

Urgent Field Safety Notice

Device commercial name: MetaVision[®] Suite, Clinical Information System. ver. 5.4x

FSCA-identifier: z-q-RCM-CE-Europe-Initial-FSCA-Report MDD14 146-DE-DRAFT-(16Nov2014), dated 16 November, 2014

Type of action: Software device modification

Date: 20 November, 2014

Attention: Ms./Mr./Dr.

Hospital name: XXX

1. Details of affected device

MetaVision Clinical Information System ver. 5.4x with 'MetaOrders' module.

2. Description of the problem

Below please find several issues related to 'MetaOrders', their risk assessment and Company's recommendations:

I. Frequency change to once a day when modifying order from PRN to non-PRN

- **Description:** When using 'Custom Frequency' to create a PRN order (Pro Re Nata = Latin for "as needed") and later editing the 'Parent Order' while the PRN tick-box is un-checked, the edited Parent Order generates 1 dose every 24 hours instead of doses as ordered in the 'Custom Frequency'.
- **Risk assessment and rationale:** Risk to patients' safety is considered low. The ordered dose is visible to the clinical team reviewing the medical chart, and the change of frequency of Orders originally provided as PRN typically would not cause significant deterioration of patient's health or death. Furthermore, when using 'Set Intervals' function to edit the 'Parent Order', the system operate as expected.
- **Recommendations:**
 - **Temporary workaround:** Use 'Set Intervals' function instead of 'Custom Frequency' to modify a PRN order to a non-PRN.
 - **Definitive solution:** Upgrade to MetaVision software release as described in section #3 below.

II. The system only cancels orders customized as 'expired' when they become due ('Immediate')

- **Description:** After performing a discontinue action on a 'Parent Order', the pending doses remain in the Cardex and are not canceled. Cancelled orders continue to appear in the 'Work list' and 'Med chart' as pending until the dose is due ('Immediate'), at which time the doses become expired.
- **Risk assessment and rationale:** Risk to patients' safety is considered low. In routine clinical workflow orders are only administered when due ('Immediate'); at that time the order will appear as expired, and will therefore not be administered by the clinical staff, and therefore this scenario is not expected to cause significant deterioration of patient's health or death.
- **Recommendations:**
 - **Temporary solution:** Deploy software script mitigating this issue as recommended in a previous

communication by iMDsoft Customer Support (which required customer approval). For verification of the script's deployment please contact our team.

- **Definitive solution:** Upgrade to MetaVision software release as described in **section #3** below.

III. Doses do not appear in a 'No Time Limit' 'Parent Order' after its modification

- **Description:** In a specific workflow and scenario associated with recurring doses, where the user modifies the 'Parent Order' after the last dose of a cycle and the first dose of the next cycle is scheduled to 12 midnight, the result is that the subsequent recurrence doses in the next cycle will not be created.
- **Risk assessment and rationale:** Risk to patients' safety is considered medium. As part of its meticulous analysis iMDsoft checked samples of numerous de-identified European customers' databases and could not find a single occurrence of the issue. While the workflow and scenario are specific, the Company considers the risk as medium because it did occur at a single customer in Australia, and the clinicians noticed the discrepancy as part of their clinical routines.
- **Recommendation:**
 - **Temporary solution:** Deploy a workaround: Review the customization settings of 'Set Intervals' and 'Customized Orders Frequencies' and make sure that where the first dose of a cycle is scheduled to 12 midnight, change it so it WILL NOT be scheduled to 12 midnight exactly (for example 5 minutes before or after).
 - **Definitive solution:** Upgrade to MetaVision software release as described in **section #3** below.

3. Advise on actions to be taken

- **Upgrade:** Use the latest hotfix release relevant for your current MetaVision version (5.46.38xx \ 5.46.44xx or 5.47.46xx), which mitigates the above-mentioned issues.
- Distribute this information to anyone relevant who uses MetaVision 'MetaOrders' in your organization.
- Ensure that a copy of this letter is provided to any other parts of your organizations to which affected devices have been transferred.
- Please complete the **Customer Response Form** below (**Appendix #1**) and return it by email to FSN@imd-soft.com immediately.

We apologize for the inconvenience caused by the abovementioned issues. We know that you share in our desire to provide superior quality products and services to both our customers and their patients.

iMDsoft confirms that this notice has been supplied to the appropriate Regulatory Agency.

Reference person:

Shlomi Revach, Customer Support Manager-EMEA, iMDsoft

Email: Shlomi.Revach@imd-soft.com

In Germany you may also contact our EU Authorized Representative, MDSS GmbH,

Tel.: +49-511-62628630, vigilance@mdss.com

Appendix #1

Customer Response Form

For: Advisory Notice - MetaVision Clinical Information System ver. 5.4x with 'MetaOrders' module

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

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

Thank you for your collaboration!

iMDsoft Customer Support

Name	Facility/Hospital	Role	Date	Signature