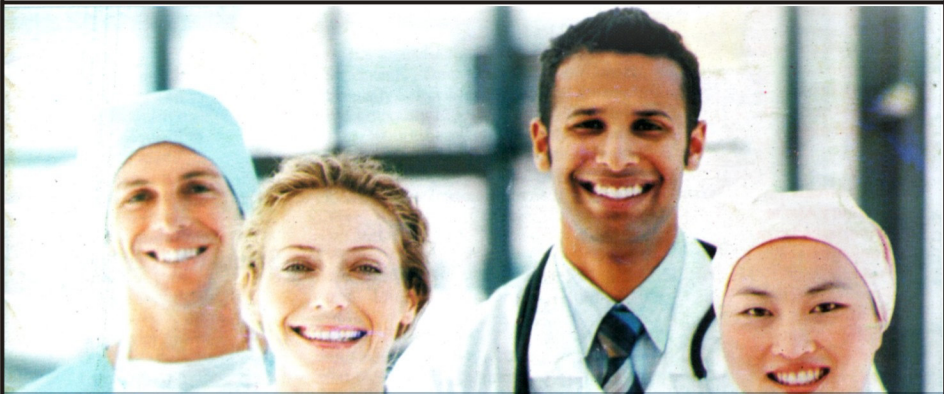




# FETAL DOPPLER

USER MANUAL - 2019



## WESTERN SURGICAL

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AN ISO 9001 : 2008 & ISO 13485 : 2015 AC 2012 CERTIFIED COMPANY

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Thanks for purchasing our company's products. Please read this operation manual before using. In order to consult it next time, please take care of it. Fill the guarantee card and sent it to the agent or the after service department of the headquarters company to confirm your right of free maintenance. If you neither fill the guarantee card nor send it to our company, we will consider that you give up your right automatically, but you will accept the servicing for whole using life all the same.

**Note:** 1.If there is any technical improvement, without further notice.

2.Do not privately disassemble. If necessary, operation and maintenance must be done by a company authorized and qualified technical personnel.

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# I. Introduction:

## 1. Doppler Fetal Heart Rate (FHR)

Detectors apply the ultrasonic Doppler principle to detect the fetal heart beat. The units are compact, lightweight, easy to operate with stable performance and high dependability.

## 2. FETAL DOPPLER has dormancy, LCD display / alarm / self-detect function

- If there is no signal more than 1 minute, it will switch to dormancy mode to save power.
- The blue backlight LCD display makes it possible that the FHR can be seen clearly irrespective of the light is bright or dark, without affecting the detection of heart beat.
- All information can be displayed on the LCD, including the charging mode/residual power indication/volume indication/alarm of abnormal FHR indication.
- Self-detect mode ensures the unit to work normally.

## \* 3. FETAL DOPPLER can hear the FHR, no display function.

**Notes:** The content of the tag "\*" "don't need a reference."

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4. This Doppler has **Ni-MH** rechargeable battery inside, which can be used repeatedly after recharging. The gallus can make it convenient to carry.
5. Normative collocation: unit, charger, gallus and operation manual.
6. Optional accessories: earphone and gel.

## II . Specification:

- Standard: EN61266:1995
- Safety Classification: BF  / Class II  / Internal power.
- Overall sensitivity:  $\geq 90$  dB (Integrated sensitivity 200mm away from the surface of the probe).
- While measuring integrated sensitivity, the Doppler frequency is  $(300 \pm 50)$  Hz, target speed is 10cm / s ~ 40cm / s .
- Target velocity and display range :  
No narrower than 65bpm-240bpm ( $\pm 2$ bpm). (Beat Per Minute).
- Alarm range: <120bpm or >160bpm

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- (Please Visit a doctor once the FHR is abnormal)

Output power :  $\leq 10\text{Mw/cm}^2$

- EMC testing data (See annex II )
- Working frequency :  $2.0\text{ MHz} \pm 10\%$
- Spatial-peak temp-peak acoustic pressure:  $\leq 0.1\text{ MPa}$ .  
Effective area of transducer:  $6.0 \pm 0.5\text{ cm}^2$
- Adapter input voltage:  $230\text{V AC}$
- Adapter input consumer(recharging) :  $\leq 5\text{VA}$
- Adapter output voltage (no load ) :  $\text{DC}12\text{V} \pm 1\text{V}$
- Battery :  $8.4\text{V Ni-MH}$  batteries
- Audio output power :  $\leq 1.8\text{ W}$
- Coupling medium impedance:  $1.5\text{-}1.6\text{ (}105\text{g/cm}^2\text{.s)}$
- Doppler frequency:  $0\text{-}3.0\text{ KHz}$
- Working time (after charged):
- FETAL DOPPLER  $\geq 2\text{hours}$ ;
- Working environment: temperature:  $+5\text{ }^\circ\text{C} \sim +40\text{ }^\circ\text{C}$   
Humidity:  $\leq 80\%$  Atmospheric pressure:  $86\text{kPa} \sim 106\text{kPa}$
- Transport and storage environment: temperature:  $-10\text{ }^\circ\text{C}$   
 $\sim +40\text{ }^\circ\text{C}$  Humidity:  $\leq 80\%$

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- Atmospheric pressure: 86kPa ~ 106kPa, well-ventilated room without corrosive gases.
- Acoustic output parameters meet the national exempted conditions released that the ultrasonic and main unit in all operated mode can meet the following requirements:
  - a) the peak negative acoustic pressure ( $p_-$ ) < 1Mpa;
  - b) the output beam of sound intensity ( $I_{ob}$ ) < 20mW/cm<sup>2</sup>;
  - c) spatial peak time average educed the sound intensity ( $I_{spta}$ ) < 100mW/cm<sup>2</sup>.

### III. The Product's Structure, Composition and Scope of Application

1. Product's structure and composition: mainly by the host, Doppler ultrasound transducer and rechargeable nickel-hydrogen batteries.
2. Product scope: fetal heart rate detection for the health department.

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## IV. Equipment components: (fig. 1)

1. The gap for fixing the gallus

2. Number and symbol on LCD display interface

Number:

The 5 beats average FHR value will display on this window.

- FETAL DOPPLER with FHR display

Interface

- \*FETAL DOPPLER without FHR display interface

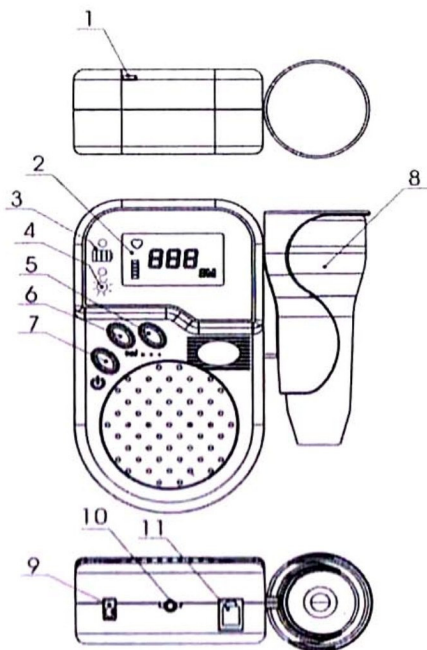


fig. 1. (Front view)

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## Symbol:



Power indicator or charge indicator



Alarm for abnormal FHR During the range of 60-99 bpm or 161-210 bpm, the alarm indicator will appear.



FHR beat display

**VOL**

Volume indicator

888

5 beats average of FHR display.

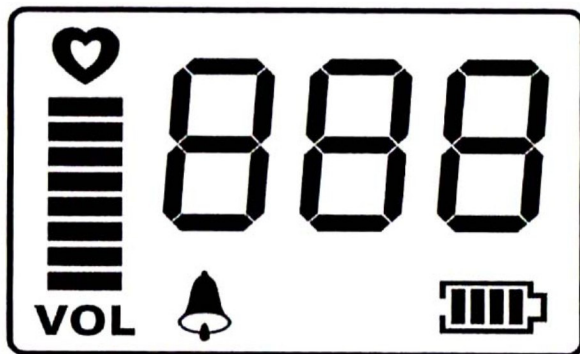


fig. 2 (LCD window)

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### **3. Charge indicator:**

Indicate the current intensity of the rechargeable battery. The indicator is red while charging, and becomes green when the battery is full charged.

### **4. Working indicator:**

The light is bright after turning on and become dark as it runs out of power.

### **5. Volume decrease button:**

Click Volume button, the volume will decrease a grade

Note: Long press 5 for more than two seconds, it will automatically switch to alarm switch

6. Increase the volume by switching click 6, the volume will increase a grade.

Note: Long press 6 for more than five seconds, it will automatically enter the "Test" interface. You shall press the turn off key to exit the interface.

### **7. Power switch:**

Click the button to turn on, press the button for more than 2 seconds to turn off

Note: During the boot-up state, press this key to open / close the backlight function.

### **8. Probe**

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## 9. Charger jack:

Connect the battery with the adapter.

## 10. Earphone jack:

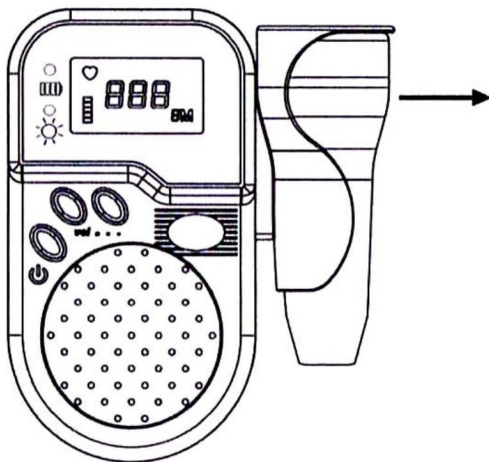
## 11. Probe jack:

Connect the main frame with the probe

## V. How to use this Doppler:

### 1. Take down / fix up the probe:

The correct way of taking out the probe from the jack is:



**fig.3(Rear view)**

Hold the unit with left hand, then take out the probe with the right hand from the probe jack (fig3). The installation of the probe is to held the unit with left hand, then put the probe with right hand in to the probe jack.

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## 2. Turn on/off

Turn on the switch, the working indicator should be bright and the Doppler will start to work; the Doppler will stop working when the indicator becomes dark.

## 3. Look for the best detecting position:

Use gel to make sure the surface of the probe is in complete contact with the skin has. Adjust the volume controller to your desired level.

**Notice:** Also you can use earphones to detect the FHR, you need to connect the earphone well first, and then search for the best position.

### Attention:

- **After use, please turn off the unit, wipe the coupling gel off the probe and fix the probe back to the probe jack.**
- **When the working indicator becomes dark or the sound is quiet, the Doppler needs to be recharged immediately.**
- **Do not drag the probe along the abdomen otherwise it will cause interference.**

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#### 4. Volume controller adjust method:

Each time pressing the volume increasing key, the volume will increase till it reaches the maximum. Each time pressing the decreasing key, the volume will reduce.

#### 5. Affirm the fetal heart:

**FETAL DOPPLER:** when FHR can be heard instantly, please do not read the FHR value immediately. The FHR data will be displayed automatically and will change as the baby's heart rate changes.

**\*FETAL DOPPLER:** After hearing the fetal heart sound you can get the FHR by counting FHR, first for 15 seconds and times by 4 (the time and the method of count depend on the doctor)

#### 6. Alarm switch setting

This is FETAL DOPPLER specific feature. Long press the volume increase button 2 seconds, it will

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automatically activate this feature.

When the fetal heart rate values are out of the range ( 120 ~ 160), the device will alarm. The icon  will appear when the alarm is activated, press the button to turn on / off the alarm function.

## 7. Warning tone

- This is specific feature.
- No signal input within 1 minute, there will be a "drop" warning tone.
- No signal input within 3 minutes, there will be a "bit" tone, then the system will turn off automatically.

## 8. Back light function

This is specific feature. Boot - up state machine key switch is defined as the on / off backlight button. Backlight can be maintained for 15 seconds (that is, within 15 seconds when no signal is input or signal weak backlight will automatically shut down).

## 9. The cleanliness and disinfection after using:

Turn off the unit after using and clean off the gel on the probe, put the probe back to the jack to protect it.

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**Notice: 75% alcohol can be used to clean and disinfect the surface of the probe.**

## **VI. How to maintain the unit**

### **1. Low battery power:**

**FETAL DOPPLER:** When battery power is low, the sensitivity will decline, the working indicator, “” will go dark and FHR on the LCD will glint or not be digitally displayed.

**\* FETAL DOPPLER:** Working indicator light will go dark and eventually fade out; the sensitivity will decline, the FHR will be not clearly heard.

### **2. Charging method:**

Connect the AC adapter to the main power supply and then by connect to the Doppler unit. The charging indicator LCD will light normally. It needs about 8-12 hours charge again.

**Note:** The first charge time should be 8 to 12 hours in order to extend battery life. The continuous charge time shall be no longer than 12 hours for normally use.

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### 3. Preservation method:

Prevent Doppler from being destroyed by any liquid please do not immerse the unit and probe in any liquid or water.

**Notice: If the Doppler outer shell is dirty after using, please use the neuter cleanser to clean it, strictly prohibited to use any other organic materials to clean the unit including industry alcohol.**

### VII. Attention

- Caution : Before using, take the probe off and then turn on the Doppler. After using, first turn off the Doppler and then put probe back. Otherwise, there will be noise because of the reflection of ultrasound.
- Do not use telephone or cordless telephone within 10 meters while the unit is working, otherwise it cannot work normally.
- Charging time should be between 8-12 hours, except first charging between 12-16 hours. (more than 12 hours),
- Turn off the unit after using to prolong the lifetime of the rechargeable battery.

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- Use only the specified AC adapters and batteries (supplied) for the unit. Others it may cause the risk of fire, electric shock or injury.
- Please use probe carefully as the probe is damaged by customers which is not covered under the free warranty.
- If the device hasn't been used for three months, please charge it, otherwise, battery will be damaged
- Note: Under the guidance of doctor, detect fetal heart rate for pregnant women after 12 weeks' pregnancy.

## VIII. Shelf-life and Warranty

### 1. Shelf-life

Precise electronic components are the main parts of the Doppler; the host machine shelf-life is 3 years, except probe, battery and earphone (option).

### 2. Warranty:

The unit is backed by one-year limited warranty. During the warranty period, which starts from

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the date of purchase, the defective parts will be repaired free of charge. (excluding the probe and optional earphone), Please note that you will be charged for the cost of shipping the unit from service office to your residence.

### **3. Yearly safety check:**

- The following safety check should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.
- Inspect the safety relevant labels for legibility.
- Verify the device functions properly as described in the instructions for use.
- Inspect the unit and accessories for mechanical and functional damage, the data should be recorded in the operating manual. If the device can not work normally, it has to be repaired.

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## **IX. Trouble Shooting**

**1. Malfunction :** While the unit is working normally, working indicator fails to light up/ no sound.

### **Possible cause:**

- a. The rechargeable battery is going to be power off.
- b. Battery is damaged;
- c. The unit is damaged.

### **Solution:**

- a. Recharge the unit;
- b. Contact the agent to change battery;
- c. Contact the agent to repair.

**2. Malfunction:** Connect the adapter and turn on the power switch, working indicator is not bright as well as charging indicator.

### **Possible cause :**

- a. No AC power available;
- b. Adapter and unit are not properly connected;
- c. The adapter is damaged.

### **Solution:**

- a. Check AC power socket by qualified electrician;

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- b. Make sure the connection between adapter and the unit is correct
- c. Contact the agent.

**3. Malfunction: Working indicator is bright while the unit is working normally; but charging indicator is not bright, cannot be charged and several days later, the unit cannot work anymore.**

**Possible cause:**

- a. No power available or adapter is damaged;
- b. Adapter cannot work normally or bad connection;
- c. Circuit of the adapter is damaged or charging indicator is not available;

**Solution:**

- a. Repair the power socket by qualified electrician;
- b. Contact the agent to repair it;
- c. Contact the agent to buy adapter or battery.

**4. Malfunction: Turn on the power switch, working indicator becomes bright; but there's no sound while touching the surface of probe.**

**Possible cause:**

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- a. Volume controller is adjusted too low to hear sound;
- b. The rechargeable battery is nearly power off, faulty circuit;
- c. Probe is damaged;

**Solution:**

- a. Release the volume controller;
- b. Charge the unit for 8 to 12 hours;
- c. Return the unit to the supplier for repair

**5. Malfunction: Uncomfortable noise is heard while using it to detect FHR.**

**Possible cause:**

- a. The rechargeable battery is near depletion of power.
- b. Not enough coupling gel between the probe and abdomen
- c. Noise occurs while dragging the probe on the abdomen
- d. Probe is damaged.

**Solution:**

- a. Recharge the unit;
- b. Ensure sufficient gel is used between the probe and abdomen
- c. Use gentle pressure on the abdomen to ensure well connection of the probe;

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d. Contact the agent to buy new probe.

## **6. Malfunction: Sensitivity is not sufficient.**

### **Possible cause:**

- a. The rechargeable battery is going to be power off.
- b. No sufficient coupling gel;
- c. Too much pressure is being applied to the pregnant woman's abdomen and muscles are not relaxed causing loud noise and interference
- d. The probe is not located in the optimum position;
- e. Sensitivity of probe declined.

### **Solution:**

- a. Recharge the unit;
- b. Ensure sufficient gel is used between the probe and abdomen;
- c. Gentle press on the patient to ensure well connection of the probe and make patient relax;
- d. Find the best position;
- e. Contact the agent to replace the probe.

## **7. Malfunction: Digital is not stable while 500D+ is working.**

### **Possible cause:**

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- a. While dragging the probe on the abdomen, there will be interference;
- b. Fault operation to connect the probe to the unit ;
- c. There is an interference source in the local vicinity within 10 m (e.g. high frequency electronic equipment, cell/mobile phone or cordless phones are working);
- d. The Doppler is damaged.

### **Solution:**

- a. Determine optimum position and after about 5-10 seconds, it will get the accurate FHR; turn off the unit and turn on again;
- b. Ensure proper connection.
- c. The unit must be relocated away from the interference source;
- d. Contact the agent to repair.

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## Labels in the manual



TYPE BF APPLIED PART



CLASS II equipment



Be careful



Environment:  $+5^{\circ}\text{C}$  —  $+40^{\circ}\text{C}$



Waterproof



Up not more than 4 floors

**IPX4**

Splash proof

In order to protect your right for repairing service, please take a few minutes to fill out the warranty card as below:

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### 7.3 WARRANTY CERTIFICATE

western surgical product is warranted to be free from electrical and mechanical defects in material and workmanship, under normal use. The western surgical product must not have been moved from the site of original installation. A new or remanufactured part to replace the defective part will be provided without charge for the part itself, through an authorized western surgical service dealer. The replacement part assumes the unused portion of the warranty.

#### WESTERN SURGICAL WILL NOT BE RESPONSIBLE FOR:

1. Damage or repairs required as a consequence of faulty installation or application by others.
2. Damage or repairs needed as a consequence of any misapplication, negligent handling, improper servicing, unauthorized alteration, or improper operations.
3. Failure to start due to voltage conditions, blown fuses, open circuit breakers or other damages due to the inadequacy or interruption of electrical service.
4. Damage as a result of floods, winds, fires, lightning, accidents, corrosive atmosphere, or other conditions beyond the control of western surgical
5. Parts not supplied or designated by western surgical.

Date of Installation	Installed By
Model No.	Serial No.
Warranty Period	
Name of Doctor & Address :	

Customer Sign. With Stamps

Marketed By: Western Surgical  
Sign. With Stamps

#### No Claim Warranty :

1) Any Defect Throughtout Power Supply

2) Any Physical Damage

3) Under Warranty Standby Unit Not Provide

4) Under Warranty When Company Send Parts or Machine we Imidiat send to Buyer.

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