

26 July 2023

**FIELD SAFETY NOTICE**  
**for Distribution Partners of**  
**Hamilton Medical Ventilators HAMILTON-C1/T1/MR1**  
**Reference #: FSCA 2023-07-03**

**Recipients:**

- Distribution partners of Hamilton Medical ventilators and their service engineers.

Dear Distribution Partner,

This Field Safety Notice (FSN) provides information on a Hamilton Medical ventilator malfunction which was reported to Hamilton Medical AG by users:

Hamilton Medical AG is recalling certain of the ventilators' HAMILTON-C1/T1/MR1 control boards 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 (this is an 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.

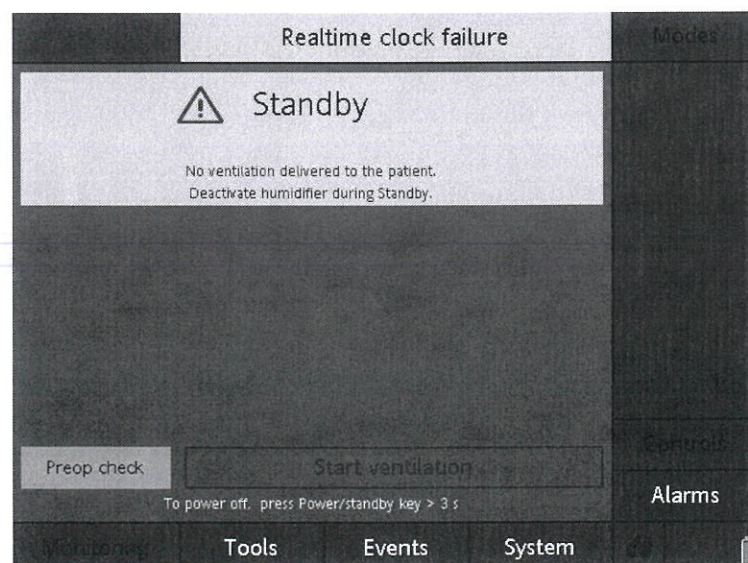


Figure 2: Realtime Clock Failure

**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.

**Affected Devices:** HAMILTON-C1/T1/MR1 devices with serial numbers shown in attached Lists “FSCA 2023-07-03 List of Affected Devices” and “FSCA 2023-07-03 List of Affected MSPs” are affected by leaking capacitors. Unless identified on the lists, no other devices are affected by this Field Safety Corrective Action.

Product numbers of affected devices:

HAMILTON-C1: 161001

HAMILTON-T1: 161006 / 161009

HAMILTON-MR1: 161010

**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.

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

**Mandatory service activities on affected devices:**

- For affected devices listed in “FSCA 2023-07-03 List of Affected Devices” identify the end customer, exchange the control board (refer to Installation Guide 612186), and return them with RGA.
- Trace down the affected boards listed in “FSCA 2023-07-03 List of Affected MSPs”.
  - If they are on local stock, return them with RGA.
  - If they were used for repair of an end customer device, identify the end customer, exchange the control boards (refer to Installation Guide 612186), and return them with RGA.

**Additional actions to  
be taken by  
distribution partners:**

- Distribution partners are requested and obliged to notify the local authorities if Hamilton Medical AG has not already done so. The report to the local authorities must be made in accordance with your local regulations, but no later than 10 working days after the receipt of this safety notification.

Please contact [vigilance.med.global@hamilton-medical.com](mailto:vigilance.med.global@hamilton-medical.com) if you have any further questions regarding reportability. The evidence, that the local authorities have been informed, must be filed in TASK 2 of ky2help.

- Translate the End-Customer FSN to your local language, where applicable, and send it to the affected end-customers immediately.
- Collect the confirmation sheets from end customers. File the documents locally. This must be completed by 09.Sep.2023.
- If the end customer does not respond promptly, the distribution partner must send and document at least three attempts to the end customer. If the end customer does not provide a response, document internally, and no further action needs to be taken with respect to this end customer.
- Ensure that the outlined service activities above are performed.

**Manufacturer:**

Hamilton Medical AG  
Via Crusch 8  
CH-7402 Bonaduz  
Switzerland

**Contact:**

Hamilton Medical AG  
Technical Support  
Parc Industrial Vial 10  
CH-7013 Domat/Ems  
Tel. +41 58 610 10 20  
Email: [techsupport@hamilton-medical.com](mailto:techsupport@hamilton-medical.com)

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

**Confirmation — For Hamilton Medical’s Distribution Partners**

**Field Safety Notice**

**Reference #: FSCA 2023-07-03**

By signing this document, I confirm that I have received and noted the current FSN, 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 all affected end customers have been informed of this Field Safety Notice and that all signed confirmations are archived locally.

Name:

..... MOHD ISMADI KOSIN .....

Company:

..... STARMEDIK SDN BHD .....

Country:

..... MALAYSIA .....

Date:

..... 01 AUGUST 2023 .....

Signature:

.....  .....

**Sign this confirmation sheet.**

**Complete and attach the document "Confirmation - For Hamilton Medical’s Distribution Partners" to TASK 1 in ky2help no later than 45 calendar days after receipt of the Field Safety Notice.**

