

Index 2XL 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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Unpacking and Inspection

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 <u>techservices@flukebiomedical.com</u> or call 1-800- 648-7952 or 1-425-446-6945.

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 currier 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 1-800-648-7952 or 1-425-446-6945.

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

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Index 2XL

Users Guide

Chapter 1 Introducing Index 2XL

Capabilities

Index 2XL allows accurate verification of pulse oximeters by allowing you to test them in a variety of ways. The Index 2XL 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 Index 2XL to the medical and health industry to allow measuring pulse oximeters currently on the market against widely accepted performance standards.

Using Index 2XL as a virtual patient's index finger, you set the Index 2XL device to simulate a patient with virtually any combination of blood oxygen conditions. When the pulse oximeter under test connects to the Index 2XL Simulator, measure its responses against Index 2XL's stored 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. If the results differ, Index2 reports the percentage by which the pulse oximeter is out of agreement. Electrically, Index 2XL can verify probe diodes, wire continuity, LEDs, and oximeter accuracy.

Like all of Fluke Biomedical's hardware and software systems, the Index 2XL SpO₂ Simulator is backed by Fluke Biomedical's superior support system. If Index 2XL 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 2XL Compatibility

The Index 2XL Simulator can quickly establish the state of any given pulse oximeter and determine the performance qualities of the device. Index 2XL 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 preprogrammed into Index 2XLF and FE a number of different R-values versus SpO₂ curves for specific manufacturers. This ensures that Index 2XL provides the closest possible simulation. It is also possible to download additional R-value curves directly into Index 2XL for non-volatile storage and use. Additionally, the Index FE has adapter cables to test most popular oximeters and probes through electrical simulations.

Note

Index 2XL is not intended to be a pulse oximeter calibrator.

Index 2XL 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 (FE 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 4" 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 Index 2XL package as shipped include:

F Version

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

FE Version

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

Registration Card

Once the Index 2XL is successfully up and running, complete the postage-paid Index 2XL registration card and mail it to Fluke Biomedical.

Precautions

Observe these precautions when using the Index 2XL; like any electronic equipment, it should be adequately protected both when moving and in storage.

▲ Caution

When connecting Index 2XL to a peripheral, such as a PC's RS232 serial port or printer, power OFF both Index 2XL and the peripheral device during connection and disconnection. Failure to follow this precaution may result in damage to the equipment.

Index 2XL 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 Index 2XL to ensure that the power switch cannot accidentally turn on during shipment.
- Always connect Index 2XL to its charger when not in use. Index 2XL allows continuous charging, a practice that ensures full power charge whenever needed. Index 2XL may also be used while charging.
- Always turn off Index 2XL and connect it to its charger when the low battery alarm sounds. Index 2XL can be used within about 1 minute of commencing charge. (Index 2XL 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 Index 2XL 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 Index 2XL's battery. Based on the testing below, Index 2XL bears the CE mark.

Electromagnetic Interference and Susceptibility

EC EMC Directive 89/336/EEC

EN 50081-1, CLASS A-Emissions

The Index 2XL 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 Index 2XL 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 Index 2XL 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

1-3

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'met 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

Index 2XL, 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 Index 2XL prior to use in these kinds of environments.

Safety

Index 2XL 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

Index 2XL operates below 75 VDC, thus EN 61010-1 is not applicable.

Getting Started

Unpack Index 2XL from the shipping carton. Check that the shipment is complete and all parts are intact.

Starting Index 2XL 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:

- Fluke Biomedical with model number and version
- Software version number and information
- Make of last selected test equipment
- 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 Index 2XL Simulator, with the softkeys **SIM**, **LMTS**, **PRBE**, **AUTO**, 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 Index 2XL 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 $Sp0_2$ levels from 35 to 100%, and the heart rate from 25 to 250 BPM.

1. The LCD indicates current Sp0₂ 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 Index 2XL finger probe attachment. Position the pulse oximeter LEDs on the bottom of Index 2XL's 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 Index 2XL LCD.

Note

Oximeters take from 5 to 20 pulses to respond to a change in simulated SpO_2 or BPM.

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Index 2XL

Users Guide

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.



Figure 2-1. Sphygmomanometer

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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 (O₂) 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, SaO_2 , 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.

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

Figure 2-2. Formula for Determining Saturated Oxygen Level

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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.

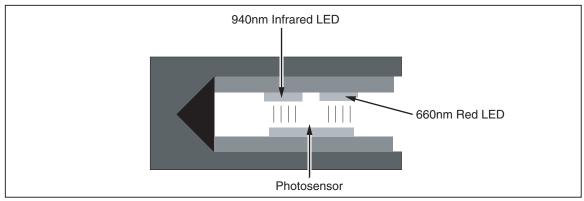


Figure 2-3. Diagram of Sample Finger Probe for a Typical Pulse Oximeter

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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 (SaO₂).

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 SaO₂ 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.

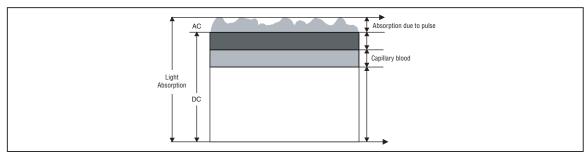


Figure 2-4. Diagram of Light Absorbers in Tissue

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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

esl007.eps

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 2XL Overview

The Index 2XL "Finger" (Index 2XL F and FE Versions)

The Index 2XL 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 SpO_2 (Saturation of Peripheral Oxygen) through the index finger (as opposed to the earlobe or toe) tissue.

Inserting the Index 2XL finger into the pulse oximeter probe effectively connects the two devices for testing purposes.

Note

When connecting a finger sensor, onto Index 2XL'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.

Index 2XL Electrical Testing (Index 2XL FE 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 Index 2XL, thus eliminating the probe from the circuit. FBC makes specific cables to connect the electrical port on the Index 2XL 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, Index 2XL 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

Index 2XL 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 Index 2XL to a computer to control Index 2XL and run all tests.

Evaluating Test Results

Index 2XL 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 Index 2XL, simulating devices which have readout resolutions of 1 % (oximeters) or repeatability of simulations better than 1 % is mandatory. Index 2XL 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 Index 2XL 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.

Index 2XL Functionality

Figure 3-1 illustrates the basic functions of the Index 2XL system.

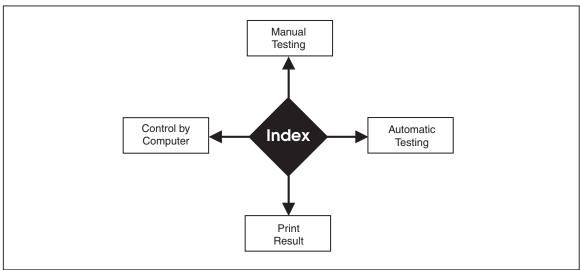


Figure 3-1. Basic Index 2XL Functions

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Chapter 4 The Index 2XL Main Menus

Introduction

When you first turn on an Index 2XL, the simulator sequentially displays the following screens for about one second each before ending with the Main Menu 1 screen:

- Fluke Biomedical Corp and model number and version
- Software version number and information
- Make of last selected test equipment



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 Index 2XL Main Menu 1

The Index 2XL Main Menu 1 choices give you access to the full Index 2XL 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.)



esl010.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
- **TLC** to set the transmission level control
- **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.



esl011.eps

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

- **O2** to set up Sp02 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.



esl012.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

The softkey **AUTO** allows you to create and run tailored test procedures.



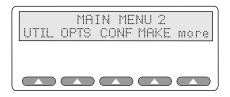
esl013.eps

AUTO menu options include:

- **PROG** to select a test to run
- **RUN** to start a stored test program
- **DEFS** to restore all autosequences
- **esc** softkey to return to Main Menu 1

The Index 2XL 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 Index 2XL serial (RS232) port, and adjust the contrast of the Index 2XL LCD screen.



esl161.eps

The choices available at the Main Menu 2 include:

- **UTIL** to change the display and configure the RS232
- **OPTS** to open the Advanced Options menu
- **CONF** to launch the Configuration menu
- **MAKE** to select the pulse oximeter being tested
- **more** to toggle Main Menu 1

Each of these Index 2XL Main Menu choices is discussed separately in the next few chapters.

Note

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

4-3

Index 2XL

Users Guide

Chapter 5 Configuring Index 2XL

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 Index 2XL to match the make of pulse oximeter(s) you will be testing. Index 2XL 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 Index 2XL's memory using the Make menu.

1. To get to the Make menu, press **more** from the Index 2XL Main Menu 1.



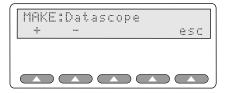
esl015.eps

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



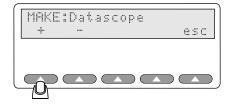
esl169.eps

You will see the following appear in Index 2XL's LCD display:



sl016.eps

3. Press the softkey for the + or - to scroll through Index 2XL'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 Index 2XL:

- BCI[®] (3101)
- Criticare® (504)
- Datascope[®] (Passport)
- Datex® (CardioCap, Ultima, Satellite Trans, AS/3, 251)
- HP® (Merlin)
- Nellcor® (N-100, 200)
- Nihon-Kohden[®] (Lifescope)
- Novametrix[®]
- Ohmeda[®] (3700) and Nova
- Respironics®
- Philips Medical Systems (PMS M1190)
- Nonin

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 2XL by these manufacturers. Fluke Biomedical assumes the responsibility for the R-Curves, and any results obtained from the use of Index 2XL.

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 Index 2XL.

▲ Caution

Other manufacturers' oximeters can be electronically tested by Index 2XL, but will require special care in preparation of an adapter cable and interpretation of the results. Damage could occur to Index 2XL or the oximeter if the adapter cable is not correct. See "How to Customize a Make Not Included Within Index 2XL" on page 22 of this chapter for more information.

Note

Six additional manufacturer's profiles are incorporated in Index 2XL. These six profiles may be changed at the Download Make menu by selecting **Make** at Main Menu 2. Refer to Appendix E, Computer Control, for information on how to download a manufacturer's profile into Index 2XL.

- M1191 New
- M1191 Old
- N-10
- Palco 300[®]
- Nonin
- Invivo[®] *

5-3

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

Index 2XL

Users Guide

Chapter 6 Setting and Changing Simulation Factors

About Simulations and Presets

One of the main functions of Index 2XL as a SpO₂ simulator is to test the performance of a pulse oximeter for any possible patient condition. Index 2XL 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 with Index 2XL allows you to test an oximeter and determine its weaknesses, if any. Index 2XL 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 Index 2XL Main Menu.



esl010.eps

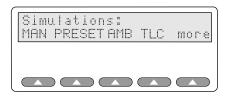
The Simulations Menu

The Simulations menu appears in the Index 2XL 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
- **TLC** to set up transmission level control
- **esc** to return to previous menu (Main Menu 2)

Note

Do not connect the Index 2XL FE to two pulse oximeters simultaneously. The simulator must synchronize with Red and IR signals from only one oximeter.



esl030.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 Index 2XL default of 96%, or the BPM default of 75, use MAN .
PRESET	Allows you to select from the Index 2XL presets for patient conditions, including:
	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 Index 2XL sunlight default, use AMB .
TLC	Allows you to change the Transmission Level Control.

Note

To set a patient condition other than that of the Index 2XL default of "normal," use **PRESET**.

Changing the Default SpO2 Setting

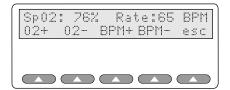
The default settings (for the current session from power-up, when no prior changes have been made) are for a simulated patient with 96% saturated oxygen levels and with a pulse of 75 beats per minute.

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



sl031.eps

The manual settings screen appears on the Index 2XL LCD, displaying the current SpO2 and BPM:

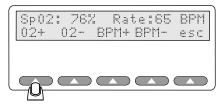


esl032.eps

Setting the O2 Saturation Level

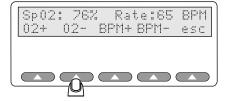
You can raise or lower, as needed, the simulated degree of oxygen saturation in the virtual patient.

1. To raise the O_2 level two steps at a time, press **O2+**.



esl033.eps

2. To lower the O_2 level two steps at a time, press O_2 -.



esl034.eps

6-3

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

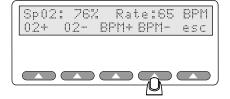
Index 2XL also lets you adjust the pulse, for a customized virtual patient.

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



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

esl035.eps



esl036.eps

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

Returning to the Index 2XL Main Menu 1

To return to the Index 2XL Main Menu, press **esc** twice.

Using Index 2XL Preset Patient Conditions

The Index 2XL preset feature combines SpO₂ levels, heart rates, signal strength, motion, and pulse amplitude into seven 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			[mmaaata#]
				Saturation	Frequency	Amplitude	[presets#]
Normal	98 %	55 BPM	5.0 %	-	-	0 %	00
Weak Pulse	90 %	95 BPM	0.65 %	-	-	0 %	01
Bradycardia	88 %	45 BPM	5.0 %	-	-	0 %	02
Нурохіс	70 %	95 BPM	2.0 %	-	-	0 %	03
Neonate	90 %	180 BPM	1.0 %	-	-	0 %	04
Tachycardia	85 %	130 BPM	1.2 %	-	-	0%	05
Geriatric	92 %	95 BPM	2.4 %	-	-	0 %	06
Obese	93 %	90 BPM	3.0 %	-	-	0 %	07

Table 6-3. Level 1 Presets

Dun and Name	Catumatian	Pulse Signal	Motion			[mwoosto#]	
Preset Name	Preset Name Saturation Rate	Strength	Saturation	Frequency	Amplitude	[presets#]	
Normal/ Tap	98 %	55 BPM	5.0 %	78 %	2.5 Hz	7 %	08
Normal/ Shiver	98 %	55 BPM	5.0 %	78 %	6.0 Hz	15 %	09
Weak Pulse/ Tap	90 %	95 BPM	0.65 %	60 %	4.3 Hz	1 %	10
Weak Pulse/ Shiver	90 %	95 BPM	0.65 %	60 %	6.0 Hz	3 %	11
Brachycardia/ Shiver	88 %	45 BPM	5.0 %	68 %	6.0 Hz	10 %	12
Hypoxic/ Tap	70 %	95 BPM	2.0 %	50 %	4.3 Hz	3 %	13
Hypoxic/ Shiver	70 %	95 BPM	2.0 %	50 %	6.0 Hz	8 %	14
Neonate /Shiver	90 %	180 BPM	1.0 %	70 %	6.0 Hz	5 %	15

Tabl	le 6-	4. I	Level	2	Pres	ets

Preset Name Sa	Saturation	Pulse Rate	Signal Strength	Motion			[munnets#]
	Saturation			Saturation	Frequency	Amplitude	[presets#]
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 %	0/1	18	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

An option to set the Motion Level of the simulation presets is configurable and can be found in the configuration menu. Motion Level is stored in non-volatile memory and therefore does not have to be reset every time Index is powered on. All selections will include Level 0 presets. The defaults will be level 0 (no motion). Motion Level 3 includes all simulations.

Motion Level 1 is recommended when testing pulse oximeters with Masimo Set technology. Use Motion Level 2 when testing pulse oximeters with Nellcor Motion technology.

Index 2XL is preset to simulate the SpO₂ and pulse rate ratios.

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



The Simulations menu appears in the Index 2XL LCD:



esl037.eps

esl038.eps

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



The values preset at the factory appear on the Index 2XL LCD screen:

esl039.eps



esl040.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, Index 2XL returns to its default (normal) preset patient condition simulation.

Setting the Light Artifact

You can set a light artifact with Index 2XL to test oximeters under different simulated ambient (surrounding) light conditions. The available simulations are as shown in Table 6-5.

Table 6-5. Light Artifacts

Light Type	Frequency	Description
Sunlight	n/a	Index 2XL 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.



esl041.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 O_2 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

3. 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.

Transmission Level Control

Up until the advent of Transmission Level Control (TLC), Index 2XL SpO₂ simulations were based on a fixed finger-thickness uniquely defined for each pulse oximeter make. Since the implementation of TLC, pulse oximeters and probe performance can be more thoroughly tested over a range of simulated finger thicknesses. In simple terms, TLC is a variable attenuation of the RDC and IRDC terms, selectable over the entire range of 0-4095 counts for each make of the pulse oximeter.

Access this attenuation selection option from the SIMULATION menu.



esl038.eps

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

- + to increase transmission level control
- - to decrease transmission level control
- **STEP** to select the step size
- **DFLT** to reset to factory-defined transmission level control
- **esc** softkey to return to the Simulations menu

Using the TLC options, adjust the attenuation level while observing the change in pulse oximeter readings.

The attenuation level set in the TLC menu is global, and retained for all other simulations performed by the Index 2XL until it is changed or the Index 2XL rebooted. The TLC level can be restored to the default setting for the current make by selecting the **DFLT** softkey from the Transmission Level Control menu.

Note

The default TLC level is based on the original RDC and IRCD settings for the selected make defined in the original release of the Index 2XL. The default level will, therefore, vary from make to make. This change ensures compatibility for current Index 2XL users.

Setting 02 and Pulse Rate Step Size

You can vary the size of the steps for O_2 and pulse rates used when setting up tests and testing oximeters with Index 2XL.

If you select an O_2 step size of **5**, for example, then when you increase or decrease SpO_2 , the SpO_2 will increase or decrease by **5%**.

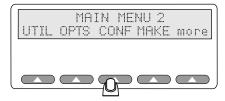
Note

Step amounts come in to play in three places from the Index 2XL Main Menus:

- With the Simulation option **MAN** (manual) submenu
- With the LMTS (limits) option 02 | 02 Alarm and BPM | Rate Alarm submenu
- With the **CONF** (configuration) option in the Main Menu 2

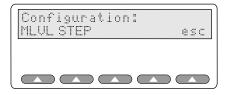
Set the step amount for SpO2 levels using the following steps:

- 1. To choose a step amount for the SpO₂ level and the pulse rate, press **CONF** from the Main Menu 2.
- 2. Select **STEP** to change the step levels for either the SpO2 or BPM:



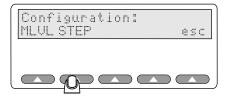
sl170.eps

You will see the screen change to display the Configuration menu with the options MLVL (motion level) and STEP:



3. Select **STEP** to change the step levels for either the SpO2 or BPM:

esl160.eps



esl044.ens

4. To increase or decrease the ${\rm O}_2$ step amount, press **O2+** or **O2-**, respectively, as needed.



esl046.eps

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



esl047.eps

6. Once you have finished setting the ${\rm O}_2$ 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.

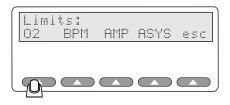
Testing Pulse Oximeter Limits

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.



The following menu appears in Index 2XL's LCD:



esl049.eps

esl048.eps

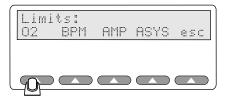
Note

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 with Index 2XL.

1. To set the oxygen limits, press **LMTS** at the Index 2XL Main Menu 1 if you are not already there. Then, press the softkey **O2** in the Limits menu.



The Index 2XL display changes to present these options:

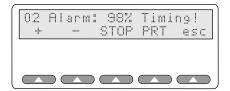
esl049.eps



esl051.eps

When setting new oxygen limits, Index 2XL 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.



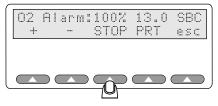
esl052.eps

- 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

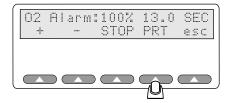
Continue pressing + or - until the O_2 percent you want to test for is displayed. Each press p the softkey + or - resets the timer internally and Index 2XL restarts the timing.

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 Index 2XL display the "elapsed time to alarm" for the specified simulation level.



esl053.eps

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



esl054.eps

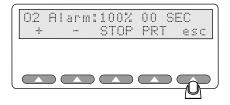
The results will be sent out the RS232 and the Centronics ports to an attached printer.

Note

You can connect Index 2XL 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 Index 2XL 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:

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



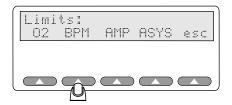
esl055.eps

Simulating the Pulse Rate

Use the Index 2XL to simulate a variety of patient conditions, while you observe the effect of a changing pulse rate with a static SpO_2 on the pulse oximeter, as well as the effects of using a changing pulse rate with a changing SpO_2 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 the Index 2XL 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 Index 2XL LCD:



esl057.eps

Note

Notice, as with most Index 2XL 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, Index 2XL 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 Index 2XL 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 Index 2XL's **STOP** softkey immediately.



The timer stops, and displays the elapsed seconds.

esl059.eps

Note

Pressing the softkeys + or - resets the Index 2XL Rate Alarm timer.

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



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

esl060.eps

Note

Connect Index 2XL 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 Index 2XL 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.



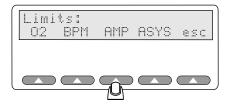
esl061.eps

Simulating Pulse Amplitude

The peak-to-peak amplitude of the blood pressure wave simulated by Index 2XL 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 using Index 2XL.

1. To access the pulse amplitude alarm menu, press **LMTS** from the Index 2XL Main Menu 1, and then **AMP** from the Limits menu:



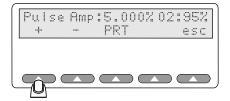
esl062.eps

2. The Pulse Amplitude menu displays in the Index 2XL 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.

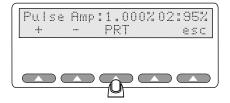
4. To lower the percentage of AC factors in the simulated blood condition, press the – softkey:



esl065.eps

The amplitude will *decrease* by 1% with every softkey press (with a 0.1% decrease for each value below 1%). 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 Index 2XL 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 Index 2XL to other systems or peripherals, see "Appendix A: Printing & Data Transfer".

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

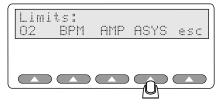
6. When you are done, press the softkey esc to return to the Limits menu.

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. Index 2XL can measure the response time of these alarms.

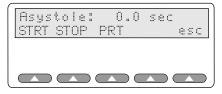
Index 2XL can simulate asystole (lack of cardiac electrical activity) to further test an oximeter. Set up the asystole test with these steps:

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



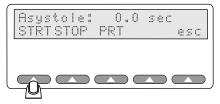
esl068.eps

You will see the Asystole menu display in the Index 2XL LCD screen:



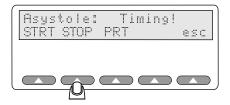
esl069.eps

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



esl070.eps

4. The asystole simulation starts and the LCD shows the "Timing!" message. When the alarm sounds, press the softkey **STOP**.



esl071.eps

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

Note

You can connect Index 2XL 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**.



esl072.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:

For information on how to connect Index 2XL 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

Index 2XL provides several pre-defined test programs to automatically sequence tests. You would ordinarily have to manually set each test parameter every time you started Index 2XL 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 Index 2XL's 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, Index 2XL 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 1 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.

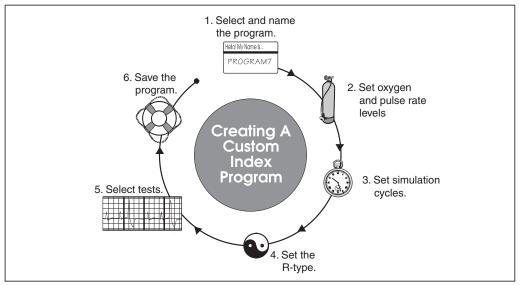


Figure 8-1. The Program Creation Sequence

esl073.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 Index 2XL's 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.
O ₂ Alarm Test	Set Index 2XL to either test or bypass the SpO ₂ limits test.
BPM Alarm Test	Set Index 2XL 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 Index 2XL to either test or bypass the amplitude test.
Motion Test	Set Index 2XL to test the oximeter for patient motion.
Use Presets	Set Index 2XL 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 **AUTO** on the Index 2XL Main Menu 1. See the section "Creating a Custom Test Program" for the additional parameters available under each option.



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



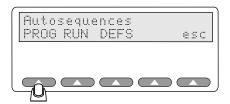
The Autosequences menu provides the following options:

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

esl074.eps

esl075.eps

PROG lets you define or edit a set of program parameters that you can have Index 2XL run automatically when needed.



esl076.eps

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



sl077 ens

Pressing the softkey **DEFS** lets you restore any or all of the Index 2XL programs to their default factory settings.



esl078.eps

Creating a Custom Test Program (Autosequence)

Setting up a custom program in Index 2XL 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 Index 2XL's 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:

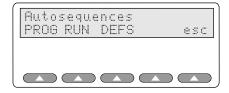
1. Press the softkey **AUTO** on the Index 2XL Main Menu 1.



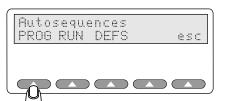
The Autosequences menu displays the following:

esl074.eps

esl080.eps



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



esl076.eps

This Autosequences screen appears on the Index 2XL LCD, with the **Sequence**: indicating the current program (in this instance, Program 0).

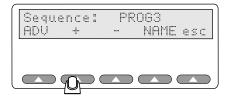


esl082.eps

You can then modify one of Index 2XL's pre-programmed test programs, from PROG0 through PROG13. The screen displays the last program selected, for example, if you were last using Program 5, Index 2XL 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).



esl083.eps

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



esl084.eps

Optionally Renaming the Test Program

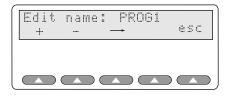
You can rename any of the Index 2XL test programs. The name can be from one to eight characters in length, containing letters, numbers, and spaces; for example "TEST1", "TEST22A" or "DS TEST".

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



sl085.eps

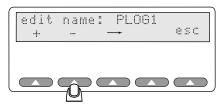
The LCD screen shows the program name for the last program used (or PROG 0 the first time Index 2XL is powered up):



esl086.eps

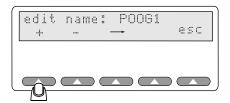
- 2. The cursor blinks over the first selected character. To edit the program name, move between positions using the (arrow) softkey \rightarrow .
- 3. To edit the characters in the name, use + or softkeys to increment or decrement the alphabetic character.
 - Since this option opens with position one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



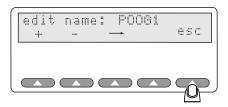
esl087.eps

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.

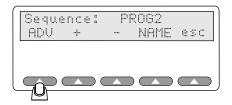


esl090.eps

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.



esl091.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 Index 2XL Main menu.)

Selecting Print Settings

You can customize an Index 2XL 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**.



esl092.eps

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



esl093.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 an Index 2XL test printout, refer to "Appendix A: Data Transfer Notes".



sl094.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 02 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:



sl095.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 Index 2XL 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

 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

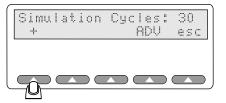
- Use + and/or to adjust the pulse rate up or down.
- Press NEXT as many times as needed to enter up to ten different test values.
 When you are done setting a time in cycles (or to bypass this screen), press ADV to continue.

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 Index 2XL 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).



sl099.eps

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

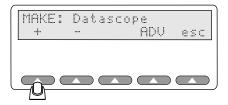


esl100.eps

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 Index 2XL 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.

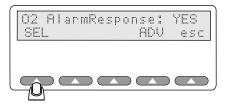


esl102.eps

Choosing Your Tests

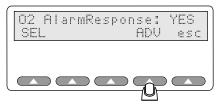
Your next step in creating a custom program is to choose the tests that you want Index 2XL to run. Use the following procedure:

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



esl103.eps

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



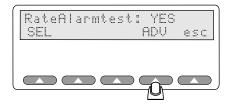
esl104.eps

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



esl105.eps

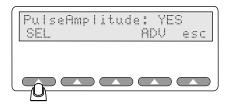
4. When you are done (or to simply bypass this screen), press **ADV** to continue.



esl106.eps

Selecting Pulse Amplitude

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



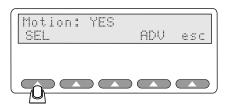
esl107.eps

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

Selecting Motion

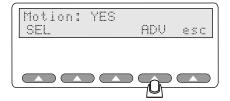
Index 2XL can also test an oximeter's sensitivity to patient motion.

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



esl108.eps

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

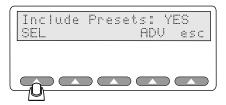


esl109.eps

Selecting Presets

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

1. Press **SEL** to use Index 2XL's pre-programmed patient types (normal, weak heart, obese, or geriatric, for example).



esl110.eps

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



esl111.eps

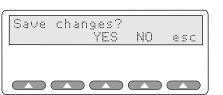
Saving Your Program

Saving the program values and parameters is the final step in creating a custom Index 2XL program.

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



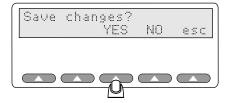
2. Pressing **esc** prompts you to save your program.



esl113.eps

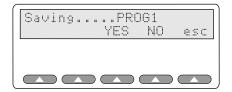
esl112.eps

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 Index 2XL 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

2. 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.

- 3. 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).
- 4. 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) Index 2XL autosequence program to its default state, that is, the way it was programmed at the factory, at any time.

1. 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* Index 2XL 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. Index 2XL 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 quickly flashes the message "Loading defaults Please Wait..." 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 Index 2XL (Index FE 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 Index 2XL, but will require special care in preparation of an adapter cable and interpretation of the results. Damage could occur to Index 2XL 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.

Index 2XL 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 Index 2XL using the appropriate adapter cable.

Note

The Index 2XL FE 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, Index 2XL, or both.

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



esl124.eps

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

- Verifying that a Probe Test Board is installed in your Index 2XL
- 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 Type

The user can then choose the specific probe test.

- LED and photodiode electrical test (Step 3)
- Photodiode detector optical test (Step 4)

Note

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

• Pin-to-pin resistances (Step 5)

LED Testing

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



esl126.eps

Index 2XL applies 1.0 mA current AC signal source to the red and infrared LEDs. Index 2XL 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 2.0:

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



esl127.er

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 LED (red and infrared) result for Nellcor probes. A resulting zero or two is bad, since 0.0 V indicates a short condition and 2.0 V an open circuit.

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 Index 2XL measures the resulting photodiode output. The red LED then goes out and again Index 2XL 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 2XL 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 SpO_2 sensor. Reusable SpO_2 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.ens

Index 2XL 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).

Index 2XL 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.

Index 2XL

Users Guide

Chapter 10 Adjusting the LCD Screen

Introduction

Users may adjust the Index 2XL 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 Index 2XL LCD itself.

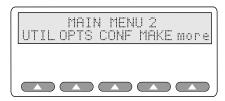
LCD Contrast Settings

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 the Index 2XL Main Menu 1.



The Main Menu 2 displays in Index 2XL's LCD:



esl131.eps

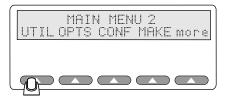
esl015.eps

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:



The Utilities menu allows you to choose from these options:

esl132.eps

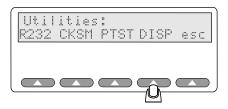


esl133.eps

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:



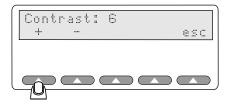
esl134.eps

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



asi135 and

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.

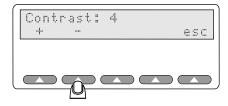


esl136.eps

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.

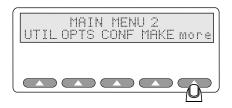


esl137.eps

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.



esl139.eps

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

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Index 2XL

Users Guide

Chapter 11 Manufacturers Mode

Introduction

Fluke Biomedical has included several features in the Index 2XL 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 Index 2XL, 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 WindowsTM "HyperTerminal" program.

To test a pulse oximeter using a PC, connect Index 2XL 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 Index 2XL using the computer; Index 2XL 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 Index 2XL to allow you the widest array of simulation, with the capability for direct control of the following Index 2XL 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 Index 2XL computer control command. Refer to "Appendix A: Printing & Data Transfer", for information on Index 2XL's RS232 port and how to set communications parameters (baud rate and parity settings).

Mathematical Background

Index 2XL 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=redac/reddc

iredac/ireddc

math_bg_formula.eps

Oximeters perceive Index 2XL 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 **T**est and "IREDUUT" is for **I**nfra**R**ed light, Unit Under **T**est.

The Index 2XL calculates the R-value (as far as the oximeter is concerned) with this formula:

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 Index 2XL. 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 Index 2XL 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, Index 2XL 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 Index 2XL 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:

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

sl142.ens

This is the equation used to obtain the R-values used in Index 2XL, and presented on the Index 2XL LCD panel.

11-3

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.

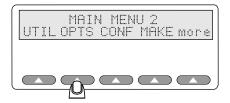
Note

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

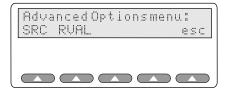
Access the manufacturers' test settings with the Index 2XL's LCD panel.

Press the softkey **OPTS** on Index 2XL's Main Menu 2.



esl143.eps

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



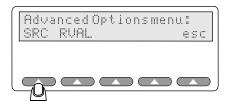
esl144.eps

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

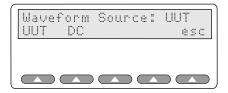
Setting the Signal Source

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



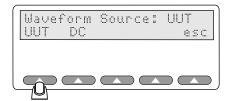
esl145.eps

The Waveform Source screen provides two options:



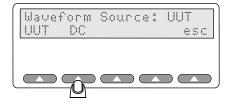
sl146.eps

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



sl147.eps

3. Alternatively, press **DC**. Index 2XL 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 Index 2XL based on their original amplitude.

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

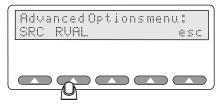
Setting the R-Value

You can also enter a custom R-value with Index 2XL using the following procedure:

1. Access the Advanced Options menu (if you have not already done so) by pressing **OPTS** on Index 2XL's Main Menu 2.

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2. Press **RVAL** on the Advanced Options menu:



You will see a screen appear similar to the following:

esl149.eps



sl150.eps

3. 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:



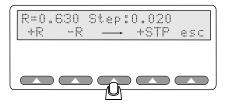
esl151.eps

4. 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.

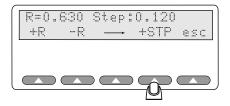
1. First, use the arrow softkey to set the Index 2XL cursor under the step digit that you want to adjust. The cursor (flashing in the digit field) highlights first "0" in the sample above of 0.020. Advance to the next digit position by pressing -->.



esl152.eps

2. Continue to press --> until the cursor is where you want it. Each time you press -->, the cursor moves one position to the right.

3. 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

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

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Index 2XL

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Chapter 12 Creating Your Own R-Curve

Introduction

Index 2XL 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 Index 2XL's "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 Index 2XL.
- 2. From the INDEX MAIN MENU 1 select SIM | MAN, set:

```
SpO2 = 100\%

BPM = 100
```

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

Step
$$= 0.010$$

Note

TheR-value displayed on the Iindex 2 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:

SpO2	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 Index 2XL

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

Where: [rcurve sets Index 2XL 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) to Index 2XL. Basically, at the DOS prompt, set the following:

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



PN 2227040 Rev. A

INDEX R-CURVE DATA SHEET

Date:	Recorded by:
Pulse Oximeter Model:	
Pulse Oximeter Serial Numbe	r:
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

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Appendices

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В	Error Messages and Corrective Measures	
C	Accessories List	C-1
D	Specifications	D-1
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F	Typical Questions and Answers	F-1
G	Custom Probe Test Cables and Electrical Simulation Cables	
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Appendix A Printing and Data Transfer

Introduction

This Appendix provides information on the Index 2XL simulator's RS232 and printer ports, including how to configure the port on your printer or computer.

Index 2XL 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 Index 2XL. The Data Computer Equipment (DCE) wiring configuration is shown Figure A-1.

Index 2XL RS232 Configuration

Fluke Biomedical offers a bi-directional serial null modem cable for connect the Index 2XL to your computer (IBM compatible) or serial printer. Please specify Fluke Biomedical *Part Number 2238626* when ordering.

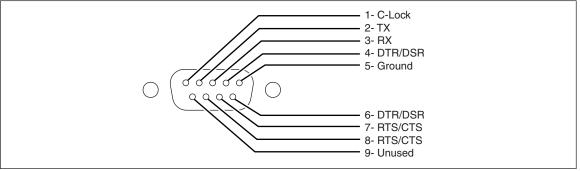


Figure A-1. Male D Cable End

esl165.eps

C-Lock

Pin 1 of the serial connector provides the Index 2XL'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

Index 2XL 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.

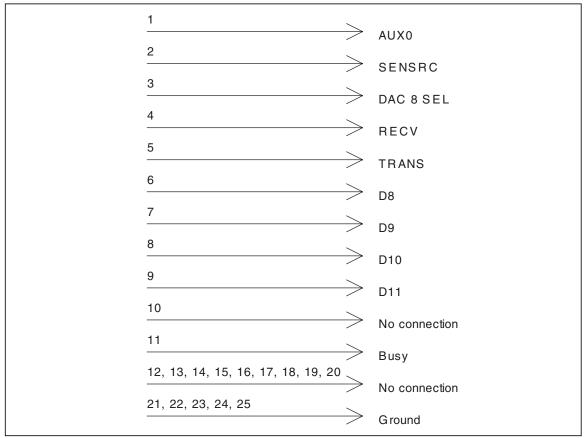


Figure A-2. Index 2XL Parallel Port D-25

esl154.eps

A Standard D-25 pin to Centronics printer cable works with Index 2XL. Please specify Fluke Biomedical *Part Number 2238072* when ordering.

Configuring the Serial (RS232) Port

Configure Index 2XL to match your printer's or computer's communications needs by setting baud rate and parity. Once configured, you can then send Index 2XL's test results directly from Index 2XL 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 Index 2XL through a computer with the Index 2XL's built-in RS232 serial port.

When communicating with Index 2XL 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 Index 2XL Main menu 2 (first press **more** if you are viewing Main Menu 1).



esl014.eps

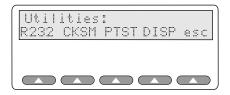
You will see the following menu appear in Index 2XL's LCD display:



esl131.eps

2. Press **UTIL** to access the Utilities menu.

3. The following Utilities screen offers four configurable options:



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

esl133.eps



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.

 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.

Table A-1. Communication Parameters

When you finish setting the communication control parameters:

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

Printing

Sample Index 2XL Test Results Output

The Index 2XL Autosequence printout shown below requires using the previous settings to establish communication between the Index 2XL 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: 2.0		
Control#: Serial #: Model:		
Mfr: Location: Technician: Date:		
Simulations: NELLCOR		
	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 RPM	81 95	
9 80% 100 BPM	80 100	
	79 105	
Alarm Response Time:12	Seconds at 95% 02	
Hi Rate Alarm Response BPM	Time:10 secs at 80	
Lo Rate Alarm Response BPM		
Pulse Amplitude Test	signal is lost.	
Motion Response Time:		
End of test.		

esl155.eps

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Appendix B Error Messages and Corrective Measures

Introduction

This Appendix lists all of the error messages or beeps that may appear on Index 2XL'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 Index 2XL 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 Index 2XL into the Index 2XL 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. Index 2XL 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 Index 2XL's finger probe attachment. Make sure the Pulse Oximeter's finger probe is centered and pushed as far forward as possible on Index 2XL's finger probe attachment.

Appendix C Accessories List

Introduction

Table C-1 presents a list of accessories available for Index 2XL. The User's Guide and a battery charger (U.S. or European) are standard equipment.

Table C-1. Accessories

Description	Part Number
Index User's Guide	2226196
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

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Appendix D **Specifications**

Equipment Specifications

The following specifications apply to the Index 2XL models F and FE.

%O2	
Range	35 to 100 %
Resolution	1 %
Accuracy	100 to 75 %: ±1 % ± accuracy of the pulse oximeter under test. 74 to 50 %: ±3 % ± 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 % <u>+</u> 1 BPM
Pulse Amplitude	
Range	0 to 20 %
Resolution	From 1% to 20%, keys change in units of 1.0. From 1% to 0.1%, keys change in units of 0.1. From 0.1% to 0.0%, keys change in units of 0.025.
Battery Life	At least 4 hours of continuous use
Probe Test	Index 2XL FE 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.

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Test Signal	Pulsed between the two LEDs, constant current level at 1.0 mA
Test Results	Nominal range of 0 to 20,000

Note

The above specifications are for pre-programmed makes only, 20 % pulse amplitude SpO_2 . 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 Index 2XL via its RS232 port. To control Index 2XL by computer:

- 1. Switch Index 2XL 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:
 - Fluke Biomedical Corp and model number and version
 - Software version number and information
 - Make of last selected test equipment
 - Main Menu 1 screen



esl009.ep

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

Note

See "Appendix A: Printing & Data Transfer" for information on how to configure Index 2XL'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 Index 2XL.

Note

You will need communications software to send data to Index 2XL. 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.

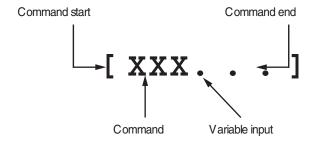
Index 2XL's LCD displays each command that the computer sends to Index 2XL, as in the example shown here:



esl166.eps

Command Syntax

Computer commands sent to Index 2XL must observe a standard format:



esl156.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 Index 2XL 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 Index 2XL as the same value:

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

Computer Control Commands

Table E-1 shows valid commands for controlling Index 2XL by computer.

Table E-1. Valid Commands

Command	Description	Values	Example
AC	Sets the AC amplitude.	0 to 255	[AC100]
AMB	Sets the ambient light artifact simulation.	0 to 30	[AMB15]
ВРМ	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]
IPLETH	Uses Index 2XL's pleth waveform.		[IPLETH]
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]
ОХҮ	Sets the SpO2 percent for the selected make.	35 to 100	[OXY96]
PROBE	Performs and returns the electrical probe test results. Displays tests by line.		[PROBE]
Q	Quits the communications session and returns Index 2XL to Index 2XL 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 2XL.	various	[RCURVE>{slot #; 0-5}:{curve name; 9 chars}:{TLC;0- 255}:{tech level; 0-3;}:{r- values; 51 values}]
RDC	Red transmissivity.	0 to 4095	[RDC1000]
SETTINGS	Retrieves the current Index 2XL settings in this format: Index 2XL Settings:		[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		

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Table E-1. Valid Commands (cont.)

Command	Description	Values	Example
	IRAC = 1000 RDC = 1024		
	IRAC = 1024 Light Flash: Unit Under Test AC = 100 % AMB = 0 % Make = Nellcor.		
SHAPE	Indicates that the next 64 numbers represent a pleth wave shape.		[SHAPE1.000, 3.9, 4.9,]
SRCF	Selects DC or fixed signal source level.		[SCRF]
SRCU	Selects the test unit's signal source level.		[SCRU]
UPLETH	Uses user's pleth waveform.		[UPLETH]
VER	Displays the Index 2XL version number		[VER]
TLC	Transmission Control Level	0-4095	[TLC3178]

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 Index 2XL 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 Index 2XL 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.

Index 2XL 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.

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The Baud Rate in Index 2XL 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.

Appendix F Typical Questions and Answers

Introduction

- 1. How do I connect a probe from a pulse oximeter to Index 2XL?
 - 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 2XL finger probe attachment.
- 2. What type of probes can be connected to Index 2XL?
 - Index 2XL 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 2XL finger probe attachment and their photo diodes can placed over the LED output of the Index 2XL finger probe attachment.
- 3. How should probes be positioned on the Index 2XL finger probe attachment?
 - Most common probes need to be centered and as far on the Index 2XL finger probe as possible. The exception to this is the Ohmeda permanent finger probe. The Index 2XL 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 2XL 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 %.

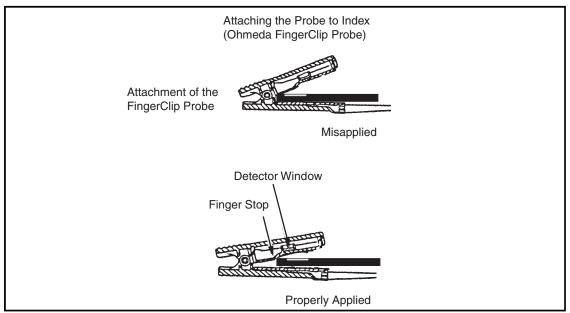


Figure F-1. Attaching the Probe to Index 2XL

esl157.eps

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 2XL 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 2XL. What do I do?

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

Airshields, Inc. Ivy Biomedical
Atom Medical Corp. Marquette (Eagle)

Baxter Healthcare Corp. MDE(Medical Data Electronics)

Century Medical Inc. Mennen Medical

Colin Medical Instruments Corp. North American Drager

Corometrics Medical Systems Pace-Tech. Inc.

Critikon, Inc. Protocol Systems, Inc.

Datascope Corp. Pryon Corp
Drager (Europe) Siemens

Edentec Sleeptrace/Areca Science

Fukuda Denshi SpaceLabs

Synectics Witt Biomedical

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

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

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 2XL.

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 2XL as needed for pulse oximeters that are not preprogrammed into Index 2XL. 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 2XL?

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

Switch 1 Position	Function	ON	OFF	Setting for Index 2XL
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			

Table F-1. Seiko DPU 411 DIP Switch

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Index 2XL

Users Guide

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 2XL FE.

Making Probe Test Cables

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

Figure G-1. Typical Oximeter Probe 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

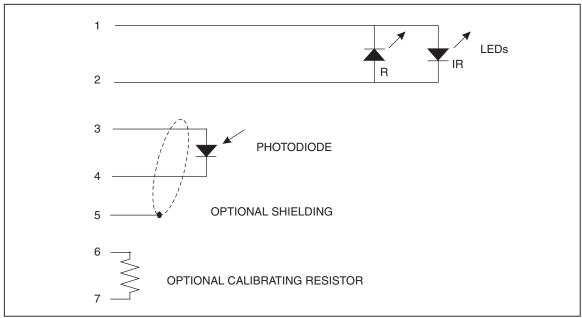


Figure G-1. Typical Oximeter Probe

esl159.eps

Index 2XL 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

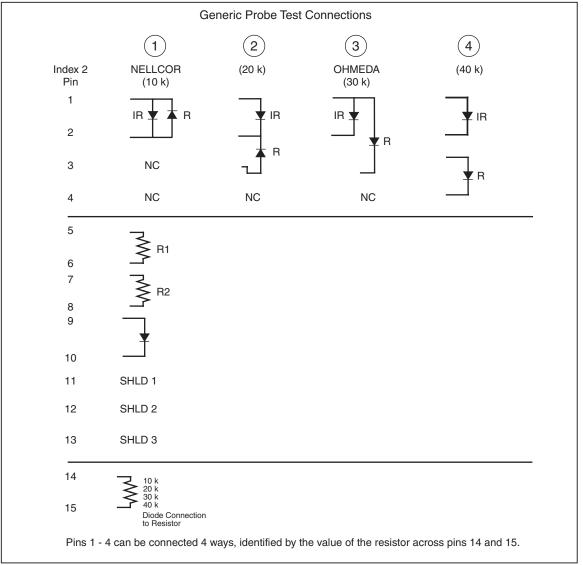


Figure G-2. Generic Probe Test Connections

esl164.eps

Note

Because of the many different ways probes can be connected, your Index 2XL is designed to work with an interface cable that adapts the Index 2XL 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 2XL 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.

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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, Index 2XL 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 Index 2XL. Connect them as R1 and R2 in Figure C-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.

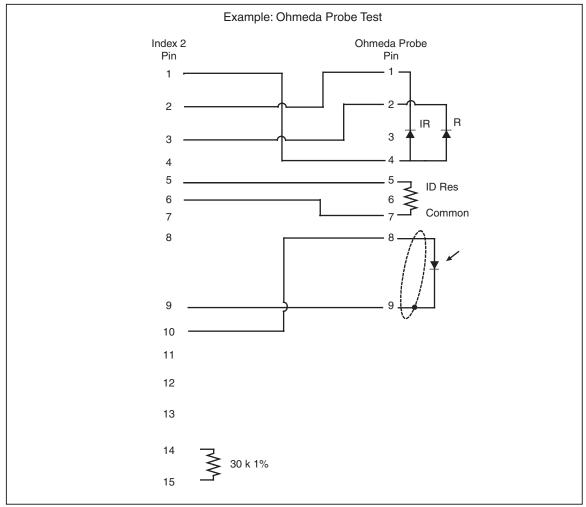


Figure G-3. Example: Ohmeda Probe Test

esl168.eps

Making Electrical Simulation Cables

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

⚠ Caution

To avoid damage to the oximeter and the Index 2XL, 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 Index 2XL 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 Index 2XL, 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 2XL.

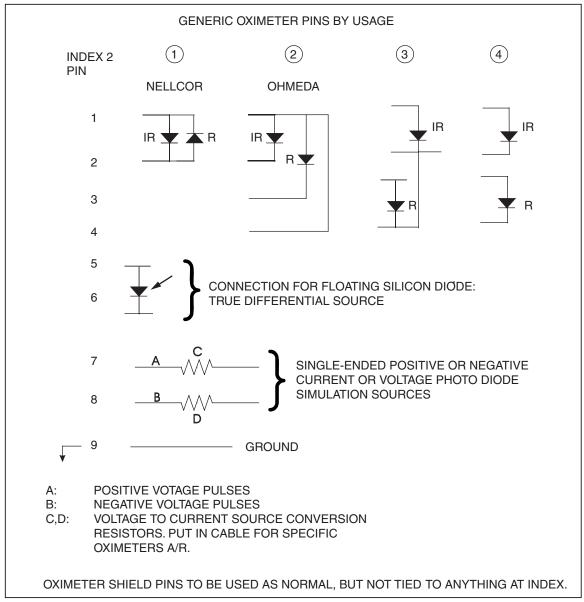


Figure G-4. Generic Pins by Usage

esl162.eps

Pins 1 through 4 show the different ways oximeter probes can have their LEDs connected. For example, if Index 2XL were used to simulate an Ohmeda probe, the Ohmeda drive pins would be connected to the Index 2XL 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 Index 2XL 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, Index 2XL 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 Index 2XL ground, but there may be exceptions. Again, only a thorough study and understanding of the oximeter interface circuits can answer these questions.

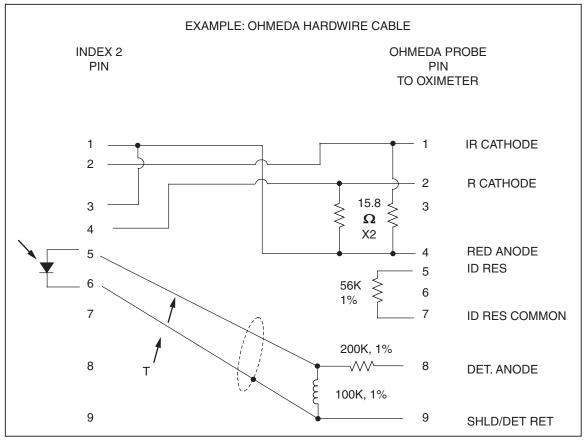


Figure G-5. Example: Ohmeda Hardware Cable

esl163.eps

Appendix H Glossary

Introduction

The glossary presents certain medical, electronic and Index 2XL-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).]

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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 Index 2XL 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.

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Index 2XL

Users Guide