HICO
MEDICAL SYSTEMS

Instructions for Use

Hypo/Hyperthermia Unit

HICO-VARIOTHERM 550

CE 0124

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1 General information

Read the information provided here so that you can quickly become familiar with the HICO-VARIOTHERM 550 and use its functions to their full extent.

1.1 Information regarding these instructions

These operating instructions are a component of the HICO-VARIOTHERM 550 (referred to in the following as the “unit”) and provide important information for the commissioning, safety, intended use, and maintenance of the unit.

All figures and drawings in these operating instructions are for general illustration purposes and are not definitive in terms of the details of their construction.

The operating instructions must always be available, preferably in the vicinity of the unit. They must be read and applied by all persons who are responsible for the following:

- Commissioning
- Operation
- Cleaning
- Maintenance
- Troubleshooting

1.2 Warnings

The following types of safety notes are used in these operating instructions:

⚠DANGER

A DANGER note identifies an imminent danger situation.

Failure to avoid such a dangerous situation will cause severe injury or even death.

► Follow the instructions given in this danger note to avoid the danger of death or severe injury to people.

⚠WARNING

A WARNING note identifies a potentially dangerous situation.

Failure to avoid such a dangerous situation can lead to severe injuries.

► Follow the instructions in this warning note to avoid the risk of injuries to persons.

⚠CAUTION

A CAUTION note identifies a potentially dangerous situation or a risk of property damage.

Failure to avoid such a dangerous situation can lead to minor or moderate injuries and damage to property.

► Follow the instructions in this caution note to avoid the risk of injury to people and damage to property.

NOTE

A note highlights additional information to assist you when working with the unit.

1.3 Limitation of liability

All technical information, data, and notes on installation, operation, and maintenance contained in this manual were up-to-date at the time of printing and are provided to the best of our knowledge based on our previous knowledge and experience. No claims can be derived on the basis of information, illustrations, or descriptions provided in these operating instructions.

The manufacturer accepts no responsibility for loss in the event of:

- Failure to follow the operating instructions
- Imintended use
- Improper repairs
- Technical modifications
- The use of non-approved spare parts
- Unauthorised conversions and changes

Translations are made to the best of our knowledge. We will not assume liability for mistakes in translations, even if the translation was done by us or ordered by us. Only the original German text is binding.

1.4 Copyright

Subject to changes in contents and technical modifications.

1.5 Manufacturer's address

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2 Safety

This chapter contains important safety information for working with this unit.
This unit complies with the specified safety regulations. However, imintended use can lead to personal injury or property damage.

2.1 Intended use

This unit is solely intended for the cooling or heating of water pads[1] used to cool or warm a patient. Any use of the unit for a purpose other than the use described above is considered imintended use.
The pads available as accessories may only be used with HICO units for use in the treatment of hypo/hyperthermia.

⚠WARNING

Danger due to imintended use!

It is dangerous to use the unit improperly and/or use the unit for any other purpose than the described purpose.

- ► Only use the unit for its intended purpose.
- ► Follow the procedures described in these operating instructions.
- ► Use only with original accessories.

Claims of any type due to damage resulting from imintended use are excluded.

The owner is the sole bearer of the risk.

[1] In these operating instructions, the term “water pad” describes all Hico accessories such as water mats, water blankets, water collars, etc. (see also section 12.2 “Accessories”)

2.2 Personnel requirements

NOTE

- ► Work on/with the unit may only be carried out by persons who are authorised for this work because of their education and qualifications. In addition, these persons must be authorised to perform the work by owner.
- ► Only allow personnel who will be trained, taught, instructed, or are who undergoing general training to work on or with the unit under the supervision of an experienced person.
- ► Persons who are under the influence of drugs, alcohol, or medication that affects their responsiveness may under no circumstances carry out work on or with the unit.
- ► Hazards can result when the unit is used improperly by untrained personnel.
- ► In addition to the operating instructions, all generally valid legal and otherwise binding regulations for the prevention of accidents and protection of the environment as well as general health and safety requirements must be followed. The owner must instruct his personnel accordingly.

2.3 General safety instructions

NOTE

Follow the general safety instructions below for safe handling of the unit:

- ► Ensure that the unit (mains cable, housing, couplings, etc.) and water pads are in good condition before commissioning.
- ► Lay hoses and water pads without creases and kinks.
- ► Do not touch the hoses and water pads with pointed or sharp objects. The system cannot work correctly with perforated pads.
- ► Fill the unit's tank with sterile filtered tap water[2] to which a disinfectant[3] has been added.
- ► Only operate the unit after the tank has been closed by screwing on the cap.
- ► Position the unit on a level surface and operate; slope of installation surface ≤ 3%.
- ► Height difference between the unit and water pad < 1 m.
- ► Do not cover unit. There are ventilation slots on the bottom and back and ventilation slots and inlets for ventilators on the sides.
- ► Monitor the automatic functional test when switching the unit on.
- ► Perform an automatic functional test manually at least once a day during continuous operation.
- ► Medical electrical equipment is subject to special precautions regarding EMC and must be installed and put into operation according to the EMC instructions contained in the accompanying documents.
- ► Portable and mobile RF communications equipment can affect medical electrical equipment.

[2] Depending on the quality of the water (e.g. its hardness, among other things), the lifetime of the parts of the unit that come into contact with water may be reduced.

[3] For example 10 ml SANOSIL mixture (from Sanosil, Farchant) ⇨ (1000 ml sterile filtered tap water + 10 ml Sanosil solution). Alternatively, a different long-term disinfectant and preservative can also be used, e.g. Micropur or Certisil. If you have any questions, please contact the Customer Service department of pfm medical hico gmbh.
The use of a disproportionately high amount of disinfectant can reduce the lifetime of parts of the unit that come into contact with water!

- ► Check the water flow and water level of the unit regularly during operation.
- ► Only operate the unit with an appropriate water level.
- ► Keep the ambient temperature in the range of 10-30°C for hyperthermia operation, 10-23°C for hypothermia operation, and 3-60°C when in storage.
- ► Apply appropriate measures to position the patient on or under the water pad (if necessary).
- ► Do not use water pads as electrical insulation pads in combination with HF surgery.
- ► Intermediate layers between the patient and water pad (bed sheets, surgical drapes, gel pads, etc.) adversely affect the heat transfer.
- ► Only operate the unit with HICO water pads and original accessories.
- ► Do not operate the unit in an oxygen-enriched environment or in the presence of combustible gases.
- ► In hyperthermia mode, do not use or combine the unit together with other heat sources.
- ► Do not operate the unit in the vicinity of heat sources (spotlights, direct sunlight, radiators, radiant heaters, etc.).
- ► Perform maintenance and conduct safety checks according to these operating instructions.

2.4 Potential hazards

2.4.1 Danger of hypothermia or hyperthermia

⚠WARNING

There is a risk of the patient becoming overheated or undercooled.

- ► The body temperature of the patient must be monitored at all times when using the HICO-Variotherm 550.

3 Transport and setup

3.1 Scope of delivery and transport inspection

The scope of delivery of the HICO-VARIOTHERM 550 consists of:

- HICO-VARIOTHERM 550 unit
- Mains cable (3 meters)
- Hose holder
- Operating instructions
- Hose extension
- Water pads (optional according to order)

NOTE

► Check the delivery for completeness and for any visible damage.

► Immediately report an incomplete delivery or damage caused by inappropriate packaging or transport to the forwarding agent, the insurance company, and the supplier.

3.2 Unpacking

To unpack the unit:

- Take the unit out of its box and remove the packaging material.
- Place the unit on a smooth, level surface with sufficient load bearing capacity.

⚠CAUTION

Condensation in the unit can lead to failure of the unit.

► After unpacking, the unit must be acclimatised for at least two hours before commissioning when the actual ambient temperature differs from the specified ambient temperature by more than 8°C.

3.3 Disposal of the packaging material

The packaging protects the unit from damage during transport. The packaging materials are selected on the basis of environmentally friendly and disposal-related factors and are therefore recyclable.

Returning the packaging material back into the material cycle saves raw materials and decreases the amount of waste produced. Dispose of packaging materials that are no longer required at the collection points for the “Green Dot” recycling system or of your local recycling system.

NOTE

► If possible, keep the original packaging throughout the unit’s lifetime so that you can repack the unit properly in case of repair.

4 Commissioning

This chapter contains important instructions for commissioning the unit. Please follow these instructions to prevent hazards and damage.

4.1 Safety instructions

⚠WARNING

Injuries and property damage can occur when commissioning the unit!

Follow the safety instructions below to prevent hazardous situations:

- ► The weight of the unit is approx. 17 kg.
- ► The unit should only be transported, unpacked, and installed by two people.
- ► Do not use the unit directly next to or stacked on top of other equipment.
- ► If it is necessary to operate the unit directly next to or stacked on top of other equipment in spite of this, then it necessary to observe the unit to ensure that it is being used for its intended purpose.

4.2 Setup

4.2.1 Requirements on the installation site / operating location

For safe and trouble-free operation of the unit, the installation site must fulfil the following requirements:

- It must have sufficient load bearing capacity (weight of unit approx. 17 kg).
- It must be level.
- It must be horizontal (slope ≤ 3%).
- It must provide 20 cm space on both sides of the unit.
- It must ensure adequate ventilation of the unit, including upward ventilation in an equipment trolley.
- It must be at the same level as the water pad, i.e. next to the patient's bed (max. height difference approx. 0.5 m), for example.

The carrier and the five-castor stand (see sections 4.2.2 and 4.2.3 below) available as accessories meet all of these requirements.

NOTE

- ► If the unit is not horizontal, then the display on the front of the unit will display the water level incorrectly.
- ► If the unit is far below the level of the water pad, then the circulation of water may be interrupted when the patient is heavy. Furthermore, water may flow back into the unit and cause the water tank to overflow when the water filling neck is open and the unit is switched off.

For optimal operation of the unit, the installation site should meet

- the following environmental conditions:
  - Ambient temperature: 20°C ◊ 3°C
  - Relative humidity: 50% ◊ 20%
  - Air pressure: 700 hPa to 1060 hPa

⚠WARNING

Performance limitations in terms of the attainable pad transition temperatures under extreme ambient conditions or due to the pad selected (see section 6.2.8 “Schematic performance charts”) may also lead to restrictions in the scope of intended use.

⚠CAUTION

Condensation in the unit can lead to failure of the unit.

- ► If the actual ambient temperature differs from the specified ambient temperature by more than 8°C during installation of the unit, then allow the unit to acclimatise for at least two hours before use.

4.2.2 Setting up with the unit carrier (optional)

The stand, which is optionally available as an accessory, makes the stationary HICO VARIOTHERM 550 mobile.

Install the unit together with the stand as follows:

- Assemble the stand as described in its operating instructions (K2B0045).
- There are two slots in the base of the stand. Place the HICO-VARIOTHERM 550 on the base of the stand so that the slots and the threads in the base of the unit are aligned with each another.
- The base of the stand is screwed to the unit using a knurled thumb screw.

⚠CAUTION

Injuries and property damage may occur when installing and using the stand with the unit!

► When assembling the stand, follow the safety instructions in the assembly and operating instructions for the stand!

► The stand only serves to carry HICO systems!

► Do not use any aggressive detergents; the stand is not suitable for use in washing systems!

► The stand should be checked at least once a year to ensure all components are fully functional:
Are the screw connections still tight?
Clean the castors of dirt and grime so that the brakes work properly and the electrical conductivity is not reduced.

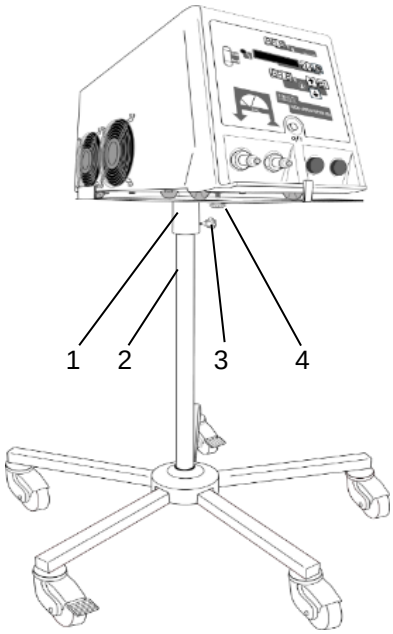
If a defect is detected, use only original spare parts as replacements and only allow parts to be replaced by a specialist or customer service.

4.2.3 Installation with five-castor stand (optional)

The five-castor stand available as an accessory makes the HICO-VARIOTHERM 550, which was designed as a stationary unit, mobile.

Install the unit together with the stand as follows:

- Assemble the five-castor stand as described in its operating instructions.
- Place the base plate (1) on the vertical tube (2) of the five-castor stand.
- Fasten the plate using the star knob (3).
- There is a safety screw (4) in the base plate; place the HICO-VARIOTHERM 550 on the plate so that the screw and the thread in the base of the unit are aligned with each another.
- Secure the unit in place by screwing the safety screw into the base of the unit.



⚠CAUTION

Injuries and property damage may occur when installing and using the five-castor stand with the unit!

► Five-castor stand assembly: For the safe operation and firm stand of the system, it must be ensured when assembling the five-castor stand that the cylinder (2) in the centre section and castors are safely mounted on all 5 spokes of the five castor base in accordance with the assembly instructions and the safety instructions.

► The five-castor base can only be used to mount HICO systems!

► Do not use any aggressive detergents; the five-castor base is not suitable for use in washing systems!

► All components of the five-castor base should be checked for full functionality at least once a year:

► Are the screw connections still tight?

► Clean the castors of dirt and grime so that the brakes work properly and the electrical conductivity is not reduced.

► This should be checked directly after assembly and at regular intervals during the operating period (during / at the recommended annual maintenance interval)

► If a defect is detected, use only original spare parts as replacements and only allow parts to be replaced by a specialist or customer service.

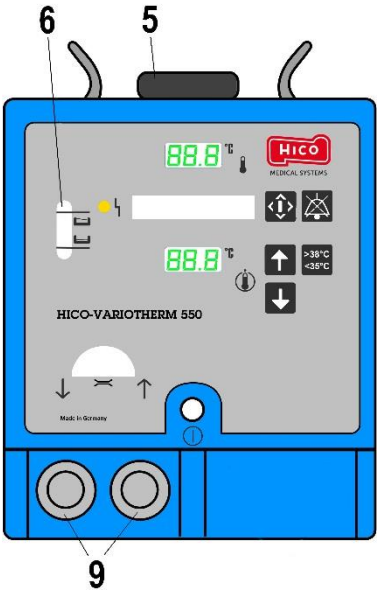
4.3 Connecting the HICO-VARIOTHERM 550

⚠WARNING

Danger due to water in connection with electricity.

► Only connect the unit to the mains supply after it has been filled.

4.3.1 Filling the system



- Unscrew the cap from the water filling neck (5), e.g. with a coin. Take care not to lose the seal ring of the cap.
- Observe the water level indicator (6) while filling. After filling, the water level should be slightly below the MAX mark.
- Fill the unit's tank with sterile filtered tap water[4] to which a disinfectant[5] has been added.
- After filling, screw the cap hand-tight back onto the water filling neck until it is properly sealed.

NOTE

The use of a disproportionately high amount of disinfectant can reduce the lifetime of parts of the unit that come into contact with water! When filling the unit for the first time, please follow the procedure described in section 6.2.1.

⚠WARNING

Danger due to water in connection with electricity.

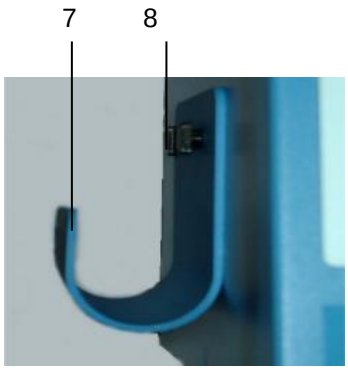
Water conducts electricity.

► If water overflows when filling the unit, then the unit must first be thoroughly dried and should only be connected to the mains supply and switched on after it has completely dried out.

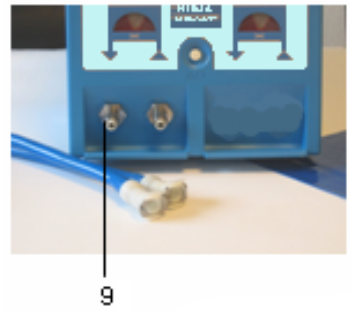
[4] Depending on the quality of the water (e.g. its hardness, among other things), the lifetime of the parts of the unit that come into contact with water may be reduced.

[5] For example 10 ml SANOSIL mixture (from Sanosil, Farchant) ⇨ (1000 ml sterile filtered tap water + 10 ml Sanosil solution). Alternatively, a different long-term disinfectant and preservative can also be used, e.g. Micropur or Certisil. If you have any questions, please contact the Customer Service department of pfm medical hico gmbh.
The use of a disproportionately high amount of disinfectant can reduce the lifetime of parts of the unit that come into contact with water!

4.3.2 Connecting the water pads



- The hose holder (7) provided makes it easier to lay the hoses between the pad and the unit. To attach the holder, loosen the two knurled thumb screws (8) on the left-hand side of the unit and then use them to fasten the holder to the unit.



- Push the hose connectors of a hose extension onto the two hose connections (9) on the unit.
- Push the hose pad connectors of the hose extension onto the two hose connections on the water pad.
- The connectors are properly connected to each other when the locking mechanisms on the connectors engage their corresponding counterparts so that the connection will no longer come loose by itself.
- You can release the connection again by pushing the metal plate on the hose connector and then pulling out the connector.

NOTE

► The hose extension connections cannot be “confused” when connecting them to the unit because it makes no difference which direction the water flows through the water pad.

► Water pads can also be disconnected when the unit is switched on. It is normal in this case for water to drip out of the connector and does not indicate leakage or a defect.
In the heating mode at 39°C: Reduce the nominal temperature before disconnecting the water pad.
In the cooling mode at 15°C: Raise the nominal temperature slightly before disconnecting the water pad.
Otherwise the water in the unit’s circuit can briefly rise above the upper temperature limit or drop below lower temperature limit, and the unit may trigger various alarms.

4.3.3 Electrical connection

⚠CAUTION

Hazard due to electrical current

Defective cables and/or plugs as well as faults in the power supply can cause life-threatening electric shock!

► Check the condition of the unit's cable and plug before connecting!

► To avoid the risk of electric shock, this unit must only be connected to a mains connection with a protective conductor!

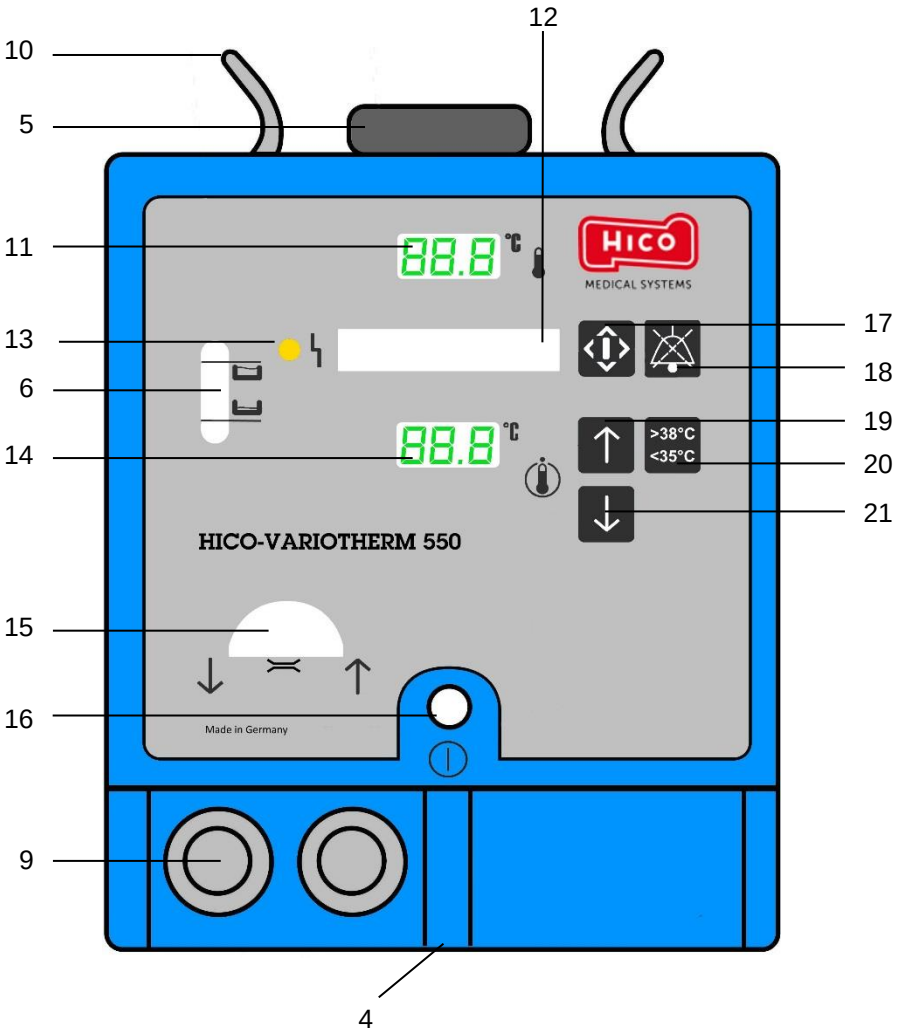
Please follow the instructions below when making the electrical connections to ensure safe and trouble-free operation of the unit:

- Before connecting the unit, compare the electrical data (voltage and frequency) on the nameplate to the electrical data of your mains power supply. This data must match to prevent the unit from being damaged.
  When in doubt, please ask your electrician for advice.
- The electrical power outlet must be protected by a 16A circuit breaker.
- Use the cable supplied with the unit to connect the unit to the mains supply. The power cable socket is located on the rear of the unit (see section 5.1 "Views of the unit, control elements, and display elements").
- The power supply at the installation site must meet the requirements for electrical systems in hospitals and medical environments (see VDE 0100-710:2012-10 *"Low-voltage electrical installations Part 7-710: Requirements for special installations or locations - Medical locations."*).

5 Design and function

This chapter contains important information about the design and function of the unit.

5.1 Views of the unit, control elements, and display elements



4) Thread for safety screw (in base plate)
5) Water filler neck with screw cap
6) Water level indicator
9) Hose connections
10) Handles
11) Temperature display for water pad
12) Display for status and error messages
13) Error light
14) Temperature display for nominal value
15) Water flow display
16) Power switch
17) Function test
18) Mute audio
19) Increase the nominal temperature value
20) Release < 35°C / > 38°C
21) Decrease the nominal temperature value

Rear view (excerpt) of the unit with microfuse and power cable socket.

5.2 Safety devices

5.2.1 Sensors

During operation, the HICO-VARIOTHERM 550 monitors

- the water level in the unit
- if the water temperature in the circuit matches the nominal temperature value set
- if the unit is connected to power
- if the unit is functionally safe

and emits alarms in case of malfunctions (see section 6.3).

⚠WARNING

The HICO-VARIOTHERM 550 application system does not have a function for monitoring the patient's measured values.

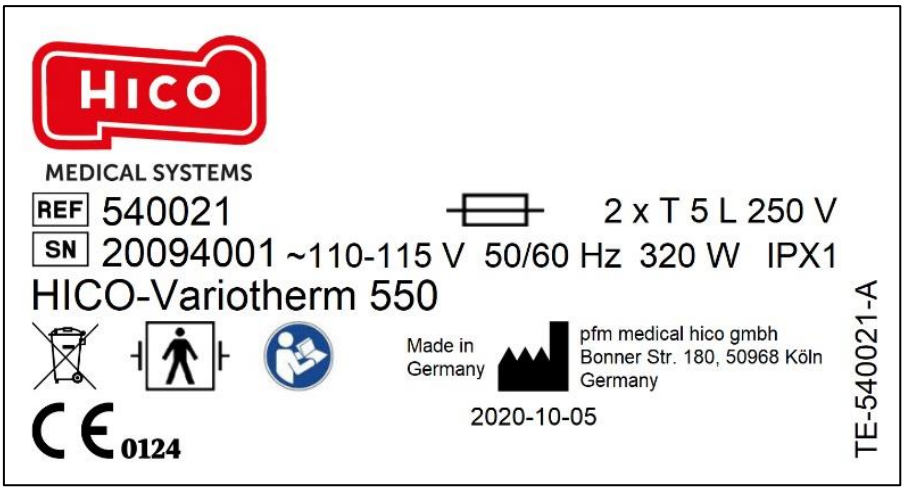
► The core temperature of the patient to be treated must be monitored regularly independent of the application system.

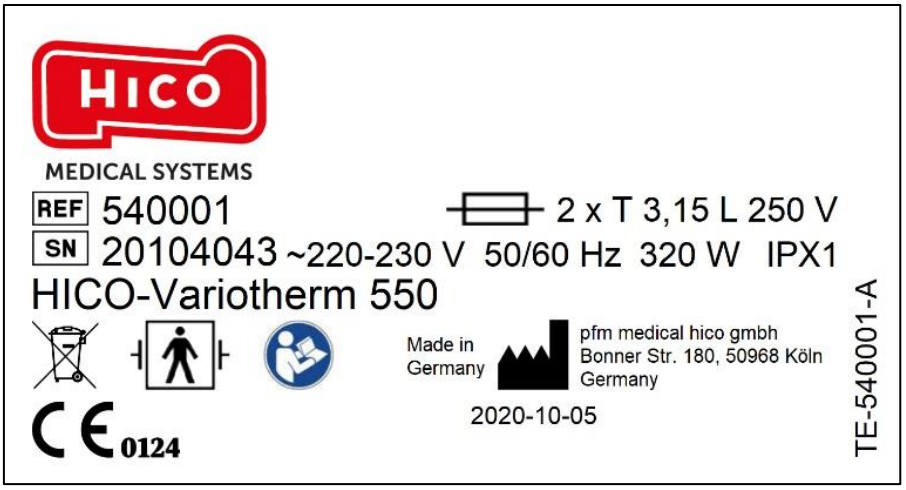
► The temperature settings for the transition temperatures on the pad must be entered manually in the system by the user, and the individual course of therapy should be corrected or adjusted accordingly.

The system should only be used/put into operation by users who are qualified to use the system properly!

5.3 Nameplate

The nameplate with the connection and performance data is located on the rear of the unit:





5.4 Function

5.4.1 Basic principles

The HICO-VARIOTHERM 550 hypo/hyperthermia unit serves the purpose of cooling or warming patients using water pads. The latest safety and application-related knowledge about water pad systems was applied during the development of the unit.

Heat is transferred between the patient and the water pad solely through surface contact. Thanks to its high heat capacity and heat conductivity, water is an ideal transmission medium for this type of application.

The sterile filtered tap water is cooled or heated to a temperature between 15°C and 39°C in a water tank inside the unit by thermoelectric elements and is pumped continuously through the water pad by a centrifugal pump.

The transition temperature to be reached on the pad depends on the environmental conditions and the size of the pad.

The HICO-VARIOTHERM 550 is characterised by its safe and easy use, reliability, and compact design.

Using its electronic control, the temperature transferred to the patient can be adjusted accurately while simultaneously maintaining high operational safety.

The transition temperature on the patient when warming normally should not exceed 40°C to prevent the risk of burning when used for a long period of time. This not only a risk when the transition temperature is too high, but also when it is too low. To minimise this risk in case of an equipment failure while warming a patient, the HICO-VARIOTHERM 550 switches off electronically and electrically when a water temperature higher than 41.5°C is reached.

Transition temperatures < 35°C and > 38°C must be consciously set by the user and closely monitored.

This virtually rules out the risk of local accumulations of heat, whereby the requirements for the installation site and the site of use also must be fulfilled.

Performance restrictions in terms of the pad transition temperatures that can be reached under extreme ambient conditions and for the selected combination of pads can also lead to restrictions when used for its intended purpose.

The HICO-VARIOTHERM 550 is easy and intuitive to operate, and thus helps prevent incorrect use.

⚠WARNING

Risk due to overestimation or underestimation of the performance of the system!

Using the unit can also be hazardous when used for its intended purpose if the desired temperatures cannot be reached due to the ambient conditions.

The reliable therapeutic use of the system requires the user to weigh the risks carefully and continuously monitor and care for the patient.

5.4.2 Indications / contraindications / side effects

Indications

In general, the HICO VARIOTHERM 550 can be used in hypo/hyperthermia treatment for the following purposes:

- To supply heat to the patient in case of intraoperative or postoperative hypothermia
- To supply or withdraw heat from the patient to stabilise the patient's temperature (normothermia)
- To withdraw heat in case of malignant hyperthermia.

⚠WARNING

Risk due to overestimation or underestimation of the performance of the system!

Using the unit can also be hazardous when used for its intended purpose in the following cases:

► Improper understanding of physical interactions among external accessories and due to ambient conditions (pad size, ambient temperature, etc.)

► Individual and unpredictable patient reactions

The reliable therapeutic use of the system requires the user to weigh the risks carefully and continuously monitor and care for the patient.

Side effects

The materials used in water pad systems have no known side effects.

In applications, the transfer of heat using water pads may be considered unsatisfactory if the following is true:

- Less than 20% of the surface of the water pad comes into contact with the patient
- The contact pressure reduces skin circulation. In this case there is an additional risk of bedsores.

In warming applications and the corresponding specific increase of the patient's temperature, there is always a risk of burning during long-term applications and when the temperature is too high.

In cooling applications and the corresponding specific reduction of the patient's temperature (therapeutic hypothermia), there is also a risk of burning (freezer burn) just like in warming applications, and the following side effects can arise, for example:

- Autonomous reactions (among others, shivering)
- Electrolyte imbalances
- Excess urination (diuresis fluctuations)
- Hyperglycaemia (glycaemic fluctuations)
- Greater blood loss (due to reduced blood-clotting factors)
- Changes in the pharmacokinetics
- Higher wound infection rates (sepsis)
- Risk of decubitus

In addition, this can cause reversible dilated pupils; for this reason, dilated and unresponsive pupils in an undercooled patient is not necessarily a sign of a serious brain injury.

In addition to the described side effects in adults during therapeutic hypothermia, for newborns the following also needs to be considered:

- (Severe) pulmonary hypertension
- Viscosity increase (clotting disorders and manifest thrombosis) in patients with polycythaemia (polycythaemia > 65% only after hemodilution),
- Thrombocytopenia
- Arterial hypertension
- Hypovolemia
- PPHN (persistent pulmonary hypertension of the newborn)
- Bradycardia
- Haematuria

⚠CAUTION

In paediatrics after perinatal hypoxia/ischaemia, moderate hypothermia of 33-34°C within the first 6 hours for a period of 48-72 hours causes a significant improvement in the neurological outcome between the age of 12-18 months.

The inclusion criteria for newborns is ≥ 36 weeks of pregnancy and an age < 6 hours with acute encephalopathy and peripartum asphyxia.

The exclusion criteria is an age > 6 hours and newborns in extremis.

Contraindications

- Advanced malignant underlying disease
- Persistent state of shock / cardiopulmonary instability
- Pregnancy
- Coma due to other causes
- Body temperature below 30°C upon admission
- Time between cardiac arrest and initiation of resuscitation of more than 15 minutes
- Distal application of an arterial clamp

⚠WARNING

Uncontrolled hypo/hyperthermia associated with increased patient mortality.

- ► If the body temperature falls below 32°C, then life-threatening complications may occur such as cardiac arrhythmia, metabolic disturbances, and cardiac arrest.
- ► After hypothermia treatment, the temperature of the patient should be increased by no more than 0.25-0.5°C per hour. Warming too rapidly also leads to arrhythmias and ventricular fibrillation with the subsequent risks.
- ► When used on ischaemic limbs, there is an increased risk of tissue damage and shock.

⚠CAUTION

- ► For the low-risk and reliable application of hypo/hyperthermia treatment, it is of utmost importance to externally and continuously monitor the body core temperature (e.g. by measuring the temperature in the urinary bladder).
- ► Mild to moderate therapeutic hypothermia requires the user to weigh the risks carefully and continuously monitor and care for the patient to detect side effects, prevent pressure-induced lesions, and ensure the efficiency of the system.
- ► Due to the excellent heat conductivity of water, the patient may cool down when the unit is switched off or the water pad is disconnected from the unit. Only leave the water pad in contact with the patient during normal operation.
- ► No distal application of an arterial clamp!

NOTE

Because new discoveries are constantly being made in the field of hypo/hyperthermia, the information provided here does not claim to be current or complete.

The pfm medical hico gmbh is not responsible or liable for negligent or incorrect use and cannot provide any medical recommendations or procedures. The user must independently decide what to use and how to proceed.

6 Control and operation

This chapter contains important instructions and information for operating the unit. Please follow these instructions to avoid danger and prevent damage.

6.1 Before switching on

6.1.1 Check the unit

Inspect the unit for external damage.

Check the water level before and after

- switching on the unit and
- connecting a water pad.

The water level must be between both marks on the water level indicator (6), preferably just below the maximum mark. The difference in volume between the two marks is approx. 0.5 litre.

Fill with sterile filtered tap water to which a disinfectant has been added when the following applies:

- The water level is below the minimum mark.
- You want to connect an empty water pad and the water level is below the maximum mark.

6.1.2 Water pads

- Only connect original HICO hose extensions with HICO water pads to the HICO-VARIOTHERM 550.
- Check the water pads for external damage before connecting. Use only undamaged pads.
- Have a collecting basin ready in case a pad should start leaking.
- Place a thin fleece between the water pad and the patient’s skin.

Water pads can be connected and disconnected regardless of whether the unit is switched on or off.

NOTE

Disconnecting water pads when the unit is switched on:

- ► In the heating mode at 39°C: Reduce the nominal temperature before disconnecting the water pad.
- ► In the cooling mode at 15°C: Raise the nominal temperature slightly before disconnecting the water pad.

  Otherwise the sterile filtered tap water in the unit's circuit can briefly rise above the upper temperature limit or drop below lower temperature limit, and the unit may trigger various alarms.

NOTE

Intermediate layers between the patient and water pad (bed sheets, surgical drapes, gel pads, etc.) adversely affect the heat transfer.

- ► A thin absorbing cotton linen/sheet should be positioned between the patient's skin and the pads. Direct skin contact with the pad, which is made of plastic, can lead to skin damage and increases the risk of decubitus.
- ► Make sure there are no creases in the fleece after placement.

6.2 Operation

6.2.1 Switching on for the first time

- Switch the unit on using the pushbutton (16); when switched off, the pushbutton is flush with the front panel.

- If the temperature setting is higher than 38°C or lower than 35°C, then check if the temperature setting is actually correct before pressing the release key (20).
- Run the unit for about two minutes to remove any air from the circuit in the unit.
- Check the water level on the indicator (6); if necessary, switch off the unit using the pushbutton (16), disconnect it from the mains supply, and refill it with sterile filtered tap water to which a disinfectant has been added.
- Connect a water pad to the unit; the pad and the unit should be at the same level.
- Reconnect the unit to the mains supply, switch it on, and run it for another two minutes to force all the air out of the water pad.
- Check the water level on the indicator (6) again; if necessary, switch off the unit using the pushbutton (16), disconnect it from the mains supply, and refill it with sterile filtered tap water to which a disinfectant has been added.

6.2.2 Switching on in normal operation

- Switch the unit on using the pushbutton (16); when switched off, the pushbutton is flush with the front panel.

- If the temperature setting is higher than 38°C or lower than 35°C, then check if the temperature setting is actually correct before pressing the release key (20).
- Check the water level on the indicator (6), especially if you have connected an unfilled water pad.
- After use, switch the unit off using the pushbutton (16) and disconnect the plug from the mains supply.

6.2.3 Functional test

After switching the unit on, it automatically performs a function test. During this test, monitor the displays to ensure they behave as described in the following:

- A short audible alarm indicates that the unit is ready in case of a power failure alarm.

The unit now checks its autonomous safety device and does the following:

- Shows the result in the display (12)
- The temperature displays (11) and (14) show 88.8
- The error light (13) lights up.
- The audible alarm is triggered.

This test takes a few seconds.

⚠CAUTION

If the unit does not pass all functional tests successfully, then the unit is no longer safe to operate.

Do not operate unit in the following cases:

► The unit does not sound the short signal tone for the power failure alarm when switching on.

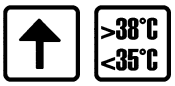
► The automatic function test automatically switches the unit off because it has detected a defect in the independent safety device.

► One or more displays are defective.

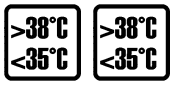
In these cases, have the unit checked by HICO customer service.

6.2.4 Setting the temperature

- Set the nominal value for the water temperature - i.e. the temperature on the contact area between water pad and patient - using the two arrow keys (19) and (21). The temperature can be adjusted in increments of 0.1°C between 15°C and 39°C. The temperature display (14) shows the nominal temperature setting.



- For temperature settings above 38°C, press the up arrow key (19) and the release key (20) at the same time.



- For temperature settings below 35°C, press the down arrow key (21) and the release key (20) at the same time.

⚠WARNING

► At temperatures below 35°C, heat is withdrawn from the patient at a higher rate.

► At temperatures over 38°C, the patient is provided with heat at a higher rate.

► Regardless of the temperature, parts of the body that are subjected to increased pressure may suffer from pressure necrosis and/or burns. This applies especially to long-term applications and high-risk patients.[5]

⚠CAUTION

To ensure reliable indications and safe operation, note the information in sections 4.2.1, 5.4.2, 6.2.8, and 6.2.9!

External conditions and pad size influence the nominal temperature setting, e.g. very high or low temperature settings may not be reached under some circumstances in environments with high or low ambient temperatures and/or when connecting one large pad or two smaller water pads. In this case, set the temperature to a lower or higher value until the unit can reliably regulate the temperature.

Check the water flow on the display (15)!

[5] Cf. S. M. Scott, Thermal blanket injury in the operating room, Arch. Surg. 34, page 181, 1967

Heat transfer:

Heat is only transferred (supplied or withdrawn) between the patient and the water pad if the temperature of the water pad is higher or lower than the skin temperature of the patient on the contact surface.

The rate of heat transfer is directly proportional to the following:

- The difference between the skin temperature and the water pad temperature
- The size of the contact area

Intermediate layers impair heat transfer (e.g. surgical drapes or gel pads).

Example of a temperature difference:

The heat transfer from the pad to the patient doubles when the temperature difference between the water pad and the patient is doubled. If the patient's skin has a temperature of 34°C on the contact area and the water pad temperature is raised from 36°C to 38°C, then the heat transfer will double because the temperature difference is doubled from 2°C to 4°C.
Due to the thermoregulation of the patient, this is only an approximation.

6.2.5 Temperature control mode

⚠WARNING

There is a risk of the patient becoming overheated or undercooled.

► The patient's body temperature must be monitored when using the unit and water pad on the patient.

If the nominal temperature is set to a value between 35°C and 38°C, then the unit will start normal operation automatically after it is switched on and after the function test, and will maintain the water temperature in the water circuit of the system at the temperature setting.

If the nominal temperature is set to a value higher than 38°C or lower than 35°C, then the unit will emit an audible alarm, and the message "NOMINAL VALUE <35/>38°C!", "RELEASE KEY" will appear in the display (12).

Check if the nominal temperature setting is correct, and only press the release key (20) if it is correct.

The unit starts the temperature control mode, and the display (12) shows "HEATING ACTIVE" or "COOLING ACTIVE".

⚠CAUTION

Only leave the water pad in contact with the patient during normal operation.

Due to the excellent heat conductivity of water, the patient may cool down when the unit is switched off or the water pad is disconnected from the unit.

NOTE

If a nominal temperature is not reached within 60 minutes after switching on the system due to external conditions and the size of the pad, then an alarm message (TEMP.DIFF >1 °C) will appear (see section 6.3.2 "Alarm descriptions during operation").

In this case, adjust the temperature setting so it matches the actual value displayed.

Check the water flow on the display (15)!

6.2.6 Handling water pads

NOTE

- ► Avoid contact with hot, sharp, and pointed objects.
- ► When disconnecting a water pad from a unit that is switched off, the pad should be lower than the unit. This prevents backflow, and the pads stay sufficiently filled with sterile filtered tap water for the next use.
- ► Water pads connected to the unit should never be stored at a higher level than the unit, e.g. never on top of the unit. Otherwise the sterile filtered tap water will flow from the pad back into the unit and overflow.
- ► Water pads should be stored rolled up whenever possible. Creases and kinks can damage the material.
- ► Avoid direct sunlight. Heat and UV rays will damage the material.

6.2.7 Using the water pads

The water pads can be placed horizontally and be used both as an underlay underneath the patient and as a cover over the patient. It is also possible to use smaller pads and blankets as a wrap if necessary. It is important to ensure the pad and the hoses are free of creases and kinks after placement so that the water flow is not affected and no unnecessary pressure is applied to the patient. Make sure the contact surface between the pad and the patient is as large as possible given the particular pad size. It is recommended to use a thin fleece as an intermediate layer. Direct skin contact with the pad, which is made of plastic, can lead to skin damage and increases the risk of decubitus. Make sure here as well that there are no creases in the fleece after placement.

External conditions and pad size influence the nominal temperature setting, e.g. very high or low temperature settings may not be reached under some circumstances when connecting one large pad or two smaller water pads. After starting the unit, monitor the nominal and actual temperature differences and, after approx. 45-40 min of operation, set the temperature on the unit to a lower or higher nominal value that approximately corresponds to the actual value.

NOTE

- ► See also section 4.2.1 “Requirements on the installation site / operating location” and section 6.1.2 “Water pads”.
- ► For trouble-free and stable operation, the difference between the nominal temperature setting and actual temperature displayed on the unit should not be greater than 1°C.
- ► The thicker the intermediate layers between patient and water pad are (bed sheets, surgical drapes, gel pads, etc.), the poorer the heat transfer.

6.2.8 Schematic performance charts

Explanation:

The data for the performance charts was obtained in an appropriate setting in the laboratory at three different ambient temperatures and for three different pad combinations.

Desired pad temperatures: 39°C[6] and 15°C at an

Ambient temperature: 10°C, 20°C, and 30°C

Water temperature at start of test: 20°C

Pads used:

1 smallest pad: LxW: (50 x 30) cm / area: 1,500 cm²

1 largest pad: LxW: (170 x 50) cm / area: 8,500 cm²

1 head wrap

1 vest

NOTE

The pad sizes selected are representative of other HICO pad sizes used in applications.

The following performance charts illustrate limit value analyses (at extreme conditions) for ambient temperatures, pads, and settings based on data obtained according to standard laboratory procedures.

This leads to the following restrictions:

- At an ambient temperature of 30°C, a minimal temperature of only 22°C can be expected for the smallest pad.
- At an ambient temperature of 30°C, a minimal temperature of only 23°C can be expected for the largest pad.
- At an ambient temperature of 30°C´, a minimal temperature of only 21°C can be expected for the head wrap.
- At an ambient temperature of 30°C, a minimal temperature of only 23°C can be expected for the vest.

The values shown the performance charts are approximate values.

[6] In accordance with the requirements of DIN EN 80601-2-35, the temperature of the system is limited to 40°C.

Performance charts:

The temperature limit values[7] to be reached within 10 minutes to 60 minutes (see diagrams 1-3) after startup and adjustment of the temperature setting during operation under laboratory test conditions.

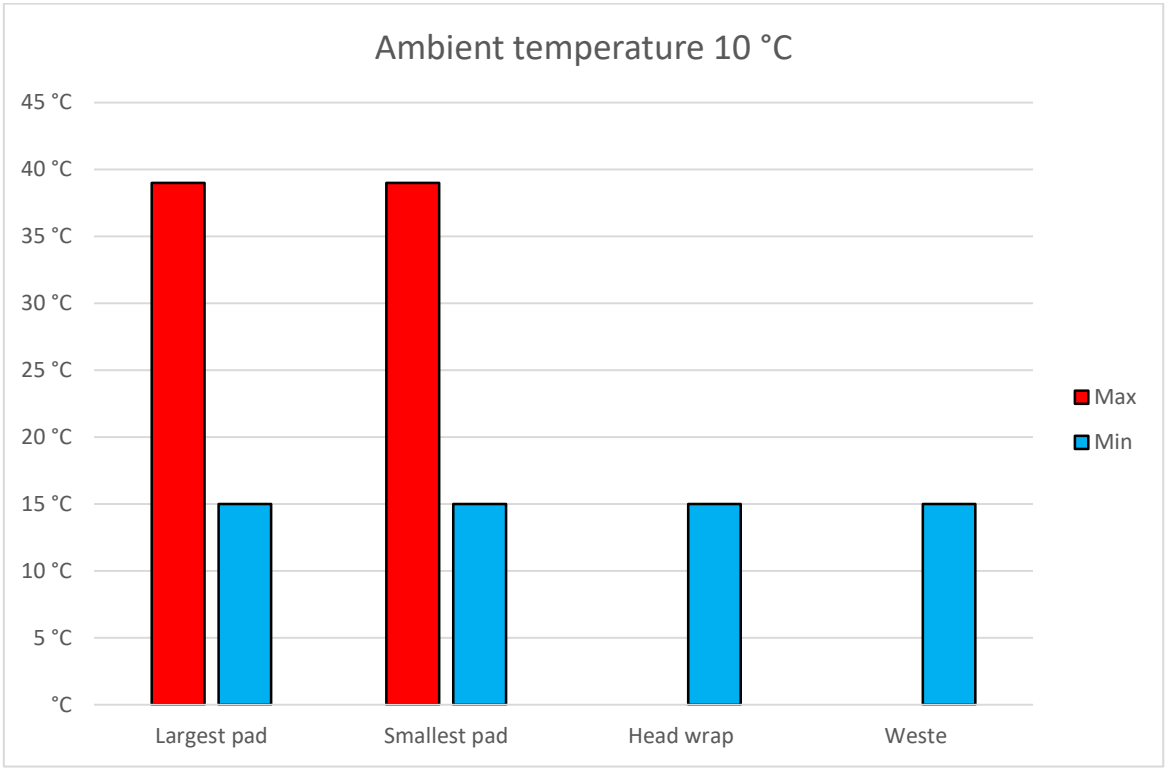
⚠CAUTION

In actual applications, the temperature limit values may differ!!

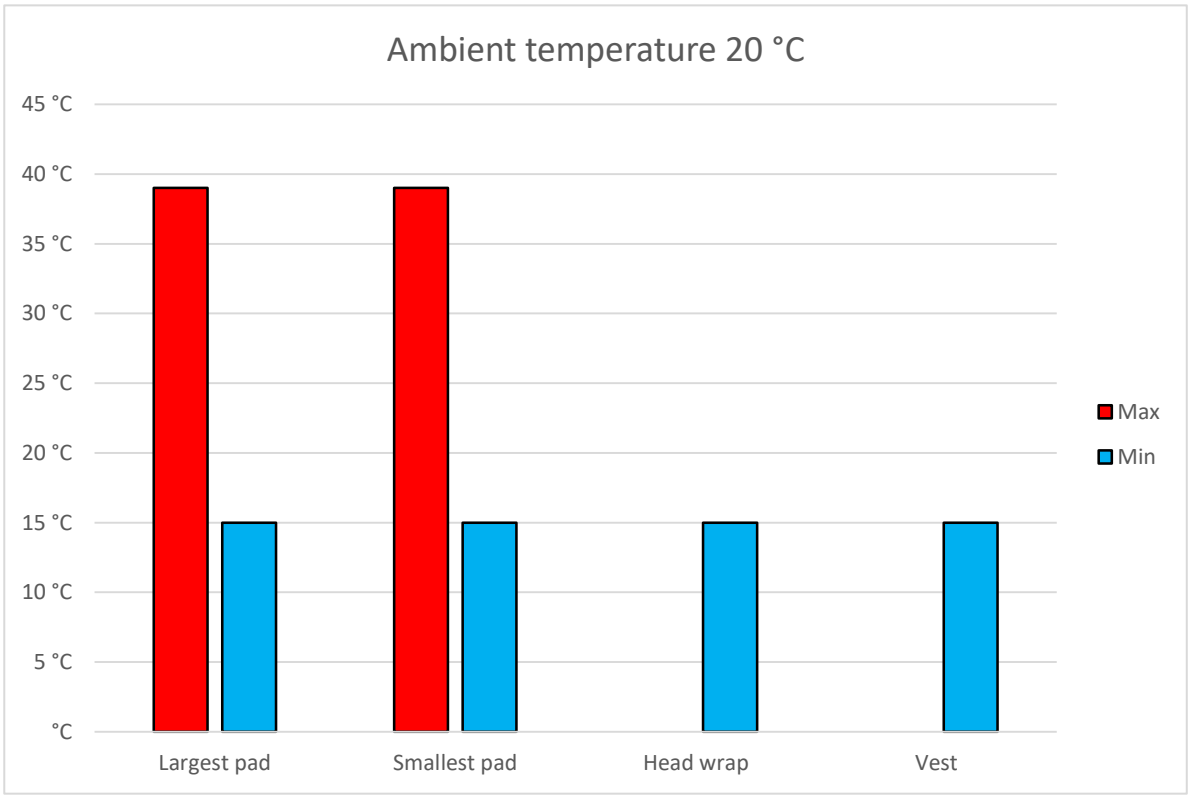
When used in actual applications, follow the instructions and note the warnings and information, etc., from the relevant sections:

4.2.1	Requirements on the installation site / operating location
5.4.1	Basic principles
5.4.2	Indications / contraindications / side effects
6.2.5	Temperature control mode
6.2.7	Using the water pads
6.2.8	Schematic performance charts
6.2.9	Responsibilities during operation
6.3.2.2	Alarms; *Display message:* TEMP.DIFF > 1°C

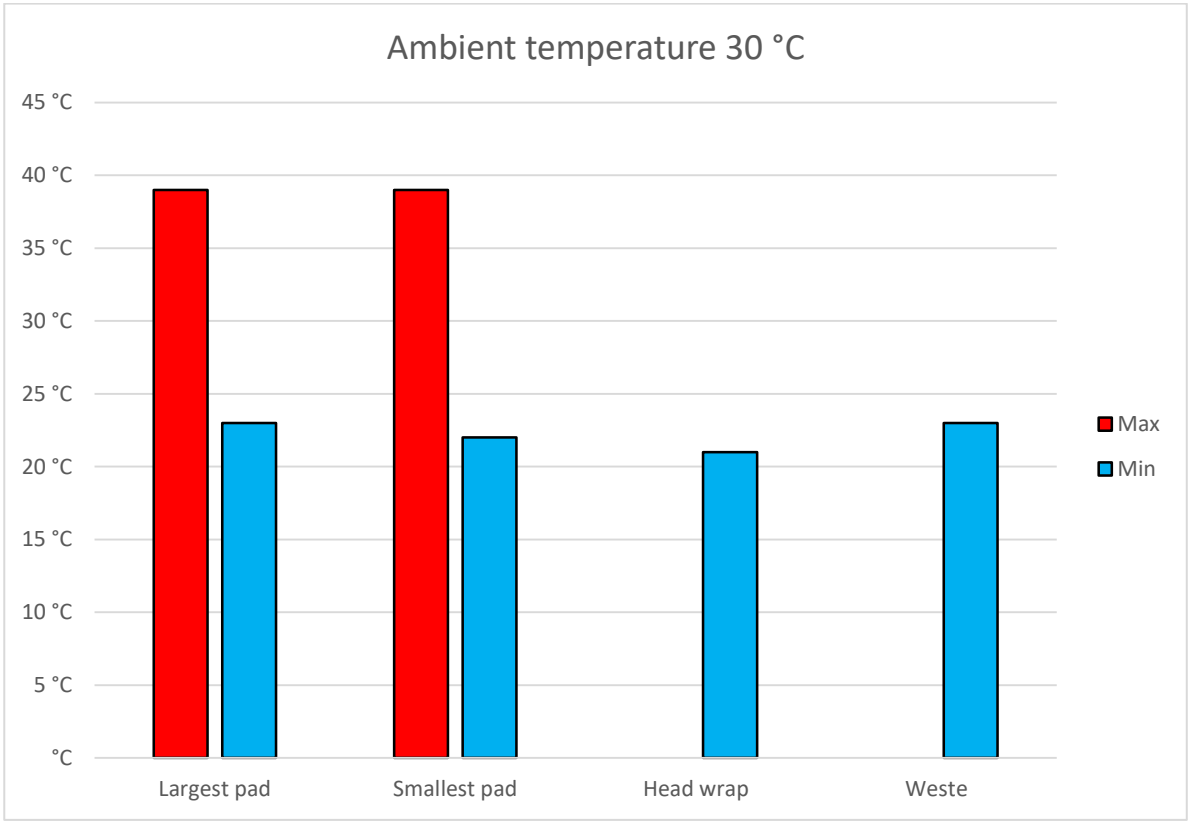
[7] The temperatures shown are reference values from the schematic performance charts of the laboratory analyses. They do not claim to be completely accurate when actually using the system.



Performance chart 1



Performance chart 2



Performance chart 3

6.2.9 Responsibilities during operation

6.2.9.1 Indication-based

⚠WARNING

Risk due to overestimation or underestimation of the performance of the system!

Using the unit can also be hazardous when used for its intended purpose in the following cases:

- ► Improper understanding of physical interactions among external accessories and due to ambient conditions (pad size, ambient temperature, etc.)
- ► Individual and unpredictable patient reactions

The reliable therapeutic application of the system requires the user to carefully weigh the risks between the desired indication and the performance of the system, as well as to continuously monitor and care for the patient in terms of side effects and preventing the formation of pressure ulcers due to heat or cold.

For the low-risk application of hypo/hyperthermia treatment, it is of utmost importance to externally and continuously monitor the body core temperature, e.g. by measuring the temperature in the urinary bladder, because uncontrolled hypo/hyperthermia is associated with increased patient mortality. See section 5.4.2 for indications / side effects / contraindications.

NOTE

The medical information provided here does not claim to be complete since new discoveries are constantly being made in the field of hypo/hyperthermia. The pfm medical hico gmbh is not responsible or liable in any way for negligent or incorrect use and cannot provide any medical recommendations or procedures. The user must independently decide what to use and how to proceed.

6.2.9.2 System-related

Check the water flow

During operation, check the water flow in the unit and the pad at regular intervals. The sight glass of the water flow indicator (15) features an impeller. When the flow of water is optimal, it is impossible to focus on the individual blades of the impeller.

Performing a function test

During long-term operation, check the independent safety device manually at least once every day. For this purpose, press the function test key (17) during operation. The unit then tests the safety electronics:

- The alarm sounds
- The temperature displays show 88.8
- The yellow error light (13) lights up
- The display shows FUNCTION TEST.
- After passing the test, the display shows the message “FUNCTION TEST OK”, and the unit automatically resumes normal operation.

⚠CAUTION

If the function test was not completed successfully, then the unit is no longer safe to operate. In this case;

► Do not use the unit on a patient.

► Have the unit inspected by Customer Service.

Checking the temperature control mode

During long-term operation, check the nominal temperature setting and actual temperature values shown in the display regularly; see section 6.2.5 and 6.3.2.

6.2.10 Operating language

The status and error messages in the display (12) can be displayed in the following languages: German, English, French, Spanish, Italian, and Polish.

Set the display language as follows:

- Switch the unit on.
- Hold the “Audio paused” (18) key down for about 4 seconds; the last language setting used appears in the display.

- Keep pressing the “Nominal value higher” (19) arrow key until the desired language appears in the display.
- About 10 seconds after the last input, the unit will return to its previous operating status, and the last language displayed is the active language.

6.3 Alarms

6.3.1 General information

The unit always emits both visual and audible alarms. The operator is therefore notified immediately in case of a malfunction, which increases the operational reliability of the system. The display (12) shows the error that caused the alarm (except in the case of a power failure alarm).

The alarms are assigned a medium priority[8]. Ignoring an alarm can result in the following:

- Minor injuries or discomfort within a period of time that is usually not long enough for manual corrective action (immediately).
- Reversible injuries within a period of time that is usually long enough for manual corrective action (promptly).
- Death or irreversible injury within an undefined period of time that is greater than the “promptly” time period (delayed).

If the system sounds an alarm for the reasons described in section 6.3.2, then the alarm can be reset as follows depending on the expected result.

- Pressing the “Mute audio” key (18) interrupts the audible alarm for 10 minutes. The error message can be read in the display (12). The error light (5) continues to flash as long as the alarm condition is present. The alarm condition must be eliminated according to the alarm message shown on the display (12).
- The unit will switch all functions off. The audible alarm cannot be interrupted. Switch off the unit using the mains switch (16), take it out of service, and if necessary, have it inspected by a service technician (Customer Service / Medical Technology).

NOTE

Before pressing the “Mute” key (18) or the mains switch (16) to suppress the alarm or take the unit out of service, please read the error message in the display!

[8] Source: DIN EN 60601-1-8 Table 1 – Alarm condition priorities

6.3.2 Description of alarms during operation

6.3.2.1 Display message: WATER LEVEL!?

The unit triggers this alarm when the water level drops below the MIN mark on the water level indicator (6) during operation. The display shows “WATER LEVEL!?”, the yellow error light (13) flashes, and a pulsating signal tone sounds.

- Press the “Mute audio” key (18) to interrupt the audible alarm for 10 minutes.
- Immediately fill up sterile filtered tap water to which a disinfectant has been added, until the water level is just below the MAX mark (6) (see section 4.3.1 “Filling the system”).

⚠CAUTION

► When the water level is too low, adequate water circulation can no longer be guaranteed.

► A water level that is too low can cause damage to components of the unit and consequently lead to the total failure of the unit.

6.3.2.2 Display message: TEMP.DIFF > 1°C

If the temperature of the water pad deviates from the temperature setting by more than 1°C during operation, then the unit will trigger this alarm. The display shows “TEMP.DIFF. > 1°C”, the yellow error light (13) flashes, and a pulsating signal tone sounds.

- Press the “Mute audio” key (18) to interrupt the audible alarm for 10 minutes.
- Change the temperature setting until the unit is able to regulate the temperature reliably.

NOTE

► Connecting or disconnecting a water pad during operation can create a temperature difference that causes the alarm to trigger.

► The alarm can be triggered due to unfavourable room temperatures because the specified nominal temperature (e.g. 15°C or 39°C) cannot be reached in this case. Change the temperature setting until the unit is able to regulate the temperature reliably.

► After switching on the unit and changing the temperature setting, this alarm function is suppressed for a defined period of time.

6.3.2.3 Display message: ALARM TEST DEFECTIVE→CUSTOMER SERVICE

The unit triggers this alarm if it has detected an error during the automatic or manual function test or has determined that the autonomous safety device does not respond. The display shows “ALARM TEST DEFECTIVE” and “→CUSTOMER SERVICE”, the yellow error light (13) flashes, and a pulsating signal tone sounds.

The audible alarm **cannot** be interrupted using the “Mute audio” key (18).

- Switch off the unit using the mains switch (16).
- Switch the unit back on.

⚠CAUTION

If the unit still emits an alarm, then take it out of service and have it inspected by a service technician (Customer Service / Medical Technology).

6.3.2.4 Display message: UNDERTEMPERATURE CHECK UNIT

The unit triggers this alarm when the temperature in the water tank drops below the lower limit of the measuring range (approx. 9°C). The display shows “UNDERTEMPERATURE” and “CHECK UNIT”. The yellow error light (13) flashes and a pulsating signal tone sounds. The temperature display shows – – . – .

The audible alarm **cannot** be interrupted using the “Mute audio” key (18).

- Switch off the unit using the mains switch (16).
- Take the unit to a warmer environment and wait for about 2 hours.
- Switch the unit back on.

⚠CAUTION

► Only store the unit in the permissible temperature range (3-60°C), otherwise the unit may become damaged.

► Only operate the unit in the permissible temperature range (10-30°C) in the hyperthermia mode and (10-23°C) in the

hypothermia mode, otherwise it will not function reliably and can become damaged (note the information in section 4.2.1 “Requirements on the installation site / operating location”!)

If the unit still emits an alarm, take it out of service and have it inspected by a service technician (Customer Service / Medical Technology).

6.3.2.5 Display message: CHECK UNIT→CUSTOMER SERVICE

The unit triggers this alarm in case of various defects. The display shows “CHECK UNIT” and “CUSTOMER SERVICE”, the yellow error light lamp (13) flashes, and a pulsating signal tone sounds.

The audible alarm **cannot** be interrupted using the “Mute audio” key (18).

- Switch off the unit using the mains switch (16).

Take the unit out of service and have it inspected by a service technician (Customer Service / Medical Technology).

6.3.2.6 Power failure alarm

The unit triggers this alarm when the power supply fails during operation. The yellow error light (13) is lit and a signal tone sounds. All other displays have no function. The power accumulator in the unit can maintain the alarm for at least 10 minutes in the event of a power failure.

The audible alarm **cannot** be interrupted using the “Mute audio” key (18).

- Switch off the unit using the mains switch (16).

NOTE

The alarm automatically turns off when the power supply returns.

The last temperature setting is stored in the unit.

When power is restored, the temperature setting stored must be checked by the user and confirmed before the unit returns to normal operation (see section 6.2 “Operation”).

7 Cleaning and disinfection

This chapter contains important information on cleaning and disinfecting the unit. Please follow these instructions to avoid damage caused by incorrect cleaning of the unit and to assure trouble-free operation.

7.1 Safety instructions

⚠CAUTION

Follow the safety instructions below before starting to clean the unit.

- ► Disconnect the mains plug before you start cleaning and disinfecting the unit.
- ► Do not allow any fluids to get inside the unit.
- ► Let the unit dry completely before switching it on again.

⚠CAUTION

Sensitive surfaces.

The surfaces of the unit and the pads can be destroyed when you use the wrong cleaning agents and disinfectants.

- ► Use only disinfectants based on aldehydes, ammonium compounds, or alcohols that do not affect ABS plastics, PVC, or PU on all surfaces and parts.
- ► If possible, do not use any disinfectants based on phenol derivatives because these will shorten the lifespan of plastic materials.

7.2 Unit

7.2.1 Water circuit

7.2.1.1. General Information for cleaning the water circuit

The cleaning process consists of a total of three steps. Thoroughly clean the unit (basic cleaning) and the accessories first, then disinfect the unit, and then flush and refill the unit. The unit should be cleaned and disinfected every 14 days. You must wear disposable gloves during the entire cleaning process and avoid contact with the sterile filtered tap water and the disinfectant.

7.2.1.2. Basic cleaning

Disconnect the unit from the mains power supply and remove any accessories that may be connected to it. Completely empty the unit and all accessories (e.g. water pads, extension hoses, etc.). Refill the unit with a neutral cleaner (follow the manufacturer's instructions) and use only sterile filtered tap water to dilute the cleaner. Connect the parts and accessories to be cleaned to the unit and connect the unit to the mains power supply. Use the arrow buttons to set the temperature to 35°C. Turn on the unit and leave it on for 30 minutes. Disconnect the unit from the mains power supply and remove the connected parts and accessories. Completely empty the unit and all accessories.

7.2.1.3. Disinfection

For disinfection purposes, any VAH[9]-listed disinfectant that is free of phenolic derivatives can be used. Suitable disinfectants include Terralin protect, Gigasept FF, Gigasept AF, Mikrozid AF, or Sanosil S003.

Note the dosage recommended by the corresponding manufacturer of the disinfectant. If necessary, prepare a disinfectant solution according to the instructions of the manufacturer of the disinfectant. Fill the unit with the disinfectant or the disinfectant solution. Connect the device to the mains power supply and connect all parts and accessories to be disinfected to the unit. Switch on the unit and allow it to run for about two minutes so that the disinfectant can be distributed throughout the circuit; if necessary, add more

[9]German Association for Applied Hygiene (**V**erband für **A**ngewandte **H**ygiene), and the list is available from the mhp-Verlag, Wiesbaden

disinfectant or disinfectant solution. Switch off the unit and note the exposure time specified by the manufacturer of the disinfectant. After the exposure time has expired, disconnect the unit from the mains power supply and completely empty the unit and all accessories.

⚠CAUTION

Do not apply any cleaning and decontamination methods other than the ones recommended by pfm medical hico gmbh.

Before introducing new methods, have them checked together with pfm medical hico gmbh.

This is the only way to make sure that the unit will not be damaged by the new method.

7.2.1.4. Flushing and refilling

Fill the unit with sterile filtered tap water[10]. Connect the unit to the power supply. Connect any accessories you want to use to the unit. Switch on the unit and allow the water to circulate for five minutes. Disconnect the unit from the power supply. Completely empty the unit and all accessories used.
The cleaning process is now finished. Before putting the unit back into service, refill the unit using only sterile filtered tap water to which a disinfectant has been added[11].

[10] Depending on the quality of the water (e.g. its hardness, among other things), the lifetime of the parts of the unit that come into contact with water may be reduced.

[11] For example 10 ml SANOSIL mixture (from Sanosil, Farchant) ⇨ (1000 ml sterile filtered tap water + 10 ml Sanosil solution). Alternatively, a different long-term disinfectant and preservative can also be used, e.g. Micropur or Certisil. If you have any questions, please contact the Customer Service department of pfm medical hico gmbh.
The use of a disproportionately high amount of disinfectant can reduce the lifetime of parts of the unit that come into contact with water!

7.2.2 Surfaces

If possible, use decalcified water to clean the surfaces of the unit. Only wipe the unit with a damp cloth. Use only warm water (max. 50°C) to which a mild commercial neutral cleaner has been added. Wipe off again with clean water and wipe the unit dry with a cloth.

To disinfect the surfaces of the unit, we recommend using a wipe-down or surface disinfectant from the VAH list[12] (e.g. with Mikrozid AF, Terralin protect, Gigasept AF, or Gigasept FF from S&M). When using a disinfectant, follow the instructions of the manufacturer.

Only switch on the unit after the disinfectant has evaporated completely.

7.2.3 Ventilation openings

Check the ventilation slots on both sides of the unit for dirt and dust regularly (at least every 6 months). Remove as much dirt and dust from the surface as possible. Dust deposits in the unit reduce the performance of the system. Have dirt and dust inside the unit removed by a service technician (Customer Service, Medical Technology). Do not open the unit yourself.

⚠CAUTION

Do not apply any cleaning and decontamination methods other than the ones recommended by pfm medical hico gmbh.

Before introducing new methods, have them checked together with pfm medical hico gmbh.

This is the only way to make sure that the unit will not be damaged by the new method.

[12]German Association for Applied Hygiene (**V**erband for **A**ngewandte **H**ygiene), and the list is available from the mhp-Verlag, Wiesbaden

7.3 Water pads, hose extension

If possible, use decalcified water. Wipe off the surfaces with a damp cloth only. Use only warm water (max. 50°C) to which a mild commercial neutral cleaner (Mr. Clean or Ajax) has been added.

When using a neutral cleaner, follow the instructions of the manufacturer. Wipe off again with clean water and wipe the pad until dry.

To disinfect the surfaces of the unit, we recommend using a wipe-down, surface, or spray disinfectant from the VAH list[13] (e.g. with Mikrozid AF, Terralin protect, Gigasept AF, or Gigasept FF from S&M).
When using a disinfectant, follow the instructions of the manufacturer.

Only use the pad and the hose extension again after the disinfectant has evaporated completely.

Check the pad and the hose extension for damage, deformation, or cracks and replace any damaged accessories.

⚠CAUTION

Do not apply any cleaning and decontamination methods other than the ones recommended by pfm medical hico gmbh.

Before introducing new methods, have them checked together with pfm medical hico gmbh.

This is the only way to make sure that the unit will not be damaged by the new method.

[13]German Association for Applied Hygiene (**V**erband for **A**ngewandte **H**ygiene), and the list is available from the mhp-Verlag, Wiesbaden

8 Maintenance and safety check

This chapter contains important information on the maintenance of the unit. Please follow these instructions to avoid damage to the unit caused by inadequate maintenance and to ensure trouble-free operation.

8.1 Maintenance

We recommend closing a maintenance contract with the pfm medical hico gmbh. By closing a maintenance contract, you fulfil the following requirements:

- Ordinance on Industrial Safety and Health of the German Employers' Liability Association (BetrSichV BGV A2, VBG 4) and the new BGV A3
- Medical Device Directive 93/42/EEC,
- German Medical Devices Operator Ordinance (MPBetreibV)

All of these regulations require regular technical inspection of the units.

Furthermore, maintenance by our experts ensures maximum operational reliability and the longevity of the unit.

NOTE

With proper handling and regular maintenance, the unit has a product lifetime of about 10 years.

NOTE

When handled properly, the lifespan of the necessary accessories (water pads and hose extensions) is determined by the natural aging process and wear through the use of the unit.

8.1.1 Unit

- Check the ventilation openings on the side, bottom, and back of the unit regularly for dirt and dust.
- Dust deposits in the unit reduce the performance of the system. Have dirt and dust inside the unit removed by a service technician (Customer Service, Medical Technology). Do not open the unit yourself.
- Have the Customer Service or Medical Technology departments perform the maintenance and safety checks regularly to ensure the intervals are maintained.

8.1.2 Water tank

Replace the sterile filtered tap water in the water tank at least every 2 weeks (described in section 7.2.1) as follows:

- Disconnect unit from the mains power supply.
- Place a container (bucket, bowl, etc.) below the front of the unit or place the unit over a drain (e.g. the drain of a sink).
- Unscrew the cap from the water filling neck (5), e.g. with a coin.
- Take the water drain hose and place it on one of the front hose connections (9).
- Tilt the unit forward and drain the water through the water drain hose until it is completely empty.
- Remove the water drain hose from the front hose connection and place it aside for now.
- Clean and disinfect the water circuit as described in section 7.2.1.
- Refill the unit with sterile filtered tap water to which a disinfectant has been added as described in section 4.3.1. The max. filling capacity of the unit tank is approx. 1 litre.

8.1.3 Hose connections

The seal rings (O-rings) on all hose connections are subject to aging and can become dry and brittle as a result. You should therefore coat the seal rings with a thin film of silicone paste or petroleum jelly every 6 months.

8.2 Safety check

In order to maintain legal conformity and operational reliability according to the Medical Product Directive 93/42/EEC (Appendix I, section 13.6.d) and the German Medical Devices Operator Ordinance (MPBetreibV Art. 6(1)), a safety check must be conducted on the unit every 12 months. The operator is solely responsible for ensuring these safety checks are performed. According to the MPBetreibV (section 6(4)(1+3)), this safety check may only be performed by pfm medical hico gmbh or a qualified person. The safety check covers the following points at a minimum:

- Inspection of the device and accessories for external damage, wear, and aging, and checking the legibility of the displays and labels
- Measurement of the PE resistance and the earth leakage current according to the test facility and manufacturer's data
- Check of all functions according to the operating instructions
- Check of all safety functions according to the manufacturer's data
- Check of all sensors according to the manufacturer's data (pfm medical hico gmbh provides a service manual for authorised persons for this purpose).

NOTE

In order to maintain compliance with statutory safety regulations, we recommend closing a technical safety inspection contract with an authorised company to perform the recommended annual safety check.

⚠CAUTION

For heavily soiled units or accessories returned to us for maintenance or repair where there is a suspicion of contamination due to contact with specific pathogens (e.g. MRSA), the system must be pre-disinfected with an appropriate disinfectant and packaged for transport in accordance with the decontamination requirements and material compatibility. Otherwise we reserve the right to reject such units or accessories for safety reasons, or to subject these to additional treatment (chemo-thermal) before performing a technical revision or damage analysis. Any additional costs arising from such measures shall be borne by the customer.

Questions regarding service, maintenance, or safety checks should be addressed directly to:

pfm medical hico gmbh
Bonner Str. 180
50968 Cologne
Tel.: +49 (0)2 21 / 3 76 78-0
Fax: +49 (0)2 21 / 3 76 78-85
Email: info@hico.de

9 Troubleshooting

This chapter contains important information on locating errors and troubleshooting. Please follow these instructions to prevent hazards and damage.

9.1 Safety instructions

⚠CAUTION

- ► Repairs on electric devices may only be carried out by skilled professionals, including personnel trained by the manufacturer.
- ► Improper repairs can seriously endanger the user and cause damage to the unit.

NOTE

Opening the unit by unauthorised persons will void all rights to any guarantee and warranty claims.

- ► Repairs to the unit may only be performed by the pfm medical hico gmbh or by experts trained and/or authorised by the pfm medical hico gmbh.

9.2 Causes of error and troubleshooting

Error	Possible causes	Actions
No or insufficient water circulation	1. Hoses or pads are kinked/folded 2. Connections are not tight 3. Unit is positioned too far below the water pad 4. Strong foam formation 5. High patient weight 6. Pump worn/defective	1. Ensure hoses and pads are correctly placed and positioned 2. Insert hose connections firmly into each other 3. Position the unit at the same height or higher 4. Change the water* 5. Position the unit higher than the water pad 6. Customer service*
Connectors are hard to connect	Sealing ring dry and brittle	Grease sealing ring with petroleum jelly, silicone grease, or a similar lubricant
Hose connection drips constantly	Exterior, visible sealing ring damaged or missing	Replace sealing ring*
Coupling valve of the unconnected coupler drips constantly	1. Inner sealing ring damaged 2. Inner sealing ring dirty or contaminated	1. Customer service* 2. Insert and loosen coupling several times, if necessary contact Customer Service
Alarm + display message: “ALARM TEST DEFECTIVE” “CUSTOMER SERVICE”	1. Independent safety device defective 2. Pump defective (electrical)	Customer service*
Alarm + display message: “TEMP.DIFF. > 1°C”	Connecting or disconnecting the water pad during operation	Acknowledge alarm with the “Alarm OFF” key
Alarm + Display message every 10 min.: “TEMP.DIFF. > 1°C”	1. Cooling output insufficient 2. Cooling elements or pump defective 3. Strong foam formation in the tank 4. Bypass interrupted	1. See the next line 2. Customer service* 3. Change the water* 4. Customer service*
Nominal value was not reached during cooling	Cooling capacity is insufficient because: 1. Ambient temperature too high and/or 2. nominal value too low and/or 3. water pad too large (2 water pads)	The 3 causes indicated mutually adverse affect on each other, which means at least one cause must be eliminated.

Error	Possible causes	Actions
Alarm + display message: “Water level!?” Can be acknowledged for 10 min. using the “Alarm OFF” key	1. Water level too low 2. Unit is not completely horizontal 3. Sensor deviation	1. Refill water 2. Position unit horizontally 3. Customer service*
Alarm + display message: “CHECK UNIT” “->CUSTOMER SERVICE”	1. Various defects 2. Water tank empty 3. Sensor break/short circuit T1 4. Sensor short circuit T2	1. Customer service* 2. Refill with water* 3. Customer service* 4. Customer service*
Alarm + display message: “CHECK UNIT” “UNDERTEMPERATURE”	1. Unit too cold (< 9°C) 2. Sensor break T2 3. Water tank frozen	1. Let the unit warm up at room temperature for a while* 2. Customer service* 3. Let the unit defrost*; Examine unit for frost damage (is water flowing out of the unit?) → Customer service
Unit does not function at all and acoustic alarm	1. Mains power failure 2. Mains connector does not make contact 3. Fuse defective 4. Unit defective	1. Switch off unit until power returns 2. Check the connector on unit and in the socket for correct fit 3. Customer service* 4. Customer service*

* Switch off the unit immediately

10 Disposal of an old unit

Old electric and electronic devices very often contain precious metals and valuable materials. However, they also contain harmful substances that were necessary for their function and safety.

If disposed of as residual waste or handled incorrectly, these substances can be harmful to humans and damage the environment. This device must **not** be disposed of together with normal industrial or domestic waste!

NOTE

► According to the product responsibility requirements according to Art. 22 of the German Recycling Economy and Waste Management Act (KrW-/AbfG) and Art. 2(1)(8) of the German Electrical and Electronic Equipment Act (ElektroG), the unit must be handed over to a corresponding municipal collection point or returned to the manufacturer.

NOTE

► In accordance with waste management regulations applying to the user, the water pad can be disposed of together with domestic waste for incineration.

11 Technical data and accessories

11.1 Technical data

HICO-VARIOTHERM 550

Item No. (REF):	540001 (220 V/230 V) / 540021 (115 V)
Rated voltage:	230 VAC 50/60 Hz / 115 VAC 50/60 Hz / 220 VAC 60 Hz
Power consumption:	320 W
Current consumption:	Approx. 1.5 A (220 V/230 V) / 3 A (115 V)
Nominal temperature range:	15-39°C
Safety shutdown:	41.1 - 41.5°C (autonomous safety shutdown). This results in a max. surface temperature on the pad < 41°C
Correction value:	0.5°C (Water temperature display)
Sensor element:	2 x NTC 5 K
Pump capacity:	Max. 5.5 l/min., max. 0.21 bar
Warm-up time:	Approx. 5-10 min. (20-37°C)
Cool-down time:	Approx. 5-10 min. (20-15°C)
Fuse rating:	2x T 3.15 A; L 250 V (220 V/230 V) / 2x T 5 A; L 250 V (115 V)
Class/type of protection:	I, BF (defibrillation protection)
IP type of protection:	IP X1 (drip proof)
Power supply:	Must comply with VDE 0100 Part 710:2012-10 *"Electrical safety in medical environments"*.
Risk class (93/42/EEC):	II b
Ambient temperature:	10-30°C (hyperthermia mode) 10-23°C (hypothermia mode)
Relative humidity:	Approx. 30-70%
Transport/storage temperature:	3-60°C
Air pressure:	700-1060 hPa
Tank volume:	Approx. 0.5/0.8 l (MIN/MAX)
Permissible height difference:	Max. 1 m (unit/water pad)
Dimensions WxHxD:	Approx. 200 x 290 x 440 mm
Weight:	Approx. 17 kg (empty)
Noise emission:	Approx. 50 dB(A) (1 m)
Alarm level:	> 55 dB(A) (3 m)
Test basis:	Medical Product Directive 93/42/EEC, DIN EN 60601-1, DIN EN 60601-1-2, DIN EN 80601-2-35
UMDNS code:	12-075

Subject to technical changes.

⚠WARNING

► It is not permitted to make changes to the HICO-Variotherm 550!

11.2 Accessories

- Hose extension, approx. 3 m (required accessory) REF: 550022
- Thermo-hose extension, approx. 2 m (optional accessory) REF: 660022
- Only original HICO water pads (required accessory) made of PU may be used together with the HICO-VARIOTHERM 550. Available sizes and empty weights, among others:

HICO polyurethane water pad/blanket	50 x 170 cm // 0.91 kg	REF: 550046
HICO polyurethane water pad/blanket	50 x 92 cm // 0.54 kg	REF: 550047
HICO polyurethane water pad/blanket	50 x 30 cm // 0.24 kg	REF: 550044
HICO polyurethane water pad/blanket	35 x 170 // 0.67 kg	REF: 550048
HICO polyurethane water pad/blanket	35 x 92 cm // 0.44 kg	REF: 550049
HICO polyurethane water pad/blanket	70 x 60 cm // 0.52 kg	REF: 550025
HICO polyurethane water pad/blanket	70 x 120 cm // 0.90 kg	REF: 550026

- Various PU collars for partial output of warmth are also available as accessories.

HICO collar (A)	38 x 26 cm	REF: 550081
HICO collar (D)	27 x 11 cm	REF: 550084

- HICO water drain hose (optional accessory; only used to empty the unit) REF: 550076

NOTE

► The suitability of the PU pads and PU blankets for the intended use must be decided by the user on a case-by-case basis.

Hose and pad material:	PU; free of latex, heavy metals, and phthalates.
Ambient temperature in operation:	10-30°C (hyperthermia mode) 10-23°C (hypothermia mode)
Relative humidity:	Approx. 30% to 70%
Transport and storage temperature:	3°C to 60°C without water
Air pressure:	700 to 1060 hPa

Please refer to the corresponding brochures and price lists for any further information you require on the HICO water pads.

- Five-castor base, see section 4.2.3 (optional accessory) REF: 530002
- Unit carrier (mobile); total height approx. 1 m; see section 4.2.2
  (optional accessory). REF: 602810

NOTE

When using the unit carrier, follow the corresponding instructions for use.

Excerpt of the safety information for the unit carrier:

► Assembly, handling, and use require you to follow these safety instructions carefully.

► The unit must be screwed to the insert panels using the 2 knurled thumb screws included!

► To move the carrier, you must release the brakes on the castors! Be very careful when rolling over obstacles, soft flooring, and ramps.

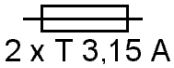
► Stationary unit carriers are to be secured using the brake castors.

► The electrically conductive castors only serve to dissipate static electricity.

► The pfm medical hico gmbh is only responsible for the safety and function of the unit carrier if the installation and operating instructions are followed in every respect, and

only if accessories specifically designed for this unit carrier from the pfm medical hico gmbh are used.

11.3 Symbols



Unit fuses

The level of protection against electrical shock in the pads corresponds to type BF protection (defibrillation protection).

Exercise caution! (e.g. do not operate the unit in the presence of combustible gases)

Observe / follow the instruction manual

Disposal

Manufacturer

Also involved in the conformity assessment procedures:
DEKRA Certification GmbH,
Handwerkstraße 15
70565 Stuttgart

12 Guidelines and manufacturer's declaration

Guidelines and manufacturer's declaration – electromagnetic emissions

Tables for medical electrical equipment, general Information:
Table 1

Guidelines and manufacturer's declaration – electromagnetic interference		
The HICO-Variotherm 550 is designed for operation in the electromagnetic environments listed in the tables and text of these operating instructions. The customer or user of the HICO-Variotherm 550 should ensure that the unit is used in an appropriate environment.		
Electrical interference measurements	**Agreement**	**Electromagnetic environment - guidelines**
HF emissions according to CISPR 11	Group 1	The HICO-Variotherm 550 uses RF energy exclusively for its internal functions. Therefore, its RF emission level is very low, and it is unlikely that it will interfere with nearby electronic devices.
HF emissions according to CISPR 11	Class B	
Emission of harmonics according to IEC 61000-3-2	(DIN EN 60601-1-2:2015 Table 2) Class A	
Emission of voltage fluctuations/flicker according to IEC 61000-3-3	Agrees	The HICO-Variotherm 550 is designed for use in facilities other than residential areas and in facilities that are directly connected to a public power supply that also supplies residential buildings.

Table 2

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The HICO-Variotherm 550 is designed for operation in an electromagnetic environment like the one listed below. The customer or user of the HICO-Variotherm 550 should ensure that the device is used in such an environment.			
Immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) according to 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 the floor is covered with a synthetic material, then the relative humidity must be at least 30%.
Electrical fast transient (EFT) / bursts according to IEC 61000-4-4	±2 kV for mains cables ±1 kV for input and output lines	±2 kV for mains cables Not applicable	The quality of the power supply voltage should correspond to that of a typical commercial or hospital environment.
Impulse voltage/surges according to IEC 61000-4-5	±1 kV differential mode voltage ±2 kV common mode voltage	±1 kV differential mode voltage ±2 kV common mode voltage	The quality of the power supply voltage should correspond to that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations according to IEC 61000-4-11	<5% U_T (>95% dip in U_T) for ½ cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (60% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Voltage dips: 0% U_T for 0.5 cycle (1 phase) 0% U_T for 1 cycle 70% U_T for 25/30 cycles (50/60 Hz) Voltage interruption: 0% U_T for 250/300 cycles (50/60 Hz)	The quality of the power supply voltage should correspond to that of a typical commercial or hospital environment. If the user of the HICO-Variotherm 550 requires continued operation during interruptions of the power supply, then we recommend supplying the HICO-Variotherm 550 with power from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field according to IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Comment: U_T is the alternating power supply voltage prior to application of the test level.			

Table 4

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The HICO-Variotherm 550 is designed for operation in an electromagnetic environment like the one listed below. The customer or user of the HICO-Variotherm 550 should ensure that the device is used in such an environment.			
Immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF interference according to IEC 61000-4-6 Radiated RF interference according to IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM and amateur bands (DIN EN 60601-1-2:2015 Table 4) 3 V/m 80 MHz to 2.7 GHz (Proximity fields for wireless communication equipment DIN EN 60601-1-2:2015 Table 9) 380 - 390 MHz 27 V/m; PM 50%; 18 Hz 430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 - 787 MHz 9 V/m; PM 50%; 217 Hz 800 - 960 MHz 28 V/m; PM 50%; 18 Hz 1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz 2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz 5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM and amateur bands (DIN EN 60601-1-2:2015 Table 4) 3 V/m 80 MHz to 2.7 GHz (Proximity fields for wireless communication equipment DIN EN 60601-1-2:2015 Table 9) 380 - 390 MHz 27 V/m; PM 50%; 18 Hz 430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 - 787 MHz 9 V/m; PM 50%; 217 Hz 800 - 960 MHz 28 V/m; PM 50%; 18 Hz 1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz 2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz 5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	Portable and mobile radio equipment should be used no closer to the HICO-Variotherm 550 and its power cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). The field strength from a stationary radio transmitter, as determined by an electromagnetic site survey[a], should be less than the compliance level[b] in all frequency ranges. Interference may occur in the vicinity of equipment marked with the following symbol. 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by the absorption and reflection from structures, objects, and people.

[a] Field strength from fixed transmitters such as base stations for radio (cellular/wireless) telephones and land mobile radios, amateur radio, AM/FM radio stations, and TV stations cannot be predicted theoretically with accuracy. To determine the electromagnetic environment of a stationary transmitter, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HICO-Variotherm 550 is used exceeds the compliance level listed above, then the HICO-Variotherm 550 should be monitored to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as re-orienting or relocating the HICO-Variotherm 550 or the use of a shielded location with higher RF shielding effectiveness and filter attenuation.

[b] The field strength should be less than 3 V/m over the frequency range of 150 kHz to 80 MHz.

Table 6

Recommended separation distance between portable and mobile RF communications equipment and the HICO-Variotherm 550

The HICO-Variotherm 550 is designed for operation in an electromagnetic environment in which RF interference is controlled. The customer or the user of the HICO-Variotherm 550 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HICO-Variotherm 550 depending on the power output of the communications equipment as indicated below.

Output power of the transmitter W	**Separation distance depending on the transmitter frequency** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose maximum output power rating is not listed in the table above, the distance can be determined using the equation shown in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the manufacturer of the transmitter.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

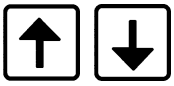
NOTE 2: These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by the absorption and reflection from structures, objects and people.

13 Quick Start Guide

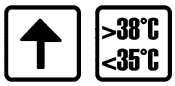
- Connect the unit to the mains supply.
- Connect the water pad to the unit.
- Check the water level on the unit.

- Switch on the unit using the mains switch and watch the automatic function test.

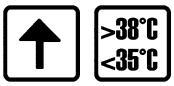
- If the nominal temperature setting is > 38°C or < 35°C when switching on the unit, then an alarm will be emitted. Acknowledge and start by pressing the release key once.



- Set the temperature with the arrow keys.



- For temperatures above 38°C, press the arrow key and the release key at the same time.



- For temperatures below 35°C, press the arrow key and release key at the same time.
- Depending on the application, place the water pad under or on top of the patient.
- Monitor the body temperature of the patient.
- Monitor the water level and water flow on the unit.

- In case of continuous operation, perform a manual function test once every day by pressing the “Function test” key.

- Acoustic alarms of medium priority (“WATER LEVEL!?” and “TEMP.DIFF > 1°C”) can be interrupted for 10 minutes using the “Mute audio” key.
- All other acoustic alarms of medium priority cannot be interrupted. Switch off the unit using the mains switch (16).

NOTE

When certain errors occur, the unit will switch off all functions. Take the unit out of service and submit it to a service technician for inspection and to restore its operational reliability.

⚠WARNING

There is a risk of the patient becoming overheated or undercooled.

► Monitor the patient's body temperature when using the unit and the water pad on the patient.

⚠CAUTION

Do not start the unit in the following cases:

► The display has failed.

► Individual segments of the temperature display have failed (temperature can no longer be read properly).

► The yellow error light (13) is continuously lit or does not light up at all (functional test).

► The alarm signal tone continues to sound or does not sound at all (functional test).

► The unit does not respond when you press a key.

► The unit does not respond as described in section 6.2.3 "Functional test" when switching on the unit or during a function test.