Inspiration HEALTHCARE

CosyTherm NT

Operating Instructions

CosyTherm^{NT}

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Contents:

Introduction:

The CosyTherm Systems are designed for use in the neonatal intensive care department, special care baby unit or maternity wards. They provide safe and controlled warming to assist newborn infants to maintain normal body temperature. The warming medium is available as:

- A mattress for use under a patient
- A blanket to be placed over a patient

In addition to warming, the mattresses also provide pressure relief. This is achieved using an integral foam pad under the flexible heating surface, ensuring no degradation of heating performance.

Different sizes and models of mattress and blanket are available to suit different cribs. All are sealed to prevent ingress of fluids and to facilitate cleaning.

The mattresses and blankets are powered at low voltage, ensuring safety for patients and operators. The temperature is controlled automatically to user-selected level. An over-temperature safety cut-out is integrated into each mattress and blanket.

The system is powered and controlled by an electronic control unit. The CosyTherm^{NT} control unit is available with a number of options, including battery operation, DC power input and patient temperature monitoring.

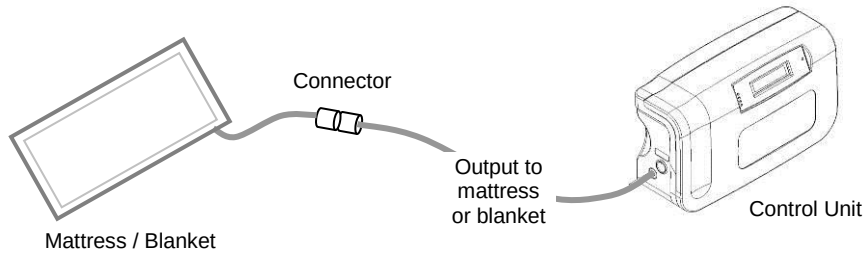
The control unit can be placed on a flat surface or mounted on a pole or rail. It has a standard mains supply input and a working voltage of 26Vdc to the mattress or blanket. The system has different ranges of pre-set operating temperatures between 28°C and 40°C and is designed to be operated continuously, maintaining a uniform heat under or over the patient.

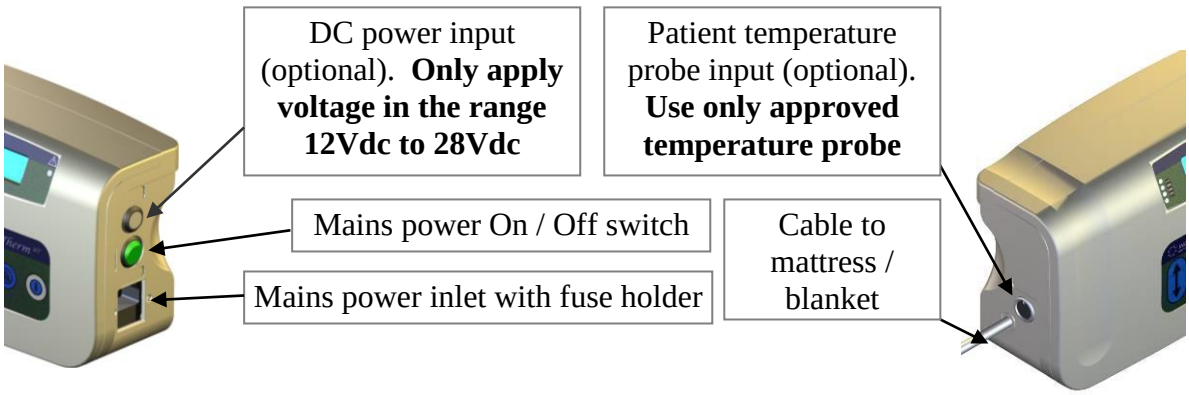
The unit can be supplied with an optional integrated patient temperature monitor.

This system is intended for use by healthcare professionals only.

Description of Parts and Range of Products

Note: Any mattress / blanket can be used with any control unit.





Model	Size	Description
NCM1	610 x 340 x 40 mm	Neonatal Mattress, Standard (610mm x 340mm)
NCM2	730 x 580 x 40 mm	Neonatal Mattress, Large (730mm x 580mm)
NCM3	610 x 430 x 40 mm	Neonatal Mattress, Medium (610mm x 430mm)
NCM4	740 x 310 x 40 mm	Neonatal Mattress, for BabyPod
NCM5	650 x 350 x 40 mm	Neonatal Mattress, (650mm 350mm)
NCM6	650 x 600 x 40 mm	Neonatal Mattress, (650mm x 600mm)
NCM7	605 x 360 x 40 mm	Neonatal Mattress, for LifeStart
NCB1	450 x 500 x 40 mm	Infant Blanket
CCU200	285 x 150 x 125 mm	CosyTherm^{NT} Control Unit – mains power only
CCU201	285 x 150 x 125 mm	CosyTherm^{NT} Control Unit – mains and battery power
CCU202	285 x 150 x 125 mm	CosyTherm^{NT} Control Unit – mains, battery and DC power
CCU203	285 x 150 x 125 mm	CosyTherm^{NT} Control Unit – mains power with patient temperature monitor
CCU204	285 x 150 x 125 mm	CosyTherm^{NT} Control Unit – mains and battery power with patient temperature monitor
CCU205	285 x 150 x 125 mm	CosyTherm^{NT} Control Unit – mains, battery and DC power with patient temperature monitor

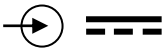
Symbols:

Warning
Read fully these operating instructions as they may affect safety or prevent damage

0
I

Power Switch
0 (Off) Power disconnected from mains power supply
I (On) Power connected to the mains power supply

Warming On / Off



DC power input

Patient temperature probe input

Battery charge status

Select

Increase (value or setting)

Decrease (value or setting)

Alarm Cancel / Reset

Type BF Equipment

Class II Equipment

0473

Product complies with the provisions of the Medical Device Directive (93/42/EEC)

Within European Union product must be disposed of in accordance with WEEE Directive

Safety

Indications for Use
Designed for use in the Neonatal Intensive Care Unit (NICU), Special Care Baby Unit (SCBU), Paediatric Intensive Care Unit (PICU), delivery suite and post-natal wards and during transport, the CosyTherm systems provides safe and controlled warming to assist newborn infants to maintain normal body temperature. In addition to providing warming, the mattress also includes a pressure relief pad.

Contraindications
It is the responsibility of the user to determine whether warming is appropriate for each individual patient. The patient warming system should not be used on patients where clinical considerations indicate that warming of the patient is not advisable.

Warnings
Do not use the warming system if there is any sign of damage. Ensure any damaged item is checked and / or repaired by a qualified engineer or technician.

Do not use the system in the presence of flammable anaesthetic gases or oxygen enriched atmospheres as these may pose an explosion hazard. Note: The mattress or blanket only may be placed in an oxygen-rich atmosphere.

Do not place gel pads on the mattress surface as this may compromise the control of the warming system.

Precautions
Refer to section on Storage and Care to prevent damage to the mattress or blanket. Ensure the mattresses and blankets are not folded or creased and do not store any other product or item on top of the mattress.

Refer to section on Setting Up to ensure patient safety. The mattress must be fitted with the printed side down and the plain surface uppermost.

Refer to section on Use and Care of Mattresses and Blankets to prevent damage, ensure patient safety and obtain best performance. Refer to section on Operation of Control Unit to prevent damage to the product and ensure safety of the user and other staff.

Refer to section on Description of Parts to prevent damage to the system and ensure safety of the patient and user.

When using the integrated temperature monitor, only use approved probe types. The patient's temperature should be monitored when using any warming system. Local hospital guidelines should be followed. It is the responsibility of the user to check the patient's temperature. Do not depend solely on alarms raised by the unit.

The Inspiration Healthcare patient warming system is not sterile. Where necessary the user should take appropriate precautions to protect the sterile field. Refer to sections on Infection Control and Cleaning to ensure safety.

The appliance coupler (mains inlet) is the disconnect device and should remain accessible during use.

Caution: United States Federal law restricts this device to sale by or on the order of a physician.

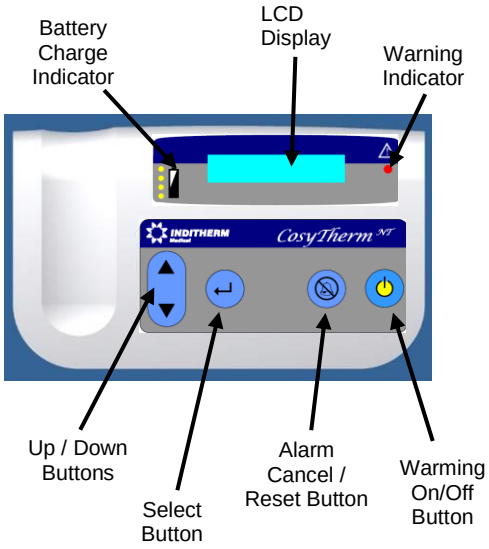
System Description

Control Unit

The control unit is a precision temperature control unit to be used in conjunction with the electrically heated blanket or mattress. All versions have mains power as standard; battery and DC power and a fully integrated patient temperature monitor are available as options.

Mains voltage is supplied to the control unit via a Class II power inlet. A connector is also provided for DC power input if the option is fitted. There is a power switch on the right side of the unit that illuminates when mains power is on.

On the front of the unit is a display and control panel from which all the functions can be accessed, there are four control buttons and an LCD display. The cable for the mattress or blanket is integrated and on the left side.



The control unit input is protected by a T3.15A fuse, which is accessible from the side of the unit in the IEC power inlet connector.

The control unit provides a 26Vdc supply to the mattress or blanket and receives temperature information back. The temperature setting is indicated on the display. The unit automatically adjusts to the type of mattress or blanket connected.

Mattress

The mattress is available in various sizes and is only designed to operate under the patient. The mattress provides an even temperature over the whole surface and is extremely flexible.

The basic construction of the mattresses remains the same throughout the range. They are water and solvent resistant and have been tested for bio-compatibility to allow skin contact during use. All seams are fully sealed by welding.

The internal patented carbon polymer material provides the heat source and an internal temperature sensor provides the output to the control unit for temperature control. The mattress has a thermal protector that will not allow the mattress to overheat.

A pressure relief pad is integrated into the mattress, underneath the flexible warming surface. This provides pressure relief without any attenuation of the warming performance.

Blanket

Blankets are designed to operate over the patient. These are constructed in the same manner as the mattresses, but without the pressure relief pad, which is replaced by a soft insulating material.

Setting Up

Ensure the surface has no folds or creases and check that the surface is not damaged prior to placing in the crib. Do not use if there is any sign of damage or wear.

The mattress must be fitted with the printed side underneath, away from the patient, and the plain surface uppermost.

See section on Operation of Control Unit for further information on setting up.

The clamp on the back of the unit can be configured to attach to either a horizontal or vertical pole or bar. To change the orientation, open the clamp jaws to their full extent and remove the two screws holding the clamp to the case using an appropriate cross-head screwdriver. Orientate the clamp as required, replace the two screws and tighten securely.

The mains power cable is supplied separately so that it can be removed easily. If the user wants to have this cable secured to prevent loss then a "P" clip is provided on the back of the unit. To retain the cable, remove the screw holding the clip in place, put the clip over the cable and screw the clip back loosely. Adjust the cable so that it fits comfortably into the inlet socket and then tighten the screw holding the clip.

Connecting and Disconnecting

A connection cable is provided to take power and control signals between the mattress or blanket and the control unit.

Note: Do not force the connector into the socket. Ensure it is correctly orientated.

Two types of connector are used, depending on specification.

BLUE Connector (standard)**:**
The **Blue** connector plugs into the connector fitted to the mattress or blanket. Align the plug and socket and push fully together. Rotate the ribbed collars clockwise to lock the connection.

To disconnect, rotate the collars anti-clockwise to unlock and pull the connectors apart.

BLACK Connector (optional)**:**
The **Black** connector plugs into the connector fitted to the mattress or blanket. Align the plug and socket and push together. It should be possible to feel a "click" as the connectors engage.

To disconnect, hold the connector bodies and pull them apart.

Note: Do not attempt to rotate or unscrew the black connectors. It is important to pull the black connectors apart straight, and not to bend or twist them.

Storage and Care

To ensure the mattress is not damaged during storage, it should be kept flat**.**

Do not fold the mattress.

Do not store any other product or item on top of the mattress.

Check the mattress or blanket for signs of damage before each use.

Avoid storing control unit, mattresses or blankets in direct sunlight.

Operation of Control Unit

Before Use
Check the unit to ensure there is no sign of damage. Clamp the control unit to an upright IV or accessories pole, a horizontal rail or place in a suitable position on a flat surface. Ensure that the weight of the unit will not cause any risk that it can topple over the item it is attached to. Connect the unit to a suitable mains power supply and position the lead so it does not cause a hazard.

Connect the socket on the control cable to the plug attached to the mattress or blanket as described in the section for Connecting and Disconnecting.

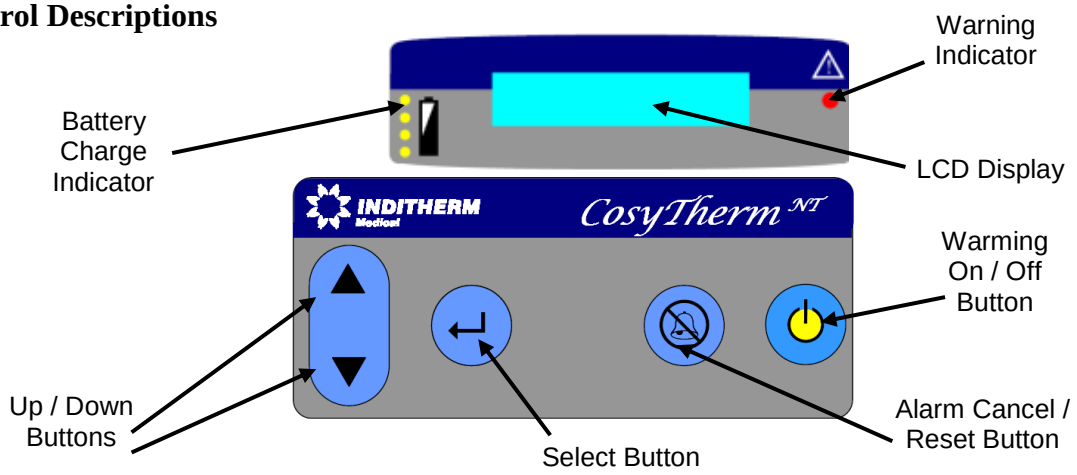
Decide whether the unit is to be operated on mains, battery or DC power (depending on options fitted). For mains power or DC power, ensure that the supply is in the specified range and that the appropriate cable is attached.

If mains power is applied and the power switch at the side of the unit is 'On' (illuminated) then the system will use mains power for operation. If fitted, the batteries will be charged automatically, whether warming is on or off. If mains power is removed or turned off then the system will automatically switch to DC power or to battery power in that order, if those options are fitted and available. If mains power is restored the unit will automatically revert to mains power. The DC power option will not charge the batteries.

Note: If the battery is completely discharged, the unit needs to be connected to the mains supply, the green button switched on and the Alarm Cancel/Reset button pressed to start the power up sequence again. The control unit can be used on mains power whilst the battery is charging.

If the optional patient temperature monitor is fitted, ensure that only the approved patient sensor or probe is used. Contact Inspiration Healthcare or their authorised local distributor for details.

Control Descriptions



Control Unit Start-Up

For mains power operation, turn on the power switch (green button) on the side of the unit and ensure the switch illuminates to indicate power on. For DC power operation, ensure the power source is in the correct range and turned 'On'.

If the battery is completely discharged and the unit does not start, press the Alarm Cancel/Reset button to start the control unit power up sequence again.

Turn on the warming by pressing the Warming On / Off button on the front panel. The system will follow the cycle below:

Display Screen Readout	Action Required	Information
BL 1.00*	None	Checking for new software
CosyTherm V1.00*	None	First screen indicating software version
English ºC ↵ to change	Option to change Language See Language Selection	If required language is set, take no action and system will automatically continue
Language English ºC	None	Screen indicates language
Range 33-37ºC	Option to change temperature range. See Temperature Range	If required range is set, take no action and system will automatically continue
Temp Range 33-37ºC	None	Screen indicates temperature range
Patient Alarms 32ºC 42ºC	Option to change patient alarms. See Setting Patient Alarms	Only if patient temperature monitor is fitted.
System Check	None	Automatic system test
System OK	None	User indication that system is ok
Testing Alarm	None	Automatic test of alarm sound
System OK	None	User indication that alarm is ok
↑ 33°C ↑	User can change temperature. See Temperature Selection	Display showing temperature. Arrows indicate warming status.

*Version numbers are shown as an example only

Language Selection
The language can only be changed at the appropriate point in the start-up sequence, see section on Control Unit Start-Up.

The language can be set to one of the following:
English ºC, English ºF, Spanish, French, German, Italian, Polish

When Language is displayed in the start-up sequence, press and release the Select Button. Within 2 seconds, press and release the Up/Down button to select the required language, the unit will cycle sequentially through the available languages each time a button is pressed and released. When the required language is shown, either press the Select button or wait a few seconds and the change will be automatically registered.

Temperature Range Selection
The temperature range can only be changed at the appropriate point in the start-up sequence, see section on Control Unit Start-Up.

The range can be set to one of the following:
33°C to 37°C in steps of 0.5°C
32°C to 39°C in steps of 0.5°C
28°C to 40°C in steps of 0.5°C*

When Range is displayed in the start-up sequence, press and release the Select Button. Within 2 seconds, press and release the Up or Down button to set the required temperature range; the unit will cycle sequentially through the available ranges each time a button is pressed and released. When the required temperature range is shown, either press the Select button or wait a few seconds and the change will be automatically registered.

* The user-selected temperature range options available may vary according to local country Medical Device regulations. Contact Inspiration Healthcare or your local approved Inspiration Healthcare distributor for further information.

Temperature Selection
The temperature can be set at any time after the self-test start up cycle has completed. The temperatures that can be set will depend on the range selected, and are changed in 0.5°C increments or decrements.

To adjust the temperature, press and release the Up button to increase the required temperature or press and release the Down button to decrease the required temperature. The unit will increase or decrease the set temperatures by 0.5ºC each time one of the buttons is pressed and released.

When the system is first switched on it will default to the most recently used range and temperature setting. The range can be changed at the appropriate point in the start-up cycle.

If the range has been changed during the self-test start up cycle the temperature defaults to the lowest selectable temperature within the chosen range.

Display Information
Depending on the options fitted to the unit it is possible to display different parameters. The standard display shows the set temperature and two arrows. The arrows indicate whether the system is warming up (∧ ∧), is at set temperature (< >) or is cooling down (∨ ∨). To change the parameter displayed, press and release the Select button. Each time the button is pressed and released it will cycle through the available parameters. If no options are configured then pressing the Select button will have no effect.

Battery Status
When the battery option is fitted, the Battery Charge Indicator will show charge status. When the battery is being charged the lights will flash in sequence, with fewer lights flashing as the unit approaches full charge. A full charge may take up to 16 hours.

When running the unit on the battery the lights will show approximately how much charge is left, with fewer illuminated lights indicating lower battery reserve. When the battery charge is low a warning message will be shown periodically on the LCD display and an alarm will sound.

Patient Temperature Monitor
The CosyTherm^{NT} offers the option of a patient temperature monitor. Use of this function will require a suitable temperature probe. Contact Inspiration Healthcare or their authorised local distributor for details of temperature probes approved for use with the CosyTherm^{NT}.

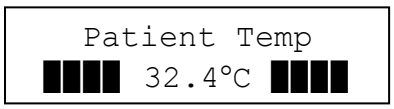
Connecting the Probe
Use only approved probes. If this function is required connect the 3 pin DIN-style plug to the input socket. This is located on the control unit left hand side panel. Note that the plug must be correctly orientated. Do not force the plug into the socket.

Caution: Ensure the patient temperature probe is not connected to any source of power.

Displaying the Patient Temperature
To display patient temperature press the “Select” button once. To revert back to the mattress set temperature press “Select” a second time. In routine use the system will check for the presence of a probe during start up. If no probe is detected it is not possible to press Select and view patient temperature. The patient temperature alarms will be disabled if no probe is present during start-up. As soon as a patient probe is connected, even when the system is already running, the patient temperature display, patient alarms and patient probe fault detection will be enabled.

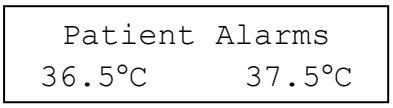
The display has bright bars alongside the patient temperature reading so it is easier to recognise which temperature is displayed at a glance. The full patient probe range is 32°C to 42°C. The system will display temperatures outside this range but accuracy is not guaranteed and should not be relied upon.

Example display of Patient Temperature



Patient Temperature Alarms
Upper and lower alarm limits can be set during the power up sequence. The default alarm limits are 42°C and 32°C respectively.

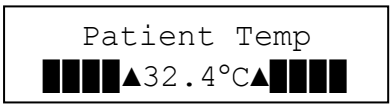
On first use the system will default to these values, however subsequently it will default to the values last entered. Any system alarm (mattress disconnect, mattress fault, mattress high temperature etc.) will have precedence over patient temperature alarms and the screen will change the display to show these alarms.



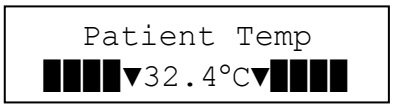
Example screen during start-up mode showing the settings of the high& low alarm levels.

If the temperature goes outside the set alarm limits for a continuous period of more than 1 minute, an alarm sounds and the Warning Indicator illuminates. The alarm will automatically reset when the temperature reverts to within the normal range for more than 2 seconds. The Warning Indicator will continue to be illuminated for the period the temperature is outside the limit. The patient temperature is automatically displayed if the patient temperature alarm sounds.

If the patient temperature is above the upper limit, upward facing arrows are displayed next to the patient temperature and if the temperature is below the lower limit downward arrows are displayed, as shown.



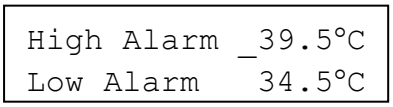
Upper limit exceeded



Lower limit exceeded

Setting Patient Temperature Alarms

To set the patient temperature alarm limits restart the unit by pressing the Reset button. During the start up sequence the patient temperature alarm levels are displayed. Press the Select button whilst they are displayed and the display will read ‘High Alarm’ and ‘Low Alarm’ and show set values.



Upper and Lower Alarm Limits displayed

Setting High Alarm

Press Select to change the underscore cursor to an arrow. This will select the Upper Patient Alarm. Use the Up/Down buttons to set the required temperature. Once the alarms are adjusted to the required temperature press Select to save the new setting. This will cause the arrow to revert back to an underscore. Alternatively wait 4 seconds and the new limits will be stored automatically.

Setting Low Alarm

Repeat the procedure above but this time press the Down arrow to move the underscore ursor to the Lower Patient Alarm. Press Select to change the underscore to an arrow. Use the Up/Down buttons to set the required temperature. Once the alarms are adjusted to the required temperature press Select to save the new setting. This will cause the arrow to revert back to an underscore. Alternatively wait 4 seconds and the new limits will be stored automatically.

Once the desired limits are stored press Select to accept or wait 4 seconds for the system to resume the self-checking sequence automatically.

Inhibiting Patient Alarms
If alarms are not needed they can be switched off. To turn off the lower alarm, set the alarm limits as described above. When the display shows 32°C press the down arrow until XXXXXX is shown and the lower alarm is now off. To turn off the upper alarm, select the high alarm. When the display shows 42°C press the up arrow until XXXXXX is shown and the upper alarm is now off. One or both limits can be turned off.

Patient Alarm Silence
If a patient alarm has been triggered it can be silenced by a short press of the Alarm Cancel button. The default silence period is 5 minutes (time between silencing the alarm and when the alarm will start to sound again if the alarm is still present). This silence period can be modified by the user. Refer to the Service Manual for more detail. Once the silence period has elapsed the alarm will sound again unless the temperature has returned within the alarm limits.

Changing the Number of Alarm Tones
The default alarm is 3 beeps repeated every minute. To avoid clashes with other equipment this can be modified. The Service Manual includes details of how to change the alarm sound defaults including the number of beeps and repeat period.

Use and Care of Mattresses and Blankets

Do not allow sharp objects to penetrate the mattress / blanket. Inspect the surface before and after each use. Mattresses and blankets should not be used if there is any sign of damage.

Do not use the blanket / mattress with any but the supplied control unit and connecting leads.

You should **not** use a gel pad. Use of gel pads may cause a loss of warming performance, as the mattress would have to heat the gel pad first. Clinical evidence is available to support the Inspiration Healthcare mattress performance in terms of pressure relieving properties, which are superior to those of gel pads.

General Performance

On initial start up, if the ambient temperature is low, the mattress / blanket will take longer to achieve the desired temperature. If the desired temperature is not achieved within 25 minutes the alarm will sound. Should this happen, the software will continue to power up the mattress for a further 10 minutes until the desired temperature is achieved. If the temperature is not achieved, the alarm will sound again and thereafter every 10 minutes until mattress/blanket is at temperature.

The mattress contains a special conductive heating material and will not cause any environmental heating. The heat given off by this material will only be felt by the user / patient when applying pressure / weight to the mattress. It is normal that the mattress or blanket do not feel particularly warm to the touch when left uncovered.

The control unit will monitor temperature performance, and when the mattress / blanket reaches the desired temperature the control unit will stop heating the mattress / blanket. If the maximum allowed temperature is exceeded the over temperature alarm will sound.
An internal safety cut-out temperature management system will operate if any fault condition causes the mattress / blanket to exceed a temperature of 43°C.

Infection Control and Cleaning Instructions

Infection Control
Infection Control and routine cleaning should be carried out in accordance with the local Infection Control Policy. Products should be decontaminated prior to servicing or being returned to the supplier. If you are returning the product to Inspiration Healthcare or local distributor, then a decontamination certificate must accompany the product and a copy of the certificate should be affixed securely to the outside of the packaging.

Cleaning Guidelines
Ensure the control unit is disconnected from the mains electricity supply before cleaning it. Clean mattress and control unit with care using a damp soapy cloth and / or disinfectant wipes. After cleaning the control unit, dry thoroughly before use.

For mattresses and blankets only; where a higher level of decontamination is required, use Sodium Hypochlorite (bleach) solution, or similar, (up to 10,000 ppm available Chlorine). After cleaning with bleach solution the mattress or blanket should be rinsed and dried.

All cleaning agents must be used in accordance with manufacturer's instructions for use.

The optional patient temperature probe designed for this unit is a single use device and should be disposed of after use.

Do not immerse the mattress, blanket or control unit in fluids.
Do not use Phenolic based products for cleaning.
Do not process the mattress, blanket or control unit in an autoclave, steriliser or automatic washer-disinfector.

Do not use cleaning or decontamination methods different from those recommended without first checking with Inspiration Healthcare.

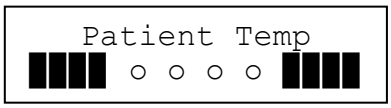
Problem Solving and Warning Messages

The Inspiration Healthcare system has a number of features integrated that check for correct performance. These will generate warning messages if appropriate, which will be shown on the display and sound the audible alarm. These are described below.

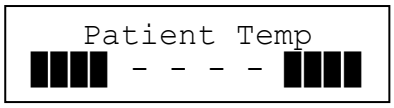
Connect Mattress / Blanket:
Normally indicates that either the mattress / blanket is disconnected, or possibly there is a fault with the connection cable or connector. Check that the connector is fully engaged. If this fails to clear the fault then press the Alarm Cancel button. If the error persists have the system checked by a qualified engineer. This error may also indicate a fault on the mattress / blanket internal temperature sensor.

Mattress Fault:
Normally indicates there is a fault within the mattress / blanket or if the thermal safety cut-out operates. Press the Alarm Cancel button. If problem persists then have the system checked by a qualified engineer. This message is also displayed if the internal fuse on the control unit output is blown.

Probe Fault Detection
If no probe is connected at the start-up of the unit the fault monitoring is disabled As soon as a patient probe has been connected the alarm and fault monitoring becomes active. If the monitoring system detects a fault on the probe this will be displayed automatically on the screen and an alarm will sound. The displayed fault will remain once the alarm has stopped sounding. Probe faults are indicated by 'oooo' or '----' being displayed as follows:



Fault - the probe cannot be detected.



Fault - the probe is not reading correctly.

The 'oooo' fault is typically caused by a probe being disconnected from a unit whilst the unit is operational or a broken probe. The '----' fault occurs if the probe itself is faulty for any other reason. In either of the events above occur, re-connect a working probe and press the Alarm Cancel button.

If the patient temperature probe still fails to read correctly the problem should be referred to a suitably qualified engineer or technician.

High Temperature Detected:
Indicates that the temperature has exceeded the maximum setting. In some cases this will not be experienced as the thermal safety cut-out will operate first.

Low Temperature Detected:
Indicates either that mattress has failed to reach temperature in the prescribed period after switching on or that the temperature of the mattress / blanket has fallen below the set value. During the warm-up period if the set temperature is not reached after 25 minutes then this warning will be displayed. Should this happen, the software will continue to power up the mattress for a further 10 minutes until the desired temperature is achieved. If temperature is still low after the second period then the message will be displayed again. In this case the system should be checked by a qualified engineer.

If any other problems are encountered, then a qualified engineer should be consulted.

Technical Specification

Mattress Construction:		Inditherm® flexible polymer heating sheet, with 18mm foam pressure relief pad under and 305g.m^{-2} expanded polyester comfort lining over. Encapsulated in latex-free, nylon fabric cover, with non-microporous polyurethane coating, fully sealed with welded seams. In-built temperature sensor and over-temperature thermal cut-out.
Temperature Ranges:		33°C to 37°C (91°F to 99°F) in steps of 0.5°C (1°F)
(User Selected)		32°C to 39°C (90°F to 102°F) in steps of 0.5°C (1°F) 28°C to 40°C (82°F to 104°F) in steps of 0.5°C (1°F)* Over-temperature safety cut-out at 43°C (109°F) *The user-selected Temperature range options may vary according to local country Medical Device regulations.
Power:	**Control Unit:**	100Vac to 240Vac (±6%), 50Hz/60Hz (auto ranging) 100 W
DC Option:		12Vdc to 28Vdc (optional)
Battery Option:		Integral rechargeable NiMH battery pack (optional)
Mattresses:		26 Vdc (nom.) 25 W to 65 W, depending on size
Dimensions:	**Control Unit:**	285 x 150 x 125 mm
Mattresses:		**Part** / **Dimensions** / **Type** NCM1 610 x 340 x 40 mm Mattress NCM2 730 x 580 x 40 mm Mattress NCM3 610 x 430 x 40 mm Mattress NCM4 730 x 310 x 40 mm Mattress NCM5 650 x 350 x 40 mm Mattress NCM6 650 x 600 x 40 mm Mattress NCM7 605 x 360 x 40 mm Mattress NCB1 450 x 500 x 40 mm Blanket Other dimensions available on request
Compliance:		EN60601-1, Class II EN60601-1-2 EN60601-2-35 93/42/EEC, EEC Medical Devices Directive - Class IIb, Type BF 73/23/EEC, EEC Low Voltage Devices Directive (2006/95/EC)
Environmental:		
Ambient Temperature (Operating):		10°C to 40°C (59°F to 104°F)
Temperature (Storage & Transport):		-10°C to 55°C (14°F to 131°F)
Relative Humidity:		30% to 75%
Atmospheric Pressure:		700 hPa to 1060 hPa

Guidance and manufacturer's declaration – electromagnetic emissions The systems are intended for use in the electromagnetic environment specified below. User should assure use is in such environment		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Systems use RF energy only for internal function. RF emissions are very low and unlikely to cause interference in nearby electronic equipment
RF emissions CISPR 11	Class B	Systems are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies them.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity The systems are intended for use in the electromagnetic environment specified below. User should assure use is in such environment			
Immunity test	IEC 60601 test level		Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	Pass	Floors should be wood, concrete or ceramic tile. If floors are synthetic material, relative humidity should be at least 30%
Electrostatic fast transient / burst IEC 61000-4-4	±2kV power supply lines ±1kV input/output lines	Pass	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1kV line to line ±2kV line to earth	Pass	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power input lines IEC 61000-4-11	<5% U_T for 0.5 cycle 40% U_T for 5 cycles 70% U_T for 25 cycles <5% U_T for 5 sec	Pass	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during mains power interruptions the battery option should be fitted or a UPS used.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	Pass	If interference is suspected it may be necessary to move the system further from sources of power frequency magnetic fields or install magnetic shielding
Conducted immunity IEC61000-4-6:1996	150kHz-80MHz 1kHz 80% AM 3Vrms AC, Power and Signals	Pass	If interference is suspected it may be necessary to move the system away from the suspected source
Radiated immunity IEC61000-4-3:2002	3V/m 2Hz AM 80-1000MHz 80% 1400-2000MHz 80% 2000-2500MHz 80%	Pass	If interference is suspected it may be necessary to move the system away from the suspected source
Note: U_T is the ac mains voltage prior to application of the test level			

Note: CosyThermNT when fitted with an adaptor plate for transport applications (part MED084) meets BS1789 (crash test) but has not been tested to other vehicle standards. It is the responsibility of the user to determine that the system meets their needs and to carry out any risk assessment necessary. For fitting to a BabyPod please see addendum to Operating Instructions.

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