May 8, 2015

Medical Device Field Safety Notice

RECIPIENTS:

- All medical and nursing staff in intensive care units where Hamilton Infant Flow Sensors are used in combination with Hamilton Medical ventilators.
- All distributors of Hamilton Infant Flow Sensors.

PRODUCT NAME:

Hamilton Medical Infant Flow Sensor, single use

INTENDED USE:

The Hamilton Medical infant flow sensor is a device to measure patient air flow and pressures with Hamilton Medical ventilators.

MODELS INVOLVED:

Hamilton Medical Infant Flow Sensor, single use (1.6 m), PN 260177
Hamilton Medical Infant Flow Sensor, single use (1.88 m), PN 155500
Hamilton Medical Infant Flow Sensor, single use (3.1 m), PN 260179

MANUFACTURER:

Hamilton Medical AG
Via Crusch 8
CH-7402 Bonaduz
Switzerland

CONTACT:

Hamilton Medical AG
Technical Support
Via Crusch 8
CH-7402 Bonaduz
Switzerland
Tel. +41 81 58 610 10 20
Fax +41 81 58 610 00 20
e-mail: techsupport@hamilton-medical.ch

REASON FOR THE MEDICAL DEVICE SAFETY ALERT:

Investigations have shown that a volume reading discrepancy may occur under a combination of several effects:

- The application of low inspiratory flows (typically < 10 l/min) to neonatal/infant patients in open bed structures (outside an incubator)
- The use of active humidifiers

Particularly during extended periods of ventilation, it may be possible that water from the humidifier may condensate within the flow sensor measurement chamber and affect the flow measurement, resulting in more volume monitored than delivered to the patient. Pressure monitoring is not affected.

ASSESSMENT OF THE SITUATION:

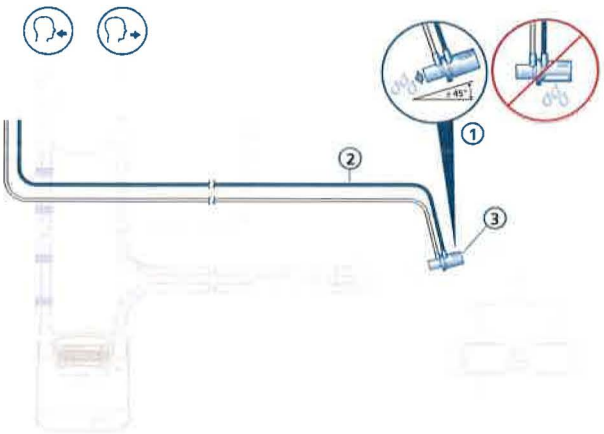
When a ventilation mode with adaptive volume control (APVcmv/CMV+) is used, the ventilator may adjust the ventilation on the inaccurate flow measurement and decrease the amount of ventilation delivered.
This may lead to a hypoventilation of the patient.

ROOT CAUSE:

The cause of the described behavior of the Hamilton Medical Infant Flow Sensor lies in the excessive water condensation on the flow sensor's measuring cavity due to too high temperature differences between the humidified breathing gas and the environment. This can lead to water accumulation when used over longer periods of time which, when exceeding a specific amount, causes inaccurate flow measurement results.

CORRECTIVE ACTION:

Immediate action required by device operators:
The operators in environments where the Hamilton Medical Infant Flow Sensor is used in combination with Hamilton Medical ventilator must be alerted about the correct positioning of the Flow Sensor within the breathing circuit as shown in the following figure:



By placing the flow sensor at an angle of at least 45°, possible water condensation is prevented.
Should water accumulate it can optimally be removed by closed suctioning.
The instruction for use for the Hamilton Medical AG Infant Flow Sensor is included in this Field Safety Notice.

Please keep this information with your Hamilton Medical ventilator's Operator's Manual.

Actions by the distributors:
Distribute this Medical Device Field Safety Notice immediately to all operators of the Hamilton Medical ventilators.

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

Frederike Brühschwein
Quality Management
HAMILTON Medical AG

Please keep this information sheet and the attached instructions for use for the Hamilton Medical AG Infant Flow Sensor with your Hamilton Medical AG ventilator's Operator's Manual.

Hamilton Medical AMILTON MEDICAL AG Ph.: +41 58 610 10 20
Via Crusch 8 Fax: +41 58 610 00 20
CH-7402 Bonaduz/Switzerland www.hamilton-medical.com