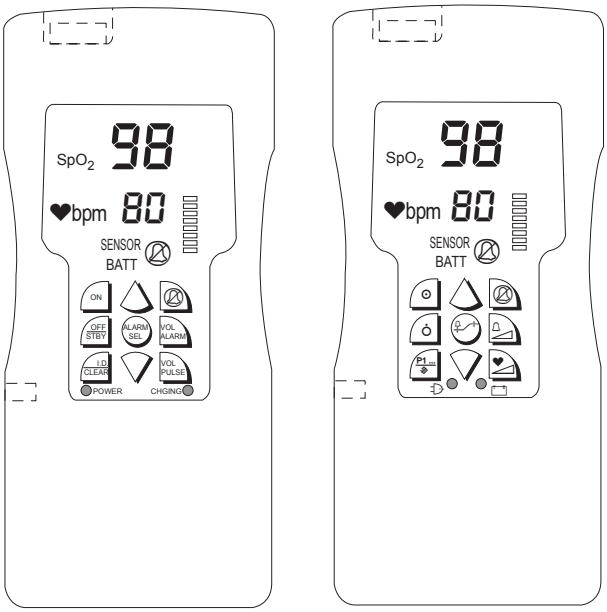
Oximeter

Clinician's Operation Manual



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Warranty & Service Information

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Limited Warranty

Smiths Medical PM, Inc. ("Seller") warrants to the original purchaser that the Product, not including accessories, shall be free from defects in material and workmanship under normal use, if used in accordance with its labeling, for two years from the date of shipment to the original purchaser.

Seller warrants to the original purchaser that the reusable oximeter sensors supplied as accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with its labeling, for one year from the date of shipment to the original purchaser (USA only).

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THE FOREGOING EXPRESS WARRANTY, AS CONDITIONED AND LIMITED, IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

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This warranty is void if the Product has been altered, misused, damaged by neglect or accident, not properly maintained or recharged, or repaired by persons not authorized by Seller. Misuse includes, but is not limited to, use not in compliance with the labeling or use with accessories not manufactured by Seller. This warranty does not cover normal wear and tear and maintenance items.

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The original purchaser's exclusive remedy shall be, at Seller's sole option, the repair or replacement of the Product. **THIS IS THE EXCLUSIVE REMEDY. In no event will Seller's liability arising out of any cause whatsoever (whether such cause is based on contract, negligence, strict liability, tort or otherwise) exceed the price of the Product and in no event shall Seller be responsible for consequential, incidental, or special damages of any kind or nature whatsoever, including but not limited to, lost business, revenues, and profits.**

Warranty Procedure

To obtain warranty service in the USA, you must request a Customer Service Report (CSR) number from Technical Service. Reference the CSR number when returning your Product, freight and insurance prepaid, to:

Smiths Medical PM, Inc.
N7W22025 Johnson Drive
Waukesha, WI 53186-1856

Phone: 262 542 3100
Toll Free (in USA only):
1-800-558-2345
Fax: 262-542-0718

Seller will not be responsible for unauthorized returns or for loss or damage to the Product during the return shipment. The repaired or replaced Product will be shipped, freight prepaid, to Purchaser.

To obtain warranty information outside of the USA, contact your local distributor.

Keep all original packing material, including foam inserts. If you need to ship the device, use only the original packaging material, including inserts. Box and inserts should be in original condition. If original shipping material in good condition is not available, it should be purchased from Smiths Medical PM, Inc.

Damages occurred in transit in other than original shipping containers are the responsibility of the shipper. All costs incurred returning devices for repair are the responsibility of the shipper.

CE Notice

Marking by the symbol CE 0473 indicates compliance of this device to the Medical Device Directive 93/42/EEC.

Authorized Representative (as defined by the Medical Device Directive):

Smiths Medical International Ltd.
Colonial Way, Watford, Herts,
WD24 4LG, UK

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Fax: (44) 1923 240273

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Chapter 1: Introduction

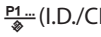
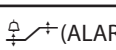
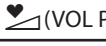
About this Manual

The Clinician's Operation Manual provides installation, operation, and maintenance instructions for the health-care professional trained in monitoring respiratory and cardiovascular activity.

The Home-Use Instruction Book provides operation and maintenance instructions for the home-use caregiver. The home-use caregiver is assumed to be trained in oximeter use by a doctor or other health-care professional. The Home-Use Instruction Book supplements, and does not replace, training provided by a health-care professional in oximeter use.

These instructions contain important information for safe use of the product. Read the entire contents of these instructions For Use, including Warnings and Cautions, before using the oximeter. Failure to properly follow warnings, cautions, and instructions could result in death or serious injury to the patient.

Definition of Symbols

SYMBOL (TEXT)	DEFINITION
	Type B equipment
	Attention, see instructions for use
	Refer servicing to qualified service personnel
	Non AP device
	Use by
	Catalog Number
	Serial Number
	Date of Manufacture
	Moisture Sensitive
	Collect Separately
Rx ONLY	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
	Do Not Reuse. One use on one patient.
⊙ (ON)	On
⏻ (OFF/STBY)	Off
	ID Clear
^ v	Up and Down Keys
	Alarm Select
	Alarm Silence
	Alarm Volume
	Pulse Volume
♥bpm	Heart Rate LED
%SpO2	Percent Oxygen Saturation
	Power LED
	Charging or low battery

KEYWORD	DEFINITION
WARNING!	Tells you about something that could hurt the patient or hurt the operator
CAUTION!	Tells you about something that could damage the monitor
NOTE!	Tells you other important information

Warnings

WARNING! Do not use this device in the presence of flammable anesthetics.

WARNING! Do not use this device in the presence of magnetic resonance imaging (MR or MRI) equipment.

WARNING! Operation of this device may be adversely affected in the presence of strong electromagnetic sources, such as electrosurgery equipment.

WARNING! Operation of this device may be adversely affected in the presence of computed tomography (CT) equipment.

WARNING! This device is intended for use by trained healthcare professionals. The operator must be thoroughly familiar with the information in this manual before using the device.

WARNING! This device must be used in conjunction with clinical signs and symptoms. This device is only intended to be an adjunct in patient assessment.

WARNING! It is the operator's responsibility to set alarm limits appropriately for each individual patient.

WARNING! Prolonged use or the patient's condition may require changing the sensor site periodically. Change the sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

WARNING! Any monitor that has been dropped or damaged should be inspected by qualified service personnel, prior to use, to ensure proper operation.

WARNING! If the accuracy of any measurement is in question, verify the patient's vital sign(s) by an alternative method and then check the monitor for proper functioning.

WARNING! When attaching sensors with Microfoam® tape, do not stretch the tape or attach the tape too tightly. Tape applied too tightly may cause inaccurate readings and blisters on the patient's skin (lack of skin respiration, not heat, causes the blisters).

WARNING! Connect the AC power cord to a grounded, three-wire outlet. Failure to comply may compromise patient isolation.

WARNING! In the event that earth ground integrity is lost, the performance of this device and/or other devices nearby may be affected due to excessive RF emissions.

WARNING! Patient safety can be compromised by the use of a power supply not supplied by Smiths Medical PM, Inc. Use only the power supply included with your monitor, or one approved by Smiths Medical PM, Inc.

WARNING! Use only SpO_2 sensors supplied with, or specifically intended for use with, this device.

WARNING! Optical cross-talk can occur when two or more sensors are placed in close proximity. It can be eliminated by covering each site with an opaque material.

WARNING! SpO_2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, for example) if necessary.

WARNING! Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, patent blue V (PBV), and fluorescein may adversely affect the accuracy of the SpO_2 reading.

WARNING! Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin (with CO-poisoning) or methemoglobin (with sulfonamide therapy), will affect the accuracy of the SpO_2 measurement.

WARNING! Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate SpO_2 and pulse rate readings.

WARNING! Remove fingernail polish or false fingernails before applying SpO_2 sensors. Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.

WARNING! Tissue damage may result from overexposure to sensor light during photodynamic therapy with agents such as verteporphin, porfimer sodium and metatetrahydroxyphenylcholrin (mTHPC). Change sensor site at least every hour and observe for signs of tissue damage. More frequent sensor site changes or inspections may be indicated depending upon the photodynamic agent used, agent dose, skin condition, total exposure time or other factors. Use multiple sensor sites.

WARNING! When connecting this monitor to any instrument, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions. Accessory equipment connected to the monitor's data interface must be certified according to the respective IEC standards, i.e. IEC 950 for data processing equipment or IEC 601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC 601-1-1 systems requirements. Anyone connecting additional equipment to the signal input port or signal output port configures a medical system, and therefore, is responsible that the system complies with the requirements of the system standard IEC 601-1-1.

WARNING! IEC 950 approved equipment must be placed outside of the patient environment. The patient environment is defined as an area 1.5 m (4.92 feet) from the patient.

Figure 1.1: Patient Environment (side)
(dimensions are not prescriptive)

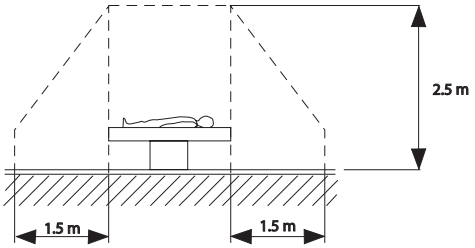
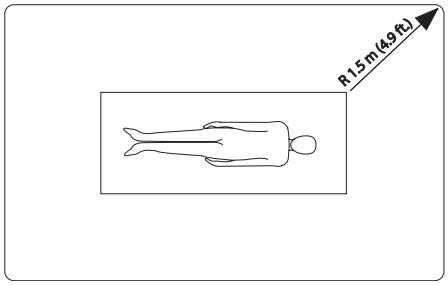


Figure 1.2: Patient Environment (top)
(dimensions are not prescriptive)



WARNING! Disconnect the AC power supply from the outlet before disconnecting it from the monitor. Leaving the AC power supply connected to an AC power outlet without being connected to the monitor may result in a safety hazard.

WARNING! Do not allow any moisture to touch the AC power supply connectors or a safety hazard may result. Ensure that hands are thoroughly dry before handling the AC power supply.

WARNING! Do not place the monitor in the patient's bed or crib. Do not place the monitor on the floor.

WARNING! Failure to place the monitor away from the patient may allow the patient to turn off, reset, or damage the monitor, possibly resulting in the patient not being monitored. Make sure the patient cannot reach the monitor from their bed or crib.

WARNING! Failure to carefully route the cable from the sensor to the monitor may allow the patient to become entangled in the cable, possibly resulting in patient strangulation. Route the cable in a way that will prevent the patient from becoming entangled in the cable. If necessary, use tape to secure the cable.

WARNING! If there is a risk of the AC power supply becoming disconnected from the monitor during use, secure the cord to the monitor several inches from the connection.

WARNING! Under certain clinical conditions, pulse oximeters may display dashes if unable to display SpO_2 and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.

WARNING! Verify that all LEDs (light emitting diodes) on the display light up upon startup of the device.

Cautions

CAUTION! The monitor is equipped with an internal rechargeable battery. Do not attempt to remove or replace the internal rechargeable battery. ⚠ Refer servicing to qualified personnel.

CAUTION! Ensure the monitor's AC rating is correct for the AC voltage at your installation site before using the monitor. The monitor's AC rating is shown on the external power supply. If the rating is not correct, do not use the monitor. Contact the Smiths Medical PM, Inc. service department or your local distributor for help.

CAUTION! Do not autoclave, ethylene oxide sterilize, or immerse the sensors in liquid.

CAUTION! Do not allow water or any other liquid to spill onto the monitor. Evidence that liquid has been allowed to enter the monitor voids the warranty.

CAUTION! Monitors not in use must be fully charged at least every five months, otherwise the battery will no longer be able to accept a charge.

CAUTION! Connect only the printer cable specifically intended for use with this device (see *Optional Supplies and Accessories*).

CAUTION! Failure to charge the monitor while it is not being used may shorten the battery life. Charge the monitor while it is not being used to ensure the longest battery life.

CAUTION! Do not attempt to stand the oximeter upright when not using the protective rubber boot. Position the oximeter on its back.

CAUTION! Pressing front panel keys with sharp or pointed instruments may permanently damage the key pad. Press front panel keys only with your finger.

CAUTION! Unplug the external power supply from the monitor before cleaning or disinfecting the monitor.

CAUTION! Chemicals used in some cleaning agents may cause brittleness of plastic parts. Follow cleaning instructions in this manual.

Notes

NOTE! SpO_2 averaging is the number of pulse beats over which the SpO_2 value is averaged; pulse averaging is the number of seconds over which the pulse value is averaged.

NOTE! The low SpO_2 alarm limit minimum test value is 80. If an operator changes the low SpO_2 alarm limit to a value less than 80, and a power down - power up sequence takes place, a minimum value of 85 takes the place of the operator entered value.

NOTE! Batteries are not user replaceable.
Service Personnel: Follow local governing ordinances and recycling instructions regarding disposal or recycling of device components, including batteries.

NOTE! Do not plug the monitor into an outlet controlled by a wall switch.

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Chapter 2: Intended Use and Monitor Features

Intended Use

The Oximeter provides fast, reliable SpO_2, pulse rate, and pulse strength measurements. It may be used in the hospital or clinical environment, during emergency air or land transport, or for in-home use. The oximeter will operate accurately over an ambient temperature range of 0 to 40°C (32 to 104°F). The oximeter works with all BCI® oximetry sensors providing SpO_2 and pulse rate on all patients from neonate to adult (see section *Choosing the Sensor* under *Attaching the Sensor to the Patient*).

The oximeter permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The oximeter has three modes of operation: Clinician Mode, Home-Use Mode, and Sleep Study Mode. Clinician Mode aids the health care professional in monitoring patient activity. The Home Use Mode permits the home-use caregiver to monitor a patient within the home environment. Finally, Sleep Study Mode allows the health care professional to record sleep study data which may later be transferred to a PC and analyzed.

Monitor Features

- Provides fast, reliable SpO_2, pulse rate, and pulse strength measurements on any patient, from neonates to adults.
- Ideally suited for use in intensive care units, outpatient clinics, emergency rooms, during emergency air or land transport, or for in-home use.
- Portable and lightweight. Weighs only 539 grams (19 ounces).
- Ergonomically designed to fit comfortably in the palm of your hand.
- Uses an internal, rechargeable battery.

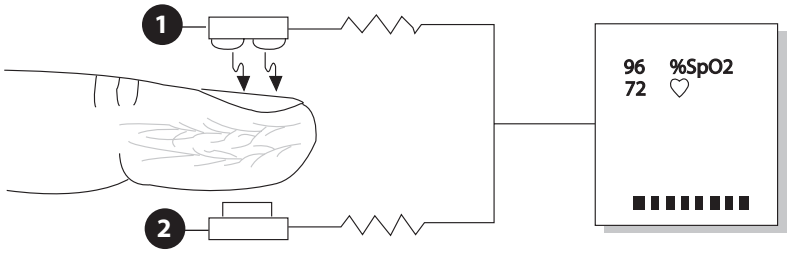
- Battery life is approximately 24 hours in continuous use. Battery fully charges in about 6 hours.
- Bright, easy-to-read LED displays indicate SpO_2 and pulse rate measurements. Brightness is user-adjustable.
- An eight-segment LED bar graph indicates pulse strength.
- Positive identification of SpO_2 or pulse rate alarm. Adjustable high and low alarm limits for SpO_2 and pulse rate measurements.
- Adjustable volume (including off) alarm and alert tones.
- Adjustable volume (including off) "beep" sounds with each pulse beat. Pitch of pulse "beep" corresponds to SpO_2 value.
- Low battery indicator lights when about 30 minutes of battery use remains.
- Connects to an optional external printer. Prints less than 15 minutes of trend data in a tabular format, or more than 15 minutes of trend data in a graphic format.
- SpO_2 and pulse rate averaging settings are user-selectable.
- Trend view allows operator to view previous patient history.
- Home-use mode allows a home-use caregiver to monitor a patient at home.
- Sleep study mode allows the health care professional to record the SpO_2 and Heart Rate values of a patient every 4 seconds for up to 12 hours.
- Sleep study mode allows the health care professional to output the data to a PC for further analysis.

Theory of Operation

The pulse oximeter determines %SpO_2 and pulse rate by passing two wavelengths of low intensity light, one red and one infrared, through body tissue to a photodetector. Information about wavelength range can be especially useful to clinicians. Wavelength information for this device can be found in the *SpO_2 Specifications* section of this manual.

Pulse identification is accomplished by using plethysmographic techniques, and oxygen saturation measurements are determined using spectrophotometric oximetry principles. During measurement, the signal strength resulting from each light source depends on the color and thickness of the body tissue, the sensor placement, the intensity of the light sources, and the absorption of the arterial and venous blood (including the time varying effects of the pulse) in the body tissues.

Figure 2.1: Theory of Operation



1 Low intensity Red and Infrared LED light sources

2 Detector

Oximetry processes these signals, separating the time invariant parameters (tissue thickness, skin color, light intensity, and venous blood) from the time variant parameters (arterial volume and SpO_2) to identify the pulses and calculate functional oxygen saturation. Oxygen saturation calculations can be performed because blood saturated with oxygen predictably absorbs less red light than oxygen-depleted blood.

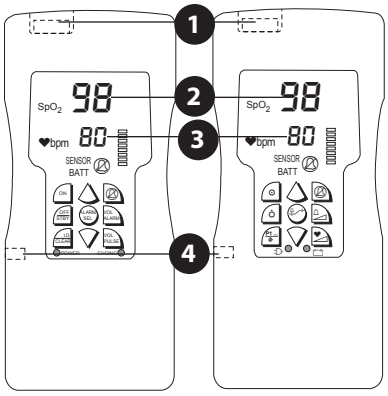
WARNING! Since measurement of SpO_2 depends on a pulsating vascular bed, any condition that restricts blood flow, such as the use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate SpO_2 and pulse rate readings.

WARNING! Under certain clinical conditions, pulse oximeters may display dashes if unable to display SpO_2 and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.

Chapter 3: Controls and Features

Monitor Front Panel

Figure 3.1: Monitor Front Panel



1 Sensor /Printer Connector

The sensor connects here, or an oximetry cable can be connected between the monitor and the sensor. The printer is also connected here.

2 SpO_2 Numeric Display

A number shows the patient's SpO_2 value in percent. Dashes (---) mean the monitor is not able to calculate the SpO_2 value.

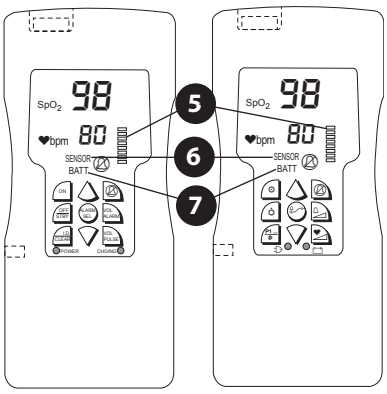
3 Pulse Rate Numeric Display

A number shows the patient's pulse rate value in beats per minute. Dashes (---) mean the monitor is not able to calculate the pulse rate value.

4 Power Supply Connector

The AC power supply connects here.

Figure 3.2: Monitor Front Panel



5 Pulse Strength Bar Graph

The pulse strength bar graph "sweeps" with the patient's pulse beat. The height of the bar graph tells the strength of the patient's pulse.

6 SENSOR Light

SENSOR flashes on and off when the sensor is not connected to the monitor, the sensor is not attached to the patient, or the sensor is not properly attached to the patient.

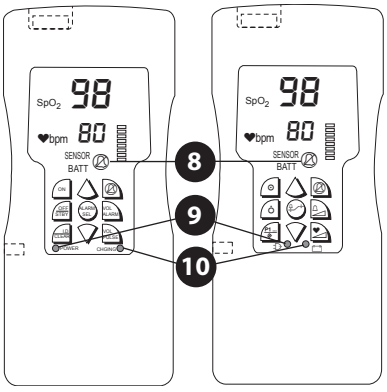
WARNING! While SENSOR is flashing, the monitor cannot measure the patient's SpO_2 or pulse rate. You must immediately check the patient's condition. After you have checked the patient's condition, you must correct the SENSOR alert.

7 BATT Light

BATT flashes on and off when about 30 minutes of battery use remains. The monitor will work until the battery becomes very weak. When the battery becomes very weak, the monitor will turn itself off.

WARNING! When BATT flashes, you must immediately charge the monitor's battery. Otherwise, the monitor turns itself off about 30 minutes after BATT begins to flash.

Figure 3.3: Monitor Front Panel



8 Alarm Silenced Light

The alarm silenced light flashes on and off when the alarm and alert tones are silenced for two minutes. The alarm silenced light remains on when the alarm and alert tones are silenced indefinitely (until canceled or until the monitor is turned off).

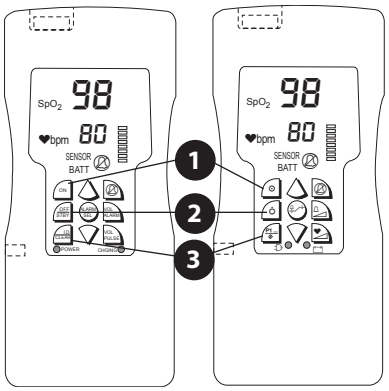
9 POWER Light

POWER light is green when the power supply is attached.

10 CHGING Light

The CHGING light is yellow when the battery is fast charging.

Figure 3.4: Operating Keys



1 ⊙ ON Key

Pressing ON turns on the monitor.

2 ⏻ OFF/STBY Key

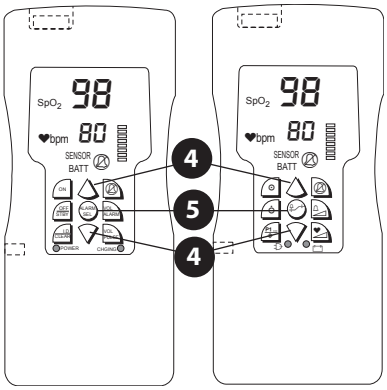
Pressing OFF/STBY turns off the monitor.

3 P1 I.D./CLEAR Key

While the sensor is connected to the monitor: Pressing I.D./CLEAR (P1) increases the patient number by one; the patient number is briefly displayed in the SpO_2 digits. Pressing and holding I.D./CLEAR for about six seconds clears all trend data and sets the patient number to 1.

While the sensor is not connected to the monitor: Pressing I.D./CLEAR (P1) causes the monitor to enter the trend view mode (two bar graph segments flash to indicate trend view mode.) During trend view mode, the last valid measurement for each patient number can be shown by pressing the ∧ or ∨ keys. The display shows Pn (n = patient number) then the measurement corresponding to that patient number. If, after 20 seconds, no keys are pressed, the monitor exits the trend view mode.

Figure 3.5: Operating Keys



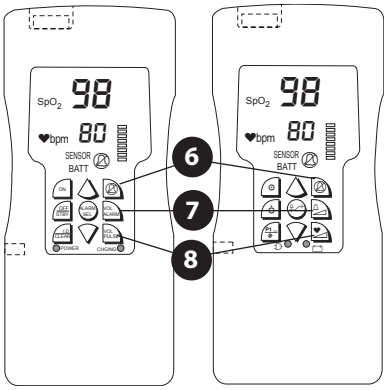
4 ∧ and ∨ Keys

The ∧ and ∨ keys are used to adjust up and down the following settings: brightness of the display; alarm limits; trend view patient numbers; SpO_2 and pulse rate averaging.

5 ALARM SEL Key

Pressing ALARM SEL cycles through each of the alarm limits for setting.

Figure 3.6: Operating Keys



6 Alarm Silence Key

Momentarily pressing the Alarm Silence key silences the alarm tone for two minutes. Pressing and holding the alarm silence key for about three seconds silences the alarm tone indefinitely (until canceled or until the monitor is turned off).

7 ALARM VOL Key

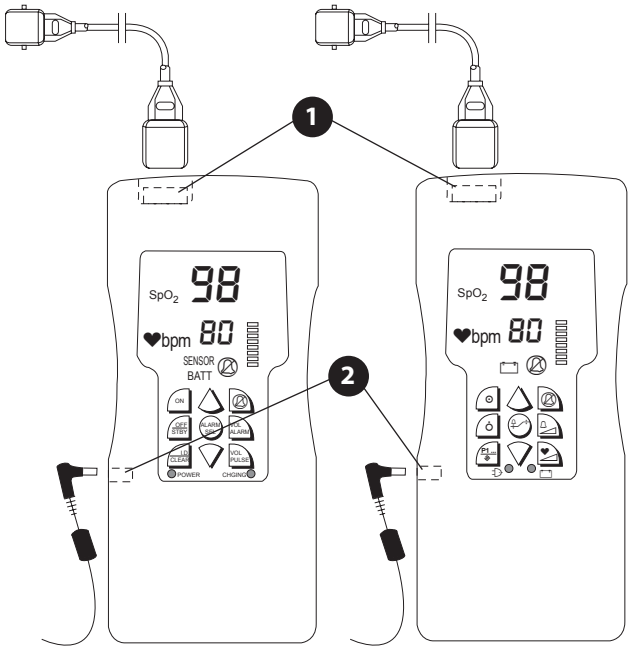
Pressing ALARM VOL key changes the alarm volume from soft to loud or loud to soft.

8 PULSE VOL Key

Pressing the PULSE VOL key changes the pulse "beep" volume.

NOTE! The pulse volume is stored after the monitor is turned off.

Figure 3.7: Connectors



1 Sensor /Printer Connector
An optional printer can be connected for printing trend data. See Printer section for more printer options.

2 AC Power Supply
AC power supply connects here.

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Chapter 4: Operating Instructions

Unpacking the Monitor

1. Carefully remove the monitor and its accessories from the shipping carton. Save the packing materials in case the monitor must be shipped or stored.
2. Compare the packing list with the supplies and equipment you received to make sure you have everything you'll need.

AC Power

CAUTION! Ensure the device's AC rating is correct for the AC voltage at your installation site before using this monitor. The monitor's AC rating is shown on the external power supply. If the rating is not correct, do not use the monitor; contact the Smiths Medical PM, Inc. Service Department, or your local distributor, for help.

Refer also to *Chapter 12: Optional Supplies and Accessories* to verify the proper AC power supply for your application.

NOTE! Do not plug the monitor into an outlet controlled by a wall switch.

8210	AC power supply 105-125VAC 60 Hz
8212	AC power supply 208-252VAC 50/60 Hz
8216	AC power supply 90-110VAC 50 Hz

NOTE! When using AC power, the Oximeter is a class II device with functional earth. This earth connection is for device electromagnetic compatibility and does not provide protection to the patient or user.

Attaching the Sensor to the Patient

What you need to know about attaching the sensor to the patient:

WARNING! Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

WARNING! When attaching sensors with Microfoam® tape, do not stretch the tape or attach the tape too tightly. Tape applied too tightly may cause inaccurate readings and blisters on the patient's skin (lack of skin respiration, not heat, causes the blisters).

Attaching the patient to the monitor requires these steps:

1. Choose the sensor.
2. Check the sensor and oximetry cable.
3. Clean or disinfect the sensor if using the reusable type. (Disposable sensors are for single-patient use and do not require cleaning or disinfecting.)
4. Attach the sensor to the patient.

WARNING! Do not place the monitor in the patient's bed or crib. Do not place the monitor on the floor.

WARNING! Failure to place the monitor away from the patient may allow the patient to turn off, reset, or damage the monitor, possibly resulting in the patient not being monitored. Make sure the patient cannot reach the monitor from their bed or crib.

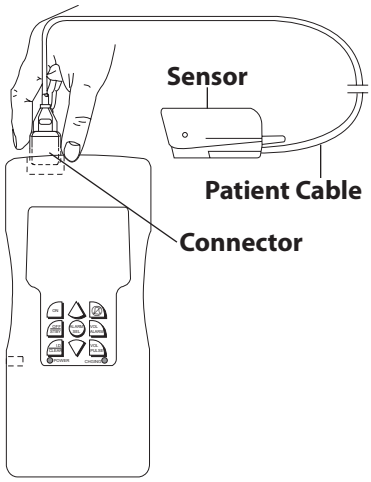
Choosing the Sensor

PATIENT	SITE	DESCRIPTION
Adult >45 kg	Finger	3044: Sensor, Adult (reusable) 3444: Sensor, Comfort Clip® (reusable)
	Finger or Toe	3043: Sensor, Universal 'Y' (reusable) 1300: Sensor, Adult (disposable) ⊗
	Ear	3078: Sensor, Ear (reusable)
Pediatric 15-45 kg	Finger	3044: Sensor, Adult (reusable) (> 20 kg) 3444: Sensor, Comfort Clip® (reusable) 3178: Sensor, Pediatric (reusable) (5-45 kg)
	Finger or Toe	3043: Sensor, Universal 'Y' (reusable) 1301: Sensor, Pediatric (disposable) ⊗
	Ear	3078: Sensor, Ear (reusable)
Infant 3-15 kg	Hand or Foot	3043: Sensor, Universal 'Y' (reusable)
	Toe	3025: Sensor, Wrap, Infant (reusable)
	Finger or Toe	1303: Sensor, Infant (disposable) ⊗
Neonate <3 kg	Hand or Foot	1302: Sensor, Neonate (disposable) ⊗
	Foot	3026: Sensor, Wrap, Neonate (reusable)

Care and Handling of the Sensor

WARNING! Misuse or improper handling of the sensor and cable could result in damaging of the sensor. This may cause inaccurate readings.

Figure 4.1: Hold the Connector

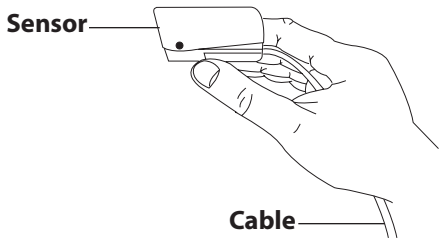


Hold the connector rather than the cable when connecting or disconnecting the finger sensor to the device as shown in Figure 4.1.

Do not use excessive force or unnecessary twisting when connecting, disconnecting, storing, or when using the sensor.

When placing the sensor on the patient, allow the cable to lay across the palm of the hand and parallel to the arm of the patient as shown in Figure 4.2.

Figure 4.2: Finger Sensor



Upon completion of patient monitoring, detach the sensor as shown in Figure 4.1 and loosely coil the finger sensor cable.

Checking the Sensor and Oximetry Cable

Follow these instructions each time before you attach the sensor to the patient. This helps ensure the sensor and oximetry cable are working properly.

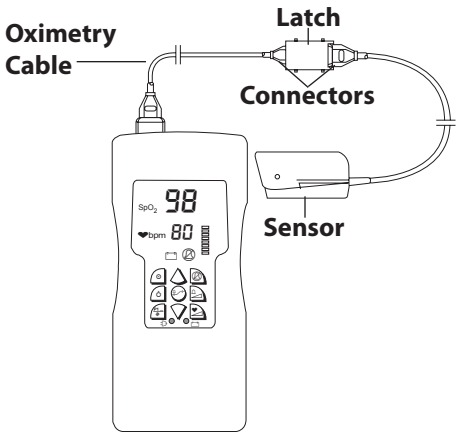
WARNING! Using a damaged sensor may cause inaccurate readings. Inspect each sensor. If a sensor appears damaged, do not use it. Use another sensor or contact your authorized repair center for help.

WARNING! Using a damaged oximetry cable may cause inaccurate readings. Inspect the oximetry cable. If the oximetry cable appears damaged, do not use it. Contact your authorized repair center for help.

1. Carefully inspect the sensor to make sure it does not appear damaged.

2. If using the oximetry cable, carefully inspect the oximetry cable to make sure it does not appear damaged.

Figure 4.3: Attaching the sensor and oximetry cable to the monitor



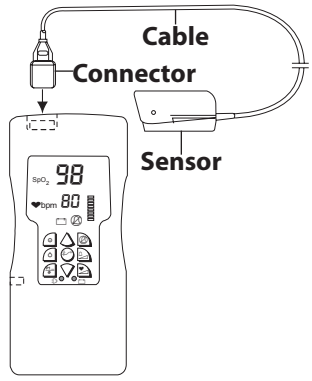
3. If using the oximetry cable:

   a. If the sensor is not already connected to the oximetry cable, connect the sensor to the oximetry cable as shown. Push the connectors together firmly and close the latch to secure the connectors.

   b. If the oximetry cable is not already connected to the monitor, connect the oximetry cable to the monitor as shown. Push the connector firmly into the monitor.

WARNING! Failure to carefully route the cable from the sensor to the monitor may allow the patient to become entangled in the cable, possibly resulting in patient strangulation. Route the cable in a way that will prevent the patient from becoming entangled in the cable. If necessary, use tape to secure the cable.

Figure 4.4: Attaching the Sensor to the Monitor

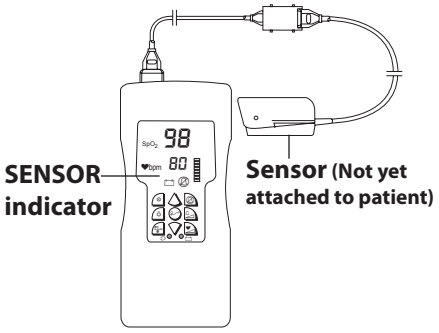


4. If not using the oximetry cable: Connect the sensor to the monitor as shown. Push the connector firmly into the monitor.

5. If the monitor is not already on, press the ON key to turn on the monitor.

6. Before the sensor is attached to the patient, check the integrity of the sensor, oximetry cable, and oximeter as follows:

Figure 4.5: Check the integrity



   a. Make sure the red light in the sensor is illuminated.

b. Make sure the SENSOR indicator is flashing as follows:

- For 'Y' sensors, wrap sensors, and disposable sensors: Align the sensor's red light with the detector so they are less than 0.3 cm (1/8 inch) away from each other. Make sure the SENSOR indicator is flashing on the oximeter.

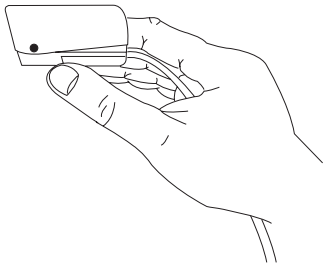
- For the finger sensor and ear sensor: Make sure the SENSOR indicator is flashing on the oximeter.

NOTE! Obstructions or dirt on the sensor's red light or detector may cause the checks to fail. Make sure there are no obstructions and the sensor is clean.

WARNING! If any of the integrity checks fail, do not attempt to monitor the patient. Use another sensor or oximetry cable, or contact the equipment dealer for help if necessary.

7. You are now ready to attach the sensor to the patient.

Figure 4.6: Attach the finger sensor



Attach the finger sensor to the patient as shown. Be sure to fully insert the patient's finger into the sensor. For patients with long fingernails, use the universal 'Y' sensor.

Cleaning or Disinfecting the Sensors

Clean or disinfect reusable sensors before attaching to a new patient.

CAUTION! Do not autoclave, ethylene oxide sterilize, or immerse the sensors in liquid.

CAUTION! Unplug the sensor from the monitor before cleaning or disinfecting.

Clean the sensor with a soft cloth moistened in water or a mild soap solution. To disinfect the sensor, wipe the sensor with isopropyl alcohol.

Turning On the Monitor

To turn on the monitor:

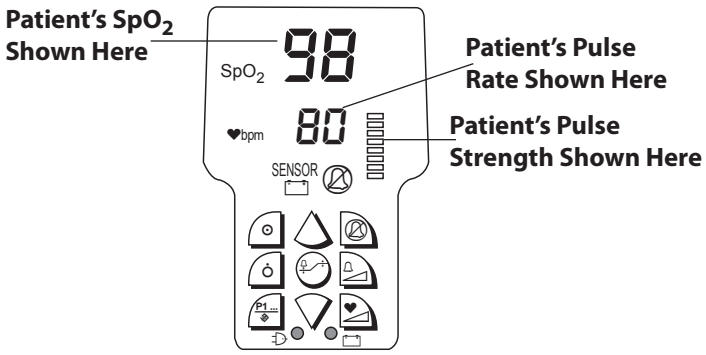
1. Press the ON (⊙)key.

When turned on, the monitor does the following:

- The pulse strength bar graph segments light one at a time.
- The monitor's software revision is momentarily displayed.
- The patient number is momentarily displayed.
- The monitor is in Clinician Mode.

WARNING! Verify that all LEDs (light emitting diodes) on the display light up upon startup of the device.

Figure 4.7: SpO_2, Pulse Rate, and Pulse Strength Bar Graph



2. After a few seconds the % SpO_2 value, pulse rate, and pulse strength bar graph should be shown. If not, see the Troubleshooting section for help.

3. The monitor has available three averaging settings for SpO_2 and pulse. To change the averaging setting, press and hold the ⌄ arrow key while turning on the monitor. While holding the ⌄ key, press the ⌃ key to scroll through the following averaging selections:

SpO2 AVERAGING	PULSE AVERAGING
4	8
8	8
16	8
16	16

NOTE! SpO_2 averaging is the number of pulse beats over which the SpO_2 value is averaged; pulse averaging is the number of seconds over which the pulse value is averaged.

NOTE! Increasing or decreasing the averaging setting does not affect the data update rate.

WARNING! Do not place the monitor in the patient's bed or crib. Do not place the monitor on the floor.

WARNING! Failure to place the monitor away from the patient may allow the patient to turn off, reset, or damage the monitor, possibly resulting in the patient not being monitored. Make sure the patient cannot reach the monitor from their bed or crib.

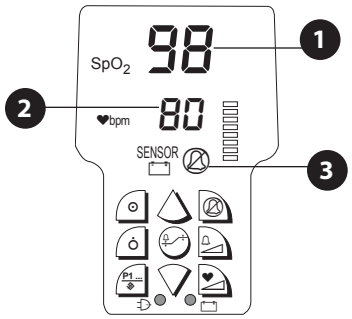
Alarms

Alarms warn you about an abnormal patient condition.

An alarm turns on when:

- the patient's SpO_2 reading matches or exceeds the SpO_2 alarm range, or
- the patient's pulse rate reading matches or exceeds the pulse rate alarm range.

Figure 4.8: Alarm Example



1 SpO_2 numbers flash during an SpO_2 alarm.

2 Pulse rate numbers flash during a pulse rate alarm.

3 Alarm tone will sound if the ALARM SILENCE light is off. Alarm tone will not sound if the ALARM SILENCE light flashes or is on.

During an alarm:

- the numbers flash that correspond to the alarm.
- the alarm tone sounds, if not silenced. The alarm tone sounds like a siren: dee, doo, dee, doo.

NOTE! Both the SpO_2 and pulse rate numbers will flash if both readings match or go beyond their alarm range.

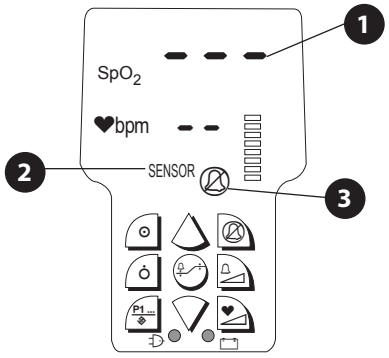
Alerts

An alert warns you about an abnormal monitor condition.

An alert turns on when:

- the sensor is not connected to the monitor, or
- the sensor is not attached to the patient, or
- the sensor is not properly attached to the patient.

Figure 4.9: Alert Example



1 Dashes may be displayed. Dashes mean that the monitor is not able to determine the SpO_2 and/or pulse rate.

2 Sensor light flashes on and off.

3 Alert tone will sound if the ALARM SILENCE light of off. Alert tone will not sound if the ALARM SILENCE light flashes or is on.

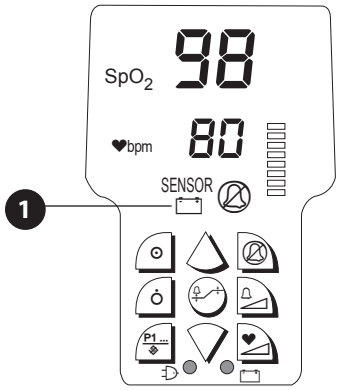
During an alert:

- the SENSOR light flashes.
- the alert tone sounds, if not silenced. The alert tone is a single-tone sound with a pause: beep beep, pause, beep beep.

WARNING! While SENSOR is flashing, the monitor cannot measure the patient's SpO_2 or pulse rate. You must immediately check the patient's condition. After you have checked the patient's condition, you must correct the SENSOR alert. See *Correcting the Sensor Alert* in the *Maintenance* section for help.

BATT Attention

Figure 4.10: BATT Attention Example



1 BATT ( )light flashes on and off during a BATT Attention

During the BATT attention:

- a short burst of beeps sounds every 30 seconds.
- the BATT light flashes on and off.

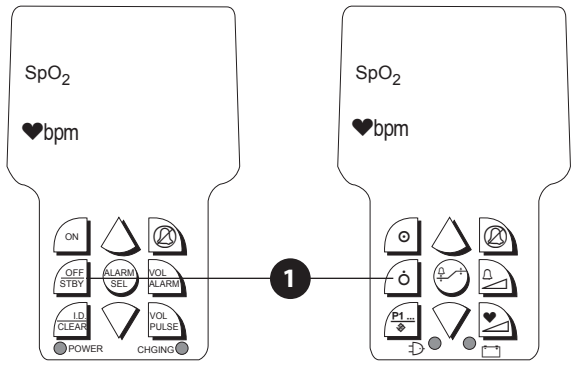
WARNING! When BATT flashes, you must immediately charge the monitor's battery. Otherwise, the monitor turns itself off about 30 minutes after BATT begins to flash. See *BATT attention* in the *Troubleshooting* section for help.

TYPE	DISPLAY INDICATOR	LED INDICATOR	EFFECTS	AUDIO
ALARMS (High Priority)	Numbers corresponding to violated parameter will flash (SpO_2 and pulse rate)		Overrides Alerts.	Two tones sound, alternating twice per second. (siren)
ALERTS (Medium Priority)	Dashes may be displayed.	The sensor indicator blinks.	Overrides pulse beeps.	Two beeps of the same tone occur every second. (beep, beep, pause, beep, beep)
Information Signal		BATT flashes on and off during a BATT Attention.	Overrides all audio (one shot)	Three to five beeps occur once every 30 seconds.

Turning Off the Monitor

Turn off the monitor when you are not monitoring a patient.

Figure 4.11: Turning Off the Monitor



1 To turn off the monitor, press the OFF/STBY key.

Checking the Monitor's Performance

Pulse oximeters do not require user calibration. If checking the function of the device is desired, an optional Oximetry Patient Simulator (Smiths Medical PM catalog number 1606) is available as an accessory. The simulator attaches to the oximeter in place of the sensor or oximetry cable. It provides a known SpO_2 and pulse rate signal to the oximeter. This allows the oximeter's performance to be checked.

NOTE! The 1606 Oximetry Patient Simulator does not calibrate the monitor; the monitor does not require calibration. The 1606 provides a known SpO_2 and pulse rate to the monitor that allows you to check the monitor's performance.

NOTE! The 1606 Oximetry Patient Simulator cannot be used to assess the accuracy of a pulse oximeter and/or sensor.

NOTE! Follow the instructions included with the Oximetry Patient Simulator.

Chapter 5: Changing the Monitor's Settings

Silencing Alarm and Alert Tones

The alarm and alert tones can be silenced for two minutes or indefinitely (until canceled or until the monitor is turned off).

1. To silence the alarm and alert tones for two minutes, momentarily press the ALARM SILENCE key. If alarm and alert tones were already silenced, you must press the alarm silence key again. The alarm silenced indicator flashes during the two-minute time-out.

2. To silence the alarm and alert tones indefinitely, press and hold the alarm silence key for about three seconds. The alarm silenced indicator lights steady while alarms are silenced indefinitely.

3. To cancel either the indefinite or the two-minute alarm and alert tone silenced condition, momentarily press alarm silence key; the alarm silenced indicator turns off.

Changing the Alarm and Alert Tone Volume

The alarm and alert tones sound at one of two volumes: soft or loud.

To change between soft and loud volume, press the ALARM VOL ( ) key.

Changing the Brightness of the Display

WARNING! Adjusting the display too dim may cause the display to be difficult to read in bright light. Make sure the display is bright enough to be seen under all light conditions.

Use the ^ or v keys to change the brightness of the display:

- To increase the brightness of the display, press the ^ key.
- To decrease the brightness of the display, press the v key.

Changing the Pulse Beep Volume

A "beep" tone sounds with each pulse beat. The volume of the "beep" can be positioned to three settings: soft, loud, and off. To adjust the volume to the 'off' setting, push the PULSE VOL ( ) key once. From the 'off' setting, set the volume to 'soft' by pressing the key once, or press the key twice in quick succession to set the volume to 'loud'.

Changing the Alarm Limits

Each measurement, SpO_2 and Rate, has a high and low alarm limit setting.

Press the ALARM SEL key until the alarm limit you want to change is shown, then press the ^ or v key to increase or decrease the setting.

ALARM SEL KEY PRESS	DISPLAY	ALARM LIMIT
First Press	--- HI	--- = High SpO_2 alarm limit. (Example only.)
Second Press	85 Lo	85 = Low SpO_2 alarm limit. (Example only.)
Third Press	HI 155	155 = High pulse rate alarm limit. (Example only.)
Fourth Press	Lo 50	50 = Low pulse rate alarm limit. (Example only.)
Fifth Press	97 74	97 = SpO_2 measurement. (Example only.) 74 = Pulse rate measurement. (Example only.)

NOTE! " – – – " in the display means the limit is set to off.

NOTE! Alarm limits are non-overlapping. You cannot set the high alarm equal to or lower than the low alarm and you cannot set the low alarm equal to or higher than the high alarm.

NOTE! While setting alarm limits, if no keys are pressed for twenty seconds, the alarm limit setting mode is exited and the SpO_2 and pulse rate measurements are shown.

NOTE! Alarms are not active while setting alarm limits; however, alarms are active as soon as you exit the alarm limit setting mode.

NOTE! Alarms can be tested while the monitor is in use by setting alarm limits such that the measured parameter is outside alarm limits. Be sure to restore limits to the required setting after testing.

NOTE! The low SpO_2 alarm limit minimum test value is 80. If an operator changes the low SpO_2 alarm limit to a value less than 80, and a power down - power up sequence takes place, a minimum value of 85 takes the place of the operator entered value.

NOTE! This monitor's alarm limit settings are saved at power down. But if the low SpO_2 limit is set below 80, it will be reset to 85 when the monitor is powered up again.

WARNING! To avoid confusion, be aware of alarm limits of similar monitors in the same area when adjusting alarm limits of this device.

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Chapter 6: Patient Numbers & Trend Data

Description

Whenever the monitor is on, it stores one SpO_2 and one pulse rate reading every thirty (30) seconds. The stored readings are called *trend* data. The monitor remembers trend data for up to 99 patients and 24 hours of run-time.

Trend data is saved for each patient number. When you turn on the monitor, the patient number is automatically incremented and displayed during the power-up sequence if valid trend data was collected from the previous patient. If no valid trend data was collected from the previous patient, the patient number is displayed only and is not incremented. The monitor remembers all the trend data and all the patient numbers for up to 99 patients and 24 hours of run-time.

Trend data for any patient can be viewed on the monitor. Trend data for all patients can be printed on the optional printer.

NOTE! See *Printer* section for information on printing trend data.

Manually Incrementing the Patient Number

1. The SpO_2 sensor must be connected to the monitor. If the SpO_2 sensor is not connected to the monitor, connect the SpO_2 sensor.

2. Press the I.D./CLEAR ($\frac{P1}{\diamond}$) key to increment the patient number. The new patient number is momentarily displayed and trend data for the new patient is automatically saved.

Viewing Trend Data

1. The SpO_2 sensor must be disconnected from the monitor. If necessary, disconnect the SpO_2 sensor from the monitor.

2. Press the I.D./CLEAR (P1 ···)key; the following sequence occurs:

   a. The middle two pulse bars flash., indicating the monitor is in "trend view" mode. The two pulse bars continue to flash until the mode is exited.

   b. The current patient number is shown for a few seconds.

   c. The last valid data for the corresponding patient number is shown in the SpO_2 and pulse rate displays. If no valid data was collected, "– – –" is shown.

   d. Pressing the ∧ or ∨ keys will increase or decrease the patient number; the patient number will be shown for a few seconds then the last valid data corresponding to the patient number will be shown.

   e. To exit the "trend view" mode, press the I.D./CLEAR (P1 ···) key.

NOTE! If no keys are pressed for 20 seconds, the monitor automatically exits the "trend view" mode.

Clearing Trend Data

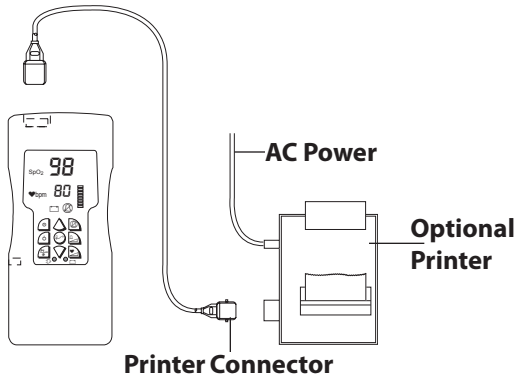
1. The SpO_2 sensor must be connected to the monitor. If necessary, connect the SpO_2 sensor to the monitor.

2. Press and hold the I.D./CLEAR (P1 ···)key for about six seconds. While you are holding the I.D./CLEAR key, the message CLr flashes on the display to tell you the trend data for all patients is about to be cleared. When the trend data is cleared, the display shows P 1.

Chapter 7: Printer

Description

Figure 7.1: Oximeter and Printer



Data can be printed in trend data mode. In this mode up to 24 hours of previously stored data, collected from 1 to 99 patients, is printed.

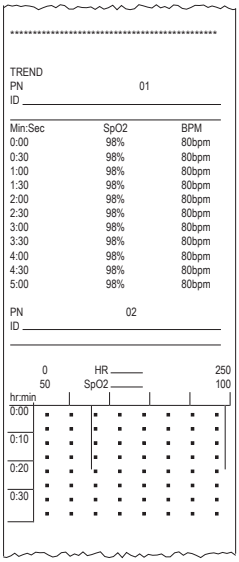
Whenever the monitor is on, it stores one SpO_2 and pulse rate reading every thirty (30) seconds.

- If less than 15 minutes of data is collected for one patient, the trend data is printed in a tabular format if " 123 " mode is selected.

- If more than 15 minutes of data is collected for one patient, the trend data is printed in a graphic format if "LLL" mode is selected.

The monitor remembers trend data for up to 99 patients and 24 hours of run-time. The trend data can be printed at any time on the optional printer.

Figure 7.2: Sample Trend Printout



Selecting Print Mode For Trend Data

1. Keep the ALARM SEL (⏻/+) key pressed for 5 seconds. 123 or LLL appears in the SpO_2 display.
2. 123 = numerical print-out
3. LLL = graphic print-out (only possible with Seiko DPU 201 GSU or Seiko DFU 411 S printers).
4. Select mode with arrow key. The selection remains stored and will apply when the monitor is next switched on.
5. To return to measurement press ⏻/+ ALARM SEL key once.

If a key is not pressed within 20 seconds, the monitor automatically returns to measurement.

Compatible Printers

Printer requirements:

FUNCTION	SPECIFICATION
I/O Port	Serial RS-232C
Data Type	ASCII
Data Format	9600 baud, 1 start bit, 8 data bits, 1 stop bit, no parity
I/O Connector	Standard DB-9
Graphics Interface	Seiko Printer Graphics Interface

Compatible Printers:

MANUFACTURER	MODEL NUMBER
Seiko	DPU-201GSU
Seiko	DPU-411-21BU (120 V 60 Hz) DPU-411-21BE (220 V 50 Hz) **NOTE! A DB-9 to DB-25 pin adapter will be required.**

For information on printers and printer accessories, contact your authorized sales representative.

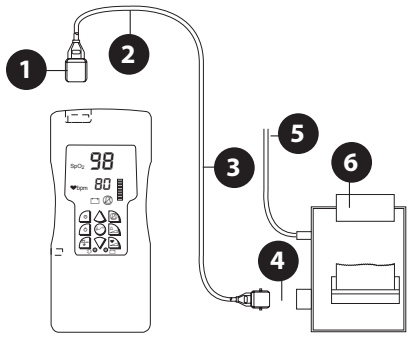
What You'll Need for Printing

You'll need these items to print trend printouts:

- Oximeter
- Printer Cable (see the Optional Supplies and Accessories section for ordering information).
- Compatible printer (purchased from one of the printer manufacturer's distributors).
- Accessories required for the printer, such as paper, power supply or charger, and so on (purchased from the printer manufacturer's distributor).

Setting Up the Monitor and the Printer

Figure 7.3: Setting up the Oximeter and Printer



1 Sensor Connector

2 Printer Cable

3 DB-9 Null Modem Cable

4 DB-9 Printer Connector

5 To AC Power

6 Printer

1. Refer to the printer's operation manual and make sure the printer's RS-232 data format is set up as follows:
   - Data Type: ASCII
   - Data Format: 9600 baud, 1 start bit, 8 data bits, 1 stop bit, no parity
2. Connect the printer adapter's connector to the sensor connector.
3. Connect the printer adapter's DB-9 connector to the mating connector on the printer. (If necessary, connect the printer adapter's DB-9 connector to a DB-9 to DB-25 adapter, then connect the adapter to the printer.)
4. Connect the printer's power source to the printer as described in the printer's operation manual.

CAUTION! Use only the printer cable specifically intended for use with this device (see Optional Supplies and Accessories).

5. Make sure the printer has paper loaded and is ready to print as described in the printer's operation manual.

Trend Printouts

Collecting Trend Data

Whenever the monitor is on, it stores one SpO_2 and one pulse rate reading every thirty (30) seconds. The stored readings are called trend data. The monitor remembers trend data for up to 99 patients and 24 hours of run-time. The trend data can then be printed at any time on the optional printer.

Trend data is saved for each patient number. When you turn on the monitor, the patient number is automatically incremented and displayed during the power-up sequence if valid trend data was collected from the previous patient. If no valid trend data was collected from the previous patient, the patient number is displayed only and is not incremented. The monitor remembers all the trend data and all the patient numbers for up to 99 patients and 24 hours of run-time.

Manually Incrementing the Patient Number

1. The SpO_2 sensor must be connected to the monitor. If necessary, connect the SpO_2 sensor to the monitor.

2. Press the I.D./CLEAR (P1...) key to increment the patient number. The new patient number is momentarily displayed and trend data for the new patient is automatically saved.

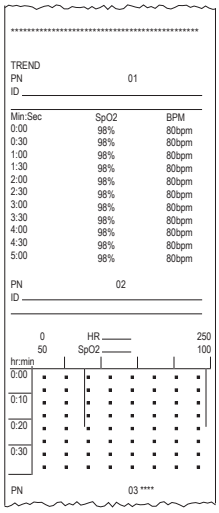
Clearing Trend Data

1. The SpO_2 sensor must be connected to the monitor. If necessary, connect the SpO_2 sensor to the monitor.

2. Press and hold the I.D./CLEAR (P1...) key for about six seconds. While you are holding the I.D./CLEAR (P1...) key, the message CLr flashes on the display to tell you the trend data for all patients is about to be cleared. When the trend data is cleared, the display shows P 1.

Printing Trend Data

Figure 7.4: Printing Trend Data



1. Set up the monitor and printer as previously described.
2. Disconnect the SpO_2 sensor from the monitor.
3. Connect the printer cable to the monitor.
4. Turn on the printer.
5. Turn on the monitor. The monitor prints the trend data for each patient, from patients 1-99, as shown in the sample printout.
6. If there is no trend data at all, the message "*******" is printed.
7. If no valid data is collected for a patient number, "****" is printed.
8. If valid data is collected for a patient number for less than one minute, only the last measurement is printed.
9. If data is collected for a patient number for more than one minute, the relative time since the first measurement is shown for that patient.
10. Dashes indicate invalid or unavailable data (for example, the patient's finger was removed from the SpO_2 sensor).
11. Pressing the I.D./CLEAR (P1) key increments the patient number, and trend data is collected for the new patient number.

NOTE! If unexpected characters or question marks are printed, turn the printer off and on to reset the printer.

Chapter 8: Operating Modes

About the Monitor's Operating Modes

The monitor has three operating modes: clinician mode (previously described), home-use mode and sleep study mode.

- The clinician mode is intended for health-care professionals trained in monitoring respiratory and cardiovascular activity.
- The home-use mode is intended for caregivers trained in oximeter use by a doctor or other health-care professional.
- The sleep study mode is intended for health-care professionals trained in monitoring respiratory and cardiovascular activity.

While the monitor is in the clinician mode, all monitor functions operate as described previously in this manual.

NOTE! Accessing Home Use Mode and Sleep Study Mode may only be done from the Clinician Mode. It is not possible to access Home Use Mode from Sleep Study Mode or vice versa.

Home Use Mode

While the monitor is in home-use mode:

- Alarm limits can be viewed but cannot be changed.
- The alarm and alert tone is set to loud and cannot be changed.
- Alarm and alert tones can be silenced for two minutes but cannot be silenced indefinitely.
- SpO_2 averaging is set to 8 beats; pulse rate averaging is set to 8 seconds.
- Patient numbers and trend view are disabled.
- Trend data is collected for one patient.
- Trend data from the patient can be printed. The printout is the same as during clinician mode, except "Home Mode" replaces "Patient Number" on the printout.
- All other functions of the monitor work as in clinician mode.

Setting Up the Monitor for Home-Use

1. Set the high and low alarm limits for SpO_2 and pulse rate to the values prescribed by the doctor:
   - High SpO_2 alarm limit.
   - Low SpO_2 alarm limit.
   - High pulse rate alarm limit.
   - Low pulse rate alarm limit.
2. Clear trend data if necessary. (Press and hold I.D./CLEAR (P1) until P 1 is displayed.)
3. Put the monitor into the home-use mode as follows (Make sure that the monitor is in Clinician Mode prior to executing the following commands!):
   a. Turn off the monitor.
   b. Press and hold the ALARM VOL key, then press the ON key.
   c. While holding the ALARM VOL key, H flashes in the pulse rate display.
   d. When H stops flashing and lights steady (in about 6 seconds), release the ALARM VOL key. The monitor is now in home-use mode.
4. Verify the monitor is in the home-use mode:
   a. Turn off the monitor.
   b. Turn on the monitor while observing the display; H should be shown briefly when the monitor is turned on. If not, repeat step 3 above.
5. Verify the high and low alarm limits for SpO_2 and pulse rate are set to the values prescribed by the doctor. Press ALARM SEL to show each of the alarm limits one-at-a-time.
6. Turn off the monitor.

Equipment and Supplies Checklist for Home-Use

Provide the following to the home-use caregiver:

QUANTITY	CAT.NO.	DESCRIPTION
1	3303	Oximeter
1	8210	AC Adapter, 105-125VAC 60Hz
1	8212	AC Adapter, 208-252VAC 50/60Hz
1	8216	AC Adapter, 90-110VAC 50Hz
1	3353	Protective rubber boot with carrying case
*	3049	Adhesive Strips (Adhesive Tape)
1	1854	Home-Use Instruction Book
* Quantity prescribed by doctor.		

The doctor will prescribe the type and quantity of the sensors needed for home-use:

QUANTITY	CAT.NO.	DESCRIPTION
*	3044	Sensor, Reusable, Finger
*	3178	Sensor, Pediatric, Finger
1	3311	Cable, Oximetry, 5 Feet
*	3444	Sensor, Comfort Clip®
*	1300	Sensor, Disposable, Adult
*	1301	Sensor, Disposable, Pediatric
*	1302	Sensor, Disposable, Neonate
*	1303	Sensor, Disposable, Infant
* Quantity prescribed by doctor.		

The home-use caregiver will also need these supplies and reference materials:

QUANTITY	DESCRIPTION
1	Scissors (for trimming adhesive strips or adhesive tape).
*	Isopropyl alcohol and a soft, clean cloth (or alcohol wipes) for disinfecting monitor and reusable sensor.
1	Written instructions on how to respond to the monitor's alarms.
1	Emergency phone numbers for the doctor.
1	Emergency phone number for the hospital emergency room.
1	Emergency phone number for local paramedics or police.
1	Phone number for equipment supplier in case the equipment fails.
* Quantity prescribed by doctor.	

Training the Home-Use Caregiver

1. The home-use caregiver must be trained in CPR.
2. Make sure the monitor's alarm limits are properly set and that the monitor is in the home-use mode.
3. Inform the caregiver that the oximeter is not to be used as an apnea monitor.
4. (Following the Home-Use Instruction Book while teaching these tasks may help you and the caregiver.) Show the home-use caregiver how to:
   - Connect the AC power supply to the monitor.
   - Interpret the POWER and CHARGING lights.
   - Visually inspect the sensor and oximetry cable.
   - Connect the sensor to the oximetry cable.
   - Connect the oximetry cable to the monitor.
   - Turn on the monitor.
   - Route the cable safely from the patient to the monitor to prevent possible patient strangulation.

- Attach the sensor(s) prescribed by the doctor.
- Measure the SpO_2, pulse rate, and pulse strength bar graph readings.
- Change the brightness of the display.
- Change the pulse beep volume.
- Turn off the alarm and alert tones for two minutes.
- Turn on the alarm and alert tones.
- Interpret the alarms.
- View the alarm limits.
- Interpret the SENSOR alert.
- Interpret the BATT attention.
- Turn off the monitor.

5. Tell the caregiver how to respond:

   - In case of a patient emergency, including what therapy to provide the patient.
   - In case an alarm sounds, including what therapy to provide the patient.
   - In case the sensor alert sounds.
   - In case the batt attention sounds.
   - In case the caregiver has trouble operating the equipment.

Turning Off Home-Use Mode

1. Turn off the home-use mode (put the monitor into the clinician mode) as follows:
   a. Turn off the monitor.
   b. Press and hold the PULSE VOL (♥) key, then press the ON (⊙) key.
   c. While holding the PULSE VOL key, H flashes in the pulse rate display.
   d. When H stops flashing, and patient number Pn (n = patient number) lights steady, (in about 6 seconds), release the key. The monitor is now in clinician mode.
2. Verify the monitor is in the clinician mode:
   a. Turn off the monitor.
   b. Turn on the monitor while observing the display; the software revision then the patient number should be displayed during power-up. If not, repeat step 1 above.

Sleep Study Mode

While the monitor is in sleep study mode:

- Patient numbers and trend view are disabled.
- A new trend block is started each time the monitor is turned on.
- Trend data from the patient is stored and may then be output to a PC.
- Following the header, the SpO_2 and pulse rate trend block is output in ASCII as follows:

```
****************
Sleep Study
SpO2 Pulse
97  67
98  69
98  71
98  71
****************
Sleep Study
SpO2 Pulse
97  67
98  69
98  71
98  71
```

- Each pair of data points represents a four second block of data. For each trend block, the header "Sleep Study" appears preceding the trend block, indicating that a break has occurred in the data.
- Trend data from the patient is stored every four seconds. The SpO_2 data consists of a minimum display value over the four second interval. Refer to the Turning on the Monitor section for information on SpO_2 and pulse rate display values (specifically "averaging"). Since patient ID numbers are disabled in sleep study mode, the trend printout will have the header "Sleep Study" (as shown above) for each patient block. New patient blocks may only be accessed when the unit is turned off, then on.

- When trend memory is full (i.e. after approximately 12 hours of operation), the data storage will begin at the start of memory, thereby overwriting the oldest data (the most recent data is always retained).
- The serial communication setup is the same as in the clinician mode (9600 baud, 1 start bit, 8 data bits, 1 stop bit, no parity).
- All other functions of the monitor work as in the clinician mode.

Setting Up the Monitor for Sleep Study Mode

NOTE! When entering or exiting Sleep Study mode previous memory will be lost.

1. Put the monitor into the sleep study mode as follows (Make sure that the monitor is in Clinician Mode prior to executing the following commands!):
   a. Turn off the monitor.
   b. Press and hold the ALARM SEL (🔔) key, then press the ON (⊙) key.
   c. While holding the ALARM SEL key, SLP flashes in the pulse rate display.
   d. When SLP stops flashing and lights steady (in about 6 seconds), release the ALARM SEL key. The monitor is now in sleep study mode.
2. Verify the monitor is in the sleep study mode:
   a. Turn off the monitor.
   b. Turn on the monitor while observing the display; SLP should be shown briefly when the monitor is turned on. If not, repeat step 1 above.

Turning Off Sleep Study Mode

1. Turn off the sleep study mode (put the monitor into the clinician mode) as follows:

   a. Turn off the monitor.

   b. Press and hold the Alarm Silence key, then press the ON (⊙) key.

   c. While holding the Alarm Silence key, SLP flashes in the pulse rate display.

   d. When SLP stops flashing, and patient number Pn (n = patient number) lights steady, (in about 6 seconds), release the key. The monitor is now in clinician mode.

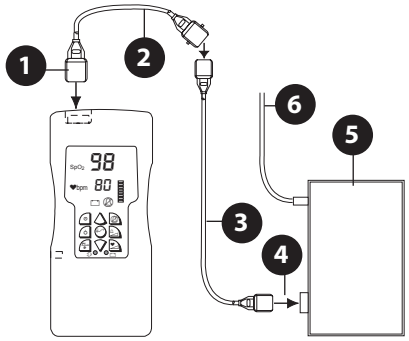
2. Verify the monitor is in the clinician mode:

   a. Turn off the monitor.

   b. Turn on the monitor while observing the display; the software revision then the patient number should be displayed during power-up. If not, repeat step 1 above.

PC Communication Setup

Figure 8.1: Setting up the Oximeter and Printer



1 Sensor Connector

2 Printer Cable

3 DB-9 Null Modem Cable

4 DB-9 Printer Connector

5 PC

6 To AC Power

1. Power up the monitor.
2. Connect the printer communication cable to the monitor.
3. Set up the communication software to accept the following RS-232 data format:
   - Data Type: ASCII
   - Data Format: 9600 baud, 1 start bit, 8 data bits, 1 stop bit, no parity
4. Connect the standard RS232 null modem cable's DB-9 connector to the mating connector of the printer cable.
5. Connect the standard RS232 null modem cable's DB connector to the mating connector on the PC.

NOTE! The modem cable is an industry standard RS232 modem cable.

Transferring Sleep Study Data to a PC

1. Set up the monitor, cables, and PC as previously described.

2. Turn on the PC and load the communication software, setting the serial communication defaults as previously described.

3. Turn on the monitor.

4. Dashes indicate invalid or unavailable data (for example, the patient's finger was removed from the SpO_2 sensor).

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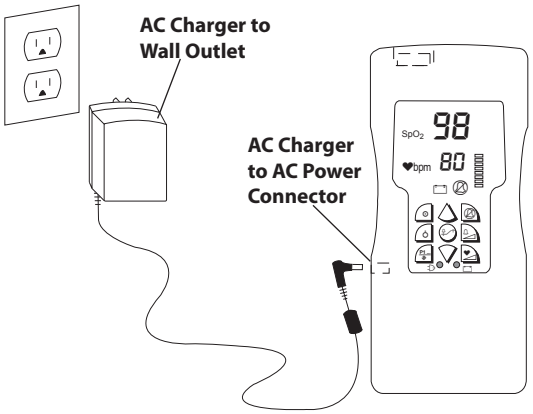
Chapter 9: Charging the Monitor

Figure 9.1: Connecting AC Power



WARNING! Do not allow any moisture to touch the AC power supply connectors or a safety hazard may result. Ensure that hands are thoroughly dry before handling the AC power supply.

CAUTION! Ensure the device's AC rating is correct for the AC voltage at your installation site before using this monitor. The monitor's AC rating is shown on the external power supply. If the rating is not correct, do not use the monitor; contact the Smiths Medical PM, Inc. service department, or your local distributor, for help.

1. Connect the AC charger as shown. Refer to *Chapter 12, Optional Supplies and Accessories*, to verify the proper AC power supply for your application.

   - Connect the AC Charger to the AC Power Connector of the monitor first and the AC Charger to the Wall Outlet second.

WARNING! If there is a risk of the AC power supply becoming disconnected from the monitor during use, secure the cord to the monitor several inches from the connection.

2. Make sure the POWER ( ) indicator lights up on the charger. If not, see the *Troubleshooting* section.
3. CHGING ( ) indicator lights while the monitor's battery is charging.
4. Device is fully charged when the CHGING light turns off.
5. The monitor's battery will fully charge in about 6 hours (NiMH). A fully charged battery provides approximately 24 hours (NiMH) of use.
6. The device may be operated while charging.

WARNING! Disconnect the AC power supply from the outlet before disconnecting it from the monitor. Leaving the AC power supply connected to an AC power outlet without being connected to the monitor may result in a safety hazard.

CAUTION! Monitors not in use must be fully charged at least every five months, otherwise the battery will no longer be able to accept a charge.

Chapter 10: Maintenance

Schedule of Maintenance

MAINTAIN THIS ITEM	HOW OFTEN	BY DOING THIS
Battery	When BATT is flashing, or after the monitor has been used under battery power. Monitors in storage or not in use must be fully charged at least every 5 months.	Follow the instructions for charging the monitor.
Repositioning the sensor	At least once every 4 hours.	Follow the instructions for attaching the sensor.
Disinfecting the #3044 reusable sensor	Before attaching the sensor to the patient.	Follow the instructions for attaching the #3044 reusable sensor.
Disinfecting the monitor and the AC power supply	When necessary.	1. Disconnect the monitor from the AC power supply. 2. Disconnect the AC power supply from the wall outlet and from the monitor. 3. Wipe the surfaces of the monitor and the AC power supply with a soft, clean cloth dampened in isopropyl alcohol. Use only a cloth that is dampened, not wet. **CAUTION! Do not allow isopropyl alcohol to enter any of the openings on the monitor. Evidence that liquid has been allowed to enter the monitor voids the warranty.**

Correcting the SENSOR Alert

Follow these steps to correct the sensor alert:

1. Make sure the sensor's connector is firmly seated in the monitor's connector.

2. Make sure the sensor is properly attached to the patient. See *Attaching the Sensor to the Patient* section for help.

3. Make sure the adhesive tape used to hold the sensor is not wrapped too tightly. Wrapping the tape too tightly may prevent the monitor from measuring the SpO_2 and pulse rate.

4. If the sensor alert is still on, contact your doctor or the equipment dealer for help.

Storage

Whenever possible, the monitor should be stored at room temperature in a dry environment..

If it is necessary to store the monitor for an extended period of time, the unit should be packed in its original shipping container. Storing the monitor for a long period of time may degrade the battery capacity. Batteries should be removed from the monitor before storing.

Storage specifications are as follows:

- Temperature: -40°C to 75°C (-40°F to 167°F)

- Relative Humidity: 10% to 95% (noncondensing)

Chapter 11: Troubleshooting

PROBLEM	POSSIBLE CAUSE	SOLUTION
SENSOR alert.	Sensor may not be properly connected to monitor.	Make sure sensor connector is firmly seated in monitor connector.
	Sensor may not be properly attached to patient	See *Attaching the Sensor* to the Patient.
	Adhesive tape may be too tight on patient.	Loosen adhesive tape.
	Sensor, interface cable, or monitor may be defective.	Contact authorized repair center for help.
BATT attention.	Monitor's battery has become weak from use.	See *Charging the Monitor.*
SpO_2, pulse rate, or pulse bar graph not shown on monitor. or Pulse rate value erratic, intermittent, or incorrect. or SpO_2 value erratic, intermittent, or incorrect.	Patient may be moving.	Have patient remain as still as possible.
	Connectors from sensor to monitor may not be firmly seated.	Make sure all connectors between sensor and monitor are firmly seated.
	Sensor may not be properly attached to patient.	See *Attaching the Sensor to the Patient.*
	Adhesive tape may be too tight on patient.	Loosen adhesive tape.
	Sensor, interface cable, or monitor may be defective.	Contact authorized repair center for help.
Monitor does not turn on when ON key is pressed.	Battery needs charging.	See *Charging the Monitor*.
	Monitor may be defective.	Contact authorized repair center for help.
Monitor turns off suddenly.	Battery needs charging.	See *Charging the Monitor*.

PROBLEM	POSSIBLE CAUSE	SOLUTION
POWER indicator does not light when AC power supply is attached.		Make sure the AC power supply is firmly connected to the wall outlet and to the monitor. Make sure the wall outlet is not controlled by a switch. Make sure AC power is available at the wall outlet. (Plug a lamp or a radio into the same wall outlet and see if the lamp or radio turns on.)
	AC power supply or monitor may be defective.	Contact authorized repair center for help.
CHGING does not light on the monitor.	Monitor's battery may be charged.	See *Charging the Monitor*.
No printout on optional printer.	Printer power not connected, or printer power switch is off.	Make sure the power is connected to the printer and the printer power switch is on.
	Printer interface connectors not firmly seated.	Make sure printer interface cables are firmly seated. Insure that the proper communication protocol has been selected for the printer.
	Printer or monitor may be defective.	Contact authorized repair center for help.

EMI Interference

CAUTION! This device has been tested and found to comply within the limits for medical devices to IEC 601-1-2:1993, EN 60601-1-2:1994, and the Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in the heath-care and home environments (for example, cellular phone, mobile two-way radios, electrical appliances), it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

The monitor is designed for use in environments in which the signal can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the monitor may not operate correctly.

The monitor generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity. Disruption may be evidenced by erratic readings, cessation of operation, or other incorrect function. If this occurs, the site of use should be surveyed to determine the source of this disruption, and actions taken to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the other receiving device.
- Increase the separation between the interfering equipment and this equipment.

If assistance is required, contact the Smiths Medical PM, Inc. Service Department or your local representative.

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Chapter 12: Optional Supplies and Accessories

CAT. NO.	DESCRIPTION	QTY
1300	Sensor, Oximetry, Disp., Adult Finger	10/box
1301	Sensor, Oximetry, Disp., Ped. Finger, 15-45 kg	10/box
1302	Sensor, Oximetry, Disp., Neonate, <3 kg	10/box
1303	Sensor, Oximetry, Disp., Infant, 3-15 kg	10/box
1606	Simulator & Cable, oximetry, 1.5 m (5 ft)	each
1850	Manual, Clinician's Operation (Oximeter)	each
1851	Manual, Service (Oximeter)	each
1854	Manual, Home use Instruction Book (Oximeter)	each
3025	Sensor, Oximetry, Wrap, Infant, 3-15 kg	each
3026	Sensor, Oximetry, Wrap, Neonate, <3 kg	each
3043	Sensor, Oximetry, Universal 'Y'	each
3044	Sensor, Oximetry, Finger	each
3049	Strips, Adhesive	40/pkg.
3078	Sensor, Oximetry, Ear	each
3134	Tape, Attachment, Neonatal	50/pkg.
3135	Tape, Attachment, Infant	50/pkg.
3136	Tape, Attachment, Neonatal	100/pkg.
3137	Tape, Attachment, Infant	100/pkg.
3138	Posey Wrap, Attachment, Universal 'Y'	10/pkg.
3178	Sensor, Pediatric, Finger, 5-45 kg	each
3311	Cable, Oximetry, 1.5 m (5 ft)	each
3350	Cable, Printer Interface (for #3303)	each
3353	Protective rubber boot with carrying strap & Tilt Stand	each
3354	Pole Mount Bracket	each
3444	Sensor, Oximetry, Finger, Comfort Clip®	each
8210	AC Power Supply, 105-125VAC 60 Hz	each
8212	AC Power Supply, 208-252VAC 50/60Hz	each
8216	AC Power Supply, 90-110VAC 50 Hz	each

Ordering Information

For ordering information, contact your local distributor or the Smiths Medical PM, Inc. Customer Service Department.

Smiths Medical PM, Inc.
N7W22025 Johnson Drive
Waukesha, WI 53186 USA

Phone: (262) 542-3100
Toll Free (in USA only):
1-800-558-2345
Fax: (262) 542-0718

Email Address: info.pm@smiths-medical.com

Chapter 13: Specifications

Parameters Monitored

SpO_2, Pulse Rate, and Pulse Strength

Displays, Indicators, & Keys

SpO_2:	3-digit LED display, 10.9 mm (0.43 inches) high. Display update rate = 1Hz
Pulse Rate:	3-digit LED display, 9.5 mm (0.375 inches) high. Display update rate = 1Hz
Pulse Strength:	Logarithmically scaled 8-segment LED bar graph. Display update rate = 60Hz. The display is not proportional to pulse volume.
SENSOR:	Sensor alert indicator.
BATT:	Low battery indicator.
Silenced:	Alarm and alert tone silenced indicator.
Keys:	Nine control keys provided.
Brightness:	Adjustable brightness of SpO_2, pulse rate, and bar graph displays.

Indicators

POWER:	Indicates oximeter connected to AC power.
CHGING:	Indicates oximeter battery is charging.

SpO_2

Range:	0-100%
Accuracy [1]:	±2% at 70-100% ±3% at 50-69%
Alarm Limits:	High 100-50% and off in 1% steps. Low 50-99% and off in 1% steps. Factory Default Values: High: OFF Low: OFF
Averaging:	4, 8, or 16 pulse beat average.

Because pulse oximeter measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within the A_{RMS} of the value measured by the co-oximeter. The 3303 has been validated in human desaturation studies on 10 healthy adult volunteers. The study was conducted at oxygen concentrations evenly distributed over an SaO_2 range of 50-100%.

Sensors

Red:	660nm, 2mW (typical)
Infrared:	905nm, 2-2.4mW (typical)

Pulse Rate

Range:	30-254 BPM
Accuracy:	±2% at 30-254 BPM
Alarm Limits:	High 250-5 BPM and off in 5 BPM steps. Low 5-250 BPM and off in 5 BPM steps. Factory Default Values: High: OFF Low: Off
Averaging:	8 or 16 second average.

Alarm Indicators

Alarm Volume:	45dBA - 85dBA at 1 meter distance (adjustable)

Two-tone audible alarm with user-adjustable volume and two-minute or indefinite alarm silence. Corresponding numeric display flashes.

Sensor Alert Indicator

Single-tone audible alarm with same volume and silence as alarm tone.

Printer Output

Data saved every thirty (30) seconds can be printed (trend).

Battery

Type:	Internal rechargeable or NiMH; not user replaceable.
Charge Time:	NiMH: Fully charges in about 6 hours.
Use Time:	Approximate continuous use: 24 hours (NiMH).
Indicators:	BATT indicator lights when about 30 minutes of battery use remains.

AC Charger

Wall Mount Style:	Input of 105-125 VAC 60Hz Input of 90-110 VAC 50Hz (Optional)
Table Top Style:	Input of 208-252 VAC, 50/60Hz

Dimensions

Width:	84 mm (3.3 inches)
Height:	184 mm (7.25 inches)
Depth:	47 mm (1.85 inches)
Weight:	539 grams (19 ounces) including battery

Environmental Specifications

Temperature:	Operating: 0 to 40° C (32 to 104° F) Storage: -40 to +75° C (-40 to +167° F)
Relative Humidity:	Operating: 15 to 95%, non-condensing Storage: 10 to 90%, non-condensing

Calibration

Factory-calibrated over 50 % to 100 % SpO_2 using human blood samples to functional saturation. Test methods available upon request. No in-service calibration required.

Appendix A: Guidance and Manufacturer's Declaration

Guidance and Manufacturer's Declaration

The 3303 Pulse oximeter is intended for use in the electromagnetic environment specified in the tables within this appendix.

NOTE! The customer or user of the 3303 pulse oximeter should ensure that it is used in such an environment.

Electromagnetic Emissions - Emissions Test

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
RF emissions CISPR 11	Group 1	The 3303 pulse oximeter 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 3303 pulse oximeter is suitable for use in all establishments, including: • Domestic establishments. • Establishments directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	NA	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	NA	

Electromagnetic Emissions – Immunity

IMMUNITY		ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	**IEC 60601 TEST LEVEL** • ± 6 kV contact • ± 8 kV air **COMPLIANCE LEVEL** • ± 6 kV contact • ± 8 kV air	Floors should be made of: • Wood • Concrete • 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	**IEC 60601 TEST LEVEL** • ±0.5 kV to ± 2 kV for power supply lines. • ±0.25 kV to ±1 kV for input/output lines **COMPLIANCE LEVEL** • ±0.5 kV to ±2 kV for power supply lines. • ±0.25 kV to ±1 kV for input/output lines.	A.C. Mains power voltage should be the typical quality of a: • Commercial environment. • Hospital environment.
Surge IEC 61000-4-5	**IEC 60601 TEST LEVEL** • ±1 kV differential mode • 2 kV common mode **COMPLIANCE LEVEL** • ±1 kV differential mode • ±2 kV common mode	

IMMUNITY		ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	**IEC 60601 TEST LEVEL** • <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 seconds. **COMPLIANCE LEVEL** • <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 seconds.	A.C. Mains power voltage should be the typical quality of a: • Commercial environment. • Hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.		
Power frequency (50/60 Hz) IEC 61000-4-8	**IEC 60601 TEST LEVEL** 3 A/m **COMPLIANCE LEVEL** 3 A/m	Power frequency magnetic fields should be the typical levels of a: • Commercial environment • Hospital environment
Conducted RF IEC 61000-4-6	**IEC 60601 TEST LEVEL** • 3 V rms • 150 kHz to 80MHz **COMPLIANCE LEVEL** • 3 Vrms 80% AM modulation @ 1kHz • 150 kHz to 80 MHz.	**Recommended separation distance:** *d =1.2*

IMMUNITY		ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Radiated RF IEC 61000-4-3	**IEC 60601 TEST LEVEL** • 3 V/m • 80 MHz to 2.5 GHz **COMPLIANCE LEVEL** • 3 V/m 80% AM • 80 MHz to 1 GHz	**Recommended separation distance:** $d = 1.2\sqrt{P}$ 80 MHz to 800 Mhz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

- P = Manufacturer's output power in watts (W).
- d = Recommended distance in meters (m).

Field strengths from fixed RF transmitter watts (as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range.[b]

CAUTION! Interference may occur in the vicinity of equipment marked with the following symbol: 

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: 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 RF 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 3303 pulse oximeter is used exceeds the applicable RF transmitter compliance level above, the 3303 pulse oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 3303 pulse oximeter.

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

Recommended Separation Distances

The 3303 pulse oximeter is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. The customer or the user of the 3303 pulse oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 3303 pulse oximeter as recommended below, according to the maximum output power of the communications equipment.

The recommended separation distances between portable and mobile RF communication equipment and the 3303 pulse oximeter is:

RATED MAXIMUM OUTPUT POWER OF RF TRANSMITTER (WATTS)	SEPARATION DISTANCE ACCORDING TO THE FREQUENCY OF RF TRANSMITTER (METERS)		
	150 kHz to 80MHz $d = 1.2\ \sqrt{P}$	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 determined 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: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

WARNING! The monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the monitor should be observed to verify normal operation in the configuration in which it will be used.

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Appendix B: Revision History

REVISION	DATE
Rev. 19	May, 2007
CHANGES	
• Changed company logo and added manufacturer's address to back cover. • Added warning to verify that all LEDs light up upon startup of the device. • Updated Theory of Operation. • Added note about how increasing or decreasing the averaging setting has no affect on the data update rate. • Added note about how the 1606 Oximetry Patient Simulator cannot be used to asses the accuracy of a pulse oximeter and/or sensor. • Added note about how to test alarms while the monitor is in use. • Added warning to be aware of alarm limits of similar monitors in the same area. • Added desat study information to SpO2 Accuracy section of Chapter 13. • Added Alarm Volume spec to Alarm Indicators section of Chapter 13. • Added Guidance and Manufacturer's Declaration to Appendix A. • Moved Revision History from Appendix A to Appendix B.	

REVISION	DATE
Rev. 18	January, 2007

CHANGES

- Added Warnings about AC Power to Chapters 1, 4 and 9.
- Added Warning about certain clinical conditions causing the oximeter to display dashes or erroneous values.
- Added Caution about cleaning agents to Chapter 1.
- Updated sensor tables with consistent wording.
- Restored missing alarm priorities summary table.
- Restored missing printout description.
- Updated monitor operating temperature.
- Updated trademark information.
- Updated Warranty Statement
- Removed the hyphen from Comfort Clip.
- Updated company email address.

REVISION	DATE
Rev. 16	June, 2006

CHANGES

- Added "Read IFU" warning to Chapter 1.
- Took out ® in Smiths logo
- Removed 1310 and 1311 per EAR 106-06.
- Added Rx Only symbol, REF symbol, SN symbol, Do not reuse symbol, and Collect Separately WEEE directive symbol.
- Added "dropped or damaged" warning and photodynamic warning.
- Added "water ingress" caution, alternative method of verifying accuracy caution, unplug power before cleaning caution, setting alarm limits caution, and damaging key pads caution.
- Added SpO_2 averaging note and dysfunctional hemoglobins note.
- Updated sensor table (pg 4-3) per EAR 107-06

REVISION	DATE
Rev. 15	March, 2005
CHANGES	
• Removed the statement that claims that pressing the I.D./ CLEAR key will cause printing to stop (pg7-6) • Added 1310 DOT reusable finger sensor and 1311 sensor tape. • Updated Smiths family copyright statement. • Updated registered trademark statements. • Changed font to Myraid Pro. • Added Revision History page. • Updated the Smiths logo to include a ®	

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