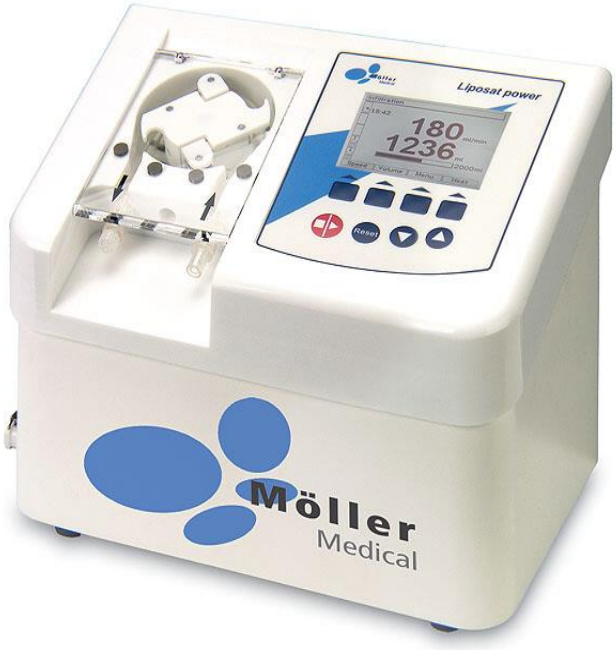
en

Instruction for use

Liposat® power



IMPORTANT

READ CAREFULLY BEFORE USE

KEEP THESE INSTRUCTIONS FOR FUTURE CONSULTATION

Manufacturer

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Product description

Any use of the product assumes precise knowledge of the application and attention to these instructions for use. This set of instructions does not replace professional instruction to the user by a certified medical device consultant. The product should be used only by persons who have the required training, knowledge and experience (§2 Section 2 MPBetreibV).

The use of parts that do not correspond to the original manufacture may damage performance and safety.

Only the original parts as supplied by the manufacturer should be used.

Intended use (intended purpose)

The *Liposat® power* is a peristaltic pump used both for medical indications, including those accompanied by a change in fatty tissue, and for aesthetic body shaping.

The *Liposat® power* is used to administer tumescent local anaesthesia, other aqueous infusion solutions, as well as endogenous subcutaneous tissue and its components, into the body.

The *Liposat® power* peristaltic pump may only be used with the tubing set *Liposat® power* made by Möller Medical.

Essential performance feature

The ***Liposat® power*** does not have any essential performance feature.

Manufacturer

The manufacturer can consider itself responsible for the safety, reliability and usability of the device only if repairs and maintenance are performed by persons authorised to do so. All work that requires the use of tools must be done by a technical service authorised by the manufacturer or by the manufacturer itself.

Under the ElektroG [Electronics Act], the manufacturer is obligated to take back old devices.

MöllerMedical

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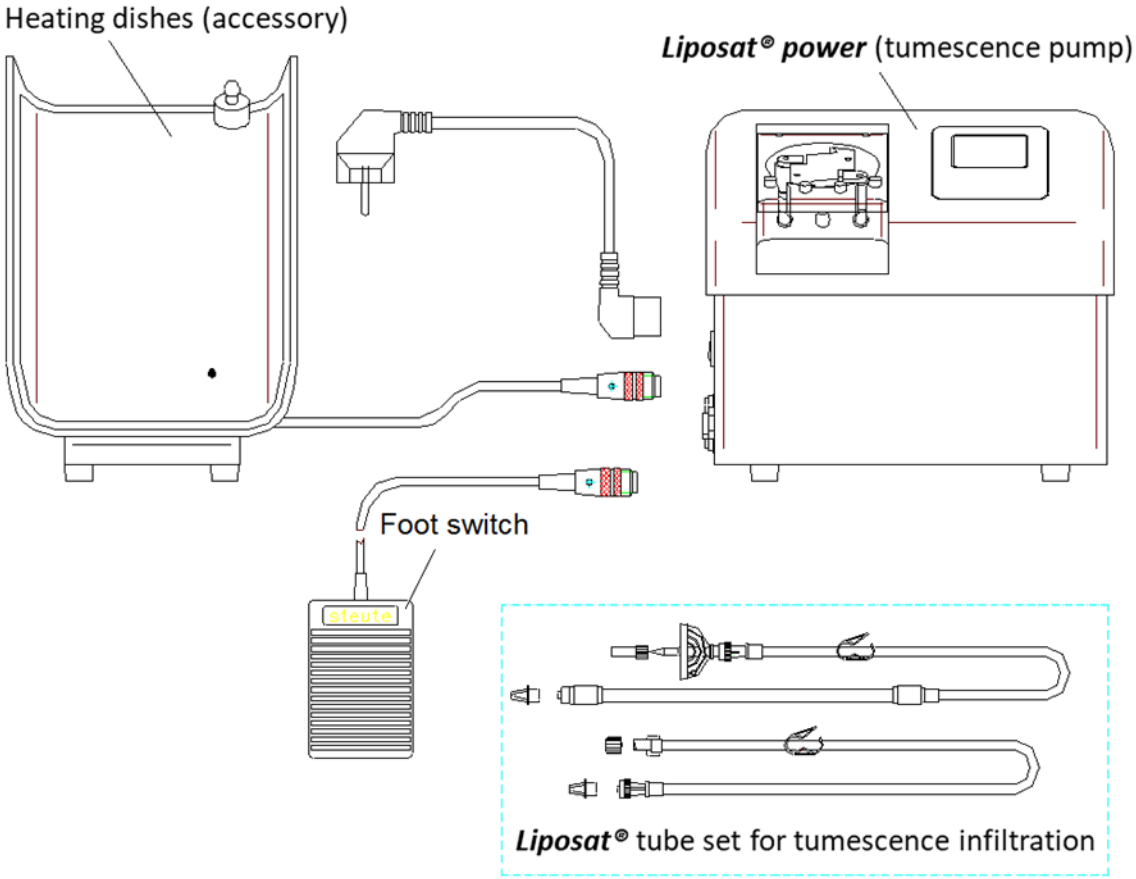
Product description

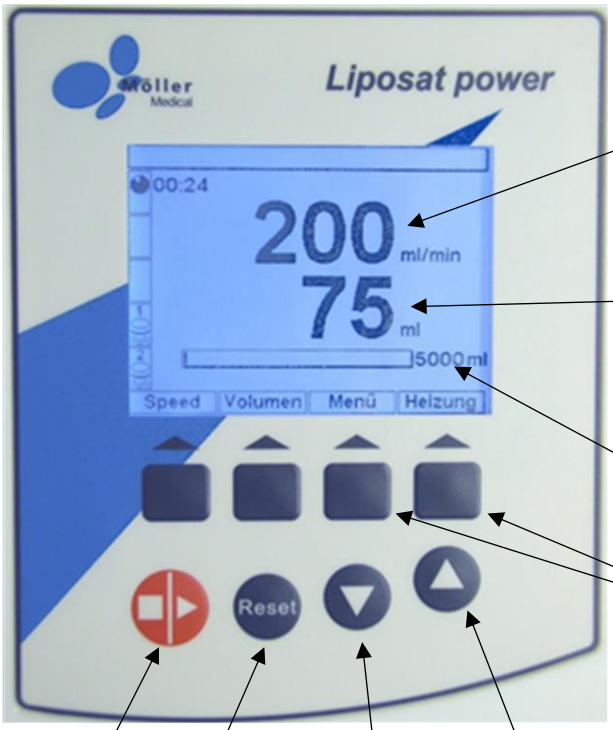
Product overview



Liposat® power configuration

Using the Liposat® power

The device is turned on with the ON – OFF switch on the left side of the device.
The device then performs a self-test. The software version, the device number and the manufacturer are shown on the display.



Pump flow rate [ml/min]

(Infiltration volume per time unit)

Already infiltrated volume [ml]

Preselected infiltration volume [ml]

Soft key buttons

Up button

Down button

RESET button

Start/Stop button

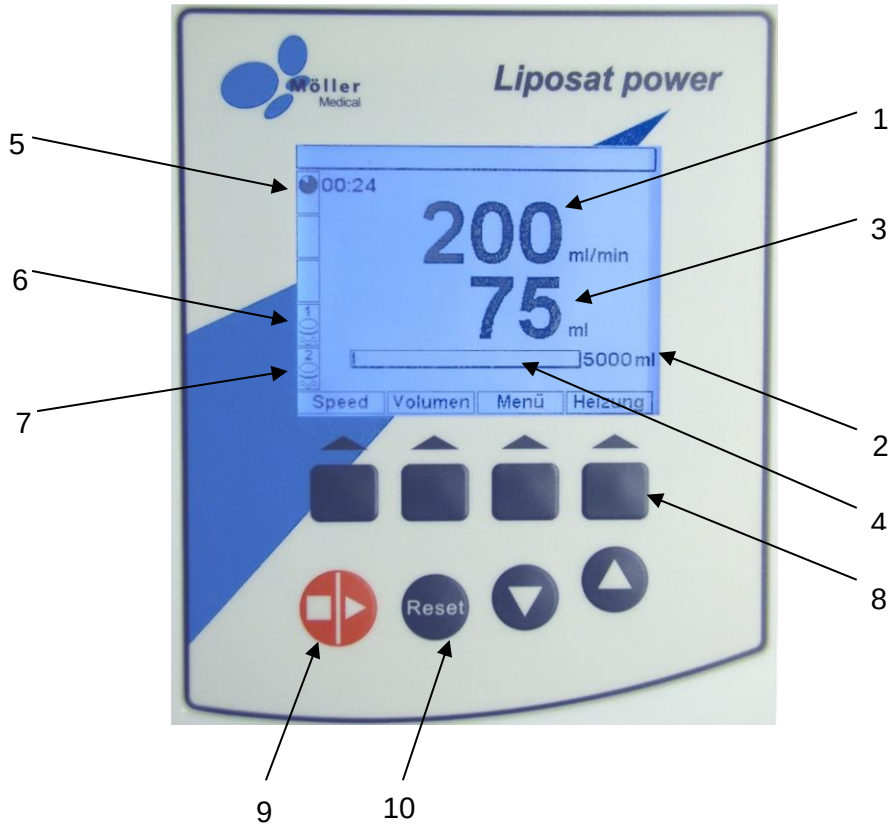
You can set the basic settings of the device with the **soft key** buttons.

The soft key button **Speed** sets the flow rate (ml/min) of the pump. The flow rate can be raised with the **Up button** or lowered with the **Down button** at intervals of 10 from 40 ml/min to 300 ml/min.

The maximum infiltration amount (ml) is adjusted with the soft key button **Volume**. The infiltration volume can be raised with the Up button or lowered with the Down button at intervals of 100 from 500 ml/min to 5000 ml/min.

The pump can be started or stopped at any time with the **Start/Stop** button. The **Foot switch** (accessory) has the same function as the **Start/Stop** button.

Product description



Example of infiltration application

→ Adjusted flow rate = 180 ml/min
→ Adjusted infiltration volume = 2000 ml

After the pump was started, 180 ml/min will be infiltrated for 11.1 minutes (infiltration time).

All necessary information is shown on the display.

1 – Selected flow rate (ml/min)
2 – Selected infiltration volume (ml)
3 – Infiltrated volume (ml)
4 – Infiltrated volume (ml) – as a bar chart
5 – Infiltration time
6 – Heating dish 1 active
7 – Heating dish 2 active

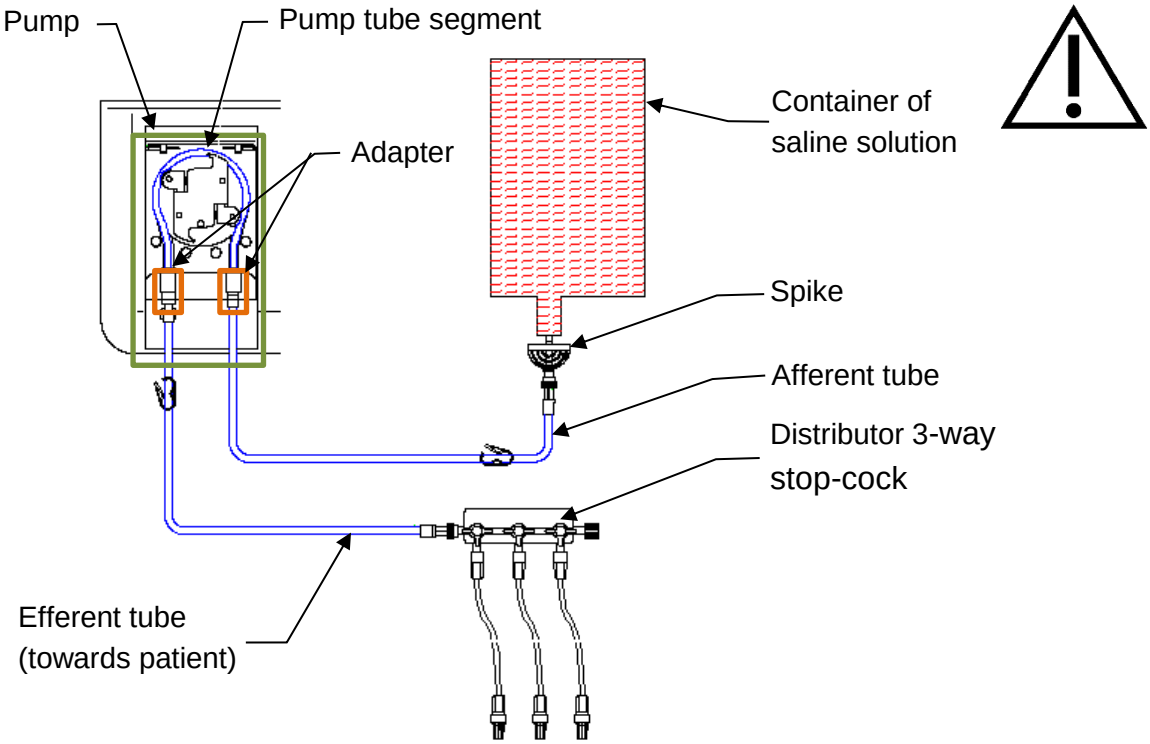
If the pump is stopped by pressing the **Stop button** (9), you can delete the infiltrated volume and infiltration time by using the **Reset button** (10).

Every patient needs a new sterile tube set in order to avoid infections, for example.

Liposat® power configuration

Before usage, inspect the original packed tube set for shelf life and damages. Do not use expired, damaged, dirty or wet tube sets.

Load the pump tube segment into the pump. The **pump tube segment** can be found between the **adapters**, which are intended to be attached into the adapter receptacle of the pump. **Follow the flow direction arrow on the pump.** The pump rotates to the left (counter clockwise). Saline solution must be pumped out of its container towards the patient.



The pump tube segment is firmly attached to the 1.5-metre long PVC Afferent tube with its spike, in order to draw saline solution out of the container.

Connect one side of the **Efferent tube** to the tube pump segments Luer connector. Connect the other end of the Efferent tube to the distributor 3-way stopcock.

Always ensure that all hoses lie unencumbered and are not pinched or kinked.

Use the "**Reset Function**" to prime the tube set. For this purpose, start the pump with a new tube set and previously selected data. The device will then flush the tube set with saline solution. As soon as saline solution pours out of the infiltration cannula and no air can be found in the tubing (tube set completely primed), stop the pump by using the **Start/Stop** button.

Since the infiltration amount, which has been drawn so far and is now shown on the display is meaningless for the application, delete these data by pressing the **Reset** button.

After puncturing with the cannula, restart the pump. The pre-selected infiltration amount and infiltration time are now shown on the display.

Product description

Accessories may be attached to the ***Liposat® power***. One or two heating dishes serve to maintain the temperature of the pre-heated containers of saline solution. The heating dishes will be turned on and off by using the soft key button **Heating** (8). Press the button **Heating** to enter the settings menu. You can activate and deactivate the heating by pressing the two middle buttons.The functioning of the heating dishes is displayed on the left side of the display (6, 7 – see page 9).

As the infiltration is completed, a sound will be generated and the pump stops automatically. The infiltration may be interrupted at any time by pressing the **Start/Stop** button (9).

No settings will be changed by interrupting the infiltration. However, these settings can be changed at any time.

The device does not require any technical maintenance by the user. Prior to using, the device must be prepared according to the applicable hygiene guidelines.

For device disinfection and cleaning, please refer to chapter Cleaning and on page 28.

Repeat technical safety monitoring

Annual safety check-up (STK according to the Ordinance on Medical Device Operation – MPBetreiberV) is to be done every 12 months.

If the device is not functioning safely and/or is not to be operated safe, it must be send back to technical service immediately. Technical service may only be performed by the manufacturer (service@moeller-medical.com) or an authorized service provider.

Liposat® power configuration

Technical data

Article number	**00002274**
Dimensions of the device:	(WxHxD) 270 mm x 220 mm x 180 mm
Weight:	approx. 10 kg
Minimum operating life:	8 years
Electrical connection:	
Mains voltage:	100 – 240 VAC (alternating current)
Mains frequency:	50 – 60 Hz
Current use:	0,85 – 0.37 A
Protection class:	I
Applied part B:	Tube set for tumescence infiltration ***Liposat® power*** REF-Nr.: 00002251
General characteristics:	
Permissible operating conditions:	
Temperature:	+10°C to +40°C
Humidity:	30 to 75% relative humidity
Permissible transportation and storage conditions:	
Temperature:	-10°C to +50°C
Humidity:	Less than 90% relative humidity
Protection:	IP 30
Flow rate range of the pump:	40 ml/min to 300 ml/min (variable adjustment)
Pumping precision:	± 15%
Disposal:	The device has a lithium battery, which must be disposed separately at the end of the life of the device

General safety instructions

Obligations to the operator

The operator takes responsibility for the proper operation of the medical device. The Ordinance on operation places a number of obligations on the user and responsibility as part of his activity in using medical devices.

The device should be used only by medically trained professionals and by personnel trained to use the device. Read the IFU of all system components thoroughly and completely before using.

Follow the IFU and pay attention to the warnings before use.

Make yourself familiar with all system components.

If you have no experience with similar products and / or need training, contact the manufacturer or its sales representatives in order to arrange for a training session. The manufacturer publishes information about licensed sales agents around the world.

The device should not be operated with electrical supply networks that have questionable earth connections. The mains voltage must correspond to the information on the identification plate. No liquids should get into the electrical parts. Unplug the device plug before cleaning.

The plug connections to the ***Liposat® power*** (mains cable, foot switch, heating dishes) should be plugged in or unplugged only when the device is turned off.

Only the original parts that are supplied should be used.

The heating dishes (accessory) for the sodium chloride package should be reviewed for mechanical damage before each use. If the sodium chloride package is preheated, the user should make sure that the temperature of the sodium chloride solution does not exceed 38°C. The temperature sensor of the heating dishes gives the temperature of the sodium chloride package. This must be inserted in the heating dish at least 5 minutes before use. If the temperature sensors record a temperature greater than 38°C, the pump will turn off and the notice **"Bag too hot"** will appear in the display.

No other objects should be attached between the heating dish and the sodium chloride package, since these could prevent from a correct recording of the temperature by the sensors.

The heating dishes serve to hold the sodium chloride packages at the proper temperature of approximately 38°C.

The heating dishes do **not** heat up the sodium chloride package from lower temperature level.

Liposat® power configuration

The sodium chloride package must always lie with its surface solidly on the temperature sensor.

The user must decide whether monitoring the body temperature of the patient is necessary and at what intervals that should occur in order to avoid any medical risks (hypothermia, hyperthermia, etc.).

A maximum of two heating dishes (accessories) may be attached to the ***Liposat® power*** tumescence pump.

The ***Liposat® power*** can be used either standing up straight (e.g., on a table) or hanging on the surgical suction device ***Vacusat® power*** (a product of Möller Medical GmbH).

If using this latter device combination, one should assemble the fasting hooks set on the back side of the ***Liposat® power*** using the screws that are supplied.

The manufacturer can consider itself responsible for the safety, reliability and usability of the device only if:

- assembly, expansions, new settings, changes or repairs are done only by authorised persons who have the necessary professional knowledge, and
- the electrical installation of the room in question corresponds to requirements, and
- the device is used according to the instructions for use, which is a part of the product, and
- the personnel who operate the product meet the given, pertinent requirements, such as those regarding medical qualification.

The operator should dispose the device according to currently applicable rules and standards.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

General safety instructions

Explanation of the safety symbols that are used

Important notices are specially marked off in this instructions for use. These notices are a condition for preventing dangers to the patient and the service personnel as well as to avoid damage to the product or functional disturbances.

Caution

Information

Typ B applied part

“ON” (power)

“OFF” (power)

Start-stop button

Reset button for infiltrated volume and infiltration time

Down button for the reduction of the infiltration speed and volume

Up button for the increase of the infiltration speed and volume

Alternating current

Return and disposal according to WEEE Directive

Consult instructions for use

Liposat® power configuration

	Serial number
	Catalog number
	Batch code
	Use by YYYY-MM-DD
	Sterilised using ethylene oxide
	Do not re-use
	Do not resterilise
	Manufacturer
	Do not use if package is damaged
	Contains or presence of phthalates
	Stacking limit, do not store more than 3 packs high
	Attention: Under US Federal law, this device may be only sold to a physician or ordered by a physician.

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

General safety instructions

One-time use

Reuse of one-time use articles carries the potential risk of infection for the patient or the user. Contaminated articles can lead to injuries, illness or death of the patient. Cleaning, disinfection and sterilisation can damage important material characteristics and product parameters in a way that leads to the breakdown of the product.

Warnings

- Use of this product does not automatically lead to significant loss of weight.
- Use of this product must occur with special care. Chronic diseases of the patient (e.g., diabetes, heart disease, vascular disease, lung disease, obesity), the status of the tissue, the use of medications, blood coagulation, wound healing and the age of the patient all affect the outcome and must be taken into consideration.
- Loss of body materials (blood, lymph, tissue fluid, etc.) can occur through intra-operative or post-operative use of the product and may negatively affect the patient's haemodynamic situation. A substitution of body materials is therefore to be considered by the user.

Precautions

- This product should be used only by doctors experienced in human medicine who have sufficient experience in lipoplasty.
- Factors that may affect the success of the operation and subsequent results depend on the level of experience of the operator, the possible combination with other products and the prevailing hygienic conditions.
- Results of the operation may change over time and are not necessarily permanent.
- All reusable parts of the product must be sterilised. All parts that are not reusable must be changed before use on the next patient.

Transport

The following safety points must absolutely be followed when transporting the device. Damage to the device and other material damage can thereby be avoided.

- Absolutely follow the transport instructions on the package.
- Follow the prescribed storage conditions.
- Follow the prescribed maximum storage height.
- Parts that are piled too high may fall over or be damaged.

Dimensions, weight, and transport instructions

Dimensions of the ***Liposat® power*** with packaging:	(LxWxH) = 390 mm x 330 mm x 335 mm
Weight:	approx. 12 kg
Transport and storage conditions	
Temperature:	-10°C to +50°C
Humidity:	Less than 90% relative humidity

A maximum of 3 cartons may be piled on one another during transport.

The outer packaging consists of a corrugated cardboard folding carton. The packaging inner parts are made of PE foam.

A danger of fire exists because of the easily flammable packaging material. Use no open fire and do not smoke!

For any possible service, it is recommended that you save the packaging. Do not throw it away. Use it for any shipment. Product damage may occur during transportation in improper containers or by inappropriate packaging. The sender has the responsibility for proper packaging.

Assembly and start-up

Make sure that the package has been delivered to you undamaged. Immediately report any transportation damage to the shipper.

Unpacking the device and checking the content of the delivery

The delivery of the *Liposat® power* always consists of a cardboard box.

When unpacking the ***Liposat® power***, make sure that no parts remain in the package.

The following are part of the delivery: (one piece each)

- ***Liposat® power***
- Mains cable
- Instructions for use in “German”
- Instructions for use in "English"
- Fastening hooks for the device combination with the ***Vacusat® power*** (Möller Medical GmbH), including fastening screws

Additional equipment that is not part of the scope of delivery of the device

Additional equipment attached to the analogue and digital interfaces of the device must give evidence of their corresponding EN specifications (e.g., EN 60950 data processing devices and EN 60601 for electro medical devices).

In addition, all configurations must conform to the current version of system standard EN 60601-1.

The person who attaches additional devices is the one configuring the system and is therefore responsible for the maintenance of the current version of the system standard EN 60601-1.

For further questions, contact the manufacturer.

(MDD: 13.6.c, IEC 60601-1: 16)

Liposat® power configuration

Suitable operating environments

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

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

The ***Liposat® power*** is not approved for use in aircrafts or military applications. The appropriate EMC requirements for these environments have not been tested.

Application for defibrillation and electrosurgical devices

It is not permitted to use the ***Liposat® power*** together with electrosurgical devices.

Assembly and start-up

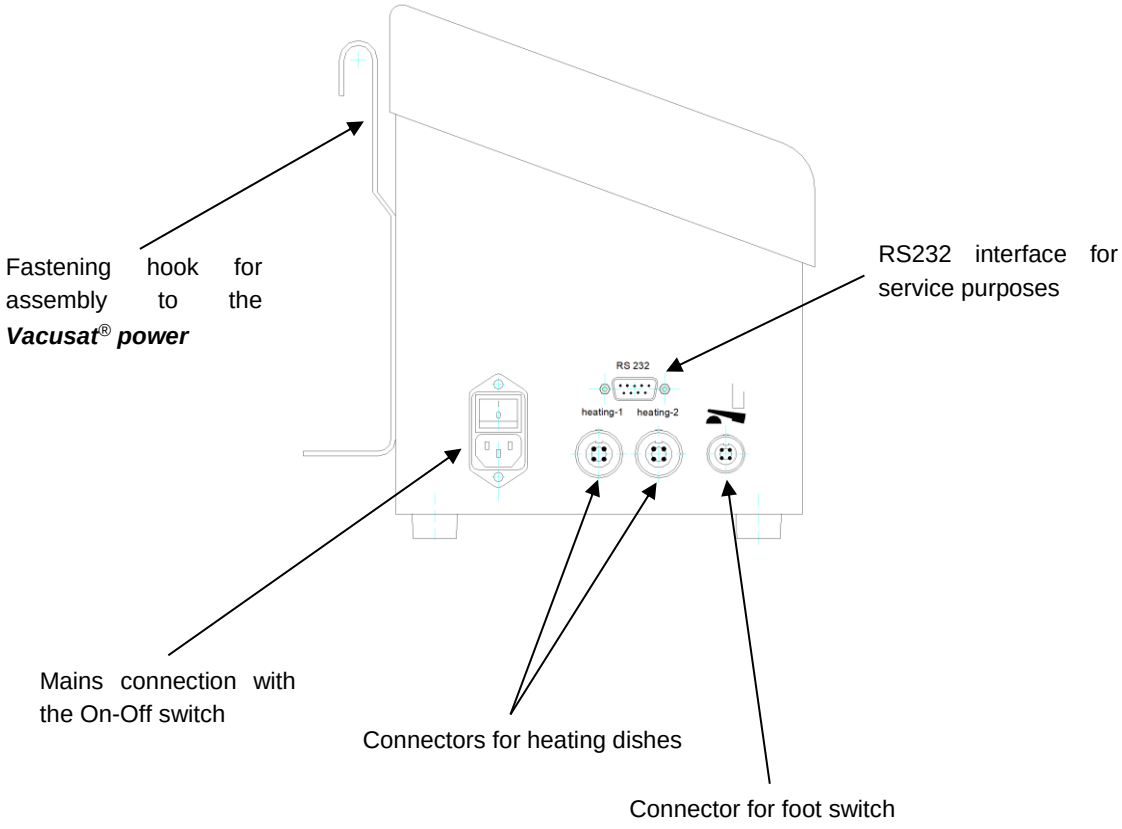
Starting up the Liposat® power

When installing the ***Liposat® power***, ensure that:

- a sufficient distance from other devices is maintained. The ***Liposat® power*** requires a space of at least 30 cm in height and width.
- the device can be turned off via the ON/OFF switch and disconnected from the mains by unplugging the mains cable.
- the ***Liposat® power*** is not operated in the direct proximity of or stacked with other devices, as this may result in faulty operation. If operation as described above cannot be avoided, monitor the ***Liposat® power*** and other devices to verify specified normal use.

When using as a tabletop device, proceed in the following prescribed order:

- Take the ***Liposat® power*** tumescence pump out of its packaging and place it on an appropriate sturdy location.
- Connect the supplied mains cable on the housing side of the device and plug the plug into a socket with an attached earth conductor. Follow the electricity values given on the identification plate of the device.
- The device is ready for operation when the mains switch is turned on to position I.



Liposat® power configuration

When setting up the **device combination** with the ***Vacusat® power*** surgical suction device, please proceed in the given order:

- Take the ***Liposat® power*** tumescence pump out of its packaging and place it on an appropriate sturdy location.
- Screw the 2 fastening hooks into the back side of the ***Liposat® power*** tumescence pump with the 4 fastening screws (raised flathead screw with M5x8 hexagon socket).
- Hang the ***Liposat® power*** tumescence pump on the upper hanging rail of the ***Vacusat® power*** surgical suction device using the screwed-in fastening hooks.
- Connect the supplied mains cable to the housing side of the device and plug the plug into a socket with an attached earth conductor. Follow the electricity values given on the identification plate of the device.
- The device is ready for operation when the mains switch is turned on to position I.

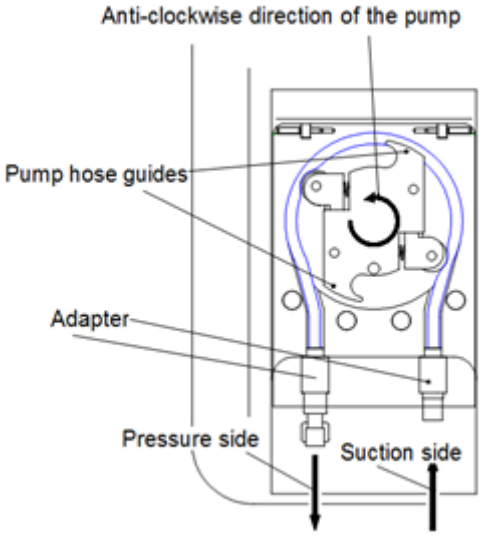
Image:

Liposat® power tumescence pump as a combination with the ***Vacusat® power*** surgical suction device and 2 heating dishes (accessories).

Assembly and start-up

The **"*Liposat® power*"** tumescence pump should be used only with the sterile tube set from Möller Medical, **"*Liposat® power* tube set for tumescence infiltration - REF 00002251".**

In order to push the sodium chloride solution through the tube system, the tube must be inserted into the pump. Proceed as follows for this procedure:



1. **Ensure that the pump turns counter-clockwise.** The turning direction of the pump corresponds to the pump direction of the sodium chloride solution.
2. Then open the front panel of the pump. The pump will be automatically stopped by a safety cut-off. The notice **"Door opened!"** will appear in the display.
3. Insert the adapter of the suction side (Afferent tube) of the pump (see the illustration).
4. Turn the pump rotor by hand counter-clockwise. The tube will be loaded into the pump.
5. Fixate the tube by fitting the Adapter into its corresponding fixture (see illustration).
6. Now insert the spike into the sodium chloride package.
7. With the LuerLock connector, connect the connection hose on the pressure side (Efferent tube) of the pump to the pump hose.
8. Connect the free ends of the connecting hase with the stopcock or a cannula.
9. Close the front panel of the pump. The display indicator **"Door opened!"** disappears.
10. The pump is now ready for operation and can pump the sodium chloride solution.

Once again observe the use description for the ***Liposat® power*** starting on page 8.

Alarms and service personnel

Alarm conditions

Alarm 1: Rotor cover opened

Physiological alarm condition	None
Technical alarm condition	Opening sensor of the cover activated
Alarm limit	None
Alarm delay	< 1 s
Alarm signal delay	< 1 s
Alarm signal	Visible
Alarm signal description in the display	Door opened!
Audio pause	None

Alarm 2: Package temperature too hot

Physiological alarm condition	None
Technical alarm condition	Temperature sensor reports greater than 43.0°C for the package with the tumescence solution
Alarm limit	43.0°C
Alarm delay	1 s
Alarm signal delay	< 1 s
Alarm signal	Audible/visible
Alarm signal description in the display	Bag too hot!
Audio pause	None

Workplaces of the service personnel

Any handling of the device assumes exact knowledge of this instruction for use and conformity with it.
This instruction for use does not replace instructions from the user.
Use of the device is authorised only for professional personnel.

Assistance with problems

The Liposat® power should not be opened by the user!

The user should not use any tool to work on the product!

In this chapter possible operating disturbances will be dealt with that might occur with the *Liposat® power* tumescence pump.

Several possibilities for solutions are given for each problem. The suggestion given first is usually the most obvious.
If the problem is not solved by the initial solution suggestion, the suggestions should be worked through in the given order until the problem is fixed.
The ***Liposat® power*** must always be turned off when disconnecting or connecting the connectors.

If the problems cannot be solved by the solutions described here, contact the service department of the manufacturer service@moeller-medical.com or one of the specialized dealers authorized by the manufacturer.

Problem	Solution
No function, the display remains off.	The ***Liposat® power*** tumescence pump is not plugged in or is incorrectly connected to the power supply. Check the power supply, possibly switch on multible socket, check the feeds, and check the building fuse.
The pump does not turn.	The front panel of the pump is open. Pay attention to the display **"Door opened!"** in the display panel. Close the front panel and restart the pump by pressing the Start/Stop button or the foot switch.
The foot switch does not react.	The connecting cable of the foot switch is not connected.

Liposat® power configuration

Set amount does not correspond to the actually delivered amount.	The set amount is recorded and evaluated through the proportional revolution speed of the pump. If the set amount does not correspond to the requested amount, this may be caused by one of the following: • The tube is squeezed or pinched. • The valves are not open correctly (e.g., distributor 3-way tap). • The spike is not correctly inserted in the package for tumescence solution. • The package with tumescence solution is empty. • The pump is equipped with an additional safety function that prevents the burst of the tube system. With inner pressure of >2.5 bar in the tube, the spring-loaded rollers of the pump motor open, and as a result there is no further build-up of pressure in the tube system.
Moisture has penetrated into the mains plug.	**Remove the plug from the device and from the socket. Let the plug dry out.**
If these steps are not successful, the device must be checked technically. For this purpose, contact the manufacturer or a specialist dealer authorized by it.	

Service station

If these steps are not successful, the device must be technically checked. For this purpose, contact the manufacturer or a specialist dealer authorised by it.

Before disposal or return of the ***Liposat® power***, an appropriate disinfection procedure must rule out any possible risk of infection.

Consumables are accordingly to be disposed of according to hygiene guidelines.

Service note

<u>Never</u> open the device while it is connected to the electricity network.

Attention: Even then internal parts of the device may be conducting electricity.

Servicestation of Möller Medical GmbH

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Cleaning and care

Cleaning and disinfection

No humidity must be allowed to enter into the device.

Before cleaning and disinfecting the device surfaces, disconnect the mains plug. Use a lint-free, soft cloth for cleaning and disinfecting.

The device is cleaned with a wet cloth in the form of a "scour-wipe-disinfection". Dipping or spraying the device may cause hazards.

Cleaning shall be carried out with a dampened cloth with mild soap solution or 70% solvent isopropanol.

After cleaning disinfect the surfaces of ***Liposat® power*** with a pH neutral approved disinfectant on detergence-alcohol-basis with up to 70% alcohol (e.g. Propan-1-ol, recommended disinfectant: Meliseptol®). During disinfection, do always follow the instructions of the disinfectant manufacturer.

Ensure that the cleaning and disinfecting agents have evaporated before using the ***Liposat® power*** in an application.

Visual check: The sockets of all connections and cable plugs must be free of all dirt and moisture.

Maintenance

Upon reach of the STC date you will be informed by the ***Liposat® power*** device itself during the booting process.

Repairs, upgrades or changes of the ***Liposat® power*** may only be performed by Möller Medical GmbH or a company specifically authorized by the manufacturer. In the latter case, the work performed must be documented, signed and dated. Changes to the device by third parties are not permitted. A technical safety check must be performed at least every 12 months. Use the ***Liposat® power*** only if the device is functionally and/or operationally safe. If this is not the case, have it immediately serviced.

Cleaning and care

Disposal

The present device contains material which must be disposed in accordance with environmental regulations. This device is subject to the European Directive 2012/19/EU on Waste Electric and Electronic Equipment (WEEE2). The identification plate of the device bears the symbol of the crossed through garbage bin.

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

Accessories and consumables

- **Heating dishes for *Liposat® power***

  Order no.: 00002542

  (Two items with attachment kit

  for ***Vacusat® power***)

  Dimensions of the heating dishes

  with packaging:
  (L x W x H) 540 mm x 300 mm x 300 mm

  Weight: approx. 4.8 kg

- **Electrical foot switch (2 m cable)**

  with start / stop function

  Order no.: 93003545

- **Electrical foot switch (5 m cable)**

  with start / stop function

  Order no.: 00003982

- **Sterile tube set**

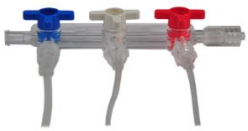
  ***Liposat®* tube set for tumescence infiltration**

  Order no.: 00002251

  (10 items per box)

- **3-way tap (sterile)**

  Order no.: 00002278



Electromagnetic compatibility

Electromagnetic emissions

The ***Liposat® power*** is suitable for use in the stated electromagnetic environment. Customers and/or operators of the ***Liposat® power*** should ensure that they use the ***Liposat® power*** in such an environment.

Measurement of emitted interference	**Level of conformity**	**Electromagnetic environment guidelines**
High-frequency radiated interference as per CISPR 11	Group 1	To satisfy its intended function, the ***Liposat® power*** must emit electromagnetic energy. Electronic devices in the vicinity could be influenced.
High-frequency line-conducted interference as per CISPR 11	Class B	For areas of application, see chapter „*Suitable operating environments*".
Harmonic emissions acc. to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions acc. to IEC 61000-3-3	Complies	

Electromagnetic immunity

Immunity test / standard	**IEC 60601 - testing level**	**Compliance level**	**Electromagnetic environment guidelines**
Electrostatic 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 made of wood or concrete or fitted with ceramic tiles. If the floor is provided with a synthetic material, relative humidity must be at least 30%.
Rapid transient electrical 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 andoutput lines	The quality of the supply voltage should be comparable to that for a typical shop or hospital environment.

Liposat® power configuration

Immunity test / standard	IEC 60601 - testing level	Compliance level	Electromagnetic environment guidelines
Surges IEC 61000-4-5	±1 kV differential mode voltage ±2 kV common mode	±1 kV differential mode voltage ±2 kV common mode	The quality of the supply voltage should be comparable to that for a typical shop or hospital environment.
Voltage dips, short interruptions and voltage variations IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 1/2 period 40 % UT (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 UT) for 5 seconds	< 5 % U_T (> 95 % dip in U_T) for 1/2 period 40 % UT (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 UT) for 5 seconds	The quality of the supply voltage should be comparable to that for a typical shop or hospital environment. We recommend an uninterrupted power supply or battery for operators of the product demanding continuous function even during an interrupted power supply.
Magnetic field in power supply frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 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 alternating mains voltage prior to the application of the testing level.			

The ***Liposat® power*** meets all test levels according to 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 ***Liposat® power*** indicated by the manufacturer. Non-observance may result in a reduction of the device's performance.

Operation of the ***Liposat® power*** with additional accessories such as transducers or cables, which 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.

Electromagnetic compatibility

<table>
<tr><th>Immunity test / standard</th><th>IEC 60601 - testing level</th><th>Compliance level</th><th>Electromagnetic environment guidelines</th></tr>
<tr><td>Conducted HF disturbances in accordance with IEC 61000-4-6</td><td>3 Veff
150 kHz to
30 MHz

6 Veff in ISM and amateur radio frequency bands between 150 kHz and 80 MHz</td><td>3 Veff

6 Veff</td><td rowspan="2">Portable and mobile radio transmitting devices, including the cables, should be used in proximity of the Liposat® power within 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
with P as nominal transmitter power in Watt (W) according to transmitter manufacturer stipulations and d as recommended safety distance in meters (m).
According to an on-site[a)] examination, the field intensity of stationary radio transmitters ought to be lower than the compliance level[b)].
Disturbances may occur in the environment of devices carrying the following symbol.
  </td></tr>
<tr><td>Radiated HF disturbance value acc. to IEC 61000-4-3</td><td>3 V/m
80 MHz to
2,7 GHz

Table 9 of IEC 60601-1-2 Ed. 4</td><td>3 V/m
80 MHz to
2,7 GHz

Table 9 of IEC 60601-1-2 Ed. 4</td></tr>
<tr><td colspan="4">Note:
NOTE 1: The higher frequency range applies to 80 MHz and 800 MHz.
NOTE 2: These guidelines may not be applicable to all cases. The diffusion of nominal electromagnetic factors is influenced by absorption and reflection of buildings, objects and people.</td></tr>
<tr><td colspan="4">a) The field strength of stationary emitters, such as base stations for mobile phones and mobile terrestrial radio systems, amateur radio stations, AM and FM radio and television emitters, cannot be theoretically accurately predicted. To determine the electromagnetic environment in terms of the stationary emitters, a study of the site should be considered. If the measured field strength in the location in which the Liposat® power is used exceeds the applicable RF compliance level above, the Liposat® power should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Liposat® power.
b) Above the frequency range of 150 kHz to 80 MHz the field strength should be lower than 3 V/m.</td></tr>
</table>

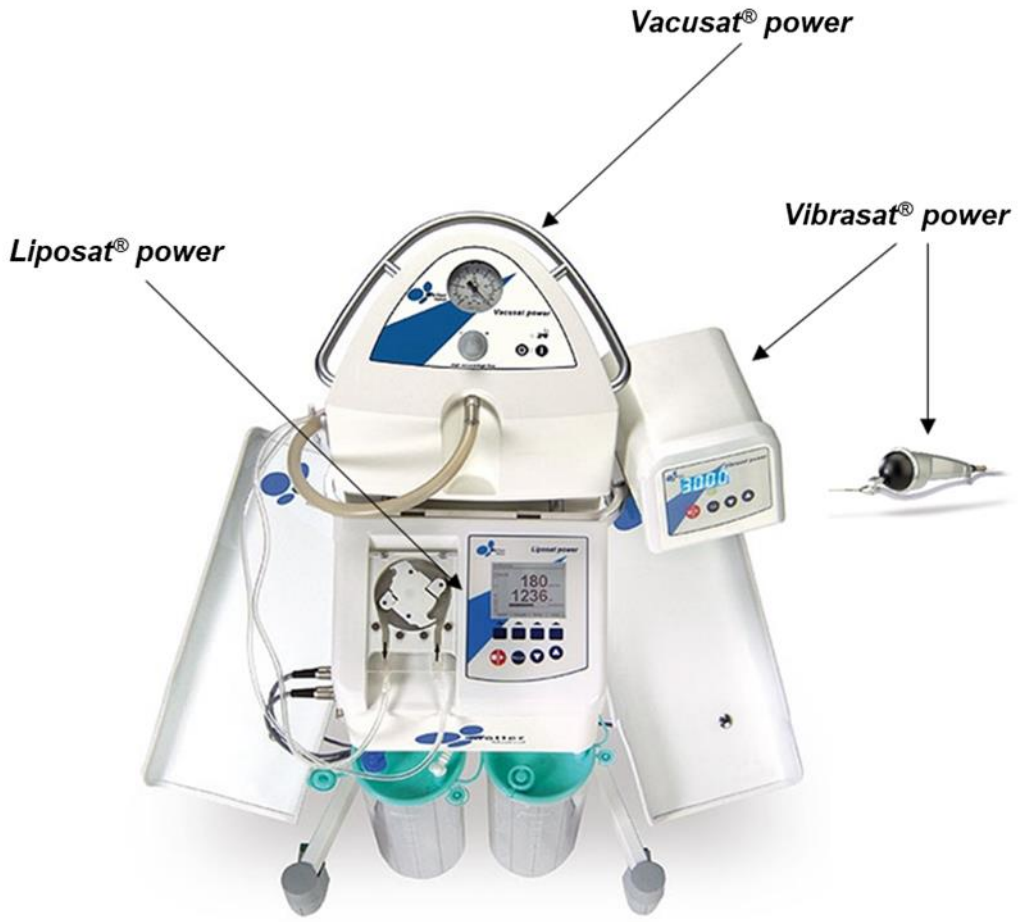
Recommended safety distances

See chapter "*Electromagnetic immunity* ".

Liposat® power configuration

***Liposat® power* configuration** is the complete medical system for local anesthesia with tumescent solution, consisting of:

- ***Liposat® power –*** medical infiltration pump for tumescence solution
- ***Vacusat® power –*** medical suction device
- ***Vibrasat® power –*** medical vibration drive system for Power Assisted Liposuction with corresponding liposuction cannulas and disposables.



Revision 2021-02 T

Software version 019.01.05

CE 0482

Order number for
Instructions for use
(REF) 20007191

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