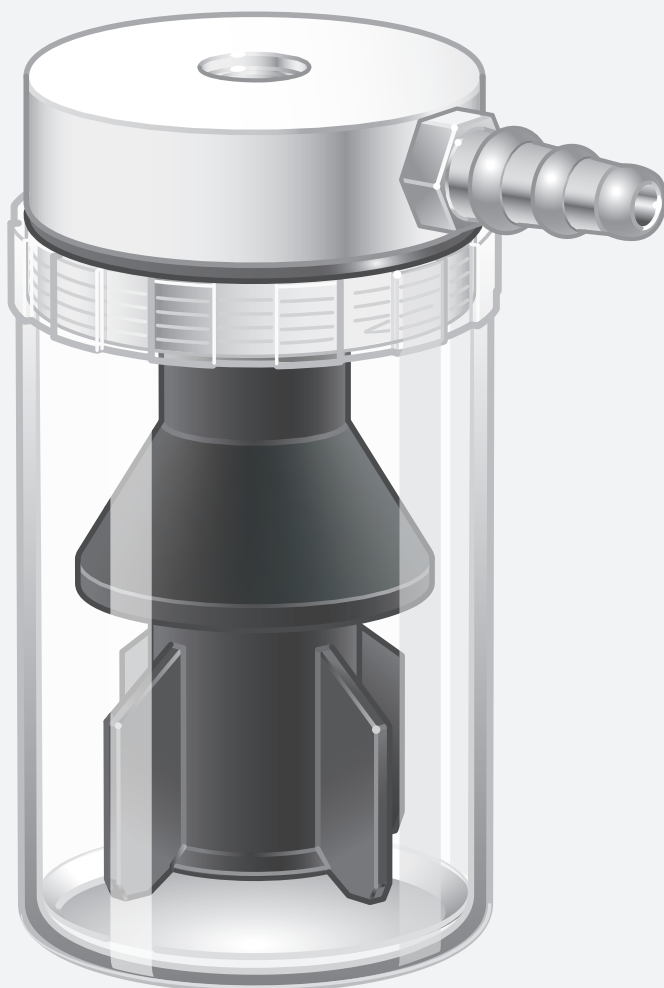


OPERATING INSTRUCTIONS

MEDAP  
MECHANICAL OVERFLOW PROTECTION

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.

V01 2020-07





## Table of contents

<b>1</b>	<b>Introduction .....</b>	<b>5</b>
1.1	Environmental protection.....	5
1.1.1	Packaging .....	5
1.1.2	ATMOS products.....	5
1.2	How to use these operating instructions .....	5
1.2.1	General .....	5
1.2.2	Symbols .....	5
1.2.2.1	Actions and responses .....	5
1.2.3	Definitions .....	6
1.2.3.1	Design of safety notes .....	6
1.2.3.2	Design of other notes .....	6
1.2.4	Symbols used .....	6
1.3	Basic requirements.....	7
1.3.1	Use in accordance with the intended purpose .....	7
1.3.2	Applicable standards.....	7
1.3.3	Application .....	8
1.3.4	Interface description.....	8
1.3.4.1	Vacuum connection tube .....	8
<b>2</b>	<b>Safety notes .....</b>	<b>9</b>
2.1	General safety notes .....	9
<b>3</b>	<b>Initial operation, operation and use.....</b>	<b>10</b>
3.1	General.....	10
3.2	Equipment inspection .....	10
3.3	Mounting the mechanical overflow protection .....	11
3.4	Mounting to the tapping unit.....	11
3.5	Dismantling the mechanical overflow protection .....	12
<b>4</b>	<b>Cleaning and disinfection.....</b>	<b>13</b>
4.1	General.....	13
4.2	Cleaning .....	14
4.2.1	General .....	14
4.2.2	Cleaning procedure.....	14
4.3	Disinfection.....	15
4.3.1	General .....	15
4.3.2	Suitable disinfectants .....	15
4.3.3	Disinfection procedure .....	16
4.3.4	Disinfection procedures .....	16
<b>5</b>	<b>Maintenance.....</b>	<b>17</b>
5.1	General.....	17



5.2	Repairs .....	17
5.3	Service hotline .....	17
5.4	Malfunctions and troubleshooting .....	17
5.5	Sending in the device .....	17
<b>6</b>	<b>Technical specifications .....</b>	<b>19</b>
6.1	Technical specifications .....	19
6.2	Ambient conditions .....	19

# 1 Introduction

## 1.1 Environmental protection

### 1.1.1 Packaging

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

### 1.1.2 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.

## 1.2 How to use these operating instructions

### 1.2.1 General

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 in the operating instructions.
- Store these operating instructions in a location near the product.

### 1.2.2 Symbols

#### 1.2.2.1 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
	<b>DANGER!</b> 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.
	<b>WARNING!</b> Indicates a potential risk to persons or property which may result in health hazard or grave property damage.	
	<b>CAUTION!</b> Indicates a potential risk to property which may result in property damage.	

Tab. 1: Design of safety notes




**1.2.3.2 Design of other notes**








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

Pictogram	Descriptor	Reference to
	<b>NOTE</b>	Additional assistance or further useful information.
	<b>ENVIRONMENT</b>	Proper disposal.

Tab. 2: Design of other notes

**1.2.4 Symbols used**

Symbols	Identification
	Labelling for class I products which were developed and marketed in compliance with the Medical Devices Directive 93/42/EEC.
	Labelling in compliance with the IEC 60601-1 standard. Symbol for 'Follow operating instructions'.
	Packaging label. Symbol for 'Keep dry'.

Symbols	Identification
	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'.
	Labelling in compliance with the ISO 15223-1 standard. Symbol for 'Order number'.
	Labelling in compliance with the ISO 15223-1 standard. Symbol for 'Name and address of the manufacturer as well as date of manufacture'.
	Material designation for the plastic PC (Polycarbonate).

Tab. 3: Symbols

### 1.3 Basic requirements

#### 1.3.1 Use in accordance with the intended purpose

The product satisfies the basic requirements set forth in Annex I to Council Directive 93/42/EEC concerning medical devices (Medical Devices Directive) as well as the applicable national (German) codes and the Medical Devices Act (MPG) in Germany. 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.

#### Accessories

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

Use other accessories, combinations and parts subject to wear only if these are intended expressly for the application and will not adversely affect performance features or safety requirements.

#### 1.3.2 Applicable standards

The product satisfies the basic requirements set forth in Annex I to Council Directive 93/42/EEC concerning medical devices (Medical Devices Directive) as well as the applicable national (German) codes and the Medical Devices Act (MPG) in Germany.

**1.3.3 Application**

The mechanical overflow protection (REF 5752 1699) is designed for use in connection with FINA tapping units. The mechanical overflow protection protects the tapping units from oversuction during the suction process. The mechanical overflow protection device is suitable for continuous operation. The mechanical overflow protection device can be reused when prepared accordingly.

**1.3.4 Interface description**

**1.3.4.1 Vacuum connection tube**

The vacuum connection tube is used to connect the mechanical overflow protection device and the septic fluid jar.

**Technical specifications**

- Shore hardness of 60
- Inner diameter 6–8 mm
- Length 50 cm (± 10 cm)
- Vacuum resistant down to -95 kPa (may not collapse)

**Prerequisites**

- The vacuum connection tube must comply with the hospital's standards for hygiene.
- The inner diameter of the vacuum connection tube must match the outer diameter of the tube connector on the aluminium body.

The vacuum connection tube will be referred to only as 'connection tube' below.



## 2 Safety notes

### 2.1 General safety notes

**DANGER!**

Defective device!

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

Only use original accessories or spare parts.

**WARNING!**

Infection hazard caused by not using overflow protection or by using an improperly mounted overflow protection!

Septic fluids will enter the tapping unit during extraction. Discontinue using the tapping unit. Clean and disinfect the tapping unit and have it repaired by a shop authorised by ATMOS to do so.

**WARNING!**

Risk of injury!

Worn or damaged products can cause injuries.

Use only products which are in perfect condition.

**WARNING!**

Overflow protection device!

If the overflow protection device closes during operation, the overflow protection device, complete with lid, must be removed and a new overflow protection device must be mounted.

**CAUTION!**

Oversuction!

Proper functioning of the mechanical overflow protection is only assured when the product is operated in a vertical position.

Operate the product only in vertical position.

**WARNING!**

Foaming!

Foam may be created when extracting secretion. Foam may impair the function of the overflow protection.

Use a commercially available foam inhibitor.

## 3 Initial operation, operation and use

### 3.1 General

---

**WARNING!**

Risk of injury / property damage!

The product may not be used for the following purposes or under the following conditions:

- The container of the overflow protection device may not be used as a septic fluid jar.
  - The container of the overflow protection device must not come into contact with strong acids or alkaline solutions.
  - The overflow protection device may not be pressurised with overpressure.
- 

**CAUTION!**

Property damage!

If the float is not fitted properly in the overflow protection device or if it is not used, liquid may enter the tapping unit and damage it.

Ensure correct fit of the float.

---

### 3.2 Equipment inspection

---

**DANGER!**

Equipment inspection!

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

---

- Check whether the unit has been properly cleaned and that there are no residues or soiling.
- Do not use damaged components. In particular, there must be no cracks in the container.
- After assembly, check that the float moves freely, e.g. by shaking the whole overflow protection device.

**3.3 Mounting the mechanical overflow protection**

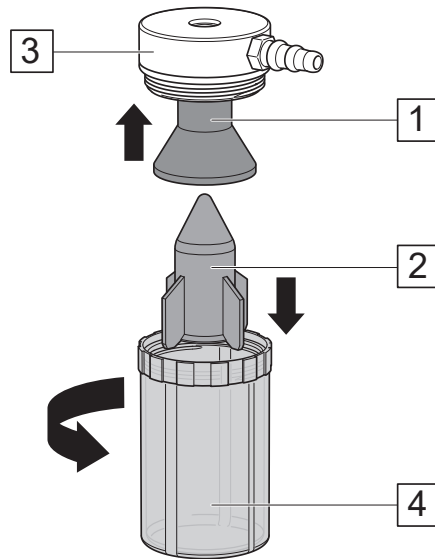


Fig. 1: Mounting the mechanical overflow protection

**Mounting the mechanical overflow protection**

- ☒ Plug the rubber cap (1) onto the aluminium body (3).
- ☒ Insert the float (2) with the tip pointed upwards into the overflow container (4).
- ☒ Screw the overflow container (4) onto the aluminium lid (3).

**3.4 Mounting to the tapping unit**

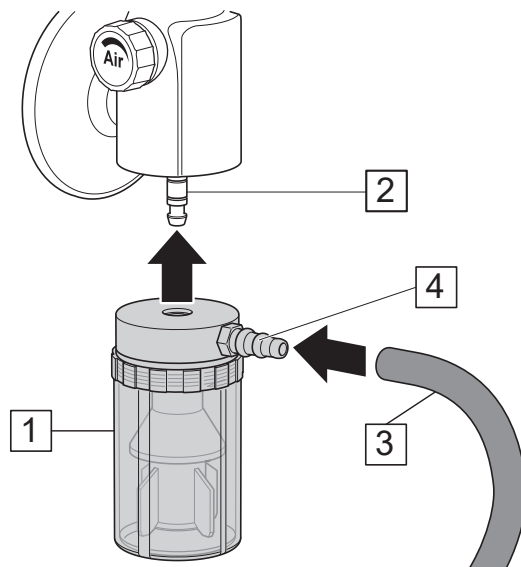
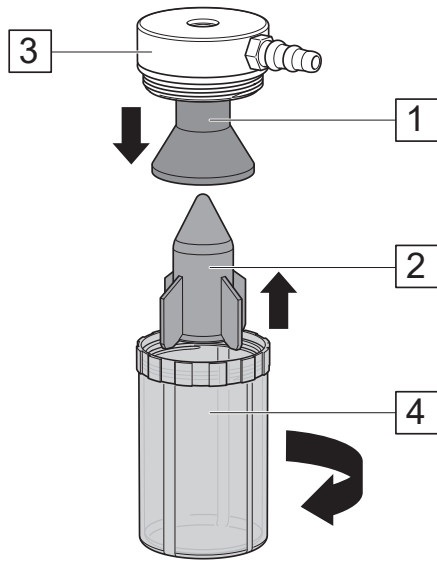


Fig. 2: Connection of the mechanical overflow protection device

**Connection of the mechanical overflow protection device**

- ☒ Plug the overflow protection device (1) directly onto the tube connector (2) on the housing of the tapping unit and press upwards until it stops.
- ☒ Attach the connection tube (3) to the tube connector (4) of the mechanical overflow protection device and connect it with the designated tube connector of the septic fluid jar.
- ☒ For disassembly, first remove the connection tube from the tube connector of the mechanical overflow protection device. Then remove the complete overflow protection device with lid from the tube connector of the tapping unit. Hold the tapping unit steady with one hand while doing so.

### 3.5 Dismantling the mechanical overflow protection



#### Dismantling the mechanical overflow protection

- ☒ Unscrew the overflow container (4) from the aluminium body (3).
- ☒ Remove the rubber cap (1) from the aluminium body (3).
- ☒ Remove float (2) from the overflow container (4).

Fig. 3: Dismantling the mechanical overflow protection

## 4 Cleaning and disinfection

### 4.1 General

The product must be cleaned and wipe disinfected after each use.

**DANGER!**

Risk due to incorrect use of detergents and disinfectants!

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

**WARNING!**

Infection hazard!

Product may be contaminated.

Always wear gloves for cleaning and disinfection.

**WARNING!**

Infection hazard!

Particles of grime may become encapsulated and cause the product not to achieve 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. fluorides, 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 approved detergents and disinfectants only. 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!

Perform visual and functional inspections after each cleaning and disinfection process.

**CAUTION!**

Property damage due to tension cracks!

Do not treat polysulphone containers with strong acids or alkaline solutions.

**NOTE**

The container of the overflow protection device, the float, the float cage and the seals are all disposables. Depending on the cleaning process used, the canister is subjected to a greater or lesser amount of material-related wear. Check the proper condition of the container before each use. Replace the container if any damage is visible.

**4.2 Cleaning****4.2.1 General****NOTE**

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

In the event of heavily contaminated surfaces, use concentrated all-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 dampened 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!

**4.2.2 Cleaning procedure**

- Use the correct dose of all-purpose detergent with water for the degree of surface contamination and in accordance with the detergent manufacturer's instructions.
- Thoroughly wipe off the product with a soft cloth slightly dampened in an all-purpose detergent solution.
- Ensure that the product is free of contamination and encapsulated particles of grime.
- Wipe the product thoroughly with a soft cloth slightly dampened in clean water.
- Ensure that the product is free of detergent residues.
- Dry the product with a dry, absorbent and lint-free cloth.
  - ✓ This will help to reduce pathogen growth on the product's surface.
- Wipe or spray disinfect the product after each cleaning.

4.3 Disinfection

4.3.1 General



**NOTE**

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



**CAUTION!**

Material damage due to excessive exposure times!

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

Observe the exposure time specified by the disinfectant manufacturer.



**DANGER!**

Infection hazard!

The product is used in the treatment of patients. Contaminated components may be hazardous to the patient's health.

Prepare the product in accordance with hygiene guidelines before every use!

4.3.2 Suitable disinfectants

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

- Aldehydes
- Quaternary compounds
- Guanidine derivatives

Ingredient group	Active ingredients
Aldehydes	2-ethyl-1-hexanal, formaldehyde, glutardialdehyde, glyoxal, o-phthaldialdehyde, succinaldehyde
Quaternary 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

**4.3.3 Disinfection procedure**

- After each cleaning process, wipe or spray disinfect the product in accordance with the disinfectant manufacturer's instructions.
- Ensure that the product is free of disinfectant residue.
- Perform visual and functional inspections.

**4.3.4 Disinfection procedures**

<b>Equipment components</b>	<b>Wipe, spray disinfection<sup>1</sup></b>
Overflow container	X
Aluminium lid	X
Float / rubber cap	X
O-ring	X

Tab. 5: Disinfection procedures

<sup>1</sup> Before disinfection, remove contamination and residues from the parts and dry well.



## 5 Maintenance

### 5.1 General

Maintenance, repairs and periodic 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 authorised ATMOS service partner. This ensures that repairs and testing are carried out professionally, original spare parts are used and warranty claims remain unaffected.

### 5.2 Repairs

The following issues may require repairs by the manufacturer or an authorised service partner:

- Liquid has penetrated the device.
- Performance has significantly decreased.
- Inexplicable notifications appear.
- Abnormal noises occur.
- Functional faults cannot be rectified according to the measures in chapter Malfunctions and troubleshooting [▶▶ page 17].

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

Make a note of the defects and the REF number on the type plate and inform your ATMOS representative.

Observe the information in chapter Sending in the device [▶▶ page 17].

### 5.3 Service hotline

+49 7653 689-0

### 5.4 Malfunctions and troubleshooting

Defect	Source of malfunction	Troubleshooting
Reduced or no flow rate	Seals damaged	Replace seals
	Aspiration system is leaking	Check aspiration system
Oversuction of the tapping unit despite overflow protection	Foaming	Use commercially available foam inhibitor
	Seals damaged	Replace seals
	Tapping unit mounted at an angle	Operate tapping unit in horizontal position only
	Overflow protection device contaminated	Clean the overflow protection device

Tab. 6: Troubleshooting

### 5.5 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 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](http://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.

## 6 Technical specifications

### 6.1 Technical specifications

Weight	approximately 160 g
Dimensions (W x H x D)	approximately 50 x 96 x 80 mm
Pressure range	-100 to 0 kPa*

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

### 6.2 Ambient conditions

Temperature	-40 °C to +60 °C (shipping)
	+10 °C to +40 °C (operation)
Relative humidity	10% to 95% (shipping)
	30% to 75% (operation)
Atmospheric pressure	500 hPa to 1050 hPa (shipping)
	500 hPa to 1050 hPa (operation)



**Manufacturer:**

Acare Technology Co., Ltd  
5F.-4, No.24, Wuquan 2nd Rd.  
Xinzhuang Dist.,  
New Taipei City 242 Taiwan

**Distributor:**

ATMOS  
MedizinTechnik GmbH & Co. KG  
Ludwig-Kegel-Str. 16  
79853 Lenzkirch  
GERMANY  
Phone: +49 7653 689-0  
[www.atmosmed.com](http://www.atmosmed.com)