Index 2

SpO_2 Simulator

BIO-TEK® INSTRUMENTS, INC.

Index-2 Series Manual Update

PN 5171010, Rev. A4

INTRODUCTION

As part of Bio-Tek's continuing product improvement, enhancements and changes have been made to the Index-2. The expanded capabilities presented in this update are now available in the most recent Index-2MF and Index-2MFE versions. The Index-2MF and Index-2MFE are being offered as base units. New features and functionality include the following:

1. New Pulse-Strength Capabilities
2. New Computer Control Commands
3. Improved Probe Test
4. Improved Line Pickup Simulations
5. Additional Motion Artifacts
6. Improved Timing
7. Player Mode.

New Pulse-Strength Capabilities

The arterial wave amplitude can be varied in units of signal strength. Signal strength, which is the ratio of IRAC/IRDC, is a recognized physiological measure of arterial pulse strength. This will replace the arbitrary scale of 0 to 100% utilized by the pre "P" version Index.

The keyboard range and standard computer control range of signal strength is now 0.0 to 20%.

The range for pulse amplitude is 0 to 20%. For the LCD/keyboard interface, the same screen is kept as earlier versions, with plus (+) and minus (-) keys. The following rules apply:

- The default at the screen opening is 6%. This is the same as the pre-"P" version Index unscaled 100%, and corresponds to a healthy person's signal strength.
- From 1 to 20%, the keys increment/decrement in units of 1.0.
- From 1% to 0.1%, the keys operate in units of 0.1.
- From 0.1% to 0.0%, the keys increment/decrement in units of 0.025. Inputs below 6% are rounded internally to the nearest 0.024%, and above 6% are rounded to the nearest 0.072%. The displayed value is the rounded value nearest the value displayed per the preceding increment/decrement rules.

New Computer Control Commands

[tap] – Causes tapping artifact: a motion wave of 3.5 Hz.

[shiver] – Causes shiver artifact: a motion wave of 6.0 Hz.

[nomotion] –Turns off tap and shiver motion waves.

[mamp nnn] – Where nnn is 0 to 100; corresponds to signal strength of the non-arterial wave, tap, or shiver. Leading zeros are not required.

[moxy nnn] – Where nnn is the entry resolution of 0 to 100, and sets the oxygen value of the non-arterial wave, tap or shiver. Leading zeros are not required.

[mfreq nn.nnn] – Sets the tap or shiver frequency in Hertz. Entry resolution is 0.001 Hz. Internal resolution at 60 Hz is about 0.2 Hz. To let the user know the effects of input rounding, we output the rounded value on the RS-232. For example, if the user enters **[**mfreq 60.1**],** the result will be 60.1882, which is the closest it can achieve. Entry resolution is 0.001; however, the resolution of the value stored and used is near 0.2 Hz at 60 Hz.

[presets nn] – Selects a specific preset, where nn ranges from 00 to 23. A range of 00 to 23 for nn corresponds to preset motion selections shown in the presets table on page 3 of this update.

[player] –Turns on the player mode.

[AC nn.nnn] – Where nn.nnn is the pulse strength and may be set from 0 to 6 for all saturation values, and 0 to 20 for oxy values over 80. Leading zeros are not required except for values less than one. An entry of .025, rather than 0.025, will be interpreted as a signal strength of 25, and will be replaced by the default value, 6.

[hires n.nnn] – Where 0 <= n.nnn <= 1.000. At the low end of the signal strength scale, there is a high-resolution mode of operation, accessible only through computer control as follows: Entry resolution is 0.001; however, the resolution of the value stored and used is .005%. Entries not divisible by 0.005 will be rounded down. The user is responsible for entering values less than one with a leading zero to the left of the decimal point.

CAUTION: For values less than 1, it is necessary to enter a leading zero. For example, the user must enter 0.1, not .1. An entry of .1 will be interpreted as signal strength of 1. Out-of-range entries default to 6, which is a normal level.

In real life, signal strengths over 6% always correspond to saturation in the 90's; therefore, the 80% limit should be of no physiological consequence.

NOTE: Index-2 normally responds to computer control commands by calculating all simulation values for each new simulation commanded. This may take over one second and interrupts the wave generation.

Improved Probe Test

In probe tests performed on previous versions of Index-2, a forward-voltage drop of > 4.0 volts across either the LEDs or photodiode resulted in an **OPEN** message. The new version indicates **> 4.0** when detecting a forward-voltage drop greater than 4.0 volts.

The reason for the change is that some probe manufacturers cascade diodes in series. This will raise the forward-voltage drop. To make a more meaningful test, the Index-2 Series will indicate the forward voltage is over 4.0 volts instead of assuming that the diode is open. The user should be aware that > 4.0 could indicate either an open diode or that the drop has exceeded the Index-2's forward-voltage test range.

Improved Line Pickup Simulations

50 and 60 Hz selections from the keyboard will be unchanged. Bio-Tek has replaced the earlier 4-point 50/60 artifact with a 16-point wave-table-based sine wave.

Additional Motion Artifacts

New pulse oximeters are now featuring Signal Extraction Technology, which enables them to correctly monitor arterial oxygen saturation during the presence of motion. Therefore, in addition to the new features listed above, the Index-2M version now includes physiological motion artifact available in the preset mode. The table below indicates the presets that are available for the Index-2M.

Preset Name	Sat	Pulse Rate	Signal Strength	Motion Sat	Motion Freq	Motion Amp	[presets nn]
Normal	98%	55 BPM	5.0%	-	-	0%	00
Normal/Tap	98%	55 BPM	5.0%	78%	2.5 Hz	7%	01
Normal/Shiver	98%	55 BPM	5.0%	78%	6.0 Hz	15%	02
Weak Pulse	90%	95 BPM	0.65%	-	-	0%	03
Weak Pulse/Tap	90%	95 BPM	0.65%	60%	4.3 Hz	1%	04
Weak Pulse/Shiver	90%	95 BPM	0.65%	60%	6.0 Hz	3%	05
Brad	88%	45 BPM	5.0%	-	-	0	06
Brad/Shiver	88%	45 BPM	5.0%	68%	6.0 Hz	10%	07
Hypox	70%	95 BPM	2.0%	-	-	0%	08
Hypox/Tap	70%	95 BPM	2.0%	50%	4.3 Hz	3%	09
Hypox/Shiver	70%	95 BPM	2.0%	50%	6.0 Hz	8%	10
Neonate	90%	180 BPM	1.0%	-	-	0%	11
Neonate/Shiver	90%	180 BPM	1.0%	70%	6.0 Hz	5%	12
Tach	85%	130 BPM	1.2%	-	-	0%	13
Geriatric	92%	95 BPM	2.4%	-	-	0%	14
Obese	93%	90 BPM	3.0%	-	-	0%	15
Brady Tap#2	88%	45 BPM	5.0%	96/100 %	3.9 HZ	0/4 %	16
HypoxTap#2	70%	95 BPM	2.0%	96/100 %	4.3 HZ	0/3 %	17
WeakTap#2	80%	95 BPM	0.9%	96/100 %	3.6 HZ	0/1	18
NormalTap#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%	93/97 %	.5 HZ	0/4.2 %	21
LowFreq2	70%	75 BPM	1%	96/100 %	.5 HZ	0/4.2 %	22
SlowTap	80%	75 BPM	1%	96/100 %	2 HZ	0/3 %	23

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

Improved Timing

Rates (BPMs) for all simulations are now controlled using a crystal. Previous Index-2 models utilized software for rate control. The result from this change is an increase in timing accuracy, which will exceed the stated accuracy published in the Index-2 specification.

Player Mode

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

Data will be sent via the Index serial input and loaded directly into the red AC and infrared AC digital-to-analog converters (DACs). The output waves of the DACs will thus be controlled by the amplitude values and update rate of the serial port. Data sampling rate and playback rate will be equal. Data will be nominally sent at 9600 baud to Index N,8,1. However, this rate may be adjusted to control playback rate in terms of points/second. The N,8,1 must not change.

Once you have your player file, which should be named with a .BIN extension, you will need to create a small batch file. These two files should be placed in the same directory (or folder). The batch file should consist of the following commands:

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

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

When you are ready to use Player Mode:

- Send [player] to the Index via computer control.
- In DOS*, go to the directory that has the two files and issue the following command:

  LD filename (example: LD 8sec.BIN), and press **enter**.

This will initiate Player Mode. To stop the playback, press **control-C**. To get Index out of Player Mode, press any key on Index.

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

INDEX® 2 SERIES

User's Guide

JULY 1997

PART NUMBER 5171010
REVISION A
BIO-TEK® INSTRUMENTS, INC.

Notices

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Revision

Revision	Date	Changes
A	July 1997	First Issue

Precautions

When connecting Index 2 to a peripheral, such as an RS-232 serial port, or printer, both Index 2 and the peripheral device should be powered **OFF** during connection and disconnection. Failure to follow this precaution may result in damage to the equipment.

Index 2 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 2 so that the power switch cannot be accidentally turned on during shipment, and
- Always connect Index 2 to its charger when not in use. Index 2 may be charged continuously, and this practice will ensure full charge whenever needed. Index 2 may also be operated while charging.
- Always turn off Index 2 and connect it to its charger when the low battery alarm sounds. Within about 1 minute of commencing charge, Index 2 may be run with the charger attached. (Index 2 picks up 2 or more hours of battery run time for each hour of charger connect time, even when running with the charger connected.)
- Avoid placing Index 2 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 2's battery.

CE **Based on the testing below, Index 2 bears the CE mark.**

Electromagnetic Interference and Susceptibility

EC EMC Directive 89/336/EEC

EN 50081-1, CLASS A-Emissions

The system 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 system 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.

Warning: If Index 2 is connected to a battery charger while being operated in the **Electrical Simulation Mode,** it is possible for the user to experience a spike in the voltage on the line to the battery charger, producing erratic results. If you suspect this has occurred, retest the oximeter with the battery charger disconnected.

USA FCC CLASS A

Warning: Changes or modifications to this unit not expressly approved by the manufacturer could void the user's authority to operate the equipment.

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 are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. Like all similar equipment, this equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of

this equipment in a residential area could cause interference, in which case the user will be required to correct the interference at his own expense.

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.

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

Safety

Index 2 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.

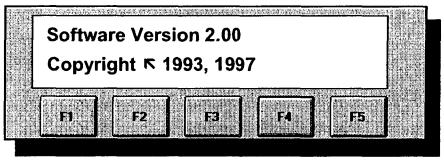
EC Directive 73/23/EEC, Low-Voltage Directive

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

Getting Started

Powering Up Index 2

- Unpack Index®. 2 from the shipping carton and slide the power switch to the "I" position. Power up the system. You should briefly see the following startup message...



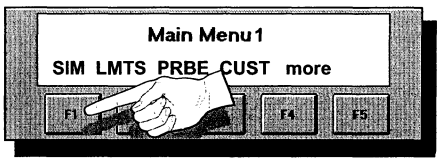
...after which the Index 2 Main Menu will appear, showing you the major headings for the four main functions of the Index 2 device.

√ If you see a message warning you that your battery is low, you need to attach the battery charger. Call Bio-Tek for assistance if needed.

√ The selected Make: XXXXXXX will also be displayed. See Page vi, or Chapter 5 for menus to select Make.

From Main Menu 1,

- ...press **SIM** then **MAN** to access the Simulations Menu. This menu allows you to set oxygen saturation levels and heart rate (BPM).
- ...the Simulations Menu appears in the Index 2 LCD.
- Press **MAN** to set the $Sp0_2$ levels from 35 to 100%, and the heart rate from 25 to 250 BPM.



F Version (Optical Finger)

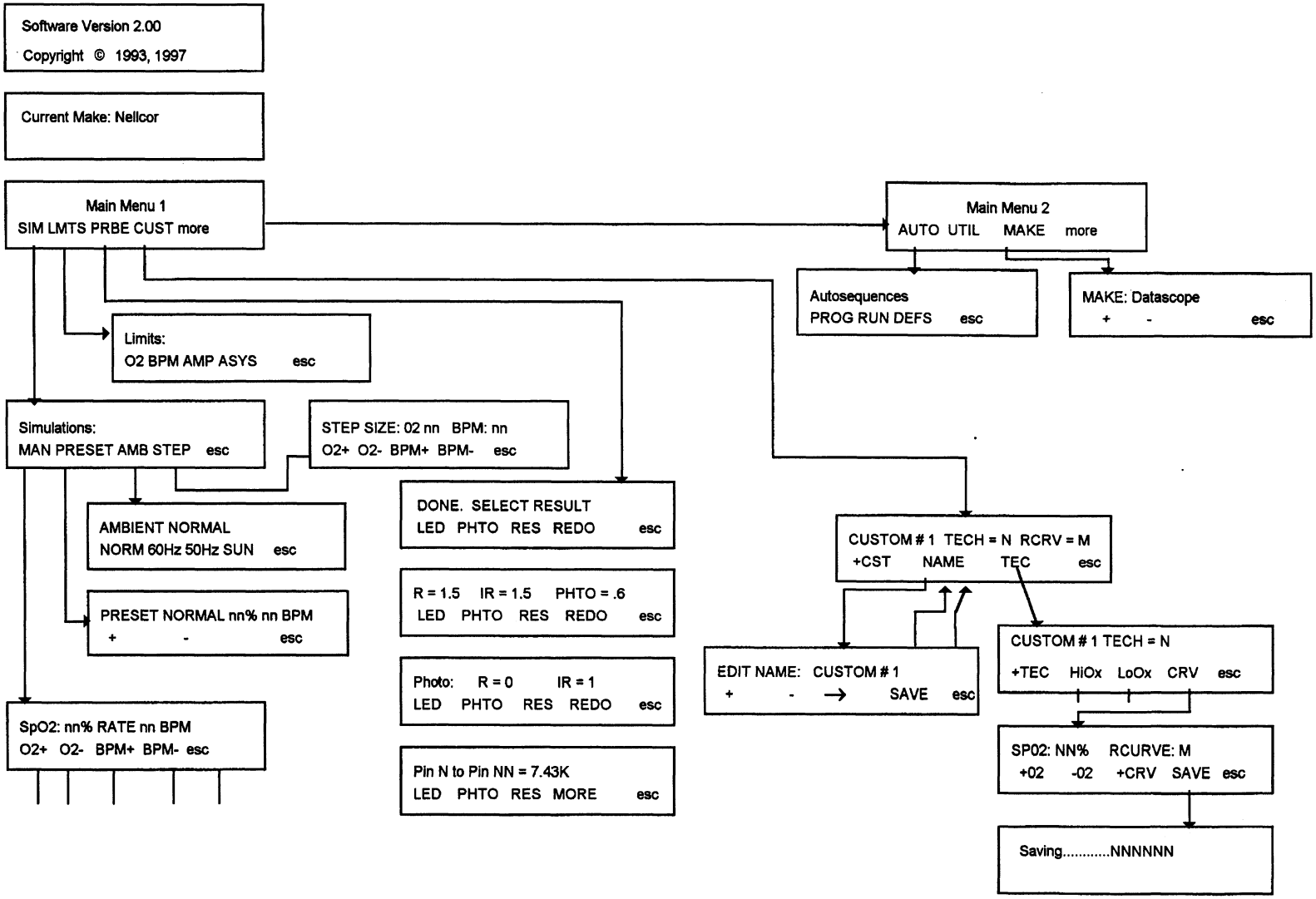
- Connect the finger probe from the Pulse Oximeter being tested to the Index 2 finger probe attachment. The LEDs from the pulse oximeter must be placed on the bottom of Index 2's finger probe attachment.

- Select the desired SpO_2 and Heart Rate settings by pressing the appropriate + / - Function keys, and viewing the settings on the Index 2 LCD display.

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

E Version (Electrical Simulation)

- Connect the pulse oximeter being tested (with the appropriate adapter cable) to the 9-pin connector labeled "oximeter".


Software Version 2.00
Copyright © 1993, 1997
Current Make: Nellcor
Main Menu 1
SIM LMTS PRBE CUST more
Main Menu 2
AUTO UTIL MAKE more
Autosequences
PROG RUN DEFS esc
MAKE: Datascope
+ - esc
Limits:
O2 BPM AMP ASYS esc
Simulations:
MAN PRESET AMB STEP esc
STEP SIZE: 02 nn BPM: nn
O2+ O2- BPM+ BPM- esc
AMBIENT NORMAL
NORM 60Hz 50Hz SUN esc
PRESET NORMAL nn% nn BPM
+ - esc
SpO2: nn% RATE nn BPM
O2+ O2- BPM+ BPM- esc
DONE. SELECT RESULT
LED PHTO RES REDO esc
R = 1.5 IR = 1.5 PHTO = .6
LED PHTO RES REDO esc
Photo: R = 0 IR = 1
LED PHTO RES REDO esc
Pin N to Pin NN = 7.43K
LED PHTO RES MORE esc
CUSTOM # 1 TECH = N RCRV = M
+CST NAME TEC esc
EDIT NAME: CUSTOM # 1
+ - → SAVE esc
CUSTOM # 1 TECH = N
+TEC HiOx LoOx CRV esc
SP02: NN% RCURVE: M
+02 -02 +CRV SAVE esc
Saving.....NNNNNN

Contents

Chapter 1:
Introduction

This chapter introduces Index 2, describes its features, and instructs you how to set up the system and power it up. Also included are instructions on how to contact Bio-Tek, if needed, and information about this manual.

Thank You

Thank you for purchasing Bio-Tek's **Index® 2 SpO_2 Simulator**, one of the first pulse oximeter testers of its kind available. Index 2 allows you to verify the operation of your pulse oximeters by testing them in a variety of ways. In fact, Index 2 provides simulations that allow testing of the complete pulse oximeter, including the optical sensors.

Introducing Index 2

For the first time, there is now a reliable way to gauge the condition and performance of standard pulse oximeters. Bio-Tek has provided Index 2 to the medical and health industry so that the performance of the pulse oximeters currently on the market can be determined.

Using Index 2 as a virtual patient's index finger, you set the Index 2 device to simulate a patient with virtually any combination of blood oxygen conditions. When the pulse oximeter to be tested is connected to the Index 2 device, the response of the pulse oximeter can be measured against Index 2's stored set of predetermined readings for a patient with the preset saturation levels and pulse conditions to see whether the pulse oximeter's results match the simulations, or to what degree (%) the pulse oximeter is out of agreement. Electrically, Index 2 can verify probe diodes, wire continuity, LEDs, and oximeter accuracy.

Like all of Bio-Tek's hardware and software systems, the Index 2 SpO_2 Simulator is backed by Bio-Tek's superior support system. If Index 2 ever fails to work perfectly, please refer to the phone, fax, Internet and BBS numbers at the end of this chapter to contact Bio-Tek's Technical Support Staff.

Index 2 Compatibility

The purpose of the Index 2 device is to quickly establish the state of any given pulse oximeter and to determine the performance qualities for the device. Index 2 can test and evaluate virtually any pulse oximeter on the market today.

Because each pulse oximeter manufacturer uses a slightly different technology and algorithm to measure SpO_2, Bio-Tek has pre-programmed into Index 2F, E, and FE a number of different R-values *vs* SpO_2 curves for specific manufacturers. This ensures that Index 2 provides the closest possible simulation. It is also possible to download additional R-value curves directly into Index 2 for non-volatile storage and use. Additionally, Index 2E and FE have optional adapter cables to test most popular oximeters and probes through electrical simulations. Index 2 is not intended to be a pulse oximeter calibrator.

Index 2 Features

- Saturated oxygen (SpO_2) simulations can be conducted with saturation levels between 35% and 100% (in 1% increments).
- Index 2 tests the complete probe and electronics assembly optically or electrically.
- Probe continuity check (E and FE versions)
- Users can set the heart rates variable 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 5" x 2" footprint.
- Programmable autosequences.
- Computer controllable.
- Menu-driven, using soft key interface and a 2-line by 24-character LCD (liquid crystal display) supertwist, alphanumeric display.
- Uses rechargeable lead acid battery, with 8 hours of continuous operation and built-in low battery indicator.

Package Contents

The contents of the Index 2 package as shipped includes:

F Version

- The Index 2 Pulse Oximeter Tester
- Battery Charger
- User's Guide and Registration Card
- Ohmeda and Nellcor Probe Adapters (optical)

E Version

- The Index 2 Pulse Oximeter Tester
- Battery Charger
- User's Guide and Registration Card
- Ohmeda and Nellcor Probe and Oximeter Adapter Cables (Electrical)

FE Version

- The Index 2 Pulse Oximeter Tester
- Battery Charger
- User's Guide and Registration Card
- Ohmeda and Nellcor Probe and Oximeter Adapter (Electrical)
- Ohmeda and Nellcor probe adapter (optical cables)

About This Manual

The intent of this user's guide is to quickly instruct the new user on how to set up and operate the Index 2 Pulse Oximeter Tester from Bio-Tek Instruments, Inc. To this end, we've employed certain conventions to help you read and understand this manual.

First, any important information will be indicated in this way, with the associated information icon as appears to the left of this paragraph.

Major topic headings start a new page (like **About This Manual**, above) to give you a visual and style clue that a new major subject is being broached. One or more subheadings will appear below each major heading.

Finally, when you are directed to press a particular button on the Index 2, you will see this Index 2 Icon, showing you which button to push:

Registration Card

Once you have got the Index 2 device up and running successfully, please take a moment to fill out the postage-paid Index 2 Registration card and mail it to Bio-Tek.

Help

If your new Index 2 system fails to start or operate successfully, please contact Bio-Tek immediately.

Technical Assistance on the Internet

The best way to contact Bio-Tek is to log onto Bio-Tek's Technical Assistance Center Web Site. You will find application notes, typical questions and answers and more supported. Electronic communication is available via:

INTERNET Site

http://www.biotek.com

E-Mail

bmdtac@biotek.com

Bulletin Board Service

(802) 655-4107 (Technical Assistance Center)

Writing To Bio-Tek

If you prefer, you can write a letter with your comments and send it to:

Bio-Tek Instruments, Inc.

Technical Assistance Center

Highland Park, Box 998

Winooski, VT USA 05404-0998

Europe

Adquipment Medical BV

Rontgenweg 13, P.O. Box 2012

NL-3200 CA

Spijkenisee, The Netherlands

Phone Support

You can telephone the Technical Assistance Center between 8:30 AM and 5:00 PM Eastern Standard Time (EST), and/or Customer Service between 8:00 AM and 5:30 PM EST, Monday through Friday, except holidays.

Technical Assistance Center
(800) 242-4685

Bio-Tek Instruments Main Number
(802) 655-4040

Customer Service
(800) 451-5172

International Customer Service & Service Department (in US)
(802) 655-4740

International Customer Service & Service Department (Europe)
(31) 181-612151

Facsimile Support

You may send a facsimile of your questions and/or requests for help 24 hours a day to the following numbers:

Technical Assistance Center

(802) 655-3399

(32) 3-825479 (Europe)

Customer Service
(802) 655-7941

International (Europe)
(31) 181-612184

Whichever method of contact you choose, please provide the following information:

- Your name / company
- Product name and serial number
- The specific steps which reproduce your problem
- A daytime phone number
- A Fax number (if available)

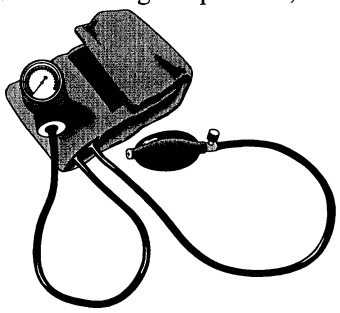
Chapter 2:
Blood Oxygen & Pulse Oximeters

This chapter gives a brief overview of some of the physiological considerations that come into play when using both a pulse oximeter and Index 2. Blood oxygen, hemoglobin and blood pressure are all discussed here, as are the workings of the pulse oximeter.

What Is Blood Pressure?

Blood pressure readings provide us with valuable information about the condition of our bodies, indicating health or the lack of it. With our fingertips, we can feel the waves of blood pressure (our *pulse*) most perceptibly at the pulse points in our wrists and neck, but blood pressure is actually (and naturally) the strongest in our aorta, where the blood leaves our heart.

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.



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.

Gasses In Blood

But blood pressure is not the whole story, 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 of saturated oxygen, a blood-gas sensing device must be used, and must be capable of detecting the wide range of nominal values for these gases. Gas concentrations in blood, specifically oxygen (O_2) and carbon dioxide (CO_2), 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 a little over a decade ago. Today, pulse oximeters are virtually required equipment in situations where the monitoring of arterial oxygen saturation (SaO_2) 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 SaO_2 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*), HbO_2/SAT, to unsaturated (or *reduced*) hemoglobin, Hb.

The oxygen saturation, SaO_2, is defined as the ratio of the concentration of oxyhemoglobin ($cHbO_2$) to the concentration of HbO_2 + Hb ($cHbO_2$ + cHb). Oxygen saturation is commonly expressed as a percentage and is calculated according to the formula below:

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

Figure 2-1: *Formula for Determining Saturated Oxygen Level*

Using this information, a correctly calibrated and operating pulse oximeter can accurately predicting 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.

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.

The illustration below shows a typical pulse oximeter configuration, noting the location of the red and infrared LED's.

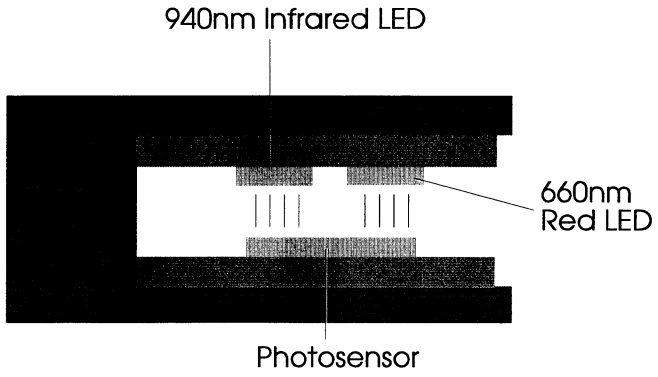


Figure 2-2: *Diagram of Sample Finger Probe for a Typical Pulse Oximeter*

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

But it's not quite that simple. Pulse oximeters must also calculate out the effect of absorption caused by the presence of venous and capillary blood and soft tissue in order to obtain the true SaO_2 figure. 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).

The illustration below shows the different AC and DC components graphically.

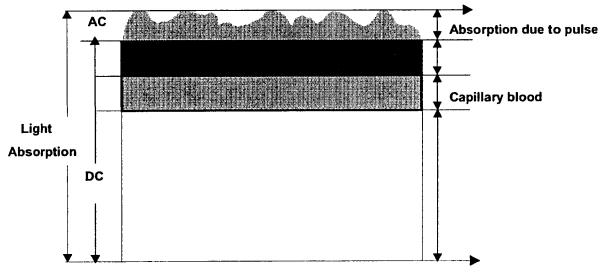


Figure 2-3: *Diagram of Light Absorbers in Tissue*

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

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

Figure 2-4: *AC/DC Infrared and Red Absorption Ratio*

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

REFERENCES

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

Chapter 3:
Index 2: An Overview

This chapter gives an overview of the operation of the Bio-Tek Index 2 system, to help you better understand the design of the system.

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

The Index 2 system has a patented optical finger that takes the place of an actual patient's index finger, and works with any pulse oximeter that detects SpO_2 through the tissue of an index finger (as opposed to the earlobe or toe).

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

When connecting a finger probe onto Index 2's "finger," make sure that the red LED's (light emitting diodes) are on the bottom and that the probe is on as far as possible.

Index 2 Electrical Testing (Index 2 E and FE Versions)

Electrical testing of oximeters is similar to optical testing except that all simulations are output through the electrical port on the back of the Index 2, thus eliminating the probe from the circuit. 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.

Setting Settings

Once connected, you can set up Index 2 to simulate virtually any patient condition, with programmable SpO_2 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 5% up to 100%.

Running Tests

Index 2 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 2 to a computer and have the computer control Index 2 to run the tests.

Evaluating Test Results

Results can be printed directly to a printer connected to Index 2 via the built-in serial RS-232 port and the centronics parallel printer port for study and archiving purposes. Results can also be sent over a serial cable directly to a computer, for evaluation and/or storage in a database, etc.

Index 2 Functionality

The illustration below shows in simplified terms the basic functionality of the Index 2 system.

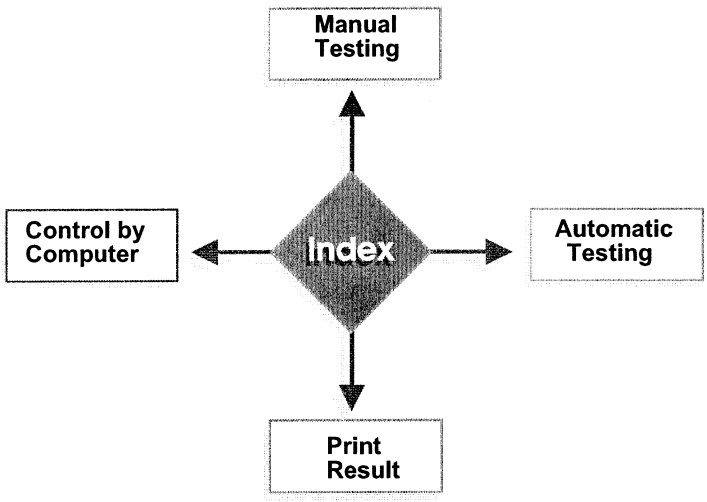


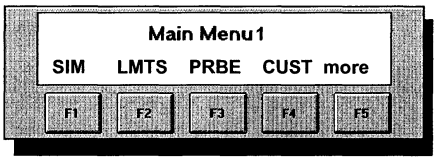
Figure 3-1: Basic Index 2 Functions

Chapter 4:
The Index 2 Main Menu

This chapter discusses the Main Menu for Index 2; subsequent chapters discuss the submenus and how they are used to access Index 2 functions and operate Index 2.

The Index 2 Main Menu

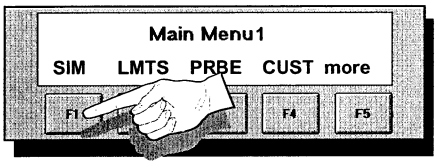
When you first turn on Index 2, the Bio-Tek Index 2 version message displays for one second and then you'll see the Index 2 Main Menu 1:



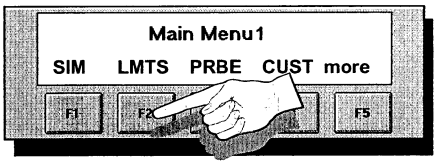
If at powerup the batteries are low and in need of recharging, the following message will appear on the first line: Warning! Battery Low!

Index 2's Main Menu 1

The Index 2 Main Menu 1 choices give you access to the full Index 2 system. Each softkey and its associated menu choices are explained below.

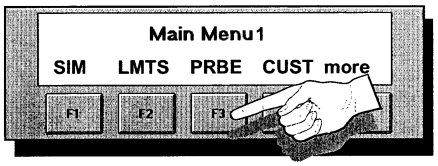


SIM sends you to the Simulation Menu for setting oxygen saturation levels and heart rates (BPM) .

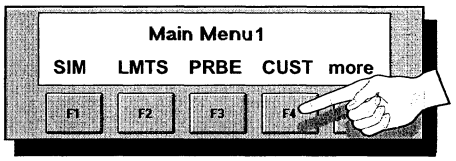


LMTS sends you to the Alarm Limits Menu for running the following tests:

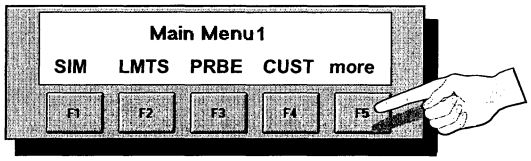
- SpO_2 Alarm Limits & Response Time
- Rate Alarm Limits & Response Time
- Pulse Amplitude Limits
- Motion Artifact Limits



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



CUST sends you to the Custom Menu, which lets you create custom makes by choosing a light technology and R-Curve. These may be stored for later use. Custom makes are used when the pulse oximeter you are testing is not included in the factory preset makes.



more sends you to Main Menu 2 (which allows you to select a pulse oximeter type by make), select Automatic Mode (which allows you to create and run tailored test procedures), configure the Index 2 serial (RS-232) port (set baud rate, data bits, etc.), and adjust the contrast of the Index 2 LCD screen.

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

Pressing **esc** at any point within Index 2 acts like an Escape key and will always return you to any previous menu, until you have returned to the Index 2 Main Menu.

Chapter 5:
Configuring Index 2 To Match A Specific Make Of Oximeter

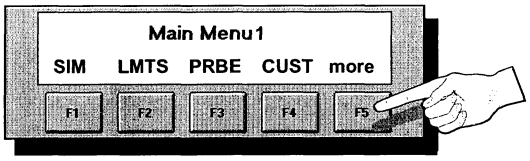
This chapter explains how to configure Index 2 for optimum compatibility with the pulse oximeter(s) you will be testing by selecting an existing pulse oximeter make, or creating a custom make.

In order to test a pulse oximeter optically via Finger or electrically, technology of light and R-Curve data must be known. You can configure Index 2 to match the make of pulse oximeter(s) you are using and will be testing. Index 2 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'll be testing.

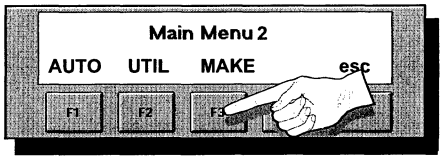
Accessing The Make Menu

To change the make of the pulse oximeter stored in Index 2's memory, you first access the Make Menu...

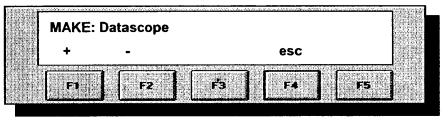
- To get to the Make Menu, press **more** from the Index 2 Main Menu ...



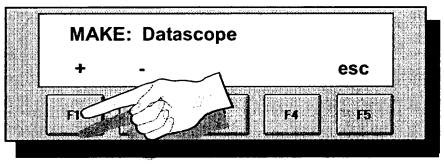
- ... you'll then see Index 2's second menu, Main Menu 2:



- Press **MAKE**. You'll see the following appear in Index 2's LCD display:



- Press + or - to scroll through Index 2's pre-programmed makes.



The following makes of oximeters have been validated to perform properly both electronically and with their probes, and are pre-programmed into Index 2:

- 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)
- Respironics™

The R-Curves for the devices listed above were developed by Bio-Tek in cooperation with the manufacturers. The cooperative venture does not represent an endorsement of Index 2 by these manufacturers. Bio-Tek assumes the responsibility for the R-Curves, and any results obtained from the use of Index 2.

*HP electronic cable is not available – it has been validated with the probe only.

Caution! 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 2.

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

Note: Six additional manufacturer's profiles are incorporated in Index 2. 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 2.

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

*The R-Curves for these devices are specified from100 to 80% O_2 only.

- To return to Main Menu 2, press **esc**.
- Then, to return to Main Menu 1, press **esc** again.

To add or subtract R-Curves from this list, see *Chapter 12, Creating Your Own R-Curve.*

How to Customize a Make Not Included Within Index 2

Index 2 has incorporated many popular oximeter makes into its data base. Unfortunately, there are many more manufacturers that cannot be incorporated due to Index resource limitations and oximeter availability.

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

Index 2 accuracy specifications are not valid for user-defined custom makes. Index 2 can provide specified repeatability of +/- 1 standard deviation.

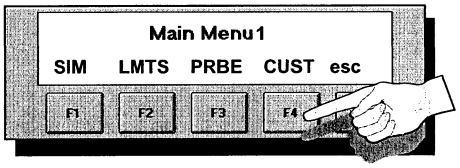
Technology Options	Typical Oximeter
1. Normal Intensity	Nellcor, BCI
2. Low Intensity	Hewlett-Packard, Ohmeda, Invivo
3. High Intensity	Datex
4. Very High Intensity	None Known

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

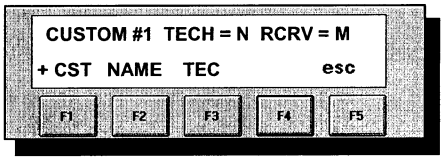
Once a technology and a curve have been determined, you may save the custom make for future use.

Operation

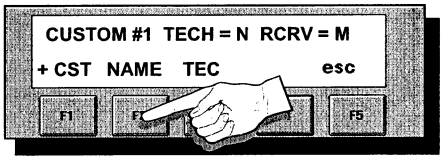
1. To access the custom menu, press **CUST** from the main menu.



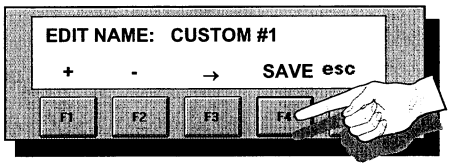
You will see the following menu:



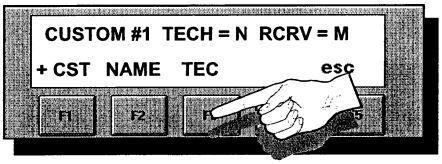
Here, you can choose the slot to customize by pressing + **CST** to cycle through the available names. Custom #1 through #5 are the default factory names. You can also change the name by pressing the **NAME** key:



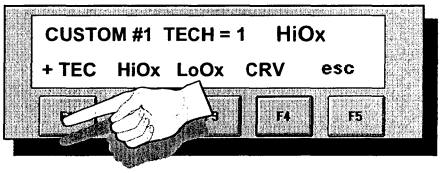
There are five available slots for saving custom makes. Press + or - to change the alphabet. Press ✹ to move the character. Press **SAVE** to save the name and the results:



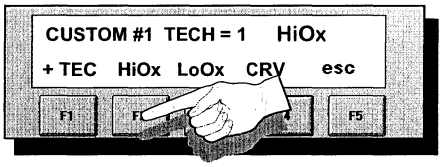
2. Press the **TEC** key to test for technology type.



You can now select a technology type #1 - #4. Technology types offer various light level thresholds to try. Refer to the table on page 22 for a list of technology light levels. You may already know which technology to use based on the manufacturer's information. If not, continue to step 4 for process of elimination testing.

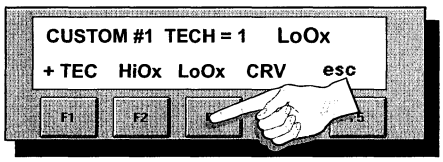


4. Press the **HiOx** key to test oximeter stability at the high oxygen setting.



You will hear a beep and the menu will change to **HiOx**. With the oximeter probe connected to Index 2, look for a steady reading on the oximeter. The number may be in the low 90s, but not necessarily. If the oximeter is not displaying a stable number, change technology type to the next number (2, then 3, then 4) to find a technology that gives a steady reading.

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

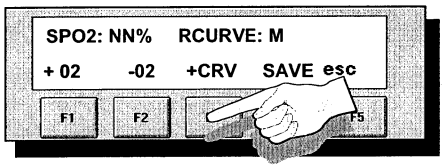


Press **HiOx** once more after a stable reading is achieved at low oxygen levels to verify that high oxygen is still stable. Once a technology is found that locks on and gives stable readings at low and high oxygen levels, note these readings as seen on the oximeter and refer to the R-Curve Option table on page 23.

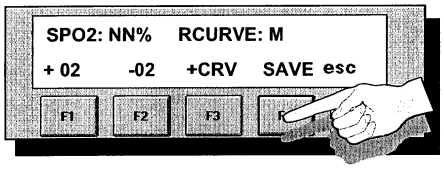
Find a high level and a low level that are similar to your readings, and move to the left of the chart for a curve number to use in the next step. Press **CRV** to advance to the next and final step.

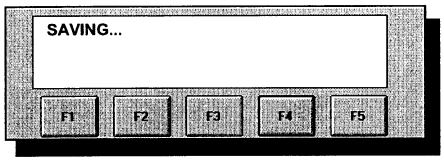
6. Choose an R-Curve that best fits this oximeter.

   To do this, press the + **CRV** key to advance through the list of installed MFG R-Curves by number. (Refer to the R-Curve Options table on page 23.) You should know this from the manufacturer's information, or from the previous steps.



   Use the + **O2** and **-O2** keys to verify that the oximeter tracks the curve up and down the O_2 scale (70 to 100% O_2 should be sufficient). Once a best curve fit is determined, press **SAVE** to save the custom make.





   The custom make will now appear on the make list on Main Menu #2.

"Custom Make" percent O_2 accuracy is not guaranteed. Index 2 can only guarantee accuracy of repeatability in this mode of operation.

Chapter 6:
Setting & Changing Simulation Factors

This chapter discusses how to use the Index 2 Simulations Menu to set the simulated level (in percent) of SpO_2 in the "patient's" blood and the plethwave beats per minute (BPM). Also explained is how to set the ambient light default and how to select one of Index 2's preset medical conditions.

About Simulations & Presets

One of the main functions of Index 2 when acting as an SpO_2 simulator is to test the performance of a pulse oximeter for any possible patient condition. Index 2 allows you to set any combination of blood-oxygen levels, heart rates and pulse amplitude, to simulate virtually a range of medical physical conditions, and to set an ambient light artifact.

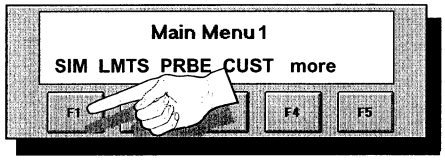
By setting such a group of default factors with Index 2, you can effectively test an oximeter and determine its weaknesses (if any). Index 2 will show you (and optionally print) areas in your pulse oximeter performance that may be unacceptable, or it will document correct performance.

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

Setting Simulations

To access the Simulations Menu...

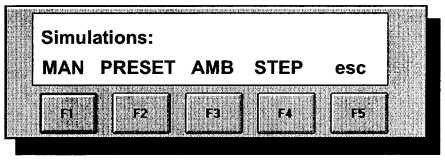
•... press **SIM** from the Index 2 Main Menu ...



•... the Simulations Menu appears in the Index 2 LCD.

The Simulations Menu

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



There are four user choices on this menu (in addition to the standard **esc** for leaving the menu). They are:

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 Index 2's default of 96%, or the BPM default of 75, use **MAN**.

PRESET Allows you to select from the Index 2 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 of less than 60 BPM)

- A tachycardic patient (one with an excessively rapid pulse)

- Motion

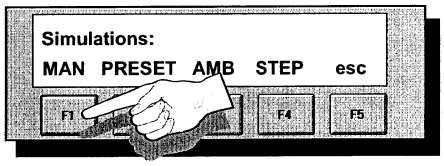
To set a patient condition as other than Index 2's default of "normal," use **PRESET**.

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 2's sunlight default, use **AMB**.

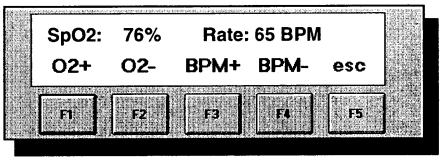
STEP Allows you to set a step size for both SpO_2 and BPM settings. The default setting for Index 2 is to increase or decrease SpO_2 settings by 2% at a time (that is, with each button push), and to increase or decrease BPM settings by 5 beats per minute at a time. For a finer or coarser level of change, use **STEP**.

How To Change The Default SpO_2 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...



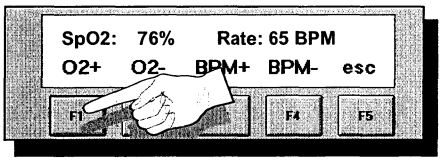
- ... the Manual Settings Screen appears on the Index 2 LCD:



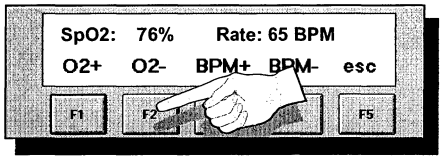
Setting the O_2 Saturation Level

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

- To raise the O_2 level one step at a time, press **O2+**.



- To lower the O_2 level one step at a time, press **O2-**.

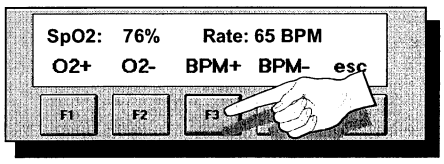


Press the key(s) as many times as needed to adjust the SpO_2 level.

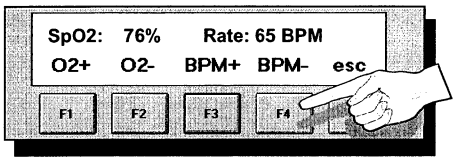
Raising Or Lowering The Pulse Rate

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

- To raise the pulse rate five beats at a time, press **BPM+.**



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



Press the key(s) as many times as needed to adjust the BPM.

Returning to the Index 2 Main Menu

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

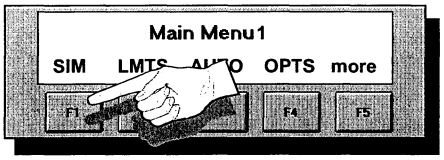
Using Index 2's Preset Patient Conditions

Index 2's Preset feature combines SpO_2 levels, heart rates and pulse amplitude into seven preset conditions which simulate a broad range of normal and abnormal patients. 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.

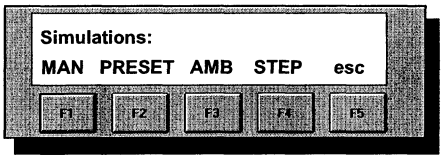
Index 2 is preset to simulate the SpO_2 and pulse rates ratios for the following conditions:

Condition (Preset)	SpO_2	Pulse Rate	Pulse Amplitude	Waveform
Normal	98%	60 BPM	100%	Normal
Weak Pulse	90%	95 BPM	10%	Normal
Bradycardia	88%	45 BPM	100%	Normal
Tachycardia	85%	130 BPM	20%	Normal
Geriatric	92%	95 BPM	40%	Normal
Obese	93%	90 BPM	50%	Normal
Motion	96%	75 BPM	100%	Motion

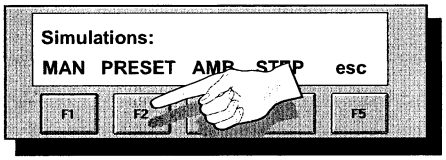
- To access the Simulations Menu (if you aren't already there), press **SIM** from Main Menu 1 ...



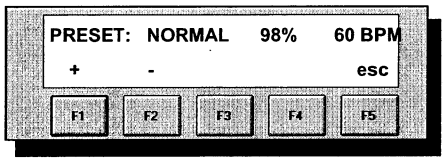
- ... the Simulations Menu appears in the Index 2 LCD.



- To select a preset patient condition, press **PRESET** from the Simulations Menu...



- ... the Preset Settings Screen appears on the Index 2 LCD:



Press **+** or **-** to scroll through the list of available presets.

- If you want to return to Main Menu 1 at this time, press **esc** again.

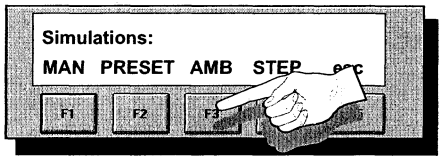
Upon leaving the Presets menu, Index 2 returns to its default (Normal) preset patient condition simulation.

Setting the Light Artifact

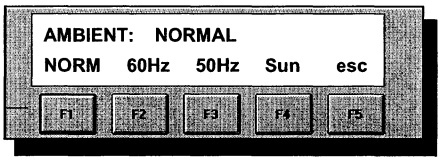
You can set a light artifact with Index 2, as well, to test oximeters under different simulated ambient (surrounding) light conditions. The available simulations are:

Light type	Frequency	Description
Sunlight	*n/a*	Index 2 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. BPM are fixed at 45.
Artificial	60 Hz	Simulated by superimposing 60 Hz noise on the pleth wave. BPM are fixed at 45.

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

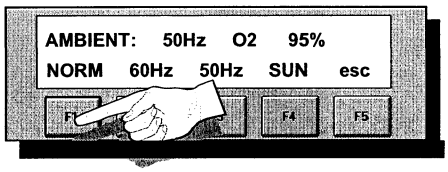


You'll see the screen change to one similar to this:



The O_2 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 any other Function key to select the desired ambient light presets.



3. Once you have set an ambient light setting, you can return to the Simulations (**SIM**) Menu by pressing **esc.** Press **esc** again to return to Main Menu 1.

Setting Steps

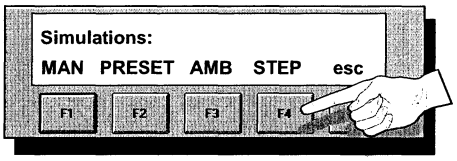
You can vary the size of the steps for O_2 and pulse rates used when setting up tests and testing oximeters with Index 2.

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

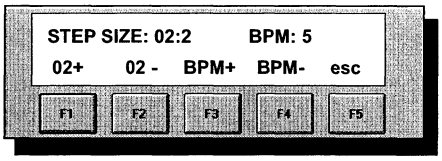
Step amounts come in to play in three places in the Index 2 menu structure:

- On the Simulations (**SIM**) Menu's "**MAN**" (Manual Test) submenu
- On the Limits (**LMTS**) Menu's "**02 Alarm**" and "**Rate Alarm**" submenus
- And on the Autosequences (**AUTO**) Menu's "**PROG**" submenus for setting the SpO_2 level and the pulse rate.

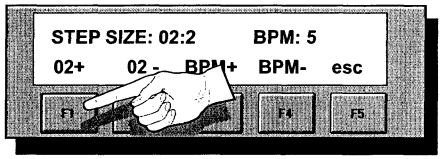
1. To choose a step amount for the SpO_2 level and the pulse rate, press **STEP** from the Simulations Menu...



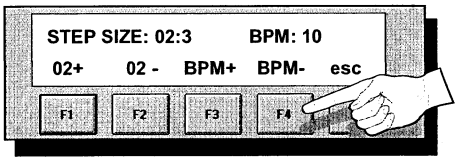
You'll see the screen change to one similar to this:



2. To increase or decrease the O_2 step amount, press **O2+** or **O2-**, respectively, as needed.



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



4. Once you have finished setting the O_2 and pulse rate step amount, you can return to the Simulations (**SIM**) Menu by pressing **esc.** Press **esc** again to return to Main Menu 1, if desired.

Chapter 7:

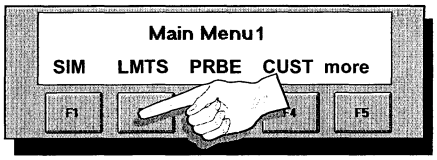
Testing The Pulse Oximeter for SpO_2, BPM, Pulse Amplitude, & Asystole Limits

Once you have determined the range in which you want to test a pulse oximeter for SpO_2 and rate, you can then test the pulse oximeter for upper and lower limits for response time. This chapter discusses how to use the Index 2 LMTS (Limits) Menu in order to set and test for those limits.

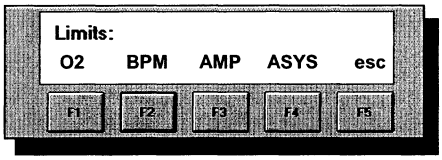
Testing Pulse Oximeter Limits

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

- To get to the Limits menu, press **LMTS** from the Index 2 Main Menu ...



- ... and you'll see the following menu appear in Index 2's LCD display:

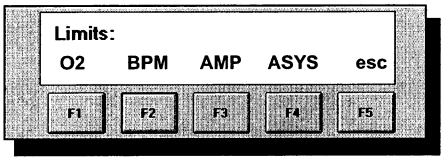


Notice, as with every menu in Index 2, that **esc** always returns you to the previous menu, in this case the Main Menu.

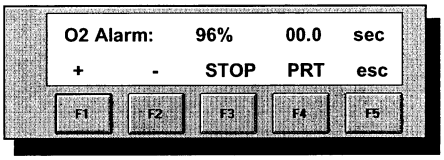
Simulating Oxygen Conditions

You can set the oxygen levels using Index 2 to test the sensitivity of your pulse oximeter.

1. To test the oxygen limits press **LMTS** at the Index 2 Main Menu if you are not at the Limits Menu. Then, press **O2** at the Limits Menu...



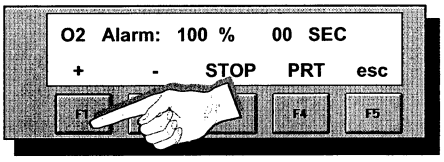
- The LCD display will change to show you a new set of choices, as shown below.



Notice, as with every menu in Index 2, that the softkey is reserved as the "**esc**ape" key, which will always return you to the previous menu, in this case the Limits Menu.

When setting a new oxygen limit, Index 2 displays the last setting used (or 96% if not previously changed) and resets the time to **00** seconds.

2. Press + or - to start the timer.

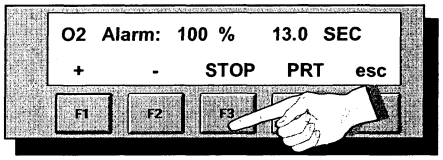


- Pressing + will **increase** by the step amount (by the step amount set previously using the Simulations menu, **SIM**).
- Pressing - will **decrease** by the step amount.

Continue pressing + or - until the O_2 percent you want to test for is displayed. Each time you press + or - the timer internally will reset and begin timing again.

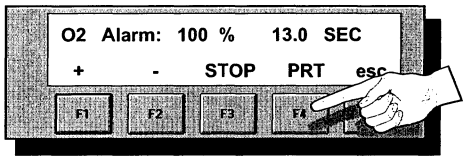
3. The display will show **Timing!**

   - After a certain amount of time, if the O_2 setting is outside the oximeter's alarm limit, the alarm will sound on the pulse oximeter being tested. Press **STOP** immediately.



   - The timer will stop, and Index 2 will display the elapsed time to alarm for the specified simulation level.

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



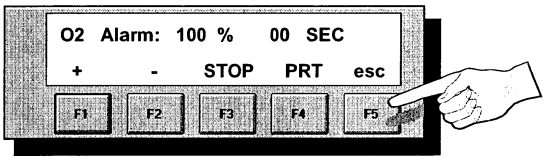
- The results will be sent out the RS-232 and the centronics port

You can connect Index 2 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 2 to other systems or peripherals, see ***Appendix A: Printing & Data Transfer***.

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

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

5. When you are finished testing the pulse oximeter for SpO_2 readings, press **esc** to return to the Limits (**LMTS**) Menu.

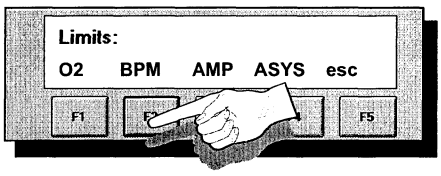


Simulating The Pulse Rate

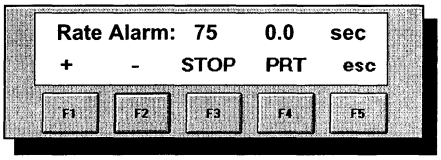
By varying the pulse rate (beats per minute) of the simulated patient index finger (or electrically), you can have Index 2 simulate a variety of patient conditions and observe the effect of the changing pulse rate with a static SpO_2 on the pulse oximeter, as well as the effects of a changing pulse rate with a changing SpO_2 percentage.

How To ...

1. To access the pulse rate alarm menu, press **LMTS** from the Index 2 Main Menu and then press **BPM** to access the Pulse Rate Alarm Menu...



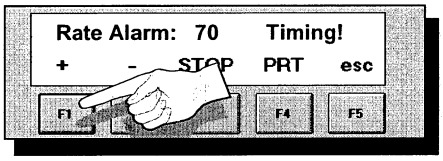
- ... you will see the Pulse Rate Alarm Menu display on the Index 2 LCD, which looks like this:



Notice, as with every menu in Index 2, that the last softkey is reserved as the "**esc**ape" key, which will always return you to the previous menu, in this case the Limits Menu.

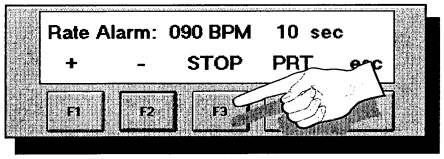
2. When setting a new BPM limit, Index 2 always starts with the last pulse rate setting.

- Press **+** and the simulator will **increase** the pulse rate from the set value +5. Each time the button is pressed, the BPM will increase by 5.



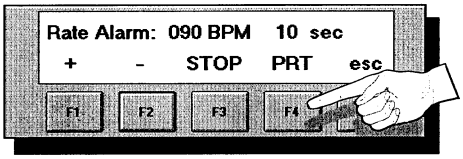
- Press **-** and the simulator will **decrease** the pulse rate from the set value -5. Each time the button is pressed, the BPM will decrease by 5 .
- The display will show **Timing!**

3. After a certain amount of time, if the selected simulation rate exceeds the oximeter alarm rate, the alarm will sound on the pulse oximeter being tested. You should then press **STOP** on Index 2 immediately.



- The timer will stop, with the number of seconds which have passed left displaying. (The counter will restart if **+** or **-** is pressed.)

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



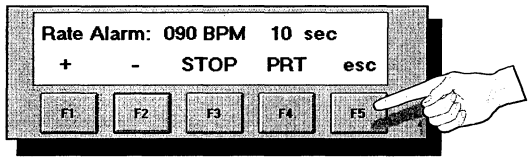
- The results will be sent to the RS-232 and centronics port.

You can connect Index 2 to any printer with a serial port or parallel centronics-type port or to any IBM-compatible PC, including laptops and notebooks. For information on how to connect Index 2 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 (**LMTS**) Menu.



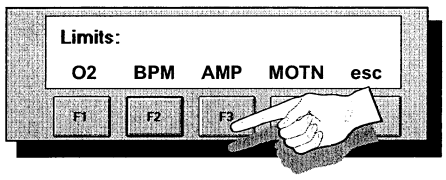
Simulating Pulse Amplitude

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

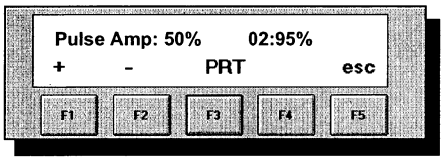
How To...

You can quickly set a pulse amplitude limit using Index 2.

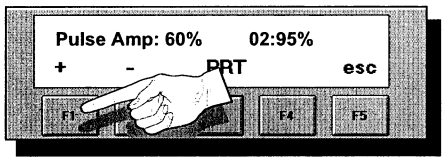
1. To access the pulse amplitude alarm menu, press **LMTS** from the Index 2 Main Menu and then **AMP** from the Limits Menu:



   - You will see the Pulse Amplitude Menu display in the Index 2 LCD screen:

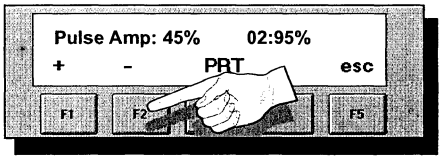


2. To raise the percentage of AC factors in the simulated blood condition, press + :



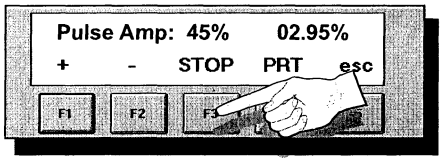
   - The amplitude will **increase** in jumps of 5% every time the button is pushed.

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

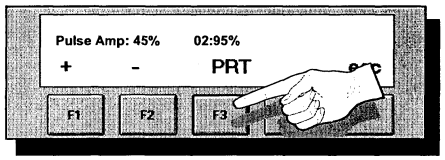


- The amplitude will **decrease** in jumps of 5% every time the button is pushed (with a 1% decrease for each value below 10%).

4. After a certain amount of time, if the pulse amplitude rate exceeds the oximeter alarm rate, the alarm will sound on the pulse oximeter being tested. You should then press **STOP** on Index 2 immediately.



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



- The results will be sent to the RS-232 or centronics port.

You can connect Index 2 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 2 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:

```
Pulse Amplitude Test
------------------------
At 40% the signal is lost
```

6. When you are done, press **esc** to return to the Limits (**LMTS**) Menu.

Simulating Asystole or No Pulse

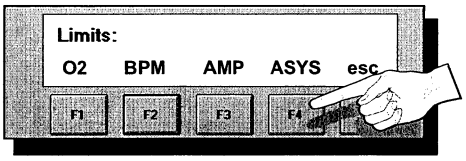
In a clinical setting, a no-pulse condition is life threatening. Most pulse oximeters sound alarms under this condition. Index 2 can measure the response time of these alarms.

How To...

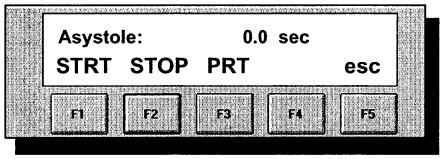
Index 2 can simulate asystole in order to further test an oximeter. Here's how:

1. To set up asystole factor for testing a pulse oximeter's sensitivity, first press **LMTS** from the Index 2 Main Menu to access the Limits Menu.

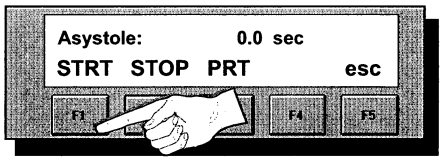
- Then, press **ASYS** at the Limits Menu to access the Asystole Menu:



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

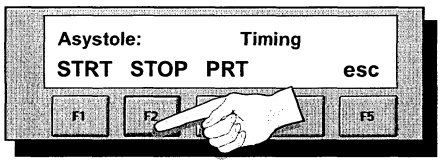


2. To start the Asystole test, press **START**.



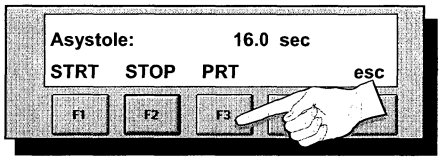
- The timer will start and the asystole simulation will begin. The LCD screen displays **Timing!** while the seconds are ticked off.

3. To stop the test, press **STOP**:



- The timer will stop and the elapsed time will display in seconds.

4. To review the results of the test, press **PRT**.



- The results will be sent to the RS-232 and centronics port.

You can connect Index 2 to any printer with a serial or parallel centronics-style port or to any IBM-compatible PC, including laptops and notebooks.

For information on how to connect Index 2 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:

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

5. When you are done, press **esc** to return to the Limits (**LMTS**) Menu.

Chapter 8:
Using Index 2 Test Programs to Automatically Test Pulse Oximeters

This chapter explains how to set up, save, and use test programs so that you can let Index 2 automatically sequence through a series of tests for you.

The AUTO Menus

Index 2 allows you to use pre-defined test programs to automatically sequence through tests; tests which you would ordinarily have to do manually by setting each test parameter every time you started Index 2 and connected it to a pulse oximeter for testing. Pre-defined test programs save you time, as well as saving you from having to repeatedly reset test parameters for every pulse oximeter testing session.

You can use Index 2's nine pre-defined programs (also called *autosequences*), or you can customize any or all of them and then 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 2 will run through the tests one by one, at the settings you determine and for the amount of 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

From the AUTO Menu you define a set of parameters, half of which are set to either *on* or *off* (by specifying either **Yes** or **No**), the other half by setting a value. The parameters are discussed on the next page.

Each variable is set in one of two ways:

- either by pressing the key labeled **SEL** (for change SELection)
- or by pressing **+** or **-** to increase or decrease a value.

You 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

The illustration below shows in a simple, graphic way, the steps involved in creating a custom program

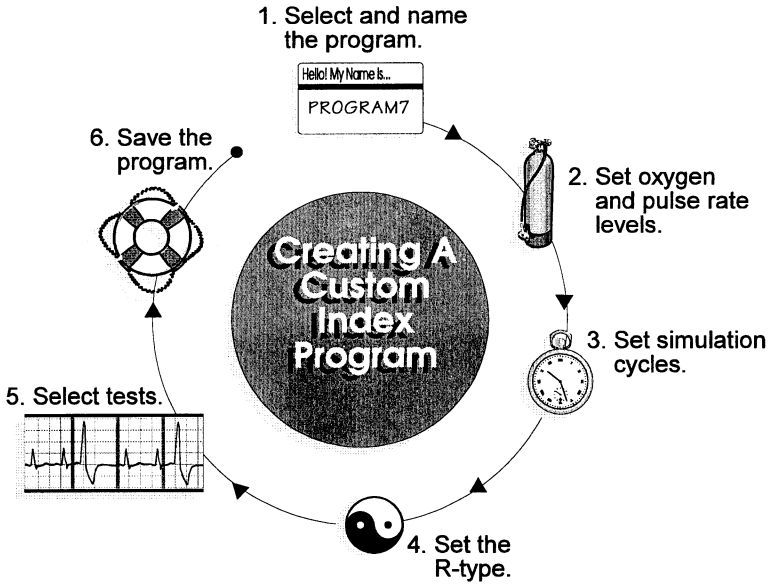


Figure 8-1: *The Program-creation Sequence*

The Automatic Test Parameters

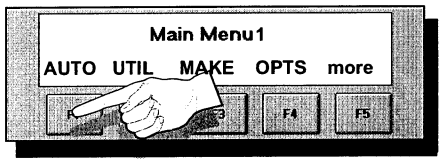
The parameters you will be defining follow. Defaults are different for each program.

☑ **Program Name**	Enter a name for this program. You can use Index 2's defaults of **PROG0** through **PROG9** 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 actual test results for each of the tests. The default printout will display summary information only.
☑ **SpO_2 Setting #1**	Set the percent oxygen level for the first test.
☑ **SpO_2 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/all subsequent tests.
☑ **Cycle Number of Pleth Waves**	Set a cycle time by selecting number of pleth waves. The cycle time selected applies to each test in the sequence.
☑ **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 2 to either test or bypass the SpO_2 limits test.
☑ **BPM Alarm Test**	Set Index 2 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 2 to either test or bypass the amplitude test.
☑ **Motion Test**	Set Index 2 to test the oximeter for patient motion.
☑ **Use Presets**	Set Index 2 to allow for the selection of preset patient conditions (geriatric, obese, normal, etc.) at test time.

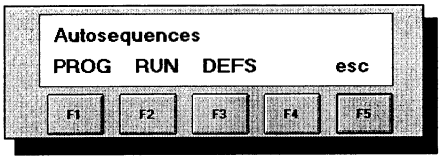
Accessing the Autosequences Menu (AUTO)

To access the Autosequences Menu ...

- ... press **AUTO** on the Index 2 Main Menu 2

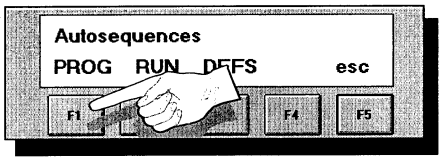


- ... and you'll see the following menu appear in Index 2's LCD display:

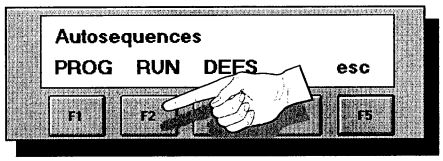


Menu Choices

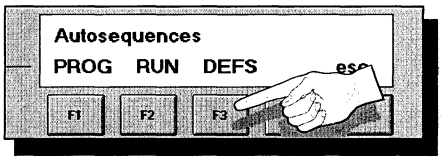
The Autosequences Menu provides you with three choices:



PROG lets you define or edit a set of parameters for a program which you can have Index 2 run automatically whenever needed.



RUN lets you select and run any of up to nine pre-defined programs automatically.



DEFS lets you return any or all of the Index 2 programs to their default factory settings.

Notice, as with every menu in Index 2, that the last key is reserved as the Escape key, which will always return you to the previous menu, in this case the Index 2 Main Menu.

Creating A Custom Test Program (Autosequence)

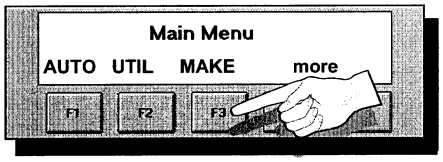
The technique for creating a custom program in Index 2 is easy and intuitive. You simply access the Autosequences Menu, enter or select a program name, define the program's parameters (enter test levels and so on), and then save the program. The program can then be run at any time after saving.

And because the program remains in Index 2's non-volatile memory, it is unaffected if the instrument's power is turned off. The only way the program can be changed is if you modify it or return to its default (factory-shipped) state.

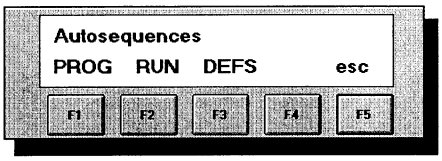
Selecting A Test Program

1. First, if you aren't there already, access the Autosequences Menu ...

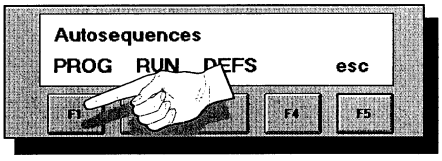
- ... press **AUTO** on the Index 2 Main Menu 2



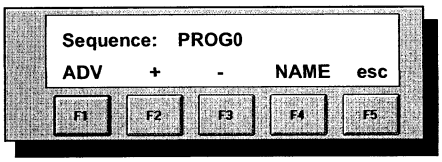
- ... and the Autosequences menu will display:



2. Select **PROG** to begin defining a custom autosequence program...

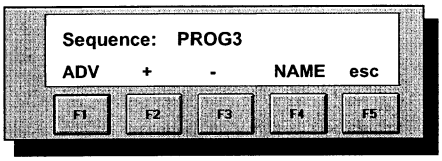


3. ... you'll see the first of the Autosequences screens appear on the Index 2 LCD, labeled **Sequence**:

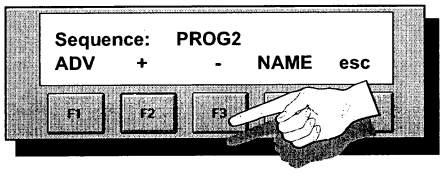


You can then select one of Index 2's pre-programmed test programs, PROG0 through PROG9, to modify. PROG0 through PROG9 are identical as shipped from Bio-Tek.

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



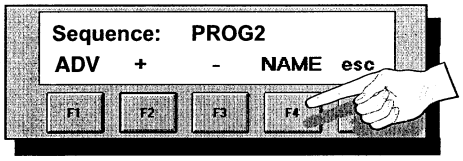
- ... or, to scroll through the list of programs (in *descending* alphanumeric order), press - ...



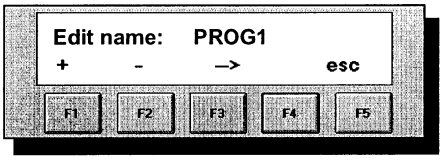
Optionally Renaming The Test Program

You can give the Index 2 test program any name you wish. This name can be from one to eight characters in length and can contain letters, numbers, and spaces; for example "`TEST1`", "`TEST22A`" or "`HP TEST`".

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



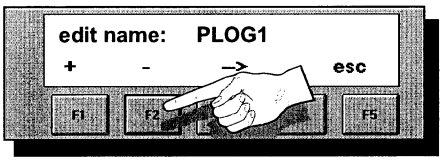
- The LCD screen will change to this...



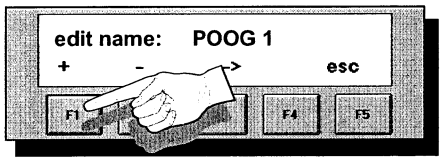
To edit a name, you use → to select a letter position in the name. In the example below, the second position has been selected (where the letter "**R**" now is).

- To select position one, you do not need to press →;
- To select the position two, press → **once**
- To select the position three, press → **twice** ... and so on.

- Once the letter position has been selected, press **-** to decrease the letter or number as in the example below (notice that the **R** is now an **L**) ...

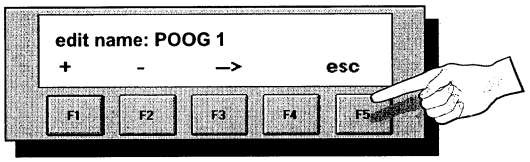


- ... or press the **+** to increase the letter or number in sequence, as shown below (notice that the **L** is now an **O**) ...

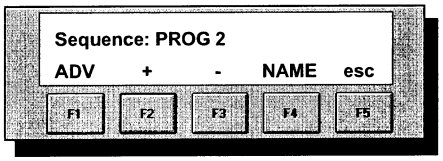


Any changes that you make to a program name are effective immediately. Pressing **esc** operates as it does on any other screen and simply returns you to the previous screen or menu. Pressing **esc** ***does not*** return the program name to its previous value. To reset a program name, you must re-enter it using **NAME**.

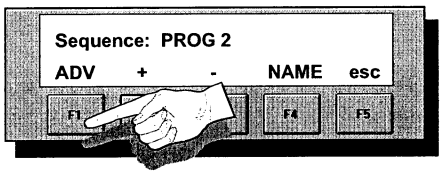
- When you have finished editing the program name, press **esc** to return to the **Sequence** Menu.



You will then see the **Sequence** screen appear again on the LCD screen. (The program name, if altered, will reflect the new name and will display following the title **Sequence:**)



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

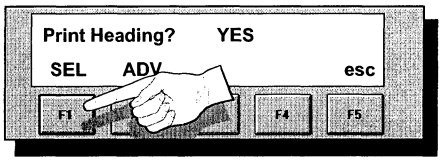


At any time during the program-definition process you can press **esc** and return to this initial **Sequence** screen. (Pressing **esc** at the **Sequence** screen returns you to the Autosequences Menu and will prompt you to save or not save your program; from there, pressing **esc** returns you to the Index 2 Main Menu.)

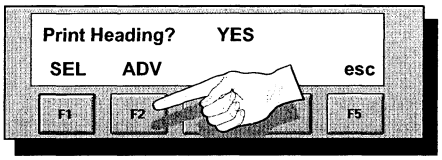
Selecting Print Settings

You can customize an Index 2 program to include optional heading and actuals information at print time...

- Press **SEL** to change the **Print Heading:** response from **No** to **Yes** as needed.

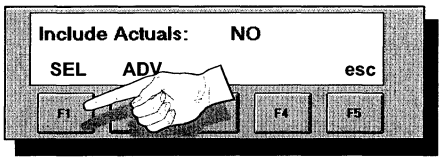


- Move to the next step in the process by pressing **ADV**:



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

For information on what is in an Index 2 test printout, refer to ***Appendix A: Data Transfer Notes.***

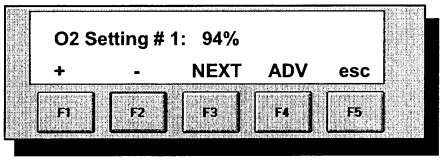


- Press **SEL** to change the **Include Actuals:** response from **Yes** to **No** as needed.
- Move to the next step in the process by pressing **ADV**.

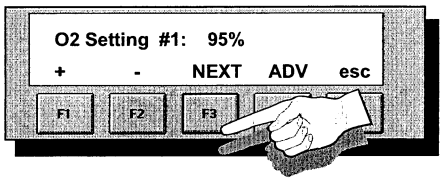
Setting the 0_2 Level

You can set up to ten different oxygen levels and up to ten different pulse rates in Index 2 for Index 2 to automatically simulate.

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



- Press **+** and/or **-** to adjust the simulated oxygen level up or down for the first O_2 test (1% O_2 per button push). You can set up to 10 O_2 tests. Pressing at **O2 Setting #10** brings you back to **O2 Setting #1**.



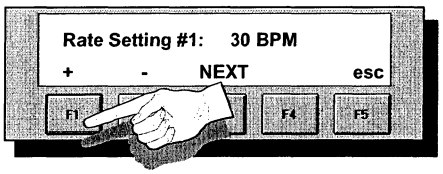
- Press **NEXT** to set the Heart Rate.

If you don't plan to test for O_2, just press **ADV** to bypass these settings.

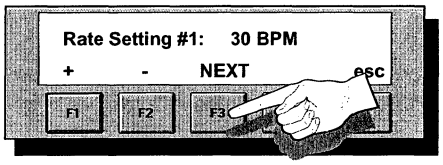
Setting the Pulse Rate

You can set up to 10 different pulse rates for Index 2 to use during a single autosequence program.

- Again, use **+** and/or **-** to adjust the beat per minute (BPM) up or down for the first pulse rate test (1 beat per button push).



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



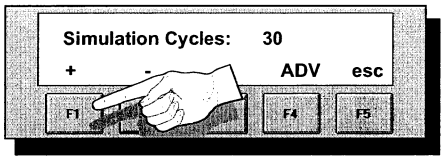
  - Use **+** and/or **-** in the same way as before to adjust the pulse rate up or down (1 beat per button push).

  - Press **NEXT** as many times as needed to enter up to 10 different test values.

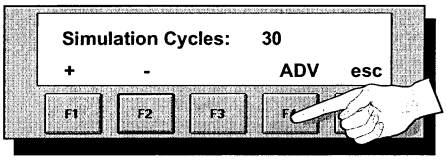
Setting The Simulation Cycle

Oximeters take a fixed number of cycles to evaluate a change in input and respond. You can set the expected response time (in waveform cycles) after which Index 2 will double beep. The double beep informs 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. To do so....

- Use **+** and/or **-** in the same way as before to adjust the time in cycles, up or down (by 5 pleth cycles per button push).



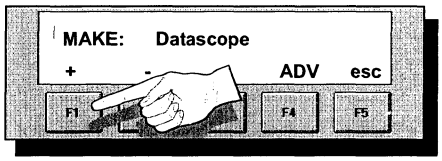
- When you are done setting a time in cycles (or to bypass this screen), press **ADV** to continue...



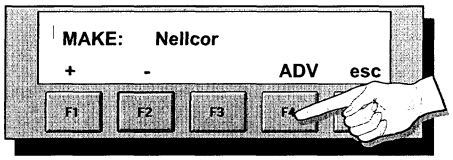
Selecting The Make

You next select the make of pulse oximeter to be tested.

- Press **+** or **-** to scroll up and down the list of pre-programmed oximeter types. For more information on configuring Index 2 for a specific make of oximeter, refer to **Chapter 5**.



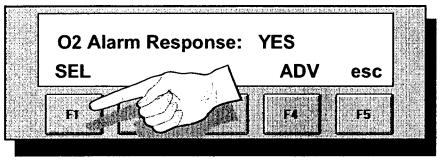
- When you are done, press **ADV** to continue...



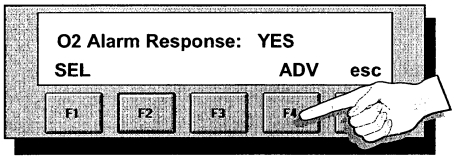
Choosing Your Tests

Your next step in creating a custom program is to choose the tests that you want Index 2 to run. To do so.... .

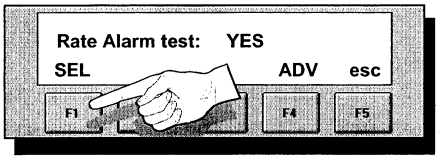
- .... Press **SEL** to change the **O2 Alarm Response:** response from **NO** to **YES**, or **YES** to **NO**, as needed.



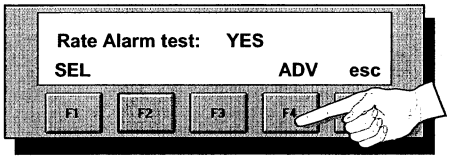
- When you are done (or to simply bypass this screen), press **ADV** to continue...



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

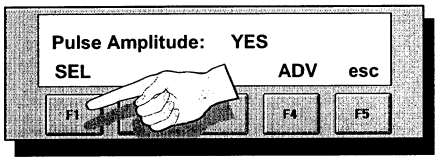


- When you are done (or to simply bypass this screen), press **ADV** to continue...



Selecting Pulse Amplitude

- Next, press **SEL** to change the **Pulse Amplitude:** response from **NO** to **YES**, or **YES** to **NO**, as needed.

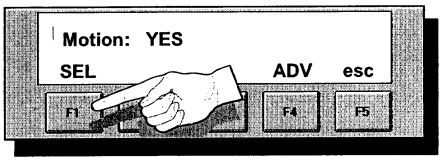


- When you are done (or to simply bypass this screen), press **ADV** to continue...

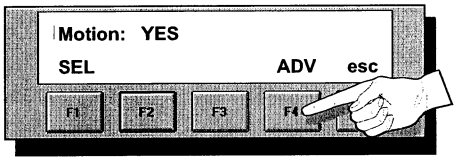
Selecting Motion

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

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



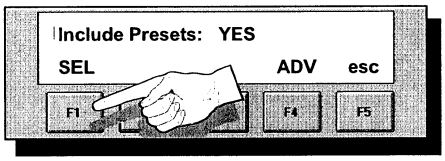
- When you are done (or to simply bypass this screen), press **ADV** to continue...



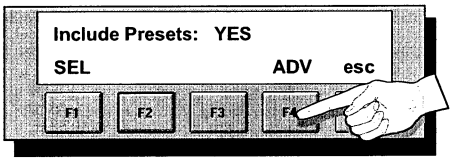
Selecting Presets

Next, select the make of pulse oximeter to be tested.

- Press **SEL** to use Index 2's pre-programmed patient types (normal, weak heart, obese, etc.).



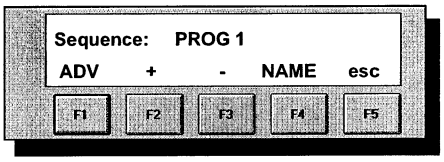
- When you are done (or to simply bypass this screen), press **ADV** to continue.



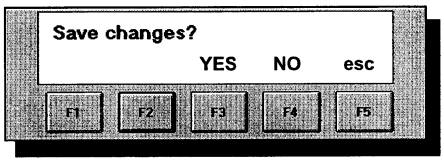
You'll be returned to the Sequence Menu.

Saving Your Program

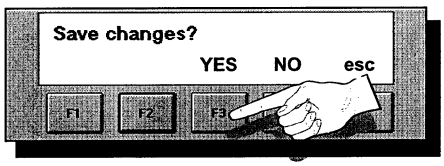
The final step in creating a custom Index 2 program is to save it. When you press **esc** at any time (press **esc** twice or **ADV** from the **Include Presets:** screen), you are returned to the Sequence Menu:



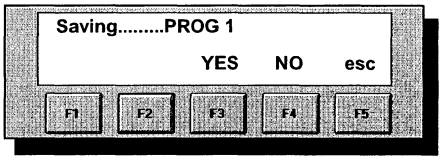
Pressing **esc** there will prompt you to save your program...



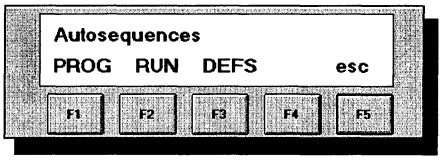
- Press **YES** to save your program, or **NO** to skip ...



- If you press **YES**, you'll see a message informing you that your program is being saved:



- 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):

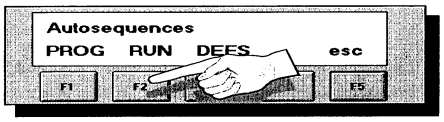


Running An Automatic Test Program

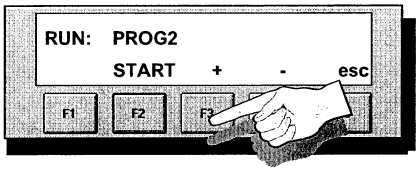
You can run a saved Index 2 program at anytime. Here's how.

1. From the Autosequences Menu....

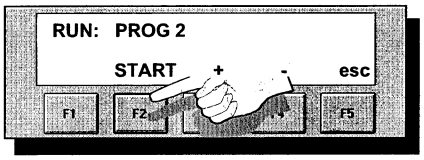
- ... press **RUN** to display the Run Screen...



- At the Run Screen, use **+** or **-** to find the program you want to run, if it isn't the first program automatically displayed...



2. To run the program, press **START** ...



3. The program will prompt you as needed to press **ADV**.

4. When finished, you will be given the option of printing the results (as well as the number of copies to print).

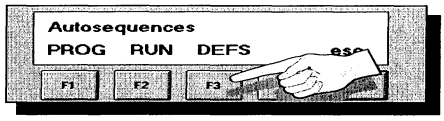
5. Press **esc** to return to the Run screen. Press **esc** again to return to the Autosequences Menu.

Returning An Automatic Test Program To Its Default State

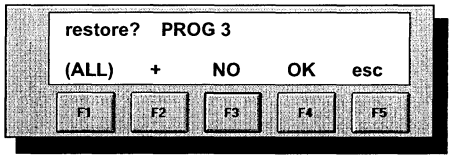
You can return a modified (and saved) Index 2 autosequence program to its default state (the way it was programmed at the factory) whenever necessary.

1. From the Autosequences Menu....

- ... press **DEFS** ...

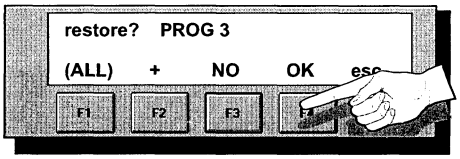


- You'll see a screen display, similar to the following:

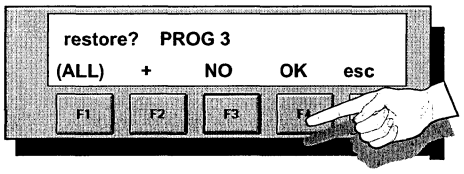


2. Use **+** to find the program you want to reset, if it isn't the first program automatically displayed.

- Or, use **ALL** to reset ***all*** Index 2 autosequence programs.



3. Press **OK** to reset the defaults.



You'll briefly see a message similar to **Loading defaults....**

Chapter 9:
Electrical Probe Test Description (Index 2E and FE Versions Only)

This chapter explains how to use Index 2E and FE Versions to verify the electrical continuity and integrity of most oximeter probes.

Electrical Probe Testing

Bio-Tek has validated that the following oximeter probes can be functionally tested using Index 2 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 2, but will require special care in preparation of an adapter cable and interpretation of the results. Damage could occur to Index 2 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.

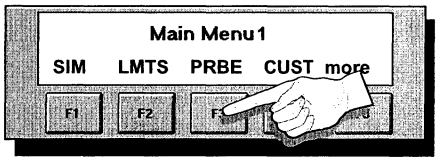
Index 2 allows you to verify the electrical continuity and integrity of most oximeter probes using the following steps:

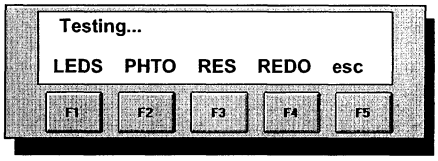
1. Connect the probe under test to the back of the Index 2 using the appropriate adapter cable.

Note: Index 2E and 2FE are shipped with Nellcor and Ohmeda probe and oximeter adapters. Please contact Bio-Tek regarding the availability of additional adapter cables.

Note: Attempting to create adapter cables without all details of the oximeter probe operating scheme could result in damage to the oximeter, Index 2, or both.

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





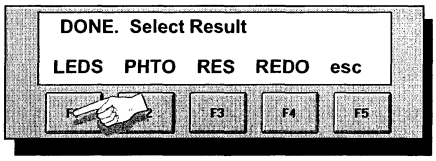
This key enters Probe Test menu and does three things:

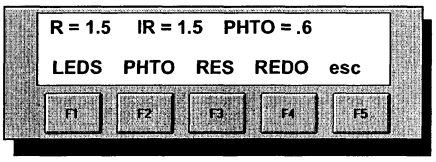
- Verifies that a Probe Test Board is installed in your Index 2
- Checks whether or not a probe adapter cable is connected to the probe port
- Performs all measurements for LED, photodetector, and resistance tests.

The user can then choose the specific probe test: result to be displayed.

- LED and photodiode electrical test (Step 3)
- Photodiode detector optical test (Step 4)
- Pin-to-pin resistances (Step 5)

3. Press **LEDS** key:





Index 2 applies 1.0 mA current AC signal source to the red and infrared LEDs. The test is performed on each diode separately (electrically) to see if 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 2.0 or greater will be displayed as "OPEN"

The photodiode is also tested and should read about 0.6 volts if electrically good.

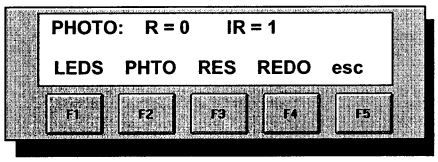
Users can use the resultant numbers as a baseline for similar probes. 1.6 for example may be a typical LED (red and infrared) result for Nellcor probes. It's safe to say that a 0 or 2 is considered bad.

Users can log voltage readings from operational probes to develop baseline values for comparison purposes when testing marginal, defective, or suspect probes.

These values are continually updated.

4. Press **PHTO** key

The red LED is illuminated and the resulting photodiode output measured. Then it is turned off and the output measured. The difference indicates the size of the response to a 1 mA LED illuminating current. The same is also done with the infra-red LED. The preceding is repeated multiple times to average out ambient light, and the result is displayed as a pair of numbers; one for red, and one for infrared, on a fixed scale that gives an indication of photodiode response to each color. The higher the number, the more response. Numbers can range from 0-2000 or more. It is a nominal value only. This test looks at the probe as a functioning entity. Numbers close to zero support a faulty probe diagnosis.

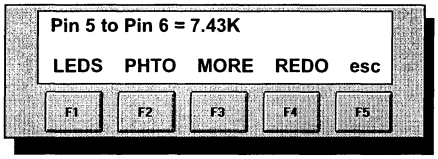


Note: Since these displayed numbers will vary due to both the general probe condition and as a function of the distance and angle between the two LEDs and the photodetector, care should be taken to maintain alignment when inspecting the SpO_2 sensor. Reusable SpO_2 sensors with built-in spring clips will typically maintain consistent alignment between the LEDs and the photodetector and therefore yield rather repeatable results. However, test results when inspecting a flexible disposable "tape style" probe will fluctuate unless the optimal mechanical position of the probe is maintained. 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 photodetector.

These values are continually updated.

5. Press **RES** key

Index 2 checks for resistances between all wires (every pin to every other pin excepting these wire pair combinations where a LED would draw normal current; these are tested separately). If any resistances under 150,000 Ohms exist, they will be displayed. By pressing the "more" key, all pin combinations that have resistances will be displayed. 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.



Note: These values are **NOT** continually updated. **REDO** must be used when checking for intermittent connections.

Chapter 10:
Adjusting The LCD Display

Index 2 users can adjust the LCD display to make it darker or lighter to improve legibility in different lighting conditions. This chapter discusses how to do that.

Adjusting Index 2's LCD Contrast

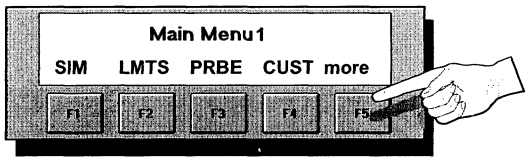
Index 2 lets you adjust the contrast of the LCD (liquid crystal display) screen to adjust for different ambient light.

This function is **not** the same as setting an ambient light artifact (sunlight/artificial light) for oximeter testing under the Simulations (**SIM**) Menu. This is only for adjusting the screen contrast on the Index 2 LCD itself.

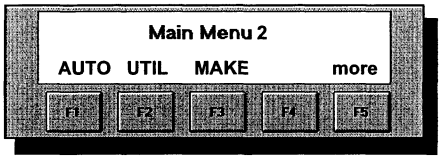
---

1. To adjust the LCD contrast, you need to access the Utilities menu, which is accessible from Main Menu 2. To access the Utilities Menu ...

- ... press **more** on the Index 2 Main Menu 1...

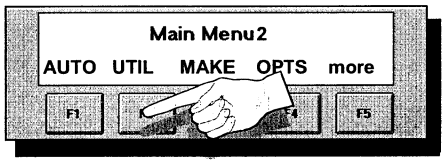


- ... and you'll see the following menu appear in Index 2's LCD display:

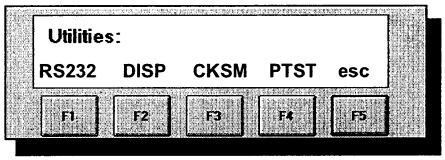


Pressing **esc** will return you to **Main Menu 1**.

- Press **UTIL** to access the Utilities Menus:

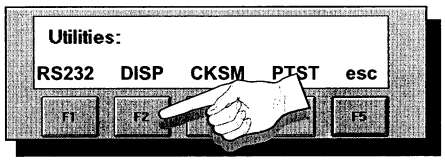


You'll see a screen similar to this appear:

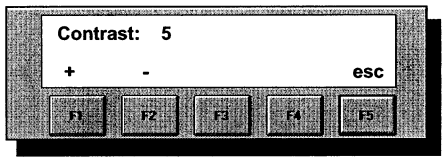


For information on **RS-232**, **CKSM** and **PTST** functions, refer to **Appendix A, Printing and Data Transfer**. Pressing **esc** will return you to **Main Menu 2**.

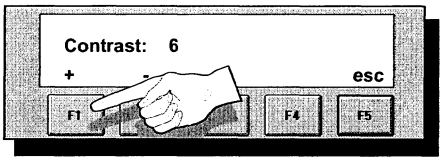
- Press **DISP** to access the LCD controls:



- You'll see a screen similar to this appear:



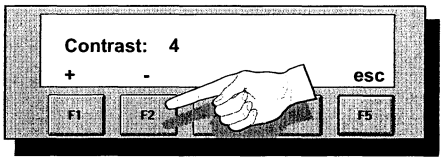
2. To adjust the contrast of the LCD ...



- ... press **+** to *increase* the contrast of the LCD. Continue to press **+** to change the contrast until it suits you and the lighting conditions.

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

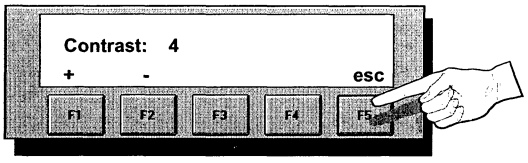
- ... or press **-** to decrease the LCD contrast...



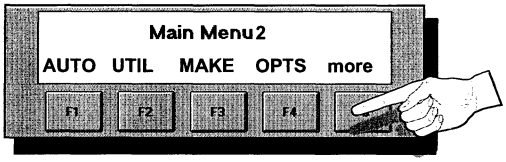
The third and fourth keys are not activated for LCD contrast adjustment.

3. When the LCD is to your liking...

- ... press **esc** to return to the Utilities Menu...



- ... and press **esc** again to return to Main Menu 2...



- From there, you can press **esc** yet again to return to Main Menu 1...

Chapter 11:
Manufacturers' Mode

Bio-Tek has included special features in Index 2 designed specifically to aid the manufacturers of pulse oximeters.

Index 2 has special features intended to facilitate the following functions:

- 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 2, manufacturers of pulse oximeters can test their products using a standard PC. All that is required is that the computer have a serial communications (COM) port and a communications program, such as the Microsoft Windows™ "**Terminal**" program.

To test a pulse oximeter using a PC, Index 2 is connected to the computer via one of the communications ports, while the unit being tested can be connected to the computer via the second port.

Using the computer, you send special commands to Index 2, which Index 2 then acts on to test the oximeter. Because the oximeter is also connected to the computer, you can then monitor the unit being tested for its responses. You can then 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 using a reference probe. Oximeters can then be tested against it. Alternatively, you can complete the procedures with a reference oximeter, and probes can be tested against it.

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 oximeter's design.

Bio-Tek has equipped Index 2 to allow you the greatest scope in simulation, with the capability for direct control of the following Index 2 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

See ***Appendix E: Computer Control*** for more information on the Index 2 computer control commands, and ***Appendix A: Printing & Data Transfer***, for information on Index 2's RS-232 port and how to set communications parameters (baud rate and so on).

Mathematical Background

Index 2 assumes that any oximeter being tested uses the "ratio of ratios" formula, where a quantity "R" is correlated with SpO_2, and where the dc terms are fixed attenuations and the ac terms are peak-to-peak measures of additional attenuation due to the pleth wave. The "ratio of ratios" formula is:

$$R = \frac{redac/reddc}{iredac/ireddc}$$

Oximeters perceive Index 2 to be using a variant of the above formula which causes the dc terms to "drop out." The Index 2 formula for the R value (as far as the oximeter is concerned) is shown below.

In the formula, "REDUUT" means **RED**-light, **U**nit **U**nder **T**est and "IREDUUT" is for **I**nfra**R**ed light, **U**nit **U**nder **T**est.

$$\frac{\frac{(0 <= ac <= 255)}{255} * \frac{(0 <= rdc <= 4095)\ REDUUT}{4095} * \frac{(0 <= rac <= 4095)}{4095}}{\frac{(0 <= rdc <= 4095)\ REDUUT}{4095}}$$

$$\frac{\frac{(0 <= ac <= 255)}{255} * \frac{(0 <= irdc <= 4095)\ IREDUUT}{4095} * \frac{(0 <= irac <= 4095)}{4095}}{\frac{(0 <= irdc <= 4095)\ IREDUUT}{4095}}$$

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. Also, REDUUT and IREDUUT are modulated by red-light dc (**rdc**) and infrared light dc (**irdc**), which are transmissivity numbers. Zero would mean that no UUT (Unit Under Test) pulse would be allowed to pass through Index 2. 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 2 maximum pleth amplitude. The default value for **irac** is 1,000. Values for **rac** range from 400 to 4,000, corresponding to R values of .400 to 4.000. This covers the required range.

By having the pleth attenuation operate on the **dc** attenuated UUT flash, Index 2 becomes immune to fluctuations in oximeter flash amplitude, which can vary considerably.

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 2 R Value Equation

By dropping out terms which equate to 1, and by accounting for the dc terms being transmissivities, we can reduce the above equation to this:

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

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

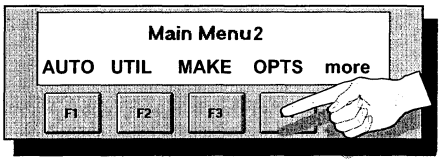
Although the equation eliminates the effect of changes in the UUT flash amplitude on the R value, bulk attenuation of the finger is an important characteristic. By varying **rdc** or **irdc** values and determining how large a range of variation is "not seen" by the oximeter being tested, you can get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

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.

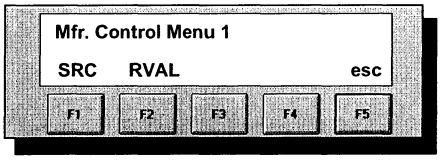
Accessing Manufacturers' Tests

You have access to manufacturers' settings through Index 2's LCD panel.

1. To access the manufacturers' tests of Index 2, press **OPTS** on Index 2's Main Menu 2...



- You'll see this menu appear in the LCD display:

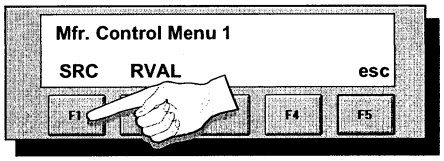


The following are the valid keys on the MFR (Manufacturers') Control Menu:

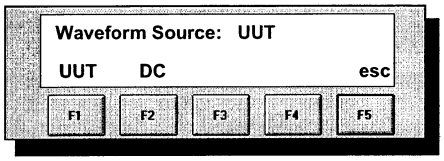
SRC	Sets the pulse signal source
RVAL	Sets the R Value
esc	Returns you to the Options Menu

Setting the Signal Source

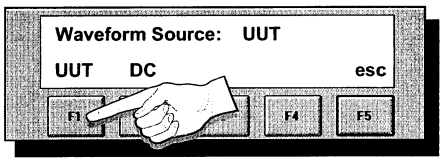
1. To set the signal source, press **SRC** on the Manufacturers' Control Menu:



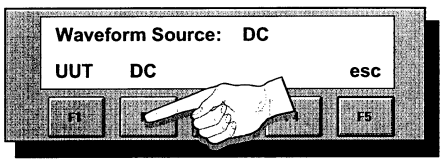
- You'll see a screen appear similar to the following:



2. Press **UUT** to select the oximeter (the Unit Under Test, or UUT) as the source for the pulse amplitude signal...



... or press **DC**. Index 2 will ignore the oximeter's pulse amplitude and will use instead a fixed DC level for infrared and red pulse simulations.



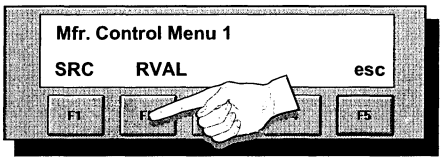
The signals will pass through Index 2 based on their original amplitude.

3. To return to the Manufacturers' Control Menu, press **esc**.

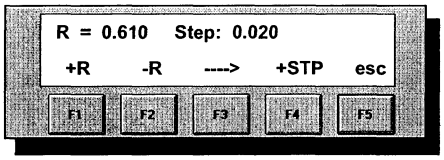
Setting The R Value

You can also enter a custom R value with Index 2. To do so, access the Manufacturers' Control Menu (if you haven't already done so) by pressing **OPTS** on Index 2's Main Menu 1. Then...

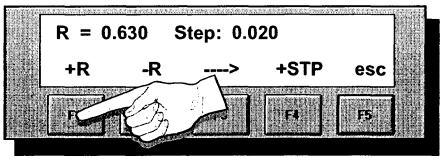
1. Press **RVAL** on the Manufacturers' Control Menu:



- You'll see a screen appear similar to the following:



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

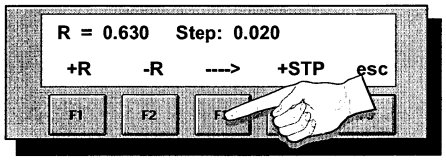


- Continue pressing **+R** or **-R** until the desired R Value is displayed.

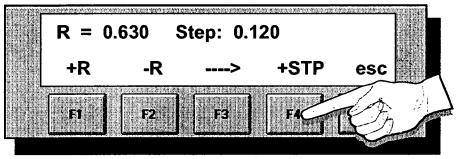
Adjusting The Step Amount

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

1. First, set the Index 2 cursor under the part of the step amount that you want to adjust. The cursor (though invisible) is now under the first "0" in the sample above of 0.020. To move it from that position, press **-->**.



2. Continue to press **-->** until the cursor is where you want it. Each time you press **-->**, the cursor moves one position.
3. When the cursor is where you want it, press **STP** to increase the numeric value at the cursor position. In the sample that follows, the step is increasing in the third position by one to 0.120:



4. You can now continue to use **+R** or **-R** to adjust the R value.
5. When you are done, press **esc** to return to the Manufacturers' Control Menu, and from there press **esc** again to return to the Options Menu. Finally, press **esc** a third time to return to Index 2's Main Menu 1.

Chapter 12:
Creating Your Own R-Curve

This chapter explains how to create an R-Curve and download it to one of Index 2's "download slots" for future use.

Index 2 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. 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 looking at the chart on page 22, by checking with the manufacturer, or by trial and error.

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 91 of this chapter).

To generate an R-Curve from a pulse oximeter:

1. Set up the Pulse Oximeter and attach it to Index 2

Note: This procedure can only be completed using the Manufacturer's "M" version of Index 2.

---

2. From the INDEX MAIN MENU 1 select SIM | MAN, set:

   SpO_2 = 100%

   BPM = 100

3. From the INDEX MAIN MENU 1 select OPTS | MFR | RVAL, set:

   Step = 0.010

Note: The R-Value displayed on Index 2 will automatically be set to a value that corresponds to the SpO_2 value displayed on the Pulse Oximeter.

---

4. Step the R-value up by 0.010 and record the SpO_2 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 SpO_2 percentage. For example:

SpO_2	R-Val	
99	.48	
99	.49	All three R-value readings have same SpO_2 value. (Avg. = .49)
99	.50	

5. Continue recording R-values until SpO_2 = 50%

How to download the R-Curve into Index 2:

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

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

   Where: [rcurve> sets Index 2 up to receive an R-Curve:

   - **2** places the curve in download slot 3 (0-6)
   - **N-10** is the name to appear (must be 9 characters)
   - **250** is the infrared DC Value
   - **245** is the Red DC Value
   - **151** is the start of the R-Value numbers

2. Use the LD.BAT file as described on page 110 to download a curve (Filename) to Index 2. Basically, at the DOS prompt, set the following:

   Mode COM1: 96, N, 8, 1

   Copy [Filename] COM1:

PN 5191001 Rev. A

INDEX R-CURVE DATA SHEET

Date: _____ Recorded by: _____

Pulse Oximeter Model: _____

Pulse Oximeter Serial Number: _____

Pulse Oximeter Verified On: _____

Probe Used: _____

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

Notes: _____

Avg. R-Value	SpO_2	Avg. R-Value	SpO_2	Avg. R-Value	SpO_2
	100		83		66
	99		82		65
	98		81		64
	97		80		63
	96		79		62
	95		78		61
	94		77		60
	93		76		59
	92		75		58
	91		74		57
	90		73		56
	89		72		55
	88		71		54
	87		70		53
	86		69		52
	85		68		51
	84		67		50

Appendix A:
Printing & Data Transfer

This Appendix provides information on the Index 2 RS-232 port and printer, including how it is configured and how the port on your printer or computer should be configured to communicate with Index 2.

Index 2 provides a male D (9 pin) bi-directional serial port located at the back end of the unit, for the transfer of data to a computer or printer, and for the computer-controlled functioning of Index 2. The Data Computer Equipment (DCE) wiring configuration is shown in the figure below.

Index 2 RS-232 Configuration

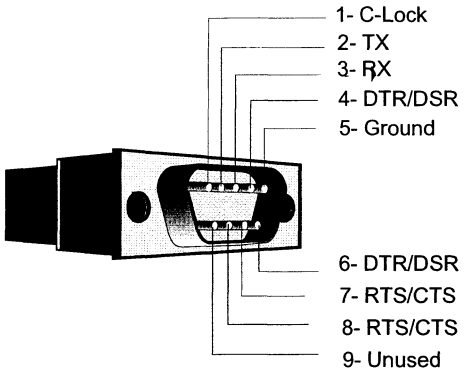


Figure A-1: *Male D Cable End*

In addition, a Bio-Tek bi-directional serial null modem cable is available for connecting Index 2 to your computer (IBM compatible) or printer. In order for Index 2 to communicate with your computer, a straight-through RS-232 cable, with pins 2 and 3 reversed, is required.

C-Lock

A synchronized pulse is available on pin 1 of the 9-pin serial connector. 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 0-63. The pulse is a negative going attenuated logic level. For more information, refer to **Appendix E: Computer Control.**

Printer Port

Index 2 also has a Centronics parallel printer port. Information that is available for printing is sent out both the serial and parallel ports. Index 2's parallel port is configured as follows:

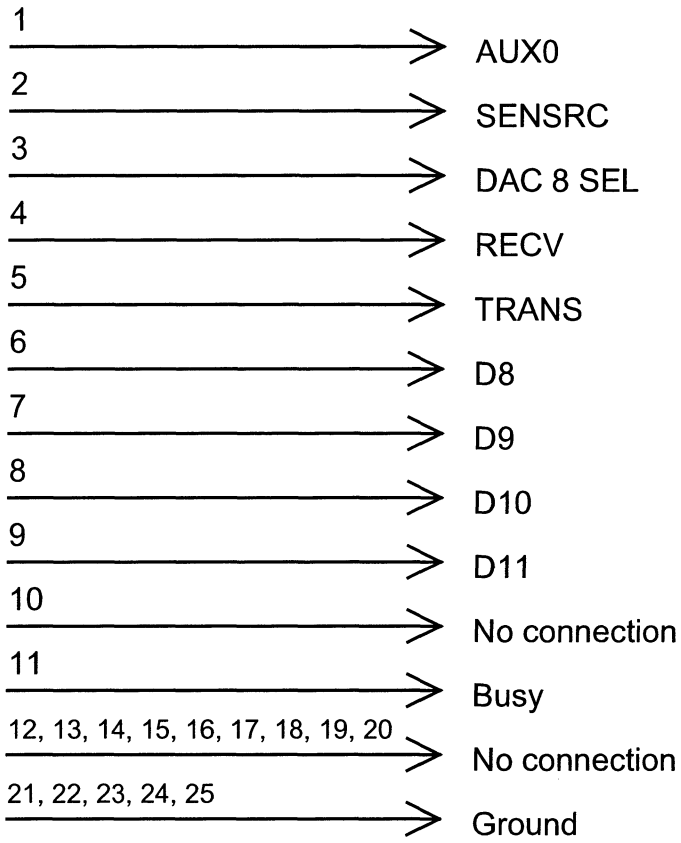


Figure A-2: *Index 2 Parallel Port D-25*

A Standard D-25 pin to Centronics printer cable will work with Index 2. The cable may be ordered from your Bio-Tek representative. Please specify Bio-Tek **Part Number 75035** when ordering.

Configuring The Serial (RS-232) Port

You can configure Index 2 to exactly match your printer's or computer's communications needs by setting baud rate, etc. Once configured, you can then print Index 2's test results directly from Index 2 to a printer through a serial connection.

You can also send data to your computer or control Index 2 through a computer, if you have installed communications software on your computer system, through Index 2's built-in RS-232 serial port.

To do so, you need a printer (or computer) with a serial port (or a cable with a serial-to-parallel converter) and a serial cable.

When communicating with Index 2 through a computer, you can set the baud rate to suit your system at the following bytes per second:

- 300 bps
- 600 bps
- 1200 bps
- 2400 bps
- 9600 bps

Parity can be set to:

- None
- Even
- or Odd

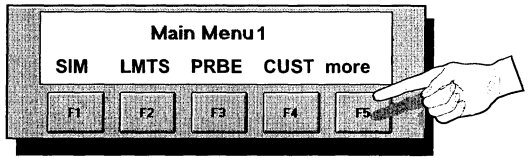
Bit sizes:

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

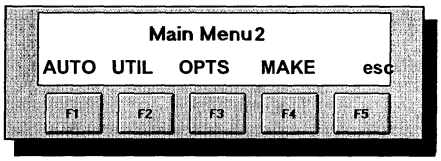
How To ...

1. To access the Utilities menu, first go to Main Menu 2...

- ... press **more** on the Index 2 Main Menu 1...

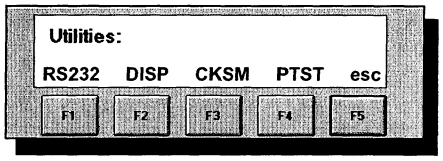


- ... and you'll see the following menu appear in Index 2's LCD display:

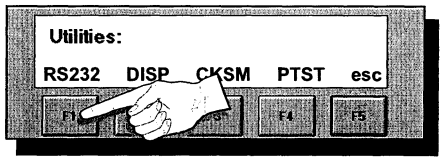


- Press **UTIL** to access the Utilities Menus.

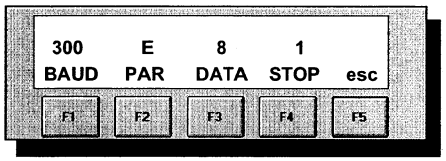
  You'll see a screen similar to this appear:



2. Press **RS-232** to set the RS-232 port parameters.



You'll see a screen similar to this appear:



3. Use the appropriate keys to set the baud rate, parity type, and data and stop bit sizes that you need to communicate with a printer or other device.

BAUD	Each press of the button increases the baud rate from **300** to **600**, **1200**, and **2400** bps. When **2400** is displayed, a button push then shows **300**.
PAR	Pressing this button toggles the parity from No parity (**N**) to Even parity (**E**) 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**.

4. When you are done:

- Press **esc** to return to the Utilities Menu.
- Press **esc** again to return to the Index 2 Main Menu 2.
- Press **esc** again to return to the Index 2 Main Menu 1.

Printing

Sample Index 2 Test Results Output

A sample Autosequence printout is shown below.

- The optional header is all information from the `Control#` field down to the `Tested by` 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`.

```
Bio-Tek Instruments, Inc.
SPO2 Simulator Ver: 2.00
-------------------------------------
Control#: _____________________________
Serial #: _____________________________
Model: ________________________________
Mfr: __________________________________
Location: _____________________________
Technician: ___________________________
Date: _________________________________

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

Appendix B:
Error Messages & Corrective Measures

This Appendix lists all of the error messages or beeps that may appear on Index 2's LCD screen during normal operation. Solutions are given for each message.

Messages

Warning! Low Battery The battery has given all that it can give. Although the battery included with Index 2 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 2 into the Index 2 charger jack and plug the instrument into a 120v wall socket (USA) or a 220V socket. Make sure your charger is rated for the proper line voltage.

Leave the battery charger charging for at least 12 hours to fully recharge. Disengaging and using the battery prior to the full 12 hour charge time will result in an incomplete charge. Index 2 may only work for a very short time under such circumstances.

Beeps

Three beeps	You've pressed a button that is not activated for the particular screen or function. Try again.
Continuous beeps	Warning! Low Battery

Other Error Indications

Pulse Oximeter Not Reading SpO2 or Heart Rate

The LEDs on the Pulse Oximeter must be positioned on the bottom of Index 2's finger probe attachment. Make sure the Pulse Oximeter's finger probe is centered and pushed as far foward as possible on Index 2's finger probe attachment.

Appendix C:
Accessories List

This Appendix provides a list of available accessories for use with Index 2.

The following is a list of accessories available for Index. The User's Guide and a battery charger (U.S. or European) are standard equipment.

Part Number	Description
51701000	Index User's Guide
3362013	Carrying Case
48274	Charger (U.S.A.)
48776	Charger (Europe)
75029	RS-232 Cable
71072	Printer Cable
5173002	Nellcor Optical Probe Adapter
5173001	Ohmeda Optical Probe Adapter
See price list	Electrical Probe Adapters
See price list	Electrical Oximeter Adapters

Appendix D:
Index 2 Specifications

This Appendix provides specifications for Index 2.

Specifications

$\%O_2$	Range:	35%-100%
	Resolution:	1%
	Accuracy:	100-75%: ± 1% ± accuracy of the pulse oximeter under test. 74-50%: ± 3% ± the accuracy of the pulse oximeter under test. <50% unspecified
	Repeatability:	± 1 standard deviation
Rate	Range:	30 - 250 BPM
	Resolution:	1 BPM
	Accuracy:	1% ± 1 BPM
Pulse Amplitude	Range:	0 - 100% Nominal
	Resolution:	1%
		Pulse amplitude is 20% of maximum pass-through brightness.
Battery	Life:	At least 4 hours of continuous use.
Specifications-Probe Test		Index 2E and FE versions only
Continuity/ Resistance	Test Matrix:	Measures all combinations of possible interconnections in an XX point matrix.
	Range:	250 Ω to 150 kΩ
	Accuracy:	± 5% of reading
LED/Detector Voltage Test	Test Format:	Measures the voltage drop across Red LED, infrared LED, and the photodetector when the internally generated test signal is applied.
	Test Signal:	Constant current source @ 1.0 mA

LED/Detector Voltage Test (Cont.)	Open Circuit:	2.5 V max
	Measurement/ Display Range:	0.0 V to 4 V
	Accuracy:	± 5% of reading, 0.4 to 4 V
Dynamic Test	Test Format:	Photodetector/diode response to both the red and infrared light generated by the probe when pulsed by an internal test signal.
	Test Signal:	Pulsed between the two LEDs Constant current level @ 1.0 mA
	Test Results:	Nominal range of 0 to 2000
Checksum		The sum of all locations in the program chip. For service use only.

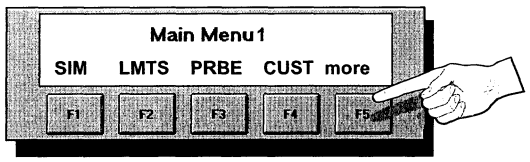
The above specifications are for preprogrammed makes only, 100% pulse amplitude SpO_2. Results for Presets, custom makes, and various pulse amplitudes are unspecified and depend on the algorithm of the specific pulse oximeter being tested.

Appendix E:
Computer Control

This Appendix explains how to use a computer to control Index 2 for the automatic testing of pulse oximeters.

You can set up a program to control Index 2 through communications via its RS-232 port. To control Index 2 by computer....

1. Switch Index 2 on. The Main Menu 1 will display following the startup screens:



2. Connect Index 2 to the computer by connecting the two RS-232 ports (the computer's and Index 2's) by means of a serial or null-modem cable. Index 2's RS-232 port is a male D 9-pin port.

See ***Appendix A: Printing & Data Transfer*** for information on how to configure Index 2's RS-232 port to match the speed, bit settings, and parity of your computer system's serial port.

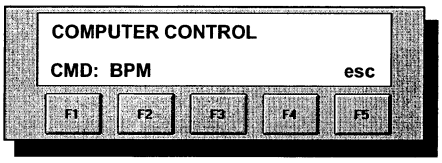
---

3. To initiate computer control, send a control character from your computer to Index 2.

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

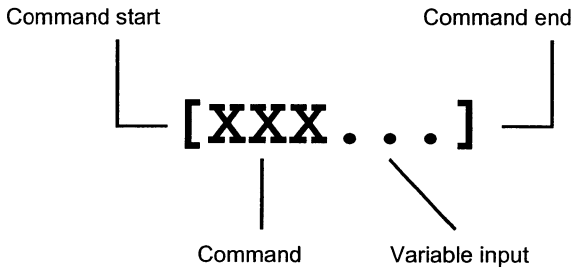
While in computer control, the first four keys are disabled. The **esc** key remains available and can be used to terminate computer control and return control back to the Index 2 system.

Each command that the computer sends to Index 2 will be displayed in Index 2's LCD window:



Command Syntax

Commands sent to Index 2 are required to be in a standard format:



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 2 will properly interpret all numbers that follow a command. In the cases where a string of numbers is the input value, use spaces or commas to separate the numbers (such as 1.232, 1.3449, 3.0, and so on). For example, all of the following commands and values are valid as shown, and would be interpreted by Index 2 as the same value:

[IRdc33]

[IRdc,33]

[IRDC 33]

[IRDC, 33]

Computer Control Commands

The following are the valid commands for controlling Index 2 by computer.

Command	Description	Values	Example
AC	Sets the AC amplitude.	0 to 255	[AC100]
AMB	Sets the ambient light artifact simulation.	0 to 30	[AMB15]
BPM	Sets the pulse rate (beats per minute).	25 to 250	[BPM180]
CPHASE	C-lock phase control. Allows for the synchronization of the pleth waveform with an ECG monitor. The signal is 0-5 volts (limited by 4.7k) and can be synchronized to any part of the pleth waveform. Available at Pin 1 of the RS-232 port.	0 to 65	[CPHASE45]
IPLETH	Uses Index 2's *pleth* waveform.	- -	[IPLETH]
IRAC	Sets the infrared light AC amplitude peak to peak attenuation for the pulse oximeter under testing.	0 to 4095	[IRAC1000]
IRDC	Sets the infrared transmissivity.	0 to 4095	[IRDC1000]
MAKE	Selects the desired make 0-15. Returns the name via RS-232. MAKE: Name		[MAKE0]
OXY	Sets the SpO_2 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 2 to Index 2 control.	- -	[Q]
RAC	Sets the red light AC amplitude peak to peak attenuation for the pulse oximeter under testing.	0 to 4095	[RAC4000]
RCURVE	Sends a new R-curve to Index 2.	various	[RCURVE, 0, NELLCOR, 2.00, 1.999, 1.899, 1.799, 1.699.....]
RDC	Red transmissivity.	0 to 4095	[RDC1000]

Command	Description	Values	Example
SETTINGS	Retrieves the current Index 2 settings in this format: Index 2 Settings: ---------- oxy displayed after set by [oxy NN] command BPM=75 Note: Modifying the following 4 variables inhibit oxy display until the next [oxy NN] command RAC = 610 IRAC = 1000 RDC = 1024 IRAC = 1024 Light Flash: Unit Under Test AC = 100 % AMB = 0 % Make = Nellcor.	- -	[SETTINGS]
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 2 version number	- -	[VER]

RCURVE

A sample of the format is below:

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

Description is:

[RCURVE> identifies this to computer control as an r curve data stream

3: the curve number. Range is 0 to 5. There are 6 total downloadable R curves. The colon is a field separator.

Pulse oximters use different intensities of light. RCurves 0-3 are reserved for oximters that use normal intensities of light. RCurve #4 is reserved for pulse oximeters that use higher intensities of light, RCurve #5 is for pulse oximeters that use lower light intensities.

123456789 this field can be any combination of 9 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, if 972 is wanted, use 097. 1000 becomes 100. 17 becomes 020. Leading zeros are required!

YYY rdc value for this oximeter. Same format as irdc.

: field separator.

zzz R values inthe range 0 to 250. These will be multiplied by .01 inside Index 2 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. A total of 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 begining to the end of the oximeter name. Use the MAKE selection screen and [settings] to verify download.

SHAPE

The structure of the command is:

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

The above computer control command is used as follows. The format must be followed precisely or it will not work. All the command must be on one line.

[SHAPE>	Start of the command.
N	Wave identifier. range 0-3. 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 using the LD.BAT program created below. This program requires that MODE.COM be in the same directory or on 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*

Where *FILENAME* is the name of the file with one SHAPE command. Each of the 4 shape commands must be in its own file.

Downloaded shapes are volatile. They are lost when Index 2 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 2 will switch to your downloaded wave upon receipt of a [UPLETH] command. It will switch back to the stored internal pleth wave on receipt of an [IPLETH] command.

The Baud Rate in Index 2 must be set to match the LD.BAT Baud Rate setting. For example:

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

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:
Interpreting Index 2 Results (O2 Simulations)

This Appendix defines a Transfer Standard.

Index 2 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).

Bio-Tek has measured the operational characteristics of different makes of oximeters, all believed to be properly calibrated and operating correctly. These measurements are accessed by the user when you select a MAKE for testing.

For a Transfer Standard such as Index 2, simulating devices which have readout resolutions of 1% (oximeters) or repeatability of simulations better than 1% is mandatory. Index 2 repeatability is conservatively specified at better than $\pm$ 1 standard deviation.

Bio-Tek's experience with oximeters characterized by MAKE is that the oximeters track the SpO_2 simulations typically, within 1% to 2% from 100% - 60%. Below 60% many of pulse oximeters have unspecified accuracies and 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%, $\pm$ 1%.

Appendix G:

Typical Questions and Answers

This Appendix provides answers to some typical questions about Index 2's operation and functionality.

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

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 2 finger probe attachment.

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

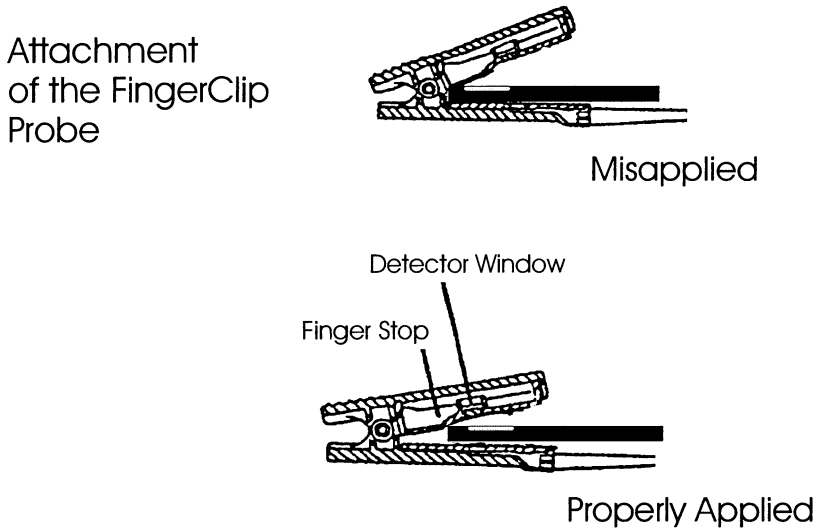
Index 2 is designed for an adult size finger. Adult size permanent probes and disposable probes can be tested. Other styles of probes (ear probes) can also be used as long as the physical size is such that their LED's can be positioned on the bottom of the Index 2 finger probe attachment and their photo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

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

Most common probes need to be centered and as far on the Index 2 finger probe as possible. The exception to this is the Ohmeda permanent finger probe. The Index 2 finger probe attachment should only be positioned within the contour of the Ohmeda permanent finger probe. (See the illustration that follows for positioning). These

instructions are only for the Ohmeda Finger Clip probe. (Ohmeda has two styles of permanent finger probes.)

Attaching the Probe to INDEX (Ohmeda Finger Clip Probe)



4. **I have connected the probe to Index 2 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%.**

   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 2 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 photodetector. This could also be a problem when using a disposable probe on a patient.

5. **I can't find the make of the pulse oximeter I am testing within Index 2. What do I do?**

Index 2 currently has curves for many oximeters.

If the pulse oximeter under test is one of the following, use the "Nellcor" make selection:

Airshields, Inc.
Atom Medical Corp.
Baxter Healthcare Corp.
Century Medical Inc.
Colin Medical Instruments Corp.
Corometrics Medical Systems
Critikon, Inc.
Datascope Corp.
Drager (Europe)
Edentec
Fukuda Denshi
Synectics
Witt Biomedical
Ivy Biomedical
Marquette (Eagle)
MDE(Medical Data Electronics)
Mennen Medical
North American Drager
Pace-Tech. Inc.
Protocol Systems, Inc.
Pryon Corp
Siemens
Sleeptrace/Areca Science
SpaceLabs

If you still don't get good results or have a make of oximeter not listed, see Chapter 5 to create a "custom make" for your brand of oximeter.

Use the "Ohmeda" make for the following brands of pulse oximeters:

Marquette (other than Eagle monitor)

Hellige

S&W

Radiometer

Corometics

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

Elmed

Bruker

Use custommakes for names not listed.(Refer to Chapter 5.) You can also use W-Index Software to add R-Curves and pleth waves to Index 2 with a computer.

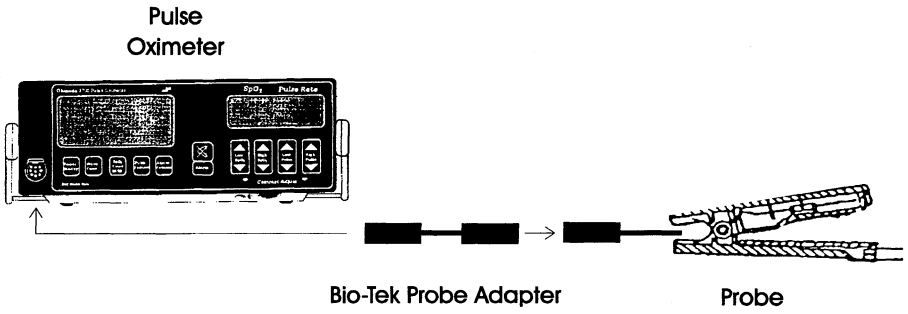
6. **I have selected the Nellcor make and am testing disposable probes. The results on the monitor are OK at high saturation levels (90-100%), but as I go lower the readings on the pulse oximeter vary from the setting.**

This is because each Nellcor disposable probe is calibrated differently and it is necessary to use the Bio-Tek adapter that forces the pulse oximeter to use the calibration curve that matches that of Index 2 . The same is true for Ohmeda probes - an in-line adapter forces the monitor to the calibration curve that matches that of Index 2.

8. Does the user have to use the Nellcor and Ohmeda Probe Adapters?

It is necessary, when using Index 2 with Ohmeda (all probes) and Nellcor (disposable probes) Pulse Oximeters, to use an in-line adapter to insure the most accurate results. Index 2 will work without these adapters on these pulse oximeters, but there will be a noticeable difference between Index 2 setting and the pulse oximeter reading as you go lower in saturation. The manual stated accuracy is true with or without this adapter installed.

The Nellcor and Ohmeda probe adapter are both used in the same manner. The adapters go in line with the probe under test and the pulse oximeter. See diagram below.



Nellcor Adapter BTI #5170502 or

Ohmeda Adapter BTI #5172009

***Note**: Bio-Tek provides you with both probes at no cost.*

9. **How did Bio-Tek 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 2 as needed for pulse oximeters that are not preprogrammed into Index 2. The operators manual describes how to download R-curves. All that is needed is a computer and the pulse oximeter.

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

The definition for SaO2 read from a pulse oximeter is Sp02. This has become a standard in recent years.

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

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

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

Appendix H:

Building and Wiring Probe Adapters and Electrical Oximeter Adapters with Index 2 E and EF

This Appendix explains how to test probes, make custom probe adapter cables, and electrically simulate probes on patient-connected oximeters.

Making Probe Test Adapters

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

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

Typical probe failure modes are:

1. Wires open or shorted to other wires
2. Diodes open or shorted
3. Resistors, if present, open or shorted to other leads
4. Leads shorted to shields and/or other leads.

Index 2 is designed to find all these failure modes. Note that the LEDs may be connected in one of four ways (see ***Figure A-2***):

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

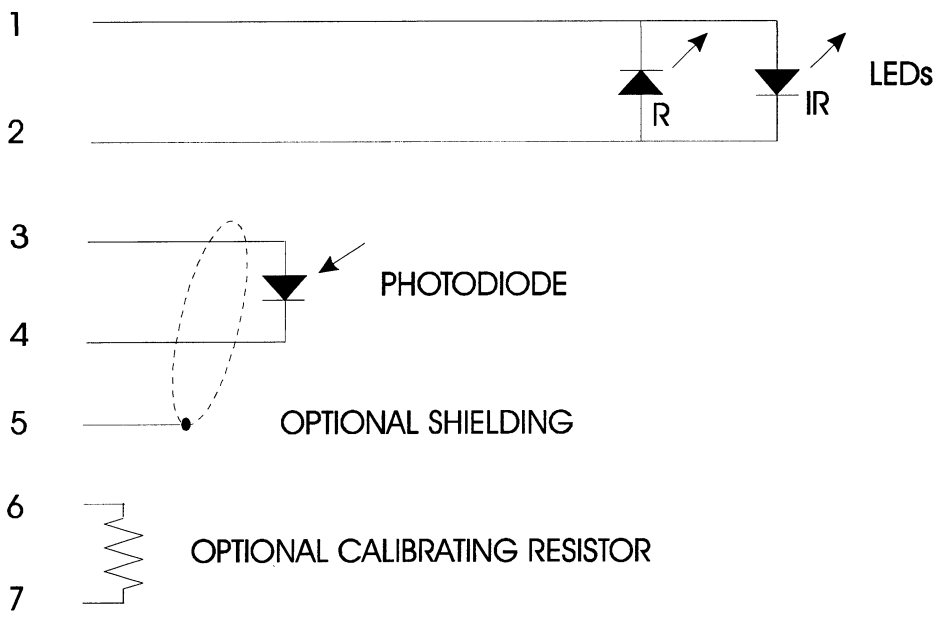
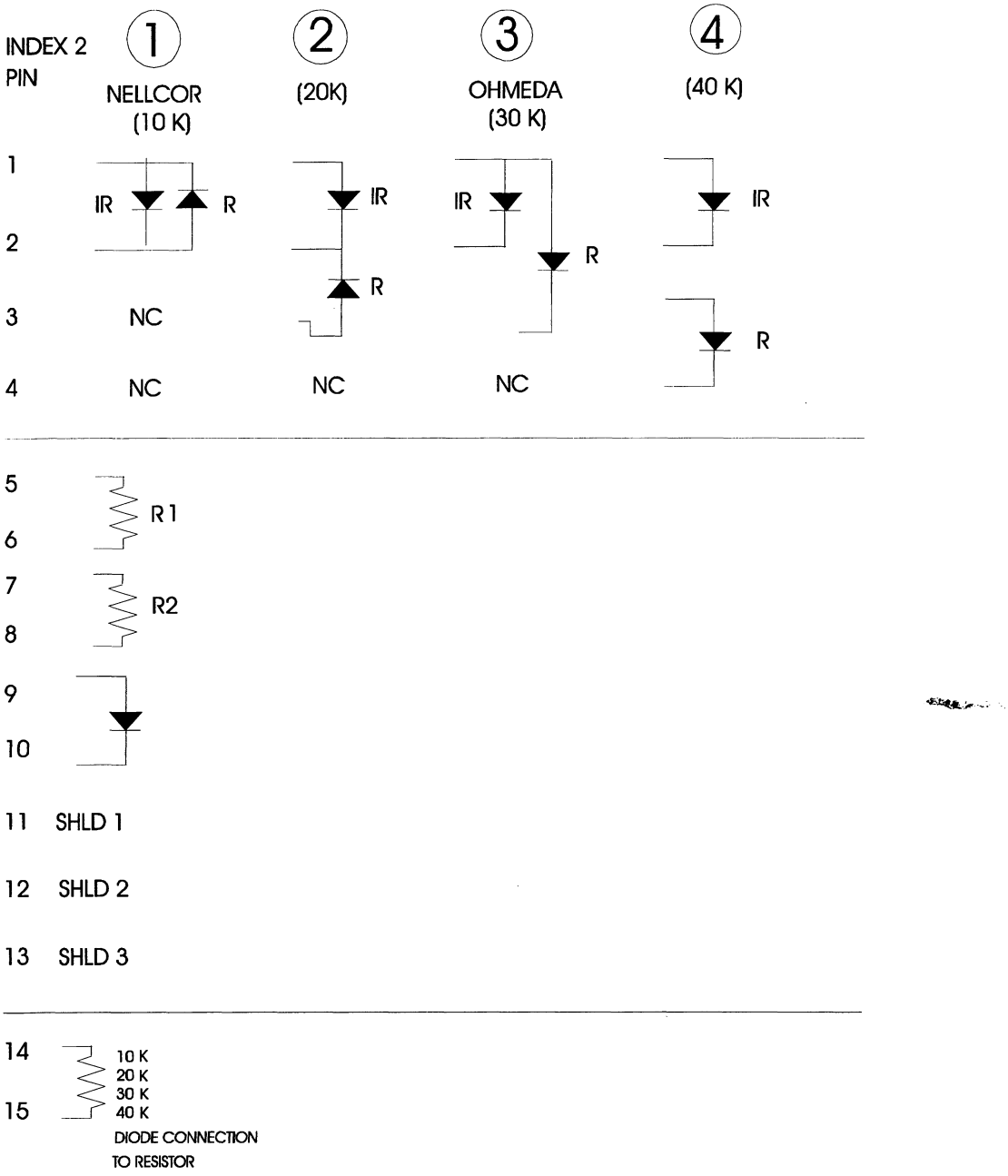


Figure A-1. Typical Oximeter Probe



PINS 1 - 4 CAN BE CONNECTED 4 WAYS, IDENTIFIED BY THE VALUE OF THE RESISTOR ACROSS PINS 14 AND 15.

Figure A-2. Generic Probe Test Connections

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

If you need to test a probe which is not supported by Bio-Tek 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. The figure 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 2 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 the following table:

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 2 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 2. Connect them as R1 and R2 in ***Figure A-2***.
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 A-3*, an example of the Ohmeda probe test connections.

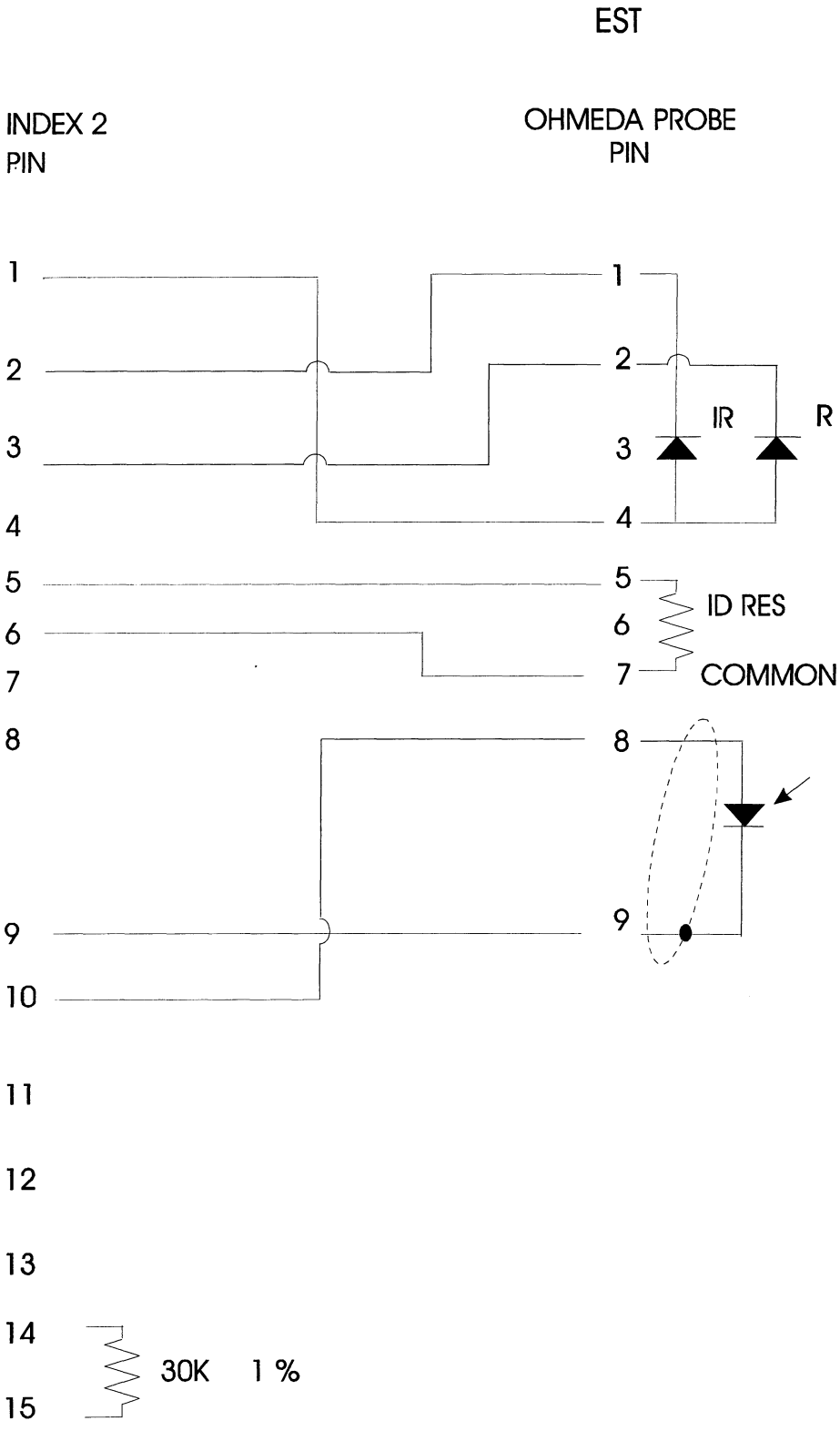


Figure A-3. Example: Ohmeda Probe Test

Making Oximeter Adapter Cables

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

Because of the great variety of probe LED drive schemes and photodiode sensing circuits, **extreme caution** should be used by anyone attempting to create their own interface cable.

At a minimum, you should be familiar with all the electronic details of:

1. The oximeter LED drive circuit
2. How the oximeter decides if a probe is present
3. Whether the photodiode input amplifier circuit is:
    - Single-ended, or
    - Differential, or
    - A current-to-voltage converter, or
    - Grounded photodiode, or
    - DC biased photodiode
    - Photodiode floated separately from the LEDs?
    - Polarity of the photodiode connections?

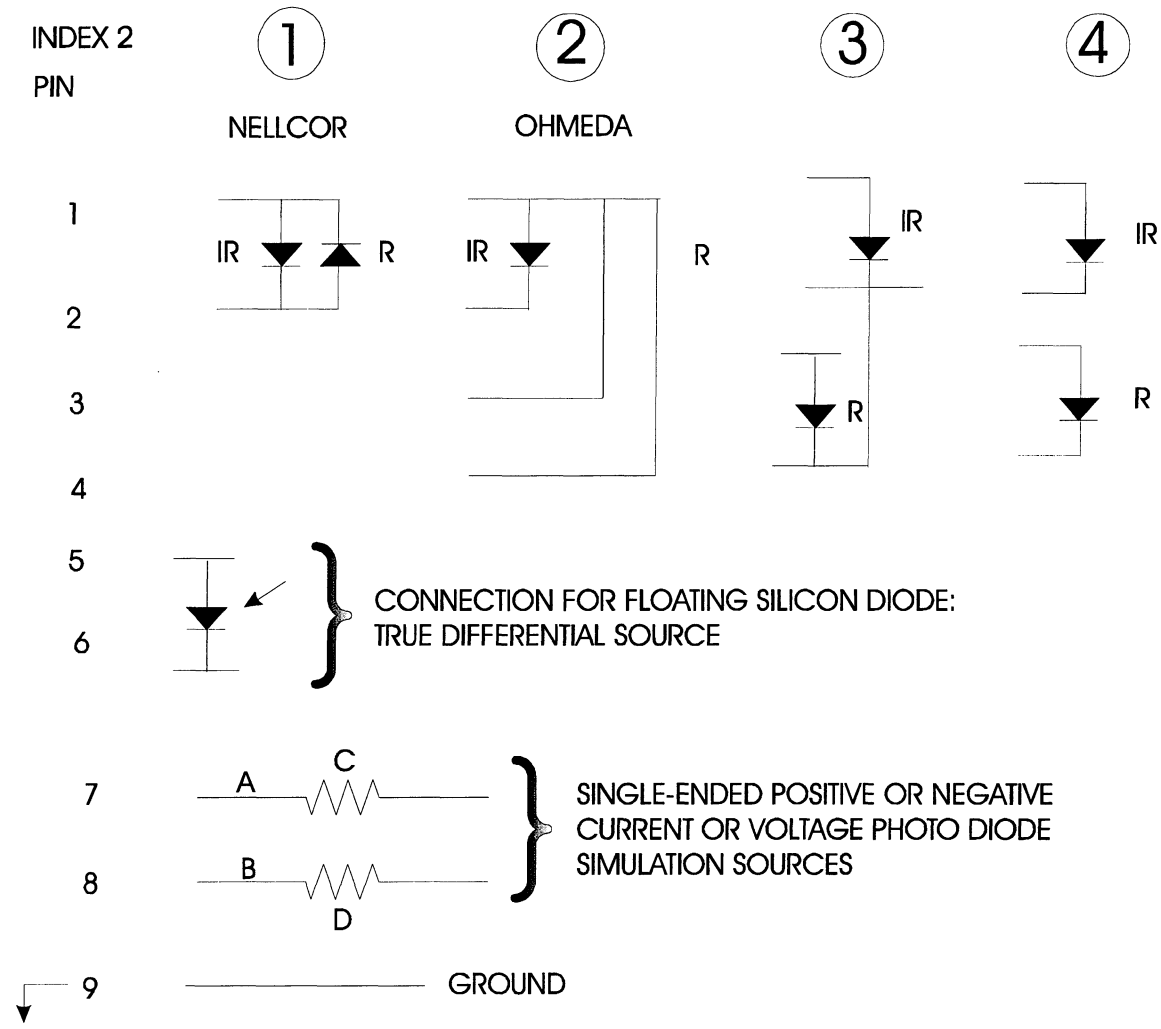
Warning! The above is by no means an exhaustive list of features requiring consideration in the design of an interface cable from Index 2 to an oximeter.

Failure to take into account all the relevant details of the oximeter's probe operating scheme could result in damage to the oximeter, the Index 2, or both.

UNDER NO CIRCUMSTANCE SHALL BIO-TEK BE RESPONSIBLE FOR ANY SUCH DAMAGE.

Use of the information presented here constitutes acknowledgment and assumption of the risks involved in any "do it yourself" oximeter test interface from Index 2 to any oximeter.

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



A: POSITIVE VOLTAGE PULSES
B: NEGATIVE VOLTAGE PULSES
C, D: VOLTAGE TO CURRENT SOURCE CONVERSION RESISTORS. PUT IN CABLE FOR SPECIFIC OXIMETERS A/R.

OXIMETER SHIELD PINS TO BE USED AS NORMAL, BUT NOT TIED TO ANYTHING AT INDEX..

Figure A-4. Generic Pins by Usage

Pins 1 through 4 show the different ways oximeter probes can have their LEDs connected. For example, if Index 2 is used to simulate an Ohmeda probe, the Ohmeda drive pins would be connected to the Index 2 connector on pins 1 through 4 as shown. Current scaling resistors may be required (see ***Figure A-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 2 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 A-2***, the actual Ohmeda interface cable).

In some cases, it may be advantageous to **not** use the floating diode source. In these cases, Index 2 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 on the figure.

Normally, oximeter shield pins should not be tied to Index 2 ground, but there may be exceptions. Again, only a thorough study and understanding of the oximeter interface circuits can answer these questions.

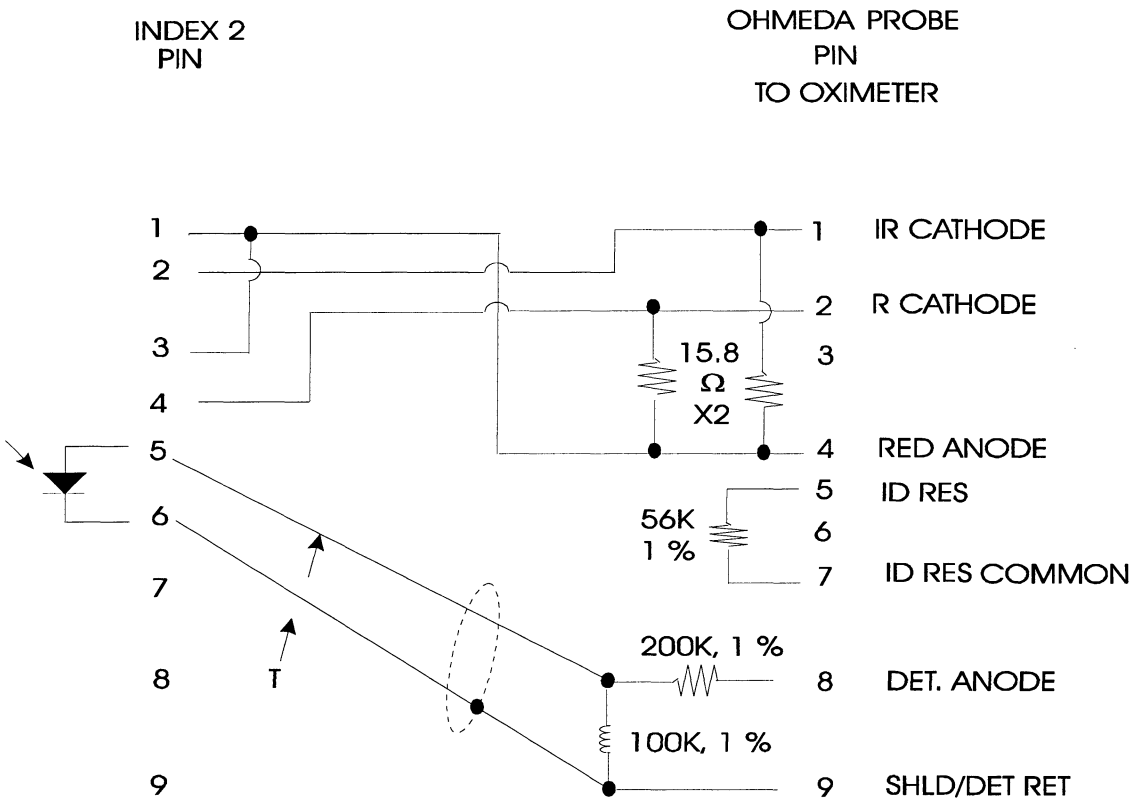


Figure A-5. Example: Ohmeda Hardware Cable

Glossary

This glossary presents certain medical, electronic and Index-specific terms, the understanding of which may aid in the understanding of the operation of Index. A number of the definitions that appear in this glossary are from ***The American Heritage Dictionary*** *(Houghton Mifflin, 1987, Microsoft Bookshelf 1992). 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 of a 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 unit of measurement that denotes the number of discrete signal elements, such as bits, that can be transmitted per second. Bits per second (bps) means the number of binary digits transmitted in one second. [After J.M.E. Baudot (1845-1903).]

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 minute blood vessels that connect the arteries and veins.

centimeter-gram-second system — A coherent system of units for mechanics, electricity, and 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 nonprotein, 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. It was defined in 1790 as one ten-millionth (10^7) of the earth's quadrant passing through Paris but 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-second system — A coherent system of units for mechanics in which the basic units of length, mass, and time are the meter, kilogram, and second.

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

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

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

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

non-invasive 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 Georg S. Ohm (1787-1854).]

pulse The rhythmical throbbing of **arteries** produced by the regular contractions of the heart.

pulse oximeter A **non-invasive**, arterial, oxygen-saturation monitors which measure 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.

RS-232 The RS-232 interface provides an electrical description for connecting peripheral devices to computers using either a 25-pin connector or a 9-pin connector. There are actually two types of RS-232 interfaces: the data terminal equipment interface (DTE) and the data communication equipment interface (DCE). Generally speaking, personal computers are DTE devices and peripherals (printers, mice, modems, Index, etc.) are 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.*

SaO_2 Saturated oxygen. The ratio of the concentration of oxyhemoglobin ($cHbO_2$) to the concentration of the two principle types of blood **hemoglobin**: saturated hemoglobin (HbO_2) plus reduced hemoglobin (Hb).

serial port An **asynchronous** COMmunication port/address to which a peripheral—such as a printer, a mouse or Index—is connected to a computer or other device. Serial (COM) ports send and receive bits of

	data one at a time over a single line, as opposed to parallel communications where multiple wires in the cable allow data to be sent in multiple bits. *SEE ALSO* RS-232.
SpO_2	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, as of the brain or heart, especially *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. *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 t he 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	In a periodic wave, the distance between two points of corresponding phase in consecutive cycles.

Index

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Index 2