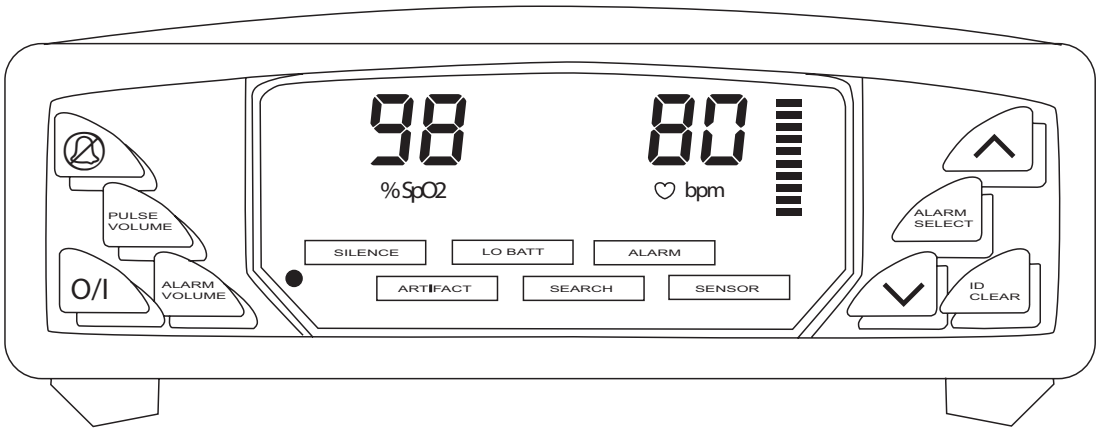
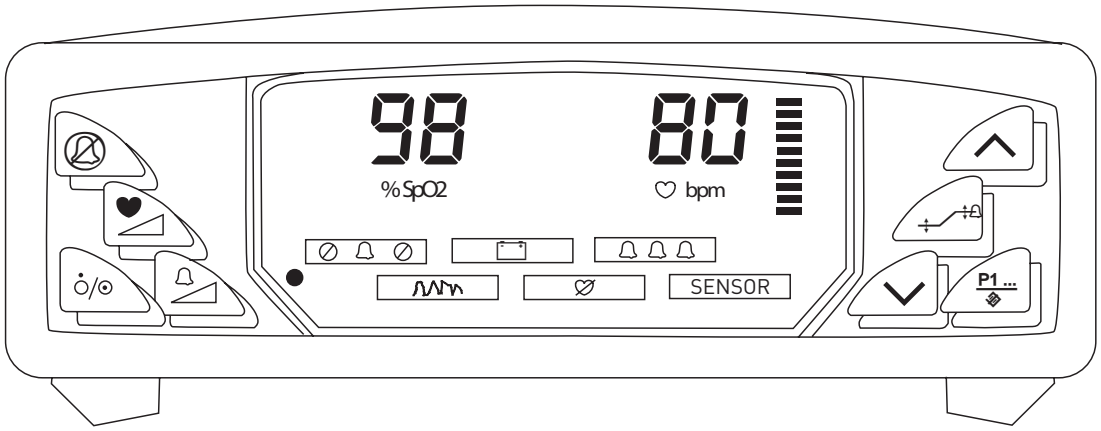
BCI™

Oximeter

Clinician's Operation Manual





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smiths medical

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Warranty and Service Information

Proprietary Notice

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Warranty

Limited Warranty

Smiths Medical PM, Inc. ("Seller") warrants to the original purchaser that the Product, not including accessories, shall be free from defects in materials 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).

Disclaimer of Warranties

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.

Seller disclaims responsibility for the suitability of the Product for any particular medical treatment or for any medical complications resulting from the use of the Product. This disclaimer is dictated by the many elements which are beyond Seller's control, such as diagnosis of patient, conditions under which the Product may be used, handling of the Product after it leaves Seller's possession, execution of recommended instructions for use and others.

Conditions of Warranty

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.

Limitation of Remedies

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 in 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

Telephone: 262-542-3100
Toll Free: 1-800-558-2345 (USA only)
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 service 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.

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

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

Phone: (44) 1923 246434
Fax: (44) 1923 240273

Australian Representative:

Smiths Medical Australasia Pty. Ltd.
61 Brandl Street, Eight Mile Plains,
QLD 4113, Australia

Tel: +61 (0) 7 3340 1300

Chapter 1: Introduction

About the 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 manual depicts the two available front panels for the 3304.

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 monitor. Failure to properly follow warnings, cautions and instructions could result in death or serious injury to the patient.

Definition of Symbols

SYMBOL	DEFINITION
Rx ONLY	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
	Type CF equipment
	Type B Equipment
	Attention, see instructions for use.
	Refer servicing to qualified service personnel.
	Do not reuse. One use on one patient.
%SpO2	Percent Oxygen Saturation
bpm	Pulse Rate LED (beats per minute)
	Alarm SILENCE
	On/Off
	Pulse Volume
	Alarm Volume
	Up and Down Arrows
	Alarm Select
P1	ID/CLEAR
	Moisture Sensitive
	Non AP Device
	Output Voltage
	Input Voltage
	Printer output
⎓	Direct Current
	Speaker

SYMBOL	DEFINITION
REF	Catalog Number
	Date of Manufacture
 Collect Separately	**Disposal (EU Countries)** Under the Waste Electrical and Electronic Equipment (WEEE) Directive 2006/96/EC and implementing regulations, all devices and service items within the scope of the Directive purchased new after August 13, 2005 must be sent for recycling when ultimately becoming waste. Devices and items must not be disposed of with general waste. If purchased before that date, they may also be sent for recycling if being replaced on a one-for-one, like-for-like basis (this varies depending on the country). Recycling instructions to customers using Smiths Medical products are published on the internet at: **http://www.smiths-medical.com/recycle**
	**Disposal (other countries)** When disposing of this device, its batteries or any of its accessories, ensure that any negative impact on the environment is minimized. Contact your local waste disposal service and use local recycling or disposal schemes. Separate any other parts of the equipment where arrangements can be made for their recovery; either by recycling or energy recovery. The main batteries are potentially harmful and will require separate disposal according to manufacturer's instructions or local regulations. **Note: If applicable, EU, national or local regulations concerning waste disposal must take precedence over the above advice.**

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 conducted transients or strong electromagnetic (EM) or radiofrequency (RF) sources, such as electrosurgery and electrocautery equipment, x-rays, and high intensity infrared radiation.

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

WARNING! Any monitor that has been dropped or damaged should be inspected by qualified service personnel, prior to use, to insure 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! 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! This device is intended for use by persons trained in professional health care. The operator must be thoroughly familiar with the information in this manual before using the device.

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 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).

WARNING! Connect the Wall Mount Charger to grounded, three-wire outlet. Failure to comply may compromise patient isolation.

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 approved by Smiths Medical PM, Inc.

WARNING! Verify the functionality of any remote alarm system connected to this monitor before leaving the patient unattended.

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

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, fluorescein, and patent blue V (PBV) may adversely affect the accuracy of the SpO_2 reading.

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 pulse rate and SpO_2 readings.

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

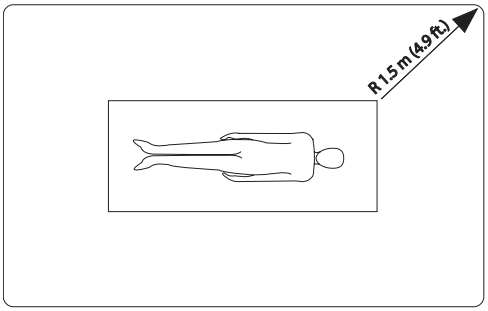
WARNING! Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin (with CO-poisoning) or methemoglobin (with sulfonamide therapy), will affect the accuracy of the SpO_2 measurement.

WARNING! Tissue damage may result from overexposure to sensor light during photodynamic therapy with agents such as verteporphin, porfimer sodium, and metatetrahydroxyphenylchlorin (mTHPC). Change the sensor site at least every hour and observe for signs of tissue damage. More frequent sensor site changes/inspections may de 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 systems requirements. Anyone connecting additional equipment to the signal input port or the 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.

WARNING! IEC 950 approved equipment must be placed outside 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



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, hi 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! Do not disassemble unit, not user serviceable. ⚠ Refer to qualified service personnel.

CAUTION! The monitor is equipped with an internal rechargeable battery. Do not attempt to remove or replace the internal rechargeable battery. Refer servicing to an authorized repair center.

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

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. Do not autoclave, ethylene oxide sterilize, or immerse the monitor in liquid. Evidence that liquid has been allowed to enter the monitor voids the warranty.

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

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

Notes

NOTE! If the digital outputs are enabled and a low battery condition is present, the digital outputs will be activated.

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

NOTE! Increasing or decreasing the averaging setting has no effect on the data update rate.

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Chapter 2: Intended Use and Monitor Features

Intended Use

The 3304 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.

Monitor Features

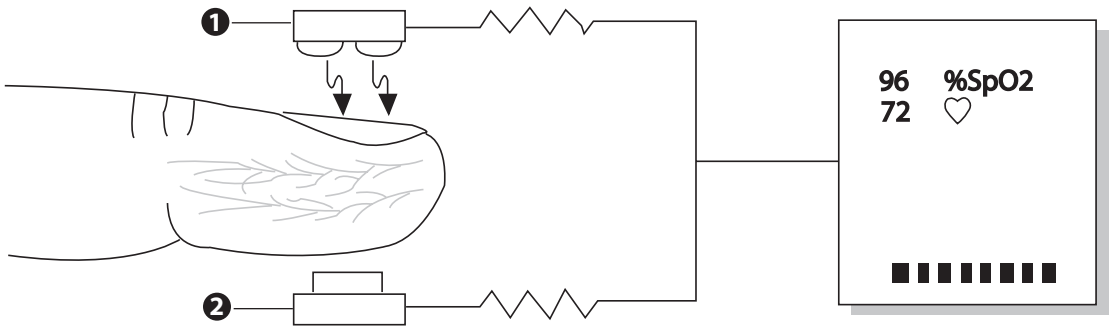
- Provides fast, reliable SpO_2, pulse rate, and pulse strength measurements on any patient, from neonates to adults.
- Ideally suited for use in intensive care units, outpatient clinics, emergency rooms, during emergency air or land transport, or for in-home use.
- Portable and lightweight. Weighs only 850 grams (30 ounces).
- Ergonomically designed to hang on a bed rail or be transported using the convenient handle.
- Uses an internal, rechargeable battery.
- Battery life is approximately 4.5 hours in continuous use (new). Battery fully charges in about 6 hours.
- Bright, easy-to-read LED displays indicate SpO_2 and pulse rate measurements. Brightness is user-adjustable.
- A ten-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 for alarm and alert tones (including silence).
- Adjustable volume (including silence) "beep" sounds with each pulse beat. Pitch of pulse "beep" corresponds to SpO_2 value.
- User-adjustable delayed audible system alarms.
- Low battery indicator lights when about 30 minutes of battery use remains.
- Connects to an optional external printer or any RS-232 compatible terminal. Prints a continuous datalog and trend data in tabular format.
- SpO_2 and pulse rate averaging settings are user-selectable.
- Artifact indicator informs user of excess motion and other artifacts.
- Connects to optional analog output adapter, providing output of the monitor's measured values.
- Connects to optional digital alarm adapter to send output to a remote sensing location.
- User-adjustable trend storage rate, ranging from 4 to 30 seconds per sample, for many applications including sleep studies.
- Home-Use Mode allows a home-use caregiver to monitor a patient at home.

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: SpO_2 Theory Of Operation



❶ Low intensity red and infrared LED light sources
❷ 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 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 & Features

Monitor Front Panel

Figure 3.1: Domestic Display and Keypad

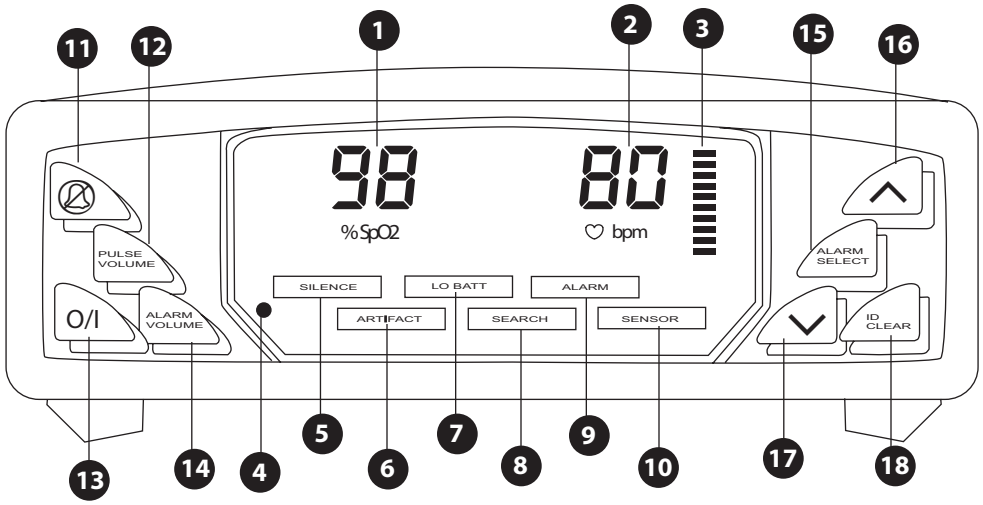
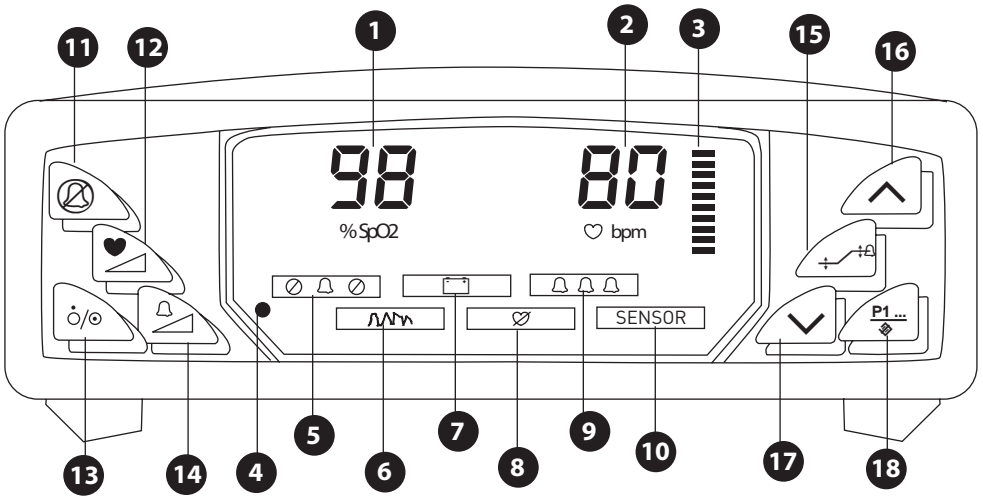


Figure 3.2: International (MDD) Display and Keypad



1 SpO_2 Numeric Display

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

2 Pulse Rate Numeric Display

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

3 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.

4 AC Power Indicator (●)

The AC Power Indicator is green when the power supply is attached.

5 Alarm SILENCE Indicator (SILENCE)

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

6 Artifact Indicator (ARTIFACT)

The ARTIFACT indicator ( ) is illuminated in the presence of excess motion or other artifacts.

7 Low Battery Indicator (LO BATT)

The low battery indicator ( ) is illuminated and a short burst of beeps occurs 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 LO BATT ( ) flashes, you must immediately charge the monitor's battery. Otherwise, the monitor turns itself off about 30 minutes after LO BATT begins to flash.

8 SEARCHing Indicator (SEARCH)

The SEARCHing light ( ) indicates that the monitor is looking for a pulse. Audio pulse tone is disabled during this time.

9 Alarm Indicator (ALARM)

The ALARM indicator ( ) is illuminated during an alarm condition.

10 Sensor Indicator (SENSOR)

SENSOR lights when the sensor is not connected to the monitor, the sensor is not attached to the patient, or to indicate a "searching too long" warning.

WARNING! While SENSOR is lit, 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.

11 Alarm SILENCE ( )

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). Pressing the alarm silence key ( ) when the alarms are silenced, activates the alarms.

12 Pulse Volume ( )

Pressing and holding the PULSE VOLUME key ( ) and simultaneously pressing the up or down arrow key, gradually changes the pulse beep volume.

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

13 Device On/Off (/I Domestic) (MDD)

Pressing the on/off key turns the monitor on or off, depending on the previous condition.

14 Alarm Volume ( )

Pressing and holding the ALARM VOLUME key ( ) and simultaneously pressing the up or Down arrow key, gradually changes the alarm volume.

15 Alarm Select ( )
Pressing the ALARM SELECT key ( ) cycles through each of the alarm limit settings. Pressing and holding at power up will start the setup mode.

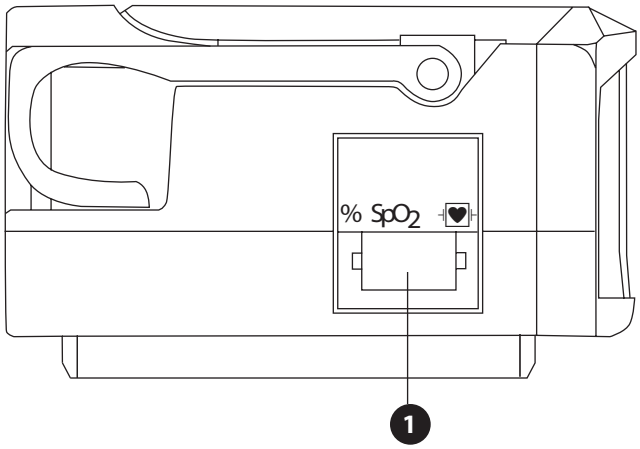
16 UP arrow ( ) Alarm Limit/Alarm Volume Adjustment/Brightness Adjustment
The up and down arrow keys are used to adjust up and down the following settings: brightness of the display; alarm limits; SpO_2 and pulse rate averaging, data log and trend interval, RS-232 mode of operation, delayed audible system alarms, and alarm and pulse volume adjust.

17 DOWN arrow ( ) Alarm Limit/Alarm Volume Adjustment/Brightness Adjustment
The up and down arrow keys are used to adjust up and down the following settings: brightness of the display; alarm limits; SpO_2 and pulse rate averaging, data log and trend interval, RS-232 mode of operation, delayed audible system alarms, and alarm and pulse volume adjust.

18 ID/CLEAR ( )
While the sensor is connected to the monitor pressing the I.D./CLEAR key ( ) increases the patient number by one. The patient number is briefly displayed in the SpO_2 area. Pressing and holding the I.D/CLEAR key ( ) for about six seconds clears all trend data and sets the patient number to 1.

Monitor Side Panel

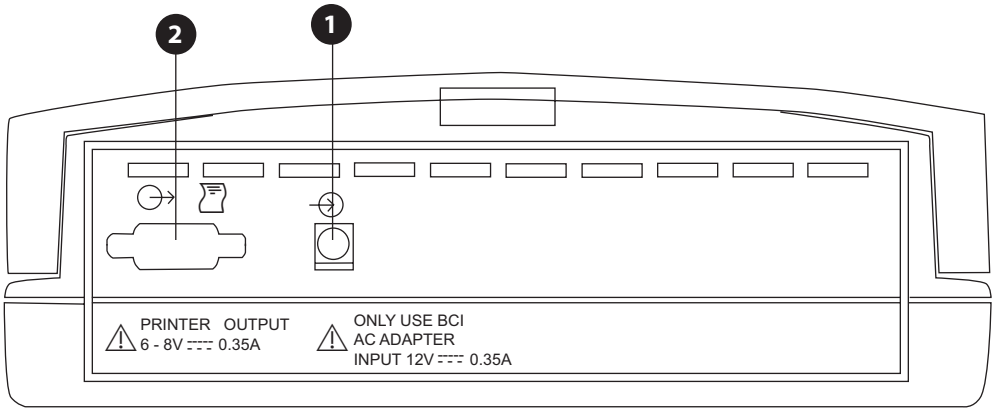
Figure 3.3: Side Panel Connectors



1 Sensor Connector
The sensor connects here. An oximetry cable, connecting the monitor and the sensor, is also connected here.

Monitor Back Panel

Figure 3.4: Back Panel Connectors



1 AC Power Connector

AC power supply connects here.

2 Printer/PC Connector

An optional printer can be connected for printing trend and datalog data. See the Printer section for more printer options. The monitor may also be connected to a PC using this connector.

Chapter 4: Operating Instructions

Unpacking the Monitor

Carefully remove the monitor and its accessories from the shipping carton. Save the packing materials in case the monitor must be shipped or stored.

Compare the packing list with the supplies and equipment you received to make sure you have everything you'll need.

Attaching the Sensor to the Patient

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

WARNING! Incorrectly applied sensors may give inaccurate readings. ⚠ Refer to the sensor insert for proper application instructions.

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).

To attach the patient to the monitor:

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.) (See *Cleaning or Disinfecting the Sensors* section in this chapter for more information.)
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

Choose the appropriate sensor from the following chart.

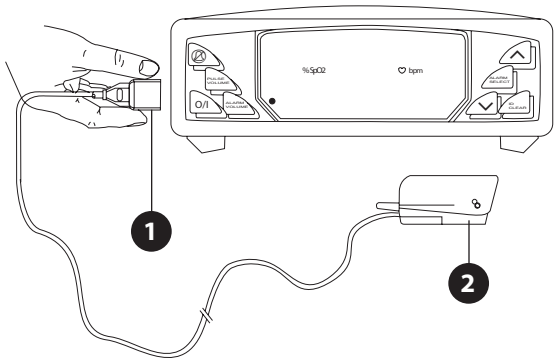
PATIENT	SITE	DESCRIPTION
Adult over 45 kg	Finger	3044: Sensor, Adult (reusable) 3444: Sensor Comfort Clip® (reusable)
	Finger or Toe	3043: Sensor, Universal 'Y' (reusable) 1300: Sensor, Disposable, Adult Finger
	Ear	3078: Sensor, Ear (reusable)
Pediatric 15-45 kg	Finger	3044: Sensor, Adult (reusable) (>20 kg) 3444: Sensor Comfort Clip® (reusable) 3178: Sensor, Pediatric Finger (5-45 kg)
	Finger or Toe	3043: Sensor, Universal 'Y' (reusable) 1301: Sensor, Disposable, Ped. Finger
	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, Disposable, Infant
Neonate under 3 kg	Hand or Foot	1302: Sensor, Disposable, Neonate
	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.

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

Figure 4.1: Disconnecting or connecting the finger sensor.



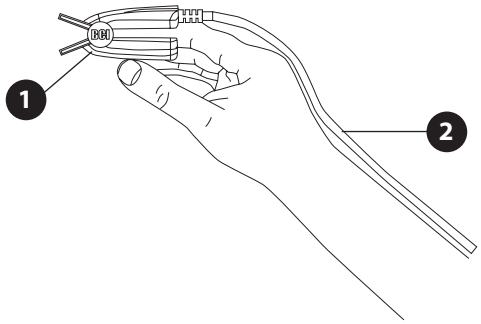
1 Connector

2 Sensor (finger sensor shown for illustration only)

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 top of the hand and parallel to the arm of the patient as shown in Figure 4.2.

Figure 4.2: Positioning the cable of the finger sensor.



1 Sensor (finger sensor shown for illustration only)

2 Cable

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.

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

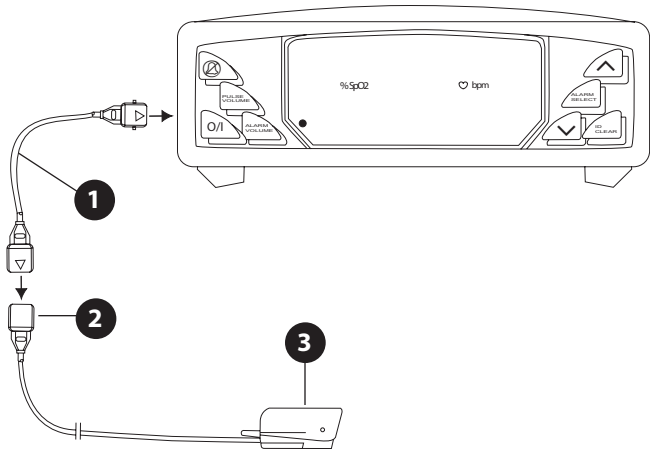
If using the oximetry cable, carefully inspect the oximetry cable to make sure it does not appear damaged.

Figure 4.3: Attaching Sensor And Oximetry Cable To Monitor.

1 Oximetry Cable

2 Connector Retaining Clip

3 Sensor (Finger Sensor shown for illustration only)



If using the oximetry cable:

1. 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.

2. 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.

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

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.

If not using the oximetry cable:

1. Connect the sensor to the monitor. Push the connector firmly into the monitor.

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.

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

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

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

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

      - For the finger sensor and ear sensor: Make sure the SENSOR indicator is lit 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.

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

Cleaning or Disinfecting the Sensors

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

WARNING! 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.

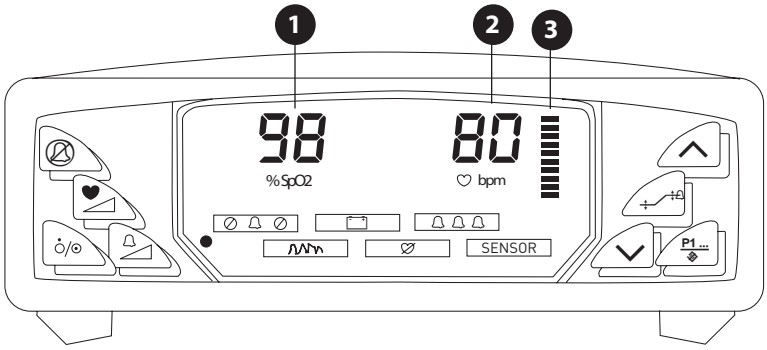
Turning On the Monitor

To turn on the monitor, press the on/off key (⏻/| domestic) (⏻/⏻ MDD). 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.

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

Figure 4.4: SpO_2, Pulse Rate, And Pulse Strength Bar Graph.



1 Patient's SpO_2

2 Patient's Pulse Rate

3 Patient's Pulse Strength

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.

The monitor has available three averaging settings for SpO_2 and pulse. To change the averaging setting, press and hold the appropriate key while turning on the monitor as shown in the following chart:

POWER UP KEY PRESS	SPO_2 AVERAGING	PULSE AVERAGING
^	16	16
v	4	8
NO KEYS PRESSED (Default)	8	8

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! Averaging returns to the default setting each time the monitor is turned on.

NOTE! Increasing or decreasing the averaging setting has no effect on 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.

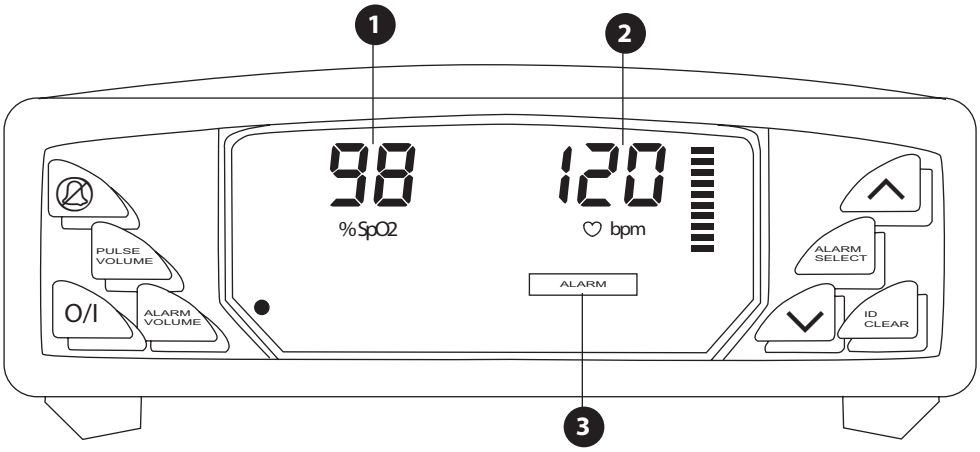
Alarms

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.
- the patient's pulse rate reading matches or exceeds the pulse rate alarm range.
- there is a lost pulse condition (the sensor no longer detects a pulse while a finger is inserted in the sensor, when a pulse was previously detected).

Figure 4.5: Alarm Example



1 & 2 During an alarm: the numbers flash that correspond to the alarm.

3 During an alarm: ALARM LED ( ) flashes

During an alarm, the alarm tone sounds, if not silenced. The alarm tone consists of two bursts of five monotone beeps, repeated every 10 seconds.

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

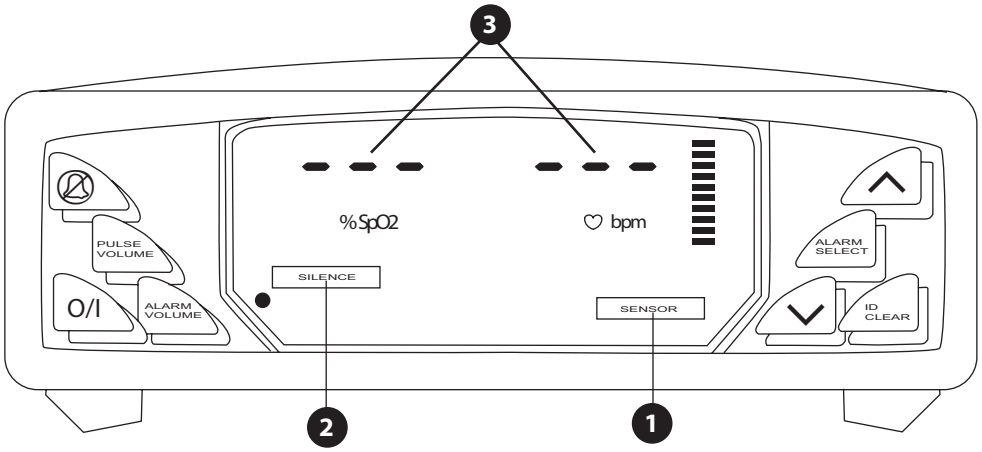
Alerts

An alert warns you about an abnormal monitor condition.

An alert turns on when:

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

Figure 4.6: Alert Example



1 During an alert, the SENSOR message illuminates.

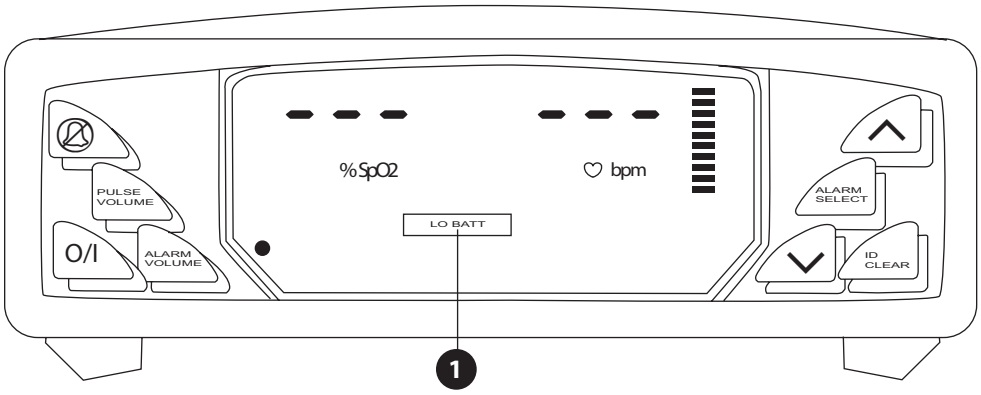
2 During an alert, the alert tone sounds, if not silenced (SILENCE or ⊘🔔⊘). The alert sound is a single tone pair of beeps with a 20 second pause: beep beep, pause, beep beep.

3 During an alert, the monitor cannot measure the patients SpO_2 or pulse rate. Dashes are displayed.

WARNING! While SENSOR is lit, 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.

LO BATT Attention

Figure 4.7: BATT Attention Example



1 During the Low Battery attention, the low battery indicator (LO BATT or) flashes on and off. A short burst of five beeps sounds every 30 seconds.

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

NOTE! If the digital outputs are enabled and a low battery condition is present, the digital outputs will be activated.

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, Inc. 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/ECG 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).

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 SILENCE indicator ( ) flashes during the two-minute time-out.

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

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, ranging in volume from soft or loud (and vice versa).

To change from soft to loud volume, press and hold the ALARM VOLUME key ( ) while pressing the up and down arrow keys (and).

Adjusting 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 and 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 key.

Changing the Pulse Beep Volume

A "beep" tone sounds with each pulse beat. To change from soft to loud volume, press and hold the PULSE VOLUME key ( ) while pressing the up or down arrow key (and).

Changing the Setup Modes

The following modes are user adjustable:

- trend storage interval mode: 4 to 30 seconds
- RS-232 output mode: printer, analog, digital
- audible system alarms disable interval mode: OFF, 15, 30, or 45 seconds.

To change the default settings press and hold the ALARM SELECT key ( ) during power-up. Each mode may be adjusted using the up and down arrow keys (and). Switching from one mode to another is done by pressing the ALARM SELECT key ( ).

The first option of the setup mode is the trend storage interval. Use the up and down arrow keys (and) to change the interval at which trend data is stored from 4 to 30 seconds.

Pressing ALARM SELECT ( ) then gives the option to change the RS-232 output mode between printer (P), analog (A), and digital (d).

Pressing ALARM SELECT ( ) again, gives the option to adjust the audible system alarms delay between off, 15, 30, and 45 seconds. When delay is off, the system alerts will be activated after 20 seconds of searching. This search time can be increased by increasing the delay.

Pressing ALARM SELECT ( ) again saves the setup changes and exits setup mode.

Changing the Alarm Limits

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

Press the ALARM SELECT key ( ) until the alarm limit you want to change is shown, then press the up or down key (∧ and ∨) 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! Alarm limits are retained during power cycles, except for the following note.

NOTE! If either the low or high SpO_2 alarm limit is set below 80%, it will reset to 85% or higher when the monitor is next powered on.

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! The alarm actions occur for each violated alarm, even if more than one alarm is violated at the same time.

NOTE! Alarms may be tested while the monitor is in use by setting alarm limits such that the measured parameter is outside alarm limits. Return limits to the required settings after testing.

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

Chapter 6: Patient Numbers & Trend Data

Description

Whenever the monitor is on, it stores one SpO_2 and one pulse rate reading every four (4) to thirty (30) seconds. These intervals are adjustable as described later in this chapter. The stored readings are called *trend* data. The monitor remembers trend data for up to 99 patients and 90 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, only the patient number is displayed and is not incremented.

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

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.

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

Adjusting The Data Storage Interval

Press and hold the ALARM SELECT key ( ) during power-up.

The data storage interval will appear on the display, showing the default interval of 30 seconds.

Use the up or down keys (∧ and ∨) to increase or decrease the storage interval. The interval range is 4 seconds to 30 seconds.

STORAGE INTERVAL (SECONDS)	RUN-TIME (HOURS)
4	12
5	15
8	24
10	30
20	60
30	90

Clearing Trend Data

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

Press and hold the I.D./CLEAR key (P1 ···) for about six seconds. While you are holding the I.D./CLEAR key (P1 ···), 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.

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Chapter 7: Printer

Description

The 3304 has a built-in interface for an external printer. An external printer or PC may be connected to the Printer/PC connector on the back of the monitor.

Data Log Printout

Figure 7.1: Sample Data Log Printout

```
**********************
DATA LOG

ID_____________________
_______________________
          SpO2 BPM
           --   --
           97%  91bpm
           97%  83bpm
           97%  87bpm
           97%  88bpm
           96%  88bpm
           96%  92bpm
           97%  88bpm
           97%  87bpm
           97%  83bpm
           97%  80bpm
           98%  80bpm
           98%  80bpm
           98%  80bpm
           98%  84bpm
           98%  84bpm
           --   --
```

In the data log mode, the patient's SpO_2 and pulse rate values are printed in real time, once every five (5) seconds.

Figure 7.2: Sample Trend Printout

```
**********************
TREND

PN             01
H :M :S   SpO2 BPM
00:00:00   98%  60bpm
00:00:30   98%  60bpm
00:01:00   98%  60bpm

PN             02
H :M :S   SpO2 BPM
00:00:00   98%  60bpm  A
00:00:30   90%  94bpm

PN             03
H :M :S   SpO2 BPM
00:00:00   89%  51bpm  A
00:00:30   88%  45bpm

PN             04
H :M :S   SpO2 BPM
00:00:00   88%  45bpm

PN             05
H :M :S   SpO2 BPM
00:00:00   --   --
```

Whenever the monitor is on, it stores one SpO_2 and pulse rate reading every four (4) to thirty (30) seconds, depending on the user's needs (See the *Adjusting the Data Storage Interval* section). A thirty second interval is the default setting. The trend data can be printed at any time on the optional printer.

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 Null Modem
Approvals	IEC 950 / IEC 601-1

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.

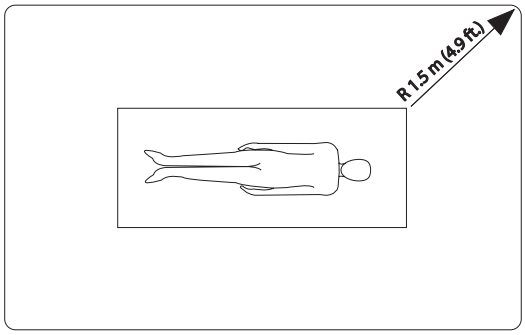
What You'll Need for Printing

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, adapter (i.e. DB-9 to DB-25 standard adapter for use with DPU 411 printer), and so on (purchased from the printer manufacturer's distributor).

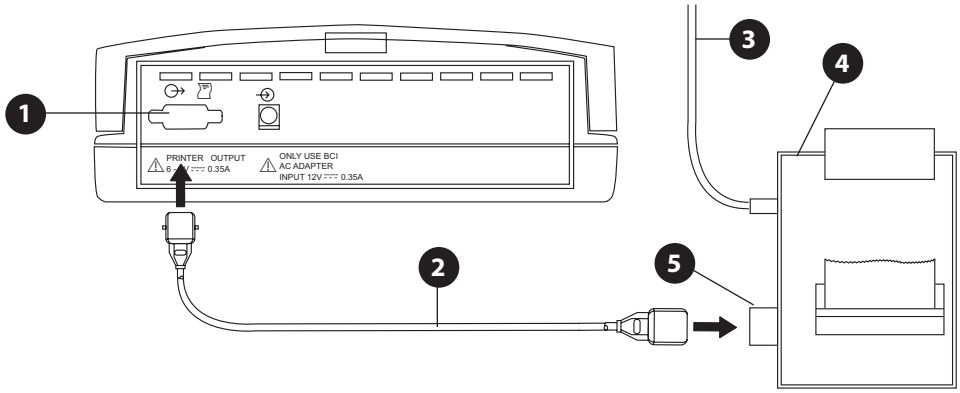
WARNING! IEC 950 approved equipment must by placed outside of the "patient environment." The patient environment is defined as an area 1.5 m (4.92 feet) from the patient.

Figure 7.3: Patient Environment



Setting Up the Monitor and the Printer

Figure 7.4: Setting Up The Oximeter And The Printer.



1 Printer/PC Connector

2 Printer Cable (Catalog #3361)

3 Printer AC Power Connection

4 Optional Printer

5 DB-9 Printer Connector

1. Turn the monitor on and select PRINTER output mode:
   a. Press the ALARM SELECT key ( ) during power-up. The adjustable setup modes are displayed.
   b. Using the ALARM SELECT key ( ), select the OUT mode and press the up key ( )to choose "P" (PRINTER).
   c. Press the ALARM SELECT key ( ) again until the patient number is displayed.

NOTE! If the LO BATT indicator ( ) is lit, connect the monitor to the wall mount charger.

2. 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
3. Connect the printer cable's DB-9 connector to the mating connector on the monitor.
4. Connect the printer cable's DB-9 connector to the mating connector on the printer.
5. Connect the printer's power source to the printer as described in the printer's operation manual.
6. Make sure the printer has paper loaded and is ready to print as described in the printer's operation manual.

Printing Data Log

1. Set up the monitor and printer as previously described.

2. Connect the SpO_2 sensor to the patient and to the monitor as previously described.

3. Turn on the printer.

4. Turn on the monitor. The monitor prints SpO_2 and pulse rate measurement once every five (5) seconds, as shown in the sample printout.

5. Pressing I.D./CLEAR key (P1 ...) prints a new header and increments the patient number; real-time data is printed once every five (5) seconds again.

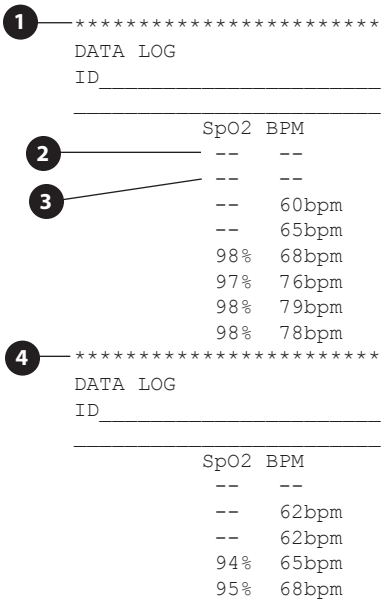
6. The monitor continues to store trend data, even while printing the data log.

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

8. If you disconnect the SpO_2 sensor while printing the data log, the data log printout continues (dashes are printed to indicate invalid or unavailable data). The data log continues to print until the monitor is turned off.

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

Figure 7.5: Printing Data Log



1. Monitor is turned on with SpO_2 probe connected to monitor; a header is printed.

2. First Real-Time Data is printed immediately after header.

3. Real-Time Data ia printed once every five seconds.

4. Pressing the I.D./CLEAR key causes another header to be printed; Real-Time Data is printed once every five seconds.

Note that the patient number is incremented also and the monitor continues to store trend data even when printing the data log.

Trend Printouts

Collecting Trend Data

Whenever the monitor is on, it stores one SpO_2 and one pulse rate reading every four (4) to thirty (30) seconds, as set during power-up (See the *Adjusting the Data Storage Interval* section). The stored readings are called *trend* data. The monitor remembers trend data for up to 99 patients and 90 hours of run-time (data storage interval set to 30 seconds). 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.

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 key (P1 ...) 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 key (P1 ...) for about six seconds. While you are holding the I.D./CLEAR key (P1 ...), 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

1. Set up the monitor and printer as previously described.

2. Disconnect the SpO_2 sensor from the monitor.

3. Turn on the printer.

4. Turn on the monitor. The monitor prints the trend data for each patient, from patients 1-99, as shown in the sample printout.

5. If there is no trend data at all, the message " **** " is printed. If no valid data is collected for a patient number, -- is printed.

6. If valid data is collected for a patient number for less than one minute, only the last measurement is printed.

7. 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.

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

9. A printed 'A' indicates the presence of artifact in the signal. A printed 'L' indicates a low pulse

10. If you connect the SpO_2 sensor while printing trend data, the trend printout continues. If the SpO_2 sensor is connected to the monitor after all trend data for all patient numbers has been printed, a data log printout starts.

11. If you press the I.D./CLEAR key (P1 ...) while printing trend data, the trend printout stops and a data log printout starts. Pressing the I.D./CLEAR key (P1 ...) also increments the patient number, and trend data is collected for the new patient number while the data log is printing.

Figure 7.6: Printing Trend Data

```
**********************
TREND

PN              01
H :M :S   SpO2 BPM
00:00:00   98%  60bpm
00:00:30   98%  60bpm
00:01:00   98%  60bpm

PN              02
H :M :S   SpO2 BPM
00:00:00   98%  60bpm  A
00:00:30   90%  94bpm

PN              03
H :M :S   SpO2 BPM
00:00:00   89%  51bpm  A
00:00:30   88%  45bpm

PN              04
H :M :S   SpO2 BPM
00:00:00   88%  45bpm

PN              05
H :M :S   SpO2 BPM
00:00:00   --  45bpm
```

1. Monitor is turned on with SpO_2 probe disconnected from monitor:; the trend printout is started.

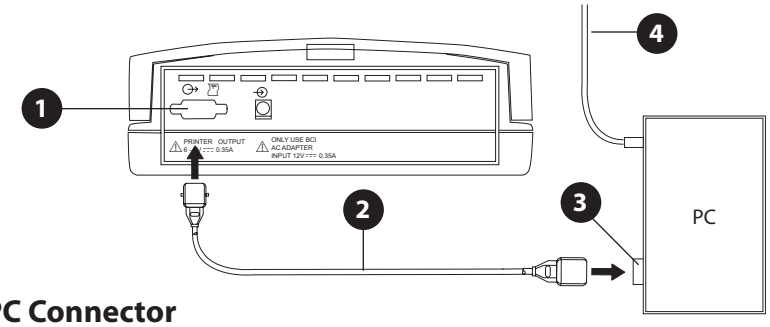
2. The trend printout shows the relative time since the first measurement for that patient number.

3. Data was collected from patient number 05 for less than one minute; only the last measurement is printed. Dashes indicate invalid or unavailable data (for example, the patient's finger was removed from the SpO_2 probe.

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

PC Communication Setup

Figure 7.7: Setting Up The Oximeter And The PC.



1 Printer/PC Connector

2 DB-9 Straight Through cable (Catalog #3362)

3 DB-9 PC Serial Connector

4 PC AC Power Connection

1. Power up the monitor. Make sure that the PRINTER output mode is selected (see the *Setting Up the Monitor* and the *Printer* section.)

2. 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

3. Connect the PC cable's (Catalog # 3362) DB-9 connector to the mating connector of the monitor.

4. Connect the PC cable's (Catalog # 3362) DB-9 connector to the mating connector on the PC.

Transferring 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. To output trend data, disconnect the SpO_2 sensor, otherwise, connect the sensor to output a data log.

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

6. If the SpO_2 sensor is reconnected while the trend data is being output to the PC, the output continues. If the SpO_2 sensor is reconnected to the monitor after all of the trend data has been output, a data log output will start.

Chapter 8: Operating Modes

About the Monitor's Operating Modes

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

Home Use Mode

While the monitor is in home-use mode:

- Alarm limits can be viewed but cannot be changed.
- Alarm and alert tones may not be adjusted.
- 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 number advancement is 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.
- Interval and delayed audio system alarm setup options are disabled.
- 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 key (P1) until P1 is displayed.)
3. Put the monitor into the home-use mode as follows:
   a. Turn off the monitor.
   b. Press and hold the ALARM VOLUME key (), then press the on/off key O/I (domestic) ⊙/Ó (MDD).
   c. While holding the ALARM VOLUME key (), H flashes in the pulse rate display.
   d. When H stops flashing and lights steady (in about 6 seconds), release the ALARM VOLUME key (). The monitor is now in home-use mode.
4. Verify the monitor is in the home-use mode:
   a. Turn off the monitor by pressing and holding the I.D./CLEAR key (P1), then pressing and releasing the on/off key O/I (domestic)- ⊙/Ó (MDD).
   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 SELECT ( ) to show each of the alarm limits one-at-a-time.)
6. Turn off the monitor by pressing and holding the I.D./CLEAR key ( ), then pressing and releasing the on/off key O/I (domestic)- (MDD).

Equipment and Supplies Checklist for Home-Use

Provide the following to the home-use caregiver:

QUANTITY	CAT. NO.	DESCRIPTION
1	3304	Oximeter
1	1611	Battery Charger 105-125 VAC 60 Hz
1	1612	Battery Charger 208-252 VAC 50/60 Hz
1	1613	Battery Charger 90-110 VAC 60 Hz
*	3049	Adhesive Strips (Adhesive Tape)
1	1861	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
*	3444	Sensor, Reusable, Comfort Clip®
*	3178	Sensor, Pediatric Finger (5-45 kg)
1	3311	Cable, Oximetry, 1.5 m (5 Feet)
*	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

The home-use caregiver must be trained in CPR.

Make sure the monitor's alarm limits are properly set and that the monitor is in the home-use mode.

Inform the caregiver that the oximeter is not to be used as an apnea monitor.

(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 wall mount power supply to the wall outlet.
- make sure the wall mount power supply outlet is not controlled by a wall switch.
- connect the monitor to the wall mount power supply.
- make sure the monitor's POWER indicator is lit.
- 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 LO BATT attention.
- turn off the monitor.

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 LO BATT attention sounds.
- in case the caregiver has trouble operating the equipment.

Turning Off Home-Use Mode

Turn off the home-use mode as follows:

1. Turn off the monitor.
   a. Press and hold the PULSE VOLUME key ( ), then press the on/off key O/I (domestic) (MDD).
   b. While holding the PULSE VOLUME key ( ), H flashes in the pulse rate display.
   c. 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.

Setting Up the Monitor for Sleep Study Mode

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

To access the monitors sleep study mode, execute the following steps:

1. Turn the monitor OFF.
2. Press and hold the ALARM SEL ( ) key, then press the ON/OFF key O/I (domestic) (MDD). This will enable the monitors setup menu at power up.
3. Repeatedly press the ALARM SEL ( ) key until nor ("normal") is displayed.
4. Press the up or down key (or) until SLP is displayed.
5. Again press the ALARM SEL ( ) key to exit the setup menu and display the current patient number.

NOTE! The monitor mode is NOT displayed at power up and can only be observed in the monitors setup menu. To ensure the correct mode of operation, the setup menu should be checked at power up to verify mode of operation.

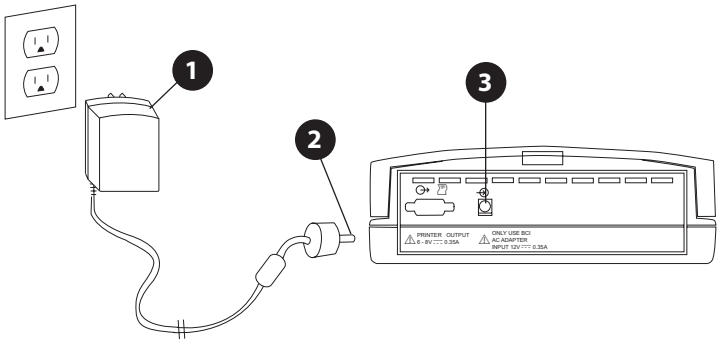
Turning Off Sleep Study Mode

To disable the sleep study mode, and return the monitor to the clinician mode, execute the following steps:

1. Turn the monitor OFF.
   a. Press and hold the ALARM SEL ( ) key, then press the ON/OFF key O/I (domestic) (MDD). This will enable the monitor's setup menu at power up.
   b. Repeatedly press the ALARM SEL ( ) key until SLP is displayed.
   c. Press the up or down key (or) until nor ("normal") is displayed.
   d. Again press the ALARM SEL ( ) key to exit the setup menu and display the current patient number.
2. The monitor is now in clinician mode

Chapter 9: Charging the Monitor

Figure 9.1: Connecting AC Power



1 AC Charger to Wall Outlet.

2 AC Charger to AC Power Connector.

3 AC Power Connector.

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 wall mount charger as shown.

   - 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 monitor. If not, see the *Troubleshooting* section.

3. The green indicator lights while the monitor's battery is charging and connected to AC power.

4. The monitor's battery will fully charge in about six (6) hours. A fully charged battery provides approximately 4.5 hours of use (new).

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! The monitor contains a lead-acid. If the battery fails to hold a charge or otherwise becomes inoperable, the battery should be replaced and the old battery should be disposed of properly. Lead acid batteries should not be disposed of in normal trash containers. They should be sent to the proper facilities so that the metals in them may be reclaimed and/or recycled. Lead Acid Battery: In the US, 1-800-822-8837 will also provide information about the proper disposal of the lead-acid battery. Regulations in Europe vary from country to country. Consult local authorities for information about the proper disposal of the lead acid battery.

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Chapter 10: Maintenance

Schedule of Maintenance

MAINTAIN THIS ITEM	HOW OFTEN	BY DOING THIS
Battery	When LO BATT ( ) indicator is flashing, or after the monitor has been used under battery power.	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 reusable sensor.	Before attaching the sensor to the patient.	Follow the instructions for disinfecting the reusable sensor.
Disinfecting the monitor and the wall mount charger.	When necessary.	1. Disconnect the monitor from the wall mount charger. 2. Disconnect the wall mount charger from the wall outlet and from the monitor. 3. Wipe the surfaces of the monitor and the wall mount charger 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.

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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.
LO 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 O/I ( ) 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.*
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 supply 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.
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.

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Chapter 12: Optional Supplies & 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, Oximeter	each
1611	Battery Charger 105-125 VAC 60 Hz	each
1612	Battery Charger 208-252 VAC 50/60 Hz	each
1613	Battery Charger 90-110 VAC 60 Hz	each
1857	Manual, Clinician's Operation (3304)	each
1858	Manual, Service (3304)	each
1861	Manual, Home Use Instruction Book (3304)	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 feet)	each
3351	Adapter, Analog Output	each
3352NO	Adapter, Digital Output (Nurse Call – open circuit)	each
3352NC	Adapter, Digital Output (Nurse Call – closed circuit)	each
3361	Cable, Printer Interface	each
3362	Cable, PC Interface	each
3444	Sensor, Oximetry, Finger, Comfort Clip®	each

Ordering Information

Outside the USA, for ordering information, contact your local distributor. In the USA, for ordering information, contact the customer service department at the address or phone number below:

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

Phone: (262) 542-3100
Toll-Free: (800) 558-2345
Fax: (262) 542-0718

E-mail address: info.pm@smiths-medical.com

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Chapter 13: Specifications

Parameters Monitored

SpO_2, Pulse Rate, and Pulse Strength

Displays, Indicators, & Keys

SpO_2:	3-digit LED display, 0.43 inches (10.9 mm) high.
Display update rate:	1Hz
Pulse Rate:	3-digit LED display, 0.43 inches (10.9 mm) high.
Display update rate:	1Hz
Pulse Strength:	Logarithmically scaled 8-segment LED bar graph.
Display update rate:	60Hz
SENSOR:	Sensor alert indicator.
LO BATT ( ):	Low battery indicator.
SILENCE ( ):	Alarm and alert tone silenced indicator.
ALARM ( ):	Alarm indicator.
ARTIFACT ( ):	Indicates the presence of motion artifact.
SEARCH:	Indicates that the monitor is looking for a pulse.
Keys:	Eight control keys provided.
Brightness:	Adjustable brightness of SpO_2, pulse rate, and bar graph displays.
Power:	Indicates oximeter connected to AC power.

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.
Averaging:	4, 8, or 16 pulse beat average.

[1] 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 3304 has been validated on 10 adult volunteers that did not have health problems and were non-smokers. 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 1 BPM steps. Low 5-250 BPM and off in 1 BPM steps.
Pulse Tone:	Pitch corresponds to SpO_2. Volume adjustable to off.
Averaging:	8 or 16 second average.

Alarm Indicators

User-adjustable volume from 45dBA to 85dBA and two-minute or indefinite alarm silence. Audible alarm consists of 2 bursts of 5 beeps repeated every 20 seconds. Corresponding numeric display flashes.

Sensor Alert Indicator

Same volume and silence as alarm tone. Audible alarm consists of a pair of beeps repeated every 10 seconds.

Printer Output

SpO_2 and pulse rate can be printed every five (5) seconds (data log). Data saved every four (4) to thirty (30) seconds can be printed (trend).

Battery

Type:	Internal rechargeable lead acid; not user replaceable.
Charge Time:	Fully charges in about 6 hours.
Use Time:	Approximately 4.5 hours continuous use (new).
Indicators:	LO 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 60Hz (Optional)
Table Top Style:	Input of 208-252 VAC 50/60Hz

Dimensions

Width:	216 mm (8.5 inches)
Height:	82 mm (3.24 inches)
Depth:	140 mm (5.5 inches)
Weight:	850 grams (30 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 95%

Appendix A: Outputs

Analog Outputs

1. Attach the Analog Output Printer Adapter (Cat #3351) to the printer/PC connector located on the back of the monitor.
2. Enter the setup mode by pressing and holding the ALARM SELECT key ( ) at power-up.
3. Press the ALARM SELECT key ( ) one more time to get the "oUt P" message.
4. Use the up arrow ( ) to select the "A (analog)" mode.
5. The analog output is equal to 10 mV times the measurement on the display (5 volts full-scale).

MEASUREMENT	FULL SCALE
SpO_2	0-1 Volt
Rate	0-1 Volt

In order to provide zero and full-span reference voltages for the user, the 3304 will generate:

- 1 VDC if sensor is not plugged into the unit
- 0 VDC if sensor is plugged into the unit, but no finger in the sensor ("dashes" on the screen).

Gain and offset calibration procedure:

1. Plug the sensor in but do not put your finger into the sensor.
2. Adjust the offset setting of the chart recorder to display 0% SpO_2 and 0 bpm Pulse Rate.
3. Unplug the sensor.
4. Adjust the gain setting of the chart recorder to display 100% SpO_2 and 250 bpm Pulse Rate.

ANALOG OUTPUTS	
Configuration	Optional, attached and powered by communication port
Channels	Two, Pulse Rate and SpO_2 SpO_2: 0-100% = 0-1.00 VDC Rate: 30-250 bpm = 0.12-1.00 VDC
Resolution	SpO_2: 9.7mV per count Rate: 3.9 mV per count

Digital Outputs

WARNING! Verify the functionality of any remote alarm system connected to this monitor before leaving the patient unattended.

1. Attach the Digital Alarm Output Printer Adapter (Cat #3352NO or #3352NC) to the printer/PC connector located on the back of the monitor
2. Enter the setup mode by pressing and holding the ALARM SELECT key () at power-up.
3. Press the ALARM SELECT key () one more time to get the "oUt P" message.
4. Use the up arrow (^) to select the "d" (digital) mode.

When enabled, the digital outputs for any audible alarm will activate. An audible alarm is considered any alarm that will sound provided it is not silenced. These alarms include high or low SpO_2, Lost Pulse, sensor is off the finger (not receiving a valid pulse), and low battery.

Appendix B: Guidance and Manufacturer's Declaration

Guidance and Manufacturer's Declaration

The 3304 pulse oximeter is intended for use in the electromagnetic environment specified in the tables within this appendix.

NOTE! The customer or user of the 3304 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 3304 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 3304 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%.

IMMUNITY		ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Electrical fast transient/burst IEC 61000-4-4	**IEC 60601 TEST LEVEL** • ±0.5 kV to ±2 kV for power supply lines. • ±0.25kV to ±1kV for input/ output lines. **COMPLIANCE LEVEL** • ±0.5 kV to ±2 kV for power supply lines. • ±0.25kV to ±1kV 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	
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.	
Note: U_T is the A.C. mains voltage prior to application of the test level.		

IMMUNITY		ELECTROMAGNETIC ENVIRONMENT GUIDANCE
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:** $d = 1.2$
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 1.0 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 transmitters, 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 3304 pulse oximeter is used exceeds the applicable RF transmitter compliance level above, the 3304 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 3304 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 3304 pulse oximeter is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. The customer or the user of the 3304 pulse oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 3304 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 3304 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.

Appendix C: Revision History

REVISION	DATE	COMMENT
Rev. 12	2008-02	• Added new BCI and Smiths Medical logos to front cover. • Updated ON/OFF key for the domestic monitor keypad. • Added Australian Representative to Warranty and Service section and back cover. • Updated symbol chart. • Added WEEE Recycling instructions to symbol chart. • Updated warnings, cautions and notes. • Added warning about incorrectly applied sensors giving inaccurate readings. • Changed "co-oximeter" to "CO-oximeter" in desat study info in SpO_2 specs. • Fixed sentence on page B-3 about field strengths from fixed RF transmitters. • Deleted Smiths Medical logo from back cover.

REVISION	DATE	COMMENT
Rev. 11	2007-05	• 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. • Added note about alarm limits being retained during power cycles. • Added warning to be aware of alarm limits of similar monitors in the area. • Added desat study information to SpO2 specifications section in Chapter 13. • Added information about alarm volume to Alarm indicators in Chapter 13. • Added Appendix B: Guidance and Manufacturer's Declaration. • Moved Revision History from Appendix B to Appendix C.

REVISION	DATE	COMMENT
Rev. 10	2007-01	• Added warnings about AC power. • Added caution about cleaning agents causing brittleness. • Added warning about the monitor displaying dashes or erroneous values in certain conditions. • Changed numerous cautions and notes to warnings. • Added warning to check for correct AC voltage to Chapter 9. • Updated trademark information. • Updated Proprietary Notice in Warranty section. • Removed hyphen from Comfort Clip. • Updated e-mail address. • Updated Revision History.

REVISION	DATE	COMMENT
Rev. 9	2006-06-01	• Added this Revision History • Converted font to Myraid Pro • Updated format • Added registered trademark information to Table of Contents. • Added Patent information to Table of Contents • Added Rx Only symbol, WEEE symbol, and Do Not Reuse symbol to chart in Chapter 1. • Added photodynamic therapy warning and dropped or damaged warning. • Added accuracy verification caution, damage to front panel keys caution, and operator's responsibility to set alarm limits caution. • Added dysfunctional hemoglobins note. • Added IFU Note to Chapter 2. • Removed 1310 and 1311 everywhere in manual. • Updated parts list in Chapter 13. • Updated Line Art.

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