

Index 2MF

SpO2 Simulator

Users Manual

Warranty and Product Support

Fluke Biomedical warrants this instrument against defects in materials and workmanship for one full year from the date of original purchase. During the warranty period, we will repair or, at our option, replace at no charge a product that proves to be defective, provided you return the product, shipping prepaid, to Fluke Biomedical. This warranty does not apply if the product has been damaged by accident or misuse or as the result of service or modification by other than Fluke Biomedical. **IN NO EVENT SHALL FLUKE BIOMEDICAL BE LIABLE FOR CONSEQUENTIAL DAMAGES.**

Only serialized products and their accessory items (those products and items bearing a distinct serial number tag) are covered under this one-year warranty. **PHYSICAL DAMAGE CAUSED BY MISUSE OR PHYSICAL ABUSE IS NOT COVERED UNDER THE WARRANTY.** Items such as cables and nonserialized modules are not covered under this warranty.

Recalibration of instruments is not covered under the warranty.

This warranty gives you specific legal rights, and you may also have other rights which vary from state to state, province to province, or country to country. This warranty is limited to repairing the instrument to Fluke Biomedical's specifications.

Warranty Disclaimer

Should you elect to have your instrument serviced and/or calibrated by someone other than Fluke Biomedical, please be advised that the original warranty covering your product becomes void when the tamper-resistant Quality Seal is removed or broken without proper factory authorization. We strongly recommend, therefore, that you send your instrument to Fluke Biomedical for factory service and calibration, especially during the original warranty period.

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Follow standard receiving practices upon receipt of the instrument. Check the shipping carton for damage. If damage is found, stop unpacking the instrument. Notify the carrier and ask for an agent to be present while the instrument is unpacked. There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. Inspect the instrument for physical damage such as bent or broken parts, dents, or scratches.

Technical Support

For application support or answers to technical questions, either email techservices@flukebiomedical.com or call 1-800- 850-4608 or 1-440-248-9300.

Claims

Our routine method of shipment is via common carrier, FOB origin. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim. If the instrument is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact Fluke Biomedical or your local sales representative.

Standard Terms and Conditions

Refunds and Credits

Please note that only serialized products and their accessory items (i.e., products and items bearing a distinct serial number tag) are eligible for partial refund and/or credit. Nonserialized parts and accessory items (e.g., cables, carrying cases, auxiliary modules, etc.) are not eligible for return or refund. Only products returned within 90 days from the date of original purchase are eligible for refund/credit. In order to receive a partial refund/credit of a product purchase price on a serialized product, the product must not have been damaged by the customer or by the carrier chosen by the customer to return the goods, and the product must be returned complete (meaning with all manuals, cables, accessories, etc.) and in “as new” and resalable condition. Products not returned within 90 days of purchase, or products which are not in “as new” and resalable condition, are not eligible for credit return and will be returned to the customer. The Return Procedure (see below) must be followed to assure prompt refund/credit.

Restocking Charges

Products returned within 30 days of original purchase are subject to a minimum restocking fee of 15 %. Products returned in excess of 30 days after purchase, but prior to 90 days, are subject to a minimum restocking fee of 20 %. Additional charges for damage and/or missing parts and accessories will be applied to all returns.

Return Procedure

All items being returned (including all warranty-claim shipments) must be sent freight-prepaid to our factory location. When you return an instrument to Fluke Biomedical, we recommend using United Parcel Service, Federal Express, or Air Parcel Post. We also recommend that you insure your shipment for its actual replacement cost. Fluke Biomedical will not be responsible for lost shipments or instruments that are received in damaged condition due to improper packaging or handling.

Use the original carton and packaging material for shipment. If they are not available, we recommend the following guide for repackaging:

- Use a double-walled carton of sufficient strength for the weight being shipped.
- Use heavy paper or cardboard to protect all instrument surfaces. Use nonabrasive material around all projecting parts.
- Use at least four inches of tightly packed, industry-approved, shock-absorbent material around the instrument.

Returns for partial refund/credit:

Every product returned for refund/credit must be accompanied by a Return Material Authorization (RMA) number, obtained from our Order Entry Group at 1-800- 850-4608 or 1-440-248-9300.

Repair and calibration:

To find the nearest service center, goto www.flukebiomedical.com/service, or

In the U.S.A.:

Cleveland Calibration Lab

Tel: 1-800-850-4606

Email: globalcal@flukebiomedical.com

Everett Calibration Lab

Tel: 1-888-993-5853

Email: service.status@fluke.com

In Europe, Middle East, and Africa:

Eindhoven Calibration Lab

Tel: +31-402-675300

Email: ServiceDesk@fluke.com

In Asia:

Everett Calibration Lab

Tel: +425-446-6945

Email: service.international@fluke.com

Certification

This instrument was thoroughly tested and inspected. It was found to meet Fluke Biomedical's manufacturing specifications when it was shipped from the factory. Calibration measurements are traceable to the National Institute of Standards and Technology (NIST). Devices for which there are no NIST calibration standards are measured against in-house performance standards using accepted test procedures.

WARNING

Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazards or improper operation. Fluke Biomedical will not be responsible for any injuries sustained due to unauthorized equipment modifications.

Restrictions and Liabilities

Information in this document is subject to change and does not represent a commitment by Fluke Biomedical. Changes made to the information in this document will be incorporated in new editions of the publication. No responsibility is assumed by Fluke Biomedical for the use or reliability of software or equipment that is not supplied by Fluke Biomedical, or by its affiliated dealers.

Manufacturing Location

The Index 2MF Pulse Oximeter Analyzer is manufactured in Everett, Washington by Fluke Biomedical, 6920 Seaway Blvd., Everett, WA, U.S.A.

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Chapter 1

Introducing the Index 2MF

Capabilities

The Index 2MF SpO₂ Simulator (hereafter the Simulator) allows accurate verification of pulse oximeters by allowing you to test them in a variety of ways. The Simulator provides simulations that allow thorough testing of the complete pulse oximeter, including the optical sensors.

For the first time, there is now a reliable way to gauge the condition and performance of standard pulse oximeters. Fluke Biomedical provided the Simulator to the medical and health industry to allow measuring pulse oximeters currently on the market against widely accepted performance standards.

Using the Simulator as a virtual patient's index finger, you set the the Simulator to simulate a patient with virtually any combination of blood oxygen conditions. When the pulse oximeter under test connects to the Simulator, measure its responses against a set of predetermined readings for a patient with the preset saturation levels and pulse conditions. This procedure matches the pulse oximeter's results against the simulations. Electrically, the Simulator can verify probe diodes, wire continuity, LEDs, and oximeter accuracy.

Like all of Fluke Biomedical's hardware and software systems, the Simulator is backed by Fluke Biomedical's superior support system. If the Simulator ever fails to work perfectly, please refer to the phone, fax, and Internet numbers at front of this book to contact Fluke Biomedical's Technical Support Staff.

Index 2MF Compatibility

The Simulator can quickly establish the state of any given pulse oximeter and determine the performance qualities of the device. The Simulator can test and evaluate most oximeters in the market today.

Because each pulse oximeter manufacturer uses a slightly different technology and algorithm to measure SpO₂ (Saturation of Peripheral Oxygen), Fluke Biomedical has pre-programmed into the Simulator a number of different R-values versus SpO₂ curves for specific manufacturers. This ensures that the Simulator provides the closest possible simulation. It is also possible to download additional R-value curves directly into the Simulator for non-volatile storage and use. Additionally, the MFE version of the Simulator has adapter cables to test most popular oximeters and probes through electrical simulations.

Note

The Simulator is not intended to be a pulse oximeter calibrator.

Index 2MF Features

- Conduct saturated peripheral oxygen (SPO₂) simulations with saturation levels between 35% and 100% (in 1% increments)
- Complete probe and electronics assembly testing either optically or electrically (FE version only)
- Probe continuity check (MFE version)
- Variable heart rate settings from 30 beats per minute to 250
- Preset simulations reproduce several patient conditions
- Alarm tests for response time, recovery time, and pulse amplitude
- Portable, weighing in at under 3 pounds, with a 10" x 10" footprint
- Programmable auto sequences
- Computer controllable
- Menu driven with softkey interface and 2-line by 24-character LCD (liquid crystal display) supertwist, alphanumeric display
- Rechargeable lead acid battery, with 8 hours of continuous operation and built-in low battery indicator

Package Contents

The contents of the Simulator package as shipped include:

F Version

- Index 2MF Pulse Oximeter Tester
- Battery Charger
- User's Guide and Registration Card

FE Version

- Index 2MF Pulse Oximeter Tester
- Battery Charger
- Users Guide and Registration Card
- Ohmeda and Nellcor Probe and Oximeter Adapter (electrical cables)

Registration Card

Once the the Simulator is successfully up and running, complete the postage-paid registration card and mail it to Fluke Biomedical.

Precautions

Observe these precautions when using the Simulator; like any electronic equipment, it should be adequately protected both when moving and in storage.

⚠ Caution

When connecting the Simulator to a peripheral, such as a PC's RS232 serial port or printer, power OFF both the Simulator and the peripheral device during connection and disconnection. Failure to follow this precaution may result in damage to the equipment.

The Simulator battery life can be seriously shortened by leaving the instrument turned on for many hours after the low battery alarm sounds. To avoid damage:

- Package and handle the Simulator to ensure that the power switch cannot accidentally turn on during shipment.
- Always connect the Simulator to its charger when not in use. The Simulator allows continuous charging, a practice that ensures full power charge whenever needed. The Simulator may also be used while charging.
- Always turn off the Simulator and connect it to its charger when the low battery alarm sounds. The Simulator can be used within about 1 minute of commencing charge. The Simulator picks up two or more hours of battery run-time for each hour of charger connect time, even when running with the charger connected.
- Avoid placing the Simulator in contact with, or in close proximity to, Electrosurgery units (ESUs), MRIs, and defibrillators.
- Only use an appropriately rated battery charger to avoid damage to the Simulator's battery. Based on the testing below, the Simulator bears the CE mark.

Electromagnetic Interference and Susceptibility

EC EMC Directive 89/336/EEC

EN 50081-1, CLASS A-Emissions

The Simulator has been type tested by an independent testing laboratory and found to meet the requirements of EC Directive 89/336/EEC for Radiated Emissions and Line Conducted Emissions. Verification was to the limits and methods of EN 55011. The device is classified as EN 55011, Group 1, Class A.

EN 50082-1 Immunity

The Simulator was also tested and found to meet requirements for Electrostatic Discharge Susceptibility, Radiated Susceptibility, and Electrical Fast Transient/Burst Susceptibility. Verification of compliance was conducted to the limits and methods of EN 50082-1:1992, IEC 801-2, IEC 801-3, and IEC 801-4.

Note

If using a battery charger while the Simulator is in the Electrical Simulation Mode, the user may observe a spike in the voltage on the line to the battery charger, thereby producing erratic results. If you suspect this has occurred, retest the oximeter with the battery charger disconnected.

USA FCC CLASS A

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules.

These limits provide reasonable protection against harmful interference when operating the equipment in a commercial environment. Like similar medical equipment, this

equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area could cause interference, in which case the user will be required to correct the interference.

Canadian Department of Communications Class A

This digital apparatus does not exceed Class A limits for radio emissions from digital apparatus set out in the Radio Interference Regulations of the Canadian Department of Communications.

Le present appareil numerique n'emet pas du bruits radioelectriques depassant les limites applicables aux appareils numerique de la Class A prescrites dans le Reglement sur le brouillage radioelectrique edicte par le ministere des Communications du Canada.

Note

The Simulator, like many pulse oximeters, may have its operation affected by strong electromagnetic sources, such as electrosurgery equipment. It may also be affected by imaging equipment, such as Magnetic Resonance Imaging (MRI). It is the user's responsibility to verify performance of the Simulator prior to use in these kinds of environments.

Safety

The Simulator is a battery-powered device which operates at voltages that are considered intrinsically safe. Independent laboratory approval to a test standard is thus not required. The battery charger used must meet the safety requirements for your country.

EC Directive 73/23/EEC, Low-Voltage Directive

The Simulator operates below 75 VDC, thus EN 61010-1 is not applicable.

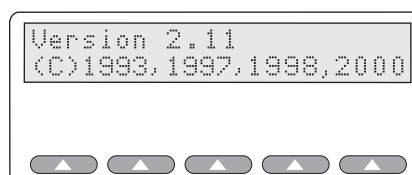
Getting Started

Unpack the Simulator from the shipping carton. Check that the shipment is complete and all parts are intact.

Starting the Simulator and Using Menus

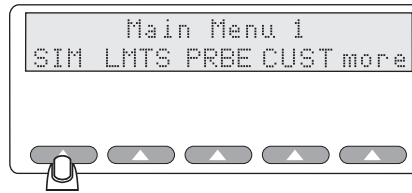
Slide the power switch to the "I" (on) position to power up the system. The LCD sequentially displays the following screens for about two seconds each before ending on the Main Menu 1 screen:

- Bio-Tek Instruments Inc. with model number and version
- Software version number and copyright years
- Make of last selected R-curve
- Main Menu 1 screen



esl001.eps

When the Main Menu 1 displays in the LCD, the following options are available:



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The Main Menu 1 consists of the primary test functions available to the Simulator, with the softkeys **SIM**, **LMTS**, **PRBE**, **CUST**, and **more**. Press the up arrow below the menu item to select a menu option, change a setting, or to advance to additional menus.

Note

If you see a message warning you that your battery is low, you need to attach the battery charger. Call Fluke Biomedical for assistance if needed.

Toggle between Main Menu 1 and Main Menu 2 with the **more** softkey.

For example, you have these options at the Main Menu 1 screen:

Press the softkey **SIM**, and then **MAN** to open the Simulations menu. The menu “Simulations:” appears in the Simulator LCD. This menu allows you to set oxygen saturation levels and heart rate in beats-per-minute (BPM).

Press the softkey **MAN** to set the SpO₂ levels from 35 to 100%, and the heart rate from 25 to 250 BPM.

1. The LCD indicates current SpO₂ level and BPM. Additional softkey options now available allow you to set the SpO₂ levels (**02+** and **02-**), as well as increase and decrease the BPM (**BPM+** and **BPM-**).

Return to the previous menu, Main Menu 1, by pressing the **esc** softkey. For detailed information on using the test features, refer to the relevant chapter in this users guide.

Using the Optical Finger Probe (All Versions)

Connect the finger probe of the pulse oximeter under test to the Simulator finger probe attachment. Position the pulse oximeter LEDs on the bottom of the Simulator finger probe attachment.

From the Main Menu 1, select the SpO₂ and Heart Rate settings by pressing the appropriate **+** or **-** (plus or minus) keys, and viewing the settings displayed on the the Simulator LCD.

Note

Oximeters take from 5 to 20 pulses to respond to a change in simulated SpO₂ or BPM.

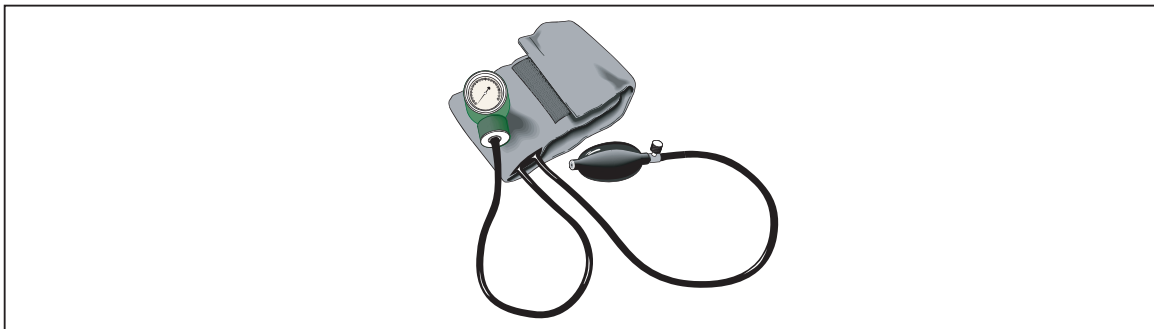
Chapter 2

Blood Oxygen and Pulse Oximeters

Blood Pressure

Blood pressure readings provide valuable information about the condition of our bodies, indicating health or the lack of it. As the heart contracts (*systole*) and relaxes (*diastole*), the volume of freshly-oxygenated blood increases and decreases measurably within the artery walls. This action causes the artery walls to expand and contract in rhythm with the heart. The force of the blood exerted upon the artery walls is what is called *blood pressure*. Contraction produces the highest pressure, and relaxation the lowest.

A sphygmomanometer (shown in Figure 2-1) is one tool for measuring blood pressure. When our blood pressure is taken, it is measured at the brachial artery in the forearm in millimeters of mercury (*mmHg*). If our blood pressure reading is at or near 120 mmHg (*systolic*) over 80 mmHg (*diastolic*), we are considered to be in peak health, all else being normal.



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Figure 2-1. Sphygmomanometer

Gases in Blood

Blood pressure is not the whole story, however, since the exact concentration of gases such as carbon dioxide and especially oxygen in your blood cannot be determined by a simple blood pressure test.

To determine gas concentrations accurately, specifically saturated oxygen, a blood-gas sensing device must be used, and must be capable of detecting the wide range of nominal values for these gases. Gas concentrations in blood, specifically oxygen (O_2) and carbon

dioxide (CO₂), can be expressed as milliliters of gas per liter of blood, and can be indicated by the partial pressure that the gases exert in your blood at a given temperature.

Pulse Oximeters

Because of their ease of use in many hospital- and critical-care situations, pulse oximeters have greatly increased in popularity since their introduction. Today, pulse oximeters are virtually required equipment in situations where the monitoring of arterial oxygen saturation (SaO₂) is essential, such as when anesthesia is in use, both during an operation and in post-operative recovery, intensive care, transport, and patient home care.

Pulse oximeters have proven to be capable and reliable, being highly accurate in measuring blood SaO₂ in the range of 80-100%, while at the same time needing little, if any, calibration. No patient preparation is required before using the pulse oximeter; in addition, the devices are so simple to operate that specialized training is unnecessary.

How Pulse Oximeters Work

Pulse oximeters are defined as non-invasive, arterial, oxygen-saturation monitors which measure the ratio of two principal forms of hemoglobin in the blood: saturated arterial hemoglobin (also called *oxyhemoglobin*), HbO₂/SAT, to unsaturated (or *reduced*) hemoglobin, Hb.

The arterial oxygen saturation, SaO₂, is defined as the ratio of the concentration of oxyhemoglobin (cHbO₂) to the concentration of HbO₂ + Hb (cHbO₂ + cHb). Oxygen saturation is commonly expressed as a percentage and is calculated according to the formula in Figure 2-2.

$$SaO_2 = \frac{cHbO_2}{cHbO_2 + cHb} \times 100\%$$

esi004.eps

Figure 2-2. Formula for Determining Saturated Oxygen Level

Using this information, a correctly calibrated and operating pulse oximeter can accurately predict the level of oxygen in the blood, which in turn provides valuable data about the health of a patient, and in the case of anesthesia and post-operative recovery, the status of the patient.

Spectrophotometry

Pulse oximeters operate on the principle known as *spectrophotometry*, using wavelengths of light to determine the concentration of oxygen in the blood. Because we already know the wavelengths for the light absorption of blood hemoglobin, we can mathematically determine the arterial oxygen saturation in a patient's blood.

The light emitting diodes (LED's) of a pulse oximeters shine two types of light—near infrared light (at 940 nanometers) and red light (at 660 nanometers)—wavelengths that pass through the skin and which are absorbed by both the oxyhemoglobin and the reduced hemoglobin. These light beams pass through the index finger of a patient to photo detectors on the opposite side of the pulse oximeter.

Figure 2-3 shows a typical pulse oximeter configuration, noting the location of the red and infrared LED's.

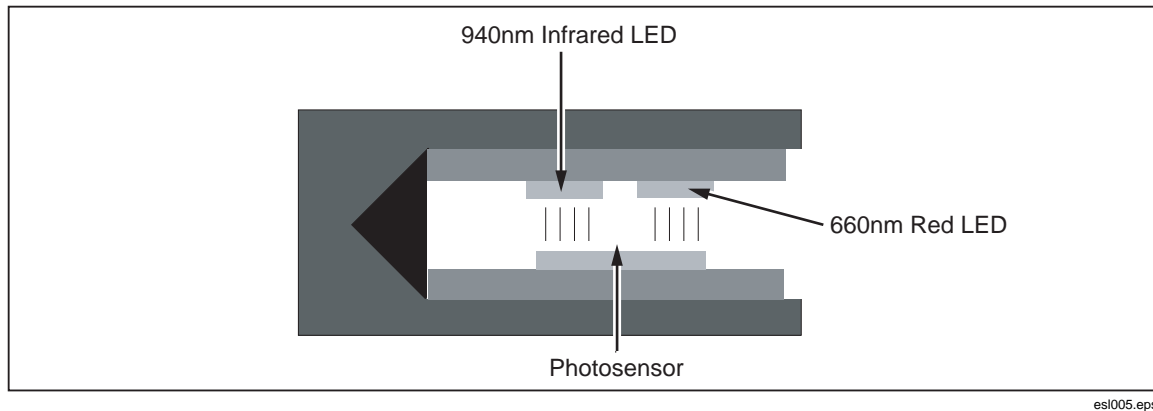


Figure 2-3. Diagram of Sample Finger Probe for a Typical Pulse Oximeter

Using this dual light emitting and sensing technology, the pulse oximeter determines the amount of light absorbed by the blood and calculates the percent of oxygen saturation (SaO_2).

However, it is not quite that simple. Pulse oximeters must also calculate out the effect of absorption caused by the presence of venous and capillary blood and soft tissue in order to obtain the true SaO_2 value. To do so, pulse oximeters use a system that distinguishes between "AC" components (the pulsating arterial blood) and "DC" components (the *non*-pulsating components mentioned just above).

Figure 2-4 shows the different AC and DC components graphically.

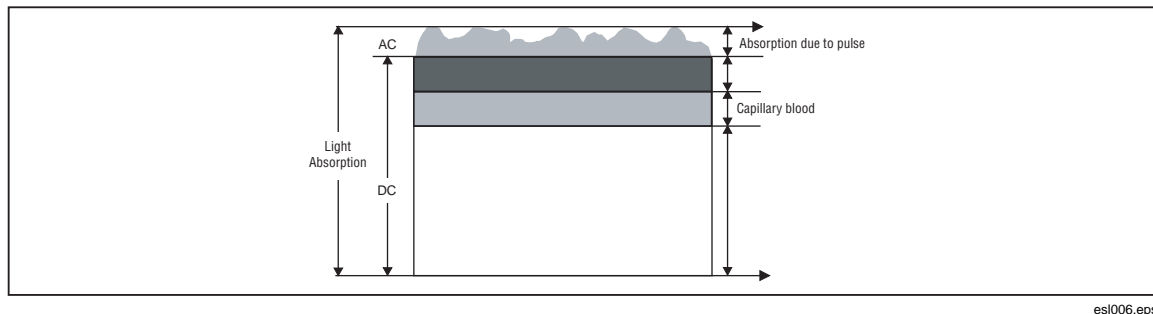


Figure 2-4. Diagram of Light Absorbers in Tissue

The pulse oximeter determines the AC component of absorbency at each wavelength and divides this by the corresponding DC (amplitude) component. This results in a "pulse-added" absorbency that is independent of the light intensity. The ratio (R) of these pulse-added absorbances is calculated using the formula shown in Figure 2-5.

$$R = \frac{AC_{660}/DC_{660}}{AC_{940}/DC_{940}}$$

Figure 2-5. AC/DC Infrared and Red Absorption Ratio

When the ratio of red-to-infrared absorbance equals 1.00, the saturation is approximately 81%.

References

- *Accuracy and Precision of Fourteen Pulse Oximeters*, B. Hannhart, *et al*, Neonatal Intensive Care, Nov./Dec. 1991.
- *Clinical Pulse Oximetry*, Thomas L. Petty, MD, Anesthesiology, v. 70, no. 1, Jan. 1989.
- *Oximetry/Blood Gas*, ---, Medical Electronics, Oct. 1989.
- *The Concise Columbia Encyclopedia*, (Columbia University Press, 1991), Microsoft Bookshelf, 1992.

Chapter 3

Index 2MF Overview

The Index 2MF "Finger"

The Simulator system has a patented optical “finger” that takes the place of an actual patient's index finger. This finger works with any pulse oximeter that detects SpO₂ (Saturation of Peripheral Oxygen) through the index finger (as opposed to the earlobe or toe) tissue.

Inserting the Index finger into the pulse oximeter probe effectively connects the two devices for testing purposes.

Note

When connecting a finger sensor, onto the Simulator's “finger,” make sure that the red LEDs (light emitting diodes) are on the bottom and that the pulse oximeter fingertip sensor is on as far as possible.

Simulator Electrical Testing (MFE Version only)

Electrical testing of oximeters is similar to optical testing. However, all electrical testing simulations are output through the electrical port on the back of the Simulator, thus eliminating the probe from the circuit. FBC makes specific cables to connect the electrical port on the Simulator to oximeter port for electrical testing. Check FBC website or price list for details about these specific cables. A separate probe check is performed via the probe port on the back of the unit that analyzes LEDs, photodiodes, and wire resistance for potential problems.

Simulation Settings

Once connected, the Simulator can simulate virtually any patient condition, with programmable SpO₂ ranges from 35% to 100%, pulse rates from 30 BPM to 250 BPM, and an amplitude factor (non-pulsatile components such as soft tissue and venous blood, also called the *DC component*) of 0% to 20%.

Running Tests

The Simulator runs through a series of simulations to test the sensitivity and performance limits of the pulse oximeter in question. You can run one test or a series of tests, with

stable or fluctuating oxygen and pulse levels. You can even connect the Simulator to a computer to control the Simulator and run all tests.

Evaluating Test Results

The Simulator is what may be called a "Transfer Standard." Such a standard lets you take measurements on an unknown device, and see how closely it compares to a known device measured with the same transfer standard (or an identical one).

Fluke Biomedical has measured the operational characteristics of different makes of oximeters, all believed to be properly calibrated and operating correctly. Users access these measurements when selecting an oximeter *make* for testing.

For a Transfer Standard such as the Simulator, simulating devices which have readout resolutions of 1 % (oximeters) or repeatability of simulations better than 1 % is mandatory. The Simulator repeatability is conservatively specified at better than ± 1 standard deviation.

In Fluke Biomedical's experience with oximeters characterized by *make*, oximeters track the SpO₂ simulations typically within 1 % to 2 % from 100 % - 60 %. Below 60 %, many pulse oximeters have unspecified accuracies; results can vary widely. That means, for example, that if you have set up a simulation of 92 %, you can expect your oximeter to read 92 %, ± 1 %.

Print results for study and archiving purposes directly from the Simulator via the built-in serial RS-232 port or the Centronics parallel printer port. Results can also be sent over a serial cable directly to a computer, for onscreen evaluation or storage in a database.

Simulator Functionality

Figure 3-1 illustrates the basic functions of the Simulator system.

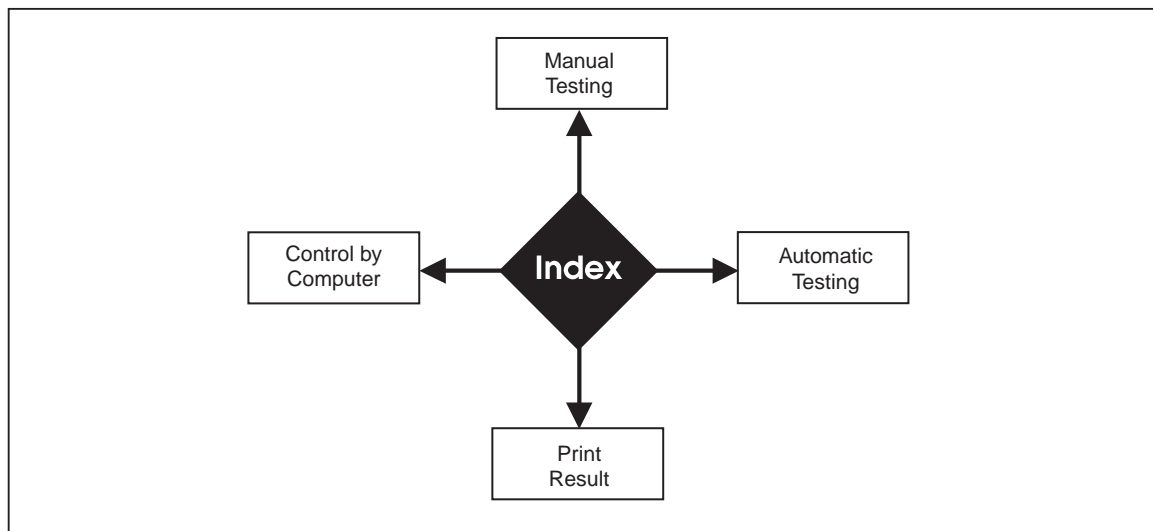


Figure 3-1. Basic Simulator Functions

esl008.eps

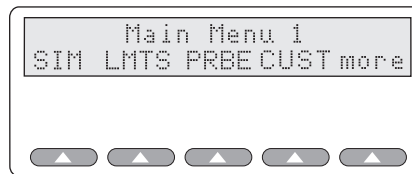
Chapter 4

The Main Menus

Introduction

When you first turn on the Simulator, it sequentially displays the following screens for about one second each before ending with the Main Menu 1 screen:

- Bio-Tek Instruments Inc. and model number and version
- Software version number and copyright years
- Make of last selected R-curve



esl009.eps

Note

If at power-up, the batteries are low and in need of recharging, the message “WARNING! BATTERY LOW!” appears on the LCD.

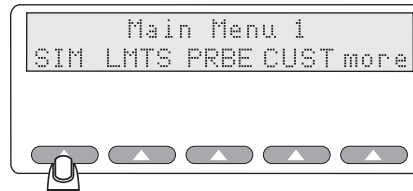
The Main Menu 1

The Main Menu 1 choices give you access to the full Simulator system. This section explains each softkey and its associated menu choices.

Note

*Pressing the **esc** softkey (visible in many menu screens) returns you to a previous menu. Pressing **more**, when visible, toggles between menus.*

SIM lets you set oxygen saturation levels and heart rates (BPM.)

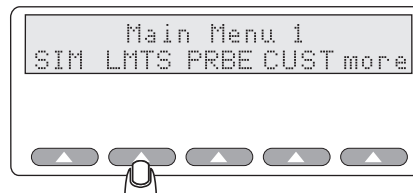


fgg010.eps

Selecting **SIM** opens the menu displaying the following:

- **MAN** to run manual simulations
- **PRESET** to run factory-defined simulations
- **AMB** to set ambient light levels
- **CUST** to create custom makes
- **esc** softkey to return to Main Menu 1

LMTS lets you set the alarm limits for oxygen, beats per minute, pulse amplitude, and lets you set up a timer for asystole.

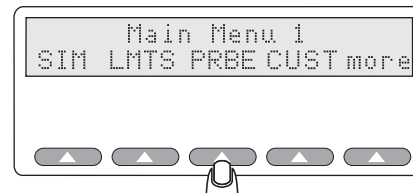


fgg011.eps

Selecting **LMTS** opens the menu displaying the following:

- **O2** to set up SpO2 alarm limits level and response time
- **BPM** to set up rate alarm limits and response time
- **AMP** to select pulse amplitude limits
- **ASYS** to set up asystole

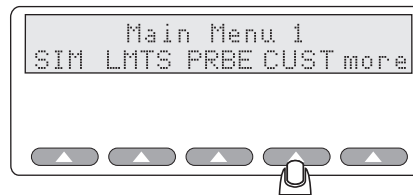
PRBE offers the electrical probe test menu to analyze oximeter probe integrity. Tests include LED voltages, photo diode results, and pin-to-pin resistance.



fgg012.eps

Selecting **PRBE** tests attached probes and displays the following options:

- **LEDS** to view the red and infrared LEDs
- **PHTO** to view photo diode results
- **RES** to view pin-to-pin resistance
- **REDO** (requires an attached probe)
- **esc** softkey to return to Main Menu 1

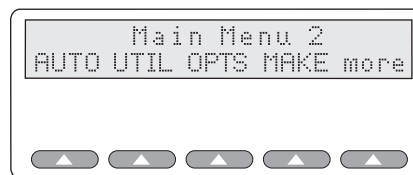


fgg013.eps

The **CUST** menu options are for creating custom makes by choosing a light technology and R-Curve. This custom make can be stored for later use. Custom makes are used when the pulse oximeter being tested is not in the factory preset makes.

The Main Menu 2

The softkey **more** toggles between Main Menu 1 and Main Menu 2. Main Menu 2 allows you to select a pulse oximeter type by make, configure the Simulator serial (RS232) port, and adjust the contrast of the LCD screen.



fgg161.eps

The choices available at the Main Menu 2 include:

- **AUTO** to create and run tailored test procedures
- **UTIL** to change the display and configure the RS232
- **OPTS** to open the Advanced Options menu
- **MAKE** to select the pulse oximeter being tested
- **more** to toggle Main Menu 1

Each of these Main Menu choices is discussed separately in the next few chapters.

Note

*Pressing **esc** at any point within the Simulator will always return you to any previous menu, until you have returned to Main Menu 1 or 2.*

Chapter 5

Configuring the Simulator

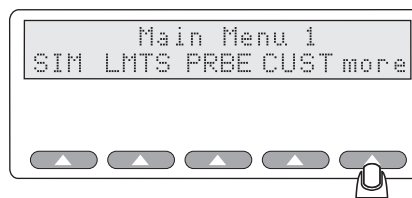
Configuring for Specific Oximeter Make

Light technology and R-Curve data must be known in order to test a pulse oximeter, optically via finger or electrically. You can configure the Simulator to match the make of pulse oximeter(s) you will be testing. The Simulator stores the definitions for different makes of pulse oximeters. You can change variables for each of the pulse oximeter types to match the devices you will be testing.

Accessing the Make Menu

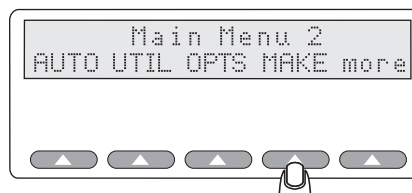
Change the make of the pulse oximeter stored in the Simulator's memory using the Make menu.

1. To get to the Make menu, press **more** from Main Menu 1.



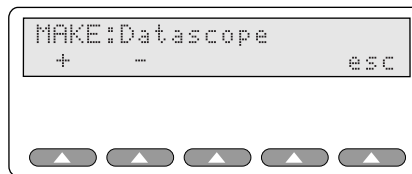
fgg014.eps

2. You will then see the screen for the Main Menu 2. Press the softkey **MAKE**.



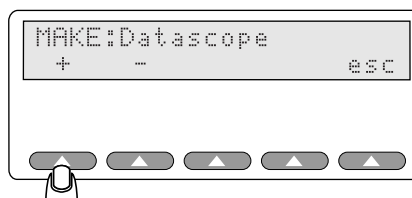
fgg169.eps

You will see the following appear in the Simulator's LCD display:



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3. Press the softkey for the **+** or **-** to scroll through the Simulator's pre-programmed pulse oximeter makes and models. In the screen that follows, the selected make is the Datascope.



esl017.eps

4. To return to Main Menu 2, press **esc**.
5. Then, to return to Main Menu 1, press the softkey **more**.

Verified Oximeter Makes

The following makes of oximeters have been verified as working properly, both electronically and with their probes, and are pre-programmed into the Simulator:

- BCI[®] (3101)
- Criticare[®] (504)
- Datascope[®] (Passport)
- Datex[®] (CardioCap, Ultima, Satellite Trans, AS/3, 251)
- HP[®] (Merlin)
- Masimo[®]
- Nellcor[®] (N-100, 200)
- Nihon-Kohden[®] (Lifescope)
- Ohmeda[®] (3700) and Nova
- Respironics[®]

R-Curve Specifications

Fluke Biomedical, in cooperation with the manufacturers, developed the R-Curves for the devices listed previously.

Note

The cooperative venture does not represent an endorsement of Index 2MF by these manufacturers. Fluke Biomedical assumes the responsibility for the R-Curves, and any results obtained from the use of Index 2MF.

Note

Some oximeters utilize technology and probes licensed from other manufacturers. The R-Curve selected must correspond to the technology used to ensure accurate results. Please consult oximeter manufacturer for the correct technology and corresponding R-Curve within the Simulator.

⚠ Caution

Other manufacturers' oximeters can be electronically tested by the Simulator, but will require special care in preparation of an adapter cable and interpretation of the results. Damage could occur to the Simulator or the oximeter if the adapter cable is not correct. See the "Customizing a Make Not Included Within Index 2MF" section in this chapter for more information.

Note

*Six additional manufacturer's profiles are incorporated in the Simulator. These six profiles may be changed at the Download Make menu by selecting **Make** at Main Menu 2. Additionally, five CUSTOM R-Curves can be stored in the Simulator. Refer to Appendix E, Computer Control, for information on how to download a manufacturer's profile into the Simulator.*

- Sat-trak®
- Nonin Onyx®
- N-10
- Palco 300®
- Invivo®
- Invivo®*

* The R-Curves for these devices are specified from 100 to 80% O₂ only.

Customizing a Make Not Included Within Index 2MF

The MF version of the simulator has incorporated many popular oximeter makes into its data base. Unfortunately, there are many more manufacturers that cannot be incorporated due to Simulator resource limitations and oximeter availability.

The Simulator has a "custom make" feature that allows you to create a make using just the oximeter. The Simulator requires two elements to perform a simulation on a given oximeter: Technology of light or light intensity and R-Curve. The Simulator will work with most oximeters with excellent results once these choices are entered. These two elements can be obtained from the manufacturer directly, or by trial and error. Table 5-1 lists typical oximeters that have the various technology options and Table 5-2 lists oximeters with their R-Curve parameters.

Note

The Simulator accuracy specifications are not valid for user defined custom makes. The Simulator can provide specified repeatability of ± 1 standard deviation.

Table 5-1. Oximeters with Technology Options

Technology Options	Typical Oximeters
Normal Intensity	Nellcor, BCI
Low Intensity	Hewlett-Packard, Ohmeda, Invivo
High Intensity	Datex
Very High Intensity	None known

Table 5-2. Oximeters with R-Curve Parameters

Curve No.	Brand	HiOx Level Oxy @ R = 0.7	LoOx Level Oxy @ R = 1.0
1	BCI	93	82/83
2	Criticare	94	80/79
3	Datascope	94	85
4	Datex	95	84
5	Hewlett-Packard	96	85
6	Nellcor	93	80
7	Hihon Kohden	94	84
8	Novamatrix	96	87/88
9	Ohmeda	95	86/85
10	Respironics	93	80

Once a technology and a curve have been determined, save the custom make for future use.

Operation

To access the custom menu, press **CUST** from the main menu.

Chose the slot to customize by pressing **+CST** to cycle through the available names. Custom #1 through #5 are the default factory names. To change the name press **NAME**.

There are five available slots for saving custom makes. Press **+** or **-** to change the alphabet. Press **→** to move the character. Press **SAVE** to save the name and the results.

Press **TEC** to test for technology type.

Select the appropriate technology type #1 - #4. Technology types offer various light level thresholds. Refer to Table 5-1 for a list of technology light levels. The technology to use may already be known based on the manufacturer's information. If not, continue for process of elimination testing.

Press **HiOx** to test oximeter stabuility at the high oxygen setting.

The beeper sounds and the menu changes to HiOx. With the oximeter probe connected to the Simulator, look for a steady reading on the oximeter. The number may be in the low 90s, but not necessarily. If the oximeter is not displaying a stable number, change technology types again to find a stable reading.

Once a stable reading has been obtained, press **LoOx** to verify that the pulse oximeter is stable at low oxygen levels. The number should be near 80%, but may be further away. Change technology types to find a stable reading.

Press **HiOx** once more after a stable reading is achieved at low oxygen levels to verify that high oxygen is still stable. Once a technology is found that locks on and gives stable readings at low and high oxygen levels, note these readings as seen on the oximeter and refer to the R-Curve list in Table 5-2.

Find a high level and low level that are similar to your readings and move to the left of the chart for a curve number to use in the next step. Press CRV to advance to the next and final step.

Choose an R-Curve that best fits this oximeter.

To do this, press **+CRV** to advance through the list of installed MFG R-Curves by number. See Table 5-2. This number was determined in the previous step.

Use the **+O2** and **-O2** keys to verify that the oximeter tracks the curve up and down the O₂ scale (70 to 100 % should be sufficient). Once a best curve fit is determined, press **SAVE** to save the custom make.

The custom make appears in the make list in Main Menu 2.

Note

“Custom Make” percent O2 accuracy is not guaranteed. The Simulator can only guarantee accuracy of repeatability in this mode of operation.

Chapter 6

Setting and Changing Simulation Factors

About Simulations and Presets

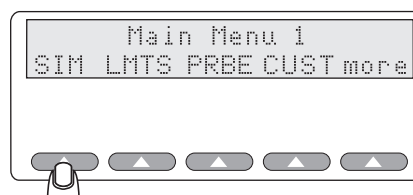
One of the main functions of the Simulator is to test the performance of a pulse oximeter for any possible patient condition. The Simulator allows you to set any combination of blood-oxygen levels, heart rates, and pulse amplitude, as well as simulate a virtual range of medical physical conditions and set an ambient light artifact.

Setting this group of default factors allows you to test an oximeter and determine its weaknesses, if any. The Simulator will display and optionally print areas in your pulse oximeter performance that may be unacceptable, and document correct performance.

The simulations set here are used as the defaults when testing the pulse oximeter.

Setting Simulations

To access the Simulations Menu, press the softkey **SIM** from the Main Menu.



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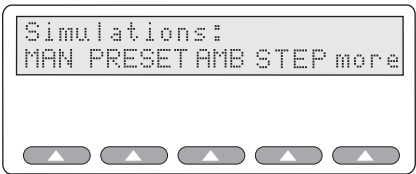
The Simulations Menu

The Simulations menu appears in the LCD with these choices:

- **MAN** to manually set the O2 and BPM
- **PRESET** to set a patient's health condition
- **AMB** to set an ambient light artifact
- **STEP** to change step size for saturation and BPM
- **esc** to return to previous menu (Main Menu 1)

Note

Do not connect the MFE version to two pulse oximeters simultaneously. The simulator must synchronize with Red and IR signals from only one oximeter.



fgg030.eps

Additional settings become available in the Simulations menu, as detailed in Table 6-1.

Table 6-1. Simulations Menu Selections

Selection	Description
MAN	Allows you to set the SpO ₂ levels, from 35% to 100%, and the pulse rate from 30 BPM to 250 BPM. To set the SpO ₂ level other than the default of 96%, or the BPM default of 75, use MAN .
PRESET	Allows you to select from the presets for patient conditions, including: <ul style="list-style-type: none">• A normal patient• A patient with a weak pulse• An obese patient• A geriatric patient• A bradycardic patient (one with an abnormally slow pulse below 60 BPM)• A tachycardic patient (one with an excessively rapid pulse)• Motion
AMB	Allows you to set an ambient light artifact for sunlight or two types of artificial light. To set an ambient light condition other than sunlight default, use AMB .
STEP	Allows you to set a step size for both SpO ₂ and BPM settings. The default setting for the Simulator is to increase or decrease SpO ₂ settings by 2 % per button push and to increase or decrease BPM settings by 5 BPM per button push. For finer or coarser level change, use STEP .

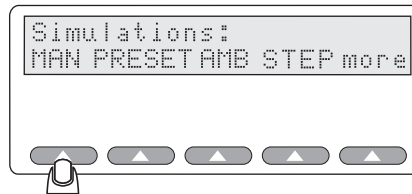
Note

*To set a patient condition other than that of the Simulator default of “normal,” use **PRESET**.*

Changing the Default SpO₂ Setting

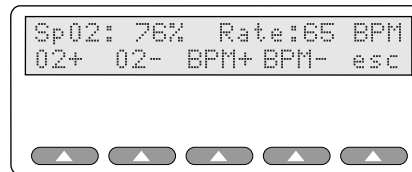
The default settings (for the current session from power-up, when no prior changes have been made) are for a simulated patient with 96% saturated oxygen levels and with a pulse of 75 beats per minute.

To change either of these settings, press **MAN** on the Simulations Menu.



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The manual settings screen appears on the LCD, displaying the current SpO₂ and BPM:

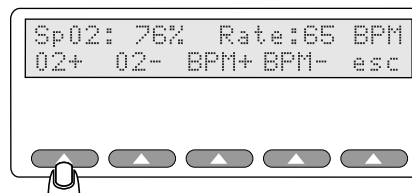


esl032.eps

Setting the O₂ Saturation Level

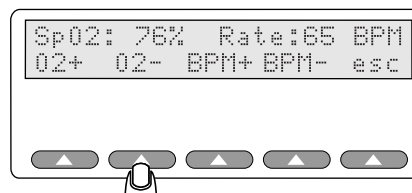
You can raise or lower, as needed, the simulated degree of oxygen saturation in the virtual patient.

1. To raise the O₂ level two steps at a time, press **O2+**.



esl033.eps

2. To lower the O₂ level two steps at a time, press **O2-**.



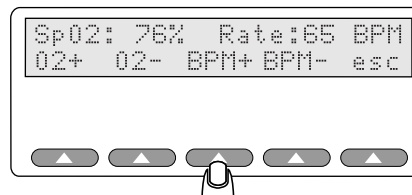
esl034.eps

3. Press the softkeys to raise (**O2+**) or lower (**O2-**) as many times as needed to adjust the SpO₂ level.

Raising or Lowering the Pulse Rate

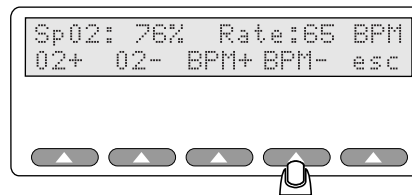
The Simulator also lets you adjust the pulse, for a customized virtual patient.

1. To raise the pulse rate five beats at a time, press the softkey BPM+.



esl035.eps

2. To lower the pulse rate five beats at a time, press the softkey BPM-.



esl036.eps

3. Press the appropriate softkey(s) as many times as needed to adjust the BPM.

Returning to Main Menu 1

To return to the Main Menu, press **esc** twice.

Using Preset Patient Conditions

The Simulator preset feature combines SpO₂ levels, heart rates, signal strength, motion, and pulse amplitude into 24 preset conditions, which simulate a broad range of normal and abnormal patient conditions. The intent of this feature is to challenge the pulse oximeter under test with a variety of patient conditions to show operation over a complete range. The preset values are not meant for use as "clinical calls" and are generic in scope.

Table 6-2. Level 0 Presets

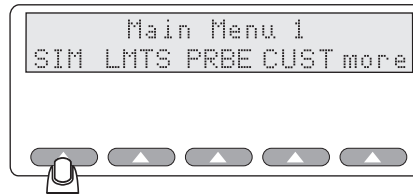
Preset Name	Saturation	Pulse Rate	Signal Strength	Motion			[presets#]
				Saturation	Frequency	Amplitude	
Normal	98 %	55 BPM	5.0 %	-	-	0 %	00
Normal/ Tap	98 %	55 BPM	5.0 %	78 %	2.5 Hz	7 %	01
Normal/ Shiver	98 %	55 BPM	5.0 %	78 %	6.0 Hz	15 %	02
Weak Pulse	90 %	95 BPM	0.65 %	-	-	0 %	03
Weak Pulse/ Tap	90 %	95 BPM	0.65 %	60 %	4.3 Hz	1 %	04
Weak Pulse/ Shiver	90 %	95 BPM	0.65 %	60 %	6.0 Hz	3 %	05
Bradycardia	88 %	45 BPM	5.0 %	-	-	0 %	06
Brachycardia/ Shiver	88 %	45 BPM	5.0 %	68 %	6.0 Hz	10 %	07
Hypoxic	70 %	95 BPM	2.0 %	-	-	0 %	08
Hypoxic/ Tap	70 %	95 BPM	2.0 %	50 %	4.3 Hz	3 %	09
Hypoxic/ Shiver	70 %	95 BPM	2.0 %	50 %	6.0 Hz	8 %	10
Neonate	90 %	180 BPM	1.0 %	-	-	0 %	11
Neonate /Shiver	90 %	180 BPM	1.0 %	70 %	6.0 Hz	5 %	12
Tachycardia	85 %	130 BPM	1.2 %	-	-	0%	13
Geriatric	92 %	95 BPM	2.4 %	-	-	0 %	14
Obese	93 %	90 BPM	3.0 %	-	-	0 %	15
Brady Tap #2	88 %	45 BPM	5.0 %	96/100 %	3.9 Hz	0/4 %	16
Hypox Tap #2	70 %	95 BPM	2.0 %	96/100 %	4.3 Hz	0/3 %	17
Weak Tap #2	80 %	95 BPM	0.9 %	96/100 %	3.6 Hz	0/1 %	18
Normal Tap #2	93 %	55 BPM	5.0 %	96/100 %	2.5 Hz	0/3 %	19
Asystole	91 %	90 BPM	2.0 %	96/98 %	1.1 Hz	0/1.1 %	20
LowFreq1	80 %	75 BPM	1.0 %	93/97 %	0.5 Hz	0/4.2 %	21
LowFreq2	70 %	75 BPM	1.0 %	96/100 %	0.5 Hz	0/4.2 %	22
Slow Tap	80 %	75 BPM	1.0 %	96/100 %	2.0 Hz	0/3.0 %	23

Note

When presets with tap or shiver are selected, there is a 10-second delay before the motion simulation starts. This delay will prevent an oximeter from "locking on" to patient parameters from a previous simulation.

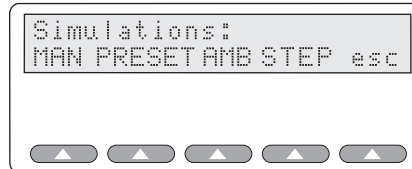
The Simulator is preset to simulate the SpO₂ and pulse rate ratios.

1. Access the Simulations menu by pressing the softkey **SIM** in Main Menu 1.



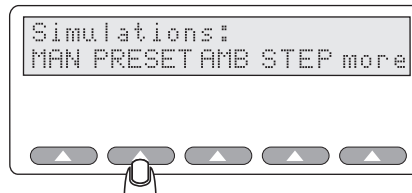
fgg010.eps

The Simulations menu appears in the LCD screen:



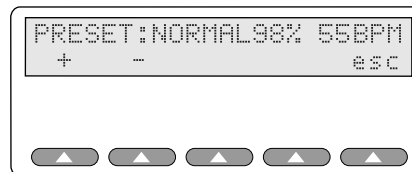
fgg038.eps

2. To view the preset patient condition, press the softkey **PRESET**.



esi039.eps

The values preset at the factory appear on the LCD screen:



esi040.eps

3. Press the softkey under the + or - to scroll through and select from the available presets.
4. Return to the Main Menu 1 at this time, press **esc** again.

Note

Upon leaving the Presets menu, the Simulator returns to its default (normal) preset patient condition simulation.

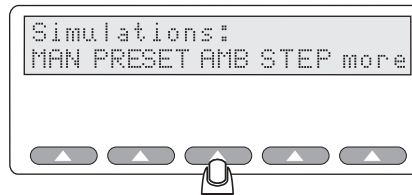
Setting the Light Artifact

You can set a light artifact with the Simulator to test oximeters under different simulated ambient (surrounding) light conditions. The available simulations are as shown in Table 6-3.

Table 6-3. Light Artifacts

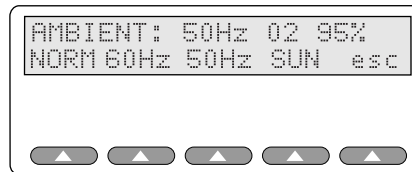
Light Type	Frequency	Description
Sunlight	<i>n/a</i>	Simulates sunlight by controlling the output from an LED so that a light level is added to the simulation. This light level is present both between, and during, red and infrared pulses.
Artificial	50 Hz	Hz (Hertz) is the frequency of the light measured in cycles per second. Artificial light is simulated by superimposing 50 Hz noise on the pleth wave.
Artificial	60 Hz	Simulated by superimposing 60 Hz noise on the pleth wave.

1. To select an ambient light condition, press **AMB** from the Simulations menu.



fgg041.eps

The AMBIENT setting displays the last setting used, in this example, NORMAL, which is changed using the softkeys shown here:

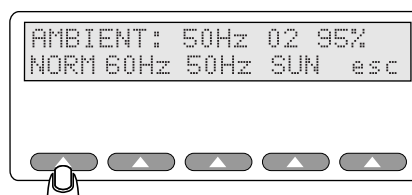


esl042.eps

Note

*The O₂ and BPM simulation used is the one last set using the **SIM** menu, or the default as shipped, if no changes have yet been made.*

2. Press a softkey to change the preferred ambient light presets from those used in a previous test:



esl043.eps

- Once you have selected an ambient light setting, you can return to the Simulations menu by pressing **esc**. Press **esc** again to return to Main Menu 1.

Setting O₂ and Pulse Rate Step Size

You can vary the size of the steps for O₂ and pulse rates used when setting up tests and testing oximeters with the Simulator.

If you select an O₂ step size of **5**, for example, then when you increase or decrease SpO₂, the SpO₂ will increase or decrease by **5%**.

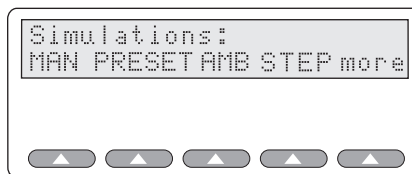
Note

Step amounts come in to play in three places from the Main Menus:

- With the Simulation option **MAN** (manual) submenu
- With the **LMTS** (limits) option **02 | 02 Alarm and BPM | Rate Alarm** submenu
- With the **AUTO** (Autosequence) menu's **PROG** submenu for setting SpO₂ level and pulse rate

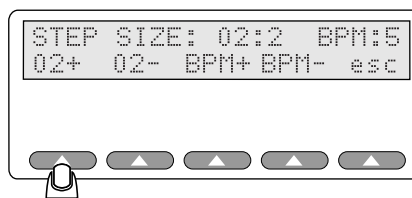
Set the step amount for SpO₂ levels using the following steps:

- To choose a step amount for the SpO₂ level and the pulse rate, press **STEP** from the simulations menu.



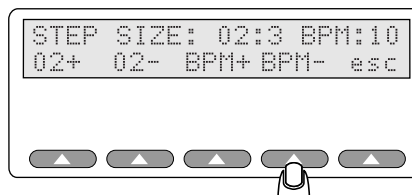
esi170.eps

- To increase or decrease the O₂ step amount, press **O2+** or **O2-**, respectively, as needed.



esi046.eps

- To increase or decrease the pulse rate step amount, press **BPM+** or **BPM-** as needed.



esi047.eps

- Once you have finished setting the O₂ and pulse rate step amount, press **esc** to return to the Simulations menu. Press **esc** again to return to Main Menu 1.

Chapter 7

Testing the Pulse Oximeter Limits

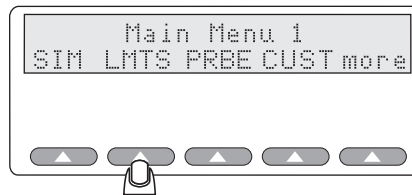
Introduction

Once you have determined the range in which you want to test a pulse oximeter for SpO₂ and rate, you can test the pulse oximeter for upper and lower limits for response time.

Testing Pulse Oximeter Limits

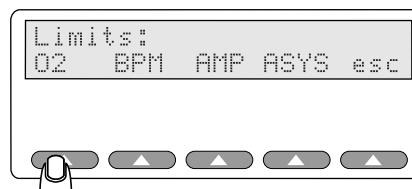
You can set your oximeter to sound an alarm whenever any pre-determined limits are reached during the testing of your pulse oximeter.

From the Main Menu 1, press the **LMTS** softkey.



fgg011.eps

The following menu appears in the LCD:



esl049.eps

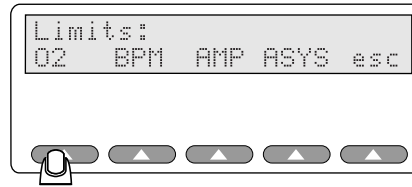
Note

Exit this menu with the softkey **esc**, which always returns you to the previous menu, in this case the Main Menu 1.

Simulating Oxygen Conditions

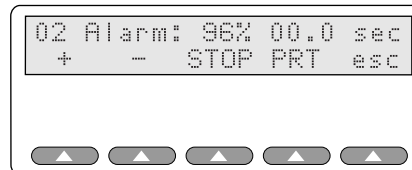
You can test the sensitivity of your pulse oximeter by setting the simulated oxygen levels.

1. To set the oxygen limits, press **LMTS** at the Main Menu 1 if you are not already there. Then, press the softkey **O2** in the Limits menu.



esl049.eps

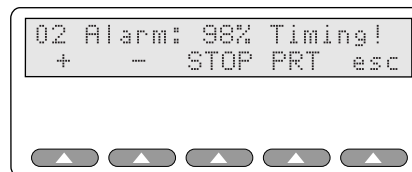
The display changes to present these options:



esl051.eps

When setting new oxygen limits, the Simulator displays the last setting used (or 96% if not previously changed) and resets the time to **00.0** seconds.

2. Press the softkeys **+** or **-** to start the timer, and the screen displays the “Timing!” message.



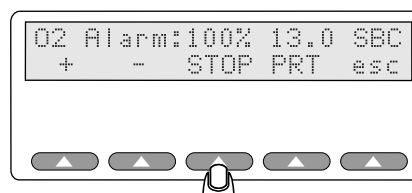
esl052.eps

- Pressing the softkey **+** (plus) will *increase* by the step amount set previously using the Simulations menu without affecting the timing function.
- Pressing the softkey **-** (minus) will *decrease* by the step amount without affecting the timing function.

Note

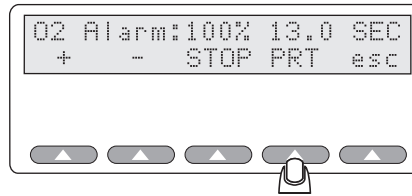
*Continue pressing **+** or **-** until the O₂ percent you want to test for is displayed. Each press of the softkey **+** or **-** resets the timer internally and restarts the timing.*

3. If the O₂ setting is outside the oximeter's alarm limit, the alarm will sound on the pulse oximeter being tested after a period of time. Press **STOP** immediately. This stops the timer, and displays the “elapsed time to alarm” for the specified simulation level.



esl053.eps

4. To print the results of the alarm, press **PRT**.



esl054.eps

The results will be sent out the RS232 and the Centronics ports to an attached printer.

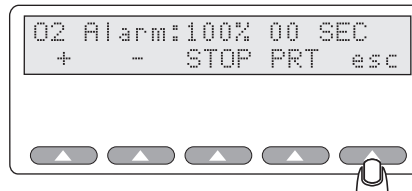
Note

You can connect the Simulator to any printer with a serial or parallel Centronics-type port or to any IBM-compatible PC, including laptops and notebooks. For information on how to connect the Simulator to other systems or peripherals, see "Appendix A: Printing & Data Transfer".

If a printer or computer is attached, your results should look like this example:

```
O2 Alarm Response Time:
-----
13.0 sec
```

5. When you are finished testing the pulse oximeter for SpO₂ readings, press **esc** to return to the Limits menu.



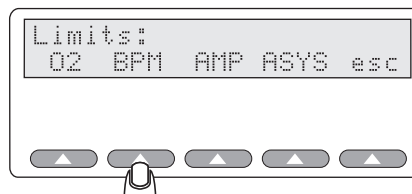
esl055.eps

Simulating the Pulse Rate

The Simulator simulates a variety of patient conditions, while you observe the effect of a changing pulse rate with a static SpO₂ on the pulse oximeter, as well as the effects of using a changing pulse rate with a changing SpO₂ percentage.

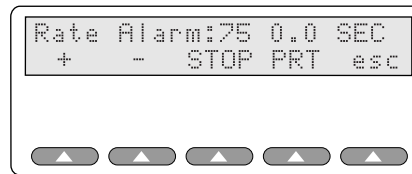
You can vary the pulse rate (beats per minute) of the simulated patient index finger or simulate the pulse rate electrically.

1. To access the pulse rate alarm menu, press the softkey **LMTS** from Main Menu 1, and then press **BPM** to access the Rate Alarm menu.



esl056.eps

You will see this pulse Rate Alarm menu displayed on the LCD:



esl057.eps

Note

*Notice, as with most menus, the last softkey, **esc**, will always return you to the previous menu, in this case the Limits menu.*

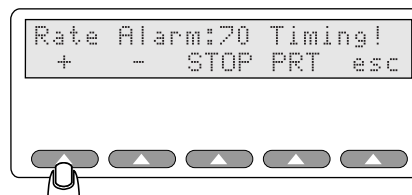
When setting a new BPM limit, the Simulator always starts with the last pulse rate setting.

- Press **+** and the simulator will incrementally *increase* the pulse rate from the value shown on the display.

Note

Pressing the softkey + (plus) will increase by the step amount set previously using the Simulations menu without affecting the timing function. Pressing the softkey - (minus) will decrease by the step amount without affecting the timing function

- The Simulator displays the message “Timing!” and maintains an internal timer until you press **STOP** or the + or - softkeys.



esl058.eps

- Press **-** and the simulator will *decrease* the pulse rate from the displayed value with each softkey press.
2. If the selected simulation rate exceeds the oximeter alarm rate, the alarm will sound on the pulse oximeter being tested after a period of time. You should then press the **STOP** softkey immediately.



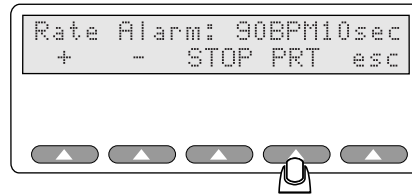
esl059.eps

The timer stops, and displays the elapsed seconds.

Note

*Pressing the softkeys **+** or **-** resets the Rate Alarm timer.*

3. Press softkey **PRT** to send the testing results to the printer.



esl060.eps

The results will be sent to the RS232 and Centronics port.

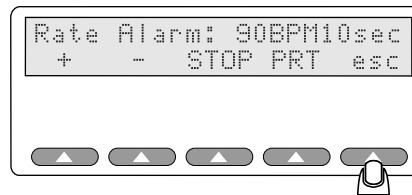
Note

Connect the Simulator to any printer with a serial port or parallel Centronics port, or to any IBM-compatible PC, including laptops and notebooks. For information on how to connect to other systems or peripherals, see "Appendix A: Printing & Data Transfer".

If a printer or computer is attached, you will see results that look something like this example:

```
Rate Alarm Response Time
-----
10.0 sec
```

Press **esc** to return to the Limits menu.



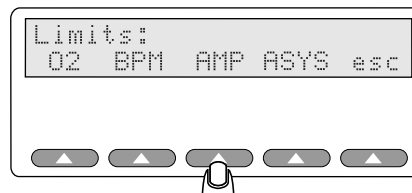
esl061.eps

Simulating Pulse Amplitude

The peak-to-peak amplitude of the simulated blood pressure wave can be increased or decreased. Decreasing amplitude corresponds to a weakening pulse. You can decrease amplitude to find where the oximeter fails to find the pulse.

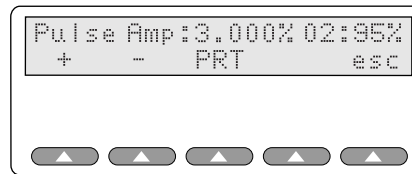
You can quickly set a pulse amplitude limit.

1. To access the pulse amplitude alarm menu, press **LMTS** from Main Menu 1, and then **AMP** from the Limits menu:



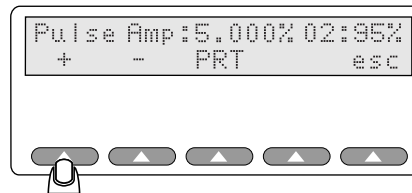
esl062.eps

2. The Pulse Amplitude menu displays in the LCD screen:



esl063.eps

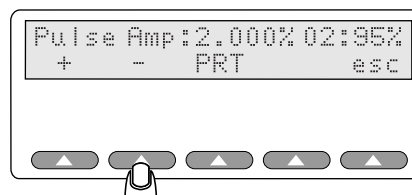
3. To raise the Pulse Amp percentage (AC factors) in the simulated blood condition, press the softkey **+**:



esl064.eps

The amplitude will *increase* in increments of 1% with every softkey press.

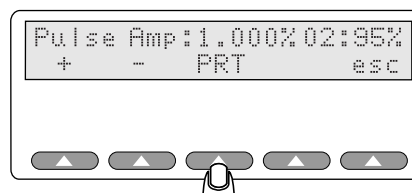
4. To lower the percentage of AC factors in the simulated blood condition, press the **-** softkey:



esl065.eps

The amplitude will *decrease* by 1% with every softkey press down to 1 %. From 1 % to 0.1 % the value will decrease by 0.1 %. Below 0.1 %, the value will decrease by 0.025 % per button press. Inputs below 6 % are rounded internally to the nearest 0.024 %, and above 6 % are rounded to the nearest 0.072 %. The displayed value is the rounded value nearest the value displayed per the preceding increment/decrement rules. If the pulse amplitude rate exceeds the oximeter alarm rate, the alarm will sound on the pulse oximeter being tested after a period of time.

5. To print the results of the alarm, press the **PRT** softkey.



esl067.eps

The results will be sent to the RS232 or Centronics port.

Note

You can connect the Simulator to any printer with a serial port or parallel Centronics-style port or to any IBM-compatible PC, including laptops and notebooks. For information on how to connect to other systems or peripherals, see “Appendix A: Printing & Data Transfer”.

An attached computer or printer produces results that look something like this example:

```
Pulse Amplitude Test
-----
At 8% the signal is lost
```

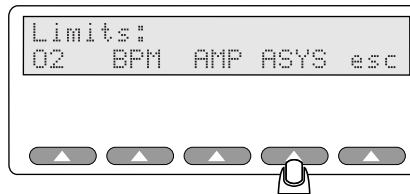
6. When you are done, press the softkey esc to return to the Limits menu.

Simulating Asystole or No Pulse

In a clinical setting, a no-pulse condition is life threatening. Most pulse oximeters sound alarms in response to this condition. The Simulator can measure the response time of these alarms.

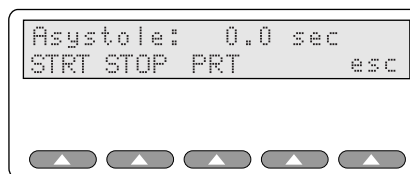
The Simulator can simulate asystole (lack of cardiac electrical activity) to further test an oximeter. Set up the asystole test with these steps:

1. To set up asystole condition for testing a pulse oximeter's sensitivity, first press **LMTS** from Main Menu 1.
2. Then, press **ASYS** at the Limits menu to access the Asystole menu:



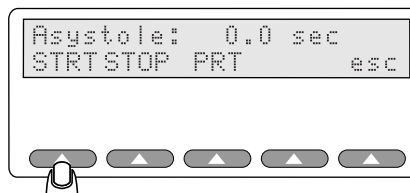
esi068.eps

You will see the Asystole menu display in the LCD screen:



esi069.eps

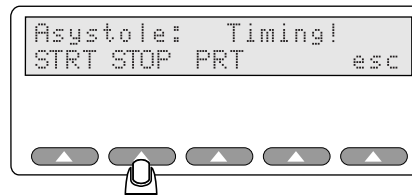
3. Press the **START** softkey to begin the asystole test.



esi070.eps

4. The asystole simulation starts and the LCD shows the “Timing!” message.

When the alarm sounds, press the softkey **STOP**.



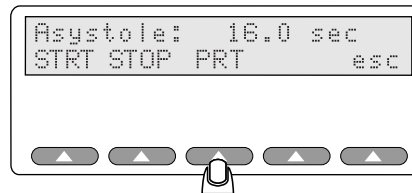
esi071.eps

The timer ceases counting and the elapsed time (in seconds) displays on the screen.

Note

You can connect the Simulator to any printer with a serial or parallel Centronics-style port or to any IBM-compatible PC, including laptops and notebooks.

5. To print the results of the test for review or archiving, press **PRT**.



esi072.eps

Selecting PRT sends results to the RS232 and Centronics ports. With a printer or computer attached, the results should look something like this example:

```
Asystole Response Time
-----
24.0 sec
```

For information on how to connect to other systems or peripherals, see “Appendix A: Printing & Data Transfer”.

6. When you are done, press the softkey **esc** to return to the Limits menu.

Chapter 8

Using Test Programs

The AUTO Menus

The Simulator provides several pre-defined test programs to automatically sequence tests. You would ordinarily have to manually set each test parameter every time you start the Simulator and connected it to a pulse oximeter for testing. Pre-defined test programs save you time, allowing you to avoid resetting test parameters for every pulse oximeter testing session.

You can use fourteen pre-defined programs (also called *autosequences*), or you can customize any or all of them and save them for repeated use. This allows you to run tests on specific equipment or for specific patient conditions as often as needed, without having to re-enter the settings every time.

Using a pre-defined program, the Simulator will run through the tests one by one, at the settings you determine and for the time for each test that you specify. You are only prompted to press a button to begin each test in sequence.

You can even tailor the test reports to contain only the information you want to see; for example, excluding or including the device information header (which contains serial numbers, device names and so on).

Navigating Through the Programming Process

Define a set of parameters starting at the Main Menu 2 by selecting **AUTO**. Set the variables for autosequencing, after you have selected to program, run, or change programs, in one of two ways:

- Pressing **+** or **-** to increase or decrease a value
- Pressing the key labeled **SEL** (to accept the values shown in display)

Move to the next screen in the series as you define your automatic program by pressing **ADV** when available (you can also use **ADV** to bypass any screen, as needed).

The Program Definition Cycle

Figure 8-1 shows in a simple, graphic way, the steps involved in creating a custom program.

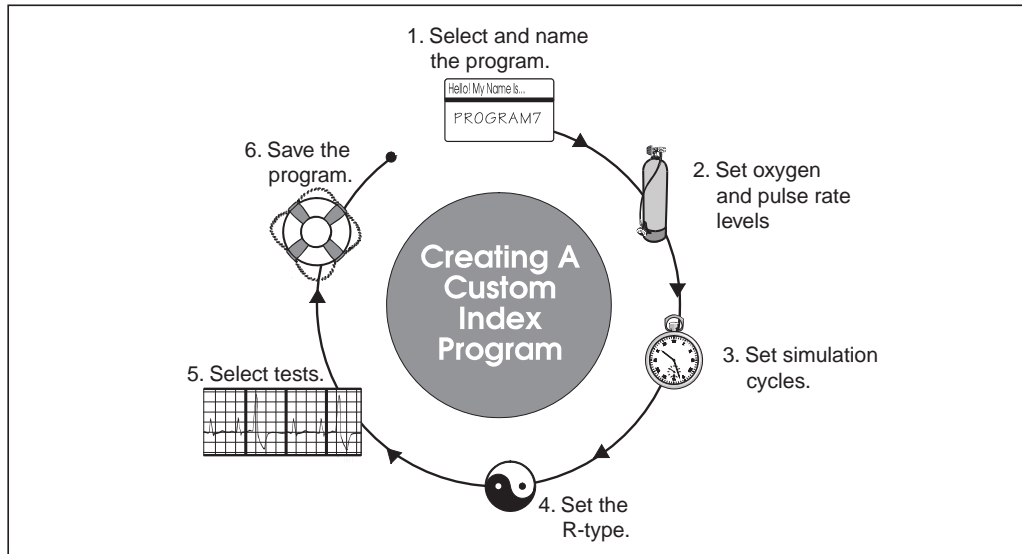


Figure 8-1. The Program Creation Sequence

esi073.eps

The Automatic Test Parameters

Parameters listed in Table 8-1 are different for each program, viewable or changeable in the LCD screen.

Table 8-1. Automatic Test Parameters

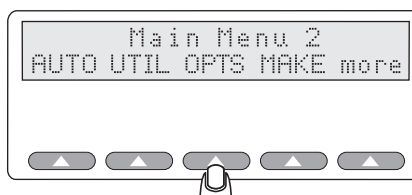
Name	Description
Program Name	Enter a name for this program. You can use defaults of PROG0 through PROG13 for the name, or you can enter any name of up to eight-characters in length. The name can include letters (A-Z), numbers (0-9), and spaces.
Print Heading	Set whether you want the heading page to print.
Print Actuals	Set whether you want the actuals to print. Actuals are the test results for each of the tests. The default printout returns summary information only.
SpO2 Setting #1	Set the percent oxygen level for the first test.
SpO2 Setting 2-9	Set the percent oxygen level for any/all subsequent tests.
Pulse Rate Setting #1	Set the BPM (beats per minute) for the first test.
Pulse Rate Setting 2-9	Set the BPM (beats per minute) for any or all subsequent tests.
Cycle Number of Pleth Waves	Set a cycle time by selecting number of pleth waves. The selected cycle time applies to each test in the sequence.

Table 8-1. Auto Test Parameters (cont.)

Name	Description
Make	Set the make of machine being tested, such as Nellcor, HP, Criticare, Ohmeda, Invivo Research, and so on.
O₂ Alarm Test	Set the Simulator to either test or bypass the SpO ₂ limits test.
BPM Alarm Test	Set the Simulator to either test or bypass the BPM units test. If Yes, an alarm will sound at the conclusion of testing the pulse rate.
Pulse Amplitude Test	Set the Simulator to either test or bypass the amplitude test.
Motion Test	Set the Simulator to test the oximeter for patient motion.
Use Presets	Set the Simulator to allow for the selection of preset patient conditions (geriatric, obese, normal, etc.) at test time.

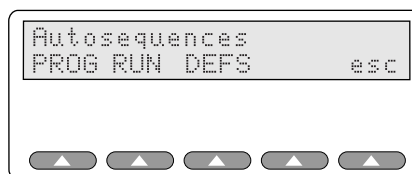
Accessing the Autosequences Menu (AUTO)

To access the Autosequences menu, press **more** on Main Menu 1 and then press **AUTO** on Main Menu 2. See the section “Creating a Custom Test Program” for the additional parameters available under each option.



fgg181.eps

After you press **AUTO**, the following options become available:

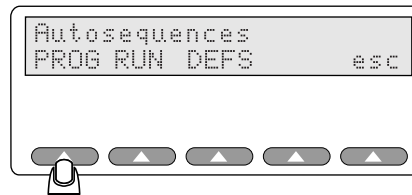


esl075.eps

The Autosequences menu provides the following options:

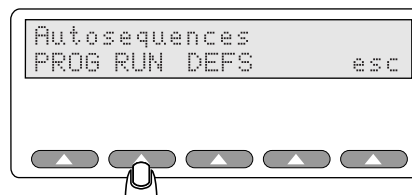
- **PROG** to define and edit programs
- **RUN** to start an autosequence
- **DEFS** to restore defaults
- **esc** to return to prior menus

PROG lets you define or edit a set of program parameters that you can have run automatically when needed.



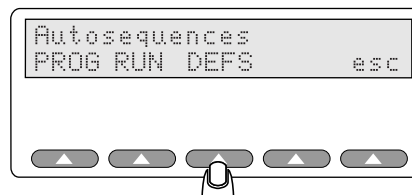
esl076.eps

Press the softkey **RUN** to run any of the up to fourteen autosequences (pre-defined test programs).



esl077.eps

Pressing the softkey **DEFS** lets you restore any or all of the programs to their default factory settings.



esl078.eps

Creating a Custom Test Program (Autosequence)

Setting up a custom program in requires a few simple steps:

- access the Autosequences menu
- enter or select a program name
- define program parameters (enter test levels, for example)
- save the program

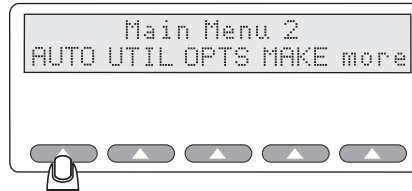
The program can then be run at any time after saving.

Since the program remains in non-volatile memory, it is unaffected if the instrument's power is turned off. The program will only be changed if you modify it or return to its default (factory-shipped) state.

Selecting a Test Program

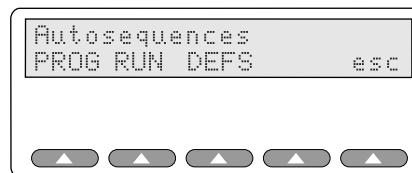
Start by accessing the Autosequences menu:

1. Press the softkey **AUTO** on Main Menu 2.



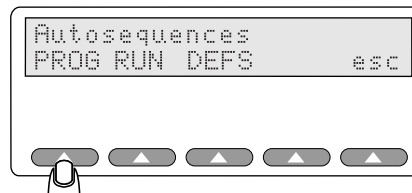
fgg132.eps

The Autosequences menu displays the following:



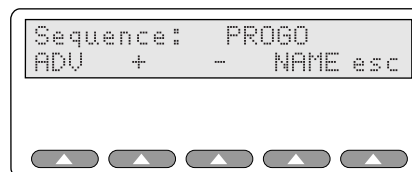
esl080.eps

2. Select **PROG** to define a custom autosequence program.



esl076.eps

This Autosequences screen appears on the LCD, with the **Sequence:** indicating the current program (in this instance, Program 0).

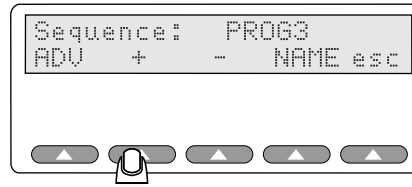


esl082.eps

You can then modify one of the pre-programmed test programs, from PROG0 through PROG13. The screen displays the last program selected, for example, if you were last using Program 5, the Simulator displays **PROG 5** when you select **PROG**.

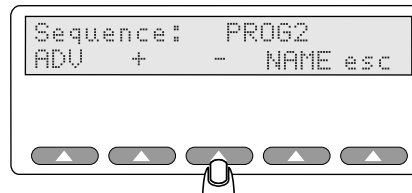
PROG0 through PROG13 are identical as shipped from Fluke Biomedical.

- To scroll through the list of programs (in *ascending* alphanumeric order), press softkey **+** (plus sign).



esi083.eps

- To scroll through the list of programs (in *descending* alphanumeric order), press softkey - (minus sign).

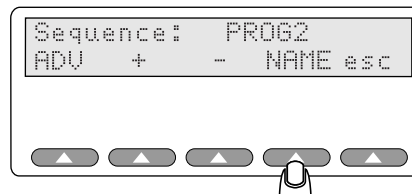


esi084.eps

Optionally Renaming the Test Program

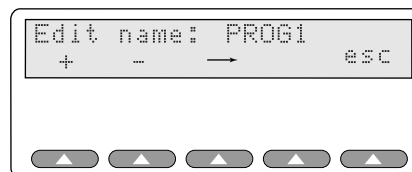
You can rename any of the test programs. The name can be from one to eight characters in length, containing letters, numbers, and spaces; for example “TEST1”, “TEST22A” or “DS TEST”.

1. To edit the program name, press **NAME**.



esi085.eps

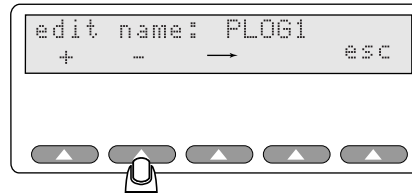
The LCD screen shows the program name for the last program used (or PROG 0 the first time the Simulator is powered up):



esi086.eps

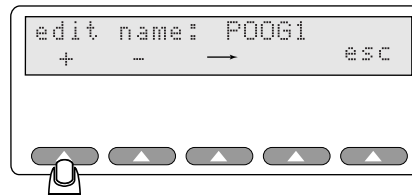
2. The cursor blinks over the first selected character. To edit the program name, move between positions using the (arrow) softkey →.
3. To edit the characters in the name, use + or - softkeys to increment or decrement the alphabetic character.
 - Since this option opens with position one selected, you do not need to press →
 - To select the position two, press → once
 - To select the position three, press → twice

4. The name is limited to eight characters maximum. Continuing to press the softkey → eventually returns the cursor to the first character.
5. In the example below, the second position was changed (the letter “R” in PROG 1). Press - to decrease the letter or number as in the example below until you reach the letter L (notice that the R is now an L).



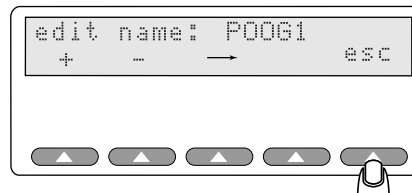
esl087.eps

6. Or, press + to increase the letter or number in sequence; as shown below, notice that the L is now an O.



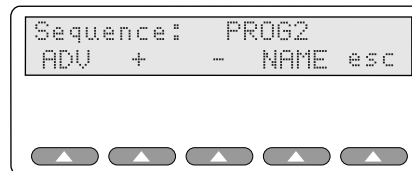
esl088.eps

7. When you have finished editing the program name, press **esc**. You will be asked if you want to save the changes.
8. Press **Yes** to save or **No** to not save.
9. Press **esc** to return to the Autosequence menu.



esl089.eps

The **Sequence** screen appears on the LCD screen. The program name, if altered, will follow the message “**Sequence:**” and display the new name.

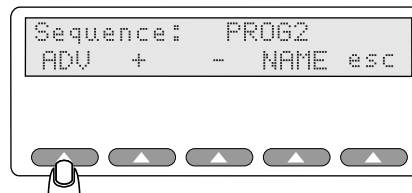


esl090.eps

Configuring the Program

From the Sequence menu, re-configure the parameters and values in a program, which may include everything from BPM to oximeter model being tested; this section details resetting those program's values and parameters.

1. Press **ADV** to begin defining your program.



esi091.eps

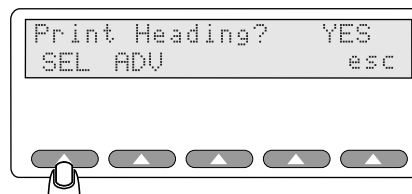
Note

*At any time during the program-definition process, you can press **esc** and return to this initial **Sequence** screen. (Pressing **esc** at the **Sequence** screen returns you to the Autosequences menu and will prompt you to save or not save your program; from there, pressing **esc** returns you to the Main menu.)*

Selecting Print Settings

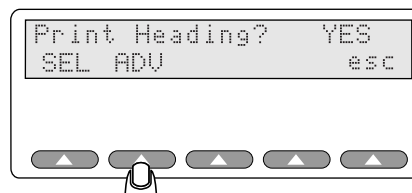
You can customize a program to include optional heading and actuals information at print time with the following procedure:

1. Press **SEL** to toggle the **Print Heading?** from **No** to **Yes**.



esi092.eps

2. Move to the next step in the process by pressing **ADV**:

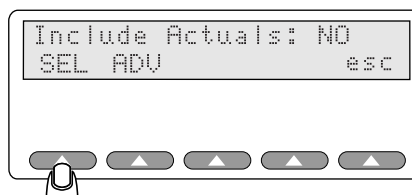


esi093.eps

You can then set whether or not you want to print the *actuals*. Actuals refer to the observed test data. If you select not to have actuals printed, you will see summary information only.

Note

For information on a test printout, headings, and actuals, refer to "Appendix A: Data Transfer Notes".



esl094.eps

3. Press **SEL** to change the **Include Actuals:** response from **YES** to **NO** as needed.
4. Move to the next step in the process by pressing the softkey **ADV**.

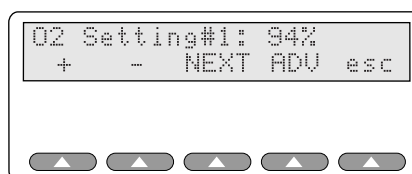
Setting the O₂ Level

You can set up to ten different oxygen levels and up to ten different pulse rates for the simulation autosequences.

Note

*In each screen, the softkey **ADV** moves ahead to the next settable option. Use the **NEXT** softkey to simply advance through the O₂ and rate level settings for each test.*

1. After selecting a test, set the oxygen level for test number one:



esl095.eps

2. Press **+** or **-** to adjust the simulated oxygen level up or down for the first O₂ test (1% O₂ per button push). You can set up to ten O₂ tests. Pressing **NEXT** at **Rate Setting #10** brings you back to **O₂ Setting #1**.



esl096.eps

3. Press **NEXT** to set the simulated pulse rate.

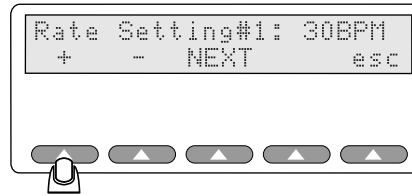
Note

*If you do not plan to test for O₂, press **ADV** to bypass these settings.*

Setting the Pulse Rate

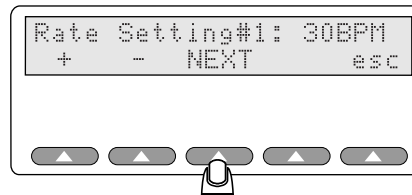
You can set up to ten different pulse rates for the Simulator to use during a single autosequence program.

1. Again, use **+** and/or **-** to adjust the BPM up or down for the first pulse rate test.



esl097.eps

2. Press **NEXT** to set the pulse rate for each additional rate test, if required. You can set up to ten rate tests. Pressing **NEXT** at **Rate Setting # 10** brings you back to **O2 Setting #1**.



esl098.eps

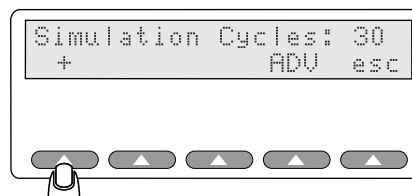
- Use **+** and/or **-** to adjust the pulse rate up or down.
- Press **NEXT** as many times as needed to enter up to ten different test values. When you are done setting a time in cycles (or to bypass this screen), press **ADV** to continue.

Setting the Simulation Cycle

Oximeters require a fixed number of cycles to evaluate and respond to a change in input. You can set the expected response time (in waveform cycles), after which the Simulator will beep twice. The double beep alerts you that the oximeter response to the simulation should be complete.

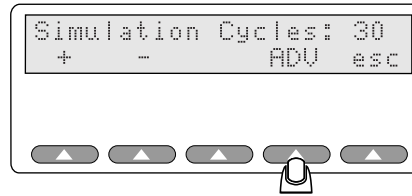
You can set the time, in pleth wave cycles, that each simulation in the autosequence program will run before a double beep, using the following procedures:

1. Use **+** and/or **-** to adjust the time in cycles, up or down (by five pleth cycles per button push).



esl099.eps

2. When you are done setting a time in cycles (or to bypass this screen), press **ADV** to continue.

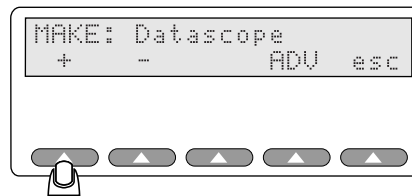


esl100.eps

Selecting the Make

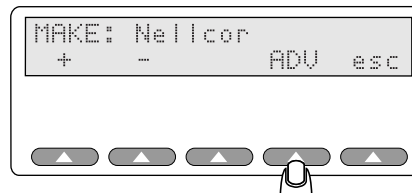
Next, select the make of the pulse oximeter that you will be testing.

- Press **+** or **-** to scroll up and down the list of pre-programmed oximeter types. For more information on configuring the Simulator for a specific make of oximeter, refer to Chapter 5.



esl101.eps

- Once you have selected the oximeter make, press the softkey **ADV** to continue.

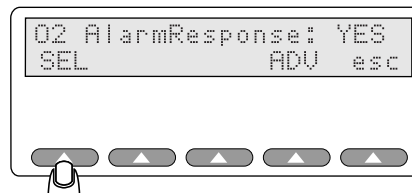


esl102.eps

Choosing Your Tests

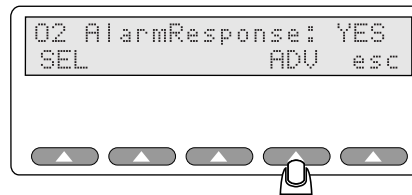
Your next step in creating a custom program is to choose the tests that you want the Simulator to run. Use the following procedure:

- Press **SEL** to toggle the **O2 Alarm Response:** response between **NO** and **YES**, as needed.



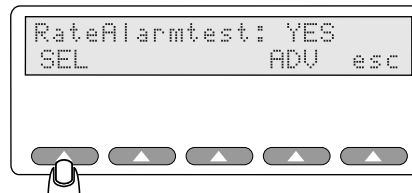
esl103.eps

- When you are done (or to simply bypass this screen), press **ADV** to continue.



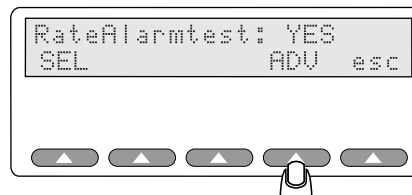
esl104.eps

- Next, press **SEL** to change the **Rate Alarm Test** response from **NO** to **YES**, or **YES** to **NO**, as needed.



esl105.eps

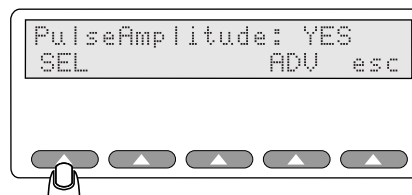
- When you are done (or to simply bypass this screen), press **ADV** to continue.



esl106.eps

Selecting Pulse Amplitude

Press **SEL** to toggle the **Pulse Amplitude** response from **NO** to **YES**, as needed.



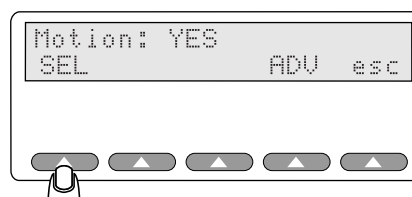
esl107.eps

When you are done (or to simply bypass this screen), press **ADV** to continue.

Selecting Motion

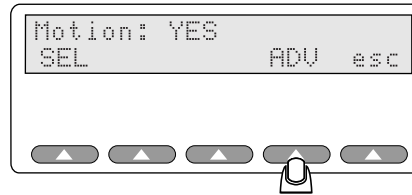
the Simulator can also test an oximeter's sensitivity to patient motion.

- Press **SEL** to turn the motion test option on or off (**YES** or **NO**):



esl108.eps

- When you are done (or to simply bypass this screen), press **ADV** to continue.

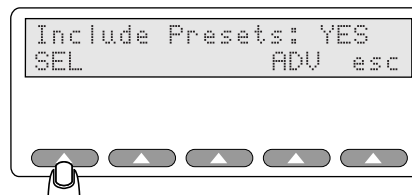


esl109.eps

Selecting Presets

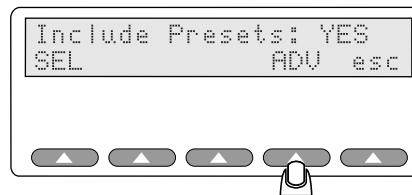
Next, select if the pre-programmed patient types will be used..

- Press **SEL** to use pre-programmed patient types (normal, weak heart, obese, or geriatric, for example).



esl110.eps

- When you are done (or to simply bypass this screen), press **ADV** to continue, which returns you to the Sequence menu.

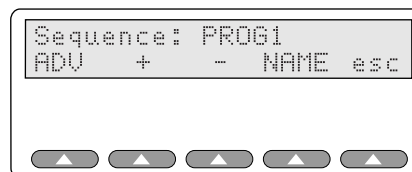


esl111.eps

Saving Your Program

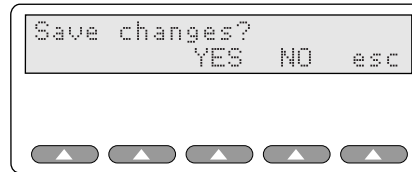
Saving the program values and parameters is the final step in creating a custom program.

- Press the **esc** softkey at any time (press **esc** twice or **ADV** from the **Include Presets:** screen) to return to the Sequence menu:



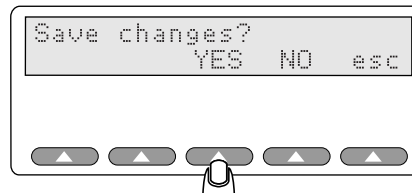
esl112.eps

- Pressing **esc** prompts you to save your program.



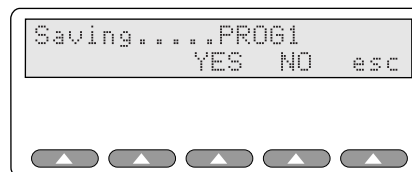
esl113.eps

3. Press **YES** to save your program, or **NO** to skip.



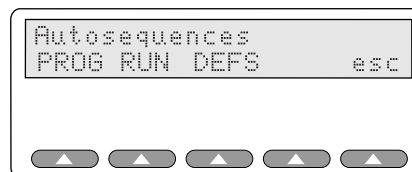
esl114.eps

- If you press **YES**, you will see a message indicating your program is being saved:



esl115.eps

- If you press **NO**, you will be returned to the Autosequences menu without saving the new program (or without saving modifications to an existing program, whichever applies):

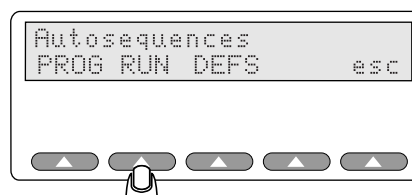


esl116.eps

Running an Automatic Test Program

You can run a saved program at any time with the following procedure:

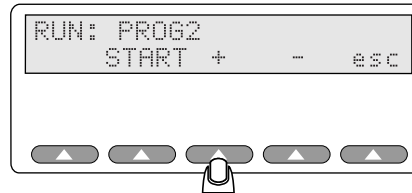
1. Start at the Autosequences menu.



esl117.eps

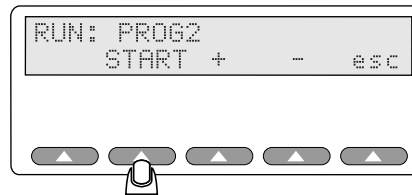
- Press **RUN** to display the "RUN:" screen.

- At the RUN screen, use **+** or **-** to display the program to be run, if it is not the first program automatically displayed.



esl118.eps

- To run the displayed program, press the softkey **START**.



esl119.eps

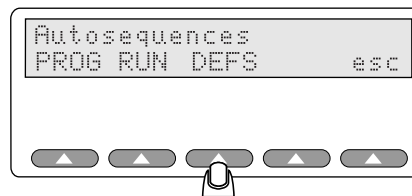
The program will prompt you as needed to press **ADV** to move from test to test.

- When finished, the LCD screen displays the message “Program 2 Complete!” and presents the option of printing the results (as well as the number of copies to print).
- Press **esc** to return to the Run screen. Press **esc** again to return to the Autosequences menu.

Returning an Automatic Test Program to Default State

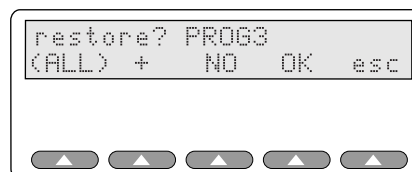
You can return a modified (and saved) autosequence program to its default state, that is, the way it was programmed at the factory, at any time.

- From the Autosequences menu, press the **DEFS** softkey.



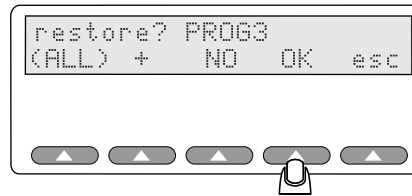
esl120.eps

A screen similar to the following displays the question “restore?” and the program number:



esl121.eps

2. Use **+** to locate the program you want to reset, if it is not the first program automatically displayed. Or, use **ALL** to restore defaults for *all* autosequence programs.



esl122.eps

3. Press **OK** to reset the defaults for the listed program.



esl123.eps

- If you selected **(ALL)**, the LCD flashes the message “**Loading defaults - Please Wait...**” until restoration is complete. the Simulator returns to the Restore program screen. Exit this by pressing **esc**.
- If you selected a single program (by pressing OK in the restore screen), the LCD indicates the restoring of the program selected, and then returns to the Restore program screen. Exit this by pressing **esc**.

Chapter 9

Electrical Probe Test

Electrical Probe Testing

Fluke Biomedical has validated that the following oximeter probes can be functionally tested using the Simulator (MFE Version only) when connected via the correct probe cable adapter:

- BCI®(3101)
- Criticare® (504)
- Datascope® (Passport)
- Nellcor® (N-100)
- Nihon-Kohden® (Lifescope)
- Novametrix®
- Ohmeda® (3700)
- Respironics®

⚠ Caution

Other manufacturers' oximeter probes can be tested by the Simulator, but will require special care in preparation of an adapter cable and interpretation of the results. Damage could occur to the Simulator or the oximeter probe if the adapter cable is not correct. Do not plug other brands of oximeter probes into an adapter cable unless you know that the pinouts and impedances are the same.

The Simulator allows you to verify the electrical continuity and integrity of most oximeter probes using the following steps:

1. Connect the probe under test to the back of the the Simulator using the appropriate adapter cable.

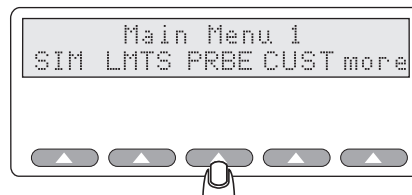
Note

The MFE version ships with Nellcor and Ohmeda probe and oximeter adapters. Please contact Fluke Biomedical regarding the availability of additional adapter cables.

⚠ Caution

Attempting to create adapter cables without all details of the oximeter probe-operating scheme could result in damage to the oximeter, the Simulator, or both.

2. Press the **PRBE** softkey at Main Menu 1:



Fgg012.eps

The **PRBE** softkey initiates a testing sequence that includes:

- Verifying that a Probe Test Board is installed in the Simulator
- Checking whether or not a probe adapter cable is connected to the probe port
- Performing all measurements for LED, photo detector, and resistance tests



esl125.eps

Probe Test Selection

The user can then choose the specific probe test.

- LED and photodiode electrical test
- Pin-to-pin resistances
- Photodiode detector optical test

Note

During the photodiode test, the finger probe being tested should not be attached to the Index finger.

LED Testing

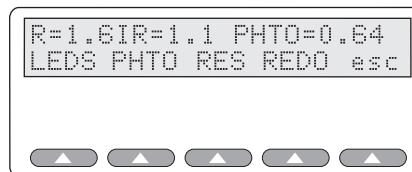
The Probe test should end with the following menu displayed. Press the **LEDS** softkey:



esl126.eps

The Simulator applies 1.0 mA current AC signal source to the red and infrared LEDs. The Simulator performs the electrical test separately on each diode to confirm they are functioning properly. The voltage drop across each element is measured and displayed. Values can range from 0.0 to 4.0:

- 0.0 Volts = LED shorted
- 1.4 +/- Volts = LED OK
- Any value of 4.0 or greater will be displayed as "> 4.0."



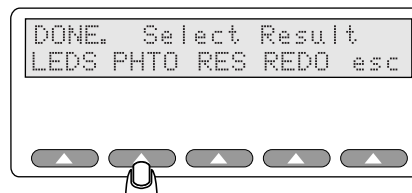
esl127.eps

The LEDS test should return a PHTO reading of approximately 0.6 volts if electrically good. Use the resulting numbers as a baseline for similar probes. For example, 1.6 may be a typical red LED and 1.1 a typical IR LED result for Nellcor probes. A 0.0 results would indicate a shorted diode, while >4.0 V would indicate either an open diode or that the voltage drop across the diodes has exceeded the Simulator's forward-voltage test range.

Photodiode Test

This test looks at the probe as a functioning entity. Numbers close to zero support a faulty probe diagnosis.

Test the photodiode probe by pressing the **PHTO** key.



esl172.eps

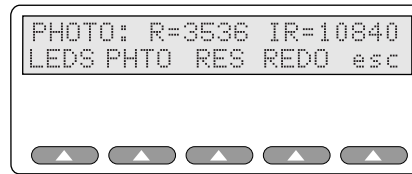
The red LED lights up and the Simulator measures the resulting photodiode output. The red LED then goes out and again measures the output. The difference indicates the response to a 1 mA LED illuminating current.

The same test measures the infrared LED.

Both tests are repeated multiple times to average out ambient light, with the results displayed as a pair of numbers; one for red, and one for infrared, on a fixed scale giving an indication of photodiode response to each color. A higher number yields more response. Numbers can range from 0-20,000 or more. It is a nominal value only.

Develop baseline values for comparison purposes when testing marginal, defective, or suspect probes by logging voltage readings from operational probes.

These values update continually during testing.



esl128.eps

Note

During the photodiode test, the finger probe being tested should not be attached to the Index 2MF finger.

Displayed numbers will vary due to both the general probe condition and as a function of the distance and angle between the two LEDs and the photo detector.

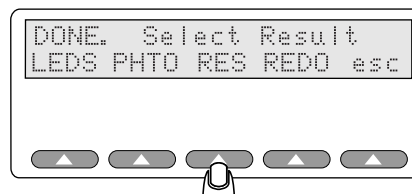
Take care to maintain alignment when inspecting the SpO₂ sensor. Reusable SpO₂ sensors with built-in spring clips typically maintain consistent alignment between the LEDs and the photo detector, therefore yielding consistent results.

However, test results when inspecting a flexible disposable "tape style" probe will fluctuate unless you take care to maintain the optimal mechanical position of the probe. As a suggestion, wrap the disposable probe on a small white plastic cylinder or tube (not your finger) to maintain the mechanical alignment of the LEDs to the photo detector.

These values update continually.

Resistance Testing

Press **RES** key at the "DONE. SELECT RESULT" screen.

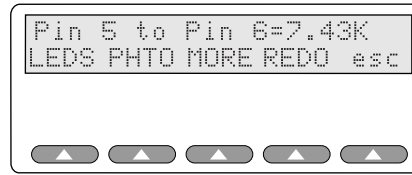


esl173.eps

The Simulator checks for resistances between all wires (separately testing each one, every pin to every other pin, except for those wire pair combinations where a LED would draw normal current).

The Simulator displays resistances under 150,000 Ohms.

Pressing the **MORE** softkey displays all pin combinations that have resistances. Results must be interpreted in context of the probe schematic; some probes contain resistors, some do not. A resistance where none should exist indicates a faulty probe. For example, a resistance between a resistor shown on the probe schematic as floating and one of the LED or photodiode leads would certainly be faulty.



esl129.eps

Note

*These values do **not** update continually. Use **REDO** when checking for intermittent connections.*

Chapter 10

Adjusting the LCD Screen

Introduction

Users may adjust the liquid crystal display (LCD) screen, increasing or decreasing the contrast to accommodate different ambient lighting situations.

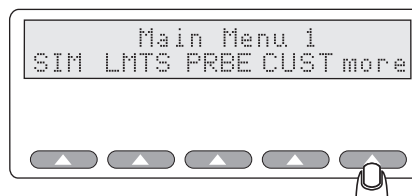
Note

This function is not the same as setting an ambient light artifact (sunlight/artificial light) for oximeter testing under the Simulations menu. The steps outlined here allow adjusting the screen contrast on the LCD itself.

LCD Contrast Settings

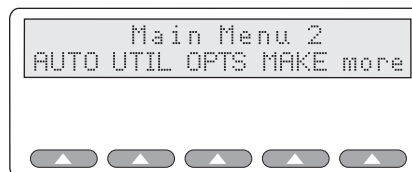
To adjust the LCD contrast, access the Utilities menu directly from the Main Menu 2. To access the Utilities menu, proceed as follows:

1. Press **more** on Main Menu 1.



fgg015.eps

The Main Menu 2 displays in LCD:



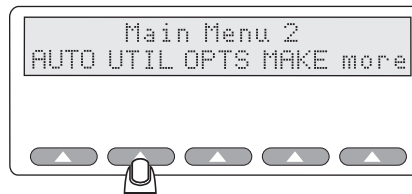
fgg161.eps

Note

Pressing **more** returns you to Main Menu 1.

Pressing **esc** in any of the following screens returns you to Main Menu 2.

2. Press **UTIL** to access the Utilities Menus:



fgg143.eps

The Utilities menu allows you to choose from these options:

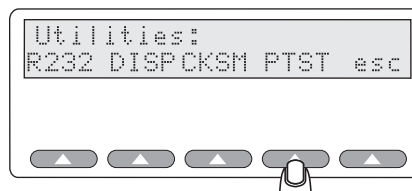


fgg133.eps

Note

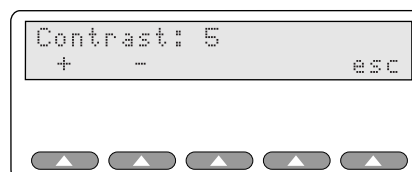
For information on **RS232**, **CKSM**, and **PTST** functions, refer to “Appendix A, Printing and Data Transfer”. Pressing **esc** will return you to **Main Menu 2**.

3. Press **DISP** to access the LCD controls:



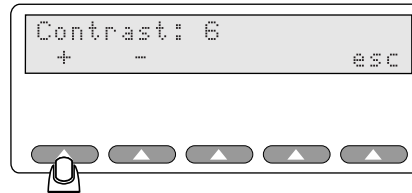
fgg134.eps

The LCD shows the current contrast level setting, which may or may not be the default value (5).



esl135.eps

4. Adjust the contrast of the LCD by pressing **+** to *increase* the contrast of the LCD. Continue to press softkey **+** to change the contrast until it suits you and the lighting conditions.

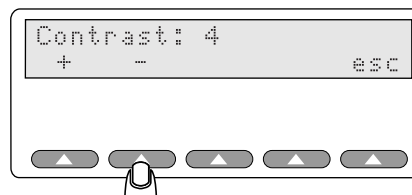


esl136.eps

Note

*The maximum level that the contrast can be set to is **7** (the minimum setting is **0**).*

5. Press softkey **-** to decrease the LCD contrast.

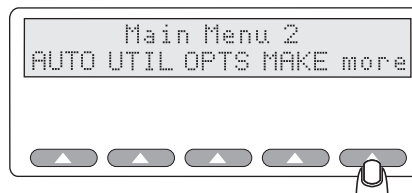


esl137.eps

Note

The third and fourth keys are not activated for LCD contrast adjustment.

6. When the LCD contrast is acceptable, press **esc** to return to the Utilities menu.
7. Press **esc** again to return to Main Menu 2.



fgg139.eps

8. From the Main Menu 2, press the softkey **more** to return to Main Menu 1.

Chapter 11

Manufacturers Mode

Introduction

Fluke Biomedical has included several features in the Simulator specifically designed to aid manufacturers of pulse oximeters. Those features ease the following manufacturing-specific needs:

- The automatic production testing of pulse oximeters
- The automatic production testing of oximeter probes
- The design and development of new pulse oximeters

Automated Testing

With the Simulator, manufacturers of pulse oximeters can test their products using a standard PC. The computer must have a serial communications (COM) port and a communications program, such as the Microsoft Windows™ “HyperTerminal” program.

To test a pulse oximeter using a PC, connect the Simulator to the computer via one of the communications ports, with the unit under test connected via a second communications port.

You send special commands to the Simulator using the computer; the Simulator then acts on the commands to test an oximeter. You can additionally use the computer to monitor responses of the unit under test (UUT). With the computer, you can do any of the following:

- Log the oximeter's responses for a production test record
- Compare the oximeter's responses to preset limits to determine whether the system passes or fails quality standards

You can complete these procedures by testing oximeters against a reference probe. Alternatively, you can test the probes against a reference oximeter.

Manufacturer Parameters Available For Simulations

Although percent oxygen and beats per minute are sufficient for a basic check of an oximeter, these simulations cannot by themselves probe the limits of an oximeter's performance in order to evaluate the its design.

Fluke Biomedical has equipped the Simulator to allow you the widest array of simulation, with the capability for direct control of the following the Simulator functionality:

- Bulk red light attenuation
- Bulk infrared light attenuation
- Peak-to-peak red pleth wave amplitude control
- Peak-to-peak infrared pleth wave amplitude control
- Shape of the pleth wave
- Simultaneous attenuation of both red and infrared by selected percent
- Generation of simulated ambient light

Note

See “Appendix E: Computer Control” for more information on the the Simulator computer control command. Refer to “Appendix A: Printing & Data Transfer”, for information on the RS232 port and how to set communications parameters (baud rate and parity settings).

Mathematical Background

The Simulator assumes that any oximeter under test uses the “ratio of ratios” formula, where a quantity “R” correlates with SpO₂, the *dc* terms are fixed attenuations, and the *ac* terms are peak-to-peak measures of additional attenuation due to the pleth wave (see the next section for help interpreting the formulas). The “ratio of ratios” formula is:

$$R = \frac{\text{redac}/\text{reddc}}{\text{iredac}/\text{iredc}}$$

math_bg_formula.eps

Oximeters perceive the Simulator to be using a variant of the above formula, which causes the *dc* terms to “drop out”.

Note

*In the following formula, “REDUUT” means **RED**-light, **Unit Under Test** and “IREDUUT” is for **InfraRed** light, **Unit Under Test**.*

The the Simulator calculates the R-value (as far as the oximeter is concerned) with this formula:

$$\frac{(0 \leq ac \leq 255)}{255} * \frac{(0 \leq rdc \leq 4095) \text{ REDUUT}}{4095} * \frac{(0 \leq rac \leq 4095)}{4095}$$

$$\frac{(0 \leq rdc \leq 4095) \text{ REDUUT}}{4095}$$

esl140.eps

$$\frac{(0 \leq ac \leq 255)}{255} * \frac{(0 \leq irdc \leq 4095) \text{ IREDUUT}}{4095} * \frac{(0 \leq irac \leq 4095)}{4095}$$

$$\frac{(0 \leq irdc \leq 4095) \text{ IREDUUT}}{4095}$$

esl141.eps

Notes on the Formulas

The *ac* term above attenuates both red and infrared pleth waves identically, to control simulated pleth strength. The default value is 255. In addition, red-light *dc* (*rdc*) and infrared light *dc* (*irdc*) modulate REDUUT and IREDUUT, which are transmissivity numbers. Zero would mean that no UUT (Unit Under Test) pulse would be allowed to pass through the Simulator. Attenuation would be 4,095 minus the value set. The default value here is 1,000.

Red-light *ac* (*rac*) and infrared light *ac* (*irac*) are true attenuations. A value of 1,000, for example, means that the pleth wave will attenuate the UUT pulse by approximately 25% of the maximum pleth amplitude. The default value for *irac* is 1,000. Values for *rac* range from 400 to 4,000, corresponding to .400 to 4.000 R-values; this covers the required range.

By having the pleth attenuation operate on the *dc* attenuated UUT flash, the Simulator becomes immune to fluctuations in oximeter flash amplitude, which can vary considerably.

Note

To reduce the corresponding dc term only, you increase the pleth amplitude term; conversely, to increase only the pleth amplitude term, you reduce the corresponding dc term. Keep this in mind when setting up performance limits tests.

The R-Value Equation

By dropping out terms that equate to one, and by accounting for the *dc* terms being transmissivities, we can reduce the previous equation to this:

$$R = \frac{rac / (4095 - rdc)}{irac / (4095 - irdc)}$$

esl142.eps

This is the equation used to obtain the R-values used in the Simulator, and presented on the LCD screen.

Although the equation eliminates the effect of changes in the UUT flash amplitude on the R-value, bulk attenuation of an actual finger is an important characteristic. By varying *rdc* or *irdc* values and determining how large a range of variation is “not seen” by the oximeter being tested, you can get a good idea of the oximeter's electronics' dynamic range and its processing capability. This is independent of finger thickness and pigmentation.

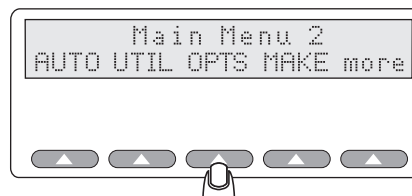
Note

By varying the ac term, you can determine the oximeter's ability to track and hold a pleth wave as it weakens to zero, and then re-acquire the wave as it strengthens.

Accessing Manufacturers' Tests

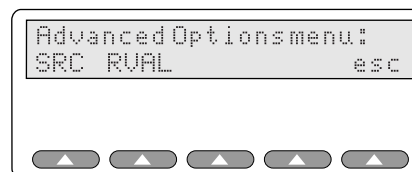
Access the manufacturers' test settings with the LCD screen.

Press the softkey **OPTS** on Main Menu 2.



fgg181.eps

The Advanced Options menu displays in the LCD with two menu options in addition to the escape softkey.



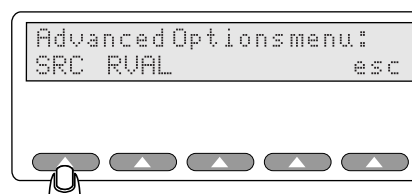
esl144.eps

The following options become available on the Advanced Options menu:

- **SRC** Sets the pulse signal source
- **RVAL** Sets the R-value
- **esc** Returns you to the Options Menu

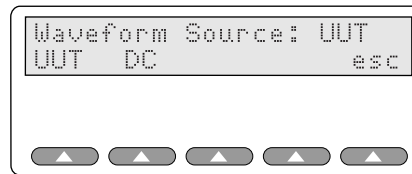
Setting the Signal Source

1. Press the **SRC** softkey on the Advanced Options menu:



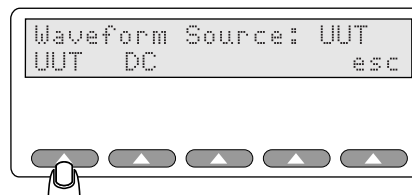
esl145.eps

The Waveform Source screen provides two options:



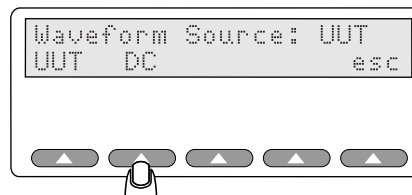
esl146.eps

2. Select the oximeter by pressing **UUT** (Unit Under Test) as the source for the pulse amplitude signal.



esl147.eps

3. Alternatively, press **DC**. The Simulator will ignore the oximeter's pulse amplitude and will use instead a fixed *dc* level for infrared and red pulse simulations.



esl148.eps

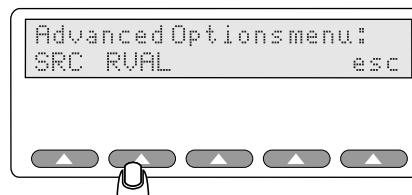
The signals will pass through the Simulator based on their original amplitude.

4. To return to the Advanced Options menu, press **esc**.

Setting the R-Value

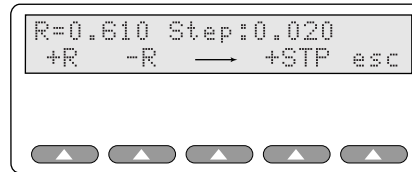
You can also enter a custom R-value using the following procedure:

1. Access the Advanced Options menu (if you have not already done so) by pressing **OPTS** on Main Menu 2.
2. Press **RVAL** on the Advanced Options menu:



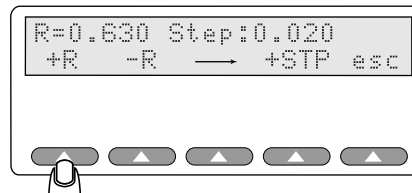
esl149.eps

You will see a screen appear similar to the following:



esl150.eps

- To raise or lower the R-value one step-amount at a time, use the softkeys **+R** or **-R**. In the sample below, the step amount is 0.020, and thus pressing the softkey **+R** raises the previous R-value from 0.610 to 0.630:



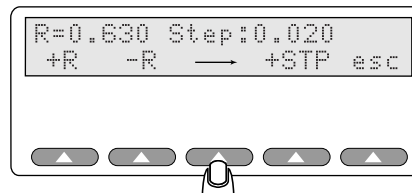
esl151.eps

- Continue pressing the softkeys **+R** or **-R** until the required R-value displays on the LCD.

Adjusting the Step Amount

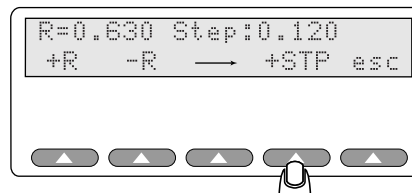
You can adjust the step to change the value that increases or decreases the R-value with each button push.

- First, use the arrow softkey to set the cursor under the step digit that you want to adjust. The cursor (flashing in the digit field) highlights first "0" in the sample above of 0.020. Advance to the next digit position by pressing **-->**.



esl152.eps

- Continue to press **-->** until the cursor is where you want it. Each time you press **-->**, the cursor moves one position to the right.
- With the cursor highlighting the digit you want to change, press **+STP** to increase the numeric value. In the sample that follows, the step is increasing in the second position by one to 0.120:



esl153.eps

- You can now continue to use the softkeys **+R** or **-R** to adjust the R-value.
- When you are done, press **esc** to return to the Advanced Options menu, then press **esc** again to return to Main Menu 2.

Chapter 12

Creating Your Own R-Curve

Introduction

The Simulator will store six download R-Curves into download slots according to specific light levels. You may trade a preprogrammed make for one that you use more regularly. This chapter explains how to create an R-Curve and download it to one of the “download slots” for future use.

The six slots are organized by light level technology as follows:

- Download Slot 1 = Medium Light
- Download Slot 2 = Medium Light
- Download Slot 3 = Medium Light
- Download Slot 4 = Medium Light
- Download Slot 5 = Low Light
- Download Slot 6 = Low Light

It is important that you save the R-Curve for the manufacturer in the correct light level slot. You can verify this by checking with the manufacturer or by trial and error. For comparison purposes, Nellcor and BCI use medium light level technology while Hewlett-Packard, Ohmeda and Invivo use low light level technology and Datex uses high light level technology.

You will need a computer, an RS-232 cable with a null modem, the oximeter to be characterized, a pencil, and the sample Index R-Curve Data Sheet (found on page 4 of this chapter).

Generating an R-Curve from a Pulse Oximeter

1. Set up the Pulse Oximeter and attach it to the Simulator.
2. From MAIN MENU 1 select SIM | MAN, set:

SpO₂ = 100%
BPM = 100

3. From MAIN MENU 2 select OPTS | RVAL, set:

Step = 0.010

Note

The R-value displayed on the Simulator will automatically be set to a value that corresponds to the SpO₂ value displayed on the Pulse Oximeter.

4. Step the R-value up by 0.010 and record the SpO₂ reading from the Pulse Oximeter. Make sure not to record an R-value until you can determine an “average” R-value, as more than one R- can correspond to the same SpO₂ percentage. For example:

SpO ₂	R-Val
99	.48
99	.49
99	.50

All three R-value reading have same SpO₂ value (Avg. = .49)

5. Continue recording R-values until SpO₂ = 50%

Downloading an R-Curve into the Simulator

1. Create an ASCII file with the numbers obtained on the data sheet. The file should look like this:

```
[rcurve:Ⓜ2 :N-10
:250:245:152,151,149,147,146,145,143,141,139,137,136,134,133,132,131,127,124,123,121,119,118,116
,114,112,111,110,108,106,104,102,100,098,096,094,092,090,088,086,084,081,078,076,073,070,067,064
,061,058,055,051,046,] •••••
```

Where: [rcurve sets the Simulator up to receive an R-Curve:

2 places the curve in download slot 3 (0-5)

N-10 is the name to appear (must be no more than 9 characters)

250 is the infrared DC Value

245 is the Red DC Value

152 is the start of the R-Value numbers (152 is a three-digit number for 50% SPO₂)

2. Use the LD.BAT file as described on page E-5 to download a curve (Filename). Basically, at the DOS prompt, set the following:

Mode COM1: 96, N, 8, 1
Copy [Filename] COM1:

Short Form Instructions

PN 2227040 Rev. A

INDEX R-CURVE DATA SHEET

Date: _____ Recorded by: _____

Pulse Oximeter Model: _____

Pulse Oximeter Serial Number: _____

Pulse Oximeter Verified On: _____

Probe Used: _____

Heart Rate Used: _____ R-Curve Downloaded in Position Number: ____

Notes: _____

Avg. R-Value	SpO ₂	Avg. R-Value	SpO ₂	Avg. R-Value	SpO ₂
	100		83		66
	99		82		65
	98		81		64
	97		80		63
	96		79		62
	95		78		61
	94		77		60
	93		76		59
	92		75		58
	91		74		57
	90		73		56
	89		72		55
	88		71		54
	87		70		53
	86		69		52
	85		68		51
	84		67		50

Appendices

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C	Accessories List	C-1
D	Specifications	D-1
E	Computer Control.....	E-1
F	Typical Questions and Answers	F-1
G	Custom Probe Test Cables and Electrical Simulation Cables	G-1
H	Glossary.....	H-1

Appendix A

Printing and Data Transfer

Introduction

This Appendix provides information on the Simulator's RS232 and printer ports, including how to configure the port on your printer or computer.

The Simulator provides a male D (9-pin) bi-directional serial port located at the back side of the unit, for the transfer of data to a computer or printer, and for computer control of the Simulator. The Data Computer Equipment (DCE) wiring configuration is shown Figure A-1.

Index 2MF RS232 Configuration

Fluke Biomedical offers a bi-directional serial null modem cable for connect the Simulator to your computer (IBM compatible) or serial printer. Please specify Fluke Biomedical *Part Number* 2238626 when ordering.

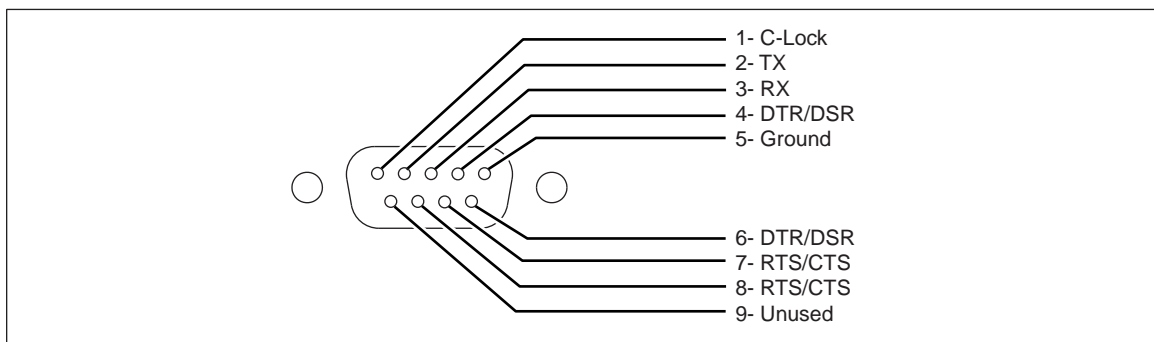


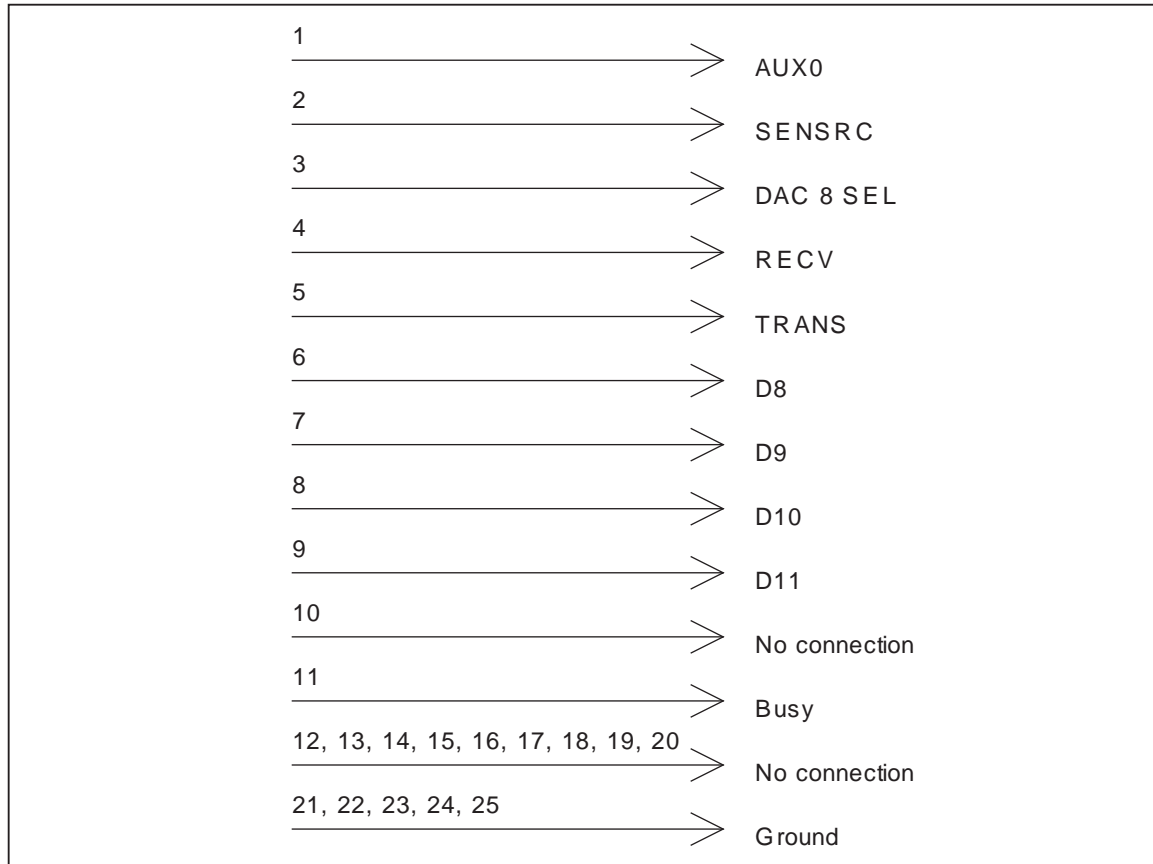
Figure A-1. Male D Cable End

C-Lock

Pin 1 of the serial connector provides the Simulator's synchronized pulse. This pulse is normally in phase with the start of each 64-point pleth wave. The phase of the sync pulse with regard to the wave can be varied using the [CPHASE *nn*] command, where *nn* is a number in the range of 0 to 63. The pulse is a negative going attenuated logic level. For more information, refer to "Appendix E: Computer Control".

Printer Port

The Simulator also has a Centronics parallel printer port. Information to be printed is sent out both the serial and parallel ports. Figure A-2 shows the pin-out for the parallel port.



esl154.eps

Figure A-2. Index 2MF Parallel Port D-25

A Standard D-25 pin to Centronics printer cable works with the Simulator. Please specify Fluke Biomedical *Part Number 2238072* when ordering.

Configuring the Serial (RS232) Port

Configure the Simulator to match your printer's or computer's communications needs by setting baud rate and parity. Once configured, you can then send the Simulator's test results directly from the Simulator to a printer through a serial connection.

If you have installed communications software on your computer system, you can also send data to your computer or control the Simulator through a computer with the the Simulator 's built-in RS232 serial port.

When communicating with the Simulator through a computer, you can choose from the following to match your system requirements.

Bits per Second:

- 300 bps
- 600 bps
- 1200 bps

- 2400 bps
- 9600 bps

Parity:

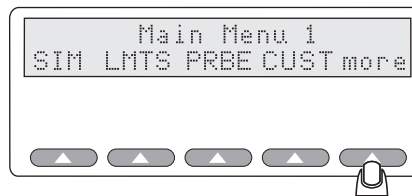
- None
- Even
- Odd

Stop and data bits:

- 1 or 2 stop bits
- 7 or 8 data bits

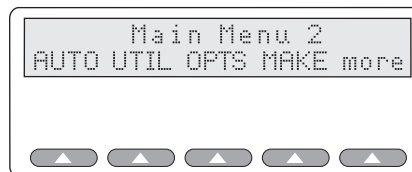
Accessing the Utilities Menu

1. Press **UTIL** on the the Simulator Main menu 2 (first press **more** if you are viewing Main Menu 1).



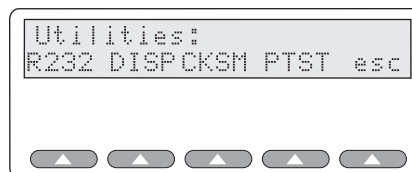
fgg014.eps

You will see the following menu appear in the Simulator 's LCD display:



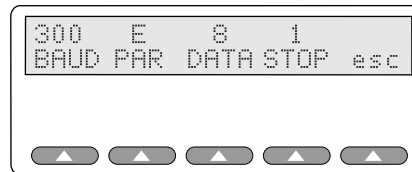
fgg161.eps

2. Press **UTIL** to access the Utilities menu.
3. The following Utilities screen offers four configurable options:



fgg133.eps

4. Press **R232** to set the RS232 port parameters:



esl167.eps

5. Press the softkey under the baud rate, parity type, and data and stop bit sizes to set the correct communications parameters for your printer or other device.

Table A-1 describes parameters used for PC to peripheral communication.

Table A-1. Communication Parameters

Parameter	Description
BAUD	Each press of the button decreases the baud rate from 9600 to 2400 , 1200 , 600 , and 300 bps. When 300 is displayed, a button push then shows 9600 .
PAR	Pressing this button toggles the parity from No parity (N) to Even parity (E) to Odd parity (O) and back.
DATA	Pressing this button toggles the data bits back and forth from 7 to 8 .
STOP	Pressing this button toggles the stop bit back and forth from 1 to 2 .

When you finish setting the communication control parameters:

- Press **esc** to return to the Utilities menu.
- Press **esc** again to return to the Main menu 2.
- Press **more** to return to the Main menu 1.

Printing

Sample Index 2MF Test Results Output

The Simulator Autosequence printout shown below requires using the previous settings to establish communication between the Simulator and a printer.

- The optional header is all information from the “Control#” field down to the “Technician” field.
- Actuals are all information under the “Settings:” heading. A normal report includes only the fields Alarm Response Time, Rate Alarm Response Time, and Pulse Amplitude Test.

```

Fluke Biomedical
SPO2 Simulator Ver: 2.00
-----
Control#: _____
Serial #: _____
Model: _____
Mfr: _____
Location: _____
Technician: _____
Date: _____

Simulations: NELLCOR
-----
Settings:                Actual:
#      O2      RATE      O2      RATE
1      100%    60 BPM    99      59
2      95%     65 BPM    95      64
3      90%     70 BPM    90      70
4      85%     75 BPM    85      75
5      84%     80 BPM    84      80
6      83%     85 BPM    83      85
7      82%     90 BPM    82      90
8      81%     95 BPM    81      95
9      80%    100 BPM    80     100
10     79%    105 BPM    79     105
-----
Alarm Response Time:12 Seconds at 95% O2
-----
Hi Rate Alarm Response Time:10 secs at 80
BPM
Lo Rate Alarm Response Time:10 secs at 80
BPM
-----
Pulse Amplitude Test
                At 85%, the signal is lost.
-----
Motion Response Time:          10 Seconds
-----
End of test.

```

esl155.eps

Appendix B

Error Messages and Corrective Measures

Introduction

This Appendix lists all of the error messages or beeps that may appear on the Simulator's LCD screen during normal operation. Solutions are given for each message.

Messages

If the battery has run down, the following message appears:

Warning! Low Battery

Although the battery included with the Simulator can run continuously for up to 8 hours, it does need regular recharging, especially after long periods of disuse. In addition, the battery can only be recharged a certain number of times, after which it needs to be replaced.

To recharge the battery, plug the battery charger that came with the Simulator into the Simulator charger jack and plug the battery charger into a wall socket, using the proper line cord.

Note

To fully recharge the battery, allow the battery charging at least 12 hours. Disconnecting the battery charger and using the battery prior to the full 12 hour charge time will result in an incomplete charge. The Simulator may only work for a very short time under such circumstances.

Beep Indications

Three beeps

You have pressed a button that is not activated for the particular screen or function. Try again.

Continuous beeps

Continuous beeps warn of a low battery. See the recharging instructions above.

Other Error Indications

Pulse Oximeter Not Reading SpO2 or Heart Rate

The display reads: "NO RED LED NO IRED LED Check probe or press esc"

The LEDs on the Pulse Oximeter must be positioned on the bottom of the Simulator 's finger probe attachment. Make sure the Pulse Oximeter's finger probe is centered and pushed as far forward as possible on Simulator's finger probe attachment.

Appendix C

Accessories List

Introduction

Table C-1 presents a list of accessories available for the Simulator. The User's Guide and a battery charger (U.S. or European) are standard equipment.

Table C-1. Accessories

Description	Part Number
Index 2MF User's Guide	3341210
Carrying Case	2204282
Charger (USA)	2521465
RS232 Cable	2238626
Printer Cable	2238072
Electrical Probe Test Cables	See price list
Electrical Simulation Cables	See price list

Appendix D

Specifications

Equipment Specifications

The following specifications apply to the Index 2MF and 2MFE.

%O2

Range	35 to 100 %
Resolution	1 %
Accuracy	100 to 75 %: ± 1 % \pm accuracy of the pulse oximeter under test. 74 to 50 %: ± 3 % \pm the accuracy of the pulse oximeter under test. <50 %: unspecified
Repeatability	± 1 standard deviation

Rate

Range	30 to 250 BPM
Resolution	1 BPM
Accuracy	1 % ± 1 BPM

Pulse Amplitude

Range	0 to 20 %
Resolution	1 %

Battery Life At least 4 hours of continuous use

Battery Charger

Type	Lead-Acid battery charger only
Input	100 – 250 V, 60 – 60 Hz, 0.3 A
Output	12 V dc, 0.5 A

Probe Test Index 2MFE version only

Continuity/Resistance Test

Test Matrix	Measures all combinations of possible interconnections in an XX point matrix.
Range	250 Ω to 150 k Ω
Accuracy	± 5 % of reading

LED/Detector Voltage Test

Test Format	Measures the voltage drop across Red LED, infrared LED, and the photo detector when the internally generated test signal is applied.
Test Signal	Constant current source at 1.0 mA
Open Circuit	2.5 V max
Measurement/Display Range	0.0 to 4 V
Accuracy	± 5 % of reading, 0.4 to 4 V

Dynamic Test

Test Format.....	Photo detector/diode response to both the red and infrared light generated by the probe when pulsed by an internal test signal.
Test Signal	Pulsed between the two LEDs, constant current level at 1.0 mA
Test Results	Nominal range of 0 to 20,000
Checksum	The sum of all locations in the program chip. For service only.

Note

The above specifications are for pre-programmed makes only, 20 % pulse amplitude SpO₂. Results for Presets, custom makes, and various pulse amplitudes are unspecified and depend on the algorithm of the specific pulse oximeter being tested.

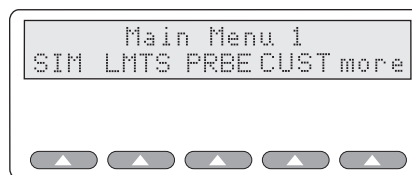
Appendix E

Computer Control

Introduction

You can set up a program to communicate with and control the Simulator via its RS232 port. To control the Simulator by computer:

1. Switch the Simulator power on using the slide switch. The LCD sequentially displays the following screens for about one second each before ending on the Main Menu 1 screen:
 - Bio-Tek Instruments Inc. and model number and version
 - Software version number and copyright years
 - Make of last selected test equipment
 - Main Menu 1 screen



esi009.eps

2. Connect the Simulator to the computer by connecting the RS232 cable to both the the Simulator and the computer's ports. Use a serial or null-modem cable. The RS232 port is a male DB 9-pin port.

Note

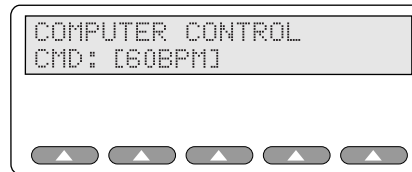
See "Appendix A: Printing & Data Transfer" for information on how to configure the Simulator's RS232 port to match the speed, bit settings, and parity of your computer system's serial port.

3. To initiate computer control, send a left bracket ([) from your computer to the Simulator.

Note

You will need communications software to send data to Index 2MF. Any commercial DOS or Windows communications package — such as Procomm from Datastorm Technologies, Smartcom from Hayes, Bit Software's Bitcom, or Microsoft Windows' "HyperTerminal" program — will do. Consult the user's guide that came with your communications package for set up and communications instructions.

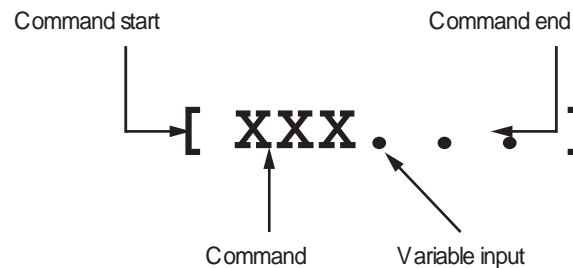
the Simulator's LCD displays each command that the computer sends to the Simulator, as in the example shown here:



esi166.eps

Command Syntax

Computer commands sent to the Simulator must observe a standard format:



esi156.eps

Commands are case insensitive and when a value is required, the input value is always numeric (except in the case of a make name, such as Nellcor) and the Simulator will properly interpret all numbers that follow a command. In the cases where a string of numbers is the input value, separate the numbers (such as 1.232, 1.2449, 3.0) with spaces or commas. For example, all of the following commands and values are valid as shown, and would be interpreted by the Simulator as the same value:

[IRdc33]
[IRdc,33]
[IRDC 33]
[IRDC, 33]

Computer Control Commands

Table E-1 shows valid commands for controlling the Simulator by computer.

Note

The Simulator normally responds to computer control commands by calculating all simulation values for each new simulation commanded. This may take over one second and interrupts the wave generation.

Table E-1. Valid Commands

Command	Description	Values	Example
AC ^[1] nn.nnn	Sets the AC amplitude. Leading zeros are not required except for values less than one. An entry of .025, as opposed to 0.025, will be interpreted as a signal strength of 25 and will be replaced by the default value of six.	00.001 to 20.000	[AC 10.001]
AMB	Sets the ambient light artifact simulation.	0 to 30	[AMB15]
BPM	Sets the pulse rate (beats per minute).	25 to 250	[BPM180]
CPHASE	C-lock phase control. Allows for the synchronization of the pleth waveform with an ECG monitor. The signal is 0 to 5 volts (limited by 4.7k) and can be synchronized to any part of the pleth waveform. Available at Pin 1 of the RS232 port.	0 to 65	[CPHASE45]
HIRES ^[1] n.nnn	At the low end of the signal strength scale, there is a high resolution mode of operation, accessible only through computer control as follows: Entry resolution is 0.001; however the resolution of the value stored and used is 0.005 %. Entries not divisible by 0.005 will be rounded down. The user is responsible for entering values less than one with a leading zero to the left of the decimal point.	0 to 1.000	[HIRES 0.955]
IPLATH	Uses Index 2MF's pleth waveform.	- -	[IPLATH]
IRAC	Sets the infrared light AC amplitude peak-to-peak attenuation for the pulse oximeter under test.	0 to 4095	[IRAC1000]
IRDC	Sets the infrared transmissivity.	0 to 4095	[IRDC1000]
MAKE	Selects the desired make 0 to 15. Returns the name via RS232. MAKE: Name		[MAKE0]
MAMP nnn	Corresponds to signal strength of the non-arterial wave, tap, or shiver. Leading zeros not required.	0 to 100	[MAMP 100]

Command	Description	Values	Example
MFREQ ⁽¹⁾ nn.nnn	Sets the artificial light artifact frequency in Hertz. Internal resolution at 60 Hz is about 0.2 Hz. To let the user know the effects of input rounding, the rounded value is output on the RS-232. For example, if the user enters [mfreq 60.1], the result will be 60.1882. Entry resolution is 0.001; however, the resolution of the value stored and used is near 0.2 Hz at 60 Hz.	45.000 to 75.000	[MFREQ 60.1]
MOXY nn	Sets the oxygen value of the non-arterial wave, tap, or shiver. Leading zeros are not required.	0 to 100	[MOXY 75]
NOMOTION	Turns off tap and shiver motion waves.	- -	[NOMOTION]
OXY	Sets the SpO2 percent for the selected make.	35 to 100	[OXY96]
PLAYER	Turns on the player mode.	- -	[PLAYER]
PRESETS nn	Selects a specific preset, where nn ranges from 00 to 23. A range of 00 to 23 for nn corresponds to preset motion selection shown in the presets in Table 6-2.	00 to 23	[PRESETS 05]
PROBE	Performs and returns the electrical probe test results. Displays tests by line.	- -	[PROBE]
Q	Quits the communications session and returns Index 2MF to Index 2MF control.	- -	[Q]
RAC	Sets the red light AC amplitude peak-to-peak attenuation for the pulse oximeter under test.	0 to 4095	[RAC4000]
RCURVE	Sends a new R-curve to Index 2MF.	various	[RCURVE, 0, NELLCOR, 2.00, 1.999, 1.899, 1.799, 1.699 ...]
RDC	Red transmissivity.	0 to 4095	[RDC1000]
SETTINGS	Retrieves the current Index 2MF settings in this format: Index 2MF Settings: ----- oxy displayed after set by [oxy NN] command BPM=75 Note: Modifying the following 4 variables inhibits oxy display until the next [oxy NN] command. RAC = 610 IRAC = 1000 RDC = 1024 IRAC = 1024 Light Flash: Unit Under Test AC = 100 % AMB = 0 % Make = Nellcor.	- -	[SETTINGS]

Table E-1. Valid Commands (cont.)

Command	Description	Values	Example
SHAPE	Indicates that the next 64 numbers represent a pleth wave shape.	- -	[SHAPE1.000, 3.9, 4.9,...]
SHIVER	Causes shiver artifact, a motion wave of 6.0 Hz.	- -	[SHIVER]
SRCF	Selects DC or fixed signal source level.	- -	[SCRF]
SRCU	Selects the test unit's signal source level.	- -	[SCRU]
TAP	Causes tapping artifact, a motion wave of 3.5 Hz	- -	[TAP]
UPLETH	Uses user's pleth waveform.	- -	[UPLETH]
VER	Displays the Index 2MF version number	- -	[VER]
[1] For values less than 1, it is necessary to enter a leading zero. For example, 0.1 must be entered instead of .1. A .1 entry will be interpreted as a signal strength of 1. Out of range entries default to six, which is a normal level. In reality, signal strengths over 6 % always correspond to saturation in the 90s therefore the 80 % limit should be of no physiological consequence.			

R-CURVE

The following is a sample of the format. Refer to Table E-2 for descriptions.

```
[ RCURVE>3:123456789:xxx:YYY:zzz,zzz, . . . . . zzz, ]
```

Table E-2. R-CURVE Format

Format	Description
[RCURVE>	Identifies this to computer control as an R-curve data stream.
3:	The curve number. Range is 0 to 5. There are six total downloadable R-curves. The colon is a field separator. Pulse oximeters use different intensities of light. R-curves 0 to 3 are reserved for oximeters that use normal intensities of light. R-curve #4 is reserved for pulse oximeters that use higher intensities of light; R-curve #5 is for pulse oximeters that use lower light intensities.
123456789	This field can be any combination of up to nine alpha-numerics or space characters. NOTHING ELSE! Typically, it will be an oximeter brand name.
xxx	The irdc value for this oximeter. Range is 0 to 1000, divided by 10 and rounded. For example, for 972 , use 097 (1000 becomes 100, and 17 becomes 020). Leading zeros are required!
YYY	Rdc value for this oximeter. Same format as irdc.
:	Field separator
zzz	R-values in the range 0 to 250. These will be multiplied by .01 inside the Simulator to be in the range 0 to 2.50. Leading zeros are required. Commas are required. No spaces are allowed. A comma after the last value is required. 51 values are required, corresponding to 50 thru 100 percent oxy, read left to right.
]	Right bracket identifies the end of the data stream.

The above data stream *must* all be on one line.

When downloaded, the computer control screen shall show the message from the beginning to the end of the oximeter name. Use the MAKE selection screen and [settings] to verify download.

SHAPE

Use this command structure, all in one line:

```
[SHAPE>N:YYY,YYY,YYY.....,]
```

Table E-3 describes the fields used in the command. All the command must be on one line, and the format must be followed precisely or it will not work.

Table E-3. SHAPE Format

Format	Description
[SHAPE>	Start of the command.
N	Wave identifier. Range 0 to 3. Wave 0 will be generated first; wave 1 will be second, etc.
:	A field delimiter.
YYY,	A three-digit number in the range of 000 to 100. Leading zeros are required.
]	Command end designator.

LD.BAT File

Both SHAPE and RCURVE commands can be downloaded from the computer to the simulator using the LD.BAT program detailed below. This program requires that MODE.COM be in the same directory or at least in the path.

Create a batch file with the following instructions:

```
Mode Com1: 9600,N,8,1
Copy%1 Com1:
```

At the DOS prompt, type:

```
LD FILENAME
```

Note that *FILENAME* is the name of the file with one SHAPE command. Each of the four shape commands must be in its own file.

Downloaded shapes are volatile; that is, not saved in memory. They are lost when the Simulator is turned off.

Each shape is independent. After loading 4, you can then load, for example, a different shape into [SHAPE>2, and only the third pleth wave in a series of 4 would be changed.

The Simulator will switch to your downloaded wave upon receipt of a [UPLETH] command. It will switch back to the stored internal pleth wave on receipt of an [IPLETH] command.

The Baud Rate in the Simulator must be set to match the LD.BAT Baud Rate setting as shown in Table E-4.

Table E-4. Baud Rate Settings

LD.BAT Setting	Baud Rate
30	300
60	600
12	1200
24	2400
96	9600

Note

When using the LD.BAT program to download waveform shapes, only download one waveform shape or R-Curve file at a time. Do not string several shapes or R-Curves into one file for download.

Player Mode

Player mode permits files of red and infrared readings, taken off an oximeter, to be "played back" through the Simulator in real time. These are long-duration files (player files) of real physiological behavior. These files are only available from select pulse oximeter manufacturers. Fluke Biomedical does not supply them.

Player file data is uploaded through the Simulator's serial port and loaded directly into the red AC and infrared AC digital-to-analog converters (DACs). The output waves of the DACs are controlled by the amplitude values and update rate of the serial port. Data sampling rate and playback rate will be equal. Data will nominally be set at 9600 baud N,8,1. However, this rate may be adjusted to control playback rate in terms of points/second. The N,8,1 must not change.

Once a player file (named with a .BIN extension) is obtained, a small batch file needs to be created and placed in the same directory (or folder). The batch file should consist of the following commands:

- mode com1:96,n,8,1
- :label
- copy /b %1 com1:
- goto label

Note

The /b in the batch file forces DOS to handle the file as a binary file.

To use the Player Mode:

1. Send [player] to the Simulator via computer control.
2. In DOS, go to the directory that has the two files and issue the following command:
LD filename (example: LD 8sec.bin), and press ENTER.

Note

In order to use Player Mode, it may be necessary to boot the PC in DOS mode. Some PCs have a conflict with driver files. This conflict appears to be resolved when the PC is actually booted in DOS mode (versus opening a "DOS box" from Windows).

To stop the playback, press CONTROL-C. To get the Simulator out of Player Mode, press any Simulator softkey.

Appendix F

Typical Questions and Answers

Introduction

1. How do I connect a probe from a pulse oximeter to Index 2MF?

With the pulse oximeter turned on, look for the visible red light coming from the probe. This side of the pulse oximeter finger probe must go on the bottom of the Index 2MF finger probe attachment.

2. What type of probes can be connected to Index 2MF?

Index 2MF is designed for an adult-size finger. Adult-size permanent probes and disposable probes can be tested. Other styles of probes (ear probes) may be used as long as the physical size is such that their LED's can be positioned on the bottom of the Index 2MF finger probe attachment and their photo diodes can be placed over the LED output of the Index 2MF finger probe attachment.

3. How should probes be positioned on the Index 2MF finger probe attachment?

Most common probes need to be centered and as far on the Index 2MF finger probe as possible. The exception to this is the Ohmeda permanent finger probe. The Index 2MF finger probe attachment should only be positioned within the contour of the Ohmeda permanent finger probe. Refer to Figure F-1. These instructions are only for the Ohmeda Finger Clip probe. (Ohmeda has two styles of permanent finger probes.)

4. I have connected the probe to Index 2MF and selected a manual simulation of 96 % SpO₂ and a heart rate of 75 BPM. The heart rate on the pulse oximeter reads 75 BPM but the SpO₂ reading on the pulse oximeter is 93 %.

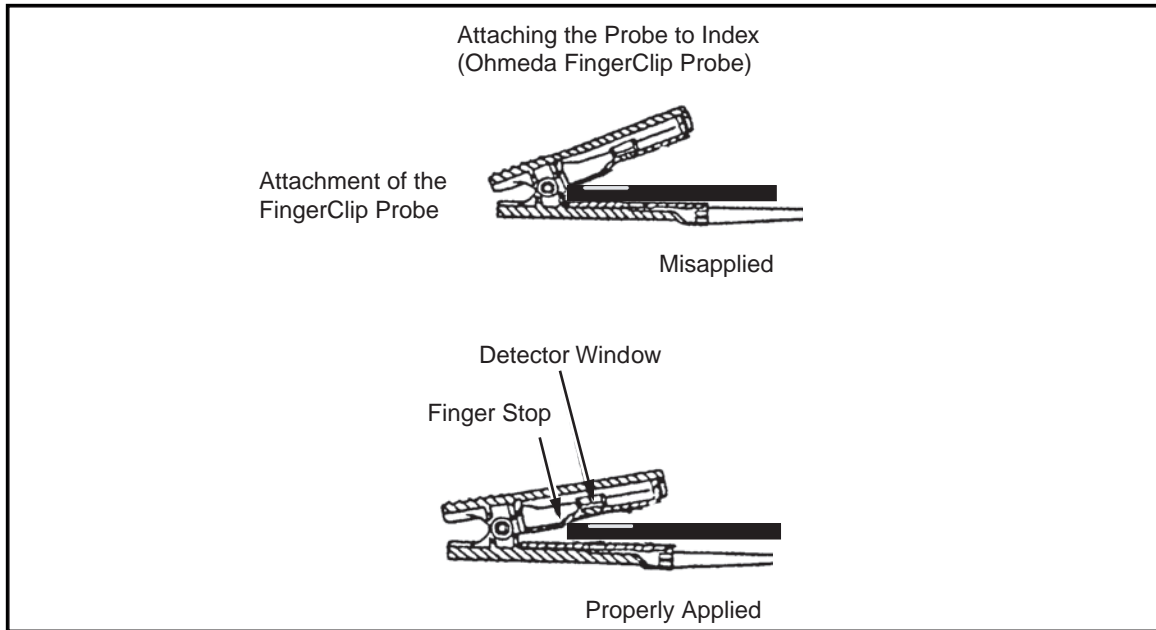


Figure F-1. Attaching the Probe to Index 2MF

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The low readings may be because the Pulse Oximeter under test is a *Nellcor* unit but the user has Ohmeda selected. Make sure the make selected in Index 2MF agrees with the make of the pulse oximeter being tested. Many manufacturers use different “R” curves for measurement.

You might try repositioning the probe for closer results, especially disposable probes. With disposable probes, it is difficult to ensure consistent alignment of the LEDs to the photo detector. This could also be a problem when using a disposable probe on a patient.

5. I cannot find the make of the pulse oximeter I am testing with Index 2MF. What do I do?

Index 2MF currently has curves for many oximeters. If the pulse oximeter under test is one of the following, use the *Nellcor make* selection:

Airshields, Inc.

Atom Medical Corp.

Baxter Healthcare Corp.

Century Medical Inc.

Colin Medical Instruments Corp.

Corometrics Medical Systems

Critikon, Inc.

Datascope Corp.

Drager (Europe)

Edentec

Fukuda Denshi

Synectics

Ivy Biomedical

Marquette (Eagle)

MDE(Medical Data Electronics)

Mennen Medical

North American Drager

Pace-Tech, Inc.

Protocol Systems, Inc.

Pryon Corp

Siemens

Sleeptrace/Areca Science

SpaceLabs

Witt Biomedical

Substitute the *make* Ohmeda for the following brands of pulse oximeters:

- *Marquette (other than Eagle monitor)*
- *Hellige*
- *S&W*
- *Radiometer*
- *Corometrics*

Use the *make* BCI for the following brands of pulse oximeters:

- *Elmed*
- *Bruker*

6. I have selected the Nellcor make and am testing disposable probes. The results on the monitor are OK at high saturation levels (90 to 100 %), but as I go lower, the readings on the pulse oximeter vary from the setting.

This is because each Nellcor disposable probe is calibrated differently. The same is true for Ohmeda probes - an in-line adapter forces the monitor to the calibration curve that matches that of Index 2MF.

7. How did Fluke Biomedical obtain the R-curves?

We worked with each manufacturer and they sent us a pulse oximeter for characterization. The curves were then verified on several pulse oximeters of that brand. It is possible to download additional R-curves to Index 2MF as needed for pulse oximeters that are not preprogrammed into Index 2MF. The operator's manual describes how to download R-curves. All that is needed is a computer and the pulse oximeter.

8. Some pulse oximeters indicate SaO2 and some indicate SpO2. Which is it?

The definition for SaO2 read from a pulse oximeter is SpO2. This has become a standard in recent years.

9. How do I set up the DPU-411 Printer to work with Index 2MF?

Table F-1 shows the correct DIP switch settings (parallel) for the Seiko DPU 411 Printer when used with Index 2MF. The table also shows switch settings for serial printing.

Table F-1. Seiko DPU 411 DIP Switch

Switch 1 Position	Function	ON	OFF	Setting for Index 2MF
1	Input Method	Parallel	Serial	Parallel
2	CR Function	CR & LF	CR only	CR only
3	Print Mode	40 column	80 column	80 column
4	Character Set	Ordinary	Special	Ordinary
5	Zero Font	0	0	ON
6	Int. Character Set			

Appendix G

Custom Probe Test Cables and Electrical Simulation Cables

Introduction

This Appendix explains how to make custom probe adapter cables and electrical simulation cables to be used with your Index 2MFE.

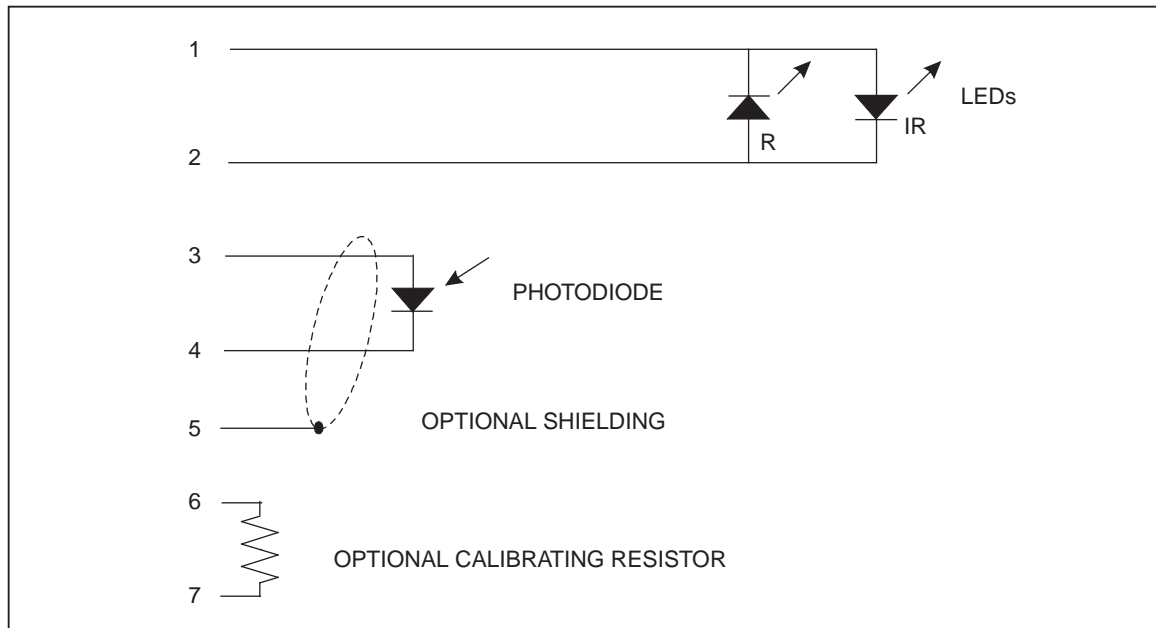
Making Probe Test Cables

Index 2MFE can be used to test probes using custom probe adapter cables.

Figure G-1 shows a typical oximeter probe. It consists of two LEDs and one photodiode. In addition, it may also contain an LED spectrum characterizing resistor or two. Some of the wires may be shielded.

Typical probe failure modes are:

- Wires open or shorted to other wires
- Diodes open or shorted
- Resistors, if present, open or shorted to other leads
- Leads shorted to shields and/or other leads

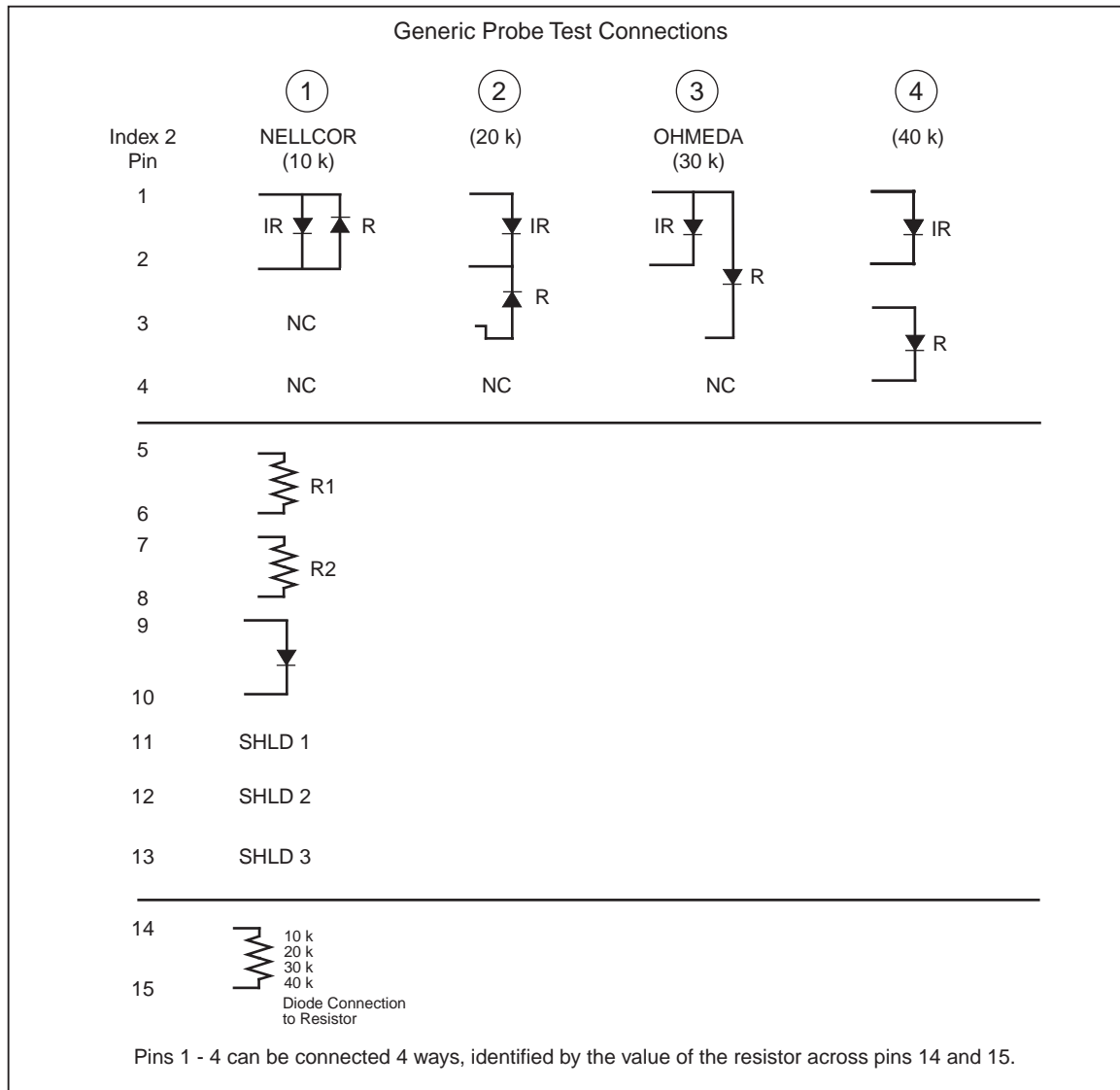


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Figure G-1. Typical Oximeter Probe

The Simulator is designed to find all these failure modes. Note, as shown in Figure G-2, that the LEDs may be connected in one of four ways:

1. Back to back (typical of Nellcor)
2. Common cathode
3. Common anode (typical of Ohmeda)
4. Completely separate



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Figure G-2. Generic Probe Test Connections

Note

Because of the many different ways probes can be connected, your Simulator is designed to work with an interface cable that adapts the Simulator connector to the probe connector.

If you need to test a probe which is not supported by Fluke Biomedical at this time with an interface cable, the following information will enable you to make your own interface cable.

Pins 1 through 4 are reserved for LED connections. Figure G-2 shows the four possible LED arrangements and how to connect each to pins 1 through 4. For example, the typical Nellcor type probe uses only pins 1 and 2 and has the IR LED anode on pin 1.

How does Index 2MF know which LED arrangement is being used? See pins 14 and 15. A 1 % resistor is placed across these pins. The value of the resistor versus the LED arrangement is given in Table G-1.

Table G-1. Resistances with LED Arrangements

Technology Options	Typical Oximeter
10 K	Back to back (typical of Nellcor)
20 K	Common cathode
30 K	Common Anode (typical of Ohmeda)
40 K	Completely separate

Before testing the probe, the Simulator reads this resistor to determine the LED connection being tested.

Examining the 15-pin connector further:

1. Up to two LED calibration resistors can be tested by the Simulator. Connect them as R1 and R2 in Figure G-1.
2. The probe photodiode is to be connected to pins 9 and 10 as shown.
3. Finally, up to three shields can be tested for shorts to other leads. These would be connected to any of pins 11, 12, or 13.

Refer to Figure G-3, an example of the Ohmeda probe test connections.

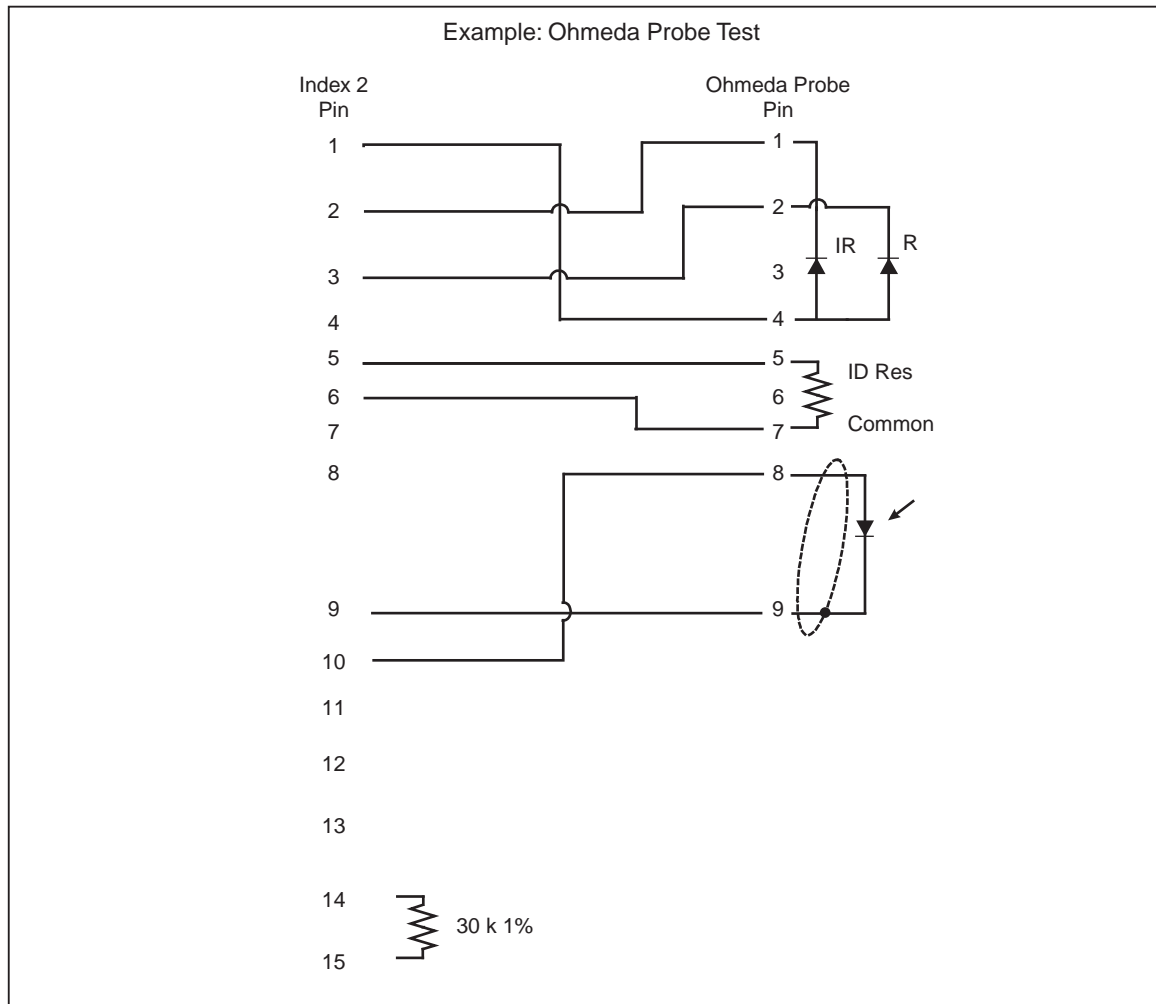


Figure G-3. Example: Ohmeda Probe Test

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Making Electrical Simulation Cables

Index 2MFE is capable of electrically simulating a probe on a patient connected to an oximeter.

⚠ Caution

To avoid damage to the oximeter and the Simulator, do not attempt to use a self-made interface cable. Use only the cable supplied with the unit. Use of the information presented here constitutes acknowledgment of risks involved with using any “do-it-yourself” oximeter test interface between the Simulator and any oximeter.

The following list is not exhaustive, but you should be familiar with all of the electronic details of:

- The oximeter LED drive circuit
- How the oximeter decides if a probe is present
- Whether the photodiode input amplifier circuit is characterized as follows:
 - Single-ended
 - Differential
 - A current-to-voltage converter
 - Grounded photodiode
 - DC biased photodiode
- Photodiode floated separately from the LEDs
- Polarity of the photodiode connections

⚠ Caution

To avoid damage to the oximeter and the Simulator, take into account all of the relevant details of the oximeter’s probe operating scheme. Under no circumstances shall Fluke Biomedical be responsible for any damages.

Figure G-4 is the hardwire test interface from the Index 2MF.

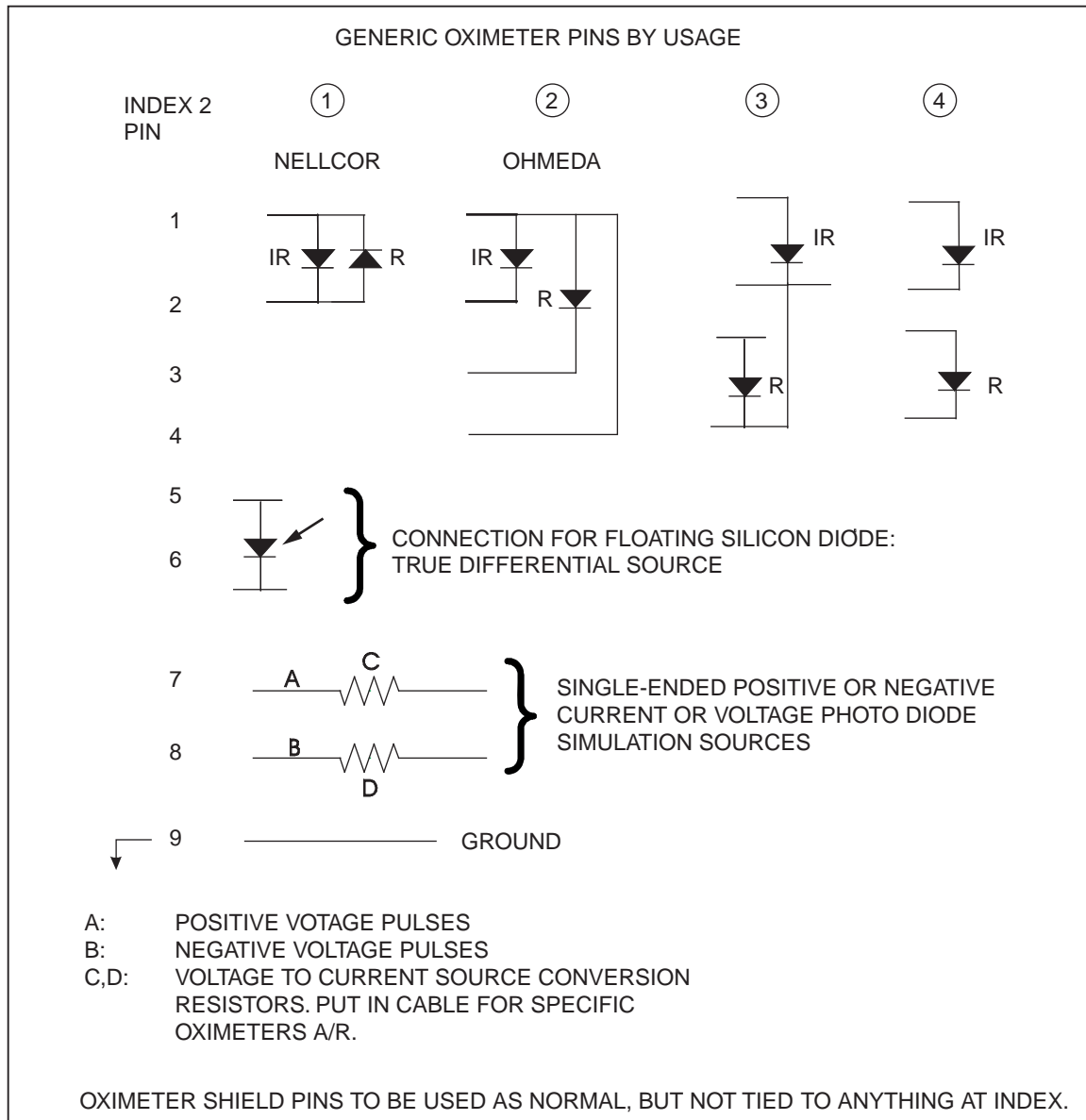


Figure G-4. Generic Pins by Usage

esi162.eps

Pins 1 through 4 show the different ways oximeter probes can have their LEDs connected. For example, if the Simulator were used to simulate an Ohmeda probe, the Ohmeda drive pins would be connected to the Simulator connector on pins 1 through 4 as shown. Current scaling resistors may be required (see Figure G-5, the actual Ohmeda interface cable).

An oximeter expects to see light flashes detected by a floating silicon photodiode. Pins 5 and 6 of the Simulator provide a floating silicon photodiode, which is driven with the simulated signal. It must be connected to the correct polarity inputs of the oximeter. Scaling resistors on its output may be required (see Figure G-5, the actual Ohmeda interface cable).

In some cases, it may be advantageous to **not** use the floating diode source. In these cases, the Simulator provides a ground pin at pin 9, and both positive and negative simulation voltage signals on pins 7 and 8. These may be converted to current signals by appropriate scaling resistors as noted in Figure G-5.

Normally, oximeter shield pins should not be tied to the Simulator ground, but there may be exceptions. Again, only a thorough study and understanding of the oximeter interface circuits can answer these questions.

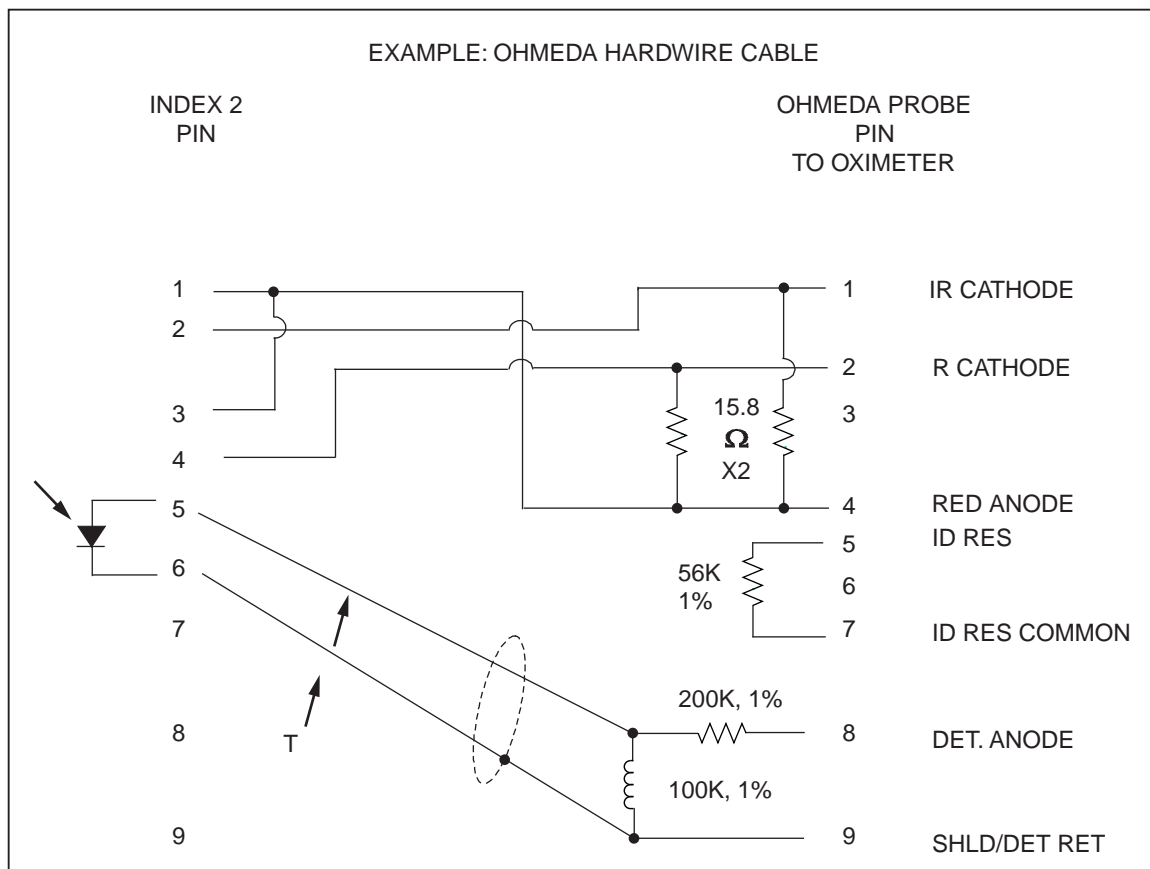


Figure G-5. Example: Ohmeda Hardware Cable

Appendix H

Glossary

Introduction

The glossary presents certain medical, electronic and the Simulator-specific terms, the understanding of which may aid in the operation of the Fluke Biomedical Index2[®] SpO₂ Simulator.

Definitions that appear in this glossary are from *Merriam-Webster Online Dictionary, 2005* and *Newton's Telecom Dictionary, 18th Edition, 2006*. Words that appear in a definition in **boldface** are themselves defined elsewhere in this glossary.

AC component

The pulse factors of the blood measured by oximetry.

Ampere

A unit of electric current in the **meter-kilogram-second** system. It is the steady current that when flowing in straight parallel wires of infinite length and negligible cross section, separated by a distance of one **meter** in free space, produces a force between the wires of 2×10^{-7} **newtons** per meter of length. [After André Marie Ampère (1775-1836).]

aorta

The main trunk of the systemic **arteries**, carrying blood from the left side of the heart to the arteries of all limbs and organs except the lungs.

artery

Any branching system of muscular tubes that carry blood away from the heart.

asynchronous

Signals sent to a computer at irregular intervals. Data is transmitted at irregular intervals by preceding each character with a start bit and following it with a stop bit.

Asynchronous transmission allows a character to be sent at random after the preceding character has been sent, without regard to any timing device.

baud

A transmission speed measurement across a medium. Baud (after J.M.E. Baudot, 1845-1903) denotes the number of discrete signal elements, such as bits, transmitted per second. Often confused *with* bits per second (bps, which means the number of binary digits transmitted in one second), the baud rate measures the number of changes per second in a sine-wave signal.

bigeminy

A **cardiovascular** condition wherein the pulse occurs in groups of two rapid beats with a pause following each pair of beats.

blood pressure

The pressure of the blood within the arteries, primarily maintained by contraction of the left **ventricle**.

BPM

Beats per minute. See **pulse**.

bradycardia

A **cardiovascular** condition characterized by an abnormally slow heartbeat of less than 60 beats per minute.

cardiovascular

Of, pertaining to, or involving the heart and the blood vessels.

capillary

One of the tiny blood vessels that connect the arteries and veins.

centimeter-gram

A coherent system of units for mechanics, electricity, and **second system** magnetism, in which the basic units of length, mass, and time are the centimeter, gram, and second.

DC component

SEE R-Value

dyne

A **centimeter-gram-second** unit of force, equal to the force required to impart an acceleration of one centimeter per second per second to a mass of one **gram**.

globin

A simple protein obtained from hemoglobin.

gram

A metric unit of mass and weight, equal to one-thousandth (10^{-3}) of a kilogram, about 0.035 ounces.

heme

The non-protein, ferrous-iron-containing component of **hemoglobin**.

hemoglobin

The oxygen-bearing, iron-containing conjugated protein in vertebrate red blood cells, consisting of about 6 per cent **heme** and 94 per cent **globin**.

Hertz (Hz)

A unit of frequency equal to one cycle per second. Used to measure electrical current and light, especially ultraviolet radiation (as in fluorescent light).

infrared

Of, pertaining to, or being electromagnetic radiation having **wavelengths** greater than those of visible light and shorter than those of **microwaves**.

kilogram

The fundamental unit of mass in the International System, about 2.2046 pounds.

LCD

Liquid crystal display; a digital display consisting of a liquid crystal material between sheets of glass that becomes readable in the presence of an applied voltage.

meter

The fundamental unit of length, equivalent to 39.37 inches, in the metric system. Originally defined in 1790 as one ten-millionth (10^7) of the earth's quadrant passing through Paris, the meter was redefined in 1960 as the length equal to 1,650,763.73 wavelengths in a vacuum of the orange-red radiation of krypton 86.

meter-kilogram

A coherent system of units for mechanics in which the basic units of **second system** length, mass, and time are the meter, kilogram, and second.

microwave

An electromagnetic wave having a wavelength in the approximate range from one millimeter to one meter, the region between infrared and short wave radio wavelengths.

nanometer

One-billionth (10^{-9}) of a **meter**.

nanosecond

One billionth (10^9) of a second (one thousand-millionth of a second). Electricity travels approximately one foot per nanosecond.

newton

In the meter-kilogram-second system, the unit of force required to accelerate a mass of one kilogram one meter per second per second that is equal to 100,000 dynes. [After Sir Isaac Newton (1642-1727).]

non-invasive

A medical procedure neither invasive nor involving an invasive action, not tending to spread, especially not tending to invade healthy tissue.

ohms

A unit of electrical **resistance** equal to that of a conductor in which a current of one **ampere** is produced by a potential of one **volt** across its terminals. [After George S. Ohm (1787-1854).]

pulse

The regular expansion of an artery caused by the ejection of blood into the arterial system by the contractions of the heart.

pulse oximeter

A **non-invasive**, arterial, oxygen-saturation monitor that measures the ratio of two principle forms of **hemoglobin** in the blood.

PVCs

Premature ventricular contractions. A condition characterized by an irregular heartbeat caused by an abnormal, or ectopic, ventricular pacemaker.

resistance

The opposition to electric current characteristic of a medium, substance, or circuit element.

RS232

The RS232 interface provides an electrical description for connecting peripheral devices to computers using either a 25-pin connector or a 9-pin connector.

Generally speaking, personal computers are data terminal equipment (DTE) devices and peripherals such as printers, mice, modems, and the Index2 are data communication equipment (DCE) devices. When connecting two like devices (a printer connected to Index, for example), you must use a null modem cable. See also **serial port**.

R-Value

The non-pulsating components of tissue, specifically the tissue bed, the **venous** blood, the **capillary** blood, and nonpulsatile arterial blood. Also referred to as the DC component.

SaO₂

Abbreviation for saturated oxygen, SaO₂ is the ratio of the concentration of oxyhemoglobin (cHbO₂) to the concentration of the two principle types of blood hemoglobin: saturated hemoglobin (HbO₂) plus reduced hemoglobin (Hb).

serial port

An **asynchronous** communication (COM) port or address by which a peripheral, such as a printer, a mouse, or even the Simulator connects to a computer or other device. Serial (COM) ports send and receive data one bit at a time over a single line, as opposed to parallel communications where multiple wires in the cable send data in multiple bits. See also **RS232**.

SpO₂

The type of saturated oxygen measured with a pulse oximeter.

tachycardia

A *cardiovascular* condition characterized by an excessively rapid heartbeat.

venous

1. Of or pertaining to a vein or veins.
2. Returning to the heart through the great veins.

ventricle

A small anatomical cavity or chamber in the heart, although also the brain. Used in context of this manual, ventricle refers to (a), the chamber on the left side of the heart that receives arterial blood from the left atrium and contracts to drive it into the aorta; and (b) the chamber on the right side of the heart that receives venous blood from the right atrium and drives it into the pulmonary artery.

volt

1. The International System unit of electric potential and electromotive force, equal to the difference of electric potential between two points on a conducting wire carrying a constant current of one ampere when the power dissipated between the points is one watt.
2. A unit of electric potential and electromotive force equal to 1.00034 times the International System unit. [After Count Alessandro Volta (1745-1827).]

wavelengths

Distance between two points of corresponding phase in consecutive cycles in a periodic wave.

