Fetal Doppler

User Manual

Revision History

This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change.

Contents of this manual are subject to change without prior notice.

- Revision number: 2.0
- Software revision: Refer to the boot interface of the equipment
- Release time: October. 2022

Contact Information

Hunan Accurate Bio-Medical Technology Co., Ltd.

6th Floor,Biyang Industrial Zone,Lijiacun Road,Xueshi Street of Yuelu District,410208 Changsha,Hunan Province,PEOPLE' S REPUBLIC OF CHINA

TEL/FAX: +86 731-84118539

EC REP Shanghai International Holding Corp.GmbH(Europe)

Add:Eiffestrasse 80,20537 Hamburg,Germany

Tel: +49-40-2513175 Fax:+49-40-255726

Responsibility of the Manufacturer

The manufacturer only considers itself responsible for any effects on safety, reliability and performance of the equipment:Assembly operations, repairs are carried out by persons authorized by the manufacturer, and the device is used in accordance with the instructions for use.

⚠WARNING:

This device is not intended for treatment. The intended use is for detecting Fetal Heart Rate. If the FHR result is distrustful, please use other methods such as stethoscope to verify immediately.

Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

⚠WARNING：

A WARNING label advises against certain actions or situations that could result in personal injury or death.

⚠CAUTION：

A CAUTION label advises against actions or situations that could damage equipment,produce inaccurate data, or invalidate a procedure.

NOTE：

A NOTE provides useful information regarding a function or a procedure.

Contents

1 Safety Guidance

This unit is internally powered equipment; the degree of shock protection is type BF applied part.Type BF applied part protection means that these patient connections will comply with permitted leakage currents, dielectric strengths of IEC 60601-1.

1.1 Safety Precautions

⚠**WARNING and** ⚠**CAUTION messages must be observed. To avoid the possibility of injury, observe the following precautions during the operation of the device.**

⚠**WARNING：** Notification of any serious events related to the device should be reported by the user and/or patient to the manufacturers and competent authorities in member countries

⚠**WARNING:** This device is not explosion-proof and cannot be used in the presence of flammable anaesthetics.

⚠**WARNING:** Do not throw batteries in fire as this may cause them to explode.

⚠**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 equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ **CAUTION:** Do not attempt to recharge normal dry-cell batteries, they may leak, and may cause a fire or even explode.

⚠ **CAUTION:** Don't touch signal input or output connector and the patient simultaneously.

⚠ **CAUTION:** Pocket Fetal Doppler is a tool to aid the healthcare professional and should not be used in place of normal fetal monitoring. This is not intended for fetal use.

⚠ **CAUTION:** Please use the probe provided by the manufacturer.

⚠ **CAUTION:** Do not pull the line of probe longer than 1 meters, or else the probe may break away from the connector.

⚠ **CAUTION:**The device must be serviced only by authorized and qualified personnel.

⚠**CAUTION:**When the home users use this device, they should read the manual carefully, and consult a doctor, dealer or manufacturer if necessary

⚠**CAUTION:**The device is designed for continuous operation and is 'ordinary'. Do not immerse in any liquid (i.e. not drip or splash- proof).

⚠**CAUTION:** Keep the device clean. Avoid vibration.

⚠ **CAUTION:** Do not use high temperature sterilizing process and E-beam or gamma radiation sterilization.

⚠**CAUTION:** Electromagnetic Interference-Ensure that the environment in which the device is operated is not subject to any sources of strong electromagnetic interference, such as radio transmitters,mobile telephones, etc. Keep them far away.

⚠**CAUTION:** The user must check that the equipment does not have visible evidence of 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.

⚠**CAUTION:**

Please use a gel that meets the YY/T 0299 standard, or meets the corresponding IEC or ISO standard, otherwise it may affect the performance of the device and may damage the probe of device.

⚠ **CAUTION:**The battery must be properly disposed according to local regulation after their use.

⚠ **CAUTION:** The battery must be taken out from the battery compartment if the device will not be used for a long time.

⚠ **CAUTION:**The battery must be taken out from the battery compartment if the device will not be used for a long time.

⚠ **CAUTION:**The device shall only be used if the battery cover is closed.

⚠**CAUTION:**Battery must be stored in cool and dry place.

⚠**CAUTION:**If use rechargeable battery, to insure capability and life, please fully charge batteries before first use, normally, batteries must be continuously charged over 14 hours or charged according to the guidance displayed on the battery.

⚠ **CAUTION:**Please don't set anode and cathode of the battery wrongly.

⚠**CAUTION:**The valid period of this product is five years.

⚠**CAUTION:**After the service life, please return the products to the manufacturer or disposal the products according to local regulations.

⚠ **CAUTION:**This device cannot be used with defibrillator or high frequency surgical unit.

⚠ **CAUTION:**Please choose the accessories authorized by our company otherwise the device may be damaged.

⚠ **CAUTION:**Please keep the probe from edge tool.

⚠ **CAUTION:**Please use machine under the environment without strong electromagnetic field,which may influence measure result.

Remove the battery if the equipment is not likely to be used for some time.

⚠The device requires no calibration.

⚠The device contains no user serviceable parts.

⚠The user must check that the equipment functions safely and see that it is in proper working condition before being used.

⚠No modification of this equipment is allowed.

⚠**DISPOSAL:**Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact your local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.

⚠Battery Disposal:Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

⚠Recycling the batteries:When the battery no longer holds a charge, it should be replaced. The batteries are recyclable. Remove the old battery from the battery cover and follow your local recycling guidelines.

⚠Manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE

PERSONNEL in parts repair.

⚠Magnetic and electrical fields are capable of interfering with the proper performance of the Fetal Doppler. For this reason, make sure that all external devices operated in the vicinity of the Fetal doppler comply with the relevant EMC requirements. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

⚠Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for dataprocessing 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 connecting additional equipment to medical electrical equipment configures a medical system complies with the requirements for medical electrical systems. 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.

1.2 Symbols

Mark	Summary	Mark	Summary
	Caution, consult accompanying		Down button
	Type BF Applied part		Serial Number
	Probe Connector		Refer to user manual documentsDocuments
	ON/OFF		Date of Manufacturer
	Up button		Manufacturer

IPX2	Protected against access to hazardous parts with a finger and against vertically falling water drops when enclosure tilted up to 15° drops when enclosure tilted up to 15° finger and against vertically falling water drops when enclosure tilted up to 15°	IPX1	Protected against access to hazardous parts with a finger and against vertically falling water drops
CE 0123	The symbol indicates that the device complies with the European Council		
EC REP	Authorized Representative in the European Community		
	The symbol indicates that the device should be sent to the special agencies according to local Environmental Regulations.		

2 Introduction

2.1 Intended use

Fetal Doppler is a hand-held obstetrical unit, which can be mainly used to detect the fetal heartbeat rate (FHR) and the sound of the fetal heart beat (SFH).

2.2 Features

There are ten different models available: AD50A, AD51A, AD50C, AD51C，AD50B, AD51B ，AD50D, AD51D，AD50D11, AD51D11

The features of the Dopplers are listed in the following chart:

	LCD Display	TFT Display	Probe Socket	Headphone Socket	Powered by Alkaline Batteries	Powered by Lithium Batteries（Have Micro USB）
AD50A	√	×	√	√	√	×
AD51A	×	√	√	√	√	×
AD50C	√	×	√	√	*	*
AD51C	×	√	√	√	*	*
AD50B	√	×	√	√	×	√
AD51B	×	√	√	√	×	√
AD50D	√	×	√	√	×	×
AD51D	×	√	√	√	×	×
AD50D11	√	×	√	√	×	√
AD51D11	×	√	√	√	×	√

√ = means it has this function × = means it doesn't have this function

* means optional

2.3 Main Unit

2.3.1 Appearance

NOTE:

The pictures and interfaces in this manual are for reference only.

This device is a non-invasive handhold Fetal Doppler with an internal speaker. This device has the following special features that will enhance your product use, refer Figure 1,2,3,4.

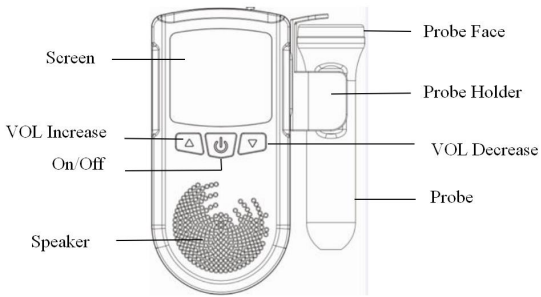


Figure 1 Front Panel of the Device

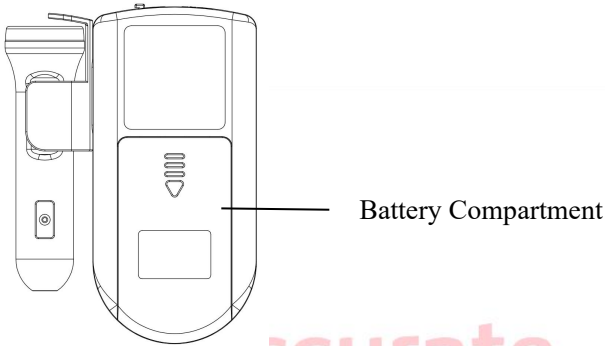


Figure 2 Rear Panel of the Device

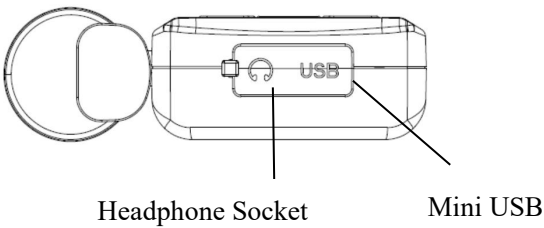


Figure 3 Top Panel of the Device

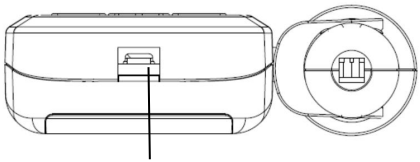


Figure 4 Bottom Panel of the Device

2.3.2 Display

Models AD50A,AD50C,AD50B,AD50D,AD50D11 are LCD screen whose panel for display units is showing in Figure 5.

Models AD51A,AD51C,AD51B,AD51D,AD51D11 are TFT screen whose panel for display units is showing in Figure 6,7.

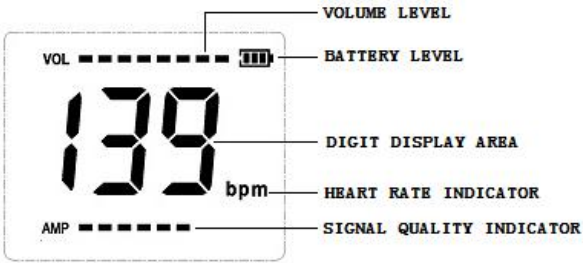


Figure 5 Digit Display Mode of LCD

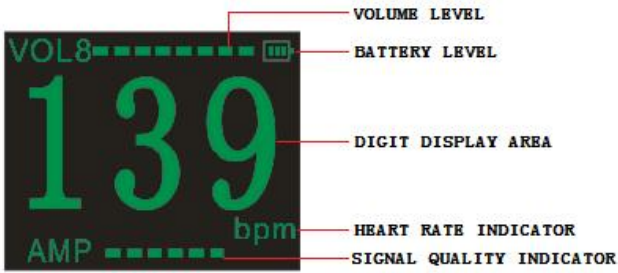


Figure 6 Digit Display Mode of TFT

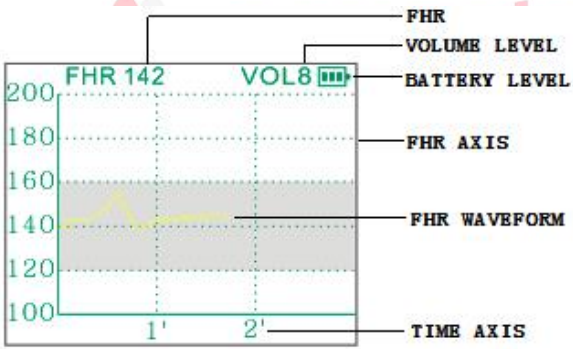


Figure 7 Waveform Display Mode of TFT

2.3.3 Buttons

Power Button ⏻

Function: Power on/off, change digit display mode of TFT into waveform display mode of TFT

Power on: Push the button once.

Change mode: Push the button once after power on.

Power off: Push down the button and hold 3 seconds to power off.

Volume Button ▲▼

Function: adjust volume

▲: Push the button to increase the volume

▼: Push the button to decrease the volume

Earphone socket 🎧

Function: for outputting audio signals, the earphone or line-in cable connects to the Doppler via this socket.

Probe Socket

Connect the 2.5MHz obstetrical probes or supplied by the manufacturer to the Doppler through the probe socket.

⚠CAUTION：

Do not try to connect any other plug to the probe socket except the plug of the probes mentioned above.

Probe cable cannot be pulled up to one metre long

Figure 8　2.5 MHz obstetrical probe

3 Basic Operation

3.1 switch on/off

Turn the device on by pressing the On/Off button for 1 second. LCD/TFT display will be switched on to indicate the power status .Push down On/Off button and hold 3 seconds to power off. the device automatically shuts itself off after 2 minutes if it is not being used. This complete power shutdown preserves the life of the batteries and ensures the device will be ready for operation in case it was accidentally left on.

3.2 Obtaining Doppler signals

NOTE：

In some cases, fetal heart beats at 12 weeks gestation can not be detected due to the maternal physical difference and the operator’ s technique. Perform fetal heart examining using the following procedures:

1) Confirm the fetus’ s position by hand.

2) Determine the probable probe location for optimal FHR examining.

3) Take out the probe and switch on the Doppler.

4) Apply a certain amount of coupling gel to the probe faceplate and place the probe against the abdomen at the predetermined location. Move the probe around or tilt it until clear and rhythmic heart sound is heard from the headphone or speaker. At the same time, a numeric FHR is displayed on the LCD/TFT.

CAUTION: Put the probe on the best detecting position to get better detecting effect.Positions with strong placental sounds or umbilical blood flow sound should be avoided.

If pregnant woman adopts horizontal position and the fetus position is normal, put the probe on the position of lower navel midline to get the clearest FHR sound.It is impossible to examine FHR unless a fetal heart sound is present. The fetal pulse can be distinguished from the maternal pulse by feeling the mother’ s pulse during the examination.

3.3 Volume controller

The audio level can be adjusted using the " ▲","▼"buttons. Push the " ▲ "button will increase the volume, while push the " ▼ " button will decrease it.

3.4 Display mode

For the TFT model, there are two display modes(Digit Display and Waveform Display) which can be changed if short press the On/Off button "⏻" (less than 1 second).

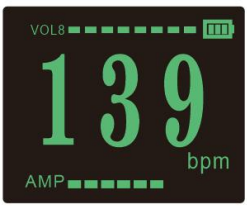


Figure 9 Digit Display

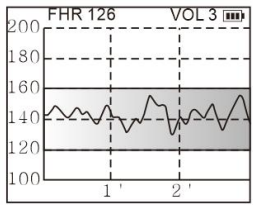
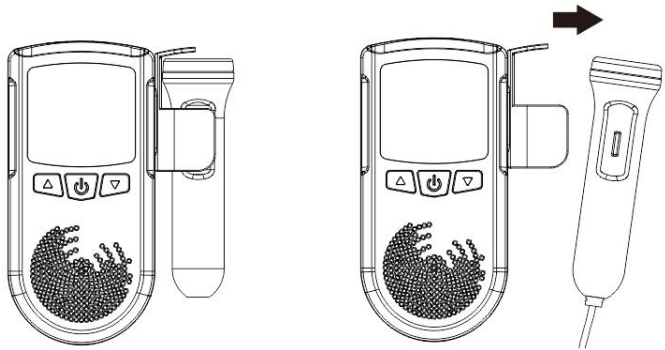


Figure 10 Waveform Display

3.5 Probe Operation

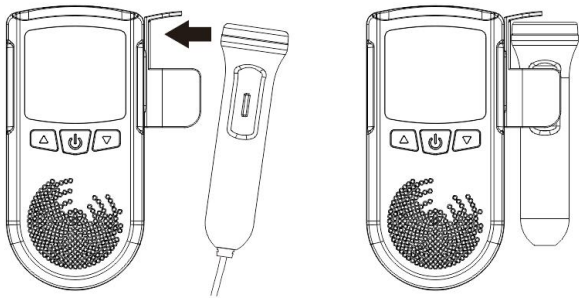
3.5.1 Taking out the probe

Hold the main unit with one hand. Pinch the probe and pull it outwards using mild force.



3.5.2 Placing the probe

Hold the main unit with one hand. Pinch the probe and align it with the probe holder. Push the probe inwards using mild force until it clicks in position.



⚠**CAUTION:** Do not take out or place the probe when the Doppler is on. Remember to take out the probe before switching on the Doppler,

and place the probe after switching off the Doppler.

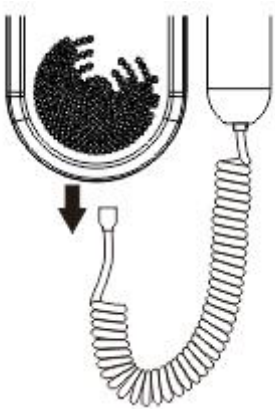
3.5.3 Replacing the Probe

Remove the old probe:

Switch off the Doppler,hold the main unit with one hand and pinch the jacket of the mini USB socket. Lift the jacket up slightly and pull it out with mild force; take out the probe.

Replace it with a new probe:

Put the USB socket of new probe into the probe interface of the Doppler.



⚠**NOTE:** Place the temporarily unused probe carefully and avoid falling off, splash or stress, etc. When the Doppler is not used for a long time, it is recommended connect the probe to the Doppler and keep them safely in the package.

3.6 Battery

3.6.1 Battery

AD50A, AD51A, AD50C, AD51C are powered by two alkaline batteries (LR6,AA,1.5V*2).

AD50B, AD51B,AD50D, AD51D,AD50D11, AD51D11 are powered either by one 14500 Lithium battery (DC 3.7V).

3.6.2 Battery Energy Indication

there is a battery symbol  in the top right corner of LCD/TFT.

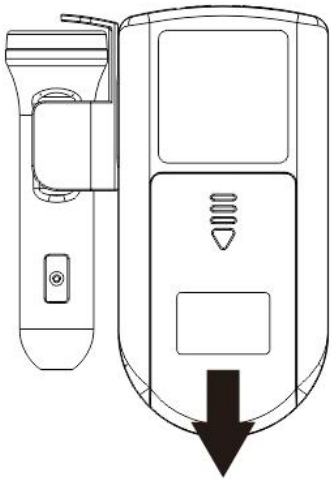
When the power is low, the empty battery symbol  flashes,to remind the customer to change another new battery or charge the battery (only the chargeable battery can be charged.).

3.6.3 Replacing the Batteries

CAUTION: Make sure the Doppler is shut down before opening the battery compartment.

The rear panel is upturned. First open the battery compartment, then take out the battery from the battery compartment.

Put two alkaline batteries/one lithium battery into the battery compartment (as for the direction of battery, please refer to the instruction inside the battery compartment), at last close the battery compartment.



CAUTION: The battery must be taken out from the battery compartment if the device will not be used for a long time.

3.8 Product specifications

Product Name: **Fetal Doppler**

ModelNo.:AD50A, AD51A, AD50C, AD51C，AD50B, AD51B ，AD50D, AD51D，AD50D11, AD51D11

Safety: Complies with: IEC60601-1

Classification:

Anti-electric Shock Type: Internally powered equipment

Anti-electric Shock Degree: Type B equipment 

Liquid Proof Degree:

Main unit: Degree of protection:IPX1

Probe: Prevent from water splashing, degree of protection: IPX2.The probe is treated as the applied part .

Degree of Safety in Presence of Flammable Gases: Equipment not suitable for use in presence of flammable gases

Working System: Continuous running equipment

EMC: Group I Class B

Physical Characteristic

Size: 140 mm (Length) ×95 mm (Width) ×30 mm (Height)

Weight: about 180g (including probe, excluding battery)

Environmental Specifications

Temperature range: 0 °C ~ 40 °C

Humidity range: 30% to 90%

Atmospheric pressure range: 60.0kPa ~ 110.0kPa

Transportation and Storage

Temperature range: -10 ° C ~ 60 ° C

Humidity range: 10% to 93%

Atmospheric pressure range: 50.0kPa ~ 110.0kPa

Display: 1.77" LCD display

FHR Measuring Range: 50 BPM ~ 240 BPM (BPM: beat per minute)

Resolution: 1 BPM

Accuracy: ± 2 BPM

Power Consumption :< 0.8 W

Auto Shut-OFF: After 2 minute no signal, power off automatically.

Battery Type Recommended: Two pieces of 1.5 V DC batteries (SIZE AA LR6) or one piece 14500 Lithium battery (DC 3.7V).

Standard Configuration:2.5 MHz Ultrasound Probe

Nominal Frequency: Continuous wave Doppler

Working Frequency: 2.5 MHz±5%

Audio bandwidth and power: 250Hz ~1.25kHz, 1.5W

Ultrasonic output power:< 40mW

Space peak time peak sound pressure:< 0.35MPa

Effective ultrasonic transmitting/receiving area： 2.45cm ±30％

Comprehensive sensitivity shall not be less than 90dB at a distance of 200mm from the probe surface

Table 1. Sound output level technical data of ultrasonic probe

Index Label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index		0.016	0.121		0.957		(a)
Index component value			0.105	0.121	0.957	0.235	
Acoustic Parameters	$p_{r.a}$ at Z_{MI} (MPa)	0.026					
	P (mW)		21.66		21.66		#
	P_{1-1} (mW)		8.84		8.84		
	Z_s (cm)			3.8			
	Z_b (cm)					3.8	
	Z_{MI} (cm)	2.7					
	$Z_{pii,a}$ (cm)	2.7					
	f_{awf} (MHz)	2.501	2.501		2.501		#
Other Information	prr (Hz)	1					
	srr (Hz)	--					
	n_{pps}	1					
	$I_{pa,a}$ at $Z_{pii,a}$ (W/cm^2)	0.01					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$ (mW/cm^2)	10.19					
	I_{spta} at Z_{pii} or Z_{sii} (mW/cm^2)	16.23					
	P_r at Z_{pii} (WPa)	0.032					

Operating Control Conditions	Frequency	2.5MHz

NOTE 1： Only one operating condition per index.
NOTE 2： Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.
NOTE 3： Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.
NOTE 4： If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.
NOTE 5： If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.
NOTE 6： The depths zpii and zpii,a apply to NON-SCANNING MODES, while the depths zsii and zsii,a apply to SCANNING MODES.
(a) Intended use does not include cephalic so TIC is not computed
No data reported

4 Maintenance

4.1 Maintenance

This device requires very little maintenance. However, it is important to continuing function of the unit and the health of the patients that the unit is cleaned and examined regularly per the following guideline:Annually inspect the main unit and probes for signs of cracks or breaks in the mechanical housing. Inspect cables and connectors for signs of wear or failure. The user should discontinue use of the unit with any sign of loss of housing integrity. Contact Manufacturer Technical Services

Department or your local representative for instructions.It is recommended that the internal rechargeable battery be replaced every two years. Contact Manufacturer Technical Services Department or your local representative for instructions of replacing the internal battery.

4.2 Cleaning

Before cleaning, switch off and take out the batteries.Keep the outside surface of the device clean and free of dust and dirt, clean exterior surface (display screen included) of the chassis with a dry, soft cloth.If necessary, clean the chassis with a soft cloth soaked in a solution of soap, or water and wipe dry with a clean cloth immediately.Wipe the probe with soft cloth to remove any remaining ultrasound coupling gel. Clean with soap and water only.

CAUTION

Don't use strong solvent, for example, acetone.Never use an abrasive such an steel wool or metal polish.Do not allow any liquid to enter the product, and do not immerse any parts of
the device into any liquids.Avoid pouring liquids on the device while cleaning.Don't remain any cleaning solution on the surface of the device.

NOTES

Wipe the surface of probe with 70% ethanol, self-air dry, or clean with a clean, dry cloth.

4.3 Trouble shooting

- Poor sound quality

- Inadequate gel use
- Try and relocate the probe for a better signal
- Signal from other equipment

Heart Rate inaccurate

- Try and relocate the probe for a better signal
- nsure maternal sounds are not mixing with fetal sounds

Battery indicator flashing

- The battery will run out soon, please replace it with new batteries, if the machine is a lithium battery, please charge battery in time

4.4 Warranty

The unit can not be repaired by users themselves. All services must be done by the engineers approved by manufacturer. We warrant that each product we sold to you is free from defects in labor and materials and shall conform to its product specifications as defined in the user documentation. If the product doesn't function as warranted during the warranty period, we will repair or replace it without charge.

After the instrument is out of the service life, it should be disposed in time. The disposal of the scrap should follow the relevant regulations of the country or region for the management of such products to prevent

environmental pollution. If there is any technical problem, please contact the manufacturer directly.

Appendix A

The ME EQUIPMENT OR ME SYSTEM is suitable for home healthcare environments

EMC Information-Guidance and Manufacture's Declaration

A. 1 Electromagnetic emissions - for all equipment and systems

Guidance and manufacture’s declaration – electromagnetic emission	
Emission test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuation /flicker emission IEC 61000-3-3	Not applicable

A.2 Electromagnetic immunity - for all equipment and systems

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	±2 kV power supply lines±1 kV signal input/output 100 kHz repetition frequency	Not applicable
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input linesIEC 61000-4-11	Not applicable	Not applicable
Power frequency magnetic fieldIEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V0,15 MHz – 80 MHz6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3 V0,15 MHz – 80 MHz6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz
Radiated RF IEC61000-4-3	10 V/m80 MHz – 2,7 GHz80 % AM at 2 Hz	10 V/m80 MHz – 2,7 GHz80 % AM at 2 Hz
NOTE UT is the a.c. mians voltage prior to application of the test level.		

A.3 Electromagnetic immunity - for all equipment and systems

that are not life-supporting

Guidance and Declaration——Electromagnetic Immunity			
The Device is suitable for use in the electromagnetic environment Specified below.The customer or the user of the device should assure that it is used in such an environment			
Immunity test	IEC60601 Test Level	Compliance level	Eletromagnetic environment——Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3Vrms 1	$d=[\frac{}{E_1}]\sqrt{P}$ $d=[\frac{3.5}{E_1}]\sqrt{P}$ $d=[\frac{7}{E_1}]\sqrt{P}$
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	3V/m	3V/m	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. 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 device is used exceeds the applicable RF compliance level above, the devices should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
B. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

A.4 Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the Fetal Doppler

The Fetal Doppler is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communicationsequipment (transmitters) and the Fetal Doppler as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output power of Transmitter W	Separation Distance(m) Corresponding to Frequency of Transmitter	
	80MHz~ 800MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz ~ 2.5GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23

For transmitter at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer.
Note 1: From 80 MHz to 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 structure, objects and people

A.5

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	IEC60601-1-2Test Level (V/m)	Compliance level (V/m)
	385	380－390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430－470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710	704－787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800－960	GSM 800/900, TETRA 800, iDEN 820, CDMA	Pulse modulation 18 Hz	28	28
	870					
	930					

			850, LTE Band 5			
	1720 1845 1970	1 700 – 1 990	GSM1800;CDMA 1900; GSM1900;DECT;LTEBand1,3,4,25;UMTS	Pulse modulation 217 Hz	28	28
	2450	2 400 – 2 570	Bluetooth,WLAN,802.11b/g/n,RFID2450,LTE Band 7	Pulse modulation 217 Hz	28	28
	5240 5500 5785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9

A.6

Guidance and manufacturer’s declaration - electromagnetic Immunity				
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	Test Frequency	Modulation	IEC60601-1-2 Test Level (A/m)	Compliance level (A/m)
	30 kHz	CW	8	8
	134,2 kHz	Pulse modulation 2.1 kHz	65	65
	13,56 kHz	Pulse modulation 50 kHz	7,5	7,5

A.7

RE Declaration of Conformity (DoC)

Unique identification of this DoC: .....

We,

Hunan Accurate Bio-Medical Technology Co., Ltd.
6th Floor, Biyang Industrial Zone, Lijiacun Road, Xueshi Street of Yuelu District, 410208 Changsha, Hunan Province, PEOPLE'S REPUBLIC OF CHINA

Declare under our sole responsibility that the product:

Product name: Fetal doppler
Trade name: N/A

Type or model: AD50A, AD50A1, AD51A, AD51A1, AD50B, AD50B1, AD51B, AD51B1, AD50C, AD50C1, AD51C, AD51C1, AD50D, AD50D1, AD51D, AD51D1, AD50D11, AD51D11

to which this declaration relates is in conformity with the essential requirements and other relevant requirements of the RE Directive (2014/53/EU).
The product is in conformity with the following standards and/or other normative documents:

HEALTH & SAFETY (Art. 3(1)(a)): EN 62311:2008

EMC (Art. 3(1)(b)): EN 301 489-1 V2.2.3:20 19, EN 301 489-17 V3.2.4:2020

SPECTRUM (Art. 3(2)): EN 300 328 V2.2.2:2019

OTHER (incl. Art. 3(3) and voluntary specs): .....
(title and/or number and date of issue of the standard(s) or other normative document(s))

Limitation of validity (if any): .....

Supplementary information:

Notified body involved: N/A.....
Technical file held by:
Hunan Accurate Bio-Medical Technology Co., Ltd.
6th Floor, Biyang Industrial Zone, Lijiacun Road, Xueshi Street of Yuelu District, 410208 Changsha, Hunan Province, PEOPLE'S REPUBLIC OF CHINA

Place and date of issue (of this DoC):
Signed by or for the manufacturer: ..... Tang Liqing 08/15/2022 .....
(Signature of authorised person)

Name (in print): LI JIANYING
Title: ..... Head of R&D .....

Accessories

Accessories		
NO	Item	Quantity
1	Main unit	1
2	2.5MHz probe	1
3	Manual	1
4	QC certificate	1
5	Charging cable(800mm)	1
6	Battery	AA LR6 or one 14500 Lithium battery

Charger stand- An CB approved according to IEC 60601-1 adaptor	
Input	100 to 240 VAC, 50/60Hz
Output	5V DC，1A
Length of Charging cable	800mm