

August 28, 2017

Medical Device Field Safety Corrective Action Update

- RECIPIENTS:**
- All medical, nursing and service staff where the HAMILTON-C2/C3 ventilator is used (intensive care ward, intermediate care ward, emergency ward, long-term acute care hospital or in the recovery room) and their service engineers.
 - All distributors of the HAMILTON-C2/C3 ventilator and their service engineers.

PRODUCT NAME: HAMILTON-C2 and HAMILTON-C3 ventilator unit

INTENDED USE: The HAMILTON-C2/C3 ventilator is intended to provide positive pressure ventilator support to adults and pediatrics and optionally infants and neonates.

Intended areas of use:

- In the intensive ward, intermediate care ward, emergency ward, long-term acute care hospital or in the recovery room.
- During transfer of ventilated patients within the hospital

The HAMILTON-C2/C3 ventilator is a medical device intended for use by qualified trained personnel under the direction of a physician and within the limits of its stated technical specifications.

MODELS INVOLVED: HAMILTON-C3 (PN 160005)
HAMILTON-C2 (PN 160001)

SERIAL NUMBERS: All

MANUFACTURER: Hamilton Medical AG
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**REASON FOR THE
MEDICAL DEVICE
SAFETY ALERT:**

The analysis of a customer complaint has identified an issue relating to the battery charge of the HAMILTON-C2/C3 batteries after a usage of two and a half years. After two and a half years, the battery fuel gauge may indicate a higher battery charge as to what is available. The technical failure 444001 "low battery" high priority alarms are triggered, alerting the operator both acoustically and visually before entering ambient mode.

**ASSESSMENT OF
THE SITUATION:**

When batteries are depleted, the operator is alerted by high priority alarms and if the ventilator is not immediately connected to an AC power outlet, the ventilator will switch into ambient mode.

The alarm is triggered in every case to alert medical staff.

ROOT CAUSE:

The analysis of the CER has identified an issue relating a discrepancy between the estimated and the actual remaining battery charge level of the HAMILTON-C2/C3 battery. The cause of the described situation results from the natural or physical aging of the batteries. An analysis of the different batteries over a period of 10 years with the technical failure 444001 was performed with both the HAMILTON-C2/C3 devices. The number of complaints with the technical failure 444001 where the alarm triggered less than 5 minutes before entering ambient mode is 57. This gives a failure rate of 0.46%. From the analysis, it was observed that the technical failure 444001 was triggered two years or later after the batteries were installed.

**CORRECTIVE
ACTION:****Action required by device operators:**

The operator or service personnel should make themselves familiar with the batteries' date of installation and manufacturing date and react in time if the battery is more than two years in operation or maximum three years from the manufacturing date.

To check a battery's manufacturing date perform the following:

- Open the battery door.
- Remove battery using a screwdriver to move the metal locking clip.
- Push up the retainer clip and slide out the battery.

The battery's manufacture date is engraved on the top of the battery connector (IEYYWWVV). The date is encoded as follows: In the example IE164523, the year is 2016 (16), the week is 45 and the software version is 23.



- Replace any battery with a manufacturing date greater than three years prior to the actual date.

- Any battery in operation for more than two years prior to the actual date should be replaced.
- If the battery is less than two years old attach a label stating the manufacturing date or the commissioning date of the battery (if known) manually on the battery or the ventilator which contains this battery and check it periodically against the current date.
- Slide the battery back into slot until it clicks and close the battery door.

Further information can be found in the operator's and service manual.

Please keep this information with your HAMILTON-C2/C3 ventilators instructions for use.

Actions by the distributors:

- During the yearly maintenance or servicing of the HAMILTON-C2/C3 ventilators, conduct a "State of Health" check on the batteries in the ventilators. Information on how to use the state of health calculator for Li-ion batteries can be found in Ky2help.
- Replace any batteries of the HAMILTON-C2/C3 that are two years or more in operation.

Action by the manufacturer:

- Inform the service personnel to exchange the HAMILTON-C2/C3 batteries every two years to reduce the probability of reoccurrence.
- Include a possibility to label the battery commissioning date on the battery.

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.**

Confirmation from Hamilton Medical’s End Customers

Medical Device Correction references #:

- Z-1371-2018 for the HAMILTON-C2
- Z-1372-2018 for the HAMILTON-C3

You can fill out and submit this form form online at:

https://www.hamilton-medical.com/en_US/Public/Landing-pages/Medical-Device-Correction-HMI-FCA-0012

Or, if you prefer to fill out the a physical copy, please fill, sign and return this confirmation sheet by e-mail to Bret Everett at bret.everett@hamiltonmedical.com. If you submit the form online, you do not need to email a copy to Bret Everett.

By signing this document, I confirm that I, and employed users who operate the HAMILTON-C2/C3, have received and understood this Medical Device Correction Letter. I confirm that I, and employed users who operate the HAMILTON-C2/C3, will follow the instructions specified in this Medical Device Correction Letter.

Printed name:

Job title:

Company/Healthcare facility name:

City, State:

Date (MM/DD/YYYY):

Signature:
