

Urgent Field Safety Notice

Device commercial name: MetaVision[®] Suite, Clinical Information System

Relevant product version: 6.0.x – 6.9.x.; **applicable only for customers with specific software versions.**

FSCA-identifier: MCR #104

Type of action: Advice given by MANUFACTURER regarding the use of the device /Device modification

Date: xx September 2017

Attention: Ms./Mr./Dr XXX.

Hospital name: XXX

1. Details of affected device

MetaVision Clinical Information System - version 6.x

2. Description of the problem

• **Problem:**

- Software malfunctions with the MetaVision ICU system resulted in an unnoticed Order Management Driver (OMD) failures. As a result, the OMD did not create specific medication doses of medication orders exceeded the horizon at the department (usually 7 days) per treatment plan.
- This led to the non-provision of specific medication doses to several patients until the issue was identified by the customer.

• **Clinical risk assessment:**

Risk of 'missing' non-documented continues medications by the healthcare providers, and the non-provision of planned treatment to ICU patients who are admitted to the unit for longer than the horizon set at the department (usually 7 days).

• **Cause:**

The Company has analyzed this problem, and the root cause has been identified as software malfunctions in the System source code.

• **Identified mitigation/solution:**

- **Temporary mitigation:** Customers using Order Management module in MetaVision 6.0x-6.9x should daily review continues orders prescribed for a period longer than the horizon set for their department (usually 7 days) to ensure that doses were indeed created for those orders beyond the horizon.
- Customers should carefully review the MetaVision OMD behavior either using surveillance tools provided by the Company (Sentry, DB job) or other effective tools – this to ensure no failure in its services occurred. If a failure identified – the OMD should be restarted to prevent further implications.
- **Definitive solution/corrective action:** Use the HotFix release which mitigates the above-mentioned issue and upgrade to MetaVision version XXX (release date will be communicated by iMDsoft Customer Support separately).

3. Advise on actions to be taken

• **Immediate:**

- Deploy temporary mitigations as advised in **section #2.**

- Distribute this information to anyone relevant who uses MetaVision the affected software in your organization.
- Ensure that a copy of this letter is provided to any other parts of your organization to which affected devices have been transferred.
- **Definite:** Deploy MetaVision HotFix which will be released soon according to your internal organizational processes. iMDsoft Customer Support will update you separately on the HotFix release date.
- Please complete the **Customer Response Form** below (**Appendix #1**) and return it by email to FSN@imd-soft.com.

We apologize for the inconvenience caused by the above-mentioned problem, and we will continue to do our best to keep patient safety at all times.

iMDsoft confirms that this notice has been supplied to the appropriate National Competent Authority.

Reference person:

Anat Eden, Director of Customer Support

Email: Anat.Eden@imd-soft.com

Appendix #1

Customer Response Form

For: Advisory Notice - MetaVision Clinical Information System – Version 6.x

This iMDsoft Advisory Notice (**Ref.**) has been read and understood by the undersigned and has been communicated within the referenced organization/hospital as applicable.

Please scan and mail to: FSN@imd-soft.com

Thank you for your collaboration!

iMDsoft Customer Support

Name	Organization/Hospital	Role	Date	Signature