

**Urgent Medical Device Recall**  
**Dräger Carina Sub-Acute Care Ventilator**  
**Part Number 5704110, UDI Number 04048675398516, All Serial Numbers**  
**Possible Contamination of the Breathing Gas with 1,3-Dichloropropan-2-ol**

June 2023

**Risk Manager**  
**Director, Clinical Engineering**

Dear Madam, Sir,

The purpose of this letter is to advise you that Draeger is voluntarily recalling the Dräger Carina Sub-Acute Care Ventilator, Part Number 5704110, UDI Number 04048675398516, all serial numbers, due to possible contamination of the breathing gas with 1,3-Dichloropropan-2-ol.

With a view to determining the long-term stability of the PE-PUR foam used for sound insulation in Carina ventilators, we subjected devices of different ages to biocompatibility tests. For Carina ventilators operated for periods of up to 15 years, no age-related degradation or decay products associated with degradation were found in those standard tests.

However, in some of the standard tests we measured concentrations of 1,3-Dichloropropan-2-ol that exceed the acceptable uptake level during continuous use (>30 days) in pediatric patients. Our investigations determined that a setting of higher minute volumes lead to lower concentrations in the breathing air. At a minute volume greater than 3.6 l/min, the measured concentrations were in the acceptable range for continuous use on adult patients.

1,3-Dichloropropan-2-ol is a constituent of the foam, which was not discovered in the breathing gas in previous biocompatibility tests conducted within the framework of product approvals and modifications.

During the course of our market surveillance activities, no complaints relating to this problem have come to our attention

#### **Risk to Patient Health**

In literature, 1,3-Dichloropropan-2-ol is considered to be acutely toxic and a potential carcinogen. However, we have not received any reported symptoms of an acute toxic reaction or any other complaints relating to this issue via our market surveillance. No carcinogenic effect could be proven in human studies so far. Our risk assessment reveals only a low risk of additional cancer cases by comparison with the general cancer risk.

Although Dräger discontinued production of the Carina ventilator in 2019, we are planning to remove the foam from Carina ventilators still in use and replace with a newly designed blower cover, without additional foam, for noise reduction purpose.

**Identification of the affected medical devices:**

According to our records, you have received at least one Carina device. All devices could be affected by this issue.

**Necessary action:**

You may continue using your Carina ventilator until it has been modified, provided the following conditions are met:

- the set minute volume exceeds 3.6 l/min and,
- only adult patients are ventilated and,
- only a Dräger ventilation hose with leak valve is used.

According to current planning, the new designed blower cover will be available in the early part of the fourth quarter of 2023. Once available, your local Dräger Service representative will contact you to arrange a date for the update to be carried out free of charge.

Once your Carina ventilator has been updated, you can again use it as before. The modification will not change the overall function of the Carina ventilator.

Please ensure that all users and maintenance staff of the above-mentioned products within your organization are made aware of this Urgent Medical Device Recall Notice. Please complete and return the attached Medical Device Recall Return Response Acknowledgment and Receipt Form to confirm this. Please also notify us if you have already taken your device out of service. If you have made the products available to third parties, please forward this information to them.

Please keep this information until the modification has been completed.

We apologize in advance for any inconvenience caused by this measure. We consider this a necessary measure to increase patient safety. We thank you for your support.

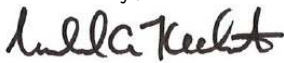
If you have any questions regarding the operation of your Carina Ventilator, please contact Dräger Service Technical Support between the hours of 8:00 AM – 8:00 PM EST at 1-800-437-2437 (press 2 at the prompt, then 2, then 2 again).

If you have any questions regarding this Urgent Medical Device Recall notice, please contact Michael Kelhart between the hours of 8:00 AM – 4:30 PM EST at 267-664-1131 or via email at [mike.kelhart@draeger.com](mailto:mike.kelhart@draeger.com).

Adverse events or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm) or by phone at 1-800-FDA-1088.

The US Food and Drug Administration has been advised of this action.

Sincerely,



Michael A. Kelhart  
Director, Quality  
Draeger, Inc.

Attachment – Medical Device Recall Return Response Acknowledgment and Receipt Form