TEC COM GmbH

TECOTHERM NEO

MEDICAL EQUIPMENT for THERMOREGULATION of NEONATE and INFANTS

Instructions for Use

Revision November 2015
Applicable for software version 063/02.17 and higher
Applicable for Serial numbers 2015/24/01 and higher

Contents and abbreviations

Abbreviations

IfU	Instruction for Use
BCT	Body Core Temperature, as measured via the Rectum using appropriate rectal temperature probes, see 7.4
SF	System Failure

1 Intended Use

This Instructions for Use (IfU) presents a detailed introduction into the operation modes of TECOTHERM NEO from TEC COM GmbH.

The thermoregulation system, TECOTHERM NEO is designed for controlled comfortable cold & heat treatment procedures. By means of mattresses or aqua wraps, cold and heat is applied to the total body, body parts or specific areas of neonate depending on the therapy objective.

One main application is induced hypothermia treatment of neonate affected with Hypoxic Ischemic Encephalopathy.

The IfU contains a Technical Description and technical data.

TECOTHERM NEO exhibits SERVO CONTROL operation as a modern excellence feature using MENU assistance.

TECOTHERM NEO has been equipped with two microcomputers and with numerous monitoring and alarm features which guarantee a high standard of treatment and operation safety.

Note: The Manufacturer carries responsibility for basic safety, reliability and capability of the TECOTHERM NEO system only when

- local electrical installation fully meets the requirements of the IfU.
- initial operation is performed according prescribed Instruction procedure by authorized personnel.
- TECOTHERM NEO is operated according to the instructions and statements of said IfU.

1.1 Indications for Use

The TECOTHERM NEO is a temperature management system for pediatric patients, indicated for controlling and monitoring patient's temperature through conductive heat transfer.

1.2 Contraindications for Use

No general contraindications are known. For possible adverse effects study the relevant treatment and therapy protocols.

Avoid direct contact of mattress or cool wrap with patient's skin!

Avoid direct contact of mattress or cool wrap with fresh or non- closed wounds, infectious areas, areas with ulceration and abscesses, rash and burns.

1.3 Operators Profile

TECOTHERM NEO is intended for use by healthcare professionals only. Operating a TECOTHERM NEO requires:

- Education as Healthcare Professional
- Experience in using life support and life sustaining equipment
- Experience in using medical electrical equipment
- Personnel must be trained in the use of the TECOTHERM NEO before operating the device.

Note: Operator is requested to carefully check all accepted default or personally set parameters for correctness and adequacy before starting treatment.

2. Information for Customers Service & Technical support

For Technical Support in German please contact: TEC COM GmbH

Phone	+49 - 345 - 120 52 04
Fax	+49 - 345 – 120 52 11
E mail	info@teccom-halle.de

For Technical Support in English please contact: Inspiration Healthcare Ltd

Phone	+44 - 1455 840555
Fax	+44 - 1455 841464
E mail	info@inspiration-healthcare.co.uk

The manufacturer TEC COM or authorized representatives will instruct and introduce the operation personnel prior putting the equipment into operation

Additional information, technical support, additional manuals may be requested from the manufacturer and any authorized distribution partner.

Manufacturer
TEC COM GmbH
Gesellschaft für Technik, Technologie und Vermarktung
Am Krümmling 1
D-06184 Kabelsketal
Germany

Supplier
Inspiration Healthcare Limited
Gildor House
West Street
Earl Shilton
Leicestershire LE9 7EJ
United Kingdom

Type label

TECOTHERM NEO
Serial Number 2015 / 24 / 01
100-130V / 200-240V 50-60Hz max. 350W
Class I / Schutzklasse I IP20 Made in Germany
Fuses / Sicherungen: 5x20mm 250VAC
100-130V: S4AH / T4AH 200-240V: S2,5AH / T2,5AH
Manufacturer / Hersteller: TEC COM GmbH
Am Krümmling 1
D-06184 Kabelsketal
CE 0494

3. Device Description

The TECOTHERM NEO system is designed for controlled cold & heat treatment procedures and application of specific cold and heat doses to neonates and babies. The system applies cold and heat to total body, body parts and particular areas depending on therapy target by means of mattresses and/or aqua wraps.
One main application is hypothermia treatment of neonate affected by Hypoxic Ischemic Encephalopathy (HIE).

TECOTHERM NEO consists of a unique cold & heat generating device, applied parts like mattresses and wrap, interconnecting hoses (tubing set), accessories. Applied parts are connected to the device via hoses by self- sealing quick- disconnect couplings.

The patient is provided with cold and heat according therapy target in a fully controlled way by a circulating fluid. This circulating fluid is cooled or warmed in the device and flows through the mattress or wrap continuously supplying the patient with therapeutically prescribed doses.

Patient temperatures are measured with approved calibrated probes connected to the TECOTHERM NEO device. Temperature data is permanently communicated to the device Operational System.

Circulation of thermalizing fluid to provide cold and heat, accurately reaching set points and operating at set point temperatures accurately with max. deviation of +/-0,3°C, monitoring the treatment, and alarming when exceeding or falling below temperature limits are performances of TECOTHERM NEO.

TECOTHERM NEO is a system with built-in physiologic closed loop circuit PCLC.

TECOTHERM NEO is electronically divided into an **Operational System** and a **Controlling System.** Both sub systems are microcomputer (µC) based. Both µC communicate permanently to ensure safe and proper operation according to therapy needs.

A comfortable user MENU will guide the operator to the treatment modes, advise how to proceed the treatment and how to manage treatment details.

Menu language may be preselected using Sub–Menu “Language”: English, Deutsch, Espanol …

TECOTHERM NEO offers three separate treatment modes to induce hypothermia and to re-warm the patients. TECOTHERM NEO uses 2 independent temperature probes:

- rectal probe for measuring Body Core Temperature (BCT), mandatory required for SERVO mode.
- skin probe for measuring skin abdominal or forehead temperature etc, optional.

The three treatment modes are

I SERVO CONTROL Programmable Complete Treatment Mode

II SERVO CONTROL Constant Rectal Temperature Mode

III Constant Mattress Temperature Mode

The Operator selects the treatment mode I, II or III and treatment parameters for inducing **hypothermia,** normothermia or hyperthermia following the MENU instructions. Attention: Temperature probes must be properly placed before treatment procedure can start.

Attention Treatment and selection of treatment procedure is fully within the responsibility of the therapist, physician or trained qualified medical personnel.

Attention For neonate and other patient hypersensitivity or restricted compatibility to hypothermia and / or hyperthermia is in general not known. Neonate receiving such treatment must be under careful observation.

4. Symbols, Indications

Important Information 

Attention, Caution, Warning 

Electrical Hazard ! 

Do not touch contacts! 

Applied Part Type BF 

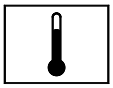
Consult Instruction for Use 

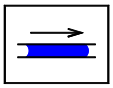
Rectal Temperature Sensor socket 

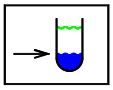
Skin Temperature Sensor socket 

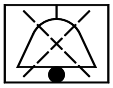
Key “Turn On” 

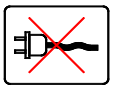
System failure 

Temperature Alarm 

Alarm No or restricted Flow 

Alarm Low fluid level 

Symbol AUDIO paused 

No Mains Power (separate LED indicator) 

Internal System Failure (separate LED indicator) 

5. Warnings, Precaution guidelines

Warnings

- Modification of the TECOTHERM NEO not authorized by the manufacturer is not allowed.
- Do not open the device! Risk of electrical shock.
  Opening the device is restricted to service and other authorized personnel.

- Do not remove cover part. Risk of electrical shock when touching inner parts and components.
- The TECOTHERM NEO device must be plugged to the mains only to shockproof sockets. Mains voltage must be 100-130V or 200-240V with 50-60 Hz. Use only cord supplied with the device or a medical grade approved equivalent cord not longer than 2,5 m.
- **Caution** During operation and treatment: The operator must not **simultaneously** touch the patient and metallic device parts (plug / connector sockets, grounded connected parts at the device rear, contacts of fuse compartment).

- Both temperature probe sockets on the front of device and the USB socket on the rear are marked with ESD warning symbols.
  They are sensitive against discharge of static electricity, their electrical contacts should not be touched with the fingers or tooling. When connecting probes or USB stick to their sockets the following precautionary procedure is required:
  Before plugging, touch the fan protective grid at the rear with your other hand.
  It is recommended that all staff involved in using TECOTHERM NEO receive an explanation of the ESD warning symbol and training in ESD precautionary procedures.
  That training should include, in addition to the precautionary procedure prescribed above, general information on the origin, the possible impact and the prevention of electrostatic charging.

- Repair and maintenance are restricted to authorized personnel only!
- For a reliable and safe operation use only original components, applied parts and spare parts supplied or recommended by the manufacturer.
- Substitution of original parts or components of the TECOTHERM NEO system by parts or components which are not licensed by the manufacturer is likely to put the system and the patient at risk!
- Only use **Sterile Water** as the circulating fluid. Otherwise it would be possible to put the system and the patient at risk!

- Use only temperature probes in accordance with IfU and with the technical specification of the manufacturer.
  
  Applying different probes may lead to incorrect and wrong temperature data.
  This is likely to put patients at significant risk!

- Ensure that probes are properly connected to the TECOTHERM NEO socket marked "**R**" (Rectal for Body Core Temperature) and "**S**" (Skin for Surface Temperature).
- Ensure that Rectal and Skin Temperature Probes are correctly placed in/on the patient and that probes are properly secured.
  
- Do not use TECOTHERM NEO with or in presence of flammable agents.

Safety, Reliability

Caution For a reliable and safe operation of the TECOTHERM NEO use only original components, parts and spare parts and accessories supplied or licensed by the manufacturer.
Use only such components, parts and accessories for hypothermia treatment with a TECOTHERM NEO system!

Warning Substitution of original parts or components of the TECOTHERM NEO system by parts or components which are not licensed by the manufacturer is likely to put the system and the patient at risk!

Precautions

Consider within Intended Use

Note: Therapeutic Induced Total Body Hypothermia is a systemic treatment method. Select target temperatures cautiously.

Re- warming: Select low re-warming rates to smoothly reach normal BCT of 37°C. Patient body mass may severely influence re- warming. The larger the mass the slower the re- warming.

Further notes

When TECOTHERM NEO is run in the Constant Mattress Temperature Mode to lower body core temperature an independent temperature measurement is required to monitor hypothermia.

Note that in this mode applied treatment temperature and duration do not allow a realistic estimation of the actual degree of lowering of patient's BCT.

- Medical electrical equipment needs special precautions regarding Electromagnetic Compatibility and needs to be installed and put into service according to the Electromagnetic Compatibility information provided below in 17. EMC guidance.
- Portable and mobile RF communication equipment can affect medical electrical equipment. Observe the recommended separation distances listed below in 17. EMC guidance.
- The TECOTHERM NEO device should be subject to regular maintenance and service, see section 13.
- Refill with Sterile Water regularly every 2 months, see section 8.5.
- Note Circulation may stop, fluid flow stops.

  In such cases mattresses may cool neonate or patient slowly down. Especially during treatment re-warming phase neonate may suffer from extraction of body heat back into the mattress. Change such condition soon!
- The operator or the user should not apply other cleaning, disinfecting and decontamination procedures than those recommended by the manufacturer. If in doubt contact your local representative.

Precaution Notes for placement

Location

- The TECOTHERM NEO device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the TECOTHERM NEO should be observed to verify normal operation in the configuration in which it will be used.
- The unit must be placed in such a way that it could be easily disconnected from mains power. Removing the mains plug must be always possible.
- The unit must be placed horizontally onto a plane support
- The system is fan cooled. Sufficient space must be allocated so that a free flow of air from all sides can reach the bottom of the device when it is in operation.
- Device should be located so that there is a distance of at least 15cm between rear side and a wall or another limiting surface to ensure free outflow of the cooling air.
- Do not place the device into small cabinet compartment or onto small scale boards. Do not cover the device!
- The unit should be placed avoiding air to be blown towards the patient.
- The unit should be placed so that optical blink alarms are clearly seen and acoustic alarms are clearly audible.

- Do not place mattresses and hoses onto hot or warm supports during operation
- Do not place the device during operation near intensive heat sources.

Attention Ensure there is enough space around the TECOTHERM NEO not to obstruct passage of acting personnel. Ensure that hoses, cable cord, temperature probes etc. do not form obstacles.

- Ensure that placement of TECOTHERM NEO is not forming trapping zones for hands and fingers to avoid contusions and other injuries.
- In case of reusable mattresses and wraps, apply a **thin disposable interlayer** which must at least fully cover the mattress with some border. Such interlayer must be coated at lower side with plastic coating to prevent penetration of blood, liquids or liquid media onto the upper surface of the mattress and to protect the patient.
- Note: Place mattress/aqua wrap onto a ≈ 10 - 20 mm thick foam material that has good thermal insulation during operation.

Using an incubator

When using an incubator to perform hypothermia treatment:

- Pay attention that there is enough space to properly place mattress or cool wrap. Otherwise kinking of hose set and / or tubing near mattress and mattress folding may cause restricted fluid flow, bad circulation or even flow blocking
- Place the hoses set in a way that the hoses are in a straight line. Fasten the hoses in such a way to avoid kinking of the tubing near the mattress
- Note: Place mattress onto a ≈ 10 - 20 mm thick foam material that has good thermal insulation during operation.

Note: Do not put mattress directly onto compact silicon inlays used in incubators.

Attention Ensure that incubator heaters are shut off! Ensure that there is no forced air circulation. It may cool down the neonate in a re- warming phase of the treatment.

Indications for hazardous substances

TECOTHERM NEO does not contain parts or substances stemming from derivatives of blood or human / animal tissues.

TECOTHERM NEO does not contain parts made of Latex or its derivatives.

TECOTHERM NEO Applied Parts do not contain parts made of PVC with DEHP softener / plasticizer

Thermalizing Fluid is Sterile Water.

- Skin contact with fluid is harmless.

Ambient Conditions

To ensure a proper operation in normal use pay attention to the following conditions

- **Protection** The device should be protected from dampness and wetness (e.g. splash water.)
- Do not operate device in rooms where flammable mixtures of anaesthesia gases with oxygen, laughing gas N_2O or air may evolve.
- To have full cooling power ambient temperature should not exceed 27°C. Otherwise the TECOTHERM NEO system may not achieve the lowest possible set temperature if using a large mattress.
- Relative Humidity during treatment within a range of 30 % - 80 %
- Ensure that during treatment / operation no installations, systems, devices and the like are operating or are intended to operate next to TECOTHERM NEO and producing

  ultraviolet radiation

  intense infrared radiation

  strong electromagnetic radiation

  mechanical shocks, vibrations.

6. TECOTHERM NEO operating functions

Operators should familiarize themselves with the operating instructions. It is of crucial importance that they are fully familiar with the actions to be taken in the case of alarms and initial operating errors occurring during use.

Operators should furthermore develop an understanding of the TECOTHERM NEO as a system, comprising of a physiologic closed-loop circuit (PCLC).

6.1 The physiologic closed-loop circuit (PCLC)

In accordance with specified applications (see 1.1) TECOTHERM NEO is used to regulate rectal measured body core temperature of patients, which is a physiologic variable, in a specific way or to maintain it at a constant level. Following an as rapid as possible cooling down to 33.5°C this temperature is subsequently to be maintained over a 72 hour period, followed by a gradual steady re-warming up to 37°C within a period of 7 hours or longer.

This is achieved by placing the patient into effective thermal contact with a coolant fluid perfusion mattress (see 8.7). The temperature of the fluid determines the changes which will take place in the patient's core body temperature: if it is lower than that of the patient, the patient's temperature will fall – if it is higher the patient's temperature will rise. The greater the difference in temperature between patient and the fluid the faster the change in the patient's core body temperature, whereby a change of 0.5°C/hour should already be considered being rather "rapid". The mattress temperature (i.e. the average temperature of the fluid) must obviously be maintained within certain limits in order to prevent possible damage to tissue (frostbite, burns). These limits are set at **12°C** and **39°C** respectively, whereby temperatures around 12°C are needed only during the initial treatment phase to allow for an as rapid as possible cooling down process; subsequently these temperature levels will no longer be required.

In order to achieve the intended progression in the patient's core body temperature the mattress must be kept at the correct temperature level, at all times. The right temperature will depend on a number of factors: what is the current stage of treatment; what are the (changing) ambient conditions, environmental factors; how effective is the thermal contact between mattress and the patient; how intensive or reduced is the patient's own level of thermal output. First of all, sufficient information concerning the patient's current core body temperature must be available in order to determine the correct mattress temperature required. However, the impact of external factors is often rather complex and difficult to assess, so that manual setting of the mattress temperature by the operator will often result in more or less wide fluctuations of the core temperature around the target level, especially as the actual results of a temperature adjustment do rarely become apparent within less than a half-hour period. This also does lead to increased nursing requirements, since repeated adjustments in temperature will become necessary.

The operator is spared these complex considerations and corresponding decision-making process by the automatic temperature control system performing these tasks in the two automatic operating modes. The operator now merely needs to schedule the overall intended progression of change in the patient's core body temperature in advance, using a limited number of parameters, which can be intuitively understood. The temperature control system using the rectal temperature measurements subsequently calculates the exact mattress temperature required, on a continuous basis, in order to stay within the set schedule. The TECOTHERM NEO temperature control module ensures that the mattress delivers the temperature required based on these calculations, as fast as possible.

Like any other temperature control system TECOTHERM NEO comprises a closed-loop control circuit. Any deviation from target settings is counteracted **immediately**. Assuming that the rectal temperature measurement is 0.1° higher than it should be, at any given point in time, the control system would lower the mattress temperature by 1° if the internally programmed amplification factor had a value of 10. With a certain delay this lowering of mattress temperature will result in a corresponding decrease in rectal temperature and the subsequent gradual convergence back towards the target value. As a result the decrease in mattress temperature will in turn be reduced. Thus the cycle is closed and since the regulated rectal temperature is a physiologic variable of measurement this represents a **physiologic closed-loop circuit (PCLC)**.

During the initial stages of treatment, i.e. rapid cooling down of the patient, an inevitable **overshoot** will occur – actual values will in fact fall somewhat **short** of the target value of 33.5°C. Standard parameters have been chosen to reduce such overshoot to below **0.5°**. A stable status is subsequently reached within a **settling time** of approx. **1 hour**; there are **no** remaining deviations from set parameters. During this constant phase, which usually lasts about 72 hours, potential fluctuations will be less than **0.3°**.
Following commencement of the re-warming phase there will initially be a rise in mattress temperature. Only after a **response period** of approx. **30 minutes** will there be any noticeable change in rectal temperature. This will subsequently increase only gradually as well and therefore initially lag marginally behind the intended progression. This **tracking error** is gradually reduced and will in any event always remain below **0.5°**.

This **physiologic closed-loop circuit** can obviously operate properly only if all elements of this functional chain do perform their designated tasks as intended. Assuming normal operations of the TECOTHERM NEO unit a number of additional requirements need to be met:

- The thermalizing fluid must circulate at a flow rate sufficiently high to ensure an efficient thermal transfer to or away from the patient. This process is monitored by the unit and, if required, the operator will be alerted to initiate appropriate corrective measures.
- There must be sufficient thermal contact between the fluid perfusion mattress and the patient, as any change in mattress temperature may otherwise have no or only limited effect on rectal temperature. It is of crucial importance for the operator to position the mattress correctly and in accordance with the operating instructions (see

8.7). The equipment can detect any fault in this respect only after lapse of the response period of approx. 30 minutes, at the earliest, if despite constant adjustment of mattress temperature the expected reaction in rectal temperature does not occur and the rectal temperature eventually moves outside the permissible range of +/- 0.5° around the target value. Only at that point in time will a temperature alarm be activated.

- Rectal temperature, as the measurement ultimately to be regulated, must be recorded accurately. Incorrect measurements taken over an extended period of time, regardless of cause, would immediately result in an unwanted change in the patient's actual core body temperature.

  Example: An incorrectly placed rectal probe (e.g. slipped out) will record a temperature lower than the actual core body temperature, since the rectal probe will now measure the air temperature in proximity of the rectum. The current temperature measurement is shown on the display. This temperature will in fact be lower than the rectal target temperature of 33.5°C. Consequently there is now a deviation in temperature (**cause**). This will immediately result in an increase in mattress temperature (**effect**), since the unit's control system will work to again increase the core body temperature, which is now perceived being too low. Upon activation of the alarm, the operator can conclude from the low rectal temperature recording shown on the display that the rectal probe may have slipped out and will need to check this immediately.

6.2 Fallback mode

Amongst various possible causes which may lead to a malfunctioning of the physiologic closed-loop circuit the systematically false recording of rectal temperature would be the most disadvantageous, especially if it went unnoticed for an extended period of time. Only this kind of false measurement would lead directly to the wrong core body temperature for the patient. Such false readings can have a number of different causes:

- incorrect placement of the rectal probe, e.g. slipped out
- excessively high levels of electromagnetic interference from the environment
- deficiencies in contact(s) at plug connections
- defective rectal probe.

Unfortunately it is not possible to permanently monitor the rectal probe with the aid of a second control probe, as the insertion of 2 rectal probes would be impossible in the case of an infant. The otherwise recommended control by means of an additional skin probe is not sufficiently accurate and too exposed to potential external impact for such readings to be used in arriving at an informed decision. For these reasons measuring results taken from the rectal probe are checked as to plausibility, whereby it will depend upon the relevant stage of treatment as to what range of values for rectal temperature recordings will be classified as being plausible and therefore acceptable. In the case of measurements occurring systematically outside this specified **range of acceptance**

TECOTHERM NEO will stop operating as a **physiologic closed-loop circuit** and instead switch into **fallback mode**. The operator will be alerted and informed about the current status and subsequently needs to decide upon an appropriate course of action. Depending upon the stage of treatment a choice of suitable options will be given for the unit to immediately resume operations. The operator can now follow these prompts or make changes according to his own assessment of what actions may be required.

The key characteristic of the **fallback mode** is, that the required mattress temperature will no be longer calculated by the temperature control system, but that it now needs to be specified by the **operator**. In order to be able to take an informed decision under these circumstances the operator immediately needs to arrange for alternative methods of continuing a reliable recording of the patient's rectal temperature, completely independent from the TECOTHERM NEO system.

Although it will generally be possible to continue the current treatment process up to the end entirely in fallback mode, one should always try to identify and eliminate the actual cause of any false measurement. If no obvious reasons can be detected a replacement of the rectal probe is recommended. As soon as acceptable measurements are available again the unit will switch back automatically into the **physiologic closed-loop circuit** operating mode and the operator will be advised accordingly. Only in rare cases is it possible, that measurements may again be correct but still marginally remain outside the valid range of acceptance. If the operator can see that the measurements are indeed correct and there is still no automatic reversal, then this reversal can be prompted through use of the **"Servo"** button.

6.2.1 Plausibility limitations in rectal temperature measurement

In accordance with the designated applications for the TECOTHERM NEO system (see 1.1) it would be possible in the extreme case for the rectal temperature of a "patient" (not necessarily an infant!) to vary between 30°C and 38°C, at the beginning of the treatment cycle. Initial temperature recordings between 29°C and 39°C are consequently categorized as plausible readings. In the case of measurements outside this range the control system cannot be started and activation will be denied, with corresponding notification.

This comparatively broad range of tolerances, however, does not entail any untenable elements of risk. On the one hand it can be assumed, that intensive care and monitoring of the process is safeguarded during the initial stages of treatment, when the rapid achievement of stable conditions is the primary objective. The range of acceptable tolerances on the other hand is rapidly reduced following the initial stages of treatment until a status of stable condition has been reached. From that point forward the acceptable range of tolerances will be merely **1°** above or below the corresponding set target value. In the event of adjustments being made to the relevant target values the

corresponding threshold values will change accordingly, e.g. they will rise during the re-warming phase at the same speed as the rectal temperature target value.

Besides the monitoring of compliance with these absolute tolerance thresholds rectal temperature measurements are also checked as to their speed of change. The threshold value in this respect is **0.3°/minute**. Any changes faster than this, as in the case of the probe having slipped-out, will be read and evaluated as non-plausible and will trigger the switch to fallback mode.

6.2.2 Operations during fallback mode

As soon as the fallback mode has been activated, due to an infringement of tolerance thresholds, the operator must intervene and determine how the mattress temperature is to react from that point on forward. In this context it very much depends on the current stage of treatment in deciding on how best to proceed in an expedient manner. Correspondingly parameters are set for immediate activation of the fallback mode which will, at least initially, not result in any additional exposure to risks. The operator will need to adjust these parameters to prevailing conditions. With the aid of the graphic display the operator can obtain a good indication from the diagram of the progression of mattress temperature up to that point. Only once these steps have been taken is it advisable to commence with any trouble-shooting efforts or even a replacement of the rectal probe, in order to restore automatic operations as quickly as possible.

Depending on the current stage of treatment two essentially different types of parameters and optional settings are available for operations in fallback mode.

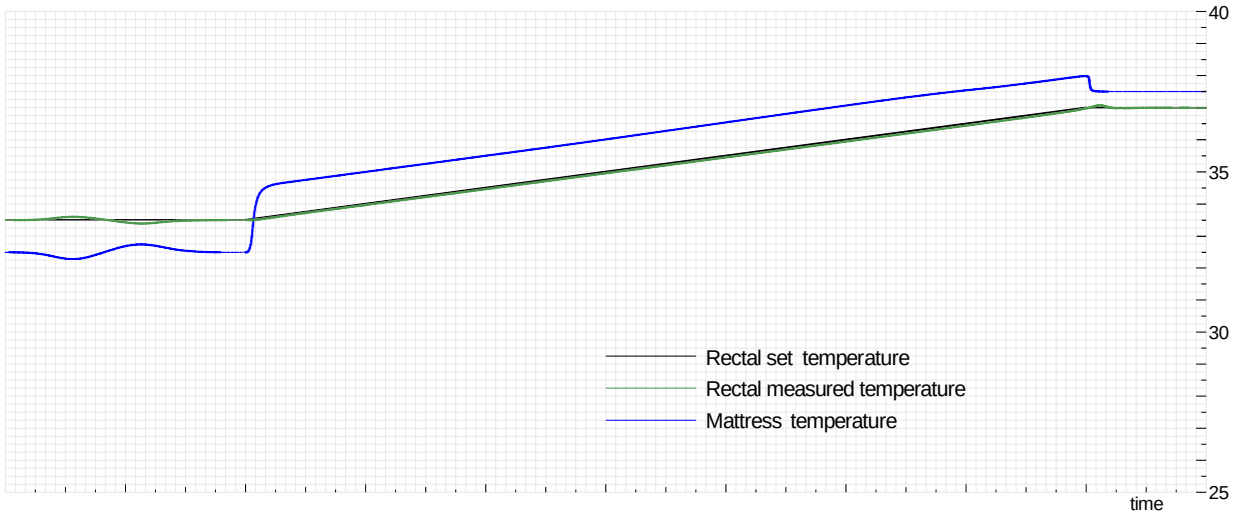
If the rectal temperature is to be either kept constant or to be adjusted to a specific value as quickly as possible, then the mattress temperature will be used as an immediate control parameter which can be reset, if required, at any time.

During the initial phase of rapid cooling down to e.g. 33.5°C the pre-defined setting for fallback mode will be a mattress temperature of 20°C. This will initially ensure that the cooling down process, once initiated, will be continued. Depending on how far the cooling down process has progressed up to this point, the temperature level of 20°C may still be too high or otherwise already too low. This needs to be assessed by the operator on the basis of an independent measurement of the patient's actual rectal temperature and the temperature will subsequently need to be adjusted accordingly. As soon as the (independently measured) rectal temperature does approach the target value of 33.5 °C additional adjustments to mattress temperature will become necessary, in order to stabilize the temperature at 33.5°C and to prevent any further cooling down of the patient.

In phases during which the rectal temperature is to be kept constant, e.g. at 33.5°C or finally at 37°C, the pre-setting for the mattress temperature will be the same as that for the rectal temperature to be maintained at a constant level. Depending on ambient

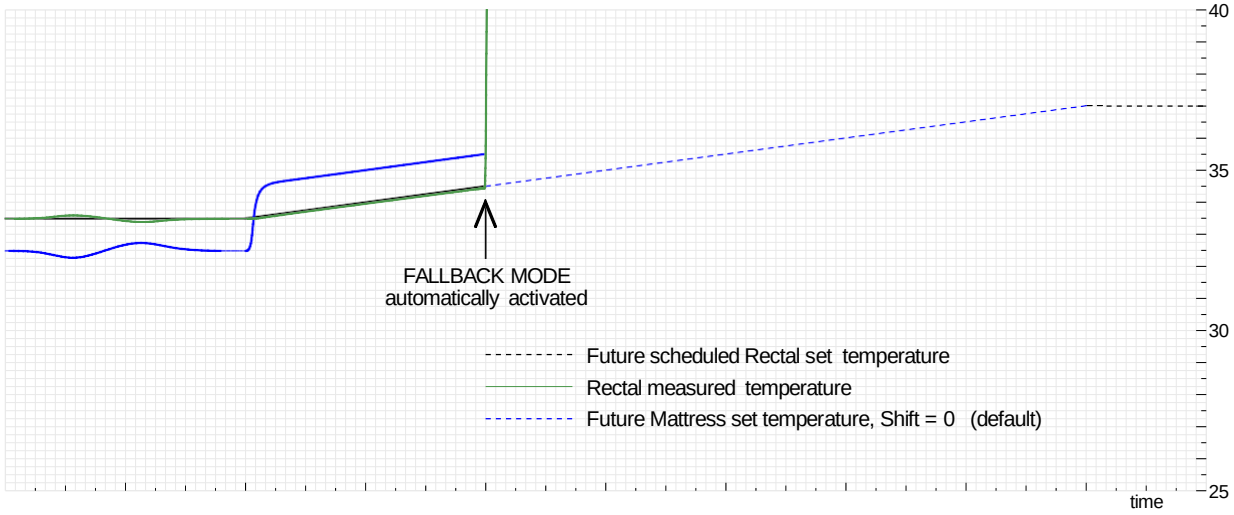
conditions as well as the patient this may be marginally too high or somewhat too low. The progression of mattress temperature up to that point, as shown in the diagram, will provide useful guidance in this respect for corrective measures to be taken. If the fallback mode continues to hold any longer, the operator will again have to assess, on the basis of independently taken readings of the patient's rectal temperature, whether the choice of mattress temperature has been correct.

Different criteria do apply during treatment phases when the rectal temperature is to be gradually adjusted at a pre-determined speed. It is known that in this case the mattress temperature will gradually change, at the same speed, albeit with a certain delay with regard to the pre-determined rectal temperature. A correspondingly accurate automatic re-warming can schematically be illustrated as follows:

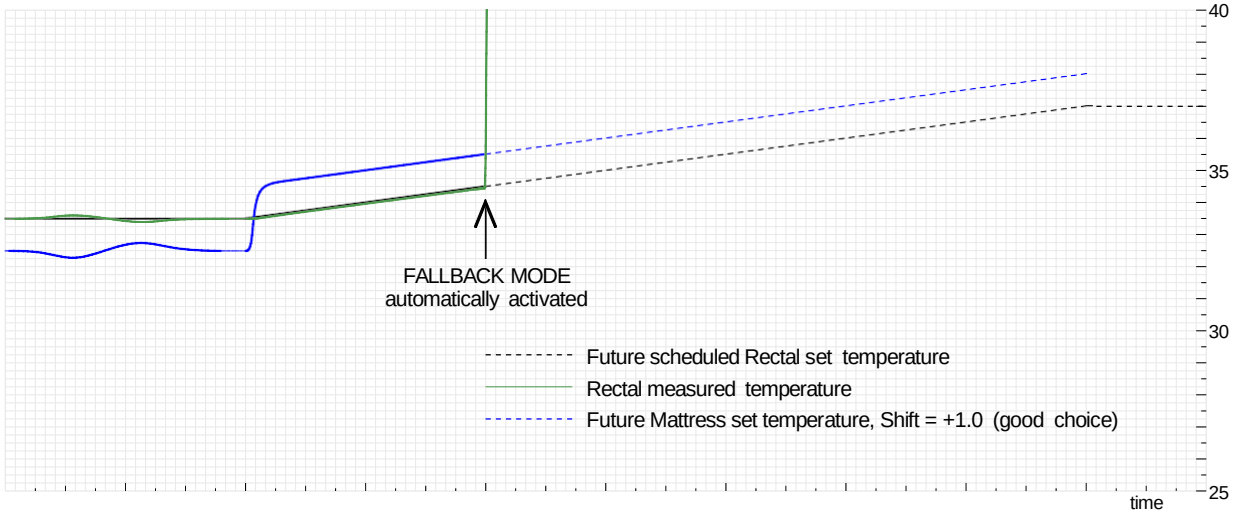


In practice, however, the mattress temperature will not always need to be exactly 1° above the rectal temperature and depending on the patient it may be even higher, as well as lower, than the rectal temperature. Certain fluctuations may also be due to interference, as indicated in the left segment of the diagram.

If the fallback mode is activated following parameters are applied: the target value for the mattress temperature will be set at the currently applicable target value for the rectal temperature. In further progression it will gradually rise at the same speed at which the rectal temperature is set to increase, as schematically shown in the following illustration:



Comparing this illustration with the preceding one it becomes apparent, that the pre-determined parameters cannot produce in the originally desired progression in rectal temperature: Mattress temperatures would systematically fall 1° short of requirements. In these cases the operator therefore is given an option to **offset** the future progression of mattress temperature by an appropriate margin (maximum up to ±3°). The following graphic illustrates how treatment would progress once the operator had interpreted the progression of mattress temperature up to that point correctly and adjusted the system accordingly to the appropriate level of **offset**:



7. TECOTHERM NEO System

TECOTHERM NEO system, components and accessories:

- TECOTHERM NEO device
- Application parts like mattresses and cooling wraps
- Temperature probes with connectors
- Extension cables for single use Temperature probes
- Hose set, thermally shielded to connect application parts to the device
- Fill-up set, includes necessary components for filling/re- filling
- Thin protective interlayer for multiple use mattresses and cooling wraps
- Electrical Power cord, up to 2,5 m

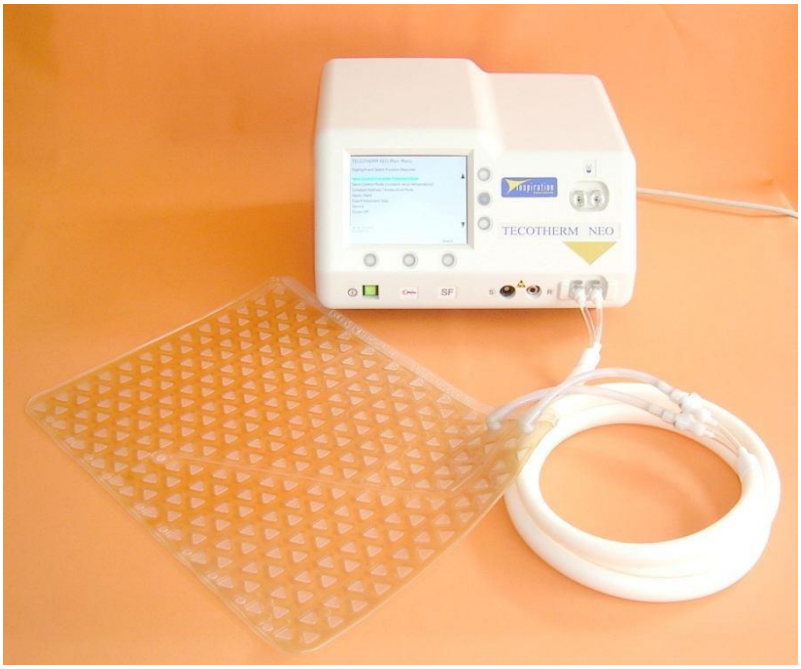
Warning: The use of accessories other than those specified in this Instruction for Use, in particular Power cord, Temperature probes and their Extension cables, may result in increased emissions or decreased immunity of the TECOTHERM NEO Hypothermia System.

Warning: Accessories specified for use with TECOTHERM NEO, especially Power cord, Temperature probes and their Extension cables, should not be used with other medical electrical equipment or systems. This may result in increased emissions or decreased immunity of the medical electrical equipment or system in question.

Optional accessories:

- Repair set for small mattress defects like punctures and flaws
- Fluid Emptying Aid for mattress
- Storage boxes

Aqua Wrap/Mattress **TC-MATT-NEO** for total body cooling of neonate and infants for Multiple Use,
Aqua Wrap/Mattress **TC-MATT-DISP** for total body cooling of neonate and infants for Single Use,
Aqua Pad Mattress **TC-MATT (L)** for total body cooling 50 x 90 cm (medium size), for Multiple Use,
Interlayer Foils **TC-FFL** separate mattresses/wraps from patient body preventing intimate direct contact with Multiple Use Application parts.



For total body cooling treatment the TECOTHERM NEO device pumps thermalizing fluid along the hydraulic lines through mattresses or wraps to lower or increase body core temperature to the set value. Operators may preselect the most appropriate treatment procedure and target temperatures.

During circulation the microcomputer of the Control Board is permanently comparing / analyzing the measured and set rectal temperatures. The larger the deviation between the two temperatures the more cooling or heating power is to be supplied by the TECOTHERM NEO device.

The circulating liquid extracts heat from or delivers heat to the patient. Circulation is monitored by the controlling system. Heating and cooling rates also are monitored by the microcomputer of the controlling system and checked for observing defined limits.

Treatment procedure temperatures for inducing hypothermia in neonate are strictly limited

- Rectal Temperature standing for BCT (lower limit / upper limit) in the treatment modes I and II — 32°C / 38°C
- Mattress temperature — 12°C / 39°C

Device internal temperature alarm limits — 10°C lower limit, 41°C upper limit

7.1 TECOTHERM NEO operating modes

TECOTHERM NEO is designed as a physiologic closed- loop control system (PCLCS) see section 6.1.

Note All parameters can be changed from set position at ANY TIME should the need arise. Select menu mode “Options” .Changes will be stored on the TECOTHERM NEO and can be seen on later analysis.

Three treatment and operation modes of TECOTHERM NEO

I Programmable Complete Treatment Mode (Servo controlled)

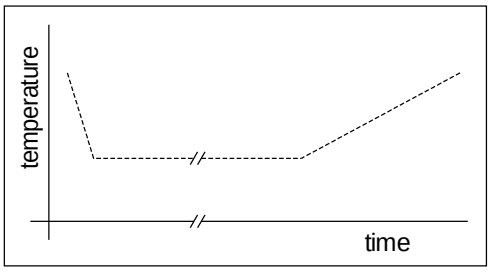
II Servo Control Mode (constant rectal temperature)

III Constant Mattress Temperature Mode

Note The operator can permanently follow the Rectal Temperature on the display screen, see section 7.3.

7.1.1 Programmable Complete Treatment Mode (Servo controlled), Treatment profiles

System is designed for inducing hypothermia in a patient by total body cooling. Details for initial operation see section 8.



Note This mode with its target temperatures and profiles is based upon the TOBY Study protocol (see reference) for inducing hypothermia in neonate suffering from Hypoxic Ischemic Encephalopathy. TOBY protocol recommends a set target rectal temperature of 33,5°C (default), then in treatment section 2 holding it constant for 72 h followed by a linear increase to 37°C over at least 7 h in treatment section 3.

Treatment mode I generally allows selecting and setting rectal temperatures within a range **32°C to 38°C**. For treatment sections 1 and 2, however, setting is limited to **32 33,5°C 35°C**. Duration of treatment section 2 can generally be set within 1 to 100 h, and in treatment section 3 between 1 and 24 h.
Temperature is accurately adjusted and finely tuned in all treatment sections.

All the pre-defined standard values of temperatures and durations as recommended by the TOBY protocol may be modified to some extent by the user prior to starting the treatment as well as later on whilst treatment is already running.

Within “Servo Control Complete Treatment Mode“ the user can set up to 9 (user-defined) **Treatment Profiles**.

When changes are made to the default temperatures or times **before the start** of treatment, the user is given an option to save this new settings as a **treatment profile**. If selecting this option, this new settings will get the next free **treatment profile** number (from 1 to 9) for identification. If the starting point for the changes was a previously generated **treatment profile**, it can be redefined instead of creating another new treatment profile.

After a treatment profile has been saved, there is available a further option to declare this profile as the **future default**. Accepting this option with "**Yes**", in the future each new call of this treatment mode will offer exactly this set of defaults. So treatment can be started immediately, without first having to make any changes.

Once the user has created at least one own treatment profile, when selecting the “Servo Control Complete Treatment Mode” in addition to the displayed temperatures and times corresponding to the profile declared as standard, the option to choose another profile will be offered. The corresponding specifications are each displayed immediately. So the user can see the temperature and time defaults the treatment would proceed with.

In the delivery state of TECOTHERM NEO system there exists just the **profile № 0** with the above mentioned standard specifications according TOBY protocol. This profile cannot be overridden, it always remains unchanged. Any changes can only be saved into a user-defined profile. If there is no more free number available (9 profiles have been created already), only profile № 9 can be redefined.

Of course, the process of creating a treatment profile can be canceled at any time. In any case, the treatment will always be performed using the temperature and time settings that are shown on the display at the time of pressing the button "**Start**".

During the treatment, temperature and time settings can be changed if necessary by pushing the "Options" button. However, these changes cannot be saved in profiles during the course of treatment. They apply only to the currently running treatment.

Necessary TECOTHERM NEO system equipment to run Programmable Complete Treatment Mode is

- TECOTHERM NEO device
- Mattress or wrap for total body cooling, filled, maybe protecting interlayer
- Rectal Temperature Probe (Skin temperature probe is optional)
- Themally shielded hoses to connect mattress to the device.

All equipment parts should be checked and prepared to start treatment, see section 8 of this IfU. Patient – neonate – should be placed onto the aqua wrap/mattress.
Rectal probe should be inserted and secured.

Operation Mode I has four (4) treatment sections / phases 1 … 4.

To start treatment follow and observe the instructions of the MENU.

Treatment section 1 Rapid Cooling- Down Phase

TECOTHERM NEO is operating to cool down as fast as possible. The system is operating with maximum cooling power. Body heat from the patient/ neonate is extracted by the cooling mattress and transferred to the circulating fluid. The central device cooling unit extracts the heat and cools the fluid on demand.
The default target set temperature in this automatic mode is 33,5°C as recommended by the TOBY protocol.
When rectally measured BCT is reaching the target temperature 33,5°C the system will reduce the cooling power automatically.
Control board microcomputer determined a sufficiently small deviation of measured and set temperature to start power reduction. Control system approaches set temperature without remarkably overshooting or undershooting.

Treatment section 2 Cooling Phase

Reaching the set temperature 33,5°C the system continues treatment to hold BCT of the patient constant. Treatment time is preselected by the operator (default 72 h). The Rectal (BCT) temperature is pre-selected (default 33,5 °C). Typically, deviations of BCT from set temperature will be $\leq$ 0,2°C.
The control board permanently compares measured rectal temperature with set BCT 33,5°C. The central cooling unit is permanently adjusting the temperature of the circulating fluid to hold BCT at 33,5°C $\pm$ 0,5 °C. If during treatment section 2 BCT of the patient is increasing / decreasing caused by disturbances the difference between measured and set rectal temperature increases.
The system initially will respond with more cooling power or increased warming.
If deviation exceeds 0,5 °C in any direction, for some longer time the internal monitoring system will detect this discrepancy. TECOTHERM NEO starts alarming.

Treatment section 3 Re- Warming Phase

After cooling phase 2 the system automatically starts the re- warming phase. If needed, this phase can be started from menu “Options” at any time before cooling phase 2 automatically ends. Re-warm target Rectal (BCT) Temperature and time to achieve this are pre-selected (Default BCT 37°C and 7 hours).
The TECOTHERM NEO system will linearly increase the BCT until selected target temperature 37°C is reached.
System then stops re- warming. BCT remains at the selected value.
In case of disturbances the system is responding as described in section 2.

Treatment section 4 (optional) Holding BCT at Normal Temperature

The operator can continue the treatment. TECOTHERM NEO will automatically continue to hold neonate at the selected BCT 37°C or at a modified temperature.
Operator can finish such treatment at any time using menu “Options”.
To continue the treatment with further warming or cooling you must leave treatment mode I and select treatment mode II or mode III.

NOTE: All parameters can be changed from set position at ANY TIME should the need arise. Changes will be stored on the TECOTHERM NEO and can be seen on later analysis.

In treatment mode I all temperatures / time dates are recorded/ logged and can be read out/ transferred to an USB stick, see section 7.3 for the USB port.

Fallback Mode

Note: Consulting section 6.2.2 is strongly recommended

- TECOTHERM NEO will perform treatment of the patient very safely as long as rectal temperature of the patient is accurately measured. If measured temperature deviates more than 1°C from the expected value TECOTHERM NEO will switch from automatic to the Fallback Mode being a **manual mode**. Now the operator has to assess BCT by choosing appropriate mattress temperature. Details see **section 6.2.2.**
- As long as fallback mode is active, BCT monitoring requires installation of another **independent accurate calibrated temperature probe** (rectal probe or bladder catheter sensor) with a separate display showing the rectal temperature.
- Substitution of the used rectal probe by a new one of the same type is a First Aid Measure. Install it into the rectum and connect it to the device front panel socket “R”. If failure cause is eliminated TECOTHERM NEO will automatically switch back to servo treatment mode I.

7.1.2 Servo Control Mode (constant rectal temperature)

In this mode system is designed for inducing hypothermia in a patient by total body cooling. Details for initial operation see section 8.

Note In treatment mode II you can select treatment temperatures in a wider range than in mode I: Target **rectal temperatures** or BCT **30° ….. 38°C.**

Treatment temperatures and durations can be defined more freely in the treatment sections. But after ending a treatment section, the reached final temperature will be maintained constant for unlimited time. Operator is requested to either continue, or to introduce a new section by changing treatment parameters (temperatures, duration), or to stop the treatment.

If a time of **0 h** (default) is selected to reach target temperature, the TECOTHERM NEO will try to reach that temperature as fast as possible. By selecting a reasonable time interval operator can define an appropriate cooling or warming rate.

Necessary TECOTHERM NEO system equipment to run treatment is

- TECOTHERM NEO device
- Mattress or wrap for total body cooling, filled, maybe protecting interlayer
- Rectal Temperature Probe
- Thermally shielded hoses to connect mattress to the device.

All equipment parts should be checked and prepared to start treatment, see section 8 of this IfU. Patient – neonate- should be placed onto the mattress/ cool wrap.
Rectal probe should be inserted and secured.

To start treatment follow the instructions of the MENU.
The TECOTHERM NEO device pumps thermalizing fluid through mattresses or wraps and back to the device. During circulation the microcomputer of the Control Board is permanently comparing/analyzing the measured and set rectal temperatures.

The larger the deviation between the two temperatures the more cooling or heating power is to be supplied by the TECOTHERM NEO device.

After having reached set rectal temperature the system automatically retains this temperature.

Treatment section 1 Rapid Cooling- Down Phase

Note that depending on initial BCT and target BCT this section may be a warming up as well. TECOTHERM NEO is operating to cool down as fast as possible. The system is operating with maximum cooling power. Body heat from the patient / neonate is extracted by the cooling mattress and transferred to the circulating fluid. The central device cooling unit extracts the heat and cools the fluid on demand.
The operator can preselect target rectal temperature within **30°C 38°C,** say 33,5°C e.g. When rectally measured BCT is reaching the target temperature system will reduce the cooling power automatically. Control board microcomputer determined a sufficiently small deviation of measured and set temperature to start power reduction.

Control system approaches set temperature without remarkably overshooting or undershooting.
Alternatively, a time interval could have been selected to reach the final temperature.

Treatment section 2 Cooling Phase

This is a constant temperature phase.
Reaching set temperature of section 1 system continues treatment to automatically hold BCT of the patient constant. It permanently compares measured rectal temperature with set BCT. The central cooling unit is permanently adjusting temperature of circulating fluid to **hold BCT at selected value**.
Operator may either finish treatment or change treatment parameters during treatment operation (MENU entry "**Modifying Treatment**".) Then Control board attempts to reach the new target temperatures as fast as possible or within the pre-defined time interval. That is, a new section 1 has been started. For example, this might be a slow re-warming within 7 hours.

Elapsed treatment times are shown in the display feature DIAGRAM.
Observing the temperature profiles the operator is able to check the temperature constancy over the treatment time. Rectal temperature is held within a temperature range ± 0,5 °C , say 33,5 °C ± 0,5 °C. Typical deviations are < 0,2°C.

NOTE TECOTHERM NEO will not alarm the end of any section. The operator must observe whether the intended time of treatment elapsed!

If during treatment section 2, BCT of the patient is increasing/decreasing caused by disturbances the difference between measured and set rectal temperature increases. The system initially will respond with more cooling power or increasing warming.
If deviation exceeds 0,5 °C in any direction, for some longer time the internal monitoring system will detect this discrepancy. TECOTHERM NEO starts alarming.

NOTE All parameters can be changed from set position at ANY TIME should the need arise. Changes will be stored on the TECOTHERM NEO and can be seen on later analysis. All temperatures / time dates are recorded / logged and can be read out / transferred to an USB stick, see section 7.3 for the USB port.

Fallback Mode

Note: Consulting section 6.2.2 is strongly recommended

- TECOTHERM NEO will perform treatment of the patient very safely as long as rectal temperature of the patient is accurately measured. If measured temperature deviates more than 1°C from the expected value TECOTHERM NEO will switch from automatic to the **Fallback Mode** being a manual mode. Now the operator has to assess BCT by choosing appropriate mattress temperature. Details section 6.2.2.
- As long as fallback mode is active BCT monitoring requires installation of another independent accurate calibrated temperature probe (rectal probe or bladder catheter sensor) with a separate display showing the rectal temperature.
- Substitution of the used rectal probe by a new one of the same type is a First Aid Measure. Install it into the rectum and connect it to the device front panel socket “R”. If failure cause is eliminated TECOTHERM NEO will automatically switch back to servo treatment mode II.

7.1.3 Constant Mattress Temperature Mode

This Treatment mode is designed for inducing hypothermia in a patient by total body cooling. Details for initial operation see section 8.

Note **Treatment Mode III** is a **non-servo controlled** mode. Rectal Temperature is no more a reference variable for automatically running the treatment.

Selectable mattress temperature range is 12°C …. 39°C. In Treatment Mode III the operator is fully responsible for performing and selecting a treatment procedure. He has to select appropriate mattress temperatures and treatment times for inducing hypothermia and re warming.

NOTE During Initial treatment phase operator should observe treatment very carefully and when needed correct / adapt treatment parameters.

Under normal conditions of heat transfer it takes about 15 minutes to warm up the mattress from 20°C to 37°C. Naturally, the core temperature of a patient being placed onto the mattress cannot follow such a high speed of temperature change.

Attention Only the **Mattress temperature** is permanently displayed on the screen in the display feature LARGE SIZE NUMBERS.
If using the TECOTHERM Rectal or Skin probes, temperatures are displayed only in the display feature DIAGRAM (as profile and in the parameter boxes). One **cannot rely** on these temperatures, however, if Mode III is used as **Fallback Mode** for a Servo Mode in case the rectal temperature measurement was in doubt.

Necessary TECOTHERM NEO system equipment to run treatment mode III is

- TECOTHERM NEO device
- Mattress or wrap for total body cooling, filled, maybe protecting interlayer
- Thermally shielded hoses to connect mattress to the device.

Attention External Temperature Probe ! 

If the internal rectal temperature measurement is in doubt, BCT monitoring requires installation of an independent accurate calibrated temperature probe (rectal probe or bladder catheter sensor) with a separate display screen showing the rectal temperature. The **screen should indicate rectal BCT clearly and visible from distance.**

All equipment parts should be checked and prepared to start treatment, see section 8 of this IfU.

Treatment Procedure

Section Cool Down Phase Start treatment following the MENU instructions. Select mattress temperature and treatment time 0 h to cool down the patient as fast as possible, or different time to cool in a definite rate.
Measured BCT being 1,0°C higher before approaching the target rectal temperature operator should enhance the mattress temperature up to 34 - 34,5°C. Depending on the rate of approaching operator may decide to select slightly higher or lower mattress temperatures to smoothly reach target value. Keep in mind that changes in mattress temperature as a rule are seen in the BCT only after 30 minutes.

In the **Cooling Phase** to hold BCT at the **Target Temperature Value** the operator should observe the BCT regularly**.** Deviations should be corrected by slightly changing mattress temperature if need arises.

After termination of Cooling Phase (say 72 hours) the operator is requested to perform the transition into **Re- warming Phase**. Following the MENU Options the operator is required to select new treatment parameters. Start re-warming cautiously rising mattress temperatures to 34- 35°C. Observing the rewarming rate, the operator must reduce / enhance mattress temperature on demand. Maximal mattress temperature is 39°C. It is possible and useful to initiate a linear rise of the mattress temperature with an appropriate rate of temperature rise.
For neonates, rewarming to normothermia should take at least 7 hours.
Keep in mind: Patient body mass may severely influence the re-warming. The larger the mass the slower the re-warming.
All temperatures / time dates are recorded / logged and can be read out / transferred to an USB stick, see section 7.3, USB port.

7.2 TECOTHERM NEO Hypothermia system Information

For the TECOTHERM NEO Hypothermia system no ESSENTIAL PERFORMANCES have been determined.

TECOTHERM NEO is a light- weight, efficient and powerful hypothermia system

Options		Cooling/Warming, Normothermia
Dimensions		375 x 190/ 215 x 310 mm (W x L x H)
Mass / Weight		7,2 kg
Operation modes	automatic	I Servo Control Complete treatment mode
	automatic	II Servo Control Constant Rectal Temperature
	manual	III Constant Mattress Temperature
Mattress temperatures for Total Body cooling		
Neonate and babies, children up to 50 kg body mass		+12 °C to + 39 °C
Temperature constancy		± 0,3 °C
Temperature accuracy		0,1 °C
Body Core Temperature control range		Mode I 32°C … 33,5°C … 38°C
		Mode II 30°C …. 38°C

Hydraulic circulation system

Fluid	Sterile Water
Reservoir capacity	approx. 250 ml
Fluid flow rate in operation	up to 300ml/ min, with mattress up to 500 ml/ min short circuited
Circulation System pressure	max. 0,5 bar
Electrical power consumption	< 350 W (mains 100-130V / 200-240V 50-60Hz)

Applied Parts

Rectal Probes	TC-FMT400/AOR-D/10 single use
	TC-FMT400/POR reusable
	TCM1837A, single use
Skin Probes	TC-FMT400/AS-D10 single use
	TC-FMT400/AS-THT reusable
Adaptor cable for disposable rectal probe	TC-FMT400/AEC-P reusable
Adaptor cable for disposable skin probe	TC-FMT-400/AEC-THT reusable
Adaptor cable for disposable rectal probe	TC989803162601, reusable
Aqua Pad TC-MATT (L)	Reusable, Manufacturer Inspiration Healthcare
Material	PUR polyurethane, transparent
Dimensions	50 x 90 cm
Volume	500 ml fluid
Mass (empty)	750 g
Cool Wrap TC-MATT-NEO	Reusable, Manufacturer Inspiration Healthcare
Material	PUR polyurethane, transparent
Dimensions	620 x 420 mm
Volume	300 - 350 ml fluid
Mass (empty)	155 g
Cool Wrap TC-MATT-DISP	Single Use, Manufacturer Inspiration Healthcare
Material	PUR polyurethane, coated
Dimensions	620 x 420 mm
Volume	300 - 350 ml fluid
Mass (empty)	220 g

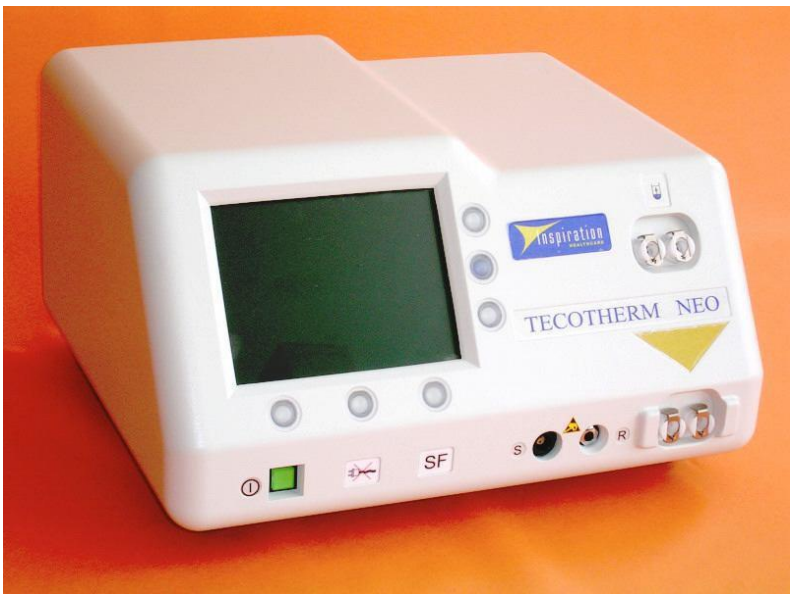
Modules and Main Components are

- Central Cooling / Warming Module
- Hydraulic Module for controlled circulation of thermalizing fluid
- Micro Computer controlled **Operating** and **Control Board**,
- MENU, user interface
- Display for visualization of MENU operations and treatment / therapy scenario.
- Alarm and monitoring system
- Temperature probes

Detailed software is implemented.

Indicators and operation key elements / buttons are clearly arranged at the front panel. Mains socket and sockets for USB are positioned at the rear side.

Figure TECOTHERM NEO Hypothermia Device



More details, see section 7.3

Central Cooling / Warming module

The Central Cooling / Warming module is a thermoelectric based unit which cools or warms the circulating fluid. This module is controlled and monitored by means of a microcomputer in the Control Board and supplied by a modern efficient switching power supply. It is fan cooled to remove heat produced by the Peltier elements.

It is operating exactly to reach the target temperatures adjusted by the operator, and hold them constant according treatment protocol.

Hydraulic Module and Circulation System

The Hydraulic Module is made of a pump, pressure valve, inner fluid container, quick disconnect couplings to connect hoses and mattresses, aqua wraps, and an internal flow meter to detect circulation flow volume. Pump is driving the thermalizing fluid to circulate through the mattresses/aqua wraps. Operation pump pressure is limited to 0.5 bar.

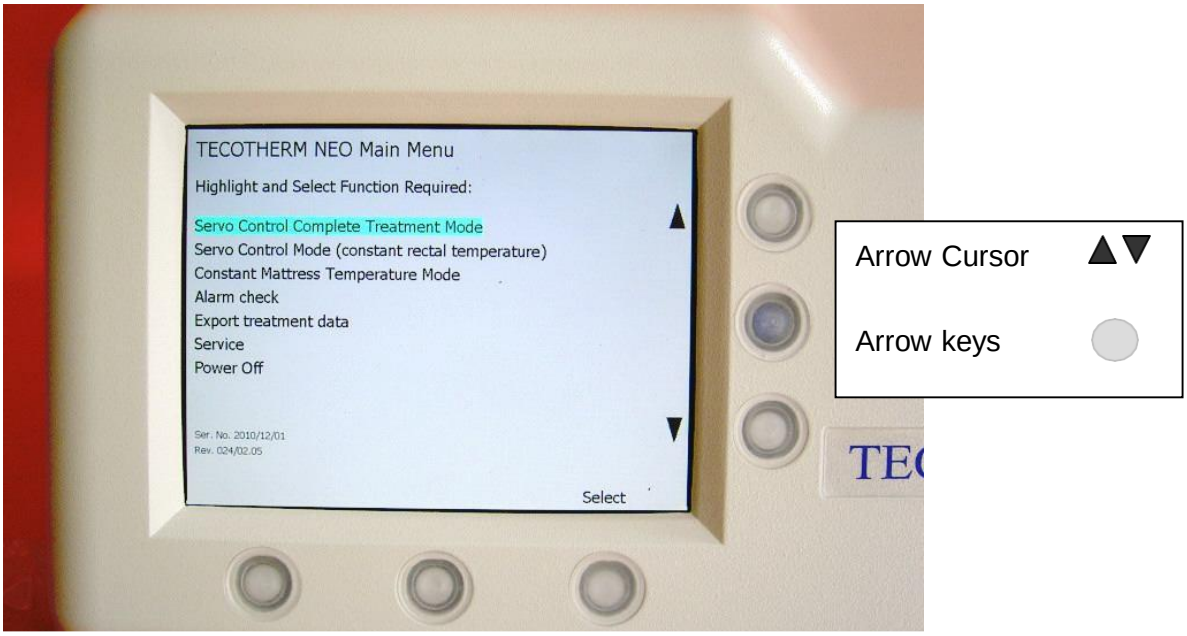
Micro Computer controlled Operating Board and Control Board, MENU

TECOTHERM NEO is furnished with an **Operating Board** and a **Control Board** to control its internal operation features. Both boards are based on their separate powerful microcomputers which are in permanent communication.
TECOTHERM NEO has three main operation and treatment modes. The operator can select operation modes using the MENU, see section 7.1.

A large display serves as **user interface** for the operator. MENU operations and treatment modes are visualized on the display screen.
The operator either selects, confirms or modifies treatment modes, treatment options, operations and settings using MENU operation **Arrow Keys** to move to MENU entries. Pushbuttons below display screen enable performing instructions like Select, Confirm, Cancel, Apply, Start etc.

Currently selectable instructions and entries are highlighted turquoise.

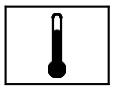
Display with MENU

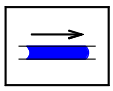


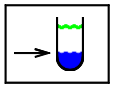
Alarm System and Monitoring Features

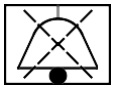
Alarm symbols shown on the display are indicating system troubles and failures

System failure. 

Temperature Alarm. 

Alarm No or restricted flow 

Low fluid level 

Audible alarm, paused 

TECOTHERM NEO is equipped with detailed alarm and monitoring elements. Main purpose is monitoring and detection of temperatures and flow of the circulating fluid, of internal temperatures in the Central Cooling/Warming module, of the temperature limits, mains power failure.
When detecting deviations from the limits and/or failures the alarm system initiates optical and audible alarms, and the above shown indicators appear on the screen.
Details on indicators see section 4.

Mains Power failure  and a certain internal system failure 

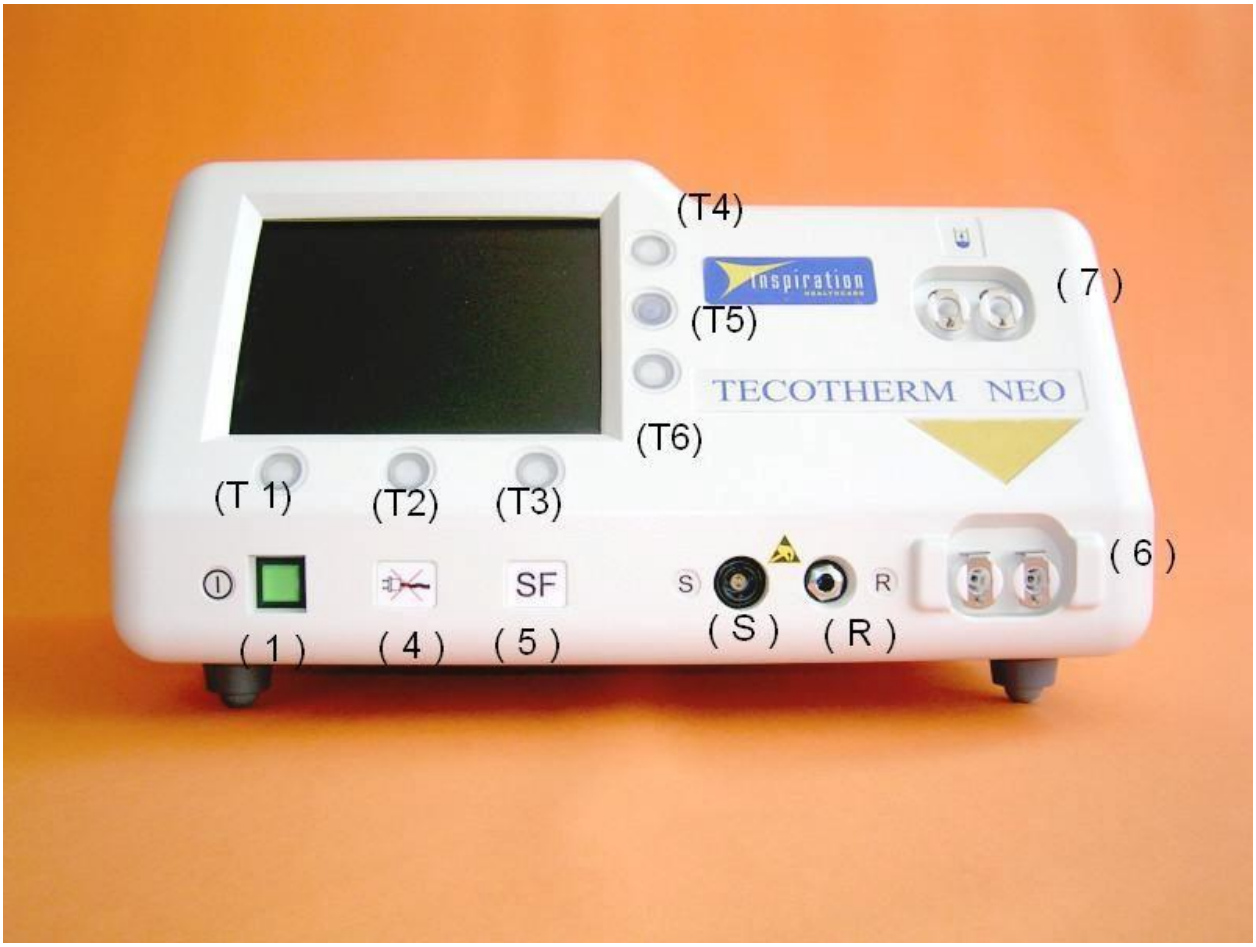
are indicated by LED indicators in the lower front panel part just below the display screen. Details see section 11 Alarm System.

Mains Cable Cord

TECOTHERM NEO is plugged via a medical grade cable cord to a shock-proofed mains socket with 100-130V or 200-240V and 50-60Hz. Cable should be 2,5 m long and approved for shock- proofed sockets only.

7.3 Indicators and Operation Key elements, Display screen

Figure TECOTHERM NEO front panel view



(1) Pushbutton to power the device on, marked **"I"**

(S) Temperature Probe Socket Skin Probe

(R) Temperature Probe Socket Rectal Probe

(4) LED Indicator **Mains Failure**

(5) LED Indicator **System Failure "SF"**

(T 1) Pushbutton for MENU operations, meaning indicated on display

(T 2) Pushbutton for MENU operations, meaning indicated on display

(T 3) Pushbutton for MENU operations, meaning indicated on display

(T 4) Pushbutton ▲ Arrow Key: menu upwards or increase value

(T 5) Pushbutton Pausing Audible Alarm

(T 6) Pushbutton ▼ Arrow Key: menu downwards or decrease value

(6) Female Coupling / socket for connecting hoses or mattresses

(7) Female Coupling / socket for connecting fill- up set for filling

Figure TECOTHERM NEO Rear side

(8) Mains Socket

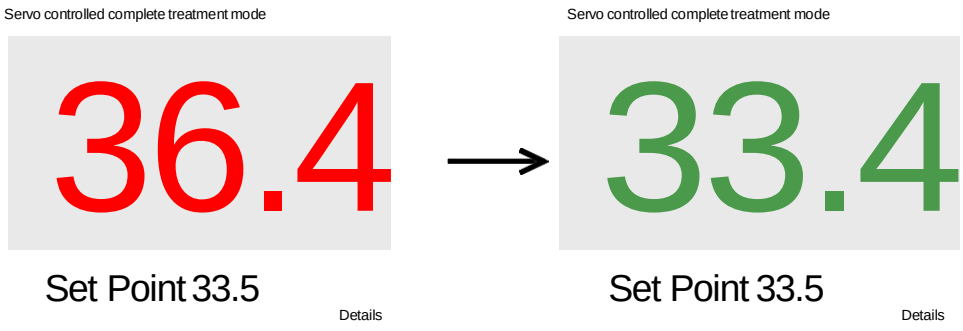
(9) USB socket

Further details see section 7.9

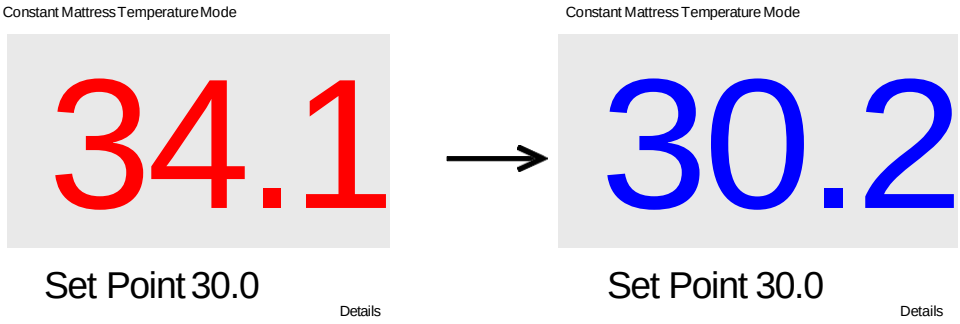
Indicating Temperatures at the Display screen
Running the 3 main treatment modes, see section 7.2, treatment temperature is shown on the screen in a large size (display feature **LARGE SIZE NUMBERS**).

Rectal temperature is displayed when selecting treatment mode I or II. **Mattress temperature** is shown when selecting treatment mode III.

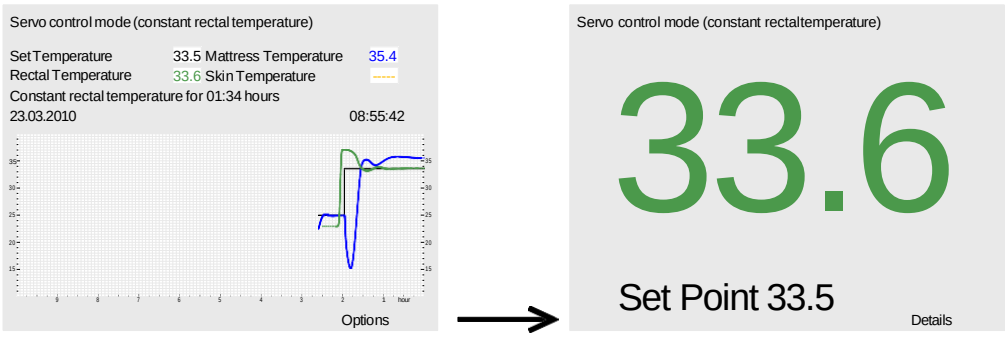
Treatment modes I and II As long as measured Rectal Temperature deviates more than 0,5 °C from the Set Point the rectal temperature is appearing **RED**.So for example if Set Point is 33,5°C a measured rectal temperature of 36,4 °C is displayed **RED**. Only when deviation is < 0,5°C colour changes to **GREEN**.



Treatment mode III As long as measured Mattress Temperature deviates more than 0,5 °C from the Set Point the mattress temperature is appearing **RED** .So for example if Set Point is 30,0°C a measured temperature of 34,1 °C is displayed **RED**. Only when deviation is < 0,5°C colour changes from **RED** to **BLUE**.



60 seconds after starting treatment in each of the main treatment modes the display feature **DIAGRAM** is changed to the feature **LARGE SIZE NUMBERS**.
Here shown for treatment mode II Servo Control Constant rectal temperature**.**



7.4 External Temperature Probes

Patient Temperatures should be measured using approved calibrated Temperature probes recommended by the manufacturer, only.

TECOTHERM NEO applies Rectal Temperature probes and a Skin temperature probe:

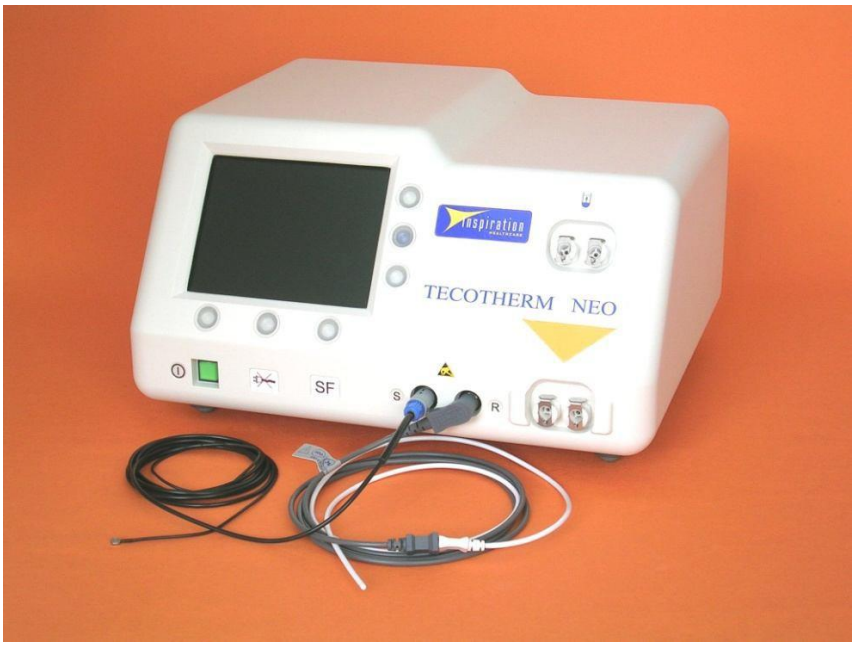
Rectal Probes	TC-FMT400/AOR-D/10 single use
	TC-FMT400/POR reusable
	TCM1837A, single use
Skin Probes	TC-FMT400/AS-D10 single use
	TC-FMT400/AS-THT reusable
Adaptor cable for disposable rectal probe	TC-FMT400/AEC-P reusable
Adaptor cable for disposable skin probe	TC-FMT-400/AEC-THT reusable
Adaptor cable for disposable rectal probe	TC989803162601, reusable

NOTE Rectal probe and Skin probe connectors have their **individually mating sockets R and S!** Ensure correct connections!

Body core temperature BCT is measured with the rectal probe. Ensure that the probe is correctly inserted in the patient and that it is properly secured. Also ensure that the probe is properly connected to the TECOTHERM NEO socket marked Ⓡ !

The second temperature probe (reference probe) is directly plugged to the TECOTHERM NEO socket Ⓢ . It serves as a means independently monitoring a second patient temperature.

Figure TECOTHERM NEO with Temperature Probes



7.5 Hoses, Hydraulic lines

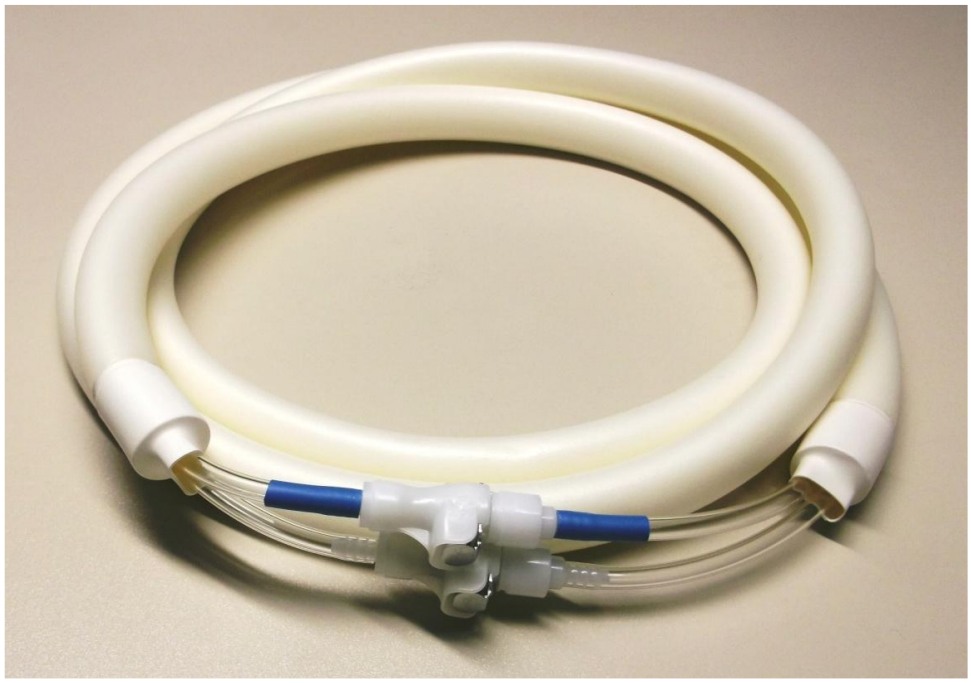
The hose set is composed of fluid tubing made of transparent polyurethane material, and a thermally shielding envelope made of silicone foam material. One of the two lines is marked blue at both ends.

Mattresses or wraps are connected to TECOTHERM NEO by means of the hoses. Hoses are connected to the device with male connectors, to the mattresses with female connectors. No need to take account of the blue marking.

Male connectors are plugged to the device ports (6), see section 7.3. and 8.3. Mattresses and other applied parts are connected to the female connectors of the hoses.

The blue marking facilitates identification of flow direction within a non-transparent mattress bearing in mind that liquid leaves the device at the left port (6).
All connectors are self- sealing quick disconnect couplings.

Figure Hoses



Standard size of hoses is **2 m.** 1m or 3 m upon request.

Special medical diagnostic checkups and applications like MRI with need of patient cooling require lack of metallic parts. In such cases mattresses are directly connected to hoses of various size and length up to 5m without using any couplings avoiding disturbing metallic springs.

NOTE Prior to order such special application contact your service partner or the manufacturer.

7.6 Fill- up set for Filling / Refilling thermalizing fluid.

Fill- up set is a 500 ml fluid container made of HD polyethylene or of polypropylene material, marked every 50 ml.

The cap has two connecting adapters made of polyurethane tubing equipped with male QDC couplings. To fill – up / refill TECOTHERM NEO device with sterile water, male connectors are plugged to ports (7) in the device front panel, section 7.3.

Figure Fill- up set

7.7 Thermalizing Fluid

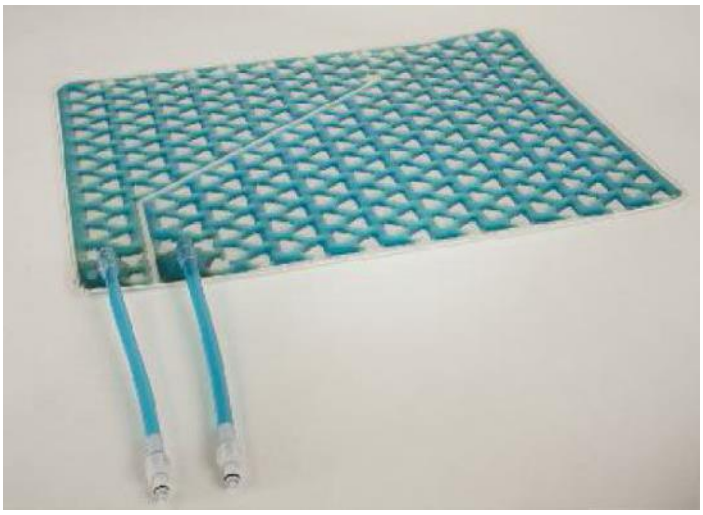
TECOTHERM NEO uses Sterilized Water as a circulating fluid to bring cold and heat to the patient. Sterilized Water can be sourced locally or supplied in 5 l containers made of HD polyethylene or of polypropylene.

7.8 Mattresses, Cool Wraps and protective layers

For transfer of cold and heat to the neonate or generally to a patient within total body treatment **cool wraps** and **mattresses** are used. All have connector parts connecting them to the hoses, see Figures.

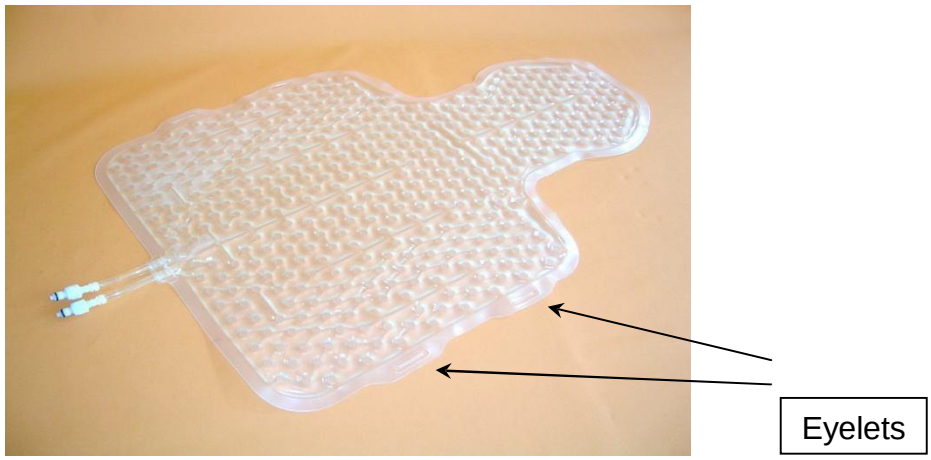
Both types are limited to working pressure ≤ 0,5 bar.

Figure Mattress Therm Aqua Pad, 50 x 90 cm, with male QDC connectors



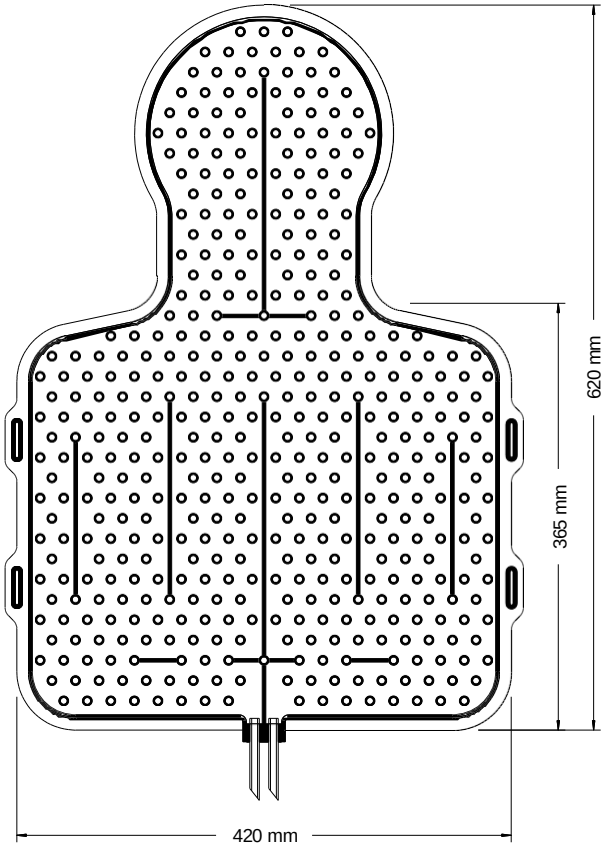
Mattresses of Therm Aqua Pad type are multi- use applied parts for total body cooling, see section 7.2 for sizes and details.

Figure Cool wrap TC-MATT-NEO/TC-MATT-DISP 42 x 62 cm with male QDC connectors



Figure

Cool Wrap TC-MATT-NEO/TC-MATT-DISP with its typical pattern structure to ensure proper flow and fluid distribution



The shown wrap is specified for Multiple Use. Details see section 7.2 for size and details. Wraps intended for Multiple Use are made of transparent PUR material.
The working pressure is limited to ≤ 0,5 bar.

For positioning TNEO cool wraps we recommend small felt fixation tapes. Tapes are fed through eyelets at right and left sides of the wrap then forming a loop. Both tape ends are knotted. The operator may select, by choosing the appropriate loop length, to what extent the neonate or patient is wrapped. For details see section 8.7.

Protecting Foil layer

Use **thin disposable interlayer** which must at least fully prevent direct contact of neonate skin with mattress or wrap intended for multiple use. Such interlayer must be coated at lower side with thin plastic coating to prevent penetration of blood, body liquids or other liquid media onto the upper surface of the mattress and to protect the patient against liquid escaping the mattress.

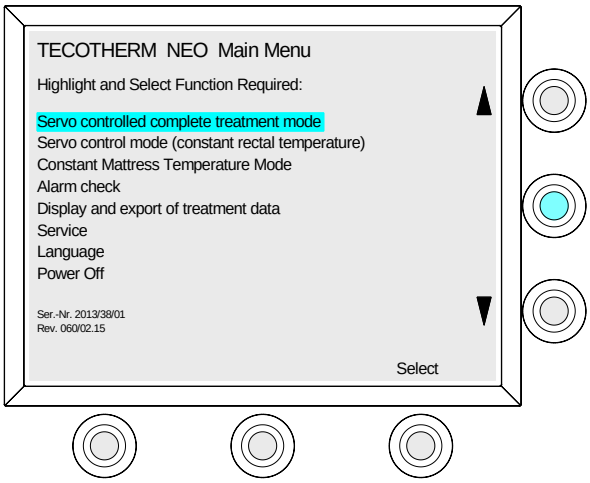
7.9 MENU and the User Interface

The operator is working within the framework of the Operator System (Operation Board).
TECOTHERM NEO provides a comfortable Men- Machine Interface: **MENU** as the **User Interface**, display screen as **Visual Interface** and **Pushbuttons /** Keys to move along the MENU instruction entries.
Display visualizes MENU operations and treatment procedures

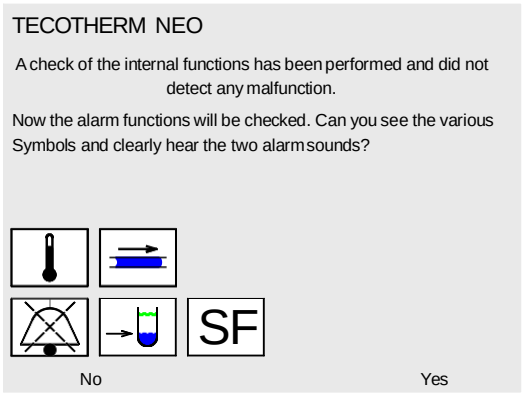
The operator either selects, confirms or modifies treatment modes, treatment options, operations and parameter settings using the **Arrow Keys** to move to MENU entries. Such active entry is coloured turquoise. Direction of movement corresponds to the arrow keys, see section 7.3.
Pushbuttons below display screen enable performing instructions like Select, Confirm, Cancel, Apply, Start etc.

TECOTHERM NEO Main MENU always serves as a Starting point for navigation. Using Main MENU the operator selects a Menu language: entry Language, see section 8.3.

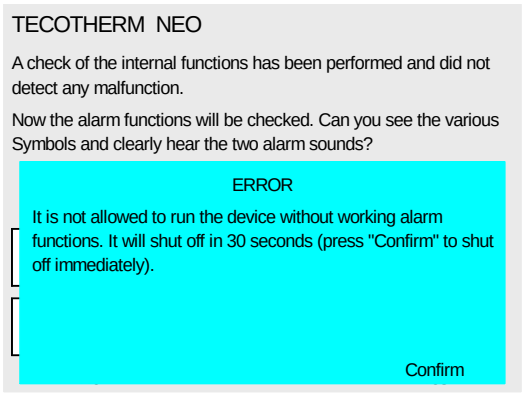
Entries at the MENU left side are accessible for the operator except entry SERVICE. Access to entry SERVICE is only for service personnel using a password.



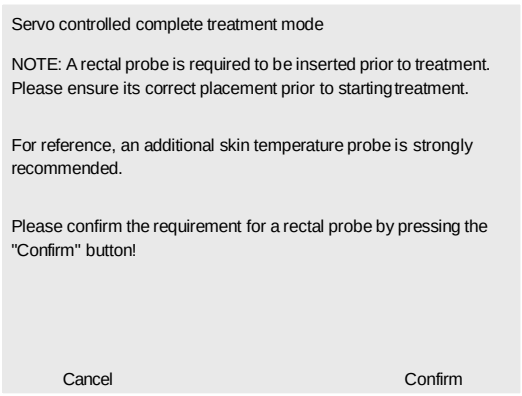
Alarms and troubles are indicated optically by ICON symbols



Important entries, instructions, notes and failures are displayed as turquoise- highlighted Pop- Up Windows



Important conditions and preconditions to perform treatments are displayed on the screen. The operator has to **Confirm** or **Cancel.**

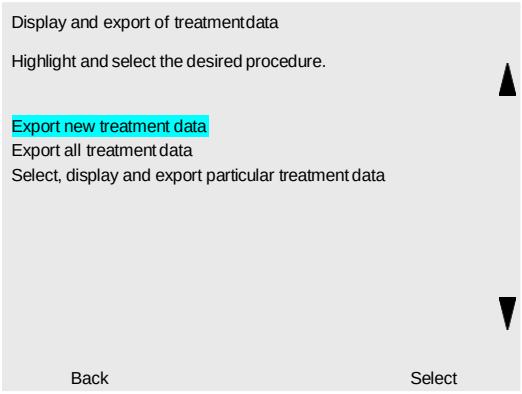


7.10 Display and export of treatment data

To read out and export treatment data and data log files select Entry **Review and export of treatment data** in the Main MENU.

This submenu offers 3 options:

- Export new treatment data
- Export all treatment data
- Select, review and export particular treatment data.



Here, "new treatment data" means all those treatments which never have been exported so far, including in any case a possibly just only finished treatment.

Option "Select, review and export particular treatment data" provides a comfortable possibility to graphically represent the complete progress of an earlier treatment identified by date and time at which it has been started. If necessary, this data can then be copied to a USB stick.

To find a specific patient record, the user must first select the year of the treatment, then the month, the day and finally the specific treatment itself. Should there be more entries than available lines, the list automatically scrolls when the last (or the first) line is reached. The function can also be used to simply display the graphics, without actually exporting the data at the end.

To perform export plug an USB stick into the USB port (9) at the rear side of the device. Then follow MENU instructions. The operator gets a message on the screen notifying the user whether or not data export was successful. After successful export unplug USB stick.

8. TECOTHERM NEO Hypothermia System Putting into Operation

8.1 Initial Set Up / Initial Operation

The manufacturer or authorized service personnel should initially set up TECOTHERM NEO system. The operators should be trained how to run the system.

8.2 Pre- operation Check up 

Caution Ensure that power cord matches the shockproof socket at site (100-130V or 200-240V, 50-60Hz).

Caution Ensure that right proper temperature probes have been prepared and prepositioned.

Caution Ensure that proper mattress / wrap and maybe interlayer foils have been prepared and prepositioned.

Pre- operation Check up 

Prior to putting the system into operation, check the **conditions of section 5** to ensure safe and proper operation:

Warning: For a reliable and safe operation use only original components and applied parts (mattresses) supplied or recommended by the manufacturer. Otherwise proper and safe operation cannot be guaranteed.

- Check that only sterile water is used as circulating fluid to avoid a risk to the neonate. Otherwise damages of device components may occur.
- Check type of mattress / wrap and maybe prescribed interlayer. Use only thin interlayers with plastic coating.
- Check whether the right temperature probe is prepared. Its connector must match the socket “R” at the device front panel
- Without rectal temperature probe plugged to port “R” it is **not possible** to start treatment modes I and II.

If all this preconditions are fulfilled device can be put into operation.

8.3 Initial Operation by the customer

If mattress is positioned into an incubator read notes in section 5.

Plug the cable cord into rear socket (8). Then plug the system to the mains into shock-proofed socket.

Fuse data see section 14, Technical Data, and type label.

Note Immediately after plugging to mains TECOTHERM NEO is in its Stand-by mode. Key (1) is lit light green.

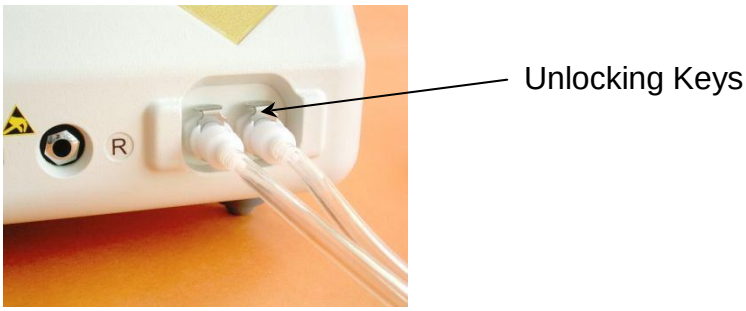
Next Step Connect mattress / cool wrap to the TECOTHERM NEO

Prior to connecting check whether

- mattress / wrap is filled completely. If empty or only partially filled, see section 8.5 for filling instructions.
- defects like punctures and flaws are existing. If fluid escapes replace or repair defect mattress / wrap.
- tubing of hoses and mattress / wrap is kinked or situation may appear to kink.

Connect QDC couplings of hoses to the QDC counterparts of the mattress. Then plug to the ports (6) at the device right lower front part, see figure. If they do not engage properly push metallic unlocking keys at the QDC, then repeat plug procedure.

Figure Connection to ports (6)



Note To unlock push metallic unlocking keys downwards.

Place completely filled mattress/ cool wrap onto a ≈ 10 - 20 mm thick plastic- foam material that has good thermal insulation, e.g. in a prepared incubator.

Note In case of Incubators see section 5.

Place a thin protective interlayer with plastics coating at the bottom downwards onto the mattress if it is of multiple use type. Protective interlayer should be somewhat larger than the mattress and fully cover the mattress with a border for wrapping the mattress.

Connecting Temperature Probes to TECOTHERM NEO device

NOTE: For treatment modes I and II a rectal probe is required.

NOTE Ensure that only calibrated probes are used!

Patient temperature measurement must be accomplished only with probes approved by the manufacturer of the TECOTHERM NEO as listed in section 7.4. Only these have been tested as required and ensure a sufficiently accurate and reliable temperature measurement even in an unfavorable electromagnetic environment. Using other temperature probes is likely to put the patient at risk!

Rectal Probes	TC-FMT400/AOR-D/10 single use
	TC-FMT400/POR reusable
	TCM1837A, single use
Skin Probes	TC-FMT400/AS-D10 single use
	TC-FMT400/AS-THT reusable
Adaptor cable for disposable rectal probe	TC-FMT400/AEC-P reusable
Adaptor cable for disposable skin probe	TC-FMT-400/AEC-THT reusable
Adaptor cable for disposable rectal probe	TC989803162601, reusable

NOTE Rectal probe and Skin probe connectors have their **individually mating sockets R and** S

If patient is already prepared for treatment:

Ensure that the rectal probe is correctly plugged to its socket “R”. Probe must be correctly inserted in the patient and properly secured.

The reusable rectal probe D- RB2A must be plugged to socket “R” directly.
Rectal probes for single use must be connected to their respective extension cables, and these in turn plugged to socket “R”.
Always insure to keep **dry** the connection between probe and extension cable!

If a skin probe is used plug it correctly to its socket “S”. Place it correctly abdominal or at the forehead and secure it.

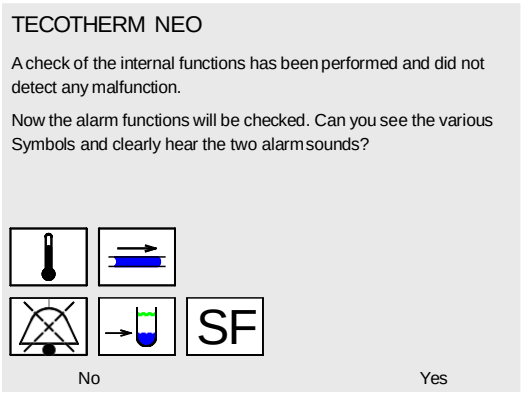
Putting TECOTHERM NEO into operation

After passing the above mentioned preparations you may put system into operation: Press Pushbutton (1). The lit key changes to intensive Green.

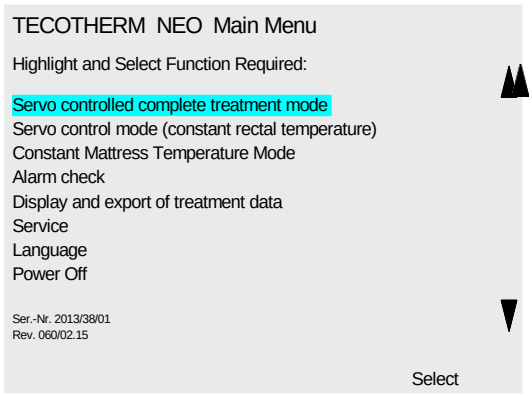
Note TECOTHERM NEO is running a self- test to check internal functions followed by a test of the alarm functions.

Display screen must be illuminated, LED indicators (4) and (5) must flash. Device is emanating an intensive BEEP, followed by a blue flash of the T5 button and intensive

double BEEP. The operator is asked to confirm **YES** by pressing key T3, that one can see the various symbols and clearly hear the two alarm sounds. Should anything be wrong, answer **NO** pressing key T1 or simply do nothing. Device will shut down.



After confirmation **YES** the TECOTHERM NEO Main MENU is displayed.



Using Main MENU and pushing arrow keys the operator can select entry Language and is led to a list of available languages (English, Deutsch, Español, …..). After selection display screen promptly shows the Main Menu in the selected language.

Pushing arrow keys T4 and T6 you may select the operation / treatment mode, see section 7.1. Selected entry is highlighted turquoise.

After selection of a treatment mode: **Follow the Instructions in the MENU**.

Adjustment of treatment parameters, treatment start

In main menu, select one of the treatment modes, details see section 7.1:

I Programmable Complete Treatment Mode (Servo controlled mode)

II Servo Control Mode (constant rectal temperature)

III Constant Mattress Temperature Mode

All treatment modes are specified by their respective menus.

The menu approach to induce hypothermia in a patient is described in detail in an example on page 53.

Note Pay attention to the entries highlighted turquoise. Entry instructions are requesting adjustment to treatment temperatures and times / durations pushing the arrow keys ▲ ▼ once or repeatedly.

Treatment options are subdivided into different phases. All details for the 3 treatment modes and their phases can be found in section 7.1.

Having selected treatment mode, having accepted default values or modified the relevant treatment parameters, and having positioned the neonate on the mattress, press button **Start**. Treatment begins. In treatment modes I and II, the measured rectal temperature must be within 29°C to 39°C. Otherwise, Start will be denied because rectal temperatures outside this range are regarded to be unacceptable (measured incorrectly).

Treatment is started

Normally TECOTHERM NEO reaches the set rectal temperature 33,5°C after 25 – 35 min (small mattress 30x 45 cm) and 30 – 35 min (cool wrap). Have in mind that cooling down rate is depending on weight of the patient and on the ambient temperature: the higher, the more time is required.

TECOTHERM NEO is programmed to reach target rectal temperature 33,5°C or any other selected temperature as soon as possible if no other rate input is chosen by the operator (time to reach final temperature > 0 h).
The operator may observe the temperature – time profile in the display feature DIAGRAM and actual temperature values in the small parameter boxes in the upper part.

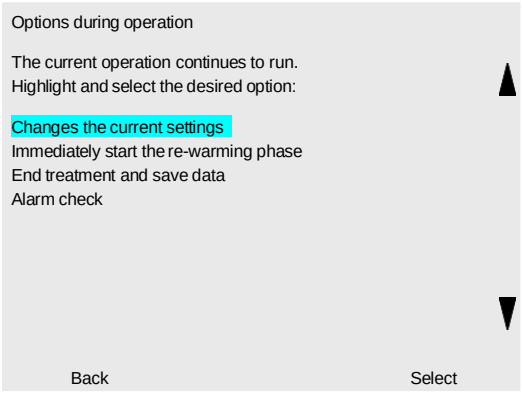
Independent on treatment mode, feature **DIAGRAM** changes after **60 seconds** automatically to feature **LARGE SIZE NUMBERS**.

Treatment is running

Treatment is executing according to and depending on selected treatment mode and applied treatment parameters. All treatment data like temperatures / time dates are automatically recorded/ logged and can be read out / transferred to an USB stick.

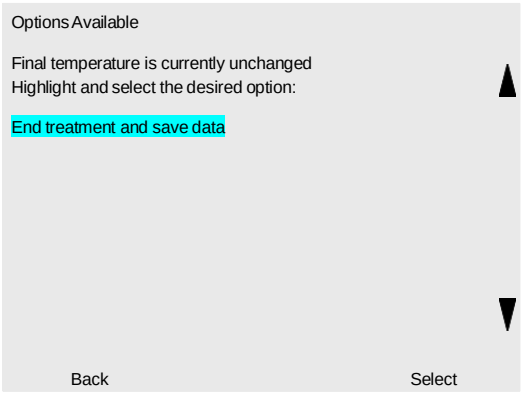
We recommend that during treatment operator should from time to time monitor patient temperatures. This is especially important during transition from cooling section 3 to re warming section 4.

NOTE: All parameters can be changed from set positions pushing key T3 Options and selecting entry Change the current settings, see below. You may go back to the original settings pushing key T1 Back.



End treatment

When treatment approaches the end the operator may continue with a treatment section 4, see section 7.1. Otherwise following the MENU instructions he is requested to select the instruction End Treatment and save data using the arrow keys.



Doing so you return to the main menu. From there, you can start another treatment, export stored treatment data or turn off the device.

Export treatment data/ Data storage

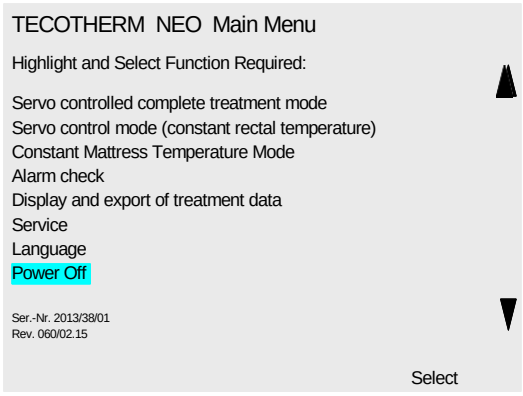
To read out and export treatment data and data log files select entry Display and export of treatment data in the Main MENU. To perform export plug an USB stick into the USB port (9) at the device rear side. Then follow MENU instructions, push Select.
The operator gets an information on the screen whether data export was successful.
After successful export unplug USB stick.

After successful export push key T3 Confirm to return to Main MENU.
It is not necessary to export new data immediately after the end of a treatment. All data are stored by the TECOTHERM NEO on a memory card with large capacity.

8.4 Stop operation / Turn off device

To stop or to interrupt operation turn back to the TECOTHERM NEO Main MENU.

Then push Arrow Key ▼ to move to entry Power off and finally push button “Select”.



After few seconds device is shut off.

NOTE Push button (1) is lit (but dimmed) as long as system is plugged to mains. Only unplugging mains cause green push button light to turn off.

Disconnection from mains: Unplug the cable cord from the mains shock-proofed socket or from the rear socket (8). Only after this the device is completely disconnected from mains!

Example How to perform hypothermia treatment in Treatment Mode III
Exemplary approach: Treatment Mode III Constant Mattress Temperature

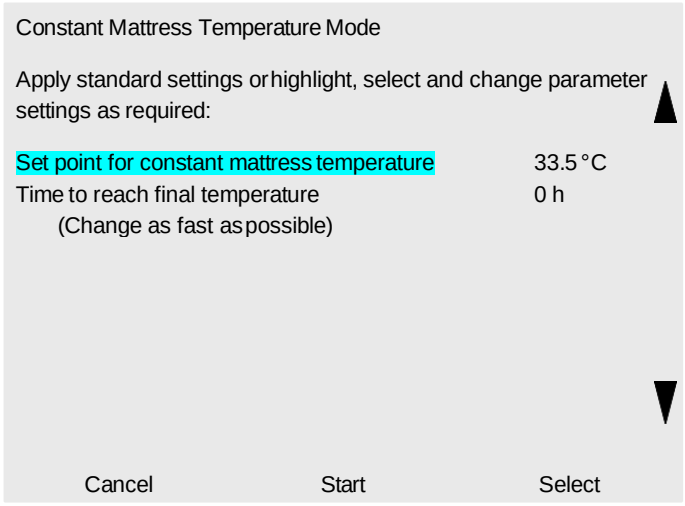
Treatment Mode III **Constant Mattress Temperature**

NOTE Selected Instruction entry is highlighted turquoise

1st Step Set Mattress temperature
→ Use key T3 **Select**

- Standard set 33,5°C displayed
  Moving to a different temperature say 28°C pushing arrow key ▼
  → 28,0 °C

Then Push Key T3 **Apply** set temperature and store it



2nd Step

Select Time to reach set final temperature

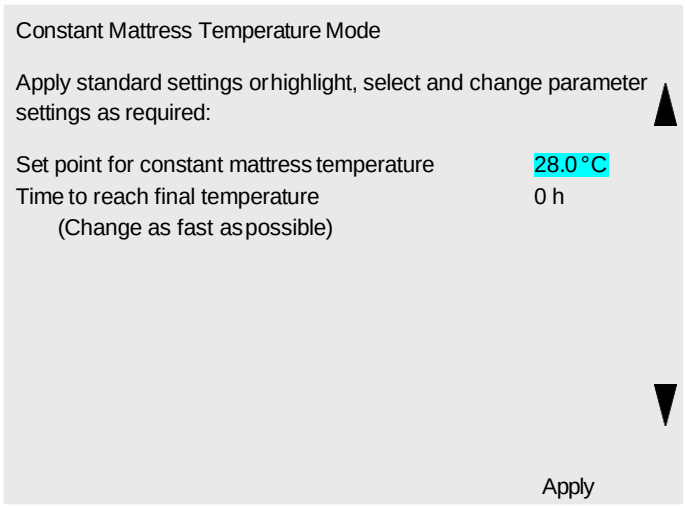
→ Use key T3 **Select**

- Standard time 0 h is displayed
- Keep this value: change as fast as possible to reach 28°C

Or adjust another time

→ pushing arrow key ▼to adjust new time, say 2 h
2 h is displayed

Then Push Key T3 **Apply** time and store it.



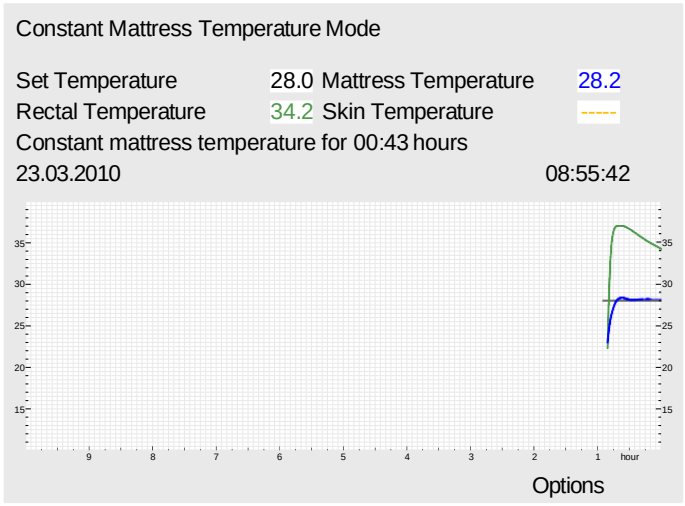
3rd Step

Instruction **Start**

→ Push key T2 **Start**

Display feature DIAGRAM with treatment parameter boxes is displayed.

Treatment starts. 60 seconds later display feature LARGE SIZE NUMBERS appears displaying current mattress temperature.



8.5 TECOTHERM NEO system: Filling / Refilling Procedures

TECOTHERM NEO's hydraulic module is equipped with an internal fluid tank of 250 ml volume containing circulating fluid. This container is prepared and prefilled by the manufacturer ready for operation.

To ensure a safe operation and a proper fluid circulation prior to each treatment fill/refill device and mattresses properly and correctly.

Attention Do not use partially filled mattress in hypothermia treatment. 

Procedures:
Preparation of fresh or empty / drained mattress:

- Check mattress for defects and damages like punctures and flaws.
- Place mattress horizontally spread onto a plane support (table).
- Connect QDC couplings of hoses to the mattress QDC counterparts. Then plug to the ports (6) at the device right lower front part, see section 8.3 of this IfU.

Preparation of fill- up set, see also section 7.6 of this IfU.

- Check fill- up set to see whether defects, damages, leaks are existing.
- Fill- up fluid bottle with sterile water up to the mark 450 ml.
- After filling close bottle cap tightly.

Filling / Refilling

- Connect QDCs of the fill-up bottle to the refill port QDC counterparts (7) at the device front face
- Put TECOTHERM NEO device into operation, see section 8 of this IfU.
- In Main MENU, select desired Treatment Mode and start operation.
- Now lift fill- up bottle and turn it until cap is directed downwards.

Attention If Flow rate alarm is appearing ignore it or push key T5 to silence audible alarm (AUDIO paused,  is appearing at the display.)

- Fill up until air bubbles inside the fill- up bottle disappear.
- Then disconnect bottle QDC from ports (7)).
- To remove residual air bubbles in the mattress via mattress tubing outlet, move and swing mattress slightly after filling operation. Air must be given the possibility to move upwards. The blue marking of the hoses helps to identify the flow direction within a non-transparent mattress.
- Re- fill the fluid bottle with sterile water and connect it again as described above. Continue filling up until air bubbles inside the fill- up bottle disappear again.
- If audible alarm is active, silence it by pushing blue button T5. Close an open Pop-Up window if activated.

Continue TECOTHERM NEO operation for 1 min. If within this time period alarm “No Flow” is appearing or reappearing follow the instructions in the display Pop- Up window. End procedure as described above. Now TECOTHERM NEO system is ready to perform the intended treatment.

Note A large mattress like Therm Aqua Pad 50 x 90 may require more than 450ml of liquid during filling / refilling process, and the fill-up bottle becomes empty. In that case fill up the bottle again and proceed as described above.

Refilling TECOTHERM NEO device during treatment

TECOTHERM NEO device is put into operation, mattress is correctly connected and treatment is properly running. During treatment symbol **Low liquid level** is appearing. Low liquid level may be caused by loss of fluid, see section 11.4.

Lack of sterile water/ low liquid level is indicated by the symbol  appearing at the screen accompanied by an audible alarm. Button T5 is lit blue.
You have to refill sterile water.

Proceed as follows

1. Push key T5 to silence audible alarm. AUDIO paused,  is appearing at the display.
2. If not prepared fill the fill- up fluid bottle with sterile water up to the upper mark **450 ml**. After filling close bottle cap tightly.
3. Turn bottle until cap is directed downwards and keep in this orientation until the whole fill-up procedure will be finished.
4. Connect QDC of the fill-up bottle to the refill port QDC counterparts (7) at the device front face.

Attention If alarm  **No Flow** appears ignore it or push button T5 again.

5. Refill until symbol  disappears, continue filling until rising air bubbles in the bottle disappear.

6. Observe liquid level in the bottle, keep it in mind.
7. Now disconnect the refill bottle from the device.

If alarm Low liquid level is reappearing repeat refilling procedure as described.

Attention Frequent or permanent appearance of the alarm indicates a malfunction or system failure. Please, follow sections 11.4 and 11.6.

Substitution of sterile water see section 13.3

8.6 Draining a used mattress

First drain liquid from the inner container:

- Disconnect hoses
- Connect the empty Re-fill bottle instead, with cap upwards
- Start mattress mode and wait until all liquid is in the bottle
- Ignore (or mute) any flow alarm or fluid level alarm
- Disconnect bottle, discard fluid and connect again as described.

Now drain liquid from the mattress:

- Connect mattress to the refill port couplings (7) at the device front face, turn mattress upwards
- Wait for about 1 minute until all the liquid is drained from the right half of the mattress
- Disconnect mattress and re-connect with connectors swapped, turn mattress upwards
- Wait for about 1 minute until all the liquid is drained from the mattress
- Disconnect mattress
- Disconnect Re-fill bottle, discard fluid.

8.7. Application of mattresses to patients

Hypothermia in neonate and infants is induced by whole body cooling. For that the following mattresses are available, see also section 7.8:

Dimensions

Cool wraps TC-MATT-NEO and TC-MATT-DISP	420 x 620 mm
Reusable Aqua Pad TC-MATT (L)	500 x 900 mm

Attention: Do not kink hose set and tubing! Do not fold mattress!
Kinking and folding will stop fluid circulation and hence cooling or warming operation of the TECOTHERM NEO system.
Alarm  **No Flow** may appear.
For further details see section 11.3, too.

Before applying to human body pay attention to the following items 

- Use only mattresses specified in accordance with the intended application to neonate and babies.
- Place protective interlayer between multiple use mattress surface and neonate skin; see below
- Mattresses must not be touched with sharp or tipped objects due to risk of puncture damage. Liquid may escape!

Attention: Avoid direct contact of mattress or cool wrap with fresh or non- closed wounds, infectious areas, areas with ulceration and abscesses, rash and burns. 

Application

Place mattress horizontally spread onto a plain support. Ensure that mattress and ports (6) are on the same level, approximately.

- Use only mattresses specified or recommended by TEC COM as the manufacturer of the TECOTHERM NEO systems, or authorized distributors.
- In case of multiple use mattresses, use a **thin** disposable protective interlayer which must at least fully cover the mattress with 5 cm larger border area all around. Such protective interlayer must be coated at lower side with plastics coating to prevent penetration of blood, liquids or liquid media onto the surface of the mattress. It also provides protection against fluid escaping from the mattress and coming in contact with the patient's skin. After use, discard protective interlayer.
- Place mattress onto a ≈ 10 - 20 mm thick thermally insulating layer (elastic foamy plastics) for ensuring good thermal insulation during hypothermia operation.

Application of mattress type Cool Wrap

TC-MATT-NEO and TC-MATT-DISP Cool wraps are designed and performed for neonate in a way to induce hypothermia more appropriately, see figure in section 7.8 and below. The size of the lower part is abt. 420x360mm. Neonate can be wrapped to an extent not disturbing other treatments or actions with the patient, diagnostics e.g.

Place cool wrap horizontally spread onto a plain support. Ensure that mattress and ports (6) are on the same level, approximately.

Place mattress onto a ≈ 10 - 20 mm thick thermally insulating layer (elastic foamy plastics) for ensuring good thermal insulation during hypothermia operation.

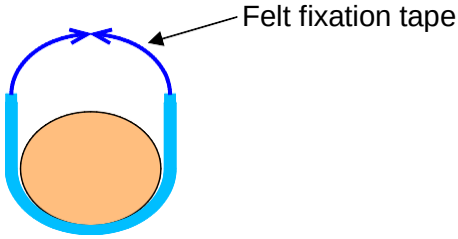
Maybe place protective interlayer onto the cool wrap mattress.

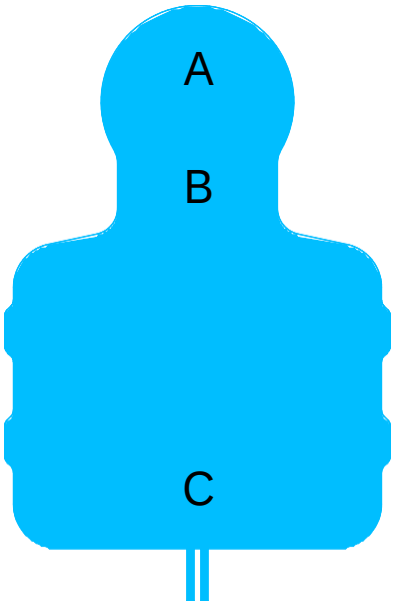
Place neonate onto A - B - C region. Place head onto **A**. Feet should be located at part **C** and body / chest along part **B.**

Place neonate in a way to allow partial wrapping around the body below axilla.

NOTE Do not touch axilla. Avoid chafing!

For positioning T NEO cool wraps use small felt fixation tapes. Tapes are fed through eyelets at right and left sides of the wrap then forming a loop. Both tape ends are knotted. The operator may select by choosing the appropriate loop length to what extent the neonate or patient is wrapped.





Wrap neonate only to an extent that free access to the patient is ensured.
Wrap creates a cool ambient around and near neonate.

9. Hygienic Requirements

We draw your attention to the following minimal hygienic requirements for the application of TECOTHERM NEO hypothermia system, procedures and components.

To meet these minimal hygienic requirements we recommend a careful disinfecting cleaning of applied parts (mattresses etc., hoses, QDC and temperature probes.)
This disinfecting cleaning may be performed by wiping with a mild liquid disinfectant appropriate for medical purposes.

9.1. Cleaning and Disinfecting TECOTHERM NEO

Attention Prior to cleaning and disinfecting switch off system

 and unplug mains!

The external cleaning and disinfecting of the device including hoses should be performed using a damp sponge or cloth both soaked with a liquid disinfectant, or a spray disinfectant in combination with a dry cloth.

Clean and disinfect device bottom side (ventilation holes) generally once every 1-2 months and just before next treatment as a part of the system preparation.

Inspect once every three months that air ventilation holes in the device bottom side are not fluff covered and free from dust. Remove fluff and dust using a small vacuum cleaner.

9.2 Mattresses, thermally insulated hoses, tubing

Some mattresses can be used multiple times and must be cleaned / disinfected. Usually such mattresses will not directly come into contact with normal skin surface due to the protective interlayer. After treatment, disinfectant cleaning of the mattress should be performed by wiping a mild liquid disinfectant appropriate for medical purposes.

Attention Do not try to sterilise mattress! 

Attention: Application of multiple use mattresses is only allowed in combination with thin fabric protective interlayer coated with plastics coating at bottom side. Such interlayer components are part of the TECOTHERM NEO accessories and can be supplied by the distributors or the manufacturer. Such protective interlayer is disposable single-use product. 

Attention: When the mattress has been in contact with blood or human secretion during treatment, it must not be used more than once! Dispose of mattress in accordance with local standards for single use items.
The same holds for hoses and couplings after such contact. 

Note Drain and replace fluid in the mattresses at least every 2 months after last filling.

9.3 Temperature Probes

Reusable Temperature Probes

Rectal and Skin Temperature Probes are delivered as autoclavable applied parts. Probes have to be disinfected and sterilised after treatment as usual in clinical practice of I C U.
For details read the Instructions for Use of the manufacturer of the temperature probes.

Disposable Temperarature Probes, Single Use

Dispose of such temperature probes after use in accordance with local standards for single use items.

The corresponding Adapter and Extension Cables, however, are reusable. After use disinfecting cleaning should be performed, see section 9.2.

Caution Keep cable connectors dry to ensure proper probe and device operation! Do not dip them into liquids!

10. Storage and Transport

10.1 Storage of the TECOTHERM NEO Device

The TECOTHERM NEO Hypothermia Equipment includes the Basic TECOTHERM NEO device unit, electrical mains cable, fill- up set and hoses. Keep all parts together. Store equipment in a closed cabinet.

Basic Unit The TECOTHERM NEO basic unit should be stored in a closed cabinet to protect it against mechanical damage and dust. Put it onto a solid board horizontally standing on feet.
Store in a dry ambient.

Mains cable Keep cable near by the basic unit. Put it into a separate plastic storage bag. Close bag.

Fill- up Set The empty set is supplied in a box or bag.
Put filled or partially filled set into the set box beside the basic unit.
Keep cap tightly closed to avoid leakage of coolant fluid. Protect QDC couplings against mechanical damage. Disinfect it prior putting back.
Store in a dry ambient.

Hoses Hoses are supplied in a closed airtight plastic envelope or a closed box.
Keep it closed until preparing TECOTHERM NEO for operation.
After use disinfect hoses and put them back into the box or the plastic envelope.
Keep hoses near by the basic unit.

10.2 Storage of mattresses

- Fresh or unused empty mattresses have to be stored in the original box or package. Storage in a dry and dark environment.
- Filled or partially filled used or unused mattresses containing fluid must be stored in a **closed** storage box in a **cool and dark** environment*).
- Drain and replace fluid after a 2 month storage period. For replacement procedure, see section 13.4. After replacing fluid, store mattress as described above.

Storage time for empty fresh mattresses in the closed storage box or envelope should be no more than 3 years.

*) The mattress material is polyurethane plastic. It is slightly permeable for water and ethanol. Fluid evaporates from the mattress surface if storage box is not closed. Fluid volume is reduced.

10.3 Transport

TECOTHERM NEO is a light- weight hypothermia system with weight 7,2 kg when the fluid reservoir is full.
Carry it to move the device over short distances or use an appropriate trolley.

When carrying do not touch or damage display screen.

11. Alarm system, malfunctions, incident management

Five (5) alarm functions are activated during operations to indicate any malfunction of the system. Alarms during operations are indicated by an **acoustic** signal and a corresponding symbol on the display. The push-button T5 will light up at the same time and may be used to switch the acoustic alarm to mute, for a period of eight (8) minutes.

Alarm functions are all of medium priority.
No patient- assigned alarms exist.

The alarm “No mains power / No system voltage” has a sound level of dB(A) 63 approximately, the other alarms of dB(A) 57, approximately.

Interruption of power supply does not influence or alter the alarm settings. They are automatically restored when power is on and alarm cause is persisting.

Assignment of alarm functions to failures and conditions:

System alarm Internal system failure.

Temperature alarm System operation temperature deviation of more than ± 0,5°C from set temperature.

No flow No or very restricted circulation of the fluid.

Fluid level low Fluid deficit in the internal fluid container.

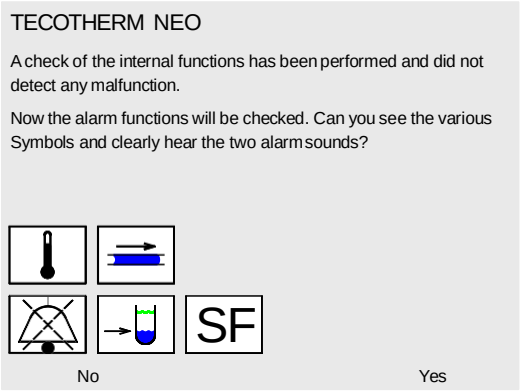
AUDIO paused.

No mains power No system voltage due to mains power failure.

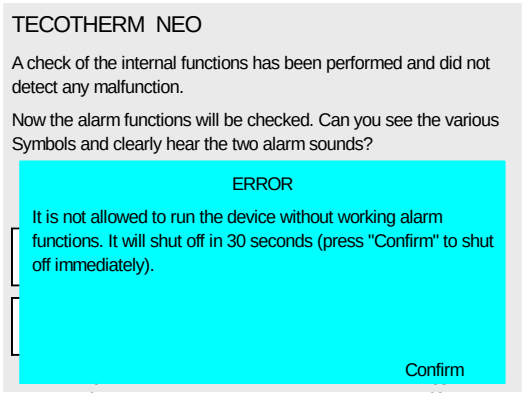
Alarm **No Mains Power** appears when device operation is stopped due to lack of electrical power. Hence this kind of alarm cannot be displayed at the display screen.
This failure is indicated optically by a separate LED lit indicator (4) at the device lower front side part, see section 7.3, and by a separate intensive audible alarm. This alarm can be silenced finally pushing key T5 AUDIO paused.

NOTE Whenever an alarm is appearing, first push key T5 to silence audible alarm (AUDIO paused,  is appearing at the display.)

After Switch On of the TECOTHERM NEO the operation readiness of the alarm system is automatically checked through self- testing.
Display screen is showing the Information

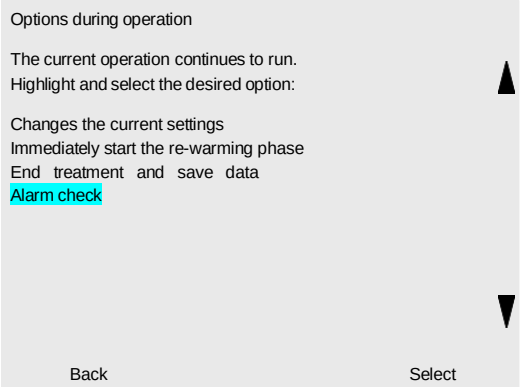


Confirm YES when you see the various symbols and clearly hear the two alarm sounds.
If not press NO. The display then shows a Pop Up window ERROR.
It is not allowed to run the device without working alarm functions. TECOTHERM NEO will shut off at after 30 seconds.



Push key T3 Confirm to immediately shut off device !

Operator can select at any time during treatment operation an Alarm Check using MENU. First push key T3 Options and than use arrow keys to highlight this function.



In some critical cases, for instance a potential disruption in normal circulation of the coolant fluid, there will be not only just the warning symbol shown on the display, but a detailed text display with instructions will be appearing first. This text field will give information concerning the nature of the fault, as well as providing instructions as to what measures need to be taken to eliminate the problem. This text field will not disappear automatically, even though the AUDIO alarm might have been silenced. It must be separately closed, using push button T3, thus allowing sufficient time for the information displayed to be read and understood by the operator.

Note: Prior to closing a Pop Up window the AUDIO alarm must be silenced, otherwise it will re-appear again and again.

In the same way, detailed information and advice is given, if the system switched back from automatic to FALLBACK MODE caused by problems with rectal temperature measurement.

11.1 System Alarm, System failure SF

System Alarm is caused by a serious internal failure.

Two (2) SF alarm features are used:

1 Symbol SF is displayed at the screen , display feature **DIAGRAM,** accompanied by acoustic alarm.

2 System alarm SF LED (5) in the lower part of the front panel. The LED pictogram is activated accompanied by acoustical alarm.

Caution System failure will not be reset automatically,

symbol SF clearly visible remains on display!

Device cannot longer be used in this error state.

We draw your attention to a very rare event

System alarm SF can be released **accidently.** Symbol is appearing at the screen.

1. Step Unplug mains connector from the device socket at rear side

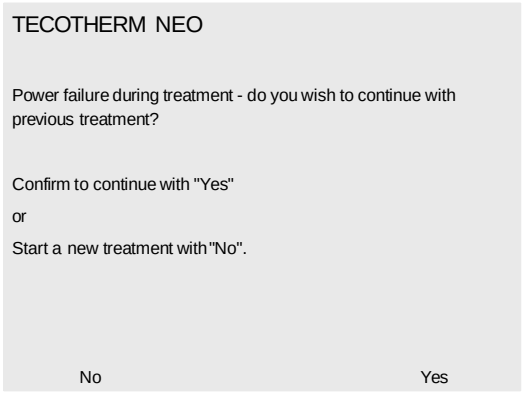
→ TECOTHERM NEO is switched **OFF.**

Wait 5 seconds. Plug mains connector back to the device socket

→ TECOTHERM NEO is switched **ON**.

If System alarm SF disappeared continue treatment.

Note: Previous treatment normally is continued after confirming **Yes** at the screen appearing when power returned:



If System alarm SF remains or is appearing again after some short time

→ **Shut off device by unplugging Mains cable**

SF Symbol **System Alarm** is displayed at the screen.

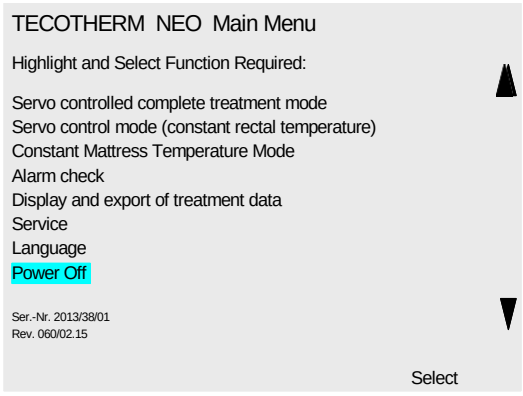
Caused by Failure in the TECOTHERM NEO system
- Defective Central Cooling Module
- Defective pump
- Temperature exceeding internal limits
- Communication problems between Operational System and Control system

Measures **Step1 has been carried out, but did not solve the problem:**

Shut off device by unplugging Mains cable

Or Push key T3 Options, end treatment and return to the Main MENU.
Pushing key T6 select Power Off and turn off device.

NOTE It is not allowed to **Turn On** the device again.



Device cannot further be used. Contact your local service provider, for assistance.

If possible Replace TECOTHERM NEO device by a replacement unit or a spare unit. Put it into operation according IfU.

SF **System Alarm** Alarm feature 2

SF LED (5) in the lower part of the front panel is activated.

In case a serious communication error between Operational Board and subordinated Control Board emerged, after 10 seconds the Control Board creates an acoustic alarm, and SF LED (5) is lit. System continues operating with the set parameters unless operator is silencing audible alarm pushing key T5 **AUDIO paused.** Then, another 10 seconds later the Control Board will **switch off** the device.

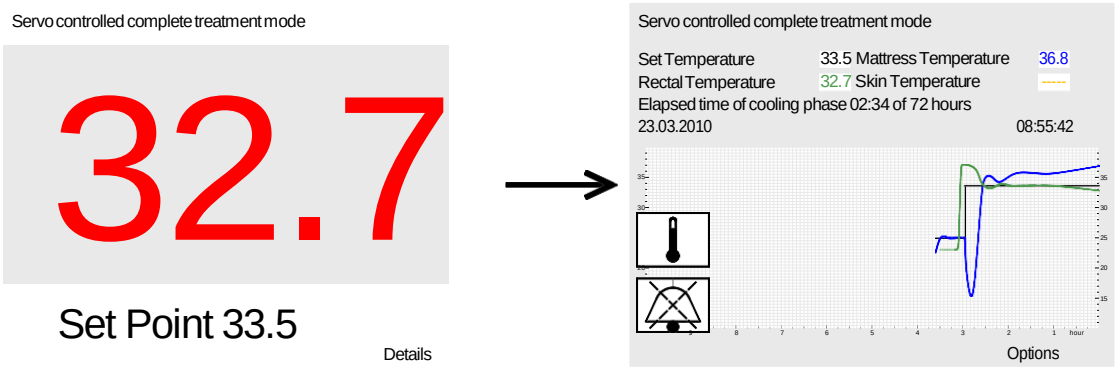
The operator can now analyse the situation and make an attempt to restore device operation by turning it **ON** again.

In any case subsequently contact your service partner.

11.2 Temperature alarm

Temperature alarm

The display changes from Temperature indication LARGE NUMBER to DIAGRAM feature indicating the alarm symbol. Audible alarm also appears.



Current Rectal Temperature → Temperature alarm, alarm paused

Caused by Rectal Temperature probe disconnected from the device or sensor break
Rectal Temperature probe is detached from patient
System operation temperature deviates more than ± 0,5°C from set rectal temperature
Mattress temperature incorrectly measured
Fan cooling insufficient
Power of Central Cooling Module insufficient.

NOTE When alarm is appearing push key T5 to silence audible

 alarm (AUDIO paused,  is appearing at the display.)

There are now **8 minutes** to resolve the problem.

Elimination/ Management

Attention **Check immediately** whether Rectal Temperature probe is correctly connected to the device and correctly positioned and secured in the patient.

The operator should check and analyse the temperature profiles in the DIAGRAMM feature. Look at first the temperatures in the upper part of the display and check whether indicated temperatures are corresponding to the treatment section temperature settings and are plausible and make sense.

In all following cases 1 - 5 If possible replace TECOTHERM NEO device with a replacement unit or a spare unit. Put new system into operation following IfU.

Case 1 There is no indication of patient rectal temperature, in the DIAGRAM feature

Device immediately switches to **FALLBACK MODE**, and first a decision on the future progression of the mattress temperature is required, see section 6.2.

Measure Check whether Rectal Temperature Probe is plugged correctly to the socket **R.** If not plug connector tightly.

If cause is eliminated, rectal temperature reappears in the information box. Observe display until measured rectal temperature approaches the set rectal temperature.

If no success probe may have a sensor break or is electrically short circuited.

In this event, replace rectal probe with a prescribed rectal temperature probe correctly in the rectum of the patient, secure it. Plug the probe into socket **R** . Observe temperature indicator at the display.

If still no temperature indication appears repeat procedure with another new rectal probe. If this still fails, turn off the device, see section 8.4.

Contact and inform your local service.

Case 2 All temperatures are indicated. Rectal temperature deviates more than 0,5°C from the set rectal temperature.

Note In treatment sections 2 Cooling phase and 3 Re- warming phase a maximum deviation of +/- 0,5°C is allowed (alarm limit).

Example Indicated rectal temperature is lower than set rectal temperature 33,5°C.

Measure Check whether rectal probe is placed in its correct position or slipped out completely or partially. The more it is slipped out the lower is the detected and indicated temperature (approaching ambient temperature).
If slipped out place probe into correct position and secure it.

Example Indicated rectal temperature is higher than set rectal temperature 33,5°C.

Measure Cooling capacity of the device may be reduced.
System is fan cooled. May be free flow of air is restricted.
Check whether device is placed onto a soft layer or pillow or the like, which restricts free flow of air from the bottom side.
If so place device onto a plane solid support.
Check whether distances to surrounding walls are at least 15 cm!

Case 3 Check Mattress temperature indication

If mattress temperature is not indicated in the DIAGRAM feature the Control board cannot regulate to hold rectal temperature constant.

Measure Push key T3 Options, stop treatment. In Main MENU select entry Power Off using arrow keys and then push T3 Select. Device is shut down.
Do not switch on the device again! Contact your local service.

Case 4 Check ambient conditions

Check whether ambient temperature is too high exceeding 27°C. This can be caused by an external heat or infra- red radiation source, within or near the incubator.
Remove causes as appropriate.
Observe rectal temperature. It should reach the set temperature after some time.
If measured rectal temperature more and more deviates from the set rectal temperature the device is defective. Push key T3 Options, stop treatment. In Main MENU select entry Power Off using arrow keys and then push T3 Select. Device is shut down.
Do not switch on the device again! Contact your local service.

If possible replace TECOTHERM NEO device by a replacement unit or a spare unit. Put new system into operation following IfU.

Case 5 External heat sources below mattress

Check whether a warming mattress like electrically heated mattresses in incubators is placed below the mattress.
Remove causes as appropriate.

Observe rectal temperature. It should reach the set temperature after some time.
If measured rectal temperature more and more deviates from the set rectal temperature the device is defective. Push key T3 Options, stop treatment. In Main MENU select entry Power Off using arrow keys and then push T3 Select. Device is shut down.
Do not switch on the device again! Contact your local service.

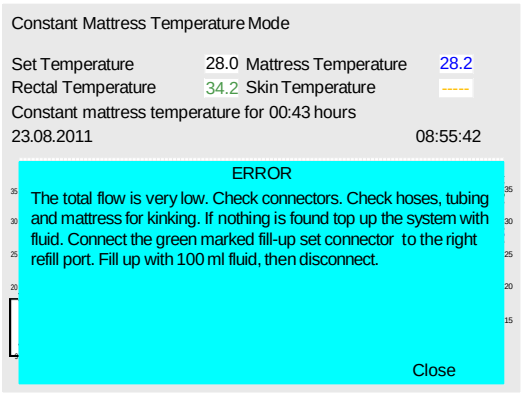
If possible replace TECOTHERM NEO device by a replacement unit or a spare unit. Put new system into operation following IfU.

11.3 Flow rate alarm

Flow rate alarm Insufficient circulation of fluid.

Maintenance of the treatment temperature is no longer guaranteed. An acoustic alarm will sound and a Pop-Up window will inform the operator what actions need to be taken in order to restore normal circulation.

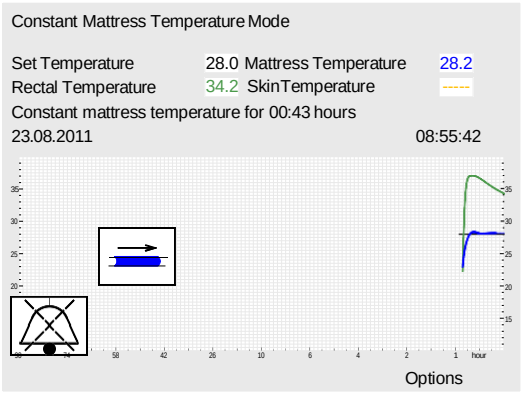
Example:



Caution: We recommend to first pause the acoustic alarm

 by pressing the lit up push button T5.

Please study the instructions for the correction of errors carefully and then close the text display window. The diagram will reappear and the icons will remind you that although the acoustic alarm has been switched to mute the error still remains:



You now have **a period of 8** minutes to deal with the problem, following which the acoustic alarm will be activated again. Although the acoustic alarm can be switched again to mute, the problem nevertheless remains and needs to be resolved. As long as this state of alarm does exist the unit is no longer able to regulate the patient's temperature in the required manner!

No or very limited circulation / flow of the fluid

Alarm indicates that for more than 10 seconds mattress gets too little fluid, or flow is very low due to some blocking, or there is somewhat too little fluid in the mattress.

Possible causes may be

1 Pump is not working or with insufficient power
2 Kinking of hose set and / or tubing near mattress; mattress folded; couplings disconnected.
3 Flow blocked, small blocking obstacles in the couplings or tubing.
4 Lack of circulating fluid (slight deficit)

There are now **8 minutes** to resolve the problem.

Elimination/ Management

Case 1 Pump is defective / not working

System alarm SF is additionally appearing at the screen. Proceed as described in section 11.1: Stop treatment, shut off the device.

Push key T3 Options, stop treatment. In Main MENU select entry Power Off using arrow keys and then push T3 Select. Device is shut down.
Do not switch on the device again!

If possible replace TECOTHERM NEO device by a replacement unit or a spare unit. Put new system into operation following IfU.

Contact your local service provider for inspection of the defective device.

Case 2 and 3 Inspection for kinking or blocking.

If you observe any kinking of tubing or folding of mattress, eliminate it.
Disconnect all couplings and re-connect them.
Reverse flow direction in hoses and mattress by interchanging the 2 male couplings of hoses in ports (6).
Replace hoses if indications of flow blocking are found.

If problems remain contact and inform your local service provider.

Case 4 Volume of circulating liquid slightly too little

Lack of fluid is rather small, **Low Fluid Level** alarm will not yet be activated. Adding sterile water will restore circulation.
Proceed as follows (see for details section 8.5):

Plug connectors of the fill-up bottle to the refill port QDC counterparts (7) at the device front face. Lift fill- up bottle and turn it until cap is directed downwards. Observe liquid level in the refill container. After adding approximately **100 ml** disconnect connectors. Observe whether symbol **No Flow** disappears.

Should the problem persist, stop treatment and contact your local service provider for assistance.

If possible: Replace TECOTHERM NEO device by a replacement unit
or a spare unit. Start treatment according IfU.

11.4 Alarm: Fluid level low see section 11.6, too

Alarm fluid level too low: Little or no fluid in the container.

NOTE When alarm is appearing push key T5 to silence audible alarm (AUDIO paused,  is appearing at the display.)

This alarm indicates a lack of fluid inside the inner container. There are now **8 minutes** to resolve the problem, until AUDIO alarm will re-appear.

Attention Check immediately whether liquid is escaping or was escaping from the device.
Check immediately whether a leakage is in the mattress or hoses.

If a big leak or fluid volume is seen below or near the device **immediately shut off** the device. Contact your local service provider.

Possible causes for this alarm are

1 Leakage in the TECOTHERM NEO device / Hydraulic Module.
2 Lack of fluid caused by leakage in hoses, at couplings or in mattress.
3 Slow loss of fluid caused by evaporation through mattress surface.

Elimination / Management

If leakage or / and indication of escaped liquid / traces of liquid in your immediate inspection were not found refill the system. For refilling sterile water follow the procedure of section 8.5.
Continue treatment following Main MENU instructions.

If alarm persists and symbol is not disappearing a more systematic troubleshooting is required.

Case 1 Check / inspection of the device

Inspect the support area below the device, device bottom and lower casing parts for traces and indications of escaping liquid / moisture.

If you find a substantial or medium leak: Immediately Shut Off the device following the instructions in the Main MENU. **Unplug mains.** Contact your local service.

If you find only a small leak contact your local service provider for assistance how to proceed.

Case 2 Check / inspection of mattresses and hoses

Inspect the mattress, hoses, couplings for traces and indications of liquid / moisture.
If you do not find a leakage that could explain the loss of fluid proceed as follows:

Refill Sterile water liquid in accordance with section 8.5.

Symbol  must vanish. Observe the display screen.

Once alarm disappeared, start a systematic inspection and search for leakage. If leakage is small and no spare components are at hand, try to provisionally seal the leak as to finish patient treatment:

Close the small leak by means of an adhesive tape or appropriate plasters (non-permeable). After finishing the treatment, replace the defective part or repair the mattress using the repair kit. Mattress must be empty and dry.

You can either stop treatment or temporarily continue until the problem is finally resolved. Contact your local service.

If there is a big leakage, replace this defective component immediately.

Note: If the **alarm repeatedly appears**, check mattress, hoses, connectors and tubing once again to detect if and where fluid escapes permanently. In such cases, see instructions here in this section 11.4 and 11.6.

After finishing the treatment, replace the defective mattress or repair it using the repair kit. For this, mattress must be empty and dry.

Attention After refilling, the TECOTHERM NEO is ready for use.
Usually the added fluid has a different temperature than the system fluid.
Temperature alarm as described in section 11.2 may appear.

We recommend to push key T5 to silence audible alarm (AUDIO paused,  is appearing at the display.)

Within a few minutes the system will reach the set operation temperature, alarm symbols will disappear.

11.5 Alarm: No Mains Power

No system voltage, mains power failure
Accompanying audible alarm with higher sound intensity.

Device operation is stopped, display is dark.
This failure is indicated optically by a separate LED lit indicator (4) at the device lower front side part, see section 7.3, and by a separate intensive continuous audible alarm.
The alarm can be silenced pushing key T5 AUDIO paused.

Caused by No supply from the mains.
Accidental shut off of the system.
Disconnected mains cable.
Blown fuses.
Internal defect in the TECOTHERM NEO device.

Elimination/ Management

Check whether key (1) is lit slightly green. If not lit TECOTHERM NEO is disconnected from mains grid.
If **only** the TECOTHERM NEO device is shut off (and **no other equipment in the room**) check that cable cord is tightly plugged to the mains socket and to the device rear socket. If unplugged, plug it tightly.

Fuses

Check fuses. Fuses are located in a small compartment of the device socket. Unplug mains cable and pull- out the small fuse compartment. Replace the defective fuses. Fuse types and ratings are indicated on the device rear plate / type label and in the Technical Specification at the end of these Instructions for Use.

Note If fuse blowing again appears stop operation. Contact your local service.

Internal defect in the TECOTHERM NEO device

If the Switching Power Supply SPS fails or the SPS is not supplying the internal operating voltages 5 VDC and 24 VDC, TECOTHERM NEO will stop operation. Display is not operating (dark). LED Indicator (4) is activated and lit up brightly green, audible alarm of higher sound intensity is generated.
The alarm can be silenced pushing key T5 AUDIO paused.

To continue treatment is impossible. Contact your local service provider!

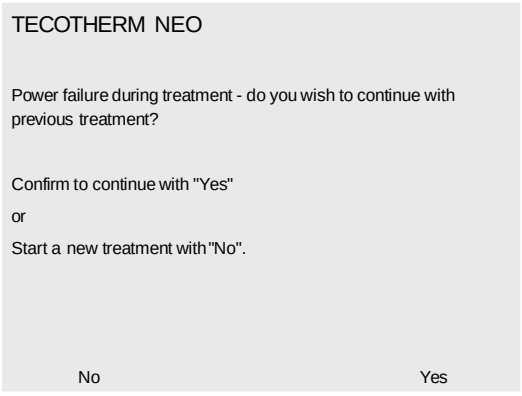
If possible: Replace TECOTHERM NEO device by a replacement unit or a spare unit. Put new system into operation / start operation following individual Instruction for Use.

Loss of mains power.

For the moment there is nothing to do. Device will continue the interrupted treatment as soon as power returns.

TECOTHERM NEO is designed to continue operation in the previous treatment mode when mains voltage reappears. If the interruption period was **shorter than 60 minutes** the previous system configuration will be restored and treatment continued.

The operator is asked wheter to continue the interrupted treatment or not, see MENU screen picture below. If yes, the log files created before the power loss will be continued, too.



If you wish to continue the interrupted treatment, confirm YES . Otherwise, to start a new treatment push key T1 NO . With NO you enter the Main MENU, where you can shut down the device as well.

11.5 Fluid escapes from the TECOTHERM NEO System

Also see section 11.4 of this IfU.

Attention Large amount of fluid is observed escaping from the system.

Possibly alarm **Low Fluid Level**  is appearing because of leakage.

Attention Skin contact with the fluid is harmless.
But do not swallow or ingest fluid!

Case 1 Large amount of fluid escapes from the TECOTHERM NEO device

Management Stop operation by unplugging mains. Do not touch device before!

Caused by Suddenly appearing internal leak in the circulation system.
Fluid is escaping from inside the unit due to defect or leaking parts or components.
Splashes and wetness at, near or below the device.

If possible: Replace TECOTHERM NEO device by a replacement unit or a spare unit.
Put new system into operation following this IfU
Contact your local service provider.

Case 2 Fluid escapes from the mattress or hoses

Management: Stop operation by unplugging mains.

Caused by Suddenly appearing defect or leak in the mattress, along hoses or in coupling connections.
Wetness in the close vicinity of the patient is possible.

Try to localize the defect or leak.
If you find the defect: Replace defective component. Small leaks may be provisionally seald as to finish treatment, by means of an adhesive tape or appropriate plasters, see also section 11.4.

NOTE Possibly you have to refill fluid, see section 8.5.

After replacement or repair, re-connect TECOTHERM NEO device to the mains. It will automatically resume the treatment with the same settings as before unplugging, see section 11.5.
Contact your local service provider.

12. Training & Qualification of personnel

Hypothermia treatment of patients requires skilled personnel.

Operators must ensure they have been adequately trained on treatment operations with the TECOTHERM NEO system for inducing systemic hypothermia within Intended Use.

They should know how to manage unusual situations, and deal with problems and malfunctions in treatment operations for inducing systemic hypothermia with the TECOTHERM NEO system.

Sales partners offer training courses and provide information on necessary software updates. They also inform on modernizations and technical improvements.

For more information contact your authorized service provider, see section 2 and 15.

13. Service, preventive maintenance, Software Update

13.1 Service & Maintenance

To ensure and maintain a safe and proper long-term operation of the TECOTHERM NEO equipment regular system inspection by an authorized service provider is necessary. The inspection has to be done in compliance with current local legal rules and regulations.

The manufacturer recommends system check and calibration at least every 12 months. A check of the basic electrical safety must be carried out and documented annually.

Preventive maintenance measures

TECOTHERM NEO hypothermia system requires only few regular service and maintenance measures.
To sustain its operating readiness and reliable use we recommend some preventive activities as follows:

13.2 Cleaning the ventilation hole structure (device bottom)

NOTE Inspection of the bottom ventilation holes should be made every 1-2 months. Dust and flues may cover the holes and reduce cooling capacity. To remove dust and flues, use a small vacuum cleaner if necessary.

We recommend hygienic cleaning of the bottom every 1-2 months. This disinfecting cleaning may be performed by wiping with a mild liquid disinfectant appropriate for medical purposes.

13.3 Substitution of Sterile Water in the device

The sterile water fluid circulating in the TECOTHERM NEO system should be substituted, and the system cleansed every 2 months. It is recommended to perform the cleansing procedure using a Chlorine Dioxide tablet, which is available from Inspiration Healthcare Limited.

The cleansing procedure is as follows:

 **Wear disposable gloves and discard them after completing this procedure.**

Note: A Chlorine Dioxide tablet 1.5 – 4ppm (1.5 – 4mg/L) is required for this process. This tablet can be sourced locally or from Inspiration Healthcare.

First drain the liquid from the inner container:

- Disconnect hoses
- Connect the empty Re-fill bottle instead, with cap upwards
- Start mattress mode and wait until all liquid is in the bottle
- Ignore (or mute) any flow alarm or fluid level alarm
- Stop mattress mode
- Disconnect bottle, discard fluid into a sink

Secondly, prepare the cleansing solution:

- Pour 450 ml of sterile water into the Re-fill bottle
- Add one Chlorine Dioxide tablet 1.5 – 4ppm (1.5 – 4mg/L)
- Close bottle cap tightly
- Wait until tablet is dissolved completely
- This may take half an hour, shaking the bottle will speed up the process

Thirdly, fill up the cleansing solution: (**Immediately after the tablet is dissolved**)

- Connect hoses with mattress to the device
- Connect the fill-up bottle to the refill ports at the device front face
- Turn bottle until cap is directed downwards and keep in this orientation
- Start mattress mode and wait until most of the liquid is transferred into the device and rising air bubbles in the fill-up bottle disappear completely
- Disconnect bottle, discard rest of fluid into a sink
- Let the cleansing solution circulate for 10 minutes
- Stop mattress mode

After that, drain the cleansing solution from the inner container just as described above.

Finally, fill up the system with fresh sterile water:

- Connect hoses with mattress to the device
- Pour in 450 ml of sterile water into the Re-fill bottle
- Connect the fill-up bottle to the refill ports at the front of the device
- Turn bottle until cap is directed downwards and keep in this orientation
- Start mattress mode and wait until most of the liquid is transferred into the device and rising air bubbles in the fill-up bottle disappear completely
- Disconnect bottle
- Let the sterile water circulate for 5 minutes
- Stop mattress mode

Now, the device can be used for another patient or stored up to 2 months.

13.4 Substitution of Sterile Water in mattresses and cool wraps

Mattresses and Cool Wraps completely or partially filled and stored for a longer time should be subject to sterile water substitution every 2 months.
Details see sections 8.5 and 8.6.

13.5 Check / calibration of temperature probes

We recommend checking and calibration of the reusable temperature probes within every 2 years, in accordance with Technical Specification / Manual of the temperature probe manufacturer.

To ensure proper operation and intended use of the TECOTHERM NEO system,
use only probes authorized by the manufacturer TEC COM GmbH or Inspiration Healthcare Limited.

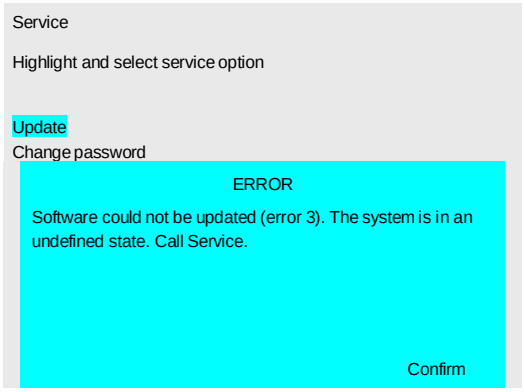
If other temperature probes are used, a correct temperature measurement is not guaranteed. Likely this would put the patient at significant risk!

13.6 Software Update

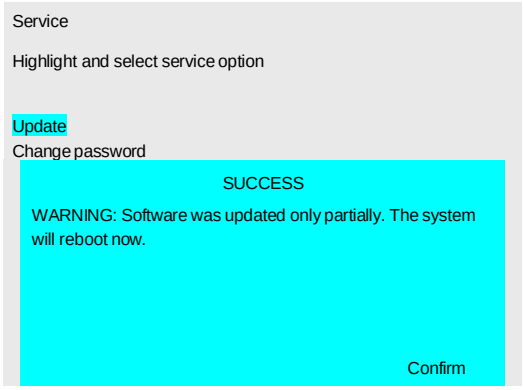
Ensure that the TECOTHERM NEO applies latest software versions.
Customers will be informed on software updates by the manufacturer and / or authorised service provider.

Normally software Update is done by service personnel.

Error in the up date process is indicated at the display screen of the MENU in a Pop Up window highlighted turquoise, see below.
If possible, additional instructions will be displayed how to further proceed.



Sometimes there may be an only partial update. TECOTHERM NEO system then will reboot. This is not an error, but only an information that it was intended to update only some components of the software, not all.



If necessary customer should consult the TECOTHERM NEO manufacturer TEC COM GmbH or Authorized Service Representative for assistance and support.

14. Technical Data / TECOTHERM NEO Specification

Options	Cooling & Warming
Dimensions	375 x 190 / 215 x 310 mm (W x H x D)
Weight without accessories	approx. 7,2 kg
Central Cooling Module	Thermoelectrically based module
Treatment temperature control ranges	Mattress + 12°C to + 39°C Rectal BCT + 30°C to + 38°C
Patient weight max.	≤ 50 kg
Control Systems	
Control System	1. Microcomputer: hardware control
Operating System	2. Microcomputer: MENU system
MainTreatment Modes automatically	Servo Control Complete Treatment
automatically	Servo Control Constant Rectal Temperature
manually	Constant Mattress Temperature
Temperature Constancy	± 0,3 °C
Hydraulic Circulation System	
System pressure max.	0,5 bar
Flow rate without / with mattress	500 ml / min (shorted) / up to 300 in use
Internal Fluid reservoir capacity	approx. 250 ml
Circulating Fluid	Sterile Water
Connectors / Couplings	Quick Disconnect Couplings
Fill Up / Refill	Fill Up Set
Electrical Parameters	
Supply Voltage / Mains	100-130V and 200-240V, 50-60 Hz
Power consumption	max. 350 W
Fuses (2 pieces)	5x20mm, 250VAC, slow, high breaking capacity at 100-130V: S 4A H, at 200-240V: S 2,5A H
Earth Leakage Current	< 400 µA
Mains Power Cord	2,5 m with hospital grade plug
Patient Safety / Alarms	
Lower Temperature alarm limit	+ 10°C
Upper Temperature alarm limit	+ 41°C
Set Temperatures, lower limit	+ 12°C
Set Temperatures, upper limit	+ 39°C
Alarm System, 5 Channels, Blink LED	optical and audible alarms
Alarm No Mains	Sound pressure level approx. 63 dB(A)
Alarm System Failure	Sound pressure level approx. 57 dB(A)
Alarm No or restricted flow	Sound pressure level approx. 57 dB(A)
Alarm Low fluid level	Sound pressure level approx. 57 dB(A)
Alarm Temperature deviation	Sound pressure level approx. 57 dB(A)
Ambient conditions	
Operation / Treatment A m b i e n t Temperatures	+ 5 °C to + 27 °C
Operation / Treatment Relative Humidity	10% to 75%, not condensating
System safety	
Protection class	Class 1, Risk Class II b, Type BF
Standards	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
Certificate	CE 0494

IP-20

Device of **Class I** for use with shockproof mains sockets
Class of risk IIb acc. ann. IX of Medical Device Directive 93/42/EEC.
Type BF applied parts

15. CE Declaration of Conformity

Manufacturer: TEC COM GmbH
Address: Am Krümmling 1
D-06184 Kabelsketal, Germany

The manufacturer, using a Production Quality Management System certified according EN ISO 13485:2012 + AC:2012 (ISO 13485:2003 + Cor 1:2009) herewith declares that each actual device **TECOTHERM NEO** complies to the requirements of

Medical Device Directive	93/42/EEC
Safety, general	EN 60601-1: 2007
Electromagnetic Compatibility	EN 60601-1-2: 2007
Usability	EN 60601-1-6: 06.2008
Alarm systems	EN 60601-1-8: 09.2008
Physiologic closed loop systems PCLS	EN 60601-1-10:2008
Safety of mattresses etc	EN 60601-2-35: 2009:10 E/F
Restriction of Hazardous Substances Directive	2011/65/EU

The general requirements of Medical Device Directive 93/42/ EEC are fulfilled acc.
ann. I Essential Requirements
ann. III EC type examination.

Device Code UMDNS: 12-068. In accordance with MDD 93/42/EEC (as amended), Annex IX, Rule 9, the device is Class IIb.

Each device is produced in full compliance with the technical documentation underlying the EC type examination procedures.

Place, date Kabelsketal, November 2015

Signature 

Manufacturer

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Gesellschaft für Technik,
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E Mail: info@inspiration-healthcare.co.uk

16. Disposal

This device must **not** be disposed of as common industrial or household waste. It **must** be delivered to a local regular collecting point, to a waste disposal company or returned to the distributor or the manufacturer.

17. EMC guidance for TECOTHERM NEO

Guidance and manufacturer's declaration – electromagnetic emissions		
The TECOTHERM NEO is intended for use in the electromagnetic environment specified below. The customer or the user of the TECOTHERM NEO should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The TECOTHERM NEO uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The TECOTHERM NEO is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The TECOTHERM NEO is intended for use in the electromagnetic environment specified below. The customer or the user of the TECOTHERM NEO should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance -**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply line Not applicable, because not present.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for ½ cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec	< 5 % U_T (> 95 % dip in U_T) for ½ cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TECOTHERM NEO requires continued operation during power mains interruptions, it is recommended that the TECOTHERM NEO be powered from a non- interruptible power supply or a battery.
Power frequency (50 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The TECOTHERM NEO is intended for use in the electromagnetic environment specified below. The customer or the user of the TECOTHERM NEO should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance -**
			Portable and mobile RF communications equipment should be used no closer to any part of the TECOTHERM NEO, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1{,}2\ \sqrt{P}$
			$d = 1{,}2\ \sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 2{,}3\ \sqrt{P}$ 800 MHz to 2,5 GHz
			where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strength from fixed RF transmitters as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location the TECOTHERM NEO is used exceeds the applicable RF compliance level above, the TECOTHERM NEO should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as re-orienting or relocating TECOTHERM NEO. b Over the frequency range 150 kHz to 80 MHz field strength should be less than 3 V/m..			

Note on Radiated RF: Interference field strength more than 3 V/m may affect the "Rectal Temperature control" by causing erroneous Rectal Temperature measurements. However, TECOTHERM NEO is safe up to 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the TECOTHERM NEO

The TECOTHERM NEO is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Customer or user of the TECOTHERM NEO can help to prevent electromagnetic interference by maintaining at least minimum distance between portable and mobile RF communications equipment (transmitters) and TECOTHERM NEO as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2 \sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2,3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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