

SmartMonitor 2 PS

Parents' Guide

The logo features a large, stylized letter 'C' in a serif font. Inside the curve of the 'C', there is a heart shape formed by two overlapping, elegant, calligraphic lines. **Circadiancare**<sup>TM</sup>  
*Pediatric Care*

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## WHAT IS THE PURPOSE OF THE SMARTMONITOR 2 PS?

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The SmartMonitor 2 PS is designed to monitor and record breathing (respiration) heart (cardiac) activity and SpO<sub>2</sub> levels (functional oxygen saturation). The monitor alerts you if any of these activities exceeds the limits prescribed by your physician.

Patient alarm limits are set by your home care provider before you receive your monitor. During your child's monitoring, when your child's breathing effort, heart activity and SpO<sub>2</sub> levels are not within these set boundaries, an indicator light comes on and an alarm sounds. This manual explains how to set up the monitor, how to monitor your child, and how to transfer the information. Other auxiliary devices may also be used with the monitor. If your physician prescribes any of auxiliary devices, your home care provider can discuss them with you.

## **INTRODUCTION**

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### **ABOUT THIS MANUAL**

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This manual provides all the information you need to set up and operate the Circadiance SmartMonitor 2 PS and explains how to use it to monitor your child. Carefully read and understand this manual before using the system.

### **INDICATIONS FOR USE**

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The SmartMonitor 2 PS is intended for use in the continuous monitoring of respiration, heart rate, and SpO<sub>2</sub> levels of infant, pediatric, and adult patients. It detects and alarms for periods of high or low heart rate, high or low breath rate, and high or low saturation. When used as an infant monitor it is intended for use in a home or hospital environment. For infants only, it monitors and alarms for central apneas. When used as a pediatric or adult monitor, it is intended for use in a hospital environment.



## WARNINGS AND CAUTIONS

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Please read this section carefully before using the SmartMonitor 2 PS.

*CAUTION:* U.S. federal law restricts this device to sale by or on the order of a physician.

### WARNINGS

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*A warning indicates the possibility of injury to the user or operator.*

- Before using the monitor, charge the internal battery pack. Connect the power supply to the device, and ensure that it is plugged into a functional AC wall outlet for a minimum of 12 hours.
- The monitor will not operate without the internal battery pack. Contact your home care provider if the device does not operate properly.
- Place the monitor on a secure and level surface to prevent the device from falling. Do not place the monitor on the floor or in any location where the device could become a tripping hazard. Do not place the monitor in a crib, ensuring that the baby cannot roll onto the device's hard surface.
- If an emergency occurs and access to the telephone is required while the monitor is connected to the telephone wall jack, unplug the phone cord from the wall jack and connect a working telephone to the jack.
- Do not use the device in the presence of a flammable anaesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide.
- Do not defibrillate a child who is attached to the monitor.
- Do not use skin creams, electrode gels, oils or lotions under the sensors.

- The monitor may not be able to detect all episodes of inadequate breathing. If a child has apnea due to choking (obstructive apnea), the monitor could mistake movement caused by choking for breathing.
- The SmartMonitor 2 PS is a monitoring device only. It does not prevent the loss of breathing or heart activity, nor will it restore breathing or heart activity. It will not prevent death.
- Anyone using the SmartMonitor 2 PS should be trained in current Cardiopulmonary Resuscitation (CPR), which is a proper way to restore breathing and heart activity.
- Do not place the monitor or external power supply in any position that might cause it to fall on the child. Do not lift the monitor by the power supply cord or patient cable; use only the handle on the monitor.
- Do not allow the patient cables, lead wires or power supply cable to become tangled, coiled, crossed, or wrapped around the child's neck, arms, or legs. This could result in strangulation.
- Do not block the speaker or place items in front of the speaker located on the front of the device. This could prevent the monitor alarm from being heard.
- Never use the monitor on your child while your child is being bathed. This could result in electrical shock to your child.
- Do not connect the child to the monitor if the monitor is placed in the Communications Mode. If apnea and heart alarms do not work when the monitor is in this mode.
- Do not use the monitor at the same time as other impedance monitors. This may cause missed apneas due to interference.
- Inspect the power cords and cables often for any signs of damage. Replace a damaged cord or cable immediately.
- Do not use non-safety style lead wires and patient cable configurations with this monitor. Their use may pose a risk of severe electrical shock or death. Refer to the instructions in this manual to ensure proper connections. Use only Circadiance recommended safety lead wires, patient cables, electrodes and sensors.
- The monitor should be placed in an area out of reach of the patient to minimize the risk of small parts being inhaled or swallowed and the risk of fingers or flesh being entrapped in the device.
- The monitor shall only be used on one patient at a time.

- Pins of connectors identified with the ESD warning symbol should not be touched. Connections should not be made to these connectors unless ESD precautionary procedures are used. Precautionary procedures include methods to prevent build-up of electrostatic discharge (e.g., air conditioning, humidification, conductive floor coverings, and non-synthetic clothing), discharging one's body to the frame of the equipment or system or to earth or a large metal object, and bonding oneself by means of a wrist strap to the equipment or system or to earth.
- Explosion hazard. Do not use the monitor in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- If an alarm condition occurs while the alarm silence period is active, the only alarm indications will be visual displays and symbols related to the alarm condition.
- This manual, accessory directions for use, all precautionary information, and specifications should be read before use.
- Do not use damaged cables. Do not immerse the cables in water, solvents, or cleaning solutions. (The cables are not waterproof.)
- The SpO<sub>2</sub> sensor site must be changed every four (4) hours. Note: Exercise extreme caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when the sensor is not frequently moved. Assess site at least every two (2) hours with poorly perfused patients.
- If the SpO<sub>2</sub> sensor is damaged in any way, discontinue use immediately.
- To prevent damage, do not soak or immerse the SpO<sub>2</sub> sensor in any liquid solution.
- Elevated levels of Carboxyhemoglobin (COHb) or Methemoglobin (MetHb) may lead to inaccurate SpO<sub>2</sub> measurements.
- Failure to apply the SpO<sub>2</sub> sensor properly may cause incorrect measurements.
- Do not touch the monitor and the child simultaneously.
- Do not rock the child or sleep in the same bed with the child while monitoring. Touching or moving near the child, monitor or cables could cause the monitor to miss apneas.

## CAUTIONS

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*A caution indicates the possibility of damage to the device.*

- Perform the functional self-test if the monitor has been x-rayed by an airport security check.
- Disconnect the power supply during lightning storms to reduce risk of electrical shock to your equipment. The SmartMonitor 2 PS will not download by modem when the power supply and phone line are disconnected.
- If your child is breathing quietly and the respiration light flashes more or fewer times than your child breathes, contact your home care provider for service.
- Do not send information via modem during electrical storms. Information could be lost or equipment could be damaged.
- Handle the lead wires carefully to prevent them from breaking inside the insulation. Always grasp the lead wire at the strain relief area to remove them from the electrodes or patient cable.
- Any foreign matter that gets into the enclosure of the monitor may cause malfunction.
- The use of accessories other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts or internal components could degrade signal quality and may result in increased emissions or decreased immunity of the equipment or system.
- If you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, if the device is dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken, discontinue use and contact your home care provider.
- Check the monitor's respiration light. Listen while the child breathes, and watch the respiration detection light on the monitor. While the child is breathing quietly, the light should flash once and only once for each breath the child takes. However the light may flash additional times when the child is moving. If the child is breathing quietly and the respiration light flashes more or fewer times than your child breathes, stop using the device and contact your home care provider.

## HOW DOES THE MONITOR WORK?

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Your child's breathing is measured simply by placing two electrodes on the sides of the child's chest under his or her arms. As the child's chest moves, during breathing, the impedance between the electrodes will change. The monitor detects these changes for determining the child's breathing effort. If the monitor does not detect these changes in breathing effort, a light will come on and an alarm will sound. The monitor also uses the electrodes on the chest to monitor heart activity by picking up the electrical changes produced by the heart. If the monitor detects the heart rate outside the range ordered by the physician, a light will come on and an alarm will sound. The device also monitors blood oxygen levels (SpO<sub>2</sub>) through a sensor attached to the child's toe or finger. If the monitor detects SpO<sub>2</sub> values outside the range ordered by the physician, a light will come on and/or an alarm will sound.

## HOW THE ALARMS OPERATE

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Whenever your child's breathing effort, heart activity and SpO<sub>2</sub> levels are not within the limits set by your physician, an indicator light will come on and an alarm will sound. The monitor has two types of alarms: patient and system.

Patient Alarms: A beeping alarm indicates one of the following patient alarm events:

- Apnea: Child has stopped breathing for longer than the limit set by your physician.
- Low Breath Rate: Breath rate is lower than the limit set by your physician.
- Low Heart Rate: Heart Rate lower than the limit set by your physician.
- High Heart Rate: Heart Rate is higher than the limit set by your physician.
- Low SpO<sub>2</sub>: SpO<sub>2</sub> level is lower than the limit set by your physician.
- High SpO<sub>2</sub>: SpO<sub>2</sub> level is higher than the limit set by your physician.









System Alarms: A constant audible alarm indicates one of the following monitor conditions:











- Loose lead (for breathing and heart activity)
- Probe Off (for SpO<sub>2</sub>)
- Low Battery (or Very Low Battery)
- Memory Full (or Memory Almost Full)
- Accidental Power-Off
- Internal System Error

Lights on the monitor indicate which of these conditions exists. See the sections “Monitoring Your Child,” “Responding to Patient Alarms,” and “Responding to System Alarms” for more information about alarms.







**CAUTION:** *The monitor may also alarm if there is an internal system error. If your monitor alarms and the lights are not illuminated, or if all of the lights are blinking on and off, look at the LCD display on the bottom of the device. If there is an internal error, a code will be displayed. Discontinue use of the monitor, and contact your home care provider.*

## SYMBOLS

SYMBOL	DEFINITION
	Attention: Read accompanying documents.
	European Declaration of Conformity
	Separate collection for electrical and electronic equipment per EC Directive 2002/96/EC
	European Representative
	Type BF Applied Part (also shows Patient Cable Connector location)
	RESET Button
	POWER Off/On Button
	Apnea Alarm Light

SYMBOL	DEFINITION
	Respiration Light
	Low Heart Rate Alarm Light
	High Heart Rate Alarm Light
	Low Battery Light
	Memory Full Light
	Loose Lead Light
	Heart Rate Light
	Power Light
	Charger Light
	Power Supply Connection
	Input/Output Connection
	Modem Port



SYMBOL	DEFINITION
	Nurse Call Connection (for institutional use only)
<b>SN</b>	Serial Number
<b>BPM</b>	Beats Per Minute
<b>BrPM</b>	Breaths Per Minute
<b>%</b>	Percent of SpO <sub>2</sub>
	High SpO <sub>2</sub> Alarm Light
	Low SpO <sub>2</sub> Alarm Light
	ESD Warning Symbol
	Connector Position
<b>IPX1</b>	Drip Proof Equipment
	Class II (Double Insulated)
<b>SpO<sub>2</sub></b>	Oxygen Saturation

## **FCC PART 68 TELECOM INFORMATION**

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### **REGISTRATION NUMBER AND REN**

This monitor's modem complies with Part 68 of the Federal Communication Commission (FCC) rules. On the bottom of the monitor is a label that contains, among other information, the FCC registration number and the ringer equivalence number (REN) for the modem. If requested, this number must be provided to the telephone company. The FCC registration number is: CMV MM 05B 4000-20.

### **USOC JACK**

The monitor's modem is designed to be used on standard device telephone lines. The suitable USOC jack (Universal Service Order Code connecting arrangement) for this modem is RJ11C or RJ11W (single line).

### **COMPLIANT ACCESSORIES**

The telephone cord and modular plug provided with this equipment are compliant with applicable Federal Communication Commission (FCC) rules. This equipment is designed for connection to the premises wiring and telephone network using a compatible modular jack that is also compliant. See installation instructions for details.

## **NUMBER OF RENs**

The Ringer Equivalence Number (REN) is used to determine the number of devices that may be connected to a telephone line. Excessive RENs on a telephone line may result in the devices not ringing in response to an incoming call. In most but not all areas, the sum of RENs should not exceed five (5.0). To be certain of the number of devices that may be connected to a line, as determined by the total RENs, contact the local telephone company.

*CAUTION: If this SmartMonitor 2 PS or SmartMonitor 2 PSL modem causes harm to the telephone network, the telephone company will notify you in advance that temporary discontinuance of service may be required. But if advance notice is not practical, the telephone company will notify you as soon as possible. Also, you will be advised of your right to file a complaint with the Federal Communications Commission (FCC) if you believe filing a complaint is necessary.*

## **CHANGES IN SERVICE**

The telephone company may make changes in its facilities, equipment, operations, or procedures that could affect the operation of this equipment. If this happens, the telephone company will provide advance notice in order for you to make necessary modifications to maintain uninterrupted service.

## **PROBLEMS**

If trouble is experienced with this SmartMonitor 2 PS or SmartMonitor 2 PSL modem, please contact your home care provider or Circadiance at 1-888-825-9640 for repair or warranty information. If the equipment is causing harm to the telephone network, the telephone company may request that you disconnect the equipment until the problem is resolved.

## REPAIRS

No repairs are to be made by you. Whenever a technical problem occurs that you cannot handle, contact your home care provider. Unauthorized repairs void registration and warranty.

## PARTY LINES

Connection to party line service is subject to state tariffs. Contact the state public utility commission, public service commission or corporation commission for information.

*CAUTION: If your home has specially wired alarm equipment connected to the telephone line, ensure that the installation of the monitor's modem does not disable your alarm equipment. If you have questions about what will disable alarm equipment, consult your telephone company or a qualified installer.*

## INDUSTRY CANADA REQUIREMENTS

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### IC ABBREVIATION

This equipment meets the applicable Industry Canada Terminal Equipment Technical Specifications. This is confirmed by the registration number. The abbreviation, IC, before the registration number signifies that registration was performed based on a Declaration of Conformity indicating that Industry Canada technical specifications were met. It does not imply that Industry Canada approved the equipment. The IC number is: 9141A-400020.

## **REN**

The Ringer Equivalence Number (REN) for this terminal equipment is 0.5B. The REN is an indication of the maximum number of devices allowed to be connected to a telephone interface. The termination on the interface may consist of any combination of devices subject only to the requirement that the sum of the RENs of all the devices does not exceed five.

## **INDUSTRY CANADA CS-03 NOTICE**

**NOTICE:** The Industry Canada (IC) label on the monitor identifies certified equipment. This certification means that the equipment meets certain telecommunications network protective, operational and safety requirements as prescribed in the appropriate Terminal Equipment Technical requirements document(s). The Department does not guarantee the equipment will operate to the user's satisfaction.

Before installing the monitor, users should ensure that it is permissible to be connected to the facilities of the local telecommunications company. The equipment must also be installed using an acceptable method of connection. The customer should be aware that compliance with the above conditions might not prevent degradation of service in some situations.

The Circadian Service Center should coordinate repairs to certified equipment at 1-888-825-9640. Any repairs or alterations made by the user to this equipment, or equipment malfunctions, may give the telecommunications company cause to request the user to disconnect the equipment.

Users should ensure, for their own protection, that the electrical ground connections of the power utility, telephone lines, and internal metallic water pipe system, if present, are connected together. This precaution may be particularly important in rural areas.

**CAUTION:** *Users should not attempt to make such connections themselves, but should contact the appropriate electric inspection authority, or electrician, as appropriate.*

## **FCC PART 15**

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

Because this equipment generates, uses, and can radiate radio frequency energy, if it is not installed and used in accordance with the instructions, it may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. This can be determined by turning the equipment off and on. If this equipment does cause harmful interference to radio or television reception, you are encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Plug the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

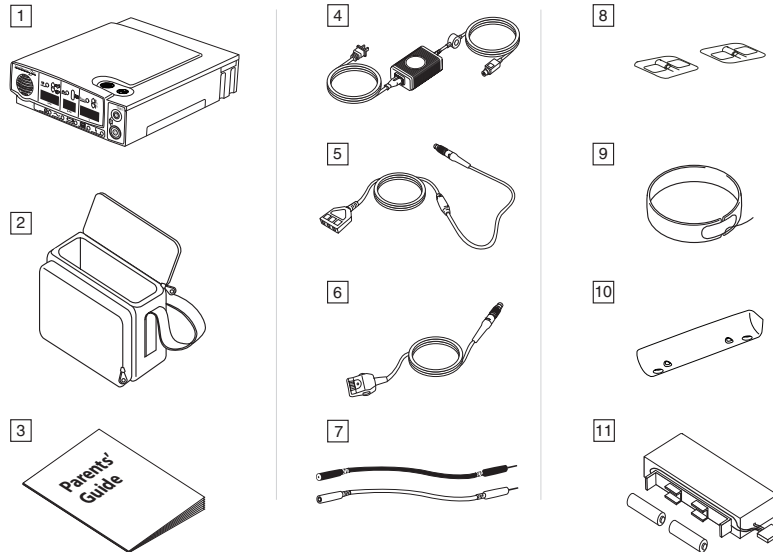
This device complies with Part 15 of the FCC rules. Operation of this device is subject to the following conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference that may cause undesired operation.

**CAUTION:** *Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.*

## GETTING TO KNOW THE MONITOR

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When you receive the SmartMonitor 2 PS, make sure that you have all the necessary items and that they are not damaged. Immediately report anything missing or damaged to your home care provider.

The standard package should include the following (see illustration above):

1. SmartMonitor 2 PS device
2. Soft Carrying Case (optional)

3. Parents' Guide
4. Power Supply part number 1043623
5. ECG Patient Cable
6. Oximeter Patient Cable
7. Lead Wires
8. Electrodes
9. Electrode Belt
10. Handle/Stand and Screws (screws not shown)
11. Battery Pack
12. Symbol Reference Card (not shown)



## **SMARTMONITOR 2 PS FEATURES**

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This section describes the physical features of the monitor.

### **TOP PANEL FEATURES**

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#### **POWER BUTTON**

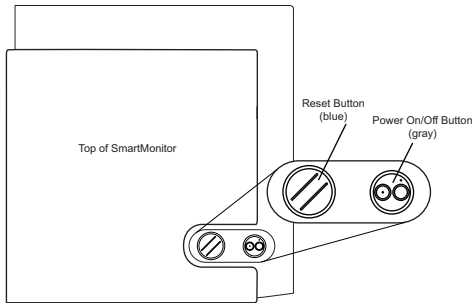
The gray POWER button turns the monitor on. When you turn the monitor on, all lights and the alarm come on briefly and the monitor performs a system test. After a pause, monitoring will begin.

To turn the monitor off, do the following:

- Press and hold the blue RESET button.
- Press and release the gray POWER button.
- Wait 2 seconds, then release the RESET button.

## RESET BUTTON

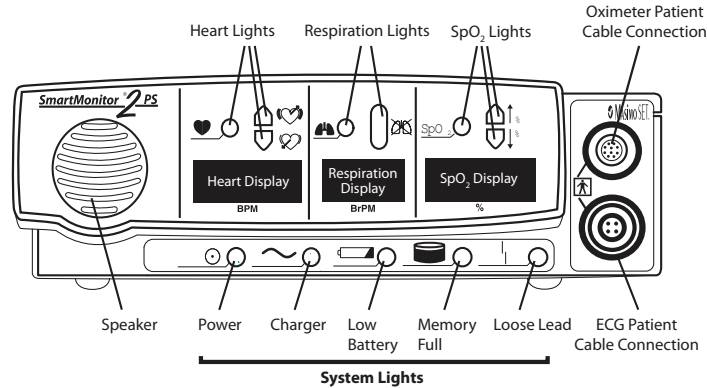
The blue RESET button (shown in the illustration below) resets the alarm lights on the monitor. It also silences the Memory Full (or Memory Almost Full) and Low Battery warning alarms. For more information, see the section “Responding to Alarms.” The RESET button also answers a ringing modem phone call when in monitoring mode.



*NOTE: Pressing the RESET button will not silence Patient or Loose Lead alarms*

## FRONT PANEL FEATURES

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### PATIENT INPUT CONNECTORS

Two patient input connectors appear on the monitor. The top connector supports connection of the oximeter patient cable. The bottom connection is for the ECG patient cable.

### DISPLAY OF VALUES

Values for heart rate, breath rate, and SpO<sub>2</sub> level are viewable from the front panel display. The SpO<sub>2</sub> level display may also show “OFF” if no SpO<sub>2</sub> sensor is installed when the monitor is turned on.

**NOTE:** Values will only appear on the display if your home care provider has enabled this feature.

## **RESPIRATION LIGHTS**

The green respiration light blinks with each breath the monitor detects. The red apnea alarm light will come on if the monitor detects a pause in breathing that is longer than the limit set by your physician.

## **HEART LIGHTS**

The green heart light blinks with each heartbeat the monitor detects. The red high alarm light comes on when the monitor detects a heart rate higher than the limit set by your physician. The red low alarm light comes on when monitor detects a heart rate lower than the limit set by the physician.

## **SpO<sub>2</sub> LIGHTS**



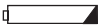


The SpO<sub>2</sub> light will appear green when the probe is connected to the patient and is monitoring the SpO<sub>2</sub> level. If the probe is disconnected or not transmitting a signal, the SpO<sub>2</sub> light will appear red. The red high light comes on when the monitor detects an SpO<sub>2</sub> level higher than the limit set by the physician. The red low light comes on when the monitor detects an SpO<sub>2</sub> level lower than the limit set by the physician.

## **SPEAKER**

The monitor speaker allows you to hear any alarm that sounds during monitoring. This speaker uses two internal buzzers, and you may notice two slightly different tones when the device is alarming.

## SYSTEM LIGHTS

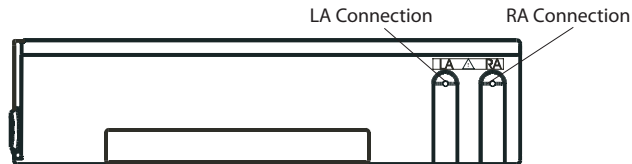
The lights across the bottom of the front panel indicate if the monitor is working properly:

LIGHT	INDICATES
Power 	The power to the monitor is turned on.
Charger 	The power supply is plugged into the monitor. (Blinking if charging battery; solid if battery is fully charged.)
Low battery 	The battery power is low and needs to be charged.
Memory full 	The monitor memory is full or almost full.
Loose lead 	An electrode, cable, or lead wire connection is loose at one of the plug-in-ports or the electrodes are not making good contact with the patient's skin.

## SIDE PANEL FEATURES

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The right side panel features the two connections shown below.

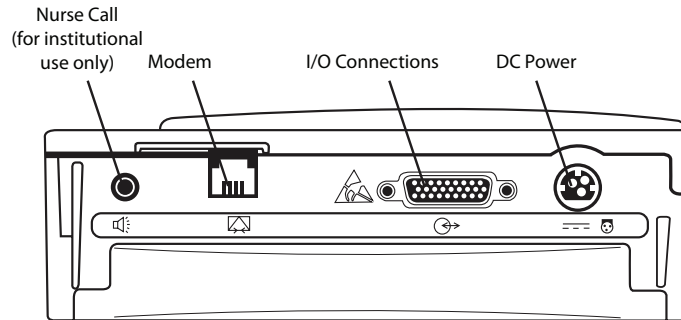


## SELF-TEST CONNECTOR

You use the Self-Test Connector when performing a Functional Self-Test to make sure the lead wires, patient cables and monitor are working properly. See the section “Performing a Functional Self-Test” for more information.

## BACK PANEL FEATURES

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### **NURSE CALL (INSTITUTIONAL/HOSPITAL USE ONLY)**

This feature is for institutional/hospital use only.

### **MODEM (OPTIONAL)**

The SmartMonitor 2 PS may be equipped with a modem to transfer the memory to the child's home care provider. See the section "Transferring the Monitor's Information" for more information. See the sections FCC Part 15 and Industry Canada CS-03 Notice for information on connecting the modem to the telephone line.

## I/O CONNECTOR

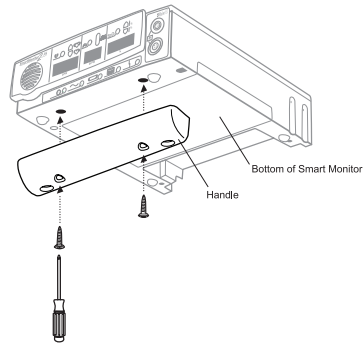
This connector connects the monitor with other devices.

## DC POWER

Use the DC Power connector with the power supply. Whenever the monitor is not in portable use (on battery power only), it should be connected to the power supply.

## STAND

The monitor comes with a removable handle. The handle also acts as a stand that elevates the front panel display when the monitor is placed on a flat surface.





## RESPIRATION, HEART, AND SpO<sub>2</sub> MONITORING

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After you unpack your monitor and make sure you have all the parts, follow the steps listed below to set it up.

### **Step 1: Set the Monitor on a Clean, Flat Surface.**

- Be sure the speaker is not blocked.
- To avoid interference, be sure that no other electrical appliances are within three feet of the unit.
- Make sure the monitor is close enough to connect to the child comfortably.

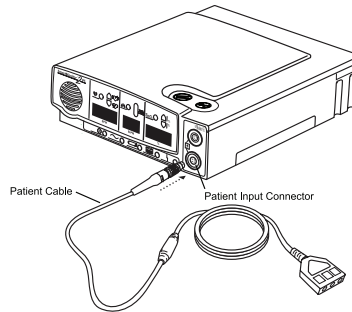
*WARNING: Do not place the monitor in bed with a child.*

### **Step 2: Connect the ECG Patient Cable to the Monitor.** See the illustration at the end of this step.

- Insert the round end of the ECG patient cable into the bottom round connector found on the front of the monitor.
- Insert the connector with the red dot facing up. The connector will snap into place.
- To remove the ECG patient cable, grasp it at the end of the patient input connector and gently pull back. You should feel the connector body slide back and unlock the connector as you pull.

*CAUTION: Do not twist or turn the ECG patient cable to remove it from the monitor as this may damage the ECG patient cable and/or monitor.*

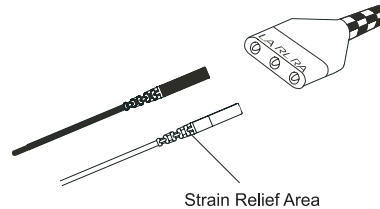
*CAUTION: Do not place the ECG patient cable over the top of the crib rail. The cable should be placed between the vertical bars.*



### Step 3: Connect the Lead Wires to the ECG Patient Cable.

The larger end of the ECG patient cable has three openings, marked **LA** (black), **RL** (green) and **RA** (white).

- Take the white lead wire, and insert it into the opening marked RA.
- Take the black lead wire, and insert it into the opening marked LA.
- Firmly push each lead wire in until the socket snaps into place.

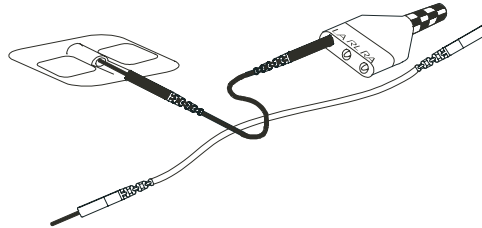


**CAUTION:** When you need to remove a lead wire, grasp and pull at the strain relief area located near the connecting tip. Do not grasp the wire.

**NOTE:** Use of the third (green - RL) electrode and lead wire is normally not required but may help reduce excessive false low heart rate alarms.

**Step 4: Connect the Lead Wires to the Electrodes.**

- Insert the black LA lead wire into one electrode.



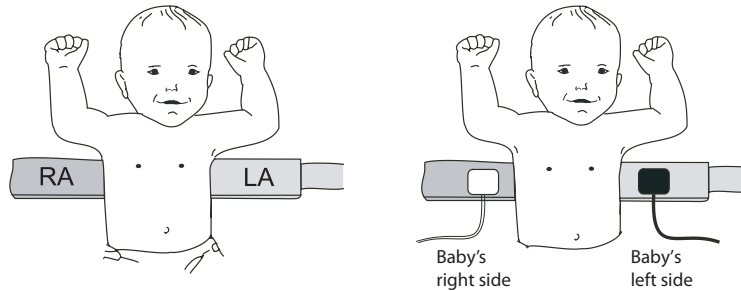
- Insert the white RA lead wire into the other electrode.
- Make sure the metal tips of the lead wires are fully inserted into the electrodes.

*NOTE: Your home care provider may provide you with stick-on electrodes that have the lead wires already attached. In this case, this step is not necessary. Refer to "Disposable Self-Adhesive Electrodes" later in this section.*

**Step 5: Attach the Electrodes to the Child Belt.**

- Place the electrode belt on a flat surface.
- Lay your child on the belt so that the belt is aligned with the child's nipples. (See illustration.)

- Place the electrodes, Velcro-side down, on either side of the belt as follows:



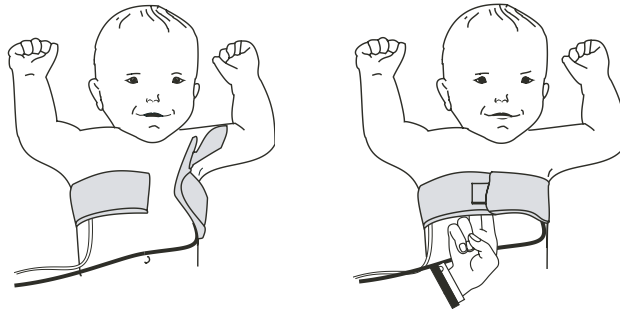
- Place the electrode with the white lead wire on the child's right side.
- Place the electrode with the black lead wire on the child's left side.
- Place the electrodes far enough apart so that when the belt is wrapped around the child, the electrode will be located along the mid-line of the side just below or lined up with the nipples.
- Be sure the lead wires and ECG patient cable are leading down and away from the child's face and neck. (S

*NOTE: The white lead wire location is illustrated with a white electrode, the black with a black electrode.*

### Step 6: Wrap the Electrode Belt Around the Child.

- Wrap the belt around the child's chest and fasten it with the Velcro tab.

The belt should be snug enough so that you can only insert two of your fingers (with your hand lying flat against the child) between the belt and the child.



**NOTE:** For newborns and very small babies, you may need to shorten the belt by cutting off a part of the end. Be sure to leave enough room to fasten the belt securely.

**WARNING:** Route the lead wires downward to avoid strangulation.

**NOTE:** Remove the electrode belt and the lead wires when your child is not being monitored. Long-term wear may be uncomfortable.

These steps describe only one method for electrode placement and positioning. Your home care provider may show you another method.

## DISPOSABLE SELF ADHESIVE ELECTRODES

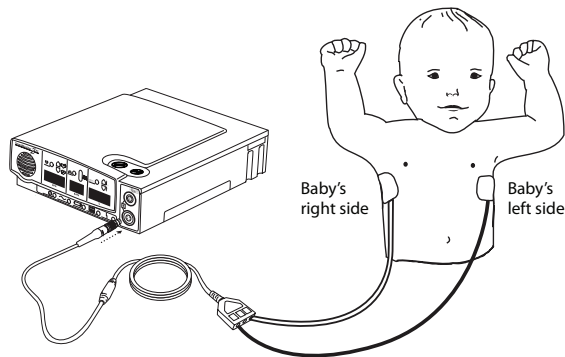
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Follow the steps below if you are using disposable electrodes.

- Attach lead wires to the Self Adhesive Electrodes if not pre-attached.
- Ensure that the child's skin is clean and dry.
- Place the electrode with the white lead wire on the child's right side, along the mid-line of the side, two finger widths below or lined up with the nipples.
- Place the electrode with the black lead wire on the child's left side, along the mid-line of the side, two finger widths below or lined up with the nipples.
- An electrode belt is not needed with disposable electrodes.

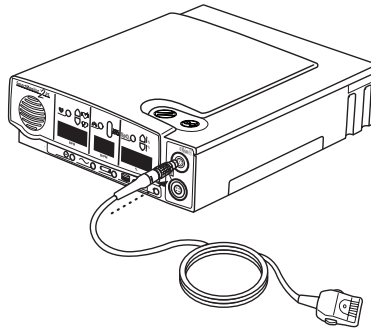
**NOTE:** *Use of the third (green - RL) electrode and lead wire is normally not required but may help reduce excessive false low heart rate alarms. Place the green third electrode along the outside of the child's upper thigh.*

**WARNING:** *Do not use oils, lotion or powder on the area of skin on which the electrodes will be placed. A false reading may result.*



### Step 7: Connect the Oximeter Patient Cable to the Monitor.

- Insert the round end of the oximeter patient cable into the top round connector found on the front of the SmartMonitor 2 PS.
- Line up the notch on the connector, and push until you feel the connector snap into place.
- To remove the oximeter patient cable, grasp it at the base of the patient input connector and gently pull back. You should feel the connector body slide back and unlock the connector as you pull.



**CAUTION:** Do not twist or turn the oximeter patient cable to remove it from the SmartMonitor 2 PS as this may damage the oximeter patient cable and/or monitor.

**WARNING:** The oximeter patient cable should not be placed over the top of the crib rail. It should be placed between the vertical bars to avoid strangulation.

**NOTE:** If the oximeter patient cable or probe is not connected when the monitor is turned on, the % (percent) display will show "OFF" and SpO<sub>2</sub> alarms will not sound. If the sensor is connected while the monitor is on, the SpO<sub>2</sub> function will resume normal operation from that point including SpO<sub>2</sub> alarms.

### Step 8: Connect the Sensor to the Oximeter Patient Cable; Then Connect the Sensor to the Child.

The SmartMonitor 2 PS can be used with compatible Masimo sensors for use in monitoring patients' SpO<sub>2</sub> levels:

- LNOP NeoPt Neonatal Preterm Single Patient Use Adhesive Sensor (indicated for use with Patients weighing < 1 kg (1,000 grams).
- LNOP Neo Neonatal Single Patient Use Adhesive Sensor (indicated for use with patients weighing < 10 kg (10,000 grams).
- LNOP Pdt Pediatric Single Patient Use Adhesive Sensor (indicated for use with patients between 10 and 50 kgs (10,000 to 50,000 grams)
- LNOP YI Multi-site Reusable Sensor with Standard Wrap (indicated for use with patients weighing > 1 kg (1,000 grams))
- LNOP YI Multi-site Reusable Sensor with Standard Petite Wrap (indicated for use with patients weighing > 1 kg (1,000 grams))

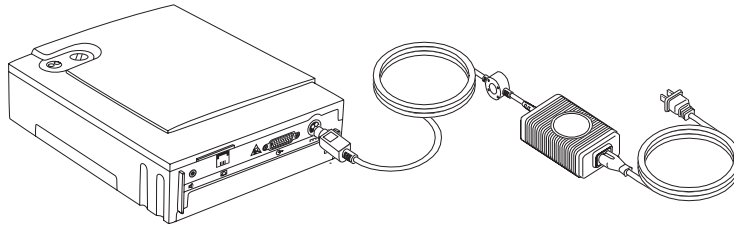
Please see the instructions packaged with the sensors for directions.

SENSOR ACCURACY	
Saturation (%SpO <sub>2</sub> ) - During no motion conditions	Neonates 70 - 100% +/- 3 digits (+/- 1 Std. Dev.)
Saturation (%SpO <sub>2</sub> ) - During motion conditions	Neonates 70 - 100% +/- 3 digits (+/- 1 Std. Dev.)
Pulse Rate (bpm) - During no motion conditions	Neonates 25 to 240 +/- 3 digits
Pulse Rate (bpm) - During motion conditions	Neonates 25 to 240 +/- 3 digits



### Step 9: Connect the Power Supply.

- Insert the connector of the power supply into the socket on the back panel of the monitor. (See the illustration that follows.)
- The flat side of the connector faces upward.
- Push until the connector is fully inserted. A gentle tug on the connector will confirm that it is locked in place.
- Plug the power cord into the power supply.
- Plug the power supply into a power outlet. The green charge light on the monitor will now come on.



- To remove the power supply from the monitor, grasp the power supply connector at the base of the connector and gently pull back. You should feel the connector body slide back and unlock the connector as you pull. Do not twist or turn the power cable to remove it from the monitor.

**CAUTION:** *The Power Supply Connector must be plugged into the monitor's DC Power Input as shown in the illustration above. The Power Supply Connector can only be inserted as shown above.*

**WARNING:**        *Do NOT use the device if the power cord is damaged. Contact your home care provider.*

**NOTE:**        *When the monitor is not being used portably, keep the power supply connected and plugged into an AC outlet at all times. The batteries cannot be overcharged.*

## RESPONDING TO ALARMS

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### PATIENT ALARMS

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A patient alarm indicates that your child's breathing, heart activity, or SpO<sub>2</sub> is outside the limits prescribed by your physician. The information in this section can help you respond appropriately to patient alarms. Read this section carefully. If you have any questions, please contact your home care provider.

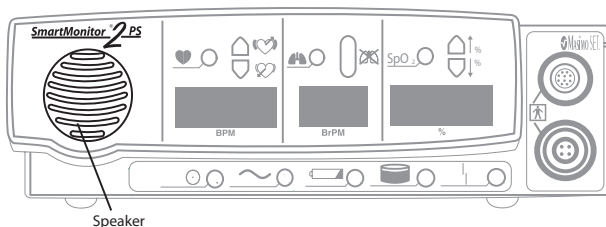
### TESTING THE ALARM

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Before you use the monitor, test to see if you can hear the alarm in different rooms while there is noise in your house.

**CAUTION:** *Be aware that the alarm sound is very loud.*






- Always keep the area in front of the speaker clear.
- Turn the monitor on (without the child attached) to sound the alarm. Make sure you can hear the alarm in different areas of your home.





**NOTE:** *The monitor contains multiple buzzers and alarm sounds. If a buzzer/alarm sound changes or no longer functions, contact your home care provider immediately.*

## IF AN ALARM SOUNDS: PATIENT ALARMS

If an alarm sounds while you are monitoring your child, check your child first. Then follow the instructions below to respond to lights and alarms. Always check your child's skin color. Is it normal? Always check to see if your child is breathing. If your child is not breathing, intervene and provide stimulation as you have been instructed.



LIGHT	ALARMS	CHECK CHILD'S CONDITION	RESPOND LIKE THIS
Red Apnea  and/or Low Heart 	Intermittent (1 beep/sec)	Skin color is pale or blue. Child is not breathing or is choking.	Respond as instructed by your physician or in your CPR class. An example of your response could be as follows: <ul style="list-style-type: none"> <li>• Gently pat the child. The child may start breathing and correct the cause of the alarm on his/her own.</li> <li>• If the child does not start breathing, start physical stimulation immediately.</li> <li>• If the child starts breathing, note it on your log sheet.</li> <li>• Press the RESET button to reset any alarm lights.</li> </ul>
Red Apnea  and/or Low Heart  or Low SpO <sub>2</sub> ↓%	Intermittent (1 beep/sec.)	Child is responsive and is breathing. Color is good.	<ul style="list-style-type: none"> <li>• Wait for a few seconds. Watch to see if the child's breathing and color remain normal.</li> <li>• If alarm continues, see section titled "Reducing False Alarms".</li> <li>• Check the monitor to see which light is on. Note it on your log sheet.</li> <li>• Check sensors.</li> </ul>
Red High Heart 	Intermittent (2 beeps/sec.)	Child is crying.	<ul style="list-style-type: none"> <li>• If the child has frequent high heart rate alarms not associated with crying, notify the physician.</li> <li>• Calm the child.</li> <li>• Check the monitor to see which light is on. Note the light on your log sheet.</li> </ul>




LIGHT	ALARMS	CHECK CHILD'S CONDITION	RESPOND LIKE THIS
Red Low SpO <sub>2</sub> ↓%	Intermittent (1 beep/sec)	<p>Skin color is pale or blue. Child is not breathing or choking.</p> <p>Skin color is pale or blue. Child is breathing.</p>	<p>Use previous response under "Apnea/Low Heart Rate."</p> <p>Observe the child closely and respond as instructed by the physician or in your CPR class. If condition does not improve, notify the physician or EMS.</p>
Red High SpO <sub>2</sub> ↑%	Intermittent (2 beeps/sec)	Skin color is pink, child is breathing.	Note alarm on the log sheet and report to the home care provider or physician as instructed.
Yellow Loose Lead 	Continuous	Child is breathing and is responsive. Color is good.	<ul style="list-style-type: none"> <li>• Check the connections between the electrodes, lead wires, ECG patient cable, and the monitor.</li> <li>• If something has come loose, reconnect it and press the RESET button. The alarm should stop.</li> <li>• If the alarm continues, see the section "Performing a Functional Self Test."</li> </ul>
Yellow Loose Lead 	Continuous	Child is breathing and is responsive. Color is good.	<p>If the monitor passed the Functional Self Test, turn off the monitor. Then, check the following items:</p> <ul style="list-style-type: none"> <li>• The electrodes - They should be clean and there should be no cracks on the surface.</li> <li>• The child's skin - Make sure that where the electrodes are placed is clean and free from oil, lotions, perspiration.</li> <li>• The electrode belt - Make sure it is snug and is keeping the electrodes in place.</li> </ul>




LIGHT	ALARMS	CHECK CHILD'S CONDITION	RESPOND LIKE THIS
Red SpO <sub>2</sub> Light <b>SpO<sub>2</sub></b>	Continuous	Child is breathing and is responsive. Color is good.	Check the connections between the SpO <sub>2</sub> probe, oximeter patient cable and monitor. If something has come loose, reconnect it and press the RESET button. The alarm should stop.

## SYSTEM ALARMS

A system alarm indicates that the monitor may not be functioning properly or at optimum capacity. The information in this section will help you respond appropriately to system alarms. When a monitor system alarm occurs, one of the lights at the bottom of the front panel will come on.

IF THIS LIGHT IS ON...	AND THIS CONDITION EXISTS...	IT MEANS...
Power 	Continuous green light, no alarm	Normal operation. The green power indicator light will come on and stay on for as long as the monitor is on.
Charger 	Continuous or blinking green light, no alarm	Normal operation. The green charger light will come on and blink when the battery is charging and stay on when the battery is fully charged while the power supply is plugged into an active outlet and connected to the monitor.

IF THIS LIGHT IS ON...	AND THIS CONDITION EXISTS...	IT MEANS...
Low Battery 	Flashing yellow light, continuous alarm  Continuous yellow light, continuous alarm	<p>This is a warning that the battery voltage is very low and should be recharged soon. (See “Charging the Battery” in this manual.) Press the RESET button to temporarily silence the alarm. The alarm will resound in 2 minutes if the monitor has not been plugged in. The yellow light will continue to flash.</p> <p>This is a warning that the battery is too low for the monitor to operate properly. The monitor must be recharged. Turn the monitor off. Then, recharge the battery. (See “Charging the Battery” in this manual.)</p> <p>If you do not reconnect the power supply, the system will automatically shut down.</p>
Memory Full 	Flashing yellow light, continuous alarm  Flashing yellow light, no alarm	<p>When the monitor’s Memory Almost Full parameter is reached, the Memory Full light will flash. The alarm will sound continuously. (The alarm will sound only if your home care provider programs your monitor to do so at the 50% full or at 80% full). Press the RESET button to silence the alarm. The light will blink every second.</p> <p><i>NOTE: Memory Almost Full is a warning condition. You can continue monitoring. Contact your home care provider to download the data from the monitor. Note that the Memory Almost Full alarm will sound every time the monitor is powered off and back on.</i></p>
Memory Full 	Continuous yellow light, continuous alarm	<p>The monitor’s memory is 100% full. Press the RESET button to silence the alarm. The light will stay on continuously. Then contact your home care provider to download the data from the monitor.</p> <p><i>NOTE: The Memory Full alarm will sound every time the monitor is powered off and then back on.</i></p> <p><i>NOTE: The alarm will sound only if your home care provider programs your monitor to do so.</i></p>

IF THIS LIGHT IS ON...	AND THIS CONDITION EXISTS...	IT MEANS...
Loose Lead 	Continuous yellow light and continuous alarm	<p>The yellow loose lead light and the alarm may sound continuously when there is a problem with any of the following:</p> <ul style="list-style-type: none"> <li>• lead wires</li> <li>• electrodes</li> <li>• electrode belt</li> <li>• patient cable</li> <li>• connections between the child's skin and the electrodes, the lead wires, the patient cable and the device</li> </ul>
Loose Lead 	Continuous yellow light and no alarm	If you correct the problem, the alarm will stop. However, the yellow light remains on until you press the RESET button.
Power 	Continuous green light, continuous alarm, with no other lights lit.	<p>Check the display on the bottom of the monitor for error messages. If no error messages, the monitor was turned off improperly causing a sibling alarm.</p> <p>To resolve:</p> <ul style="list-style-type: none"> <li>• Press and hold the blue RESET button.</li> <li>• Press and release the gray POWER button.</li> <li>• Wait 2 seconds then release the RESET button.</li> </ul>
All Lights	All lights are blinking and the alarm sounds for 3 seconds and then off for 1 second.	<p>Check the display at the bottom of the monitor for error messages. If there is an error message, enter it in on your log sheet.</p> <p>Turn the monitor off and then back on. If the monitor functions normally, continue to use the monitor.</p> <p>If your monitor does not function normally, contact your home care provider to service the monitor.</p>



IF THIS LIGHT IS ON...	AND THIS CONDITION EXISTS...	IT MEANS...
SpO <sub>2</sub> <b>SpO<sub>2</sub></b>	Continuous red light and continuous alarm (if enabled)	Check that the SpO <sub>2</sub> probe has not become dislodged from the patient or that the probe has not been disconnected from the monitor or the oximeter patient cable. If you correct the problem, the alarm will stop. However, the red light remains on until you press the RESET button.

## REDUCING FALSE ALARMS

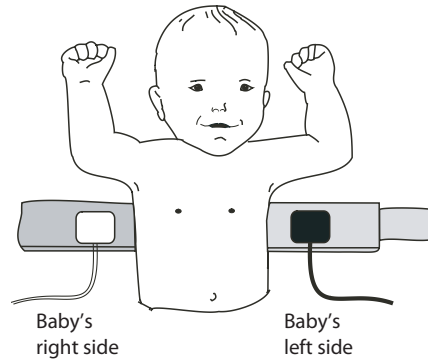
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Proper electrode placement will minimize false alarms.

- Make sure the electrodes are placed along the mid-line of the side, two finger widths below or lined up with the nipples.
- If using the black reusable electrodes with the Velcro belt, ensure the belt is quite snug. Place the electrodes far enough apart so that when the belt is wrapped around the child, the electrode will be located along the mid-line of the side, two finger widths below or lined up with the nipples.
- The skin should be clean and dry; if the skin is unusually dry you may add a few drops of moisture (water) to the child's skin prior to electrode belt placement.
- When using the black reusable electrodes, make sure that the electrode surface is clean.
- Use of the third (green - RL) electrode and lead wire is normally not required but may reduce excessive false low heart rate alarms. Place the green electrode along the outside of the child's upper thigh.

- Check for correct placement of the SpO<sub>2</sub> (oxygen) sensor.

**WARNING:** Do not place electrodes on the top of your child's chest. This may result in false alarms.



**NOTE:** The white lead wire location is illustrated above with a white electrode, the black lead wire location with a black electrode.

## MONITORING YOUR CHILD

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### TURNING THE MONITOR ON

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You have properly set up your monitor and understand both how the monitor functions and how to respond to alarms. You are now ready to begin monitoring your child's breathing, heart activity and SpO<sub>2</sub> level according to the schedule prescribed by the physician.

Push the POWER button. The monitor performs a system check. The lights on the front of the monitor will come on briefly and the alarm will beep twice. Within 10 seconds, the green respiration and heart lights begin to blink. If the lights do not blink, check that you have attached the electrode belt properly to the child, that the lead wires are pushed in, and that the cables are connected.

Once your child is properly connected to the monitor and the power is on, the following should occur:

- The green (battery) charger light is on (solid or blinking).
- The green power light is on.
- The green respiration light and green heart light are blinking. The SpO<sub>2</sub> light is on (green).
- LEDs display numeric values, when display is enabled. All other lights should be off.
- If the lights do not blink, refer to the steps found in "Setting up the Monitor" in this manual and be sure you have followed all instructions.

**WARNING**      *If the alarm does not beep twice after the POWER button is pushed, contact your home care provider immediately.*

## TURNING THE MONITOR OFF - SIBLING ALARM

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The monitor has a built-in safety feature called a sibling alarm. If the monitor is not turned off in a specific sequence, the green power light will remain on and the alarm will sound continuously. This safety feature makes sure the power is not accidentally turned off. To turn the monitor off:

- Press and hold the blue RESET button.
- Press and release the gray POWER button.
- Wait two seconds then release the RESET button.

When the monitor is turned off without pushing the RESET button first, the green power light will remain on and the Sibling Alarm will sound. To silence the Sibling Alarm:

- Press the POWER button, and make sure that the power light is illuminated.
- Press and hold the blue RESET button.
- Press and release the gray POWER button.
- Wait 2 seconds, and then release the RESET button.
- To resume monitoring, press the gray POWER button.

If the monitor is alarming and there is an error code number displayed on the bottom LCD of the monitor, it may indicate an internal software error. In this case, a special power off procedure is required.

- Press and hold the RESET button. While still holding down the RESET button, press and hold the POWER button. Hold both buttons down for 5 seconds.
- Release POWER button; continue to hold the RESET button until the monitor turns off.

*NOTE: This power-off procedure is also required if the battery is drained.*

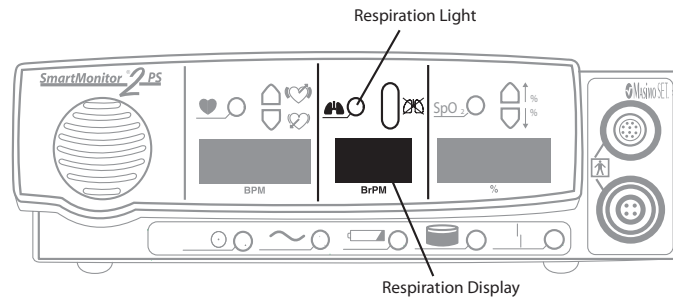
## MONITORING YOUR CHILD'S BREATHING

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### RESPIRATION LIGHT

The green respiration light will blink in rhythm with each breath that the monitor detects. The light should blink only once for each breath, although it may flash more times when your child is moving.

Your child's average respiration rate will appear on the front panel display above BrPM, when the display is enabled.



**WARNING** Listen and watch your child breathe. If the respiration light flashes more times or fewer times than your child breathes, contact your home care provider immediately.

## **APNEA ALARM LIGHT**

When the monitor detects a pause in breathing longer than the limit set by your physician, the following will occur.

The red apnea light will come on and the alarm will beep once every second. When the monitor detects breathing again, the beeping alarm stops. The red light will stay on until you press the RESET button.

**Low Breath Rate.** Your home care provider may have set your monitor to signal Low Breath Rate. If so, the following will occur:

- Breath rate falls below the setting, but pauses are short and do not cause an apnea alarm.
- The apnea light will blink twice each second, and the alarm will beep once each second.

If the monitor detects a pause in breathing longer than the limit set by your physician, during a Low Breath Rate alarm, the apnea light will change from flashing to constant.

**WARNING:**            *Contact your home care provider immediately if apnea alarms occur while the child is breathing.*

## MONITORING YOUR CHILD'S HEART ACTIVITY

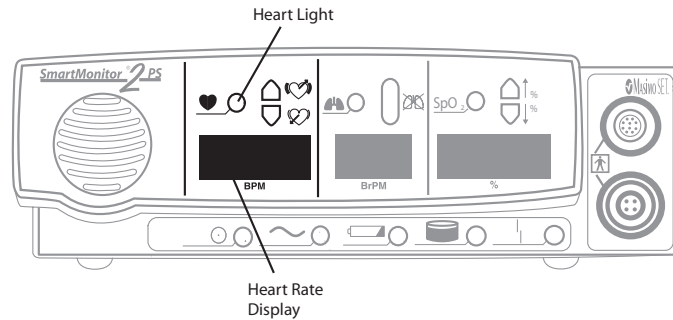
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### HEART RATE LIGHT/DISPLAY

The green light marked “heart” blinks with each heartbeat the monitor detects.

The patient's average heart rate will appear on the front panel display “BPM” when the display is enabled.

See the illustration that follows for the locations of these features.



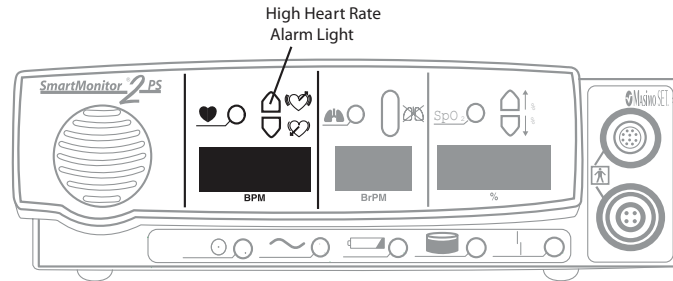
## HIGH HEART RATE ALARM LIGHT

The monitor determines if your child's heart rate is higher than the limit set by your physician. The monitor will alert you by the following:

- The red light marked high will come on and the alarm beeps twice each second.
- The beeping alarm stops when that condition no longer exists.

**NOTE:** *The red light will stay on until you press the blue RESET button.*

See the illustration that follows for the location of the High Heart Rate Alarm Light.





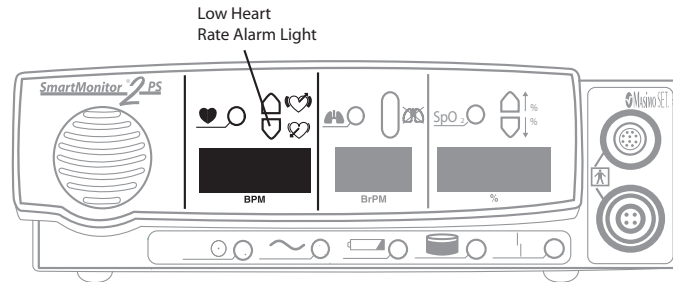
## LOW HEART RATE ALARM LIGHT

When the monitor determines that your child's heart rate is lower than the limit set by your physician, the following will occur:

- The red light marked low heart rate will come on.
- The alarm beeps once every second.
- The beeping alarm stops when that condition no longer exists.

**NOTE:** *The red light stays on until you press the blue RESET button.*

See the illustration that follows for the location of the Low Heart Rate Alarm Light.



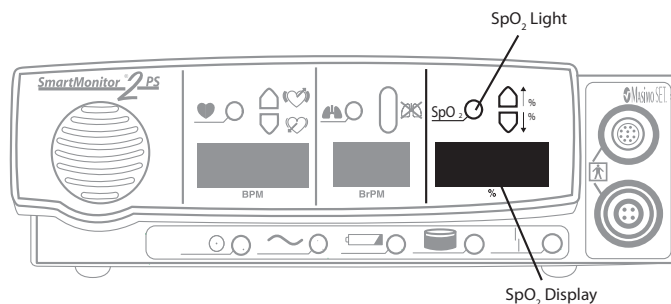
## MONITORING YOUR CHILD'S OXYGEN SATURATION LEVEL

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### SpO<sub>2</sub> LIGHT/DISPLAY

The SpO<sub>2</sub> light will appear solid green when the probe is connected to the patient and is monitoring the SpO<sub>2</sub> level. If the probe is disconnected or not transmitting a signal, the SpO<sub>2</sub> light will appear solid red. This light may briefly change to orange when the sensor is first applied or adjusted.

Your child's average SpO<sub>2</sub> level will appear on the front panel display above % when the display is enabled.

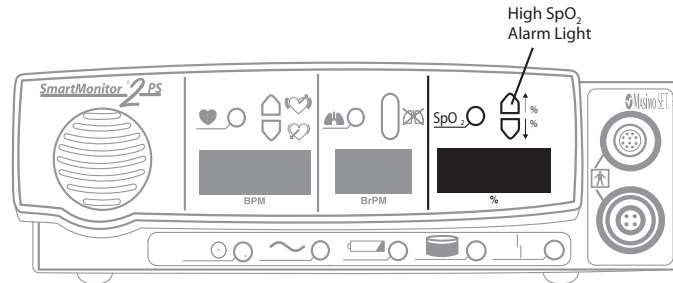


**NOTE:** If you are not monitoring oxygen saturation levels, the LCD display shows "OFF."

## HIGH SpO<sub>2</sub> ALARM LIGHT

When the monitor determines that the child's SpO<sub>2</sub> level is higher than the limit set by the physician, the following will occur:

- The red light marked High SpO<sub>2</sub> Alarm Light will come on, and the alarm beeps twice each second.
- The beeping alarm stops when the condition no longer exists.

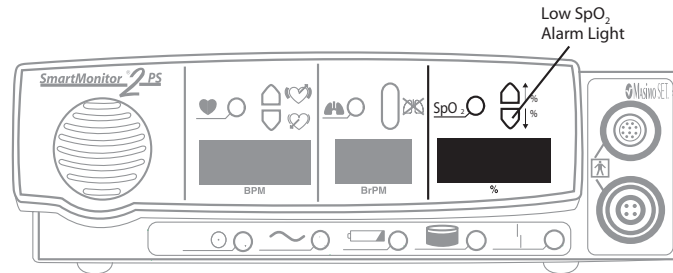


**NOTE:** *The red light stays on until you press the blue RESET button.*

## Low SpO<sub>2</sub> ALARM LIGHT

When the monitor determines that the child's SpO<sub>2</sub> level is lower than the limit set by the physician, the following will occur:

- The red light marked Low SpO<sub>2</sub> Alarm Light will come on, and the alarm beeps once each second.
- The beeping alarm stops when the condition no longer exists.



**NOTE:** *The red light stays on until you press the blue RESET button.*

## **PORTABLE OPERATION OF THE MONITOR**

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The monitor is designed for portable use. When the power supply is not used, the monitor relies on the previously charged internal battery for power. The green charger light will be off during portable operation.

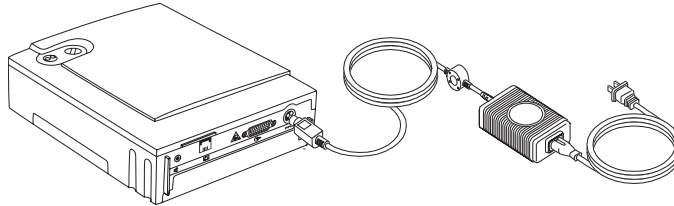
Circadiance recommends that the monitor be used with the power supply whenever possible. However when the monitor is used without the power supply, the monitor is fully functional. All alarms are operational. With a fully charged battery, the monitor will run for 15 hours. The amount of time to completely recharge a fully depleted battery is eight hours.

## **CHARGING THE MONITOR**

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**Battery:** As a rule, a fully charged battery can operate for 15 hours. This may vary, however, depending on the level of use, number of alarms, and other factors. When the low battery light comes on, you should recharge the battery immediately. A fully drained battery should be recharged for 8 hours. When you need to recharge the monitor's battery, follow the steps below:

- Connect the power supply to the back panel of the monitor. (See illustration.) The flat side of the connector faces upward.
- Plug the power supply into a power outlet. The green charger light comes on solid if the battery is fully charged or blinks if the battery is charging.



*NOTE: Fully drained batteries need about eight hours to recharge.*

If the monitor is turned on, the yellow low battery light blinks until the minimum charge level is reached. Then, the yellow light goes off.

*CAUTION: Only use Circadiance batteries. The power supply connector must be plugged into the monitor's DC Power Input as shown in the illustration above.*

## TRANSFERRING THE MONITOR'S INFORMATION

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The monitor contains a memory system that automatically records information about each monitoring session. This information can be transferred (or downloaded) to a computer to be reviewed by your physician. You may be involved in the download if your monitor is equipped with a modem or memory card. Whatever method you use, you must transfer data when you get a memory 100% full condition. You may choose to transfer data at any time or whenever you are instructed to do so by your home care provider or physician.

### MODEM DOWNLOAD

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*NOTE: The monitor must be plugged into the electrical outlet during modem downloads.*

There are three ways to download with a modem. The first choice involves the modem automatically calling the home care dealer. This is called Modem Auto Dial. This doesn't involve any action on your part. It is important to know that the modem inside the unit may use the phone line. If you are going to use this feature, you should give more specific instructions to the caregiver.

The second choice is called Modem Auto Answer in Communications mode. The child is not monitored while the device is in Communications mode. When the home care provider calls the patient's phone number, the device will automatically answer and begin transfer of data.

The third option involves you, the home care provider, calling to the modem built inside the monitor while the patient is being monitored. This is called Modem Auto Answer in Monitor mode (patient being monitored). You must contact the caregiver when it is time to transfer the data through the modem. All three options appear next.

### **MODEM AUTO DIAL**

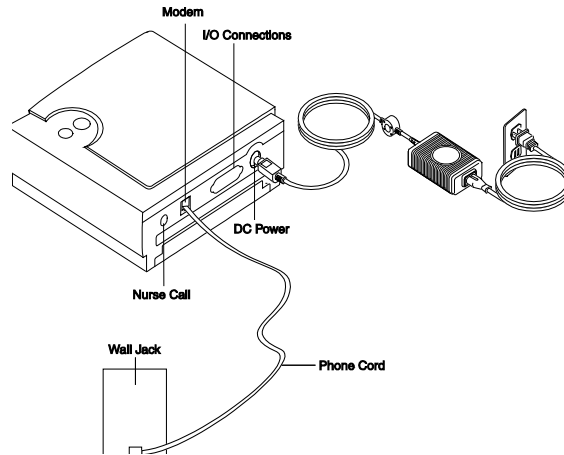
*NOTE: The monitor must be plugged into the electrical outlet during modem download.*

To have the monitor call the computer for a download, it must be programmed with a Host Phone Number, which is the phone number to be called for a connection with the computer as well as the date and time to call. If the phone number field is blank, no attempt to call will be made. These must be set up in the monitor before it is placed in the patient home. When the preset time for download approaches or when the memory full light illuminates, follow these instructions:

- Plug the telephone wire into the modem connector on the back of the monitor. (See illustration.)
- Plug the other end of the phone wire into the wall phone jack.
- You can disable call waiting in this mode of download by entering the disable code (\*70) prior to entering the telephone number on the monitor.



**NOTE:** *The patient must be monitored in order for the download to occur. (Monitor ON)*



**NOTE:** *Refer to the Synergy-E software for instruction on receiving a call from the monitor.*

**NOTE:** *The modem will continue calling every 30 minutes for four hours until it connects with the computer. If no connection is made, the modem will try again the next day at the pre-selected time. For example, if the modem is programmed to call at 7 a.m. but fails to make a connection after eight attempts, it will stop trying. The next day at 7 a.m., it will try again. This will continue until a connection is made.*

**NOTE:** *Be aware that some features available on your phone may interfere with the download: Call Waiting, Call Forwarding, and Party Lines all increase the likelihood of problems when downloading. Call Waiting cannot be disabled when receiving a phone call.*

**WARNING:** *If there is an emergency and access to the telephone is required while the modem is in use, remove the phone cord from the modem slot and use a working phone.*

## **MODEM AUTO ANSWER IN COMMUNICATIONS MODE**

The monitor must be connected to AC power during modem download.

1. Connect a phone cord from the wall jack to the modem connector on the back of the monitor.
2. To allow the monitor to work with the modem, place the monitor in Communications Mode:
  - Press and release the POWER button to turn the monitor on.
  - Press and hold the blue RESET button.
  - Wait until the monitor alarms.
  - Release the RESET button. Briefly press and release the RESET button again (located at the top of the monitor). The monitor's bottom display will read "Communication Mode is Now Active."

The monitor beeps every 10 seconds whenever it is in the Communications Mode. This is a reminder that the monitor is powered on for working with the computer, Memory Card, or modem, but not for monitoring the child.

Do not connect the child to the monitor when in the Communications Mode; the apnea and heart rate alarms are not operational in this mode.

- The home care provider should now call to retrieve the information. The phone may ring, but do not answer. The modem answers the call and connects the monitor to the computer through the phone line.

3. The amount of time to transfer the information will vary. When the transfer is complete the monitor will beep five times. After the transfer, you may disconnect the phone line from the monitor and the phone will work normally. Turn the monitor off in the normal way.
  - Press and hold the blue RESET button.
  - Press and release the gray POWER button.
  - Wait two seconds, and then release the RESET button.
  - You can now resume monitoring the patient.

*NOTE: Be aware that some features available on your phone may interfere with the download: Call Waiting, Call Forwarding, and Party Lines all increase the likelihood of problems when downloading. Call Waiting cannot be disabled when receiving a phone call.*

### **MODEM AUTO ANSWER IN MONITOR MODE**

The monitor must be connected to AC power during modem download.

1. Connect a phone cord from the wall jack to the modem connector on the back of the monitor.
2. To allow the monitor to work with the modem when the monitor is in monitor mode (the patient is being monitored):
  - When the home care provider calls for a download and the phone rings, the caregiver should press and hold down the blue RESET button until the phone stops ringing.
  - This indicates that the monitor has answered the call.

3. The home care provider will now use the Synergy-E software to transfer the monitor information.

*NOTE: If there is an emergency and access to the telephone is required while the modem is in use, remove the phone cord from the modem slot and use a working phone.*

4. The amount of time to transfer the information will vary. When the transfer is complete the monitor will beep five times. After the transfer, disconnect the phone line from the monitor and the phone will work normally.

*NOTE: Be aware that some features available on your phone may interfere with the download: Call Waiting, Call Forwarding, and Party Lines all increase the likelihood of problems when downloading. Call Waiting cannot be disabled when receiving a phone call.*

## **TRANSFERRING THE MONITOR'S DATA TO A MEMORY CARD**

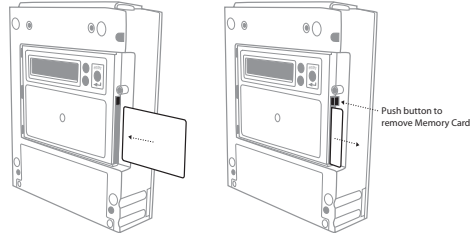
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The memory card is a credit-card-sized electronic memory transfer device that transfers monitor data.

When you are ready to use the Memory Card to transfer monitor data, follow the steps below:

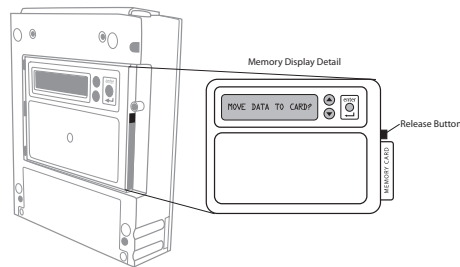
- Make sure the monitor is off.
- Unscrew the single screw on the right of the LCD display cover.
- Remove cover.

- With the Memory Card facing you, slide the card into the slot provided on the side panel of the monitor. The location of the memory card logo will be on the bottom edge and facing you. (See illustration.)



- Press the POWER button ON. After a short delay, the display will read:  
INITIALIZING PLEASE WAIT  
Then,  
MENU MODE? ENTER PROPER KEY SEQUENCE  
Press the ENTER button within 10 seconds:  
The display will read SMARTMONITOR 2 PS MENU SELECTION.

**NOTE:** All data in the memory card at the time of a download will be overwritten.



- Press the down arrow until you see “Move Data To Card?”
- Press the ENTER button. The word NO will begin to blink. To select YES, press either arrow button.
- Press the ENTER button. The display will now show “Transferring Data.” Once the transfer is complete, the display will change to “Data Transferred.”
- Turn the monitor power OFF. Press and hold blue RESET button. Press and release gray POWER button. Continue to hold blue RESET button.
- Once the monitor is powered off, press the black RELEASE button by the memory card to remove it from the monitor.

## CARING FOR YOUR MONITOR

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Use the information in this section to care for your monitor.

**CAUTION:** Use only Circadiance accessories with the monitor.

### CLEANING INSTRUCTIONS

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Before you begin cleaning, turn the monitor OFF, unplug it from the electrical outlet, and disconnect all accessories. Never immerse the monitor or any of the accessories in water, and do not spray cleaner directly on them. Apply water or cleaner to a soft cloth, and gently wipe the components to clean them. The table below provides instructions for caring for the various components.

COMPONENT	CLEANING INSTRUCTIONS
Monitor, Power Supply and Safety Lead Wires	Use a clean cloth and any of the following to clean these components: Unscented dishwashing detergent. 3% hydrogen peroxide solution (the kind found in most stores). 91% Isopropyl alcohol (the kind found in most stores). 10% bleach solution. Germicidal cloth.
Electrodes	Do not attempt to clean the disposable style electrodes. Clean the carbon electrodes with a mild soap and water. They must be rinsed well to remove any traces of soap film. Soap film can prevent heart and breathing signals from being picked up clearly from the monitor. Make sure that the electrodes are completely dry before using.
Electrode Belt	Wash by hand with a mild soap and water. Rinse thoroughly, and air-dry only.

COMPONENT	CLEANING INSTRUCTIONS
Soft Carrying Case (optional)	Although the care label in the carrying case suggests machine washing in warm water, the appearance of the carrying case will change noticeably after washing. Circadiance recommends that you wipe the case with a damp cloth or sponge using a light detergent, if necessary. Air-dry only.
Sensors	Follow the instructions packaged with the sensors for information on cleaning.

## PERFORMING A FUNCTIONAL SELF-TEST

The monitor's functional self-test checks that all the features of the device are functioning properly. You should perform a functional self-test at least once a week or according to the instructions given by your home care provider. You should also perform the test:

- After a lead wire is changed
- After one of the patient cables is changed
- When the monitor has been scanned by airport x-ray machines.

To perform the functional self-test, follow the steps listed below.

- Insert the ECG patient cable into the socket located on the front of the monitor.
- Connect the lead wires to the ECG patient cable. Insert the white lead wire into the opening labeled RA. Insert the black lead wire into the opening labeled LA.
- Connect the lead wires to the functional self-test socket on the side panel of the monitor. Insert the white lead wire into the RA opening and then the black lead wire into the LA opening.
- Insert the oximeter patient cable into the socket located on the front of the monitor.



- Connect the SpO<sub>2</sub> sensor to the oximeter patient cable and place the sensor over your finger.
- Turn on the monitor. You will hear two short beeps and the lights on the front come on briefly then go off.
- After all the alarm lights go out, the green power and charger lights remain on and the green heart and respiration lights are blinking. All numeric displays will begin displaying values.
- The heart and respiration lights continue to blink for about 30 seconds.
- When the green lights stop blinking, the red low heart light will come on within about seven seconds and the alarm beeps once every second.
- Next, the red apnea light comes on (the amount of time before the red apnea light comes on is determined by the apnea delay parameter selected at the time the monitor was set up) and the low (heart) light remains on. (There should be no green heart or respiration light flashes during this time).
- Remove the SpO<sub>2</sub> sensor from your finger. The SpO<sub>2</sub> light will turn red and the SpO<sub>2</sub> display will show dashes.
- Reapply the SpO<sub>2</sub> sensor to your finger.
- Follow the instructions in the “Self-Test Troubleshooting” section, if necessary.
- Remove the lead wires from the functional self-test socket.
- The loose lead light will come on, and the alarm changes from beeping to continuous. This indicates that the monitor, patient cables, and lead wires are working properly.
- Now turn the monitor off.
- Press and hold the blue RESET button.
- Press and release the gray POWER button.
- Wait 2 seconds, then release the RESET button.

## SELF-TEST TROUBLESHOOTING

Follow the instructions given if any of the described conditions occur. Start the test over once the problem has been corrected.

ALARM	CONDITION	SOLUTION
Low Battery	If the low battery light stays on longer than half a minute, the batteries are completely discharged.	<ul style="list-style-type: none"> <li>• Turn the monitor off using the correct power off procedure described in “Turning the Monitor off – Sibling Alarm” in this manual.</li> <li>• Make sure the power supply is plugged into a live power outlet and is properly connected to the monitor. (See “Charging the Battery” for more information).</li> <li>• Plug monitor in for 30 minutes to allow monitor to charge. This will provide sufficient charge to allow you use of the monitor while it continues to charge. (The monitor should remain plugged into an electrical outlet.)</li> <li>• Allow the monitor’s battery to recharge for 8 hours. If the monitor cannot be used because the battery is completely discharged contact your home care provider.</li> <li>• To operate the monitor and recharge battery, follow the procedures as described next in “Troubleshooting” under the Condition “No power, battery drained.”</li> </ul>
Memory Full	The monitor’s full memory setting has been violated.	Press the RESET button to silence the alarm. The monitor’s memory needs to be transferred and cleared. Contact your home care provider for specific instructions.
Loose Lead	Indicates loose or bad lead wires and/or patient cable.	Check all connections and/or replace lead wires first, then the patient cable if necessary.

**WARNING:** *The monitor’s lights and alarms should respond as just described. If not, contact your home care provider before monitoring your child.*

**WARNING:** *Do not use your monitor if the alarm sounds weak or does not activate twice upon initial startup.*

## TROUBLESHOOTING

Whenever a technical problem occurs which you cannot handle, contact your home care provider. Do not try to fix the monitor. The following table describes how to resolve common problems:

PROBLEM	POSSIBLE CAUSE	INSTRUCTIONS
Monitor will not Operate.	Monitor disconnected from power supply, batteries discharged.	Plug power supply into monitor and outlet.
	No power at outlet.	Locate an outlet with power.
	Defective power supply.	Contact your home care provider.
	Internal part failure.	Contact your home care provider.
All lights will flash together and the alarm will beep in unison with the flashing lights. Pressing the RESET button will not silence alarm.	Internal error condition detected by the monitor.	<p>If an error number is displayed on the LCD (the LCD is located on the bottom of the monitor), record this information. Contact your home care provider.</p> <p>If there is an internal software error, a special power off procedure is required.</p> <ul style="list-style-type: none"> <li>• Press and hold the RESET button. While still holding down the RESET button press and hold the POWER button. Hold both buttons down for 5 seconds.</li> <li>• Release POWER button and continue to hold the RESET button until the monitor turns off.</li> </ul>

PROBLEM	POSSIBLE CAUSE	INSTRUCTIONS
Alarm Sound Continuous, No Lights.	<p>Incorrect power-off sequence.</p> <p>Internal part failure.</p>	<ul style="list-style-type: none"> <li>• Press the POWER button, and ensure that the power light is illuminated.</li> <li>• Press and hold the RESET button. Press and release the POWER button. Wait two seconds. Then release the RESET button.</li> </ul> <p>Contact your home care provider.</p>
Alarm Sound Continuous, No Lights.	No power, battery drained.	<p>Connect power supply. Use Power-Off to silence alarm.</p> <ul style="list-style-type: none"> <li>• Press and hold the blue RESET button.</li> <li>• Press and release the gray POWER button. Wait five seconds. Then release the RESET button.</li> </ul> <p>Prior to use, allow the battery to charge approximately 30 minutes. You may then operate the monitor while it is plugged in. Allow the battery to charge for 6 hours before using the monitor on battery power.</p> <p>Contact your home care provider.</p>
Alarm sounds weak.	<p>Internal part failure.</p> <p>Low battery.</p>	<p>Contact your home care provider.</p> <p>Charge battery.</p>

PROBLEM	POSSIBLE CAUSE	INSTRUCTIONS
Loose lead. Continuous alarm; light remains on.	<p>Connections between electrode/sensor lead wires and patient cables are not properly made.</p> <p>Defective lead wires.</p> <p>Defective patient cables.</p>	<p>Verify the following:</p> <ul style="list-style-type: none"> <li>(a) child's skin underneath the electrodes/sensors is clean</li> <li>(b) electrodes/sensors are clean</li> <li>(c) lead wires are fully inserted into the electrodes/sensors and patient cables</li> </ul> <p>Replace lead wires, and perform a Functional Self-Test.</p> <p>Replace patient cables, and perform a Functional Self-Test.</p>
SpO <sub>2</sub> light remains red or orange when connected to child.	<p>Connections between the sensor, oximeter patient cable and monitor have not been made properly.</p> <p>Defective sensor.</p>	<p>Check all connections.</p> <p>Verify the following:</p> <ul style="list-style-type: none"> <li>(a) child's skin underneath the sensor is clean</li> <li>(b) sensor is clean</li> <li>(c) connector is fully inserted into oximeter patient cable</li> <li>(d) sensor light is properly aligned</li> </ul> <p>Replace sensor. Contact home care provider.</p>

PROBLEM	POSSIBLE CAUSE	INSTRUCTIONS
Unable to download via modem.	<p>AC power not connected to the monitor.</p> <p>The monitor is not connected to phone line or not connected to phone (wall) jack.</p> <p>Device power off.</p> <p>Incorrect modem selection on computer.</p> <p>Defective power supply, phone cord, or phone splitter.</p>	<p>Plug the monitor into AC power before performing a download, and verify that the charging light is on.</p> <p>Connect phone line to monitor and to phone (wall) jack.</p> <p>Turn the monitor's power on, and verify that power light is on.</p> <p>Verify modem selection on computer.</p> <p>Replace power supply, replace phone cord, plug phone cord directly into phone (wall) jack.</p>

## SPECIFICATIONS

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### DEVICE SIZE

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Dimensions	5.72 cm x 18.42 cm x 22.86 cm
Weight	1.35 kg

### ELECTRICAL RATINGS

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AC Power Consumption	100-240VAC 50/60Hz 36W
DC Power Consumption	12VDC 3.0Amps max.
Li Ion Rechargeable Battery Pack	7.4VDC 4.4AH or greater

### ENVIRONMENTAL CONDITIONS

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Operating Temperature	41° to 104° F (5° to 40°C)
Operating Humidity	15 to 95% non-condensing
Storage Temperature	-20°C to 60°C
Storage Humidity	15 to 95% non-condensing
Battery Charge Temperature	50° to 95° F (10° to 35°C)

## **IEC CLASSIFICATION**

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This device is designed to conform to the following standards:

IEC 60601-1      General Requirements for Safety of Medical Electrical Equipment

IEC/EN 60601-1-2:2001 (2nd Edition)      Immunity for Medical Electrical Equipment

The SmartMonitor 2 PS system is classified as follows:

- Type of protection against electric shock:      Class II/Internally Powered
- Degree of protection against electric shock:      Type BF Applied Part
- Degree of protection against ingress of water:      IPX1 - Drip Proof
- Mode of operation:      Continuous

## **DISPOSAL**

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When necessary, dispose of the monitor in accordance with local regulations. If you are subject to the WEEE/RoHS directives, contact Circadiance at 1-888-825-9640 for the passport for recycling this product.



## EMC REQUIREMENTS

**GUIDANCE AND MANUFACTURER’S DECLARATION - ELECTROMAGNETIC EMISSIONS:** This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.


EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11	Group 1	The device 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 B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes..
Harmonic emissions IEC 61000-3-2	Class A (not applicable for device with rated power of 75 W or less)	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

**GUIDANCE AND MANUFACTURER’S DECLARATION - ELECTROMAGNETIC IMMUNITY:** This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV 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	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for supply mains ±1 kV for input/output lines	Mains power quality should be that of a typical home or hospital environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV for common mode	Mains power quality should be that of a typical home or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles 70% $U_T$ (30% dip in $U_T$ ) for 25 cycles <5% $U_T$ (>95% dip in $U_T$ ) for 5 sec	<5% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles 70% $U_T$ (30% dip in $U_T$ ) for 25 cycles <5% $U_T$ (>95% dip in $U_T$ ) for 5 sec	Mains power quality should be that of a typical home or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field 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 hospital or home environment.
<b>NOTE:</b> $U_T$ is the AC mains voltage prior to application of the test level.			

**GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC IMMUNITY:** This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM Bands <sup>a</sup>	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. <b>Recommended separation distance:</b> $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 1.2 \sqrt{P} \text{ 80 MHz to 800 GHz}$ $d = 2.3 \sqrt{P} \text{ 800 MHz to 2.5 GHz}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). <sup>b</sup>  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>c</sup> , should be less than the compliance level in each frequency range. <sup>d</sup>  Interference may occur in the vicinity of equipment marked with the following symbol: 
	10 Vrms 150 kHz to 80 MHz in ISM Bands <sup>a</sup>	10 V	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	

**NOTE 1:** At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

**a:** The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

**b:** The compliance levels in the ISM frequency bands between 150 kHz and MHz and in the frequency range 80 MHz and 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an individual factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

**c:** Field strength from fixed transmitters such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the monitor.

**d:** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THIS DEVICE:** The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

RATED MAXIMUM POWER OUTPUT OF TRANSMITTER (WATTS)	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (METERS)			
	150 kHz TO 80 MHz OUTSIDE ISM BANDS $d = 1.2 \sqrt{P}$	150 kHz TO 80 MHz IN ISM BANDS $d = 1.2 \sqrt{P}$	80 MHz TO 800 MHz $d = 1.2 \sqrt{P}$	800 MHz TO 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

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

**NOTE 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE 2:** The ISM (industrial, scientific, and medical) bands between 150 kHz and 90 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

**NOTE 3:** An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range of 80 MHz and 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

**NOTE 4:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

## Masimo Oximeter Sensor

The Masimo Oximeter Sensor uses a two-wavelength pulsatile system to distinguish between oxygenated and deoxygenated blood. Signal data is obtained by passing red (rd) (660 nm wavelength) and infrared (ir) (905 nm wavelength) light through a capillary bed (for example a fingertip, a hand or a foot) and measuring changes in light absorption during the pulsatile cycle. This information may be useful to clinicians. The radiant power of the light is rated at 0.79mW (max.). The Masimo Oximeter Sensor with red and infrared light-emitting diodes (LEDs) that pass light through the site to a photodiode (photodetector). The photodetector receives the light, converts it into an electronic signal and sends it to the Masimo Oximeter Module (internal to SmartMonitor 2 PS) for calculation.

## GLOSSARY

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**Apnea** - An absence of breathing (respiration).

**Central apnea** - No respiratory effort, caused when the brain fails to send the appropriate signals to the breathing muscles to initiate respirations.

**Obstructive apnea** - Cessation of airflow into or out of the mouth or nose although efforts to breath continue. Such obstructions may result from a spasm of the larynx, reflux, or other causes.

**Cardiopulmonary Resuscitation (CPR)** - A procedure used after cardiac arrest in which cardiac massage, mouth-to-mouth resuscitation, and drugs are used to restore breathing.

**Electrode** - A conductor used to establish electrical contact between the monitor and the child's skin.

**Electro Magnetic Interference (EMI)** - Undesirable signals caused by electrical energy. When EMI occurs at high frequencies, it is also called Radio Frequency Interference (RFI).

**Functional Self-Test** - A user-performed test to verify that the monitor, patient cables and lead wires are working properly.

**Heart rate** - The number of heart beats per minute.

**Impedance** - The opposition offered by an electrical circuit to the flow of an alternating current, measured by the ratio of the effective applied voltage to the effective current. This is the method used by the monitor to detect your child's respiration.

**LA Connection** - The opening on the patient cable marked LA is the connector for the black lead wire.

**Modem** - A device that allows the home care provider or hospital to work with a monitor through telephone lines.

**Oximeter** - A photoelectric device that measures the amount of oxygen and other fluids in the blood.

**% (Percent) SpO<sub>2</sub>** - a measurement of how much oxygen is contained in blood. Usually measured via a finger, toe or ear sensor.

**RA Connection** - The opening on the patient cable marked RA is the connector for the white lead wire.

**Respiration** - The act of inhaling and exhaling air.

**RL connection** - Use of the third (green - RL) electrode and lead wire is normally not required, but may help reduce excessive false low heart rate alarms. This is placed on the outer thigh of the child's left leg.

**SpO<sub>2</sub> Levels** - A measurement of how much oxygen is contained in the blood.

**Strain Relief Area** - Located at the connecting tip of the lead wires or cables, this area has added insulation surrounding the wires to prevent breakage when handled. This area is to be grasped when removing lead wires.

*NOTE: The following study involved the SmartMonitor 2 predicate device and is being used as the basis for performance evaluation of the monitor. The study was done with infant patients only.*

## SMARTMONITOR 2 CLINICAL SUMMARY

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The SmartMonitor 2 was evaluated in a clinical study according to the most recent FDA recommendations. These recommendations are available in the “Guidance for Apnea Monitor 510(k) Submission” released in 2002.

The study was completed with babies less than 1 year of age who were in need of an apnea monitor. The recorded information was analyzed to identify the number of 10-second apnea events detected by the monitor. The same events were then scored by a physician. SmartMonitor 2 sounded an alarm for 51 of 100 apnea events scored by the physician and did not alarm for 49 scored apnea events. Out of every 100 alarms, 54 sounded when the baby was breathing normally. Forty-six alarms actually indicated apnea. On average, the monitor sounded a false alarm once every 67 minutes.

With all apnea monitors, you can expect a certain amount of false alarms. Often times these false alarms are caused by the baby’s movement and the amount of contact made by the electrodes on the baby’s skin. In the home environment, your baby’s apnea monitor will be set to detect and alarm for apneas that are greater than 15 to 20 seconds rather than the 10 seconds used in the clinical study. When an apnea event occurs that is longer than 15 to 20 seconds, often the baby’s heart rate will slow down. As an added safety feature, SmartMonitor 2 also detects and alarms for this slowdown in the baby’s heart rate.

If you would like additional clinical information about the function of the monitor prescribed for your baby, contact your home care provider or your physician.





# Circadiance<sup>TM</sup> Pediatric Care

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