Operating Manual

Quality Connect low-pressure hose system

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CE 0482

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Version 2.4.

Contents

* Subject to technical changes!

1 Foreword

These operating instructions are intended to assist you in using the Quality Connect low-pressure hose system. The operating instructions are divided into individual chapters.

Please note:

- Before using this product for the first time, read these operating instructions carefully and completely.
- Always act in accordance with the instructions given in the operating instructions.
- Keep these operating instructions close to the product.

2 Basic requirements

Proper and intended usage:

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

2.1 Purpose

Low-pressure hose system for medical gases, for coupling into a tapping point or gas-type specific screw coding, DIN, NIST, DISS; colour coding and gas-type specific according to DIN EN ISO 5359.

2.2 Accessories / variants

Products and accessories are only permitted with ISO colour coding. In Germany, Austria and Switzerland, products with colour-neutral labelling are also permitted

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.

Standard / norm	Title
DIN EN ISO 780	Packaging – Delivery packaging – Graphic symbols for handling and storing packages
DIN EN ISO 15223-1	Medical devices – Symbols to be used in the labelling of medical devices, marking and information to be provided – Part 1: General requirements
DIN EN 1041	Information provided by the manufacturer of medical devices
DIN EN ISO 5359	Anaesthetic and respiratory equipment – Low-pressure hose systems for use with medical gases
DIN EN ISO 9170-1	Tapping point for medical gas pipeline systems – Part 1: Tapping points for medical compressed gases and vacuum
DIN 13260-2	Supply systems for medical gases – Part 2: Dimensions and assignment of plugs and gas-type specific connection points for tapping points
DIN EN 13544-2	Respiratory therapy equipment – Part 2: Hose systems and connectors; German version EN 13544-2:2002+A1:2009
DIN EN ISO 14971	Medical devices – The application of risk management to medical devices
DIN EN 62366-1	Medical devices – Part 1: Application of usability to medical devices

ISO 10993-1	Biological evaluation of medical devices – Part 1: Assessments and inspections as part of a risk management system
ISO 18562-1	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
ISO 15001	Anaesthetic and respiratory equipment - Compatibility with oxygen

3 Safety information – Warnings, precautions and identification information

Symbol	Description
CE 0482	This symbol indicates that the device complies with the regulation 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	CAUTION is used to indicate a potentially hazardous situation which, if not avoided, may result in property damage.
	Manufacturer
	Date of manufacture
	Marking of packaging material, symbol for "protect from moisture"
	UDI Unique Device Identification
	Medical device
	Batch number

SN	Serial number
REF	Catalogue number
NON STERILE	Not sterile
	Temperature range
 or 	Refers the user to the necessity of consulting the operating instructions.
	DO NOT USE OIL

4 Before initial usage

Read all instructions before use!

This operating manual is intended to show trained professionals how to install and operate the device. They promote safety and protect your device from damage. If you do not understand information or instructions in this document, do not use the device and contact your supplier.

4.1 Safety notes

 WARNING

- **Intended usage / user**
- The low-pressure hose should only be operated by trained medical professionals under the direct supervision of a licensed physician.
- The low-pressure hose may only be used for the purpose described in this operating manual.
- The configuration of the overall system and the verification of its functionality are the responsibilities of the medical staff.
- The functionality and suitability of the product for the respective application must be checked by the user before each use (especially the connection parts, tightness

and suitability with regard to material, working pressure and flow rate)!

- **Maintenance / repairs**
- 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. There is a danger of fire and explosion due to the compressed gas. This product must be kept free of oils, greases, lubricants and hand creams (especially when processing oxygen and nitrous oxide).
- Observe the fire protection regulations when processing gases that promote combustion.
- If leaks are detected in this product, contact the customer service department immediately.
- When attaching an accessory, check the connector to make sure it is connected tightly and securely!
- There is a danger of fire due to escaping oxygen! Do NOT use this product near flames, flammable/explosive substances, vapours or gases.
- Never smoke in an area where oxygen is being used.
- Do not exceed the 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 the original accessories and spare parts!
- **Danger: Risk of injury!**
- A worn or damaged product can cause injuries. Only use this product when it is in perfect condition!
- **Danger: Property damage!**
- Make sure that no mechanical forces can act on the connection hose, hose connectors and tapping plugs. Mechanical forces could lead to malfunctions or damage!
- Never use contaminated tapping plugs!
- The plug-in valve can be damaged if an incorrect tapping plug is connected.
- **Danger: Malfunction!**
- Do not subject the product to torsional forces; this will impair the functionality. Attach accessories only when there is no torsion, pulling or tensile load!
- **Danger: Environmental conditions**
- If the temperature exceeds or falls below the ambient temperature range during transport and/or storage, then we cannot guarantee the accuracy, function, mechanical strength or seal of this product.
- **Danger: Health hazard!**

- For the screw connection on the device side, pay attention to the type of gas and the tight fit of the connection.
- ***When using oxygen, a kink in the connection hose could interrupt the oxygen supply. The connection hose must <u>not</u> be kinked!***
- An improperly secured product could loosen and cause injuries.
- **Danger: Reduced performance!**
- The length and inner diameter of the product being used can influence the maximum amount of gas available. Check the gas quantity actually available at the tapping device!
- **Cleaning:**
- Do NOT sterilize.

5 Technical specifications

CAUTION

- **Do not permanently expose the low-pressure hose to temperatures above 50 degrees!**
- **Do not expose low-pressure hoses to tensile/pulling forces exceeding 1000 N!**

Product	Quality Connect
Classification according to Medical Device Directive 93/42/EEC	Class IIa
Requirement	According to DIN EN ISO 5359
Connection types	Gas-type specific plug or screw connections in accordance with the applicable national standards and norms
Inlet	Angle connector – specific to the gas type, according to DIN 13260 part 2 or other gas-type specific screw connection
Outlet	NIST fitting – specific to the gas type according to DIN EN ISO 5359 Or other gas-type specific screw connection

Hose identification	Colour coding according to DIN EN ISO 5359 (ISO 32), Imprint of the type of gas and date of hose manufacture
Rated supply pressure for compressed gases	400 kPa to 500 kPa ±10
Pressure drop	< 500 mbar at 3.2 bar and 200 l/min
Maximum operating pressure	14 bar
Bursting pressure	According to ISO 5359: 5600 kPa at 23°C and 4000 kPa at 40°C
Temperature: Transport and storage	-15°C to 50°C (The hose may not be permanently exposed to temperatures above 50°C.)
Temperature: Operations	-15°C to 50°C (The hose may not be permanently exposed to temperatures above 50°C.)
Miscellaneous	Anti-static resistance < 10^6 Ω/m NF EN ISO 8031
Identification of the hose: Serial number, LOT, GTIN / UDI, CE marking, date of manufacture, expiry date, safety symbols	

5.1 Variants

Short text	Assignment of gas type to colour
Connection hose O_2 (neutral)	Black
Connection hose O_2 – ISO 32 colour-coded	White
Connection hose AIR (neutral)	Black
Connection hose AIR – ISO 32 colour-coded	Black/white
Connection hose AIR/O_2 colour-coded	Black/white
Connection hose AIR/O_2 (neutral)	Black
Connection hose VAC (neutral)	Black
Connection hose VAC ISO colour-coded	Yellow
Connection hose CO_2 ISO colour-coded	Grey
Connection hose N_2O ISO colour-coded	Blue
Connection hose spiral (neutral)	Black

6 Initial commissioning, installation and service life

CAUTION
• **Please refer to the manufacturer's documentation for the operation of the tapping plugs and the connection devices.**

6.1 Initial commissioning:

Checking the device:

- You should carry out a wipe-down disinfection before the device is first used.
- Check that the product is in working order and has no contamination or damage.

6.2 Installation:

When installing the central gas supply (ZGV) hose, make sure that the inlet connector locks into place on the gas connection. The outlet connector with union nut has to be screwed tight by hand and completely screwed to the consumer connection.

CAUTION
• **Do not kink the gas hose.** • **The outlet connector with union nut has to be screwed tight by hand and completely screwed to the consumer connection**

6.3 Service life:

Information:

The service life of the hose is intended to be **max. 10 years** according to ISO 5359.

7 Instructions for cleaning and care

CAUTION
• Please be sure to observe the application instructions from the detergent and disinfectant manufacturer. Also, follow the currently applicable hygiene regulations for the hospital. • Do not use disinfectants that are based on phenols or halogen-releasing or oxygen-releasing agents! Use surface disinfectants based on aldehydes and quaternary ammonium compounds. These are included in the current list from the "German Society for Hygiene and Microbiology". • **Caution**: improper cleaning and disinfection may result in property damage. • **NOT** suitable for sterilization. • **Never** disassemble this product.

- **NEVER** immerse the low-pressure hose in liquids.
- Do **NOT** use strong solvents or abrasives.
- Do **NOT** clean with aromatic hydrocarbons.

Basic information:

This product must be cleaned and wipe disinfected after each use.
Parts that come into contact with the patient's breathing air must be disinfected.

This product should not have contact with oil, grease or flammable liquids: this would create a risk of fire.

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

Described product:
Quality Connect

WARNINGS:	Do not use disinfectants containing phenol. Do not use strong solvents or abrasive cleaners. Do not clean with aromatic hydrocarbons. Do not autoclave! Do not sterilize! Do not immerse in liquids!
The medical device manufacturer for preparing a medical device for reuse has validated the instructions listed as SUITABLE. 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 has to be wiped clean at regular intervals or at the latest after each patient in accordance with the applicable hygiene standard.
Preparation for decontamination:	Disconnect the unit from the gas supply before cleaning and disinfection.
Cleaning: Manual	For this process: 1. Wipe the outside of the product with a lint-free cloth soaked in alcohol (isopropanol 99.9%) or detergent. When doing so, do not allow any liquid to enter the inside of the hose or the tapping point. 2. Wipe dry with a dry, lint-free cloth.
Disinfection: Manuell	3. Wipe the outside of the product with a lint-free cloth soaked in disinfectant. When doing so, do not allow any liquid to get inside the hose or the tapping point.

	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 the device with a dry, lint-free, low-germ cloth. Do not allow any liquid to get inside the hose or the tapping point.
Manufacturer 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 has to be performed after each cleaning and disinfection.
Packing:	▪ The device must be kept in the packaging validated by DEHAS for transport.
Storage:	▪ Temperature/humidity: -15°C to 50°C (Do not permanently expose the hose to temperatures above 50°C). ▪ Store the product in a dry, clean place free from lubricants, oil and other contaminants.
Transport:	▪ Temperature/humidity: -15°C to 50°C (The hose should not be permanently exposed to temperatures above 50°C).
Additional information:	N/A
Contact:	DEHAS Medical Systems GmbH, Wesloer Straße 107-109, 23568 Lübeck Tel.: +49 451 80904-0, Fax: +49 451 80904-111, E-Mail: info@dehas.de

Visual and functional tests has to be carried out after each cleaning and disinfection.

8 Inspection and 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.

8.2 Carrying out maintenance and inspections

The following maintenance procedures and inspections shall be carried out:

- Inspection and maintenance -> semi-annually by the user
- Replacing the O-ring, flat sealing ring **->** every 2 years by a trained user or the manufacturer
- Repairs -> only by trained, authorized specialists or the manufacturer

The device should be cleaned regularly after use and checked for signs of damage. The performance should also be monitored. Furthermore, all seals used in the device must be checked regularly to make sure that they are in perfect condition and functioning properly. They should be replaced when necessary.

8.3 Leakage test

A dummy fitting should be connected to the outlet connection. Then, the hose system should be subjected to the following specified test pressures for a minimum of 60 seconds. The following test pressures shall be applied to the hose:

- For hoses used for compressed medical gases: 1400 kPa
- For hoses used for vacuum: 500 kPa

The leakage must then be measured.

8.4 Malfunctions and troubleshooting

Error	Possible source of error	Troubleshooting
No or reduced output at the tapping device	Hose is leaking	Check the connection hose and replace if necessary
	Connection hose is kinked / damaged	Notify the technical service department
	System is leaking	
	Central gas supply system has failed	
Gas is escaping at the screw connection	Seal on the screw connection is defective	Replace the seal Notify the technical service department
	Screw connection is not tightened	Check the screw connection and re-tighten if necessary
Gas escapes at the tapping points when the tapping plug of the connection hose is connected	The seal at the tapping point is defective	Notify the technical service department Establish a supply at another tapping point Replace the seal on the plug valve. If necessary, replace the plug valve completely.
The tapping plug of the connection hose cannot be inserted into the tapping point	Connection hose and tapping plug have not been properly selected or the tapping plug is damaged.	Check connection hose and tapping plug. Use correct connection hose if necessary.
	Tapping point is for the wrong type of gas.	Use the correct tapping point
	Tapping point is defective or contaminated.	Notify the technical service department. Have the tapping point checked.
The screw connection cannot be tightened	Screw connection is incorrect	Check the screw connection
	The thread is damaged	

9 Warranty

The warranty period for this product is 12 months, starting from the date of sale, in accordance with the following conditions:

If, within the applicable period, a device defect should occur, then the dealer shall – after written notification thereof and substantiation that the device has been stored, installed, maintained and operated in accordance with the instructions of the dealer and in accordance with standard industry practice, and that no modifications, substitutions or changes were made to the product – correct such a defect by suitable repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE A WARRANTY.

The dealer is not authorized to make oral warranties about the merchandise described in this contract. Any such statements are not binding and not part of the sales contract. Thus, this written second statement is a final, complete and exclusive statement of the contractual terms.

– Subject to technical changes!

10 Product returns

Please contact your retailer concerning this. They will help to coordinate the return. It is important that you provide a description of the error or malfunction so that the return can be processed effectively. All returns must be shipped in sealed containers to prevent damage. The specialist retailer is not responsible for any devices that are damaged during transport.

11 Disposal

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

This device and its packaging contain no hazardous materials. No special precautions are required when disposing of the device and its packaging.
Please recycle.

EG-Konformitätserklärung

EC Declaration of Conformity

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

Produkt/	**ZGV Anschluss-Schläuche; Steckverbindungen für med. Gase und Vakuum; Geräte Schlauchverbindungen**
***Medical product*:**	*Central gas supply tubes; connectors for medical gases and vacuum; device hose connections*
Klassifikation/ *Classification*:	**IIa** Regel 2, Anhang IX, Medizinprodukterichtlinie 93/42/EWG *Rule 2, 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 15223-1
	EN ISO 14971	EN ISO 9170-1	EN ISO 9170-2
	DIN 13260-2	EN 13544-2	EN 62366-1
	ISO 10993-1	EN ISO 10524-1	EN ISO 10524-3
	EN ISO 15001	EN ISO 7396-1	DIN EN ISO 18082
	ISO 18562-1		
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		
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12 Manufacturer specifications

Manufacturer:

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