

OPERATING INSTRUCTIONS

MEDAP BUBBLE HUMIDIFIER

MEDAP 



Subject to technical modification!

Illustrations and technical specifications may vary slightly from those in these Operating Instructions as a result of ongoing product development.

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Table of contents

| | | |
|----------|--|-----------|
| 1 | Introduction | 5 |
| 1.1 | Foreword | 5 |
| 1.2 | How to use these operating instructions | 5 |
| 1.2.1 | Abbreviations | 5 |
| 1.2.2 | Symbols | 5 |
| 1.2.2.1 | Cross-references | 5 |
| 1.2.2.2 | Actions and responses | 5 |
| 1.2.3 | Definitions | 6 |
| 1.2.3.1 | Design of safety notes | 6 |
| 1.2.3.2 | Structure of notes | 6 |
| 1.3 | Symbols used..... | 6 |
| 1.4 | Disposal..... | 7 |
| 1.4.1 | Packing | 7 |
| 1.4.1.1 | ATMOS products | 7 |
| 1.5 | Overview | 8 |
| 1.6 | Basic requirements..... | 8 |
| 1.6.1 | Use in accordance with the intended purpose | 8 |
| 1.6.2 | Applicable standards..... | 8 |
| 1.6.3 | Intended purpose | 9 |
| 1.6.3.1 | Possible applications | 10 |
| 1.6.4 | Interface description..... | 10 |
| 1.6.4.1 | Dimensions for the gas type specific connection for compressed gas | 10 |
| 2 | Safety notes | 12 |
| 2.1 | General safety notes | 12 |
| 2.2 | Product safety notes..... | 13 |
| 3 | Initial operation..... | 15 |
| 3.1 | Equipment inspection | 15 |
| 3.2 | Mounting..... | 15 |
| 3.2.1 | General | 15 |
| 3.3 | Connection to a flowmeter and inhalation system..... | 16 |
| 3.3.1 | Connection of the LS FLOW O2 flowmeter | 16 |
| 3.3.2 | Connection of the S FLOW O2 flowmeter..... | 16 |
| 3.3.3 | Connection of the FINA FLOW O2 flowmeter | 17 |
| 3.3.4 | Connection of O2 pressure reducing valve with flowmeter | 17 |
| 4 | Operation | 18 |
| 4.1 | Functional test..... | 18 |
| 4.2 | Working with the product..... | 18 |
| 5 | Taking the unit out of operation..... | 19 |



5.1 Procedure 19

5.2 Disassembly of bubble humidifier 19

6 Cleaning and disinfection 20

6.1 General 20

6.2 Cleaning 21

6.2.1 General 21

6.2.2 Cleaning procedure 21

6.3 Disinfection 21

6.3.1 General 21

6.3.2 Suitable disinfectants 22

6.3.3 Disinfection procedure 22

6.3.4 Disinfection procedures 22

6.4 Product-specific safety notes 23

6.5 Assembly after cleaning and disinfection 23

7 Maintenance 24

7.1 General 24

7.2 Malfunctions and troubleshooting 24

7.3 Period tests 24

7.4 Repairs 24

7.5 Service hotline: 24

7.6 Type plate 25

7.7 Sending in the device 25

8 Technical specifications 26

8.1 General data 26

8.2 Ambient conditions 26

8.3 Technical specifications 26

8.4 Dimensions and weight 26

8.5 Relative and absolute humidity in relation to the flow 27

9 Approved accessories 28

9.1 Accessories 28

1 Introduction

1.1 Foreword

Your facility has selected the leading-edge medical technology made by ATMOS. We sincerely appreciate the trust you have placed in us.

1.2 How to use these operating instructions

These operating instructions are provided to familiarise you with the features of this ATMOS product. They are subdivided into several chapters.

Please note:

- Please read these operating instructions carefully and completely before using the product for the first time.
- Always proceed in accordance with the information contained herein.
- Store these operating instructions in a location near the product.

1.2.1 Abbreviations

| | |
|-----|---|
| EN | European standard |
| EEC | European Economic Community |
| VDE | Verband der Elektrotechnik Elektronik Informationstechnik (Association for Electrical, Electronic & Information Technology) |

1.2.2 Symbols

1.2.2.1 Cross-references

References to other pages in these operating instructions are identified with a double arrow symbol „»»“.

1.2.2.2 Actions and responses




The „☒“ symbol identifies an action taken by the user while the „✓“ symbol identifies the reaction that this will induce in the system.

Example:

- ☒ Turn on the light switch.
 - ✓ Lamp lights up.

1.2.3 Definitions



1.2.3.1 Design of safety notes

| Pictogram | Descriptor | Text |
|---|--|--|
|  | DANGER! Indicates a direct and immediate risk to persons, which may be fatal or result in most serious injury. | The text for the safety note describes the type of risk and how to avert it. |
|  | WARNING! Indicates a potential risk to persons or property which may result in health hazard or grave property damage. | |
|  | CAUTION! Indicates a potential risk to property which may result in property damage. | |

Tab. 1: Design of safety notes




1.2.3.2 Structure of notes








Notes not referring to personal injury or property damage are structured as follows:

| Pictogram | Descriptor | Reference to |
|---|--------------------|---|
|  | NOTE | Supplementary assistance or further useful information without potential injury to persons or property damage is described in the text of the note. |
|  | ENVIRONMENT | Information regarding proper disposal. |

Tab. 2: Structure of notes

1.3 Symbols used

| Symbols | Identification |
|---|--|
|  | Labelling for products which were developed and are marketed in compliance with the 93/42/EEC Medical Products Directive. Class Is, Im, IIa, IIb and III products are also marked with the identifying number for the notified body. |
|  | Labelling in compliance with the ISO 15223-1 standard. Symbol for "Product number". |
|  | Labelling in compliance with the ISO 15223-1 standard. Symbol for "Name and address of the manufacturer as well as date of manufacture". |

| Symbols | Identification |
|---|---|
|  | Labelling in compliance with the ISO 15223-1 standard. Symbol for "Serial number". |
|  | Labelling in compliance with the ISO 15223-1 standard. Symbol for "Follow Operating Instructions". |
| >PSU< | Material designation for the plastic PSU (polysulphone). |
|  | Packaging label. Symbol for "Keep dry". |
|  | Packaging label. Symbol for "Fragile! Handle with care". |
|  | Labelling in compliance with the ISO 15223-1 standard. Symbol for "Temperature limitations". |
|  | Labelling in compliance with the ISO 15223-1 standard. Symbol for "Relative humidity". |
|  | Labelling in compliance with the ISO 15223-1 standard. Symbol for "Atmospheric pressure". |

Tab. 3: Symbols

1.4 Disposal



WARNING!

Infection hazard!

The product or some of its components may be contaminated after use.

Clean and disinfect the product before disposal.

1.4.1 Packing

The packing is made of materials compatible with the environment. ATMOS will dispose of the packing materials upon request.

1.4.1.1 ATMOS products

ATMOS will take back used products or those which are no longer in service.

Please contact your ATMOS representative for more detailed information.

1.5 Overview

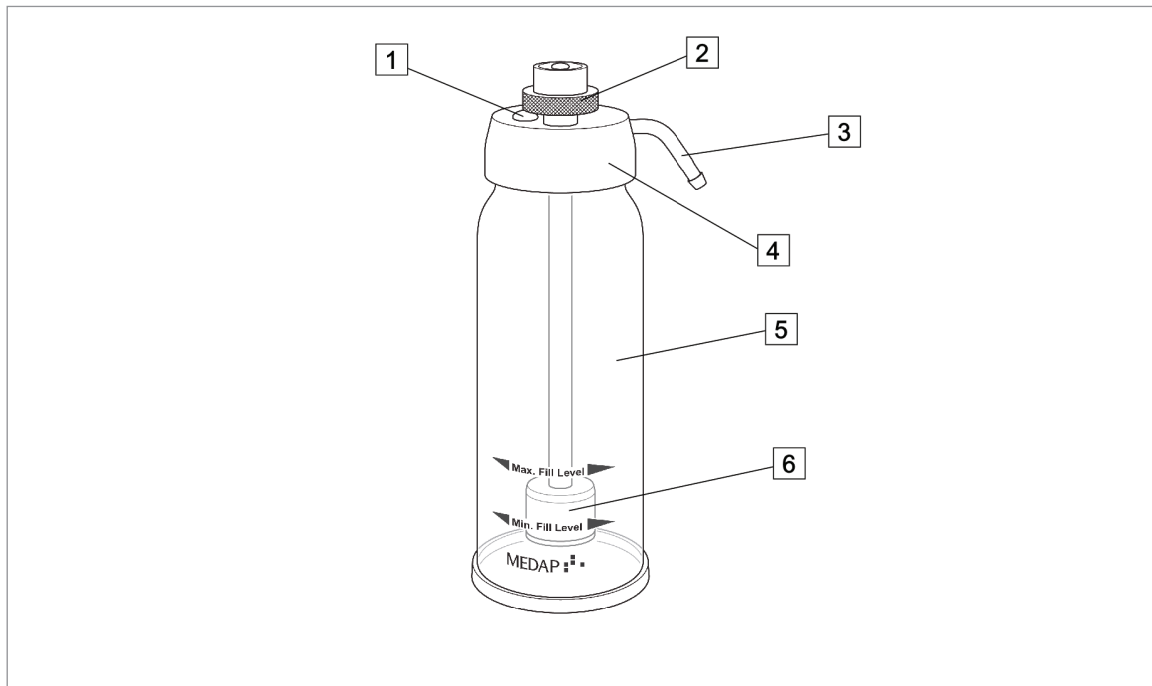


Fig. 1: Overview of bubble humidifier

- | | |
|-------------------------|-------------------------|
| 1 Pressure-relief valve | 4 Bubble humidifier cap |
| 2 Knurled nut | 5 Humidifier bottle |
| 3 Connector | 6 Bubbler |

1.6 Basic requirements

1.6.1 Use in accordance with the intended purpose

Product

As per appendix IX of the Medical Products Directive 93/42/EU this product belongs to class IIa.

In accordance with this directive the product may only be used by persons who have been instructed how to use this product by an authorised person.

This product is to be used exclusively for human medicine.

When employed in a commercial or business use, this product shall be entered in the inventory.

Accessories

Accessories or combinations of accessories may be utilised only as and when indicated in these operating instructions.

Other accessories, combinations of accessories and consumable items may be used only if they have a valid certification, are intended expressly for the particular use and will not adversely affect performance, the prescribed ambient conditions or safety requirements.

1.6.2 Applicable standards

The product satisfies the basic requirements set forth in Annex I to the 93/42/EU Directive drafted by the Medical Products Council (Medical Products Directive) as well as the applicable national (German) codes and the Medical Products Act in Germany. This has also been demonstrated through the application of the corresponding standards, which have been harmonised with the 93/42/EEC Directive.

1.6.3 Intended purpose

| | |
|-------------------------------------|--|
| Name: | Bubble humidifier |
| Main function: | The bubble humidifier is designed to humidify oxygen within the scope of an inhalation therapy. |
| Medical indications / application: | Humidification of the oxygen coming out of a central gas supply system or an oxygen cylinder |
| Specification of the main function: | <p>The bubble humidifier is connected to the outlet of a flowmeter. The flowmeter is supplied with medical oxygen either via the terminal unit oxygen of a central gas supply system or via a gas cylinder.</p> <p>The oxygen coming from the flowmeter is transmitted through the sputterer of the bubble humidifier. The patient is supplied with the humidified oxygen via inhalation accessories corresponding to the specific use.</p> <p>Connection of the bubble humidifier is made to a central oxygen supply with a supply pressure of 300 to 500 kPa +/-10 % or to the pressure regulator of a gas cylinder, whereby the initial pressure of the pressure regulator lies between 300 and 500 kPa +/-10 %.</p> |
| User profile: | Doctor, medically trained staff |
| Patient groups: | Patients of all ages |
| Application organ: | Lung |
| Application time: | For continuous operation; in practice short-term use on the patient (< 30 days) |
| Application site: | The application site is the clinical environment and doctor's practices. The application of the product may only be performed by medically trained and introduced staff. |
| Contraindications: | <p>The bubble humidifier may not be used for the following purposes:</p> <ul style="list-style-type: none">• Outside the medical sector• In MR areas• In the home care sector• Being operated directly by the patient• For patients, whose nose, mouth and throat have been bypassed• For connection to respiratory systems• For connection to incubators• In neonatology• For the nebulization of medicaments• For gases other than medical oxygen• With central gas supply systems with other supply pressures than 300 to 500 kPa +/-10 % <p>The humidifier bottle may not:</p> <ul style="list-style-type: none">• Be used as septic fluid jar for aspirations• Come into contact with strong acids and bases |
| The product is: | Not active |
| Sterility: | No sterile product |

Single-use product /
reprocessing:

The device and parts of the accessories are reusable. For information on reprocessing, cleaning and disinfection please see the operating instructions.

1.6.3.1 Possible applications

The bubble humidifier is designed for connection to an oxygen flowmeter (FINA FLOW O2, S FLOW O2, LS FLOW O2 and O2 pressure regulator with flowmeter).

Connection to O2 flowmeter:

Here the adapter UNF 9/16" - G 3/8" REF 5752 2745 is used. The flow of volume supplied to the bubble humidifier is regulated by:

- S FLOW O 15
- S DFLOW O 15
- LS FLOW O 15
- LS DFLOW O 15
- FINA FLOW O 15
- FINA DFLOW O 15

Connection to O2 pressure reducing valve with flowmeter:

Here the adapter UNF 9/16" - G 3/8" REF 5752 2745 is used. The flow of volume supplied to the bubble humidifier is regulated by O2 pressure regulator with flowmeter 0-15 l/min.

All the components of the humidifier can be reused following appropriate conditioning. Only devices or parts which are approved by ATMOS for combination in accordance with the accessory list or in accordance with the mounting point description may be used in conjunction with the humidifier.

The unit may only be operated by medical personnel who have acquired relevant skills through appropriate medical training and who can, on the basis of professional experience and instruction in regulations relevant to safety, evaluate the work they carry out and can recognise potential risks which may arise during the work.

The bubble humidifier is suitable for continuous operation, i.e. long-term applications (> 30 days) are possible. The devices may only be used by temperatures between +15 °C to +30 °C and relative humidity 30 to 75 % and be transported and stored at temperatures between -15 °C to +50 °C and relative humidity between 10 and 95 %.

The geometric gas coding for the input screw connection of the humidifier depends on the MEDAP standard, O2: G3/8".

1.6.4 Interface description

All devices and accessories which are combined with the product must be listed in the accessories list or meet the specifications of the interface description. The configuration of the overall system as well as the functional testing are subject to the overall responsibility of the medical staff. Functionality and suitability of the connected accessory for each intended application must be checked by the operator before every use. This includes the functionality of the connector components, its air tightness and suitability regarding material properties, working pressure and flow rate.

1.6.4.1 Dimensions for the gas type specific connection for compressed gas

Humidifier input

The geometric gas coding for the input screw connection of the humidifier depends on the MEDAP standard (O2 corresponds to inside thread G3/8").

Only use a flowmeter with precise flowmeter regulation and the ability to exactly dose the respiratory gas.

Humidifier output

A respiratory tube with a internal diameter of 5 mm suitable for the specific application.

Inhalation accessories

Inhalation accessories (e.g. O₂ mask, O₂ funnel) matching the respiratory tube or connection over a catheter adapter (3.5 mm) for O₂ nasal probe and O₂ cannula.

2 Safety notes

2.1 General safety notes

**DANGER!**

Defective product!

Using incorrect spare parts and accessories can cause injuries or equipment failure.

Only use original accessories or spare parts.

**DANGER!**

Dosing!

When applying oxygen and respiratory air in their function as a medication, it is absolutely necessary to measure the flow rate, as per the monograph in the European Pharmaceuticals Reference.

**DANGER!**

Danger to life!

The undosed supply of gases is hazardous to the patient.

Use only tapping units with dosing system.

**DANGER!**

Fire/explosion hazard!

Air, oxygen and oxygen compounds react explosively with oils, greases and lubricants. Fire and explosion hazard due to compressed gases.

Keep product free of oils, greases, lubricants and hand cream. Only use lubricants which are approved by ATMOS. Observe fire protection regulations when dealing with combustion-enhancing gases. Contact Technical Services about any leakages in the product.

**DANGER!**

Fire hazard!

Fire hazard as a result of escaping oxygen.

Never smoke near equipment which carries oxygen and avoid using open fires or glowing objects. Check tight fitting and firm seat of the connector when mounting accessories.

**DANGER!**

Fire hazard!

The product may ignite if the maximum operating pressure or the maximum operating temperature is exceeded.

Do not exceed the maximum operating pressure or maximum operating temperature.

**WARNING!**

Risk of injury!

Worn or damaged products can cause injuries.

Use only products which are in perfect condition.

2.2 Product safety notes**DANGER!**

Danger to life!

The user must check the functionality and suitability of the components for the respective application.

**DANGER!**

Incorrect use can result in fatalities!

Instructions for using components made by other manufacturers are not part of these operating instructions.

Ensure that the manufacturer's instructions are followed.

**CAUTION!**

Property damage!

Exposure to UV rays can cause material fatigue. The stability would no longer be ensured.

Do not expose the product to strong UV light.

**DANGER!**

Health hazard!

Pay attention that the product is connected to the appropriate gas type and that the screw connection is firmly seated.

**WARNING!**

Risk of injury!

Hazard resulting from incorrect handling.

Follow the operating instructions for all accessories.

**WARNING!**

Malfunction!

No mechanical forces of the connected accessory may affect the product in order to avoid functional failures or damages.

**WARNING!**

Ambient conditions!

If the ambient temperature range specified for shipping, operation and/or storage conditions is not maintained, then no guarantee can be assumed for the accuracy, mechanical strength or sealing of the product.

**WARNING!**

Configuration of the overall system!

The configuration of the overall system as well as the functional testing are subject to the overall responsibility of the medical staff. The operator must check proper functionality and suitability of the product for each intended application before every use, in particular connection parts, tightness and suitability concerning material, work pressure and flow rate.

**WARNING!**

Risk of injury!

Products which are improperly mounted can loosen and cause injuries.

Mount the product properly.

3 Initial operation

3.1 Equipment inspection

**DANGER!**

Product testing!

Only product parts which are in perfect condition can ensure proper functioning of the product. The product parts will thus have to be carefully inspected before mounting.

**WARNING!**

Infection hazard!

Contaminated components may endanger the health of the staff and the patients.

Ensure the product is prepared as per hygiene standards before using it for the first time.

**NOTE**

In order to ensure the functionality, carry out a functional check prior to use.

- Ensure that the unit has been properly cleaned and that there are no residues or soiling.
- Ensure proper functionality of the unit.
- Ensure that product components made of plastic and rubber are in perfect condition and show no signs of ageing.
- Do not use damaged parts.

3.2 Mounting

3.2.1 General

**WARNING!**

Configuration of accessory!

The structure of the products connected before and after the bubble humidifier is crucial for proper functioning. Use of improper accessory will reduce the tapping unit's performance or even cause the unit to fail.

All upstream and downstream products must be listed in the list of accessories or comply with the interface description.

**WARNING!**

Tensile forces!

The connected accessories must not exert any mechanical forces which could adversely affect the secure seating of the product.

**WARNING!**

Tensile forces!

Hold the basic unit with one hand when installing or removing accessories in order to compensate for the tensile forces which are created.

**NOTE**

Refer to the manufacturer's instructions for information on using the connected units.

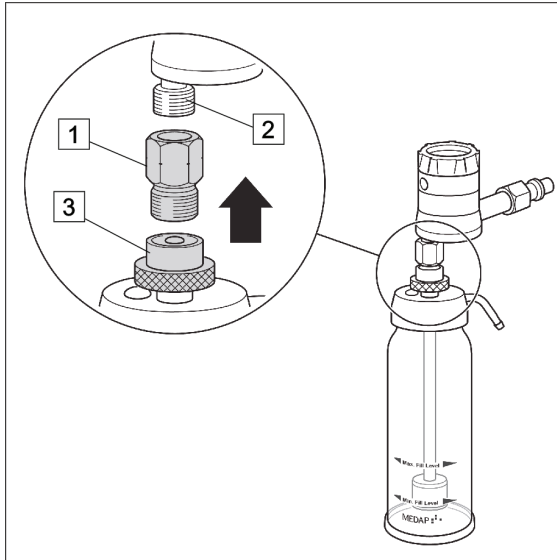
3.3 Connection to a flowmeter and inhalation system**3.3.1 Connection of the LS FLOW O2 flowmeter**

Fig. 2: Connection of the LS FLOW flowmeter

- ☒ Ensure that the adapter contains a flat gasket.
- ☒ Ensure that the cap nut of the humidifier contains a flat seal.
- ☒ Fill the humidifier bottle up to the marking "Max. filling level" with distilled water and screw the bubble humidifier cap into place.
- ☒ Screw adapter (1) to the flowmeter output (2) and tighten finger-tight until stop.
- ☒ Screw cap nut (3) of the bubble humidifier to the adapter and tighten finger-tight until stop.
- ☒ Pay attention that no tensile forces affect the bubble humidifier.

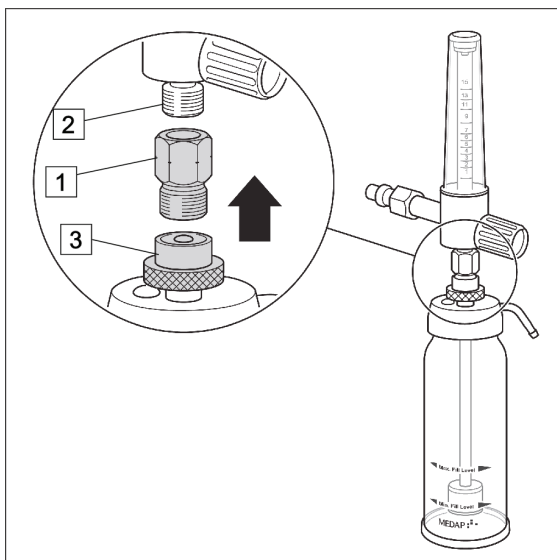
3.3.2 Connection of the S FLOW O2 flowmeter

Fig. 3: Connection of the S FLOW flowmeter

- ☒ Ensure that the adapter contains a flat gasket.
- ☒ Ensure that the cap nut of the humidifier contains a flat seal.
- ☒ Fill the humidifier bottle up to the marking "Max. filling level" with distilled water and screw the bubble humidifier cap into place.
- ☒ Screw adapter (1) to the flowmeter output (2) and tighten finger-tight until stop.
- ☒ Screw cap nut (3) of the bubble humidifier to the adapter and tighten finger-tight until stop.
- ☒ Pay attention that no tensile forces affect the bubble humidifier.

3.3.3 Connection of the FINA FLOW O2 flowmeter

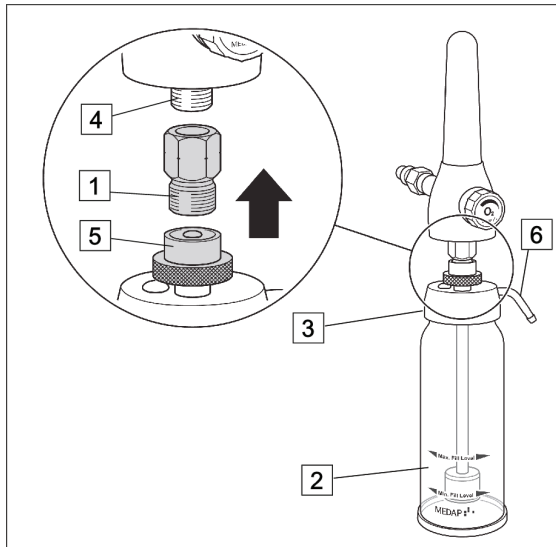


Fig. 4: Connection of the FINA FLOW flowmeter

- ☒ Ensure that the adapter (1) contains a flat gasket.
- ☒ Ensure that the cap nut of the humidifier contains a flat seal.
- ☒ Fill the humidifier bottle up to the marking "Max. filling level" (2) with distilled water and screw the bubble humidifier cap (3) into place.
- ☒ Screw adapter to the flowmeter output (4) and tighten finger-tight until stop.
- ☒ Screw cap nut (5) of the bubble humidifier to the adapter and tighten finger-tight until stop.
- ☒ Connect inhalation accessory to the connector (6) using a connection tube ($\varnothing = 5 \text{ mm}$).
- ☒ Pay attention that no tensile forces affect the bubble humidifier.

3.3.4 Connection of O2 pressure reducing valve with flowmeter

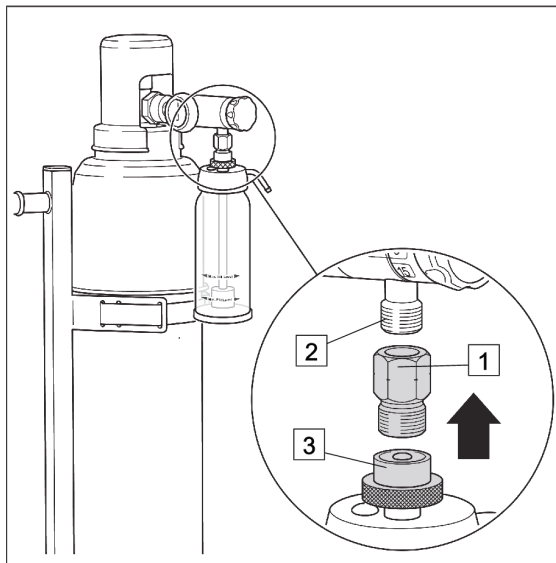


Fig. 5: Connection of O2 pressure reducing valve with flowmeter

- ☒ Ensure that the adapter contains a flat gasket.
- ☒ Ensure that the cap nut of the humidifier contains a flat seal.
- ☒ Fill the humidifier bottle up to the marking "Max. filling level" with distilled water and screw the bubble humidifier cap into place.
- ☒ Screw the adapter (1) onto the connector (2) on the pressure reducer and tighten it finger-tight until it stops.
- ☒ Screw cap nut (3) of the bubble humidifier to the adapter and tighten finger-tight until stop.
- ☒ Pay attention that no tensile forces affect the bubble humidifier.

4 Operation

4.1 Functional test

**DANGER!**

Functional check!

The product is used in the treatment of patients. Any restriction in the unit's performance can result in serious complications in treatment.

Perform a complete functional check every time before using the unit.

4.2 Working with the product

**DANGER!**

Incorrect use can result in fatalities!

Using drugs in the bubble humidifier is not permitted.

Regular operation

- Exchange distilled water at least every 24 hours and after every patient.
- Fill humidifier bottle only up to the maximum filling level (Indication "Max. filling level").
- Regularly monitor the filling level (min. filling level) and refill if necessary.
- Open oxygen supply at the flowmeter and set flow according to the doctor's instructions.

5 Taking the unit out of operation

5.1 Procedure

Taking the unit out of operation

- Close the oxygen supply when treatment is completed.
- Undertake preliminary disinfection before reconditioning the bubble humidifier.

5.2 Disassembly of bubble humidifier

- Remove the inhalation accessories.
- Unscrew the bubble humidifier from the flowmeter.
- If necessary unscrew the adapter from the bubble humidifier cap.
- Unscrew the bubble humidifier cap.
- Unscrew the sputterer from the bubble humidifier cap.
- Empty the humidifier bottle.
- Clean and disinfect the unit components.

6 Cleaning and disinfection

6.1 General

The product must be cleaned as well as disinfected after every use.



DANGER!

Risk due to incorrect use of detergents and disinfectants!

It is strictly advised to observe the manufacturer instructions regarding how to use the detergents and disinfectants as well as the valid hospital hygiene rules.



DANGER!

Infection hazard!

Product may be contaminated.

Always wear gloves for cleaning / disinfection.



DANGER!

Infection hazard!

Particles of grime may become encapsulated and lead to the product not reaching the desired germ-reduction after disinfection.

Before disinfection, the product must be cleaned thoroughly of contamination and encapsulated particles of grime.



CAUTION!

Improper cleaning and disinfection can cause property damage!

Do **not** use the following products for cleaning and disinfection:

- Products containing alcohol (e. g. hand disinfectants)
- Halogenides (e. g. fluorites, chlorides, bromides, iodides)
- Dehalogenating compounds (e. g. fluorine, chlorine, bromine, iodine)
- Products that may scratch the surface (e. g. scouring agents, wire brushes, wire wool)
- Standard commercial solvents (e. g. benzene, thinner)
- Water containing iron particles
- Cleaning sponges containing iron
- Products containing hydrochloric acid

Use a soft, lint free cloth or a soft nylon brush to clean the product.



CAUTION!

Improper cleaning and disinfection can cause property damage!

Use only as much detergent and disinfectant as required.



CAUTION!

Improper cleaning and disinfection can cause property damage!

After each cleaning and disinfection process, carry out the functionality test.

6.2 Cleaning

6.2.1 General



NOTE

Use only all-purpose cleaners which are slightly alkaline (soap solution) and contain tensides and phosphates as the active cleaning agents.

In the event of heavily contaminated surfaces, use concentrated multi-purpose detergent.



CAUTION!

Improper cleaning can cause property damage!

Residues of physiological saline solutions (e. g. sodium chloride) can attack the surfaces of the product.

Remove residues of physiological saline solutions with a cloth dipped in clean water. Then dry the product with a dry, lint free cloth.



CAUTION!

Improper cleaning can cause property damage!

Do not spray cleaning agent directly into the joints or gaps and never use a high-pressure cleaning unit!

6.2.2 Cleaning procedure

- Use the correct dose of multi-purpose detergent with water for the degree of surface contamination and in accordance with the instructions of the detergent manufacturer.
- Thoroughly wipe off the product with a soft cloth slightly wetted in a multi-purpose detergent solution.
- Ensure that the product is free of contamination and encapsulated particles of grime.
- Thoroughly wipe off the product with a soft cloth dipped in clean water.
- Ensure that the product is free of detergent residues.
- Dry product with a dry, absorbent and lint free cloth.
 - ✓ This will help to reduce pathogen growth on the product's surface.
- Disinfect the product after every cleaning process.

6.3 Disinfection

6.3.1 General



NOTE

In the event of product surfaces that are very dirty, carry out an additional cleaning procedure before disinfecting.



DANGER!

Reduced performance!

Only clean the product by manual disinfection.

Ensure that no disinfectants enter the unit. Check the functionality of the product after each disinfection.

**DANGER!**

Material damage due to excessive exposure times!

Exceeding the specified exposure time of the disinfectant may damage the surfaces.

Observe the specified exposure time of the disinfectant manufacturer.

6.3.2**Suitable disinfectants**

Only surface disinfectants based on the following combinations of active ingredients may be used for disinfection:

- Aldehydes
- Quarternary ammonium compounds
- Guanidine derivatives

| Ingredient group | Active ingredients |
|--------------------------------|--|
| Aldehydes | 2-ethyl-1-hexanal, formaldehyde, glutardialdehyde, glyoxal, o-phthaldialdehyde, succinaldehyde |
| Quarternary ammonium compounds | Alkyl-didecyl-polyoxethyl ammonium propionate, alkyl-dimethyl-alkylbenzyl ammonium chloride, alkyl-dimethyl-ethyl ammonium chloride, alkyl-dimethyl-ethylbenzyl ammonium chloride, benzalkonium propionate, benzalkonium chloride (alkyl-dimethyl-benzyl ammonium chloride, coco-dimethyl-benzyl ammonium chloride, lauryl-dimethylbenzyl ammonium chloride, myristyl-dimethyl-benzyl ammonium chloride), benzethonium chloride, benzyl-dihydroxyethyl-coco-alkyl ammonium chloride, dialkyl-dimethyl ammonium chloride (didecyldimethyl ammonium chloride), didecyl-methyl-oxyethyl ammonium propionate, mecetronium-ethyl sulfate, methyl-benzethonium chloride, n-octyl-dimethyl-benzyl ammonium chloride |
| Guanidine derivatives | Alkyl-biguanide, chlorhexidine-digluconate, cocospropylene-diamine guanidinium diacetate, oligomeric biguanide, polyhexamethylene biguanide hydrochloride (oligo-diimino imido-carbonyl imino-hexamethylene, polyhexanide) |

Tab. 4: Active ingredients of disinfectants

6.3.3**Disinfection procedure**

- Disinfect the product in accordance with the instructions of the disinfectant manufacturer after every cleaning process.
- Ensure that the product is free of disinfectant residue.
- Perform visual and functional inspections.

6.3.4**Disinfection procedures**

Different disinfection procedures may be used for the various components, depending on the properties of the materials.

| Components | Disinfection ¹ |
|---|---------------------------|
| Bubble humidifier cap | X |
| Sputterer | X ² |
| Humidifier bottle | X |
| ¹ After exposure (as prescribed in the manufacturer's instructions) remove disinfectant residues from the components using a moist cloth and dry them afterwards. ² The sputterer is resistant to most acids, saline solutions and organic solutions in liquid and gaseous state. The sputterer is resistant in alkaline range to pH 9 | |

Tab. 5: Disinfection procedures

6.4 Product-specific safety notes



NOTE

For notes on cleaning and disinfection of the connected components please refer to the respective operating instructions.

6.5 Assembly after cleaning and disinfection

- Fill the humidifier bottle up to the marking, maximum filling level.
- Screw the bubble humidifier cap to the humidifier bottle.
- Connect the humidifier bottle to the flowmeter with an adapter.
- Mount the inhalation accessories to the humidifier.

7 Maintenance

7.1 General

Maintenance, repairs and period tests may only be carried out by persons who have the appropriate technical knowledge and are familiar with the product. To carry out these measures the person must have the necessary test devices and original spare parts.

ATMOS recommends: Work should be carried out by an authorized ATMOS service partner. This ensures that repairs and testing are carried out professionally, original spare parts are used and warranty claims remain unaffected.



DANGER!

Health hazard!

The product is used in the treatment of patients. The product or some of its components may be contaminated.

Clean and disinfect the product before maintenance and repair. Repair work may be performed by personnel authorized by ATMOS.

7.2 Malfunctions and troubleshooting

| Defect | Source of malfunction | Corrective actions |
|------------------------------|---------------------------------|---|
| No or reduced humidification | Gaskets are missing / defective | Check / replace gaskets |
| | Knurled nut not tightened | Tighten knurled nut finger-tight |
| | Sputterer pores clogged | Check sputterer and have it replaced, if required |
| | Pressure-relief valve defective | Replace pressure-relief valve |
| | Flowmeter defective | Replace flowmeter |

Tab. 6: Corrective actions

7.3 Period tests

At least every 12 months a test must be performed.

7.4 Repairs

The following may require repairs from the manufacturer or an authorized service partner:

- The performance has significantly decreased.
- Abnormal noises occur.
- Functional faults cannot be rectified according to the measures in chapter Malfunctions and troubleshooting [▶▶ page 24].

If defects are detected the product may not be used any longer.

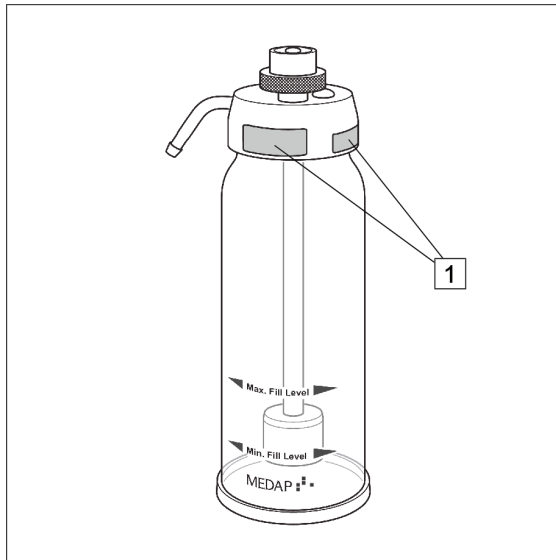
Make a note of the deficiencies and the REF number on the data plate and inform the responsible ATMOS Service.

Observe the information in chapter Sending in the device [▶▶ page 25].

7.5 Service hotline:

+49 7653 689-0

7.6 Type plate



Positions of the type plates (1) on the product.

Fig. 6: Type plate position

7.7 Sending in the device

- Remove and properly dispose of consumables.
- Clean and disinfect the product and accessories according to the operating instructions.
- Place used accessories with the product.
- Fill in the form QD 434 „Delivery complaint / return shipment“ and the respective **decontamination certificate**.

This form is enclosed with each delivery and can be found at www.atmosmed.com.

- The device must be well padded and packed in suitable packaging.
- Place the form QD 434 „Delivery complaint / return shipment“ and the respective **decontamination certificate** in an envelope.
- Affix the envelope to the outside of the package.
- Send the product to ATMOS or to your dealer.

8 Technical specifications

8.1 General data

| | |
|--|-----------|
| Classification as per Appendix IX of the 93/42/EEC Directive | Class IIa |
|--|-----------|

8.2 Ambient conditions

| | |
|--|---------------------|
| Temperature: Shipping / storage | -15 °C to +50 °C |
| Temperature: Operation | +15 °C to +30 °C |
| Gas temperature range | +15 °C to +30 °C |
| Relative humidity: Shipping / storage | 10 % to 95 % |
| Relative humidity: Operation | 30 % to 75 % |
| Atmospheric pressure: Shipping / storage | 700 hPa to 1060 hPa |
| Atmospheric pressure: Operation | 700 hPa to 1060 hPa |

8.3 Technical specifications

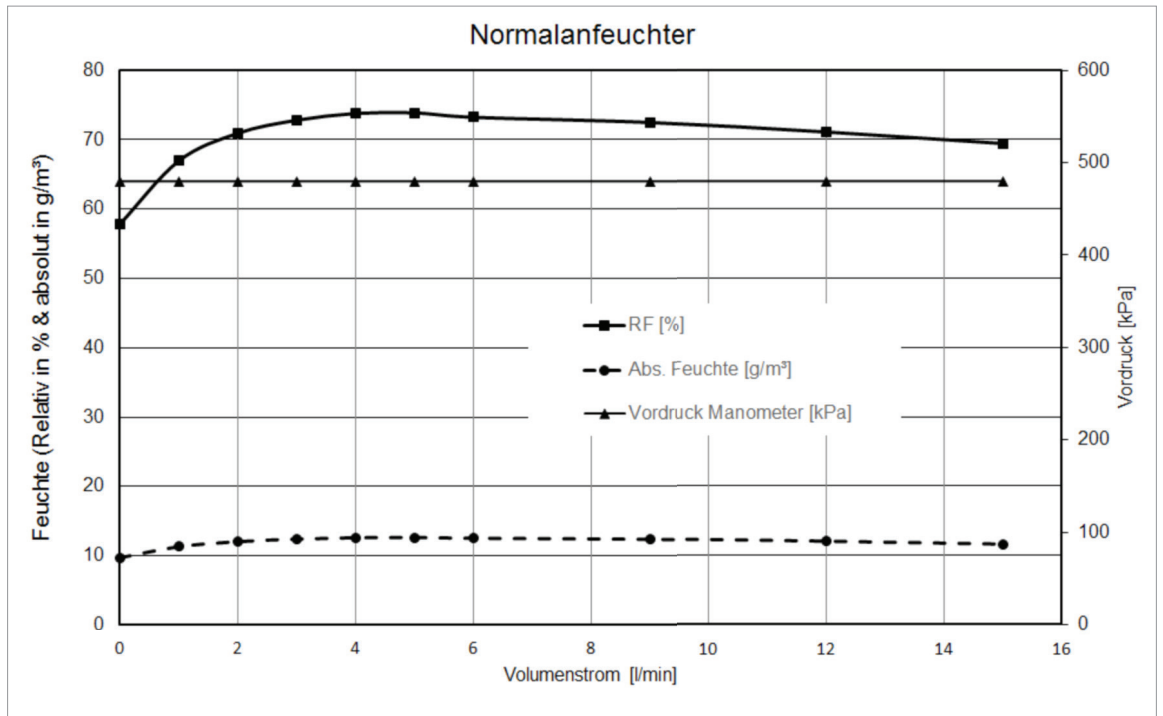
| | |
|---|---------------------|
| Operating pressure | 300–550 kPa* (±10%) |
| Maximum flow of O ₂ | 5–15 l/min |
| Opening the pressure-relief valve at | 110 kPa* (±10%) |
| Filling volume of distilled water | 100 ml |
| Connection thread of O ₂ flowmeter | G3/8" |
| Connecting nipple for tube | 5 mm |
| Sound pressure level | < 50 dB (A) |
| Leakage (ISO 5367) | 120 ml/min |
| Resistance at 15 l/min (ISO 5367) | 3,4 hPa/l/min |
| Compliance (ISO 5367) | 0,34 ml/hPa |

* 100 kPa = 1 bar = 1000 mbar = 750 mmHg

8.4 Dimensions and weight

| | |
|------------------------|-------------------|
| Dimensions (L x W x H) | 200 x 70 x 100 mm |
| Weight | 340 g |

8.5 Relative and absolute humidity in relation to the flow



9 Approved accessories

9.1 Accessories

The following accessories are not part of the scope of delivery and must be ordered separately.

| | |
|-----------|---|
| 5752 2745 | Adapter for humidifier and oxygen connection tube for hand-held nebuliser |
| 5750 6522 | Humidifier bottle for bubble humidifier MEDAP |
| | Pressure regulator O2 with flowmeter (see price info) |
| | FINA FLOW O 15 (see price information) |
| | FINA DFLOW O 15 (see price information) |
| | S DFLOW O 15 (see price information) |
| | LS FLOW O 15 (see price information) |
| | LS DFLOW O 15 (see price information) |

Tab. 7: Accessories

Notes

Notes

Notes



■ **Manufacturer:**

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