

Press Release

June 03, 2019

Urgent Medical Device Recall (Correction)

RECIPIENTS:	All healthcare professionals (nursing and service staff where the HAMILTON-G5 ventilators are used (intensive care ward, intermediate care ward, emergency ward, long-term acute care hospital or in the recovery room), Directors of Respiratory Care, Critical Care Units, Risk Management, and Service Engineers
PRODUCT NAME:	HAMILTON-G5 Ventilator unit
MODELS INVOLVED:	HAMILTON-G5 (PN 159001)
SERIAL NUMBERS:	All serial numbers below 16192 with software versions \leq 2.60
INTENDED USE:	The HAMILTON-G5 Ventilator is designed for intensive care ventilation of adult and pediatric patients, and optionally infant and neonatal patients. The device is intended for use in the hospital and institutional environment where health care professionals provide patient care. The HAMILTON-G5 ventilators are intended for use by properly trained personnel under the direct supervision of a licensed physician. The HAMILTON-G5 ventilators may be used for transport within a hospital or hospital type facility provided compressed gas is supplied.
MANUFACTURER/ RECALLING FIRM:	Hamilton Medical AG Via Crusch 8 CH-7402 Bonaduz Switzerland
RECALLING CONTACT: (USA CUSTOMERS):	Hamilton Medical, Inc. 4990 Energy Way Reno, NV 89502 United States Tel. +1 775 858 3200 Fax +1 775 856 5621 e-mail: techsupport@hamiltonmedical.net

**REASON FOR THE
URGENT MEDICAL
DEVICE RECALL
(CORRECTION):**

Hamilton Medical AG is updating all HAMILTON-G5 Ventilators [(PN 159001 that contains the software versions ≤ 2.60) with a newly developed software version 2.80, to reduce the probability of the user message "Panel connection lost" and ventilator entering an ambient state. The user error message is due to a blocked or terminated communication between the ventilation unit processor and the interaction panel processor.

On February 11, 2019 and March 20, 2019, Hamilton Medical AG issued safety communications to the users for the Hamilton G5 Ventilators [(PN 159001), due to the "Panel connection lost" error.

RISK TO HEALTH:

While there have been complaints due to the user message error: "Panel connection lost", no patient injury or harm were reported. The user message error "Panel connection lost" can occur sporadically, and release both a visual and an acoustical high-priority alarm to alert medical staff. In an event the user message error "Panel connection lost" occurs, the HAMILTON-G5 ventilator can cease ventilation and enter an ambient state. When the HAMILTON-G5 ventilator enters an ambient state, the following conditions apply:

- The inspiratory channel and expiratory valves are opened, allowing patient to breathe room air unassisted.
- Ventilator sounds a high priority alarm with visual blinking LEDs alerting medical staff.

**ACTION REQUIRED BY
DEVICE OPERATOR:**

A In the event of the error occurring, the HAMILTON-G5 Ventilator ceases ventilation and enters an ambient state.

- Check and monitor your patient for safety.
- Provide alternative ventilation.
- Turn off the affected Hamilton G5 Ventilator.
- Contact your distributor (techsupport@hamiltonmedical.net) and have the HAMILTON-G5 Ventilator updated with software version 2.80

ROOT CAUSE:

The investigation of the user message error "Panel connection lost" is due to the blocked or terminated communication between the ventilator unit processor and the interaction panel processor leading to the user error message "Panel connection lost" and ventilator entering the ambient.

Please keep this information with your HAMILTON-G5 ventilators Operators Manual.

**ADDITIONAL
INFORMATION:**

If you are aware of any incidents related to this issue or if you have any questions, please contact Hamilton Medical Inc. immediately at Tel. +1 775 858 3200, and/or e-mail: techsupport@hamiltonmedical.net, to provide information regarding those events so regulatory reporting obligations can be fulfilled.

Please keep this information sheet with your HAMILTON-G5 Ventilators Operators Manual.

We appreciate your support in this matter and sincerely regret any inconvenience that this action may cause you. We consider this action necessary to ensure that our customers receive only safe and effective products with high quality.



R. L. Curtis
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Ray Curtis
Team Leader Quality and Vigilance
Hamilton Medical AG

Please keep this information sheet with your HAMILTON-G5 ventilators Operators Manual.