Field Safety Notice, Medical Device Correction #74977

RayStation 4.5, 4.7, 4.9, 5, 6, 7, 8A, 8B, 9A, 9B, 10A, 10B, RayPlan 1, 2, 7, 8A, 8B, 9A, 9B, 10A, 10B, including some of the service packs

To determine if your version is affected, see build numbers listed in PRODUCT NAME AND VERSION below

February 19th , 2021
RSL-P-RS FSN Class III 74977

ISSUE

This notice concerns an issue found with the Merge beams functionality in RayStation/RayPlan. For some LINAC types, merging clinical beams with beams of approximate dose may lead to the approximate dose erroneously labeled as clinical dose. Merge beams can be used manually, in scripting, or as part of the Automated breast planning feature.

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 3D-CRT or IMRT photon planning in RayStation/RayPlan who use LINAC models with Jaw movement rule set to 'Per segment', such as Elekta Agility, or LINAC models with Jaw movement rule set to 'Fixed' and 'Dual-layer MLC', such as Varian Halcyon.

LINAC models with Jaw movement rule set to 'Per beam' are not affected by this notice. Likewise, models with Jaw movement rule set to 'Fixed' are not affected unless they are modelled as 'Dual-layer MLC'.

Only treatment plans with the treatment techniques 3D-CRT and SMLC are affected. Plans with other treatment techniques, such as VMAT, Conformal Arc, Static Arc and DMLC, are not affected. Plans for TomoTherapy machines are not affected. Neither are plans for electrons, protons, carbon ions or helium ions.

PRODUCT NAME AND VERSION

Affected versions: RayStation 4.5, 4.7, 4.9, 5, 6, 7, 8A, 8B, 9A, 9B, 10A, 10B, RayPlan 1, 2, 7, 8A, 8B, 9A, 9B, 10A, 10B, including some of the service packs. 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 '4.5.1.14', '4.7.2.5', '4.7.3.13', '4.7.4.4', '4.7.5.4', '4.7.6.7', '4.9.0.42', '5.0.1.11', '5.0.2.35', '5.0.3.17', '6.0.0.24', '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', '9.1.0.933', '9.2.0.483', '10.0.0.1154', '10.0.1.52' or '10.1.0.613'. If so, this notice applies to your version.

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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 (6.1.1.2)	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
RayStation/RayPlan 9B Service Pack 1 (9.2.0.483)	07350002010297
RayStation/RayPlan 10A (10.0.0.1154)	07350002010303
RayStation/RayPlan 10A Service Pack 1 (10.0.1.52)	07350002010365
RayStation/RayPlan 10B (10.1.0.613)	07350002010310

DESCRIPTION

To support a field-in-field approach, two or more beams can be merged to create a single beam. The Merge beams functionality can be used in three scenarios:

- Manual 'Merge beams' in the 3D-CRT module
- Scripting when using the action MergeBeamSegments
- Automated breast planning

Depending on the beam setup and machine constraints, the dose may be automatically invalidated as part of the merge. However, the dose of the merged beam will be displayed and be incorrectly labeled with the dose engine used for the target beam, that is, the beam that the other beams are merged into.

For performance reasons, optimization of photon plans is performed using the SVD dose engine which is less accurate than the dose engines used for final dose calculation. The dose distribution will then be displayed as 'Approximate' and it will not be possible to approve or export the plan until a final dose calculation using a clinical dose engine has been performed. Dose calculated with a dose engine validated for final dose is displayed as 'Clinical'.

In some cases, when merging two beams where the first beam has clinical dose and the second beam has approximate dose, the dose of the resulting beam will be labeled as 'Clinical', although dose for some of the beam segments is still calculated with the SVD dose engine and it should be labeled 'Approximate: Mixed dose'. The difference between approximate and final 'Clinical' dose is in most cases small, but there can be body sites such as lung where the difference can be significant.

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ACTIONS TO BE TAKEN BY THE USER

- **Manual 'Merge beams' in the 3D-CRT module**
  Scenario: When merging a beam B1 with other beams (e.g., B2 and B3) in the 3D-CRT module.
  Action: If the target beam B1 has a clinical dose before the merge, make sure that all the beams to be merged (B2 and B3) also have a clinical dose computed with the same dose engine.
- **Scripting when using the action MergeBeamSegments**
  Scenario: When running a script containing the action MergeBeamSegments as below:
  beam_set.MergeBeamSegments(TargetBeamName="B1", MergeBeamNames=["B2", "B3"])
  Action: If the target beam B1 has a clinical dose before running the script, make sure that the beams to be merged (B2 and B3) also have a clinical dose computed with the same dose engine.
- **Automated breast planning**
  Scenario: When creating a treatment plan in the Automated breast planning module, the generated breast plan has two beams: A1 and A2.
  Actions:
    1. Change module to Plan optimization.
    2. Invalidate the dose for both the A1 and A2 beams by changing a beam property that can easily be restored (e.g., change the couch angle from 0 to 1).
    3. Set the beam property back to the intended value (e.g., set the couch angle back to 0 for both beams).
    4. Compute final dose.
- Educate planning staff and all users about this workaround.
- Inspect your product and identify all installed units with the above software version number(s).
- **Confirm that 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 2021 (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.

I am approving this document
Stockholm, Sweden
2021.02.19 13:58:24 +01'00'

For regulatory information, please contact quality@raysearchlabs.com

RaySearch will notify the appropriate regulatory agencies about this Field Safety Notice.

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CONFIRMATION OF RECEIPT

<mark>**PLEASE CONFIRM THAT YOU HAVE RECEIVED THIS FSN**</mark>

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):

_____

_____

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