SALTER LABS

15 January 2015

FAO Martin Fleming, HM Assistant Coroner for Surrey
HM Coroner's Court
Station Approach
Woking
Surrey
GU22 7AP

Inquest touching the death of Gaenor Moore
Regulation 28 Report – Action to Prevent Future Deaths

Dear Sir,

This letter constitutes Salter Labs' reply to the Regulation 28 Report dated 24 November 2014 issued further to the inquest touching the death of Gaenor Moore.

Firstly, Salter wishes to extend our sincere condolences to the family of Gaenor Moore; it is never easy to lose a loved one regardless of the circumstances.

Secondly, we would like to reassure you that Salter Labs takes our responsibilities as medical device manufacturers very seriously and are fully committed to patient safety. Upon learning of the incident via notice of the inquest, we immediately requested the suspect E7600 bubble humidifier be returned or otherwise made available to us so that we could examine it for manufacturing defects even though no defects were suggested in the documentation we received. To date, the humidifier has not been returned to Salter for analysis. We filed an initial Vigilance Report with the UK Medicines and Healthcare Products Regulatory Agency (MHRA) promptly, and will provide an updated Vigilance Report to include information obtained as a result of the inquest and corrective actions described here-in.

Three concerns were raised In Section 5 of the Regulation 28 Report:

1. ***The lack of oxygen flow to the nasal cannula as a result of the screw cap to the humidifier not being properly engaged.***

   Background

   Cross Threading Risk

   We note the Coroner's conclusion that the cap to the humidifier was not properly engaged at the time of the engineer's examination, and the Coroner's conclusion that it is "*more likely than not that the lack of oxygen made less than a minimal contribution to her death*". We believe that this accurately reflects evidence heard at the inquest that this type of oxygen delivery system is not

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intended as life sustaining, but is instead prescribed for supplementary oxygen and patient comfort.

We would like to bring to your attention several points that weren't necessarily relevant to the inquest but speak to the potential for corrective actions.

Cross Threading Incidence

Difficulties with humidifier cross-threading are rare. Like all medical device companies, Salter maintains a risk management file on our products in accordance with EN ISO 14971:2012. Salter has manufactured over 16,700,000 bubble humidifiers with this lid design over the last four years. During this time, we have received only one other report of potential cross threading, which was unconfirmed (there was no patient injury in the other incident, which occurred in the USA). This complaint rate equates to an overall cross-threading incident rate of only 0.12 Complaints per Million (CPM).

Safety Valve

Each Salter bubble humidifier already includes a safety valve to detect blockages and leaks as follows:

- If there is a downstream blockage in the system between the humidifier and the patient (such as a kinked tube), pressure will build up in the humidifier and a safety valve will open to relieve pressure and produce an audible whistle to notify the user - an alarm system warning of blockages.
- The safety valve can also be used to check for leaks including, but not limited to, leaks caused by cross-threading the lid. If the user or carer intentionally blocks the oxygen flow (which can be done simply by pinching the tube) at a point past the humidifier outlet and the safety valve does not open and whistle, it indicates there is a leak in the system.

The current Salter labeling on Salter 7600-series humidifiers provides a diagram and instructions for how to test for leaks. It reads *"To test for leaks: Turn on O2 source to 6 LPM and block outlet. Humidifier should sound in 5 seconds or less. If not, check connections"*.

Corrective Actions

Thread Design – Corrective Action Complete

As noted in the independent engineering report discussed at the Inquest, Salter bubble humidifiers incorporate a double helix thread design. The current thread design was utilised intentionally, to improve ease of use while also reducing the opportunity for cross-threading.

As a result of this incident and in light of the Coroner's recommendation, Salter convened an internal multi-disciplinary technical design review in December 2014 to evaluate the thread design on several commercially available bubble humidifiers, including the Salter Labs 7600 series bubble humidifier. The design review team determined that:

- The double-start thread significantly reduces the number of rotations necessary to secure the lid to the bottle. Since hand rotations are difficult for individuals with reduced dexterity, this design feature significantly improves ease of use of the humidifier for some users. The Salter

humidifier required less rotation to secure the lid than any of the other humidifiers evaluated. This is an important design consideration for the typical humidifier user or carer.

- Some of the other humidifiers evaluated utilise a finer thread pitch. The relatively course thread pitch on the Salter humidifier makes cross-threading both less likely and more noticeable to the user or carer.

The design review team concluded that the current Salter humidifier thread design is appropriate for this application and that the risk associated with cross-threading has been reduced as far as possible. The results of this review, together with the current overall cross-threading incident rate of 0.12 CPM, have been documented in Salter's humidifier risk management file.

Product Labeling – Corrective Action Pending

In addition to the current product labeling that advises users to check for leaks and provides instructions on how to check for leaks (as described above), Salter will add two more statements to the labeling in all languages:

- After the current instructions for adding water, we will add *"Replace lid and check that it is sealed properly"* or equivalent.
- Before the current instructions to check for leaks, we will advise users why it is important that they check for leaks by adding the phrase *"Leaks may partially or fully reduce oxygen being delivered to the patient"* or equivalent.

These labeling changes will be implemented for all product manufactured after 15 February 2015 (i.e., lot codes 021615 and later).

2. **Absence of a visual or audible alarm on concentrator machine (product number INV-IRC5PO2AWN) to indicate the loss of oxygen flow to the nasal cannula when the screw cap to the humidifier (manufactured by Salter Labs) was tightened and cross threaded.**

This concern is best addressed by the concentrator manufacturer cited in your report, Invacare Rehabilitation. However, as we point out just above, the humidifier actually does have a blockage warning system and a simple test for leaks. Further, though your concern references humidifiers *"manufactured by Salter Labs"* specifically, we would like to point out that all brands of bubble humidifiers compatible with the Invacare style of concentrator are similarly designed with a bottle and screw-on lid, and have some risk of being cross-threaded.

3. **Accompanying training and literature did not reference the implications to oxygen flow in the event of failing to properly engage the screw cap to the humidifier.**

This concern is best addressed by the equipment provider cited in your report, Dolby Vivisol. You will recall that you heard oral evidence from Dolby Vivisol during the Inquest that they will be updating their literature and training to make sure the risk of cross threading the humidifier lid is made even more explicit. Additionally, we would like to note that Dolby Vivisol has accepted Salter Labs offer to review the updated literature before finalising it. We will take this opportunity to ensure that Dolby Vivisol include reference to the safety valve as explained above.

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Thank you for the opportunity to reply to your recommendations from the inquest. Salter bubble humidifiers have a long and safe record of enhancing the comfort of patients undergoing supplementary oxygen therapy, by preventing drying of the mucous membranes in the nose and mouth, ensuring adequate hydration, and preventing increased viscosity of secretions. Salter continually monitors the use of our devices in the field, and is constantly looking for ways to further enhance the design, manufacturing and labelling of all our products. Please do not hesitate to contact me if you have any further questions or concerns.

Regards,

[redacted]

[redacted]

Vice President, Quality and Regulatory Affairs
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