

## Urgent Field Safety Notice

**Device commercial name:** MetaVision® Suite, Clinical Information System

**Relevant product version:** 6.7.x – 6.10.x.; **applicable only for customers with specific software versions and configuration (customization).**

**FSCA-identifier:** MCR #115

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

**Date:** xx July 2018

**Attention:** Ms./Mr./Dr XXX.

**Hospital name:** XXX

### 1. **Details of affected device**

MetaVision Clinical Information System - version 6.7x -6.10x

### 2. **Description of the problem**

- **Problem:**

- Software malfunctions with the MetaVision ICU system resulted in wrong calculation of dose after rescheduling the order.
- This will occur only if:
  - the system is customized not to display the 'Orders & Task List' (the option 'Always open Dose Entry when validating Doses' is unchecked in the customization tool),
  - the dose requiring validation includes all information needed (this is not always the case because some doses should be validated with second signature – per hospital's workflow, some doses created from the "no full data" order style – which requires specification of missing information and some doses require details to be populated by a nurse during its administration etc.).
- This leads MetaVision display and calculate the dose with 0 minutes duration and therefore, also the volume, and might affect the fluid-in results.

- **Clinical risk assessment:**

if calculations are negatively affected it might have a clinical significance over healthcare providers decision making.

- **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:**

- Ensure customers' workflow include the validation of doses through the Order Entry or Dose and Task List windows - so order properties including dose start and end time will be reviewed.
- Customers should review total intake calculations to ensure doses validated are calculated properly.

- **Definitive corrective solution:** The customer must install the Software release which mitigates the above-mentioned issue and upgrade to MetaVision version 6.x (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 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](mailto: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:**

Yaniv Cohen, Customer Support Manager - EMEA

Email: [Yaniv.Cohen@imd-soft.com](mailto:Yaniv.Cohen@imd-soft.com)

## Appendix #1

### Customer Response Form

**For: Advisory Notice - MetaVision Clinical Information System – Version 6.7x-6.10x**

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](mailto:FSN@imd-soft.com)

Thank you for your collaboration!

iMDsoft Customer Support

Name	Organization/Hospital	Role	Date	Signature