Yes, you can.®

1 5 JAN 2015

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

15 January 2015

Dear Sir

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

I write in response to the Regulation 28 report issued on 24th November 2014 following the inquest into the death of Gaenor Moore. I am writing in my capacity as Managing Director on behalf of Invacare (UK) Limited ("Invacare").

In your report you have highligted a number of concerns and asked that further consideration is given to equipment and accompanying information to prevent a recurrence of the death. I will deal with these points further below, in the order they are raised, after providing background information that Invacare believes is relevant in the circumstances.

Equipment background

Invacare manufacturers concentrator units which are prescribed for supplementary oxygen for home use. The units are supplied to various customers throughout the United Kingdom, one of which is Dolby Vivisol. These customers are then responsible for the onward supply of our units, together with provision of training and literature, to the end user. Invacare itself has no direct involvement with the end user.

Invacare is aware that a small percentage of oxygen concentrator units are supplied in the United Kingdom with a humidifer. I can confirm that the company has no involvement with the provision of this accessory. I provide further detail on this under the heading *"Concern 1 - Humidifier"*.

BHTA British Healthcare Trades Association

INVACARE LIMITED
Pencoed Technology Park Pencoed Bridgend CF35 5AQ UK
Tel: +44 (0)1656 776200 Fax: +44 (0)1656 776201
www.invacare.co.uk
Registered in Cardiff No. 5178693

Equipment use

Invacare's concentrator unit is not intended as life sustaining equipment; as accepted in the evidence of [redacted] and [redacted] at the inquest. In addition, this fact is expressly provided for in the international standard that outlines the safety requirements for oxygen concentrators; ISO 8359.

The purpose of the concentrator unit is explicitly set out in our manuals with this relevant wording being inserted since December 1999. Each concentrator is packed and delivered containing a manual and so they are provided as a matter of course to each of our customers. They in turn extract and provide relevant information from them to caregivers and patients who use the product. The most up to date version of the manuals are available on our website and customers are informed that they can access them.

The therapeutic, as opposed to life sustaining, use of the concentrator is widely known throughout the industry and by relevant parties, from the prescribing physician right through to the end user. It is common, and should be of no medical concern, for a patient prescribed a home oxygen unit to have spells off oxygen; also accepted in the evidence of [redacted] at the inquest. It follows therefore, that it is not appropriate for the Invacare unit to be used for acutely ill patients who require oxygen for life sustaining purposes.

As a result, Invacare respectfully submits that, taking into account the facts and circumstances relevant to the inquest, and the matters that are the subject of the Regulation 28 report, appropriate actions have been taken to reduce or eliminate risk as far as possible to prevent injury or death related to intended use of its equipment.

However, as a responsible organisation committed to continuous improvement, Invacare has reviewed your report and is responding to each of your concerns as relevant to our position.

Concern 1 - Humidifer

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

At the inquest, expert engineer [redacted] referred in evidence to an Invacare manual. This manual referred to our concentrator units being supplied with humidifer bottles. I am not aware of which version of the manual was relied upon in evidence however I can report that enquiries were made following the inquest and I confirm that our manuals have not referred to humdifier bottles supplied with concentrator units for many years. The manual referred to in evidence is therefore not representative of current or recent past editions of the concentrator unit manual.

Yes, you can.

Further, I can confirm that we do not produce or provide humidifer bottles in the United Kingdom. As such, it is appropriate for Salter Labs, as a manufacturer of humidifier bottles, to directly address this point in their response.

Concern 2 - Alarm

" Absence of a visual or audible alarm on concentrator machine (product number INV – IRC 5PO2AWN) to indicate the loss of oxygen flow to the nasal cannula when the screw cap to the humidifer (manufactured by Salter Labs) was tightened and cross threaded."

The alarms presently on Invacare's concentrator unit are in place to properly detect the output of oxygen from the unit itself and issues such as power failures, degradation of oxygen quality, blockages in the tubes and overheating of the appliance.

The unit and the alarms present on it are fully compliant with the applicable Oxygen Concentrator Standards; IEC60601-1 and ISO8359, as required by the European Medical Devices Directives. Oxygen concentrators that comply with these standards are recognised as safe to operate.

ISO8359 set out requirements for manuals in respect of containing appropriate technical descriptions together with a comprehensive list of warnings to be provided. The required warnings/alarms are featured on the Invacare concentrator units. The standards do not require any additional alarms.

Invacare has however still given consideration to whether it is possible to have either a visual or audible alarm on the concentrator machine that detects the loss of oxygen flow when the humidifier cap is not properly engaged. The company has concluded that as a responsible organisation it has properly assessed the risks to the intended user and has appropriate alarms in place to counter these. Further, it has concluded that an alarm to indicate loss at the humidifier point would be technically complex such that it would introduce unacceptable risks and inconvenience to the end user without any benefits to counter or justify them. Examples of these are:

- The alarm suggested is still no guarantee that the end user is receiving oxygen as there are the possibility of leaks in the tubing after the humidifer (which can be up to 40 or 50 feet/10 to 18 meters long for user convenience) or the "fire safe" device that sits at the patient end of the oxygen line. The only guarantee of oxygen flow from the humidifer onwards is by monitoring or testing the flow at the cannula end;

- The proposed alarm would require additional lengthy wiring and connection points which may increase the potential for leaks and as a result, erroneous alarms, or the potential for wiring problems. There is then a greater risk of the user ignoring all/any alarm;

- There can be potential confusion in patients on flow rates prescribed and that which is detected by an alarm (as there can be a loss of up to 0.5 litres of flow after the oxygen goes through the humidifier);

- The proposed alarm would have to be put as close as possible to the user which would as a result tether a much shorter area of use therefore preventing the user walking freely around their house as would be expected, add risk from additonal weight and potentially excessive wiring, potentially cause a trip hazard and possibly promote non-compliance due to the encombering nature of the device.

Invacare's position is supported by the evidence given at the inquest by expert engineer; [redacted] I note that the initial view expressed by [redacted] was that consideration should be given to such an alarm however he qualified this by stating it would be difficult to do so. I understand that subsequently in his evidence [redacted] accepted that there were sensible alarms on Invacare's unit and that there was no need for any additional alarms.

Concern 3 – Training & Literature

" 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 humidifer"

As stated earlier, Invacare does not have any direct involvement with any training or literature provided to the end user. Specifically, we have no involvement at all with any humidifer bottles that may be added on as an accessory to our concentrator units. Suppliers such as Dolby Vivisol are directly responsible for providing the training and literature provided to the end user. Invacare therefore consider, save for a few points as noted below, that it is appropriate for Dolby Vivisol to take the lead in respect of this point.

I can confirm that Invacare's current manuals already contain clear guidance on securely fastening the caps on humidifer bottles that may be added on as an accessory. As part of our review following the inquest we have agreed to enhance the guidance provided.

We intend to do so by updating the manuals provided to customers such as Dolby Vivisol, with the concentrator units.

We have not yet finalised the exact language that will be featured in the update, however we anticipate a form of words similar to the following text would be added to the existing warnings in the manuals:

Confirm that the humidifier cap is not cross threaded on the humidifier bottle.

Failure to properly install the humidifier bottle or other accessories to the concentrator will impact the flow of oxygen.

This upate will be phased into all Invacare manuals within the next several months. As is our usual practice, a technical update will also be sent to all customers in Europe to confirm that our manuals have been updated.

I can confirm that Invacare have liaised with Dolby Vivisol directly in relation to the current training and literature provided and the amendments they propose to make. Invacare have also updated Dolby Vivisol on the amendments we intend to roll out.

Whilst noting that our literature, as supplied to the customer, will reference the fact that failing to properly engage the cap to a humidifer may have an effect on oxygen flow, this must be factored in alongside the key points that there may be other factors which affect flow and that our equipment is not intended to be life sustaining.

I trust that I have provided the information required and that this was of assistance.

Yours faithfully

[redacted]

[redacted]
Managing Director
Invacare (UK) Limited