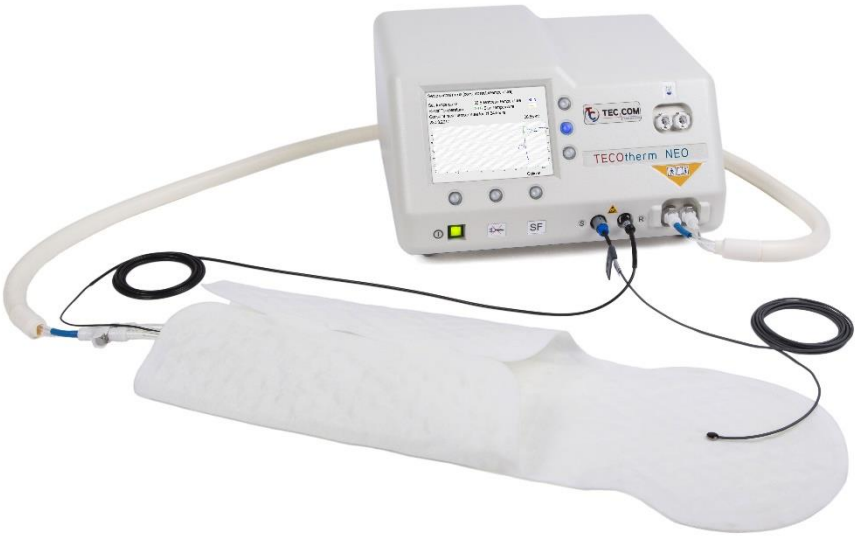
Distributed by:

TECOtherm NEO Hypothermia System

Instructions for use of devices from software version 063/02.18



Note:
Before use, read this information carefully to familiarize yourself with the system. This is the only way to ensure safe and proper use of the TECOtherm NEO hypothermia system.

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1 General information

1.1 Signs and symbols

	Important information
	Attention, important notice! Warning!
	Caution, electric current!
	Caution, do not touch contacts!
	Applied part type BF
	Follow the instructions for use!
	Socket for rectal temperature sensor
	Socket for skin temperature sensor
	"Switch on" button
	Temperature alarm
	Flow rate alarm

	Fluid level too low
	Acoustic alarm paused
	Mains failure, power failure (separate LED display)
	Internal system error (separate LED display)
	Do not dispose of with household waste!
	Date of manufacture
	Manufacturer
	Serial number
	CE marking to declare that the product complies with applicable EU requirements

1.2 Instructions for safe use

TECOtherm NEO is intended for use by healthcare professionals only.	
Modifications to TECOtherm NEO are not allowed!	
Only the accessories listed in the Annex and specified for use with TECOtherm NEO must be used; otherwise correct function is not guaranteed!	
The device may only be opened by authorized personnel. There is a risk of electric shock.	
If the device is in operation, the user must not simultaneously touch the patient and metallic device parts (e.g., sockets of plug contacts, protective conductor-connected metal parts of the rear side, or contacts of fuse holders).	
The two sockets for the temperature sensors on the front of the device and the USB socket on the back are marked with the ESD warning sign. They are sensitive to discharges of static electricity; their contacts must not be touched by fingers or tools. When plugging in the temperature sensors or the USB stick, the **following ESD protection measure is required**: Touch the fan protection grid on the rear of the device with your other hand first. It is necessary to train all persons working with the TECOtherm NEO with regard to the importance of the ESD warning sign and ESD protection measures. In addition to the protective measure prescribed above, this training should also contain general information on the occurrence, possible effect and prevention of electrostatic charges.	

1.2.1 Indications of hazardous substances

TECOtherm NEO and application parts do not contain any parts of

- derivatives of human blood or human or animal tissue
- Latex

Application parts for TECOtherm NEO do not contain PVC with DEHP plasticizer.

2 Intended Use Of The Device

2.1 Intended Use

The TECOtherm NEO hypothermia system is used for the targeted, precisely controlled and comfortable stationary temperature treatment by means of a mattress, with which the temperature control (cooling or warming) of the entire body or of body parts takes place as a function of the therapy objective.

The manufacturer assumes responsibility for basic safety, reliability and performance of the TECOtherm NEO system if:

- The existing electrical installation at the installation site complies with the requirements of the user manual as well as the legal and normative requirements.
- The installing and commissioning has been carried out by authorized personnel.
- The TECOtherm NEO system is operated in accordance with the instructions for use.

2.2 Contraindications for use/side effects

No general contraindications are known. The following instructions must nevertheless be observed by the user:

Therapeutic whole body hypothermia is a systemic treatment method. Be careful when choosing the target temperatures during cooling. For re-warming, select low speeds to slowly bring the body to the core temperature of 37° C.

The heart rate of the patients must be monitored. Patients with cardiac rhythm disorders or very low heart rate require particularly careful monitoring.

Patients with known hypersensitivity to cooling and warming must only be treated under supervision.

Open or infected wounds/burns, rashes and other affected regions of the skin must not come into direct contact with the application parts of TECOtherm NEO.

Cooling can cause shivering to a patient. Shivering counteracts the cooling of the body. The device registers this, controls against it and reports an alarm if necessary.

2.3 Requirements for operators and users

TECOtherm NEO is intended for use by healthcare professionals only.

The TECOtherm NEO may only be used and operated by persons who meet the following qualifications and requirements:

- Medical training
- Work experience in intensive care, especially for use in neonatological and child intensive care units (ICU)
- Experience in dealing with medical-electrical devices and systems
- Instruction and training in the use of TECOtherm NEO **before** commencing treatment by the manufacturer or an authorized representative. The sales and service partners provide instruction and training measures and inform about necessary updates of the software. Information is also provided about design updates and technical improvements.

As an operator or user, you must be familiar with the TECOtherm NEO operation and possible troubleshooting BEFORE USE. Read the instructions carefully. Users must be familiar with the modes of operation and procedures of hypothermia treatment.

The user is required to carefully check the data entered or selected in the menu for correctness and appropriateness before starting hypothermic treatment.

The user is responsible for setting a suitable mode and for setting the required parameters of the treatment.

2.4 Environmental Requirements

For proper operation, the following conditions must be observed during proper use:

The room temperature should not exceed 27 °C or fall below 5 °C for prolonged time periods. Otherwise, the lowest adjustable temperature is no longer reached, particularly in the case of large mattresses. The system no longer achieves its full performance.

The device must be protected against moisture (e.g., splashes) and protected against humidity and splashes during operation.

The permissible relative humidity during treatment is 30%–80%.

The device must not be operated in rooms where combustible gas mixtures occur, e.g., anesthetic with oxygen or nitrous oxide N2O.

In the vicinity of the TECOtherm NEO, no equipment, devices and equipment may be in operation or put into operation during treatment that:

- Generate ultraviolet radiation
- Generate infrared radiation
- Generate strong electromagnetic interference with high intensity (e.g., HF surgery equipment or magnetic resonance tomographs)
- Generate or trigger mechanical shocks or shaking or strong vibrations

3 Introduction and Brief Description

The TECOtherm NEO device pumps temperature regulation fluid (temperature control medium) circulating from the device through heat-insulated hoses to the treatment mattress and back into the device. The aim is to bring the core temperature of the patient wrapped in the mattress to the target temperature. The ACTUAL body core temperature is measured via a rectal temperature sensor and compared with the SETPOINT temperature. Depending on the deviation of the ACTUAL temperature from the SETPOINT temperature and the heating or cooling capacity of the device, the temperature of the circulating fluid is automatically adjusted by the TECOtherm Neo.

If necessary, the skin temperature of the patient can be monitored with the aid of an additional skin temperature sensor. However, the skin temperature is not a control variable for the control system.

Target temperatures and treatment times can be user defined within certain limits (cf. “14 Technical Specifications“).

4 System Description

4.1 Overview of system components

The TECOtherm NEO hypothermia system consists of at least the following components:

Designation	Designation
TECOtherm NEO device, incl. installed software	Sets and controls temperature and data storage
Power cable	Connects the device to the mains
Mattress	Serves patient temperature
Constant-temperature medium	Flows through the mattress, serves for temperature control
Hose kit	Connects the mattress to the device, creating a circulating fluid cycle.

Designation	Designation
Refill sets	Used to fill the system with temperature regulation fluid
External rectal temperature sensor	Controls and checks the core body temperature

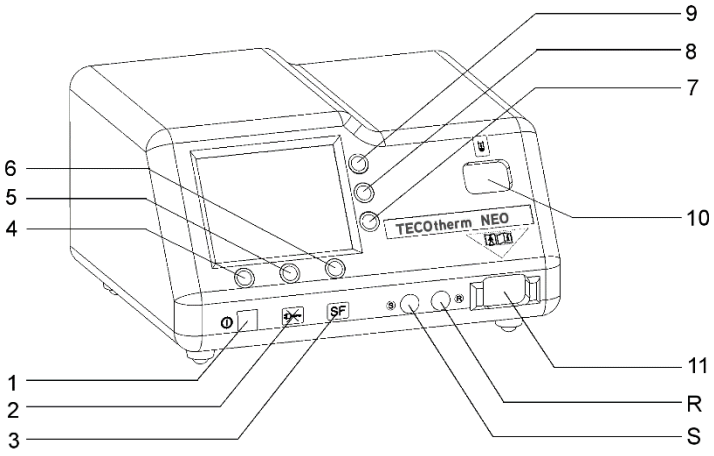
Optionally, the following accessories can also be used:

Designation	Description
Fleece cover cloth (for reusable mattresses)	Used to protect reusable mattress or patient (see section 4.5 Cover cloth (interlayer))
Mattress repair set	Set for repairing minor defects on the mattress
External skin temperature sensor	Used for optional skin temperature measurement

Only the accessories specified in “I APPENDIX – Equipment and Accessories“ must be used with TECOtherm NEO. This is the only way to ensure safe operation of the hypothermic system!

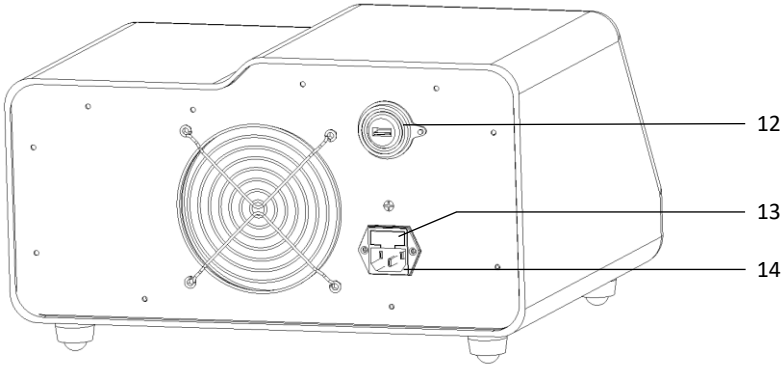
4.2 TECOtherm NEO device

4.2.1 TECOtherm NEO – Front Side



No.	Designation	Description
1	Switch-on button	Switches the device on.
2	Power failure status LED	lights in case of power failure
3	“System error” status LED	lights in case of system errors
4 - 6	Function keys	Execute the action options displayed on the screen
7	Key for menu arrow ▼	Moves cursor down or decreases numerical value
8	“Alarm mute” key	Mutes the acoustic alarm temporarily
9	Key for menu arrow ▲	Moves cursor up or increases numerical value
10	Coupling connectors for refill set	Serves for connecting the refill set for filling/refilling temperature regulation fluid
11	Coupling connectors for hose kit	Used to connect a hose kit. The liquid flows out of the device via the left connection and returns to the device via the right connection.
R	Connector socket for rectal temperature sensor (R= Rectal)	Used to connect a rectal temperature sensor
S	Socket for skin temperature sensor (S = skin)	Used to connect a skin temperature sensor

4.2.2 TECOtherm NEO – Rear Side



No.	Designation	Description
12	USB port	Connects a USB stick to store data
13	Fuses	behind the panel of the mains plug socket: 2 replaceable fuses (cf. type plate)
14	Mains plug socket	Connects a power cord to the power supply

4.2.3 Display Menu

The menu is shown via the display. Individual menu items can be selected using the function keys and menu arrow keys. The starting point and end point for navigation is always the main menu. Selected menu items are highlighted in turquoise.

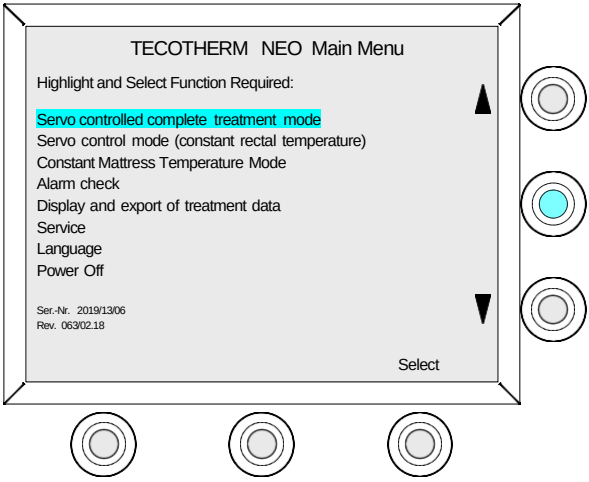


Illustration example, menu language: English

All menu items are accessible to the user except for the SERVICE menu item in the main menu. This is only accessible with a password for authorized service technicians.

Acoustic alarms are optically supported by symbols on the display. Important instructions, notes and errors are communicated to the user in turquoise POP-UP windows.

4.3 Power cable

The power cable is used to connect the TECOtherm NEO to a protective contact socket for power supply.

The power cable is only permitted for connection to protective contact sockets with 100-130 V or 200-240 V and 50-60 Hz. The power cable must have a length of 2.5 m.

4.4 Mattress

The mattress is used for the whole body temperature control of patients, in particular of newborns and infants. It is connected to the TECOtherm NEO via the hose kit, and temperature regulation fluid flows through it. To improve the temperature control of the patient, a mattress can be wrapped around the body as required and closed with straps on the fastener loops.

Mattresses are available for single and multiple use. Details are listed in Appendix “I APPENDIX – Equipment and Accessories“. Please feel free to contact our Service Department.

The device with connected mattress must not be filled under pressure. The mattress must remain flexible and soft so that the patient does not get pressure marks.	⚠
Direct contact of the mattresses with the patient's skin should be avoided, especially in the case of newborns. A suitable cover cloth is to be used on the mattress; cf. “I APPENDIX – Equipment and Accessories“.	⚠

Example figure: Disposable mattress

4.5 Cover cloth (interlayer)

The cover cloth is used for the mutual protection of patients and mattresses.

On the one hand, the patient is protected from contact with temperature regulation fluid in the event of a leakage from the mattress, and on the other hand, the mattress is protected from possible contamination by the patient's body. The cover cloths to be used are listed in section “I APPENDIX – Equipment and Accessories“.

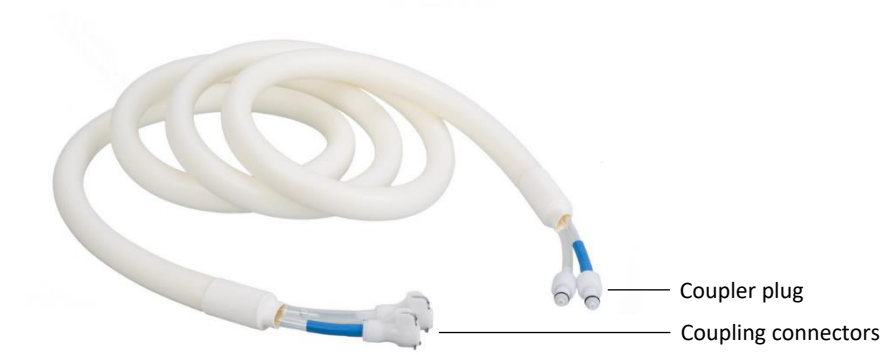
When reusable mattresses are used, the use of a thin, moisture-impermeable fleece cloth (coated on one side with plastic) is mandatory for the protection of patients and mattresses.

4.6 Hose kit

The hose kit is used for coupling the mattress to the TECOtherm NEO device and consequently produces the circulation of the temperature regulation fluid.

The hose kit consists of two inner liquid-conducting hoses and the jacket hose for thermal insulation. The standard length of the hose kit is 2 m. All couplings are self-sealing.

One of the two hoses of the hose kit is marked blue at both ends. The blue markings indicate which mattress side is connected to which device socket. This facilitates the determination of the direction of flow between the device and the mattress, since the liquid flows out of the device to the left hose socket and is returned via the right hose socket.



4.7 Refill sets

The TECOtherm NEO device can be filled or refilled with temperature regulation fluid using refill sets. The refill set consists of a specially prepared 500 ml container with two connecting hoses and self-sealing coupling plugs.

4.8 External temperature sensors

TECOtherm NEO has connections for a rectal temperature sensor and an optional temperature sensor for measuring skin temperature.

The body core temperature in the rectum can be measured via the **rectal temperature sensor** and the temperature regulator can be controlled. The sensor is connected to the device via the socket marked "R“.

A **skin temperature sensor** can be used as a reference sensor if required. It is used for independent temperature monitoring of the patient, but is not necessary for the operation of the device and is not used for control. It is connected to the device via the socket marked “S”.

Temperature sensors approved by the manufacturer of TECOtherm NEO are listed in the appendix (cf. I APPENDIX – Equipment and Accessories).

The TECOtherm NEO hypothermic system must only be operated with temperature sensors approved by the manufacturer.	⚠
Observe the correct assignment of the temperature sensors to the connector sockets R (rectal temperature sensor) and S (skin/skin temperature sensor) on the TECOtherm NEO device!	⚠
Ensure correct positioning of the rectal sensor in the patient! Fix and secure the sensor against slipping out!	⚠

5 Overview of the operating modes

	Operating modes	cooling phase **Phase (1)**	Therapy phase **Phase (2)**	Constant heating phase **Phase (3)**	Optional heat retention phase **Phase (4)**
(I)	**Automatic treatment acc. to program 0** Pre-set with TOBY protocol data Cannot be overwritten Suitable for complete therapies	max. cooling capacity to rectal target temperature 33.5 °C	72 h period at constant rectal target temperature with typical deviation of ≤ 0.2 °C; premature termination possible	7 h to reach target temperature of 37 °C	Holding temperature 37 °C
	Automatic treatment with manual input of parameters or storage with programs 1 - 9 Suitable for complete therapies	Target temperature adjustable in the range of 32 - 38 °C (standard value: 33.5 °C)	Therapy duration of 1 – 100 h, adjustable	Adjustable period of 1 - 24 h to reach target temperature of 36 - 38 °C	Holding temperature 36 - 38 °C equal to setting in phase 3
(II)	**Setting to constant rectal temperature** Individual treatment phases can be performed by the user with rectal temperature as the control parameter Suitable for therapy phases, not for complete therapies	Adjustable rectal target temperature of 30 – 38 °C; Time to reach target value is adjustable between 0 – 24 h;	The cooling phase with the set rectal temperature lasts until manual abort or change in the target temperature.	Adjustable rectal target temperature of 30 – 38 °C; Time to reach target value is adjustable between 0 – 24 h;	----------
(III)	**Setting to constant mattress temperature** The treatment is entirely controlled by the user through the mattress temperature. The rectal temperature is no longer a reference parameter. Suitable for therapy phases, not for complete therapies.	Adjustable mattress target temperature of 12 - 39 °C; Time to reach target value is adjustable between 0 - 24 h; Operator observation required.	The cooling phase with the set mattress temperature lasts until manual interruption or change in the mattress temperature	Adjustable mattress target temperature of 12 - 39 °C; Time to reach target value is adjustable between 0 - 24 h; Operator observation required.	----------

5.1 Description of the operating modes

Regardless of the operating mode, all temperatures as well as cooling and warming rates are logged by the device. These can be read via a USB stick.

5.1.1 Automatic operation by program

The treatment in automatic operation according to programs is planned and defined in advance by setting temperature-time profiles.

Program 0: In the factory default state of the TECOtherm NEO system, program no. 0 is set, according to TOBY protocol with the following temperature-time profile:

Rectal in the treatment phase cooling (therapy phase)	33.5° C
Duration of treatment phase cooling (therapy phase)	72 h
Rectal temperature after warming (temperature retention phase)	37° C
Duration of the re-warming phase	7 h

This program cannot be overwritten; it is stored permanently. The standard values for temperatures and times set in accordance with the TOBY protocol can be changed by the user within certain limits before the treatment and also during the treatment.

Programs 1– 9: Nine programs can be created and saved individually by the user (to be saved as programs no. 1 to no. 9). The parameters can be defined within the following limits:

Rectal in the treatment phase cooling (therapy phase)	32 – 38° C
Duration of treatment phase cooling (therapy phase)	1 - 100 h
Rectal temperature after warming (temperature retention phase)	36 – 37° C
Duration of the re-warming phase	1 - 24 h

If changes are made to the specified temperatures or times before the start of the treatment, the option is provided to store this new set of specifications as a separate treatment program. If you select this option, this new set of specifications will receive the next available program number (from 1 to 9) for identification. If the starting point for the changes made was an already previously created separate treatment program, this can optionally also be redefined instead of creating an additional treatment program.

After a treatment program has been saved, the user is presented with the option to set this program as the default. If this option is accepted by pressing “Yes“, this set of specifications are provided in the future each time this operating mode is selected, so that the treatment can be started immediately without having to make any changes.

Even after the treatment has been started, the temperature and time specifications can be changed if necessary by calling the parameter screen with the “Options“ button. However, such changes cannot be stored in the treatment programs during ongoing treatment. They only apply to the current treatment.

In operating mode I, there are 4 treatment phases:

1. Phase/cooling phase: In the cooling phase, the temperature is regulated at maximum power until the target value is reached. The target temperature is preset to 33.5° C in this automated mode according to the TOBY protocol.

2. Phase/therapy phase: After the setpoint temperature has been reached, the control system automatically changes to the therapy phase in which the setpoint temperature is maintained for the duration preselected by the user.

If temperature deviations > 1° C occur during this phase when comparing the measured rectal temperature with the setpoint temperature, this is detected by the monitoring system and an alarm is triggered. The device automatically goes into the fallback mode (cf. “5.2 The Fallback Mode – for Patient Safety“).

3. Phase/warming phase: As soon as the second phase is completed, the warming phase automatically follows. It is also possible to switch to phase 3 in the “Options“ menu before the second phase finishes.

The TECOtherm NEO system increases the body core temperature linearly until the selected target temperature of the temperature retention phase is reached. In case of faults, the control system reacts in the same way as in phase 2.

4. Phase/temperature retention phase (optional): After completion of re-warming, the connection of a temperature retention phase is optionally possible. The TECOtherm NEO maintains a previously defined constant rectal temperature in this phase. You can extend this phase for any length of time. You can cancel the temperature retention phase by terminating the program via the menu.

5.1.2 Control to constant rectal temperature

When controlling to constant rectal temperature, the target rectal temperature (= body core temperature) and the time until the target value of the rectal temperature is reached can be set within the following limits:

Target value for constant rectal temperature (target temperature for therapy phase)	32 – 38° C
Time to reach target value	0 - 24 h

You can choose the duration of therapy at your discretion. After the end of each treatment phase, the target temperature reached is maintained indefinitely.

If you select a time of “0 h” to reach a target temperature, TECOtherm NEO will try to reach the target value as soon as possible. At selection of the duration, the user can also predetermine a cooling rate/warming rate himself.

1. Phase/cooling phase: In the cooling phase (depending on the situation, this could also be a warming phase), the device operates at maximum power to ensure that the target temperature is reached as quickly as possible.
Alternatively, a time can be specified within which the target temperature is to be reached.

2. Phase/therapy phase: The target temperature is then maintained until the user interrupts the therapy phase or makes a change to the target temperature (menu display: “Change treatment”). After you manually change the target temperature, the control system will attempt to reach the new target temperature as soon as possible or within a predetermined time.

3. Phase/warming phase: After the end of the therapy phase, the transition to re-warming must take place. Once the new target temperature has been reached, it is kept constant **(temperature retention phase)** until the treatment is terminated.

If plausibility limits are violated, the device perceives this as a fault and automatically goes into the fallback mode (cf. “5.2 The Fallback Mode – for Patient Safety“).

The parameters within the defined framework must be defined by a trained and experienced physician	
The user must check for himself whether the intended treatment duration = holding time has elapsed. If necessary, all parameters can be changed at any time.	
This operating mode is suitable for therapy periods, but not for complete therapies.	

5.1.3 Setting to constant mattress temperature

When you set to a constant mattress temperature, the target mattress temperature (= body core temperature) and the time until the target value of the mattress temperature is reached can be set within the following limits:

Target value for constant mattress temperature	12 – 39° C
Time to reach target value	0 - 24 h

This operating mode is usually executed without a rectal probe. However, it can also be executed with a rectal probe, but the values of the rectal temperature here have only an informative character and do not have a controlling effect on the control parameters.

The performance of the TECOtherm NEO is characterized by a very rapid cooling of the mattress temperature, e.g., the device cools down the mattress (without patient) within 10 minutes from the mattress temperature 20° C to 12° C. It should be noted that the core temperature of a patient placed on the mattress cannot follow this temperature change not as quickly by far.

This operating mode is suitable for therapy periods, but not for complete therapies.	
In this operating mode, the treatment must be completely monitored by the user and, if necessary, adapted. The rectal temperature is no longer a reference variable!	
In the "Setting to constant mattress temperature" operating mode, **the body core temperature must be monitored by a regular temperature measurement!** The temperature should then be displayed on a suitable display and clearly visible to the user. Otherwise, a sufficiently accurate assessment of the actually achieved lowering of the patient's core temperature is not possible.	
The TECOtherm NEO large display permanently displays only the mattress temperature, not the rectal temperature. In the CHART on the display, you can follow the current rectal temperature (if rectal sensor is used) and the skin temperature in the info boxes.	

1. Phase/cooling phase: to achieve cooling as rapidly as possible, the lowest mattress temperature that can be expected for the patient is set in the menu (“target value for constant mattress temperature”). It should be borne in mind that a reaction of the body core temperature

to a change in the mattress temperature can only be detected after about ½ hour.

The parameters within the defined framework must be defined by a trained and experienced physician 

2. Phase/therapy phase: The therapy phase now beginning with a constant mattress temperature requires regular monitoring of the patient/his body core temperature by the user to correct the mattress temperature if necessary.

3. Phase/warming phase: After the end of the therapy phase, the transition to re-warming must take place. For this purpose, the mattress temperature must be changed manually and carefully increased. For newborns, warm-up to normal temperature should take place at a rate of not more than 0.5° C/h. This means that warming from 33.5° C to 37° C takes at least 7 hours.

The user must observe the size or weight of the patient when performing rapid warming. The higher the size or weight, the slower the warming.

If plausibility limits are violated, the device considers this a fault.
The device automatically switches into the temperature alarm state.

5.2 The Fallback Mode – for Patient Safety

The fallback mode is used for safety and protects the patient in case of faulty operation. Among all the causes which can lead to a faulty operation of the physiological closed-loop control loop, systematic incorrect measurements of the rectal temperature would be the most serious, in particular if they were not noticed over a prolonged period of time. Only these result directly in an incorrectly displayed core temperature of the patient. Such erroneous measurements can have various causes, e.g.:

- Rectal sensor not correctly placed or slipped out
- Rectal sensor defective
- Contact problems on the plug connections

For protection, the measured values of the rectal sensor are automatically checked for plausibility. If plausibility limits are exceeded, the device switches to the fallback mode and an alarm sounds.

In the fallback mode, the required mattress temperature is no longer calculated by a temperature controller, but must be specified by the user. To be able to make an informed decision in such a case, the user must immediately obtain another temperature measurement source, independent of the TECOtherm NEO, to continue to measure the rectal temperature of the patient reliably.

In addition to the rectal temperature sensor, a skin temperature sensor can provide guidance. However, it should be noted that the skin temperature only permits limited conclusions about the core temperature.

Although it is basically possible to complete an ongoing treatment entirely in the fallback mode, the user should always try to find and eliminate the cause of the incorrect measurements. If there are no obvious reasons, changing the rectal sensor is recommended.

If the user is convinced of the correctness of the function, the user should end the fallback mode and return to the normal course of treatment. If the user does not do this, the device automatically switches back into operation as a physiologically closed control loop as soon as acceptable measured values are available again.

In the event of a failed rectal sensor, the sensor must be replaced. Alternatively, the user must use an independent source of measuring the rectal temperature.

5.2.1 Plausibility limits of the rectal temperature

In accordance with the purpose of TECOtherm NEO, it is considered possible that the rectal temperature of a patient at the beginning of the treatment could be between 30° C and 38° C in an extreme case. Accordingly, initial temperatures between 29° C and 39° C are still considered plausible. With measured values outside of **29° C – 39° C**, the control cannot be started, and the start is rejected with appropriate information.

The acceptance limits are quickly narrowed after the start of the treatment until the treatment phase is reached. From then on, only **deviations of a maximum of 1° C** from the respectively valid rectal setpoint value are accepted.

In addition to monitoring these absolute limits, the measured values of the rectal temperature are also checked for how quickly they change. A maximum of **0.3° C/**minute is considered plausible and consequently acceptable. Faster changes, such as would occur when the sensor slides out, for example, are evaluated as not plausible and also trigger the fallback mode.

5.2.2 Working method in the fallback mode

How the parameters for a continuation of this mode are to be changed depends on the status of the ongoing treatment.

For immediate start-up of the fallback mode, parameter specifications are defined that do not pose any danger initially. The user must evaluate these settings and change them if necessary. The mattress temperature chart can be used for guidance. Only then is it advisable to troubleshoot and possibly even replace the rectal sensor to return to automatic operation as quickly as possible.

For each treatment phase, two fundamentally different types of defaults and setting options for the fallback mode are available:

Operating mode	Options in fallback mode
Automatic operation by programs (Operation mode I)	• The device operates at a target temperature of 20° C until it is manually set. • The user must manually set the mattress temperature between 12°–39° C.
Control to constant rectal temperature (Operation mode II)	• The device works with the last set target temperature. • The user must manually set the mattress temperature between 12°–39° C.
Control to constant mattress temperature (Operation mode III)	Since no rectal probe is used, there is no fallback mode for operating mode III.

5.2.2.1 Fallback mode in cooling phase

The fallback mode automatically sets a mattress temperature of 20° C. This ensures that cooling is continued or maintained.
Depending on the cooling stage, 20° C can be too high or too low. The user must evaluate this setting, using an independent measurement of the actual rectal temperature of the patient and correct it accordingly. The following options are available in the control menu:

1. Modify the running program
2. Start the warming phase immediately
3. End treatment, close log
4. Test alarm function

5.2.2.2 Fallback mode in the warming phase

It is known that the rectal temperature changes with a time delay depending on the patient's mass compared to the mattress temperature due to heat/cold losses, but usually at a certain interval (e.g., ± 1-2° C) from the specified rectal temperature. Therefore, the mattress temperature must be higher than the current rectal temperature in the warming phase.

If the fallback mode is activated, the setpoint value of the mattress temperature is first set to the currently valid setpoint value of the rectal temperature and then rises slowly. The user can then appropriately change the setpoint value of the mattress temperature by setting a shift of -3.0° C to +3.0° C in the menu.

The following options are available in the control menu:

1. Modify the running program (individual setting of the mattress temperature by the user)
2. End treatment, close log
3. Test alarm function

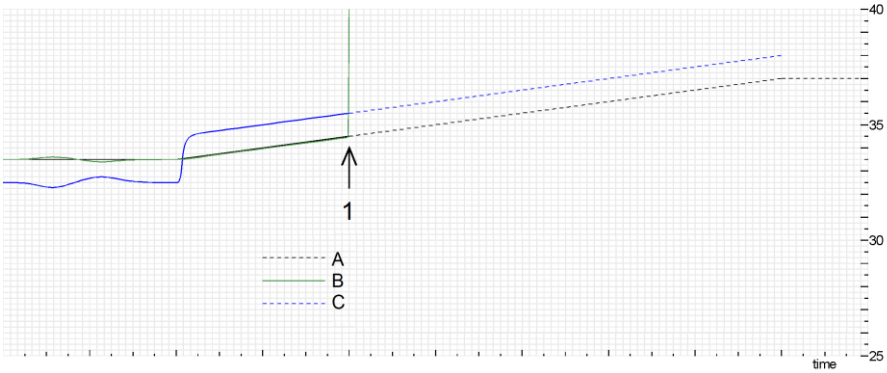


*Figure: Automatic re-warming, with error message and activation of the fallback mode as well as manual shift of the future setpoint value, **1:** Fallback mode activated automatically; **A:** Future setpoint of the rectal temperature; **B:** Measured rectal temperature; **C:** Future setpoint value of mattress temperature (shift = +1.0, good choice)*

6 Installation of the device and operation

Only the application and accessories belonging to the hypothermic system and approved by the manufacturer may be used, since otherwise no perfect function is guaranteed!

Defective parts must not be used.

The TECOtherm NEO must not be placed directly next to other devices and/or used stacked with other devices. Should this nevertheless be necessary, the TECOtherm NEO must be observed and the intended operation checked.

Ensure that the TECOtherm NEO is positioned so that:

- No snag spots are created to avoid crushing.
- No tripping spots are created (e.g., due to hoses, cables, etc.).
- Visual alarms can be clearly seen and acoustic alarms can be clearly heard.
- The cooling air inlet on the underside of the device is not impeded.
- The cooling air outlet at the rear of the device is not obstructed (minimum distance from the rear of the device: 15 cm) and that it is not directed towards the patient.
- The mains plug can be disconnected from the mains supply without difficulty.

Hoses and mattresses may not be stored on a hot or warm underlay during operation.

6.1 Commissioning

TECOtherm NEO must be installed and put into service for the first time by the manufacturer or by a representative authorized by the manufacturer.

The desired menu language is selected via the entry “Language” in the main menu.

6.2 Filling/Refilling/Emptying of Mattress and TECOtherm NEO

The TECOtherm NEO contains an internal liquid container for the circulating temperature regulation fluid. The device and mattress must be correctly filled with the prescribed temperature regulation fluid before the start of each treatment to ensure safe operation of the device and good circulation of the liquid.

Only temperature regulation fluids approved by the manufacturer may be used to avoid risk situations or harm to the patient. In addition, damage to the device may otherwise occur. The released temperature regulation fluid ensures optimum operation and the longevity of the hypothermic device with little effort.

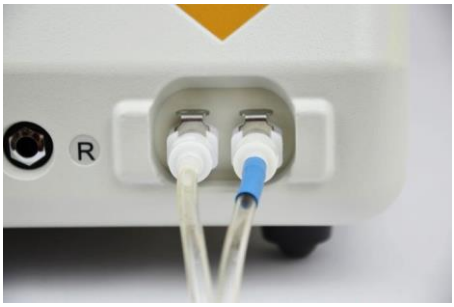
If this is not possible due to country-specific legal requirements, it is possible to operate the TECOtherm NEO with an alternative fluid. This is only permitted in exceptional cases after consultation with the service partner and requires instruction.

The mattress must be completely filled for the treatment.

6.2.1 Filling process

1. Check mattress, hose kit and refill set for defects or damage such as small cracks or holes.
2. Spread an intact mattress on a flat surface.
3. Connect the mattress to the TECOtherm NEO device using the hose kit.

The fluid flows out of the device via the left connection and is returned to the device via the right connection.



The coupling plugs must be plugged in until they latch to achieve a tight connection. If necessary, press the metallic release button down when connecting. If the coupling plugs latch correctly, the metal release buttons protrude slightly upward.

4. Switch on the TECOtherm NEO device.
5. Fill the refill set with temperature regulation fluid up to the 450 ml mark.
6. Close the lid of the refill set tightly.
7. Connect the refill fitting with the associated coupling connectors to the front of the TECOtherm NEO device for refilling.
8. In the main menu, select and start the operating program “Set to constant mattress temperature”.
9. Hold the refill set with the lid down. Allow the temperature regulation fluid to flow in until no more air bubbles rise in the refill set.

> When filling, the alarm “No circulation” possibly occurring may be ignored. The AUDIO alarm sound can be muted by pressing the “Alarm mute” button.

10. Decouple the refill set.
11. Position the mattress below the device height and hold it with hose plugs pointing upward to allow air bubbles to rise in the mattress. Swivel the mattress to remove most air bubbles present therein via the hose outlet. The blue markings on the hose facilitate determination of the direction of flow.
12. Refill the refill set if necessary and connect. Fill the device and mattress further until no air bubbles rise again in the refill set.

> In the case of large mattresses, it is possible that more liquid than 450 ml is required during filling/refilling and consequently the refilling set must be refilled during the filling process. To do this, disconnect the refill set from the device, refill it again and continue the filling process as described.

13. Decouple the refill set.
14. Close any still open error pop-up window.

15. Allow the device to continue running for approx. 1 minute. If a level alarm occurs again, follow the instructions in the pop-up window on the display.

6.2.2 Refill process

The TECOtherm NEO system can also be refilled during operation or treatment. Refill at the latest when the alarm  "Fill level too low" occurs. The treatment does not have to be interrupted.

1. Pause the audible alarm if necessary by pressing the "Alarm mute" button

Check whether:

a. Troubleshooting")
b. The mattress is properly connected (cf. section "6 Installation of the device and operation")
c. Refill system as described in section "6.2 Filling/Refilling/Emptying of Mattress and TECOtherm NEO".

The alarm symbol "Fill level too low" should disappear automatically during the refilling process. If the alarm occurs repeatedly, proceed according to section "11

Troubleshooting". There is a malfunction.

6.2.3 Emptying TECOtherm NEO and mattress

To empty a mattress, the inner fluid container of TECOtherm NEO must first be emptied. Once the device has been emptied, the mattress can be emptied.

1. Decouple the hose kit from the device
2. Couple an empty refill set to the device and hold them with the lid pointing upward.
3. Start the device in the program "Set to constant mattress temperature" at room temperature (approx. 22° C) and wait until the entire temperature regulation fluid has collected in the refill set. Ignore any flow or fill level alarms; if desired, pause alarm with the "Alarm mute" button.
4. End the program, uncouple and empty refill set.
5. Dispose of temperature regulation fluid via a water drain.
6. Connect the mattress to the two refill couplings of the device. Hold the mattress above the device. The hose connections of the mattress must point downward.
7. Wait until the temperature regulation fluid is emptied out of one half of the mattress (approx. 1 min) Uncouple the mattress, and reconnect it to the re-fill couplings, reversing the coupler plugs and hold the mattress above the device. The hose connections of the mattress must point downward to allow temperature regulation fluid to flow out.

8. Wait until the remaining temperature regulation fluid is emptied out of the mattress (approx. 1 minute).
9. Decouple the mattress.
10. Couple the refill set and let the temperature regulation fluid flow in.
11. Decouple the refill set and dispose of temperature regulation fluid via a water drain.

TECOtherm NEO can now be filled with fresh temperature regulation fluid for treatment or stored empty.

6.3 Commissioning and Operation of the TECOtherm NEO System

Before commissioning, first prepare the required accessories and check for damage. Operating mode I (“Automatic operation according to programs") and operating mode II ("Set to constant rectal temperature”) require a rectal temperature sensor for control. This is not absolutely necessary in operating mode III (“Set to constant mattress temperature”).

When you install the device, refer to the instructions in section”2.4 Environmental Requirements“.

1. Plug the power cable into the mains plug socket on the housing rear wall of the TECOtherm NEO and then connect the device to a protective contact socket.

   The power cable is only permitted for connection to protective contact sockets with 100-130 V or 200-240 V and 50-60 Hz.

   Immediately after connection to the mains, the device switches to the standby state. The “on” button lights up slightly light green.
2. Prepare the heat-insulating underlay at the level of the device, e.g., foam (10 - 20 mm thick), if necessary in a prepared incubator.
3. Place the mattress on a heat-insulating underlay.

   When using an incubator, make sure that the incubator is not smaller than the mattress and that the mattress lies longitudinally in the incubator.
   - Otherwise, kinks and folds can occur in the mattress, so that the circulation of the temperature regulation fluid is hindered or even blocked.
   - Do not place the mattress directly on the silicone inserts of the incubator.
   - The incubator is not temperature controlled (neither heated nor cooled by circulation of cooler air).

4. Connect the mattress to the TECOtherm NEO device using the hose kit (cf. section “6.2 Filling/Refilling/Emptying of Mattress and TECOtherm NEO“)

   Attach the hose of the hose kit so that no kinking occurs at the mattress connections.

   When using an incubator, make sure that you thread the tube fitting through a central opening on the incubator in such a way that it can be connected to the mattress in the longitudinal direction without kinks occurring.

5. Check whether: The mattress is completely filled by holding the filled mattress against light to better see any air bubbles in the mattress.
   a. If empty or only partially filled, fill the mattress as described in section “6.2 Filling/Refilling/Emptying of Mattress and TECOtherm NEO“.
   b. A hole or crack is visible in the mattress or hose kit. If fluid leaks, replace defective parts.
   c. The hose kit and mattress are kinked or if there is a risk of kinking during the treatment. Eliminate kinks, since otherwise good flow through the mattress is not possible.
6. In case of a mattress for multiple use: for the mutual protection of patients and mattress, place a thin, absorbent but water-impermeable cloth on the mattress with the plastic film pointing toward the mattress. The cloth must be of such a size that the mattress is completely covered and about 5 cm of edge around the mattress can be hit.
7. Connect temperature sensor:

   Only temperature sensors approved by the manufacturer of TECOtherm NEO must be used (cf. “I APPENDIX – Equipment and Accessories“)

   Only these have been subjected to the necessary tests and ensure reliable temperature measurement even under unfavorable electromagnetic ambient conditions. The use of other temperature sensors represents an unpredictable risk for the patient.

   a. Connect reusable rectal temperature sensor with the jack plug directly to the device socket (R) OR
   b. Connect the rectal temperature sensor to the corresponding adapter cable for single use. Connect this with its other end to the device socket (R).

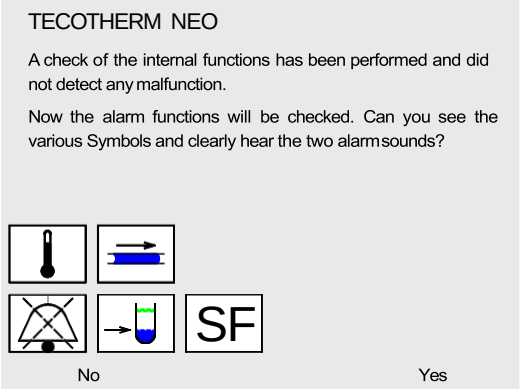
      The plug connection from the sensor to the adapter cable must always be kept dry for proper operation.

c. If necessary, connect a skin temperature sensor with the plug directly to the device socket (S).

8. Switch on the TECOtherm NEO device.

9. Internal device functions are automatically checked. Acknowledge functions using function keys (yes/no)



If the symbols cannot be seen or the two alarm sounds cannot be clearly heard, acknowledge with “no”. In this case, the device switches off after 30 s, since safe operation cannot be guaranteed. Inform the Service Department. Use a replacement device.

6.3.1 Starting Treatment

Before starting treatment, check that the device has been correctly put into operation (cf. section “6.3 Commissioning and Operation of the TECOtherm NEO System“)

Under certain circumstances, pre-warming of the mattress makes sense:

If a patient is already in therapy and is to be transferred to a new mattress, this mattress MUST be pre-warmed to ensure treatment success.

1. Position the patient on the mattress. For full body temperature control, the head is placed on the smaller round mattress part and the upper body lies on the wider, more angular part.
2. Position the rectal temperature sensor in the rectum of the patient and secure it against slipping out!
3. Optional: Position and attach the skin temperature sensor on the skin.
4. To improve temperature control, envelop patients in mattress: pull suitable tape through eyelet(s) of mattress, wrap the mattress around the patient's body and

connect tapes on opposite sides appropriately (knots, loop, etc.) Care must be taken that the mattress does not lie too tightly; the degree of tightening must be appropriate to the situation.

Mattress and hose must not be kinked. Otherwise, the flow and temperature control are impeded or even stopped.

5. Select the treatment program from the main menu. The following programs are available:
   - Automatic HIE treatment by program
     Profile 0 is preset, and profiles 1-9 can be saved individually according to treatment and then retrieved for the next treatment.
   - Set to constant rectal temperature
   - Set to constant mattress temperature
6. Adjust treatment parameters if necessary
7. Start treatment. Select the “Start” function in the selected program.

In operation mode I (“Automatic operation according to programs") and mode II ("Set to constant rectal temperature"), the measured rectal temperature must be in the range 29° C to 39° C; otherwise, the start is rejected. Rectal temperatures outside this range are assessed as unacceptable or faulty.

In normal operation and under the stated operating conditions, the TECOtherm NEO system can reach a rectal temperature (= target temperature) of 33.5° C approx. 30 minutes after the start. This time may be longer, depending on the size of the patient and the ambient temperature.

If no cooling rate has been preselected in the menu, the TECOtherm NEO tries to reach the selected target temperature as quickly as possible in each operating program.

6.3.2 Monitoring during treatment

The user must check the treatment on site at regular intervals to be able to notice any complications occurring in a timely manner and take measures against them.

This applies in particular to the cooling phase and the transition from the therapy phase to the warming phase. The user must also ensure that the rectal sensor is always seated correctly.

If necessary, the user can make changes to the program in each operating program via the “Options” menu item.

Especially in the case of newborns, care must be taken during the warming phase to ensure that fault conditions are quickly eliminated.

6.3.3 Ending treatment

After the end of a treatment program (cooling phase, therapy phase and warming phase), a predefined final temperature is maintained until the user terminates the treatment. To do this, select the “End treatment, close protocol” menu item. The device thereby terminates any temperature control.

You can then return to the main menu, from where you can start a new treatment, export stored treatment data or switch off the device.

6.3.4 Displaying and exporting treatment data

The treatment data are automatically stored inside the device during the treatment. The data can be exported to a USB stick. To do this, proceed as follows:

1. Connect a USB stick to the USB port on the back of the housing.
2. Select the “Display and export treatment data” menu item in the main menu.
3. Select one of the three options in the following submenu:
    - Export new treatment data
    - Export all treatment data
    - Select, display and export specific treatment*
4. The user is informed about the success or failure of the export via a message in the menu. After successful export, the USB stick can be removed.

* Explanation of the option **“Select, display and export specific treatment”**:

This option allows you to display the entire course of a treatment (or test phase) in a graph. The prerequisite is that it took longer than approx. one hour.

You select a treatment based on its starting time. The selection is made using the “Up arrow” or “Down arrow” button. Select the year of treatment sought, then the month, the day and the specific treatment itself.

These data can be displayed on a graph and, if required, also exported to a USB stick.

7 Switching off

If no treatments are pending for a longer time, you can switch off the device:

1. Go to the main menu.
2. Select the “Switch off” menu item.

Then TECOtherm NEO switches off. As long as the device is not disconnected from the mains, the on/off button remains lightly green. When you disconnect it from the mains by pulling out the mains plug, the light green light goes out completely.

8 Cleaning

To enable hygienically impeccable treatments on a permanent basis, compliance with the minimum requirements described below is mandatory.

Observe the prescribed cleaning and replacement intervals and the requirements of the temperature regulation fluid used: cf. “II APPENDIX – Internal cleaning“.

Users should not use cleaning methods other than those recommended by the manufacturer. If in doubt, contact the Service Department or the manufacturer.

8.1 Cleaning the outside of the TECOtherm NEO device

The outside of the device and the hose kit may only be cleaned by wiping with a mild wiping disinfectant and a soft cloth customary in hospitals.

Clean the underbody (perforated bottom) at intervals of one to two months, but in any case before restarting.

Remove lint trim from the ground air intake holes with a small vacuum cleaner.

8.2 Cleaning the outside of the mattress and hose kit

Mattresses for multiple use may only be cleaned by wiping with a mild wiping disinfectant and a soft cloth customary in hospitals. During cleaning, attention must be paid to signs of wear. If necessary, replace the mattress with a new one.

If mattresses, hose kit, etc. come into contact with blood or human body fluids, with open wounds or with infectious skin areas during treatment, they may only be used once. They are to be disposed of properly in the same way as disposable articles.

8.3 Cleaning the outside of temperature sensors

8.3.1 Reusable temperature sensors

The respective manufacturer's instructions must be observed for the cleaning of the reusable rectal and skin temperature sensors approved for the TECOtherm NEO. Details can be found in the operating instructions of the temperature sensors.

8.3.2 Temperature sensors for single use

The temperature sensors approved for the TECOtherm NEO for single use must be properly disposed of after the end of treatment; country-specific requirements must be observed. If individual parts can be reused according to the manufacturer's instructions, they must be cleaned according to the manufacturer's instructions.

The plug connection from the sensor to the adapter cable must always be kept dry for proper operation.

9 Transport

The TECOtherm NEO device is a powerful hypothermic device with a low weight of 7.2 kg. Transport from room to room over smaller distances can be done by hand or with a small trolley.

The device must not be exposed to mechanical shocks/shaking or strong vibrations during operation.

Basically, the device must be treated gently. Impacts on the display can shatter it.

10 Storage and shelf life

The TECOtherm NEO device and all accessories must be stored in a **dry, clean and light-protected environment** unless otherwise specified.

Components	Additional specific storage conditions
TECOtherm NEO device	The TECOtherm NEO device is generally empty upon delivery. **The device may only be stored empty.** The environmental conditions for storage from the section “14 Technical Specifications” must be observed. The device must be cleaned according to the interval specified in “II APPENDIX – Internal cleaning “.
Storage mattress, hose kit, refill set	Cleaned and empty, observe cleaning interval, cf. “II APPENDIX – Internal cleaning “, observe expiration date

11 Troubleshooting

11.1 General information on the alarm and monitoring system

TECOtherm NEO has a comprehensive internal monitoring system for the temperature of the circulating fluid, flow, pump delivery pressure and set limit temperatures.

Failure of the mains power and internal system errors are displayed in the lower area of the front of the housing. Other faults are shown on the display by alarm symbols, some of which are supported by acoustic alarms:

	System error
	Temperature alarm
	Flow rate alarm
	Fluid level too low

	Acoustic alarm paused
	Mains failure, power failure (separate LED display)
	Internal system error (separate LED display)

Repairs, in particular with opening of the housing, must only be carried out by authorized specialists. Considerable danger can be created for you and patients due to improper repairs

Pause the AUDIO alarm first.

If errors are detected, the user receives information on the cause of the fault in a pop-up window on the display as well as about measures to remedy the faults. The instructions must be followed.

The window does not close automatically to allow the user enough time to read and understand the notes. To close the window, confirm the error messages using the appropriate function key.

The pop-up notification window can only be closed if the alarm has been paused. Otherwise, the notification window appears again.

A paused alarm reactivates after eight minutes. The cause of the error must be found and eliminated; otherwise no successful treatment is possible.

The following overviews are intended to help you find and eliminate the cause of a fault.

11.2 System alarm

Description	
	Instead of displaying the current rectal temperature, you see a dark display and the SF icon lights. A recurring acoustic alarm sounds.

First measure
We recommend that you first pause the acoustic alarm by pressing the blue illuminated button “Alarm mute”. If the fault is not rectified, the audible alarm sounds again after eight minutes. If there is a communication error between the operating system and the control system inside the device, the control system triggers an acoustic alarm after 10 s. The device switches off after another 10 s.

Visual displays	Possible cause	Measure
The SF symbol lights on the device.	The device controller detects a serious defect in the device.	Switch off the device by pulling out the mains plug. Wait 5 – 10 s and then plug the mains plug back in. If the SF system alarm has disappeared, the treatment may be continued. If the SF system alarm continues, there is a serious error. Pull the power plug again and inform the Service Department. The treatment must not be continued with this device. Use a replacement device. The Service Department must be informed about each system error alarm.

If error causes cannot be corrected, the device must be switched off. Exchange the device with a replacement device and inform the service department.

11.3 Temperature alarm

Description
Instead of a display of the current rectal temperature, you see the chart with level alarm symbol (on the left). A recurring acoustic alarm sounds.
First measure
We recommend that you first pause the acoustic alarm by pressing the blue illuminated button “Alarm mute”. The suppression of the alarm sound is indicated by the symbol “Alarm paused” in the display. If the fault is not rectified, the audible alarm sounds again after eight minutes.

Visual displays	Possible cause	Measure
Rectal temperature is not displayed in the displayed error case chart.	Rectal sensor has slipped out from the patient or has been removed.	The rectal sensor must be properly reintroduced into the patient's rectum and securely fixed.
	Rectal sensor has (partially) slipped out from the patient.	The rectal sensor must be properly reintroduced into the patient's rectum and securely fixed.
	Cooling assembly is impeded in its performance.	Place the device on a level, solid surface Make certain that cooling air can be sucked in unimpeded. Check whether the air outlet on the rear of the device is at least 15 cm from the wall.
	Ambient temperature is too high (greater than 27° C).	Ensure an ambient temperature of max. 27° C.
	Heat sources have too great an influence.	Check whether a switched-on heat source (infrared) is present on or in the incubator. Check whether there is a heat source under the mattress. Eliminate the cause!
	Cooling fluid with a different temperature was filled.	The device compensates for the temperature difference. The device must be observed further.
Rectal temperature is not displayed in the displayed error case chart.	Rectal sensor is no longer correctly connected to the device.	The connection of the rectal sensor to the device must be checked (unplug and re-insert).
	Rectal sensor is inoperable.	The rectal sensor must be replaced by another approved rectal sensor.
Mattress temperature is not displayed in the displayed error case chart.	Mattress is defective.	The mattress must be replaced by another approved mattress.

If error causes cannot be corrected, the device must be switched off. Exchange the device with a replacement device and inform the service department.

11.4 Flow rate alarm

Description
 Instead of displaying the current rectal temperature, you will see the diagram with the character displayed (on the left) and an error message with the indication “The flow rate is very low…”. A recurring acoustic alarm sounds.
First measure
 We recommend that you first pause the acoustic alarm by pressing the blue illuminated button “Alarm mute”. The suppression of the alarm sound is indicated by the symbol “Alarm paused” in the display. If the fault is not rectified, the audible alarm will sound again after eight minutes.

Visual displays	Cause	Measure
Error case diagram with the “Flow alarm” symbol	Folds or kinks are present in mattress and/or hoses.	Remove kinks and improper loads on the mattress or hoses
	Hose couplings have come loose.	Connect the hose connectors to the device in such a way that they engage firmly.
	Too little cooling liquid is circulating or cooling liquid flows too slowly.	Cooling liquid must be filled with refilling equipment until the flow alarm disappears.

If error causes cannot be corrected, the device must be switched off. Exchange the device with a replacement device and inform the service department.

11.5 Fluid level alarm

Description
 Instead of a display of the current rectal temperature, you see the diagram with level alarm symbol (on the left). A recurring acoustic alarm sounds.
Initial measures
 We recommend that you first pause the acoustic alarm by pressing the blue illuminated button “Alarm mute”. The suppression of the alarm sound is indicated by the symbol “Alarm paused” in the display. If the fault is not rectified, the audible alarm will sound again after eight minutes.

Visual displays	Cause	Measure
Error case diagram with the “Fluid level alarm” symbol	Leakage in the TECOtherm NEO device; coolant leaks.	Visual inspection of the device, in particular on the bottom of the device. Small leak: Refill temperature regulation fluid; contact Service Department. Big leak: Switch off the device and disconnect the mains plug, put the replacement device into operation, contact Service Department.
	Leakage in hoses or matresses Leaking hose couplings Cooling fluid leaks	Visual inspection of hoses, hose couplings and mattress with regard to wetness and moisture. Small leak: Seal the leak with adhesive tape or plaster tape provisionally; seal the mattress with repair kit if necessary; refill the temperature control liquid. Big leak: replace defective component with approved replacement component

Normally, newly supplied cooling fluid has a different temperature. The temperature difference can trigger a downstream temperature alarm. This should disappear after a short time, since the system regulates the temperature independently. If this is not the case, proceed as described in the relevant section.

11.6 Power Failure/Mains Outage Alarm

Description	
	Instead of displaying the current rectal temperature, you see a dark display and the LED (9) lights brightly. A high continuous tone is output as an alarm.
First measure	
	We recommend that you first pause the acoustic alarm by pressing the blue illuminated “Alarm mute” button. This permanently deactivates this alarm.

Visual displays	Cause	Measure
Dark display and the LED (9) lights brightly	Device was switched off unintentionally.	Switch the device back on.

Visual displays	Cause	Measure
On switch lights in light green		
Dark display and the LED (9) lights brightly On switch is not illuminated.	Power failure	If only the TECOtherm NEO has no power, check the mains connection from the socket to the device or contact a building services technician.
	Defective fuse	Have a building services technician change the device fuse. Please refer to the nameplate for the approved fuse value. If the fuse burns out again immediately, take the device out of operation and contact the Service Department.
	There is a device defect (e.g., of the power supply unit) affecting the power supply.	Do not continue using the device; contact the Service Department. Use a replacement device.

In the event of power interruptions of fewer than 60 min, the system status is then automatically restored and the user is asked whether the interrupted treatment is to be continued. Already created but interrupted log files can be continued in this way.

12 Maintenance and Service

12.1 General Notes

Maintenance, safety inspections and repairs may only be carried out by the manufacturer or by personnel expressly authorized by the manufacturer.

Inspections are to be carried out in accordance with applicable legal provisions and regulations, usually every 12 months. In addition, basic electrical safety (STK) must be inspected and documented annually.

12.1.1 Preventive maintenance

To maintain reliable operational readiness of the TECOtherm NEO hypothermia system, we recommend the following preventive measures:

- Cleaning“

- Observe cleaning interval and regulations for the device and application parts as described in “II APPENDIX – Internal cleaning “.
- Inspection and calibration of reusable temperature sensors in accordance with the manufacturer's instructions for use/technical specifications, at the latest after two years.

12.1.2 Software updates

The manufacturer or its service partners provide information about upcoming software updates. We recommend always using the latest software version. It is also possible only to update individual software components.

The manufacturer or service partner usually carries out updates. Errors when updating the program software are displayed in the display (in turquoise). In addition and if possible, information is provided on how to proceed further.

13 Disposal

This device must NOT be disposed of via general commercial or household waste!

It MUST be delivered to a corresponding collection point or suitable disposal company or returned to the dealer or manufacturer.

14 Technical Specifications

No significant performance characteristics were determined for the TECOtherm NEO.

Specification	Device
General	
Dimensions (H x W x D)	215 mm x 375 mm x 310 mm
Weight without accessories	Approx. 7.2 kg
Internal fluid reservoir	Filling volume approx. 250 ml
Max. permissible weight of patient	< 50 kg
Display	6.5” LCD color display (132 x 99 mm), Resolution 640 x 480 pixels
Internal data memory	4 GB
Permissible ambient conditions	
Room temperature during operation	+5° C to +27° C
Relative humidity during operation	30% RH to 80% RH, without condensation
Storage conditions	
Room temperature at storage (empty)	+5° C to +60° C

Specification	Device
Operating parameters	
Operating modes	1) Automatic treatment by program 2) Set to constant rectal temperature 3) Control to constant mattress temperature
Adjustable range of SETPOINT treatment temperature	Mattress +12° C to +39° C Rectal +32° C to +38° C
Cooling time of the mattress temperature from 20° C to 12° C	10 min
Temperature stability	< 0.3° C
Maximum pressure in the system	0.5 bar
Flow	Approx. 500 ml/min (depending on mattress size)
Alarm system/patient safety	
Alarm Types	Optical (flashing LED) and acoustic alarms
Sound pressure level alarm Power failure	Approx. 63 dB(A)
Sound pressure level Other alarms (system error, low fill level, temperature error, flow rate error)	Approx. 57 dB(A)
Lower temperature alarm limit	+10° C
Upper temperature alarm limit	+41° C
Electrical characteristics	
Electrical connection (rated voltage)	100-130 V and 200-240 V, 50-60 Hz
Max. power consumption	350 W
Fuses (2 pieces)	5X20 mm, 250 V AC, sluggish, high shutdown capacity at 100-130 V: T 4 A H, at 200-240 V: T 2.5 A H
Ground leakage current	< 400 µA
Permissible power cord	Max. 2.5 m long, connection to protective contact plug
Device safety	
Protection class	Class 1, risk class IIb,  type BF
Protection against penetration of foreign bodies, dust and water	IP20 • Protection against the penetration of foreign bodies > 12.5 mm • Not protected against water ingress.
Standards applied:	DIN EN 60601-1, DIN EN 60601-1-2, DIN EN 60601-1-6, DIN EN 60601-1-8, DIN EN 60601-1-10, DIN EN 60601-2-35 E/F
Conformity mark	CE 0494

14.1 Electromagnetic Compatibility (EMC)

Electromagnetic compatibility (EMC) guidelines apply to medical-electrical devices such as TECOtherm NEO. The user must ensure that the device is installed and operated according to the following instructions.

Portable and mobile HF communication devices can influence the function of medical electrical devices. Maintain minimum distances specified in the EMC Guideline.

Note on radiated HF disturbances: Interference field strengths above 3 V/m may affect the “rectal temperature regulation“ by causing incorrect rectal temperature measurements. However, the TECOtherm NEO remains safe up to interference field strengths of 10 V/m.

14.1.1 Guidelines and manufacturer’s declaration – Electromagnetic interference emission

Electromagnetic interference measurements	Conformity	Electromagnetic environment – guideline
HF emissions According to CISPR 11	Group 1	The TECOtherm NEO uses HF energy exclusively for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
HF emissions According to CISPR 11	Class A	The emission characteristics of this device allow its use in the industrial sector and in hospitals (CISPR 11, Class A). When used in the residential area (for which CISPR 11 typically requires Class B), this device may not provide adequate protection against radio services. If necessary, the user must take corrective measures such as conversion or realignment of the device.
Emission of Harmonics According to EN/IEC 61000-3-2	Class A	
Emission of Voltage fluctuations/flickers according to IEC 61000-3-3	Complies	

14.1.2 Guidelines and manufacturer's declaration – Electromagnetic interference emission

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidelines
Electrostatic discharge Electricity (ESD) According to EN/IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood or concrete or be provided with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient Electric disturbances/ Bursts According to EN/IEC 61000-4-4	± 2 kV for mains lines ± 1 kV for input and output lines	± 2 kV for mains line Not applicable because not present	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surge voltage/surges According to EN/IEC 61000-4-5	± 1 kV voltage Outer conductor-outer conductor ± 2 kV voltage Outer conductor ground	± 1 kV voltage Outer conductor-outer conductor ± 2 kV voltage Outer conductor ground	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage dips, Short-term interruptions and fluctuations of the supply voltage according to IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for ½ period 40% U_T (60% dip in U_T) for 5 periods 70% U_T (30% dip in U_T) for 25 periods < 5% U_T (> 95% dip in U_T) for 5 seconds	< 5% U_T (> 95% dip in U_T) for ½ period 40% U_T (60% dip in U_T) for 5 periods 70% U_T (30% dip in U_T) for 25 periods < 5% U_T (> 95% dip in U_T) for 5 seconds	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the TECOtherm NEO user requests continued operation even if power supply interruptions occur, it is recommended to power the TECOtherm NEO from an uninterrupted power supply or battery.
Magnetic field at the supply frequency (50 Hz) According to EN/IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency should comply with the typical values, as they correspond to the commercial and hospital environment.

Note: U_T is the AC line voltage prior to application of the test level.

14.1.3 Guidelines and manufacturer's declaration – Electromagnetic interference emission

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidelines
Conducted HF disturbance variables According to EN/IEC 61000-4-6	3 $V_{r.m.s.\ value}$ 150 kHz to 80 MHz	3 V	Portable and mobile radios should not be operated at a shorter distance from the TECOtherm NEO (including the lines) than the recommended protection distance. This is to be calculated according to the equation applicable to the transmission frequency **Recommended protection distance:** $d = 1.2 \sqrt{P}$ for 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ for 800 MHz to 2.5 GHz where P is the nominal power of the transmitter in watts (W) as specified by the transmitter manufacturer and d is the protective distance in meters (m). The field strength of stationary radio transmitters should be lower than the level of correspondence [b] at all frequencies according to an on-site examination[a]. Disturbances are possible in the vicinity of devices bearing the following symbol. 
Radiated HF disturbance variables According to EN/IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1: The higher frequency range applies at 80 MHz and 800 MHz.
NOTE 2: These guidelines may not be applicable in all cases. The spread of electromagnetic quantities is influenced by absorption and reflection of buildings, objects and people.

a The theoretical field strength of stationary transmitters such as radio telephone and mobile agricultural radio equipment base stations, amateur radio transmitters, AM and FM radio and TV transmitters cannot be precisely determined in advance. To assess the electromagnetic environment with respect to stationary transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where the TECOtherm NEO is used exceeds the above compliance level, the TECOtherm NEO must be observed to demonstrate proper functioning. If unusual performance characteristics are observed, additional measures are required, e.g., a changed orientation or another location of the TECOtherm NEO.

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

14.1.4 Recommended safe distances between portable and mobile HF telecommunications equipment and TECOtherm NEO

The TECOtherm NEO is intended for operation in an electromagnetic environment, in which HF disturbances are controlled. The user of the TECOtherm NEO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communication equipment (transmitters) and the system, depending on the output power of the communication device, as indicated below.

Rated power of the transmitter W	**Protection distance depending on the transmission frequency m**		
	150 kHz to 80 MHz $1.2\sqrt{p}$	**80 MHz to 800 MHz** $1.2\sqrt{p}$	**800 MHz to 2.5 GHz** $2.3\sqrt{p}$
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 rated power is not specified in the above table, the recommended protection distance *d* in meters (m) can be determined with the aid of the associated specified equation, where *P* is the maximum rated power of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: The higher frequency range applies at 80 MHz and 800 MHz.

NOTE 2: These guidelines may not be applicable in all cases. The spread of electromagnetic quantities is influenced by absorption and reflection of buildings, objects and people.

15 Service Information

Information material, instructions for use and technical information can be requested from the manufacturer TEC COM and from service/sales partners.

Manufacturer

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I. APPENDIX – Equipment and Accessories

Due to national restrictions, accessories may not be available in your country. For information or orders, contact your local distributor or Inspiration Healthcare Limited.

Accessories	Article		Manufacturer, Article number
TECOtherm NEO device	----		TEC COM GmbH, TC-NEO-BU
Therm Aqua Pad Mattresses	Multiple use,		Kleeven Medical B.V.
Material	PUR polyurethane film, transparent		
Dimensions	300 mm x 450 mm	500 mm x 900 mm	
Filling volume	Approx. 300 ml	Approx. 500 ml	
Mass (empty)	Approx. 220 g	Approx. 750 g	
TCmatt NEOmulti Mattress	Multiple use,		Tec Com Medizintechnik GmbH
Material	PUR polyurethane film, transparent		
Dimensions	620 mm x 420 mm		
Filling volume	300 - 350 ml		
Mass (empty)	155 g		
TCmatt NEOsingle Mattress	Single use		Tec Com Medizintechnik GmbH
Material	PUR polyurethane film, transparent		
Dimensions	620 mm x 420 mm		
Filling volume	300 - 350 ml		
Mass (empty)	220 g		
Cover cloth	e.g., Raucodrape cover cloth (450 x 750 mm) A thin intermediate layer prevents direct contact between application parts and patients. This allows safe multiple use.		e.g., Lohmann & Rauscher International
Hose kit	Length: 2 m		TEC COM GmbH, TC-NEO-MCC2
Refill sets	----		TEC COM GmbH, TC-NEO-CRS
Rectal temperature sensor	METKO FMT400/POR, reusable.		METKO
	METKO FMT400/AOR-D5, single use, in combination with adapter cable FMT400/AEC-P or FMT400/AEC/Z-P		METKO
	METKO FMT400/AOR-D6, single use, in combination with adapter cable FMT400/AEC-P or FMT400/AEC/Z-P		METKO
	Philips M1837A, single use, in combination with adapter cable 989803162601.		Philips
	Adapter cable 989803162601		Philips
Skin temperature sensor	METKO FMT400/AS-THT, reusable.		METKO
	METKO FMT400/AS-D, single use, in combination with adapter cable FMT400/AEC-THT		METKO

	Adapter cable FMT400/AEC-THT	METKO
	Measurement Specialties Model 4499, single use	Measurement Specialties Inc.
Constant-temperature medium (temperature regulation fluid)	Sterile water	
Cleaning tablets	TECOpure	TEC COM GmbH, TC-CDT-EN (english), TC-CDT-DE (german)
	Short-circuit bridge	TC-NEO-KSB

II. APPENDIX – Internal cleaning

For the safe operation and maintenance of the performance of the TECOtherm NEO over the entire service life, it is necessary to clean the internal circuit of the device and the application parts (mattresses and hose kit) regularly. Cleaning is recommended after each treatment. Cleaning at **least every 2 months** is mandatory and must be carried out using the following cleaning procedure:

Cleaning must be carried out with a solution of chlorine dioxide (prepared with the aid of a tablet TECOpure, cf. “I APPENDIX – Equipment and Accessories” and sterile water.

Before cleaning, the device and all connected application parts must be emptied. To empty any filled parts, proceed according to the instructions in “6.2.3 Emptying TECOtherm NEO and tress“.

Wear disposable gloves during the following steps and dispose of them after completion of the complete cleaning process.

A) Preparation of the cleaning solution

- Add 450 ml of sterile water to the refill set.
- Add a TECOpure cleansing tablet to this.
- Close the refill set tightly.
- Wait until the cleaning tablet is completely dissolved (this should take approx. two minutes; the process can be accelerated by gentle shaking).

B) Fill in the cleaning solution.

Fill the cleaning solution in the TECOtherm NEO immediately after the cleaning table has completely dissolved.

- Connect the hose kit.
- Connect the reusable mattress to be cleaned or, if you only use disposable mattresses, connect the hose kit with the help of the short-circuit bridge to create a cycle.
- To do this, connect the refill set to the upper connections of the device.
- Turn the bottle so that the lid is facing downward.
- Start the constant mattress mode with a target temperature of 22° C.
- Wait until most of the liquid has flowed into the device and no more air bubbles rise in the refill set.
- If the fluid in the refill set is not sufficient to fill the system completely:
    - Disconnect the refill set from the device:
    - Add 450 ml of sterile water to the refill set.
    - Repeat the filling process
- Disconnect the refill set from the device.

C) Cleaning process

- Let the cleaning solution circulate for 10 minutes in the constant mattress mode at 22° C.
- Empty the device and all connected application parts according to “6.2.3 Emptying TECOtherm NEO and mattress“.
- Fill the appliance and the cleaned application parts with sterile water according to “6.2.1 Filling process“.
- Let the sterile water in the device and all parts of the application circulate for five minutes in the constant mattress mode at 22° C.
- Empty the device and all connected application parts according to “6.2.3 Emptying TECOtherm NEO and mattress“.

The device and the application parts are now cleaned and ready for further storage. If you need the device immediately afterward for a treatment, proceed according to “6.2.1 Filling process“.