

26 July 2023

URGENT
Medical Device Correction
for End-Customers using
Hamilton Medical Ventilators HAMILTON-C1/T1/MR1
Reference #: FSCA 2023-07-03

- 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)).

Dear End-Customer,

This Medical Device Correction provides information on a Hamilton Medical ventilator malfunction which was reported to Hamilton Medical AG by users:

Hamilton Medical AG is recalling the control boards of certain HAMILTON-C1/T1/MR1 ventilators after receiving reports that the device may interrupt ventilation due to a faulty capacitor. Hamilton Medical AG received nine complaints involving ventilation interruption, while neither serious injuries nor deaths related to this issue were reported.

Failure description:

A degrading capacitor on the control board might leak electrolyte onto the control board, causing a short circuit on the board and/or the capacitor might lose its function. The primary function of this capacitor is to provide energy to store “Realtime Clock” information in case of total loss of power (external AC supply and battery) for example during storage.

As a result of the short circuit, affected HAMILTON-C1/T1/MR1 ventilators might switch to the “Ambient State”.

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



Figure 1: The display indicates “Ambient State”, and a red message with a Technical Fault number (example, a different Technical Fault number might be displayed)

In case the “Realtime Clock” information is lost as a result of a degraded capacitor, the display will show a “Realtime clock failure” and the user will be notified to set date and time (see Figure 2). For further information see chapter “Setting date and time” in the respective Operator’s Manual.

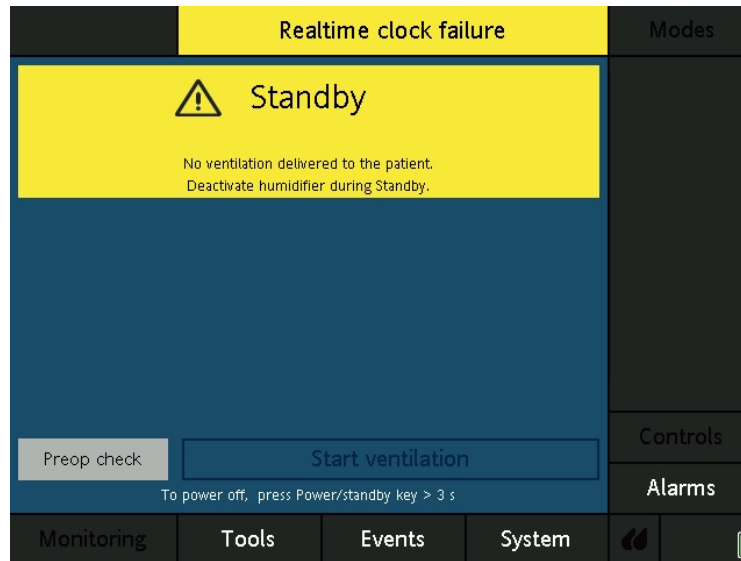


Figure 2: Real Time Clock failure

Failure effect:

In case of “Ambient State”, active ventilation is no longer provided to the patient. The device is constantly alarming audibly and visually.

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

A loss of “Realtime Clock” information does not have any severe consequence. This situation can only occur during startup of the ventilator. The “Realtime Clock” information needs to be set. Once date and time have been set by the user, the user needs to restart the device and ventilation can be started according to settings.

Patient risks: If the ventilator switches to “Ambient State” it will alarm and open the airways without active ventilation allowing spontaneous breathing. Serious consequences or death may result for patients which do not breathe spontaneously until the caretaker provides alternative ventilation.

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.

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

Actions to be taken by End-Customers:

- Contact Hamilton Medical technical support by calling 800-426-6331, option 2 or emailing reno.techsupport@hamiltonmedical.com to determine which, if any, devices you may have with this potential malfunction and schedule onsite service.
- Please sign the enclosed/attached sheet to confirm that, as an End-Customer, you have received and duly noted this Medical Device Correction.

US Contract Manufacturer:	Hamilton Medical Inc. 4655 Aircenter Circle, Reno, Nevada 89502	Contact:	Hamilton Medical Inc. Technical support Tel. +1-800-426-6331, option 2 Email: reno.techsupport@hamiltonmedical.com
----------------------------------	---	-----------------	---

Adverse reactions or quality problems experienced with this product should be reported to FDA’s MedWatch:

- Online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (form available to fax or mail), or
- Call FDA (800) FDA-1088”

Please keep this Medical Device Correction with your HAMILTON-C1/T1/MR1 Operator’s Manual.

We appreciate your support in this matter and sincerely regret any inconvenience you may experience because of the malfunction described above.

Confirmation — For HAMILTON MEDICAL Ventilator End-Customers

Medical Device Correction

Reference #: FSCA 2023-07-03

By signing this document, I confirm that I have received and noted the current Medical Device Correction, stating that the ventilator might go into “Ambient State” due to a leaking capacitor on the control board.

By signing this document, I confirm that I have received and duly noted the Medical Device Correction and will follow the instructions regarding the malfunction.

Name:
Company:
Country:
Date:

Signature:

Sign and return this information sheet by email to Bret Everett, Hamilton Medical's US National Service Manager, at bret.everett@hamiltonmedical.com.

Note:

The local distribution partner is always the first point of contact in this matter.