WEINMANN Emergency Medical Technology GmbH + Co. KG
PO Box 57 01 53 • 22770 Hamburg • GERMANY

Hamburg, May 2025

Important safety information:

Field Safety Corrective Action on a medical device

Reference: FSCA MMS2_2025-05.01_PSSConnector

Sender:
WEINMANN Emergency Medical Technology GmbH + Co. KG

Addressee:
Users and operators and specialist trade partners

Medical devices affected (trade name and article no. of products)**:**

WEINMANN MEDUMAT Standard² ventilators produced between 2023-06-01 and 2023-12-18 or those that received a new connection for ventilation hose (e.g. through repair or maintenance) during this period are affected.

Company Headquarters
WEINMANN Emergency
Medical Technology GmbH + Co. KG
Frohbösestraße 12 • 22525 Hamburg • GERMANY
T: +49 40 88 18 96-0
F: +49 40 88 18 96-480
www.weinmann-emergency.com

Center for Production, Logistics, Service
WEINMANN Emergency
Medical Technology GmbH + Co. KG
Siebenstücken 14 • 24558 Henstedt-Ulzburg
GERMANY

Business Management
Dipl.-Volksw. Marc Griefahn
Dipl.-Kfm. Philipp Schroeder
Dipl.-Volksw. André Schulte

Registration Court
Hamburg Municipal Court
Dept. A # 115967
V.A.T. # DE288367727
WEEE Reg. # DE 47913245

Creditor ID
DE35ZZZ00000353971

General Partner
WEINMANN Emergency
Management GmbH, Hamburg

Registration Court
Hamburg Municipal Court
Dept. B # 38144

Certified QM System meeting
EU 2017/745, Annex IX
ISO 9001 + EN ISO 13485

Banking Connections

Deutsche Bank AG Hamburg
IBAN DE87 2007 0000 0646 9639 00
SWIFT DEUTDEHH

Hamburger Sparkasse AG
IBAN DE44 2005 0550 1032 2626 67
SWIFT HASPDEHHXXX

Commerzbank AG Hamburg
IBAN DE14 2004 0000 0632 0071 00
SWIFT COBADEHHXXX

	MEDUMAT Standard²	Serial number range affected
Basic devices	**WM 28710-01** MEDUMAT Standard², ventilator, basic device	The affected serial numbers can be found using the following link: DE-EN_SN-Nr_FSCA_MMS2_2025-05.01_PSSConnector.pdf
	WM 28710-02 MEDUMAT Standard², ventilator, basic device with CO2 measurement	
	WM 28710-03 MEDUMAT Standard², ventilator, basic device with compressed gas connection on the rear	
	WM 28710-04 MEDUMAT Standard², ventilator, basic device with CO2 measurement and compressed gas connection on the rear	
Sales variants	**WM 29300** MEDUMAT Standard², ventilator with compressed gas connection on the rear, with MEDUtrigger and ventilation modes CPR, RSI, IPPV, CPAP and Demand mode	
	WM 29500 MEDUMAT Standard², ventilator with CO2 measurement, MEDUtrigger and ventilation modes CPR, RSI, IPPV, CPAP and Demand mode	
	WM 9400 MEDUMAT Standard², ventilator on LIFE-BASE 1 NG XL	
	WM 9410 MEDUMAT Standard², ventilator on LIFE-BASE 3 NG	
	WM 9719 MEDUMAT Standard², ventilator on LIFE-BASE 4 NG for oxygen cylinder 2.5 l	
	WM 9870 MEDUMAT Standard², ventilator on LIFE-BASE 1 NG XS	
	WM 9895 MEDUMAT Standard², ventilator on LIFE-BASE light XS	
	WM 9913 MEDUMAT Standard² (ventilator) with MEDUCORE Standard² (monitor/defibrillator) on LIFE-BASE 1 NG XL	
	WM 9931 MEDUMAT Standard² (ventilator) with MEDUCORE Standard² (monitor/defibrillator) on LIFE-BASE 3 NG	
Kit, maintenance/repair	**WM 15983** Kit, supplementary maintenance, 8 years, for MEDUMAT Standard², compressed gas connection on the side	
	WM 28980 Pneumatics for MEDUMAT Standard² (compressed gas connection, side), complete, technically refurbished in exchange	
	WM 15946 Kit, ventilation hose connection, including O-ring (without clamps)	

To whom it may concern,

Quality and safety are our top priority. Consequently, applying our accustomed consistency and transparency, we request that you implement this Safety Corrective Action, so that users can continue to deploy our products on patients as usual.

1. Description of problem and cause:

As part of our regular quality controls, we have noticed that there are more and more reports of the connector for the ventilation hose breaking on the MEDUMAT Standard² during the change of the breathing circuit. This problem is due to a specific batch of installed connectors.

2. What is the risk to the patient?

As long as there is no indication of a broken ventilation hose connection during a change of the breathing circuit or a function check, there is no increased risk for the patient when using MEDUMAT Standard². These devices can therefore be used as usual until the ventilation hose connection is replaced.

If a device with a broken or loose ventilation hose connection is used, it is conceivable that the pressure inside the device will increase, which may have a negative effect on ventilation performance. As soon as there is any suspicion of a broken or loose ventilation hose connection, the device should not be used until it has been repaired.

3. Action:

Please have the affected component (in this case the ventilation hose connection) replaced in all MEDUMAT Standard² with an affected serial number by your responsible WEINMANN service.

4. What action do you need to take now?

If you are a specialist dealer:

1. Use the attached **report form** to confirm receipt of this letter no later than **2025-06-30.**
2. Check the serial numbers listed online (DE-EN_SN-Nr_FSCA_MMS2_2025-05.01_PSSConnector.pdf) and determine which of your customers has received a corresponding device.
3. Ensure that your customers with affected devices are aware of this safety information and the associated Safety Corrective Action:
    - Forward this FSN (Field Safety Notice) to the affected customers.
    - Have your customers confirm receipt of the letter.
    - In turn, ask your customers to have the Safety Corrective Action carried out by the responsible WEINMANN service.
4. For affected devices that you still have access to, arrange for the affected component to be replaced by the responsible WEINMANN service.

If you are a user or operator:

1. Use the attached **report form** to confirm receipt of this letter no later than **2025-06-30.**
2. Check the serial numbers listed online (DE-EN_SN-Nr_FSCA_MMS2_2025-05.01_PSSConnector.pdf) and determine which of the devices you have access to.
3. Please only send us the affected MEDUMAT Standard² ventilator (without any other accessories). We can only ensure fast processing if you follow this instruction.

Contact
If you have any questions, or need assistance, please contact your local service partner or Technical Service:

Phone: +49 40 88 18 96 – 0
E-mail: AfterSalesService@weinmann-emt.de

Best regards,

WEINMANN Emergency
Medical Technology GmbH + Co. KG

André Schulte
Managing Director

Dr. Florian Dietz
PRRC
Global QRA Manager

This document was compiled electronically and is valid without signatures.

Attachments

- Form: “Report back on safety information”
- Link to list of serial numbers affected: https://www.weinmann-emergency.com/fileadmin/data/47_fsca/MMS2_2025-05.01/DE-EN_SN-Nr_FSCA_MMS2_2025-05.01_PSSConnector.pdf

Please use the digital reply form at:
FSCA MMS2_2025-05.01_PSSConnector | WEINMANN Emergency (weinmann-emergency.com)
or complete this reply form and return it to us by e-mail, fax, or mail to:

E-mail: **AfterSalesService@weinmann-emt.de**
Fax: **+49 40 88 18 96 - 490**

WEINMANN Emergency Medical Technology GmbH + Co. KG
After Sales Service
Frohbösestraße 12
22525 Hamburg, GERMANY

☐ **I hereby confirm receipt of this letter** and that I **have read, understood and will implement its contents**. **This letter has been brought to the attention of all users of the product and of other people in my organization who need to be informed**.
If the products have been passed on to third parties (applies to specialist dealers, for example), a **copy of this information has been passed on to them**.

Please complete in full in block capitals:

☐ Company/organization details:

Customer no.: _____

Company/organization + address: _____

_____

_____

☐ **I am no longer in possession of the medical device:**

☐ **The new owner is (company + address)**

_____

_____

☐ **We have disposed of the following medical devices (enter name of medical device incl. serial number):**

_____

_____

_____ _____
Date, signature Name (in block letters)

_____ _____
Position (in block letters) E-mail address (in block letters)