OPERATING INSTRUCTIONS

MEDAP TAPPING UNIT S AIR B 800 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.

V04 2020-05

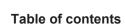




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1 Introduction

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 ' \boxtimes ' symbol identifies an action taken by the user, while the ' \checkmark ' symbol identifies the reaction that this will induce in the system.

Example:

✓ Lamp lights up.

1.2.3 Definitions

1.2.3.1 Design of safety notes

Pictogram	Descriptor	Text
	DANGER!	The text for the safety note
\[\left[\] \]	Indicates a direct and immediate risk to persons which may be fatal or result in most serious injury.	describes the type of risk and how to avert it.
	WARNING!	
\(\si\)	Indicates a potential risk to persons or property which may result in health hazard or grave property damage.	
_	CAUTION!	
<u> </u>	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
i	NOTE	Supplementary assistance or further useful information.
φ	ENVIRONMENT	Information regarding proper disposal.

Tab. 2: Design of other notes

1.2.4 Symbols used

Symbols are attached to products, type plates and packaging.

Symbols Identification	
0 1 2 4	Labelling for products which were developed and are marketed in compliance with the Medical Devices Directive 93/42/EEC. Class Is, Im, IIa, IIb and III products are also marked with the identifying number of the Notified Body.
SN	Labelling in compliance with the ISO 15223-1 standard. Symbol for 'Serial number'.
REF	Labelling in compliance with the ISO 15223-1 standard. Symbol for 'Product number'.



Symbols	Identification
	Labelling in compliance with the IEC 60601-1 standard.
	Symbol for 'Follow operating instructions'.
_	Labelling in compliance with the ICO 45222.4 standard
444	Labelling in compliance with the ISO 15223-1 standard. Symbol for 'Name and address of the manufacturer as well as date of
	manufacture'.
\wedge	Labelling in compliance with the IEC 62570 standard.
MR	Symbol for 'Conditionally MR safe'.
.31.	Packaging label.
7	Symbol for 'Keep dry'.
	Packaging label.
I	Symbol for 'Fragile! Handle with care'.
44	Packaging label.
<u> </u>	Symbol for 'Top'.
N/C	Labelling in compliance with the ISO 15223-1 standard.
1	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

1.2.5 Disposal



WARNING!

Infection hazard!

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

Clean and disinfect the product before disposal.

1.2.5.1 Packaging

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

1.2.5.2 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.

1.3 Overview

MEDAP :

1.3.1 S AIR B 800

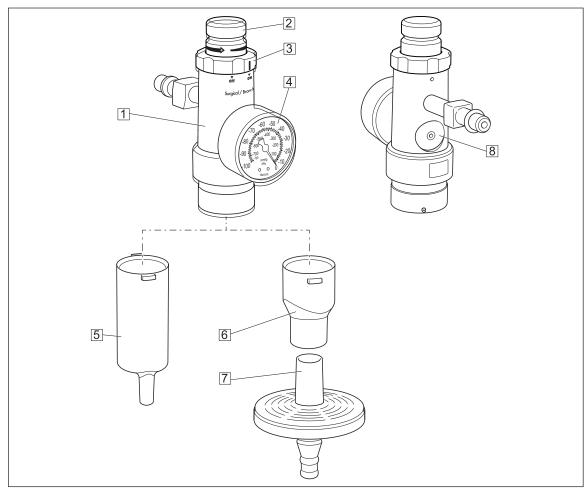


Fig. 1: Overview of S AIR B 800

- 1 S AIR B 800
- 2 Control valve
- 3 ON/OFF button
- 4 Vacuum gauge

- 5 Mechanical overflow protection
- 6 Adapter for hydrophobic filter
- 7 Hydrophobic bacterial and viral filter
- 8 Safety valve at patient side



1.3.2 S AIR B 800 versions

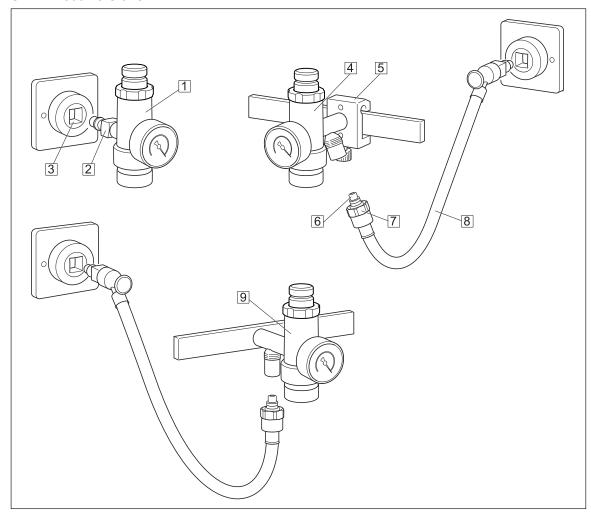


Fig. 2: Overview of the versions S AIR B 800

- 1 Version A
 - Tapping unit with integrated gas pin
- 2 Plug
- 3 Terminal unit
- 4 Version B
- Tapping unit with rail clamp and NIST connection
- 5 Rail clamp

- 6 NIST nipple
- 7 NIST screw connection
- 8 Connection tube
- 9 Version C

Tapping unit for screw connection, with NIST connection

1.4 Basic requirements

1.4.1 Use in accordance with the intended purpose

Product

As per Annex IX to the Medical Devices Directive 93/42/EEC, 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 commercial or business use, this product must 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.

1.4.2 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. This is certified by compliance with harmonised standards such as IEC 60601-1 and related standards and the respective special sections.

1.4.3 Intended purpose

Name: S AIR B 800

Main function: Aspiration of secretion, blood, serous fluids, vomit and rinsing fluids

along with any contained particles.

Medical indications /

application:

For all applications which require aspiration, e.g. general surgeries (e.g. aspiration of wound cavities, abscesses), bronchial aspiration, during and aspiration of appropriation of aspiration of aspiration and in pourseurgery.

during endoscopy for aspiration of secretions and in neurosurgery.

Specification of the main

function:

Drainage and temporary collection of body fluids. For compressed air supply, the S AIR B 800 is connected to a terminal unit for compressed air of a central medical gas supply system with a pressure of 250–600 kPa. A septic fluid jar, which has to be used,

allows for temporary collection of drained body fluids.

User profile: Doctor, medically trained staff

Patient groups: Patients of all ages

Application organ: Natural and artificial body orifices

Application time: Tapping unit designed 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 which have a central compressed air supply system. The product may only be applied by medically trained and instructed

staff.



Contraindications: The SAIR B 800 may not be used for the following purposes:

· Outside the medical sector

- In MR areas > 4.7 tesla
- · In the home care sector
- · Being operated directly by the patient
- For vacuum extraction
- For the aspiration of flammable or explosive liquids
- For the aspiration of smoke that is generated during HF and laser surgery without the connection of an intermediate smoke filter
- With central gas supply systems having supply pressures other than 250–600 kPa.

Furthermore, the S AIR B 800 is not suitable for drainage and thoracic drainage. Usage in combination with disposable thoracic drainage systems with integrated vacuum regulation is excepted from this restriction.

The product is: Active

Sterility: Not a 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.

1.4.4 S AIR versions

The connection of the S AIR to the terminal unit for compressed air depends on the model being used.

Version A: Tapping unit with integrated gas pin

· S AIR is fitted directly to the terminal unit.

Version B: Tapping unit with rail clamp and NIST connection

 S AIR is designed for mounting to a 25–35 x 10 mm equipment rail in accordance with DIN EN 19054 and is supplied from a terminal unit for compressed air via a NIST connection with a connection tube and gas probe.

Version C: Tapping unit for screw connection, with NIST connection

• S AIR is designed for direct screw-mounting to mobile suction units (intensive care trolley / surgical trolley) and compact suction units (solo carrier frame) and is supplied from a terminal unit for compressed air via a NIST connection with a connection tube and gas probe.

The SAIR B 800 is available in the following versions:

- S AIR B 800 Wall DIN (REF 5752 5686)
- S AIR B 800 Wall MEDAP (REF 5752 5687)
- S AIR B 800 Wall BS (REF 5752 5688)
- S AIR B 800 Wall NF (REF 5752 5689)
- S AIR B 800 Wall SS (REF 5752 5690)
- S AIR B 800 Equipment rail (REF 5752 5691)
- S AIR B 800 Screw connection (REF 5752 5692)



1.4.5 Interface description

All devices and accessories which are combined with the tapping unit must be listed in the accessories list or meet the specifications of the interface description. The configuration of the overall system as well as 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, airtightness and suitability regarding material properties, working pressure and flow rate.

1.4.5.1 Vacuum connection tube

The vacuum connection tube is used to connect the tapping unit and the septic fluid jar.

Technical specifications

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

Prerequisites

- It must be possible to sterilise the vacuum connection tube or it must be a sterilised disposable item.
- The inner diameter of the vacuum connection tube should match the outer diameter of the tube connector on the septic fluid jar cap of the pump.

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

1.4.5.2 Hydrophobic bacterial and viral filter

In its function as overflow protection, the hydrophobic bacterial and viral filter protects the product against ingress of particles, fluid and foam. In its function as bacterial and viral filter, it protects the product from the ingress of bacteria and viruses.

Prerequisites

- Pore size ≤ 1.0 μ.
- The tube connector must match the tube being used.
- The hydrophobic bacterial and viral filter must close tightly against water passage at an absolute pressure of up to 10 kPa.
- If required, observe direction of flow (see note on the hydrophobic bacterial and viral filter).

1.4.5.3 Septic fluid jar including septic fluid jar cap

The septic fluid jar and septic fluid jar cap are used to collect the extracted secretions.

Prerequisites

- · Low leakage.
- · Always fasten the septic fluid jar securely.
- The outer diameter of the tube connector on the patient side should match the inner diameter
 of the suction tube.

1.4.5.4 Suction tube

The suction tube is used to connect the tube connector on the septic fluid jar on the patient side and the fingertip or the utensil.



Technical specifications

- · Shore hardness of 60
- Inner diameter 6-8 mm
- Length 1.3-3.0 m
- Vacuum resistant down to -95 kPa (must not collapse).

Prerequisites

• The outer diameter of the tube connector on the patient side of the septic fluid jar cap must match the inner diameter of the suction tube.

1.4.5.5 Fingertip

The fingertip serves to vent the suction tube in order to be able to quickly interrupt the aspiration process.

Prerequisites

- · It must be possible to sterilise the fingertip or it must be a sterilised disposable item.
- The outer diameter of the tube connector on the patient side should match the inner diameter of the suction tube.

1.4.5.6 Utensil

The suction catheter, lance, etc., are referred to as utensils. The utensils are used to extract septic fluids.

Prerequisites

- The inner diameter of the utensil's connector must match the outer diameter of the fingertip.
- · The utensil must be sterilisable or a sterile single-use item.
- · Biocompatibility.
- · For endobronchial extraction, a utensil with side openings must be used.

1.4.5.7 Mechanical overflow protection

The mechanical overflow protection device protects the product from the ingress of particles and fluid. Tube connector must match the vacuum connection tube.

2 Safety notes

2.1 General safety notes



DANGER!

Danger to life!

Danger due to unauthorised modifications.

The product may not be modified.



WARNING!

Risk of injury!

Hazard resulting from incorrect handling.

Be absolutely sure to observe the operating instructions for all the products used in the configuration.



CAUTION!

ATMOS recommends always having another aspirator ready to hand. That way you can perform aspiration even in the event of product failure.

2.2 Product safety notes



WARNING!

Risk of injury to mucous membranes!

Endobronchial aspiration in paediatrics and neonatology requires particularly careful limitation of the vacuum.



WARNING!

Risk of injury!

ATMOS products may be used only when fully functional.

Check to ensure that the ATMOS product is fully functional and in good working order prior to use.



DANGER!

Infection hazard due to oversuction!

To avoid the ingress of fluid or foam into the product or the vacuum source, a hydrophobic bacterial filter must be used. If secretion enters the inside of the unit, the product must immediately be taken out of operation. Clean and disinfect the product and have it repaired by a service technician authorised by ATMOS to do so.



DANGER!

Infection hazard due to contamination!

To avoid the ingress of fluid or foam into the product or the vacuum source, a hydrophobic bacterial and viral filter must be used. If bacteria or viruses enter the inside of the unit, the product must immediately be taken out of operation. Clean and disinfect the product and have it repaired by a service technician authorised by ATMOS to do so.





WARNING!

Impacts!

Impacts may cause damage to sensitive, precision mechanical components.

Do not expose the product to impacts.



WARNING!

Measuring accuracy / oversuction!

The product may only be operated in a vertical position.



WARNING!

Foaming!

Foam may be created when extracting secretion. Foam is detrimental to the functioning of the mechanical overflow protection. This raises the risk that secretions may penetrate the product and cause it to break down.

Use an ordinary foam inhibitor.



WARNING!

Non-permissible load!

If the permissible load is exceeded, leakages may occur at the connection between the terminal unit and gas probe.

In accordance with DIN EN ISO 9170-1, the overall weight of the product and accessories may not exceed 2 kg.



WARNING!

Backflow of aspirated secretion!

In the event of oversuction, the aspirated secretion may flow back to the patient if there is secretion still left in the suction tube.

Before replacing the septic fluid jar in the event of oversuction or switching off the vacuum, always remove the tube from the patient first.



WARNING!

Risk of injury!

Immediately replace the hydrophobic bacterial and viral filter if it is discoloured, contaminated or oversucked.

Furthermore, the filter must be changed if the vacuum displayed is above -0.3 bar / -30 kPa when the vacuum controller is in the 'max' position and the suction tube is open.



WARNING!

Risk of injury!

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

- · Never throw, hit or drop the product.
- The product is not suitable for vacuum extraction.
- The product may not be used without a hydrophobic filter.
- The product may not be used without a bacterial and viral filter.
- The product may not be used without a septic fluid jar.
- The product may not be used without a fingertip.
- · The product is not autoclavable.



3 Initial operation

3.1 Product inspection



DANGER!

Product inspection!

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 staff and 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 function check prior to use.

3.2 Connection to the terminal unit

3.2.1 General



NOTE

Please refer to the manufacturer's instructions for the particular terminal unit for information on connecting the gas probe to the terminal unit.

3.2.2 Version A

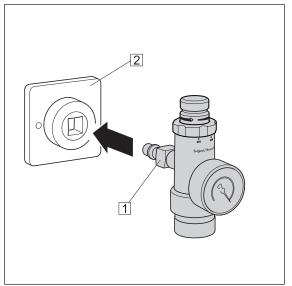


Fig. 3: Version A

Tapping unit with integrated gas pin

☑ The tapping unit (1) is plugged directly into the terminal unit (2).

3.2.3 Version B

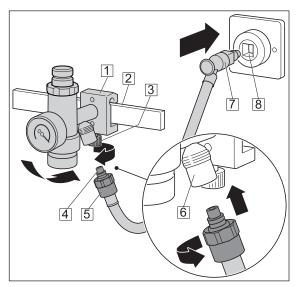


Fig. 4: Version B

Tapping units with rail clamp and NIST connection

- ☑ With the upper edge of the guide groove at the front, position the rail clamp (1) at a slight angle onto the equipment rail (2) and then press it against the equipment rail and allow it to click into place.
- ☑ Tighten the handle screw (3) of the rail clamp.
- ☑ Make sure that the rail clamp is correctly secured and that the tapping unit is in a stable position on the equipment rail.
- ☑ Insert the NIST nipple (4) of the connection tube into the NIST connection (6) of the tapping unit and tighten down the NIST screw connection (5) by hand.
- ☑ Plug the gas probe (7) of the connection tube into the terminal unit (8).

3.2.4 Version C

The tapping unit for screw connection may be connected to an intensive care trolley, surgical trolley or solo aspiration set carrier frame. The solo aspiration set carrier frame is used to show the assembly.

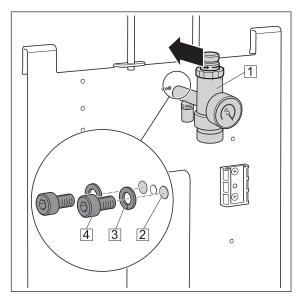
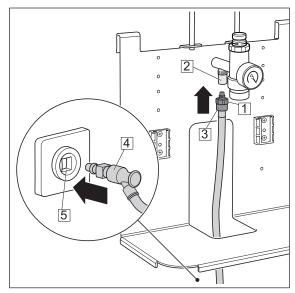


Fig. 5: Version C

Tapping unit for screw connection, with NIST connection

- ☑ Press the tapping unit (1) up against the carrier frame.
 - ✓ The drilled holes of the tapping unit are positioned over the drilled holes (2) of the carrier frame.
- ☑ Put the lock washers (3) onto the hexagon screws (4).
- ☑ Use the hexagon screws to screw the tapping unit into place.





- ☑ Insert the NIST nipple (1) of the connection tube into the NIST connection (2) of the tapping unit and tighten down the NIST screw connection (3) by hand.
- ☑ Plug the gas probe (4) of the connection tube into the terminal unit (5).

Fig. 6: Connection tube

3.3 Mounting the accessories

3.3.1 General



WARNING!

Tensile forces!

The connected accessories must not exert any mechanical forces which could adversely affect the secure fit 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 additional information on the use of the septic fluid jar and the extraction utensil.



NOTE

The particle filter must be changed whenever the product is prepared for use.



3.3.2 Mounting the mechanical overflow protection

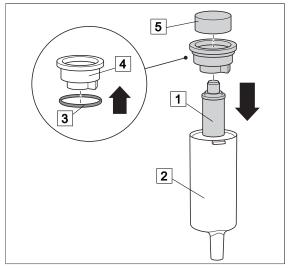


Fig. 7: Mounting the mechanical overflow protection

Mounting the mechanical overflow protection

- ☑ Insert the float (1) into the overflow container (2).
- \boxtimes Fit the sealing ring (3) to the cap (4).
- ☑ Insert the cap into the overflow container.
- ☑ Fit the particle filter (5) to the cap.

3.3.3 Connection of the mechanical overflow protection

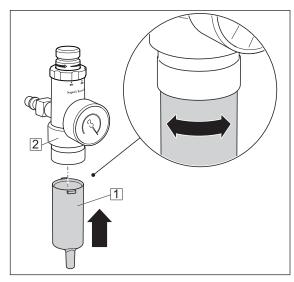


Fig. 8: Mounting/removing the mechanical overflow protection device

Mounting the mechanical overflow protection device

- ☑ Plug the overflow protection device (1) directly onto the tapping unit (2) and press it up as far as it will go.
- ☑ Turn the overflow protection device (1) to the right.
 - ✓ The overflow protection device is locked.

Removing the mechanical overflow protection device

- ☑ Turn the overflow protection device (1) to the left.
 - ✓ The overflow protection device is unlocked.
- ☑ Pull the overflow protection device down.



3.3.4 Connection of hydrophobic bacterial and viral filter

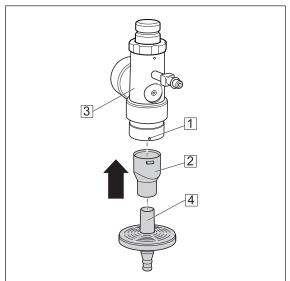


Fig. 9: Mounting the hydrophobic bacterial and viral filter

Mounting the hydrophobic bacterial and viral filter

- ☑ Undo the grub screw (1) using an Allen key.
- ☑ Insert the adapter (2) for the hydrophobic filter directly into the tapping unit (3).
- ☑ Rotate the adapter and, at the same time, push up until the lug engages in the slot.
- ☑ Tighten the grub screw using an Allen key.
- ☑ Fit the hydrophobic bacterial and viral filter

 (4) to the adapter for the hydrophobic filter
 and push up.



4 Operation

4.1 Functional test

Prior to using the system, the operator should check that the product is fully functional and in good condition.



NOTE

Connecting several septic fluid jars in series can cause delayed suction effect and reduced suction power.

Prior to each use, carry out the following functionality checks:

Version A: Tapping unit with integrated gas pin

• The tapping unit is correctly plugged into the terminal unit.

Version B: Tapping unit with rail clamp and NIST connection

· The tapping unit is locked firmly to the equipment rail.

Version C: Tapping unit for screw connection, with NIST connection

 Tapping unit is firmly screwed to the intensive care trolley, surgical trolley or aspiration set carrier frame solo.

All versions:

- The product has been properly cleaned and neither residue nor contamination are present.
- The control valve can be easily turned and the ON/OFF button is functioning.
- The hydrophobic overflow protection device and the bacterial and viral filter are mounted, fully functional and no residue is trapped in it.
- The tube connectors are firmly secured and tightly sealed, and no mechanical forces are acting on the tubes.
- The plastic and rubber product parts are in perfect condition and show no signs of ageing.
- · A septic fluid jar is connected to the tapping unit.

4.2 Use in conjunction with magnetic resonance imaging scanners



WARNING!

Danger to life!

Please strictly observe the operating instructions of your magnetic resonance imaging scanner.



WARNING!

Risk of injury!

Accessories of the product (e.g. trolley, carrier frame, connection tube, rail clamp) may be affected by the magnetic field.

If the product is used in conjunction with accessories within the 0.5 mT line, all connected accessories must be MR compatible. Observe the operating instructions of all connected accessories or consult the manufacturer of the product.



NOTE

If the product is used in conjunction with accessories outside the 100 mT line, the product does not create artefacts on the MR images.

4.3 Setting the vacuum level

MEDAP :



DANGER!

Infection hazard!

In the event of oversuction, the hydrophobic bacterial and viral filter must no longer be used.

Replace the hydrophobic bacterial and viral filter with a new one.



WARNING!

Vacuum setting!

Make the vacuum settings very carefully! The regulating mechanism is sensitive.



WARNING!

Air inlet!

The bore holes on the rear side of the unit must always be kept free so that airflow is always ensured.



NOTE

Check the vacuum setting once again immediately before using the unit!

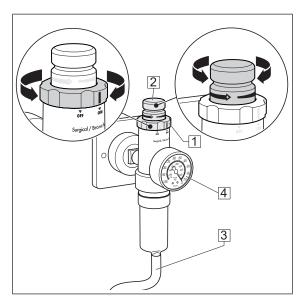


Fig. 10: Setting the vacuum level

Setting the vacuum for treatment

- ∑ Turn the ON/OFF button (1) to the OFF position and connect the tapping unit [▶ Page 17].
- ☑ Turn the control valve (2) clockwise and close as far as it will go.
- ☑ Bend the connection tube (3) that leads to the septic fluid jar.
- ☑ Use the control valve to set the required value for treatment.
- ☑ Use the control valve to set the required value for treatment.

Increase the vacuum: Turn the control valve anticlockwise.

Reduce the vacuum: Turn the control valve clockwise.

- ⊠ Read the value on the vacuum gauge (4).
 Should it not be possible to shut off or increase the vacuum as required, refer to the troubleshooting table to find the cause.
- ⊠ Release the connection tube (4) that leads to the septic fluid jar.



5 Taking the unit out of operation

5.1 Completing the aspiration process



NOTE

Refer to the medical gas distributor instructions for information regarding detaching the gas probe from the terminal unit.

- ☑ Remove the suction tube from the patient.
- ☑ Turn the ON/OFF button to the OFF position and close the control valve.
- ☑ Empty the septic fluid jar and clean or replace it.
- 🗵 Remove the connection tubes and the overflow protection device / the hydrophobic bacterial and viral filter from the tapping unit and from the septic fluid jar and recondition or discard them.
- □ Clean the components [>> Page 26]
- ☑ Disconnect the gas probe from the terminal unit.

Version B: Tapping unit with rail clamp and NIST connection

🗵 Remove the product from the equipment rail. For this purpose, undo the handle screw and lift the product off the equipment rail.

5.2 Disassembly

5.2.1 General



WARNING!

Tensile forces!

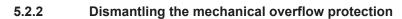
Hold the basic unit with one hand when installing or removing accessories in order to compensate for the tensile forces which are created.



WARNING!

Tensile forces!

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



MEDAP :

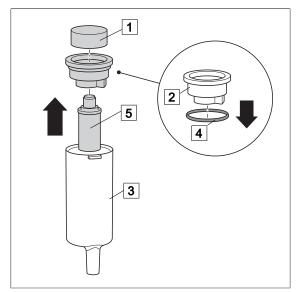


Fig. 11: Dismantling the mechanical overflow protection device

- ⊠ Remove the particle filter (1) from the cap
 (2).
- ☑ Remove the cap from the overflow container (3).
- ⊠ Remove the sealing ring (4) from the cap
 (2).
- ☑ Pull float (5) out of the overflow container.



6 Cleaning and disinfection

6.1 General

The product must be wipe or spray disinfected after every 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 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. 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 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 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 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 highpressure cleaning unit!

6.2.2 Cleaning procedure

- ☑ Use the correct dose of all-purpose detergent with water for the degree of surface contamination and in accordance with the instructions of the detergent manufacturer.
- ☑ 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.
- ☑ Thoroughly wipe off the product with a soft cloth dipped 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 disinfect the product after every cleaning process.

6.3 Disinfection

6.3.1 General



NOTE

In the event that product surfaces 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.







CAUTION!

Material damage due to excessive exposure times!

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

Observe the exposure time specified by 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
- · 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-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, 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, oliogomeric biguanide, polyhexamethylene biguanide hydrochloride (oligo-diimino imiodocarbonyl imino-hexamethylene, polyhexanide)

Tab. 4: Active ingredients of disinfectants

6.3.3 Disinfection procedure

- ☑ 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.

6.4 Product-specific safety notes



DANGER!

Health hazard!

The product may not be disassembled for cleaning or disinfection. During cleaning and disinfection, pay attention to ensure that no cleaning agent, disinfectant or other contamination is able to enter the product.





DANGER!

Risk to patient!

Oversuction of products results in them no longer being functional. There is considerable risk to the patient if the tapping unit is not cleaned properly after being exposed to oversuction, as safety equipment could be clogged.

After oversuction, products must be dismantled and cleaned thoroughly by authorised service staff.



CAUTION!

Property damage due to sterilisation!

Do not sterilise the product.



CAUTION!

Property damage!

Using non-colour-fast surgical drapes can cause discolouration of surfaces.

Only use colour-fast surgical drapes.



NOTE

For the cleaning and disinfection of versions B and C, disconnect the connection tube with the NIST screw connection from the tapping unit.



7 Maintenance

7.1 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.



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 authorised by ATMOS.

7.2 Periodic tests

At least every 5 years a test must be performed.

7.3 Malfunctions and troubleshooting

Defect	Source of malfunction	Corrective actions
No or low vacuumNo or reduced flow rate	The ON/OFF button is in the OFF position	Turn the ON/OFF button to the ON position
Regulation of displace- ment not possible	The connection tube is not connected to tapping unit	Connect connection tube according to operating instructions
	Connection tube too long	Shorten connection tube to a maximum length of 50 cm
	Connection tubes collapse	Use special connection tubes (vacuum proof up to –95 kPa)
	Full septic fluid jar, overflow protection system closed	Empty/replace septic fluid jar, replace overflow protection device
	Oversuction of hydrophobic bacterial and viral filter	Replace hydrophobic bacterial and viral filter
	Seal damaged	Replace seal
	Suction system is leaking	Check suction system
	ON/OFF button is defective	Contact technical service
	Central supply system failure	
	Gas probe connection is loose	
	Vacuum gauge is defective	
	Control valve is defective	

Defect	Source of malfunction	Corrective actions
Oversuction of product despite protective system	Tapping unit mounted at an angle	Operate tapping unit in a vertical position only
	Overflow protection device contaminated	Cleaning / replacing the overflow protection device
	No foam inhibitor used	Use standard commercial foam inhibitor

Tab. 5: Malfunctions and troubleshooting

7.4 Repairs

MEDAP :

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

Terminal unit for the wrong

gas type

- · Liquid has penetrated the device.
- · The performance has significantly decreased.
- · Inexplicable notifications appear.
- · Abnormal noises occur.

Gas probe does not fit into

the terminal unit

 Functional faults cannot be rectified according to the measures in chapter Malfunctions and troubleshooting [>> page 30].

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 your responsible ATMOS representative.

Observe the information in chapter Sending in the device [>> page 32].

7.5 Service hotline

+49 7653 689-0

7.6 Type plate position

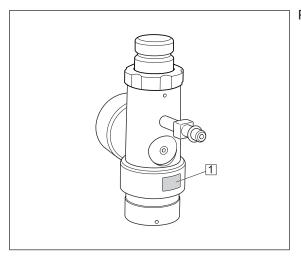


Fig. 12: Type plate position

Position of the type plate (1).

Check gas type

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

Classification as per Annex IX to Directive 93/42/EEC	Class IIa
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8.2 Technical specifications

Nominal pressure, gas supply	250 to 600 kPa*
Vacuum regulation range of S AIR B 800	0 to −78 kPa*
Suction performance of S AIR B 800 (Freeflow)**	max. 36 l/min. at 500 kPa*
Air consumption gas-jet pump	max. 63 l/min. at 500 kPa*
Vacuum gauge	Accuracy class 2.5
Use in MR environment	MR conditional (tapping unit without trolley or carrier frame) up to 4.7 T*** within 100 mT

^{* 100} kPa = 1 bar = 1000 mbar = 750 mmHg

8.3 Ambient conditions

Temperature	-20 °C to +60 °C (shipping)
	+5 °C to +50 °C (operation)
Relative humidity	10% to 95% (shipping)
	10% to 95% (operation)
Atmospheric pressure	700 hPa to 1060 hPa (shipping)
	700 hPa to 1060 hPa (operation)

8.4 Dimensions and weight

Dimensions S AIR B 800 (W x H x D)	52 x 140 x 120 to 155 mm
Weight S AIR B 800	580 to 720 g

^{**} in accordance with EN 10079-3. Depending on the design of the gas supply system, the actual performance of the tapping unit may be reduced.

^{*** 1} T = 1000 mT= 10000 Gauss



9 Approved accessories

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

9.1 Accessories

5752 5695	S AIR mobile suction unit basic equipment / compressed air
5752 5696	S AIR mobile suction unit complete unit / compressed air / 2 x 3 l
5752 5697	S AIR mobile suction unit complete unit / compressed air / 2 x 4 I / PSU
5752 5698	S AIR mobile suction unit complete unit / compressed air / 2 x 4 I / PC
5752 5693	S AIR compact suction unit basic equipment / compressed air
5752 5694	S AIR compact suction unit complete unit / compressed air / 2 x 1 l
5752 5632	Mechanical overflow protection
5752 5634	Adapter for hydrophobic filter
5752 5256	Aspiration set for carrier frame solo
5752 5288	Equipment carrier for aspiration set carrier frame solo
5752 5314	Surgical trolley
5750 8021	Tube holder
see MEDAP tube list	AIR connection tube with NIST screw connection

Tab. 6: Accessories

9.2 Accessories for compact suction unit / compressed air basic equipment

The suction units can be used in combination with the following application sets.

5752 5645	AS septic fluid aspiration / 2 x 1 l / reusable	
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Tab. 7: Accessories for compact suction unit / basic vacuum equipment

9.3 Accessories for mobile suction unit / basic compressed air equipment

The suction unit can be used as a surgical aspirator by combining it with the following application sets.

5752 2067	AS surgical aspiration / 2 x 5 l
5752 5664	AS surgical aspiration / 2 x 4 I / PSU
5652 5665	AS surgical aspiration / 2 x 4 I / PC
5752 2068	AS surgical aspiration / 2 x 3 l
5752 4940	AS surgical aspiration / 2 x 3 l / Serres®
310.0401.0	Serres® disposable suction liner 3 I, with gelling agent (20 pieces)
310.0411.0	Serres® disposable suction liner 3 I, without gelling agent (24 pieces)
5752 2049	Vacuum shift
5752 4538	Bowl for trolley, round

Tab. 8: Accessories for mobile suction unit / vacuum basic equipment

9.4 Consumables

5752 5635	Hydrophobic bacterial and viral filter (disposable)
5752 5633	Particle filters (100 pieces)
006.0009.0	Suction tube, silicone, Ø 6 mm, 1 m
5750 5483	Vacuum connection tube, 8 x 14 mm, by the metre
000.0347.0	Fingertip

Tab. 9: Consumables



■Hersteller:

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