

URGENT IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Incorrect Entry of Height and Weight Values

Product: MOSAIQ

Scope: MOSAIQ customers using Version 2.0 and higher

Notification Released: September 2019

Description of Problem:

The user may inadvertently enter Metric values into Height and Weight fields labeled with US Standard units.

Details:

The Vitals/Lab Data entry window will be presented if there is missing information when entering a drug order or checking the drug order status. The window will always default to US Standard units the first time the window is opened for each user. Height will have units of inches (in) and Weight will have units of pounds (lbs).

In order to switch the units to Metric, the user must click on the Metric units radio button. Once this is selected, the Height units will change to centimeters (cm) and Weight units will change to kilograms (kg).

Customers who use Metric units in all other parts of the software might not notice the default radio button setting and the units displayed on the Vitals/Lab Data entry window. Metric values are being entered for Height and Weight when US Standard values are expected.

Clinical Impact:

If the units are left defaulted to US Standard, but Metric measurements are entered, the resulting BSA will be much larger than expected. If undetected, a patient could receive a BSA based drug dose higher than necessary.

Recommended User Action:

Be sure to note that the Vitals/Lab Data entry window always defaults to US Standard units the first time the window is opened for each user. Click on the Metric units radio button if Height and Weight are to be entered in centimeters (cm) and kilograms (kg). The units preference is saved per user for each subsequent time the window opens.

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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, on the content of this letter.

Elekta Corrective Actions:

The issue will be resolved in a future MOSAIQ release. You will be informed when the fix is available through a Product Bulletin.

This notice has been submitted 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 within 30 days.

Classification: Important Field Safety Notification	FCO Reference Number: 371-01-MSQ-016
Description: Incorrect Entry of Height and Weight Values	

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 has been informed on the content of this notice and that it has been inserted into the applicable copy of the User Manual, or added on record with the applicable User Manual:	
Name:	Title:
Signature:	Date: