



نتقدم بثقة
Moving Forward
with Confidence



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 210 dated 24/9/2023 Regarding NCMDR Field Safety Corrective Action of Disposable breathing circuits for MEDUMAT Transport from (mfr: Weinmann).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
Twitter: dgpa_dc Email: dg-padc@moh.gov.om



Circular No. 210/2023

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رؤية عمان 2040
Oman Vision 2040

08 -03-1445 H

24 -09-2023

Field Safety Corrective Action of Disposable breathing circuits for MEDUMAT Transport from Weinmann.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19712
Product	Disposable breathing circuits for MEDUMAT Transport
Description	Disposable breathing circuit.
Manufacturer	Weinmann.
The affected products	Disposable breathing circuits for MEDUMAT Transport from the production period 10/4/2022 to 5/25/2023. Refer to the attachment for WM article No. and Designation.
Reason	The elbow 90° (WM 28821) installed in the disposable breathing circuits listed above may not meet its specifications, and as a result may become detached from the BiCheck sensor (WM 22430).
Action	<ul style="list-style-type: none">- The customers will be provided with a specification-compliant replacement elbow in a large resealable plastic bag. Please replace the elbow as described in the attachment. Replaced elbows should be scrapped.- Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General



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

Hamburg, September 23

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

Reference: FSCA MMT_PSS_Winkel 2023-09.01

Sender:
WEINMANN Emergency Medical Technology GmbH + Co. KG

Addressee:
Users and operators, and specialist trade partners

Affected medical devices (trade names and article numbers of the products):

The affected products are disposable breathing circuits for MEDUMAT Transport from the production period 10/4/2022 to 5/25/2023. This concerns the following articles:

WM article no.	Designation
28657	VENTcirc-MMT breathing circuit with BiCheck, 2 m
28483	VENTcirc-MMT breathing circuit with CO2 and BiCheck, 2 m
28690	VENTcirc-MMT breathing circuit with CO2, 2 m
28695	VENTcirc-MMT breathing circuit, 2 m
28688	VENTcirc-MMT breathing circuit with CO2, 3 m
28227	VENTcirc-MMT breathing circuit with CO2 and BiCheck, 3 m
15837	Set of 10, VENTcirc-MMT breathing circuit with CO2, 2 m
15842	Set of 50, VENTcirc-MMT breathing circuit, 2 m
15840	Set of 10, VENTcirc-MMT breathing circuit, 2 m
28226	VENTcirc-MMT breathing circuit with BiCheck, 3 m

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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

15756	Set of 50, VENTcirc-MMT breathing circuit with BiCheck, 2 m
15754	Set of 10, VENTcirc-MMT breathing circuit with BiCheck, 2 m
15839	Set of 50, VENTcirc-MMT breathing circuit with CO2, 2 m
28691	VENTcirc-MMT breathing circuit, 3 m
15766	Set of 10, VENTcirc-MMT breathing circuit with CO2 and BiCheck, 2 m
15851	Set of 10, VENTcirc-MMT breathing circuit with CO2, 3 m
15841	Set of 25, VENTcirc-MMT breathing circuit, 2 m
15768	Set of 50, VENTcirc-MMT breathing circuit with CO2 and BiCheck, 2 m
15838	Set of 25, VENTcirc-MMT breathing circuit with CO2, 2 m
15852	Set of 10, VENTcirc-MMT breathing circuit, 3 m
15767	Set of 25, VENTcirc-MMT breathing circuit with CO2 and BiCheck, 2 m
15855	Set of 10, VENTcirc-MMT breathing circuit with CO2 and BiCheck, 3 m
15755	Set of 25, VENTcirc-MMT breathing circuit with BiCheck, 2 m
15917	Set of 10, VENTcirc-MMT breathing circuit with BiCheck, 3 m

To whom it may concern,

Quality and safety are our top priority. Consequently, applying our accustomed consistency and transparency, we request you to implement this corrective action in fulfillment of your duty to cooperate according to medical device legislation, so that users can continue to deploy our products safely on patients.

You must not use the above listed disposable breathing circuits until the action recommended below has been implemented.

1. Description of problem and cause:

In the course of our regular internal quality control inspections, it has come to our attention that in rare cases the elbow 90° (WM 28821) installed in the disposable breathing circuits listed above does not meet its specifications, and as a result may become detached from the BiCheck sensor (WM 22430).



2. What is the risk to the patient?

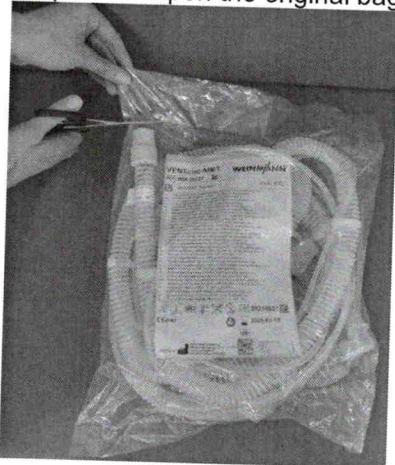
The above error can cause an elbow to disconnect during ventilation.

This disconnection is detected by the device's alarm system, and an alarm alerts the user to reconnect it.

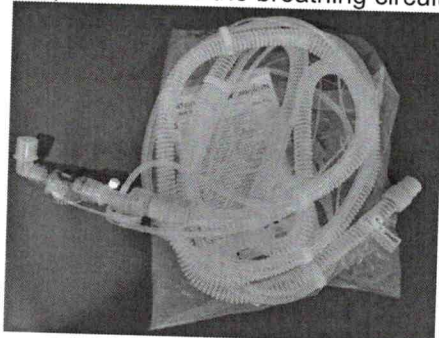
3. Corrective action

We will provide you with a specification-compliant replacement elbow in a large resealable plastic bag (you will need to keep this for later). Replace the elbow as described below. Please note that the breathing circuits are not sterile, even though the original vacuum-packing suggests so. You can safely remove the breathing circuit and carry out the procedure as described below.

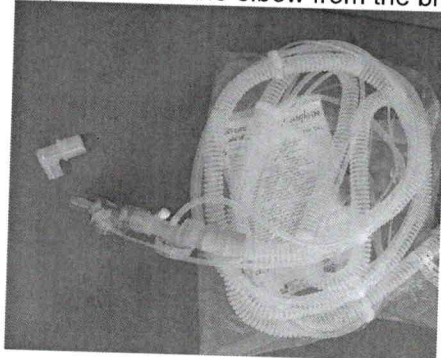
Step 1: Cut open the original bag of the disposable breathing circuit at the top.



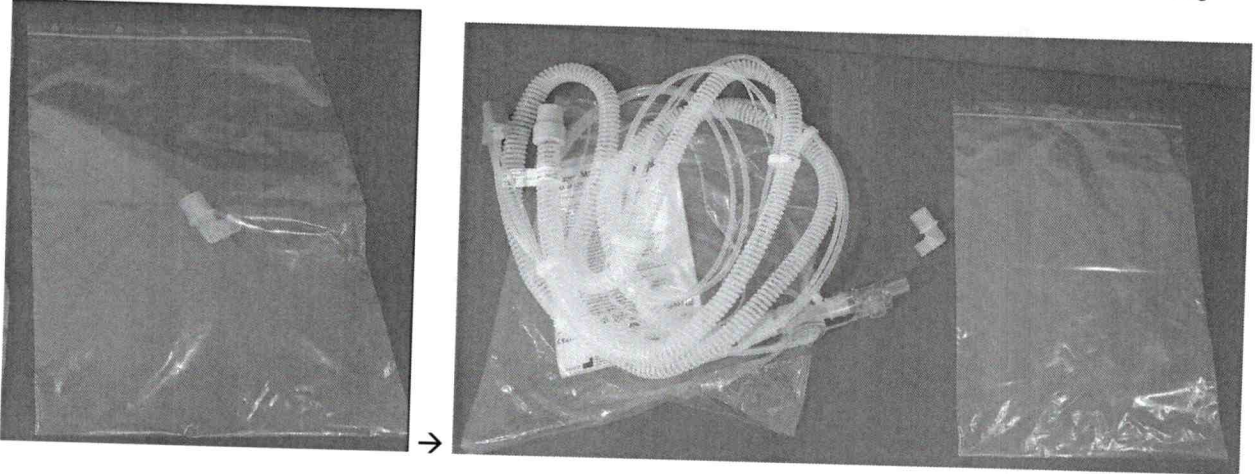
Step 2: Remove the breathing circuit, leaving the article label inside the bag. Do not throw the bag away.



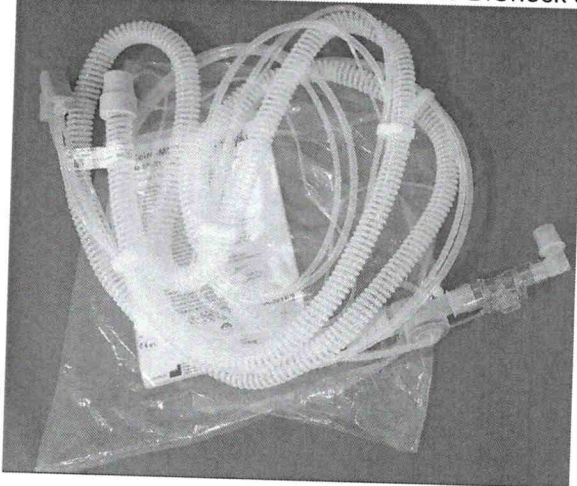
Step 3: Detach the elbow from the breathing circuit and discard it.



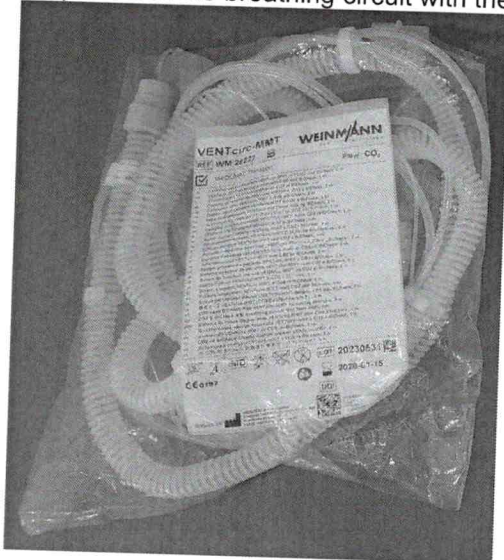
Step 4: Take the replacement elbow out of the plastic bag you received from us. Do not throw the bag away.



Step 5: Connect the new elbow to the BiCheck sensor of the breathing circuit.



Step 6: Pack the breathing circuit with the replaced elbow back into the original bag containing the label.



Step 7: Place the breathing circuit and bag into the plastic bag and then seal it.



Detailed video instructions on replacing the elbow can also be found at:
[Elbow replacement guide FSCA MMT EW PSS 2023-09.01](#)

We are aware of the inconvenience caused to you by the above action. For sustainability reasons, we have decided against replacing the entire breathing circuit.

4. What action should the addressee take?

Are you a specialist dealer?

- Use the attached **report form** to confirm receipt of this letter no later than **2023-10-20**.
- Make sure that everyone needing to be notified is aware of this safety information.
- If you have existing stocks, please carry out the above action and inform us accordingly.
- Replaced elbows should be scrapped.

If you have already resold or passed on the medical devices:

- Forward a copy of this letter to the customers concerned.
- Have your customers confirm receipt of the letter.
- Send the quantity of replacement elbows to the customer.
- Request your customers in turn to carry out the safety procedure described above.

Are you a user?

- Use the attached **report form** to confirm receipt of this letter no later than **2023-10-20**.
- Make sure that everyone needing to be notified is aware of this safety information.
- If you have existing stocks, please carry out the above action and inform us accordingly.
- Replaced elbows should be scrapped.

Please carry out all corrective action promptly.

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

Contact

If you have any questions, or need assistance, please contact your local dealer, or contact us directly:

Phone: +49 40 88 18 96 – 120

E-mail: Kundenservice@weinmann-emt.de.

Best regards,

WEINMANN Emergency
Medical Technology GmbH + Co. KG

André Schulte
Managing Director

ppa. Dennis Horstmann
Authorized Signatory
Head of Supply Chain + Quality Management

Attachments

Form: "Report back on safety information"

List of affected order numbers

Report back to WEINMANN Emergency by 2023-10-20

on safety information: Reference FSCA MMT_PSS_Winkel 2023-09.01

Please fill in this report form in full and return it by e-mail, fax or mail to:

E-mail: **CustomerService@weinmann-emt.de**
Fax: **+49 40 88 18 96 - 490**

WEINMANN Emergency Medical Technology GmbH + Co. KG
Customer Service
Frohbösestraße 12
22525 Hamburg, GERMANY

- ☐ I hereby confirm receipt of this letter and that I have read, understood and will implement 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 article:

☐ The article has been resold

☐ The article has been used up

Date, signature

Name (in block letters)

Position (in block letters)

e-mail address (in block letters)

List of affected order numbers

According to our records, the following orders are affected within your organization: