Proven Clinical Information Systems

Date: 11 February 2021

Urgent Field Safety Notice
MetaVision Suite

For Attention of*:TBD

Contact details of local representative (name, e-mail, telephone, address etc.)*
TBD

Urgent Field Safety Notice (FSN)
MetaVision Suite
Risk of misleading clinical judgement.

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	MetaVision Suite is a standalone software as a medical device (SaMD) Clinical Information System, Anaesthesia Patient Data Management System and Electronic health Record
1.	2. Commercial name(s)
	MetaVision Suite
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	The MetaVision Suite 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 suite 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 preset specification; and (iv) the electronic display of medical device data.
1.	5. Device Model/Catalogue/part number(s)*
	MetaVision Suite 6.x
1.	6. Software version
	MetaVision Suite versions 6.10.x, 6.11.0000-6.11.0081, 6.12.0000-6.12.0005
1.	7. Affected serial or lot number range
	MetaVision Suite versions 6.10.x, 6.11.0000-6.11.0081, 6.12.0000-6.12.0005
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Orders in MetaVision remain displayed in active status, even after last dose was administered by the healthcare providers. This scenario might occur in the following circumstances: - Continuous orders with stop method “number of doses”. - PRN orders with any stop method, apart from “No Time Limit”
2.	2. Hazard giving rise to the FSCA*
	Displaying orders in active status, even though there are no more doses to administer to the patient, might mislead the physicians’ clinical judgment while reviewing the treatment plan and lead to temporary deterioration in patient’s health.
2.	3. Probability of problem arising
	Reasonably probable
2.	4. Predicted risk to patient/users
	A temporary deterioration in the patient’s health due to miss of medication dosage(s) or the temporary provision of treatment or clinical decisions based on misleading information.

2.	5. Further information to help characterise the problem
	The issue may pose the abovementioned risk for customers using the workflow described
2.	6. Background on Issue
	Issue resulted from a software malfunction
2.	7. Other information relevant to FSCA
	Closely review and monitor continuous orders planned with stop method 'number of doses' and PRN orders planned with any stop method, apart from 'no time limit'. - Ensure treatment per accurate plan is provided.

	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 Uninstall affected and malfunctioned software version and install the corrective software version provided to you as soon as possible.	
3.	2. By when should the action be completed?	Specify where critical to patient/end user safety With no further unjustifiable delay after the receipt of the corrective software version
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justification why none 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 Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	With no further delay
3.	7. Is the FSN required to be communicated to the patient /lay user?	N/A
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? *	No
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	Kiryat Atidim, # 4, POB 58178, Tel Aviv, 6158101
	c. Website address	**www.imd-soft.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	**Yoav Palit** **Director of Compliance** 

	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.