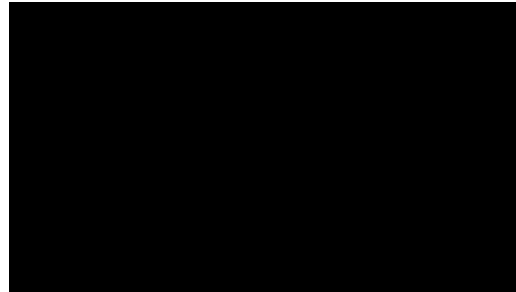


Drägerwerk AG & Co. KGaA, 23542 Lübeck

Addressee (company)
Department
Max Sample
Sample Street 100
City, zip code
Country



Subject heading

January 16, 2019

Dear _____,

we have recently provided you with a Safety Notice for our disposable breathing circuits/-sets. Unfortunately a little but relevant error occurred on the attached list of potentially affected material numbers: A part number which is potentially affected (MP00371) was missing, instead MP001347 was listed, which is not affected.

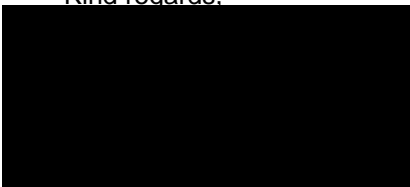
Hence we corrected the list (page 3/5) and herewith provide you with the corrected version.

If you have any sets of MP00371 in your inventory please proceed as described and confirm the result with the customer reply and order form.

We apologize for the inconvenience this will cause but it is essential that all potentially affected material is checked.

Thank you for your cooperation.

Kind regards,



Attachment

Safety Notice, 5 pages

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
VAT no. DE135082211

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

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

Drägerwerk AG & Co. KGaA, 23542 Lübeck

To our customers of disposable breathing circuits/-sets

December 2018

Important Safety Notice!!!

Possible hose short circuit

Only disposable breathing circuits on the attached list are affected

Coaxial hose systems are not affected!

Dear Sir/Madam,

During the course of our global post market surveillance activities, two cases have been reported to us in which the incorrect connection of the breathing circuit resulted in the patients concerned not being connected to the anesthesia machine. The connections of the anesthesia machine and of the y-piece were short-circuited. Consequently, the patients did not receive the expected ventilation. In one of the two cases the patient in question suffered irreversible harm. In the other case the patient experienced a temporary and reversible deterioration in condition.

The correct set-up of the breathing circuit is illustrated in the Instructions for Use not only of the hose systems but also of the anesthesia machines and ventilators. Connection to the device must be checked prior to use. It is easy to detect if a breathing circuit has not been pre-assembled correctly because it will not be a single cohesive hose system but two separate sub-systems.

If a short-circuited breathing circuit is not detected during the essential and compulsory pre-use check, it will not be possible to ventilate the patient. This can result in a deterioration to the patient's health and condition. Depending on the type of patient monitoring, this will be detected when the inspiratory O2 concentration falls or the oxygen saturation level declines, and a corresponding alarm will be given.

The precise cause of the aforementioned cases has not yet been conclusively determined. It cannot be completely ruled out that incorrectly pre-assembled breathing circuits were shipped despite intensive quality controls. Furthermore, breathing circuits are specially designed to allow the user to change the hose configuration so that the water trap is in the optimal position. In other words, the error can also occur if the breathing circuit was correctly pre-assembled.

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Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

Before each use, and also after any temporary disconnection, please make sure to check whether the breathing circuit is assembled such that both the inspiratory and the expiratory connector of the ventilator or anesthesia machine are each connected to the y-piece.

According to our records, it is possible that breathing circuits that may be affected, i.e. that may have been incorrectly pre-assembled, were shipped to you during the past two years. We attach a list of material numbers that may be affected. The material numbers of the breathing circuits can be found on the respective packaging (see photo).

Please inform all potential users in your facility and check your existing stocks by following the check instructions in the attachment and use the attached form "Customer feedback and order" to confirm to us that you have carried out the checks. The form can also be used to order a free replacement if you find any breathing circuit that have been incorrectly pre-assembled.

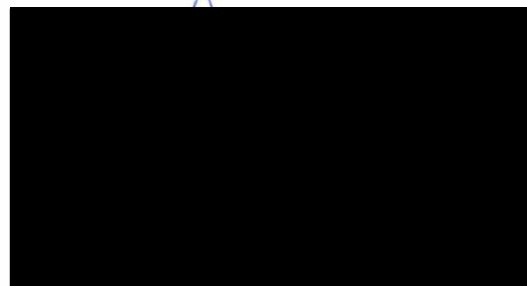
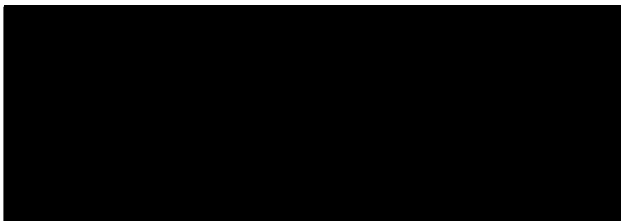
Please send the form in any case, even if you haven't identified any incorrectly pre-assembled breathing circuits.

We are currently working to further improve the manufacturing/assembly process, and all breathing circuits that are currently being shipped have been subjected to additional checks.

We apologize for any inconvenience caused by this measure.

The authorities have been notified of this action.

With kind regards



Attached:

- Material number list
- Check instructions
- Form "Customer feedback and order"

Potentially affected material numbers:

Breathing Circuits/Anesthesia Sets

MP00334	Breathing circuit adult (1,8m)
MP00337	Breathing circuit adult (1,8m)
MP00349	Breathing circuit adult (1,8m)
MP00350	Breathing circuit adult (2,5m)
MP00351	Breathing circuit pediatric (1,8m)
MP00352	Breathing circuit pediatric (2,5m)
MP00361	Breathing circuit pediatric (1,8m)
MP00362	Breathing circuit pediatric (1,8m)
MP00365	Anesthesia set adult (1,8m/1,5m)
MP00366	Anesthesia set adult (2,5m/1,5m)
MP00371	EN - Anesthesia set adult (1,8m/1,5m)
MP00372	Anesthesia set adult (1,8m/1,5m)
MP00374	Anesthesia set pediatric (1,8m/1,1m)
MP00375	Anesthesia set pediatric (1,8m/1,1m)
MP01326	Breathing circuit adult (1,8m)
MP01340	Breathing circuit pediatric (1,8m)
MP01341	Breathing circuit pediatric (1,8m)
MP01348	Breathing circuit adult (2,5m)
MP01350	Breathing circuit adult (1,8m)
MP02720	Anesthesia set adult (2,8m/1,5m)
MP02721	Anesthesia set adult (2,8m/1,5m)



position of material number

Pack2Go

MP01656	Evita VPack inv w CO2 Cuvette
MP01657	Evita VPack invasive
MP01674	Savina invasive VentPack Basic
MP01682	APack Watertrap Adult

Set2go

MP07955	Set2Go Anesthesia 1 (A)
MP07956	Set2Go Anesthesia 2 (A)
MP07981	Set2Go Ventilation 27 (A)
MP07988	Set2Go Anesthesia 15(A)
MP07989	Set2Go Ventilation 29 (A)
MP07991	Set2Go Ventilation 30(A)
MP07992	Set2Go Ventilation 31(A)
MP07994	Set2Go Ventilation 33 (A)

MP07933	Set2Go Ventilation 46 (A)
MP07938	Set2Go Ventilation 26 (A)
MP07996	Set2Go Ventilation 35 (A)
MP07997	Set2Go Ventilation 36 (A)
MP07937	Set2Go Ventilation 44 (A)
MP07936	Set2Go Ventilation 45 (A)

Check instructions

Images showing correct “open ends” and incorrect “open ends” (test instructions):

Part Numbers: MP00337, MP00372, MP02720, MP02721, MP00334, MP00361, MP00362, MP00371, MP00374, MP00375, MP01682.

ok



not ok



Part Numbers: MP00349, MP00350, MP00351, MP00352, MP01326, MP01340, MP01341, MP01348, MP01350, MP00365, MP00366, MP01656, MP01657, MP01674, MP07933, MP07936, MP07937, MP07938, MP07955, MP07956, MP07981, MP07988, MP07989, MP07991, MP07992, MP07994, MP07996, MP07997.

ok



not ok



Customer feedback and order

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

D R Ä G E R	To:	< To be completed by subsidiaries / distributors >	
	Department:		
	Dräger representative		
	Telephone:		Fax:
	E-mail:		

Answer:	Possible hose short circuit
---------	------------------------------------

C U S T O M E R D A T A	(Please complete)		
	Healthcare facility:		
	Contact person:		
	Telephone:		Fax:
	E-mail:		
	Address:		
	Address 2:		
	City:		Country:

(Please complete)	
We hereby confirm receipt of the Dräger safety notice sent in December 2018 regarding the breathing circuits. Our staff has been informed.	
<input type="checkbox"/> We have not identified any incorrectly pre-assembled breathing circuits.	
<input type="checkbox"/> We have identified ___ pcs. of material number _____ as incorrectly pre-assembled breathing circuits. Please send us replacement free of charge.	

(Please complete and sign)	
Title/position:	
Name:	(Please use capital letters)
Signature:	Date: