

Field Safety Notice, Medical Device Correction #157634

RayStation/RayPlan 2024B

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

May 13, 2025

RSL-P-RS-FSN Class III 157634

ISSUE

This notice concerns an issue found with export of minimum, maximum or average CT sets created from 4D CT sets in RayStation/RayPlan 2024B. The Hounsfield units may be incorrect after DICOM export from RayStation.

To the best of our knowledge, the issue has not caused any patient mistreatment. 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 creating minimum, maximum or average CT sets from 4D CT sets.

PRODUCT NAME AND VERSION

The product affected by this notice are sold under the trade name RayStation/RayPlan 2024B. 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 "16.0.0.847 ". 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/RayPlan 2024B	16.0.0.847	0735000201077820240625

DESCRIPTION

4D CT image sets show the same anatomy over a time range, e.g., a breathing cycle. In RayStation, a standard 3D CT image set can be created from the 4D CT image set by taking the average, maximum or minimum voxel values from the 4D data.

The voxel values in a DICOM CT set are converted to Hounsfield units (HU) that can be used when calculating estimated radiation dose. This is a linear conversion, based on the DICOM attributes *Rescale Intercept (0028,1052)* and *Rescale Slope (0028,1053)*.

If the original 4D voxel data contains values that result in a HU range that cannot be represented with short integer (16 bit) values (-32,768 to 32,767 or 0 to 65,535, depending on if negative values are allowed or not), the *Rescale Slope* and *Rescale Intercept* of the generated average, maximum or minimum CT image set will be incorrect when exported from RayStation. The HU will be correct in RayStation, but if the

generated CT image set is exported and used in another device or re-imported into RayStation, the HU values will be incorrect.

When the error occurs, RayStation incorrectly sets *Rescale Slope* = 1 and *Rescale Intercept* = 0. The magnitude of the error in HU depends on how much these incorrect values differ from the original, correct values.

There are two ways to identify incorrectly exported data, depending on if RayStation or RayPlan is used:

Option 1: Using scripting in RayStation

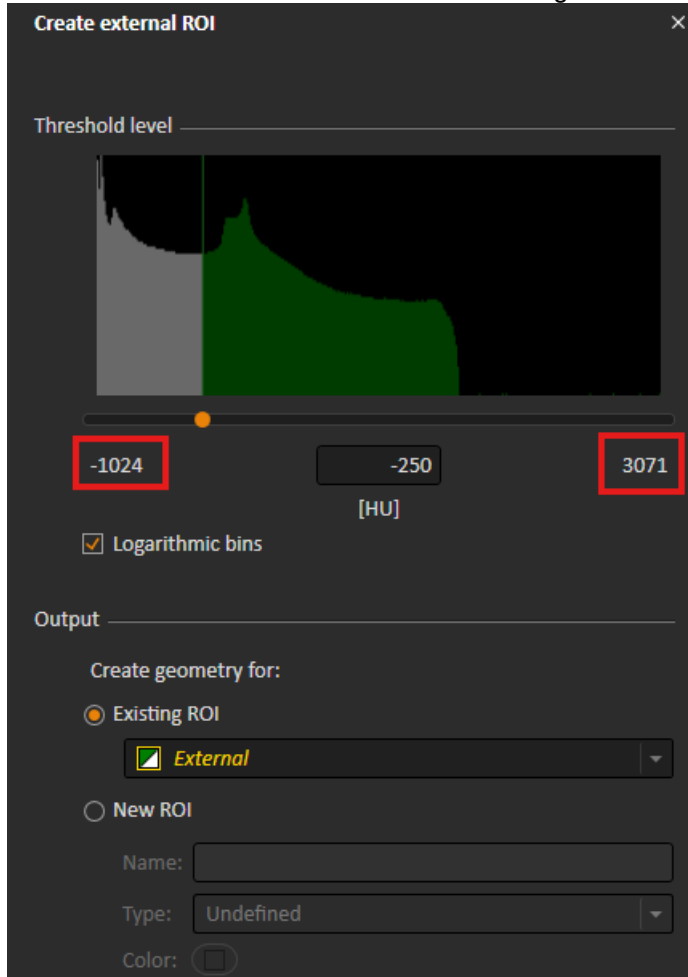
In RayStation, find the correct values of *RescaleSlope* and *RescaleIntercept* for the CT in question. These values can be found through scripting.

- patient.Cases[*CASE NAME*].Examinations[*EXAMINATION NAME*].Series[0].ImageStack.ConversionParameters.RescaleIntercept
- patient.Cases[*CASE NAME*].Examinations[*EXAMINATION NAME*].Series[0].ImageStack.ConversionParameters.RescaleSlope

In the exported DICOM CT files, verify that the value of “(0028,1052) *Rescale Intercept*” is the same as *ConversionParameters.RescaleIntercept* and that “(0028,1053) *Rescale Slope*” is the same as *ConversionParameters.RescaleSlope*. If the values are not the same, the *Rescale Slope* and *Rescale Intercept* in the DICOM files are incorrect and the DICOM files should not be used.

Option 2: Using RayPlan

Open either the *Create external ROI* dialog or the *Gray level threshold* dialog for the CT in question. The maximum and minimum HU values for the image sets are shown in the dialog (marked in red below):



Export the CT image set and find “(0028,0103) *Pixel representation*” in the exported DICOM CT files. This DICOM attribute will describe if the data is represented as signed or unsigned short.

- If the pixel representation is 0 = unsigned and the minimum and maximum values shown in the dialog are in the interval [0, 65535], the *Rescale Slope* and *Rescale Intercept* in the DICOM files are correct. If the minimum or maximum or both are outside the interval, the *Rescale Slope* and *Rescale Intercept* in the DICOM files are incorrect and the DICOM files should not be used.
- If the pixel representation is 1 = signed and the minimum and maximum values shown in the dialog are in the interval [-32767, +32767], the *Rescale Slope* and *Rescale Intercept* in the DICOM files are correct. If the minimum or maximum or both are outside the interval, the *Rescale Slope* and *Rescale Intercept* in the DICOM files are incorrect and DICOM files should not be used.

ACTIONS TO BE TAKEN BY THE USER

- Do not export 3D CT image sets generated from 4D CT data in RayStation without verifying correct *Rescale Slope* and *Rescale Intercept* as described above.
- A DICOM export filter that ensures correct export of generated image sets will be made available. Please contact RaySearch support for assistance.

- 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 is resolved in RayStation v2025 (subject to market clearance in some markets). If customers wish to continue using versions of RayStation affected by this notice, all users must 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.

CONFIRMATION OF RECEIPT

PLEASE CONFIRM THAT YOU HAVE RECEIVED THIS FSN

Reply to the same email address that sent you this notice(fsn@raysearchlabs.com), 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.

From: _____ (name of institution)

Contact person: _____ (please print)

Telephone no: _____

Email: _____

I have read and understood the notice.

Comments (optional):

