Dräger medical
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Dräger Medical b.v.,
P.O. Box 10.100, 5680 GA Best, The Netherlands

To the customers and users/patients of the Dräger Carina™*home*, Home Care Ventilator

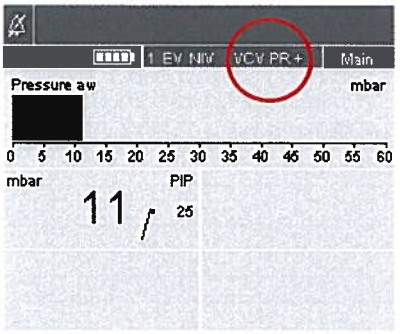
December 18th, 2008

Important safety notice!
Possible reduced volume delivery to the patient without an alarm, affecting all Carina™*home* ventilators (with software version 1.1 - 2.4)

Info/measures for caregiver: inform affected users/patients, follow the instructions below, verify device settings
Info/measures for user/patients: contact your home care provider or physician with respect to this letter

Dear Sir or Madam,

Within the framework of our world wide post market surveillance activities and the continuous quality control of our products, we have determined that, under specific conditions as described below, a disconnection of the pilot line may not be alarmed by a "pilot line disconnect" alarm (for further details please see background information "Pilot Line disconnect Alarm" on page 2 of this letter). An open pilot line may potentially result in a substantial reduction in tidal volume delivery.



This phenomenon was identified by Dräger engineers and, as of the date of this notice, has not been reported by our customers and no injury has been noticed. Although we have not received reports from patients, we want to inform you about this phenomenon to further reduce the possibility of occurrence.

Patients shall contact their home care provider or physician to insure the proper precautions to be taken as described below until an improved device software and/or hardware is available.

Figure 1

Specific conditions

The above mentioned device behavior in case of a disconnection of the pilot line is only applicable to patients:

- ventilated in the Volume Control Ventilation, Pressure Regulated (VCV-PR) mode or in the Pressure Support Ventilation (PSV) with Volume Guarantee mode. The mode is displayed on the upper portion of the front panel as seen in figure 1, and
- using the Expiration or "mushroom" valve hose set as seen in figure 2, and
- not using additional external monitoring as indicated in our Instructions for Use (IfU), and
- dependent to ventilator.

Figure 2

Dräger Medical b.v.
Kanaaldijk 29
5683 CR Best
The Netherlands

Postal address:
P.O. Box 10.100
5680 GA Best
The Netherlands
Phone +31 499 331 331
Telefax +31 499 331 222
E-Mail: medical.best@draeger.com
http://www.draeger.com

Bank account:
ING Bank – The Hague
Account nr. 67.12.10.777

Trade Register:
Oost-Brabant nr. 34064187

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Further background information:

Pilot Line disconnect Alarm

When a patient is being ventilated in the VCV-PR (Volume Control Ventilation – Pressure Regulated) mode or the PSV (Pressure Support Ventilation) mode with Volume Guarantee and the pilot line becomes disconnected, a "pilot line disconnect" alarm may not be generated. A disconnected pilot line will cause a leak to occur and the device will lower the inspiratory pressure, Pinsp, until the lower pressure limit of the volume guarantee mode, Pvgmin, is reached reducing the delivered volume. The reduction in volume delivery is dependent on the set Pvgmin.

If no additional monitoring is used, the reduced ventilation volume administered to the patient may not be noticed; therefore a hazardous situation for the patient depending on external ventilation could not be ruled out!

Until an improved software/hardware solution will be available the following transitional solution must be followed:

- Set a realistic lower pressure limit, Pvgmin, to prevent large reductions in the delivered tidal volume
- When a filter is used; position the filter between the patient and the hose
- In particular for patients depending on ventilation use additional monitoring as described in the according instructions for use:

WARNING
Patients depending on ventilation need either monitoring of expiratory tidal volume, or monitoring of expiratory minute volume, or monitoring of end tidal expiratory CO2 concentration.
Connect an external monitor complying with ISO 21647 to the hose system.
Otherwise no alarm is activated, if the patients ventilation deteriorates.

(WARNING as shown in the current Carina™*home* instructions for use)

Dräger is currently developing solutions to eliminate or minimize the described device behavior and our goal is to resolve this situation as quickly as possible. You will be contacted by your home care provider or physician to schedule the update of your Carina™*home*.

We would like to apologize for any inconvenience this may have caused you and we would like to thank you in advance for your support during this situation. Please do not hesitate to contact your home care provider or physician for further information, questions or comments.

Yours sincerely,

Rob Aanssen
President & CEO
Dräger Medical b.v.