06 May 2024

FIELD SAFETY NOTICE

for End Customers using
Hamilton Medical Ventilator HAMILTON-C6
Field Safety Corrective Action Reference #: FSCA 2024-04-01

Recipients: Healthcare facilities (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)) owning or using HAMILTON-C6 ventilators.

Dear End Customer,

This Field Safety Notice (FSN) 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 FSN, the newest available software version 1.2.3 contains the required fix and shall be installed without undue delay to minimize overall risk during use of HAMILTON-C6.

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

The scope of this mandatory Field Safety Corrective Action (FSCA) extends to the following software versions[1]:

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

This FSCA 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 field safety corrective action. 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 field safety corrective action from February 2023).

Hamilton Medical AG
Via Crusch 8, 7402 Bonaduz
Switzerland

☎ +41 58 610 10 20
techsupport@hamilton-medical.com
www.hamilton-medical.com

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 understands and resolves the issue.
Compromised or stopped ventilation until ventilation is manually re-initiated or alternative means of ventilation become effective may cause a drop in SpO_2.
Depending on the individual patient and the specific situation, the occurrence of the software anomaly could potentially result in brain damage caused by hypoxemia.

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 FSN. 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 FSN.
- Attach this FSN to each affected device's operator's manual in order to ensure quick access.

Note:

Your local distribution partner is always your first point of contact in this matter.

Manufacturer:

Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Contact:

Hamilton Medical AG
Technical Support
Parc Industrial Vial 10
7013 Domat/Ems
Switzerland
Tel. +41 58 610 10 20
E-mail: techsupport@hamilton-medical.com

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 may have to be reported to the manufacturer through the local distributor and may be reported to the local competent authority.

Sincerely,

Anne-Catherine Morancy Meister
Hamilton Medical AG, Team Leader Vigilance

Attachment 1: Confirmation from Hamilton Medical's End-Customers

Field Safety Notice reference #: FSCA 2024-04-01

Please fill, sign and return this confirmation sheet by e-mail to your Hamilton Medical AG distribution partner.

By signing this document, I confirm that I received and understood this FSN.
I confirm that I will follow the instructions specified in this FSN.

Printed Name:

Job Title:

Company/Healthcare Facility name:

Town/Country:

Date (DD/MM/YYYY):

Signature:

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06 May 2024

FIELD SAFETY NOTICE

for Distribution Partners of
Hamilton Medical Ventilator HAMILTON-C6
Field Safety Corrective Action Reference #: FSCA 2024-04-01

Recipients: Distribution partners of Hamilton Medical AG (HMAG) and their service engineers

Dear Distribution Partner,

This Field Safety Notice (FSN) 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 FSN, the newest available software version 1.2.3 contains the required fix and shall be installed without undue delay to minimize overall risk during use of HAMILTON-C6.

Affected Device:

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

The scope of this mandatory Field Safety Corrective Action (FSCA) extends to the following software versions[1]:

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

This FSCA 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 field safety corrective action. 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 field safety corrective action from February 2023).

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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 understands and resolves the issue. Compromised or stopped ventilation until ventilation is manually re-initiated or alternative means of ventilation become effective may cause a drop in SpO_2. Depending on the individual patient and the specific situation, the occurrence of the software anomaly could potentially result in brain damage caused by hypoxemia.
Mandatory service activities on affected devices:	Update affected devices to software version 1.2.3.

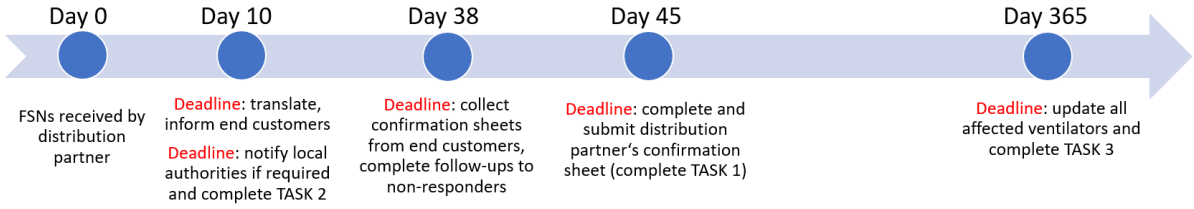
Additional actions to be taken by distribution partners:

- Actions under **TASK 1** in ky2help (to be completed within **45 calendar days total** after receiving the distribution partner FSN):
  - Translate the End Customer FSN to your local language if necessary and send it to all of your affected end customers (i.e., the ones who still have devices with the affected software versions) immediately. These two actions should take no more than 10 calendar days.
    NOTE: Content changes to the End Customer FSN beyond translation are prohibited unless they are authorized by HMAG.
  - Collect the confirmation sheets that are part of the End Customer FSN from your affected end customers and store them. If an end customer does not respond promptly, send and document at least three follow-up attempts to that end customer in reasonable time intervals. This should take no more than an additional 28 calendar days.
  - Complete the confirmation sheet (attachment 1 of the FSN for distribution partners) and add it to TASK 1 in ky2help. This should take no more than 7 additional calendar days after each of your affected end customers received your third reminder or provided their confirmation sheet to you.
  - If an end customer does not provide a response within 7 calendar days after your third reminder, document this internally (including the tracking of all reminders). The tracking of reminders shall be provided to HMAG upon request. After that, no further action needs to be taken regarding this end customer.
  - If your end customer declares that they are not willing to perform the FSCA, request a written and signed letter from their institution where they state that they have received and understood the End Customer FSN and where they furthermore declare that they are not going to perform the FSCA (including a rationale and the number of devices in question). In addition, the letter needs to confirm that the end customer facility takes full responsibility for any malfunction or incident that may arise as a result of the FSCA not being performed. Forward the letter to HMAG Technical Support or inform them if your request for a company letter is declined. HMAG may inform the respective competent authority.

- Actions under **TASK 2** in ky2help (to complete within **10 calendar days** after receiving the distribution partner FSN):
  - Distribution partners are requested to notify the local authorities of their country of operation with the exception of countries where the reporting is done by HMAG: Austria, Czech Republic, Germany, Switzerland and the United Kingdom.
    The report to the local authorities must be made in accordance with your local regulations.
  - Please contact vigilance.med.global@hamilton-medical.com if you have any further questions regarding reportability or if you require support with questions from your local authority that you cannot answer on your own. The evidence of you having informed local authorities must be filed in TASK 2 of ky2help. Alternatively, please file a written rationale with reference to local law if reporting of this FSCA to your local authority is not required.

- Actions under **TASK 3** in ky2help (to complete as soon as possible but not later than **1 year** after receiving the distribution partner FSN):
  - Perform the software update to version 1.2.3 on all of your end customers' affected devices.
  - Complete TASK 3 in ky2help by uploading documented evidence of successful completion of the software update (e.g. log files)

- Contact HMAG Technical Support (contact data is in the footer of this FSN) if you or your end customer require support or answers related to technical questions connected to this FSCA.



Manufacturer:
Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Technical Contact:
Hamilton Medical AG
Technical Support
Parc Industrial Vial 10
7013 Domat/Ems
Switzerland
Tel. +41 58 610 10 20
E-mail: techsupport@hamilton-medical.com

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 may be reported to the relevant local competent authority.

Sincerely,

Anne-Catherine Morancy Meister
Hamilton Medical AG, Team Leader Vigilance

Attachment 1: Confirmation from Hamilton Medical's Distribution Partners

Field Safety Notice reference #: FSCA 2024-04-01

Please fill and sign this confirmation sheet and attach it to TASK 1 in ky2help.

By signing this document, I confirm that I received and understood this FSN.
I confirm that I will follow the instructions specified in this FSN.

Number of end customers affected by this FSCA in your country	…… (please fill in)
Did you inform all affected end customers?	☐ Yes ☐ No, my rationale is as follows: …… …… ……
Number of received, signed confirmation sheets from end customers	…… (please fill in)
I confirm that I have sent 3 reminders to end customers that have **not** returned a filled and signed confirmation sheet. I documented the content and date of these reminders.	☐ Yes ☐ No, my rationale is as follows: …… …… ……

Printed Name:

Job Title:

Company name:

Country:

Date (DD/MM/YYYY):

Signature:
