Mesalvo

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31.08.2026

Urgent Field Safety Notice

Meona – Incorrect aggregation of drain and probe volumes in the fluid balance

Date	31.08.2026
Manufacturer's reference number	IQMS-29
Competent authority reference	Germany (BfArM): 37642/26 · Norway (NoMA): 26/30207
For the attention of	Users of Meona; nursing and medical management of intensive care and general wards; medical device safety officers; IT management

1. Affected products

Product type	Software as a medical device – clinical workplace system with electronic patient chart (CIS/PDMS)
Trade name	Meona
UDI-DI	4262357191084
Basic UDI-DI	426235719MEOHH
Primary clinical purpose	Documentation and display of the clinical course of treatment, including physician orders, nursing administration documentation and fluid balance
Model	Release V
Affected software versions	**Affected (defect present from) → corrected with:**

	Release line 2024.10: from **2024.10.30** → corrected with **2024.10.33** Release line 2025.04: from **2025.04.18** → corrected with **2025.04.22** Release line 2026.03: from **2026.03.0-RC7** (release candidate) → corrected with **2026.03.1** (and hotfix **2026.03.0.3**) In each case the stated version and all subsequent versions up to the corrected version are affected.
Serial numbers / lots	not applicable
Associated products	none. Documentation is performed manually by nursing staff; no external devices are controlled.

2. Reason for the field safety corrective action

Description of the problem

When documenting a bag change on drains, probes and stomata – including chest drains, cerebral/CSF drains and stomata such as colostomy, ileostomy and nephrostomy – the user is asked, after entering the drained volume, whether the volume is to be documented as intake or as output.

This entry is recorded correctly and is displayed correctly in the individual documentation under “Accesses, probes and drains”. The error lies in the automatic transfer of these volumes into the fluid balance: there, the direction for probes and drains is reversed. A volume documented as output is entered into the balance as intake and vice versa. Oral intake as well as infusions and intravenous administrations are balanced correctly.

Hazard giving rise to this action

As a result, the total balance shown in the chart may be incorrect in the probe and drain component. If the balance is used to manage fluid therapy – for example for volume, diuretic or catecholamine decisions – an incorrect balance may lead to a treatment decision that is not appropriate to the patient's needs. Treatment situations with high drained volumes via drains and probes are particularly affected.

Probability of occurrence

The error occurs reproducibly whenever a bag change with a drained volume is documented for the affected documentation classes. It concerns exclusively the automatic aggregation in the balance, not the individual documentation.

Foreseeable risk to patients

No patient harm is known to the manufacturer. The risk arises indirectly from a possible misinterpretation of the displayed balance and exists only for ongoing treatments in which the balance is used to manage therapy. For completed treatments and patients already discharged there is no continuing risk, as no further treatment decisions are made on that basis.

The risk is further limited by the fact that the individual documentation of the drained volumes remains correct and traceable, that the drained volume is physically legible on the

container, and that the displayed information must, in accordance with the instructions for use, be checked critically in any case.

Background

The deviation was introduced with an earlier correction and was identified in the course of customer reports in August 2026. It was present in delivered versions from versions 2024.10.30, 2025.04.18 and 2026.03.0-RC7 (release candidate).

Further scoping information

The error affects exclusively the automated fluid-balance calculation in the context of the intensive care chart (probe/drain component). The individual documentation of intake/output values is correct on both general and intensive care wards; the general-ward balance is correct. The effect is configuration-dependent and reproducible in the intensive care configuration. Affected documentation classes: chest, cerebral/CSF and subdural drains as well as stomata (colostomy, ileostomy, nephrostomy).

3. Actions

Actions to be taken by the user

- Forward this notice to all persons who need to be aware of it within your organisation – in particular to nursing staff and the medical management of the areas in which drains, probes and stomata are documented.
- Until the corrected version is installed: for ongoing treatments, do not use the fluid balance shown in the chart as a basis for decisions without checking it, where bag changes with a drained volume were documented in the period under review. The probe and drain component must be recalculated from the individual documentation under “Accesses, probes and drains”; those values are correct.
- Install the correction available for your release line (**2024.10.33, 2025.04.22 or 2026.03.1; hotfix 2026.03.0.3**). The correction is available immediately and can be applied as a standalone correction (hotfix).
- Respond to the manufacturer using the enclosed reply form by **14.09.2026** (14 days from the dispatch date).

Note on treatment records already documented

The error occurred in the calculation of the balance, not in the stored individual values. Affected balance displays cannot therefore be identified automatically. The manufacturer can state the period during which the error was present in your version, as well as the affected documentation types.

A retrospective correction of treatment records already documented will not be carried out. Completed documentation is not altered retrospectively; this is in line with the principles of medical documentation. The corrected version therefore does not recalculate balances already displayed, but takes effect from installation for further documentation.

Whether and to what extent a retrospective review of treatment courses is carried out is decided by the treating institution. The individual values required for this are present in Meona and correct; the probe and drain component of a balance can be recalculated from them.

Actions taken by the manufacturer

- The corrected version is available; it has been merged into the affected release lines and can be applied immediately as a standalone correction (hotfix). Installation route (self-installation or by the manufacturer): see reply form.
- Notification of the competent authorities in the affected markets.

Is a response required?

Yes. Please confirm receipt of this notice and implementation of the actions using the enclosed form.

Transmission to patients or lay users

Not required. The product is used exclusively by medical professionals in healthcare institutions.

4. General information

Type of this notice	Initial notice
Follow-up notice foreseen	No
Manufacturer	Mesalvo Freiburg GmbH, Heinrich-von-Stephan-Strasse 25, 79100 Freiburg, Germany
Website	www.mesalvo.com
Contact	Rudolf Wagner, Person Responsible for Regulatory Compliance (Art. 15 MDR), **prrc@mesalvo.com**
Competent authority informed	Yes. The competent authority in your country has been informed of this field safety corrective action. In Germany the case is registered with the Federal Institute for Drugs and Medical Devices (BfArM) under reference 37642/26.
Attachments	Reply form; information on installing the correction
Name / signature	Rudolf Wagner, PRRC

Transmission of this notice

This notice is to be passed on to all persons who need to be aware of it within your organisation or in any organisation to which affected products have been transferred. Please forward this notice to other organisations where applicable. Please retain this notice until the actions have been completed.

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Customer Reply Form to the Field Safety Notice

Meona – fluid balance (probes/drains) · IQMS-29

1. Field Safety Notice (FSN) information	
FSN reference number *	IQMS-29
FSN date *	31.08.2026
Product / device name *	Meona
UDI	UDI-DI 4262357191084 / Basic UDI-DI 426235719ME-OHH
Affected versions	from 2024.10.30 / 2025.04.18 / 2026.03.0-RC7 and subsequent versions
Corrected with	2024.10.33 / 2025.04.22 / 2026.03.1 (Hotfix 2026.03.0.3)
Version currently in use (please complete)	
Serial / lot numbers	not applicable (software; scoped by version)

2. Customer details	
Account number	
Healthcare organisation name *	
Organisation address *	
Department / unit	

Contact name *	
Title or function	
Telephone number *	
Email *	
Medical device safety officer – name / email	

3. Customer action undertaken		
☐	I confirm receipt of the Field Safety Notice and that I have read and understood its content.	
☐	The information and required actions have been brought to the attention of all relevant users (nursing, medical management, IT).	
☐	Until the correction is installed, the displayed fluid balance is not used as an unchecked basis for decisions (interim measure per FSN).	
Correction – please select one option:		
☐	(a) We will install the provided correction / hotfix ourselves.	Planned date: ____
☐	We request Mesalvo to install the correction.	Planned date: ____
☐	(b) We will apply the correction with the next service pack.	Service pack / date: ____
☐	I have a query – please contact me.	

Print name *	
Signature *	
Date *	

4. Return acknowledgement to sender	
Email	**prrc@mesalvo.com**
Postal address	Mesalvo Freiburg GmbH, Heinrich-von-Stephan-Straße 25, 79100 Freiburg, Germany
Deadline for returning this form *	**14.09.2026** (14 days from the dispatch date)

Mandatory fields are marked with *.

It is important that your organisation takes the actions detailed in the FSN and confirms receipt. Your reply is the evidence we need to monitor the progress of the corrective action.

Customer Reply Form · Field Safety Notice · Meona · IQMS-29