

Drägerwerk AG & Co. KGaA, 23542 Lübeck

**To the users of
Dräger Catheter Mounts
ErgoStar CM 40, ErgoStar CM 45,
ErgoStar CM 55, ErgoStar CM 60**

October 2025

Important Safety Notice

Possible leaks due to cracks in the attached list of affected products

Dear Sir or Madam,

As part of our global market monitoring, we have become aware of cases in which cracks have formed in the hose of some specific *ErgoStar* catheter mounts. In no case we were informed of any negative effects on the health of the affected patients. However, this cannot be completely ruled out if this happens again.

In case such cracks form during use, leakage will occur. Depending on the size of the leakage and the selected ventilation pressure, the ventilator / anaesthesia device can compensate for this. If the leakage cannot be compensated for, ventilation is restricted, and the patient may experience desaturation/hypoxia. Ventilators according to ISO 80601-2-12 and anaesthesia devices according to ISO 80601-2-13 will generate visual and audible alarms according to the set alarm limits.

Our analyses are still ongoing. At this time, we cannot rule out, that the listed *ErgoStar* will exhibit cracks during use.

Identify affected products based on the list of affected products in the attachment.

Any unused *ErgoStar* in your stock shall not be used.

All components in the affected *Set2Go* and *Pack2Go* except for the *ErgoStar* may be used properly.

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

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Lübeck, Germany
Postal address:
23542 Lübeck, Germany
Tel +49 451 882-0
Fax +49 451 882-2080
info@draeger.com
www.draeger.com

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

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

Registered office: Lübeck
Commercial register:
District Court of Lübeck HRB 7903 HL
General partner:
Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
District Court of Lübeck HRB 7395 HL
VAT no. DE135082211

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

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

Dräger recommends the alternative product MP01850 ErgoStar CM 50 as a suitable replacement.

This product is not affected by the current issue and can replace your stock free of charge through your Dräger representative. Please note that it is not the identical item, but a comparable alternative from our portfolio. Please contact your local Sales and Service representative for further information.

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

The authorities are being informed about this measure in parallel.

Yours faithfully,



Sebastian Henning
Product Management
Business Unit Hospital Consumables & Accessories



Oliver Möller
Post Market Surveillance
Quality and Regulatory Affairs

Attachments

- 1: List of affected products
- 2: Reply Card

Attachment I: List of affected products

Part no.	UDI	Material Description
MP01840	04048675420736	ErgoStar CM 40
MP01845	04048675420729	ErgoStar CM 45
MP01855	04048675420705	ErgoStar CM 55
MP01860	04048675420699	ErgoStar CM 60
MP07209	04048675666844	Set2go Ventilation 77 (A)
MP07214	04048675674061	Set2go Ventilation 79 (A)
MP07218	04048675677123	Set2go Ventilation 82 (A)
MP07224	04048675692638	Set2go Ventilation 84 (A)
MP07225	04048675694205	Set2go Ventilation 85 (A)
MP07232	04048675716426	Set2go Ventilation 85 (A)
MP07234	04048675723981	Set2go Ventilation 91 (A)
MP07238	04048675744115	Set2Go Ventilation 95(A)
MP07248	04048675770688	Set2go Ventilation 100 (A)
MP07249	04048675770800	Set2Go Ventilation 101 (A)
MP07251	04048675792888	Set2go Ventilation 105 (A)
MP07252	04048675800422	Set2Go Ventilation 108 (A)
MP07263	04048675800446	Set2Go Ventilation 109 (A)
MP07267	04048675803119	Set2Go Ventilation 111 (A)
MP07268	04048675803133	Set2Go Ventilation 112 (A)
MP07272	04048675813989	Set2go Ventilation 113 (A)
MP07273	04048675813927	Set2go Ventilation 114 (A)
MP07905	04048675633068	Set2Go Ventilation 72 (A)
MP07907	04048675607205	Set2Go Ventilation 70(A)
MP07912	04048675595632	Set2Go Ventilation 66 (A)
MP07917	04048675569879	Set2go Ventilation 62 (A)
MP07921	04048675652960	Set2Go Ventilation 56(A)
MP07922	04048675635611	Set2Go Ventilation 53 (A)
MP07924	04048675633709	Set2Go Ventilation 76 (A)
MP07926	04048675569084	Set2go Ventilation 54 (A)
MP07927	04048675569305	Set2go Ventilation 55 (A)
MP07935	04048675570059	Set2go Ventilation 52 (A)
MP07938	04048675559436	Set2Go Ventilation 26 (A)
MP07949	04048675547440	Set2Go Ventilation 21 (A)
MP07950	04048675420033	Set2Go Ventilation 1 (A)
MP07951	04048675437123	Set2Go Ventilation 2 (A)
MP07952	04048675443650	Set2Go Ventilation 3 (A)
MP07954	04048675446811	Set2Go Ventilation 5 (A)
MP07972	04048675544364	Set2Go Ventilation 14(A)
MP07977	04048675546238	Set2Go Ventilation 16 (A)
MP07992	04048675555162	Set2Go Ventilation 31(A)
MP07993	04048675557319	Set2Go Ventilation 32 (A)
MP07994	04048675557333	Set2Go Ventilation 33 (A)
MP07995	04048675558101	Set2Go Ventilation 34 (A)
MP12060	04048675713685	CombiStar Plus Filter + HME straight

MP20370	04048675714521	Pack2Go Evita invasive Vpack CO2 Cuvette
MP20371	04048675714545	Pack2Go Evita invasive Vpack
MP20375	04048675714620	Pack2Go invasive Vpack Coax
MP20376	04048675714644	Pack2Go invasive Vpack Basic
MP20377	04048675714668	Pack2Go Evita inv. Vpack Coax/CO2 Cuv.
MP20378	04048675714682	Pack2Go Evita invasive Vpack Coax

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 on Dräger Catheter Mounts ErgoStar CM 40, ErgoStar CM 45, ErgoStar CM 55, ErgoStar CM 60 – Possible leaks due to cracks			
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:
	Quantity of affected units:		
	☐ We acknowledge receipt of the Safety Notice and that the information contained therein has been brought to the attention of all affected users.		
☐ We would like to order MP01850 as replacement in the quantity of affected units claimed above.			
(Please complete and sign)			
Title/position:			
Name: (Please print in capitals)			
Signature: Date:			