

MONITOR
 your fetus at home with your doctor
 SHARE
 sounds and ultrasonic graphs with everyone

Altention

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### Manufacturer's responsibility —

Manufacturer's responsibility of conder said responsible for any effects on safety. Accordancy of conder said responsible for any effects on safety. Assembly operations, extensions, read-planeties, modifications or register accented out by present authorized by our company, and the electrical resultants or the selected connected with national standard and the way of the control of the selection of the Warning. This device in not intended for treatment. The intended use late of the selecting Fetal heart Rate. If the FIFF result is districted, please use other methods such as selection copie verify immediately.

# Warranty

done by the engineers approved by manufacturer. We warrant that each product we sell 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. Misuse, improper maintenance may

# CONTENTS -

Chapter 3 Outlook and Configuration.
Chapter 4 General Operation.
Chapter 5 Key of Symbols.
Chapter 6 Product Specification.
Chapter 8 Maintenance
Chapter 8 Cleaning, Disinfecting and Sterilization

8.1 Cleaning 8.2 Disinfecting and Sterilization...

Chapter 9 Solutions for Possible Problems Chapter 10 Small Tips Appendix 1 Appendix 2 Appendix 3

Chapter 1 Safety Guidance
This unit is intensity powered equipment: the degree of shock protection is type Co ragisted part.

The control of the Control of

Safety Precautions
To avoid any possible danger, please operate the device according to safety guidance as following:
I. It is a precision device, Please don't open it by yourself.

2. The device must be serviced only by authorized and qualified

2. The device must be serviced only by authorized and qualified personnel.

2. The device must be serviced by authorized and qualified personnel or long time, lead to the other backwise, the used batteries should be disposable according to local law of environmental protection.

4. The device is designed for continuous operation and is ordinary, Do and the control of the protection of the personnel or the personnel of the perso

inferience, such as rado transmittes mobile telephones, etc. Keep them for aimy.

The such as a such as a

Main Features:
The probe and main units integrated together
Delicate and compact design, portable to use
Particular 2 Headphone Sockets design can let expectant mother and
father hear the fetal heart sound together
High sensitive doppler probe

Baby Sound A'B Pocket Fetal Doppler is a hand held equipment for denoting Fetal Heart Rate(FHR) without Conducting Fetal Heart Rate(FHR) without Conduct daily delection of FRR by themselves. Pregnart women can operate by themselves to heart Fetal Heart sound and calculate FIR1 to reside the purpose of pre-monitoring and fetal caring.

Sound B.
Baby Sound A is for simple auscultation. Baby Sound B is a high

Baby Sound A is for simple auscultation. Baby Sound B is a high performance model with LCO displat display. Baby Sound A and Baby Sound B are integrated with 2MHz probe. They are all available for user replaceable batteries, Both of the two models have audio output. Both can be connected to a computer, CD or tape with recording cable to record the fetal heart sound and share fetal's heart beat with family and friends via Network.

Chapter 2 Introduction —

Main Features:

- High sensitive doppler probe

Low ultrascound output intensity, much lower than the relative
government standard and with high safe quality

Low power consumption, two AAA size batteries can last more than 8
hours for continuous use (depend on battley type and volume)

Can be connected to a computer or recorder to record the fetal heart - Lan be connected to a computer or recorder to record me teat near sound with recording cable
 - LCD PHR Display with high accuracy (Baby Sound B only)
 - Screen will be looked automatically without signal for 15s, which is convertient for pregnant women to operate individually (Baby Sound B only) Find Blast
Signal Symbol
LOD Blagdoy

THE

Chapter 4 General Operation

1. Before the first use, please open the battery cover, and install two AAA size batteries.

2. Plug headphore into the Headphore Socket.

3. Power Orrevolve up the ON-OFF/Volume Knob on the left side panel

3. Power Chrzevotve up the ON-DPF-Volume Knob on the left side panel to power on the equipment. For Baby Sound A, the LED indicating light will be in green color. For Baby Sound B, the LCD display is \_\_\_\_\_.
4. Find the position of fetal heart. Alf first, please feel the position of the fetal heart by hand. Find out the best direction for detecting the fetal heart by hand. Find out the best direction for detecting the fetal heart. Apply a liberal amount of get to the faceplate of probe; place heart. Apply a liberal amount of gel to the faceplate of probe; place the faceplate of probe at the best position for detecting fetal heart. Adjust the probe to obtain an optimum audio signal ideally by angling the probe around. Adjust the volume according to requirements. Using demonstration is as Fig. 1-4



Attention: Don't adjust the Volume Knob in a very high volume when Chapter 3 Outlook and Configuration

(B) I

finding the fetal heart position.

5. FHR calculation: For Baby Sound A, calculate FHR with hearing 5. FIH Calculation: Passy's South A, Calculate FIH; with neating fetal heart sound, and keep hearing 1-2 minutes per time. For Baby Sound B, At the moment of detecting FIHR signal, the LCD will display the flashing fetal heart signal symbol, and display real-time FHR simultaneously.
6. After operation, revolve down the ON-OFF / Volume Knob to power off.
7. Use soft cloth to wipe the gel from the probe

### Chapter 5 Key of Symbols Symbol Description



### Chapter 6 Product Specification

Product Name: Baby Sound Pocket Fetal Doppler Model No.: Baby Sound A/B Safety: Complies with: IEC 1:2005-60601 Classification: Anti-electroshock Type: Internally powered equipment.

Classification: Anti-electrosnock type: Internally powered equipment.

Anti-electroshock Degree: Type B applied part Harmful Liquid Proof
Degree: Ordinary equipment (sealed equipment without liquid proof)

Main unit: Degrees of protection provided by

enclosure: IPX1
Degree of Safety in Presence of Flammable Gases: Equipment not Suitable for use in presence of flammable gases
Working System: Continuous running equipment
FMC: Group I Class R

Suitable Using Range: Suitable for use after the 12th week of Suitable using Hange: outcome into use used to the pregnancy Physical Characteristic: Size: (L)110 mm x (W)55 mm x (H)16.8 mm (the space between probe culmination and upper panel is 26 mm) Weight: About 80 g (including batteries)

Weight, About 80 g (including batteries) Environment: Environment: Frequency (Including September 1) (

Chapter 7 Maintenance —

Chapter 7 Maintenance
The device is frangible and must be handled with care. Gel must be wiped from the probe after use. These precausions will prolong the life of the urit.
The user must check that the equipment does not have visible evidence of damage that may affect patient safety or Pocket Fetal Doppler

capability before use. The recommended inspection interval is once per month or less. If damage is evident, replacement is recommended

per month or less. If damage is evident, replacement is recommended to the control asset.

If the control is the control in the control is the control is the control in the control in the control in the control is the control in th

manufacturer to get help.

Chapter 8 Cleaning, Disinfecting and Sterilization \_\_\_\_

Chapter & Cleaning, Disinfecting and Sterilization — 1.1 Cleaning — 1.1 Cleaning — 1.2 Cleaning

other methods.

2. Do not use high temperature sterilizing process and E-beam or gamma radiation sterilization.

3. The recommended periods of cleaning, sterilization and disinfecting are once per mornh.

4. Metr cleaning, sterilization and disinfecting users must inspect whether have any obvious damage which could affect the patient settley and instrument performance poposiby.

Chapter 9 Solutions for Possible Problems

If it appears the problems below when you use the Baby Sound please solve them as follows:

Problems	Possible reasons	Solutions
Week sound	Volume is too low Power is low Not daub the gel	Adjust the Volume knob Change the batteries Duab the gel
Noise	Volume is too high Power is low Disturbance from the outside signal	Adjust the volume knob Change the batteries Keep it away from the outside signal
Low sensitivity	Position of the probe is not correct	Adjust the position of the probe

Chapter 10 Small Tips
Essentially of feel Monitor-Modern medicine think that, FHR is important
get to identify less health, by recoding FHR charges can observe feel
get to identify less health, by recoding FHR charges can observe feel
symptoms. Feel monitor inspect EHR date charges by identify is feel
sent sound markly. Feel monitor is a powerful guarantee to improve
percentional safely. Feel heart rate charges most obviously in the
following three precisions.

- Within 30 minutes after pregnant women get up
   Within 60 minutes after pregnant women finish lunch
   Within 30 minutes before pregnant women go to bed

a, winnin a) minutes better programs women go to zero for the above there provide, because of the charge of the lettus status of pregnant women, the activity of foot dispessing needs the felsus to provide more copyant, relatively, the copyant for lettus become lase. It is leasy to more copyant, relatively, the copyant for lettus become lase, the leasy to display the healthy status for the fetus best. The above three period states on only be tested for pregnant women themselves, so FHA dismession more than the properties of the state of the contractive of the contractive more than the contractive of the contractive more than the contractive of the contractive for the contractive contractive the contractive for the contractive contractive

## Guidance and manufacturer's declaration-electromagnetic immunity for all EQUIPMENT Appendix 1 Guidance & manufacturers declaration-electromagneticemissions for all EQUIPMENT and SYSTEMS and SYSTEMS

Guidance and manufacturer's declaration- electromagnetic emission

The Pocket Fetal Doppler(Baby Sound B) magnetic environment specified below. The customer of the user of the Pocket Fetal Doppler(Baby Sound B) should assure that it is used in such an environment. Emission test Electromagnetic environment.

Electromagnetic environment Guidance

The Pocket Fetal Doppler uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

The Pocket Fetal Doppler is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic

Emission test Compliance

RF emission CISPR 11

Group 1



Guidance and manufacturer's declaration electromagnetic

immunity						
electromagneti	c environs Fetal Dop	ment specified be pler(Baby Sound	is intended for use in the slow. The customer or the d B )should assure that it	9		
Immunity test	IEC	Compliance	Flectromagnetic			

1	Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
	Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
	Power frequency (50Hz/60Hz) magnetic field IEC81000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declarationelectromagnetic immunity - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration electromagnetic interunity.

The Pocket Fetal Department you of 8) is intended for use in the electromagnetic endormonst spocified below. The outcomer or the user of the device should assure that it is used in such in environment. IEC 60601 test Complianc Electromagnetic level environment-guidance

Conducted RF IEC 81000-4-6	3 Vers 150 kHz to 80 MHz	3 Vins	Portable and mobile RF communications equipment should be used no closer to any part of the Pocket Fetal Doppler, including cables, then the recommended
Radiated RF IEC 81003-4-3	3 Vm 80 MHz to 2.5 GHz	3 V/m	separation distance collisizates from the equation appoints to the the equation appoints on the the equation appoints on the the equation appoints of the equation of the equ

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM- for EQUIPMENT or SYSTEM that are not LIFE SUPPORTING

	distances between portable and the Pocket Fetal Doppi	e and mobile RF communications ler(Baby Sound B)
raciated RF disturbances ar prevent electromagnetic into and mobile RF communicati	e controlled. The customer or eference by maintaining a mir	magnistic environment in which the user of the device can help irrum distance between portable and the Pocket Fetal Doppier as ower of the communications
Rated maximum output	Separation distance acco	rding to frequency of transmitter (m)
power of transmitter (W)	80 MHz to 800 MHz x = (42) (37	800 MHz to 2.6 GHz
		2-13710
0.01	0.1167	0.2334
0.4	0.0500	0.7278

3.6893

NOTE 1 At 80 MHz and 800 MHz, the senaration distance for the bisher frequency range

applies.

NOTE 2 These guidelines may not apply in all situations Electromagnetic propagation is affected by absorption and reflection from situatures, objects and people.

7.3786

23.3334

Acoustic output reporting table cwDmode Nominal frequency: 2.0 MHz Transducer Model:---(S/N:---)

Two-way attenuation  $S = \sum S_x + S_x$ 

Doppler Frequency

) = 30 log  $_{2}$   $\left(\frac{f_{2}(z,y)}{f_{2}(z,y)}\right)$  Density (3-Au)(+8-C

5.55

5.76

5.82

5.02

5.52 5.76

5.49

Velocity of Target (cm/s)

				TIS			TIB Non- scan	тіс
Index label  Maximum index label		м	Non-scan		scan			
			Scan	$A_{\rm spec} \leq 1000^{\circ} \ A_{\rm spec} \geq 1000^{\circ}$				
		0.012		-	0.024	0.11	(a)	
	Pro (MPa)		0.017					
	P (mW)				-		3.8	
	Min of $P_{\sigma}(z_{\sigma}), I_{sphere}Z_{\sigma}$ (mW)					2.53		
	Z, (cm)					2.94		
Associated	$Z_{to}$ (cm)					2.94		
acoustic parameters	Z, (cm)						0.41	
	Z at max J <sub>sta</sub> (cm)		0.37					
	$d_{ex}(Z_{j_i})$ (cm)						0.57	
	f <sub>red</sub> (MHz)		1.99		-	1.99	1.99	A
	Dim of A <sub>opt</sub>	X (cm)			-	1.90	1.99	
		Y (cm)			-	1.01	1.01	
	t <sub>a</sub> (µsec)		CW					
	per (Hz)		CW					
Other	p, at max / (MPa)		0.018					
Other Information	$d_{eg}$ at max $I_{pl}$ (cm)						0.58	
	Inca at max MI (W/cm <sup>2</sup> )		9.43					
	Focal Length FL x							
	oca cargon	FLy						

### Pocket Fetal Doppler Baby Sound A

Manufacturer: Contec Medical Systems Co., Ltd.

No. 112 Ginhuang West Street, Economic & Technical Development Zone,
Grihuangdia, Hebel Province, Gesold, PEDPLE: S. REPUBLIC OF CHINA
EC-Representative: Shariphal international Holding Corp
Gind Effectives 20537 80, Hamburg, Germany



Distributor: SANA MEDITECH Guitard 80 , 5-8 08014 Barcelona SPAIN http://babyheartbeat.eu

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