Dolby VIVISOL
Home Respiratory Care

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

15th January, 2015.

Dear Sir,

The Inquest touching the death of Gaenor Moore ("the Deceased")
Regulation 28 Report- Action to Prevent Future Deaths dated 24.11.2014 ("the Report")

I refer to the above.

The Report instructed Dolby Vivisol ("the Company") to issue a response to the concerns raised in the Report and I confirm that I am authorised to respond on the Company's behalf in my capacity as Managing Director.

I will first provide a brief background about the Company and then address the concerns as far as they are applicable to the Company.

The Company

The Company is involved in the supply of specialist respiratory medical equipment to both NHS and private care homes and other private customers, including the oxygen concentrator and humidifier ("the Equipment") being used by the Deceased at the time of her death. We are mainly concerned with the procurement, installation and delivery of such equipment, and therefore cannot comment on concerns relating to the manufacture or design of the Equipment.

When the Company receives an order from a physician to install home oxygen with a patient we visit the patient's location, usually their own home or a care home, and conduct an installation. The installation process is comprised of conducting a risk assessment to ensure that it is safe to install the Equipment and then we put the equipment in place, test the equipment to ensure that it is working correctly and train the patient or their carer how to properly use and maintain the equipment. As reinforcement to the on-site training we also provide a range of instruction material explaining how to correctly use individual pieces of equipment as well as more general educational pieces of information explaining how the patient can stay safe whilst using oxygen therapy and how the patient can contact the Company via our 24/7 contact centre if they have any questions or concerns.

The Coroner's concerns

The Report cited the following three concerns that have arisen following the death of the Deceased:

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

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";*

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"*

I will outline the Company's response to each of these concerns in turn, and in particular I will give details of any action which has been taken or planned (as well as a timetable for such action), or alternatively explain why responsive action is not proposed by the Company.

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

As stated above, the Company cannot respond on points relating to the manufacture or design of the Equipment. Concerns about these issues should properly be addressed by the manufacturer of the oxygen concentrator and/or humidifier (Invacare (UK) Limited and Salter Labs respectively).

We do however note your finding that it is more likely than not that "*the lack of oxygen made less than a minimal contribution to [the Deceased's] death and that she died from natural causes*" (paragraph 3, *Investigation and Inquest*).

As far as this concern may relate to the installation of such equipment by Company staff, and/or training of the patient or nursing staff operating the equipment, please see our response to concern number 3 (below).

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

As stated above, the Company cannot respond on points relating to the manufacture or design of the Equipment. Concerns about the design of the concentrator machine should properly be addressed by Invacare (UK) Limited.

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

The Company is committed to ensuring the highest levels of patient safety. As such, we continually review our training procedures and equipment literature to ensure that it is as comprehensive and up-to-date as possible. As you are aware, full oral evidence was provided by the Company about this at the Inquest by [redacted] Field Services Manager.

The Company currently supplies the patient with a leaflet called "Your Oxygen Concentrator" which provides details of how the concentrator works, how it is set up, the care of the concentrator and how to troubleshoot any problems. The leaflet instructs the patient on how to check the flow, there is also a list of Do's and Don'ts to assist the patient with day to day usage. In the event that a patient requires a humidifier there is a separate leaflet provided at installation. The leaflet provides details of how to clean, refill and fit the humidifier bottle, it states "take care that you do not overtighten or cross the screw thread".

It is proposed that the humidifier leaflet will be modified to provide increased awareness of the impact caused by failure to connect the humidifier bottle correctly. Also there will be greater emphasis on the need to confirm the flow of oxygen from the nasal cannula. These enhancements will be reinforced during the patient/carer training provided by the Dolby Vivisol technicians.

In light of the concern raised in the Report, I can confirm that the Company is taking the following action:

3.1 The Company is actively liaising with Salter Labs which manufactures the humidifier. Salter Labs has proposed additional wording on the product instructions in order to avoid leaks, and warn about the potential effect of a leak on the oxygen supply. The Company's correspondence with Salter Labs is currently on-going, although I am informed by Salter Labs that updated labels will be attached to relevant products manufactured after 15 February 2015. Upon receiving the update from Salter Labs we will correspondingly review and/or update our instructions and training material.

3.2 The Company is actively liaising with Invacare (UK) Limited in relation to amendments proposed to their current instructions, which will warn about the potential effect of a failure to properly fasten a humidifier cap to its oxygen concentrator. The correspondence with Invacare is currently on-going, although I am told that Invacare proposes to update its instructions within the coming months. Upon receiving the final update from Invacare we will correspondingly review and/or update our instructions and training material.

3.3 Once all draft amendments to current literature have been finalised, the proposed amendments will be sent as soon as possible to NHS contract managers for approval

3.4 When approval is obtained from the NHS contract managers, the updated literature will be sent to all current and future Equipment users. The amendments will be specifically highlighted to current humidifier patients.

3.5 Any amendments will be immediately communicated to the relevant Company staff, and the nature and effect of the amendments will be specifically reinforced during the patient/carer training provided by Company technicians when Equipment is installed in the future.