To our customers of

Fabius MRI

December 2021

Important Safety Notice

Potentially fluctuating O2 flow.

Only the following products are affected:

Fabius MRI, only devices with the following serial numbers are affected:

ASPH-0015	ASPE-0008	ASPJ-0021	ASPH-0003	ASPF-0023	ASPH-0001	ASPJ-0022
ASPH-0010	ASPF-0001	ASPK-0002	ASPH-0004	ASPF-0024	ASPF-0002	ASPH-0016
ASPJ-0023	ASPJ-0019	ASPK-0001	ASPH-0009	ASPF-0025	ASPF-0003	
ASPJ-0024	ASPJ-0020	ASPF-0005	ASPJ-0011	ASPH-0002	ASPF-0004	

Dear Sir or Madam,

With this letter we want to inform you about Fabius MRI anesthesia machines that might have a different behavior of the oxygen supply as you expect. A limited number of devices has been shipped with a failure within the internal O2 line system.

If the O2 central supply pressure is not stable, the O2 fresh gas flow might deviate from the adjusted value. The flow tubes/flowmeter will still display the O2 flow properly at any time. However, insufficient oxygenation of the patient cannot be excluded.

In case you are using nitrous oxide the integrated sensitive oxygen ratio controller (S-ORC) ensures that the delivered fresh gas contains at least 25% oxygen at any time.

Your local Dräger representative will contact you to schedule repair of your affected devices.

Actions to be taken:

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:
District Court of Lübeck HRB 7395 HL

Chairman of the Executive Board of
Drägerwerk AG & Co. KGaA and
Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske

Until the repair has been concluded you may continue using the device under constant supervision as long as appropriate O2-monitoring is in place and a suitable alarm limit is set. Please consider a suitable buffer when adjusting the O2 flow.

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 available to all users at least until the repair 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 Fabius MRI devices manufactured by Drägerwerk AG & Co. KGaA that is affected by this issue. In order to identify the serial number of your device/s, you may check the type plate.

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

Oliver Möller

Post Market Surveillance
Quality & Regulatory Affairs
Medical Division