VITALMAX 530

PULSE OXIMETER

OPERATOR'S MANUAL

CAUTION: Federal law (U.S.) restricts this device to sale by or on the order of a physician.

PaceTech™ Medical Monitors Inc.

...Excellence in Patient Monitoring

510 Garden Avenue. N. Clearwater, FL 33755
Phone: (727) 442-8118 • Fax: (727) 443-7257

Rev.4 10/96

Table of Contents

SECTION 1 - INTRODUCTION

SECTION 2 - CONTROLS and CONNECTORS

SECTION 3 - DISPLAYS AND INDICATORS

SECTION 4 - ALARM LIMITS SETUP AND VIOLATIONS

SECTION 5 - TIME AND DATE

SECTION 6 - MONITOR OPERATION

SECTION 7 - OXYGEN SATURATION MONITORING

SECTION 8 - PRINTER OPERATION

APPENDIX I - PRODUCT SPECIFICATIONS

APPENDIX II - BATTERY OPERATION

APPENDIX III - MAINTENANCE

SECTION 1 - INTRODUCTION

A. About This Manual

This operators manual has been prepared to provide information on the correct use of the *VITALMAX 530 SERIES* compact, digital vital sign monitor. It contains performance specifications and information for routine installation, operation and maintenance. It is intended for health care professionals trained in monitoring cardiovascular and respiratory activity.

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.

If the monitor is being used for the first time, follow each section in the manual sequentially. Each section builds on descriptions from the previous. Since this manual describes a full-featured monitor, disregard any descriptions that refer to features not installed in your monitor. If the monitor is set up, and you are already familiar with its operations, then proceed to the section that describes those functions you will use.

B. Warranty

Pace Tech, Inc., warrants each monitor to be free of defects in materials and workmanship for a period of one (1) year from the date of purchase. The warranty on all cuffs, probes, printers, and accessories is three (3) months.

If you discover a defect, Pace Tech will, at its option, replace or repair the product at no charge provided the monitor is returned to Pace Tech during the warranty period, transportation charges prepaid.

This warranty does not apply if the product:

- has been damaged from improper operation (misuse) or failure to follow operating instructions provided with the product (misapplication or negligence).
- has been damaged because it has been improperly connected to other equipment.
- has been damaged by accident.
- has been tampered with or modified without the express permission of Pace Tech.
- has had the serial number removed or defaced.This is the only warranty from Pace Tech, and supersedes all other warranties, expressed or implied otherwise.

This warranty is non-transferable and applies only to the original purchaser and does not extend to subsequent owners of the product.

Please fill out the self-addressed warranty registration card enclosed in the back of this Operators Manual and return it to Pace Tech, Inc. Also, save the original shipping container for service and repair returns.

For technical and service information, refer to the Service Manual, your dealer, or the Customer Service Department at Pace Tech, Inc., 510 Garden Ave. N, Clearwater, Florida 33755, phone: (727) 442-8118, (800) 722-3024, fax: (727) 443-7257.

C. General Safety

1. INDICATIONS

The *VITALMAX 530 SERIES* is intended for use by persons trained in professional health care to measure and monitor the following parameters:

- Blood oxygen saturation (SpO_2 or Pulse oximetry)
- Pulse (SpO_2) signal strength
- Pulse rate (SpO_2)

Additional options offered are:

- Add-on 27 column thermal printer
- Carrying case
- Pole mount assembly

2. CONTRAINDICATIONS - *Situations where risks associated with the use of the monitor are greater than the benefits.*


This monitor is <u>not</u> intended to be used as an apnea monitor.


This monitor is <u>not</u> intended to be used during MRI (Magnetic Resonance Imaging).

3. NOTES - *Supplemental information which is relevant to the equipment but should not be used to direct action*

NOTE:
- Notes will appear throughout the operators manual in this format.

4. WARNINGS - *Indicate the possibility of injury due to patient or operator associated with the use or the misuse of the monitor.*

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

Use only accessories supplied with this monitor or specifically intended to be used with this monitor.

Do not use this device in the presence of flammable anesthetics.

Electrical shock hazard may occur when covers are removed. Do not remove covers or panels. Refer servicing to qualified personnel.

There is no defibrillator synchronization output on this monitor. Make no connections between this monitor and a defibrillator.

Enclosure leakage current is limited internally by this monitor's adapter to less than 100 micro amperes (μA); however, always consider additional leakage current that can be caused by other equipment used on the patient at the same time as this monitor.

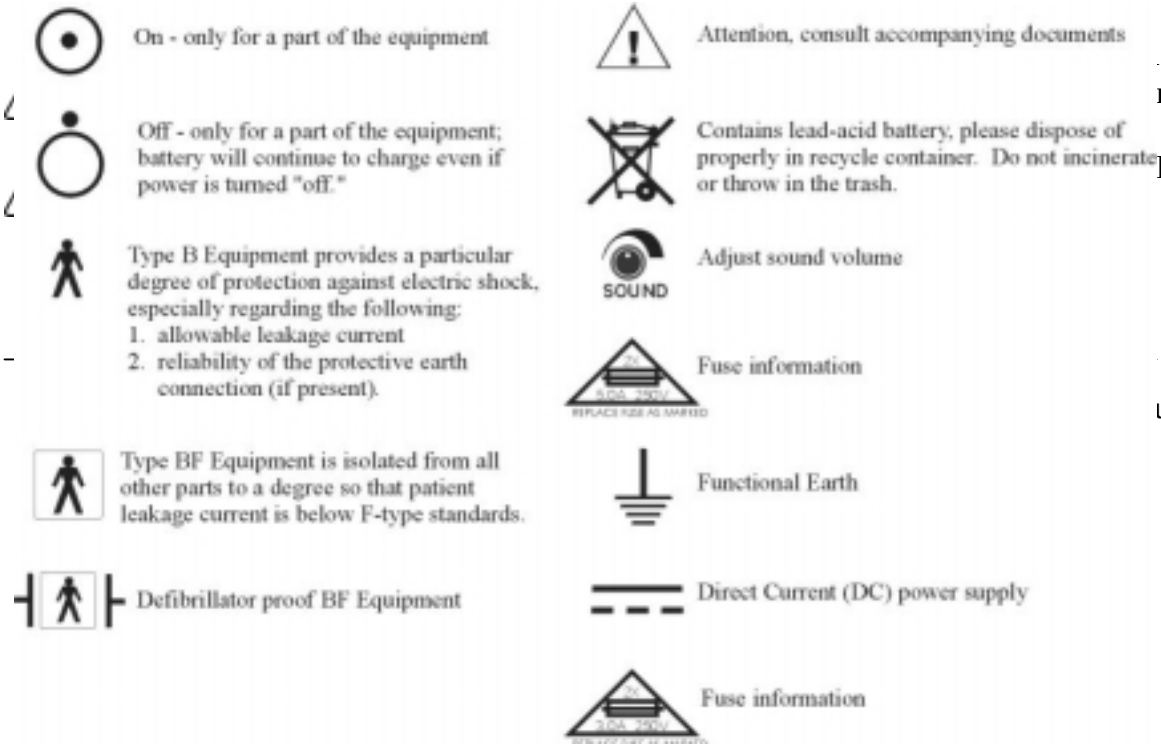
To ensure that the leakage current protection remains within the specifications, use only the AC adapter supplied with, or specifically intended to be used with this monitor.

Connection of non-isolated devices to the RS-232 connector may cause chassis leakage to exceed the specification standards.

To prevent electrical hazards to all personnel, this monitor must be properly grounded. The AC adapter supplied with the equipment provides for this protection. Do not attempt to defeat this protection by modifying the cords or using ungrounded adapters.

Patient connections are Type B. Use insulated probes for all connections. Do not let patient connections contact other conductive parts, including earth. See instructions for patient connections in this manual.

5. CAUTIONS - *Indicate a condition that may lead to equipment damage or malfunction.*



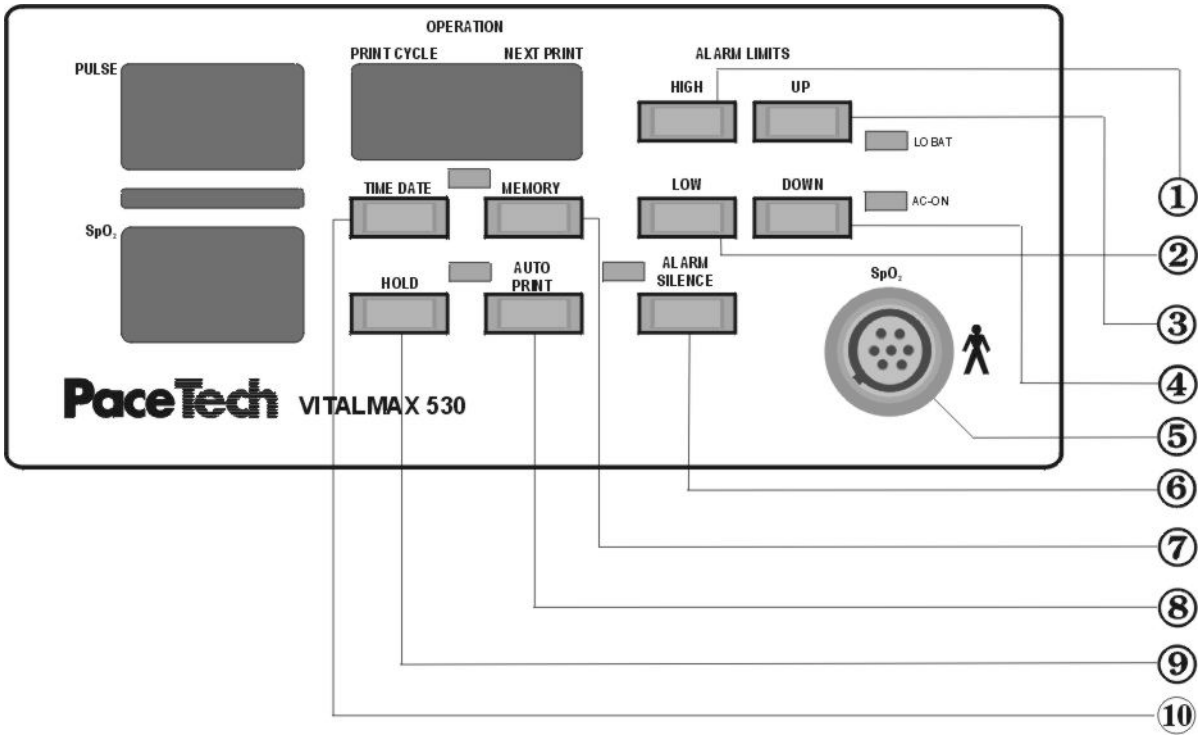
.10-120V/50-60
nal battery.

lug the monitor

ures.

SECTION 2 - CONTROLS AND CONNECTORS

A. Front Panel



1. HIGH This pushbutton will adjust the previously programmed Upper alarm limits.

2. LOW This pushbutton will adjust the previously programmed lower alarm limits.

3. UP This pushbutton will:
   - increase the alarm limits, print cycle time, alarm reset interval, time and date,
   - initiate the memory recall in ascending order.

4. DOWN This pushbutton will:
   - decrease the alarm limits, print cycle time, alarm reset interval, time and date,
   - initiate the memory recall in descending order.

5. SpO2 This receptacle accepts the pulse oximetry extension cable plug.

6. ALARM SILENCE This pushbutton will:
   - silence the alarms for a selected period of time, or
   - program the automatic alarm reset interval.

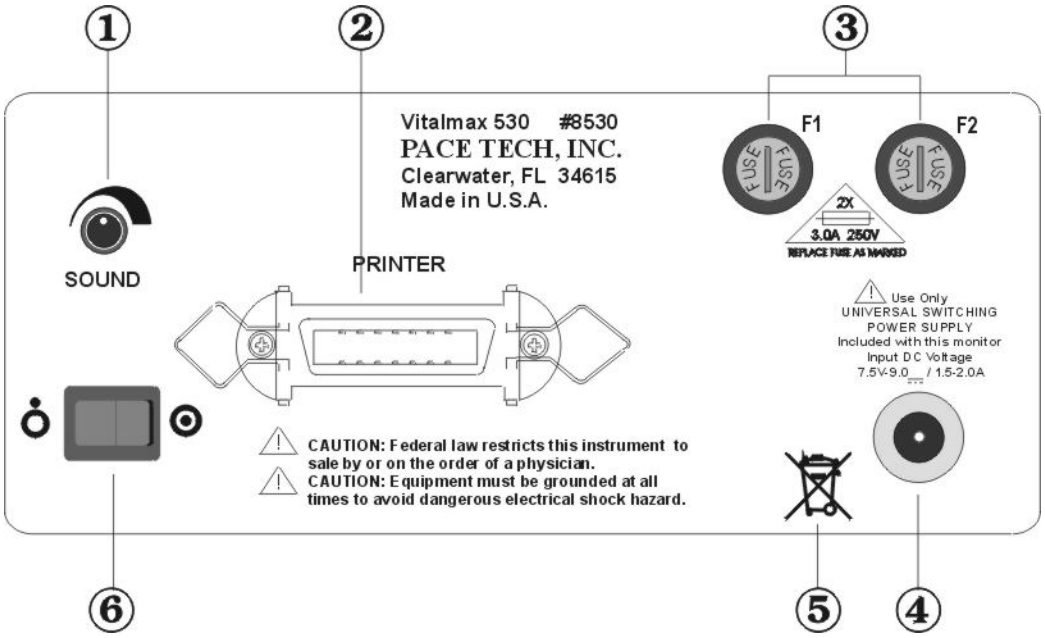
7. MEMORY This pushbutton will recall previous readings in the memory while monitoring in the Auto modes.

8. AUTO PRINT This pushbutton places the monitor into the Auto mode of operation.
Repeated readings will be printed at desired set intervals of time.

9. HOLD This pushbutton places the monitor on Hold and aborts the Auto print mode. The PRINT CYCLE and NEXT PRINT LED displays will blink as long as the monitor is on Hold.

10. TIME/DATE This pushbutton allows viewing and setting of the time and date.

B. Rear Panel



1. SOUND This knob adjusts the volume of the pulse sounds; turning the knob clockwise will increase the volume, turning the knob counter clockwise will decrease the volume. This knob does not silence the audio alarms or control the alarm volume.

2. PRINTER This receptacle provides parallel signal lines to the optional add-on 27 column thermal printer.

3. FUSE HOLDERS The monitor is equipped with two fuses, designated F1 and F2, which each protect a different power input:

F1- This fuse protects the internal battery. If it is blown, then the monitor can continue to operate on the AC power supply. Battery operation is not possible until the fuse is replaced.

F2- This fuse protects the AC power supply line. If it is blown, then the monitor can continue to operate under battery power. However, the monitor cannot be recharged until this fuse is replaced.

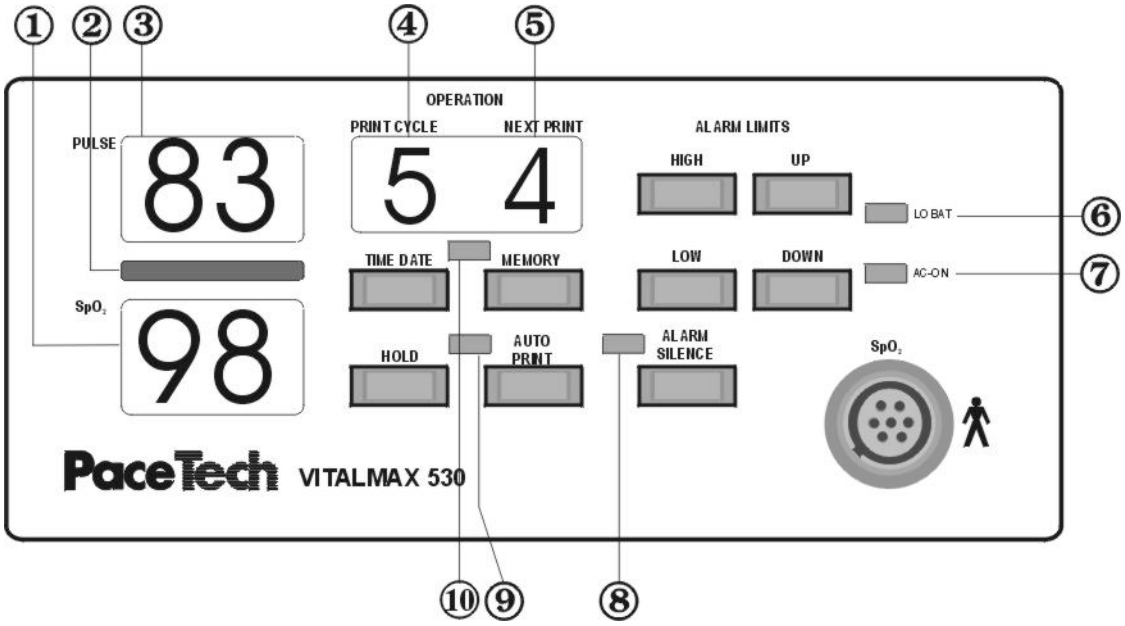
4. 7.5-9.0 V / 1.5-2.0 A This receptacle accepts the Universal Switching Power Supply used for continuous AC operation or to charge the battery.

5. BATTERY DISPOSAL SYMBOL Contains lead-acid battery, please dispose ofproperly in recycle container. Do not incinerateor throw in the trash.

6. POWER This toggle switch turns the power from on to off. The monitor will continue to charge the battery as long as the unit is plugged in, even if the power switch is in the off position.

SECTION 3 - DISPLAYS AND INDICATORS

A. Front Panel



1. SpO2 2 digit numeric display
   - shows percentage of Oxygen Saturation (SpO2) in the blood
   - displays SpO2 alarm limits
   - indicates a violation of a SpO2 alarm limit by flashing

2. BAR GRAPH Indicates the SpO2 pulse signal relative strength.

3. PULSE 3 digit numeric display
   -shows SpO2 Pulse rate per minute
   -displays SpO2 Pulse alarm limits
   -indicates a violation of a SpO2 Pulse alarm limit by flashing.

4. PRINT CYCLE 2 digit numeric display
   - shows programmable Auto Cycle time
   - shows programmable automatic alarm reset interval
   - displays real time and date
   - flashes when the Auto cycle is on Hold.

5. NEXT PRINT 2 digit numeric displays
   - shows the time left before the next Auto Cycle begins
   - displays real time and date

- flashes when the monitor is on Hold.

6. LO BAT LED which lights up when the battery is discharged and indicates the need of charging with AC current.

7. AC ON LED which lights up when the monitor is connected to AC current.

8. ALARM SILENCE LED which lights up when the alarm audio indicator is turned off.

9. AUTO PRINT LED which lights up when the Auto mode is initiated.

10. MEMORY LED which lights up when the memory recall is initiated.

SECTION 4 –ALARM LIMITS SETUP and VILOATIONS

A. Determining Previously Selected Alarm Limits

The factory alarm limits are not in effect each time the monitor is powered up; the previously selected alarm limits remain in the memory.

The alarm limits are checked by pressing the **HIGH** pushbutton to determine the upper alarm limits and by pressing the **LOW** pushbutton to determine the lower alarm limits. The parameters are displayed individually in the following sequential order on the respective display as either the **HIGH** or **LOW** pushbutton is pressed:

(1) SpO2 (2) Pulse

All the high alarms limits can be determined by continuing to press **HIGH** pushbutton. The high and low alarm limits of the individual parameter can be checked by pressing the **HIGH** then **LOW** pushbutton as you continue through the cycle.

B. Changing / Setting Alarm Limits

The alarm limits are set or changed by pressing the **UP** pushbutton to increase the alarm limit or by pressing the **DOWN** pushbutton to decrease the alarm limit while each parameter is displayed in the respective display.

If no change is desired, or after a change has been made, wait five (5) seconds and the monitor will return to normal operations.

C. Activating Preset Factory Alarm Limits

To set or activate the preset factory alarm limits, simultaneously press the HIGH and LOW pushbuttons for two (2) seconds. A beep will sound and immediately all the alarms limits will set to the factory default limits.

The factory alarm limits and range of programmable limits (non-overlapping) are:

PARAMETERS	FACTORY LIMITS		RANGE OF PROGRAMMABLE LIMITS	
	LOWER LIMIT	UPPER LIMIT	LOWER LIMIT	UPPER LIMIT
SpO2	90%	100%	0-99%	0-100%
Pulse	40 bpm	120 bpm	0-249 bpm	0-250 bpm

NOTE:

• The high SpO2 limit will be displays as “ 00" since the SpO2 LED numeric display is a two digit display.

D. Violations

When a parameter reading violates an alarm limit, the audible alarm will sound and the display will continue to flash until:

- another reading is taken which is within the alarm limits
- the alarm limit is changed or
- the monitor is turned off.

In addition, the audible alarm will sound until the SILENCE pushbutton is pressed.

E. Sensor Off Alarm

The monitor will alert the operator if:

- the SpO2 probe becomes disconnected from the patient,
- there is no data input, or
- the extension cable becomes disconnected from the monitor.

Immediately the **SpO_2** display will register “ 0" and the alarm will sound. When the pulse signal is restored, the monitor will resume normal operations.

F. Alarm Silence

1. AUTO MODE

When the **SILENCE** pushbutton is pressed, the **SILENCE** LED just above the pushbutton will light up indicating that the audible alarm has been silenced. The LED indicator will remain lit until the **SILENCE** pushbutton has been pressed again, or the programmed interval time for the audible alarm has passed. The audible alarms are reactivated at that time.

2. MANUAL MODE

When you follow the above procedure in Manual mode, the LED indicator will remain lit until the SILENCE pushbutton has been pressed again, or the programmed interval time for the audible alarm has passed, but the audible alarm will not be reactivated automatically.

G. Programmable Automatic Alarm Reset

The monitor is programmed for the audible alarm to be reactivated after a selected interval of time. There is no factory set interval for the automatic alarm reset. The previously selected alarm reset interval will be displayed. This interval can be set to a selected interval of time form 10 seconds to 5 minutes, or 99 minutes.

To change this interval of time from 10 seconds to 5 minutes:

1. Press and hold down the **SILENCE** pushbutton for 6 seconds until you hear the second beep sound. The previously selected alarm reset interval then will be displayed in the **CYCLE TIME** display.

2. Press the **UP** or **DOWN** pushbutton until the desired interval is displayed in the **CYCLE TIME** display (between ten seconds and five minutes.)

To obtain a selected interval of 99 minutes:

1. Press only the **DOWN** pushbutton until 99 is displayed in the **CYCLE TIME** display.

Ten seconds after the **UP** or **DOWN** pushbutton is released, the monitor will resume normal operations.

H. Alarm Override

The operator may choose to override the programmed alarm intervals if he or she is in full time attendance. To override the programmed alarm intervals, simply push the SILENCE pushbutton twice.

To re-establish the alarm, follow the programmable automatic alarm reset instructions in the previous paragraph.

SECTION 5 – TIME / DATE

A. Time and Date

The monitor has a built-in time and date microchip (clock chip) which displays the time of day in military time or a 24-hour clock. This microchip has its own battery backup time keeper, which will not lose time when the monitor is turned off. The clock chip is set in the factory to the correct time and date, but it will have to be changed for daylight savings time, leap year or change of time zones.

When the monitor is powered up, the time will be displayed in the 4 digit LED display labeled **CYCLE TIME** and **NEXT CYCLE** in the following format: 16:10

To check or change the time or date:

1. Press the **TIME/DATE** pushbutton.

2. Press the **UP** pushbutton to increase or the **DOWN** pushbutton to decrease the number.

The readings will cycle in the following sequence each time the **TIME/DATE** pushbutton is pressed:

:10	minute
16:	hour
5	Day
1	month
1996	year
16:10	military time or 24-hour clock

If you check or change the time and do not continue the cycle to another reading, after ten seconds the monitor will revert to normal operations and again display the time of day (16:10).

When the monitor is in the *Hold* mode, the readout in the **CYCLE TIME** and **NEXT CYCLE** display will continue to blink until the **HOLD** pushbutton is pressed again.

SECTION 6 - MONITOR OPERATION

A Modes of Operation

The *VITALMAX 530 SERIES* has two operating modes: *Manual and Auto Print.*

1. MANUAL

Manual is the normal power-up mode of operation for the monitor. This is a semi-automatic mode for the functions of the monitor: SpO2 and pulse.

The Manual mode is entered automatically by powering up the monitor. The monitor will detect if the SpO2 probe has been applied and will initiate the first reading automatically.

2. AUTO PRINT

The Auto Print mode is used ONLY when the printer is connected to the monitor and a hard copy printout is desired at intervals called cycle times.

In the Auto Print mode, the parameters are continually updated, but the printout reflects ONLY the reading obtained at the desired intervals.

a. After pressing the Power switch, press the AUTO pushbutton. The previously selected cycle time will appear on the PRINT CYCLE display.

b. To change the cycle time, press either the UP or DOWN pushbutton until the desired cycle time appears on the PRINT CYCLE display.

c. After either the UP or DOWN pushbutton is released, the first reading of the cycle will begin.

d. If the previously selected cycle time is desired and changes are not required, it is unnecessary to do anything after first pressing the AUTO pushbutton.

e. There are no factory preset cycle times. The PRINT CYCLE display will indicate the cycle- time in the memory from the previously selected cycle time.

The choices of cycle times are:

Seconds	:10,	:20,	:30,	:40,	:50
Seconds displayed as	.1	.2	.3	.4	.5
Minutes	1 through 99				

The NEXT PRINT display, indicates the minutes remaining until the next cycle will begin (10,5, 2, etc.). The time will be displayed in minutes until there is less than one minute left; then the time remaining will be displayed in seconds such as (.5, .4, .3, etc.). A maximum of 250 readings can be printed or saved in the memory for recall.

B. Hold

If for some reason print cycle must be canceled, the cycle can be interrupted at any time by pressing the HOLD pushbutton.

The PRINT CYCLE and NEXT PRINT displays will blink until the HOLD pushbutton is again pressed to revert to the previous mode.

C. Power Interruption

1. AC OPERATION

If momentary power interruption occurs, the monitor will automatically switch to battery operation. The monitor will not turn off and the readings in the memory will be retained.

2. BATTERY OPERATION

If the Power switch is turned off and on, the monitor will revert to the Manual mode and the display will not show the readings. All readings in the memory are lost when the monitor is turned OFF.

D. Memory Recall

The readings are stored in memory when the monitor is in the Auto mode.

The previous readings in the memory can be recalled by pressing the MEMORY RECALL pushbutton. The MEMORY RECALL LED will light up as long as the monitor is in the Memory Recall mode indicating observation of previous readings.

The first (initial) reading of the patient will be displayed in the respective displays and the number 1 will be displayed in the NEXT PRINT display to indicate the first reading.

If you want to recall other readings of the patient:

1. Press the UP pushbutton to sequence through the readings in ascending order.

2. The readings of the patient will be displayed in the respective displays and the corresponding number of the reading (2, 3, 4, etc.) will be indicated in the NEXT PRINT display.

3. The readings can be recalled in ascending order (forward) by pressing the UP pushbutton or in descending order (backward) by pressing the DOWN pushbutton (4, 3, 2 etc.)

4. During the Memory Recall mode, the monitor will continue to take readings without interruption.

5. When the MEMORY RECALL pushbutton is pressed again or after an approximately five (5) seconds the monitor will revert to normal operations.

6. Up to 250 readings can be recalled in ascending or descending order.

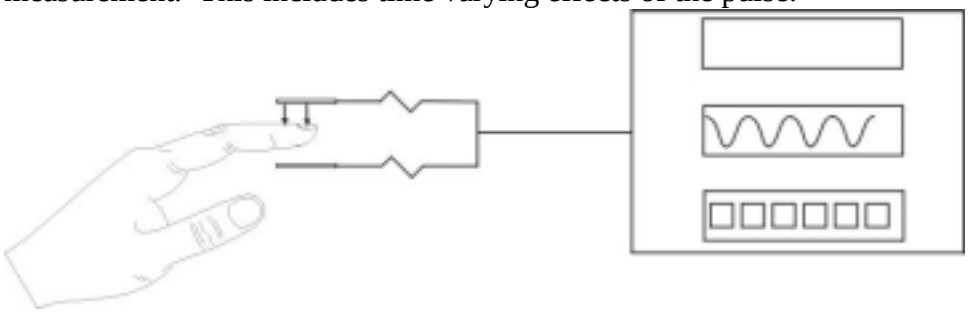
7. All readings are lost when the monitor is turned OFF.

NOTE:
Patient readings are stored in the memory only when the AUTO pushbutton is pressed and the AUTO LED indicator is ON.

SECTION 7 - OXYGEN SATURATION MONITORING

A. Theory of Operation

The monitor uses the infrared method (IR) to determine the SpO_2 and pulse rate. Two wavelengths of light, one red and one infrared, are passed through body tissue to a photo detector. Plethysmographic (waveform) techniques are used to identify the pulse. Spectrophotometric oximetry principles, which are used for each light source, are dependent upon the color and thickness of body tissue, sensor placement, intensity of light sources and absorption of arterial and venous blood in the body tissue during measurement. This includes time varying effects of the pulse.



To identify the pulse and calculate oxygen saturation, the monitor processes these signals, separating the time-invariant parameters (venous blood, tissue thickness, and skin color) from the time-varying parameters (arterial volume). Blood saturated with oxygen predictably absorbs less red light than oxygen depleted blood, thus oxygen saturation calculations are obtained. Measurements are displayed both visibly and audibly. Oxygen saturation and pulse rate measurements are displayed digitally and are updated with each pulse beat. Pulse amplitude is displayed qualitatively. Additionally, the tone that signals each pulse beat varies in pitch to reflect the increase or decrease in oxygen saturation, rising and falling proportionately as saturation increases and decreases.

B. Patient Connections

To ensure conformance with all safety and performance specifications, use only the recommended accessories. These are available from Pace Tech using the following part numbers:

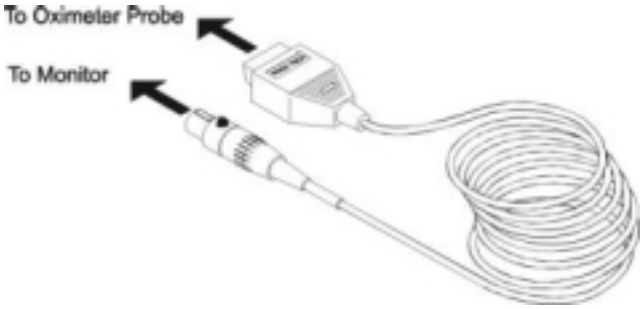
Pulse Oximeter Accessories	Quantity	Order No.
Finger Probe, Reusable	One	4510
Universal ‘Y’ Probe, Reusable	One	4520
Patient Extension Cable, 6 ft	One	4536
Infant Wrap Probe, Reusable	One	4550
Adult/Neonatal Wrap Probe, Reusable	One	4555
Micorfoam® Surgical Tape (1" x 5.5 yds)	2 Rolls	4535
Ear Lobe Clip (use w/Universal ‘Y’ Probe)	One	4565
Adult Wrap Probe, Disposable	Pack of 10	4588

Pediatric Wrap probe, Disposable	Pack of 10	4589

1. CONNECTING A PROBE

a. Properly align the connector on the patient cable with the SpO_2 receptacle located on side panel of the monitor.

b. Push in firmly until the connector fully seats.



2. DISCONNECTING A PROBE

Holding the patient cable collar, gentle pull on the cable.

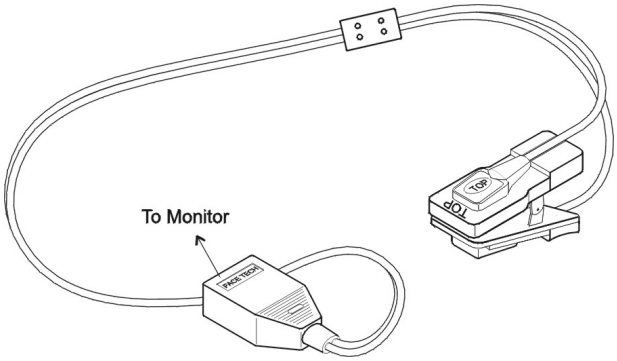
Select the appropriate oximeter probe and application technique from the following pictures and descriptions:

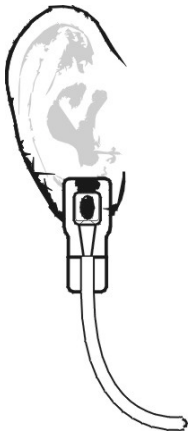
Earlobe Clip (#4565) and Universal "Y" Probe (#4520), Reusable

Attach the optional Earlobe clip to the Universal "Y" probe by sliding the "Y" probe's light source side (labeled "top") into the earlobe clip's open side (labeled "top") and the "Y" probe's detector side into the earlobe clip's opaque side

Earlobe Clip Application for Adults

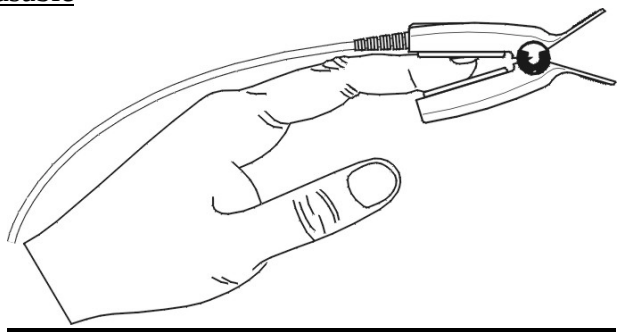
Rub the patients earlobe with an alcohol prep for 1-2 minutes. Then attach the probe and earlobe clip to a fleshy portion of the patient's earlobe with the light source to the outside.



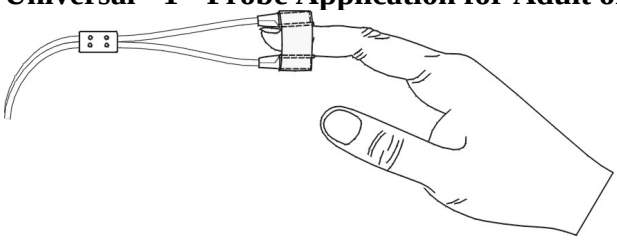


Finger Probe Application for Adults (#4510), Reusable

Attach the finger probe to the patient as shown. Be sure to fully insert the patient's finger into the probe. Run the cable along the back of the hand. For patients with long fingernails, use the Universal "Y" probe or adult/neonatal warp probe.

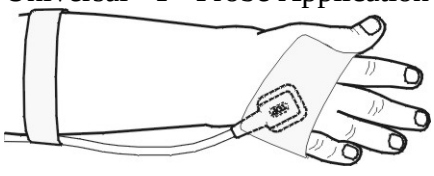


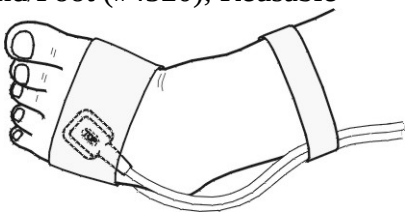
Universal "Y" Probe Application for Adult or Pediatric Finger (#4520), Reusable



Attach the Universal "Y" probe to the finger with the light source side to the fingernail. Line up the light source side with the detector side, so the source and detector are in the same plane. Secure the probe and cable with Microfoam® tape, being careful not to overly tighten the tape.

Universal "Y" Probe Application For Infants- Hand/Foot (#4520), Reusable





Attach the Universal "Y" probe to a fleshy portion of the infant's hand/foot. Attach the probe with the light source side on the top or outside of the hand/foot to keep the detector side away from ambient light. Line up the light source side with the detector side, so the source and detector are in the same plane. Secure the probe with Microfoam® tape, being careful not to overly tighten the tape

Infant Wrap Probe Application - Toe (#4550), Reusable

Attach the optional Infant Wrap probe with the light source side to the toenail.

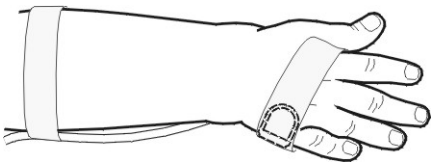
Infant Wrap Probe Application - Foot (#4550), Reusable

Attach the optional Infant Wrap probe with the fleshy portion of the foot.

Attach the probe with the light source side on the top or outside of the toe/foot to keep the detector side away from ambient light. Line up the light source side with the detector side, so the source and detector are an the same plane. Secure the probe with Microfoam® tape, being careful not to over tighten the tape.

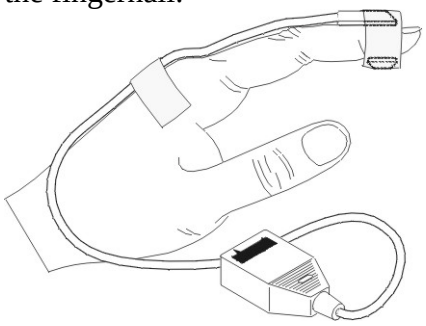
Adult / Neonatal Wrap Probe Application – Hand (#4555)

Attach the optional Adult/Neonatal Wrap probe to the fleshy part of the hand.



Adult / Neonatal Wrap Probe Application – Finger (#4555), Reusable

Attach the optional Adult/Neonatal Wrap probe to the finger with the light source side to the fingernail.



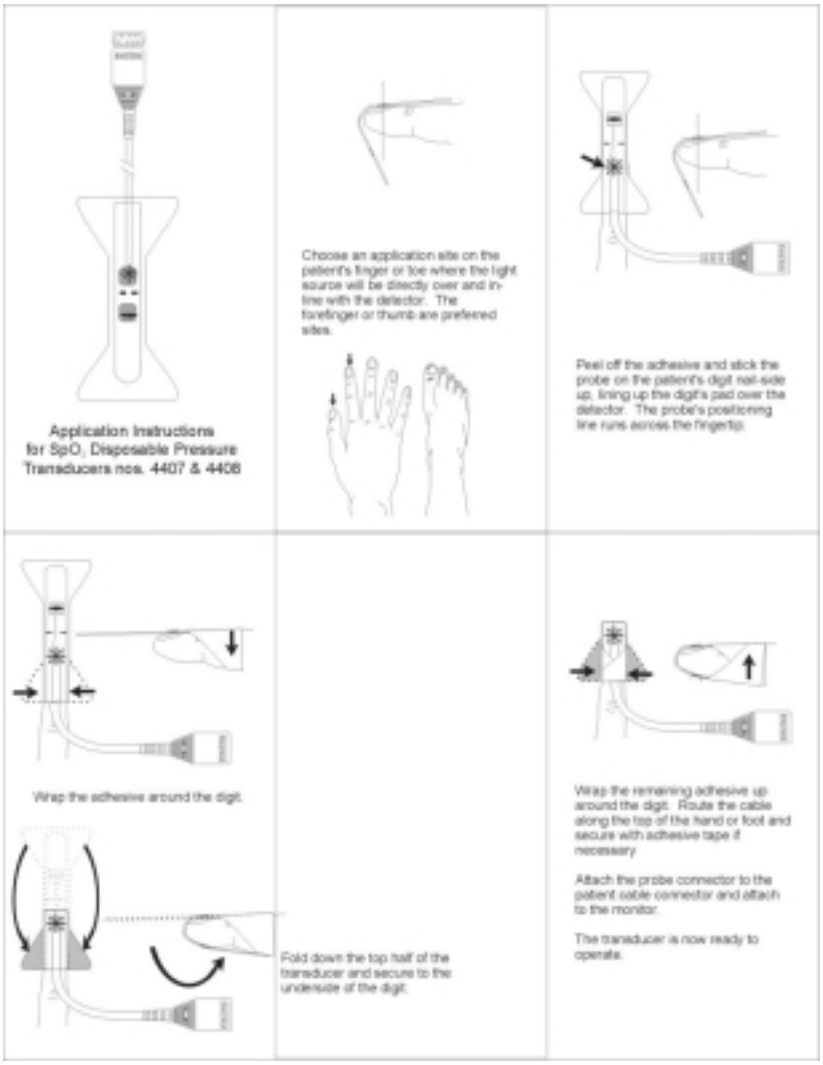
Line up the light source side with the detector side, so the source and detector are in the same plane. Secure the wrap probe and cable with Microfoam® tape, being careful not to over tighten the tape.

Application of the Disposable Adult Wrap Probe Order # 4588 and Disposable Pediatric Wrap ProbeOrder # 4589

Step 1: Choose an application site on the patient's finger or toe where the light source will be directly over and in-line with the detector (as shown to the right).

Step 2: Peel off the adhesive backing and place on the patient's foot or hand.

Step 3: Then fold down the top half of the transducer and secure to the underside of the foot or hand, making sure that the emitter lights align properly.



Step 4: Finally, route the cable along the top of the hand or foot and secure with adhesive tape if necessary.

C. SpO_2 Monitoring

1. OPERATING INSTRUCTIONS

a. Connect the patient extension cable to the receptacle on the side panel of the monitor.

b. Select an SpO_2 transducer based on application requirements and connect the appropriate probe to either the patient extension cable or directly to the monitor. (Refer to the illustration of SpO_2 accessories for the correct probe application on the previous pages.)

c. Turn the **POWER** switch on the front panel to "on". When powered up, all display digits will momentarily show "8" to give visual assurance that the display is fully functional.

d. Set alarms according to instructions listed previously in Section 4 of this manual.
The monitor will immediately proceed to continuously monitor the SpO_2. The percentage of oxygen saturation is averaged over eight beats and the pulse rate is averaged over eight seconds.

The LED bar graph will indicate the SpO_2 pulse signal strength with variable height display.

The pulse beep sounds as each pulse beat is detected. When a drop in SpO_2 value is detected, a lower beep tone will sound. The volume of the SpO_2 tone and other non-alarm sounds can be adjusted by the **SOUND** knob located on the side panel.

2. CAUTIONS AND WARNINGS

 Stretching the Microfoam® tape and attaching the tape too tightly to the skin may generate inaccurate readings and cause blisters on the patient's skin. Lack of skin respiration, not heat, causes the blister.

 Reposition the probe to another site at least once every 18-20 hours (maximum 24 hours) to allow the patient's skin to respire.

 Loss of pulse signal can occur if:
the sensor is too 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, or
the patient experiences shock, hypotension, severe vasoconstriction, severe anemia, hypothermia, arterial occlusion proximal to the sensor, or cardiac arrest.

 Inaccurate measurements may be caused by:
incorrect application or use of a sensor,
significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin,
significant levels of indocyanine green, methylene 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 pulsations
electrosurgical interference, or

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. Pulse Beep

The monitor is programmed to beep with each pulse signal.

The volume of the SpO_2 pulse beep can be adjusted but it cannot be turned off.

The pulse beep varies in pitch to reflect the increase or decrease in oxygen saturation, rising and falling proportionately as saturation increases and decreases.

SECTION 8 - PRINTER OPERATION

A 27 column thermal printer is available for use with the VITALMAX 530 and will produce a hard copy of the patient's vital signs, time, and date.

A. Printer Operation

1. RECOMMENDED THERMAL PAPER

Thermal paper can vary considerably in thermal sensitivity and abrasiveness. Using the proper thermal paper helps to ensure that the print quality will be acceptably dark and reduces print-head wear. The recorder's warranty may be limited if an unspecified paper is used.

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

Thermal Printer Paper - 27 Column (4 rolls) Order No. 3006

Thermal paper should be stored in the dark at an average ambient temperature of less than 25° C and a relative humidity of less than 65%. Under these conditions, the paper remains printable for at least 5 years. Also printed paper, when stored under these conditions, will retain its printed image legibility for a minimum of 7 years.

2. LOADING THE PAPER

Cut the end of the paper horizontally as shown in Illustration 9-a.

To open the paper holder, place your thumb on the paper holder cover and pull the cover up and back as shown in Illustration 9-b.

Insert the tip of the paper into the insertion slot and press the **PAPER FEED** pushbutton. (The outside of the thermal paper is in the front.). Insert the paper as shown in illustration 9-a. Keep the **PAPER FEED** pushbutton depressed until the end of the paper comes out of the paper cutter.

Illustration 9-a

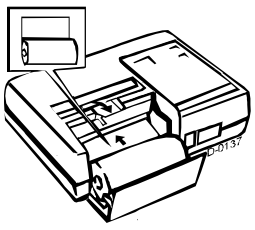
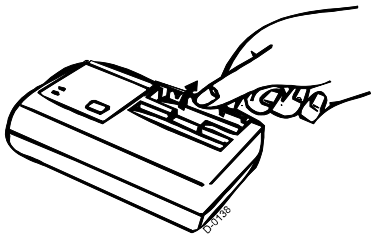


Illustration 9-b



B. Printing Mode Options

1. TO PREPARE FOR USE

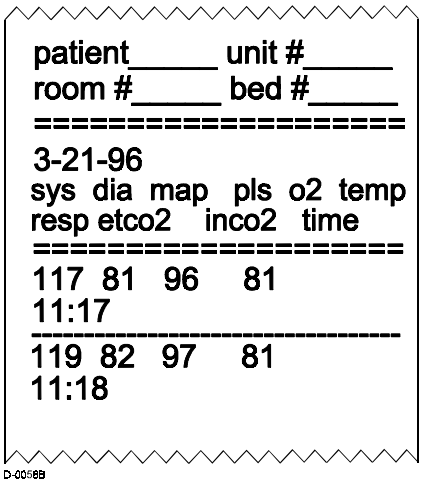
Attach the connectors of the printer cable to the receptacles on the back of the printer and on the rear panel of the monitor.

Turn ON the power to both the printer and the monitor.

Remember to turn OFF the printer whenever the monitor is turned OFF so the printer will not deplete the battery of the monitor.

2. TO PRINT IN REAL TIME

In order to obtain a print-out during the entire monitoring period, turn the printer ON at the beginning of the patient monitoring procedure. When the AUTO pushbutton is pressed, all parameters will be automatically displayed at the end of each determination cycle. Up to 250 readings can be printed.



3. TO PRINT ONLY AT CONCLUSION OF MONITORING

The printer should be in the OFF position during the Auto Print monitoring period. Then, at the end of the patient monitoring procedure, but before the monitor is turned off, turn the printer ON. Previously collected data, which has been stored in the unit, will then be down-loaded to the printer, providing one set of vitals for each programmed cycle.

4. TO OBTAIN A DUPLICATE PRINTOUT

In order to obtain a duplicate copy of the printout (whether option 2. or 3. above was used), with the monitor still ON, turn the printer OFF, then turn the printer back ON again. A duplicate copy of the original vital sign data will be printed.

⚠ As long as the monitor is not turned off, all programmed cycle data will remain stored in the unit; turning the monitor off clears the monitor's memory of all information.

⚠ The printer operates from the battery of the monitor. Remember to turn the printer OFF when the monitor is turned OFF so the printer does not deplete the battery of the monitor.

APPENDIX I - PRODUCT SPECIFICATIONS

A. MECHANICAL DESCRIPTION

Size	2.25" H x 5.5" W x 8.25" D (5.72 cm x 13.97 cm x 20.96 cm)
Weight	3 lbs 11.7 oz. (1.67 kg)

B. POWER REQUIREMENTS

Operation	AC/DC
Internal battery	6 V 3.3 AH sealed lead-acid
Battery operating time	2-2.5 hours full charge
Battery charge time	8-10 hours
Fuses	Two 3.0A, 250 V, Fast Blow

C. PERFORMANCE SPECIFICATIONS

PULSE OXIMETRY (SpO2)

Saturation range	0-100%, adult/pediatric/neonate
Saturation averaging	8 beat average
Saturation accuracy	±2% (70-100)±3% (50-69%), (0-49% unspecified)
Saturation alarm limits	Upper: 100% Lower: 0-99%
Pulse rate range	30 – 254
Pulse rate averaging	8 second average
Pulse rate accuracy	±2 % @ 30 - 100 bpm
Pulse alarm limits	Upper 0-250 bpm Lower 0-249 bpm
Pulse tone	Pitch adjusts with SpO2
Volume adjustable	
Pulse rate display	
Digital, pulse amplitude	
Sensor types	Finger, Universal "Y", ear lobe clip, disposable and reusable wrap probes

D. DISPLAYS

Parameters	High intensity red LED 0.3/0.4"
Pulse strength	10 segment logarithmic red LED bar graph
Signal Indicators	Yellow and green signal LED

E. PRINTER

Type	Add-on 27 column thermal printer

Output	ASCII parallel
Printing width	46mm
Printing speed	Approx. 0.8 lines per second
Paper requirements	Thermal printer paper 7m (L) x 58mm (W) 25mm roll diameter

F. ENVIRONMENT SPECIFICATIONS<

Temperature	
Operating	40ø F-110ø F (4.4ø C-43.3ø C)
Relative humidity	
Operating	20-80% (non-condensing)

SPECIFICATIONS SUBJECT TO CHANGE WITHOUT NOTICE.

APPENDIX II - BATTERY OPERATION

A. Battery

The monitor is equipped with an internal battery, 6V/ 7.0 AH sealed lead acid. This allows the monitor to operate for up to 6-8 hours under its own power.

The battery is continuously charged whenever the AC power is connected to the monitor. Charging time when the battery is fully discharged is between 15 and 20 hours.

Continuous charging will not harm the battery's expected service life with daily on-battery use.

The **LO BAT** LED indicator lights up when the battery is discharged and should be charged with AC current. Do not turn the monitor on after the **LO BAT** LED indicator is lit without first connecting it to AC main power.

B. Power Supply

The internal battery of the monitor is charged with an AC adapter. Two AC adapters are available in order to allow the battery to be charged from AC input voltage either 110-120V / 50-60 Hz or 220-240 / 50-60 Hz.

CAUTION: Equipment damage may result if an incorrect power supply is used.
Excessively long power cords may affect the safety and effectiveness of the delivered power.

Be sure the power cord is suitably heavy-gauged and rugged for the application. Avoid a light-gauge power cord sharing a heavy load.

Replace an old, worn damaged, or kinked power cord with a new one suited for the application.

C. Charging the Battery

Recharging is more rapid if it is done soon after on-battery use and even more so if the monitor is not turned on while charging.

1. Connect the AC Adapter to the receptacle on the rear panel of the monitor. Plug the power cord into a 100-250V / 50-60 Hz AC current, using a hospital grade (USA) grounding receptacle.

2. Verify that the AC ON LED comes on and stays on brightly and continuously after connecting to the power outlet. An unusually dim AC ON LED may indicate that the AC power is weak at the outlet. Unusual brightness may indicate excessive voltage. Either condition merits a checkup by a qualified technician.

3. After the battery has been charged, unplug the power cord, and turn the monitor on. If the display lights up and the number "8" appears momentarily, the monitor should be fully charged and is ready for normal operations.

Be aware that any power connection that is often cycled or flexed over an extended period of time will eventually wear out and thereby become unreliable or dangerous.

D. Optimizing The Battery Life

1. DISCHARGE CYCLES AND DEPTH

Each discharge cycle advances the battery's age, in particular a deep discharge. Try to avoid deep discharges of the battery.

Try to charge the battery at every suitable opportunity, preferably before the LO BAT LED comes on.

2. TEMPERATURE

Heat also accelerates the battery's aging, becoming quite significant above 86ºF (30ºC).

Avoid storing the monitor in sun-exposed compartments. It is preferable to store the monitor in a cool environment.

3. STATE OF CHARGE

A fully charged battery ages more slowly than a discharged batterry. Charge the monitor promptly after using it on-battery.

If the monitor stands discharged for an extended period of time (days), the battery capacity may take either several charge/discharge cycles or an extended charge time (several days) to fully recover.

4. EXTENDED IDLE TIME

Continuous charging will not harm the battery's expected service life with daily on-battery use.

However, if the monitor is not going to be used for a long period of time (weeks or months), charge with the power switch turned "off" for about 16 hours. Then unplug the AC power and store the monitor in a cool dry area, protected from dust.

At least every month charge the battery for about 16 hours. When use is anticipated, again charge the battery about 16 hours in advance to develop full available charge.

While in storage protect the power switch from accidental activation. If the battery were to become discharged this way for an extended time (weeks), it would permanently lose capacity.

E. Battery Disposal

 This is the universal symbol which indicates that proper disposal is required for the lead-acid battery. Do not throw the battery in the trash or incinerate the battery. The lead acid battery should be placed in the recycling bin.

F. Fuses

The monitor is equipped with two fuses which are located on the rear panel. Designated F1 and F2, each fuse protects a different power input.

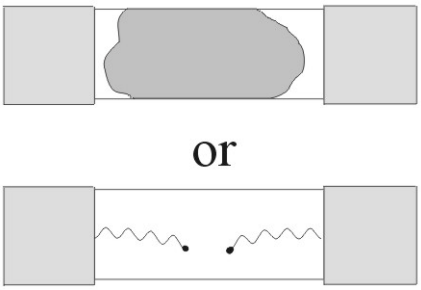
F1 

This fuse protects the internal battery. If this fuse is blown, the monitor will continue to operate on the AC Power supply. Battery operation is not possible until the fuse is replaced.

F2 

This fuse protects the AC Power supply line. If it is blown, themonitor can continue to operate under battery power. However, the battery cannot be charged until this fuse is replaced.

To determine if a fuse is blown, look to see if it has a grey, dark, or shiny coating on the inside of the glass portion, or if the wire is broken, distorted, or melted, as illustrated to the right.

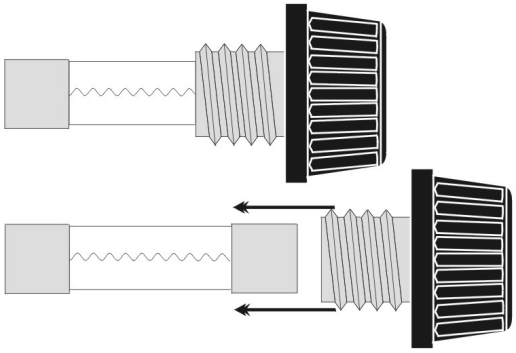


To replace a blown fuse, follow these instructions.

1. Turn the fuse holder counter-clockwise until it comes free and remove it from the monitor's rear panel.

2. Remove the fuse from the fuse holder and replace it only with a 3.0A 250V fuse,fast blow.

3. Insert the fuse holder back into the rear panel and turn it clockwise until it is snug.



APPENDIX III - MAINTENANCE

A. Monitor

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

WARNING: Electrical shock and flammability hazard - always turn the monitor off and disconnect it from AC main 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 disinfection 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 disinfection/sterilization process is completed. 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.