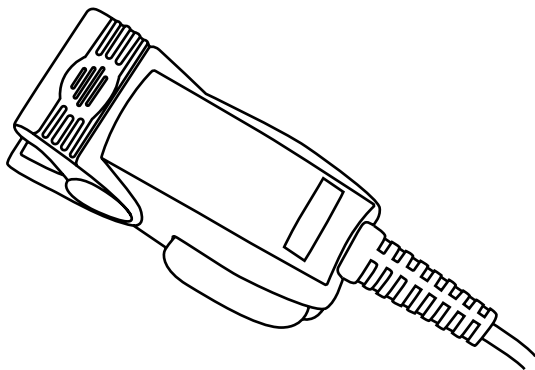


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SPO2 SENSOR FOR OMNI VITAL SIGN PATIENT MONITOR

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USER GUIDE

ADIME913-S



Thank you for your purchase.

.....

**Viva Diagnostics maintains
a strong practice of ongoing
development of products and
commercial research.**

.....

**We recognize that starting and maintaining a medical
practice is expensive. We'll help make the process cost-
effective and elegant. Additionally, our team of specialists
will ensure everything you need works as efficiently as
possible, so you can effectively treat your clients.**

Table of Contents

- 4 Intended Use
- 4 Measurement Principle
- 5 Warnings
- 6 Inaccurate Measurements May Be Caused By
- 7 Appearance
- 7 How To Use
- 9 Important Notes
- 10 Specifications
- 11 Classifications
- 12 Symbol Definitions
- 13 Warranty

Intended Use:

The SpO₂ Sensor is intended for noninvasive spot-checking or continuously monitoring functional arterial oxygen saturation and pulse rate with oximeter equipment.

The SpO₂ Sensor is intended for pediatric patients in hospitals, hospital-type facilities, and home environments.

NOTE: The illustrations used in this manual may differ slightly from the appearance of the actual product. The specifications are subject to change without prior notice.

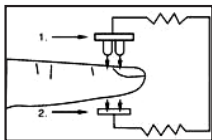
Measurement Principle:

The principle of the Pulse Oximetry Sensor is as follows: A mathematical formula is established using Lambert-Beer Law according to the Spectrum Absorption Characteristics of Reductive Hemoglobin (RHb) and Oxyhemoglobin (HbO₂) in red and near-infrared zones.

Operation Principle of The Instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted by Capacity Pulse Scanning and Recording Technology so that two beams of different wavelengths of light (660nm red and 905nm near-infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element will be shown on the oximeter's display through the process in electronic circuits and microprocessors.

Diagram of Operation Principle

1. Red and Infrared-Ray Emission Tube
2. Red and Infrared-Ray Receipt Tube



WARNINGS:

1. Before use, carefully read the manual.
 2. This sensor is for use only with compatible monitors, instruments, or Oximeter modules; using it with anything other than compatible instruments, monitors, or modules may result in improper performance.
 3. The sensor is contraindicated for use on active patients
 4. Fingernail polish, artificial fingernails, poorly perfused fingers, extremely large fingers, or improper sensor placement may cause inaccurate measurement results.
 5. The operation may be affected by electromagnetic solid sources.
 6. The sensor is not recommended for use when imaging equipment is in use, such as Magnetic Resonance Imaging (MRI), etc.
 7. Do not immerse the sensor in any liquid; do not sterilize it with ETO.
 8. Please stop using the sensor immediately if it is damaged in any way.
 9. Please stop using the sensor immediately if it gets wet; wipe it dry immediately.
 10. Do not clip or wrap the measuring position too tightly.
 11. When continuously monitoring, check and reposition the sensor to an alternate location every four hours.
 12. Be careful with the cable placement as to reduce the possibility of patient entanglement or strangulation.
 13. Use according to the pulse oximeter or monitor's operation manual when connecting the sensor with another device.
 14. This equipment should not be used adjacent to or stacked with other equipment.
- Rx ONLY: "Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner."**

Inaccurate Measurements May Be Caused By:

1. Significant levels of dysfunctional hemoglobin (such as carboxyhemoglobin or methemoglobin).
2. Intravascular dyes such as indocyanine green or methylene blue.
3. High ambient light; shield the sensor area if necessary.
4. Excessive patient movement.
5. High-frequency electrosurgical interference and defibrillators.
6. Venous pulsations.
7. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
8. The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
9. The patient is in cardiac arrest or is in shock.
10. Fingernail polish or false fingernails.
11. Weak pulse quality (low perfusion).
12. Low hemoglobin.

Appearance:

Simple Introduction: The adult sensor (small size) is for a person who is older than 12 years old.



How To Use:

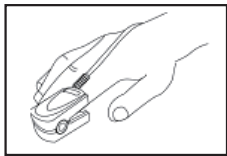
- A.** Select a suitable site for the sensor, such as the preferred location of the index finger.
 - a.** Alternative sites recommended are the middle and ring fingers.
- B.** Fit the finger as illustrated in the image below.
 - a.** The patient's finger must be fixed right to the end of the sensor.
 - b.** When using the adult sensor, ensure that the bottom of a fingernail is positioned at the mark on the side of the sensor to get an accurate measurement.



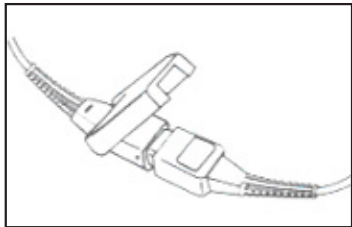
Recommended Position

How To Use (Continued):

- C.** The sensor should be oriented in such a way that the cable is positioned along the top of the hand, as pictured below.



- D.** Plug the sensor into the unit, as pictured, and verify proper operation as described in the instrument's operator manual.
- a.** Hold the connector rather than the cable when connecting or disconnecting the finger sensor to the oximeter.
 - b.** Do not twist unnecessarily or use excessive force when using, connecting, disconnecting, or storing the sensor.



Important Notes:

1. Please unplug the sensor from the monitor before cleaning or disinfecting.
2. Properly clean or disinfect the sensor before attaching it to a new patient to avoid infection.
3. Clean the sensor and patient contact surfaces with water and a cloth or a mild soap solution and cloth.
4. To disinfect the sensor, wipe the sensor and patient contact surface with a disinfecting solution.
* We recommend 70% isopropyl alcohol as a disinfecting solution.
5. Don't sterilize using irradiation, steam, or ethylene oxide.

Specifications:

SpO₂

Measuring Range: 70%~100%

Accuracy: 70%~100% $\pm 2\%$; <70% **Unspecified**

Resolution: 1%

| Compare To Reference CO-Oximeter Functional SaO ₂ | Functional SaO ₂ 70-100% Arms | # of Points | Specification 70-100% Arms |
|---|--|-------------|----------------------------|
| M-50 SpO ₂ Sensor On MD300 Handheld Pulse Oximeter | 2.0 | 247 | Pass Arms of 3 |

Pulse Rate:

Measurement Range: 30~235bpm

Accuracy: 30~100 ± 2 bpm; 100~235 $\pm 2\%$

Resolution: 1bpm

Probe LED Specifications:

| | Wavelength | Radiant Power |
|-----|----------------|---------------|
| RED | 660 \pm 3nm | 3.2mW |
| IR | 905 \pm 10nm | 2.4mW |

Environment Requirements:

Operation Temperature: 5~40 C^o

Storage Temperature: -40~+55 C^o

Ambient Humidity: $\leq 80\%$ no condensation in operation







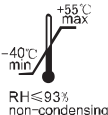






$\leq 93\%$ no condensation in storage

Atmosphere Pressure: 86kPa~106kPa

Classifications:

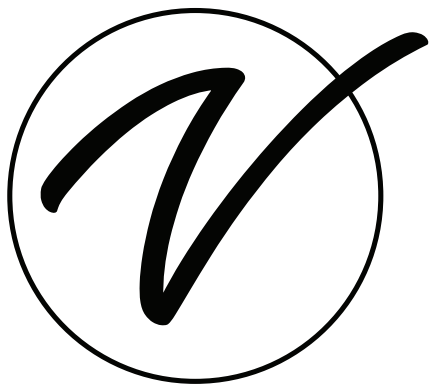
- According to the degree of protection against electric shock: TYPE BF APPLIED PART;
- According to the degree of protection against ingress of water, IPX1
- According to the mode of operation: CONTINUOUS OPERATION
- If you have any questions regarding this information, please get in touch with our Customer Service Department.
- Latex Free. No toxicity, which meets the biology compatibility requirement.
- The functional tester cannot be used to assess the accuracy of the Oximeter.
- The user can use this function tester to measure the Oximeter.
- The test methods used to establish the SpO2 accuracy is clinical testing. The Oximeter used to measure the arterial hemoglobin oxygen saturation levels and these levels are to be compared to the levels determined from arterial blood sampling with a CO-Oximeter.

Symbol Definitions:

| Symbol | Definition |
|---|---|
|  | Caution |
|  | Follow instruction for use |
|  | Type BF applied part |
| IPX1 | Protected against dripping water |
|  | Keep upright |
|  | Fragile |
|  | Protected from moisture |
|  | Storage temperature and relative humidity |
|  | Manufacturer's information |
|  | Don't throw away |
|  | Recyclable |
|  | European union approval |
|  | Authorized representative in the European community |
|  | Waste electrical and electronic equipment |

Warranty

1. Viva Diagnostics (the "Company" or "Tiger Companies") warrants to the purchaser that the product will be free from defects in workmanship and materials for a period of 1 year from the date of purchase. The warranty period is not extended if we repair, replace, exchange, or provide a refund for the product (as determined in our sole discretion). We may change the availability of this limited warranty at our discretion, but any changes will not be retroactive.
2. These warranties are not assignable or transferable to any other person, including, without limitation, any subsequent owner or other transferee of the product.
3. This Warranty does not apply to: (a) damage caused by misuse, tampering, abuse, neglect, or accident; (b) damage caused by improper installation, modification, or service; (c) alteration of the serial number; or (d) use that violates the instructions furnished by the Company will void this warranty.
4. The sole responsibility of the Company shall be limited to (a) the repair or replacement (in its sole discretion) of any component of the product which fails to conform to this; (b) a refund the purchase price of such product (in its sole discretion), at no cost to the purchaser for the period of the warranty, or (c) an exchange for a similar product, comparable in function and price.
5. Contact the Company directly at 1-(800)-805-1790 to obtain service under this warranty. If it becomes applicable to send a defective product to the Company, a Return Authorization Number must first be obtained from the Company. In order to obtain service under this warranty, purchaser may be required to provide the Company with the following items (a) proof of purchase, (b) photographs and or videos (of the damage, and (c) a written testimonial describing the defect.
6. Products shipped without prior Return Authorization and Return Authorization Number may not be accepted, and the Company will not be responsible for their disposition and/or cost of return to the owner.
7. The Company will not assume any responsibility for any loss or damage incurred in shipping and or delivery.
8. The product(s) must be returned within 14 calendar days of receiving the return authorization from the Company and must include the original proof of purchase for the warranty to be honored.
9. Any implied warranties that the purchaser may have are limited to the duration of the warranties described above. There are no further warranties that extend or apply beyond the face hereof, and the Company expressly disclaims and excludes any and all warranties of merchantability or fitness for a particular purpose. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.
10. THE REMEDIES DESCRIBED ABOVE ARE YOUR SOLE AND EXCLUSIVE REMEDIES AND THE COMPANY'S ENTIRE LIABILITY FOR ANY BREACH OF THIS LIMITED WARRANTY. OUR LIABILITY SHALL UNDER NO CIRCUMSTANCES EXCEED THE ACTUAL AMOUNT PAID BY YOU FOR THE DEFECTIVE PRODUCT, NOR SHALL WE UNDER ANY CIRCUMSTANCES BE LIABLE FOR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL OR PUNITIVE DAMAGES OR LOSSES, WHETHER DIRECT OR INDIRECT. SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATIONS OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE LIMITATION MAY NOT APPLY TO YOU.
11. This warranty gives you specific legal rights, and you may also have additional rights which vary from state to state.



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