en

INSTRUCTIONS FOR USE

Vibrasat® Pro

The new premium system for liposuction and infiltration

MöllerMedical

IMPORTANT

READ CAREFULLY BEFORE USE

KEEP FOR FUTURE CONSULATION

Contents

Contents

1 General safety information

1.1 Explanation of the safety symbols used

In these instructions for use, important information is indicated visually. These references are prerequisites 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 used in the instructions for use:

Caution! Hazard for patients, operating personnel and third parties.

Information or help

1.1.2 Symbols appearing on the device:

Applied part Type B

Serial number (the first 4 digits indicate the year and month of manufacture in YYMM format)

CE 0482

Conformity in accordance with the Medical Device Directive 93/42 EEC

Observe instruction manual

Manufacturer

Complies with ANSI/AAMI ES 60601-1
CAN/CSA 22.2 No. 60601-1-08

Alternating current

Return and disposal as per the WEEE Directive

O

Device switched off

I

Device switched on

Device selector switch on / standby

Foot switch

	Start/stop button
	Up button to increase the stroke rate
	Down button to lower the stroke rate
	Device connected to superordinate control unit
	Control device warning message

1.1.3 Symbols appearing on the packaging:

	Consult instructions for use
	Catalogue number
	Batch code
	Serial number (the first 4 digits indicate the year and month of manufacture in YYMM format)
	Use by YYYY-MM-DD
	Sterilised using ethylene oxide
	Not suitable for use with MRI
	Single use
	Do not resterilise
	Do not use if package is damaged
	Stacking limit, do not store more than 4 packs high
	Keep dry

	Restriction on relative storage humidity
	Storage temperature limitation
	Manufacturer
CE 0482	Conformity in accordance with the Medical Device Directive 93/42 EEC
	Consult instructions for use
	Applied part Type B
	Keep in a place protected against sunlight
	Caution! Observe transport and storage conditions.
Rx Only	Attention: Under US federal law, this device may be only sold to a physician or ordered by a physician.

1.2 Explanation of the format conventions used

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

Font	**Use**
Bold and italics	Buttons in instructions.
Small capitals	Dialogue fields and submenus in running text.
Italics	Device options, buttons and references to chapter and sections in the running text.

The use of the ***Vibrasat® Pro*** is subject to thorough knowledge and observance of these instructions for use, which are delivered as part of the product. Store the instructions for use for the ***Vibrasat® Pro*** carefully. 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, expansions, resetting, changes or repairs are performed by individuals authorised by the manufacturer.

- The electrical installation in the room in question complies with the relevant 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 other use exept those described in the operating instruction is not intended and will result in an exclusion of warranty and liability

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

1.4 Operator's obligation to exercise diligence

The operator is responsible for the proper operation of the medical device. In line with the German Medical Device 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*** .

Whenever the ***Vibrasat® Pro*** is handled and used, precise knowledge and compliance with these instructions for use is necessary. 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 impaired 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-carrying 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 subject the devices to strong heat or fire.
- Do not subject the devices to hard impacts.
- 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.

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). Anyone who connects additional devices becomes 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 impaired.

1.7 Single use

Reuse of single-use devices creates a potential risk of patient or user infections. 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 the used single-use product 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 (user)

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.

2 Intended use

2.1 Proper use – intended use Vibrasat® Pro

The ***Vibrasat® Pro***, consisting of the control unit and a handle with a connecting cable has the intended use to vibrate cannulas n particular to support the hand movement of the user.

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*** does not have any 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

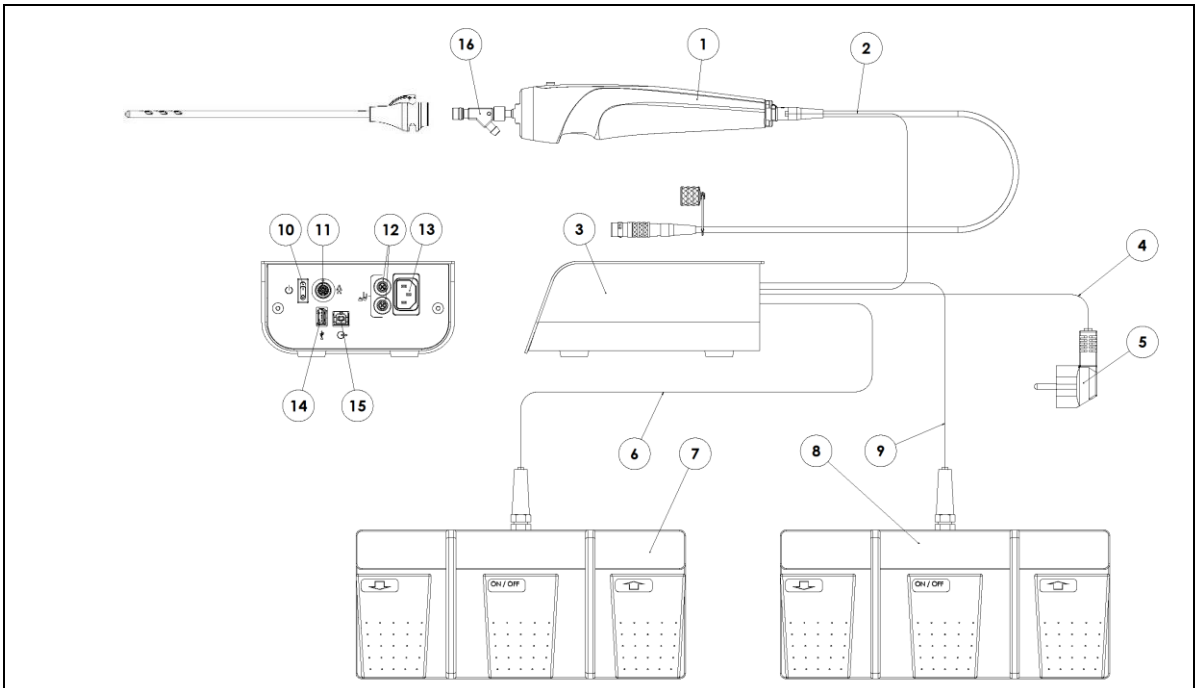


Figure 1

1	***Vibrasat® Pro Wand*** handle	9	Foot switch cable
2	***Vibrasat® Pro Wand*** connecting cable	10	On / Off switch
3	***Vibrasat® Pro Console*** control device	11	Connection socket for ***Vibrasat® Pro Wand***
4	Mains cable	12	Connection sockets for foot switch
5	Mains plug	13	Mains input socket
6	Foot switch cable	14	USB socket, service interface
7	Foot switch	15	USB socket
8	Foot switch	16	***Vibrasat® QuickLock*** cannula holder

3.1 Vibrasat® Pro Wand (handle)

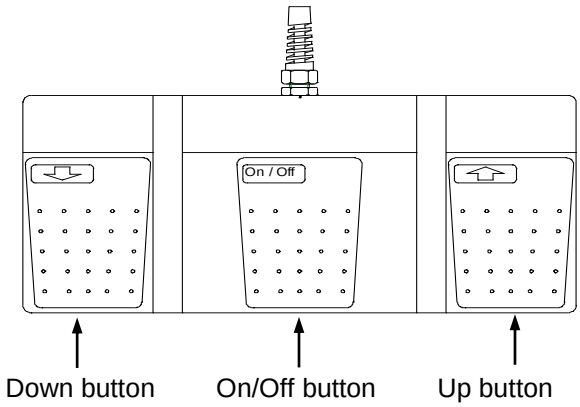
The ***Vibrasat® Pro Wand*** handle (*Figure 1*, *Point 1*) transfers very rapid vibrations in an axial direction to a cannula connected to the handle and thus supports the user's hand movements.

3.2 Vibrasat® Pro Console

The ***Vibrasat® Pro Console*** (*Figure 1, Point 3*) is the control unit for the ***Vibrasat® Pro***. There is an On / Off switch on the rear of the device for the device standby mode and for the device interfaces for the foot switch (2 foot switches can be operated simultaneously) ***Vibrasat® Pro Wand*** and mains plug. All the application parameters are controlled using the capacitive buttons on the front of the ***Vibrasat® Pro Console*** .

The ***Vibrasat® Pro Console*** software can be updated using the USB interface on the rear (*Figure 1, Point 14)*. It must be noted that this is a service interface. The procedure is described in *Chapter 8*.

3.3 Foot switch



The foot switches (*optionally available as accessories*) can be set in the same way as the buttons on the ***Vibrasat® Pro Console***.

Both foot switches behave identically.

Both connection sockets on the rear are equal.

3.4 Cannulas

Only the designated Möller Medical GmbH cannulas may be attached to the ***Vibrasat® Pro Wand*** handle. An up-to-date list of the available cannulas can be found in our Brochure or on our website www.moeller-medical.com.

4 Setup and commissioning

Make sure that the box is not damaged on delivery to you. The forwarder 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 scope of supply

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

Packaging unit ***Vibrasat® Pro Console***:

- 1 ***Vibrasat® Pro* Console**
- 1 mains cable
- 1 USB service interface release key
- 1 instructions for use

Packaging unit ***Vibrasat® Pro Wand***

- 1 ***Vibrasat® Pro Wand***
- 1 cannula holder
- 10 O-rings (not sterile)
- 1 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

  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 aircrafts 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 cannula holder must be processed as per the reprocessing instructions provided by the manufacturer.

If the devices ***Vibrasat® Pro Console*** and ***Vibrasat® Pro Wand*** had been exposed to temperature or humidity fluctuations during transport or other change of place, they need to rest for at least 2 hours in the operating environment before restart.

- Place the ***Vibrasat® Pro Console*** on a suitable, stable surface or, if available, use the ***Vibrasat® Pro*** fastening kit. Fasten the fastening kit to a standard rail. Put the ***Vibrasat® Pro Console*** on the plate and secure it to the fastening kit using the screw supplied.
- Connect the foot switch (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 On / Off 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 cannula holder to the handle ***Vibrasat® Pro Wand.***

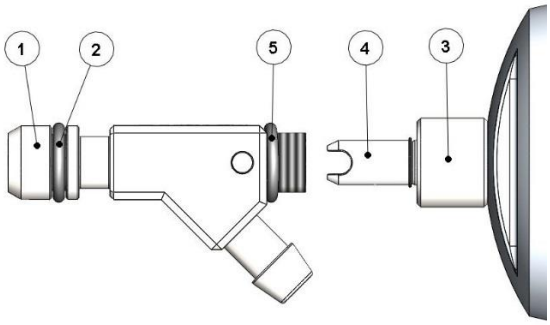


Figure 2

1. Push the cannula holder (*Figure 2, Point 1*) onto the fork-shaped pin on the handle (*Figure 2, Point 4*). The tube connection can be aligned upwards or downwards as required. The alignment of the tube connection can be rotated by 180° if necessary. The O-rings (Figure 2*, Point 2 and 5*) must be in perfect condition.
2. Attach the cannula holder by tightening the lock nut (*Figure 2, Point 3*) against the O-ring by hand.

The cannula holder must be locked into place!

The O-ring prevents the nut from becoming loose during use. Do not use tools. The use of tools damages the device.

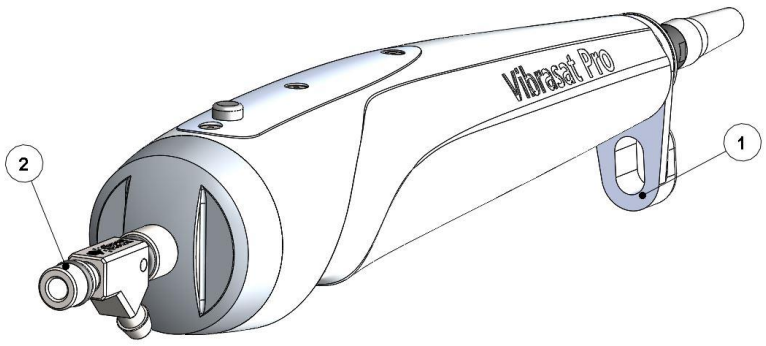


Figure 3

- Attach a suitable suction tube (available as an accessory) on the cannula holder.
  1. Push the tube through the tube holder on the rear end of the handle (*Figure 3, Point 1*).
  2. Attach the suction tube to the tube connection of the cannula holder (*Figure 3, Point 2*).

Figure 4

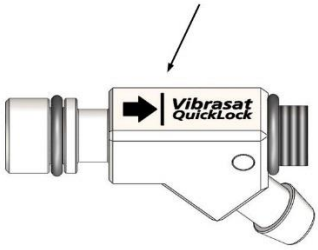


Figure 5

- Connect a suitable cannula for the application to the cannula holder. For this, hold the lock (*Figure 4, Point 1*) pressed down whilst attaching until the square of the cannula hold locks into place. Then push the cannula at the attachment further, beyond the marked line (*Figure 5*), until it audibly clicks into place.

The ***Vibrasat® Pro*** is now ready for use.

4.4 Disassembly

- Press the unlocking button on the cannula attachment and pull the cannula out of the cannula holder.
- Firstly pull the suction tube out of the cannula holder and then out of the tube holder.
- Turn the lock nut of the cannula holder anticlockwise vis-à-vis the handle ***Vibrasat® Pro Wand*** and push the released nut up to the handle housing.
- Pull the cannula holder off the handle.
- Pull the connecting cable of the ***Vibrasat® Pro Wand*** off the ***Vibrasat® Pro Console***.

After each use, the ***Vibrasat® Pro Console*** must be processed as per the hygiene guidelines (see *Chapter 6*) and the ***Vibrasat® Pro Wand*** must be processed as per the reprocessing instructions provided by the manufacturer.

5 Application and operation

Always note:

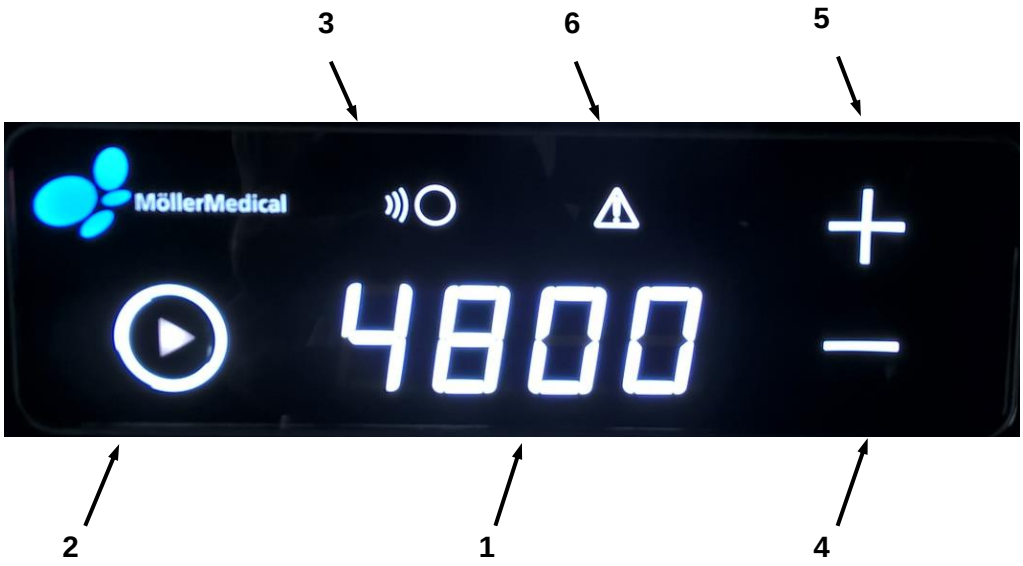
- The handle may only be loaded in an axial direction.
- The device switches off for safety reasons if subjected to excessive radial force.
- Large radial forces will damage the handle.
- If the cannula holder (connection for suction tube and suction cannula) is subjected to excessive forces, the handle will be damaged.
- 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 On / Off switch on the rear, a brief display test is performed. After starting, the display shows the last set value when the device was switched off (stroke rate per minute = vibration speed).

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. A description of this can be found in *Chapter 5.2.1.1.*

5.1.1 Display



1. **Segment display** shows the set stroke rate per minute
2. **Start / Stop** – vibration button ON/OFF
3. **Signal display** – connected to the superordinate control unit
4. **Minus** - button to lower the stroke rate
5. **Plus** - button to increase the stroke rate
6. **Warning** – in the event of malfunctions (e.g. handle is not connected)

5.2 Operation

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

5.2.1 Setting the vibration speed *Vibrasat® Pro Wand*

Setting the desired vibration speed in strokes per minute. The setting can be made at any time with one of the following actions:

- Press the Plus / Minus buttons on the ***Vibrasat® Pro Console***
- Press the Up / Down buttons on the foot switch

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

5.2.1.1 Boost function

The boost function can only be activated on the ***Vibrasat® Pro Wand*** .

Press the button on the ***Vibrasat® Pro Wand*** for longer than 2 seconds to start the boost with 6000 strokes per minute for max. 1 minute. The button must remain pressed during this time. The device then switches automatically to the last set vibration speed.

6000 is shown briefly on the ***Vibrasat® Pro Console***. 60 s is then decremented on the display. If during the boost, the foot switch or play button on the ***Vibrasat® Pro Console*** is pressed, the vibration is switched off and the 60 s timer is reset. The timer is also reset if the button on the ***Vibrasat® Pro Wand*** is released within 60 seconds.

Repeat activation of the boost function can cause the temperature of the handle to rise.

5.2.2 Vibration control

Switching the cannula vibration on and off:

- Press the Start / Stop button on the ***Vibrasat® Pro Console***
- Press the button on the ***Vibrasat® Pro Wand***
- Press the On / Off button on the foot switch

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

5.2.3 Warning notices

If prohibited operating states occur during vibration, the ***Vibrasat® Pro Wand*** is switched off and a corresponding warning ID is shown on the display. In addition, the warning symbol is displayed.

The error must be acknowledged with the Start / Stop button and the vibration switched on before the ***Vibrasat® Pro Console*** switches on the ***Vibrasat® Pro Wand*** again.

Alternatively switch the ***Vibrasat® Pro Console*** off and on again.

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

Warning displays

Warning ID	Error description	Solution
100	Motor speed does not correspond to set value	Reduce the load and check that the ***Vibrasat® Pro Wand*** is running smoothly.
106 - 108	Device initialisation failed	Contact the service centre.

6 Cleaning and care

6.1 *Vibrasat® Pro Wand*

You will find all the information on processing the ***Vibrasat® Pro Console*** in the following section. The reprocessing of the handle ***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*

- 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 display 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 power switch. Check the power supply, possibly switch on multiple sockets, check supply lines.
Drive plunger still not functioning	The handle connecting cable is not connected. Check the plug connection.
Foot switch does not react	The connecting cable for the foot switch is not connected. Check the plug connection.
If none of the measures described are successful, contact the Möller Medical GmbH service centre.	

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.

Service:

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

Möller Medical GmbH service centre:

Möller Medical GmbH
Wasserkuppenstrasse 29-31
36043 Fulda, Germany

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

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

8.1 Software update

- Observe the order of the update. Deviations can result in the software update being cancelled or unsuccessful.

Service

The ***Vibrasat® Pro Console*** software can be updated via the USB service interface on the rear. To update, proceed as follows:

1. Disconnect the ***Vibrasat® Pro Console*** from the power supply. Switch the mains switch on the rear of the ***Vibrasat® Pro Console*** to ON.
2. Remove the protective cap from the USB service interface using the USB release key.
3. Copy the firmware made available by the service centre to a USB stick. The USB stick must be empty and may only contain the firmware file (without subdirectories).
4. Insert the USB stick into the USB service interface.
5. Connect the ***Vibrasat® Pro Console*** to the power supply and observe the display.
6. The display briefly shows “UPd” followed by a sequence from “U1” to “U5”.
7. If the update was successful, “IO” is shown as the final display. If the update was not successful, the respective update warning is shown (see table below) and the old firmware is retained on the device. If a warning is shown, check the update steps or contact the service centre.
8. Following a successful update, disconnect the ***Vibrasat® Pro Console*** from the mains.
9. Remove the USB stick and close the service centre using the USB cover.
10. Makes sure that the On/Off switch is set to On and connect the ***Vibrasat® Pro Console*** to the mains. Observe the display.
11. Note the software version displayed. If it does not correspond with the update, repeat the steps above.
12. The ***Vibrasat® Pro Console*** is now updated.

Display of update warning

Update warning ID	Error description	Solution
1	The firmware on the USB stick is not valid firmware.	Check the transferred firmware.
2 - 8	Transfer of the firmware to the ***Vibrasat® Pro Console*** failed.	Contact the service centre.
9, 10	The serial number of the firmware is incorrect.	Contact the service centre.

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 this device. 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 device is disposed of in compliance with the national requirements of the WEEE Directive.

11 Appendix

11.1 Key technical data

Article number

Catalogue number ***Vibrasat® Pro***	REF 00003920
Catalogue number ***Vibrasat® Pro Wand*** (handle)	REF 00003922
Catalogue number ***Vibrasat® Pro Console*** (control unit)	REF 00003921

Dimensions

Vibrasat® Pro Console	Width x height x depth = 170 mm x 90 mm x 205 mm
Vibrasat® Pro Wand	Diameter x length = 52 mm x 300 mm

Weight *Vibrasat® Pro*

Vibrasat® Pro Wand	approx. 0.7 kg
Vibrasat® Pro Console	approx. 1.2 kg

Surface temperature of applied part

Vibrasat® Pro Wand	< 43°C with given duty cycle
Duty cycle	The device is designed for a duty cycle of 30 minutes with a subsequent break of 60 minutes. This cycle may be repeated as often as necessary.

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:

Exposure to shocks	< 2.5 ahv(m/s2)
Noise emission value	< 75 (dB(A))

11.2 General data

Transport and storage instructions:

Temperature	-10°C to +50°C
Air humidity	Less than 90% relative humidity

Weight with packaging:

Dimensions ***Vibrasat® Pro Wand*** with packaging:	Width x height x depth: 400 mm x 85 mm x 190 mm
Dimensions ***Vibrasat® Pro Console*** with packaging	Width x height x depth: 297 mm x 145 mm x 228 mm

Store device in a dry place.

Operating conditions:

Temperature	+10°C to + 25°C
Air humidity	30 to 75% relative humidity

Protection type

Vibrasat® Pro Console	IP 20
Vibrasat® Pro Wand	steam sterilisable

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*** must not be stacked or set up next to or with other devices.

If operation close to or stacked on other devices is necessary, the ***Vibrasat® Pro*** must be observed in order to check proper operation with this set-up.

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*** series devices are suitable for use in the stated electromagnetic environment. Customers or operators of these device should ensure that they are used in such an environment.

Immunity test / standard	**IEC 60601 - testing level**	**Compliance level**	**Electromagnetic environment - guidelines**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Rapid transient electrical disturbances/ bursts IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input and output lines	±2 kV for power supply lines ±1 kV for input and output lines	The quality of the supply voltage should be comparable to that for a typical shop or hospital environment.
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 IEC 61000-4-11	< 5 % U_T (> 95% dip in U_T) for 1 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles	< 5 % U_T (> 95% dip in U_T) for 1 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles	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.

Appendix

Immunity test / standard	**IEC 60601 - testing level**	**Compliance level**	**Electromagnetic environment - guidelines**
Magnetic field in power supply frequency (50/60 Hz) IEC 61000-4-8	N/A	N/A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. The device contains sensitive components.
Note: U_T is the AC mains voltage prior to application of the test level.			
RF conducted disturbance acc. to IEC 61000-4-6 Radiated RF disturbance acc. to IEC 61000-4-3	3 Veff 150 kHz to 30 MHz 6 Veff in ISM and amateur radio frequency bands between 150 kHz to 80 MHz	3 Veff 150 kHz to 30 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*** meets all test levels according to IEC60601-1-2 Edition 4 (Tables 4 to 9).

11.5 Recommended safety distances

Do not operate the devices of the ***Vibrasat® Pro*** series directly next to or stacked with other devices. If operation close to or stacked on other devices is necessary, observe the devices in the ***Vibrasat® Pro*** series to ensure they are operating correctly.

11.6 Accessories

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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