Instruction manual

Outlet pressure reducer (adjustable)

QualityREG INLINE

Keep this instructions!

CE 0482

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Version 1.6

Content

1 Introduction

These operating instructions are intended to provide you information in using the QualityREG INLINE adjustable outlet pressure reducer.

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 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

The QualityREG INLINE adjustable outlet pressure reducer is used for the pressure-reduced delivery of medical gases for various medical devices from the fields of medicine and therapy.

- For direct connection to a central gas supply system. The pressure reducer reduces the respective inlet pressure to an outlet pressure that is as constant as possible.
- Only for supplying medical equipment in accordance with the technical data on the type plate and the operating instructions.
- For in-hospital, stationary use only.
- Only for the medical gas specified on the device.
- The pressure reducer must not be used as a shut-off valve.
- The pressure reducer does not have a safety device to protect downstream devices in the event of overpressure.

The information and safety instructions for the medical gases to be used must always be observed.

2.2 Technical description

The QualityREG INLINE adjustable outlet pressure reducer is a single-stage, direct-acting, spring-loaded pressure regulator without upstream pressure compensation. A metal diaphragm serves as the seal to the atmosphere. The connection on the device side is made via a NIST screw connection. The outlet pressure is continuously adjustable from 0.1 to 6 bar. The inlet pressure may be max. 8 bar.

The pressure reducer has no safety device to protect downstream equipment. In the event of a malfunction, the set pressure can rise to the gas supply pressure.

2.3 Delivery / variants and accessories

Article no.	GTIN / UDI	Description
D-ESD-DIN-AIR-R	4251411702670	QualityREG outlet pressure reducer AIR adjustable
D-ESD-DIN-O2-R	4251411702687	QualityREG outlet pressure reducer O2 adjustable
D-ESD-DIN-N2O-R	4251411700478	QualityREG outlet pressure reducer N2O adjustable
D-ESD-DIN-CO2-R	4251411703356	QualityREG outlet pressure reducer CO2 adjustable

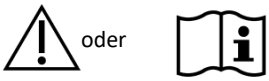
2.4 Used Standards

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.

Standard / Norm	Title
DIN EN ISO 10524-1	Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flowmeters
DIN EN ISO 10524-4	Pressure regulators for use with medical gases - Part 4: Low pressure regulators
DIN EN 1041	Provision of information by the manufacturer of medical devices
DIN EN 62366-1	Medical devices - Part 1: Application of serviceability 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 13554-2	Respiratory therapy equipment - Part 2: Tubing systems and connectors
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 within a risk management system
ISO 15001	Anaesthetic and respiratory equipment - Compatibility with oxygen

3 Safety information - Warnings, cautions, and labeling information

Symbole	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.
 WARNING	Indicates a potentially hazardous situation which, if not prevented, may result in death or serious injury.
 ATTENTION	When this sign is used, it is used to indicate 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 idenfitier
NON STERILE	Product non-sterile

	Temperature limit
	Refers to the need for the user to consult the instructions for use.
	Observe 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

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 instructions

WARNING

- These operating instructions are an integral part of the device and must be available to the user at all times.
- As with all medical products, the use of this tapping point pressure reducer without precise knowledge of its operation could result in injury to the patient.
- The QualityREG INLINE outlet pressure reducer may only 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.
- The QualityREG INLINE outlet pressure reducer has a gas-specific connection. The connection must not be modified and adapted to other gases or connection systems.
- Ensure that the supply pressure is within the range specified in the technical data of the QualityREG INLINE.
- Never use a leaking or defective device!
- Medical gases are drugs and may only be administered under the supervision of qualified medical personnel who are familiar with the precautionary measures for the respective application.
- Before operating the device, it is essential to check that the type of gas is correct and that the upstream and downstream devices are connected correctly and firmly.
- Not suitable for operation in the vicinity of strong magnetic fields, e.g. magnetic resonance imaging.
- Use only CE-marked accessories that are suitable for use with the device according to their intended purpose and connection (see chapter "Combination with downstream devices").
- Never attempt to open the pressure reducer, as spring-loaded parts may come loose and cause injury.
- To avoid infection or bacterial contamination, observe the section "Maintenance and care".
- The pressure reducer must not be immersed in liquids and must not be sterilized.
- No foreign substances or liquids must be allowed to enter the interior of the device. This applies in particular to dust and disinfectants.
- Be sure to wash your hands before working on the oxygen supply.
- Make sure that the pressure reducer does not come into contact with oil or grease, either during operation or storage. Oil and grease, e.g. hand creams, can react violently with pressurized gases (especially oxygen and nitrous oxide). Risk of explosion!
- Do not use any lubricants or lubricating agents.
- Smoking and naked flames are strictly prohibited in the vicinity of oxygen-carrying fittings.
- The connections of the device must fit directly to the connections of gas supply or downstream devices. Do not use transition pieces.
- Only suitable for in-clinic, stationary operation.

- Do not make any technical or structural modifications.
- Observe storage and operating conditions.
- Do not use the device for direct patient supply.
- Do not connect several devices in series.
- Maintenance, repairs and periodic inspections may only be carried out by authorized personnel who have the appropriate technical knowledge and expertise.
- If leaks are detected in the product, contact customer service immediately.
- When attaching accessories, check the connecting piece for tightness and secure seating!
- Do not exceed the maximum operating pressure and maximum operating temperature.
- Do not use the product under any circumstances if it is contaminated!

4.2 Safety instructions for handling medical gases

Oxygen (O2) increases flammability and combustibility and promotes the combustion of flammable substances. Greases and oils, e.g. hand cream or lubricants, may self-ignite on contact with pressurized oxygen. Ensure good ventilation. High concentrations may cause damage to health. Do not smoke and no open fire.

Nitrous oxide (N2O) has a strong anesthetic effect and increases flammability and combustibility and promotes the combustion of flammable substances. Fats and oils, e.g. hand cream or lubricants, can self-ignite on contact with pressurized nitrous oxide. At high concentrations, there is a risk of oxygen deficiency and respiratory arrest. Ensure good ventilation. Do not smoke and no open fire.

Carbon dioxide (CO2) has a central energizing effect at low concentrations and a paralyzing effect (respiratory arrest) at higher concentrations. Ensure good ventilation.

Nitrogen (N2) can reduce the O2 content of the breathing air at high delivery rates in confined spaces. Provide for ventilation.

5 Technical data

Product	QualityREG INLINE
Classification according to Medical Device Directive 93/42/EEC	Class IIb
Requirement	According to DIN EN ISO 10524-1 and -4
Gas types	Available for all non-corrosive gas types

Available standards	German (DIN), French (NF), British (BS), Scandinavian (SS, AGA), Swiss (CH, Carbamed), Italian (UNI).
Permissible inlet pressure	Max. 8 bar
Outlet pressure	stepless 0,1 - 6 bar
Nominal gas flow	20 l/min
Operating temperature	-40 to +70°C
Transport / storage temperature in original packaging	-40°C to +70°C
Rel. humidity during operation and storage	5% to 95% rel. humidity, non-condensing
Air pressure during operation	900 hPa to 1100 hPa
Air pressure during storage	115 hPa to 2000 hPa
Marking: Serial number, LOT / UDI-DI, UDI - PI, CE marking, date of manufacture, safety symbols.	

6 Transportation and packing

The transport and storage of the device (e.g. shipment to the manufacturer) may only take place in suitable, stable packaging, e.g. original packaging.

7 Commissioning, installation and service life

ATTENTION

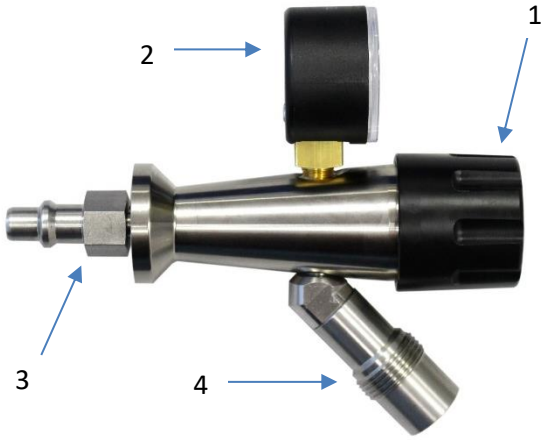
- **Never open the QualityREG outlet pressure reducer. Otherwise, the correct function is no longer guaranteed!**
- **The user or operator is responsible for the use and operation of the device and accessories.**
- **Wash your hands thoroughly before each activity with the oxygen supply. Hydrocarbon compounds (e.g., oils, greases, cleaning alcohols, hand creams or residues of adhesive plasters) can lead to explosive reactions if they come into contact with highly compressed gases.**
- **Medical gases are drugs and may only be used appropriately for the patient as instructed by the responsible physician.**

7.1 Commissioning

- A function check must be carried out before the device is put into operation after a longer storage period (longer than 6 months).
- All connections of the gas tapping point, the device, connection devices and accessories must be undamaged, clean and free of oil and grease! Contamination of the pressure reducer can ignite.
- The pressure gauge indicates the outlet pressure relative to the ambient pressure. Observe the ambient pressure (high altitude, overpressure) when setting the pressure.
- Check pressure gauge display. If the unit is defective, the pressure gauge will show the central supply gas pressure applied to the inlet. Never use a leaking or defective device.

7.2 Components of the pressure reducer

Position	Description
1	Dial
2	Outlet pressure gauge
3	Inlet connection
4	Output connection



7.3 Installation

1. Check the type plate to ensure that the device is suitable for the intended use (type of gas, pressure). The maximum permissible inlet pressure of the device must be equal to or higher than the max. Line pressure.
2. Turn the setting wheel of the device to the left (counterclockwise) as far as it will go.

ATTENTION: Turn the setting wheel to the stop only with slight force. .

3. Prepare the connecting devices and accessories required for operation in accordance with the relevant operating instructions.

ATTENTION: The gas and the pressure reducer cool down during operation. This can lead to hypothermia of the patient.

4. Connect the pressure reducer with the inlet connection to the gas tapping point. 5.
5. Connect the connecting devices and accessories to the output connection of the device properly.

ATTENTION: The connections must fit directly. Do not use adapters or modify the connections on the devices.

6. Read the outlet pressure on the pressure gauge and adjust it if necessary by turning the adjustment dial.

7. Do not leave the pressure reducer and patient unattended during operation. Check the pressure setting by checking the pressure gauge display at suitable intervals.

ATTENTION
• If the outlet pressure reducer is not working properly, remove the unit and refer to the troubleshooting guide at the end of this manual.

7.4 Decommissioning and storage

Turn the adjusting wheel of the pressure reducer to the left (counterclockwise) as far as it will go. Allow the gas in the pressure reducer to flow out.

ATTENTION: Only turn the handwheel to the stop with little force.

1. Remove the connection devices and accessories from the device.
2. Remove the device from the gas tapping point.
3. Store the pressure reducer in a clean, dust-free and dry place until next use.

If the pressure reducer is not to be used for a longer period of time, perform cleaning (see chapter "Cleaning and care instructions").

After carrying out cleaning and care, it is recommended to store it in a closed PE bag. The ambient conditions must be observed (see chapter "Technical data"). It is essential to observe the maintenance periods and service life of the device when it is stored, otherwise the device may not be recommissioned.

8 Cleaning and care instructions

ATTENTION
• Please be 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-splitting agents! • Do not bring into contact with oil, grease or flammable liquids - there is an increased risk of fire.

- Caution, improper cleaning and disinfection may result in material 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 instructions:
After each use, the product must be cleaned and wipe disinfected.

8.1 Cleaning

. Do not use cleaning agents that release chlorine or oxygen. Alcohol-containing or re-lubricating cleaning agents can ignite in contact with compressed oxygen or nitrous oxide.

Clean the surface of the pressure reducer with a dry cloth or a disposable cloth moistened with clean water. Do not allow any liquid to get inside the pressure reducer.

8.2 Disinfection

Only use approved preparations from the group of surface disinfectants to disinfect the pressure reducer. Observe the manufacturer's instructions for use.

For reasons of material compatibility, preparations based on the active ingredients of:

- Aldehydes
- Quaternary ammonium compounds

Example of approved preparations:

- Incidin rapid, Ecolab Deutschland Gmbh
- Terralin protect, Schülke & Mayr
- Antifect extra, Schülke & Mayr

Due to possible damage to materials, preparations based on:

- Halogen-releasing compounds
- Strong organic acids
- Oxygen-scavenging compounds

For users in the Federal Republic of Germany, we generally recommend the use of disinfectants that are registered in the respective current VAH list (VAH: Verbund für Angewandte Hygiene e.V., mhp Verlag GmbH, Wiesbaden). The VAH list also states the active ingredient base of each disinfectant.

For countries in which the VAH list is not known, the recommendation of the active ingredient bases mentioned above applies.

The outside of the pressure reducer must be disinfected at regular intervals in accordance with the applicable hygiene standard.

1. The outside of the pressure reducer must be disinfected at regular intervals in accordance with the applicable hygiene standard.

2. Disconnect all gas connections and devices before cleaning.

3. Wipe the outside of the pressure reducer with a cloth moistened with non-oxidizing disinfectant and water.

4. Wipe dry with a dry cloth.

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

9 Inspection & Maintenance

9.1 General

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

9.2 Carrying out maintenance and inspections

The pressure reducer must be cleaned regularly after use and checked for signs of damage. Before each use, the product must be subjected to a visual and functional check.

All seals used in the product must be checked regularly for perfect condition and correct function and replaced if necessary.

After 2 years, maintenance must be carried out, including the replacement of all wearing parts. If this period is exceeded, the liability of DEHAS expires. The safety and function of the device can only be guaranteed if it is maintained by DEHAS or authorized companies using original DEHAS spare parts!

9.2.1 Functional check

A visual inspection for mechanical damage must be performed at least every 6 months under bright, glare-free lighting. This includes the inspection of

- Input connection
- Housing
- Pressure gauge
- Adjusting wheel
- Output connection
- Readability of nameplate and gas type plate
- Connections and pressure gauge aligned with device axes
- Connections and pressure gauge: Tight fit

The setting wheel must be smooth-running.

It is essential that you also observe the maintenance periods for devices in storage, otherwise the pressure reducing valve must not be used when it is removed from storage.

If you find any faults during the function test or during operation, you must remove the pressure reducing valve from service immediately. Contact your dealer to rectify the fault.

10 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 2nd statement is the final, complete and exclusive representation of the terms of the contract.

- Subject to technical changes!

11 Returns

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.

12 Troubleshooting

Malfunction	Cause	Corrective
Connection between gas sampling point and device is leaking.	Inlet connection damaged. Seal of the outlet pressure reducer is damaged.	Repair by DEHAS or an authorized dealer.
Outlet pressure increases	Valve seat dirty or damaged	Repair by DEHAS or an authorized dealer.
Leakage in the housing	Diaphragm defective	Repair by DEHAS or an authorized dealer.

13 Disposal

For proper disposal of the device, please contact an approved certified disposal company. The locally, regionally or domestically applicable regulations and laws must be observed.

14 Combination with downstream deavices and accessories

The user or operator is responsible for the use and operation of the pressure reducing valve and the connected devices.

Downstream devices and accessories must be suitable for the pressure reducing valve and the application and must meet the following criteria:

- They must be medical devices with CE marking.
- They must be labeled with the same gas type as the pressure reducer.

ATTENTION
• Risk of confusion of the gas type when using non-gas type-specific connections (e.g. hose nozzle). • When using hose nozzles, there is a risk of the hose slipping off.

For questions or professional advice, please contact us or visit us on the Internet at www.dehas.de.

Declaration of conformity

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GERMANY

CE 0482

REF QualityREG INLINE

Classification	IIb
Rule:	Clause 3.2 Rule 11 in Annex IX of the MDD

We hereby declare under our sole responsibility that the above mentioned products comply with the provisions of the following EC Council Directives and Standards. All supporting documents are kept at the premises of the manufacturer and the notified body.

Guideline:	General Application Directives: Medical Device Directive (MDD), Council Directive 93/42/EEC of June 14, 1993 Annex II, 3 on Medical Devices of the European Parliament.	
Standards:	DIN EN ISO 10524-1 DIN EN ISO 10524-4 DIN EN 1041 DIN EN 62366-1 DIN EN ISO 14971 DIN EN ISO 15223-1	DIN EN ISO 5359 DIN EN 13554-2 DIN EN ISO 780 ISO 10993-1 ISO 15001

Notified Body:	DNV Medcert GmbH / CE 0482
Adress:	Pilatuspool 2, 20355 Hamburg; GERMANY
Certificate No.:	4153DE410200327 Expiration date: 05/2024
Traceability:	Traceability via serial number
Valid from/to:	27-03-2020 Until expiration date
Manufacturing Representative:	Jens Meincke
Position:	Quality Management / Regulatory Affairs
Date of issue:	03-04-2020

15 Manufacturer Information

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