

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

COMPANY
NAME

ADDRESS LINE 1

ADDRESS LINE 2

ZIP CODE CITY

COUNTRY (SELECTION: ALL AFFECTED DEVICE CUSTOMERS IN DACH + IS, COMING

Important safety notice: field safety corrective action on a medical device

MEDUCORE Standard²: software modification

Dear Sir or Madam,

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 stability of the MEDUCORE Standard².**

From

WEINMANN Emergency Medical Technology GmbH + Co. KG

Addressee

Users and operators of MEDUCORE Standard², as well as specialist dealers

Medical devices affected

MEDUCORE Standard² defibrillator/monitoring system – all serial numbers are affected.

Description of problem

In two individual cases, a software fault meant that MEDUCORE Standard² defibrillator/monitoring systems did not start up properly and it was then impossible to continue operating them. It was possible to operate the devices again after a restart.

Risk to the patient

We consider the risk to the patient low, as restarting the device results in only a short delay to the start of therapy.

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WEINMANN Emergency
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www.weinmann-emergency.com

Center for Production, Logistics, Service
WEINMANN Emergency
Medical Technology GmbH + Co. KG
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
DE35ZZ00000353971

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

Remedy

We have developed a new software version 1.5 which optimizes device start-up and eliminates the above-mentioned cause of the device malfunction.

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.

What you now have to do as an operator or user:

- **All MEDUCORE Standard² devices must be demonstrably updated with the new software version 1.5.** The software update file for this 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.
 - a. Install software version 1.5 on all your devices. The instructions for performing the software update can be found in Section 5.16 "Updating the software" of the Instructions for Use for the MEDUCORE Standard².
 - 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 operation of the device associated with software version 1.5 compared to the predecessor version.
- You can continue using your MEDUCORE Standard² until the update is installed, but you and your staff should note that if the device does not start up properly, the device should be switched off and then back on again.
- 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 the products have been passed to third parties (e.g. applies to specialist dealers), **please provide them with a copy of this information (if applicable, your customers too)**.
- Please use the attached reply form **to confirm receipt of this letter and that it has been passed on**.

What you now have to do as a specialist dealer:

- 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 Standard² in the "Device information" user menu. (User menu → System settings → Device information)
- **All MEDUCORE Standard² devices must be demonstrably updated to the new software version 1.5.** The update files for this are available for you to download at no charge from the **Login area** of our website www.weinmann-emergency.com.
 - a. Install software version 1.5 on all your devices. As an alternative to you and your staff performing the software update, you can make the new device software version 1.5 available to your affected customers. The integrated operator menu means that every operator can

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update his MEDUCORE Standard² independently.

Performance of a software update is described in **Section 5.16 “Updating the software”** of the Instructions for Use for MEDUCORE Standard².

- 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 Standard².
 - 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.
- There are no functional changes to operation of the device associated with software version 1.5 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 Standard² until the update is installed, but you and your staff should note that if the device does not start up properly, the device should be switched off and then back on again.
 - 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.

Kind regards,

for WEINMANN Emergency
Medical Technology GmbH + Co. KG



Report to WEINMANN Emergency

Regarding "MEDUCORE Standard² safety information: software modification" dated June 2018

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 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 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 capitals)

Position (in block capitals)

e-mail (in block capitals)