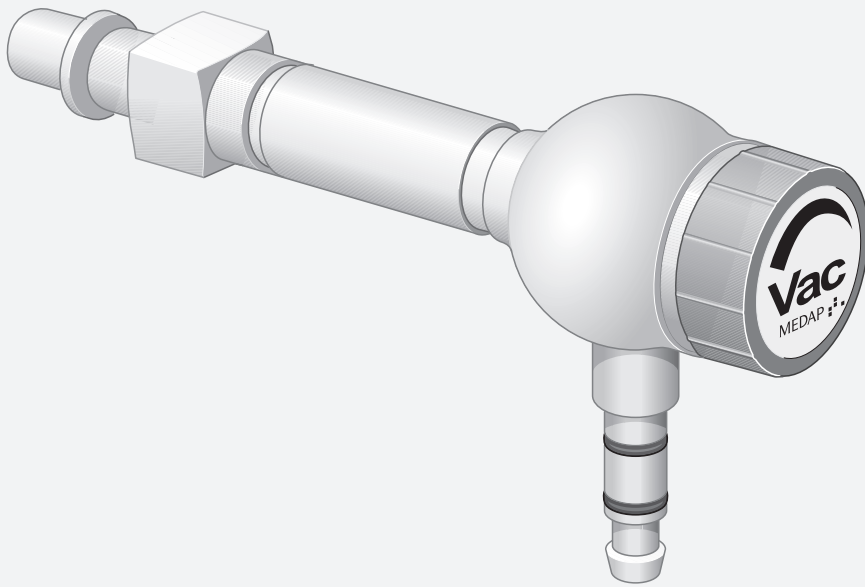


OPERATING INSTRUCTIONS
MEDAP
FINA FINE REGULATOR VAC

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.

V10 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 'Name and address of the manufacturer as well as date of manufacture'.
	Labelling in compliance with the ISO 15223-1 standard. Symbol for 'Product number'.

Symbols	Identification
	Labelling in compliance with the ISO 15223-1 standard. Symbol for 'Serial number'.
	Labelling in compliance with the IEC 60601-1 standard. Symbol for 'Follow operating instructions'.
>PA<	Material designation for the plastic PA (polyamide).
	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

1.3 Disposal

1.3.1 General

Used products or parts thereof may be contaminated. To prevent potential infection, please clean and disinfect the product prior to return/disposal.

1.3.2 Packaging

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

1.3.3 **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.

1.4 **Overview**

1.4.1 **FINA Fine regulator VAC**

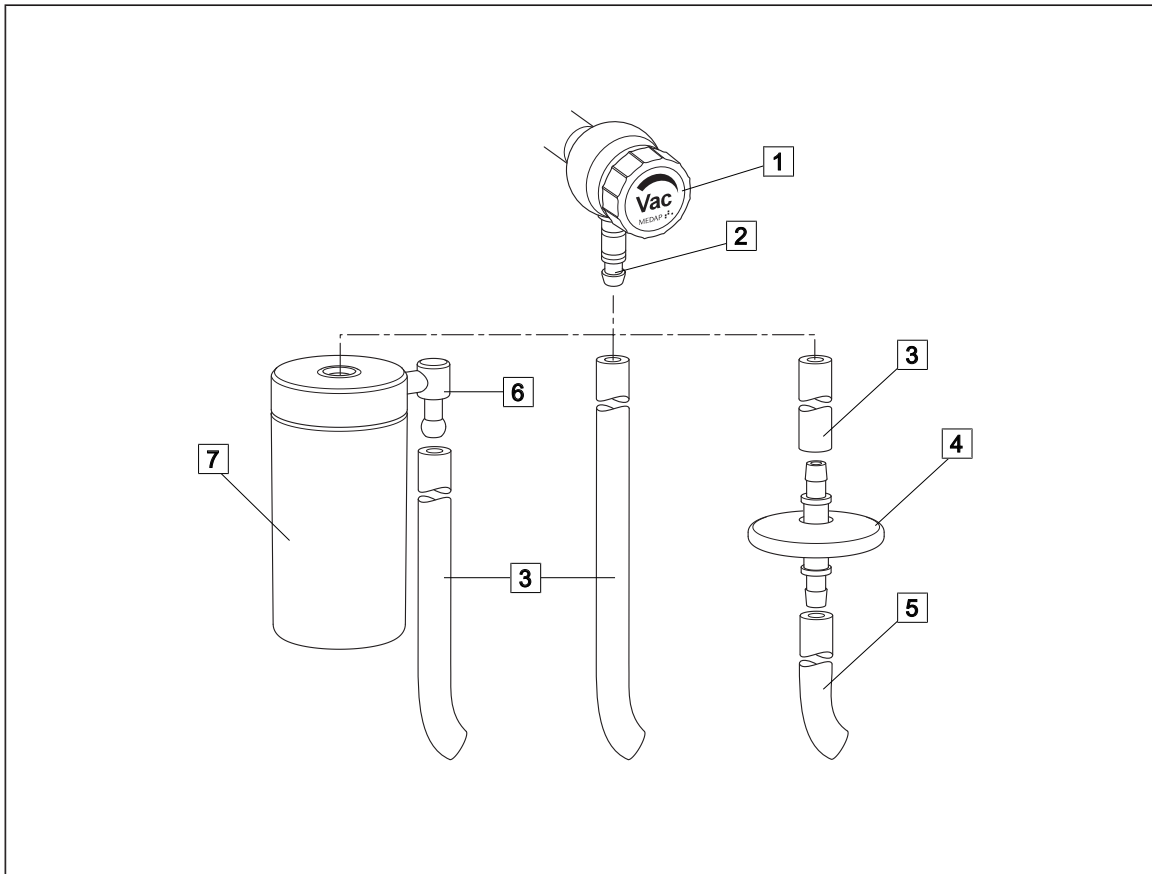


Fig. 1: Overview of FINA fine regulator VAC

- | | |
|---|---|
| 1 Adjusting screw | 5 Vacuum connection tube B
Inner diameter 6 mm |
| 2 Tube connector VAC | |
| 3 Vacuum connection tube A
Inner diameter 6 mm | 6 Tube connector for mechanical overflow protection |
| 4 Hydrophobic bacterial and viral filter | 7 Mechanical overflow protection |

1.4.2 Versions of FINA fine regulator VAC

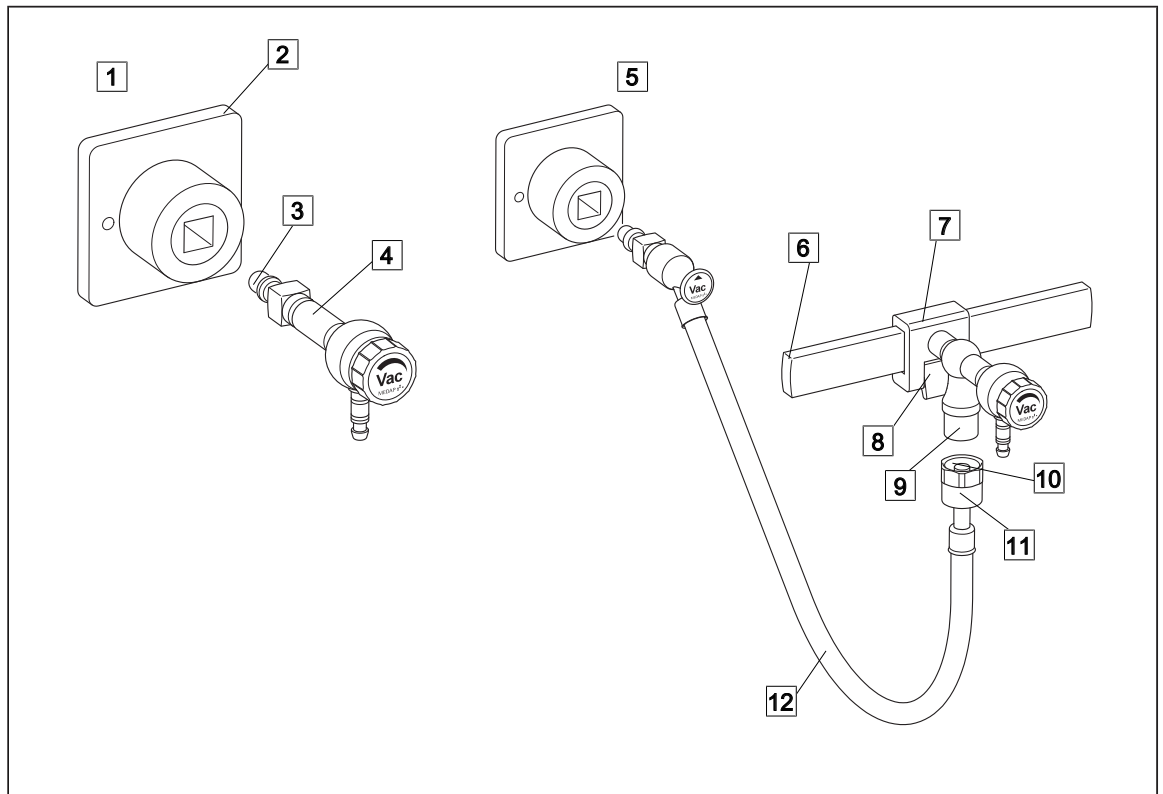


Fig. 2: Overview of FINA fine regulator VAC versions

- | | |
|---|--------------------|
| 1 Version A | 6 Equipment rail |
| Tapping unit with integrated gas pin | 7 Rail clamp |
| 2 Terminal unit VAC | 8 Locking lever |
| 3 Gas pin VAC | 9 NIST housing |
| 4 Fine regulator inlet | 10 NIST nipple |
| 5 Version B | 11 Cap nut |
| Tapping unit with rail clamp and NIST connection | 12 Connection tube |

1.5 Basic requirements

1.5.1 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.

1.5.2 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 Products 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.

1.5.3 Intended purpose

Name:	FINA FRV VAC
Main function:	Aspiration of secretion, blood, serous fluids, vomit and rinsing fluids along with any contained particles
Medical indications / application:	For all aspirations where a regulation of the vacuum strength is not necessary and a regulation of the volume flow is sufficient, e.g. general surgeries (aspiration of wound cavities, abscesses) and bronchial aspiration of adults.
Specification of the main function:	Drainage and temporary collection of body fluids. For the supply of vacuum, FINA FRV VAC is connected to a terminal unit for vacuum of a central medical gas supply system with a pressure of -100 kPa to -60 kPa. A septic fluid jar, which has to be used, allows for temporary collection of the drained body fluids.
User profile:	Doctor, medically trained staff
Patient groups:	Surgical aspiration: patients of all ages; bronchial aspiration of adults
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:	The FINA FRV VAC may not be used for the following purposes: <ul style="list-style-type: none"> • Outside the medical sector • In MR areas • In the home care sector • Being operated directly by the patient • If not reducing the vacuum of the central gas supply poses a danger for the patient (e.g. in drainage, in paediatrics and neonatology). Usage in combination with disposable thoracic drainage systems with integrated vacuum regulation is excepted. • 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 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.

1.5.4 Versions of FINA fine regulator VAC

The connection of the terminal unit to FINA FRV VAC depends on the model being used:

Version A: Tapping unit with integrated gas pin

- FINA FRV VAC is fitted directly to the terminal unit.

Version B: Tapping unit with rail clamp and NIST connection

- FINA VAC is designed for mounting onto an equipment rail 25 x 10 mm and is supplied via a NIST connection with vacuum from a terminal unit connected using a connection tube with gas probe.

Products and accessories are only permitted with ISO colour coding. In Germany, Austria and Switzerland, products with neutral colour coding are also permitted.



NOTE

The products are supplied with ISO coding. The scope of delivery includes a label for neutral colour coding.

The product is available in the following versions:

- FINA fine regulator VAC Wall MEDAP (REF 5752 3712)
- FINA fine regulator VAC Wall DIN (REF 5752 3713)
- FINA fine regulator VAC equipment rail (REF 5752 3714)

1.5.5 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.

1.5.5.1 Dimensions for the gas type specific connection for compressed gas

The dimensions for plugs or terminal units are subject to national standards DIN 13260-2 (Germany) and MEDAP standard, depending on the product type.

1.5.5.2 Vacuum connection tube

The vacuum connection tube is used to connect the hydrophobic bacterial and viral filter with the septic fluid jar cap.

Technical specifications

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

Prerequisites

- The vacuum connection tube must comply with the hospital's standards for hygiene.
- The inner diameter of the vacuum connection tube must match the outer diameter of the hydrophobic bacterial and viral filter.
- The inner diameter of the vacuum connection tube must match the outer diameter of the tube connector on the bacterial and viral filter.

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

1.5.5.3 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 from 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).

1.5.5.4 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.

1.5.5.5 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 of 6 - 8 mm
- Length 1.3 m - 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.

1.5.5.6 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.

1.5.5.7 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.

1.5.5.8 Mechanical overflow protection

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

2 Safety notes

2.1 General safety notes



WARNING!

Risk of injury!

ATMOS products may be used only when fully functional.

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



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.



DANGER!

Defective device!

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

Only use original accessories or spare parts.



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



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 contaminants into the product or the vacuum source, a hydrophobic bacterial 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!

Risk of oversuction!

The tapping unit may only be used with the mechanical overflow protection in an upright position.

**DANGER!**

Risk of injury to mucous membranes!

Endobronchial aspiration in paediatrics and neonatology requires particularly careful limitation of the vacuum. For the regular endobronchial aspiration in paediatrics and neonatology, ATMOS also offers paediatric versions with a higher level of setting convenience.

**WARNING!**

Impacts!

Impacts may cause damage to sensitive, precision mechanical components.
Do not expose the product to impacts.

**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!**

Foaming!

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

Use an ordinary foam inhibitor.

**WARNING!**

Measuring accuracy / oversuction!

The product may only be operated in a vertical position.

**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 unit.
 - 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 storage, the unit should be protected against damage by using cloths, for example.
-

3 Initial operation

3.1 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.



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.

- Check whether all tubes are undamaged.
- Check whether the unit has been properly cleaned and that there are no residues or soiling.
- Do not use damaged components.

3.2 Connection to the terminal unit

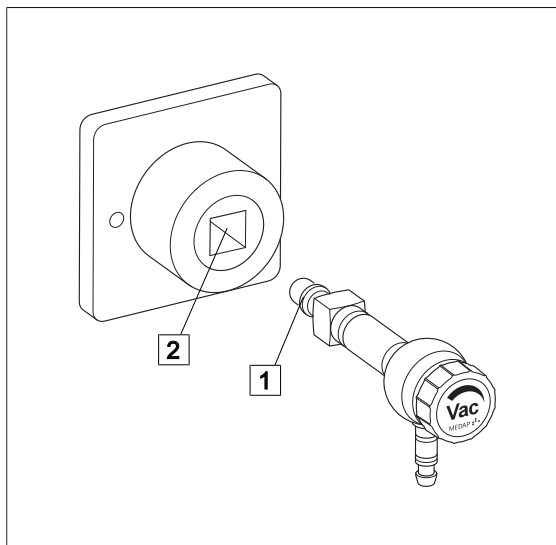
3.2.1 General



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

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

Fig. 3: Version A

3.2.3 Version B

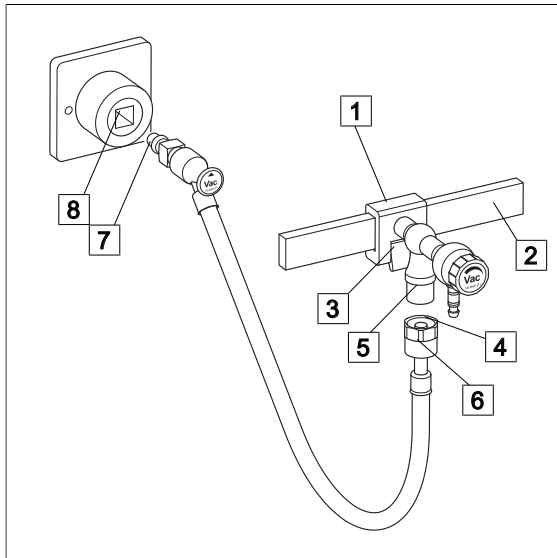


Fig. 4: Version B

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 on the equipment rail (2) and then press it against the equipment rail and allow it to click into place.
- ☒ Make sure that the rail clamp is correctly secured and that the tapping unit is in a stable position on the equipment rail. The locking lever (3) must be flush with the rail clamp.
- ☒ Insert the NIST nipple (4) of the connection tube into the NIST connection (5) of the tapping unit and tighten down 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.

3.3.2 Connection of the mechanical overflow protection

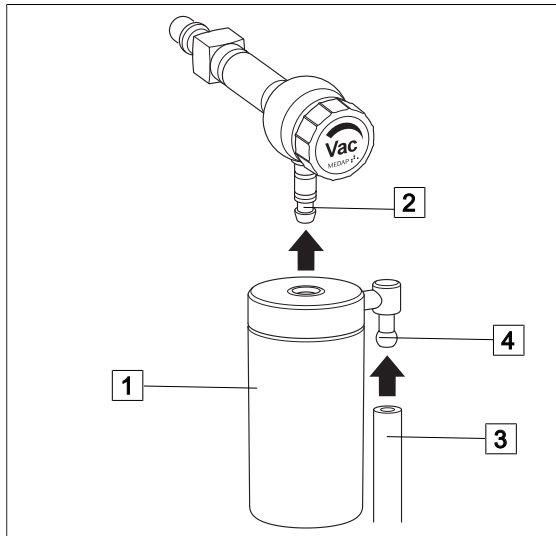


Fig. 5: Connection of the mechanical overflow protection

Connection of the mechanical overflow protection

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

3.3.3 Connection of the hydrophobic bacterial and viral filter

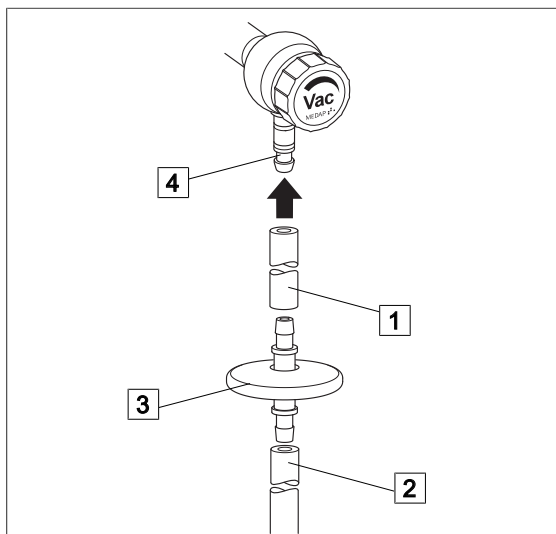
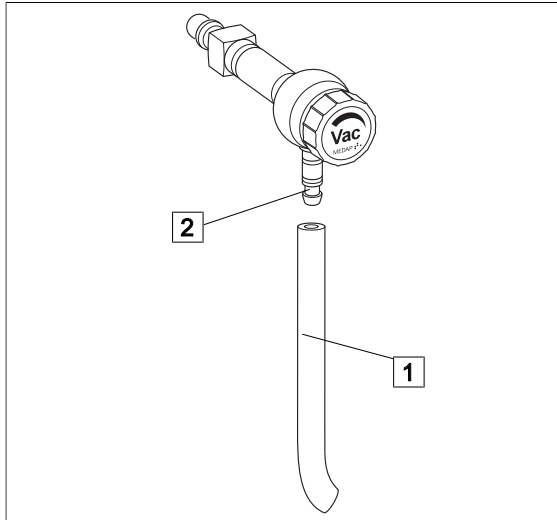


Fig. 6: Connection of the filter

Connection of the hydrophobic bacterial and viral filter

- ☒ The connection tubes (1) and (2) are plugged onto the tube connectors of the filter (3).
- ☒ Check the flow direction of the filter. The inlet side must face the patient, and the outlet must face the tapping unit.
- ☒ Then plug the connection tube (1) onto the tube connector (4) on the housing of the tapping unit.
- ☒ Connect the connection tube (2) with the designated tube connector of the septic fluid jar.

3.3.4 Connection of the septic fluid jar with integrated overflow protection



Connection of the septic fluid jar with integrated overflow protection

- ☒ Attach the connection tube (1) to the tube connector (2) on the housing of the tapping unit and connect it to the tube connector of the septic fluid jar.

Fig. 7: Connection of the septic fluid jar

4 Operation

4.1 Function test

**DANGER!**

Function check!

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

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

**NOTE**

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

Perform a complete function check of the tapping unit prior to use. During functional testing, pay attention to the following conditions:

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 gas probe of the connection tube is seated correctly in the terminal unit.
- The NIST connection to the tapping unit has no leak.
- The tapping unit is locked firmly to the equipment rail.

All versions:

- The overflow protection device and the hydrophobic bacterial and viral filter are mounted and 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 components are in perfect condition and show no signs of ageing
- A septic fluid jar is connected to the tapping unit.

4.2 Setting the flow

**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!**

Flow rate setting!

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

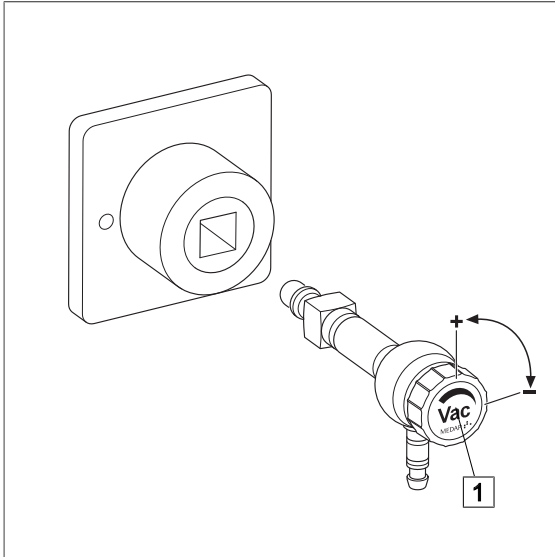
**WARNING!**

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.

**NOTE**

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



- ☒ Open the adjustment screw (1) by turning it anticlockwise.
- ☒ Use the adjustment screw to set the flow rate to the required value for the treatment.
- ☒ In case of insufficient flow rate, refer to the troubleshooting table for the cause.

Fig. 8: Working with the unit

5 Taking the unit out of operation



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 shut-off valve and 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.
- Disconnect the gas probe from the terminal unit.

Version B: Tapping unit with rail clamp

- Remove the unit from the equipment rail. For this purpose, pull the locking lever and lift the unit off the equipment rail.

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.



DANGER!

Infection hazard!

Product may be contaminated.

Always wear gloves for cleaning and disinfection.



DANGER!

Infection hazard!

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

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



CAUTION!

Improper cleaning and disinfection can cause property damage!

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

- Products containing alcohol (e.g. hand disinfectants)
- Halogenides (e.g. 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 slightly 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.
- Thoroughly wipe off the product 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 ammonium compounds
- Guanidine derivatives

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

Tab. 4: Active ingredients of disinfectants

6.3.3**Disinfection procedure**

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

6.4**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 drapes.

**NOTE**

For the cleaning and disinfection of version B, 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. Any restriction of performance of the product can result in complications during treatment.

Check proper function of the product each time it is reconditioned.

Users need not carry out any maintenance work beyond the usual daily cleaning and care.

7.2 Periodic tests

Observe the country specific requirements regarding periodic tests.

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 	Fine regulator not connected	Attach the fine regulator in accordance with the operating instructions
	The connection tube is not connected to tapping unit	Connect connection tube according to operating instructions
	Connection tube too long	Shorten the 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 system
	Oversuction of hydrophobic filter	Replace hydrophobic filter
	Seal damaged	Replace seal
	Suction system is leaking	Check suction system
	Central gas supply system failure	Contact Technical Service
	Probe connection loose	
Fine regulator defective		
	Adjusting screw defective	

Defect	Source of malfunction	Troubleshooting
Oversuction of device despite protective system	Tapping unit mounted at an angle	Operate tapping unit in a vertical position only
	Overflow protection device contaminated	Clean overflow protection device
	No foam inhibitor used	Use standard commercial foam inhibitor
	No hydrophobic filter used	Use hydrophobic filter
Gas probe does not fit into the terminal unit	Wrong terminal unit selected	Check the designation of the terminal unit
Fine regulator is leaking	Seal is missing or defective	Have fine regulator checked
	There is a leak in the housing	
	Accessories are not tightened	Check fit of accessory

Tab. 5: 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 28].

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

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

Observe the information in chapter Sending in the device [▶▶ page 29].

7.5 Service hotline

+49 7653 689-0

7.6 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

Nominal pressure, gas supply	-100 kPa to -60 kPa*
Flow rate (freeflow)**	Approximately 30 l/min
Performance class	HF/HV (High Flow / High Vac)

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

** 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.

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 (L x W x H)	32 x 65 x 120 mm
Weight	250 - 450 g (depending on attachment)

9 Approved accessories

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

9.1 Accessories

5752 1698	Mechanical overflow protection
5752 3330	Aspiration set for equipment rail / 1 l
5752 5669	Aspiration set for wall mount / 1 l

Tab. 6: Accessories

9.2 Consumables

5750 0630	Hydrophobic bacterial and viral filter
006.0009.0	Suction tube, silicone, Ø 6 mm, 1 m
000.0347.0	Fingertip

Tab. 7: Consumables



■ **Manufacturer:**

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