

Field Safety Notice, Medical Device Correction #65340

**RayCare: 2C SP2, 2C SP3, 3A SP1, 3B
and 4A
August 4, 2020
RSL-D-66-013**

Issue

This notice concerns an issue found in the Image viewer of RayCare PACS when visualizing a fusion with a study consisting of multiple image series in the same frame of reference. Under certain circumstances, an incorrect secondary image may be used when visualizing the fusion.

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 review of the described image registration.

Intended audience

This notice is directed to all users of RayCare who perform offline image review or visualize image registrations with the RayCare PACS Image viewer.

Product name and version

The product affected by this notice is sold under the trade names RayCare: 2C SP2, 2C SP3, 3A SP1, 3B and 4A. To determine if the version you are using is affected, open the About RayCare dialog in the RayCare application and check if the build number reported there is 2.2.2.30782, 2.2.3.53423, 3.0.1.43597, 3.1.0.60341 or 4.0.0.60621. If so, this notice applies to your version.

The UDIs of the affected products:

0735000201021120190307, 0735000201032720200117, 0735000201025920190909,
0735000201028020191220 and 0735000201034320200616

Description

The issue occurs when the planning image is part of a larger study with multiple image series in the same frame of reference.

Behaviour for RayCare 2C, RayCare 3A and RayCare 3B (including service packs)

When performing offline image review in RayCare 2C, RayCare 3A and RayCare 3B, an offline image review task will guide the user to the Image viewer with the treatment image related to the fraction and the planning image selected. When starting the task, an error message might be displayed stating: Review files not available. However, when the user verifies the data in RayCare PACS, the data is correctly transferred and available.

When visualising the treatment image, e.g. CBCT in RayCare PACS using the Image viewer, the registration object will be selected correctly. If the planning image is part of a larger study with multiple image series in the same frame of reference, it is possible that the incorrect dataset is selected as the secondary image. It will not be possible to select another dataset from the study to correct this behaviour.

Before the offline image review task is opened, RayCare verifies that the correct images are selected. When this is not the case, the offline image review task cannot be performed. The status of the offline image review and the related comments will not be transferred to RayTreat in RayCare 3A and RayCare 3B.

Detectability of this problem is high when performing an offline image review task. The user is blocked from performing the offline image review with the incorrect planning image.

To detect if the correct data is selected in the Image viewer of RayCare PACS, the user can examine the date and time of the image series in the Image viewer and in the RayCare PACS data. If a registration exists with multiple datasets of the same frame of reference, a non-treatment related dataset may be used for comparison resulting in an incorrect visualisation. The error might also occur for datasets unrelated to treatment.

To be able to perform the offline image review in RayCare 2C, RayCare 3A and RayCare 3B, an administrator can delete the image series that will not be used for offline image review in the same frame of reference as the planning image. The deleted data should be stored in a separate location and can be imported into RayCare PACS after the final treatment session of the patient.

Behaviour for RayCare 4A

When performing offline image review in RayCare 4A from an offline image review task or from the offline image review workspace, the correct primary and secondary image sets will be selected. The user will be able to perform offline image review correctly.

When visualising the treatment image in RayCare PACS using the Image viewer, the registration object will be selected correctly. If the planning image is part of a larger study with multiple image series in the same frame of reference, it is possible that the incorrect dataset is selected as the secondary image. The incorrect visualisation may also occur when visualising datasets not related to treatment, but with a registration referencing a dataset that is part of a study with multiple image series in the same frame of reference. It will not be possible to select another dataset from the study to correct this behaviour. The dataset that will be selected is the image series that has the earliest image series date and time in the study.

Actions to be taken by the user

- Be aware that registration of a treatment image with a corresponding study with multiple image series in the same frame of reference might block the offline image review. Verify the correctness of the data in RayCare PACS before using the data for any decision making.
- Please educate 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 RayCare, scheduled for market release in December 2020 (subject to market clearance in some markets). If customers wish to continue using versions of RayCare 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 RayCare 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 quality@raysearchlabs.com

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

Digitally signed by

The logo for RaySearch Laboratories, featuring the company name in blue and black text next to a stylized starburst graphic.
Date: 2020.08.04
15:59:47 +02'00'

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 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):

