

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

Company  
 (Department)  
 Name  
 Address 1  
 Address 2  
 Postal code City  
 (Country)

Hamburg, April 2019

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

MEDUCORE Standard<sup>2</sup>: software modification

Dear customers,

Quality and safety are our top priority, which is why we would like to act swiftly and transparently as usual and **ask you for your support in implementing a corrective action which will further increase the operational safety of the MEDUCORE Standard<sup>2</sup>.**

### From

WEINMANN Emergency Medical Technology GmbH + Co. KG

### Addressee

Users and operators of MEDUCORE Standard<sup>2</sup>, as well as specialist dealer partners

### Medical devices affected

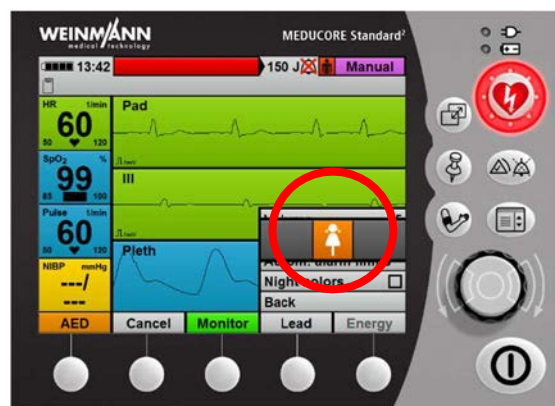
MEDUCORE Standard<sup>2</sup> monitor/defibrillator – all serial numbers with software version ≤ 1.5 are affected.

### Description of problem:

During internal tests, we found out that an incorrect energy for the shock delivery is displayed to the user in certain situations. This situation occurs when a change is made to another patient group during shock capacitor charging or when the shock capacitor is charged.

### Risk to the patient

The risk to the patient is the delivery of inadequate shock energy.



**Remedy:**

If you change the patient group during shock capacitor charging or when the shock capacitor is charged, the shock capacitor must be manually discharged internally.

We have developed a new software version 1.7, which is now available. With this software version, the shock capacitor is discharged internally when the patient group is changed, so that the correct energy for the shock delivery is always displayed.

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

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

- **All MEDUCORE Standard<sup>2</sup> devices must have evidence of having been updated with the new software version 1.7.** The software update file for this now is available to download free of charge for all customers authorized to receive updates in the **Login area** of our website [www.weinmann-emergency.com](http://www.weinmann-emergency.com).
  - a. Install software version 1.7 on all your devices. The instructions for performing the software update can be found in Section 5.16 "Update software" of the Instructions for Use for the MEDUCORE Standard<sup>2</sup>.
  - 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 are not entitled to perform updates, your specialist dealer who is authorized to update the device or a member of WEINMANN staff will be in touch shortly to discuss the procedure going forward.
- There are no functional changes to the operation of the device associated with software version 1.7 compared to the predecessor version.
- You can continue using your MEDUCORE Standard<sup>2</sup> until the update is installed. But please ensure that you and your staff manually discharge the shock capacitor internally when the patient group is changed during or after the charging.
- Please ensure that this **safety information** is brought to the attention of all users of the above-mentioned product and 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.**
- Please use the attached reply form to **confirm receipt of this letter or that it has been forwarded.**

**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 of any other people to be informed. **Please also pass this letter on to your customers for this purpose.**
- Please check the software version of your MEDUCORE Standard<sup>2</sup> in the "Device information" user menu. (User menu >>> System settings >>> Device information)
- **All MEDUCORE Standard<sup>2</sup> devices must have evidence of having been updated to the new software version 1.7.** The update files for this are available for you to download at no charge from the **Login area** of our website [www.weinmann-emergency.com](http://www.weinmann-emergency.com).

- a. Install software version 1.7 on all your devices. As an alternative to you and your staff performing the software update, you can make the new device software version 1.7 available to your affected customers. Every owner/operator can update his MEDUCORE Standard<sup>2</sup> independently using the integrated Operator menu.  
Performance of a software update is described in **Section 5.16 “Update software”** of the Instructions for Use for MEDUCORE Standard<sup>2</sup>.
  - b. Please return a device-specific report to us on 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 MEDUCORE Standard<sup>2</sup>.
  - 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.com](http://www.weinmann-emergency.com).
- There are no functional changes to operation of the device associated with software version 1.7 compared to predecessor versions. As manufacturers, we do not therefore consider it necessary to repeat instruction in line with the MPBetreibV [Medizinprodukte-Betreiberverordnung - regulations governing the owners/operators of medical devices].
  - You can continue using your MEDUCORE Standard<sup>2</sup> until the update is installed, but you and your staff must ensure that you manually discharge the shock capacitor internally if you change the patient group during shock capacitor charging or when the shock capacitor is charged.
  - 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.
  - 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 your local specialist dealer or ourselves directly. We will 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](mailto:AfterSalesService@weinmann-emt.de).

Kind regards,

WEINMANN Emergency  
Medical Technology GmbH + Co. KG

Managing Director

Authorized Signatory  
Management of Supply Chain + Quality Management

# Report to WEINMANN Emergency

Regarding "MEDUCORE Standard<sup>2</sup> safety information: software modification" dated April 2019

Original letter sent to:

Insert ADDRESSEE FIELD as on page 1 of covering letter

Company

Name

Address

Zip code 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

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 from those of the addressee as follows:

Your customer no.:

\_\_\_\_\_

Company + address:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

I am no longer in possession of the medical device:

The device has been scrapped

New owner is (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 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.

\_\_\_\_\_  
Date, signature

\_\_\_\_\_  
Name (in block letters)

\_\_\_\_\_  
Position (in block letters)

\_\_\_\_\_  
E-mail address (in block letters)