



Digital Fingertip Pulse Oximeter

KINGSTAR INC is a leading China Digital Fingertip Pulse Oximeter manufacturers, suppliers and exporter. Digital Fingertip Pulse Oximeter is very easy and convenient for us to read the blood oxygen saturation and pulse of the human body by clipping the finger. It can be used by ourselves to observe the health.

www.antigentestdevice.com



KINGSTAR INC is a professional leader China Digital Fingertip Pulse Oximeter manufacturers with high quality and reasonable price.

Product Introduction

Using a digital Fingertip Pulse Oximeter, you can check pulse rates and blood oxygen saturation levels quickly. Digital screen allows us to read the data conveniently. Small size makes it portable.

Product Parameter (Specification)

Basic Information	
Power Supply	two AAA 1.5V alkaline batteries
Power Consumption	smaller than 50mAh
Automatically Power-off	The product automatically shuts off when no signal can be detected within 10 seconds
Dimension	Approx. 63mm×34mm×30mm
SPO2	
Measurement range	35%~100%
Accuracy	±2% (80%~100%) ;±3% (70%~79%)
PR	

Measurement range	25~250BPM
Accuracy	±2BPM
Operation Environment	
Operation Temperature	5°C ~ 40°C
Storage Temperature	-10°C ~ 50°C
Operation Humidity	15% ~ 80%
Storage Humidity	10% ~ 90%
Operation Air Pressure	86kPa ~ 106kPa
Storage Air Pressure	70kPa ~ 106kPa

Product Feature and Application

Digital Fingertip Pulse Oximeter is an easy read medical device with colorful TFT screen.

Focus On Your Health

rapid analysis | clear display | light and convenient

Fingertip Pulse Oximeter



Colorful TFT Screen

The clear screen makes the process easier to use



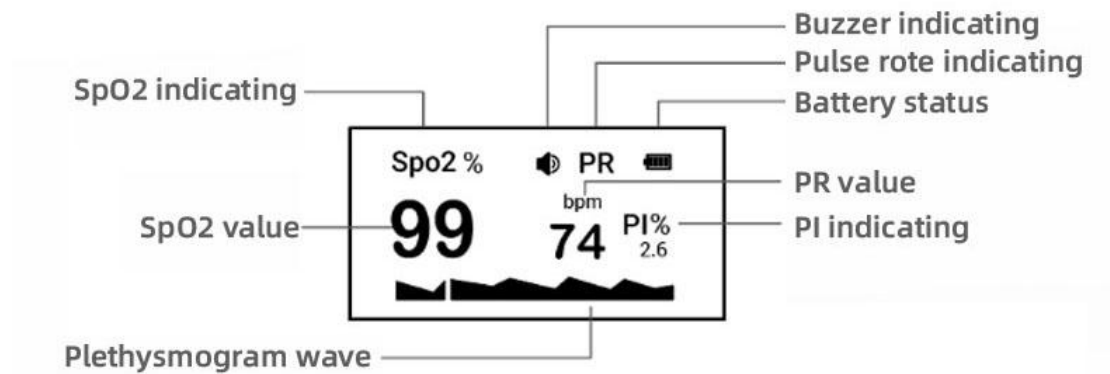
Digital Fingertip Pulse Oximeter with the following characteristics will help you understand the signal on the screen better. And you can also change the display direction by press the button once.

A Key Measure

Multidirectional display, data can be stored and analyzed



Display Introduction



Two-direction Display

Multidirectional display



Product Details

Our digital fingertip pulse oximeter has buzzer which can be turned on or off. Data can be stored and analyzed which will help you observe the health better.

Eight Major Advantages



Turn the buzzer
ON or OFF



OEM & set starting
up logo



SpO2 and PI display
with buzzer



Convenient
And Light



Colorful TFT
screen



Data can be
stored and analyzed



Two-direction
display



Waveform & intensity
bargraph with Pulse Rate



Measuring Steps

I Hold the product in one hand with the front panel facing the palm. Put the other hand's big finger on the battery cabinet lids press sign, press downwards and push the lid open at the same time. Install batteries into the slots per the "+" and "-" symbols as shown in Figure 1.

Cover the lid onto the cabinet and push it upwards to make it close well.

I Press Clip's press sign in the figure 1 and open the clip. Let the testee's finger put into the rubber cushions of the clip, make sure the finger is in the right position as shown in Figure 2, and then clip the finger.

I Press the power and function switch button on the front panel to turn on the product.

Using first finger, middle finger or ring finger when doing test. Don't shank the finger and keep the testee at ease during the process. The readings will be displayed on the screen a moment later as shown in Figure 3.

I The positive and negative electrodes of batteries should be installed correctly. Otherwise the device will be damaged.

I When install or remove batteries, please follow the correct operation sequence to operate. Otherwise the battery compartment will be damaged.

I If the pulse oximeter isn't used for long time, please remove the batteries of it.

I Make sure to place the product on the finger in a correct direction. The LED part of the sensor should be at the backside of the patient hand and photodetector part at the inside. Make sure to insert the finger to suitable depth into the sensor so that the fingernail is just opposite to the light emitted from the sensor.

I Don't shake the finger and keep the testee calm during the process.

I Data update period is less than 30 seconds.

Figure 1

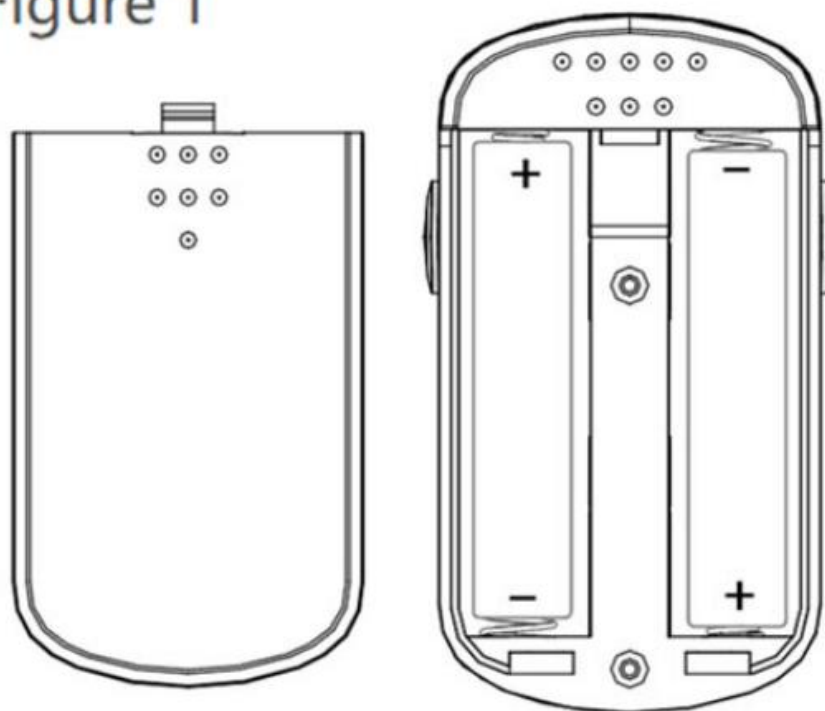


Figure 2

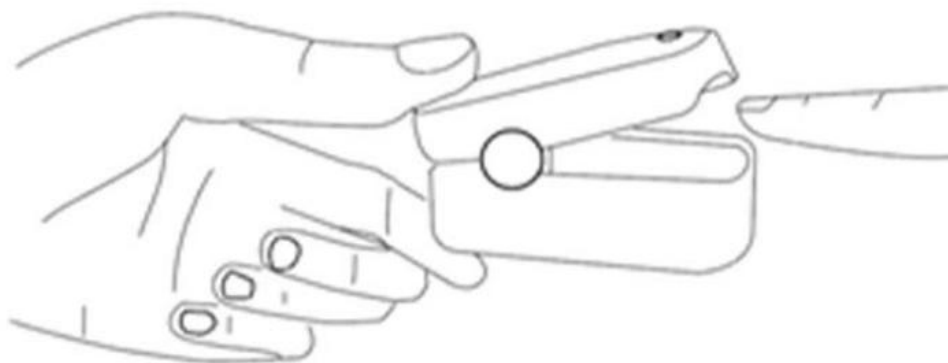
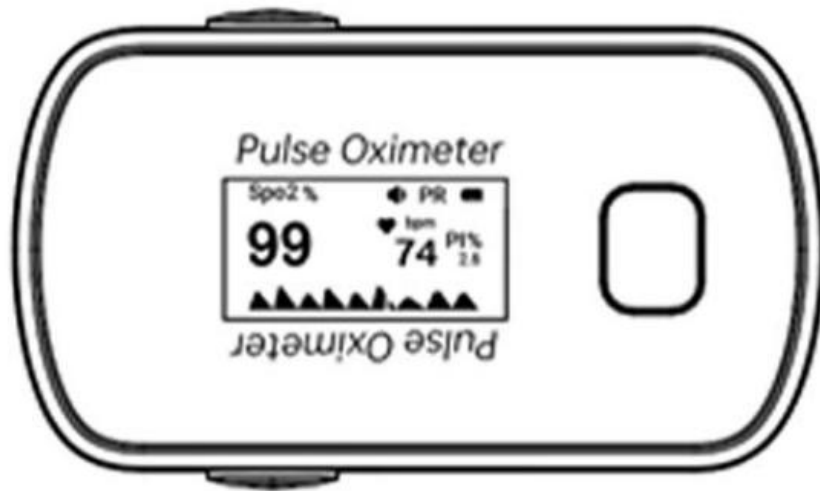


Figure 3



Function Description

- When the data has been displayed on the screen, short press the "POWER/FUNCTION" button one time, the display direction will be rotated. (as shown in Figure 4,5)
- Then short press the "POWER/FUNCTION" button twice, the display direction will be restored to the previous state. And buzzer indicating will disappear at the same time, the buzzer will be turned off.
- When the received signal is inadequacy, "- - -" will be displayed on the screen. (as shown in Figure 6)
- The product will automatically be powered off when no signal after 10 seconds. (as shown in Figure 7)

Figure 4

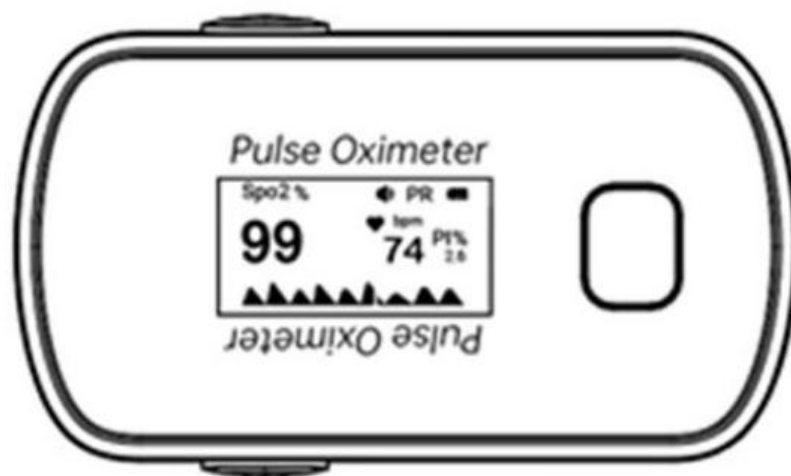


Figure 5

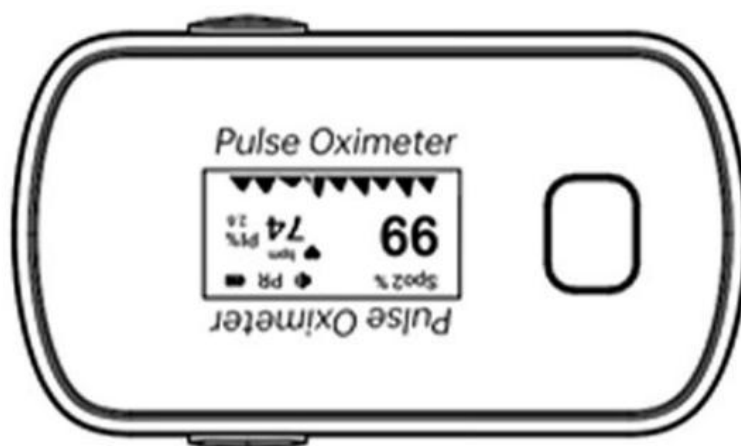


Figure 6

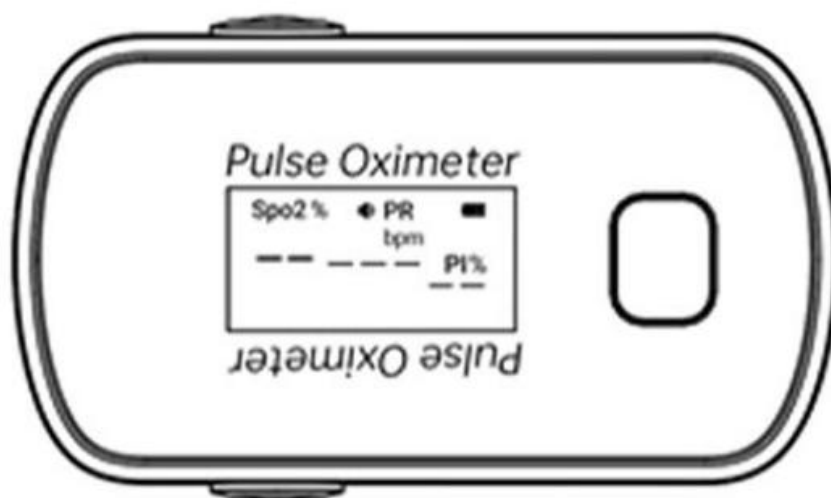
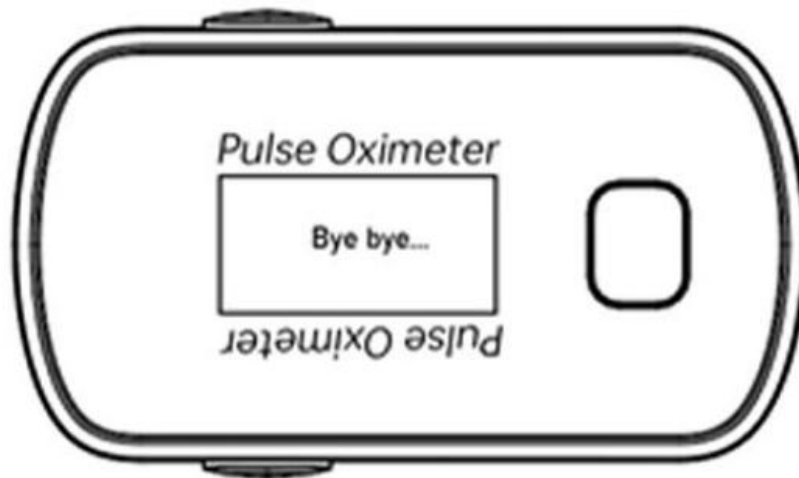


Figure 7

**NOTE:**

I Before measuring, the pulse oximeter should be checked whether it is normal, if it is damaged, please don't use.

I Don't put the pulse oximeter on extremities with arterial catheter or venous syringe.

I Don't perform SpO₂ monitoring and NIBP measurements on the same arm simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the reading of the SpO₂ value.

I Don't use the pulse oximeter to measure patients whose pulse rate is lower than 30bpm, which may cause incorrect results.

I The measurement part should be chosen well perfusion and be able to fully cover the test window of the sensor. Please clean the measurement part before place the pulse oximeter, and ensure drying.

I Cover the sensor with opaque material under the condition of strong light. Failure to do so will result in inaccurate measurement.

I Make sure that there is no contamination and scar on the tested part. Otherwise, the measured result may be incorrect because the signal received by the sensor is affected.

I When used on different patients, the product is prone to crossed contamination, which should be prevented and controlled by the user. Disinfection is recommended before using the product on other patients.

I Incorrect placement of the sensor may affect the accuracy of the measurement, and it is at the same horizontal position with heart, measurement effect is the best.

I The highest temperature of sensor contacts with patient's skin don't be allowed more than 41°C.

I 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 even 2 hours.

Product Qualification

The following is the certificates of Digital Fingertip Pulse Oximeter.

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Benannt durch/Designated by
 Zentralfstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.bfarm.de
 ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
 Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
 (Devices in Class IIa, IIb or III)

No. G1 092582 0009 Rev. 00

Manufacturer: Suzhou Yongchang Electronic Science
 Technology Co., Ltd.
 1 Floor, No. 40 Jingnan Road,
 Economic and Technological
 Development Zone, 221000 Suzhou,
 PEOPLE'S REPUBLIC OF
 CHINA

Facility(ies): Suzhou Yongchang Electronic Science Technology Co., Ltd.
 4F Building C5, 40 Jingnan Road, Economic and Technological
 Development Zone, 221000 Suzhou, PEOPLE'S REPUBLIC OF
 CHINA

**Product Category(ies): Vital Signs Monitor,
 Handheld Pulse Oximeter,
 Fingertip Pulse Oximeter,
 Multiparameter Patient Monitor**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1966201

Valid from: 2019-11-26
Valid until: 2024-05-28

Date, 2019-11-26

Christoph Dicks
 Head of Certification/Notified Body

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 TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany



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ZERTIFIKAT ◆ **CERTIFICATE** ◆ 認證證書 ◆ **CERTIFICADO** ◆ **CERTIFICAT**



Product Service

Certificate

No. Q5 092582 0008 Rev. 00

Holder of Certificate: Suzhou Yangsheng Electronic Science Technology Co., Ltd
 210000 Suzhou, Jiangsu Province, China
 Suzhou Yangsheng Electronic Science Technology Co., Ltd

Facility(ies): Suzhou Yangsheng Electronic Science Technology Co., Ltd
 4F Building C8, 40 Jingzhen Road, Economic and Technological Development Zone, 221000 Suzhou, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution of Vital Signs Monitor, Handheld Pulse Oximeter, Fingertip Pulse Oximeter, Multiparameter Patient Monitor
 Production and Distribution of Wrist Type Blood Pressure Monitor, Infrared Thermometer, Arm Type Blood Pressure Monitor, Fetal Doppler

Applied Standard(s): EN ISO 13485:2016
 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
 DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1866204
Valid from: 2019-04-30
Valid until: 2022-04-29

Date, 2019-04-30 Stefan Preiß

