU (HPQC 3280)	
Scope:	Sites affected will be those running Monaco 5.10.01.
Description:	<p>In version 5.10.01, the Isodose Control 100% isodose value (second in the list) was linked to the Dose Normalization value so users would always have a known normalization value linked to 100% when in relative mode. This however limits the user to only one defined value available above 100%. When the 100% isodose value is edited on the isodose control, the Dose Normalization is automatically updated. If the user does not notice this update and then rescales to a relative isoline and does not read the Dose Normalization value displayed on the rescale bar, the rescale could be other than intended.</p> <p>Applying an isodose template could automatically update the Dose Normalization value. When rescaling at this point, rescales will be relative to the new dose normalization value and again the user could fail to read the dose normalization value displayed in the rescale bar and Dose Normalization panel.</p>
Clinical impact:	The dose distribution and monitor units may not reflect the intent when the dose normalization value is updated. There is a remote probability that non-serious injury could occur.

This Notice has been notified to the appropriate Regulatory Authorities

IMPORTANT FIELD SAFETY NOTICE

Unintended Update of Dose and MU (HPQC 3280) (continued)	
Workaround:	The workaround is to only assign one value greater than 100% as the system is defaulted so the 100% isodose line and dose normalization values are not affected. When rescaling, the dose normalization value is displayed next to the rescale value being entered by the user.
Solution:	This problem will be resolved in Monaco Patch Release 5.10.02.
Technical Reference:	None
Contact:	If you have any queries about this Notice, please contact your local Elekta office.

Incorrect Assignment of Bolus (HPQC 3322)	
Scope:	Sites affected will be those running Monaco 5.10.00 and greater.
Description:	When the user optimizes, then changes the bolus assignment of the beams, and then selects "Calculate" (not "Optimize" again), the bolus assignment to beams can get scrambled. Beams that should have bolus assigned do not and beams that do not have bolus assigned calculate with bolus. The dose distribution and Monitor Units are incorrect for the bolus assignment of the beams. Also, the reports show beam information that is incorrect for the bolus assignment. The DRP and Prescription page are not updated correctly. Skin doses could either be higher or lower than intended and this increase or decrease in dose could exceed 5%.
Clinical impact:	The dose distribution and monitor units will be incorrect for the indicated bolus assignment. There is a remote probability that serious injury could occur.
Workaround:	There is no workaround using the described workflow. However, the problem can be avoided by changing any bolus assignment before optimization.
Solution:	This problem will be resolved in Monaco Patch Release 5.10.02.
Technical Reference:	None
Contact:	If you have any queries about this Notice, please contact your local Elekta office.

This Notice has been notified to the appropriate Regulatory Authorities

IMPORTANT FIELD SAFETY NOTICE

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 two safety issues 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-003
Description:	Unintended Update of Dose and MU Incorrect Assignment of Bolus		
Scope:	Sites affected will be those running Monaco 5.10.00 or Monaco 5.10.01		
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 notified to the appropriate Regulatory Authorities