## Pulse Oximeter for Sleep Screening

**Operation Manual** 



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## **Clinician's Operation Manual**

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### Warranty & Service Information

### **Proprietary Notice**

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### **Limited Warranty**

BCI, Inc. warrants each new device to be free from defects in workmanship and materials under normal use and service for a period of two (2) years from the date of shipment. The sole obligation of BCI, Inc. under this warranty will be to repair or replace, at its option, products that prove to be defective during the warranty period. The foregoing shall be the sole warranty remedy. Except as set forth herein, seller makes no warranties, either expressed or implied, including the implied warranties of merchantability and fitness for a particular purpose. No warranty is provided if the products are modified without the express written consent of BCI, Inc., and seller shall not be liable in any event for incidental or consequential damage. This warranty is not assignable.

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Repairs for devices manufactured by BCI, Inc. under warranty must be made at authorized repair centers. If the device needs repair, contact your local distributor or the BCI, Inc. service department. When calling, have the device's model and serial number ready.

If you need to ship the device, pack the device and accessories carefully to prevent shipping damage. All accessories should accompany the device.

BCI, Inc.	Phone: (262) 542-3100	
N7 W22025 Johnson Road	Fax: (262) 542-3325	
Waukesha, WI USA 53186-1856	Toll Free; (800) 558-2345	
email: info@smiths-bci.com		

## **CE Notice**

Marking by the symbol  $C \in C_{0473}$  indicates compliance of this device to the Medical Device Directive 93/42/EEC.

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

Graseby Medical Ltd. Colonial Way, Watford, Herts, UK WD2 4LG Phone: (44) 1923 246434 Fax: (44) 1923 240273

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

## Warnings, Cautions, & Notes

## **Symbol Definitions**

SYMBOL	DEFINITION
Ŕ	Type BF equipment
$\triangle$	Attention, consult accompanying documents
4	Refer servicing to qualified service personnel
SN	Serial Number
REF	Catalog Number
	Printer On/Off
$\sim\sim$	Date of Manufacturing
8	Do not reuse
%	On/Off
8	Non AP device
LOT	Lot Number
23	Use By
IPX1	Drip Proof

### Warnings

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

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! 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! Prolonged use or the patient's condition may require changing the sensor site periodically. Patients setting up the device at home should be instructed of the signs/symptoms of sensor misuse (e.g., pressure sores from prolonged application) and should be advised to move the sensor to another finger if necessary.

WARNING! When attaching sensors with Microfoam®<sup>1</sup> tape, do not stretch the tape or attach the tape too tightly. Any device (tape, Velcro<sup>™</sup>) applied too tightly may cause inaccurate readings and blisters on the patient's skin (lack of skin respiration, not heat, causes the blisters).

<sup>&</sup>lt;sup>1</sup> Microfoam® is a registered trademark of the 3M Company

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 the signal output port configures a medical system, and, therefore, is responsible that the system complies with the requirements of the system standard IEC 601-1-1.

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.

#### PATIENT ENVIRONMENT



### Cautions

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 or those who have access to the oversight of a professional health care provider. The operator must be thoroughly familiar with the information in this manual and/or the "Home User's Guide" before using the device.

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

CAUTION! When printing, or advancing the paper, place the oximeter on its' side to prevent paper jams.

### Notes

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

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

NOTE! Use only SpO<sub>2</sub> sensors supplied with, or specifically intended for use with, this device.

NOTE! SpO<sub>2</sub> measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a 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<sub>2</sub> 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<sub>2</sub> readings.

NOTE! Remove fingernail polish or false fingernails before applying SpO<sub>2</sub> sensors. Fingernail polish or false fingernails may cause inaccurate SpO<sub>2</sub> readings.

NOTE! Batteries are designed to be replaceable by individuals trained in this procedure. Follow local governing ordinances and recycling instructions regarding disposal or recycling of device components, including batteries.

NOTE! SpO<sub>2</sub> averaging is the number of pulse beats over which the SpO<sub>2</sub> value is averaged; pulse averaging is the number of seconds over which the pulse value is averaged.

NOTE! Hazards arising from software errors have been minimized. Hazard analysis was performed to meet EN60601-1-4:2000.

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 an opaque material.

NOTE! All user and patient accessible materials are non-toxic.

## **Chapter 1: Introduction**

### About the Manual

The Operation Manual provides installation, operation, and maintenance instructions for health-care professionals and other users, trained in monitoring respiratory and cardiovascular activity.

### **Theory of Operation**

The oximeter determines  $\text{SpO}_2$  and pulse rate by passing two wavelengths of low intensity 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.





1. Red and infrared LED light sources

2. Detector

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<sub>2</sub>) 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.

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 pulse and  $SpO_2$  readings.

## **Chapter 2: Intended Use and Monitor Features**

### **Intended Use**

This device is a handheld pulse oximeter that measures  $SpO_2$ , pulse rate, and pulse strength. It may be used as a spot check device in the hospital or clinical environments. Additionally, it may be used to collect long term data in overnight sleep screening studies in the sleep lab or home. The oximeter will provide reliable measurements on patients ranging from neonate to adults for spot checking applications and from pediatric to adult for sleep screening applications when using the appropriate catalog accessories. The oximeter will operate accurately over an ambient temperature range of 32 to 131°F (0 to 55°C).

This device is not intended for continuous patient monitoring, but can be used for spot checking and/or long-term data collection applications. There are no audible or visible patient alarms.

### **Monitor Features**

- Provides fast, reliable SpO<sub>2</sub>, pulse rate, and pulse strength measurements on any patient, from neonates to adults for spot-checking applications and on pediatric to adults for sleep screening applications.
- Ideally suited for use in overnight sleep screening applications allowing printing of summated data results.
- Three modes of operation: Verification Mode for spot checking, Data Collection Mode for long term data collection in sleep screening environments and Trend Printing Mode for outputting summarized trend data to the built-in printer or to a PC.
- Device automatically enters Data Collection Mode after 10 minutes of continuous use.
- Minimal LED display during Data Collection Mode lengthens battery life (I.e. display is reduced to a single flashing bar).
- Portable and lightweight. Weighs only 13 ounces (369 grams)., with batteries.
- Ergonomically designed to fit comfortably in the palm of your hand.
- Uses four (4) standard "AA" (type IEC LR6) alkaline cells.
- Battery life (Alkaline Cells):
  - 2 sleep screening cycles (1 cycle = 10 minutes with display on, 8 hours with display off, 5 minutes printing)

or

- Intermittent monitoring: 1 min on, 2 min off (= 1 cycle) 80 hours or 1600 cycles
- Bright, easy-to-read LED displays indicate SpO<sub>2</sub> and pulse rate measurements.
- An eight-segment LED bar graph indicates pulse strength in the Verification Mode.
- Low Battery Indicator flashes when about 30 minutes of battery use remains.
- Capable of 12 hours of data storage.

### **Monitor Front Panel**





### 1. Sensor/Serial Connector

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

### 2. SpO<sub>2</sub> Numeric Display

A number shows the patient's  $\text{SpO}_2$  value in percent. Dashes (--) mean the monitor is not able to calculate the  $\text{SpO}_2$  value in Verification Mode.  $\text{SpO}_2$  display in Data Collection Mode will be one flashing bar to conserve battery life.

### 3. Pulse Rate Numeric Display

A number shows the patient's pulse rate value in beats per minute. Dashes (---) mean the monitor is not able to calculate the pulse rate value in Verification Mode. In Data Collection Mode, the Heart Rate display will be blank to conserve battery life.

### 4. Pulse Strength Bar Graph

In Verification Mode, the pulse strength bar graph "pulses" with the patient's pulse beat. The height of the bar graph shows the patient's pulse strength.

### 5. Low Battery Indicator

A Low Battery Indicator will be indicated by the top bar graph LED quickly flashing about once every second.

### Figure 3.2: Monitor Operating Keys



## 6. % ON OFF Key

Pressing this key turns the monitor ON and OFF.

## 7. 🖹 PRINT Key

### See Chapter 4 for more details on the three modes.

**Verification Mode**: In this mode, momentarily pressing the  $\overline{\square}$  key will not activate the printer as the printer function is suppressed in this mode. Pressing and holding the  $\overline{\square}$  key in the Verification Mode will advance the paper. Reloading the paper is allowed in this mode. Pressing and holding the  $\overline{\square}$  key at power up will erase trends, even if the trend memory is clear.

**Data Collection Mode**: In this mode, momentarily pressing the  $\overline{\square}$  key will not activate the printer as the printer function is suppressed in this mode. However, in the Data Collection Mode, pressing and holding this key will advance the paper in the printer. Reloading the paper is allowed in this mode.

**Trend Printing Mode**: Momentarily pressing the  $\overline{\square}$  key will activate a printout (statistical sleep screening information). Pressing the  $\overline{\square}$  key during the printout will terminate the printout. Pressing and holding the  $\overline{\square}$  key will advance the paper. Holding the  $\overline{\square}$  key for 6 to 8 seconds at power up will clear the trend and switch the unit into Verification Mode. Reloading the paper is allowed in this mode.

NOTE! All data will be irretrievably lost when the trend data is cleared.

## **Chapter 4: Operating Instructions**



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.

### **Unpacking the Monitor**

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

### Installing the Batteries

The oximeter uses 4 standard "AA" alkaline cells, IEC Type LR6.

To install/replace the batteries:

- 1. Depress the battery door tab and lift up.
- 2. Install the negative end of each battery first, compressing the battery terminal spring until the positive terminal clears the positive tab. Press the battery down into place.
- 3. Place battery door tabs into the slots of the monitor back panel, depress the door tab and press the door into place.

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

NOTE: The unit will hold data for about one and a half minutes with no battery power. This allows for battery replacement without loss of stored data.

Figure 4.0: Installing the Batteries.

## Attaching the Sensor to the Patient

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



WARNING! Prolonged use or the patient's condition may require changing the sensor site periodically. Patients setting up the device at home should be instructed of the signs/symptoms of sensor misuse (e.g., pressure sores from prolonged application) and should be advised to move the sensor to another finger if necessary.



WARNING! When attaching sensors with Microfoam® tape, do not stretch the tape or attach the tape too tightly. A sensor applied too tightly by any method (tape, Velcro<sup>™</sup>) may cause inaccurate readings and blisters on the patient's skin (lack of skin respiration, not heat, causes the blisters).

Attaching the patient to the monitor requires these steps:

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

### **Choosing the Sensor**

Choose the appropriate sensor from the following chart.

PATIENT	SITE	DESCRIPTION
Adult	Finger	3044: Sensor, Adult (reusable)
> 45 Kg		3444, Comfort Clip™ Finger Sensor (reusable)
	Finger or Toe	3043: Sensor, Universal "Y" (reusable)
		1300: Sensor, Disposable, Adult Finger
		1310: D.O.T Sensor
		1311: D.O.T Sensor
	Ear	3078: Sensor, Ear (reusable)
Pediatric	Finger	3044: Sensor, Adult (reusable)
15-45 Kg		3444, Comfort Clip™ Finger Sensor (reusable)
	Finger or Toe	3043: Sensor, Universal "Y" (reusable)
		1301: Sensor, Disposable, Ped. Finger
	Ear	3078: Sensor, Ear (reusable)
Infant	Hand or Foot	3043: Sensor, Universal "Y" (reusable)
3-15 Kg (for spot-check	Тое	3025: Sensor, Wrap, Infant (reusable)
only)	Finger or Toe	1303: Sensor, Disposable, Infant
Neonate	Hand or Foot	1302: Sensor, Disposable, Neonate
< 3 Kg (for spot-check only)	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 damage to the sensor. This may cause inaccurate readings.

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

#### Figure 4.1: Disconnecting or connecting the sensor.



2. Cable

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

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

#### Figure 4.2: Positioning the cable of the finger sensor.

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

### Checking the Sensor and Oximetry Cable

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



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



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

- 1. Carefully inspect the sensor to make sure it does not appear damaged.
- 2. If using the oximetry cable:
  - a. Carefully inspect the oximetry cable to make sure it does not appear damaged.
  - b. If the sensor is not already connected to the oximetry cable, connect the sensor to the oximetry cable. Carefully align and push the connectors together firmly and close the latch to secure the connectors.
  - c. If the oximetry cable is not already connected to the monitor, connect the oximetry cable to the monitor. Carefully align and push the connector firmly into the monitor.
- 3. If not using the oximetry cable, connect the sensor to the monitor. Push the connector firmly into the monitor.
- 4. If the monitor is not already on, press the % key to turn on 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.

5. Before the sensor is attached to the patient, check the integrity of the sensor, oximetry cable, and oximeter by making sure the red light in the sensor is illuminated.

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

6. 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

- 1. To turn on the monitor, press the % key. When turned ON, the monitor does the following:
  - The pulse strength bar graph segments rapidly light the bottom and top LED.
  - The monitor's software revision is momentarily displayed.

Figure 4.3: SpO<sub>2</sub>, pulse rate, and pulse strength bar graph.



- 1. Patient's SpO<sub>2</sub> Shown Here
- 2. Patient's Pulse Shown Here
- 3. Patient's Pulse Strength Shown Here

## Low Battery Indicator

- 1. The Low Battery Indicator is the top LED segment of the pulse strength bargraph.
- 2. The Low Battery Indicator will flash rapidly when the batteries need to be replaced.
- 3. The Low Battery Indicator and "**trn**" will flash rapidly if the monitor is trying to print and there is not enough battery life for printing. This indicator will go away when the printing stops.



WARNING! When the LOW BATTERY INDICATOR flashes, you must immediately replace the monitor's batteries. Otherwise, the monitor turns itself off about 30 minutes after the highest bargraph LED begins to flash in any mode.

### **Turning Off the Monitor**

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

To turn off the monitor, press the % key. To turn off the monitor in the Data Collection Mode, the % key must be pressed and held for 6 seconds.

NOTE! Once the monitor is powered off in the Data Collection Mode, it cannot resume collection of trend data without clearing all previously obtained data.

## **Checking the Monitor's Performance**

Pulse oximeters do not require user calibration. If checking the function of the device is desired, an optional Oximeter/ECG Patient Simulator (Catalog No. 1606HH) is available as an accessory. The simulator attaches to the oximeter via the 3311 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 1606HH Oximeter/ECG Patient Simulator does not calibrate the monitor; the monitor does not require calibration. The 1606HH provides a known  $SpO_2$  and pulse rate to the monitor that allows you to check the monitor's performance.

NOTE! Follow the instructions included with the 1606HH Oximeter/ECG Patient Simulator.

## **Operating Modes**

The monitor has three operating modes: Verification Mode, Data Collection Mode, and Trend Printing Mode.

- Verification Mode is intended for use in spot checking and for verification of correct sensor placement.
- Data Collection Mode is intended for use in long-term data collection in sleep screening environments.
- Trend Printing Mode is intended for use in the output of the trend data summation to the printer or a full computer data download.

## **Verification Mode**

Verification Mode is intended for use in spot checking and for verifying that the user has correct placement of the finger sensor.

- The monitor will enter the Verification Mode as soon as trend memory is cleared.
- In this mode the patient will be able to position the sensor on his/her finger (or appropriate site) and obtain SpO<sub>2</sub> and heart rate data on the display.
- This mode will last for 10 minutes of continuous valid data collection.
- If the monitor is powered down during this mode, it will be powered up in this mode and the verification timer will be reset.
- Once the verification timer reads 10 minutes, the monitor exits the Verification Mode and enters the Data Collection Mode.
- The user functions in Verification Mode are:
  - The display will show % SpO<sub>2</sub> and heart rate values (if available, otherwise "dashes" [--] for invalid data are displayed).
  - The % key will turn the unit OFF without changing modes.
  - Pressing the → key momentarily will not activate the printer. The printer function is suppressed in this mode.
  - Pressing and holding the 🖾 key will advance the paper (see pg. 7-5) Reloading the paper is allowed in this mode.
  - Pressing and holding the ∠ key at power up will erase trends, even if the trend memory is already clear.
  - The serial link to the PC computer will be suppressed in this mode.

### **Data Collection Mode**

Data Collection Mode is intended for use in long-term collection of data in sleep screening environments.

- The Data Collection Mode will be entered when the verification timer reaches 10 minutes.
- Once the trend data collection process has been started, trend memory will be filled continuously until the end-of-memory is detected (approx. 12 hours) or the monitor is powered down.
- Invalid data (such as sensor off) is stored in trend memory, but is not used in the statistical calculations.
- The user functions in Data Collection Mode are:
  - The SpO<sub>2</sub> display will show one flashing bar and heart rate display will be blank (see Fig. 4.4).
  - Pressing and holding the % key for six (6) seconds will turn off the unit. While pressing the % key, the flashing bar will flash at a higher frequency indicating that the unit is about to be powered down.

## NOTE! If the % key is released before the six seconds elapses, the bar will return to its normal flashing pattern.

• After the power down, the unit will power up in the Trend Printing Mode.

## NOTE! Once the monitor is powered off in the Data Collection Mode, it cannot resume collection of trend data without clearing all previously obtained data.

- Momentarily pressing the È key will not activate the printer in the Data Collection Mode. The printer function is suppressed in this mode.
- Pressing and holding the → key will advance the paper (see pg. 7-5). Reloading the paper is allowed in this mode.
- The serial link to the PC computer will be suppressed in this mode.

## **Trend Printing Mode**

The Trend Printing Mode is intended for use in the output of the trend data summation to the built-in printer or to a PC for a full computer data download.

- The Trend Printing Mode is entered after the monitor is powered down in the Data Collection Mode, and powered back up, or when the trend memory becomes full.
- The user functions in Trend Printing Mode are:
  - The SpO<sub>2</sub> display will be blank and the heart rate display will flash "Lrn". The oximetry function will be suppressed in this mode (see Fig. 4.5).
  - Pressing the % key will turn off the power. After power down, the unit will be powered up to the same Trend Printing mode.
  - Briefly pressing the → key will activate a printout (statistical sleep screening information, see Fig. 7.1) Pressing the → key during the printout will terminate the printout. Printing the printout can be repeated an unlimited number of times.
  - Pressing and holding the key will advance the paper (see pg. 7-5). Reloading the paper is allowed in this mode.
  - Holding the → key for 6 to 8 seconds at power up will clear the trend data and switch the unit into Verification Mode (see Ch. 6).
  - The serial link to a PC will start as soon as the monitor is powered up. If a miscommunication between the monitor and the PC occurs, turning 'Off' the monitor and then back 'On' will re-establish the link. (see Appendix A for output protocol)





Figure 4.4: Data Collection Mode display



## **Chapter 5: Instructions for Training the Home User**

## Equipment and Supplies Checklist for Home Use

QUANTITY	CAT. NO.	DESCRIPTION
1		Handheld Oximeter
1	1884SSHU	Home Users Guide

\*The physician or home care provider will provide the type and quantity of the sensors

needed for home use.

*	3044	Sensor, Reusable, Finger
*	3444	Sensor, Reusable, Finger
1	3311	Cable, Oximetry, 5 Feet (1.5 meters)
*	1300	Sensor, Disposable, Adult
*	1301	Sensor, Disposable, Pediatric
*	1310, 1311	D.O.T Sensor, Adult
*	3049	Adhesive Strips (Adhesive Tape)

The home user may also need these supplies and reference materials:

1	Scissors (for trimming adhesive strips or adhesive tape).
1	Phone number for equipment supplier in case of equipment problems.

### **Training the Home User**

- Make sure all previous trend data has been printed and that the trend memory is cleared by pressing and holding the key for 6-8 seconds at power up.
- 2. Replace batteries if unsure of life expectancy (i.e. will they last long enough to complete the sleep screening? See p.2-1 for battery life expectancy)
- 3. (Following the Home User's Guide while teaching these tasks may help you and the home user.) Show the home user how to:
  - a. visually inspect the sensor and oximetry cable.
  - b. connect the sensor to the oximetry cable.
  - c. connect the oximetry cable to the monitor.
  - d. turn on the monitor.
  - e. route the cable safely from the patient to the monitor to prevent possible entanglements and dangerous situations (tripping, strangulation) etc.
  - f. attach the sensor prescribed by the doctor.
  - g. read the SpO<sub>2</sub>, pulse rate, and pulse strength bar graph readouts displayed on the monitor.
  - h. know when the monitor has gone into the Data Collection Mode and how the monitors display will look.
  - i. turn off the monitor only upon completion of test.
  - j. call home care provider if monitor is accidentally turned off before test completion occurs.

## **Chapter 6: Trend Data**

## Description

Whenever the monitor is on, it stores one  $SpO_2$  and one pulse rate reading every 4 seconds. The stored readings are called *trend* data. The monitor remembers trend data for at least 12 hours of run-time, possibly more, depending upon battery condition.

A summary of trend data can be printed on the built-in printer or stored data can be downloaded to a computer.

Trend data will be preserved for about one and a half minutes, without battery power, allowing battery replacement without losing trend data.

### **Clearing Trend Data**

- 1. Turn the monitor off.
- 2. Press and hold the  $\overline{\square}$  key, then turn the monitor on. Do not release the  $\overline{\square}$  key.
- 3. *cLr* will flash in the monitors' display, while the  $\overline{\Box}$  key is pressed.
- 4. When cLr stops flashing, the trend data is cleared. Release the  $\overline{\Box}$  key.

NOTE! Holding the  $\overline{\square}$  key for 6 to 8 seconds at power up will clear the trend data and switch the unit into Verification Mode. See pg. 7-5 on use of  $\overline{\square}$  key for Paper Feed.

## **Chapter 7: Printer**

## Description

Up to 12 hours of previously stored data can be printed as a summation of data from the monitors built-in printer or as a data download to a computer.

## **Trend Summary Printout**

To print the trend summary from the monitor's built-in printer:

- 1. The monitor must be in the Trend Printing Mode.
- 2. The Trend Printing Mode will be entered after the monitor is powered down in the Data Collection Mode or when the trend memory becomes full.
- 3. Press the  $\stackrel{\frown}{=}$  key to print out the summary report.
- 4. Press the 🖾 key again to stop printing or unit will stop printing after the summary report has been printed.

The trend summary printout from the monitor's built-in printer will contain the following sections: (see Figure 7.1: Sample Trend Printout)

- Report Title The first section will contain a report title to indicate that a new printout has begun.
- Patient Information The patient information section supplies a space for the user to write the following patient information on the printout:
  - Patient name
  - Date
  - Diagnosis
  - Comments
  - Start time
- Study Duration The study duration section reports the total time consumed by separating the data into the following three items:
  - Total duration
  - Excluded time (due to invalid data caused by sensor disconnect, artifact, etc.)
  - Total valid sample
- Study Maximums and Minimums The study maximums and minimums section contains the following information:
  - Low SpO<sub>2</sub> The lowest recorded SpO<sub>2</sub> value taken from the total valid sample.
  - Time of Lowest SpO<sub>2</sub> Records the time the lowest SpO<sub>2</sub> reading occurred (clock does not ignore invalid data when determining lowest SpO<sub>2</sub> time).
  - High PR The highest recorded pulse rate value taken from the total valid sample.
  - Low PR The lowest recorded pulse rate value taken from the total valid sample.
  - Avg.  $SpO_2$  The average  $SpO_2$  value from the total valid sample.

- SpO<sub>2</sub> STD The standard deviation is a measure of the variability of the sample. The larger the standard deviation of the sample data, the more variability there is in the sample.<sup>1</sup>
- Statistics The statistics section contains information calculated from the valid data only. The following information is supplied in the statistics section:
  - % Time per SpO<sub>2</sub> range This section displays the percent of the valid sample time that the readings were in a specified range. (Sample must be > 1% to be accounted for here.)
  - Time per SpO<sub>2</sub> range This section displays the total valid sample time that the readings were in a specified range.
  - Total duration below 90%  $SpO_2$  This section displays the total valid sample time that the SpO<sub>2</sub> readings were below 90%.
  - Total duration 88% SpO<sub>2</sub> & below This section displays the total valid sample time that the SpO<sub>2</sub> readings were 88% and below.
  - Longest single event with SpO<sub>2</sub> 88% & below This section displays the duration of the longest single event when the % SpO<sub>2</sub> value was 88% or below.
  - Started at This section displays the time the longest single event with  $SpO_2 88\%$  and below began.
- Summary Complete This final section will contain a notification that the summary is complete. This section is important because of the pauses that occur during printing.

NOTE! Only stored data will be printed. Real-time printing is not available.

NOTE! The monitor uses a "relative time" clock. The times indicated on the printout are relative to the start of the study. When the monitor switches from Verification to Data Collection Mode, it restarts the "relative" time clock to 00:00:00.

<sup>1</sup> The standard deviation, s, is calculated by:  $s = \sqrt{\frac{\sum (X - \overline{X})^2}{n-1}}$  where X is the sample value,  $\overline{X}$  is

the sample mean, and n is the number of samples. Note: The data sample is generally not normally distributed.



### Figure 7.1: Sample Trend Printout

### What You'll Need for Printing

You'll need these items to print trend printouts:

- Oximeter with installed printer
- Printer Paper: 1-inch wide thermal, Catalog No. 6012.

## **Trend Printouts**

### **Collecting Trend Data**

Whenever the monitor is on, it stores one  $SpO_2$  and one pulse rate reading every 4 seconds. The stored readings are called *trend* data. The monitor remembers trend data for up to 12 hours of run-time, depending upon battery life.

Trend data will be preserved for about one and a half minutes, without battery power, allowing battery replacement without losing trend data.

Trend memory will contain data for only one patient.

Trends will be cleared by pressing and holding the  $\overline{\square}$  key for 6 to 8 seconds, at power-up. A "clr" message will flash to indicate that trend clear is about to happen.

New data will not overwrite old data when the end of memory is reached.

NOTE! Turning the monitor OFF and back ON during Trend Collection will "freeze" trend information and place the monitor in the Trend Printing Mode. The monitor must have the trend data cleared and reset to begin Trend Collection again.

### **Paper Feed**

To advance paper through the printer, press and hold  $\overline{\square}$  for 3 seconds (not at power up). The paper-feed will start. Press the  $\overline{\square}$  key again to stop the printer, otherwise the printer will stop in about 25 seconds after printing 30 empty lines. This is enough time to flip the device over and slide the paper end into the slot until the printer captures the paper and feeds it through. If the user feeds the paper in a shorter period of time, the printer can be stopped by pressing the  $\overline{\square}$  key again.

### Fig 7.2 Paper Advance



1. Paper exit.

CAUTION! When printing, or advancing the paper, place the oximeter on it's side to prevent paper jams. Also, cutting the paper as shown below will facilitate feeding paper into the printer.

Fig 7.3 Paper Shape



## **Chapter 8: PC Communication Setup**

### Description

The device will send out Trend Data to a PC through the sensor connector. To accomplish this, the sensor must be disconnected from the device. Additional cables are required to connect the device to a PC. The communication device will be dormant if the system is not in the Trend Printing Mode. The following items will be needed:

- 1. Printer Adapter Cable (Catalog No. 3350)
- 2. DB-9 Modem Cable (Catalog No.3339)

## **PC Communication Setup**

- 1. Power up the monitor.
- 2. Connect the printer communication cable labeled "BCI" to the monitor.
- 3. Connect the standard RS-232 null modem cable's DB-9 connector to the mating connector of the printer cable labeled "Printer".
- 4. Connect the standard RS-232 null modem cable's DB connector to the mating connector on the PC.

### NOTE! The DB-9 modem cable is an industry standard RS-232 null modem cable.

### NOTE! SEE APPENDIX A FOR DATA FORMAT INFORMATION





## **Chapter 9: Maintenance**

MAINTENANCE:	HOW OFTEN:	BY DOING THIS:
Replace battery	When Low Battery Indicator is flashing or 12-15 hours of battery use has elapsed.	Follow the instructions for installing the batteries.
Disinfect the reusable sensor	Before attaching the sensor to the patient.	Follow the instructions for cleaning the reusable sensor.
Disinfect the monitor	When necessary.	1. Remove the batteries from the unit.
		NOTE: print tend data before cleaning. Trend data will be lost if batteries are disconnected more than one and a half minutes.
		2. Wipe the surfaces of the monitor with a soft, clean cloth dampened in isopropyl alcohol. Use only a cloth that is dampened, not wet.
		CAUTION! Do not allow isopropyl alcohol or any liquid to enter any of the openings on the monitor.

### Schedule of Maintenance

### Storage

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

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

Storage specifications are as follows:

Temperature:-40°C to 75°C (-40°F to 167°F)Relative Humidity:10% to 95% (noncondensing)

Problem	Possible Cause	Corrective Action
No pulse shown on the bargraph.	Patient cable or sensor is disconnected from the oximeter.	Check sensor connections to the patient cable and to the oximeter.
	Sensor is incorrectly positioned on the patient.	Reposition the sensor.
	Poor patient perfusion.	Reposition the sensor.
	Defective sensor or patient cable.	Try a new sensor or contact your authorized repair center for help.
	Monitor is in the Data Collection or Trend Print Mode.	None required.
Pulse rate is erratic, intermittent, or incorrect.	Sensor incorrectly positioned.	Reposition the sensor.
	Patient motion	Patient must remain still to obtain an accurate measurement.
SpO <sub>2</sub> value is erratic,	Poor patient perfusion.	Reposition the sensor
intermittent, or incorrect.	Patient motion.	Patient must remain still to obtain an accurate measurement.
The oximeter doesn't	Batteries weak.	Replace the batteries.
turn on.	Batteries not installed or batteries incorrectly installed.	Ensure the batteries are installed correctly.
The oximeter displays only one flashing LED with no SpO <sub>2</sub> or heart rate	The oximeter has been on continuously and collecting data for 10 minutes and has gone into the Data Collection Mode.	If not collecting trend data, press and hold the % key for 6 seconds, which will turn off the unit. To return monitor to Verification Mode, hold key for 6 to 8 seconds at power up. This will clear the trend data and switch the unit to the Verification Mode.
No printout on built-in	Batteries are weak.	Replace the batteries.
printer.	Batteries are not properly installed.	Ensure the batteries are installed properly.
	No trends in memory.	Take trend data.
	Printer interface malfunction.	Contact your authorized repair center for help.
E00	ROM Error	Contact service representative
E01	RAM Error	Contact service representative

## Chapter 10: Troubleshooting

## **EMI Interference**

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

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

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

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

If assistance is required, contact a service representative.

## **Chapter 11: Optional Supplies & Accessories**

Cat. No	Description	Quantity
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
1606HH	Simulator & Cable, Oximeter, 5 ft.	each
1884SS	Manual, Operation	each
1885	Manual, Service	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.
3143	Attachment, OxiLink <sup>®</sup> Small Finger	100/ctn
3143B	Small Finger OxiLink <sup>®</sup>	10/box
3144	Attachment, OxiLink <sup>®</sup> Medium Finger	100/ctn
3144B	Medium Finger OxiLink ®	10/box
3145	Attachment, OxiLink <sup>®</sup> Large Finger	100/ctn
3145B	Large Finger OxiLink <sup>®</sup>	10/box
3311	Cable, Patient (Oximetry Extension)	each
3339	PC Adapter Cable	each
3350	Cable, Printer Interface	each
3418	Boot Protective 3401	each
3415	Case, Carrying	each
3444	Comfort Clip™ finger Sensor	each
6012	Paper, Printer	4/pk

### **Ordering Information:**

For ordering information, contact your local distributor or the BCI, Inc. customer service department.

 BCI, Inc.
 Phone: (262) 542-3100

 N7 W22025 Johnson Road
 Fax: (262) 542-3325

 Waukesha, WI USA 53186-1856
 Toll Free; (800) 558-2345

 email : info@smiths-bci.com

## **Chapter 12: 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

SpO2:	LED numeric display, 0.43 inches (10.9 mm) high
Pulse Rate:	LED numeric display, 0.43 inches (10.9 mm) high
Pulse Strength:	Logarithmically scaled 8-segment LED bargraph
Low Battery Indicator:	1 Segment LED
Keys:	% On/Off key
	/Ē∕ key

## SpO<sub>2</sub>

Range:	0 - 99% Functional SpO2 (1% increments)
Accuracy:	$\pm 2$ at 70 - 99% less than 70% is unspecified
Alarms:	None
Averaging:	4 pulse beat average
Display Response:	The display is to functional saturation.
Display Update Rate:	1 Hz (SpO2); 60 Hz (pulse strength)
Calibration:	Factory calibrated over the range of 70% to 100% SpO2 using human blood samples to functional saturation. Test methods available upon request. No in-service calibration is required.
Sensor:	Red660nm, 2mW (typical)Infrared905nm, 2-2.4mW (typical)

## Pulse Rate

Range:	30-254 BPM (1 bpm increments)
Accuracy:	$\pm 2\%$ or 2 BPM, which ever is greater
Averaging:	8 second average
Display Update Rate:	1 Hz

## **Printer**

1 inch wide paper thermal printer (# 6012)

15 characters per line with two dots between symbols

5x7 dot characters

## **Power Requirements**

Four standard "AA" alkaline cells (IEC Type LR6)

## **Battery Life**

Alkaline Cells:	2 sleep screening cycles (1 cycle = 10 minutes with display on, 8 hours with display off, 5 minutes printing)
	or
	Intermittent monitoring: 1 min on, 2 min off (= 1 cycle) 80 hours or 1600 cycles

## Dimensions

Width:	2.75 inches (69.85 mm)
Height:	6.6 inches (167.64 mm)
Depth:	1.43 inches (36.322 mm)
Weight:	13 ounces (369 grams) with batteries

## **Environmental Specifications**

Operating Temp .:	0 - 55° C (32 - 131° F)
Storage Temp.:	-40 - 75° C (-40 - 167° F)
Relative Humidity:	10 - 95% (storage), non-condensing 15 - 95% (operating), non-condensing

## Appendix A: Data Format

### Data format.

Baud rate: 19200, 8 bits, one start, one stop, no parity check.

Data output starts in the Trend Printing Mode as soon as power is turned on.

Data transmission is unidirectional from the oximeter to the receiving device. The CTS (clear-to-send) line from the receiving device to the oximeter can be used to control data flow.

After data pack has been sent, data communications stop, and can be resumed by cycling the power of the oximeter.

Data pack consists of binary data. The overall structure of the pack is shown in the table below:

Byte 0	Least significant byte of the length of the data block (excluding check sum)
Byte 1	Most significant byte of the length of the data block (excluding check sum)
Byte 2	First byte of the data block
Byte 3	Second byte of the data block
Byte 4 byte n	The rest of the data block
Byte n+1	Least significant byte of the check sum, which is the sum of all bytes in the data block
Byte n+2	Most significant byte of the check sum

As indicated in the table, each pack includes length, data block and check sum. Data in the data block represents four-second samples.

Data blocked is compressed. The compression method is described below.

Each stored data byte is split into low and high nibbles, except for the cases described later. Each nibble can have a signed value in the range of -7 to 7. Bits 0 to 3 are used for SpO2, bits 4 to 7 are used for the Pulse Rate. To obtain the n+1-st value, the value of the corresponding nibble should be added to the n-th value (considering sign). For example, if n-th SpO2 value is 96%, and bits 0 to 3 contain a signed -1 (0xf in HEX notation), then the n+1-st value is 96% - 1 = 95%.

A special case is a byte 0x88 (88-hex). This byte is used for a marker. If this marker is found in the byte sequence, the byte immediately following the marker byte is SpO2 value in the range 30 to 100 (value 255 means "no data"). The byte immediately following SpO2 is Pulse Rate in the range of 30 to 254 (value 255 means "no data").

The next byte and all sequential bytes are the bytes divided into low and high nibbles, until the next marker is found.

This method allows for almost 2:1 data compression rate.

The following table shows an	example of data	de-compression:
0	1	1

Byte in HEX	De-compression
88	Marker byte, expect the next byte to be SpO2;
60	SpO2 value, HEX 60 equals to 96% SpO2 decimal, expect the next byte to be Pulse Rate;
52	Pulse Rate, HEX 52 equals to 82 bpm decimal, expect the next byte to be the byte divided into low and high nibbles;
fO	Low nibble is 0, SpO2 = $96\% + 0 = 96\%$ ; High nibble is -1, Pulse Rate = $82bpm - 1 = 81 bpm$ ;
ef	Low nibble is -1, SpO2 = 96% - 1 = 95%; High nibble is –2, Pulse Rate = 82bpm – 2 = 80 bpm;
30	Low nibble is 0, SpO2 = $95\% + 0 = 95\%$ ; High nibble is 3, Pulse Rate = $80$ bpm + 3 = $83$ bpm;

Note: Your service representative can supply an ANSI C de-compression routine.

## Appendix B: Setting the Optional Real Time Clock

- 1. Clear trend memory by pressing and holding the print key at power up until CLR stops flashing.
- 2. Turn the monitor off. Power on the monitor and continue to hold the on key for 6-8 seconds. The version number should be displayed and then the display will go blank except for one set of digits. This is the minutes setting.
- 3. Adjust the minutes by pressing the print key until the desired setting is reached.
- 4. Press the power key again to show the hour setting. Use the print key to set the desired hour.
- 5. Press the power key again to show the day setting. Use the print key to set the desired day.
- 6. Press the power key again to show the month setting. Use the print key to set the desired month.
- 7. Press the power key again to show the year setting. Use the print key to set the desired year.
- 8. Press the power key again to exit the time setting menu. After the power key is pressed a time stamp is printed and the monitor turns itself off.
- 9. Verify that the correct time stamp was printed. If the correct time and date was not printed, repeat steps 2 through 9 until the proper time and date is verified.

The time and date can be verified by repeating step 2 and then pressing the print key until the current time and date is printed and the monitor turns itself off.



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