

Drägerwerk AG & Co. KGaA, 23542 Lübeck, Germany

To our customers of
Vapor 2000 and Vapor 3000

November 2025

Important Safety Notice

Possible impurities from production process in Vaporizer

Only the following products are affected:

Vapor 2000 and Vapor 3000 (*part number M35054 and M36500*) as listed in the attachment, all other devices are not affected

Dear Sir or Madam,

During the course of our production controls, Dräger detected a certain component of the Vapor 2000 and Vapor 3000 was not delivered by the relevant supplier in accordance with the specification. Impurities – resulting from the production process at the supplier site – were found inside a certain production lot of the Vaporizers. There are no reports from customers regarding the detected deviation (impurities) or information on any adverse impact on the health of the patients.

To reach a patient, the impurities need to move with the gas flow into the anesthesia device the Vaporizer is attached to. Before those impurities can be ingested or inhaled by the patient they would need to pass the patient system of the anesthesia device and the patient hose system. According to common clinical practice and Instructions for Use of anesthesia devices inspiratory filters are used to protect patients from particles.

As the Vaporizers in question were only recently shipped/distributed, it is likely they have not yet been placed into clinical use.

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Bank details:
Commerzbank AG, Lübeck
IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230

Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner:
Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL
UID-Nr. DE135082211

Chairman of the Supervisory Board
for Drägerwerk AG & Co. KGaA
and Drägerwerk Verwaltungs AG:
Stefan Lauer

Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

Actions to be taken:

DO NOT to use the affected Vaporizers. Please complete and return the attached reply card to confirm this. You will be contacted by your local Draeger representative to arrange for the replacement of your Vaporizer.

If you have already placed the vaporizer into clinical use, we ask you to clean the patient part of the anaesthesia device(s) according to the Instructions for use. The use of inspiratory filters is recommended.

Please ensure that all users of the above-mentioned products and other persons within your organization are made aware of this Important Safety Notice. If you have provided the products to third parties, please forward a copy of this information.

Please keep this information at least until the measure 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 Vapor 2000 or Vapor 3000 manufactured by Drägerwerk AG & Co. KGaA that may be affected by this issue and listed in the attachment.

Contact:

If you have any questions, please do not hesitate to contact your local Dräger representative. We apologize for any inconvenience caused by this measure.

We thank you for your support.

With kind regards

Sonja Hillmer
Director Post Market Surveillance
Quality & Regulatory Affairs
Medical Division

Stephan Scheuch
Product Management
Business Unit Therapy
Medical Division

European Single Registration Number: DE-MF-000005329

Attachment:

List of affected medical devices including their UDI
Reply card

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Vapor 3000	(01)04048675301363(11)250911(21)AS UK-0534(93)M36500-30
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Vapor 2000	(01)04048675228059(11)251020(21)AS UK-1540(93)M35054-45

Attachment 2: Reply Card

Reply Card

Please fax or e-mail this form to your Dräger representative!

D R Ä G E R	To:	< To be completed by relevant subsidiaries/dealers >	
	Department:		
	Dräger Representative		
	Fax:		
	Phone:		
	E-mail:		
Re: Important Safety Notice Possible impurities from production process in Vaporizer			
C U S T O M E R D A T A	(Please complete)		
	Hospital:		
	Customer name:		
	Phone:		Fax:
	E-mail:		
	Address:		
	Address 2:		
	Town/city:		Country:
☐ We acknowledge receipt of the Safety Notice and that the information contained therein has been brought to the attention of all affected users. We will not use the vaporizer.			
(Please complete and sign)			
Title/position: _____ Name: _____ (Please print in capitals) Signature: _____ Date: _____			