URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Incorrect Movement of the Treatment Table

Product: MOSAIQ®

Scope: Sites affected will be those:
1. Running MOSAIQ® and,
2. Treating on linear accelerators with the RATM license

Notification Released: June, 2017

Description of Problem:
The Machine Characterization (MAC) file is instrumental to the correct operation of MOSAIQ® and your Elekta Linac. Patient safety is a priority and of paramount of importance for us.
Elekta has become aware of the potential for incorrect characterization of couch values, which would lead to incorrect table movement when using Couch Move Assistant (CMA) feature in MOSAIQ®.
Verification tests are included with this notice. It is mandatory that you complete these tests before proceeding with any further patient treatments.

Details:
If the MAC file is set up incorrectly, it is possible that table shifts can be made in the wrong direction.

Clinical Impact:
Patients can be treated at the wrong table position.

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

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Recommended User Action:
If you are using the Couch Move Assistant (CMA) feature in MOSAIQ®, please run the verification test(s) below to ensure that your table is operating correctly. You should only run the tests applicable to your clinical workflows on all of your Elekta linacs that are configured for CMA. If the test(s) pass successfully, please sign the Acknowledgement form and return the form to Elekta. If the test(s) fail please contact your local Elekta Care Support Center for assistance.

If you are not using the CMA feature in MOSAIQ®, please sign the Acknowledgement form, add a note to confirm that the CMA functionality is not used at your clinic and then return the form to Elekta.

If you have questions about the applicability of this customer notification, please contact your local Elekta Care Support Center before completing and returning the Acknowledgement form to Elekta.

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MOSAIQ Elekta Customer Verification Test for the Automated Table Movement

This document specifies the tests for customer verification of the Automated Table Movement (ATM). This includes the Couch Move Assistant (CMA). This verification checklist outlines the necessary tests for Elekta Service personnel and customers to ensure the integrity of the installed applications in the configured environment. The intent is that the site personnel test each item, and if satisfied, initial and date each item to confirm their verification. Items in the checklist that are not installed or configured must be marked "N/A" (not applicable).

1 Prerequisites

To complete this verification, a patient with these requirements is necessary:

- Reference images
  - CT
  - 4 DRRs (AP/PA, Left and Right Lateral)
- RT Plan with Structure Sets
- Imaging fields:
  - MV fields (AP and RT Lateral)
  - kV fields (PA and LT Lateral, for SYNERGISTIQ only)
  - CT field (for SYNERGISTIQ only)

You can use an existing QA or a phantom patient if they have all the necessary requirements. If it is necessary to create a patient, see step 1 in

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Promoting the RTP Plan into MOSAIQ.

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2 Machine Characterization Approval

Machine Characterization Approval for verification Test

☐ Approve the Machine Characterization if necessary.

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3 Creating your Reference Data

ID	Test Step
1	CT scan your Image Guided Radiotherapy (IGRT) phantom. Make sure the CT data set information of the IGRT phantom, such as the patient name, medical record number, gender, and DOB are the same in the Treatment Planning System (TPS), MOSAIQ, and XVI. This makes sure that the SYNERGISTIQ workflow is successful. For a non-SYNERGISTIQ workflow, it is good clinical practice to make sure that all data is consistent between the systems. You can also use the reference data of the ball bearing phantom that is provided with XVI.
2	Make sure that the isocenter is placed accurately on the IGRT phantom in the TPS. This makes sure that the IGRT test outcomes are clinically acceptable according to the phantom specific user manual.
3	Contour additional structures to facilitate with IGRT if necessary.
4	Create 4 beams (AP/PA, RT LAT/LT LAT) that are 10 x 10 cm field size, 10 MU, and set the collimator to 0 with associated DRRs. In MOSAIQ, check the **Use for Tx Definition** checkbox for the DRRs.
5	Export the CT images, RT Structure Sets, and the RT Plan to the MOSAIQ software and include the DRRs. For non-SYNERGISTIQ workflows, export the CT images, RT Structures Sets, and the RT Plan to XVI.

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4 Promoting the RTP Plan into MOSAIQ

ID	Test Step
1	Create the patient in the MOSAIQ software with the same name, medical record number, gender, and DOB to match the information in the TPS.
2	Promote the RT Plan in the MOSAIQ software. **Note**: Do not use any special characters or symbols in the prescription names and keep them under 16 characters long.

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4.1 Site Setup

ID	Test Step
1	Click **Site Setup** in the Diagnoses and Interventions window.

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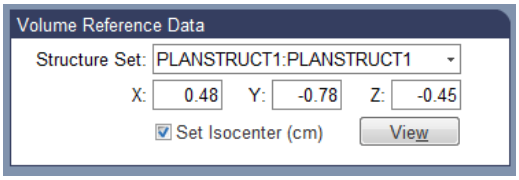
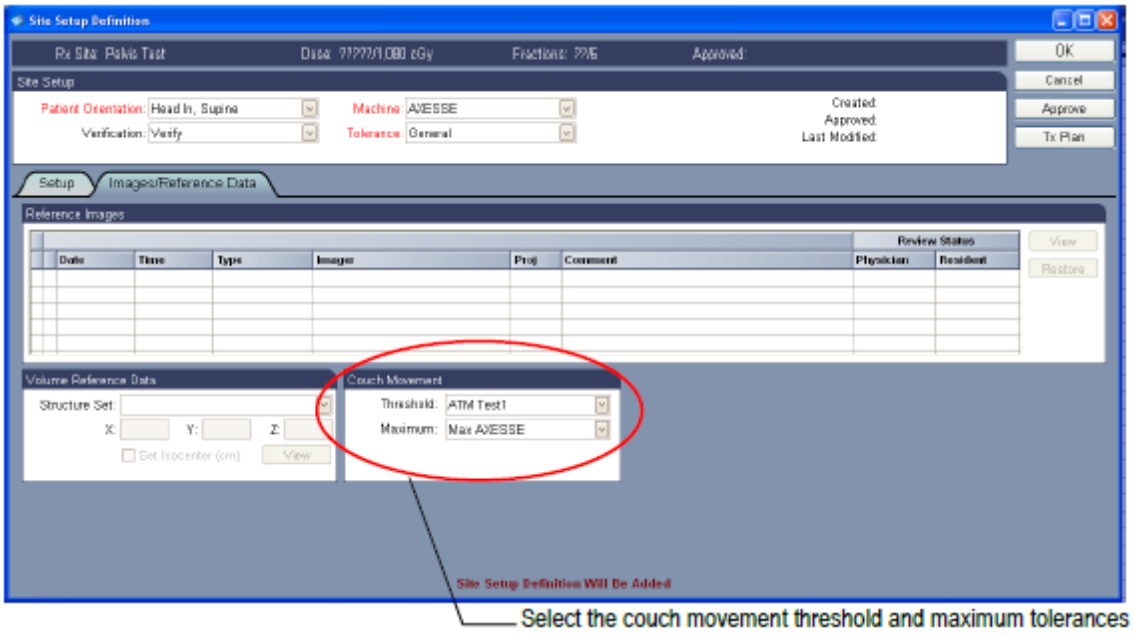
ID	Test Step
2	Select the **Volume Reference Data** tab (in MOSAIQ 2.60 and higher) or the **Images/Reference Data** tab (in MOSAIQ 2.50) and verify the Isocenter placement.  In the Site Setup Definition, make sure that the table values are selected in the **Couch Movement** group. Make sure the table **Threshold** and **Maximum** values are set before you approve the Site Setup Defintion. **Note**: Configure the table Threshold and Maximum values in the Department Setup See LPNMSQ0061, Automated Table Movement Product Note for more information. 
3	Approve the Site Setup Definition.

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4.2 Imaging Fields Set Up only for SYNERGISTIQ

ID	Test Step
1	Open the PA and LT LAT treatment fields. • Change the **Type** field to **KV Setup**. • Add the appropriate **Source** angle: 180 for PA and 90 for Left Lateral. • Select the **XVI Preset that is most appropriate for your phantom.**
2	Create a CT field. • Select a field and click **Tx Field**. • Change the **Type** field to **CT**. • Select the **XVI Preset that is most appropriate for your phantom.**

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5 Loading Reference Data to XVI from MOSAIQ Test only for SYNERGISTIQ

ID	Test Step
1	Launch this software: • MOSAIQ on the SEQUENCER • XVI: Click the **MOSAIQ** button. • iView
2	Select the patient in the MOSAIQ software.
3	Click **RO Treat**.
4	Click **QA Mode**.

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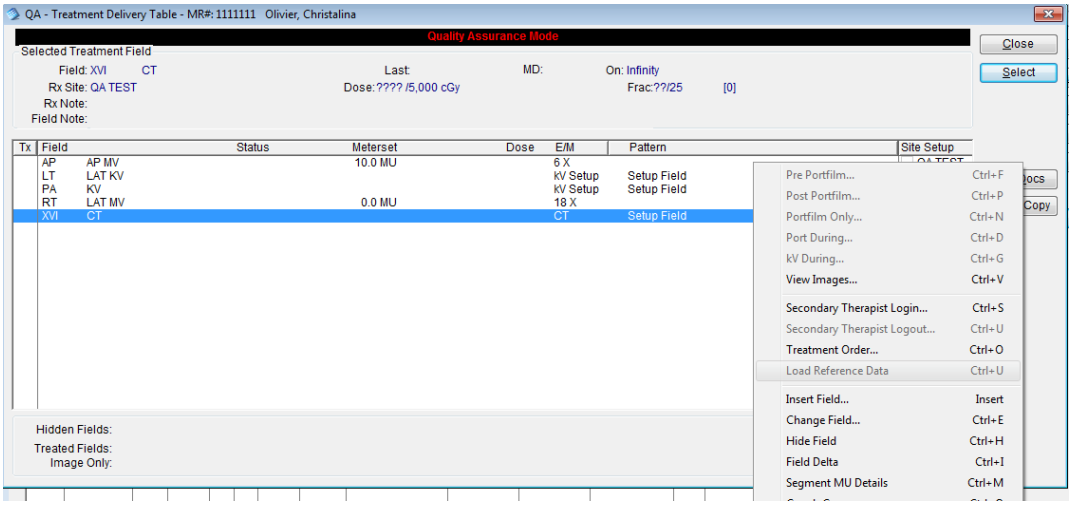
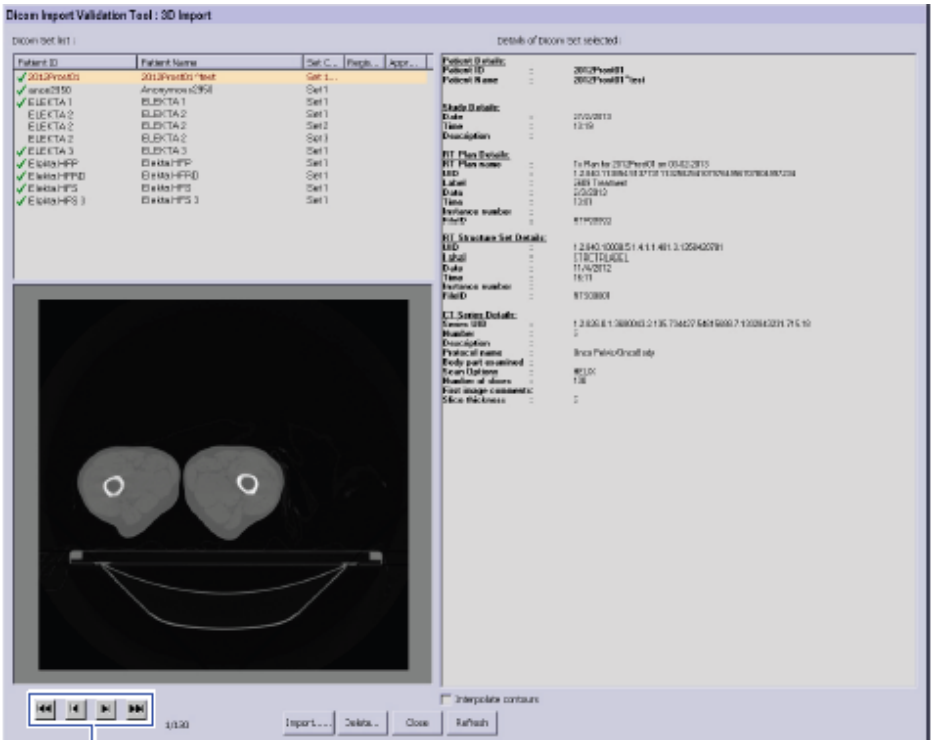
ID	Test Step
5	In the Treatment Delivery Table, right-click and select **Load Reference Data.** 
6	Make sure the DIVT: 3D Import window opens in XVI. The patient name is listed with a green check mark next to it. Select the name and click **Import**. 

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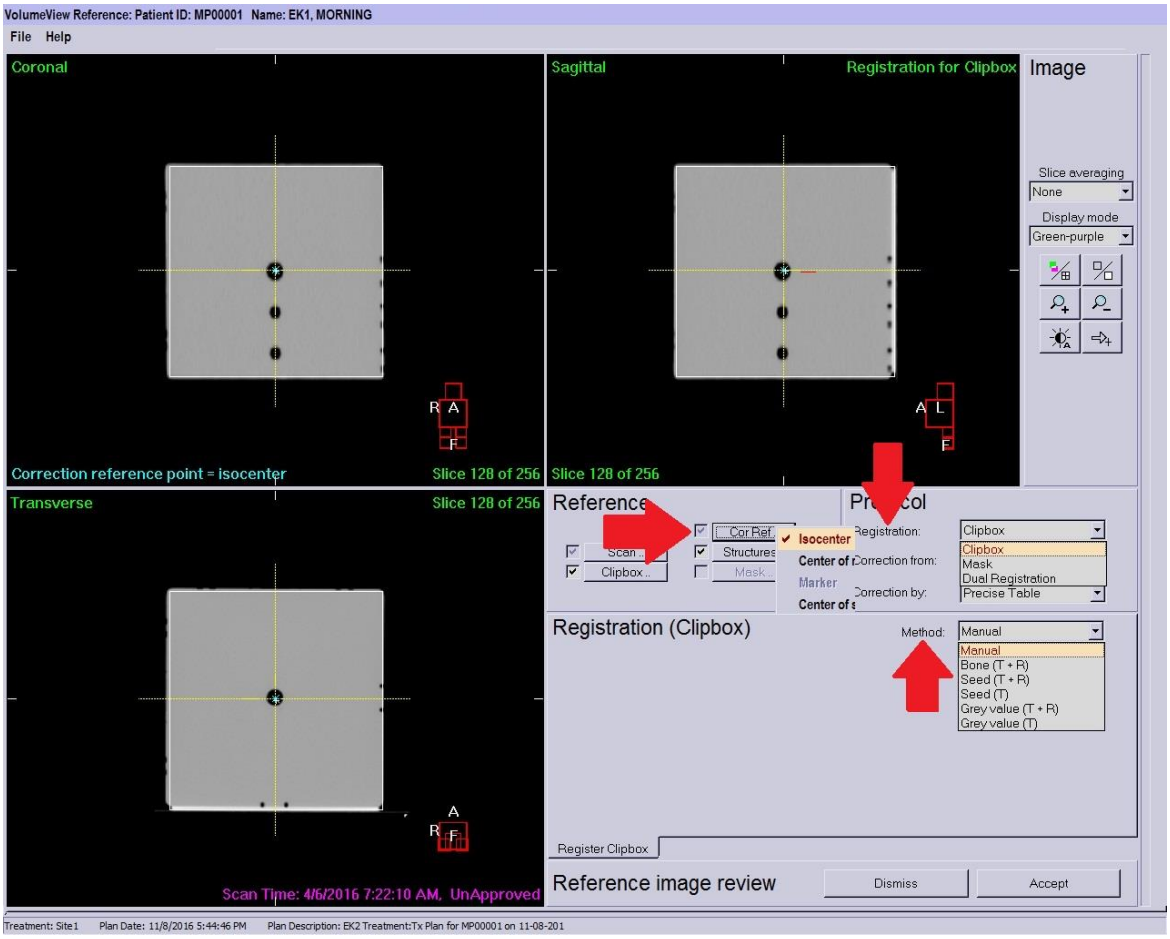
ID	Test Step
7	Set these Reference Volume fields in the VolumeView Registration window: • Correction Ref: **Isocenter** • Registration: **Clipbox** • Method: **Manual** 
8	Click **Accept**.

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6 3D Image Review: XVI VolumeView Test with Precise Table

ID	Test Step
1	Place the IGRT phantom on the treatment table, and line up to the crosshairs/lasers (use gantry crosshairs at 0, 90 and 270 degrees if lasers are floating). Make sure the orientation and level of the IGRT phantom is correct. Set up your IGRT phantom to the offset in all 3 axis before you proceed with imaging. Refer to the user manual of your IGRT phantom regarding the offset.
2	Select the **CT** field in the MOSAIQ software (SYNERGISTIQ only)
3	Verify the preset listed in the **CT** field in the MOSAIQ software matches the selected Preset in XVI. (SYNERGISTIQ only)
4	Move the gantry into position and set up the XVI hardware to clear the interlocks in XVI.
5	Click **kV Beam On** to acquire the CBCT.
6	Use the **Manual method** to Register the 2 images. Make sure the isocenter and any TPS contours line up on the “Localization” scan the same way they were drawn on the “Reference” scan.

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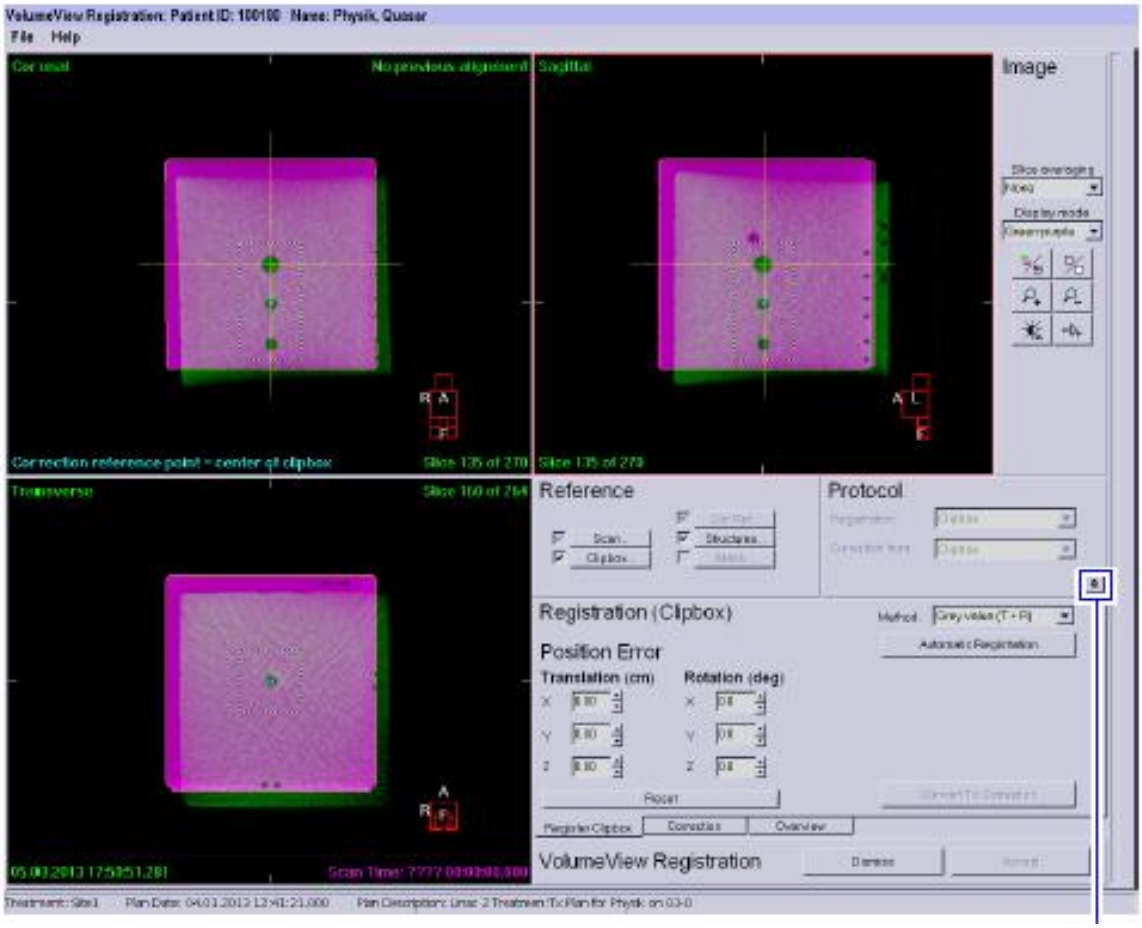
ID	Test Step
7	When the images are closely aligned, use the **Grey value (T)** registration for the Precise table. 
8	Click **Convert to correction**, note the calculated shifts, and click **Accept**.
9	Verify that the shift values and directions match in XVI and the Couch Move Assistant (CMA) window in the MOSAIQ software.
10	In the MOSAIQ software, if Distributed Review is licensed in XVI, click **Send** in the Couch Move Assistant (CMA) window. If Distributed Review is not licensed in XVI, click **Send/Record.**
11	Verify the **Set** and **Actual** positions match what is in the Couch Move Assistant (CMA) window and the **Console Integrity Table** tab.
12	Use the Function Keypad to auto move the table.

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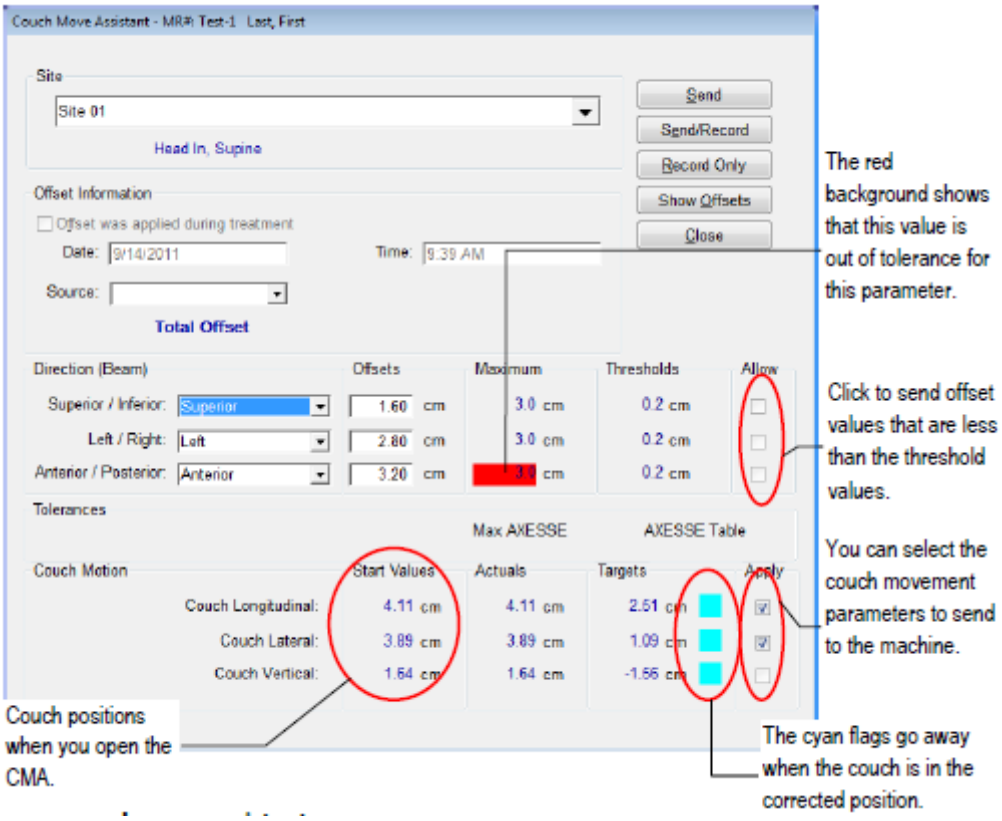
13	Go inside the room and make sure that the table moved in the correct direction and with the correct values by verifying that the lasers are on the isocenter of the phantom. Refer to the user manual for each specific IGRT phantom for information regarding clinically acceptable tolerances.
14	Click **Close** in the Couch Move Assistant (CMA) window. 
15	Record the **CT Field** in MOSAIQ.
16	Right-click and select **Localization Trend Review.**
17	Verify that the shifts are recording correctly.
18	Close the Treatment Delivery Table and go to the Home workspace.
19	Click **Images** on the Consolidated Work List.
20	Verify the CBCT image for the patient displays in the Work List.
21	Highlight the CBCT image and click **Review** in the Work List Details pane to open the Image Review window.

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ID	Test Step
22	Make sure the CBCT and CT overlay in the Image Review Workspace and the Third Party Offset (TPO/SRO) is applied. If Distributed Review is licensed in XVI, the SROs are exported through DICOM and the CBCT is automatically associated to the correct site with the shifts associated. If Distributed Review is not licensed in XVI, click the **Site** field and select the correct site and associated TPOs, then click **Save.**
23	Perform orthogonal KV imaging followed by registration in MOSAIQ to confirm that the table moves were correct.

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7 2D kV: XVI PlanarView Test

ID	Test Step
1	Put the IGRT phantom on the treatment table and line up to the crosshairs/lasers (use gantry crosshairs at 0, 90 and 270 degrees if lasers are floating). Make sure the orientation and level of the IGRT phantom is correct. Set up your IGRT phantom to the offset in all 3 axis before you continue with imaging. Refer to the user manual of your IGRT phantom regarding the offset.
2	Select the Left Lateral **kV Setup** field.
3	Verify that the field name and preset match in XVI and MOSAIQ (SYNERGISTIQ only)
4	Move the gantry into position and set up the XVI hardware to clear the interlocks in XVI. The MOSAIQ software does not provide positional verification for kV fields. Make sure you are at the correct gantry angle on **Integrity** before you **kV beam on.**
5	Acquire the kV field and make sure it auto exports out of XVI to MOSAIQ.
6	Record the kV field in the MOSAIQ software.
7	Repeat steps 1-6 for the PA kV Setup field. The kV images from XVI 5.0 and above will auto associate to the kV field in MOSAIQ. Prior versions of XVI must manually associate the kV image to the kV field (XVI 4.2 and 4.5).
8	Close the Treatment Delivery Table and go to the Home workspace.
9	Click the **Images** tab on the Consolidated Work List.
10	Verify that the kV images for the patient display in the Work List.
11	With MOSIAQ 2.5, highlight both kV images in the image worklist and click **Review** in the Work List Details pane to open the Image Review window. With MOSAIQ 2.60 and forward, select one of the orthogonal images and click **Calculate Offset** and both images will be selected.

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12	Click **Register** in the Image Review window to open the MOSAIQ Stereoscopic Image Registration window for a 2D kV image match. • Choose **Manual Registration** to align the isocenter and the TPS contours of the DRR with the kV portal image. **Greyscale Registration** can be difficult because the phantoms may not have high density material to allow for a robust registration. • Click **OK** to "Accept" the shifts.
13	Make sure the Couch Move Assist window shows the offset values and click **Send**.
14	Verify that the **Actuals** and **Set** values are correct in the MOSAIQ software and on the Linac Integrity console.
15	Go inside the room and make sure that the table moved in the correct direction and with the correct values by verifying that the lasers are on the isocenter of the phantom. Refer to the user manual for each specific IGRT phantom for information regarding clinically acceptable tolerances

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8 2D MV: iViewGT Imaging Test (for sites without XVI)

ID	Test Step
1	Put the IGRT phantom on the treatment table and line up to the crosshairs/lasers (use gantry crosshairs at 0, 90 and 270 degrees if lasers are floating). Make sure the orientation and level of the IGRT phantom is correct. Set up your IGRT phantom to the offset in all 3 axis before you continue with imaging. Refer to the user manual of your IGRT phantom regarding the offset.
2	Open the patient chart, click **RO Treat**, choose **QA Mode** and select the **AP MV field**, RMC and select **Portfilm Only**. Once the treatment field is populated on Integrity, place the iViewGT in **iCom** mode to auto populate the treatment field into iViewGT and acquire a single exposure. Record the **AP MV field** in the MOSAIQ software. Repeat for the **RT LAT MV Field.**
3	The portal images should auto export from iViewGT to MOSAIQ.
4	Close the Treatment Delivery Table and go to the Home workspace.
5	Click the **Images** tab on the Consolidated Work List.
6	Verify that the MV images for the patient display in the Work List.

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7	With MOSIAQ 2.5, highlight both MV images in the image worklist and click **Review** in the Work List Details pane to open the Image Review window. With MOSAIQ 2.60 and forward, select one of the orthogonal images and click **Register** and both images will be selected
8	In the Stereoscopic Image Registration window select one of the images and choose **Manual Registration** method. Click **Calculate Offset**
9	Align the isocenter and the TPS contours of the DRR with the MV portal images. Click **OK** to "Accept" the shifts.
10	Make sure the Couch Move Assist window shows the offset values and click **Send**.
11	Verify that the **Actuals** and **Set** values are correct in the MOSAIQ software and on the Linac Integrity console. Move the Table using the FKP.
12	Go inside the room and make sure that the table moved in the correct direction and with the correct values by verifying that the lasers are on the isocenter of the IGRT phantom. Refer to the user manual for each specific IGRT phantom for information regarding clinically acceptable tolerances

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Elekta Corrective Actions:
At this time Elekta is investigating whether any further corrective action is required.

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:	371-01-MSQ-011
Description	Incorrect Movement of the Treatment Table		

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:

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