TECOTHERM NEO

MEDICAL EQUIPMENT for HYPOTHERMIA of NEONATE and INFANTS

Instructions for Use

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Abbreviations

IfU	Instruction for Use
BCT	Body Core Temperature
SF	System Failure

2. Preface

2.1 Intended Use

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

The Hypothermia System TECOTHERM NEO is designed for controlled comfortable cold & heat treatment procedures. By means of mattresses or cool wraps cold and heat is applied to the total body, body parts or 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 Desription and technical data.

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

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

We highly recommend that the operator is familiar with the operation modes and capabilities of the TECOTHERM NEO. Prior to putting into operation carefully read these IfU!

This IfU is associated with a software version. The valid version number is displayed at the lower left part of operator's MENU display screen after switching on the device.

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.

2.2 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 abcesses, rash and burns.

2.3 Requirements: Operators Profile

Operating a TECOTHERM NEO requires

- Healthcare Professional experienced in using life support and life sustaining equipment
- Personnel must be trained in the use of the TECOTHERM NEO before operating the device.

3. Informations 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 representives will instruct and introduce the operation personnel prior putting the equipment into operation

Information, technical support, additional manuals may be requested from any authorized distribution partner.

Manufacturer TEC COM GmbH
Gesellschaft für Technik, Technologie und Vermarktung
Böllberger Weg 170
D-06128 Halle/Saale
Germany

Type label

4. Short Description of the Equipment

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

Another application designed for controlled hypothermia treatment is Total Body Treatment of Children up to body mass of 50 kg.

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 physiologically safe water- based 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 when exceeding or falling below temperature limits are Essential Performances of TECOTHERM NEO.

TECOTHERM NEO is electronically divided into a **Operational System** and a **Controlling System.** Both sub systems are micro computer (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 Main Menu: 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) and
- skin probe for measuring skin abdominal or forehead temperature etc

The three treatment modes are

(1) SERVO CONTROL Programmable Complete Treatment Mode

(2) SERVO CONTROL Constant Rectal Temperature Mode

(3) Constant Mattress Temperature Mode

The Operator selects the treatment mode 1, 2 or 3 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.

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.

5. Symbols, Indications

Important Information 

Attention, Caution, Warning 

Electrical Hazard ! 

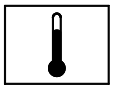
Applied Part Type BF 

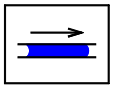
Rectal Temperature Sensor socket 

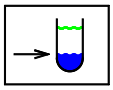
Skin Temperature Sensor socket 

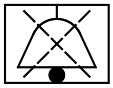
Key “Turn On” 

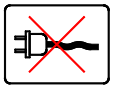
System failure. 

Temperature Alarm 

Alarm No or restricted Flow. 

Alarm Low fluid level. 

Symbol AUDIO paused 

No Mains Power 

Internal System Failure 

6. Warnings, Precaution guidelines

- **Warnings**
- 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 230 VAC/ 50 Hz or 110 VAC/ 60 Hz. Use only cord supplied with the device or a medical grade approved equivalent cord not longer than 2,5 m.
- Repair and maintenance are restricted to authorised personnel only!
- For a reliable and safe operation use only original components, applied parts and spare parts supplied or recommended by the manufacturer.
- Only TECOmed (or approved substitute) should be used as circulating fluid.
- 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 Rectal and Skin Temperature Probes are correctly placed in / on the patient and that probes are properly secured. Also ensure that probes properly connected to the TECOTHERM NEO socket marked "**R**" (Rectal for Body Core Temperature) and "**S**" (Skin for Surface Temperature).

  The same holds for bladder temperature probes measuring children's BCT. Use probes with the correct mating connector to the "**R**" socket.

Caution

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 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 in the Technical Description and Service & Maintenance Manual.

- Portable and mobile RF communication equipment can affect medical electrical equipment. Observe the recommended separation distances listed in the Technical Description.
- The TECOTHERM NEO device should be subject to regular maintenance and service, see section 13
- Fill and replace fluid regularly every 3 months, see section 8.5.
- Only TECOmed (or approved substitute) should be used.
- 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 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 unit must be placed horizontally onto a level 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.
- Do not place the device into small cabinet compartment or onto small scale boards. Do not cover the device!
- 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.
- 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 and leave 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.
- Check type of mattress and interlayer. Use **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/ cool 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 or the like.
- 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/ animally 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 TECOmed is made of 70 % water, 30% pure Ethyl alcohol. Very small quantity < 0,3 % denaturing agent Methyl- Ethyl- Ketone MEK is added. Details see Safety Data Sheet.

- Caution Do not swallow or ingest fluid.
- Skin contact with TECOmed fluid is harmless.
- Note After use close TECOmed containers tightly

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.)
- 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 of a big 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

  strong electromagnetic radiation

  ultraviolet radiation

  intense infrared radiation

  mechanical shocks, vibrations.

- Do not intensively illuminate the device.

•

NOTE Information and Advice for operators

Users and Operators should intensively read the I f U to become familiar with all instructions and technical details

To acquaint operators and users with instructions and measures to handle alarms and situations under single fault conditions is important.

Operator is requested to become mentally familiar with the treatment equipment as a physiological closed- loop control system PCLCS *) , see section **7.**

Note for operators and users To be familiar with instructions and measures to handle alarms and situations under single fault conditions is important.

Note for operators and users When placing the TECOTHERM NEO device positions and motions of patient, operators and other personnel have to be taken into consideration. Circumstances and situations near TECOTHERM NEO site before, during and after treatment have to be considered.

Note for operators Consider possible mechanical means for positioning, supporting or erecting the patient during treatment. They may block or reduce fluid circulation

We recommend that operator should independently monitor patient temperatures during treatment.

*) PCLCS and Mental Model

To develop an imagination on cause and effect in TECOTHERM NEO treatment mode 1, Section III, a realistic single fault condition scenario is assumed: **Rectal Temperature Sensor is slipped out the patient's rectum**.

The probe now detects a much lower temperature measuring ambient air temperature near the neonate rectum. This temperature shown at the display screen strongly deviates from the BCT 33,5 °C (cause). To reduce the deviation TECOTHERM NEO is increasing the fluid / the mattress temperature (effect): the Control Board responds with activation of warming to increase the " pretended BCT, appearently to low ".
After 5 minute period the device indicates temperature alarm. Display is showing confusing temperature data: Low rectal temperature, normal skin temperature, high mattress temperature. But a mentally prepared operator decide to immediately inspect and check the position of the rectal probe.

7. TECOTHERM NEO Hypothermia System

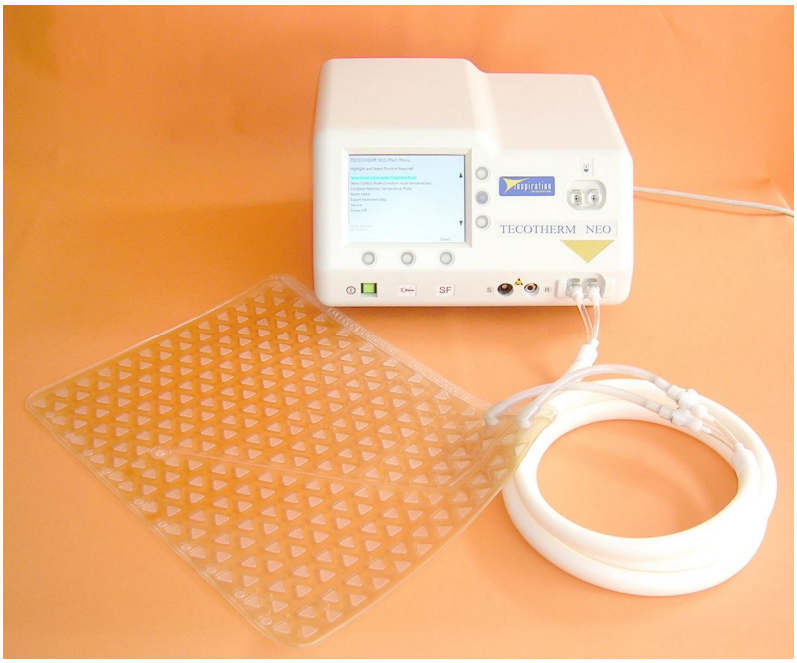
7.1 Description of the System

TECOTHERM NEO Hypothermia system, system components and accessories

- TECOTHERM NEO device
- Application parts like mattresses, cooling wraps, cooling pads
- Temperature probes with connectors to the device
- Hose set, thermally shielded to connect application parts to the device
- Fill-up set, includes necessary components for filling/ re- filling TECOmed
- 5 litre **TECOmed** fluid, canned in PE or PP container
- Thin protective interlayer
- Electrical Power cord, up to 2,5 m

Optional

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



Cooling wraps for total body cooling of neonate and infants for Multiple Use Mattresses for Total Body Cooling are **Therm Aqua Pad** 30 x 45 cm (small size) and 50 x 90 cm (medium size)

Interlayer separate mattresses/ wraps from patient body preventing intimate direct contact.

For total body cooling treatment the TECOTHERM NEO device pumps TECOmed along the hydraulic lines through mattresses / wraps or pads to lower or increase body core temperature to the set value. Users may preselect the most appropriate treatment procedure and target temperatures.
During circulation the micro computer of the Control Board is permanently comparing/ analysing the measured and set rectal temperatures. The larger the deviation between the two temepratures the more cooling or heating power is to be supplied by the TECOTHERM NEO device.

Rectal temperature stands for body core temperature BCT.

Treatment procedure temperatures for inducing hypothermia in neonate are strictly limited

• Rectal Temperature standing for BCT (lower limit / upper limit) in the treatment mode 1	32°C/ 35°C
• Mattress temperature	12°C/ 39°C
Device internal temperature alarm limits	10°C lower limit 41°C upper limit

Treatment and operation modes of TECOTHERM NEO

TECOTHERM NEO is designed as a physiological closed- loop control system PCLCS , see this section**.**

Three treatment and operation modes of TECOTHERM NEO

1 Programmable Complete Treatment Mode (Servo controlled mode)

2 Servo Control Mode (constant rectal temperature)

3 Constant Mattress Temperature Mode

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

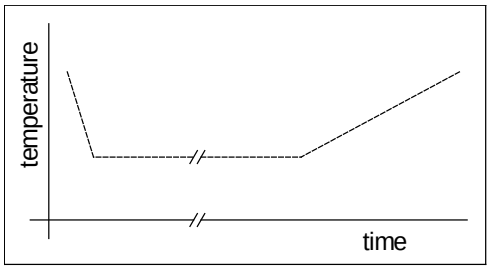
Treatment Mode 1

Programmable Complete Treatment Mode (Servo controlled mode)

(automatic mode, treatment protocol)

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

Note This mode is limited to temperatures and profiles stated in the TOBY Study protocol (see reference) for inducing hypothermia in neonate suffering from Hypoxic Ischemic Encephalopathy



Rectal temperatures can be selected and set within a range **32°C to 38°C**.
Temperature is accurately adjusted and finely tuned.

Necessary TECOTHERM NEO system equipment to run treatment is

- TECOTHERM NEO device
- Mattress for total body cooling, filled, protecting foil interlayer
- Rectal Temperature Probe, Skin temperature probe
- 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 mattress/ cool wrap. Rectal probe should be inserted and secured.

To start treatment you have to follow and observe the instructions of the MENU.

Operation Mode 1 has five (5) treatment sections/ phases.

Treatment section I (optional) Thermal preparation of the mattress

Prior to start hypothermia treatment you may prepare the mattress thermally. Following treatment procedure will be performed by the system independently on this section. Whether such preparation is appropriate depends on your information state on the neonate you have to treat. A mattress precooled to 18 – 22°C may shorten the cooling-down treatment section II.

Treatment section II 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 eytracted by the cooling mattress and transferred to the circulating fluid. The central device cooling unit extracts the heat and cools the fluid on demand.
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/ undershooting.

Treatment section III 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). 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.
If during treatment section III 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.

Treatment section IV Re- Warming Phase

After cooling phase III the system automatically starts the re- warming phase. 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 III.

Treatment section V (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.

Having in mind the PCLCS in this **treatment mode 1**

Along all treatment phases the Control Board is permanently - every 2 seconds - analysing temperatures and temperature differences. It instructs the central cooling unit to cool or warm the circulating fluid depending on the results of this analysis. The circulating fluid then extracts or transfers thermal energy from/ to the patient. Circulation is monitored by the Control board.

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.

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

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

Attention Fallback Mode

If treatment is interrupted or any reason for stopping operation in Automatic Treatment Mode 1 you may continue treatment using Treatment Mode 3 Constant Mattress Temperature which is a manual mode.
Note Such treatment is a true alternative solution to continue treatment under mode 3 conditions (Fallback Case)

Note Study details of treatment mode 3 prior to change treatment, see below.

Note Transition from automatic mode to Treatment Mode 3 Constant Mattress Temperature must be performed by the operator:

- TECOTHERM NEO rectal temperature probe should be disconnected and removed.

- 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.

- Note Operator may continue to use the skin sensor connected to port "**S**" of the TECOTHERM NEO device as an auxiliary means if no other probes are available. That temperature is displayed on the screen in the small parameter boxes in the upper part of the display feature DIAGRAM and as temperature profile in the display feature DIAGRAM, see section 7.3 of this IfU.
- Change to the Main MENU and select treatment mode 3 Constant Mattress Temperature Mode.
- If transition to fallback mode must be done during treatment section II (cooling down): To cool down fast and efficiently to reach BCT 33,5°C select low mattress temperatures (12 – 15°C). Then follow the instructions of treatment mode 3, see below this section.
- During treatment phase III or IV: Follow instructions of treatment mode 3, see this section below.

Treatment Mode 2

SERVO CONTROL Constant Rectal Temperature Mode

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 2 you can select treatment temperatures in a wider range than in mode 1: Target rectal temperatutes or BCT **30° ….. 38°C.**

Treatment temperatures and duration can be defined more freely in the treatment sections. But after ending a treatment section operator is either requested to continue or to introduce a new section by changing treatment parameters (temperatures, duration).

Necessary TECOTHERM NEO system equipment to run treatment is

- TECOTHERM NEO device
- Mattress for total body cooling, filled, protecting foil interlayer
- Rectal Temperature Probe
- 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 mattress/ cool wrap.
Rectal probe should be inserted and secured.

To start treatment follow the instructions of the MENU.
The TECOTHERM NEO device pumps TECOmed through mattresses / wraps or pads and back to the device. During circulation the micro computer of the Control Board is permanently comparing/ analysing 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 is keeping this temperature for a preselected time.

Treatment section I (optional) Thermal preparation of the mattress

Prior to start hypothermia treatment you may prepare the mattress thermally. Following treatment procedure will be performed by the system independently on this section. Whether such preparation is appropriate depends on your information state on the neonate you have to treat. Further details to continue see **treatment mode 1**

Treatment section II 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 operator can preselect target rectal temperature within **30°C …. 38°C.**
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/ undershooting.

Treatment section III Cooling Phase

Reaching set temperature the system continues treatment to automatically hold BCT of the patient constant. Treatment time and target rectal (BCT) temperature are preselected by the operator. System continues to hold BCT 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 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.
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.

If during treatment section III 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 Ending section III TECOTHERM NEO will not alarm the operator !

After finishing this section the operator is requested to select rewarming treatment parameters following the MENU entry **Modify current treatment**. Selection of target rectal temperature, say 37°C, and treatment time. Starting treatment rewarming is automatically run. The rewarming rate is shown on the display screen.

The TECOTHERM NEO system will linearly increase the BCT until selected target temperature is reached.
System then stops further re- warming and holds BCT at the selected value.
In case of disturbances the system is responding as described in section III.

The operator can continue the treatment. TECOTHERM NEO will automatically continue to hold patient at the selected BCT or at a modified temperature.
Operator can finish such treatment at any time.

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.

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.

Attention Fallback Case

If treatment is interrupted or any reason for stopping operation in Treatment Mode 2 SERVO Controlled Constant Rectal Temperatue you may continue using Treatment Mode 3 Constant Mattress Temperature which is a non-servo controlled mode.

Note Such treatment is a true alternative solution to continue treatment under Treatment Mode 3 conditions (Fallback Case)

Note Study details of treatment mode 3 prior to change treatment, see below.

Note Transition from Automatic Mode to Treatment Mode 3 Constant Mattress Temperature must be performed by the operator:

- TECOTHERM NEO rectal temperature probe *) should be disconnected and removed. It is inactive
- 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.
- Note Operator may continue to use the skin sensor connected to port "**S**" of the TECOTHERM NEO device as an auxiliary means if no other probes are available. That temperature is displayed on the screen in the small parameter boxes in the upper part of the display feature DIAGRAM and as temperature profile in the display feature DIAGRAM, see section 7.3 of this IfU.
- Change to the Main MENU and select treatment mode 3 Constant Mattress Temperature Mode.
- If transition to fallback mode must be done during treatment section II (cooling down): To cool down fast and efficiently to reach BCT 33,5°C select low mattress temperatures (12 – 15°C). Then follow the instructions of treatment mode 3, see next part below.
- If transition to fallback mode must be done during treatment phase III or IV: Follow instructions of treatment mode 3, see this section below.

*) If no independent rectal temperature probe is available you may use TECOTHERM NEO rectal probe. That temperature is displayed at the screen in the **small parameter box**, upper part of the display feature DIAGRAM. **Numbers are small!**

Treatment Mode 3 Constant Mattress Temperature Mode

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

Note **Treatment Mode 3** is a **non-servo controlled** mode. Rectal Temperature is no more a reference variable for automatically running the treatment.

In Treatment Mode 3 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.

Attention Treatment Mode 3 serves as a **Fallback Mode** for Treatment Modes 2 and 3 !

Attention in Fallback Mode External Temperature Probe !

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.**

Controlled mattress temperature range 12°C …. 39°C

Necessary TECOTHERM NEO system equipment to run treatment is

- TECOTHERM NEO device
- Mattress for total body cooling, filled, protecting foil interlayer
- 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 should be placed onto the mattress/ cool wrap.
Rectal probe should be inserted and secured.

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

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

Attention **Mattress temperature** is permanently displayed on the screen in the display feature LARGE SIZE NUMBERS.
If using the TECOTHERM Skin probe skin temperature is displayed permanently in the display feature DIAGRAM (as profile and in the parameter box)

NOTE If no independent temperature probe is available the TECOTHERM NEO rectal probe may be used for indicating BCT on the display (feature DIAGRAM, small parameter box).

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

Treatment section I (optional) Thermal preparation of the mattress

Prior to start hypothermia treatment you may prepare the mattress thermally. Following treatment procedure will be performed by the system independently on this section. Whether such preparation is appropriate depends on your information state on the patient you have to treat. Further details to continue see **treatment mode 1**

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 when 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 steplike select slightly larger or smaller 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 hour ½ .

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

After termination of Cooling Phase the operator is requested to perform the transition into **Rewarming Phase**. Following the MENU Options the operator is asked for selection of a new treatment.
Selecting / applying new mattress temperatures and treatment times TECOTHERM NEO will run with that mattress temperature re- warming rate. Maximal mattress temperature is 39°C. Start rewarming cautiously rising mattress temperatures to 34- 35°C, then stepwise slowly to higher temperatures.
Keep in mind: Patient body mass may severely influence the rewarming. The larger the mass the slower the rewarming
The operator should observe the re warming and reduce / enhance mattress temperature on demand.

All mattress temperatures / time dates are recorded/ logged and can be read out/ transferred to an USB stick, see section 7.3, USB port.

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.

7.2 Informations on TECOTHERM NEO Hypothermia Device

Essential Parameters, Performance

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	1 Servo Control Complete treatment mode
	automatic	2 Servo Control Constant Rectal Temperature
		3 Constant Mattress Temperature
Mattress temperatures for Total Body cooling		
Neonate and babies		+12 °C to + 38 °C
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		1 32°C … 33,5°C … 38°C,
		2 30°C …. 38°C

Hydraulic circulation system

Fluid	TECOmed
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	≤ 345 W, 230 VAC, 50 Hz

Application Parts

Patient Temperature Probes	2 Probes: Rectal Probe; Skin Probe
Rectal Probe (Neonate)	D-RB2A
Skin Probe (Neonate)	D-S06RGA
Mattress Therm Aqua Pad	Material PUR polyurethane, transparent
Dimensions	300 x 450 mm
Volume	300 ml fluid
Mass (empty)	220 g
Dimensions	500 x 900 mm
Volume	600 ml fluid
Mass (empty)	approx. 750 g
Cool Wrap / MattressT NEO Pad M	Material PUR polyurethane, transparent
Dimensions	640 x 440 mm
Volume	300 - 350 ml
Mass (empty)	155 g

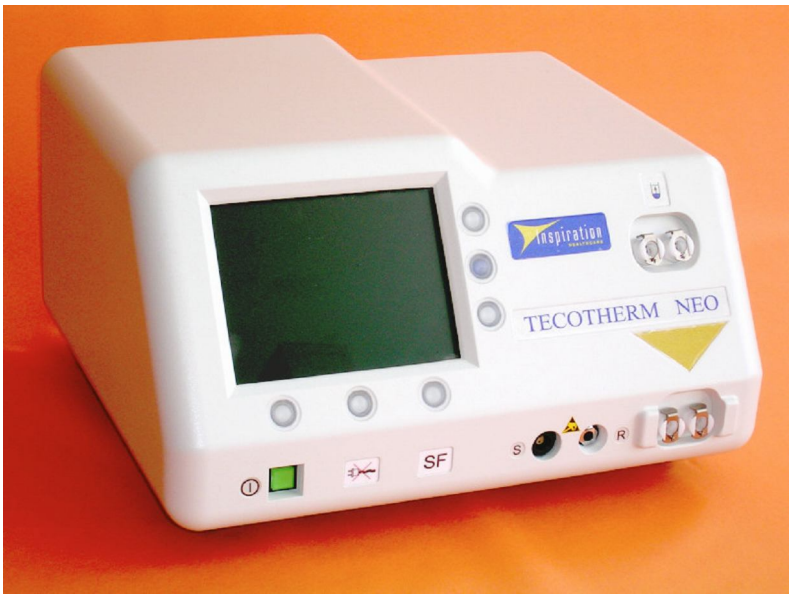
Modules and Main Components are

- Central Cooling / Warming Module
- Hydraulic Module for controlled circulation of TECOmed 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 TECOmed fluid. This module is controlled and monitored by means of a micro computer 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, cool wraps, and an internal flow meter to detect circulation flow volume. Pump is driving the TECOmed fluid to circulate through the mattresses/ applied parts. Operation pump pressure is limited to 0,5 bar.

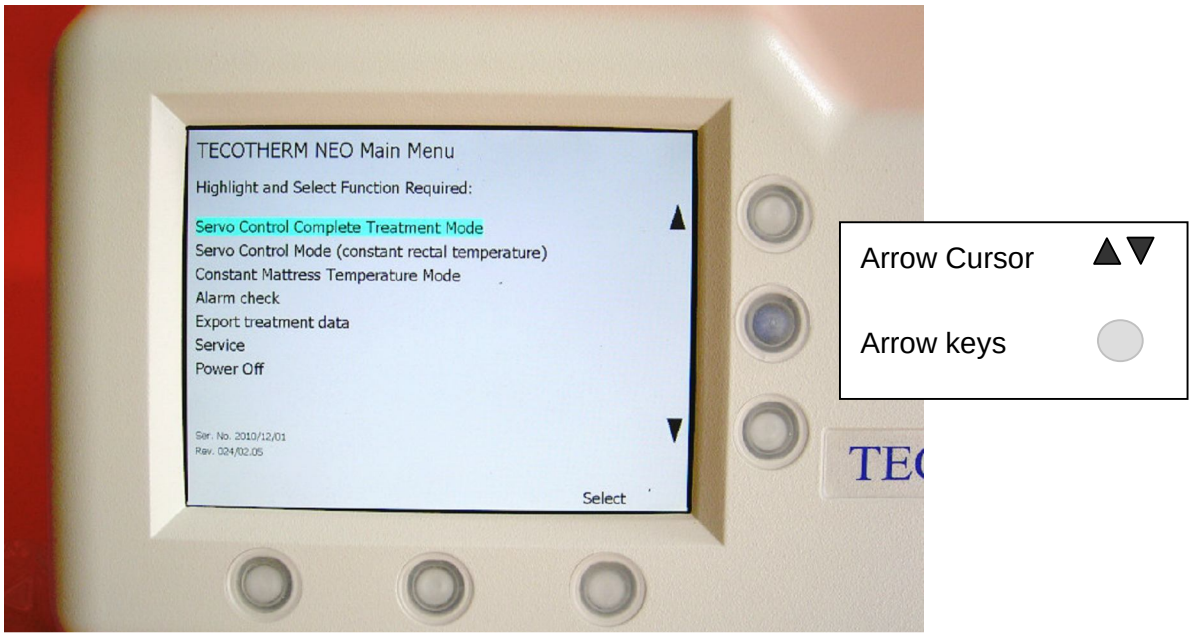
Micro Computer controlled Operating Board and Control Board, MENU

TECOTHERM NEO is furnished with **an Operating Board** and a **MENU** as user interface, and with a **Control Board** to control its operation features. Both boards are based on their separate powerful micro computers which are in permanent communication (master OP – slave CB.)
TECOTHERM NEO has three main operation and treatment modes. The operator can select operation modes using the MENU.

A large display serves as **user interface** for the operator. MENU operations and treatment modes are visualized on the display screen.
The user 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.

Current instructions and entries are highlighted turquoise.

Display with MENU



System Alarm and Monitoring Features

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

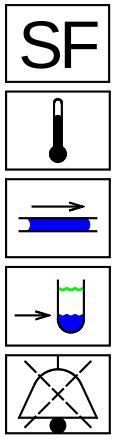
System failure.

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 5

Mains Power failure  and certain internal system failure  are indicated by LED indicators in the lower front panel part just below the display screen. Details see Section 11 Alarms

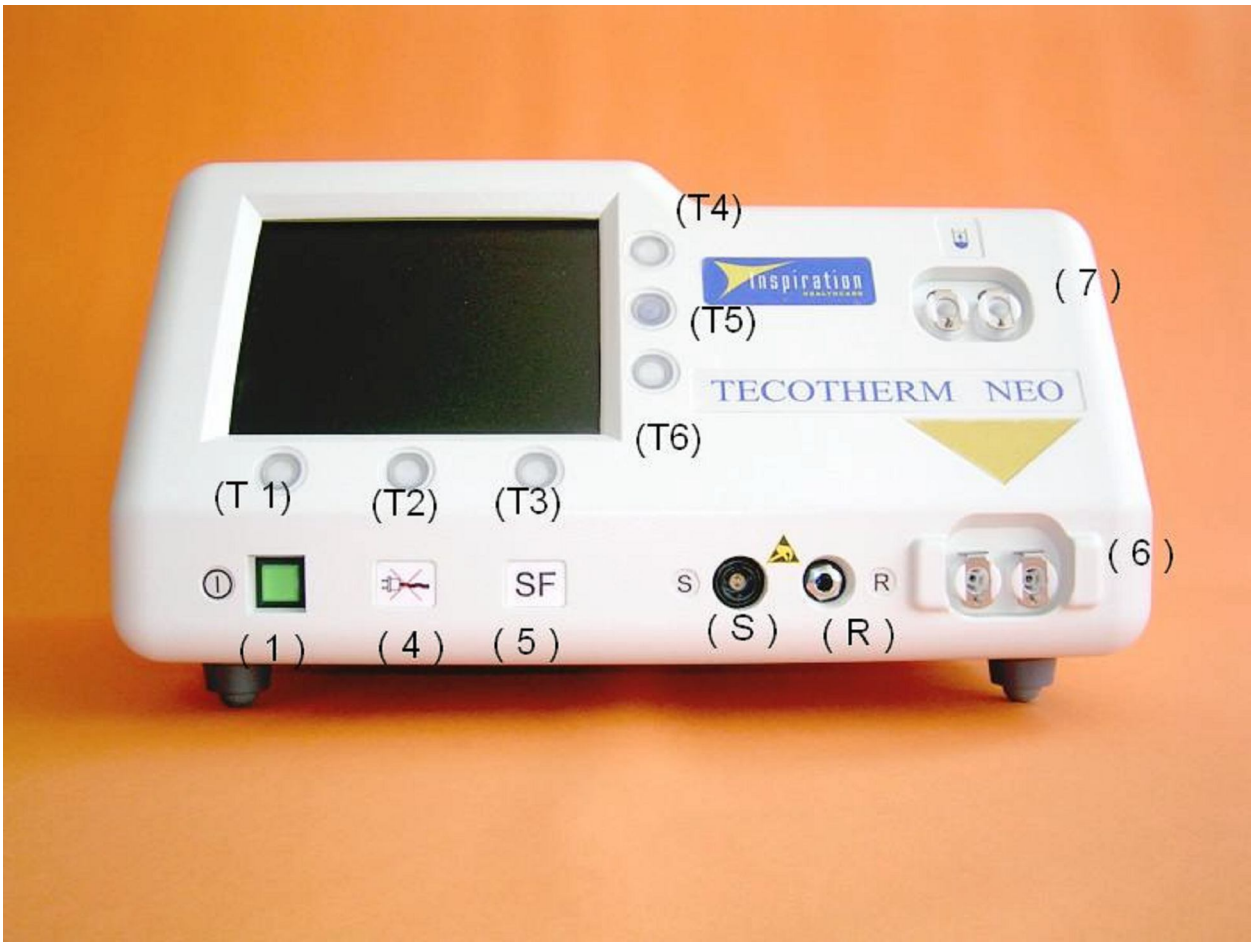
Details see next section 7.3

Mains Cable Cord

TECOTHERM NEO is plugged via medical grade cable cord to a 230 or 110VAC shock- proofed mains socket. 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 "On" "I"

(S) Temperature Probe Socket Skin Probe

(R) Temperature Probe Socket Rectal Probe

(4) LED Indicator Mains Failure/ Mains Power OFF

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

(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 Initiating Audible Alarm paused.

(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 TECOmed

Figure TECOTHERM NEO Rear side

(8) Mains Socket

(9) USB socket

(10) Network socket (not operating)

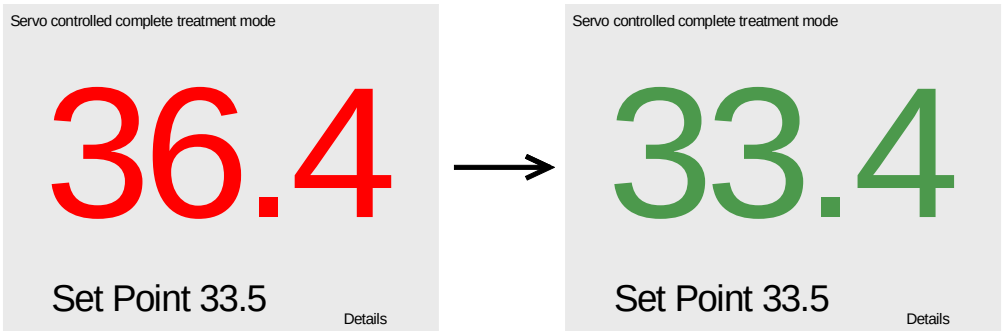
Further details see Section 7.9

Indicating Temperatures at the Display screen

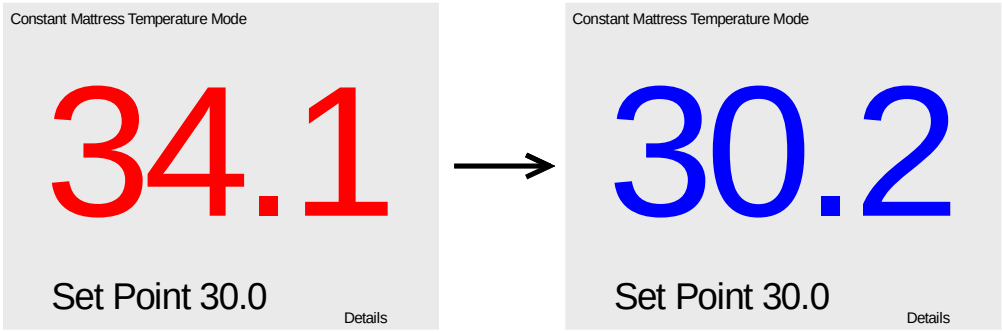
Running the 3 main treatment modes, see section 7.2, treatment temperature is shown on the screen in a large size (display feature LARGE SIZE NUMBER)

Rectal temperature is displayed when selecting treatment mode 1 or 2. **Mattress temperature** is shown when selecting treatment mode 3.

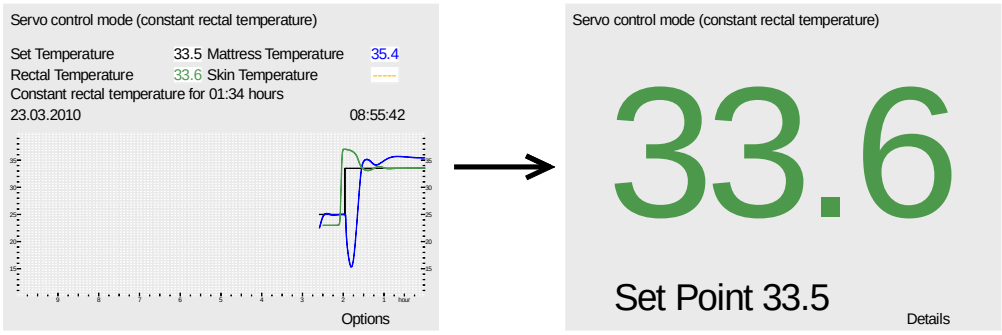
Treatment modes 1 and 2 As long as measured Rectal Temperature deviates more than 0,5 °C from the Set Point the rectal temperature is appearing **RED** .So for example if Set Point is 33,5°C a measured rectal temperature of 36,4 °C is displayed **RED**. Only when deviation is < 0,5°C colour changes to **GREEN**.



Treatment mode 3 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 NUMBER**.
Here shown for treatment mode 2 Servo Control Constant rectal temperature**.**



7.4 Application part, External Temperature Probes

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

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

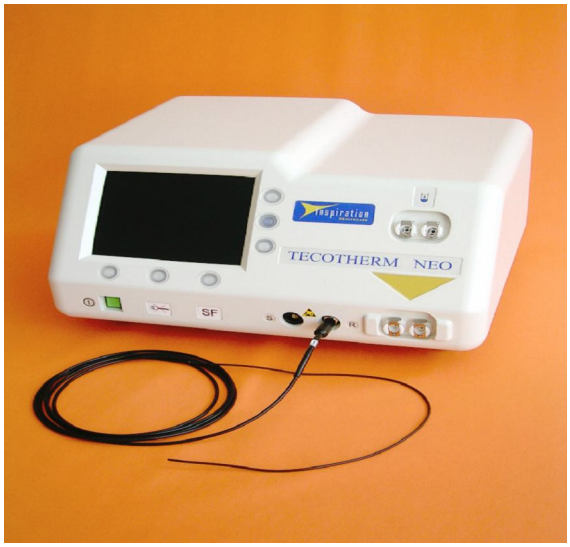
Rectal Probe for Neonate	Type D- RB2A, with Audio Jack, Reusable, autoclavable.
Skin Probe for Neonate	Type D- S06RGA, with REDEL connector reusable, autoclavable

NOTE Rectal probe and Skin probe connectors have their **individually mating sockets R and S !** No confusion possible!

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 Ⓡ ! see Figure below.

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 Rectal Temperature Probe



7.5 Hoses, Fluid circulation line

The hose set is composed of fluid tubing made of transparent polyurethane material, and a thermally shielding envelope made of silicone foam material.

Mattresses, wraps and pads 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.

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.
All connectors are self- sealing quick disconnect couplings.

Figure Hoses

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

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 TECOmed thermalizing fluid.

Fill- up set is a fluid container made of HD polyethylene or of polypropylene material. The cap has two connecting adapters with male QDC couplings plugged to ports (7) in the device front panel, see section 7.3.
Container volume of TECOmed liquid is 500 ml, marked every 100 ml

Figure Fill- up set

7.7 TECOmed Thermalizing Fluid

TECOTHERM NEO uses TECOmed as a circulating fluid to bring cold and heat to the patient. TECOmed is supplied in 5 l containers made of polypropylene or HD polyethylene.
TECOmed is composed of 70% water, 30 % ethanol and additives. For details see Safety Data Sheet.
Figure 5 l Container

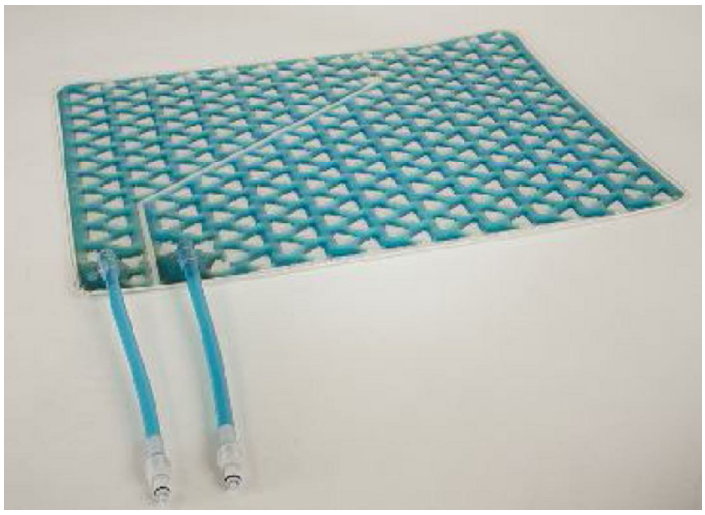
7.8 Mattresses, Cool Wraps, Pads, cool parts and foil layer

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

Both types are limited to working pressure ≤ 0,75 bar.

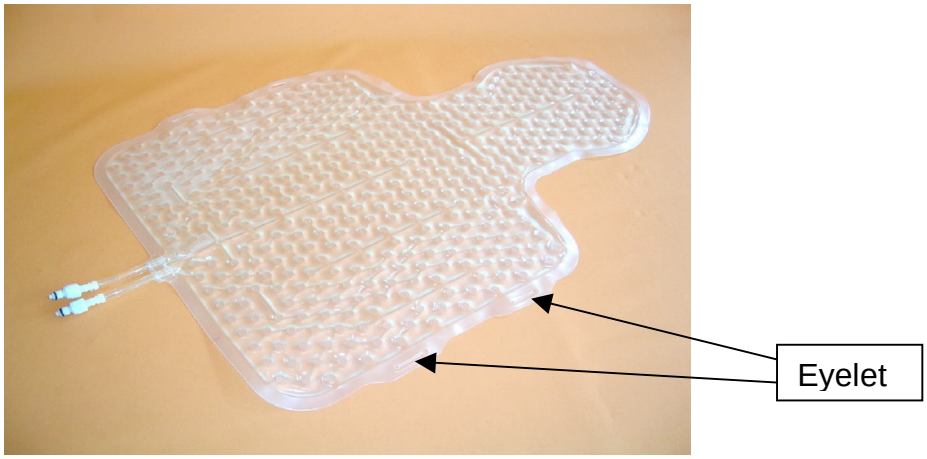
For positioning T NEO cool wraps we recommend small felt fixation tapes . Tapes are fed through eyelets at right and left sides of the wrap then forming a loop. Both tape ends are knoted. The user may select by choosing the appropriate loop length to what extent the neonate or patient is wrapped. For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

Figure Mattress Aqua Therm PAD, 30 x 45 cm, with male QDC connectors



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

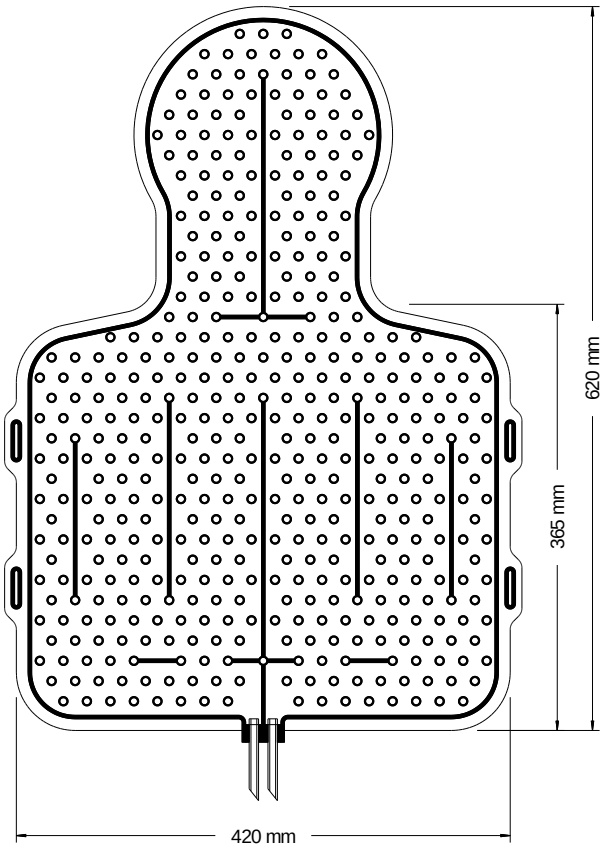
Figure Cool wrap T NEO PAD 44 x 65 cm with male QDC connectors



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. Wraps intended for Single Use are planned to be made of PVC free of DEHP.

Figure

Cool Wrap T NEO PAD with its typical pattern structure to ensure proper flow and fluid distribution



Protecting Foil layer

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

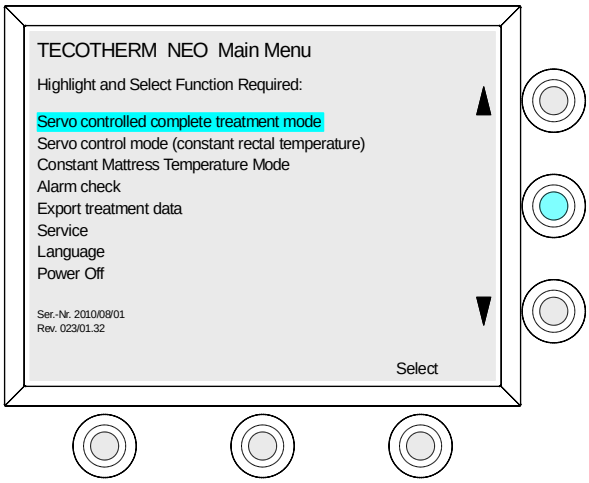
7.9 MENU and the User Interface / USB connection

The operator is working within the framework of the Operator System (Operation Board). This system is based on a Windows Operating System.
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

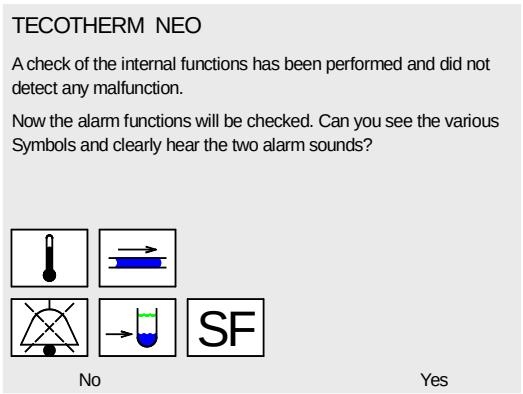
The user either selects, confirms or modifies treatment modes, treatment options, operations and parameter settings using the **Arrow Keys** to move to MENU entries. Such active entry is coloured turquoise. Direction of movement is shown by the arrow keys, see section 7.2.
Pushbuttons below display screen 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.

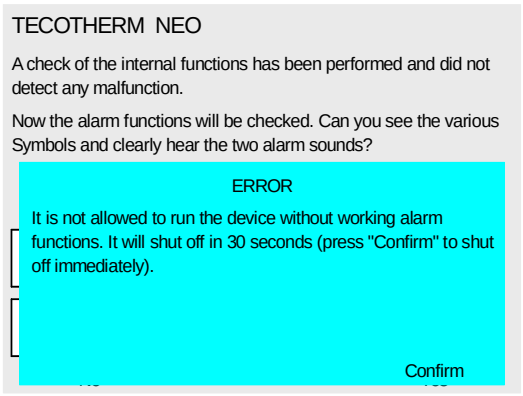
Entries at the MENU left side are accessible for the operator except entry SERVICE. Access to entry SERVICE is only for service personnel using a password.



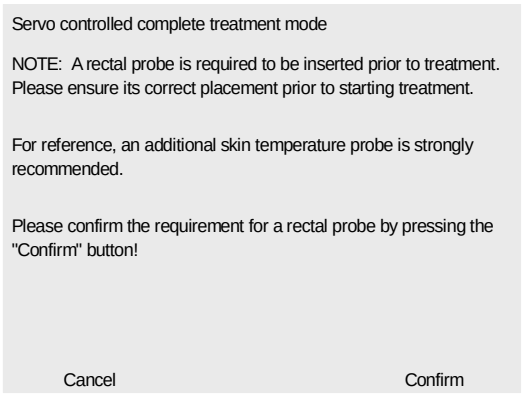
Alarms and troubles are indicated optically by ICON symbols



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.**



Treatment Data Selection and Transfer/ USB socket

To read out and export treatment data and data log files select Entry **Export Treatment Data** in the Main MENU. 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 an information on the screen whether data export was successful. After successful export unplug USB stick.

For service: Socket (9) is an USB interface port. Plugging USB hardware stick is for updating firmware and detailed data export.

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 traned how to run the system.

8.2 Initial Operation by the customer: Pre- operation Check up

Caution Ensure that power cord matches the shockproof socket at site (230V 50Hz or 110V 60Hz).

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

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

Pre- operation Check up

Prior to putting the system into operation, check the **conditions section 6** to ensure safe and proper operation:

- For a reliable and safe operation use only original components, applied parts and spare parts supplied or recommended by the manufacturer.
- Without rectal temperature probe plugged to port “R” it is **not possible** to start treatment modes 1 and 2.
- Check that TECOmed (or approved substitute) is used as circulating fluid.
- Check that TECOmed (or approved substitute) is used as circulating fluid.
- Check whether temperature probe connectors match their sockets R and S at the device front panel

8.3 Initial Operation by the customer

If mattress is positioned into an incubator read notes in Section 6.

Plug the cable cord into rear socket. Then plug the system to the mains 230 V / 50 Hz into shock-proofed socket. The equipment is prepared for operation at 230VAC.

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

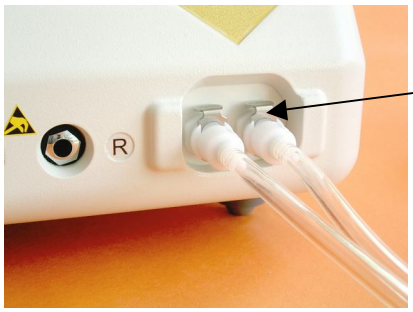
Next Step Connect mattress / cool wrap to the TECOTHERM NEO

Prior to connecting check whether

- mattress / wrap is filled completely. If empty or only partially filled, see Section 8.6 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.

Note In case of Incubators see Section 6.

Then place a thin protective interlayer with plastics coating at the bottom downwards onto the mattress. 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 (1) and (2) a rectal probe is required.

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

Rectal Probe for Neonate	Type D- RB2A, with Audio Jack, reusable, autoclavable, length 2,75 m.
Skin Probe for Neonate	Type D- S06RGA, with REDEL connector reusable, autoclavable, length 2,75 m

Caution Ensure that only calibrated probes are used

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

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

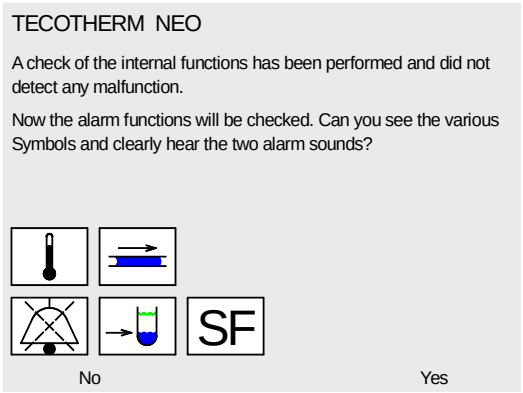
After passing the above mentioned preparations you may put system into operation:
Press Pushbutton (1). The lit key changes to intensive Green
The Initialisation Procedure is started automatically.

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

Display screen is illuminated, LED indicator (4) flashs blue, LED indicator (5) flashs green. Deviice is emanating an intensive BEEP, followed by a blue flash of the T5 indicator and intensive double BEEP.

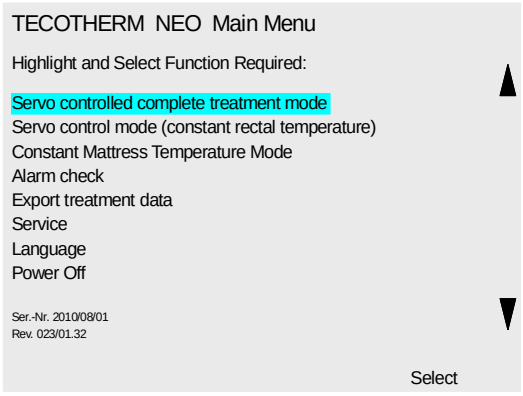
The operator is asked Can you see the various symbols and clearly hear the two alarm sounds?

Confirm **YES** pressing key T1 or **NO** pressing key T3.



If **NO**: It is not allowed to run the device without working alarm functions. TECOTHERM NEO will shut off at after 30 seconds (Pop Up window appears)

If **YES** TECOTHERM NEO Main MENU is displayed.



Using Main MENU and pushing arrow keys the operator selects entry Language and is led to a list of available languages (English, Deutsch, Espanol, …..). After selection Main Menu feature appears in the selected language on the screen.

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

Selecting one of the treatment modes, details see Section 7.1,

1 Programmable Complete Treatment Mode (Servo controlled mode)

2 Servo Control Mode (constant rectal temperature)

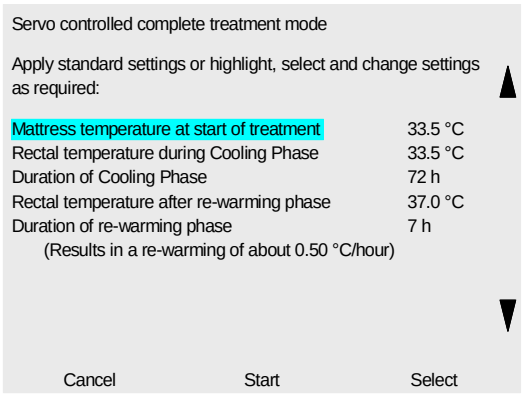
3 Constant Mattress Temperature Mode

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.

Preliminary temperature adjustment of the mattress / wrap , see Section 7.1

Prior starting treatment you may thermalize the system to a more appropriate temperature. You may input a temperature different from 33,5°C by pushing key **Select.** 33,5°C is taken as a standard set mattress temperature.

Note After a longer device down time the fluid temperature is at ambient temperature level. Starting operation the system will achieve a set mattress temperature after some warm up or cool down time.
Adjust all necessary treatment parameters for the selected treatment mode.
Then push key **START** for starting Treatment Section I “Thermal preparation of the mattress”.



Note: Treatment section “Themal preparation of Mattress” is optional

If set mattress temperature is reached system may stay ready for operation.
When neonate is placed and all is prepared push key **START** once again to start the servo controlled treatment.

Example How to perform hypothermia treatment in Treatment Mode 3

Exemplary approach: Treatment Mode 3 Constant Mattress Temperature

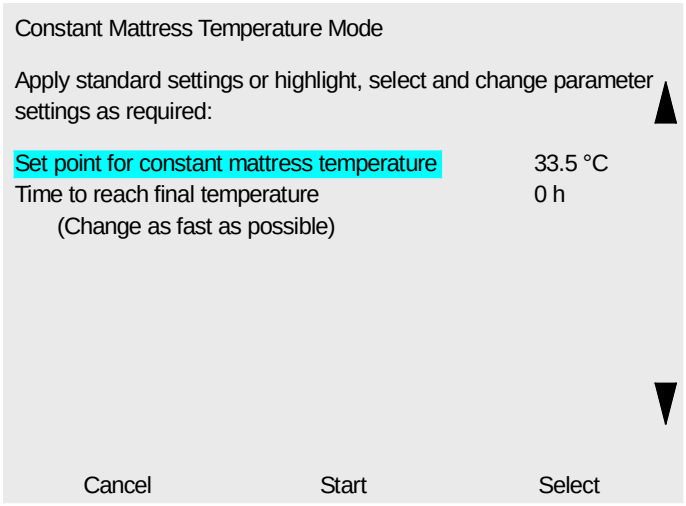
Example How to perform hypothermia treatment in Treatment Mode 3
Exemplary approach: Treatment Mode 3 Constant Mattress Temperature

Treatment Mode 3 **Constant Mattress Temperature**

NOTE Selected Instruction entry is highlighted turquoise

1. step Set Mattress temperature
→ Use key T1 **SELECT**
- Standard set 33,5°C displayed
  Moving to a different temperature say 28°C pushing arrow key ▼
  → 28,0 °C

Then Push Key T1 **Apply** set temperature and store it



2. Step

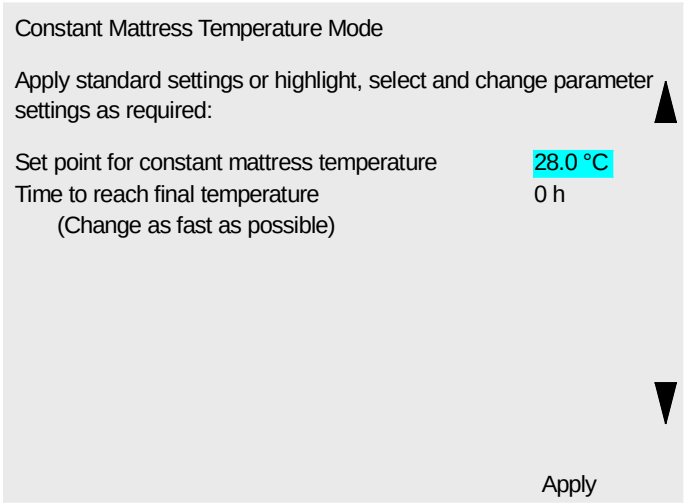
Select Time to reach set final temperature

→ Use key T1 **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 dispayed

Then Push Key T1 **Apply** time and store it.



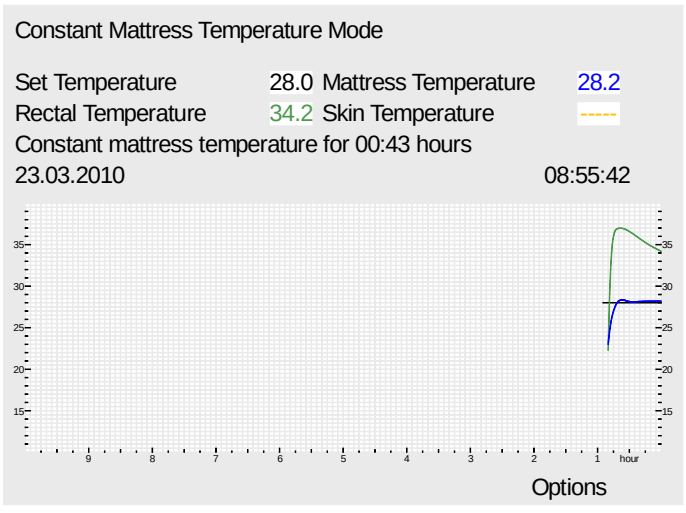
3. Step

Instruction **Start**

→ Push key T1 **Start**

Display feature DIAGRAM with treatment parameter boxes is displayed.

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



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 conditions/ temperature: the higher the more time is required.

TECOTHERM NEO is progammed 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. Or temperature values in the small parameter boxes in the upper part.

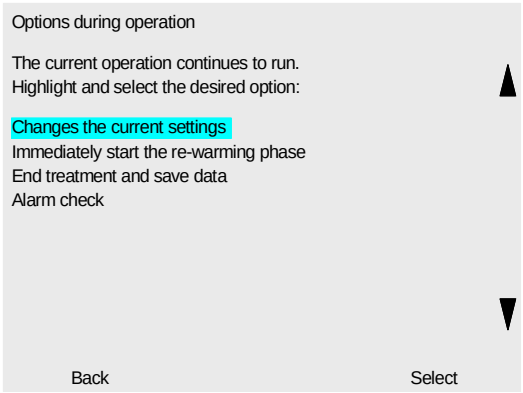
Independent on treatment mode feature DIAGRAM changes after 60 seconds automatically to feature LARGE SIZE NUMBER.

Treatment is running

NOTE: We recommend that during treatment operator should from time to time monitor patient temperatures.
This is especially important during transition from cooling section III to re warming section IV.

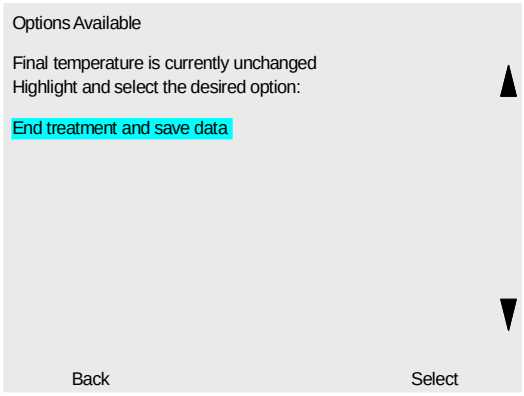
Treatment is executing according to and depending on selected treatment mode and applied treatment parameters. All treatment data like temperatures / time dates are automatically recorded/ logged and can be read out/ transferred to an USB stick.

NOTE: All parameters can be changed from set positions pushing key T1 Options and Select, at ANY TIME ,should the need arise.
The display shows the entry Change the current settings., see below. You may go back to the original settings pushing key T3 Back . Changes will be stored on the TECOTHERM NEO and can be seen on later analysis



End treatment

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

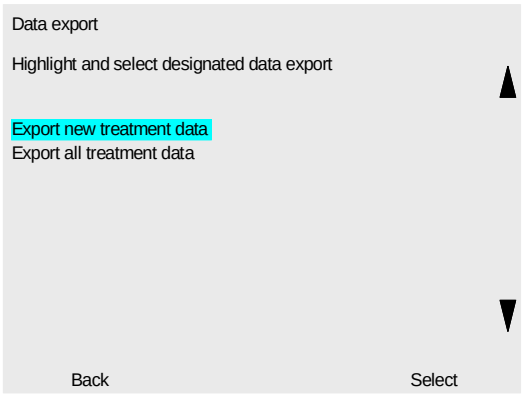


Export treatment data/ Data storage

To read out and export treatment data and data log files select Entry Export 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.

Export treatment data/ Data storage

To read out and export treatment data and data log files select Entry Export 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.



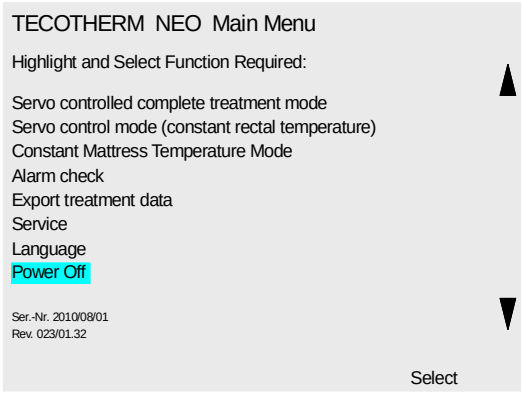
It is not necessary to export and store new current data. All data are stored by the TECOTHERM NEO on a memory card with large capacity.

After successful export push key T1 Confirm to enter Main MENU.
For stopping operation see following Section 8.4.

8.4. Stop operation/ Turn off device

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

Then you should follow the MENU instructions looking for entry Power Off: Push arrow key ▼ to move to entry POWER OFF.



After few seconds device is shut off.

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

NOTE

Finally TECOTHERM NEO system should be put into and left in a state to guarantee properly starting a new hypothermia treatment.

8.5 Filling / Refilling Procedures

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

Filling circulating fluid into the TECOTHERM NEO device

TECOTHERM NEO is put into operation, treatment is running. If during operation symbol  is appearing at the display screen indicating low liquid level/ lack of TECOmed accompanied by audible alarm and blue- blinking key T5, fill up TECOTHERM NEO (see Section 11.4).
The internal fluid container has to be refilled or filled up as described.

- Push key T5 to silence audible alarm (AUDIO paused,  is appearing at the display.)
- If not prepared fill the fill- up fluid bottle with TECOmed up to the upper mark **500 ml**. After filling close bottle cap tightly.
- Connect QDC of the fill-up bottle to the refill port QDC counterparts (7) at the device front face. Turn bottle until cap is directed downwards. Lift fill up bottle in a position ½ m higher than the TECOTHERM device. Keep this position.
- Start of filling up / refilling is indicated by rising air bubbles. Continue refilling until air bubbles disappear and inner container is filled (approx. 250 ml.) Alarm will stop, symbol  disappears.
- Disconnect bottle QDC from ports (7)). Lower fill-up bottle and turn it back into its normal vertical position. Unscrew bottle cap (1/2 revolution) for pressure compensation (a few seconds). Then close bottle cap tightly.

During operation symbol may appear again. Repeat refill procedure as described.

Caution If symbol frequently or permanently appears you have to follow instructions of Section 11.4 and 11.6. Operation failure

Substitution of TECOmed fluid → see Section 13.2

8.6 Preparation of empty or partially filled mattress

Attention Do not use partially-filled mattress in hypothermia treatment. 

Note **Filling capacity of empty mattresses**

Therm Aqua Pad 30 x 45	approx. 300 ml TECOmed
T NEO Pad M / S 40 x 60	approx. 300 - 350 ml TECOmed
Therm Aqua Pad 50 x 90	approx. 500- 600 ml TECOmed

If not prepared fill fluid bottle with TECOmed up to the upper mark **500 ml**. After filling close bottle cap tightly.

Filling procedure using **filled TECOTHERM NEO device** prepared for operation

- Connect empty or partially filled mattress/ cool wrap with QDC directly or via hoses to the unit ports (6). Place mattress horizontally onto a level support.
- Connect QDC of the fill-up bottle to the refill port QDC counterparts (7) at the device front face. Turn bottle until cap is directed downwards. Lift fill up bottle in a position ½ m higher than the TECOTHERM device. Keep this position.
- Start TECOTHERM NEO operation according to Section 8.
  Select Treatment mode 3. Fluid flows into the mattress.
- Start of filling is indicated by rising air bubbles. Continue filling until air bubbles disappear.
- Residual small bubbles in the mattress do not disturb circulation flow.
- Then disconnect fill up bottle Unscrew bottle cap (1/2 revolution) for pressure compensation (a few seconds). Then close bottle cap tightly.

Attention Big therapeutic mattresses like Therm Aqua Pad 50 x 90 may cause a lack of liquid during filling / refilling in the internal container.

Symbol  is appearing at the display screen indicating low liquid level/ lack of TECOmed accompanied by audible alarm and blue- blinking key T5.

Additionally Symbol  **No Flow** occasionally may appear.

Push T5 to silence alarm **AUDIO Paused** 

You have to fill up TECOmed. Please use a completely up to 500 ml filled bottle and repeat fill- up procedure until the mattress is ready for use. Symbol will disappear. Refer to Section 11.4, too.

8.7. Application of mattresses

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 No Flow** appears
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 mattress and neonate skin surface; 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 abcesses, rash and burns. 

Application see Notes Section 6, too

Place mattress horizontally spread onto a level 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 authorised distributors.
- Use **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 (see previous subsection)

T NEO PAD Cool wraps are designed and performed for neonate in a way to induce hypothermia more appropriately. Neonate can be wrapped to an extent not disturbing other treatments or actions with the patient, diagnostics e.g.

Place cool wrap / mattress horizontally spread onto a level 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.

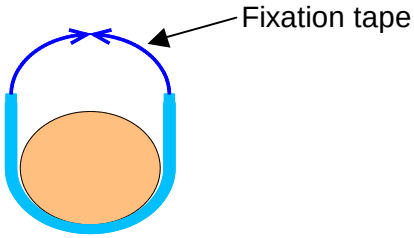
Place protective interlayer onto the cool wrap mattress.

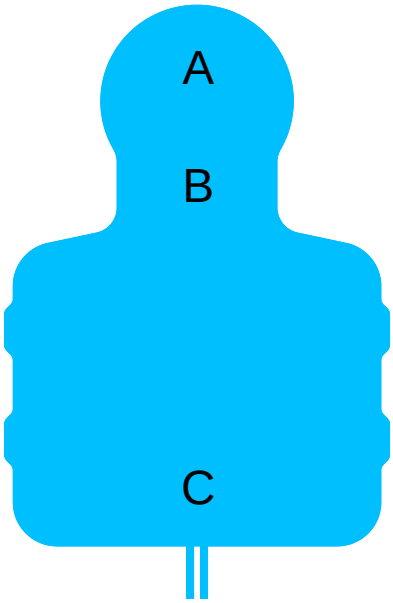
Place neonate onto A - B - C region. Place head onto **A**. Feets schould be located at part **C** and body/ chest along part **B.**

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

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 knoted. The user 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 and QDC.
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 flue covered and free from dust. Remove flues and dust using a small vacuum cleaner.

9.2 Mattresses, thermally insulated hoses, tubing

Mattresses can be used multiple times and have to be cleaned/ disinfected, see above.

Usually 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: Mattress application 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 products.

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.

Note Drain and replace TECOmed fluid in the mattresses at least every 3 months after last filling.

9.3 Temperature Probes

Rectal and Skin Temperature Probes are delivered as autoclavable applied parts.
Probes have to be disinfected and sterilised before applying them.
For details read the Instructions for Use of the manufacturer of the temperature probes.

10. Storage

10.1 Storage of the TECOTHERM 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.
Storage temperatures +5°C … +40 °C with TECOmed fluid
Storage temperatures - 5°C … +60 °C without TECOmed fluid

Mains cable Keep cable close on the 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.
Storage temperatures +5°C … +30 °C.

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

10.2 Storage of mattresses

- Fresh or unused empty mattresses have to be stored in the original box or package. Storage temperatures +5°C … + 30 °C.
- Filled or partially filled used or unused mattresses containing TECOmed fluid must be stored in a **closed** storage box in a **cool and dark** environment *).
- Drain and replace TECOmed fluid after a 3 month storage period. For replacement procedure, see Section 13.3. After replacing fluid, store mattress as above described.

Expiration date for empty fresh mattresses in the closed storage box or enveloppe 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. Storage of TECOmed

TECOmed fluid is supplied in plastic containers. Keep container sealed and closed.
Do not open can before use.
After open the can tightly screw the can cap.
Store the filled or partially filled container in a dry ambient.
TECOmed is non inflammable.

Attention Keep TECOmed away from children! It contains 30 vol. % ethanol and 0,33 vol % of the denaturing agent Methyl- Ethyl- Ketone.

10.4 Transport

TECOTHERM NEO is a light- weight hypothermia system with weight 7,2 kg when the reservoir is full.
Carry it to move the device over short distances or use an appropriate trolley.
When carrying do not touch display screen.

11 Alarms Malfunctions - Failure - Signals and Troubleshooting

Existence of alarm condition like operation failures, malfunctions and problems are indicated by optical and audible signals. During system operation 5 alarm functions are internally activated.
They are of low 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.

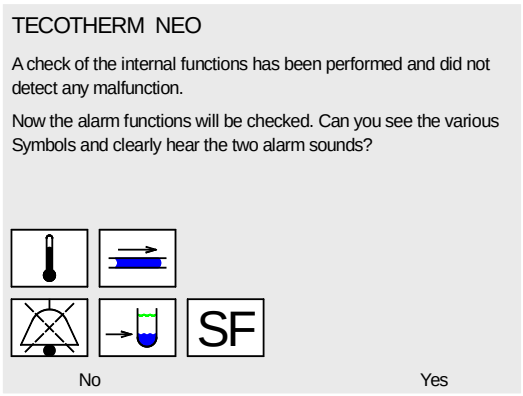
Interruption of power supply does not influence or alter the alarm settings. They are automatically reset when power is on and alarm cause is persisting.

Assignment of alarm functions to failures and conditions:

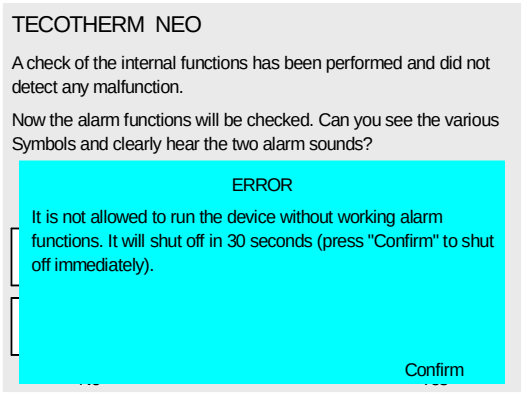
	System alarm	Internal system failure
	Temperature alarm	System operation temperature deviation of more than ± 0,5°C from set temperature
	No flow	No or very restricted fluid flow
	Fluid level low	Fluid deficit in the internal fluid container
	AUDIO paused	
	No mains power	No system voltage due to mains power failure.

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

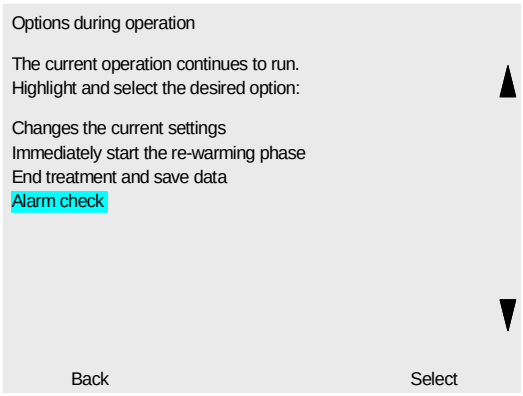
After Switch On of the TECOTHERM NEO the operation readiness of the alarm system is automatically checked through self- testing.
Display screen is showing the Information



Confirm YES when you see the various symbols and clearly hear the two alarm sounds
If not confirm NO. The display 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 T1 Confirm to immediately shut off the device !



Operator can select at any time during treatment operation an Alarm Check using MENU. Use arrow keys to highlight this function.



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 optically indicated by shown separate Symbol (4) at the device lower front side part, see section 7.3, and a separate intensive audible alarm. The alarm can be silenced pushing T5 AUDIO paused.

11.1 System Alarm, System failure SF

System Alarm is caused by an internal failure

Two (2) SF alarm features are used

1 Symbol SF is displayed at the screen , display feature **DIAGRAM,** accompanied by optical and acoustical alarms.

2 System alarm SF LED (5) in the lower part of the front panel. The LED pictogram is activated accompanied by optical and acoustical alarms. This feature is activated when the display screen is defective or not regulated by the Operational System.

Attention We draw your attention to a very rare event 

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

1. Step Pushing key T5 to silence the alarm

Unplug mains connector from the device socket at rear side →

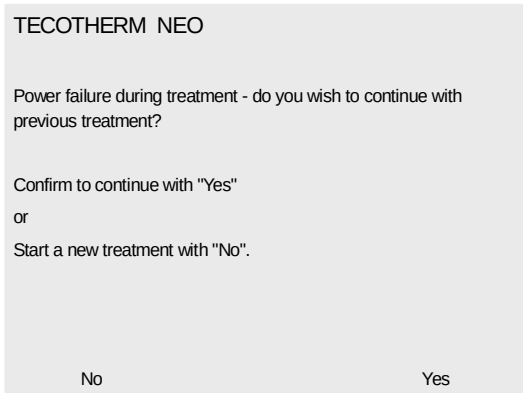
→ TECOTHERM NEO is switched **OFF.**

Wait 5 seconds. Plug mains connector 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 on the screen appearing just after power returned.



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

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

Inspect the system according following instructions

SF **System Alarm** Symbol is displayed at the screen, display feature **DIAGRAM,** accompanied by optical and audible alarms.

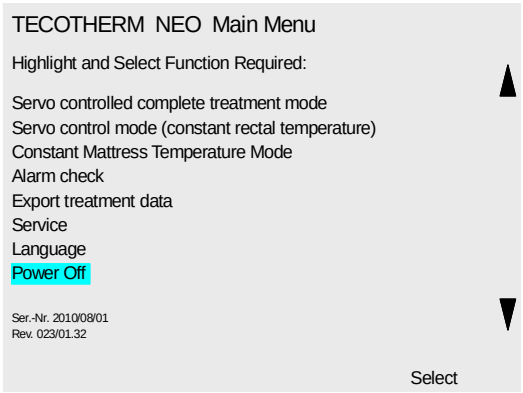
Caused by Failure in the TECOTHERM NEO system
- Defective Central Cooling Module
- Defective pump
- Temperature exceeding limits
- Internal communication problems between Operational System and Control system

Elimination/ Management Step1 did not solve the problem !

Shut off device by unplugging Mains cable

Or Push key T1 Options, turn to the Main MENU. Select Power Off by pushing key T6.

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

Display screen is shut off / not illuminated (dark)

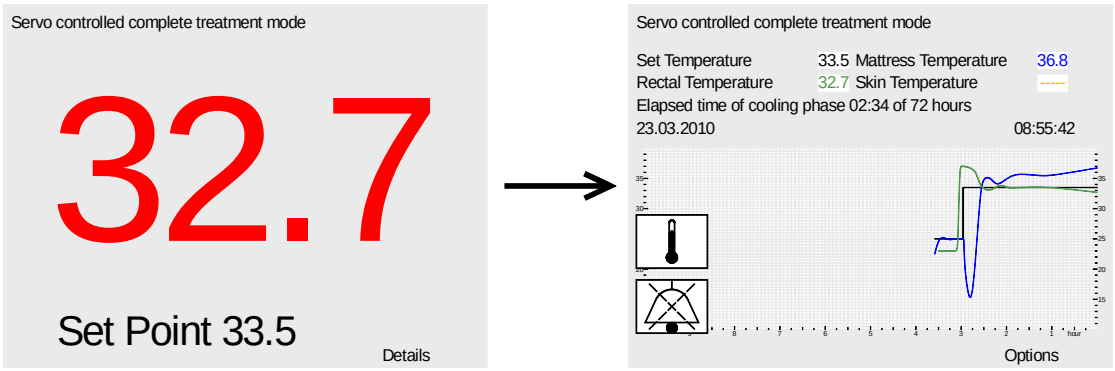
Caused by Communication error or problem between Operational Board and subordinated Control Board
The Control Board then creates an acoustic alarm, and SF LED (5) is lit.
System continues operating with the set parameters unless operator is silencing audible alarm pushing key T5 **AUDIO paused**
The Control Board then 10 seconds later is **switching off** the device

The operator can now analyse the situation. Turn **ON** the TECOTHERM NEO device to continue treatment operation.
If SF indicator alarm reappears switch system **Off.** After 5 seconds Turn On device again and try to continue in Treatment Mode 3 Constant Mattress Temperature as the Fallback Mode, see section 7.1.
If no success Shut **Off** the system and 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 and optical alarms appear.



Current Rectal Temperature → Temperature alarm, Alarm paused

Caused by Rectal Temperature probe disconnected from the device
Rectal Temperature probe is detached from patient
System operation temperature deviates more than ± 0,5°C from set rectal emperature
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 profilies 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.

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

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 no temperature indication appears repeat procedure with a new rectal probe.
If this fails you have to turn off the device, see Section 8.4.
Contact your service and inform.

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

If the 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 no temperature indication appears repeat procedure with a new rectal probe.
If this fails you have to turn off the device, see Section 8.4.
Contact your service and inform.

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

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

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

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 34,5
than set rectal temperature 33,5°C. This may be
Cause : System is fan cooled. May be free flow of air is restricted.

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

Measure Cooling capacity of the device may be reduced.
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 it onto a level hard support. Check whether distance 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 T1 Options to enter Main MENU and select entry Power Off using arrow keys. 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 to 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 temperature after some time.
If measured rectal temperature more and more deviates from the set rectal temperature the device is defective. Push key T1 Options to enter Main MENU and select entry Power Off using arrow keys. Device is shut down.
Do not switch on the device again! Contact your local service.

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

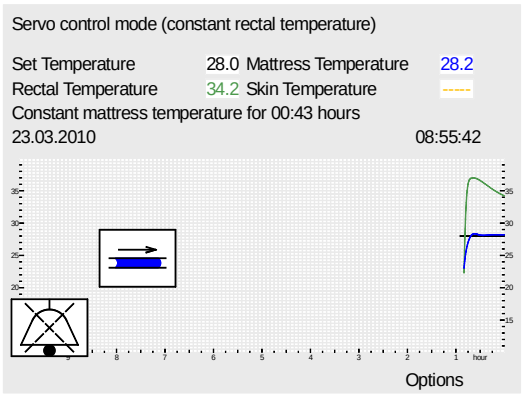
11.3 Alarm No Flow

No or very limited circulation / flow of the fluid

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

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

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



The mattress gets for more than 10 seconds too little fluid to maintain set temperature. Treatment temperature is not guaranteed.

Elimination/ Management

Case 1 Pump is defective / not working

System alarm SF is additionally appearing at the screen. How to proceeed see Section 11.1

Stop operation, shut off the device. Treatment is stopped.

If possible Replace TECOTHERM NEO device by a replacement unit or a spare unit.

Case 2 Inspect and check hoses, tubing, connecting couplings, mattress.

If you observe kinking or folding eliminate it.

Couplings Disconnect all and re-connect them.
Hoses, couplings 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.

Case 3 Volume of circulating fluid slightly too little or too little

Lack of fluid is not so big. **Low Fluid Level** alarm is not activated. Try to fill up **approx. 100 ml** fluid to enhance circulation (fill up until greater air bubbles disappear.)

Proceed as follows (see for details Section 8.5 and 8.6, too) :

- Connect only **one connector QDC of the fill-up bot**tle to the **right port** of the refill port QDC counterparts (7) at the device front face. Turn bottle until cap is directed downwards. Lift fill up bottle in a position ½ m higher than the TECOTHERM device. Keep this position.
  Observe whether symbol **No Flow** disappears.
- Note **: 5 sec** after disappearance of **No Flow symbol** → Disconnect bottle connector QDC from right port (7)). Lower fill-up bottle and turn it back into its normal vertical position. Unscrew bottle cap (1/2 revolution) for pressure compensation (a few seconds). Then close bottle cap tightly.

If you do not succeed

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

Otherwise stop treatment and immediately contact your local service for assistance.

11.4 Alarm Fluid level too low see Section 11.6, too

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.)

Caused by Leakage in the TECOTHERM NEO device / Hydraulic Module.
Lack of fluid caused by leakage in hoses, at couplings or in mattress

In the container Fluid volume is less than 1/3 for at least 10 seconds.

There are now 8 minutes to resolve the problem.

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. Proceed as in other alarm cases. Follow the instructions in the Main MENU. Contact your local service.

Elimination/ Management

If leakage or / and indication of escaped liquid/ traces of liquid in your urgent immediate inspection was not found refill the system. For refilling TECOmed follow the procedure of section 8.5.
Continue treatment following Main MENU instructions.
If alarm persists and symbol is not disappearing you have to make troubleshooting more systematically.

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 liquid/ moisture.
If you find a small or medium leak: Immediately Shut Off the device following the instructions in the Main MENU. Unplug mains. Contact / inform your local service.
If you find a small leak contact your service 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 there is a big leakage, replace this defective component immediately.

If you do not find a leakage to define the lack of fluid proceed as follows:

Refill TECOmed liquid acc. Sections 8.5 and 8.6 .

Symbol  must vanish. Observe the display screen.

If leakage is small you may replace the defective component. If no spare components are available, temporarily resolve the problem to finish patient treatment:

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

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.

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

We recommed 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.

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 optically indicated by separate LED lit indicator (4) at the device lower front side part, see section 7.3, and by a separate intensive 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 cable from mains socket.
Blown fuses.
Internal defect in the TECOTHERM NEO device

Elimination/ Management

Check whether key T1 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 are indicated on the device rear plate/ type label or in the Technical Specification at the end of these Instructions for Use).

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 or/ and 24 VDC TECOTHERM NEO will stop operation. Display is not operating (dark). LED Indicator (4) is activated and lit brightly green, audible alarm of higher sound intensity is generated.
The alarm can be silenced pushing key T5 AUDIO paused.

To continue treatment is not allowed.
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. Contact immediately your local service!

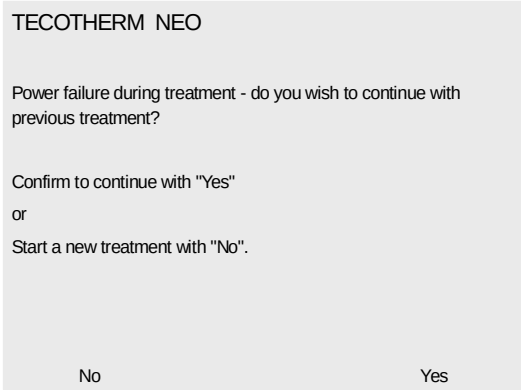
Power supply failure / No supply from the mains.

Operation is interrupted and stopped caused by mains power failure

NOTE Do **not push** key (1) to start a new operation.
TECOTHERM NEO will continue the previous treatment mode automatically when mains supply reappears.

TECOTHERM NEO is designed to continue operation in the previous treatment mode when mains voltage reappears. Treatment configuration is restored within an interruption period of **max. 60 minutes**

The operator is asked to continue the interrupted treatment or not, see MENU picture below. Confirm YES to continue or pushing key T3, NO to start a new treatment



11.6 Fluid escapes from the TECOTHERM NEO System

Also see section 11.4 of this IfU

Attention Large amounts of fluid are observed escaping from the system.

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

Attention Skin contact with the TECOmed fluid is harmless.
Do not swallow or ingest fluid!

Case 1 Fluid escapes from the TECOTHERM NEO device

Caused by Suddenly appearing internal defect or 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.

Management/ Elimination

STOP OPERATION, POWER OFF, UNPLUG MAINS.

Replace TECOTHERM NEO device by a replacement unit or a spare unit.
Put new system into operation/ Start operation following IfU
Contact your local service.

Case 2 Fluid escapes from the mattress or hoses

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.

Management/ Elimination

STOP OPERATION, POWER OFF, UNPLUG MAINS.

Try to localize the defect or leak. If you find the defect: Change defective component.

NOTE Possibly you have to refill fluid, see Section 8.5 and 8.6.

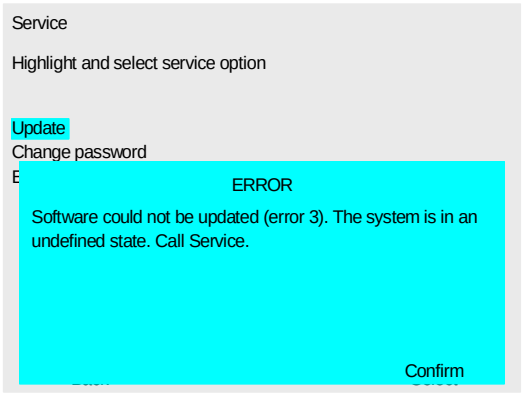
Replace TECOTHERM NEO device by a replacement unit or a spare unit.
Put new system into operation/ Start operation following IfU.
Contact your local service.

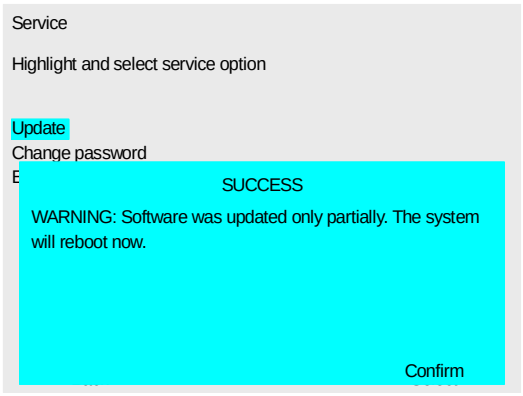
11.7 Fault Software Update Error

Normally software Up Date 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.
MENU shows instructions how to proceed if software up date is not or only partially successful. System will reboot.

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





12. Training & Qualification of personnel

Hypothermia treatment of patients requires skilled personnel.

All users must ensure they have been adequately trained

on treatment operations for inducing systemic hypothermia with the TECOTHERM NEO system within Intended Use

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

For more information contact your authorised service partner.

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.

Preventive maintenance measures

TECOTHERM NEO requires only few 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. Also check the bottom ventilation slits are clear and free from dust, 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 TECOmed fluid

The **TECOmed** fluid circulating in the **TECOTHERM NEO** system should be substituted every 3 months.
Substitution should be performed in the Treatment Mode 3 Constant Mattress Temperature.

If necessary Turn Off TECOTHERM NEO device, see Section 8.4
If necessary Put TECOTHERM NEO device onto a level table or support.

Take empty fill-up set, connect its QDC couplings to the QDC ports (6) at the device front face. Turn bottle until cap is directed upwards. Lower fill up bottle in a position lower than the TECOTHERM NEO device. Keep this position.

Start operation of the TECOTHERM NEO device according this IfU. Select treatment mode 3 in the MENU. Fluid will be pumped into the refill set bottle. Continue pumping until optical and audible signals “Fluid level too low, Refill” appear and no fluid flows into the bottle.
Stop device operation see Section 8.4, turn off.
Unplug fill-up set. Waste dispose fluid into a drain.

Fill bottle with fresh TECOmed fluid. Close bottle cap tightly.
Start refilling according to section 8.5 of this IfU.
Then repeat emptying procedure as described above.
Final step: Refill TECOTHERM NEO as described in section 8.5 of this IfU.

Substitution of TECOmed fluid is finished, TECOTHERM NEO is ready for operation.

13.4 Substitution of TECOmed fluid in mattresses and cool wraps

Mattresses and Cool Wraps completely or partially filled and stored for a longer time should be subject of TECOmed fluid substitution every 2- 3 months.
Detais see Section 8.6.

13.5 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.

13.6 Check/ calibration of temperature probes

To ensure proper operation and inteded use of the TECOTHERM NEO system use only probes authorised by the manufacturer TEC COM GmbH.

Rectal and Skin Temperature Probes are delivered as autoclavable applied parts.
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.

13.7 Safety, Reliability

Caution For a reliable and safe operation of the TECOTHERM NEO use only original components, parts and spare parts 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!

14. Technical Data / TECOTHERM NEO Specificatio

Options	Cooling & Warming
Dimensions	375 x 190 / 215 x 310 mm (W x D x H)
Weight without accessories	approx. 7,2 kg
Central Cooling Module	Thermoelectrically based module
Treatment temperature control ranges	
Neonate, Babies	Mattress + 12 °C to + 38 °C Rectal BCT + 32 °C ..33,5 ...+ 37°C
Children	Mattress + 12 °C to + 39 °C Rectal BCT + 30 °C .....+ 38°C
Patient weight max.	≤ 50 kg
Control Systems	
Operating System	1. Microcomputer with MENU
Control System	2. Micocomputer based Control
MainTreatment Modes automatically	Servo Control Complete Treatment
automatically	Servo Control Constant Rectal Temperature
	Constant Mattress Temperature
Temperature Constancy	± 0,3 °C
Hydraulic Circulation System	
System pressure max.	0,5 bar
Flow rate with / without mattress	up to 300 ml / min / up to 500ml
Internal Fluid reservoir capacity	approx. 250 ml
Circulating Fluid	TECOmed Fluid
Connectors / Couplings	Quick Disconnect Couplings
Fill Up / Refill	Fill Up Set
Electrical Parameters	
Supply Voltage / Mains	230 VAC, 50 Hz
Current	1,5 A
Fuses	2xT 2,5 A /250 VAC , träge
Power	max. 345 W
Leakage Current	< 200 µA
Mains Power Cordl	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 , lupper 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	dito
Alarm Low fluid level	dito
Alarm Temperature deviation	dito
Ambient conditions	
Operation / Treatment Ambient Temperatures	+ 5 °C bis + 27 °C
Operation/ Treatment Relative Humidity	10% - 75%, no condensation of water
Storage / Transport Filled with fluid,	+ 5°C ..... + 40°C
No fluid	-5°C ..... + 60°C
Relative Humidity	5% - 90% , no condensation of water
System safety	
Protection class	Class 1, Risk Class II b, Type BF IP 20
Standards	DIN EN 60601-1, DIN EN 60601-1-2, , DIN EN 60601-1-6, DIN EN 60601-1-8, DIN EN 60.601-1-10; DIN EN 60.601- 2- 35 E/F
Certificate	CE 0494

Device of class I for use with shockproof mains sockets, 230 V / 50 Hz
Class of risk IIb acc. ann. IX of Medical Device Directive 93/42/EEC.
Type BF applied part

15. CE Conformity declaration

Manufacturer: TEC COM GmbH
Address: Böllberger Weg 170
D-06128 Halle, Germany

The manufacturer, certified according ISO 13485
herewith declares that the actual device Hypothermia System **TECOTHERM NEO** fully 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
Physiologically closed loop systems PCLS	EN 60601-1-10:2008
Safety of mattresses etc	EN 60601-2-35: 2009:10 E/F

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

Each device is produced in full compliance with the technical documentation.

Place, date Halle, April 2010

Signature

Manufacturer
TEC COM GmbH
Gesellschaft für Technik,
Technologie und Vermarktung
Böllberger Weg 170
D - 06128 Halle / Saale

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Tel: + 44(0)1455 840555
Fax: + 44(0)1455 841464
E Mail: info@inspiration-healthcare.co.uk

16. Disposal

This device must not disposed of as common industrial waste 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.