Urgent Field Safety Notice

MetaVision Suite ver. 6.x

Date: 27/06/2023

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

Urgent Field Safety Notice (FSN)

Device commercial name: **MetaVision**

Risk addressed by this FSN: **Deterioration in patient's health, including an injury or impairment requiring medical intervention.**

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Clinical Information System. Medical Device Software (MDSW)
1.	2. Commercial name(s)
	MetaVision
1.	3. Unique Device Identifier(s) (UDI-DI)
	729011689MetaVisionX6
1.	4. Primary clinical purpose of device(s)*
	MetaVision is intended for clinical and workflow documentation, interfacing, conversion, presentation, and storage, order and medication management, decision support and analysis in the healthcare environment (e.g., high acuity and acute care). MetaVision may provide the following uses, without controlling or altering the functions or parameters of any other connected medical devices: (i) the electronic transfer of medical device data; (ii) the electronic storage of medical device data; (iii) the electronic conversion of medical device data from one format to another format in accordance with a pre-set specification; and (iv) the electronic display of medical device data.
1.	5. Device Model/Catalogue/part number(s)*
	MetaVision ver. 6.x
1.	6. Software version
	MetaVision versions 6.0, 6.9, 6.7, 6.8, 6.10, 6.11, 6.12, 6.14, 6.15, 6.16, 6.17, 6.18, 6.20
1.	7. Affected serial or lot number range
	Not Applicable
1.	8. Associated devices
	Not Applicable

2	**Reason for Field Safety Corrective Action (FSCA)***
2.	1. Description of the product problem*
	The problem When using Order template with quantity in weight units - Order / Dose quantity is calculated according to the template default weight, rather than the patient's actual dosing weight. This can be observed in various Order and Dose views, for example: in the Order Profile View, Cardex, and Dose and Task List. **Problem's scenario** In MetaVision effected versions (as above) – IF the department is using the following scenario - it might lead to the described problem:

	1. The department uses Daily Dosage. 2. The department works with a complete Order Template, with quantity in weight units (e.g., Mg./Kg.). 3. The department uses a button to automatically create an order from the template. 4. The Order / Dose is administered to a patient who has a different dosing weight than the template default weight. 5. A button is used to create the order with the template WITHOUT opening the Order Entry form. 6. Order is signed from the Shopping Cart (if relevant).
2.	2. Hazard giving rise to the FSCA*
	Possible damage to the patient: As a result of the display of incorrect Order / Dose quantity in various Order and Dose views, caused by the erroneous calculation – the healthcare provider might rely on this information and administer incorrect dose quantity to a patient. This might lead to a deterioration in the patient's condition, including an injury or impairment requiring professional medical intervention.
2.	3. Probability of problem arising
	While we understand that the described scenario may not be used by all customers - According to the analysis - the probability of this occurrence (ON/OS) is occasional. If the error is not corrected, or not observed by healthcare providers prior to the administration - similar events are likely to occur sometime during device lifetime.
2.	4. Predicted risk to patient/users
	The following could occur: Deterioration in the patient's treatment and health, including an injury or impairment requiring professional medical intervention. This predicated risk is considered tolerable based the occasional probability and serious severity.
2.	5. Further information to help characterise the problem
	None
2.	6. Background on Issue
	The problem was detected by a customer and reported to the manufacturer. The analysis found that the **root cause** is **a software malfunction**: Incorrect calculations of order quantity in weight units, for orders added to Shopping Cart when using automatic buttons.
2.	7. Other information relevant to FSCA
	iMDsoft offers alternative solution to prevent incident from occurring: - Configure the button described in the scenario to open Order Entry form with the specific template INSTEAD of entering it automatically.

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User*** ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None Approach iMDsoft support to receive the relevant Metavision HF and install it
3.	2. By when should the action be completed? — Specify where critical to patient/end user safety: As soon as the corrective software version is available for upgrade.
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. The corrective software version will eliminate the detected issue, and no further review is required.
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) — Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Corrective actions included the software malfunction fix and its release.
3	6. By when should the action be completed? — Actions have already been completed
3.	7. Is the FSN required to be communicated to the patient / lay user? — No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? Choose an item. Choose an item.

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	3. For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	Choose an item.
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	iMDsoft Ltd
	b. Address	See 1st page footer
	c. Website address	www.imd-soft.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	[redacted]

	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.