

Hamburg, January 22, 2015

Important safety notice: Corrective measure to a medical device on the market

MEDUMAT Transport: modification to device software

Dear Sir or Madam,

Quality and safety are our highest priority, which is why we would like to act swiftly and transparently as usual and **ask you for your support in implementing a corrective measure which will further increase the stability of the MEDUMAT Transport.**

From

WEINMANN Emergency Medical Technology GmbH + Co. KG

Addressees

Users and owners/operators of MEDUMAT Transport devices with device software $\geq 5.x$ and specialist dealers

Medical devices affected

MEDUMAT Transport ventilator (with and without CO₂ measurement); only devices with a software version $\geq 5.x$ are affected

Description of problem

In very rare cases, MEDUMAT Transport ventilators with software version $\geq 5.x$ have not resumed ventilation after the compressed gas supply has been disconnected and restored with a treatment in progress. In these cases, the ventilator did not issue any alarms and the display did not display a pressure and flow curve.

Cause Following a drop in pressure, coincidence of unfavorable circumstances can disrupt internal device communication in such a way that the device does not resume a treatment in progress once pressure is restored.

Remedy

We have developed a new software version 5.5; this eliminates the above-described device malfunction.

This remedy is compulsory. The BfArM [Bundesinstitut für Arzneimittel und Medizinprodukte - Federal Institute for Drugs and Medical Devices] has been informed of the procedure.

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Certified QM system

EC Directive 93/42/EEC, Annex II

General Partner
WEINMANN Emergency

Management GmbH, Hamburg
Court of Registration
Hamburg Municipal Court
Dept. B, no. 38144

Creditor ID

(EN ISO 9001/EN ISO 13485)

Board
Dipl.-Volksw. Marc Griefahn

Dipl.-Kfm. Philipp Schroeder
Dipl.-Volksw. André Schulte
Bank details
Deutsche Bank AG Hamburg

Sort code 200 700 00 ■ Account no. 646963900

SWIFT DEUTDEHH
DE35ZZZ00000353971

Hamburger Sparkasse AG
Sort code 200 505 50 ■ Account no.

SWIFT HASPDEHHXXX
IBAN DE44200505501032262667
Commerzbank AG Hamburg
Sort code 200 400 00 ■ Account no.

SWIFT COBADEHHXXX

IBAN DE14200400000632007100
IBAN DE87200700000646963900

As an owner/operator or user you must now...

- Please check the software version of your MEDUMAT Transport in the "Device data" menu. (Main menu → Options → Device data)
- **All** MEDUMAT Transport devices with a software version $\geq 5.x$ **must** provide evidence of updating to the new **software version 5.5**. The update files for this are available for you to download at no charge from the login area of our website www.weinmann-emergency.de.
 - a. Install the V 5.5 software update on all your devices with a software version $\geq 5.x$. All MEDUMAT Transport devices affected by this safety notice already have the integrated owner/operator menu. Every owner/operator can update his MEDUMAT Transport independently using this menu. Performance of a software update is described in the instructions for use for MEDUMAT Transport from software version 5.1 in Section **8.4 "Software update"**.
 - b. Please return a device-specific report to us on completion of the update by clicking on the corresponding button in the login area.
 - c. 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.
- No functional changes in the operation of the device compared to predecessor versions are associated with software version 5.5.
- As the above-described fault occurs only very rarely, you can continue using your MEDUMAT Transport devices until the update is installed. However, please note the **recommended course of action** below.
 1. Subject the ventilator and the patient to continuous monitoring during ventilation and always keep an alternative method of ventilation to hand.
 2. When changing the compressed gas supply for the device, take particular care that MEDUMAT Transport resumes ventilation once the supply is restored.
 3. However, should the above-mentioned behavior still occur: **switch the device off immediately and then back on**, and continue the ventilation in progress by pressing the "Last patient" key.
- Please ensure that this **safety information** is brought to the attention of all users of the above-mentioned products and other people to be informed in your organization.
- Please use the attached reply form **to confirm receipt of this letter**.

Contact

If you have any questions, please contact us directly - we will of course be happy to answer any questions you may have. If required, please get in touch with your contact for WEINMANN Emergency products or our Technical Service,

Tel: +49 40 88 18 96-122, E-mail: TechnischerService@weinmann-emt.de.

Yours sincerely,

André Schulte
Managing Director

ppa. Dr. Ralf Egenolf
Authorized signatory
Head of Quality Management and Regulatory Affairs

Organizational information

Please note: WEINMANN Emergency Medical Technology GmbH + Co. KG is the legal successor of the Emergency business unit of WEINMANN Geräte für Medizin GmbH + Co. KG, which originally launched the devices on to the market. WEINMANN Emergency has retained all customer addresses and the delivery territories of the Emergency business unit so that this "safety information" can be addressed to all affected users of MEDUMAT Transport.

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IBAN DE8720070000646963900

Report to WEINMANN Emergency

re safety information for "MEDUMAT Transport: modification of device software - update to V5.5" dated 22.01.2015

Original letter sent to:

Please complete this reply form in full and send it by fax, e-mail or post to:

Fax: +49 40 88 18 96 - 25 492

e-mail: vigilance@weinmann-emt.de

WEINMANN Emergency Medical Technology GmbH + Co. KG
Safety Officer for Medical Devices
Frohbösestraße 12
22525 Hamburg
GERMANY

Please complete in full in block capitals:

☐ Company details are identical to those of the addressee above.

☐ Company details differ to those of the addressee as follows:

Your customer no.: _____

Company + address: _____

☐ 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 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 will be conveyed to them.

Date, signature

Name (in block capitals)

Position (in block capitals)

E-mail (in block capitals)