

**To the customers and users of the
Fabius MRI anaesthesia systems**

June 2015

Important safety information!!!

Labelling of Fabius MRI anaesthesia systems

Affected products: Fabius MRI

Dear Madam/Sir,

As part of our global product monitoring, Dräger has become aware of cases in which the Fabius MRI or parts of the system were attracted by the magnetic field of the MRI.

If the Fabius MRI is positioned too close to the MRI, the magnetic force of the MRI can loosen parts of the Fabius MRI and cause personal injury.

To avoid this, our instructions for use and the device labelling clearly state that the device must only be used in areas where the field intensity is no more than 40 mTesla. The cases that were reported to us were caused because the device was moved through the 40 mTesla area, while it was not in use.

Please note that the Fabius MRI must not be moved or placed in areas with more than 40 mTesla (400 gauss) even when it is not used on patients.

We amended our instructions for use by the attached supplement, which contains corresponding notes and warnings.

Please add the supplement to all instructions for use of the Fabius MRI and inform any possible users in your hospital about it.

As an addition to the corrective measure described above, we decided to further improve the Fabius MRI by supplying the ventilator door with another lock in addition to the existing locking mechanism.

As soon as the lock is available, your responsible Dräger representative will contact you and arrange an appointment for a retrofitting, free of charge.

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We regret any inconvenience this information may cause but consider it necessary as a preventive measure to increase patient and user safety.

Please inform all affected users in your hospital.

We thank you for your support.

With best regards,

A handwritten signature in black ink, appearing to read 'H. Schüler', with a long horizontal line extending to the right.

Hans Ulrich Schüler
Vice President Anesthesiology
Product Management & Application Marketing