

Fingertip Puls Oximeter MD300 C53 User manual



Start-up: summarised instructions

- 1. Before use, disinfect the device and the finger used for measured.
- 2. Insert your finger into the device until the end and nail towards the screen!
- 3. Press the start / stop button
- 4. Remove the finger. The device turns off automatically.

Periodic maintenance.

1. Regular disinfection.

Thank you for choosing an Oxycure concentrator.



The Oxycure range, from left to right

Oxycure portable concentrators

Oxycure portable concentrator – Inogen G4 Oxycure portable concentrator – Inogen G3 Oxycure portable concentrator – Zen-O lite Oxycure portable concentrator – Simply Go Mini Oxycure portable concentrator – SimplyGo Oxycure portable concentrator – eQuinox

Oxycure concentrators

Oxycure – Kröber concentrator

Oxycure cylinders (gaseous oxygen)

Oxycure B2 cylinder – 0.4 m^3 Oxycure B5 cylinder – 1.0 m^3

Oxycure tanks (liquid oxygen)

Oxycure liquid oxygen tank – 25.6 m³ Oxycure portable liquid oxygen tank (1.0 m³)

More information at <u>www.oxycure.be</u>



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OPENING HOURS

From Monday to Friday

09.00 - 12.30 and 13.30 - 18.00

CUSTOMER SERVICE

0800 98 0 68

Our customer service operates 24/7.

It is exclusively to urgent installations or repairs on our medical devices.

Call to guard service

- Leave a message on the answering machine with your name and phone number and give a brief reason of your call ;
- The customer service will call you within 20 minutes ;
- If the customer service did not call you within 20 minutes, call again.

<u>Notes</u>

- 1. Technical interventions (repairs) are included in the price of the assistance of the leasing.
- 2. Deliveries of goods, outside the opening hours, will be charged.



MD300C53

Oxygen Saturation is a percentage of Oxyhemoglobin (HbO2) capacity, compounded with oxygen, by all combinative hemoglobin (Hb) capacity in blood In other words, it is consistency of Oxyhemoglobin in blood. It is a very important parameter for the Respiratory circulation System. Many respiratory diseases can result in oxygen saturation being lowered in human blood. Additionally, the following factors can reduce oxygen saturation: Automatic regulation of organ dysfunction caused by Anesthesia, Intensive Postoperative Trauma, injuries caused by some medical examinations. That situation might result in lightheadedness, asthenia, and vomiting. Therefore, it is very important to know the oxygen saturation of a patient so that doctors can find problems in a timely manner.

The fingertip pulse Oximeter features small size, low power consumption, convenient operation and portability. It is only necessary for a patient to put one of his fingers into the fingertip photoelectric sensor for diagnosis, and a display screen will show oxygen saturation. It has been proven in clinical experiments that it also features high precision and repeatability.

Measurement principle

Principle of the Oximeter is as follows: A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in glow and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 940nm 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 process in electronic circuits and microprocessor shown on the Oximeter's display through electronic circuits and a microprocessor.

Diagram of Operation Principle



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

Precautions for use

- 1. Do not use the pulse oximeter in an MRI or CT environment
- **2.** Do not use the pulse oximeter in situations where alarms are required. The device has no alarms.
- **3.** Explosion hazard: Do not use the pulse oximeter in an explosive atmosphere.
- **4.** The pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- **5.** Check the pulse oximeter sensor application site frequently to determine the positioning of the sensor and circulation and skin sensitivity of the patient.
- **6.** Do not stretch the adhesive tape while applying the pulse oximeter sensor. This may cause inaccurate readings or skin blisters.
- **7.** Before use, carefully read the manual.

- **8.** The pulse oximeter has no SpO2 alarms; it is not for continuous monitoring.
- **9.** 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.
- **10.** Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid.
- **11.** Significant levels of dysfunctional hemoglobins (such as carbonxy- hemoglobin or methemoglobin) may affect the readings.
- **12.** Intravascular dyes such as indocyanine green or methylene blue
- **13.** SpO2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, or direct sunlight, for example) if necessary.
- **14.** Excessive patient movement may cause inaccurate readings.
- **15.** High-frequency electrosurgical interference may cause inaccurate readings.
- **16.** Venous pulsations may cause inaccurate readings.
- **17.** Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- **18.** The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
- **19.** The patient is in cardiac arrest or is in shock.
- **20.** Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

Product Properties

- 1 Operation of the product is simple and convenient.
- 2 The product is small in volume, light in weight and convenient in carrying.
- 3 Power consumption of the product is low.
- 4 Low voltage warning will be indicated in visual window when battery voltage is so low that normal operation of the Oximeter might be influenced.
- 5 The product will automatically be powered off when no signal is in the product for longer than 8 seconds.

Product Operation Scope

Fingertip PULSE OXIMETER is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care and etc). Not for continuously monitoring.

The PULSE OXIMETER requires no routine calibration or maintenance other than replacement of batteries.

Operation Instructions

- 1 Installing two AAA batteries correctly.
- 2 Nip the clamp as diagram.
- 3 Insert one finger into rubber hole of the Oximeter fully.
- 4 Press the switch button once on front panel.
- 5 Your finger and body do not tremble during the Oximeter is working.
- 6 Read corresponding data from display screen.

7 Six display modes

After turning on the Oximeter, each time you press the power switch, the Oximeter will switch to another display mode, there are 6 display modes shown as follows:



When you press the power switch for a long time (more than one second), the brightness of the Oximeter will be changed by degrees, there are 10 levels on brightness; the default level is level four.

NOTE: Please use the medical alcohol to clean the rubber touching the finger inside of Oximeter, and clean the test finger using alcohol before and after each test. (The rubber inside of the Oximeter belongs to medical rubber, which has no toxin and no harm to the skin of human being).

When your finger is plugged into the Oximeter, your nail surface must be upward.



Brief Description of Front Panel



The PR Bar graph displays corresponding with the patient's pulse beat. The height of the bar graph shows the patient's pulse strength.

Product Accessories

- 1. One lanyard
- 2. Two batteries
- 3. One user manual

Battery Installation

- 1. Put the two AAA batteries into battery cassette with correct polarities.
- 2. Push the battery cover horizontally along the arrow shown as below:

Notes: Battery polarities must be correctly installed. Otherwise, damage might be caused to device.

Please put or remove batteries in right order, or is likely to damage the device bracket.



Please remove batteries if the Oximeter will not be used for a long time.

Lanyard Installation

- 1. Thread thinner end of the hang lace through the hanging hole.
- 2. Thread thicker end of the lace through the threaded end before pulling it tightly.

Maintenance and Storage

- **1.** Replace the batteries in time when low voltage lamp is lighted.
- 2. Clean surface of the fingertip Oximeter before it is used in diagnosis for patients.
- **3.** Remove batteries inside the battery cassette if the Oximeter will not be operated for a long time.
- **4.** It is best to preserve the product in a place where ambient temperature -20~55°C and humidity is <93% (no condensation).
- **5.** It is recommended that the product should be kept in a dry environment anytime. A wet ambient might affect its lifetime and even might damage the product.
- **6.** Please follow the law of the local government to deal with used batteries.

Calibration

- 1. The functional tester cannot be used to assess the accuracy of the Oximeter.
- 2. Index 2 that made by Bioteck company is a function tester. Set Tech to 1, R curve to 2, and then a user can use this particular calibration curve to measure the Oximeter.
- 3. The test methods used to establish the SpO₂ accuracy is clinical testing. The Oximeter used to measure the arterial haemoglobin oxygen saturation levels and these levels are to be compared to the levels determined from arterial blood sampling with a CO-Oximeter.

Declaration

EMC of this product complies with IEC60601-1-2 standard.

The materials which user can come into contact have no toxicity and no action on tissues, complying with ISO10993-1,-5,-10.

Detailed descriptions of product functions

1. Display Type: OLED

2. SpO2:

Measurement range: 70%-100% Accuracy: 80%-100%, \pm 2%; 70%-80%, \pm 3%; \leq 69% no definition.

3. Pulse Rate:

Measure range: 30-235 BPM Accuracy: 30~99bpm, \pm 2bpm; 100~235bpm, \pm 2% Pulse Intensity: Bargraph Indicator

4. Power Requirements:

Two AAA alkaline Batteries Power consumption: Less than 40mA Low power indication: Battery Life: Two AAA 1.5V, 600mAh alkaline batteries could be continuously operated as long as 30 hours. **5. Dimension:** Length: 49mm~51mm Width: 28mm~30mm Height: 28mm~30mm

7. Environment Requirements:

Operation Temperature: $5 \sim 40^{\circ}$ C Storage Temperature: $-20 \sim 55^{\circ}$ C Ambient Temperature: $\leq 80\%$, no condensation in operation. $\leq 93\%$, no condensation in storage

- **8. Measurement Performance in Low Perfusion Condition:** required the test equipment (BIO-TEK INDEX Pulse Oximeter tester) the pulse wave is available without failure when the simulation pulse wave amplitude is at 6%.
- **9. Interference Resistance Capacity against Ambient Light:** Device works normally when mixed noise produced by BIO-TEK INDEX Pulse Oximeter tester.

Guidance and manufacture's declaration – electromagnetic emissionsfor all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission

The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer of the user of the Pulse Oximeter should assure that it is used in such and environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The 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 emission CISPR 11	Class B	The Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low- voltage power supply network that supplies buildings used for domestic purposes.

Possible Problems and resolutions					
Problems	Possible reason	Solution			
SpO ₂ or PR is not displayed.	 Finger is not inserted correctly. Patient's SpO₂ value is too low to be measured. 	 Re-insert the finger. Try some more times, If you can make sure about no problem existing in the product. Please go to a hospital timely for exact diagnosis 			
SpO ₂ or PR reading is unstable.	 Finger is not inserted correctly. Excessive patient movement. 	 Re-insert the finger. Restrict patient/ oximeter movement. 			
The Oximeter can not be powered on.	 No battery or low power of battery.l Batteries might be installed incorrectly 	 Replace batteries. Reinstall batteries. Contact with local customer service centre. 			
	3. The Oximeter might be damaged				

Display suddenly turns off.	1. The oximeter will automatically power off when no signal is detected	1. Normal
	longer than 8 seconds.	2. Replace batteries
	2. Battery power is low.	
"Error3" or	1 .Low power	1. Change new battery
"Error4"	2. Receiving tube being shielded	2. Please contact with local
Displayed on	or damaged together with	customer service center
screen	broken connector.	3. Please contact with local
	3. Mechanical Misplace for	customer service center
	receive-emission tube	4 Please contact with local
	4. Amp circuit malfunction.	customer service center
"Error7"	1. Low power	1 Please change battery
displayed on	2. Emission tube damaged.	2 Please contact with local
screen	3. Current control circuit	customer service center
	malfunction.	3 Please contact with local customer service center

Symbol Definitions				
Symbol	Definition			
Ŕ	Type BF applied part.			
<u> </u>	Attention, consult accompanying documents.			
SpO ₂ %	Oxygen saturation			
BPM	Heart rate (BPM)			
	Low power indication			
SpÔ2	Not for continuous monitoring			
SN	Serial No.			

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