Panda® iRes Warmer Operation and Maintenance Manual





Panda iRes Warmer Operation and Maintenance Manual - English M1110737 006

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Important Safety Information

Before using the Panda iRes Warmer, read through this entire manual. As with all medical equipment, attempting to use this device without a thorough understanding of its operation may result in patient or user injury. This device should only be operated by personnel trained in its operation under the direction of qualified medical personnel familiar with the risks and benefits of this type of device. Additional precautions specific to certain procedures are found in the text of this manual.

Complete the checkout procedures in this manual before putting the unit into operation. If the unit fails any portion of the checkout procedure it must be removed from use and repaired. Do not use the warmer in the presence of flammable anesthetics; an explosion hazard exists under these conditions.

Device alarms are readable only at a viewing angle of 129° from the front of the device. Position the device for appropriate view of the display.

In the event of loss of Mains power the unit will enter a power fail alarm condition. While in power fail alarm condition a single red LED will be lit at the left side of the alarm light display. The audible alarm is a repeating series of three rapid beeps separated by a short pause. The unit will remain in power fail alarm condition for up to ten minutes, or until mains power is restored. If mains power is restored in less than 10 minutes the unit will return to operation with the same settings as when power was lost. If mains power has not been restored within ten minutes the unit will shut down and the LED indicator and alarm tones will cease. Upon restart of the system after a loss of power of greater than 10 minutes the user may need to reset SpO₂ parameters.

Always disconnect the power before performing service or maintenance procedures detailed in this manual. Apply power only if you are specifically instructed to do so as part of the procedure. Thoroughly air dry the warmer after cleaning it with flammable agents. Small amounts of flammable agents, such as ether, alcohol or similar cleaning solvents left on the warmer can cause a fire.

Only competent individuals trained in the repair of this equipment should attempt to service it as detailed in the Service Manual.

Detailed information for more extensive repairs is included in the service manual solely for the convenience of users having proper knowledge, tools and test equipment, and for service representatives trained by GE Healthcare.

WARNINGS, CAUTIONS, NOTES, and SYMBOLS: This section introduces the various types of warnings, cautions information notes and symbols used in this guide to alert you to possible safety hazards and to provide you with additional information.



WARNING: A Warning statement is used when the possibility of injury to the patient or the operator exists.



CAUTION: A CAUTION statement is used when the possibility of damage to the equipment exists.



NOTE: A Note provides additional information to clarify a point in the text.

Warnings, Cautions and Notes

This section identifies general warnings, cautions and Notes associated with the use of the Panda iRes Warmer.



WARNING:

As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.



WARNING:

Do not lean against side of warmer. Leaning against the side of the warmer may cause it to tip over.



CAUTION:

U.S. Federal law restricts this device to sale by, or on order of, a licensed medical practitioner.



CAUTION:

This device is for professional use only, by trained clinicians.

For professional use only



NOTE:

Ranges listed in this manual represent the operational ranges of the equipment. The gauge ranges may exceed operational ranges.



NOTE:

Air always means medical grade air.



NOTE:

Additional copies of this manual are available on request from the GE Healthcare office listed on the inside back cover of this manual.

 $\textbf{SYMBOLS:} \ \textbf{This section identifies the symbols that are displayed on the Panda iRes Warmer:} \\$

Symbol	Description
液	Type BF Equipment
Ţ	Functional Earth Terminal
(Protection Earth Terminal
\sim	Alternating Current
X	Alarm Silence
EC REP	European Union Representative
%	Consult instructions for use
REF	Catalog Number
SN	Serial Number
***	Manufacturer
8	Do not reuse
?	Help menu
충	Patient temperature
-\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Observation light
$\Delta \widehat{1}^{\Delta}$	Scale
~~	Date of manufacture
	Do not lean on warmer
A	Dispose of electrical and electronic equipment as unsorted municipal waste; must be collected separately
	Increase/decrease, up/down
For professional use only	Equipment shall be used only by qualified, trained medical personnel.
	Do not place items in path of heat.

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VIII

About this Manual

Scope and intended users

This manual describes the features and operation of the Panda iRes Warmer. The Panda iRes Warmer is used in hospital delivery rooms, hospital newborn nurseries and neonatal intensive care units (NICU).

The intended users for this manual consists of end users of the equipment, primarily care providers in infant delivery rooms and NICUs, and hospital biomedical engineering services.

Organization of this manual

The organization of this manual is:

Important Safety Information provides important safety information for the safety of both the patient and the care providers.

Chapter 1 - Introduction describes the Panda iRes Warmer system and the system's indications for use

Chapter 2 - System Setup and Checkout Procedures describes the procedures to set up and check out the Panda iRes Warmer prior to use.

Chapter 3 - Operating the Warmer describes the procedures to operate the Panda iRes Warmer.

Chapter 4 - Maintenance and Cleaning provides information on performing maintenance and cleaning of the Panda iRes Warmer.

Appendix A - General Use Items is a list of general use and ancillary items that may be used with the Panda iRes Warmer.

Appendix B - Specifications provides information on power requirements and accessory outlets, standards, operating environment, storage conditions, user control settings, performance and mechanical specifications.

Appendix C - Electromagnetic Compatibility (EMC) provides information on the Panda Ires Warmer's electromagnetic emissions and the electronic environment that is compatible with the use and operation of the Panda iRes Warmer.

Appendix D - Conforming with Standards and Directives provides information on the European Council Directive and the disposal of electrical/electronic equipment.

Appendix E - Additional Safety Information provides information on IEC 60601-1 3rd edition requirements

Inside back cover provides a geographically organized list of Datex-Ohmeda service centers.

References

References to other manuals pertaining to the Panda iRes Warmer are:

- Giraffe Warmer Operation and Maintenance Manual, M1110734
- SpO₂ Masimo SET Option, Operation and Maintenance Supplement, M1110918
- Resuscitation System Bag and Mask Option, Operation and Maintenance Supplement M1110023
- Resuscitation System T-piece Option Operation and Maintenance Supplement, M1109204
- Service Manual Resuscitation Giraffe and Panda Warmers, M1128929
- Service Manual Giraffe and Panda Warmers, M1128921

Chapter 1 Introduction

The Panda iRes Warmer includes:

- Recessed heater dish
- Dimmable observation lights
- Hands Free Alarm Silence
- Graphical trending features
- APGAR Timer
- Full color control panel
- Resuscitation mattress
- Progressive, adjustable alarms
- Bed tilt
- Dovetail rail system

Optional features include:

- Integrated SpO₂ monitor
- Aimable procedure light
- Integrated Resuscitation
- Tubing management wall
- In-bed weighing scale
- Elevating base
- Multiple drawer packages
- Wood accents
- Accessories



Figure 1: Panda iRes Warmer

System Description and Indications for Use

Infant radiant warmers provide infrared heat in a controlled manner to neonates who are unable to thermoregulate based on their own physiology. Infant radiant warmers may be used to facilitate the neonate's transition to the external environment or to provide a controlled open environment. An optional integrated SpO_2 monitoring feature may be used for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). An optional integrated resuscitation system may be used to provide the basic equipment required for pulmonary resuscitation of infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the infant.

Mechanical Controls and Cable Connections

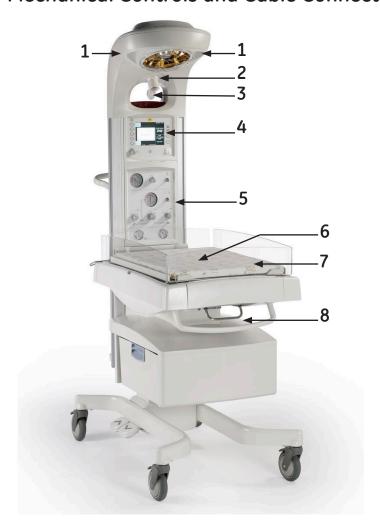


Figure 2: Panda iRes Warmer, front oblique view

Feature number	Description
1	Two dimmable observation lights
2	Aimable procedure light
3	Procedure light "On/Off" switch
4	Color display screen
5	Resuscitation system (optional)
6	Bed, with integrated scale
7	Front bedside panel
8	Bed tilt control lever

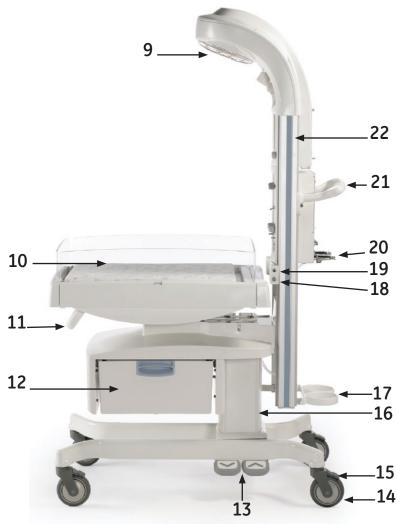


Figure 3: Panda iRes Warmer, side view

Feature number	Description
9	Recessed radiant heater
10	Side bedside panel
11	Front handle
12	Pass trough drawer
13	Two bed height adjustment pedals, up and down
14	Four caster wheels
15	Four brakes
16	Elevating column
17	Tank guard (optional)
18	Scale cable connector
19	Temperature probe Jack
20	High pressure air/oxygen yoke (optional)
21	Maneuvering handle and cord wrap
22	Dovetail rail

Mechanical Controls and Cable Connections (continued)

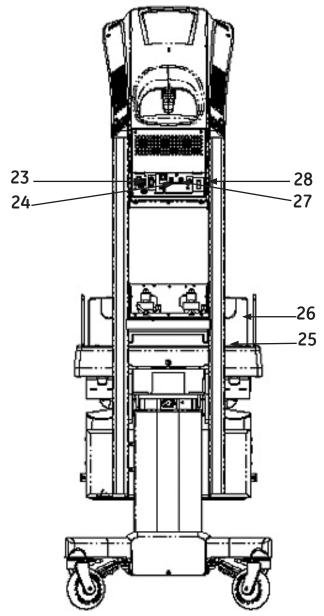


Figure 4: Panda iRes Warmer, rear view

Feature number	Description
23	RS 232 connector
24	Two accessory power outlets
25	SpO₂ Jack
26	Removable rear bedside panel
27	Power cord inlet
28	Mains Power Switch

Controls and Displays

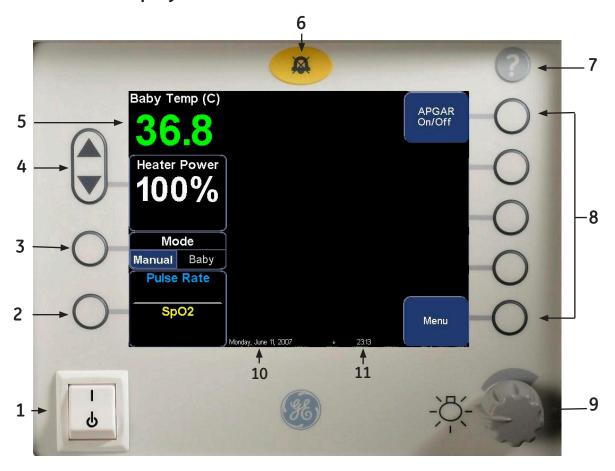


Figure 5: Control panel and color screen display

Feature number	Description
1	Power stand-by switch - On the left below the display turns the power to the warmer "On" and "Off".
2	Oximetry key (optional) - This key retains its same function at all times.
3	Mode key - To select manual or baby mode. This key retains its same function at all times
4	Temperature/power increase/decrease key - This key retains its same function at all times
5	Baby temperature - Can be displayed in degrees Celsius or degrees Fahrenheit. The default setting is degrees Celsius.
6	Alarm silence key - Alarms can be silenced by pushing the key above the display or by a wave of your hand directly in front of the alarm light.
7	Help key - The key with the "?" in the upper right corner brings up the help screen that explains alarms and functions.
8	Task keys - The five keys on the right are "soft" keys that change their function depending on what task you wish to perform. They control equipment settings and options.
9	Dimmer knob - On the right controls the brightness of the observation lights.
10-11	Date and time - Displayed at the bottom of the screen.

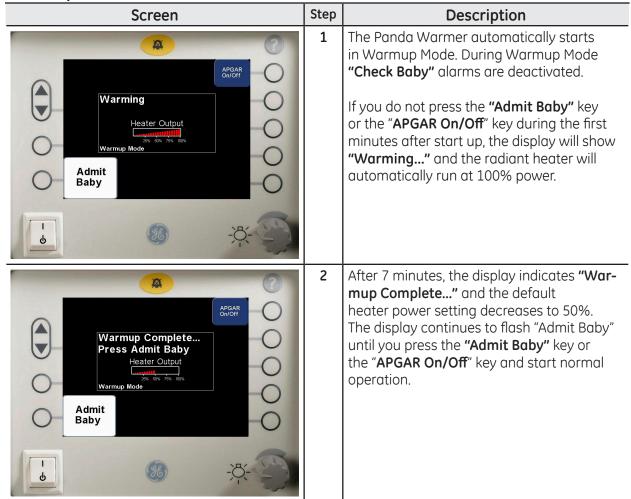
Temperature Regulation



WARNING:

Do not place the baby in the bed while in Warmup Mode. Warmup Mode is used to quickly warm and maintain heat to an empty bed. Warmup Mode is not designed for clinical use with a baby since the Check Baby Alarm is disabled.

Warmup Mode



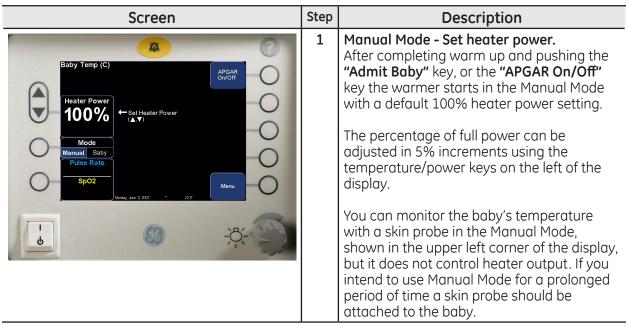
1-6

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Control Modes

The Panda Warmer has two control modes, **Manual Mode** and **Baby Mode**. In Manual Mode, the warmer controls radiant heater output from a heater power percentage setting that you enter using the control panel. In Baby Mode, the warmer controls radiant heater output based on temperature readings from a probe attached to the baby's skin (skin probe) and a set temperature (set temp) you enter using the control panel.

Manual Mode

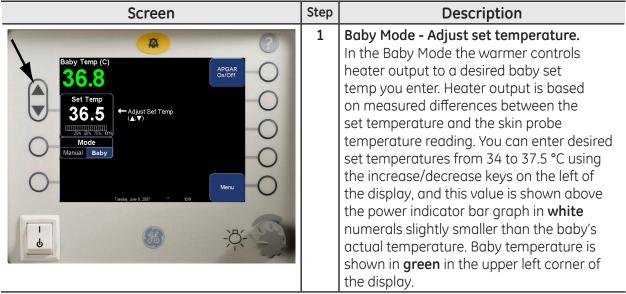




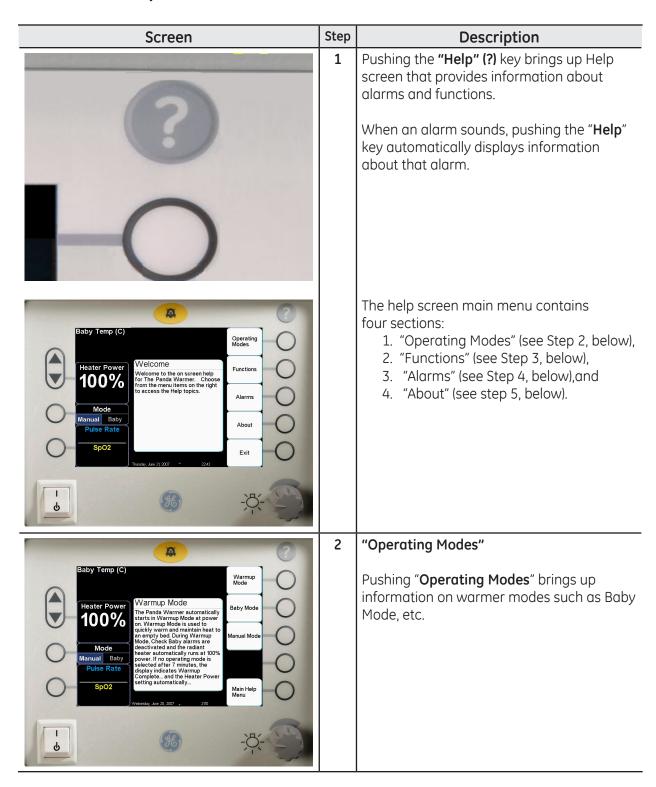
WARNING:

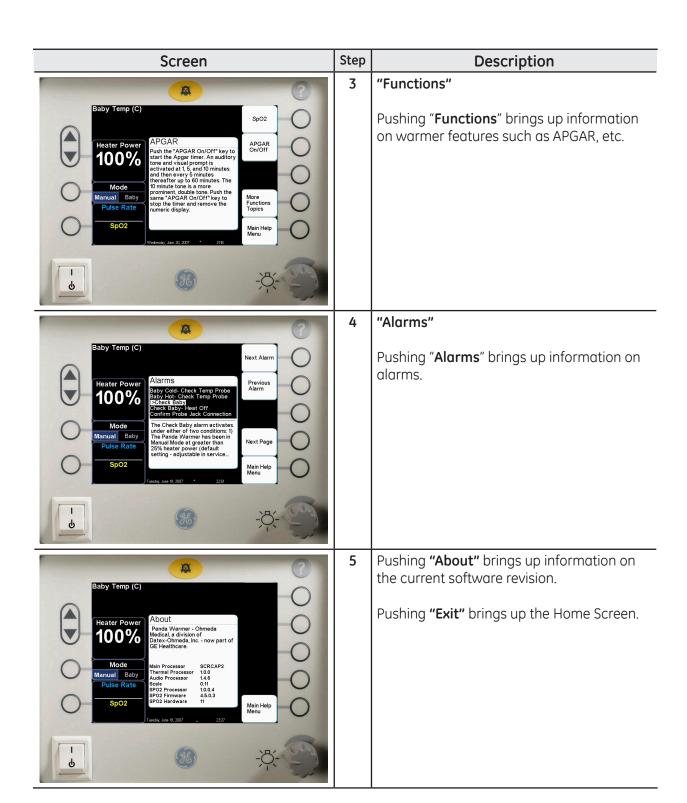
Do not leave baby unattended while the warmer is in Manual Mode. Whenever possible, use the warmer in the servo-control mode (Baby Mode). The Manual Mode requires constant monitoring of the baby's condition by the caregiver.

Baby Mode

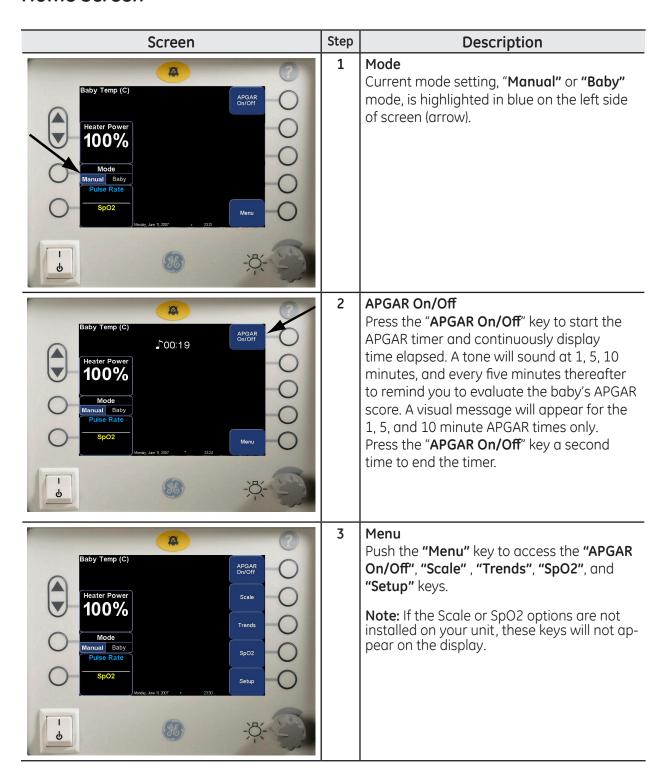


On Screen Help





Home Screen



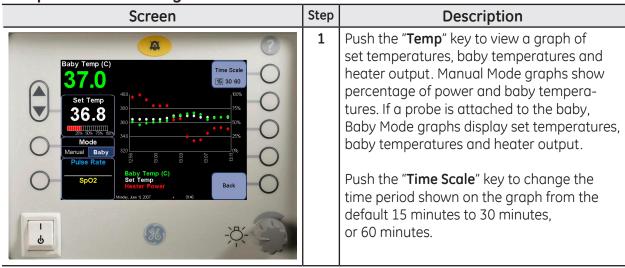
Scale (optional)

Push the "**Menu**" key to access the "**Scale**" key. If the scale jack is not plugged in, the scale key will not appear. Push the "**Scale**" soft key to start the weighing procedure and access the next menu. For more detail on performing the weighing procedure and using the scale (refer to "Using the In-Bed Scale (optional))" on page 3-17.

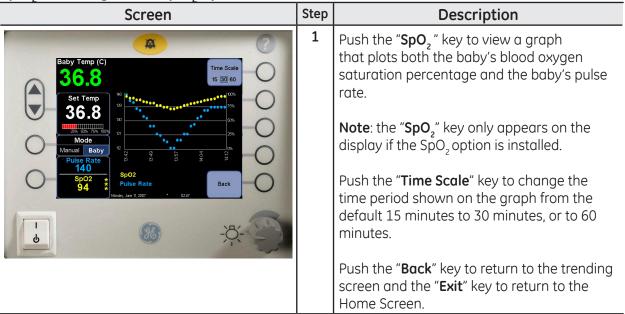
Trends

The warmer trends temperature, and SpO2 (optional). Push "**Menu**" key then the "**Trends**" key to display the trending screens.

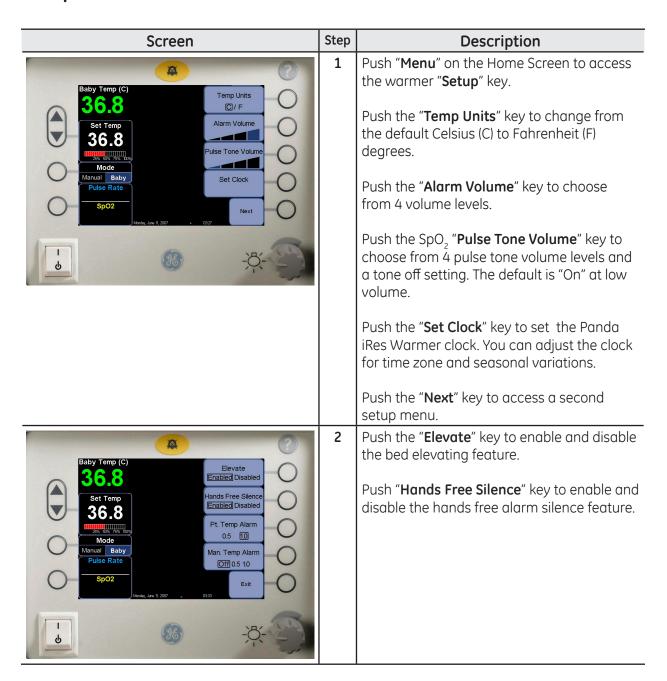
Temperature trending

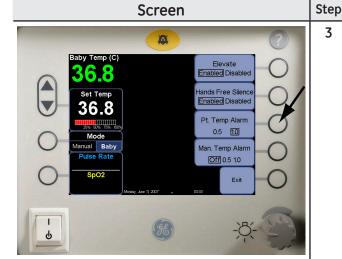


SpO₂ trending (with SpO₂ option installed)



Setup





Description

Patient Temperature Alarm
Push the "Pt. Temp Alarm" key to choose between two settings in the warmer's
Baby Mode. The 0.5 setting activates an alarm when the difference between the set Temperature and the baby's skin temperature is greater than 0.5°C. The default 1.0 setting activates an alarm when the difference between the set temperature and the baby's skin temperature is greater than 1.0°C.



4 | Manual Temperature Alarm

You can use the manual temperature alarm when you wish to manage the baby's temperature in the Manual Mode, but want to be notified when the baby's temperature drops below or rises above a threshold setting.

Place the temperature probe on the baby's skin. Push the "Man Temp Alarm" key to choose from 3 settings in the warmer's Manual Mode. The default Off setting deactivates the alarm, the 0.5 setting activates an alarm when the difference between the set temperature and the baby's skin temperature is greater than 0.5°C. The 1.0 setting activates an alarm when the difference between the set temperature and the baby's skin temperature is greater than 1.0°C. For more details on operation of the Manual Temperature Alarm, (see "Setting the manual temperature alarm" in chapter3).



NOTE: After power down, only the time setting will remain.

Alarms

Illustration 1 2 Confirm Probe Jack Connection Sol.5 Connection Confirm Probe Jack Conf

Description

There are two types alarms:

Low Priority Alarms are indicated by a blinking red alarm light, a red alarm message on the central alarm area of the display, and an intermittent audio tone.

High Priority Alarms have the same blinking red alarm light and red alarm message. The difference is that the audio tone for high-priority alarms is continuous.

Alarm features

Feature number	Description	
1	Alarm light	
2	Motion sensors	
3	Alarm silence key	
4	Alarm message	



To silence the alarm. There are two methods of silencing the alarm:

- 1. Press the yellow button at the top of the control panel.
- 2. Use the Hands Free Alarm Silence (see below).

When you silence an alarm, the text message gets smaller and moves to the top of the screen and the red alarm light goes from blinking to solid. When the alarms have been silenced, the audio tone is temporarily turned off, but the warmer remains in alarm status until the alarm condition clears. When the silence period expires, the audio tone will resume, but the silence period varies with the alarm (for greater detail about alarm priorities and silence periods, see the Alarm Table at the end of this chapter). If there are multiple alarms, the text messages alternate every 2 seconds.

Illustration



Description

Hands Free Alarm Silence

The motion sensor for the Hands Free Alarm Silence is located in the alarm light panel. Silence the alarm by gently waving your hand approximately 2-6 inches in front of the sensor.

Silencing an alarm with the Hands Free Alarm Silence works exactly the same as pressing the alarm silence button for all alarms. Using the Hands Free Alarm Silence will allow you to silence alarms without touching a panel surface.

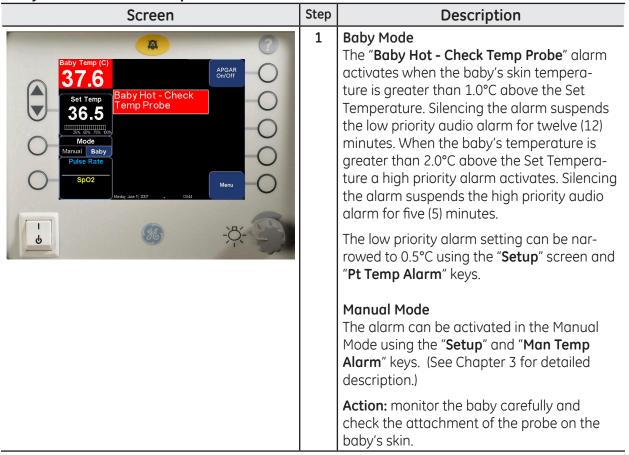


WARNING:

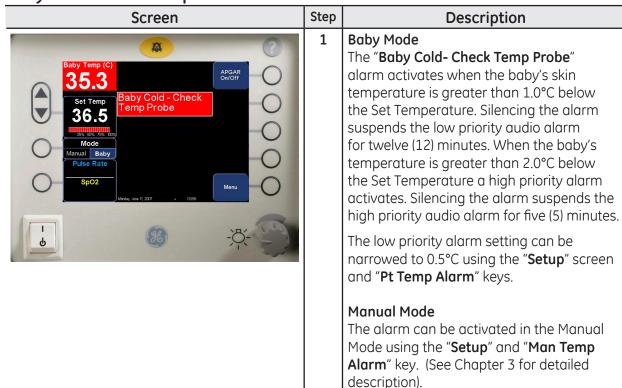
Do not block the alarm speaker located on the back of the control panel near the power outlets. Doing so may interfere with audio alarms.

Temperature regulation alarms

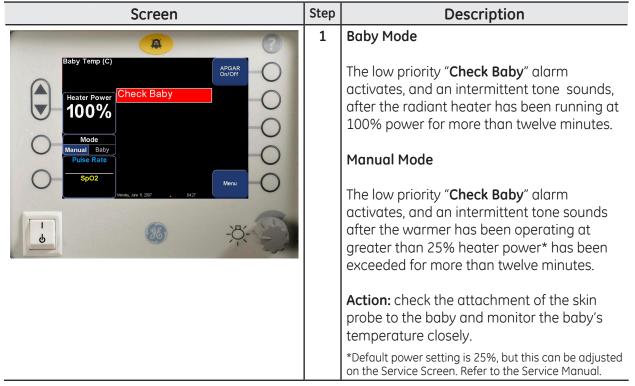
Baby Hot - Check Temp Probe



Baby Cold-Check Temp Probe



Check Baby



Action: monitor the baby carefully and check the attachment of the probe on the

baby's skin.

Check Baby-Heat Off



. Baby Mode

A continuous tone sounds after the radiant heater has been running at 100% power for more than fifteen minutes, and the "Check Baby" alarm" has gone unanswered for three minutes. The radiant heater then shuts off automatically and the high priority "Check Baby-Heat Off" alarm activates.

Description

Manual Mode

A continuous tone sounds after the warmer has been operating at greater than 25% heater power* for more than fifteen minutes, and the "Check Baby" alarm has gone unanswered for three minutes. The radiant heater then shuts off automatically and the high priority "Check Baby-Heat Off" alarm activates.

Action: silence the alarm and check the attachment of the skin probe to the baby and monitor the baby's temperature closely.

*Default power setting is 25%, but this can be adjusted on the Service Screen. Refer to the Service Manual.

Confirm Probe Jack Connection



Baby Mode

The "Confirm Probe Jack Connection" alarm activates when the skin probe jack is unplugged.

Description

Manual Mode

It will also activate when there is no probe in the jack in the Manual Mode, if the Man Temp Alarm has been set.

Action: check that the skin probe is fully inserted into the temperature probe jack. If this does not cancel the alarm, check if the Man Temp Alarm has been set. If the alarm is still not cancelled, then replace the temp probe.

Temperature Probe Failure

Screen	Step	Description
Baby Temp (C) 36.8 Set Temp 36.8 Set Temp 36.8 Mode Manual Baby Pulse Rate Sp02 Menu Menu	1	This "Temp Probe Failure" alarm activates when the difference in the two thermistors in the skin temperature probe is greater than 0.5°C for over 6 minutes. Action: replace probe.

System Failure



WARNING:

Do not use the warmer if the system failure alarm is activated. Remove the unit from service and refer to qualified personnel for repair.

If an electrical failure is detected, the system failure automatically shuts off the heater and triggers a two tone audio alarm that can not be silenced.

Action: make note of the error message and remove unit from service.

Scale Alarms

Screen	Step	Description
Baby Temp (C) Heater Power 100% Mode Manual Baby Pulse Rate Sp02 Morday, Are 11, 2007 OS37	1	Weight on scale above maximum This alarm means that the weight on the scale is above 8 kilograms (17.6 lb). Action: check for other objects on scale.

Alarm Table

Alarm	Activation Criteria	Alarm Silence	Audio Signal*	Mode
Check Baby	neck Baby Radiant % power @ 1 100% for > 12 min.		2	Baby Mode
	Radiant heater % above "check baby alarm disabled" limit for > 12 min.	12 min.	2	Manual Mode
Check Baby - Heat off	Radiant % power @ 100% for >15 min. and the "Check Baby" alarm has gone unanswered for three minutes.	15 min.	1	Baby Mode
	Radiant heater % above "check baby alarm disabled" limit for > 15 min. and the "Check Baby" alarm has gone unanswered for three minutes.	15 min.	1	Manual Mode
Baby Cold - Check Temp.	<2.0° C from Set Temp.	5 min.	1	Baby Mode
Probe	<1.0° C (<0.5° C) from Set Temp.	12 min.	2	Baby Mode
Baby Hot - Check Temp.	>2.0° C from Set Temp.	5 min.	1	Baby Mode
Probe	> 1.0° C (>0.5° C) from Set Temp.	12 min.	2	Baby Mode
Confirm Probe Jack Connection	No longer getting a reading from the temperature probe.	2 min.	2 to 1 (after 30 secs.)	Baby Mode or Manual Mode when Manual Temperature Alarm set.
Temp. Probe Failure	Two thermistors in a probe differ by 0.5° C or more.	2 min.	2 to 1 (after 30 secs.)	Baby Mode or Manual Mode when Manual Temperature Alarm set.

^{* 1=} high priority audio signal 2= low priority audio signal

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System Setup and Checkout Procedures

Mechanical checks



WARNING:

Before using the Panda Warmer, read this entire manual. Attempting to use device without a thorough understanding of its operation may result in patient or user injury.



WARNING:

Do not perform the preoperational checkout procedure while the patient occupies the unit.



WARNING:

Complete the preoperational checkout procedure section of this manual before putting the unit into operation. If the equipment fails any portion of the checkout procedure it must be removed from use and repaired.

Illustration	Step	Description
	1	Disconnect the power cord for the mechanical portion of the preoperational checkout procedure.
	2	Examine the power cord for any signs of damage. Replace the cord if damage is evident.

	_	
Illustration	Step	Description
	3	Check that the plug retaining brackets for the power cord and the accessory outlets on the back of the control panel are in place.
	4	Examine the unit overall for any damaged or missing parts.
	5	Check that all the casters are in firm contact with the floor and that the unit is stable. Lock the caster brakes and check that they hold the unit in place. Release the brakes and check that the unit moves smoothly.

Illustration	Step	Description
	6	Check the operation of all four bedside panels. The bedside panels should lock securely in the upright position.
	7	Check the operation of the bed tilt mechanism. When you squeeze the tilt control and push down on the foot of the bed the head of the bed should raise easily, and should stay in position at any angle along its tilt path when you let go of the tilt control. The bubble levels on the side bedside panels should indicate the mattress is level.

Controller checks



WARNING:

Do not use the warmer in the presence of flammable anesthetics: an explosion hazard exists under these conditions.



WARNING:

Always connect the warmer directly to a hospital grade wall outlet. Connecting to a power strip or another piece of equipment may result in power failure errors.

Illustration	Step	Description
	1	Make sure the power cord is connected to the outlet on the unit and to the rated power supply.
	2	Switch on the power at the mains switch on the back of the unit, and at the standby switch on the front control panel. Verify the following: • All the displays and indicators light • The software revision appears • The prompt tone begins

	۱	1 2
Illustration	Step	Description
Warmup Complete Press Admit Baby Heater Output Warmup Mode Admit Baby	3	Press the "Admit Baby" key to enter normal operation in Manual Mode. Select Heater Power percentage to silence the prompt tone.
	4	Connect the baby temperature probe to the jack on the right side of the bed. If using a Panda Warmer with an in-bed scale, the temperature probe jack is above the In-bed scale connection.
Baby Temp (C) 36.2 Set Temp 37.0 Unroul Temp Sp 02 Public Rate To To To	5	Check the skin probe. Warm it by placing it between your fingers, and verify that the baby temperature reading increases.

Step Illustration Description 6 Unplug the skin probe and change the warmer to Baby Mode. Check that both visual and audio alarms trigger in the Baby Mode. Panda Silence the alarm by using either the alarm silence key or the Hands Free Alarm silence. Return the warmer to Manual Mode by pressing the "Mode" key. Select a Heater Power setting to silence the prompt tone. If the unit is equipped with an elevating bed, check the operation of the bed elevation mechanism. Raise and lower the bed along its entire travel range, checking that the mechanism operates smoothly. Check that the two bed height adjustment pedals on either side of the unit raise and lower the bed height.



NOTE: If readying the bed to admit a new patient, power down the warmer for 10 seconds, then turn power back on. Allow warmer to preheat the bed in Warmup Mode.

Ancillary equipment checks

Illustration	Step	Description
	1	Check that all ancillary equipment is securely mounted.
	2	Check the operation of any ancillary equipment with reference to their appropriate operation manuals.
	3	Setup any required suction or gas supply systems. Check them for leaks as described in their respective operation manuals.



WARNING:

Do not place the warmer in a high ambient air flow environment.



WARNING:

Do not place the baby in the bed while in Warmup Mode, Service Mode, or while servicing or calibrating the unit.

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2-8

Chapter 3 Operating the Warmer

Basic Operating Procedure



WARNING:

Always set the brakes before placing a patient in the unit.



WARNING:

Do not leave the patient unattended when using the Panda iRes Warmer.



WARNING:

Check the patient's temperature periodically with an independent monitor to ensure the comfort and the safety of the patient. If the warmer is used for an extended time, it is recommended that the baby control mode be used. When an alarm is silenced, close monitoring of the patient's condition is required.



WARNING:

Use of electrosurgical units or other electrical field radiating equipment can affect the operation of the unit. Keep the patient probe lead as far away as possible from electrosurgical cables. Do not allow excess electrical cables to be laid on the bed platform. Use of electrosurgical units or other instruments that radiate electrical fields can cause indirect heating, by several tenths of a degree of the skin temperature probe due to absorbed electrical energy. When using these devices near the radiant warmer, operate the warmer in Manual Mode for maximum safety and use a skin temperature probe to monitor patient temperature. For added safety, you should consider use of the manual temperature alarm found in the Setup menu.



WARNING:

The use of phototherapy equipment or heated mattresses may raise the patient's temperature. Monitor patient temperature using a skin probe.



WARNING:

Radiant warmers may increase an infant's insensible water loss. Take appropriate measures to maintain the patient's fluid balance while caring for them in a radiant warmer.



WARNING:

Radiant energy can adversely affect blood components. When using intravenous tubing systems for delivery of blood components to patients occupying a warmer, shield any tubing with aluminum foil.



WARNING:

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Radiant energy may cause more rapid urine evaporation, and may lead to inaccurate urine diagnostic test analysis and inaccurate weight measurements. Frequent diaper changes are recommended.

3-1



WARNING:

Use Baby Mode unless Manual Mode is specifically prescribed. While both modes require patient monitoring, Manual Mode requires constant attention. In Manual Mode, you must take the responsibility for detecting changes in the environment (high air flow, direct sunlight, phototherapy lamp usage, etc.) or the patient's condition and make heater power adjustments in response to these changes. In Baby Mode, the warmer automatically adjusts heater output to maintain the desired skin temperature, reducing (but not eliminating) the need to monitor the patient and make adjustments to the Baby Mode control temperature.



WARNING:

Do not leave the baby unattended while any bedside panels are lowered or removed.



WARNING:

When bedside panels are in an upright position, ensure that the bedside panels are properly locked in place.



WARNING:

The patient probe is not isolated from earth ground. Any additional equipment used with the Panda Warmer must comply with IEC 601.



WARNING:

Bed-to-heater spacing less than approximately 85 cm will result in incorrect operation and may adversely affect the patient's condition.



WARNING:

Do not place objects in the radiant heat path. Objects will be heated and could block heat to the baby.



WARNING:

Do not hang items from the heater head.



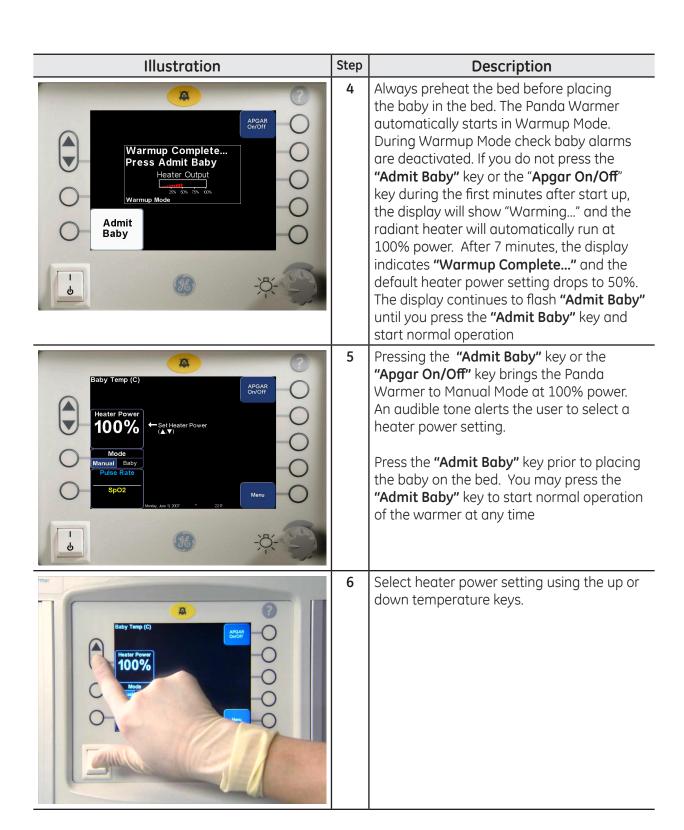
WARNING:

Do not connect unapproved equipment into accessory outlets.

Operating the Warmer (continued)

Start up

Illustration	Step	Description
	1	Plug the unit into a properly rated AC power outlet and set the caster brakes.
	2	Place the mains power switch, located by the outlets on the back of the unit, in the "On" (I) position.
Admit Baby	3	Place the power Stand By switch, located on the left side of the controller, in the On (I) position. Check the control panel to ensure the screen is working properly.



	61	
Illustration	Step 7	Place the baby in the bed
		WARNING: Do not place baby in bed during Warmup Mode.
	8	For Baby Mode operation, connect the skin temperature probe to the temperature probe jack. In the Manual Mode, use a probe if you wish to display the patient skin temperature. See "Attaching the Skin Temperature Probe" later in this section.
Baiby Temp (C) 36.2 Set Temp 36.5 Monda Baiby Monda Baiby Pulse Rate Trans, Mac 8. 202 La 102 March Monda Baiby M	9	If Baby Mode is desired, press the "Mode" key to toggle to Baby Mode. Current mode setting, "Manual" or "Baby" mode, is highlighted in blue on the left side of screen.

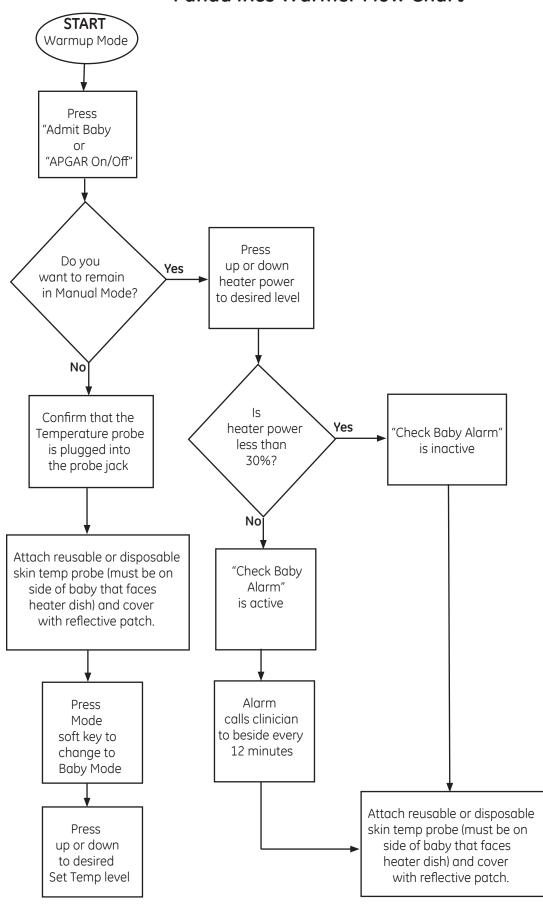
Illustration	Step	Description
Baby Temp (C) 36.2 Set Temp 36.5 Immunum Mode Manual Inky	10	Select a temperature setting using the up or down temperature keys.



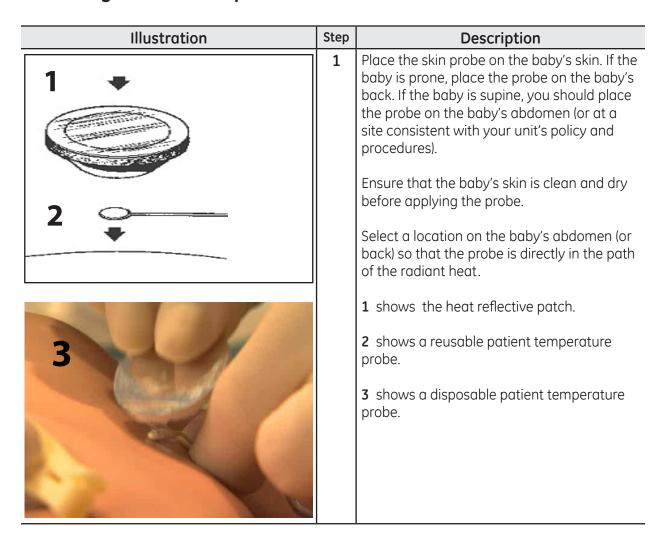
WARNING:

Do not connect unapproved equipment into accessory outlets.

Panda iRes Warmer Flow Chart



Attaching the Skin temperature Probe





WARNING:

Do **not** place the probe between the baby and the mattress; inaccurate readings will result.



WARNING:

Do **not** remove the reflective foil from the disposable probe or reflective patch. Do **not** use a probe without a reflective patch. Replace the patch when repositioning the probe or when adhesive strength degrades.



WARNING:

Do **not** pull on the probe wire. Remove the probe from the skin by gently lifting the adhesive patch. Remove the probe from the jack panel by grasping the plug at the panel



WARNING:

Regularly check that the probe is attached- if the probe is **not** in contact with the baby's skin inaccurate readings will result



WARNING:

Only use Ohmeda probes; other manufacturers probes are not calibrated to GE Healthcare equipment. Using probes from other manufacturers may cause inaccurate temperature readings, may not comply with safety standards, and will void your GE Healthcare equipment warranty.



WARNING:

When using phototherapy lamps, the probe must be directly in the path of the radiant heat of the lamp; do **not** place the probe in an area shielded from the lamp's light. The phototherapy lamp may raise the baby's skin temperature



WARNING:

Do **not** use rectal temperatures to control the baby's temperature



WARNING:

Do **not** remove the probe from its storage bag until required for use. Replace the probe if the cable or tip becomes damaged.



WARNING:

Do **not** re-use a disposable probe. Cleaning and reusing a single use probe may damage the probe and result in inaccurate readings.

Attaching the Skin Temperature (continued next page)

Attaching the Skin Temperature Probe (continued)

Illustration	Step	Description
	2	To attach the disposable probe (single use only), peel the paper backing from the adhesive side and apply to the baby's skin, with the reflective foil side up. To attach the reusable probe, use the heat reflecting patch. Place the metal side of the probe against the baby's skin, peel the paper backing from the adhesive side of the patch and place the patch over the probe with the reflective foil side up.
	3	Route the probe wire through the gaps at the corner of the bedside panels or through the one of the slots in the rear bedside panel.
	4	Plug the temperature probe into the jack.



NOTE:

The Panda iRes Warmer cannot differentiate between an increase in core temperature with cold skin (fever), and low core and skin temperatures (hypothermia). Patient temperature should be verified with an axillary thermometer.

Setting the manual temperature alarm

The "Man.Temp Alarm" is a safety mechanism that you can activate whenever you manage the baby's temperature in Manual Mode. It provides a selectable alarm set point that will notify you whenever the baby is getting too hot or too cold, just as the warmer does in Baby Mode.

To activate the alarm in Manual Mode, you must to take the following steps:

Screen	Step	Description
	1	Insert the temperature probe into the probe jack.
	2	Attach the skin temperature probe onto the baby's skin.
Baby Temp (C) 36.8 Set Temp 36.8 Set Temp 36.8 Pt. Temp Alarm 0.5 10 Man. Temp Alarm Off 0.5 10 Sp02 Mode, Are 11.207 Sp02 Exit	3	Press the "Menu" soft key on the right side of the control panel: a) Press the "Setup" soft key on the submenu b) Press the "Next" soft key on the submenu c) Press the "Man. Temp Alarm" soft key d) In most cases, the "Man.Temp Alarm" soft key will be in the off position. Select whether you want a safety notification of 0.5 or 1.0 °C around the desired baby temperature.

Illustration	Step	Description
Baby Temp (C) 36.5 War a Sa S	4	If in Manual Mode, briefly go to the Baby Mode on the left side of the control panel. Press the Mode key to change the warmer from Manual Mode to Baby Mode. Note: If in Baby Mode, skip to Step #6. NOTE: If in Baby Mode, skip to Step #6.
Baby Temp (C) 36.2 Set Temp 36.5 Mode Note Note Note Note Note Note Note Not	5	Enter the set temp that will serve as the "Man. Temp Alarm" set point.
Baby Temp (C) APOAR APO	6	Return to Manual Mode and adjust the heater power up or down to achieve the desired baby's skin temperature.

Raising or lowering the bedside panels

Illustration	Step	Description
The state of the s	1	To lower a bedside panel, pull it up and then pull the top edge away from the bed.
The state of the s		To raise a bedside panel, swing it to the upright position, then allow it to engage in the latched position.
Panda	2	To remove a bedside panel, lower the panel and hold it parallel with the floor. Press the side panel release button (arrow) with one hand and remove the panel. To replace a bedside panel, insert the panel into the fixed end pin first. Then press the side panel release button in with one hand, place the panel in position and release the pin.

Screen	Step	Description
	3	Remove the rear bedside panel by pressing the release button and lifting up on the panel.



WARNING:

The Panda iRes Warmer and Giraffe Warmer bedside panels are different heights. Use only the Panda iRes Warmer bedside panels on the Panda iRes Warmer.

Tilting the bed

Illustration	Step	Description
	1	The bed tilts twelve degrees to allow feet up or head up positioning of the baby. The tilt release is located underneath the foot of the bed. Grasp both the handle and metal release in one hand and squeeze. Push down or lift up on the foot of the bed to the desired position. Letting go of the release at any point on the tilt path locks the bed in that position.

Raising and lowering the bed



WARNING:

Before raising or lowering the bed, check that there is adequate slack in tubing and leads and that no obstructions limit the range of motion.



CAUTION

Objects placed on the warmer legs may be damaged by raising or lowering the bed and could create a tripping hazard.

Illustration

Step

If the unit is equipped with an elevating base, the bed can be raised or lowered using the bed height pedals located on the legs on either side of the warmer. The bed height can be adjusted low enough for use by a seated caregiver, or can be raised high enough for procedures performed by standing caregivers.

Fixed height bed models can be adjusted by following the instructions found in the service manual.



WARNING:

Do not attempt to adjust the fixed base while a patient is in the bed. After adjustments to the fixed base height have been made, ensure the fixed base is locked in place before placing a patient in the bed.

Using the X-ray tray



WARNING:

Never place the baby on the X-ray tray.

Illustration	Step	
	1	Lower the side bedside panel and place a film cassette on the optional tray that slides out from under the mattress for X-ray procedures. The tray slides out on either side of the bed. The cassette can be slid into the cavity under the mattress without moving the baby. Note: Mattress removed for illustrative purposes.

Using the observation and procedure lights

Illustration	Step	Description
3	1	Two observation lights are located in the heater head on either side of the heater dish (1). The observation lights serve as general illumination of the bed surface and can be set to the desired light intensity using the observation light dimmer knob located on the lower right corner of the control panel. Using the procedure light (optional) An optional aimable procedure light (2) is located just below the heater dish. The procedure light provides a more intense spot light to illuminate a precise area during procedures. The procedure light can be directed at any point on the mattress and is activated using the switch on the light handle (3). The procedure light is not intended for use during surgical procedures.

Uninterruptible Power Supply (UPS)

NOTE: This accessory to the Panda iRes Warmer product is available only in select markets. To understand availability within your region, contact your sales representative.

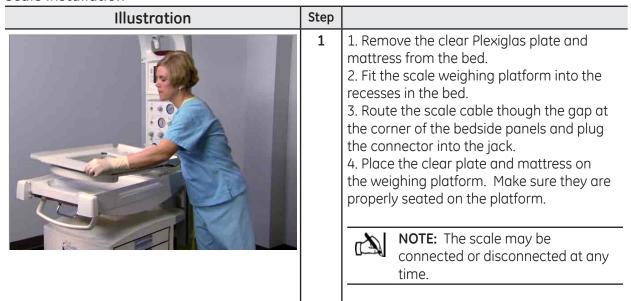
The Giraffe UPS is a medical grade power supply offering uninterruptible power supply to the Panda iRes Warmer. The UPS is designed to securely mount to a single Panda iRes Warmer via specific mounting hardware provided in the Giraffe UPS kit, or separately in the Shelf Hardware Mounting Kit. The UPS may serve to benefit customers experiencing power line voltage disturbances, or Brown Outs, or temporary power outages, or Black Outs. Per the UPS Specifications, the Giraffe UPS provides power to the Panda iRes Warmer in situations where the product is disconnected from a wall receptacle.

For specifications and a detailed description of the installation procedure, refer to the Giraffe UPS Installation Instructions (provided with the UPS).

Using the In-Bed Scale (optional)

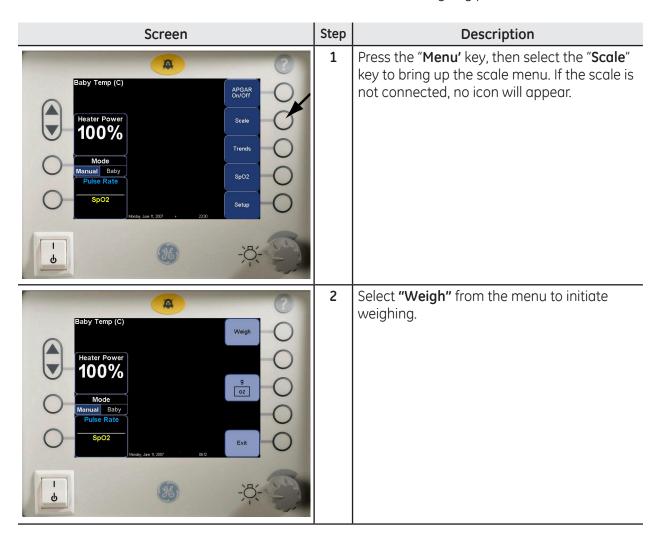
The Panda Warmer can be equipped with its own in-bed scale that is operated from the control panel screen.

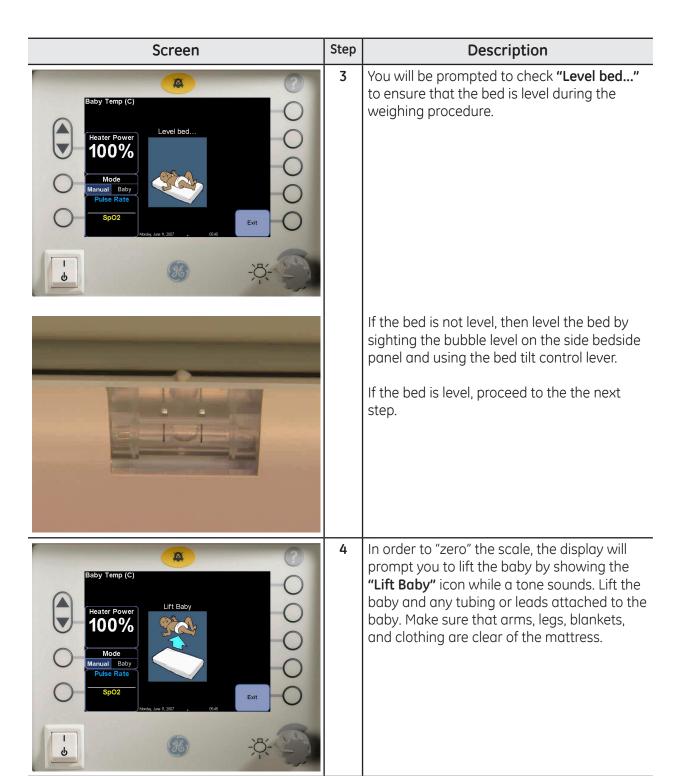
Scale installation

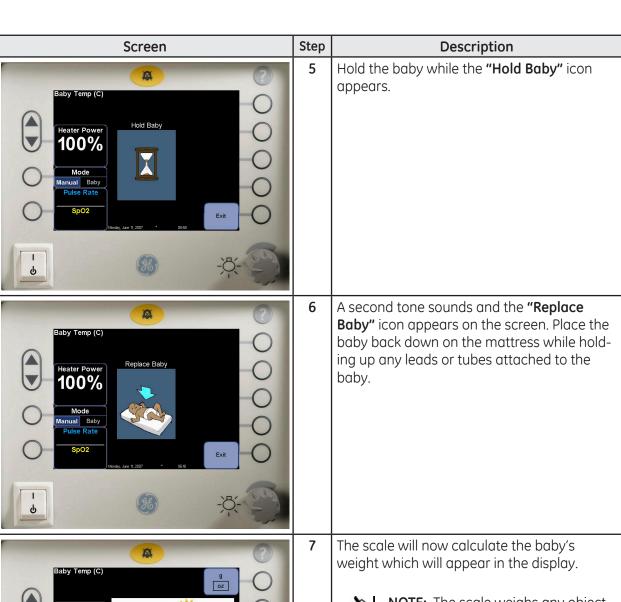


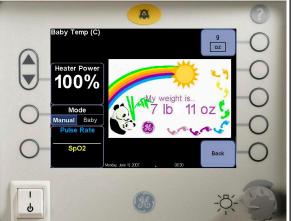
Weighing procedure

The baby should be in approximately the center of the bed. Stuffed animals and other objects should not lean against bedsides. All leads, I.V. tubes and ventilator tubes should be secured. Blankets may be tucked under the mattress, but must not be tucked under the weighing platform.



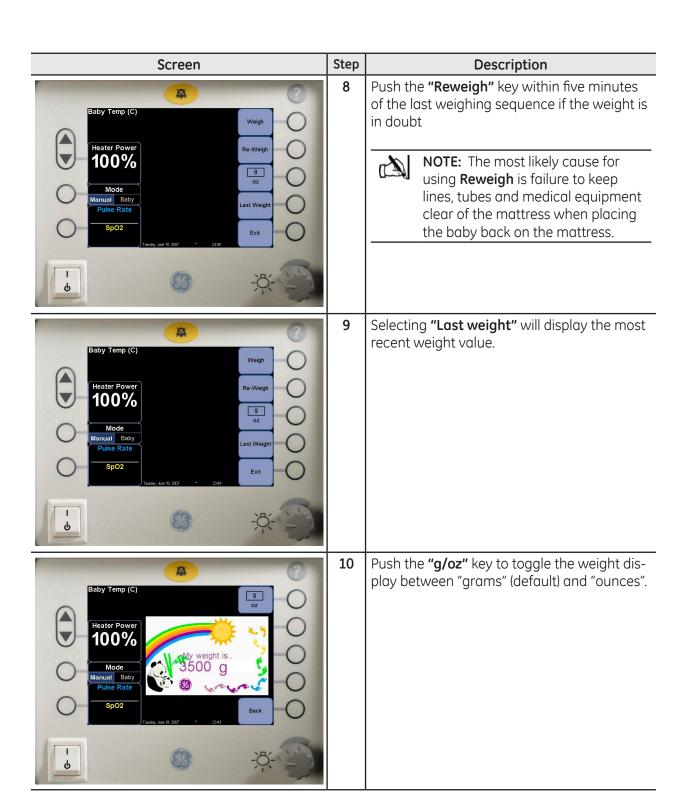








NOTE: The scale weighs any object on the platform, so if you replace the baby without holding up lead and tubes, the weight of the leads and tubes will be included with the baby's weight.



Using the Integrated SpO, Monitor (optional)

The Panda iRes Warmer can be equipped with its own integrated SpO_2 Monitor that is operated from the control panel screen.

Refer to the SpO_2 Monitor setup, check out and use instructions in the SpO_2 - Masimo SET Option, Operation and Maintenance Supplement.

Using the Integrated Resuscitation System (optional)

Refer to the integrated Resuscitation System for setup, check out and use instructions in the Bag and Mask Option, Operation and Maintenance Supplement or the Resuscitation System - T-piece Option Operation and Maintenance Supplement, depending on your Panda iRes Warmer's resuscitation equipment setup.

Mounting ancillary equipment



WARNING:

Overloading the shelves and accessory rails can affect the stability of the unit. Always try to evenly distribute the weight of accessories on both sides of the unit for a more balanced load. Limit the total load on the accessory rails to 22 kg. Do not mount more that 19 kg to one rail. Do not use more than one GCX Mount on the accessory rails at one time.



WARNING:

Do not transport with pass through drawer(s) open.

Illustration	Description	
	Rail system components mount to the uprights and provide access to commonly used equipment such as suction regulators, flowmeters, collection bottles, instrument shelves, etc. This patented design consists of a dovetail shaped aluminum extrusion and a positive locking mounting block. Mounting blocks attach various accessories to the rail system.	
	Mounting rail system components: 1. Loosen the mounting screw on the mounting block. 2. Place the mounting block in position on the rail 3. Tighten the mounting screw Release the rail system component by loosening the mounting screw.	
	 Mounting universal adapter plate. The Universal adapter plate allows bottle slides and additional bracket to mount to the rail system. 1. Loosen the two mounting screws (1) on the side of the adapter plate with the hex key provided with the plate. 2. Place the adapter plate in position on the rail. 3. Tighten the two mounting screws. Release the adapter plate by loosening the mounting screws. 	

ThermaLink

The ThermaLink Serial data interface and Nurse Call connections are options offered with the Panda Warmer. Your unit has these features if there is a 9 pin connector on the back of the heater housing, near the power receptacles.

Using the Serial Data interface



WARNING:

Remote monitoring does not replace the need for direct patient observation by qualified medical personnel.

The ThermaLink serial data output can be used with a computer or a commercial RS-232 monitor. Because of the wide variety of applications and systems, detailed information on decoding the data stream appears in the Service manual. For details of the RS-232 protocol and the connector pinout, refer to the Service manual.



WARNING:

The computer or RS-232 monitor's user program must continuously check the data link. The program should constantly verify connection to the warmer controller and check for updated data.

Using the Nurse Call System interface



WARNING:

Remote monitoring does not replace the need for direct patient observation by qualified medical personnel.



WARNING:

If you connect the Nurse Call output to system which uses the normally open connection, a disconnected Nurse Call cable will not trigger an alarm.

The Nurse Call connector lets you use the warmer with your current remote alarm system. Nurse Call alarms trigger for but are not limited to:

- Patient Temperature Alarms
- Control Temperature Alarms
- Probe Failure Alarms
- System Failure Alarms

The Nurse Call alarms works with the warmer's audible alarm. Silencing the audible alarm on the warmer stops the Nurse Call alarm even if the alarm condition still exists. At the end of the silence period, the Nurse Call alarm and the audible alarm reactivate unless the condition has been resolved. The alarm silence period ends prematurely if another alarm triggers. Refer to the Service manual for additional information on Nurse Call connections.

Nurse Call checkout

Steps	Description
1	Complete the basic operating procedure in chapter 3.
2	Verify proper operation of the Nurse Call station.
3	Connect the Nurse Call connector to the warmer.
4	Place the unit into Baby Mode and unplug the patient probe to trigger an alarm. Verify that you also get an alarm at the Nurse Call station.

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Chapter 4 Maintenance and Cleaning



WARNING:

The heater, lamps and surrounding areas are hot enough to cause skin burns. Unplug the unit and allow the heater to cool before disassembly or cleaning.



WARNING:

Always disconnect the power before performing service or maintenance procedures detailed in this manual. Apply power only if you are specifically instructed to do so as part of the procedure.



WARNING:

Thoroughly air dry the unit after cleaning with flammable agents. Small amounts of flammable agents, such as ether, alcohol or similar cleaning solvents left in the unit can cause a fire.



WARNING:

Never oil or grease oxygen equipment unless a lubricant that is made and approved for this type of service is used. Oils and grease oxidize readily, and in the presence of oxygen, will burn violently.

Repair Policy

Warranty repair and service should be performed by a GE Healthcare Service Representative or at the GE Healthcare Service and Distribution Center. To contact a GE Healthcare Service Representative, call the GE Healthcare Service Office listed on the back cover.

Do not use malfunctioning equipment, including equipment that does not pass the checkout procedure. Non-warranty repairs may be performed by a GE Healthcare Representative or by a competent, trained person who has experience in repairing devices of this nature. Refer to the Service Manual for a list of service parts and for instructions on how to service and calibrate the unit. After service, follow the checkouts procedures prior to returning the unit to service.



CAUTION:

Detailed information for more extensive repairs is included in the service manual solely for the convenience of users having proper knowledge, tools and test equipment, and for service representatives trained by General Electric.

Maintenance schedule

The unit should be maintained in accordance with the preventative maintenance procedures detailed in the Service Manual. Service maintenance must be performed by a technically competent individual.

Operator maintenance

This schedule lists the minimum frequencies. Always follow hospital and local regulations for required frequencies.

Every week

Clean the warmer and disinfect as required, or between each patient.

Service maintenance

This schedule lists the minimum frequencies. Always follow hospital and local regulations for required frequencies.

Annually

Perform the electrical safety checks as described in the service manual.

Calibrate the scale as described in the service manual.

Every two years

Replace the battery as described in the service manual.



NOTE: The battery is used to sound the power failure alarm and to power memory circuits during a power failure.

Cleaning Instructions

After each patient use, follow your hospital's infection control procedures for surface disinfection.

Wipe down the surfaces of the warmer with a soft cloth dampened with a disinfectant-detergent solution. Always follow the cleaning solution manufacturer's direction for use. Dry all surfaces with a soft cloth to remove any cleaner residue.





WARNING:

Do not clean the radiant heating element inside the protective grid.



WARNING:

Disconnect the power cord before cleaning the warmer.



CAUTION:

Electronic devices in the microprocessor controller are susceptible to damage from discharges of static electricity. These devices are adequately protected, but can be damaged if the unit is disassembled beyond that recommended for cleaning and maintenance.



WARNING:

The heater, lamps and surrounding areas are hot.





WARNING:

Do not spray cleaning solution into the vents on the back of the heater housing; this can damage electronics inside the unit.

Cleaning the Warmer

Steps	Description
1	Lower elevating base (or raise it depending upon bed height) to ergonomically comfortable
	cleaning position.
2	Turn bed off at standby power switch.
3	Unplug from power outlet.
4	Move bed to cleaning room/area.
5	If bed was previously on, allow it to cool for at least 30 minutes.
6	Obtain usual cleaning/disinfectant solution.
7	Remove all ancillary equipment (e.g. patient temperature probe, shelves, etc.)
8	Empty drawer module.
9	Remove all 4 bedside panels.
10	Unplug scale if installed.
11	Remove the clear Plexiglas plate and mattress from the bed.
12	Remove scale.
13	Remove x-ray tray.
14	Wipe down component parts of bed and chassis base with recommended cleaning solution per hospital infection control policy. Rinse and dry.
15	Reinstall chemically disinfected component parts in reverse order from breakdown steps.
16	Chemically disinfect and dry control panel.
17	Chemically disinfect and dry dove tail rails.
18	Chemically disinfect and dry drawer module.
19	Chemically disinfect elevating base and legs.
20	Re-plug scale into probe jack panel, if not already done.
21	Reattach all clean ancillary equipment (e.g. patient temperature probe, shelves, etc.).
22	Plug bed into power outlet.
23	Turn bed on at standby power switch.
24	Prepare bed for next admission.

Cleaning Solutions

Cleaning solutions that may be used safely:

Generic Formulation	Maximum Concentration
Sodium Hypochlorite (bleach)	0.5% Aqueous Solution
Glutaraldehyde	2%
Hydrogen Peroxide	6%
Iodophor Solution	0.27%
Cavicide®	100% spray

Do not use the following cleaners; they will damage the parts you are cleaning and are not recommended:

- Isopropyl Alcohol (in concentrations greater than 15%)
- Quaternary Ammonium (such as Virex)
- Solvents (such as acetone)



CAUTION:

Use of cleaning/disinfecting solutions containing chemicals not listed above, i.e. alcohol, acetone, etc., or chemicals in greater concentrations than those listed above, may damage the probe.

Cleaning and disinfecting individual components

Patient Probe (reusable)



CAUTION:

Avoid placing excessive strain on the probe lead. When cleaning, be careful not to pull on or bend the lead at the probe tip. Always remove the probe from the incubator by grasping the plug at the panel. Do not pull on the probe lead.



CAUTION:

Do not apply cold sterilization or cleaning solutions to the probe connector.



CAUTION:

Do not autoclave or gas sterilize the skin temperature probe. Do not immerse the probe in liquid cleaner. Avoid placing excessive strain on the probe lead. Always remove the probe by grasping the plug at the panel. Do not pull on the probe lead. These precautions will prevent damage to the probe.



CAUTION:

Do not allow cleaning fluid to leak into probe and electrical connectors. Equipment damage may occur.

Steps	Description
1	Determine if the patient probe is disposable or reusable:
	 Reusable probes use a separate, heat reflecting patch, are gray and have a round metal disk at the patient end. Disposable probes come with a smaller heat reflecting patch already attached, are white and have no metal disk at the patient end.
	NOTE: Disposable skin temperature probes cannot be cleaned and are intended for single patient use
2	Clean the reusable patient temperature probe by gently wiping with a soft damp cloth containing a disinfecting agent safe for use on the probe materials. Always be sure to wipe dry all cleaning agents after cleaning.

Cleaning other components



CAUTION:

Do not clean the unit with organic solvents, scouring compounds, strong acids, or strong bases. These compounds may damage components.



CAUTION:

To minimize the generation of static electricity, do not polish the side panels with a dry cloth.



CAUTION:

Do not autoclave or gas sterilize any of the plastic parts.

Divide the components according to cleaning methods. Methods other then those detailed in this section may damage the unit. Always be sure to wipe dry all cleaning agents after cleaning.

Apply the cleaning solutions with a clean cloth or sponge. Dry the parts with a clean damp soft cloth to avoid scratches.



NOTE: Do not soak parts in cleaning solutions. Always wipe parts dry of all cleaning solutions. Following these two recommendations will greatly extend the life of the parts.



NOTE: Any parts you clean with iodophor solution will stain yellow.



NOTE: Do not allow excess cleaning solution to seep in between plastic parts (for example: between the side panels and lock or hinges) where it can not be easily wiped dry with a cloth.

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Appendix A **General Use Items**

Ancillary Equipment	Part Number
Panda In-bed Scale	6600-0519-900
Giraffe Spot PT Light	6600-0845-800
Rotating IV Pole	6600-0851-800
IV Pole Dual Hook - 12"	0217-5378-800
IV Pole Dual Hook - 24"	6600-0491-80
IV Pump Mounting Post (20" x 1")	0217-5376-800
Ventilator Mounting Pole	0217-5357-800

General Use Equipment	Part Number	
Panda Mattress	6600-2057-500	
Disposable patient probe (10)	6600-0873-700	
Disposable patient probe (50)	6600-0874-700	
Reusable patient probe	6600-0875-700	
Heat reflecting probe patch (50)	0203-1980-300	
Multipurpose Clip	6600-2150-500	
Dovetail Rail Extension	6600-0852-800	
GCX Mounting Arm	6600-0894-215	
Instrument Shelf	6600-0513-801	
Tubing Management North Wall	6600-2145-500	
Tubing Management South Wall	M1092506	
Utility Post (3.5" x 1")	0217-5374-800	
Retaining Clips	6600-0055-851	
Easy-Load Cylinder Holder	6600-0836-800	
Power Strip	6600-0414-800	

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Power Requirements and Accessory Outlets

Power Requirements	Accessory Outlets
5.25 A @ 100v ~, 50/60 Hz	2 A @ 100v ~, 50/60 Hz
4.57 A @ 115v ~, 50/60 Hz	2 A @ 115v ~, 50/60 Hz
2.39 A @ 220v ~, 50/60 Hz	1A @ 220v ~, 50/60 Hz
2.28 A @ 230v ~, 50/60 Hz	1 A @ 230v ~, 50/60 Hz
2.19 A @ 240v ~, 50/60 Hz	1A @ 240v ~, 50/60 Hz

Standards

Designed to meet requirements of:	
IEC 60601-2-21 with amendment	21 CFR CH-1 Section 1020.30 (n)
IEC 60601-1 with amendment	UL 60601-1
IEC 60601-1-2 with amendment	BSEN - 45501 with amendment
CSA/CAN C22.2 # 601.1	

Operating Environment

Temperature	18 to 30°C	
Humidity	5 to 75% Non-condensing relative humidity	
Pressure	70 - 106 kPa	
Air Velocity	up to 0.3 m/sec.	
Storage conditions		
Temperature	-25 to 60°C	
Humidity	0 to 85% Non-condensing relative humidity	
Pressure	50 to 106 kPa	

User Control Settings

Patient control temperature 34-37.5°C in 0.1° increments
Radiant heat power 0-100% in 5% increments

Performance

System	
Warmer expected service life	Approx. 8 years (see Note, below).
Heater Element	360 Watts
Heater Output	27 mW/cm ²
Patient temperature measurement accuracy	± 0.3°C @ 30°C to 42°C
Temperature probe accuracy	± 0.1°C @ 30°C to 42°C
Observation Light	2 dimmable 35W halogen bulbs; estimated life 3000 hrs based on manufacturer's specifications
Procedure Light	2000 lux* average; estimated life 3000 hrs.
	*At nominal voltage.
Weight scale	
Functional range	300 g to 8 kg
Accuracy	± 10 g



NOTE: The warmer is designed to last at least 8 years in normal use when operated, maintained and serviced in accordance with the instructions provided in both the Operations and Maintenance, and Service Manuals.

Mechanical Specifications

Height:	193 - 218 cm	
Width:	64 cm.	
Depth:	119 cm	
Weight:	100 kg	
Mattress Size:	66 x 48 x 2 cm	
Bed Capacity:	14 kg	
Bed Tilt:	+/- 12 degrees continuous tilt	
Accessories		
Storage drawer package	6.8 kg maximum load	
Instrument shelf	3.6 kg maximum load	

Uninterruptible Power Supply (UPS) Specifications

For UPS specifications, refer to the Giraffe UPS Installation Instructions (provided with the UPS).

Appendix C Electromagnetic Compatibility

Electromagnetic compatibility (EMC) guidance

Safety Standards: IEC 60601-1, IEC 60601-2-19 and IEC 60601-2-21,

EMC Standards: IEC 60601-1-2 2nd ed.



WARNING:

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.



WARNING:

Portable and mobile RF communication equipment can affect Medical Electrical Equipment. Caution should be use when operating such device around Medical Electrical Equipment



WARNING:

This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the equipment/system or shielding the location.

Manufacturer's guidance and declaration regarding electronic emissions

The Giraffe warmer is intended for use in the electronic environment specified below. The user of the Giraffe warmer should ensure that it is used in such an environment.

Electromagnetic Emissions			
Emissions test	Compliance	Electromagnetic environment guidance	
RF emissions CISPR 11	Group 1	The Giraffe Warmer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class A	The Giraffe Warmer is suitable for use in all establishments, other than domestic and those direction connected to the public low voltage power supply network that supplies buildings used for domestic	
Harmonic emissions IEC 61000-3-2	Class A	purposes.	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies		

Manufacturer's guidance and declaration regarding electromagnetic immunity

The Giraffe warmer is intended for use in the electronic environment specified below. The user of the Giraffe warmer should ensure that it is used in such an environment.

Electromagnetic immunity			
Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/- 8kV air	+/- 6kV contact +/- 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2kV for power supply line. +/- 1kV for input/ output line.	+/- 2kV for power supply line. +/- 1kV for input/ output line.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-11	+/- 1kV differential Mode. +/- 2kV common mode line.	+/- 1kV differential Mode. +/- 2kV common mode line.	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % Ut(>95 % dip in Ut) for 0.5 cycle 40 %Ut (60 % dip in Ut) for 5 cycles 70 % Ut(30 % dip in Ut) for 25 cycles <5% Ut(>95% dip in Ut) for 5 sec.	<5 % Ut(>95 % dip in Ut) for 0.5 cycle 40 %Ut(60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Giraffe warmer requires continued operation during power mains interruptions, it is recommended that the Giraffe warmer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field environment IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital.



NOTE: Ut is the main voltage before application of the test level.

International Electronic Commission (IEC) guidance and manufacturer's declaration regarding electronic immunity

The Giraffe warmer is intended for use in the electronic environment specified below. The user of the Giraffe warmer should ensure that it is used in such an environment.

Electromagnetic immunity			
Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic environment guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Giraffe warmer, including cables, than the recommended separation distance calculated from the equation applicable for the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	3V	Recommended separation distance
Radiated RF	3 V/m		$d = 1.2\sqrt{P}$
IEC 61000-4-3	80 MHz to 2.5 GHz	3 V/m	Radiated RF can affect the accuracy of in-bed-scale readings. However, the
IEC 60601-2-19 & IEC 60601-	3 V/m 26 MHz to 1 GHz	3 V/m normal operation	in-bed-scale is not critical to the performance of the Giraffe warmer unit
2-21	10 V/m 26 MHz to 1 GHz	10 V/m no hazard	(see Note 1 on page B-4. $\mathbf{d} = 1.2 \sqrt{P} = 26 \text{MHz} \text{to 800 MHz}$
			$d=2.3\sqrt{P}=800$ MHz to 2.5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).
			Field strengths for fixed RF transmitters as determined by an electromagnetic site survey (see Note 3a) should be less than the compliance level in each frequency range (see Note 3b).
			Interference may occur in the vicinity of equipment Marked with the following symbol (((•)))



NOTE 1: Portable and mobile equipment can affect medical electronic equipment.



NOTE 2: At 80 MHz and 800 MHz, the higher frequencies applies.



NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

- a Field strengths from fixed transmitters such as base stations for radio, cellular/cordless telephones and land mobile radios, amateur radios, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Giraffe warmer unit is used exceeds the applicable RF compliance level above, the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Giraffe warmer.
- **b** Over the frequency range 150 KHz to 80 MHz field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the Giraffe warmer

The Giraffe warmer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Giraffe warmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Giraffe warmer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation distance in meters (m) according to frequency of transmitter				
output power of transmitter	150 kHz to 80 MHZ	80 MHz to 800 MHz	800 MHz to 2.5 GHz		
(W)	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$			
0.01	0.12	0.12	0.23		
0.1	0.38	0.38	0.73		
1.0	1.2	1.2	2.3		
10.0	3.8	3.8	7.3		
100.0	12.0	12.0	23.0		

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.



NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.



NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Appendix D Conforming with Standards and Directives



GE Healthcare has declared that this product conforms with the European Council Directive 93/42 EEC Medical Device Directive when it is used in accordance with the instructions provided in the Operation and Maintenance Manual.

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as an unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Appendix E Additional Safety Information

Statements



WARNING:

To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with protective earth.

The warmer does not adjust for patient temperature in warmup mode. When placing patient in the unit, immediately change modes to manual mode or baby mode.

No additional tasks are required to power down the device after clinical use, other than turning off the unit at the standby power switch on the front of the unit.

Isolation of the unit from the supply mains can only be achieved by turning off the device using the mains power switch on the rear of the unit. The standby switch on the probe panel will not isolate the device from the supply mains.



WARNING:

Electrical shock hazard: Before servicing, always unplug the unit from wall power.

User Responsibility

This Product will perform in conformity with the description thereof contained in this manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, GE Healthcare recommends that a telephone or written request for service advice be made to the nearest GE Healthcare Regional Service Center. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by GE Healthcare and by GE Healthcare trained personnel. The Product must not be altered without GE Healthcare's prior written approval. The user of this Product shall have the sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than GE Healthcare.

Patient Temperature Control Mode

In baby mode, the system performs the following adjustment every 30 seconds. The Baby Condition column indicates the difference between the baby skin temperature and the baby mode set temperature.

Baby Condition	Heater Output Adjustment
Warm by 0.15°C or more	Decrease by 5%
Warm by 0.06°C to 0.14°C	Decrease by 1%
Warm by 0.05°C or less	No adjustment
Cold by 0.05°C or less	No adjustment
Cold by 0.06°C to 0.14°C	Increase by 1%
Cold by 0.15°C to 0.24°C	Increase by 5%
Cold by 0.25°C to 0.34°C	Increase by 10%
Cold by 0.35°C or more	Increase by 15%

Specifications

The product is designed to meet a life span of 8 years. However, with proper maintenance and repairs, the service life can be extended as long as service parts are available.

The maximum patient weight is 40 kg (88 lbs).

During the seven minute warmup period, the radiant heater is at 100% power (\sim 27 mW/cm²). After the radiant heater has been running in warmup mode for seven minutes, the heater power setting drops to 50% (10 to 15 mW/cm²).



World Headquarters

GE Healthcare 9900 West Innovation Drive Wauwatosa, WI 53226-4856 USA Tel 1 800 345 2700

Europe, Middle East, Africa

GE Healthcare P.O. Box 900 FIN-00031 GE Finland Tel +358 10 39411 Fax +358 9 146 3310

Latin America Representatives

GE Healthcare 3350 SW 148 Avenue Suite 301 Miramar, Florida, 33027 USA Tel + 1 954 744 5600

Brazil Only

GE Healthcare Clinical Sytems Equipamentos Médicos Ltda Av. Paulista, 37 - 13° andar CEP: 01311-902 - Cerqueira César São Paulo, SP - Brasil Tel +55 11 3053 2500 Fax +55 11 3053 2573

EC REP

EC Representative

Datex-Ohmeda Ltd. Ohmeda House 71 Great North Road Hatfield Hertfordshire AL9 5EN Tel +44 1707 263570 Fax +44 1707 260065

Germany

GE Medical Systems Information Technologies GmbH Munzinger Str. 3-5 79111 Freiburg Tel. 49 761 4543 570 Fax 49 761 4543 571 Service 0800 4343258

Asia Representative

GE Healthcare
Shanghai GE (China) Hi-tech Park
No1 Huatuo Road, Zhangjiang Hi-tech Park Pudong, Shanghai,
P.R.China 201203
上海GE中国科技园
地址:中国上海市浦东张江高科技园华佗路1号, 201203

地址:中国上海市浦东张江高科技园华佗路1号, 20120 Tel + (8621) 38777888 Fax + (8621) 38777402

Australia 1300 722 229
China 800 810 8188
India 1 800 425 7255
Korea (02) 1544 4564
South Eastern Asia (65) 6277 3444



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