

Field Safety Notice, Medical Device Correction #56089

**RayStation 4.0, 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, RayStation/RayPlan 9A and
RayStation/RayPlan 9B**

March 3, 2020

RSL-D-61-413

ISSUE

This notice concerns an issue found with the dose calculation for Siemens™ Virtual Wedge in RayStation 4.0, 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, RayStation/RayPlan 9A and RayStation/RayPlan 9B.

To the best of our knowledge, the issue has 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/RayPlan who use RayStation/RayPlan for calculating dose for Siemens Virtual Wedge.

Only Siemens Virtual Wedge is affected. If this is not in use at your clinic you do not need to read further. **However, please confirm that you have read and understood this notice by replying to the notification email.**

PRODUCT NAME AND VERSION

The products affected by this notice are sold under the trade names RayStation 4.0, 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, RayStation/RayPlan 9A and RayStation/RayPlan 9B. To determine if the version you are using is affected, open the About RayStation/RayPlan dialog in the RayStation/RayPlan 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", "4.5.0.19", "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", "4.7.6.7", "4.9.0.42", "5.0.0.37", "5.0.1.11", "5.0.2.35", "5.0.3.17", "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", "9.0.0.113" or "9.1.0.933". If so, this notice applies to your version.

UDI-DI of the affected products:

Product name (build number)	UDI-DI
RayStation 4.0 (4.0.0.14) to RayStation 5 Service Pack 2 (5.0.2.35)	N/A
RayStation 5 Service Pack 3 (5.0.3.17)	07350002010020
RayStation 6/RayPlan 2 (6.0.0.24)	07350002010013
RayStation 6/RayPlan 2 Service Pack 1 (6.1.0.26, 6.1.1.2)	07350002010037, 07350002010082
RayStation 6/RayPlan 2 Service Pack 2 (6.2.0.7)	07350002010075
RayStation 6/RayPlan 2 Service Pack 3 (6.3.0.6)	07350002010242
RayStation/RayPlan 7 (7.0.0.19)	07350002010068
RayStation/RayPlan 8A (8.0.0.61)	07350002010112
RayStation/RayPlan 8A Service Pack 1 (8.0.1.10)	07350002010136
RayStation/RayPlan 8B (8.1.0.47)	07350002010129
RayStation/RayPlan 8B Service Pack 1 (8.1.1.8)	07350002010204
RayStation/RayPlan 8B Service Pack 2 (8.1.2.5)	07350002010235
RayStation/RayPlan 9A (9.0.0.113)	07350002010174
RayStation/RayPlan 9B (9.1.0.933)	07350002010266

DESCRIPTION

Due to physical limitations of the treatment machine, the maximum field opening for Siemens Virtual Wedge fields recommended by the LINAC vendor will be more restricted in the wedged direction than the maximum field opening without a wedge. Delivering a larger field opening with a virtual wedge will not result in a wedged field shape over the entire field. Instead, a high dose plateau region will be the result at the toe side of the field beyond the recommended field size, see Figure 1.

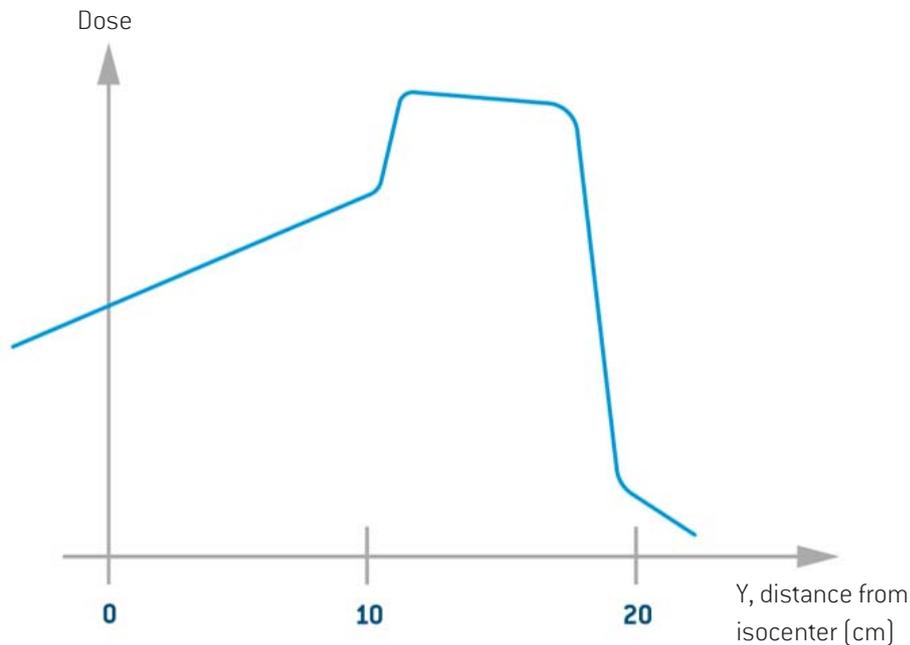


Figure 1. Example of delivered dose shape for a Siemens Virtual Wedge field outside LINAC vendor recommended field size. A high dose plateau region is formed at the toe side of the wedge beyond the recommended field size. This high dose plateau is never included in the RayStation/RayPlan dose calculation.

The field size limitation for Siemens Virtual Wedge depends on which MLC type the LINAC is equipped with and is due to hardware limitations such as the overtravel of the moving jaw. The field size limitation may be different for different wedge angles. For information about a specific LINAC treatment machine setup, refer to the LINAC vendor.

The high dose plateau region will occur at the toe side of the wedge if the requested field size is outside of the LINAC vendor recommendations. The toe side of the wedge is towards the stationary jaw.

Siemens Virtual Wedge implementation in RayStation/RayPlan

The RayStation/RayPlan implementation for Siemens Virtual Wedge is based on the assumption that the high dose plateau region should never be included in a treatment plan. Thus, the high dose plateau region is not accounted for in the RayStation/RayPlan dose computation for virtual wedges, irrespective of how the machine model is set up in RayPhysics.

In RayStation/RayPlan, it is assumed that the same Y jaw overtravel is applicable both for open fields and for fields with virtual wedges. The jaw overtravel limit is set by the *Minimum Y2 jaw position* parameter in RayPhysics shown in Figure 2.

RayStation/RayPlan will calculate a wedged beam shape for Siemens Virtual Wedge up to the overtravel limit of the Y jaws defined by the *Minimum Y2 jaw position* parameter. RayStation/RayPlan will also refuse to calculate dose for a virtual wedge if the field opening is larger at the toe end of the field than the *Minimum Y2 jaw position* parameter.

In addition to the *Minimum Y2 jaw position* parameter, the wedge parameters *Field size limits* (Figure 3) in RayPhysics will restrict the field openings possible to plan with in RayStation/RayPlan for a virtual wedge

field. Towards the toe side of a virtual wedge, either the *Minimum Y2 jaw position* parameter or the *Field size limits Max Y* parameter will determine the allowed maximum opening.

Towards the heel side of the virtual wedge, the *Field size limits Min Y* parameter will set the restriction. For more information about setting the *Field size limits* parameters, see section *Setting wedge field size limits in RayPhysics on page 6* below.

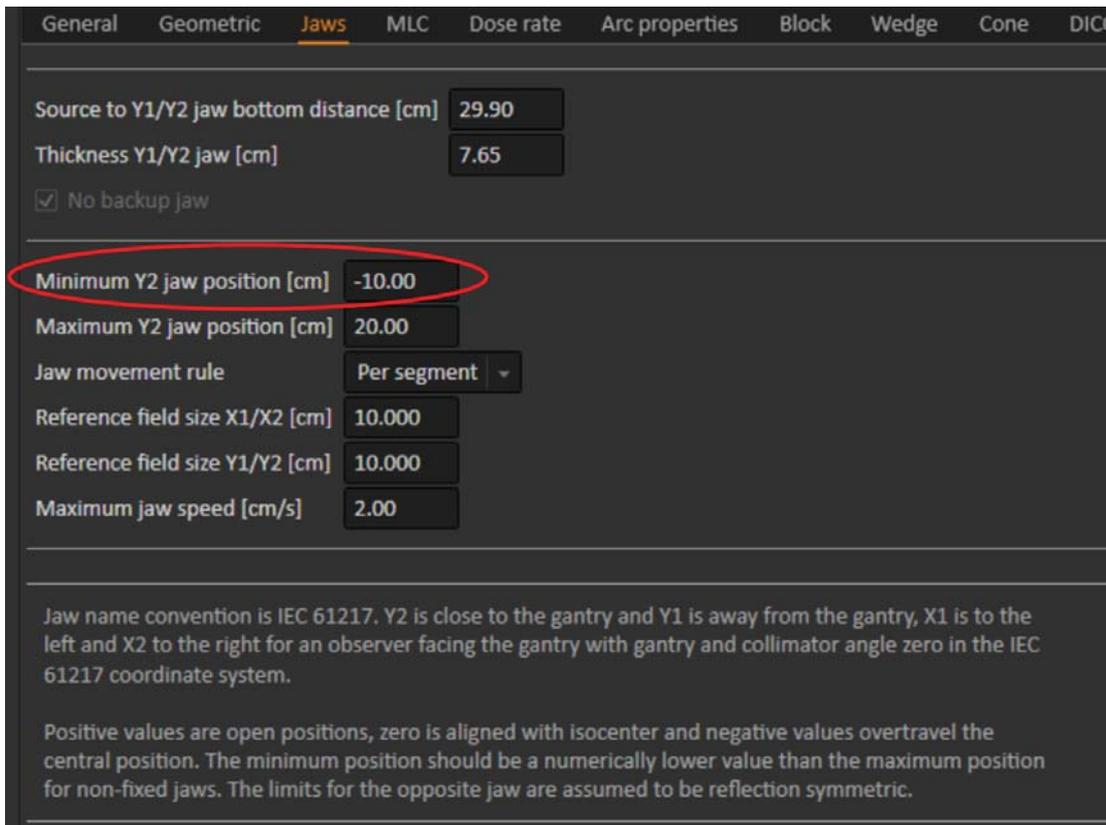


Figure 2. The *Minimum Y2 jaw position* parameter in RayPhysics sets the maximum allowed jaw overtravel in RayStation/RayPlan for both open fields and virtual wedge fields.

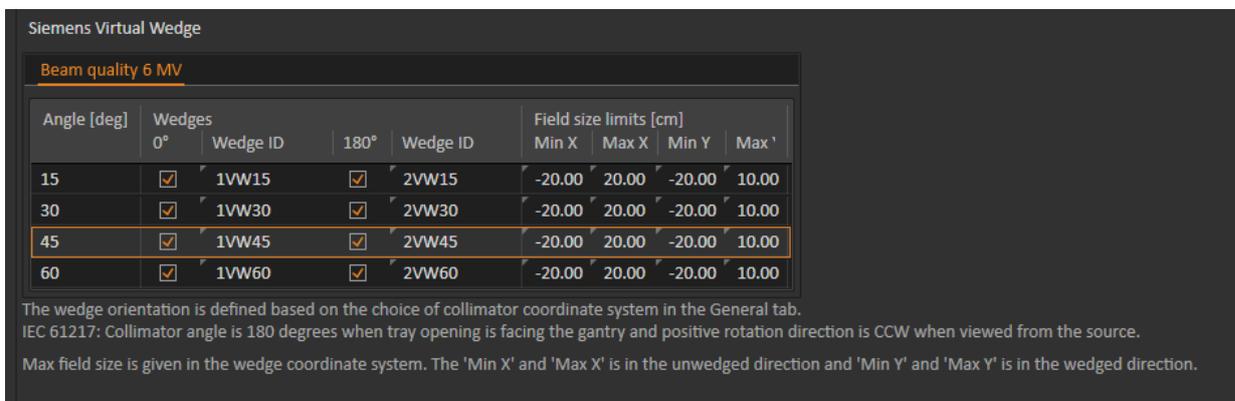


Figure 3. The wedge *Field size limits* parameters in RayPhysics shall be used to restrict the allowed field size for wedged fields. Note that the *Field size limits* are given in the wedge coordinate system.

If the combination of the *Minimum Y2 jaw position* and wedge *Field size limits* parameters in the machine model is set up to allow dose computation outside the LINAC vendor recommended field sizes, this will result in a difference between delivered dose and RayStation/RayPlan computed dose, see Figure 4.

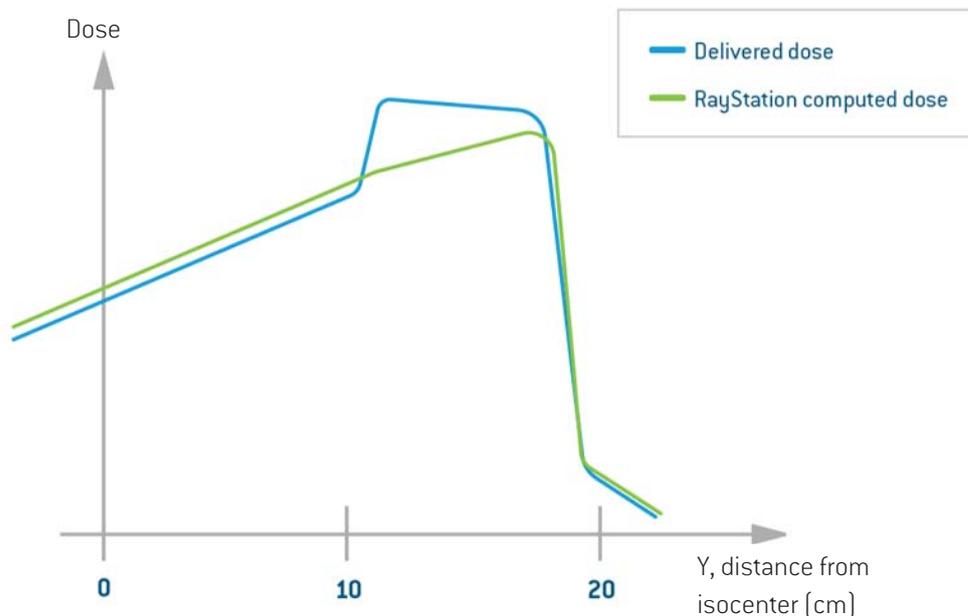


Figure 4. Example of difference between Delivered dose (blue line) and RayStation/RayPlan computed dose (green line) for a Siemens Virtual Wedge field outside LINAC vendor recommended field size, if the machine model in RayStation/RayPlan has been set up to allow too large Siemens Virtual Wedge fields.

ACTIONS TO BE TAKEN BY THE USER

- Do not use Siemens Virtual Wedge fields outside the Siemens recommended specification. If a field outside the recommended specification with a virtual wedge is sent to the LINAC, the treatment machine console (console software versions 8 and higher) will display a warning message, for example “**Initial gap > 1 cm! Proceed (y/n)?**”, or “**The distance between the static jaw and the moving jaw is greater than 1 cm. Do you want to continue? (y/n)**”. If this happens, select ‘n’ to prevent the treatment machine from delivering the field.
- In RayPhysics, use the wedge *Field size limits* parameters (Figure 3) to restrict the maximum allowed field size for a wedged field, see *Setting wedge field size limits in RayPhysics on page 6* below for details.
- Verify through measurement at the LINAC that a wedged shape is delivered for the maximum field opening allowed by the *Field size limits* parameters for each wedge angle for Siemens Virtual Wedge before clinical use.

Please educate planning staff and all users about this workaround.

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

Setting wedge field size limits in RayPhysics

Depending on which MLC type the LINAC is equipped with, the proper values for the wedge *Field size limits* parameters differ. Refer to the LINAC vendor for information about a specific LINAC treatment machine setup. The field size limits are given in the wedge coordinate system which is further described in the next section, *IEC 61217 wedge filter coordinate system on page 7*. In addition to the wedge *Field size limits* parameters, the RayPhysics parameter *Minimum Y2 jaw position* will restrict the possible field sizes that can be planned with a Siemens Virtual Wedge field in RayStation/RayPlan. RayStation/RayPlan will refuse to calculate dose with a virtual wedge if the field opening extends further at the toe end of the field than the *Minimum Y2 jaw position*.

This section gives examples on how to set the wedge *Field size limits* parameters to achieve a desired field size limit when planning in RayStation/RayPlan. The numbers are examples which will not be the correct numbers for all Siemens LINACs. Refer to the LINAC vendor for information about a specific LINAC treatment machine setup. Verify that a wedged shape is delivered by the LINAC for the selected maximum field opening allowed by the *Field size limits* parameters for all wedge angles.

To define a symmetric field that is maximum 20 cm wide in the wedged direction, set Min Y = -10 cm and Max Y = 10 cm. To define an asymmetric field size with a 20 cm opening towards the heel end of the field and a 10 cm opening towards the toe end of the field, i.e., the moving jaw going from 10 cm overtravel to fully open, set Min Y = -20 cm and Max Y = 10 cm. An example of this setup is shown in Figure 5.

It is not possible to define a constant maximum opening for both symmetric and asymmetric fields for wedges in RayPhysics. In the case of a maximum possible virtual wedge field opening of 30 cm, both central and off-axis, the wedge *Field size limits* should be set to Min Y = -15 cm and Max Y = 15 cm to avoid creating a virtual wedge field that will result in the high dose plateau region. These *Field size limits* will restrict the possibility to use a 30 cm field fully off-axis but are necessary to prevent virtual wedge fields resulting in a high dose plateau region.

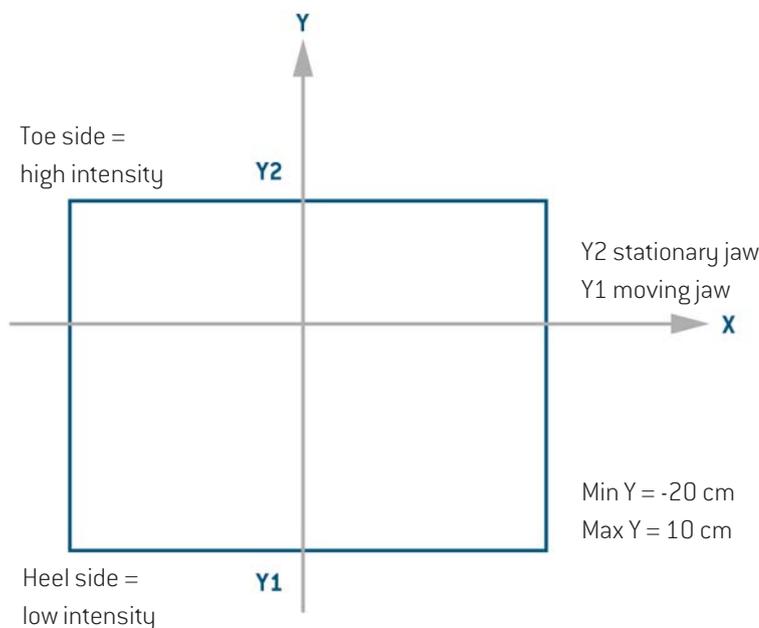


Figure 5. Example of Y jaw settings for virtual wedge with wedge orientation 0° , i.e., the IEC 61217 wedge filter and beam-limiting device coordinate system coincide. Y1 is the moving jaw and Y2 is the stationary jaw. To achieve a RayStation/RayPlan machine model that supports 20

cm opening towards the heel end of the field and 10 cm opening towards the toe end of the field, i.e., the moving jaw going from 10 cm overtravel to fully open, wedge *Field size limits* in the y-direction should be set to Min Y = -20 cm and Max Y = 10 cm.

IEC 61217 wedge filter coordinate system

The machine coordinate systems in IEC 61217 are a set of coordinate systems, each defined in relation to its mother coordinate system, starting with a fixed coordinate system which has the origin at the isocenter, the positive x-direction to the right for an observer facing the gantry, the positive y-axis from the isocenter towards the gantry along the axis of gantry rotation and the positive z-axis directed upwards from the isocenter.

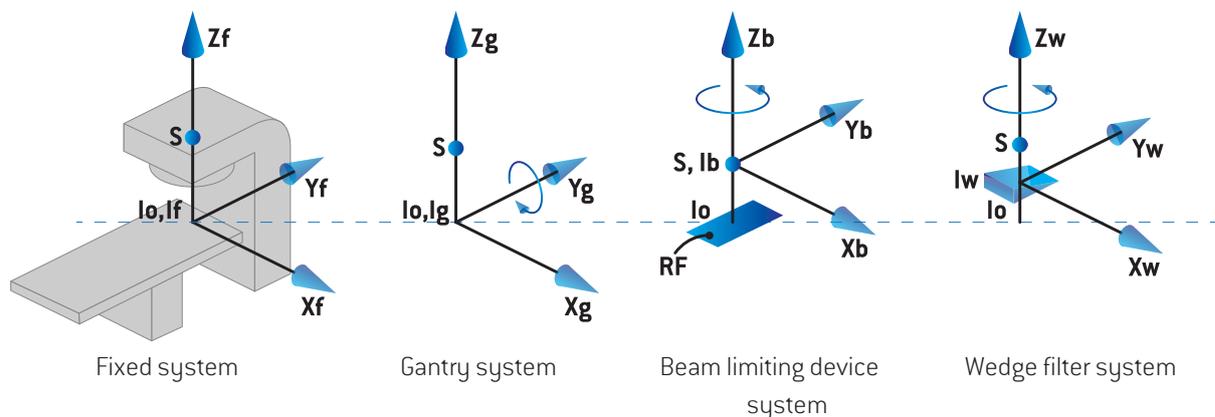


Figure 6. Machine coordinate system translations from IEC 61217 Fixed system to IEC 61217 Wedge filter system.

The wedge filter coordinate system rotates with the wedge and the positive y axis points from heel to toe of the wedge. The wedge filter coordinate system has the beam limiting device coordinate system as its mother system. In RayPhysics and the main RayStation/RayPlan application, the wedge coordinate system is defined to coincide with the selected collimator coordinate system (IEC 61217 or Non-IEC) for a wedge orientation of zero degrees. For collimator coordinate system IEC 61217, the wedge orientation is zero degrees when the toe points towards the gantry for collimator angle zero. Please refer to the RayStation/RayPlan Instructions for Use for additional information about coordinate systems.

SOLUTION

Enhancements to prevent RayStation/RayPlan from creating plans that would result in a high dose plateau region will be added to the next major version of RayStation/RayPlan, scheduled for market release in May 2020 (subject to market clearance in some markets). If customers wish to continue using versions of RayStation/RayPlan 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.

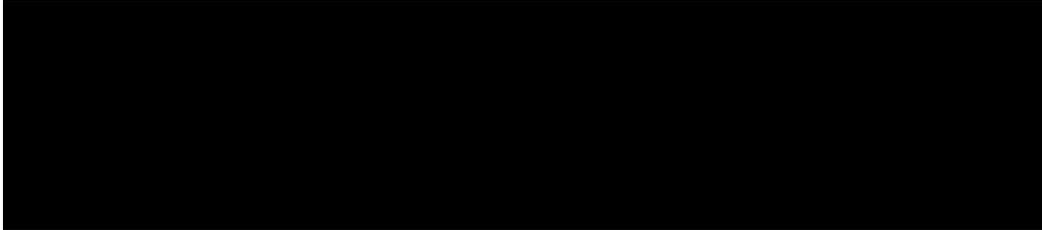
TRANSMISSION OF THIS NOTICE

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/RayPlan 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 NOTICE

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):
