BC Biomedical
A UNIT OF BC GROUP INTERNATIONAL, INC.

FINGERSIM™

PULSE OXIMETER TEST SYSTEM

USER MANUAL

BC BIOMEDICAL
FINGERSIM™
TABLE OF CONTENTS

WARNINGS, CAUTIONS, NOTICES ii

PURPOSE 1

DESCRIPTION 2

THEORY OF OPERATION 4

CONDITIONS THAT AFFECT USE 6

CHECK OUT 9

OPERATING INSTRUCTIONS 10

SPECIFICATIONS 14

SERVICE AND MAINTENANCE 15

ACCESSORIES 16

TROUBLE SHOOTING CHART 17

MANUAL REVISIONS 19

LIMITED WARRANTY 19

NOTES 20

I. GENERAL WARNINGS AND CAUTIONS

NOTICE: Do not use with reflectance or ear clip sensors. Use only with transmittance type, finger or toe sensors.

WARNING: FingerSims™ are fragile and must be handled with care; they contain glass.

CAUTION: The movement of the FingerSim™ relative to the oximeter sensor may cause erroneous pulse rate and/or oxygen saturation readings. Use the FingerSim™ Holder to facilitate pulse generation without introducing FingerSim™ movement relative to the oximeter sensor.

CAUTION: Do not use a FingerSim™ that is cracked or leaking fluid.

CAUTION: Avoid extended exposure to sunlight.

CAUTION: The SpO_2 simulation by the FingerSim™ is temperature dependent. See Table I for the appropriate adjustment. Allow at least one-hour stabilization at room temperature before using.

CAUTION: Do not store the FingerSim™ outside the recommended Long Term Storage Temperature range (32°F–104°F). **NOTE:** Temperatures outside this range for short duration are acceptable (for example during shipping).

CAUTION: When testing flexible sensors, ensure the emitter and detector are vertically aligned on opposite sides of the FingerSim™.

CAUTION: Do not use beyond the calibration date.

CAUTION: No test system can simulate all possible operating conditions a pulse oximeter may encounter. Use the FingerSim™ as an adjunct to other indications to determine proper pulse oximeter operation.

CAUTION: Improper insertion of the FingerSim™ into the Holder can cause breakage.

II. PURPOSE

The FingerSim™ Pulse Oximeter Test System enables the healthcare professional to evaluate pulse oximeter and sensor function at three simulated light absorption conditions. These absorption conditions are set to simulate a typical finger at nominally 97%, 90%, and 80% SpO_2 levels. In addition, a pulse oximeter's response to various pulse amplitudes and rates can be simulated.

Before the availability of the FingerSim™, pulse oximetry systems (oximeter plus sensor) were not easily tested. The oximeter's measurement of the small pulsatile blood component and the interrelationship of the oximeter calibration curve with the light emitting characteristics of the sensor made a true oximeter system tester difficult to conceive. The FingerSim™ System, when used as an adjunct to other indicators, aids the healthcare professional in assessing performance of both oximeter and sensor.

NOTICE:

Do not use with reflectance or ear clip sensors. Use only with transmittance type, finger or toe sensors.

CAUTION: No test system can simulate all possible operating conditions a pulse oximeter may encounter. Use the FingerSim™ as an adjunct to other indicators to determine proper pulse oximeter operation.

III. DESCRIPTION

The FingerSim™ system provides a rapid, inexpensive and convenient means of assessing the function of the entire pulse oximeter system including the oximeter sensor. A set of three FingerSims™ are included in each kit. Each of the three FingerSims™ contain a fluid with precisely controlled light absorption characteristics sandwiched between two glass slides. The concentration of the substances in the three mixtures allow the FingerSim™ to mimic the light absorbing qualities of arterial blood as measured by an oximeter at different oxygen saturation values (nominally 97%, 90%, and 80%). The 97%, 90%, and 80% FingerSims™ are easily identified by the color coded end caps (Red - 97%, Blue - 90%, and Black - 80%).

Squeezing the colored coded flat end will produce a pulsatile movement of the solution. This pulsation is detected as a pulse by the oximeter system being tested, and thus allows the oximeter to calculate and display an SpO_2 value which corresponds to the fixed light absorbing characteristics of the particular FingerSim™ being used.

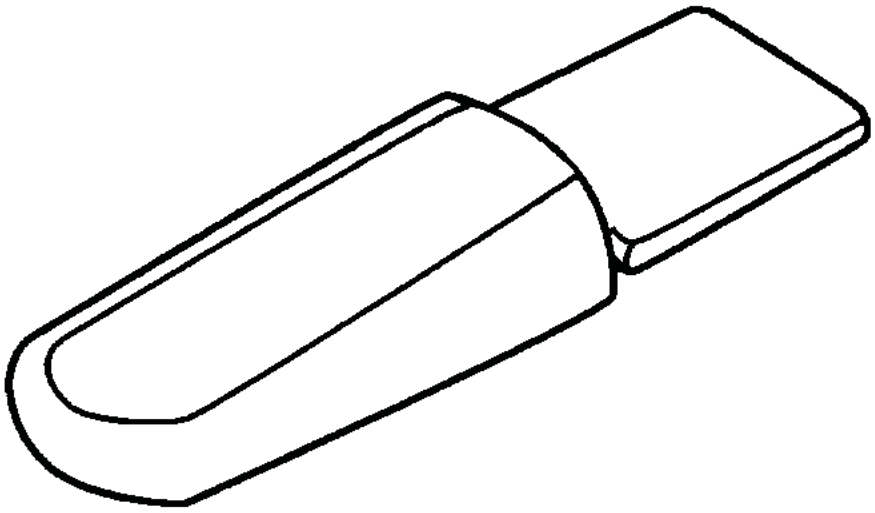


Figure 1. BC Biomedical FingerSim™

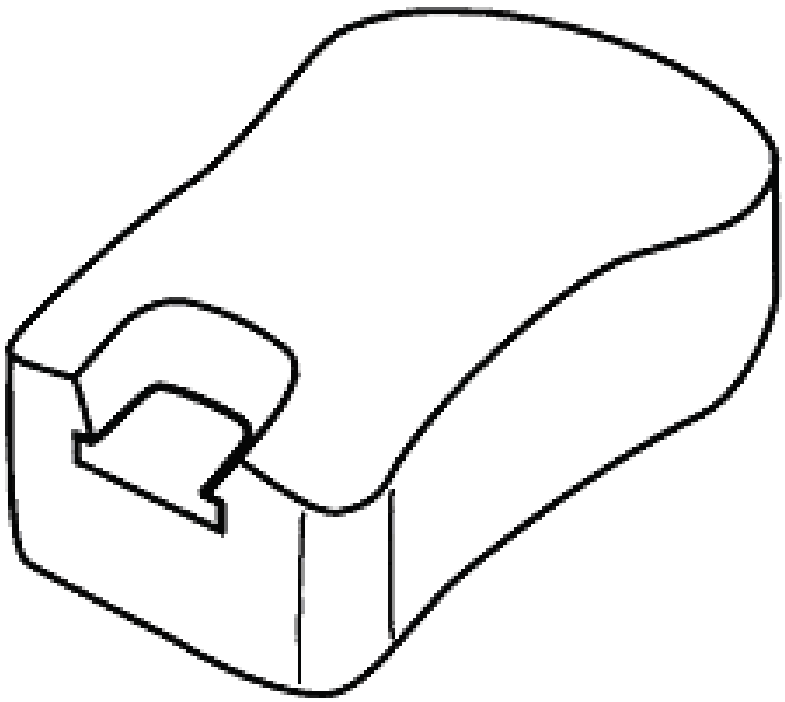


Figure 2. Replacement Holder

IV. THEORY OF OPERATION

The principle of differential light absorption is used by a pulse oximeter to determine the oxygen saturation of arterial blood (SpO_2). Red light and infrared light are differentially absorbed by oxygenated and deoxygenated hemoglobin. The pulse oximeter has a sensor with light emitting diodes (LEDs) that provides these wavelengths of light for transmittance through a measurement site, usually a finger. Based on the relative absorption of these two wavelengths of light at the measurement site, the pulse oximeter determines the relative amount of oxygenated and deoxygenated hemoglobin, which is calculated as SpO_2.

In order to make this calculation independent of skin color, finger size, etc., the pulse oximeter uses only the time varying light absorption component generated by the patient's pulse. In addition, the pulse oximeter uses the period of pulsation to measure the pulse rate.

The FingerSim™ absorbs light very much like a human finger. The overall red and infrared light absorption of the FingerSim™ approximates the overall light absorption of a typical finger. In addition, the red and infrared photo spectrometric light absorption of the inner solution approximates arterial blood as seen by the oximeter at 80%, 90% and 97% oxygen saturation levels.

Minor SpO_2 variations will be seen between oximeter manufacturers because standards correlating red and infrared light absorption to oxygen saturation in pulse oximetry are not available. Each manufacturer has developed its own correlation. In addition, minor SpO_2 variations between sensors.

In addition, minor SpO2 variations between sensors will be observed due to the fact that red and infrared emitting light sources vary slightly between sensors.

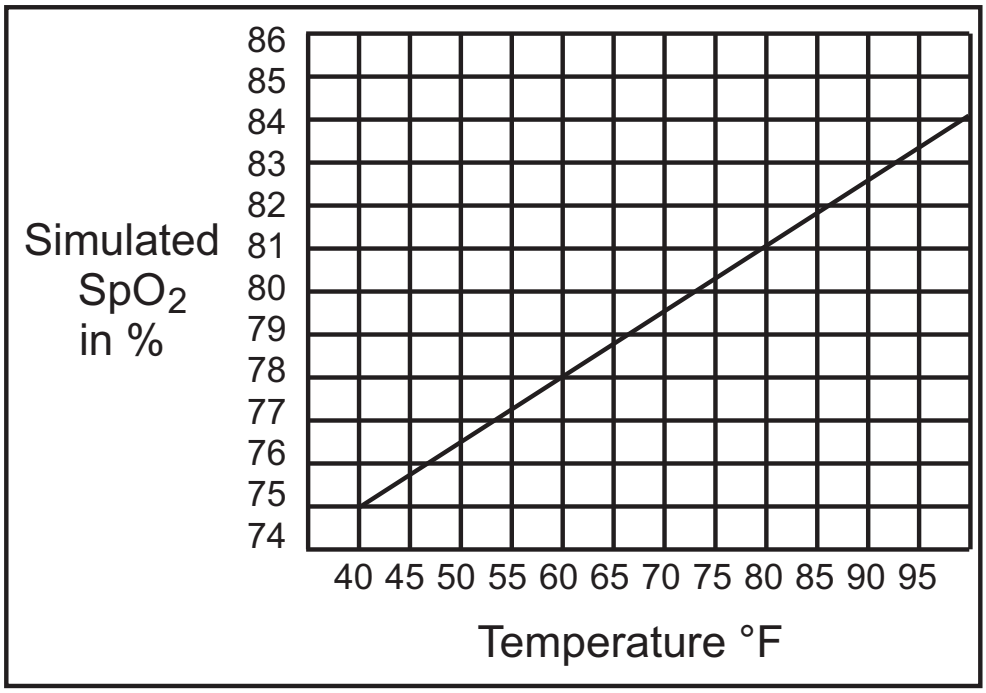
The FingerSim™ enables the healthcare professional to repeatedly test and evaluate the pulse oximeter system (oximeter and sensor) under controlled light absorption conditions.

The time varying light absorption component required by a pulse oximeter is created in the FingerSim™ by rhythmically pressing the color coded end. This creates a volume change in the distal (sensor) end of the FingerSim™, analogous to the heart creating blood pressure waves that force blood into the finger. The amplitude and rate of the pulse wave can be varied by changing the applied pressure and interval.

V. CONDITIONS THAT AFFECT USE

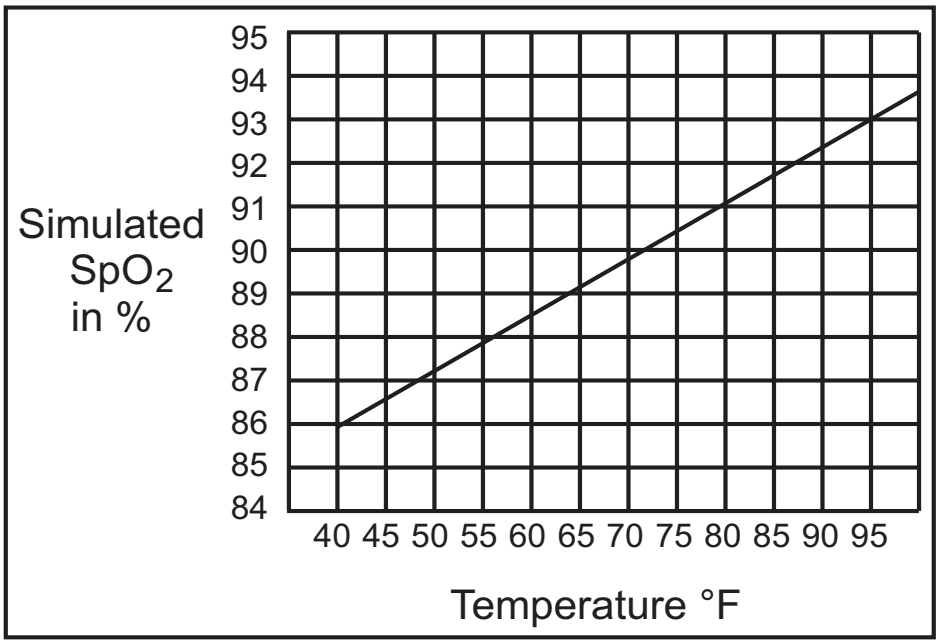
A. Ambient Temperature

Ambient temperature changes will affect the light absorption characteristics of the FingerSim™, resulting in the simulated SpO_2 value changing slightly with ambient temperature. Each FingerSim™ is calibrated at 72.5°F. If the ambient temperature is between 67.5°F and 77.5°F no modification in the expected simulation is necessary. However, if the ambient temperature is outside this range Figures 3, 4 and 5 should be used to modify the expected simulated SpO_2 value. For example, if the 80% FingerSim™ was being used at 90°F ambient temperature then the expected simulation would be increased to 83%.



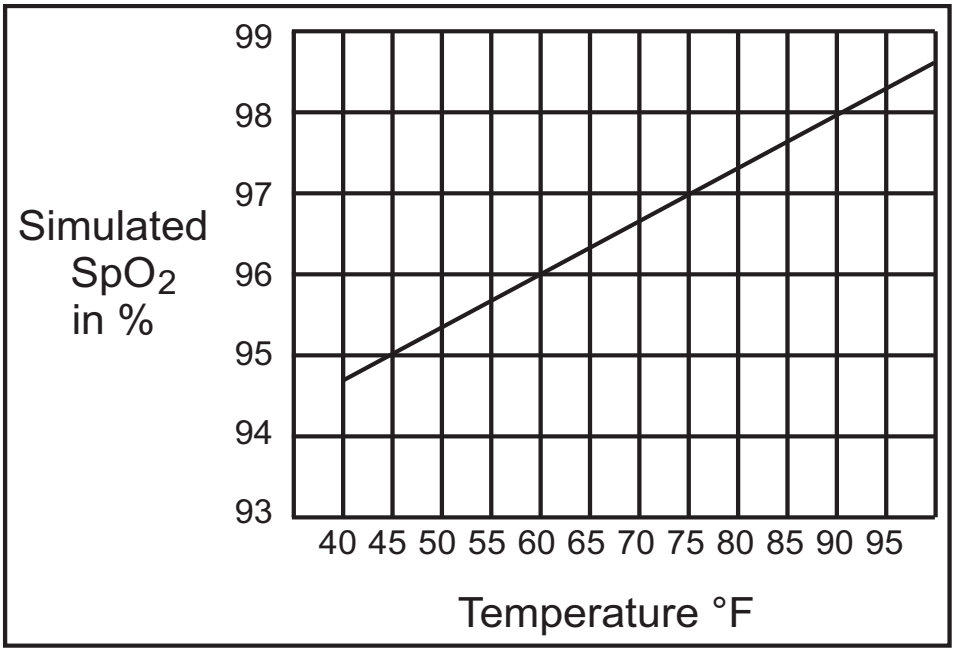
Simulated SpO_2 change with Ambient Temperature
80% FingerSim™

Figure 3. 80% SpO_2 Temperature Dependence



Simulated SpO_2 change with Ambient Temperature
90% FingerSim™

Figure 4. 90% SpO_2 Temperature Dependence



Simulated SpO_2 change with Ambient Temperature
97% FingerSim™

Figure 5. 97% SpO_2 Temperature Dependence

B. Movement Artifact

Analogous to the clinical environment, poorly attached sensors can result in movement between the oximeter sensor and the FingerSim™ causing erroneous oximeter SpO_2 and Pulse Rate readings. Be sure to attach the sensor to the FingerSim™ so that the emitting and detecting diode are vertically aligned and in direct contact with the white transmissive surface about 1/4″ to 1/2″ from the tip of the FingerSim™. Route the sensor cable in such a way that it is not influencing the sensor attachment to the FingerSim™. For sensors with cables directed to the back of the finger, route the cable through the notches in the bottom of the holder (see Figure 6).

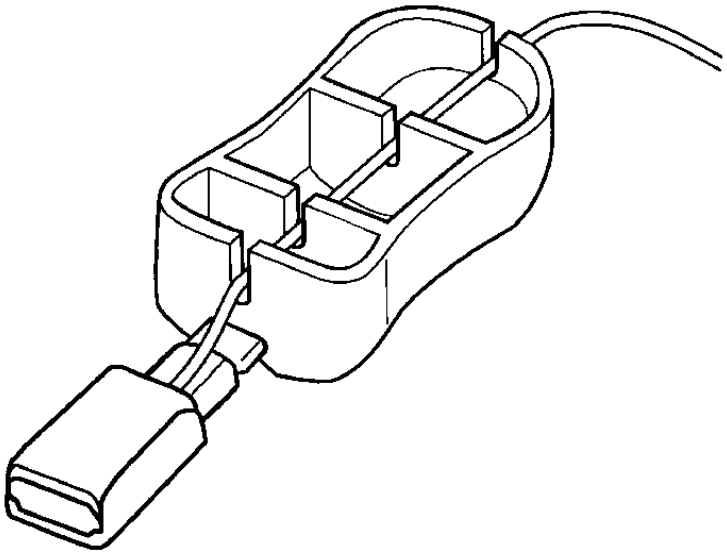


Figure 6. Sensor Cable Routing Through Holder

C. Sensor Alignment and Position

The light absorption characteristics of the FingerSim™ are specified for light passing directly through the FingerSim™. Be sure to vertically align the emitter and detector over the white transmissive surfaces about 1/4″ to 1/2″ from the tip of the FingerSim™. Misalignment or positioning on the black edges can cause erroneous readings.

VI. CHECK OUT

Before each use, visually inspect each FingerSim™ carefully. Do not use the FingerSim™ if the calibration date marked on the color coded handle has elapsed. Do not use the FingerSim™ if it is cracked and/or leaking fluid.

CAUTION: The SpO_2 simulation by the FingerSim™ is temperature dependent. Allow at least one hour stabilization at room temperature before using.

VII. OPERATING INSTRUCTIONS

A. Insert the FingerSim™ into the Holder
Carefully insert the short, flat, color coded end of the FingerSim™ into the slot provided at one end of the FingerSim™ Holder. Grasp the sides of the color coded end and gently press the FingerSim™ into the Holder until it reaches the stop of the holder (see Figure 7).

CAUTION: Improper insertion of the FingerSim™ into the Holder can cause breakage. Insert the FingerSim™ as shown in Figure 7.

CAUTION: If the FingerSim™ is used without the recommended Holder, one must be very careful to prevent movement between the sensor and the FingerSim™. Be sure no forces are applied to the sensor or sensor cable (i.e. do not hold the sensor, or touch the sensor or cable) while squeezing the color coded end of the FingerSim™ to generate the pulse signal. Motion between the sensor and the FingerSim™ may cause erroneous SpO_2 and/or Pulse Rate readings.

WARNING: FingerSim™ are fragile and must be handled with care; they contain glass.

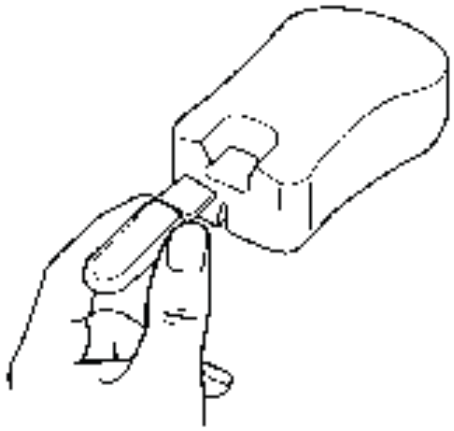


Figure 7. Positioning the FingerSim™ in the Holder

B. Attach the Sensor
Attach the sensor under test to the FingerSim™ the same way you would to a patient's finger. When testing a finger clip sensor be certain the FingerSim™ is inserted all the way to the stop of the sensor. Position flex sensors such that the emitter and detector are vertically aligned between 1/4″ and 1/2″ from the tip of the FingerSim™.

NOTICE:
Do not use with reflectance or ear clip sensors.
Use only with transmittance type, finger or toe sensors.

Route the cable in such a way that it does not influence the sensor under test. For sensors with cables directed to the back of the finger, route the cable through the Holder in the notches on the bottom (see Figure 8).

Some oximeter systems may generate readings during sensor attachment due to the relative motion between the FingerSim™ and the sensor. Allow 30 seconds for stabilization before going on to the next step.

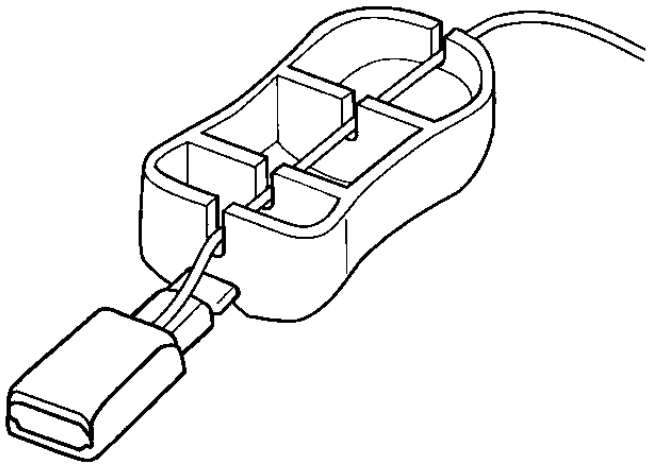


Figure 8. Sensor Cable Routing Through Holder

C. Quiescent Test
After attaching the sensor allow the oximeter system under test about 30 seconds to stabilize. The oximeter system should recognize this as a no pulse condition.

D. Oxygen Saturation Test
Gently press the FingerSims™ color coded end rhythmically keeping a minimum pressure on the FingerSim™ throughout the pulse cycle (see Figure 9). Generate the pulse by slightly increasing and decreasing the pressure. Do not tap or move your finger away from the FingerSim™. This may create unwanted motion artifact by rocking the FingerSim™. The oximeter system should recognize the simulated pulse and display a pulse rate correlating to the input. The SpO_2 display should approximate the nominal value of the FingerSim™.

NOTE: Some slight variation in the SpO_2 readings between manufacturers is possible due to each manufacturer's interpretation of how the SpO_2 value relates to the absorption of the red and infrared light in blood (see Theory of Operation).

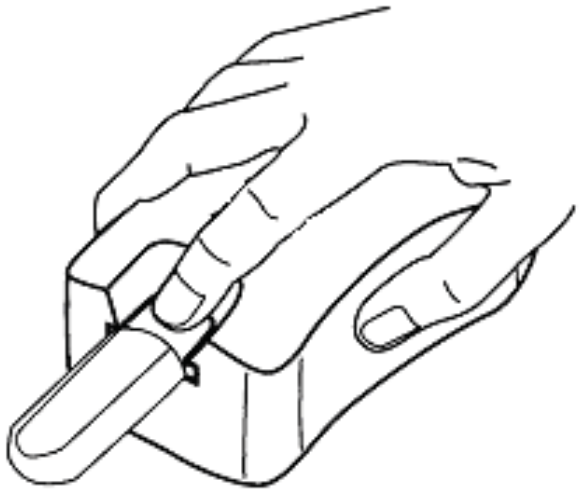


Figure 9. Generating a Simulated Pulse

E. Pulse Rate Test

Vary the input pulse rate by rhythmically pressing the FingerSim™ colored coded end at fast and slow rates. The pulse oximeter system should indicate high and low pulse rates. Verify that the pulse oximeter system recognizes each pulse generated and that there are no extra pulses indicated by the oximeter.

F. Pulse Amplitude Test

The amplitude of the pulse waveforms being generated can be varied between 0% and 5% modulation levels by changing the amount of pressure used to generate the pulse waveform. These amplitude changes should be displayed by the oximeter on the perfusion indicator (various display techniques have been used by oximeter manufacturers: colored coded L.E.D.s, L.E.D. bar graphs, L.C.D. waveforms, etc.).

VIII. SPECIFICATIONS

A. FingerSim™

Width	0.72″
Thickness	0.50″
Overall Infrared Light	20dB to 40dB Absorption (d.c.)
Overall Red Light	20dB to 40dB Absorption (d.c.)
Operating Temperature Range	65°F to 90°F
Long Term Storage	32°F to 104°F Temperature Range

Typical infrared percent modulation 0 to 5 % when squeezed

Red to Infrared Ratio (a.c.) @ 72.5°F and 660nm/910nm:

80% FingerSim™ - 1.065 to 1.100
90% FingerSim™ - 0.765 to 0.800
97% FingerSim™ - 0.573 to 0.598

B. Holder

Width	2.4″
Length	4.3″
Height	1.6″

IX. SERVICE AND MAINTENANCE

There is no service or maintenance possible with the FingerSim™ test systems. Each FingerSim™ is dated to identify its useful life. Replace any FingerSim™ that shows signs of leakage.

To clean FingerSim™ wipe with isopropyl alcohol.

X. ACCESSORIES

The following accessories function with the FingerSim™ Oximeter Testing System:

FingerSim™ Replacement Set

Includes a set of three FingerSim™, 97%, 90% and 80% SpO_2 (Nominal).

Replacement Holder

FingerSim™ Holder

BC Biomedical SPO-2000 Electronic Pulse Box Accessory

Turns FingerSim™ into a hands-free test system with six (6) calibrated pulse rates.

BC Biomedical MSP-2100 can plug into the Auxiliary port of BC Biomedical's PS-2100, PS-2200 & the NIBP-1000 Series providing a calibrated pulse rate using FingerSim™.

SPO-2000

MSP-2100

XI. TROUBLE SHOOTING CHART

Before calling Customer Support, please check the following chart for a possible solution to the problem you are experiencing.

SYMPTOMS	POSSIBLE CAUSE	POSSIBLE SOLUTION
• Oximeter measures slightly different SpO_2 values than the nominal FingerSim™ value.	• Expected variation due to manufacturing tolerances.	• Verify that minor variations in SpO_2 are not clinically significant.
• Oximeter measures high or low SpO_2 bias compared to the nominal FingerSim™ value.	• FingerSim™ is not at room temperature.	• Allow at least one hour stabilization at room temperature .
	• Room temperature not at 72.5° F.	• Adjust expected SpO_2 value (see Table I).
	• Cracked or leaking FingerSim™.	• Replace FingerSim™.
	• Outside calibration date.	• Replace FingerSim™.
	• Improper sensor attachment to the FingerSim™.	• Ensure the sensor is attached to the FingerSim™ per section VIII(B).
	• Damaged Sensor.	• Try another sensor.
	• Damaged Oximeter	• Try another oximeter

SYMPTOMS	POSSIBLE CAUSE	POSSIBLE SOLUTION
• Oximeter displays erratic SpO_2 values.	• Motion of the sensor relative to the FingerSim™.	• Use holder provided. Route cable per VII(B). Be certain sensor is seated properly on FingerSim™.
	• Damaged Sensor	• Try another sensor.
	• Damaged Oximeter	• Try another oximeter.
• No pulse when the FingerSim™ is squeezed.	• Cracked or leaking FingerSim™.	• Replace FingerSim™.
	• Damaged Sensor	• Try another sensor.
	• Damaged Oximeter	• Try another oximeter.

MANUAL REVISIONS

Revision #	Revisions Made
Rev 01	Preliminary Manual
Rev 02	Page Numbers Adjusted, Format Updated, Pictures Updated, Misc. Edits

LIMITED WARRANTY

WARRANTY: BC GROUP INTERNATIONAL, INC. WARRANTS ITS NEW PRODUCTS TO BE FREE FROM DEFECTS IN MATERIALS AND WORKMANSHIP UNDER THE SERVICE FOR WHICH THEY ARE INTENDED. THIS WARRANTY IS EFFECTIVE FOR TWELVE MONTHS FROM THE DATE OF SHIPMENT.

EXCLUSIONS: THIS WARRANTY IS **IN LIEU OF** ANY OTHER WARRANTY EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO ANY IMPLIED WARRANTY OF **MERCHANTABILITY** OR FITNESS FOR A PARTICULAR PURPOSE.

BC GROUP INTERNATIONAL, INC. IS NOT LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

NO PERSON OTHER THAN AN OFFICER IS AUTHORIZED TO GIVE ANY OTHER WARRANTY OR ASSUME ANY LIABILITY.

REMEDIES: THE PURCHASER'S SOLE AND EXCLUSIVE REMEDY SHALL BE: (1) THE REPAIR OR REPLACEMENT OF DEFECTIVE PARTS OR PRODUCTS, WITHOUT CHARGE. (2) AT THE OPTION OF **BC GROUP INTERNATIONAL, INC.**, THE REFUND OF THE PURCHASE PRICE.

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