Operating Instructions

DEMAND VALVE QualityFlow

CE 0482

Keep these instructions!

DEHAS Medical Systems GmbH

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Version 3.1.

Content

*Technical changes reserved!

1 Preface

These operating instructions are intended to provide you with assistance in using the QualityFlow demand valve. The operating instructions are divided into individual chapters.

Please note:

- Read these instructions for use carefully and completely before using the product for the first time.
- Always act in accordance with the instructions given in the operating manual.
- Keep these operating instructions close to the product.

2 Basic Requirement

Intended use:
According to Annex IX of Directive 93/42/EEC concerning medical devices, this product belongs to Class IIb. According to this directive, only medical professionals who have been instructed in the use of the product by an authorized person may use this product. This product is to be used exclusively for human medical purposes.

2.1 Intended use

The demand valve is used for the application of 100 vol% oxygen during manual ventilation with the resuscitator bag, as well as during direct non-invasive ventilation with the resuscitator mask in spontaneously breathing patients.

2.2 Accessoires / Variants

Article No.	GTIN / UDI	Description
D-2522001	4251411701314	Adapter medium, white (24/28 mm)
D-2522002	4251411701321	Adapter large, white (26/32 mm)
D-2522003	4251411701338	Adapter small, white (15/22 mm)
D-2522004	4251411701598	Adapter Laerdal/VBM f. Demand valve 25/32 mm
D-2522005	4251411701574	Adapter Ambu, white (28/32 mm)
D-2522006	4251411702908	Adapter demand valve, white 22-23-30 mm

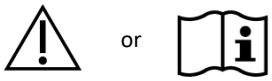
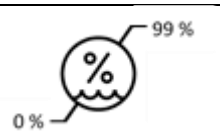
2.3 Applied standards

The product complies with the essential requirements according to Annex I of Directive 93/42/EEC (Medical Device Directive) as well as the applicable national regulations such as the Medical Devices Act (MPDG).

Standard / Norm	Titel
DIN EN ISO 780	Packaging - Shipping packaging - Graphic symbols for handling and storage of packages
DIN EN ISO 15223-1	Medical devices - Symbols, marking and information to be used in the labelling of medical devices - Part 1: General requirements
DIN EN 1041	Provision of information by the manufacturer of medical devices
DIN EN ISO 5359	Anesthesia and respiratory equipment - Low-pressure hose line systems for use with medical gases
DIN EN ISO 14971	Medical devices - Application of risk management to medical devices
DIN EN 62366-1	Medical devices - Part 1: Application of fitness for use to medical devices
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system

3 Safety Information – Warning, caution and labeling information

Symbol	Description
CE 0482	The symbol indicates that the device complies with the requirements of Regulation 93/42/EEC concerning medical devices and all applicable international standards.
WARNINGS	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	When this symbol is used, it indicates a potentially hazardous situation which, if not avoided, may result in property damage.
	Manufacturer
	Date of manufacture
	Store in a dry place / Protect from moisture / wetness

UDI	Unique Device Identification
MD	Medical device
SN	Serial number
REF	Reference number / Article number
NON STERILE	Product non-sterile
	Temperature limit
	Refers to the need for the user to consult the instructions for use.
	Follow the instructions for use
	Do not dispose of in household waste
	Do not use if packaging is damaged
	Moisture limitation during storage
	Latex free product
	Do not use oil

4 Before first of use

Read all instructions before use!

These operating instructions provide qualified personnel with instructions for installation and operation. It serves your safety and protects the product from damage. If you do not understand any information or instruction in this instruction manual, do not use the product and contact your supplier.

4.1 Safety Information

WARNINGS

- **Intended use / user**
- The demand valve may only be operated by medical professionals under the direct supervision of a licensed physician.
- As with all medical products, this demand valve could cause injury to the patient if used without precise knowledge of its operation.
- The demand valve may only be used for the purpose described in these instructions for use.
- The configuration of the overall system and the verification of its functionality are the overall responsibility of the medical personnel.
- Functionality and suitability of the product for the intended use must be checked by the user before each use.
- Check the gas cylinder or the supply line accordingly before use.
- The demand valve has a gas-specific connection. The connection must not be modified and adapted to other gases or connection systems.
- If you use a cylinder and a pressure reducer, ensure that the product is connected to the pressure reducer and the cylinder valve is properly opened before starting therapy.
- Ensure that the supply pressure is within the range specified in the technical data of the demand valve.
- **Maintenance / Repair**
- Maintenance, repairs and periodic inspections may only be carried out by authorized specialist personnel who have the appropriate expertise and are familiar with the product.
- **Danger: Fire and explosion hazard!**
- Air, oxygen and oxygen mixtures react explosively with oils, greases and lubricants. As a result of the compressed gas, there is a risk of fire and explosion. The product must be kept free of oils, greases, lubricants and hand creams.
- When handling combustion-promoting gases, observe the fire protection regulations.
- If leaks are detected in the product, contact the customer service immediately.
- When attaching accessories, check the connecting piece for tightness and secure seating!

- There is a fire hazard due to escaping oxygen! DO NOT use near flames, flammable / explosive substances, vapors or gases.
- Never smoke in an area where oxygen is administered.
- Do not exceed maximum operating pressure and maximum operating temperature.
- **Danger: Product defects!**
- The use of incorrect spare parts and accessories can lead to personal injury or functional failure. Only use original accessories and spare parts!
- **Danger: Risk of injury!**
- A worn or damaged product can lead to injuries. Only use the product when it is in perfect condition!
- Do not use the product under any circumstances if it is contaminated!
- **Danger: Damage to property!**
- No mechanical forces may act on the product with accessories to prevent malfunctions or damage!
- **Danger: Ambient conditions!**
- If the ambient temperature range is exceeded or undershot during transport and/or storage conditions, no warranty can be given for the accuracy, function, mechanical strength as well as the tightness of the product.
- **Danger: Health hazard!**
- ***When using oxygen, a kink in the connection hose can interrupt the oxygen supply. The connection hose must not be kinked!***
- An improperly fastened product can come loose and cause injury.
- **Danger: Reduction in performance!**
- Regularly check the available gas quantity at the tapping device!
- **Cleaning!**
- NOT suitable for sterilization.
- Never immerse the complete demand valve in liquids.

5 Technical data

Product	QualityFlow
Classification according to Medical Device Directive 93/42/EEC	Class IIb
Requirement	According to DIN EN ISO 5359
Connections	Connection between demand valve and hose: M12x1 Connection between hose and supply: M12x1 or tapping plug acc. to DIN 13260 / part 2
Operating temperature	-20 to +70°C
Required operating pressure	280 to 550 kPa (2.0 to 5.5 bar)
Maximum delivery capacity	200 l/min at -20° and 450 kPa
Set pressure	-0.5 kPa (-0.5 mbar)
Filter	25 micron
Transport / storage temperature in original packaging	-20°C to +40°C
Marking: Serial number, LOT, GTIN / UDI, CE marking, date of manufacture, expiration date, safety symbols.	

5.1 Variants

GTIN / UDI	Description
4251411700645	Demand valve white (without connection hose)

6 Commissioning, installation and service life

CAUTION
• **Please refer to the manufacturer's documentation for information on the operation of the connecting devices, including the ventilation bag.** • **Never open the demand valve. Otherwise, the correct function is no longer ensured!**

6.1 Commissioning

Product verification

- Before first use, the product must be subjected to wipe disinfection.
- Check that the product is in working order and does not show any contamination or damage.

6.2 Application notes

Triggered by the negative pressure of the deploying ventilation bag, the demand valve provides an O2 flow until the bag is filled. **(Follow the instructions for use of the ventilation bag).**

- ***Not suitable for invasive use directly on the tube!***
- ***Never open the demand valve! Otherwise, the correct function is no longer ensured and the product must be returned to the manufacturer for inspection.***

6.3 Installation

6.3.1 Cylinder supply → Ventilation bag

1) Connect the demand valve with connection hose via oultlet probe to an O2 pressure reducer of the O2 Cylinder supply bottle (characteristic value 400 to 500 kPa, corresponding to 4-5 bar downstream pressure)
2) Insert the demand valve into the suction opening of the ventilation bag using the corresponding adapter.

6.3.2 Central gas supply → Ventialtion bag

1) Connect the demand valve with connection hose via outlet probe to the plug in O2 coupling of central gas supply (characteristic value of the central gas supply 400 to 500 kPa, corresponding to 4-5 bar).
2) Insert the demand valve into the suction opening of the ventilation bag using the appropriate adapter.

6.4 After the use

6.4.1 Cylinder supply → Ventilation bag

1) Close the valve of the O2 bottle and disconnect the connecting hose with outlet probe from the pressure reducer of the O2 bottle.
2) Pull the demand valve out of the suction opening of the ventilation bag.
3) Prepare the demand valve according to the cleaning and care instructions.

6.4.2 Central gas supply → Ventilation bag

1) Disconnect the connecting hose with outlet probe from the the plug in O2 coupling of central gas supply.
2) Pull the demand valve out of the suction opening of the ventilation bag.
3) Prepare the demand valve according to the cleaning and care instructions.

7 Cleaning instructions

CAUTION
• Please make sure to observe the application instructions of the detergent and disinfectant manufacturer as well as the currently applicable hygiene regulations for the hospital. • Use surface disinfectants based on aldehydes and quaternary ammonium compounds; these are included in the current list of the "German Society for Hygiene and Microbiology". • **Caution, improper cleaning and disinfection may result in property damage.** • **NOT suitable for sterilization.** • **Never disassemble the product.** • **NEVER immerse the device in liquids.** • **DO NOT use strong solvents or abrasive cleaners.** • **DO NOT clean with aromatic hydrocarbons.**

7.1 Cleaning and Disinfection

Manufacturer: DEHAS Medical Systems GmbH Wesloer Str. 107-109 23568 Lübeck, OT Schlutup, Germany	Sterilization method: N/A The product is not intended for sterilization process.	

Produkt: QualityFlow

WARNING:	Do not use strong solvents or abrasive cleaners. Do not clean with aromatic hydrocarbons. Do not bring into contact with oil, grease or flammable liquids - there is an increased risk of fire. Do not autoclave! Do not sterilize! Do not immerse in liquids!
The instructions listed have been validated as SUITABLE by the medical device manufacturer for preparing a medical device for reuse. The reprocessor is responsible for ensuring that the actual reprocessing performed with the equipment, materials, and personnel used in the reprocessing facility achieves the desired results.	

INSTRUCTIONS	
	The outside of the unit must be wiped clean at regular intervals or at the latest after each patient in accordance with the applicable hygiene standard.
Preparation for cleaning and disinfection:	Disconnect all gas connections and equipment before cleaning and disinfecting.
Cleaning: Manual	For this process: 1. Wipe the surfaces of the device and accessories with a lint-free cloth soaked in water and detergent and wrung out. Do not allow any liquid to get inside the Quality Flow demand valve. 2. Wipe again with a dry, lint-free cloth.
Disinfection: Manual	3. Wipe the outside of the Quality Flow demand valve and the adapter with a lint-free cloth moistened with a non-oxidizing disinfectant. 4. Observe the exposure time of the disinfectant manufacturer according to the required spectrum of activity.
Drying:	5. After the exposure time specified by the disinfectant manufacturer, wipe dry with a dry, lint-free, low-germ cloth.
Manufacturer's Recommendation:	The manufacturer recommends the use of the disinfectant Bacillol ® 30 Foam, Bacillol ® 30 Tissues, Bode Chemie GmbH & Co. The current product data sheet of the disinfectant manufacturer must be observed.
Maintenance, control and testing:	⇒ A visual and functional check must be performed after each cleaning and disinfection.
Packaging:	▪ The device must be kept in the packaging validated by DEHAS for transport.
Storaging:	▪ Temperature: -20°C to +40°C ▪ Store in a dry place. ▪ Store the product in a dry, clean place free from lubricants, oil and other contaminants.
Transport:	▪ Temperature: -20°C to +40°C
Additional information:	N/A
Contact:	DEHAS Medical Systems GmbH, Wesloer Straße 107-109, 23568 Lübeck, OT Schlutup, Germany Tel.: +49 451 80904-0, Fax: +49 451 80904-111, E-Mail: info@dehas.de

After each cleaning and disinfection, a visual and functional check must be carried out.

8 Inspection & maintenance

8.1 General

Maintenance, repairs and periodic inspections may only be carried out by persons who have the appropriate expertise and are familiar with the product.

However, the product must be cleaned regularly after use, checked for signs of damage and its performance must be checked. Furthermore, all seals used in the product must be checked regularly for perfect condition and correct function and replaced if necessary.

8.2 Maintenance and inspections

The demand valve and connection hose must be subjected to a visual and functional check before each use.

The product should be subjected to a function and leak test at least once a year.

The deman valve does not have any parts that require maintenance. If the performance data are found to be impaired during the function and leak test, please contact your dealer.

If a connection hose is supplied, the flat seal in the M12x1 screw connection must be replaced every 2 years.

8.2.1 Functional test

Squeeze and release the resuscitation bag. With the demand valve connected, the bag should deploy in approx. 1 second.

8.2.2 Leak test

Connect the demand valve to the pressure reducer and open the gas supply to the O2 cylinder. No oxygen should escape audibly.

9 Warranty

The warranty period for the Product is 12 months from the date of sale, subject to the following terms and conditions:
Should any defect in the Product occur within the applicable period, Dealer, upon written notice thereof and upon proof that the Product has been stored, installed, maintained and operated in accordance with the instructions and in accordance with standard industry practices, and that no alterations, substitutions or modifications have been made to the Product, shall correct such defects by appropriate repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE A WARRANTY.

The dealer is not authorized to make any oral warranties about the product described in this manual, and such statements are not binding and are not part of the sales contract. Therefore, this second statement is the final, complete and exclusive representation of the terms of the contract.

- Subject to technical changes!

10 Return of goods

Please contact your dealer in this regard. They will coordinate the return shipment for you. It is important that you provide a description of the fault so that the return shipment can be processed in a targeted manner. All returns must be shipped in sealed containers to prevent damage. The dealer is not responsible for products damaged during shipping.

11 Disposal

 **CAUTION**
• Danger of infection! The product or parts of it may be contaminated after use. Clean and disinfect the product before disposal.

At the end of the service life:

Have the demand valve disposed of properly after consulting the relevant disposal company. Observe the applicable legal regulations.

EG-Konformitätserklärung
EC Declaration of Conformity

DEHAS Medical Systems GmbH| Wesloer Str. 107-109 | 23568 Lübeck, Germany

Produkt/ *Medical device*:	**Demandventile/ *Demand valves***
Artikelnummern/ *Item numbers*:	Siehe Anhang *See attached list*
Klassifikation/ *Classification*:	**IIb** Regel 11, Anhang IX, Medizinprodukterichtlinie 93/42/EWG *Rule 11, Annex IX of Medical Device Directive 93/42/ECC*

Wir erklären hiermit in alleiniger Verantwortung, dass das oben genannte Produkt mit den grundlegenden Anforderungen gemäß Anhang 1 der Medizinprodukterichtlinie 93/42/EWG übereinstimmt. Alle Belegdokumente werden in den Räumlichkeiten des Herstellers und der benannten Stelle aufbewahrt.

We hereby declare under our sole responsibility that the above product is in conformity with the basic requirements according to Annex 1 of the Medical Device Directive 93/42/EEC. All supporting documents are kept on the premises of the manufacturer and the notified authority.

Konformitätsbewertungsverfahren/ *Conformity assessment route:*	Anhang II (ohne Abschnitt 4) der Medizinprodukterichtlinie 93/42/EWG (Vollständiges Qualitätssicherungssystem) *Annex II (without section 4), Medical Device Directive 93/42/EEC (Full quality assurance system)*
Angewandte Normen/ *Applied standards:*	EN 1041 EN ISO 5359 ISO 10993-1 EN ISO 14971 ISO 15223-1
Benannte Stelle/ *Notified Body:*	DNV Medcert GmbH, Pilatuspool 2, 20355 Hamburg, Germany
Kenn-Nummer/ ID number:	CE 0482
EG Zertifikats-Nr./ *EC Certificate no.:*	4153GB410200327
Ausstellungsdatum/ *Date of issue*:	2020-03-27
Ablaufdatum/ *Expiry date*:	2024-05-27

Lübeck, 26.08.2020

Jens Meincke, Quality Manager
DEHAS Medical Systems GmbH

Anhang EG-Konformitätserklärung

Attachment EC Declaration of Conformity

Produktliste / *List of products*

Article No.	GTIN / UDI	Description
D-DV-W-M12x1	4251411700645	Demand valve white (without connection hose)
D-2522001	4251411701314	Adapter medium, white (24/28 mm)
D-2522002	4251411701321	Adapter large, white (26/32 mm)
D-2522003	4251411701338	Adapter small, white (15/22 mm)
D-2522004	4251411701598	Adapter Laerdal/VBM f. Demand valve 25/32 mm
D-2522005	4251411701574	Adapter Ambu, white (28/32 mm)
D-2522006	4251411702908	Adapter demand valve, white 22-23-30 mm

Ende der Liste / *End of list*

12 Manufacturer Information

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