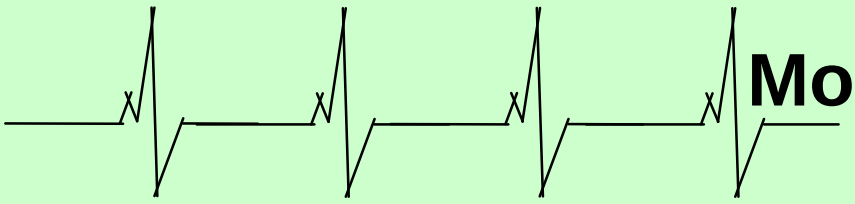
DIGIOXI



Model PO-930

PULSE OXIMETER MONITOR

Operator's Manual

DIGICARE
BIOMEDICAL TECHNOLOGY

Quality and Technology... To Touch Life

Table of Contents

SECTION 1 - Introduction

A. About This Manual

This operator's manual has been prepared to provide information on the correct use of the DIGICARE BIOMEDICAL TECHNOLOGY INC. **DIGIOXI PO-930** Pulse Oximeter patient monitor. It contains performance specifications and installation, operation and maintenance information. It is intended for trained health-care professionals.
Follow each chapter in the manual sequentially, (specially) if the monitor is being used for the first time.

B. Manufacturer's Responsibility

The manufacturer of this equipment is responsible for the effects on safety, reliability, and performance of the equipment only if:
-The equipment is used in accordance with the instructions in this manual.
-The electrical installation complies with all applicable regulations.
-Assembly operations, extensions, re-adjustments, or repairs are carried out by persons authorized by the manufacturer.
It is up to the user to ensure that any applicable regulations respecting the installation and operation of the monitor be observed. The operator should read this manual carefully and thoroughly before attempting to use the monitor.

Incorrect operation or failure of the user to maintain the monitor in accordance with proper maintenance procedures relieves the manufacturer or his agent from all consequent non-compliance, damage or injury.

C. Warranty

All products manufactured by Digicare Biomedical Technology Inc. are warranted to be free from defects in material and workmanship and to operate within published specifications, under normal use, for a period of two years from date of original shipment. The warranty on accessories is ninety (90) days.
If an examination by Digicare, discloses such products or component parts be been defective, then our obligation is limited to repair or replacement (at our option).
During the first year of service, there is no charge for parts or labor. In the second year of service, the customer is charged for labor only.

D. Unpacking and Accessories

Carefully remove the monitor and its accessories from the shipping carton. Save the packing materials in case the monitor must be shipped or stored. Ensure your **DIGIOXI PO-930** has the items listed in the SHIPPING LIST inside the carton.

E. General Safety

1 - INDICATIONS

The **DIGIOXI PO-930** is intended for use in the hospital/clinic environment to measure and monitor these parameters:

-Blood oxygen saturation (SpO_2 or pulse Oximeter);
-Pulse Rate;
- PLETHYSMOGRAM Waveform

The **DIGIOXI PO-930** is intended for use by persons trained in professional health care. The operator must be thoroughly familiar with the instructions in this manual before using the instrument.

2 - CONTRAINDICATIONS

Situations where risks associated with the use of the monitor are greater than the benefits.
The **DIGIOXI PO-930 IS NOT** intended to be used as an apnea monitor.
The **DIGIOXI PO-930 IS NOT** intended to be used during MRI (magnetic resonance imaging).

3 - WARNINGS

+ Indicate the possibility of injury due to patient or operator associated with the use or the misuse of the monitor.

4 - CAUTIONS

Indicates a condition that may lead to equipment damage or malfunction.

SECTION 2 - Technical specification

A. Mechanical Description

Size : 94x254x254mm
Weight : 3,5 Kg
Color : White and Black

B. Power Requirements

AC voltage Input : 120VAC; 60Hz (220VAC and/or 50Hz Optional)
Internal Battery : 12 VDC/2,9Ah Sealed
Battery Duration : 7 Hours.
Recharge Time : 18 Hours in use on AC line.

C. SpO_2 - Pulse Oximeter

SpO_2 Range : 0% to 100% adult/pediatric/neonate
SpO_2 Accuracy : ± 2% (70 - 100%), ± 3% (50 - 69%) unspecified (0 - 49%)
Pulse Rate Range : 30 to 250 BPM
Pulse Rate Accuracy : ± 2%
Pulse Tone : Pitch adjusted by SpO_2
Sensor Types : Finger, Universal, Wrap, Disposable.

D. Heart Rate

Heart Rate Range : 30 to 255 BPM
Heart Rate Accuracy : 2%

E. Display

Type : High Intensity CFL-LCD
Dot Matrix : 240x64 Dots
Effective Display Area : 178 mm x 69 mm x 25mm
Viewing Angle : 150°

F. Trends

15min, 1, 4, 12 and 14 hours

G. Environment Specifications

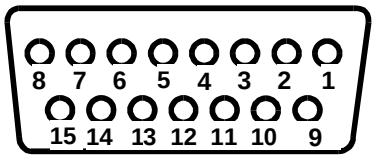
Temperature	: Operating 19°c to 35°c
	: Storage 4.5°c to 43.5°c
Relative Humidity	: Operating 20 - 80% (Non-Condensing)
	: Storage 10 - 90% (Non-Condensing)

H. RS232 OUTPUT (Optional)

Serial Output to connect the Monitor to one microcomputer.
Supply SpO2, Pulse and PLETHYSMOGRAM data.

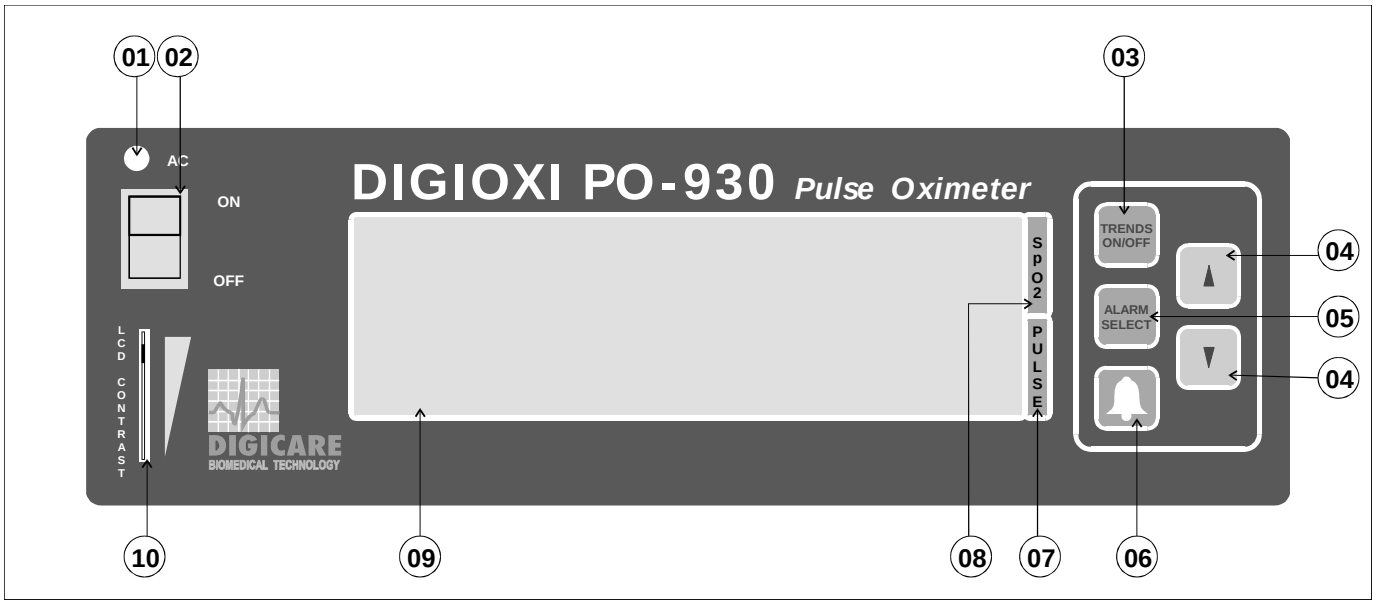
DB15

3 - GND
7 - RXD
6- TXD



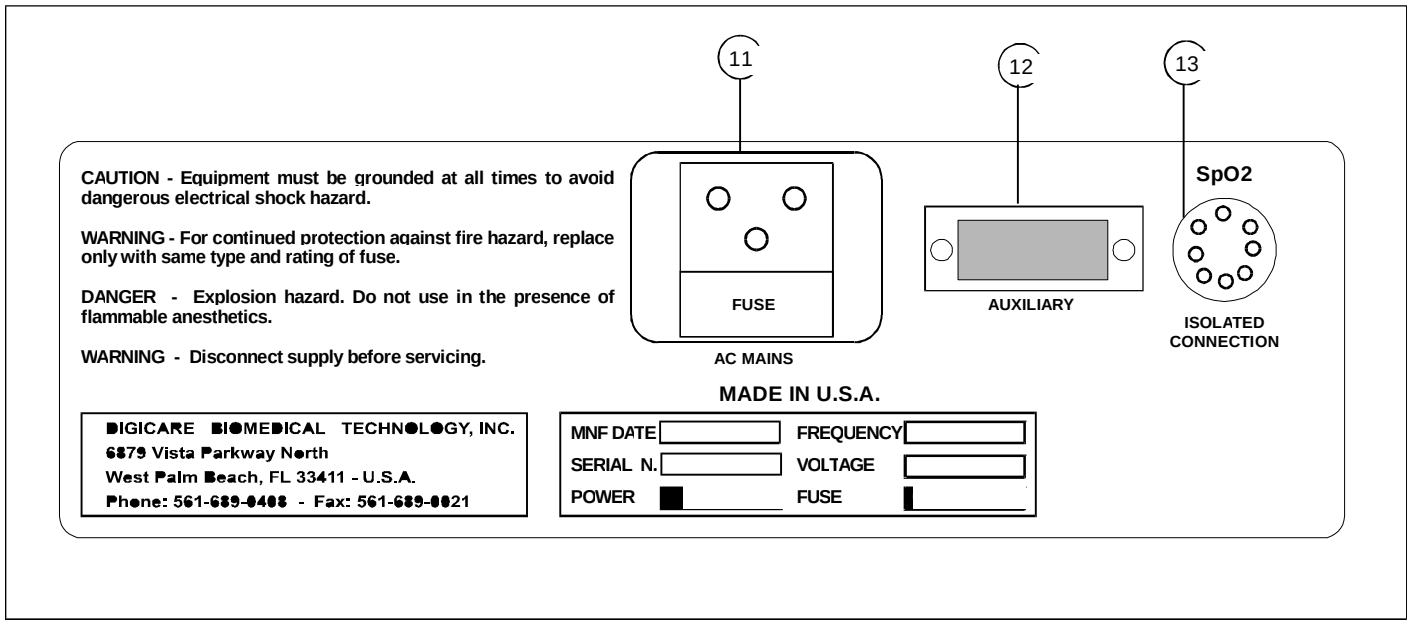
SECTION 3 - Controls, Connectors and Indicators

A. Front Panel



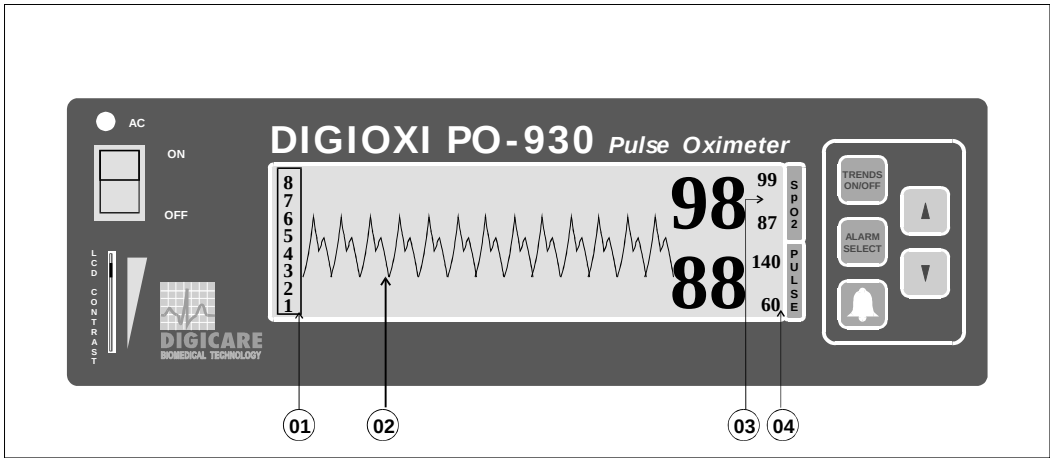
01 - AC indicator
02 - ON/OFF Switch
03 - Trends ON/OFF Push-button
04 - Increment and decrement alarm limits and pulse and alarm sounds
05 - Alarm limits select push-button
06 - Alarm Silence push-button
07 - Pulse area indicator
08 - SpO2 area indicator
09 - High Intensity CFL-LCD
10 - Backlight Contrast Adjust Trimmer

B. Rear Panel



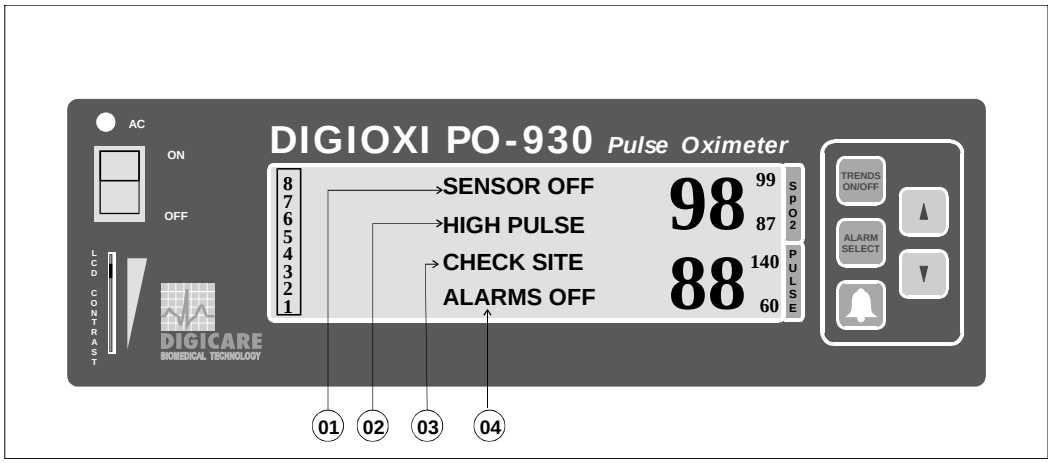
11 - IEC type with fuse holder AC line input connector
12 - RS232 Serial output connector
13 - SpO2 Probe input connector

C. Monitoring Mode Screen



01 - BAR-GRAPH - Indicates the SpO2 pulse intensity
02 - SpO2 PLETHYSMOGRAM WAVEFORM
03 - SpO2 - Indicates the SpO2 value LOW and HIGH alarm limits
04 - PULSE - Indicates the Pulse Rate value LOW and HIGH limits

D. Alarm Indicators



01 - Indicates the following alarms:
"SENSOR OFF", "NO SENSOR", "SEARCHING", "LOW SpO2", "HIGH SpO2"
02 - Indicates the following alarms:
"LOW PULSE", "HIGH PULSE"
03 - Indicates the following alarms:
"CHECK SITE", "WEAK PULSE", "LOW BAT"
04 - Indicates **"ALARMS OFF"** (No alarm sound)

SECTION 4 - Operation Instructions

A. Initial Operation

CAUTION: Read this manual completely before initiate the monitor's installation and operation.

1 - Plug the AC power cord in AC MAINS receptacle (**11**) in rear panel and in the AC OUTLET. Verify if the mains voltage corresponds to the voltage specified in the Rear Panel.

2 - The electrical installation of the room must have three pins outlets with earth connection for better protection of patients, users and equipment's.

3 - Press the switch (**02**) in front panel to power-on the monitor.

4 - The monitor begins a self-test and displays the monitorization screen.

5 - At power-on the monitor assume standards values for the following items:

- Audible Alarm : Two minutes OFF
- Pulse Rate High Limit : 140 BPM
- Pulse Rate Low Limit : 60 BPM
- SpO2 High Limit : OFF (-- --)
- SpO2 Low Limit : 87%

B. Alarm Sound On-Off

Pressing one time the key (ALARM SOUND ON-OFF) disables the ALARM SOUND for 2 minutes and ALARM OFF message flashes in screen.

Pressing again the (ALARM SOUND ON-OFF) key enables the ALARM SOUND. Pressing (ALARM SOUND ON-OFF) key for 4 seconds, disables permanently the ALARM SOUND and the message ALARM OFF appear in screen permanently.

C. Alarm Limits Selection

At power-on the SpO2 and pulse alarm limits are pre-selected.
To modify the limits, press the alarm select (**05**) push-button until the desired limit (SpO2 High, SpO2 Low, Pulse High, Pulse Low) flashes. Press the ↑ or ↓ push-button to select the limit value. Press again the alarm select (**05**) push-button until no alarm limit indicator is flashing.

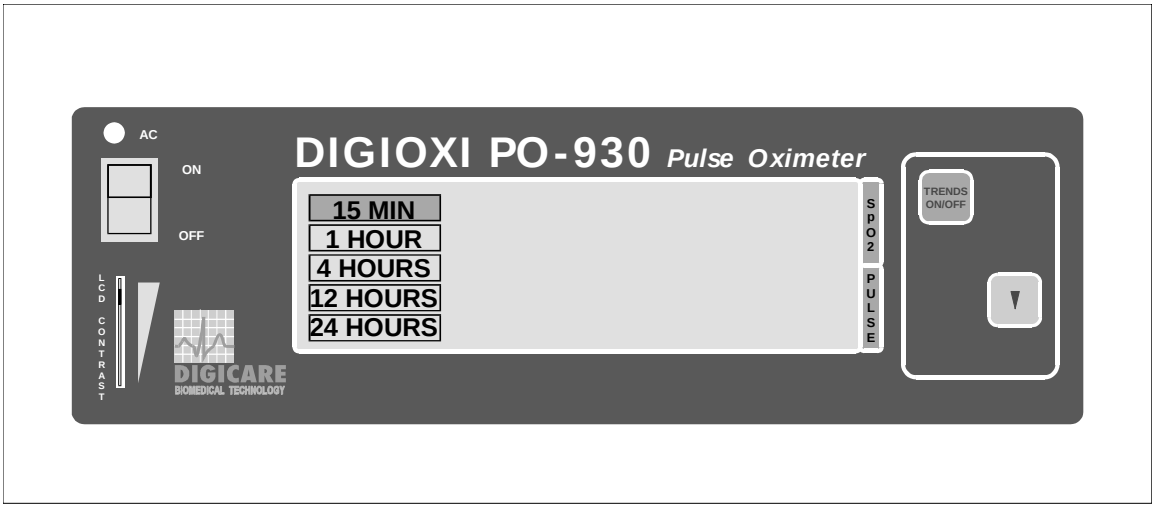
D. Beep Volume Adjust

At POWER-ON the BEEP VOLUME is pre-adjusted. To increase or decrease the BEEP VOLUME, press the alarm disable push-button. The “alarm off” message is displayed. Press the ↑ or ↓ push-button to increase or decree the pulse alarm volume.

E. Alarm Volume Adjust

At POWER-ON the Alarm Sound is pre-adjusted. To increase or decrease the Alarm Sound, the “alarm off” message could not be displayed. (Alarm Sound Enabled). Press the ↑ or ↓ push-button to increase or decree the alarm sound.

F. Trends ON/OFF



Press the **TRENDS ON/OFF** push-button.
At the left side of the display the time period options are displayed. (15min, 1H, 4H, 12H and 24H).
The selected time period flashes. To modify the time period press the ↓ push-button until the desired option flashes. To confirm the selection press again the **TRENDS ON/OFF** push-button and the Trends waveforms are displayed. To Return to normal display press the **TRENDS ON/OFF** push-button again.

SECTION 5 - Oxygen Saturation Monitoring

A. Theory of Operation

The functioning of the ***DIGIOXI PO-930*** pulse oximetry is based on the assumption that hemoglobin exists in two principle forms in the blood:

- Oxygenated (With O_2 molecules loosely bound) or HbO_2.
- Reduced (With No O_2 molecules bound) or Hb.

Arterial oxygen saturation (SpO_2) is defined as the ratio of oxygenated hemoglobin (HbO_2) to total hemoglobin (HbO_2 + Hb + other types of hemoglobin's).

$$SpO_2 = \frac{HbO_2}{HbO_2 + Hb + (\text{others Hemoglobin's})}$$

An Oximeter measures the absorption of selected wavelengths of light passing throughout a living, tissue sample. Since oxygenated hemoglobin and reduced hemoglobin absorb light as know functions of wavelengths, the relative percentage of these two constituents, and SpO2 are calculated. The problem is translating oximetry theory into a medical device is differentiating between the absorption due to oxygenated and reduced hemoglobin and the absorption due to all other tissue constituents.

The problem is solved with a two wavelength pulsatile system. The pulsation of arterial blood flow present, at a particular test site modulates the light the oximeter's probe detects. Since other fluids and tissues present at the test site generally don't pulsate, they do not modulate the light passing, through the test site area. Therefore the attenuation of light energy due to arterial blood flow can be detected, and isolated. Thus providing the basis for the necessary calculations, by using the pulsatile portion of the incoming signal.

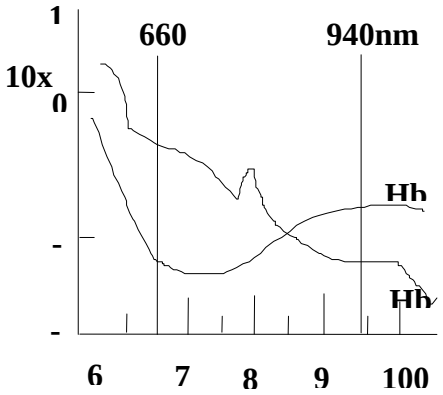


FIG.1

ABSORPTION

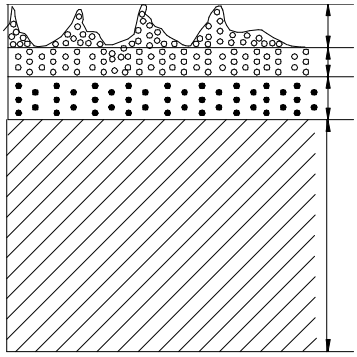


FIG.2

Two wavelengths of light, red and infrared, are utilized to gauge the presence of oxygenated and reduced hemoglobin.

Oxygenated hemoglobin (HbO_2) and reduced hemoglobin (Hb) exhibit markedly different absorption (extinction) characteristics to red and infrared lights. (FIG.1).

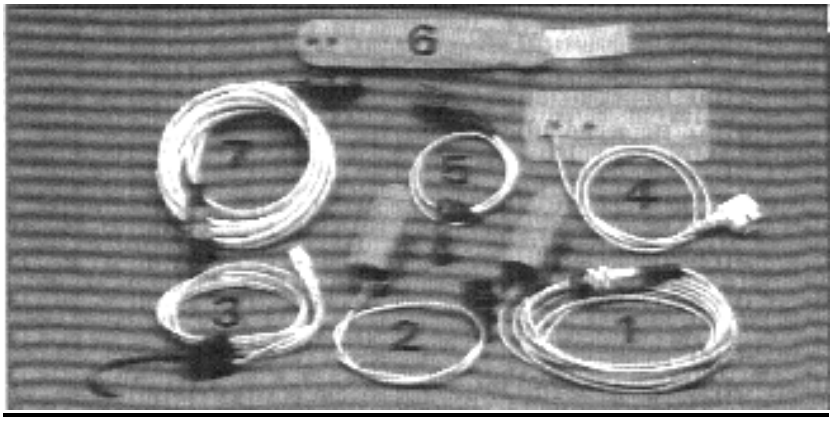
The probe's photodetector converts the light, which is partially absorbed and modulated as it passes through the tissue sample, into an electronic signal. FIG.2.

B. Patient Connections

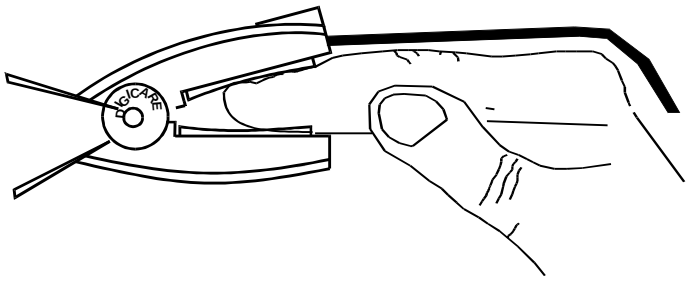
To ensure conformance with all safety and performance, use only the recommended accessories. These are available from DIGICARE using the following part number:

1 - Finger Probe 10'cord P/N -PO-710
2 - Finger Probe 1.5'cord P/N-PO-711
3 - Ear Probe P/N -PO-730
4 - Disposable Wrap Probe P/N -PO-724
5 - Wrap Probe P/N -PO-720
6 - Band for Wrap Probe P/N -PO-721
7 - SpO2 Patient Cable 10" cord P/N-PO-722

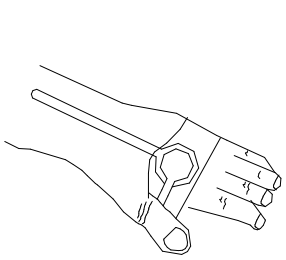
☞ 2,3,4 and 5 requires SpO2 Patient Cable P/N PO-722

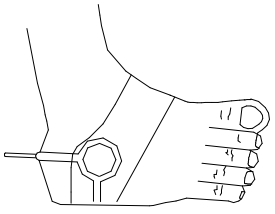


FINGER PROBE - ADULT



WRAP PROBE - NEONATAL





C. SpO_2 Monitoring

Until the patient cable is connected and the probe is placed in patient, the message SENSOR OFF is displayed in screen.

In normal operation, the monitor displays SpO_2 and Pulse Rate values, a bar graph indicating pulse height and alarm limits.

Reposition the probe at least once every 18-20 hours to allow the patient's skin to respire.

Loss of pulse signal can occur if:

- The sensor is to tight.
- There is excessive illumination (e.g., a surgical or bilirubin lamp or direct sunlight).
- The sensor is placed on an extremity with a blood pressure cuff, arterial catheter or intravascular line.

- The patient experiences shock, hypertension, severe vasoconstriction, severe anemia, hypothermia, arterial occlusion to the sensor, or cardiac arrest.

Inaccurate measurements may be caused by:

- Incorrect application of dysfunctional hemoglobin's, such as carboxyhemoglobin or methemoglobin.
- Significant, levels of indocyanine green, ethylene blue or other intravascular dyes.
- Exposure to excessive illumination, such as surgical lamps, especially ones with a xenon light source; bilirubin lamps, fluorescent lights; infrared heating lamps; or direct sunlight.
- Excessive patient movement.
- Venous pulsation's.
- Electrosurgical interference.
- Placement of the sensor on an extremity that has a blood pressure cuff, arterial catheter or intravascular line.

Do not attach a probe to the same limb with a blood pressure cuff. The data received will not be valid when the cuff is inflated. Attach the probe to the limb opposite the site used for the blood pressure cuff.

D. PLETHYSMOGRAM Waveform

The amplitude of the PLETHYSMOGRAM waveform is automatically adjusted in screen.

The Bar graph indicates the pulse signal height and varies from 1 to 8. Increasing the signal amplitude increases the Bar graph value. Bellow number 2 in bar graph, the message ***WEAK PULSE*** is displayed.

E. Alarm messages

HIGH SpO2 - Light when selecting the high SpO2 alarm limit and when the high SpO2 alarm limit is violated.

LOW SpO2 - Light when selecting the low SpO2 alarm limit and when the low SpO2 alarm limit is violated.

HIGH PULSE - Light when the high pulse alarm limits is being selected or is violated.

LOW PULSE - Light when the low pulse alarm limits is being selected or is violated.

LOW BAT - This alarm is triggered when the battery needs to be recharged.

WEAK PULSE - This message is displayed if the amplitude of the pulse signal is low causing instability in SpO2 monitoring. Check the probe installation, site perfusion and body temperature.

SEARCHING - This message is displayed when the monitor is self adjusting the ideal point of signal monitoring.

CK SITE - This "CHECK SITE" message is displayed when the monitor have not encountered a good point to signal monitoring. Check the probe installation.

PULSE - This message is displayed when the operator is adjusting the pulse alarm volume.

ALARM OFF - This message indicates the disable of the alarm sound for 2 minutes (flashing message) or disable (continue display message permanently).

PULSE OFF - This message indicates the pulse volume was reduced to minimum.

SENSOR OFF -This alarm message indicates that the sensor is not installed to the patient or a problem in the sensor.

NO SENSOR - This alarm message indicates that no sensor is connected to the monitor.

AC - This indicator light when the monitor is connected to the AC line and the battery is recharging.

☞ This indicator always lights with AC connected, even with the battery fully charged.

SECTION 6 - Maintenance

A. The Monitor

When necessary, clean the exterior surfaces of the monitor with a cloth or swab dampened with warm and a mild detergent solution. Do not allow fluids to enter the interior of the instrument.

***WARNING*: Electrical shock and flammability hazard - always turn the monitor off and disconnect it from AC mains power before cleaning.**

CAUTION: Do not autoclave or pressure sterilize this monitor. Do not stack or immerse this monitor in any liquid. Do not gas sterilize this monitor.

Do not touch, or rub the display panel with abrasive cleaning compounds, instruments, brushes, rough surfaced materials or make contact with anything that can scratch the panel.

B. Probes

The probes are the only surfaces of this monitor that come in contact with the patient. Clean the probes after each patient use.

Clean the monitor's probes with a commercial cleaning solution before attaching a new patient. Probes should be cleaned until signs of wear or splitting occur. At this time a new probe is required.

If disinfecting is required, wipe the surfaces with Isopropyl alcohol or cidex and use a water rinse. When sterilization is required, use ethylene oxide and be sure to follow hospital procedures.

Inspect the probe for wear or splitting after every disinfecting/sterilization process is complete. If wearing or splitting of the probe is found upon visual inspection, a new probe should be used.

C. Patient cables

Do not autoclave the patient cables.

Wipe the cables using soap and water or alcohol. Never submerge the cables in any liquid or allow liquids to enter the electrical connections.

WARRANTY TERMS & CONDITIONS

DIGICARE BIOMEDICAL TECHNOLOGY, INC. covers all of their monitors with a 2 year warranty:

Monitors

1st year parts and labor

2nd year labor only

Accessories

90 days on accessories warrranty

DIGICARE BIOMEDICAL TECHNOLOGY, INC. will provide the necessary parts and labor to maintain the monitor (s) listed on the Warranty Certificate in a usable condition during the covered period.

DIGICARE BIOMEDICAL TECHNOLOGY, INC. will, at its option, repair or replace any product which proves to be defective during the warranty period, if returned to the factory with prior authorization, transportation prepaid.

Not covered by this agreement are repairs necessitated by any of the following conditions:

1 - Inadequate power or power failure.
2 - Neglect, abuse or misuse of equipment.
3 - Servicing of equipment by persons other than DIGICARE INC.
4 - Any unit opened or tampered with, without prior authorization.

When returning a monitor for extended warranty repair, you must first contact DIGICARE BIOMEDICAL TECHNOLOGY, INC. to receive a Returned Goods Authorization Number (RGA #) that is to be clearly marked on top of the shipping carton. Please make sure that your company name, shipping address, area code and telephone number and person to contact is located in and/or on the box. **ANY UNIT THAT IS RETURNED TO THE FACTORY WITHOUT AN RGA# WILL BE REFUSED.**

F O R Y O U R R E C O R D S

Model # _____ Serial # _____ Dealer Name: _____

Date Equip. Purch.: _____ Expiration Date: _____

DIGICARE BIOMEDICAL TECHNOLOGY INC.
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