# **Operating Instructions**

# **DEMAND VALVE QualityFlow**



(Picture shows a demand valve with connected O2 hose)

**C E** 0482

Keep these instructions!

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*Tecl	hnical 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

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

### 2.1 Intended use

The demand valve is used to apply 100 vol% oxygen during manual ventilation with the ventilation bag, as well as during direct non-invasive ventilation with the ventilation mask for 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	Title
DIN EN ISO 780	Packaging - Shipping packaging - Graphical symbols for handling
	and storage of packages
DIN EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels,
	labeling, and information to be supplied - Part 1: General
	requirements
DIN EN ISO 20417	Medical devices - Information to be supplied by the manufacturer
DIN EN ISO 5359	Anaesthetic and respiratory equipment - Low-pressure hose
	assemblies for use with medical gases
DIN EN ISO 5356-1	Anaesthetic and respiratory equipment - Conical connectors - Part
	1: Male and female cones
DIN EN ISO 14971	Medical devices - Application of risk management to medical
	devices
DIN EN 62366-1	Medical devices - Part 1: Application of usability engineering to
	medical devices
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and
	testing within a risk management process
ISO 18562-1	Evaluation of biocompatibility of breathing gas pathways in
	healthcare applications - Part 1: Evaluation and testing within a risk
	management process
ISO 18562-2	Evaluation of biocompatibility of breathing gas pathways in
	healthcare applications - Part 2: Tests for emissions of particulates
ISO 18562-3	Evaluation of biocompatibility of breathing gas pathways in
	healthcare applications - Part 3: Tests for emissions of volatile
	organic compounds

# 3 Safety Information - Warning, caution and labeling information

Symbol	Description
<b>C E</b> 0482	The symbol indicates that the device complies with the requirements of Directive 93/42/EEC concerning medical devices and all applicable international standards.
WARNING	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
	Keep dry / Protect from moisture
UDI	Unique Device Identifier
MD	Medical device
SN	Serial number
REF	Reference number / Article number
NON	Product non-sterile
	Temperature limit
	Indicates the permissible upper and lower air pressure limits for transport and storage.
	Humidity limitation for storage
or i	Refers to the need for the user to consult the instructions for use.

	Follow the instructions for use
X	Do not dispose of in household waste
	Do not use if the packaging is damaged
×	DO NOT USE OIL
CH REP	Authorized Representative CH
UK REP	Authorized Representative UK

### 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 trained and competent medical personnel who comply with all local regulations and laws regarding the use of this type of medical device.
- As with all medical products, improper use of this demand valve without precise knowledge of its operation could result in patient injury.
- The demand valve may only be used for the intended purpose described in this instruction manual.
- The configuration of the overall system and the verification of its functionality are

the sole responsibility of the medical personnel.

- The housing of the demand valve must never be opened by the user by unscrewing. To assemble or disassemble the adapters intended for the product, please follow the instructions in Chapter 6 of this manual.
- The functionality and suitability of the product for its intended application must be checked by the user before each use.
- Check the gas cylinder or supply line accordingly before use.
- The demand valve has a gas-specific connection. The connection must not be modified or adapted for use with other gases or connection systems.
- If using a cylinder and pressure regulator, ensure that the product is connected to the pressure regulator and that 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 recurring inspections may only be carried out by authorized personnel with appropriate expertise and familiarity with the product.
- Danger: Fire and explosion hazard!
- Air, oxygen, and oxygen mixtures react explosively with oils, greases, and lubricants. Due to the compressed gas, there is a risk of fire and explosion. The product must be kept free of oils, greases, lubricants, and hand creams.
- Follow fire protection regulations when handling combustion-supporting gases.
- If leaks are detected in the product, contact customer service immediately.
- When attaching accessories, check the connection piece for tightness and secure fit!
- Escaping oxygen poses a fire hazard! DO NOT use near flames, flammable/explosive substances, vapors, or gases.
- Never smoke in an area where oxygen is being administered.
- Do not exceed the maximum operating pressure and maximum operating temperature.
- Danger: Product defects!
- The use of incorrect spare and accessory parts can cause injuries or device failure.
   Only use original accessories and spare parts!
- Danger: Risk of injury!
- A worn or damaged product can cause injuries. Only use the product in perfect condition!
- Do not use the product under any circumstances if it is contaminated!
- Danger: Damage to property!
- Mechanical forces must not be applied to the product or its accessories to avoid malfunctions or damage!
- Danger: Ambient conditions!
- If the ambient temperature range for transport and/or storage is exceeded or not met, no warranty can be given for the accuracy, function, mechanical strength, or 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 extraction device!
- Cleaning!
- NOT suitable for sterilization.
- Never immerse the entire demand valve in liquids.

# 5 Technical data

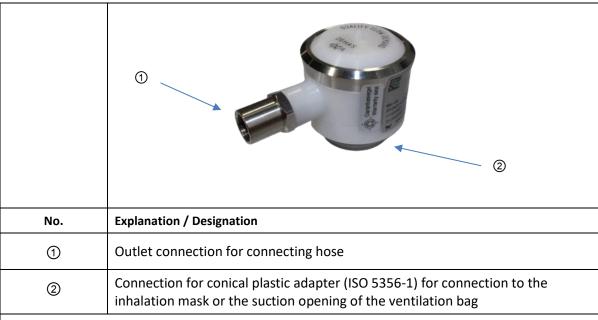
Product	Demand Valve QualityFlow O2
Klassifikation nach Medizinproduktrichtlinie 93/42/EWG	Class IIb
Requirements	According to DIN EN ISO 5359 and DIN EN ISO 5356-1 conical connectors
Connections	<ul> <li>Connection between demand valve and hose:         <ul> <li>M12x1</li> <li>9/16 DISS connection</li> <li>Rectus coupling</li> </ul> </li> <li>Demand valve outlet:         <ul> <li>Threaded connection for conical adapters according to ISO 5356-1</li> </ul> </li> <li>Connection between hose and supply:         <ul> <li>Withdrawal plug according to DIN 13260 / Part 2</li> </ul> </li> </ul>
Operating temperature	-20 bis +70°C
Required operating pressure	280 bis 550 kPa (2,8 bis 5,5 bar)
Maximum delivery capacity	≥ 160 I/min at 20° and 450 kPa
Inspiration trigger	< -1 cm H <sub>2</sub> O (< -1 mbar)
Max pressure (Cut-Out pressure for ventilation)	≤ 25 mbar

Filter	25 microns
Transport / Storage temperature in original packaging	-20°C to +40°C

### Marking

Serial number, LOT (adapter), GTIN / UDI, CE marking, date of manufacture, expiration date (hose), safety symbols

### 5.1 Design and function



### **Description of the function**

The demand valve detects a negative pressure at the patient outlet (inhalation mask) or the ventilation bag via a membrane. This negative pressure (approximately -0.5 cm  $H_2O$ ) is generated by the patient's inhalation or the suction of the ventilation bag. This triggers the opening of the demand valve, supplying the patient with oxygen or air. The greater the negative pressure exerted on the device, the higher the flow rate available at the patient connection. The flow rate depends solely on the user's inspiratory effort. Once the negative pressure falls below the activation threshold, the valve closes again (ventilation bag compression ends, or the patient stops inhaling).

# 6 Commissioning, installation and service life



### **CAUTION**

- Please refer to the manufacturer's documentation for the operation of the connection devices, including the ventilation bag.
- Never open / disassemble the main body of the demand valve. Otherwise the correct function is no longer guaranteed!

### 6.1 Putting into service

### **Product inspection:**

- Before first use, the product must be cleaned/wiped disinfected (see Chapter 7).
- Check that the product is functional and free from contamination or damage.
- Ensure that the supply hose connected to the demand valve is attached to a medical oxygen supply using the appropriate medical gas connection.
- If using an oxygen pressure regulator, check that the O<sub>2</sub> cylinder contains sufficient gas and that the cylinder valve is open.
- Perform the following tests to verify the device before each use:
  - Functional test (flow test and shut-off behavior test, see Chapter 8.2.1)
  - Leak test (see Chapter 8.2.2)

### 6.2 Notes on application

Triggered by the negative pressure of the unfolding ventilation bag, the demand valve delivers 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 / disassemble the main body of the demand valve. Otherwise the correct function is no longer guaranteed and the product must be returned to the manufacturer for inspection.

### 6.3 Installation

### 6.3.1 Mounting the adapter

Step	Activity	Figure
1	Screw the included adapter hand-tight onto the threaded connection of the demand valve by turning counterclockwise.	

# $6.3.2 \quad \text{on the cylinder supply} \rightarrow \text{Ventilation bag}$

Step	Activity
1	Connect the demand valve by attaching the outlet connection (M12x1, 9/16, or Rectus coupling) to the inlet connection of the $O_2$ hose. Then, connect the outlet connection of the $O_2$ hose (M12x1 or DIN 13260 plug) to an $O_2$ pressure regulator on the oxygen cylinder, which provides a pressure of 400 to 500 kPa (4-5 bar).
2	Insert the demand valve with the appropriate ISO 5356-1 adapter into the intake opening of the manual ventilation bag.

# 6.3.3 Mounting on the cylinder supply $\rightarrow$ Inhalation mask

Step	Activity
1	Connect the demand valve by attaching the outlet connection (M12x1, 9/16, or Rectus coupling) to the inlet connection of the $O_2$ hose. Then, connect the outlet connection of the $O_2$ hose (M12x1 or DIN 13260 plug) to an $O_2$ pressure regulator on the oxygen cylinder, which provides a pressure of 400 to 500 kPa (4-5 bar).
2	Connect the demand valve to the inhalation mask opening using the appropriate ISO 5356-1 adapter.

# $6.3.4 \quad \text{Mounting on the central gas supply} \rightarrow \text{Ventilation bag}$

Step	Activity
1	Connect the demand valve by attaching the outlet connection (M12x1, 9/16, or Rectus coupling) to the inlet connection of the $O_2$ hose. Then, connect the outlet connection of the $O_2$ hose (DIN 13260 plug) to the $O_2$ coupling of the central gas supply, which provides a pressure of 400 to 500 kPa (4-5 bar).
2	Insert the demand valve with the appropriate ISO 5356-1 adapter into the intake opening of the manual ventilation bag.

# $6.3.5 \quad \text{Mounting on the central gas supply} \rightarrow \text{Inhalation mask}$

Step	Activity
1	Connect the demand valve by attaching the outlet connection (M12x1, 9/16, or Rectus coupling) to the inlet connection of the $O_2$ hose. Then, connect the outlet connection of the $O_2$ hose (DIN 13260 plug) to the $O_2$ coupling of the central gas supply, which provides a pressure of 400 to 500 kPa (4-5 bar).
2	Connect the demand valve to the inhalation mask opening using the appropriate ISO 5356-1 adapter.

# 6.4 After use / decommissioning

# $6.4.1 \quad \text{Disassembly from the cylinder supply} \rightarrow \text{Resuscitator bag}$

Step	Activity	
1	Close the valve of the O2 cylinder and disconnect the connecting hose with the outlet connection from the pressure reducer of the O2 cylinder.	
2	Pull the demand valve out of the suction opening of the ventilation bag.	
3	Unscrew the mounted adapter from the screw thread of the demand valve by turning it clockwise.  Caution: Ensure that the adapter is only removed by turning it.  Unauthorized opening of the demand valve may lead to a loss of function of the appliance.	
4	Prepare the demand valve according to the cleaning and care instructions.	

### 6.4.2 Disassembly from the cylinder supply $\rightarrow$ Inhalation mask

6.4.2 DISas	assembly from the cylinder supply → Innalation mask		
Step	Activity		
1	Close the valve of the O2 cylinder and disconnect the connecting hose with the outlet connection from the pressure reducer of the O2 cylinder.		
2	Disconnect the demand valve and the adap	ter from the inhalation mask.	
3	Unscrew the mounted adapter from the screw thread of the demand valve by turning it clockwise.  Caution: Ensure that the adapter is only removed by turning it. Unauthorized opening of the demand valve may lead to a loss of function of the appliance.		

4 Prepare the demand valve according to the cleaning and care instructions.

# $6.4.3 \quad \text{Disassembly from the central gas supply} \rightarrow \text{Ventilation bag}$

Step	Activity	
1	Uncouple the connecting hose from the O2 coupling of the central gas supply. Please follow the instructions of the manufacturer of the corresponding tapping point socket for disconnecting the plug!	
2	Pull the demand valve out of the suction opening of the ventilation bag.	
3	Unscrew the mounted adapter from the screw thread of the demand valve by turning it clockwise.  Caution: Ensure that the adapter is only removed by turning it. Unauthorized opening of the demand valve may lead to a loss of function of the appliance.	
4	Prepare the demand valve according to the cleaning and care instructions.	

# $6.4.4 \quad \text{Disassembly from the central gas supply} \rightarrow \text{Inhalation mask}$

Step	Activity
1	Uncouple the connecting hose from the O2 coupling of the central gas supply. Please follow the instructions of the manufacturer of the corresponding tapping point socket for disconnecting the plug!
2	Disconnect the demand valve and the adapter from the inhalation mask.

Unscrew the mounted adapter from the screw thread of the demand valve by turning it clockwise.

Caution: Ensure that the adapter is only removed by turning it.
Unauthorized opening of the demand valve may lead to a loss of function of the appliance.

4 Prepare the demand valve according to the cleaning and care instructions.

## 7 Cleaning instructions



### **CAUTION**

- Please carefully follow the instructions for use of the cleaning and disinfectant manufacturer as well as the currently applicable hygiene regulations for the hospital.
- Caution: Improper cleaning and disinfection may result in material damage.
- NOT suitable for sterilization.
- NEVER disassemble the main body of the demand valve.
- NEVER immerse the demand valve in liquids.
- DO NOT use strong solvents or abrasives.
- DO NOT clean with aromatic hydrocarbons.

### 7.1 Cleaning and Disinfection

Manufacturer:

DEHAS Medical Systems

GmbH Wesloer Str. 107-109

23568 Lübeck, OT Schlutup, intended for Sterilization process.

### WARNUNG



- Do not allow the product to come into contact with oil, grease, or flammable liquids – there is an increased fire hazard.
- Cleaning and disinfecting agents can be harmful to

- health if they come into direct contact with eyes or skin.
   Read and follow all safety instructions provided by the manufacturers of the cleaning and disinfecting agents.
- Refer to the appropriate safety data sheet.
- When working with cleaning and disinfecting agents, wear appropriate personal protective equipment.

#### **General Information**

### **Purpose**

This procedure describes the proper preparation through cleaning and wipe disinfection of a demand valve as a low-risk medical device according to the guidelines of the VAH, RKI, and IHO disinfectant lists. The goal is to safely remove contamination and microbial contamination to ensure hygienic reuse.

### Responsibilities

The cleaning personnel are responsible for performing and documenting the cleaning process. The hygiene officer regularly checks compliance with the procedure.

#### **Personal Protective Measures**

- Disposable gloves
- Safety glasses or face protection (if needed)
- Liquid-repellent protective clothing (if needed)

### **Materials and Tools**

- VAH-listed disinfectant for non-invasive medical devices, active ingredient Ethanol, Propanol (Isopropanol, n-Propanol)
- Soft, lint-free cleaning cloths
- Clean work surface
- Waste container for contaminated cloths

### **Preparation for Cleaning and Disinfection:**

Disconnect all gas connections and device connections.

Remove any accessories if used:

- Inhalation mask
- Filter (HME filter / disposable)
- Ventilation bag
- DEHAS adapter (reusable)

Check the corresponding manufacturer's instructions to determine whether the used accessories are disposable or reusable.

Disposable items: Dispose of them properly.

Reusable items: Ensure that a validated cleaning and disinfection method is in place that prevents cross-contamination.

## Cleaning and disinfection of the QualityFlow O2 demand valve:

Step	Description	Execution
Coarse Cleaning	Removal of dust and visible dirt.	Wipe off coarse contamination with
		a soft, water-moistened, lint-free
		cloth.
Mild Cleaning Agent	Remove stubborn dirt.	If necessary, use a mild cleaning
Use		agent (e.g., water-based).
Disposal of Cleaning	Safely dispose of used cloths.	Dispose of used cleaning cloths
Cloths		properly.
Disinfection	Kill bacteria, viruses, and fungi.	Use a suitable VAH-listed
		disinfectant based on ethanol,
		propanol (isopropanol, n-propanol)
		and prepare it according to the
		manufacturer's instructions.
Application of	Apply disinfectant evenly.	Use a clean, soft cloth soaked in
Disinfectant		disinfectant or ready-to-use
		disinfecting wipes to treat all
		surfaces thoroughly, including hard-
		to-reach areas. Clean valve
		connections with special care,
		ensuring no liquid enters the
<u> </u>		interior.
Contact Time	Allow disinfectant to work	Follow manufacturer's instructions
Doot Clooning and	effectively.	regarding contact time.
Post-Cleaning and	Remove excess moisture.	If required, wipe off with a dry, lint- free cloth.
Drying	Chook for recidues or demage	
Visual Inspection	Check for residues or damage.	Perform a visual inspection.
Drying Documentation	Dry the cleaned demand valve.	Let it air dry on a clean surface.
Documentation	Document cleaning.	Record cleaning in the appropriate documentation.
Disposal and Cleanup	Dispose of consumables and	Remove and dispose of gloves,
Disposal and Cleanup	clean the workspace.	disinfect hands, disinfect the work
	clean the workspace.	surface, and store materials.
Draduct Increation	Chack cleaning and disinfection	Perform visual and functional
Product Inspection	Check cleaning and disinfection.	checks. If there is damage or
		functionality issues, discard the
		demand valve and have it
		technically checked.
Storage of Product	Safe storage of the device.	Store or transport the demand valve
Storage of Product	Sale storage of the device.	in DEHAS validated packaging.
		III DETIAS Validated packaging.

# Cleaning and disinfection of adapters as accessories of the demand valve:



Preparation for cleaning	Preparation for cleaning and disinfection:		
Disconnect the adapter from the demand valve (see chapter 6.4.1)			
Step	Description	Execution	
Manual Cleaning	Removal of dust and visible dirt.	Wipe off coarse contamination with	
		a soft, water-moistened, lint-free	
		cloth. Thoroughly clean connection	
		threads and hard-to-reach areas.	
Use of Mild Cleaning	Remove stubborn dirt.	If necessary, use a mild cleaning	
Agent		agent (e.g., water-based).	
Disposal of Cleaning	Safely dispose of used cloths.	Dispose of used cleaning cloths	
Cloths		properly.	
Optional Immersion	Remove contamination by	Immerse the adapter in a suitable	
Cleaning	immersion.	cleaning solution and leave it for	
		the recommended contact time	
		according to the manufacturer's	
		instructions. Ensure that it is	
		completely submerged. Move the	
		adapter lightly in the solution to	
		loosen dirt.	
Rinsing	Remove cleaning agent residues.	Rinse the adapter thoroughly with	
		distilled water to remove cleaning	
		agent residues.	
Disinfection	Kill bacteria, viruses, and fungi.	Use a suitable VAH-listed	
		disinfectant based on ethanol,	
		propanol (isopropanol, n-propanol)	
		and prepare it according to the	
		manufacturer's instructions.	
Application of	Apply disinfectant evenly.	Treat all surfaces thoroughly with a	
Disinfectant		clean, soft cloth soaked in	
		disinfectant or ready-to-use	
		disinfecting wipes, including hard-	
		to-reach areas.	
Contact Time	Allow disinfectant to work	Follow the manufacturer's	
	effectively.	instructions regarding	

Optional Immersion	Immerse the adapter in a	Immerse the adapter in a suitable
Disinfection	disinfectant solution.	disinfectant solution and disinfect
		according to the manufacturer's
		instructions. Move the adapter
		lightly in the solution to loosen dirt.
Rinsing	Remove cleaning agent residues.	Rinse the adapter thoroughly with
		distilled water to remove cleaning
		agent residues.
Post-Cleaning and	Remove excess moisture.	Wipe the adapter with a clean, dry,
Drying		lint-free cloth or let it air dry.
Visual Inspection	Check for residues or damage.	Perform a visual inspection.
Drying	Dry the cleaned demand valve.	Let it air dry on a clean surface.
Documentation	Document cleaning.	Record cleaning in the appropriate
		documentation.
Disposal and Cleanup	Dispose of consumables and	Remove and dispose of gloves,
	clean the workspace.	disinfect hands, disinfect the work
		surface, and store materials.
Product Inspection	Check cleaning and disinfection.	Perform visual and functional
		checks. If there is damage or
		functionality issues, discard the
		product and have it technically
		checked.
Storage of Product	Safe storage of the device.	Store or transport the product in
		DEHAS validated packaging.

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

The demand valve is subject to natural wear and tear after repeated manual cleaning and disinfection. To ensure functionality and safety, the product must be regularly checked for visible signs of damage.

Particular attention should be paid to the following signs of wear:

- Discoloration of the material
- Cracks, breaks, or deformations
- Changes in the surface texture
- Reduced functionality of the valve

If such signs occur, the product must not be used for safety reasons. In this case, the product must be disposed of in accordance with applicable regulations. Reprocessing or reuse is not permitted.

### 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, visually inspected for signs of damage and its performance checked. Furthermore, all seals used in the product must be visually inspected 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 functional and leak test at least once a year.

There are no maintenance-relevant parts on the demand valve. If an impairment of the performance data is detected during the function and leak test, please contact your dealer.

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

### 8.2.1 Function test (flow test and test of the shut-off behavior)

	,	
Step	Description	
1	Preparation:	
	<ul> <li>Connect the demand valve to the appropriate gas supply (e.g., oxygen).</li> </ul>	
	Ensure the demand valve is properly attached to the breathing mask or	
	ventilator bag, depending on the method being tested.	
2	Initial Check:	
	<ul> <li>Ensure all connections are secure and there are no leaks in the system.</li> </ul>	
	<ul> <li>Ensure the gas supply is turned on and the system is pressurized as</li> </ul>	
	specified by the manufacturer.	
3	For Mask Setup:	
	If no patient (or test lung) is connected, observe the valve to ensure no gas	
	flows when not inhaling.	
	If a test lung or simulator is used, let it inhale and exhale. Ensure the	
	demand valve delivers gas during inhalation and completely stops the flow	
	when inhalation ceases.	
	For Ventilator Bag Setup:	
	Squeeze the ventilator bag to simulate manual ventilation, then release it.	
	With the demand valve connected, the bag should inflate within about 1	
	second. Ensure the demand valve allows gas flow during compression and	
	stops the flow completely when no pressure is applied.	
	Observe the bag to ensure it refills without unwanted gas flowing from the	
	demand valve when not in use.	

Step	Description
4	Evaluation:
	The demand valve should immediately stop the gas flow when not in use
	or when the patient/test lung stops inhaling.
	If gas continues to flow, even slightly, it may indicate a malfunction, and
	the valve may need to be checked, adjusted, or replaced.

### 8.2.2 Leak test

Connect the demand valve to the pressure reducer and open the gas supply to the O2 cylinder. You should not hear any oxygen escaping.

### 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.

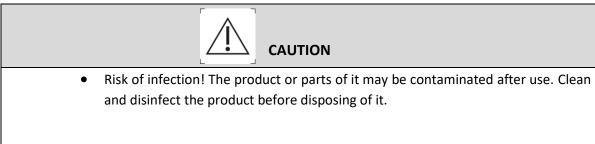
The dealer is not authorized to make any oral warranties about the product described in this manual, and such statements are not binding and are not part of the sales contract. Therefore, this second statement is the final, complete and exclusive representation of the terms of the contract.

- 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



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.

### 12 Manufacturer Information

Manufacturer DEHAS Medical Systems GmbH

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23568 Lübeck Germany

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