

Bonaduz, December 2, 2019

Partner Letter

Update on Safety Alert and Corrective Action for HAMILTON-C6

Dear valued business partners,

On March 12th 2019, Hamilton Medical released a Field Safety Notice relating to issues identified on the HAMILTON-C6 which lead to a reboot of the interaction panel (monitor).

The new software version 1.1.4 has been successful in reducing the frequency of these panel reboots and therefore the Field Safety Corrective Action can now be performed.

Required actions

To prevent harm to patients and to fulfill all legal requirements, the following corrective actions are required on your part:

1. Confirm the receipt of this information package by signing and returning the attached confirmation sheet no later than 2 months from date of this letter.
2. Inform all local authorities that the corrective action can now be started no later than 10 days from date of this letter, and send a copy of the information into ky2help. Included is a Follow-up FSCA Report Form for the national authorities.

Please add the following information to the form:

- Section 1: insert the name of the national authority, date of this report and FSCA reference number assigned by NCA.
- Section 5: complete this section with the information of your company.
- Sign the report at the end and send it to the national authority.
- Confirm that you have sent the report to the national authority by sending us a copy of the report form.
- The national authority will expect a list of all affected customers in your country; prepare this list and send it to the national authority upon request.

3. Upon receipt of this letter, start to update the HAMILTON-C6 units to software version 1.1.4.

NOTE. You must complete the software update to software version 1.1.4 as soon as possible, but not later than 12 months* from the date of this letter. Please also take note of the ky2help knowledge base entry ID 3927.

* Depending on your countries' responsible authority, a maximum timeframe of less than 12 months might be required.

4. Follow the guidance of the Hamilton Medical technical support to check and complete the FSCA with each affected unit listed with ky2help.
5. Regularly update our Technical Support department on the progress of the corrective action by entering the status into the key2help software.

For more information, see the attached Medical Device Field Safety Notice.
In ky2help, several tasks for the different steps of this FSCA were created:

- Lead-CER: Communication
- Task 1: Confirmation sheet
- Task 2: E-Mail copy to the authorities
- Task 3: Unit updated

If you have any further questions, please do not hesitate to contact us. We apologize for any inconvenience and thank you sincerely for your co-operation.

With best regards,

Hamilton Medical AG

xxx

Attachments:

- Medical Device Field Safety Notice – including confirmation sheet
- FSCA form

Confirmation Sheet

Field Safety Notice HAMILTON-C6

Subject:

HAMILTON-C6 Ventilator

Panel connection reboot

By signing this letter I confirm that I have received, read, and understood the following documents:

- Medical Device Field Safety Corrective Action

Herewith I promise that all required corrective actions will be implemented on all affected HAMILTON-C6 ventilators in my territory within the time frame defined in the partner letter. Further, I promise to provide regular feedback to Hamilton Medical's Technical Support about the progress of the corrective action.

Name:
Company:
Country:
Date:
Signature:

Sign and return this letter by mail, fax, or email to Hamilton Medical AG.

Mailing address:

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Email: Your Hamilton Medical Technical Support representative