Oximeter

Operation and Service Manual

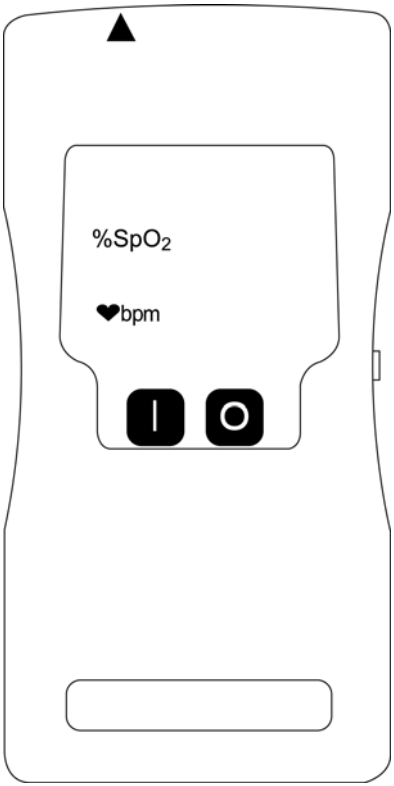

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Table of Contents

Chapter 1: Introduction 1-1

About This Manual 1-1
Proprietary Notice 1-1
Warranty 1-1
Limited Warranty 1-1
Disclaimer of Warranties 1-2
Conditions of Warranty 1-2
Limitation of Remedies 1-2
Warranty Procedure 1-3
CE Notice 1-3
Warnings, Cautions, and Notes 1-5

Chapter 2: General Description 2-1

Intended Use 2-1
Features 2-1
Description 2-2
Theory of Operation 2-4

Chapter 3: Using the Oximeter 3-1

Install the Batteries 3-1
Installing or Replacing the Batteries 3-2
Care and Handling of Sensor 3-3
Choose the Sensor 3-4
Attach the Sensor to the Patient 3-5
Clean or Disinfect the Sensors 3-5
Finger Sensor for Adult or Pediatric Finger 3-5
Attach the Sensor to the Oximeter 3-6
Measuring the Patient's % SpO2 and Pulse Rate 3-6
Patient Numbers and Spot Check Data 3-8
Manually Incrementing the Patient Number 3-8
Clearing All Spot Check Data 3-8
Low Battery Indicator 3-8
Turning Off the Oximeter 3-9
Checking the Oximeter's Performance 3-9

Chapter 4: Printer and Computer Interface 4-1

Computer Interface Description 4-1
Equipment Required 4-1
Interface Instructions 4-1
Spot Check Printouts 4-3
Collecting Spot Check Data 4-3
Manually Incrementing the Patient Number 4-3
Clearing All Spot Check Data 4-3
About the Oximeter's Batteries and Spot Check Data 4-3
Printing Spot Check Data 4-4

Chapter 5: Operator's Maintenance 5-1

Batteries 5-1
Disposal of batteries and rechargeable batteries 5-1
Sensors 5-1
Reusable Sensors 5-1
Disposable Sensors 5-2
Cleaning the Oximeter's Surfaces 5-2
Long Term Storage 5-2

Chapter 6: Operator's Troubleshooting Chart 6-1

EMI Interference 6-3

Chapter 7: Optional Supplies and Accessories 7-1

Ordering Information 7-2

Chapter 8: Specifications 8-1

Equipment Classification 8-1
Displays, Indicators, & Keys 8-1
SpO2 8-1
Pulse Rate 8-2
Auxiliary Printer Output 8-2
Power Requirements 8-2
Battery Life 8-2
Dimensions 8-2
Environmental Specifications 8-2

Chapter 9: Service Maintenance and Repair..... 9-1

General Description.....9-1
Power Supply and ON/OFF Circuitry 9-1
Digital Section 9-1
Analog Section.....9-3
LED Controller.....9-4
Signal Dictionary 9-4
Test Equipment and Tools Required 9-6
Connecting a DC Power Supply.....9-6
Voltage Test Points.....9-7
Waveform Test Points 9-9

Appendix: Assembly Drawings, Schematics & Parts Lists.....1

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Chapter 1: Introduction

About This Manual

The operator's instructions provide installation, operation, and maintenance instructions. It is intended for health-care professionals trained in monitoring respiratory and cardiovascular activity.

The service maintenance and repair section contains circuit descriptions, voltage and waveform test points, detailed parts lists, and circuit diagrams. It is intended for persons trained in service, maintenance, and repair of modern medical equipment. Thorough knowledge of this equipment's operation is required before attempting to repair this equipment.

Proprietary Notice

 Its purpose is to provide the user with adequately detailed documentation to efficiently install, operate, maintain and order spare parts for the device supplied. Every effort has been made to keep the information contained in this document current and accurate as of the date of publication or revision. However, no guarantee is given or implied that the document is error free or that it is accurate regarding any specification.

Warranty

Limited Warranty

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., N7 W22025 Johnson Drive, Waukesha, WI 53186-1856. Telephone: 1-800-558-2345. Facsimile: 262-542-3325. 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 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,
UK, WD24 4LG

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

Definition of Symbols

SYMBOL	DEFINITION
	Attention, consult accompanying documents.
	Type BF equipment
	Refer servicing to qualified service personnel.
REF	Catalog Number
SN	Serial number
	On
	Off
	Date of Manufacture
	Non AP Device
	Use by

Warnings, Cautions, and Notes

WARNING! Federal law (USA) restricts this device to sale by, or on the order of, a physician.

WARNING! This device is not intended for continuous patient monitoring. This device is intended to measure the patient's %SpO_2 and pulse rate values. There are no audible or visible alarms.

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! 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! 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 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.

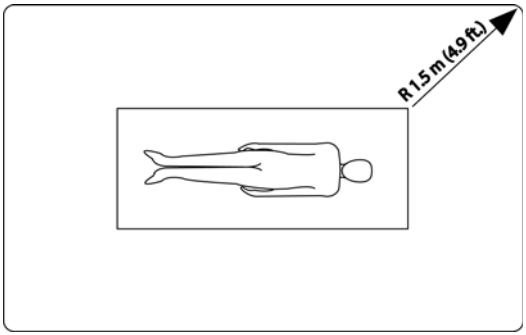

Figure 1-1: Patient Environment

WARNING! When attaching sensors with Microfoam®[1] 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).

CAUTION! Observe proper battery polarity (direction) when replacing batteries.

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

CAUTION! 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. (Notice: This device is not approved for home use by a non-health care professional.)

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

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

1. Microfoam is a registered trademark of the 3M Company.

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

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

NOTE! 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.

NOTE! 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.

NOTE! 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.

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

NOTE! The presence of dyshemoglobins, such as carboxyhemoglobin (with CO-poisoning) or methemoglobin (with sulfonamide therapy) may adversely affect the accuracy of the SpO_2 measurement.

NOTE! Hazards arising from software errors have been minimized. Hazard analysis was performed to meet EN1441: 1997.

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

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Chapter 2: General Description

Intended Use

The oximeter provides fast, reliable SpO_2 and pulse rate measurements. It can be used in the hospital or clinical environment, and during emergency air or land transport. The oximeter will operate accurately over an ambient temperature range of 32 to 131° F (0 to 55° C). The oximeter works with all BCI® oximetry sensors providing SpO_2 and pulse rate on all patients from neonate to adult.

Features

- Provides fast, reliable SpO_2 and pulse rate measurements on any patient, from neonates to adults.
- Ideally suited for use in intensive care units, in outpatient clinics, in emergency rooms, or during emergency air or land transport.
- Portable and lightweight. Weighs only 9 ounces (255 grams) without the batteries.
- Ergonomically designed to fit comfortably in the palm of your hand.
- Uses three standard alkaline batteries (type LR 14) or three rechargeable (type KR27/50) NiCad “C” cell batteries.
- Battery life is approximately twenty-four (24) hours in continuous mode or eighty (80) hours in spot check mode.
- Bright, easy-to-read LED displays indicate SpO_2 and pulse rate measurements.
- An eight-segment LED bar graph indicates pulse strength.
- Automatically turns off after patient’s finger is removed from the sensor.
- Low battery indicator lights when about two hours of battery use remains.
- Optionally connects to an external printer or computer, providing spot check printouts of SpO_2 and pulse rate readings.
- Collects up to seventeen (17) hours of spot check data for up to ninety-nine (99) patients for printout later.

Description

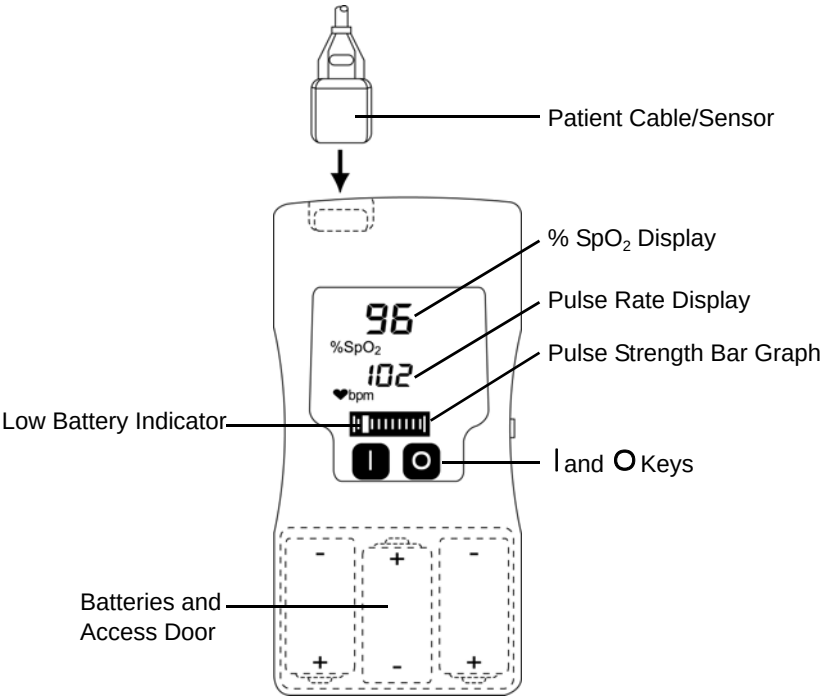

Figure 2-1: Oximeter Controls

PATIENT CABLE/SENSOR
The sensor connects here. If you need the extra length of the patient cable, attach the sensor to the patient cable, then attach the patient cable to the oximeter's PATIENT CABLE/SENSOR connector. The serial printer or PC communication cable is also connected here.

% SpO_2 DISPLAY
The % SpO_2 value is shown here. Dashes (--) indicate the oximeter is unable to calculate the SpO_2 value.

PULSE RATE DISPLAY
The pulse rate value is shown in beats per minute (BPM). Dashes (---) indicate the oximeter is unable to calculate the pulse rate value. Flashing 255 indicates the pulse rate value is greater than 255.

PULSE STRENGTH BARGRAPH

The eight-segment bar graph "sweeps" with the patient's pulse beat, indicating pulse strength. The bar graph is logarithmically scaled to indicate a wide range of pulse strengths.

| and O KEYS

Press "|" to turn on the oximeter. Press "O" to turn off the oximeter.

While the oximeter is on, momentarily pressing the "|" key increments the patient number. While the oximeter is on, pressing and holding the "|" key for about six seconds clears all the spot check data and resets the patient number to P 1.

The oximeter turns off automatically two minutes after the sensor is removed from the patient or after the sensor is disconnected from the oximeter. This feature extends the battery use time.

LOW BATTERY INDICATOR

When about two hours of battery use time remains, the left-most bar graph segment lights. The oximeter will continue to operate normally until the batteries no longer have sufficient power to operate the oximeter. At that point, the oximeter automatically turns off.

BATTERIES AND ACCESS DOOR

The oximeter's three "C" cell batteries are accessed through this door on the backside of the oximeter. See *Installing or Replacing the Batteries* for details on installing or replacing the batteries.

Theory of Operation

The oximeter determines SpO_2 and pulse rate by passing two wavelengths of light, one red and one infrared, through body tissue to a photodetector. 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.

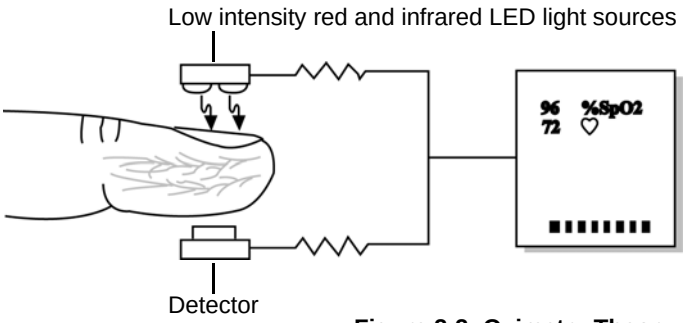

Figure 2-2: Oximetry Theory of Operation

The oximeter 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 pulse rate and calculate oxygen saturation. Oxygen saturation calculations can be performed because oxygen saturated blood predictably absorbs less red light than oxygen depleted blood.

Chapter 3: Using the Oximeter

Unpack the Oximeter

Carefully remove the oximeter and its accessories from the shipping carton. Save the packing materials in case the oximeter 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.

Install the Batteries

The oximeter uses three standard "C" cell batteries (type LR 14). You can use disposable alkaline batteries or rechargeable (type KR27/50) batteries.

If you use disposable batteries, be sure to dispose of them in compliance with your institution's guidelines and local ordinances.

If you use rechargeable batteries, it's best to have two sets of batteries on hand. That way, you can use one set of batteries in the oximeter while the other set of batteries is recharging.

> **NOTE! If you've collected spot check data for printing, make sure you print the spot check data before removing and replacing the oximeter's batteries. Removing the batteries erases spot check data from the oximeter's memory.**

Installing or Replacing the Batteries

1. Turn over the oximeter so its back is facing you.
2. Push on the thumb grip and slide the door open.
3. If you are replacing the batteries, remove the old batteries from the battery compartment.

   If the old batteries are disposable, be sure to dispose of them in compliance with your institution's guidelines and local ordinances.

   If the old batteries are rechargeable, be sure to charge them right away so they'll be ready to use again as soon as possible.

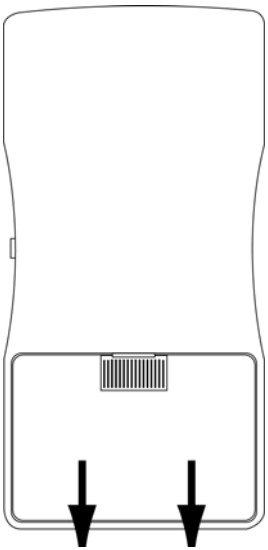

Figure 3-1: Open the Battery Door

4. Install three batteries in the oximeter battery compartment. Make sure the batteries are installed in the proper direction.

   NOTE! It is easiest to install the batteries in the sequence shown in figure 3-2.

5. Slide the battery door closed, pushing firmly until it snaps into place.

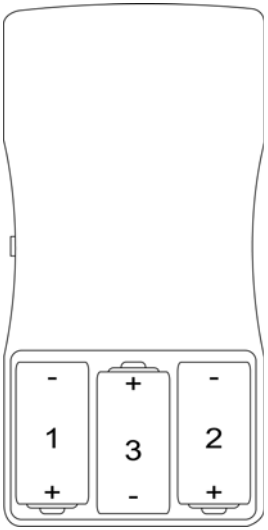

Figure 3-2: Install the Batteries

Care and Handling of Sensor

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

Hold the connector rather than the cable when connecting or disconnecting the finger sensor to the oximeter as shown in figure 3-3.

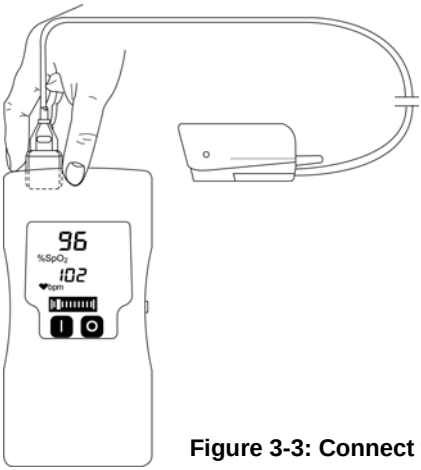

Figure 3-3: Connect the Finger Sensor

Do not use excessive force, unnecessary twisting, or kinking 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 3-4.

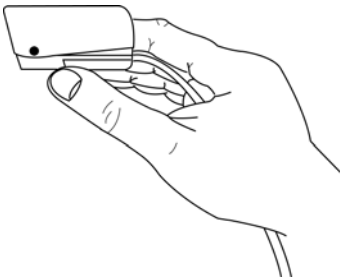

Figure 3-4: Position the Sensor Cable

Upon completion of patient monitoring, detach the sensor and loosely coil finger sensor cable. Do **not** wrap the finger sensor cable around the oximeter.

Choose the Sensor

Choose the appropriate sensor from the following chart. Refer to the sensor insert for application instructions.

Patient	Site	Description
Adult >45 Kg	Finger	3044: Sensor, Reusable, Adult 3444: Sensor, Reusable, Comfort Clip® 1310: D.O.T. Reusable Oximetry Sensors
	Finger or Toe	3043: Sensor, Universal "Y" 1300: Sensor, Disposable, Adult, Finger
	Ear	3078: Sensor, Ear
Pediatric 15-45 Kg	Finger	3044: Sensor, Reusable, Adult 3444: Sensor, Reusable, Comfort Clip® 3178: Sensor, Reusable, Pediatric
	Finger or Toe	3043: Sensor, Universal "Y" 1301: Sensor, Disposable, Pediatric, Finger
	Ear	3078: Sensor, Ear
Infant 3-15 Kg	Hand or Foot Toe Finger or Toe	3043: Sensor, Universal "Y" 3025: Sensor, Wrap, Infant 1303: Sensor, Disposable, Infant
Neonate <3 Kg	Hand or Foot Foot	1302: Sensor, Disposable, Neonate 3026: Sensor, Wrap, Neonate

Attach 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).**

Clean or Disinfect the Sensors

Clean or disinfect the reusable sensors before attaching 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.

Finger Sensor for Adult or Pediatric Finger

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.

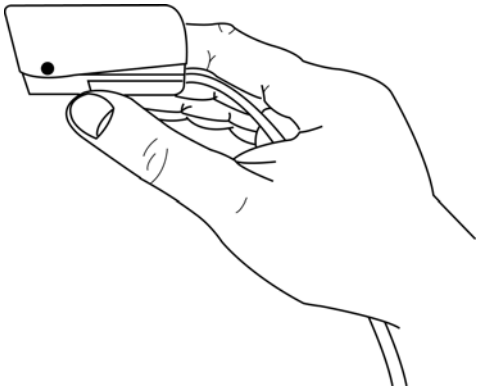

Figure 3-5: Attach the Finger Sensor

Attach the Sensor to the Oximeter

- Attach the sensor connector to the oximeter's PATIENT CABLE/ SENSOR connector.
- If you need the extra length of the patient cable, attach the sensor to the patient cable, then attach the patient cable to the oximeter's PATIENT CABLE/SENSOR connector.

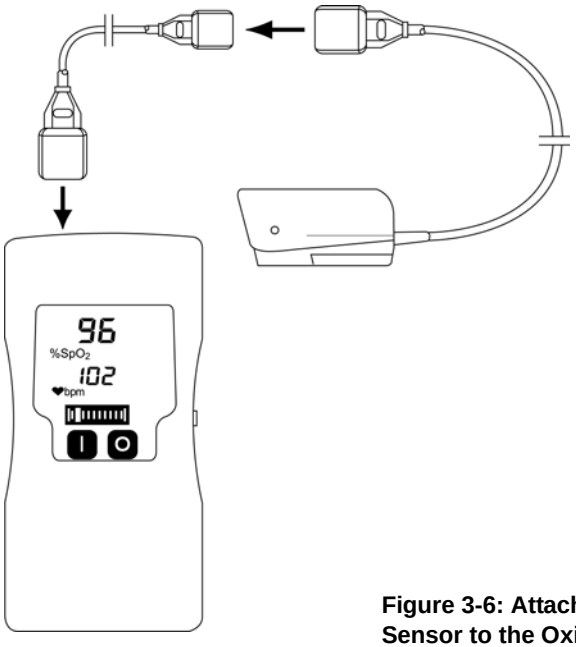

Figure 3-6: Attach the Sensor to the Oximeter

Measuring the Patient's % SpO_2 and Pulse Rate

To begin measuring the patient's SpO_2 and pulse rate, press the " ⏽" key. When turned on, the oximeter goes through this power-up sequence:

- The pulse strength bar graph segments light one at a time.
- The oximeter's software revision is momentarily displayed.
- The patient number for spot check printouts is momentarily displayed. The format for the patient number display is "P" followed by the number. For example, P 14 means the patient number is 14.

After a few seconds the % SpO_2 value, pulse rate, and pulse strength bar graph should be shown. If not, see *Operator's Troubleshooting Chart* for help.

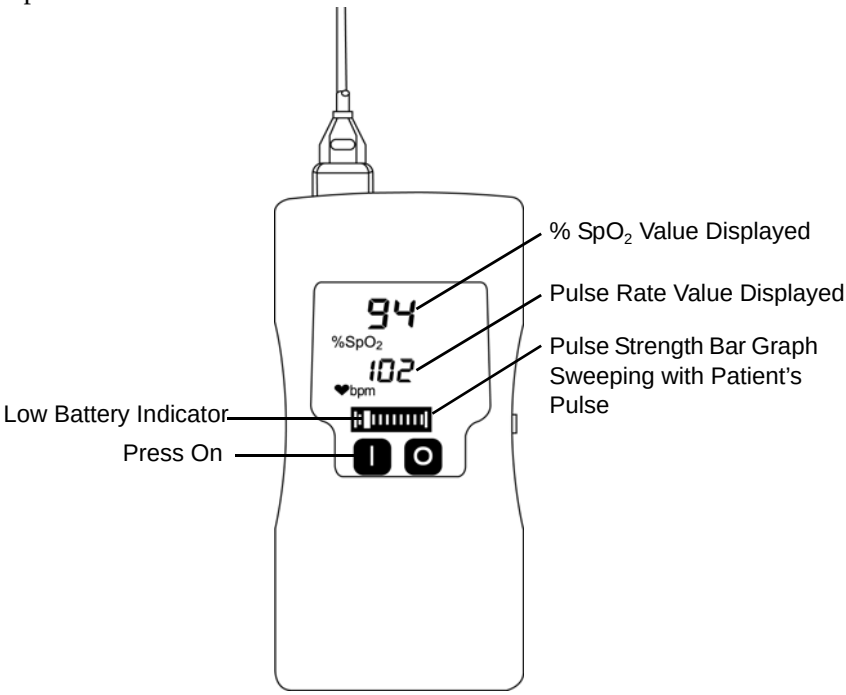

Figure 3-7: SpO_2 Pulse Rate and Pulse Strength Bar Graph

The SpO_2 display shows the patient's blood oxygen saturation, calculated as a percentage. The pulse rate display shows the patient's pulse rate in beats per minute (BPM). The pulse strength bar graph shows the patient's pulse strength; the bar graph is scaled logarithmically to indicate a wide range of pulse strengths.

Patient Numbers and Spot Check Data

Whenever the oximeter is on, it stores one SpO_2 and pulse rate reading every thirty (30) seconds. The stored readings are called *spot check* data. The oximeter remembers spot check data for up to ninety-nine (99) patients and seventeen (17) hours of run-time. The spot check data then can be printed at any time on the optional printer.

Spot check data is saved for each patient number. When you turn on the oximeter, the patient number is automatically incremented and displayed during the power-up sequence if valid spot check data was collected from the previous patient. When the patient number is incremented, then spot check data is saved for the new patient number. If no valid spot check data was collected from the previous patient, the patient number is displayed only and is not incremented. The oximeter remembers all the spot check data and all the patient numbers for up to ninety-nine (99) patients and seventeen (17) hours of run-time.

Manually Incrementing the Patient Number

Press the "↑" key while the oximeter is on to manually increment the patient number. The new patient number is momentarily displayed and spot check data for the new patient is automatically saved.

Clearing All Spot Check Data

Press and hold the "↑" key for about six seconds while the oximeter is on to clear all spot check data and reset the patient number to P 1. While you are holding the "↑" key, the message Clr flashes on the display to notify you that the spot check data for all patients is about to be cleared. When the spot check data is cleared, the display shows P 1.

See *Spot Check Printouts* for more information on printing spot check data.

Low Battery Indicator

When about two hours of battery use time remains, the left-most bar graph segment lights. The oximeter will continue to operate normally until the batteries no longer have sufficient power to operate the oximeter. At that point, the oximeter automatically turns off.

Turning Off the Oximeter

Press the **"O"** key to turn off the oximeter.

The oximeter turns off automatically two minutes after the sensor is removed from the patient or after the sensor is disconnected from the oximeter. This feature extends the battery use time.

> **NOTE! At power up, when the sensor is disconnected and patient data is stored, the oximeter will turn off automatically two minutes after the oximeter executes its print patient routine.**

Checking the Oximeter's Performance

Pulse oximeters do not require user calibration. To check the function of the device, an optional Oximeter/ECG Patient Simulator is available as an accessory (BCI® Cat# 1606HH). The simulator attaches to the oximeter in place of the sensor or patient cable. It provides a known SpO_2 and pulse rate signal to the oximeter, allowing the oximeter's performance to be checked.

Follow the instructions included with the Oximeter/ECG Patient Simulator.

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Chapter 4: Printer and Computer Interface

Computer Interface Description

The oximeter can transfer stored data to a PC. Information Data Log and Spot Checks will be displayed/saved to a file in the format as shown in the *Spot Check Printouts* section of this manual.

Equipment Required

1. Hand Held Oximeter
2. 3350 Printer Cable
3. 3339 PC Adapter Cable
4. Communication settings:

Baud rate	9600
Data bits	8
Stop bits	1
Parity	none
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

Interface Instructions

1. Disconnect the sensor from the oximeter.
2. Connect the printer adapter cable (part #3350) to the sensor connector on the unit.
3. Connect 9-pin connector of PC adapter cable (part #3350) to the printer adapter cable (part #3339). Be sure to connect the 3339 to the end of the 3350 cable marked as “printer.”

4. Using the PC adapter cable (part #3339), connect the 9-pin connector of the PC adapter cable to the COM port on the PC as shown in figure 4-1.

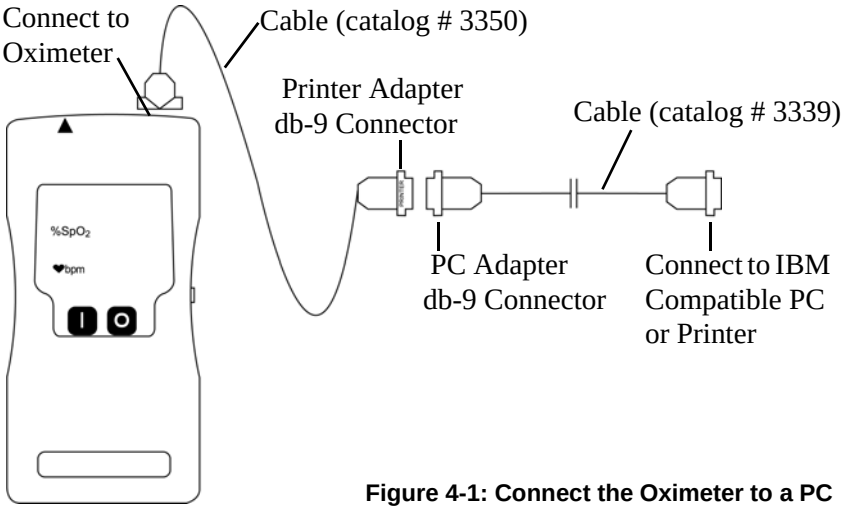

Figure 4-1: Connect the Oximeter to a PC

⚠ **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.**

Spot Check Printouts

Collecting Spot Check Data

Whenever the oximeter is on, it stores one SpO_2 and pulse rate reading every thirty (30) seconds. The stored readings are called *spot check* data. The oximeter remembers spot check data for up to ninety-nine (99) patients and seventeen (17) hours of run-time. The spot check data then can be printed at any time on the optional printer.

Spot check data is saved for each patient number. When you turn on the oximeter, the patient number is automatically incremented and displayed during the power-up sequence if valid spot check data was collected from the previous patient. When the patient number is incremented, then spot check data is saved for the new patient number. If no valid spot check data was collected from the previous patient, the patient number is displayed only and is not incremented. The oximeter remembers all the spot check data and all the patient numbers for up to ninety-nine (99) patients and seventeen (17) hours of run-time.

Manually Incrementing the Patient Number

Press the "↑" key while the oximeter is on to manually increment the patient number. The new patient number is momentarily displayed and spot check data for the new patient is automatically saved.

Clearing All Spot Check Data

Press and hold the "↑" key for about six seconds while the oximeter is on to clear all spot check data and reset the patient number to P 1. While you are holding the "↑" key, the message Clr flashes on the display to notify you that the spot check data for all patients is about to be cleared. When the spot check data is cleared, the display shows P 1.

About the Oximeter's Batteries and Spot Check Data

NOTE! If you've collected spot check data for printing, make sure you print the spot check data before removing and replacing the oximeter's batteries. Removing the batteries erases spot check data from the oximeter's memory.

Printing Spot Check Data

1. Set up the oximeter and the printer as previously described.
2. Disconnect the SpO_2 sensor from the oximeter.
3. Turn on the printer.
4. Turn on the oximeter. The oximeter prints the spot check data for each patient, from patients 1-99, as shown in the sample printout.
5. If there is no spot check data at all, the message **** is printed.
6. The oximeter does not automatically turn itself off when printing spot check data.
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).

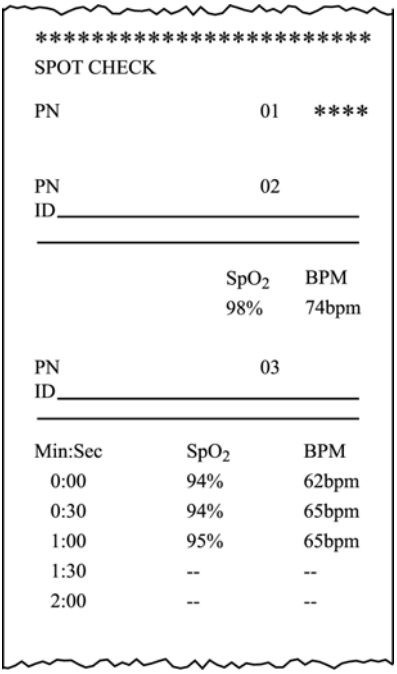

Figure 4-2: Print Spot Check Data

Chapter 5: Operator's Maintenance

Batteries

When about two hours of battery use time remains, the left-most bar graph segment lights. The oximeter will continue to operate normally until the batteries no longer have sufficient power to operate the oximeter. At that point, the oximeter automatically turns off.

Replace weak or dead batteries with new disposable batteries or freshly charged NiCad batteries. See *Installing or Replacing the Batteries* for instructions.

Disposal of batteries and rechargeable batteries

Batteries and rechargeable batteries

- do not throw into fire - risk of explosion.
- do not force open - danger of corrosion.
- do not recharge normal batteries.
- Batteries and rechargeable batteries must be treated as special waste.
- dispose of in accordance with local waste disposal regulations.

For information contact the local environmental protection offices or licensed waste disposal contractors.

Sensors

⚠ **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.**

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

Reusable Sensors

Clean the reusable sensor's surfaces with a soft cloth moistened in a mild soap solution. If disinfection is required, wipe the reusable sensor's surfaces with a soft cloth moistened in isopropyl alcohol. Do not allow liquid to enter any of the sensor's openings.

Disposable Sensors

Disposable sensors are for single-patient use only. Disposable sensors can be repositioned on the same patient as long as the correct SpO_2 and pulse rate values are shown after repositioning. Disposable sensors cannot be cleaned or repaired; discard them if they become soiled or no longer work.

Cleaning the Oximeter's Surfaces

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

Clean the oximeter's surfaces with a soft cloth moistened in a mild soap solution. If disinfection is required, wipe the oximeter's surfaces with a soft cloth moistened in isopropyl alcohol. Do not allow any liquid to enter any of the oximeter's openings.

Long Term Storage

Remove the batteries from the oximeter before long term storage, or if the oximeter won't be used for 6 months or more. This protects the oximeter from damage due to batteries leaking acid.

Store the oximeter in its original shipping carton and packing materials to help protect the oximeter from damage during storage.

Chapter 6: Operator's Troubleshooting Chart

Problem	Possible Cause	Corrective Action
No pulse shown on the bar graph.	Patient cable or sensor is disconnected from the oximeter. Sensor is incorrectly positioned on the patient. Poor patient perfusion. Defective sensor or patient cable.	Check sensor connections to the patient cable and to the oximeter. Reposition the sensor. Reposition the sensor. Try a new sensor or contact your authorized repair center for help.
Pulse rate is erratic, intermittent, or incorrect.	Sensor incorrectly positioned. Patient motion	Reposition the sensor.
SpO_2 value is erratic, intermittent, or incorrect.	Poor patient perfusion. Patient motion.	Reposition the sensor Patient must remain still to obtain an accurate measurement.
The oximeter doesn't turn on.	Batteries weak. Batteries not installed or batteries incorrectly installed.	Replace the batteries. Ensure the batteries are installed correctly.

The oximeter turns off unexpectedly.	The oximeter turns itself off automatically two minutes after the sensor is removed from the patient or after the sensor is disconnected from the oximeter. This feature extends the battery use time.	None.
	Batteries are weak or dead.	Replace the batteries.
No printout on optional printer.	Printer power not connected or printer power switch is Off.	Connect the printers power source and turn on the printer.
	Printer interface assembly not securely connected.	Push on both ends of the printer interface assembly to ensure all the connections are tight.
	Printer interface malfunction.	Contact your authorized repair center for help.
	No trends in memory.	Collect trend data.
	Sensor must be disconnected for spot check output.	Disconnect sensor.
E00	ROM Error	⚠ Refer servicing to qualified service personnel. Contact Smiths Medical PM, Inc. Service
E01	RAM Error	⚠ Refer servicing to qualified service personnel. Contact Smiths Medical PM, Inc. Service

EMI Interference

⚠ **CAUTION! This device has been tested and found to comply with the limits for medical devices to the IEC 601-1-2:1993, EN 60601-1-2:1994, 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 seem to 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 Smiths Medical PM, Inc. Service Department or you local representative.

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Chapter 7: Optional Supplies and Accessories

Cat. No	Description	Quantity
1300	Sensor, Oximetry, Disposable, Adult Finger	10/box
1301	Sensor, Oximetry, Disposable, Pediatric, Finger, 15-45 Kg	10/box
1302	Sensor, Oximetry, Disposable, Neonate, < 3 Kg	10/box
1303	Sensor, Oximetry, Disposable, Infant, 3-15 Kg	10/box
1310	D.O.T. Reusable Oximetry Sensors	3/box
1311	D.O.T. Sensor Replacement Tape	24/pkg
1606HH	Simulator & Cable, Oximeter, 5 ft.	each
1818R	Manual, Operation (English and Spanish) and Service (English)	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, Oximetry, Pediatric Finger	each
3311	Cable, Patient, 5 ft.	each
3315	Case, Carrying	each
3318	Protective Boot with Strap	each
3339	PC Adapter Cable	each
3444	Sensor, Oximetry, Finger, Comfort Clip®	each
3350	Cable, printer interface	each

Ordering Information

For ordering information, contact your local distributor or the Smiths Medical PM, Inc. customer service department.

Smiths Medical PM, Inc.
N7 W22025 Johnson Drive
Waukesha, WI 53186 USA

Phone: 262 542 3100
Fax: 262 542 3325

Email Address: info@smiths-bci.com

Chapter 8: Specifications

Equipment Classification

Type of Protection Against Electric shock:	Internally Powered
Mode of operation:	Continuous
Degree of Protection Against ingress of Liquids:	IPX1, drip proof
Degree of Mobility:	Portable
Degree of Protection Against Electric Shock:	Type BF
Safety Requirements:	EN60601-1; 1990

Displays, Indicators, & Keys

SpO_2:	LED numeric display, 0.46 inches (11.68 mm) high
Pulse Rate:	LED numeric display, 0.38 inches (9.65 mm) high
Pulse Strength:	Logarithmically scaled 8-segment LED bar graph
Keys:	I & O keys

SpO_2

Range:	0-99%
Accuracy:	±2% at 70-99%
Averaging:	8 pulse beat average
Display Response	The display is to functional saturation. The pulse strength bar graph is not proportional to pulse volume.
Display Update Rate	1 Hz (SpO_2); 60 Hz (pulse strength)
Calibration	Factory calibrated over range 70% to 100% SpO_2 using human blood samples to functional saturation. Test methods available upon request. No in-service calibration required.
Sensors	Red 660nm, 2mW (typical) Infrared 905nm, 2-2.4mW (typical)

Pulse Rate

Range:	30-254 BPM
Accuracy:	±2% at 30-254 BPM
Averaging:	8 second average
Display Update Rate	1 Hz

Auxiliary Printer Output

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

Power Requirements

Uses three standard alkaline (type LR 14) or nickel-cadmium “C” cell batteries (type KR27/50).

Battery Life

Approximately 24 hours in continuous mode or 80 hours in spot check mode.

Dimensions

Width:	3.25 inches (82.6 mm)
Height:	6.3 inches (160 mm)
Depth:	1.25 inches (31.75 mm)
Weight:	9 ounces (255 grams) without the batteries

Environmental Specifications

Operating Temp.:	0-55° C (32-131° F)
Storage Temp.:	-34-70° C (-29-158° F)
Relative Humidity:	10-95% (storage), non-condensing 15-95% (operating), non-condensing

Chapter 9: Service Maintenance and Repair

The service maintenance and repair section contains circuit descriptions, voltage test points, and waveform test points. The Appendix contains detailed parts lists and circuit diagrams. It is intended for persons trained in service, maintenance, and repair of modern medical equipment. Thorough knowledge of this equipment's operation is required before attempting to repair this equipment.

General Description

The oximeter contains one circuit board. This board contains all power supply, microprocessor, date acquisition, and display circuitry.

Power Supply and ON/OFF Circuitry

The power supply is built around a switch mode regulator IC U10. It is configured as a fly-back regulator to convert input voltage in the range of 2.7-4.5 VDC into +5VDC output voltage. Negative voltage used by the analog section is generated as a "by-product" of the main +5VDC supply. Charge pump C55-D4-C69 is used to convert pulsatile voltage on the output LX of U10 into negative voltage in the range of –4VDC to –6VDC. The V-RAM voltage used by the on-off circuitry and RAM is generated either from the battery, or from VCC when unit is on. V-RAM is taken straight from the battery due to the maximum voltage being 4.5V. V-RAM may approach +3VDC as the battery power gets depleted, however, this voltage is high enough to retain trend data in RAM. Capacitor C70 is used to maintain V-RAM when batteries are being replaced. It can keep information in RAM for more than 1.5 minutes.

On/Off circuitry is built around U7A-U7B flip-flop, which directly controls regulator IC U10.

Digital Section

Microprocessor U11 is Hitachi HD64180. Its address and data buses are connected to the One Time Programmable Read Only Memory (OTP ROM) U12 and Random Access Memory (RAM) U24. Memory Address Decoder is implemented using U17A demultiplexer chip.

Memory address map is shown in the following table:

Device	Address Space
OTP ROM	0..FFFF
RAM	10000..1FFFF
Display Select Signal	20000..2FFFF

Display Select Signal DSP-LD is used to latch displayed data into U22 and U23 LED drivers.

Address decoder for Input/Output Interface devices is implemented using U17B demultiplexer chip.

The I/O address space is divided according to the following table:

I/O Address Space	Device
0..3F	Used by Z180 for internal registers
40..7F	Input port
80..BF	Output port

Watch dog timer U18 is used to reset microprocessor in case of ESD and at power up. Its internal comparator is used to compare battery voltage offset by Vr voltage coming from digitally controlled potentiometer with internal U18 voltage reference. The output of the comparator (signal BATT) is used to detect battery voltage. The following battery states are distinguished by this measurement system:

Battery Voltage	Condition
2.7V	Dead battery level-units shuts itself off
3.0V	Low battery level-signal to user
4.5V	Ok battery level

RS-232 communication interface is built around Q3, Q5, and Q6. It converts CMOS voltage levels into RS-232 bipolar voltage levels. Inverter U16C is used to disable communication interface circuitry when oximetry probe is plugged in to reduce power consumption and eliminate cross-talk between communication and probe reading.

Internal timer 1 of U11 is used as a tone generator to drive piezo speaker through connector J5.

Analog Section

Analog to Digital Converter (ADC) U6 is a 12 bit, successive approximation sampling ADC. The ADC+IN signal input comes from TP22. VREF is used here as a pseudo ground. The ADC is configured as a differential input converter with the –IN input connected to VREF. This allows the +IN signal to range from 2.5V to 5V. The ADC transfers data with a 3 wire serial interface. ADCLK synchronizes the data transfer with each bit being transmitted on the falling ADCCLK edge and captured on the rising ADCLK edge. /ADCS must beheld low when the ADC transmits data.

LED Drive circuitry is used to turn on and off the oximetry probe LED's, precisely controlling the current through them. The second half of the variable potentiometer U5 is used to generate voltage between 0 and 2.5VDC. U5 is controlled, serially, by the processor. Operational amplifier U2B together with transistor Q7 create a constant current sink. The current is proportional to the voltage generated by variable potentiometer. The H-bridge Q8-Q9 is used to activate either LED, red or infrared, inside the oximeter probe. The following table describes the states of the H-bridge:

RED-DRV	IR-DRV	FET-ON	Function
1	0	1	Red LED is on
0	1	1	Infrared LED is on
X	X	0	"Open circuit" state

In this table, 1 indicates logic 1, 0 indicates logic 0, and x indicates either logic 0 or 1.

The "Open circuit" state is used to check for a possible probe cable fault. In case of probe cable fault, one of the LED wires can short to the ground shield causing high current through the probe LED. To prevent this, before turning any LED on, the processor checks the cable by "floating" the H-bridge. If the cable is shorted CON3 and CON2 connections are pulled low, and comparator U9A generates /PRB_FAULT signal, which causes the processor to shut down the LED excitation cycle and generate the appropriate message.

The differential photo amplifier formed by U1 and U3A, converts the photodetector's current output to a voltage at T10 (VAMB). Amplifier U3B offsets the signal at T10 allowing a wider signal range. Comparator U9B is used to inform the microprocessor if U3A is saturated by an excess of ambient light. VAMB is passed through blocking capacitor C77 to remove the signal's DC component. The signal is then buffered and amplified by U27A. Gain is defined by the first channel of digital potentiometer U5. The output of U27A is routed to the integrator-filter-offset circuitry U27B, controlled by analog switch S53. The output of the integrator is then routed to the ADC for measurement.

LED Controller

LED controller is built around U22 and U23 buffers. Data is latched into buffers by DSP-LD signal. Signal/DSP-EN is used to disable LED's at power up to limit initial surge current.

Signal Dictionary

This section lists, in alphabetical order, the signal names used on the schematics. The signal's origin, destination, and purpose are described.

Signal	Description
ADCLK ADOUT /ADCS	3 wire serial interface for analog to digital converter U6.
/AMB-FAULT	Signal informing processor about excess of ambient light.
ANA+5	Filtered VCC. ANA+5 powers the analog circuitry.
ANA-5	ANA-5 powers the analog circuitry.
BASE	Keeps integrator U27B fro saturating during data acquisitions.
BATT	Signal from watchdog timer U18 to inform processor of low battery condition.
CAP-GND	Signal used to short blocking capacitor C77 to ground.
CTS0	Serial Port Clear To Send handshake signal from external RS-232 communication device.

CON2, CON3	Probe LED's driving signals.
/DSP-EN	Enable display drivers signal.
DSP-LD	Signal used to load data into display drivers.
FET-ON	Used to control MOSFET H-bridge Q8 and Q9, which powers probe LED's.
INTGAT	Signals used to enable integrator U27B.
IR-DRV	Used to control MOSFET H-bridge Q8 and Q9, which powers probe LED's.
/NMI	Non-Maskable Interrupt that signals watch dog timer time-out.
PON	Power on signal.
CLK	Clocks data into digital potentiometer chip U5.
POT-LD	POT-LD is used to select digital potentiometer chip U5.
SDI	Serial Data Input to digital potentiometer chip U5.
PRB-DET	PRB-DET is used to inform processor if probe is plugged in.
/PRB-FAULT	Signal used to inform processor about probe cable problem.
QUIET	Signal used to shut down power down supply during data acquisition.
RX	External RS-232 receive (CTS0) line.
RED-DRV	Used to control MOSFET H-bridge Q8 and Q9, which powers probe LED's.
RESET	System reset signal generated by the watch dog timer U18.
RST-INT	Resets integrator U27B by shorting capacitor C50.
SHT-DWN	Output of the microprocessor to turn unit off.
TX	External RS-232 transmit line.
/TEN	Signal which enables RS-232 driver. Is connected to PRB-DET signal.

TXA0	Asynchronous serial communication transmit signal to RS-232.
VAMB	VAMB is the output of the front-nd differential amplifier.
V-BT	Battery voltage
VR	Output voltage from the digitally controlled potentiometer.
VREF	2.5VDC reference to voltage.
V-RAM	Voltage used to maintain trend information in RAM.
VCC, VDD	5VDC used for digital output supply voltage.
/WDT	Watch dog timer strobe

Test Equipment and Tools Required

To diagnose and repair the full extent of possible malfunctions on the oximeter and display board, you will need the following test equipment and tools:

- DMM volts/ohms/amps, with MΩ input impedance or greater.
- Oscilloscope, 50 MHz, with 10 MΩ input impedance or greater.
- Variable output DC power supply, 0-5 VDC at 200 mA or greater.
- Small Phillips screwdriver
- Small flat blade screwdriver
- Needle nose pliers
- Diagonal cutters
- Clip leads
- Low-power microscope or magnifying glass
- Soldering iron and solder
- Solder wick or solder remover

Connecting a DC Power Supply

To verify some of the voltage measurements that follow, you'll need to connect a variable output DC power supply in place of the three "C" cell batteries. You must be careful to observe the polarity of J9 when doing this. Follow these steps to connect a DC power supply in place of the "C" cell batteries:

CAUTION! Be sure to observe the polarity of the battery connections. Failure to observe the polarity may cause fuse F1 to blow.

1. Remove the three “C” cell batteries.
2. Connect the DC power supply’s “+” output to J9-1.
3. Connect the DC power supply’s “-” or “ground” output to J9-2.

Voltage Test Points

Unless otherwise noted, all voltages are measured with respect to ground at P1-2.

Location	Condition	Nominal and Range
T19	Oximeter on.	5 VDC, ± 0.1 VDC
ANA+5 (T18)	Same as T19.	Same as T19.
FLTR+5	Same as TP14.	Same as T19.
ANA-5	Same as TP15.	Same as TP15.
FLTR-5 (T16)	Same as TP15.	-4.8 VDC to –6.2 VDC
V-REF (T17)	Oximeter on.	2.5 VDC
V-RAM	Oximeter on. Oximeter off.	T19 minus 0.7 VDC. V_BT minus 0.7 VDC.
U11-71	Oximeter on.	3.072 MHz, 50% duty cycle.
Low battery LED.	When battery voltage drops to 3.00 VDC.	Low battery LED first turns on at 3.00 VDC, ±0.2 VDC.
Low battery shut off.	Oximeter on, battery voltage slowly dropping.	Oximeter shuts off when battery voltage drops to 2.7 VDC, ± 0.2 VDC.

Automatic shut off.	Turn on oximeter and place finger in sensor. Remove finger from sensor. Remove sensor from oximeter. Turn on oximeter.	Oximeter should turn off 2 minutes (± 5 seconds) after finger is removed from sensor. Oximeter should turn off in 2 minutes (± 5 seconds).
Current draw through J9-1 (total battery current).	Oximeter on, sensor attached to oximeter, no finger in the sensor, with battery voltage at 3.5 VDC, ±0.2 VDC.	110 mA, ± 15 mA

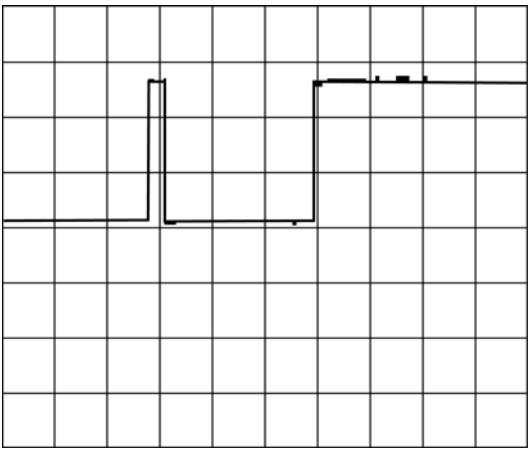
Waveform Test Points

The following oscilloscope screens show typical waveforms from the sensor detector's amplifier and data acquisition circuits. Unless otherwise noted:

- The waveforms are measured with respect to ground at J9-2.
- The oscilloscope is triggered on T2, falling edge.
- The waveforms are measured with the finger sensor attached to the oximeter, but no finger inserted in the sensor.

Measurement at T2

2V/DIV
0.4mS/Div

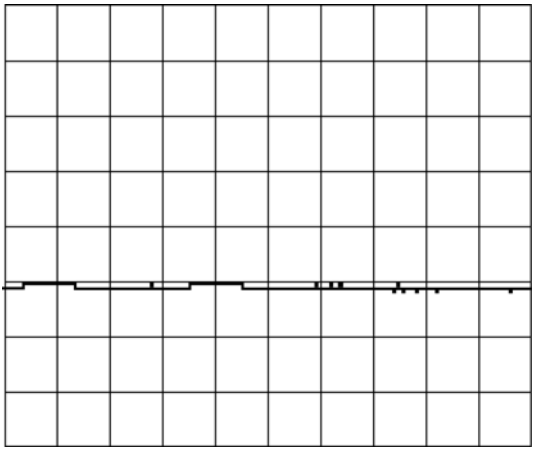


0V

Connect CH1 probe to T10, T21, T22, T24. Verify the signal shown in the respective figures.

Measurement at T22

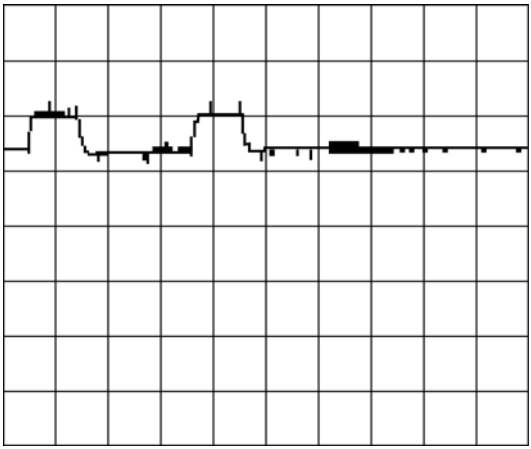
2V/DIV
0.4mS/Div



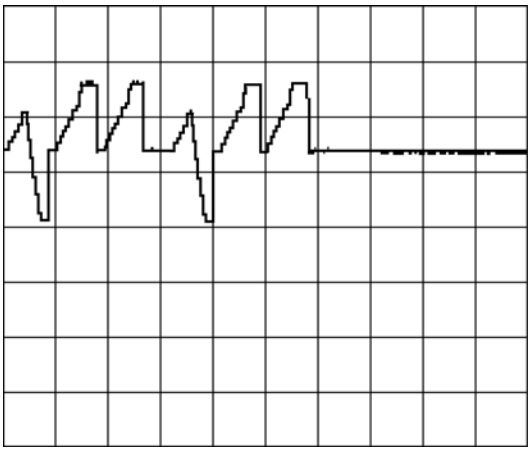
0V

Measurement at T24

2V/DIV
0.4mS/Div



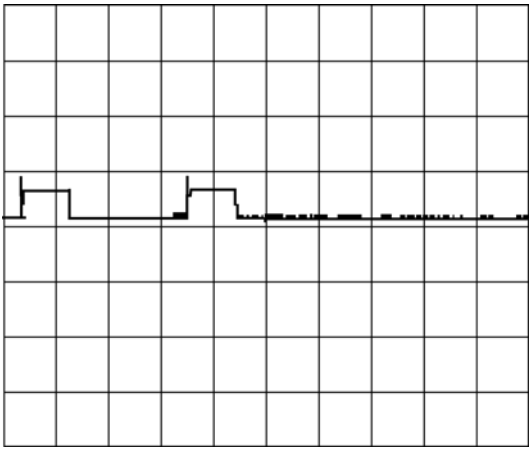
0V



0V

Measurement at T24

2V/DIV
0.4mS/Div



0V

Remove all scope connections from the oximeter board.

Functional Testing

Disconnect the oximetry test fixture. Turn oximeter board off and then on again. Connect Finger probe to oximeter board and put your finger in the probe. Verify SpO_2 and Pulse Rate readings are displayed.

Verify that the pulse tone is heard when the pulse strength bar lights up.

Remove finger from finger probe. Verify “dashes.”

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Appendix

Assembly Drawings, Schematics & Parts Lists

Number	Description	Item	Number of pages
71000A23	F/ASM OXIMETER REDESIGN BOM	A-1	1
71000A23	F/ASM OXIMETER REDESIGN	A-2	1
71264B1	PWB ASM MAIN BOARD REDESIGN	A-3	1
71264B1	PWB ASM MAIN BOARD REDESIGN PARTS LIST	A-4	3
71264S1	MAIN BOARD REDESIGN SCHEMATIC	A-5	5

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smiths

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Patient Monitoring and Ventilation

CE 0473

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