

# Field Safety Notice, Medical Device Correction #119693

## RayCare 6A

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

**July 31<sup>st</sup>, 2023**

**RSL-P-RC FSN Class III 119693**

### ISSUE

This notice concerns an issue found in RayCare 6A where extended domain object values in RayCare configurable documents may become unintentionally overwritten with empty values in certain circumstances. 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 the issue.

### INTENDED AUDIENCE

This notice is directed to all users of RayCare 6A who use the RayCare configurable documents and extended domain objects.

### PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayCare 6A. 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 is "6.0.0.60553". 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
RayCare 6A (6.0.0.60553)	0735000201056320220617

### DESCRIPTION

RayCare supports user configurable documents that can contain data from extended domain objects defined by the user. When an extended domain object (EDO) field is hidden in a RayCare configurable document, the saved value for that EDO can be unintentionally overwritten with an empty value. The issue occurs for documents that include a writable EDO field and a field rule to hide the field. If the document is added to a patient and then completed or approved while the EDO field is hidden, the saved value of the EDO will be overwritten with an empty value. This will affect the value displayed for the EDO in other documents within the same context as well as the report database.

### ACTIONS TO BE TAKEN BY THE USER

- Manually verify the document templates that have been configured by system administrators in the system. Make sure no document template includes an EDO field that has the Read-Only property set to "No" and Rules for display configured to hide or display the field.
- Educate staff and all users about this defect if there are RayCare configurable documents already in use which are affected by the issue.

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- Educate staff with “System administrator” role to not use field rules to hide or display writable EDO fields in RayCare configurable documents.
- 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 RayCare, scheduled for market release in December 2023 (RayCare 2024A), (subject to market clearance in some markets) and future versions. If customers wish to continue using RayCare, they 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](mailto: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, stating you have read and understood it.**

Alternatively, you can email or phone your local support to acknowledge this notice.

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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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