May 18, 2026

FIELD SAFETY NOTICE

Hamilton Medical AG device Breathing circuit set, coaxial

Reference #: FSCA-2026-05-03

Field Safety Corrective Action

Type: End user information

For Attention of: Healthcare facilities, physicians and end users which have purchased and/or are using Hamilton Medical AG device Breathing circuit set, coaxial for the ventilators HAMILTON-C1, HAMILTON-T1 and HAMILTON-MR1.

Information on Affected Devices:

Device name	Product number	UDI-DI	Lot numbers
Breathing circuit set, coaxial	260127 260128 260167 260168	07630002802956 07630002802963 07630002802970 07630002802987	Between 200379 and 205050 (including both)

The preassembled adult/pediatric Breathing circuit set, coaxial with PN 260127, 260128, 260167, and 260168 are intended to be used to connect the HAMILTON-C1/T1/MR1 ventilators to the patient tube or respiratory mask during ventilation. The therein included single-use expiratory valve set for HAMILTON-C1/T1/MR1 is an accessory for the exhalation gas path. Its main function is to control expiratory gas flow and maintain user-set pressure levels. No other breathing circuit sets or expiratory valve sets, apart from those included in the breathing circuit set, coaxial specified above, are affected by this FSCA. This explicitly excludes neonatal valves, individually packaged expiratory valves, and reusable expiratory valves.

Figure 1: Breathing circuit set, coaxial; Single use, adult/pediatric expiratory valve set (with transparent membrane)

Hamilton Medical AG
Via Crusch 8, 7402 Bonaduz
Switzerland

☎ +41 58 610 10 20
fieldactions.med.global@hamilton-medical.com
www.hamilton-medical.com

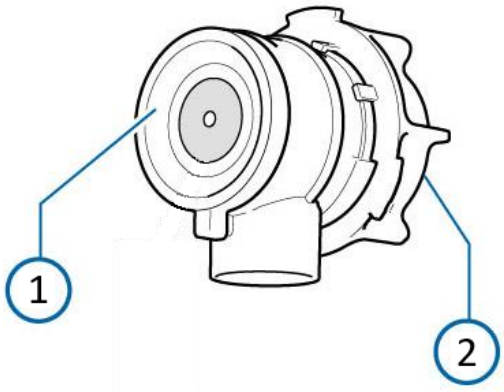

Figure 2: 1) Expiratory valve membrane; 2) Expiratory valve body

Dear Sir or Madam,

This Field Safety Notice (FSN) provides information on single use Hamilton Medical AG breathing circuit set, coaxial (adult/pediatric) used with the ventilators HAMILTON-C1, HAMILTON-T1 and HAMILTON-MR1 (breathing circuit sets for other ventilators are not affected).

A. Reason for Field Safety Corrective Action (FSCA)

During Post Market Surveillance activities, Hamilton Medical AG became aware of an issue with certain breathing circuits set, coaxial. In these affected breathing circuits sets, coaxial, the membrane of the expiratory valve sets might be found to be sticking to the expiratory valve body. This will result in an "exhalation obstructed" alarm on the ventilator.

Description of the product problem:	Certain lots of the expiratory valve set pre-assembled to the breathing circuit set, coaxial (as indicated in the chart at the beginning of this FSN) do not perform as intended. In some cases, the expiratory valve membrane adhered to the expiratory valve body's sealing ring, thereby impairing valve opening and expiratory gas flow. The issue is not detected during the pre-operative test of the ventilator unless a test lung is actively ventilated. In case of an adhering expiratory valve membrane, the malfunction appears within the first breaths after ventilation is initiated.
Problem effect:	When the expiratory gas flow is impeded, the end-expiratory pressure is too high, or the end-expiratory flow is too low. Consequently, the ventilator triggers the high priority alarm „Exhalation Obstructed". The obstructed air is released through the device, e.g. the obstruction valve opens so that the patient can exhale through the inspiratory limb.
Patient risks:	An obstruction of expiratory flow results in inadequate ventilation and impaired gas exchange. Such an obstruction would trigger a high priority alarm during the first breaths and hence, healthcare professionals at bedside are informed immediately and must react accordingly. Hamilton Medical AG received

complaints about the harm described. Nevertheless, serious long-term consequences have not been reported.

Required user actions if problem occurs:

In case of “exhalation obstructed” alarm on the ventilator, the user is requested to perform the following steps:

1. Disconnect the patient from the ventilator and ensure alternative means of ventilation (e.g. alternative ventilator, hand bagging, etc.).
2. Once patient safety is ensured, remove the expiratory valve set and overcome the membrane adhesion by detaching the membrane from the expiratory valve body once.

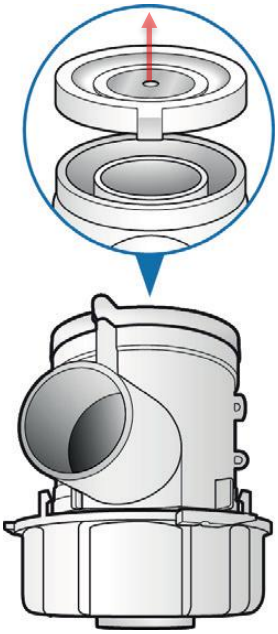

Figure 3: How to remove expiratory valve membrane

3. Place the membrane back onto the body. Then, ensure the membrane is aligned with the expiratory valve body with the metal facing up (do not press onto the metal) and install the expiratory valve set into the exhaust port on the ventilator.

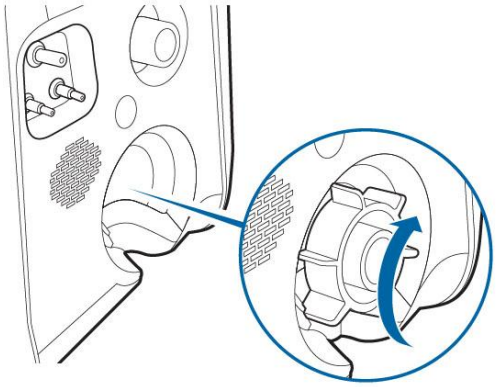

Figure 4: How to insert expiratory valve set into ventilator

4. Alternatively, use a new expiratory valve set.

For further information, refer to respective Instructions for use of your breathing circuit set, coaxial or Operator's Manual of the ventilator in use (HAMILTON-C1, HAMILTON-T1, HAMILTON-MR1).

B. Type of Action to mitigate the risk

To mitigate the risk associated with a potentially adhesive expiratory valve membrane, the user is advised to verify unimpeded expiratory gas flow prior to use.

After performing the pre-operative test, ventilate a test lung using the following settings:

Mode: PCV+

PEEP: 5 mbar

Pcontrol: 5 mbar

TI: 1 s

Rate: 12 b/min

If no "exhalation obstruction" alarm is issued, the expiratory valve is safe to use.

If the "exhalation obstruction" alarm is triggered, do not use the breathing circuit set, coaxial. The breathing circuit set, coaxial must be discarded and replaced.

Due to the reliability of the tests described above, it is not necessary to place breathing circuit sets, coaxial with the lot numbers mentioned above in quarantine. They can be used safely if the specified precautions are followed.

C. Required Actions to be taken by the user

- Inform all potential users of affected coaxial breathing circuit sets, coaxial within your facility about this issue. Make sure recommended actions are followed.
- You may continue to use breathing circuit sets, coaxial with lot numbers mentioned above according to their labelling. Mitigate potential risks by following the actions described in point "B. Type of Action to mitigate the risk".
- Please fill in and sign the Healthcare Facility Reply Form (page 6) and send it to your Hamilton Medical distribution partner or subsidiary. This must be conducted as quickly as possible, but no later than 30 calendar days after receiving the Field Safety Notice.

The Competent Authority of your country has been informed about this communication to users. The local distribution partner or Hamilton Medical subsidiary, as approved by Hamilton Medical AG to conduct all activities around Hamilton Medical devices, is always the first point of contact in this matter.

Manufacturer:	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland	**Contact:**	Hamilton Medical AG Vigilance Team Via Crusch 8 7402 Bonaduz Switzerland Tel. +41 58 610 10 20 E-Mail: fieldactions.med.global@hamilton-medical.com

Please keep this FSN in your data records.

Important notice:
The local distribution partner or subsidiary of Hamilton Medical AG remains the first point of contact for the management of technical interventions.
We appreciate your support in this matter and sincerely regret any inconvenience you may experience because of the issue described above.

Sincerely,

Vigilance Team
Hamilton Medical AG

(document without signature)

Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
Please keep this field safety notice with your coaxial breathing circuit set Instructions for use.
Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Healthcare Facility Reply Form

Please fill in points 2. and 3., sign and return this Healthcare Facility Reply Form to your Hamilton Medical AG distribution partner or subsidiary no later than 30 calendar days after receiving the Field Safety Notice.

1. Field Safety Notice (FSN) information	
FSN Reference number	FSCA-2026-05-03
FSN Date	May 18, 2026
Device name	Breathing circuit set, coaxial
Lot numbers	Between 200379 and 205050 (including both)

Please fill in

2. Healthcare Facility Details	
Healthcare Organization Name	
Address	
Country	
Contact Name	
Title or Function	
Telephone number	

Please fill in and sign

3. Action undertaken on behalf of Healthcare Organization (tick all that apply and if applicable indicate quantity)	
☐	I confirm receipt of the FSN and that I read and understood its content.
☐	The information and required actions have been brought to the attention of all relevant users and executed.
Print Name	
Signature	
Date	

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.
Your organization's reply is the evidence we need to monitor the progress of the corrective action.