



URGENT IMPORTANT FIELD SAFETY NOTIFICATION

- Subject:** Incorrect Enhanced Dynamic Wedge (EDW) or Virtual Wedge (VW) Calculations
- Product:** Monaco®
- Scope:** Sites affected will be those:
1. Running Monaco®:
 - a. V 5.00.00 (including 5.00.01, 5.00.02, 5.00.03, 5.00.04), or
 - b. V 5.10.00 (including 5.10.01, 5.10.02, 5.10.04), or
 - c. V 5.11.00 (including 5.11.01), or
 - d. V 5.20.00, and
 2. Using the Collapsed Cone Algorithm, and
 3. Using Varian Enhanced Dynamic Wedges (EDW) or Siemens Virtual Wedges (VW)

Notification Released: December, 2016

Description of Problem:

EDW or VW wedge files can be loaded into incorrect energies using Treatment Unit (TU) Storing. No warning or consistency checking is done for EDW or VW files when adding these to the database.

Details:

TU Storing should not allow or should give an error message if the user attempts to add an EDW or VW file for a certain energy beam to a Collapsed Cone model file for a different energy. Currently the user is not warned when there is a mismatch.

Clinical Impact:

If an EDW or VW file is used for the wrong energy, dose errors will result.

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



Field Corrective Action Reference: **FCA-IMS-0021**

This notice reference: 382-01-MON-008
HPQC 3911

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Recommended User Action:

The problem is detectable when following routine procedures for commissioning a beam model. A reminder that when reinstalling a beam model, it is also necessary to repeat the QA checks performed on the original model.

The Elekta Regional Support staff will contact you and will help review all EDW or VW beam models to ensure that all files are correct. You may also initiate this process by contacting Elekta Care by phone or by opening a support ticket through the Support Plus portal.

Elekta Corrective Actions:

This problem will be resolved in a patch to Monaco® 5.11.00.

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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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-008
Description Incorrect Enhanced Dynamic Wedge (EDW) or Virtual Wedge (VW) Calculations	

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: