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

Hamburg, July 2020

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

Reference: FSCA MMS2 2020-07.01

From
WEINMANN Emergency Medical Technology GmbH + Co. KG

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

Medical devices concerned (trade name)
MEDUMAT Standard² emergency and transport ventilator; all device serial numbers since product launch 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

In very rare cases it might happen that MEDUMAT Standard² cannot be switched on in battery mode (with no mains power supply connected). This means that, after the power button is pressed, the screen will remain dark and the device will not start.

We suspect the cause to be ESD damage to the device electronics, which might have been caused by touching the contacts in the battery compartment (such as during cleaning).

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Center for Production, Logistics, Service
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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

It may not be possible to start the device in battery mode (without additional mains power supply). This can lead to a delay to therapy.
This problem does not occur when starting with the mains power supply connected.

3. Corrective action

Until now, starting of the device in battery mode was not explicitly checked in the function check. So the MEDUMAT Standard² function check will be extended to include an additional item covering startup in battery mode. This means that in future the device must be switched on in battery mode or removed from the wall mount before switching on in order to carry out a function check. After switching on in battery mode, the function check can then be carried out as usual in the wall mount on the mains and oxygen supply of the vehicle. We also show you the changed procedure again in the following video: https://youtu.be/d8x7CIPjOGY

To make sure that the device was really switched on in battery mode, we have developed a new software version 4.15 and produced a supplement to the instructions for use.

The following corrective action must therefore be carried out:

- Update MEDUMAT Standard² to the new software version 4.15.
- Add the supplied insert to the instructions for use.
- Observe the safety information and the information relating to the modified function check on the insert.

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

If MEDUMAT Standard² cannot be switched on in battery mode with no mains power supply connected, have the device repaired.

You can continue using your MEDUMAT Standard² until the corrective action described has been performed.

Please perform all **corrective action by no later than 8/31/2020**.

If you are an operator, user or specialist dealer partner of MEDUMAT Standard², please proceed as follows:

- If you have passed the above-mentioned products on to third parties, please also forward this letter to your customers.
- Please use the attached report form to **confirm to us receipt of this letter or that it has been forwarded** by no later than 8/15/2020.
- Download the new software version 4.15 for MEDUMAT Standard². The update files for this are available for you to download from the **WEINMANN login area** of our website at www.weinmann-emergency.com (software package: *MEDUMAT_Standard2_SW_4.15.zip).*
- **Install software version 4.15 on all your devices**. Performance of a software update is described in Section 4.15 “Updating software” of the instructions for use for MEDUMAT Standard².

- Make 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_Standard2_SW_4.15.zip* software package as an alternative.

- If you have no WEINMANN Emergency login, you can apply for one by means of a simple registration process at www.weinmann-emergency.com. Otherwise, please get in touch with your contact for WEINMANN Emergency products.

- Add to the instructions for use for MEDUMAT Standard² the **insert** which can likewise be found in software package *MEDUMAT_Standard2_SW_4.15.zip*. As an alternative to the login area, you can also find the insert in the Download Area of our website.

- Please ensure that **this safety information is brought to the attention of** all users of the above-mentioned products and of other people to be informed in your organization.

Contact
If you have any questions, 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

Report to WEINMANN Emergency

Regarding MEDUMAT Standard² safety information: Reference: FSCA MMS2 2020-07.01

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 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 **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)