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SmartMonitor 2 PS
SmartMonitor 2 PSL
Professional Operator's Manual

PHILIPS

Children's Medical Ventures

Warranty

Children's Medical Ventures, LLC warrants that the monitor will be free from defects in materials and workmanship for a period of two years from the time of purchase. Children's Medical Ventures, LLC accessories are warranted to be free of defects in materials and workmanship for a period of 90 days from the time of purchase.

The Children's Medical Ventures, LLC 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 Children's Medical Ventures, LLC.

User/Owner Responsibility

This Philips Children's Medical Ventures 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 are 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 Philips Children's Medical Ventures;
- 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 Philips Children's Medical Ventures Model 5000 Simulator according to the Checkout Procedure Manual 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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SmartMonitor 2 PS

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Introduction

Unpacking and Inspection

When you receive the SmartMonitor 2 PS, unpack the shipping case and do the following:

- 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 Philips Children's Medical Ventures.

About This Manual

This manual provides all the information you need to set up and operate the SmartMonitor 2 PS and explains how to use it to monitor the patient's vital functions. Carefully read and understand this manual before using the system.

Indications for Use

The SmartMonitor 2 PS is intended for use in the continuous monitoring of respiration, heart rate, and SpO_2 levels of infant, pediatric, and adult patients. It detects and alarms for periods of high or low heart rate, high or low breath rate, and high or low saturation. When used as an infant monitor it is intended for use in a home or hospital environment. For infants only, it monitors and alarms for central apneas. When used as a pediatric or adult monitor, it is intended for use in a hospital environment.

What Is the Purpose of the SmartMonitor 2 PS?

SmartMonitor 2 PS is an apnea monitor designed to monitor and record the patient's breathing (respiration), heart (cardiac) activity and SpO_2 (functional oxygen concentration) levels. The monitor alerts you if any of these activities exceed the limits prescribed by the physician.

Patient alarm limits are set by the health care professional before the monitor is delivered to the patient. During monitoring, when the breathing effort, heart activity and SpO_2 level are not within these set boundaries, an indicator light comes on and an alarm sounds. This manual explains how to set up the monitor how to monitor the patient, and how to transfer information.

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

Summary of Clinical Performance Evaluation

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

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.

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 in 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 (less than or equal to 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 Philips Children's Medical Ventures 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 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	Caucasian	African American	Asian	Hispanic	Other	Mean Birth Weight (grams)	Mean Gestational 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

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 SmartMonitor 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

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

Warnings

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

- Before using the monitor, charge the internal battery pack. Connect the power supply to the device, and ensure that it is plugged into a functional AC wall outlet for a minimum of 12 hours.
- The monitor will not operate without the internal battery pack. However, the internal battery pack ensures proper shutdown in the event of power failure to the device. Without the internal battery pack, loss of data is possible in the event of power loss.
- Place the monitor on a secure and level surface to prevent the device from falling. Do not place the monitor on the floor or in any location where the device could become a tripping hazard. Do not place the monitor in a crib, so that the patient will not roll onto the device's hard surface.
- If an emergency occurs and access to the telephone is required while the monitor is connected to the telephone wall jack, unplug the phone cord from the wall jack and connect a working telephone to the jack.
- Do not defibrillate a patient who is attached to the monitor.
- Do not use skin creams, electrode gels, oils or lotions under the sensors.
- The monitor may not be able to detect all episodes of inadequate breathing. If a patient has apnea due to choking (obstructive apnea), the monitor could mistake movement caused by choking for breathing.
- The SmartMonitor 2 PS is a monitoring device only. They do not prevent the loss of breathing or heart activity, nor will they restore breathing or heart activity. These devices will not prevent death.
- Anyone using the SmartMonitor 2 PS should be trained in current infant/adult Cardiopulmonary Resuscitation (CPR), which is a proper way to restore breathing and heart activity.
- The monitor is not intended for use with cardiac or diaphragmatic pacemaker patients.
- Do not allow the patient cables, lead wires, sensor cables or power supply cable to become tangled, coiled, crossed, or wrapped around the patient's neck, arms, or legs. This could result in strangulation.
- Do not block the speaker or place items in front of the speaker located on the front of the unit. This could prevent the monitor alarm from being heard.
- Never use the monitor on the patient while the patient is being bathed. This could result in electrical shock and/or damage to the equipment.
- Disconnect the power supply and phone line during lightning storms to reduce risk of electrical shock to the patient.
- If monitoring two or more patients 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.

- Do not connect the patient to the monitor if the monitor is placed in the Communications Mode. The alarms do not work when the monitor is in this mode.
- Do not use the monitor at the same time as other impedance monitors. This may cause missed apneas due to interference.
- Do not rock the patient or sleep in the same bed with the patient while monitoring. Touching or moving near the patient, monitor, or cables could cause the monitor to miss apneas.
- Inspect the power cords and cables often for any signs of damage. Replace a damaged cord or cable immediately.
- Do not use non-safety style lead wires and patient cable configurations with this monitor. Their use may pose a risk of severe electrical shock or death. Refer to the instructions in this manual to ensure proper connections. Use only Philips Children's Medical Ventures recommended safety lead wires, patient cables, electrodes and sensors.
- Pins of connectors identified with the ESD warning symbol should not be touched. Connections should not be made to these connectors unless ESD precautionary procedures are used. Precautionary procedures include methods to prevent build-up of electrostatic discharge (e.g., air conditioning, humidification, conductive floor coverings, non-synthetic clothing), discharging one's body to the frame of the equipment or system or to earth or a large metal object, and bonding oneself by means of a wrist strap to the equipment or system or to earth.
- Do not touch the device and the patient simultaneously.
- The conductive parts of electrodes and patient cables should not contact other conductive parts, including earth.
- The SpO_2 sensor site must be changed every four (4) hours. Note: Exercise extreme caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when the sensor is not frequently moved. Assess the site at least every two (2) hours with poorly perfused patients.
- If the SpO_2 sensor is damaged in any way, discontinue use immediately.
- To prevent damage, do not soak or immerse the SpO_2 sensor in any liquid solution. Do not attempt to sterilize.
- Intravascular dyes may lead to inaccurate SpO_2 measurements.
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO_2 measurements.
- Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO_2 measurements.
- Failure to apply the SpO_2 sensor properly may cause incorrect measurements.
- Do not use the monitor or the SpO_2 sensor during MRI scanning.
- Avoid placing the SpO_2 sensor on any extremity with an arterial catheter or blood pressure cuff.
- Do not use during High Frequency surgical procedures.
- Explosion hazard. Do not use the monitor in the presence of flammable anesthetics or other flammable substances in combination with air, oxygen-enriched environments, or nitrous oxide.
- If an alarm condition occurs while the alarm silence period is active, the only alarm indications will be visual displays and symbols related to the alarm condition.
- The monitor is to be operated by qualified personnel only. This manual, accessory directions for use, all precautionary information, and specifications should be read before use.

- Do not use damaged patient cables. Do not immerse the patient cables in water, solvents, or cleaning solutions. (The patient cable connectors are not waterproof.) Do not sterilize by irradiation, steam or ethylene oxide. See the cleaning instructions in the directions for use for reusable patient cables.
- The Nurse Call feature of this device is for convenience only in a medically supervised environment. The audible indication provided by the Nurse Call system is not to be relied upon as the primary indication of the operating state of the device or of patient events.
- The Nurse Call feature should be considered a backup to the monitor device's primary alarm system. The operator should not rely solely on the Nurse Call feature.

Cautions

A caution indicates the possibility of damage to the device.

- Perform the functional self-test if the monitor has been x-rayed by an airport security check.
- Do not send information via modem during electrical storms. Information could be lost, or equipment could be damaged.
- Handle the lead wires carefully to prevent them from breaking inside the insulation. Always grasp the lead wire at the strain relief area to remove them from the electrodes or ECG patient cable.
- Any foreign matter that gets into the enclosure of the monitor may cause malfunction.
- Use only Philips Children's Medical Ventures-supplied sensors and accessories. Use of other accessories could degrade signal quality.
- If you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, if the device is dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken, discontinue use and contact your home care provider.
- If the patient is breathing quietly and the respiration light flashes more or fewer times than the patient breathes, contact Philips Children's Medical Ventures for service.
- 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 Philips Children's Medical Ventures for further assistance. Use of a third (RL) electrode and lead wire is normally not required but may help reduce excessive false low heart rate alarms.

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

1. When a monitor is susceptible to electromagnetic interference, the situation should be corrected to ensure safe monitoring.
2. To test for EMI at the pateint's home, the following steps must be performed.
    - Set the monitor apnea duration to 20 seconds (infants only).
    - 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 (infants only).
    - 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 constitutes failure of this test.

If the monitor fails this test, ensure 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 Philips Children's Medical Ventures for further assistance. Use of a third (RL) electrode may help reduce EMI.

WARNING: If monitoring two or more patients in the same area, keep the monitors, patients, 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.

How Does the SmartMonitor 2 PS Work?

The SmartMonitor 2 PS monitors and records a patient's breathing (respiration), heart (cardiac) activity and SpO_2 level, and alerts the caregiver if any of these activities exceeds the limits prescribed by the physician.

The patient alarm limits are set before the monitor is given to the patient. If during monitoring the patient's breathing effort, heart activity, and SpO_2 level 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 PS, how to monitor a patient, how to transfer the information to the physician, and how to use other devices with monitors.

Breathing is measured by placing two electrodes on the patient's chest under his or her arms. As the patient's chest moves during breathing, the impedance between the electrodes changes. The monitor detects these changes to determine the patient's breathing effort. If the monitor 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.

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

The SmartMonitor 2 PS monitors SpO_2 levels through sensors attached to the patient. You can record extended studies with electronic memory using the on-board PCMCIA card.

How the Alarms Operate

Whenever the patient's breathing effort, heart activity and SpO_2 levels are not within the limits set by the physician, an indicator light will come on and an alarm will sound. The monitor has two types of alarms: patient and system.

Patient Alarms: An intermittent audible and visual indicator alerts the patient during the following alarm events:

- Apnea: Patient has stopped breathing for longer than the limit set by the physician.
- Low Breath Rate: Breath rate is lower than the limit set by the physician.
- Low Heart Rate: Heart Rate is lower than the limit set by the physician.
- High Heart Rate: Heart Rate is higher than the limit set by the physician.
- Low SpO_2: SpO_2 level is lower than the limit set by the physician.
- High SpO_2: SpO_2 level is higher than the limit set by the physician.

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

- Loose lead
- Loose Probe
- Low Battery
- Memory Full
- Accidental Power-Off
- Internal System Error

Lights on the monitor indicate which of these conditions exists. See the section “Monitoring” for more information on alarms.

The monitor 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 the monitor and contact Philips Children’s Medical Ventures Customer Service at 1-800-345-6443.

Symbols Table

Symbol	Definition
	Attention: Consult accompanying documents
CE 0086	European Declaration of Conformity
	Separate collection for electrical and electronic equipment per EC Directive 2002/96/EC
EC REP	European Representative
	Type BF Applied Part (also shows Patient Cable Connector location)
	Reset Button
	Power Off/On Button
	Apnea Alarm Light (infants only)
	Respiration Light
	Low Heart Rate Alarm Light
	High Heart Rate Alarm Light
	Low Battery Light
	Memory Full Light
	Loose Lead Light

Symbol	Definition
	Heart Rate Light
	Power Light
	Charger Light
	Power Cord Connection
	Input / Output Connection
	Modem Port (Optional)
	Nurse Call Connection
SN	Serial Number
	Three Electrodes Per Package
	Four Electrodes Per Package
BPM	Beats Per Minute
BrPM	Breaths Per Minute
SpO_2	Oxygen Saturation
%	Percent
	High SpO_2 Alarm Light
	Low SpO_2 Alarm Light
	ESD Warning Symbol
IPX1	Drip Proof Equipment
	Power Supply Connector Position

Registration Number and REN

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

USOC Jack

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

Compliant Accessories

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

Number of RENs

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

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

Changes in Service

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

Problems

If trouble is experienced with this modem, please contact your homecare provider or Philips Children's Medical Ventures at 1-800-345-6443 for repair or warranty information. If the equipment is causing harm to the telephone network, the telephone company may request that you disconnect the equipment until the problem is resolved.

Repairs

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

Party Lines

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

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

Industry Canada Requirements

IC Abbreviation

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

REN

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

Industry Canada CS-03 Notice

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

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

The Philips Children's Medical Ventures 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.

FCC Part 15

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

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

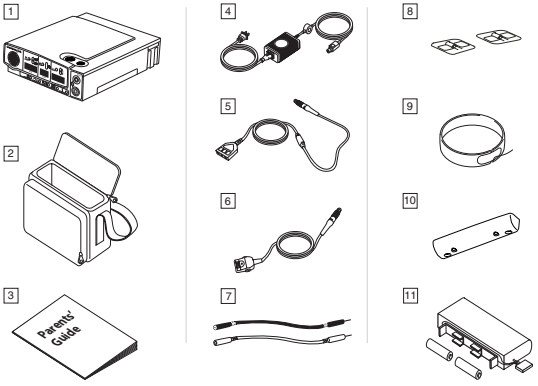
However, there is no guarantee that interference will not occur in a particular installation. This can be determined by turning the equipment off and on. If this equipment does cause harmful interference to radio or television reception, you are encouraged to try to correct the interference by one or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

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

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

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

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



When you receive the SmartMonitor 2 PS, make sure that you have all the necessary items and that they are not damaged. Immediately report anything missing or damaged to Philips Children's Medical Ventures.

The standard package should include the following:

1. SmartMonitor 2 PS
2. Soft Carrying Case
3. Parents' Guide
4. Power Supply and Power Cord. Your new monitor is supplied with an external power supply (P/N 1031372) and a 3-wire AC input cord. If you do not have a grounded (3-wire) power outlet, contact Philips Children's Medical Ventures Customer Service at 1-800-345-6443 to obtain a 2-wire power supply (P/N 1016966) and AC input cord. The 3-wire supply and the 2-wire supply both provide the same level of operator and patient safety according to IEC 60601-1. However, when the monitor is used on a patient who has other medical equipment connected at the same time, the 3-wire power supply may provide greater immunity to electrical noise for the monitor and other medical equipment.

   NOTE: The appearance of the power supply and cord will vary, depending on country of use. In the illustrations in this guide, the power supply is represented by a standard U.S. domestic 2-wire configuration.

5. ECG Patient Cable
6. Oximeter Patient Cable
7. Lead Wires
8. Electrodes
9. Electrode belt
10. Handle/Stand
11. Battery Pack
12. Symbol Reference Card (not shown here)
13. Phone Line Splitter (not shown here) (optional)
14. Phone Line Cord (not shown here) (optional)

NOTE: Oximeter sensors are not included in the standard package and need to be ordered separately.

SmartMonitor 2 PS Features

This section describes the physical features of the monitor.

Top Panel Features

Power Button

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

To turn the monitor off, do the following:

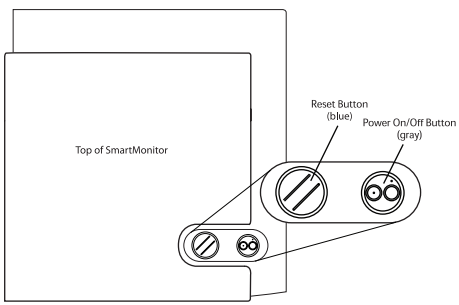
- Press and hold the blue RESET button.
- Press and release the gray POWER button.
- Wait 2 seconds, and then release the RESET button.

NOTE: When the Hospital Mode Control parameter is set to YES, this special key sequence is not required. The alarm set points will also be displayed one at a time during the power up sequence.

When the Hospital Mode Control parameter is set to YES, the Silence Alarm Feature is enabled. This allows the user to silence the audible alarm for 60 seconds when the alarm is being caused by a physiologic event(s). The user can silence the alarm by pressing the RESET button. If the physiologic event(s) is still active after 60 second(s), the alarm will sound again. This feature only affects the audible portion of the alarm. The front panel displays will blink when the silence period is active.

Reset Button

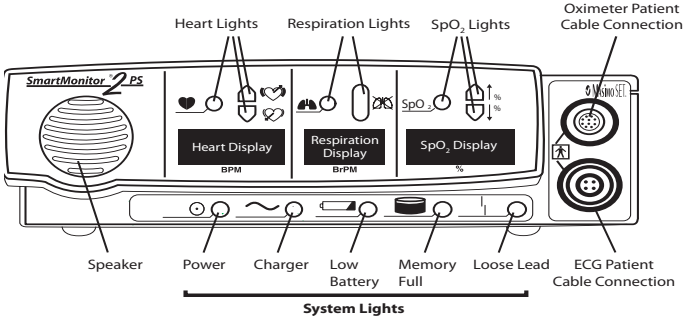
The blue RESET button resets the alarm lights on the monitor. It also silences the Memory Full (or Memory Almost Full) and Low Battery warning alarms. For more information, see the section "Responding to Alarms" later in this manual. The RESET button also answers a ringing modem phone call when in monitoring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



Front Panel Features

Patient Input Connectors

Two patient input connectors appear on the monitor. The top connector supports connection of the SpO_2 patient cable. The bottom connection is for the Heart/Respiration patient cable.



Display of Values

Values for heart rate, breath rate and SpO_2 level are viewable from the front panel display. You can increase the brightness of Display Values on the monitor by pressing the ▲ or ▼ buttons.

NOTE: You can disable this feature through the user interface on the bottom of the monitor. You can also disable the oximeter functionality through the user interface.

Respiration Lights

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

SpO_2 Lights

The green SpO_2 light **SpO2** will appear solid when the probe is connected to the patient and is monitoring a strong signal. A solid orange light will appear if the device is monitoring the SpO_2 level. If the probe is disconnected, is not transmitting a signal, or is transmitting a moderate or marginal signal, a red SpO_2 light will appear. The red high light ↑% comes on when the SmartMonitor 2 PS detects an SpO_2 level higher than the limit set by the physician. The red low light ↓% comes on when the SmartMonitor 2 PS detects an SpO_2 level lower than the limit set by the physician.

Speaker

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

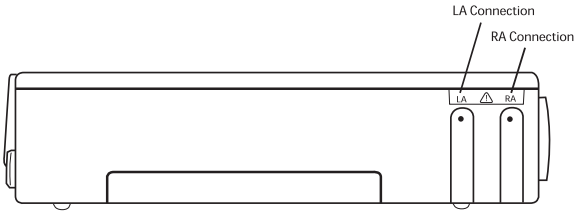
System Lights

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

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

Side Panel Features

The right side panel features the two connections shown below.

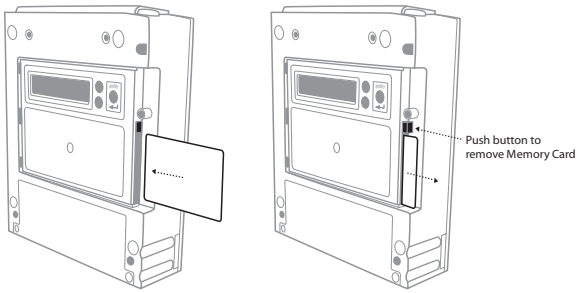


Self-Test Connector

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

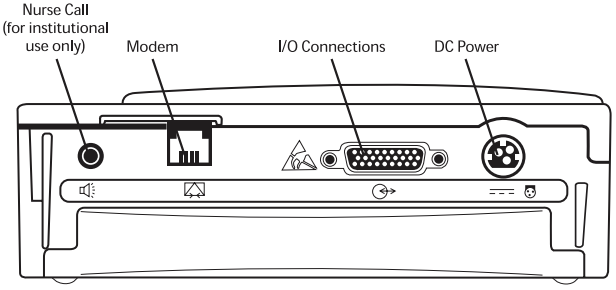
Memory Card (Optional)

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



Back Panel Features

The back panel features are shown in the illustration below.



Nurse Call (Optional)

The nurse call feature allows the monitor to be connected to a nurse call station

Modem (Optional)

The monitor is equipped with a modem to transfer the monitor's memory to the physician. See the section on "Transferring Monitor Memory" for more information. See the sections "FCC Part 15" and "Industry Canada CS-03 Notice" for information on connecting the modem to the telephone line.

I/O Connections

This connector connects the monitor with other devices.

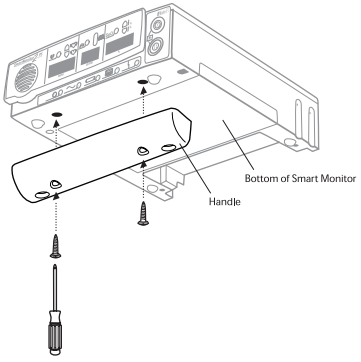
Ensure that the devices used do not exceed SELV (Safety Extra Low Voltage) levels as described in EN60601-1.

DC Power

Use the DC Power connector with the power cord/battery charger. Whenever the monitor is not being transported (on battery power only) it should be connected to the battery charger.

Stand

The monitor comes with a removable handle. The handle also acts as a stand that elevates the front panel display when the monitor is placed on a flat surface. The handle, along with connection screws and rubber feet, is packaged with the device.



Setting Alarm and Recording Limits

The monitor 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 Setup

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

The Monitor Setup 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 Setup Menu, the monitor is in Menu mode.

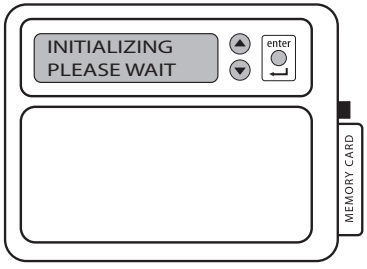
NOTE: The monitor will beep once every 10 seconds to signal that it is powered on and in Menu mode.

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

Memory Display Detail



  Then,

  MENU MODE? ENTER PROPER KEY SEQUENCE

- Press the keys in the following sequence within 10 seconds:

  DOWN ARROW button, UP ARROW button, UP ARROW button, ENTER button, ENTER button, ENTER button.

- The display will read SMARTMONITOR 2 PS MENU SELECTION.
- The monitor's menu has over 40 entries that are presented in a continuous loop. Use the UP ARROW button to display the next menu entry.
- Use the DOWN ARROW button 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 button to choose the menu path you want to review.

There are four menu paths to choose from:

- All Menu
- Alarm Menu
- Recording Menu
- System Menu.

Once the changes are completed, turn the monitor 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.

NOTE: When you power the monitor off and then back on, the new values will be implemented.

When the Hospital Mode Control parameter is set to YES, the special key sequence is not necessary to turn the monitor off.

The SmartMonitor 2 PS Parameters

The following menu flow is for All Menus. This path encompasses menus for Alarm, Recording, and System. For instance, to quickly access an alarm setting, select the Alarm Menu.

Standard values for Alarms and Recording parameters appear in bold.

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
View Prior Events	VIEW PRIOR EVENTS?	This menu option allows the user to view a summary of the ten most recent physiological events via the LCD screen. To view events: • Press the ENTER button to activate. • Press ▲ or ▼ to change the selection to Yes. Then press the ENTER button. • Press ▲ or ▼ to browse through the most recent events (up to ten). • Press the ENTER button to exit this menu option.	All Menus System Menus
Patient Name	PATIENT NAME	To enter the Patient Name: • Press the ENTER button to begin entering the patient name. • Press ▲ or ▼ to browse through the alphabet and select the letter you need. When the letter you want appears, press the ENTER button. Press the ENTER button 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 the ENTER button. NOTE: 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 Identification Number	PATIENT ID NUMBER	To enter the Patient ID: • Press ▲ or ▼ until Patient ID is displayed. • Press the ENTER button to activate. • Press ▲ or ▼ to browse through the numbers and select the digit you need. When the digit you want displays, press the ENTER button. • When you have finished the ID, press ▲ or ▼ until the ^ appears. Then press the ENTER button. NOTE: ^ 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
Standard Alarm Parameters	STD ALARM PARAMETERS Are Selected Or Are Not Selected	• Press the ENTER button to activate. • Press ▲ or ▼ to change the selection. • When you have your selection displayed, press the ENTER button.	All Menus Alarm Menu
Standard Record Parameters	STD RECORD PARMS. Are Selected Or Are Not Selected	• Press the ENTER button to activate. • Press ▲ or ▼ to change the selection. • When you have your selection displayed, press the ENTER button.	All Menus Record Menu
Standard System Parameters	STD SYSTEM PARMS. Are Selected Or Are Not Selected	• Press the ENTER button to activate. • Press ▲ or ▼ to change the selection. • When you have your selection displayed, press the ENTER button.	All Menus System Menu
Apnea Alarm Setpoint (Infants only)	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 Setpoint	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 Setpoint	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** NOTE: 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 monitor, the current Bradycardia alarm set point, and the patient's average resting heart rate.	All Menus Alarm Menu

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
Tachycardia Alarm Setpoint	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
Tachycardia Alarm Delay	TACHY ALARM DELAY IN SECONDS	Enables a delay to the audible alarm. Values: **0 and 5 seconds** Standard value: **5 seconds** NOTE: 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 monitor, 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

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
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 with the Apnea Alarm set to 20 seconds and the Apnea for Record 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
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 with the Bradycardia Alarm set to 70 BPM and the Bradycardia for Record 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

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
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
Respiration Rate Record	RECORD RESP RATE?	This parameter allows the user to select whether or not the Breath-To-Breath and 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 and the Average Heart Rates will be recorded. Values: **YES or NO** Standard value: **YES**	All Menus Record Menu
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
Oximeter Control	OXIMETER ENABLED	This parameter allows the user to disable/enable the internal Oximeter. Values: **YES and NO** Standard value: **YES**	All Menus Alarm Menus Record Menu System Menu
Front Panel Control	ENABLE PANEL DISPLAY	This parameter allows the user to enable/disable the Front Panel Display. Values: **YES and NO** Standard value: **YES**	All Menus System Menu
Oximeter Probe Off Functionality	PROBE OFF FUNCTION	This parameter allows the user to select what system actions the monitor will take when an "Oximeter Probe Off" condition occurs. Values: **No Events Or Alarms – Not documented in equipment log, no audible alarms** **Do Events, No Alarms – Documented in equipment log, no audible alarm sounds** **Do Events, Do Alarms – Event documented in log and alarm sounds** Standard value: **Do Events, Do Alarms**	All Menus System Menu

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
Low SpO_2 Alarm Setpoint	LOW SpO_2 ALARM	This parameter allows the user to modify the Low SpO_2 Alarm Threshold. Values: **75, 80, 82, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, Off** Standard value: **85** This parameter is skipped if the system parameter, oximeter enabled, is set to **NO**	All Menus Alarm Menu
High SpO_2 Alarm Setpoint	HIGH SpO_2 ALARM	This parameter allows the user to modify the High SpO_2 Alarm Threshold. Values: **90, 91, 92, 93, 94, 95, 96, 97, 98, 99, Off** Standard value: **OFF** This parameter is skipped if the system parameter, oximeter enabled, is set to **NO**	All Menus Alarm Menu
SpO_2 Alarm Delay	OXIMETER DELAY	This parameter allows the user to modify the Oximeter Alarm Delay Value which is associated with the Low SpO_2 Alarm Values: **1, 5** Standard value: **5**	All Menus Alarm Menu
Low SpO_2 for Record	SpO_2 RECORD LIMIT	This parameter allows the user to modify the Low SpO_2 for Record Threshold. When the parameter is set to the default value, after a Probe Off/Low SpO_2 condition, the alarm will be delayed for 5 seconds to allow the oximeter reading to stabilize. Values: **75, 80, 82, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, Off** Standard value: **OFF**	All Menus Record Menu
SpO_2 Record	RECORD SpO_2?	This parameter allows the user to disable/enable the recording of the SpO_2 values. Values: **YES and NO** Standard value: **YES**	All Menus Record Menu
Plethysmograph Record	REC PLETHYSMO-GRAPH?	This parameter allows the user to disable/enable the recording of the Plethysmograph waveform. Values: **YES and NO** Standard value: **YES**	All Menus Record Menu

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
Pulse Rate Record	RECORD PULSE RATE?	This parameter allows the user to disable/enable the recording of the Oximeter Pulse Rate values. Values: **YES and NO** Standard value: **NO**	All Menus RecordMenu
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 monitor recording when a physiological parameter is violated in the external auxiliary device. Select from: • OFF • Trigger when high • Trigger when low See the section "Using Auxiliary Equipment." Standard value: **OFF**	All Menus Record Menu

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
External Equipment Trigger	EXT. EQUIP. TRIGGER	Ext. Equip. Trigger allows external equipment to cause an entry in the monitor's Equipment Log when an equipment parameter is violated in the external auxiliary device. Select from: • OFF • Trigger when high • Trigger when low See the section "Using Auxiliary Equipment." Standard value: **OFF**	All Menus Record Menu
When the auxiliary equipment channels are turned on and the auxiliary equipment is not connected to the monitor, a flat line will be recorded and reported. The auxiliary channels enable you to interface other signals to monitor. Options for each of these channels are best defined with the System Software. External auxiliary devices can be interfaced to provide SpO_2, 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 Manual* for more information.			
Date Format Selection	DATE FORMAT	This parameter allows the user to display the date in either U.S. or international formats Values: **Month/Day/Year** **Day/Month/Year** Standard Value: **Month/Day/Year**	All Menus System Menu
Date	DATE	To enter the date: • Press the ENTER button to begin. • Press ▲ or ▼ until the number required is displayed. • Press the ENTER button 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 the ENTER button to begin. • Press ▲ or ▼ until the number required is displayed. • Press the ENTER button 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

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
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: **ON**	All Menus System Menu
Phone Number for Computer	COMPUTER PHONE #	Enter the phone number of the modem on the computer end of the download. NOTE: You may enter *70 first, then the phone number to disable Call Waiting if necessary. Be sure to enter the phone number without dashes or spaces. • Press the ENTER button to begin. • Press ▲ or ▼ until the number required is displayed. • Press the ENTER button to select. • Once you have entered the phone number, press ▲ or ▼ until the ^ appears. Then press the ENTER button. 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
Time To Call the Computer	WHEN TO CALL	To enter the Time to call: • Press ▲ or ▼ until WHEN To CALL is displayed. • Press the ENTER button to activate. • Press ▲ or ▼ to browse through the numbers and select the digit you need. When the digit you want displays, press the ENTER button. • Enter the time in Military Time. • When you have finished, press the ENTER button. • 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 3-1-03 at 4:00AM, but the memory reaches the Memory Full Alert at 3:00PM on 2-1-03, then the monitor will initiate a call at 4:00AM on 2-2-03. Standard value: **ON**	All Menus System Menu

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
Move Data to Card	MOVE DATA TO CARD? (other possible messages) Insert Card – Retry Transferring Data… Data Transferred	This menu is used to download the recorded data to the Memory Card. To move data to the Memory Card: • Press the ENTER button. The word NO will begin to blink. • To select YES, press either arrow button. • Should a Memory Card not be inserted, the monitor will ask for the card. • Place the card in the 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 monitor. 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, or the patient name and patient ID. • The memory should be cleared before using the monitor 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 monitor, it 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 monitor.

System Setup Menu

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

- Press the POWER button. 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 the ENTER button.
- Scroll to ALL MENUS, and press the ENTER button.

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

Menu Option	LCD Display	Description of Option or Instructions
Heart Rate Computation Method	HEART RATE METHOD	Establishes the method by which the monitor computes the Average Heart Rate. Values: 4 Beat Average, Time Average Standard value: Time Average
Hospital Mode Control	ENABLE HOSPITAL MODE	This parameter allows the user to enable/disable the Hospital Mode system functions. Values: YES and NO Standard value: NO *NOTE: Monitors equipped with the Hospital Alarm feature will have the parameter set to YES when they come from the factory.*
Oximeter Averaging Time	OX AVERAGING TIME	This parameter allows the user to modify the Oximeter Averaging Time Value. Values: 2-4, 4-6, 8, 10, 12, 14, 16 Standard value: 8

Menu Option	LCD Display	Description of Option or Instructions
Alarm Hold-Off Delay Following Probe Off	OX PROBE ON DELAY	This parameter allows the user to modify the Alarm Hold-Off Delay Time after exiting a Probe Off condition. This parameter is factory set but can be adjusted to eliminate nuisance alarms. After a Probe Off condition, the Low SpO_2 Alarm will be delayed for five seconds to allow the oximeter reading to stabilize. Values: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, Off Standard value: 5
Date Format Selection	DATE FORMAT	This parameter allows the user to display the date in either U.S. or international formats. Values: MONTH/DAY/YEAR, 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 38,400 BPS. This setting should not be changed unless directed to do so by Philips Children's Medical Ventures Customer Service.
Modem Speed - Host	MODEM SPEED – HOST	The default setting is 115,500 BPS. This setting should not be changed unless directed to do so by Philips Children's Medical Ventures Customer Service.
Embedded Software Revision	SOFTWARE REVISION	Display-only menu. Displays the revision of the Embedded Application Code.
Maintenance Mode Software Revision	MMODE SW REVISION	Display-only menu. Displays the revision of the Maintenance Mode Code.
Boot Block Software Revision	BBLK SW REVISION	Display-only menu. Displays the revision of the Boot Block Code.
Oximeter Central Processing Unit Software Revision	OX CPU SW REVISION	Display-only menu. Displays the revision of the Oximeter CPU Code.

Menu Option	LCD Display	Description of Option or Instructions
Oximeter Digital Signal Processor Software Revision	OX DSP SW REVISION	Display-only menu. Displays the revision of the Oximeter Digital Signal Processor Code.
Serial Number	SERIAL NUMBER	Display-only menu. Displays the Serial Number.
Language Selection	SELECT A LANGUAGE	Permits the selection of seven languages for displaying the LCD menus. Standard value: ENGLIS

View Menu Mode

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

- Press the POWER button. After a short delay, the display will read:

  INITIALIZING PLEASE WAIT

  Then,

  MENU MODE? ENTER PROPER KEY SEQUENCE
- Press the following keys in the following sequence within 10 seconds:
- Press the ENTER button once.
- Use the ▲ ▼ Up and Down arrow buttons to scroll through the menus.

NOTE: The caregiver can download monitor data to a Memory Card using the View Menu but cannot make any changes to the settings in the monitor.

Using Auxiliary Equipment

There are four auxiliary channels available on the monitor. These channels provide the mechanism for connecting external devices to the monitor. All External Devices must interface to the monitor via the Auxiliary Interface Box, P/N H4010. The output of these devices must be within the range of –1.25 to +1.25 volts.

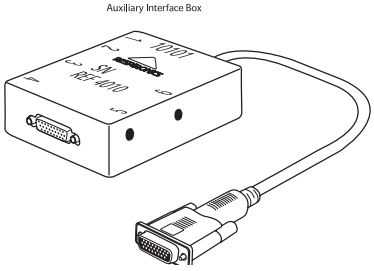
NOTE: Setup of auxiliary channels can be done only through the Synergy-E software. Refer to the Synergy-E Manual for more information.

The SmartMonitor 2 PS is programmed with 15 signal definitions to interpret the auxiliary signals it receives. For each of the four 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 monitor.

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 monitor.

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



NOTE: 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 monitor's menu. For example, if you wish to record additional SpO_2 and Pulse channels, you would need two auxiliary cables and this will use two auxiliary channels.

Information required to set up or change the "definition" includes the devices voltage and value range. This information must come from the manufacturer of the device.

Using Nurse Call Equipment

WARNING: The Nurse Call feature of this device is for convenience only in hospital environment. The audible indication provided by the Nurse Call system is not to be relied upon as the primary indication of the operating state of the device or of patient events.

WARNING: The Nurse Call feature should be considered a backup to the monitor's primary alarm system. The operator should not rely solely on the Nurse Call feature.

WARNING: Before making any connection to the rear-panel Nurse Call connector, the operator must verify that the equipment being connected does not exceed SELV (Safety Extra Low Voltage) levels as described in EN60601-1.

Interface of the monitor with a Nurse Call system is possible via the jack located on the rear panel of the monitor. Use of a standard 3.5mm stereo phone plug is sufficient for this procedure. Two sets of relay contacts (one Normally Open and one Normally Closed) are available via the three contacts of the stereo phone plug. These contacts are as follows: tip-NO, ring-NC and sleeve-Common.

The monitor relay is de-energized when the monitor is OFF, or when the monitor is ON and an alarm condition exists. The relay is energized when the monitor is ON and no alarm condition exists. The appropriate set of relay contacts for interfacing varies based on the make and model of the Nurse Call system used.

The following table summarizes the Nurse Call relay status based on the operating condition of the monitor:

Monitor Status	Relay Status
Monitor OFF	De-energized
Monitor ON Monitoring Mode No Alarm Condition	Energized
Monitor ON Monitoring Mode Continuous Alarm Condition	De-energized
Monitor ON Monitoring Mode 1 beep/second Alarm Condition	De-energized & Energized once per second
Monitor ON Monitoring Mode 2 beeps/second Alarm Condition	De-energized & Energized twice per second
Monitor Shut Down Due to Error	De-energized
Monitor ON Menu Mode	Energized but De-energized briefly every 10 seconds
Monitor ON Communication Mode	Energized but De-energized briefly every 10 seconds

Patient Setup

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

- Ensure Memory has been cleared prior to delivery to new patient.
- Review use of the monitor and its accessories with the caregiver(s). Be sure to perform the Functional Self-Test. A self-test should be performed weekly or whenever lead wires or ECG 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 monitor on a Clean, Flat Surface.

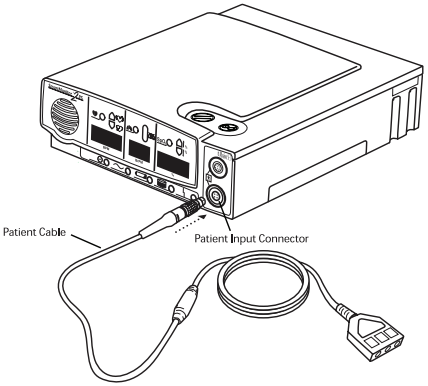
- Be sure the speaker is not blocked.
- To avoid interference, be sure that no other electrical appliances are within three feet of the monitor, patient, and patient leads.
- Make sure the monitor is close enough to connect to the patient comfortably.

WARNING: The monitor should not be placed in bed with the patient.

Step 2: Connect the ECG Patient Cable to the monitor.

- Insert the round end of the ECG patient cable into the bottom round connector found on the front of the monitor.
- Line up the notch on the connector and push until you feel the connector snap into place.
- To remove the ECG patient cable, grasp it at the base of the patient input connector and gently pull straight back. You should feel the outer sleeve slide back and unlock the connector as you pull.

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

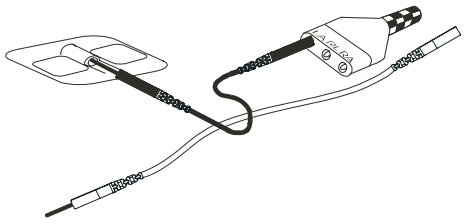


WARNING: The ECG patient cable should not be placed over the top of the crib rail. The cable should be placed between the vertical bars.

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

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

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

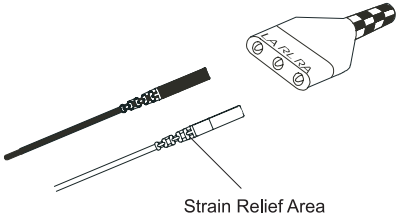


WARNING: When you need to remove a lead wire, grasp and pull at the strain relief area located near the connecting tip. Do not grasp the wire.

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

Step 4: Connect the Lead Wires to the Electrodes.

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



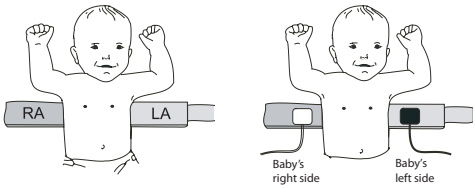
NOTE: Refer to the section "Disposable Self-Adhesive Electrodes" if using this type of electrode.

NOTE: The 3M Red Dot ECG Electrode is compatible for use with the SmartMonitor 2 PS.

NOTE: For electrode belt instructions (infant use only), follow Step 5. For self adhesive electrodes, follow Step 6.

Step 5: Attach the Electrodes to the Infant Belt (Infants Only).

- Place the electrode belt on a flat surface.
- Lay the patient on the belt so the belt is aligned with the patient's nipples (see illustration below).
- Place the electrodes, Velcro®-side down, on either side of the belt as follows:
  - Place the electrode with the white lead wire (RA) on the patient's right side.
  - Place the electrode with the black lead wire (LA) on the patient's left side.



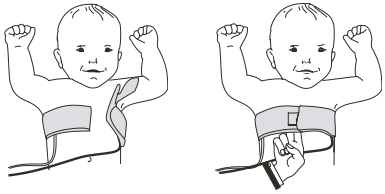
- Place the electrodes far enough apart so that when the belt is wrapped around the patient, the electrode will be located along the mid-line of the side just below or lined up with the nipples.

WARNING: Be sure the lead wires and ECG patient cable are leading down and away from the patient's face and neck (see illustration below).

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

- Wrap the belt around the patient's chest and fasten it with the Velcro tab.
- The belt should be snug enough so that you can only insert two of your fingers (with your hand lying flat against the patient) between the belt and the patient.

NOTE: For 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.



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

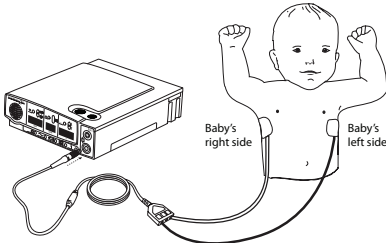
Step 6: Attach the Self Adhesive Electrodes

a. Follow the steps below if you are using disposable electrodes on an infant.

- Attach the lead wire to the Self Adhesive Electrodes if not pre-attached.
- Ensure the patient's skin is clean and dry.
- Place the electrode with the white lead wire on the patient'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 patient'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.

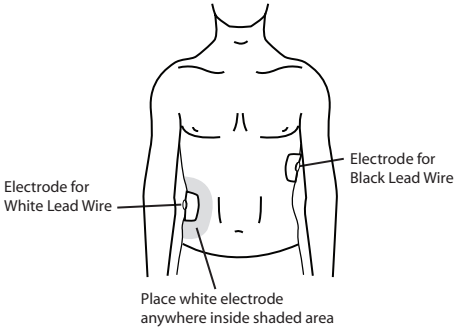
NOTE: Use of the third (green - RL) electrode and lead wire is normally not required but may help reduce excessive false low heart rate alarms. Place the green electrode along the outside of the patient's upper thigh.

WARNING: Do not use oils, lotion, or powder on the area of skin that the electrodes will be placed, false alarms may result.



b. Follow the steps below if you are using disposable electrodes on an adult patient: (Hospital Use Only)

- Attach the lead wires to the Self Adhesive Electrodes (if not pre-attached).
- Ensure the patient's skin is clean and dry.
- Place the electrode with the white lead wire on the patient's right side, under the armpit near the lower portion of the rib cage, as shown in the illustration below.
- Place the electrode with the black lead wire on the patient's left side, under the armpit and in line with the nipples, as shown in the illustration below.



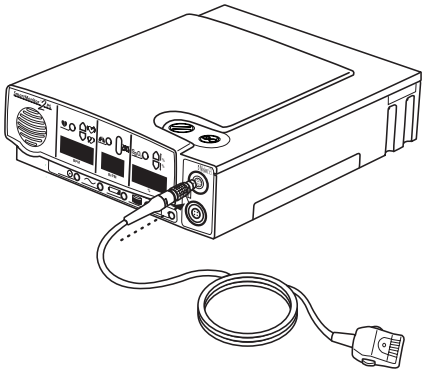
Step 7: Connect the Oximeter Patient Cable to the monitor.

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

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

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

NOTE: If the oximeter patient cable or probe is not connected when the monitor is turned on, the % (percent) display will show OFF and SpO_2 alarms will not sound. If the oximeter patient cable is connected while the monitor is on, the SpO_2 function will resume normal operation from that point forward, including SpO_2 alarms.



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

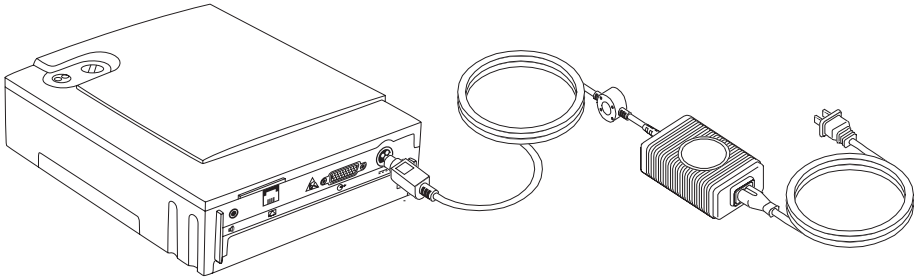
The following Masimo sensors are compatible for use in monitoring patients' SpO_2 levels:

- LNOP NeoPt – Neonatal Preterm Single Patient Use Adhesive Sensor (indicated for use with patients weighing < 1kg) (1000 grams)
- LNOP Neo – Neonatal Single Patient Use Adhesive Sensor (indicated for use with patients weighing < 10 kg) (10,000 grams)
- LNOP Pdt – Pediatric Single Patient Use Adhesive Sensor (indicated for use with patients between 10 and 50 kgs (10,000 to 50,000 grams)
- LNOP YI Multi-site Reusable Sensor with Standard Wrap (indicated for use with patients weighing > 1 kg (1,000 grams))
- LNOP Adt - Adult Single Patient Use Adhesive Sensor (indicated for use with patients weighing > 30 kg (30,000 grams))
- LNOP YI Multi-site Reusable Sensor with Standard Petite Wrap (indicated for use with patients weighing > 1 kg (1,000 grams))

Please see the instructions packaged with the sensors for placement directions.

Step 9: Connect the Power Cord/Battery Charger.

- Insert the connector of the power cord/battery charger into the socket on the back panel of the monitor (see illustration below). The flat side of the connector faces upward.
- Push until the connector is fully inserted into place. A gentle tug on the connector will confirm that it is locked in place.
- Plug the power cord/battery charger into the power supply, and then plug the power cord into a power outlet. The green charger light on the monitor will now come on.
- To remove the power supply from the monitor, grasp the power supply connector at the base of the connector and gently pull back. You should feel the connector body slide back and unlock the connector as you pull.



WARNING: Do not use the device if the power cord is damaged. Contact Philips Children's Medical Ventures.

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

NOTE: When the monitor is not operating portably, keep the power cord/battery charger connected and plugged into an AC outlet at all times. Ensure that the AC outlet has been installed to conform to the National Electrical Code. The batteries cannot be overcharged. The green charger light stays on as long as the charger is connected.

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

NOTE: If you see an alarm with an error code of 1A00, or if an alarm cannot be silenced, it may be related to the redundant battery system. See "Troubleshooting" later in this manual to correct the problem.

Hospital Mode

The monitor's Hospital Mode Control parameter is set to NO when it comes from the factory. This control enables the features of Hospital Mode, specifically:

- elimination of the sibling protection mechanism
- silence alarm feature for patient alarms
- alarm setpoint review at power on.

To make changes to this parameter, refer to the section "System Setup Menu" earlier in this manual.

If the monitor is going to be used in a home setting, make sure that the Hospital Mode Control parameter is set to NO.

NOTE: Monitors equipped with the Hospital Alarm feature will have the parameter set to YES when they come from the factory.

PATIENT ALARM

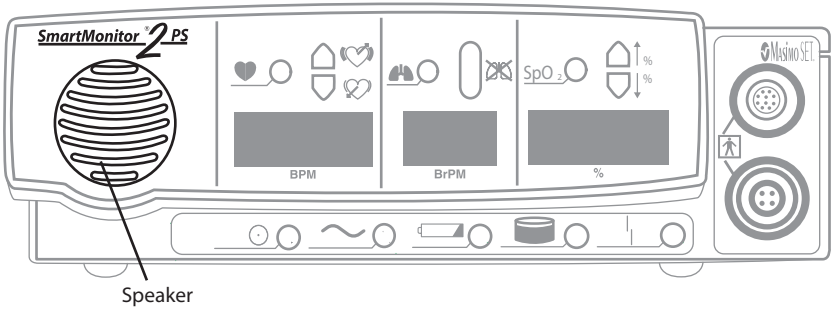
A Patient Alarm indicates that the patient's breathing, heart activity or oxygen saturation is outside the limits prescribed by the physician. The information in this section can help you respond appropriately to patient alarms. Read this section carefully. If you have any questions, please contact Philips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

TESTING THE ALARM

Before you use the monitor, test to determine 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. Do not place the monitor in the bed with the patient or direct the speaker toward the patient.

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



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

If an Alarm Sounds

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

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

Light	Alarm	Check Patient's Condition	Respond like this
Red Low SpO_2 ↓ %	Intermittent (1 beep/sec.)	Skin color is pale or blue. Patient is not breathing or choking. Skin color is pale or blue. Patient is breathing. If patient is receiving supplemental oxygen.\ Skin color is pink, patient is breathing.	• Use the response under apnea/low heart rate above. • Observe the patient closely and respond as instructed by the physician or in your CPR class. If the condition does not improve, notify the physician or EMS. • Check the oxygen cannula and oxygen delivery device. Increase oxygen as ordered by physician. • Notify physician or EMS immediately if condition does not improve or recurs frequently. Record alarm on log sheet. • Wait a few seconds. Watch to determine if the patient's breathing and color remains normal. If alarm continues, see the section "Reducing False Alarms." Check sensors.
Red High SpO_2 ↑ %	Intermittent (2 beeps/ sec.)	Skin color is pink, patient breathing.	• Note alarm on the log sheet and report to the physician as instructed.

Light	Alarm	Check Patient's Condition	Respond like this
Yellow Loose Lead	Continuous	Patient is breathing and is responsive. Color is good.	• Check the connections between the electrodes, lead wires, ECG patient cables, and monitor. • If something has come loose, reconnect it and press the RESET button. The alarm should stop. • If the alarm continues to sound, see the section "Performing a Functional Self Test." If the monitor passed the Functional Self-Test, turn off the monitor. Then, check the following items: • The patient's skin – Make sure that where the electrodes are placed is clean and free from oil, lotions, powder and perspiration. • Check the connections between the electrodes, lead wires, patient cable, and the monitor. • The electrodes – They should be clean and there should be no cracks on the surface. • The electrode belt – Make sure it is snug and is keeping the electrodes in place. • If something has come loose, reconnect it and press the RESET button. The alarm should stop.
Red SpO_2 Light **SpO_2**	Continuous	Color is good. Patient is breathing and is responsive.	• Check the connections between the SpO_2 probe, oximeter patient cable and monitor.

NOTE: Patient alarms cannot be silenced with the RESET button except when the hospital mode control parameter is set to "yes." 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 system alarm occurs, one of the lights at the bottom of the front panel will come on.

If this light is on	And this condition exists	It means...
Power ⊙	Continuous green light, no alarm.	Normal Operation. The green power indicator light will come on and stay on for as long as the monitor is on.
Charger ~	Continuous or blinking green light, no alarm.	Normal Operation. The green charger light will come on and blink when the battery is charging and stay on when the battery is fully charged while the battery charger is plugged into an active outlet and connected to the monitor.
Low Battery ▭	Flashing yellow light, continuous alarm. Continuous yellow light, continuous alarm.	This is a warning that the battery voltage is very low and should be recharged soon. (See the section "Charging the Monitor's Battery" later in this manual.) Press the RESET button to temporarily silence the alarm. The alarm will resound in 2 minutes if the monitor has not been plugged in. The yellow light will continue to flash. This is a warning that the battery is too low for the monitor to operate properly. The monitor must be recharged. Turn the monitor off. Then, recharge the battery. (See "Charging the Battery" in this manual). If you do not recharge the battery, the system will automatically shut down.
Memory Full ⛁	Flashing yellow light, continuous alarm. Flashing yellow light, no alarm.	When the monitor's Memory Almost full parameter is reached, the Memory Full light will flash. The alarm will sound continuously. The alarm will sound only if the monitor has been programmed to do so at the 50% full or at 80% full. Press the RESET button to silence the alarm. The light will blink every second. *NOTE: Memory Full is a warning condition. You can continue monitoring. However, you should download the memory to resolve the alarm.* *NOTE: The Memory Full alarm will sound each time the monitor is powered on.*

If this light is on	And this condition exists	It means...
Memory Full	Continuous yellow light, continuous alarm. Continuous yellow light, no alarm.	The monitor's memory is 100% full. Press the RESET button to silence the alarm. The light will stay on continuously. You must transfer data when you get a memory 100% full condition. (See "Transferring SmartMonitor 2 PS Memory" in this manual for more information.) *NOTE: The alarm will sound only if the monitor has been programmed to do so.*
Loose Lead	Continuous yellow light and continuous alarm	The yellow loose lead light and the alarm may sound continuously when there is a problem with any of the following: • Lead wires • Electrodes • Electrode belt • ECG Patient cable, or • Connections between the patient's skin and the electrodes, the lead wires, the patient cable(s), and the monitor.
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 bottom panel display for error messages. If no error messages are displayed, the monitor was turned off improperly causing a sibling alarm. To resolve: Press and hold the blue RESET button. Press and release the gray POWER button. Wait two seconds then release the RESET button.
All	All lights are blinking and the alarm will come on for three seconds and then off for one second.	Check the bottom LCD 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. If not contact Philips Children's Medical Ventures for service.
SpO_2 SpO_2	Continuous red light and continuous alarm (if enabled)	Check that the SpO_2 probe has not become dislodged from the patient or that the probe has not been disconnected from the monitor or oximeter patient cable. If you correct the problem, the alarm will stop. However, the red light remains on until you press the RESET button.

NOTE: When the Hospital Mode Control parameter is set to YES, the Silence Alarm feature is enabled. This allows the user to silence the audible alarm for 60 seconds when the alarm is being caused by a physiologic event(s). The user can silence the alarm by pressing the RESET button. If the physiologic event(s) is still active after 60 second(s), the alarm will sound again. This feature only affects the audible portion of the alarm. The front panel indicators are not affected.

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 patient, 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 patient's skin prior to electrode belt placement.
- When using the black reusable electrodes, ensure that the electrode surface is clean.
- Use of the third (green - RL) electrode and lead wire is normally not required, but may help reduce excessive false low heart rate alarms. Place the green electrode along the outside of patient's upper thigh.
- Check for correct placement of the SpO_2 (oxygen) sensor.
- Verify that the appropriate SpO_2 (oxygen) sensor is used for the patient's weight.

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

TURNING THE MONITOR ON

After you have properly set up the monitor, and learned how the monitor functions and how to respond to alarms, you can begin monitoring the patient's breathing, heart activity and SpO_2 level according to the schedule prescribed by the physician.

Push the POWER button. The monitor performs a system check. The lights on the front of the monitor will come on briefly and the audible alarm will beep twice. Within 10 seconds, the green respiration, heart, and SpO_2 lights will begin to blink. If the lights do not blink, check that you have attached the electrode belt or electrodes properly to the patient, the lead wires are pushed in, and that cables are connected. Once the patient is properly connected to the monitor and the power is on, the following should occur:

- The green (battery) charger light is on (if the monitor is plugged into an AC outlet).
- The green power light is on.
- The green respiration light, green heart light, and green SpO_2 light are blinking.
- All other lights should be off.
- If the lights do not blink, refer to the steps found in "Home Setup" earlier in this manual. Be sure you have followed all instructions.

NOTE: If the Hospital Mode Control and front panel parameter are set to YES, then each of the following will appear briefly on the front panel display during startup:

- After all the lights have turned on and the audible alarm has sounded briefly, the Apnea Alarm LED will light up and value of the Apnea System parameter will appear above BrPM on the front panel display.
- The Bradycardia (low heart rate) Alarm LED will light up and the value of the Bradycardia System Parameter will appear above BPM on the front panel display.
- The Tachycardia (high heart rate) Alarm LED will light up and the value of the Tachycardia System Parameter will appear above BPM on the front panel display.
- The Low SpO_2 Alarm LED will light up and the value of the Low SpO_2 System Parameter will appear above SpO_2 on the front panel display.
- The High SpO_2 Alarm LED will light up and the value of the High SpO_2 System Parameter will appear above SpO_2 on the front panel display.

Turning the Monitor off - Sibling Alarm

The SmartMonitor 2 PS has a built-in safety feature called a sibling alarm. If the monitor is not turned off in a specific sequence, the green power light will remain on and the alarm will sound continuously. This safety feature makes sure the power is not accidentally turned off. To turn the monitor off:

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

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

- Press 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.

NOTE: If the Hospital Mode Control parameter is set to YES, then the Sibling Alarm feature is disabled. You may turn the monitor on and off by pressing the POWER button.

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

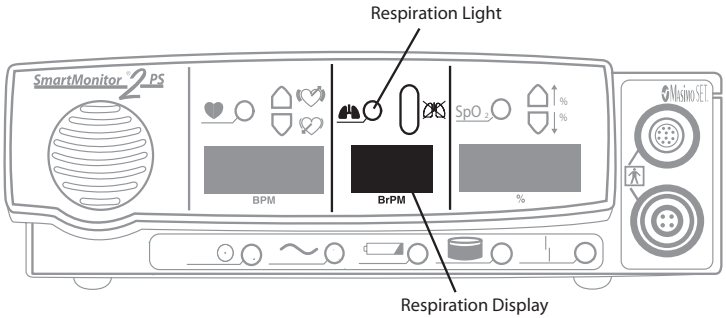
- Press and hold the RESET button. While still holding down the RESET button, press and hold the POWER button. Hold both buttons down for 5 seconds.
- Release POWER button; continue to hold the RESET button until the monitor turns off.

Monitoring Breathing

Respiration Light/Display

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

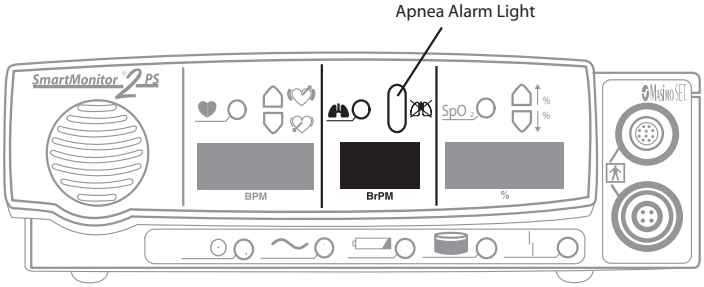
The patient's average respiration rate will appear on the front panel display above BrPM when the display feature is enabled.



Apnea Light

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



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

Low Breath Rate

If the monitor is programmed to detect Low Breath Rate, the following will occur:

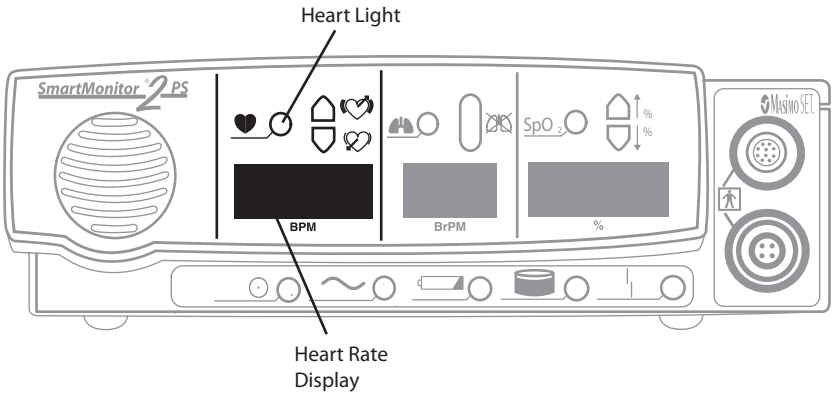
- If the breath rate falls below the setting but pauses are short and do not cause an apnea alarm, the apnea light will blink twice each second and the alarm will beep once each second.
- During a Low Breath Rate alarm, if the monitor detects a pause in breathing longer than the limit set by the physician, the apnea light will change from flashing to constant.

WARNING: If apnea alarms continue, and the patient is breathing normally, verify lead placement or check for low amplitude respiration and contact Philips Children's Medical Ventures immediately.

HEART RATE LIGHT/DISPLAY

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

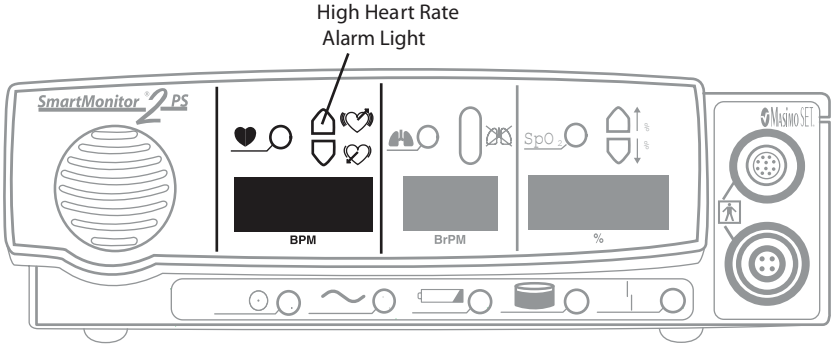
The patient's average heart rate will appear on the front panel display above BPM when the display feature is enabled.



HIGH HEART RATE LIGHT

The monitor determines if the patient's heart rate is higher than the limit prescribed 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.

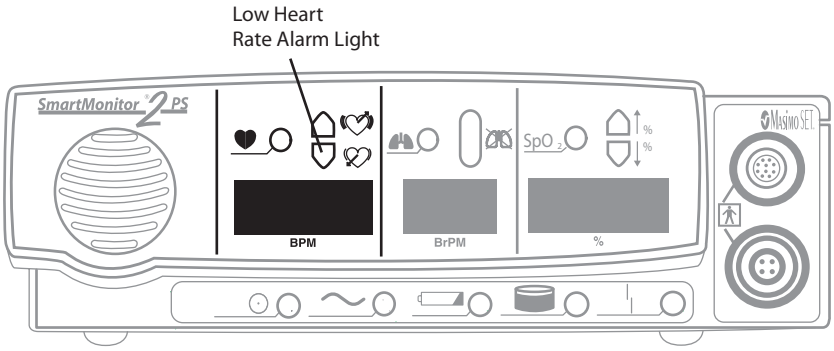


NOTE: The red light stays on until you press the blue RESET button.

Low Heart Rate Light

When the monitor determines that the patient's heart rate is lower than the limit prescribed 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.



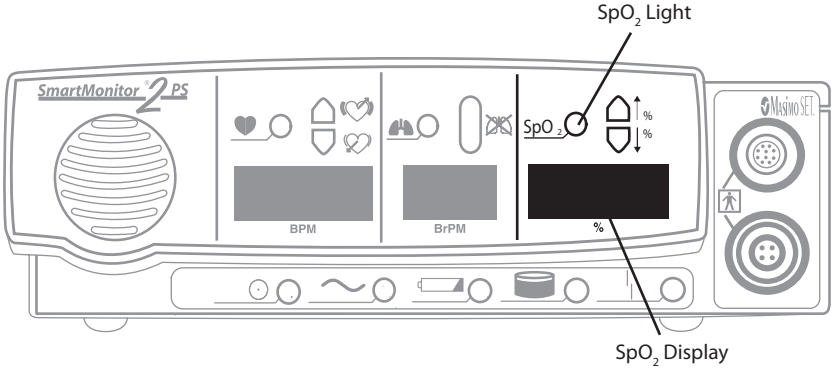
NOTE: The red light stays on until you press the blue RESET button.

Monitoring the Patient's Oxygen Concentration Level

SpO2 Light %

The green SpO_2 light will appear solid when the probe is connected to the patient and a strong signal is detected. A solid orange light will appear if the device is monitoring the SpO_2 level with a moderate signal. If the probe is disconnected or not transmitting a signal, a red SpO_2 light will appear.

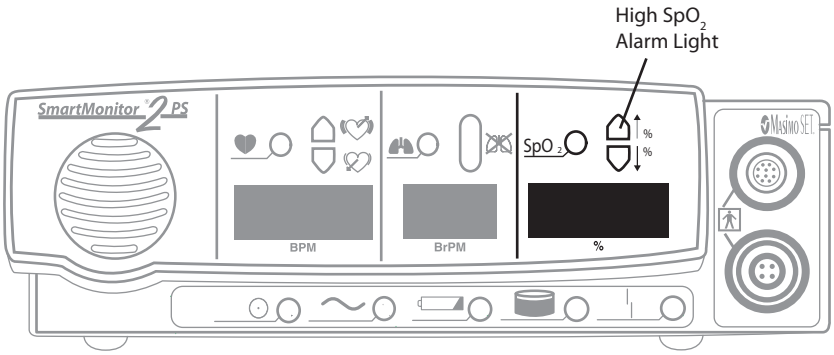
The patient's average SpO_2 level will appear on the front panel display above % when the display feature is enabled.



High SpO_2 Alarm Light ↑%

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

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

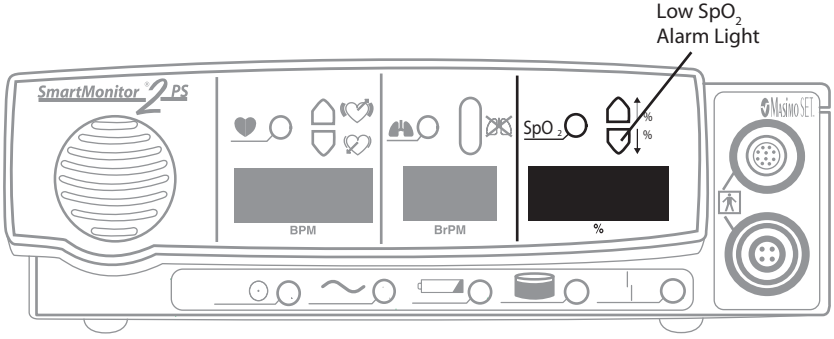


NOTE: The red light stays on until you press the blue RESET button.

Low SpO_2 Alarm Light ↓%

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

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



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

Portable Operation of the SmartMonitor 2 PS

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

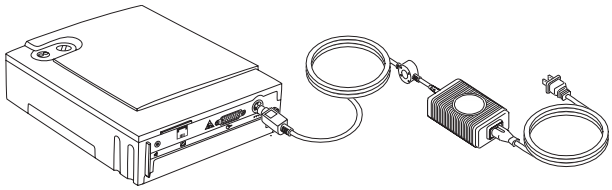
Philips Children's Medical Ventures recommends that the monitor be used with the power cord/battery charger whenever possible. However, when the monitor is used without the power cord/battery charger the monitor is fully functional. All alarms are operational. With a fully charged battery, the monitor will run for 15 hours with the oximeter off. Please note that the front panel display (if enabled) will be dimmed to conserve battery life, and you will not be able to adjust the brightness in this mode. The amount of time to completely recharge a fully depleted battery is 8 hours.

SmartMonitor 2 PS includes a redundant battery system. A rechargeable battery pack and two AAA alkaline batteries are located in the battery compartment. If there is a failure in the rechargeable pack, the AAA batteries generate an alarm. If the rechargeable pack is nearly completely discharged, the alarm will also sound. This may occur when the battery pack is first installed in a new monitor or if a monitor is unused for two months or longer. Always unplug the battery pack cable is you are not going to use the monitor for an extended period of time. This prevents unnecessary alarms upon future reconnection.

Charging the Monitor's Battery

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

- Insert the connector of the power supply into the socket on the back panel of the monitor. (See illustration below.) The flat side of the connector faces upward.
- Push until the connector is fully inserted into place. A gentle tug on the connector will confirm that it is locked in place.
- Plug the power cord/battery into a power outlet.
- The green charger light comes on solid if the battery is fully charged or blinks when the battery is charging.
- If the monitor is turned on, the yellow low battery light blinks until the minimum charge level is reached. Then, the yellow light goes off
- To remove the power supply from the monitor, grasp the power supply connector at the base of the connector and gently pull back. You should feel the connector body slide back and unlock the connector as you pull.



NOTE: Fully drained batteries need about 8 hours to recharge.

SmartMonitor 2 PS Battery Pack

Warnings

- Never change the battery pack while the power supply is plugged in and/or the monitor is being operated.
- 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.
- Do not disassemble or modify the battery. The battery contains safety and protection devices that, if damaged, may cause the battery to heat, rupture, or ignite.

Cautions

- 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 Philips Children's Medical Ventures-supplied battery packs. Use of other battery packs could cause malfunction.
- When the battery is worn out, insulate the terminals with adhesive tape or similar materials before disposal.

Battery Installation Instructions

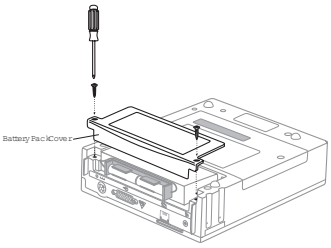
The monitor uses two types of batteries. Rechargeable batteries are used for power during portable operation. Alkaline batteries provide a back-up alarm function if the rechargeable batteries fail. The rechargeable batteries are contained inside a battery pack. Two alkaline, size AAA, batteries are placed into a AAA holder located on the side of the rechargeable pack.

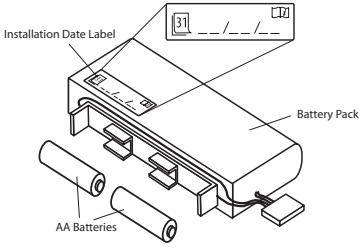
NOTE: Before installing a new or replacement battery pack, write the installation date on the label provided on the battery pack.

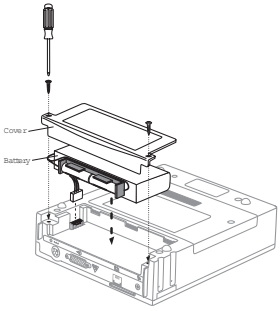
1. Turn the monitors' power off using the correct Power-off procedure, and unplug the external power supply from the monitor.
2. Loosen (counter clock-wise) both screws from the battery pack cover and remove the cover.

3. To remove the battery pack, pull firmly upward when lifting the 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 batteries in accordance with your area's environmental laws.
4. Insert the alkaline batteries into the AAA holder. The correct polarity is marked on the AAA holder.
5. Insert the connector of the new battery pack into the plug located in the upper left corner. It can only be inserted one way. Place the battery pack in the battery compartment. Secure the battery pack properly.
6. Close the battery pack cover and fasten with the screws. Connect the external power supply to the monitor and ensure that it is plugged into a functional AC wall outlet for a minimum of 8 hours. There is no need to power on the monitor to charge the battery pack.

NOTE: The expected rechargeable battery life is two years. The alkaline batteries should be replaced at least once each year to ensure their function, if needed, for backup in the case of a battery pack failure. When you turn on the monitor and an error code of 1A00 is displayed on the LCD, the AAA batteries may need to be replaced. See "Troubleshooting" later in this manual.







NOTE: If you plug a discharged battery pack into a new or recently stored monitor, it will alarm continuously with no lights. Unplug the battery pack and follow the steps to correct the problem in "Troubleshooting" later in this manual. If you are not going to use the monitor for an extended period of time (longer than two months), unplug the battery pack cable.

Transferring SmartMonitor 2 PS Information

The monitor contains a memory system that automatically records information about each monitoring session. This information can be transferred (or downloaded) to a computer to be reviewed by 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. Additionally, you may choose to transfer data at any time or whenever it is considered necessary by the physician.

Memory Management in the Monitor

When data is successfully transferred to a Memory Card or downloaded to Synergy-E, the data appears to be erased in the monitor. 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. 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 monitor has collected new data and needs the space occupied by the old data.

It is recommended that you erase the memory between each patient use. Please note that this feature will not clear the system parameter settings (alarm and record limits) or the patient name and ID number.

Using the "Clear Memory" function in the System Parameters menus will erase all data regardless of whether or not it has been downloaded.

To Recover the Old Data Using a Memory Card

Transfer the data to the card using the monitor. 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 monitor.

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 monitor.

Modem Download

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

There are three ways to download with a modem. The first choice involves the modem automatically calling the homecare 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. The patient is not monitored while the device is in Communications mode. When the homecare provider calls the patient's phone number, the device will automatically answer and begin transfer of data.

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

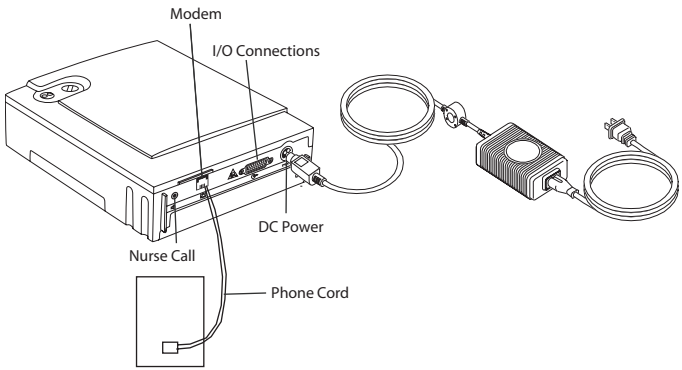
Modem Auto Dial

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

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

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

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



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

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

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

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

Modem Auto Answer in Communications Mode

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

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

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

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

   - The homecare provider should now call to retrieve the information. The phone may ring, but do not answer. The modem answers the call and connects the monitor to the computer through the phone line.
3. The amount of time to transfer the information will vary. When the transfer is complete the monitor will beep five times. After the transfer, you may disconnect the phone line from the monitor and the phone will work normally. Turn the monitor off in the normal way.
   - Press and hold the blue RESET button.
   - Press and release the gray POWER button.
   - Wait two seconds, and then release the RESET button.
   - You can now resume monitoring the patient.

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

Modem Auto Answer in Monitor Mode

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

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

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

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

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

Transferring Monitor Data to a Memory Card

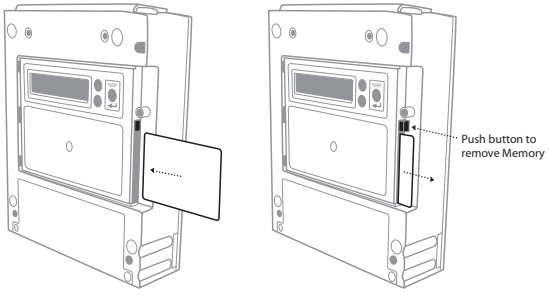
The Memory Card is a credit-card-sized electronic memory transfer device that transfers monitor data. This is an optional feature of monitor and may not be installed on every unit.

NOTE: You may also use a compact flash card with a Memory Card adapter.

NOTE: All data in the Memory Card at the time of a download will be overwritten. For more information, refer to the section "Setting Alarms and Recording Limits" earlier in this manual.

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

1. Make sure the monitor is off.
2. With the Memory Card label facing you, slide the card into the slot provided on the side panel of the monitor. The location of the Memory Card logo will be on the bottom edge and facing you.



3. Press the POWER button ON. After a short delay, the display will read:

   INITIALIZING PLEASE WAIT

   Then,

   MENU MODE? ENTER PROPER KEY

   SEQUENCE

4. Press the ENTER button within 10 seconds.

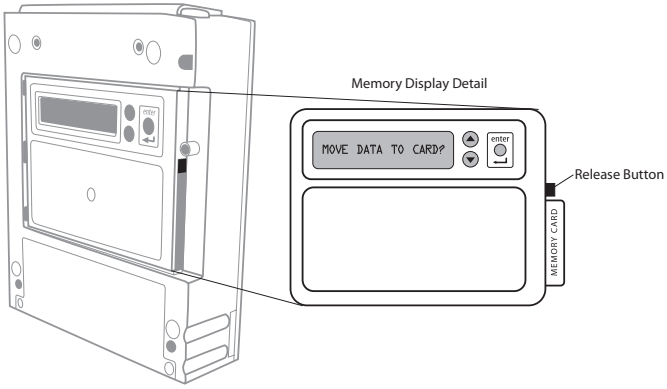
   The display will read SMARTMONITOR 2 MENU

   SELECTION.

5. Press the ▼ arrow until you see “Move Data To Card?”
6. Press the ENTER button. The word NO will begin to blink. To select YES, press either arrow button.
7. 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 steps 1-6.

- 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.”



NOTE: The memory in the monitor will not be automatically cleared. The recorded data in the monitor 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 Monitor Data Using a Computer

Data can be downloaded from the monitor by direct connection to a computer.

The Synergy-E software is required to download the monitor.

The monitor 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 monitor and the computer before turning the monitor 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 monitor 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 monitor display will read "Monitor is in Communication Mode".

- The monitor 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 monitor is powered on for working with the computer, Memory Card, or modem but not for monitoring the patient.

NOTE: Refer to the Synergy-E software for instruction on Direct Connection Downloading of the monitor.

Caring for the SmartMonitor 2 PS

CAUTION: Use the information in this section to keep the monitor functioning well.

CAUTION: Use only Philips Children's Medical Ventures accessories with the monitor.

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, Patient Cables and Lead Wires

Use a clean cloth and any of the following:

- Unscented dish washing detergent
- 3% hydrogen peroxide solution
- 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.
- Ensure 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.
- Philips Children's Medical Ventures 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. Fumigating a Roach/Insect-infested Unit
   - Place the unit inside a Zip-lock type 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 power supply 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 dish washing detergent or 3% Hydrogen Peroxide solution to clean the outside of the monitor.
   - If necessary, return the unit to Philips Children's Medical Ventures 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 monitor's 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 a patient cable is changed.

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

1. Insert the ECG patient cable into the socket located on the front of the monitor.
2. Connect the lead wires to the ECG patient cable. Insert the white lead wire into the opening labeled RA. Insert the black lead wire into the opening labeled LA.
3. Connect the lead wires to the functional self-test socket on the side panel of the monitor. Insert the white lead wire into the RA opening and then the black lead wire into the LA opening.
4. Insert the SpO_2 patient cable into the socket located on the front of the monitor. Connect the SpO_2 sensor to the patient cable and place the sensor over your finger.
5. Turn on the monitor. You hear two short beeps and the lights on the front come on briefly then go off.
6. After all the alarm lights go out, the green power and charger lights remain on and the green heart and respiration lights are blinking. All numeric displays will begin displaying values.
7. The heart and respiration lights continue to blink for about 30 seconds.
8. When the green lights stop blinking, the red low heart light will come on within about seven seconds and the alarm beeps once every second.
9. 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 (infants only). (There should be no green heart or respiration light flashes during this time).
10. Remove the SpO_2 sensor from your finger. The SpO_2 light will turn red and the SpO_2 display will show dashes.
11. Reapply the SpO_2 sensor to your finger.
12. Follow the instructions in the "Self-Test Troubleshooting" section, if necessary.
13. 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.
14. The loose lead light will come on, and the alarm changes from beeping to continuous. This lets you know the monitor, patient cables, and lead wires are working properly.
15. 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 occurs. 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 section "Turning the Monitor Off – Sibling Alarm" earlier in this manual. • Make sure the power supply is plugged into a live power outlet and is properly connected to the monitor. (See "Charging the Battery" for more information). • 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 eight hours before using the monitor on battery power.
Memory Full	The monitor's memory has reached the Memory Full parameter. Press the RESET button to silence the alarm. The monitor's memory needs to be transferred Self-Test may continue.
Loose Lead	Indicates loose or bad electrodes, lead wires, and/or patient cable. Check all connections and/or replace lead wires first, then the patient cable(s) if necessary.

WARNING: The monitor's lights and alarms should respond as described above. If not, contact Philips Children's Medical Ventures Service before using the unit to monitor a patient.

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

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 monitor.

The table below lists some common problems:

Problem	Possible Cause	Instructions
Monitor will not turn on	The monitor is disconnected from the power cord/battery charger; batteries are discharged. No Power at outlet. Defective power cord/battery charger. Internal part failure.	Plug the power cord/battery charger into the monitor and outlet. Locate an outlet with power. Contact Philips Children's Medical Ventures. Contact Philips Children's Medical Ventures.
All lights will flash together and the alarm will beep in unison with the flashing lights. Pressing RESET will not silence alarm. 0001 displayed on bottom LCD display. 1B01 displayed on bottom LCD display.	Internal error condition was detected by the monitor or Battery not connected or Internal failure with monitor.	Reduce likelihood of electrostatic discharge around the monitor. or Contact Philips Children's Medical Ventures If an Error number is displayed on the LCD (the LCD is located on the bottom of the monitor), record this information. Contact Philips Children's Medical Ventures. 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 five seconds • Release POWER button; continue to hold the RESET button until the monitor turns off.

Problem	Possible Cause	Instructions
1A00 or 1A01 displayed on bottom LCD display.	Problem with AAA batteries; try replacing them.	• Open the battery compartment, unplug the battery pack, and replace the AAA batteries. • Plug the power supply cable into the monitor and the power supply cord into the AC outlet, then connect the battery pack cable to the monitor. When you turn the monitor on, the error code should not appear. If these steps do not resolve the problem, contact Philips Children's Medical Ventures Customer Service.
Alarm Sound Continuous, No Lights	A discharged battery pack is plugged into a new or recently stored monitor (i.e., the monitor has been unused for two months or longer). NOTE: SmartMonitor 2 PS includes a redundant battery system. There are a rechargeable battery pack and two AAA alkaline cells located in the battery compartment. The purpose of the AAA cells is to generate an alarm if there is a failure in the rechargeable pack (the alarm also sounds when the pack is nearly completely discharged). This can occur when the battery pack is first installed in a new monitor or in a monitor that has been unused for two months or longer.	Follow this sequence of steps exactly: • Unplug the battery pack. • Plug the power supply cable into the monitor and the power supply cord into the AC outlet. • Plug the battery pack cable into the monitor. If the above steps do not resolve the problem, contact Philips Children's Medical Ventures Customer Service. NOTE: If you are not going to use the monitor for an extended period of time, unplug the battery pack cable to prevent unnecessary alarms upon reconnection.
Alarm Sound Continuous, No Lights or 0001 displayed on bottom LCD display.	No power, battery drained or disconnected. or Battery not connected.	Ensure battery is connected. Connect power supply. Use Power-Off to silence alarm. • Press and hold the blue RESET button. • Press and release the gray POWER button. Wait two seconds, and 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 eight hours before using the monitor on battery power.

Problem	Possible Cause	Instructions
Alarm Sound Continuous, No Lights	Incorrect power-off sequence.	• Press the POWER button, and make sure that the power light is illuminated. • Press and hold the RESET button. Press and release the POWER button. Wait two seconds, then release the RESET button.
Alarm sounds weak or only one alarm tone is heard at Power Up.	Internal part failure or Low battery.	Contact Philips Children's Medical Ventures. Charge battery.
Loose lead or Light and front display remains on.	Connections between sensors, electrodes, lead wires, and patient cables are not properly made. or Defective lead wires or patient cable(s) or Defective electrodes or Internal part failure.	Verify that (a) patient's skin underneath electrodes is clean, (b) electrodes are clean, and (c) lead wires are fully inserted into the electrodes and ECG patient cable. Replace lead wires or patient cables and perform Functional Self-Test or Replace electrodes and Contact Philips Children's Medical Ventures.
SpO_2 light remains red or orange when connected to patient.	Connections between the sensor, oximeter patient cable and monitor have not been made properly or Defective Sensor.	Check all connections. Verify that (a) patient's skin underneath sensor is clean, (b) sensor is clean, and (c) sensor and oximeter cable connections are secure or Replace sensor.

Problem	Possible Cause	Instructions
Unable to download via modem.	AC power not connected to the monitor or The monitor is not connected to phone line or not connected to phone (wall) jack or Device power off or Incorrect modem selection on computer or Defective power supply, phone cord, or phone splitter.	Plug the monitor into AC power before performing a download, and verify that the charging light is on. or Connect phone line to monitor and to phone (wall) jack or Turn the monitor's power on, and verify that power light is on or Verify modem selection on computer or Replace power supply, replace phone cord, plug phone cord directly into phone (wall) jack.
Unable to communicate by direct connect.	Download cable was not connected to the monitor and the computer prior to turning on the monitor. Defective host cable. Incorrect COM port selection on computer.	Connect the download cable to the monitor and the computer before turning the monitor on. Replace host cable. Verify COM port selection on computer.

Specifications

Device Size

Dimensions:	2.25” x 7.25” x 9.0” (5.72 cm x 18.42 cm x 22.86 cm)
Weight:	3.0 lbs. (1.35 kg)
Shipping Weight:	8.5 lbs. (3.9 kg)

Electrical Ratings

Power Supply: 100-240 VAC 50/60 Hz 36W

SmartMonitor 2 PS: 12VDC, 3.0 Amps max.

Li Ion Rechargeable Battery Pack: 7.4 VDC, 4.4AH nominal

Environmental Conditions

Operating Temperature:	41º to 104ºF (5ºC to 40ºC)
Operating Humidity:	15% to 95% RH, non-condensing
Storage Temperature:	-4º to 140ºF (-20ºC to 60ºC)
Storage Humidity:	15 to 95% RH, non-condensing
Battery Charging Temperature:	50º to 95ºF (10ºC to 35ºC)

Standards Compliance

This device is designed to conform to the following standards:

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

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

The SmartMonitor 2 PS system is classified as follows:

Type of protection against electric shock: Class II/Internally Powered

Degree of protection against electric shock: Type BF Applied Part

Degree of protection against ingress of water: IPX1

Mode of operation: Continuous

Disposal

When necessary, dispose of the monitor in accordance with your local regulations. If you are subject to the WEEE/RoHS directives, refer to www.healthcare.philips.com for the passport for recycling this product.

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
	SpO_2 Range and Accuracy	1% to 100% (Display) 70% to 100% (Calibration) ± 3% (± 1 Std Dev) During No Motion Conditions Neonates: 70% - 100%±3 digits (± 1 Std Dev) Adults: 70% - 100%±2 digits (± 1 Std Dev) During Motion Conditions Neonates: 70% - 100%±3 digits (± 1 Std Dev) Adults: 70% - 100%±3 digits (± 1 Std Dev)
	Pulse Rate (BPM)	During No Motion Conditions Neonates: 25 to 240 ± 3 digits Adults: 25 to 240 ± 3 digits During Motion Conditions Neonates: 25 to 240 ± 5 digits Adults: 25 to 240 ± 5 digits
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
	High SpO_2	Off, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99%
	Low SpO_2	Off, 75, 80, 82, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95%
	Loose Connection	Base Impedance exceeds 2000 ±200Ω
	Low Battery Warning	Battery voltage low, power supply required promptly
	Low Battery Shutdown	Battery voltage too low to continue without power supply
	Full Memory	Memory is 50% full or 80% full, repeats when memory is 100% full

Memory Capacity	Non-Volatile Memory	4 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.
Signal Channels	Internal	QRS, heart rate trend, and impedance (breath rate). Saturation, pulse rate and plethysmograph
	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, High SpO_2 Alarm, Low SpO_2 Alarm, Low SpO_2 Record
	Event Duration	Alarm duration plus current pre- and post-settings totaling 45, 60, 75, 90 seconds
	Apnea Record (Infants only)	Off or 6 to 40 seconds in two-second intervals
	Bradycardia Record	Off or 50 to 100 Beats per Minute in five-BPM intervals

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A (not applicable for device with rated power of 75 W or less)	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level (FDA)	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands	3 V	$d = 1.2\sqrt{P}$
	10Vrms 150 kHz to 80 MHz outside ISM bands	10 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

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

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

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

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

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This Device

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

Rated Maximum Power Output of Transmitter W	Separation Distance According to Frequency of Transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance ***d*** in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Masimo Oximeter Sensor

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

Glossary

Apnea – The cessation of breathing (respirations).

Central apnea – No respiratory effort.

Obstructive apnea – Cessation of airflow into or out of the mouth or nose although efforts to breath continue.

Bradycardia – Slowing of the heart rate below the age specified rate for five 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 patient's skin.

Functional Self-Test – A user-performed test to verify the monitor, ECG patient cable, and lead wires are working properly.

Heart rate – The number of heart beats per minute.

Impedance – A method used by the monitor to detect respiration.

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

Modem – A device that allows the homecare provider or hospital to work with a monitor through telephone lines.

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

% (Percent) SpO_2 – A measurement of how much oxygen is contained in blood. Usually measured via a finger, toe or ear sensor. Note that the SpO_2 measurement indicates the functional saturation.

RA Connection – The opening on the ECG patient cable marked "RA" is the connector for the white lead wire.

Respiration – The act of inhaling and exhaling air (breathing).

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.

SmartMonitor 2 PSL

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Introduction

Unpacking and Inspection

When you receive the SmartMonitor 2 PSL, unpack the shipping case and do the following:

- 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 Philips Children's Medical Ventures.

About This Manual

This manual provides all the information you need to set up and operate the SmartMonitor 2 PSL and explains how to use it to monitor the patient's vital functions. Carefully read and understand this manual before using the system.

Indications for Use

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

The SmartMonitor 2 PSL is not for use in the home environment.

What Is the Purpose of the SmartMonitor 2 PSL?

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

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

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

Summary of Clinical Performance Evaluation

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

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.

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 in 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 (less than or equal to 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 Philips Children's Medical Ventures 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 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	Caucasian	African American	Asian	Hispanic	Other	Mean Birth Weight (grams)	Mean Gestational 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

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 SmartMonitor 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

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

Warnings

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

- Before using the monitor, charge the internal battery pack. Connect the power supply to the device, and ensure that it is plugged into a functional AC wall outlet for a minimum of 12 hours.
- The monitor will not operate without the internal battery pack. However, the internal battery pack ensures proper shutdown in the event of power failure to the device. Without the internal battery pack, loss of data is possible in the event of power loss.
- Place the monitor on a secure and level surface to prevent the device from falling. Do not place the monitor on the floor or in any location where the device could become a tripping hazard. Do not place the monitor in a crib, so that the patient will not roll onto the device's hard surface.
- If an emergency occurs and access to the telephone is required while the monitor is connected to the telephone wall jack, unplug the phone cord from the wall jack and connect a working telephone to the jack.
- Do not defibrillate a patient who is attached to the monitor.
- Do not use skin creams, electrode gels, oils or lotions under the sensors.
- The monitor may not be able to detect all episodes of inadequate breathing. If a patient has apnea due to choking (obstructive apnea), the monitor could mistake movement caused by choking for breathing.
- The SmartMonitor 2 PSL is a monitoring device only. They do not prevent the loss of breathing or heart activity, nor will they restore breathing or heart activity. These devices will not prevent death.
- Anyone using the SmartMonitor 2 PSL should be trained in current infant/adult Cardiopulmonary Resuscitation (CPR), which is a proper way to restore breathing and heart activity.
- The monitor is not intended for use with cardiac or diaphragmatic pacemaker patients.
- Do not allow the patient cables, lead wires, sensor cables or power supply cable to become tangled, coiled, crossed, or wrapped around the patient's neck, arms, or legs. This could result in strangulation.
- Do not block the speaker or place items in front of the speaker located on the front of the unit. This could prevent the monitor alarm from being heard.
- Never use the monitor on the patient while the patient is being bathed. This could result in electrical shock and/or damage to the equipment.
- Disconnect the power supply and phone line during lightning storms to reduce risk of electrical shock to the patient.
- If monitoring two or more patients 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.

- Do not connect the patient to the monitor if the monitor is placed in the Communications Mode. The alarms do not work when the monitor is in this mode.
- Do not use the monitor at the same time as other impedance monitors. This may cause missed apneas due to interference.
- Do not rock the patient or sleep in the same bed with the patient while monitoring. Touching or moving near the patient, monitor, or cables could cause the monitor to miss apneas.
- Inspect the power cords and cables often for any signs of damage. Replace a damaged cord or cable immediately.
- Do not use non-safety style lead wires and patient cable configurations with this monitor. Their use may pose a risk of severe electrical shock or death. Refer to the instructions in this manual to ensure proper connections. Use only Philips Children's Medical Ventures recommended safety lead wires, patient cables, electrodes and sensors.
- Pins of connectors identified with the ESD warning symbol should not be touched. Connections should not be made to these connectors unless ESD precautionary procedures are used. Precautionary procedures include methods to prevent build-up of electrostatic discharge (e.g., air conditioning, humidification, conductive floor coverings, non-synthetic clothing), discharging one's body to the frame of the equipment or system or to earth or a large metal object, and bonding oneself by means of a wrist strap to the equipment or system or to earth.
- Do not touch the device and the patient simultaneously.
- The conductive parts of electrodes and patient cables should not contact other conductive parts, including earth.
- Do not use during High Frequency surgical procedures.
- Explosion hazard. Do not use the monitor in the presence of flammable anesthetics or other flammable substances in combination with air, oxygen-enriched environments, or nitrous oxide.
- If an alarm condition occurs while the alarm silence period is active, the only alarm indications will be visual displays and symbols related to the alarm condition.
- The monitor is to be operated by qualified personnel only. This manual, accessory directions for use, all precautionary information, and specifications should be read before use.
- Do not use damaged patient cables. Do not immerse the patient cables in water, solvents, or cleaning solutions. (The patient cable connectors are not waterproof.) Do not sterilize by irradiation, steam or ethylene oxide. See the cleaning instructions in the directions for use for reusable patient cables.
- The Nurse Call feature of this device is for convenience only in a medically supervised environment. The audible indication provided by the Nurse Call system is not to be relied upon as the primary indication of the operating state of the device or of patient events.
- The Nurse Call feature should be considered a backup to the monitor device's primary alarm system. The operator should not rely solely on the Nurse Call feature.

Cautions

A caution indicates the possibility of damage to the device.

- Perform the functional self-test if the monitor has been x-rayed by an airport security check.
- Do not send information via modem during electrical storms. Information could be lost, or equipment could be damaged.
- Handle the lead wires carefully to prevent them from breaking inside the insulation. Always grasp the lead wire at the strain relief area to remove them from the electrodes or ECG patient cable.
- Any foreign matter that gets into the enclosure of the monitor may cause malfunction.
- Use only Philips Children's Medical Ventures-supplied sensors and accessories. Use of other accessories could degrade signal quality.
- If you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, if the device is dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken, discontinue use and contact your home care provider.
- If the patient is breathing quietly and the respiration light flashes more or fewer times than the patient breathes, contact Philips Children's Medical Ventures for service.
- 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 Philips Children's Medical Ventures for further assistance. Use of a third (RL) electrode and lead wire is normally not required but may help reduce excessive false low heart rate alarms.

How Does the SmartMonitor 2 PSL Work?

The SmartMonitor 2 PSL monitors and records a patient's breathing (respiration), and heart (cardiac) activity, and alerts the caregiver if any of these activities exceeds the limits prescribed by the physician.

The patient alarm limits are set before the monitor is given to the patient. If during monitoring the patient'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 PSL, how to monitor a patient, how to transfer the information to the physician, and how to use other devices with monitors.

Breathing is measured by placing two electrodes on the patient's chest under his or her arms. As the patient's chest moves during breathing, the impedance between the electrodes changes. The monitor detects these changes to determine the patient's breathing effort. If the monitor 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.

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

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 monitor has two types of alarms: patient and system.

Patient Alarms: An intermittent audible and visual indicator alerts the patient during the following alarm events:

- Apnea: Patient has stopped breathing for longer than the limit set by the physician.
- Low Breath Rate: Breath rate is lower than the limit set by the physician.
- Low Heart Rate: Heart Rate is lower than the limit set by the physician.
- High Heart Rate: Heart Rate is higher than the limit set by the physician.

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

- Loose lead
- Loose Probe
- Low Battery
- Memory Full
- Accidental Power-Off
- Internal System Error

Lights on the monitor indicate which of these conditions exists. See the section "Monitoring" for more information on alarms.

The monitor 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 the monitor and contact Customer Service at 1-800-345-6443.

Symbols Table

Symbol	Definition
	Attention: Consult accompanying documents
	Type BF Applied Part (also shows Patient Cable Connector location)
	Reset Button
	Power Off/On Button
	Apnea Alarm Light (infants only)
	Respiration Light
	Low Heart Rate Alarm Light
	High Heart Rate Alarm Light
	Low Battery Light
	Memory Full Light
	Loose Lead Light
	Heart Rate Light
	Power Light
	Charger Light
	Power Cord Connection
	Input / Output Connection
	Modem Port (Optional)
	Nurse Call Connection
SN	Serial Number
	Three Electrodes Per Package
	Four Electrodes Per Package
BPM	Beats Per Minute

Symbol	Definition
BrPM	Breaths Per Minute
	ESD Warning Symbol
IPX1	Drip Proof Equipment
	Power Supply Connector Position
	Class II (Double Insulated)

FCC Part 68 Telecom Information

Registration Number and REN

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

USOC Jack

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

Compliant Accessories

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

Number of RENs

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

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

Changes in Service

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

Problems

If trouble is experienced with this modem, please contact your homecare provider or Philips Children's Medical Ventures at 1-800-345-6443 for repair or warranty information. If the equipment is causing harm to the telephone network, the telephone company may request that you disconnect the equipment until the problem is resolved.

Repairs

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

Party Lines

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

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

IC Abbreviation

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

REN

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

Industry Canada CS-03 Notice

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

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

The Philips Children's Medical Ventures 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.*

FCC Part 15

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

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

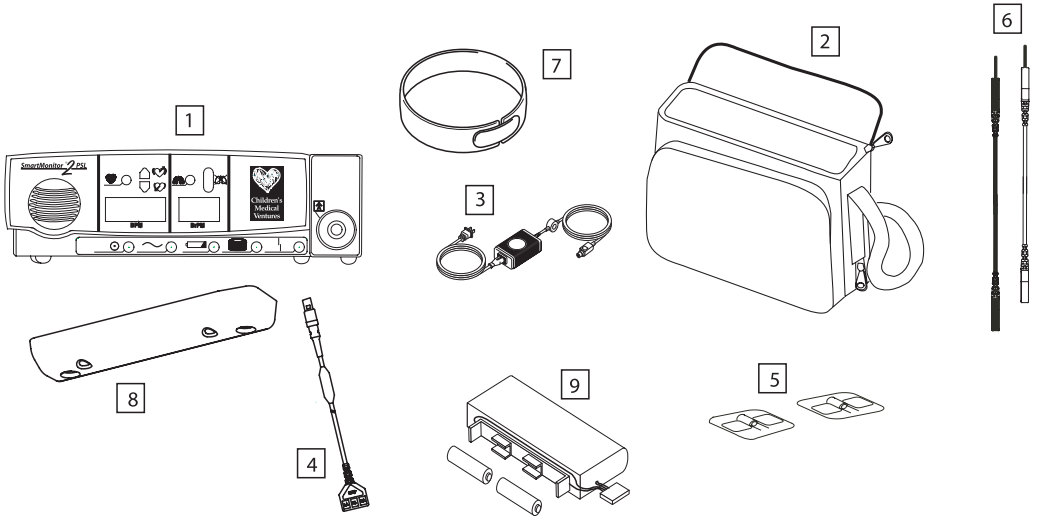
However, there is no guarantee that interference will not occur in a particular installation. This can be determined by turning the equipment off and on. If this equipment does cause harmful interference to radio or television reception, you are encouraged to try to correct the interference by one or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

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

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

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

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



When you receive the SmartMonitor 2 PSL, make sure that you have all the necessary items and that they are not damaged. Immediately report anything missing or damaged to Philips Children's Medical Ventures.

The standard package should include the following:

1. SmartMonitor 2 PSL
2. Soft Carrying Case
3. Power Supply and Power Cord. Your new monitor is supplied with an external power supply (P/N 1031372) and a 3-wire AC input cord. If you do not have a grounded (3-wire) power outlet, contact Philips Children's Medical Ventures Customer Service at 1-800-345-6443 to obtain a 2-wire power supply (P/N 1016966) and AC input cord. The 3-wire supply and the 2-wire supply both provide the same level of operator and patient safety according to IEC 60601-1. However, when the monitor is used on a patient who has other medical equipment connected at the same time, the 3-wire power supply may provide greater immunity to electrical noise for the monitor and other medical equipment.

   NOTE: The appearance of the power supply and cord will vary, depending on country of use. In the illustrations in this guide, the power supply is represented by a standard U.S. domestic 2-wire configuration.

4. ECG Patient Cable
5. Electrodes
6. Lead Wires
7. Electrode belt
8. Handle/Stand
9. Battery Pack
10. Symbol Reference Card (not shown here)
11. Phone Line Splitter (not shown here) (optional)
12. Phone Line Cord (not shown here) (optional)

SmartMonitor 2 PSL Features

This section describes the physical features of the monitor.

Top Panel Features

Power Button

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

To turn the monitor off, do the following:

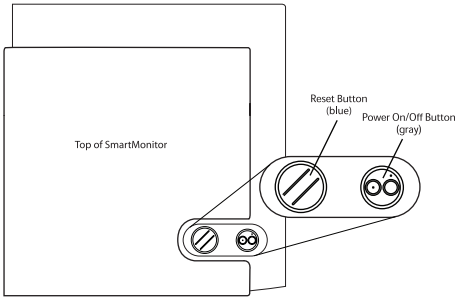
- Press and hold the blue RESET button.
- Press and release the gray POWER button.
- Wait 2 seconds, and then release the RESET button.

NOTE: When the Hospital Mode Control parameter is set to YES, this special key sequence is not required. The alarm set points will also be displayed one at a time during the power up sequence.

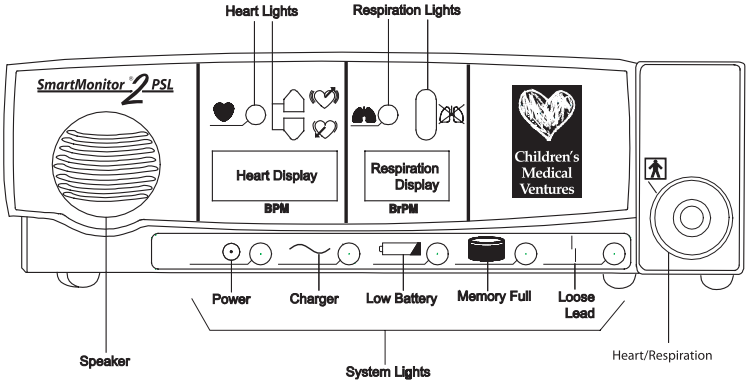
When the Hospital Mode Control parameter is set to YES, the Silence Alarm Feature is enabled. This allows the user to silence the audible alarm for 60 seconds when the alarm is being caused by a physiologic event(s). The user can silence the alarm by pressing the RESET button. If the physiologic event(s) is still active after 60 second(s), the alarm will sound again. This feature only affects the audible portion of the alarm. The front panel displays will blink when the silence period is active.

Reset Button

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



Front Panel Features



Display of Values

Values for heart rate and breath rate are viewable from the front panel display. You can increase the brightness of Display Values on the monitor by pressing the ▲ or▼ buttons.

NOTE: You can disable this feature through the user interface on the bottom of the monitor. You can also disable the oximeter functionality through the user interface.

Respiration Lights

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

Speaker

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

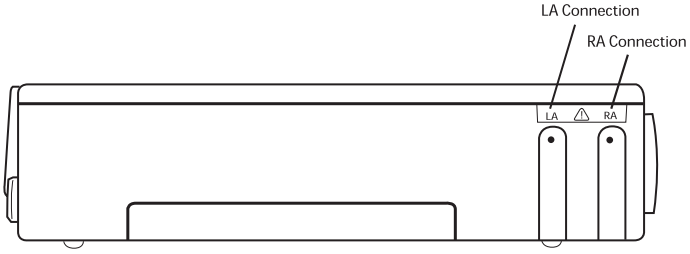
System Lights

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

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

Side Panel Features

The right side panel features the two connections shown below.

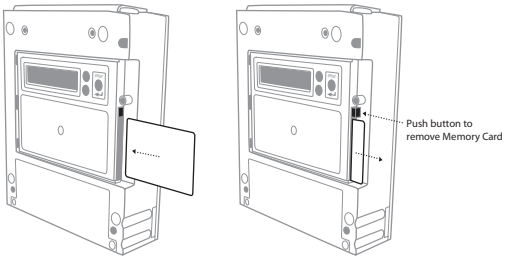


Self-Test Connector

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

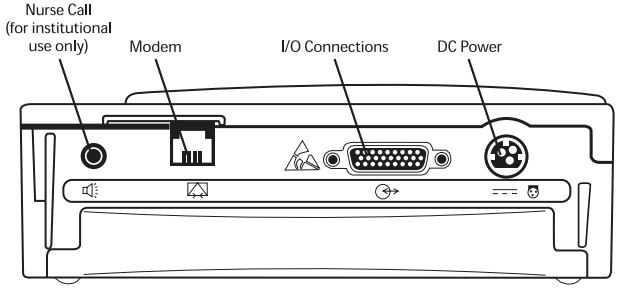
Memory Card (Optional)

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



Back Panel Features

The back panel features are shown in the illustration below.



Nurse Call (Optional)

The nurse call feature allows the monitor to be connected to a nurse call station.

Modem (Optional)

The monitor is equipped with a modem to transfer the monitor's memory to the physician. See the section on "Transferring Monitor Memory" for more information. See the sections "FCC Part 15" and "Industry Canada CS-03 Notice" for information on connecting the modem to the telephone line.

I/O Connections

This connector connects the monitor with other devices.

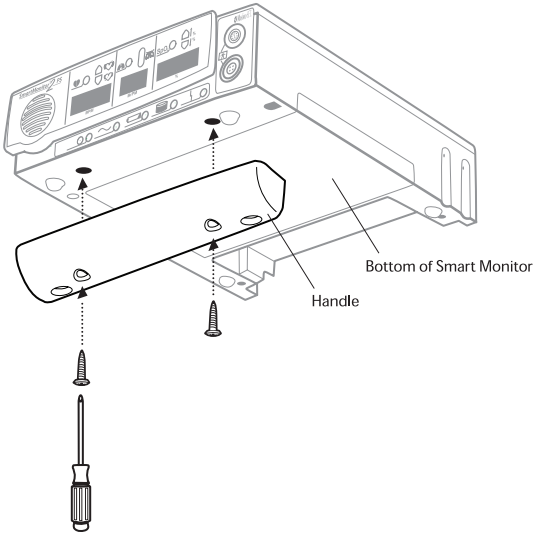
Ensure that the devices used do not exceed SELV (Safety Extra Low Voltage) levels as described in EN60601-1.

DC Power

Use the DC Power connector with the power cord/battery charger. Whenever the monitor is not being transported (on battery power only) it should be connected to the battery charger.

Stand

The monitor comes with a removable handle. The handle also acts as a stand that elevates the front panel display when the monitor is placed on a flat surface. The handle, along with connection screws and rubber feet, is packaged with the device.



Setting Alarm and Recording Limits

The monitor 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 Setup

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

The Monitor Setup 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 Setup Menu, the monitor is in Menu mode.

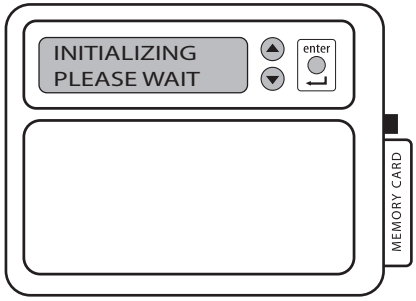
NOTE: The monitor will beep once every 10 seconds to signal that it is powered on and in Menu mode.

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

Memory Display Detail



Then,

MENU MODE? ENTER PROPER KEY SEQUENCE

- Press the keys in the following sequence within 10 seconds:

  DOWN ARROW button, UP ARROW button, UP ARROW button, ENTER button, ENTER button, ENTER button.
- The display will read SMARTMONITOR 2 PSL MENU SELECTION.
- The monitor's menu has over 40 entries that are presented in a continuous loop. Use the UP ARROW button to display the next menu entry.
- Use the DOWN ARROW button 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 button to choose the menu path you want to review.

There are four menu paths to choose from:

- All Menu
- Alarm Menu
- Recording Menu
- System Menu.

Once the changes are completed, turn the monitor 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.

NOTE: When you power the monitor off and then back on, the new values will be implemented.

When the Hospital Mode Control parameter is set to YES, the special key sequence is not necessary to turn the monitor off.

The SmartMonitor 2 PSL Parameters

The following menu flow is for All Menus. This path encompasses menus for Alarm, Recording, and System. For instance, to quickly access an alarm setting, select the Alarm Menu.

Standard values for Alarms and Recording parameters appear in bold.

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
View Prior Events	VIEW PRIOR EVENTS?	This menu option allows the user to view a summary of the ten most recent physiological events via the LCD screen. To view events: • Press the ENTER button to activate. • Press ▲ or ▼ to change the selection to Yes. Then press the ENTER button. • Press ▲ or ▼ to browse through the most recent events (up to ten). • Press the ENTER button to exit this menu option.	All Menus System Menus
Patient Name	PATIENT NAME	To enter the Patient Name: • Press the ENTER button to begin entering the patient name. • Press ▲ or ▼ to browse through the alphabet and select the letter you need. When the letter you want appears, press the ENTER button. Press the ENTER button 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 the ENTER button. NOTE: 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 Identification Number	PATIENT ID NUMBER	To enter the Patient ID: • Press ▲ or ▼ until Patient ID is displayed. • Press the ENTER button to activate. • Press ▲ or ▼ to browse through the numbers and select the digit you need. When the digit you want displays, press the ENTER button. • When you have finished the ID, press ▲ or ▼ until the ^ appears. Then press the ENTER button. NOTE: ^ 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
Standard Alarm Parameters	STD ALARM PARAMETERS Are Selected Or Are Not Selected	• Press the ENTER button to activate. • Press ▲ or ▼ to change the selection. • When you have your selection displayed, press the ENTER button.	All Menus Alarm Menu
Standard Record Parameters	STD RECORD PARMS. Are Selected Or Are Not Selected	• Press the ENTER button to activate. • Press ▲ or ▼ to change the selection. • When you have your selection displayed, press the ENTER button.	All Menus Record Menu
Standard System Parameters	STD SYSTEM PARMS. Are Selected Or Are Not Selected	• Press the ENTER button to activate. • Press ▲ or ▼ to change the selection. • When you have your selection displayed, press the ENTER button.	All Menus System Menu
Apnea Alarm Setpoint (Infants only)	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 Setpoint	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 Setpoint	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** NOTE: 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 monitor, the current Bradycardia alarm set point, and the patient's average resting heart rate.	All Menus Alarm Menu

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
Tachycardia Alarm Setpoint	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
Tachycardia Alarm Delay	TACHY ALARM DELAY IN SECONDS	Enables a delay to the audible alarm. Values: **0 and 5 seconds** Standard value: **5 seconds** NOTE: 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 monitor, 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

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
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 with the Apnea Alarm set to 20 seconds and the Apnea for Record 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
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 with the Bradycardia Alarm set to 70 BPM and the Bradycardia for Record 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

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
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
Respiration Rate Record	RECORD RESP RATE?	This parameter allows the user to select whether or not the Breath-To-Breath and 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 and the Average Heart Rates will be recorded. Values: **YES or NO** Standard value: **YES**	All Menus Record Menu
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
Front Panel Control	ENABLE PANEL DISPLAY	This parameter allows the user to enable/disable the Front Panel Display. Values: **YES and NO** Standard value: **YES**	All Menus System 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

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
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 monitor recording when a physiological parameter is violated in the external auxiliary device. Select from: • OFF • Trigger when high • Trigger when low See the section "Using Auxiliary Equipment." Standard value: **OFF**	All Menus Record Menu
External Equipment Trigger	EXT. EQUIP. TRIGGER	Ext. Equip. Trigger allows external equipment to cause an entry in the monitor's Equipment Log when an equipment parameter is violated in the external auxiliary device. Select from: • OFF • Trigger when high • Trigger when low See the section "Using Auxiliary Equipment." Standard value: **OFF**	All Menus Record Menu
When the auxiliary equipment channels are turned on and the auxiliary equipment is not connected to the monitor, a flat line will be recorded and reported. The auxiliary channels enable you to interface other signals to monitor. Options for each of these channels are best defined with the System Software. External auxiliary devices can be interfaced to provide SpO_2, 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 Manual* for more information.			
Date Format Selection	DATE FORMAT	This parameter allows the user to display the date in either U.S. or international formats Values: **Month/Day/Year** **Day/Month/Year** Standard Value: **Month/Day/Year**	All Menus System Menu

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
Date	DATE	To enter the date: • Press the ENTER button to begin. • Press ▲ or ▼ until the number required is displayed. • Press the ENTER button 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 the ENTER button to begin. • Press ▲ or ▼ until the number required is displayed. • Press the ENTER button 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: **ON**	All Menus System Menu
Phone Number for Computer	COMPUTER PHONE #	Enter the phone number of the modem on the computer end of the download. NOTE: You may enter *70 first, then the phone number to disable Call Waiting if necessary. Be sure to enter the phone number without dashes or spaces. • Press the ENTER button to begin. • Press ▲ or ▼ until the number required is displayed. • Press the ENTER button to select. • Once you have entered the phone number, press ▲ or ▼ until the ^ appears. Then press the ENTER button. 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 the ENTER button to activate. • Press ▲ or ▼ to browse through the numbers and select the digit you need. When the digit you want displays, press the ENTER button. • Enter the time in Military Time. • When you have finished, press the ENTER button. • 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 3-1-03 at 4:00AM, but the memory reaches the Memory Full Alert at 3:00PM on 2-1-03, then the monitor will initiate a call at 4:00AM on 2-2-03. Standard value: **ON**	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 download the recorded data to the Memory Card. To move data to the Memory Card: • Press the ENTER button. The word NO will begin to blink. • To select YES, press either arrow button. • Should a Memory Card not be inserted, the monitor will ask for the card. • Place the card in the 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 monitor. 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

Menu Option	LCD Display	Description of Option or Instructions	Menu Path
Clear Memory	CLEAR MEMORY?	Permits the memory to be erased. NOTE: Erasing memory does not affect the alarm and / or the record parameters, or the patient name and patient ID. • The memory should be cleared before using the monitor 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 monitor, it 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 monitor.

System Setup Menu

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

- Press the POWER button. 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 the ENTER button.
- Scroll to ALL MENUS, and press the ENTER button.

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

Menu Option	LCD Display	Description of Option or Instructions
Heart Rate Computation Method	HEART RATE METHOD	Establishes the method by which the monitor computes the Average Heart Rate. Values: 4 Beat Average, Time Average Standard value: Time Average
Hospital Mode Control	ENABLE HOSPITAL MODE	This parameter allows the user to enable/disable the Hospital Mode system functions. Values: YES and NO Standard value: NO *NOTE: Monitors equipped with the Hospital Alarm feature will have the parameter set to YES when they come from the factory.*
Date Format Selection	DATE FORMAT	This parameter allows the user to display the date in either U.S. or international formats. Values: MONTH/DAY/YEAR, 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%

Menu Option	LCD Display	Description of Option or Instructions
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 38,400 BPS. This setting should not be changed unless directed to do so by Philips Children's Medical Ventures Customer Service.
Modem Speed - Host	MODEM SPEED – HOST	The default setting is 115,500 BPS. This setting should not be changed unless directed to do so by Philips Children's Medical Ventures Customer Service.
Embedded Software Revision	SOFTWARE REVISION	Display-only menu. Displays the revision of the Embedded Application Code.
Maintenance Mode Software Revision	MMODE SW REVISION	Display-only menu. Displays the revision of the Maintenance Mode Code.
Boot Block Software 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.
Language Selection	SELECT A LANGUAGE	Permits the selection of seven languages for displaying the LCD menus. Standard value: ENGLIS

View Menu Mode

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

- Press the POWER button. After a short delay, the display will read:

  INITIALIZING PLEASE WAIT

  Then,

  MENU MODE? ENTER PROPER KEY SEQUENCE
- Press the following keys in the following sequence within 10 seconds:
- Press the ENTER button once.
- Use the ▲ ▼ Up and Down arrow buttons to scroll through the menus.

NOTE: The caregiver can download monitor data to a Memory Card using the View Menu but cannot make any changes to the settings in the monitor.

Using Auxiliary Equipment

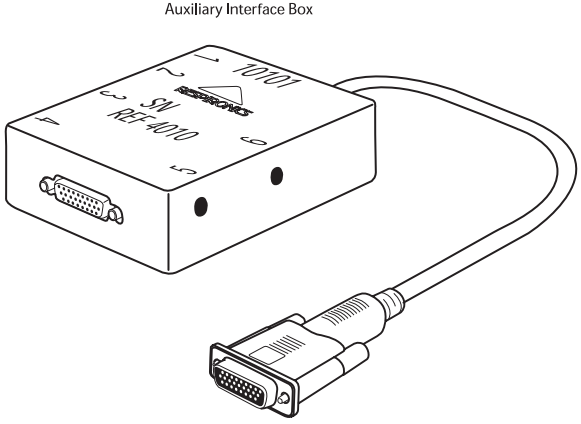
There are four auxiliary channels available on the monitor. These channels provide the mechanism for connecting external devices to the monitor. All External Devices must interface to the monitor via the Auxiliary Interface Box, P/N H4010. The output of these devices must be within the range of –1.25 to +1.25 volts.

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

The SmartMonitor 2 PSL is programmed with 15 signal definitions to interpret the auxiliary signals it receives. For each of the four 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 monitor.

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



NOTE: 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 monitor's menu. For example, if you wish to record additional SpO_2 and Pulse channels, you would need two auxiliary cables and this will use two auxiliary channels.

Information required to set up or change the "definition" includes the devices voltage and value range. This information must come from the manufacturer of the device.

Using Nurse Call Equipment

WARNING: The Nurse Call feature of this device is for convenience only in hospital environment. The audible indication provided by the Nurse Call system is not to be relied upon as the primary indication of the operating state of the device or of patient events.

WARNING: The Nurse Call feature should be considered a backup to the monitor's primary alarm system. The operator should not rely solely on the Nurse Call feature.

WARNING: Before making any connection to the rear-panel Nurse Call connector, the operator must verify that the equipment being connected does not exceed SELV (Safety Extra Low Voltage) levels as described in EN60601-1.

Interface of the monitor with a Nurse Call system is possible via the jack located on the rear panel of the monitor. Use of a standard 3.5mm stereo phone plug is sufficient for this procedure. Two sets of relay contacts (one Normally Open and one Normally Closed) are available via the three contacts of the stereo phone plug. These contacts are as follows: tip-NO, ring-NC and sleeve-Common.

The monitor relay is de-energized when the monitor is OFF, or when the monitor is ON and an alarm condition exists. The relay is energized when the monitor is ON and no alarm condition exists. The appropriate set of relay contacts for interfacing varies based on the make and model of the Nurse Call system used.

The following table summarizes the Nurse Call relay status based on the operating condition of the monitor:

Monitor Status	Relay Status
Monitor OFF	De-energized
Monitor ON Monitoring Mode No Alarm Condition	Energized
Monitor ON Monitoring Mode Continuous Alarm Condition	De-energized
Monitor ON Monitoring Mode 1 beep/second Alarm Condition	De-energized & Energized once per second
Monitor ON Monitoring Mode 2 beeps/second Alarm Condition	De-energized & Energized twice per second
Monitor Shut Down Due to Error	De-energized
Monitor ON Menu Mode	Energized but De-energized briefly every 10 seconds
Monitor ON Communication Mode	Energized but De-energized briefly every 10 seconds

Patient Setup

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

- Ensure Memory has been cleared prior to delivery to new patient.
- Review use of the monitor and its accessories with the caregiver(s). Be sure to perform the Functional Self-Test. A self-test should be performed weekly or whenever lead wires or ECG 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 monitor on a Clean, Flat Surface.

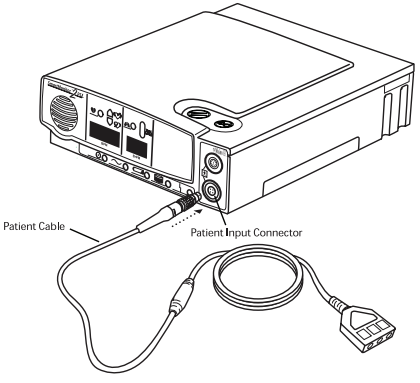
- Be sure the speaker is not blocked.
- To avoid interference, be sure that no other electrical appliances are within three feet of the monitor, patient, and patient leads.
- Make sure the monitor is close enough to connect to the patient comfortably.

WARNING: The monitor should not be placed in bed with the patient.

Step 2: Connect the ECG Patient Cable to the monitor.

- Insert the round end of the ECG patient cable into the bottom round connector found on the front of the monitor.
- Line up the notch on the connector and push until you feel the connector snap into place.
- To remove the ECG patient cable, grasp it at the base of the patient input connector and gently pull straight back. You should feel the outer sleeve slide back and unlock the connector as you pull.

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

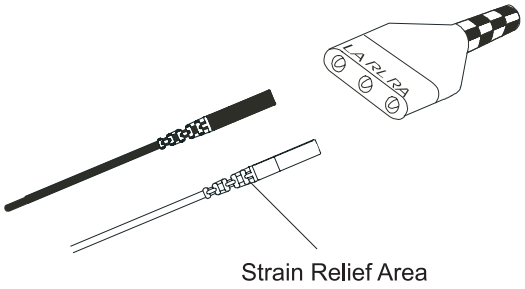


WARNING: The ECG patient cable should not be placed over the top of the crib rail. The cable should be placed between the vertical bars.

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

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

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

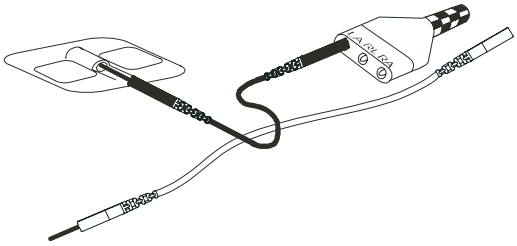


WARNING: When you need to remove a lead wire, grasp and pull at the strain relief area located near the connecting tip. Do not grasp the wire.

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

Step 4: Connect the Lead Wires to the Electrodes.

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



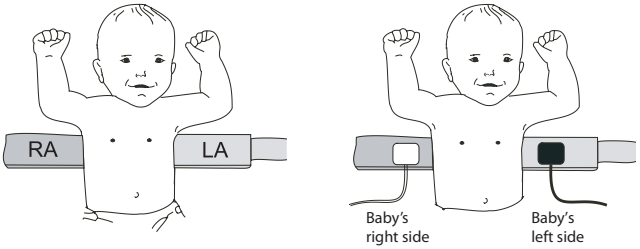
NOTE: Refer to the section "Disposable Self-Adhesive Electrodes" if applicable.

NOTE: The 3M Red Dot ECG Electrode is compatible for use with the SmartMonitor 2 PSL.

NOTE: For electrode belt instructions (infant use only), follow Step 5. For self adhesive electrodes, follow Step 6.

Step 5: Attach the Electrodes to the Infant Belt (Infants Only).

- Place the electrode belt on a flat surface.
- Lay the patient on the belt so the belt is aligned with the patient's nipples (see illustration below).
- Place the electrodes, Velcro®-side down, on either side of the belt as follows:
  - Place the electrode with the white lead wire (RA) on the patient's right side.
  - Place the electrode with the black lead wire (LA) on the patient's left side.



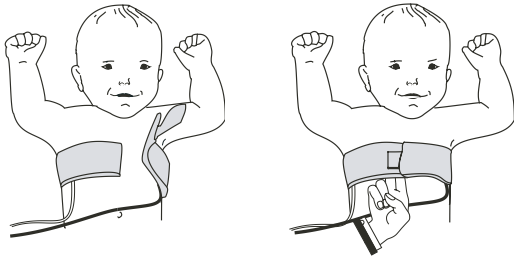
- Place the electrodes far enough apart so that when the belt is wrapped around the patient, the electrode will be located along the mid-line of the side just below or lined up with the nipples.

WARNING: Be sure the lead wires and ECG patient cable are leading down and away from the patient's face and neck (see illustration below).

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

- Wrap the belt around the patient's chest and fasten it with the Velcro tab.
- The belt should be snug enough so that you can only insert two of your fingers (with your hand lying flat against the patient) between the belt and the patient.

NOTE: For 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.



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

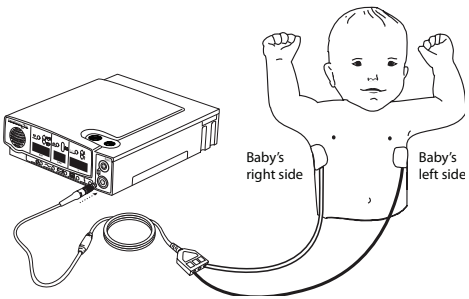
Step 6: Attach the Self Adhesive Electrodes

a. Follow the steps below if you are using disposable electrodes on an infant.

- Attach the lead wire to the Self Adhesive Electrodes if not pre-attached.
- Ensure the patient's skin is clean and dry.
- Place the electrode with the white lead wire on the patient'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 patient'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.

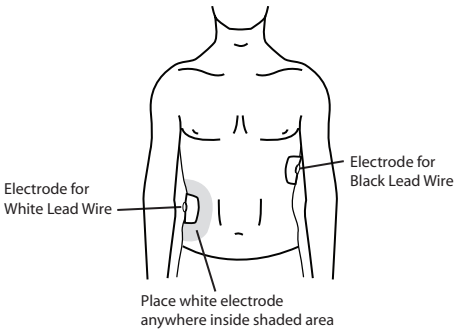
NOTE: Use of the third (green - RL) electrode and lead wire is normally not required but may help reduce excessive false low heart rate alarms. Place the green electrode along the outside of the patient's upper thigh.

WARNING: Do not use oils, lotion, or powder on the area of skin that the electrodes will be placed, false alarms may result.



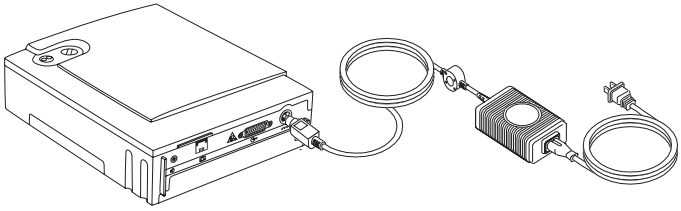
b. Follow the steps below if you are using disposable electrodes on an adult patient: (Hospital Use Only)

- Attach the lead wires to the Self Adhesive Electrodes (if not pre-attached).
- Ensure the patient's skin is clean and dry.
- Place the electrode with the white lead wire on the patient's right side, under the armpit near the lower portion of the rib cage, as shown in the illustration below.
- Place the electrode with the black lead wire on the patient's left side, under the armpit and in line with the nipples, as shown in the illustration below.



Step 7: Connect the Power Cord/Battery Charger.

- Insert the connector of the power cord/battery charger into the socket on the back panel of the monitor (see illustration below). The flat side of the connector faces upward.
- Push until the connector is fully inserted into place. A gentle tug on the connector will confirm that it is locked in place.
- Plug the power cord/battery charger into the power supply, and then plug the power cord into a power outlet. The green charger light on the monitor will now come on.
- To remove the power supply from the monitor, grasp the power supply connector at the base of the connector and gently pull back. You should feel the connector body slide back and unlock the connector as you pull.



WARNING: Do not use the device if the power cord is damaged. Contact Philips Children's Medical Ventures.

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

NOTE: When the monitor is not operating portably, keep the power cord/battery charger connected and plugged into an AC outlet at all times. Ensure that the AC outlet has been installed to conform to the National Electrical Code. The batteries cannot be overcharged. The green charger light stays on as long as the charger is connected.

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

NOTE: If you see an alarm with an error code of 1A00, or if an alarm cannot be silenced, it may be related to the redundant battery system. See "Troubleshooting" later in this manual to correct the problem.

Hospital Mode

The monitor's Hospital Mode Control parameter is set to NO when it comes from the factory. This control enables the features of Hospital Mode, specifically:

- elimination of the sibling protection mechanism
- silence alarm feature for patient alarms
- alarm setpoint review at power on.

To make changes to this parameter, refer to the section "System Setup Menu" earlier in this manual.

If the monitor is going to be used in a home setting, make sure that the Hospital Mode Control parameter is set to NO.

NOTE: Monitors equipped with the Hospital Alarm feature will have the parameter set to YES when they come from the factory.

PATIENT ALARM

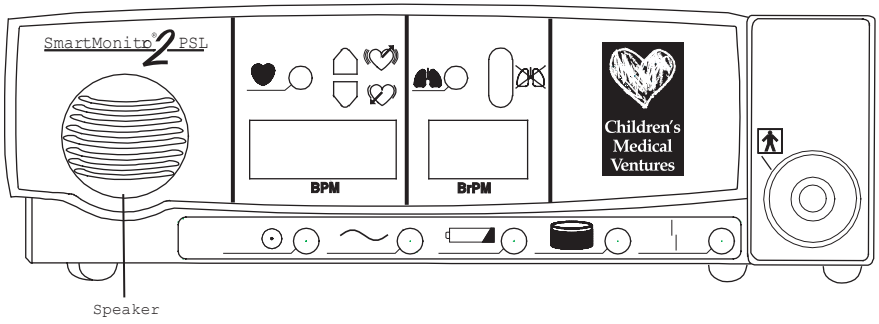
A Patient Alarm indicates that the patient's breathing, heart activity or oxygen saturation is outside the limits prescribed by the physician. The information in this section can help you respond appropriately to patient alarms. Read this section carefully. If you have any questions, please contact Philips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

TESTING THE ALARM

Before you use the monitor, test to determine 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. Do not place the monitor in the bed with the patient or direct the speaker toward the patient.

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



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

If an Alarm Sounds

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

Light	Alarm	Check Patient's Condition	Respond like this
Red Apnea and/or Low (Heart)	Intermittent (1 beep/sec.)	Skin color is pale or blue. Patient is not breathing or is choking.	Respond as instructed by the physician or in your CPR class. • Gently pat the patient. The patient may start breathing and correct the cause of the alarm on his/her own. • If the patient does not start breathing, start physical stimulation immediately. • If the patient starts breathing and corrects the cause of the alarm, note it on your log sheet. • Press the RESET button to reset any alarm lights.
Red Apnea and/or Low (Heart	Intermittent (1 beep/sec.)	Patient is breathing and is responsive. Color is good.	• Wait for a few seconds. Watch to see if the patient's breathing and color remain normal. • If the alarm continues, see the section "Reducing False Alarms." • Check the monitor to see which light is on. Note it on your log sheet. • Check the sensors.
Red High (Heart)	Intermittent (2 beeps/ sec.)	Patient is crying.	• If the patient has frequent high heart rate alarms not associated with crying, please notify the physician. • Calm the patient. • Check the monitor to see which light is on. Note the light on your log sheet.

Light	Alarm	Check Patient's Condition	Respond like this
Yellow Loose Lead	Continuous	Patient is breathing and is responsive. Color is good.	• Check the connections between the electrodes, lead wires, ECG patient cables, and monitor. • If something has come loose, reconnect it and press the RESET button. The alarm should stop. • If the alarm continues to sound, see the section "Performing a Functional Self Test." If the monitor passed the Functional Self-Test, turn off the monitor. Then, check the following items: • The patient's skin – Make sure that where the electrodes are placed is clean and free from oil, lotions, powder and perspiration. • Check the connections between the electrodes, lead wires, patient cable, and the monitor. • The electrodes – They should be clean and there should be no cracks on the surface. • The electrode belt – Make sure it is snug and is keeping the electrodes in place. • If something has come loose, reconnect it and press the RESET button. The alarm should stop.

NOTE: Patient alarms cannot be silenced with the RESET button except when the hospital mode control parameter is set to "yes." 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 system alarm occurs, one of the lights at the bottom of the front panel will come on.

If this light is on	And this condition exists	It means...
Power ⊙	Continuous green light, no alarm.	Normal Operation. The green power indicator light will come on and stay on for as long as the monitor is on.
Charger ~	Continuous or blinking green light, no alarm.	Normal Operation. The green charger light will come on and blink when the battery is charging and stay on when the battery is fully charged while the battery charger is plugged into an active outlet and connected to the monitor.
Low Battery ▭	Flashing yellow light, continuous alarm. Continuous yellow light, continuous alarm.	This is a warning that the battery voltage is very low and should be recharged soon. (See the section "Charging the Monitor's Battery" later in this manual.) Press the RESET button to temporarily silence the alarm. The alarm will resound in 2 minutes if the monitor has not been plugged in. The yellow light will continue to flash. This is a warning that the battery is too low for the monitor to operate properly. The monitor must be recharged. Turn the monitor off. Then, recharge the battery. (See "Charging the Battery" in this manual). If you do not recharge the battery, the system will automatically shut down.
Memory Full ⛁	Flashing yellow light, continuous alarm. Flashing yellow light, no alarm.	When the monitor's Memory Almost full parameter is reached, the Memory Full light will flash. The alarm will sound continuously. The alarm will sound only if the monitor has been programmed to do so at the 50% full or at 80% full. Press the RESET button to silence the alarm. The light will blink every second. *NOTE: Memory Full is a warning condition. You can continue monitoring. However, you should download the memory to resolve the alarm.* *NOTE: The Memory Full alarm will sound each time the monitor is powered on.*

If this light is on	And this condition exists	It means...
Memory Full	Continuous yellow light, continuous alarm. Continuous yellow light, no alarm.	The monitor's memory is 100% full. Press the RESET button to silence the alarm. The light will stay on continuously. You must transfer data when you get a memory 100% full condition. (See "Transferring SmartMonitor 2 PSL Memory" in this manual for more information.) *NOTE: The alarm will sound only if the monitor has been programmed to do so.*
Loose Lead	Continuous yellow light and continuous alarm	The yellow loose lead light and the alarm may sound continuously when there is a problem with any of the following: • Lead wires • Electrodes • Electrode belt • ECG Patient cable, or • Connections between the patient's skin and the electrodes, the lead wires, the patient cable(s), and the monitor.
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 bottom panel display for error messages. If no error messages are displayed, the monitor was turned off improperly causing a sibling alarm. To resolve: Press and hold the blue RESET button. Press and release the gray POWER button. Wait two seconds then release the RESET button.
All	All lights are blinking and the alarm will come on for three seconds and then off for one second.	Check the bottom LCD 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. If not contact Philips Children's Medical Ventures for service.

NOTE: When the Hospital Mode Control parameter is set to YES, the Silence Alarm feature is enabled. This allows the user to silence the audible alarm for 60 seconds when the alarm is being caused by a physiologic event(s). The user can silence the alarm by pressing the RESET button. If the physiologic event(s) is still active after 60 second(s), the alarm will sound again. This feature only affects the audible portion of the alarm. The front panel indicators are not affected.

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 patient, 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 patient's skin prior to electrode belt placement.
- When using the black reusable electrodes, ensure that the electrode surface is clean.
- Use of the third (green - RL) electrode and lead wire is normally not required, but may help reduce excessive false low heart rate alarms. Place the green electrode along the outside of patient's upper thigh.

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

TURNING THE MONITOR ON

After you have properly set up the monitor, and learned how the monitor functions and how to respond to alarms, you can begin monitoring the patient's breathing and heart activity according to the schedule prescribed by the physician.

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

- The green (battery) charger light is on (if the monitor is plugged into an AC outlet).
- The green power light is on.
- The green respiration light and green heart light are blinking.
- All other lights should be off.
- If the lights do not blink, refer to the steps found in "Home Setup" earlier in this manual. Be sure you have followed all instructions.

NOTE: If the Hospital Mode Control and front panel parameter are set to YES, then each of the following will appear briefly on the front panel display during startup:

- After all the lights have turned on and the audible alarm has sounded briefly, the Apnea Alarm LED will light up and value of the Apnea System parameter will appear above BrPM on the front panel display (infants only).
- The Bradycardia (low heart rate) Alarm LED will light up and the value of the Bradycardia System Parameter will appear above BPM on the front panel display.
- The Tachycardia (high heart rate) Alarm LED will light up and the value of the Tachycardia System Parameter will appear above BPM on the front panel display.

TURNING THE MONITOR OFF - SIBLING ALARM

The SmartMonitor 2 PSL has a built-in safety feature called a sibling alarm. If the monitor is not turned off in a specific sequence, the green power light will remain on and the alarm will sound continuously. This safety feature makes sure the power is not accidentally turned off. To turn the monitor off:

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

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

- Press 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.

NOTE: If the Hospital Mode Control parameter is set to YES, then the Sibling Alarm feature is disabled. You may turn the monitor on and off by pressing the POWER button.

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

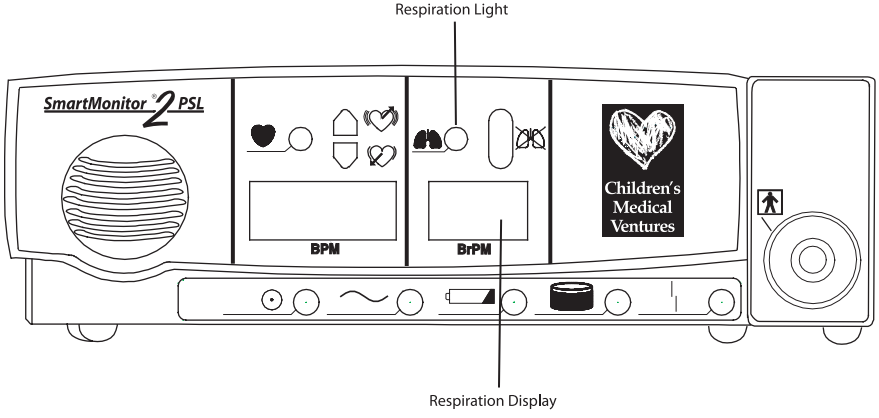
- Press and hold the RESET button. While still holding down the RESET button, press and hold the POWER button. Hold both buttons down for 5 seconds.
- Release POWER button; continue to hold the RESET button until the monitor turns off.

Monitoring Breathing

Respiration Light/Display

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

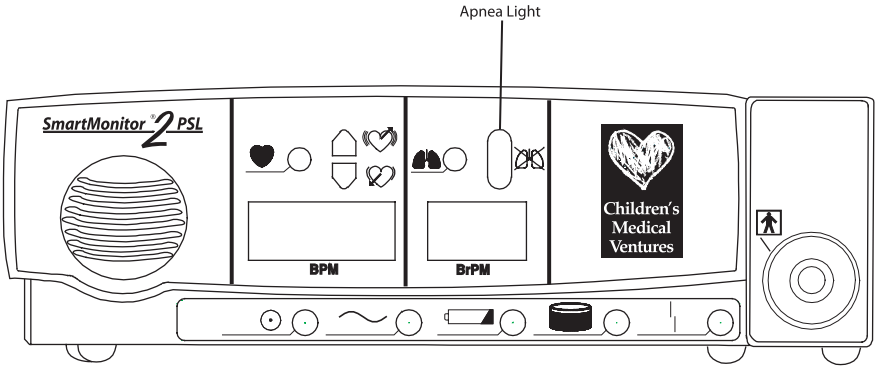
The patient's average respiration rate will appear on the front panel display above BrPM when the display feature is enabled.



Apnea Light

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



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

Low Breath Rate

If the monitor is programmed to detect Low Breath Rate, the following will occur:

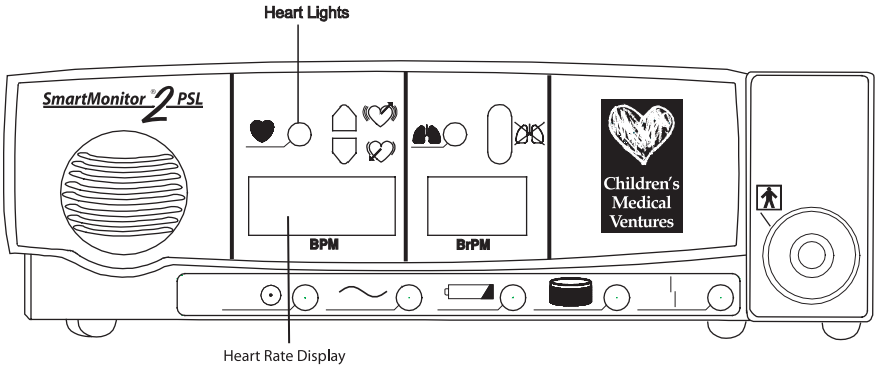
- If the breath rate falls below the setting but pauses are short and do not cause an apnea alarm, the apnea light will blink twice each second and the alarm will beep once each second.
- During a Low Breath Rate alarm, if the monitor detects a pause in breathing longer than the limit set by the physician, the apnea light will change from flashing to constant.

WARNING: If apnea alarms continue, and the patient is breathing normally, verify lead placement or check for low amplitude respiration and contact Philips Children's Medical Ventures immediately.

HEART RATE LIGHT/DISPLAY

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

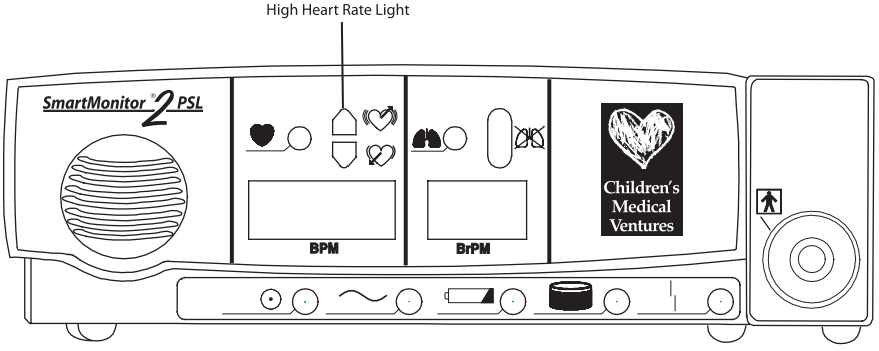
The patient's average heart rate will appear on the front panel display above BPM when the display feature is enabled.



HIGH HEART RATE LIGHT

The monitor determines if the patient's heart rate is higher than the limit prescribed 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.

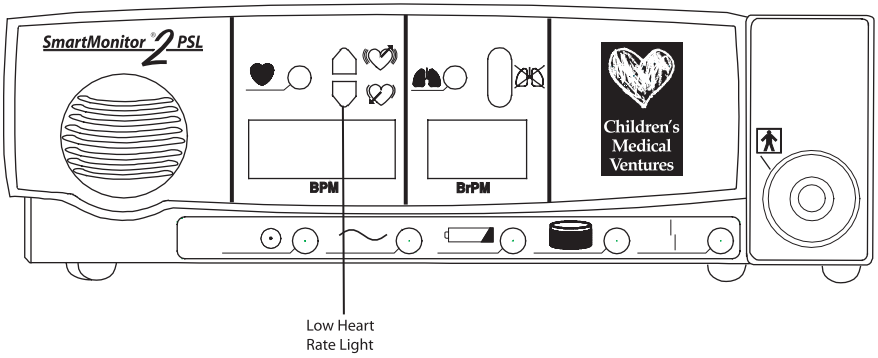


NOTE: The red light stays on until you press the blue RESET button.

Low Heart Rate Light

When the monitor determines that the patient's heart rate is lower than the limit prescribed 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.



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

Portable Operation of the SmartMonitor 2 PSL

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

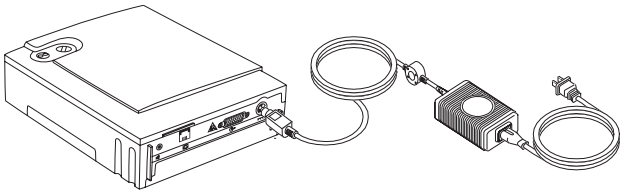
Philips Children's Medical Ventures recommends that the monitor be used with the power cord/battery charger whenever possible. However, when the monitor is used without the power cord/battery charger the monitor is fully functional. All alarms are operational. With a fully charged battery, the monitor will run for 15 hours with the oximeter off. Please note that the front panel display (if enabled) will be dimmed to conserve battery life, and you will not be able to adjust the brightness in this mode. The amount of time to completely recharge a fully depleted battery is 8 hours.

SmartMonitor 2 PSL includes a redundant battery system. A rechargeable battery pack and two AAA alkaline batteries are located in the battery compartment. If there is a failure in the rechargeable pack, the AAA batteries generate an alarm. If the rechargeable pack is nearly completely discharged, the alarm will also sound. This may occur when the battery pack is first installed in a new monitor or if a monitor is unused for two months or longer. Always unplug the battery pack cable is you are not going to use the monitor for an extended period of time. This prevents unnecessary alarms upon future reconnection.

Charging the Monitor's Battery

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

- Insert the connector of the power supply into the socket on the back panel of the monitor. (See illustration below.) The flat side of the connector faces upward.
- Push until the connector is fully inserted into place. A gentle tug on the connector will confirm that it is locked in place.
- Plug the power cord/battery into a power outlet.
- The green charger light comes on solid if the battery is fully charged or blinks when the battery is charging.
- If the monitor is turned on, the yellow low battery light blinks until the minimum charge level is reached. Then, the yellow light goes off
- To remove the power supply from the monitor, grasp the power supply connector at the base of the connector and gently pull back. You should feel the connector body slide back and unlock the connector as you pull.



NOTE: Fully drained batteries need about 8 hours to recharge.

SmartMonitor 2 PSL Battery Pack

Warnings

- Never change the battery pack while the power supply is plugged in and/or the monitor is being operated.
- 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.
- Do not disassemble or modify the battery. The battery contains safety and protection devices that, if damaged, may cause the battery to heat, rupture, or ignite.

Cautions

- 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 Philips Children's Medical Ventures-supplied battery packs. Use of other battery packs could cause malfunction.
- When the battery is worn out, insulate the terminals with adhesive tape or similar materials before disposal.

Battery Installation Instructions

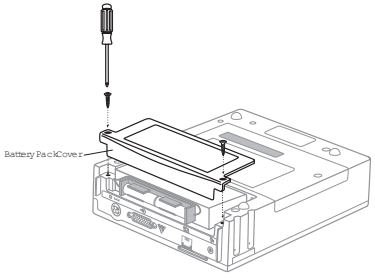
The monitor uses two types of batteries. Rechargeable batteries are used for power during portable operation. Alkaline batteries provide a back-up alarm function if the rechargeable batteries fail. The rechargeable batteries are contained inside a battery pack. Two alkaline, size AAA, batteries are placed into a AAA holder located on the side of the rechargeable pack.

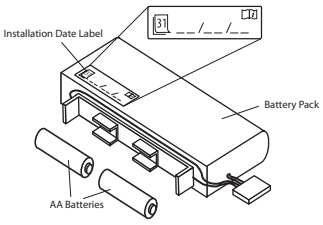
NOTE: Before installing a new or replacement battery pack, write the installation date on the label provided on the battery pack.

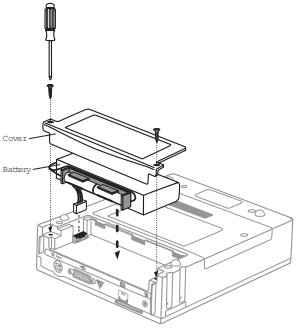
1. Turn the monitors' power off using the correct Power-off procedure, and unplug the external power supply from the monitor.
2. Loosen (counter clock-wise) both screws from the battery pack cover and remove the cover.
3. To remove the battery pack, pull firmly upward when lifting the battery pack out. 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 batteries in accordance with your area's environmental laws.

4. Insert the alkaline batteries into the AAA holder. The correct polarity is marked on the AAA holder.
5. Insert the connector of the new battery pack into the plug located in the upper left corner. It can only be inserted one way. Place the battery pack in the battery compartment. Secure the battery pack properly.
6. Close the battery pack cover and fasten with the screws. Connect the external power supply to the monitor and ensure that it is plugged into a functional AC wall outlet for a minimum of 8 hours. There is no need to power on the monitor to charge the battery pack.

NOTE: The expected rechargeable battery life is two years. The alkaline batteries should be replaced at least once each year to ensure their function, if needed, for backup in the case of a battery pack failure. When you turn on the monitor and an error code of 1A00 is displayed on the LCD, the AAA batteries may need to be replaced. See "Troubleshooting" later in this manual.







NOTE: If you plug a discharged battery pack into a new or recently stored monitor, it will alarm continuously with no lights. Unplug the battery pack and follow the steps to correct the problem in "Troubleshooting" later in this manual. If you are not going to use the monitor for an extended period of time (longer than two months), unplug the battery pack cable.

Transferring SmartMonitor 2 PSL Information

The monitor contains a memory system that automatically records information about each monitoring session. This information can be transferred (or downloaded) to a computer to be reviewed by 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. Additionally, you may choose to transfer data at any time or whenever it is considered necessary by the physician.

Memory Management in the Monitor

When data is successfully transferred to a Memory Card or downloaded to Synergy-E, the data appears to be erased in the monitor. 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. 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 monitor has collected new data and needs the space occupied by the old data.

It is recommended that you erase the memory between each patient use. Please note that this feature will not clear the system parameter settings (alarm and record limits) or the patient name and ID number.

Using the "Clear Memory" function in the System Parameters menus will erase all data regardless of whether or not it has been downloaded.

To Recover the Old Data Using a Memory Card

Transfer the data to the card using the monitor. 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 monitor.

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 monitor.

Modem Download

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

There are three ways to download with a modem. The first choice involves the modem automatically calling the homecare 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. The patient is not monitored while the device is in Communications mode. When the homecare provider calls the patient's phone number, the device will automatically answer and begin transfer of data.

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

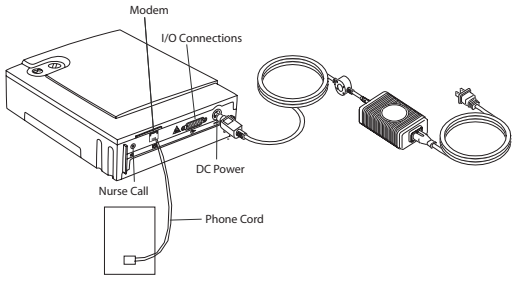
Modem Auto Dial

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

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

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

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



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

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

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

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

Modem Auto Answer in Communications Mode

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

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

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

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

   - The homecare provider should now call to retrieve the information. The phone may ring, but do not answer. The modem answers the call and connects the monitor to the computer through the phone line.
3. The amount of time to transfer the information will vary. When the transfer is complete the monitor will beep five times. After the transfer, you may disconnect the phone line from the monitor and the phone will work normally. Turn the monitor off in the normal way.
   - Press and hold the blue RESET button.
   - Press and release the gray POWER button.
   - Wait two seconds, and then release the RESET button.
   - You can now resume monitoring the patient.

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

Modem Auto Answer in Monitor Mode

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

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

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

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

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

Transferring Monitor Data to a Memory Card

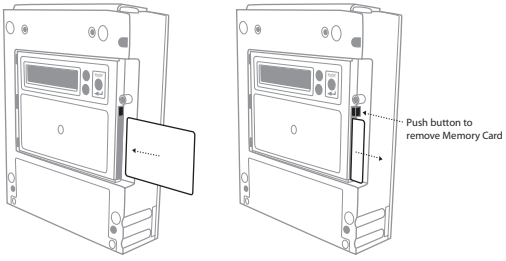
The Memory Card is a credit-card-sized electronic memory transfer device that transfers monitor data. This is an optional feature of monitor and may not be installed on every unit.

NOTE: You may also use a compact flash card with a Memory Card adapter.

NOTE: All data in the Memory Card at the time of a download will be overwritten. For more information, refer to the section "Setting Alarms and Recording Limits" earlier in this manual.

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

1. Make sure the monitor is off.
2. With the Memory Card label facing you, slide the card into the slot provided on the side panel of the monitor. The location of the Memory Card logo will be on the bottom edge and facing you.

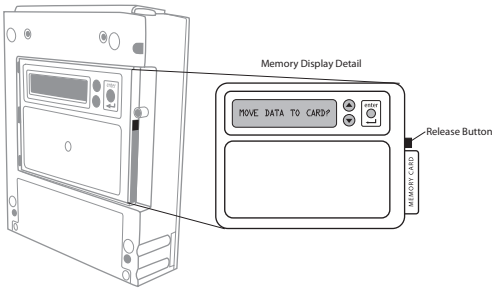


3. Press the POWER button ON. After a short delay, the display will read:
   INITIALIZING PLEASE WAIT
   Then,
   MENU MODE? ENTER PROPER KEY
   SEQUENCE
4. Press the ENTER button within 10 seconds.
   The display will read SMARTMONITOR 2 MENU
   SELECTION.
5. Press the ▼ arrow until you see "Move Data To Card?"

6. Press the ENTER button. The word NO will begin to blink. To select YES, press either arrow button.
7. 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 steps 1-6.

- 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."



NOTE: The memory in the monitor will not be automatically cleared. The recorded data in the monitor 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 Monitor Data Using a Computer

Data can be downloaded from the monitor by direct connection to a computer.

The Synergy-E software is required to download the monitor.

The monitor 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 monitor and the computer before turning the monitor 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 monitor 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 monitor display will read “Monitor is in Communication Mode”.

- The monitor 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 monitor is powered on for working with the computer, Memory Card, or modem but not for monitoring the patient.

NOTE: Refer to the Synergy-E software for instruction on Direct Connection Downloading of the monitor.

Caring for the SmartMonitor 2 PSL

CAUTION: Use the information in this section to keep the monitor functioning well.

CAUTION: Use only Philips Children's Medical Ventures accessories with the monitor.

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, Patient Cables and Lead Wires

Use a clean cloth and any of the following:

- Unscented dish washing detergent
- 3% hydrogen peroxide solution
- 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.
- Ensure 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.
- Philips Children's Medical Ventures 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. Fumigating a Roach/Insect-infested Unit
   - Place the unit inside a Zip-lock type 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 power supply 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 dish washing detergent or 3% Hydrogen Peroxide solution to clean the outside of the monitor.
   - If necessary, return the unit to Philips Children's Medical Ventures 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 monitor's 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 a patient cable is changed.

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

1. Insert the ECG patient cable into the socket located on the front of the monitor.
2. Connect the lead wires to the ECG patient cable. Insert the white lead wire into the opening labeled RA. Insert the black lead wire into the opening labeled LA.
3. Connect the lead wires to the functional self-test socket on the side panel of the monitor. Insert the white lead wire into the RA opening and then the black lead wire into the LA opening.
4. Turn on the monitor. You hear two short beeps and the lights on the front come on briefly then go off.

5. After all the alarm lights go out, the green power and charger lights remain on and the green heart and respiration lights are blinking. All numeric displays will begin displaying values.
6. The heart and respiration lights continue to blink for about 30 seconds.
7. When the green lights stop blinking, the red low heart light will come on within about seven seconds and the alarm beeps once every second.
8. 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).
9. Follow the instructions in the "Self-Test Troubleshooting" section, if necessary.
10. 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.
11. The loose lead light will come on, and the alarm changes from beeping to continuous. This lets you know the monitor, patient cables, and lead wires are working properly.
12. 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 occurs. 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 section "Turning the Monitor Off – Sibling Alarm" earlier in this manual. • Make sure the power supply is plugged into a live power outlet and is properly connected to the monitor. (See "Charging the Battery" for more information). • 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 eight hours before using the monitor on battery power.
Memory Full	The monitor's memory has reached the Memory Full parameter. Press the RESET button to silence the alarm. The monitor's memory needs to be transferred Self-Test may continue.
Loose Lead	Indicates loose or bad electrodes, lead wires, and/or patient cable. Check all connections and/or replace lead wires first, then the patient cable(s) if necessary.

WARNING: The monitor's lights and alarms should respond as described above. If not, contact Philips Children's Medical Ventures Service before using the unit to monitor a patient.

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

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 monitor.

The table below lists some common problems:

Problem	Possible Cause	Instructions
Monitor will not turn on	The monitor is disconnected from the power cord/battery charger; batteries are discharged. No Power at outlet. Defective power cord/battery charger. Internal part failure.	Plug the power cord/battery charger into the monitor and outlet. Locate an outlet with power. Contact Philips Children's Medical Ventures. Contact Philips Children's Medical Ventures.
All lights will flash together and the alarm will beep in unison with the flashing lights. Pressing RESET will not silence alarm. 0001 displayed on bottom LCD display. 1B01 displayed on bottom LCD display.	Internal error condition was detected by the monitor or Battery not connected or Internal failure with monitor.	Reduce likelihood of electrostatic discharge around the monitor. or Contact Philips Children's Medical Ventures If an Error number is displayed on the LCD (the LCD is located on the bottom of the monitor), record this information. Contact Philips Children's Medical Ventures. 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 five seconds • Release POWER button; continue to hold the RESET button until the monitor turns off.

Problem	Possible Cause	Instructions
1A00 or 1A01 displayed on bottom LCD display.	Problem with AAA batteries; try replacing them.	• Open the battery compartment, unplug the battery pack, and replace the AAA batteries. • Plug the power supply cable into the monitor and the power supply cord into the AC outlet, then connect the battery pack cable to the monitor. When you turn the monitor on, the error code should not appear. If these steps do not resolve the problem, contact Philips Children's Medical Ventures Customer Service.
Alarm Sound Continuous, No Lights	A discharged battery pack is plugged into a new or recently stored monitor (i.e., the monitor has been unused for two months or longer). NOTE: SmartMonitor 2 PSL includes a redundant battery system. There are a rechargeable battery pack and two AAA alkaline cells located in the battery compartment. The purpose of the AAA cells is to generate an alarm if there is a failure in the rechargeable pack (the alarm also sounds when the pack is nearly completely discharged). This can occur when the battery pack is first installed in a new monitor or in a monitor that has been unused for two months or longer.	Follow this sequence of steps exactly: • Unplug the battery pack. • Plug the power supply cable into the monitor and the power supply cord into the AC outlet. • Plug the battery pack cable into the monitor. If the above steps do not resolve the problem, contact Philips Children's Medical Ventures Customer Service. NOTE: If you are not going to use the monitor for an extended period of time, unplug the battery pack cable to prevent unnecessary alarms upon reconnection.
Alarm Sound Continuous, No Lights or 0001 displayed on bottom LCD display.	No power, battery drained or disconnected. or Battery not connected.	Ensure battery is connected. Connect power supply. Use Power-Off to silence alarm. • Press and hold the blue RESET button. • Press and release the gray POWER button. Wait two seconds, and 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 eight hours before using the monitor on battery power.

Problem	Possible Cause	Instructions
Alarm Sound Continuous, No Lights	Incorrect power-off sequence.	• Press the POWER button, and make sure that the power light is illuminated. • Press and hold the RESET button. Press and release the POWER button. Wait two seconds, then release the RESET button.
Alarm sounds weak or only one alarm tone is heard at Power Up.	Internal part failure or Low battery.	Contact Philips Children's Medical Ventures. Charge battery.
Loose lead or Light and front display remains on.	Connections between sensors, electrodes, lead wires, and patient cables are not properly made. or Defective lead wires or patient cable(s) or Defective electrodes or Internal part failure.	Verify that (a) patient's skin underneath electrodes is clean, (b) electrodes are clean, and (c) lead wires are fully inserted into the electrodes and ECG patient cable. Replace lead wires or patient cables and perform Functional Self-Test or Replace electrodes and Contact Philips Children's Medical Ventures.
Unable to download via modem.	AC power not connected to the monitor or The monitor is not connected to phone line or not connected to phone (wall) jack or Device power off or Incorrect modem selection on computer or Defective power supply, phone cord, or phone splitter.	Plug the monitor into AC power before performing a download, and verify that the charging light is on. or Connect phone line to monitor and to phone (wall) jack or Turn the monitor's power on, and verify that power light is on or Verify modem selection on computer or Replace power supply, replace phone cord, plug phone cord directly into phone (wall) jack.

Problem	Possible Cause	Instructions
Unable to communicate by direct connect.	Download cable was not connected to the monitor and the computer prior to turning on the monitor. Defective host cable. Incorrect COM port selection on computer.	Connect the download cable to the monitor and the computer before turning the monitor on. Replace host cable. Verify COM port selection on computer.

DEVICE SIZE

Dimensions:	2.25” x 7.25” x 9.0” (5.72 cm x 18.42 cm x 22.86 cm)
Weight:	3.0 lbs. (1.35 kg)
Shipping Weight:	8.5 lbs. (3.9 kg)

ELECTRICAL RATINGS

Power Supply: 100-240 VAC 50/60 Hz 36W

SmartMonitor 2 PSL: 12VDC, 3.0 Amps max.

Li Ion Rechargeable Battery Pack: 7.4 VDC, 4.4AH nominal

ENVIRONMENTAL CONDITIONS

Operating Temperature:	41º to 104ºF (5ºC to 40ºC)
Operating Humidity:	15% to 95% RH, non-condensing
Storage Temperature:	-4 to 140ºF (-20ºC to 60ºC)
Storage Humidity:	15 to 95% RH, non-condensing
Battery Charging Temperature:	50º to 95ºF (10ºC to 35ºC)

STANDARDS COMPLIANCE

This device is designed to conform to the following standards:

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

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

The SmartMonitor 2 PSL system is classified as follows:

Type of protection against electric shock: Class II/Internally Powered

Degree of protection against electric shock: Type BF Applied Part

Degree of protection against ingress of water: IPX1

Mode of operation: Continuous

DISPOSAL

When necessary, dispose of the monitor in accordance with your local regulations.

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 ±200Ω
	Low Battery Warning	Battery voltage low, power supply required promptly
	Low Battery Shutdown	Battery voltage too low to continue without power supply
	Full Memory	Memory is 50% full or 80% full, repeats when memory is 100% full
Memory Capacity	Non-Volatile Memory	4 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.
Signal Channels	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
	Event Duration	Alarm duration plus current pre- and post-settings totaling 45, 60, 75, 90 seconds
	Apnea Record (Infants only)	Off or 6 to 40 seconds in two-second intervals
	Bradycardia Record	Off or 50 to 100 Beats per Minute in five-BPM intervals

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A (not applicable for device with rated power of 75 W or less)	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

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

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

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

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

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

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This Device

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

Rated Maximum Power Output of Transmitter W	Separation Distance According to Frequency of Transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

Glossary

Apnea – The cessation of breathing (respirations).

Central apnea – No respiratory effort.

Obstructive apnea – Cessation of airflow into or out of the mouth or nose although efforts to breath continue.

Bradycardia – Slowing of the heart rate below the age specified rate for five 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 patient's skin.

Functional Self-Test – A user-performed test to verify the monitor, ECG patient cable, and lead wires are working properly.

Heart rate – The number of heart beats per minute.

Impedance – A method used by the monitor to detect respiration.

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

Modem – A device that allows the homecare provider or hospital to work with a monitor through telephone lines.

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

% (Percent) SpO_2 – A measurement of how much oxygen is contained in blood. Usually measured via a finger, toe or ear sensor. Note that the SpO_2 measurement indicates the functional saturation.

RA Connection – The opening on the ECG patient cable marked "RA" is the connector for the white lead wire.

Respiration – The act of inhaling and exhaling air (breathing).

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.

Manufactured for

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