Circadiance™
Pediatric Care

SmartMonitor® 2 PS

Professional Series

Parents' Guide

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What is the Purpose of the SmartMonitor 2 PS?

The SmartMonitor 2 PS is designed to monitor and record breathing (respiration) heart (cardiac) activity and SpO_2 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_2 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 an auxiliary device, your home care provider can discuss them with you.

Introduction

About This Manual

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

The SmartMonitor 2 PS is intended for use in the continuous monitoring of respiration, heart rate, and SpO_2 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

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

Warnings

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.
- 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. The 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.

- 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_2 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_2 sensor is damaged in any way, discontinue use immediately.
- To prevent damage, do not soak or immerse the SpO_2 sensor in any liquid solution.
- Elevated levels of Carboxyhemoglobin (COHb) or Methemoglobin (MetHb) may lead to inaccurate SpO_2 measurements.
- Failure to apply the SpO_2 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.
- Do not use the monitor on more than one person at a time.
- 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.

Cautions

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.
- 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.
- 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?

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_2) through a sensor attached to the child's toe or finger. If the monitor detects SpO_2 values outside the range ordered by the physician, a light will come on and/or an alarm will sound.

How the Alarms Operate

Whenever your child's breathing effort, heart activity and SpO_2 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_2: SpO_2 level is lower than the limit set by your physician.
- High SpO_2: SpO_2 level is higher than the limit set by your physician.

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

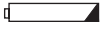
- Loose lead (for breathing and heart activity)
- Probe Off (for SpO_2)
- Low Battery (or Very Low Battery)
- Memory Full (or Memory Almost Full)
- Accidental Power-Off
- Internal System Error

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.

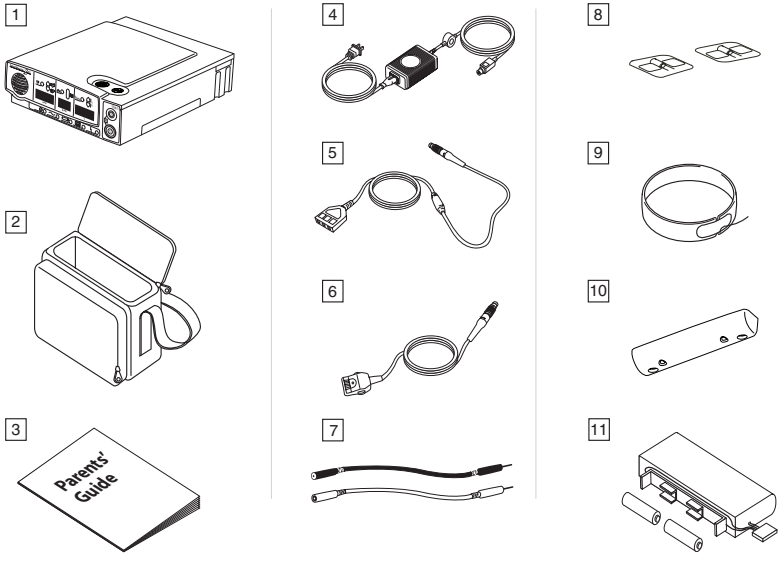
Symbols

Symbol	Definition
	Attention: Read accompanying documents.
	Type BF Applied Part (also shows Patient Cable Connector location)
	RESET Button
	POWER Off/On Button
	Apnea Alarm Light
	Respiration Light
	Low Heart Rate Alarm Light
	High Heart Rate Alarm Light

Symbol	Definition
	Low Battery Light
	Memory Full Light
	Loose Lead Light
	Heart Rate Light
	Power Light
	Charger Light
	Power Supply Connection
	Input/Output Connection
	Nurse Call Connection (for institutional use only)
SN	Serial Number
BPM	Beats Per Minute
BrPM	Breaths Per Minute
%	Percent of SpO_2

Symbol	Definition
	High SpO_2 Alarm Light
	Low SpO_2 Alarm Light
	ESD Warning Symbol
	Connector Position
IPX1	Drip Proof Equipment
	Class II (Double Insulated)
SpO_2	Oxygen Saturation
	Compliant with the Waste Electrical and Electronic Equipment and Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (WEEE/RoHS) Recycling Directives.

Getting to Know the Monitor



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 and Power Cord. Your new monitor is supplied with an external power supply (P/N 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

This section describes the physical features of the monitor.

Top Panel Features

POWER Button

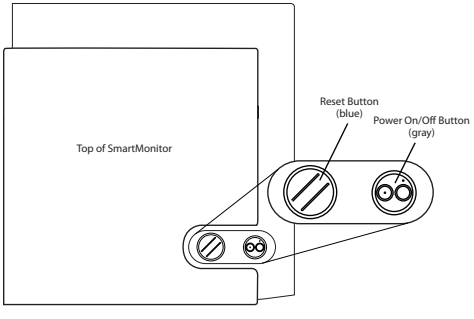
The gray POWER button turns the monitor on. When you turn the monitor on, all lights and the alarm come on briefly and the monitor performs a system test. After a pause, monitoring will begin.

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.

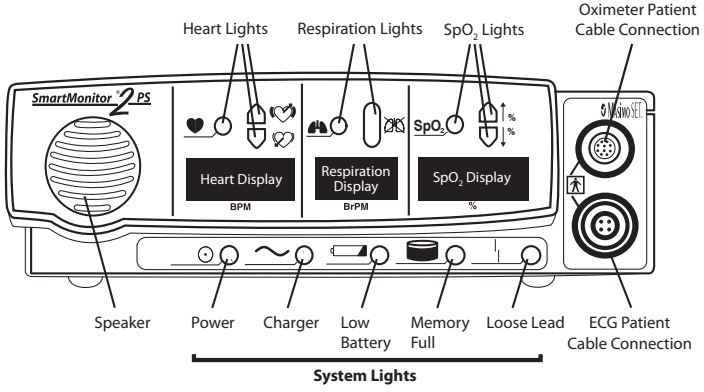
RESET Button

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."



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

Front Panel Features



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_2 level are viewable from the front panel display. The SpO_2 level display may also show "OFF" if no SpO_2 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_2 Lights

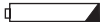
The SpO_2 light will appear green when the probe is connected to the patient and is monitoring the SpO_2 level. If the probe is disconnected or not transmitting a signal, the SpO_2 light will appear red. The red high light comes on when the monitor detects an SpO_2 level higher than the limit set by the physician. The red low light comes on when the monitor detects an SpO_2 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.

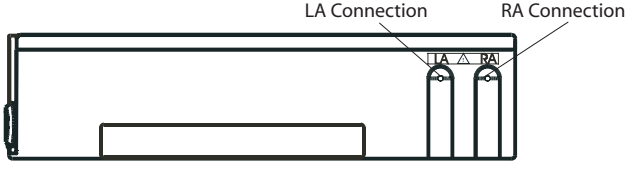
System Lights

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

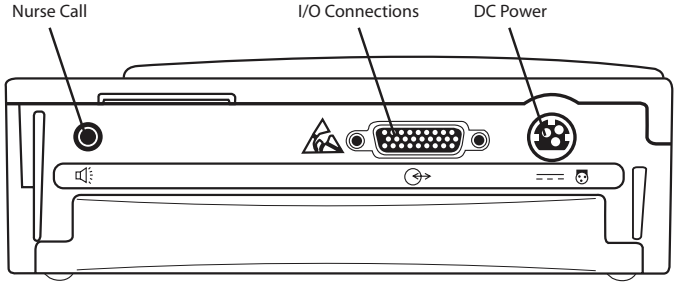
The right side panel features the two connections shown below.



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



Nurse Call (Institutional/Hospital Use Only)

This feature is for institutional/hospital use only.

I/O Connector

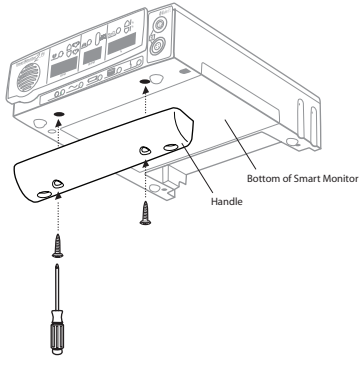
This connector connects the monitor with other devices.

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_2 Monitoring

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.

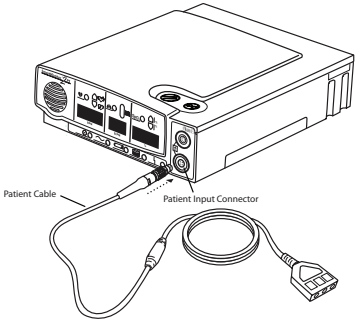
WARNING: *Do not place the monitor in bed with a child.*

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.*

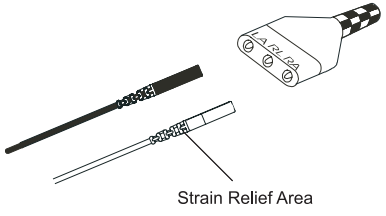
CAUTION: *Do not place the ECG patient cable over the top of the crib rail. The cable should be placed between the vertical bars.*



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.

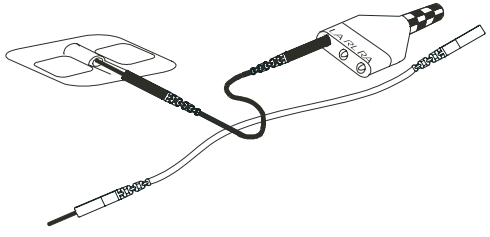


CAUTION: *When you need to remove a lead wire, grasp and pull at the strain relief area located near the connecting tip. Don not grasp the wire.*

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.

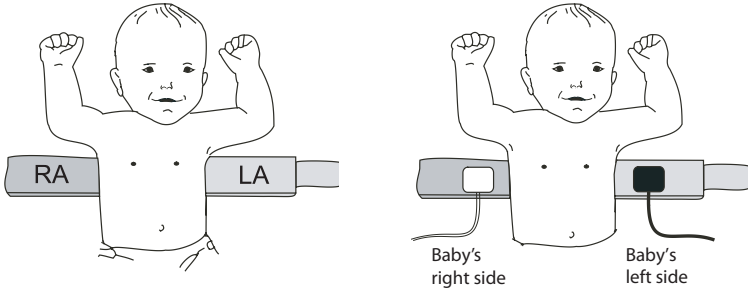


- Insert the white RA lead wire into the other electrode.
- Make sure the metal tips of the lead wires are fully inserted into the electrodes.

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:



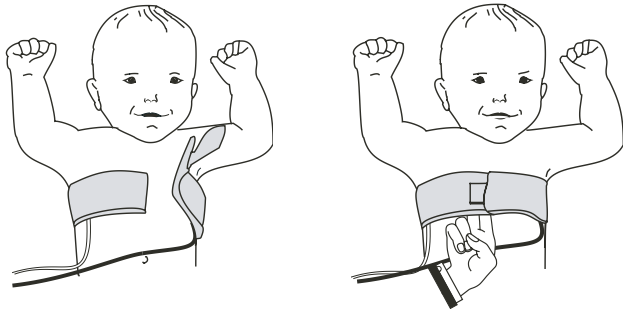
  - Place the electrode with the white lead wire on the child's right side.
  - Place the electrode with the black lead wire on the child's left side.
- Place the electrodes far enough apart so that when the belt is wrapped around the child, the electrode will be located along the mid-line of the side 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.

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.

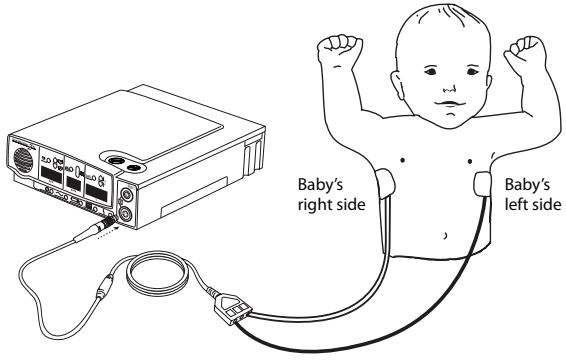
Disposable Self Adhesive Electrodes

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.

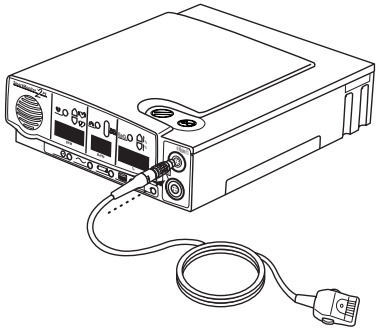
NOTE: *Use of the third (green - RL) electrode and lead wire is normally not required but may help reduce excessive false low heart rate alarms. Place the green third electrode along the outside of the child's upper thigh.*

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_2 alarms will not sound. If the sensor is connected while the monitor is on, the SpO_2 function will resume normal operation from that point including SpO_2 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_2 levels:

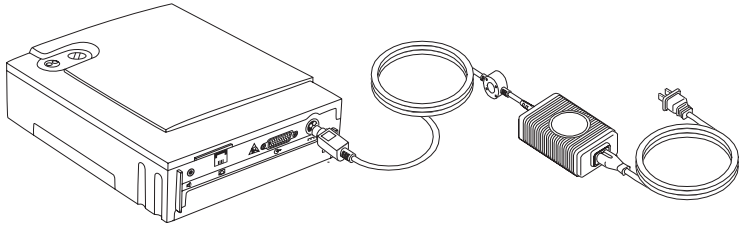
- LNOP NeoPt Neonatal Preterm Single Patient Use Adhesive Sensor (indicated for use with Patients weighing < 1 kg (1,000 grams).
- LNOP Neo Neonatal Single Patient Use Adhesive Sensor (indicated for use with patients weighing < 10 kg (10,000 grams).
- LNOP Pdt Pediatric Single Patient Use Adhesive Sensor (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 (%SpO2) - During no motion conditions	Neonates 70 - 100% +/- 3 digits (+/- 1 Std. Dev.)
Saturation (%SpO2) - 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

Patient Alarms

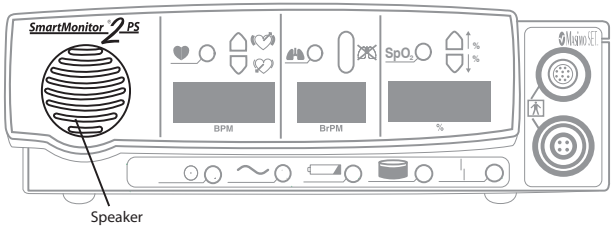
A patient alarm indicates that your child's breathing, heart activity, or SpO_2 is outside the limits prescribed by your physician. The information in this section can help you respond appropriately to patient alarms. Read this section carefully. If you have any questions, please contact your home care provider.

Testing the Alarm

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: • Gently pat the child. The child may start breathing and correct the cause of the alarm on his/her own. • If the child does not start breathing, start physical stimulation immediately. • If the child starts breathing, note it on your log sheet. • Press the RESET button to reset any alarm lights.
Red Apnea and/or Low Heart or Low SpO_2 ↓%	Intermittent (1 beep/ sec.)	Child is responsive and is breathing. Color is good.	• Wait for a few seconds. Watch to see if the child's breathing and color remain normal. • If alarm continues, see section titled "Reducing False Alarms". • Check the monitor to see which light is on. Note it on your log sheet. • Check sensors.
Red High Heart	Intermittent (2 beeps/ sec.)	Child is crying.	• If the child has frequent high heart rate alarms not associated with crying, notify the physician. • Calm the child. • Check the monitor to see which light is on. Note the light on your log sheet.

Light	Alarms	Check Child's Condition	Respond Like This
Red Low SpO_2 ↓%	Intermittent (1 beep/sec)	Skin color is pale or blue. Child is not breathing or choking. Skin color is pale or blue. Child is breathing.	Use previous response under "Apnea/Low Heart Rate." 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.
Red High SpO_2 ↑%	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.	• Check the connections between the electrodes, lead wires, ECG patient cable, and the monitor. • If something has come loose, reconnect it and press the RESET button. The alarm should stop. • If the alarm continues, see the section "Performing a Functional Self Test."
Yellow Loose Lead	Continuous	Child is breathing and is responsive. Color is good.	If the monitor passed the Functional Self Test, turn off the monitor. Then, check the following items: • The electrodes - They should be clean and there should be no cracks on the surface. • The child's skin - Make sure that where the electrodes are placed is clean and free from oil, lotions, perspiration. • The electrode belt - Make sure it is snug and is keeping the electrodes in place.
Red SpO_2 Light **SpO_2**	Continuous	Child is breathing and is responsive. Color is good.	Check the connections between the SpO_2 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.
Low Battery 	Flashing yellow light, continuous alarm Continuous yellow light, continuous alarm	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. 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.) If you do not reconnect the power supply, the system will automatically shut down.
Memory Full 	Flashing yellow light, continuous alarm Flashing yellow light, no alarm	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. *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.*

If this light is on...	And this condition exists...	It means...
Memory Full 	Continuous yellow light, continuous alarm	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. *NOTE: The Memory Full alarm will sound every time the monitor is powered off and then back on.* *NOTE: The alarm will sound only if your home care provider programs your monitor to do so.*
Loose Lead	Continuous yellow light and continuous alarm	The yellow loose lead light and the alarm may sound continuously when there is a problem with any of the following: • lead wires • electrodes • electrode belt • patient cable • connections between the child's skin and the electrodes, the lead wires, the patient cable and the device
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.	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. To resolve: • Press and hold the blue RESET button. • Press and release the gray POWER button. • Wait 2 seconds then release the RESET button.

If this light is on...	And this condition exists...	It means...
All Lights	All lights are blinking and the alarm sounds for 3 seconds and then off for 1 second.	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. Turn the monitor off and then back on. If the monitor functions normally, continue to use the monitor. If your monitor does not function normally, contact your home care provider to service the monitor.
SpO_2 **SpO_2**	Continuous red light and continuous alarm (if enabled)	Check that the SpO_2 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.

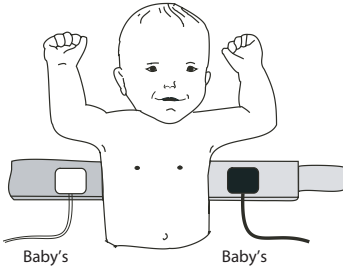
Reducing False Alarms

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_2 (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

Turning the Monitor On

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_2 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_2 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

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.

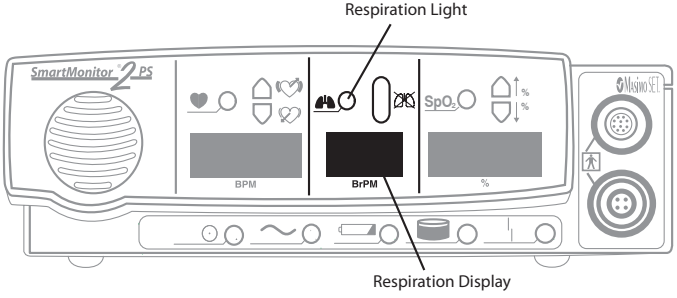
NOTE: This power-off procedure is also required if the battery is drained.

Monitoring Your Child's Breathing

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.

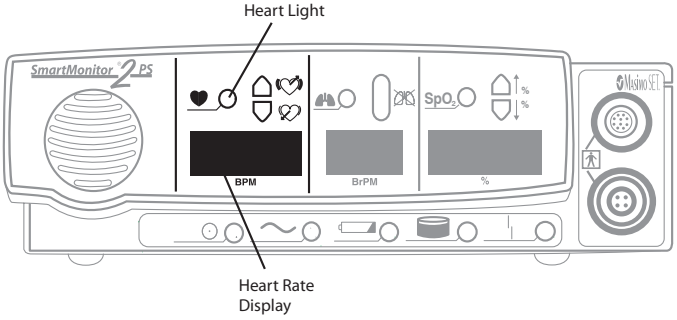
Monitoring Your Child's Heart Activity

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.



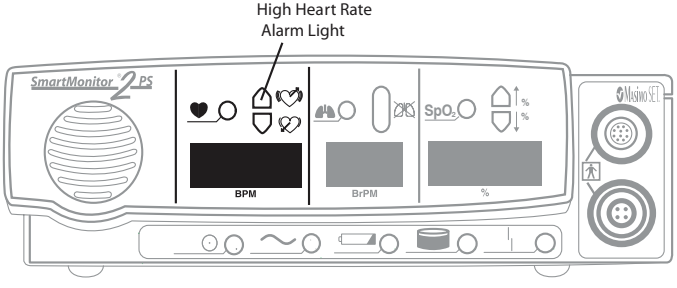
High Heart Rate Alarm Light

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.



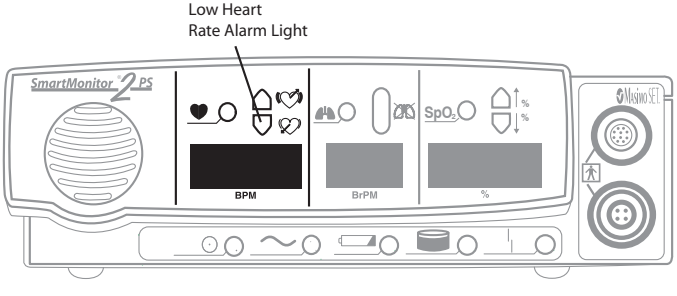
Low Heart Rate Alarm Light

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.

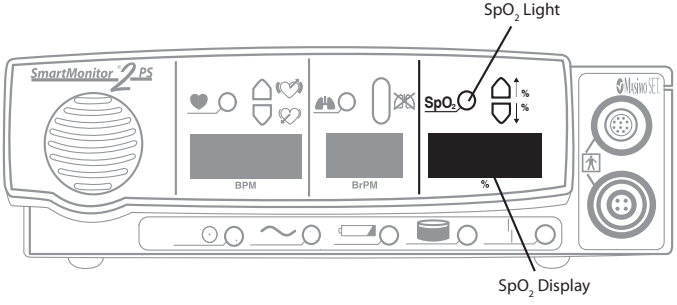
See the illustration that follows for the location of the Low Heart Rate Alarm Light.



SpO_2 LIGHT/DISPLAY

The SpO_2 light will appear solid green when the probe is connected to the patient and is monitoring the SpO_2 level. If the probe is disconnected or not transmitting a signal, the SpO_2 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_2 level will appear on the front panel display above % when the display is enabled.

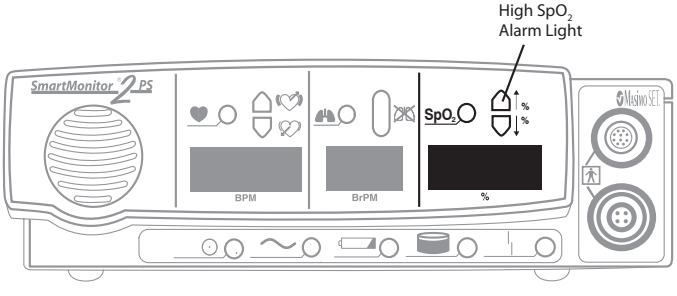


NOTE: If you are not monitoring oxygen saturation levels, the LCD display shows "OFF."

High SpO_2 Alarm Light

When the monitor determines that the child's SpO_2 level is higher than the limit set by the physician, the following will occur:

- The red light marked High SpO_2 Alarm Light will come on, and the alarm beeps twice each second.
- The beeping alarm stops when the condition no longer exists.

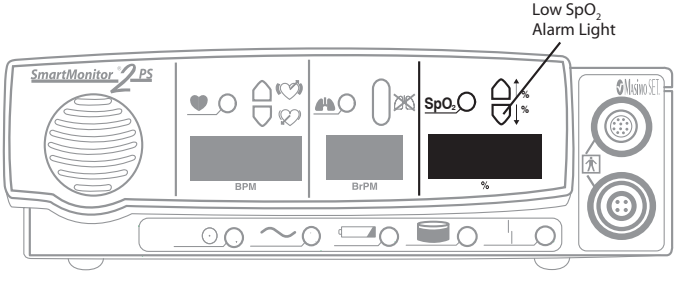


NOTE: The red light stays on until you press the blue RESET button.

Low SpO_2 Alarm Light

When the monitor determines that the child's SpO_2 level is lower than the limit set by the physician, the following will occur:

- The red light marked Low SpO_2 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

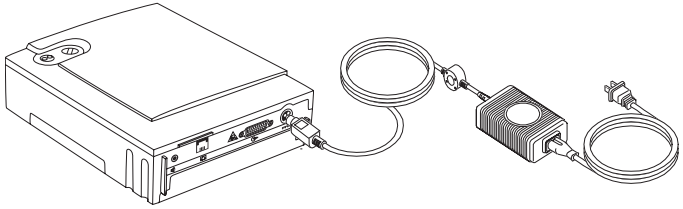
The monitor is designed for portable use. When the power supply is not used, the monitor relies on the previously charged internal battery for power. The green charger light will be off during portable operation.

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

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

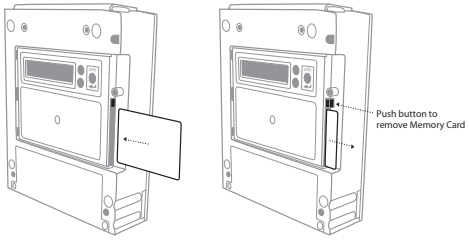
The monitor contains a memory system that automatically records information about each monitoring session. This information can be transferred (or downloaded) to a computer to be reviewed by your physician. You must transfer data when you get a memory 100% full condition. You may choose to transfer data at any time or whenever you are instructed to do so by your home care provider or physician.

Transferring the Monitor's Data to a Memory Card

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

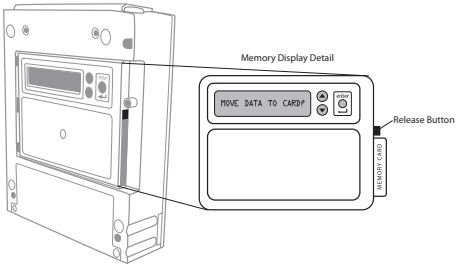
  Then,

  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

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

CAUTION: Use only Circadiance accessories with the monitor.

Cleaning Instructions

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_2 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_2 sensor from your finger. The SpO_2 light will turn red and the SpO_2 display will show dashes.
- Reapply the SpO_2 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.	• Turn the monitor off using the correct power off procedure described in "Turning the Monitor off – Sibling Alarm" in this manual. • 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). • 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.) • Allow the monitor's battery to recharge for 6 hours. If the monitor cannot be used because the battery is completely discharged contact your home care provider. • To operate the monitor and recharge battery, follow the procedures as described next in "Troubleshooting" under the Condition "No power, battery drained."
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.	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. If there is an internal software error, 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 and continue to hold the RESET button until the monitor turns off.

Problem	Possible Cause	Instructions
Alarm Sound Continuous, No Lights.	Incorrect power-off sequence.	• Press the POWER button, and ensure that the power light is illuminated. • Press and hold the RESET button. Press and release the POWER button. Wait two seconds. Then release the RESET button.
	Internal part failure.	Contact your home care provider.
Alarm Sound Continuous, No Lights.	No power, battery drained.	Connect power supply. Use Power-Off to silence alarm. • Press and hold the blue RESET button. • Press and release the gray POWER button. Wait five seconds. Then release the RESET button. 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 8 hours before using the monitor on battery power. Contact your home care provider.
Alarm sounds weak.	Internal part failure.	Contact your home care provider.
	Low battery.	Charge battery.

Problem	Possible Cause	Instructions
Loose lead. Continuous alarm; light remains on.	Connections between electrode/sensor lead wires and patient cables are not properly made.	Verify the following: (a) child's skin underneath the electrodes/sensors is clean (b) electrodes/sensors are clean (c) lead wires are fully inserted into the electrodes/sensors and patient cables
	Defective lead wires.	Replace lead wires, and perform a Functional Self-Test.
	Defective patient cables.	Replace patient cables, and perform a Functional Self-Test.
SpO_2 light remains red or orange when connected to child.	Connections between the sensor, oximeter patient cable and monitor have not been made properly.	Check all connections. Verify the following: (a) child's skin underneath the sensor is clean (b) sensor is clean (c) connector is fully inserted into oximeter patient cable (d) sensor light is properly aligned
	Defective sensor.	Replace sensor. Contact home care provider.

Specifications

Device Size

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

Electrical Ratings

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

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

IEC Classification

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

WEEE/ROHS Recycling Directives

If you are subject to the WEEE/RoHS recycling directives, please contact Circadiance Customer Service at +1-724-858-2837 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.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV 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.
NOTE: 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
			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. **Recommended separation distance:** $d = 1.2\sqrt{P}$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM Bands [a]	3 V	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
	10 Vrms 150 kHz to 80 MHz in ISM Bands [a]	10 V	$d = 1.2\sqrt{P}$ 80 MHz to 800 GHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	10 V/m 80 mHz to 2.5 GHz	10 V/m	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). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [c], should be less than the compliance level in each frequency range. [d] Interference may occur in the vicinity of equipment marked with the following symbol:

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.

Glossary

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.

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

% (Percent) SpO_2 - 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_2 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

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™
Pediatric Care

For more information or to order SmartMonitor2 products and accessories, contact:

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