



FINGER PULSE OXIMETER

USER'S MANUAL V1.3

Section 1 Safety

1.1 Instructions for the Safe Operation and Use of the Pulse Oximeter

- Do not attempt to service the pulse oximeter. Only qualified service personnel should attempt any needed internal servicing.
- Do not use the oximeter in situations where alarms are required.
- 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 every hour.
- 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.
- The following reasons will cause interference.
 - High-frequency electrosurgical.
 - Placement of a sensor on an extremity with a blood pressure cuff arterial catheter, or intravascular line.
 - The patient has hypotension severe vasoconstriction severe anemia or hypothermia.
 - The patient is in cardiac arrest or is in shock.
 - Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

1.2 Warnings

- WARNING:** EXPLOSION HAZARD — Do not use the oximeter in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.
- WARNING:** Do not throw batteries in fire as this may causes them to explode.
- WARNING:** Do not use the pulse oximeter in an MRI or CT environment.
- CAUTION:** Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity.
- CAUTION:** Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.
- WARNING:** Do not attempt to recharge normal dry-cell batteries, they may leak. And may cause a fire or even explode.
- CAUTION:** Never use sharp or pointed objects to operate the front-panel switches.
- CAUTION:** The battery must be taken out from the battery compartment if the device will not be used for a long time.
- CAUTION:** The device shall only be used if the battery cover is closed.
- CAUTION:** The battery must be proper disposed according to local regulation after their use.
- WARNING:**The oximeter is not intended to use in ICU, because the device's alarm does not meet requirements of EN 60601-1-8.

1.3 Definitions and Symbols

Symbol	Description	Symbol	Description
	Type BF Equipment		Information of manufacture, including name and address
	Refer to the instruction manual /booklet		Serial NO*
	When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling	Warning:	The information you should know to protect patients and medical staff from possible injury
Caution:	The information you should know to protect the equipment from possible damage	Note:	The important information you should know

Section 2 Introduction

2.1 Display Parameter and Brief Device Description

SpO2 (Functional oxygen saturation), is the amount of oxyhemoglobin expressed as a percentage of the Functioning Hemoglobin. Functioning Hemoglobin is capable of carrying oxygen and includes oxygenated hemoglobin (HbO2) and deoxygenated hemoglobin (Hb).

PR (Pulse Rate), measured in beats per minute (bpm), is the frequency of heart beats.

Plethysmogram: The amount of light absorbed by the varying quantities of arterial blood changes with the pulse beats, the waveform is named Plethysmogram. This waveform and its variation is used for assigning signal integrity, physiological and artifactual changes such as perfusion changes, dysrhythmia, motion artifact, and electrical interference.

2.2 Intended Use

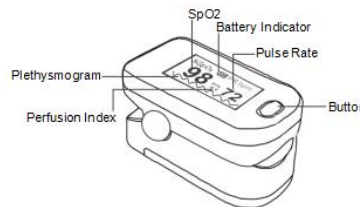
This product is suitable for the clinic, oxygen bar, sports health (using it before or after activity, not advised to use during activity), community health care, and aviation etc.

2.3 Contraindication

It is not for intensive care and person whose finger is injured.

Section 3 Installation, Setup, and Operation

3.1 Description



Note: when battery power is at lowest level, the battery capacity indicates symbol of "□" in OLED, remind users of replacement of battery.

3.2 Operation

3.2.1 Install battery

Installing two AAA batteries into battery cassette in correct polarities and cover it (as Figure 3.2.1.1)

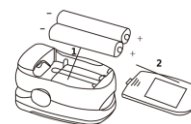


Figure 3.2.1.1

3.2.2 Turn the Pulse Oximeter on

Put one of fingers into rubber pad of the oximeter inside (it is best to put the finger thoroughly) with nail surface upward (as Figure 3.2.2.1), then releasing the clamp. Press the button, oximeter will go into the working status.

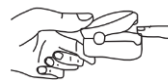


Figure 3.2.2.1

3.2.3 Read correspondent data from display screen

3.2.4 Reading data transmission

When the measurement is completed and network is available, the upload procedure will be started automatically, it will end with "Successes " or " fail"

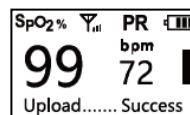
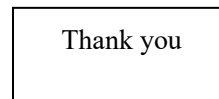


Figure 3.2.4.1

3.2.5 The product will automatically turn off when there is no finger inserted for more than 10 seconds or after upload is finished with below picture.



3.2.6 Network indicator description

SIMBOL	DESCRIPTION
	SIM card is not inserted
	No signal
	Signal is weak
	Signal is normal
	Signal is good
	Signal is perfect
	Network is no-connection

3.3 Device information display

Switch on device and hold the button for 10 second, the device enter to device information page to check :
IMEI, ICCID, device version , network signal

Page 1/2 *
IMEI: XXXXXXXXX
ICCID: XXXXXXXXXX
CIMI: XXXXXXXXX
F8_1.01.01
Exit

Page 2/2 *
ePco: XXX
Cops:X Cereg: X
Rsrp: XXXX
CGATT: X
CGACT: X
Exit

Hold the button, the screen will move to next page.
Press button 1 time, the * move at "Exit" , and hold the button, then quit this device information display, back to measurement page.

Or , leave this page for 60 seconds, it will back to back to measurement page

Section 4 Maintenance

4.1 Cleaning

Switch off the power and take out the batteries before cleaning. Cleaning exterior surface (OLED display screen included) of the unit with a dry and soft cloth. Use 75% density of medical alcohol to clean the surface and use dry fabric with little alcohol to avoid alcohol permeates into the device.

4.2 Disinfection

Disinfect the machine after using by the patient if multiple patient use the machine in the hospital. Use 75% density of medical alcohol to clean the surface that contacting with the patient.

CAUTION: Don't use strong solvent. For example, acetone.

CAUTION: Never use an abrasive such as steel wool or metal polish.

CAUTION: Do not allow any liquid into the product, and do not immerse any parts of the device into any liquids.

CAUTION: Avoid pouring liquids on the device while cleaning.

CAUTION: Don't remain any cleaning solution on the surface of the device.

4.3 Warranty

The host product' design life is 2 years, and 1 years warranty. Under normal circumstances, the malfunction of the product during the warranty period (from the date of purchase) should be sent back to the company for maintenance, and our company is responsible for all maintenance costs (users should cover the freight themselves).

Outside the warranty period, our company shall charge some maintenance fee (users should cover the freight themselves) if the product has broken down and is sent back for maintenance. The battery is beyond the scope of the warranty. If you have the purchase and sale contract, the costs of the maintenance shall be in accordance with the purchase and sale contract execution. Besides, it is recommended that users should use them no more than five years. And over the using life, the using risks may increase due to the equipment' aging.

4.4 Maintenance

- Replace the batteries timely when battery indication is low. Clean surface of the Pulse Oximeter before it is used in diagnosis for patients.
- Remove the batteries inside the battery cassette if the Oximeter will not be operated for a long time.
- It is better to preserve the product in a place where ambient temperature is -20 - 55°C and humidity is 10%-95%.
- Regular inspection to make sure that no obvious damage existed to affect the safety and performance of device.
- No flammable substance, overtop or lower temperature and humidity existed in operation conditions.

4.5 Troubleshooting

Table 4.5 Troubleshooting

Problems	Possible Reason	Resolutions
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Oxyhemoglobin or heart rate can not be shown normally.	1. Finger is not plugged correctly. 2. Patient's perfusion is too low to be measured.	1. Retry by plugging the finger. 2. 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.
Oxyhemoglobin or heart rate is shown unstably.	1. Finger might not be plugged deep enough. 2. Finger is trembling or patient's body is in movement status.	1. Retry by plugging the finger. 2. Try not to move. Let the patient keep calm.
The oximeter can't go into the working state.	1. Power of batteries might be inadequate or not be there at all. 2. Batteries might be installed incorrectly. 3. The Oximeter might be damaged.	1. Please replace batteries. 2. Please reinstall the batteries. 3. Please contact with local customer service center.
The screen are suddenly off.	1. The product is automatically standby or sleep when no signal is detected longer than 8 seconds. 2. Power quantity of the batteries is exhausted.	1. Normal. 2. Replace the batteries.

4.6 Disposal

To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect or decontaminate the device appropriately before disposing of it in accordance with your country's law for equipment containing electrical and electronic parts.

Section 5 Specification

Physical Characteristics

Machine Dimensions: 58mm (L) x 32mm (W) x 33mm (H)

Machine Weight -approx: 54g (including 2 x AAA battery)

Classification

Anti-electric Shock Type: Internally powered equipment

Anti-electric Shock Degree: Type BF equipment

EMC: Group 1 Class B

Mode of operation: Continuous Operation

Enclosure Degree of ingress protection: IP22

※IP22 means shell of this product can withstand the water dropping to the surface when the shell deviate 15 degree from horizontal surface.

Power

Internal:	2 x AAA 1.5V alkaline battery
Power Consumption:	30mA (Normal)

Environmental

Operating Temperature:	5°C to 40°C
Storage Temperature:	- 20°C to 55°C
Relative Humidity:	15% to 85% non-condensing

Electronics Parameters

Parameter	Value	
SpO2 (Oxygen saturation)	35 - 100%	
PR (Pulse Rate)	25 - 250 bpm	
PI (Perfusion Index)	0 - 30%	
Resolution	SpO2 (Oxygen saturation)	1%
	PR (Pulse Rate)	1 bpm
	PI (Perfusion Index)	0.1%
Measure Accuracy:	SpO2 (Oxygen saturation)	2% (80% - 100%) 3% (70% - 80%) Unspecified (<70%)
	PR (Pulse Rate)	2 bpm
	PI (Perfusion Index)	1% (0 - 20%) Unspecified (20% - 30%)
A _{rms} *		

* A_{rms} accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- Arms of the reference measurements in a controlled study.

Applicable models

0010-20-00189

Manufactured for : Telli Health LLC

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