Dräger

Drägerwerk AG & Co. KGaA, 23542 Lübeck

To the
Regional Managers,
Country Managers,
and
Regional Quality Managers (for forwarding to dealers)

May 15, 2018

Urgent, please deal with immediately!

Field Safety Corrective Action: Important Safety Notice!
Dräger Fabius, Apollo & Perseus devices with S-ORC:
- **Distribution of an important Safety Notice until 31/05/2018**
- **Replacement of S-ORC 31/03/2019**

Please inform your sales and service staff immediately!

Dear Madam or Sir,

Unfortunately, we have to inform you about a Field Safety Corrective Action concerning the Fabius Family.
In the course of conducting production quality checks, we became aware of a device where it was possible to dose 100% N_2O. To date, we are not aware of any reports of this occurring in devices currently in distribution.The above-mentioned anesthesia machines are equipped with a mechanical O_2 minimum dosage module (S-ORC). This safety feature prevents the user from inadvertently setting hypoxic gas mixtures (with less than 21% oxygen) at the fresh gas mixer when N_2O is selected as one of the carrier gases. Our investigation determined that the root cause was a burr not being removed from an internal component of the S-ORC during the production process. The production process has already been corrected. Nevertheless, we cannot completely rule out that the devices listed in the attached serial number list are equipped with an S-ORC module which also has a burr which, in the worst case can impair the mechanics of the module.

Due to the possible risk of person injury, we need to inform all affected customers about the identified risk with the attached Safety Notice.

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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

Measure 1:
Please identify the customers in your sales and service organisation by means of the distribution list, send out the attached important Safety Notice to them and confirm completion of this measure until 31/05/2018.
Please keep records in your facility to demonstrate that you carried out the notification process. Registered letter with reply card is recommended for this action.

Measure 2:
Replace S-ORCs for all customers as described in the attached Technical Service Bulletin (TSB) until 31/03/2019.

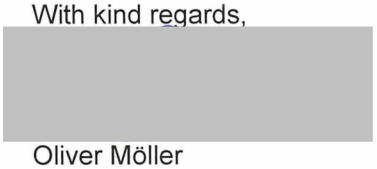
If you have any questions, please contact Mr Peter Kuepper, via his Email address peter.kuepper@draeger.com, or by phone +49 451 882 - 3980.

We regret any inconvenience this action will cause for your organisation, but it is necessary due to product liability reasons and must be executed on short notice. We are aware of the effects that this will have on ongoing business activities but kindly ask you to co-operate and help us ensure that the action is taken as quickly as possible.

The Competent Authorities of the effected countries are informed about this action.

Thank you very much for your understanding and cooperation.

With kind regards,



Oliver Möller
Deputy Safety Officer for Medical Devices
Post Market Surveillance
Drägerwerk AG & CoKGaA

Attachments:

- Country List
- Important Safety Notice
- Technical Service Bulletin