

June 02, 2025

FIELD SAFETY NOTICE
for healthcare facilities, physicians and end users
regarding Hamilton Medical Ventilator – HAMILTON-C6
Reference#: FSCA-2025-06-04
Field Safety Corrective Action
On-site device repair

Recipients: Healthcare facilities, physicians and end users which have purchased and/or are using Hamilton Medical ventilator HAMILTON-C6 with the specific serial numbers (SN) indicated below.

**Affected
Product:**

Ventilator name	Part number	Serial Number (SN)
HAMILTON-C6	160021	from 13636 till 13950 and from 13966 till 14753

Time frame: The document “**Confirmation — For Hamilton Medical ventilator HAMILTON-C6 Healthcare facilities/End Users**” must be provided to local approved retailers of Hamilton Medical with the confirmation of repair as quickly as possible, but no later than 45 days after receiving the Field Safety Notice and performance of the repair.

Dear Sir or Madam,

This Field Safety Notice (FSN) provides information on precautionary **corrective action** for certain serial numbers (SN) of the ventilator HAMILTON-C6 from Hamilton Medical AG. No other Hamilton Medical ventilators are affected by this corrective action.

A. Background /Description of the issue

Hamilton Medical AG received information from the supplier of the ESM-Board which is installed in the HAMILTON-C6, indicating that certain ESM-Board may contain a mechanically damaged ceramic capacitor. **Since only certain** serial numbers of the HAMILTON-C6 are affected with the defective ESM-Board, this FSN is limited to these devices defined above.

Important: The HAMILTON-C6 ventilators went through the standard final quality control tests and no issue was found.

Further, there were no complaints received regarding the issue described above. The corrective action mentioned herein is of precautionary nature, whereby all hospitals and healthcare professions using any of the affected HAMILTON-C6 devices are requested to allow the repair of such devices.

Issue effect:

Damage to the capacitor could, over time, lead to a loss of its function due to oxidation or similar degradation processes. The worst-case scenario is a local short circuit of the aforementioned capacitor, with different outcomes depending on the device state.

HAMILTON-C6 is going to be started: The affected HAMILTON-C6 device could then not be started.

HAMILTON-C6 is already started and in use for ventilation with a patient: If the short circuit would occur during use of the HAMILTON-C6 ventilator, the ventilation would be interrupted but the HAMILTON-C6 device would nevertheless alarm about ambient state or panel connection loss. The ventilator must then be replaced by an alternative device.

Patient risks:

If the issue would occur before/during the startup or during standby of the HAMILTON-C6 (no patient's involvement at the start of the device), no risk for a patient is expected.

If the issue occurs during the use of the HAMILTON-C6 (i.e., during active ventilation of a patient), healthcare personal is immediately alerted about the problem. An alternative device for ventilation would then be needed.

To Hamilton Medical AG's current knowledge, the probability of this occurring during patient use is considered very low. However, the potential consequence of loss of ventilation could result in serious injury or death if not immediately recognized and managed by healthcare professionals.

B. Corrective Action

Hamilton Medical AG has decided to pro-actively repair affected HAMILTON-C6 devices by exchanging the ESM-Board through the responsible local organizations/partners which are going to contact your facility.

Required actions to be taken by healthcare facilities/end users:

We kindly ask you to review your HAMILTON-C6 ventilators and check for the SN within the scope mentioned above.

Please make sure that the healthcare professional teams are made aware about this FSN.

Affected devices must receive a new ESM-Board which is organized by the local partner as per servicing protocol.

Please sign the enclosed/attached sheet to confirm that, as healthcare facility, you have received and noted this FSN, and that the affected ESM-Boards from the identified HAMILTON-C6 devices were replaced accordingly.

The local distribution partner as approved by Hamilton Medical AG to conduct all activities around the Hamilton Medical devices 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 Parc Industrial Vial 10 7013 Domat/Ems Switzerland Tel. +41 58 610 10 20 E-Mail: fieldactions.med.global@hamilton-medical.com
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Please keep this field safety notice in your data records (e.g., with the respective ventilators).

Important notice:

The local distribution partner remains the first point of contact for the management of technical interventions. Please remember that Hamilton Medical devices must be subjected to annual preventive maintenance performed by personnel trained and certified by Hamilton Medical AG.

Adverse situations and/or reports of functional problems relating to units not subjected to the preventive maintenance as indicated above, will not be managed by Hamilton Medical AG or the local distributor and may imply the report to the local competent authorities.

The local distribution partner of Hamilton Medical AG will contact you as soon as possible. Please already prepare a list of the affected HAMILTON-C6 ventilators.

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)

Confirmation — For Hamilton Medical ventilator HAMILTON-C6 Healthcare facilities/End Users

Field Safety Notice

Reference #: FSCA-2025-06-04

By signing this document, I confirm that I have received and noted the current FSN. I also confirm that the affected Hamilton Medical ventilators HAMILTON-C6 have been repaired by the local distribution partner of Hamilton Medical AG.

I herewith also enclose the compiled and signed FSN.

Product:	Number of <u>affected and repaired</u> products:
HAMILTON-C6	

By signing this document, I confirm that no further affected HAMILTON-C6 devices (with the defective ESM-Board) are in the inventories and/or are used by our healthcare facility.

Name:

Healthcare Facility:

Role:

Country:

Date:

Signature:

Sign and return this information sheet by email to your Hamilton Medical AG distribution partner.

Note:

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