

To our customers of the
Sub-Acute Care Ventilator
Carina

June 2023

Important Safety Notice

Possible contamination of the breathing gas

All Carina ventilators with the part number 5704110 could be affected

Dear Madam/Sir,

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 of devices 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 show that the 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.

In literature this substance is considered to be acutely toxic and potentially 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

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proven in human studies so far. Our risk assessment reveals only a slight risk of additional cancer cases by comparison with the general cancer risk.

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

Necessary action:

You can 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.

You will then be contacted by one of our Dräger Service staff or your service partner to arrange a date for the update to be carried out free of charge.

Once your Carina ventilator has been modified, 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 Important Safety Notice. Please complete and return the attached reply card 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.

The responsible authorities have been notified of this action.

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.

Contact:

If you have any questions, please do not hesitate to contact your local Dräger representative.

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.

With kind regards

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



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