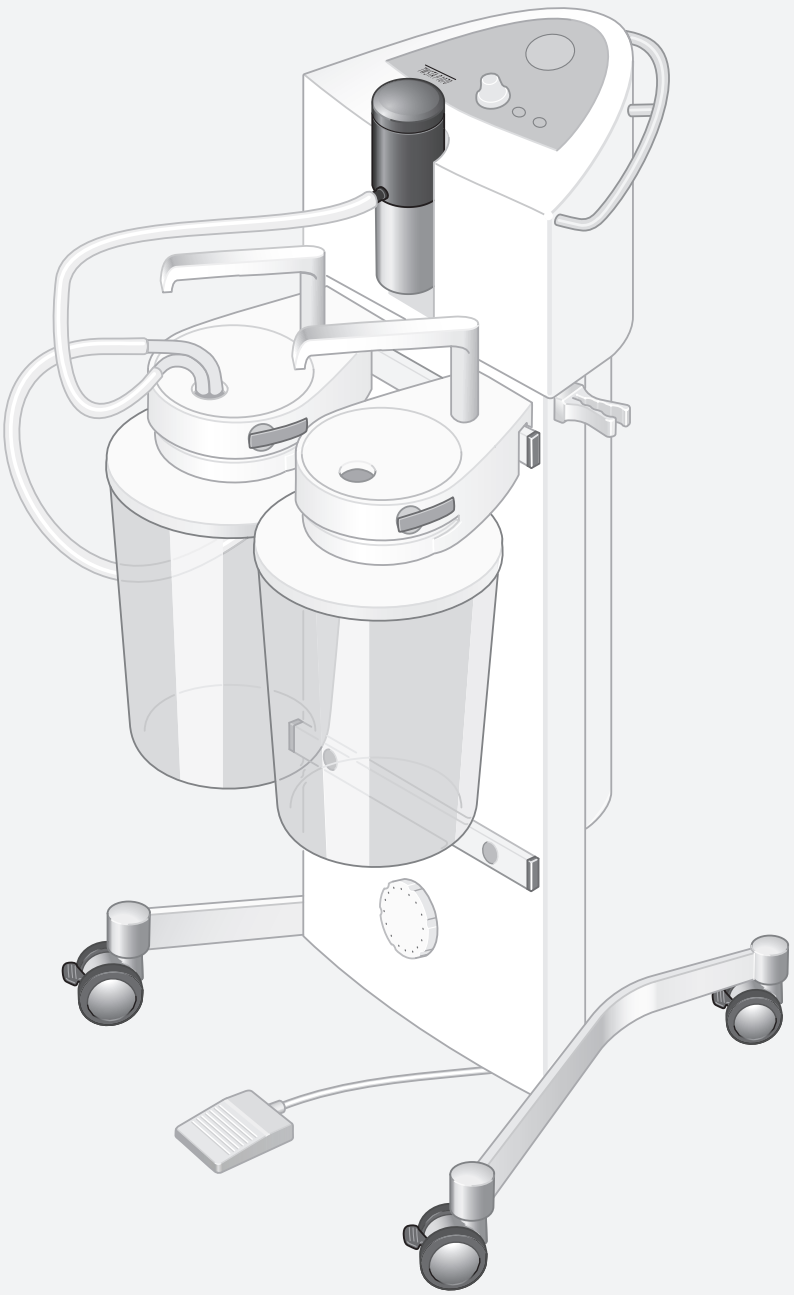
OPERATING INSTRUCTIONS

SURGICAL ASPIRATOR
MEDAP-TWISTA SP 1070

MEDAP



GA 5752 1555 GB 30

Subject to technical modification!

Illustrations and technical specifications may vary slightly from those in these Operating Instructions as a result of ongoing product development.

V30 2024-06

CE 0124

Table of contents

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

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 Structure of notes

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

Pictogram	Descriptor	Reference to
	**NOTE**	Supplementary assistance or further useful information without potential injury to persons or property damage is described in the text of the note.
	**ENVIRONMENT**	Information regarding proper disposal.

Tab. 2: Structure of notes

1.2.4 Explanation of pictures, symbols and codes

Symbols are affixed to products, type plates and packaging.

Symbols	Identification
CE 0124	This device complies with the relevant requirements of EU regulations.
	Follow operating instructions (blue)
	Consult operating instructions
	Manufacturer

Symbols	Identification
	Date of manufacture Country of manufacture: Germany
REF	Reference number
UDI	Unique Device Identifier of a medical device
MD	Medical device
SN	Serial number
IP X1	Specification of the degree of protection against the ingress of solids and moisture
	Symbol for foot switch —> standby mode. The device can be put into standby mode using the foot switch
	Professional disposal
	Potential equalization
	Fuse
	On, connected to the power supply
	Off, disconnected from the power supply
	This side up
	Fragile, handle with care
	Keep dry
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

Tab. 3: Pictures, symbols and codes

1.2.5 UDI code

(01)	UDI-DI: Identification of the manufacturer and the device
(11)	Date of manufacture
(13)	Packing date
(21)	Serial number

Tab. 4: UDI code

1.2.6 Disposal

1.2.6.1 Packing

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

1.2.6.2 ATMOS products

ATMOS will take back used products or those which are no longer in service.

Please contact your ATMOS representative for more detailed information.

1.2.7 Used electrical devices

Within the European Economic Community

This product is governed by EC Directive 2002/96/EC (Directive on Waste Electrical and Electronic Equipment). This product has not been registered for use in private households. Disposal at municipal collection points for used electrical equipment is not authorised. Please contact your ATMOS representative for more detailed information on correct and legal disposal.

Outside the European Economic Community

When disposing of this product, ensure compliance with the applicable national regulations on the handling and disposal of used electrical equipment.

1.3 Overview

1.3.1 Overview of TWISTA SP 1070

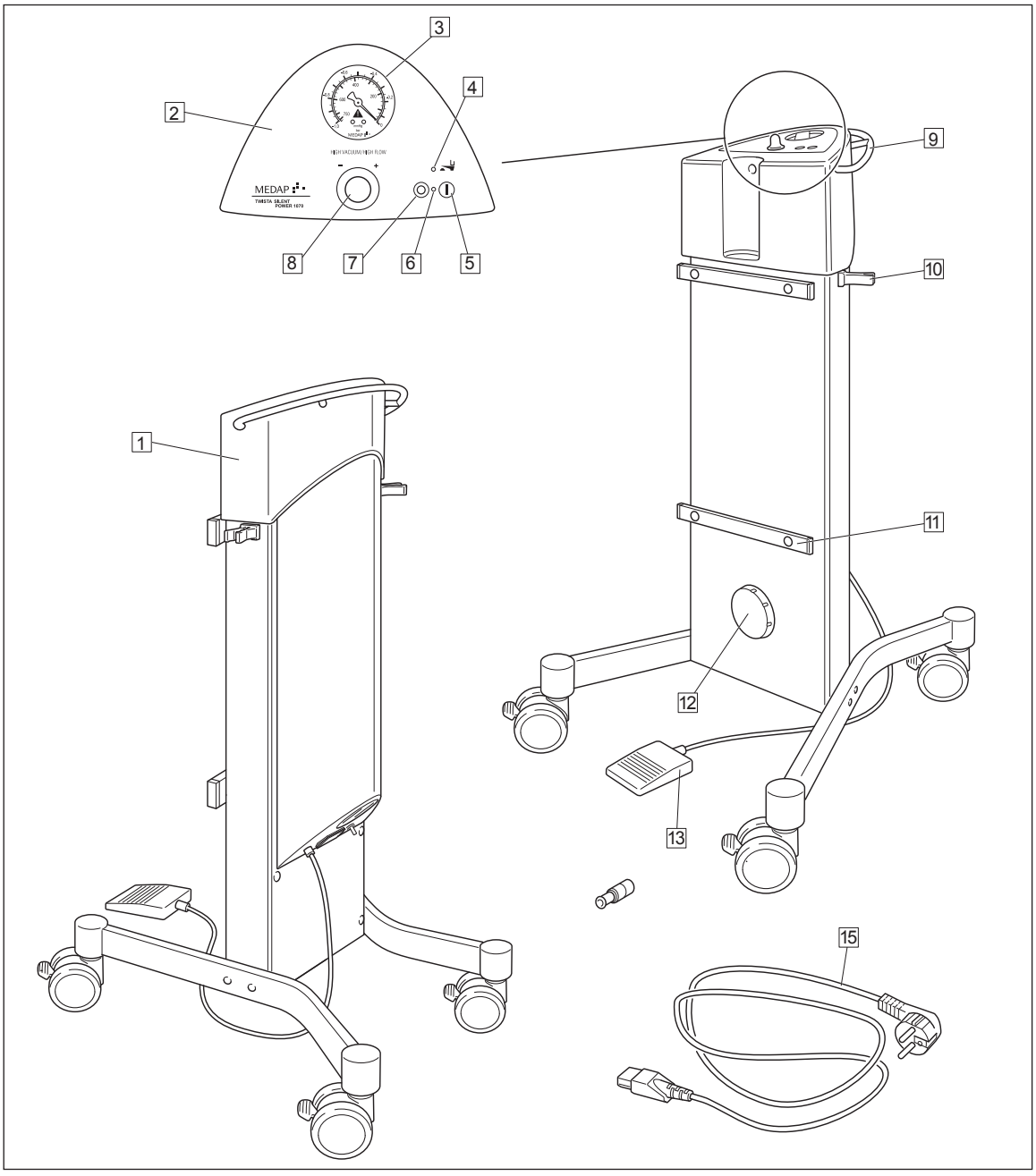


Fig. 1: Overview of TWISTA SP 1070

1 Aspirator basic equipment
2 Control panel
3 Vacuum gauge
4 Control light foot switch
5 ON switch
6 Power control light
7 OFF switch
8 Regulating knob
9 Push bar
10 Tube holder
11 Equipment rail
12 Bacterial filter cap
13 Foot switch
14 Tube connector
15 Mains cable

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 a 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 requirement set forth in Annex I to the 93/42/EU Directive drafted by the Medical Products Council (Medical Products Directive) as well as the applicable national (German) codes and the Medical Products Act in Germany. This has also been demonstrated through the application of the corresponding standards which have been harmonised with Directive 93/42/EEC.

1.4.3 Intended purpose

Product name:	TWISTA SP 1070
Main functions:	Aspiration of secretion, blood, serous fluids and rinsing fluids along with any contained particles and temporary collection of these fluids
Intended use:	Drainage and temporary collection of body fluids. A negative pressure is generated by means of an electrical aspiration pump. A septic fluid jar, which must be installed, allows for temporary collection of the drained body fluids.
Intended users / user profile:	Doctors, trained medical staff
Intended patient target groups:	Patients of all age groups with and without restrictions
Medical conditions to be diagnosed, treated or monitored:	Patients requiring aspiration, e.g., in the operating theatre
Organ(s) applied to:	Natural and artificial body orifices
Duration of application:	Device designed for continuous application; in practice, short-term use on the patient (<30 days)
Use environment:	Environments for use are the hospital/clinical environment and doctor’s practices. The device may only be used by trained and instructed medical staff.
Patient selection criteria:	All patients requiring aspiration

Indications:	For all applications requiring aspiration, e.g., general surgical interventions (aspiration of wound cavities, abscesses), aspiration of the nasopharynx, during endoscopy for aspiration of secretion or rinsing fluids, and in neurosurgery.
Medical contra-indications:	• Vacuum extraction • Smoke Evacuation • Drainages in the low-vacuum range (e.g., thoracic and wound drainage) • Use without a smoke evacuation filter if aggressive vapours are also generated during the aspiration of liquids due to easily volatile components (e.g., when using iodine as a disinfectant) • In areas subject to explosion hazards (AP-M and AP-G areas) • In the standard equipment version in heart surgery or in surgeries on the central nervous system. This requires separate equipment providing reliable protection against equipotential bonding between the patient and contacting, fluid-filled metal parts.
Other contra-indications:	• Outside the medical field • In the homecare area • Use directly by the patient or his/her relatives • For aspiration of flammable or explosive liquids
Warnings:	None
The product is:	active
Sterility / specific microbial state:	Non-sterile device
Single-use product / reprocessing:	The device is intended for multiple use. The device and parts of the accessories are reusable. For information on reprocessing, cleaning and disinfection, please see the operating instructions.

1.4.3.1 Versions

These operating instructions apply to the versions listed below:

TWISTA SP 1070 230 V; 50 Hz / 60 Hz (REF HM57521554)

- Basic equipment
- Mains cable
- Foot switch
- Filter papers (10 pieces)
- Allen key (REF HM57504687)

TWISTA SP 1070 127 V; 60 Hz (REF HM57521559)

- Basic equipment
- Mains cable
- Foot switch
- Filter papers (10 pieces)
- Allen key (REF HM57504687)

1.4.4 Interface description

1.4.4.1 Hydrophobic bacterial and viral filter

NOTE

The use of a hydrophobic bacterial and viral filter is not necessary if a suitable hydrophobic bacterial and viral filter is integrated for a specific purpose in the septic fluid jar of a disposal suction liner.

The hydrophobic bacterial and viral filter protects against contaminants which could be present in the form of particles or aerosols in the gas drawn in. Moreover, the hydrophobic filter serves as protection against oversuction; the filter closes off the flow of gas to the product in the event of oversuction. In its function as bacterial and viral filter, it protects the inside of the aspirator from the ingress of bacteria and viruses. The ATMOS product (REF HM57521783) is a hydrophobic bacterial and viral filter with a pore size of 0.2 µm.

Prerequisites:

- Pore size ≤ 1,0 µm
- Use a bacterial and viral filters suitable for the particular application.
- The tube connector must match the tube being used.
- Hydrophobic filter must close tightly against water passage at an absolute pressure of up to 10 kPa.
- Observe the direction of flow, if applicable (see note on hydrophobic filter).

1.4.4.2 Vacuum connection tube

The vacuum connection tube is used to connect the aspirator (tube connector or overflow protection device) and the septic fluid jar.

Technical specifications:

- Shore hardness of 60
- Internal diameter of 6-8 mm
- Tube length maximum of 60 cm ±10 cm
- Vacuum resistant down to −95 kPa (may not collapse)

Prerequisites:

- The internal diameter of the vacuum connection tube should match the outer diameter of the tube connector on the septic fluid jar cap of the pump.

1.4.4.3 Septic fluid jar including septic fluid jar cap

The septic fluid jar is used to collect the septic fluids extracted.

Technical specifications:

- Vacuum resistant down to −95 kPa (may not collapse)

Prerequisites:

- Must be equipped with an overflow protection device or must be connected to an external overflow protection system.
- Low leakage
- Capacity of 1 l to 5 l
- Always fix septic fluid jars firmly and ensure safe connection to the equipment rail 25 x 10 mm of the TWISTA SP 1070.
- The outer diameter of the tube connector on the patient side should match the inner diameter of the suction tube.

1.4.4.4 Suction tube

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

Technical specifications:

- Shore hardness of 60
- Internal diameter of 6-8 mm
- Length 1.3–3.0 m
- Vacuum resistant down to -95 kPa

Prerequisites:

- The suction tube must comply with the hospital's standards for hygiene.
- The suction tube may not collapse.
- 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.

1.4.4.5 Utensil

The suction catheter, lance, or Yankauer suction tip 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 suction tube.
- The utensil must be sterilisable or a sterile single-use item.
- Biocompatibility

1.4.4.6 Rinsing fluid jar

Any container may be used as rinsing fluid jar.

Prerequisites:

- The rinsing fluid jar must have a capacity of less than 250 ml.
- The rinsing fluid jar shall be easy to clean and disinfect.

1.4.4.7 Bacterial filter paper

The bacterial filter paper prevents the ambient air from contamination. Only bacterial filter papers (REF HM57505045) must be used.

1.4.4.8 Application sets

Application sets augment the basic unit. Application sets can be configured as required, using individual accessories.

Prerequisites:

- Suitable connection tubes must be selected.
- The interface descriptions for the aspirator must be observed.

1.4.4.9 Vacuum shift

The vacuum shift is used to switch between two septic fluid jars.

Prerequisites:

- The tube connector must match the tube being used.

1.4.4.10 Equipotential bonding cable

Equipotential bonding cable acts as the connection between the aspirator and the equipotential bonding pin with equipotential bonding rail for protection against electric shock.

2 Safety notes

2.1 General safety notes

DANGER!

Danger to life!

Danger due to unauthorised modifications.

The product may not be modified.

DANGER!

Explosion hazard!

The product does not have explosion protection and is not approved for use in Class AP-M hazardous locations.

Do not use the product in the AP-M area.

DANGER!

Explosion hazard!

The product must not be used for the aspiration of flammable or explosive liquids.

WARNING!

Risk of infection due to using no or a defective hydrophobic bacterial and viral filter!

Secretions enter the aspirator during aspiration.

Stop using the aspirator. Clean and disinfect the aspirator and have it repaired by a service technician authorised by ATMOS to do so.

DANGER!

Danger to life!

For open heart operations and those to the central nervous system, there may be equipotential bonding between the user and the patient.

The product may not be used with components for aspiration that are metal and conductive. For use on open hearts and the central nervous system, CF protective class equipment is necessary.

DANGER!

Incorrect use can result in fatalities!

Instructions for using components made by other manufacturers are not part of these operating instructions.

Ensure that the manufacturer’s instructions are followed.

DANGER!

Danger to life!

Electric shock!

Check to ensure that the available mains voltage corresponds with the specifications on the type plate before connecting the mains plug. Product can only be separated from the power supply by unplugging at the socket.

DANGER!

Danger to life!

Electric shock resulting from an object being inserted from the outside into the case and its making contact with live components.

Never insert any objects into the case.

DANGER!

Potentially fatal due to electrical shock!

The product may only be connected to voltage supplies with protected earth connections.

WARNING!

Risk of injury!

ATMOS products may be used only when fully functional.

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

DANGER!

Danger to life!

Patient may be endangered as a result of incorrect use.

Follow the operating instructions for all accessories.

WARNING!

Risk of injury!

Electrical devices (e. G. mobile phones, radios, magnetic resonance tomographs) may interfere with the functioning of the product when used near the product.

Do not use electrical devices that may interfere with the functionality of the product in the vicinity of the product.

Observe the specifications in the technical data of the OR table with regard to electromagnetic compatibility (transmission and resistance).

Observe the specifications from the technical data for the use of electrical devices and respond to any effects on the device or the product.

WARNING!

Risk of infection due to improper handling!

Applicable rules for hygiene have to be observed in order to avoid infection or bacterial contamination when suctioning off and disposing of secretions. Observe the intended purpose of the bacterial filter. Use only sterile catheters during extraction and ensure that the patient is not injured during the procedure. Always wear gloves while working.

WARNING!

Allergic reactions due to contact!

The materials used have been tested for their tolerability. In very rare cases, contact with accessible materials on the device and its accessories may cause allergic reactions. This applies in particular to contact injuries in conjunction with prolonged contact. If this occurs, seek medical attention immediately.

WARNING!

Tripping hazard due to cables!

Injuries and fractures are possible.

Lay connecting cables properly.

2.2 Product safety notes

DANGER!

Infection hazard!

Risk of bacteria and viruses entering the aspirator.

A bacterial and viral filter protects the inside of the aspirator against contamination by bacteria and viruses.

Use a bacterial and viral filter which also provides protection against oversuction.

DANGER!

Infection hazard!

The bacterial filter paper provides additional protection against contamination of the ambient air.

Do not operate the aspirator without a bacterial filter paper.

CAUTION!

Property damage due to oversuction!

The product may only be operated with the overflow protection in place as otherwise oversuction could occur. A hydrophobic filter offers an additional protection against oversuction. It closes off the flow of gas to the product. Particles in the gaseous phase may clog the hydrophobic filter.

Use a bacterial and virus filter which also protects the inside of the aspirator from bacteria and viruses.

CAUTION!

Observe ambient conditions!

If the ambient conditions are undercut or exceeded during transportation, storage or operation, functionality may be affected.

Conduct a functional check and rectify any deficiencies.

CAUTION!

Property damage!

Excessive exposure of plastic housing components to ultraviolet radiation leads to premature material fatigue, resulting in breakage.

Protect the product against direct sunlight.

CAUTION!

Property damage!

Proper functioning of the mechanical overflow protection is only assured with the product in upright position.

Place the product in upright position during operation. Operation is only permitted when the castors are in a locked position.

CAUTION!

Property damage!

The aspirator may not be lifted or carried using the push bar.

CAUTION!

Property damage due to overheating!

Ventilation slots on the rear side of the device. The ventilation slots must always remain open.

Report all serious incidents that have occurred in connection with this product to the manufacturer and your national competent authority.

3 Initial operation

3.1 General

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. ATMOS recommends always having an alternative suction option ready. This enables aspiration even in the event of product failure.

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.

CAUTION!

Property damage due to oversuction!

The product must only be operated with an overflow protection device.

CAUTION!

Property damage due to material failure!

Do not exceed the permissible overall load of 10 kg of each of the equipment rails of the trolley.

NOTE

Different septic fluid jar holders and septic fluid jar caps can be fitted to the equipment rails of the trolley. Be absolutely sure to observe the operating instructions for all the products used in the configuration.

The scope of delivery includes these operating instructions, as well as the individual components in accordance with the ordered product versions [▸▸ Page 12].

Remove the product from its packaging and check the shipment for completeness and to ensure the scope of delivery is intact.

3.2 Scope of delivery

- Basic equipment,
- Two stands, each with 2 castors (braked),
- Mains cable,
- Foot switch,
- Two tube holders,

Installation material:

- Eight screws,
- Four lockwashers,
- Four plastic discs,
- Four blind plugs,
- Allen key.

3.3 Mounting the stand

CAUTION!

Property damage!

Improperly mounted stands cause danger of tipping over.

Make sure that you have a right and a left stand and that the stands are mounted properly.

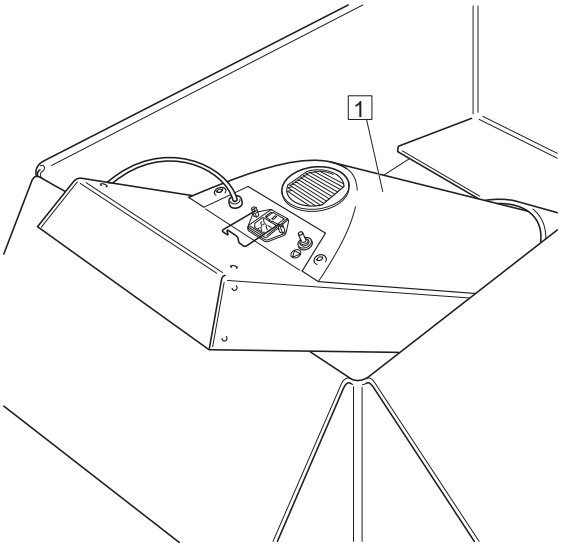


Fig. 2: Assembly position

Position for installation

☒ Remove stands, installation material and accessories from the packing.

☒ Place the basic equipment (1) on the ground with the top face down on the ground.

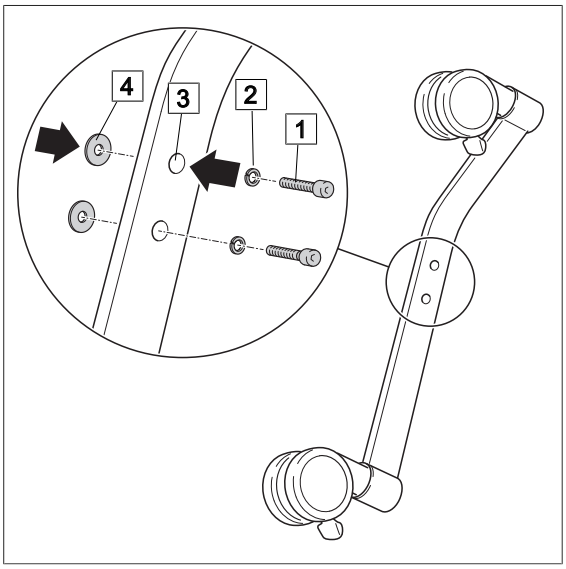


Fig. 3: Pre-mounting the stand

Pre-mounting the stand

☒ Guide the screw (1) with lockwasher (2) through the bore hole in the stand (3).

☒ Insert plastic disc (4) in screw.

☒ Pre-assemble the remaining screw joints in the same manner.

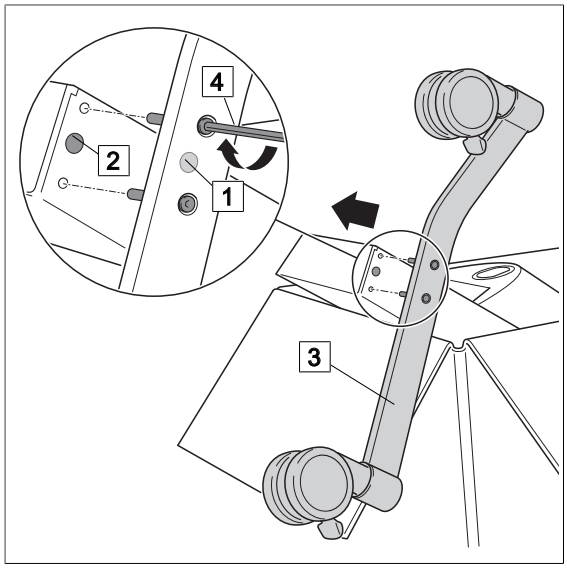


Fig. 4: Securing the stands

Mounting the first stand

☒ Place the red point of the stand (1) on the red point of the basic equipment (2).

✓ The longer part of the stand (3) must point to the floor.

☒ Screw in screw joints with Allen key (4) and tighten slightly.

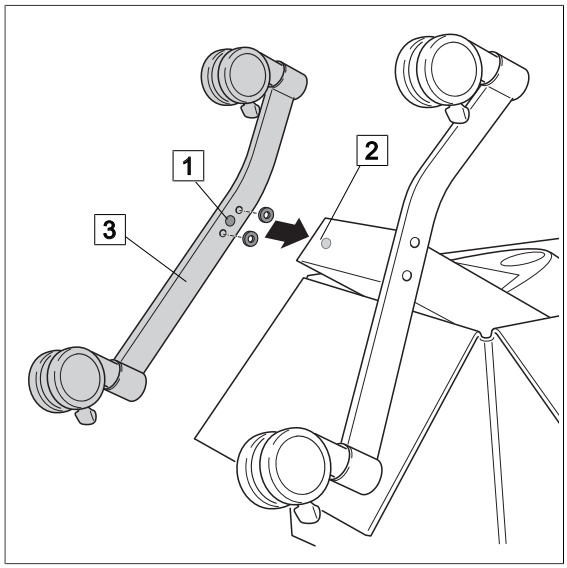


Fig. 5: Securing the stands

Mounting the second stand

☒ Place the green point of the stand (1) on the green point of the basic equipment (2).

✓ The longer part of the stand (3) must point to the floor.

☒ Screw in screw joints with Allen key and tighten slightly.

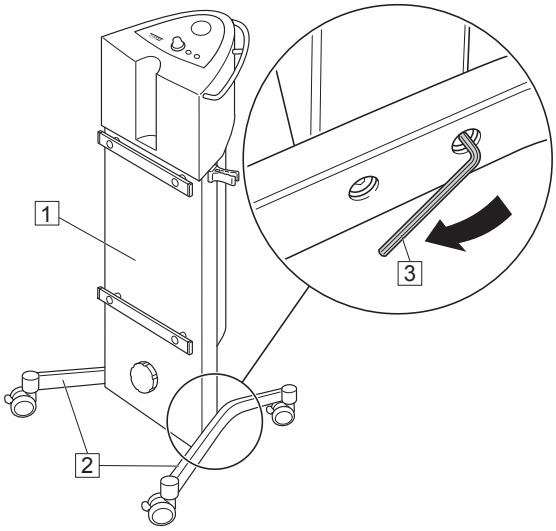


Fig. 6: Aligning and fixing stands

Aligning and fixing stands

☒ Position the aspirator (1) on an even surface.

✓ The longer parts of the stand (2) are located on the front of the equipment.

✓ Stands are aligned.

☒ Hand tighten screws to maximum with Allen key (3).

✓ Stands are fixed.

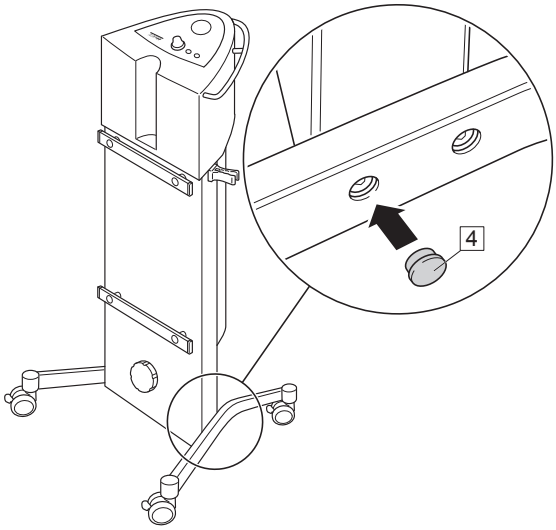


Fig. 7: Fit the blind plugs

☒ Fit the blind plugs (4).

3.4 Mounting the tube holder

The tube holders are screwed into place on the right and left sides of the equipment rail.

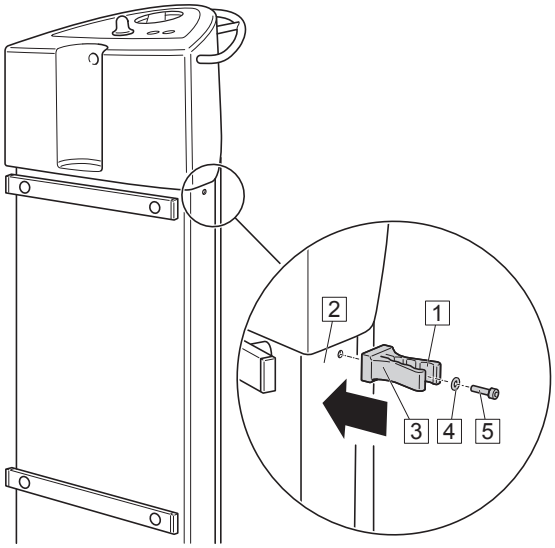


Fig. 8: Mounting the tube holder

☒ Press the tube holder (1) onto the device (2).

☒ Threaded hole (3) of the tube holder.

☒ Insert the washer (4) and screw (5) into the threaded hole.

☒ Tighten tube holder using a screwdriver.

3.5 Mounting the foot switch

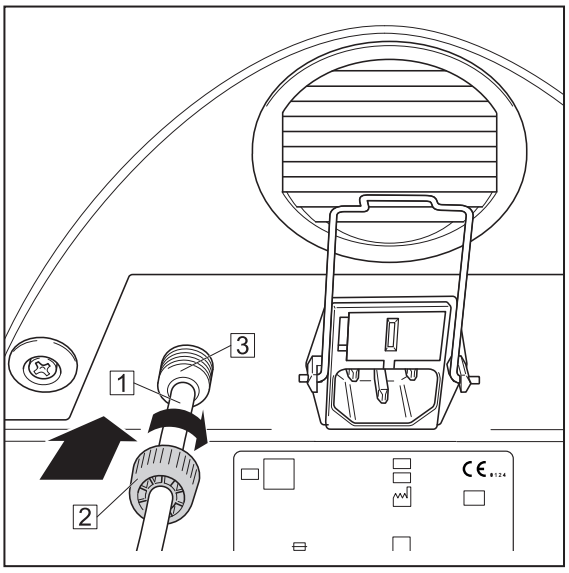


Fig. 9: Mounting the foot switch

☒ Insert the cable end (1) into the cap nut (2).

☒ Insert the cable end into the tube connector (3) on the aspirator.

☒ Tighten the cap nut.

✓ The foot switch is mounted.

3.6 Overflow protection device/tube connector

The aspirator can only be operated with an overflow protection device which prevents liquid and foam from entering the vacuum source. In addition, there must be protection to prevent contamination of the vacuum source.

The aspirator can be operated either with the mechanical overflow protection (REF HM57521775) in conjunction with the hydrophobic bacterial and viral filter (REF HM57521783), or with the tube connector in conjunction with separate protection against oversuction and contamination.

WARNING!

Infection hazard due to oversuction!

To protect the aspirator from oversuction, the aspirator may only be operated with the overflow protection in place.

CAUTION!

Property damage!

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

Ensure correct seat of the float.

3.6.1 Mounting the mechanical overflow protection device (REF HM57521775)

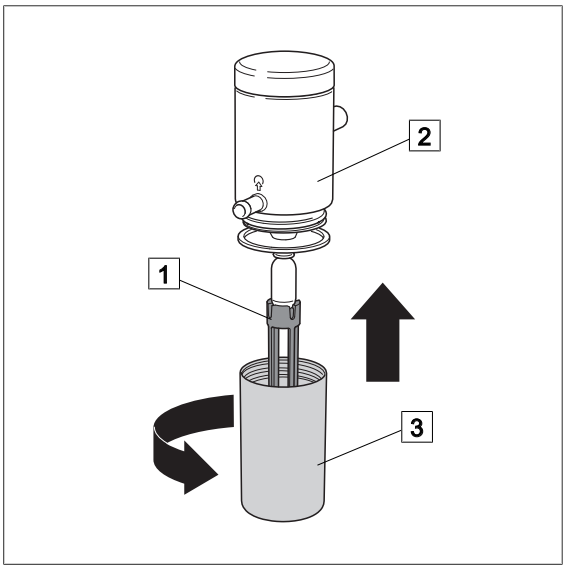


Fig. 10: Mounting the overflow protection device

Mounting the overflow protection device

☒ Engage float cage (1) with float into the lid (2) of the overflow protection device.

☒ Screw overflow container (3) onto the lid.

3.6.1.1 Inserting the overflow protection device

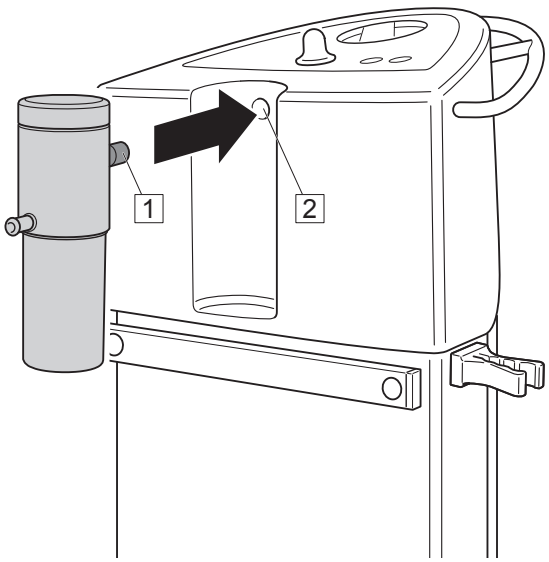


Fig. 11: Inserting the overflow protection device

Inserting the overflow protection device

☒ Insert the tube connector (1) of the overflow protection device completely into the opening (2) on the device.

3.6.2 Mounting the hydrophobic bacterial and viral filter (REF HM57521783) in the mechanical overflow protection (REF HM57521775)

The overflow protection device offers the possibility to subsequently connect a hydrophobic bacterial and viral filter to the mechanical overflow protection. It is required, if the aspirated gas contains aerosols. It protects the inside of the pump from both humidity and bacteria and viruses.

CAUTION!

Property damage due to foaming!

Foam may be created when extracting secretion. Foam is detrimental to the functioning of the mechanical overflowprotection. This gives rise to the risk of secretions entering and damaging the aspirator.

Always use a hydrophobic bacterial and viral filter and a commercially available foam inhibitor.

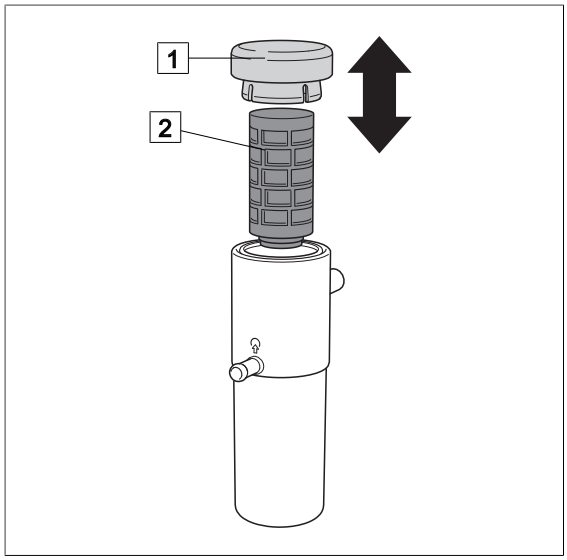


Fig. 12: Mounting the hydrophobic bacterial and viral filter

Inserting the hydrophobic bacterial and viral filter (with pore size of 0.2 µm) into overflow protection device

☒ Remove the lid (1) from filter housing by lifting upwards.

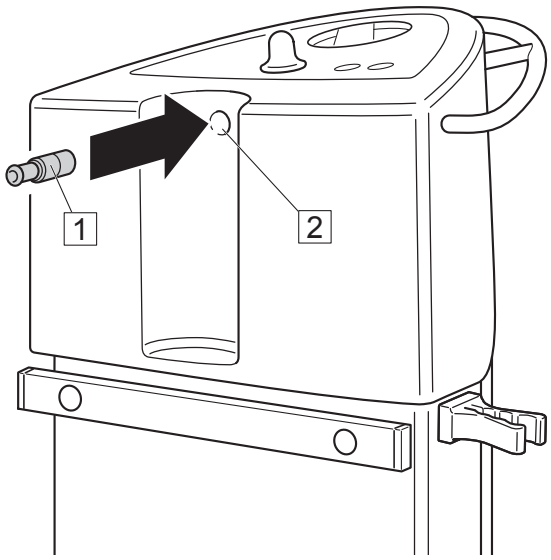
☒ Fit the hydrophobic bacterial and viral filter (2).

☒ Close filter housing with cover.

3.6.3 Inserting the tube connector

If the equipment is operated with a tube connector, a separate overflow protection device must be fitted.

For disposable aspiration systems with integrated bacterial filter, an additional virus filter should be used between the tube connector and the disposable aspiration system.

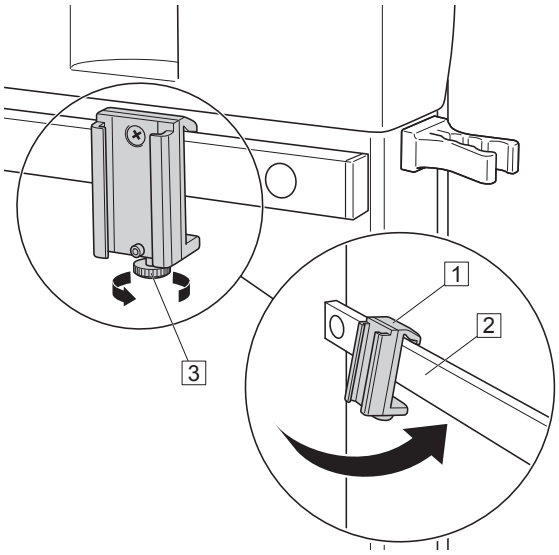


☒ Insert the tube connector (1) into the opening (2) on the equipment.

Fig. 13: Inserting the tube connector

3.7 Mounting point for rail clamp (REF HM57522048)

Containers with an equipment mount may be attached to the rail clamp mount.



Attaching the rail clamp

☒ Attach rail clamp (1) to equipment rail (2).

☒ Lock rail clamp with the locking screw (3).

Fig. 14: Attaching the rail clamp

3.8 Mounting the vacuum shift (REF HM57522049)

The vacuum shift is used to switch between two septic fluid jars.

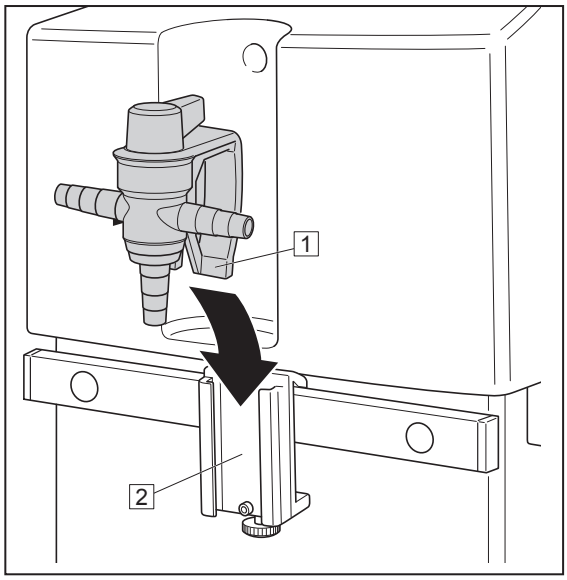


Fig. 15: Attaching the vacuum shift

Mounting the vacuum shift

☒ Attaching rail clamp [⏩ Page 27].

☒ Attach equipment mount (1) of vacuum shift to rail clamp (2).

3.9 Mounting the tubes

Mounting the tubes will be described in the following examples:

- Overflow protection device [⏩ 3.9.1 on page 29]
- Tube connector with ATMOS disposable suction system [⏩ 3.9.2 on page 29]
- Tube connection of overflow protection device with septic fluid jar cap (REF HM57500390) [⏩ 3.9.3 on page 30]
- Tube connection of overflow protection device with septic fluid jar cap (REF HM57505655) [⏩ 3.9.4 on page 30]
- Tube connection of overflow protection device with septic fluid jar cap (REF HM57525432) [⏩ 3.9.5 on page 31]
- Tube connection for vacuum shift (REF HM57522049)[⏩ 3.9.6 on page 31]

3.9.1 Mounting the tube to the tube connector of the ATMOS disposable suction system

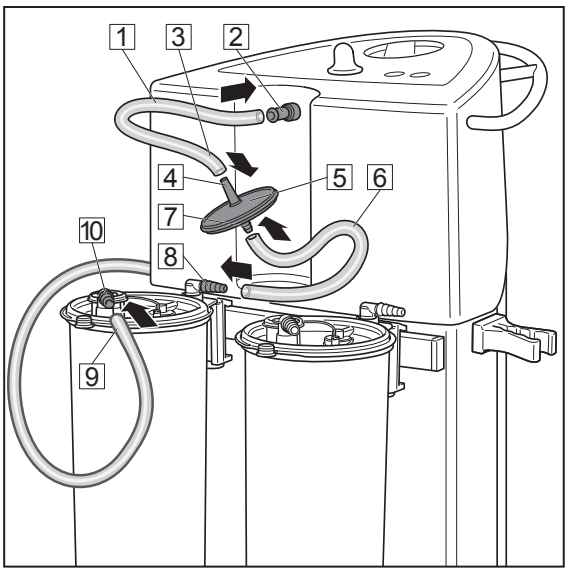


Fig. 16: Tube connector

☒ Attach the connection tube (1) to the tube connector (2).

☒ Attach the free end of the connection tube (3) to the conical connection (4) of the hydrophobic bacterial and viral filter (5) (REF HM57524514).

☒ Attach the second connection tube (6) to the free end of the hydrophobic bacterial and viral filter (7).

☒ Attach the free end of the connection tube (6) to the L-connector of the ATMOS external canister (8).

☒ Attach the suction tube (9) to the tube connector of the ATMOS suction bag (10).

3.9.2 Mounting the tube to the overflow protection device

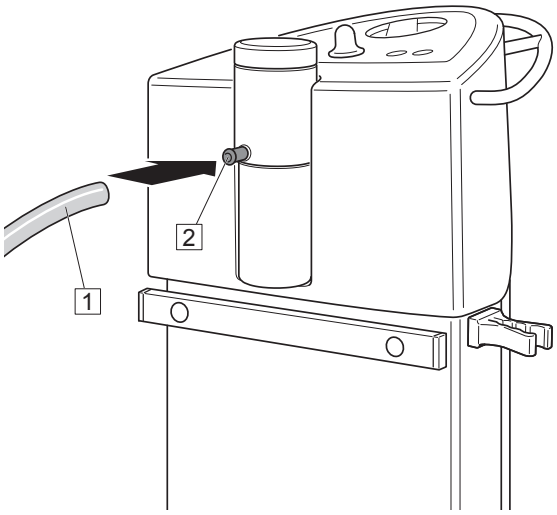


Fig. 17: Overflow protection device

☒ Attach the connection tube (1) to the tube connector (2) of the overflow protection device.

3.9.3 Tube connection of overflow protection device with septic fluid jar cap (REF HM57500390)

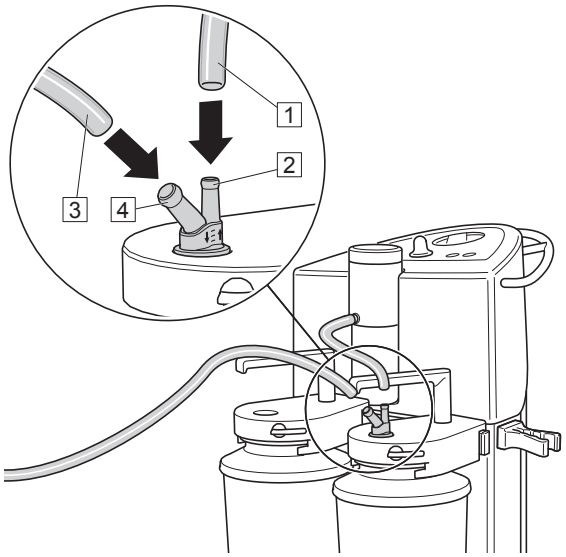


Fig. 18: Mounting the tubes

☒ Attach the connection tube (1) to the straight tube connector (2) of the cap plug.

☒ Attach the suction tube (3) to the second tube connector (4) of the cap plug.

3.9.4 Tube connection of overflow protection device with septic fluid jar cap (REF HM57525655)

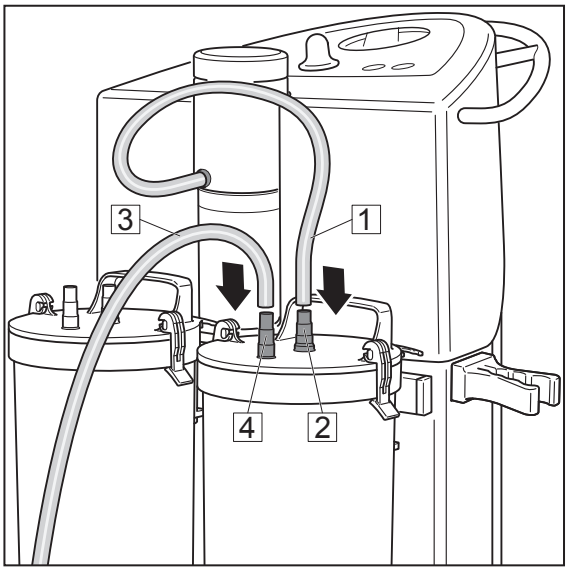


Fig. 19: Mounting the tubes

☒ Attach the connection tube (1) to the tube connector in the middle of the septic fluid jar cap (2) (marked with "Vacuum").

☒ Attach the suction tube (3) to the tube connector of the septic fluid jar cap (4) at the patient side (marked with "Patient").

3.9.5 Tube connection of overflow protection device with septic fluid jar cap (REF HM57525432)

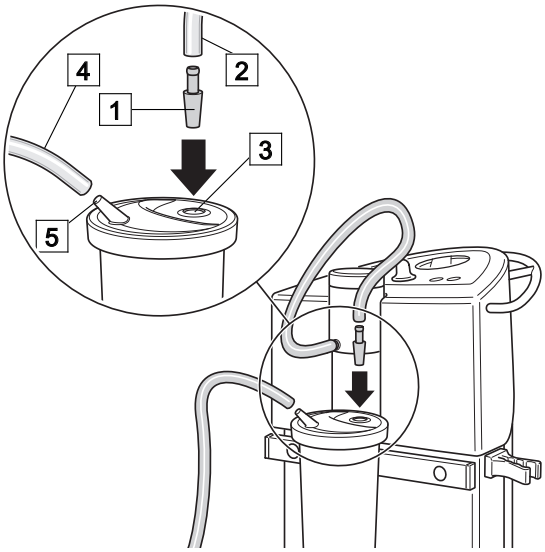


Fig. 20: Mounting the tubes

☒ Plug adapter (REF HM57522295) (1) onto the connection tube (2).

☒ Insert the adapter with the connection tube into the septic fluid jar cap (3).

☒ Attach the suction tube (4) to the patient side tube connector (5) on the septic fluid jar cap.

3.9.6 Tube connection for vacuum shift (REF HM57522049)

The mounting of the tubes is described using the septic fluid jar cap (REF HM57525655) as an example.

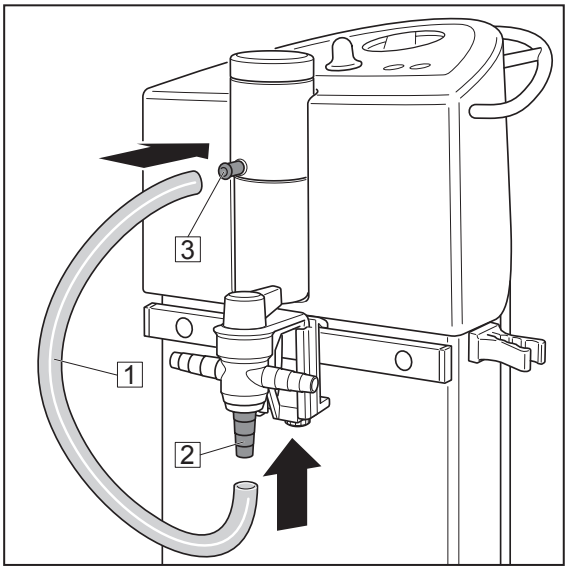


Fig. 21: Mounting the tubes

☒ Connect the connection tube (1) to the lower adapter (2) of the vacuum shift.

☒ Attach the other end of the connection tube to the tube connector (3) on the overflow protection device.

✓ Overflow protection device and vacuum shift are connected by the tube.

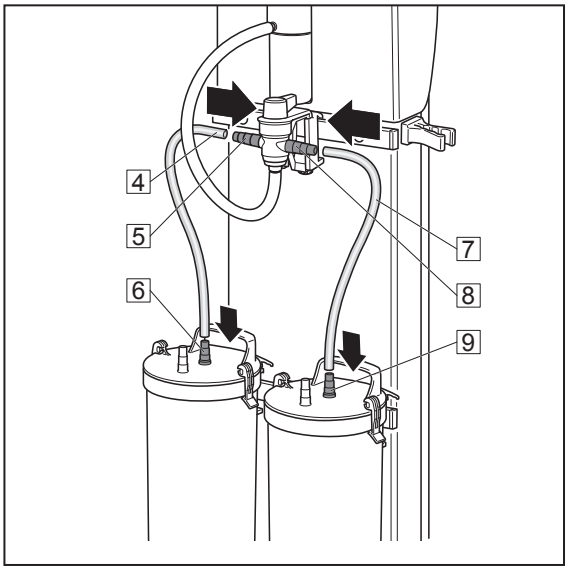


Fig. 22: Mounting the tubes

☒ Attach the connection tube (4) to the left tube connector (5) of the vacuum shift.

☒ Attach the other end of the connection tube in the middle of the left septic fluid jar cap (6) (marked with "Vacuum").

☒ Attach the connection tube (7) to the right tube connector (8) of the vacuum shift.

☒ Attach the other end of the connection tube in the middle of the right septic fluid jar cap (9) (marked with "Vacuum").

3.10 Connecting/disconnecting the mains cable

NOTE

The plug must always be accessible to ensure that the aspirator can be unplugged from the power source at any time.

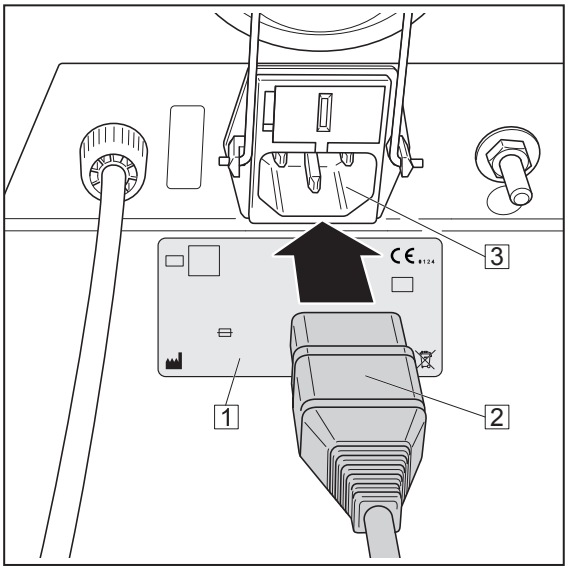


Fig. 23: Connecting the mains cable

Connecting the mains cable

☒ Check to ensure that the mains voltage is identical to the specifications given on the type plate (1).

☒ Plug the mains cable (2) into the equipment socket (3) and connect to the mains socket.

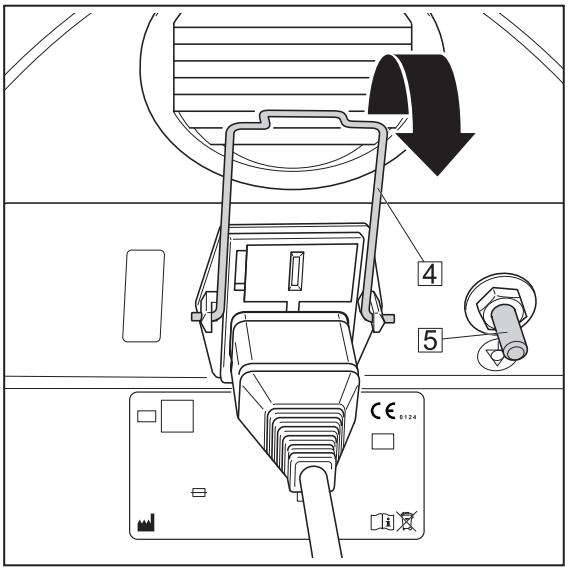


Fig. 24: Bracket

Securing mains cable

☒ Secure the mains cable with the bracket (4) on the aspirator.

☒ Connect the potential equalisation cable to the equalisation pin (5).

Disconnecting the mains cable

☒ Pull the bracket up.

☒ Pull the mains plug out of the power socket.

☒ Detach the mains cable from the aspirator.

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 check:

- All components are properly attached.
- The mains cable is undamaged.
- Components made of plastic or rubber (e.g. control panel film, tube, septic fluid jar cap, septic fluid jar) are in good condition and show no damage due to ageing.
- Bacterial filter paper is in proper condition.
- The overflow protection device and / or hydrophobic bacterial and viral filter are mounted and functional.
- The overflow protection device and / or hydrophobic bacterial and viral filter have been properly cleaned and neither residue nor contamination are present.
- Tube connectors and septic fluid jar cap are tightly seated and do not leak.
- No mechanical forces are acting on the tubes.
- Tubes may not be kinked.
- Maximum vacuum of approximately −90 kPa is reached within about 20 seconds when the connection tube is held shut.
- The vacuum can be infinitely variably regulated throughout the entire range.
- The septic fluid jar is attached to the aspirator.
- The aspirator has been properly cleaned and neither residue nor contamination are present.
- Damaged parts have been replaced by new parts.

4.2 Suction

DANGER!

Danger to life!

Electric shock!

Check to ensure that the available mains voltage corresponds with the specifications on the type plate before connecting the mains plug. Product can only be separated from the power supply by unplugging at the socket.

DANGER!

Infection hazard!

Risk of bacteria and viruses entering the aspirator.

A bacterial and viral filter protects the inside of the aspirator against contamination by bacteria and viruses.

Use a bacterial and viral filter which also provides protection against oversuction.

WARNING!

Risk of infection due to using no or a defective hydrophobic bacterial and viral filter!

Secretions enter the aspirator during aspiration.

Stop using the aspirator. Clean and disinfect the aspirator and have it repaired by a service technician authorised by ATMOS to do so.

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.

CAUTION!

Property damage due to oversuction!

The product may only be operated with the overflow protection in place as otherwise oversuction could occur. A hydrophobic filter offers an additional protection against oversuction. It closes off the flow of gas to the product. Particles in the gaseous phase may clog the hydrophobic filter.

Use a bacterial and virus filter which also protects the inside of the aspirator from bacteria and viruses.

CAUTION!

Property damage due to foaming!

Foam may be created when extracting secretion. Foam is detrimental to the functioning of the mechanical overflow protection. This gives rise to the risk of secretions entering and damaging the aspirator.

Always use a hydrophobic filter and, if possible, a commercially available foam inhibitor.

CAUTION!

Risk of injury!

If the rollers are not braked, the product could roll into a different position during suction.

All the rollers must be braked during operation.

NOTE

In the event that the hydrophobic bacterial and viral filter has been tripped, switch off the aspirator. Empty and clean or replace all parts.

NOTE

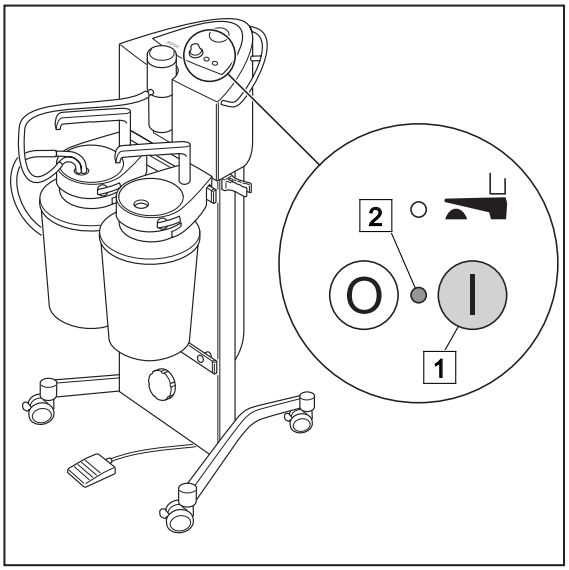
Monitor the filling level in the septic fluid jar before and after aspiration and, if larger volumes are being extracted, during aspiration.
When the maximum filling level is reached, switch off the aspirator and empty the septic fluid jar.

We recommend keeping an additional septic fluid jar in operational position on an equipment rail as a spare jar to ensure quick switch to an empty jar.

NOTE

Rinse the suction tube briefly with clean water after each extraction cycle.

4.2.1 Switching on the aspirator



☒ Switch on the aspirator (1).

✓ The green power control light (2) is illuminated.

Fig. 25: Switching on the aspirator

4.2.2 Setting the vacuum level

NOTE

Refer to the troubleshooting guide if there is insufficient vacuum or no vacuum at all.

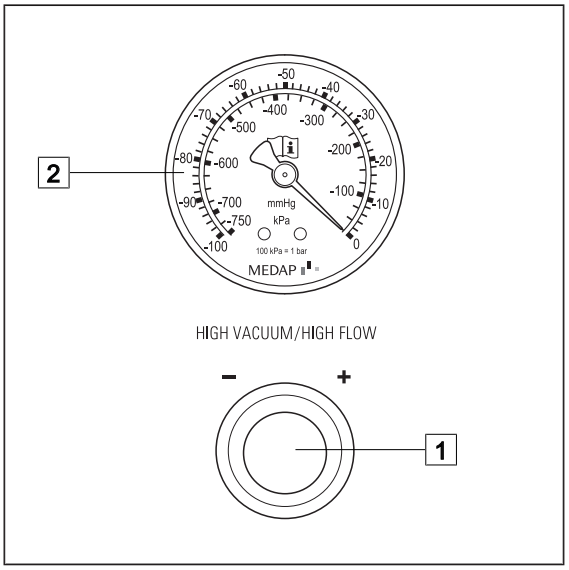


Fig. 26: Setting the vacuum level

Setting the vacuum level

☒ Kink the suction tube on the patient side and hold it closed. Set the vacuum with the regulating knob (1) and check.

Increasing vacuum

☒ Turn the regulator knob (1) to the right.

☒ Read the value on the vacuum gauge (2).

Reducing vacuum

☒ Turn the regulator knob (1) to the left.

☒ Read the value on the vacuum gauge (2).

4.2.3 Operating the footswitch

The appliance can be transferred to energy-saving standby mode using the foot switch.

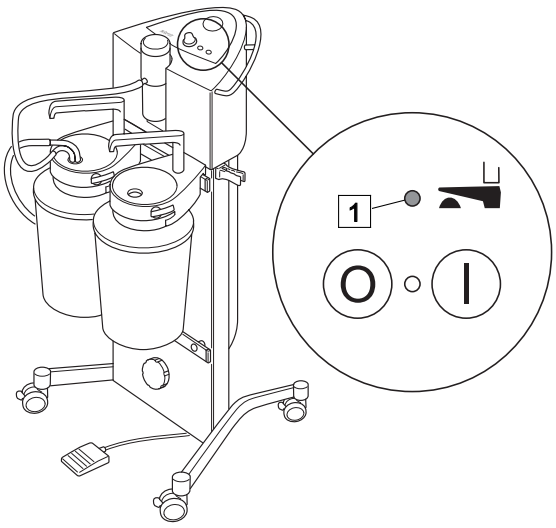


Fig. 27: Foot switch

☒ Operate the foot switch.

- ✓ Aspirator is set to stand-by mode.
- ✓ Yellow light emitting diode (1) is illuminated.

☒ Operate the foot switch again.

- ✓ Yellow light emitting diode goes out.
- ✓ Aspirator is set to operating mode.

4.2.4 Setting the vacuum shift

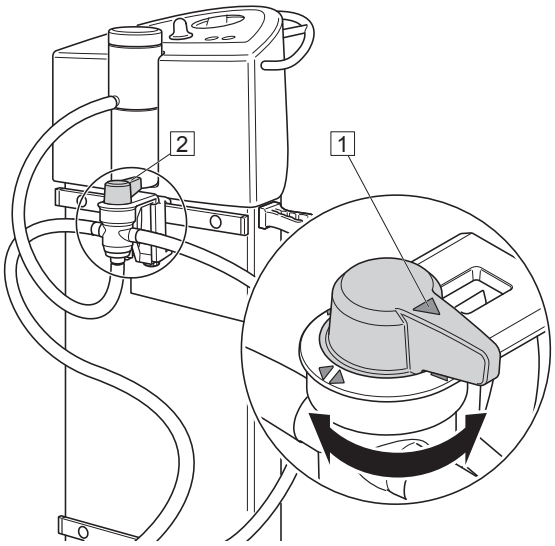


Fig. 28: Vacuum shift

The vacuum shift can be set in four different ways

- Arrow (1) on the rotary switch (2) of the vacuum shift points to the right: Suction material will be conducted into the septic fluid jar on the right.
- Arrow (1) on the rotary switch (2) of the vacuum shift points to the left: Suction material will be conducted into the septic fluid jar on the left.
- Arrow (1) on the rotary switch (2) of the vacuum shift points forwards: Suction material will be conducted into the septic fluid jars on the left and right.
- Arrow (1) on the rotary switch (2) of the vacuum shift points to the back: Vacuum shift is switched off, aspiration process is halted.

4.3 Replacing the bacterial filter paper

WARNING!

Infection hazard!

Any and all the parts of the product could be contaminated.

Wear gloves and be absolutely sure to follow the hygiene rules during all cleaning and reconditioning work.

NOTE

Using the aspirator requires daily replacement of the bacterial filter paper.

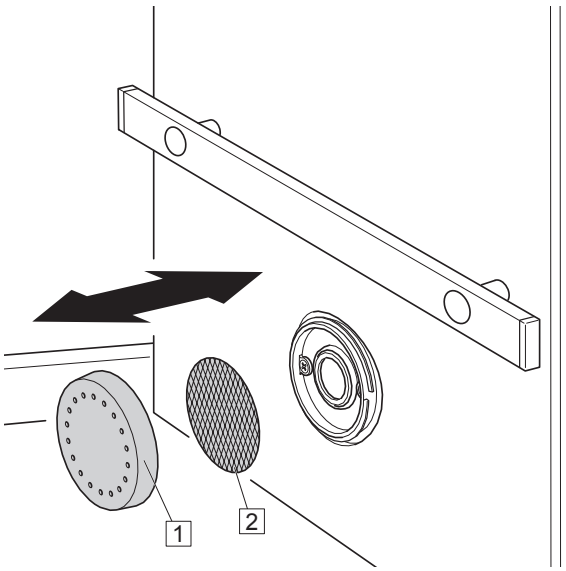


Fig. 29: Replacing the bacterial filter paper

☒ Screw off cap (1).

☒ Remove used bacterial filter paper (2).

☒ Clean and wipe-disinfect the cap.

☒ Insert new bacterial filter paper into the cap.

✓ Fine-structured side faces towards the pump.

☒ Screw on cap.

☒ Connect the aspirator.

5 Taking the unit out of operation

5.1 Completing the aspiration process

☒ Remove the tube from the patient.

☒ Switch off the aspirator.

☒ Empty the septic fluid jar.

☒ Clean the components.

5.2 Emptying the septic fluid jar

DANGER!

Infection hazard!

Any and all of the components in the septic fluid jar might be contaminated.

Always wear gloves when emptying the septic fluid jar and be absolutely sure to follow the hygiene rules.

CAUTION!

Property damage!

If the septic fluid jar is held by the septic fluid jar cover (REF HM57525432) the septic fluid jar may fall. Do not hold the septic fluid jar by the cap.

CAUTION!

Property damage!

The connection between the septic fluid jar and the septic fluid jar cap may have loosened during use.

Check that the connection between the septic fluid jar and the septic fluid jar cap is secure.

NOTE

Monitor the filling level in the septic fluid jar before and after aspiration and, if larger volumes are being extracted, during aspiration.

When the maximum filling level is reached, switch off the aspirator and empty the septic fluid jar.

5.3 Disassembly

5.3.1 Detaching tubes

The disassembly of the tubes is described using the septic fluid jar cap (REF HM57525655) as an example.

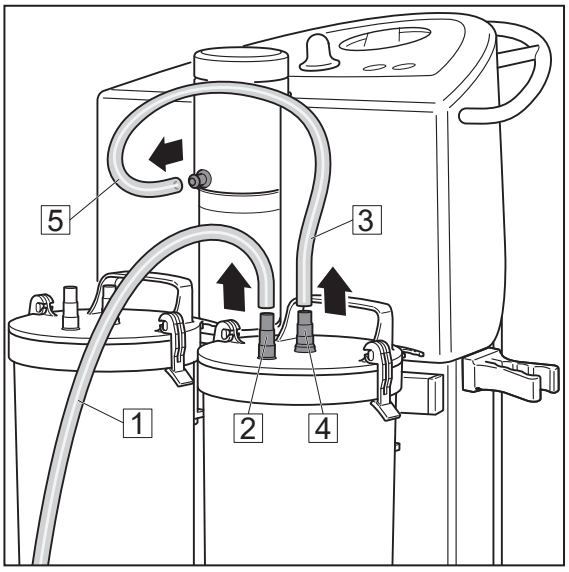


Fig. 30: Disassembly of tubes

☒ Remove the suction tube (1) from the tube connector (2) on the patient side.

☒ Switch off the aspirator.

☒ Remove the connection tube (3) from the tube connector in the middle of the septic fluid jar cap (4).

☒ Remove the connection tube (3) from the overflow protection device (5).

5.3.2 Removing the overflow protection device

NOTE

Avoid damages to the edge of the float.

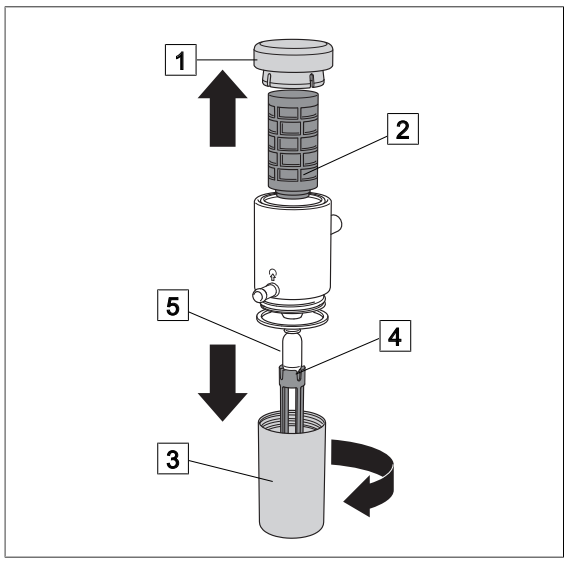


Fig. 31: Removing the overflow protection device

☒ Remove cap (1) from filter housing upwards.

☒ Remove the hydrophobic bacterial and viral filter (2).

☒ Screw off cap (3) from the overflow protection device.

☒ Detach float cage (4) and remove float (5).

6 Cleaning and disinfection

6.1 Cleaning

6.1.1 General

All the components in the aspirator which come into contact with septic fluid must be cleaned and disinfected after each use.

DANGER!

Danger to life!

Electric shock!

Remove the mains plug from the socket before cleaning / disinfection.

DANGER!

Danger to life!

Electric shock!

Liquid should never be allowed to enter live parts.

DANGER!

Risk due to incorrect use of detergents and disinfectants!

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

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

CAUTION!
Property damage due to changes in materials!
Almost all the components in the product are made of plastic. Solvents, some disinfectants and some cleaning agents can soften plastic or cause tension fissures.
Do not use alcohol-containing agents to clean the surfaces. Follow the instructions for using disinfectants.

CAUTION!
Property damage due to tension cracks!
Acids or bases may cause tension cracks.
Do not treat polysulphone containers with strong acids or alkaline solutions.

NOTE
To clean the operating foil, rotate the regulation button to the left and unscrew to remove. After cleaning, screw the regulation button back into place and rotate fully to the right.

NOTE
Refer to the respective manufacturer's instructions for information on cleaning and disinfection.

6.1.2 General

CAUTION!
Improper cleaning can cause property damage!
Residues of physiological saline solutions (e.g. sodium chloride) can attack the surfaces of the product.
Remove residues of physiological saline solutions with a cloth dipped in clean water. Then dry the product with a dry, lint-free cloth.

CAUTION!
Improper cleaning can cause property damage!
Do not spray cleaning agent directly into the joints or gaps and never use a high-pressure cleaning unit!

NOTE

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

In the event of heavily contaminated surfaces, use concentrated multi-purpose detergent.

6.1.3 Cleaning procedure

☒ Use the correct dose of multi-purpose detergent with water for the degree of surface contamination and in accordance with the instructions of the detergent manufacturer.

☒ Thoroughly wipe off the product with a soft cloth slightly wetted in a multi-purpose detergent solution.

☒ Ensure that the product is free from contamination and encapsulatedparticles 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.

6.2 Disinfection

6.2.1 General

NOTE

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

CAUTION!

Material damage due to excessive exposure times!

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

Observe the specified exposure time of the disinfectant manufacturer.

NOTE

The septic fluid jar, all the components in its cap, and the tubes are consumption materials. Depending on the cleaning process used they are subject to greater or lesser wear and tear due to the materials used. Inspect all components for proper functionality before use. Replace them in case of any signs of damage.

NOTE

Using surgical drapes which are not colour-fast can cause discolouration in plastic components.

6.2.2 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, oliogomeric biguanide, polyhexamethylene biguanide hydrochloride (oligo-diimino imiodo-carbonyl imino-hexamethylene, polyhexanide)

Tab. 5: Active ingredients of disinfectants

6.2.3 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.

6.2.4 Disinfection procedures

Different disinfection procedures may be used for the various components, depending on the properties of the materials.

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

Components	In solution[1]	Wipe / spray disinfection[2]
Aspirator basic equipment		X
Foot switch		
Mains cable		
Cap of bacterial filter	X	X
Float / float cage		
Rinsing fluid jar		
Connection tube / Suction tube		

Components	In solution[1]	Wipe / spray disinfection[2]
Housing of overflow protection device		X
Hydrophobic bacterial and viral filter (REF HM57521783)[3]	Disposable	
Bacterial filter paper	When in use, must be replaced daily	

[1]After exposure (as prescribed in the manufacturer's instructions), rinse components thoroughly with water and dry them afterwards.

[2]After exposure (as prescribed in the manufacturer's instructions) remove disinfectant residues from the components using a moist cloth and dry them afterwards.

[3]Replace the hydrophobic bacterial and viral filter immediately if it is discoloured, contaminated or oversucked. Furthermore, the filter must be exchanged, 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.

Tab. 6: Disinfection procedures

7 Maintenance

7.1 General

Maintenance, repairs and period tests may only be carried out by persons who have the appropriate technical knowledge and are familiar with the product. To carry out these measures, the person must have the necessary test devices and original spare parts.

ATMOS recommends: Work should be carried out by an authorised ATMOS service partner. This ensures that repairs and testing are carried out professionally, original spare parts are used and warranty claims remain unaffected.

WARNING!

Health hazard!

The aspirator is used in the treatment of patients. The aspirator or parts of the unit may be contaminated. Prior to returning the aspirator for inspection or repair, remove the bacterial and viral filter and all tubes and clean and disinfect the equipment.

7.2 Period tests

At least every 12 months a repeat test of the electrical safety should be performed according to IEC 62353.

ATMOS recommends an inspection according to the manufacturer‘s specifications.

NOTE

After running for 3000 operating hours a check should be carried out on the unit. This check must only be performed by authorised personnel.

7.3 Visual and functional inspections

To ensure correct operation, it is necessary to have visual and functional inspections performed by a trained person prior to each use.

Documentation of the results of the visual and functional inspections is recommended and should include the date and signature of the person who performed the inspections. The following table can be used as a template.

Suggestion:

No.	Inspection	Defects are present		No defects
1	Has the product been cleaned and disinfected according to the hygiene guideline?	❑	☒ Do not use the product any longer. ☒ Clean and disinfect the product according to the guidelines.	❑
	Comment:			
2	Are there cracks in the individual components?	❑	☒ Do not use the product any longer. ☒ Inform service personnel.	❑
	Comment:			
3	(Space for other tests)	❑		❑
	Comment:			

Tab. 7: Visual and functional inspections

7.4 Malfunctions and troubleshooting

No.	Malfunction	Cause	Remedy
1	Aspirator does not start operation, operating status display is illuminated.	Vacuum is still present.	Switch off the aspirator, turn regulating knob to the left, switch on the aspirator.
		The motor is defective.	Have the equipment repaired by a service technician authorised by ATMOS.
2	Aspirator does not start operation, operating status display is not illuminated.	Aspirator is in standby mode.	Switch off standby mode using the foot switch. The aspirator starts operating. If the foot switch is operated again, the aspirator switches back into standby mode.
3	Aspirator does not start operation, operating status display is not illuminated.	Equipment or mains plug is not seated properly in the socket.	Check the equipment and mains plugs for proper contact.
		None or improper voltage.	Check the building fuse, check the specifications on the type plate.
		The mains fuse is defective.	Replace mains fuse.
4	Equipment cannot be switched on and off.	The electronics are defective.	Have the equipment repaired by a service technician authorised by ATMOS.
5	Aspirator operates but operating status display is not illuminated.	LED on the operating status display is defective.	Have the equipment repaired by a service technician authorised by ATMOS.
6	Vacuum cannot be regulated.	The membrane regulator is defective.	Have the equipment repaired by a service technician authorised by ATMOS.

No.	Malfunction	Cause	Remedy
7	Aspirator working but vacuum gauge indicates no vacuum.	The vacuum gauge is defective.	Have the equipment repaired by a service technician authorised by ATMOS.
8	Reduced / no flow rate	Septic fluid jar cap is not in the correct position.	Position septic fluid jar cap properly.
		Hydrophobic filter is clogged (vacuum gauge indicates vacuum).	Replace hydrophobic filter.
		Crack in the tube.	Replace tube.
		Seal is contaminated.	Replace seal.
		Porous seal of septic fluid jar cap.	Replace seal.
		Bent clamp, septic fluid jar cap does not close.	Replace septic fluid jar cap.
		Septic fluid jar is full, mechanical overflow protection is closed (vacuum gauge indicates vacuum).	Empty the septic fluid jar and clean or replace septic fluid jar and mechanical overflow protection.
		Mechanical overflow protection is contaminated with exudate.	Clean overflow protection device or replace septic fluid jar cap.
		Tube connection in septic fluid jar cap is clogged.	Clean the tube connection.
		Suction tip is clogged.	Clean suction tip.
		The motor is defective.	Have the equipment repaired by a service technician authorised by ATMOS.
9	Aspirator has been exposed to oversuction.	No mechanical overflow protection device and no hydrophobic bacterial filter installed.	Aspirator may no longer be used. Have the equipment repaired by a service technician authorised by ATMOS.
		Mechanical overflow protection device is sticking; no hydrophobic bacterial filter used.	

Tab. 8: Malfunctions and troubleshooting

7.5 Replace mains fuse

WARNING!

Electric shock!

Disconnect the electrical plug before changing the fuses.

CAUTION!

Property damage!

You may only use fuses of the following type:

- 2 x T 1.6 A H / 250 V for nominal voltage 230 V AC (REF HM57521554)
- 2 x T 2.5 A H / 250 V for nominal voltage 127 V AC (REF HM57521559)

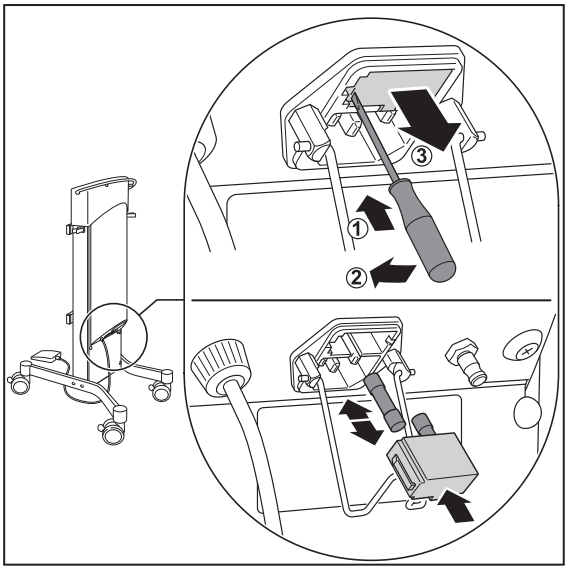


Fig. 32: Replacing fuses

☒ Release the bracket (1).

☒ Disconnect equipment plug.

☒ Use a screwdriver to open the fuse holder (3) from the side (2).

☒ Remove the fuse holder (3).

☒ Remove the fuses from the fuse holder.

☒ Insert new fuses.

☒ Insert new fuses and click into place.

7.6 Repairs

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

- Liquid has penetrated the device.
- The performance has significantly decreased.
- Inexplicable notifications appear.
- Abnormal noises occur.
- Functional faults cannot be rectified according to the measures in chapter Malfunctions and troubleshooting [⏩ page 47].

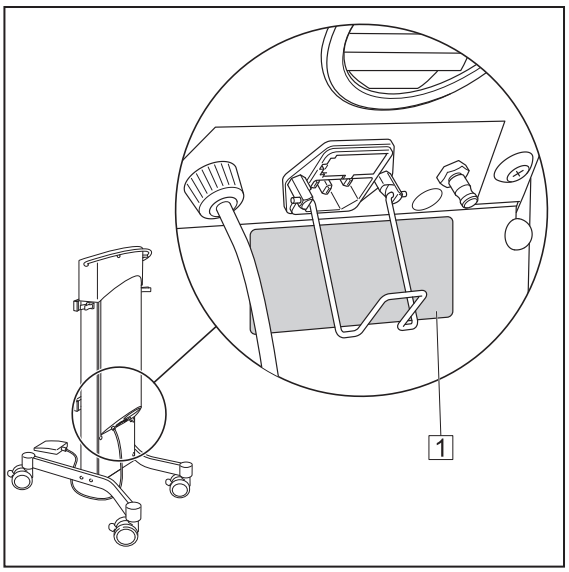
If defects are detected, the product may not be used any longer.

Make a note of the deficiencies and the REF number on the type plate and inform the responsible ATMOS Service.

Inform the appropriate foreign representative outside Germany.

Observe the information in chapter Sending in the device [⏩ page 50].

7.7 Type plate



Position of the type plate (1) on the product.

Fig. 33: Type plate

7.8 Spare parts

Spare parts may be replaced by the end user. We will supply suitably trained and qualified staff with a complete list of spare parts on request.

HM57524982	Foot switch
HM57523082	Repair set, bacterial filter cap
HM57522096	Float and float cage (10 pieces of each)
HM57522097	Overflow container (4 items)
HM57522098	Seals for overflow protection device
HM57505384	Regulating knob
HM57523451	Tube connector

Tab. 9: Spare parts

7.9 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** in a envelope.

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 a envelope.

☒ Affix the envelope to the outside of the package.

☒ Send the product to ATMOS or to your dealer.

8 Technical specifications

8.1 Device

Input voltage	230 V~ ± 10%; 50/60 Hz Special voltage: 127 V~ ± 10 %; 60 Hz
Current consumption	max. 1.1 A (at 230 V~, 50/60 Hz) max. 1.6 A (at 127 V~, 60 Hz)
Power consumption	max. 250 VA (230 V) max. 210 VA (127 V)
Fuses	T 1.6 A H / 250 V (for 230 V~, 50/60 Hz) T 2.5 A H / 250 V (for 127 V~, 60 Hz)
Suction capacity at the device inlet	58 l/ min (± 6 l) at 50 Hz 68 l/ min (± 7 l) at 60 Hz
Maximum achievable vacuum: • at sea level (0 m) • at 500 m • at 1,000 m • at 1,500 m • at 2,000 m	 -90 kPa -84 kPa -79 kPa -73 kPa -68 kPa
Vacuum adjustment	with stepless vacuum regulator
Vacuum display	-1...0 bar per gauge (class 1.6)
Pump	Rotary vane pump
Available canister systems	Reusable secretion canister: 1 l PSU 2.5 l glass 3 l PSU 4 l PC 4 l PSU 5 l glass Interfaces for the use of disposable systems: 1 l 2 l 3 l
Mode of operation	Continuous operation
Protective earth conductor resistance Earth leakage current Touch current Patient leakage current	max. 0.1 Ω max. 5 mA max. 0.1 mA max. 0.1 mA
Environmental conditions: Transport/storage • Temperature range • Air humidity without condensation • Air pressure	 -15...+50 °C 10...95 % 700...1060 hPa

Environmental conditions: Operation • Temperature • Air humidity without condensation • Air pressure	 +15...+40 °C 30...75 % 700...1060 hPa
Max. operating altitude (NN)	2,000 m
Contamination level	2
Overvoltage category	II
Dimensions (H x W x D)	1000 mm x 500 mm x 560 mm
Weight	Approx. 26 kg (without canister)
Periodic tests	Repeat test of electrical safety every 12 months. Recommended: Inspection according to the manufacturer's specifications.
Protection class against electric shock (acc. to EN 60601-1)	I
Classification of applied parts	Type BF applied parts 
Degree of protection	IPX1
CE marking	CE 0124
Reference number (REF) • 230 V • 127 V	 HM57521554 HM57521559

9 Approved accessories

9.1 Accessories

HM5752 1775	Mechanical overflow protection device with chamber for hydrophobic bacterial and virus filter
HM57505228	Septic fluid glass jar 5.0 l
HM57505227	Septic fluid glass jar 2.5 l
HM57505297	Septic fluid jar 3.0 l PSU
HM57525656	Septic fluid jar, 4 l, PSU with equipment mount
HM57525658	Septic fluid jar, 4 l, PC with equipment mount
HM57525431	Septic fluid jar / rinsing fluid container, 1 l, PSU with equipment mount
HM57500390	Septic fluid jar cap (for connection to equipment rail, without overflow protection device)
HM57505362	Septic fluid jar cap with integrated overflow protection
HM57525432	Septic fluid jar cap, silicone, with integrated overflow protection
HM57525655	Septic fluid jar cap, 4 l PSU
HM57525657	Septic fluid jar cap, 4 l PC
HM57520184	Cap plug 9/12 (plastic)
HM57503474	Equipotential bonding cable
HM57522048	Rail clamp for equipment mount / metal
HM57522540	Rail clamp for equipment mount / plastic
HM57522049	Vacuum shift
HM57522295	Tube adapter
401.0300.0	ATMOS external canister 3 l
401.0200.0	ATMOS external canister 2 l
401.0100.0	ATMOS external canister 1 l
401.0301.0	ATMOS suction bag 3 l with gelling agent (70 pcs.)
401.0201.0	ATMOS suction bag 2 l with gelling agent (100 pcs.)
401.0101.0	ATMOS suction bag 1 l with gelling agent (100 pcs.)
401.0302.0	ATMOS suction bag 3 l (70 pcs.)
401.0202.0	ATMOS suction bag 3 l (100 pcs.)
401.0102.0	ATMOS suction bag 3 l (100 pcs.)
401.0091.0	Vacuum serial tube for ATMOS suction bag (20 pcs.)
401.0092.0	T-connector for ATMOS external canister (10 pcs.)

Tab. 10: Accessories

9.2 TWISTA SP 1070

HM57525671	TWISTA SP 1070 complete unit / 2 x 4 l / PSU
HM57525672	TWISTA SP 1070 complete unit / 2 x 4 l / PC
HM57524855	TWISTA SP 1070 complete unit / 2 x 3 l

Tab. 11: TWISTA SP 1070

9.3 Application sets

The TWISTA SP 1070 basic equipment must be fitted out with one of the following application sets (AS) as required for the intended use or application.

Application sets can also be equipped with additional accessories according to individual requirements. Connection tubes must then also be considered. Individual selection requires to comply with the interface description of the basic equipment.

NOTE

A detailed description of the individual application set will be found in the current price list.

HM57522067	AS surgical aspiration / 2 x 5 l
HM57522068	AS surgical aspiration / 2 x 3 l
HM57525801	AS surgical aspiration / 2 x 3 l / ATMOS
HM57524940	AS surgical aspiration / 2 x 3 l / Serres®
HM57525665	AS surgical aspiration / 2 x 4 l / PC
HM57525664	AS surgical aspiration / 2 x 4 l / PSU

Tab. 12: Application sets

9.4 Consumables

HM57505045	Bacterial filter paper (100 pieces)
006.0009.0	Suction tube, silicone, Ø 6 mm, 1 m (minimum purchase 5 m)
HM57505483	Vacuum connection tube, 8 x 14 mm, by the metre
HM57524514	Hydrophobic bacterial and viral filter
HM57521783	Hydrophobic bacterial and viral filter for overflow protection
HM57524928	Smoke evacuation filter

Tab. 13: Consumables

10 Notes on EMC

WARNING!

Medical electrical equipment is subject to special precautions with regard to EMC and must be installed according to the following EMC notes.

Guidance and manufacturer's declaration – ambient conditions

The product is suitable for use in the following environments:

- In professional healthcare facilities such as medical practices, hospitals/clinics, first-aid facilities and operating theatres/rooms.
  It is not suitable for use in the vicinity of HF surgical devices and in settings outside of an HF-shielded room of a magnetic resonance imaging system.
- Special environments such as factory or military facilities and medical areas near HF surgical devices, short-wave therapy equipment, or within an HF-shielded room of a magnetic resonance imaging system.

The customer or user must ensure that the device is used in a prescribed environment.

Guidance and manufacturer's declaration– key features

WARNING!

Please note the technical data in this manual. The essential features are fully usable even in the presence of electromagnetic disturbances.

Guidance and manufacturer's declaration – electrical components

The product has the following electrical components:

Type	REF	Max. cable length
Power cable European standard	HM57503609	4 m

Guidance and manufacturer's declaration– warnings

WARNING!

The use of electrical components and accessories other than those specified or provided by the manufacturer may cause increased electromagnetic interference or reduced immunity to electromagnetic interference and result in faulty operation of the device.

WARNING!

Portable RF communications equipment (e.g. radios, antenna cables) should not be used within 30 cm* of any parts or cables of the product as specified by the manufacturer. Failure to do so may lead to a reduction in the device's performance.

*The distance may be reduced at higher immunity test levels.

WARNING!

Placement on top of or next to another device should be avoided. This could result in faulty operation. If such placement cannot be avoided, the proper functioning of the device must be monitored regularly.

If possible, please switch off any nearby devices that are not in use.

MEDAP

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