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

Hamburg, July 2021

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

Reference: FSCA MCS2 2021-07.1

From
WEINMANN Emergency Medical Technology GmbH + Co. KG

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

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

- MEDUCORE Standard²; monitor/defibrillator WM 45300.
- Affected devices are listed in the annex.

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.

Company Headquarters
WEINMANN Emergency
Medical Technology GmbH + Co. KG
Frohbösestraße 12 • 22525 Hamburg • GERMANY
T: +49 40 88 18 96-0
F: +49 40 88 18 96-480
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

1. Description of problem
In the course of our regular quality controls in Production, we noticed that during a particular production period (see annex: serial numbers affected), one of the electronic components of the MEDUCORE Standard² may deviate from original specifications during operation.
This can lead to a device malfunction (such as display of incorrect measured values) or even device failure.

2. Risk to the patient
The above fault may result in incorrect therapy, or even make therapy impossible.

3. Corrective action

The following corrective action must be performed:

- Check and, if necessary, replacement of the affected electronic component of the MEDUCORE Standard² by WEINMANN Emergency.

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

You must not continue to use your MEDUCORE Standard² until the corrective action described has been performed. You must decommission the device.

Please confirm receipt of this letter by **July 30th, 2021** and perform all actions by no later than **August 31st, 2021**.

The paragraphs below describe the process you need to follow.

a. **If you are an owner/operator, user or WEINMANN specialist dealer of MEDUCORE Standard² in Germany, proceed as follows:**

- Please use the attached report form to **confirm to us receipt of this letter, and that it has been forwarded as appropriate, by no later than July 30th, 2021**.

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

- 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 <u>owner/operator</u> or <u>user</u> of MEDUCORE Standard² <u>in France</u>, proceed as follows:**

- Please use the attached report form to **confirm to us that this letter has been received or forwarded, regardless of other actions,** by no later than **July 30th, 2021**.
- Please ensure in your organization that this **safety information is brought to the attention** of all users of the above-mentioned product and of other people to be informed.
- Contact the **WEINMANN service partner responsible for you**, referencing this Field Safety Notice (FSN) *FSCA MCS2 2021-07.1*, to coordinate and implement the above measures on all affected MEDUCORE Standard².
- 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 an <u>authorized WEINMANN service partner</u> for MEDUCORE Standard² <u>in France</u>, proceed as follows:**

- Please use the attached report form to **confirm to us that this letter has been received or forwarded, regardless of other actions,** by no later than **July 30th, 2021.**
- Please ensure in your organization that this **safety information** is brought to the attention of all users of the above-mentioned products and of other people to be informed.
- Please ensure that this **safety information** is brought to the attention of all your customers for the above-mentioned products and of 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 FCO_FSCA_MCS2 2021-07.1* separately from this letter.
  The *Field Change Order* explains the procedure for performing the remedial measures described above.
- Please perform all **actions by no later than August 31st, 2021** and **confirm that the actions have been performed** on the document described in *Field Change Order.*

Contact
If you have any questions or need support, 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

Annexes
„Field safety notice received“ report form
Table of serial numbers affected

Report to WEINMANN Emergency by 2021-07-30

Regarding MEDUCORE Standard² safety information: Reference: FSCA MCS2 2021-07.01

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**
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)

Table 1: Serial number of affected MEDUCORE Standard²

2110	2130	2156	2173	2191	2205
2111	2131	2157	2174	2193	2206
2112	2132	2158	2175	2196	2207
2113	2133	2159	2176	2197	2208
2114	2134	2160	2177	2198	2209
2115	2135	2161	2178	2199	2210
-	2136	-	2179	2200	-
-	2137	-	2180	2201	-
	2138		2181	2202	
	2139		2182	-	
	2140		2183	-	
	2141		2184		
	2142		2185		
	2143		2186		
	2144		2187		
	2145		-		
	2146		-		
	2147				
	2148				
	2149				
	-				
	-				