HILOTHERM®

ChemoCare-CIA

Instruction for Use

CE 0123

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Before commissioning the Hilotherapy system, the instructions for use must be read. Pay special attention to the instructions
Caution and Caution ***/Warning***.

Caution describes a situation in which the device or the connected modules can be damaged.

Caution /Warning describes a situation in which people can be harmed.
Increased attention and care should be applied.

1. General description

1.1 Purpose

The HILOTHERAPIE by means of the Hilotherm ChemoCare-CIA system serves the purposeof physicalthermotherapy, which locally maintains a constant temperature in the therapeutically ideal range. Applications lasting several hours can be carried out at a constant temperature without temperature deviations. Used prophylactically for scalp cooling, HILOTHERAPY with tels de s ChemoCare – CIA System reduces or prevents chemotherapy-induced alopecia (CIA) that otherwise occurs without cooling.

Therapeutic Principle:
During chemotherapy, all rapidly dividing body cells are attacked. Hair cells have the second fastest rate of division in the human body and for this reason many chemotherapy drugs cause hair loss (alopecia). They attack the hair follicles during the growth phase and cause hair loss about two weeks after the start of chemotherapy.
By cooling the scalp, the damage to the hair follicles caused by chemotherapy can be limited. Bylowering the temperature of the scalp by a few degrees immediately before, during and after the administration of chemotherapy drugs, the blood flow to the hair follicles is reduced. This prevents or limits hair loss.

With the Hilotherapy System HILOTHERM ChemoCare is consisting of the temperature control unit and precisely fitting cuffs directly attached to the skin, the tissue temperature is set locally in the area of the hands and feet or the scalp to a value confirmed by clinical studies and kept constantly cool.
The therapy device with the cuffs and connection tubes forms a closed circulatory system through which the cooling medium flows and keeps the set temperature constant.

1.2 Areas of application

Thermotherapy with the H ILOTHERM ChemoCare-CIA is used prophylactically before, during and after chemotherapy infusion to reduce the risk of developing chemotherapy-induced-alopecia.

Duration of use

See Item 3.8

1.3 Indications and contraindications

Indications for hilotherapy

The indication for hilotherapy (local reduction of tissue temperature) is chemotherapy-induced alopecia (CIA)

Scalp cooling (cooling cap) can be used for all solid tumors that are treated with cytostatics such as taxanes (e.g. docetaxel), alkylating agents (e.g. cyclophosphamide) and anthracyclines/DNA intercalation (e.g. doxorubicin). These drugs attack the rapidly dividing cells and the keratinocytes, which leads to hair loss (Paus et al., 2013). CIA occurs about two weeks after the start of chemotherapy.

Contraindications to hilotherapy

All forms of cold applications are contraindicated if cryoglobulinemia, cold hemagglutination and cold urticaria caused by histamine release / cold contact urticaria occur.
Scalp cooling must not be used in the following conditions:

- Malignant hematological diseases (leukemia, non-Hodgkin lymphoma and other generalized lymphomas)
- Cold allergy
- Cold agglutinin
- Scalp metastases
- Imminent bone marrow ablation chemotherapy
- Imminent cranial irradiation

1.4 Requirements for operators

The operation of the Hilotherapy device is simple and can be carried out by nursing staff or the patient himself. However, the application should be supervised by qualified medical personnel.
Before commissioning, the instructions for use must be known and the operator must familiarize himself with the device. In particular, the application of the cuff must be done carefully.

1.5 Device description

The Hilotherapy System HT 02-ck is a transportable system for local professional cold treatment. It consists of a cooling unit and a headcuff.
It is characterized by its easy handling and easy operation.
The temperature of the ChemoCare-CIA unit regulates itself during use.
The device is intended for continuous operation.

The Hilotherapy cooling unit essentially consists of the following components:

Cooling unitWith the cooling unit, distilled water is tempered to the exact degree and kept constant.
ControlThe controller records the data in the device via sensors and regulates all processes. With the keys (item 04) the desired value for the temperature is entered.

DisplayThe display (item 03) shows the set values and the operating status.

The following describes the use of a cooling unit of the ChemoCare-CIA system.

01 Kupplungen (only on the right side)
02 Feeding tube
03 Display
04 Keyboard
05 Level indicator and drain pants
06 Ventilation slots
07 Carrying handle

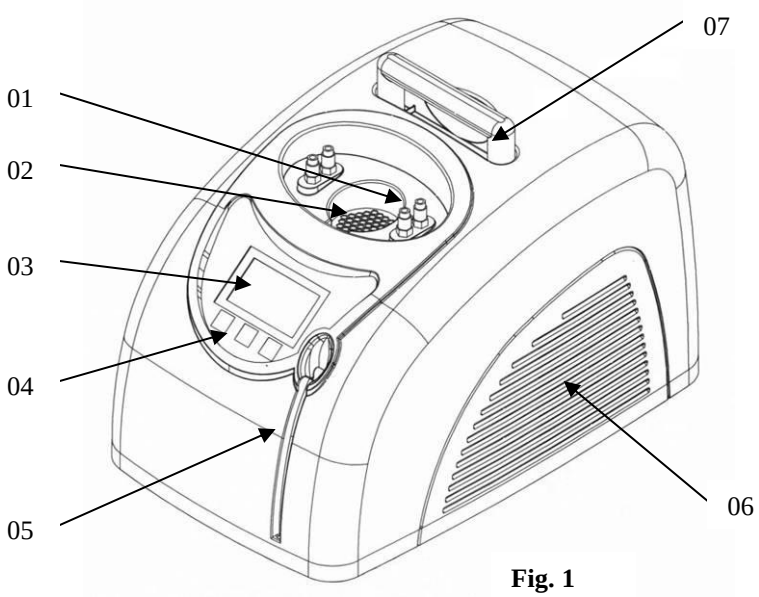


Fig. 1

2. Safety instructions

2.1 General safety instructions

- Before use, the user must check the correct condition of the device and user part.
- The therapy facility always consists of the Hilotherapy device, connecting tube and a cuff.
- Only original Hilotherapy devices and cuffs may be connected and used.
- When switched off, the good thermal conductivity of water can lead to an unwanted change in body temperature in large cuffs (cooling when applying heat, heating when applying cold).
- If the intended use cannot take place due to malfunctions, the cuff must be removed.
- During application, especially when using several or large cuffs, the patient's body temperature should be monitored.
- The hilotherapy system must not be operated in the incubator.
- The cuffs can be damaged by the penetration of sharp objects.
- The flow of the channels in the cuffs can be prevented by folding the cuffs or by pressing.
- The flow of the hoses can be prevented by buckling.
- The tank may only be filled with demineralized water.
- When filling with demineralized water, the power plug must not be plugged in.
- The lateral ventilation slots must not be closed or covered. The device may only be operated in a horizontal position on a fixed flat surface.
- The device must not be put into operation if not all aggregates and displays are working properly.
- In the event of malfunctions, the device must be switched off immediately. It may only be restarted when the fault has been resolved. In the event of critical or unclear errors, the manufacturer must be notified.
- Interfaces for the service area and data exchange must not be used when a patient is connected to the device.
- ***Warning:*** A self made technical change on the device is not allowed

2.2 Hazard statements

- The housing must not be opened.
- Before carrying out maintenance measures, the device must be disconnected from the power supply.
- Maintenance may only be carried out by qualified service technicians.
- The AC voltage source shall correspond to the specified range located on the nameplate on the back of the device.
- The Hilotherapy system may only be connected to mains voltages connected to a reliable protective mass conductor. Do not use the system if the functionality of the external, protective mass conductor is questionable.
- In order to ensure fire protection, care must be taken when replacing the fuses that only fuses of the same type and with the same nominal values are used (see type plate).

2.3 Electromagnetic compatibility

In the case of medical electrical equipment, special attention must be paid to electromagnetic compatibility (EMC). This means that the devices must be installed and put into operation in accordance with the EMC instructions contained in these operating instructions (see instructions and manufacturer's declaration in the annex).
Portable and mobile radio communication equipment can affect medical equipment.
Warning: The Hilotherapy system should not be operated alongside/on other equipment. Should this be necessary, the hilotherapy system must be monitored to ensure safe operation.

2.4 Environmental conditions

The ambient temperatures for safe operation are between + 10 °C and + 26 °C.
At higher temperatures, the guaranteed cooling capacity cannot be provided. If the device has been exposed to temperatures that are far outside the specified temperature range, it should be waited before commissioning until the device has reached room temperature.
The humidity in the room should not exceed 70%. Higher humidity can lead to condensation on the hoses and cuffs.

Caution: Accumulation of condensation can lead to a risk of slipping on the floors. If this is detected, appropriate security measures must be initiated

Protect the device from excessive heat, dust and direct sunlight.
Warning: The Hilotherapysystem is not intended for operation in highly explosive environments and must be kept away from flammable gases and liquids.

3. Commissioning / device start / cooling

3.1 Functional control

Before commissioning the Hilotherapy system, equipmente and user parts must be checked for damage (see Chapter 2. Safety instructions).
Caution: The system may only be put into operation if all components are undamaged.

3.2 Installation

- The Hilotherapydevice is placed on a horizontal, flat, hard storage surface.
- The device must be set up in sucha way that air circulation is not impeded.
- A minimum distance of 20 cm on the side and 10 cm on the top must be maintained to other devices or furniture.
- The system must be set up in such a way that disconnection from the power grid is not made more difficult.
- Make sure that the device vents are not directed to the patient.

3.3 Initial commissioning and start after water change

Attention: During initial commissioning and after water change, the pump system must be vented before switching on the Hilotherapy device.

- For venting, the vent syringe with the plug-in sleeve on the front clutches.
- Pull out the air with the syringe.
- Remove the vent syringe.


Caution:
If the pump starts up and no water is pumped into the cuff, the pump must be vented again.

3.4 Filling and switching on

- Fill the water container with demineralized water. The level indicator should be located at the "max" marker.
- During initial commissioning and after water change, the pump system shall be ventilated if necessary - see 3.3.
- Plug in the power plug.
- Turn on the device at the main switch on the back of the device. When switched on, the device checks itself. At the end of the self-test, an acoustic signal sounds and the symbol for the pre-cooling of the cooling medium appears on the display.

Here, the water in the tank is cooled down to the necessary operating temperature for 15minutes. During this time, pump operation through the head sleeve is not possible.

- This time should be used to put the cooling sleeve on the user in accordance with section 3.5 below.
- After reaching the operating temperature, a start symbol appears on the display

3.5 Prepare and put on the head cuff

Important note: The cooling effect of scalp cooling is increased by previous ***moistening of the hair.***



Adjust the flexible cooling cuff to the shape and size of the head with the help of Velcro straps.



Select the right neoprene cap and put it on.
Use Velcro tape to adjust the flexible cooling sleeve to fit the shape and size of the head




Connect the extensionhose.
Pull the hose insulation over the extension hose and close the insulation.

For a perfect fit, 2 fixing bandages can be used.

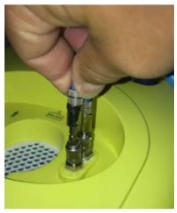
- It is more comfortable to run the fixing strap of the fixing hood over the chin.



- For perfect fitting 2 elastic fixing straps can be used

3.6 Connecting the cuffs and hose attachment

- Cuff and connection hose are connected (audible snapping of the locking grommets into the couplings).
- The hose is plugged into the couplings with the closure grommets.
- The swapping of feed and return is permissible and does not lead to malfunctions.

- When putting on, make sure that the cuffs are not placed over sharp edges or pointed objects.
- The uncoupling of the cuffs is carried out by retracting the gripping ring.
- Attention: When disengaging the hoses, water can escape, hose only disconnect when the device is switched off

3.7 Starting and Stopping the Application / Power Interrupt

- By pressing the button ↵ ,the pump is started and terminated through the cuff.

- At the main switch on the back, the device is switched off.
- If the device is not used for a long time, it must be disconnected from the supply network by unplugging the mains plug.

Short-term power interrupt

If the device is briefly disconnected from the power supply, for example to transport the device to another room in order to continue using it there on the same patient, the pre-cooling time of 15 minutes can be skipped after switching the device on again. The pumping process is restarted by pressing the right Enter key twice.

3.8 Duration of application

Cooling times:

- The cooling times depend on the type of chemotherapy (substances).
- In general, compliance with the pre-, during- and post-cooling times is largely responsible for the cosmetic result of scalp cooling.
- A pre-cooling time of at least 30 minutes is always required.
- The cooling during chemotherapy and the post-cooling time depends on the type of chemotherapy. The post-cooling times should be calculated after the infusion of the drug causing hair loss (see table).
- Depending on the hair structure, the pre-cooling time should be adjusted, e.g. increased from half an hour to a whole hour.

It is recommended to start cooling at application of the chemotherapy	**least 30 – 45 min *before* *(pre-cooling time)***
cooling the infusion,	**during**
and cooling after infusion for	**60 min – 2.5 hours after *(post-cooling time).***

Recommendations for ***pre-cooling time:***

- ***+15 minutes*** >> with very dense or Afro-Caribbean hair, or if after the first cycle many hairs have been lost despite cooling

Recommendations for the ***post-cooling time:***

- If significant hair loss occurs after the first cycle, the post-cooling time can be extended by 30 minutes to an hour to increase the probability ofsuccess.
- Overview of the recommended post-cooling times depending on theapplied therapy regimen

Therapy regimen	Post-cooling time in hours
EC (60/900) q2w or q3w and other Athrazyklines	2 -2,5
Paclitaxel 175 q3w	1,5
Paclitaxel 80 q1w	1
Nab Paclitaxel 125 mg	1,5
Nab Paclitaxel 330 q2w (GAIN2)	1,5
TCb (AUC 6) q3w	1
All other substances	> 1

During the cooling process, the scalp temperature drops to about 19°C - 22°C

This is the ideal scalp temperature proven by studies to best avoid CIA.
Further lowering of the scalp temperature below this temperature range does not lead to a better therapeutic result, i.e. less hair loss.

3.9 Disturbances

Interference is indicated by an opticaland/or a short acousticsignal.
The causeand types of disturbanceare described in item 7.4.

3.10 Menu

Deviceon switched on
Main switch on
Device cools the tank contents
Pressure pump is off and cannot be activated

Device is in operation
Device cools
Pressure pump running
(rotating circle)

A flashing snowflake means that the device is in the cooling phase to the target area. If the snowflake appears permanently, the cooling temperature of the device is in the target area.

Device operation – exclamation point fast blinking and beep signal
The cooling temperature no longer comes
to the finish area
For troubleshooting, see item 7.4.

Errormessage
If an error occurs, the "**E**" indicator appears. Only the current error is displayed in coded form.
The display can only be deleted when the error has been resolved.

For troubleshooting and troubleshooting measures, see item 7.4.

4. Cleaning and disinfection

4.1 General

Caution: The device must only be cleaned after it has been disconnected from the power supply. No sharp objects may be used for cleaning.

If Hilotherm devices are used on immunocompromised people or in rooms/buildings where immunosuppressed people are present, e.g. in hospitals, then care must be taken to ensure that the cooling circuit of the devices and the surfaces of all HILOTHERM products (devices, cuffs, accessories) are hygienically safe. This requirement also applies if there is a possibility that water from the cooling circuit could get into open wounds or body openings.

The following HILOTHERM instructions in the latest version must be used for disinfecting devices, cuffs and accessories:

- QM-SIL-20241106_0x HILOTHERM hygiene guidelines
  - QM-SIL-20181019_0x Device and cuff disinfection
  - QM-SIL-20241022_0x Cooling circuit hygiene guidelines
  - QM-SIL-20241105_0x Brochure-S003 DE

These Hilotherm hygiene guidelines are also available on the Hilotherm homepage.

4.2 Device interface

Surfaces and equipment parts can be cleaned and disinfected with the usual and approved cleaning and surface disinfectants in the hospital sector.
Make sure that ***no liquids get into the device,*** especially through the vents on the sides.

4.3 Cuffs / user parts

Listed separately under point 9.7

5. Maintenance, inspection, safety control

The Hilotherapy system has been designed and manufactured to the highest quality standards.
When used as intended and carried out the intended maintenance and service measures, the device achieves a service life of 10 years and more.
In order to ensure the safety and functionality of the Hilotherapy system for a long time, the following maintenance measures must be carried out:

5.1 Replace water filters and change water – at least every 6 months

- Lift out the grid in the hopper with a small screwdriver.
- Remove the filter.
- Pull the hose of the water level indicator out of the guide on the housing.
- Remove the cover plug.
- Drain water completely.
- If necessary, the tank shall be filled with disinfectant (e.g. Sanosil) and rinse with fresh distilled water. Sanosil can remain in the water to prevent biofilm formation.
- Push the drain hose back into the guide of the housing.
- Press in the cover plug.
- Insert a new filter.
- Place the grid back over the filter.
- Fill with demineralized water via the filling hopper, to which a preservative can be added.
- Vent the device (see point 3.3).

5.2 Clean heat exchangers – at least every 6 months or in case of visible contamination

Dust deposits on the heat exchanger reduce the cooling capacity of the device.

The heat exchanger is located behind the ventilation grille on the right side of the unit.

- Remove the three Phillips screws in the floor under the ventilation grille.
  Caution: The screws with hexagon socket must not be loosened!
- Remove the ventilation grille, carefully clean with a soft brush or vacuum cleaner.
  Caution: The cooling plates on the heat exchanger must not be damaged!

5.3 Grease plug connections – at least every 6 months

The plug connections of the hoses must be greased regularly so that they are easy to plug in and ensure complete locking of the locking grommets into the couplings.

- Thinly grease the tips of the closure grommets of the cuff and hose with petroleum jelly.
- Insert and unplug the closure grommets several times into the couplings of the hose or Hilotherapy device. The petroleum jelly is thus transferred to the O-rings in the couplings.

5.4 Inspection - at least every 2 years

Visual inspection:
- Is the instructions for use complete?
- Is the nameplate complete and legible?
- Are all markings and stickers on the device correct and legible?
- Are all parts fixed to the device (no parts loosened)?
- Is the housing undamaged?
- Are the connectors for the cuff connection smooth and undamaged?
- Do all switches and buttons work properly?
- Is the main backup in the device the specified type?
- To change the fuse, pull out the slot between the main switch and the device plug. After changing the fuse, press the slot until it clicks into place audibly.
- Is the device plug with main switch undamaged?
- Is the power cord undamaged?
- Are the device and accessories clean?
- Are the ventilation slots and the heat exchanger behind them clean?
- Is the accessory in perfect condition?
- Replace the water filter and distilled water.

Testing:
- Function of the cooling unit
- Function of the pressure pump (Are the cuffs sufficiently supplied?)
- Is wear and tear recognizable? (unusual noises?)
- Function of the water level sensor (error message water level when switching on with empty water tank?)

In addition, the following tests can be carried out
- Pressure testing
- Performance tests

In the event of detecteddefects, the device may not be used untilthe defects have been remedied.

Maintenance measures may only be carried out by qualified personnel.
On request, the manufacturer supports the maintenance personnel through training and technical assistance.Info

5.5 Safety control

During production, a STK (safety inspection) is carried out as part of the final inspection.
In order to maintain operational safety, a new STK must be carried out when repair work has been carried out on the electrical system.
The operator is responsible for determining the scope of the test and the test interval (see §11 MPBetreibV). However, the STK must be carried out at the latest every 2 years at the end of the month.

5.6 Liability

HILOTHERM GmbH (as the manufacturer) is only liable for the effects on the safety, reliability and functionality of this device if:
- Assembly, extensions, new hires, modifications or repairs are carried out by authorized persons of the manufacturer.
- the parts and components used for repairs, modifications, extensions or local applications are approved by the manufacturer.
- the electrical installation to which the device is connected complies with the regulations of the local authorities.
- only the accessories approved by HILOTHERM GmbH are used.
- the device is used in accordance with the instructions for use.

5.7 Warranty

With regard to liability for material defects, the provisions of German law shall apply. This does not affect the statutory provisions of the Product Liability Act.

6. Storage, transport, disposal

6.1 Storage

The device should be stored dry and horizontally on flat ground, at a temperature of 5°C to 40°C and 10 – 70% RH and air pressure of 700 hPa – 1060 hPa.
Caution: If the device is stored below 0°C, the water of the cooling circuit must be completely emptied to avoid damage caused by freezing.

6.2 Transport

Before transport, the device must be completely emptied.
Accessories such as cables and hoses must be removed before transport.
Caution: The device may only be transported on pallet with a forwarding agent, as horizontal transport is absolutely necessary.

6.3 Disposal (WEEE Reg.-Nr. DE 25202195)

The device must not be disposed of with general commercial or household waste.
In accordance with product responsibility according to § 22 of the Recycling and Waste Management Act and the Electronics Act § 2.2 paragraph 1, the device must be handed over to a corresponding municipal collection point or returned .dem manufacturer.
When disposing of it, it should be noted that the appliance contains a refrigeration unit similar to a refrigerator (refrigerant: R134a).
Warning: There is oil in the compressor unit.

7. Technical data

7.1 Technical data

Type HT02 *ChemoCare-CIA*

Article No.	2020 0012 // 2021 1512
Rated voltage	230 VAC 50 HZ // 115 VAC 60 HZ
Power consumption	max.320 VA
Current consumption	2.5 A // 5A
Fuse value	2.5 A 250 V // 5A
Protection (electrical)	class I
Degree of protection	application part B
Protection (water and dust)	class IP 20
Risk class (93/42 EEC)	IIa
Dimensions	430 mm x 275 mm x 268 mm
Weight	10 kg
Cuff connections	1
Capacity water tank	min.1.25 liters, max. 2.25 liters
Temperature range	+ 5°C to + 25 °C (self regulating)
Control/setting tolerance	± 1°C

Refrigeration unit

Rated voltage	230 V 50 HZ
Working pressure	Pü zul. 25 bar intrinsically safe
Refrigerant	R 134a

Filling quantity	100 g
Positive displacement pump	
Rated voltage	15 V
Operating pressure	0.5 bar +0.1
Ambient conditions	
Storage temperature	minimum. + 5 °C, max. + 40 °C
Humidity storage	10 - 70% RH non-condensing
Operating humidity	10 - 70% RH non-condensing
Operating ambient temperature	+ 10 °C to + 26 °C

7.2 Characters

The following characters can be found on the device and on the packaging:

Follow the instructions for use
see accompanying documents (instructions for use)

Manufacture
(YYYY)

Device type B
(Protection against electric shock)

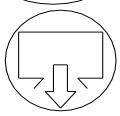
CE marking for conformity according to EU Directive 93/42/EEC
Medical devices with marking of the certification body

not for reuse /
Use only once

do not dispose of general commercial or
household waste

General warning sign. The device calls physiological effects (temperature changes) that are not obvious to the operator are.

Filling device, demineralized water filling



Drain device

7.3 Safety standards

Classification
According to the classification criteria in Annex IX EC Directive 93/42 EEC, the hilotherapy system is to be classified in **Class IIa Rule 9** (Active medical device for therapeutic purposes).
According to **GMDN**classification, the device is assigned to **No. P 42463**, the cuffs **No. P 44604.**
The Hilotherapy system is neither assigned to Appendix 1 and 2, **nor to Appendix 3** of the MPBetreibV.

Standards and guidelines
EC Council Directive 93/42/EEC on medical devices of 14 June 1993
Medical Devices Act MPG of 02 August 1994
DIN EN 60601-1
DIN EN 60601-1-2
DIN EN ISO 10993-1

HILOTHERM GmbH reserves the right to change specifications without notice.

7.4 Faults and troubleshooting

Error	Possible cause	Measures
Device without function, no display on the display	1. Power failure 2. Fuse defective 3. Fuse repeatedly defective 4. Power plug does not have a power plug Contact 5. Device defective	1. Turn off the device 2. Replace the fuse 3. Customer Service 4. Plug connection of the mains connection Check the line 5. Customer Service
Device does not cool	1. Heat exchanger with dust Added 2. Device defective	1. Heat exchanger carefully with Vacuum cleaner or soft brush clean. 2. Customer Service
No or too little water circulation	1. Pump is not vented 2. Hoses or cuff snapped off 3. Clutch not engaged 4. Pump defective	1. Venting, see section 3.3 2. Eliminate the kink 3. Press in clutches until they lock audibly 4. Customer Service
Display Display  Fast flashing symbols with exclamation mark The cooling water is outside the ideal temperature range for the application (too warm)	1. Heat exchanger with dust Added 2. Device defective 3. Ambient temperature too high	1. Open the right-side blue housing cover and carefully clean the heat exchanger with a vacuum cleaner or soft brush. 2. Customer Service 3. Operate the device in the specified temperature range Note: Cooling is still possible and should be continued
Display Display ***"E31"***	Inconsistency of calibration values in EPROM memory	1. Recalibration/Reset 2. If 1 is not successful then inform Technical Service
Display Display ***"E21"***	1. too little water in the tank 2. Level sensor is fixed	1. Refill demineralized water 2. Drain and fill repeatedly
Display Display ***"E11"***	Pumpe defect	1.Technical service
Display Display ***"E01"***	Temperature difference between the two temperature sensors detected.	1. Recalibration/Reset 2. If 1 is not successful then inform Technical Service

Display Display ***"E02"***	Temperature sensors not connected / cable break	1. . Rekalibration/Reset 2. If 1 is not successful then inform TechnicalService
Display Display ***"E03"***	Temperature too low < 3°C	1. Restart device (if, "E03" is displayed erroneously) 2. Rekalibration / Reset 3. If 1 and 2 are not successful, check the temperature Let the device warm up 4. If 1 - 3 not successful then inform technicalservice
Display Display ***"E04"***	Temperaturetoo high > 42°C	1. Restart device (if, "E03" is displayed erroneously) 2. Rekalibration / Reset 3. If 1 and 2 are not successful, check the temperature Let the device warm up 4. If 1 - 3 not successful then inform technicalservice
Display Display ***"E05"***	Increased temperature difference between the twosensors detected	1. Rekalibration/Reset 2. If 1 is not successful then inform TechnicalService
Display Display ***"E99"***	Control system defekt	1. Inform technicalservice
Plug connection of the hoses is difficult	1. O-ring is not greased 2. Plug connection is damaged	1. Easily grease the spout with petroleum jelly 2. Customer Service

Attention: Opening the device leads to the loss of warranty claims!
Exception: Right-sided blue housing cover for cleaning the heat exchanger

Hint:
In the event of an *E0x* temperature **error, resetting the temperature system settings can** fix **the problem.**
Please contact HILOTHERM for detailed information and instructions.

8. Accessories and spare parts

All spare parts and accessories are available from HILOTHERM GmbH or an authorized dealer.

Accessories

Only original HILOTHERM accessories may be used.
Caution: The use of other devices or accessories in conjunction with the Hilotherapy device is not permitted.

Standard accessory list per device:

Number	Article	Designation
1	40000332	Power cord (C,F 230V 50 Hz)
1	40000259	Connection hose
1	40000379	Vent set
1	40000237	Insulation Hilo hose 2.19 m blue PU

Spares

Only original spare and wear parts guarantee device safety and reliability.
The replacement of parts may only be carried out by qualified persons.

The hilotherapy system is constantly evolving.
To ensure that you always receive the right spare part even after technical changes, we ask you to provide us with the following data with each order:

Designation: **Type HT 02**

Serial number.....
Year of construction.....

9. Cuffs

9.1 Variants and material properties

For the Hilotherm ChemoCare-CIA System, the following cuffs are to be used for thermotherapeutic use in anatomically adapted form :

- Head cuff

Material properties:
Cuff film: TPU (thermoplastic polyurethane) – latex-free,silicone-free
cuff insulation TPU foam
Hose insulation TPU foam
Hose:TPU (thermoplastic polyurethane)
Closure grommet:Brass, nickel-plated / POM

9.2 Warnings

- The cuffs may only be used in conjunction with the Hilotherapy device.
- The cuffs must not come into contact with chemicals containing benzene and phenol.
- Before each application of the cuff, it must be checked for integrity (no blistering, no leakage). Only intact cuffs are to be used. If abnormalities occur during treatment, such as .B blistering or leakage, the application should be discontinued immediately. In the event of defects in the hose and capillary systems of the cuffs, these must be discarded.
- When handling the cuffs, care must be taken to ensure that they are not damaged by sharp objects.
- Care must be taken to ensure that the flow of the channels in the cuffs is not prevented by folding the cuffs or by pressing.
- When coupling and uncoupling the closure grommets of the hose system to the Hilotherapy device, a few drops of water may escape. It must be ensured that these do not get on wound dressings and bandages! The cuff may only be applied to intact skin or wound dressings.
- Water escaping due to any leaks usually does not pose any hygienic hazard to the user with a predetermined water change and regular maintenance and cleaning of the system.

9.3 Use of the product on the patient / intended purpose

The cuffs are used exclusively for external use.
The application to corresponding skin areas is carried out on wound dressings or directly on intact skin.
For repeated therapeutic use, we recommend the patient-related assignment of a cuff.
EM cuffs are intended for single use per patient and must not be reprocessed. With these EM cuffs, a yellow or blue-green coloration of the cuff material may occur when used over a longer period of time. This discoloration is material-related and does not pose any hygienic hazard to the user.

9.4 Risk classification of medical devices according to RKI

The risk assessment and assessment is based on the Federal Health Gazette 44 (2001): 1115-1126: Requirements for hygiene in the reprocessing of medical devices.
The operator is responsible for the implementation of the treatment measures by qualified personnel and with appropriate validated procedures.

The individual steps of the preparation must be adapted to

- the medical device
- processing
- the application on the patient.

The cuffs are intended only for contact with intact skin. Pathologically altered skin areas (e.B. abrasions, infectious wounds) or surgical wounds must be provided with a wound dressing before treatment.

With regard to the type of application of the cuffs and the resulting risk, they are classified as **uncritical medical** devices.

9.5 Application description

When coupling and uncoupling the closure grommets of the hose system to the Hilotherapy device, a few drops of water may escape. It must be ensured that these do not get on wound dressings and bandages!
The filled cuff is loosened without exerting pressure on the part of the body to be treated. Fixation measures may be necessary.
The duration of the treatment depends on the instructions of the attending physician.

9.6 Storage and transport

The cuffs are delivered with low germs in a transport and dust protection bag and in an additional outer carton.
Storage must be dust-free, dry, without exposure to UV radiation and without temperature fluctuations at room temperature.

9.7 Disinfection, cleaning and drying

Cuffs, appliances and accessories are manufactured in a clean and hygienically harmless condition and delivered accordingly. However, the condition of the products mentioned in the delivery state cannot be specified as "sterile".

9.7.1 Cuffs

Cuffs labelled as single patient use **cannot** be reprocessed and are intended only for use during treatment on a patient.
Disinfection may be required before applying the cuffs to wound dressings or to the part of the body to be treated, depending on the instructions of the attending physician.

Reprocessing / Duration of use

Cuffs that are not labeled as disposable can be cleaned, reprocessed and disinfected. This also applies to multiple sleeves that are provided with PU foam insulation on the outer surfaces.
With proper processing and depending on the frequency of use, multiple cuffs can be used over a period of about one year.
Due to frequent use of the multiple sleeves and the reprocessing process, the cuffs are subject to wear caused by the application. Wear-related defects and defects in the cuffs are not subject to any warranty claims

Agreementand disinfectionprocedures

The manual cleaning and disinfection of the cuffs must be carried out after treatment on the patient with conventional and approved cleaning and surface disinfectants in the hospital area. Corresponding information such as the list of approved disinfectants and recommendations for disinfection procedures can be found on the website of the Robert Koch Institute (www.rki.de)
Wipe disinfection is recommended for the smooth surfaces of the cuffs, and wipe or spray disinfection for surfaces with a material-like surface (blue insulation). Disinfection shall be carried out by qualified personnel.
The cuffs as well as the insulation are made of poleurethane, this material is well tolerated with a variety of disinfectants. With regard to compatibility, concentration and exposure time of the disinfectant, the respective manufacturer's instructions must be observed.
If properly carried out, multi-cuffs can be reprocessed over a period of about one year.
A hygiene and disinfection plan with corresponding process descriptions and work instructions as part of the quality management must be drawn up by the operator in order to be able to document a comprehensible and validated treatment process.

Example of a maschinellen cleaning and disinfection of non-critical medical devices

Cleaning, disinfection, rinsing and drying is possible in a cleaning and disinfection machine with a validated chemical or chemical-thermal process at a maximum of 55 °C. The cuff must be fixed within the device chamber in suitable holders in such a way that the film surface can be easily rinsed by the cleaning and disinfection media. The procedure should be followed by automatic drying in the device.
The application of the mechanical process must be carried out by qualified personnel in accordance with the specifications of the quality management (e.B. process description, work and procedure instructions) of the operator.

9.7.2 Basic device The surface of the devices

consists mainly of ABS plastic and, if necessary, can be ideally treated by means of wipe disinfection after selecting a suitable method and disinfectant.
A disinfection of the cooling circuit is not necessary if the maintenance specifications and regular water change are observed.

9.8 Control and testing

After successful disinfection and cleaning, a visual inspection and inspection of the cuffs is required. If the cuff film, the hoses and / or the closure spouts are damaged, the cuff must be discarded.
Before use on the patient, the cuff should be checked for tightness by connecting it to the Hilotherapy device and filling it.

9.9 Sterilization

The cuffs cannot be sterilized.

10. EMC – Safety

10.1 Specifications for EMC-compliant use

a) Operating environment:
The devices are designed for use in professional healthcare facilities. No tests have been carried out for rooms in which high-intensity EM interference occurs or in close proximity to HF surgical devices, so use of the devices there is not recommended. The HILOTHERM devices should not be used in vehicles or in aircraft.

b) Performance characteristics:
In the case of EM disturbances above the tested levels (see also a)), device functions may be switched off. In the worst case, no further cooling is possible.

c) Warning:
The use of this appliance immediately next to other appliances or with other appliances in stacked form should be avoided as this could result in incorrect operation.

d) & e) Mains supply:
Devices may only be operated using the original mains supply cable.

f) Warning:
RF communication equipment (radios) should not be used at a distance of less than 30 cm from the

10.2 Tables for EMC-correct use

A1
Table 1 (EN 60601-1-2)

	Guidelines and manufacturer's declaration - Electromagnetic emissions		
	The Hilotherm Chemocare is designed to operate in an electromagnetic environment as specified below. The customer or user of The Hilotherm Chemocare should ensure that it operates in such an environment.		
	Emission measurements	**Agreement**	**Electromagnetic Environment Guide**
	RF mailings to CISPR 11	Group 1	The Hilotherm Chemocare uses RF energy exclusively for its internal function. Therefore, its RF emission is very low and it is unlikely that neighboring electronic devices will be disturbed.
	RF mailings to CISPR 11	Class B	The Hilotherm Chemocare is suitable for use in all facilities, including those in the residential area and those directly connected to a public utility network that supplies buildingsused forresidentialpurposes.
	Transmission of harmonics according to IEC 61000-3-2	Class A	
	Emission of voltage fluctuations/flicker according to IEC 61000-3-3	jibes	

A2
Table 2 (EN 60601-1-2)

Guidelines and Manufacturer's Declaration - Electromagnetic Immunity			
The Hilotherm Chemocare is designed to operate in the electromagnetic environment specified below. The client or user of the Hilotherapy system should ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 - Test level**	**Match tuning level**	**Electromagnetic Environment - Guidelines**
Discharge of static electricity (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8kV air discharge	± 6 kV Contact discharge ± 8 kV air discharge	Floors should be made of wood or concrete or provided with ceramic tiles. If the floor is provided with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical disturbances/bursts according to IEC 61000-4-4	± 2 kV for mains cables ± 1 kV for input and output lines	± 2 kV for power lines not applicable	The quality of the supply voltage should match that of a typical business or hospital environment.

Surges according to IEC 61000-4-5	± 1 kV outer conductor outer conductor ± 2 kV outer conductor earth	± 1 kV outer conductor outer conductor ± 2 kV outer conductor earth	The quality of the supply voltage should match that of a typical business or hospital environment.
Voltage breaks, short conductor interruptions and fluctuations of the supply voltage according to IEC 61000-4-11	< 5% U_T (>95% slump of the U_T) for 1/2period 40% U_T (60% slump of the U_T) for 5 periods 70% U_T (30% collapse of the U_T) for 25 periods 5% U_T (95% slump of the U_T) for 5s	0% U_T 40% U_T 70% U_T 5000 mS	The quality of the supply voltage should match that of a typical business or hospital environment. If the user of the Hilotherm Chemocare requests continued function even in the event of interruptions in the power supply, it is recommended to feed the Hilotherm Chemocare from an uninterruptible power supply or a battery.
Magnetic field at the supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency should correspond to the typical values found in the business and hospital environment.
Note: U_T is the AC mains voltage before applying the test levels.			

A3

Table 4 (EN 60601-1-2)

Guidelines and Manufacturer's Statement - Electromagnetic immunity for ME equipment or ME systems that are not life-sustaining.			
The Hilotherm Chemocare is designed to operate in the electromagnetic environment specified below. The client or user of the Hilotherapy system should ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 - Test level**	**Conformity level**	**Electromagnetic Environmental Guidelines**
Conducted RF disturbances according to IEC 61000-4-6 Radiated RF disturbances according to IEC 61000-4-3	3 V $_{\text{EFFECTIVE value}}$ 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	U1 = 3 V E1 = 3 V/m	Portable and mobile radios should be available at no shorter distance from the Hilotherm Chemocare including the cables can be used as the recommended protective distance, which is calculated according to the equation applicable to the transmission frequency. **Recommended protective distance:** d=[] $\frac{3,5}{V1}\sqrt{P}$ d=[]for 80 MHz to 800 MHz $\frac{3,5}{E1}\sqrt{P}$ d=[]for 80 MHz to 800 MHz $\frac{7}{E1}\sqrt{P}$ with P as the rated power of the transmitter in watts (W) as specified by the transmitter manufacturer and d as

			the recommended protective distance in meters (m). The field strength of stationary radio transmitters should be lower than the compliance levelat all frequencies according to an on-site investigation[b]. Interference is possible in the vicinity of devices bearing the following figurative sign.

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

Note 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is influenced by absorptions and reflections of buildings, objects and people.

a) The field strength of stationary transmitters, such as .B base stations of radio telephones and mobile land radios, amateur radio stations, AM and FM radio and television stations cannot theoretically be precisely predetermined. In order to determine the electromagnetic environment with regard to the stationary transmitters, a study of the site should be considered. If the measured field strength at the site where the hilotherapy system is used exceeds the above compliance levels, the hilotherapy system should be observed to demonstrate its intended function. If unusual performance characteristics are observed, additional measures may be required, such as .B a change in orientation or a different location of the hilotherapy system.

b) Over the frequency range from 150 kHz to 80 MHZ, the field strength should be less than [V_1] V/m.

A4

Table 6 (EN 60601-1-2)

Recommended protection distances between portable and mobile RF telecommunications equipment and the ME device or ME system for ME devices or ME systems that are not life-sustaining.

The Hilotherm Chemocare is designed to operate in an electromagnetic environment where RF disturbances are controlled. The customer or user of the Hilotherm Chemocare can help to avoid electromagnetic interference by maintaining the minimum distance between portable and mobile RF telecommunications equipment (transmitters) and the Hilotherm Chemocare, depending on the output power of the communication device, as specified below.

Rated power of the transmitter W	**Protective distance depending on the transmission frequency m**		
	150 kHz to 80 MHz $d=[]\frac{3,5}{V1}\sqrt{P}$	80 MHz to 800 MHz $d=[]\frac{3,5}{E1}\sqrt{P}$	800 MHz to 2.5 GHz $d=[]\frac{7}{E1}\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,70	3,70	7,37
100	11,70	11,70	23,33

For transmitters whose maximum rated power is not specified in the table above, the recommended protective distance d in meters (m) can be determined using the equation belonging to the respective column, where P is the maximum rated power of the transmitter in watts (W) as specified by the transmitter manufacturer.

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

Note 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is influenced by absorptions and reflections of buildings, objects and people.

11. Declaration of Conformity

HILOTHERM®
Wittumweg 38, D-88260 Argenbühl-Eisenharz

EG-Konformitätserklärung für Medizinprodukte
(Anhang II.3 (ohne II.4) MDD)
EC-Declaration of Conformity (Annex II.3 (without II.4) MDD)

Hiermit erklären wir *We, the undersigned*	**Hilotherm GmbH** **Wittumweg 38** **D-88260 Argenbühl-Eisenharz**

In eigener Verantwortung, dass nachstehendes Medizinprodukt
Declare on our own authority that the referred medical device below

Produktgruppe /*Product Group*	**Thermotherapie System /*Thermotherapy system***
Produktbezeichnung /*Product Name*	**HILOTHERM ChemoCare-CIA / *HILOTHERM ChemoCare-CIA***
Produkttyp /*Product Type*:	**HT02 / *HT02***
Klassifizierung nach MDD / *Classsification accoring MDD*	**Klasse IIa / Class IIa**

den grundlegenden Anforderungen der nachfolgenden Richtlinie entsprechen
comply with the essential requirements of the following directive

Medizinprodukte Richtlinien 93/42/EWG
Medical Device Directive 93/42/EC

Gekennzeichnet durch
marked with

CE 0123

Benannte Stelle / Notified body:
TÜV SÜD Product Service GmbH
Ridlerstraße 65
D-80339 München

Hilotherm bestätigt ebenfalls das Einhalten folgender Richtlinie
Hilotherm also confirms the compliance to following directive

RoHS II

Diese Konformitätserklärung hat Gültigkeit bis zur Änderung geschriebener Inhalte dieser Erklärung *The declaration is valid until the change of any contend of the declaration*

Eisenharz, 2021-07-13

ppa. Klaus Janisch

Konformitätserklärung ChemoCare-CIA_ 2021-07-13