

COMPANY
NAME
ADDRESS LINE 1
ADDRESS LINE 2
ZIP CODE CITY
COUNTRY

Hamburg, January 2021

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

Reference: FSCA MMS2 2021-01.01

From

WEINMANN Emergency Medical Technology GmbH + Co. KG

Addressee

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

Medical devices concerned (trade name)

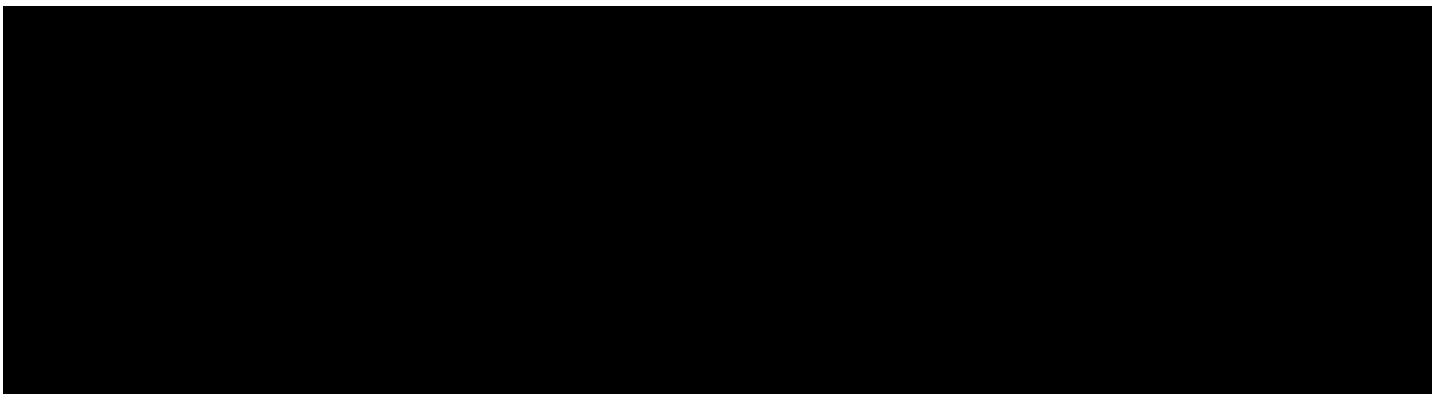
MEDUMAT Standard² emergency and transport ventilator; the serial numbers of devices affected can be found in the appended table

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 regular quality controls in Production, we noticed that during a particular production period (see annex: serial numbers affected), one of the components of the pneumatic system of the MEDUMAT Standard² may deviate from original specifications during operation. This may lead to failure of the device.



2. Risk to the patient

This makes it more likely for the device to display a device malfunction (display turns yellow) during ventilation - either following a device start or in rare instances during ventilation. This means that the device is no longer ready for use.

3. Corrective action

The following corrective action must be performed:

- Repair the device pneumatic system

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

You can continue using your MEDUMAT Standard² until the corrective actions described have been performed. You and your staff should note, however, that you should always have an alternative ventilation option to hand as described in the instructions for use. You do not need to decommission the device.

Please perform all **actions by no later than March 29th, 2021**.

The paragraphs below describe the procedure you need to follow.

a. **If you are an owner/operator or user of MEDUMAT Standard² in Germany, 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 **February 5th, 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.
- Send all affected MEDUMAT Standard² devices to the following address, referencing this Field Safety Notice (FSN) *FSCA MMS2 2021-01.01*, for the above actions to be performed:

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

OR

- Send all affected MEDUMAT Standard² devices to the **WEINMANN service partner responsible for you**, referencing this Field Safety Notice (FSN) *FSCA MMS2 2021-01.01*, for the above actions to be performed. For contact information, just go to our website at: <https://www.weinmann-emergency.com/contact/>
- 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 MEDUMAT Standard² outside Germany, 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 **February 5th, 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.
- Send all MEDUMAT Standard² devices to your WEINMANN specialist dealer to have the above-mentioned actions carried out. As the reference, quote this Field Safety Notice (FSN) *FSCA MMS2 2021-01.01*.

OR

- Send all affected MEDUMAT Standard² devices to the **WEINMANN service partner responsible for you**, referencing this Field Safety Notice (FSN) *FSCA MMS2 2021-01.01*, for the above actions to be performed. For contact information, just go to our website at: <https://www.weinmann-emergency.com/contact/>
- 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 that this letter has been received or forwarded, regardless of other actions**, by no later than **February 5th, 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.**
- Send all affected MEDUMAT Standard² devices (for example customer, demonstration, lease and trade fair devices) to the following address, referencing this Field Safety Notice (FSN) *FSCA MMS2 2021-01.01*, for the above actions to be performed:

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

OR

- Send all affected MEDUMAT Standard² devices to the **WEINMANN service partner responsible for you**, referencing this Field Safety Notice (FSN) *FSCA MMS2 2021-01.01*, for the above actions to be performed. For contact information, just go to our website at: <https://www.weinmann-emergency.com/contact/>

d. **If you are an authorized WEINMANN service partner for MEDUMAT Standard², 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 **February 5th, 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_MMS2 2021-01.01* separately from this letter.
The *Field Change Order* 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 perform all **actions by no later than March 29th, 2021** and **confirm that the actions have been performed** on the document described in *Field Change Order*.

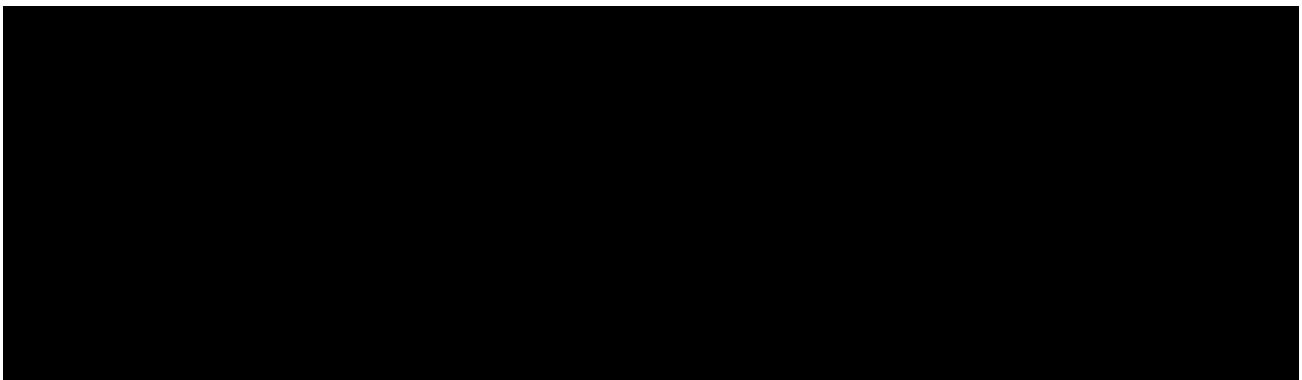
Contact

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,



Annexes

"Field safety notice received" report form

Table of serial numbers affected

Report to WEINMANN Emergency by February 5th, 2021

Regarding MEDUMAT Standard² safety information: Reference: FSCA MMS2 2021-01.01

Original letter sent to:

Insert ADDRESSEE FIELD as on page 1 of covering letter

Customer number

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)

Table 1: Serial number of MEDUMAT Standard² (MMS2) devices affected

1197	15284	15326	15375	15417	15458	15504	15550
1392	15285	15327	15376	15418	15459	15505	15551
5993	15286	15328	15377	15419	15460	15506	15552
7320	15287	15329	15378	15420	15461	15507	15553
7409	15288	15330	15379	15421	15462	15508	15554
7501	15289	15331	15380	15422	15463	15509	15555
10722	15290	15332	15381	15423	15464	15510	15556
12928	15291	15333	15382	15424	15465	15511	15557
14758	15292	15334	15383	15425	15466	15512	15558
15251	15293	15335	15384	15426	15467	15513	15559
15253	15294	15336	15385	15427	15468	15514	15560
15254	15295	15337	15386	15428	15469	15518	15561
15255	15296	15339	15387	15429	15470	15519	15562
15256	15297	15340	15388	15430	15471	15520	15563
15257	15298	15341	15389	15431	15472	15521	15564
15258	15299	15342	15390	15432	15473	15522	15565
15259	15300	15343	15391	15433	15474	15523	15566
15260	15301	15344	15392	15434	15475	15524	15567
15261	15302	15345	15394	15435	15476	15525	15569
15262	15303	15347	15395	15436	15477	15526	15570
15263	15304	15348	15396	15437	15478	15527	15572
15264	15305	15349	15397	15438	15479	15528	15573
15265	15306	15350	15398	15439	15480	15529	15574
15266	15307	15351	15399	15440	15481	15530	15575
15267	15308	15352	15400	15441	15483	15531	15576
15268	15309	15353	15401	15442	15484	15532	15577
15269	15310	15354	15402	15443	15485	15533	15581
15270	15311	15355	15403	15444	15486	15534	15582
15271	15312	15356	15404	15445	15487	15535	15583
15272	15313	15357	15405	15446	15488	15536	15585
15273	15314	15358	15406	15447	15489	15537	15587
15274	15315	15359	15407	15448	15490	15538	15588
15275	15316	15360	15408	15449	15495	15539	15589
15276	15318	15361	15409	15450	15496	15540	15591
15277	15319	15363	15410	15451	15497	15541	15592
15278	15320	15368	15411	15452	15498	15544	15593
15279	15321	15369	15412	15453	15499	15545	15594
15280	15322	15370	15413	15454	15500	15546	15595
15281	15323	15371	15414	15455	15501	15547	15596
15282	15324	15372	15415	15456	15502	15548	15597
15283	15325	15374	15416	15457	15503	15549	15598

Annex to FSCA MMS 2021-01.01
MEDUMAT Standard² serial numbers affected

15599	15647	15705	15913	16111	16182
15600	15648	15707	15916	16112	16183
15601	15649	15708	15917	16116	16184
15602	15650	15709	15918	16142	16185
15605	15651	15710	15919	16143	16186
15606	15652	15712	15920	16144	16187
15608	15653	15713	15921	16145	16188
15609	15654	15714	15922	16146	16189
15611	15655	15715	15923	16147	16190
15612	15657	15716	15927	16148	16191
15613	15658	15717	15929	16149	16192
15614	15659	15718	15945	16150	16193
15615	15662	15769	15947	16151	16194
15616	15664	15779	15950	16152	16195
15617	15665	15781	15951	16153	16196
15618	15666	15782	15952	16154	16197
15619	15667	15784	15953	16155	16198
15620	15668	15785	15955	16156	16199
15621	15669	15786	15956	16157	16200
15622	15670	15852	15966	16158	16201
15623	15671	15853	15968	16159	16202
15624	15672	15855	15969	16160	16203
15625	15673	15857	15970	16161	16204
15626	15674	15858	15972	16162	16205
15627	15675	15860	15973	16163	16206
15628	15676	15863	15974	16164	16207
15629	15677	15868	15984	16165	16208
15630	15678	15873	15985	16166	16209
15631	15679	15876	15986	16167	16210
15632	15680	15877	15987	16168	16211
15633	15681	15878	15988	16169	16212
15634	15682	15879	15990	16170	16213
15636	15683	15882	15991	16171	16214
15637	15689	15884	15992	16172	16215
15638	15690	15885	15993	16173	
15639	15691	15896	16045	16174	
15640	15698	15897	16046	16175	
15641	15699	15905	16047	16176	
15642	15700	15906	16048	16177	
15643	15701	15907	16085	16178	
15644	15702	15908	16088	16179	
15645	15703	15910	16108	16180	
15646	15704	15911	16109	16181	