Operating Instructions

DEMAND VALVE QUALITY FLOW N2O

Please Keep These Instructions!

CE 0482

DEHAS Medical Systems GmbH
Wesloer Straße 107-109
23568 Lübeck, Deutschland

Tel: (+49) 451 80904-0
Fax: (+49) 451 80904-111
www.DEHAS.de

Version 1.5.

Content

1 Foreword

This operating instruction is intended to provide you information in using the Quality Flow N2O demand valve. The operating instructions are divided into individual chapters.

Please note:

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

2 Fundamental requirements

According to Annex IX of Directive 93/42/EEC on 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

In conjunction with one of our Quality Mix N2O gas mixers, the Quality Flow N2O demand valve is used to apply the analgesic gas mixture of nitrous oxide (N2O) and oxygen (O2). It responds to the patient's inhalation.

The analgesic gas is a medicinal product. It should be used only for medical purposes on the order of a physician and according to his instructions.

The Quality Flow N2O demand valve is designed for use in any type of clinical environment. The information and safety instructions of the medical gases to be used must always be observed.

2.2 Technical description

The demand valve consists of five main components:

- Demand valve
- Demand valve adapter
- Gas connection hose (optionally available with handle)
- Anesthetic gas suction hose
- Breathing mask (Single, Double - Mask - System)

The mask is designed for the use at one single patient only to prevent cross-contamination between patients.

The optional handle of the Quality Flow N2O demand valve is designed to be reusable. It can be cleaned and disinfected.

The demand valve provides low inspiratory resistance, which is less strenuous for the patient.

The demand valve can be operated directly in connection with a central gas supply or from a medical compressed gas cylinder with a suitable pressure reducer. A gas hose that meets the requirements of the international standard EN ISO 5359 transports the gas from the gas supply to the demand valve. The demand valve should be used with a mouth and nose mask.

2.3 Content of Delivery / Variants and accessories

Article No.	GTIN / UDI	Description
D-B-N2O-DS	4251411701772	Demandsystem N2O
D-B-N2O-DS-Blu	4251411702700	Adapter blue for Demandsystem N2O
D-B-N2O-DS-HG	4251411701079	Handle (optional)
DIN-N2O-NIST-NIST-2,00	4251411702052	ISO Low pressure connection tube N2O (optional)
DIN-O2-NIST-NIST-2,00	4251411702014	ISO Low pressure connection tube O2 (optional)
DIN-O2/N2O-DISS-RC-Ku – 3,00	4251411701826	ISO Low pressure connection tube O2/N2O rectus coupling DISS (optional)
D-ESD-SS-N2O	4251411701413	Pressure reducer N2O (optional)
D-ESD-SS-O2	4251411701406	Pressure reducer O2 (optional)

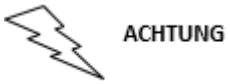
2.4 Applied Standards

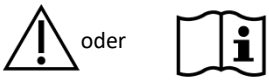
The product complies with the essential requirements according to Annex I of Directive 93/42/EEC (Medical Devices Directive) and the applicable national regulations such as the Medical Devices Act (MPG).

Standard / Norm	Titel
DIN EN 1041	Provision of information by the manufacturer of medical devices
DIN EN 62366-1	Medical devices - Part 1: Application of usability to medical devices
DIN EN ISO 14971	Medical devices - Application of risk management to medical devices
DIN EN ISO 15223-1	Medical devices - Symbols to be used, marking and information to be provided on medical devices - Part 1: General requirements
DIN EN ISO 5359	Anaesthetic and respiratory equipment - Low pressure tubing systems for use with medical gases
DIN EN ISO 780	Packaging - Shipping packaging - Graphical symbols for handling and storage of packages
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing as part of a risk management system

ISO 15001	Anaesthetic and respiratory equipment - Compatibility with oxygen

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.
	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	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
MD	Medical device
SN	Serial number
REF	Reference number / Article number
UDI	Unique Device Identification

EC REP	Authorized Representative
	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 use

Please 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 manual, do not use the product and contact your supplier.

4.1 Safety instructions

WARNING

Intended use / User

- - The Quality Flow N2O demand valve may only be operated by healthcare professionals under the direct supervision of a licensed physician.
- - As with all medical products, the Quality Flow N2O demand valve may cause injury to the patient if used without precise knowledge of its operation.
- - The Quality Flow N2O demand valve has only to be used for the purpose described in these operating instructions.
- - 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 respective intended use must be checked by the user before each use.
- - This demand valve is only intended for use with analgesic gas for medical purposes. Check the gas cylinder or the supply line accordingly before use.
- - The Quality Flow N2O 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 Quality Flow N2O demand valve.
- Maintenance / repair
- - Maintenance, repairs and periodic inspections may only be carried out by authorized specialist personnel who have the appropriate technical and specialist knowledge.
- Danger: Fire hazard!
- - The analgesic nitrous oxide/oxygen gas mixture is not flammable, but it can drastically increase the speed and severity of a combustion process. Oil and/or grease become highly flammable in the presence of oxygen-enriched ambient air. The product must be kept free of oils, greases, lubricants, hand creams or other hydrocarbon - based substances.
- - Many hand creams and moisturizers contain kerosene and petroleum bases that are highly flammable and should never come in contact with the demand valve. Make sure your hands are clean and dry before working with the unit.
- - Observe the fire protection regulations when handling gases that promote combustion.
- - If leaks are detected in the product, contact customer service immediately.
- - When attaching accessories, check the connector for tightness and secure fit!
- - There is an accelerated risk of fire due to escaping oxygen / oxygen mixture! DO NOT use near flames, flammable / explosive substances, vapors or gases.
- - Never smoke in an area where oxygen / oxygen mixture is being administered.
- - Do not exceed maximum operating pressure and maximum operating

temperature.

- - Danger: Product defect!
- - The use of incorrect spare parts and accessories can lead to personal injury or functional failure. Only use original Accessoires 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: Material damage!
- - No mechanical forces may act on the product with accessories to avoid 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 incorrectly fastened product can come loose and cause injuries.
- - Danger: Reduced Performance!
- - Regularly check the available gas volume on the tapping device!
- - The maximum flow rate (peak flow) through the Quality Flow N2O demand valve may be limited in the following situations and consequently lead to increased work of breathing for the patient:
- If the pressure reducer used or the supply system for the analgesic gas does not meet the specification.
- If an extension, tubing is used that is not listed in these instructions for use with the Quality Flow N2O demand valve.
-
- Cleaning:
- - NOT suitable for sterilization.
- - Never immerse the complete Quality Flow N2O demand valve in liquids.

5 Technical data

Product	Quality Flow N2O
Classification according to Medical Device Directive 93/42/EEC	Class IIb
Requirement	According to DIN EN ISO 5359
Connections	Quick coupling / nipple
Operating temperature	-40 to +70°C

Required operating pressure	270 to 550 kPa (2.7 to 5.5 bar)
Maximum delivery capacity	160 l/min at 20° and 450 kPa
Set pressure	< -0.1 kPa (< -0.1 mbar)
Filter	25 micron
Transport / storage temperature in original packaging	-40°C to +70°C
Marking: Serial number, LOT / UDI-DI, UDI - PI, CE marking, date of manufacture, safety symbols.	

5.1 Variants / Accessoires

Article No.	GTIN / UDI	Description
D-B-N2O-DS	4251411701772	Demandsystem N2O
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D-ESD-SS-N2O	4251411701413	Pressure reducer N2O (optional)
D-ESD-SS-O2	4251411701406	Pressure reducer O2 (optional)

6 Commissioning, Installation and shelf life

Caution
• **Do not open the Quality Flow N2O demand valve. Otherwise, the correct function is no longer ensured!**

6.1 Commissioning

Product testing:

- Before first use, the product must be subjected to wipe disinfection.
- Check that the product is in working order and does not show any soiling or damage.
- When using masks (disposable product), the instructions for use of the respective manufacturer must be observed.

6.2 Application notes

- ***Not suitable for invasive use on the tube!***
- ***Never open the Quality Flow N2O 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 / central gas supply

Before use, check both the hose and the Quality Flow N2O demand valve for external damage or contamination.

Caution
• The device has not to be connected or used if there is any doubt about its condition.

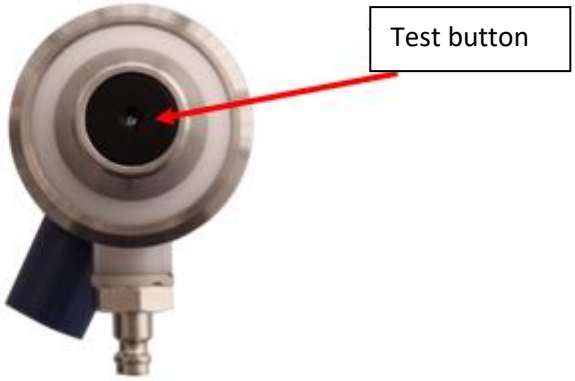
The Quality Flow N2O demand valve is supplied with a gas-specific plug intended for connection to the pressure outlet of a suitable gas supply. The pressure outlet can be a tapping point of a central gas supply or a gas cylinder with pressure reducer.

Caution
• When using a gas cylinder, it must be ensured that the cylinder content is sufficient for the upcoming therapy.

- Connect the gas-specific plug connection to the pressure outlet of a suitable gas supply.
- If the gas-specific plug is connected with a screw thread, this connection must be screwed tight before the supply pressure is switched on.
- If quick couplings are used, the correct fit of the connection must be checked by carefully applying tension to the gas hose before activating the supply pressure.
- Note: The supply hose is also optionally available with an integrated handle and a gas-specific quick coupling.

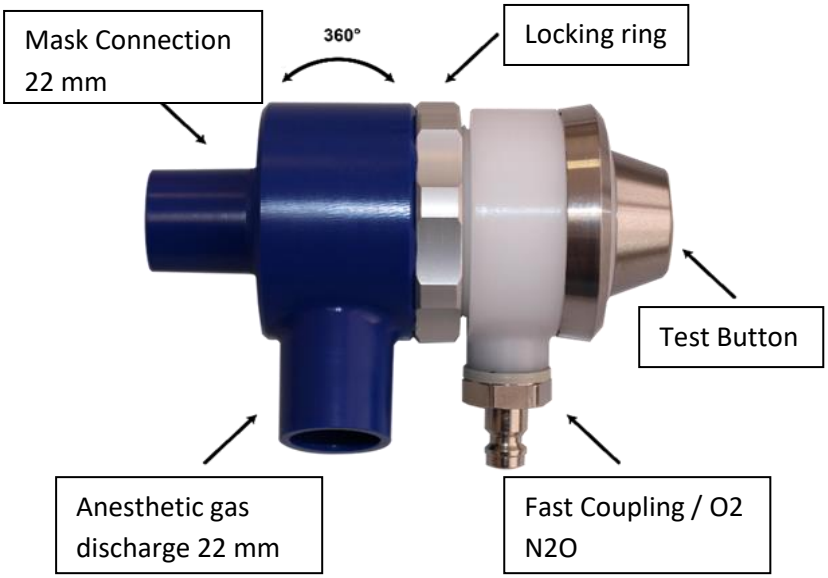
6.3.2 Check before use

Check the proper functioning of the Quality Flow N2Os demand valve before starting therapy by pressing the test button. The gas should flow out immediately when the test button is pressed and stop again as soon as the test button is released. The test button is only used for functional testing and must not be used for administering the drug!



Caution
• **The test button is used exclusively for testing the function of the device. This test button is not used to apply the drug during application.** • If the Quality Flow N2O demand valve does not function properly, remove the device and read the troubleshooting guide at the end of this user manual.

6.3.3 Connecting the adapter / connecting the anesthetic gas supply, connecting the mask



1. Connect the adapter with the screw thread to the Quality Flow N2O demand valve.
2. Fix the adapter to the Quality Flow N2O demand valve using the locking ring so that the anesthetic gas outlet points downwards.
3. Connect a drain hose for anesthetic gas suction to the anesthetic gas drain 22 mm outlet of the adapter.
4. Connect a Face mask to the 22 mm mask connection by plugging it into the adapter (both a single and a double mask system are possible)

6.4 Application

The patient should press the facemask over the nose and mouth and inhale. The deeper the patient inhales, the greater the amount of gas is delivered.

The Quality Flow N2O demand valve is intended to use for self-administration of analgesic gas and should not be used for longer than prescribed.

Check the contents of the gas cylinders (if applicable) while using the Quality Flow N2O demand valve and ensure that no one can trip over the hose.

6.5 After User

6.5.1 Cylinder supply / central gas supply

1) Close the N2O / O2 supply and disconnect the withdrawal plug from the pressure reducer or release the quick coupling.
2) Remove / Disconnect the anesthetic gas outlet (hose) and mask.
3) Remove / Disconnect the adapter by loosening the locking ring.
4) Prepare Quality Flow N2O demand valve and adapter according to cleaning and care instructions.
5) Dispose of the used mask as a single-use item according to the manufacturer's 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. • Do not use disinfectants based on phenols and halogen- or oxygen-releasing agents! 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.**

Basic Notes:

The product must be cleaned and disinfected by wiping after each use.
Parts that come into contact with the patient's breathing air must always be disinfected.

7.1 Maintenance:

Do not bring into contact with oil, grease or flammable liquids - There is an increased risk of fire.

7.2 Cleaning

WARNINGS:	Do not use cleaning agents that release chlorine or oxygen.
Cleaning: Manual	1. Disconnect all gas Connections and Equipment before cleaning. 2. Wipe the surfaces of the device and accessories with an in water and detergent soaked and wrung out cloth. Do not allow liquid to get inside of the Quality Flow N2O demand valve 3. Wipe the surface with a dry cloth.

7.3 Disinfection

WARNINGS:	Do not use disinfectants containing alcohol or phenol.
Disinfection: Manual	The outside of the Quality Flow N2O demand valve must be disinfected at regular intervals or at the latest after each patient in accordance with the applicable hygiene standard.
Disinfection guide	1. Disconnect all gas connections and equipment before cleaning. 2. Wipe the outside of the Quality Flow N2O demand valve and the adapter with a cloth moistened with non-oxidizing disinfectant and water. Do not allow liquid to get inside of the Quality Flow N2O demand valve 3. Wipe the Surface with a dry cloth.

The above instructions have been validated as SUITABLE by the medical device manufacturer for the preparation of a medical device for its reuse (EN ISO 17664:2017). The reprocessor is responsible for ensuring that the reprocessing actually carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired results.

For users in Germany, the use of disinfectants is recommended which are entered in the current DGHM list.

- Follow the prescribed exposure time of the disinfectant manufacturer.
- Ensure that the product is free of disinfectant residues.

Manfacturers 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.

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

8 Inspection & Maintenance

8.1 General Notes

Maintenance, repairs and periodic inspections has to be be carried out by persons who have the appropriate expertise and specialist knowledge only.

The product has to 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 Performing of maintenance and inspections

festgestellt werden, setzten Sie sich bitte mit Ihrem Händler in Verbindung.

The Quality Flow N2O demand valve with accessories 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 an impairment of the performance data is detected during the function and leak test, please contact your dealer.

8.2.1 Check of function

Check the proper functioning of the Quality Flow N2O demand valve Quality Flow N2O Quality Flow N2O before starting therapy by pressing the test button. The gas should flow out immediately when the test button is pressed and stop again as soon as the test button is released.

8.2.2 Leak Test

Connect the Quality Flow N2O demand valve to the pressure reducer and open the gas supply on the O2 cylinder. No gas 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 shelf life:

Have the Quality Flow N2O demand valve disposed of properly after consulting the relevant disposal company. Observe the applicable legal regulations.
Disposable products, such as masks, must be disposed of properly according to the instructions of the respective manufacturer.

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 9 und 11, Anhang IX, Medizinprodukterichtlinie 93/42/EWG *Rule 9 and 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***

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D-ESD-SS-O2	4251411701406	Pressure reducer O2

Ende der Liste / ***End of list***

12 Manufacturer Information

Manufacturer: DEHAS Medical Systems GmbH
Wesloer Straße 107-109
23568 Lübeck, Germany
Tel: 0451/80904-0
Fax: 0451/80904-111
Email: Info@dehas.de
Homepage: www.dehas.de

CE 0482

Distributed by: DEHAS Medical Systems GmbH
Wesloer Straße 107-109
23568 Lübeck, Germany
Tel: 0451/80904-0
Fax: 0451/80904-111
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Rev. 1.5. 07/2023