

WEINMANN Emergency Medical Technology GmbH
 PO Box 57 01 53 • 22770 Hamburg • GERMANY

Hamburg, May 2026

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

Reference: FSCA MMS2 2026-05.01 PSSUnnoticedLeak

Sender:
 WEINMANN Emergency Medical Technology GmbH

Addressee:
 Users and operators as well as specialist dealers

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

MEDUMAT Standard²	
Basic devices	WM 28710-01 MEDUMAT Standard ² , ventilator, basic device without CO ₂ measurement
	WM 28710-02 MEDUMAT Standard ² , ventilator, basic device with CO ₂ measurement
	WM 28710-03 MEDUMAT Standard ² , ventilator, basic device without CO ₂ measurement and with compressed gas connection on the rear
	WM 28710-04 MEDUMAT Standard ² , ventilator, basic device with CO ₂ measurement and compressed gas connection on the rear

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Center for Production, Logistics, Service
 WEINMANN Emergency Medical Technology GmbH
 Siebenstücken 14 • 24558 Henstedt-Ulzburg
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Business Management
 Dipl.-Volksw. Marc Griefahn, Dipl.-Kfm. Philipp Schroeder,
 Dipl.-Volksw. André Schulte

Registration Court
 Hamburg Municipal Court, Dept. B # 194350
 V.A.T. # DE288367727; WEEE Reg. # DE 47913245

Creditor ID DE35ZZ00000353971

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 DEUTDE33

Hamburger Sparkasse AG
 IBAN DE44 2005 0550 1032 2626 67
 SWIFT HASPDE33

Commerzbank AG Hamburg
 IBAN DE14 2004 0000 0632 0071 00
 SWIFT COBADE33

Sales variants	WM 29300 MEDUMAT Standard ² , ventilator without CO ₂ measurement
	WM 29500 MEDUMAT Standard ² , ventilator with CO ₂ measurement
	WM 29350 MEDUMAT Standard ² , ventilator without CO ₂ measurement and with compressed gas connection on the rear
	WM 29550 MEDUMAT Standard ² , ventilator with CO ₂ measurement and compressed gas connection on the rear

Dear Sir or Madam,

Quality and safety are our top priority, which is why we want to act consistently and transparently as usual and kindly request that you implement this corrective action as part of your duty to cooperate in accordance with medical device legislation, so that users can continue to use our products safely on patients.

1. Description of problem and cause:

As part of our ongoing post-market surveillance, an analysis has shown that the most common usage-related incidents in the context of emergency ventilation are caused by undetected leakage and disconnections. These can result from movement and unintentional manipulation during ventilation.

- Leak during mask ventilation
- Leak in the airway device
- Leak or disconnection at the breathing circuit, e.g.:
 - Connection for ventilation hose
 - Measuring circuit connector
 - Ventilation hose
 - PEEP control tube
 - Pressure measuring tube
 - FlowCheck sensor
 - CO₂ measuring tube
 - Elbow
 - Breathing system filter

2. What is the risk to the patient?

Leaks may prevent the patient from receiving ventilation as set by the user. If a disconnection occurs in the breathing circuit or between the ventilator and the patient, effective ventilation cannot be delivered. This may expose the patient to life-threatening injuries.

3. Measures during ventilation

Observe the safety information in the instructions for use and the enclosed supplement. Perform a function check before each use.

During ventilation, watch for leaks and disconnections, and pay close attention to any alarms that indicate these issues.

The following **high-priority alarm (red)** may indicate a major leak or a life-threatening disconnection:

- Airway pressure low

The following **high-priority alarms (red)** may also indicate leaks or life-threatening disconnections:

- Apnea (during non-invasive ventilation)
- MVe low (only devices with flow measurement)
- Leak on patient side (only with CCSV option)

The following measured values may indicate a leakage or a disconnection:

- Low or no expiratory tidal volume (Vte)
- Low or no expiratory minute volume (MVe)
- Little or no pressure built up (pressure curve or pressure gauge)

4. What measures should be taken by the addressee?

Along with this letter you will receive

- a reply form
- a notice for display in ambulance stations
- a supplement to the instructions for use with additional information

Are you a specialist dealer?

1. Use the attached **reply form** to confirm receipt of this letter no later than **2026-06-26**.
2. Ensure that your customers employing the above-mentioned devices take note of this safety information.
3. Forward a copy of this letter, together with its attachments, to the affected customers.
4. Ask your customers to confirm receipt of the notice.
5. Instruct your customers to implement the safety measures as described above.

Are you a user or an operator?

1. Use the attached **reply form** to confirm receipt of this letter no later than **2026-06-26**.
2. Ensure that all users of the above-mentioned devices are made aware of this safety note and, in particular, are trained in the procedures to follow during ventilation (see item 3). To help you in this regard, we have compiled a template for a notice that can be displayed in all ambulance stations to draw users' attention specifically to the issue, and a supplement to the instructions for use.

This corrective action is mandatory. The responsible authority has been notified accordingly.

Contact

If you have any questions or require any assistance, please consult your local specialist dealer or contact us directly:

Phone: +49 40 88 18 96 – 0

E-mail: customerservice@weinmann-emt.de

Best regards,

WEINMANN Emergency
Medical Technology GmbH

André Schulte
Managing Director

Dr. Florian Dietz
PRRC
Director Global QRA

This document was issued electronically and is therefore valid without signatures.

Attachments

Notice for display in the ambulance station

Reply form

Supplement to the instructions for use

Please use the digital reply form at:

FSCA MMS2 2026-05.01 Feedback | WEINMANN Emergency

(<https://www.weinmann-emergency.com/field-safety-corrective-actions/fsc-a-mms2-2026-0501>)

or complete this reply form and return it to us by e-mail, fax, or mail to:

E-mail: customerservice@weinmann-emt.de

Fax: +49 40 88 18 96 – 481

WEINMANN Emergency Medical Technology GmbH
Customer Service
Frohösestraße 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)