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 31st, 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)	073500020103962021052 4
RayCare 5A SP1 (5.0.1.60052)	07350002010464202203 05
RayCare 5B SP1 (5.1.1.60246)	07350002010532202203 16
RayCare 5B SP2 (5.1.2.60028)	07350002010624202206 13
RayCare 5B SP3 (5.1.3.60023)	07350002010693202210 27
RayCare 6A (6.0.0.60553)	07350002010563202206 17

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.

RaySearch Laboratories AB (publ), P.O. Box 45169 SE-104 30 Stockholm Sweden, Visitors: Eugeniavägen 18C Phone +46 8 510 530 00

www.raysearchlabs.com

ACTIONS TO BE TAKEN BY THE USER

- Manually verify the patient's medication list with respect to included substances when adding an 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 RayCare, they must upgrade to the new version.

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.

David Hedfors

I am approving this document
Stockholm, Sweden
2023.07.31 10:56:26 +02'00'

RaySearch Laboratories AB (publ), P.O. Box 45169 SE-104 30 Stockholm Sweden, Visitors: Eugeniavägen 18C Phone +46 8 510 530 00

www.raysearchlabs.com

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):

_____

_____

RaySearch Laboratories AB (publ), P.O. Box 45169 SE-104 30 Stockholm Sweden, Visitors: Eugeniavägen 18C Phone +46 8 510 530 00

www.raysearchlabs.com