⚠ IMPORTANT SAFETY NOTICE
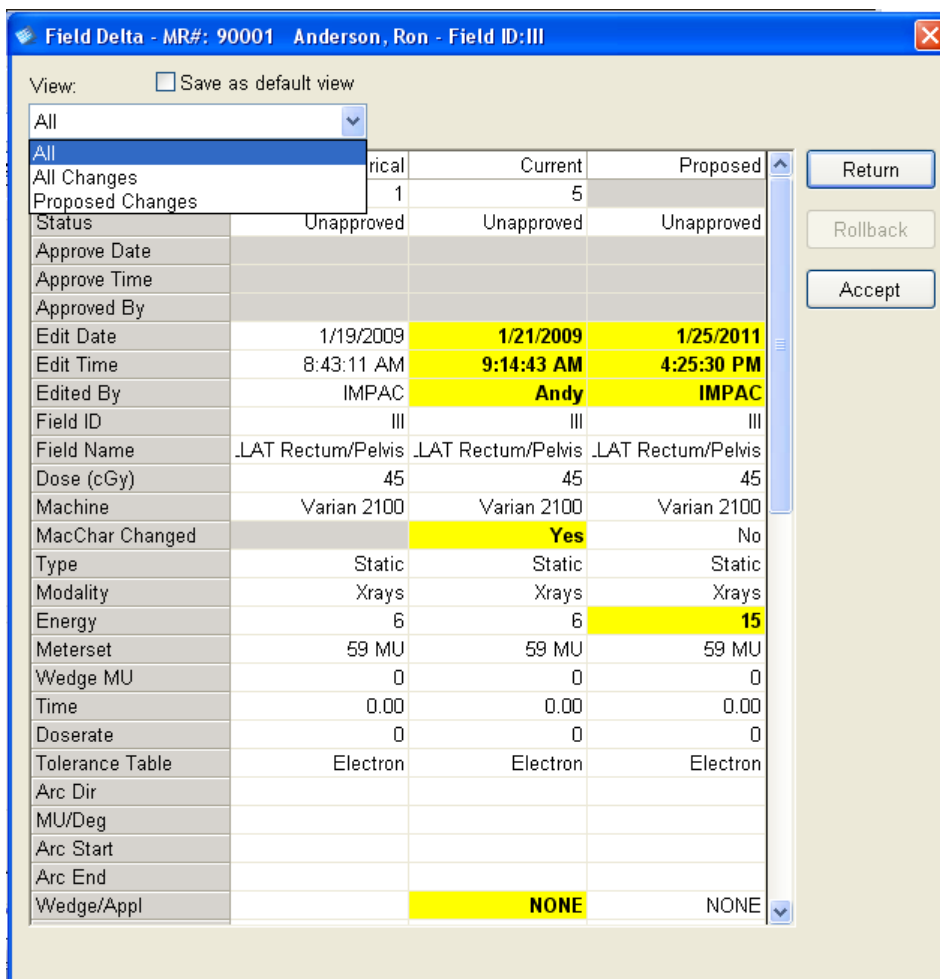
MOSAIQ: Field Edit Delta Display

MOSAIQ's Field Edit Delta display feature is designed to minimize the risk of applying inadvertent changes to the Treatment Field Definition form. It lists and/or highlights the changes to the Treatment Field Definition form since the last approval or delivery of the associated treatment field. Prior to version 2.41, MOSAIQ was shipped with this feature enabled, but a user with sufficient application rights could disable it in Department Setup according to a site's clinical preferences.

A patient was mistreated after a user made and saved an inadvertent change to the definition of a treatment field in MOSAIQ. The mistreatment occurred at a site that had disabled the feature. After the mistreatment, Elekta re-assessed the risk and concluded that it outweighed any benefit of allowing users to disable the feature. Beginning with MOSAIQ 2.41, the Field Edit Delta Display is no longer configurable (i.e. it cannot be disabled by a user).

Elekta AB owns and operates IMPAC Medical Systems, Inc. the manufacturer of MOSAIQ

In addition to the Field Edit Delta display feature, the following measures reduce the risk of applying inadvertent treatment field definition changes:

- Field change warnings option at the time of delivery – pre-treatment check
- Field change warnings option at the time of delivery – field selected for delivery
- The Beams Eye View in the treatment field definition form is a clear visual indicator of any changes to Jaw positions and/or MLC shape

Recommendation

For all sites running MOSAIQ versions below 2.41, Elekta strongly recommends that you check MOSAIQ's Department Setup for the Field Edit Delta Display option. If it is enabled (checked), keep it enabled. If it is disabled (unchecked), enable it by checking the corresponding box and saving the change. Although there is no foolproof means to completely prevent the application of inadvertent changes, and ultimately the user is responsible for all changes made, the Field Edit Delta Display has proven to be an effective means to reduce the related risk. An upgrade to MOSAIQ 2.41 is not necessary to reduce the risk and is not mandatory.

Configurable Risk Mitigations

Elekta would like to take this opportunity to make you aware of these other configurable settings that help to ensure that your patients receive the treatment that was planned. Please note that while Elekta has determined that the risks related to disabling these features have been reduced to as low as reasonably practicable (ALARP) by product design and other risk control measures, there is a greater residual risk if you choose to disable any of them than if you keep them enabled. Elekta recommends that you retain the manufacturer's settings with which the product is installed and upgraded.

Feature	Benefit
Verification Configuration	Patient verification is configurable for conventional radiotherapy. The Verification Configuration window lets departments customize machine and patient-related parameter verification. It lets you configure which parameters are verifiable.
Require Field Approval for Treatment Delivery	A beam that is not approved will not be available for treatment.
Require Calibration Approval for Treatment Delivery	For proton therapy, a beam with a calibration status that is not approved will not be available for treatment delivery.
Verify Machine	Used to enable treatment machine verification. The system verifies that the machine connected to the MOSAIQ workstation is the same machine specified in the treatment field.
Dose Tracking Check	If the user selects a field for treatment that will not contribute dose to its prescription site, or is not associated with a prescription site, the user is alerted by a warning message.
Use Secondary ID (IDB) for Medical Image Import	This feature enables you to associate medical images with the patient's secondary identifier.
Lock Field On Plan Import	Locks the status of a treatment field when you import it from RTP Import. The default is not selected. If selected, all treatment fields imported from RTP Import are locked when imported. If you select this option, be aware that you cannot change the field ID or delete the field once it is imported. To change the field ID of the treatment field, you must do it at the time of the import.
Barcode or fingerprint scanning	The patient may be selected by scanning either their patient-specific barcode or their fingerprint.
Disable Capture Console	Used to disable automatic capture of the treatment machine console settings.
Confirm Selection of Auto-Setup	Used to display the Send Auto-Setup Parameters message box when you click Auto-Setup in the Verified Treatment dialog box.
Auto Groups	Parameters can be assigned to Auto groups, which are defined in the configuration file. These groups are structured such that each group moves independently. Applies to Varian C-Series linacs only.
Auto Setup	Auto Setup is configurable and each parameter may be turned off. Each treatment machine may have different parameters that are available for auto setup.

For questions, concerns, and requests for upgrade, email support@impac.com (North America and Rest of World) or europe.support@impac.com (Europe) or call:

United States	1-800-488-4672	Netherlands	00 800 4672 2222
Australia	1-800-420692	New Zealand	0800-449224
Austria	0800 005 003	Portugal	8008-60282
Belgium	0800-71560	Singapore	800-1204294
France	0800-901281	Spain	900-991937
Germany	0800-664-4968	Sweden	020-79-3490
Hong Kong	800-901702	Switzerland	0800-561563
Ireland	1-800-570033	Taiwan	00801-13-7789
Israel	1-80-9214848	United Kingdom	00-800-4672-2222
Italy	800-787669		
General European (toll charged)	44 1293 654320		

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Please distribute this notice to any and all users of MOSAIQ at your organization who are potentially affected by this issue.

ELEKTA

Confirmation of Receipt

Product	MOSAIQ
Subject	MOSAIQ: Field Edit Delta Display
Reference	CAR0271

Please sign and date this form and return it in one of the three ways indicated below

I acknowledge receipt and understanding of this notice.

Site Name _____

Recipient's Name _____

Recipient's Title _____

Signature _____

Date _____

NORTH AMERICA and ASIA	EUROPE and AFRICA

Fax to: **702-992-5002**
    / **ATTN: Elekta OIS Support**
	Fax to: **+44 (0)1293 654401**
	    / **ATTN: Elekta OIS support**

Scan and email to : **support@impac.com**
    / **ATTN: Elekta OIS Support**
	Scan and email to : **europe.support@impac.com**
	    / **ATTN: Elekta OIS Support**

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    USA
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	    UK