

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

Hamburg, November 2019

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

Reference: FSCA MCS2 2019-11.1

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 Standard²; monitor/defibrillator WM 45300, affecting all serial numbers up to and including SN 1494

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

When the device starts up, it may not start properly and then display a device fault (display goes yellow) or the screen may stay switched off; in this case, the “device fault” alarm is output after approx. 30 s. 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.

This is caused by a timing fault in the software in conjunction with the wiring.

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Medical Technology GmbH + Co. KG
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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
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

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 remedies must be performed:

- Update to new software version 1.9
- Replace cable WM 45328 (Deficore board/mainboard cable)
- Replace cable WM 45317 (ECG connection/mainboard cable)

The software version remedies the timing fault; the software update is not associated with any functional changes compared to the preceding version. As manufacturer, we do not therefore 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 Standard² until the remedial measures described have 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 5/31/2020**.

The paragraphs below describe the process you need to follow.

a. If you are an owner/operator or user of MEDUCORE Standard² in Germany, 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 11/29/2019.
- Send all MEDUCORE Standard² devices to the address below to have the above-mentioned measures carried out:

**Center for Production, Logistics, Service
WEINMANN Emergency Medical Technology GmbH + Co. KG
Siebenstücken 14
24558 Henstedt-Ulzburg, GERMANY**

- 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.**

b. If you are an owner/operator or user of MEDUCORE Standard² outside Germany, 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 11/29/2019.
- Send all MEDUCORE Standard² devices to your WEINMANN specialist dealer to have the above-mentioned measures carried out.
- 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.**

c. 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 11/29/2019.
- 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 this letter on to your customers for this purpose.**
- Send all MEDUCORE Standard² devices (for example customer, demonstration, lease and trade fair devices) to the address below to have the above-mentioned measures carried out:

**Center for Production, Logistics, Service
WEINMANN Emergency Medical Technology GmbH + Co. KG
Siebenstücken 14
24558 Henstedt-Ulzburg, GERMANY**

- 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.

d. If you are an authorized WEINMANN service partner for MEDUCORE Standard², 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 11/29/2019.
- 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 this letter on to your customers for this purpose.**
- You will be receiving the document *Field Change Order 2019-01* separately from this letter.
The *Field Change Order 2019-01* explains the procedure for performing the remedial measures described above. Perform these remedial measures on all customer devices and on your own demonstration, lease and trade fair devices.

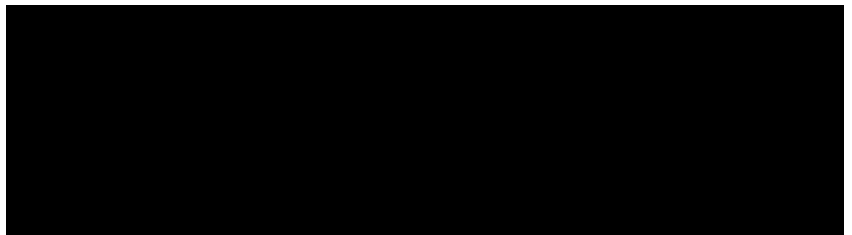
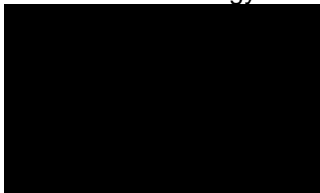
- Please ensure that this **safety information** is brought to the attention of all users of the above-mentioned products and other people to be informed in your organization.
- Please perform all **remedial measures by no later than 5/31/2020** and **confirm that the remedial measures have been performed** on the document described in the *Field Change Order 2019-01*.

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



Annex
Report form

Report to WEINMANN Emergency

regarding MEDUCORE Standard² safety information: Reference: FSCA MCS2 2019-10.1

Original letter sent to:

Insert ADDRESSEE FIELD as on page 1 of covering letter

Company

Name

Address

Zip code City

COUNTRY

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

After-Sales 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)