CONTEC10A User Manual

Pocket Fetal Doppler

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Responsibility of the Manufacturer

The manufacturer is responsible for safety, reliability and performance of this device only in the condition that:

Assembly operations, repairs are carried out by persons authorized by the manufacturer, and the device is used in accordance with the instructions for use.

Warranty

The device cannot be repaired by users. All services must be done by the engineers approved by the manufacturer. Upon request, our company may provide circuit diagrams, components list, graphs and other information that necessary for maintenance. The warranty of this device covers all device failures caused by invalidation of material components or production processes. During warranty period, all failure parts can be repaired or replaced free of charge. Man-made damages are excluded.

In this document, the following terms are used:

WARNING: A WARNING provides information that you should know to avoid possible injury to patient and medical workers.

CAUTION: A CAUTION provides information that you should know to avoid possible damage to the device.

NOTE: A NOTE provides useful information for better understanding.

1 Safety Guidance

This unit is an internally powered equipment and the degree of shock protection is type CF applied part .

Type CF protection means that these patient connections will comply with permitted leakage currents, dielectric strengths of IEC 60601-1.

To avoid possible injury, please obey the following precautions during the operation of the device.

WARNING:

- Pocket Fetal Doppler is a handheld device for FHR detecting purpose, it cannot take the place of routine pregnancy check-up or fetal monitoring.
- The device cannot be used for treatment purpose. If you have any doubt about the FHR result, please use other methods such as stethoscope to verify.
- Do not use the device in the presence of flammable gases, such as anesthetics, otherwise it may cause explosion.
- Modification to the device is prohibited, and its maintenance must be performed by authorized and qualified engineers.
- Do not throw batteries in fire as this may cause explosion.
- Do not attempt to recharge normal alkaline batteries, otherwise it may cause leakage current, then leading to fire or even explosion.
- The ultrasonic probe adopts ceramic material, please handle it with care, and avoid falling, collision, weight causing damages.
- Please keep the device out of the reach of children and pets.
- This device contains probe wire, which may cause suffocation. Please keep away from children.
- Do not stretch the probe wire longer than 1 m, otherwise it may lead to spring deformation and unable to recover.
- The one who does not have self-expression ability can not operate the device.
- The patient is expected to be the operator.
- Equipment can not be repaired and maintained in the course of use.

CAUTION:

- The device must be serviced only by authorized and qualified personnel.
- Keep the device clean. Avoid vibration.
- High temperature disinfection, E-beam or gamma radiation sterilization to the device is forbidden.
- 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 the device during using away from high-frequency surgical equipment.
- The following safety checks should be performed once every two years or as specified in the institution's test and inspection protocol by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.
  Inspect the device for mechanical and functional damage.
  Inspect the safety relevant labels for legibility.
  Verify that the device functions properly as described in the instructions for use.
  Maintenance to the device if it works abnormally or above tests fail.
- The typical service life of the new and unused batteries is 300 measurements under the condition that each operation time is 60s.
- Batteries must be taken out from the battery compartment if the device will not be used for a long time.
- The device shall only be used with battery compartment cover closed.
- Battery must be stored in cool and dry places.
- Avoid short circuit or reversed installation of batteries.
- The service life of this product is five years. Expired devices should be returned to the manufacturer for recycle or disposed of according to local regulations.
- Used battery must be properly disposed of according to local regulations.
- The material of device enclosure is ABS, it meets the requirements of ISO 10993-5& ISO 10993-10.
- Please choose biocompatible coupling agent to avoid skin allergy.

2 Introduction

2.1 Overview

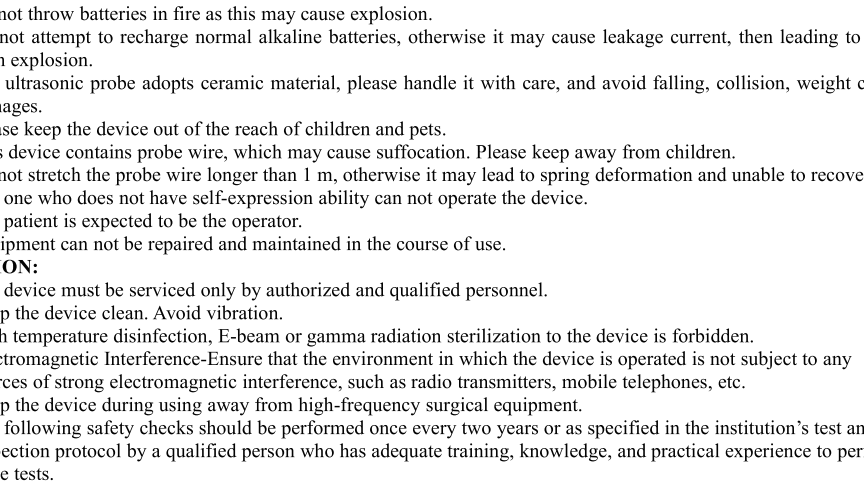
Pocket Fetal Doppler is a hand-held FHR detection device, it is easy to operate, and can be used in hospital, clinic for daily self-check by pregnant woman.

It contains components of ultrasonic signal transmitter and receiver, analog signals processing unit, FHR calculating unit, LCD display control unit, etc.

2.2 Standard configuration

1. Pocket Fetal Doppler 1
2. User manual 1

3 Appearance and Structure

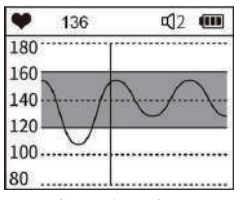


1. Display screen 2. Volume+ 3. Power button 4. Volume- 5. Speaker 6. Probe 7. Battery compartment cover 8. Headphone socket

3.1 Display

The device has the following interfaces:

Digits interface



Curve interface

No.	Symbols	Function description
1		Fetal heart signal indicator
2		Battery level indicator
3		Volume
4	3MHz	Probe working frequency
5	136	Fetal heart rate value (unit:beats/min)

3.2 Buttons

Power button: Function: on/off control, interface switching

Long press this button to turn on/off the device, short press the button to switch between digits interface and curve interface.

＋ Volume+: press this button to increase the volume, there are 5 levels.

— Volume-: press this button to decrease the volume.

3.3 Headphone Socket

Headphone Socket: a socket for audio output, can be connected to earphones or voice recorders for audio input

4 Basic Operations

4.1 FHR detection

① Startup
Press power button to turn on the device.

② Find the position of fetus:
Find the optimal position for detecting fetal heart rate by feeling fetus position with hands. Apply proper amount of gel to the probe acoustic surface; attach the probe acoustic surface to the belly of pregnant woman, and move the probe to obtain an optimum audio signal. Adjust the volume according to your necessary.

③ FHR measurement
After hearing clearly and regularly fetal heart sound, a flickering fetal heart symbol appears on the screen. Please keep the probe stable to measure accurately and obtain correct FHR value.

④ After measurement is completed, long press power button to turn it off.

NOTE:

①Put the probe on the most appropriate detecting position to get better detecting results.

②Do not put the probe on the position where Placental Blood Sound(PBS) or Umbilical Sound (UMS) is very strong.

③If the pregnant women takes supine position and the fetus position is normal, you can obtain the clearest fetal heart sound at the lower part of navel midline.

④The device can not detect FHR unless clear fetal heart sound is heard.

4.2 Interface switch

After turning on the device, short press power button to switch interfaces between digits interface and curve interface.

4.3 Taking Out Probe and Placing Probe

The probe is magnetically fixed. Remove it from main unit for use, and place it on the side of enclosure after use, it will be fixed magnetically.

4.4 Over-limit prompt

Normal FHR range is 120 BPM~160 BPM, values within this range are displayed in green on the screen. When the FHR is too slow or too fast that exceeding this range, the value is displayed in red, prompting the pregnant women to go further examination in order to ensure fetus safety.

4.5 Battery replacement

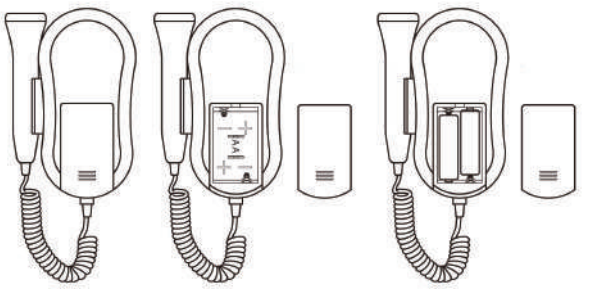
Batteries can be replaced by user. In normal working, the battery level information is displayed on the screen. The number of squares within the battery icon represents remaining battery level. An empty battery icon means low battery, and user needs to replace them. If the battery is too low to maintain system's normal working, the device prompts "Low Power!" and then turns off.

①Remove batteries

Turn over the device to show rear panel, push down the battery compartment cover to open it, and take out the batteries.

②Install batteries

Follow the polarity marks to install batteries, and close the battery compartment cover.



5 Symbols

Symbols	Description	Symbols	Description
	Type CF applied part	SN	Serial number
	Refer to instruction manual/booklet		Recycle
IP22	Degree of protection provided by enclosure		Manufacturer
	Waste disposal symbol		Manufacture Date
CE 0123	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.	EC REP	European Representative
	This side up		Storage and Transport Temperature limitation
	Fragile, handle with care		Storage and Transport Humidity limitation
	Keep dry		Storage and Transport Atmospheric pressure limitation

6 Product Specification

Product Name: Pocket Fetal Doppler
Model: CONTEC10A
Classification:
Type of protection against electric shock: Internally powered equipment.
Degree of protection against electric shock: Type CF applied part
Harmful Liquid Proof Degree:
Main unit: normal device, no water-proof ability
Probe: IP22, Degree of Safety in Presence of Flammable Gases: Equipment not suitable for use in presence of flammable gases.
Working System: Continuous running equipment.
Physical Characteristics
Dimension: 157 mm(L) × 99 mm(W) × 27 mm(H)
Weight: About 207 g (including batteries)
Environment
Working:
Temperature: ＋5 ℃ ～ ＋40 ℃
Humidity: ≤80％
Atmospheric Pressure: 70 kPa~l06 kPa
Transport and Storage:
Temperature: -10℃~+55℃
Humidity: ≤93％
Atmospheric Pressure: 50 kPa~l06 kPa
Display: 1.77" 262K display
FHR Performance
FHR Measuring and display Range: 50 BPM ~ 240 BPM (BPM: beats per minute)
Resolution: 1 BPM
Accuracy: ±2 BPM
Auto shutdown: After 1 minute no signal, power off automatically.
Battery Type: Two 1.5V batteries (AA LR6)
Ultrasound coupling agent requirement: acoustic impedance: $(1.5\times10^6\sim1.7\times10^6)$Pa·s/m; acoustic attenuation≤0.05dB/(cm·MHz)

Ultrasound Probe:
Nominal Frequency: 3.0 MHz
Working Frequency: 3.0 MHz ± 10%
Ultrasonic Output Power: P < 20 mW
Working Mode: Continuous wave Doppler
Effective Radiating Area of Transducer: ≤208 mm^2
Peak-negative acoustic pressure: P_- < 1 MPa
Output Beam Intensity: I_{ob} < 20 mW/cm^2
Spatial-peak Temporal-average Derived Intensity: I_{spta} < 100 mW/cm^2
Note: In all working application modes, mechanical index: MI<1, thermal index: TI<1.

7 Maintenance, Cleaning and Disinfection

7.1 Maintenance

The probe acoustic surface is fragile and must be handled with care. Gel must be wiped from the probe after use. These precautions will prolong the service life of the device.

Before use, user needs to check the device to ensure that there is no obvious damage that may affect patient safety or device performance, and the cables of transducer components does no have cracks or other damage phenomenons. The recommended inspection interval is once per month or less. If there is any damage, replace the damaged part before use.

The device should undergo periodic safety testing, including leakage current testing, to ensure proper patient isolation from leakage currents. The recommended testing interval is once every two years or as specified in the institution's test and inspection protocol.

The accuracy of FHR is controlled by the device and cannot be adjusted by user. If the FHR result is uncertain, please use other methods such as stethoscope to verify or contact local distributor or manufacture to get help.

7.2 Cleaning

Before cleaning, turn the device off and take out the batteries.

Keep the outside surface of the device clean and free of dust and dirt, clean enclosure surface (display screen included) with a dry, soft cloth. If necessary, clean the enclosure 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:

- Do not use strong solvent, for example, acetone.
- Never use an abrasive such as 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.
- Do not leave any cleaning solution on the surface of the device.

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

7.3 Disinfection

After each time of use, clean the device enclosure, probe, etc., by above cleaning method, and then disinfect the probe with 70% ethanol.

Wipe the probe with a clean, dry cloth to remove any remaining moisture.

CAUTION: Never try to disinfect the probe or device by low temperature steam or other methods.

8 Solutions for Possible Problems

If it appears following problems when you use the device, please solve them as below:

Problems	Possible reasons	Solutions
Unable to startup or it turns off immediately after turning on	•bad contact of battery •low battery •device failure	•correctly install batteries to ensure good contact •replace batteries •return it to the manufacturer for maintenance
Large noise	•no coupling agent applied •noise caused by dragging the probe on the belly •probe is not placed on the optimal position	•apply proper coupling agent to the probe •when searching the fetal heart sound, lift the probe and move it to change the position, also you can adjust the angle between the probe and belly to obtain better signal •find proper fetal heart position
Low sensitivity	•probe is not placed on the optimal position •no coupling agent applied	•move the probe or adjust the probe angle •apply proper coupling agent to the probe
Random digits appear when detecting FHR	•the friction between probe and belly makes the device misdisplay •there is interference nearby, such as high-frequency machine or cellphone •fetus position changes due to fetal movement	•the value appeared after hearing stable fetal heart sound is the fetal heart rate •working environment should away from interference source •move the probe to the optimal position where the clearest sound is heard

Appendix 1 The Importance of Domestic Fetal Monitoring

Modern medicine believes that:
FHR is a useful tool in identifying fetal health. By recording FHR changes, users can observe fetal hypoxia, fetal distress, nuchal cord and other symptoms. Domestic fetal monitoring detects FHR changes mainly by listening to fetal heart sound, which is a powerful support in improving gestational safety.
The change of fetal heart rate is most obvious in the following three periods for a pregnant women:
1. Within 30 minutes after getting up
2. Within 60 minutes after lunch
3. Within 30 minutes before going to bed

During above three periods, because of the changes in physical status of pregnant women and food digestion activities, the needs for oxygen supply increase, relatively, the oxygen for fetus become less, which may easily cause symptoms such as fetus anoxia. Testing the FHR within these periods is the most appropriate to reflect the healthy status of fetus.
We advise the pregnant women to take 3 measurements a day (once per morning, noon and evening), 1 to 2 minutes for each measurement, and record the measurement results for medical reference by doctors.
Generally, the normal fetal heart rate is: 120 BPM~160 BPM; slightly higher: 161 BPM~180 BPM; too high: above 181 BPM; slightly lower: 119 BPM~100 BPM; too low: below 99 BPM.
This device can detect the fetal heart sound for fetus above twelve weeks. FHR readings too high or too low requires a hospital visit for further checks to ensure fetal safety.
Note: As each person's physique is different, the gestational week at which fetal heart sounds can be detected will be different.

Appendix 2 Acoustic Output Reporting Table

Transducer Model: CW Doppler Operating Mode: CW Mode Working Frequency:3.0MHz

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.0072	0.0173		0.032		-
Index Component Value				0.0142	0.0173	0.032	0.0245	
Associated acoustic parameters	$p_{r,a\ at\ z_{MI}}$	MPa	0.0127					
	P	mW		2.053		2.053		-
	$P_{1\times1}$	mW		1		1		
	Z_s	cm			2.53			
	Z_b	cm					2.53	
	Z_{mi}	cm	0.82					
	$Z_{pii,a}$	cm	3.03					
	f_{awf}	MHz	2.981	2.981		2.981		-
Other information	prr	Hz	0					
	Srr	Hz	-					
	n_{pps}		-					
	$I_{pa,a}$ at $z_{pii,a}$	mW /cm^2	0.0012					
	$I_{spta,a}$ at $z_{pii,a}$ or $z_{sii,a}$	mW /cm^2	1.251					
	I_{spta} at z_{pii} or z_{sii}	mW /cm^2	2.475					
	p_r at z_{pii}	MPa	0.0146					
Operating control conditions	—		—					

Appendix 3

Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
The CONTEC10A is intended for use in the electromagnetic environment specified below. The customer or the user of the [Code SI] should assure that it is used in such an environment	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
The CONTEC10A is intended for use in the electromagnetic environment specified below. The customer or the user of the CONTEC10A should assure that it is used in such an environment		
Immunity Test	**IEC 60601 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Power frequency (50 / 60Hz) magnetic field IEC 61000-4-8	30 A/m	30A/m

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity		
The CONTEC10A is intended for use in the electromagnetic environment specified below. The customer or the user of the CONTEC10A should assure that it is used in such an environment		
Immunity Test	**IEC 60601 Test level**	**Compliance level**
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz	10 V/m 80 MHz – 2,7 GHz
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.		
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 CONTEC10A is used exceeds the applicable RF compliance level above, the CONTEC10A should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CONTEC10A.		

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity							
The CONTEC10A is intended for use in the electromagnetic environment specified below. The customer or the user of the CONTEC10A should assure that it is used in such an environment							
	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Modulation b) (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
	450	380 –390	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
	710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
	810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28
	1720 1845 1970	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4,25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28
	5240 5500 5785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.							
The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E=\frac{6}{d}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.							

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.
- 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.
- 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."
- 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 CONTEC10A including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Active medical devices are subject to special EMC precautions and they must be installed and used in accordance with these guidelines.

Note:
When the device is disturbed, the data measured may fluctuate, please measure repeatedly or in another environment to ensure its accuracy.