

Field Safety Notice, Medical Device Correction #52889 #52672 #52971

**RayStation 4.0, RayStation 4.3 (InverseArc),
RayStation 4.5, RayStation 4.7, RayStation
4.9 (RayPlan 1), RayStation 5, RayStation 6
(RayPlan 2), RayStation/RayPlan 7,
RayStation/RayPlan 8A,
RayStation/RayPlan 8B and
RayStation/RayPlan 9A**

**December 18th, 2019
RSL-D-61-406**

ISSUE

This notice concerns three issues found with RayStation 4.0, RayStation 4.3 (InverseArc), RayStation 4.5, RayStation 4.7, RayStation 4.9 (RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2), RayStation/RayPlan 7, RayStation/RayPlan 8A, RayStation/RayPlan 8B and RayStation/RayPlan 9A:

- i. The Map ROI options in the ROI list in the Structure Definition module may generate unintended ROI geometries
- ii. Elekta guard leaf behavior. There is an interoperability issue with Elekta regarding setting of guard leaves.
- iii. SSD, when intended as source-to-surface distance, it sometimes gives source-to-skin distance.

To the best of our knowledge, these issues have not caused any patient mistreatment or other incidents. However, the user must be aware of the following information to avoid incorrect dose calculations during treatment planning.

INTENDED AUDIENCE

This notice is directed to all users of RayStation, who use

- multiple image sets for organ delineation or
- Elekta LINACs or
- DRR images for setup or
- scripts using SSD.

PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayStation 4.0, RayStation 4.3 (InverseArc), RayStation 4.5, RayStation 4.7, RayStation 4.9 (RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2), RayStation/RayPlan 7, RayStation/RayPlan 8A, RayStation/RayPlan 8B and RayStation/RayPlan 9A. To determine if the version you are using is affected, open the About RayStation dialog in the RayStation application and check if the build number reported there is “4.0.0.14”, “4.0.1.4”, “4.0.2.9”, “4.0.3.4”, “4.3.0.14”, “4.5.0.19”, “4.5.1.14”, “4.5.2.7”, “4.7.0.15”, “4.7.1.10”, “4.7.2.5”, “4.7.3.13”, “4.7.4.4”, “4.7.5.4”, “4.9.0.42”, “5.0.0.37”, “5.0.1.11”, “5.0.2.35”, “6.0.0.24”, “6.1.0.26”, “6.1.1.2”, “6.2.0.7”, “6.3.0.6”, “7.0.0.19”, “8.0.0.61”, “8.0.1.10”, “8.1.0.47”, “8.1.1.8”, “8.1.2.5” and “9.0.0.113”. If so, this notice applies to your version.

The UDIs of the affected product versions:

Product name (build number)	UDI
RayStation 4.0 (4.0.0.14) to RayStation 5 Service Pack 2 (5.0.2.35)	N/A
RayStation 6/RayPlan 2 (6.0.0.24)	0735000201001320161214
RayStation 6/RayPlan 2 Service Pack 1 (6.1.0.26, 6.1.1.2)	0735000201003720170501, 0735000201008220170529
RayStation 6/RayPlan 2 Service Pack 2 (6.2.0.7)	0735000201007520170630
RayStation 6/RayPlan 2 Service Pack 3 (6.3.0.6)	0735000201024220190923
RayStation/RayPlan 7 (7.0.0.19)	0735000201006820171130
RayStation/RayPlan 8A (8.0.0.61)	0735000201011220180608
RayStation/RayPlan 8A Service Pack 1 (8.0.1.10)	0735000201013620180918
RayStation/RayPlan 8B (8.1.0.47)	0735000201012920181209
RayStation/RayPlan 8B Service Pack 1 (8.1.1.8)	0735000201020420190214
RayStation/RayPlan 8B Service Pack 2 (8.1.2.5)	0735000201023520190524
RayStation/RayPlan 9A (9.0.0.113)	0735000201017420190612

DESCRIPTION

i. Map ROI options in the ROI list may generate unintended ROI geometries

There is an issue with the options ‘Map ROI(s)’ and ‘Map ROI(s) reversed’, only available by right-clicking in the ROI list in the Structure Definition module, that may lead to unintended ROI geometries when mapping ROIs using a rigid-only registration.

If the rigid registration is modified after the Structure Definition module was first opened, the modifications will not be taken into account when mapping ROIs between the image sets. Instead, the rigid registration that existed between two image sets when the Structure Definition module was opened will be used for mapping ROIs. This means that the mapping will use an obsolete transformation leading to unintended ROI geometry positions.

ii. Elekta guard leaf behavior

Since the Elekta delivery system may adjust leaves in the treatment plan, the delivered plan may not match the plan the dose was computed for.

Elekta guard leaves are the first leaves behind the y-jaws that are moved to the same position as the last leaf pair in the field. All leaf positions must be fully specified in the treatment plan. Because of this, guard leaves are set by the Treatment Planning System (TPS). However, the Record and Verify (R&V) system or the Treatment Control System (TCS) can have a feature that automatically sets guard leaf positions that

will override the prescription from the TPS for those leaves. It might be possible to select this feature in the R&V system or in the TCS. Contact the suppliers of your R&V system and TCS for more information.

Be aware that the guard leaf positions in RayStation may vary for different plan types:

- When openings are created in the 3D-CRT module using “Treat and protect”, RayStation does not open any additional leaf pair behind the y-jaws for Elekta machines.
- Similarly, when segments are manually edited (Edit MLC and jaws) – no additional leaf pair is opened.
- However, RayStation does open one additional leaf pair for Elekta machines in some other workflows:
 - Optimization: only for 3D-CRT and SMLC, not for DMLC and VMAT.
 - Create rectangular field

Note that extra leaf pairs will be opened only for segments where the y-jaws are positioned exactly at the edge of a leaf.

There is no setting in RayPhysics that allows the user to set if an additional leaf pair shall be opened. The decision is based on the relative positions of the MLC and the jaws; if the MLC is closer to the source than the jaws, the jaws are considered to be “the primary collimator” and the leaves open to get a sharper penumbra.

iii. SSD: `beam.GetSSD()` and SSD in DRR

The script method `beam.GetSSD()` can return source-to-skin distance instead of the expected source-to-surface distance, depending on when it is run. The same issue affects the SSD display in DRR views in the report and in exported DRRs. In addition, in RayStation 4.0, 4.5 and 4.3 InverseArc, the SSD in the report DRR may show other values than the source-to-skin or source-to-surface distance. The magnitude of the error will depend on the extension of any bolus, fixation or support ROI in the beam center path.

The issue affects electron, photon and BNCT beams only, since `beam.GetSSD()` cannot be used for ion beams and SSD is not displayed in the DRR for ion beams. Only scripting, exported DRRs and DRR images in the plan report are affected. SSD in the plan report is correct in the Beam data section, where both the source-to-skin and source-to-surface values are displayed. SSD is also correct in the RayStation graphical user interface (GUI).

For setup beams, the DRRs show correct value, but the script method is affected by the issue.

ACTIONS TO BE TAKEN BY THE USER

- i. Do not use the options ‘Map ROI(s)’ or ‘Map ROI(s) reversed’, only available by right-clicking in the ROI list. Instead, use the Copy ROI geometries dialog available in the Structure Definition module or the Map ROIs dialog available in the Deformable Registration module.
- ii. Be aware that the Elekta guard leaf setting from RayStation may be overridden by the R&V system or TCS. Contact the suppliers of your R&V system and TCS for more information. Scripting can be used to position the guard leaves according to the settings of the delivery system to avoid the overrides.
- iii. Do not use the `beam.GetSSD()` scripting method. If needed in scripting, see RayCommunity.
- iv. Do not use the SSD value displayed in the DRR in the plan report or exported DRR. Instead, use the SSD value displayed in the Beam data section of the plan report.

Please educate planning staff and all users about these workarounds.

Inspect your product and identify all installed units with the above software version number(s), then confirm you have read and understood this notice by replying to the notification email.

SOLUTION

i. The Map ROI issue will be resolved in a future version of RayStation, scheduled for market release in May 2020 (subject to market clearance in some markets).

ii. The Elekta guard leaves issue will be resolved in a future version of RayStation, scheduled for market release in May 2020 (subject to market clearance in some markets).

iii. The SSD issue will be resolved in the next version of RayStation, scheduled for market release in December 2019 (subject to market clearance in some markets).

If customers wish to continue using versions of RayStation affected by this notice, all users must maintain awareness of this notice. Alternatively, customers can choose to upgrade to the new version once it becomes available for clinical use.

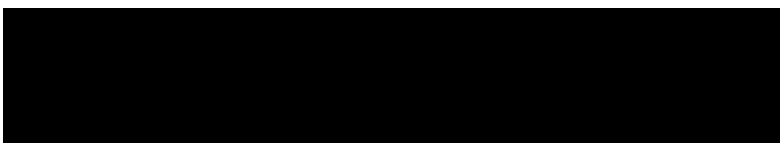
TRANSMISSION OF THIS NOTICE

This notice needs to be passed on to all those who need to be aware within your organization. Please maintain awareness of this notice as long as any version of RayStation affected by this issue is in use to ensure effectiveness of the workaround.

Thank you for your cooperation, and we apologize for any inconvenience.

For regulatory information, please contact quality@raysearchlabs.com

The undersigned confirms that the appropriate Regulatory Agencies will be notified.



PLEASE CONFIRM THAT YOU HAVE RECEIVED THIS FSN

Reply to the same email address that sent you this notice, stating you have read and understood it.

Alternatively, you can email or phone your local support to acknowledge this notice.

If you want to attach a signed reply form to the email, please fill in the below. You can also fax this form to 888 501 7195 (US only).

From: _____ (name of institution)

Contact person: _____ (please print)

Telephone no: _____

Email: _____

I have read and understood the notice.

Comments (optional):
