Pulse Oximeter
USER MANUAL
MD-A3

Product Information

    Model: MD-A3

    Product Name: Pulse Oximeter

    Manufacturer Date: See product label

Edition

First Edition: June, 2020

Regulatory and Safety Specifications

Standard

The product is made under the ISO13485 quality system certified by TUV PS. The product has passed the CE certification.

Declaration

The pulse oximeter is a Class IIa device and complies with the requirements of the Council Directive 93/42/EEC concerning medical devices and carries CE-marking accordingly.

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1．Product Operation Scope

This Pulse Oximeter is a kind of innovated medical detection device with non-invasive and continuous features for artery SPO2 and PR detection. It is portable and easy to measure the SPO2 and PR value quickly and precisely.

This can be through the finger Pulse Oximeter to measure human blood oxygen saturation and heart rate. This product is suitable for family, clinic, oxygen bar, sports health (use before and after exercise is not recommended for use during exercise), community health and other ranges. It's for ages from 15 to 60 years old patients. This product is not suitable for monitoring the patient's prolonged use.

2．General Description

Haemoglobin Saturation is percentage of Oxyhemoglobin (HbO2) capacity , compounded with oxygen , by all combinativable haemoglobin (Hb) obin (HbO2) capacity in blood . In other words , it is consistence of Oxyhemoglobin in blood . it is a very important ecological parameter for Respiratory circulation System . Many respiratory diseases can result in haemoglobin saturation being lowered in human blood . Moreover, the following factors can also lead to problems in oxygen supply, so that human haemoglobin saturation might be reduced ：Automatic Organic Regulation Malfunction caused by Anesthesia, Intensive Postoperative Trauma, hurts resulted in by some medical examination and etc. In the situation, illnesses, such as light head, asthenia, vomitory and etc, might happen to patients and even endanger the patient＇s life. Therefore, it is very important to know Hemoglobin saturation of patient timely in clinical medical aspects. So that doctors can find problems in time.

The fingertip pulse oximeter features in small volume, low power consumption convenient operation and being portable. It is only necessary for patient to put one of his fingers into a fingertip photoelectric sensor for diagnosis, and a display screen will directly show measured value of hemoglobin Saturation. It has been proved in clinical experiments that it features in rather high precise and repeatability.

3．Measurement principle

Principle of the oximeter is as follows：An experience formula of data process is established taking use of Lambert beer Law according to Spectrum Absorption Characteristics of reductive hemoglobin (R Hb)and Oxyhemoglobin (O2 Hb) in glow and near- infrared zones. Operation principle of the instrument is 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 human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of LED through process in electronic circuits and microprocessor.

4．Appearance introduction

Button

Display screen

SPO2

Pulse Rate Value

Perfusion Index Value
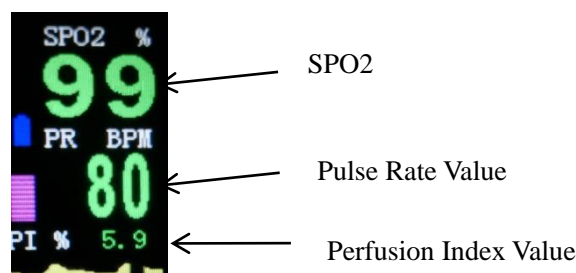
5. Features

5.1　TFT display, 4 display interface, figure and Oxygen volume chart display together on interface;

5.2　Adjust the display interface direction manually, according to the patient observation data needs;

5.3　Audible alarm function;

5.4　Low Power consumption. 50 hours continuous to work.

5.5　Low Perfusion ≤0.4%.

5.6　An alarm will show on display when low voltage happens;

5.7　Automatic power off when no signal in 8 s
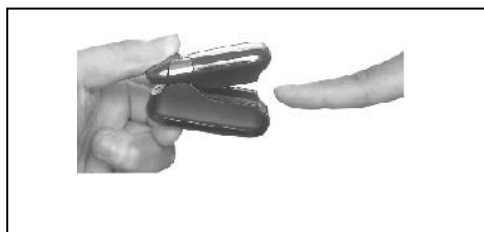
5.8　Small and light weight, convenient to carry.

6. Operation Instructions

6.1 The product Operation Instructions

6.1.1 Installing two AAA batteries into battery cassette in correct polarities and cover it.
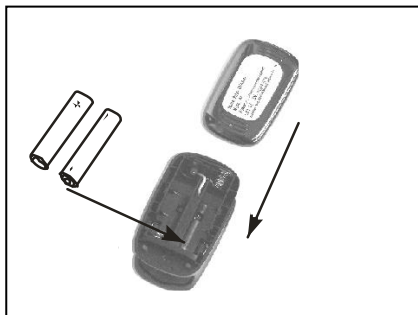
6.1.2 Plug one of fingers into rubber hole of the Oximeter (it is best to plug the finger thoroughly) nail surface upward, then releasing the clamp.

6.1.2.1 Press the switch button once on front panel.

6.1.2.2 Your finger do not tremble during the Oximeter is working. Your body is not recommended in moving status.

6.12.3 Read correspondent date from display screen.

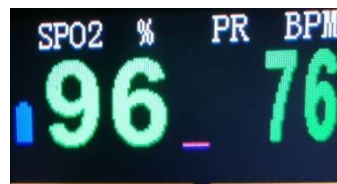## 6.2 Operation Instructions

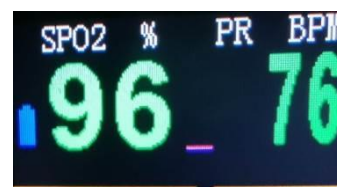6.2.1 Display Description （4 interface diagrams）

Interface 1

Interface 2

Interface 3

Interface 4

6.2.2 A3 button operating instructions:

6.2.2.1 Put into two AAA batteries according to the instructions, the A3 will turn on automatically and display interface 1; then put into finger for measuring, if there is finger for detection and without operation, it   power off automatically in 8s.

6.2.2.2 When there is battery, but the Pulse Oximeter power off, press the button, it will be opened.

6.2.2.3 During the measurement (there is a measurement signal and figure), press the button shortly, the interface can turns from interface 1 to interface 4 circularly.

6.2.2.4 Short Press the button during the measurement; it can turn to settings menu interface.

6.3 Low power alarm

When the battery power appears low, the battery power indicate for empty on OLED, reminding the user to replace the battery; (the battery capacity indicates symbol of "▱"in OLED to remind user to replace battery.)

6.4 Pulse rate and SPO2 alarm

When a certain physiological parameter of the patient exceeds the set alarm high and low range, a physiological alarm is triggered, and the parameter in the parameter area will change color, reminding the user to pay attention to the measurement parameter.

The font color of SPO2 parameter values within the range of 85-99 is green, and the font color of parameter values outside the range is orange;

If the PR parameter value is within the range of 50-120, the font color is green, and the parameter value outside the range is orange;

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

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

Further the instrument is meant only for screening/measurement purpose ,please consult a physician for any treatment or medical advice for any symptom.

7. Product Classification

Product classification information of pulse oximeter is shown in Table 1.

Table 1 Product Classification

Classification basis	Safety classification
Classification by electric shock prevention type	Internal power supply equipment, general portable without defibrillation protection Belt equipment
Classification by electric shock resistance	BF type application part
Classification by operating mode	Continuously running equipment.
Classification by protection against harmful ingress	IPX1
Classified by safety when used with flammable anesthetic gas mixed with air or with flammable anesthetic gas mixed with oxygen or nitrous oxide	Equipment not to be used with flammable anesthetic gas mixed with air or with flammable anesthetic gas mixed with oxygen or nitrous oxide
Classification according to the disinfection and sterilization methods recommended by the manufacturer	Disinfection and sterilization equipment recommended by the manufacturer.
Classification By management category	Class II
Classification by electromagnetic compatibility	Group I Class B equipment.

8. Power Specification

Table 2   Power Specification

Parameter	Specification
Fuse	466series, 0.5A 6.3V
Battery	d.c. 3V AAA(×2)
	When the battery is almost exhausted, the pulse oximeter will automatically shut down

9. Technical Specification

The data update period, data averaging, and other signal processing have an effect on the display and transmission of SpO2 and pulse rate. According to the alarm limit and the difference between the displayed values, the delay time for generating the alarm signal is 1 second. ~ 20 seconds. The maximum alarm state delay time is 4 seconds, and the maximum alarm signal is generated.

The delay time is 20 seconds, the average alarm state delay time is 2 seconds, and the average alarm signal delay is10 seconds. The statistics of each decentralized state conform to the statistical analysis.

> Since the measurement results of the pulse oximeter device conform to the statistical distribution, only about 2/3 of the measurement results fall within the $\pm$ marginal value measured by the CO-oxygen saturation meter. The oxygen volume map of the pulse oximeter has been normalized.
>
> **Note** — The pulse oximeter is calibrated to display functional oximetry and does not need to be calibrated during use.

Table 3 Pulse oximeter specification

Parameter	Specification
SpO_2 measurement range	35% $\sim$ 99%
SpO_2 measurement accuracy [1]	90%-99%, accuracy: $\pm1\%$; 70%-89%, accuracy$\pm2\%$; $\leq70\%$, no specified
Pulse Rate Measurement range	30 bpm $\sim$240 bpm
Pulse Rate measurement accuracy	±1 bpm
SpO2 value and refresh rate of pulse rate	around 1 second
Pulse Rate Volume	Non-modulated
Wavelength range2	500nm $\sim$ 1000nm
Maximum luminous power	150 mW
PR Display	Digital
Screen	TFT display "0.96" inch
Power consumption	150mW in normal measurement; 0.2uA in shutdown state;

1. Controlled blood oxygen monitoring in healthy, non-smoking adult volunteers to obtain sensor accuracy (according to EN ISO9919). These SpO2 readings have been compared with the CO-oxygen saturation meter measurement results of arterial blood standards. In order to represent the general population, at least 10 subjects (male and female) with different skin colors were collected to verify the accuracy of SpO2. Functional testing equipment cannot be used to evaluate the accuracy of pulse oximeters and the accuracy of blood oxygen sensors.

2. Understanding the wavelength range can help clinicians to perform photodynamic therapy.

10.Physical Specification

The physical specifications of the host are shown in Table 4.

Table 4 The physical specification of the host

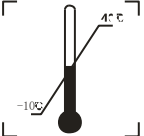| Parameter	A3
Size(mm)	63×41×31

11. Environment Specification

The environmental specifications of the pulse oximeter are shown in Table

Table 5 The environmental specifications of the pulse oximeter

Parameter	Specification
Operating Temperature	0℃ ～ 40℃
Storage and transportation Temperature	-20℃ ～ +60℃
Relative humidity in operation	15%~80%,Non-condensing
Relative humidity during storage and transportation	10%~95%, Non-condensing
Operating atmospheric pressure	59 kPa ～ 107.4 kPa
Atmospheric pressure during storage and transportation	22 kPa ～ 107.4 kPa

12．Logo Description

Signs	Notes on the signs
🏃	Type BF Applied Part
⚠	Attention, see instruction for use!
〰|	Date of manufacture
↑↑	The carton should be lift in the right way of upward during transportation

	The goods is fragile, please handle with care
	Keep moisture off the packing carton
	Storage temperature should be marked clear on the carton
	Prohibition of free throw

13．Troubleshooting

Trouble	Possible Reason	Solution
The SpO2and Pulse Rate display instable	1. The finger is not places inside enough. 2. The finger is shaking or the patient is moving.	1. Place the finger properly and try again. 2. Let the patient keep calm.
The device can not turn on	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The device's malfunction.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
The indicator light is off suddenly	1. The device will power off automatically when it gets no signal for 8 seconds. 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

14．Accessory

AAA battery-----------------------2 pcs（optional）

Hang String------------------------1 pc

User Manual ----------------------1 pc

15．Warranty

15.1 Warranty

The unit can not be repaired by users themselves. All services must be done by the engineers approved by TVS Electronics. The unit is guaranteed for a period of 12 months, valid from the date of purchase. TVS Electronics warrants that each product we sell you is free from defects in labor and materials and shall conform to its product specifications as defined in the user documentation. If the product doesn't function as warranted during the warranty period, we will repair or replace it without charge. Misuse, improper maintenance may void the warranty.

TVSE Take-Back & Recycling Program

Overview

The new E-waste (Management) Rules, 2016 have been notified by the Ministry of Environment, Forest and Climate Change, Govt. of India vide notification dt.23.03.2016 and shall come into force with effect from 1st Oct, 2016. According to these Rules, the Producer shall be responsible for channelization of waste electrical and electronic equipment (popularly known as "WEEE"). This will ensure that the e-waste is disposed of in an environmentally friendly manner and will address the leakage to the informal sector. Phase wise collection targets have been set for Producers to collect e-waste (either in number or weight) and shall be 30% of the quantity of waste generation during first two 2 years of implementation of the Rules, 40% during 3rd & 4th year, 50% during 5th & 6th year and 70% from 7th year onwards.

TVS-E Commitment

TVS-E is committed to environmentally sound management of e-waste taking all steps required to ensure that e- waste are managed in a manner which shall protect health and environment against any adverse effects which may result from hazardous substance contained in such wastes. TVS-E assures that the covered products & Accessories,Consumables and spares do not contain lead, mercury, cadmium, hexavalent chromium, poly- brominated biphenyls or poly-brominated di-phenyl ethers above a specified threshold. The threshold for cadmium is 0.01% by weight in homogeneous material, for all other substances, the threshold is 0.1% by weight in homogeneous material.

Introduction

E-waste is any electrical/electronic product or an accessory which is not useable and it is at its end of life for example old defective products like Printers, Keyboards, Mouse, User terminal etc.

E-waste has been defined as "waste electrical and electronic equipment, whole or in part or rejects from their manufacturing and repair process, which are intended to be discarded". Whereas Electrical and electronic equipment has been defined as "equipment which is dependent on electrical currents or electro-magnetic fields to fully functional". E-waste generally consists of those substances contained in an electronic product which can bring adverse effects to the atmosphere and hence managing it in a proper way is important. Apart from affecting the environment it can also affect the health of the people.

Waste Collection

TVS-E has put in place a pan India collection mechanism to assist its customers in depositing their e-waste as per the new E-waste (Management) Rules, 2016 effective from 1st October, 2016.

You can deposit the WEEE at the nearest Collection Point. Details of the location of Collection Points and Collection Centres are also available on this website.

TVS-E assures all its customers that all its e-waste collected under these Rules will be recycled/ disposed of by an authorized e-waste Recycler as per the E-waste Management Rules, 2016.

Do's and Dont's

Do's:

- Always drop your used electronic products & Accessories/Consumables /spares/ batteries and packaging materials after the end of their life at the nearest collection point.

- Separate the packaging material according to responsible waste disposal options and sorting for recycling.

- Keep the product in isolated area, after it becomes non-functional/un-repairable so as to prevent its accidental breakage

Dont's:
- The product is not meant for re-sale of any unauthorized agencies/scrap dealers

- Never dump e-waste in garbage bins

- Do not dispose off your product in at municipal waste bins

- Do not throw used batteries into household waste.

FAQs

1. What is e-waste?

E-waste means electrical and electronic equipment, whole or in part discarded as waste

by the consumer or bulk consumer as well as rejects from manufacturing, refurbishment

and repair processes.

2. What is end-of-life of product?

End-of-life of the product means the time when the product is intended to be discarded by the user.

3. How can you dispose of your e-waste?

You can deposit your e-waste at any of our Collection Points mentioned on our website.

4. WHAT CAN I RECYCLE?

Under E-Waste Management & Handling Rules 2016, we will accept and recycle all TVS-E products like Printers, Keyboards, Mouse, User terminal, Cartridges are accepted for recycling.

5. What is EPR (Extender Producer Responsibility)?
   EPR means responsibility of any producer of electrical and electronic equipment, for channelization of e-waste to ensure environmentally sound management of such waste.

6. Do consumers have to pay for getting their electronics recycled?

   Consumers do not have to pay any fee for recycling of TVS-E products

7. Is there any monitory benefit/discount linked to this take-back and recycling program?

   As of now there is no monitory benefit/discount linked to this program. The main benefit of this program is cleaner, safer and green environment.

8. What will happen if the product is not properly handled and is given/sold to scrap dealer like any other ordinary scrap?

   In case eWaste is sold to unauthorized dealers, they don't have scientific tools to recycle the products and therefore they are not authorized by the Pollution Control Board. In open area they burn the plastic parts, break the seal of parts which carries gases and try to extract metals. Such smoke and gases pollute the environment. Also hazardous residual are thrown in landfills which is dangerous for land, water, air and living beings.

9. How can you participate in the TVS-E Recycling Program?
   You can dispose of a used TVS-E product very easily and responsibly. Simply call at
   1800 425 4528 and drop it at your nearest Collection point's .All these E-waste will

be consolidated and forwarded to Tumkur Collection point for final disposal through Authorized E-waste Recycler

10. What are the negative effects of improper recycling and dismantling of old electrical & electronic items?

- If the material is disposed off in open, then it may cause health risks and damage to environment

- Presence of heavy metals such as cadmium, lead etc and other toxic substances may pose risk to health and environment

- Burning of rubber & Plastic in open area causes air pollution.

- Batteries contain hazardous elements which may affect the health & environment, if not disposed off properly.

11. How to safely handle the product while disposing off?

- Old defective product should be kept separately from other products.

- Product should not be dropped in garbage bins containing municipal waste.

- It should be handed over to authorized recycler for safe recycling.

- Product should not be handed over to any recycler who does not have proper recycling facilities

12. What are health hazards and effects on environment if the product is dismantled by the consumer themselves?

All the electronic products are safe to use, but if the consumer dismantles or breaks them, they might be exposed to health hazards due to the chemical substances present in the products, which further can pollute the environment.