

Drägerwerk AG & Co. KGaA, 23542 Lübeck

**To the Customers of the
Dräger VentStar Helix heated (N) Plus
VentStar Helix dual b (N) Plus
VentStar Aquapor dual b (N) Plus**

July 2025

Important safety notice!!!

Possible Detachment of Plug Connection/ Contamination of Plug Connection

List of Affected Products/ Lot Numbers

Part no.	Designation	UDI-DI	Affected Lot Numbers
MP02608	VentStar Helix heated (N) Plus	04048675411758	173887, 173787, 173547, 173335 173334
MP02650	VentStar Helix dual b (N) Plus	04048675396109	173964, 173696, 173182
MP07150	VentStar Aquapor dual b (N) Plus	04048675557999	173786, 173633, 173628, 173785, 173436, 173413, 173431

Dear Sir or Madam,

We have become aware that a limited batch of our neonatal heated VentStar Plus breathing circuits (MP02608, MP02650; MP07150) has not been manufactured properly. Instead of Isopropanol food plant lubricant was applied to the surface of a plug connection during the assembly process. The failure reduces the strength of the connection. It can further not be excluded that the lubricant contaminated the breathing circuit. We have not received any reports from customers by now.

Potential Health Impact

If the circuit detaches during use, the patient will no longer be ventilated. Ventilators according to ISO 80601-2-12 will generate visual and audible alarms according to the set alarm limits. However, desaturation and serious health impact cannot be excluded. If the Food Plant lubricant contaminated the breathing hose it might enter the patient's airways. According to the Safety Data Sheet of the manufacturer aspiration may cause pulmonary edema and pneumonitis.

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Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
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General partner:
Drägerwerk Verwaltungs AG
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Chairwoman of the Executive Board of
Drägerwerk AG & Co. KGaA: Maria Dietz

Chairman of the Executive Board of
Drägerwerk Verwaltungs AG: Stefan Lauer

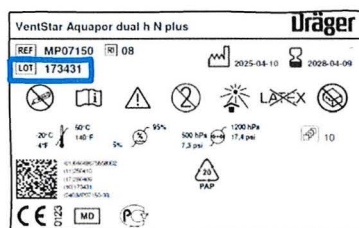
Executive Board:
Stefan Dräger (Chairman)
Stefanie Hirsch
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

Dräger has already stopped distribution of further affected breathing circuits. However, according to our records, you have already received products of the affected batches.

Necessary Action

Identify affected products by means of the [lot number](#) printed on the product label (refer to Picture) and the list of affected products in the header of this letter.

Do not use circuits of the affected batch.



The products can be discarded. You do not need to return them to us.

Please inform all potential users in your facility. If you have forwarded affected products to third parties, please also forward this important safety notice.

We ask that you complete the enclosed Reply Card to confirm you have received this information and that all affected parts have been discarded.

The affected circuits can be replaced free of charge by your Dräger representative.

We apologize in advance for any inconvenience caused by this measure.

The authorities are being informed about this measure in parallel.

Yours faithfully,

J. Sherry

Theresa Strampfer
Head of Product Area Systems
Business Unit Hospital Consumables & Accessories

Chris Röhl

Oliver Möller
Post Market Surveillance
Quality and Regulatory Affairs

Attachment: Reply Card, 1 page

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 for Dräger VentStar Helix heated (N) Plus, VentStar Helix dual b (N) Plus and VentStar Aquapor dual b (N) Plus, July 2025			
C U S T O M E R D A T A	(Please complete)		
	Hospital:		
	Customer name:		
	Phone:		Fax:
	E-mail:		
	Address:		
	Address 2:		
		Country:	
	Town/city:		
	Quantity of affected units:		
<input type="checkbox"/> We acknowledge receipt of the safety notice. The information contained therein has been brought to the attention of all affected users. The affected units have been discarded.			
(Please complete and sign)			
Title/position: _____			
Name: _____ (Please print in capitals)			
Signature: _____ Date: _____			