

Urgent Field Safety Notice

Evondos® Service
Evondos FSCA 31397
Notification of corrective action

Date: 15.8.2019

ATTENTION: ALARM NOT ESCALATED IN THE EVONDOS® TELECARE SYSTEM NOTIFICATION CHAIN IF USER'S E-MAIL ADDRESS IS NOT CONFIGURED.

Details on affected devices:

Evondos® Service consists of Evondos® E300 Medicine Dispensing Robot and Evondos® Telecare. Evondos service utilizes multidose packaged medicines in strips of medicine sachets provided by the pharmacies as a separate service (ADD).

Evondos E300 gives the medicine sachet to the client according to the medication schedule and instructs him to take the medication. The Evondos® Telecare System monitors medicine taking and operation of the robots and is management tool of the Evondos® Service.

This concerns all products in customer use and the Evondos® Telecare System software version 1.0.94.0.

Description of the problem:

If an administrator adds a user without configured e-mail address to an alarm chain, alarm escalation will not work correctly, and the alarm will not be escalated from the Telecare System to recipients SMS, e-mail or voice call. It will send SMS to the first recipient in the notification chain.

Alarm not delivered if medicines cannot be given or medicine not taken by the patient, care continuity jeopardized. Evondos took immediate preventive action. As preventive action the contact details configured in the notification chains were reviewed and missing e-mail addresses were filled. Notification chains are currently in continuous automatic monitoring to prevent the fault in new configurations until the corrective action is deployed. Residual risk is remote.

Advise on action to be taken by the user:

No action needed by the user.

As preventive action, if e-mail address is not added, Evondos will add it automatically. No information will be sent to the e-mail address added by Evondos. It has been specified by the e-mail address format @test.test.

Software fault causing the behaviour will be corrected as corrective action. After correction, no e-mail address will be needed. @test.test e-mails will be removed after the update.

Action will be completed no later than 30.9.2019.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate) Please transfer this notice to other organisations on which this action has an impact. (If appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

Contact reference person:

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The undersigned confirms that this notice has been notified the appropriate Regulatory Agency

Signature

Mika Apell, COO