

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, August 2020

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

Reference: FSCA MMS2 2020-08.01

From: WEINMANN Emergency Medical Technology GmbH + Co. KG

Addressee: Users and owners/operators, specialist dealer partners

Medical devices affected (trade name and serial numbers of products):

MEDUMAT Standard² emergency and transport ventilator; the following serial numbers (SN) are affected:

- | | | |
|-----------------|-----------------|-----------------|
| ▪ 14123 – 14138 | ▪ 14176 – 14193 | ▪ 14264 – 14268 |
| ▪ 14140 – 14151 | ▪ 14195 | ▪ 14270 – 14279 |
| ▪ 14153 | ▪ 14208 – 14219 | ▪ 14282 – 14286 |
| | ▪ 14229 – 14248 | ▪ 14301 – 14312 |

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

In the course of our routine in-production quality inspections, it has come to our notice that a pneumatic component of the device from a specific production period does not fully comply with our specification. As a result, there is a very small likelihood that the device will not start and will indicate a device fault (display turns yellow), or that it will no longer release gas during ventilation (and also give an alarm accordingly). This means the device is no longer ready for use.

We have not received any reports back from the market on this to date. We are therefore carrying out this corrective action as a preventive measure.

Page 1 of 4

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

Production, Logistics & Service Center
WEINMANN Emergency
Medical Technology GmbH + Co. KG
Siebenstücken 14 • 24558 Henstedt-Ulzburg • Germany
SWIFT

Managing Directors
Dipl.-Volksw. Marc Griefahn
Dipl.-Kfm. Philipp Schroeder
Dipl.-Volksw. André Schulte

Registry Court
Hamburg District Court
Dept. A, no. 115967
VAT ID no. DE288367727
WEEE reg. no. DE 47913245

Creditor ID
COBADEHHXXX

General Partner
WEINMANN Emergency
Management GmbH, Hamburg

Registry Court
Hamburg District Court
Dept. B, no. 38144

Certified QM System
EC Directive 93/42/EEC, Annex II
DE35ZZZ00000353971

Bank Details

Deutsche Bank AG Hamburg
IBAN DE87 2007 0000 0646 9639 00
SWIFT DEUTDEHH

Hamburger Sparkasse AG
IBAN DE44 2005 0550 1032 2626 67
SWIFT HASPDEHHXX

Commerzbank AG Hamburg
IBAN DE14 2004 0000 0632 0071 00
(EN ISO 9001/EN ISO 13485)

2. Risk to the patient

Ventilation therapy cannot be started, or the device may stop the gas supply during ventilation. This can lead to a delay to therapy.

3. Remedy

The following remedial measure must be carried out for devices with one of the above serial numbers:

- Revision of the device pneumatics.

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

Please perform the remedial measure immediately.

The paragraphs below describe the process you need to follow.

- a. If you are a MEDUMAT Standard² **owner/operator, user or specialist dealer in Germany, Poland, the Netherlands or Bahrain**, 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 8/31/2020**.
- Please send all affected MEDUMAT Standard² devices to the following address, referencing this Field Safety Notice (FSN) *FSCA MMS2 2020-08.01*, for the above measure to be performed:

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

- 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 MEDUMAT Standard² **owner/operator, user or specialist dealer in the People's Republic of China**, 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 8/31/2020**.
- Send all MEDUMAT Standard² devices to your WEINMANN specialist dealer to have the above measure carried out. As the reference quote this Field Safety Notice (FSN) *FSCA MMS2 2020-08.01*.
- 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.
- If you have passed the above-mentioned 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 **authorized WEINMANN service partner** for MEDUMAT Standard² **in the People's Republic of China**, proceed as follows:

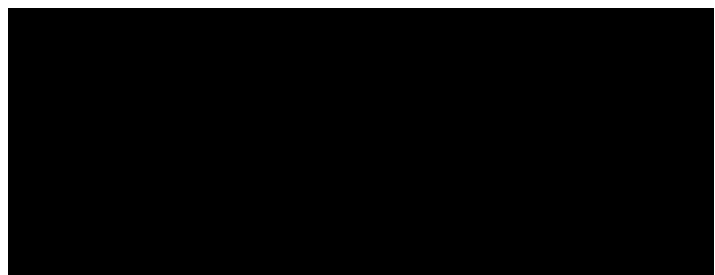
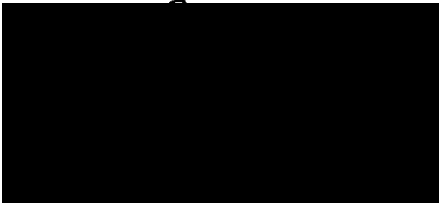
- Please use the attached report form to **confirm to us receipt of this letter, or that it has been forwarded**, by **no later than 8/31/2020**.
- Ensure that this **safety information** is brought to the attention of all your customers for the above-mentioned products and any other people to be informed.
- You will be receiving the document *Field Change Order (FCO) 2020-08.01* separately from this letter. The *Field Change Order 2020-08.01* explains the procedure for performing the remedial measure described above. Perform this remedial measure on all affected devices in your region.
- Please **perform the remedial measure immediately**, and **confirm that it has been performed** on the document described in the *Field Change Order 2020-08.01*.

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



Report to WEINMANN Emergency

Regarding MEDUMAT Standard² safety information: Reference: FSCA MMS2 2020-08.01

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

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)