# Urgent Field Safety Notice

**concerning**

***Voluntary Recall of the medical device MANUJET III***

*2023-11-28*

**Sender:**
VBM Medizintechnik GmbH
Einsteinstr. 1
72172 Sulz a.N.
Germany

**Adressee:**

*VBM customers who have received the medical device with the affected batch.*

**Identification of the medical devices concerned:**

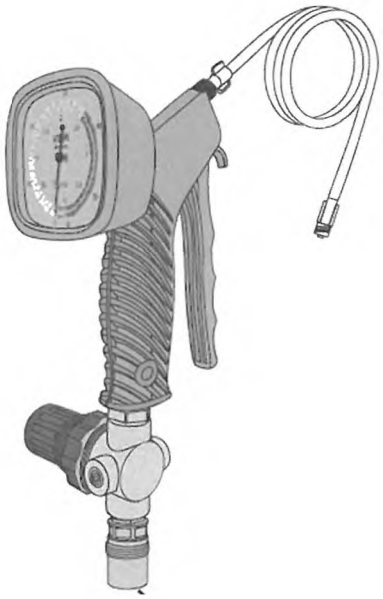
| | |
|---|---|
| Article description: | Manujet III |
| Modell: | N/A |
| Article number: | 30-01-003 |
| Serial-Nr. / Chargen-Nr.: | See cover letter |
| UDI-Nr. | 04250105615456 |
| SRN-Nr. | See cover letter |

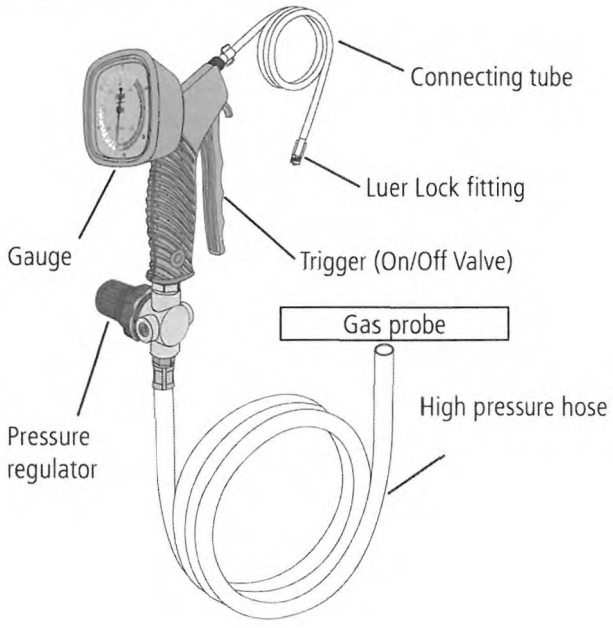
The Manujet III is part of the medical products division for trans-tracheal ventilation

It is recommended for emergency wards, emergency trolleys, ambulances and operating theatres, as it enables a patient to be oxygenated quickly and efficiently.

Ventilation is carried out in conjunction with a transtracheal catheter or a coniotomy set, which are inserted through the cricoid membrane. Ventilation is achieved by manually and intermittently jetting oxygen through the catheter.

The patient can be ventilated continuously by pressing the trigger.





## Description of the problem including the identified cause:

VBM Medizintechnik GmbH has initiated a voluntary recall for the products listed in Annex I (FSCA).
Background:
Following feedback received that air was leaking from a scale on the Manujet III, a SCAR (Supplier Corrective Action Request) was sent to the supplier of the pressure cell supplier to investigate the problem. After the supplier responded to the SCAR, it turned out that the soldering on the affected pressure cell had not been carried out correctly and the diaphragm had become partially detached from the base plate. The supplier has limited this potential fault to a specific supplier batch.

Cause:
It was probably soldered too hot, which can have a negative impact on the strength of the soldered connection.
Based on this error analysis, the supplier informed us of a residual risk regarding the detachment of the membrane from the base plate for this supplier batch.

Risk for patients, users or third parties:
VBM's investigation has shown that even if the soldered connection between the membrane and the base plate is completely detached, the patient's oxygenation is guaranteed.
The risk was categorised by VBM as not a serious incident by means of a health hazard evaluation.

## What measures are to be taken by the addressee?

Please block the products affected in Appendix 1 and return them to VBM Medizintechnik GmbH or dispose them in consultation with VBM with documented proof of disposal.

Please observe the information in the Field Safety Notice and document the products you have identified on the attached response form.

We would kindly ask you to take care of the matter immediately after receiving this safety information.
If you have any questions, please contact the person listed below.

## Passing on the information described here:

Please ensure in your organisation that all users of the above-mentioned products and other persons are aware of this customer information. If you have supplied the products to third parties, please forward a copy of this information or inform the contact person specified below.

Please keep this information at least until the measure has been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

## Contact person:

VBM Medizintechnik GmbH
Elke Reiser
Phone: +49 7454 95 96 661
Fax: +49 7454 95 96 33
E-Mail: fieldsafetynotice@vbm-medical.de

We regret the inconvenience caused to you but see this action as a preventive measure to ensure a high level of patient safety.

Yours sincerely
VBM Medizintechnik GmbH

Elke Reiser
Vigilance Manager / Person of Regulatory Compliance

| *<Illustration / Information to the problem or correction* |
| --- |
| **N/A**<br>**(The pressure capsule is installed in the factory of the Manujet III, therefore not visually detectable by the user)** |

# Response Form

Datum: *JJJJ-MM-TT*

VBM Medizintechnik

Please return the completed reply form within
2 working days

<Item name and affected item numbers>

We have read and understood the instructions in the safety information:

| | | | |
|---|---|---|---|
| **Name (Print)** | | | |
| **Signature / Date** | | | |
| **Title:** | | | |
| **Telephone number:** | | | |
| **E-Mail:** | | | |
| **Organisation / Company** | | | |
| **Street** | | **Postal Code** | |
| **Town** | | **Country** | |

| **Number of <affected products, article number> of each batch you own** | | | |
|---|---|---|---|
| **Batch** | **Quantity** | **Batch** | **Quantity** |
| | | | |
| | | | |
| | | | |
| | | | |

| **Unknown batch(es)** | |
|---|---|
| Number of <affected products, article number> whose batch numbers you do not have, but which match the illustration: | |

| **Anzahl der *<betroffenen Produkte, Artikelnummer> die an andere Organisationen weitergeleitet wurden:*** | | | |
|---|---|---|---|
| **Batch** | **Quantity** | **Batch** | **Quantity** |
| | | | |
| | | | |
| | | | |
| | | | |
| **If the lines listed are not sufficient, please provide an extra list with the requested data.** | | | |

| Contact information of VBM | | |
|---|---|---|
| **Please send the completed reply form within 2 working days to:** | | |
| **E-Mail** | **Fax** | **Postal** |
| fieldsafetynotice@vbm-medical.de | +49 (0) 7454 / 95 96 99560 | VBM Medizintechnik GmbH<br>-Reklamation/Service-<br>Einsteinstraße 1<br>72172 Sulz a. N. |