TEC COM GmbH

# TECOTHERM NEO

## MEDICAL EQUIPMENT for HYPOTHERMIA of NEONATES and INFANTS

Addendum 1 to

# Instructions for Use

Applicable for software version 038/02.13 and higher, revision August 2011

# 6. TECOTHERM NEO operating functions

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

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

## 6.1 The physiological closed-loop circuit (PCLC)

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

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

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

This also does lead to increased nursing requirements, since repeated adjustments in temperature will become necessary.

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

Like any other temperature control system TECOTHERM NEO comprises a closed-loop control circuit. Any deviation from target settings is counteracted **immediately**. Assuming that the rectal temperature measurement is 0.1° higher than it should be, at any given point in time, the control system will lower the mattress temperature by 0.8° since the internally programmed amplification factor has a value of 8. With a certain element of delay this lowering of mattress temperature will result in a corresponding decrease in rectal temperature and the subsequent gradual convergence back towards the target value. As a result the decrease in mattress temperature will in turn be reduced. Thus the cycle is closed and since the regulated rectal temperature is a physiological size of measurement this represents a **physiological closed-loop circuit (PCLC)**.

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

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

- The temperature regulating fluid must circulate at a flow rate sufficiently high to ensure an efficient thermal transfer to or away from the patient. This process is

monitored by the unit and, if required, the operator will be alerted to initiate appropriate corrective measures.

- There must be sufficient thermal contact between the coolant fluid perfusion mattress and the patient, as any change in mattress temperature may otherwise have no or only limited effect on rectal temperature. It is of crucial importance for the user to position the mattress correctly and in accordance with the operating instructions (see 8.7). The equipment can detect any fault in this respect only after lapse of the response period of approx. 30 minutes, at the earliest, if despite constant adjustment of mattress temperature the expected reaction in rectal temperature does not occur and the rectal temperature eventually moves outside the permissible range of +/- 0.5° around the target value. Only at that point in time will a temperature alarm be activated.
- Rectal temperature, as the measurement ultimately to be regulated, must be recorded accurately. Incorrect measurements taken over an extended period of time, regardless of cause, would immediately result in an unwanted change in the patient's actual core body temperature.

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

## 6.2 Fallback mode

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

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

Unfortunately it is not possible to permanently monitor the rectal probe with the aid of a second control probe, as the insertion of 2 rectal probes would be impossible in the case of an infant. The otherwise recommended control by means of an additional skin probe is not sufficiently accurate and too exposed to potential external impact for such readings to be used in arriving at an informed decision. For these reasons measuring results taken from the rectal probe are checked as to plausibility, whereby it will depend upon the relevant stage of treatment as to what range of values for rectal temperature recordings will be classified as being plausible and therefore acceptable. In the case of measurements occurring systematically outside this specified **range of acceptance** TECOTHERM NEO will stop operating as a **physiological closed-loop circuit** and instead switch into **fallback mode**. The operator will be alerted and informed about the current status and subsequently needs to decide upon an appropriate course of action. Depending upon the stage of treatment a choice of suitable options will be given for the unit to immediately resume operations. The operator can now follow these prompts or make changes according to his own assessment of what actions may be required.

The key characteristic of the **fallback mode** is, that the required mattress temperature will not be longer calculated by the temperature control system, but that it now needs to be specified by the **user**. In order to be able to take an informed decision under these circumstances the operator immediately needs to arrange for alternative methods of continuing a reliable recording of the patient's rectal temperature, completely independent from the TECOTHERM NEO system.

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

### 6.2.1 Plausibility limitations in rectal temperature measurement

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

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

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

### 6.2.2 Operations during fallback mode

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

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

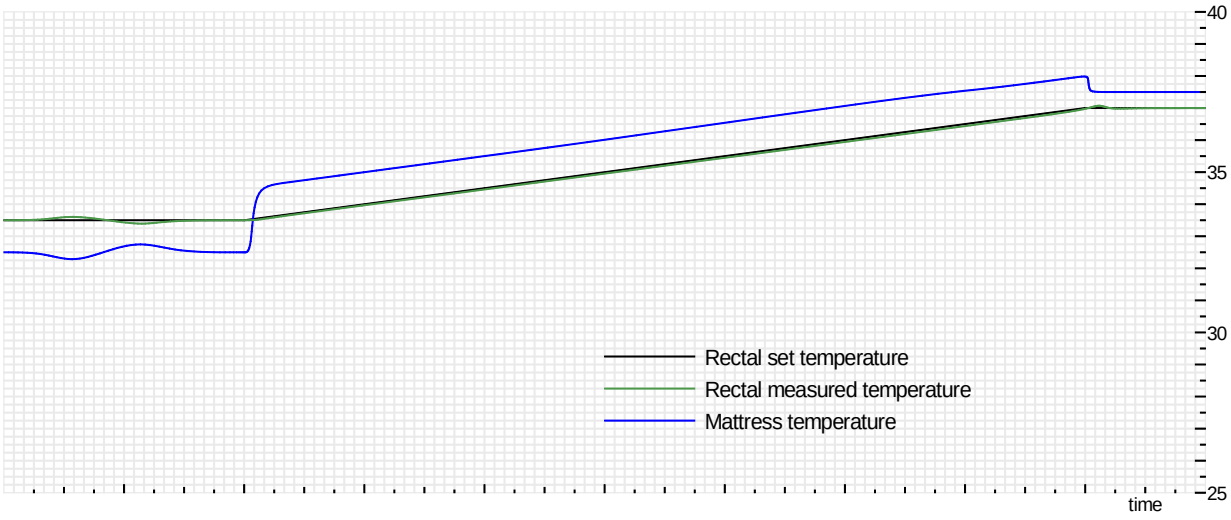
If the rectal temperature is to be either kept constant or to be adjusted to a specific value as quickly as possible, then the mattress temperature will be used as an immediate control parameter which can be reset, if required, at any time.

During the initial phase of rapid cooling down to e.g. 33.5°C the pre-defined setting for fallback mode will be a mattress temperature of 20°C. This will initially ensure that the cooling down process, once initiated, will be continued. Depending on how far the cooling down process has progressed up to this point, the temperature level of 20°C

may still be too high or otherwise already too low. This needs to be assessed by the operator on the basis of an independent measurement of the patient's actual rectal temperature and the temperature will subsequently need to be adjusted accordingly. As soon as the (independently measured) rectal temperature does approach the target value of 33.5 °C additional adjustments to mattress temperature will become necessary, in order to stabilise the temperature at 33.5°C and to prevent any further cooling down of the patient.

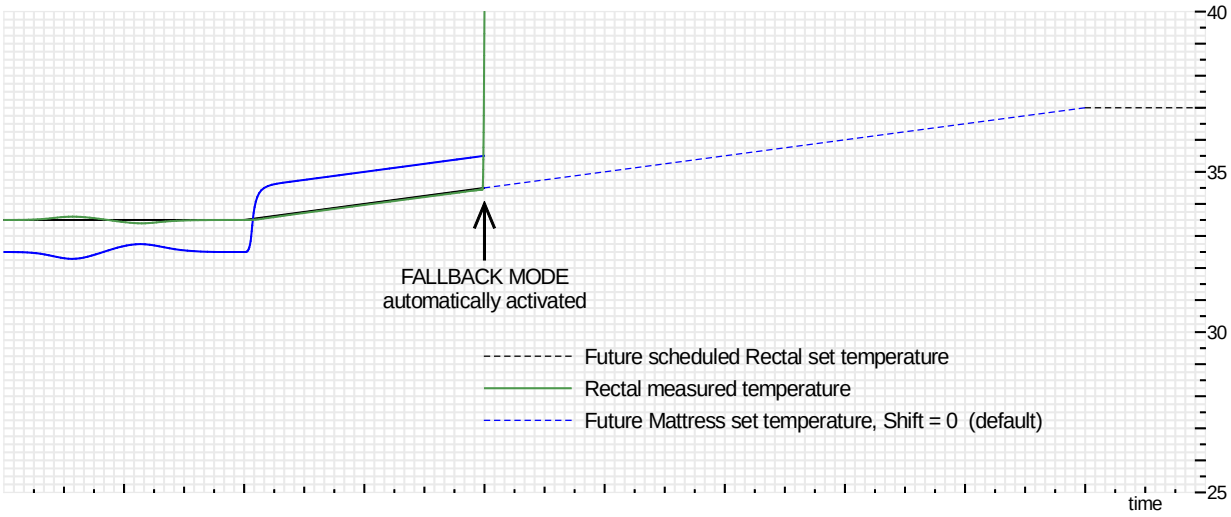
In phases during which the rectal temperature is to be kept constant, e.g. at 33.5°C or ultimately 37°C, the pre-setting for the mattress temperature will be the same as that for the rectal temperature to be maintained at a constant level. Depending on ambient conditions as well as the patient this may be marginally too high or somewhat too low. The progression of mattress temperature up to that point, as shown in the diagram, will provide useful guidance in this respect for corrective measures to be taken. If the fallback mode continues to hold any longer, the operator will again have to assess, on the basis of independently taken readings of the patient's rectal temperature, whether the choice of mattress temperature has been correct.

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

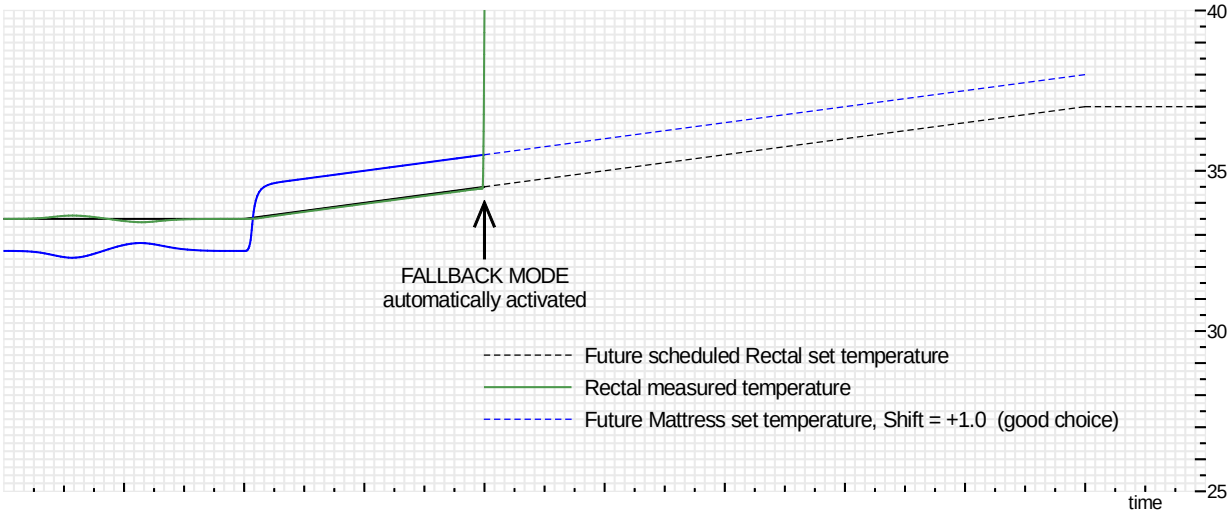



In practice, however, the mattress temperature will not always need to be exactly 1° above the rectal temperature and depending on the patient it may be even higher, as well as lower, than the rectal temperature. Certain fluctuations may also be due to interference, as indicated in the left segment of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

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




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



## 7.1 Description of system, operating modes

The so called **thermal preparation of the mattress phase**, familiar from the two operating modes of

I SERVO CONTROL Programmable Complete Treatment Mode

II SERVO CONTROL Constant Rectal Temperature Mode

during which the mattress could be warmed up or cooled to a suitable level of temperature, already prior to the commencement of actual treatment, is **no longer** available. This simplifies use of the equipment and does prevent the occurrence of potential operating errors.
Immediate adjustment of the patient's temperature is safeguarded, in any event.

## 11. Alarm system, malfunctions, incident management

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

In the critical case of a potential disruption in normal circulation of the coolant fluid there will no longer be just the warning symbol shown on the display, but an additional text display with instructions will be appearing as well. This text field will give information concerning the nature of the fault, as well as providing instructions as to what measures need to be taken to eliminate the problem. This text field will not disappear automatically but must be separately closed, using a push button, thus allowing sufficient time for the information displayed to be read and understood by the user.

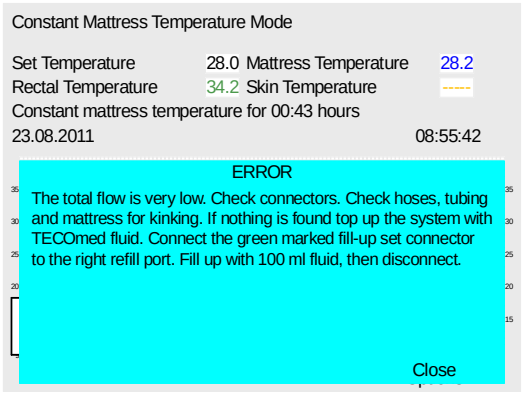
In a number of instances it will be necessary to recharge the system with additional TECOmed cooling fluid, whilst at the same time preventing any potential escape of air from the system. This is accomplished by not attaching the refill-set to the unit using both connectors, as would be normal procedure, but attaching only the plug marked green to the connector on the right. The unit will now draw TECOmed from the refill tank and air will flow back through the check valve into the refill container, without anything being able to escape from the unit.

## 11.3 Flow rate alarm

Flow rate alarm  Insufficient circulation of cooling fluid.

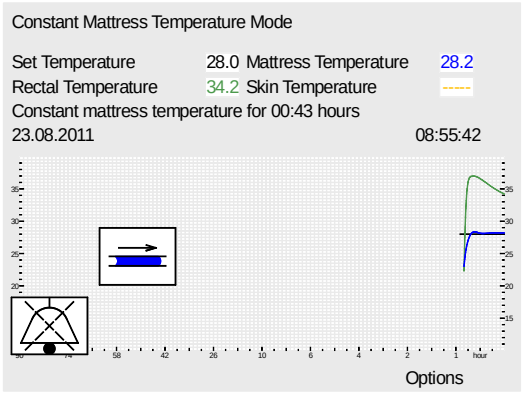
Maintenance of the treatment temperature is no longer safeguarded. An acoustic alarm will sound and a pop-up window will inform the operator what actions need to be taken in order to restore normal circulation.

Example:




**Caution**: We recommend to initially pause the acoustic alarm by pressing the lit up push button T5.

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




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