SmartMonitor® 2

Professional Operator's Manual

Warranty

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

RESPIRONICS INC.®
1001 Murry Ridge Lane
Murrysville, Pennsylvania
15668-8550 USA

RESPIRONICS®
Deutschland
Gewerbestrasse 17
82211 Herrsching Germany

User/Owner Responsibility

This Respironics equipment and the authorized 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, maintenance, and calibration of equipment;
- Replacement of components as required for safe and reliable operation;
- Replacement of ineffective parts with parts supplied by Respironics, Inc.;
- Equipment which 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 this monitor should be verified with a Respironics Model 5000 Simulator according to the Checkout Procedure Manual #H580-4000-00 between each patient use and/or every 6 to 12 months, 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

Unpacking and Inspection

When you receive the SmartMonitor® 2, unpack the shipping case and:

- Carefully examine the contents.
- Save the shipping carton.
- Make sure you have all the necessary items and that they are not damaged.
- Report anything missing or damaged to Respironics.

About this Manual

This manual provides all the information you need to set up and operate the Respironics SmartMonitor 2 and explains how to use it to monitor the 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?

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

Patient alarm limits are set by the health care professional before the SmartMonitor 2 monitor is delivered to the patient. During monitoring, when the 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 the baby, and how to transfer information.

Other devices may be used with the SmartMonitor 2. Refer to the section Using Auxiliary Equipment for further information.

Summary of Clinical Performance Evaluation

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.

Study Design

This was a multi-center, prospective, non-randomized study carried out at six clinical sites in the United States. Infants in nurseries and other settings appropriate for attended monitoring, who were considered to be appropriate candidates for cardio-respiratory monitoring, were recruited and enrolled into the study.

Methods

Enrollment was competitive and each site was instructed to continue patient enrollment until a sample size of at least 100 qualified central apneas was obtained.

Inclusion Criteria

Spontaneously breathing, newborn infant (≤ 12 months of age), either gender without regard to ethnicity.

Appropriate candidate for cardio-respiratory monitoring including any one or more of the following:

- Diagnosis of cardiac, respiratory or neurological disease
- Witnessed or suspected episodes of apnea or periodic breathing
- Gestational age less than or equal to 36 weeks
- History of sibling(s) experiencing ALTE's or SIDS
- Patients requiring supplemental oxygen

Exclusion Criteria

Any candidate with one or more of the following was excluded from enrollment:

- Presence of an artificial airway
- Receiving mechanical ventilation
- Receiving continuous positive airway pressure (CPAP)
- Presence of a cardiac or diaphragmatic pacemaker

Each patient was connected to a data acquisition system that included the Respironics Inc. SmartMonitor and SmartMonitor 2 and the Alice System. Respiration and heart rate signals were recorded using infant electrocardiogram electrodes. The Alice system was used to gather physiological signals and record signals for airflow, breathing effort, and movement.

All Alice System data were reviewed by a qualified, credentialed clinician, using an Alice polysomnograph system. Waveforms were manually reviewed and scored on an electronic medium. The beat/breath detection and alarm channels from the SmartMonitor and SmartMonitor 2 were hidden prior to scoring by the clinician. The clinician identified apnea, bradycardia, and tachycardia events on the Alice System.

Events were identified as required by the *Guidance for Infant/Child Apnea Monitor 510(k) Submissions*, released 2002.

Results

Summary of Results

Compared to the SmartMonitor, the new SmartMonitor 2 identified 6.8% more apneas. The SmartMonitor 2 also had 12.3% fewer false alarms and missed 6.8% fewer central apneas than the SmartMonitor. The results of this study demonstrate that the new SmartMonitor 2 is substantially equivalent to the predicate SmartMonitor. A detailed breakdown of study results is provided in the following sections.

Recruitment Summary

Total # Enrolled	# Evaluated	# with 1 or more central apneas	Total # of *apneas* in analysis
54 patients	52 patients	35 patients	142

Two patients were enrolled but not included in the evaluation. Only the first six apneas were used from any individual patient.

Demographic Summary

				Ethnicity						
Clinical Site	Number of Patients	# Male	# Female	Cauca-sian	African American	Asian	Hispanic	Other	Mean Birth Weight (grams)	Mean Gesta-tional Age (Weeks)
Site #1	10	6	4	10	0	0	0	0	1779.70	31.10
Site #2	5	4	1	3	2	0	0	0	2340.40	32.80
Site #3	10	2	8	2	2	2	3	1	3746.90	39.20
Site #4	7	3	4	4	2	0	1	0	1387.00	30.00
Site #5	13	4	9	8	1	0	4	0	1504.46	29.77
Site #6	7	5	2	6	1	0	0	0	2565.43	34.86
Total	**52**	**24**	**28**	**33**	**8**	**2**	**8**	**1**	**2220.65 (Mean Value)**	**32.95 (Mean Value)**

Diagnosis Summary

Diagnosis	Site # 1	Site #2	Site #3	Site #4	Site #5	Site #6	Totals by Diagnosis
Prematurity	10	0	0	7	13	0	**30**
RDS, Resp. Failure, HMD	3	0	0	3	5	0	**11**
ALTE, Apnea, AOI, AOP	8	2	8	6	5	4	**33**
Bronchiolitis, Pneumonia, RSV	0	3	0	1	0	6	**10**
Gastro-Esophageal Reflux	0	0	0	2	1	1	**4**
Broncho-Pulmonary Dysplasia	0	0	0	2	2	0	**4**
Other	5	2	5	10	10	2	**34**
Totals by Site	**26**	**7**	**13**	**31**	**36**	**13**	**126**

Results for Both Monitors by Site

Study Site	SmartMonitor			SmartMonitor 2		
	Apnea with Alarm	No Apnea with Alarm	Apnea without Alarm	Apnea with Alarm	No Apnea with Alarm	Apnea without Alarm
Site #1	25	21	20	28	21	17
Site #2	2	2	3	2	2	3
Site #3	3	12	6	3	13	6
Site #4	10	21	10	11	11	9
Site #5	21	19	25	18	19	28
Site #6	7	22	10	11	19	6
Totals	**68**	**97**	**74**	**73**	**85**	**69**

Analysis of Results

SmartMonitor Apnea with Alarm	SmartMonitor 2 Apnea with Alarm	Difference (SmartMonitor 2 – SmartMonitor)	% Difference
68	73	5	6.8
The sensitivity for SmartMonitor is 100*68/142 = 47.89% with 95% confidence limits (39.44%, 56.42%). The positive predictive value for SmartMonitor is 100*68/165 = 41.21% with exact 95% confidence limits (33.62%, 49.13%). The sensitivity for SmartMonitor 2 is 100*73/142 = 51.41% with 95% confidence limits (38.25%, 54.30%). The positive predictive value of Smart Monitor 2 is 100*73/158 = 46.20% with exact 95% confidence limits (38.25%, 54.30%).			

SmartMonitor No Apnea with Alarm (False Alarm)	SmartMonitor 2 No Apnea with Alarm (False Alarm)	Difference (SmartMonitor 2 – SmartMonitor)	% Difference
97	85	-12	-12.3%
The false apnea rate for SmartMonitor is 97/(95.95) = 1.01. The false apnea rate for SmartMonitor 2 is 85/95.95 = 0.89.			

SmartMonitor Apnea with No Alarm (Missed Event)	SmartMonitor 2 Apnea with No Alarm (Missed Event)	Difference (SmartMonitor 2 – SmartMonitor)	% Difference
74	69	-5	-6.8%

Warnings and Cautions

Please read this section carefully before using the SmartMonitor 2 to monitor a 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 Respironics 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 off to the monitor.
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 the baby while the 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 the baby.
15. Remove the electrode belt and the lead wires when the baby is not being monitored. Long-term wear may be uncomfortable.
16. Never use an extension cord with the power cord/battery charger as this may cause a fire and/or tripping hazard.
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 Respironics 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 apnea*s* 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 the baby or sleep in the same bed with the baby while monitoring. Touching or moving near the 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 Respironics to have it serviced.
3. Do not send information via modem during electrical storms. Information could be lost or equipment could be damaged.
4. 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.
5. Insure that the auxiliary devices used do not exceed SELV (Safety Extra Low Voltage) levels as described in EN60601-1. It is the dealer's responsibility to ensure that auxiliary devices comply with either UL2601-1 or UL544.

How Does the SmartMonitor 2 Work?

SmartMonitor 2 monitors and records a patient's breathing (respiration) and heart (cardiac) activity and alerts the caregiver if either of these activities exceeds the limits prescribed by the physician.
The patient alarm limits are set before the SmartMonitor 2 is given to the patient. If during monitoring the patient's breathing effort and heart activity is 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 a patient, how to transfer the information to the physician, and how to use other devices with SmartMonitor 2.
A baby's breathing is measured by 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 to determine the baby's breathing effort. If the SmartMonitor 2 does *not* detect these changes in breathing effort for longer than the physician-ordered time, 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 limit outside the range ordered by the physician, a light will come on and an alarm will sound.

How the Alarms Operate

Whenever the patient's breathing effort and heart activity are not within the limits set by the 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 the physician
- **Low Heart**: Heart Rate is lower than the limit set by the physician
- **High Heart**: Heart Rate is higher than the limit set by the 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 section on *Monitoring the Baby* for more information about alarms.

The SmartMonitor 2 may also alarm if there is an internal system error. If the 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 and logged into the memory. Discontinue use of monitor and contact Respironics Technical Support 1-800-345-6443.

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

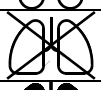
Operating Temperature:	5ºC to 45ºC
Operating Humidity:	20%RH to 95%RH, non-condensing
Storage Temperature:	-20ºC to +65ºC
Storage Humidity:	10%RH to 95%RH, non-condensing
Battery Charging Temperature:	10ºC to 35ºC

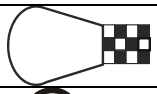
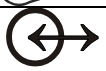
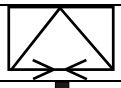
IEC Classification

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 Alarm Light
	Respiration Light
	Low Heart Rate Alarm Light
	High Heart Rate Alarm Light
	Low Battery Light

Symbol	Definition
	Memory Full Light
	Loose Lead Light
	Heart Rate Light
	Power Light
	Alternating Current (charging)
	Direct Current (power connection)
	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 RENs for the calling area.

If the SmartMonitor 2 causes 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 you 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 to maintain uninterrupted service.

If trouble is experienced with the SmartMonitor 2, please contact the Respironics Service Center at 1-800-345-6443 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 Respironics Service Center should coordinate repairs to certified equipment at 1-800-345-6443. 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 requirement that the sum of Ringer Equivalent Numbers of all the devices does not exceed five (5.0).

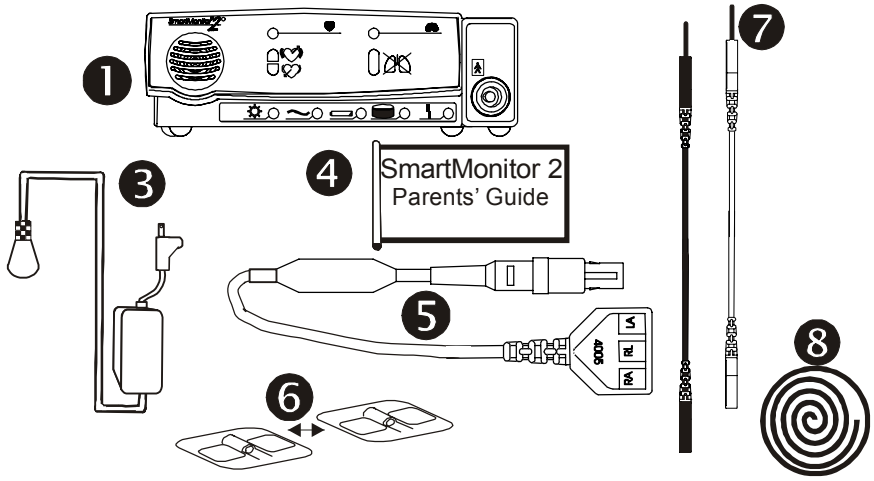
FCC Part 15

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to 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 Respironics.

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

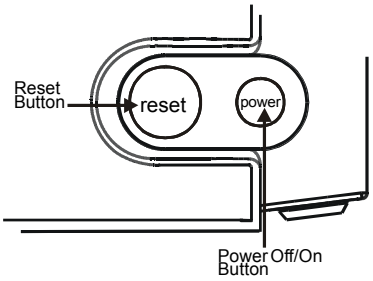
The gray **POWER** button turns the SmartMonitor 2 **on**. When you turn the monitor **on**, all lights and the alarm come on briefly and the monitor performs a system test. After a pause, monitoring will begin.

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

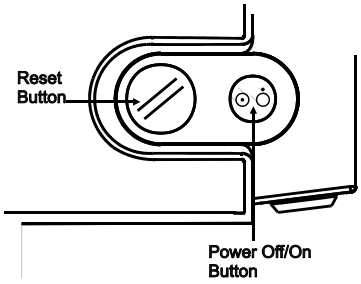
- ❑ Press and hold the blue **RESET** button.
- ❑ Press and release the gray **POWER** button.
- ❑ Wait 2 seconds, and then release the **RESET** button.

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.

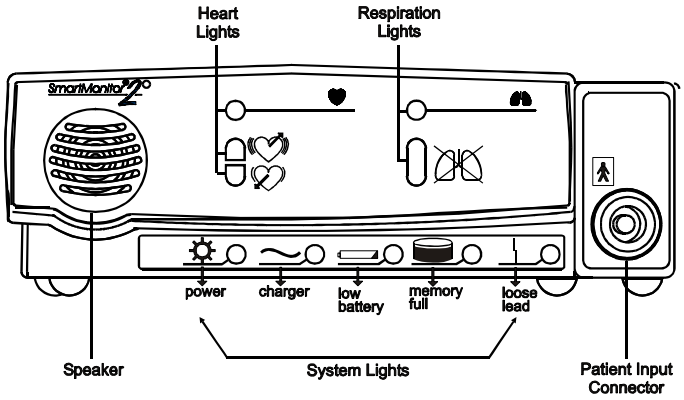
Front Panel Features

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 the 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 the physician. The red low light comes on when SmartMonitor 2 detects a heart rate lower than the limit set by the physician.

Speaker

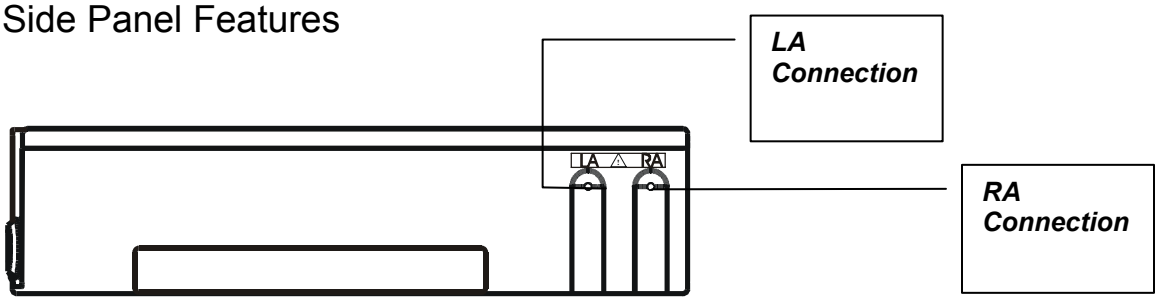
The SmartMonitor 2 speaker allows you to hear any alarm that sounds during monitoring.

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 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

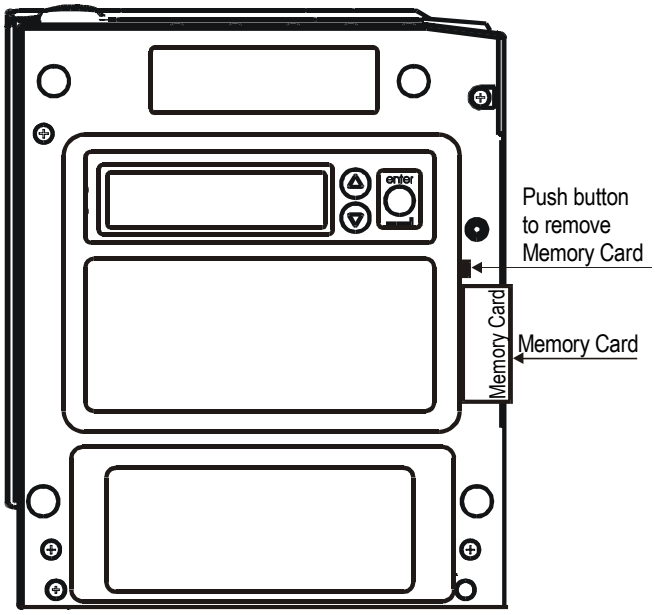


Self-Test Connector

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.

Memory Card (*Optional*)

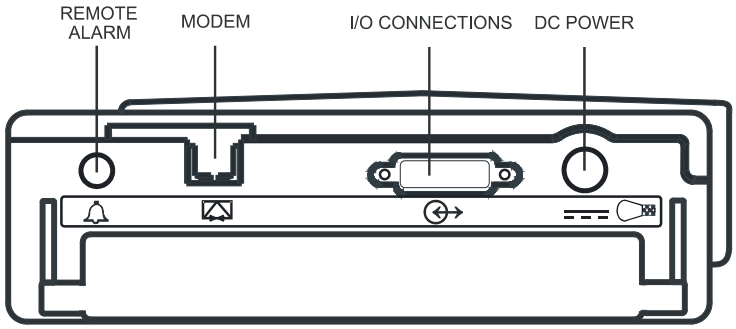
The Memory Card transfers monitor data out of the monitor to give to the physician. See the section on *Transferring Monitor Memory* for more information.



Back Panel Features

Remote Alarm *(Optional)*

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 physician. 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 battery charger.

I/O Connector

This connector connects the SmartMonitor 2 with other devices. Ensure that the devices used do not exceed SELV (Safety Extra Low Voltage) levels as described in EN60601-1.

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Setting Alarm and Recording Limits

The SmartMonitor 2 has the ability to program alarm and recording limits as prescribed by the physician. There are two methods, including direct connect via serial link to a computer or manually through the display on the bottom of the monitor.

Manual Set-Up

Remove the display door from the bottom of the monitor. Beneath the display door you will find the display or LCD and 3 buttons. These buttons are used to key in a "Password" into the monitor. The menu system has 3 passwords. Each password allows access to a different level of options. These 3 levels are: Monitor Set-Up, System Set-Up, and view only. The following discusses these in detail.

The Monitor Set-Up Menu is used to select all alarm and recording settings. You can adjust settings manually, by modem, or by direct communication. When you access the Monitor Set-Up Menu, the SmartMonitor 2 is in Menu mode.

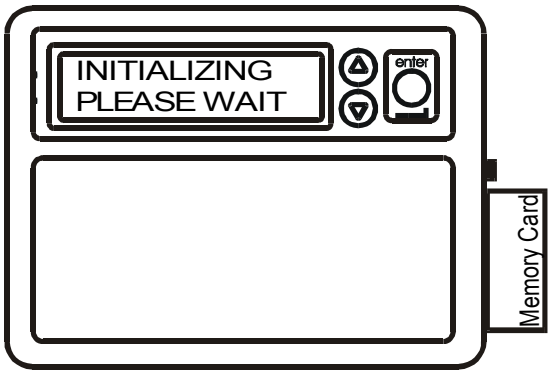
The SmartMonitor 2 will beep once every 10 seconds to signal that it is powered on and in Menu mode.

To Set or Modify Parameters Manually, Enter Menu Mode

- ❑ Press the **POWER** button to turn the monitor **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:
- ❑ Down arrow, Up arrow, Up arrow, ENTER, ENTER, ENTER
- ❑ The display will read SMARTMONITOR 2 MENU SELECTION.
- ❑ The SmartMonitor 2 menu has 34 entries that are presented in a continuous loop. Use the **up arrow key** to display the next menu entry.
- ❑ Use the down arrow key to display the preceding menu entry.
- ❑ When the parameter you want to change is displayed, press the **ENTER** button. The current value for the parameter displayed will flash.



- ❑ Use the ▲ or ▼ key to change the parameter to the desired value.
- ❑ When the desired value is displayed, press the **ENTER** button to accept the value.
- ❑ Press the up arrow to choose the menu path you want to review.

There are 4 menu paths to choose from:

- ❑ All Menus
- ❑ Alarm Menu

- ❑ Recording Menu
- ❑ System Menu

The SmartMonitor 2 parameters for these menus are in the chart located in Appendix A.

Once the changes are completed turn the SmartMonitor 2 off by pressing the following buttons:

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

When you power the SmartMonitor 2 off and then back on, the new values will be implemented.

The SmartMonitor 2 Parameters

The following menu flow is for All Menus. That encompasses menus for Alarms, Recording, and Systems. To quickly access, for instance, an alarm setting, select the Alarm Menu.

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
PATIENT NAME	PATIENT NAME	*To enter the Patient Name:* ▪ Press **Enter** to begin entering patient name. ▪ Press ▲ or ▼ to browse through the alphabet and select the letter you need. When the letter you want appears, press **Enter**. Press **Enter** twice to place a space in between the first and last name. ▪ When you have finished the name, press ▲ or ▼ until the ^ appears. Then press **Enter.** The ^ is just before the letter “a”. ▪ Press ▲ to proceed to the next menu or ▼ to move to the previous menu.	All Menus Alarm Menu Record Menu System Menu
PATIENT ID	PATIENT ID NUMBER	*To enter the Patient ID*: ▪ Press ▲ or ▼ until **Patient ID** is displayed. ▪ Press **Enter** to activate ▪ Press ▲ or ▼ to browse through the numbers and select the digit you need. When the digit you want displays, press **Enter**. ▪ When you have finished the ID, press ▲ or ▼ until the ^ appears. Then press **Enter**. ^ is just before “0”. ▪ Press ▲ to proceed to the next menu or ▼ to move to the previous menu.	All Menus Alarm Menu Record Menu System Menu

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
STD Alarm Parameters	Are Selected Or Are Not Selected	▪ Press **Enter** to activate. ▪ Press ▲ or ▼ to change the selection. ▪ When you have your selection displayed press **Enter.**	All Menus Alarm Menu
STD Record Parameters	Are Selected Or Are Not Selected	▪ Press **Enter** to activate. ▪ Press ▲ or ▼ to change the selection. ▪ When you have your selection displayed press **Enter.**	All Menus Record Menu
STD System Parameters	Are Selected Or Are Not Selected	▪ Press **Enter** to activate. ▪ Press ▲ or ▼ to change the selection. ▪ When you have your selection displayed press **Enter.**	All Menus System Menu
Apnea Alarm	APNEA ALARM in seconds	Establishes the amount of time of no respiration detection prior to activation of the apnea alarm. Values: 10, 15, 20, 25, 30, 40 seconds Standard value: **20 seconds**	All Menus Alarm Menu
Low Breath Rate Alarm	LOW BREATH ALARM BrPM	Establishes the alarm set point based on frequency of detected respiratory effort. Values: OFF, 4, 5, 6, 7, 8, 9, 10, 12, 14, 16, 18, 20, 25, 30 breaths per minute Standard value: **OFF**	All Menus Alarm Menu
Bradycardia Alarm	BRADYCARDIA ALARM BPM	Establishes the LOW heart rate alarm set point based on the average detected ECG signal. Values: 40, 50, 60, 70, 80, 90, 100 beats per minute Standard value: **80 bpm**	All Menus Alarm Menu
Bradycardia Alarm Delay	BRADY ALARM DELAY in seconds	Enables a delay to the audible alarm Values: 0 or 5 seconds Standard value: **0 seconds** If this parameter is set to 5 seconds, the audible alarm will not activate unless the alarm set point is violated for 5 seconds or more. This is a physician decision and is based on such factors as the known condition of the patient, number of short Bradycardia alarms documented by the SmartMonitor 2, the current Bradycardia alarm set point, and the patient's average resting heart rate.	All Menus Alarm Menu
Tachycardia Alarm	TACHYCARDIA ALARM BPM	Establishes the HIGH heart rate alarm set point based on the average ECG signal. Values: OFF, 90, 100, 110, 130, 150, 170, 190, 200, 210, 220, 230, 240, 250, 270 beats per minute Standard value: **230 bpm**	All Menus Alarm Menu

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
Tachycardia Alarm Delay	TACHY ALARM DELAY In seconds	Enables a delay to the audible alarm. Values: 0 and 5 seconds Standard value: **5 seconds** If this parameter is set to 5 seconds, the audible alarm will not activate unless the alarm set point is violated for 5 seconds or more. This is a physician decision and is based on such factors as the known condition of the patient, number of short Tachycardia alarms documented by the SmartMonitor 2, the current Tachycardia alarm set point, and the patient's average resting heart rate.	All Menus Alarm Menu
Record Mode	RECORD MODE	Establishes the method that the data is recorded under. Values: EVENT, CONTINUOUS, EVENT LOG, Standard value: **EVENT** EVENT – Active waveforms are recorded each time a patient parameter is violated and an entry is made into the Patient Events Log. EVENT LOG - Patient alarms are acknowledged by an entry in the Patient Events Log but no waveforms are recorded. CONTINUOUS - Active waveforms are recorded continuously, regardless of alarm conditions. All equipment-related events are entered in the Equipment Events Log.	All Menus Record Menu
Apnea for Record	APNEA RECORD LIMIT in seconds	Allows active waveforms to be recorded during the respiratory pauses prior to activation of the Apnea alarm. Values: OFF, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40 seconds Standard value: **16 seconds** When in Event Mode and the Apnea Alarm is set to 20 seconds and the Apnea for Record is set to 16 seconds, the system will perform as follows: For a respiratory pause of <16 seconds, no waveforms will be recorded and no alarm will occur. For a respiratory pause of >16 seconds, but less than 20 seconds, waveforms will be recorded, but no alarm will occur. For a respiratory pause of >20 seconds, waveforms will be recorded and an alarm will occur.	All Menus Record Menu

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
Bradycardia for Record	BRADY RECORD LIMIT BPM	Allows active waveforms to be recorded during a bradycardia event prior to activation of the Bradycardia alarm. Values: OFF, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100 beats per minute Standard value: **OFF** When in Event Mode and the Bradycardia Alarm is set to 70 BPM and the Bradycardia for Record is set to 80 BPM, the system will perform as follows: For a heart rate of >80 BPM, no waveforms will be recorded and no alarm will occur. For a heart of >70 BPM and <80 BPM, waveforms will be recorded but no alarm will occur. For a heart rate of <70 BPM, waveforms will be recorded and an alarm will occur.	All Menus Record Menu
Pre/Post Time	PRE/POST TIME in seconds	This parameter allows the user to prescribe both the number of seconds that waveforms are recorded prior to the occurrence of a physiologic event and after the event has terminated. **PRE** defines the number of seconds that waveforms will be recorded prior to the event. **POST** defines the number of seconds that waveforms will be recorded after the event has terminated. Values: 30/15, 30/60, 45/45, 60/30, 30/30, 75/15, 60/15, 45/15 seconds Standard value: **30/15 seconds**	All Menus Record Menu
Impedance Record?	RECORD IMPEDANCE?	This parameter allows the user to select whether or not the respiration waveform will be recorded. Values: YES or NO Standard value: **YES**	All Menus Record Menu
Record Respiration Rate	RECORD RESP RATE?	This parameter allows the user to select whether or not the Breath-To-Breath & the Average Respiration Rates will be recorded. Values: YES or NO Standard value: **YES**	All Menus Record Menu
Heart rate Record?	RECORD HEARTRATE?	This parameter allows the user to select whether or not the Beat-To-Beat & the Average Heart Rates will be recorded. Values: YES or NO Standard value: **YES**	All Menus Record Menu

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
ECG Record	RECORD ECG?	This parameter allows the user to select whether or not the ECG waveform will be recorded. Values: YES or NO Standard value: **YES**	All Menus Record Menu
Auxiliary 1 Record	RECORD AUXILIARY 1	This parameter allows the user to select whether or not waveforms will be recorded on Auxiliary 1. Standard value: **OFF** For additional information refer to the Auxiliary Signal Interface section of this manual.	All Menus Record Menu
Auxiliary 2 Record	RECORD AUXILIARY 2	This parameter allows the user to select whether or not waveforms will be recorded on Auxiliary 2. Standard value: **OFF** For additional information refer to the Auxiliary Signal Interface section of this manual.	All Menus Record Menu
Auxiliary 3 Record	RECORD AUXILIARY 3	This parameter allows the user to select whether or not waveforms will be recorded on Auxiliary 3. Standard value: **OFF** For additional information refer to the Auxiliary Signal Interface section of this manual.	All Menus Record Menu
Auxiliary 4 Record	RECORD AUXILIARY 4	This parameter allows the user to select whether or not waveforms will be recorded on Auxiliary 4. Standard value: **OFF** For additional information refer to the Auxiliary Signal Interface section of this manual.	All Menus Record Menu
External Physiological Trigger	EXT. PHYSIO TRIGGER	Ext. Physio. Trigger allows external equipment to trigger a SmartMonitor 2 recording when a physiological parameter is violated in the external auxiliary device. Select from: OFF Trigger when high Trigger when low See Using Auxiliary Equipment	All Menus Record Menu
External Equipment Trigger	EXT. EQUIP. TRIGGER	Ext. Equip. Trigger allows external equipment to cause an entry in the SmartMonitor 2 Equipment Log when an equipment parameter is violated in the external auxiliary device. Select from: OFF Trigger when high Trigger when low See Using Auxiliary Equipment	All Menus Record Menu

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
When the auxiliary equipment channels are turned on and the auxiliary equipment is not connected to the SmartMonitor 2, a flat line will be recorded and reported. The auxiliary channels enable you to interface other signals to SmartMonitor 2. Options for each of these channels are best defined with the System Software. External auxiliary devices can be interfaced to provide Sp02, Pulse, EtCO2, pH, or any analog signal in the range of –1.25 to +1.25 volt. The Synergy-E™ software will allow you to customize the channel label, voltage range, and value scale. For instance an ***Oximeter*** may have a range of 0-1 volt and a scale of 0-100%. Refer to the Synergy-E Operators Manual for more information.			
Date	DATE	*To enter the date*: ▪ Press Enter to begin. ▪ Press ▲ or ▼ until the number required is displayed. ▪ Press **Enter** to select. ▪ Once you have entered the date the display will stop flashing. ▪ Press ▲ to proceed to the next menu or ▼ to move to the previous menu.	All Menus System Menu
Time	TIME	*To enter the Time*: ▪ Press Enter to begin. ▪ Press ▲ or ▼ until the number required is displayed. ▪ Press **Enter** to select. ▪ Once you have entered the time the display will stop flashing. ▪ Press ▲ to proceed to the next menu or ▼ to move to the previous menu.	All Menus System Menu
Rate Display	RATE DISPLAY	Controls whether the patient's respiration and heart rate will be displayed on the bottom panel display during monitoring. Values: ON, OFF Standard Value: **OFF**	All Menus System Menu
Phone Number for Computer	COMPUTER PHONE #	Enter the phone number of the modem on the Computer end of the download. You may enter *70 first then the phone number to disable Call Waiting if necessary. ▪ Press **Enter** to begin. ▪ Press ▲ or ▼ until the number required is displayed. ▪ Press **Enter** to select. ▪ Once you have entered the phone number press ▲ or ▼ until the ^ appears. Then press **Enter**. Any other information following after the ^ will be cleared. ▪ Press ▲ to proceed to the next menu or ▼ to move to the previous menu.	All Menus System Menu

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
Time To Call the Computer	WHEN TO CALL	*To enter the Time to call*: ▪ Press ▲ or ▼ until **WHEN To CALL** is displayed. ▪ Press **Enter** to activate. ▪ Press ▲ or ▼ to browse through the numbers and select the digit you need. When the digit you want displays, press **Enter**. ▪ Enter the time in Military Time. ▪ When you have finished, press **Enter**. ▪ Press ▲ to proceed to the next menu or ▼ to move to the previous menu.	All Menus System Menu
Call Computer when memory is full	DIAL IF MEMORY FULL	You may select from On or Off. Once the Memory Full Alert is reached the monitor will attempt to call at the next scheduled calling time. As an example, if the Dial If Memory Full is turned **ON** and the call date and time is set to 3-1-01 at 4:00AM, but the memory reaches the Memory Full Alert at 3:00PM on 2-1-01, then the monitor will initiate a call at 4:00AM on 2-2-01.	All Menus System Menu
Move Data to Card	MOVE DATA TO CARD? (other possible messages) Insert Card – Retry Transferring Data… Data Transferred	This menu is used to down load the recorded data to the PCMCIA card. To move data to the PCMCIA card: ▪ Press the **ENTER** button. The word **NO** will begin to blink. ▪ To select **YES** press either arrow button. ▪ Should a PCMCIA card not be inserted the monitor will ask for the card. ▪ Place card in slot located just below the display. ▪ Press the **ENTER** button. ▪ The display will now show **"Transferring Data…."**. Once the transfer is complete the display will show **"Data Transferred".**	All Menus System Menu
Memory Status	MEMORY STATUS X PERCENT FULL	This is a display-only menu. It provides an indication of the amount of memory in use by the SmartMonitor 2. This display cannot be changed. The Memory Status setting takes into account the Patient Event Log, Equipment Event Log, and Waveform Memory.	All Menus System Menu
Clear Memory	CLEAR MEMORY?	Permits the memory to be erased. NOTE: Erasing memory does not affect the alarm and / or the record parameters. ▪ The memory should be cleared before using the SmartMonitor 2 on a new patient or after the data has been downloaded and saved. ▪ Once the memory is cleared the unit will display the following: "**It Is Cleared**".	All Menus System Menu

After the new parameters have been entered into the SmartMonitor 2, the monitor must be turned off to exit Menu Mode.

To set the parameters through the Synergy-E computer software, refer to the *Synergy-E Manual* for instructions on communicating with the SmartMonitor 2.

System Set-up Menu

SmartMonitor 2 also has a System Set-up Menu, which displays the entire menu of parameters. This includes very seldom-used menu choices. In addition to some menus previously seen, you will have access to the following menus. To access this menu, do the following:

- ❑ 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 ▲ Up arrow 3 times.
- ❑ Press the **ENTER** button 3 times.
- ❑ Scroll to MENU OPTIONS and press ENTER.
- ❑ Scroll to SYSTEM MENU and press ENTER.

The following table lists the additional options available from the System menu:

Menu Option	**LCD Display**	**Description of Option or Instructions**
Date Format	DATE FORMAT	Permits the selection of two formats for displaying the DATE: MONTH/DAY/YEAR or DAY/MONTH/YEAR Standard value: **Month/Day/Year**
Memory Full Alert	MEMORY FULL ALERT	Two options are available: 80% full or 50% full. When the memory usage reaches the selected limit (50% or 80%), the unit will generate an alarm. Standard value: **50%**
Memory Full Audible	MEMORY FULL AUDIBLE	Used to enable/disable the audible alarm when the unit reaches the selected memory almost full limit (50%/80%). NOTE: This parameter does not affect the visual indicator; it cannot be disabled. Values: ON, OFF Standard Value: **OFF**
Modem Speed - Monitor	Modem Speed-Monitor	The default setting is 38,400Bps. This setting should not be change unless directed to do so by Respironics Technical Support.

Menu Option	LCD Display	Description of Option or Instructions
Modem Speed - Host	Modem Speed – Host	The default setting is 115,500Bps. This setting should not be change unless directed to do so by Respironics Technical Support.
Software Revision	SOFTWARE REVISION	Display-only menu. Displays the revision of the Embedded Application Code.
Mmode SW Revision	MMODE SW REVISION	Display-only menu. Displays the revision of the Maintenance Mode Code.
Bblk SW Revision	BBLK SW REVISION	Display-only menu. Displays the revision of the Boot Block Code.
Serial Number	SERIAL NUMBER	Display-only menu. Displays the Serial Number.

View Menu Mode

Should there be a need, the SmartMonitor 2 also allows you to use a View Only option of the Menu Selections.

The caregiver can download monitor data to a PCMCIA card using the View Menu but cannot make any changes to the settings in the monitor.

- ❑ 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 once.
- ❑ Use the ▲ ▼ Up and Down arrow button to scroll through the menus.

Using Auxiliary Equipment

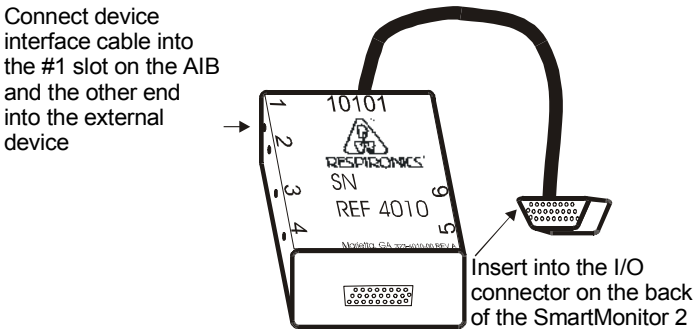
There are 4 auxiliary channels available on the SmartMonitor 2. These channels provide the mechanism for connecting External Devices to the SmartMonitor 2. All External Devices must interface to the SmartMonitor 2 via the Auxiliary Interface Box, P/N 4010. The output of these Devices must be within the range of –1.25 to +1.25 volts.

Setup of auxiliary channels can only be done through the Synergy-E software. Refer to the Synergy-E manual for more information.

SmartMonitor 2 is programmed with 15 signal definitions to interpret the auxiliary signals it receives. For each of the 4 auxiliary channels you can choose from the list of 15. These are user configurable with the Synergy-E software. Refer to the Synergy-E manual for more information on auxiliary signal configuration for the SmartMonitor 2.

Any of the four signals can be programmed to record at one time. The Auxiliary Interface Box, AIB, connects to the I/O Connections port.

- ❑ Connect the AIB to the back of the SmartMonitor 2.
- ❑ Connect appropriate interface cable to the number 1 slot on the AIB. The other end of the cable should be connected to the auxiliary device.



Before turning on the SmartMonitor 2 insure that the external devices are connected.

For every signal you want to record, you will need to connect an auxiliary cable to the AIB and remember to turn on the Auxiliary Channels in the SmartMonitor 2 menu. For example if you wish to record SpO_2 and Pulse you would need 2 auxiliary cables and this will use 2 auxiliary channels.

Information required to setup or change the “definition” includes the devices voltage and value range. This information must come from the Manufacturer of the device.

Using the Respironics Model 930 Oximeter

When the SmartMonitor 2 is interfaced to the 930 Oximeter, it can be configured to trigger recordings when the Oximeter alarms.

Attach the Auxiliary Interface box to the SmartMonitor 2 and the 4304 cable to the 930 Oximeter. Enter the System Set-up menu mode and go to Ext. Physio Trigger and set to Trigger When High. When the Oximeter alarms the SmartMonitor 2 will record all programmed channels that are turned on.

Dealer Preparation for Home Setup

Electromagnetic interference (EMI) may adversely affect monitor function. It is recommended that the monitor be tested in the use environment using the following procedure.

When a monitor is susceptible to electromagnetic interference, the situation should be corrected to ensure safe monitoring.

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.

To test for EMI at the patient's home, the following steps must be performed.

- Set the SmartMonitor 2 apnea duration to 20 seconds.
- Connect the monitor to a patient simulator with all cables extended out rather than coiled up.
- Set the simulator to output respiration and heart beats at rates and amplitudes that are appropriate and in the normal range with respect to the patients' age.
- Determine that the monitor detects respiration and heartbeats, at the rates to which the simulator is set.
- Place the simulator in the apnea mode for two (2) minutes.
- Determine that the monitor continues to alarm for apnea at full volume beginning at 20 seconds. Alarming at reduced volume, false heart rate alarms, or self-silencing of the apnea alarm before the end of the simulated apnea constitute failure of this test.

If the monitor fails this test, insure that the cautions found at the beginning of this test have been carefully followed and repeat the test. If the monitor continues to fail the test, it is an indication that the monitor may not function properly in its current environment. Contact Respironics for further assistance. Use of a third (RL) electrode may help reduce EMI.

Home Setup

This section is an overview of the steps you should follow to set up the SmartMonitor 2 in the patient's home. **Read the entire manual** prior to relying upon this section (alone) to set up a SmartMonitor 2.

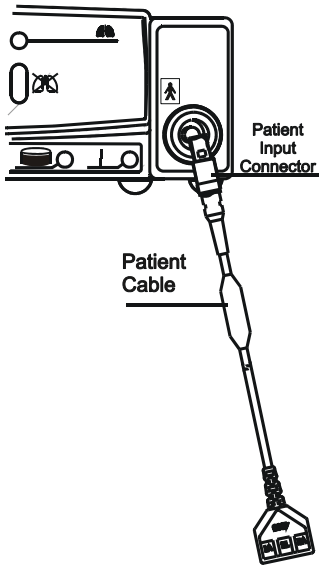
- ❑ Ensure Memory has been cleared prior to delivery to new patient.
- ❑ Review use of the SmartMonitor 2 and its accessories with the caregiver(s). Be sure to demonstrate the Functional Self-Test. Encourage the use of this test at least weekly and whenever lead wires, or patient cables are changed.
- ❑ Stress the importance of electrode positioning, belt snugness, clean electrodes, and clean skin.
- ❑ Leave your emergency phone number(s) and procedures with the caregiver(s).

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 monitor, patient and patient leads.
- ❑ Make sure the monitor is close enough to connect to the baby comfortably.

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

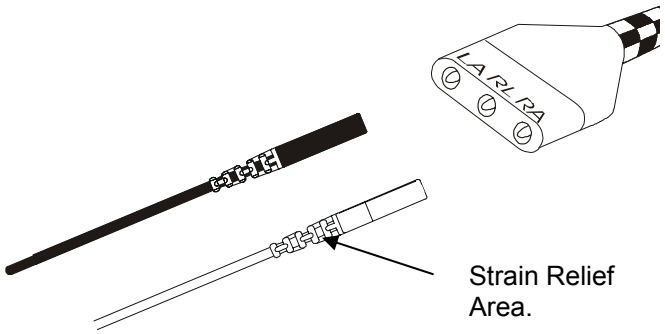
- ❑ Insert the round end of the patient cable into the bottom round connector found on the front of the SmartMonitor 2.
- ❑ Line up the notch on the connector and push until you feel the connector snap into place.
- ❑ To remove the patent cable, grasp the patient cable at the base of the patient input 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).

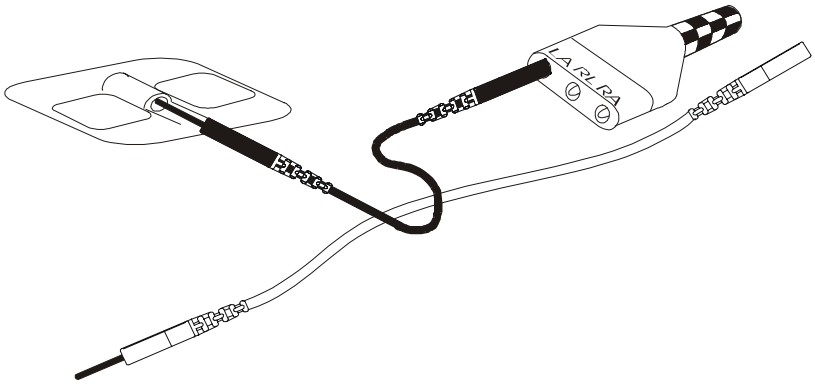
- ❑ Take the **white** lead wire and insert it into the opening marked **RA**.
- ❑ Take the **black** lead wire and insert it into the opening marked **LA**.
- ❑ Firmly push each lead wire in until the socket snaps into place.



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.

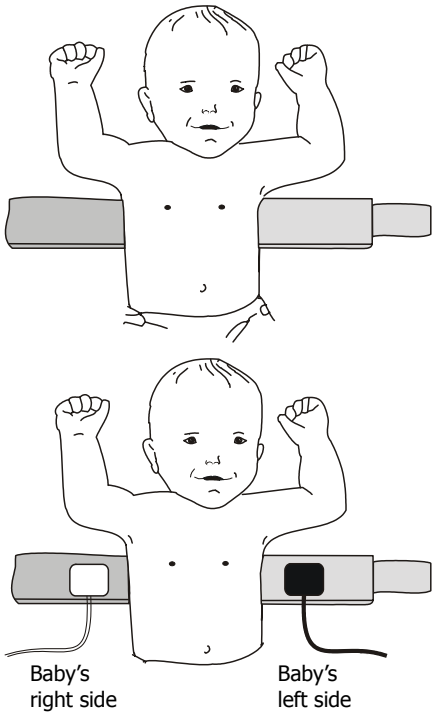
Step 4: Connect the Lead Wires to the Electrodes.



- ❑ 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 the 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).

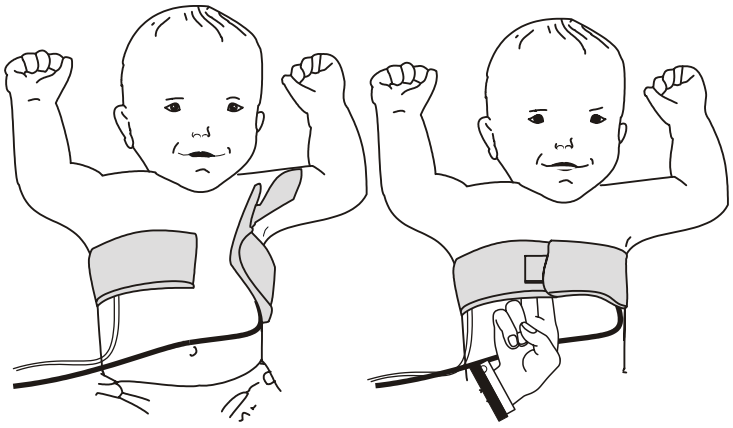


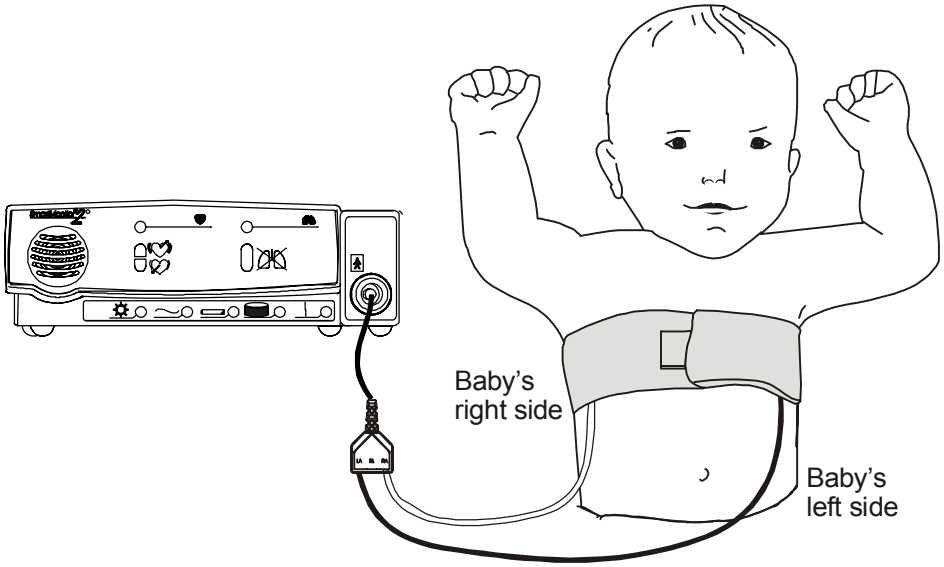
The white lead wire location is illustrated with a white electrode.

Step 6: Wrap the Electrode Belt around the Baby.

- ❑ Wrap the belt around the baby's chest and fasten it with the white 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 it. Be sure to leave enough room to fasten the belt securely.




Baby's
right side
Baby's
left side

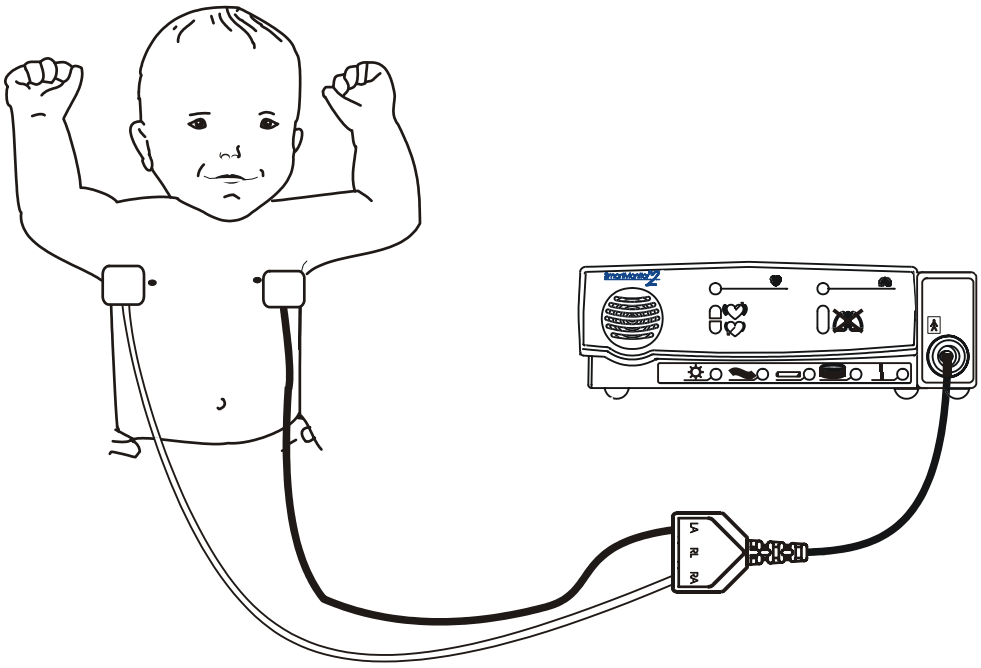
Disposable Self Adhesive Electrodes

Follow the steps below if you are using disposable electrodes.

- ❑ Attach lead wire to the Self Adhesive Electrodes if not pre-attached.
- ❑ Ensure 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 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 nipples.
- ❑ An electrode belt is not needed when using disposable electrodes

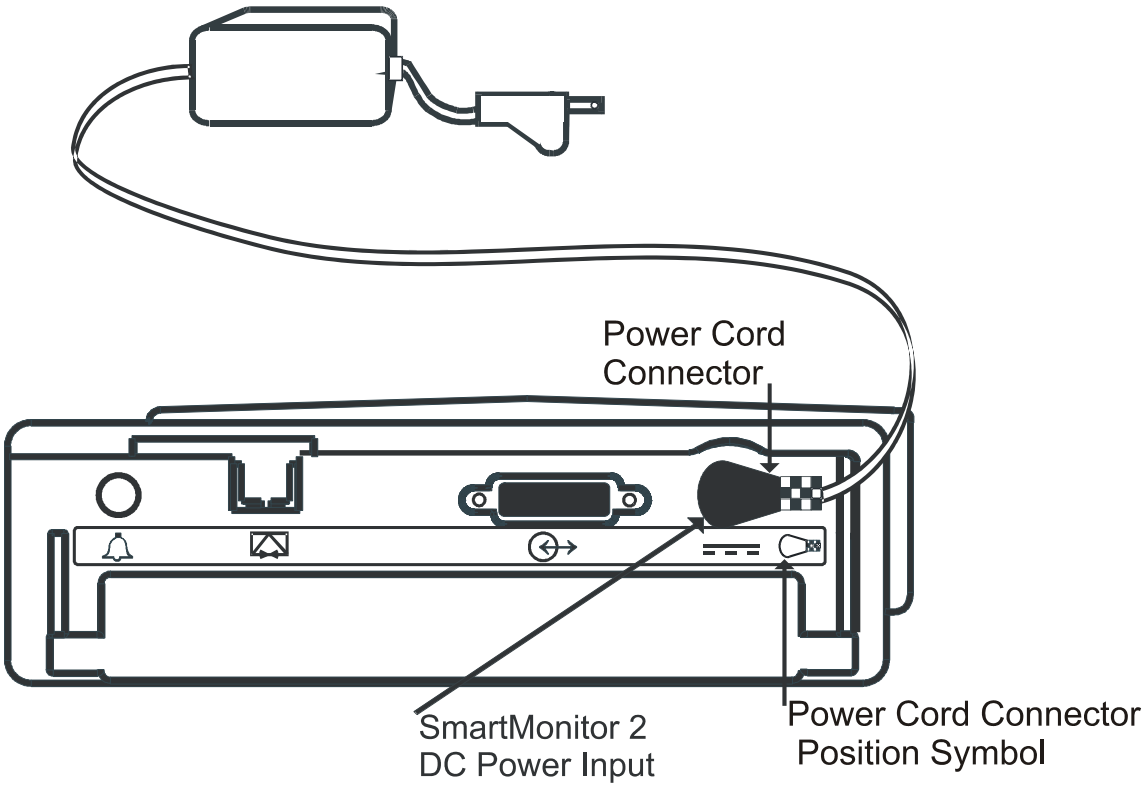
Use of the third (green - RL) electrode and lead wire is normally not required, but may help reduce EMI interference. Place the green electrode along the outside of baby's upper thigh.

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).
- Push until the connector is fully inserted into place.
- Then plug the power cord/battery charger into a power outlet. The green charger light on the monitor will now come on.



When the SmartMonitor 2 is not operating 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). 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 above. The Power Cord Connector can only be inserted as shown above.

Responding to Alarms

Patient Alarm

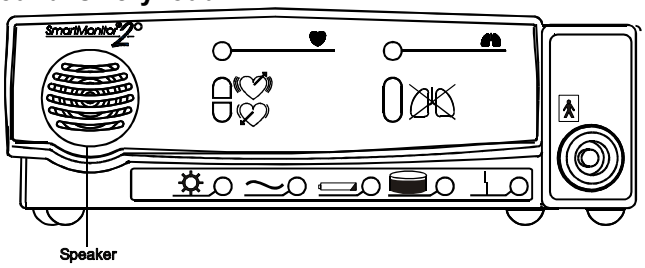
A Patient Alarm indicates that the baby's breathing or heart activity is outside the limits prescribed by the physician. The information in this section can help you respond appropriately to patient alarms. Read this section carefully. If you have any questions, please contact Respironics.

Testing the Alarm

Before you use the monitor, test to see if you can hear the alarm from different rooms while there is noise in the 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 in the home.
- If the alarm is not loud enough to hear around the home, a Remote Alarm may be required. This device will allow you to hear the alarm from a different room from where the monitor is located.



If an Alarm Sounds

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

Light	Alarm	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 the physician or in your ***CPR*** class. An ***example*** of your response could be as follows: ❑ 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 and corrects the cause of the alarm, note it on your log sheet. ❑ Press the **RESET** button to reset any alarm lights.

Light	Alarm	Check Baby's Condition	Respond like this
Red Apnea and/or Low (Heart)	Intermittent (1beep/sec.)	Baby is breathing and is responsive. Color is good.	❑ Wait for a few seconds. Watch to see if the baby'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.
Red High (Heart)	Intermittent (2 beeps/sec.)	Baby is crying.	❑ If the baby has frequent high heart rate alarms not associated with crying please notify the physician.
Red Loose Lead	Continuous	Baby is breathing and is responsive. Color is good.	❑ 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 alarm continues to sound see section *Performing a Functional Self Test*.
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.

Responding to 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.

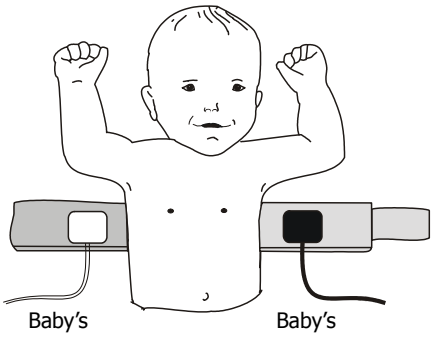
If this light is on	**And this condition exists**	**It means...**
Power	Continuous green light, no alarm.	Normal Operation. The green **power** indicator light will come on and stay on for as long as the monitor is on.
Charger	Continuous green light, no alarm.	Normal Operation. The green **charger** light will come on and stay on while the 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.	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 SmartMonitor 2 to operate properly. The SmartMonitor 2 must be recharged. Turn the monitor off. Then, recharge the battery. (*See Charging the Battery* in this manual). If you do not recharge the battery, the system will automatically shut down.
Memory Full	Flashing yellow light, continuous alarm	When the SmartMonitor 2's Memory Almost full parameter is reached, the Memory Full light will flash. The alarm will sound continuously. The alarm will sound only if the dealer programs the 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. Memory full is a warning condition. You can continue monitoring. The caregiver should contact the dealer to resolve the alarm.
Memory Full	Continuous yellow light, continuous alarm	SmartMonitor 2 memory is 100% full. Press the **RESET** button to silence the alarm. The alarm will sound only if the dealer programs the SmartMonitor 2 to do so. The light will stay on continuously. The caregiver should contact the dealer to resolve the alarm. *(*See *Transferring the Monitor Memory* in this manual for more information).

If this light is on	And this condition exists	It means...
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, or ❑ Connections between the baby's skin and the electrodes, the lead wires, the patient cable, and the SmartMonitor 2.
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 are displayed, 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 will come on for 3 seconds and then off for 1 second.	Check the display for error messages. If there is an error message, enter it 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.

- 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 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 ensure 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.

Refer to the Synergy-E Manual for more information on how to check signal quality using a modem or using a direct-connect cable.

Monitoring the Baby

Turning the SmartMonitor 2 on

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

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 and that lead wires are pushed in, and that cables are connected.
Once the 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 continuously. 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, and 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, and then release the **RESET** button.
- To resume monitoring, press the gray **POWER** button.

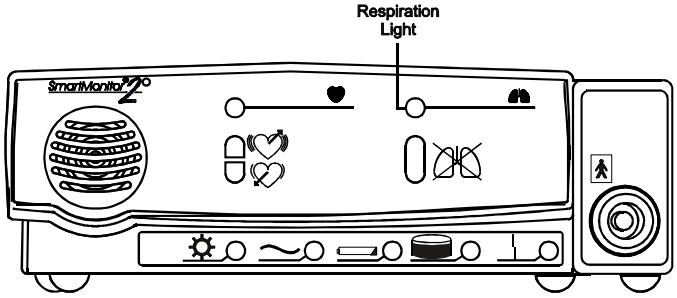
If there is an internal software error, a special power off procedure is required.

- 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 the Baby's Breathing

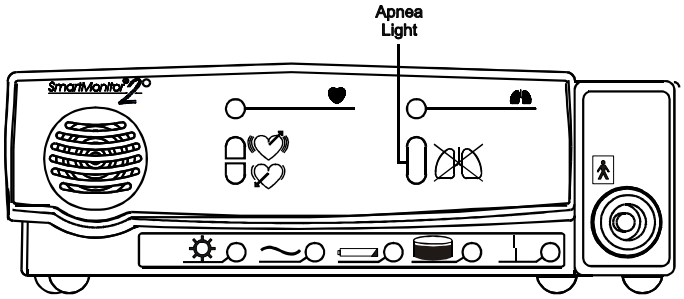
Respiration Light

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 the baby is moving.



Apnea Light

When the SmartMonitor 2 detects a pause in breathing longer than the limit set by the 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. You, the health care professional, may have set the 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.

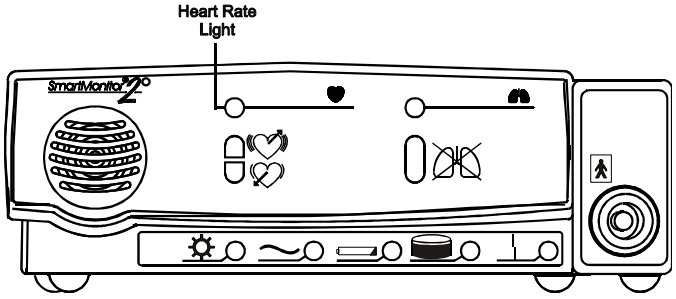
If the SmartMonitor 2 detects a pause in breathing longer than the limit set by the physician, during a Low Breath Rate alarm, the **apnea** light will change from flashing to constant.

Contact Respironics immediately if apnea alarms occur while the baby is breathing.

Monitoring the Baby's Heart Activity

Heart Rate Light

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

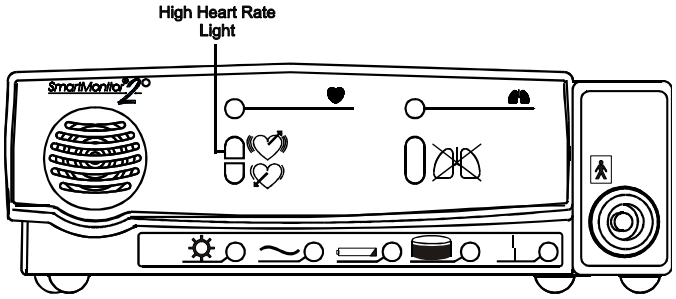


High Heart Rate Light

SmartMonitor 2 determines if the baby's heart rate is higher than the limit set by the physician. The monitor will alert you by the following:

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

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

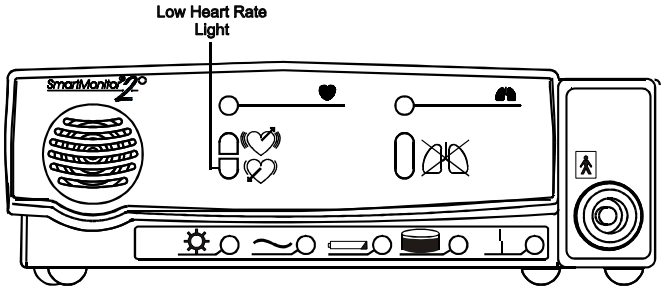


Low Heart Rate Light

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

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

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



Portable Operation of the SmartMonitor 2

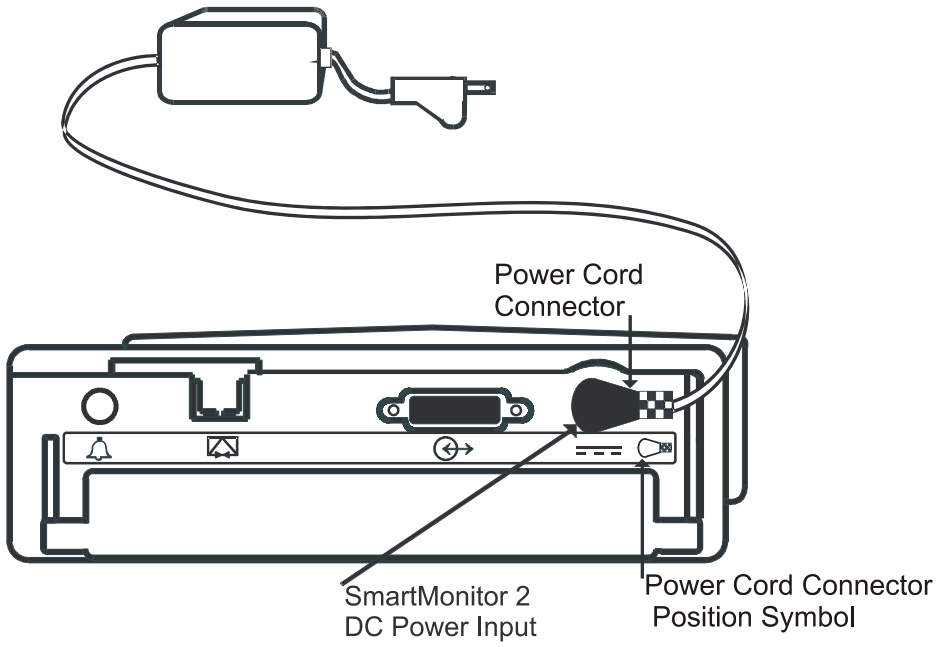
The SmartMonitor 2 is designed for portable use. When the power cord is not used, the monitor relies on a previously charged internal battery for power.

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

SmartMonitor 2 Battery Pack

Warnings

A warning indicates a potentially harmful situation.

- ❒ Never change the battery pack while the battery charger is plugged in and/or the SmartMonitor 2 is being operated.
- ❒ Do not operate the SmartMonitor 2 with the battery pack removed (and the Battery Charger connected). There is no power loss alarm feature under these conditions.
- ❒ Do not disassemble the battery pack or batteries. The batteries contain electrolytes, which can cause injury to eyes, skin, and clothing.
- ❒ Do not dispose of the old battery in fire or incinerator. The battery pack contains ingredients that could be explosive and cause serious personal injury.

Cautions

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

- ❑ The battery pack has a **locking connector**. Do not attempt to remove the battery pack without releasing the latch on the connector. Doing so will damage the battery wires.
- ❑ Use only Respironics-supplied battery packs. Use of other battery packs could cause malfunction.

Battery Installation Instructions

1. Turn the monitors' power off using the correct Power-off procedure, and unplug the external power supply from the SmartMonitor 2.
2. Loosen (counter clock-wise) both screws from the battery pack cover and remove the cover. See figure 1.
3. The battery pack is held in place by Velcro strips. To remove the battery pack, pull firmly upward when lifting battery pack out. Disconnect the battery pack by pressing the latch on the black connector, which is located in the upper left corner. Safely dispose of all old battery packs in accordance with your area's environmental laws.
4. Insert the connector of the new battery pack into the plug located in the upper left corner. It can only be inserted one way. See figure 2. Place the battery pack in the battery compartment. Secure the battery pack in the proper position by aligning the Velcro on the battery pack to the Velcro in the battery compartment.
5. Close the battery pack cover and fasten with the screws. See figure 1. Connect the external power supply to the SmartMonitor 2 and insure that it is plugged into a functional AC wall outlet for a minimum of 6 hours. There is no need to power on the SmartMonitor 2 to charge the battery pack.

The expected battery life is 2 years.

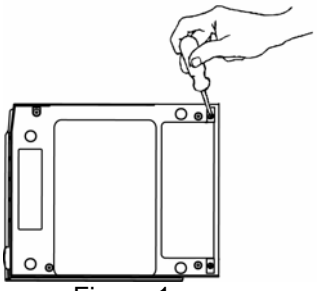


Figure 1

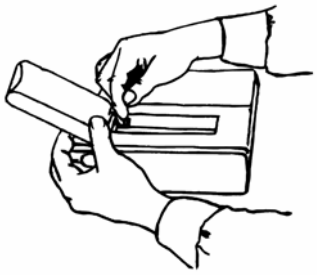


Figure 2

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 the physician. There are several different ways to transfer this information.

Whatever method you use, you *must* transfer data when you get a **memory 100% full** condition. And, you may *choose* to transfer data at any time or whenever it is considered necessary by the dealer or physician.

Memory Management in the SmartMonitor 2

When data is successfully transferred to a PCMCIA card or downloaded to Synergy-E, the data appears to be erased in the SmartMonitor 2. It no longer counts toward the reading of "Percent Memory Full" on the LCD or in Synergy-E. Because of this memory management system, it is not necessary to erase the memory after every download. It is recommended that you do erase the memory between each patient use.
Using the "Clear Memory" function in the System Parameters menus will erase all data regardless of whether or not it has been downloaded.

Should a data file become corrupted or lost on the PC running Synergy-E, the data may still be recovered from the monitor. The data can be recovered using Synergy-E until the SmartMonitor 2 has collected new data and needs the space occupied by the old data.

To recover the old data using a PCMCIA card

Transfer the data to the card using the SmartMonitor 2. Now import the card into Synergy-E. When prompted with "Only obtain data not previously retrieved?" answer **NO** to obtain all data. Synergy-E will then display all the data that was in the SmartMonitor 2.

To recover the old data by downloading using Synergy-E

Clear the Checkbox in the monitor communications screen which reads, "Only retrieve data not previously downloaded?". Synergy-E will then display all the data that was in the SmartMonitor 2.

Modem Download

There are 3 ways to download with a modem. The first choice involves the modem automatically calling the home care dealer. This is called Modem Auto Dial. This doesn't involve any action on the caregivers' part. It is important to know that the modem inside the unit may use the phone line. If you are going to use this feature you should give more specific instructions to the caregiver.

The second choice is called Modem Auto Answer in Communications mode. This option in 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 you, the home care dealer, calling to the modem built inside the monitor while the baby is being monitored. This is called Modem Auto Answer in Monitor mode (baby being monitored). You must contact the caregiver when it is time to transfer the data through the modem. We will discuss all three.

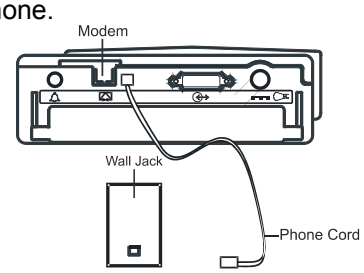
Modem Auto Dial

The SmartMonitor 2 must be connected to AC power during modem download.

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 for a connection with the computer as well as the date and time to call. If the phone number field is blank, no attempt to call will be made. These must be set up in the SmartMonitor 2 before it is placed in the patient home. When the preset time for download approaches or when the memory full light illuminates, follow these instructions:

If there is an emergency and access to the telephone is required while the 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.



Refer to the Synergy-E software for instruction on receiving a call from the SmartMonitor 2.

Modem will continue calling every 30 minutes, for 4 hours until it connects with the computer. If no connection is made, the modem will try again the next day at the pre-selected time. For example, if the modem is programmed to call at 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

The SmartMonitor 2 must be connected to AC power during modem download.

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

4. 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 can now resume monitoring the baby.

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

Modem Auto Answer in Monitor Mode

The SmartMonitor 2 must be connected to AC power during modem download.

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

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

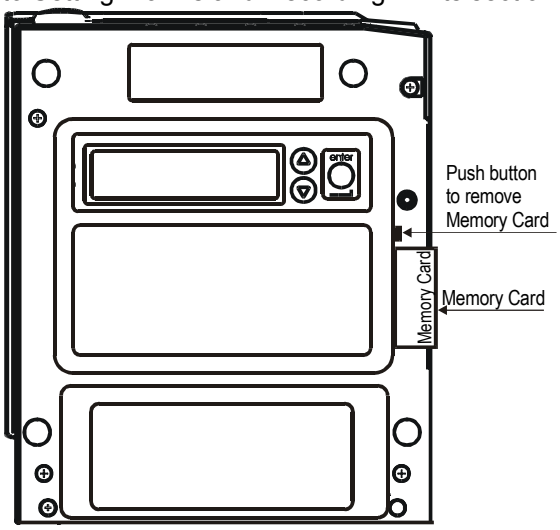
2. To allow the SmartMonitor 2 to work with the modem when the monitor is in monitor mode (the baby is being monitored):
   - ❑ When the Home Care Dealer calls for a download and the phone rings, the caregiver should press and hold down the blue **RESET** button.
   - ❑ Hold down the RESET button until the phone stops ringing indicating that the monitor has answered the call.
3. The dealer will now use the Synergy-E software to transfer the SmartMonitor 2 information.
4. 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.

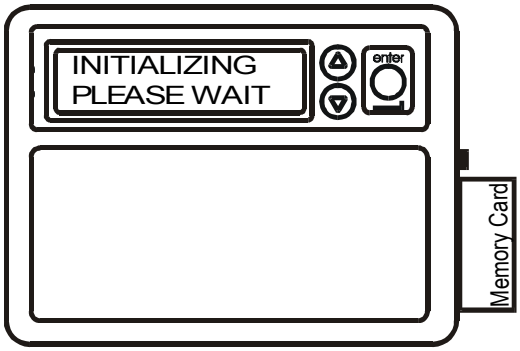
Be aware that some features available on your phone may interfere with the download: Call Waiting, Call Forwarding, and Party Lines all increase the likelihood of problems when downloading. Call Waiting cannot be disabled when receiving a phone call.

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. For more information refer to Setting Alarms and Recording Limits section of this manual





The illustration above is a close up of the LCD display on the bottom of the SmartMonitor 2.

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

1. Make sure the SmartMonitor 2 is **off**.
2. 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).
3. Press the **POWER** button ON. After a short delay, the display will read:
4. INITIALIZING PLEASE WAIT
5. Then,
6. MENU MODE? ENTER PROPER KEY SEQUENCE
7. Press the keys in the following sequence within 10 seconds:
8. Press the **ENTER** button.
9. The display will read SMARTMONITOR 2 MENU SELECTION.
10. Press the ▼ arrow until you see “Move Data To Card?
11. Press the **ENTER** button. The word NO will begin to blink. To select **YES** press either arrow button.
12. Press the **ENTER** button. The display will now show Transferring Data… Once the transfer is complete the display will change to Data Transferred.

If the card has data on it the following is displayed after step 11.

- The display may show Card Full-Overwrite?
- 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.

The memory in the monitor will not be automatically cleared. The recorder data in the SmartMonitor 2 will be “Flagged” as downloaded information and, if it is not cleared before the next download, the Synergy-E software will exclude those duplicated events. Synergy-E has the ability to retrieve all the data if desired. Refer to the Synergy-E Manual for more information.

Transferring SmartMonitor 2 Data Using a Computer

Direct Connection can download the SmartMonitor 2 data to a computer. The Synergy-E software is required to download the SmartMonitor 2.

The SmartMonitor 2 can be placed in Communication Mode or Monitoring Mode. If Monitoring Mode is chosen, all alarms and record parameters are functional.

Communications Mode Setup

The download cable must be connected to the SmartMonitor 2 and the computer before turning the SmartMonitor 2 on.

- Connect the download cable to the I/O connections port on the monitor and the COM Port on the computer.
- The monitor can be placed in Communications Mode.
- Press and release the **POWER** button to turn the SmartMontior 2 on.
- Press and hold the blue **RESET** button.
- Wait until the monitor alarms constantly.
- 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 when it is in the Communications Mode but is not electronically connected or linked to anything. 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.

Refer to the Synergy-E software for instruction on Direct Connection Downloading of the SmartMonitor 2.

Caring for the SmartMonitor 2

Use the information in this section to keep the SmartMonitor 2 functioning perfectly.

Use only Respironics 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 Lead Wires

- Use a clean cloth and any of the following:
  - Unscented dishwashing detergent
  - 3% hydrogen peroxide solution (the kind found in most stores) to clean the monitor unit.
  - 91% Isopropyl alcohol
  - 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 by 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.
- Respironics recommends that you wipe the case with a damp cloth or sponge using a light detergent, if necessary. Air-dry only.

Insect Infestation Decontamination Procedures

1: <u>Fumigating a Roach/Insect-infested Unit</u>

- Place the unit inside a Zip-lock® plastic bag, i.e. fruit/vegetable bag or large freezer bag.
- Insert a pest strip or Roach Motel™ inside the bag with the unit.
- Seal the bag tightly, and leave it at room temperature or warmer for a minimum of 30 days.

During the incubation period, any insect eggs inside the unit will hatch. Consequently, the offspring will evacuate the unit and be killed by the chemicals from the pesticide.

- After 30 days, remove the unit from the bag. Dispose of the bag, and clean the unit thoroughly as directed below.

2: Cleaning the unit

Warning: Never clean the monitor while the monitor is in use or the battery charger is plugged into an electrical outlet. **Never immerse the unit in water**. Do not clean the monitor with rubbing alcohol.

- ❑ After the above procedures have been completed, remove the battery and open the unit in an ESD protected (grounded, static free) area. *
- ❑ Using de-ionized compressed air/gas duster suitable for use on electronics, blow out all of the remains of any insect contamination.
- ❑ Close the unit and re-install the screws and battery pack.
- ❑ Use a clean cloth with an unscented, alcohol-free dishwashing detergent or 3% Hydrogen Peroxide solution to clean the outside of the monitor.
- ❑ If necessary, return the unit to Respironics for repair.

- Units under warranty will not be charged for labor / re-certification, but will be charged for any damaged or repaired components.

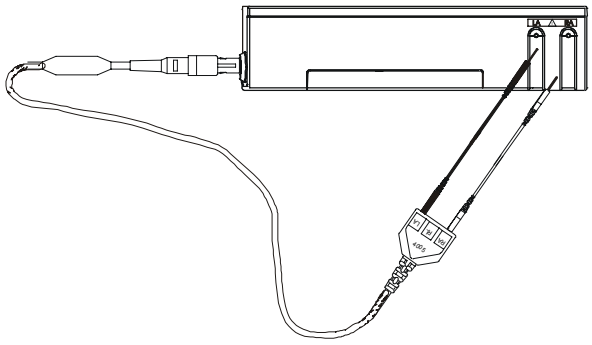
Performing a Functional Self-Test

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 the 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. 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 SmartMonitor 2. Insert the white lead wire into the **RA** opening and then the black lead wire into the **LA** opening.
- ❑ Turn on the monitor. You 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. To remove lead wires, grasp and pull the strain relief area located near the connecting tip. **Do not grasp the wire.**
- ❑ 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.	❑ Turn the monitor off using the correct Power Off procedure described in the Turning the Monitor Off – Sibling Alarm 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 *Charging the Battery* for more information). ❑ Allow the battery to charge approximately 30 minutes. You may then operate the monitor while it is plugged in. Allow the battery to charge for 6 hours before using the monitor on battery power.
Memory Full	The SmartMonitor 2 memory has violated the Memory Full parameter.	Press the **RESET** button to silence the alarm. The SmartMonitor 2 memory needs to be transferred Self-Test may continue.
Loose Lead	Indicates loose or bad electrodes, lead wires, and 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 Respironics Service before using the unit to monitor a baby.
Do not use the monitor if the alarm sounds weak or does not activate upon initial power-on.

Troubleshooting

Whenever a technical problem occurs that the caregiver cannot handle, he or she should contact the dealer. **The caregiver should 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.	Plug power cord/battery charger into monitor and outlet.
	No Power at outlet.	Locate an outlet with power.
	Defective power cord/battery charger.	Contact Respironics.
	Internal part failure.	Contact Respironics.
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. ❑ 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.
Alarm Sound Continuous, No Lights	Incorrect Power-Off Sequence.	❑ 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
Alarm Sound Continuous, No Lights	No power, battery drained.	Connect power cord/battery charger. Use Power-Off to silence alarm. ❑ Press and hold the blue **RESET** button. ❑ Press and release the gray **POWER** button. Wait 2 seconds, then release the **RESET** button. 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.
	Internal part failure.	Contact Respironics.
Alarm sounds weak.	Internal part failure.	Contact Respironics.
	Low battery	Charge battery.
Loose lead Light remains on.	Connections between electrodes, lead wires, and patient cable are not properly made.	Verify that (a) baby's skin underneath 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 Respironics.
Unable to download via modem.	AC power not connected to SmartMontior 2.	Plug the SmartMonitor 2 into AC power before performing a modem download.
Unable to communicate by direct connect	Download cable was not connected to the SmartMonitor 2 and the computer prior to turning on the SmartMonitor 2.	Connect the download cable to the SmartMonitor 2 and the computer before turning the SmartMonitor 2 on.

Ordering Information

Part Number	Item
990	SmartMonitor 2 Remote Alarm
990-100	SmartMonitor 2 Remote Alarm Cable, 100 feet
H407	SmartMonitor 2 Soft Carrying Case
418	SmartMonitor 2 Replacement Battery
424	SmartMonitor 2 Parents' Guide
H425	SmartMonitor 2 Professional Manual
H580-4000-00	SmartMonitor 2 Checkout Procedure
937	CPR Poster Set
4004	SmartMonitor 2 Memory Card, 10MB
H4005	SmartMonitor 2 Patient Cable
H4006	SmartMonitor 2 Host Download Cable
H4009	SmartMonitor 2 Power Cord/Battery Charger Domestic 120VAC/60HZ
H4010	Smart Monitor 2 Auxiliary Interface Box
H4011	SmartMonitor 2 Power Cord/Battery Charger International 230VAC/50HZ
5000	SmartMonitor 2 Simulator, ECG/Respiration
9510	Small Disposable Sticky Electrodes, 3 electrodes per set, Pkg., of 5 sets
9515	Large Disposable Sticky Electrodes, 3 electrodes per set, Pkg., of 5 sets
9520-1	Safety Lead Wires, Pin-to-Socket, 24 in., .080 in. socket
9521-1	Safety Lead Wires, Pin-to-Socket, 40 in., .080in. Socket 5 pair per package.
9916-12	Start-up Accessory Kit, 6 pair electrode belts, 6 pair carbon electrodes, and 6 pair safety pin to socket lead wires
9916	Accessories Starter Kit, 2 electrode belts, 2 pair reusable electrodes, 2 pair of pin to socket lead wires.
16510-1	Electrodes, Reusable
16530-1	Electrode Belt
1030192	SmartMonitor 2 PS Homecare Patient Cable, Metal

Visit www.respironics.com for a complete list of products and reorder numbers, or contact Customer Service at 1-800-345-6443 or 724-387-4000 to obtain a product catalog (#1027825).

Glossary

Apnea - An absence of breathing (respirations).

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.

Bradycardia – Slowing of the heart rate below the age specified rate for 5 seconds or greater.

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 – This is the method used by SmartMonitor 2 to detect respiration.

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

Modem - A device that allows the 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.

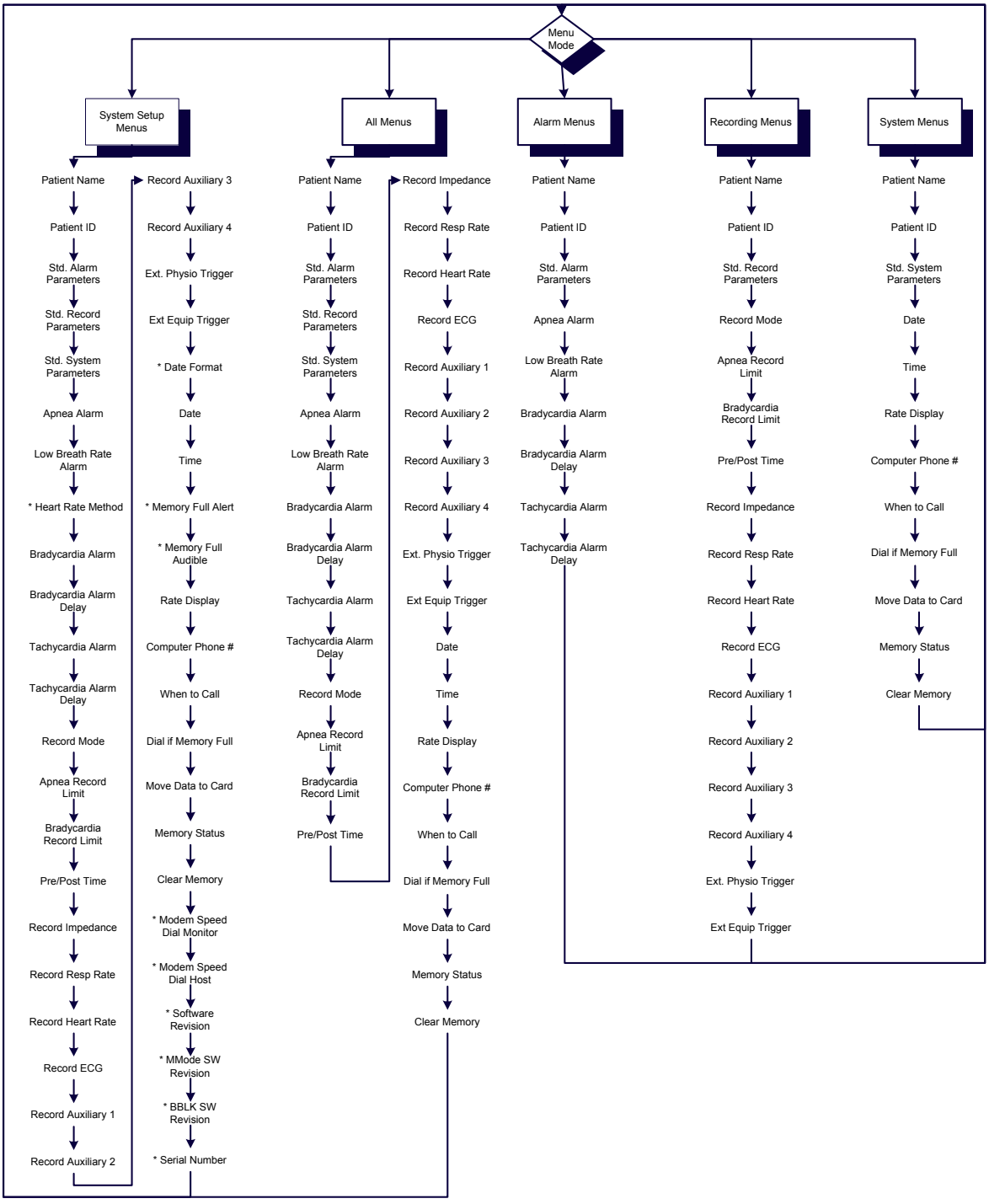
Respiration - The act of inhaling and exhaling air.

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.

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.

Appendix A

Flow Chart of SmartMonitor 2 Parameters



Specifications

Input Signal Range	ECG Sensitivity	10 to 275 BPM, 0.5 mV; 10 to 150 BPM, 0.2 mV
	Respiration Sensitivity	4 to 150 BrPM @ 2 Ohms; 8 to 75 BrPM @ 0.5 Ohm; 30 BrPM @ 0.15 Ohm
Alarms	Apnea	Delay settings of 10, 15, 20, 25, 30, 40 seconds
	Low Breath Rate	Off, 4,5, 6, 7, 8, 9, 10, 12,14, 16, 18, 20, 25, 30 BrPM
	Bradycardia	40, 50, 60, 70, 80, 90, 100 BPM. Optional delay of 5 seconds
	Tachycardia	Off, 90, 100, 110, 130, 150, 170, 190, 200, 210, 220, 230, 240, 250, 270 BPM
	Loose Connection	Base Impedance exceeds 2000 ± 200 Ohms
	Low Battery Warning	Battery voltage low, power cord/battery charger required promptly
	Low Battery Shutdown	Battery voltage too low to continue with out Power cord/battery charger
	Full Memory	Memory is 50% full or 80% full, repeats when memory is 100% full
SmartMonitor 2 Memory System Capacity	Non-Volatile Memory	2 MB
	Logs	1000 Patient event listings, 1000 Equipment event listings
	Waveform events*	500 HR trend and impedance; or 100 ECG QRS, HR trend, and impedance; or 21 hours of continuous HR trend and impedance.
		* Oximetry or other signals can be recorded with reduced capacity
Signal Channels	Internal	QRS, heart rate trend, and impedance
	Oximeter	Saturation and pulse, or pulse rate
	External Input	Airflow, pH, strain gauge, or other low frequency physiological signals, +/- 1.25 V maximum
Event Parameters	Internal	Apnea Record, Apnea Alarm, Low Breath Rate, Bradycardia for Record, Bradycardia Alarm, Tachycardia Alarm
	Oximeter	+3.5V to +5.0V during alarm condition
	Event Duration	Alarm duration plus current pre- and post-settings totaling 45, 60, 75, 90 seconds
	Apnea Record	Off or 6 to 40 seconds in two-second intervals
	Bradycardia Record	Off or 50 to 100 Beats per Minute in five-BPM intervals
Electrical	Safety Standards	Meets CSA, C22.2 No. 601-1 and UL2601-1 and EN60601-1
	Certification	CSA/NRTL
	Power Input: SmartMonitor 2	10.5 VDC
	Power Input Power Cord/Battery Charger	120 V, 60Hz or 230 V, 50 Hz
	Batteries	Rechargeable NIMH, 18 – 21 hours continuous use; recharge time, 6 hours @ 77° F; Shelf life, 30 days if fully charged, expected battery life is 2 years.
Physical	Size	HWD: 4’ x 91/4” x 9” (11.2 x 23/5 x 22.9 cm)
	Weight	2.6 lbs. (1.18 kg)
	Shipping Weight	8.5 lbs. (3.9 Kg)

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