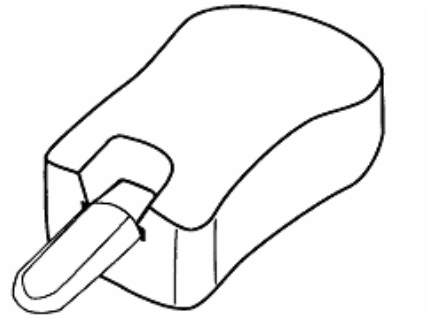
INSTRUCTION AND SERVICE MANUAL

BC BIOMEDICAL FINGERSIM™ PULSE OXIMETER TEST SYSTEM



BC Biomedical
BC Group International, Inc.
9415 Gentry Ave.
St. Louis, MO 63125

PROBLEMS?
Check Section XII
"Trouble Shooting Chart"

then, if still troubled call:

BC Biomedical Customer Support
800-242-8428
314-638-3800
FAX 314-638-3200

CONTENTS

FIGURES

I. GENERAL WARNINGS AND CAUTIONS

CONTRAINDICATION: 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: Federal law restricts this device to sale by or on the order of a physician.

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 Charts 6, 7 and 8 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. Insert the Phantom as shown in Figure 7.

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 BC Biomedical 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 BC Biomedical FingerSim™ System, when used as an adjunct to other indicators, aids the healthcare professional in assessing performance of both oximeter and sensor.

CONTRAINDICATION: 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 BC Biomedical 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.

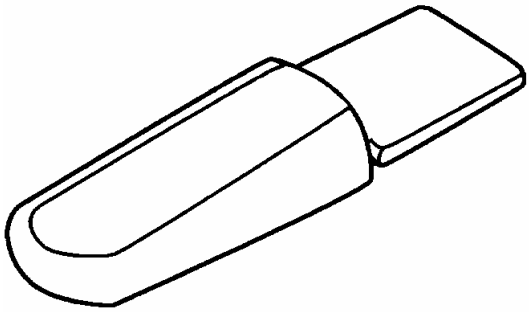


Figure 1. BC Biomedical FingerSim™

A holder is provided to stabilize the FingerSim™ while the pulsatile movement of the internal solution is generated.

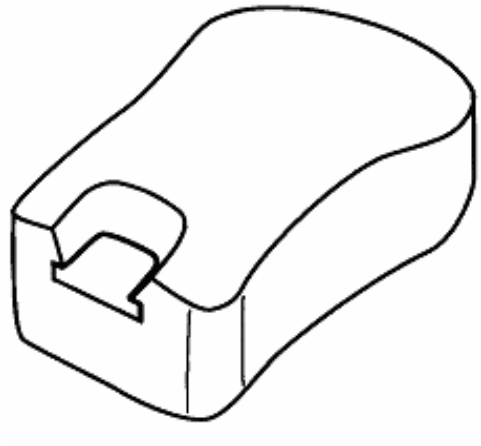


Figure 2. BC Biomedical Replacement Holder

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 (see Figures 3, 4, and 5).

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 and inevitably some differences have developed (see "Health Devices" June 1989). In addition, minor SpO_2 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.

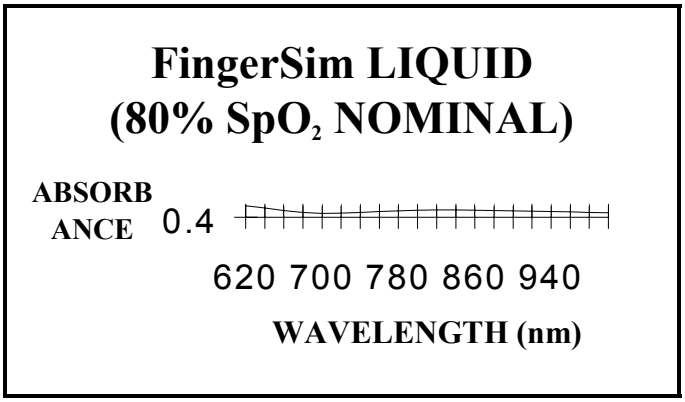


Figure 3. 80% SpO_2 Absorption Spectrum

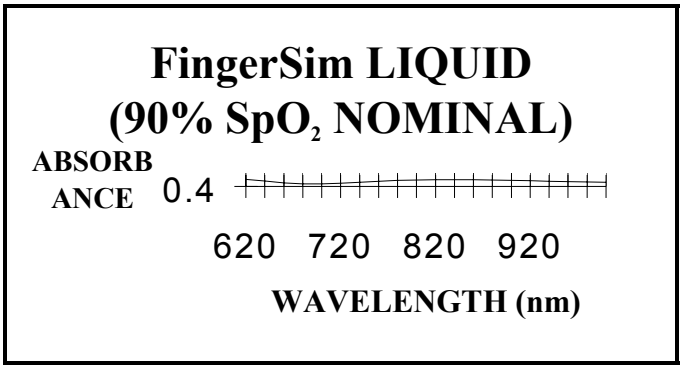


Figure 4. 90% SpO_2 Absorption Spectrum

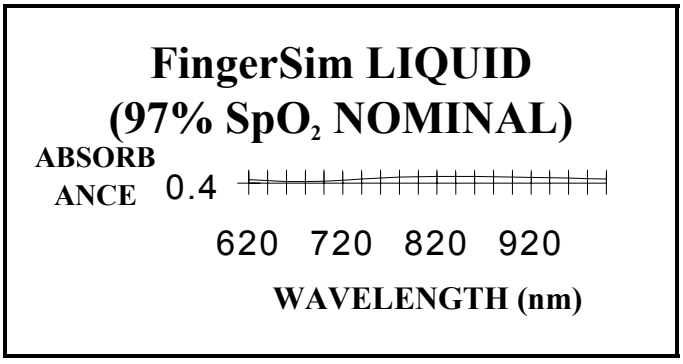
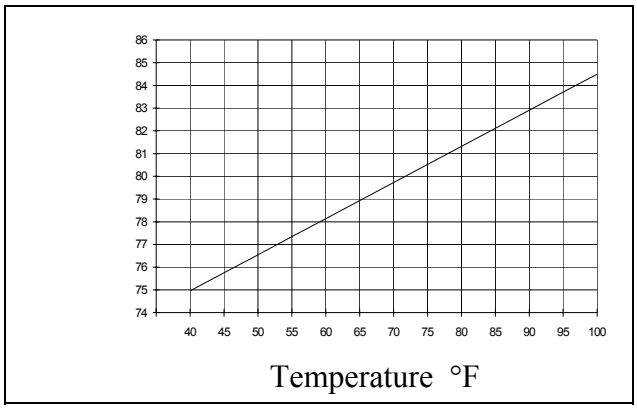


Figure 5. 97% SpO_2 Absorption Spectrum

V. CONDITIONS THAT AFFECT USE

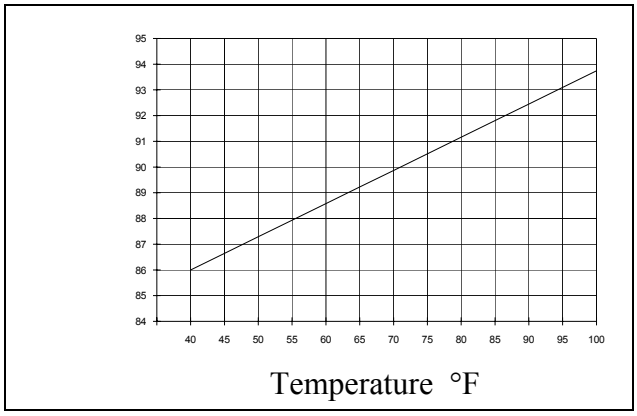
A. Ambient Temperature

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 6, 7 and 8 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%.



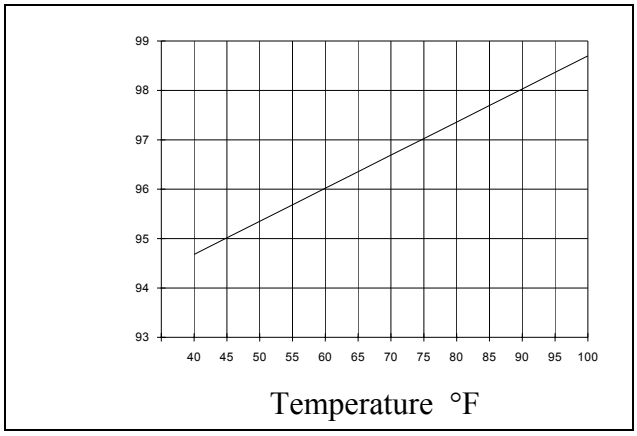
Simulated SpO_2 change with Ambient Temperature 80% FingerSim™

Figure 6. 80% SpO_2 Temperature Dependence



Simulated SpO_2 change with Ambient Temperature 90% FingerSim™

Figure 7. 90% SpO_2 Temperature Dependence



Simulated SpO_2 change with Ambient Temperature 97% FingerSim™

Figure 8. 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 ¼" to ½" 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 9).

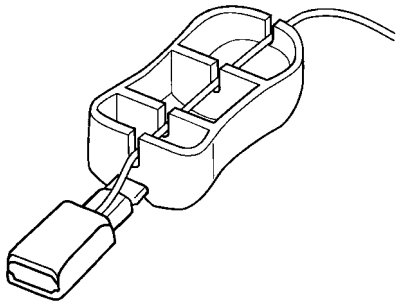


Figure 9. Sensor Cable Routing Through Holder

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 ¼" to ½" 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. See Charts 6, 7 and 8 for the appropriate adjustment. 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 10).

CAUTION: Improper insertion of the FingerSim™ into the Holder can cause breakage. Insert the FingerSim™ as shown in Figure 10.

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.

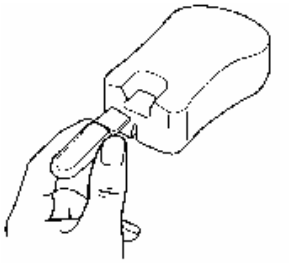


Figure 10. Positioning the FingerSim™ in the Holder

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 ¼" and ½" from the tip of the FingerSim™.

CONTRAINDICATION: 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 11).
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.

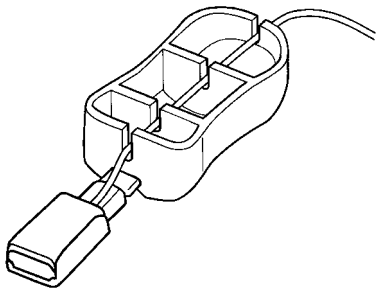


Figure 11. Sensor Cable Routing Through Holder

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 FingerSim's™ color coded end rhythmically keeping a minimum pressure on the FingerSim™ throughout the pulse cycle (see Figure 12). 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).

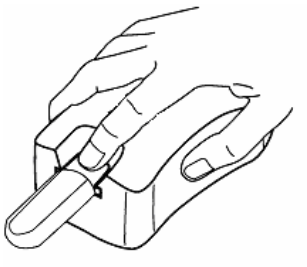


Figure 12. Generating a Simulated Pulse

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	.72”
Thickness	.50”
Overall Infrared Light Absorption d.c.)	20dB to 40dB
Overall Red Light Absorption (d.c.)	20dB to 40dB
Operating Temperature Range	65° F to 90° F
Long Term Storage Temperature Range	32° F to 104° F
Typical infrared percent modulation when squeezed	0 to 5 %

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. WARRANTY

BC GROUP INTERNATIONAL, INC. (BC Biomedical) warrants to the purchaser that each FingerSim™ shall be free of defects in materials and workmanship such that each system when properly used shall perform to specifications supplied within this manual until the calibration date marked on the FingerSim™ has elapsed. Note: This warranty specifically excludes any internal glass breakage. BC Biomedical shall replace all FingerSims™ or accessories found to be defective in accordance with this warranty, free of charge, for which BC Biomedical has been notified by the purchaser that there is a defect, provided said notification occurs within the applicable warranty period (i.e. before the calibration date). This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any FingerSims™ or accessories delivered to the purchaser which are found to be defective in any manner whether such remedies be in contract, tort or by law.

The FingerSim™ contains a substance prepared to very exact proportion and are assembled under precise specifications. They are not repairable and must be replaced at the first sign of deterioration or damage. Any sign of tampering or any kind of misuse or abuse shall void the warranty in its entirety.

DISCLAIMER/EXCLUSIVITY OF WARRANTY. THE EXPRESS WARRANTIES SET FORTH IN THIS MANUAL (SECTION X) ARE EXCLUSIVE AND NO OTHER WARRANTIES OF ANY KIND, WHETHER STATUTORY, WRITTEN, ORAL, OR IMPLIED INCLUDING WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY SHALL APPLY.

XI. 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

XII. 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 1 hour stabilization at room temperature .
	• Room temperature not at 72.5° F.	• Adjust expected SpO_2 value (see Charts 6, 7, and 8).
	• 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.
• 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.

For further information contact:

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March 20, 2003