

June 24th, 2022

FIELD SAFETY NOTICE – For HAMILTON C6 Distributors

HAMILTON-C6 ventilator – Loose status indicator board

Recipients:	<ul style="list-style-type: none">• All distributors of HAMILTON-C6 ventilators and their service engineers.• 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).
Product / Software concerned:	HAMILTON-C6 (PN160021)
Reason for the field safety notice:	<p>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:</p> <ol style="list-style-type: none">1. The status indicator board may become loose1. Water ingress may lead to oxidation2. Loose contact is detected as technical fault multiple times within a very short time3. 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 detecting 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.

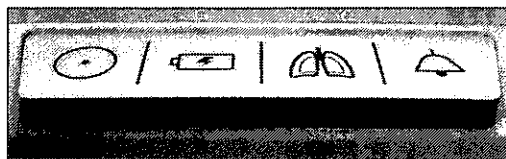
Hamilton Medical is issuing this Field Safety Notification to inform our distributors and service technicians and provide information on how to act.

Actions to solve the issue:

- 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.

Actions for distributors / service technicians:

- Identify all end-customers using HAMILTON C6
- Contact your end-customers and distribute immediately this Field Safety Notice to all HAMILTON-C6 end-customers in order to raise awareness on status indicator board may become loose
- Inform customers of the need to communicate immediately to the distributor any case of a loosen status indicator board
- Complete the Field Safety Notice confirmation sheet and send it back to Hamilton Medical AG.
- Replace immediately the front housing containing the loosen status indicator board on impacted HAMILTON C6 and give feedback to the Hamilton Medical AG Service Team (see below).



Pic. 1 Loosening



Pic. 2 NOT loosening

Manufacturer:

Hamilton Medical AG
Via Crusch 8
CH-7402 Bonaduz
Switzerland

Contact:

Should you have any questions please do not hesitate to get in contact with us.

Hamilton Medical AG
Technical Support
Parc Industrial Vial 10
CH-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 that this may cause.

Hajek
Michaela
22503

Digital
unterschieden von
Hajek Michaela 22503
Datum: 2022.06.24
18:01:58 +02'00'

Dr. Michaela Hajek
Vigilance Department
Hamilton Medical AG

Mueller
Stephan
Walter 22045

Digital
unterschieden von
Mueller Stephan
Walter 22045
Datum: 2022.06.28
14:49:34 +02'00'

Stephan Müller
Quality and Regulatory Department
Hamilton Medical AG

Confirmation Sheet – For HAMILTON C6 Distributors

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

Number of customers impacted: 79

I have informed (number of contacted customers): _____ customers

- All impacted customers have been informed of this field safety notice
- All impacted customers acknowledged receipt of this field safety notice

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:

NUR JAHIRAH OTHMAN

Company:

STAR MEDIK SDN BHD

Country:

MALAYSIA

Date:

14/7/2022

STAR MEDIK SDN. BHD.

200501005964

Signature:



43, Jalan Tiara Sentral 2, Nilai Utama Enterprise Park,
71800 Nilai, Negeri Sembilan, Malaysia.
T: +6.06.799.8113 E: info@starmedik.com

Sign and return this letter by email to Hamilton Medical AG to the responsible Hamilton Medical Technical Support contact.