November 17, 2026

FIELD SAFETY NOTICE

Hamilton Medical AG ventilator HAMILTON-C6

Reference #: FSCA-2026-11-06

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 ventilator HAMILTON-C6.

Information on Affected Devices:

Device name	Product number	UDI-DI	Serial numbers	Blower revision (not visible to user)
HAMILTON-C6	160021	07630002808590	< 17196 17357 17358 17361 17362 17363	00 and 01

Dear Sir or Madam,

This Field Safety Notice (FSN) provides information on Hamilton Medical AG ventilators HAMILTON-C6.

A. Reason for Field Safety Corrective Action (FSCA)

During Post Market Surveillance activities, Hamilton Medical AG became aware that blower modules (Rev. 00 and 01) in HAMILTON-C6 ventilators with the serial number < 17196, 17357, 17358, 17361, 17362, 17363 may reach the end of their service life earlier than expected in rare cases. If this occurs during active ventilation the ventilator may display an alarm (e.g. “blower speed low”) and transition to ambient state.

Description of the product problem: Certain ventilators with serial numbers as indicated in the table at the beginning of this FSN are equipped with a blower module that is prone to reach the end of its service life earlier than expected. In some cases, the ventilator was alarming with technical events or technical faults (e.g. TE 231009 “blower speed low” or TF 431001 “blower fault”), indicating a technical fault of the blower. The issue might occur even if the pre-operative test of the ventilator passed.

Problem effect: If the ventilator alarms with a technical fault during active ventilation with a patient, the device might transition to ambient state, resulting in loss of mechanical ventilation and requiring immediate provision of alternative ventilation.

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Patient risks:	A ventilator transitioning to ambient state would trigger a high-priority alarm and hence, healthcare professionals at bedside are informed immediately and must react accordingly. Ambient state may result in suffocation and, in a worst-case scenario, death in a ventilator-dependent patient if alternative ventilation is not provided promptly. Hamilton Medical AG has received complaints involving ventilators transitioning to the ambient state. No serious injuries or deaths associated with this issue have been reported to Hamilton Medical AG.
Required user actions if problem occurs:	In case an ambient state (including ambient alarm) occurs, perform the following steps: 1. Provide alternative ventilation immediately. 2. You must switch off ventilator power to exit the "Ambient State". 3. Once patient safety is ensured, it is required to have the ventilator serviced. For further information see chapter "Ambient State" in the Operator's Manual for HAMILTON-C6 ventilators (Doc 624945/05, chapter 7.9.3).

B. Type of Action to mitigate the risk

To reduce the probability of a HAMILTON-C6 blower reaching the end of its service life earlier than expected, Hamilton Medical AG is introducing a phased reduction of the blower-timer threshold for replacing the blower (the blower timer is a calculated indicator of blower lifetime). Previously, the blower replacement was indicated when the timer reached 100% (which is still applicable for blower with revision 02).

During the next yearly preventive maintenance, which is conducted by an approved service technician, the blower will be replaced in accordance with the service manual 627038 REV 09 (or later versions), if the timer has reached the replacement-threshold or is expected to reach the threshold within the following 12 months.

The threshold will be reduced annually by 12.5%. Consequently, blowers will be exchanged in 2026 and 2027 as soon as they reach a calculated blower timer of 87.5%, in 2028 if they reach a blower timer of 75%, in 2029 if they reach a blower timer of 62.5% and in 2030 if they reach a blower timer of 50%. Previously, replacement was indicated at 100% blower timer.

Overview:

Year	New blower-timer replacement threshold
2026 / 2027	87.5%
2028	75%
2029	62.5%
2030 onwards	50%

Immediate user actions are not required. To arrange the next regular yearly preventive maintenance, get in contact with the service technician responsible for maintenance of HAMILTON-C6 devices.

Note: In case the HAMILTON-C6 turned into ambient state, service besides the yearly preventive maintenance must be requested by the user and may lead to an exchange of the blower.

C. Required Actions to be taken by the user

- Inform all potential users of affected HAMILTON-C6 ventilators within your facility about this issue.
- You can continue to use HAMILTON-C6 ventilators. 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 5) and send it to your Hamilton Medical representative. This must be conducted as quickly as possible, but no later than 30 calendar days after receiving the Field Safety Notice.

Your local competent authority has been informed about this communication to users.
Your local Hamilton Medical representative 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:
Your local Hamilton Medical representative 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 HAMILTON-C6 Operator's Manual.
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 representative no later than 30 calendar days after receiving the Field Safety Notice.

1. Field Safety Notice (FSN) information	
FSN Reference number	FSCA-2026-11-06
FSN Date	November 17, 2026
Device name	HAMILTON-C6
Serial numbers	<17196, 17357, 17358, 17361, 17362, 17363

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)	
☐	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.