OPERATING INSTRUCTIONS
MEDAP
MECHANICAL OVERFLOW PROTECTION

GA 5752.2175 GB 13
Subject to technical modification!
Illustrations and technical specifications may vary slightly from those in these Operating Instructions as a result of ongoing product development.

V13 2017-08

CE
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<tr>
<td>6.3</td>
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<td>19</td>
</tr>
</tbody>
</table>
1 Introduction

1.1 Environmental protection

1.1.1 Packing
The packing is made of materials compatible with the environment. ATMOS will dispose of the packing 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 herein.
• 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

<table>
<thead>
<tr>
<th>Pictogram</th>
<th>Descriptor</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="DANGER!" /></td>
<td>DANGER!</td>
<td>Indicates a direct and immediate risk to persons, which may be fatal or result in most serious injury.</td>
</tr>
<tr>
<td><img src="image" alt="WARNING!" /></td>
<td>WARNING!</td>
<td>Indicates a potential risk to persons or property which may result in health hazard or grave property damage.</td>
</tr>
<tr>
<td><img src="image" alt="CAUTION!" /></td>
<td>CAUTION!</td>
<td>Indicates a potential risk to property which may result in property damage.</td>
</tr>
</tbody>
</table>

Tab. 1: Design of safety notes

1.2.3.2 Design for other notes

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

<table>
<thead>
<tr>
<th>Pictogram</th>
<th>Descriptor</th>
<th>Reference to</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="NOTE" /></td>
<td>NOTE</td>
<td>Supplementary assistance or further useful information.</td>
</tr>
<tr>
<td><img src="image" alt="ENVIRONMENT" /></td>
<td>ENVIRONMENT</td>
<td>Proper disposal.</td>
</tr>
</tbody>
</table>

Tab. 2: Design for other notes

1.2.4 Symbols used

<table>
<thead>
<tr>
<th>Symbols</th>
<th>Identification</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="CE" /></td>
<td>Labelling for Class I products, developed and marketed in compliance with Medical Device Directive 93/42/EEC.</td>
</tr>
<tr>
<td><img src="image" alt="i" /></td>
<td>Labelling in compliance with the IEC 60601-1 standard. Symbol for &quot;Follow Operating Instructions&quot;.</td>
</tr>
<tr>
<td><img src="image" alt="Umbrella" /></td>
<td>Packaging label. Symbol for &quot;Keep dry&quot;.</td>
</tr>
</tbody>
</table>
### Symbols and Identification

<table>
<thead>
<tr>
<th>Symbols</th>
<th>Identification</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Packaging label" /></td>
<td>Packaging label. Symbol for &quot;Fragile! Handle with care&quot;.</td>
</tr>
<tr>
<td><img src="image2.png" alt="Temperature limitation" /></td>
<td>Labelling in compliance with the ISO 15223-1 standard. Symbol for &quot;Temperature limitations&quot;.</td>
</tr>
<tr>
<td><img src="image3.png" alt="Relative humidity" /></td>
<td>Labelling in compliance with the ISO 15223-1 standard. Symbol for &quot;Relative humidity&quot;.</td>
</tr>
<tr>
<td><img src="image4.png" alt="Atmospheric pressure" /></td>
<td>Labelling in compliance with the ISO 15223-1 standard. Symbol for &quot;Atmospheric pressure&quot;.</td>
</tr>
<tr>
<td><img src="image5.png" alt="Product number" /></td>
<td>Labelling in compliance with the ISO 15223-1 standard. Symbol for &quot;Product number&quot;</td>
</tr>
<tr>
<td><img src="image6.png" alt="Manufacturer information" /></td>
<td>Labelling in compliance with the ISO 15223-1 standard. Symbol for &quot;Name and address of the manufacturer as well as date of manufacture&quot;.</td>
</tr>
<tr>
<td><img src="image7.png" alt="Material designation" /></td>
<td>Material designation for the plastic PSU (polysulfone).</td>
</tr>
</tbody>
</table>

| 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 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. 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 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.

1.3.3 Application
The mechanical overflow protection (REF 5752 1698) 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 respectively.

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
• Internal diameter of 6 - 8 mm
• Length 50 (±10 cm)
• Vacuum resistant down to -95 kPa (may not collapse).

Prerequisites
• The silicone tube must comply with the hospital's standards for hygiene.
• The inside diameter of the vacuum connection tube must match the outside diameter of the tube connector on the lid.

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 MAQUET 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 device.
Use a standard commercial 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 may not come into contact with strong acids or bases.
- The overflow protection device may not be pressurised with over-pressure.

**CAUTION!**
Property damage!
If the float is not seated properly in the overflow protection device or if this is not used, liquid may enter the tapping unit and damage it.
Ensure correct seat 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 using the unit.

- 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 jar.
- After assembly, check that the float moves freely, e.g. by shaking the whole overflow protection device.
3.3 Mounting the mechanical overflow protection

Mounting the mechanical overflow protection

- Insert the float (1) into its float cage (2).
- Plug the float cage onto the lid (3).
- Screw overflow container (4) onto the lid.

Fig. 1: Mounting the mechanical overflow protection

3.4 Mounting to the tapping unit

Connection of mechanical overflow protection

- Plug the overflow protection device (1) directly on the tube connector (2) on the housing of the tapping unit and press upwards to the stop.
- Attach the connection tube (3) to the tube connector (4) of the mechanical overflow protection device and connect it with the appropriate 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.

Fig. 2: Connection of mechanical overflow protection
3.5 Dismantling the mechanical overflow protection

- Unscrew the overflow container (1) from the lid (2).
- Remove float cage (3) from the lid.
- Pull float (4) out of the float cage.

Fig. 3: Dismantling the mechanical overflow protection
4 Cleaning and disinfection

4.1 General

The product must be cleaned as well as wipe 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.

WARNING!
Infection hazard!
Product may be contaminated.
Always wear gloves for cleaning and disinfection.

WARNING!
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 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 jar 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 jar before each use. Replace the jar 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 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!

4.2.2 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.
- Wipe or spray disinfect the product after every cleaning.
4.3 Disinfection

4.3.1 General

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

**CAUTION!**
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.

**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 regulations 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
- Quarternary compounds
- Guanidine derivatives.

<table>
<thead>
<tr>
<th>Ingredient group</th>
<th>Active ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aldehydes</td>
<td>2-ethyl-1-hexanal, formaldehyde, glutardialdehyde, glyoxal, o-phthalaldehyde, succinaldehyde</td>
</tr>
<tr>
<td>Quarternary compounds</td>
<td>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-oxethyl ammonium propionate, mecontronium-ethyl sulfate, methyl-benzethonium chloride, n-octyl-dimethyl-benzyl ammonium chloride</td>
</tr>
<tr>
<td>Guanidine derivatives</td>
<td>Alkyl-biguanide, chlorhexidine-digluconate, cocospropylene-diamine guanidinium diacetate, oligomeric biguanide, polyhexamethylene biguanide hydrochloride (oligo-diimino imido-carbonyl imino-hexamethylene, polyhexanide)</td>
</tr>
</tbody>
</table>

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 instructions of the disinfectant manufacturer.
- Ensure that the product is free of disinfectant residue.
- Perform visual and functional inspections.

4.3.4 Disinfection procedures

<table>
<thead>
<tr>
<th>Equipment components</th>
<th>Wipe, spray disinfection¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overflow container</td>
<td>X</td>
</tr>
<tr>
<td>Lid</td>
<td>X</td>
</tr>
<tr>
<td>Float / float cage</td>
<td>X</td>
</tr>
<tr>
<td>O-ring</td>
<td>X</td>
</tr>
</tbody>
</table>

Tab. 5: Disinfection procedures

¹ Before disinfection remove contaminations and residues from the parts and dry well.
5 Maintenance

5.1 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.

5.2 Repairs

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

- Liquid has penetrated the device.
- The 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 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 17].

5.3 Service hotline:

+49 7653 689-0

5.4 Malfunctions and troubleshooting

<table>
<thead>
<tr>
<th>Defect</th>
<th>Source of malfunction</th>
<th>Corrective actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduced or no flow rate</td>
<td>Seals damaged</td>
<td>Replace seals</td>
</tr>
<tr>
<td></td>
<td>Suction system is leaking</td>
<td>Check suction system</td>
</tr>
<tr>
<td>Oversuction of the tapping unit</td>
<td>Foaming</td>
<td>Use standard commercial foam inhibitor</td>
</tr>
<tr>
<td>despite overflow protection</td>
<td>Seals damaged</td>
<td>Replace seals</td>
</tr>
<tr>
<td></td>
<td>Tapping unit mounted at an angle</td>
<td>Operate tapping unit in horizontal position only</td>
</tr>
<tr>
<td></td>
<td>Overflow protection device contaminated</td>
<td>Clean overflow protection device</td>
</tr>
</tbody>
</table>

Tab. 6: Corrective actions

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 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.
6 Technical specifications and spare parts

6.1 Technical specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>approximately 130 g</td>
</tr>
<tr>
<td>Dimensions (W x H x D)</td>
<td>approximately 50 x 101 x 64 mm</td>
</tr>
<tr>
<td>Pressure range</td>
<td>-100 to 0 kPa*</td>
</tr>
</tbody>
</table>

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

6.2 Ambient conditions

<table>
<thead>
<tr>
<th>Condition</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>-15° C to +50° C (shipping)</td>
</tr>
<tr>
<td></td>
<td>+10° C to +40° C (operation)</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>less than 100% (shipping)</td>
</tr>
<tr>
<td></td>
<td>30 % to 75 % (operation)</td>
</tr>
<tr>
<td>Atmospheric pressure</td>
<td>700 hPa to 1060 hPa (shipping)</td>
</tr>
<tr>
<td></td>
<td>700 hPa to 1060 hPa (operation)</td>
</tr>
</tbody>
</table>

6.3 Spare parts

<table>
<thead>
<tr>
<th>Spare part</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Float and float cage (10 pieces of each)</td>
<td>5752 2096</td>
</tr>
<tr>
<td>Overflow container (4 items)</td>
<td>5752 2097</td>
</tr>
<tr>
<td>Tube connector (10 pcs.)</td>
<td>5752 2291</td>
</tr>
<tr>
<td>Set of seals overflow protection FINA</td>
<td>5752 5247</td>
</tr>
<tr>
<td>Float cage</td>
<td>5752 1593</td>
</tr>
</tbody>
</table>

Tab. 7: Spare parts