

SmartMonitor[®] 2

Parents' Guide

 **Circadian**[™]
Pediatric Care

Warranty

Circadiance warrants that the monitor will be free from defects in materials and workmanship for a period of one year from the time of purchase. Circadiance accessories are warranted free of defects in materials and workmanship for a period of 90 days from the time of purchase.

The Circadiance equipment and authorized accessories are designed to function as described in the operator's manual. The user/owner of this equipment shall have sole responsibility and liability for any injury to persons or damage to property (including this equipment) resulting from:

- Operation not in accordance with supplied operating instructions;
- Maintenance not in accordance with authorized maintenance/operational instructions;
- Service by anyone other than a factory authorized service representative;
- Modification of the equipment or accessories; or
- Use of damaged or unauthorized components and accessories.

THIS LIMITED WARRANTY IS IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, TO THE EXTENT THAT STATE OR FEDERAL LAW PROHIBITS EXCLUSIONS OF IMPLIED WARRANTIES, ANY SUCH IMPLIED WARRANTY IMPOSED BY LAW SHALL BE LIMITED TO A PERIOD OF NINETY (90) DAYS FROM THE DATE OF THE INITIAL PURCHASE FROM CIRCADIANCE



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User/Owner Responsibility

The Circadiance monitor and accessories are designed to work as described in the operator's manual. The user(s) of this equipment should not use parts that have failed, exhibit excessive wear, are contaminated, or otherwise ineffective. The monitor and its accessories should not be modified. The following list incorporates the owner's responsibilities:

- Periodic check and maintenance of equipment;
- Replacement of components as required for safe and reliable operation;
- Replacement of ineffective parts with parts supplied by Circadiance, Inc.;
- Equipment that is not functioning properly must not be used until all necessary maintenance has been completed and a factory-authorized service representative has certified the equipment as ready for use;
- The monitor and any of its accessories should not be modified;
- As a general rule, the proper performance of the monitor should be verified with a Respirationics Model 5000 Simulator according to the Checkout Procedure Manual #H580-4000-00 between each patient use or every 6 to 12 months or whichever is more frequent.

The user of this equipment is responsible for reading, understanding, and following the Warning and Caution statements throughout this manual.

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Introduction

About this Manual

This manual provides all the information you need to set up and operate the Circadiance SmartMonitor[®]2 and explains how to use it to monitor your baby's vital functions. Carefully read and understand this manual before using the system. Words that appear in ***Bolded Italics*** are defined in the Glossary in the back of this manual.

Indications for Use

The SmartMonitor 2 is intended for use in continuous monitoring of ***heart rate*** and ***respiration*** of infant patients in a home, hospital or portable environment. Its primary function is detection of ***central apnea***. Its secondary function is measurement of heart rate.

What is the Purpose of the SmartMonitor 2?

The SmartMonitor 2 is an ***apnea*** monitor designed to monitor and record your baby's breathing (***respiration***) and heart (cardiac) activity. The monitor alerts you if either of these activities exceeds the limits prescribed by your physician.

Patient alarm limits are set by your health care professional before you receive your SmartMonitor 2 monitor. During monitoring, when your baby's breathing effort and heart activity are not within these set boundaries, an indicator light comes on and an alarm sounds. This manual explains how to set up the SmartMonitor 2, how to monitor your baby, and how to transfer the information.

Other devices may be used with the SmartMonitor 2:

- Respironics 930 ***Oximeter***
- Nellcor N-200 Pulse Oximeter
- Nellcor NPB-295 Pulse Oximeter
- Masimo Radical Oximeter
- Nova Cosmo ETC02
- Nova Cosmo Oximeter
- Ohmeda OXI Pulse Oximeter
- Synectics pH Meter
- Sandhill pH Meter

If your physician prescribes any of these devices, your health care professional can discuss them with you.

Warnings and Cautions

Please read this section carefully before using the SmartMonitor 2 to monitor your baby's breathing and heart activity.

Warnings

A *warning* indicates a potentially harmful situation.

1. SmartMonitor 2 may not be able to detect all episodes of inadequate breathing. If a baby has **apnea** due to choking (**obstructive apnea**), the monitor could mistake movement caused by choking for breathing.
2. SmartMonitor 2 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.
3. Anyone using the SmartMonitor 2 to monitor an infant should be trained in current infant **Cardiopulmonary Resuscitation (CPR)**, which is a proper way to restore breathing and heart activity.
4. The SmartMonitor 2 is not intended for use with cardiac or diaphragmatic pacemaker patients.
5. When using the monitor near patients on oxygen, the monitor must be kept at least three (3) feet away from the oxygen tank (source) or other flammable gases to prevent a fire hazard.
6. Place the monitor on a sturdy and level surface to prevent the monitor from falling.
7. Do not place the monitor on the floor. It may become a tripping hazard.
8. Do not place the monitor in the crib. The baby may roll on the hard surface and be injured.
9. Use only those accessories provided by your health care professional with this monitor.
10. Do not allow the patient cable, lead wires or power cord/battery charger cable to become tangled, coiled, crossed, or wrapped around the baby's neck, arms, or legs. This could result in strangulation.
11. Do not connect to an electrical outlet controlled by a wall switch to prevent inadvertently turning the power to the monitor off.
12. Do not block the speaker or place items in front of the speaker located on the front of the unit. This could prevent the monitor alarm from being heard.
13. Never use the monitor on your baby while your baby is being bathed. This could result in electrical shock and/or damage to the equipment.

14. Disconnect the power cord/battery charger and phone line during lightning storms to reduce risk of electrical shock to your baby. The SmartMonitor 2 will not download by modem when the power cord/battery charger and phone line are disconnected.
15. Remove the **electrode** belt and the lead wires when your baby is not being monitored. Long-term wear may be uncomfortable.
16. Never use an extension cord with the power cord/battery charger.
17. Be aware of signal interference that can occur from external sources. Electronic signals are required for the SmartMonitor 2 to function. Sources of external interference could cause the monitor to miss apnea and heart rate alarms. Even though the monitor contains methods and techniques which can provide protection from external sources of interference, you should operate the monitor as follows:
 - Keep monitoring equipment, patient and patient leads at least three (3) feet away from all electrical appliances. Some examples of this include TV sets, electric blankets, air conditioners, microwave ovens, cordless telephones, cellular phones, waterbeds, and home computers.
 - Synthetic fabric from draperies or rugs can also cause interference due to static electricity. Touching a conductive material with a grounded path, such as a wall or crib, before handling the patient or the SmartMonitor 2 often prevents static build-up problems.
 - Strong transmitter signals from TV, radio, airport, police, fire, and ambulance stations could be picked up as heart and/or breath signals. If located less than one (1) mile from one or more of these sources, the monitor may be affected.
18. In some locations, the monitor will not work properly. If the monitor is affected by external interference in the area, you may not be able to use the monitor. Contact Circadiance for further assistance. Use of a **third (RL) electrode** may help reduce electrical interference.
19. If monitoring two or more infants in the same area, keep the monitors, patient, patient cables and lead wires at least three (3) feet apart. Having the patient cables and lead wires close together may cause missed apneas due to interference.
20. Do not connect the infant to the SmartMonitor 2 if the monitor is placed in the *Communications Mode*. The apnea and heart alarms do not work when the SmartMonitor 2 is in this mode.
21. Do not use the SmartMonitor 2 at the same time as other **impedance** monitors. This may cause missed apneas due to interference.
22. Do not rock your baby or sleep in the same bed with your baby while monitoring. Touching or moving near your baby, monitor, or cables could cause the monitor to miss apneas.

Cautions

A caution indicates a condition that may lead to equipment damage, malfunction, or inaccurate operation.

Federal law (US) restricts this device to sale by, or on the order of a licensed physician. This instrument should be used only under the supervision of a physician.

1. Perform the functional self-test if the SmartMonitor 2 has been x-rayed by an airport security check.
2. Do not place liquids on or near the SmartMonitor 2. Liquids may damage the electronic components inside the monitor. Should liquid spill onto monitor, shut monitor off and call your home care dealer to have it serviced.
3. Check the monitor's respiration light. Listen while your baby breathes and watch the respiration detection light on the monitor. While your baby is breathing quietly, the light should flash once and only once for each breath the baby takes, although it may flash additional times when the baby is moving. If your baby is breathing quietly and the respiration light flashes more or fewer times than your baby breathes, contact your home care dealer for service.
4. Do not send information via modem during electrical storms. Information could be lost or equipment could be damaged.
5. 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.

How Does the SmartMonitor 2 Work?

Your baby's breathing is measured by simply placing two **electrodes** on the baby's chest under his or her arms. As the baby's chest moves during breathing, the impedance between the electrodes changes. The SmartMonitor 2 detects these changes for determining the baby's breathing effort. If the SmartMonitor 2 does *not* detect these changes in breathing effort, a light will come on and an alarm will sound.

SmartMonitor 2 also uses the electrodes on the chest to monitor heart activity by picking up the electrical changes produced by the heart. If the SmartMonitor 2 detects the heart rate outside the range ordered by your physician a light will come on and an alarm will sound.

How the Alarms Operate

Whenever your baby's breathing effort and heart activity are not within the limits set by your physician, an indicator light will come on and an alarm will sound.

The SmartMonitor 2 has two types of alarms: *patient* and *system*.

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

- **Apnea:** Baby has stopped breathing for longer than the limit set by your physician
- **Low Heart:** Heart Rate lower than the limit set by your physician
- **High Heart:** Heart Rate higher than the limit set by your physician

System Alarms: A constant audible alarm indicates one of the following SmartMonitor 2 conditions:

- Loose lead
- Low Battery
- Memory Full (or Memory Almost Full)
- Accidental Power-Off
- Internal System Error

Lights on the SmartMonitor 2 indicate which of these conditions exists. See the sections on *Monitoring Your Baby*, *Responding to Patient Alarms* and *Responding to System Alarms* for more information about alarms.



The SmartMonitor 2 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 unit. If there is an internal error, a code will be displayed. Discontinue use of monitor and contact your health care dealer.

Electrical Ratings

Model 4009 Power Cord/Battery Charger:	120VAC 60Hz 7.2W
Model 4011 Power Cord/Battery Charger:	230VAC 50Hz 7.2W
SmartMonitor 2:	10.5-11.5VDC 0.1-1A
Model 418 Ni-MH Rechargeable Battery Pack:	6VDC 1.85Ah or greater

Environmental Conditions

















Operating Temperature:	5°C to 45°C
Operating Humidity:	20%RH to 95%RH, non-condensing
Storage Temperature:	-20°C to +65°C
Storage Humidity:	10%RH to 95%RH, non-condensing
Battery Charge Temperature:	10°C to 35°C

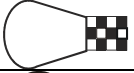

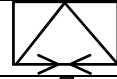


IEC Classification

The SmartMonitor 2 is classified as:

- Class II/Internally Powered
- Type BF Applied Part
- Ordinary Protection against the ingress of liquids
- Not suitable for use in the presence of a flammable anesthetic mixture with air or with nitrous oxide
- Continuous Operation

Symbols Table

Symbol	Definition
	Attention: Important information that should be read
	Attention: Read accompanying documents
	Type BF Applied Part also shows Patient Cable Connector location
IOIOI	Serial Port
	Reset Button
	Power Off/On Button
	Apnea Light
	Respiration Light
	Low Heart Rate Light
	High Heart Rate Light
	Low Battery Light
	Memory Full Light
	Loose Lead Light
	Heart Rate Light
	Power Light
	Alternating Current
	Direct Current

	Power Cord Connector Position
	In-put / Out-put connection
	Modem Port
	Remote Alarm Connection
SN	Serial Number
REF	Part Number
	Three Electrodes per package

FCC Part 68 Notice

The SmartMonitor 2 complies with part 68 of the FCC Rules. On the bottom of the SmartMonitor 2 are labels that contain, among other information, the FCC Registration Number and Ringer Equivalent Number (REN) for this equipment. If requested, this information must be provided to your telephone company.

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

If the SmartMonitor 2 caused harm to the telephone network, the telephone company will notify you in advance that temporary discontinuance of the service may be required. But if advance notice is not practical, your telephone company will notify the customer as soon as possible. Also, you will be advised of your rights to file a complaint with the FCC if you believe it is necessary.

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

If trouble is experienced with the SmartMonitor 2, please contact the Circadiance Service Center at 1-888-825-9640 for repair and/or warranty information. If the trouble is causing harm to the telephone network, your telephone company may request that you remove the equipment from the network until the problem is resolved.

Industry Canada CS-03 Notice

NOTICE: The Industry Canada (IC) label on the SmartMonitor 2 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 SmartMonitor 2, 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 Circadiance 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.

The Ringer Equivalent Number (REN) assigned to the SmartMonitor 2 provides an indication of the maximum number of terminals allowed to be connected to a telephone interface. The termination of an interface may consist of any combination of devices subject only to the requirements that the sum of Ringer Equivalent Numbers of all the devices does not exceed five (5.0).

FCC Part 15

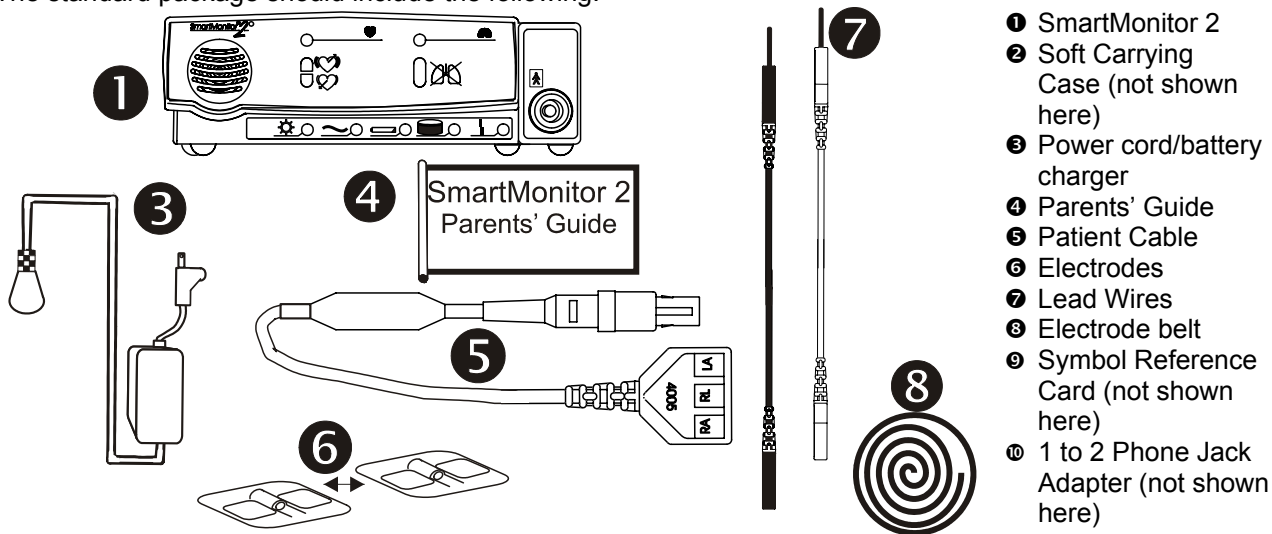
NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, following part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications.

Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Getting to Know the Monitor

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

The standard package should include the following:



- ❶ SmartMonitor 2
- ❷ Soft Carrying Case (not shown here)
- ❸ Power cord/battery charger
- ❹ Parents' Guide
- ❺ Patient Cable
- ❻ Electrodes
- ❼ Lead Wires
- ❽ Electrode belt
- ❾ Symbol Reference Card (not shown here)
- ❿ 1 to 2 Phone Jack Adapter (not shown here)

SmartMonitor 2 Features

This section describes the physical features of the SmartMonitor 2 unit.

Top Panel Features

POWER Button

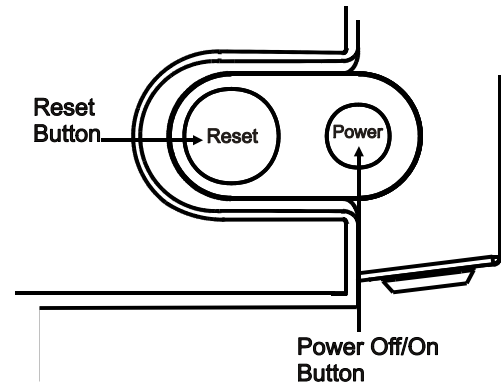
The gray **POWER** button turns the SmartMonitor 2 **on**. When you turn the monitor **on**, all lights and the alarm come on briefly and the monitor performs a system test. After a pause, monitoring will begin.

To turn the monitor **off** do the following:

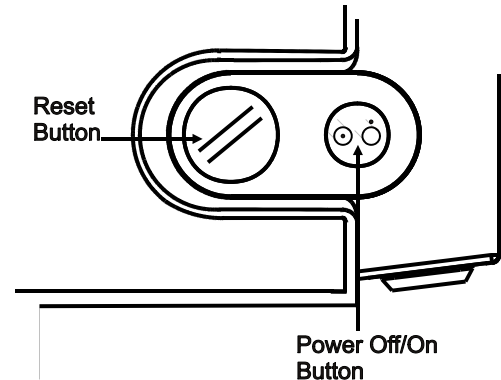
- Press and hold the blue **RESET** button.
- Press and release the gray **POWER** button.
- Wait 2 seconds then release the **RESET** button.

RESET Button

The blue **RESET** button resets the alarm lights on the SmartMonitor 2. It also silences the Memory Full (or Memory Almost Full) and Low Battery warning alarms. For more information, see the section on *Responding to Alarms*. The **RESET** button also answers a ringing **modem** phone call when in monitoring mode.



There are two styles of top panels. Illustrated here are the two different styles.



Remember that the **RESET** button will not silence patient or loose lead alarms.

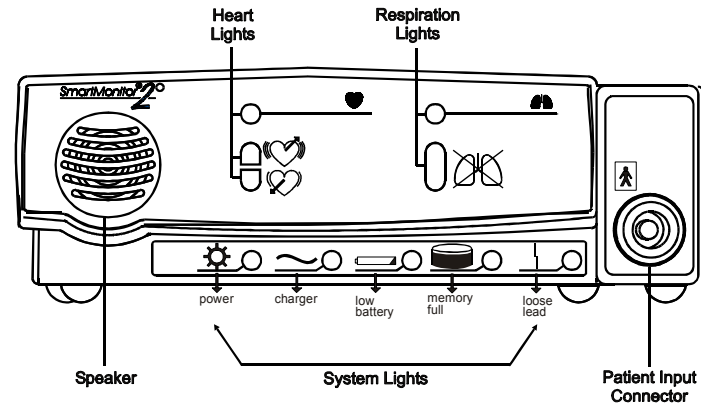
Front Panel Features

Patient Input Connector

The **Patient Input** connector is for the Patient Cable.

Respiration Lights

The green **respiration** light blinks with each breath the SmartMonitor 2 detects. The red **apnea** light will come on if the SmartMonitor 2 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 SmartMonitor 2 detects. The red **high** light comes on when the SmartMonitor 2 detects a heart rate higher than the limit set by your physician. The red **low** light comes on when SmartMonitor 2 detects a heart rate lower than the limit set by your physician.

Speaker

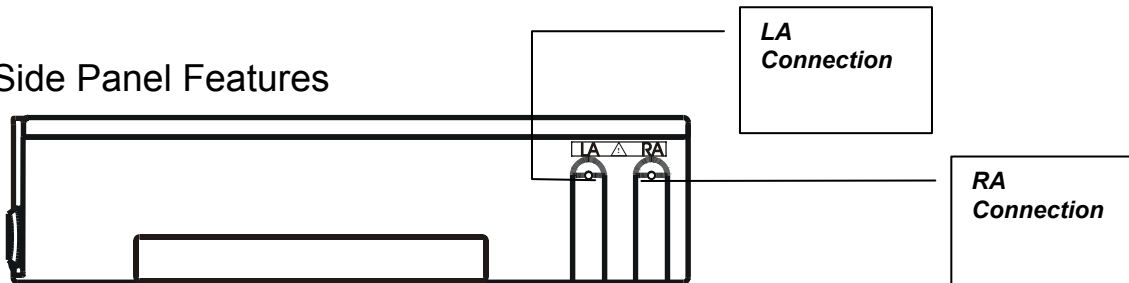
The SmartMonitor 2 speaker allows you to hear any alarm that sounds during monitoring.

System Lights

The lights across the bottom of the front panel indicate if the SmartMonitor 2 is working properly:

Light	Indicates
Power	The power to the SmartMonitor 2 is on.
Charger	The power cord/battery charger is on and plugged into the SmartMonitor 2.
Low battery	The battery power is low and needs to be charged.
Memory full	The SmartMonitor 2 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



Self-Test Connector

You use the Self-Test Connector when performing a **Functional Self-Test** to make sure the lead wires, patient cable and SmartMonitor 2 are working properly. See the section, *Performing a Functional Self-Test* for more information.

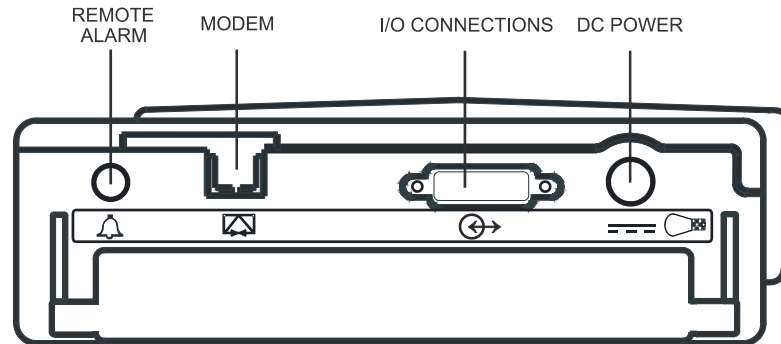
Back Panel Features

Remote Alarm (Optional)

If your dealer provided the optional Remote Alarm, connect it here. The Remote Alarm allows you to hear the audible alarms from a different room.

Modem (Optional)

The SmartMonitor 2 may be equipped with a modem to transfer the SmartMonitor 2 memory to the home care dealer. See the section on *Transferring Monitor Memory* for more information. See the sections on *FCC Part 68* and *IC CS-03* for information on connecting the modem to the telephone line.



DC Power

Use the DC Power connector with the power cord/battery charger. Whenever the SmartMonitor 2 is not in portable use (on battery power only) it should be connected to the power cord/battery charger.

I/O Connector

This connector connects the SmartMonitor 2 with other devices.

Setting Up the SmartMonitor 2 for Respiration and Heart Monitoring

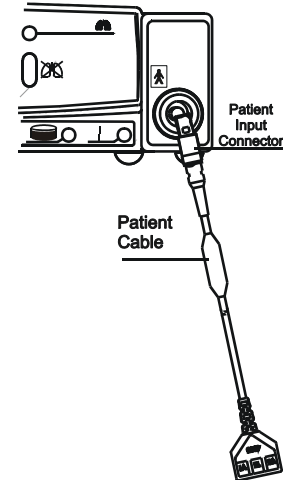
After you unpack your SmartMonitor 2 and make sure you have all the parts, follow the steps listed below to set it up:

Step 1: Set the SmartMonitor 2 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 baby comfortably.

Step 2: Connect the Patient Cable to the SmartMonitor 2.

- Insert the round end of the patient cable into the bottom round connector found on the front of the SmartMonitor 2.
- Line up the notch on the connector and push until you feel the connector snap into place.
- To remove the patient cable, grasp the patient cable at the base of the patient input connector and gentle pull back. Do not grasp and pull the patient cable to remove from the SmartMonitor 2.



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

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

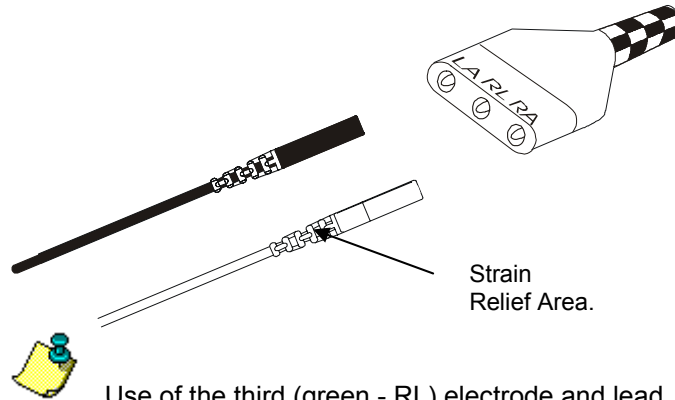
Take the **white** lead wire and insert it into the opening marked **RA**.

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.

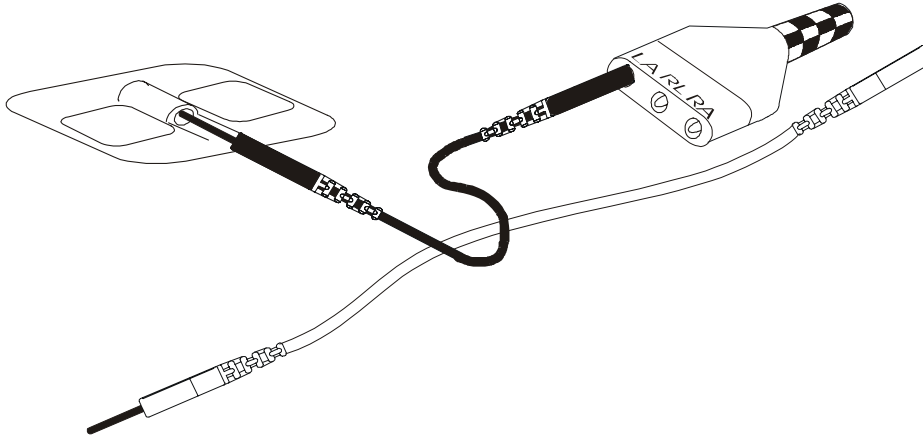


When you need to remove a lead wire, grasp and pull at the strain relief area located near the connecting tip. **Do not grasp the wire.**



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

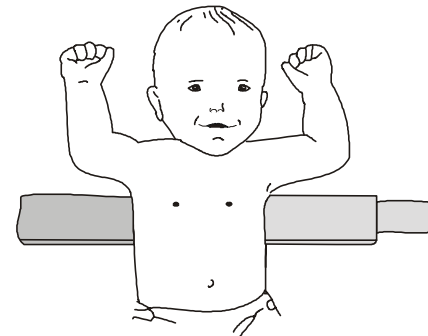
Step 4: Connect the Lead Wires to the Electrodes.



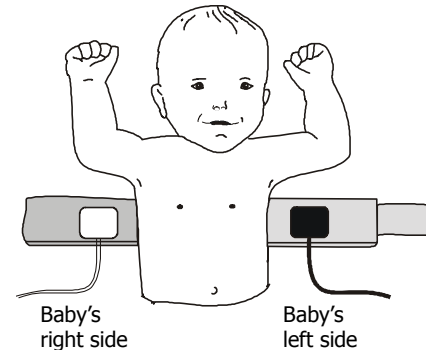
- Insert the black **LA** lead wire into one electrode.
- Insert the white **RA** lead wire into the other electrode.
- Make sure the metal tips of the lead wires are fully inserted into the electrodes.

Step 5: Attach the Electrodes to the Infant Belt.

- Place the electrode belt on a flat surface.
- Lay your baby on the belt so the belt is aligned with the baby'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 *baby's right* side.
 - Place the electrode with the **black** lead wire on the *baby's left* side.



- Place the electrodes far enough apart so that when the belt is wrapped around the baby, 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 patient cable are leading down and away from the baby's face and neck (see illustration).

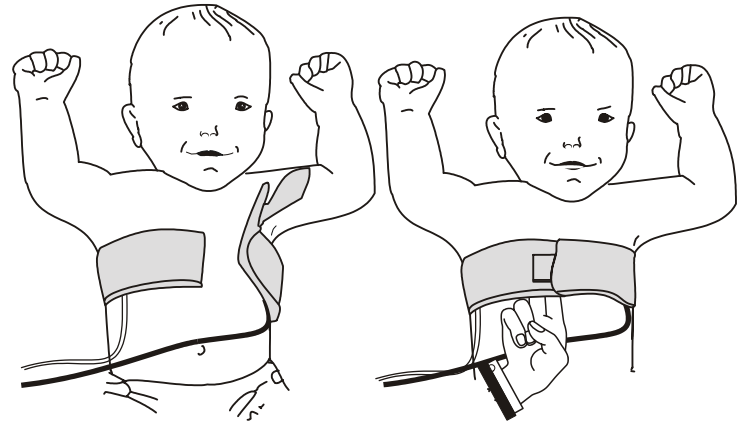


The white lead wire location is illustrated with a white electrode.

Step 6: Wrap the Electrode Belt around the Baby.

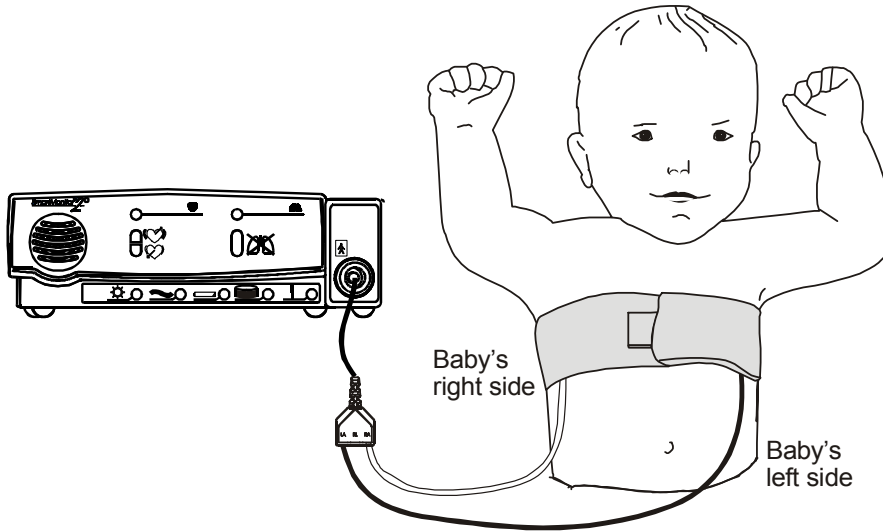
Wrap the belt around the baby's chest and fasten it with the Velcro tab.

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



With 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.

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



Insert the black LA lead wire into the Velcro side of one electrode. Place the electrode with the black lead wire on the baby's left side.

Insert the white RA lead wire into the Velcro side of one electrode. Place the electrode with the white lead wire on the baby's right side.

Disposable Self Adhesive Electrodes

Follow the steps below if you are using disposable electrodes.

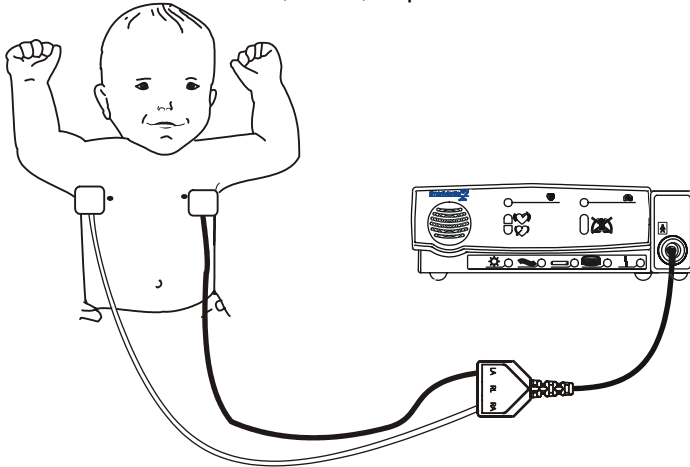
- Attach lead wires to the Self Adhesive Electrodes if not pre-attached.
- Insure the infant's skin is clean and dry.
- Place the electrode with the **white** lead wire on the baby's **right** side, along the mid-line of the side, two finger widths below or lined up with the nipples.
- Place the electrode with the **black** lead wire on the baby'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 when using disposable electrodes.



Use of the third (green - RL) electrode and lead wire is normally not required, but may help reduce EMI interference. Place the green third electrode along the outside of baby's upper thigh. (Not on the inside of the thigh, the inside can cause discomfort).



Do **not** use oils, lotion, or powder on the area of skin that the electrodes will be placed.



Step 7: Connect the Power Cord/Battery Charger.

- Insert the round connector of the power cord/battery charger into the socket on the back panel of the SmartMonitor 2 (see illustration).
- Line up the notch on the connector.
- Push until the connector is fully inserted.
- Plug the power cord/battery charger into a power outlet. The green charge light on the monitor will now come on.



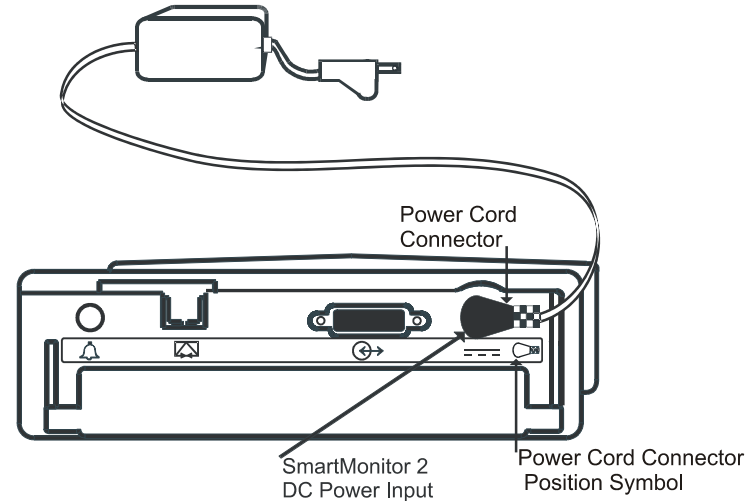
When the SmartMonitor 2 is not being used portably, keep the power cord/battery charger connected and plugged into an AC outlet at all times. Insure that the AC outlet has been installed to conform to the National Electrical Code (NEC) i.e., a licensed electrician. The batteries cannot be overcharged. The green charger light stays on as long as the charger is connected.



The Power Cord Connector must be plugged into the SmartMonitor 2 DC Power Input as shown in the illustration to the right. The Power Cord Connector can only be inserted as shown to the right.



Do NOT use device if power cord is damaged. Contact your dealer.



Responding to Alarms

Patient Alarms

A Patient Alarm indicates that your baby's breathing or heart activity 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 dealer.

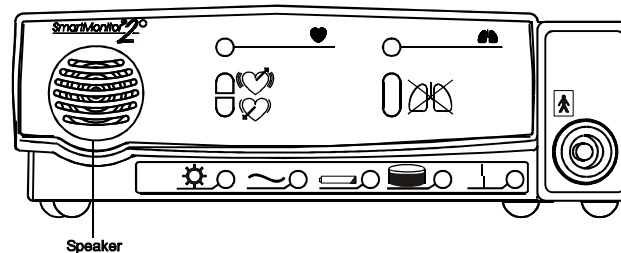
Testing the Alarm

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 baby attached) to sound the alarm. Make sure you can hear the alarm in different areas of your home.
- If the alarm is not loud enough to hear around the home, ask your dealer for a Remote Alarm. This device will allow you to hear the alarm in a different room from where the monitor is located.



If an Alarm Sounds

If an alarm sounds while you are monitoring your baby, check your baby first. Then follow the instructions below to respond to lights and alarms. Always check your baby's skin color. Is it normal? Always check to see if your baby is breathing. If your baby **is not** breathing, follow the Respond Like This instruction.

Light	Alarms	Check Baby's Condition	Respond Like This
Red Apnea and/or Low (Heart)	Intermittent (1 beep/sec)	Skin color is pale or blue. Baby 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"> • Gently pat the baby. The baby may start breathing and correct the cause of the alarm on his/her own. • If the baby does not start breathing start physical stimulation immediately. • If the baby starts breathing, note it on your log sheet. • Press the RESET button to reset any alarm lights.
Red Apnea and/or Low (Heart)	Intermittent (1 beep/sec.)	Baby is responsive and is breathing. Color is good.	<ul style="list-style-type: none"> • Wait for a few seconds. Watch to see if the baby's breathing and color remain normal. • If alarm continues, see section titled "<i>Reducing False Alarms</i>". • Check the monitor to see which light is on. Note it on your log sheet.
Red High (Heart)	Intermittent (2 beeps/sec.)	Baby is crying.	<ul style="list-style-type: none"> • If the baby is on breathing medications and gets frequent high heart rate alarms, please note alarm on your log sheet and call your physician or home care dealer.
Red Loose Lead	Continuous	Baby is breathing and is responsive. Color is good.	<ul style="list-style-type: none"> • Check the connections between the electrodes, lead wires, 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 section on <i>Performing a Functional Self Test</i>.

Light	Alarms	Check Baby's Condition	Respond Like This
Red Loose Lead	Continuous	Baby 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 baby'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.





Patient alarms cannot be silenced with the **RESET** button. The alarm will stop only when the patient signals are within the alarm limits.

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 SmartMonitor 2 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 green light, no alarm	Normal operation. The green charger light will come on and stay on while the power cord/battery charger is plugged into an active outlet and connected to the SmartMonitor 2.
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 <i>Charging the Battery</i> 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 SmartMonitor 2 to operate properly. The SmartMonitor 2 must be recharged. Turn the monitor off. Then, recharge the battery. (See <i>Charging the Battery</i> in this manual).</p> <p>If you do not reconnect the charger, the system will automatically shut down.</p>

If this light is on	And this condition exists	It means...
Memory Full	Flashing yellow light, continuous alarm	<p>When the SmartMonitor 2 Memory Almost Full parameter is reached, the Memory Full light will flash. The alarm will sound continuously. (The alarm will sound only if your dealer programs your SmartMonitor 2 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>Memory Almost Full is a warning condition. You can continue monitoring. Please contact your dealer to resolve the alarm.</p>
Memory Full	Continuous yellow light, continuous alarm	<p>SmartMonitor 2 memory is 100% full. Press the RESET button to silence the alarm.</p>  <p>The alarm will sound only if your dealer programs your SmartMonitor 2 to do so.</p> <p>The light will stay on continuously. Then contact your dealer to resolve the alarm. (See also <i>Transferring the Monitor Memory</i> in this manual for more information).</p>
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"> • Lead wires • Electrodes • Electrode belt • Patient cable, or • Connections between the baby's skin, and the electrodes, the lead wires, the patient cable, and the SmartMonitor 2.

If this light is on	And this condition exists	It means...
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 for error messages. If no error messages, the SmartMonitor 2 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.
All	All lights are blinking and the alarm sounds for 3 seconds and then off for 1 second.	Check the display 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.

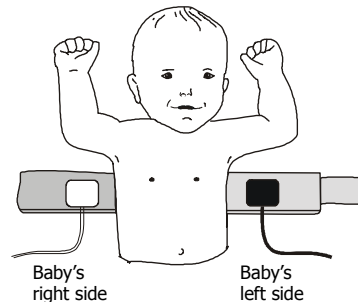
Reducing False Alarms

Proper electrode placement will minimize false alarms.

Insure 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, insure the belt is quite snug. Place the electrodes far enough apart so that when the belt is wrapped around the baby, 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 baby's skin prior to electrode belt placement.
- When using the black reusable electrodes insure that the electrode surface is clean.

- The optional green (RL) electrode and lead wire may help reduce **EMI** interference. Place the green electrode along the outside of baby's upper thigh.



The white lead wire location is illustrated with a white electrode.

Monitoring Your Baby

Turning the SmartMonitor 2 on

You have properly set up your SmartMonitor 2, understand how the monitor functions and how to respond to alarms. You are now ready to begin monitoring your baby's breathing and heart activity according to the schedule prescribed by your health care professional.

Push the **POWER** button. The SmartMonitor 2 performs a system check. The lights on the front of the SmartMonitor 2 and the alarm come on briefly. 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 baby, that the lead wires are pushed in, and that the cables are connected.

Once your baby is properly connected to the SmartMonitor 2 and the power is on:

- The green (battery) **charger** light is on.
- The green **power** light is on.
- The green **respiration** light and the green **heart** light are blinking.
- All other lights should be off.
- If the lights do not blink, refer to the steps found in the *Setting up the SmartMonitor 2* section in this manual and be sure you have followed all instructions.

Turning the Monitor off - Sibling Alarm

The SmartMonitor 2 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 continually. This safety feature makes sure the power is not accidentally turned off. To turn the SmartMonitor 2 off:

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

When the SmartMonitor 2 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 and hold the blue **RESET** button.
- Press and release the gray **POWER** button.
- Wait 2 seconds then release the **RESET** button.
- To resume monitoring, press the gray **POWER** button.

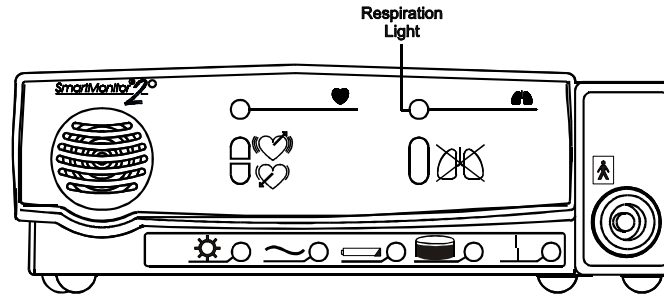
If there is an internal software error, a special power off procedure is required.

- 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; continue to hold the **RESET** button until the monitor turns off.

Monitoring Your Baby's Breathing

Respiration Light

The green **respiration** light will blink in rhythm with each breath that the SmartMonitor 2 detects. The light should blink only once for each breath, although it may flash more times when your baby is moving.

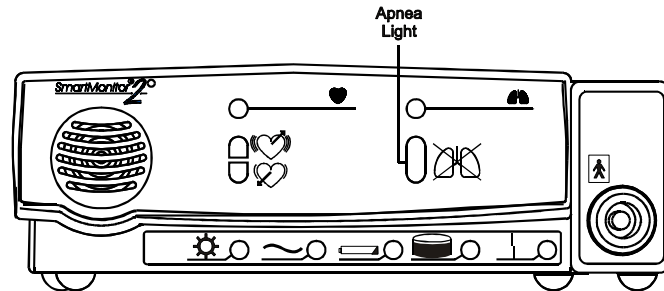


Listen and watch your baby breathe. If the respiration light flashes more times or fewer times than your baby breathes, contact your dealer immediately.

Apnea Light

When the SmartMonitor 2 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 SmartMonitor 2 detects breathing again, the beeping alarm stops. The red light will stay on until you press the **RESET** button.



Low Breath Rate. Your health care professional may have set your SmartMonitor 2 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 SmartMonitor 2 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.

Monitoring Your Baby's Heart Activity

Heart Rate Light

The green light marked **heart** blinks with each heartbeat the SmartMonitor 2 detects.

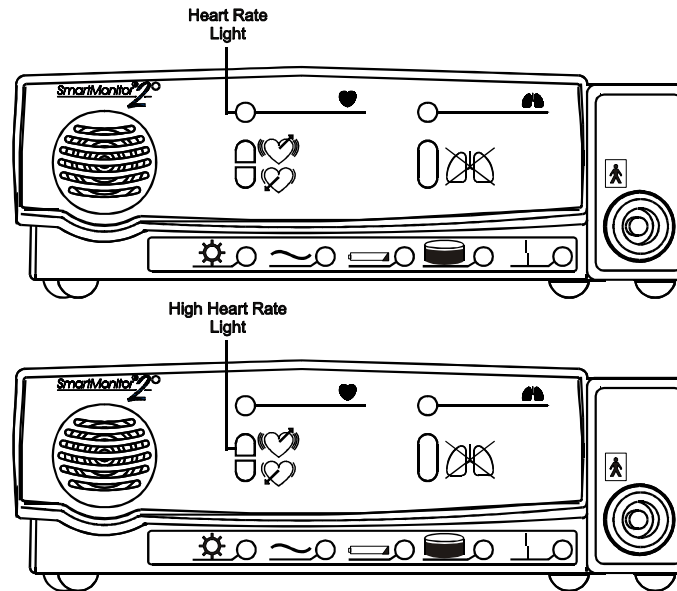
High Heart Rate Light

SmartMonitor 2 determines if your baby'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.



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



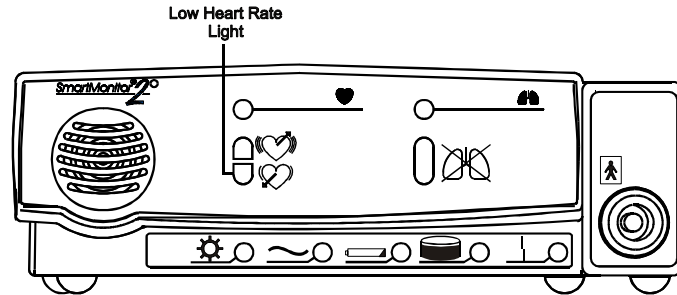
Low Heart Rate Light

When the SmartMonitor 2 determines that your baby's heart rate is lower than the limit set by your physician the following will happen:

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



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



Portable Operation of the SmartMonitor 2

The SmartMonitor 2 is designed for portable use. When the power cord is not used, the monitor relies on the previously charged internal battery for power.

Circadiance recommends that the SmartMonitor 2 be used with the power cord/battery charger whenever possible. However, when the monitor is used without the power cord/battery charger the SmartMonitor 2 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 6 hours.

Charging the SmartMonitor 2 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 6 hours. When you need to recharge the SmartMonitor 2 battery, follow the steps below.

- Connect the power cord/battery charger to the back panel of the SmartMonitor 2.
- Plug the power cord/battery charger into a power outlet. The green **charger** light comes on.
- If the SmartMonitor 2 is turned on, the yellow **low battery** light blinks until the minimum charge level is reached. Then, the yellow light goes off.

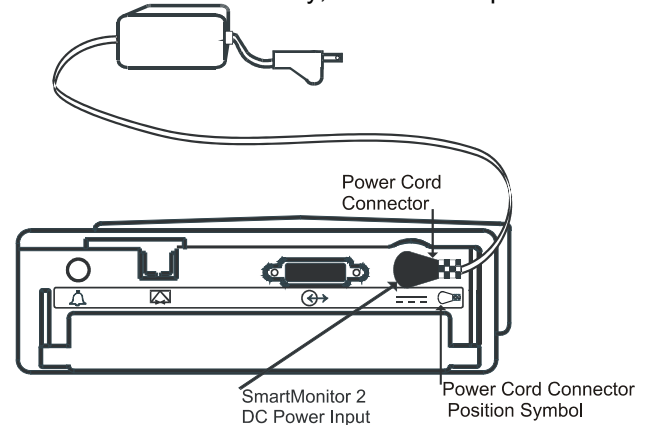


Fully drained batteries need about 6 hours to recharge.



Unit should be at room temperature 65°F to 85°F while charging or batteries may not reach a full charge. Only use Circadiance batteries.

The Power Cord Connector must be plugged into the SmartMonitor 2 DC Power Input as shown in the illustration to the right. The Power Cord Connector can only be inserted as shown.



Transferring SmartMonitor 2 Information

The SmartMonitor 2 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 dealer or physician.

Modem Download



SmartMonitor 2 must be plugged into the electrical outlet during modem downloads.

There are 3 ways to download with a modem. The first choice involves the modem automatically calling your 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 your phone line. If your home care dealer is going to use this feature they will give you more specific instructions.

The second choice is called Modem Auto Answer When in Communications mode. This option is basically the same as Modem Auto Dial, the difference is the baby is not being monitored and the device is in Communications mode when the home care dealer calls.

The third option involves the home care dealer calling to the modem built inside the monitor while the baby is being monitored. This called Modem Auto Answer When Monitoring. The home care dealer must contact the caregiver when it is time to transfer the data through the modem. We will discuss all three.

Modem Auto Dial

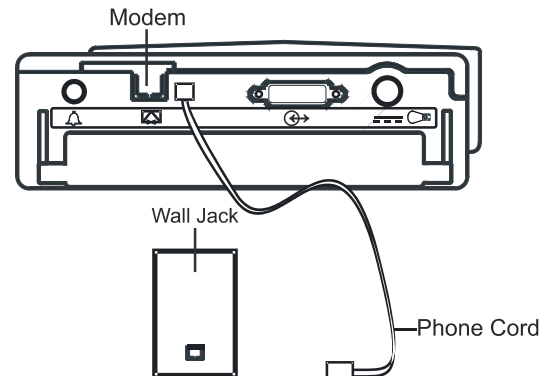


SmartMonitor 2 must be plugged into the electrical outlet during modem downloads. To have SmartMonitor 2 call the computer for a download it must be programmed with a Host Phone Number, which is the phone number to be called to connect with the computer as well as the date and time to call. If this feature is going to be used, your dealer will have programmed these before you receive the monitor. When the preset time for download approaches or when the memory full light illuminates, follow these instructions:



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

- Plug the telephone wire into the modem connector on the back of the SmartMonitor 2 (see illustration).
- Plug the other end of the phone wire into the wall phone jack.
- The SmartMonitor 2 will continue to monitor your baby during download. All alarms are functional.



The monitor will continue calling every 30 minutes, for 4 hours, until it connects with the computer. If no connection is made, the monitor will try again the next day at the pre-selected time. For example, when the modem is programmed to call at 7am but fails to make a connection after 8 attempts it will stop trying. The next day at 7am it will try again. This will continue until a connection is made.

Modem Auto Answer in Communications Mode



SmartMonitor 2 must be plugged into the electrical outlet during modem downloads.

1. Connect a phone cord from the wall jack to the modem connector on the back of the SmartMonitor 2.
2. To allow the SmartMonitor 2 to work with the modem, place the monitor in Communications Mode:
 - Press and release the **POWER** button to turn the SmartMonitor 2 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. The SmartMonitor 2 display will read "Monitor is in Communication Mode".
 - The SmartMonitor 2 beeps every 10 seconds whenever it is in the Communications Mode. This is a reminder that the SmartMonitor 2 is powered on for working with the computer, memory card, or modem, but NOT for monitoring the infant.



Do not connect the infant to the SmartMonitor 2 when in the Communications Mode, the apnea and heart rate alarms are not operational in this mode.

- The home care dealer should now call to retrieve the information. The phone may ring, but do not answer. The modem answers the call and connects the SmartMonitor 2 to the computer through the phone line.
3. The amount of time to transfer the information will vary. When the transfer is complete the SmartMonitor 2 will beep 5 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 2 seconds, and then release the **RESET** button.
 - You may now reconnect the baby and resume monitoring.

Modem Auto Answer in Monitor Mode



SmartMonitor 2 must be plugged into the electrical outlet during modem downloads.

1. Connect the phone cord from the wall jack to the modem connector on the back of the SmartMonitor 2.



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

2. To allow the SmartMonitor 2 to work with the modem when the monitor is in monitor mode (the baby is being monitored):
 - When the home care dealer calls for a download and the phone rings, you should press and hold down the blue **RESET** button.
 - Hold down the **RESET** button until the phone stops ringing indicating the monitor has answered the call.
 - The amount of time to transfer the information will vary. When the transfer is complete the SmartMonitor 2 will beep 5 times.
 - After the transfer, disconnect the phone line from the monitor and the phone will work normally.



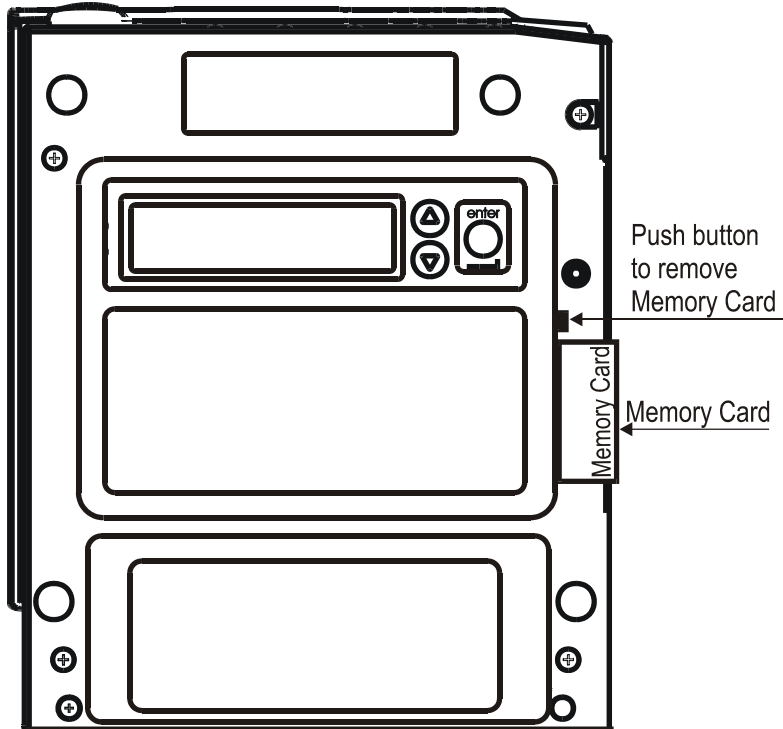
Be aware that some features available on your phone may interfere with the download: Call Waiting, Call Forwarding, and Party Lines all increase the likelihood of problems when downloading. Call Waiting cannot be disabled when receiving a phone call.

Transferring SmartMonitor 2 Data to a Memory Card

The Memory Card is a credit-card-sized electronic memory transfer device that transfers monitor data. *This is an optional feature of SmartMonitor 2 and may not be installed on every unit.*

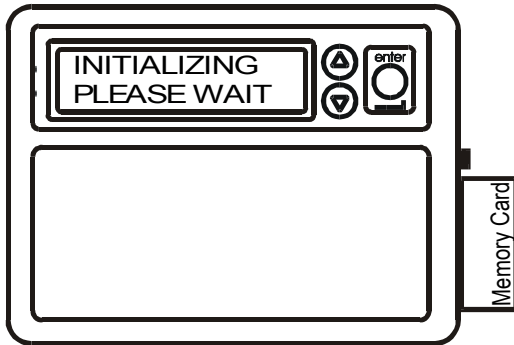


All data in the memory card at the time of a download will be overwritten.



When you are ready to use the Memory Card to transfer SmartMonitor 2 data, follow the steps below:

- Make sure the SmartMonitor 2 is **off**.
- With the Memory Card facing you slide the card into the slot provided on the side panel of the SmartMonitor 2. 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 keys in the following sequence within 10 seconds:
- Press the **ENTER** button.
- The display will read SMARTMONITOR 2 MENU SELECTION.



Close up of LCD display on the bottom of the SmartMonitor 2.

- Press the ▼ 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.

Caring for Your SmartMonitor 2

Use the information in this section to care for your SmartMonitor 2.



Use only Circadiance accessories with the SmartMonitor 2.

Cleaning Instructions

Turn the monitor **OFF**, unplug it from the electrical outlet, and disconnect all accessories before you begin cleaning. Never immerse the monitor or any of the accessories in water or spray cleaner directly on them. Apply water or cleaner to a soft cloth and gently wipe the components to clean them.

Monitor, Power

Cord/Battery Charger 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) to clean the monitor unit.
 - 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.
- Insure that the electrodes are completely dry before using.

Soft Carrying Case

- 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.

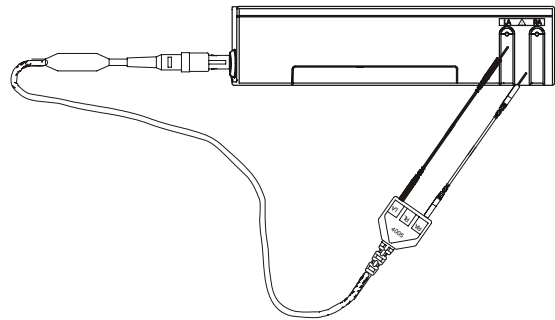
Performing a Functional Self-Test

The SmartMonitor 2 functional self-test checks that all the features of the unit are functioning properly. You should perform a **functional self-test** at least once a week or according to the instructions given by your health care professional. You should also perform the test:

- After a lead wire is changed
- After the patient cable is changed

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

- Insert the patient cable into the socket located on the front of the monitor.
- Connect the lead wires to the patient cable. Inset 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 SmartMonitor 2. Insert the white lead wire into the **RA** an opening and then the black lead wire into the **LA** opening.
- Turn on the monitor. You will hear a short beep 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.
- 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 7 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).
- 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 lets you know the SmartMonitor 2, patient cable, 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, and then release the **RESET** button.

Self-Test Troubleshooting

Follow the instructions given below if any of the conditions described 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"> • Turn the monitor off using the correct Power Off procedure described in the <i>Turning the Monitor off – Sibling Alarm</i> section in this manual. • Make sure the power cord/battery charger is plugged into a live power outlet and is properly connected to the monitor. (See <i>Charging the Battery</i> for more information). • Allow the SmartMonitor 2 battery to recharge for 6 hours. If the monitor cannot be used because the battery is completely discharged contact your Home Care Dealer.
Memory Full	The SmartMonitor 2 full memory setting has been violated.	Press the RESET button to silence the alarm. The SmartMonitor 2 memory needs to be transferred and cleared. <i>Contact your dealer for specific instructions.</i>
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.



The SmartMonitor 2 lights and alarms should respond as described above. If not, contact your dealer before monitoring your baby.

Do not use your monitor if the alarm sounds weak or does not activate upon initial power-on.

Troubleshooting

Whenever a technical problem occurs which you cannot handle, contact your dealer. **Do not try to fix the SmartMonitor 2.** Following are some common problems.

Problem	Possible Cause	Instructions
Monitor will not Operate	Monitor disconnected from power cord/battery charger, batteries discharged. No Power at outlet.	Plug power cord/battery charger into monitor and outlet. Locate an outlet with power.
	Defective power cord/battery charger.	Contact your dealer.
	Internal part failure.	Contact your dealer.
All lights will flash together and the alarm will beep in unison with the flashing lights. Pressing RESET will not silence alarm.	Internal error condition detected by SmartMonitor 2.	Reduce likelihood of electrostatic discharge around SmartMonitor 2. Contact your dealer. If an Error number is displayed on the LCD (the LCD is located on the bottom of the monitor), record this information. Contact your dealer. If there is an internal software error, a special power off procedure is required. <ul style="list-style-type: none"> • 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.
Alarm Sound Continuous, No Lights	Incorrect Power-Off Sequence.	<ul style="list-style-type: none"> • Press the POWER button and insure that the power light is illuminated. • Press and hold the RESET button. Press and release POWER. Wait two seconds then release the RESET button.

Problem	Possible Cause	Instructions
	No power, battery drained.	<p>Connect power cord/battery charger. Use Power-Off to silence alarm.</p> <ul style="list-style-type: none"> • Press and hold the blue RESET button. • Press and release the gray POWER button. Wait 2 seconds, then release the RESET button. <p>Prior to use, allow 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>
	Internal part failure.	Contact your dealer.
Alarm sounds weak.	Internal part failure.	Contact your dealer.
	Low battery	Charge battery.
Loose lead Light remains on.	Connections between electrodes lead wires, and patient cable are not properly made.	<p>Verify that</p> <ul style="list-style-type: none"> (a) baby's skin underneath the electrodes is clean, (b) electrodes are clean, and (c) lead wires are fully inserted into the electrodes and patient cable.
	Defective lead wires.	Replace lead wires and perform Functional Self-Test.
	Defective patient cable.	Replace patient cable and perform Functional Self-Test.
	Defective electrodes.	Replace electrodes.
	Internal part failure.	Contact your dealer.
Unable to download via modem.	AC power not connected to SmartMonitor 2.	Plug the SmartMonitor 2 into an electrical outlet during downloads.

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 baby'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 the SmartMonitor 2, patient cable, 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

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

Modem - A device that allows the dealer 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. An instrument that measures the oxygen levels in an enclosed controlled space such as an incubator or bioreactor.

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 infants left leg.

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.

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 health care professional. SmartMonitor 2 sounded an alarm for 51 of 100 apnea events scored by the health care professional 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 slow down 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 health care provider or your baby’s doctor.

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