Hamburg, July 2025

Important safety information:
Field Safety Corrective Action on a medical device

Reference: FSCA MMS2_2025-07.01_SW5.7BugBT

Sender:
WEINMANN Emergency Medical Technology GmbH + Co. KG

Addressee:
Users and operators as well as specialist trade partners and service partners

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

WEINMANN MEDUMAT Standard² ventilators with firmware versions 5.7 & 5.9 are affected. These are devices with a delivery date in the period from 2025-01-27 to 2025-06-26 and devices that have received an update to the affected firmware versions (in short: FW 5.7 & FW 5.9). In addition, the software option "**Bluetooth®** data transmission for MEDUMAT Standard²" (WM 28945) must have been activated on these devices.

	MEDUMAT Standard²
Basic devices	**WM 28710-01** MEDUMAT Standard², ventilator, basic device
	WM 28710-02 MEDUMAT Standard², ventilator, basic device with CO_2 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 CO_2 measurement and compressed gas connection on the rear
Sales variants (example)	**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 CO_2 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 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
Loan devices	**WM 28950** Loan device, MEDUMAT Standard² (compressed gas connection on the side)
	WM 28944 Loan device, MEDUMAT Standard² (compressed gas connection on the rear)
Further articles for maintenance, updates, and options	**WM 17878** Kit, retrofitting hardware option flow measurement for MEDUMAT Standard² up to SN 4999
	WM 17607 Maintenance kit 12 years MEDUMAT Standard² to SN 4999
	WM 15984 Maintenance kit 12 years MEDUMAT Standard² from SN 5000
	WM 28770 Circuit board/PCB mainboard MEDUMAT Standard²
	WM 29438 Firmware update version 5.x for MEDUMAT Standard²

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 Field Safety Corrective Action, so that users can continue to deploy our products on patients as usual.

1. Description of problem and root cause:

As part of our continuous market monitoring, we have found that MEDUMAT Standard² with a firmware version 5.7 or 5.9 experiences a device failure if an additional Bluetooth® connection request is sent to the device during an existing Bluetooth® connection. This may be the case, e.g. when using electronic patient documentation systems.

MEDUMAT Standard² devices without the active software option "Bluetooth® data transmission for MEDUMAT Standard²" (WM 28945) are not affected by this problem. As soon as the corresponding software option is activated, these devices are also affected.

2. What is the risk to the patient?

In the above-mentioned situation, therapy is not possible or only possible after a delay. In this case, an alternative means of ventilation must be used.

3. Action:

The remedy is to downgrade to firmware version 5.5. This firmware version enables the safe use of MEDUMAT Standard².

The following steps must be followed to carry out the downgrade:

1. Download the required firmware version 5.5 for MEDUMAT Standard².
    a. The downgrade file is available to download from our download page (https://www.weinmann-emergency.com/sw-downgrade-55-mms2) (firmware package: MEDUMAT_Standard2_FW_5.5_downgrade.zip).
    b. The downgrade can only be carried out securely with this firmware file. Files that are already in circulation for an update to firmware version 5.5 are not suitable for a downgrade.
    c. It is important to note the patient presets on the affected devices.
2. Install firmware version 5.5 on all affected devices.
    a. Chapter 4 "Updating software" of the instructions for use for MEDUMAT Standard² includes details on how to carry out a software update, the firmware downgrade is carried out in the same way.
    b. The current MEDUMAT Standard² instructions for use from software version 5.1 are available in the download center (https://weinmann-emergency.canto.de/v/downloadEN/)
3. The downgrade process can theoretically lead to changes in the presets in the device. We therefore recommend checking the patient presets after the downgrade.
    a. The patient presets can be found in the operator menu (cf. instructions for use for MEDUMAT Standard² in Chapter 6.3.8 "Presets patient").
    b. Particular attention should be paid to the presets for the ventilation pause during manual CPR, the maximum airway pressures during CPR and the preset volumes for different patient groups.
4. Please report to us that you have downgraded your firmware for the specific device.
    a. Use the online form on the firmware download page to do this (https://www.weinmann-emergency.com/sw-downgrade-55-mms2).
    b. If that form is not accessible, please use the documentation form included in the MEDUMAT_Standard2_SW_5.5_downgrade.zip firmware package as an alternative means of reporting back to us.
5. Please perform all **corrective actions by no later than 2025-08-31**.

Prompt implementation of this action is particularly relevant for customers who wish to continue using Bluetooth® data transmission reliably and securely.

4. What actions do you need to take now?

If you are a specialist trade partner or service partner:

1. Use the attached **report form** to confirm receipt of this letter no later than **2025-08-15.**
2. Check which of your customers have received MEDUMAT Standard² with the affected firmware versions (5.7 & 5.9), taking firmware updates into account.
3. Ensure that your customers with the affected devices are aware of this FSN (Field Safety Notice) including the associated Field Safety Corrective Action:
    - Forward this FSN to the affected customers
    - Have your customers confirm receipt of the FSN.
    - Request that your customers then carry out the Field Safety Corrective Action.
4. For affected devices that you still have access to, implement the remedy (downgrade to firmware version 5.5).
5. For service partners: If you still have mainboards from the delivery period 2025-01-27 to 2025-07-11 (e.g. as part of a maintenance kit), make sure that you downgrade to firmware version 5.5 after installation as required.

If you are a user or operator:

1. Use the attached **report form** to confirm receipt of this letter no later than **2025-08-15**.
2. Check which of your MEDUMAT Standard² devices have the affected firmware versions (FW 5.7 & FW 5.9) installed, taking firmware updates into account.
3. Implement the remedy (downgrade to firmware version 5.5) on the affected devices.

Contact
If you have any questions or need assistance, please contact your specialist dealer or your WEINMANN contact (Contact | WEINMANN Emergency).

Best regards,

WEINMANN Emergency
Medical Technology GmbH + Co. KG

This document was compiled electronically and is valid without signatures.

Attachments

- Form: “Report on field safety notice”

Please use the digital reply form at:
FSCA MMS2_2025-07.01 Feedback | WEINMANN Emergency (weinmann-emergency.com)
(https://www.weinmann-emergency.com/field-safety-corrective-actions/fsca-mms2-2025-0701/feedback)
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)