Instruction for use

Neonatal warming bed

THERMOCARE K

D2011_01

THERMOCARE K	**WY2030 /**	_____
Under-pad heating device	WY2010 /	_____
Year of manufacture:		_____
Software	LFSE	V 1.00

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Normal use

The neonatal warming bed THERMOCARE K is used for warming care of infants up to 12 kg weight and for performing basic therapies such as oxygen therapy and phototherapy or similar. It is suitable for continuous operation and complies with the "Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use EN-60601-2-35:2010".

General safety instructions

The user must be thoroughly acquainted with this instruction for use. The warming bed must only be used under medical supervision by qualified persons only who are acquainted with the use and risks of under-pad heating devices.

This instruction for use must be kept ready to hand for the user.

The under-pad heating device must be used with the original Weyer gel pad order No. WY0620 only. Otherwise the safety features of the neonatal warming bed are impaired.

When the under-pad heating device is switched off, the gel pad may cause a reduction of the patient's temperature. When nevertheless the neonatal warming bed shall be used with switched off under-pad heating device, for insulation purposes a foam pad or woollen nappy, at least 2 cm thick, must be placed between patient and gel pad.

In order to ascertain the safe operation of the neonatal warming bed, we recommend inspections at regular intervals to be performed by qualified persons.

In order to maintain the nominal state of the neonatal warmng bed we recommend preventive maintenance at regular intervals to be performed by authorized qualified persons. For normal operating conditions we recommend yearly intervals whereas under unfavourable ambient conditions and in case of high duty use half-yearly intervals should be observed.

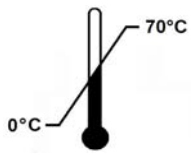
When connecting additional devices to the warming bed the latest version of the "General requirements for the safety of medical electrical systems EN 60601-1-1 + Supplement A1" must be observed. The max. power input is specified at the take-off sockets and must be considered. The total leakage currents of the connected additional devices must not exceed 250 µA.

We can only be held responsible for the safety features of the neonatal warming bed when preventive maintenance and repairs are carried out by authorized qualified persons, by observing our instructions and by using original spare parts.

Transport and storage

For transport and storage the following conditions should be observed:

Temperature:



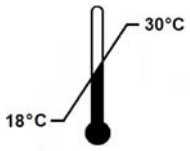
Relative air humidity:	15 to 95 %
Atmospheric pressure	210 to 1100 hPa

The neonatal warming bed must not be exposed to strong vibrations, such as e.g. transport over cobblestone pavement.

Ambient requirements

The neonatal warming bed can be used under the following operation conditions:

Temperature:



Relative air humidity: 15 to 95 %
Atmospheric pressure 860 to 1100 hPa

The neonatal warming bed is not suitable for the use in explosion-hazardous areas.

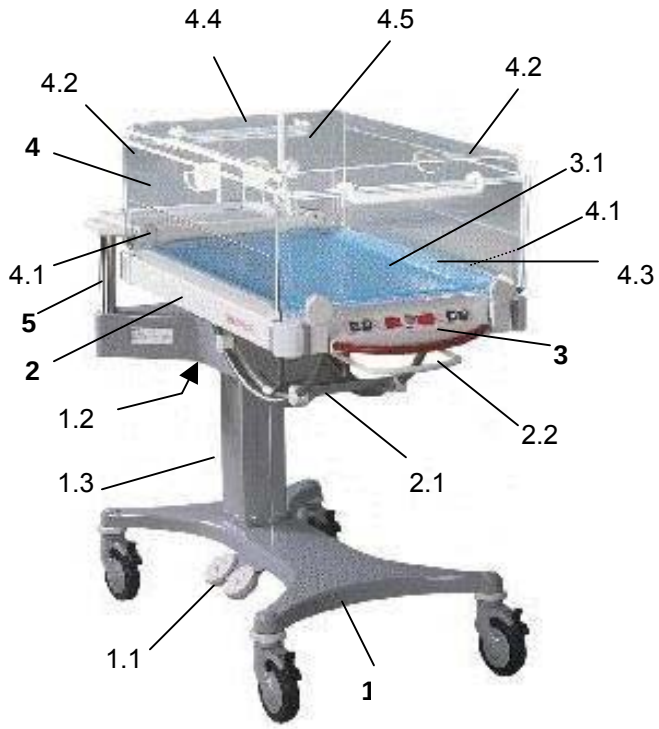
Installation

For installation of the neonatal warming bed it has to be considered that heating or air conditioning devices may change the effect of the neonatal warming bed. Therefore a distance of 1 m should be kept clear. The distance of 1 m should also be kept between two warming beds. Places in draughts, at cold walls or windows as well in direct sunlight should be avoided.

Structure and operating principle

The neonatal warming bed THERMOCARE K consists of the following components assemblies:

1. **Trolley**
   - 1.1 Height-adjustment
   - 1.2 Electrical distribution / Take-off sockets
   - 1.3 Upgrade items / accessories
2. **Bassinet**
   - 2.1 Tilting facility
   - 2.2 Catch
3. **Under-pad heating device**
   - 3.1 Thermo-conductive gel pad
4. **Perspex wall assembly with canopy**
   - 4.1 Safety side walls
   - 4.2 Seiten walls
   - 4.3 Front wall
   - 4.4 Rear Wall
   - 4.5 Canopy
5. **High-grade steel tubes**
   with instrument and monitor shelf
   (Upgrade items / accessories)



1. Trolley

The trolley supports the complete device. It has four antistatic swivel castors, (3 with total lock, 1 with directional lock for easy movability). Four bumpers are provided to protect from damages during a transport.

1.1 Height adjustment

The warming bed is height-adjustable by foot pedals, i.e. the complete device is moved electromotively, including the connected additional devices. The foot pedals can be arranged at the front or at the side of the device. As an option a second pair of pedals can be provided.

1.2 Electrical distribution / Take-off sockets

2 take-off sockets ~ 230 V and the power connection for the under-pad heating device are arranged below the rearside of the trolley.

1.3 Upgrade items / Accessories

A shelf or a drawer assembly with 2 drawers are available for storing necessary material (refer to page 18).

2. Bassinet

The bassinet with tilting facility is arranged on the trolley. Raised sides prevent the infant from trundling out of the bassinet.

2.1 Tilting facility

The tilting facility below the bassinet allows a head up / feet down position up to 20° and a feet up / head down position up to 10°. A catch (2.2) is provided to fix the bassinet in the desired tilt position.

3. Under-pad heating device

An electical heating device is incorporated in the bottom of the bassinet. The temperature is precisely controlled to the selected value. The heat is accumulated in a gel pad (3.1) which conducts it to the patient (conductive heat transfer).

The actual under-pad temperature and the selected temperature are permanently displayed. Deviations from the temperature selection, system faults as well as interruption of the power supply are alerted visually and audibly.

The temperature display does not give a reliable indication as to the patient's body temperature. Therefore the patient's temperature must be checked in regular intervals or monitored.

When the under-pad heating device is switched off, the gel pad (3.1) may cause a cooling of the patient. When nevertheless the warming bed shall be used with switched off under-pad heating device, for insulation purposes a foam pad or woollen nappy, at least 2 cm thick, should be placed between patient and gel pad.

4. Perspex wall assembly with canopy

The four perspex walls protect the patient from draught and falling from the bassinet. The warming bed can be closed with the canopy (4.5), in that case oxygen can be supplied through the oxygen connector in the rear wall (4.4) into the interior. The open corners of the wall assembly allow a sufficient supply of air and prevent an accumulation of CO_2 in the interior. For better accessibility during treatment the two side walls (4.2) can be folded down with one hand. When the canopy (4.5) is not attached, also the front wall (4.3) can be folded down. Two safety side walls (4.1) are additionally provided to protect the patient when the side walls are folded down. When the safety side walls (4.1) are not in use they can be retracted into the bassinet.

Cables and tubes connected to the patient are passed through the grommets and the gate in the rear wall (4.4).

5. High-grade steel tubes

with instrument and monitor shelf (Upgrade items / accessories)

Two high-grade steel tubes are provided at the rear of the warming bed for fixing upgrade items and accessories. Additional devices can be placed on the instrument and monitor shelf.

When connecting additional devices to the warming bed the latest version of the "General requirements for the safety of medical electrical systems EN 60601-1-1 + Supplement A1" must be observed. The max. power input is specified at the take-off sockets and must be considered. The total leakage currents of the connected additional devices must not exceed 250 µA.

Start-up

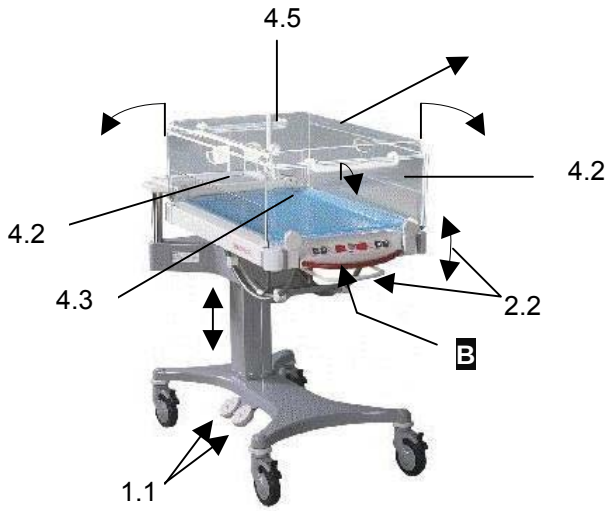
Qualified persons only should install and start-up the warming bed and instruct the user's personnel.

Before start-up all components of the warming bed must be checked for correct and secure position as well as for correct function.

The under-pad heating device must be equipped with a 9V battery which is included in the delivery of the device. The battery compartment B is placed below the bassinet.

Prior to operation the warming bed must be prepared in cold condition according to chapter "Cleaning and disinfection" (page 24).

Function check of the moving mechanical components



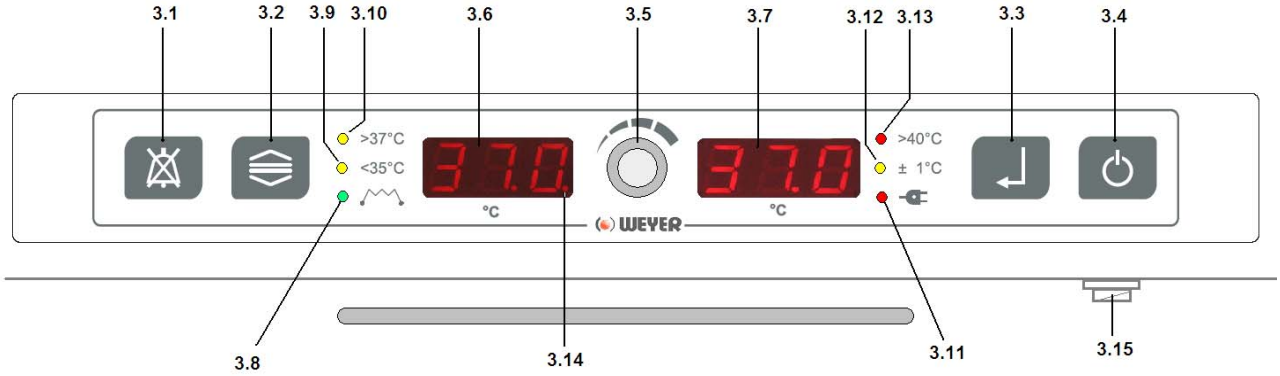
Move the bassinet with the foot pedals (1.1) to the lowest and then to the highest position. Make sure that no items or devices are placed within in the moving range.

Unlock the catch (2.2) below the frontside of the bassinet by pulling and tilt the bassinet to feet up / head down and then in reverse position. Check in several positions whether the catch (2.2) locks automatically when being released and whether the bassinet is fixed in this position.

For checking the functions of the perspex walls take off the canopy (4.5). Unlock the side walls (4.2) and the front wall (4.3) by lifting and fold them down. They must latch securely again simply by folding up.

Before switching on the under-pad heating device make yourself acquainted with the following control elements and displays.

Functions of the under-pad heating device



3.1 Key audio alarm pause. By pressing the key in case of high or low temperature alarm, the audio alarm is paused for 15 minutes. The length of the alarm pause depends on the alarm priority.

3.2 a) Unlocking key for the extended temperature range (30°C to 35°C and 37°C to 38.5°C).
b) Activation of brightness adjustment of the displays 3.6 and 3.7 with knob 3.5.

3.3 Enter key for confirming the desired under-pad temperature (selection).

3.4 Key heating On / Off.

3.5 a) Rotary knob for selection of the under-pad temperature.
b) Brightness adjustment of displays 3.6 and 3.7

3.6 a) Temperature selection display.
b) Error display.

3.7 a) Actual temperature display.
b) Error display.

3.8 Pilot lamp (green) heating power. Lights when heating power is available.
When the lamp lights, the bassinet will heat-up, when it does not light, the bassinet will cool-off.

3.9 Warning lamp (yellow). Lights in case of temperature selection below 35°C.

3.10 Warning lamp (yellow). Lights in case of temperature selection above 37°C.

3.11 Warning lamp (red). When it lights together with a permanent audio alarm the power supply of the under-pad heating device is interrupted. The alarm can be reset by switching off the heating (3.4). After reinstallation of the power supply the heating must be switched on again.

3.12 Warning lamp (yellow). Flashes in case of deviation between selected and actual temperature above 1°C.

3.13 Warning lamp (red). Flashes in case of bassinet temperature above 40°C.

3.14 Flashing point. Indicates that the internal processor is working.

3.15 Central switch-off button for under-pad heating.

Switch on the under-pad heating device

Switch-on test:

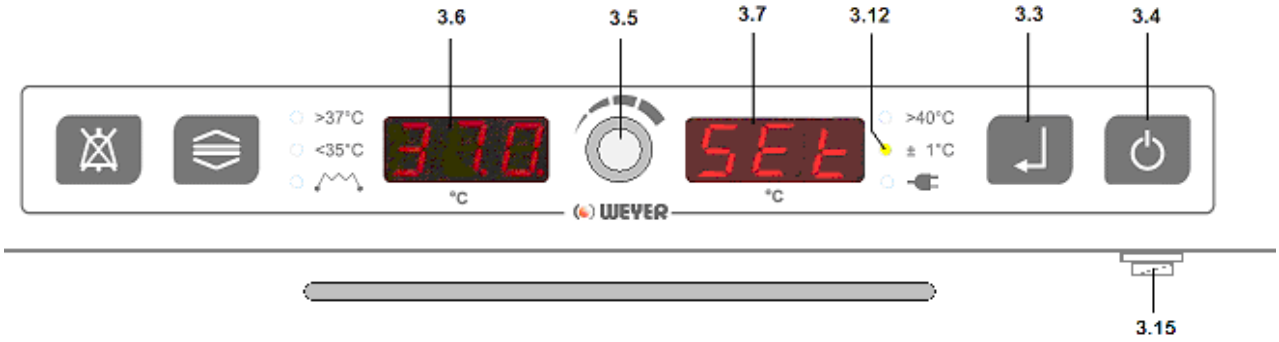
First of all make sure that the warming bed is connected to the power supply.

Press key (3.4) until the under-pad heating device is switched on. A tone sounds and all displays light-up for 2 seconds. Both displays (3.6) and (3.7) indicate the value 88.8. Check during the 2 seconds whether all displays light up and the tone sounds. Simultaneously the internal processor automatically checks the vital functions of the electronical control. When the under-pad heating device is not switched on, press key (3.15) (righthand below the bassinet).

When the internal automatic switch-on test was not successful, the reason will be displayed as an error code.

Start heating:

When the under-pad heating device is switched on after being switched off for more than 10 minutes, the value 37.0°C flashes in the temperature selection display (3.6) while the actual temperature display (3.7) indicates SET. Furthermore an indicative alarm tone sounds at intervals of 5 seconds.



Now the temperature value suggested in display (3.6) can either be entered by pressing key (3.3) or adjusted with the rotary knob (3.5). The adjusted value must be entered by pressing key (3.3). Then the under-pad heating device will heat according to the selection.

When the under-pad heating device is switched on after being switched off for less than 10 minutes, it will start heating with the last temperature selection.

Temperature selection:

The temperature selection is devided in two ranges, i.e. the "standard" range (35°C to 37°C) and the "extended" range (30°C to 35°C and 37°C to 38.5°C).

In the standard range the temperature can be adjusted with the rotary knob (3.5) in increments of 0.1°C. Each increment is confirmed by a short tone. The temperature is increased by turning the knob (3.5) clock-wise and reduced by turning it anti-clockwise. During adjustment the currently selected temperature flashes. This temperature is entered by pressing key (3.3) and will then be permanently indicated in display (3.6). When key (3.3) is not pressed within 10 seconds after adjustment the under-pad heating device will continue to operate with last setting.

When a temperature value in the extended range (30°C to 35°C and 37°C to 38.5°C) shall be selected, turn knob (3.5) briefly, the display (3.6) flashes. Now the desired temperature can be adjusted while keeping key (3.2) pressed. This temperature is entered by pressing key (3.3) and will then be permanently indicated in display (3.6). When key (3.3) is not pressed within 10 seconds after adjustment the under-pad heating device will continue to operate with last setting.

When the selected temperature is lower than 35°C the yellow warning lamp (3.9) lights. When the selected temperature is higher than 37°C the yellow warning lamp (3.10) lights.

Remark for heating up:

Heating up the bassinet from ambient temperature to 37°C will take approx. 15 minutes. It may take up to 10 minutes more until the gel pad itself has reached the selected temperature.

Brightness adjustment of the temperature display:

When key (3.2) is pressed during operation, the brightness of displays (3.6) and (3.7) can be adjusted with rotary knob (3.5).

Alarm system:

The under-pad heating device provides an alarm system with 4 priority levels:

High - Medium - Low - Indicative

The alarms are indicated visually and audibly (audio alarm).

The quicker the sequence of alarm tones and the shorter the pauses, the higher is the alarm priority.

Audio alarms can be paused with key (3.1) for a certain period. The pause period is according to the alarm priority.

Audio alarms are paused automatically for a certain period when they were caused by a logical action of the user, e.g. in case of temperature adjustment.

The most common alarms which are released during operation are mentioned in the following list. A complete list of alarms can be found on pages 20 to 23.

Hazard/ Error condition	Alarm priority			Warning lamp	Temperature display		Action needed	Consequence when neglected
					Selection	Actual		
Battery capacity not sufficient for power failure alarm	Indic-ative	Mute	- , -	None	e.g.  every 15 Sec. 	e.g.  every 15 Sec. 	Replace battery.	Power failure alarm not sufficiently secured.
Temperature more than 1°C below selection	Medium	Inter-mittent	Yes 1.)	● ±1°C Yellow	e.g. 	e.g. 	Pause audio alarm. 2.) Watch the patient's temperature. If necessary relocate the patient or place an isolating blanket between patient and pad.	Patient cools down and becomes hypothermic.
Temperature more than 1°C above selection. (Possibly sun-light, external warming devices?)	Medium	Inter-mittent	Yes 1.) 2.) 3.)	● ± 1°C Yellow	e.g. 	e.g. 	Pause audio alarm. 2.) Watch the patient's temperature. If necessary relocate the patient or place an isolating blanket between patient and pad.	Patient becomes hyperthermic for a short while. After automatic safety switch-off he can become hypo-thermic again.
Interruption of power supply	Medium	Perm-anent	No	● Red	Dark	Dark 	Switch off under-pad heating, re-install power supply. If necessary relocate the patient or place an isolating blanket between patient and pad.	Patient cools down and becomes hypothermic.
Selection > 37°C	Indic-ative	Mute	- , -	● >37°C Yellow	> 37°C 	e.g. 	Increased attention, check patient's temperature	Patient's core temperature increases.
Selection < 37°C	Indic-ative	Mute	-,-	● <37°C Yellow	< 37°C 	e.g. 	Increased attention, check patient's temperature	Patient's core temperature can fall.

1.) Automatic alarm pause caused by a logical action of the user (e.g. temperature adjustment).

2.) When alarms are paused repeatedly there is a permanent fault which must be removed. In such cases the heating is cut off automatically and the audio alarm can no longer be paused. Switch off the under-pad heating with key (3.4) and switch it on again when the fault has been removed.

3.) At an ambient temperature above 30°C and a temperature selection of 30°C a high temperature alarm may be released. In that case increase the temperature selection to 32°C or switch off the under-pad heating device. When the under-pad heating device is switched off, place a foam pad at least 2 cm thick or a woollen blanket between patient and gel pad in order to avoid that heat is withdrawn from the patient by the cooling gel pad.

Hazard/ Error condition	Alarm priority			Warning lamp	Temperature display		Action needed	Consequence when neglected
					Selection	Actual		
Bassinet is warmer than 40°C.	High	Inter-mittent	Yes	● >40°C also ● ± 1°C Yellow	e.g. 	e.g. 	Check whether high temperature was caused by sunlight or external warming devices. Switch off under-pad heating device temporarily. Watch temperature (residual heat). When the bassinet will not cool down, disconnect the under-pad heating device from the power supply with the central switch-off button (3.15) . Place an isolating blanket between patient and pad. Depending on the situation relocate the patient. Remove the alarm cause.	Patient can become dangerously hyperthermic. Attention: Above 42°C danger of burns.
Bassinet is warmer than 40,5°C.	High	Perm-anent	No					
Error in the control system	High	Perm-anent	No	Depending on situation		Code  up to 	Switch off the under-pad heating device immediately with central button (3.15) and have it repaired. Relocate patient.	Relay de-energized. Patient may cool down and become hypothermic.

End of operation

Switch off the under-pad heating device with key (3.4). All displays extinguish, with the exception of the actual temperature display (3.7). When the under-pad heating device is connected to the power supply, the under-pad temperature is displayed until it has fallen below 30°C.

Remark:
When the under-pad heating device is switched on again within 10 minutes after switch-off, it will start immediately with the last temperature selection.

When the under-pad heating device must be disconnected from the power supply for reasons of device failure or external influences, push central switch-off button (3.15), righthand below the bassinet.

Use

Warnings for use

General

- The neonatal warming bed is not suitable for the use in explosion-hazardous areas.
- The ambient conditions of the warming bed must in no case be influenced by any warming or air condition devices which do not comply with the system.
- Heating up the bassinet from ambient temperature to 37°C will take approx. 15 minutes. It may take up to 10 minutes more until the gel pad itself has reached the selected temperature. If necessary the heating up process can be accelerated by turning the gel pad upside down during heating up.
- The display of the neonatal warming bed does not give a reliable indication as to the patient's body temperature.
- The patient's temperature must be checked in regular intervals or monitored, e.g. with the temperature monitor APGAR-DIGITEMP order No. WY1004.
- Sunlight, draught, cold walls and windows in direct ambience to the warming bed will influence the patient's temperature balance negatively. Furthermore alarms can be caused hereby.
- When connecting additional devices to the warming bed the latest version of the "General requirements for the safety of medical electrical systems EN 60601-1-1 + Supplement A1" must be observed. The max. power input is specified at the take-off sockets and must be considered. The total leakage currents of the connected additional devices must not exceed 250 µA.
- Take care that the patient is never unattended when one or more persepex walls (4.2/4.3) of the bassinet are folded down.

Adjustment

- During height-adjustment make sure that no device components or additional devices connected to the warming bed can touch furniture items or other devices in the ambience.
- It should also be considered that accessories, which are not fixed at the neonatal warming bed, will not be moved and therefore connected lines and tubes might be pulled off.
- When moving the neonatal warming bed around bring the height adjustment into the lowest position.

Under-pad heating device

- The under-pad heating device must be used with the original Weyer gel pad order No. WY0620 only. Using other kinds of pads will influence the temperature characteristics negatively.
- The gel pad cannot destaticize, is not autoclavable and not washing-machine proof.
- The gel pad can only be bent slightly and therefore must not be folded or laid over sharp edges. Sharp instruments like needles, knives or scissors will damage or even destroy the pad.
- When the under-pad heating device is switched off, the gel pad may cause a reduction of the patient's temperature. When nevertheless the bassinet shall be used with switched off under-pad heating device, for insulation purposes a foam pad or woollen nappy, at least 2 cm thick, must be placed between patient and gel pad.

Phototherapy

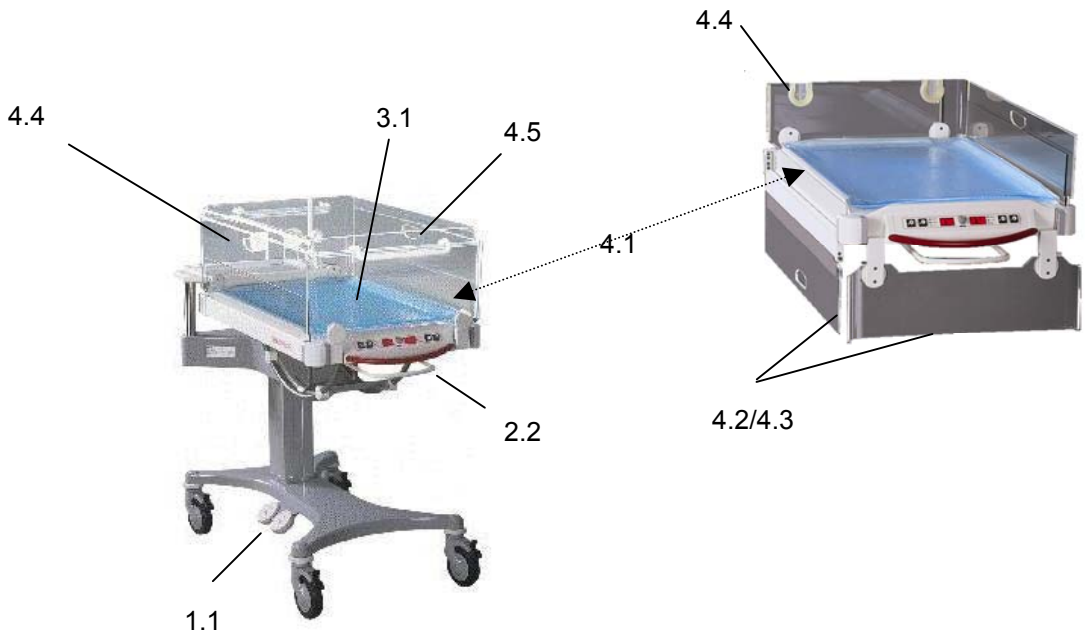
- When the warming bed is used in connection with a phototherapy device, it must be observed that patient's temperature and humidity loss can increase.
- Observe the patient's body core temperature. Reduce the temperature selection of the under-pad heating device if necessary.
- Increase the hydration for the patient according to the increased water absorption by the phototherapy.

Bassinet with perspex wall assembly

Move the bassinet to desired level with the foot pedals (1.1). Take-off the canopy (4.5). Cover the gel pad (3.1) with a **thin nappy**. Take care that the nappy does not block the wall locking system. The front and side walls (4.2/4.3) must always close smoothly and latch securely. The safety walls (4.1) should be inserted in a way that the patient cannot fall from the bassinet. For better accessibility they can be taken out of their support and inserted again set off by 180°. Thus the walls are retracted into the bassinet, allowing full access to the patient.

Cables and tubes connected to the patient should be passed exclusively through the grommets and the gate in the rear wall (4.4).

When the under pad heating device is at operation temperature, place the patient on the pad. Take care that the walls are folded up so that the patient cannot fall from the bassinet. Make sure that no body parts, cables of additional devices and tubes are squeezed. Attach the canopy (4.5), if necessary. After unlocking the catch (2.2) tilt the bassinet to the desired position. After releasing the catch check whether it has locked and the bassinet is fixed.



Temperature selection of the under-pad heating device

The temperature selection of the under-pad heating depends on several factors, e.g.:

- Age and maturity of the patient.
- Weight.
- Does the patient suffer from Hypothermia / Hyperthermia?
- Are vital functions impaired?
- Which accompanying therapies are applied?
- Is the patient clothed or unclothed?

For a mature unclothed infant a bassinet temperature of approx. 36.5°C should be selected.

For a pre-term neonate a temperature of approx. 37° to 37.5°C is recommendable.

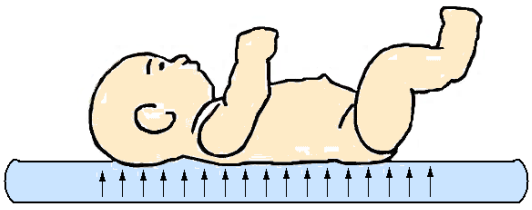
For clothed infants the bassinet temperature can be selected 0.5 to 1°C lower.

For temperature selection it must be considered that the temperature of the gel pad has a direct influence on the patient (thermal conduction).

When the pad temperature is higher than the patient's temperature, heat is supplied to the patient.

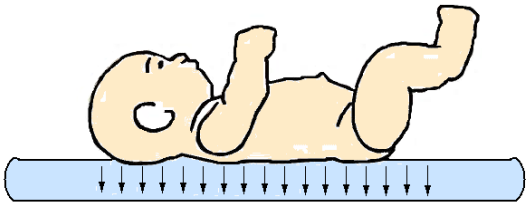
When on the other hand the pad temperature is lower than the patient's temperature, heat may be withdrawn from the patient!

Heat is conducted to the patient



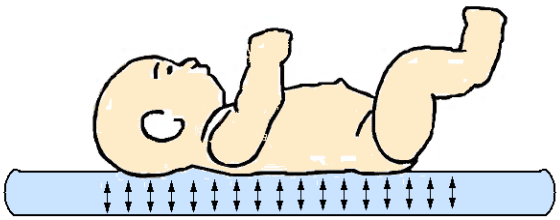
> 37,5 °C

Heat is withdrawn from the patient



< 36,5 °C

Temperature balance



36,5 °C - 37,5 °C

The patient's temperature must be checked in regular intervals or monitored.

When the under-pad heating device is switched off, the gel pad may cause a reduction of the patient's temperature. When nevertheless the warming bed shall be used with switched off under-pad heating device, for insulation purposes a foam pad or woollen nappy, at least 2 cm thick, must be placed between patient and pad!

In case of ambient temperature above 30°C and a temperature selection of 30°C a high temperature alarm may be released. In that case increase the temperature selection to 32°C or switch off the under-pad heating device.

Upgrade items / accessories

Order No.	Description
WY2060	Shelf for the trolley, with raised sides and instrument rail 25 x 10 mm at the front-end, load max. 20 kg
	or optionally:
WY2061	Drawer assembly for the trolley with 2 drawers, top side designed as shelf, with raised sides and instrument rail 25 x 10 mm at the front-end, load max. 20 kg
WY2067	High-grade steel infusion pole Ø 25 mm, 600 mm long, fixed at the instrument and monitor shelf
WY2068	High-grade steel infusion pole Ø 25 mm, height-adjustable, fixed at the instrument and monitor shelf
WY1004	APGAR DIGITEMP Temperature monitor with integrated Apgar timer, fixed at the high-grade steel tube Ø 40 mm. Timer for performing the Apgar test and monitor for measuring the patient's temperature. Normal clock mode. Timer mode with signal after 1 - 2 - 5 and 10 minutes. Skin temperature mode with high and low temperature alarm. Alarm can be reset for 15 minutes and switched off temporarily if necessary. Incl. reusable skin sensor.
	Suction / oxygen supply
WY1620	Suction unit for compressed air operation, for connection to central pipeline. Vacuum can be adjusted from 0 to 0.6 bar and switched off, suction capacity 27 l/min., incl. suction bottle 250 ml, suction lid with float assembly, suction tube with fingertip valve, pressure tube and clamp for instrument rail 25 x 10 mm
WY1604	Precision oxygen flowmeter for connection to central pipeline, pressure compensated, flow adjustable 0 to 15 l/min., incl. pressure tube and clamp for instrument rail 25 x 10 mm
WY1621	Precision oxygen flowmeter, with bubble humidifier, for connection to central pipeline, pressure compensated, flow adjustable 0 to 15 l/min., incl. pressure tube and clamp for instrument rail 25 x 10 mm
	Pressure hoses
B4980	Oxygen connection hose 3 m, white, **ISO 32**, pipeline plug DIN 13260, NIST union
B4986	Air connection hose 3 m, black-white stripe, **ISO 32**, pipeline plug DIN 13260, NIST union
B4983	Oxygen connection hose 3 m, **neutral-black**, pipeline plug DIN 13260, NIST union
B4989	Air connection hose 3 m, **neutral-black**, pipeline plug DIN 13260, NIST union
	Phototherapy
WY1816	BILICOMPACT® Phototherapy device for treatment of the neonatal hyperbilirubinemia, to be placed on warming bed THERMOCARE K, 10 energy saving lamps blue BAM/PL9/52, wave length spectrum 460 nm, integrated hour counter, handles.

Additional devices

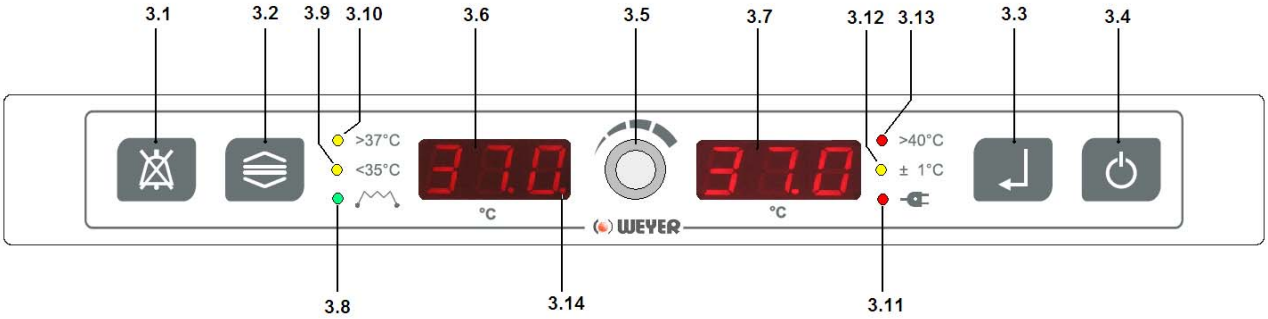
When external devices are connected to the warming bed it must be checked whether the maximum load of the monitor shelf of 20 kg is sufficient.

The "General requirements for the safety of medical electrical systems EN 60601-1-1 + Supplement A1" must be observed. The max. power input is specified at the take-off sockets and must be considered. The total leakage currents of the connected additional devices must not exceed 250 µA.

It should also be considered that accessories, which are not fixed at the neonatal warming bed, will not be moved and therefore connected lines and tubes might be pulled off.

Safety and alarm functions

Under-pad heating device



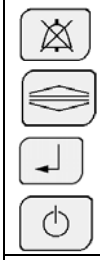
Hazard/ Error condition	Alarm priority			Warning lamp	Temperature display		Action needed	Consequence when neglected
					Selection	Actual		
Automatic switch-on test failed	Medium	Yes	No	None	Error-Code according to the detected failure.		Do not put the under-pad heating into operation.	None, as it is not possible to switch on the under-pad heating
Temperature more than 1°C <u>below</u> selection	Medium	Inter-mittent	Yes 1.)	● ±1°C Yellow	e. g. 36.0.	e. g. 34.8.	Pause audio alarm. 2.) Watch the patient's temperature. If necessary relocate the patient or place an isolating blanket between patient and pad.	Patient cools down and becomes hypothermic.
Temperature more than 1°C <u>above</u> selection. (Possibly sun-light, external warming devices?)	Medium	Inter-mittent	Yes 1.) 2.) 3.)	● ± 1°C Yellow	e. g. 36.0.	e. g. 37.5.	Pause audio alarm. 2.) Watch the patient's temperature. If necessary relocate the patient or place an isolating blanket between patient and pad.	Patient becomes hyperthermic for a short while. After automatic safety switch-off he can become hypo-thermic again.
Temperature adjustment more than 1 °C <u>above</u> actual temperature ≡ HT-alarm	Medium	Automatic alarm pause max. 10 minutes		● ±1°C yellow	e.g. 37.0.	e.g. 35.5	Wait until bassinet temperature reaches the selection ± 1°C. Watch the patient's temperature.	None
Temperature adjustment more than 1 °C <u>below</u> actual temperature ≡ LT-alarm					e.g. 35.5	z .B. 37.0.		

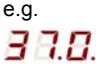
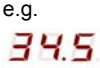
4.) Automatic alarm pause caused by a logical action of the user (e. g. temperature adjustment).

5.) When alarms are paused repeatedly there is a permanent fault which must be removed. In such cases the heating is cut off automatically and the audio alarm can no longer be paused. Switch off the under-pad heating with key (3.4) and switch it on again when the fault has been removed.

6.) At an ambient temperature above 30°C and a temperature selection of 30°C a high temperature alarm may be released. In that case increase the temperature selection to 32°C or switch off the under-pad heating device. When the under-pad heating device is switched off, place a foam pad at least 2 cm thick or a woollen blanket between patient and gel pad in order to avoid that heat is withdrawn from the patient by the cooling gel pad.

Hazard/ Error condition	Alarm priority			Warning lamp	Temperature display		Action needed	Consequence when neglected
					Selection	Actual		
Selection > 37°C	Indic-ative	Mute	- , -	● >37°C Yellow	> 37°C 	e.g. 	Increased attention, check patient's temperature	Patient's core temperature increases.
Selection < 37°C	Indic-ative	Mute	-,-	● <37°C Yellow	< 37°C 	e.g. 	Increased attention, check patient's temperature	Patient's core temperature can fall.
Bassinet is warmer than 40°C.	High	Inter-mittent	Yes	● >40°C also ● ± 1°C Yellow	e. g. 	e. g. 	Check whether high temperature was caused by sunlight or external warming devices. Switch off under-pad heating device temporarily. Watch temperature (residual heat). When the bassinet will not cool down, disconnect the under-pad heating device from the power supply with the central switch-off button (3.15) . Place an isolating blanket between patient and pad. Depending on the situation relocate the patient. Remove the alarm cause.	Patient can become dangerously hyperthermic. Attention: Above 42°C danger of burns.
Bassinet is warmer than 40,5°C.	High	Perm-anent	No					
Battery capacity not sufficient for power failure alarm	Indic-ative	Mute	- , -	None	e. g.  every 15 Sec. 	e. g.  every 15 Sec. 	Replace battery.	Power failure alarm not sufficiently secured.
Interruption of power supply	Medium	Perm-anent	No	●  Red	Dark	Dark 	Switch off under-pad heating, re-install power supply. If necessary relocate the patient or place an isolating blanket between patient and pad.	Patient will cool down and become hypothermic.
Re-installation of the power supply within 10 minutes	Indic-ative	1 x short	- , -	Mostly ● ± 1°C yellow	Last selection	Actual temper-ature	Increased attention, if necessary pause audio alarm	None
Power supply below 190 V or defective fuse in heating circuit.	Indic-ative	No	- , -	Mostly ● ± 1°C yellow	e.g.  Every 15 Sec. 	e.g.  Every 15 Sec. 	Inform facility management on this situation. Take action to increase the voltage.	Longer heating-up period and reaction after selecting a higher temperature.

Hazard/ Error condition	**Alarm priority**			**Warning lamp**	**Temperaturdisplay**		**Action needed**	**Consequence when neglected**
					Selection	**Actual**		
Defective control elements: 	Low	Perma-nent	No	None	Err.	18.1 18.2 18.3 18.4	Switch off under-pad heating device, switch it on again and check whether the error still exists. In case of continuous error condition relocate the patient. Put the under-pad heating out of operation and have it repaired.	Relay de-energized. Patient may cool down and become hypothermic.
Triac for heating voltage is permanently switched on.	Medium	Yes	Yes	● ± 1°C yellow	e.g. 37.0.	e.g. 38.5	Pause audio alarm. Watch temperature.	Safety cut-off at 40.5°C. Patient's temperature may increase considerably.
	High	Yes	No	Possibly ● >40°C	37.0. Every 15 Sec. Err.	40.8 Every 15 Sec. 41	Alarm is released when being paused for the 4th time. Switch off the under-pad heating device.	
Triac für heating voltage is not switched on.	Medium	Yes	Yes	Mostly ● ± 1°C yellow	e.g. 37.0.	e.g. 35.5	Pause audio alarm. Watch temperature. If it still falls, place an isolating blanket between patient and pad. Depending on the situation relocate the patient.	Patient cools down and becomes hypothermic
Failure audio signal generator	Medium	Not possible	Yes	None	Selection	Actual temper-ature	Put the under-pad heating device out of operation and have it repaired.	Fault may not necessarily become obvious, therefore an alarm condition may remain unrecognized.
Error A/D converter defective	High	Yes	No	None	Err.	20	Put the under-pad heating device out of operation immediately and disconnect it from the power supply with the central switch-off button (3.15) . Place an isolating blanket between patient and pad. Depending on the situation relocate the patient.	Relay de-energized. Patient may cool down and become hypothermic.
Error A/D converter time out					Err.	21		
Sensor difference > 0,5K					Err.	22		
Sensor broken					Err.	23		
Sensor short circuit					Err.	24		
Smart sensor defective or not available					Err.	25		
Temperature correction value false/illogical					Err.	26		
EEPROM error					Err.	27		
Watchdog error					Err.	28		

Hazard/ Error condition	Alarm priority			Warning lamp	Temperature display		Action needed	Consequence when neglected
					Selection	Actual		
Relay is energized, one or both contacts do not close	Medium	Yes	Yes	After a short while: ● ± 1°C yellow	e.g.  Every 15 Sec. 	e.g.  Every 15 Sec. 	Switch off the under-pad heating device. Place an isolating blanket between patient and pad. Depending on the situation relocate the patient.	Relay does not close the heating circuit. Temperature falls. Patient may cool down and become hypothermic.
After pausing the high temper-ature alarm 3 times due to defective heating circuit or external heat source	High	Yes	No	● ± 1°C yellow depending on situation: ●> 40°C redt	e.g.  Every 15 Sec. 	e.g.  Every 15 Sec. 	Switch off the under-pad heating device. Place an isolating blanket between patient and pad. Watch temperature. In case of external influence remove the the external heat source. If necessary, relocate the patient and put the under-pad heating device out of operation	Safe operation may no longer be guaranteed. Patient is overheated.
Bassinet temperature higher than 40.5 C	High	Yes	No	● ± 1°C yellow ●> 40°C red	e.g.  Every 15 Sec. 	e.g.  Every 15 Sec. 		
Failure of the safety relay	High	Yes	No	Depending on situation	e.g.  Every 15 Sec. 	e.g.  Every 15 Sec. 	Immediately disconnect the under-pad heating device from the power supply with the central switch-off button (3.15) . Place an isolating blanket between patient and pad. Watch the temperature. If necessary relocate the patient.	Safe operation no longer guaranteed. Danger of overheating!

Cleaning and Disinfection

Cleaning and disinfection must be carried out after every change of patient, but at least once a week.

Cleansing agents and disinfectants

Do not use any scouring agents for cleaning and disinfection or any of the following: alcohol-based cleaning agents, tincture of iodine 5%, carbolic acid, alcohol, ether, acetone and petrol, halogen- or oxygen-liberating compounds and strong organic acids.

Never use inflammable agents!

When choosing agents always follow the recommendations of the agent's manufacturer who is liable for the instructions about the areas that can be cleaned with the agent and for any material damage caused.

The main materials of which the neonatal warming bed is made are as follows:

Perspex walls, canopy	PMMA, polycarbonate
Bassinet, parts of the housing:	polyurethane
Pad:	polyurethane.

We recommend the use of disinfectants listed in the current list of the German Society for Hygiene and Microbiology (DGHM). The current DGHM list can be obtained from mhp-Verlag Wiesbaden. The following is a list of wipe disinfectants that can be recommended:

Incidur®	Henkel Hygiene, Düsseldorf, Germany
Gevisol	Schülke & Mayr, Norderstedt, Germany
Buraton 10F	Schülke & Mayr, Norderstedt, Germany
Bacillotox	Bode, Hamburg, Germany
Barillol 25	Bode, Hamburg, Germany
Dismozon ®pur	Bode, Hamburg, Germany
Trichlorol	Lysoform-Germany
Virkon	Tetenal- Germany
Cidex	Johnson & Johnson
Seculyse	Paragerm France
Sekupoudre	Paragerm France
Vaposeptal	Paragerm France
Seculyse	Paragerm France
Sekupoudre	Paragerm France
Vaposeptal	Paragerm France
Habitane	Zeneca Ltd., Norway
Kloramin	Norsk Medisinal Depot, Norway
Sactiv	Diversey Lever, Finland
Viraclean	Whiteley, Australia

If the neonatal warming bed is not operated in Germany, we recommend to select the disinfectant from the list of a comparable national organisation.

When using washing and disinfection machines use only cleansing agents. If alkaline or chlorine-liberating disinfectants are used, there is a danger of corrosion.

Dismantling, cleaning and disinfection

After use switch off the under-pad heating device and wait until the actual temperature display has extinguished. Disconnect the power plug.

- Remove nappies and tissues.
- Disconnect suction assemblies and patient circuits (if any).
- Empty liquid containers (if any).

Gel pad:

- Remove the pad from the bassinet
- Clean and wipe disinfect pad surface.

L Do not bend or fold the pad!

Perspex wall assembly:

- Remove all tube grommets and disinfect them in the disinfection machine or put them in disinfectant solution.
- Take-off the canopy and the safety side walls and place them on a soft, non-scratching underlay.
- Fold down the perspex walls and remove visible contamination with a soft cloth or disposable cloth soaked in cleansing agent, especially around the hinges.
  Remark: Do not use cellulose cloths for cleaning the walls as these scratch the surface of the walls.
- Wipe disinfect surface and allow disinfectant to take effect in accordance with the disinfectant manufacturer's instructions. Then wipe the walls with a soft, slightly damp cloth and wipe dry.

Castors:

The castors must be cleaned very carefully and sprayed with a disinfecting solution.

Remaining device:

Clean the remaining surfaces of the warming bed with a cloth soaked in cleansing agent. Wipe disinfect them and wipe dry.

After disinfection let the warming bed dry for at least 1 hour.

A disinfection by ultraviolet light is not recommendable as perspex and plastic components may be damaged.

After cleaning and disinfection reassemble all components of the warming bed, check them for completeness and correct function.

Waste disposal

Batteries:	Hazardous waste
Gel pad:	Domestic waste

Maintenance

Nomenclature

Qualified person	= Skilled worker, engineer, bio-medical engineer, with corresonding qualification.
Authorized qualified person	= Qualified person, who has acquainted special knowledge of a certain product.
Inspection	= Ascertainment of the actual state.
Preventive maintenance	= Measures to maintain the nominal state.
Repair	= Measures to restore the nominal state.
Maintenance	= Inspection, preventive maintenance, repair.

In order to ascertain the safe operation of the neonatal warming bed we recommend inspections by qualified persons at regular intervals.

- *Verification that the actual use is in conformance with the normal use.*
- *General condition of the device.*
- *Function and secure latching of the perspex wall assembly.*
- *Function and secure locking of height-adjustment and tilting facility.*
- *Possible damages at the device, mains cord or pad.*
- *Functions of the device and safety provisions.*
- *Measurement of the electrical safety according to the national standards and limit values actually in force.*

The battery securing the power failure alarm must be changed by qualified persons once per year, however, at the latest when the displays (3.6) and (3.7) indicate Lo + bAt. The battery compartment B is placed below the bassinet.

In order to maintain the nominal state of the warming bed we recommend preventive maintenance by authorized qualified persons at regular intervals. For normal operating conditions we recommend yearly intervals whereas under unfavourable ambient conditions and in case of high duty use half-yearly intervals should be observed. The preventive maintenance includes the following in addition to the inspection:

- *Check of: Interior wiring and connections.*
- *Check of all functions and safety-relevant parameters, especially according to EN 60601-2-35:2010.*
- *Check of the safety cut-off at > 40°C.*
- *Calibration of the under-pad heating device according to EN 60601-2-35:2010.*

We can only be held responsible for the safety features of this device when preventive maintenance and repairs are carried out by authorized qualified persons, by observing our instructions and by using original spare parts.

Devices respectively device components have to be cleaned and disinfected prior to each maintenance measure or when they are sent out to our factory for repair.

The microprocessor control recognizes failures and cuts off the under-pad heating device in case of unsafe conditions. The safety and alarm functions are listed on pages 20 to 23.

Spare and wear parts

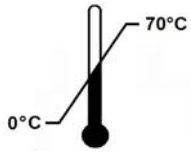
Order No.	Description
M1221	Perspex front wall 250 mm high
M1223	Perspex side wall 250 mm high
M1225	Perspex rear wall 250 mm high
	Order separately if necessary:
M1226	Gate for rear wall
WY0410	ISO oxygen connector 15/22 mm
WY0412	Silicon grommet (2x) for rear wall
M1231	Safety perspex side wall
WY2064	Perspex canopy
WY0620	Gel pad 480 x 760 mm
EG0002	Battery 9 V energy block

Technical Data

Transport and storage

For transport and storage the following conditions should be observed:

Temperature:



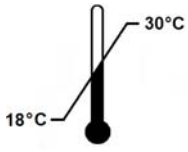
Relative air humidity: 15 to 95 %
Atmospheric pressure 210 to 1100 hPa

The neonatal warming bed must not be exposed to strong vibrations, such as e.g. transport over cobblestone pavement.

Ambient requirements

The neonatal warming bed can be used under the following operation conditions:

Temperature:

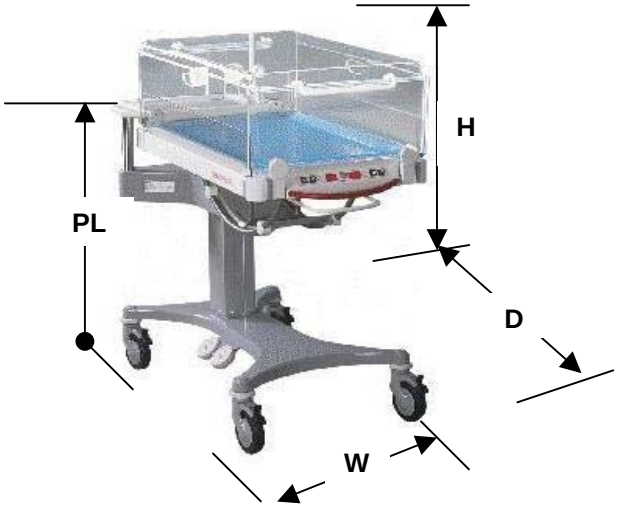


Relative air humidity: 15 to 95 %
Atmospheric pressure 860 to 1100 hPa

The neonatal warming bed is not suitable for the use in explosion-hazardous areas.

General Data

Overall dimensions	**D** = 1140 mm **W** = 585 mm **H** = 1090 to 1390 mm Weight: 70 kg
Trolley	Height adjustment with foot pedals, at choice at the front or/and side. Adjustment range: 300 mm. 4 castors Ø 125 mm, anti-static (3 with total lock, 1 with directional lock). 4 bumpers Ø 70 mm.
Bassinet	Concave shape **D** = 760 mm **W** = 480 mm
Patient level	**PL** = 850 to 1150 mm
Head-up / feet down	0 to 20°
Feet-up / head down	0 to 10°
Pad	Thermoconductive gel
Perspex wall assembly	4 walls 250 mm high, (3 completely fold-down). 2 safety sidewalls, retractable into the bassinet. 1 perspex canopy.
High-grade steel tubes	2 high-grade steel tubes Ø 40 mm with instrument and monitor shelf



Operating / Performance data

General

Operating voltage / power supply	~ 230 V / 50 Hz
Max. power input	4,0 A / 930 W
- for the under-pad heating device	0,8 A / 180 W
- for additional devices	1,1 A / 250 W
Take-off sockets	1 x ~ 230 V / 200 W
	1 x ~ 230 V / 50 W

Under-pad heating device

Temperature selection:	
- Standard range	35 to 37°C
- Extended range	30 to 35°C and 37 to 38.5°C
Increments of temperature selection	0.1°C
Resolution of the displays	0.1°C
Temperature selection display	30 to 38.5°C
Actual temperature display	0 to 50°C
Residual heat display	Down to 35°C, then automatic switch-off
Safety cut-off	At 40.5°C
Heating-up time from ambient temperature 24°C to 37°C	Approx. 15 minutes

Classification

Protection class	1
Type complete	B
Type under-pad heating	BF
MDD class	IIa

Standards

The device complies with	EN 60601-1:2006
	EN 60601-2-35:2010

Certification

CE 0197

EG-Konformitätserklärung

EC Declaration of Conformity

DECLARATION DE CONFORMITE CE

Wir · *We* · NOUS SOUSSIGNÉS,

WEYER

Herrenhöhe 4 · D-51515 Kürten-Herweg,
Deutschland · *Germany* · ALLEMAGNE

erklären in alleiniger Verantwortung, dass das Medizinprodukt
declare under our sole responsibility that the medical device
DECLARONS SOUS NOTRE ENTIERE RESPONSABILITE QUE LE DISPOSITIF MEDICAL

Bett, pädiatrisch · *Bed, pediatric* · LIT PÉDIATRIQUE

THERMOCARE K

Klasse · *Class* · *Classe* **II a**

entsprechend den Vorgaben der Richtlinie 93/42 EWG Anhang II, Artikel 3, vollständiges Qualitätssicherungssystem, unter Registrierungs Nr.: HD 60021580 0001, gefertigt wird.

is manufactured in accordance with the requirements specified in MDD 93/42 EEC, Appendix II, Section 3, full Quality Assurance system, under Registration No. 60021580 0001.

A ETE FABRIQUE CONFORMEMENT AUX EXIGENCES SPECIFIEES DANS LA DIRECTIVE 93/42/CEE ANNEXE II, ARTICLE 3, SYSTEME COMPLET D'ASSURANCE QUALITE, SOUS LE N° D'ENREGISTREMENT HD 60021580 0001.

Das Produkt trägt das unten aufgeführte Zeichen von:
The Product bears the below mentioned CE- mark by
LE PRODUIT PORTE LE SIGLE INDIQUE CI-DESSOUS

TÜV- Rheinland Product Safety GmbH, Am Grauen Stein, D-51105 Köln.

CE 0197

Diese Konformitätserklärung bleibt bis zum Erscheinen einer revidierten Ausgabe gültig.
This declaration of conformity will remain valid until a revised issue will be published.
CETTE DECLARATION DE CONFORMITE RESTE VALABLE JUSQU'A LA PARUTION D'UNE EDITION REVISEE.

Kürten, 03.05.2010		
Ort und Datum *Place and date* LIEU ET DATE	Geschäftsleitung *General Management* DIRECTION	Qualitätssicherung *Quality Assurance* ASSURANCE QUALITE