

Field Safety Notice, Medical Device Correction #15483

RayStation 4.5, RayStation 4.7, RayStation 5 and RayStation 6

January 18, 2017
RSL-D-61-319

ISSUE

This notice concerns an issue found with accelerated computation on NVIDIA GPU (Graphics Processing Unit) in RayStation 4.5, RayStation 4.7, RayStation 5 and RayStation 6 when used in a non-standard Citrix environment where the GPU settings are configured with a virtual "Citrix" graphics board (graphics card).

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 calculations during treatment planning.

A document called *RSL-D-61-320-EN-1.0 RayStation 4.5, 4.7, 5 and 6 Additional System Environment Acceptance Test Protocol GPU* is provided. This shall be used **in addition** to the tests in the System Environment Acceptance Test Protocol to verify that accelerated computation on GPU works as intended in a particular hardware and software environment.

INTENDED AUDIENCE

This notice is directed to all users of RayStation 4.5, RayStation 4.7, RayStation 5 and RayStation 6 who use accelerated computation on GPU. If there is any uncertainty whether accelerated computation on GPU is used or may be used in the future, please read the remainder of this document.

PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayStation 4.5, RayStation 4.7, RayStation 5 and RayStation 6. 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 "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", "5.0.0.37", "5.0.1.11", "5.0.2.35" or "6.0.0.24". If so, this notice applies to your version.

DESCRIPTION

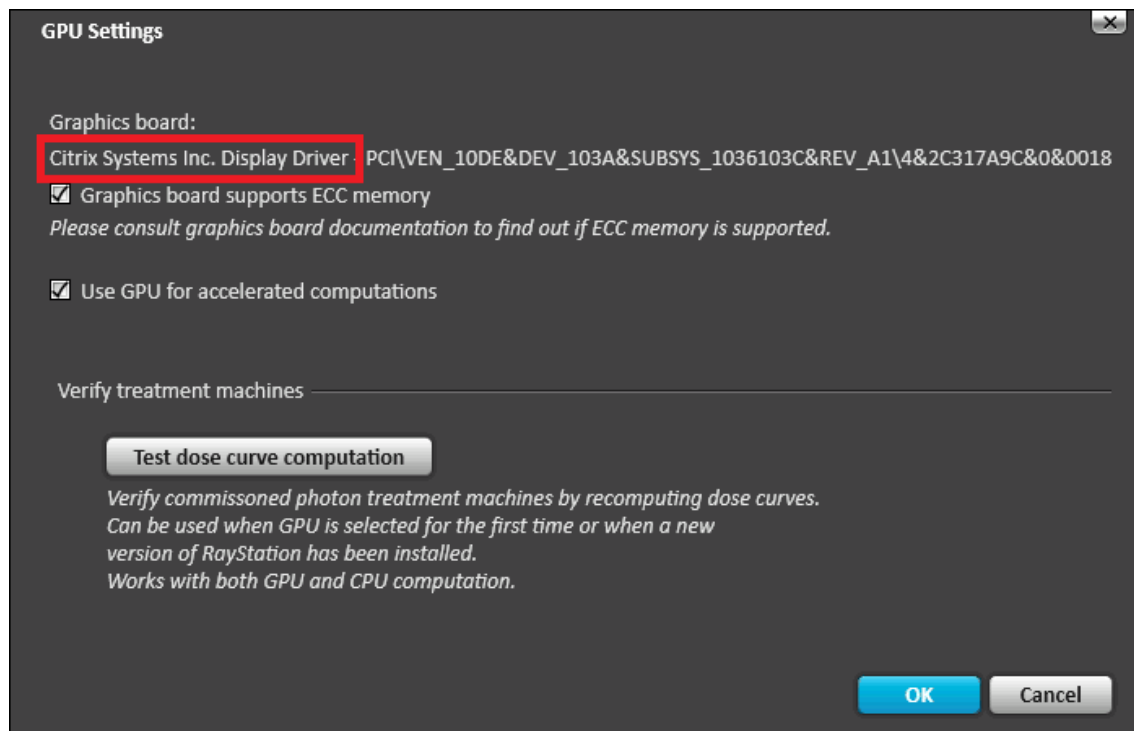
Due to a known error in NVIDIA GPU card drivers, RaySearch has prevented GPU based computations for very large computation problems. However, in an incorrect Citrix XenApp configuration, the GPU may not be correctly identified and the erroneous calculation may be allowed.

If this occurs, accelerated computation on GPU may give incorrect results for very large computation problems. Dose computation will be affected if the dose grid contains more than 134217728 voxels for a photon plan or more than 67108864 voxels for a carbon ion plan. The main effect on calculated dose is that it may be incorrectly set to zero in parts of the dose grid. Normally this would be highly detectable. There may also be some smaller impact on the dose in the non-zero region e.g., due to missing in-scatter when TERMA computation has been affected by the error.

Deformable registration may be affected for large image sets. The effect will be visible by unexpected zero vectors in part of the deformation field. In this region, only rigid registration will be used for dose and ROI (Region of Interest) mapping.

In a correct Citrix XenApp and GPU installation by RaySearch, the issue would not occur.

In an incorrect installation of Citrix XenApp, the NVIDIA GPU may be displayed as "Citrix Systems Inc. Display Driver":



An incorrect installation can be detected by opening the GPU settings in RayStation and viewing the current configuration, see ACTIONS TO BE TAKEN BY THE USER for instructions.

SYSTEM ENVIRONMENT ACCEPTANCE TEST PROTOCOL

As stated in the RayStation Instructions for Use, the System Environment Acceptance Test Protocol must be run for each installation or change in hardware or software platform hosting the application (e.g., operating system update) to verify application installation and performance.

However, the issue described in this notice is not detected by the test cases intended for verification of GPU calculations in the System Environment Acceptance Test Protocol. An Additional System Environment Acceptance Test Protocol for GPU is therefore provided, containing tests that must be run **in addition** to the tests in the System Environment Acceptance Test Protocol if accelerated computation on GPU is to be used. The document ID of the additional test protocol is: *RSL-D-61-320-EN-1.0 RayStation 4.5, 4.7, 5 and 6 Additional System Environment Acceptance Test Protocol GPU*.

ACTIONS TO BE TAKEN BY THE USER

Verify the GPU settings on each of the Citrix XenApp servers according to the instructions in this section. A correct configuration of the RayStation GPU settings will show a graphics board that has been verified

by RaySearch. The graphics boards that are verified for operation are listed in the section "Graphics card (GPU) for accelerated computations" in the System Environment Guidelines.

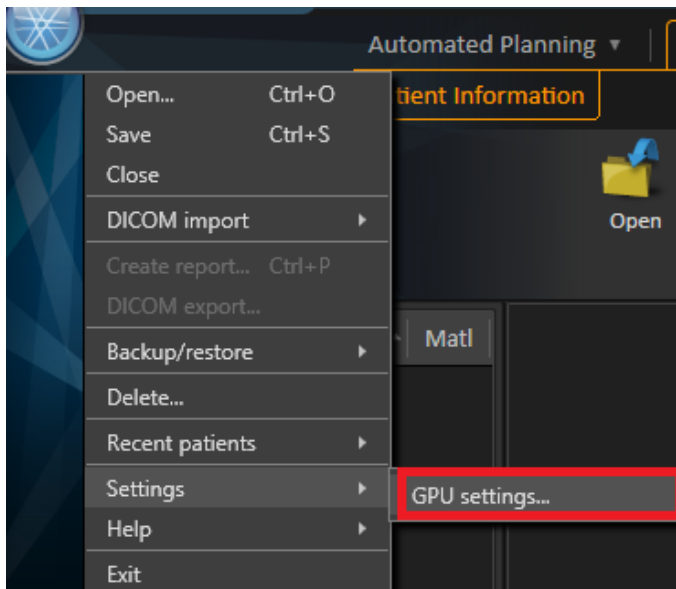
System Environment Guidelines for the applicable RayStation product versions

The following table lists the Document IDs of the System Environment Guidelines for the applicable RayStation product versions:

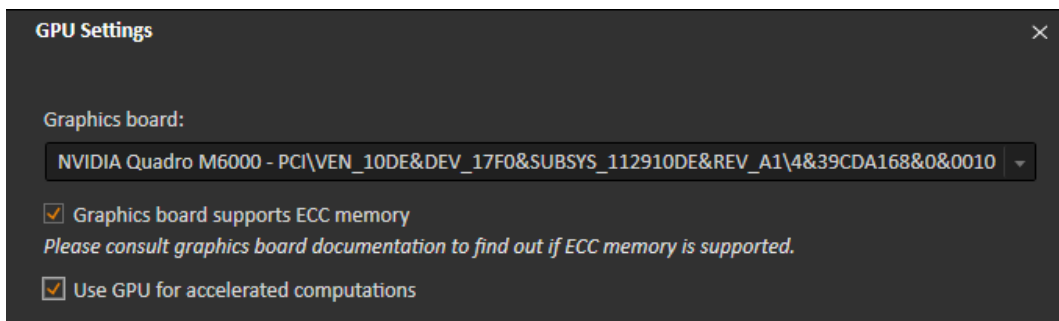
Product version	Document ID
RayStation 6	RSL-D-RS-6.0-SEG-EN-1.0-2016-12-22 RayStation 6 System Environment Guidelines
RayStation 5	RSL-D-RS-5.0-SEG-EN-1.0 2015-12-21 RayStation 5 System Environment Guidelines
RayStation 5 SP1	RSL-D-RS-5.0-SEG-EN-2.0-2016-01-26 RayStation 5 System Environment Guidelines
RayStation 5 SP2	RSL-D-RS-5.0-SEG-EN-3.0-2016-04-19 RayStation 5 System Environment Guidelines
RayStation 4.7.0	RSL-D-61-230-1.0 RayStation 4.7 System Environment Guidelines
RayStation 4.7.1, 4.7.2 and 4.7.5	RSL-D-61-230-2.0 RayStation 4.7 System Environment Guidelines
RayStation 4.7.3 and 4.7.4	RSL-D-61-230-SEG-EN-3.0-2015-09-28 RayStation 4.7 System Environment Guidelines
RayStation 4.5.0	RSL-S-00-04-1.1 RayStation 4.5 System Environment Guidelines
RayStation 4.5.1	RSL-S-00-04-2.0 RayStation 4.5 System Environment Guidelines or RSL-S-00-04-2.1 RayStation 4.5 System Environment Guidelines
RayStation 4.5.2	RSL-S-00-04-2.1 RayStation 4.5 System Environment Guidelines

Verify the GPU settings on each of the Citrix XenApp servers

1. Click the RayStation icon in the upper left corner of the view in the application and select **Settings: GPU settings....** This will open the **GPU settings** dialog.

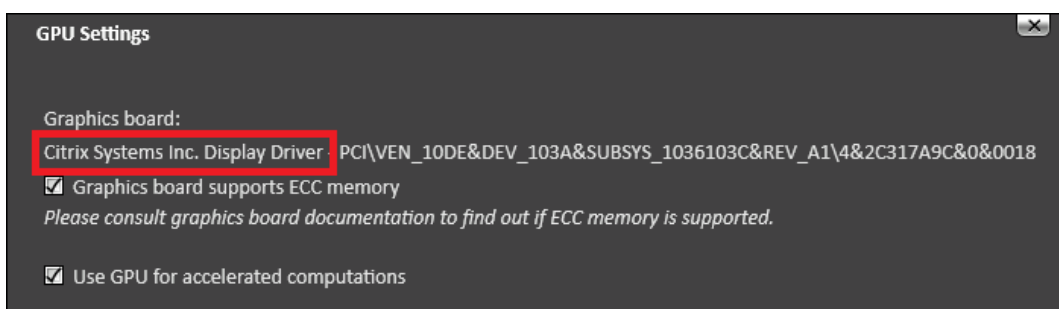


2. Check that displayed graphics board in the **GPU Settings** dialog is listed as verified for operation according to the section "Graphics card (GPU) for accelerated computations" in the System Environment Guidelines. The following figure shows an example of a correct installation:



If the graphics board is not verified for operation according to the System Environment Guidelines, the installation is incorrect. In this case, disable GPU computation and contact RaySearch Support.

3. Check if "Citrix Systems Inc. Display Driver" is displayed instead of the graphics board name. If so, the Citrix XenApp installation is incorrect.



If an incorrect installation of Citrix XenApp is detected:

- a. Set the Citrix XenApp server to maintenance mode or disable GPU computation on the erroneous server.
- b. Contact RaySearch Support for instructions on how to resolve the issue.

Please educate IT staff and all users that are members of the RayStation-Administration user group (or equivalent) about this (i.e., users with the permission to change GPU settings).

Inspect your product and identify all installed units with the above software version number(s), then confirm you have read and understood this notice (contact information below).

SOLUTION

Add the *RSL-D-61-320-EN-1.0 RayStation 4.5, 4.7, 5 and 6 Additional System Environment Acceptance Test Protocol GPU* to the location of the RayStation manuals. The location of the manuals can be local or central and is defined in the configuration file:

The location is identified in the RayStation Storage Tool in RayStation 5 and RayStation 6, or in the RayLauncher.exe.config file in RayStation 4.5 and RayStation 4.7.

The tests in the Additional System Environment Acceptance Test Protocol GPU must be performed **in addition** to the tests in the System Environment Acceptance Test Protocol to verify GPU computations whenever the hardware or software platform is changed.

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 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, at +46 8 510 530 12 or david.hedfors@raysearchlabs.com

The undersigned confirms that the appropriate Regulatory Agencies will be notified.

REPLY FORM

FIELD SAFETY NOTICE, MEDICAL DEVICE CORRECTION #15483 RAYSTATION 4.5, RAYSTATION 4.7, RAYSTATION 5 AND RAYSTATION 6 RSL-D-61-319

Preferably, reply to the same email that sent you this notice, stating you have read and understood it.

You can also email or phone your local support or support@raysearchlabs.com, +46 8 510 533 33 to acknowledge this notice.

If you want to fill in this reply form, please send it to:

- Americas market: Freddie Cardel, freddie.cardel@raysearchlabs.com, fax 888 501 7195
- Rest of the world: RaySearch Support, support@raysearchlabs.com, no fax number

From: _____ (name of institution)

Contact person: _____ (please print)

Telephone no: _____

Email: _____

I have read and understood the notice.

Comments (optional):
