

Field Safety Notice, Medical Device Correction #96130 96169

RayCare 5A and 5B including some service packs

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

March 18, 2022

RSL-P-RC-96130 96169 v 2

ISSUE

This notice concerns an issue found with the report database in RayCare 5A and 5B including some service packs. When extracting data from the RayCare report database for Yes/No fields in configurable RayCare documents, the value is set to "No" even if no value has been selected. Also, the status of the document versions is incorrect for all documents except the most recent version.

To the best of our knowledge, these issues have not caused any patient mistreatment or other incidents. However, the user must be aware of the following information to avoid incorrect information in the reports extracted from the RayCare report database.

INTENDED AUDIENCE

This notice is directed to all users of RayCare 5A and service packs and RayCare 5B who use data extracted from the report database.

PRODUCT NAME AND VERSION

The products affected by this notice are sold under the trade names RayCare 5A and 5B including some 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 any of the build numbers reported below. 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 5A (5.0.0.60390)	0735000201039620210524
RayCare 5A Service Pack 1 (5.0.1.60052)	0735000201046420220305
RayCare 5B (5.1.0.61073)	0735000201045720211217

DESCRIPTION

Values added to RayCare configurable documents are available in the RayCare SQL report database and can be extracted using standard SQL tools. Two issues have been identified with the contents of the RayCare report database:

- When using the Yes/No option fields in RayCare configurable documents and a value has not been selected, this will be incorrectly stored in the report database as “No”. The values are always correct when viewing the data via the RayCare user interface. The detectability is very low as the error only manifests in the report database.
- The version history for configurable documents may not display the correct state of a document for versions other than the most recent one. The state for all versions of the document will always be presented as the current state of the most recent version, instead of the state of the respective version. The detectability is very low as the error only manifests in the report database.

ACTIONS TO BE TAKEN BY THE USER

- Do not use the RayCare report database for extracting and analyzing values inserted using Yes/No option fields in configurable documents if the fields have not been marked as mandatory. Instead, check the data via the RayCare user interface. The user is recommended to set all Yes/No option fields to mandatory which prevents the issue from occurring.
- Do not use the RayCare report database to retrieve data based on older versions of configurable documents based on the status of the document. If the status of the document is relevant, only create reports based on the latest version of the document.
- Educate 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 March 2022 (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):
