IMPORTANT FIELD SAFETY NOTICE

PRODUCT: XVI R3.5, R4.0, R4.2, and R4.5

Date: 01-2013 **FCO Ref:** 200 01 507 071

Different DICOM RT structures with the same name show incorrectly in XVI

This Notice contains important information about the operation of your product. Elekta recommends that all users of the product follow the instructions or recommendations in this Notice.
This Notice must be put in the Important Notice section of the applicable manual.

If you have any queries about this Notice, contact your local Elekta office.

Scope: XVI R3.5, R4.0, R4.2, and R4.5

Problem: In some treatment planning systems (TPS), you can contour more than one region of interest with the same structure name. The DICOM tags do not contain sufficient information for XVI to identify the different volumes that have the same name. Therefore, if you use DICOM RT to send these volumes as one list of contours, it can cause XVI to:

- Interpolate a contour that identifies the two structures as one structure.
- Change the contour shape of the volumes in the imported CT reference data and structure sets.

Example 1: XVI changes the contour to identify the two structures as one structure. In this example, the two initial volumes are in line with each other.

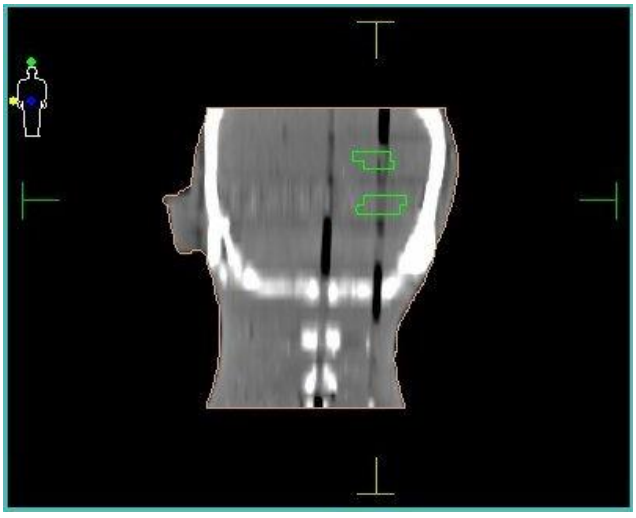

Figure 1: Two different volumes with the same structure name in the treatment planning system

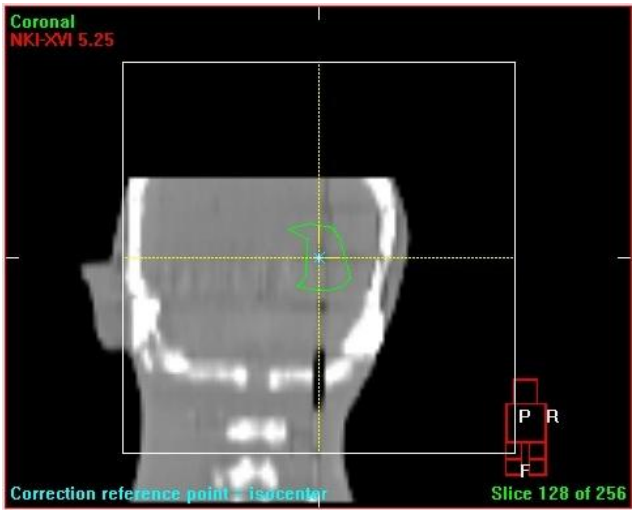

Figure 2: The two different volumes change into one volume in XVI

This Notice has been notified to the appropriate Regulatory Authority

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Example 2: XVI does not make one contour from the two contours, but it does change the shape of the two contours.

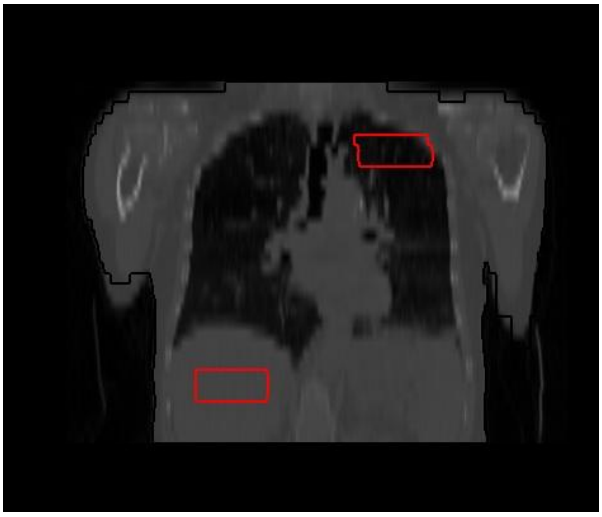

Figure 3: Two different volumes with the same structure name in the treatment planning system

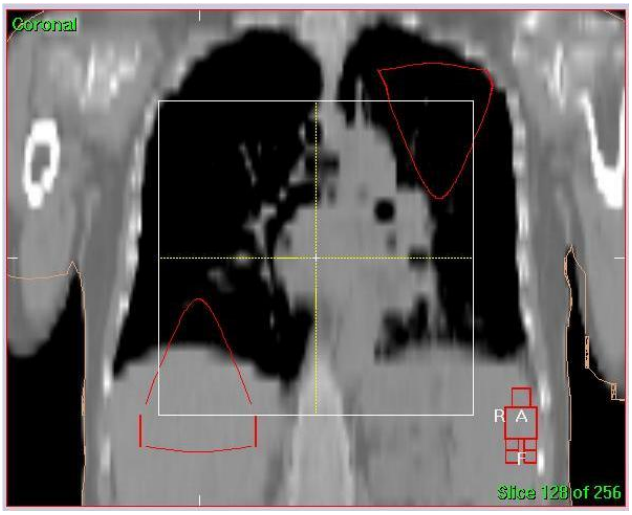

Figure 4: The shape of the contours changes in XVI

TPS usually show structure sets as a sequence of points on the axial CT slices. When these CT slices are imported into XVI and reconstructed into a 3D volume, XVI uses interpolation and triangulation algorithms to show the structure sets in 3D space in the VolumeView™ window. Assumptions are made in the interpolation procedure that are not always correct, and this can cause unusual results.

Clinical impact: XVI uses the clinical target volume (CTV) or planning target volume (PTV) structures from the TPS to make sure that the target in the VolumeView™ is in the correct position. Therefore, when XVI changes the contour shapes for the CTV or PTV, it can cause an incorrect clinical decision. This can cause clinical mistreatment.

Solution: In the TPS, give the different volumes different structure names.

After you import the patient data set from the TPS, make sure that the structure contours are correct.

A later software release of XVI will give a solution to this problem.

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Safety reference:

The following warnings and cautions are associated with this notice:

WARNING:
When you import data into the XVI patient database from the XVI DICOM transit database, make sure that all data is correct before you do the import. If the data is not correct, it can cause clinical mistreatment.

WARNING:
When you approve patient reference data, you must make sure that the correct CT image, RT plan, and structure set are imported. You must make sure that the CT image data set is complete, the plan and the isocenter are correct, and that the structure set is accurate. Make sure that all information related to orientations, scaling and points of origin are imported correctly from the treatment planning system (TPS). If you ignore this warning, it can cause clinical mistreatment.

WARNING:
When you approve patient reference data, you must make sure that the correct CT image, RT plan, and structure set are imported. You must make sure that the CT image data is complete, the plan and the isocenter are correct, and that the structure set is accurate. Make sure that all information related to orientations, scaling and points of origin are imported correctly from the TPS. If you ignore this warning, it can cause clinical mistreatment.

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FCO ACTION NOTIFICATION REPORT

<Give this Notice to the customer, and then complete and return this report to your local Elekta Office or Representative for the Configuration Database.>

Classification:	Important Field Safety Notice	**FCO Ref:**	200 01 507 071
FCO description:	Different DICOM RT structures with the same name show incorrectly in XVI		
Scope:	XVI R3.5, R4.0, R4.2, and R4.5		

Hospital:	
Device Serial No: (e.g. linac - if applicable)	**Location or Site No:**

Action on this unit/device was: (*select one*)

Note: If you use a work-order in the CLM configuration database, then you do not have to complete this section. The work-order will be used to add the information to the system.

☐ Completed as per instructions on: <date day/month/year]>

☐ Not completed because: **(***give reasons*)

☐ Not completed because the unit/device is in storage *(if applicable).*

☐ Refused by customer because: **(***give reasons*)

Acknowledgement by customer:
This notification to be signed by the customer.

The REASON and PURPOSE of this notice has been explained.

Name: ..... Title: .....

Signature: ..... Date: .....

This Notice has been notified to the appropriate Regulatory Authority

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