

Field Safety Notice, Medical Device Correction #25955

RayStation 4.9 (RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2) and RayStation 7 (RayPlan 7) January 26th, 2018 RSL-D-61-346

ISSUE

This notice concerns an issue found with the Center Beam in Field functionality in RayStation 4.9 (RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2) and RayStation 7 (RayPlan 7). When more than one beam is defined on the same isocenter, Center Beam in Field (CBF) affects all beams in a way that the user may not expect.

After using CBF, the resulting fields are clearly displayed in RayStation/RayPlan for review and approval. However, one mistreatment incident using the CBF functionality has been reported where the user failed to review the resulting beam apertures before treatment delivery.

INTENDED AUDIENCE

This notice is directed to all users of RayStation/RayPlan who use the Center Beam in Field functionality.

PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayStation 4.9 (RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2) and RayStation 7 (RayPlan 7). To determine if the version you are using is affected, open the About RayStation dialog in the RayStation/RayPlan application and check if the build number reported there is "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 or 7.0.0.19". If so, this notice applies to your version.

DESCRIPTION

The Center Beam in Field (CBF) functionality is intended for adjusting the isocenter for a beam while, as far as possible, keeping the irradiated area the same. When beams share an isocenter, e.g., after creating an opposed beam, using CBF on one beam will affect all beams that are defined with the same isocenter.

For the selected beam, CBF behaves as expected. However, additional beams that share the same isocenter are edited with the default behavior for isocenter edits, i.e., moving the aperture with the isocenter rather than adjusting the aperture to keep the same irradiated area. Even if the user selects all beams before CBF, the behavior is the same.

For photon beam shaping, areas to treat or protect can be defined with the **Aperture shaping** tools. The drawn aperture shapes are defined relative to the beam isocenter, not relative to the patient. When using CBF, areas to treat or protect will move with the isocenter in the same way as an aperture for additional beams, and can therefore not be used as a reference for the intended irradiated area.

Detectability of this problem is very high. The apertures are correctly used in dose calculation and are clearly displayed in RayStation/RayPlan for review and approval. The unexpected CBF behavior is only a problem if the plan is not properly reviewed before it is approved for treatment.

ACTIONS TO BE TAKEN BY THE USER

- Be aware that Center Beam in Field affects all beams that share the same isocenter and that apertures may be modified in a way not intended.
- Do not use Center Beam in Field after having created an opposed beam. If an opposed beam has been created, delete the opposed beam and use Center Beam in Field on the remaining beam. Then recreate the opposed beam.

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 you have read and understood this notice by replying to the notification email.

SOLUTION

This issue will be resolved in the next version of RayStation/RayPlan, scheduled for market release in May 2018 (subject to market clearance in some markets). If customers wish to continue using versions of RayStation/RayPlan affected by this Field Safety Notice, all users must maintain awareness of this Field Safety Notice. Alternatively, customers can choose to upgrade to the new version once it becomes available for clinical use.

TRANSMISSION OF THIS FIELD SAFETY 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 David Hedfors, david.hedfors@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):

