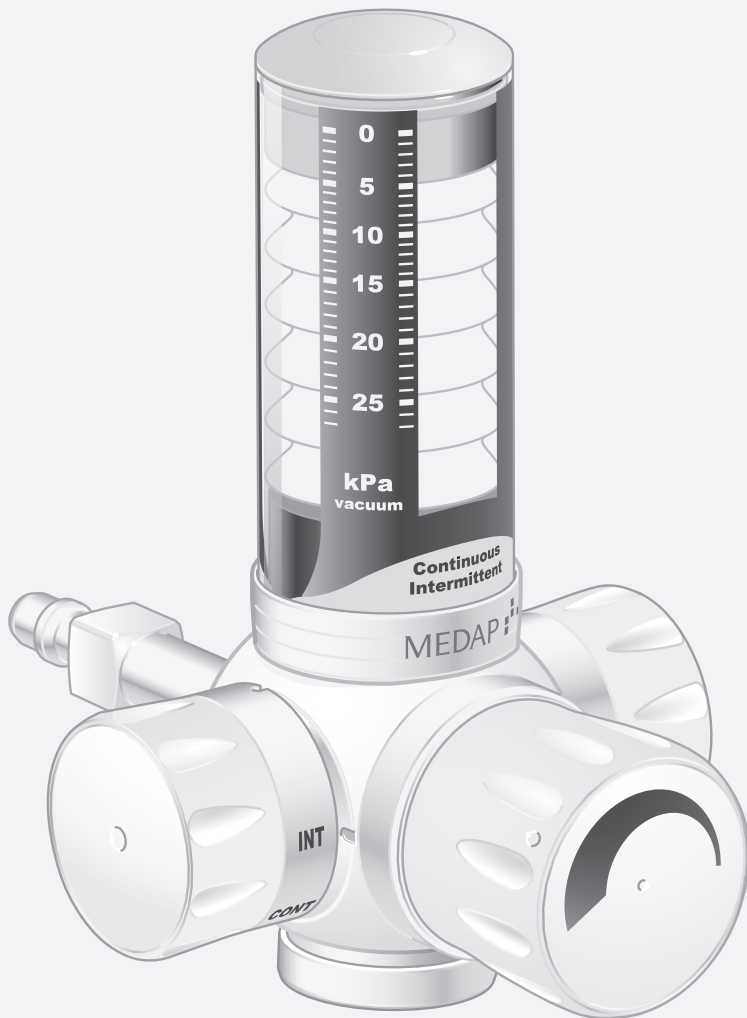


OPERATING INSTRUCTIONS

MEDAP TAPPING UNIT S VAC INT

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.

V03 2020-07





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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 '☒' 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 Design of other notes




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









Pictogram	Descriptor	Reference to
	NOTE	Supplementary assistance or further useful information.
	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
	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.
	Labelling in compliance with the ISO 15223-1 standard. Symbol for 'Serial number'.
	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 ISO 15223-1 standard. Symbol for 'Name and address of the manufacturer as well as date of manufacture'.
	Packaging label. Symbol for 'Keep dry'.
	Packaging label. Symbol for 'Fragile! Handle with care'.
	Packaging label. Symbol for 'Top'.
	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

1.2.5

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

1.3.1 S VAC INT

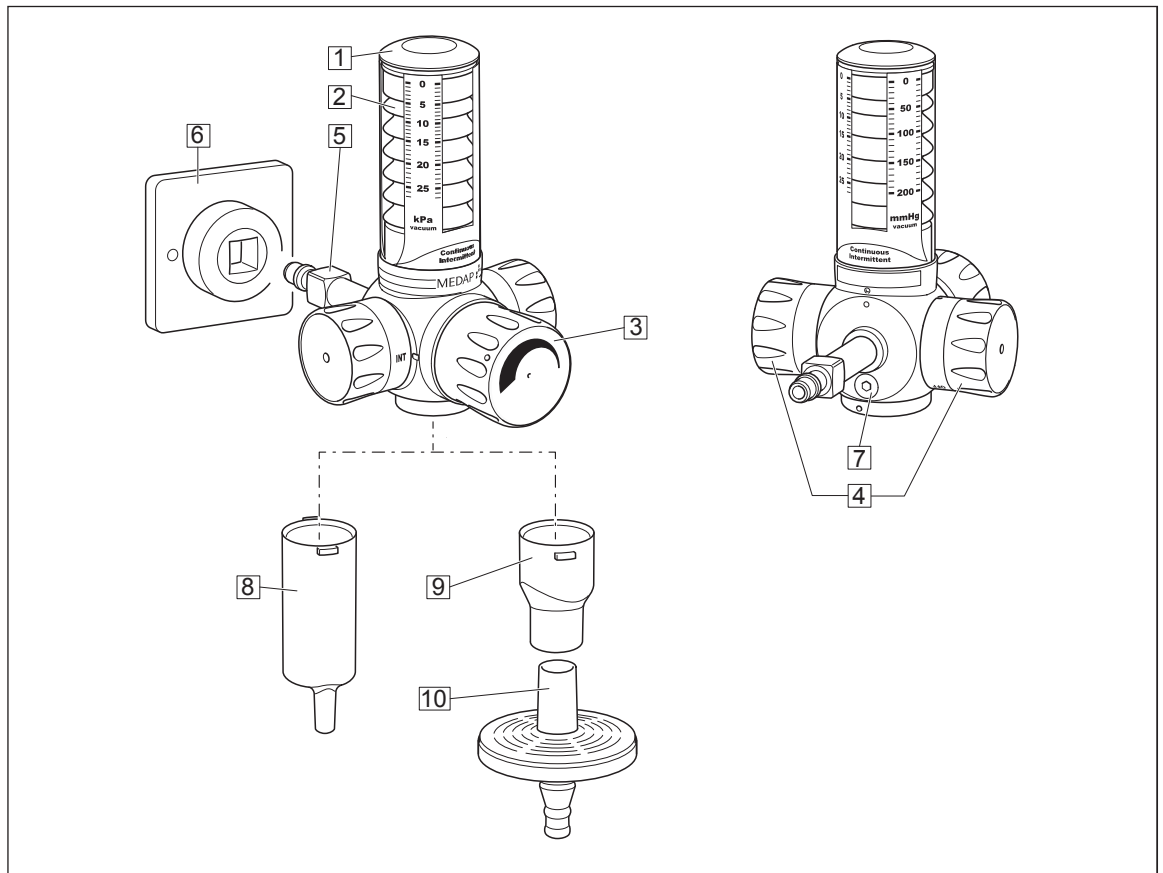


Fig. 1: Overview of S VAC INT

- | | |
|------------------------------------|--|
| 1 S VAC INT | 6 Terminal unit |
| 2 Vacuum indicator | 7 Air inlet |
| 3 Control valve | 8 Mechanical overflow protection |
| 4 Selector switch OFF - CONT - INT | 9 Adapter for the hydrophobic bacterial and viral filter |
| 5 Plug | 10 Hydrophobic bacterial and viral filter |

1.3.2 S VAC INT versions

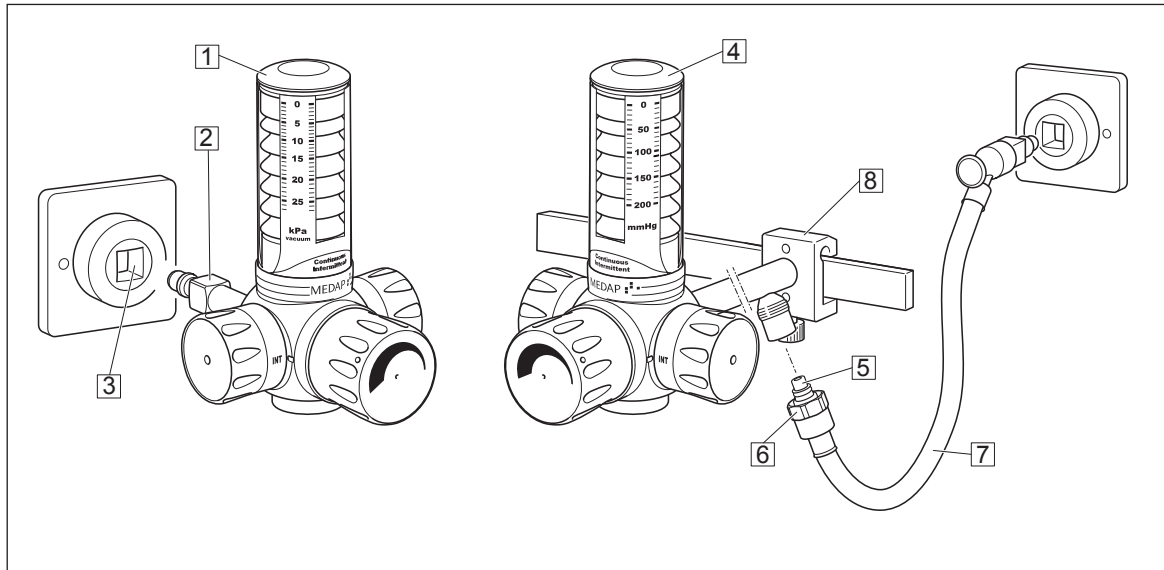


Fig. 2: Overview of S VAC INT versions

1 Version A

Tapping unit with integrated gas pin

- 2 Gas pin
- 3 Terminal unit

4 Version B

Tapping unit with rail clamp and NIST connection

- 5 NIST nipple
- 6 NIST screw connection
- 7 Connection tube
- 8 Rail clamp

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 VAC INT
Main function:	Aspiration of secretion, blood and serous fluids
Medical indications / application:	For precise regulation of vacuum for postoperative aspiration of wound exudate, secretion, blood or serous fluids. Additional fields of application are the aspiration of air as well as rinsing and wound drainage.
Specification of the main function:	<p>Drainage and temporary collection of body fluids. For the supply of vacuum, S VAC INT is connected to a terminal unit for vacuum of a central medical gas supply system (–100 kPa to –60 kPa). A septic fluid jar, which has to be used, allows for temporary collection of drained body fluids.</p> <p>In the position intermittent, the S VAC INT is particularly suitable for subglottic aspiration.</p>
User profile:	Doctor, medically trained staff
Patient groups:	Patients of all ages
Application organ:	Natural and artificial body orifices
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 which have a central vacuum source. The application of the product may only be performed by medically trained and instructed staff.
Contraindications:	<p>The S VAC INT 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 vacuum extraction• For the aspiration of flammable or explosive liquids• For the aspiration of smoke that is generated during HF and laser surgery• For bronchial aspiration, except for intermittent subglottic aspiration• For thoracic drainages• For surgical aspiration• With central gas supply systems with supply pressures other than –100 kPa to –60 kPa
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 VAC INT versions

The connection of the S VAC INT to the terminal unit depends on the model being used.

Version A: Tapping unit with integrated gas pin

- S VAC INT is fitted directly to the terminal unit.

Version B: Tapping unit with rail clamp and NIST connection

- S VAC INT is designed for mounting onto a 25–35 x 10 mm equipment rail in accordance with DIN EN 19054 and is supplied from a terminal unit for vacuum via a NIST connection with a connection tube with gas probe.

The S VAC INT is available in the following versions:

- S VAC INT Wall DIN (REF 5752 5730)
- S VAC INT Wall BOC (BS 5682) (REF 5752 5731)
- S VAC INT equipment rail (REF 5752 5732)

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. 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 (\pm 10 cm)
- Vacuum resistant down to -95 kPa (must not collapse)

Prerequisites

- 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 device, 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 against the ingress of bacteria and viruses.

Prerequisites

- Pore size $\leq 1.0 \mu$.
- 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 the 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 secretions extracted.

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 against the ingress of particles and fluid. The 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 as well as intermittent aspiration require particularly careful limitation of the vacuum.

**WARNING!**

Risk of injury!
ATMOS products may be used only when fully functional.
Check that the ATMOS product is fully functional and in good working order prior to use. ATMOS always recommends having another aspirator ready to hand. This enables aspiration even in the event of product failure.

**DANGER!**

Infection hazard due to oversuction!
To avoid the ingress of fluid or foam into the product or the vacuum source, a hydrophobic 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 contaminants into the product or the vacuum source, a 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 the 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!

Replace the hydrophobic bacterial and viral filter immediately if it is discoloured, contaminated or oversucked.

Furthermore, the filter must be changed if the vacuum displayed is 26 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 during continuous aspiration.
- The product is not autoclavable.

3 Initial operation

3.1 Product testing



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 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

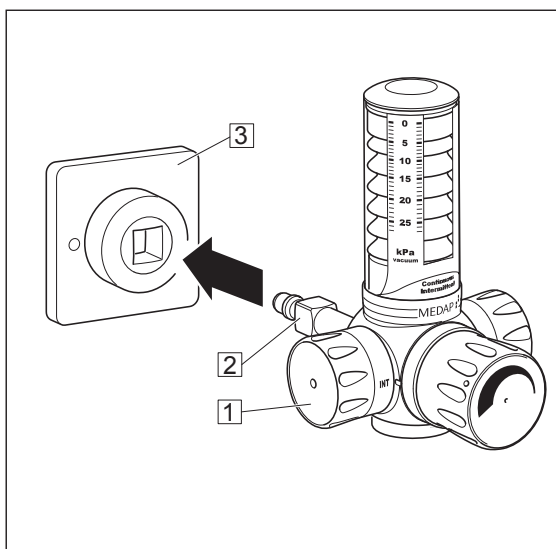
3.2.1 General



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



Tapping unit with integrated gas pin

- Set the selector switch (1) to position OFF [▶▶ page 21].
- The tapping unit (2) is plugged directly into the terminal unit (3).

Fig. 3: Version A

3.2.3

Version B

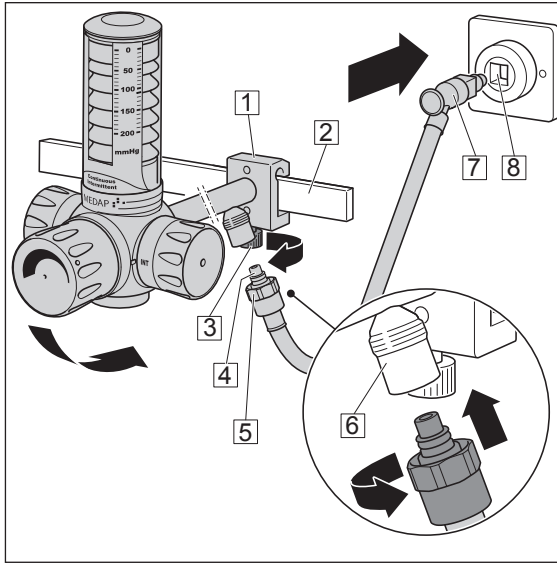


Fig. 4: Version B

Tapping units with rail clamp and NIST connection

- ☒ Position the rail clamp (1) at a slight angle with the upper edge of the guide groove on 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 (5) of the tapping unit and tighten the NIST screw connection (6) by hand.
- ☒ Plug the gas probe (7) of the connection tube into the terminal unit (8).

3.3

Mounting 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

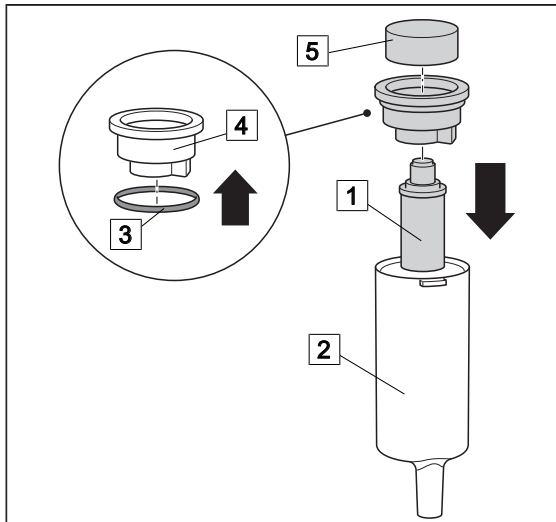


Fig. 5: Mounting the mechanical overflow protection

Mounting the mechanical overflow protection

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

3.3.3 Connection of the mechanical overflow protection

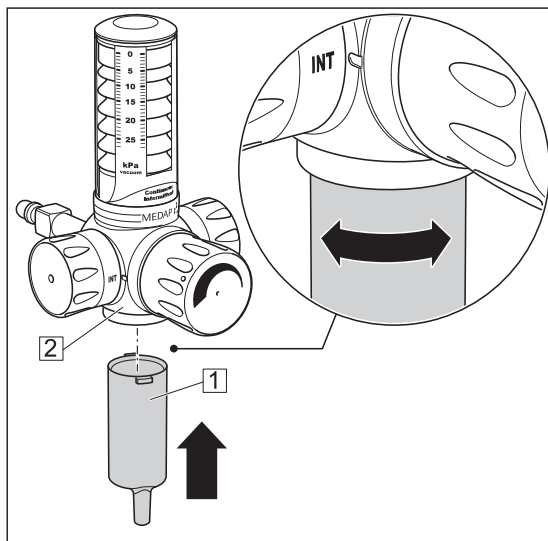


Fig. 6: Mounting/removing the mechanical overflow protection device

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

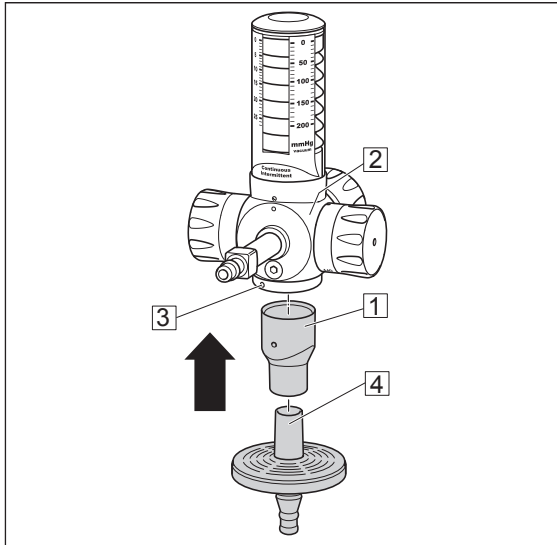


Fig. 7: Mounting the hydrophobic bacterial and viral filter

Mounting the hydrophobic bacterial and viral filter

- ☒ Remove the grub screw from the adapter (1) with an Allen key.
- ☒ Insert the adapter (1) for the hydrophobic filter directly into the tapping unit (2) and turn.
- ☒ Tighten the grub screw into the opening (3) with an Allen key.
- ☒ Fit the hydrophobic bacterial and viral filter (4) onto the adapter for the hydrophobic filter and push it up.

4 Operation

4.1 Function 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.

All versions:

- The product has been properly cleaned and neither residue nor contamination are present.
- The control valve can be easily turned and the selector switch OFF - CONT - INT is functioning.
- The overflow protection device and the hydrophobic 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 Adjusting the selector switch

**NOTE**

During intermittent aspiration, the tapping unit switches between aspiration (15 s) and non-aspiration (10 s). An authorised ATMOS service partner can change the frequency.

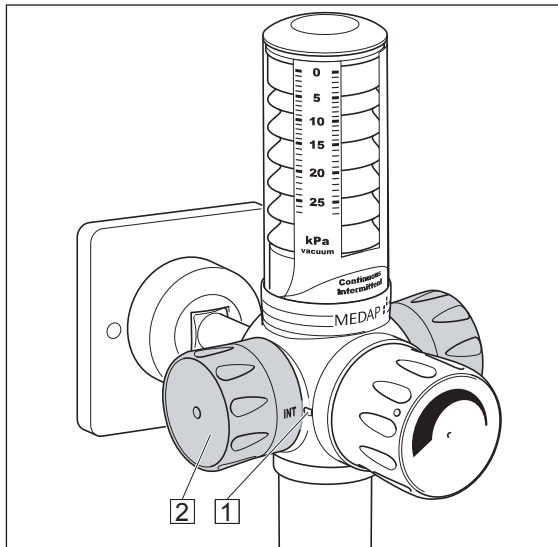


Fig. 8: Adjusting the selector switch

The selector switch has three setting possibilities

- Arrow (1) beside the selector switch (2) points to OFF: No aspiration.
- Arrow (1) beside the selector switch (2) points to CONT: Continuous aspiration.
- Arrow (1) beside the selector switch (2) points to INT: Intermittent aspiration.

4.3

Setting the vacuum level



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!

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



WARNING!

Air inlet!

The bore hole 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!

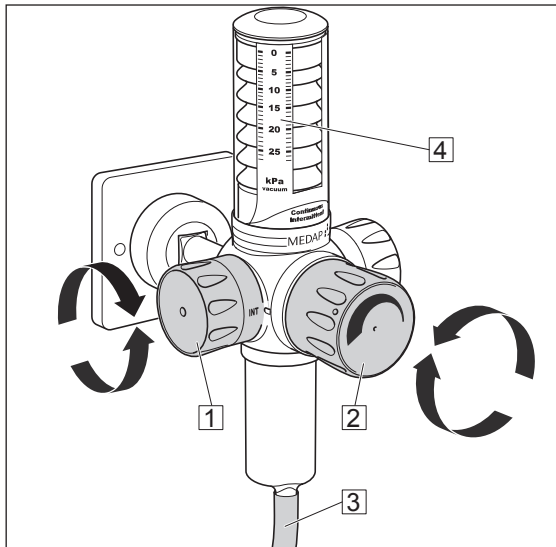


Fig. 9: Setting the vacuum level

Setting the vacuum for treatment

- ☒ Set the selector switch (1) to position OFF and connect the tapping unit [▶▶ page 17].
- ☒ Turn the control valve (2) clockwise and close as far as it will go.
- ☒ Set the selector switch (1) to position CONT or INT.
- ☒ Bend the connection tube (3) that leads to the septic fluid jar.
- ☒ Use the control valve to set the required value for the treatment.
Increase the vacuum: Turn the control valve anticlockwise.
Reduce the vacuum: Turn the control valve clockwise.
- ☒ Read the value on the vacuum indicator (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 (3) that leads to the septic fluid jar.
- ☒ Aspirate.

5 Taking the unit out of operation

5.1 Completing the aspiration process



NOTE

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

- Remove the suction tube from the patient.
- Close the control valve and set the selector switch to OFF.
- 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 from 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.

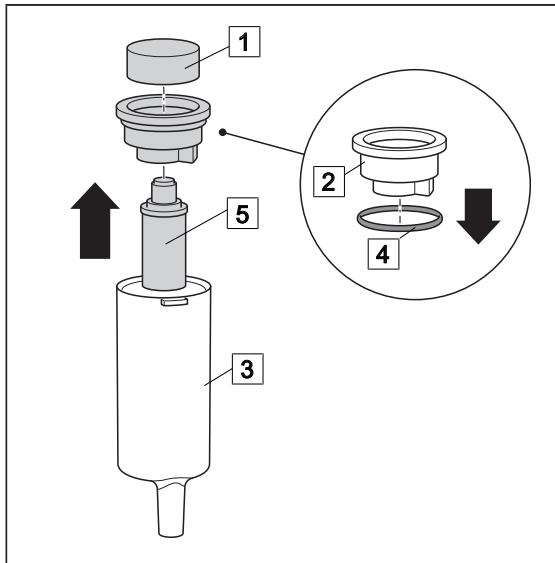


WARNING!

Tensile forces!

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

5.2.2 Dismantling the mechanical overflow protection



- 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 the float (5) out of the overflow container.

Fig. 10: Dismantling the mechanical overflow protection

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 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!

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.
- Wipe off 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 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 wipe 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-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**

- 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.

6.3.4**Disinfection procedures**

Different disinfection procedures may be used for the various components depending on the properties of the materials. Before disinfection, remove contamination and residues from the parts and dry well.

Components	Wipe, spray disinfection ¹
S VAC INT	X
Mechanical overflow protection	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.

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 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.

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	Troubleshooting
<ul style="list-style-type: none"> • No or low vacuum • No or reduced flow rate • Regulation of flow rate not possible 	Selector switch is in the position OFF	Set the selector switch to position CONT or INT
	Control valve is closed	Set the vacuum to the desired value via the control valve
	Product is not inserted correctly into the terminal unit	Check for correct fit
	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
	Selector switch defective	Contact Technical Service
	Central supply system failure	
Vacuum gauge is defective		
Control valve is defective		

Defect	Source of malfunction	Troubleshooting
No switching between aspiration and non-aspiration in the selector switch setting INT	Setting was altered	Contact Technical Service
Oversuction of product despite protective system	Tapping unit mounted at an angle	Operate tapping unit in a vertical position only
	Overflow protection device contaminated	Clean/replace overflow protection device
	No foam inhibitor used	Use standard commercial foam inhibitor
Gas probe does not fit into the terminal unit	Terminal unit for the wrong gas type	Check gas type

Tab. 5: Malfunctions and troubleshooting

7.4 Repairs

The following 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 30].

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

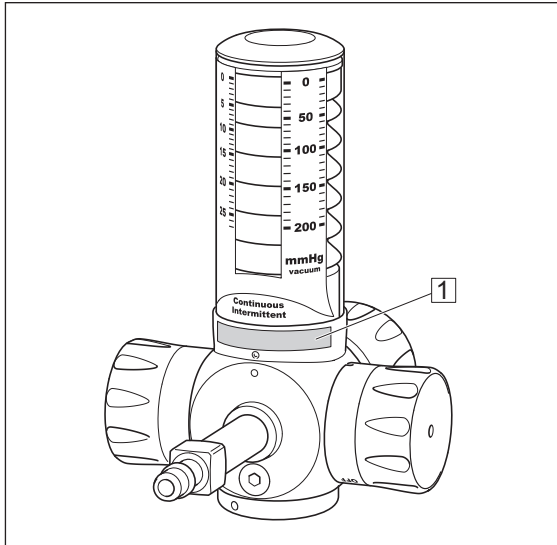
Make a note of the defects and the REF number on the type plate and inform your ATMOS representative.

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

7.5 Service hotline

+49 7653 689-0

7.6 Type plate position



Position of the type plate (1).

Fig. 11: 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 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 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

Vacuum regulation range	0 to -26 kPa*
Flow rate CONT (Freeflow)**	60 l/min
Flow rate INT (Freeflow)**	9 l/min
Accuracy	±5%
Intermittent aspiration: Ratio aspiration : non-aspiration***	Approx. 15 s :10 s

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

** in accordance with EN 10079-3 at 80 kPa and 120 l/min. Depending on the design of the gas supply system, the actual performance of the tapping unit may be reduced.

*** The aspiration time is 25–75% higher than the non-aspiration time.

8.3 Ambient conditions

Temperature	-15 °C to +50 °C (shipping)
	+10 °C to +40 °C (operation)
Relative humidity	Less than 100% (shipping)
	30% to 75% (operation)
Atmospheric pressure	700 hPa to 1060 hPa (shipping)
	700 hPa to 1060 hPa (operation)

8.4 Dimensions and weight

Dimensions (without gas pin) (W x H x D)	114 x 160 x 105 mm
Weight (without gas pin)	710 g

9 Approved accessories

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

9.1 Accessories

5752 5632	Mechanical overflow protection
5752 5634	Adapter for the hydrophobic bacterial and viral filter

Tab. 6: Accessories

9.2 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. 7: Consumables

Notes



■ **Manufacturer:**

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