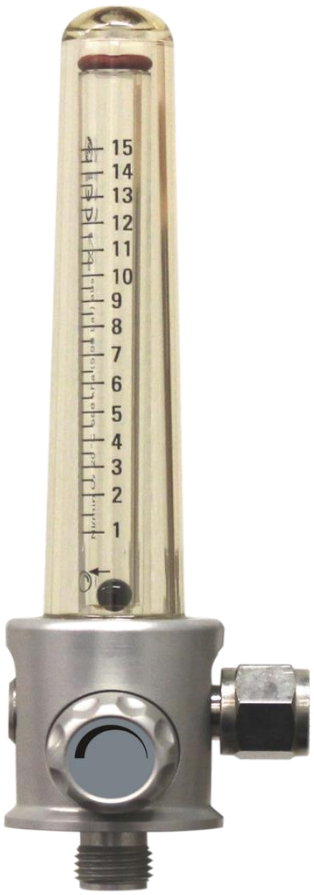
Instructions for use

Quality Flowmeter



Save these instructions!

CE 0482

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Version 2.1

CONTENT

Rev. 2.1 Version 28.01.2025

1. Preface

This user manual is intended to make it easier for the user to handle the device. Please keep this information in a safe place.

2. Purpose

The flow meter is used for precise control of oxygen or air flow for medical purposes in the low-pressure range (depending on the model).

This product is designed for use in homecare applications, hospitals, other clinical environments, and emergency services.

3. Safety information, warnings, precautions and labeling instructions

Symbol	Description
CE 0482	The symbol indicates that the device complies with the requirements of Regulation 93/42/EEC concerning medical devices and all applicable international standards.
 **WARNINGS**	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
 **CAUTION**	When this symbol is used, it indicates a potentially hazardous situation which, if not avoided, may result in material damage.
 or 	Indicates the need for the user to consult the instructions for use
	DO NOT USE OIL (keep oil and grease-free)
	Identifies the manufacturer of the medical device in accordance with EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC
	Date of manufacture
	Unique Device Identification
	Medical Device
	Non-sterile

4. Before first use

Read all instructions before use!

These instructions provide professionals with guidance on installation and operation. They are intended for your safety and to protect the device from damage. If you do not understand any information or instruction in this manual, do not use the device and contact your supplier.

WARNINGS
This product is not intended for use as a life-saving or life-sustaining device.

WARNINGS
Read the entire user manual before you or any third party use this device or demonstrate the use of this flow meter to third parties. As with all medical devices, using this device without a thorough understanding of its operation could lead to injury to the patient or the user. • **Medical gases are or should be considered as pharmaceuticals and should only be used for medical purposes as prescribed by a physician or authorized clinician and only according to their instructions.** • **The flow meter may only be operated by medical, trained personnel under the direct supervision of an approved physician.** • **The flow meter is not MRI-compatible!** • **The product with the outer tube is NOT intended for hanging equipment or bags!** • **The flow meter may only be used for the purpose described in this user manual.** • **The flow meter may only be repaired and serviced by qualified and authorized service technicians.** • **After unauthorized disassembly of the product or its components by the user, the manufacturer cannot guarantee the intended, reliable functionality.** • **Disassembly of the product for cleaning by the user is not provided by the manufacturer (see Chapter 9).** • **Sterilization of the product is not provided by the manufacturer.** • **Ensure that the medical gas supply is sufficient for the prescribed therapy and is within the pressure range specified in the device specification. If the supply is from a gas cylinder, regularly check the cylinder contents gauge.** • **This flow meter may only be used with the medical gas specified on the device label. Before use, ensure that the gas cylinder or supply contains the correct medical gas. Always verify that the flow meter is connected to the correct gas-specific supply outlet.** • **Gas-specific connectors are attached to the flow meter. Do not attempt to adapt these connectors to other gases or fittings.** • **Always adhere to EN and DIN standards for medical gas products, flow meters, and safe handling of oxygen.**

- **Do not remove the flow meter while it is under pressure.**
- **Secure the gas cylinder according to local safety regulations to a wall, stand, or cart with the appropriate holder. Do not stand in front of a flow meter or regulator outlet when opening a gas cylinder valve.**
- **Do not allow any liquid to enter this device.**
- **The accuracy of the flow meter can be significantly affected if the input pressure does not match the technical specification indicated on the device label (flow meter). Please note that the flow meter is calibrated to an input pressure of 4.5 bar.**
- **Do not directly connect the flow meter outlet to another pressure gas source, as this may damage either gas supply (e.g., connecting an O2 oxygen flow meter to an AIR/Luft flow meter via a Y-piece to mix their outputs).**
- **Only use this flow meter when the flow tube is in the intended vertical position. Otherwise, incorrect flow rates may be displayed or the device may lose its function.**
- **Ensure that the flow control valve is not obstructed or clogged and that there is no unintended pressure present. In such cases, temporary changes in gas flow may occur.**
- **Arrange the gas supply hoses carefully to avoid damage to the hoses and tripping hazards. Never pull or exert excessive force on the gas hoses as this may damage them. A leaking hose can lead to high local oxygen or other gas concentrations and thus increase the risk of fire.**

Oxygen itself is not flammable; however, the presence of an enriched oxygen concentration in the environment drastically increases the rate and severity of combustion. Oil and/or grease in the presence of an oxygen-enriched atmosphere become easily flammable. Therefore, it is important that oxygen never comes into contact with oil, grease, or other petroleum-based substances. The device must be kept oil- and grease-free!

• Do not smoke near oxygen equipment

• NOT suitable for sterilization / autoclaving

• DO NOT use if contaminated

• DO NOT clean with aromatic hydrocarbons

Caution:

The performance of the flow meter may be affected if stored or transported at temperatures outside the range of -20°C to +50°C.

The performance of the flow meter may be affected if the flow control valve is tightened too firmly when shutting off the flow (adjustment knob). Apply minimal force by turning the control knob required to shut off the gas flow.

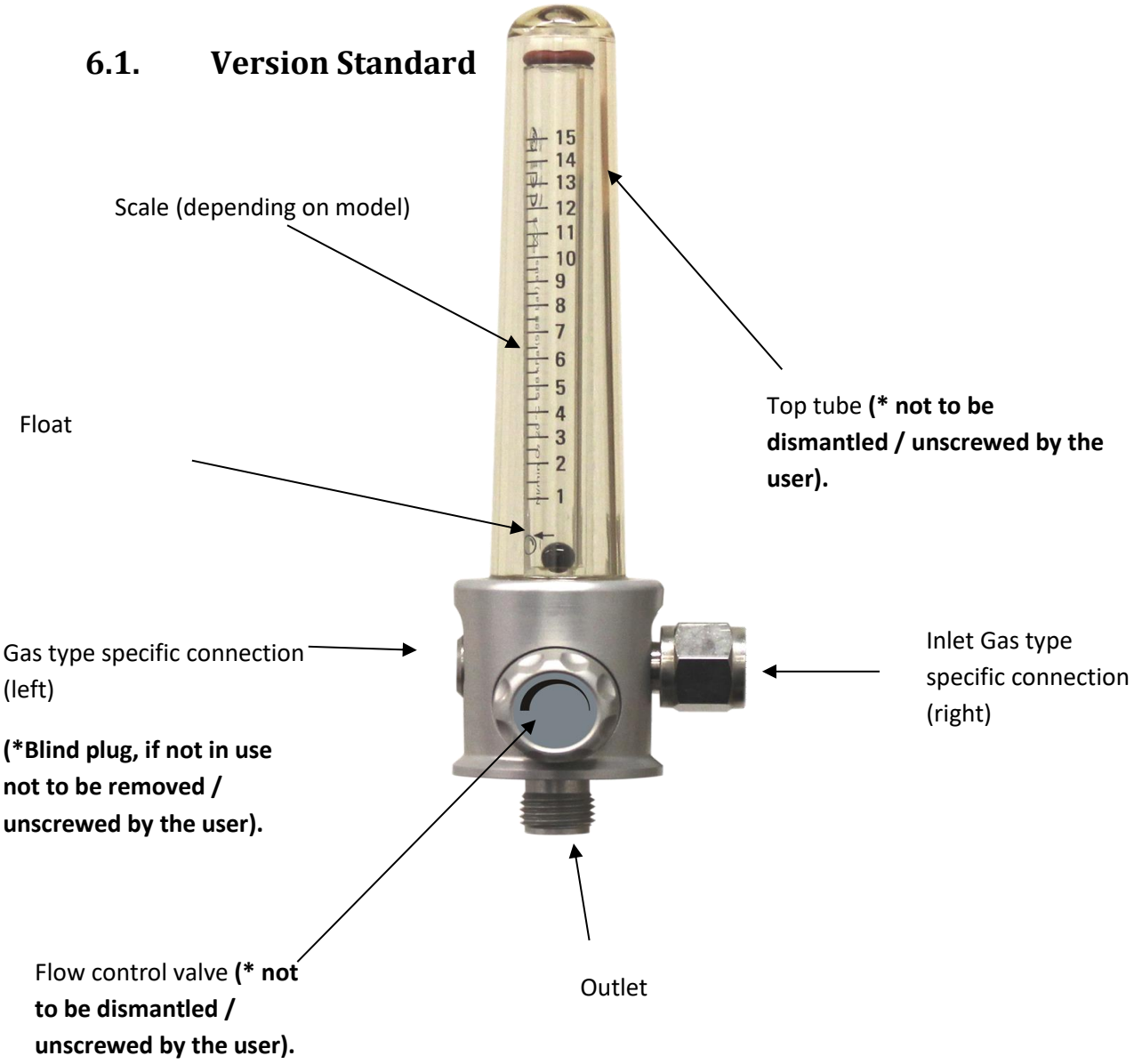
5. Performance data

Construction type:	Pressure-compensated flowmeter for medical gases. Display based on the variable area principle.
Material:	Body: Aluminum / stainless steel Flow tube: Polycarbonate (PC)
Accuracy:	Nominal pressure: ±10% or 0.5 l/min (whichever is greater) of the measured value display Temperature: 3% increase or decrease in flow rate for every 5°C increase or decrease in temperature Inlet pressure: 4% increase or decrease for every 10 kPa increase or decrease in pressure compared to the nominal pressure
Inlet pressure range/ supply pressure range:	450 kPa ± 50 kPa
Medical gases:	O2, AIR, O2/AIR. O2/NO, O2/N2O
Inlet:	G1/4”, DIN, NF, AGA, BS, Uni probe, NIST, adapter 9/16-18 UNF union nut to M8x1 external thread (if the flow meter is mounted on the gas mixer).
Output:	9/16“-18 UNF, Hose nippel, external thread G1/4”, G 3/8 “, 9/16 “ UNF
Power: Scaling	Vom Modell abhängig: 0 - 1 l/min 0 - 3 l/min 0 - 6 l/min 0 - 15 l/min 0 - 16 l/min 0 - 32 l/min 0 - 85 l/min
Ambient influences:	Transport and storage temperature: -20°C to +50°C Operating temperature: 0 °C to +50 °C Humidity: 0-95% RH non-condensing
Standards:	ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems ISO 15001 Anaesthetic and respiratory equipment. Compatibility with oxygen

	ISO 5359 Low pressure hose assemblies for use with medical gases EN ISO 14971 Medical devices. Application of risk management to medical devices EN ISO 15223-1 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements

6. Functional description

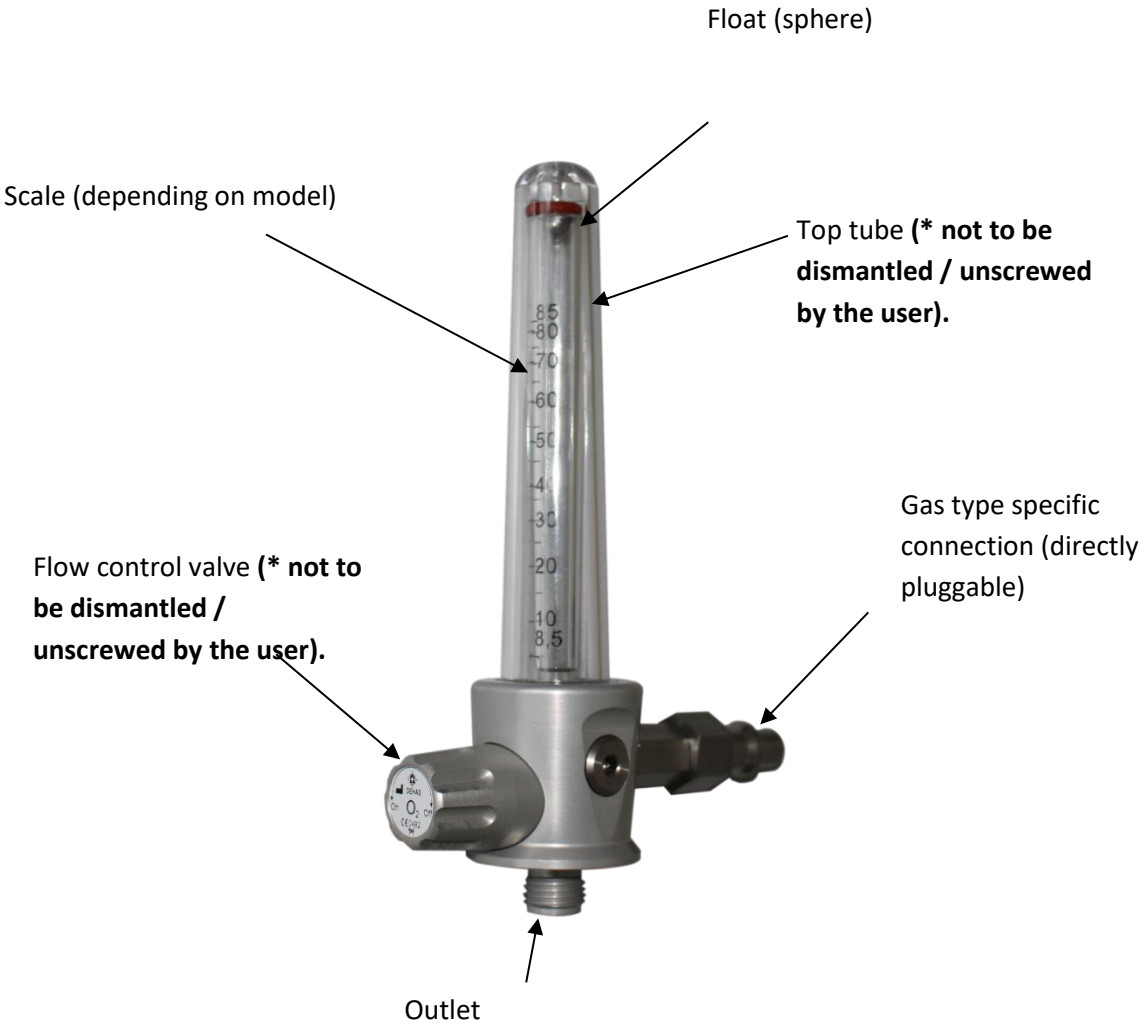
6.1. Version Standard



This illustration shows the Quality Flowmeter Standard version

***If there are any doubts about the tightness or functionality, please contact the medical technology department (see Chapter 12, Troubleshooting).**

6.2. Direct plug-in version



This illustration shows the version of the Quality Flowmeter directly pluggable (specific plugs DIN; NF; BS; SS; AGA: CH, Carbamed; UNI)

*** If there are any doubts about the tightness or functionality, please contact the medical technology department (see Chapter 12, Troubleshooting).**

7. General technical description

The flow meter enables precise control of oxygen or air flow for medical purposes in the range of 0 to 85 l/min (depending on the model). A precision-made rotating ball rises within a transparent measuring tube (floating ball principle). A scale is printed on the measuring tube, indicating the flow rate of the gas in liters per minute (l/min). The gas flow (throughput) through the measuring tube is regulated by a downstream valve.

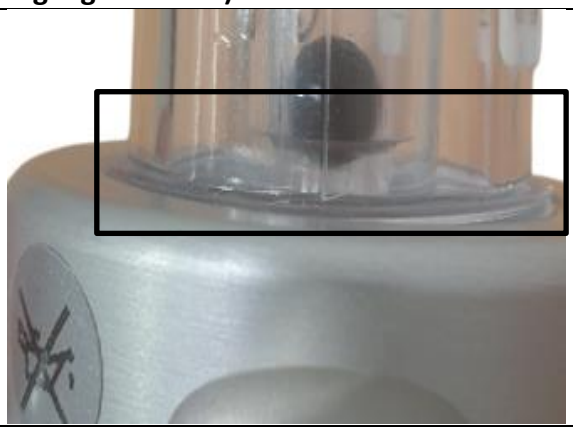
The flow meter is designed for connection to, for example, an air-oxygen mixer. However, it can also be operated as a "standalone" device for direct connection to the medical gas supply, such as an outlet point.

8. Important notes before use

Before each use, visually check the flow meter for:

- **Damage to the product**
- **Incorrect assembly (outer tube incorrectly inserted into the base body; sealing ring in the base body is pinched; components are missing)**
- **Contamination**

If the device has been damaged by a fall or impact during use, please immediately notify the medical technology department. A fall or impact on the product may cause a sealing ring or the outer tube of the flow meter to shift, potentially resulting in an unintended leakage.

Correct: Top tube is correctly inserted into the main body.	**Incorrect: The Top tube is inserted diagonally into the main body (see highlighted area).**
	

Do not connect or use the device if there are any doubts about its condition.

Before use, ensure that the operating pressure of 4.5 bar of medical gas specified by the manufacturer is used to operate the flow meter.

9. Operation

WARNINGS
Safety instructions to prevent accidents while using an oxygen extraction device: **The user is responsible for ensuring that the enrichment of the room or ambient air with a volume fraction > 21% O2 is avoided.**

9.1. Connection to the gas supply

The flow meter is supplied with a gas-specific connection designed for connection to a suitable gas-specific outlet. Gas specific outlets can be an end unit (tapping point socket) in a medical gas line system or part of a pressure regulator outlet on a gas cylinder.

If you are using a gas cylinder supply, make sure that the contents of the gas cylinder are sufficient for the planned therapy or treatment and switch on the supply at the gas cylinder. An inlet pressure of 4.5 bar is required to operate the flow meter.

Direct plug-in flow meter:

Align the flow meter to the intended vertical position. For a directly pluggable flow meter, connect the gas-specific quick connector to the corresponding gas-specific outlet. For quick connector connections (e.g., BS; DIN; NF; SS, AGA, CH; UNI), ensure the connection is properly made by gently pulling on the flow meter housing or hose (if applicable) before turning on the supply pressure.

Flow meter with gas-specific screw thread.

Align the flow meter to the intended vertical position.

For a threaded connection, tighten the connection fully by hand (do not use tools) before turning on the supply pressure.

9.2. Activation of gas flow

The flow meter must be completely closed (default setting) before activating the gas flow from the gas supply. Verify this by gently turning the adjustment knob of the flow meter clockwise until you feel slight resistance. Be careful not to overtighten and damage the adjustment valve by applying excessive force.

9.3. Connection to terminals or patients:

Connect the other end of the oxygen tubing system to the patient or the environment (devices) with the appropriate connector.

9.4. Adjusting the flow

Now, slowly turn the flow control valve (adjustment knob) counterclockwise to activate the gas flow and increase it to the desired setting.

If the flow meter does not function properly, remove it from operation and promptly report the product to your medical technology department.

9.5. Reading the flow meter correctly:

The set flow rate is read at the marking on the scale for the floating ball (top of the floating ball).

9.6. During use

Continuously monitor the gas flow and the gas cylinder level (if applicable) during therapy or treatment, ensuring a secure supply and checking that the supply hose (if applicable) is not kinked and does not pose a tripping hazard.

9.7. After the use

To put the flow meter in the inactive state, gently turn the control knob clockwise until you feel resistance. Be careful not to overtighten and damage the adjustment valve by applying excessive force. Pay attention to the ball in the flow meter; it should now indicate a value of 0.

If the supply is done through a gas cylinder, the cylinder valve must be closed after the treatment or therapy, and the flow meter must be removed.

10. Cleaning and disinfection

Ensure that the flow meter is disconnected from the gas supply before cleaning and disinfecting the product!

CAUTION
• **NOT suitable for sterilization / autoclaving.** • **DO NOT disassemble the flow meter. After disassembly, the manufacturer cannot guarantee the safe operation of the product. If the flow meter needs to be disassembled for cleaning the inner tube (flushed with compressed air), inform the medical technology department.** • **NEVER immerse the device in liquids.** • **DO NOT use strong solvents or abrasives.** • **DO NOT clean with aromatic hydrocarbons.**

The outer surface of the device must be cleaned and disinfected at regular intervals or at least after each use with the patient according to the applicable hygiene standards. If you suspect that the flow meter is contaminated, remove it from operation and report the device to the appropriate medical technology department. Never immerse the flow meter in liquid and do not attempt to disassemble the product or clean internal parts.

Cleaning and disinfection steps:

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

23568 Lübeck	**Do not autoclave!** **Do not sterilize!**	

Described Product:

Quality Flowmeter

WARNHINWEISE:	**Do not use phenol-containing disinfectants.** **Do not use strong solvents or abrasives.** **Do not clean with aromatic hydrocarbons.** **Do not autoclave!** **Do not sterilize!** **Do not immerse in liquids!**
The instructions listed have been validated as SUITABLE by the medical device manufacturer for the preparation of a medical device for reuse. 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.	

INSTRUCTIONS	
Preparation for decontamination:	**The outer surfaces of the device must be cleaned by wiping with disinfectant at regular intervals or at least after each patient, according to the applicable hygiene standards.**
Cleaning: Manual	**Für diesen Vorgang:** **1. Before cleaning, disconnect all gas connections from the device.** **2. Wipe the outer surface of the flow meter with a cloth soaked in alcohol.** **3. Dry with a dry cloth.**
Disinfection: **Manual**	**1. Before disinfection, disconnect all gas connections from the device.** **2. Wipe the outer surface of the flow meter with a cloth soaked in disinfectant.** **3. Observe the exposure time specified by the disinfectant manufacturer according to the required spectrum of activity.** **4. After the exposure time specified by the disinfectant manufacturer, wipe the device with a dry cloth.**
Manufacturer's recommendation:	**The manufacturer recommends using the disinfectant Bacillol® 30 Foam, Bacillol® 30 Tissues, Bode Chemie GmbH & Co. The current product data sheet of the disinfectant manufacturer must be observed.**

11. Service

11.1. Inspection / controls

The flow meter should be regularly cleaned, inspected for damage (before and after each use), and checked for performance. The frequency of inspections and performance checks (leakage test and flow test) depends on the usage. If the flow meter is used daily, a complete performance check may need to be performed every six months. For infrequent use, an annual inspection may be sufficient.

Leakage test

Connect the flow meter to a medical low-pressure gas supply with a nominal supply pressure (4.5 bar) as indicated on the device's nameplate, and close the flow control valve (adjustment knob). Connect the supply hose to the outlet of the flow meter and submerge the other end of the supply hose in water. The presence of gas bubbles in the water indicates a leak. A flow meter that fails these tests should not be used anymore and must be sent to the manufacturer.

Flow Test

Check the flow rates at all flow settings according to the specification, i.e., within ±10% or 0.5 l/min (whichever is higher) at 1 l/min and above.

11.2. Service and repair

Maintenance and repair of the product should only be carried out by trained and authorized technical departments. The performance of maintenance measures and inspections depends on the type of usage, usage conditions, and intensity of use. The intervals are to be determined by the user. However, the flow meter should be regularly cleaned, checked for signs of damage, and its performance verified (see above).
Additionally, all silicone seals (O-rings) used in the device must be regularly inspected for proper condition and function, and replaced if necessary. A period of 2 years is recommended by the manufacturer DEHAS.
For flow meters with indirect connection, the hose should be replaced according to the manufacturer's specified date for replacement. The manufacturing date can be found on the hose's device label.

11.3. Checking the sealing ring in the base body and checking the correct fit of the Top tube

Process step	Description	
1	Hold the flow meter in a vertical position.	
2	To check that the sealing ring is correctly seated in the base body, carefully unscrew the Top tube from the base body. Set the Top tube with the large red O-ring aside. Remove the flow meter tube from the base body and remove the ball from the flow meter measuring tube (scale). Please set both aside.	
3	Hold the flow meter in a vertical position and now check whether the thin sealing ring in the base body is tight against the base and tight against the thread of the base body and is not wavy or twisted. If this is the case, realign it.	
4	Take the flow meter measuring tube (scale) and carefully flush the inside with medical compressed air.	

5	Before reassembly, check that the small O-ring at the lower end of the flow meter measuring tube (scale) is undamaged and present.	
6	Now place the float (ball) in the flow meter tube.	
7	Now insert the flow meter measuring tube (scale), firmly into the base body until resistance is felt. The scale must be aligned in the direction of the adjustment knob (facing the user).	
8	Before fitting the measuring tube (scale), carefully flush the inside with medical compressed air.	
9	Now make absolutely sure that the black O-ring in the base body seals when inserting the Top tube and is not squeezed out of the sides. If this is the case, reposition the O-ring to the correct starting position.	

10	Now place the Top tube over the flow meter tube and carefully screw the Top tube clockwise into the thread of the base body. Due to a fine thread, only screw on hand-tight, do not overtighten.	
11	Now make absolutely sure that the large red O-ring inside the Top tube sits straight between the Top tube and the flow meter.	
12	Clean the product as described in chapter 10.	

12. Troubleshooting

Error	Possible cause	Solution to the problem
No gas flow	Flow meter is not connected correctly	Check the gas supply. Check that the gas-specific connection is connected correctly.
	Gas cylinder empty, Gas pressure too low	Change the gas cylinder. Check the gas supply.

	The medical gas terminal unit of a piping system is not connected / active.	Seek advice from someone who is authorized to operate the shut-off valves of the medical gas supply system (medical technology department).
	Inlet filter is blocked	Repair necessary (medical technology department)
Audible leakage	Seal is worn or damaged	Leakage test with leak detection spray. Repair may be necessary; sealing ring must be replaced (medical technology department).
	Pressure relief valve leaking because the inlet pressure is too high	Check that the gas supply pressure is within the 4.5 bar specification of the appliance.
	Top tube is cracked or damaged. This can be caused by a fall or impact damage.	Repair necessary. Top tube must be replaced (medical technology department).
	Top tube is inserted crookedly into the base body	Repair necessary. Top tube must be screwed correctly and straight into the base body (medical technology department). For repair / correction see chapter 11.3.
	Connection worn or damaged.	Repair necessary; replacement of the connection required (Medical Technology department)
	Connection / blind plug is not firmly screwed into the base body	Repair necessary. The connection or blanking plug must be screwed firmly into the base body (Medical Technology department).
	Gas supply hose is damaged	Replacement necessary. Replace the connection hose (Medical Technology department).
Existing gas flow despite closed regulator valve	Regulator valve or valve seat damaged	Repair necessary. Please contact the manufacturer or authorized service representative (medical technology department).
Measured set flow rate outside the tolerance values	Top tube of the flow meter is not screwed on correctly / Top tube is inserted crookedly into the base body	Please inform a trained specialist from the medical technology department. Leakage test with leak detection spray. Check that the Top tube is screwed straight and hand-tight onto the base body. The O-ring in the base body must not be pinched. For repair / correction, see chapter 11.3. If in doubt, report this to the manufacturer for repair.
	O - ring in the main body dome has slipped.	Please inform a trained specialist from the medical technology department. For repair / correction, see chapter 11.3. Leakage test with leak detection spray. Check whether the O-ring in the base body dome seals properly.

13. Articles and spare parts

Articel:

Item numbers	Description / Version / Performance
D-B-FL-1	Quality Flowmeter 0 – 1 l/min
D-B-FL-3	Quality Flowmeter 0 – 3 l/min
D-B-FL-6	Quality Flowmeter 0 – 6 l/min
D-B-FL-15	Quality Flowmeter 0 – 15 l/min
D-B-FL-16	Quality Flowmeter 0 – 16 l/min
D-B-FL32	Quality Flowmeter 0 – 32 l/min
D-B-FL-85	Quality Flowmeter 0 – 85 l/min

Spare parts:

Item numbers	Description
D-EM019681	Blanking plug base body
D-EM016583	Adapter 9/16-18 UNF union nut to M8x1 male
D-EM028496	O - ring base body
D–0232900	Top tube

14. Customer service / warranty

14.1. Warranty

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

Should a defect in the appliance occur within the applicable period, the dealer shall, upon written notice thereof and upon proof that the appliance has been stored, installed, maintained and operated in accordance with instructions and standard industry practices and that no modifications, substitutions or alterations have been made to the product, correct such defects by appropriate repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE A WARRANTY.

Dealer is not authorized to make any oral warranties about the Product described in this Agreement, and such statements are not binding and do not form part of the sales contract. Therefore, this 2nd statement is the final, complete and exclusive statement of the terms of the contract.

- Subject to technical changes!

14.2. 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 can be processed appropriately. All returns must be sent in sealed containers to prevent damage. The retailer is not responsible for devices that are damaged during transportation.

15. Disposal

This device and its packaging do not contain hazardous substances. No special precautions are required when disposing of the device and/or packaging. Please clean and disinfect before disposal and then recycle.

16. Declaration of Conformity

DECLARATION OF CONFORMITY

DEHAS Medical Systems GmbH
Wesloer Straße 107-109
23568 Lübeck
GERMANY

CE 0482

REF Quality Mix Flowmeter (all variants)

Classification: IIa

Classification 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 on the premises of the manufacturer and the notified body.

Directives: General application guidelines: Medical Device Directive (MDD), Council Directive 93/42/EEC of June 14, 1993 Annex II, 3 on medical devices of the European Parliament.

Applied standards:

EN 1041	ISO 18562-1
EN ISO 14971	ISO 18562-2
EN ISO 15001	ISO 18562-3
EN ISO 15002	ISO 10993-1

Notified Body:	DNV Medcert GmbH / CE 0482
Adress:	Pilatuspool 2, 20355 Hamburg; GERMANY
Zertifikatsnummer:	4153DE410200327 Expiration date: 05/2024
Traceability:	Traceability via serial number
Valid from/to:	27-03-2020 until expiration date
Manufacturing representative:	Quality Manager
Position:	Quality Systems
Date of issue:	03-04-2020

17. Manufacturer information

Manufacturer	DEHAS Medical Systems GmbH Wesloer Straße 107-109 23568 Lübeck Germany Phone: +49 451 80 90 4 - 112 Fax: +49 451 80 90 4 - 111 Email: Info@dehas.de Homepage: www.dehas.de	CE 0482

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