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客户名称:源动创新	客户型号:
产品型号: P600L	材　质: 128g铜版纸
成型尺寸:W90xH180mm	展开尺寸:
颜　色: 单 色	工　艺: 无

备注：装订方式为骑马钉、字体为思源系列

Babytone™

Baby Heartbeat Monitor

User’ s Manual

Model:P600L

Download App: ViHealth
iOS: App Store
Android: Google Play

www.mybabytone.com

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Section 1
Warnings and Symbols

1.1 Warnings

- Before using the device, carefully examine the Fetal Doppler (hereinafter called device) and the accessories to ensure the main unit and accessories do not have any visible damage evidence that may affect patient safety and device performance.
The recommended examination period is once per week.
- The device is not feasible to use in the environment with electrical surgical equipment.
- The device is used for fetal heart rate test, and not intended for any treatment. If the test FHR result is useless, please try to test by other clinical test methods.
- Installment, adjustment, maintenance and reparation can be carried out only by qualified or authorized personnel from manufacturer.
- The device uses very low power ultrasound doppler. It is confirmed by design calculation, laboratory test, clinical test and clinical application the device doppler energy is safe for fetus, pregnant women and other personnel. Even so, it is not appropriate to use the device continuously or with long term .
- Before using the device, please read this manual carefully and assure to be familiar with the controls, displays, features and operating techniques.Manufacture and dealer will not be responsible for any abnormal fault or safety accident caused by incorrect operation.
- This device is not explosion-proof and can not be used in the presence of flammable anaesthetics equipment.
- Do not throw battery into fire as this may explode and cause danger.

- Do not touch signal input/output connector and the patient simultaneously to avoid device damage.
- The device is a tool to aid the FHR inspection and should not be used in place of normal fetal monitoring.
- The device is designed for continuous operation and is ordinary.
- Do not immerse in any liquid (i.e. not drip or splash-proof).
- Keep the device clean. Avoid vibration.
- Do not use high temperature sterilizing process and E-beam or gamma radiation sterilization.
- The device is not subject to any sources of strong electromagnetic interference, such as radio transmitters and mobile telephones because of electromagnetic interference.
- The user must check that the equipment does not have visible damage that may affect patient safety or monitoring capability before use. The recommended inspection interval is once per month or less. If damage is evident, replacement is recommended before use.
- The device can not be used when some equipment are used, such as high frequency electrical generator, microwave oven.
- Do not use the device in the presence of flammable anesthetic mixture with oxygen or other flammable agents.
- The device is feasible for relatives such as operator, responsible organization and environmental restriction, which do not need special skills, training and knowledge.
- This operation manual is written at a level without special education, training and other needs of individual for whom they are intended. For using in hospital and clinic, the operator needs to have relative qualification certificate such as nurse certificate. For using at home, when the test data are used to diagnose, it should be analyzed by specialized medical working person.
- This minimum qualifications of service personnel is to be familiar with our device operation and service technique.

- The suitable environment is not for that for near active HF SURGICAL EQUIPMENT and the RF shielded room.
- 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.

1.2 Cautions

- The battery must be properly disposed according to local regulation after use.
- Please use the adapter according relevant national standard, do not use the device when charging.
- The information in this manual is subject to modify without notice.
- The device usage life is 3 years, after which please treat according to relative local regulations.
- Do not use strong solvent (for example, acetone) and abrasion material to clean the device.
- Do not allow any liquid to enter the device, and do not immerse any parts of the device into any liquids.
- Please choose the accessories and expendable authorized by manufacturer.
- Never try to sterilize the probe or equipment by low temperature steam or other methods.
- Pay attention to ultrasonic output safety, practice ALARA principle (As Low as Reasonably Achievable), apply as low as possible emission power to achieve satisfying exam result .Extra unnecessary ultrasonic output may increase risk of biological effects. You must always take responsibility for the safety of your patient.

1.3 Symbols

Symbol	Explanation
📖	Refer to the operation manual
⚠	Attention, refer to the accompanying documents
☒	Waste electrical and electronic equipment alone processing signs (please comply with local laws and regulations)
⏻	ON/OFF
♡	Fetal heart signal symbol
P/N	Part number
S/N	Serial number
IP22	Liquid protection degree
🏭	Date of manufacture
🏭	Manufacturer
♲	Recyclable
●	Environmental Protection
IPX1	WaterProof degree
((•))	Non-ionizing radiation

Section 2
Introduction

2.1 Overview

The device is high performance fetal heart rate detector which satisfies the requirement of hospital, clinic, community and home FHR examination.

The deviceIt is an all-in-one machine composed of probe and main unit.

2.2 Product Features

- Color display
- Build-in speaker
- Curve display
- Auto power off
- Volume Adjustment
- Bluetooth

2.3 Intended Use

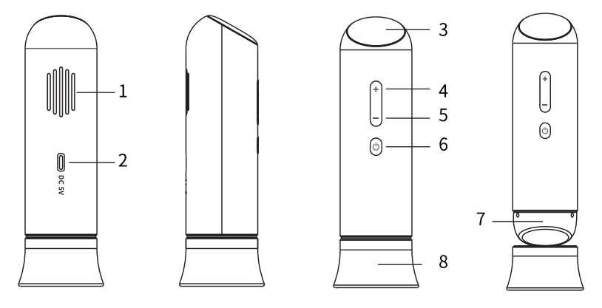
- The device is used to detect the fetal heart rate.
- It’ s not a medical device and should not be used for any medical purpose or any medical condition
- This product is intended only for general wellness use.

2.4 Standard Configuration

No.	Name	Quantity
1	Main unit	1pc
2	10ml Ultrasound Gel	1pc
3	Type-C charging cable	1pc
4	User’ s Manual	1pc

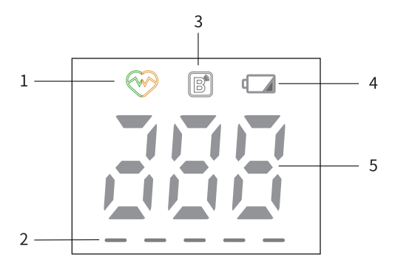
Section 3
Appearance

3.1 Main Unit



No.	Part Name	No.	Part Name
1	Speaker	5	Volume -
2	USB charging inlet	6	Power button
3	LED Display Screen	7	Ultrasound Probe
4	Volume +	8	Probe protection cover

3.2 LED Display



The explanation of display content

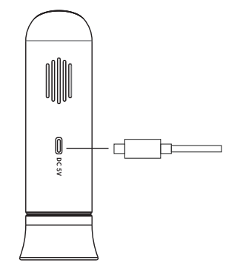
NO.	Mark	Explanation
1	♡	Fetal heart signal.It twinkles with fetal heart beat
2	- - - - -	Fetal heart signal quality indicator: include three levels: general/good/ better.
3	B	Bluetooth indicator:waiting for the bluetooth connection the symbol will flash,after the bluetooth connection is successful , the symbol will stop flick and always on.
4	▭	Battery Low power indicator:It flicks indicates needfor charge,after charge full, the battery symbol will disappear.
5	288	Fetal Heart Rate :display range is 60bpm-240bpm, when the value <100,hundred place will not display,when the value is out of range,display:“OL”
6	06	Volume level: The Volume level and heart rate value display use the same area, when there is a volume control operation, display volume level and then recover to display the current values of fetal heart rate .The volume level shows the range of 1 to 6.

Section 4
Basic Operation

4.1 Preparing to Use

- Carefully check if the device has any damage and if the accessories are integrated. If so, please contact distributor.
Keep the package for future transportation or storage.

4.2 Charge



1. First time use the device or after long time no use, shall charge for the device, please use charger with specification of DC 5V input .
2. Insert the Type-C inlet into the charging socket on main unit.(When the power is low, battery icon ▭ on the display screen will flick to prompt charging, ♡ icon flicking when the device is being charged);
3. After charging is completed, ♡ icon will light on, you can unplug the charging cable,and remove the charger from power socket.

4.3 Power on/off

Power on:Long press the power ⏻ key, the display screen will enter test interface “0” after boot screen.

Power off: Long press the ⏻ key for 3s under power on state.

4.4 Download and Use the App

Download App: ViHealth
iOS: App Store
Android: Google Play

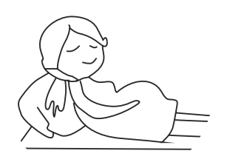
When using the Heart Monitor, run App to connect Monitor via Bluetooth. App will record your fetal heart rate and sound. You can also review/share your history data in App.

Section 5
Inspecting and Recording

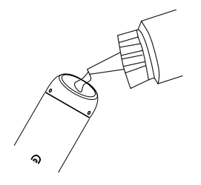
5.1 Inspecting FHR

We advise you to follow the below steps to start measure FHR.

① Pregnant woman stays happy, Lie flat or on your back;

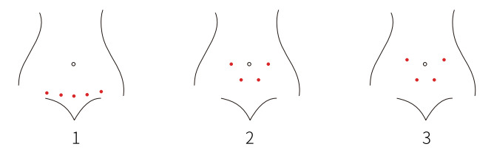


② Daub ultrasonic gel on the probe face plate to decrease noise and boost up test result;



③ Long press the power button of fetal heart monitor to power on.

④ Touch the abdomen of pregnant woman to confirm the general position of fetus.



Note:
1.Early pregnancy (Before 20 weeks)
2.Pregnant metaphase (20-32 weeks)
3.Late pregnancy (32-40 weeks)

⑤ Put the probe against pregnant women abdominal wall, move slowly within the scope of the fetus location, until hear clearly and rhythmic cardiac sound and see a stable heart rate value.

⑥ Adjusting Volume :When device is working, you can adjust volume by pressing Up or Down key to adjust volume.

⚠ CAUTIONS

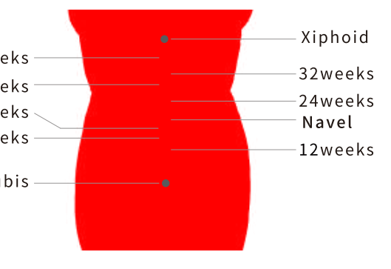
- Do not compress probe too tightly on abdomen surface to avoid to weaken signal.
- When searching for the fetal heartbeat, do not pull the probe on the abdominal surface to avoid the noise.
- Do not put the probe on the position where there is strong Placental Blood Sound or strong Umbilical Sound.
- Do not mistake mother’ s heart rate as FHR.
- Do not wear gloves to operate buttons of this device,if there are water and ultrasonic gel on your fingers ,please wash your hand first,otherwise it maybe affect inspection effect.

NOTE: Do not measure FHR unless audible and identifiable fetal sound has been heard, usually it needs 5 seconds.

NOTE: The normal value of the fetal heart rate is 120-160bpm. 100-120bpm and 160-180bpm are the critical values which should be paid some attention to. And lower than 100bpm and more than 180bpm are danger values which should be paid more attention to.

Attachment: different gestation period fetal position reference

Due to the fetus in the womb mobile at any time, the position of the heart is not fixed, you can refer to the following different gestation period at the end of uterine height to determine the scope of the fetus is roughly:



⚠ CAUTIONS

- The probe should be placed in the best position to achieve high quality detection signal.
- Unless clear cardiac sound signals are detected, otherwise can't get the right heart rate; When calculating the heart rate and cardiac sound of the beat is inconsistent, the auscultation cardiac sound results shall prevail.
- When extend the detection time, pay attention to prevent pregnant women of low blood pressure. At this time can be pregnant women pillow high head, high or leg pad.
- On access to the pregnant woman body, when using ultrasonic transducer may be a slight warming(not more than 20℃) than the surrounding temperature.
- On but not come into contact with pregnant women, the ultrasonic sensor may be a slight warming (not more than 5 ° C) than the environmental temperature.

5.2 End FHR inspect and shutdown

After ending FHR inspection, long Press the power button to power off. If no any operation within 1 minute, this monitor will auto power off.Please use clean soft cloth or tissue to wipe the remaining gel on the abdomen and surface of the probe.

Section 6
Cleaning and Disinfecting

6.1 Cleaning

Before cleaning the device, switch off this device ;

Use a soft cloth to wipe up the ultrasonic gel on the probe Keep the outside surface of the device clean and free of dust and dirty, clean exterior surface with a dry, soft cloth(include LCD display screen).

If necessary, clean the chassis with a soft cloth soaked in a solution of soap, or alcohol and wipe dry with a clean cloth immediately.

6.2 Disinfecting

- Each time before and after use,wipe the equipment enclosure surface(including LCD display screen) with an alcohol impregnated soft cloth (75% ethanol or 70% isopropanol),then use clean soft cloth to wipe dry at once.
- Wipe the probe with a clean, dry cloth to remove any remaining ultrasound gel.and wipe with an alcohol impregnated soft cloth (75% ethanol or 70% isopropanol),then use clean soft cloth to wipe dry at once or air drying.

⚠ Warning

- Do not use acetone and other strong solvent to clean.
- It is prohibited to use abrasive materials (such as steel wool or silver polish).
- The waterproof degree of this device is IPX1, only provide drop-proof ,do not soak the main unit and probe in water.
- Do not remain any cleaning fluid on the surface of the instrument.

Section 7
Maintenance and Troubleshooting

7.1 Maintenance

- Before each use, must check whether equipment may affect their safety or instrument performance obvious damage. If any damage was found, please make the necessary repairs or replacement.
- This device is precision instruments, must be handled with great care. Instruments must be wiped after use of the excess of ultrasound gel on the ultrasonic probe. The maintenance measures will extend the service life of equipment.
- Production date see label, expected life span is 3 years (life only main unit, excluding replaceable parts, and accessories).
- Manufacture will provide circuit diagram and other information in the user request , to help users to maintain the instrument parts which classified as electricity user maintenance of instrument parts by Manufacture, maintenance should be conducted by qualified technical personnel.

7.2 Troubleshooting

When using, if it appears following problems, please treat by following instruction. If fail to treat, please contact customer service personnel.

Fault phenomenons	Possible Reasons	Solutions
Unable to boot or power off immediately after boot	The battery power is serious insufficient	Charge the device
	Power on/off not according to operation regulated in instruction for use	Long Press power button to Power on/off
After startup, LED display, but there is no sound for speaker	Volume was set to lowest level	Adjust volume level
FHR value jumps disorderly when detecting	Strong electromagnetic interference source nearby	Avoid use device within strong electromagnetic interference source nearby
	Fetal movement Lead to fetal heart location change	Readjust the Probe location to find the best position
	Error display due to Probe friction with belly	Find the best fetal heart location until heard stable fetal heart sound
Low Sensitivity and too much noise when use the device	Strong electromagnetic interference source nearby	Avoid use device within strong electromagnetic interference source nearby
	No application of ultrasonic gel	Daub ultrasonic gel
	Probe position is incorrect	Readjust the Probe location to find the best position

Section 8
Warranty and After-sale Service

8.1 Warranty

Dear Customer,

Thank you for choosing our product. Our company guarantees the new instrument on the material and technological qualification for this product within 1 year (12 months) since the purchasing day, while consumables are not included in the guarantee.

Within the warranty period, Any equipment parts which break down caused by materials or product technology,we will repair or replace for free.

This warranty is inapplicable to the products undergoing any modifications, disassembles, refittings or self-repairings without the permission of our company. We're not responsible of the products damaged by accidents such as fire, thunder and lightning, flood and other disasters, intentional damage,improper installation, and improper usage.

8.2 After-sale Service

If you have any questions of use, maintenance, technical specifications or malfunction of device, please contact us.

Website: www.mybabytone.com
E-mail:support@getwellue.com

Section 9
Product Specifications

9.1 Product Name: Baby Heartbeat Monitor

9.2 Model: P600L

9.3 Physical Characteristic

- Size: 144mm ×46mm ×46 mm
- Weight: approximately104g (including battery)
- Display

approximately 1.3inch LED ;

Display contents:

- ▶ FHR;
- ▶ Battery lower power indication;
- ▶ Fetal heart signal quality;
- ▶ Volume level ;
- ▶ Bluetooth signal

9.4 Environment

9.4.1. Work environment : Temperature: 5℃~40℃
Humidity: 10-80%
Atmospheric Pressure:80~105KPa
9.4.2.Transport and Storage: Temperature: -20℃～55℃
Humidity: ⩽93%
Atmospheric Pressure:80~105KPa

9.5 Power specification

Li-lion battery :3.7Vdc 750mAh
Endurance time:⩾1h
Power Adapter (for charge):
power input:AC100-240V 50/60Hz
Output:d.c.5V ⎓ 1A

Section 10
FCC Warnning:

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-Reorient or relocate the receiving antenna.
-Increase the separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Manufacturer

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www.mybabytone.com