HAMILTON MEDICAL

December 19, 2012

Medical Device Safety Alert & Corrective Action

RECIPIENTS:

All medical and nursing staff in environments where the HAMILTON-T1 ventilator is used and their service engineers.

All distributors of HAMILTON-T1 ventilators and their service engineers.

PRODUCT NAME:

HAMILTON-T1

INTENDED USE:

The HAMILTON-T1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics.

Intended areas of use:

- In the intensive care ward or in the recovery room
- For emergency medical care or primary care
- During transport within and outside the hospital
- During transfer by rescue vehicles, jet or helicopter

The HAMILTON-T1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

MODELS INVOLVED:

HAMILTON-T1 with SW version $\leq$ 1.1.2

SERIAL NUMBERS:

All HAMILTON-T1

MANUFACTURER:

HAMILTON MEDICAL AG
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REASON FOR THE MEDICAL DEVICE SAFETY ALERT:

Unexpected high internal oxygen consumption of HAMILTON-T1 ventilators during ventilation of small pediatric patients.

ASSESSMENT OF THE SITUATION:

Unexpected high internal oxygen consumption of the HAMILTON-T1 transport ventilator may cause miscalculation of the required oxygen for long time applications with limited oxygen supply.

Potential risk: If the available oxygen supply during transport is depleted, the life of the patient may be endangered.

The potential risk situations may occur in an environment where limited amount of oxygen is available for the patient (e.g. high-pressure oxygen cylinders) and the patient is ventilated with increased oxygen concentrations.

ROOT CAUSE:

The current labeling does not include sufficient information about the internal oxygen consumption of the ventilators.

Depending on the ventilator setting and the patient's lung impedance, the internal gas consumption of the HAMILTON-T1 may be higher than expected. The internal oxygen consumption has to be taken into account in addition to the oxygen requirements for the patient's ventilation. Especially when oxygen is limited.

CORRECTIVE ACTION:

Immediate actions required by operators:

Calculate the required oxygen capacity prior to transports as follows:

Overall O2 consumption in small patients (height < 70 cm, IBW < 8 kg) in liter per minute:

O2 consumption = (MinVol + Flow Trigger) * 4 * (FiO2 – 20.9) / 79.1

Overall O2 consumption in larger patients (height > 70 cm, IBW > 8 kg) in liter per minute:

O2 consumption = (MinVol + Flow Trigger) * 1.5 * (FiO2 – 20.9) / 79.1

Example:

Patient height:	60 cm
Patient Minute Volume:	2 l/min
Set Flow Trigger:	1 l/min
Set FiO2 (%):	60
Planed duration of transport:	240 Minutes (4 hours)

Calculation of overall oxygen consumption during planned transport:

O2 consumption per minute:

*(2 l/min + 1 l/min) * 4 * (60 – 20.9) / 79.1 = 5.93 l/min*

Oxygen consumption in 240 minutes:

*5.93 l/min * 240 min = 1423 Liter*

The overall oxygen consumption for the planned transport is 1423 Liters.

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Action by the distributor:

Distribute this Medical Device Safety Alert immediately to all operators of the HAMILTON-T1 using the device

- For emergency medical care or primary care
- During transport within and outside the hospital
- During transfer by rescue vehicles, jet or helicopter

Update the HAMILTON-T1 labelling and software as soon as possible upon its availability.

Action by the manufacturer:

Rework and provide updated HAMILTON-T1 labeling (e.g., Operator's Manual).

Develop and provide updated software with optimized internal oxygen consumption and overall oxygen consumption monitoring.

We appreciate your support in this matter and sincerely regret any inconveniences 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.

Curdin Danuser
Vice President
Quality Assurance and Regulatory Affairs
HAMILTON MEDICAL AG

Please keep this information sheet with your HAMILTON-T1 Operator's Manual.

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