

WEINMANN Emergency Medical Technology GmbH + Co. KG ■ PO Box 57 01 53 ■ 22770 Hamburg, Germany

Company

Name

Address

Zip City

COUNTRY (SELECTION: ALL MEDUMAT TRANSPORT CUSTOMERS IN DACH + IS, COMING FROM CS)

Hamburg, 24 August 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

Addressee

Specialist dealer partners of MEDUMAT Transport with a software version 5.x and their customers

Medical devices affected

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

Description of problem

While ventilation is in progress, devices with software version 5.x can sporadically switch off without issuing any further alarm whilst the user is making settings in the menu.

Cause

A faulty program sequence in the device software can sporadically lead to the device switching off.

Remedy

A new software version 6.1 has been developed to eliminate the faulty behavior described above.

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

WEINMANN Emergency
Medical Technology GmbH + Co. KG
Frohbösestraße 12 ■ 22525 Hamburg
T: 040 88 18 96-0
F: 040 88 18 96 480
E: info@weinmann-emt.de
www.weinmann-emergency.de
Zentrum für Produktion, Logistik, Service
Siebenstücken 14 ■ 24558 Henstedt-Ulzburg

Registergericht
Amtsgericht Hamburg
Abt. A, Nr. 115967
USt-IdNr. DE288367727
WEEE-Reg.-Nr. DE 47913245

Zertifiziertes QM-System
EG-Richtlinie 93/42/EWG, Anh. II
(EN ISO 9001/EN ISO 13485)

Komplementär
WEINMANN Emergency
Management GmbH, Hamburg
Registergericht
Amtsgericht Hamburg
Abt. B, Nr. 38144

Gläubiger-ID
DE35ZZ00000353971

Geschäftsführung
Dipl.-Volksw. Marc Griefahn
Dipl.-Kfm. Philipp Schroeder
Dipl.-Volksw. André Schulte
Bankverbindungen
Deutsche Bank AG Hamburg
BLZ 200 700 00 ■ Konto 646963900
SWIFT DEUTDEHH
IBAN DE87200700000646963900

Hamburger Sparkasse AG
BLZ 200 505 50 ■ Konto 1032262667
SWIFT HASPDEHHXXX
IBAN DE44200505501032262667
Commerzbank AG Hamburg
BLZ 200 400 00 ■ Konto 632007100
SWIFT COBADEHHXXX
IBAN DE14200400000632007100

As a specialist dealer you must now ...

- Ensure that this **safety information** is brought to the attention of all your customers for the above-mentioned products and any other people to be informed. **Please also pass on to your customers the enclosed letter to final customers for this purpose.**
- Please check the software version of your MEDUMAT Transport in the "Device data" menu. (Main menu → Options → Device data)
- **All** MEDUMAT Transport devices with software version 5.x **must** provide evidence of updating to the new **software version 6.1**. 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 software -version 6.1 on all your devices with software version 5.x. As an alternative to you and your staff performing the software update, you can make the new software version 6.1 available to your affected customers. The integrated owner/operator menu means that from software version 5.x, every owner/operator can update his MEDUMAT Transport independently. Performance of a software update is described in Section **8.4 "Software update"** of the instructions for use entitled "MEDUMAT Transport from software version 5.1".
 - b. Please return to us a device-specific report about completion of the update by clicking on the corresponding button in the login area. For this purpose please also get your customers who perform the update independently to report each device update to you using the serial number of the MEDUMAT Transport.
 - c. If as a specialist dealer you have no WEINMANN Emergency login, you can apply for one by means of a simple registration process at www.weinmann-emergency.de.
- No functional changes in the operation of the device compared to predecessor versions are associated with software version 6.1. As manufacturers, we do not therefore consider it necessary to repeat instruction in line with the German MPBetreibV [Medizinprodukte-Betreiberverordnung – German regulations governing the owners/operators of medical devices].
- As the above-described fault occurs only very rarely, users can continue using their 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. Particularly when navigating in the menu, check to ensure that the device is running smoothly.
 3. However, should the above-mentioned behavior still occur: **switch the device back on again immediately**, 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 and that it has been passed on.**

Contact

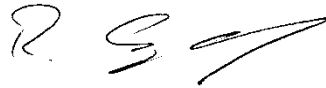
If you have any questions, please contact us directly - we will of course be happy to answer any questions you may have. If required, please feel free to contact your Area Manager or our Technical Service,
Tel: +49 40 88 18 96 - 122, e-mail: TechnischerService@weinmann-emt.de.

Yours sincerely,

WEINMANN Emergency
Medical Technology GmbH + Co. KG



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 the market.

WEINMANN Emergency has retained all customer addresses and the delivery territories of the Emergency business unit, with the result that this "safety information" can be addressed to the affected users of MEDUMAT Transport.

Report to WEINMANN Emergency

re safety information for "MEDUMAT Transport: Adaptation to device software"
dated 08/24/2015

Original letter sent to:

Insert ADDRESSEE FIELD as on page 1 of covering letter

Company

Name

Address

Zip City

COUNTRY

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

Fax: +49 40 88 18 96 - 25492

e-mail: vigilance@weinmann-emt.de

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

Please complete in full in block capitals:

Company details are identical to those of the addressee above.

Company details differ from those of the addressee above 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 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.

Date, signature

Name (in block capitals)

Position (in block capitals)

E-mail (in block capitals)

Company

Name

Address

Zip City

COUNTRY (SELECTION: ALL MEDUMAT TRANSPORT CUSTOMERS IN DACH + IS, COMING FROM CS)

Hamburg, xx. August 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

Addressee

Users and owners/operators of MEDUMAT Transport devices with software version 5.x

Medical devices affected

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

Description of problem

While ventilation is in progress, devices with software version 5.x can sporadically switch off without issuing any further alarm whilst the user is making settings in the menu.

Cause

A faulty program sequence in the device software can sporadically lead to the device switching off.

Remedy

A new software version 6.1 has been developed to eliminate the faulty behavior described above.

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

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 software version 5.x **must** provide evidence of updating to the new **software version 6.1**. 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.
 - d. Install software version 6.1 on all your devices with software version 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 Section **8.4 "Software update"** of the instructions for use entitled "MEDUMAT Transport from software version 5.1".
 - e. Please return to us a device-specific report about completion of the update by clicking on the corresponding button in the login area.
 - f. 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.
- As the above-described fault occurs only very rarely, you can continue using your MEDUMAT Transport devices until the software 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. Particularly when navigating in the menu, check to ensure that the device is running smoothly.
 3. However, should the above-mentioned behavior still occur: **Switch the device back on again immediately** 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.
- No functional changes in the operation of the device compared to predecessor versions are associated with software version 6.1. As manufacturers, we do not therefore consider it necessary to repeat instruction in line with the german MPBetreibV [Medizinprodukte-Betreiberverordnung – german regulations governing the owners/operators of medical devices].

Contact

If you have any questions, please contact your local specialist dealer or us directly - we will, of course, be happy to answer any questions you may have. If required, please feel free to contact your Area Manager or our Technical Service,

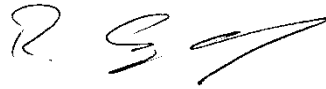
Tel: +49 40 88 18 96 - 122, e-mail: AfterSalesService@weinmann-emt.de.

Yours sincerely,

WEINMANN Emergency
Medical Technology GmbH + Co. KG



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 the market.

WEINMANN Emergency has retained all customer addresses and the delivery territories of the Emergency business unit, with the result that this "safety information" can be addressed to all affected users of MEDUMAT Transport.