

22 January 2025

**Urgent Medical Device Correction**  
**for End-Customers using**  
**Hamilton Medical Ventilators HAMILTON-C2/C3**  
**with Neonatal Option**  
**Reference#: FSCA-2025-01-01**

- Recipients:**
- Health care facilities using Hamilton Medical ventilators (e.g., intensive care units, intermediate care units, emergency rooms, long-term acute care hospitals or in the recovery room (this list is not complete)).
- Time frame for End-customers:**
- The document “**Confirmation — For HAMILTON MEDICAL Ventilator End-Customers**” must be returned to local retailers as quickly as possible, but no later than 45 days after receiving the Field Safety Notice.
  - All incidents of this type should be reported to the local distribution partner.

Dear End-Customer,

This Recall provides an updated information on Hamilton Medical ventilators HAMILTON-C2/C3:

Hamilton Medical became aware of a malfunction with our HAMILTON-C2/C3 ventilators when used long term in **neonatal** patients. If an affected device HAMILTON-C2 or HAMILTON-C3 is used **accumulatively** for 91 days in neonatal patient without a restart of the device, the device will switch to “Ambient State” and therefore stop ventilation. During the “Ambient State” the device is alarming audibly and visually until it is switched off by the user. Hence, it is mandatory to apply a periodic preventive restart of affected devices.

Hamilton Medical already informed through recall action with the reference # CER 110972 about this issue back in May 2023. This updated recall is provided with a new reference number and addresses only these two devices HAMILTON-C2/C3 where the neonatal option is installed.

Since the initiation of the first field action in May 2023, Hamilton Medical did not receive any new complaint related to the issue for the HAMILTON-C2/C3.

**Failure description:**

Affected HAMILTON-C2/C3 devices which are used for long-term ventilation in neonatal patient group will switch to the “Ambient State” if the ventilation time is exceeding 91 days.

During the “Ambient State” the ventilator will alarm audibly and visually and be displaying the following on the screen:



Figure 1: Ambient state (example, another Technical Fault number might be displayed)

**Failure effect:**

No active ventilation is provided anymore to the patient. The device is constantly alarming audibly and visually.

For further information see chapter “Ambient State” in the respective Operator’s Manual.

**Devices and Software version affected:**

All HAMILTON-C2 with SW version  $\leq 2.2.5$  and neonatal option installed  
 All HAMILTON-C3 with SW version  $\leq 2.0.9$  and neonatal option installed

Note: The installed software version of a ventilator can be viewed in the System → Info window.

**Patient risks:** If the ventilator switches to “Ambient State” it will alarm and open the airways without active ventilation. If the patient can breathe spontaneously, the ventilator will allow that. The alarm given by the ventilator indicates, that the device is in “Ambient State”. Serious consequences or death may result for patients which do not breathe spontaneously whenever the ventilation by means of an alternative device or temporary hand bagging is delayed.

**Required user actions if failure occurs:** In such a case, perform the following actions 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 (preventive maintenance. After passing the service software the device can be returned to use).

For further information see chapter “Ambient State” in the respective Operator’s Manual.

**Mandatory periodic, preventive action:** To avoid this malfunction, perform the following:  
The device needs to be restarted regularly.

Note: Switching into “standby” is not sufficient.

We recommend performing the restart of the device during the regular exchange of the breathing circuits (usually every 28 days).

**Preventing the failure from occurring:** For HAMILTON-C3: **Please conduct the Software Update and upgrade the affected devices to SW version 2.0.11 or higher as soon as possible.**

**Important:** If you are dealing with following scenario, please make sure that the instructions described above in “Mandatory periodic, preventive action” are followed:

- If SW version 2.0.11 or higher for the HAMILTON-C3 is not yet installed or is not approved in your country.
- If you use the HAMILTON-C2 for which there is no software update available.

**Actions to be taken by End-Customers:**

- Install SW version 2.0.11 (or higher as available) for the HAMILTON-C3, or
- If there is no software update available or possible, please continue to follow the instructions in this field safety notice.
- Please sign the enclosed/attached sheet to confirm that, as an End-Customer, you have received and duly noted this FSN.
- Also, please continue to notify your local distribution partner of any cases of the aforementioned malfunction.

The local distribution partner as approved by Hamilton Medical to conduct all activities around the Hamilton Medical devices is always the first point of contact in this matter.

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**Note:**

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

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.

**Please keep this information sheet with your HAMILTON-C2 or HAMILTON-C3 ventilators Instructions of use.**