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

COMPANY
NAME
ADDRESS LINE 1
ADDRESS LINE 2
ZIP CODE CITY
COUNTRY

Hamburg, February 2021

Important safety information: Field safety corrective action on a medical device

Reference: FSCA MMT 2021-02.02

From
WEINMANN Emergency Medical Technology GmbH + Co. KG

Addressee
Users and owner/operators, as well as specialist dealers and service partners

Medical devices concerned (trade name)
MEDUMAT Transport emergency and transport ventilators; All devices are affected

Dear customers,

Quality and safety are our top priority, which is why we wish to act in a consistent and transparent manner as usual and, in the context of your obligation to co-operate under medical devices legislation, ask you to implement this corrective action so that users can continue to use our products on patients safely.

1. Description of problem

From customer reports we have established that in rare cases, MEDUMAT Transport has failed during ventilation. We have identified the reason for this as a software fault which is eliminated by a software update.

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WEINMANN Emergency
Medical Technology GmbH + Co. KG
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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
EC directive 93/42/EEC, Annex II
(EN 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

2. Risk to the patient

If the device fails, the display goes black and ventilation stops; in this case, the device issues an alarm in the form of both an LED and a sound. In this case, an alternative means of ventilation must be implemented at once.

3. Corrective action

The following corrective action must be performed:

- Software update of the device

This corrective action is mandatory. The responsible authority has been informed of the procedure.

You can continue using your MEDUMAT Transport until the corrective actions described have been performed. Please use the device with particular caution; you and your staff should note that you should always have an alternative means of ventilation to hand, as described in the instructions for use. You do not need to decommission the device.

Please perform all **actions by no later than 2021-05-28**.

a. If you are an owner/operator, user or specialist dealer partner of MEDUMAT Transport, proceed as follows:

- Please use the attached report form to **confirm to us receipt of this letter or that it has been forwarded** by no later than 2021-03-18.
- If you have passed these products on to third parties, **please forward a copy of this information to them or notify us of their contact information.**
- Please ensure in your organization that this **safety information is brought to the attention** of all users of the above-mentioned product and of other people to be informed.
- Download the new software version 6.15 for MEDUMAT Transport. The update files are available to download in the WEINMANN login area on our website www.weinmann-emergency.de (software package: MEDUMAT_Transport_SW_6.13.zip).
- Install software version 6.15 on all your devices. Performance of a software update is described in Section 8.4 “Software update” of the instructions for use for MEDUMAT Transport.
- Submit a device-specific report to us on completion of the update by clicking on the corresponding button in the login area. If this is not possible, please use the documentation form included in the MEDUMAT_Transport_SW_6.13.zip software package as an alternative reporting method.
- If you have no WEINMANN Emergency login, you can apply for one by means of a simple registration process at www.weinmann-emergency.de. Otherwise, please get in touch with your contact for WEINMANN Emergency products.

Contact

If you have any questions or need support, please contact your local specialist dealer or contact us directly: Phone: +49 40 88 18 96 - 122, e-mail: AfterSalesService@weinmann-emt.de.

Kind regards,

WEINMANN Emergency
Medical Technology GmbH + Co. KG

André Schulte
Managing Director

p.p. Dennis Horstmann
Authorized Signatory
Head of Supply Chain + Quality Management

Annexes
“Field safety notice received” report form

Report to WEINMANN Emergency by 2021-03-18

re safety information for MEDUMAT Transport: Reference: FSCA MMT 2021-02.02

Original letter sent to:
Insert ADDRESSEE FIELD as on page 1 of covering letter
Customer number
Company
Name
Address
Zip code City
COUNTRY

Please fill in this report form in full and return it 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
Technical Service
Frohbösestraße 12
22525 Hamburg, GERMANY

☐ **I hereby confirm receipt of this letter** and that I **have read and understood its contents**. **This letter has been brought to the attention of all users of the product and of other people to be informed in my organization**.
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 **are identical to those of the addressee above.**

☐ Company/organization details **differ from those of the addressee as follows:**

Customer no.: _____

Company/organization + address: _____

_____

_____

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

☐ **The device has been scrapped**

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

_____

_____

_____ _____
Date, signature Name (in block letters)

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