WIT- S400 Fingertip Pulse Oximeter

OPERATION MANUAL

Caution: Careful reading is required before using the WIT-S400 Pulse Oximeter.

Product Description

Dear customer, thanks for purchasing WIT-S400 Pulse Oximeter. Careful reading is needed for proper use of this product. Please keep this operation manual properly after reading to ensure instant consultation.

Table of product information:

Product	Fingertip Pulse Oximeter
Model Code	WIT-S400 (SatTip)
Certificate No.	/
Production Date	Refer to product label
Expiration Date	3 years
Structure and component of Product	The fingertip pulse oximeter consists of mechanical enclosure, silicone pads and function boards.
Scope of application	WIT- S400 Pulse Oximeter by Multibrands is for users to measure blood oxygenation level (SpO2), pulse rate (PR) and perfusion index (PI). And the oximeter is intended to provide monitoring for medical institutions, home care and those who are interested to knowing their blood oxygen parameters.
Model description	WIT- S400 Pulse Oximeter includes SPO2, PR, and PI.
Registrant/Manufacture/ Names of Enterprises	Shenzhen Witleaf Medical Electronics co., Ltd.
Address	13/F-B2, Block 1, Senyang Science Park, No.7 Road, West District of High-Tech Park, Guangming District, 518132 Shenzhen, P.R.China
European Representative Name	Zug Medical Systems SAS
European Representative Address	291 Rue Albert Caquot, CS40095,06902 Sophia Antipolis, France

This operation manual is compiled by Multibrands International Ltd. The date and version are as follows:
Current version: V1.0
Initial version: V1.0
Release date: May 18, 2020

Declaration of Conformity

CE 0123

This product meets the requirements of the 93/42/EEC guidelines for medical products.

Statement

Maintenance Service

The warranty period of this oximeter and related accessories is mainly based on the sales agreement, and consumables are not included.
Consumables: refers to disposable consumable materials which need replacement after each use and fragile materials which need replacement termly.
The warranty period starts from the "installation date" filled in the product warranty card accompanying the product. The product warranty card is the only proof for calculating the warranty period. In order to protect your interests, please fill in the product warranty within 30 days after reception and installation, and then return the second copy to Multibrands. The warranty period will start with the date after 45 days from the "delivery date" on the packing box if the warranty fails to return to Multibrands on time.
Multibrands is responsible for the effects on safety, reliability and performance of this product, only if:

- The product is used in accordance with the instructions for use.
- All installation operation, maintenance and upgrading of this product are conducted by Multibrands authorized or approved personnel.
- The environment for storage, working and electrical environment of the product conform to the product specifications.
- The label of serial number or manufacturing logo is clear and can be identified as product of Multibrands
- Damage caused by non-artificial factors (E.g. Accidental falls, unintentional damages, etc.).

Scope of Free Services:
All products out the range of warranty ordinance, the service will be charged.
This limited warranty excludes:

- All products that out the range of warranty ordinance, the service will be charged.
- Even during the warranty period, the product needs to be repaired due to the following reasons: man-made damage, improper use, the grid voltage exceeds the specified range of products; irresistible natural disasters; replace components, accessories and consumables or repair oximeter by personnel without authorization of Multibrands.
- Customer should bear the freight if the product is transported to our company to repair, the user will have to bear the freight (including customs fees). Apart from the reasons above, and the maintenance service is chargeable. Extra fees on maintenance and accessories should be paid.

Multibrands can continue to provide chargeable maintenance services after the expiry of warranty. If the fee for maintenance is delayed or unpaid, Multibrands will suspend the maintenance service unless it is paid.

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Return Process

The below steps should be followed in goods return.
1. Obtaining return material authorization (RMA): Contact the after-sales service department of Multibrands and inform serial number which marked on the packing box and the nameplate. Returns would be rejected if the serial number is not legible.
2. Freight: Customer should bear the freight if the product is transported to our company to repair (including customs fees).

After-sales Service

Address: Multibrands International Ltd.13/F-B2, Block 1, Unit 2, Jowett Street, Bradford BD1 2JX United Kingdom.
Tel: +44 (0) 1274 307310
URL：www.multibrands . eu.com info@multibrands.eu.com
Post Code: BD1 2JX

Trademarks

Content

1. Safety Guide

1.1. Safety Information

Indications

The following information is used to indicate potential hazards or relevant information concerning patients and equipment, which should be paid attention to.

Danger	Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.
Warning	Indicates a potential hazard or important message that, if not avoided, could result in death or serious injury.
Caution	Indicates potential hazard or unsafe operation that, if not avoided, could cause slight or moderate injury or damage to equipment.
Note	Emphasize important precautions and provide application tips or other useful information to ensure that you get the most message from your product.

Danger

This device does not contain information about the danger level.

General

- ***To ensure accurate performance, users must check the oximeter and battery before use.***
- ***Do not use the oximeter during defibrillation and electrosurgery.***
- ***Do not use the oximeter in situations where alarms are required.***
- ***To avoid electronic burn by induced current, this device cannot be used in the presence of MRI occasions.***
- ***Do not use the oximeter in ICU, because the device's alarm does not meet requirements of EN 60601-1-8.***
- ***To avoid explosion hazard, do not use the equipment in the presence of oxygen-mixed atmospheres or combustible anesthetics with NOx.***
- ***Only use the oximeter to secure it to the finger. Excessive pressure to a finger can cause skin damage***
- ***Prolonged and continuous oximetering may increase jeopardy of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonate and patient of poor perfusion or immature dermogram by light collimation and proper attaching strictly according to changes of the skin. Check per 2~3 hours the sensor placement and move it when the skin deteriorates. More frequent examinations may be required for different patients.***
- ***Do not leave the oximeter unattended around children. Small items such as the battery door, battery, and lanyard may become choking hazards***
- ***Do not use this oximeter if it appears or is suspected to be damaged. Damage to internal parts can***

result in no or inaccurate readings.

- ***All servicing must be carried out by the service personnel trained and authorized by Witleaf. Authorized service personnel can ask for corresponding information from the company, including circuit diagrams, component lists, etc.***
- ***The device contains no user serviceable parts. To avoid electric shock, do not open the housing of equipment under any circumstances. And the maintenance of housing, mechanical and electronic parts can be only carried out by the service personnel trained and authorized by Witleaf.***

Cautions

- ***Properly apply and avoid using the oximeter under high ambient light sources, fluorescent lights, infrared heating lamps and direct sunlight to minimize interference that may result in no or inaccurate readings.***
- ***Electromagnetic interference - make sure that installation and operation of this oximeter is free from high electromagnetic interference, such as Mobile phone and wireless transmitters.***
- ***Only perform maintenance procedures specifically described in the manual; otherwise, return the oximeter for servicing. Improper maintenance may result in damage to the internal parts. Damage to internal parts may result in no or inaccurate readings.***
- ***Do not clean the oximeter with any chemical other than those specified in the cleaning section. These substances may affect the device's materials and damage internal parts.***
- ***Do not submerge the oximeter in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.***
- ***Never submerge the oximeter in water or any other liquid solution this may cause permanent damage to the oximeter.***
- ***Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore, all configurations shall comply with the requirements for medical electrical systems (See IEC 60601-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively). Anybody who connect devices to the equipment's signal input/output port are responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1.Attention is drawn to the fact that local laws take priority over the above-mentioned requirements. If in doubt, consult your local representative or the technical service department.***

NOTE

- ***Packages and batteries must be disposed in accordance with the currently implemented waste control regulations and placed in places that children do not have access to.***
- ***Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.***
- ***This user manual introduces this product according to the top configuration and the product you purchased may not have some configurations or functions claimed.***

- ***To ensure a normal performance, operate this equipment in assigned condition.***
- ***The oximeter display will shut off automatically if there are no readings.***
- ***The condition is limited as follows:***
  - ***Temperature: 0 ~ +40 ℃;***
  - ***Relative humidity: 15 % ~ 95 % (Noncondensing);***
  - ***Barometric: 70.0kPa ～ 106.0kPa ;***
  - ***Power Supply: two AAA batteries;***
- ***When the ambient temperature of the device changes too much, such as moving the device from one place of lower temperature to another place of higher temperature, Allow the device to remain in a room for 120 minutes where the temperature is between 0 ℃to 40 ℃.***
- ***All figures provided in this operation manual are for reference only, and may not be consistent with the picture of real product.***
- ***FUNCTIONAL TESTER cannot be used to assess the ACCURACY of a PULSE OXIMETER PROBE or a PULSE OXIMETER MONITOR.***

1.2. Equipment symbols

Symbol Description

	Warning: refer to this operational manual.		Caution, refer to this operational manual.
	Adult		Pediatric
	Manufacturer	EC REP	Authorized Representative in the European Community
CE 0123	CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.		

Transportation symbols

	Fragile: handle with caution		Temperature limit: do not expose the oximeter to extreme temperature which beyond the limit of display.
	Avoid rain		Location: With this side up.
90% 10%	Moisture Condition: do not expose the oximeter to extreme moisture which beyond the limit of display.	3	Stacking Limit: maximum to 3
106kPa 57.3KPa	Indicates the atmospheric pressure during transportation shall not be higher than 106 kpa or lower than 57.3 kpa		

2. Introduction

2.1. General introduction

2.1.1. Scope of Application

WIT- S400 Pulse Oximeter by Multibrands is for users to measure blood oxygenation level (SpO2), pulse rate (PR) and perfusion index (PI). And the oximeter is intended to provide monitoring for medical institutions, home care and those who are interested to knowing their blood oxygen parameters.

2.1.2. Contraindications

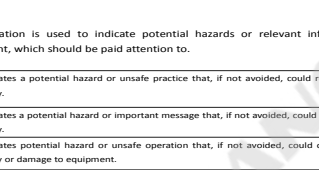
It is not for intensive care or person whose all the fingers are injured.

2.1.3. Components of Oximeter

The oximeter consists of the main unit and batteries.

2.2. Basic Components

2.2.1. Front View of WIT-S400



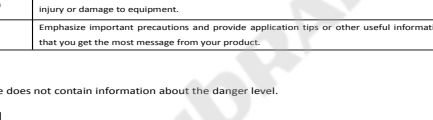


Figure 2-2 Front View of WIT-S400 and OLED Display

The front view of WIT-S400 includes screen display and a function key. The screen display measurement information concerning parameters and waveforms. The function of the keys is to control the boot, switch the screen orientation and enter or exit the function menu.
Each time press the button for less than 0.5 seconds, can switch between 6 different display interfaces. As shown in the picture above.
Note: When battery power is at the lowest level, the battery capacity displays symbol of " " in OLED, to remind users of replacement of battery.

2.2.2. Back View of S400

The WIT- S400 requires two AAA batteries to operate. Install the battery on the back of the oximeter, as shown in Figure 2-3.

Figure 2-3 Back View of WIT- S400

1. Place the WIT- S400 so that the display screen is facing downwards.
2. Push the battery cover to the right.
3. Insert two new AAA batteries and match the orientation labels (+ and -).

Note: WIT-S400 will not work if the batteries are inserted in the incorrect orientation.

4. Once the batteries are correctly inserted, put cover back on.

WARNING: Do not attempt to recharge normal alkaline batteries, they may leak and may cause fire or explosion.

2.2.3. Using WIT-S400

To take reading with the WIT-S400, follow the instruction below:

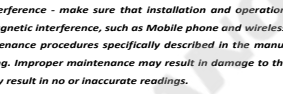


Figure 2-4 Using oximeter diagram

1. To open the WIT-S400, squeeze the back portion of the device as shown in the image above.
2. Insert one of your fingers so the sensor LED is above the fingernail.
3. Once the finger is correctly positioned, gently close the WIT-S400 by releasing the pressure on the back of the device.
4. Press the button on the front shorter than 0.5 second until the screen displays the boot interface, the WIT-S400 will display readings.

WARNING: Do not attempt to secure the WIT-S400 to the finger using external pressure. The internal spring provides the correct pressure; additional pressure may cause inaccurate readings.

The oximeter will automatic fall into standby or sleep mode after 8 seconds without finger in it.

2.2.4. Install Hanging Cable

Let the thin end of the rope go through the cable hole, next let the big point of cable go through the hole, then tighten the cable.

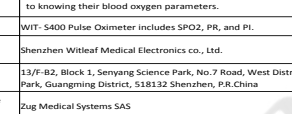


Figure 2-5 Install Hanging Cable

3. Function of WIT-S400

3.1. Menu Introduction

There are two ways to operate the button according to the pressing time, long-press is longer than 0.5 second and short press is shorter than 0.5 second. Short-press is used to select an item by moving a light bar to the line of this item, long-press is used to change the item's value, status or open a new page.
Long-press on the power button in sequence, the oximeter will display Menu page as shown in Figure 3-1~3-4. When the bar is on the second row, long-press make the screen display the next page.

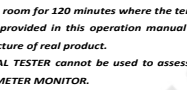


Figure 3-1

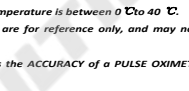


Figure 3-2

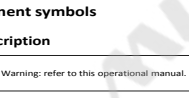


Figure 3-3

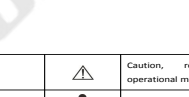


Figure 3-4

3.2. Data Analysis

3.2.1. How to start a new analysis

Long-press the button select "store" on Figure 3-1, then the display is shown as Figure 3-5. Select "OK", the status of "store" will change to "on". Then put the finger into rubber hole of the oximeter to start a new continuous measurement. The maximum of recording time is 8 hours. When the measurement is finished, take off the oximeter. Long-press the button change the status of "store" to "off" or turn on the oximeter again and then the status of "store" also display "off" as shown in Figure 3-7.

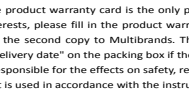


Figure 3-5

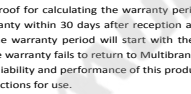


Figure 3-6

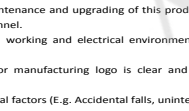


Figure 3-7

3.2.1. How to start analysis results

Now the status of "Store" is off and "Summary Graph" and "Statistics" is OK. Select "Summary Graph", long press to open the graph page as shown in Figure 3-8. Each full page display 15 minutes' data. Select "<" or ">" and long press to see the previous or next page, select "<<" or ">>" and long press to see the first or last page. Select " " to return Figure 3-7. Select "Statistics" and long press to open the Statistics page as shown Figure 3-9.

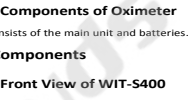


Figure 3-8

Figure 3-9

WARNING: The oximeter is NOT intended for diagnosis and the ODI4 is only for warning, if there is any abnormal about the readings please go to the hospital for further examination.
ODI4 indicates the severity of hypoxia during sleep, if this number is greater than 25, please go to the hospital for further examination.
"ODI4" (Oxygen desaturation Index of 4%) means Events of Desaturation which is not less than 4% per hour during the total recording time.
"Time" means the total recording time of last storage.
Max SpO2/PR is the maximum SpO2/PR value of the entire storage.
Min SpO2/PR is the minimum SpO2/PR value of the entire storage.
Note：If starting a new storage and the time is longer than ten minutes, the previous storage information will be replaced.
Note："Summary graph" and "Statistics" cannot be opened when the storage is empty.
WARNING: The analysis results of OD4I is only as a reference. It may be inaccurate when total sleep time is less than 2 hours or interfered by other factors,such as finger moving, device droped from the finger , etc.
WARNING: Some model is not suit for testing ODI4, before you want to test a long time, please check the device if it is suit for long time testing. During prolonged periods of use, if you feel discomfort or pain in your finger, please take off the oximeter immediately to prevent the finger injuries.

3.3. Other Settings

3.3.1. ALM Setting

The oximeter has over-limit sound prompt function. When the measured values of the SpO2 and PR parameters exceed the upper and lower limits which setting in Figure 3.3 and the Alm setting in Figure 3-2 is set to "On", the buzzer of the machine will prompt once every second. If the Alm setting in Figure 3-2 is set to "Off", the oximeter will turn off the function.
The default state is "On". The SpO2 Alm upper limits default value is 100 and the lower limits default value is 94. The PR Alm upper limits default value is 130 and the lower limits default value is 50. And it adjusts the limits value in the default direction of addition, so the symbol in the Figure 3-3 is "+".

3.3.2. Beep Setting

The oximeter has a pulse sound prompt function. If the Beep in Figure 3-2 is set to "On", the buzzer will beep with the pulse wave. If the Beep is set to "Off", the oximeter will turn off the function. The default state is "Off".

3.3.3. Demo Setting

The oximeter has a demonstration function. If the Demo in Figure 3-2 is set to "On", the oximeter will display the pre-existing demo. The default state is "Off".

3.3.4. Brightness Setting

The oximeter can adjust the screen brightness through the Brightness setting. It can be set to 1,2,3,4,5 to represent different brightness of the screen. The default state is "4".

3.3.5. Language Setting

The oximeter can support two languages simultaneously, Portuguese and English, or Spanish and English. The user can select the display language through the language setting option.

3.3.1. Reset State

The reset status is shown as "Ok", when all settings in Figure 3-2 and Figure 3-3 are in the default state. If not , the Reset state is blank.

4. SpO2

4.1. Overview

The basic principle of SpO_2 measurement is the absorption based on the spectrum of oxyhemoglobin and hemoglobin. The wavelength of red light is 905nm and the infrared light is 660nm. The optical signal with SpO_2 is firstly inducted by sensor and obtained by microprocessor through analog-to-digital converter. Finally, after a series of calculations and calibrated by blood gas analysis, parameter information are obtained, such as Pulse Oxygen Saturation (SpO_2), pulse rate（PR）, pulse waveform, and arterial pulsation.

⚠ Note

- ***One of the maximum infrared radiation powers ≤ 0.1W, red maximum radiation power ≤ 0.11W.***

4.2. User Preparation

The accuracy of SpO_2 measurement mainly depends on the quality and intensity of SpO_2 signals.Pay attention to the following guidelines.
1. Finger is the monitoring site to measure SpO2, clear the fingers before measurement, such as colorful nail polish or long nail.
2. Place the SpO2 sensor on the user's finger.

⚠Caution

- ***If the result be suspected as inaccurate in SpO2 measurement. The patient's vital signs should be checked first, the oximeter follows.***
- ***Inappropriate positioning of the SpO2 sensor or excessive ambient light will result in inaccurate measurement.***
- ***Factors such as patients' physical movement, magnetic field, electrical enclosure, improper placement of pulse oximeter sensor can cause inaccurate measurements.***
- ***Shock, anemia, hypothermia or the use of vasoconstrictors would have reduced the arterial blood flow to an undetectable level.***
- ***The accuracy of SpO2 cannot be guaranteed in a state of low perfusion and movement.***

5. PR

The pulse rate is abbreviated as PR, which means the frequency of the arterial pulse, which can be calculated by identifying the pulse wave.

NO.	Name
1	Pulse Rate (PR bpm): detected pulsations per minute.

6. Cleaning and Disinfection

6.1. Safety Information

⚠*Warning*

- ***Switch off the power and take out the batteries before cleaning.***

⚠*Caution*

- ***If you pour any liquid on the equipment by accident, please make an instant contact with service personnel or Multibrands.***

⚠*Note*

- ***Please use the materials and methods recommended by Multibrands to clean or disinfect the equipment.***
- ***Do not partially immerse the machine in liquid during cleaning.***
- ***Do not allow cleaning liquid to enter inside the machine.***
- ***Do not press the display screen hard during cleaning, otherwise the display screen glass would be damaged.***

6.2. Cleaning

Cleaning operation can be performed according to following steps:
1. Turn off the oximeter and take out the batteries.
2. Use a clean lint-free cloth to wipe dusts off the oximeter.
3. Use gauze dampened with proper amounts of detergent to wipe the surface of the oximeter.
4. Use a clean lint-free cloth to dry the oximeter.
5. Keep the oximeter dry in a ventilated environment.

The following cleaning options are available:
1. Sodium hypochlorite (Bleaching powder for washing)
2. Hydrogen Peroxide (3 %)
3. Ethanol (70 %)
4. Isopropyl Alcohol (70%)

6.3. Disinfection

The disinfectant used would cause some damages to the surface of the oximeter's housing and cables, such as spots on the plastic housing. Disinfect the oximeter when necessary.
Disinfectant recommended by this user manual:
1. Ethanol (70 %)
2. Isopropyl Alcohol (70%)
3. Perform sterile concentrate OXY(Class C/D)

7. Maintenance

Regular maintenance is essential to ensure that the equipment functions properly. This chapter contains information on periodic testing and maintenance.
1. Replace the batteries timely when battery indication is low. Clean surface of the Pulse Oximeter before it is used in diagnosis for patients.
2. Remove the batteries inside the battery compartment if the Oximeter will not be operated for a long period of time.
3. It is better to store the product in a place where temperature is -20 ~ 60℃ and humidity is 10% ~ 95%.
4. Regular inspection to make sure that no obvious damage to affect the safety and performance of the device.
5. No flammable substance, extreme high or low temperature and humidity.

⚠*Warning*

- ***All the work involving checks of the monitor should be performed by professional service personnel. Otherwise equipment failure and possible health hazards could result.***
- ***Failure on the part of the responsible individual hospital or institution using this equipment to implement a recommended maintenance schedule may cause undue equipment failure and possible health hazards.***
- ***This equipment contains no user serviceable parts. Refer servicing to qualified service personnel.***
- ***The safety checks or maintenance involving any disassembly of the equipment should be performed by professional service personnel. Otherwise, undue equipment failure and possible health hazards could result.***
- ***Do not open the equipment housings. All servicing and future upgrades must be carried out by the service personnel trained and authorized.***
- ***Do not heat batteries to above 60 °C, incinerate batteries, or short the battery terminals. Batteries may ignite, explode, leak or heat up, causing personal injury.***
- ***No modification of this equipment is allowed.***
- ***If you discover a problem with any of the equipment, contact your service personnel.***
- ***The service personnel must be properly qualified and thoroughly familiar with the operation of the equipment.***
- ***At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have any questions concerning disposal of the equipment, please contact Multibrands.***
- ***When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.***
- ***Use and store the equipment within the specified temperature, humidity, and altitude ranges.***

A.Product Specifications

A.1 Safety Specifications

A.1.1 Product Classification

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC.

The main safety features of this oximeter are as follows:
1. Anti-electroshock type: Class II oximeter and internal powered oximeter
2. EMC type: Class A
3. According to anti-electroshock degree, BF type.
4. Harmful liquid proof degree: IPX2
5. Working system: Continuous running oximeter

A.1.2 Ambient Conditions

Working Environment

- Temperature: 0 ~ 40 ℃;
- Relative Humidity: 15 % ~ 95 % (noncondensing);
- Barometric: 70.0 kpa ~ 106.0 kpa;

Storage Environment:

- Temperature: -20℃ ~60℃;
- Relative Humidity: 10 % - 95 % (noncondensing);
- Barometric: 57.3kPa ~106.0kPa;

A.1.3 Information of Power Supply

A.2Technical Specification

Parameter	Specification
Size	Main device: 64.5*38.2*35(L× W× H)
Weight	44g
Display Screen	
Type	OLED
Size	OLED: 0.96inch
Resolution	128*64
Audio Indicator	
Buzzer	No alarm function, only sound prompt
Control	
Buttons	One key

A.3 Storage of data

Parameter	Specification
Trend Data	Hours, resolution: Half a minute Maximum storage time:8h

A.4 Parameter Information

The following specification, unless specified indicated is the same as the measuring range of signal.

A.4.1 Specification of SpO2

SpO_2	
Requirement	ISO 80601-2-61:2011
Range of Measurement	0~100%
Accuracy of Measurement	In the range of 70 % ~ 100 %, the measurement error should be ±2 %; Range of 0 to 69%: none-define.
Display Resolution	1%

A.4.2 Specification of PR

PR	
Requirement	ISO 80601-2-61:2011
Range of Measurement	25bpm~250bpm
Accuracy of Measurement	±3bpm
Display Resolution	1bpm

B. EMC

Instructions for use
The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.
Warning：Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
Warning： Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."
Warning：Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Fingertip Pulse Oximeter (Model: WIT-S400), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
If any：a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER

and EQUIPMENT OR TYPE REFERENCE).
If any：the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).
Technical description
1.all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.
2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not application
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not application

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines：±2 kV input/output lines：±1 kV 100 kHz repetition frequency	Not application
Surge IEC 61000-4-5	line(s) to line(s)：±1 kV. line(s) to earth：±2 kV.	Not application
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	Not application
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	150KHz to 80MHz： 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	Not application

Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE UT is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380 –390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27
	450	430 –470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
	710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9
	810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
	1720 1845 1970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240 5500 5785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9