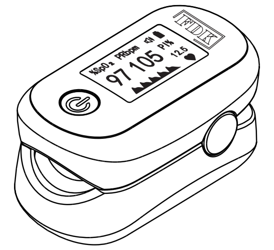
FDK

SPEAKING BLOOD OXYGEN FINGERTIP PULSE OXIMETER

USER MANUAL

Pulse Oximeter User Manual



Product Model: FT-E688 PLUS

Version: 3.0

Date: 2022-03-31

1 Product Introduction and Operation Guide

1.1 Front View

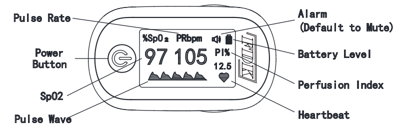


Figure 1 Front View of FT-E688 PLUS

1.2 Operation Method

A. Open the battery cover, and put the two AAA batteries into the battery compartment in correct polarities, then replace the cover;
B. Press the bottom of the equipment and open the probe, then insert one finger into the probe;
C. Press the button to turn the equipment on, and the measure interface will appear;
D. After about 8 seconds, the measurement result can be read directly from the display screen;
E. Before reading the parameters, make sure that stable numbers of the pulse oximeter interface has sustained more than 4 second;
F. The equipment will turned off automatically within 8 seconds when the finger left the probe.

1.3 Battery Installation

A. Put the two AAA batteries into battery compartment in correct polarities (Figure2).
B. Push the battery cover horizontally along the arrow shown as right.

WARNINGS:

- Battery polarities should be correctly installed, otherwise, damage may be caused to the equipment.
- Please remove the batteries if the equipment will not use for a long time.

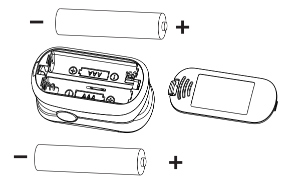


Figure 2 Battery Installation

1.4 Lanyard installation

A. Pass the thinner end of the lanyard through the hanging hole;
B. Pass the thicker end of the lanyard through the thinner end and tighten the lanyard (Figure3).

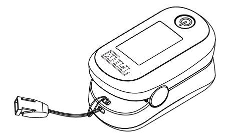


Figure 3 Lanyard Installation

1.5 Attention for Operation

A. Before use check and confirm that the people or finger size were applicable;
B. Before use check and confirm that the environment should be non-combustible material, as well as to avoid high or low temperature and humidity, but also need to pay attention to the following:
  a) To avoid glare and direct sunlight exposure;
  b) To avoid radiation infrared or ultraviolet radiation;
  c) Avoid contact with the organic solvent, mist, dust, corrosive gases;
C. The equipment should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection;
D. The equipment may not work normally on microcirculation barrier patients,Warm or rub the finger, or re-position the equipment could improve the measurement.
E. The ray between photo detector and light emitting diode should across patient's arteriole.
F. The patient should not use enamel or other makeup;
G. Avoid to insert a wet finger into the probe.

Notes:
A. The user should fully insert the finger into the probe,
B. It is recommended to let the light shine directly on the nail(Figure4);
C. Don't shake the finger and try to keep the patient still during the measurement.

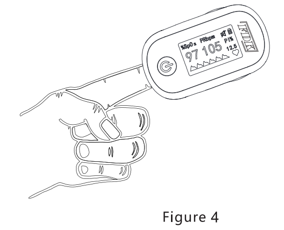
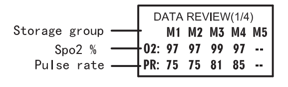


Figure 4

Storage interface

- Press the power button, the oximeter will enter the storage interface, short press the button to select the page to view the previous historical test data, without pressing the button, this page will remain for 3 seconds.

- The first measurement data (data with countdown record) after each startup will be stored, and the data at the front of the storage interface is the latest test data.



Storage Interface

Menu

After turning on the oximeter,press and hold the power button for about 2 seconds.The oximeter will display the settings menu.Short press to move"*"to a corresponding option,and hold the button to confirm your selection.

- Quickly press the power button To rotate the display.

General setup

- Short press to move "* " to the corresponding setting, and hold the button to set Alm or Beep to ON or OFF.
- When the alarm is set to ON and the measured SpO2 or PR Values go beyond the upper or lower limits, the oximeter will sound an alert.
- When alarm is set to OFF and the measured values go beyond the limit, the oximeter will not sound an alert.
- When beep is set to ON, the oximeter plays a sound indicating the pulse rate during the measurement.

- When beep is set to OFF, no pulse rate sound is played.
- Press the button to select a brightness level ranging from 1 to 5.
- The greater the value, the greater the brightness of the screen.
- While the " * " is on the default option, hold the button to restore factory settings.
- Move to LANGUAGE and long press to switch the voice function, 'EN' is English, 'ES' is Spanish.

```
        MENU
* GENERAL SETUP ENTER
  ALARM SETUP   ENTER
  DATA REVIEW   ENTER
  EXIT
```

```
  GENERAL SETUP
* ALARM       ON
  SOUND       OFF
  DEMO        PLAY
  BRIGHTNESS   3
  LANGUAGE    EN
  EXIT
```

```
  ALARM SETUP
* SPO2 ALM HI  100
  SPO2 ALM LO  94
  PR ALM HI    120
  PR ALM LO    50
  EXIT
```

Alarm setup

- Press the button to switch between options. On this screen, you can set the upper limit and lower limit of the SpO2 and PR alarms.
- Select the corresponding option and hold the button to change the upper or lower limit.
- Move "* " to the Exit option and hold the button to return to Measurement Mode.

2 Specifications

.1 Classification

Type of protection against electric shock: Ⅱ (Internally powered equipment)
Degree of protection against electric shock: Type BF-Applied part
Operating mode: Spot checking
Degree of protection against hazards of explosion: IP22

2.2 Power Requirements

Specification of battery: Two AAA (LR03)
Operating current: 25-50mA

2.3 Physical Specifications

Width*Height*Depth: 57×30×31 mm
Weight: 28g (Bare machine)

2.4 Measurement Specifications

SpO2 declared accuracy 70%~100%: ±2digits
0% ~ 69%: unspecified
SpO2 Display Range: 30%~99%
SpO2 Resolution: 1%.

PR declared accuracy : 25~250 bpm: ±3digits
PR Resolution: 1 bpm

2.5 Environmental Specifications

Temperature
Operating : +50~+104°F / +10~+40°C
Storage/Transportation: -4~+140°F / -20~+60°C
Humidity
Operating : 10~95%, noncondensing
Storage/Transportation : 10~95%, noncondensing
Atmosphere Pressure
Operating: 70~106kpa
Storage/Transportation: 50~107.4kpa

2.6 Display

Display Type: OLED/TFT
Display content: SpO2%, Pulse Rate, PI%, Bar Graph Battery Indicator, Pulse Wave

Notes:

1)The claim for oxygen saturation accuracy should be supported by clinical studies covering the entire claimed range,The fraction of inspired oxygen (FiO2) delivered to test subjects is varied to achieve a series of targeted steady-state saturation periods over the specified SpO2 accuracy range (e.g. 70 % to 100 %),then the SpO2 accuracy is calculated by comparing SpO2 readings of the pulse oximeter to the values of SaO2 determined with a Co-Oximeter.
2)The clinical trial included 11 subjects, including 6 males and 5 females, with an age range of 18 to 46 years, the subjects skin color included dark black, medium black, light color and white.

3 Maintenance,Cleaning,Disinfection

3.1 Maintenance

The equipment's design life expectancy is about 2 years, keep your equipment and accessories free of dust and dirt, and follow these rules:
A. Please clean the equipment before use according to chapter 3.2;Remove the batteries insidethe battery cassette if the equipment will not be operated for a long time;
B. Replace the batteries in time when the battery voltage indicate lamps were empty;
C. It is recommended that the equipment should be kept in a dry environment with no corrosive gases and good ventilation anytime. The moisture and high-light environments will affect its lifetime and even might damage the equipment.
D. It is best to preserve the product in a place where the temperature is between -20 to 60℃ and the relative humidity is less than 95%.
E. The packed equipment can be transported by ordinary conveyance. The equipment not be transported mixed with toxic, harmful, corrosive materials.

WARNING

- No modification of this equipment is allowed.

3.2 Cleaning

Your equipment should be cleaned on a regular basis. If there is heavy pollution or lots of dust and sand in your place, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment. Recommended cleaning agents are:
  a) Mild soap (diluted).
  b) Ethanol (70%).
To clean your equipment, follow these rules:
  a) Shut down the pulse oximeter;
  b) Clean the display screen using a soft, clean cloth dampened with a glass cleaner;
  c) Clean the exterior surface of the equipment and probe using a soft cloth dampened with the cleaner;
  d) Wipe off all the cleaning solution with a dry cloth after cleaning if necessary;
  e) Dry your equipment in a ventilated, cool place.
To avoid damage to the equipment, follow these rules:

CAUTIONS

- Always dilute according the manufacturer's instructions or use lowest possible concentration.
- Do not immerse part of the equipment in the liquid.
- Do not pour liquid onto the equipment or accessories.
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).
- If you spill liquid onto the equipment, contact us or your service personnel.

3.3 Disinfection

Clean the pulse oximeter before disinfecting it.The recommended disinfectant is ethanol 70%.Disinfection steps are the same as cleaning.

CAUTION

- Never use ETO or formaldehyde for disinfection.

3.4 Disposal

Dispose of the pulse oximeter in accordance with local environment and waste disposal laws and regulations.

4 Accessories

One lanyard.
One user manual.
One certificate card.

5 Troubleshooting

Trouble	Possible Reason	Solutions
The device can not be turned on	The batteries are drained away or almost drained away.	Replace batteries.
	The battery installation is incorrect.	Install the battery over again.
	The device works abnormally.	Please contact the product distributor

Trouble	Possible Reason	Solutions
The Spo2 and PR are not displayed normally	The finger size is too big or small	Select the suitable size finger to measure
	Excessive ambient light	Avoid the excessive ambient light irradiation
	User's blood perfusion is very low	Warm the finger and try again
The display is off suddenly	The device was set to shut down automatically in 8 seconds when there is no correct physiological signals	Normal
	The battery is almost drained away	Replace batteries
The Spo2 and PR are not displayed stably	The finger is not inserted deep enough	Replace the finger and try again
	The finger is shaking or the body is moving	Try to keep still
	Not used in the work environment required by this manual	Please use in normal working environment
	The device works abnormally.	Please contact the product distributor

6 Appendix A EMC

The equipment complies with the requirement of standard EN 60601 -1-2:20 14"Electromagnetic Compatibility – Medical Electrical Equipment".

1	Guidance and manufacturer´s declaration – electromagnetic emission		
2	The model FT-E688 PLUS is intended for use in the electromagnetic environment specified below. The customer or the user of the model FT-E688 PLUS should assure that it is used in such an environment.		
3	**Emissions test**	**Compliance**	**Electromagnetic environment – guidance**
4	RF emissions CISPR 11	Group 1	The Model FT-E688 PLUS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Class B	The FT-E688 PLUS model is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
6	Harmonic emissions IEC 61000 -3-2	Not applicable	

7	Voltage fluctuations / flicker emissions IEC 61000 -3-3	Not applicable	

Guidance and manufacturer´s declaration – electromagnetic immunity			
The Model FT-E688 PLUS are intended for use in the electromagnetic environment specified below. The customer or the user of the Model FT-E688 PLUS should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
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	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0° 0 % UT (100 % dip in UT) for 250/300 cycle at 0°	N/A	N/A

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model FT-E688 PLUS are intended for use in the electromagnetic environment specified below. The customer or the user of the Model FT-E688 PLUS should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bandsa	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	**Recommended separation distance** $d\left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz $d\left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz to 2.7GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range [b]

			Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.			

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model is used exceeds the applicable RF compliance level above, the model should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the FT-E688 PLUS.

d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

DISTRIBUTOR:
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