en

INSTRUCTIONS FOR USE

Liposat® Pro
Liposat® Pro plus

MÖLLER

IMPORTANT

READ CAREFULLY BEFORE USE

KEEP THESE INSTRUCTIONS FOR FUTURE CONSULTATION

Contents

Contents

1 General safety information

1.1 Explanation of the safety symbols used

Important information is indicated visually in these instructions for use. This information is a prerequisite for preventing hazards to patients and operating personnel, as well as for avoiding damages or malfunctioning of the device.

1.1.1 Symbols in the instructions for use

	Caution
	Information or help
	Non-ionising electromagnetic radiation

1.1.2 Symbols on the device

	Consult instructions for use
	Article number
	Medical device
	Unique identifier of a medical device
	Serial number (the first 4 digits indicate the year and month of manufacture in YYMM format)
	Manufacturer
	Alternating current
	Return and disposal as per the WEEE Directive
	Compliant with ANSI/AAMI ES 60601-1 CAN/CSA 22.2 No. 60601-1-6A:11 CAN/CSA 22.2 No. 60601-1:14

	Standby switch
	Standby switched on
	Standby switched off
	Input / Output (for energy and signals)
	USB host
	Applied part Type B
	Footswitch
	Direction of rotation: clockwise

1.1.3 Symbols in the screen

	Accept / Confirm
	Reject
	Back
	Plus (add / increase)
	Minus (minus / decrease)
	Target volume
	Start
	Prime (Rinse)
	Reset
	Reset to factory settings

General safety information

	Rotor signal
	No rotor signal
	No rotor function
	Inserting the tubing set
	Front panel open
	Main menu
	Rotate screen
	Service menu
	Volume / sound
	Deactivate sound
	Sound by pressing a button
	Signal volume on starting and stopping the pump
	Brightness
	Fault / error
	Device information
	Existing connection

1.1.4 Additional symbols on the retail packaging


Packaging unit

Production lot number, batch


Expiry date (YYYY-MM-DD)


Date of manufacture (YYYY-MM-DD)


Sales partner


Store away from sunlight


Store in a dry place


Air humidity limitation


Temperature limitation

Stacking limit, do not store more than 3 packs high


Do not use if package is damaged


Do not reuse

Do not resterilise


Single sterile barrier system


Double sterile barrier system

Single sterile barrier system with protective outer packaging

Single sterile barrier system with protective inner packaging

Sterilised using ethylene oxide

Contains or presence of phthalates

Attention: Under US Federal law, this device may be only sold to a physician or 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 format conventions used

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

Font	Use
Bold	Buttons (e.g. in instructions)
Italics	References to chapters, figures and tables

Table 1:
Use of fonts

1.3 Manufacturer’s responsibility

The manufacturer may only be regarded as responsible for the safety, reliability and suitability for use of the devices if:

- Assembly, upgrades, recalibrations, modifications or repairs are performed only by individuals authorised by the manufacturer.
- The electrical installation in the room in question complies with the applicable requirements and regulations (e.g. VDE 0100, VDE 0107 or IEC specifications).
- The devices are used in accordance with the instructions for use and the country-specific regulations and national deviations are observed.
- The conditions stated in the technical data are observed.

Any type of use other than that described in these instructions for use is not permitted and will lead to the exclusion of liability and the loss of warranty.
The manufacturer undertakes to accept old devices as per the German Electrical and Electronic Device Act (ElektroG).

1.4 Operator's duty of care

The operator is responsible for the proper operation of the medical devices. In line with the German Medical Device Operator Ordinance (MPBetreibV), the user must perform a wide range of duties and also assume responsibility when handling medical devices within the framework of his activities. Only qualified personnel may operate the Liposat® Pro devices.
Precise knowledge and compliance with these instructions for use is a prerequisite whenever the Liposat® Pro devices are used. The devices may only be operated by persons with the necessary training or knowledge and experience.

The Liposat® Pro devices are 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.

Performance and safety may be compromised if Original Equipment Manufacturer device parts are not used.
All work that requires tools must be performed by the manufacturer's technical service or parties authorised by the latter.
The user must decide whether the patient’s body temperature is to be monitored and at what intervals in order to avoid medical risks for example (hypothermia, hyperthermia etc.).

All serious incidents which occur in connection with the product are to 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 devices must not be modified.
- No liquids must be allowed to penetrate the current-conducting parts of the devices.
- Disconnect the power cable before cleaning.
- When cleaning, ensure that no cleaning agent runs into the connector sockets.
- Replace connecting cables of all kinds even if they are only slightly damaged; make sure not to roll 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.
- When removing plugs, do not pull on the cables. To remove, release the plug lock if necessary.
- Do not expose the devices to intense heat or fire.
- Do not subject the devices to hard impact.
- If heat, fumes or smoke appear, disconnect the devices from the mains immediately.
- In order to prevent damage, do not use the surfaces of the Liposat® Pro as storage places.

1.6 Non-product-related additional equipment

Additional equipment which does not belong to the devices' scope of supply and which are connected to the devices' analogue and digital interfaces must be shown to satisfy the relevant EN specifications (e.g. EN 60601 for electromedical devices). Any operator connecting additional devices is the system configurator and is thus responsible for ensuring that the valid version of the system requirements as per the standard IEC 60601-1 is observed.

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

1.7 Single use

Re-use of single-use devices creates a potential risk of infection for the patient and/or operator. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection and sterilisation may compromise essential material properties and product parameters leading to device failure.

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

1.8 Declaration on DEHP

The Liposat® Pro devices do not contain di(2-ethylhexyl) or phthalates (DEHP).

1.9 Precautionary measures

- The application results vary depending on the patient's age, site of intervention and the surgeon's experience. The application results may or may not be permanent.
- Clean all reusable components of the device according to the reprocessing instructions.
- Replace all disposable components before using the device on another patient.

Risk of infection from unsuitable aids

- Always wear your personal protective equipment. Personal protective equipment, which must be worn for all steps in which product components are contaminated, comprises: Protective gloves, protective clothing, protective glasses, mouth and nose protection.
- The Liposat® Pro devices serve to infiltrate liquids into the patient's body. Make sure only suitable liquids are used and that the solution to be infiltrated cannot be contaminated.
- Only ever perform infiltration in a sterile environment.
- The general transport conditions in your facility must be observed without fail.

1.10 Target group (users)

The Liposat® Pro devices are reserved for use by doctors who can demonstrate that they have the necessary expertise through the relevant specialist training or approved, specialist further training.

2 Intended use

2.1 Proper use

2.1.1 Intended use of the Liposat® Pro

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

The peristaltic pump Liposat® Pro may only be used with the tubing set TLA Tubing Liposat® Pro/ power from Möller Medical.

2.1.2 Intended use of the Liposat® Pro plus

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

The peristaltic pump Liposat® Pro plus may only be used with the tubing sets TLA Tubing Liposat® Pro plus and FAT Tubing Liposat® Pro plus from Möller Medical.

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

- Volume losses (blood, lymph, tissue fluid etc.) can occur intra- and postoperatively with use of this product and may negatively affect the patient's haemodynamic situation. Volume substitution must thus be considered by the user.
- Vascular injuries
- Nerve injuries
- Tissue injuries
- Organ injuries
- Death

2.4 Essential performance features

The Liposat® Pro devices have 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

3.1 Design

Figure 3:
Front view Liposat® Pro

Figure 3:
Front view Liposat® Pro plus

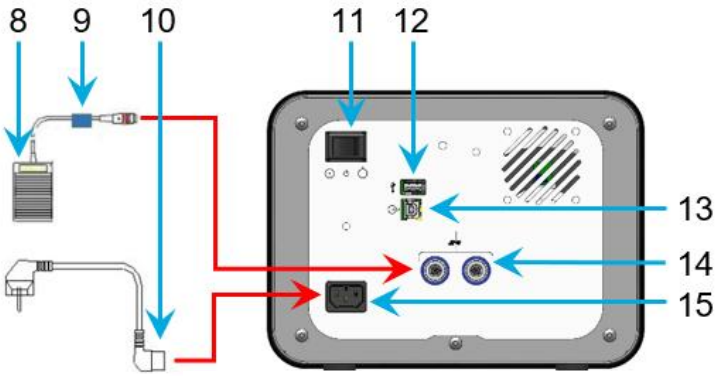


Figure 3:
Back view Liposat® Pro/Pro plus

No.	Name	No.	Name
1	Front panel	8	Footswitch
2	Rotor	9	Cable marker, blue
3	Threading loop	10	Mains cable
4	Direction of rotation (clockwise)	11	Standby switch
5	Screen	12	USB socket, service interface
6	Tube clamp	13	USB socket
7	Button for removing the rotor (only for the Liposat® Pro plus)	14	Connection sockets for footswitch
		15	Mains input socket

3.2 Liposat® Pro devices

3.2.1 Liposat® Pro

The Liposat® Pro assists you with the infiltration of sterile liquids such as TLA solutions into patients.

3.2.2 Liposat® Pro plus

The Liposat® Pro assists you with the infiltration of endogenous tissues and sterile liquids such as TLA solutions into patients.

3.3 Footswitch

You can connect two footswitches at the same time to the Liposat® Pro/Pro plus**.** Both connection sockets on the rear are equal and the footswitches behave identically. The connection socket for the footswitch has a blue ring marking. Attach the blue cable marker to the footswitch cable for secure identification of correct positioning.

When inserting the footswitch, make sure that the notch on the plug points upwards and thus fits into the socket. Assembly the other way around causes the devices to malfunction.

You can use the other cable markings to colour-code the footswitches of the other Möller Medical devices so that you can tell them apart more easily.
The Liposat®/Vibrasat® footswitch (1-pedal) is included in the scope of delivery.
The Liposat®/Vibrasat® footswitch (3-pedal) is optionally available as an accessory.

Liposat®/Vibrasat® footswitch (1-pedal)

Figure 4:
Liposat®/Vibrasat® footswitch (1-pedal)

The Liposat® Pro/Pro plus can be started and stopped by pressing the **On/Off button**.

Liposat®/Vibrasat® footswitch (3-pedal)

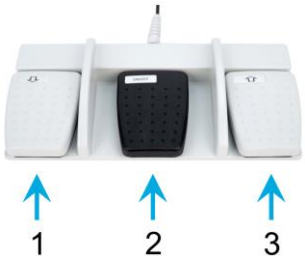


Figure 5:
Liposat®/Vibrasat® footswitch (3-pedal)

No.	Designation
1	Down button
2	On/Off button
3	Up button

Table 2:
Symbols for inserting the tubing set

By pressing the middle button (On/Off button) of the footswitch, the pump can be started and stopped. The outer buttons change the flow rate (Up/Down button).

3.4 Tubing sets

Prior to each new application, insert a new, sterile tubing set in order to avoid patient infections for example *(Section 4.5.1).*

4 Setup and commissioning

4.1 Transport and storage information

The following safety information must be observed when transporting the devices. This prevents damage to the devices and other property.

- Make sure that the box is not damaged on delivery to you.
- The forwarding agent must be notified immediately of any transport damage.
- Check all products for damage.
- Damaged products must not be used.
- Please contact your supplier immediately.

4.2 Unpacking the device and checking the delivered items

The Liposat® Pro/Pro plus is delivered in 2 packaging units. Remove all parts from the packaging.
The standard version of the Liposat® Pro/Pro plus includes the following scope of delivery:

Packaging unit 1

1x	Liposat® Pro or Liposat® Pro plus
1x	Mains cable
1x	Cable marking set
1x	USB port blocker with unlocking key
	Instructions for use

Packaging unit 2

1x	Liposat®/Vibrasat® footswitch (1-pedal)
	Instructions for use

- Do not dispose of the original packaging.
- Only send the devices in their original packaging to prevent damage during transportation.

4.3 Suitable operating environment

The Liposat® Pro/Pro plus are 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® Pro/Pro plus are not approved for use in aeroplanes and military areas. The appropriate EMC requirements for these environments have not been tested.

4.4 Use with defibrillation and RF surgical devices

- If the Liposat® Pro/Pro plus were subject to temperature and humidity fluctuations during transportation or other changes in location, the devices must be allowed to acclimatise in the operating environment for at least 2 hours before being put into service.
- Before commissioning, the Liposat® Pro/Pro plus must be processed as per the hygiene guidelines *(see chapter 6.1).*

Pay attention to the following when setting up the Liposat® Pro/Pro plus:

- Sufficient distance to other units is maintained. The devices require a space of at least 30 cm in height and width.
- The device can easily be turned off via the standby switch and disconnected from the mains by unplugging the mains cable.
- The devices must not be 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® Pro/Pro plus and other devices to verify proper use.

4.5 Setting up the Liposat® Pro/Pro plus

Prepare the Liposat® Pro/Pro plus prior to initial use as per the instructions for use *(see chapter 6.1)*.

1. Remove the corresponding unit from the packaging.
2. Place the unit on a firm and level surface.
3. Connect the supplied mains cable to the rear panel.
4. Insert the mains plug into a socket with a connected protective earth conductor.
5. Note the voltage values given on the device's rating plate.
6. Switch on the unit using the standby switch.
7. The unit is now ready for operation.

4.5.1 Inserting the tube sets

- Prior to each new application, insert a new, sterile tubing set in order to avoid patient infections for example.
- Before using the original and undamaged tubing, check the expiry date.
- Remove the tubing set properly from the sterile packaging.
- Make sure that all tubes are free, not squashed and not rolled up too tightly.

Note that the pumps rotate clockwise. This is important for the correct insertion of the tubing sets.

Explanation of symbols used	
	Rotor signal
	Inserting the tubing set
	Front panel open
	Direction of rotation: clockwise

Table 3:
Symbols for tubing insertion

When threading the tubing, you have 2 options:

- Press and hold the button **Insert tube set** on the screen.
- Guide the rotor manually with the direction of rotation (clockwise).

4.5.1.1 Insert TLA Tubing Liposat® Pro/power (Liposat® Pro)

The tumescent pump “Liposat® Pro” may **only** be used with the following tubing set:

"TLA Tubing Liposat® Pro/power" REF 00002251

Correct positioning of the tubing in the pump:
Left: Spike (connection for the infiltration medium)
Right: Luer (connection for the infiltration option)

Figure 6:
Open cover

- Open the front cover of the pump.
- The rotor automatically rotates into a suitable position for inserting the tubing set.

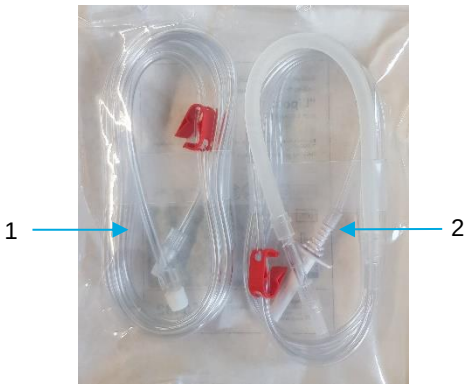


Figure 7:
Tubing set

- Remove the sterile tubing set with turbid pump segment (2) from the packaging.

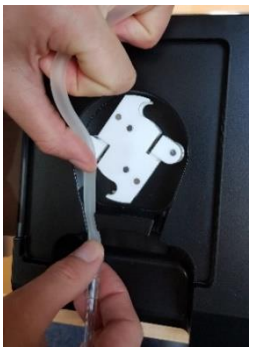


Figure 8:
Insert pump segment

- The spike is on the left side.
- Carefully press the left end of the pump segment into the left tube clamp until it clicks into place.

Figure 9:
Threading the pump segment

- Insert the tubing so that it can be optimally picked up by the rotor.
- Press and hold the **Insert tube set** button. The rotor turns and takes up the tubing set. Alternative: Turn the rotor to the right by hand.

Figure 10:
Insert pump segment

- Release the button when the tubing is threaded.
- Carefully press the remaining pump segment into the right-hand tube clamp until it clicks into place.

For TLA infiltration:

Figure 11:
Loosen cap

- Insert the spike of the tube set into the bag containing the infiltration medium.
- Loosen the cap of the Luer-Lock connector.

Figure 12:
Loosen cap

- Take tubing 1 (*Figure 7*).
- Loosen the cap of the Luer-Lock connector.

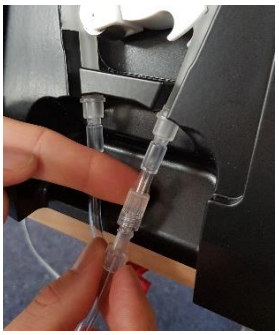


Figure 13:
Connect tubing 1 with 2

- Screw the two Luer-Lock connectors together.

Figure 14:
Done

- Close the front window.

  ➔ The tubing set is fully assembled.

Left: **Spike (infiltration medium)**
Right: **Luer (infiltration option)**

Infiltration routes with the TLA Tubing Liposat® Pro/power

Infiltration options	TLA infiltration
Sterican cannulas (with cock bank)	✓
Single TLA infiltration cannula on the vibrating handle with TLA Luer-Lock adapter	✓
Single TLA infiltration cannula on the manual handle with TLA Luer-Lock adapter	✓

Table 4:
Infiltration routes with the TLA Tubing Liposat® Pro/power

The user decides which infiltration option to use.

4.5.1.2 Inserting a tubing set in the Liposat® Pro plus

The tumescent pump “Liposat® Pro plus” may **only** be used with the following tubing sets:

TLA Tubing Liposat® Pro plus	REF 00003997
FAT Tubing Liposat® Pro plus	REF 00003948

A “FAT Tubing Liposat® Pro plus” (REF 00003948) was used for the following instructions.

4.5.1.2.1 Insert FAT Tubing Liposat® Pro plus (Liposat® Pro plus)

Figure 15:
Front view with open cover

- Open the front cover of the pump.
- The rotor automatically rotates into a suitable position for inserting the tubing set.

Figure 16:
Hose set for grease transfer

- Remove the sterile tube set from the packaging.

Figure 17:
Orientation

- The red funnel of the tubing is on the left side.
- Set the tubing length so that it can be connected to the infiltration container.

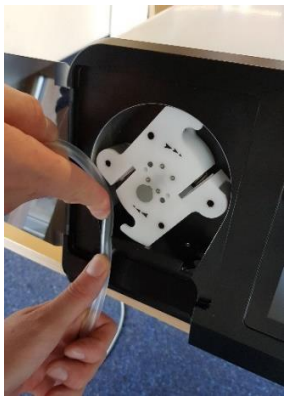


Figure 18:
Insertion

- Press the tubing set carefully into the left tube clamp until it clicks into place.

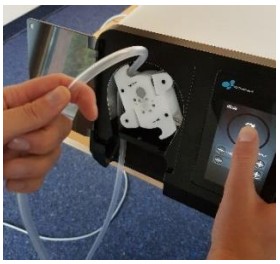


Figure 19:
Threading

- Insert the tubing so that it can be optimally picked up by the rotor.
- Press and hold the **Insert tube set** button. The rotor turns and takes up the tubing set.
  ➔ Alternative: Turn the rotor to the right by hand.

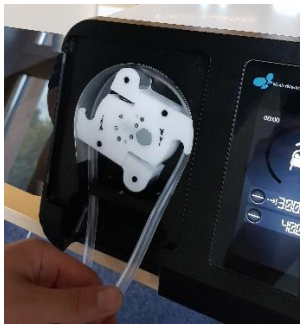


Figure 20:
Tubing set in clamp

- Release the button when the tubing is threaded.
- Carefully press the remaining tubing set into the right tube clamp until it clicks into place.

Figure 21:
Connect ends

- Connect the red funnel to the outlet of the sterile infiltration container.
- Connect the right end of the tubing to an infiltration option.
- Close the front window.

➔ The tubing set is fully assembled.

Left: **Red funnel (infiltration medium)**
Right: **Open end (infiltration option)**

Infiltration routes with the *FAT Tubing* Liposat® Pro plus

Infiltration options	FAT infiltration
Single infiltration cannula on vibrating handle	✓
Single infiltration cannula on manual handle	✓

Table 5:
Infiltration routes with the FAT Tubing Liposat® Pro plus

The user decides which infiltration option to use.

4.5.1.2.2 Insert TLA Tubing Liposat® Pro plus (Liposat® Pro plus)

A "TLA Tubing Liposat® Pro plus" (REF 00003997) was used for the following instructions.

1. Open the front cover of the pump.
2. The rotor automatically rotates into a suitable position for inserting the tubing set.
3. Remove the sterile tubing set with turbid pump segment from the packaging.
4. The spike is on the left side.
5. Carefully press the left end of the pump segment into the left tube clamp until it clicks into place.
6. Insert the tubing so that it can be optimally picked up by the rotor.
7. Press and hold the **Insert tube set** button. The rotor turns and takes up the tubing set.
   Alternative: Turn the rotor to the right by hand.
8. Release the button when the tubing is threaded.
9. Carefully press the remaining pump segment into the right-hand tube clamp until it clicks into place.
10. Insert the spike of the tube set into the bag containing the infiltration medium.
11. Close the front window.

➔ The tubing set is fully assembled.

Left: **Spike (infiltration medium)**
Right: **Luer (infiltration option)**

Infiltration routes with the TLA Tubing Liposat® Pro plus

Infiltration options	TLA infiltration
Sterican cannulas (with cock bank)	✓
Single TLA infiltration cannula on the vibrating handle with TLA Luer-Lock adapter	✓
Single TLA infiltration cannula on the manual handle with TLA Luer-Lock adapter	✓

Table 6:
Infiltration routes with the TLA Tubing Liposat® Pro plus

The user decides which infiltration option to use.

4.6 Disassembly

4.6.1 Removing the tube sets

4.6.1.1 Remove TLA Tubing Liposat® Pro/power (Liposat® Pro)

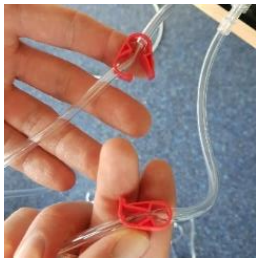


Figure 22:
Close hose clamps

- Close the hose clamps.

1. Remove the left tubing end from the left tube clamp.
2. Press the **Insert tubing** button until unthreaded.
3. Remove the right tubing end from the right tube clamp.

   ➥ Liquid can leak out with this variant.

OR

1. Remove the right tubing end from the right tube clamp.
2. Turn the red one manually to the left against the direction of rotation.
3. Remove the left tubing end from the left tube clamp.

4.6.1.2 Removing the tube set from the Liposat® Pro plus

4.6.1.2.1 Remove TLA Tubing Liposat® Pro plus (Liposat® Pro plus)

➔ Same procedure as in *chapter 4.6.1.1**Fehler! Verweisquelle konnte nicht gefunden werden.*.

4.6.1.2.2 Remove FAT Tubing Liposat® Pro plus (Liposat® Pro plus)

1. Remove the left tubing end from the left tube clamp.
2. Press the **Insert tubing** button until un-threaded.
3. Remove the right tubing end from the right tube clamp.

OR

Figure 23:
Right tubing end from tube clamp

1. Remove the right tubing end from the right tube clamp.

Figure 24:
Turn rotor manually against direction of arrow

2. Turn the red one manually to the left against the direction of rotation.

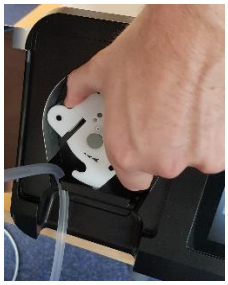


Figure 25:
Left tubing end from left tube clamp

3. Remove the left tubing end from the left tube clamp.

5 Application and operation

- All handling of a device requires precise knowledge and compliance with these instructions for use.
- The devices may only be used by specialist staff.
- Use can be safely interrupted at any time by switching off the Liposat® Pro/Pro plus.

5.1 Switching on and off

- Plug in the mains plug.
- Flip the standby switch on the back.
  A short screen test is performed.
- The start screen opens with the last set values.

The application can be safely cancelled at any time by switching off.

5.2 Screen description: Start screen

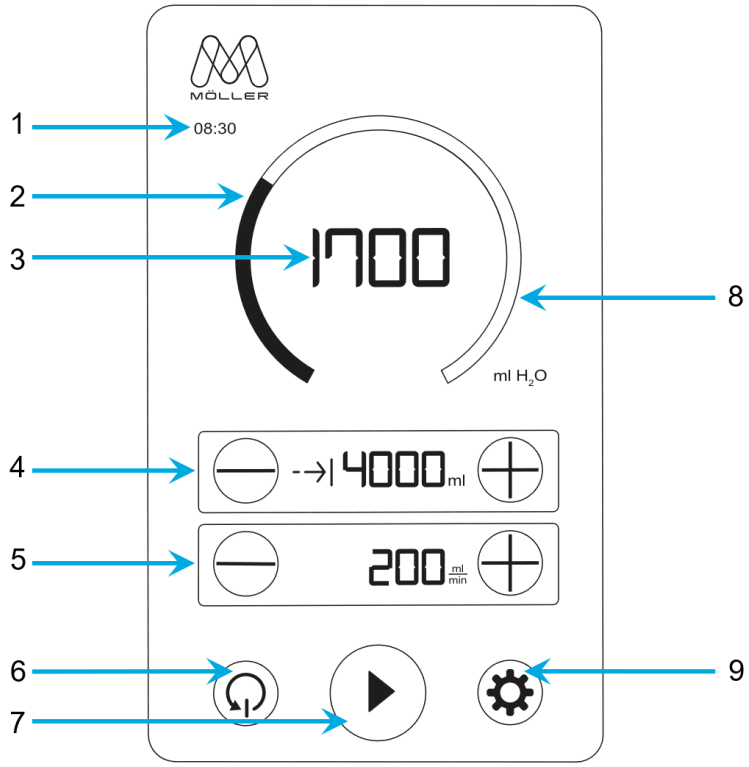


Figure 26:
Start screen display

No.	Name	Description
1	Infiltration time	Time from start of infiltration to now
2	Progress indicator	Infiltration volume (3) in relation to target volume (4)
3	Infiltration volume	Volume pumped
4	Target volume	Volume pumped until pumping pauses automatically. (Set: - decrease, + increase)
5	Flow rate	Volume pumped in one minute. (Set: - decrease, + increase)
6	Reset	Reset from: Infiltration time (1) Progress indicator (2) Infiltration volume (3)
7	Start/Stop	Start/stop conveying, control priming
8	Infiltration volume	Residual volume in relation to target volume (4)
9	Main menu	Call up the main menu

Table 7:
Start screen

5.3 Operation

The Liposat® Pro/Pro plus offer various operating options:

- Manually via the touch screen
- With the foot via the footswitch

5.3.1 Increase and decrease

- Pressing once changes the value by one level at a time.
- Press and hold (>2 seconds) to change the value, continuously until released.

5.3.2 Screen description: Main menu

The main menu can only be called up when the pump is not pumping. The settings made are maintained after restarting the device.

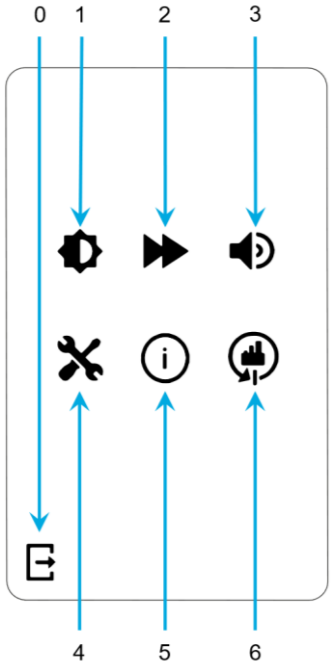
Main menu display	No.	Menu		Name
 *Figure 27: Main menu*	0			Save and exit menu item
				Add / Plus
				Deduct / Minus
	1			Set brightness
				Rotate screen
	2			Prime (Rinse)
	3			Adjusting the volume of the system sounds
				Tone for clues
				Sound by pressing a button
				Sound at pump start/stop
	4			Service menu
	5			Device information
	6			Reset to factory settings
				Accept / Confirm

Table 8: Symbols in the main menu

5.3.2.1 Set brightness

- With + and - (in 5% increments, from 10–100)
- Rotate the screen if the Vertical Mounting Kit is to be used.
- When the screen is turned, the logo illumination goes out.

5.3.2.2 Priming flow rate

- With + and - (in 50 ml/min increments, from 0–300: Liposat® Pro)
- With + and - (in 50 ml/min increments, from 0–1,000: Liposat® Pro plus)
- At 0 ml/min the priming function is deactivated.

5.3.2.3 Sound level

- With + and - (in 10% increments, from 0–100)
- At 0%, the corresponding sound is deactivated.

5.3.2.4 Service menu

Is for service only.

5.3.2.5 Manufacturer information

Provides the latest information on:

- Unit name
- Software version number
- Serial number of the unit
- Service contact of the manufacturer

5.3.2.6 Factory settings

- Settings are reset to the as-delivered state.
- The current software version remains installed.

5.3.3 Venting a tubing set

The tubing set must be bled, ...

- ... before an infiltration option is applied.
- ... if air bubbles are visible in the tubing set.
- ... when the tubing set is changed.

There are two ways to bleed the tubing set. A slow bleed is described below. The quick bleed, the priming, is found in the following section*(chapter 5.3.3.1).*

1. Press **Start/Stop** button. Pump starts.
2. Pump liquid until the tubing is free of air bubbles.
3. Press **Start/Stop** button. Pump stops.
4. Press **Reset** button. Reset infiltration time, progress indicator and infiltration volume.
5. The infiltration option can now be placed on the patient.

5.3.3.1 Priming

Priming is used to quickly deaerate and rinse the hose. As soon as the **Start/Stop** button is pressed and held for more than 2 seconds, the unit pumps at the flow rate set in the priming settings. If you release the **Start/Stop** button, the pump automatically returns to its initial state. After bleeding, press the Reset button.

5.3.4 Target volume

In the ***Target volume*** operator panel, the pumps can be set to pause automatically once a certain value has been reached. This is helpful, for example, if you wish to infiltrate a specific volume.

	Target volume (ml)	Increments	Buttons
Liposat® Pro Liposat® Pro plus	100 to 9,900 ml > 9,900 ml deactivates the target volume	100	+ increase — decrease

An acoustic signal sounds and the pump automatically stops once the target volume has been reached. Infiltration can be stopped at any time during use by pressing the **Start/Stop** button without losing the target volume. To deactivate the target volume, increase this value above 9,900 ml. Deactivation is indicated with a **minus** in the display.
If you want to infiltrate the same quantity again, press the **Start/Stop** button. The infiltrated volume is then counted up further and the pump stops after the set target volume has been infiltrated again.

5.3.5 Flow rate

Before each use, check the **Flow rate** setting in the Start screen. Set the flow rate (ml/min) of the pumps using the **Plus** or **Minus** button.

	Flow rate (ml/min)	Incre-ments	Buttons			
Liposat® Pro	50 to 300	25	+	increase	—	decrease
Liposat® Pro plus	50 to 500 500 to 1,000	25 50	+	increase	—	decrease

The flow rate can be changed at any time, even if the pump is already infiltrating. The set and displayed flow rate always refers to aqueous solutions.

- The flow rate cannot be set and displayed exactly with fat transfers due to the very different viscosities of the media. In this case, setting and display act as an indicator and do not claim to be accurate.
- During use, observe and check the actual fill level of the infiltration container and do not rely solely on the infiltration volume displayed on the screen.

5.3.5.1 Operating mode

	Flow rate (ml/min)	Operating mode	Maximum Duty cycle	Maximum deliverable volume	Necessary breaks
Liposat® Pro	50 to 300	Continuous operation S1 (DIN EN 60034-1:2013)	Without limitation	Without limitation	Without limitation
Liposat® Pro plus	50 to 650	Continuous operation S1 (DIN EN 60034-1:2013)	Without limitation	Without limitation	Without limitation
	> 650 to 1,000	Continuous operation S1 (DIN EN 60034-1:2013)	Without limitation	**12 l**	**30 min**

5.3.6 Start/Stop

To start the pump, the front window must be closed.
The pump can be started and stopped in 3 ways:

- **Start/Stop** button on the screen
- **Progress bar** on the screen
- **On/Off button** of the footswitch (accessory)

When the pump is in operation, a white ring appears around the **Start/Stop** button.

No settings are changed as a result of stopping the infiltration. To reset the infiltration time, progress indicator and infiltration volume, press the **Reset** button.

5.4 Example of infiltration

Likewise applies to theLiposat® Pro/Pro plus.

Switch on the unit

- Switch on the unit *(chapter 5.1).*

Inserting the tubing set

- Insert the appropriate tubing set into the pump.
  Liposat® Pro (*chapter 4.5.1.1)*
  Liposat® Pro plus *(chapter 4.5.1.2)*

Bleed tubing set

- Bleed the new tubing set *(chapter 5.3.3).*

Start infiltration

- Place the infiltration option on the patient.
- Start the pump *(chapter 0).*
- Bleed the tubing set *(chapter 5.3.3),* if air bubbles appear in the tubing during use or if you change the tubing set.

1 Infiltration time
2 Progress indicator
3 Infiltration volume
4 Missing Infiltration volume
5 Target volume
6 Flow rate

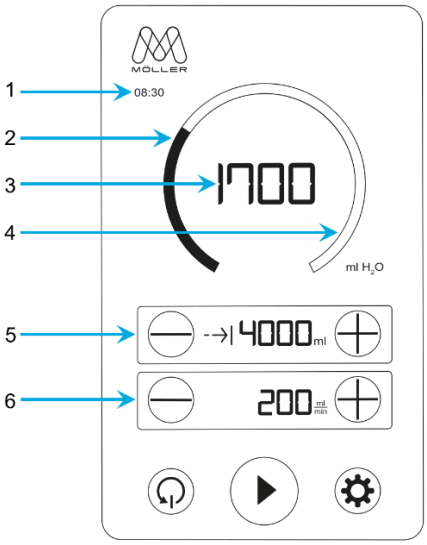


Figure 28:
Example application

If the pump continues to run at the current flow rate, it will still take 11 minutes 30 seconds to reach the target volume.

Application-related explanation

1 The pump has been running for 8 minutes and 30 seconds.

2 About 40% of the target volume has already been delivered. Indicated by the filled bar (progress indicator).

3 1,700 ml were delivered.

4 There is still ~60% to be delivered until the target volume is reached.

5 The set target volume is 4,000 ml.

6 The set flow rate is 200 ml/min.

*All millilitres refer to the volume of water.

Calculations

2) Infiltration volume / target volume = progress indicator
1,700 ml / 4,000 ml = 0.425 = 42.5%

4) Target volume - infiltration volume = Missing infiltration volume
4,000 ml - 1,700 ml = 2,300 ml

6) Residual volume / flow rate = infiltration time
2,300 ml / 200 ml/min = 11.5 min

Remove tubing set

- Remove the tubing set used *(chapter 4.6).*
- Dispose of the disposables according to your facility's biohazardous medical waste policy.

Cleaning and disinfection

- Clean the unit *(chapter 6.1).*

6 Cleaning and care

6.1 Cleaning and disinfection

- No moisture must be allowed to enter the device.
- Before cleaning and disinfecting the device surfaces, disconnect the mains plug.
- Use a lint-free, soft cloth for cleaning and disinfecting.
- Wipe the devices to clean and disinfect them. Immersing or spraying the devices may lead to hazards and destroy the devices.

Clean using a cloth dampened with a mild soap solution or 70% isopropanol solution.
After cleaning, disinfect the surfaces of the Liposat® Pro/Pro plus with a pH neutral, approved 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 devices.

Visual inspection

The sockets of all connections and plugs of the cables to be connected must be dry and free of soiling of any kind.

Liposat® Pro plus

The Liposat® Pro plus tumescent pump allows you to remove the pump rotor and the tubing clamp to make cleaning the inside of the pump easier.

Liposat® Pro

Disassembly of the tubing clamp and removal of the rotor are not possible with the Liposat® Pro.

Cleaning and care

Rotor Removal

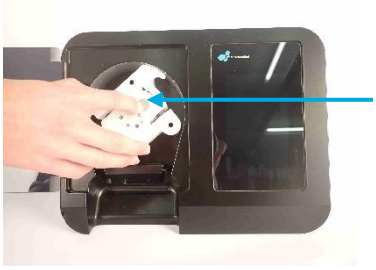


Figure 29:
Remove rotor

1. Press and hold the grey button on the rotor.
2. Pull the rotor off the motor shaft.

Figure 30:
Remove tube clamp

3. Pull the tube clamp off the pins.

4. Clean the inside of the pump.

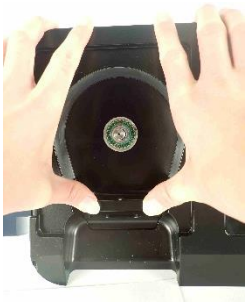


Figure 31:
Mount the tube clamp

5. Push the tube clamp onto the pins as far as it will go.

Figure 32:
Mount rotor

6. Push the rotor back onto the motor shaft until it engages.

6.2 Maintenance

The Liposat® Pro or Liposat® Pro plus will remind you of the pending date for a technical safety check during the booting process.

The service, upgrade or modification of the Liposat® Pro/Pro plus must only be performed by Möller Medical GmbH or by a facility specifically authorised to do so by the manufacturer. In the latter case, the work performed must be documented, signed and dated. Changes to the devices by third parties are not permitted. A safety check as per the German Medical Devices Operator Ordinance (MPBetreibV) must be performed at least every 12 months. All the necessary entries as per the German Medical Devices Operator Ordinance can be made in the medical devices book. Only use the Liposat® Pro/Pro plus if the devices are functionally and/or operationally safe. Otherwise they must be repaired immediately by the service team.

7 Help in the event of a fault

The Liposat® Pro/Pro plus must not be opened by the user!

This chapter describes certain problems which may occur in conjunction with the devices. The devices must always be turned off when connecting and disconnecting plug connections. If an error cannot be remedied as described below, contact the Möller Medical GmbH service centre (service@moeller-medical.com) or a partner authorised by the manufacturer.

Explanation of symbols used	
	Front panel open
	No rotor signal
	No rotor function

Table 9:
Explanation of symbols used

Problem	**Solution**
No function, the screen is off.	The device is not switched on or not connected to the power supply properly. Check the power supply, possibly switch on multiple sockets, check supply lines and building circuit breaker.
The pump does not turn.	<u>The front panel of the pump is open.</u> Look for the **Open Front Panel** symbol on the screen. → Close the front panel and start the pump. <u>The pump has no rotor signal.</u> Look for the **No Rotor Signal** and **No Rotor Function** symbols on the screen. → Open the front panel of the pump, replace the rotor, close the front panel again and start the pump.
The footswitch does not react.	The connecting cable for the footswitch is not connected.

Help in the event of a fault

Problem	Solution
Set flow rate does not comply with the actual delivered quantity.	The delivered quantity is recorded and evaluated via the pump rotor speed. If the set quantity does not correspond to the delivered quantity, this may be due to the following causes; after rectifying the causes, the delivery quantity should be correct again: • Tubing set is clamped or pinched. • Taps are not properly open (e.g. distributor tap bank). • The spike is not properly stuck into the bags with the infiltration medium. • Bag with the infiltration medium is empty. • The pump has an additional safety function which prevents the tubing set from bursting. With an inner tube pressure > 2.5 bar, the spring-loaded rollers of the pump rotor open to prevent further pressure building up in the tubing set.
Moisture has entered into the mains plug.	Pull the plug off the device and out of the socket. Allow the plug to dry.
Should these measures not prove successful, the device is to be checked by the Möller Medical GmbH service team.	

Table 10:
Help in the event of faults

8 Service

- Before disposal or return, the devices must be disinfected using a suitable disinfection procedure in order to exclude a possible risk of infection.
- Consumable materials should be disposed of in accordance with hygiene guidelines.

Service note:

- **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
E-mail: service@moeller-medical.com

8.1 Software update

- Observe the order of the update. Deviations can result in the software update being cancelled or unsuccessful.
- Note that the USB port blocker key may break if used incorrectly.

Explanation of symbols used			
	Standby switch		Main menu
	Standby On		Device information
	Standby Off		

Table 11:
Explanation of symbols used

The software can be updated via the USB service interface on the back of the units. To update, proceed as follows:

Preparation

1. Use an empty USB stick without subdirectories.
2. Copy the software to the USB stick.
   ➥ The software is provided by the service centre.
3. Set the **Standby Switch** on the back of the unit to **Standby On**.

Update unit

1. Pull out the mains plug.
2. Insert the unlocking key into the hole of the USB port blocker.
3. Carefully turn the release key to the left *(Figure 33)*.
   ➥ As soon as slight resistance is felt, carefully pull the release key to remove the USB port blocker.
4. Insert the prepared USB stick into the USB service interface.
5. Plug in the mains plug.
6. Watch the screen, the update is done automatically.
7. At the top, the screen shows the following in ascending order:
   "Update Process Step 1" → "Update Process Step 9"
8. At the bottom, the screen shows that the update was successful.
   “Success!!! Disconnect USB stick. Remove mains, wait 5 seconds and replug mains."
9. If the screen does not show this, go to the end of this chapter.
10. Pull out the mains plug.
11. Remove the USB stick.
12. Plug the USB port blocker into the USB service interface.

13. Plug in the mains plug.
14. The Start screen is displayed.
15. Call up the device information in the main menu and check whether the software version displayed there is correct.
16. If this does not match the desired version, repeat the previous steps.
    ➔ The unit is now updated.

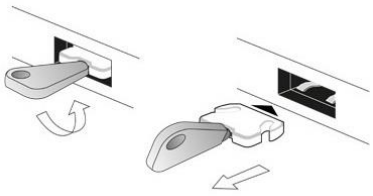


Figure33:
Remove the USB port blocker

If the update is unsuccessful

- ➥ The screen shows the corresponding update warning ID.
- ➥ The old software is kept on the device.
- ➥ Perform the corresponding troubleshooting measures.

If this does not solve the issue, contact the service centre.

Software update warnings

Warning ID	Error description	Solution
1, 2	The software on the USB stick is not valid.	Check the software on the USB stick or, if necessary, copy the software to the USB stick again.
3 - 8, 11 - 13	The transfer of the software to the device has failed.	Try to install the update again. If this fails again, contact the service centre.
14	Error reading the used USB stick.	Try to install the update again with another USB stick. If this fails again, contact the service centre.

Table 12:
Software update warnings

9 Periodic safety checks

The Liposat® Pro/Pro plus must not be opened by the user! Perform safety checks (SC) as per the German Medical Devices Operator Ordinance (MPBetreibV) at least every 12 months. The safety check is to be entered in a device book and the results of the check are to be documented. If the device is not functionally and/or operationally safe, have it immediately serviced. The safety checks can be performed by the Möller Medical GmbH (service@moeller-medical.com) service department.

10 Disposal

This device includes materials which must be disposed of in an environmentally friendly manner. The European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE2) applies to these devices. They thus bear the symbol with a crossed out bin on the rating plate.

Return reprocessed devices which 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 Annex

11.1 Technical data

Article number	
Catalogue number Liposat® Pro	REF 00003977
Catalogue number Liposat® Pro plus	REF 00003974
Dimensions	
Liposat® Pro/Pro plus	275 mm x 210 mm x 350 mm (width x height x depth)
Weight	
Liposat® Pro	approx. 5.8 kg
Liposat® Pro plus:	approx. 6 kg
Electrical connection Liposat® Pro	
Voltage	100 – 240 VAC (alternating current)
Frequency	50 – 60 Hz
Current consumption	0.5 – 0.21 A
Power consumption	50 VA
Electrical connection of the Liposat® Pro plus	
Voltage	100 – 240 VAC (alternating current)
Frequency	50 – 60 Hz
Current consumption	1.23 – 0.51 A
Power consumption	123 VA
Safety	
Protective class	I
Applied part Type	B
Sterile consumables	
TLA Tubing Liposat® Pro/power	REF 00002251
TLA Tubing Liposat® Pro plus	REF 00003997
FAT Tubing Liposat® Pro plus	REF 00003948
TLA Luer-Lock Adapter	REF 00004027

11.2 General data

Transport and storage information	
Temperature	-10 °C to +50 °C
Air humidity	< 90% relative humidity
Dimensions with packaging	Width x height x depth: 336 mm x 280 mm x 362 mm
Store the packaged devices in a dry place. **A stack of packed devices may consist of max. 3 packages.**	
Operating conditions	
Temperature	+10 °C to +40 °C
Air humidity	30 to 75% relative humidity
Atmospheric pressure	70.1 kPa – 101.3 kPa (3000–0 m MSL)
Protection type	
Protection type	IP 30 (based on IEC 60601-1)
Flow rate	
Flow rate range of the Liposat® Pro	50 ml/min to 300 ml/min
Flow rate range of the Liposat® Pro plus	50 ml/min to 1,000 ml/min
Flow accuracy	± 15% (only applies to the pump rate of aqueous solutions with a free flow and not for endogenous substances and tissues)
Noise pressure level	
Noise pressure level Liposat® Pro	< 47 dB(A)
Noise pressure level Liposat® Pro plus	< 65 dB(A)
Minimum operating lifespan	8 years

Table 13:
Transport and storage information

12 Electromagnetic compatibility

12.1 Electromagnetic emissions

The Liposat® Pro/Pro plus are suitable for use in the stated electromagnetic environment. The customer and/or operator of the Liposat® Pro/Pro plus must ensure that the devices are used in the electromagnetic environment described below.

Measurement of electromagnetic interference	**Compliance**	**Electromagnetic environment - guidelines**
High frequency emitted interference acc. to CISPR 11	Group 1	To satisfy their intended function, the Liposat® Pro/Pro plus must emit electromagnetic energy. Electronic devices in the vicinity could be influenced.
High frequency emitted interference acc. to CISPR 11	Class B	Areas of use for a suitable operating environment *(chapter 4.3)*
Harmonic emissions acc. to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker acc. to IEC 61000-3-3	Complies	

Table 14:
Types of electromagnetic emissions

12.2 Electromagnetic immunity

Immunity test	IEC 60601 - testing level	Level of conformity	Electromagnetic environment - guidelines
Discharge of static electricity (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%.
Electrical fast transients/ 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 for a typical shop or hospital environment.
Surge voltages (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 for a typical shop or hospital environment.
Voltage dips, voltage short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dips of U_T) for 0.5 cycle 40% U_T (60% dips of U_T) for 5 cycles 70% U_T (30% dips of U_T) for 25 cycles < 5% U_T (> 95% dips of U_T) for 5 seconds	< 5% U_T (> 95% dips of U_T) for 0.5 cycle 40% U_T (60% dips of U_T) for 5 cycles 70% U_T (30% dips of U_T) for 25 cycles < 5% U_T (> 95% dips of U_T) for 5 seconds	The quality of the supply voltage should be comparable to that for a typical shop 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.

Electromagnetic compatibility

Immunity test	IEC 60601 - testing level	Level of conformity	Electromagnetic environment - guidelines
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 AC mains voltage prior to application of the test level.			

Table 15:
Electromagnetic immunity (1)

The Liposat® Pro/Pro plus satisfy all test levels in accordance with IEC60601-1-2 Edition 4 (table 4 to 9).

- Portable RF communications equipment (radio equipment including its accessories such as antenna cables and external antennas) should be used no closer than 30 cm (or 12 inches) to any parts and cables of the Liposat® Pro and the Liposat® Pro plus designated by the manufacturer. Non-observance may result in a reduction of the device's performance.
- Operation of the Liposat® Pro and the Liposat® Pro plus 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>Electromagnetic immunity testing/standard</th><th>IEC 60601 - testing level</th><th>Level of conformity</th><th>Electromagnetic environment - guidelines</th></tr>
<tr><td>Conducted RF disturbance acc. to IEC 61000-4-6</td><td>3 V_{eff}
150 kHz to 30 MHz

6 V_{eff} in ISM and amateur radio frequency bands between 150 kHz and 80 MHz</td><td>3 V_{eff}

6 V_{eff}</td><td rowspan="2">Portable and mobile radio transmitting devices, including the cables, should be used in proximity of the Liposat® Pro/Pro plus within the recommended safety distance calculated according to the applicable transmission frequency equation.
Recommended separation 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 output power rating of the transmitter in watts (W) according to the transmitter manufacturer 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:  </td></tr>
<tr><td>Radiated RF 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">Notes:
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection by structures, objects and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the Liposat® Pro/Pro plus are used exceeds the aforementioned compliance level, the devices should be monitored to ensure that they are working properly. If the device is not performing as expected, additional measures may be necessary, such as changing the direction in which Liposat® Pro/Pro plus is facing or moving it to another area.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Table 16:
Electromagnetic immunity (2)

12.3 Recommended safety distances

"Electromagnetic immunity" (chapter 12.2)

13 Accessories

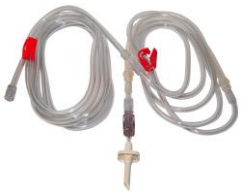
Sterile consumables

For Liposat® Pro:

TLA Tubing Liposat® Pro/power

Catalogue no.: 00002251

(Pack of 10 in a box)



For Liposat® Pro plus:

TLA Tubing Liposat® Pro plus

Catalogue no.: 00003997

(Pack of 10 in a box)

FAT Tubing Liposat® Pro plus

Catalogue no.: 00003948

(Pack of 10 in a box)

TLA Luer-Lock Adapter

Catalogue no.: 00004027

(Pack of 30 in a box)

Accessories

Liposat®/Vibrasat® footswitch (1-pedal, 2 m cable length)

Catalogue no.: 93003545

Liposat®/Vibrasat® footswitch (1-pedal, 5 m cable length)

Catalogue no.: 00003982

Accessories

Liposat®/Vibrasat® footswitch (3-pedal, 2 m cable length)

Catalogue no.: 93003517

Liposat®/Vibrasat® footswitch (3-pedal, 5 m cable length)

Catalogue no.: 00003981

Vertical mounting kit for Liposat® Pro/Pro plus

➔ for vertical attachment of Liposat® Pro/Pro plus to Vacusat® power

Catalogue no.: 00004034

Horizontal mounting kit for Liposat® Pro/Pro plus

➔ for horizontal attachment of Liposat® Pro/Pro plus to Vacusat® power

Catalogue no.: 00004035

Commercial goods

3-way tap bank (sterile)

Catalogue no.: 00002278

5-way tap bank (sterile)

Catalogue no.: 00002279

Sterican injection cannula

Catalogue no.: 00002535

Spare parts

Unlocking key with USB port blocker

Catalogue no.: 93006998

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The instructions for use are part of the product.