

# Field Safety Notice, Medical Device Correction #119464

## RayCare 5A, 5B, 6A, including service packs

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

**July 14<sup>th</sup>, 2023**

**RSL-P-RC FSN Class III 119464**

### ISSUE

This notice concerns an issue found in RayCare 5A, 5B, 6A, including service packs, where an allergy warning against medication substance (drug ingredient) will not be displayed as expected under 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 5A, 5B, 6A, including service packs, who use the patient chart functionality for medications and allergies.

### PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayCare 5A, 5B, 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 is “5.0.0.60390”, “5.0.1.60052”, “5.1.1.60246”, “5.1.2.60028”, “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 5A (5.0.0.60390)	0735000201039620210524
RayCare 5A SP1 (5.0.1.60052)	0735000201046420220305
RayCare 5B SP1 (5.1.1.60246)	0735000201053220220316
RayCare 5B SP2 (5.1.2.60028)	0735000201062420220613
RayCare 5B SP3 (5.1.3.60023)	0735000201069320221027
RayCare 6A (6.0.0.60553)	0735000201056320220617

### DESCRIPTION

The allergy warning for a medication substance (drug ingredient) will not be displayed when adding an allergy to a medication substance in the Patient chart when a patient already has a medication with that substance in one specific circumstance. That is, when a new version of the drug ingredient is added and activated in the drug ingredient value set in RayCare admin without also updating and activating a new version of the medication.

## ACTIONS TO BE TAKEN BY THE USER

- Manually verify the patient's medication list with respect to included substances when adding a new allergy to a medication substance.
- Make sure to update all medications when activating a new version of the drug ingredients value set in the RayCare admin interface.
- Educate staff and all users about the absence of a warning when adding a patient allergy.
- 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 is resolved in the RayCare 2023B, market released in July 2023 (subject to market clearance in some markets) and future versions. 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](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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