

INSTRUCTIONS FOR USE en

Thermia Pro mounted ***Thermia Pro stand-alone***



IMPORTANT

READ CAREFULLY BEFORE USE

KEEP THESE INSTRUCTIONS FOR FUTURE CONSULTATION

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1 General safety instructions

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 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

1.1.2 Symbols appearing on the device



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



Follow instructions for use



Manufacturer



Direct current



Return and disposal as per the WEEE Directive



Protection class II



Catalogue number



Standby switch



USB host

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Input connection for external power supply



Heat emission, general
(Connection for Heating Tray)

1.1.3 Symbols on the retail packaging



Consult instructions for use



Catalogue number



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



Do not use if packaging is damaged



Keep dry



Humidity, limitation



Temperature limit



Manufacturer



Keep away from sunlight



Contains or presence of phthalates



Caution



Stacking limit, do not store more than 3 packs high

General safety instructions



Attention: Under US Federal law, this device may be only sold to a physician or ordered by a physician.

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

1.2 Explanation of the format conventions used

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

Font	Use
<i>Bold and italics</i>	Buttons in instructions.
<i>Italics</i>	Device options, buttons and references to chapter and sections in the running text.

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 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 obligation to exercise diligence

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 assume responsibility when handling medical devices within the framework of his activities. Only qualified personnel may operate the devices in the **Thermia Pro** series. Whenever the devices in the **Thermia Pro** series are 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.

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The devices in the Thermia Pro series 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.

The user must decide whether the patient's body temperature is to be monitored and at what intervals to avoid medical risks for example (hypothermia, hyperthermia etc.).



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

1.5 Warning notices



- The devices must not be modified.
- No liquids must be allowed to penetrate the voltage-carrying parts of the devices.
- When cleaning, ensure that no cleaning agent runs into the connector sockets.
- Disconnect the power cable before cleaning.
- 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.
- Tighten the plug connections as securely as possible using your hands. Do not use tools.
- 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.

General safety instructions

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 the additional devices is responsible for configuring the system and for ensuring that the current version of the system requirements satisfy standard IEC 60601-1.



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

1.7 Declaration on DEHP

The devices in the **Thermia Pro** series do not contain (2-ethyhexyl), phthalates (DEHP).

1.8 Precautionary measures

Clean and disinfect all reusable components of the devices in the **Thermia Pro** series as per the instructions (see *chapter 7*) and replace all the disposable components before using the devices on another patient.

1.9 Target group (users)

These devices should only be used by doctors with experience in human medicine who also have sufficient experience in the use of infusion solutions in medical applications.

2 Intended use

The heating trays from Möller Medical GmbH are intended to be used to avoid solutions to become hypothermic. The heating trays are used in aesthetic body contouring and other medical applications.

2.1 Contraindications

- No contraindications are stated for the devices in the **Thermia Pro** series.

2.2 Complications

- Hyperthermia
- Hypothermia
- Death

2.3 Essential performance features

The devices of the **Thermia Pro** series have no key performance characteristics.

2.4 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.

Product description

3 Product description

3.1 Thermia Pro Console

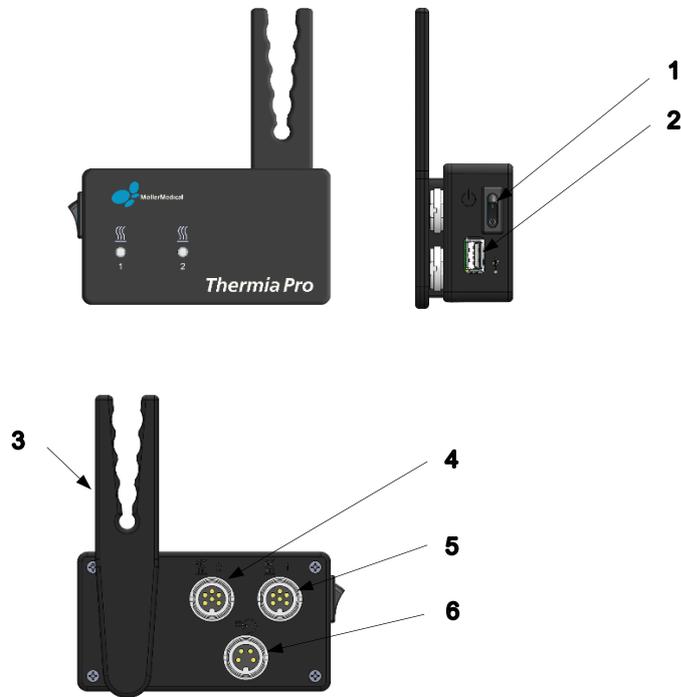
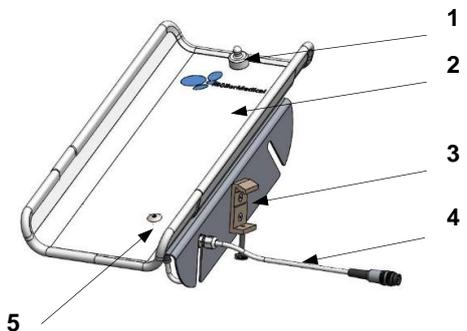


Figure 1

- 1 Standby switch
- 2 USB interface
- 3 Holder for cable
- 4 Connection socket for Heating Tray
- 5 Connection socket for Heating Tray
- 6 Mains input socket

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3.2 Thermia Pro Heating Trays mounted



Heating Tray left

Figure 2



Heating Tray right

Figure 3

- 1 Suspension system for saline bag
- 2 Heating Tray
- 3 Assembly / clamping device
- 4 Connecting cable to **Thermia Pro** Console
- 5 Temperature sensor

3.3 Thermia Pro Heating Tray stand-alone

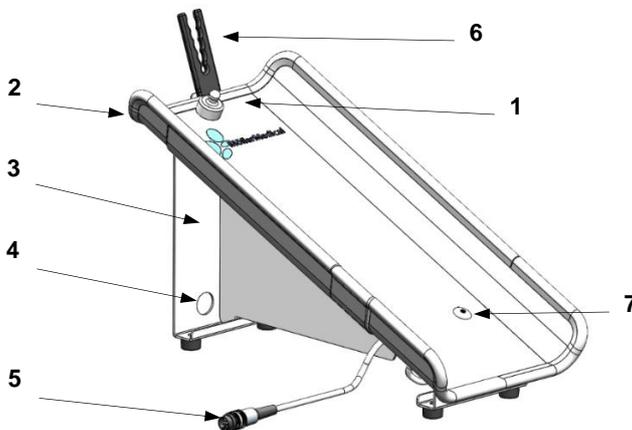


Figure 4

- 1 Suspension system for saline bag
- 2 Heating Tray
- 3 Supporting foot
- 4 Hole for connecting cable to **Thermia Pro** Console
- 5 Connecting cable to **Thermia Pro** Console
- 6 **Thermia Pro** Console holder
- 7 Temperature sensor

Setup and commissioning

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 boxes are not damaged upon 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.

4.2 Unpacking the device and checking the scope of supply

The **Thermia Pro** mounted is delivered in 2 packaging units. Make sure that no parts remain in the packaging when unpacking.

Scope of delivery:

1 packaging unit	1 packaging unit
<ul style="list-style-type: none"> • 1 Thermia Pro Console • 1 USB release key • 1 power supply • Right tube holder (incl. assembly material) • 4 adapters • 1 set of instructions for use in German • 1 set of instructions for use in English 	<ul style="list-style-type: none"> • 1 Thermia Pro Heating Trays mounted (2 Heating Trays: right, left) • 1 set of instructions for use in German • 1 set of instructions for use in English

The **Thermia Pro** stand-alone is delivered in 4 packaging units. Make sure that no parts remain in the packaging when unpacking.

Scope of delivery:

1 packaging unit	2 packaging units	1 packaging unit
<ul style="list-style-type: none"> • 1 Thermia Pro Console • 1 USB release key • 1 power supply • Right tube holder (incl. assembly material) • 4 adapters • 1 set of instructions for use in German • 1 set of instructions for use in English 	<ul style="list-style-type: none"> • 1 Thermia Pro Heating Tray stand-alone • 1 set of instructions for use in German • 1 set of instructions for use in English 	<ul style="list-style-type: none"> • 1 Thermia Pro Console holder (pre-mounted) • Screw set



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.

4.3 Suitable operating environment

The devices in the **Thermia Pro** series devices are suitable for use 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 devices in the **Thermia Pro** series 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

See chapter 4.3 "Suitable operating environment".

Setting up

5 Setting up

5.1 Setting up the Thermia Pro mounted

The Heating Trays mounted may only be used in combination with the **Vacusat® power**.



Operation without the fastening on the **Vacusat® power** is not permitted.

5.1.1 Setup on the Vacusat® power



Prepare the devices in the **Thermia Pro** mounted series prior to initial use as per the instructions for use (see *chapter 7*).

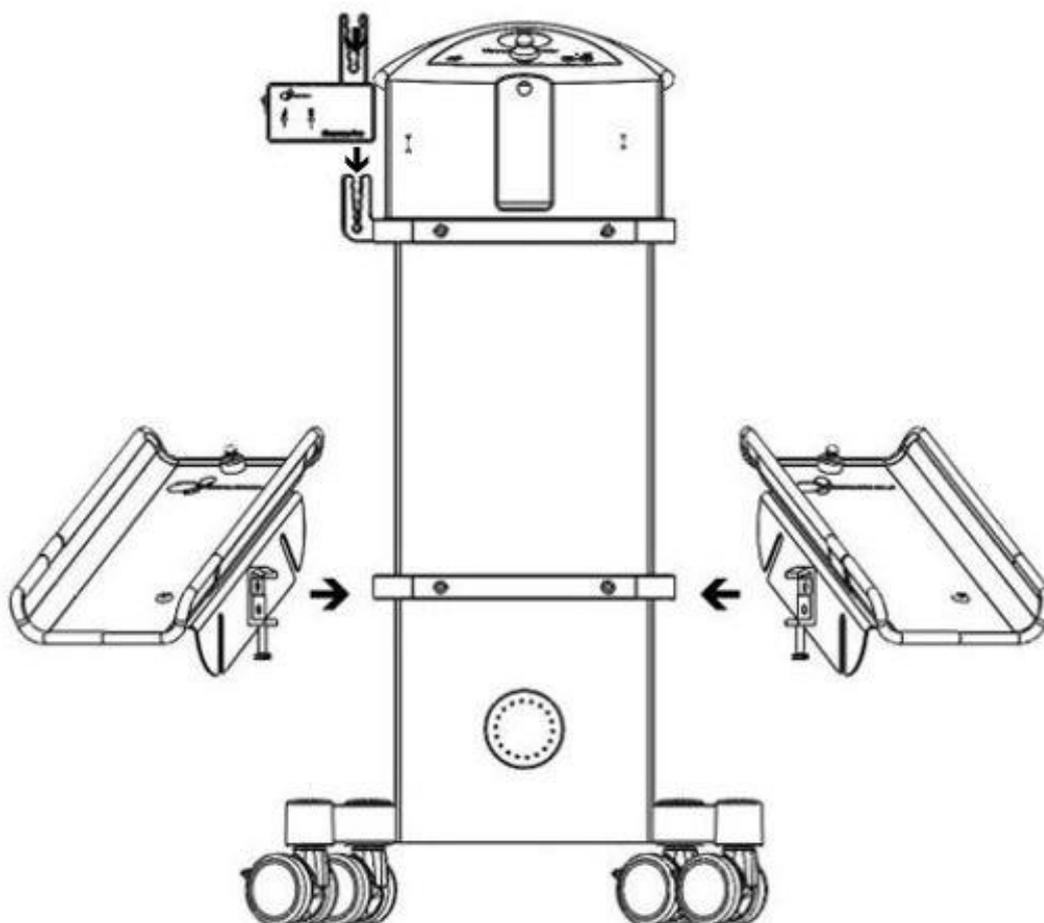


Figure 5

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1. Remove the **Thermia Pro** Console from the packaging and suspend it in the tube holder of the **Vacusat® power** (see Figure 6).

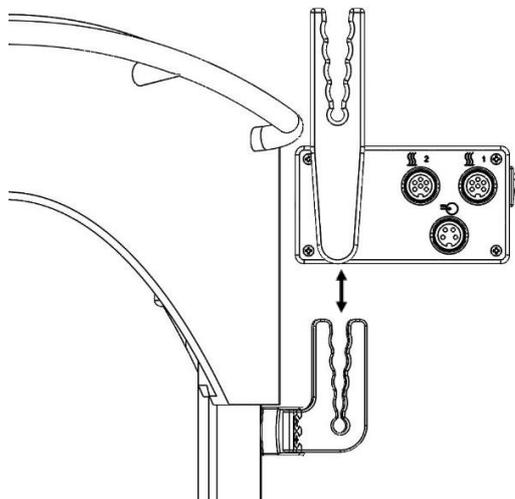


Figure 6

If there is no tube holder on the **Vacusat® power**, attach this beforehand as shown in Figure 7.

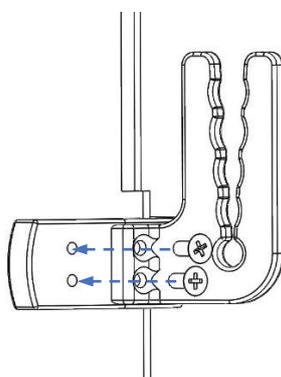


Figure 7

2. Connect the power supply to the back of the **Thermia Pro** Console housing and insert the plug into the socket. If the plug on the power supply does not match the country-specific sockets, this can be changed. To do this, press the button on the power supply adapter and push this upwards. Then install the right plug for the available socket type in the power supply.



- Only use the power supply provided.
- Note the voltage values given on the device's rating plate.

Setting up

3. Take the **Thermia Pro** Heating Trays mounted out of the packaging and secure one on the right and one of the left of the clamping rail of the **Vacusat® power** (see *Figure 5*).
4. Insert the connecting cables of the Heating Trays (see *Figure 2*, position 4) into the corresponding connection socket of the **Thermia Pro** Console (see *Figure 1*, position 4 or 5).
5. Make sure that the Heating Trays are properly seated.

5.2 Setting up the Thermia Pro stand-alone



Prepare the devices in the **Thermia Pro** stand-alone series prior to initial use as per the instructions for use (see *chapter 7.1*).

1. Take the Heating Trays of the **Thermia Pro** stand-alone out of the packaging and place on a suitable firm surface.
2. Take the pre-mounted **Thermia Pro** holder with the respective screws out of the packaging and assemble these on any Heating Tray (see *Figure 8* and *Figure 9*).
3. Remove the **Thermia Pro** Console out of the packaging and suspend in the console holder of the Heating Tray (see *Figure 10*). Connect the power supply to the back of the Console housing and insert the plug into the socket.
4. Insert the connecting cables of the Heating Trays (see *Figure 4*, position 5) into a corresponding connection socket of the **Thermia Pro** Console (see *Figure 1* position 4 or 5).

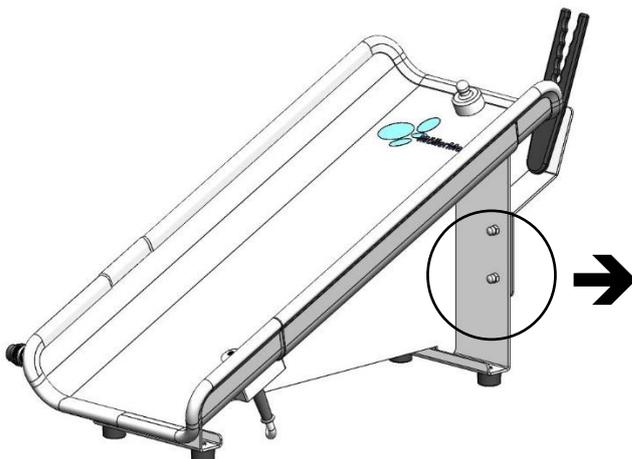


Figure 8

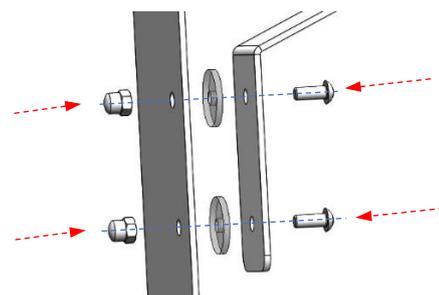


Figure 9

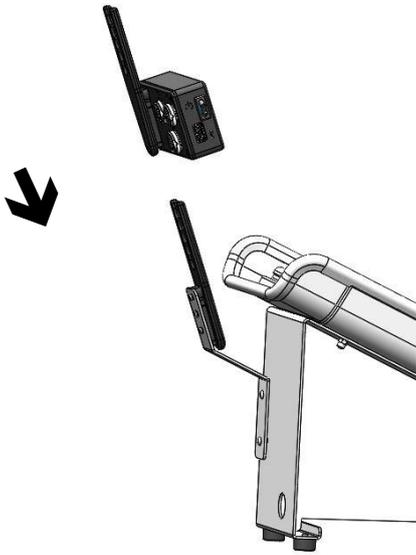


Figure 10

Startup

6 Startup

Before commissioning, the devices in the **Thermia Pro** series must be processed as per the hygiene guidelines (see *chapter 7.1*).



If the devices in the **Thermia Pro** series are subject to temperature and humidity fluctuations during transportation or other changes in location, the devices must be allowed to acclimatise for at least 2 hours before being put into service.

Note the following when setting up the devices in the **Thermia Pro** series:

- a sufficient distance from other devices is maintained. the devices require a space of at least 30 cm in height and width.
- the device can be turned off via the Standby switch and disconnected from the mains by unplugging the mains cable.
- the devices are not operated in the direct proximity of or stacked with other devices as this may result in faulty operation. If operation as described above cannot be avoided, monitor the devices in the **Thermia Pro** series and other devices to verify proper use.

Always note:



- All handling of the device requires precise knowledge and compliance with these instructions for use.
- The devices may only be used by specialist staff.

When setting up the **Thermia Pro** Heating Trays mounted and **Thermia Pro** Heating Trays stand-alone note the following:



- Check the Heating Trays for the saline bags for mechanical damage each time before use.
- The Heating Trays feature a bag holder which allows the saline bag to be positioned safely. Ensure that the saline bag used has a compatible mount.
- When preheating, make sure that the liquid temperature is not above 37°C ($\pm 1.5^\circ\text{C}$).
- The Heating Trays serve to maintain the temperature.
- The Heating Trays do not heat up the saline solution from a low level.
- The Heating Tray temperature sensors record the temperature of the saline solution.
 - For this, place the saline bag in the Heating Tray at least 5 minutes before use. Make sure that the entire surface of the bag is positioned on the temperature sensor and that there are no other objects between the temperature sensor and the bag as this could otherwise impede temperature recording.

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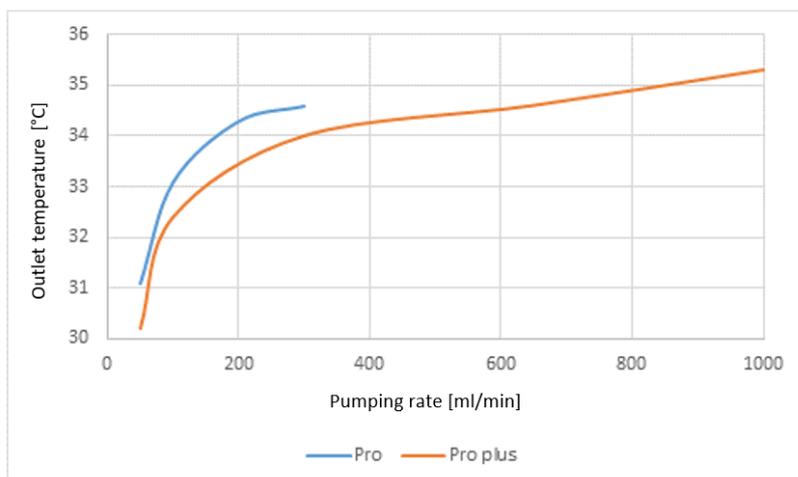
Recorded outlet temperatures of the saline solution at the hose outlet (cannula)

The following were checked:

REF 00004255	Thermia Pro stand-alone	+	REF 00004255	Thermia Pro stand-alone
REF 00003977	Liposat® Pro		REF 00003974	Liposat® Pro plus
REF 00002251	Tube sets for tumescent pump		REF 00003997	TLA Tubing Liposat® Pro plus

The tests were performed at room temperature, 24°C.

Delivery rate [ml/min]	Pro [°C]	Delivery rate [ml/min]	Pro plus [°C]
50	31.1	50	30.2
100	33.1	100	32.4
200	34.3	300	34
300	34.6	650	34.6
		1000	35.3



Startup

Either one or two Heating Trays can be connected to the **Thermia Pro** Console. Application is the responsibility of the user.

Thermia Pro mounted

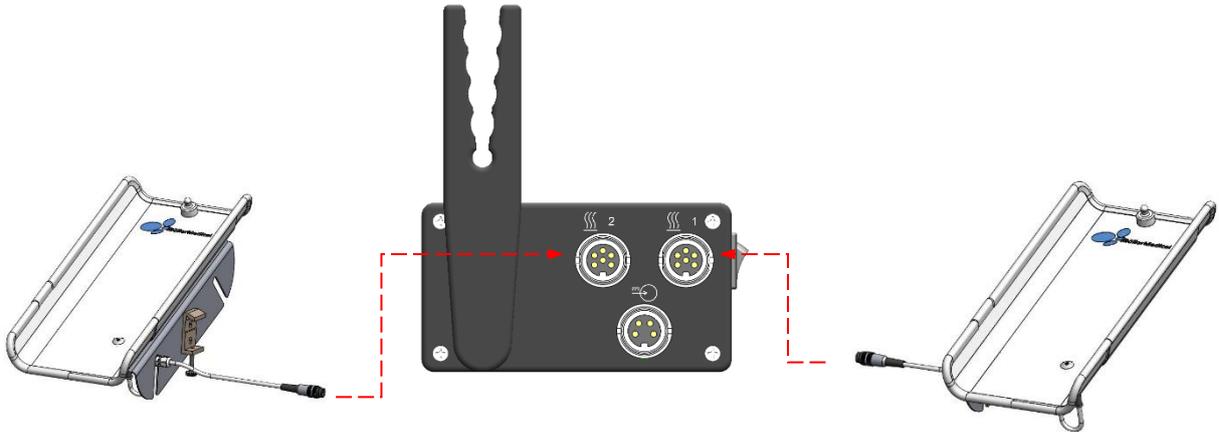


Figure 11

Thermia Pro stand-alone

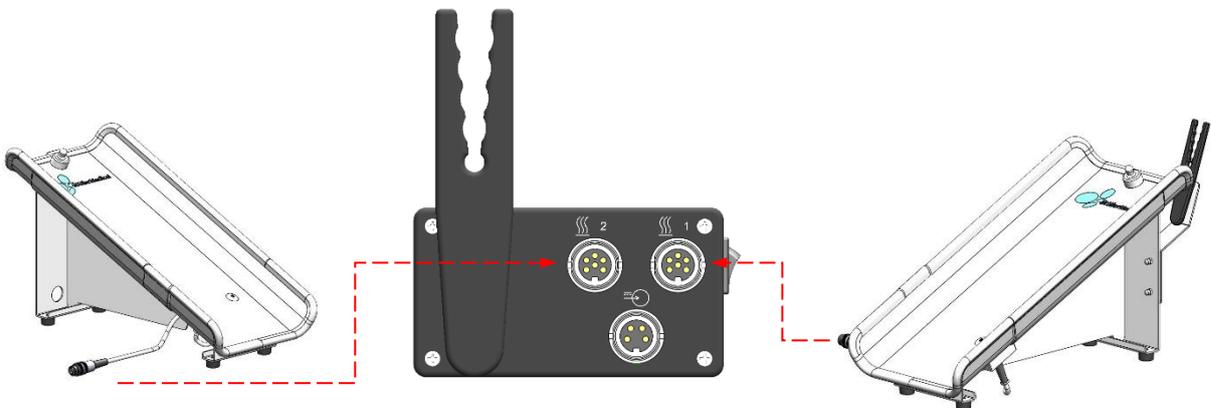


Figure 12

The standby switch switches all connected Heating Trays on or off simultaneously.

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Figure 13

The Heating Tray function is displayed via two LEDs on the front. A white LED signals that the Heating Tray is ready for use and there are no errors.

7 Cleaning and care

7.1 Cleaning and disinfection



- No moisture may 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.
- Sterilisation processes such as autoclaving and ethylene oxide sterilisation render the devices unusable.

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

After cleaning, disinfect the surfaces of the devices in the **Thermia Pro** series 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 free of all types of dirt.

8 Help in the event of a fault



The devices in the **Thermia Pro** series must not be opened by the user!

This chapter describes certain problems which may occur in conjunction with the devices. When establishing or undoing plug connections, the devices in the **Thermia Pro** series must always be switched off.

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

Problem	Solution
No function.	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.
Moisture has entered the plug.	Pull the plug off the device and out of the socket. Allow the plug to dry.
One LED remains dark	The corresponding Heating Tray was not detected. Check the plug connection.
One LED lights up yellow	The corresponding temperature sensor has recorded a temperature more than 42°C (±1.5°C). Stop the application and allow the infiltration solution to cool down.
Should these measures not prove successful, the device is to be checked by the Möller Medical GmbH service team.	

9 Service



Before disposing of or returning the devices of the **Thermia Pro** series, a suitable disinfection procedure must be carried out to rule out the risk of possible 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

www.moeller-medical.com

info@moeller-medical.com

Service

E-Mail: service@moeller-medical.com

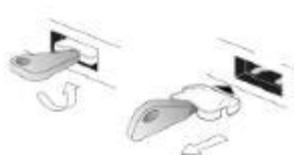
9.1 Software update Thermia Pro Console



- When updating, it is important to carry out the steps in the right order. Deviations can cause the process to be discontinued and prevent successful completion of the software update.

The **Thermia Pro** Console software can be updated via the USB service interface on the side of the device (see *Figure 1*). To update, proceed as follows:

1. Disconnect the **Thermia Pro** Console from the power supply. Switch the standby switch on the side of the **Thermia Pro** Console to **ON**.
2. Remove the protective cap from the USB service interface using the USB release key. For this, turn the key anticlockwise (see *Figure 14*).



Be careful as the key can break.

Figure 14

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 **Thermia Pro** Console to the power supply and observe the LEDs.
6. The LEDs light up alternately in white whilst the update is ongoing.
7. If the update was successful, both LEDs light up green at the same time. If the update was not successful, both LEDs flash in yellow and the old firmware is retained on the device. Check the update steps, refer to *chapter 9.1.1 "First aid"* to establish what the cause of a faulty update could be or contact the service centre.
8. Following a successful update, disconnect the **Thermia Pro** Console from the mains.
9. Remove the USB stick and close the USB service interface using the USB cover.
10. Make sure that the standby switch is set to On and connect the **Thermia Pro** Console to the mains. Observe the LEDs.
11. Should the device not behave as described above, repeat the previous steps.
12. The **Thermia Pro** Console is now updated.

Service

9.1.1 “First aid”

The update was not successful

- Was the firmware file copied correctly on the USB stick?
 - If necessary, unzip the firmware file and copy again onto the USB stick.
- Was the voltage disconnected briefly whilst the firmware was being installed?
 - Install the firmware again as described.
- Was the USB stick detected correctly?
 - Copy the firmware onto another USB stick and try the update again.

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 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.

Annex

11 Annex

11.1 Technical data

Catalogue no.

Thermia Pro mounted	REF 00004253
Thermia Pro stand-alone	REF 00004255
Thermia Pro Console	REF 00004249
Thermia Pro Heating Trays mounted (2 pieces in set)	REF 00002542
Thermia Pro Heating Trays stand-alone (2 pieces in set)	REF 00002286

Thermia Pro Console

Dimensions	Length x width x height: 118 mm x 135 mm x 43 mm
Weight without packaging (incl. power supply)	ca. 0.4 kg

Thermia Pro Heating Trays mounted

Dimensions	Length x width x height: 463 mm x 213 mm x 132 mm
Weight	ca. 1,9 kg per Heating Tray

Thermia Pro Heating Trays stand-alone

Dimensions	Length x width x height: 432x mm x 204 mm x 259 mm
Weight without packaging	ca. 2.7 kg

Electrical connection of the external power supply of the Thermia Pro Console

Voltage	100 – 240 V AC
Frequency	50 / 60 Hz
Current consumption	1.5 – 0.8 A

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Safety

Protective class	II
------------------	----

Electrical connection of the *Thermia Pro* Console

Voltage	24 VDC (DC voltage)
Current consumption	Max. 2.5 A

Safety

Protective class	II
------------------	----

11.2 General data

Transport and storage instructions:

Temperature	-10 °C to +50 °C
Air humidity	Less than 90 % relative humidity
Thermia Pro Console	Width x height x depth:
Dimensions with packaging:	300 mm x 110 mm x 210 mm
Thermia Pro Heating Trays mounted	Length x width x height:
Dimensions with packaging:	540 mm x 300 mm x 300 mm
Thermia Pro Heating Trays stand-alone	Length x width x height:
Dimensions with packaging:	540 mm x 300 mm x 300 mm

Store the packaged devices in a dry place.

A stack of packed devices may consist of max. 3 packages.

Operating conditions for the devices in the *Thermia Pro* series:

Temperature	+10 °C to +30 °C
Air humidity	30 to 75% relative humidity
Atmospheric pressure	790 hPa – 1050 hPa (0-3000 m MSL)
Minimum operating lifespan	8 years

Electromagnetic compatibility

12 Electromagnetic compatibility

12.1 Electromagnetic emissions

The **Thermia Pro** series devices are suitable for use in the stated electromagnetic environment. The customer and/or operator of the devices of the **Thermia Pro** series 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 devices of the Thermia Pro series must emit electromagnetic energy. Electronic devices in the vicinity could be influenced.
High frequency emitted interference acc. to CISPR 11	Class B	For areas of application, see <i>chapter 4.3</i> „ Suitable operating environment “
Harmonic emissions acc. to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker acc. to IEC 61000-3-3	Complies	

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12.2 Electromagnetic immunity

Immunity test	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%.
Fast transient electrical disturbance values/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.
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.

Electromagnetic compatibility

Immunity test	IEC 60601 - testing level	Compliance level	Electromagnetic environment - guidelines
Note: U_T is the AC mains voltage prior to application of the test level.			

The devices of the **Thermia Pro** series 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 devices of the **Thermia Pro** series by the manufacturer. Non-observance may result in a reduction of the device's performance.



Operation of the devices of the **Thermia Pro** series 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 considered as they have not been tested.

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Electromagnetic immunity/standard	IEC 60601-test level	Compliance level	Electromagnetic environment - guidelines
Conducted RF acc. to IEC 61000-4-6	3 V _{eff} 150 kHz to 30 MHz 6 V _{eff} in ISM and amateur radio frequency bands between 150 kHz and 80 MHz	3 V _{eff} 6 V _{eff}	Portable and mobile radio transmitting devices, including the cables, should be used in proximity of the Thermia Pro series within the recommended safety distance calculated according to the applicable transmission frequency equation. Recommended safety distance: $d = 1,2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ for 800 MHz to 2.5 GHz
Radiated HF disturbance value acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz Table 9 of IEC 60601-1-2 Ed. 4	3 V/m 80 MHz to 2.7 GHz Table 9 of IEC 60601-1-2 Ed. 4	Where P is the maximum 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 an electromagnetic site survey ^{a)} should be less than the compliance level in each frequency range ^{b)} . Interference may occur in the vicinity of e devices marked with the following symbol 
<p>Notes:</p> <p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection by structures, objects, and people.</p>			
<p>^{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 which the devices of the Thermia Pro series are used exceeds the compliance level, the devices should be monitored to ensure that they are working properly. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the devices of the Thermia Pro series.</p> <p>^{b)} Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

12.3 Recommended safety distances

See chapter 12.2 “Electromagnetic immunity”.

Accessories

13 Accessories

Thermia Pro Heating Trays mounted

(2 pieces in set)

Catalogue no.: 00002542



Thermia Pro Heating Trays stand-alone

(2 pieces in set)

Catalogue no.: 00002286



Thermia Pro Console holder

(incl. assembly material)

Catalogue no.: 20018061



USB-A Port Blocker

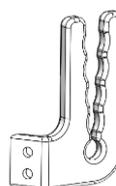
Catalogue no.: 93006998



Right tube holder

(incl. assembly material)

Catalogue no.: 30007658



Revision status: 2020-11 B
Software version: 104.00.01



Catalogue number of
instructions for use
(REF) 93007595



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