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INSTRUCTIONS FOR USE

Vibrasat® Pro

The vibrating premium handpiece
for aesthetic body contouring

MÖLLER

IMPORTANT

READ CAREFULLY BEFORE USE

KEEP THESE INSTRUCTIONS FOR FUTURE CONSULTATION

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

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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, operating personnel and third parties, 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 devices
	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
	Protection class II device
	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
	Unit switched on (Standby switched off)
	Unit switched off (Standby switched on)


Input / Output (for energy and signals)


USB host


Applied part Type B


Footswitch


Start/Stop button


Plus button (add / increase)

Minus button (subtract / decrease)


Existing connection


Warning notice

1.1.3 Additional symbols on the retail packaging


Consult instructions for use


Packaging unit

Production lot number, batch


Expiry date, YYYY-MM-DD


Date of manufacture (YYYY-MM-DD)


Store away from sunlight


Store in a dry place


Air humidity, limitation


Temperature limitation

Stacking limit, do not store more than 4 packs high

Not suitable for use with MRI


Do not use if package is damaged


Do not reuse

Do not resterilise

Single sterile barrier system

Single sterile barrier system with protective outer packaging

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) Important points
Italics	References to chapters, figures and tables

Table 1:
Format conventions used

A prerequisite for use of the Vibrasat® Pro is thorough knowledge and observance of these instructions for use, which are supplied as part of the product. Keep the instructions for use for the Vibrasat® Pro in a safe place. The device must be used only by persons who have the required training or knowledge and experience.

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 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 device. 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 Vibrasat® Pro .

Precise knowledge and compliance with these instructions for use is a prerequisite whenever the Vibrasat® Pro is used. The devices may only be operated by persons with the necessary training or knowledge and experience.

The 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.

1.5 Warning notices

- The devices must not be modified.
- No liquids must be allowed to penetrate the current-conducting parts of the device.
- When cleaning, ensure that no cleaning agent runs into the connector sockets.
- Disconnect the power cable before cleaning.
- The housing of the Vibrasat® Pro Console is only connected as functional earth with the earth contact of the power supply.
- 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.
- When reprocessing the devices, observe the reprocessing instructions in order to avoid damaging the products.
- If the vibration causes discomfort in the hand-arm area of the user, the application should be paused.

1.6 Non-product-related additional equipment

Additional equipment which does not belong to the device's scope of supply and which are connected to the device's analogue and digital interfaces must be shown to satisfy the relevant EN specifications (e.g. EN 60601 for electromedical devices). 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

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

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

1.8 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.

Sterilise all reusable components of the Vibrasat® Pro as per the reprocessing instructions and replace all the disposable components before using the Vibrasat® Pro on another patient.

1.9 Target group (users)

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

1.10 Reporting

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

2 Intended use

2.1 Proper use – intended use Vibrasat® Pro

The Vibrasat® Pro, which consists of a control unit and a handle with a connection cable and vibrates cannulas, is used in particular to support the hand movement of the user during a surgical procedure in connection with liposuction cannulas.
The Vibrasat® Pro may only be used in conjunction with Möller Medical liposuction cannulas.

2.2 Contraindications

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

2.3 Complications

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

2.4 Essential performance features

The Vibrasat® Pro has no essential performance features.

2.5 Combination with other products

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

3 Product description

The Vibrasat® Pro consists of two components

- Vibrasat® Pro Wand
- Vibrasat® Pro Console

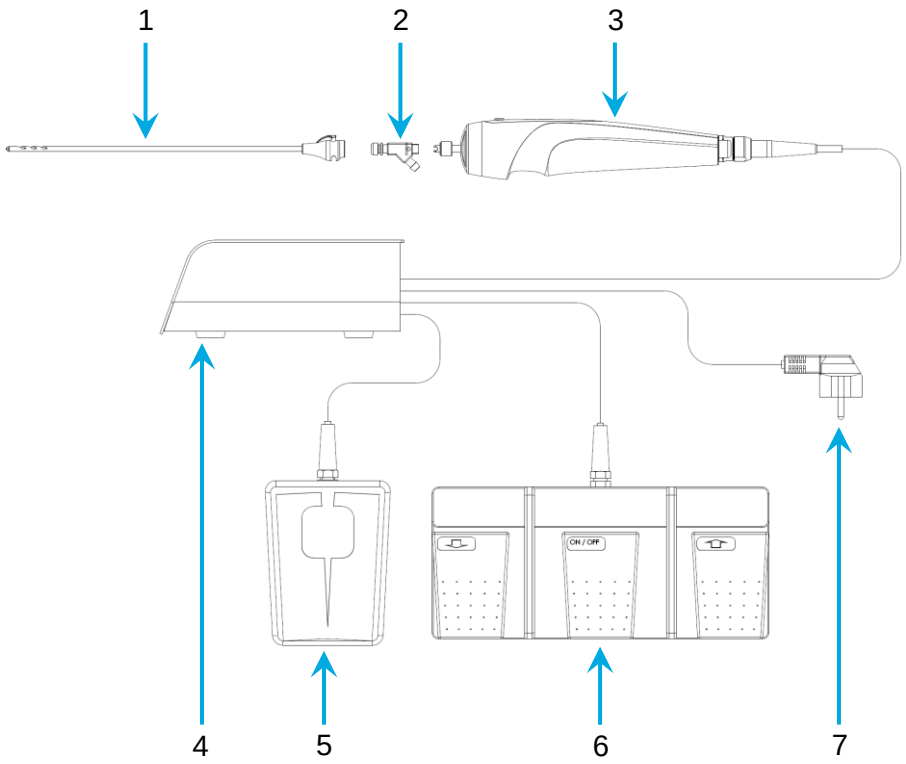


Figure 1:
Overview drawing

No.	Designation	No.	Designation
1	Cannulas	5	1-Pedal Liposat®/Vibrasat® Footswitch
2	Vibrasat® QuickLock®	6	3-Pedal Liposat®/Vibrasat® Footswitch
3	Vibrasat® Pro Wand	7	Mains cable
4	Vibrasat® Pro Console		

Table 2:
Designations

3.1 Vibrasat® Pro Wand (handle)

The handle transfers very rapid vibrations in an axial direction to a cannula connected to the handle and thus supports the user's hand movements.

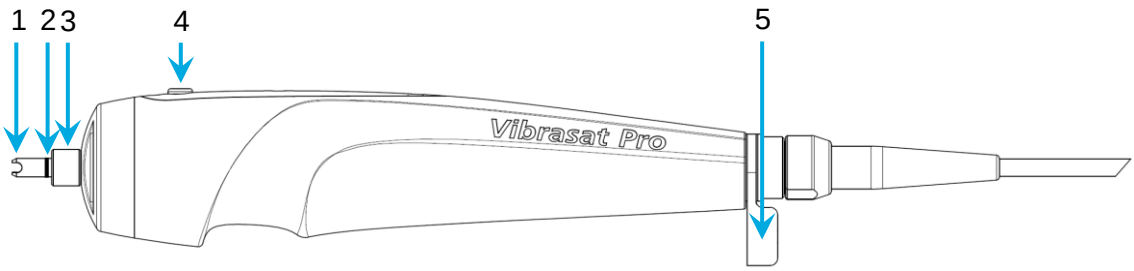


Figure 2:
Vibrasat® Pro Wand

No.	Designation	No.	Designation
1	Axis (forked)	4	Button
2	Circlip	5	Tube clamp
3	Lock nut		

Table 3:
Description

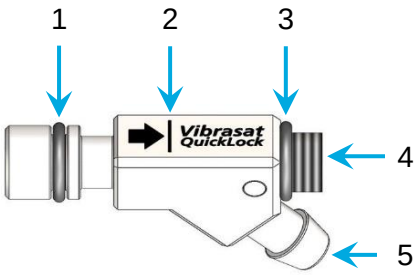


Figure 3:
Vibrasat QuickLock®

No.	Designation
1	Front O-ring
2	Marking line
3	Rear O-ring
4	Thread
5	Tubing connection

Table 4:
Description

3.2 Vibrasat® Pro Console (control unit)

The Vibrasat® Pro Console is the control unit for the Vibrasat® Pro.

Front:

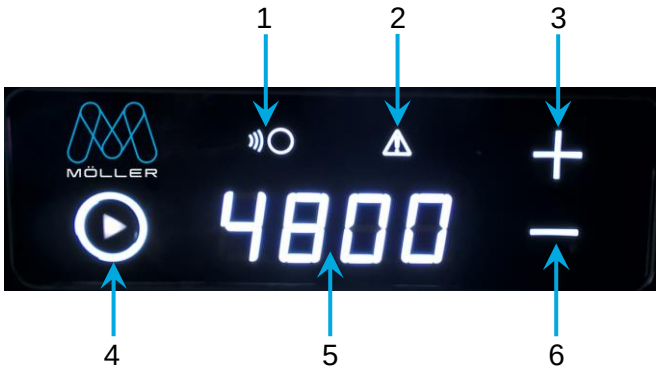


Figure 4: Screen

No.	Designation
1	Signal display
2	Warning notice
3	Plus button
4	Start/Stop button
5	Vibration speed
6	Minus button

Table 5: Description

Back:

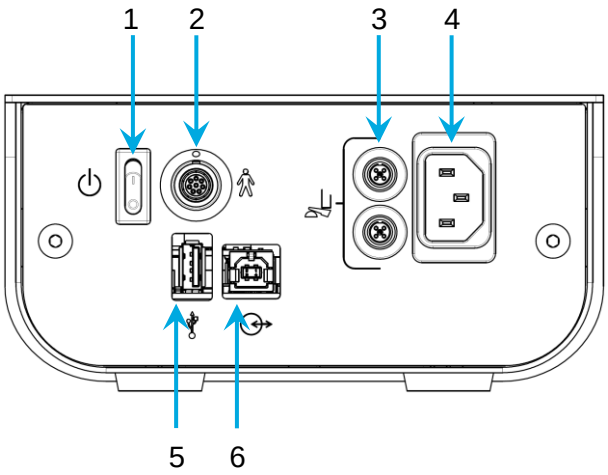


Figure 5: Back cover

No.	Designation
1	Standby switch
2	Connection socket for the Vibrasat® Pro Wand
3	Connection sockets for the Liposat®/Vibrasat® footswitch
4	Mains input socket
5	USB socket, service interface
6	USB socket

Table 6: Description

3.3 Liposat®/Vibrasat® Footswitch

2 footswitches can be operated simultaneously. Both footswitches behave identically with equal precedence. The footswitches are optionally available, as an accessory.

3.3.1 Liposat®/Vibrasat® Footswitch (1-Pedal)

By pressing the button, the Vibrasat® Pro can be started and stopped.

Figure 6:
Liposat®/Vibrasat® footswitch (1-pedal)

3.3.2 Liposat®/Vibrasat® Footswitch (3-Pedal)

By pressing the On/Off button, the Vibrasat® Pro can be started and stopped. The vibration speed can be changed using the Up/Down buttons. The operation is described in more detail in *chapter 5.2*.

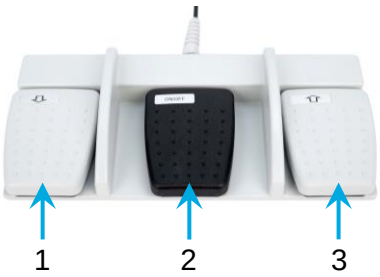


Figure 7:
Liposat®/Vibrasat® Footswitch (3-Pedal)

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

Table 7:
Description

3.4 Cannulas

Only the designated Möller Medical GmbH cannulas may be attached to the Vibrasat® Pro Wand. For an up-to-date list of available cannulas, please refer to our brochure and website www.moeller-medical.com.

Figure 8:
Cannulas

No.	Designation
1	Cannula holes
2	Cannula QuickLock®
3	Lock

Table 8:
Description

4 Setup and commissioning

- 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.

4.1 Unpacking the device and checking the delivered items

Delivery of the Vibrasat® Pro comprises at least 2 packaging units, depending on the scope of the order. Make sure that no parts remain in the packaging when unpacking.

Packaging unit Vibrasat® Pro

Packaging unit Vibrasat® Pro Console

1 x Vibrasat® Pro Console

1 x power cable

1 x USB service interface release key

Instructions for use

Packaging unit Vibrasat® Pro Wand

1 x Vibrasat® Pro Wand

1 x QuickLock®

10 x O-rings (non-sterile)

10 x circlips (non-sterile)

Reprocessing instructions

It is advisable not to dispose of the packaging and to use it again for any service required.

Only send the devices in their original packaging to prevent damage during transportation.

4.2 Suitable operating environments Vibrasat® Pro

The Vibrasat® Pro 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).

- Home healthcare

  Home practices, lodgings (places of residence, nursing homes), hotels, guest houses and stationary vehicles, provided that the devices are not connected to the vehicle's DC power supply.

The Vibrasat® Pro is not approved for use in aircraft or military applications. The appropriate EMC requirements for these environments have not been tested.

4.3 Setup and commissioning

Before commissioning, the Vibrasat® Pro Console must be processed as per the hygiene guidelines (see chapter 6).

The Vibrasat® Pro Wand and the QuickLock® must be processed as per the re-processing instructions provided by the manufacturer.

If the Vibrasat® Pro Console and Vibrasat® Pro Wand 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.

4.3.1 General information

- Place the Vibrasat® Pro Console on a suitable, stable surface or, if available, use the Vibrasat® Pro mounting kit. To do this, attach the Vibrasat® Pro mounting kit to a standard rail. Put the Vibrasat® Pro Console on the plate and secure it to the Vibrasat® Pro mounting kit using the screw supplied.
- Connect the footswitch (optional) to the Vibrasat® Pro Console using the connecting cable.
- Insert the mains cable in the designated connector on the Vibrasat® Pro Console and in a socket with a connected earth wire. Observe the voltage indicated on the identification plate.
- Press the Standby switch on the rear of the Vibrasat® Pro Console, to switch it to standby mode.
- Remove the sterile Vibrasat® Pro Wand from its packaging under sterile working conditions and connect it to the Vibrasat® Pro Console.
- Connect the QuickLock® to the handle.
- Do not use tools as they may damage the appliance.

The QuickLock® must be locked into place!

4.3.2 Commissioning

1. Check the integrity of the two O-rings on the QuickLock.
   - ➥ Replace the O-rings with a sterilised one if necessary.
   - ➥ The O-rings prevent the components from loosening during use.
2. Place the circlip on the tip of the plunger (handle).
3. Slide the circlip over the plunger towards the handle until it clicks into the notch.
4. The locking ring on the handle must be intact and seated in the groove provided.
   - ➥ Replace the circlip with a sterilised one if necessary.
   - ➥ The circlip prevents the nut and QuickLock from slipping off the handle.
5. Connect the installed control unit to the mains supply.
6. Switch on the unit using the standby switch on the control unit.
7. Pull back the handpiece and pull the cap off the plug.
   - ➥ The handpiece is part of the plug that is located at the cable end of the handle.
   - ➥ The push-pull connection prevents the cable from accidentally disconnecting from the console.
8. Insert the plug into the socket of the control unit.
   - ➥ The red dots indicate the correct alignment.
9. Push the QuickLock® onto the axle of the handle.
   - ➥ The tubing connection points upwards or downwards.
10. Screw the lock nut of the handle tightly onto the thread of the QuickLock®.
11. Push the tubing through the tube clamp on the handle.
    - ➥ One example is the TLA Luer-Lock adapter.
12. Push the tubing onto the tubing connection of the QuickLock®.
13. Keep the latch on the cannula pressed and slide it onto the QuickLock®.
    - ➥ The cannula clicks into place when it is pushed beyond the marking line.
14. Test that the cannula, QuickLock® and handle are firmly connected.

➔ The Vibrasat® Pro is now ready for use.

4.4 Disassembly

1. Pull the tubing from the tubing connection of the QuickLock®.
2. Pull the tubing out of the tube clamp on the handle.
3. Press the lock of the cannula.
4. Pull the cannula from the QuickLock®.
5. Screw on the locking nut of the handle.
6. Pull the QuickLock® off the handle.
7. Unplug the handle from the console.
8. To do this, pull back the handpiece of the plug to release the push-pull connection.
9. Use the protective cap to close the plug at the cable end of the handle.

After each use, the Vibrasat® Pro Console and the Vibrasat® Pro Wand must be reprocessed *(see chapter 6).*

5 Application and operation

Always note:

- The handle may only be loaded in an axial direction.
- The device switches off for safety reasons if subjected to strong radial force.
- Large radial forces will damage the handle.
- On the QuickLock®, the effect of strong forces can lead to damage of the handle.
- All handling of the device requires precise knowledge and compliance with these instructions for use.
- The device may only be used by specialist staff.

5.1 Vibrasat® Pro Console description of the operating elements

After switching on the device using the Standby switch on the back the control unit, a brief display test is performed. After starting, the screen shows the last vibration speed set.

The stroke rate can be set between 3000 strokes per minute and 5000 strokes per minute. The stroke rate can be set in standby mode and in vibration mode in increments of 100. The Vibrasat® Pro features a boost function. See *chapter 5.2.1.1* for a more detailed description of the boost.

5.1.1 Screen description

Figure 9:
Screen

No.	Designation	Description
1.	Signal display	Connected to the superordinate control unit
2.	Warning notice	Possible malfunctions *(chapter 5.2.3)*
3.	Plus button	Increasing the vibration speed
4.	Start/Stop button	Vibration on, vibration off
5.	Vibration speed	Strokes per minute
6.	Minus button	Reduction of the vibration speed

5.2 Operation

Vibration stress for the user when using the Vibrasat Pro can lead to VVS (vibration-induced vasospastic syndrome). Therefore, a maximum total use time of 90 mins per day should not be exceeded.

To make work as simple and convenient as possible, the Vibrasat® Pro provides various operating options.

5.2.1 Set the vibration speed

The vibration speed is given in strokes per minute. The setting range is from 3,000–5,000. The setting can be made at any time with one of the following actions:

- pressing the Plus/Minus key on the screen
- pressing the Up/Down button on the 3-pedal footswitch

Pressing once increases or reduces the vibration speed by 100 strokes/minute. Pressing for longer increases/lowers the speed continuously.

5.2.1.1 Boost function

When Boost is activated, the handle vibrates at 6,000 strokes per minute. The boost can only be activated on the handle. To activate, the button must be pressed for longer than 2 seconds. As long as the button is pressed, the boost is active, but for a maximum of one minute. Repeat activation of the boost function can cause the temperature of the handle to rise.

Display

- Activating the boost
  - ➥ Briefly, 6,000 appears on the screen.
  - ➥ Then a timer runs down from 59 to 1.
- Ending the Boost
  - ➥ The timer disappears.
  - ➥ The original vibration speed is displayed and executed

5.2.2 Switching the vibration on and off

If the Vibrasat® Pro Wand is switched on, the ring on the Start/Stop button on the display lights up.

Press the Start/Stop button.	(Vibrasat® Pro Console)
Press the button.	(Vibrasat® Pro Wand)
Press the On/Off button.	(Liposat®/Vibrasat® Footswitch)

5.2.3 Warning notices

If impermissible operating conditions occur during vibration, the Vibrasat® Pro Wand switches off. On the screen of the Vibrasat® Pro Console the corresponding warning ID and the **warning** symbol will appear. To continue, press the Start/Stop button or switch the console on and off.

If the prohibited operating states occur repeatedly, contact the Möller Medical GmbH service centre.

Warning displays

Warning ID	Error description	Solution
E 100	• Handle is not inserted correctly. • Motor speed does not correspond to set value. • The appliance cable is damaged.	• Remove the handle from the console and reconnect it. • Reduce the load and check that the Vibrasat® Pro Wand is running smoothly. • Replace the appliance cable.
E 106 - E 108	• Device initialisation failed.	• Contact the service centre.

Table 9:
Warnings displayed

6 Cleaning and care

6.1 Vibrasat® Pro Wand

The reprocessing of the Vibrasat® Pro Wand is described in a separate document. **If reprocessing is performed by a third party, pass on the relevant information to the party performing the reprocessing**.

6.2 Vibrasat® Pro Console

You will find all the information on processing the Vibrasat® Pro Console in the following section.

- Remove all connecting cables from the device prior to cleaning to prevent the user from being harmed.
- Sterilisation procedures such as autoclaving or ethylene oxide sterilisation render the Vibrasat® Pro Console unusable.
- Do not use sharp objects for cleaning.
- No liquids may be allowed to enter inside the Vibrasat® Pro Console. Therefore, spray disinfectants must not be used directly on the device.
- Use lint-free, soft cloths for cleaning and disinfection by wiping.

Clean using a cloth dampened with a mild soap solution or 70% isopropanol solution.

After cleaning, disinfect the surfaces of the device 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 device.

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

7 Help in the event of a fault

The Vibrasat® Pro must not be opened by the user!

This chapter describes certain problems that may occur in connection with the Vibrasat® Pro.

Several causes with possible solutions are given for each problem. Keep to the troubleshooting order until the fault has been remedied.

Always switch the Vibrasat® Pro off before detaching or connecting the plug connections.

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

Problem	**Solution**
No functionality, the screen is off.	The device is not switched on or not connected to the power supply properly. Insert the mains cable properly into the mains power socket and the Vibrasat® Pro and switch on the Standby switch. Check the power supply, possibly switch on multiple sockets, check supply lines.
Axle still not functioning.	The handle connecting cable is not connected. Check the plug connection.
The footswitch does not react.	The connecting cable for the footswitch is not connected. Check the plug connection.
If none of the measures described are successful, contact the Möller Medical GmbH service centre.	

Table 10:
Help in the event of a fault

8 Service

- Before disposing of or returning the Vibrasat® Pro a suitable disinfection procedure must be carried out to rule out the risk of possible infection. To this end, note the form provided on the manufacturer's page for returning and labelling goods.
- Consumable materials should be disposed of in accordance with hygiene guidelines.

Warnings for service:

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

Möller Medical GmbH service centre:

Möller Medical GmbH
Wasserkuppenstrasse 29-31
36043 Fulda, Germany

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

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

8.1 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			
	Device switched on (Standby Off)		Standby switch
	Device switched off (Standby On)		

Table 11:
Explanation of symbols used

The software can be updated via the UBS 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 **device 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 10).*
   ➥ As soon as a 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. Watchthe screen, the update is automatic.
7. The screen briefly shows “Upd” followed by a sequence from “U1” to “U9”.
8. If the update was successful, “OK” is shown as the final display.
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 installed software version is briefly displayed.
15. If this does not match the desired version, the previous steps must be repeated.
16. The device is updated.

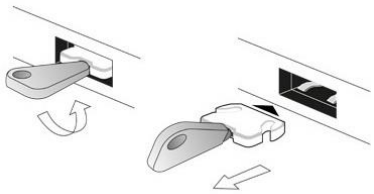


Figure 10:
Removing the USB port blocker

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	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.
2 – 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.
9, 10	The serial number of the software is incorrect.	Contact the service centre.

Table 12:
Software update warnings

9 Periodic safety checks

The service, upgrade or modification of the Vibrasat® Pro must only be performed by Möller Medical GmbH or by a person specifically authorised by the manufacturer.

All correspondingly trained persons have an appropriate certificate from the manufacturer which must be valid, as the certificates do expire. Have them show you the appropriate certificate if necessary.

All the work performed must be documented, signed and dated. Modifications to the device by third parties are not permitted. A safety check (SC) must be performed at least every 12 months. All the necessary entries can be made in the medical devices book. Only use the Vibrasat® Pro if the device is functioning safely and/or is safe to operate. In cases to the contrary, the device must be immediately repaired by the service centre.

10 Disposal

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

Return 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 Key technical data

	Vibrasat® Pro Wand	Vibrasat® Pro Console
Article number:	REF 00003922	REF 00003921
Dimensions	Diameter x length 52 mm x 300 mm	Width x height x depth: 170 mm x 90 mm x 205 mm
Weight	approx. 0.75 kg	approx. 1.2 kg
Surface temperature:	< 43°C with given duty cycle*1	

	Vibrasat® Pro
Article number:	REF 00003920
Electrical connection:	
Voltage	100 – 240 V AC
Frequency	50 – 60 Hz
Current consumption	0.65 – 0.27 A
Protective class	II
Power consumption	65 VA
Exposure:	
Noise emission value	< 75 (dB(A))

*1 TheVibrasat® Pro is designed for a duty cycle of 30 minutes followed by a break of 60 minutes. This cycle may be repeated as often as necessary.

11.2 General data

	Vibrasat® Pro Wand		Vibrasat® Pro Console
Transport and storage instructions:			
Temperature	-10°C to +50°C	=	-10°C to +50°C
Air humidity	< 100% relative humidity		< 90% relative humidity
Weight with packaging	1.05kg		1.8kg
Dimensions	Width x height x depth: 400 mm x 85 mm x 190 mm		Width x height x depth: 297 mm x 145 mm x 228 mm
Operating conditions:			
Temperature	+10°C to + 25°C	=	+10°C to + 25°C
Air humidity	30 to 75% relative humidity	=	30 to 75% relative humidity
Pressure	70.1 kPa – 101.3 kPa (3000-0 m MSL)	=	70.1 kPa – 101.3 kPa (3000-0 m MSL)
Type of protection:	steam sterilisable		IP 20
Minimum operating lifespan	8 years	=	8 years

Store device in a dry place.

The Vibrasat® Pro is subject to particular precautionary measures in terms of EMC and must be installed and commissioned in line with the current EMC instructions.

The Vibrasat® Pro may only be used directly next to or stacked with other devices if the device is constantly monitored.

If the unit cannot be constantly monitored, side-by-side or stacked arrangement is prohibited.

A list of accessories with which the Vibrasat® Pro satisfies the requirements as per 6.1 and 6.2 of IEC 60601-1-2 is provided in the accessories appendix.

Operation of the Vibrasat® Pro with additional accessories such as converters and lines which are not defined as suitable for use with the device can result in increased electromagnetic emissions or reduced interference immunity.

11.3 Electromagnetic emissions

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

Emissions test	**Compliance**	**Electromagnetic environment - guidelines**
High-frequency radiated interference as per CISPR 11	Group 1	The Vibrasat® Pro is suitable for use in all establishments, including domestic establishments and those directly connected to the public power supply network that supplies buildings used for domestic purposes.
High-frequency line-conducted interference as per CISPR 11	Class B	
Harmonic emissions acc. to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions acc. to IEC 61000-3-3	Complies	

11.4 Electromagnetic immunity

The Vibrasat® Pro is suitable for use in the stated electromagnetic environment. Customers or operators of these devices should ensure that they are used in such an environment.

Immunity test / standard	**IEC 60601 - testing level**	**Compliance level**	**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 transient/burst acc. to IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	The quality of the supply voltage should be comparable to that for a typical shop or hospital environment.
Impulse voltage (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, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dips of U_T) for 1 period 40% U_T (60% dips of U_T) for 5 periods 70% U_T (30% dips of U_T) for 25 periods	< 5% U_T (> 95% dips of U_T) for 1 period 40% U_T (60% dips of U_T) for 5 periods 70% U_T (30% dips of U_T) for 25 periods	The quality of the supply voltage should be comparable to that for a typical shop or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field acc. to IEC 61000-4-8	N/A	N/A	N/A
Note: U_T is the AC mains voltage prior to application of the test level.			

Annex

Immunity test / standard	IEC 60601 - testing level	Compliance level	Electromagnetic environment - guidelines
RF conducted disturbance acc. to IEC 61000-4-6 Radiated RF disturbance value acc. to IEC 61000-4-3	3 Veff 150 kHz to 80 MHz 6 Veff in ISM and amateur radio frequency bands between 150 kHz to 80 MHz	3 Veff 150 kHz to 80 MHz 6 Veff in ISM and amateur radio frequency bands between 150 kHz to 80 MHz	Recommended separation distance: 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 Vibrasat® Pro designated by the manufacturer. Non-observance may result in a reduction of the device's performance.
Radiated RF disturbance acc. to IEC 31000-4-3	10 V/m 80 MHz to 2.7 GHz Table 9 of IEC 60601-1-2 Ed.4	10 V/m 80 MHz to 2.7 GHz Table 9 of IEC 60601-1-2 Ed.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.			

a) Field strengths from fixed transmitters, such as base stations for radio 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 at the location where the Vibrasat® Pro is used exceeds the compliance level above, the Vibrasat® Pro should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Vibrasat® Pro.

b) Above the frequency range of 150 kHz to 80 MHz the field strength should be lower than 3 V/m.

The Vibrasat® Pro satisfies all test levels in accordance with IEC60601-1-2 Edition 4 (table 4 to 9).

11.5 Recommended safety distances

Do not operate the Vibrasat® Pro directly next to or stacked with other devices. If operation close to or stacked on other devices is necessary, observe the Vibrasat® Pro to ensure it is operating correctly.

12 Accessories

Sterile consumables

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

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

Catalogue no.: 93003517

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

Catalogue no.: 00003981

Vibrasat® Pro mounting kit

Catalogue no.: 00003973

QuickLock®

Catalogue no.: 92016792

Accessories

Spare parts

Unlocking key with USB port blocker

Catalogue no.: 93006998

Circlip

Catalogue no.: 93007034

(Pack of 10 in a box)

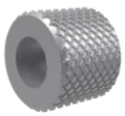
O-ring

Catalogue no.: 93007267

(Pack of 10 in a box)

Lock nut

Catalogue no.: 92016794



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

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The instructions for use are part of the product.