Instruction for use

Neonatal Resuscitation and Intensive Care System

VARIOTHERM REA-KCE

Variotherm REA-KCE	**2043/ _____**
Under-pad heating	2010/ _____
Radiant warmer	2200/ _____
Year of manufacture:	

D 2002_01

WEYER GmbH

Herrenhöhe 4 > D-51515 Kürten/Germany ++49 2207-9698-0 ++49 2207- 4750 > e-mail: info@weyermed.com

Normal use

The resuscitation and intensive care system VARIOTHERM is used for postnatal care and resuscitation, warming care, oxygen therapy as well as intensive care of infants up to 12 kg weight. It is laid out for continuous operation and conforms to the "Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use EN-60601-2-35" as well as the "Particular requirements for the safety of infant radiant warmers EN 60601-2-21".

General safety instructions

The user must be thoroughly acquainted with this instruction for use. The resuscitation and intensive care system must only be used under medical supervision by qualified instructed persons who are acquainted with the use and risks of conductive warming devices and radiant warmers for infants.

If the device shall be used for another purpose than the normal use described above, this must not be done without our written consent.

In order to guarantee the safe operation, the resuscitation and intensive care system should be subject to regular preventive maintenance measures by authorized qualified persons. For normal operating conditions we recommend yearly preventive maintenance intervals whereas under unfavourable ambient conditions and in case of high-duty use half-yearly intervals should be observed. We can only be held responsible for the safety features of this device when maintenance and modifications are carried out by authorized qualified persons, by using original spare parts.

Transport and storage

For transport and storage the following conditions should be observed:

Temperature:	0°C to 70°C
Relative air humidity:	15 % to 95 %
Atmospheric pressure	900 to 1100 hPa

The device must not be exposed to strong vibrations.

Ambient requirements

The device can be used under the following operation conditions:

Temperature:	18°C to 30° C
Relative air humidity:	15 % to 95 %
Atmospheric pressure:	900 to 1100 hPa

This device is not suitable for the use in explosion-hazardous areas.

When using HF-surgery devices are applied, it should be observed that the under-pad heating consists of electrically conductive material and that it is earthed.

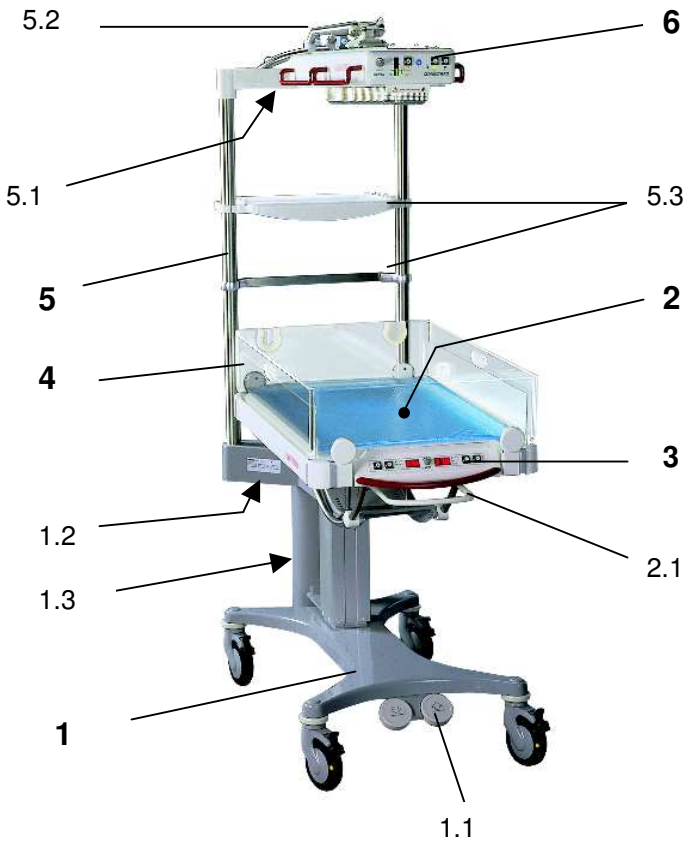
Mobile telephones may interfere the function of electro-medical devices. Therefore no mobile telephones should be used within a distance of 10 meters around the device.

It has to be considered that other heating sources, fans and cold walls may change the effect of the device. Therefore a distance of 1 m should be kept clear and the bassinet should be protected from direct sunlight. Furthermore the device should not be placed in draughts (e.g. air condition) and at windows. Fluids and inflammable agents must not be brought into touch with the radiant warmer. In order to avoid the risk of fire there must not be any inflammable material (e.g. curtains) within an area of 70 cm around the radiant warmer.

Structure and operating principle

The resuscitation and intensive care system VARIOTHERM REA-KCE consists of the following components assemblies:

1. **Mobile trolley**
   - 1.1. Height adjustment facility
   - 1.2. Electrical distribution
   - 1.3. Upgrade items
2. **Bassinet**
   - 2.1. Tilting facility
3. **Conductive under-pad heating**
4. **Wall system**
5. **Frame system**
   - 5.1. Take-off sockets
   - 5.2. Swivel facility for the radiant warmer
   - 5.3. Upgrade items/ accessories
6. **Infrared radiant warmer**



1. Mobile trolley

The solid trolley supports the complete device and is mobile on four antistatic swivel castors with total kick-stop. Additional bumpers are provided to protect device and furniture from damages.

1.1 Height adjustment facility

The working level can be adjusted by means of foot pedals, i.e. the complete device is moved electro-motively. The foot pedals can be arranged at the front or at one of the two sides of the device. As an option pedals can be provided both at the front and at the side.

1.2 Electrical distribution

Take-off sockets ~ 230 V and the low voltage transformer of the under-pad heating are arranged below the rear-side of the trolley. Furthermore the power for infrared radiant warmer and the take-off sockets (5.1.) is supplied from here.

1.3 Upgrade items

A shelf (order No. WY 2060) or drawers (order No. WY 2061) are available for storing necessary material. Furthermore an oxygen cylinder up to 10 l can be fixed at the trolley.

2. Bassinet

The bassinet is arranged on the trolley, attached to a tilting device. Raised sides prevent the infant from trundling out of the bassinet. A heating plate included in the bottom of the bassinet warms up a gel pad. This gel pad conducts the accumulated heat to the patient.

2.1 Tilting facility

The tilting device under the bassinet allows tilting positions from + 20° to-10°.

3. Conductive under-pad heating

The heating plate, which is included in the bassinet, is operated by safety low-voltage. The electronically controlled heating-plate temperature can be selected from 30°C to 38,5°C and is conducted to the patient through the gel pad.

Temperature deviations, system faults and power failure are indicated both visually and audibly. The selected bassinet temperature (selected value) as well as the actual bassinet temperature (actual value) is displayed permanently.

This device does not give any indication as to the patient's body temperature. Therefore the effect of the selected temperature on the patient must be checked in regular intervals.

4. Wall system

The four walls protect the infant from draught and falling from the bassinet. For better accessibility during treatment the front wall and the two side walls can be folded down with one hand. Two additional safety side walls are provided which can be retracted into the bassinet if necessary.

Cables and tubes are conveyed through the silicone tube guidings in the rear wall and the open corners of the wall system.

5. Frame system

The frame supports the infrared radiant warmer and is used for fixing upgrade items and accessories.

5.1 Take-off sockets

2 take-off sockets 230 V are provided in the traverse spar of the frame system, supplying power for electrical additional devices.

5.2 Swivel facility for the radiant warmer

This facility allows to swivel the radiant warmer to both sides. In side position the radiation is still focussed to the patient thus preventing him from becoming hypothermic. Thus the area above the patient is kept clear for examination, X-ray, and phototherapy.

5.3 Upgrade items / accessories

Various accessories, e.g. instrument rails, shelves, flowmeter, compressed air and vacuum devices as well as additional devices can be mounted at the frame system. The power for electrical devices, e.g. ventilators, monitors, Apgar timer etc. is supplied via the take-off sockets in the traverse spar of the frame system.

For the adaptation of additional devices the "General requirements for the safety of medical electrical systems EN 60601-1-1 + Supplement A1" must be observed.

6. Infrared radiant warmer

The radiant warmer with swivel facility, which is arranged above the bassinet, is used for pre-warming the bassinet and the walls and for maintaining the patient's body temperature during treatment. It generates infrared radiant heat in the range of 0.8 to 10 micrometer (µm). This radiant heat is not visible and is very well absorbed by the skin without injuring the patient's eyes.

The ceramic heating elements do not scale and are not affected by liquid splashes.

For dazzle-free illumination of the bassinet two light sources are integrated in the radiant warmer.

The radiation intensity effective for the patient is selected at the operating unit of the radiant warmer, defined in mW/cm². The emitted radiation intensity (actual value) is displayed and deviations from the selected value are indicated visually and audibly.

It must be emphasized that the radiant warmer does not give any indication as to the patient's body temperature. Therefore the effect of the selected radiation intensity on the patient must be checked in regular intervals.

Under certain circumstances radiation intensities above 10 mW/cm² might bring the patient in a hyperthermic condition. Therefore the radiant warmer provides a safety feature, which in case of intensities above 10 mW/cm² emitted for more than 15 minutes, will reduce the output to a safe value while an audible alarm sounds. The selected higher value can be reactivated by pushbutton for further 15 minutes. For certain applications, which are described more detailed in chapter *"Functions and alarms"* (from page 16) and *"Use"* (from page 18) this safety and alarm feature can be deactivated by a conscious action.

In order to prevent the risk of fire and accident the residual heat of the heating elements is displayed until the device has cooled off.

Start-up and functions, functional test

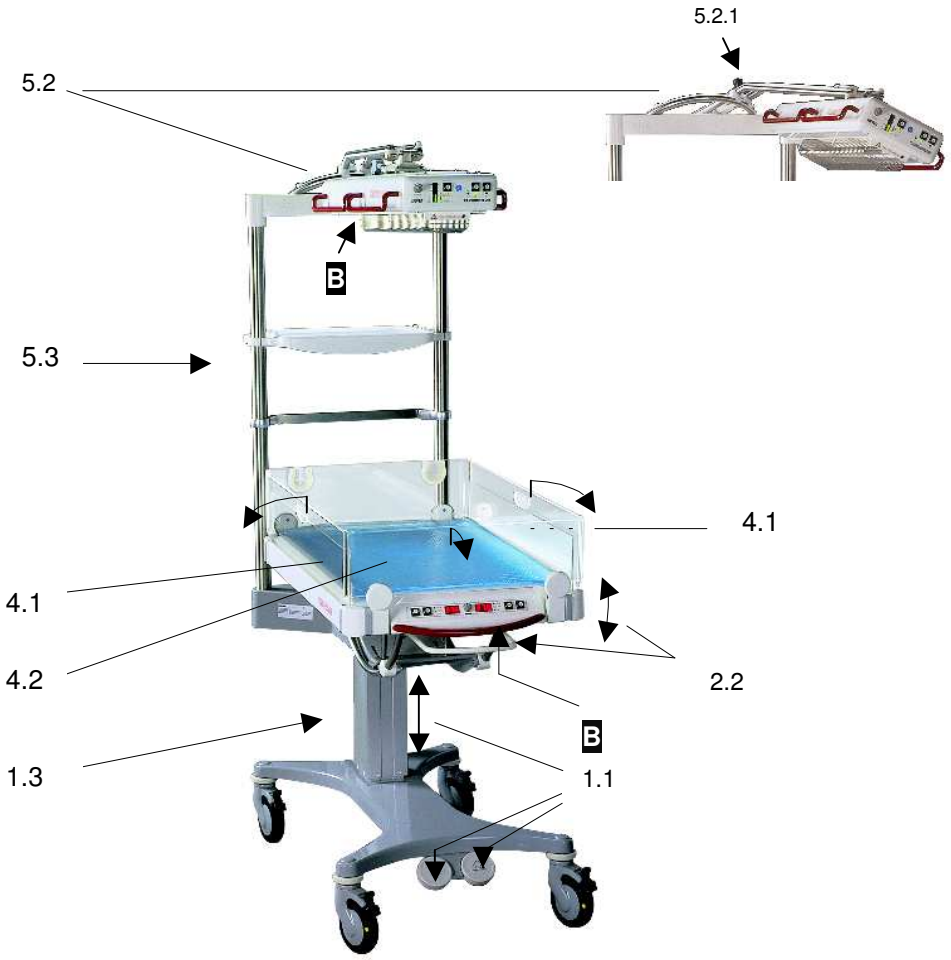
Qualified persons only should install and start-up the device and instruct user' s personnel.

When installing the device it has to be considered that other heating sources, fans and cold walls may change the effect of the device. Therefore a distance of 1 m should be kept clear and the bassinet should be protected from direct sunlight. Furthermore the device should not be placed in draughts (e.g. air condition) and at windows. Fluids and inflammable agents must not be brought into touch with the radiant warmer. In order to avoid the risk of fire there must not be any inflammable material (e.g. curtains) within an area of 70 cm around the radiant warmer.

Prior to start-up all components of the device must be checked for correct and secure position.

Clean the device in cold condition according to chapter *"Cleaning and Disinfection"* (page 32).

The functions of the moving mechanical components should be checked as follows:



Move the bassinet to the lowest and highest position by means of the foot pedals (1.1). Make sure that no items or devices are placed within in the range of the height adjustment.

Unlock the catch (2.2) below the frontside of the bassinet by pulling and tilt the bassinet in both directions. 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 wall functions unlock the walls (4.1) and (4.2) by lifting and fold them down. They must latch securely again simply by folding up.

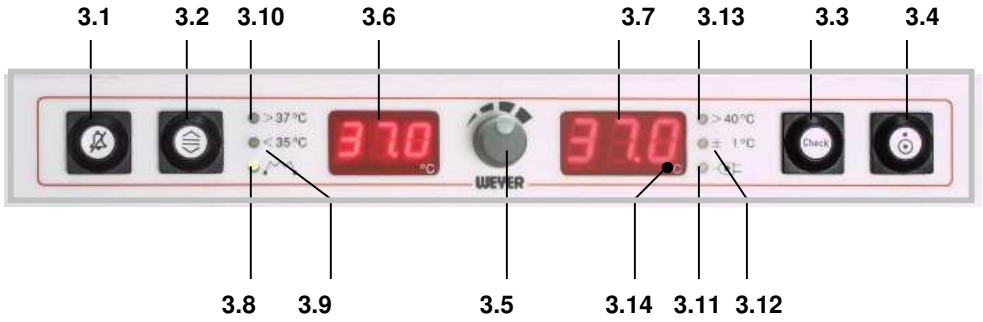
Both the under-pad heating and the radiant warmer have a 9V battery which is included in the scope of the device. The battery compartment B for the under-pad heating is placed below the bassinet and the one for the radiant warmer at the rear bottom side of the warmer, beside the type label.

After pulling and 90° turning of the latch (5.2.1) the radiant warmer can be moved to the right-hand or left-hand side. After checking this function, turn the catch (5.2.1) back by 90° and move the radiant warmer to normal position until the catch locks.

If upgrade items or accessories are mounted at the device (e.g. 1.3 and 5.3) these must be checked for secure position.

Before start-up make yourself acquainted with the following control and display elements of the device.

Functions of the under-pad heating



3.1 Button "Alarm reset"
3.2 Button "Unlocking of extended temperature range" (30°C to 35°C and 37°C to 38,5°C)
3.3 Button "System check"
3.4 Button "Heating On-Off"
3.5 Knob "Temperature selection"
3.6 Display "Selected temperature"
3.7 Display "Actual temperature"
3.8 Pilot lamp (green) "Heating power". In normal operation the lamp lights intermittently
3.9 Warning lamp (yellow) "Temperature selection below 35°C"
3.10 Warning lamp (yellow) "Temperature selection above 37°C"
3.11 Warning lamp (red) "Power failure"
3.12 Warning lamp (red) "Deviation between selected and actual temperature exceeding 1°C"
3.13 Warning lamp (red) "Bassinet temperature exceeding 40°C"
3.14 Warning lamp (red) "Heating-up period"

Start-up of the under-pad heating

First of all make sure that the device is connected to the mains supply.

Switch-on the conductive under-pad heating with button (3.4). Now a self-test checks the major displays and alarm functions. The alarm tone sounds and all displays light up for approx. 2 seconds. Both the selected temperature display (3.6) and the actual temperature display (3.7) indicate the value 88.8.

Check during these 2 seconds whether all displays, pilot lamps and the alarm tone are functioning.

If the self-test is finished without faults, now the temperature of 37.0°C is offered in the temperature selection display (3.6). The actual temperature display indicates SET and the selected temperature display (3.6) indicates 37.0°C. Both displays flash and an intermittent tone sounds.

Now the offered temperature of 37.0° can either be corfirmed by pushing button (3.1) or adjusted by the temperature selection knob (3.5). After confirming by button (3.1.) or temperature adjustment the alarm tone extinguishes.

Temperature selection

The temperature selection consists of two sections, i.e. the "standard" temperature range (35°C to 37°C) and the "extended" temperature range (30°C to 35°C and 37°C to 38.5°C).

Within the standard temperature the selected temperature can be adjusted by knob (3.5) in increments of 0.1°C. Each adjustment is confirmed by a tone. The selected temperature is increased by turning the knob clockwise and reduced by turning it anti-clockwise.

Within the extended temperature range the selected temperature can be adjusted by pushing the unlocking button (3.2) and simultaneous turning knob (3.5). During this procedure the warning lamps (3.9) and (3.10) light. After the adjustment the button (3.2) can be released. In case of a temperature selection below 35°C the warning lamp (3.9) lights and in case of a temperature selection higher than 37°C the warning lamp (3.10) lights.

Heating up from cold state

When the under-pad heating is switched-on at a bassinet temperature more than 5°C bwer than the most recently selected temperature, the device reacts as described in chapter "Start-up of the under-pad heating". A selected temperature of 37°C is offered which can either be confirmed or adjusted.

The audible low temperature alarm is deactivated for a period of 30 minutes. During this period the warning lamp (3.14) flashes. When it extinguishes, the normal operating state is reached and the audible low temperature alarm is activated.

Heating-up from partly cooled state

When the under-pad heating is switched-on at a bassinet temperature min. 1°C and max. 5°C lower than the most recently selected temperature, this temperature will be adopted automatically.

All alarms are activated, including the audible low temperature alarm. The low temperature alarm, however, can be reset by button (3.1) for a period of 15 minutes. The warning lamp (3.14) flashes and indicates normal operating mode only after 30 minutes from switching-on.

Repeated start from warm state

When the under-pad heating is switched-on at a bassinet temperature max. 1°C lower or higher than the most recently selected temperature, the device will operate in normal mode immediately. All alarms are activated.

Alarms

Deviation between selected and actual temperature exceeding 1°C:

The following alarms are released:
- Red warning lamp (3.12) flashes
- Actual temperature display (3.7) flashes
- An intermittent alarm tone sounds

By pushing button (3.1) the intermittent tone is deactivated for a period of 15 minutes, the warming lamp (3.12) lights permanently.

If the deviation between selected and actual temperature is lower than 1°C, the warning lamp (3.12) and the audible alarm extinguish.

Increased attention has to be given to the patient when the above mentioned alarms are released.

During heating-up period from cold state the audible low temperature alarm is deactivated for a period of 30 minutes (see chapter "Heating-up from cold state").

Bassinet temperature exceeding 40°C:

The following alarms are released:
- Red warning lamp (3.13) flashes
- Selected temperature display (3.6) and actual temperature display (3.7) flash
- A permanent alarm tone sounds

Furthermore at a temperature exceeding 40°C the heating is cut-off automatically.

This alarm relates to a device failure. As long as the bassinet temperature is above 40°C, the alarm tone cannot be reset with button (3.1).

Switch-off the under-pad heating with button (3.4) and make sure that the patient is cared for in another way. If this is not possible, place a foam pad min. 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.

If in case of an alarm the under-pad heating is switched-off with button (3.4), the residual actual temperature is displayed. The device is automatically switched-off when the actual temperature has dropped below 35°C.

Insufficient capacity of power failure alarm battery:

The following alarms are released:
- The displays (3.6) und (3.7) indicate Lo + bAt every 10 seconds
- The warning lamp (3.11) flashes
- A short alarm tone sounds every 10 seconds

After changing the battery the alarms are reset automatically.

Power failure alarm:

The following alarms are released:
- Warning lamp (3.11) lights
- A permanent alarm tone sounds

Switch-off the under-pad heating with button (3.4) and make sure that the patient is cared for in another way. If this is not possible, place a foam pad min. 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.

Temperature sensor alarm:

The following alarms are released:
- The displays (3.6) and (3.7) alternately indicate Err + Pt + Err XXX .
  XXX refers to an error code.
- A permanent alarm tone sounds

The alarm tone cannot be reset with button (3.1).

Switch-off the under-pad heating with button (3.4) and make sure that the patient is cared for in another way. If this is not possible, place a foam pad min. 2 cm thick or a woollen blanket between patient and gel pad in order to prevent that heat is withdrawn from the patient by the cooling gel pad.

System check

The system check serves to test the functions of the control unit. It is released by pushing the button (3.3). The following functional tests are performed:

1. Lamp and alarm test (approx. 2 seconds)
2. All displays are switched-off (approx. 1 second)
3. The selected value display (3.6) alternately indicates 37.0 and ChE

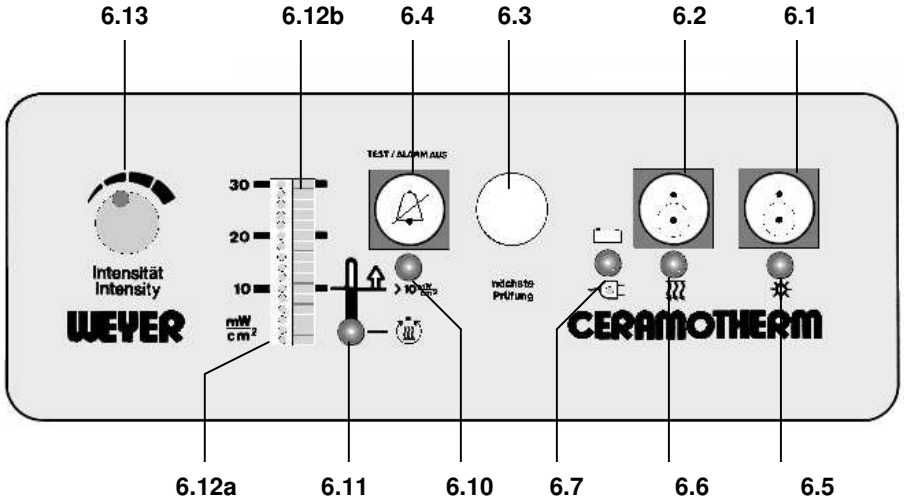
The actual temperature display should indicate a value of 37.0°C ± 0.1°C. If the deviation is larger than ± 0.1°C, the control system is not adjusted correctly.

If there are deviations in one of the mentioned functions, a safe operation is no longer guaranteed and the device must be checked by authorized qualified persons without delay.

End of operation

The conductive warming device is switched-off with button (3.4). After switching-off all displays extinguish, with the exception of the actual temperature display. The device is automatically switched-off when the actual temperature has dropped below 35°C.

Functions of the infrared radiant warmer



6.1 Button "Illumination On-Off".

6.2 Button "Heating On-Off.

6.3 Label indicating next maintenance.

6.4 Multifunctional button:
- a.) Resets the audible high intensity alarm for 1 minute.
- b.) Resets the audible low intensity alarm for 15 minutes.
- c.) Pushing the button for more than 3 seconds deactivates the 15-minutes alarm and the automatic heating capacity reduction > 10 mW/cm², which is confirmed by two short tones. The function is reactivated by pushing the button for more than 3 seconds, which is confirmed by one short tone.
- d.) Button for "Extended functional test" (page 35).

6.5 Pilot lamp (green): Illumination.

6.6 Pilot lamp (green): Heating.

6.7 Warning lamp (red): Double function:
- a.) When the lamp flashes during normal operation, the capacity of the power failure alarm battery is below 10 minutes.
- b.) When the lamp lights in connection with an permanent alarm tone, the power supply is interrupted. The alarm can be reset by switching-off the heating with button (6.2). When the power supply is reinstalled, the heating must be switched-on again.

6.10 Warning lamp (yellow) > 10 mW/cm², double function. At an intensity selection between 12 and 30 mW/cm² it indicates that increased attention must be extended to the patient.
- a.) When it lights permanently, the heating capacity will be reduced automatically when an intensity above 10 mW/cm² is emitted to the bassinet for more than 15 minutes.
- b.) When it flashes, the automatic heating capacity reduction is deactivated, and an increased attention must be extended to the patient.

6.11 Pilot lamp (green). It always lights when the heating elements are energized, i.e. when the lamp lights, the radiant warmer will heat-up, when it does not light, the radiant warmer will cool off.

6.12a LED for selected intensity and 15-minutes alarm with automatic heating capacity reduction.

6.12b Bar graph 2-30 mW/cm² for the actual intensity emitted to the bassinet and residual heat after switching-off.

6.12a+b Combination LED / Bar graph, display of various functions and alarms.

6.13 Knob with 15 increments for intensity selection.

First start of the radiant warmer

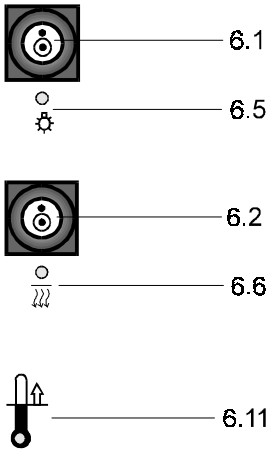
First of all make sure that the device has been connected to the power supply. The pilot lamp for the safety cut-off beside the battery compartment indicates that the unit is ready for operation.

Switch-on the light with button (6.1). The pilot lamp (6.5) and the light tubes in the radiant warmer light.

When switching-on the heating with button (6.2), the device always performs a short self-test. The alarm tone sounds and all displays and pilot lamps light up for 2 seconds.

Check during these 2 seconds whether all displays, pilot lamps and the alarm tone are functioning.

The self-test is finished automatically and the device starts heating-up. This is obvious from the pilot lamp for the heating power (6.11), which initially lights permanently. The selected radiation intensity is indicated as a spot in the LED (6.12a). Now select an intensity of 10 mW/cm² with knob (6.13). The bottommost LED-field of bar graph (6.12b) flashes until the intensity has reached the selected value.

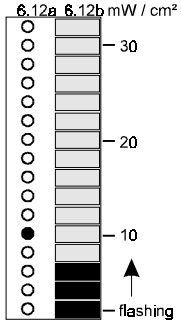
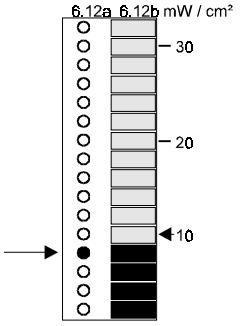
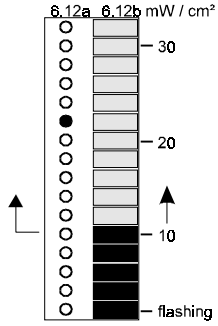
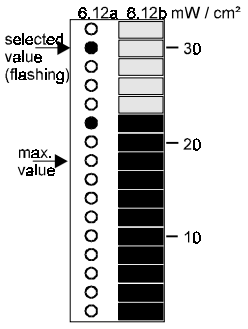


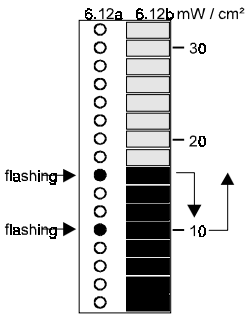
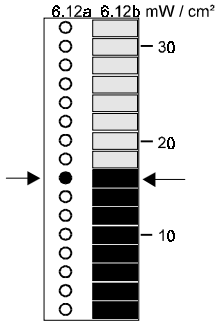
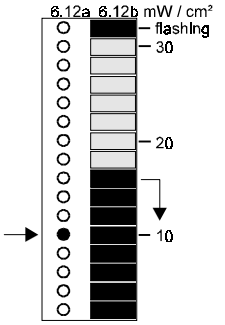
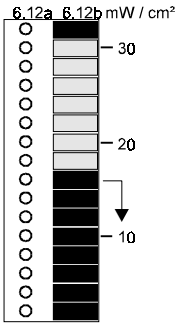
The ceramic heating elements require approx. 4 to 6 minutes until they have reached the selected intensity of 10 mW/cm².

The radiation intensity emitted by the ceramic heating elements is displayed in the right field of bar graph (6.12b). At a selected intensity of 10 mW/cm the LED´s 4 + 6 + 8 mW/cm² light-up progressively. The radiant warmer has reached the selected radiation intensity when the topmost field of the bar graph (6.12b) has reached the LED spot of display (6.12a). The pilot lamp for heating power (6.11) now lights intermittently according to the emitted radiation intensity.

For first start and after a longer time of non-use the *"Extended functional test"* (page 35) should be performed which will take approx. 20 minutes.

Functional processes and alarms

Display	Sequence of functions	Alarm
	**Heating-up** After switching-on the device with button (6.2) the heating elements will warm up. The desired radiation intensity (6.12) can be selected with knob (6.13). The heating-up state is obvious from the actual intensity display (6.12b). Depending on the selected intensity and the ambient temperature the heating-up time will be between 3 and 15 minutes.	The bottommost field of the actual intensity bar graph (6.12b) flashes until the selected intensity (6.12a) is reached. During the heating-up period an audible alarm will only be released after 15 minutes. If this is the case, low ambient temperature or a failure in the heating system could be the reason. The audible alarm can be reset for 15 minutes with button (6.4).
	**Normal operation up to 10 mW/cm²** Radiation intensity up to 10 mW/cm² cannot cause any problems and under normal conditions it is sufficient to maintain the body temperature of healthy normal-weight infants. During normal operation the topmost field of bar graph (6.12b) is at the same vertical position as the LED for selected intensity (6.12a).	No alarms
	**Increasing the radiation intensity** By turning the knob (6.13) clockwise the radiation intensity will be increased. Each adjustment is confirmed by a short tone. The selected intensity is indicated in LED (6.12a). Corresponding to the heating-up state, the bar graph (6.12b) indicates the emitted radiation intensity. The selected intensity is reached when the topmost field of the bar graph (6.12b) has reached the topmost spot of LED (6.12a).	When the emitted radiation intensity is lower than the selected intensity, a low intensity alarm is released. However, the device recognizes the conscious intensity increase and therefore only a visual alarm is released by flashing of the bottommost field of bar graph (6.12b). When the new selected intensity is reached, this flashing field will extinguish. Only if it will not be reached within 15 minutes, the low intensity alarm will sound. This audible alarm can be reset for 15 minutes by button (6.4).
	**Exceeding the maximum intensity selection** A maximum intensity of 22 mW/cm² can be selected. If the intensity knob (6.13) is set to a value, which the radiant warmer is unable to reach, the maximum possible intensity selection is indicated in LED (6.12a) by a permanent spot. The (unreachable) selected intensity is indicated in LED (6.12a) by a flashing spot.	Optical, as described.

Display	Sequence of functions	Alarm
	**Operation above 10 mW/cm² with 15-minutes alarm and automatic heating capacity reduction.** If exposed to radiation intensity > 10 mW/cm² under certain circumstances the infant' s body temperature can increase considerably. An intensity selection > 10 mW/cm² is indicated by warning lamp (6.10). If higher radiation intensity is emitted for more than 15 minutes, it is automatically reduced to 10 mW/cm². If the higher intensity should be continued, this must be confirmed by pushing the button (6.4).	In LED (6.12a) the spot for the selected intensity and the spot for 10 mW/cm² flash alternately and a short alarm tone sounds in intervals of 2 seconds. By pushing button (6.4) the alarm is reset and the selected intensity is emitted for further 15 minutes.
	**Normal operation above 10 mW/cm²** Provided that the patient' s temp erature supervised in another way, for well-founded reason the automatic intensity reduction can be deactivated by pushing button (6.4) for more than 3 seconds and it can be reactivated in the same way. It must be particularly paid attention to the danger of hypothermia in case of operation with intensity above 10 mW/cm²!	Deactivating the automatic intensity reduction with button (6.4) is confirmed by two short tones and the warning lamp (6.10) flashes. The reactivation of the automatic intensity reduction with button (6.4) is confirmed by one short tone. The warning lamp (6.10) lights, if a value > 10 mW/cm² is selected.
	**Reducing the radiation intensity** By turning the knob (6.13) anticlockwise the radiation intensity will be reduced. Each adjustment is confirmed by a short tone. The selected intensity is indicated in LED (6.12a). Corresponding to the cooling-off state, the bar graph (6.12b) displays the emitted radiation intensity. The selected intensity is reached when the topmost field of the bar graph (6.12b) has dropped to the topmost spot of LED (6.12a). The cooling-off can take 1 to 4 minutes, depending on the selected intensity.	When the emitted radiation intensity is higher than the selected intensity, a high intensity alarm is released. However, the device recognizes the conscious intensity reduction and therefore only a visual alarm is released by flashing of the topmost field of bar graph (6.12b). When the device has cooled-off to the new selected intensity, this flashing field will extinguish. If not, the high intensity alarm will sound after 15 minutes. This audible alarm can be reset for 15 minutes by button (6.4).
	**Switching-off the heating** The heating is switched-off with button (6.2) and the pilot lamp for the safety cut-off beside the battery compartment lights. For safety reasons the residual heat emitted by the heating elements is displayed in bar graph (6.12b). After cooling off below 2 mW/cm² the bar graph is switched-off automatically.	No alarm

Use

Bassinet with wall system

Bring the bassinet into the desired position by means of the foot pedals 1 of the height adjustment facility. Cover the gel pad 2 with a **thin nappy**. Make sure that the nappy is not squeezed between the walls and that it cannot block the locking system. The front and side walls 4 must always close smoothly and latch securely. The safety walls 3 must be inserted in a way that the infant 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.

Drainage tubes are conveyed through and the open corners of the front wall, ventilation tubes can be connected in level position through the tube guidings in the rear wall.

When the under pad heating has reached the steady temperature, place the patient inside the bassinet. Take care that the walls are folded up so that the patient cannot fall from the bassinet. Take care that no body parts, tubes and cables are squeezed. After unlocking the tilting device 5 incline the bassinet to the desired position.

Temperature selection of the under-pad heating

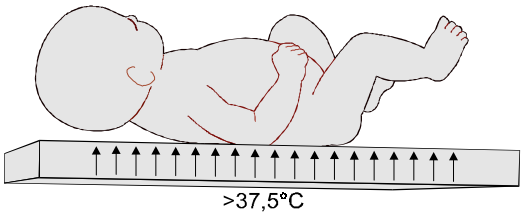
The temperature selection of the under-pad heating depends on several factors, e.g.:

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

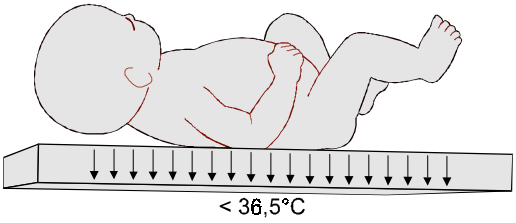
For a mature unclothed infant a bassinet temperature of approx. 36.5°C should be selected. For a pre-term neonate a temperature of approx. 37° to 37.5°C is recommendable. For clothed infants the bassinet temperature may be selected 0.5 to 1°C lower.

When selecting the temperature of the conductive under-pad heating, it must be considered that the temperature of the gel pad has a direct influence on the patient (thermal conduction). If the pad temperature is higher than the patient's temperature, heat is conveyed to the patient. If on the other hand the pad temperature is lower than the patient's temperature, heat may be withdrawn from the patient!

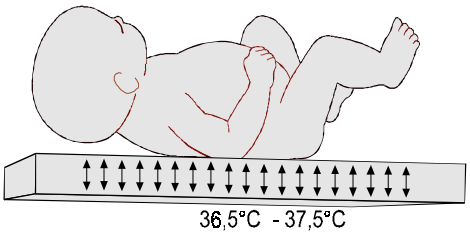
Heat is supplied to the patient



Heat is withdrawn from the patient



Heat flow in balance



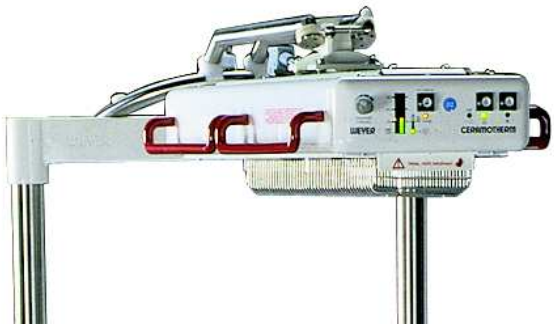
The patient's temperature must be monitored or checked in regular intervals.

When the under-pad heating is switched-off, the gel pad may cause a reduction of the patient's temperature. Therefore, if the bassinet shall be used with switched-off under-pad heating, for insulation purposes a foam pad or woollen nappy, minimum 2 cm thick, must be placed between patient and pad.

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

Radiant warmer

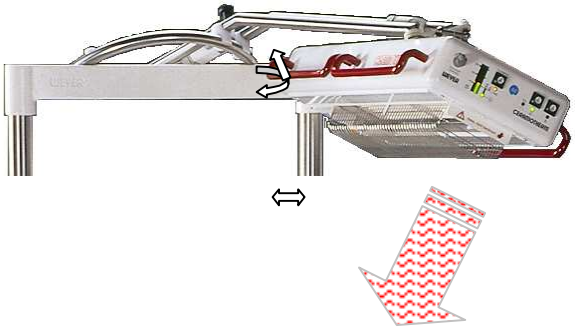
The radiant warmer generates a long-wave infrared radiation. The radiation intensity effective for the patient is selected at the operating unit of the radiant warmer, as described on page 21.



The safety guard of the heating elements can reach a temperature above 85°C. When taking infants out of the bassinet, take care that they do not grip into the safety guard.

The radiant warmer is swivel-mounted. For taking X-ray or in order to reduce the heat exposure for the personnel, it can be swivelled to either side. The radiation keeps focussed on the patient, preventing him from hypothermia.

In order to swivel the radiant warmer retract the locking knob of the swivel device and turn it by 90°. Now the radiant warmer can be swivelled to both sides. Use the two handles and do not touch the safety guard.

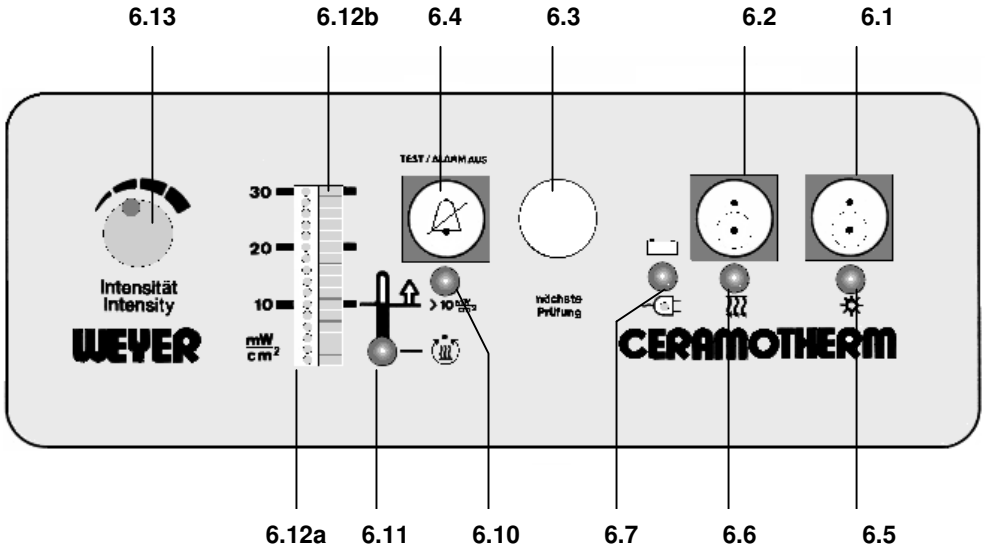


In order to return the warmer to central position again turn the locking knob by 90° and move the warmer to central position until the locking knob latches automatically.

Take care that no items whatsoever are placed within the moving radius of the radiant warmer.

For illuminating the bassinet dazzle-free two light sources are integrated in the radiant warmer, which can be switched-on at the front-side of the device, if necessary.

Intensity selection of the radiant warmer



After switching-on the heating with button (6.2), the desired radiation intensity can be selected with knob (6.13). The selected value is indicted as a spot in LED (6.12a). Now it takes about 3 to 15 minutes until the selected value is reached. The actually emitted radiation intensity is indicated in the bar graph (6.12b). The device has reached the selected intensity and is ready for operation when the bottommost field of the bar graph (6.12b) stops flashing.

The intensity selection of the radiant warmer is decisively dependent from the patient' s condition. If the radiant warmer is used for long-term care, the radiation intensity has to be selected with utmost care. The intensity selection is mainly dependent from the patient' s weight, age, maturity, the anamnesis as well as the ambient conditions.

- The smaller and immature the patient, the higher is his heat demand.
- The lower the ambient temperature, the higher is the patient' s heat demand.

If empirical values are not available, for an unclothed infant an initial intensity of 10 mW/cm² should be selected. The body temperature must be checked in regular intervals. If necessary, the intensity selection should be adjusted according to the patient temperature.

The intensity selection is ideal when neutral thermal conditions are given, i.e. when the patient' s core temperature in relaxed condition is between 36.7 and 37.3°C.

If higher radiation intensity is emitted to an infant for a longer time, under unfavourable circumstances his temperature may be increased dangerously. The radiant warmer recognizes this situation and provides an automatic function for warning and simultaneous reducing the heating capacity.

When a radiation intensity above 10 mW/cm² is emitted to the patient area for more than 15 minutes, the radiation intensity will be reduced automatically to 10 mW/cm² and an alarm is released.

In that case the LED spot for the selected value and the LED spot for 10 mW/cm² in display (6.12a) flash alternately and a short alarm tone sounds every 2 seconds. Check the patient' s temperature and push button (6.4). Now the alarm is reset and the selected intensity is emitted for further 15 minutes. The warning lamp (6.10) lights permanently and indicates that the safety function (>10 mW/cm²) is activated.

The actual intensity display (6.12b) refers to the surface of the bassinet. The radiation intensity reaching the patient's skin is approx. 4 mW/cm² higher than the displayed value because the distance of the radiant warmer to the patient surface is approx. 10 cm lower than to the surface of the bassinet.

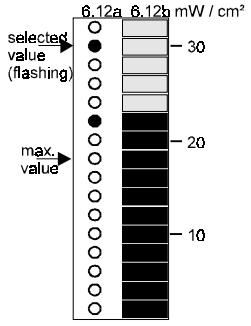
If during long-term care the patient' s demand ofheat has stabilized, and if this is above a value of 10 mW/cm², the 15-minutes-alarm and automatic heating capacity reduction can be deactivated by a conscious action. This, however, does not remove the obligation of checking the patient' s temperature in regular intervals. If the patient' s temperature is monitored, the automatic 15-minutes-alarm and the heating capacity reduction can also be deactivated.

In order to deactivate the 15-minutes-alarm and the automatic heating capacity reduction, push button (6.4) for approx. 3 seconds until two short tones sound.

When the 15-minutes-alarm and the automatic intensity reduction are deactivated, in case of an intensity selection above 10 mW/cm² the warning lamp (6.10) flashes permanently.

When the 15-minutes-alarm with automatic intensity reduction shall be reactivated, push button (6.4) for approx. 3 seconds until one short tone sounds. When in case of an intensity selection > 10 mW/cm² the 15-minutes-alarm and the automatic heating capacity reduction are activated, the pilot lamp (6.10) lights permanently.

Whenever the radiant warmer is switched-on after non-operation, the 15-minutes alarm and the automatic heating capacity reduction are activated.



Exceeding the maximum intensity selection

The maximum selectable intensity is 22 mW/cm². If the intensity knob (6.13) is set to a value, which the radiant warmer is unable to reach, the maximum selectable value is indicated in LED (6.12a) by a permanent spot. The (unreachable) selected value is indicated in LED (6.12a) by a flashing spot. In that case reduce the intensity selection to the maximum possible intensity by turning knob (6.13) anti-clockwise.

Warnings for use

General

- The patient' s temperature must be monitored or checked in regular intervals.
- The radiant warmer does not give any indication as to the patient' s temperature.
- Take care that the patient is always under observation when one or more walls (4.1 or 4.2) of the bassinet are folded down.
- Sunlight, draughts, cold walls and windows in direct ambience to the resuscitation and intensive care crib will influence the patient' s temperature balance negatively.
- The ambient conditions for the resuscitation and intensive care system must in no case be influenced by further warming or air condition devices.
- For the adaptation of additional devices the "General requirements for the safety of medical electrical systems EN 60601-1-1 + Supplement A1" must be observed.

Height-adjustment facility

- When operating the height-adjustment make sure that no items or devices are placed within in the moving range.
- It should also be considered that accessories, which are not fixed at the device, will not be moved and therefore might be pulled off.
- Before moving the resuscitation and intensive care system to another place bring the height adjustment into the lowest position.

Under-pad heating

- The under-pad heating shall only be used together with the original gel pad order No. WY 0620.
- When the under-pad heating is switched-off, the gel pad may cause a reduction of the patient' s temperature. Therefore, if the bassinet shall be used with switched-off under-pad heating, for insulation purposes a foam pad or woollen nappy, minimum 2 cm thick, must be placed between patient and pad.
- The gel pad cannot destaticize, is not autoclavable and not washing-machine proof.
- The gel mattress 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 mattress.

Radiant warmer

- It should be considered that when being exposed to a radiation intensity above 10 mW/cm² for a longer period, the patient' s temperature may be increased considerably.
- Do not place any dark metal items within the field of radiation, as after a longer period they can become dangerously hot.
- It must be mentioned that under radiant warmers the trans-epidermal humidity losses in patients can increase unconsciously.
- Never use the radiant warmer together with inflammable anaesthesia gas or other inflammable material and (cleaning) fluids as e.g. alcohol, ether etc.
- When a radiant warmer is used in connection with a phototherapy device, it must be observed that patient temperature and humidity losses can increase.
- Do not place any medical drugs or infusion fluid above the radiant warmer or within the area of radiation.
- The safety guard of the radiant warmer can reach a temperature of > 85°C. Therefore during operation it should be avoided to touch the safety guard or the top of the radiant warmer.
- Never use the radiant warmer in connection with other warming devices, if the combination has not particularly been accepted in the instruction for use.
- The actual intensity display (12b) refers to the surface of the bassinet. The radiation intensity reaching the patient' s skin is approx. 4mW/cm² higher than the displayed value because the distance of the radiant warmer to the patient is approx. 10 cm lower than to the surface of the bassinet.
- Do not place anything on top of the radiant warmer.
- Never cover the unit as long as it is warm. This would impair the convection, which increases the danger of fire.
- When moving the resuscitation and intensive care system to another place, the swivel facility of the radiant warmer must be locked in central position.

Upgrade items and accessories

A number of upgrade items and accessories are available for the resuscitation and intensive care system VARIOTHERM. External devices can also be fixed at the standardized instrument rail or placed on an instrument and monitor shelf.

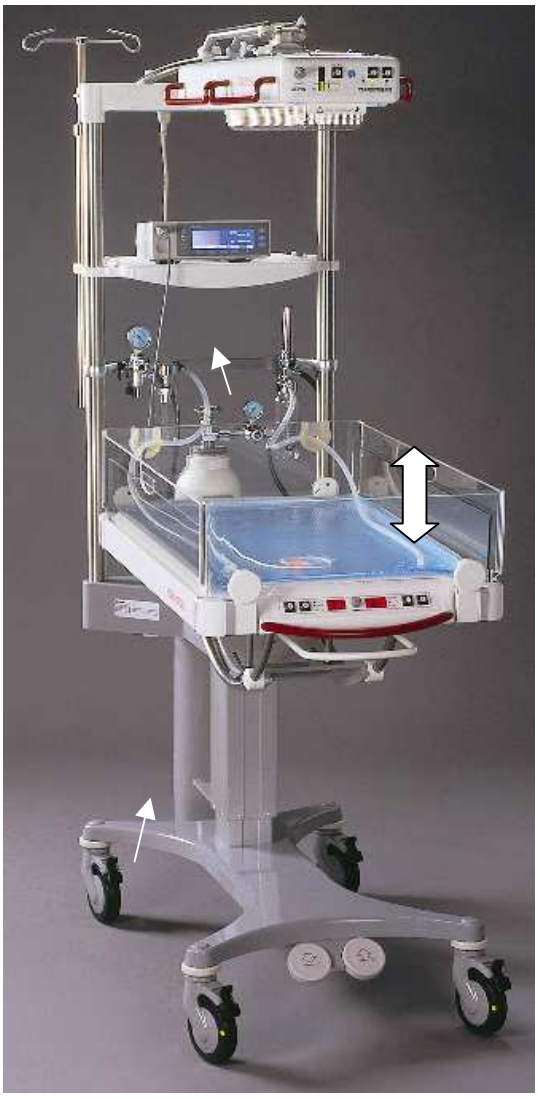
Any of the accessories mentioned in the product brochure can be combined with this unit.

When external devices are connected to the resuscitation and intensive care system VARIO-THERM, it must be checked whether the maximum load of the instrument rail or the monitor shelf of 20 kg is sufficient.

When connecting electrical devices to the take-off sockets of the resuscitation and intensive care system VARIOTHERM, the nominal power indicated beside the socket must not be exceeded.

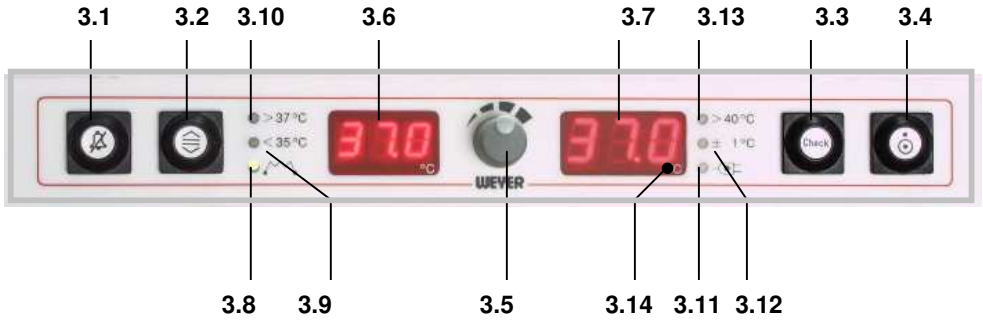
Upgrade items, accessories or external devices must be connected in a way that they are not placed in the field of radiation of the radiant warmer.

It should be considered that when operating the height adjustment facility all devices and components connected with the resuscitation and intensive care system are also be moved. Devices and components, which are not fixed at the unit will not be moved and therefore might be pulled off.



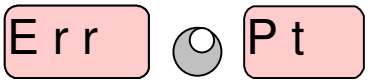
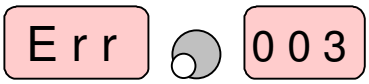
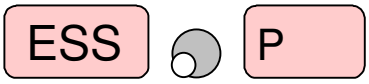
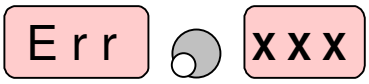
Safety and alarm functions

Under-pad heating

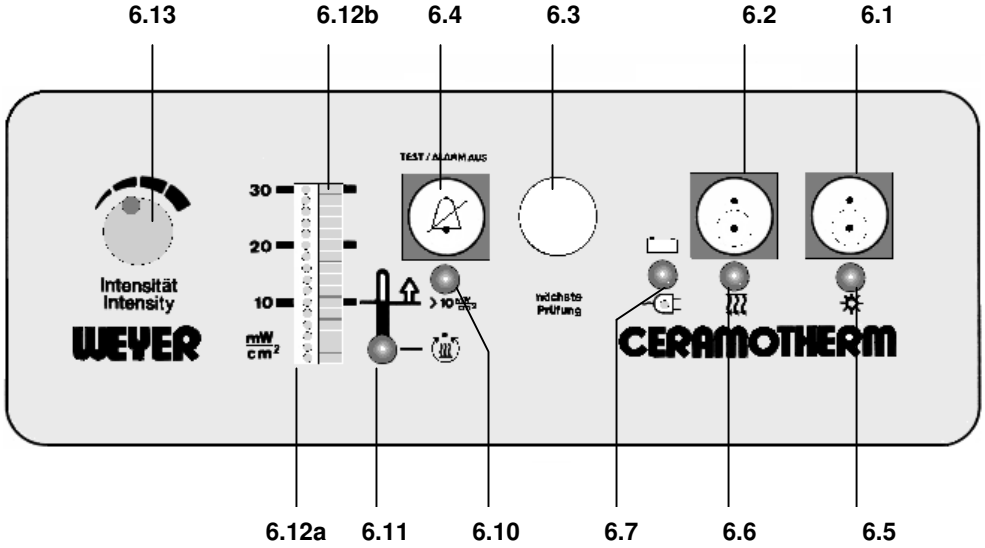


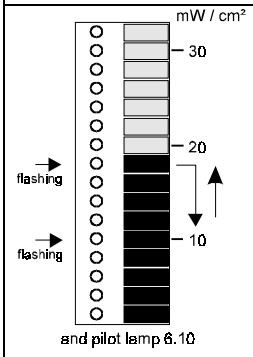
Display/ Warning lamp	Alarm tone	Cause / Effect	Measure
(3.11) flashing (3.6): LO (3.7): bAt	No alarm tone	**Battery capacity** not sufficient for power failure alarm. Audible alarm not secured for 10 minutes.	Replace battery (9V-E Block) below the bassinet.
(3.11) lighting permanently	Non resettable alarm tone	**Power failure alarm** Mains plug disconnected inconsciously or any other interruption in the power supply. No heating, patient becomes hypothermic.	Switch-off the under-pad heating with button (3.4) and make sure that the patient is cared for in another way, or place a foam pad minimum 2 cm thick or a woollen blanket between patient and gel pad.
(3.12) lighting	No alarm tone	**Temperature deviation > 1°C** Device is in heating-up state or temperature selection was adjusted by more than 1°C .	Watch the temperature.
(3.12) flashing (3.7) flashing	Intermittent alarm tone	**Temperature deviation > 1°C** Temperature deviation of more than 1°C for minimum 20 minutes. Patient temperature is influenced negatively.	Press alarm reset button (3.1) and watch the temperature. If this alarm is released repeatedly, have the device checked.
(3.13) lighting	Permenant alarm tone	**Device defective** or influenced by external heating source. Patient temperature may have increased. ⚠ Heating is cut-off by the safety system. As a consequence the patient will become hypothermic.	Switch-off the under-pad heating with button (3.4) and make sure that the patient is cared for in another way, or place a foam pad minimum 2 cm thick or a woollen blanket between patient and gel pad.
(3.14) flashing	No alarm tone	**Heating up state** After switching-on the device has not yet reached the selected temperature.	Wait until the warning lamp extinguishes. If necessary, accelerate the heating up process by switching-on the radiant warmer.

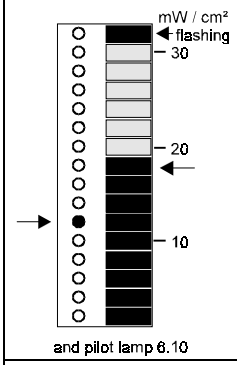
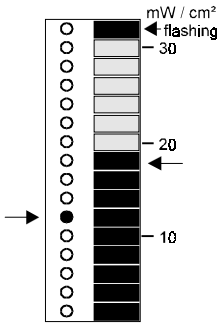
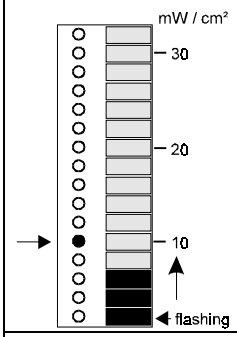
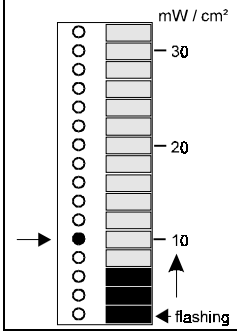
⚠ When one of the following errors is indicated in display (3.6) and (3.7), it is not possible to reset the alarm and the device must be repaired. Switch-off the under-pad heating with button (3.4) and make sure that the patient is cared for in another way, or place a foam pad minimum 2 cm thick or a woollen blanket between patient and gel pad.

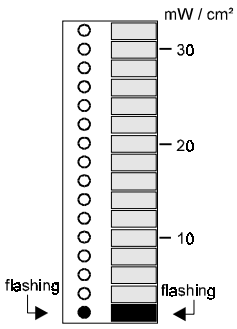
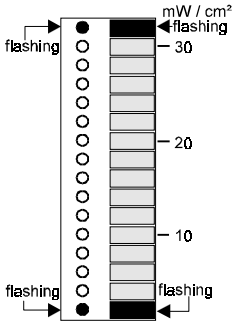
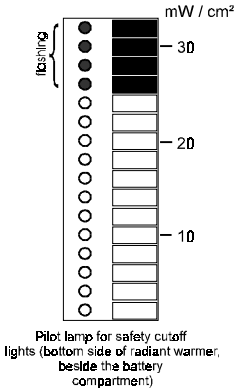
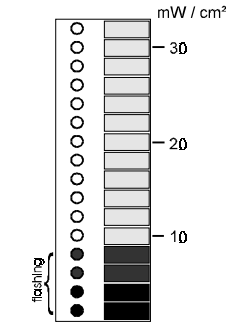
Display	Alarm tone	Error status
	Permanent tone	Sensor short circuit Sensor breakage Measuring value error
	Permanent tone	An error in the measuring sensor system was stated during the system check
	Permanent tone	Sensor breakage or short circuit
	Intermittent or permanent tone	Instead of xxx an error code number is indicated, which relates to an error on the CPU board. Switch-off the device and disconnect the mains plug for 10 seconds. Then switch the device on again and perform the system check. In case of repeated error a recalibration of the device or an exchange of the CPU board is necessary.

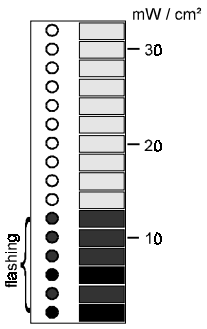
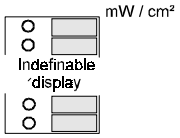
Radiant warmer



Display/Warning lamp	Alarm tone	Cause / Effect	Measure
(6.7) flashing	No alarm tone	**Battery capacity** not sufficient for power failure alarm. Audible alarm not secured for 10 minutes.	Replace battery (9V-E Block) at the rear bottom side.
(6.7) lighting, remaining displays are off	Non-resettable permanent tone	**Power failure** Mains plug disconnected inconsciously or any other interruption in the power supply. No heating, patient becomes hypothermic.	Switch-off the radiant warmer with button (6.4) and make sure that the patient is cared for in another way. Check the fuses of the device.
(6.10) lighting	No alarm tone	Intensity selection above 10 mW/cm². 15-minutes alarm and automatic heating capacity reduction is activated.	Watch the patient' s temperature.
	Intermittent alarm tone 1 : 2	**Radiation intensity >10 mW/cm²** High intensity for more than 15 minutes (15-minutes alarm and automatic heating capacity reduction). In the long run sensitive infants may become dangerously hyperthermic.	Push button (6.4), device proceeds heating with high intensity selection. Check the patient' s temperature and adjust the intensity selection, if necessary.

Display	Alarm tone	Cause / Effect	Measure
 and pilot lamp 6.10	Intermittent alarm tone 1 : 2	**High intensity** The emitted radiation intensity is higher than the selected intensity, caused by accumulation of heat, external heating source or device failure. Heating is cut-off. Patient temperature is influenced.	Reset the audible alarm with button (6.4) and watch the patient. If this alarm is released repeatedly within short time, the device must be taken out of operation and checked.
 and pilot lamp 6.10	No alarm tone	**High intensity** The emitted radiation intensity is higher than the selected intensity, caused by an adjustment of the selected intensity. Device cools off to the new selected value. Patient temperature is influenced.	None. After cooling-off device proceeds operating in normal mode.
	Intermittent alarm tone 1 : 2	**Low intensity** The emitted radiation intensity is lower than the selected intensity. The reason could be draught, convection or a device failure. Patient becomes hypothermic.	Reset audible alarm with button (6.4) and watch the patient. Watch bar graph (6.12b) whether radiation intensity will drop further. If this is the case, the device must be taken out of operation and checked.
	No alarm tone	**Low intensity** The emitted radiation intensity is lower than the selected intensity. Either the device is in the heating-up state or a higher intensity was selected (6.13). The emitted intensity is possibly not be sufficient to keep the patient warm.	Watch the patient until the selected intensity is reached.

Display	Alarm tone	Cause / Effect	Measure
	Non-resettable permanent alarm tone	**Sensor breakage** Sensor defective, interruption in the sensor line, measuring amplifier detuned or defective. No heating. Patient becomes hypothermic.	Switch-off the radiant warmer with button (6.2) and make sure that the patient is cared for in another way. Have the device checked.
	Non-resettable permanent alarm tone	**Sensor short circuit** Sensor defective, short circuit in the sensor line, measuring amplifier detuned or defective, device does not heat. Patient becomes hypothermic.	Switch-off the radiant warmer with button (6.2) and make sure that the patient is cared for in another way. Have the device checked.
	Non-resettable permanent alarm tone	**Safety cut-off** Device is overheating, patient temperature may have increased. Heating is cut-off by the safety system. As a consequence the patient will become hypothermic.	Switch-off the radiant warmer with button (6.2) and make sure that the patient is cared for in another way. Have the device checked.
	Non resettable intermittent alarm tone 1 : 1	**Device failure** in the processor system EPROM (software failure). Heating is cut-off, patient becomes hypothermic.	Switch-off the radiant warmer with button (6.2) and make sure that the patient is cared for in another way. Perform the extended functional test (page 35). Have the device checked and repaired, if necessary.

Display	Alarm tone	Cause / Effect	Measure
	Non resettable intermittent alarm tone 1 : 1	**Device failure** in the processor system (Watchdog) Heating is cut off, patient becomes hypothermic.	Switch-off the radiant warmer with button (6.2) and make sure that the patient is cared for in another way. Have the device checked and repaired, if necessary.
	Non-resettable permanent alarm tone	**Device failure** in the processor system (Watchdog) Heating is cut off, patient becomes hypothermic.	Switch-off the radiant warmer with button (6.2) and make sure that the patient is cared for in another way. Have the device checked and repaired, if necessary.

Cleaning and Disinfection

The resuscitation and intensive care system VARIOTHERM should be cleaned and disinfected for every new patient, however, at least once per week.

After use switch-off the under pad heating and the radiant warmer and wait until the residual heat displays have extinguished. Disconnect the mains plug from the socket.

- Remove nappies and tissues.
- Disconnect all suction and patient circuit systems (if any).
- Close oxygen cylinders etc. and empty liquid containers (if any).
- Clean the device with a cloth slightly saturated with a cleaning agent and wipe it dry.

No liquid must enter into the top of the radiant warmer!

The ceramic heating elements of the radiant warmer must not be treated with cleaning agents or disinfectants!

Never use inflammable disinfectants!

Do not use scouring cleaning agents. Use only disinfectants on the basis of aldehydes and quaternary ammonium merges. **Unsuitable** are tincture of iodine 5 %, carbolic acid, spirit, ether, acetone and other alcoholic agents as well as disinfectants on the basis of halogen-splitting merges, strong organic acids and oxygen-splitting merges.

After disinfection let the device dry for at least 1 hour. Do not switch-on the radiant warmer in order to accelerate the drying process.

Optionally to disinfection by spray or wiping, the device may also be gas-disinfected. After the disinfection it is recommendable to leave the device in fresh air for some time after the disinfection so that the remaining gas may escape.

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

Reassemble all components of the device, check them for completeness and perform a functional test.

Waste disposal

Fluorescent tubes:	Hazardous waste
Batteries:	Hazardous waste
Gel pad:	Domestic waste

Maintenance*

In order to verify the safe operation of the resuscitation and intensive care system VARIOTHERM, the following checks should be performed by qualified persons in regular intervals:

- *Verification that the actual use is in conformance with the normal use*
- *Visual examination of the general condition of the device*
- *Function and secure latching of the wall system*
- *Function and secure locking of the adjustment facilities (height-adjustment facility, tilting device and swivel facility of the radiant warmer)*
- *Possible damages at the device, mains cord or pad.*
- *Function of the alarm systems*
- *Function of the power failure alarm*
- *Measurement of the electrical safety according to the local standards.*

The batteries 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) of the under pad heating indicate Lo + bAt or when the warning lamp (6.7) of the radiant warmer flashes during operation.

In order to guarantee the safe operation of the resuscitation and intensive care system, it should be subject to regular preventive maintenance by authorized qualified persons. For normal operating conditions we recommend yearly maintenance intervals whereas under unfavourable ambient condition and in case of high duty use half-yearly intervals should be observed. The preventive maintenance includes the following checks in addition to the ones mentioned above:

- *Check of: Interior wiring, connections, heating elements*
- *Check of all parameters according to IEC 601-2, EN 60601-2-35 und EN-60601-2-21*
- *Check of the safety cut-off at 10 mW/cm² and 30 mW/cm²*
- *Calibration of the under-pad heating according to EN 60601-2-35*
- *Calibration of the radiant warmer according to EN 60601-2-21*

The maintenance must be performed according to our service instructions and with our calibrated measuring devices.

Neglected maintenance will cause the loss of warranty claims.

We can only be held responsible for the safety features of this device, if maintenance, repairs or modifications are carried out by authorized trained qualified persons 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.

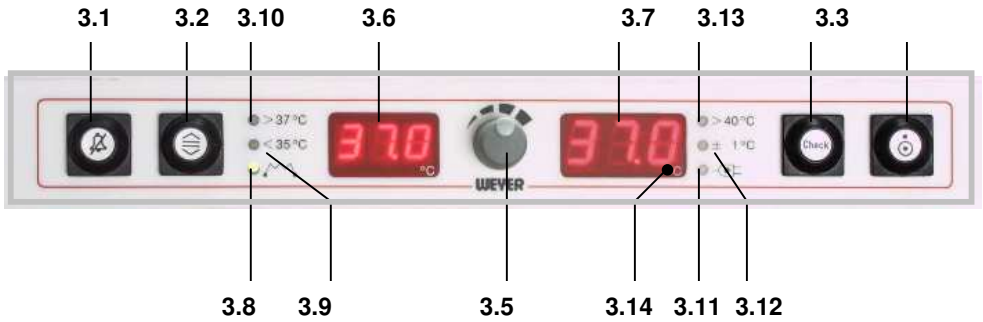
The electronic control systems of both the under-pad heating and the radiant warmer recognize failures and cut-off the heating in case of unsafe conditions. The safety and alarm functions are listed on pages 26 to 31.

The safety functions of the under-pad heating and the radiant warmer can be checked with the integrated software as described on the following pages. Special measuring devices are not necessary. However, this check does not give any indication as to the correct temperature calibration.

*

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

System check of the under-pad heating



Warm-up the under-pad heating to a temperature between 35°C and 37°C, until warning lamp (3.12) extinguishes.

Press button (3.3).

An alarm tone sounds and all displays light for 2 seconds. Both the selected and actual temperature display indicate the value 88.8 an.

⚠ **During these 2 seconds check the proper function of all displays and the alarm tone.**

The selected temperature display (3.6) alternately indicates 37.0 and ChE, while the actual temperature display must indicate a value of 37.0°C± 0.1°C.

⚠ **If the deviation is larger than ±0.1°C, the control system is not calibrated correctly.**

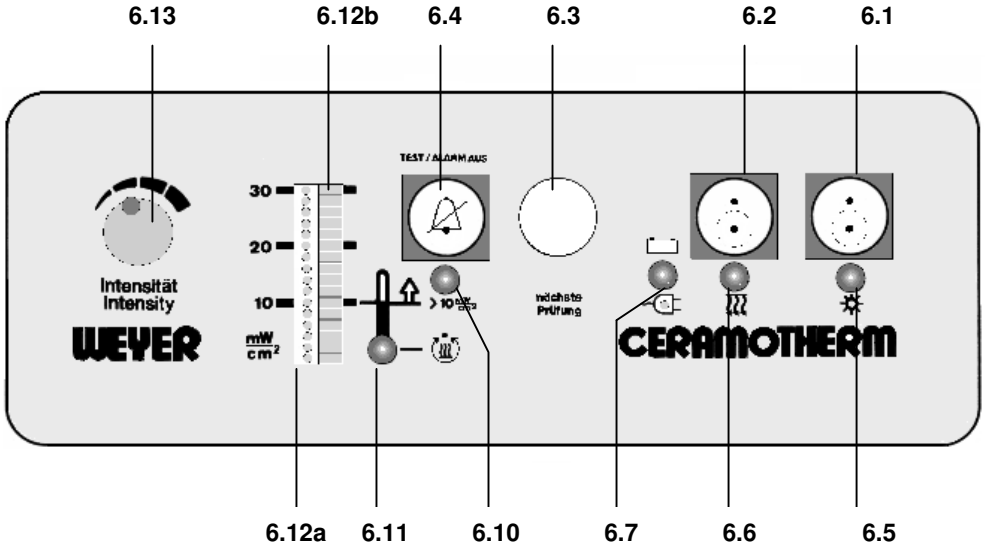
In the case of failure after the display and alarm test the displays (3.6) and (3.7) indicate an error code. The selected temperature display (3.6) indicates ERR and the actual temperature display (3.7) indicates the error number.

In that case a safe operation is no longer guaranteed and authorized qualified persons must check the device.

When the system check is finished error-free the device returns to the normal operating mode after 5 seconds.

Extended functional test of the radiant warmer

For first operation and after a longer time of non-use the following E*xtended functional test* should be performed, which will take approx. 20 minutes.



In order to start the extended functional test, the device must be warmed-up to a value above 10 mW/cm². Select an intensity of 12 mW/cm² with knob (6.13) and wait until this value is reached. The LED (6.12a) and the bar graph 6.(12b) must indicate the same value.

Now switch-off the heating with button (6.2). The bar graph for actual intensity (6.12b) indicates the residual heat of the heating elements. As long as residual heat is displayed, the extended functional test can be started.

If during the following functional test the device should be required for immediate use, the process can be interrupted by switching-on the heating with button (6.2). The device will then immediately change to normal operation mode.

In order to start the functional test, push the alarm reset button (6.4) for approx. 3 seconds until an alarm tone sounds. The test routine starts in the same way as when switching-on the radiant warmer in normal operation mode. The alarm tone sounds and the displays (6.6) - (6.7) - (6.10) - (6.11) - (6.12) light for 2 seconds.

Then the displays will extinguish. The processor now checks the measuring systems of the device. The LED' s of display (6.12a) and bar graph (6.12b) run up the bar from 2 mW/cm² to 32 mW/cm² parallel to each other and the pilot lamp (6.11) flashes. This procedure is repeated cyclically.

The pilot lamp for the safety cut-off beside the battery compartment lights and a permanent alarm tone sounds.

Press button (6.4) until the permanent alarm tone extinguishes.

As a next step the processor proceeds with the test routine for checking the safety cut-off for high intensity > 30 mW/cm² while the topmost spot of LED (6.12a) and the topmost field of bar graph (6.12b) are flashing alternately.

Now a permanent alarm tone sounds, the pilot lamp for heating power (6.11) flashes and the pilot lamp for the safety cut-off beside the battery compartment lights.

If this is the case, push the alarm reset button (6.4) until the permanent alarm tone extinguishes.

An intermittent alarm tone sounds. LED (6.12a) indicates the selected value and the spot for 10 mW/cm² flashes. Now set the intensity knob (6.13) to 10 mW/cm².

As next step the device checks whether the safety cut-off for selected intensity up to 10 mW/cm² is reactivated after a cooling period of 10 minutes. This function is indicated visually by alternate flashing of values 10 mW/cm² in the selected intensity LED (6.12a) and 12 mW/cm² in the actual intensity bar graph (6.12b).

After a period of 10 minutes a permanent alarm tone sounds and the pilot lamp for the safety cut-off beside the battery compartment lights.

If this is the case, push the alarm silence button (6.4) until the permanent tone extinguishes.

Now the test routine is finished. If there are no deviations from the described process, the device is ready for operation. If not, an authorized qualified person must check it.

If the extended functional test shall be repeated, wait until the device has completely cooled-off. Only then the device should be switched-on again, in order to pre-warm it to 10 mW/cm² for a repeated extended functional test.

Technical Data

Transport and storage

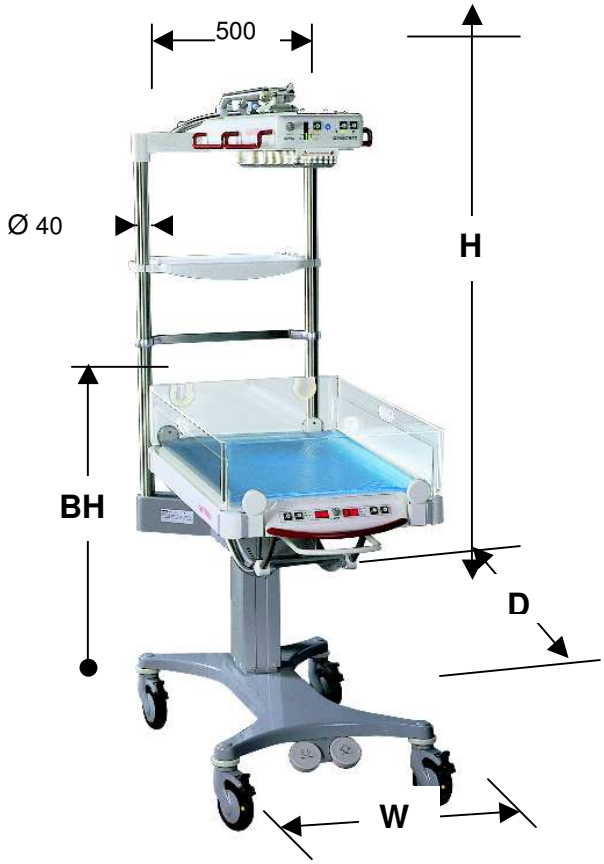
Temperature:	0°C to 70°C
Relative air humidity:	15 % to 95 %
Atmospheric pressure	900 to 1100 hPa

Ambient requirements

Temperature:	18°C to 30° C
Relative air humidity:	15 % to 95 %.
Atmospheric pressure:	900 to 1100 hPa

General Data

Complete device:
Depth = 1140 mm
Width = 585 mm
Height = 1830 to 2130 mm
Bassinet **H**eight = 850 to 1150 mm
Weight = 90 kg



Trolley:
Height-adjustment facility, operated by foot pedals, at choice at the front or at the side.
Range of adjustment: 300 mm
4 swivel castors Ø 125 mm, anti-static, with kick-stop
2 bumpers 70 mm Ø

Bassinet:
Concave shape
Depth = 760 mm
Width = 480 mm
Patient level: 850 to 1150 mm

Tilting-up: 0 to 20°
Tilting-down: 0 to 15°

Pad: Poly gel, conductive

Wall assembly:
4 walls 170 mm high (3 fold-down)
2 safety walls, retractable

Frame assembly:
2 high-grade steel pipe Ø 40 mm

Software version:

Under-pad heating:	5.0
Radiant warmer:	Ce97V1.0b

Operating/performance data

General:

Power connection:	~ 230 V / 50 Hz
Max. power input:	6,7 A / 1540 W
- for the radiant warmer:	4,0 A / 920 W
- for the under-pad heating:	0,7 A / 160W
- for additional devices:	2,0 A / 460 W
Take-off sockets:	3 pcs.- ~ 230 V according to VDE 0625/C13 – EN 60 320/C13 1 pcs.- ~ 230 V according to DIN 49464 – EN 50075 page 1

Under-pad heating:

Temperature selection:	Basic range:	35°C to 37°C
	Extended range:	30°C to 35°C and 37°C to 38,5°C
Increments of temperature selection:	0,1°C	
Resolution of displays:	0,1°C	
Selected temperature display:	30°C to 38,5°C	
Actual temperature display:	30°C to 38,5°C	
Residual heat display:	down to 35°C, then device is switched-off automatically	
Safety cut-off:	at 40°C	

Radiant warmer:

Distance to patient level:	800 mm
Mechanical arrangement:	swiveling to either side
Focus of radiation:	to the center of the bassinet (in any position)
Heating elements:	Ceramic, 2 pcs. 400 W each
Range of wave length:	1500 to 6800 nm
Intensity selection:	2 to 22 mW/cm²
Max. selected intensity:	22 mW/cm²
Selected intensity display:	LED
Increments of intensity selection:	2 mW/cm² per LED
Actual intensity display:	Bar graph 2 to 30 mW/cm²
Resolution of actual intensity display:	2 mW/cm² per LED
Residual heat display:	down to 2 mW/cm², then the device is switched-off automatically
Heating-up period from ambient temperature to max. selected value:	ca. 15 minutes
Medium heating-up speed:	< 15 seconds per mW/cm²
Cooling speed:	3 mW/cm² per minute
15-minutes alarm and automatic heating capacity reduction:	After 15 minutes > 10 mW/cm²
Safety cut-off:	12 mW/cm² at intensity selection 2 to 10 mW/cm² 32 mW/cm² at intensity selection 12 mW/cm² to max.
Illumination:	2 fluorescent tubes 18 Watt each

Classification:

Protection class 1
Device type B
Classification according to MDD: IIb

Standards:

The device conforms to:	EN 60601(edition 1996) EN 60601-2-35, 1997-12 EN 60601-2-21, 1995-12 respectively amendment A1 1998-01

Registration:

EN ISO 9001 / EN 46001:	Registration No. SY 2111759 01
Directive 93/42/EEC:	Registration No. HD 2111760 01

CE **0197**