Instruction for Use

(File No.: IFU-MPO)

Version: 01

Mobile Pulse Oximeter

Zhejiang Medzone Medical Equipment Co.,Ltd

1 Preface

Dear Customers, thank you for purchasing the Mobile Pulse Oximeter.

This instruction for use describes the characteristics and technical requirements of the device, main structure, performance, specifications, transportation, usage, operation, maintenance and storage methods, safety measures are also included, please see specific chapters.

Please read this instruction for use carefully before you using this device, and follows this instruction. This instruction will tell you how to use the device, operations which may cause to abnormal conditions, risks to causes damages to the device and human body. Any abnormal condition or damages to the device and human body which caused by without following this instruction for use, the company will not assume responsibility for safety, reliability and performance, and will not be free of charge for such failure.

This product is a medical device that can be reused.

Please keep the instruction for use well, and refer it at any time.

2 Safety

2.1 Safety information

Warning	To remind potential dangers or unsafe operations, if not avoided, may result in death or serious personal injury or property damage.
Caution	To remind potential dangers or unsafe operations, if not avoided, will lead to minor personal injury, product failure, damage or loss of property.
Attention	To emphasize important attentions, provide a description or explanation to better use this device.

2.1.1 Warnings

- Please don't open the pulse oximeter hardware with eyes looking straight the light emitting device (the eye can’t see it when infrared light opens), even the maintenance personnel shall not directly look at the light emitting device, otherwise it may be harmful to the eyes.
- Do not use this product in the presence of flammable anesthetic.
- Do not open the product casing, otherwise there may be the risk of electric shock. The maintenance of the product can only be carried out by the personnel authorized by the company.
- This product is only used as a auxiliary diagnostic tool in patients. It must be used in combination with clinical manifestations and symptoms.
- This product can be not used during nuclear magnetic resonance (MRI) examination.
- Uses who is allergic to rubbers, can not use this product.
- This product only applies to adult and children who are over 4 years old.
- This product can not be used for infants and neonates.
- This product is not suitable for patients transported from outside the hospital. Can not used in ICU environment.
- Please do not use this product at more than 40^{o}C environment, so as to avoid cauma.

2.1.2 Cautions

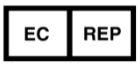
- If the product is stored, transported and used at environment outside the temperature and humidity range specified by the manufacturer, the measure results may not be able to achieve the expected performance.
- Measured users can not use cosmetics such as nail polish.
- Measured users' fingernails can not be too long.

2.1.3 Attentions

- If you use this product near the microwave oven, TV, X-ray equipment or other strong electromagnetic field, the measuring results may make mistakes; in order to avoid electromagnetic field effect, please stay away from the electrical measurement facilities, or to switch off the appliance before use.
- During measurement, following factors may affect the measurement accuracy: too strong light; in bright light no shading materials are used to cover sensors position; patient action is too large; diagnostic test; weak perfusion; effects of electromagnetic fields such as nuclear magnetic resonance equipment; non functional blood red protein concentration such as carboxyhemoglobin (COHb) and methemoglobin (MetHb); presence of certain dyes such as methylene blue, indigo carmine; inappropriate wearing the product position.
- This product dose not have measure value overrun alarm function, it is not suitable for those conditions which need alarm function.
- The oxygen saturation function is calibrated before leaving the factory, the user does not need to calibrate again in the process of using.
- During continuous measurement, it is advised to check the oxygen probe contact position every 2 hours, and move properly when skin occurs change or every 4 hours, so as to prevent long time oppression which may lead to skin changes, such as allergies, red, blisters or oppressive necrosis and so on.
- The products and its accessories and packaging (battery, plastic film, plastic boxes and cartons, etc.) shall be disposed according to local laws and regulations.
- Please get out the battery when not use the device in long time (more than 3 months)
- Please pay attention to the polarity of the battery, they shall be installed correctly, otherwise it may cause damage to the product.
- The rubber pad of the product has no stimulation, delayed type hypersensitivity reaction, cell toxicity to human body, it complies with requirements of ISO 10993-5 and ISO 10993-10.
- The product can display the oxygen saturation after calibration.

2.2 Symbols instruction

	BF type application part		Serial number
	Recycling according to local laws		Date of manufacture

	See the Instruction		Manufacturer
	Cautions		European union representative
	Warning of no SpO_2		Standby
IPX2	IP degree		Temperature range
	Humidity range		Avoid sunlight
	Keep dry		Up toward

3 Product brief

3.1 Product characteristics

The mobile pulse oximeter has a small size, low power consumption, easy to use and carry. During measurement, insert the finger into the probe, the display screen will immediately directly show the measured oxygen saturation value.

3.2 Scope

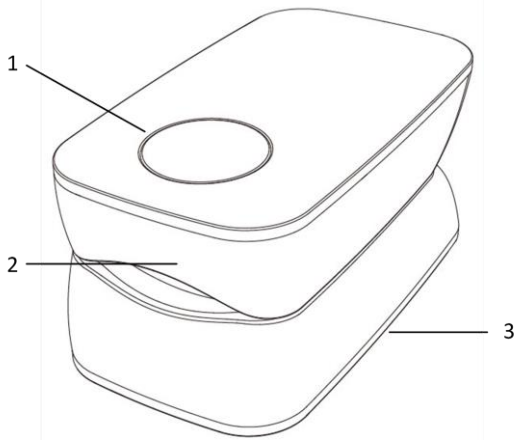
The mobile pulse oximeter is applicable to measure blood oxgen saturation and pluse in medical institute (Not applicable to ICU) or homehold, and show, analyze, store and transmit the measured blood oxygen saturation and pulse data by the blood oxygen management software.

3.2 Contraindications

- This product is only used as a auxiliary diagnostic tool in patients. It must be used in combination with clinical manifestations and symptoms.
- This product can be not used during nuclear magnetic resonance (MRI) examination.
- Uses who is allergic to rubbers, can not use this product.
- This product only applies to adult and children who are over 4 years old.
- This product can not be used for infants and neonates.

4 Prepare before use

4.1 Structure of the product



1-Power button 2-Rubber pad 3- Shell

Diagram 1. Measurement hardware structure

The mobile pulse oximeter consists of the blood oxygen management software and the measurement hardware which includes the light emitting diode, photosensitive diode, wireless communication module, micro controller (MCU), battery and other general electronic components.

4.2 How to install and change the battery

4.2.1 To press the battery cover groove, slip outward and open the battery cover;
4.2.2 To refer the battery cover reed polarity direction, insert into two No.7 alkaline battery;
4.2.3 Close the battery cover.
Warnings: When the oxygen terminal appears low voltage, please change the battery in time. If it is not used for a long time, remove the battery, so as to avoid battery leakage.

4.3 Installation and use of the blood oxygen management software, see *“Rapid use manual of mobile pulse oximeter”*

5 Method of use

5.1 Use cautions

5.1.1 The measurement time when the mobile pulse oximeter is won on the finger, is recommended for 15-60 seconds;
5.1.2 If the finger is too cold or too thin, the measurement value may be affected; during measurement, please use the thicker finger (thumb or middle finger are advised) to insert the probe completely;
5.1.3 When the pulse rate is stable and flat, the measured value is the best, this time pulse rate is also the most standard;

5.1.4 Before use the mobile pulse oximeter, the device shall be ensured in normal working condition and operation environment;
5.1.5 In order to take more accurate pulse oxygen saturation and pulse rate, the device should be used in quiet and comfortable environment;
5.1.6 To ensure patient safety, please use the manufacturer's production or recommended parts and accessories, using other accessories to the patient may cause damage or damage to the product;
5.1.7 During use the device, please stay away from the strong electric field, strong magnetic field equipment. Using the device in an inappropriate environment may cause interference or influence on the work of the device;
5.1.8 The bluetooth wireless transmission technology is a kind of short distance wireless communication technology which is widely used in the world. It includes a complete set of low interference, error detection, error correction, error control mechanism, guarantee the safe and reliable data transmission. During use, the distance between the mobile phone and the device hardware should be less than 3 meters, otherwise the measurement data may not be displayed.

5.2 Method of use

5.2.1 After install the battery correctly, press the power key to start, blue LED lights flashes and enter the Bluetooth searching state, waiting for the phone connection;
5.2.2 Take into the blood oxygen management software in the mobile phone, and press the measure button, after the mobile phone bluetooth successfully connecting to the device bluetooth, insert the finger into the rubber pad (fully extended), loosen the clamp, and the mobile pulse oximeter begin to prepare measurement;
5.2.3 Press the start button on the phone to send out the measurement order, begin to measure, after the wave is stable, click the end measurement key, the mobile phone will display the measured blood oxygen saturation and heart rate;
5.2.4 Put out the finger after measurement, and the device comes into waiting state, after 10 seconds it will go into automatic standby and power saving mode, automatic shutdown after 3 minutes, it also can manually press the power key for 3 seconds to shut down the device.

6 Maintenance and repair

6.1 Don’t fall or strongly collide the device.
6.2 Avoid high temperature or exposure to the sun!
6.3 When clean the shell or rubber pad, firstly turn off the power, use soft cotton fabric dipped in a little neutral detergent gently wipe the surface, and dry naturally, it is prohibited high temperature baking! It is recommended to clean monthly.
6.4 This product is strictly forbidden water!
6.5 Please take out the battery if long term not to use, so as to avoid battery leakage!
6.6 Do not disassemble the product body!
6.7 It is forbidden to use this product for other purposes!
6.8 The shelf life of the product is 5 years. To ensure the service life of the device, please pay attention to the device’s maintenance.

7 Troubleshooting

Abnormal phenomenon	Reason of analysis	Troubleshooting
Blood oxygen or pulse can not display	The finger does not correctly insert	Insert the finger correctly and try again
	the blood oxygen value is too low to measure	Try more time and go to hospital for confirmation
Blood oxygen or pulse display unstably	The finger does not insert deeply	Insert the finger correctly and try again
	Finger shaking or human body in movement	Do not move the finger or body
Orange lamp flashing after pressing power button	Low battery voltage	Change the battery
The software can not connect to the hardware	Low battery voltage	Change the battery
	The hardware power off automatically	Shortly press power button, blue lamp flashes, open the software to connect
	Mobile phone bluetooth function does not open	Open the mobile phone bluetooth function
No display after pressing power button	Power orange lamp flashers, low battery voltage	Change the battery

8 Specifications

Unit	Blood Oxygen saturation (SpO_2)	%
	Pulse	bpm
Measure range	Blood Oxygen saturation (SpO_2)	35%~100%
	Pulse	30bpm~240bpm
Precise	Blood Oxygen saturation (SpO_2)	±3% (when SpO_2 value is 70%～100%)
	Pulse	±2%, or ±2bpm, take the bigger one
Resolution	Blood Oxygen saturation (SpO_2)	1%
	Pulse	1bpm
Light emitting	Infrared light wavelength: 890nm	
	Red light wavelength: 663nm	

diode	The max. average output power: ≤1.5mw	
	Wavelength effect declaration: wavelength range and the max. average output power has special influence during clinical.	
Power	Internal d.c rated value: 3±10% V	
Weight	About 60 gram (not including battery)	
Dimension	6.0cm×3.4cm×3.0cm	
Operation environment	Temperature	5℃～40℃
	Humidity	30%～80%RH, Non condensing
	Air pressure	70KPa～106 KPa
Storage and transport environment	Temperature	-20℃～55℃
	Humidity	15%～95%RH, Non condensing
	Air pressure	50KPa～107.4 KPa
Equipment information	Classification of electric shock type: internal power supply equipment Classification of electric shock degree: BF type Protection against liquid: IPX1 Running mode: continuous operation Safety classification of using with flammable anesthetic gas or flammable anesthetic gas mixed with oxygen or nitrous oxide: Non AP/APG	

9 Technical instruction

9.1 Data update cycle, data averaging and signal processing

The measured SpO2 value of the product is average result of calculated data collected in a period of time. The shorter the average time is, the faster the device correspond when patients SpO2 value changes, but lower the accuracy of the measure is. On the other hand, the longer the average time is, the slower the device correspond when patients SpO2 value changes, but higher the accuracy of the measure is. The product data update cycle is 1 second.

9.2 Functional tester and patient simulator

It can use some model of functional tester and patients simulator sold in the market to verify the performance of the mobile pulse oximeter. For use step of the functional tester and patients simulator, please see their operation manual. Through these equipment can verify if the mobile pulse oximeter is functional, they can not correctly provide the correct evaluation of the accuracy of the present product SpO_2. The only way to assess the accuracy of SpO_2 measure is to compare the present product readings with traceable SaO_2 value measured by laboratory CO blood oxygen saturation meter which samples from arterial blood at the same time.

9.3 Environment effect

During the entire life cycle of mobile pulse oximeter, it will have an impact on the environment, in order to reduce the environment burden in most possible, please deal with

by following recommended methods:

Product life cycle	Environment effect advice
1.Production and processing stage	To reduce heavy metal pollution during electrical components welding process.
2.Sales (including package) stage	Disposal of battery and packaging wastes shall comply with local laws and regulations.
3. Use stage	During use, water is strictly prohibited to contact. Shall not use in more than 40℃. Do not use this product in flammable anesthetic place.
4. Disposal stage	This product and its accessories and packaging (battery, plastic film, plastic boxes, plastic boxes and cartons, etc.), please comply with the local laws and regulations to dispose.

10 Clinical research

10.1 Specification instruction

The accuracy of blood oxygen saturation of the mobile pulse oximeter is a mean square value of D-value, the formula as follows:

$$A_{\mathrm{rms}} = \sqrt{\frac{\sum_{i=1}^{n}\left(\mathrm{SpO}_{2i} - S_{\mathrm{R}i}\right)^2}{n}}$$

According to clinical trials, in range of 70%-100% the accuracy of blood oxygen saturation Arms=1.948% which is in accordance with ISO 80601-2-61:2011.

Remarks: Because the measured value of the device is a statistical probability distribution, only 2/3 measured value in in the Arms range which measured by carbon monoxide gas analyzer.

10.2 Data collection

The blood oxygen saturation accuracy test methods: choose 10 healthy volunteers, in the five stage of 100%-97%, 97%-92%, 92%-85%, 84%-78% and 77%-70% to measure SpO2, SaO2 respectively by the mobile pulse oximeter and Carbon monoxide gas analyzer.

10.3 Clinical research human characteristics

The clinical trials uses 10 healthy volunteers, 5 male and 5 female, all Han race, age from 20 to 30 years old.

10.4 Pulse accuracy rate

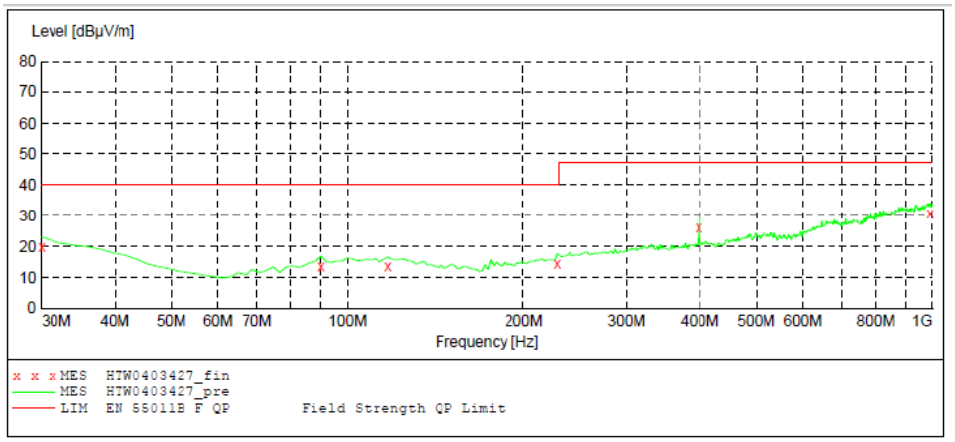
The pulse accuracy rate of the mobile pulse oximeter is expressed by the mean square (RMS) of the pulse D-value between the device and the monitoring instrument. Through clinical trial, in the range of 30bpm-240bpm, the pulse accuracy rate is 2.003%

11. Guidance and manufacturer’s declaration-electromagnetic emissions

11.1 Emission

Band width: 120kHz; Frequency range: 30MHz to 1000MHz

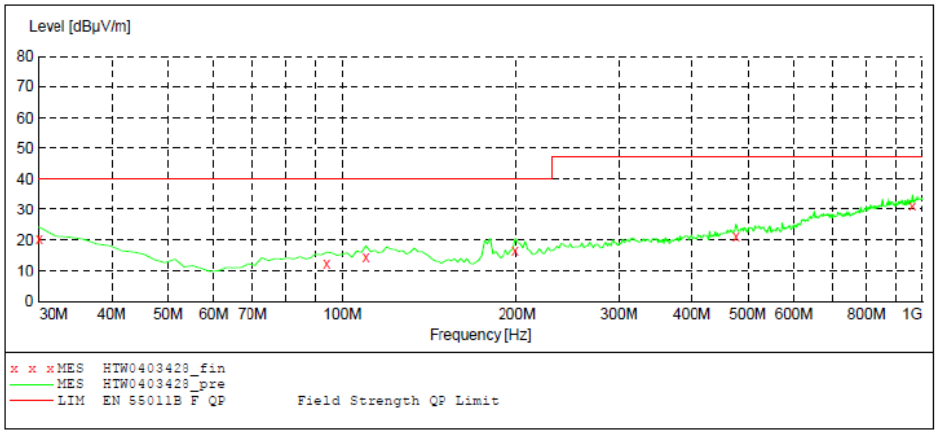
Result: Fulfilled



MEASUREMENT RESULT: "HTW0403427_fin"

4/3/2015 5:03PM

Frequency MHz	Level dBµV/m	Transd dB	Limit dBµV/m	Margin dB	Det.	Height cm	Azimuth deg	Polarization
30.000000	20.00	-10.0	40.0	20.0	QP	300.0	212.00	HORIZONTAL
90.260000	13.80	-18.8	40.0	26.2	QP	300.0	232.00	HORIZONTAL
117.470000	13.60	-18.0	40.0	26.4	QP	300.0	350.00	HORIZONTAL
228.270000	14.60	-18.2	40.0	25.4	QP	300.0	345.00	HORIZONTAL
399.330000	26.00	-13.5	47.0	21.0	QP	100.0	266.00	HORIZONTAL
992.220000	30.90	-3.1	47.0	16.1	QP	100.0	344.00	HORIZONTAL



MEASUREMENT RESULT: "HTW0403428_fin"

4/3/2015 5:15PM

Frequency MHz	Level dBµV/m	Transd dB	Limit dBµV/m	Margin dB	Det.	Height cm	Azimuth deg	Polarization
30.000000	20.40	-10.0	40.0	19.6	QP	100.0	59.00	VERTICAL
94.140000	12.30	-18.6	40.0	27.7	QP	100.0	257.00	VERTICAL
109.690000	14.40	-18.1	40.0	25.6	QP	100.0	55.00	VERTICAL
199.110000	16.80	-19.7	40.0	23.2	QP	100.0	55.00	VERTICAL
477.090000	21.40	-11.7	47.0	25.6	QP	100.0	46.00	VERTICAL
963.060000	31.10	-4.1	47.0	15.9	QP	100.0	86.00	VERTICAL

11.2 Immunity

Test frequency: 50Hz, 60Hz; Continuous field: 3 A/m; Test duration: 5m; Antenna factor: 0.917A/m; Axis: X, Y, Z.

Test results: No degradation of function, comply with EN 60601-1-2:2007+AC:2010, ISO

80601-2-61:2011 Clause 202, EN 60601-1-11:2010 Clause 12.