"DIGITAL OXIMETRY"

User's Manual

Handheld Pulse Oximeter
Model 512

January 29, 1999

Catalog No. 9100-23-00

CE
0086

About this manual

This manual is written for clinical personnel using the Novametrix Handheld Pulse Oximeter, Model 512, and the oximeter sensors and accessories intended for use with the monitor.

Model 512 Technical Description

Per requirements of IEC 601-1, the Model 512 is classified as class II equipment, internally powered, with type BF applied part, and an enclosure protection rating of IPX0. The Model 512 is Year 2000 compliant.

Transport/Storage: -10 to +55° C (14-131° F), 10-95% R.H. non-condensing
Operating Conditions: 10 to +40° C (50 to 104° F), 10-90% R.H. non-condensing

The Handheld Pulse Oximeter, Model 512, contains no user serviceable parts. Refer servicing to qualified service personnel. A technical Service Manual (9100-90) is available for use by technical personnel.

Manufacturing Quality & Safety

The Novametrix Medical Systems Inc. manufacturing facility is certified to both ISO 9001 and EN46001 (MDD93/42/EEC Annex II). Novametrix' products bear the "CE 0086" mark. The product is certified by Underwriter's Laboratories (UL) to bear the UL mark; and tested by TÜV Rheinland to IEC 601-1/EN60601-1.

Declaration of Conformity with European Union Directive

The Authorized Representative for Novametrix equipment is:

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Manual Revision History

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General Description

The Novametrix Model 512 is an easy-to-operate handheld pulse oximeter. It determines functional oxygen saturation (SpO_2) and pulse rate values and displays them to the user on a bright easy-to see display. A bargraph, indicative of the plethysmogram signal, is also displayed. The monitor is powered from two "AA" batteries. An optional external power adapter is available.

Indications for Use

The Model 512 Handheld Pulse Oximeter is indicated for use by technically skilled clinical personnel for the monitoring of oxygen saturation and pulse rate in patient areas including adult, pediatric and neonatal.

Principles of Operation

The Model 512 measures oxygen saturation and pulse rate with sensors that contain red and infrared light sources—light emitting diodes, or LEDs. Since oxygen saturated blood absorbs different amounts of light at each wavelength (red and infrared) as compared to unsaturated blood, the amount of light absorbed by the blood in each pulse can be used to calculate oxygen saturation.

The light energy from red (660 nm) and infrared (940 nm) LEDs is beamed through a sample cell—a pulsating vascular bed, the patient's finger or toe for example. The remaining light energy not absorbed by the sample cell reaches a light receptor, called a photodiode, on the opposing side of the sensor. The data received at the photodiode is sent back to the monitor where it is split into its red and infrared components, digitized, processed by a microprocessor chip, and finally displayed as a numerical value for oxygen saturation. The moment to moment changes in this signal are reflected on the bargraph display.

The Model 512 is calibrated to display "functional" saturation. This differs from the "fractional" saturation value displayed by most co-oximeters. Functional saturation represents the amount of oxyhemoglobin as a percentage of the hemoglobin that can be oxygenated. Dysfunctional hemoglobins, (COHb and METHb) are not included in the measurement of functional saturation.

- Functional Saturation = $HbO_2/100-(COHb+METHb)$; HbO_2 is fractional hemoglobin, COHb is carboxyhemoglobin, and METHb is methemoglobin.

Pulse Rate is calculated by measuring the time interval between the peaks of the infrared light waveform. The inverse of this measurement is displayed as pulse rate.

Patient Safety

For maximum patient and operator safety, the following are recommended:

- Care should be exercised to assure continued peripheral perfusion distal to the SpO_2 sensor site after application.
- Do *NOT* attach an SpO_2 sensor distal to a blood pressure cuff. Valid data *CANNOT* be processed when the cuff is inflated. Attach the sensor to the limb opposite to the site used for the blood pressure cuff.
- Keep the Model 512 and its accessories clean. Do not operate the Model 512 when it is wet due to spills or condensation.

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- Where electromagnetic devices (i.e., electrocautery) are used, patient monitoring may be interrupted due to electromagnetic interference. Electromagnetic fields up to 3 V/m will not adversely affect system performance.
- The Model 512 contains no user serviceable parts. Refer servicing to qualified service personnel. A technical Service Manual (9100-90) is available for use by technical personnel.

Warnings

WARNING:
Indicates a potentially harmful condition that can lead to personal injury.

- **Explosion Hazard:** Do NOT use the Model 512 in the presence of flammable anesthetics. Use of this instrument in such an environment may present an explosion hazard.
- **Electrical Shock Hazard:** Always turn the Model 512 off before cleaning it. Do NOT use a damaged sensor or one with exposed electrical contacts. Do not use with a damaged external power source. Refer servicing to qualified service personnel.
- **Failure of Operation:** If the monitor fails to respond as described, do not use it until the situation has been corrected by qualified personnel.
- **Patient Safety:** Care should be exercised to assure continued peripheral perfusion distal to the SpO_2 sensor site after application.
- Do not position the sensor cable in any manner that may cause entanglement or strangulation.

Cautions

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

- Do not operate the Model 512 when it is wet due to spills or condensation.
- Do not operate the product if it appears to have been dropped or damaged.
- Never sterilize or immerse the monitor in liquids.
- Do not sterilize or immerse sensors except as directed in this manual.
- No tension should be applied to any sensor cable.
- Caution: Federal (U.S.A.) law restricts this device to sale, distribution, or use by or on the order of a licensed medical practitioner.
- Operate at temperatures between 10 to +40° C (50 to 104° F), 10-95% R.H. non-condensing.
- Avoid storing the monitor at temperatures less than -10° C or greater than +55° C (<14° F or >131° F) 10-95% R.H. non-condensing

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Notes

NOTE
Indicates points of particular interest or emphasis and intended to provide for more efficient or convenient operation.

- Use only Novametrix approved sensors and accessories with the Model 512.
- This product and its accessories which have patient contact are free of latex.
- The Model 512 is Year 2000 compliant.
- **Data Validity:** As with all pulse oximeters, inaccurate SpO_2 and Pulse Rate values may be caused by;
  - Incorrect application or use of a sensor
  - Significant levels of dysfunctional hemoglobin; carboxyhemoglobin or methemoglobin
  - Significant levels of indocyanine green, methylene blue, or other intravascular dyes
  - Exposure to excessive illumination such as surgical lamps—especially ones with a xenon light source, or direct sunlight
  - Excessive patient movement
  - Venous pulsations
  - Electrosurgical interference

Symbols

Symbol	Description
	**Patient Isolation** Identifies patient isolation connection as type BF.
	**Attention** Consult manual for detailed information.

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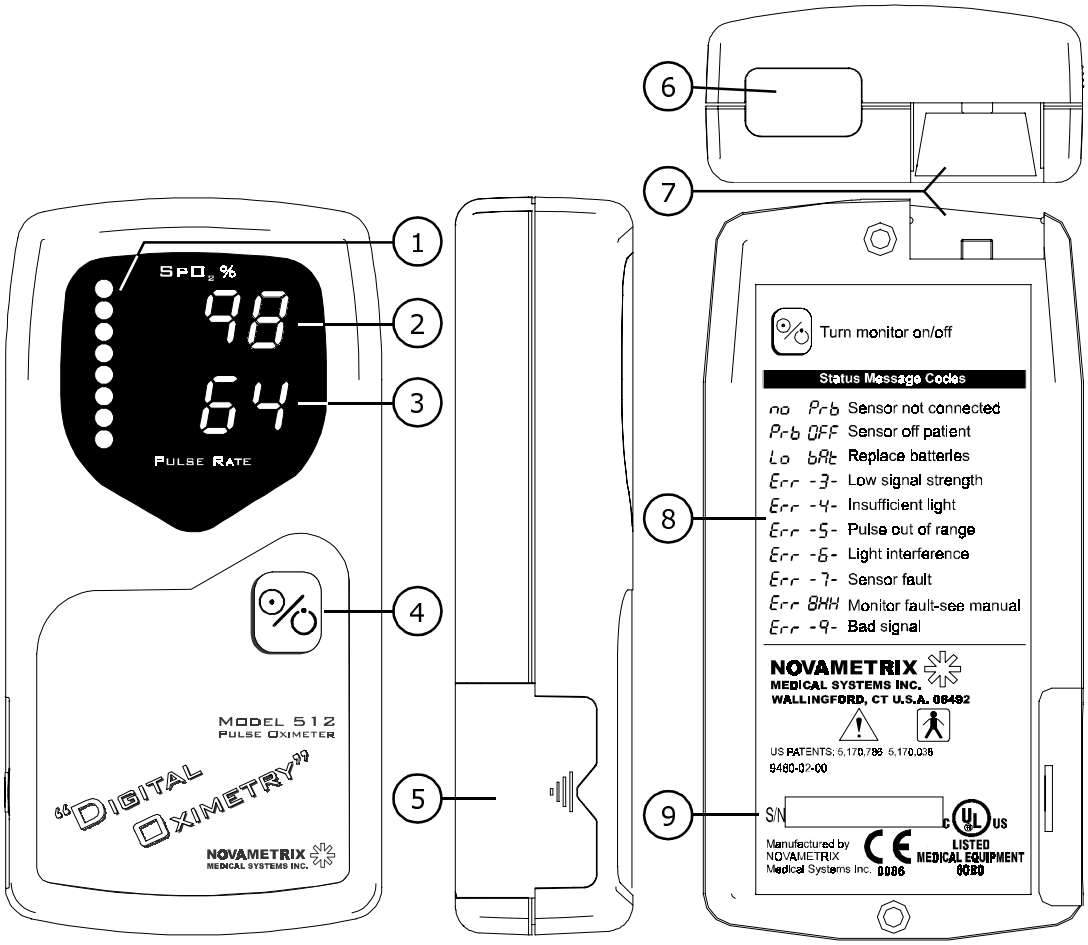
Preparation for Use

Getting Acquainted

The Model 512 Handheld Pulse Oximeter Monitor is shown below.

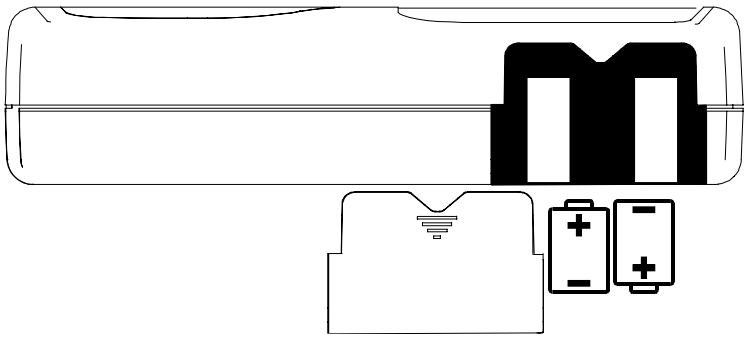


1	**Activity Bar** indicates pulsatile activity (plethysmogram signal).	6	**IR Link** Infrared communications link unused by Model 512 (Model 513 only).
2	**SpO_2 %** displays oxygen saturation value. Also error and setup messages.	7	**Sensor Input** Connect only approved Novametrix sensors.
3	**Pulse Rate** display value in beats/min. Also error and setup messages.	8	**Quick Guide** Basic reference.
4	**Power Key** turns monitor on/off.	9	**Serial Number** and other information.
5	**Battery Cover** slides from monitor to access batteries.		

Power supply options

Batteries. Fresh disposable "AA" alkaline batteries (Panasonic AM3X or equivalent) provide approximately 16 hours of operation. Battery capacity may be reduced in colder temperatures, with excessive power cycling.

To install or remove the batteries;



1. Turn the monitor off and then slide the battery cover from the unit. Remove the old batteries from the battery compartment.
2. Install fresh batteries according to the polarity diagram. Slide the battery compartment cover back into place and turn the monitor on.

Dispose of batteries in accordance with local laws. Do not mix battery types (e.g. disposable and rechargeable AA batteries). The Model 512 may not power up if the batteries are nearly depleted.

> **WARNING:**
> ⚠ Do not recharge or incinerate alkaline batteries. Attempting to do so may cause the batteries to leak or explode.

Power On/Off

To turn the pulse oximeter on, press the POWER key.

Press the power key 

- All displays are briefly illuminated and an audible tone sounds. Next, the model number (SpO_2 display) and software revision level (Pulse Rate display) are briefly indicated.

To turn the pulse oximeter off, press the POWER key.

Auto Power Off

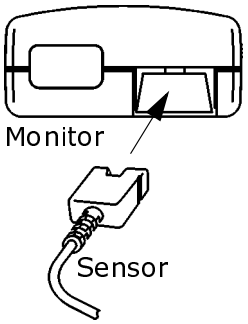
A battery power saving feature allows the pulse oximeter to shut itself off after waiting three and one-half minutes without detecting any pulsatile activity.

- If three minutes elapse without any detected pulsatile activity, the oximeter emits a two-tone audible signal once each 5 seconds for 30 seconds. If still no pulsatile activity is detected, the pulse oximeter shuts itself off.
- If at any time pulsatile activity is detected, the power off counter is reset.

Sensors and Patient Connection

Sensors plug into the receptacle on top of the monitor. Use only Novametrix SuperBright™ Sensors with the Model 512 Pulse Oximeter. Compatible sensors include;

- Reusable Sensors
  - 9168-00 Finger Sensor
  - 9169-00 Y-Sensor™
- Single Patient Use Sensors
  - 6455-00 Pediatric/Adult Foam Wrap Style
  - 6480-00 Neonatal/Pediatric Foam Wrap



Sensor Quick Check

A quick functional check of basic sensor operation.

1. With the sensor connected to the monitor but not applied to the patient, position the sensor heads so they face each other (red light shines on the detector). Is "Prb OFF" displayed?
2. Apply the sensor to your index finger. Are reasonable SpO_2 and pulse rate values displayed?
3. A YES to BOTH #1 and #2 indicates the sensor is operational. Apply the sensor to the patient as instructed.

WARNING

! Before applying to the patient, verify the sensor is physically intact, with no broken/frayed wires or damaged parts. Do not use a broken or damaged sensor or one with wet, contaminated, or corroded connectors.

! After applying to the patient, inspect the site often for adequate circulation—at least once every four hours. Do not wrap so tightly that circulation is restricted. Note the patient's physiological condition. For example, burn patients may be more sensitive to heat and pressure and require more frequent site checks.

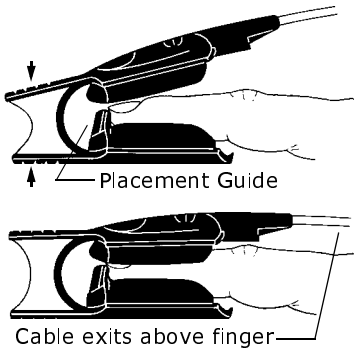
Finger Sensor (9168-00)

The reusable Finger Sensor is intended for adult and appropriately sized pediatric fingers.

To apply: Squeeze the grips. Position the fingertip as shown and release the grips.

To remove: Squeeze the grips. Slide the sensor from the finger and release the grips.

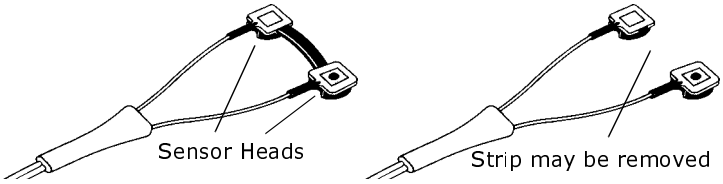
Caution: Overstretching can damage the sensor and affect oximetry readings. Do not force the sensor onto large objects such as bedrails.



Y-Sensor (9169-00)

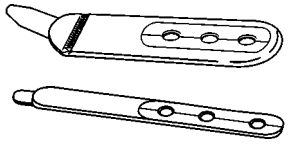
The reusable Y-Sensor is designed for use on all patients from adults to neonates.

Y-Sensor configuration. The Y-Sensor's center strip may be carefully cut away if the distance between the sensor heads needs to be reduced to less than 25mm.

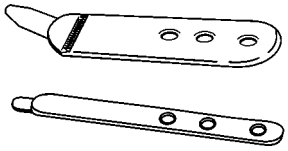


Y-Sensor applicators. The flexible and versatile Y-Sensor is applied to the patient using a variety of adhesive and non-adhesive applicators.

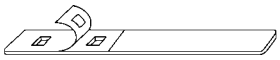
Treat applicators (except ear-clip) in accordance with hospital protocol for single-patient use. Refer to instructions packaged with the various applicators.



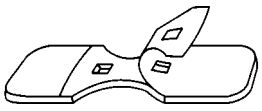
- 6929-00. Adhesive Foam Wraps, Large
  — Adult, pediatric or neonatal use.
- 6968-00. Adhesive Foam Wraps, Small
  — Neonatal or appropriately sized pediatric patient.



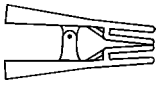
- 8836-00. Non-Adhesive Foam Wrap, Large
  — Adult, pediatric or neonatal use.
- 8943-00. Non-Adhesive Foam Wrap, Small
  — Neonatal or appropriately sized pediatric patient use.



- 8828-00. 20mm Wrap Style Y-Strip Tape (blue)
  — Neonatal foot or hand, pediatric toe or finger.
- 8829-00. 25mm Wrap Style Y-Strip Tape (green)
  — Neonatal foot or hand.

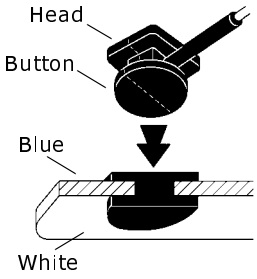


- 8831-00. 20mm Finger Style Y-Strip Tape (blue)
  — Appropriately sized pediatric or adult fingers.
- 8832-00. 25mm Finger Style Y-Strip Tape (green)
  — Adult fingers.



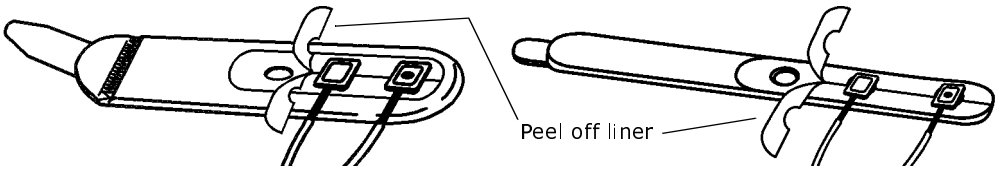
- 6131-00. Ear Clip
  — Adult or pediatric use.

Using Foam Wraps.



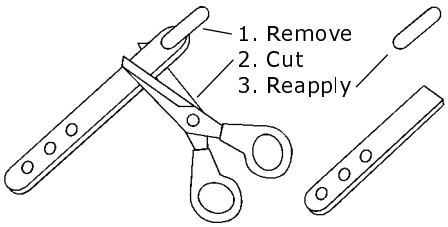
1. Press each sensor "button" through the blue side of the foam wrap.
   - Place the head with the red LED closest to the edge, and the other in either remaining hole (removing the Y-Sensor's center strip as required).
2. If using an adhesive foam tape, remove both sides of the paper liner.

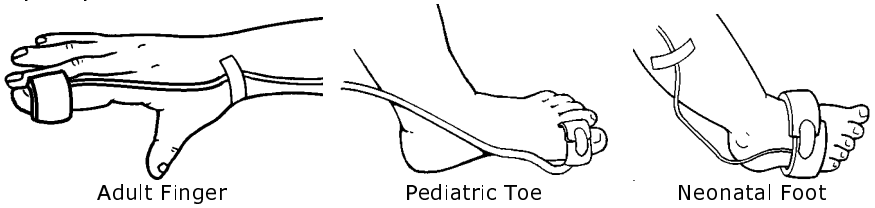
- You can also remove the liners prior to buttoning the sensor into the foam wrap if desired.



3. With the blue foam towards the patient, wrap around the site. Ensure the sensor heads are opposite each other through the tissue. Secure in place with the white plastic tab.
   - The tab on the Small foam wrap is removable, allowing shortening for a better fit. Reapply the tab to secure the wrap in place.

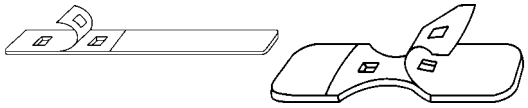
Small foam wrap



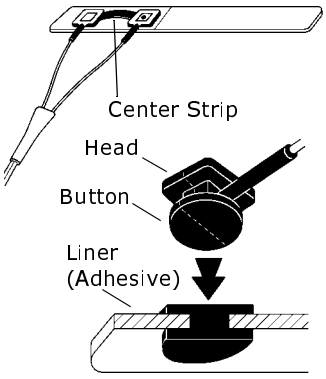


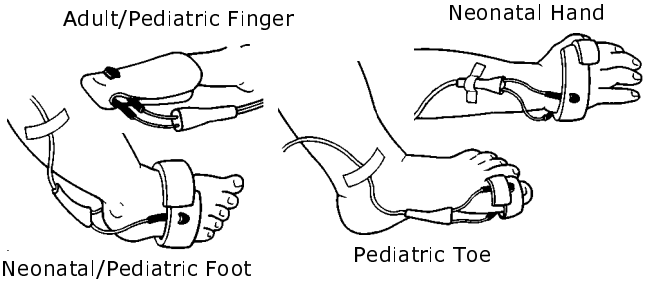
Using Y-Strip Tapes.

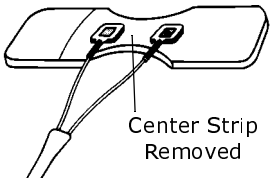
1. Remove the release liner with the holes.



2. Press each sensor "button" through the adhesive side of the tape. (Remove the Y-Sensor's center strip if required.)
3. Remove the remaining release liner. Apply the sensor/tape to the patient. Ensure the sensor heads are opposite each other.

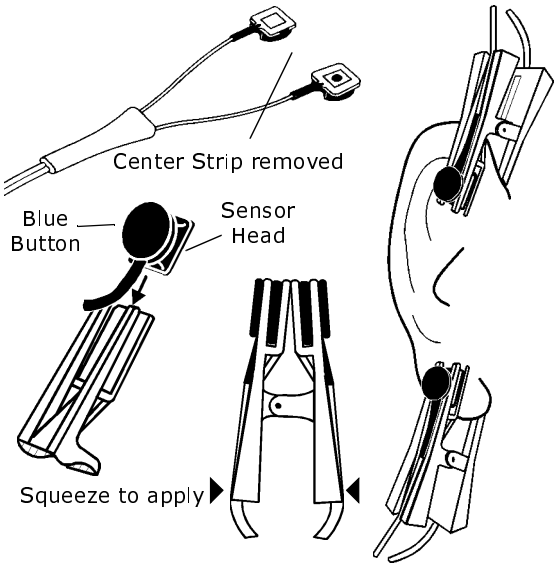






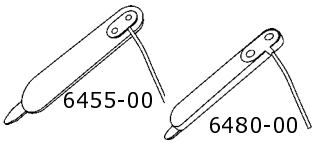
Using the Ear Clip.

1. Remove the center strip from the Y-Sensor.
2. Slide each Y-Sensor head into an Ear Clip receptacle with the blue button facing outwards.
3. Open the clip by squeezing its ends and apply it to the ear.
   - It may be necessary to rub the ear with your fingers in order to increase circulation prior to applying the sensor.
   - Adhesive Dots (8700-00) are included with the ear clip to help hold the clip to the ear.



Single Patient Use Sensors (6455-00 and 6480-00)

These Single Patient Use Sensors are for use on appropriately sized patients.



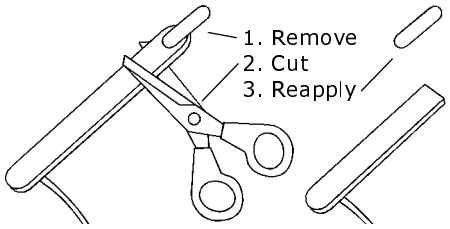
- 6455-00. Pediatric/Adult, Foam Wrap Style — Adult or appropriately sized pediatric patients.
- 6480-00. Neonatal/Pediatric, Foam Wrap Style — Neonatal or appropriately sized pediatric patients.

CAUTION:

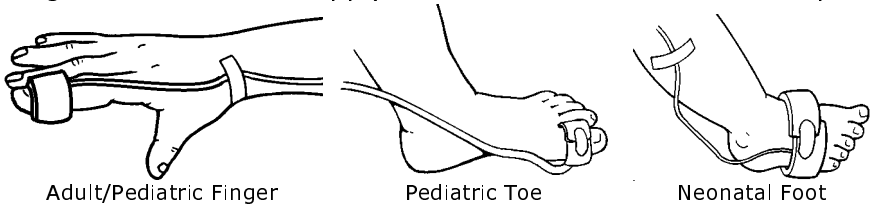
! Single Patient Use SpO_2 sensors can be reapplied to a single patient as needed, but should not be used across multiple patients. Single Patient Use sensors should not be cleaned or disinfected. System performance may be compromised as a result. Replace sensor instead.

1. Select the appropriate size sensor based on the patient type.
2. With the blue foam towards the patient, wrap around the site. Ensure the sensor heads are opposite each other through the tissue. Secure in place with the white plastic tab.

Neonatal/Pediatric

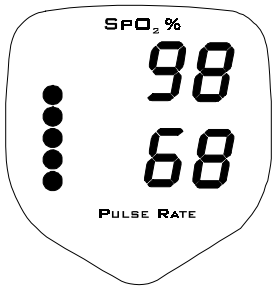


- Double-sided adhesive dots, included with the sensor, can be applied over the LED and detector components to help hold the sensor to the site.
- The tab on the Neonatal/Pediatric sensor is removable, allowing shortening for a better fit. Reapply the tab to secure the sensor in place.



Patient Monitoring

Patient Monitoring

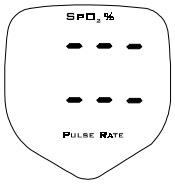


Once the pulse oximeter is powered on and a sensor is connected to the oximeter and properly applied to the patient, numerical SpO_2 and Pulse Rate values appear on the pulse oximeter's display.

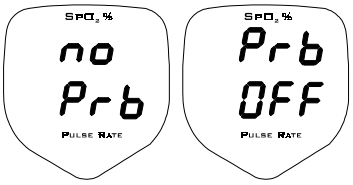
A "pulse activity bar", derived from the pulsatile signal, is also displayed. The activity bar should reflect the patient's pulse. Erratic or non-rhythmic pulse bar activity may indicate a poorly positioned or applied sensor, or may be indicative of excess patient movement at the sensor site. Check the sensor site and if necessary, attempt to reduce patient movement. The oximeter automatically adjusts the length of the bar to optimize its display.

Display Messages

The SpO_2 and pulse rate displays are also used to present system messages:

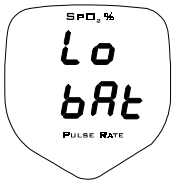


Searching for pulsatile data
When the sensor is first applied to the patient, dashes (---) are displayed for a few seconds until enough pulsatile data is collected to calculate and display SpO_2 and pulse rate values. Prolonged insufficient, erratic, or non-rhythmic pulsatile activity (in excess of 45 seconds) is indicated to the user by displaying dashes rather than continuing to display "old" and possibly no longer valid values. SpO_2 and pulse rate values will resume when "valid" pulsatile data is again detected by the sensor. (If the condition exists for greater than 90 seconds "Err -9-" is displayed instead; see below.)

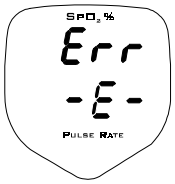


Probe Off (Prb OFF)
Sensor is connected to the pulse oximeter, but not applied to the patient.

No Probe Connected (no Prb)
Sensor is not connected to the pulse oximeter.



Low Battery (Lo bat)
Briefly displayed once each minute (with triple beep tone) when less than 30 minutes of battery capacity remains, and once each 5 seconds (with triple beep tone) when less than 15 minutes of power remain.

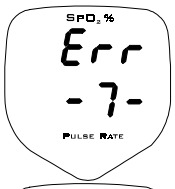


Error Conditions while Monitoring
where "E" is a numerical value as explained below. These monitoring conditions, typically transitory in nature, are automatically reset once the condition is corrected.

- **Err -3-** Low signal strength. Pulse strength as detected by the sensor is too small for proper pulse oximeter operation. Check patient status and/or reposition sensor.
- **Err -4-** Insufficient light. Sensor placed on a site too thick (or opaque) for adequate light transmission. Reposition sensor.

- **Err -5-** Pulse out of range. Pulse must be 30-250 beats/min inclusive.
- **Err -6-** Light interference. Ambient light sources (sunlight, warming lights, etc.) are interfering with sensor operation. Shield sensor from these light sources.
- **Err -9-** Bad signal. Pulse oximeter is receiving prolonged insufficient, erratic, or non-rhythmic pulsatile activity (in excess of 90 seconds). Error is accompanied by an audible alert tone. Condition may be caused by excessive motion, cardiac arrhythmia or other situations leading to poor signal. Check patient status and/or reposition sensor. SpO_2 and pulse rate values will resume, and audible alert tone is silenced, when "valid" pulsatile data is again detected by the sensor.

Sensor fault condition
Remove the sensor from use and contact qualified service personnel.



Monitor fault condition
where "HH" is a numerical value. Remove the pulse oximeter from use. Record the number shown in the Pulse Rate display and contact qualified service personnel.

Maintenance

The pulse oximeter performs a diagnostic self-test at powerup that checks the internal electronics. If this self test fails the normal monitoring display will not appear. Remove the oximeter from use and contact qualified service personnel.

The oximeter should undergo inspection and safety checks on a regular basis or according to institutional protocol. A Service Manual (Catalog No. 9100-90) containing information to assist qualified service personnel is available.

Cleaning and Sterilization

To clean and/or sterilize the oximeter and its accessories;

Pulse Oximeter

- Do not immerse the oximeter. Do not sterilize the oximeter.
- Turn the oximeter off and unplug the external adapter (if used) from the AC power source before cleaning.
- The oximeter can be cleaned and disinfected by wiping with solutions such as a 70% isopropyl alcohol, 2% glutheralhyde, or 10% bleach solution. Then wipe down with a water dampened clean cloth to rinse. Dry before use.

SpO_2 Finger Sensor

- Do not immerse the finger sensor. Do not sterilize the finger sensor.
- The sensor can be cleaned and disinfected by wiping with solutions such as a 70% isopropyl alcohol, 2% glutheralhyde, or 10% bleach solution. Then wipe down with a water dampened clean cloth to rinse. Dry before use.
- Make certain that the finger sensor windows are clean and dry before reuse.
- After cleaning the finger sensor, perform a Quick Check to verify the sensor is functional (See "Sensor Quick Check" on page 6).

SpO_2 Y-Sensor

- The Y-Sensor may be immersed—up to, but not including, the connector, in a 2% glutheralhyde solution, or 10% bleach solution. Refer to manufacturer's instructions and standard hospital protocols to determine recommended times for disinfection and sterilization.
- Rinse thoroughly with water and dry before use. (Do not rinse the connector).
- After cleaning or sterilizing the Y-Sensor, perform a Quick Check to verify the sensor is functional (See "Sensor Quick Check" on page 6).

SpO_2 Tapes and Foam Wraps

- Treat tapes and foam wraps in accordance with hospital protocol for single-patient use items.

Ear Clip

- Clean with a cloth dampened with 70% isopropyl alcohol. After cleaning, thoroughly wipe the ear clip with a clean, water dampened cloth.

Accessories

Cat. No.	Description
Monitor	
9100-00	Model 512, Handheld Pulse Oximeter
9100-23	User's Manual, Model 512
9100-90	Technical Service Manual, Model 512
315134	Transport Pouch
9276-10	Protective Rubber Boot
400038	Alkaline Battery, 1.5 vdc, AA Size (Panasonic AM3X or equiv.)
SuperBright™ Oximeter Sensors	
9169-00	Y-Sensor™ (use with DB-9 Sensors) 90 day warranty
9168-00	Finger Sensor (use with DB-9 Sensors) 1 yr. warranty
6455-00	Single Patient Use Pediatric/Adult Sensor (10 per box)
6455-25	Single Patient Use Pediatric/Adult Sensor (25 per box)
6480-00	Single Patient Use Neonatal/Pediatric Sensor (10 per box)
6480-25	Single Patient Use Neonatal/Pediatric Sensor (25 per box)
8828-00	20mm Wrap Style Y-Strip Taping System (100 per box)
8829-00	25mm Wrap Style Y-Strip Taping System (100 per box
8831-00	20mm Finger Style Y-Strip Taping System (100 per box)
8832-00	25mm Finger Style Y-Strip Taping System (100 per box)
8836-00	Non-Adhesive Foam Wraps - Large (25 per box)
8943-00	Non-Adhesive Foam Wraps - Small (25 per box)
6929-00	Large Adhesive Foam Wrap, (25 per box)
6968-00	Neonatal/Pediatric Adhesive Foam Wrap, (25 per box)
6131-50	Ear Clips (5 per box)
6131-25	Ear Clips (25 per box)
8700-00	Re-Flex Sensor Application Dots
9174-00	Extension Cable, DB-9 to DB-9, 3 feet
9175-00	Extension Cable, DB-9 to OxySnap, 4.5 feet
933-00	Extension Cable, DB-9 to Hypertronic, 8 feet
936-00	Adapter Cable, DB9 to OxySnap, 6 inch
9180-00	Adapter Cable, DB-9 to Hypertronic, 6 inch

Specifications

The Novametrix Model 512 Handheld Pulse Oximeter specifications are listed here for informational purposes only, and are subject to change without notice.

Principle of Operation
- Red/Infrared Absorption

SpO_2 (Oxygen Saturation)
- Range:0-100%
- Accuracy:70-100% ±2%, 50-69% ±3%, 0-49% unspecified, ±1 standard deviation
- Resolution:1%
- Averaging:8 seconds

Pulse Rate
- Range: 30-250 bpm
- Accuracy: ±2 bpm
- Resolution: 1 bpm
- Averaging: 8 seconds

General
- Size: 4.25 x 2.25 x 1.0 inches (10.8 x 5.7 x 2.5 cm)
- Weight: 5.7 ounces (162 g) (with batteries)
- Display: Numerics - 7 segment LED's, Pulse Bar - 8 LEDs
- Electrical: Battery - 2 AA alkaline, Capacity - 16 hours
- Operating Conditions: 10 to +40° C (50 to 104° F), 10-90% R.H. non-condensing
- Transport/Storage Conditions: -10 to +55° C (14 to 131° F), 10-95% R.H. non-condensing

Additional Features
- Auto Shut Off: Monitor automatically shuts itself off after 3.5 minutes if no data is being received.
- Low Battery Indicator: Illuminates when approximately 15 minutes of battery life remain.
- Monitor Status Messages: Error codes displayed for various monitoring related conditions.

Warranty

Equipment manufactured or distributed by Novametrix Medical Systems Inc., is fully guaranteed, covering materials and workmanship, for a period of one year from the date of shipment, except for certain disposable products and products with stated guarantees other than one year. Novametrix reserves the right to perform guarantee service(s) at its factory, at an authorized repair station, or at the customer's installation.

Novametrix' obligations under this guarantee are limited to repairs, or at Novametrix' option, replacement of any defective parts of our equipment, except fuses, batteries, and calibration gasses, without charge, if said defects occur during normal service.

Claims for damages during shipment must be filed promptly with the transportation company. All correspondence concerning the equipment must specify both the model name and number, and the serial number as it appears on the equipment.

Improper use, mishandling, tampering with, or operation of the equipment without following specific operating instructions will void this guarantee and release Novametrix from any further guarantee obligations.

Service Department

For factory repair service:
Call toll free: 1-800-243-3444
To Call Direct: (203) 265-7701
Facsimile (203) 284-0753
http://www.novametrix.com
techline@novametrix.com

Caution: Federal (U.S.A.) law restricts this device to sale, distribution, or use by or on the order of a licensed medical practitioner.