Field Safety Notice, Medical Device Correction #109886

RayStation, RayPlan 9A, 9B, 10A, 10B, 11A, 11B and 12A including service packs
To determine if your version is affected, see build numbers listed in PRODUCT NAME AND VERSION below
16th February, 2023
RSL-P-RS FSN Class III 109886

Issue
This notice concerns issues with DICOM export from the Virtual Simulation module and issues with import of Virtual Simulation plans in RayStation, RayPlan 9A, 9B, 10A, 10B, 11A, 11B and 12A including service packs.

The user must be aware of the following information to avoid incorrect treatment delivery.

Intended audience
This notice is directed to all users of RayStation who use the Virtual Simulation module.

Product Name and Version
The products affected by this notice are sold under the trade names RayStation, RayPlan 9A, 9B, 10A, 10B, 11A, 11B and 12A including service packs. 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 '9.0.0', '9.0.1', '9.1.0', '9.2.0', '10.0.0', '10.0.1', '10.0.2', '10.1.0', '10.1.1', '11.0.0', '11.0.1', '11.0.3', '11.0.4', '12.0.0', '12.1.0', '12.1.1', '12.0.3', '12.1.2', '12.0.4', '12.1.3', '13.0.0', or '13.1.0'. If so, this notice applies to your version.

The single registration number (SRN) of the manufacturer: SE-MF-000001908

Product name (build number)	UDI-DI
RayStation 9A (9.0.0.113)	07350002010174 20190612
RayStation 9A SP1 (9.0.1.142)	07350002010488 20220420
RayStation 9B (9.1.0.933)	07350002010266 20191220
RayStation 9B SP1 (9.2.0.483)	07350002010297 20200310
RayStation 10A (10.0.0.1154)	07350002010303 20200526
RayStation 10A SP1 (10.0.1.52)	07350002010365 20200526
RayStation 10A SP2 (10.0.2.10)	07350002010655 20220608
RayStation 10B (10.1.0.613)	07350002010310 20201216
RayStation 10B SP1 (10.1.1.54)	07350002010471 20220128
RayStation 11A (11.0.0.951)	07350002010389 20210518

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RayStation 11A SP1 (11.0.1.29)	0735000201043320210610
RayStation 11A SP2 (11.0.3.116)	0735000201044020210916
RayStation 11A SP3 (11.0.4.15)	0735000201063120220616
RayStation 11B (12.0.0.932)	0735000201042620211208
RayStation 11B SP1 (12.1.0.1221)	0735000201049520220312
RayStation 11B SPC1 (12.1.1.41)	0735000201058720220330
RayStation 11B SP2 (12.0.3.68)	0735000201050120220422
RayStation 11B SPC2 (12.1.2.91)	0735000201061720220517
RayStation 11B SP3 (12.0.4.12)	0735000201060020220620
RayStation 11B SPC3 (12.1.3.162)	0735000201066220221003
RayStation 12A (13.0.0.1547)	0735000201054920220616
RayStation 12A SP1 (13.1.0.144)	0735000201067920221007

Description
Export
It is possible to set a non-zero collimator angle in the Virtual Simulation module. The angle will be correct in the user interface but if the plan is DICOM exported by using the "VSIM Export" button (see **Figure 1** below), the angle will not be correct in the exported RT plan. In the exported RT plan, the DICOM attribute *Beam Limiting Device Angle (300A,0120)* is set to zero, regardless of the selected collimator angle.

It is also possible to select wedges and cones in the Virtual Simulation module. Any selected wedges or cones will be ignored at export if using the "VSIM Export" button.
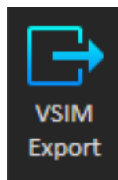

Figure 1. The "VSIM Export" button.

These issues only affect DICOM export from the Virtual Simulation module. If the Virtual Simulation plan is exported from another RayStation module or from the RayStation menu (see **Figure 2** below), the DICOM attribute *Beam Limiting Device Angle (300A,0120)* will be correct and any wedges and/or cones will be included.

Figure 2. The RayStation menu button.

Import
If an RT Plan is imported into RayStation either without defined MU values or including a block with missing information, it will be imported as a Virtual Simulation plan in RayStation. The conditions that need to be fulfilled for this to happen are:

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1. It needs to be a RT Plan with *SOP Class UID (0008,0016)* "1.2.840.10008.5.1.4.1.1.481.5"
2. All beams need to have *Radiation Type (300A,00C6)* "PHOTON" and *Beam Type (300A,00C4)* "STATIC"
3. One or more of the following things needs to be true:
    a. *Number of Blocks (300A,00F0)* is larger than 0 and *Total Block Tray Factor (300A,00F2)* is either missing or outside the interval [0.5, 1.0]
    b. There are more than 2 items in the *Block Sequence (300A,00F4)*
    c. There is at least one block with a *Block Divergence (300A,00FA)* that is not "PRESENT"
    d. There is at least one block with a *Block Transmission (300A,0102)* that is either missing or outside the range [0.0, 0.2]
    e. There is at least one block without a *Block Tray ID (300A,00F5)*
    f. There are two blocks with the same *Block Type (300A,00F8)*
    g. There is a block with *Total Block Tray Factor (300A,00F2)* that does not match the block tray transmission definitions in RayPhysics
    h. There is at least one control point without a *Cumulative Meterset Weight (300A,0134)* value specified

If a plan is imported as a Virtual Simulation plan, the user is notified with an import warning which is also stored in the import log (see **Figure 3** for an example).
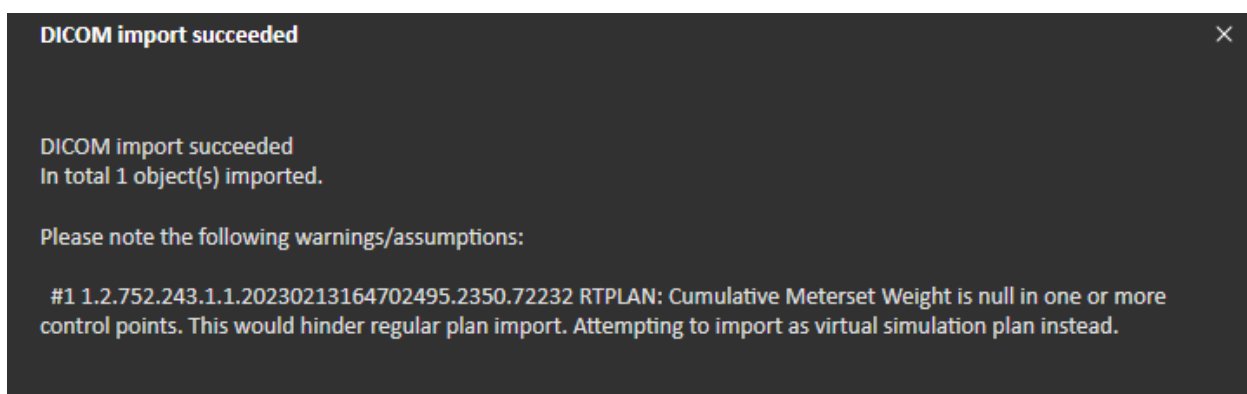

Figure 3. Example of warning displayed when Virtual Simulation import occurs.

If this type of import is triggered there are some attributes that would typically be imported that are ignored. This includes, but is not limited to:

- *Table Top Pitch Angle (300A,0140)* – will be set to 0 by the VSIM import
- *Table Top Roll Angle (300A,0144)* – will be set to 0 by the VSIM import
- Any boli referenced by beams will not be set on the imported beam for an imported virtual simulation plan
- Any wedges included in the imported RT Plan will not be imported
- Any cones included in the imported RT Plan will not be imported
- If the RT Plan contains multiple control points with different MLC positions only the positions of the first control point will be converted into a virtual aperture block

There are several validations not performed for a VSIM import, that would typically generate warnings or block the import completely.

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If dose is calculated for a plan imported as a Virtual Simulation plan, it will correspond to the plan in RayStation, but may not correspond to the original plan.

Actions to be taken by the user

- Be aware that an RT plan exported by using the "VSIM Export" button will always have the DICOM attribute *Beam Limiting Device Angle (300A,0120)* set to zero.
- Be aware that an RT plan exported by using the "VSIM Export" button will always have the DICOM attribute *Number of Wedges (300A,00D0)* set to zero and no wedge information will be exported.
- Be aware that an RT plan exported by using the "VSIM Export" button will never include the DICOM attribute *Applicator Sequence (300A,0107)* and no cone information will be exported.
- Do not use or export Virtual Simulation plans with non-zero collimator angle, wedges or cones using the "VSIM Export" button.
- Be aware that a plan imported as a Virtual Simulation plan may not contain all intended information and that some attributes affecting dose may be different from the original plan.
- Always perform dose computation for imported Virtual Simulation plans before export. Do not use the "VSIM Export" for export of such plans.

- 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 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, scheduled for market release in June 2023 (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. Maintain awareness of this notice as long as any affected version is in use.

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

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

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 Fax: +1-631-828-2137 (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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