Supplement

Vaporizer series

WARNING

To properly use this medical device, read and comply with the instructions for use and this supplement.

Supplement to the instructions for use

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To properly use this medical device, read and comply with the instructions for use and this supplement.

Instructions for use	Part number	Edition
D-Vapor/D-Vapor 3000	9037890	15 – 2020-02 and later
Dräger Vapor 2000/3000	DB01189	20 – 2017-09 and later

- Keep this supplement with the instructions for use.

This supplement updates the information of the instructions for use in the following chapters.

Information about this document

Trademarks

Trademarks owned by Dräger

Trademark
D-Vapor®
Dräger-Vapor®
Dräger Fill™

The following web page provides a list of the countries in which the trademarks are registered: www.draeger.com/trademarks

Trademarks owned by third-party manufacturers

Trademark	Trademark owner
Selectatec®	Datex-Ohmeda
Suprane®	Baxter International Inc.
SAFE-FIL™	
TORRANE™	Safeline Pharmaceuticals
Quik Fil™	Abbott Laboratories

Trademark	Trademark owner
Dismozon®	BODE Chemie
acryl-des®	Schülke & Mayr
Mikrozid®	
Perform®	
Actichlor®	Ecolab USA
Incidin®	
Oxycide®	
BruTab 6S®	Brulin
Dispatch®	Clorox
Klorsept®	Medentech
Descogen®	Antiseptica
Oxygenon®	
SteriMax®	Aseptix
Cleanisept®	Dr. Schumacher

Reprocessing

This chapter replaces the "Cleaning and disinfection" chapter.

Safety information

WARNING

Risk due to inappropriately reprocessed products

Reusable products must be reprocessed, otherwise there is an increased risk of infection.

- **Follow the infection prevention policies and reprocessing regulations of the health-care facility.**
- **Follow the national infection prevention policies and reprocessing regulations.**
- **Use validated procedures for reprocessing.**
- **Reprocess reusable products after every use.**
- **Follow the manufacturer's instructions for cleaning agents, disinfectants, and reprocessing devices.**

CAUTION

Risk due to faulty products

Signs of wear, e.g., cracks, deformation, discoloration, or peeling, may occur with reprocessed products.

Check the products for signs of wear and replace them if necessary.

D-Vapor/D-Vapor 3000

WARNING

Damage to the interior of the vaporizer can cause incorrect output concentration and may harm the patient. If liquids other than the anesthetic agents specified get into the vaporizer, this can cause malfunctions of the vaporizer and harm to the patient.

- **Do not immerse the vaporizer in cleaning agents.**
- **Detergents must not be allowed to get under the control dial.**
- **Do not allow detergents to get into the gas inlets or gas outlets, or the filling system.**
- **Do not sterilize the vaporizer.**
- **Do not use solvents on the vaporizer.**

Dräger Vapor 2000/3000

WARNING

Damage to the interior of the vaporizer can cause incorrect output concentration and may harm the patient. If liquids other than the anesthetic agents specified get into the vaporizer, this can cause malfunctions of the vaporizer and harm to the patient.

- **Do not immerse the vaporizer or the filling adapter in cleaning agents.**
- **Detergents must not be allowed to get under the control dial.**
- **Do not allow detergents to get into the gas inlets or gas outlets, or the filling system.**
- **Do not sterilize the vaporizer or the filling adapter.**
- **Do not use solvents on the vaporizer.**

Information on reprocessing

Follow the national infection prevention policies and reprocessing regulations.

Follow the infection prevention policies and reprocessing regulations of the health-care facility (e.g., concerning the reprocessing cycles).

Classifications for reprocessing

Classification of medical devices

The classification depends on the intended use of the medical device. The risk of infection transmission through the application of the product to the patient without proper reprocessing is the basis of the Spaulding classification.

Classification	**Explanation**
Non-critical	Components that come into contact only with skin that is intact
Semi-critical	Components that carry breathing gas or come into contact with mucous membranes or pathologically altered skin
Critical	Components that penetrate skin or mucous membranes or come into contact with blood

Classification of device-specific components

The following classification is a recommendation from Dräger.

Non-critical

– Control elements and device surfaces

Before reprocessing

Observe the following before reprocessing (D-Vapor, D-Vapor 3000)

1 Switch off the device.

2 Disconnect the power plug.

Validated reprocessing procedures

Overview of the reprocessing procedures of the components

Components	Surface disinfection with cleaning
Device surface	Yes (see "Surface disinfection with cleaning", page 5)

Surface disinfection with cleaning

Surface disinfectant	Manufacturer	Concentration	Contact time
Dismozon plus	BODE Chemie	1.6 %	15 min

Prerequisites:

– The surface disinfectant has been prepared in accordance with the manufacturer's instructions.
– The manufacturer's instructions, e.g., regarding shelf life or application conditions, are observed.
– An uncontaminated, lint-free cloth soaked in surface disinfectant is used for the cleaning surface disinfection.

WARNING

Risk due to penetrating liquid

Penetrating liquid may cause the following:

– Damage to the device
– Electric shock
– Device malfunctions

Ensure that no liquid penetrates the device.

Cleaning

1 Wipe off obvious soiling with a disposable cloth soaked in surface disinfectant. Dispose of the cloth.
2 Wipe all surfaces. After that, there must no longer be any soiling visible.

Surface disinfection

3 Wipe cleaned surfaces again to visibly wet all surfaces to be disinfected with surface disinfectant.
4 Wait for the surface disinfectant contact time.
5 At the end of the contact time, moisten a new, uncontaminated and lint-free cloth with water (at least drinking water quality).
6 Wipe all surfaces until no remains of the surface disinfectant, such as foam residues or streaks, are visible.
7 Wait until the surfaces are dry.
8 Check the surfaces for visible damage and, if necessary, replace the product.

Storage and transport

After reprocessing, there are no special requirements for storage and transport of the product. However, the following must be observed:

– Store dry and free of dust
– Avoid recontamination and damage during transport

All further information on storage and transport included in the accompanying documents must be observed.

Other agents and reprocessing procedures

Disinfectants

Use nationally approved disinfectants suitable for the respective reprocessing process and the intended application.

Surface disinfectants

The manufacturers of the surface disinfectants have verified at least the following spectra of activity:

– Bactericidal
– Yeasticidal
– Virucidal or virucidal against enveloped viruses

Follow the manufacturer's instructions for surface disinfectants.

The following surface disinfectants were compatible with the material at the time of testing:

Class of active ingredient	**Surface disinfectant**	**Manufacturer**	**Listing**
Chlorine-releasing agents	BruTab 6S	Brulin	EPA[1)]
	Clorox Professional Disinfecting Bleach Cleaner	Clorox	EPA
	Dispatch Hospital Cleaner Disinfectant Towels with Bleach		
	Klorsept 17	Medentech	EPA
	Actichlor plus	Ecolab USA	EPA
Oxygen-releasing agents	Descogen Liquid	Antiseptica	CE
	Descogen Liquid r.f.u.		
	Oxygenon Liquid r.f.u.		
	Dismozon plus	BODE Chemie	CE
	Oxycide	Ecolab USA	EPA
	Perform	Schülke & Mayr	CE
	SteriMax Wipes	Aseptix	CE
	Incidin OxyWipes	Ecolab USA	CE

Class of active ingredient	Surface disinfectant	Manufacturer	Listing
Quaternary ammonium compounds	acryl-des[2)]	Schülke & Mayr	CE
	Mikrozid alcohol free liquid[2)]		
	Mikrozid alcohol free wipes[2)]		
	Mikrozid sensitive liquid[2)]		
	Mikrozid sensitive wipes[2)]		
	Cleanisept Wipes Maxi	Dr. Schumacher	CE
	Surfa'Safe Premium	ANIOS Laboratories	CE
	Wip'Anios Excel		
	Tuffie 5	Vernacare	ARTG[3)]

1) United States Environmental Protection Agency
2) Virucidal against enveloped viruses
3) Australian Register of Therapeutic Goods

Dräger states that oxygen-releasing agents and chlorine-releasing agents may cause color change in some materials. Color change does not indicate that the product is not functioning correctly.

Other surface disinfectants are used at one's own risk.

After reprocessing

Preparation before re-use (D-Vapor, D-Vapor 3000)

Checking the operational readiness

Prerequisites:

– The device has been assembled and prepared so that it is ready for operation.

Procedure:

1 Check the operational readiness, see the instructions for use, chapter "Operation".

Manufacturer

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