

IMPORTANT SAFETY MESSAGE

(FIELD SAFETY NOTICE, FSN)

Date: 2015-02-23

TO

Recipients: Customers using Orbit 4

TYPE OF ACTION

Information of a corrective action.

PRODUCT INFORMATION

Product: Orbit 4

Version: 4.24.1-4.25.7

SAFETY INFORMATION

Regarding ORBFVS-965:

There may occur an erroneous status in the surgery planning, so that the planned surgery becomes registered as already performed - although it is only planned - and is no longer shown in the waiting list.

The manufacturers investigation has shown that the erroneous status can occur:

- For customers who have Orbit 4 version 4.24.1 - 4.25.7
- In addition, the following system settings must be marked:

ANJO_BLOCK_STATUS

OPJOP_BLOCK_STATUS

OPJSSK_BLOCK_STATUS

User has:

- Registered notification for surgery
- Registered any of the records, in this case were the surgeons record
- Erased surgeons record (since it was wrong)
- Saved / updated notification for surgery

Assessment of patient risk:

The risk is that the patient will not have the planned surgery on time and that there, as a consequence of this, might occur some kind of medical harm.

CORRECTIVE ACTION

Description and motivation of action

A check should be executed in the customers' production databases if there are surgical occasions with incorrect status. These must then be corrected.

Advice to users:

Please contact us at EVERY Healthcare Systems AB for us to control the operation of occasions that have incorrect status. If so, we will send a list of treatment numbers, these can then be corrected manually. Instructions will be sent in connection with the treatment number.

AUTHORITIES ARE INFORMED

EVERY Healthcare systems hereby declare that the Medical Products Agency in Sweden (Läkemedelsverket) is informed of the corrective action in the market (FSCA).

Date: 2015-02-23

CONTACT INFORMATION MANUFACTURER

If you have further questions regarding this message or the corrective actions, please contact:

Manufacturer: EVERY Healthcare Systems AB

Contact person: Katarina Lindberg

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Our priority is to maintain a high safety and quality level.

Thank you!

Jörgen Graneskog

Product owner Orbit
EVERY Healthcare Systems AB