

Field Safety Notice, Medical Device Correction #121600

RayCare 5B and 6A including service packs

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

September 6th, 2023

RSL-P-RC FSN Class III 121600

Issue

This notice concerns an issue found in RayCare 5B and 6A including service packs. Values will not be visible for documents in a read-only state when opened outside the Documents workspace when using document fields configured with single- or multi-selectable values.

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 the described issue.

Intended audience

This notice is directed to all users of RayCare 5B and 6A including service packs who use the RayCare configurable documents and RayCare domain objects.

Product Name and Version

The products affected by this notice are sold under the trade names RayCare 5B and 6A including service packs. 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 “5.1.1.60246”, “5.1.3.60023” or “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 5B SP1 (5.1.1.60246)	0735000201053220220316
RayCare 5B SP3 (5.1.3.60023)	0735000201069320221027
RayCare 6A (6.0.0.60553)	0735000201056320220617

Description

RayCare supports user configurable documents that can contain data from RayCare in predefined RayCare domain objects (RDO). The RDOs can have different types where the object has a single value or multiple values (list value). During the configuration of a list RDO, the user can select to display all values, select a single value or select multiple values. When a document is created for a patient based on a document template with one or more list RDO(s) where selection is possible and the document is not in a draft state, the selected values for the list RDOs will not be visible. In RayCare 5B, the issue occurs when the document

is opened outside of the Documents workspace. In RayCare 6A the issue occurs when the document is opened from a task in the Activities workspace. When the document is opened from other workspaces, the selected items will be displayed correctly.

Actions to be taken by the user

- Educate staff and all users to open configurable documents from the Documents workspace to avoid the issue.
- Review all configured documents and consider reconfiguration in a way that will not trigger the issue.
- 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 2023 (RayCare 2024A) (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.

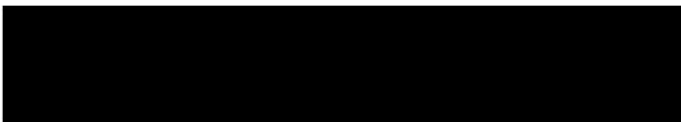
Transmission of this Notice

This notice needs to be passed on to all those who need to be aware within your organization. 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, 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):

