en

Instructions for use

Vacusat® power

MÖLLER

IMPORTANT

READ CAREFULLY BEFORE USE

KEEP THESE INSTRUCTIONS FOR FUTURE REFERENCE

Möller Medical GmbH, Wasserkuppenstraße 29-31, 36043 Fulda, Germany

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Table of contents

1 General safety information

1.1 Explanation of safety symbols used

Important information is indicated visually in these instructions for use. These indications are necessary to prevent hazards to patients and operating personnel, as well as to avoid damage and device malfunctions.

1.1.1 Symbols in the instructions for use

	Caution! Hazard for patients, operating personnel and third parties.
	Information and help
	Interference may occur in the vicinity of devices marked with this symbol.

1.1.2 Symbols on the device

	Serial number (the first 4 digits indicate the year and month of manufacture in YYMM format)
	Medical device
	Unique identifier of a medical device
	Consult instructions for use
	Manufacturer
	Alternating current
	Return and disposal as per the WEEE Directive
	Compliant with ANSI/AAMI ES 60601-1 CAN/CSA 22.2 No. 60601-1-08

Device switched off

Device switched on

Foot switch

Increasing the vacuum

Reducing the vacuum

1.1.3 Additional symbols on the retail packaging

Follow the instructions for use

Catalogue number

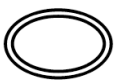
Batch code

Packaging unit

Use by YYYY-MM-DD (year-month-day)

Sterilised using ethylene oxide

Single sterile barrier system



Double sterile barrier system

Single sterile barrier system with protective outer packaging

Single sterile barrier system with internal protective packaging

General safety information

	Not suitable for use with MRI
	Do not re-use
	Do not resterilise
	Fragile, handle with care
	Do not use if package is damaged
	Stacking restriction: stack may consist of max. 3 packages
	Keep dry
	Restriction on relative storage humidity
	Storage temperature limitation
	Manufacturing date
	Sales partner
	Keep away from sunlight
	Caution! Observe transport and storage conditions.
	Attention: Under US Federal law, this device may only be sold to a physician or if ordered by a physician.

Further information about the symbols used can be found on our website:
www.moeller-medical.com/glossary-symbols

1.2 Explanation of the formatting conventions used

In these instructions for use, different fonts are used to improve orientation.

Font	Use
Bold	Buttons in the operating instructions
Italics	Device options, buttons and references to chapter and sections in the running text.

Table 1:
Explanation of formatting conventions

1.3 Manufacturer's responsibility

The manufacturer is responsible for the safety, reliability and serviceability of the device provided the following conditions are met:

Assembly, upgrades, adjustments, changes or repairs are performed only by persons authorised by the manufacturer. The electrical installation of the medicinally used room must comply with the appropriate regulations (i.e. VDE 0100, VDE 0107 or IEC regulation) and the device must be used according to the operating instructions. In addition, country-specific regulations and national deviations must be complied with.

The manufacturer agrees to accept old devices as per the German Electrical and Electronic Equipment Act (ElektroG).

1.4 Operator's obligation to exercise diligence

The operator is responsible for the proper operation of the medical device. In line with the German Medical Device Operators Ordinance (MP BetreibV), the user must meet a wide range of obligations and also assume responsibility when handling medical devices within the framework of their activities.

All handling of the Vacusat® power requires precise knowledge and compliance with these instructions for use. This instruction manual does not replace user training by the medical device consultant. Clinical applications must always be instructed by qualified personnel.

The safety information in the operating manuals of the devices used in conjunction with the Vacusat® power must also be followed.

The Vacusat® power is subject to special precautionary measures with respect to electromagnetic compatibility (EMC) and must be installed and operated in accordance with the EMC guidelines.

If one of the devices no longer works properly due to a malfunction, the device must not be used any further and must be inspected by the technical service.

All work that requires tools must be performed by the manufacturer's technical service or parties authorised by the latter.

Consumables and any bodily fluids must be disposed of according to the hygiene guidelines.

All serious incidents which occur in connection with the product must be reported to the manufacturer and the competent authorities of the member state in which the user and/or patient is based.

1.5 Warning notices

- The products of Möller Medical GmbH may only be used if they are in a fully functional condition. Check for proper condition and full functionality before use.
- No modifications to the Vacusat® power are permitted.
- Do not insert any objects into the housing. External objects inserted into the device may result in electric shock.
- Fluids must not penetrate the parts of the Vacusat® power under voltage.
- Disconnect the power cable before cleaning.
- When cleaning, ensure that no cleaning agent runs into the connector sockets.
- Replace connecting cables of all kinds as soon as they are slightly damaged; avoid rolling over cables.
- Keep the cables away from heat sources. This prevents the insulation from melting which could cause a fire or an electric shock.
- Do not use force to push plugs into sockets.
- Before connecting the mains plug, check that the mains voltage is the same as the value indicated on the rating plate. The Vacusat® power can only be disconnected from the power supply by unplugging the mains plug.

- The Vacusat® power may only be connected to power supplies with ground wire connection.
- When removing plugs, do not pull on the cables.
- To remove, release the plug lock if necessary.
- Do not subject the Vacusat® power to excessive heat or fire.
- Do not subject the Vacusat® power to strong impacts.
- If heat, fumes or smoke occur, immediately disconnect the Vacusat® power from the power supply.
- When cleaning and disinfecting the Vacusat® power, follow the instructions to avoid damaging the product.
- Do not operate the Vacusat® power within the AP-M area. The product has no explosion protection and is not intended for use in hazardous explosive AP-M areas.
- The Vacusat® power may not be used for suctioning flammable or explosive liquids.
- Risk of infection from using no or a defective hydrophobic bacteria and virus filter. When suctioning, secretions enter the suction pump. Clean and disinfect the Vacusat® power and have it repaired by a service technician authorised by Möller Medical GmbH.

- These instructions for use do not include information on using components or accessories from other manufacturers. You must observe the instructions for use of the relevant manufacturer.
- Always observe the information on electromagnetic immunity (see appendix). The function of other electrical devices can be affected when they are used in the vicinity of the Vacusat® power.
- To prevent an infection or bacterial contamination when suctioning and disposing of secretions, the relevant hygiene guidelines must be followed. Note the intended purpose of the bacteria filter. When suctioning, always use sterile suction catheters and ensure that the patient is not injured. Always wear gloves when working.
- Do not operate the Vacusat® power without the bacteria filter sheet. The bacteria filter sheet provides additional protection against contaminating the surrounding air.

- The Vacusat® power may only be operated with the overflow protection connected, otherwise it is not protected against over-suctioning. A hydrophobic filter provides additional protection against over-suctioning. It shuts off the gas flow to the product in the event of over-suctioning. Particles in the gaseous phase can lead to clogging of the hydrophobic filter.
- Carry out a function test and eliminate any defects. If the ambient conditions were exceeded or not reached during transport, storage or operation, function may be impaired.
- Increased ultraviolet radiation on the plastic parts of the housing leads to premature material fatigue, which can cause the material to break. Protect the Vacusat® power from direct sunshine.
- Place the Vacusat® power in a horizontal position during operation. The device may only be operated when the caster brakes are set. If the product is not in a horizontal position, the proper function of the mechanical overflow protection is not ensured.
- Do not carry or lift the Vacusat® power by its push handle.

1.6 Non-product-related additional equipment

Additional equipment which does not belong to the device's scope of supply and which is connected to the device's analogue and digital interfaces must be shown to satisfy the relevant EN specifications (e.g. EN 60601 for electromedical devices). In addition, all configurations must be in accordance with the current valid version of the system requirements as per the standard IEC 60601-1 +A1:2012. The person who connects additional equipment is the system configurer and thus responsible for ensuring compliance with the current version of system requirements according to IEC 60601-1 + A1:2012.

If components are used that do not correspond to the original parts, performance, safety and EMC behaviour may be impaired.

1.7 Single-use

The re-use of a single-use product presents a potential risk of infection for the patient or operator. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection and sterilisation may affect essential material properties and product parameters to the extent that this leads to failure of the articles.

Dispose of used single-use products according to your hygiene guidelines.

1.8 DEHP Declaration

The Vacusat® power contains no bis(2-ethyhexyl) phthalate (DEHP).

1.9 Precautionary measures

Application results vary depending on the patient's age, the intervention site and the surgeon's experience. The application results may or may not be permanent.

Clean and disinfect all reusable components of the Vacusat® power according to *Section 7* "*Cleaning and* " and replace all disposable components before using the Vacusat® power on another patient.

1.10 Target group (users)

The Vacusat® power is reserved for use by doctors who can demonstrate that they have the necessary expertise in liposuction through relevant specialist training or approved, specialist further training.

1.11 Use with defibrillation and RF surgical devices

The use of the Vacusat® power in combination with RF surgery or defibrillation devices is not allowed.

2 Intended use

2.1 Indications

The Vacusat® power is a powerful, low-noise suction device designed for continuous operation and is suitable for high flow and high vacuum. It can be used to suction tumescent solution, body fats, fat cells (secretions, blood and serous fluids) and the particles they contain from artificial body orifices and is intended for use on patients in: surgery, liposuction and aesthetic body contouring. The Vacusat® power should be used by trained personnel in a clinical setting or doctor's practice. The Vacusat® power is not suitable for direct application by the patient in home care situations and nor is it suitable for drainage suction. The suction device may not be used in cardiac surgery or operations on the central nervous system.

2.2 Contraindications

- Clotting disorders or intake of anticoagulant medication
- Massive hernias
- Serious heart diseases
- Serious lung diseases
- Serious liver damage
- Serious kidney damage
- Risk of thrombosis (thrombophilia)
- Diabetes

2.3 Complications

- Vascular injuries
- Nerve injuries
- Tissue injuries
- Organ injuries
- Death

2.4 Essential performance features

The ***Vacusat® power*** has no essential performance features.

2.5 Combination with other products

Only accessories that have been specified and approved by the device manufacturer should be used. Please contact the device manufacturer if you are unsure.

3 Product description

All handling of the device requires precise knowledge and compliance with these instructions for use. These instructions do not replace the user training provided by the medical device consultant. The device must only be used by persons who have the required training or knowledge and experience (Sec. 2 (2) German Medical Device Operators Act/MPBetreibV).

- Only the original parts supplied may be used.
- Performance and safety may be impaired if Original Equipment Manufacturer device parts are not used.

3.1 Design

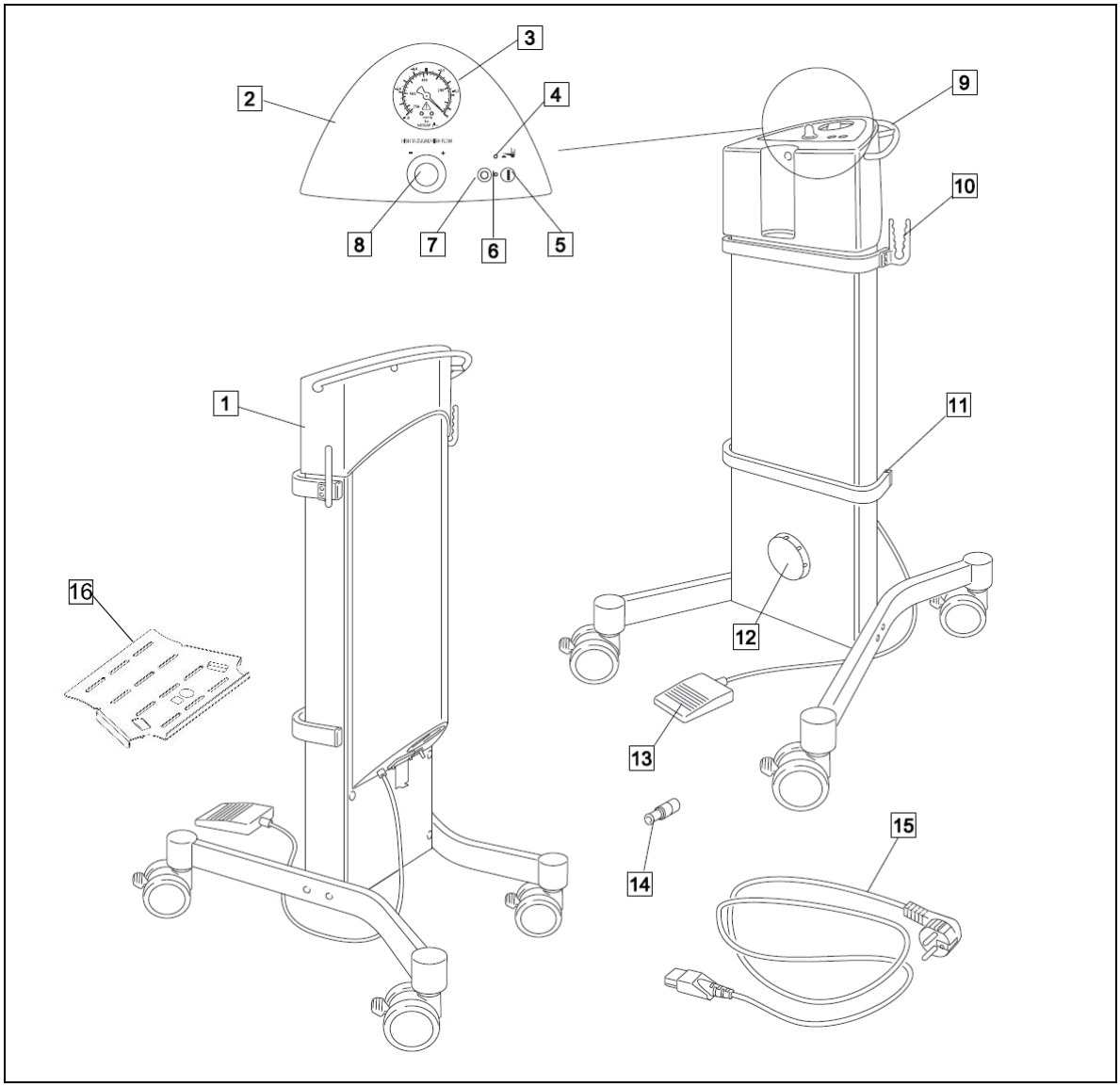


Figure 1:
Overview of the Vacusat® power

1	Suction pump	9	Push handle
2	Control panel	10	Hose holder
3	Vacuum meter	11	Device rail
4	Control lamp for foot switch	12	Cover for bacteria filter
5	ON switch	13	Foot switch
6	Control lamp for operation	14	Hose coupling
7	OFF switch	15	Mains cable
8	Control knob	16	Storage tray

3.2 Interface description

3.2.1 Hydrophobic bacteria and virus filter

It is not necessary to use a hydrophobic bacteria and virus filter if a suitable hydrophobic bacteria and virus filter is integrated for specific use in the secretion container when disposable bags are used.

The hydrophobic bacteria and virus filter protects against contaminants that may be present as particles or aerosol in the intake gas. Furthermore, the hydrophobic filter is also used as overflow protection; it shuts off the gas flow to the product in case of over-suctioning. In its function as a bacteria and virus filter, it prevents bacteria and viruses from entering the pump.

3.2.2 Disposable bag system

With the disposable bag system, fluids and secretions are collected during medical procedures and then disposed of.

The disposable bag system is not sterile.

3.2.3 Suction hose

The suction hose is the connection between the hose connector on the secretion container cover on the patient side and the applied part.

3.2.4 Applied part

The Möller Medical GmbH liposuction cannulas are applied parts. The applied part is used to suction tumescent solutions, body fats, fat cells (secretion, blood and serous fluids) and the particles they contain out of artificial body orifices.

3.2.5 Bacteria filter sheet

The bacteria filter sheet prevents contamination of the surrounding air. Only Möller Medical GmbH bacteria filters may be used.

3.2.6 Equipotential bonding cable

The equipotential bonding cable is the connection between the suction pump and the equipotential output pin with equipotential rail for protection against electric shock.

4 Installation and startup

Upon delivery, make sure that the boxes are not damaged. Check the Vacusat® power for damage. In the event that the product has defects, it should not be used and the supplier must be informed accordingly.

4.1 Transport and storage information

A maximum of 3 cartons may be stacked for transport.

Risk of fire from the highly flammable packaging material. Do not use open flames and do not smoke.

Dimensions of the Vacusat® power

With packaging	Width x height x depth 1030 mm * 360 mm * 420 mm
Weight	approx. 30 kg

Transport and storage information

Temperature	-15°C to +30°C
Air humidity	10 to 95 % relative humidity

4.2 Unpacking the device and checking the scope of supply

The delivery of the Vacusat® power Vacusat® power consists of one carton. Make sure that no parts remain in the packaging when unpacking the Vacusat® power .

The scope of delivery of the Vacusat® power includes:

• Basic device (consisting of: 1 device, 1 vacuum connecting hose, 1 mains cable, 2 foot stands with 2 casters each (with brake), 2 hose holders, 1 assembly set (8 screws, 4 spring washers, 4 plastic discs, 4 filler plugs, 1 hex key)	REF 00002252
• UK power cable	REF 93004210
• Mains cable, straight, Switzerland	REF 93004725
• Mains cable, hospital grade	REF 93006957
• 2 containers for disposable bags	REF 00002257
• 2 disposable bags, 3 litres	REF 00002256
• 2 rail clamps for device holders	REF 00002258
• 1 foot switch	REF 00002656
• Hydrophobic filter	REF 00002297
• Overflow protection with chamber for hydrophobic filter	REF 00002299
• Serial hose with elbow	REF 00002260
• Vacuum serial hose, silicone	REF 00002259
• Instructions for use Vacusat® power	REF 92007308
• Instructions for use Vacusat® power	REF 92007309

It is advisable to keep the packaging and use it again should service be required.

Always send the Vacusat® power in its original packaging in order to avoid damage during transport.

4.3 Suitable operating environment

The Vacusat® power is suitable for environments in the following areas:

Professional healthcare facilities with specific requirements:

- Clinics (A&E rooms, hospital rooms, intensive care, operating theatres, except in the proximity of active facilities with RF surgery devices or outside of the RF-shielded room for magnetic resonance imaging, first aid facilities).

The Vacusat® power is not approved for use in aircraft, vehicles or military applications. The appropriate EMC requirements for these environments have not been tested.

4.4 Commissioning

The Vacusat® power must be set up in a suitable place. Proceed in the following order:

4.4.1 Assembling the foot stand

If the foot stands are incorrectly assembled there is a risk of tipping over. Ensure that there is a right and a left foot stand and that they are assembled correctly.

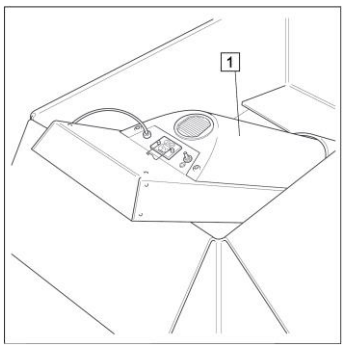


Figure 2:
Assembly position

Assembly position

- Remove the foot stands, assembly set and accessories from the packaging.
- Place the base device (1) on the edge of the packaging with the back facing upwards.

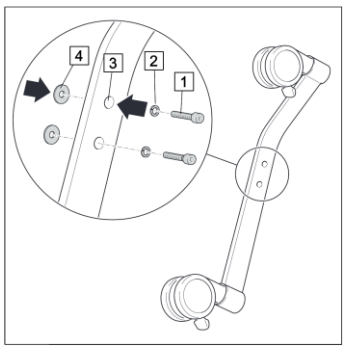


Figure 3:
Pre-assembling the foot stand

Pre-assembling the foot stand

- Guide the screw (1) with spring washer (2) through the drill hole in the foot stand (3).
- Place the plastic disc (4) over the screw.
- Assemble the remaining screw connections in the same way.

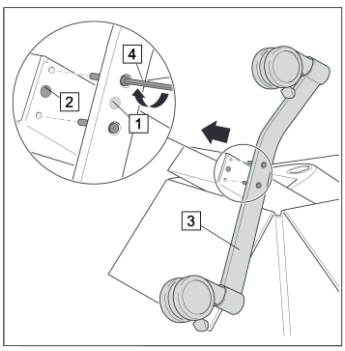


Figure 4:
Mounting the first foot stand

Mounting the first foot stand

- Place the red dot on the foot stand (1) on the red dot of the base device (2).
- The longer section of the foot stand (3) points towards the floor.
- Screw in and slightly tighten the screws with the hex key (4).

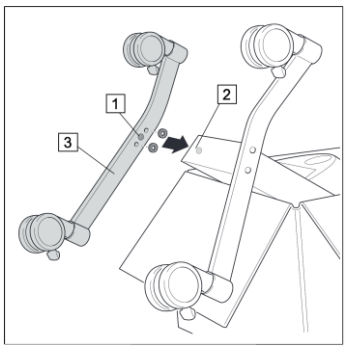


Figure 5:
Mounting the second foot stand

Mounting the second foot stand

- Place the green dot on the foot stand (1) on the green dot of the base device (2).
- The longer section of the foot stand (3) points towards the floor.
- Screw in and slightly tighten the screws with the hex key (4).

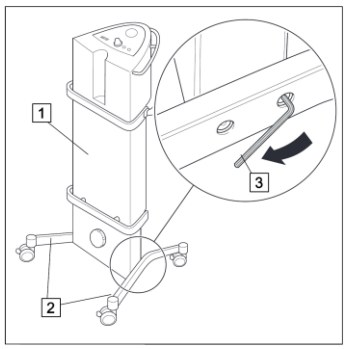


Figure 6:
Aligning and mounting the foot stands

Aligning and mounting the foot stands

- Place the suction pump (1) on a level surface.
- The longer sections of the foot stand (2) are at the front of the device.
- Align the foot stands.
- Tighten the screws with the hex key (3) with maximum manual strength.

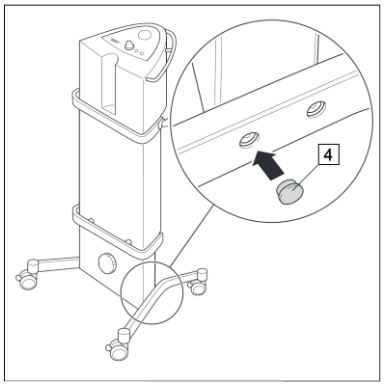


Figure 7:
Put the filler plugs (4) in.

- Put the filler plugs (4) in.

4.4.2 Assembling the hose holder

The hose holders are screwed onto the right and left of the upper device rail.

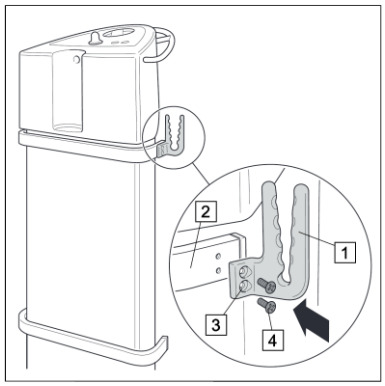


Figure 8:

Assembling the hose holder

- Press the hose holder (1) with the open side facing upwards onto the device rail (2).
- The thread holes (3) of the hose holder are above the thread holes of the device rail.
- Put the screws (4) into the thread holes.
- Tighten the screws of the hose holder with a screwdriver.

4.4.3 Assembling the foot switch

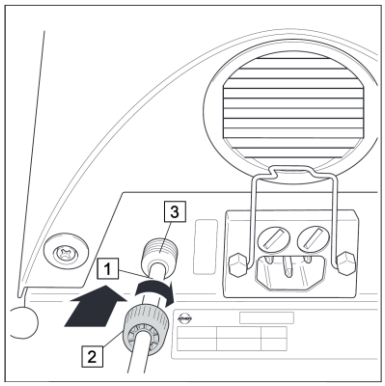


Figure 9:
Assembling the foot switch

- Plug the end of the cable (1) into the retainer nut (2).
- Plug the end of the cable into the hose connector (3) into the Vacusat® power.
- Tighten the retainer nut.

4.4.4 Overflow protection / Hose coupling

The Vacusat® power can be operated either with overflow protection or with a hose connector and downstream overflow protection.

- Always operate the Vacusat® power with connected overflow protection to protect the suction pump from over-suctioning.
- Ensure the correct position of the float. If the mechanical overflow protection float is not in the correct position or if it is not used, liquid can enter the suction pump and damage it.

4.4.4.1 Assembling the mechanical overflow protection

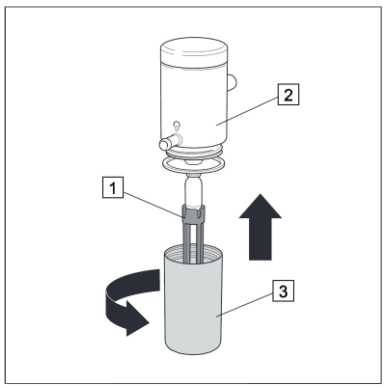


Figure 10:
Assembling overflow protection

Assembling overflow protection

- Let the float cage (1) with float click into the lid (2) of the overflow protection.
- Screw the overflow protection (3) onto the lid.

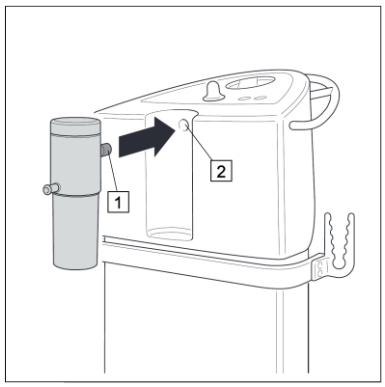


Figure 11:
Inserting the overflow protection

Inserting the overflow protection

- Plug the hose connection (1) of the overflow protection completely into the opening (2) on the device.

4.4.4.2 Assembling the hydrophobic bacteria and virus filter in the mechanical overflow protection

The overflow protection has the option of connecting a hydrophobic bacteria and virus filter after the mechanical overflow protection. It should be used if aerosols are present in the intake gas. It prevents moisture, bacteria and viruses from entering the pump.

When suctioning secretions, foam may develop. Foam impairs the function of the mechanical overflow protection. This leads to a risk that secretions may enter the suction pump and damage it.

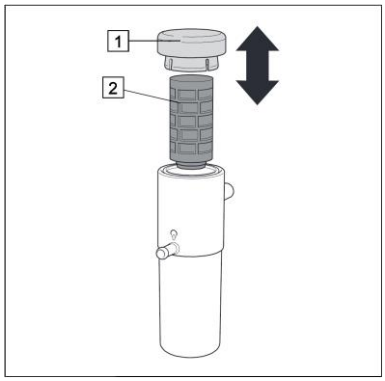


Figure 12:
Assembling overflow protection

Assembling the hydrophobic bacteria and virus filter (with pore size 0.2 µm) in the overflow protection

- Lift the lid (1) off the filter housing.
- Attach the hydrophobic bacteria and virus filter (2).
- Close the filter housing with the lid.

4.4.4.3 Plugging in the hose coupling

If the device is operated with hose coupling, it must have overflow protection. Disposable suction systems with integrated hydrophobic filter do not require additional overflow protection. The device can be operated directly with hose coupling.

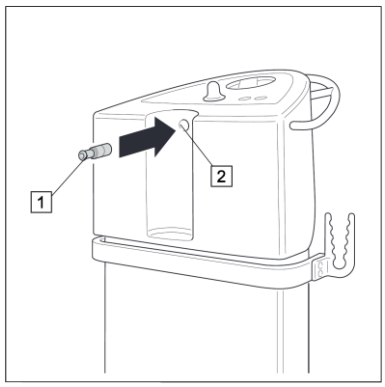


Figure 13:
Plugging in the hose coupling

- Plug the hose coupling (1) into the opening (2) on the device.

4.4.5 Rail clamp interface

Containers can be attached to the rail clamp interface with a device holder.

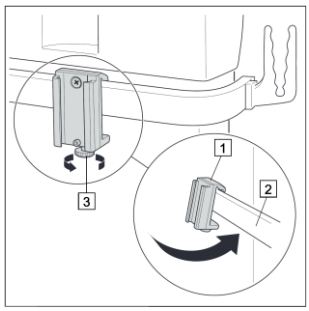


Figure 14:
Attaching the rail clamp

Attaching the rail clamp

- Hang the rail clamp (1) on the device rail (2).
- Secure the rail clamp with the retaining screw (3).

4.4.6 Assembling hoses

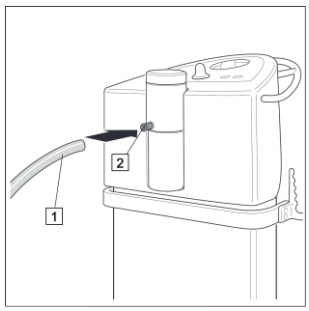


Figure 15:
With overflow protection

With overflow protection

- Plug the vacuum connection hose (1) into the hose connector (2) of the overflow protection.

OR

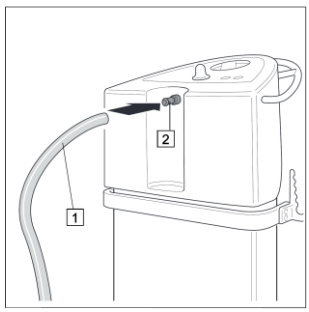


Figure 16:
Without overflow protection

Without overflow protection

- Attach the vacuum connection hose (1) to the hose coupling (2).

4.4.6.1 Installing the suction canister and disposable bag

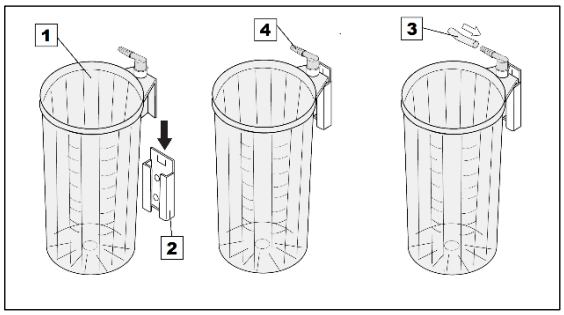


Figure 17:
Installing the suction canister

Installing the suction canister

- Place the suction canister (1) upright in the rail clamp (2).
- Connect the hose (3) with the angle connector (4) to the back of the suction canister.

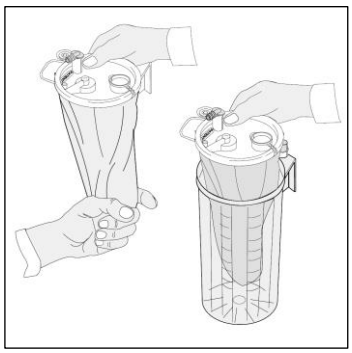


Figure 18:
Versions without adhesive strips

Versions without adhesive strips

- Unfold the disposable bag and place it in the suction canister.

OR

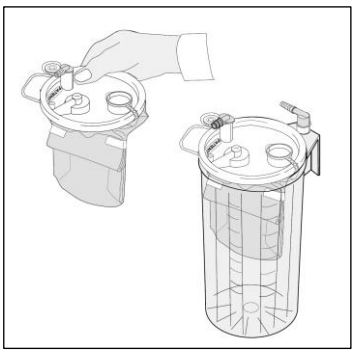


Figure 19:
Versions with adhesive strips

Versions with adhesive strips

- Place the bag as is in the suction canister or follow the directions in the preceding figure.

- The disposable bag must be placed in a suction canister of the same size.
- Ensure that the film of the disposable bag does not get caught between the canister and the lid.

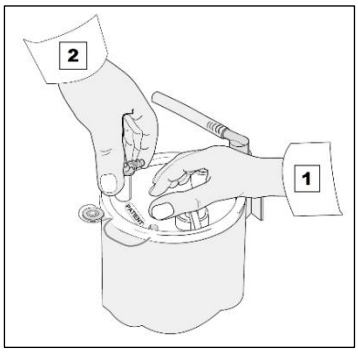


Figure 20:
Unfolding the disposable bag

Unfolding the disposable bag

- The disposable bag is unfolded by a vacuum.
- Switch the Vacusat® power on while simultaneously pressing lightly on the middle of the lid (1).
- When the disposable bag is correctly aligned, close the patient connector by hand (2) so the lid seals the suction canister.

Before use, ensure that a vacuum has formed and the disposable bag is completely unfolded.

4.4.7 Installing multiple disposable bags (in series)

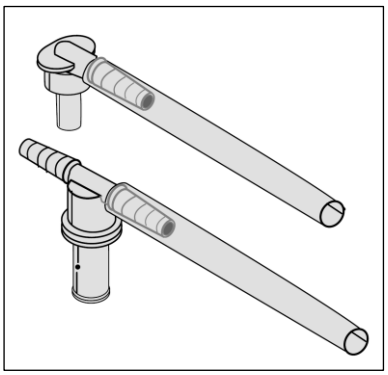


Figure 21:
Series connection option

- If large quantities of fluid are to be suctioned, the disposable bags can be connected in series using serial hoses, vacuum hoses and T-connectors.

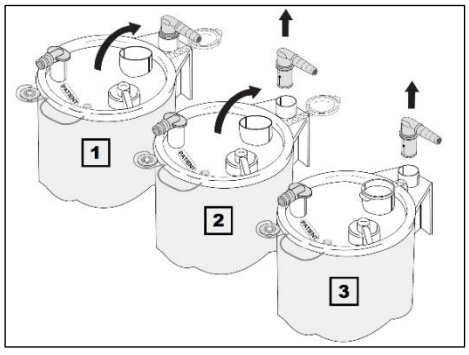


Figure 22:
Connections for use in series

- Place the bags in suction canisters (see *Section 4.4.6.1*).
- Remove the angle connectors on canisters 2 and 3 and open the serial connections 1 and 2.

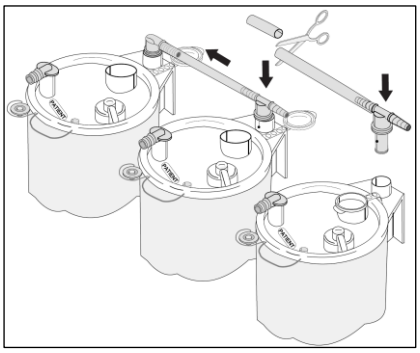


Figure 23:
Hose coupling for use in series

- Connect the suction canisters to each other with separate T-connectors and hoses.
- Cut the hose to the required length with scissors.

The T-connector and the vacuum hose are reusable and do not need to be replaced between procedures.

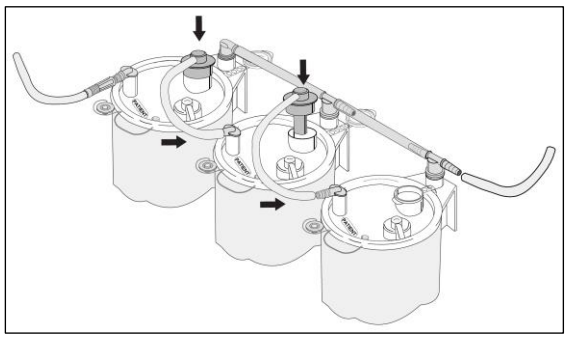


Figure 24:
Connecting for use in series

- Connect the serial hoses to the patient connector of the next disposable bag through the open serial connector opening in the disposable bag.

4.4.8 Connecting/disconnecting the mains cable

- The mains plug must always be accessible so the Vacusat® power can be disconnected from the power supply at any time.

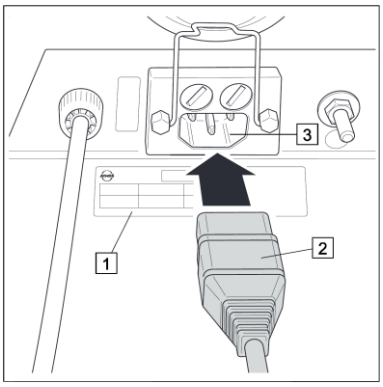


Figure 25:
Connecting the mains cable

Connecting the mains cable

- Check that the mains voltage is the same as the value indicated on the rating plate (1).
- Plug the mains cable (2) into the device socket (3) and connect it to the mains socket.

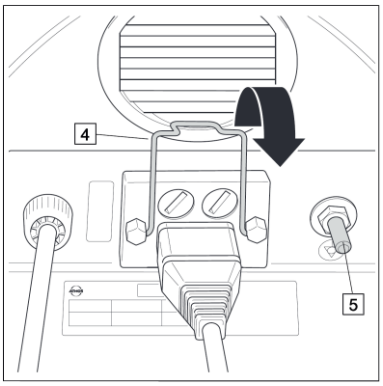


Figure 26:
Securing the mains cable

Securing the mains cable

- Secure the mains cable to the Vacusat® power with the holding clamp (4).
- Connect the equipotential bonding cable to the equipotential pin (5).

Disconnecting the mains cable

- Pull the holding clamp (4) upwards.
- Pull the mains plug from the mains socket.
- Pull the mains cable out of the Vacusat® power

4.4.9 Assembling the storage tray

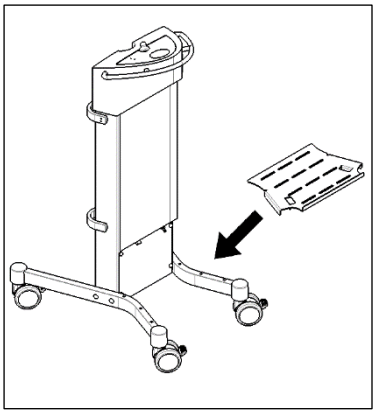


Figure 31:
Placing the storage tray

Placing the storage tray

- The storage tray is placed on the back of the Vacusat® power.
- The four curved edges of the storage tray should face downwards.
- Place the tray in such a way that the outer edges of the foot stand are encircled by the tray.
- By gently moving the storage tray in the horizontal direction, you can check whether it is placed correctly.
- It must not slip off the pedestal when moved.

- The storage tray can be loaded with a maximum of 10 kg.

- A slight back and forth movement of the tray is desirable, and this does not affect the functionality of the device.

4.5 Disassembly

4.5.1 Ending the suction procedure

The following list is only an overview. For the detailed procedure, read the following steps in *Section 4.5.2* and *Section 4.5.3*.

- Remove the hose from the patient.
- Switch the Vacusat® power off.
- Empty the suction canister.
- Clean the components.

4.5.2 Emptying the suction canister

Always wear gloves when emptying the suction canister and follow the hygiene guidelines. All parts of the suction canister can be contaminated.

Check the filling level of the suction canister before and after suctioning, as well as during the suction process if there are large quantities to be suctioned. Once the “Maximum” mark is reached, switch the Vacusat® power off and empty the suction canister.

4.5.3 Disassembling hoses

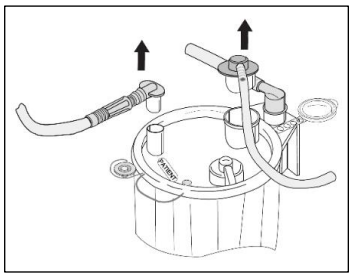


Figure 27:
Disconnecting hoses and connectors

- After the suction process, detach the patient hose, the angle connector and, if applicable, the serial hose and other connectors.

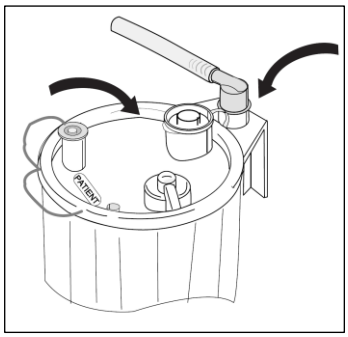


Figure 28:
Closing the patient connection and the series connection

- Close the connection to the patient connector plug on the lid of the disposable bag.
- Also close the serial connection if using a series of bags.

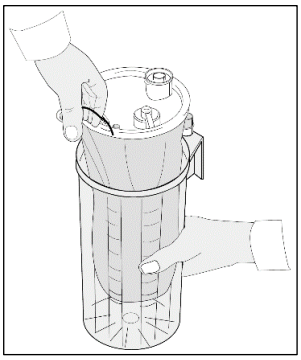


Figure 29:
Unfolding the disposable bag

- Switch the vacuum source off and lift the disposable bag out of the canister by the handle.

Only switch the Vacusat® power off once the disposable bag is closed.

Do not remove or dispose of the reusable suction canister, the angle connector and silicone vacuum hoses unless necessary.

4.5.4 Disassembling the overflow protection

Avoid damaging the edge of the float.

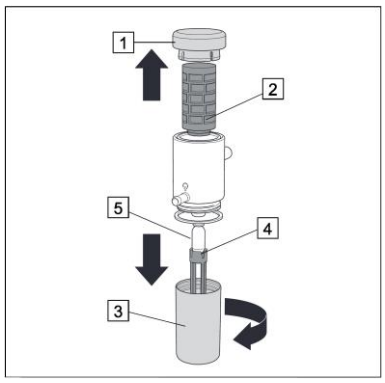


Figure 30:
Disassembling the overflow protection

- Lift the lid (1) off the filter housing.
- Remove the hydrophobic bacteria and virus filter (2).
- Unscrew the lid (3) of the overflow protection.
- Detach the float cage (4) and remove the float (5).

5 Use and operation

- All handling of the device requires precise knowledge and compliance with these instructions for use.
- These instructions do not replace user training.
- The device may only be used by qualified personnel.

5.1 Function test

The user must check the product for functioning and proper condition before use.

Using a series of multiple suction canisters may result in delayed suction and reduced suction power.

Carry out the following function test before every use:

- All components are firmly attached.
- The mains cable is not damaged.
- Plastic and rubber components (e.g. control panel, hose, suction holder cover, suction holder) are in perfect condition with no signs of aging.
- The bacteria filter sheet is in perfect condition.
- Overflow protection and/or hydrophobic bacteria and virus filter are attached and functioning.
- Overflow protection and/or hydrophobic bacteria and/or virus filter are properly cleaned and no residue or dirt is present.
- Hose connectors and suction canister cover are firmly in place and tightly sealed.
- No mechanical forces are acting on the hoses.
- The hoses may not have kinks.
- The maximum vacuum of approx. -90 kPa is reached within approx. 20 seconds once the vacuum connection hose is closed.
- The vacuum can be continuously adjusted in the entire range.
- The suction canister is properly connected to the Vacusat® power.
- The device is properly cleaned (no residue or dirt present)
- Damaged parts must be replaced with new ones.

Use and operation

Documenting the result of the visual and function test with the date and signature of the inspector is recommended. The following table can be used as a template:

No.	Test	Defects present		No defects
1	Has the product been cleaned and disinfected according to the hygiene guidelines?	☐	• Do not use the product. • Clean and disinfect the product according to specifications.	☐
	Notes:			
2	Do any individual components have tears?	☐	• Do not use the product. • Notify service.	☐
	Notes:			
3	(space for additional tests)	☐		☐
	Notes:			

Table 2:
Function test

5.2 Suctioning

5.2.1 Warning notices

- Before connecting the power plug, check that the mains voltage is the same as the value indicated on the rating plate. The Vacusat® power can only be disconnected from the power supply by unplugging the mains plug.
- Danger from ingress of bacteria and viruses into the pump. A bacteria and virus filter protects the inside of the pump from contamination with bacteria and viruses. Use bacteria and virus filters for additional protection against over-suctioning.
- There is a risk of infection from using no or a defective hydrophobic bacteria and virus filter. If secretions get into the Vacusat® power when suctioning, clean and disinfect the Vacusat® power and have it repaired by a service technician authorised by Möller Medical GmbH.

- If over-suctioning occurs, the suctioned secretion can flow back to the patient if any secretion is still in the hose. Remove the hose from the patient before replacing the secretion container in the event of over-suctioning or switching off the vacuum.
- Only operate the Vacusat® power with overflow protection connected to protect against over-suctioning. A hydrophobic filter provides additional protection against over-suctioning. It shuts off the gas flow to the product in the event of over-suctioning. Particles in the gaseous phase can lead to clogging of the hydrophobic filter. Use a bacteria and virus filter that additionally prevents bacteria and viruses from entering the pump.
- When suctioning secretions, foam may develop. Foam impairs the function of the mechanical overflow protection. There is a risk that secretions can enter the Vacusat® power and damage the Vacusat® power. Always use a hydrophobic filter and a commercial foam inhibitor if possible.

- When attaching the hydrophobic bacteria and virus filter, the Vacusat® power must be switched off, all parts emptied and reprocessed or replaced.
- Check the filling level of the suction canister before and after suctioning, as well as during the suction process if there are large quantities to be suctioned. Once the “Maximum” mark is reached, switch the Vacusat® power off and empty the suction canister. We recommend attaching a reserve suction canister in an operating position on a device rail to ensure a faster switch to an empty container.

5.2.2 Switching Vacusat® power on

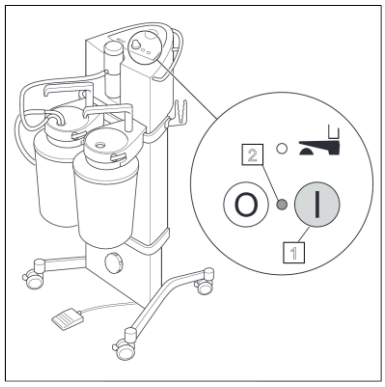


Figure 31:
Switching *Vacusat® power on*

- Switch the Vacusat® power on (1)
- Control lamp for operation (2) lights up green.

5.2.3 Setting the vacuum

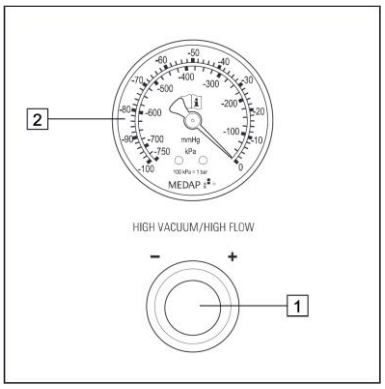


Figure 32:
Setting the vacuum

Setting the vacuum

- Bend the suction hose leading to the patient or hold it closed. Set the vacuum with the control knob (1) and check it.

Increasing the vacuum

- Twist the control knob (1) to the right.
- Read the set value on the vacuum meter (2).

Reducing the vacuum

- Twist the control knob (1) to the left.
- Read the set value on the vacuum meter (2).

If no or too little vacuum is generated, see *Section 7* "*Help in the event of a fault*".

5.2.4 Using the foot switch

With the foot switch, the device can be switched to energy-saving stand-by mode.

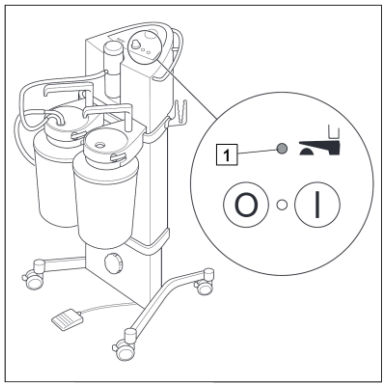


Figure 33:
Using the foot switch

- Press the foot switch.
- The Vacusat® power is switched to stand-by mode.
- The LED lights up yellow (1).
- Press the foot switch again.
- The yellow LED goes out.
- The Vacusat® power is switched to operating mode.

5.3 Replacing the bacteria filter sheet

Wear gloves for all cleaning and disinfection tasks. Follow the hygiene guidelines. Parts of the Vacusat® power can be contaminated.

Change the bacteria filter sheet of the Vacusat® power daily.
(when in use)

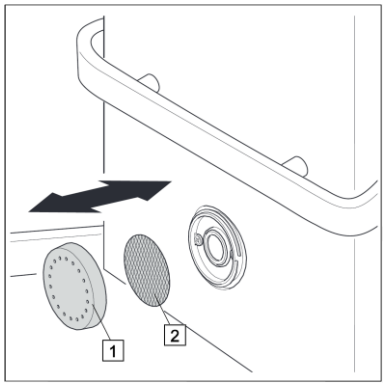


Figure 34:
Replacing the bacteria filter sheet

- Unscrew the lid (1).
- Remove the used bacteria filter sheet (2).
- Clean the lid and wipe disinfect it.
- Put a new bacteria filter sheet into the lid. The finely textured side faces the pump.
- Screw the lid on.
- Switch the Vacusat® power on.

6 Cleaning and disinfection

- No moisture must be allowed to enter into the device.
- Before cleaning and disinfecting the device surfaces, disconnect the mains plug.
- Use soft, lint-free cloths for cleaning and disinfecting.
- Wipe the devices to clean and disinfect them. Immersing or spraying the device may lead to damage.
- To clean the control panel, turn the control knob to the left to twist it off. After cleaning, screw the control knob back on and twist it to the right as far as it goes.

- Clean using a cloth dampened with mild soap solution or 70 % isopropanol solution.
- After cleaning, disinfect the surfaces of the Vacusat® power with an approved pH-neutral, detergent-alcohol-based disinfectant with up to 70 % alcohol (e.g. propan-1-ol, recommended disinfectant: Meliseptol®).
- During disinfection, follow the instructions of the disinfectant manufacturer.
- Ensure that the cleaning and disinfecting agents have fully evaporated before using the Vacusat® power .

Visual check:

The sockets of all the connections and plugs of the cables to be connected must be free of all types of dirt.

7 Help in the event of a fault

The Vacusat® power must not be opened by the user.

This section describes certain problems that may occur in conjunction with the Vacusat® power

Several possible solutions are given for each problem. The first solution proposed is generally the most likely. The solutions proposed should be executed in the order provided until the error is remedied.

The Vacusat® power must always be turned off when connecting and disconnecting plug connections.

If an error cannot be remedied in this manner, contact the Möller Medical GmbH service centre (service@moeller-medical.com).

No.	Problem	Cause of error	Remedy
1	Vacusat® power does not start, the operating display lights up.	No vacuum is present yet.	Switch the Vacusat® power off, twist the control knob to the left, switch the Vacusat® power on.
		Motor is defective.	Have repairs made by a service technician authorised by Möller Medical.
2	Vacusat® power with foot switch does not start, the yellow LED lights up.	Vacusat® power is in stand-by mode.	Switch off stand-by mode with the foot switch. The Vacusat® power starts up. When the foot switch is pressed again, the Vacusat® power is in stand-by mode again.
3	The Vacusat® power ***r*** does not start, the operating display does not light up.	Device or mains plugs are not plugged in properly.	Check that the device and mains plugs are firmly plugged in.
		No or incorrect mains voltage.	Check the mains fuse, check information on the rating plate.
		Mains fuse is defective.	Replace the mains fuse.
4	The Vacusat® power cannot be switched on or off.	Defective electronic component.	Have repairs made by a service technician authorised by Möller Medical.
5	The Vacusat® power starts, but the operating display does not light up.	Operating display LED is defective.	Have repairs made by a service technician authorised by Möller Medical.

Help in the event of a fault

No.	Problem	Cause of error	Remedy
6	The vacuum cannot be regulated.	Membrane control is defective.	Have repairs made by a service technician authorised by Möller Medical.
7	The Vacusat® power suctions, but the vacuum meter indicates no vacuum.	Vacuum meter is defective.	Have repairs made by a service technician authorised by Möller Medical.
8	Little/no suction power.	Suction canister cover is not properly closed.	Put the suction canister cover on correctly.
		Hydrophobic filter is clogged (vacuum meter indicates vacuum).	Replace the hydrophobic filter.
		Tear in the hose.	Replace hose.
		Gasket is dirty.	Replace gasket.
		Porous gasket on the secretion holder cover.	Replace gasket.
		Clamp is bent, suction canister cover does not close.	Replace suction canister cover.
		Suction canister is full, mechanical overflow protection is closed (vacuum meter indicates vacuum).	Empty the suction canister, clean or replace the suction canister and mechanical overflow protection.
		Mechanical overflow protection is contaminated with secretions.	Clean the overflow protection or replace the suction canister cover.
		Hose connection in the suction canister cover is clogged.	Clean the hose connection.
		Suction adapter is clogged.	Clean the suction adapter.
		Motor is defective.	Have repairs made by a service technician authorised by Möller Medical.
9	The Vacusat® power was over-suctioned.	No mechanical overflow protection and no hydrophobic bacteria filter were used.	The Vacusat® power may no longer be used. Have repairs made by a service technician authorised by Möller Medical.
		Mechanical overflow protection is clogged, no hydrophobic bacteria filter is used.	
If none of the measures described are successful, contact the Möller Medical GmbH service centre.			

Table 3
Help in the event of a fault

8 Service

- Before disposing of or returning the Vacusat® power, a suitable disinfection procedure must be carried out to rule out the risk of possible infection.
- Dispose of consumables according to the hygiene guidelines.

Service:

- Never open the device when it is connected to the mains power supply.
- Even when not connected to the mains, internal parts may still be live.

Möller Medical GmbH service centre:

Möller Medical GmbH
Wasserkuppenstrasse 29-31
36043 Fulda, Germany

Tel. +49 (0) 661 / 94 19 5 – 0
Fax +49 (0) 661 / 94 19 5 – 850
http://www.moeller-medical.com
info@moeller-medical.com

Service
Tel: +49 (0) 661 94195 - 108
Fax: +49 (0) 661 94195 – 850
E-mail: service@moeller-medical.com

8.1 Replacing the mains fuses

- Pull the device plug before replacing mains fuses.
- Only the following types of fuses may be used:
  2 x T 1.6 A / 250 V AC.

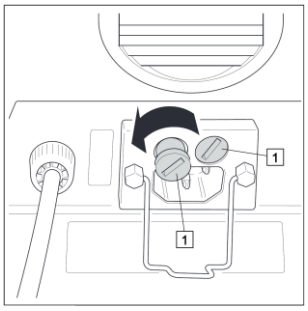


Figure 35:
Loosen fuse inserts

- Pull the device plug.
- Twist the fuse inserts (1) with a screwdriver or coin.

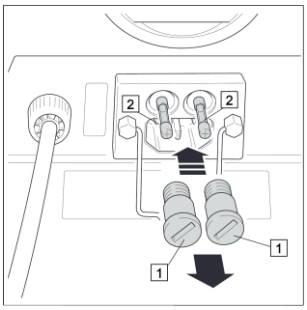


Figure 36:
Replacing the fuses

- Remove the fuse inserts (1).
- Take the fuses (2) out of the fuse inserts.
- Insert new fuses.
- Replace the fuse inserts and screw them in.

8.2 Repairs

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

- Liquid has entered the device.
- Power is considerably reduced.
- Unexplained messages are displayed.
- Unusual sounds occur.
- Malfunctions cannot be remedied by actions in Section 7 “Help in the event of a fault”.

Do not continue to operate the Vacusat® power if you detect defects.

Make a note of the defects and the article number on the rating plate and inform the responsible Möller Medical GmbH office.

Outside Germany, inform the responsible international office.

Note the information in *Section 8.4* “*Sending the device*”.

8.3 Rating plate

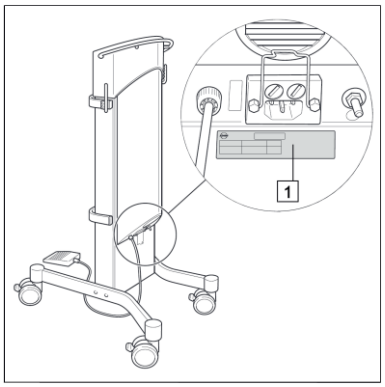


Figure 37:
Rating plate

- Position of the rating plate (1) on the product.

8.4 Sending the device

- Remove and dispose of consumables properly.
- Clean and disinfect the product and accessories according to the instructions for use.
- Enclose the accessories used.
- Fill out form FB_77 “Handling contaminated products”. The form is included with the product and is available at www.moeller-medical.com.
- Pack the product well with suitable padding.
- Put the form FB_77 “Handling contaminated products” in the envelope.
- Glue the envelope to the outside of the packaging.
- Send the product to Möller Medical GmbH or your dealer.

9 Periodic safety checks

Carry out safety checks (SC) as per the German Medical Devices Operators Ordinance (MPBetreibV) on the Vacusat® power at least every 12 months.

- The safety check must be entered in the device book and the results of the check must be documented.
- If the device is not functionally and/or operationally safe, have it repaired immediately by the device service.
- The safety checks can be performed by the Möller Medical GmbH (**service@moeller-medical.com**) service department.

10 Disposal

This device contains materials which must be disposed of in the interest of environmental protection. The European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE2) applies to this device. This device therefore bears the symbol of a crossed-out bin on the rating plate.

Return devices that are no longer used to Möller Medical GmbH. This ensures that the devices are disposed of in compliance with the national requirements of the WEEE Directive.

11 Appendix

11.1 Key technical data

Catalogue number Vacusat® power	REF 00002252
Voltage	230 V AC (alternating current)
Frequency	50 Hz / 60 Hz
Current consumption	1.1 A
Fuses	T 1.6 AH
Protective class	I
Dimensions (assembled)	Width x height x depth: 1000 mm x 500 mm x 560 mm
Weight	approx. 26 g
Suction power	58 l/min ± 6 l/min at 50 Hz 68 l/min ± 6 l/min at 60 Hz (measured at the device, this value may change depending on the suction container used)
Vacuum (max.)	0.1 bar (100 mbar) at NN NN= normal null (1 bar = 1000 mbar = 100 kPa)
Minimum operating lifespan	8 years
Load capacity of the storage tray	Maximum 10 kg

11.2 General data

Transport and storage instructions:

Temperature	-15°C to +30°C
Air humidity	10 to 95 % relative humidity
Weight with packaging:	Approx. 30 kg
Dimensions of Vacusat® power with packaging:	Width x height x depth: 1030 mm x 360 mm x 420 mm

Store device in a dry place.

A stack may consist of max. 3 packages

Appendix

Operating conditions:

Temperature	+15°C to +30°C
Air humidity	30 to 75 % relative humidity
Pressure	79.4 kPa – 101.3 kPa / max. application height 2000 m
Type of protection:	IPX1
Accuracy:	Tolerance of vacuum meter: Accuracy class 2.5 (DIN 16005) This is equivalent to ± 2.5 % of the scale range
Noise pressure level:	Approx. 53 (dB(A))

Vacuum depending on altitude

Altitude	Ultimate vacuum of pump	Ultimate vacuum of pump
2000m	-68 kPa	-510 mmHg
1500 m	-73 kPa	-548 mmHg
1000 m	-79 kPa	-593 mmHg
500 m	-84 kPa	-630 mmHg
0m	-90 kPa	-675 mmHg

- The Vacusat® power is subject to special precautionary measures with respect to electromagnetic compatibility (EMC) and must be installed and operated in accordance with the EMC guidelines.
- The Vacusat® power may not be used immediately adjacent to or stacked up with other equipment. If operation close to or stacked on other devices is necessary, the Vacusat® power must be monitored in order to check proper operation with this set-up.
- A list of the accessories with which the Vacusat® power meets the requirements as per 6.1 and 6.2 of IEC 60601-1-2 is included in the accessories appendix.
- Operating the Vacusat® power with additional accessories such as converters and cables that are not defined as suitable for use with the device can result in increased electromagnetic emissions or reduced interference immunity.

11.3 Electromagnetic emissions

The Vacusat® power is intended for use in the electromagnetic environment specified. The customer and/or operator of the Vacusat® power should ensure that the Vacusat® power is used in an electromagnetic environment as described below.

Measurement of emitted interference	**Compliance**	**Electromagnetic environment - guidelines**
High-frequency emitted interference according to CISPR 11	Group 1	To function as intended, the ***Vacusat® power*** must emit electromagnetic energy. Electronic devices in the vicinity could be influenced.
High-frequency emitted interference according to CISPR 11	Class B	For areas of application, see *Section 4.3* "*Suitable operating environment"*
Harmonic emissions acc. to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker acc. to IEC 61000-3-3	Complies	

Table 4:
Electromagnetic emissions

11.4 Electromagnetic immunity

Immunity test / standard	**IEC 60601 - testing level**	**Compliance level**	**Electromagnetic environment / guidelines**
Electro- static discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Rapid transient electric disturbances / bursts IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input and output lines	±2 kV for power supply lines ±1 kV for input and output lines	The quality of the supply voltage should be comparable to that of a typical commercial or hospital environment.
Surges (surges) IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	The quality of the supply voltage should be comparable to that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 1/2 period 40 % U_T (60 % dip in U_T) for 5 periods 70 % U_T (30 % dip in U_T) for 25 periods < 5 % U_T (> 95 % dip in U_T) for 5 seconds	< 5 % U_T (> 95 % dip in U_T) for 1/2 period 40 % U_T (60 % dip in U_T) for 5 periods 70 % U_T (30 % dip in U_T) for 25 periods < 5 % U_T (> 95 % dip in U_T) for 5 seconds	The quality of the supply voltage should be comparable to that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Magnetic field in power supply frequency (50/60 Hz) IEC 61000-4-8	30 A/m	300 A/m	Magnetic fields of the supply frequency should conform with the typical values found in commercial or hospital environments.
Note: U_T is the AC mains voltage prior to application of the test level.			

Appendix

Table 5:
Electromagnetic immunity (1)

The Vacusat® power complies with all test levels in accordance with IEC60601-1-2 Edition 4 (tables 4 to 9).

- Portable RF communications equipment (radio devices) (including their accessories such as antenna cables and external antennas) should not be used closer than 30 cm (or 12 inches) from the parts and cables of the Vacusat® power indicated by the manufacturer. Non-observance may result in a reduction of the device's performance.
- Operation of the Vacusat® power with additional accessories such as transducers or cables that are not defined for the intended use with the device may result in increased electromagnetic emissions, reduced immunity to interference or faulty operation.

The requirements for use in aviation, transportation and military fields have not been taken into account as they have not been tested.

Appendix

Electromagnetic immunity/standard	IEC 60601- Test level	Level of conformity	Electromagnetic environment / guidelines
RF conducted disturbance acc. to IEC 61000-4-6	3 V_{eff} 150 kHz to 30 MHz 6 V_{eff} in ISM and amateur radio frequency bands between 150 kHz and 80 MHz	3 V_{eff} 6 V_{eff}	Portable and mobile radio transmitting devices should not be used in proximity of the Vacusat® power including the cables, at less than the recommended safety distance calculated according to the applicable transmission frequency equation. **Recommended safety distance:** $d = 1{,}2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the nominal power of the transmitter in watts (W) and d is the recommended safety distance in metres (m). Field strengths from fixed RF transmitters, as determined by a site survey [a]) should be less than the compliance level in each frequency range [b]). Interference may occur in the vicinity of devices marked with the following symbol: 
Radiated RF disturbance acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz Table 9 of IEC 60601-1-2 Ed.4	3 V/m 80 MHz to 2.7 GHz Table 9 of IEC 60601-1-2 Ed.4	

Notes:

NOTE 1: The higher frequency range applies at 80 MHz and 800 MHz.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection by structures, objects and people.

[a]) Field strengths from fixed transmitters, such as base stations for radio telephones and land mobile radios, amateur radios, AM and FM radio and TV transmitters cannot theoretically be predicted accurately. To determine the electromagnetic environment in terms of the stationary emitter, a study of the site should be considered. If the measured field intensity at the site in which the Vacusat® power is used exceeds the preceding compliance levels, the Vacusat® power should be monitored to ensure it is functioning as intended. Unusual performance characteristics may require additional measures, such as changes to the alignment or location of the Vacusat® power.

[b]) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 6:
Electromagnetic immunity (2)

11.5 Recommended safety distances

See *Section 12.4 "Electromagnetic interference resistance*".

12 Accessories

- **Disposable bag (unsterile)**

  REF.: 00002256

- **Filter sheet**

  REF.: 00002296

- **Hydrophobic filter**

  REF.: 00002297

- **Overflow protection with chamber for hydrophobic filter**

  REF.: 00002299

- **Foot switch**

  REF.: 00002656

- **Vacuum connecting hose**

  8 x 14 x 1000

  REF.: 00002255

- **Vacuum serial hose**

  Silicone 175 mm with T-connector

  REF.: 00002259

- **Serial hose**

  287 mm with elbow, blue

  REF.: 00002260

- **Containers for disposable bags**

  REF.: 00002257

- **TISSU-TRANS FILTRON 2000 ***

  REF.: 3-TT-FILTRON 2000
  *Only available in certain markets, please contact your local distributor.

- **Rail clamp**

  REF.: 00002258

- **Vacuum switch Vacusat®**
  REF.: 00004288

- **Storage tray**
  REF.: 92018855

An up-to-date list of the available accessories can be found on our website www.moeller-medical.com or in our brochure.

CE 0482

Catalogue number of
Instructions for use
(REF) 92007309

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MÖLLER

The instruction for use is part of the product.