05 June 2024

URGENT
Medical Device Recall
for End Customers using
All Hamilton Medical Ventilator HAMILTON-C6 with software version SW v1.1.4, v1.1.5., and v1.1.6
Medical Device Correction Reference #: FSCA 2024-04-01

This document is intended for physicians, health care professionals, distributors, and users of these medical devices. This letter contains important information for the continued safe and proper user equipment.

Please review the following information with all members of your staff who need to be aware of the contents of this communbication. It is important to understand the implications of this communication.

Dear End Customer,

This Medical Device Correction Letter provides information about an identified software anomaly that is associated with the use of ventilator software on the ventilator HAMILTON-C6. In addition to the steps to follow as identified in this letter, the newest available software version 1.2.3 contains the required fix and shall be installed without delay to minimize overall risk during use of HAMILTON-C6.

There has been one report of serious injury, one death, and 16 complaints related to this software issue to date.

Affected Device:

HAMILTON-C6,
Product Number (PN): 160021 (UDI: 07630002808590)
with software versions indicated below

The scope of this mandatory Medical Device Correction extends to the following software versions[1]:

- **SW v1.1.4**
- **SW v1.1.5**
- **SW v1.1.6**

This Medical Device Correction aims to have the affected HAMILTON-C6 ventilators on the market updated to SW v1.2.3.

[1] Note: HAMILTON-C6 ventilators with software versions 1.1.1, 1.1.2 and 1.1.3 are also affected by this issue but were already updated to software version 1.1.4 in 2019 through a Medical Device Correction. Versions 1.2.1 and 1.2.2 (with software option INTELLiVENT-ASV) are not affected by this issue. Both are subject to a software update to version 1.2.3 through a different Medical Device Correction from February 2023).

Failure description:

Suctioning tool software anomaly during open suctioning:

If the following sequence of events takes place, the HAMILTON-C6 ventilator will enter *sensor fail mode*, but will never re-initiate ventilation after the patient is reconnected to the ventilator, which it normally should:

1. The user presses the hard key “O2 enrichment”, then
2. The user disconnects the endotracheal tube from the ventilator circuit for open suctioning, then
3. A sensor error is initiated e.g. due to kinked flow sensor tubing and the ventilator switches to sensor fail mode, then
4. The patient is re-connected to the ventilator and sensor fail mode is still active.
5. Ventilation is not re-initiated by the ventilator.

Required user actions if failure occurs:

If ventilation is not re-initiated in the described scenario, there are 4 ways to re-initiate it:

- Select and confirm a control setting (even without a change of the value), or
- Select and confirm a new ventilation mode, or
- Switch the ventilator to standby mode and restart ventilation from standby mode, or
- Switch the ventilator off and switch it on again

Failure effect:

Under the circumstances described in the *failure description* section, reconnection of the patient is not recognized by the ventilator and ventilation is not re-initiated. The user will always be present during the suction maneuver.
The user will wait for the automatic re-initialization of ventilation. It may take a certain amount of time for them to realize that this does not happen. After that, the user may not be able to manually re-initiate ventilation in due time as per one of the 4 ways described above. If this is the case, they might decide to ventilate the patient by alternative means.

Patient risks:

Occurrence of this software anomaly may result in prolonged duration of the suction maneuver associated with a loss of ventilation until the user recognizes and takes steps to resolve the issue by manually bagging or placing the patient on an alternative ventilation device.

Compromised or stopped ventilation may result in interruption and/or loss of ventilation which may lead to hypoventilation, hypoxemia, bradycardia, hypercarbia, and/or increased intracranial pressure. Depending on the individual patient and the specific situation, the occurrence of the software anomaly could potentially result in apnea and/or death in the most vulnerable patients.

Actions to be taken by End Customers:

- Check the software version of HAMILTON-C6 devices in your facility, consult your local distribution partner if clarification and/or a software update is required. They will support you with updating your affected devices with high priority.
- Read and sign the confirmation sheet on the last page of this letter. Forward it to your distribution partner no later than 28 calendar days upon receipt.
- Ensure that your medical staff is aware of the content of this letter.
- Attach this letter to each affected device's operator's manual in order to ensure quick access.

Note:

Your contact in this matter is Bret Everett, the US Director of Technical Support and Services.

Manufacturer:
Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Contact:
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We appreciate your support in this matter and sincerely regret any inconvenience you may experience with this issue. Adverse reactions or quality problems experienced with the use of this product should be reported to the manufacturer through the local distributor and reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Attachment 1: Confirmation from Hamilton Medical's End Customers

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You can fill out and submit this form form online at:

https://www.hamilton-medical.com/en_US/Public/Landing-pages/Medical-Device-Correction-HMI-FCA-0010

Or, if you prefer to fill out the a physical copy, please fill, sign and return this confirmation sheet by e-mail to Bret Everett at bret.everett@hamiltonmedical.com. If you submit the form online, you do not need to email a copy to Bret Everett.

By signing this document, I confirm that I received and understood this Medical Device Correction Letter.
I confirm that I will follow the instructions specified in this Medical Device Correction Letter.

Printed name:

Job title:

Company/Healthcare facility name:

City, State:

Date (MM/DD/YYYY):

Signature:
