To Customers using
Dräger Devapor

February 2014

Important Safety Information!!!

Dräger Devapor model sold until end of 2005:
The Low Pressure Leak Test may not detect the full range of potential internal leaks!
A reduction in the fresh gas volume delivered may be the consequence!

Dear Sir or Madam,

This safety note is applicable to the Dräger **Devapor** vaporizer (see picture below left side), sold until end of 2005. The successor product Dräger D-Vapor is not affected.

Potentially affected Devapor

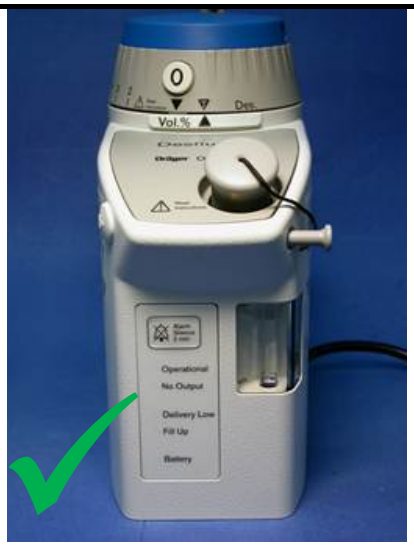
M32600
Devapor, German Variant

M32938
Devapor, English Variant

M32939
Devapor, French Variant

M33385
Devapor, Italian Variant

M33386
Devapor, Spanish Variant



Not affected D-Vapor

Dräger has recently been informed by GE Healthcare as the original equipment manufacturer of the Devapor (distributed between 1996 and 2005) that a specific lot of seals was used by GE for remanufacture, factory overhaul and maintenance of Devapor vaporizers period between August 12th, 2005 and December 3rd, 2012, in which seals may not have the required durability.

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Bank number 230 501 01
IBAN DE15 2305 0101 0001 0711 17
SWIFT code NOLADE21SPL

Company headquarters: Lübeck
Commercial register:
Municipal Court Lübeck HRB 4358 HL

Chairman of the Executive Board:
Professor Dr. Nikolaus Schweickart

General managers:
Stefan Dräger (Chairman)
Dr. Herbert Fehrecke
Andreas Frahm
Gert-Hartwig Lescow
Anton Schrofner

A malfunction of the seal may result in a fresh gas leak. If such leak is not detected it can result in a release of fresh gas to the ambient air and consequently in a reduction of fresh gas volume delivered to the breathing system. The reduction in fresh gas flows can impact the flow of oxygen delivered to the patient, potentially resulting in deviations in oxygen gas concentration and light anaesthesia. The required gas monitoring of the anaesthesia device will detect and indicate concentration deviations. In addition, the clinician(s) may become exposed to released nitrous oxide.

The pre-operative check described in the Instructions for Use of the anaesthesia workstation includes a low pressure leak test which, in its current scope, may not detect the full range of leaks which may be caused by seal wear degradation in the vaporizers. If the pre-operative low-pressure leak test is performed at a dial position of 12 Vol%, the integrity of the internal seal can be clearly determined.

We have determined that potentially affected Devapor devices may be operated at your facility. If you are still using any Devapor devices, Dräger Medical highly recommends you to

- Perform the pre-operative check which includes the low-pressure leak test as described in the Instructions for Use of your anaesthesia workstation at 0 Vol% as well as at 12 Vol% dial position with every of your Devapor units.

- If the leak test fails, please repeat the test without Devapor to make sure that the vaporizer is the root cause of the leak.

- **Discontinue the use of each Devapor you clearly can assign a leak to** and quarantine it;

- To arrange the necessary actions for the affected Devapor vaporizer(s) we ask you to contact Marc-Oliver.Froeske@draeger.com or Bennet.Plaehn@draeger.com

  and report the actual disposition status and the part number and both serial numbers of each unit. We will supply you with an address-labeled shipping container and ask you for sending the device(s) to the named repair center of GE Healthcare.

- Continue to routinely perform the low pressure leak test within the scope of the pre-operative check with all your Devapor vaporizers - despite they may have passed the initial test or have been reworked under this Corrective Action already. All Devapors can be used without restrictions as long as no deviation is observed during the tests.

We recommend you to add this amendment of the test procedure to the Instructions for Use of every anaesthesia device you have in use or to update internal test instructions you may have developed.

By initiating this corrective action Dräger Medical follows the recommendation from the original equipment manufacturer GE Healthcare. You may have received already a similar notice in regard to the functionally-equivalent vaporizers GE Healthcare Tec 6 / Tec 6 plus.

In respect of the age of the potentially affected devices the repair is done by GE Healthcare **free of charge for units returned until June 30th, 2014**. The product will be set to general status “END OF LIFE” after December 31st, 2014 which means that no service or repair support will be possible anymore.

We regret any inconveniences this may cause; please let us know if you need any further assistance or additional information.

With best regards,

Dräger Medical GmbH

[redacted]
Vice President
Anesthesiology Application
Product and Application Management

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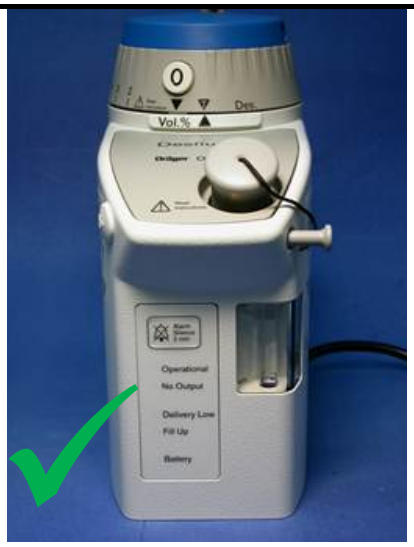

Not affected D-Vapor

Dräger has recently been informed by GE Healthcare as the original equipment manufacturer of the Devapor (distributed between 1996 and 2005) that a specific lot of seals was used during the manufacturing process of Devapor vaporizers produced after August 12th, 2005, in which seals may not have the required durability.

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We have determined that potentially affected Devapor devices may be operated at your facility. The respective devices are listed below, to be identified by the Serial Number. The S/N is located on the back side of the device as shown in the image.

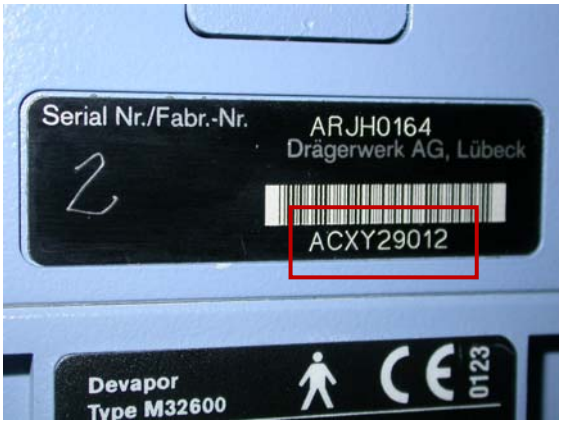
AEXE05006
AEXE10024
AEXE21055
AEXE39059
AEXE43043
AEXE49002
AEXE49003

AEXG02028
AEXG11012
AEXG15008
AEXG19004
AEXG24008
AEXG24022
AEXG24036

AEXF04014
AEXF09005
AEXF12007
AEXF17013
AEXF17058

AEXH08011

AEXK28002



If you are still using one or more of these devices, please **discontinue the further operation**. To arrange the necessary actions for the affected Devapor vaporizer(s) we ask you to contact

Marc-Oliver.Froeske@draeger.com or Bennet.Plaehn@draeger.com

and report the actual disposition status and the part number and both serial numbers of each unit. We will supply you with an address-labeled shipping container and ask you for sending the device(s) to the named repair center of GE Healthcare.

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With best regards,

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