



GIMA

PROFESSIONAL MEDICAL PRODUCTS

OXY-4 PULSE OXIMETER PULSOXIMETRU PULSOXIMETER PULSSIOKSIMETRI PULSNI OKSIMETAR PULZOXIMÉTER ПУЛСОВ ОКСИМЕТЪР PULSOXYMETER

Use and maintenance book

Manual de utilizare și întreținere

Instruktioner för användning och underhåll

Käyttö- ja huolto-ohjeet

ATTENTION: The operators must carefully read and completely understand the present manual before using the product.

AVERTISMENT: Orice accident grav produs, privitor la dispozitivul medical fabricat de firma noastră, trebuie semnalat producătorului și autorității competente în statul membru pe teritoriul căruia își are sediul utilizatorul.

OBS: Det är nödvändigt att meddela tillverkaren och de behöriga myndigheterna i den berörda medlemsstaten, om alla allvariga olyckor som inträffat i samband med den medicintekniska utrustning som levererats av oss.

VAROITUS: Kaikista vakavista tapaturmista, jotka liittyvät toimittamamme lääkinnällisen laitteen käyttöön, on ilmoitettava valmistajalle sekä oman asuinpaikan jäsenmaan toimivaltaiselle viranomaiselle

PAŽNIA: Potrebno je prijaviti svaku ozbiljnu nezgodu koja se dogodila u vezi s isporučenim medicinskim proizvodaču i nadležnom tijelu države članice u kojoj se nalazi.

Priručnik za uporabu i održavanje

Kezelési és karbantartási útmutató

Инструкции за употреба и поддръжка

Instructies voor gebruik en onderhoud

FIGYELEM: A gyártónak, illetve a székhely szerinti tagállam illetékes hatóságának jelezni kell bármilyen olyan súlyos balesetet, amely az általunk szállított orvostechnikai eszközzel kapcsolatban történt

FIGYELMEZTETÉS: Всички сериозни инциденти, които са настъпили във връзка с доставеното от нас медицинско изделие, трябва да се сигнализират на производителя и на компетентния орган на държавата членка, в която производителят е установен.

WAARSCHUWING: Alle ernstige ongelukken die zich in verband met het door ons geleverde medische hulpmiddel voordoen, moeten gemeld worden aan de fabrikant en aan de bevoegde instantie van de lidstaat waar u gevestigd bent

REF 35093



Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com



CH REP

Medicare AG, Hauptstr. 51
5024 Küttigen, Schweiz
CHRN-AR-20002506





INSTRUCTIONS TO USER

Read these instructions carefully before using this equipment. These instructions describe the operating procedures to be followed strictly. Failure to follow these instructions can cause measuring abnormality, equipment damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.


- The contents contained in this manual are subject to change without notice.
- The uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for over 2 hours- If any abnormal condition is found, please change the position of Pulse Oximeter.
- For the individual patients, there should be a more prudent inspecting in the placing process. The device can not be clipped on the edema and tender tissue.
- The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man, can not stare at the light.- The Pulse Oximeter is not a treatment device.
- Testee can not use enamel or other makeup on the finge.
- Testee's fingernail can not be too long- Please peruse the relative content about the clinical restrictions and caution.

1. SAFETY

1.1 Instructions for Safe Operations

- Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance with regard to sensors and clips. It is recommended that the device should be inspected minimally before each use. When there is obvious damage, stop using the oximeter.
- Necessary maintenance must be performed by qualified service technicians ONLY. Users are not permitted to maintain it by themselves.
- The oximeter cannot be used together with the devices and accessories not specified in Use's Manual.
- Special attention should be paid while the Pulse Oximeter is used constantly when the ambient temperature over 37°C, burning hurt may occur because of over-heating of the sensor at this situation.

1.2 Attentions

-  - Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- The device should be kept out of the reach of children.
 - If the oximeter gets wet, please stop using it and do not resume operation until it is dry and checked for correct operation. When it is carried from cold environment to warm and humid environment, please do not use it immediately. Allow at least 15 minutes for Pulse Oximeter to reach ambient temperature.
 - DO NOT press the keys on front panel with sharp materials or sharp points.
 - High temperature or high pressure steam disinfection to the oximeter is not permitted. Refer to User's Manual for instructions of cleaning and disinfection.
 - The finger should be put in properly and correctly.
 - Do not shake the finger. Keep at ease during measurement.
 - Do not put wet finger directly into sensor.
 - Do not let anything block the emitting light from the device.
 - Ensure that there is artery vessel within measuring site where the light transmits through.
 - Vigorous exercise and the interference from the electrosurgical device may affect the measuring accuracy.
 - If the first reading appears with poor waveform (irregular or not smooth), then the reading is unlikely true, the more stable value is expected by waiting for a while, or a restart is needed when necessary.

2. OVERVIEW

SpO₂ is the saturation percentage of oxygen in the blood, so called O₂ concentration in the blood; it is defined by the percentage of oxyhemoglobin (HbO₂) in the total hemoglobin of the arterial blood. SpO₂ is an important physiological parameter to reflect the respiration function; it is calculated by the following method:

$$\text{SpO}_2 = \text{HbO}_2 / (\text{HbO}_2 + \text{Hb}) \times 100\%$$

HbO₂ are the oxyhemoglobins (oxygenized hemoglobin), Hb are those hemoglobins which release oxygen.

2.1 Features

- Large true color OLED display of SpO₂, PR Pulse Bar, PI & Plethysmogram.
- Innovative 4 directions display.
- Automatic power on/off.
- Audible & visible over-limit indication.
- Shift parameter display between PR and PI.

2AAA alkaline batteries with low power consumption.

- Low battery voltage indication.

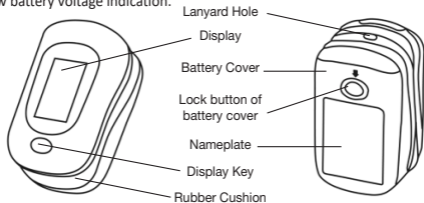



Figure 1

2.2 Major Applications and Scope

The Fingertip Oximeter is compact, convenient to use and carry and with low power consumption. You just need to put the fingertip into the sensor of the device, the SpO₂ value will appear on the screen immediately.

The Fingertip Oximeter can detect SpO₂ and pulse rate through patient's finger. This device is applicable to home, hospital (including internal medicine, surgery, anesthesia, pediatrics, emergency room etc.), oxygen bar, the community medical center, alpine area and it also can be used before or after sports, and the like.

 This device is not appropriate to be used for continuous monitoring.

2.3 Principle of Measurement

Based on Lambert-Beer law, the light absorbance of a given substance is directly proportional with its density or concentration. When the light with certain wavelength emits on human tissue, the measured intensity of light after absorption, reflecting and attenuation in tissue can reflect the structure character of the tissue by which the light passes. Due to that oxygenated hemoglobin (HbO₂) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light (600nm~1000nm wavelength), by using these characteristics, SpO₂ can be determined. SpO₂ measured by this Pulse Oximeter is the functional oxygen saturation -- a percentage of the hemoglobin that can transport oxygen. In contrast, hemoximeters report fractio-

nal oxygen saturation – a percentage of all measured hemoglobin, including dysfunctional hemoglobin, such as carboxyhemoglobin or methaemoglobin. Clinical application of pulse oximeters: SpO₂ is an important physiological parameter to reflect the respiration and ventilation function, so SpO₂ monitoring used in treatment has become more popular. (For example, such as monitoring patients with serious respiratory disease, patients under anesthesia during operation and premature and neonatal infants) The status of SpO₂ can be determined in timely manner by measurement and will allow finding the hypoxemia patient earlier, thereby preventing or reducing accidental death caused by hypoxia effectively.

Factors affecting SpO₂ measuring accuracy (interference reason)

- Intravascular dyes such as indocyanine green or methylene blue.
- Exposure to excessive illumination, such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight.
- Vascular dyes or external used color-up product such as nail enamel or color skin care.
- Excessive patient movement.
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- Exposure to the chamber with High pressure oxygen.
- There is an arterial occlusion proximal to the sensor.
- Blood vessel contraction caused by peripheral vessel hyperkinesias or body temperature decreasing.

Factors causing low SpO₂ Measuring value (pathology reason)

- Hypoxemia disease, functional lack of HbO₂.
- Pigmentation or abnormal oxyhemoglobin level.
- Abnormal oxyhemoglobin variation.
- Methemoglobin disease.
- Sulfhemoglobinemia or arterial occlusion exists near sensor.
- Obvious venous pulsations.
- Peripheral arterial pulsation becomes weak.
- Peripheral blood supply is not enough.

2.4 Caution

A. The finger should be placed properly (see the figure 3 of this manual), or else it may cause inaccurate measurement.



- B. The SpO₂ sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
- C. The SpO₂ sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.
- D. Do not fix the SpO₂ sensor with adhesive or else it may result in venous pulsation and inaccurate measure of SpO₂.
- E. Make sure the optical path is free from any optical obstacles like rubberized fabric.
- F. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.
- G. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.

3. BATTERY INSTALLATION

1. Press the lock button of the battery cover, meanwhile, pull the cover back and take it out.
2. Refer to Figure 2, insert two AAA size batteries into the battery compartment properly.
3. Replace the cover. Please make sure that the batteries are correctly installed since the incorrect installation may cause the device inoperable.

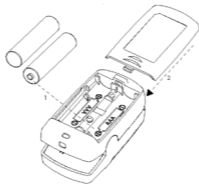


Figure 2
Battery Installation

4. OPERATION

4.1 Start Measurement

1. Open the clip as shown in Figure 3.

2. Put finger into the rubber cushions of the clip (make sure the finger is in the correct position), and then clip the finger.
3. The device will power on automatically in 2 seconds, and start to display software version number.
4. Next enter into data display screen (as shown in Figure 4). The user can read the values and view the waveform from display screen.



Figure 3 Put finger into the Oximeter



Figure 4 A1

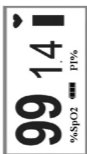


Figure 4 A2



Figure 4 A2



Figure 4 A2



Figure 4 C1



Figure 4 C2



Figure 4 D1



Figure 4 D2




Screen Description:

“%SpO2”: The title of SpO2; “99”: SpO2 value, unit:%;

“PR”: The title of Pulse Rate; “65”: Pulse Rate value, unit: bpm (beat per minute);

“♥”: Pulse beat icon; “◆”: Pulse bar-graph;

“PI%”: The title of Perfusion Index; “1.4”: Perfusion Index value, unit: %;

“”: Battery power indicator.

5. Change display direction

Four directions display alternately. Short time press “Display Key” to flip the screen 90° each time in a cyclical manner as shown in Figure

4. When the screen displays towards the left side, the plethysmogram will be viewed.

6. Shift parameter display between PR and PI during measurement Long time press the “Display Key”, shift the parameter display between PR and PI. But when the PR is shifted to PI display and no button operation is performed after 20 seconds, the PI will change to PR display automatically.

4.2 Over-limit indication and Beep Silence

When measuring, if SpO2 value or pulse rate value exceeds the limit, the device will beep automatically and the value which exceeds its limit will flash on the screen (Refer to chapter 4 for the detailed information). When the beep sound is activated by over-limit, it will become silent or d-active at the following situations:

1. The SpO2 and PR value return to normal range.
2. Press Display Key to mute. If this over-limit event persists, the Pulse Oximeter will resume beeping automatically later in 2 minutes.
3. Remove the finger from the Pulse Oximeter or SpO2 probe.

5. TECHNICAL SPECIFICATIONS

A. SpO2 measurement:

dual-wavelength LED sensor with wavelength:

Red light: 663 nm, Infrared light: 890 nm. Maximal average optical output power: $\leq 1.5\text{mW}$ Measuring range: 35%~100%

Measuring accuracy:

$\leq 3\%$ for SpO2 range from 70% to 100% SpO2 low over-limit: 90%

B. Pulse Rate measurement:

Measuring range: 30bpm~240bpm

Measuring accuracy: $\pm 2\text{bpm}$ or $\pm 2\%$ (whichever is greater)

Pulse Rate over-limit: high over-limit: 120bpm; low over-limit: 50bpm

C. Perfusion Index (PI) Display

Range: 0.2%~20%

D. Audible & visual over-limit indication

When measuring, if SpO2 value or pulse rate value exceeds the limit, the device will beep automatically and the value which exceeds its limit will flash on the screen. The Oximeter will shut down automatically in 8 seconds with no signal.

E. Display: Color OLED Display

F. Power supply requirement:

2 x LR03 (AAA) alkaline batteries Working voltage: 2.2V~3.3VDC Operating current: $\leq 40\text{mA}$

G. Environment requirement Operating Temperature: 5 ~40°C Operating Humidity: 30~80% Atmospheric pressure: 70~106kPa

H. The performance under low perfusion condition

The accuracy of SpO2 and PR measurement still meets the specification described above when the pulse modulation amplitude is as low as 0.6%.

I. Resistance to ambient light interference:

The accuracy of SpO2 and PR measurement still meets the specification described above when the device is tested by SpO2 simulator (Fluke Biomedical Index 2 series) while setting the emulating interference of sun light and 50Hz/60Hz fluorescent light.

J. Dimensions: 60 mm (L) × 33 mm (W) × 30 mm (H)

Net Weight: 35g (including battery)

K. Classification:

The type of protection against electric shock: Internally powered equipment.

The degree of protection against electric shock: Type BF applied parts.

The degree of protection against harmful ingress of liquids: Ordinary equipment without protection against ingress of water.

Electro-Magnetic Compatibility: Group I, Class B.

6. ACCESSORIES

A. A lanyard

B. Two batteries

C. A carrying pouch

D. A User Manual



Note: The accessories are subject to change. Detailed items and quantity see the Packing List.

7. REPAIR AND MAINTENANCE

The expected service life (not a warranty) of this device is 5 years. In order to



ensure its long service life, please pay attention to the use of maintenance.

A. Please change the batteries when the low-voltage indicator lightens.

B. Please clean the surface of the device before using. Wipe the device with 75% alcohol wipes, and then let it dry in air or wipe it dry. Do not allow liquid to enter the device.

C. Please take out the batteries if the oximeter will not be used for for any more than 7 days.


D. The recommended storage environment of the device is -20°C to 60°C ambient temperature and 10% to 95% relative humidity with atmospheric pressure: 50kPa~107.4kPa.

E. The Pulse Oximeter is calibrated in the factory before sale, so there is no need to calibrate it during its life cycle. However, if it is necessary to verify its precision routinely, the user can do the verification by means of SpO2 simulator, or it can be done by the local third party testing house.

7.1 Cleaning and Disinfecting Instruction

Surface-clean sensor with a soft cloth damped with a solution such as 75% isopropyl alcohol, if low-level disinfection is required, use a mild bleach solution. Then surface-clean by soft cloth damped ONLY with clean water and let air dry or wipe it dry.

Caution: Do not sterilize by irradiation steam, or ethylene oxide. Do not use the Pulse Oximeter if it is damaged visually

 High-pressure sterilization cannot be used on the device. Do not immerse the device in liquid.

It is recommended that the device should be kept in a dry environment

8. TROUBLESHOOTING

Trouble	Possible Reason	Solution
The SpO2 and Pulse Rate display instable	<ol style="list-style-type: none"> 1. The finger is not placed far enough inside. 2. The finger is shaking or the patient is moving. 	<ol style="list-style-type: none"> 1. Place the finger correctly inside and try again. 2. Let the patient keep calm
Cannot turn on the device	<ol style="list-style-type: none"> 1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The device is malfunctioning. 	<ol style="list-style-type: none"> 1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center

No display	1. The device will power off automatically when it gets no signal for 8 s. 2. The batteries are almost drained	1. Normal. 2. Change batteries.
------------	---	------------------------------------















Declaration of Conformity:

The manufacturer hereby declares that this device complies with the following standards:

IEC 60601-1 IEC60601-1-2

IEC60601-1-11, ISO 80601-2-61 and follows the provisions of the council directive MDD93/42/EEC.

9. KEY OF SYMBOLS

Symbol	Description	Symbol	Description
	Type BF applied part		WEEE disposal
	Caution: read instructions (warnings) carefully		Keep away from sunlight
	Follow instructions for use		Keep in a cool, dry place
%SpO ₂	Oxygen saturation (percentage)		Medical Device complies with Directive 93/42/EEC
PR	Pulse rate (beats per minute)		Product code
	Pulse beat icon		Lot number
	Low battery voltage		Manufacturer
	Serial number		Date of manufacture

CONDIZIONI DI GARANZIA GIMA

Si applica la garanzia B2B standard Gima di 12 mesi.



Smaltimento: Il prodotto non deve essere smaltito assieme agli altri rifiuti domestici. Gli utenti devono provvedere allo smaltimento delle apparecchiature da rottamare portandole al luogo di raccolta indicato per il riciclaggio delle apparecchiature elettriche ed elettroniche.

**INFORMATION ON ELECTROMAGNETIC COMPATIBILITY****Electromagnetic compatibility****Levels of compliance with the EN 60601-1-2:2015 standard**

- ESD immunity 15kV in air and 8kV on contact (EN 61000-4-2)
- Burst immunity 2kV/100kHz (EN 61000-4-4)
- Surge immunity (EN 61000-4-5): 1kV common/2kV differential
- Magnetic field (EN 61000-4-8): 30A/m
- Immunity to rf currents in the range 150kHz-80MHz (EN 61000-4-6) 3V modulation 80% 1kHz 6V modulation 80% 1kHz for the following frequency ranges: 6.765 MHz ÷ 6.795 MHz 13.553 MHz ÷ 13.567 MHz 26.957 MHz ÷ 27.283 MHz 40.66 MHz ÷ 40.70 MHz
- CISPR emissions 11 class B
- EN 61000-3-2 class A Harmonic currents
- PST, DT, DC Flickers

Immunity to RF fields (EN 61000-4-3):

Field (V/m)	Frequency	Modulation
3	80MHz - 2700MHz	1kHz AM 80%
27	380MHz - 390MHz	18Hz PM 50%
28	430MHz - 470MHz	18Hz PM 50%
9	704MHz - 787MHz	217Hz PM 50%
28	800MHz - 960MHz	18Hz PM 50%
28	1700MHz - 1990MHz	217Hz PM 50%
28	2400MHz - 2570MHz	217Hz PM 50%
9	5100MHz - 5800MHz	217Hz PM 50%

Warnings:

Even if it complies with EN 60601-1-2, the medical device may interfere with other devices in the vicinity. The device should not be used next to or stacked with other equipment. Install the device away from other equipment which radiates high frequencies (short waves, microwaves, electrosurgical units, mobile phones).

The device is designed to operate in an electromagnetic environment in which RF

radiated disturbances are under control. The customer or the operator can help prevent electromagnetic interference by ensuring a minimum distance between mobile and portable RF communication devices (transmitters) and the medical device, as recommended below, in relation to the maximum output power of the radio communication devices

Rated maximum output power of transmitter (W)	Distance (m) of separation according to the frequency of the transmitter		
	from 150kHz to 80MHz $d = 1.2 \sqrt{P}$	from 80MHz to 800MHz $d = 1.2 \sqrt{P}$	from 800MHz to 2.5GHz $d = 2.3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters whose rated maximum output power is not listed above, the recommended separation distance d in metres (m) can be calculated using the equation applicable to the transmitter frequency, where P is the rated maximum power transmitter output in Watts (W) according to the transmitter manufacturer.

Notes:

- (1) The highest frequency range must be applied at 80 MHz and 800 MHz
- (2) These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and by the reflection from structures, objects and people.