

June 24th, 2022

FIELD SAFETY NOTICE – For HAMILTON C6 End-Customers

HAMILTON-C6 ventilator – Loose status indicator board

- Recipients:**
- All health care facilities using HAMILTON-C6 ventilators (intensive care ward, intermediate care ward, emergency ward, long-term acute care hospital or in the recovery room).
 - All distributors of HAMILTON-C6 ventilators and their service engineers.

Product / Software concerned: HAMILTON-C6 (PN160021)

Reason for the field safety notice: Analysis of customer complaints revealed a hardware issue related to the status indicator board which can become loose and may result in a loose contact to the mainboard and potentially oxidation of this contact due to ingress of water (e.g., disinfectants). The defective contact results in a detected technical fault. The two sequences of events can be summarized as follows:

1. The status indicator board may become loose
1. Water ingress may lead to oxidation
2. Loose contact is detected as technical fault multiple times within a very short time
3. An overflow of log entries of TE 246041 (taLLS_alarmLedError) force the ventilator into “Safety ventilation” or “Ambient state with Panel connection lost message displayed.

HAMILTON C6 operator’s manual provides the following elements:

- **Status indicator board:** *Set of indicator lights on the front of the ventilator unit show important ventilation and device status information. If communication between the ventilator monitor (referred to as the interaction panel in alarm messages) and the ventilator unit is disrupted, the status indicators on the front of the ventilator body display critical ventilation information, including alarm status*
- **Safety ventilation:** *In the event of certain technical failures, the ventilator switches to Safety ventilation. This gives you time to arrange for corrective actions, including organizing a replacement ventilator. If these conditions occur when using HiFlowO2, the ventilator switches to Safety mode. The following conditions apply to ventilation in Safety ventilation:*
 - *The ventilator does not monitor patient inputs in Safety ventilation.*
 - *In Safety ventilation, the blower runs constantly to create inspiratory pressure (ΔP_{insp}) (Tables 7-6 and 7-7). In Safety mode, the blower creates a constant pressure of 5 cmH₂O at the inspiratory port.*
 - *In Safety ventilation, the expiratory valve switches system pressure levels between PEEP and inspiratory pressure.*
 - *You must turn off ventilator power to exit Safety ventilation.*

- **Ambient state:** *If the technical fault alarm is serious enough to possibly compromise safe ventilation, the ventilator enters the Ambient state. The following conditions apply to ventilation in the Ambient state:*
 - *The inspiratory channel and expiratory valves are opened, letting the patient breathe room air unassisted.*
 - *Provide alternative ventilation immediately.*
 - *You must turn off ventilator power to exit the Ambient state.*

Hamilton Medical AG is informing that in Canada one (1) ambient status was detected whilst a status indicator board was loose. Our Risk Assessment concluded this to be an almost impossible situation but for a passive patient, an ambient ventilation state may lead to a serious deterioration in state of health.

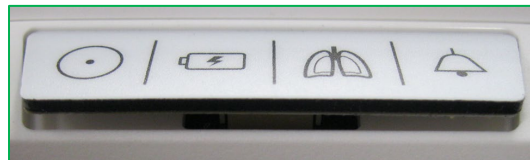
However, in case such a situation occurs, the ventilator displays the high-level alarm (audible and visible) making this defect highly detectable.

Up to date there is no patient harm reported.

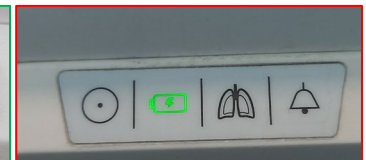
Hamilton Medical is issuing this Field Safety Notification to inform our end customers and provide information on how to act.

Actions to solve the issue:**Action for end-customer**

- In case of a loose status indicator board observed by the user, the front housing containing the status indicator board shall be replaced. This replacement prevents the water ingress that may lead the HAMILTON C6 into ambient state.
- Check the HAMILTON C6 and inform the distributor immediately if you detect the loosening of the status indicator board (see below).



Pic. 1 Loosening



Pic. 2 NOT loosening

- Be aware that a loose status indicator board may not lead immediately to an ambient state, however it shall be replaced immediately to avoid any risk to the patient.
- In case you detect a loosen indicator board, please contact your local Hamilton Medical AG service engineer.
- Your local distributor or a Hamilton Medical AG service engineer has also been informed and will contact you shortly.
- Acknowledge receipt of this Field Safety Notice by completing the confirmation sheet attached and return it to the distributor
- According to HAMILTON C6 operator's manual, make sure to have always an alternative means of ventilation available when using ventilation devices.

Manufacturer:

Hamilton Medical AG
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Contact: Should you have any questions please do not hesitate to get in contact with us.

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We appreciate your support in this matter and sincerely regret any inconvenience that this may cause.

Dr. Michaela Hajek
Vigilance Department
Hamilton Medical AG

Stephan Müller
Medical Quality and Regulatory Department
Hamilton Medical AG

Please keep this information sheet with your HAMILTON-C6 Operator's Manual.

Confirmation Sheet – For HAMILTON C6 End-Customers

Field Safety Notice

Subject: HAMILTON-C6 ventilator loose status indicator board

By signing this letter, I confirm that

- I have received, read, and understood the following documents:
Field Safety Notice HAMILTON-C6 ventilator loosen status indicator board

- I undertake to immediately report any loose status indicator board I observe

Name:

Company:

Country:

Date:

Signature:

Sign and return this letter by email to your Hamilton Medical product distributor.