WARNINGS AND CAUTIONS

WARNING

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

WARNING

The OXYSHUTTLE+ 2 Pulse Oximeter should only be operated from a Critikon-approved power converter. Use of non-approved devices may cause a hazard to the patient or operator and can damage the OXYSHUTTLE+ 2 Pulse Oximeter.

WARNING

The OXYSHUTTLE+ 2 Pulse Oximeter should be operated from its internal battery if the integrity of the grounded, hospital-grade electrical outlet is in doubt.

WARNING

Do NOT incinerate or mutilate the battery. It may burst or release toxic materials.

WARNING

The OXYSHUTTLE+ 2 Pulse Oximeter should be operated from its internal battery if electrocautery devices are to be used on the patient.

WARNING

To prevent a shock hazard during maintenance operations, unplug the power converter from the ac power source and turn the instrument off before performing any of the operations described in Section Four of this manual.

WARNING

Possible explosion hazard if used in the presence of flammable anesthetics.

CAUTION

Operating electrocautery devices near the OXYSHUTTLE+ 2 Pulse Oximeter may cause false output readings because of electrical interference. The instrument will recover and give correct readings when the source of the interference is removed.

CAUTION

High levels of carboxyhemoglobin or methemoglobin may decrease accuracy of the oxygen saturation measurement. Cardiac dyes or other dyes that change arterial pigmentation may also decrease instrument accuracy.

CAUTION

The display screen is covered with an antiglare coating. Do not use abrasive cleaners or solvents that may scratch the surface.

CAUTION

Do not soak the sensor in any liquid cleaning solution,

CAUTION

Do not autoclave the sensor.

CAUTION

High ambient light levels may interfere with the proper measurement of oxygen saturation and cause displayed numbers to be suspect. If a high output light source (special procedure lamp, bilirubin light, for example) must be used in the vicinity of the sensor, note the value of oxygen saturation displayed with the light on and off. if a difference is noted between measured levels, the sensor should be shielded from the light source by wrapping opaque material around it.

CAUTION

Do not scratch the Omni-Sat^{+} Sensor's clear optical surfaces. To protect it, keep the sensor cable and the system cable coiled.

Do not strain the sensor cable. The internal conductors may be crimped or broken by rough handling.

 - ATTENTION - Consult accompanying documents.

 - Type BF

SpO_2 - Oxygen Saturation Value

BPM - Heart Rate, Beats per Minute

CE
0086

Manufactured by :-
Critikon Inc.
Imperial House
Celtic Lakes
Newport
Gwent
NP1 9UH
UK

WARRANTY

Your instrument, covered by the warranty enclosed with this shipment, has been carefully made and rigidly inspected to ensure that it will conform to the high standards of accuracy and dependability characteristic of all Critikon instruments. if property used and maintained, the instrument should give superior service for many years.

SHIPPING DAMAGE

Each Critikon instrument is carefully examined and checked before it is shipped. Visually and operationally check your instrument as soon as it is received. if it is damaged in any way, you must file a claim with Critikon. In the event of shipping damage, save the packing material and cartons. Call the Critikon Service number (below). A Critikon representative will contact the freight carrier claims agent and coordinate repair or replacement of the damaged equipment.

CRITIKON SERVICE

in the UK call: Johnson &Johnson Professional Products Ltd.
CRITIKON DIVISION
The Braccans, London Road
Bracknell, Berkshire RG 12 2AT
Tel: 03 44 - 86 40 90
Fax: 03 44 - 86 40 91

in Germany call: Johnson &Johnson Professional Products GmbH
CRITIKON
Aspelohe 27
22848 Norderstedt
Tel: 040 - 528 66-00
Fax: 040 - 528 66-490

in France call: Johnson & Johnson Santé S.A.
CRITIKON DIVISION
1. Centrale Parc, Avenue Sully-Prudhomme
92298 Chatenay - Malabry Cedex
Tel: (1) 40 91 28 10
Fax: (1) 40 91 28 11

IMPORTANT NOTICE

Critikon maintains responsibility for the effects on safety, reliability and performance of the equipment only if:

Assembly operations, extensions, readjustments, modifications or repairs are performed by Critikon-authorized personnel;

The electrical installation of the facility complies with the electrical code requirements of the local governing agency;

The equipment is used in accordance with the instructions for use.

CONTENTS

FIGURES

TABLES

1.1 DESCRIPTION

The Critikon OXYSHUTTLE+ 2 Pulse Oximeter is a non-invasive instrument for continuous monitoring of arterial blood oxygen saturation (SpO_2) and pulse rate. The instrument uses the principle of light absorption to determine percent oxygen saturation.

The OXYSHUTTLE+ 2 Pulse Oximeter (Figure 1-1) is a small, lightweight unit that functions as a stand-alone, real-time pulse oximeter. The unit may be operated from an ac power source using the external power converter or from an internal battery. The battery will power the OXYSHUTTLE+ 2 Pulse Oximeter for up to 12 hours.

The OXYSHUTTLE+ 2 Pulse Oximeter uses a full range of semi-disposable and reusable sensors.

The OXYSHUTTLE+ 2 Pulse Oximeter instrument tests itself at power-up and uses extensive diagnostic checks to monitor system performance during instrument operation. Should an error be detected, the OXYSHUTTLE+ 2 Pulse Oximeter will provide an audible warning and other information to assist in correcting the problem.

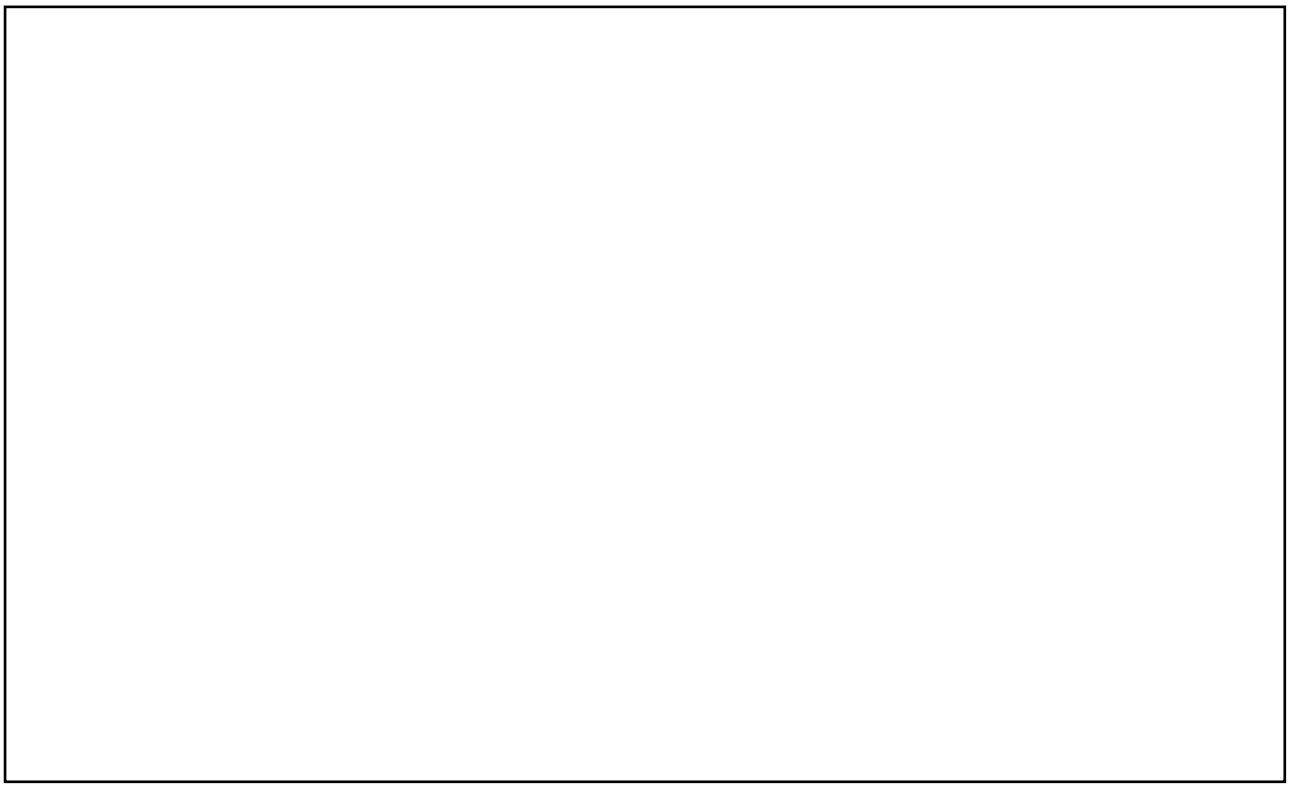

Figure 1-1 OXYSHUTTLE+ 2 Pulse Oximeter

1.2 OPERATING FEATURES

Figures 1-2 through 1-4 show the operating controls and features of the OXYSHUTTLE+ 2 Pulse Oximeter instrument. These are described in Tables 1-1 and 1-2.

Figure 1-2 OXYSHUTTLE+ 2 Pulse Oximeter Display (Table 1-1)

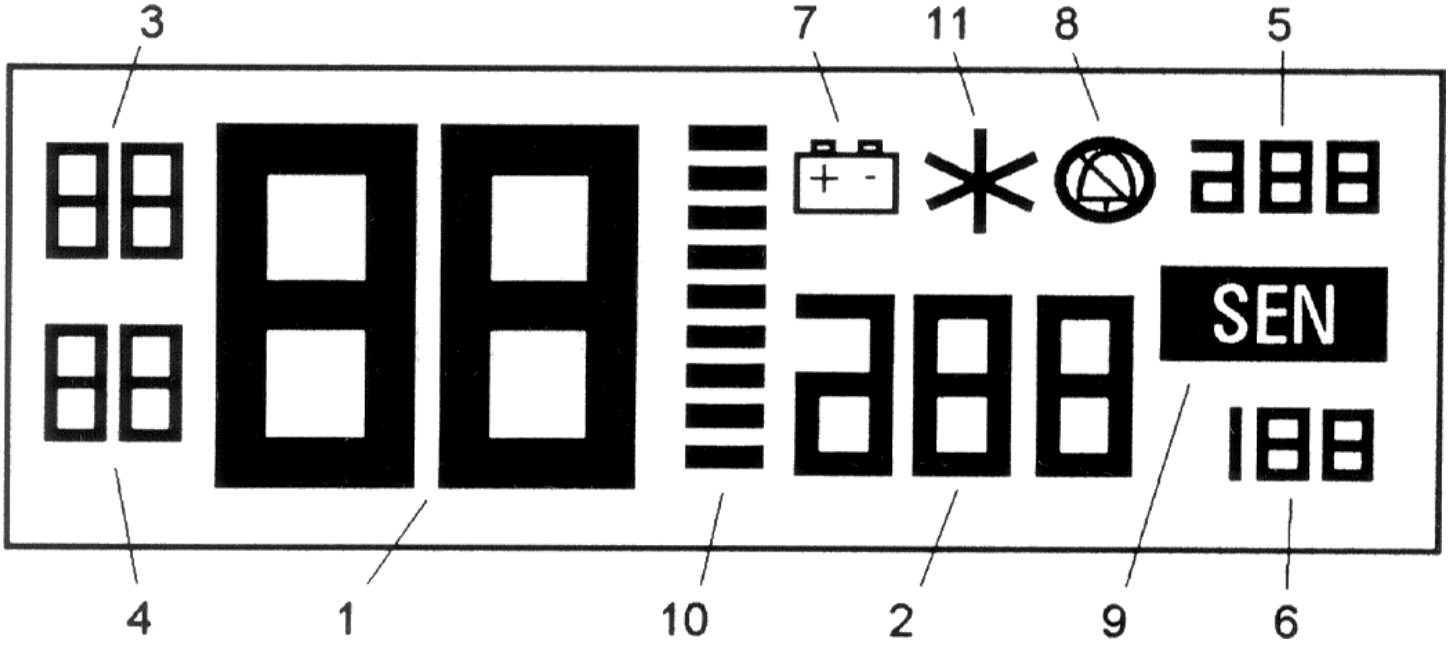

Table 1-1 OXYSHUTTLE+ 2 Pulse Oximeter Display

1 SpO_2	During normal operation, SpO_2 is displayed continuously in percent.
2 BPM	During normal operation, pulse rate is displayed continuously in beats per minute (bpm).
3 SpO_2 High Alarm Limits	Displays high oxygen saturation alarm limit setpoint.
4 SpO_2 Low Alarm Limits	Displays low oxygen saturation alarm limit setpoint.
5 Pulse Rate High Alarm Limit	Displays high heart rate alarm limit setpoint.
6 Pulse Rate Low Alarm Limit	Displays low heart rate alarm limit setpoint.
7 Battery	Illuminates when the power converter is not connected. Flashes when the battery requires recharging.
8 Alarm Inhibit	Flashes once per second (slow) when audible alarms are temporarily disabled. Flashes 4 times per second (fast) when alarms are disabled.
9 Sensor Symbol	illuminates when the sensor is not connected. Flashes when a sensor error has been detected.
10 Pulse Bar	Provides relative indication of signal strength during patient monitoring.
11 Asterisk	Reserved for future use.

Table 1-2 Front Panel Controls and Indicators

12 0/1	Controls power to the OXYSHUTTLE+ 2 Pulse Oximeter. Press quickly and release to turn the power on and off. Press and hold for 2 seconds to disable the pulse tone.
13 Alarm Inhibit Key	Inhibit audible alarm for a 2-minute period. If pressed while alarm is inhibited, will reenable alarm. Press and hold for five seconds to disable audible alarms (warning tone sounds every 3 minutes). Press and hold for five seconds again to reenable audible alarms.
14 ALARM LED	Visual indication of high or low SpO_2 alarm setpoint violation and quality alarm.
15 Step Key	Press the up or down portion of the key to change the selected limit in the indicated direction. Hold the key down to rapidly change the limit value. The Low Limit value is automatically adjusted to maintain a minimum separation of 5 between the Low and High Limits. Press the up or down portion of the key in Average Interval Adjust Mode to adjust the Averaging Interval to one of three predefined intervals (6, 12, 18 seconds).
16 Select Key	Press the key to select the alarm limit or other selection to change. The selected alarm limit will flash 4 times per second to indicate that it is selected. Repeated presses of the Select Key will cycle from SpO_2 Low Limit to SpO_2 High Limit, to Pulse Rate Low Limit, to Pulse Rate High Limit, to “H” for Heart Tone, to “A” for Averaging Interval, and back to off.

Figure 1-4 Rear Panel Features (Table 1-3)

Table 1-3 Rear Panel Features

1	POWER CONVERTER	Input connector for the supplied power converter connector that allows line powered operation.

1.3 SYSTEM SPECIFICATIONS

1.3.1 Oxygen Saturation (SpO_2)

- Measurement Range: 0 - 99% SpO_2
- Accuracy: ± 2%; 70-100% SpO_2
  Not specified; 0-70% SpO_2
- Noise: ± 1% SpO_2
- Averaging Interval: 6, 12, 18 seconds, user selectable

1.3.2 Heart Rate

- Measurement Range: 30-250 beats per minute
- Accuracy: ± 1 bpm
- Averaging Interval: 6, 12, 18 seconds, user selectable

1.3.4 MECHANICAL SPECIFICATIONS

- Size
  H x W x D: 3.5 x 10 x 9 in. (8.9 x 25.4 x 22.9 cm)
- Weight: 3.7 lb.(1.68 kg)
- Environmental
  Temperature
  Operating: 15 to 40C
  Storage: -29 to 50C
  Humidity: 85% max., non-condensing
  Duty Cycle: continuous

SECTION TWO
INSTALLATION

2.1 UNPACKING INSTRUCTIONS

Carefully unpack the carton and place the contents on a dear work area. Inspect the parts for shipping damage. If you feel damage has occurred, stop unpacking and follow the instructions at the front of this manual under "Shipping Damage".

Compare the contents of the box with the packing list. If any discrepancies are noted, call Critikon Service.

2.2

SPACE REQUIREMENTS The OXYSHUTTLE+ 2 Pulse Oximeter is very compact; it measures 3.5 in. high, 10 in. wide and 9 in. deep (9x25.2x22.7 cm). If the OXYSHUTTLE+ 2 Pulse Oximeter is to be operated while attached to the power converter, a grounded, hospital-grade electrical outlet should be within 7 feet (2.1 meters) of the instrument.

2.3

ELECTRICAL REQUIREMENTS

The internal battery will operate the unit for a minimum of 12 hours before recharging is required. The power converter supplied with your OXYSHUTTLE+ 2 Pulse Oximeter allows for continuous operation while recharging the battery system. The power converter should only be plugged into a grounded, hospital-grade electrical outlet. Power required is 3 watts, maximum. Power converters are available to operate at line voltages of 100 Vac, 120 Vac, 220 Vac and 240 Vac with appropriate country specific plugs.

SECTION THREE
OPERATION

3.1

LEARNING TO USE THE OXYSHUTTLE+ 2 PULSE OXIMETER

Before operating the OXYSHUTTLE+ 2 Pulse Oximeter, read this section carefully. It gives all the operating procedures in sequential order. it will also alert you to any necessary precautions.

WARNING

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

Table 3-1 is a summary of routine system operations. When you have become familiar with instrument functions, use this table as a quick reminder for routine steps.

TABLE 3-1 OPERATING INSTRUCTIONS

Action	Paragraph
-STARTUP	
Connecting the Sensor	3.2.1
Turning The Unit On And Off	3.2.2
- USER CUSTOMIZATION	3.3
- SENSOR APPLICATION	3.5
- PATIENT MONITORING	3.6
- ALARM REPORTING	3.7

3.2 SYSTEM STARTUP

3.2.1 Connecting the Sensor

Insert the cable connector into the mating connector on the system cable by aligning the locator tabs on both connectors and pressing the cable connector gently into the system cable connector.

SYSTEM STARTUP

CAUTION

Do not scratch the Omni-Sat+ Sensor's dear optical surfaces. To protect it, keep the sensor cable and the system cable coiled.

Do not strain the sensor cable. The internal conductors ma crimped or broken by rough handling.

3.2.2 Turning The Unit On And Off

The unit is powered on by pressing the 0/1 key once. The unit will perform system diagnostics including a display test and then beep once to indicate that audible signals are active and that it is ready for operation.

The user set alarm limit values are retained while the Unit is turned off as long as the battery does not fully discharge. If the battery ever becomes fully discharged, the previously set alarm limit values may be lost. In this case the unit will reset to these default values:

	SpO_2	Pulse Rate
Low Limit:	85	50
High Limit:	99	120

3.3

USER CUSTOMIZATION

3.3.1 Pulse Tone Feature

An audible pulserate indication corresponding to the measured pulse rate is available. The pitch of this pulse tone is proportional to the SpO_2 value, thus allowing detection of changes in SpO_2 levels without watching the display.

The pulse tone may be disabled by holding down the 0/1 key for two seconds. The pulse tone will be enabled by default when the unit is turned on normally. To view or change the volume level, press the Select Key 5 times. The display will blank except for a large “H” and the Pulse Bar that will show the currently selected volume level. The volume level can be adjusted using the Step Key

3.3.2 Alarm Limits

The unit allows the user to select both high and low alarm setpoints for SpO_2 and Pulse Rate via front panel buttons. The alarm limit ranges are:

	SpO_2	Pulse Rate
Low	0,60-94	0,30-199
High	65-99	35-250

The user may change high and low alarm limits at any time during normal operation. The user must first press the Select Key to select the alarm limit to change. The selected alarm limit will flash 4 times per second to indicate that it is selected. Repeated presses of the Select Key will cycle from SpO_2 Low Limit to SpO_2 High Limit, to Pulse Rate Low Limit, to Pulse Rate High Limit, and back to off. Pressing the up arrow on the Step Key will increase the selected Alarm Limit. Pressing the down arrow on the Step Key will decrease the selected Alarm Limit. The allowed values for the SpO_2 High Limit are 65-99. The allowed values for the SpO_2 Low Limit are 0, 60-94. The allowed values for the Pulse Rate High Limit are 35-250. The allowed values for the Pulse Rate Low Limit are 0, 30-199. The unit will automatically adjust the limits to maintain a difference of at least 5 units.

The SpO_2 High Limit is disabled whenever the high limit is set to 99. The Pulse Rate High Limit is disabled whenever the high limit is set to 250. Either Low Limit is disabled whenever the low limit is set to 0.

Pressing and holding either the up arrow or down arrow on the Step Key will cause the selected Alarm Limit to continue to increment or decrement. The rate of change will increase if the key is held down.

if either measured value falls outside the low or high limits, the unit will signal an alarm condition by blinking a red alarm LED once per second. If the measured value remains outside the limits for more than 9 seconds, the audible alarm will sound. The audible alarm is a high-low-high sequence to distinguish it from pulse tones. The alarm inhibit button disables the audible alarm for 2 minutes. if the alarm inhibit button is pressed a second time, the audible alarm will be immediately reactivated.

3.3.3 Averaging Interval

The interval over which pulses are averaged for calculating SpO_2 and pulse rate is selectable over time periods ranging from 6 seconds to 18 seconds in 6-second increments. The default averaging interval is 12 seconds that is optimum for most monitoring conditions. Certain patients may require longer or shorter measurement intervals depending on circumstances. To view or change the averaging interval, press the Select Key 6 times. The display will blank except for a large “A” and the SpO_2 display that will show the currently selected interval. if no other action is taken, the monitor will exit the Averaging Interval Adjust Mode in 2 seconds.

To change the interval, press either the up or down portion of the Step Key within the 2-second period. The monitor will exit this mode and return to the monitoring mode automatically 2 seconds after the last keypress. When the monitor is powered off, the selected Averaging Interval is retained in memory.

3.4 USE OF THE OXYSHUTTLE+ 2 PULSE OXIMETER

Once the alarm limits are set you are ready to begin patient monitoring.

3.4.1 SYSTEM POWER SOURCES

The primary source of power for the OXYSHUTTLE+ 2 Pulse Oximeter is a Nickel Cadmium battery. An ac power supply/ battery charger is also provided. The external power pack will charge the battery while the Oximeter is on or off. The internal battery will allow operation of the Oximeter for a minimum of 12 hours and will recharge in 14 to 16 hours.

WARNING

The OXYSHUTTLE+ 2 Pulse Oximeter should only be operated from a Critikon-approved power converter. Use of non-approved devices may cause a hazard to the patient or operator and can damage the OXYSHUTTLE+ 2 Pulse Oximeter.

3.5 SENSOR APPLICATION

The Omni-Sat+ Sensor family includes a dedicated Finger Sensor, soft flexible semidisposable Neonatal and Adult sensors and an Ear sensor.

The Omni-Sat+ Oximeter Sensor family is designed especially for easy and practical monitoring of oxygen saturation on adult, pediatric, and neonatal patients in a variety of conditions on various patient sites. When spot checks of SpO_2 values are needed or when limited hand movement is expected, a finger sensor may be used on pediatric and adult patients. Flexible sensors are suggested for applications where the sensor will be applied for extended periods of time or when monitoring sites other than adult or pediatric fingers are used. The Omni-Sat+ Ear Sensor is especially useful in sleep or exercise labs or on patients who cannot tolerate a finger sensor.

The patient monitoring site should be well perfused and selected for minimum movement. The site should be clean and free of any abnormal features that could cause absorption or scattering of light.

When using the finger as a monitoring site, fingernail polish and false nails should be removed. it may be necessary to trim fingernails before attaching the sensor because long fingernails may cause incorrect positioning of the sensor on the patient's finger.

The primary goal when using a flexible sensor such as the Omni-Sat' semidisposable sensor is to pick a monitoring site that allows the LED source and detector assemblies of the sensor to be aligned. These flexible probes allow the sensor to be secured to the patient, while permitting limited patient movement.

Follow the instructions in the following sections for determining the best application for each patient. if the sensor has been properly applied to an appropriate site on the patient, the instrument will begin to display SpO_2 values on the front panel and pulse tones will be heard. if insufficient light is reaching the detector, SpO_2 will not be displayed and the SpO_2 display will show dashes in the lower portion of the SpO_2 number area. If too much light is reaching the detector, the dashes will show in the upper portion of the SpO_2 number area. Adjust or reposition the sensor until values are displayed.

NOTE

Regardless of the means or area of sensor attachment, the sensor should be removed periodically so that the application site can be inspected for signs of any unusual reaction.

NOTE

Sensors should be cleaned and disinfected before each use (Refer to Section 4). Do not expose to temperatures above 120° F (48.8° C).

3.5.1 ADULT AND PEDIATRIC APPLICATION

The typical monitoring site for adults is a finger. The Omni-Sat+ Finger Sensor is available specifically for this application. The Omni-Sat+ Ear Sensor may also be used for monitoring on the ear of adult patients.

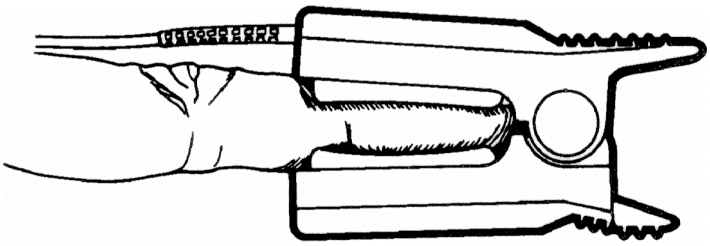

Figure 3-1 Placement of Finger in Finger Sensor

Using the Omni-Sat+ Finger Sensor. The Omni-Sat+ Finger Sensor is recommended for spot saturation measurements or for long- term monitoring where the finger is restricted from excessive motion. To use the Omni-Sat+ Finger Sensor, simply insert the patient's finger into the sensor as shown in Figure 3-1. The sensor cable should lie along the dorsal surface of the finger. insert the finger as far forward as it will go, to position the sensor source over the fingernail or nailbed. if you wish, especially whenever patient motion poses a problem, you may lightly tape the sensor cable to the finger or hand. Make certain that the tape does not impede circulation.

Applying The Omni-Sat+ Ear Sensor. Clip the sensor to the patient's earlobe with the cable exit in front of the car. The cable may be wrapped around the ear (Figure 3-2) or, when head motion is expected, may be looped up and under a soft terry cloth headband (Figure 3-3). For best results, before applying the sensor, gently massage the earlobe between two fingers for a minute or wipe with an alcohol wipe or a rubefacient to increase capillary perfusion at the monitoring site.

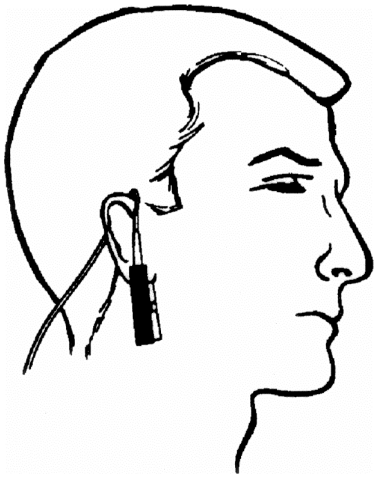

Figure 3-2 Ear Sensor with Cable around Pinna of Ear

Using The Omni-Sat+ Ear Sensor. The Omni-Sat+ Ear Sensor may also be used for monitoring oxygen saturation. Ear sensors are typically used on adults during general anesthesia or during sleep or exercise testing.

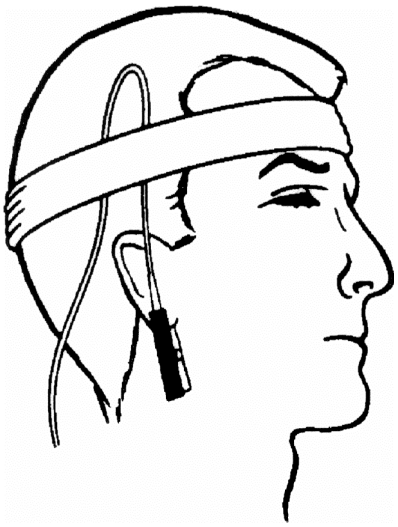

Figure 3-3 Ear Sensor with Cable Under Headband

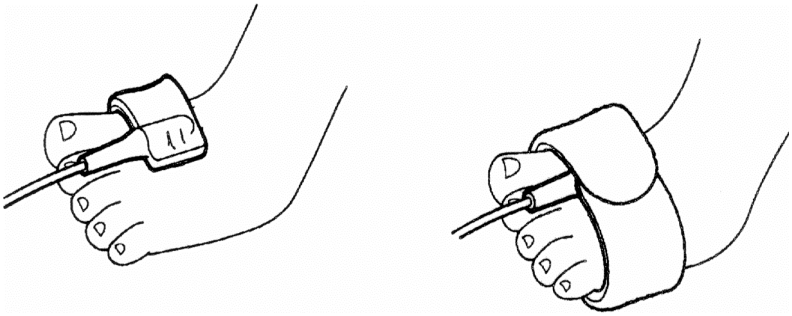

Figure 3-4 Applying the Semi-Disposable Sensor to infant

Using The Semidisposable Sensor. Soft flexible Semi-Disposable sensors are recommended for use on neonatal, pediatric and adult patients. These flexible sensors may be applied at various sites on patients, depending on body size and development. Frequently used areas on neonates include hands and feet, but other application sites may be used, including the dorsal surface of the leg. The most common site for use on pediatric and adult patients is the finger.

Applying The Semi-Disposable Sensor (see Figure 3-4 and 3-5).

a. Gently bend the sensor into a half circle or c-shape and carefully apply to the chosen patient site.

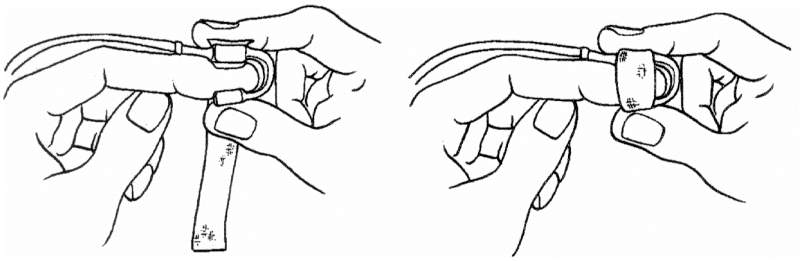

Figure 3-5 Applying the Semi-Disposable Sensor to Pediatric or Adult

b. Gently hold the sensor in place on the patient site and observe the instrument operation.

c. When the instrument begins to display numbers, the sensor has been properly applied. Adjust or reposition the sensor if needed.

d. Once the sensor is properly positioned on site, wrap the adhesive wrap around the sensor and sensor site.

e. The sensor should be removed periodically to inspect the application site.

3.6 PATIENT MONITORING

The bar graph display can be used as a measure of relative signal quality. The pulse bar tracks the signal strength of the absorption signal. A deflection of five segments indicates sufficient signal level to meet the accuracy specification. If a smaller deflection is obtained, it may be desirable to move the sensor to an area with better perfusion to increase the signal quality.

When the instrument has acquired a signal, an audible pulse will track the pulse rate. The audible pulse is triggered by the photoplethysmographic signal. The pitch of this pulse is proportional to the SpO_2 value, thus allowing detection of changes in SpO_2 levels without watching the display.

If no pulse signal is detected for approximately 12 seconds, the display will show clashes.

3.7 ALARM REPORTING

The instrument provides both audible and blinking visual alarms to alert the operator to out-of-limit operating conditions. Pressing ALARM INHIBIT will disable the audible alarm for a two minute period. If ALARM INHIBIT is pressed a second time, the audible alarm will be reenabled.

Press and hold the Alarm inhibit key for 5 seconds to disable the audible alarms. Alarms will remain disabled until the Alarm inhibit key is again held for 5 seconds or until the power is cycled on the monitor. The monitor will always power on with alarms enabled. The Alarms Inhibited icon on the display will flash once per second (slow) when alarms are inhibited for 2 minutes. The Alarms Inhibited icon will flash four times per second (fast) and a three beep audible signal will sound every 3 minutes when alarms are disabled.

The OXYSHUTTLE$^+$ 2 Pulse Oximeter constantly monitors the SpO_2 and Pulse Rate values to ensure that they are within set limits. An alarm will trigger whenever the calculated value falls outside the setpoints. A nine-second delay is provided on the audible alarm. This audible alarm consists of a "triple-beep" every two seconds.

NOTE

Setting the SpO_2 high alarm limit to 99 disables SpO_2 High Alarm limit checking. Setting the Pulse Rate high alarm limit to 250 disables Pulse Rate high alarm limit checking.

In addition to limit checking of the SpO_2 and Pulse Rate values, the instrument also monitors the signal quality level of the SpO_2 and Pulse Rate. A continuous tone called a signal quality alarm will activate whenever the measured pulse signal is of insufficient quality to allow calculation of SpO_2. Visual indication consists of dashes on the SpO_2 and Pulse Rate display. This tone will also sound if the instrument detects a disconnected sensor.

SECTION FOUR
ROUTINE MAINTENANCE

4.1 CLEANING THE INSTRUMENT

To clean the OXYSHUTTLE+ 2 Pulse Oximeter and Power Converter, wipe with a mild detergent. Wring applicator nearly dry before wiping. Do not allow solution to drip into the instrument. Do not spray cleaning solutions onto the front or rear panels.

WARNING

To prevent shock hazard during maintenance operations, unplug the power converter from the ac power source and turn the OXYSHUTTLE+ 2 Pulse Oximeter off before performing any of the operations described in this section of the manual.

CAUTION

The display screen is covered with an antiglare coating. Do not use abrasive cleaners or solvents that may scratch the surface.

Omni-Sat+ sensors should be cleaned before each use by wiping with an isopropyl alcohol pad or a mild detergent. To prevent scratching the sensor's optical surfaces, abrasive-cleaning solutions should not be used.

CAUTION

Do not soak the sensor in any liquid cleaning solution.

4.2 DISINFECTING THE INSTRUMENT

External surfaces of the OXYSHUTTLE+ 2 Pulse Oximeter and power converter may be disinfected by wiping with a sponge or cloth moistened with Cidex™. Do not allow solution to drip into instrument. Do not spray disinfectant solutions onto the front or rear panels.

CAUTION

Do not autoclave the sensor.

4.3 DISINFECTING THE OMNI-SAT+ SENSOR

The Omni-Sat+ Sensor may be disinfected using cold-sterilization techniques. The recommended procedure is to wipe the sensor and cable with an isoproponal wipe or an applicator moistened with Cidex™.

4.4 SENSOR MAINTENANCE

The sensors are designed as reusable components. Long-life operation can be achieved with proper care. Do not strain the sensor cable. Rough handling may crimp or even break the cable's internal conductors. When not in use, the sensor should be coiled and secured with the wrap provided. A sensor showing nicks or cuts in the cable should be replaced to prevent degrading electrical isolation.

4.5 USER PREVENTIVE MAINTENANCE

The OXYSHUTTLE+ 2 Pulse Oximeter and its accompanying power converter contain no operator-serviceable parts. The only user maintenance requirement is a

periodic inspection of the instrument to ensure safe and reliable operation. Sensor and power converter cables should be checked before each use to ensure their integrity.

If these inspections reveal a problem, the institution's service organization should be notified to correct the defect. A damaged instrument should never be put into service until appropriate repairs have been made by a qualified service person.

At least quarterly, a detailed safety inspection of the OXYSHUTTLE+ 2 Pulse Oximeter should be conducted by a biomedical service technician. The OXYSHUTTLE+ 2 Pulse Oximeter and power converter should be inspected for any external damage that could compromise patient safety. This should also include a close inspection of interconnecting cables for damage. in addition to the safety inspection, a check of instrument leakage current and withstand voltage should be made to ensure the OXYSHUTTLE+ 2 Pulse Oximeter complies with local regulatory requirements. Tests should be conducted with the OXYSHUTTLE+ 2 Pulse Oximeter operating from the power converter supplied with the instrument.

A service manual for the OXYSHUTTLE+ 2 Pulse Oximeter is available for use by qualified service personnel. The manual provides qualified individuals with information necessary to correct most instrument failures. Critikon and/or factory service information can be obtained from your local Critikon representative or by contacting Critikon directly.

The internal battery can be replaced by removing the seven screws on the bottom of the OXYSHUTTLE+ 2 Pulse Oximeter and then removing the cover.

WARNING

Do NOT incinerate or mutilate the battery. It may burst or release toxic materials.

The OXYSHUTTLE+ 2 Pulse Oximeter runs a continuous self-test to ensure proper operation.

SECTION FIVE
TROUBLESHOOTING

5.1 INSTRUMENT SELF-TEST

When the instrument is powered on, several diagnostic routines are automatically performed. These include checking the microprocessor, system memory and 1/0 control logic. The software version number is also displayed on the LCD during the power-on routine. in addition, during operation, the microprocessor continuously checks internal voltage and current levels as part of the on-going background tests. if the microprocessor detects an unacceptable deviation in any of the monitored parameters, an error condition is noted and the following occurs:

Normal system operation is suspended.

The instrument displays "F" along with a failure code.

The "Alarm" tone is sounded.

Pressing the Alarm inhibit key will silence the alarm. The cause of the error can be determined by referring to the Table 5-2. Make a note of this error code; you will need it and the software version number should you call Critikon Service for assistance. The instrument may be reset by turning the system off, then back on again. if the failure condition persists, call Critikon Service.

5.2 TROUBLESHOOTING

To assist in identifying problems and failures, the following troubleshooting guide, Table 5-1, is provided. The troubleshooting guide attempts to identify problems that might be experienced. Additional technical information for authorized service personnel may be obtained by contacting Critikon Technical Support Department.

5.3 SYSTEM ERROR CODES

When a failure condition is detected, the instrument displays an error code that can be used to diagnose the problem. Table 5-2 contains a list of failure codes and explanations.

Table 5-1 TROUBLESHOOTING GUIDE (SHEET 1 OF 2)

Problem	Possible Causes and Remedies
No display when power turned on	1. Battery discharged; connect external power converter. 2. Nondisplayable failure; call Critikon Service
No display when power turned on (Power converter connected)	1. Completely discharged battery. Allow up to 10 minutes to recharge to a minimum level. 2. No ac power at power converter. 3. Defective power converter. 4. Non-displayable failure; call Critikon Service
Short battery operating life; less than 12 hours.	1. Insufficient charge time; allow 16 hours for power converter to fully charge battery. 2. instrument left on battery power while not in use; turn unit OFF when not in use for long periods of time. 3. Defective or worn battery; replace.
SpO_2 display reads ı--ı after placing sensor on the patient	1. Improper sensor alignment. Check sensor alignment. See section 3.5. 2. Insufficient perfusion at site. Change sites. 3. Excessive high ambient light levels causing instrument to saturate. Shield sensor from ambient light.
Erratic SpO_2 Readings	1. Improper sensor alignment. Check sensor alignment. 2. Insufficient perfusion at site. Change sites. 3. Excessive high ambient light levels causing instrument to saturate. Shield sensor from ambient light.

Table 5-2 TROUBLESHOOTING GUIDE (SHEET 2 OF 2)

Problem	Possible Causes and Remedies
Sensor symbol illuminated but not flashing	1. Sensor disconnected. Reconnect sensor. 2. Rep ace sensor.
Sensor symbol flashing persists after sensor connect	1. Sensor error. Remove sensor and reconnect, 2. Replace sensor. 3. If the problem persists, call Critikon Service
Display shows IT 11011	1. Battery power drained. Check the connections between the OXYSHUTTLE+ 2 Pulse Oximeter and the Power Converter and check that the Power Converter is plugged into the wall.
Other FAILURE codes	1. System failure. Note the failure code number and turn the OXYSHUTTLE+ 2 Pulse Oximeter power off then back on using the key on the front panel. 2. if the problem persists, call Critikon Service

SECTION SIX
THEORY OF OPERATION

6.1 HISTORY OF METHODOLOGY

Measurement of arterial blood oxygen saturation is of diagnostic value and can aid the clinician in assessment of the efficacy of patient treatment. Historically, oxygen saturation has been measured by withdrawing a blood sample. following arterial puncture and analyzing the sample using multi-wavelength spectrophotometric means for determination of several species of hemoglobin. invasive procedures for obtaining the arterial samples are not, however, without risk of complications.

Non-invasive means for determination of arterial blood oxygen saturation have been available for a number of years. Until recently, however, they were not widely applied clinically, probably due to practical difficulties associated with their use. As size and complexity of devices and sensors have decreased, their clinical applications have increased and today non-invasive oxygen saturation measurements are routinely made in various patient groups. Ventilator setting changes may be made with results available to the clinician at once so that critically ill patients may be managed more effectively. During sleep studies, oximeters have been used to confirm the presence and severity of sleep apnea and nocturnal hypoxemia. The oximeter can be useful for detecting exercise-induced hypoxemia during cardiac and/or pulmonary stress testing. Continuous monitoring of patients undergoing surgical procedures requiring general anesthesia permits early detection of hypoxemia.

The Critikon OXYSHUTTLE^{+} 2 Pulse Oximeter is a new generation of arterial blood oxygen saturation monitors. It combines the simplicity and the ease of operation of pulse oximetry with a complete line of reusable and semi-disposable sensors. The OXYSHUTTLE^{+} 2 Pulse Oximeter uses new sophisticated signal gathering and signal processing techniques to function on patients who are otherwise difficult to monitor or who are in "noisy" environments.

6.2 INSTRUMENT OPERATION

The Critikon OXYSHUTTLE^{+} 2 Pulse Oximeter employs a sensor containing two light-emitting diodes that are located opposite a photo detector. The two wavelengths of light emitted by the LED's pass through the tissue at the application site. By analyzing the time-variant change in light transmitted through the tissue, pulsatile flow of blood through the arterial vascular bed during systole can be characterized as a photoplethysmographic waveform. The amplitude of the waveform is dependent on the magnitude of the change in the arterial pulse, the wavelengths or light energy utilized and the arterial blood hemoglobin saturation. Arterial blood oxygen saturation is calculated by analyzing the pulsatile waveform relative to the amplitude of detected light at each wavelength and applying Beer's law.

Since the OXYSHUTTLE^{+} 2 Pulse Oximeter considers only the pulsatile blood flow, there is no interference from non-pulsatile sample sources such as venous blood, cartilage tissue and bone. The OXYSHUTTLE^{+} 2 Pulse Oximeter also employs a patented technique for reducing the effect of movement on the oxygen saturation measurement.

7.1 PARTS AND SUPPLIES

OXYSHUTTLE+ 2 Pulse Oximeter	9101
Power Converter, OXYSHUTTLE+ 2 Pulse Oximeter (UK PlugX220 v/50 Hz)	9165
Power Converter, OXYSHUTTLE+ 2 Pulse Oximeter (Euro PlugX220 v/50 Hz)	9166
Power Converter, OXYSHUTTLE+ 2 Pulse Oximeter (US Plug)(120 v/60 Hz)	9167
Power Converter, OXYSHUTTLE+ 2 Pulse Oximeter (Table TopX220 v/50 Hz)	9092
Reusable Sensors:	
Omni-Sat+ Finger Sensor	9084
Omni-Sat+ Ear Sensor	9120
SemiDisposable Sensors:	
Neonatal Sensor	9130
Adult Sensor	9136