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 Standard², ventilator, basic device without CO_2 measurement
	WM 28710-02 MEDUMAT Standard², ventilator, basic device with CO_2 measurement
	WM 28710-03 MEDUMAT Standard², ventilator, basic device without CO_2 measurement and 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

Company Headquarters
WEINMANN Emergency Medical Technology GmbH
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
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. B # 194350
V.A.T. # DE288367727; WEEE Reg. # DE 47913245

Creditor ID DE35ZZZ00000353971

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

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
  - CO_2 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.

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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.

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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

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Please use the digital reply form at:
FSCA MMS2_2026-05.01 Feedback | WEINMANN Emergency
(https://www.weinmann-emergency.com/field-safety-corrective-actions/fsca-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
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)

MEDUMAT Standard²

Ventilator

Safety information

Supplement to the instructions for use

This is a supplement to the instructions for use. Please read this safety information along with the instructions for use before using the product. Failure to observe the information contained therein can result in serious injuries or even death.

Table of Contents

Sicherheitsinformation

Dieser Sicherheitshinweis sind eine Ergänzung zum Kapitel „Sicherheitshinweise" der Gebrauchsanweisung des Gerätes. Beachten Sie auch immer die Gebrauchsanweisung. Die Gebrauchsanweisung und diese Ergänzung finden Sie unter www.weinmann-emergency.com.

⚠ WARNUNG

Therapiegefährdung oder Therapieausfall durch Leckagen oder Diskonnektionen während der Beatmung!

Leckagen während der Beatmung können das applizierte Atemvolumen oder den Atemwegsdruck verringern. Wenn schwerwiegende Leckagen auftreten oder eine Diskonnektion zwischen Patient und Gerät vorliegt, kann der Patient nicht beatmet werden. Dies kann den Patienten schwer oder lebensbedrohlich verletzen.

⇒ Geeignetes Monitoring ($etCO_2$, SpO_2 oder exspiratorische Volumenmessung MVe) verwenden.

⇒ Sofort auf Alarme und Störungen reagieren, die auf Leckagen oder Diskonnektionen hinweisen (Atemwegsdruck ↓, MVe ↓, Patientenseitige Leckage (im CCSV-Modus)).

⇒ Korrekten Sitz von Maske oder Atemwegshilfe prüfen.

⇒ Alle Verbindungen des Patientenschlauchsystems zwischen Gerät und Patient auf Diskonnektionen prüfen.

Safety information

This safety information supplements the "Safety information" chapter of the instructions for use for the device. Please also always observe the instructions for use. The instructions for use and this supplement can be found at: www.weinmann-emergency.com.

⚠ WARNING

Risk of compromised therapy or therapy failure due to leaks or disconnections during ventilation!

Leaks during ventilation can reduce the applied tidal volume or airway pressure. If a serious leak occurs or there is a disconnection between the patient and the device, the patient cannot be ventilated. This may result in serious or life-threatening injury to the patient.

⇒ Use suitable monitoring ($etCO_2$, SpO_2 or expiratory volume measurement MVe).

⇒ Respond immediately to alarms and malfunctions that indicate leaks or disconnections (Airway pressure ↓, MVe ↓, Leakage on patient side (in CCSV mode)).

⇒ Check that the mask or airway device is correctly positioned.

⇒ Check all breathing circuit connections between the device and the patient for disconnections.

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