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

Hamburg, September 2024

Important safety information:

Field Safety Corrective Action on a medical device

Subject: FSCA MMT_MMS2_2024-10.01_CO2wCPR

Sender:
WEINMANN Emergency Medical Technology GmbH + Co. KG

Addressee:
Users and operators as well as specialist dealers

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

This FSCA concerns all WEINMANN MEDUMAT Transport and MEDUMAT Standard² ventilators with CO_2 measurement. These are the following articles:

	MEDUMAT Standard² with CO_2 measurement	**MEDUMAT Transport with CO_2 measurement**
Basic devices	**WM 28710-02** MEDUMAT Standard², ventilator, basic device with CO_2 measurement	**WM 28415** MEDUMAT Transport, ventilator, basic device with CO_2 measurement
	WM 28710-04 MEDUMAT Standard², ventilator, basic device with CO_2 measurement and compressed gas connection on the rear	

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Center for Production, Logistics, Service
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Business Management
Dipl.-Volksw. Marc Griefahn
Dipl.-Kfm. Philipp Schroeder
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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

Sales variants	**WM 29500** MEDUMAT Standard^2, ventilator with CO_2 measurement	**WM 28400** MEDUMAT Transport, ventilator with CO_2 measurement
	WM 29550 MEDUMAT Standard^2, ventilator with CO_2 measurement and compressed gas connection on the rear	
Loan devices	**WM 28950** MEDUMAT Standard^2 loan device with CO_2 measurement	**WM 28615** MEDUMAT Transport loan device, ventilator with CO_2 measurement
	WM 28944 MEDUMAT Standard^2 loan device with CO_2 measurement and compressed gas connection on the rear	

Dear Sir or Madam,

Quality and safety are our top priorities, which is why we want to act consistently and transparently as usual and kindly request that you implement this Field Safety 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:
Chest compressions can lead to high-frequency air movements (typically 100–120/min) at the patient connection opening of the ventilation hose, which is where the gas sample for the $etCO_2$ measurement is taken. The air movements can be detected by the devices as “pseudo breaths” and may affect the accuracy of the $etCO_2$ measurement due to their high frequency. This could result in the $etCO_2$ measurement being erroneously displayed as too low and implausible alarms possibly being triggered.

This issue associated with $etCO_2$ measurement using the side-stream method is already known on the market. A selection of market observation and academic studies are provided here for your information:

- https://www.sciencedirect.com/science/article/abs/pii/S0300957220302094
- https://www.capnoacademy.com/2018/10/03/rogue-capno-waves-resuscitation-team-notes-unusual-waveform-during-cpr/
- https://www.intechopen.com/chapters/65689
- https://www.researchgate.net/publication/295373123_High_Incidence_of_Chest_Compression_Oscillations_Associated_With_Capnography_During_Out-of-Hospital_Cardiopulmonary_Resuscitation

Why is WEINMANN drawing attention to this issue if it is already known on the market?
The importance of CO_2 measurement in resuscitation has increased in recent years, with resuscitation efforts derived from the CO_2 measurement also increasing in importance as a result. In order to avoid potential harm to the patient, we view it as our duty to draw your attention as users of our devices specifically to this $etCO_2$ measurement issue.

2. What is the risk for the patient?
Erroneously low $etCO_2$ measurements can lead to incorrect decisions being taken when performing resuscitation accompanied by possible harm to the patient.

3. Action
Please observe the safety information that will be included in the instructions for use of the MEDUMAT Standard² and MEDUMAT Transport ventilators in the future:

⚠ WARNING

Delay in treatment due to abnormal CO_2 measurement during chest compressions!
The device's CO_2 measurement function is **not** designed for the high frequencies (100/min to 120/min) encountered during chest compressions. Chest compression can be detected by the device as high-frequency breathing, which can result in the $etCO_2$ measurement being erroneously displayed as too low and trigger implausible alarms. This can confuse the user and delay treatment.
⇒ Do **not** rely on the $etCO_2$ measurement as the sole indication for stopping cardiopulmonary resuscitation!
Please note: The $etCO_2$ measurement and the CO_2 curve can still be used for:

- checking the tube position;
- identifying the return of spontaneous circulation (ROSC) by a sudden increase in the $etCO_2$ measurement.

The safety information can also be found in the "Supplement to the instructions for use". This "Supplement to the instructions for use" must be included with the instructions for use for the above-mentioned devices.

You can download the "Supplement to the instructions for use" here or order a free copy using the reply form.
Link to "Supplement to the instructions for use" MEDUMAT Standard²
Link to "Supplement to the instructions for use" MEDUMAT Transport

Link to reply form:
FSCA MMT_MMS2_2024-10.01_CO2wCPR | WEINMANN Emergency (weinmann-emergency.com)

4. What measures should be taken by the addressee?

Are you a specialist dealer?

1. Please confirm receipt of this notice using the **reply form** supplied by **11/20/2024** at the latest.
2. Ensure that your customers employing the above-mentioned devices take note of this safety information and receive the supplement to the instructions for use.

If you have already resold or otherwise passed on the device:

3. Forward a copy of this notice and the supplement to the instructions for use to the relevant 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. Please confirm receipt of this notice using the **reply form** supplied by **11/20/2024** at the latest.

2. Ensure that all users employing the above-mentioned devices take note of this safety information and receive the supplement to the instructions for use. To help you in this regard, we have compiled a template for a notice that can be posted in all ambulance stations to draw users' attention specifically to the issue.

3. Ensure that the "Supplement to the instructions for use" is included with all instructions for use.

Please implement these measures promptly.

This Field Safety Corrective Action is a compulsory measure. 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 + Co. KG

André Schulte
Managing Director

p.p. Dr. Florian Dietz
PRRC
Head of Global QRA

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

Attachments

Form: "Reply regarding safety information"

Links:
Reply form:
FSCA MMT_MMS2_2024-10.01_CO2wCPR | WEINMANN Emergency (weinmann-emergency.com)

Supplements to the instructions for use:
Link to "Supplement to the instructions for use" MEDUMAT Standard²
Link to "Supplement to the instructions for use" MEDUMAT Transport

Please use the digital reply form at:
FSCA MMT_MMS2_2024-10.01_CO2wCPR | WEINMANN Emergency (weinmann-emergency.com)
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 + 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):**

_____

_____

☐ **Please send me ___ printed copies of the supplement to the MEDUMAT Transport instructions for use at the address specified above.**

☐ **Please send me ___ printed copies of the supplement to the MEDUMAT Standard² instructions for use at the address specified above.**

_____ _____
Date, signature Name (in block letters)

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