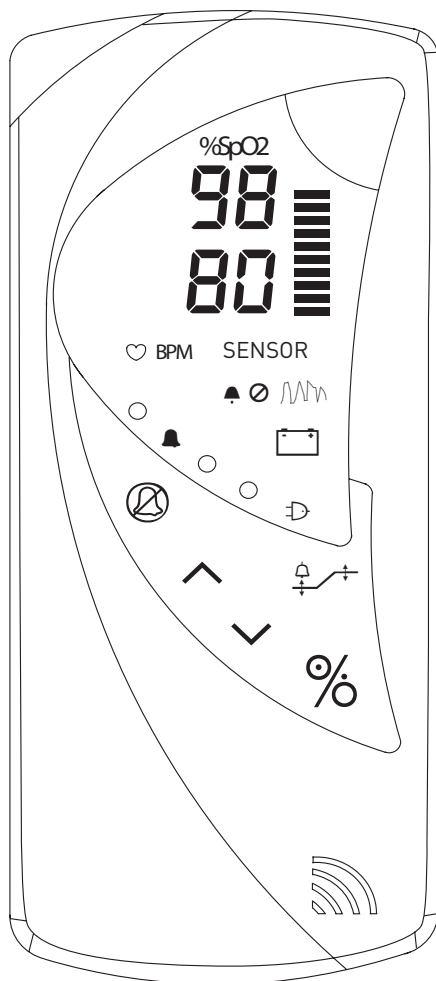


TM
SurgiVet

Veterinary V3402 HandHeld Digital Pulse Oximeter

Operation Manual



en English

Catalog Number V1896

Version 4, April 2008

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smiths medical

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The serial autocorrelation technology in the monitor is covered by U.S. Patent No. 5,558,096.

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Warranty and Service Information

Proprietary Notice

Information contained in this document is copyrighted by Smiths Medical PM, Inc. and may not be duplicated in full or part by any person without prior written approval of Smiths Medical PM, Inc. Its purpose is to provide the user with adequately detailed documentation to efficiently install, operate, maintain and order spare parts for the device supplied. All information contained in this document is believed to be current and accurate as of the date of publication or revision, but does not constitute a warranty.

Warranty

Limited Warranty

Smiths Medical PM, Inc. ("Seller") warrants to the original purchaser that the Product, not including applicable accessories, shall be free from defects in material and workmanship under normal use, if used in accordance with its labeling, for two years from the date of shipment to the original purchaser.

Seller warrants to the original purchaser that the reusable oximeter sensors supplied as accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with its labeling, for one year from the date of shipment to the original purchaser (USA only).

Seller warrants to the original purchaser that the AC Power supply/charger supplied, with the exception of part number 3005, shall be free from defects in materials and workmanship under normal use, if used in accordance with its labeling, for 1 year from the date of shipment to the original purchaser (USA only).

The foregoing shall be the sole warranty remedy. Except as set forth herein, seller makes no warranties, either expressed or implied, including the implied warranties of merchantability and fitness for a particular purpose. No warranty is provided if the products are modified without the express written consent of SMPM, Veterinary Division, and seller shall not be liable in any event for incidental or consequential damage. This warranty is not assignable.

Warranties are subject to change. Please contact Smiths Medical PM Inc. Veterinary Division, for current warranty information.

Loaner Device (Domestic Sales Only)

Smiths Medical PM, Inc. (SMPM) Veterinary Division, will for the period of warranty make available at no charge, loaner devices (domestic sales only) if in the opinion of SMPM Veterinary Division, the repair of the customer's device would require an unreasonable period of time to repair, and there is a suitable loaner available during the time of the repair.

SMPM Veterinary Division may make available loaner devices, for a fee, should it be requested while an out of warranty device is in for service. The customer is responsible for shipping the loaner device back.

Disclaimer of Warranties

THE FOREGOING EXPRESS WARRANTY, AS CONDITIONED AND LIMITED, IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Seller disclaims responsibility for the suitability of the Product for any particular medical treatment or for any medical complications resulting from the use of the Product. This disclaimer is dictated by the many elements which are beyond Seller's control, such as diagnosis or patient, conditions under which the Product may be used, handling of the Product after it leaves Seller's possession, execution of recommended instructions for use and others.

Conditions of Warranty

This warranty is void if the Product has been altered, misused, damaged by neglect or accident, not properly maintained or recharged, or repaired by persons not authorized by Seller. Misuse includes, but is not limited to, use not in compliance with the labeling or use with accessories not manufactured by Seller. This warranty does not cover normal wear and tear and maintenance items.

Limitation of Remedies

The original purchaser's exclusive remedy shall be, at Seller's sole option, the repair or replacement of the Product. **THIS IS THE EXCLUSIVE REMEDY. In no event will Seller's liability arising out of any cause whatsoever (whether such cause is based in contract, negligence, strict liability, tort or otherwise) exceed the price of the Product and in no event shall Seller be responsible for consequential, incidental, or special damages of any kind or nature whatsoever, including but not limited to, lost business, revenues and profits.**

Warranty Procedure

To obtain warranty service or repair of SurgiVet® equipment in the USA, please contact Clinical Support to obtain a Return Authorization Number. Please provide the serial number of all equipment that will be returned. **Any equipment returned for evaluation must be cleaned and decontaminated prior to being handled by our service technicians.** For cleaning instructions, please refer to the appropriate section in the operation manual. If equipment is returned prior to cleaning, and in our opinion it represents a potential biological hazard, the equipment will be returned to the sender as is.

Reference the return authorization number when returning your Product, freight and insurance prepaid by Purchaser, to:

Smiths Medical PM, Inc.
Veterinary Division
Attn: Repairs / return #
N7W22025 Johnson Drive
Waukesha, WI 53186

Clinical Support
Telephone: 1-262-513-8500
Toll-Free: 1-888-745-6562 (USA only)
Fax: 1-262-513-9069
Web: www.surgivet.com

NOTE! Shipments received without a return number will be returned to sender.


Seller will not be responsible for unauthorized returns or for loss or damage to the Product during the return shipment. The repaired or replaced Product will be shipped, freight prepaid by Seller, to Purchaser.

To obtain warranty information outside the USA, contact your local distributor.

Keep all original packing material, including foam inserts. If you need to ship the device, use only the original packaging material, including inserts. Box and inserts should be in original condition. If original shipping material in good condition is not available, it should be purchased from Smiths Medical PM, Inc. Veterinary Division.

Damages occurred in transit in other than original shipping containers are the responsibility of the shipper. All costs incurred returning devices for repair are the responsibility of the shipper.

CE Notice

Marking by the symbol  indicates compliance of this device to the Medical Device Directive 93/42/EEC.

 Authorized Representative (as defined by the Medical Device Directive):

Smiths Medical International Ltd.	Tel: (44) 1923 246434
Colonial Way, Watford, Herts,	Fax: (44) 1923 240273
WD24 4LG, UK	

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
















Chapter 1: Introduction



About this Manual

The Operation Manual provides installation, operation, and maintenance instructions for veterinary health-care professionals and other users, trained in monitoring respiratory and veterinary activity.

These instructions contain important information for the safe use of the product. Read the entire contents of these Instructions For Use, including Warnings and Cautions, before using the monitor. Failure to properly follow warnings, cautions and instructions could result in death or serious injury to the patient.

Definition of Symbols

SYMBOL	DEFINITION
	Type CF Equipment.
	Attention, see instructions for use.
	Refer servicing to qualified service personnel.
	Alarm Select
	Input voltage
	Printer On/Off
	Direct Current
	Alarm silence
	On/Off
	Non AP device
	Up and Down Arrows
	Alarm LED
	Alarm Silenced LED
	Artifact LED
	Low Battery LED
	External power/Battery eliminator
	Heart Rate LED
	Date of Manufacture
	Use by
IPX1	Drip Proof (monitor only)
%SpO₂	Percent Oxygen Saturation
	Moisture sensitive
Rx ONLY	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a Licensed Veterinarian.

 Collect Separately	Disposal (EU Countries) Under the Waste Electrical and Electronic Equipment (WEEE) Directive 2006/96/EC and implementing regulations, all devices and service items within the scope of the Directive purchased new after August 13, 2005 must be sent for recycling when ultimately becoming waste. Devices and items must not be disposed of with general waste. If purchased before that date, they may also be sent for recycling if being replaced on a one-for-one, like-for-like basis (this varies depending on the country). Recycling instructions to customers using Smiths Medical products are published on the internet at: http://www.smiths-medical.com/recycle
	Disposal (other countries) When disposing of this device, its batteries or any of its accessories, ensure that any negative impact on the environment is minimized. Contact your local waste disposal service and use local recycling or disposal schemes. Separate any other parts of the equipment where arrangements can be made for their recovery; either by recycling or energy recovery. The main batteries are potentially harmful and will require separate disposal according to manufacturer's instructions or local regulations. Note: If applicable, EU, national or local regulations concerning waste disposal must take precedence over the above advice.
KEYWORD	DEFINITION
WARNING	Tells you something that could hurt the patient or hurt the operator.
CAUTION	Tells you something that could damage the device.
NOTE	Tells you other important information.

Warnings

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

WARNING! Do not use this device in the presence of magnetic resonance imaging (MR or MRI) equipment.

WARNING! Use only SpO₂ sensors supplied with, or specifically intended for use with, this device.

WARNING! Do not plug the monitor into an outlet controlled by a wall switch.

WARNING! This device is intended for use by persons trained in professional health care. The operator must be thoroughly familiar with the information in this manual before using the device.

WARNING! This device must be used in conjunction with clinical signs and symptoms. This device is only intended to be an adjunct in patient assessment.

WARNING! It is the operator's responsibility to set alarm limits appropriately for each individual patient.

WARNING! Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

WARNING! ELECTRICAL SHOCK HAZARD when cover is removed. Do not remove covers. Refer servicing to qualified personnel.

WARNING! In the event that earth ground integrity is lost, the performance of this device and/or other devices nearby may be affected due to excessive RF emissions.

WARNING! Any monitor that has been dropped or damaged should be inspected by qualified service personnel, prior to use, to insure proper operation.

WARNING! If the accuracy of any measurement is in question, verify the patient's vital sign(s) by an alternative method and then check the monitor for proper functioning.

WARNING! Remove device batteries prior to long term storage.

WARNING! When attaching sensors with Microfoam[®] tape, do not stretch the tape or attach the tape too tightly. Tape applied too tightly may cause inaccurate readings and blisters on the patient's skin (lack of skin respiration, not heat, causes the blisters).

WARNING! Operation of this device may be adversely affected in the presence of strong electromagnetic sources, such as electrosurgery equipment.

WARNING! Operation of this device may be adversely affected in the presence of computed tomograph (CT) equipment.

WARNING! Use only SpO₂ sensors supplied with, or specifically intended for use with, this device.

WARNING! SpO₂ measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, for example) if necessary.

WARNING! Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, patent blue V (PBV), and fluorescein may adversely affect the accuracy of the SpO₂ reading.

WARNING! Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate pulse rate and SpO₂ readings.

WARNING! Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin, will affect the accuracy of the SpO₂ measurement.

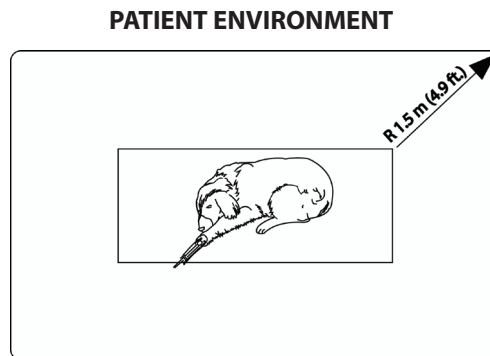
WARNING! The monitor was not designed or tested to be an apnea monitor.

WARNING! Optical cross-talk can occur when two or more sensors are placed in close proximity. It can be eliminated by covering each site with an opaque material.

WARNING! Tissue damage may result from overexposure to sensor light during photodynamic therapy with agents such as verteporphin, porfimer sodium, and metatetrahydroxyphenylchlorin (mTHPC). Change the sensor site at least every hour and observe for signs of tissue damage. More frequent sensor site changes/inspections may be indicated depending upon the photodynamic agent used, agent dose, skin condition, total exposure time or other factors. Use multiple sensor sites.

WARNING! When connecting this monitor to any instrument, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions. Accessory equipment connected to the monitor's data interface must be certified according to the respective IEC standards, i.e., IEC 60950 for data processing equipment or IEC 601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC 601-1-1 systems requirements. Anyone connecting additional equipment to the signal input port or the signal output port configures a medical system, and, therefore, is responsible that the system complies with the requirements of the system standard IEC 601-1-1.

WARNING! IEC 60950 approved equipment must be placed outside the "patient environment". The patient environment is defined as an area 1.5 m (4.92 feet) from the patient.



WARNING! Disconnect the AC power supply from the outlet before disconnecting it from the monitor. Leaving the AC power supply connected to an AC power outlet without being connected to the monitor may result in a safety hazard.

WARNING! Do not allow any moisture to touch the AC power supply connectors or a safety hazard may result. Ensure that hands are thoroughly dry before handling the AC power supply.

WARNING! Failure to place the monitor away from the patient may allow the patient to turn off, reset, or damage the monitor, possibly resulting in the patient not being monitored.

WARNING! Failure to carefully route the cable from the sensor to the monitor may allow the patient to become entangled in the cable, possibly resulting in patient strangulation. Route the cable in a way that will prevent the patient from becoming entangled in the cable. If necessary, use tape to secure the cable.

WARNING! If there is a risk of the AC power supply becoming disconnected from the monitor during use, secure the cord to the monitor several inches from the connection.

WARNING! Under certain clinical conditions, pulse oximeters may display dashes if unable to display SpO₂ and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.

WARNING! Verify that all LEDs (light emitting diodes) on the display light up upon startup of the device.

Cautions

- CAUTION!** Do not autoclave, ethylene oxide sterilize, or immerse the monitor or sensors in liquid. Always disconnect the power source and remove all batteries before cleaning or disinfecting the monitor.
- CAUTION!** Should the device become wet, wipe off all moisture and allow sufficient time for drying before operating.
- CAUTION!** The monitor should be operated from its internal power source if the integrity of the protective earth conductor is in doubt.
- CAUTION!** Pressing front panel keys with sharp or pointed instruments may permanently damage the keypad. Press front panel keys only with your finger.
- CAUTION!** Do not allow water or any other liquid to spill onto the monitor. Unplug the external power supply from the monitor before cleaning or disinfecting the monitor. Evidence that liquid has been allowed to enter the monitor voids the warranty.
- CAUTION!** Ensure the device's AC rating is correct for the AC voltage at your installation site before using the monitor. The monitor's AC rating is shown on the external power supply. If the rating is not correct, do not use the monitor; contact the Smiths Medical PM, Inc. Clinical Support department, or your local distributor, for help.
- CAUTION!** Connect only the printer/PC interface cable specifically intended for use with this device (see *Optional Supplies and Accessories*).
- CAUTION!** Chemicals used in some cleaning agents may cause brittleness of plastic parts. Follow cleaning instructions in this manual.

Notes

- NOTE!** Batteries are user replaceable. Follow local governing ordinances and recycling instructions regarding disposal or recycling of device components, including batteries.
- NOTE!** When using AC power, the Digital Oximeter is a class II device with functional earth. This earth connection is for device electromagnetic compatibility and does not provide protection to the patient or user.
- NOTE!** It is recommended that batteries be used with the monitor when operating with AC power to prevent monitor shutdown with loss of AC power.
- NOTE!** SpO₂ averaging is the number of pulse beats over which the SpO₂ value is averaged; pulse averaging is the number of seconds over which the pulse value is averaged.
- NOTE!** All user and patient accessible materials are non-toxic.
- NOTE!** Each input and output connection of the monitor is electrically isolated.
- NOTE!** Performance and safety test data are available upon request.
- NOTE!** To comply with government requirements for patient monitoring, the indefinite high priority alarm, medium priority alarm, and low priority alarm tone silence feature may not be available in monitors shipped to your country.

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Chapter 2: Intended Use and General Information

Intended Use

The Veterinary Handheld Digital Pulse Oximeter is a low cost monitor for spot checking or continuous monitoring of SpO₂, pulse rate and pulse strength. The monitor is a battery powered pulse oximeter. It may be used in the hospital or clinical environment, and during emergency land transportation. The oximeter will operate accurately over an ambient temperature range of 32 to 131°F (0 to 55°C). The oximeter works with all SurgiVet® oximetry sensors providing SpO₂ and pulse rate on all patients from neonatal to adult.

This device is intended for continuous patient monitoring with adjustable alarm limits as well as visible and audible alarm signals.

NOTE! The monitor was not designed or tested to be an apnea monitor.

Monitor Features

- Provides fast, reliable SpO₂, pulse rate, and pulse strength measurements.
- Ideally suited for use in intensive care units, outpatient clinics, emergency rooms, and during emergency land transport.
- Portable and lightweight. Weighs only 454 grams (16 ounces), with batteries.
- Ergonomically designed to fit comfortably in the palm of your hand.
- Uses six (6) standard “AA” (type IEC LR6) alkaline batteries.
- Battery life is approximately twenty-four (24) hours without printing.
- Bright, easy-to-read LED displays indicate SpO₂ and pulse rate measurements.
- An eight-segment LED bar graph indicates pulse strength.
- Adjustable volume (including silence) “beep” sounds with each pulse beat. Pitch of pulse “beep” corresponds to SpO₂ value.
- Positive identification of SpO₂ or pulse rate alarm. Adjustable high and low alarm limits for SpO₂ and pulse rate measurements.
- Adjustable volume for alarm and alert tones (including silence).
- User-adjustable delayed audible system alarms.
- SpO₂ and pulse rate averaging settings are user-selectable.
- Artifact indicator informs user of excess motion and other artifacts.
- User-adjustable trend storage rate, ranging from 4 to 30 seconds per sample, for many applications.
- Low battery indicator lights when about 30 minutes of battery use remains. A yellow Low priority alarm LED turns on and an audible 5-beep burst notifies the user of low battery life.
- Data log prints SpO₂ and pulse rate readings in real time, once every five (5) seconds through the IR port to an optional printer.

Theory of Operation

The pulse oximeter determines %SpO₂ and pulse rate by passing two wavelengths of low intensity light, one red and one infrared, through body tissue to a photodetector. Information about wavelength range can be especially useful to clinicians. Wavelength information for this device can be found in the *SpO₂ Specifications* section of this manual.

Pulse identification is accomplished by using plethysmographic techniques, and oxygen saturation measurements are determined using spectrophotometric oximetry principles. During measurement, the signal strength resulting from each light source depends on the color and thickness of the body tissue, the sensor placement, the intensity of the light sources, and the absorption of the arterial and venous blood (including the time varying effects of the pulse) in the body tissues.

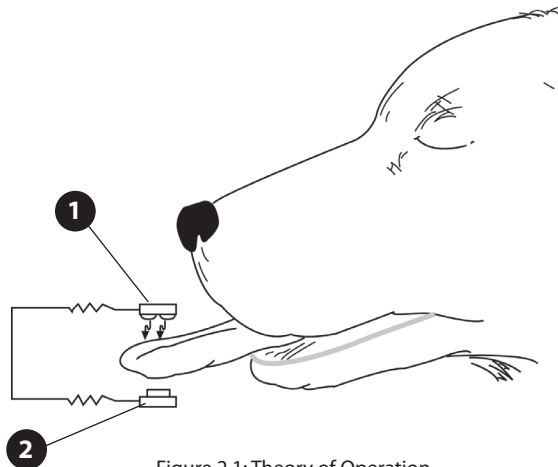


Figure 2.1: Theory of Operation

1 Low intensity Red and Infrared LED light sources

2 Detector

Oximetry processes these signals, separating the time invariant parameters (tissue thickness, skin color, light intensity, and venous blood) from the time variant parameters (arterial volume and SpO₂) to identify the pulses and calculate functional oxygen saturation. Oxygen saturation calculations can be performed because blood saturated with oxygen predictably absorbs less red light than oxygen-depleted blood.

WARNING! Since measurement of SpO₂ depends on a pulsating vascular bed, any condition that restricts blood flow, such as the use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate SpO₂ and pulse rate readings.

WARNING! Under certain clinical conditions, pulse oximeters may display dashes if unable to display SpO₂ and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.

Patented Technology

The Handheld Digital Oximeter incorporates patented technology and noise reducing hardware to enhance the oximeter's ability to detect pulse amplitude in patients with poor peripheral perfusion. *Blood Pulse Detection Method Using Autocorrelation*, patent number 5,558,096, analyzes a digitized signal, in real time, and compares it with previous pulse data. If similar characteristics to previous data are recognized, the device confirms a valid pulse. In essence, an individual's pulse data is retained and used as a template to accept or reject future pulse signals. Patented technology, digital signal processing, and a greatly improved signal to noise ratio, provide for improved performance.

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Chapter 3: Controls and Features

Monitor Front Panel

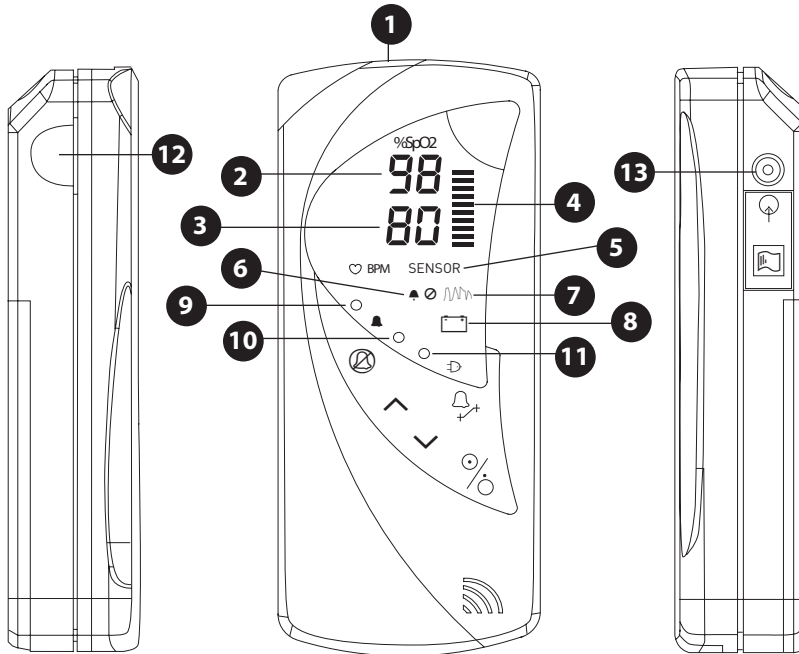


Figure 3.1: Monitor Controls, and Features

1 Sensor/Printer Connector

The sensor connects here, or an oximetry extension cable can be connected between the monitor and the sensor. The serial printer or PC communication cable is also connected here.

2 SpO₂ Numeric Display

A number shows the patient's SpO₂ value in percent. Dashes (--) mean the monitor is not able to calculate the SpO₂ value.

3 Pulse Rate Numeric Display

A number shows the patient's pulse rate value in beats per minute. Dashes (--) mean the monitor is not able to calculate the pulse rate value.

4 Pulse Strength Bar Graph

The pulse strength bar graph "sweeps" with the patient's pulse beat. The height of the bar graph shows the patient's pulse strength.

5 Sensor Problem Alert Indicator

This indicator lights steadily to inform the operator of an oximeter sensor problem.

6 Alarm Silence Indicator

This indicator flashes during temporary two-minute alarm silence. The indicator lights steadily during permanent/indefinite alarm silence.

7 Artifact Alert Indicator

This indicator informs the operator about the presence of excess artifacts.

8 Low Battery Indicator

During a Low Battery Attention, this LED is lit and an audible burst of 5 beeps notifies the user that approximately 30 minutes of battery use remains.

9 High Priority Alarm LED (red)

This LED flashes twice every second during a high priority condition. This signal indicates that immediate operator attention is needed.

10 Low Priority Alarm LED (yellow)

This LED indicates a low priority alarm, which lights steadily during a low priority alarm condition.

11 Line/Power Indicator (green)

This LED lights steadily while external power is applied.

12 IR Printer Output

The Digital Oximeter can transmit data to an optional HP printer via an infrared link through this port.

13 AC Power Jack

An optional AC power supply connects here.

Monitor Operating Keys

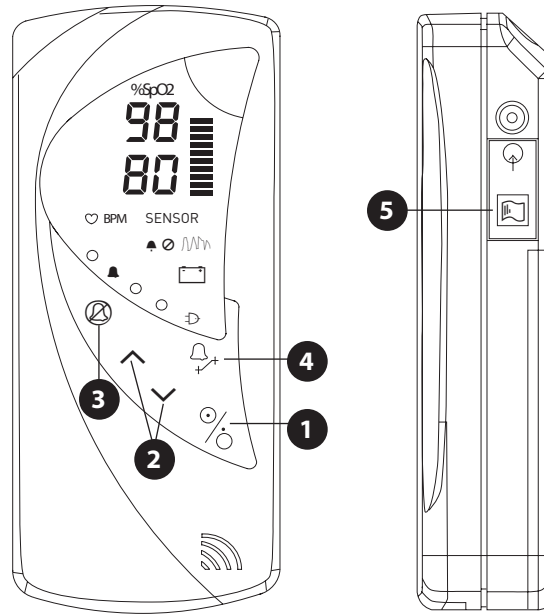


Figure 3.2: Monitor Operating Keys

1 % ON/OFF Key

Pressing this key turns the monitor ON and OFF.

2 ^ Up and v Down Arrows

The Up and Down arrow keys are used to adjust the following settings:

- Alarm Limits
- %SpO₂/Pulse Rate averaging
- Trend Interval
- Low Priority Alarms Delay
- Alarm Volume
- Pulse Volume

3 [Silence Icon] Alarm Silence

Momentarily pressing the Alarm Silence key disables the alarm tone for two (2) minutes. Pressing and holding the Alarm Silence key for about three (3) seconds disables the alarm tone indefinitely (until canceled or the monitor is turned off). To cancel either the indefinite or the two-minute alarm and alert tone silenced condition, momentarily press the Alarm Silence key. The Alarm Silenced indicator will turn off.

4 [Bell Icon] Alarm Select

Pressing this key cycles through each of the alarm settings.

5 [Print Icon] PRINT/CLEAR Key

Located on the side of the monitor. Pressing this key will send data to the optional IR printer. Pressing the key again will stop printing. Pressing and holding the Print/Clear key will clear the trend data.

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Chapter 4: Operating Instructions

WARNING! This device must be used in conjunction with clinical signs and symptoms. This device is only intended to be an adjunct in patient assessment.

Unpacking the Monitor

1. Carefully remove the monitor and its accessories from the shipping carton. Save the packing materials in case the monitor must be shipped or stored.
2. Compare the packing list with the supplies and equipment you received to make sure you have everything you'll need.

Install the Batteries

The oximeter uses 6 (six) standard "AA" alkaline cells, IEC Type LR6.

To install/replace the batteries:

1. Depress the battery door tab and lift up.
2. Install the negative end of each battery first, compressing the battery terminal spring until the positive terminal clears the positive tab. Press the battery down into place.
3. Place battery door tabs into the slots of the monitor back panel, depress the door tab, and press the door into place.

NOTE! If you install disposable batteries, be sure to dispose of them in compliance with your institution's guidelines and local ordinances.

NOTE! The unit will hold data for about one and a half minutes with no battery power. This will insure the safety of trend data during battery replacement.

AC Power

Refer also to *Chapter 12: Optional Supplies and Accessories* to verify the proper AC power supply for your application.

NOTE! The AC power supply does not act as a battery charger.

NOTE! Do not plug the monitor into an outlet controlled by a wall switch.

- | | |
|------|---------------------------------------|
| 1611 | AC power supply 105 - 152 VAC 60Hz |
| 1612 | AC power supply 208 - 252 VAC 50/60Hz |
| 1613 | AC power supply 90 - 110 VAC 60Hz |

NOTE! When using AC power, the Digital Oximeter is a class II device with functional earth. This earth connection is for device electromagnetic compatibility and does not provide protection to the patient or user.

NOTE! Intermittent use of AC power will require functional "AA" cells to maintain memory and keep the oximeter from defaulting to clinician mode from other modes.

Attaching the Sensor to the Patient

WARNING! Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

WARNING! When attaching sensors with Microfoam[®] tape, do not stretch the tape or attach the tape too tightly. Tape applied too tightly may cause inaccurate readings and blisters on the patient's skin (lack of skin respiration, not heat, causes the blisters).

Attaching the patient to the monitor requires these steps:

1. Choose the sensor.
2. Check the sensor and oximetry cable.
3. Clean or disinfect the sensor if using the reusable type (Disposable sensors are for single-patient use and do not require cleaning or disinfecting).
4. Attach the sensor to the patient.

Choosing the Sensor

Choose the appropriate sensor from the following chart.

PATIENT	SITE	SENSOR #/DESCRIPTION
Small/Medium Animal up to 60 pounds	Pinna (ears), Toe Webbing, Tongue	V1711: Large 'Y' Sensor V1702: Mini 'Y' Sensor V3078: Mini Clip Sensor
	Rectum/Tail	V1700: Reflectance Sensor V1710: Tail Wrap Sensor
	Hock, Achilles Tendon, etc.	V1707: Universal 'C' Sensor
Large Animals over 60 pounds	Pinna (ears), Toe Webbing, Tongue	V1711: Large 'Y' Sensor V1702: Mini 'Y' Sensor V3078: Mini Clip Sensor
	Rectum/Tail	V1700: Reflectance Sensor V1710: Tail Wrap Sensor
	Hock, Achilles Tendon, etc.	V1707: Universal 'C' Sensor
Equine	Tongue	V1707: Universal 'C' Sensor

Care and Handling of the Sensor

WARNING! Misuse or improper handling of the sensor and cable could result in damage to the sensor. This may cause inaccurate readings.

Hold the connector rather than the cable when connecting or disconnecting the sensor to the device as shown in Figure 4.1.

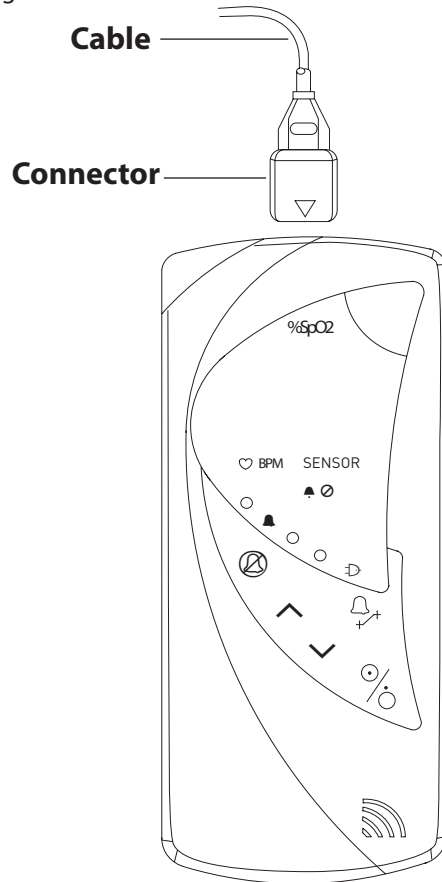


Figure 4.1: Disconnecting or connecting the sensor.

Do not use excessive force or unnecessary twisting when connecting, disconnecting, storing, or when using the sensor.

Pulse Oximeter Sensors

NOTE! ⚠ Please see insert accompanying each sensor for further details.

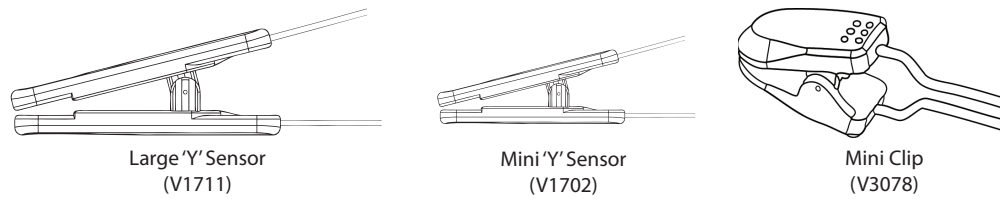


Figure 4.2: Lingual Sensors

Attach the sensor and clip to the patient's tongue. Make sure the light source is topside of the tongue.

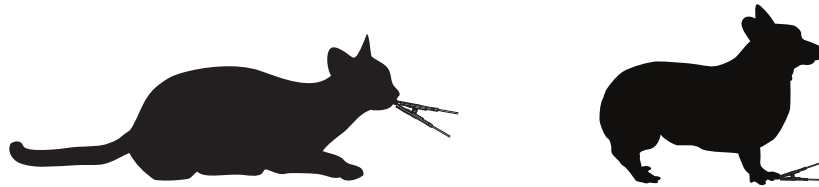


Figure 4.3: Attaching the Sensor to the Animal

Reflectance Sensors



Figure 4.4: Reflectance Sensors

For best results while using the tail wrap sensor (V1710), apply to the ventral base of the tail with the divider positioned centrally. Moisten the fur and parting at the application site or shaving a small area is required. The sensor works best on medium to large sized patients.

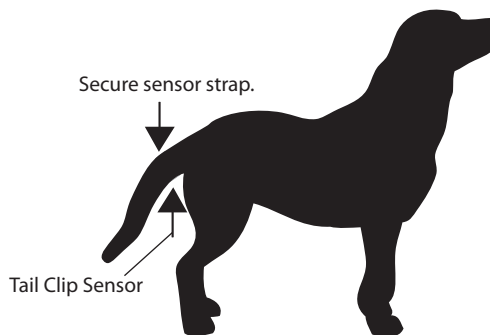


Figure 4.5: Attaching the Sensor to the Animal

For best results while using the reflectance sensor (V1700), apply to the base of the tail. This sensor can also be used rectally if needed.

When using either of the reflectance sensors, ultrasound gel is recommended to enhance performance. Fur, dark pigmentation, poor perfusion and movement can affect the sensor's ability to obtain accurate readings.

Pulse Oximeter Sensor Application Tips

There is some variation depending on the manufacturer, but there are three basic types of pulse oximeter sensors made for the small animal patient:

- Large and Mini 'Y' sensors
- Mini Clip sensor
- 'C' sensor (may also be used on large animals)
- Tail Wrap sensor
- Reflectance sensor

It is very important to have a variety of sensors in order to monitor the majority of the small animal patients. It is also important to select the proper sensor for animals based on their size, color, fur type, medical condition, and type of procedure.

Testing Sensor Function

- 1. To test the large and mini 'Y' sensor functions**, turn on the monitor with the lingual sensor attached. View the sensor to make sure a red light is being emitted, then place the sensor on a small finger (without nail polish). Rest the hand with the sensor on it on a table to minimize motion. Note that in most cases the red light should be shining in the same direction as the overhead or surgical lights. It is important that the light receptor is shielded in order to avoid interference from ambient light. Once placed on a patient site, the red light should be shining continuously. In some cases a blinking light indicates that the tissue thickness is either too thin or thick. Once the sensor is placed properly, both the SpO₂ and pulse rate should appear in a short period of time (10-15 seconds).
- 2. Testing the 'C' sensor is performed in the same manner.** This is a stronger sensor and can be used with greater tissue thickness.
- 3. Testing the tail wrap and reflectance sensors are performed in the same manner**, but it should be pressed between thumb and index finger or into the palm of your hand.

Primary Applications for Sensors

Large and Mini 'Y' Sensor and Mini Clip Sensor

- The primary application site is the tongue for most animals. On cats and small dogs, fold the tongue like a taco or use a wet gauze pad of single thickness folded over the tongue, and then place the sensor over the gauze.
- Other sites include the prepuce or vulva of larger dogs, the achilles tendon of a cat or small dog, ears, or toe webbing.

C Sensor

- For cats and small breed dogs, place the sensor on the thigh, metatarsal or metacarpal, or hock near the saphenous vein.
- For larger breed dogs, place the sensor over the Achilles tendon, tongue, prepuce or vulva, or through toe webbing.
- It may be necessary to wet and part the fur with water in order to get the sensor closer to the skin of the patient.
- For large animals (e.g. horses), place the sensor on the tongue.

Tail Wrap Sensor and Reflectance Sensor

- In most animals, wet and part the fur at the ventral tail base and use the straps on the tail wrap to hold the tail wrap sensor in place.
- When using the reflectance sensor, wet and part the fur at the ventral tail base and use non-adhesive tape to hold the sensor in place. The reflectance sensor may be used rectally if the patient has a small or no tail.
- It may be necessary to shave a small spot on the ventral tail base in patients with a thick undercoat, such as a Husky.

Limitations


Experience will quickly tell you which probes work best under different conditions. Fur, dark pigmentation, poor perfusion, and movement can all affect the sensors ability to obtain accurate readings. Well-perfused sites with little or no hair are preferable. It is also important to note that some anesthetic drugs, such as Xylazine (Rompun), Acepromazine, or Medetomidine (Domitor) can affect peripheral pulse pressures causing very weak pulsations. All pulse oximeters require a good quality pulse to work properly. Other drugs, such as ketamine, can cause the tongue to twitch, limiting the use of a lingual clip on that site.

Checking the Sensor and Oximetry Cable

Follow these instructions each time before you attach the sensor to the patient. This helps ensure the sensor and oximetry cable are working properly.

WARNING! Using a damaged sensor may cause inaccurate readings. Inspect each sensor. If a sensor appears damaged, do not use it. Use another sensor or contact your authorized repair center for help.

WARNING! Using a damaged oximetry cable may cause inaccurate readings. Inspect the oximetry cable. If the oximetry cable appears damaged, do not use it. Contact your authorized repair center for help.

1. Carefully inspect the sensor to make sure it does not appear damaged.
2. If using the oximetry cable, carefully inspect the oximetry cable to make sure it does not appear damaged.
3. If using the oximetry cable:
 - a. If the sensor is not already connected to the oximetry cable, connect the sensor to the oximetry cable. Push the connectors together firmly and close the latch to secure the connectors.
 - b. If the oximetry cable is not already connected to the monitor, connect the oximetry cable to the monitor. Push the connector firmly into the monitor.
4. If not using the oximetry cable, connect the sensor to the monitor. Push the connector firmly into the monitor.
5. If the monitor is not already on, press the  key to turn on the monitor.

WARNING! If any of the integrity checks fail, do not attempt to monitor the patient. Use another sensor or oximetry cable, or contact the equipment dealer for help if necessary.

6. Before the sensor is attached to the patient, check the integrity of the sensor, oximetry cable, and oximeter as follows:
 - a. Make sure the red light in the sensor is illuminated.

NOTE! Obstructions or dirt on the sensor's red light or detector may cause the checks to fail. Make sure there are no obstructions and the sensor is clean.

7. You are now ready to attach the sensor to the patient.

Cleaning or Disinfecting the Sensors

Clean or disinfect reusable sensors before attaching to a new patient.

WARNING! Do not autoclave, ethylene oxide sterilize, or immerse the sensors in liquid.

CAUTION! Unplug the sensor from the monitor before cleaning or disinfecting.

Clean the sensor with a soft cloth moistened in water or a mild soap solution. To disinfect the sensor, wipe the sensor with isopropyl alcohol.

Turning On the Monitor

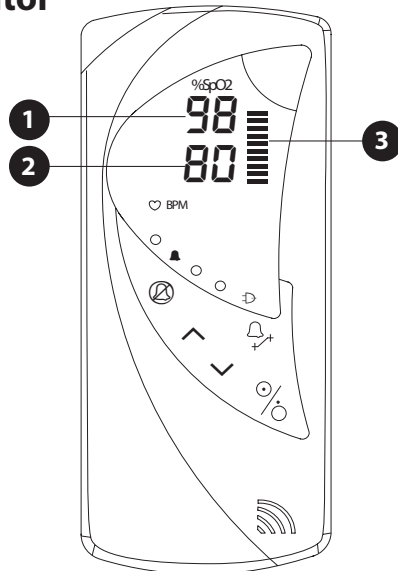


Figure 4.6: SpO₂, pulse rate, and pulse strength bar graph.

- 1 Patient's SpO₂ Shown Here**
- 2 Patient's Pulse Shown Here**
- 3 Patient's Pulse Strength Shown Here**

1. To turn on the monitor, press the $\frac{\%}{\text{O}}$ key. When turned ON, the monitor does the following:
 - The top segment of the pulse strength bar graph illuminates.
 - The monitor's software revision is momentarily displayed.
 - The patient number is momentarily displayed.

WARNING! Verify that all LEDs (light emitting diodes) on the display light up upon startup of the device.

- The monitor has two averaging settings for %SpO₂ and pulse rate. To change the averaging setting, press and hold the ^ Up Arrow while turning on the monitor. This will set the %SpO₂ and pulse rate averaging to 16/16. Press and hold the v Down Arrow while turning on the monitor to set the %SpO₂ and pulse rate averaging to 4/8.

NOTE! Increasing or decreasing the averaging setting has no effect on the data update rate.

NOTE! SpO₂ averaging is the number of pulse beats over which the SpO₂ value is averaged; pulse averaging is the number of seconds over which the pulse value is averaged.

High Priority Alarms

A high priority alarm warns you about an abnormal patient condition.

A high priority alarm is activated when:

- the patient's SpO₂ reading matches or exceeds the SpO₂ alarm range.
- the patient's pulse rate reading matches or exceeds the pulse rate alarm range.

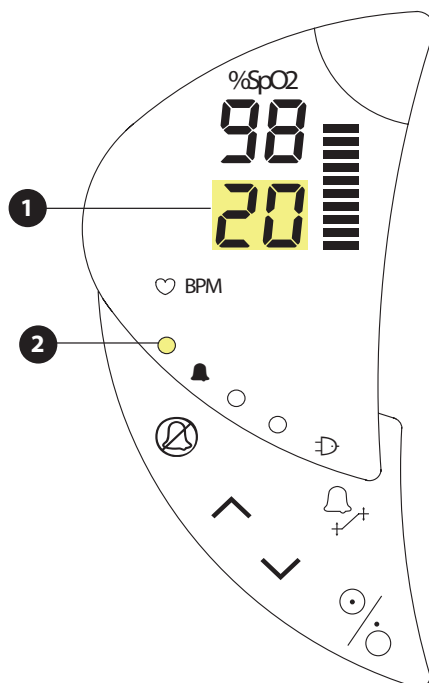


Figure 4.7: Alarm Example

1 During a high priority alarm, the numbers flash that correspond to the alarm.

2 The high priority alarm LED flashes.

- The alarm tone sounds, if not silenced. The high priority alarm tone consists of 3 short bursts, a pause, followed by 2 more short bursts.

Note: The alarm tone does not sound if the Alarm Silenced indicator is on or flashing.

NOTE! Both SpO₂ and pulse rate numbers will flash if both readings match or exceed their alarm range.

Low Priority Alarms

A low priority alarm warns you about an abnormal monitor condition.

A low priority alarm is activated when the:

- Sensor is not connected to the monitor.
- Sensor is not attached to the patient.
- Sensor is not properly attached to the patient.
- Signal contains artifact.

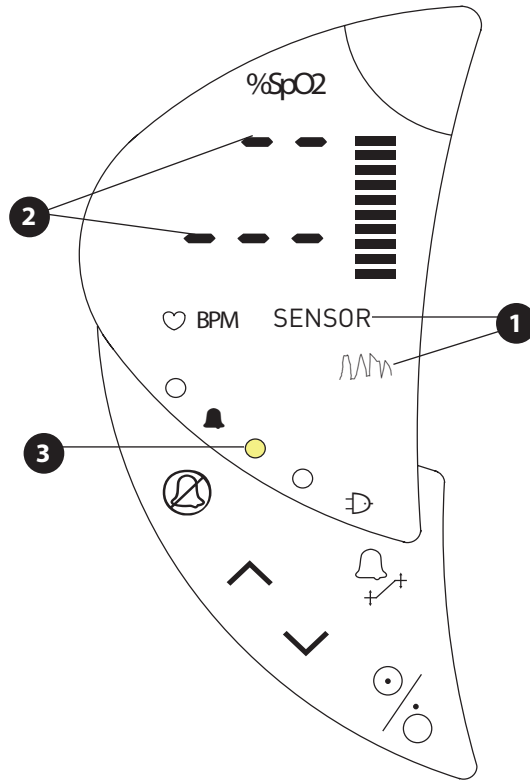


Figure 4.8: Alert Example

- 1 During a low priority alarm, the SENSOR or Artifact indicator illuminates.**
- 2 During a low priority alarm, the monitor cannot measure the patient's SpO₂ or pulse rate. Dashes are displayed.**
- 3 The Low Priority LED lights steadily and the low priority alarm tone sounds, if not silenced. The low priority alarm tone consists of 2 long bursts.**

Note: The alert tone does not sound if the Alarm Silenced indicator is on or flashing.

WARNING! While SENSOR is lit, the monitor cannot measure the patient's SpO₂ or pulse rate. If the Artifact indicator is lit, the patient's readings may not reliably reflect his/her actual condition. The patient's condition should be checked immediately. After checking the patient's condition, correct the SENSOR or Artifact low priority alarm. See *Correcting the SENSOR/Artifact Alert* in the *Troubleshooting* section for help.

Low Battery Indicator

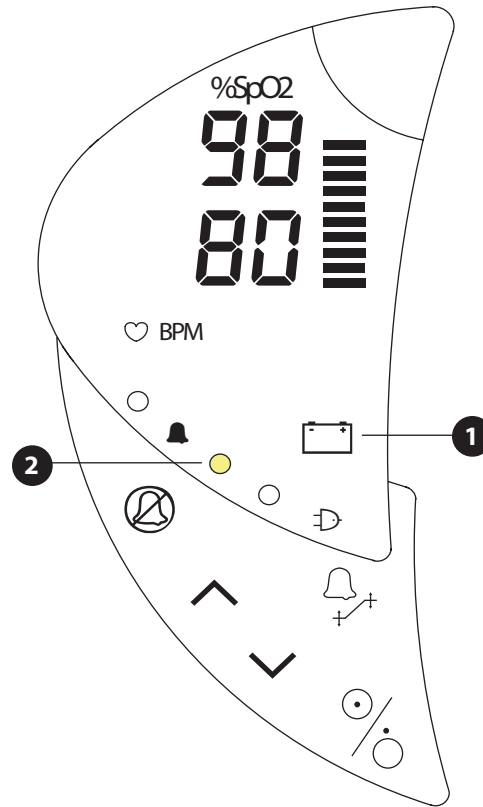



Figure 4.9: Low Battery Attention

- 1** The Low Battery indicator (red) lights up steadily until the batteries are replaced.
- 2** The Low Priority Alarm LED (yellow) indicator lights up steadily and the low battery tone sounds.

WARNING! When the LOW BATTERY INDICATOR is illuminated, you must immediately replace the monitor's batteries. Otherwise, the monitor turns itself off about 30 minutes after the low battery indicator illuminates.

NOTE! The Alarm Silence key cannot disable the Low Battery audible tone.

During a LOW BATTERY ATTENTION:

- The Low Battery indicator  lights up steadily.
- The low priority alarm LED lights up steadily.
- A series of five high pitch "beeps" will sound every minute until the batteries are replaced.

High and Low Priority Alarm Summary

TYPE	DISPLAY INDICATOR	LED INDICATOR	EFFECTS	AUDIO
High Priority Alarms	Numbers corresponding to violated alarm will flash (SpO ₂ and pulse rate)	High priority alarm LED (red) flashes	Overrides pulse beeps	Alarm tone sounds
Low Priority Alarms	Attention indicators light up steadily: SENSOR or Artifact	Low priority alarm LED (yellow) lights up steadily	Overrides pulse beeps	Low priority alarm tone sounds
Information Signal	Low battery indicator	Low priority alarm LED lights steady	Overrides all audio (one shot)	5 beeps that occur once every 30 seconds

Turning Off the Monitor

Turn off the monitor when you are not monitoring a patient.

To turn off the monitor, press the $\%/\text{O}$ key.

Checking the Monitor's Performance

Pulse oximeters do not require user calibration. If checking the function of the device is desired, an optional Oximeter Patient Simulator (Smiths Medical catalog number 1606) is available as an accessory. The simulator attaches to the oximeter in place of the sensor or oximetry cable. It provides a known SpO₂ and pulse rate signal to the oximeter. This allows the oximeter's performance to be checked.

NOTE! The 1606 Oximeter Patient Simulator does not calibrate the monitor; the monitor does not require calibration. The 1606 provides a known SpO₂ and pulse rate to the monitor that allows you to check the monitor's performance.

NOTE! The 1606 Oximeter Patient Simulator cannot be used to assess the accuracy of a pulse oximeter and/or sensor.







NOTE!  Follow the instructions included with the Oximeter Patient Simulator.

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Chapter 5: Changing the Monitor's Settings



Silencing Alarm Tones

The high and low priority alarm tones can be silenced for two minutes or indefinitely (until canceled or until the monitor is turned off).

1. To silence the alarm tones for two minutes, momentarily press the Alarm Silence key . If alarms were already silenced, you must press the Alarm Silence key  again. The alarm SILENCE indicator  flashes during the two-minute time-out.
2. To silence the alarm and alert tones indefinitely, press and hold the Alarm Silence key  for about three seconds. The alarm SILENCE indicator  lights steady while alarms are silenced indefinitely.
3. To cancel either the indefinite or the two-minute alarm tone silenced condition, momentarily press Alarm Silence key  the alarm silenced indicator turns off.




Changing the Pulse Beep Volume

A "beep" tone sounds with each pulse beat. The volume of the "beep" can be adjusted to fifteen (15) settings and off.

To adjust the volume to the 'off' setting, press and hold the  Down Arrow. From the 'off' setting, set the volume by pressing the  Up Arrow. The volume is increased/decreased with each key press.

Changing the Alarm Limits

Each measurement, SpO₂ and Pulse Rate, has a high and low alarm limit setting.

Press the Alarm Select key  until the alarm limit you want to change is shown, then press the Up or Down key  or  to increase or decrease the setting.

ALARM SEL KEY PRESS	DISPLAY		ALARM LIMIT
First Press.	---	H I	--- = High SpO ₂ alarm limit (Example only.)
Second press.	85	Lo	85 = Low SpO ₂ alarm limit (Example only.)
Third press.	H I	155	155 = High pulse rate alarm limit (Example only.)
Fourth press.	Lo	50	50 = Low pulse rate alarm limit (Example only.)
Fifth press.	97	74	97 = SpO ₂ measurement (Example only.) 74 = Pulse rate measurement (Example only.)

WARNING! Be aware of alarm limits of similar units in the same area when adjusting alarm limits of this device to avoid confusion.

NOTE! “ – – – ” in the alarm limit display means the limit is set to off.

NOTE! Alarm limits are non-overlapping. You cannot set the high alarm equal to or lower than the low alarm and you cannot set the low alarm equal to or higher than the high alarm.

NOTE! Alarm limits are retained through power cycles, with the exception of the following note.

NOTE! If either the low or high SpO₂ alarm limit is set below 80%, they will reset to 85% or higher when the monitor is next powered on.

NOTE! While setting alarm limits, if no keys are pressed for twenty seconds, the alarm limit setting mode is exited and the SpO₂ and pulse rate measurements are shown. Changes are saved.

NOTE! Alarms are not active while setting alarm limits; however, alarms are active as soon as you exit the alarm limit setting mode.


NOTE! The alarm actions occur for each violated alarm, even if more than one alarm is violated at the same time.

NOTE! Alarms may be tested while the monitor is in use by setting alarm limits such that the measured parameter is outside alarm limits. Return limits to the required settings after testing.

Setup Mode



Setup mode allows the user to change the settings for the following options:

- Trend Data Storage Interval, see Chapter 6, *Patient Numbers & Trend Data*, for descriptions
- Alarm Volume
- Low Priority Alarms Delay
- Permanent Silence Disable

To enter Setup Mode, press and hold the  Alarm Select key while turning the monitor on.



Alarm Volume

The volume of the alarm tone can be adjusted through a range of 13 settings. The alarm volume cannot be disabled through the Setup Mode.


To adjust the volume of the alarm tone, press the  Alarm Select key twice upon entering Setup Mode. The display will show **AL 3** and an audible alarm tone will sound. To increase the volume, press the  Up Arrow. The alarm volume setting ranges from 3 to 15.

Low Priority Alarms Delay



The Low Priority Alarms Delay feature delays the audible low priority alarm during a SpO₂ searching or artifact event for a specified amount of time.

To set the delay interval, press the  Alarm Select key three times upon entering Setup Mode. The display will show **dl OFF**. To adjust the delay interval, press the  Up Arrow. The delay interval choices are OFF, 15, 30, or 45 seconds.

Permanent Silence Disable

Alarm audio can be disabled by using the  Alarm Silence key, for 2 minutes or permanently as previously described in this chapter.

Permanent silence disable in the Setup Mode will allow the user to set the alarm audio preferences (2 minute silence or permanent silence).

1. To set the alarm audio preferences, press the  Alarm Select key four times upon entering Setup Mode.
2. The display will show **Pr Aud** if the monitor has been set to allow the user to permanently disable the alarm audio.
3. To only permit 2 minute alarm silence, press the  Down Arrow. The display will show **2 Aud**.

NOTE! If set to 2-minute alarm silence, the alarm audio can only be disabled for 2 minutes.

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Chapter 6: Patient Numbers and Trend Data

Description

Whenever the monitor is on, it stores one SpO₂ and one pulse rate reading every four (4) to thirty (30) seconds. These intervals are adjustable as described later in this chapter. The stored readings are called *trend* data. The monitor remembers trend data for up to 99 patients and 90 hours of run-time.

Trend data is saved for each patient number. When you turn on the monitor, the patient number is automatically incremented and displayed during the power-up sequence. If valid trend data was collected from the previous patient, the patient number is incremented. If no valid trend data was collected from the previous patient, the patient number is displayed only and is not incremented.

Trend data for all patients can be printed on the optional printer.





Trend data will be preserved for about one and a half minutes, without battery power, allowing battery replacement without losing trend data.

NOTE! See *Printer* section for information on printing trend data.

Incrementing the Patient Number



The patient number will be advanced at power up if any patient data has been collected during the previous on time.

Adjusting the Trend Storage Interval

1. Enter Setup Mode: press and hold the  Alarm Select key while turning the monitor on.
2. Press the  Alarm Select key once. The trend storage interval will appear on the display, showing the default interval of 30 seconds.
3. Use the  Up or  Down Arrow keys to increase or decrease the trend storage interval. The interval range is 4 seconds to 30 seconds.

SAMPLE INTERVAL (SECONDS)	RUN-TIME (HOURS)
4	12
5	17
8	24
10	34
20	68
30	90

Clearing Trend Data

To clear trends, press and hold the PRINT  key for 15 seconds. The  message on the 7-segment displays will flash to indicate that the trend clear is about to happen.

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Chapter 7: Printer

Description

Data can be printed in either data log, or trend data mode. In the trend data mode, up to 90 hours of previously stored data, collected from 1 to 99 patients, is printed. Data log prints real time data. A maximum of twenty-four (24) characters will be printed on one line. Data will be printed at a rate of one line every 5 seconds.

```

TREND
PN    01
H :M :S    SpO2  BPM
00:00:00   96%   120bpm
00:00:30   97%   119bpm
PN    02
H :M :S    SpO2  BPM
00:00:00   --%   120bpm
00:00:30   97%   119bpm
  
```

Figure 7.1: Sample Trend Printout

```

DATA LOG
SpO2    BPM
98%     70bpm
97%     72bpm
  
```

Figure 7.2: Sample Data Log

What You'll Need for Printing

You'll need these items to print trend printouts:

- Digital Oximeter.
- Optional infrared HP 82240B printer. (Trend and Data Log Print outs), part #8411
- Accessories required for the printer, such as paper, can be purchased from an authorized distributor.

WARNING! When connecting this monitor to any instrument, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions. Accessory equipment connected to the monitor's data interface must be certified according to the respective IEC standards, i.e., IEC 60950 for data processing equipment or IEC 601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC 601-1-1 systems requirements. Anyone connecting additional equipment to the signal input port or the signal output port configures a medical system, and, therefore, is responsible that the system complies with the requirements of the system standard IEC 601-1-1.



Trend Printouts

Collecting Trend Data

Whenever the monitor is on, it stores one SpO₂ and one pulse rate reading every four (4) to thirty (30) seconds. The stored readings are called *trend data*. The monitor remembers trend data for up to 99 patients and 90 hours of run-time. The trend data can then be printed at any time on the optional printer.

Trend data is saved for each patient number. When you turn on the monitor, if valid trend data was collected from the previous patient, the patient number is automatically incremented. If no valid trend data was collected from the previous patient, the patient number is displayed only, and is not incremented.

Follow these steps for trend data printouts:



1. Turn on the printer.
2. Disconnect the SpO₂ sensor from the patient and to the oximeter as previously described.
3. Turn on the monitor.
4. Align the IR sensor on the Digital Oximeter with the IR sensor on the printer as shown in figure 7-1 or, as described in *Chapter 9: PC Communication Setup*.
5. Depress the  print key (not at start up). The oximeter prints the SpO₂ and pulse rate measurements as shown in the sample printout.
6. Dashes indicate invalid or unavailable data (for example, the patient's finger was removed from the SpO₂ sensor).
7. Depress the  print key to quit printing, or the unit will print all stored trend data.

NOTE! If unexpected characters or question marks are printed, turn the monitor off and on to reset the printer.

Data log

The data log is a real time printout of patient data. Data will be printed at a rate of one line every 5 seconds.

Follow these steps for data log printout:

1. Turn on the printer.
2. Connect the sensor to the monitor and the patient.
3. Align the IR sensor on the Digital Oximeter with the IR sensor on the printer.
4. Press the print  key to begin printing.
5. Press the print  key again to stop printing.

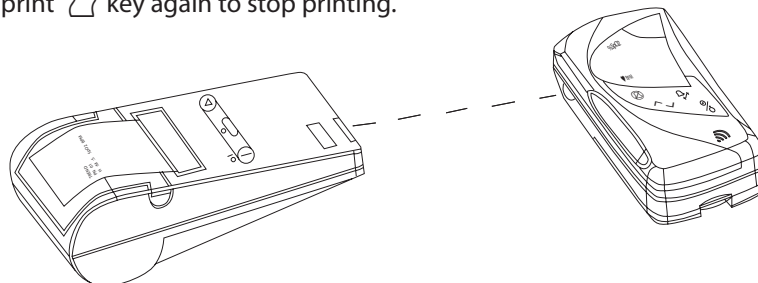


Figure 7.1: Aligning the Printer and Oximeter

Chapter 8: PC Communication Setup

Description

The device will send out Trend Data through the sensor connector when the sensor / patient cable is not plugged in. An additional cable is used to connect the device to a serial printer or PC computer. The following items will be needed:

1. Printer Cable
2. DB-9 Null Modem Cable
3. DB-9 Printer Connector

PC Communication Setup

1. Power up the monitor.
2. Connect the printer communication cable to the monitor.
3. Set up the communication software to accept the following RS-232 data format :
 - Data Type: ASCII
 - Data Format: 9600 baud, 1 start bit, 8 data bits, 1 stop bit, no parity
4. Connect the standard RS-232 null modem cable's DB-9 connector to the mating connector of the printer cable.
5. Connect the standard RS-232 null modem cable's DB connector to the mating connector on the PC.

NOTE! The DB-9 null modem cable is an industry standard RS-232 modem cable.

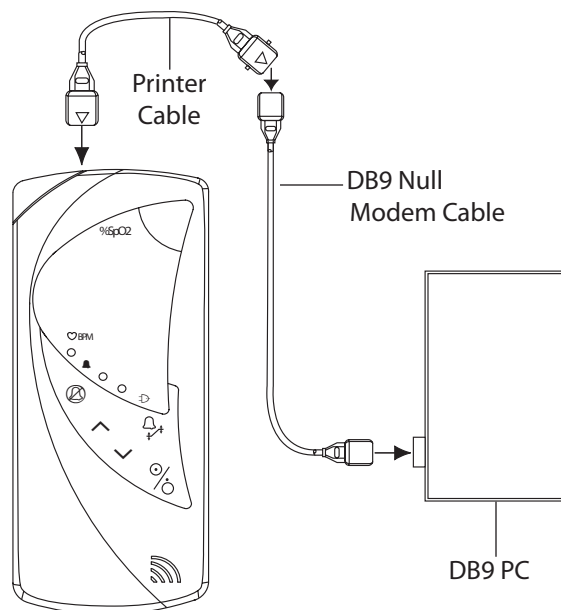


Figure 8.1: PC Communication Setup

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Chapter 9: Maintenance

Schedule of Maintenance

MAINTAIN THIS ITEM	HOW OFTEN	BY DOING THIS
Battery	When Low Battery Attention indicator is flashing, and/or audible battery indicator sounds.	Follow the instructions for installing the batteries.
Disinfecting the reusable sensor.	Before attaching the sensor to the patient.	Follow the instructions for cleaning the reusable sensor.
Disinfecting the monitor.	When necessary.	<ol style="list-style-type: none"> 1. Remove the batteries from the unit. <i>Note: Print trend data before cleaning. Trend data will be lost if batteries are disconnected more than one and a half minutes.</i> 2. Wipe the surfaces of the monitor with a soft, clean cloth dampened in isopropyl alcohol. Use only a cloth that is dampened, not wet. <p>CAUTION! Do not allow isopropyl alcohol or water to enter any of the openings on the monitor. Evidence that liquid has been allowed to enter the monitor voids the warranty.</p>

Storage

Whenever possible, the monitor should be stored at room temperature in a dry environment.

If it is necessary to store the monitor for an extended period of time, the unit should be packed in its original shipping container. Storing the monitor for a long period of time may degrade the battery capacity. Batteries should be removed from the monitor before storing.

Storage specifications are as follows:

Temperature: -40°C to +75°C (-40°F to +167°F)
 Relative Humidity: 10% to 95% (noncondensing)

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Chapter 10: Troubleshooting

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
No pulse shown on the bargraph.	Patient cable or sensor is disconnected from the oximeter. Sensor is incorrectly positioned on the patient. Poor patient perfusion. Defective sensor or patient cable.	Check sensor connections to the patient cable and to the oximeter. Reposition the sensor. Reposition the sensor. Try a new sensor or contact your authorized repair center for help.
Pulse rate is erratic, intermittent, or incorrect.	Sensor incorrectly positioned. Patient motion	Reposition the sensor. Patient must remain still to obtain an accurate measurement.
SpO ₂ value is erratic, intermittent, or incorrect.	Poor patient perfusion. Patient motion.	Reposition the sensor Patient must remain still to obtain an accurate measurement.
The oximeter doesn't turn on.	Batteries weak. Batteries not installed or batteries incorrectly installed.	Replace the batteries. Ensure the batteries are installed correctly.
The oximeter turns off unexpectedly.	Batteries are weak or dead.	Replace the batteries.
No printout on optional printer.	Batteries are weak. Batteries are not properly installed. No trends in memory. Sensor must be disconnected for trend data printout. Printer interface malfunction. Printer and oximeter alignment incorrect (for infrared printers)	Replace the batteries. Ensure the batteries are installed properly. Take trend data. Disconnect the sensor. Contact Smiths Medical PM, Inc. Veterinary Clinical Support for help. Realign printer and oximeter.
E00	ROM Error	Contact Smiths Medical PM, Inc. Veterinary Clinical Support or your local distributor
E01	RAM Error	Contact Smiths Medical PM, Inc. Veterinary Clinical Support or your local distributor
Sensor	Patient cable or sensor is disconnected from the oximeter. Sensor is incorrectly positioned on the patient. Poor patient perfusion. Defective sensor or patient cable	Check sensor connections to the patient cable and to the oximeter. Reposition the sensor. Reposition the sensor. Try a new sensor or contact Smiths Medical PM, Inc. Veterinary Clinical Support for help.
Artifact	Patient motion	Patient must remain still to obtain an accurate measurement.

EMI Interference

CAUTION! This device has been tested and found to comply within the limits for medical devices to IEC 601-1-2:1993, EN 60601-1-2:1994, and the Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in the health-care and home environments (for example, cellular phone, mobile two-way radios, electrical appliances), it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

The monitor is designed for use in environments in which the signal can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the monitor may not operate correctly.

The monitor generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity. Disruption may be evidenced by erratic readings, cessation of operation, or other incorrect function. If this occurs, the site of use should be surveyed to determine the source of this disruption, and actions taken to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the other receiving device.
- Increase the separation between the interfering equipment and this equipment.

If assistance is required, contact the Smiths Medical PM, Inc. Clinical Support Department or your local representative.

Chapter 11: Optional Supplies and Accessories

CAT. NO	DESCRIPTION	QTY
1606	Simulator & Cable , Oximeter, 1.5m (5 ft)	each
1611	Battery Bypass 105-125 VAC 60Hz (domestic)	each
1612	Battery Bypass 208-252 VAC 50/60Hz (international)	each
1613	Battery Bypass 90-110 VAC 60Hz (Japan)	each
V1700	Sensor, Oximetry, reflectance (R/E, Small/Medium)	each
V1702	Mini 'Y' Clip	each
V1707	Sensor, Oximetry, Universal 'C'	each
V1709	Clip, Replacement for use with V1707	10/pkg
V1710	Tail Wrap Sensor	each
V1711	Large 'Y' Clip	each
V1896	Manual, Operation Handheld Digital Pulse Oximeter	each
V3078	Mini Clip	each
3311	Oximetry Cable 1.5m (5 ft)	each
3339	PC Adapter Cable	each
3350	Cable, Printer Interface	each
3419	Protective Rubber Boot with Carrying Strap	each
8411	Infrared HP Printer MCP8850B	each
8416	Printer Paper	4/pkg

Ordering Information

For ordering information, contact your local distributor or the Smiths Medical PM, Inc. Veterinary Clinical Support.

Smiths Medical PM, Inc.
N7W22025 Johnson Drive
Waukesha, Wisconsin 53186-1856

Telephone: (262) 513-8500
Toll-Free: (888) 745-6562
Fax: (262) 513-9069
Website: www.surgivet.com

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Chapter 12: Specifications

Equipment Classification

Type of Protection Against Electric shock:	Internally Powered
Mode of operation:	Continuous
Degree of Protection Against ingress of Liquids:	IPX1, drip proof
Degree of Mobility:	Portable
Degree of Protection Against Electric Shock:	Type CF
Safety Requirements:	EN60601-1: 1990

Displays, Indicators, & Keys

SpO ₂ :	LED numeric display, 7.62 mm (0.30 inches) high
Pulse Rate:	LED numeric display, 7.62 mm (0.30 inches) high
Pulse Strength:	Logarithmically scaled 8-segment LED bargraph







Indicators:  Low Battery indicator

SENSOR Sensor alert indicator

 Alarm Silence

 Artifact

LEDs: High Priority (red)
Low Priority (yellow)
Line Power (green)

Keys:  On/Off key
 PRINT key
 Alarm Silence
 Up Arrow
 Down Arrow
 Alarm Select

SpO₂

Range:	0 - 99% Functional SpO ₂ (1% increments)
Accuracy ¹ :	±2 at 70 - 99% ±3 at 50 - 69%
Alarms:	Low: 50%-99% and OFF High: 50%-99% and OFF Steps: 1%
Factory Defaults:	Low: OFF High: OFF
Averaging:	4/8/16 pulse beat average (selectable)
Display Response:	The display is to functional saturation. The pulse strength bar graph is not proportional to pulse volume.
Display Update Rate:	1 Hz (SpO ₂); 60 Hz (pulse strength)
Calibration:	Factory calibrated over the range of 50% to 100% SpO ₂ using human blood samples to functional saturation. Test methods available upon request. No in-service calibration is required.
Sensor:	Red 660nm, 2.0 mW Infrared 905 nm, 2.0 - 2.4 mW

¹ Because pulse oximeter measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within the A_{RMS} of the value measured by the CO-oximeter. The 3402 has been validated in human desaturation studies on 10 adult volunteers that did not have health problems and were non-smokers. The study was conducted at oxygen concentrations evenly distributed over an SaO₂ range of 50 to 100%.

Pulse Rate

Range:	20-350 bpm (1 bpm increments)
Accuracy:	±1 beat or 2%, whichever is greater
Alarms:	Low: 5-350 bpm and OFF High: 5-350 bpm and OFF Steps: 5 bpm
Factory Defaults:	Low: OFF High: OFF
Averaging:	8 or 16 second average (selectable)
Display Update Rate:	1 Hz

Audible Alarm Indicators

Audible alarm with user-adjustable volume and two minute or indefinite alarm silence.

Alarm Volume:	45dBA to 85 dBA at 1 meter distance (adjustable)
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Trend Storage Interval

4 to 30 seconds (selectable)	
Default:	30 seconds
Steps:	1 second

Power Requirements

AC Power supplies:

1611	AC power supply 105-125VAC 60Hz
1612	AC power supply 208-252VAC 50/60Hz
1613	AC power supply 90-110VAC 60Hz

Or six standard "AA" alkaline cells (IEC Type LR6)

Battery Life

Alkaline Cells: 24 hours with no printing.

Dimensions

Width:	69.85mm (2.75 inches)
Height:	167.64mm (6.6 inches)
Depth:	36.322mm (1.43 inches)
Weight:	595 grams (1lb. 5 ounces) with batteries and optional boot

Environmental Specifications

Operating Temp.:	0 to 55° C (32 to 131° F)
Storage Temp.:	-40 to +75° C (-40 to +167° F)
Relative Humidity:	15 to 95% (operating), non-condensing 10 to 95% (storage), non-condensing

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Appendix A: Guidance and Manufacturer's Declaration

Guidance and Manufacturer's Declaration

The V3402 pulse oximeter is intended for use in the electromagnetic environment specified in the tables within this appendix.

NOTE! The customer or user of the V3402 pulse oximeter should ensure that it is used in such an environment.

Electromagnetic Emissions - Emissions Test

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
RF emissions CISPR 11	Group 1	The V3402 pulse oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The V3402 pulse oximeter is suitable for use in all establishments, including: <ul style="list-style-type: none"> • Domestic establishments. • Establishments directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	NA	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	NA	

Electromagnetic Emissions – Immunity

IMMUNITY		ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	IEC 60601 TEST LEVEL	Floors should be made of: <ul style="list-style-type: none"> • Wood • Concrete • Ceramic tile If floors are covered with synthetic material, the relative humidity should be at least 30%.
	<ul style="list-style-type: none"> • ± 6 kV contact • ± 8 kV air 	
	COMPLIANCE LEVEL	
	<ul style="list-style-type: none"> • ± 6 kV contact • ± 8 kV air 	

IMMUNITY		ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Electrical fast transient/burst IEC 61000-4-4	IEC 60601 TEST LEVEL <ul style="list-style-type: none">• ± 0.5 kV to ± 2 kV for power supply lines.• ± 0.25 kV to ± 1 kV for I/O lines.	A.C. Mains power voltage should be the typical quality of a: <ul style="list-style-type: none">• Commercial environment.• Hospital environment.
	COMPLIANCE LEVEL <ul style="list-style-type: none">• ± 0.5 kV to ± 2 kV for power supply lines.• ± 0.25 kV to ± 1 kV for I/O lines.	
Surge IEC 61000-4-5	IEC 60601 TEST LEVEL <ul style="list-style-type: none">• ± 1 kV differential mode• ± 2 kV common mode	
	COMPLIANCE LEVEL <ul style="list-style-type: none">• ± 1 kV differential mode• ± 2 kV common mode	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	IEC 60601 TEST LEVEL <ul style="list-style-type: none">• $< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle.• $< 40\% U_T$ ($> 60\%$ dip in U_T) for 5 cycles.• $< 70\% U_T$ ($> 30\%$ dip in U_T) for 25 cycles.• $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 seconds.	
	COMPLIANCE LEVEL <ul style="list-style-type: none">• $< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle.• $< 40\% U_T$ ($> 60\%$ dip in U_T) for 5 cycles.• $< 70\% U_T$ ($> 30\%$ dip in U_T) for 25 cycles.• $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 seconds.	
Note: U_T is the A.C. mains voltage prior to application of the test level.		

IMMUNITY		ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Power frequency (50/60 Hz) IEC 61000-4-8	IEC 60601 TEST LEVEL	Power frequency magnetic fields should be the typical levels of a: <ul style="list-style-type: none">• Commercial environment• Hospital environment
	3 A/m	
	COMPLIANCE LEVEL	
	3 A/m	
Conducted RF IEC 61000-4-6	IEC 60601 TEST LEVEL	Recommended separation distance: $d = 1.2$
	<ul style="list-style-type: none">• 3 V rms• 150 kHz to 80MHz	
	COMPLIANCE LEVEL	
	<ul style="list-style-type: none">• 3 Vrms 80% AM modulation @ 0.5kHz• 150 kHz to 80 MHz.	
Radiated RF IEC 61000-4-3	IEC 60601 TEST LEVEL	Recommended separation distance: $d = 0.18 \sqrt{P}$ 80 MHz to 800 Mhz $d = 0.35 \sqrt{P}$ 800 MHz to 2.5 GHz
	<ul style="list-style-type: none">• 3 V/m• 80 MHz to 2.5 GHz	
	COMPLIANCE LEVEL	
	<ul style="list-style-type: none">• 20 V/m 80% AM• 80 MHz to 1 GHz	

- P = Manufacturer's output power in watts (W).
- d = Recommended distance in meters (m).

Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range ^b.

CAUTION! Interference may occur in the vicinity of equipment marked with the following symbol:

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed RF transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the V3402 pulse oximeter is used exceeds the applicable RF transmitter compliance level above, the V3402 pulse oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the V3402 pulse oximeter.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

The V3402 pulse oximeter is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. The customer or the user of the V3402 pulse oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the V3402 pulse oximeter as recommended below, according to the maximum output power of the communications equipment.

The recommended separation distances between portable and mobile RF communication equipment and the V3402 pulse oximeter is:

RATED MAXIMUM OUTPUT POWER OF RF TRANSMITTER (WATTS)	SEPARATION DISTANCE ACCORDING TO THE FREQUENCY OF RF TRANSMITTER (METERS)		
	150 kHz to 80MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 0.18 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.35 \sqrt{P}$
0.01	0.12	0.018	0.035
0.1	0.38	0.057	0.11
1	1.2	0.18	0.35
10	3.8	0.57	1.1
100	12	1.8	3.5
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p><i>NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</i></p> <p><i>NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</i></p>			

WARNING! The monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the monitor should be observed to verify normal operation in the configuration in which it will be used.

Appendix B: Revision History

REVISION	DATE	COMMENT
Rev. 4	2008-04	<ul style="list-style-type: none"> • Added CE Notice and European Representative to Warranty section and back cover. • Added WEEE Recycling instructions and Smiths URL. • Added warning to verify that all LEDS light up upon start up of the device. • Update Theory of Operation. • Added a note about increasing or decreasing the averaging setting having no effect on the data update rate. • Added a note about how the 1606 Oximeter Patient Simulator cannot be used to assess the accuracy of a pulse oximeter and/or sensor. • Added desat study information to the SpO2 Accuracy spec. • Added Appendix A: Guidance and Manufacturer's Declaration. • Added this Revision History. • Deleted any mention of "Veterinary Division."

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EC REP Authorized Representative (as defined by the Medical Device Directive):

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