Field Safety Notice, Medical Device Correction #76924

RayCare 4A

April 1st, 2021
RSL-P-RC FSN Class III 76924

ISSUE

This notice concerns an issue found with a warning in RayCare 4A, alerting the user that a patient has an allergy to a medication substance. If the medication is added to the patient chart before the allergy is added, the warning is not displayed.

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 issue.

INTENDED AUDIENCE

This notice is directed to all users of RayCare 4A Clinic license, who use the patient chart functionality for Medications.

PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayCare 4A. 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 “4.0.0.60621”. 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 4A (4.0.0.60621)	07350002010343

DESCRIPTION

When a user adds an active allergy to a medication substance that is already included in the medication list of the patient, no warning is displayed. The warning is only displayed when the user edits the allergy or adds the allergy, before the medication is added to the medication list.

ACTIONS TO BE TAKEN BY THE USER

- Manually verify the patient’s medication list in the patient chart when adding an active allergy to a medication substance.
- 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.**

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SOLUTION

This issue is resolved in the RayCare 4B SP1, market released in March 2021 (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.

RaySearch will notify the appropriate regulatory agencies about this Field Safety Notice.

David Hedfors

I am approving this document
Stockholm, Sweden
2021.04.01 11:44:36 +02'00'

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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):

_____

_____

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