Meierhofer Medizitechnik GmbH
Werner-Eckert-Str. 12
81829 München
www.meierhofer.com
Actor-ID/SRN: DE-MF-000008662

Field Safety Notice No. : 03
Safety Corrective Action No.: 001

Date*: 02.08.2024

Urgent Field Safety Notice (FSN)

Instructions for Use
concerning
M-PDMS

Adressee*: Application Managers M-PDMS, Users

Sender*:
Account Manager/Project Manager Meierhofer AG, Werner-Eckert-Straße 12, 81829 München, Germany – email: support@meierhofer.com; phone: +49 89 442316-112
Contact person in Germany
Meierhofer Medizintechnik GmbH, Emilienstraße 15, 04107 Leipzig, Germany, email: support@meierhofer.com; phone: +49 89 442316-112

Meierhofer
Based on:
Template SFN_MMT & MAG (V2.0, 18.02.2022) / External

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Risk addressed by FSN

1. Information on affected product
Product name(s)*
M-PDMS - Patient data management for intensive/intermediate care units and anesthesia
Primary clinical purpose of the product*
M-PDMS is a patient data management system for the presentation and documentation of clinical data. The product supports medical professionals in their diagnosis and therapy planning, as well as risk management.
Product variant incl. UDI*
M-PDMS, UDI: 04262352280035
Software version
3.2.x; 3.3.x
Serial number(s) affected
All serial numbers of this version

2. Reason for Field Safety Corrective Action (FSCA)
Description of the product problem*
If a syringe pump is suddenly switched to standby mode, the interface does not recognize this. This means that the last known flow rate continues to be transmitted. The syringe pump interval continues to be displayed in the medication and the volume is still included in the balance calculation. If the interface needs to be restarted, all currently running syringe pump intervals are stopped for all patients without an end time. This means that syringe pumps that are running correctly are also stopped, so that the undocumented volume is not included in the balance. Manual editing of the automatic intervals is not possible. A support ticket must therefore be opened in each of these cases.
Hazard giving rise to the FSCA*
It is possible for the patient to receive too much or too little fluid in individual cases, leading to an imbalance in the patient's fluid balance. By implementing the measures described below, this risk is reduced to the residual risk that exists when the interface is working correctly.
Probability of problem arising
- Multiple times per day for individual patients (plus balance)
Predicted risk to patient/users
- No user risk. Due to the inclusion of the patient's clinical condition in accordance with the M-PDMS safety instruction as well as visibly incorrect documentation in the patient curve, a medium risk for the patient must be assumed.
Background on the Issue
- The cause of the problem is a changed behavior of the syringe pump interface when handling the stop time of continuous doses in fluid management.
Other information relevant to the FSCA
- The behavior affects all versions of the interface software that are released and in use with the M-PDMS versions specified above.

3. Type of action to mitigate the risk*

Action to be taken by the addressee*

☐ Identify product ☐ Disable product

☐ On-site product modification/inspection

☒ Follow patient management recommendations

☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

☐ Other ☐ None

Further details on the measure(s) identified

Description of a safe application until implementation of the measure *	The automatic syringe pump transfer must not be used until the software correction has been delivered. The documentation must be done manually. The automatic transfer can be specifically switched off by the support team. This does not affect the transfer of data from other medical devices. Please make an appointment with the support team to selectively deactivate the syringe pump transfer.
By when should the action be completed?	09.08.2024

Is a customer reply required?* (If yes, attach form specifying deadline for return)	No

Action Being Taken by the Manufacturer

☒ On-site product modification/inspection
☒ Software upgrade ☐ IFU change
☐ Other ☐ None

Further details on the measure(s) identified

By when should the action be completed?	Indicate where this is critical to the safety of patients/end users.

Is the FSN required to be communicated to the patient?	n/a

If yes, has manufacturer provided additional information suitable for the patient in a patient information sheet?

n/a n/a

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4. General information*

FSN Type*	☒ New ☐ Update
For updated FSN: reference number and date of previous FSN	
For Updated FSN, key new information as follows:	
key differences in devices affected and/or action to be taken	
Further advice expected in follow-up FSN*	
If follow-up FSN expected, what is the further advice expected to relate to:	
Update of the interface software for infusion technology	
Anticipated timescale for follow-up FSN	
The Federal Institute for Drugs and Medical Devices has received a copy of this notification.*	
Attachments:	none
Name	Mirjam Stamm
Date	02.08.2024
Signature Person responsible for regulatory compliance (according to MDR Article 15)	

Transmission of this Field Safety Notice

This notice must be passed on all those who need to be aware within your organization and/or any organization where the potentially affected products have been transferred.
(Depending on the case)

Please forward this message to other organizations affected by this measure.
(depending on the situation)

Please maintain awareness of this notice and the resulting actions for an appropriate period of time to ensure the effectiveness of the corrective actions.

Please keep this information at least until the measure has been completed.

Please report any incidents related to the product to the manufacturer, distributor or local representative and, if applicable, the competent national authority, as this will provide important feedback.

Note: Fields marked with * are required for all FSNs. Others are optional.