

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

Hamburg, June 2020

## **Important safety notice: Field safety corrective action on a medical device**

**Reference:** FSCA MCS2 2020-06.1

### **From**

WEINMANN Emergency Medical Technology GmbH + Co. KG

### **Addressee**

Users and owners/operators, specialist dealer partners

### **Medical devices affected** (trade name and article no. of products):

- MEDUCORE Standard<sup>2</sup>; monitor/defibrillator WM 45300.
- Devices affected are:
  - o All serial numbers up to and including 1766
  - o Serial numbers 1782 to 1785
  - o Serial numbers 1787 to 1796
  - o Serial number 1798

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**

On device start-up, it may happen that the device does not start correctly and displays a device fault (display goes yellow). This means that the device is not ready for use at that point.

The device will generally start if the device is started up again; it then also remains ready for use.

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**Center for Production, Logistics, Service**  
WEINMANN Emergency  
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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

This is caused by a memory fault in the software.

## **2. Risk to the patient**

The device cannot be started up the first time it is switched on. This can lead to a delay to therapy.

## **3. Remedy**

The following remedy must be performed:

- Update to new software version 1.11

The memory fault is eliminated in this software version. Compared to the previous version, the software version is not linked to any functional changes, so as manufacturer, we do not consider it necessary to repeat instruction.

This remedial measure is mandatory. The responsible authority has been informed of the procedure.

You can continue using your MEDUCORE Standard<sup>2</sup> until the remedial measure described has been performed, but you and your staff should please be aware that you should start up the device again immediately if a first attempt is unsuccessful. You do not need to decommission the device.

Please perform all **remedial measures by no later than 7/21/2020**.

The paragraphs below describe the process you need to follow.

### **a. If you are an owner/operator or user of MEDUCORE Standard<sup>2</sup>, 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 7/7/2020.
- Download the new software version 1.11 for MEDUCORE Standard<sup>2</sup>. The update files are available to download **in the WEINMANN login area** on our website [www.weinmann-emergency.com](http://www.weinmann-emergency.com) (software package: *MEDUCORE\_Standard\_2\_SW\_1.11.zip*).
- **Install software version 1.11 on all your devices.** Performance of a software update is described in Section 5.16 "Updating software" of the instructions for use for MEDUCORE Standard<sup>2</sup>.
- 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 as an alternative reporting method; this form is included in the *MEDUCORE\_Standard\_2\_SW\_1.11.zip* software package.
- If you have no WEINMANN Emergency login, you can apply for one at [www.weinmann-emergency.com](http://www.weinmann-emergency.com) by means of a simple registration process. Otherwise, please get in touch with your contact for WEINMANN Emergency products.
- Please ensure that this **safety information is brought to the attention** of all users of the above-mentioned product and of other people to be informed in your organization.
- 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.**

**b. If you are a WEINMANN specialist dealer, proceed as follows:**

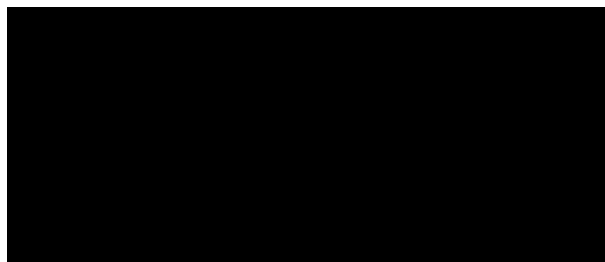
- Please use the attached report form to **confirm to us receipt of this letter or that it has been forwarded** by no later than 7/7/2020.
- Ensure that this **safety information** is brought to the attention of all your customers for the above-mentioned product and of any other people to be informed. **Please also pass this letter on to your customers for this purpose.**
- Download the new software version 1.11 for MEDUCORE Standard<sup>2</sup>. The update files are available to download **in the WEINMANN login area** on our website [www.weinmann-emergency.com](http://www.weinmann-emergency.com) (software package: *MEDUCORE\_Standard\_2\_SW\_1.11.zip*).
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- Please ensure that this **safety information is brought to the attention** of all users of the above-mentioned product 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](mailto:AfterSalesService@weinmann-emt.de).

Kind regards,

WEINMANN Emergency  
Medical Technology GmbH + Co. KG



# Report to WEINMANN Emergency

Regarding MEDUCORE Standard<sup>2</sup> safety information: Reference: FSCA MCS2 2020-06.1

Original letter sent to:

Please fill in this report form in full and return it by e-mail, fax or mail to:

e-mail: [AfterSalesService@weinmann-emt.de](mailto: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)