Dräger medical
A Dräger and Siemens Company

Dräger Medical AG & Co. KG, Moislinger Allee 53-55, D-23558 Lübeck

June 2007

To customers

in possession of Dräger anaesthesia machines

equipped with additional patient monitors

Important safety information!

Device combination "anaesthesia machine with additional patient monitor" not sufficiently stable and liable to tip over if incorrect or non-approved modification kits are used.

Dear Sir or Madam,

During the course of our product monitoring activities an incident has come to our attention in which the castor of a Cato anaesthesia machine broke when the machine was being moved. The machine tipped over, but did not cause injury to patient or hospital personnel.
Following an investigation of the incident, it was found that the machine had been retrofitted with an additional patient monitoring system but that the necessary modification kit had not been used. Dräger Medical had not approved this combination of devices!

Before approving device combinations, Dräger Medical always carries out extensive compatibility tests and safety investigations. To ensure that such device combinations are sufficiently stable and are not liable to tip over, e.g. during transport within the hospital, the trolley requires modification in some cases. For this purpose, the device-specific modification kits contain not only mechanical elements to connect the device and patient monitor, but also trolley components (e.g. castors, weighting elements etc.).

Our market observation has also revealed that Dräger anaesthesia machines are sometimes retrofitted with additional monitoring equipment, either by external service providers or indeed by the hospitals themselves, without taking care to ensure that the device combination is sufficiently stable and is not liable to tip over (i.e. insufficiently stabilized trolley).

In view of these findings, Dräger Medical would like to remind operators that Dräger anaesthesia machines may only be upgraded or retrofitted with additional patient monitoring systems if the approved modification kits are used. The manufacturer is responsible for ensuring the reliability and safety of the device combination, and also has liability in this connection. In such cases, the manufacturer is the company contracted to perform the upgrade or retrofit, or the hospital if this is performed in-house.

If you have upgraded or retrofitted Dräger anaesthesia machines yourself or have arranged for this to be done by external service providers, we recommend checking the reliability and safety of such device combinations. Your usual contact at Dräger Medical Sales&Service will be happy to assist you in this matter, and can help you verify whether your device combination has been approved by Dräger or whether a modification kit is available for this particular combination.

We believe this action is a necessary preventive measure to increase the safety of patients and operators.

With kind regards
Dräger Medical AG & Co. KG
Head of Business Unit Perioperative Care

[redacted]

Dräger Medical AG & Co. KG
Moislinger Allee 53-55
D - 23558 Lübeck
Postanschrift: 23542 Lübeck
Telefon +49-18 05-3 72 34 37
Telefax +49-4 51-8 82-37 79
E-mail: business-support@draeger.com
www.draeger.com
UID-Nr.: DE812119413
Steuernummer 22 283 42757

Commerzbank AG, Lübeck
Konto-Nr. 0146795 00
BLZ 230 400 22
IBAN: DE95 2304 0022 0014 8795 00
SWIFT-Code: COBA DE FF 230
Dresdner Bank AG, Lübeck
Konto-Nr. 371 077 400
BLZ 230 800 40
IBAN: DE28 2308 0040 0371 0774 00
SWIFT-code: DRES DE FF 230

Sparkasse zu Lübeck
Konto-Nr. 107 111 7
BLZ 230 501 01
IBAN: DE15 2305 0101 0001 0711 17
SWIFT-Code: HSHN DE H1 SPL

Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRA 4435 HL

Komplementär:
Dräger Medical Verwaltungs AG
Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRB 5035
Vorsitzender des Aufsichtsrates:
Dipl.-Kfm. Theo Dräger
Vorstand:
Dipl.-Ing. (BA) Stefan Dräger (Vors.)
Dipl.-Kfm. Roland Jaksch