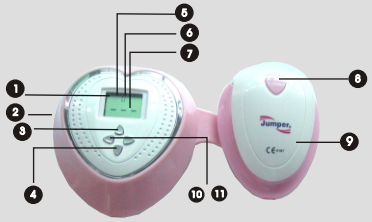
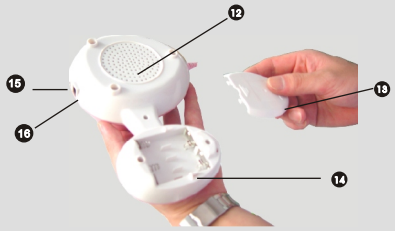
Controls and indicators



1. LCD screen
2. volume /on offkey
3. function key
4. recording key
5. fetal heart signal display
6. status show
7. fetal heart rate digitaldisplay
8. decoration key / nofunction
9. Probe
10. 11. no function



12. bugle hole
13. battery cover
14. battery storehouse
15. headset jack
16. charger jack

build in battery

1、use pollex backwardsto undraw the battery

2、swith away the batterycover

3、build in the batteryaccording anode and cathode withbatter AAA

4、up with the battery cover

Jumper

AngelSounds®

INSTRUCTION MANUAL

Fetal Heart Detector
JPD-100S

Manufacturer

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CE Mark

This CE mark on a product denotes conformity whit the European Council Directive 93/42/EEC(MDD) concerning medical devices

Authorised representative in the european community:

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JUMPER MEDICAL CO., LIMITED
Rev:20050407-001 A2005
Issue: 2005/04/07
Print in China

CE 0197

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Operation procedure

1、Indicator light No.3 isshining when open the volume button LCD screen state hint area show digitalls1.

2、Apply coupling gelto unit probe as shown indiagram

3、Make the probe stickto the belly, move it slowly,until hear the fetal

Use only the specified batterytype and insert the battery accordingto polarity instruction
Always dispose of empty batteries in accordance with regulations. Do not dispose together with household garbage

4、Listening music、standard fetal heart sounds、recording

Soft music was storedin instrument, first open volume on-off knob, press function key,LCD screen state hintarea show digital is2, and play the soft music at thesame time; once again press function key, then LCD screen state hint area show digital is 3, and enter fetal heart demonstration state at the same time, instrument play standard fetal heartbeat sounds of clinic record; Thirdly time press function key , LCD screen state hint area show digital is 4, instrument enter preparation of fetal heart recording state, press recording key, the instrument begin record fetal heartbeat sounds and hold itself in the machine inner part; once again press function key , LCD screen state hint area show digital is 1, instrument return to fetal heart monitoring state.

Computer recording:

We willbe able to recordthe fetal heartbeat soundsby computer, keepit for memory, operation step as blows:

(1) First, put a headof route that therandom machine provides toheadphones socket of instrument, anotherhead of route isjointed to microphone of computer, careless contection.

(2) Install related software ofrecording in the computer, open software interface of recording.

(3) Find fetal heart, pointthe computer software andstart recording sounds when you listen clearof fetal heart sounds

Warning

! Device is sealedand NOT user-serviceable.
Device must be serviced by authorized and qualified personnel to maintain safety, and reliability.
Damage may result if the AngelSounds JPD-100S is knocked or dropped.

! Caution, See instructions for use

01	02	03	04	05	06
07	08	09	10	11	12
2005	2006	2007	2008	2009	2010

Date of Manufacture

Symbols

Transport and storage conditions

Temperature:
from -10℃ to 60℃

Humidity:
from 0% to 95%

Air Pressure:
from 500hpa to 1060hpa

Upward

Water-proof

Non-hook

Layer limit 15

Preventive maintenance

General
The equipment is designed to require a minimum amount of maintenance. To obtain the best performance and maintain safety, the following checks should be carried out quarterly or annually, depending on usage.
Check the AngelSounds JPD-100S for damage or cracks which may allow the ingress of liquids or gel.

Cleaning and disinfecting
Cleaning: Wipe the instrument case with a cloth dampened in soap or a detergent solution and wipe dry with a clean cloth.
Disinfection: If soiled, clean as above, then wipe the instrument case with an alcohol-impregnated(70% ethanol or isopropyl).

Guarantee

The instrument is guaranteed for a period of 12 months from the date of purchase against defects in materials or workmanship. Any AngelSounds JPD-100S which is proven to be defective within this period shall, at Jumper Medical Co., Limited, be either repaired or replaced free of charge, providing that:
1The AngelSounds JPD-100S has not been damaged by misuse, mishandling or attempted repair.
2The AngelSounds JPD-100S is returned to Jumper Medical Co., Limited, carriage paid.

Technical specifications

Operating condition:

Do NOT leave the AngelSounds JPD-100S exposed to direct sunlight.
Operating temperature :0-40℃. R.H. :0%-85%
Battery: IEC 6F22 9V alkaline

Safety check list:

The AngelSounds JPD-100S Fetal Heart Detector is designed to comply with BS5724 part 1, IEC601-1,UL544 and other international medical safety standards for battery-operated (internally powered) medical equipment.

Classification:

Type of protection against electric shock: Internally powered equipment
Degree of protection against electric shock: Type B
Type B protection means that this equipment will comply with
EN 60601-1/ Medical Electrical Equipment Part 1:
IEC 60601-1 General Requirements for safety

EN 60601-1-2/ Standard for electromagnetic compatibility
IEC 60601-1-2 requirements for medical electrical equipment

U.S. Federal law restricts this device to use on or by the order of a physician.
Degree of protection against harmful ingress of water: Ordinary equipment
Mode of operation: design for continuous operation
Degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE:
Do not use in the presence of flammable anaesthetics
This detector is not explosion-proof and must not be used in the presence of flammable anaesthetics.

Statement
The MEDICAL DELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS (this instruction).
Portable and mobile RF communications equipment can affect MEDICAL EELECTRICAL EQUIPMENT.

The equipment is without a manual sensitivity adjustment, hence:
The minimum amplitude or value of PAITIENT physiological signal is ⩾90dB

Warning:
Operation of the EUIPMENT or SYSTEM below this amplitude or value may cause inaccurate results.
Warning:
The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the EQUIPMENT or SYSTEM as replacement parts for internal components, may result in increased EMISSION or decreased IMMUNITY of the EQUIPMENT or SYSTEM.

Ultrasound safety considerations and data

General
Diagnostic ultrasound has been in use for over 25 years with no confirmed adverse effects on patients or instrument operators at the intensities typical of present diagnostic instruments. Although the total absence of adverse effects to human subjects after such extensive use at diagnostic power levels is gratifying, available data are not conclusive and the possibility that biological effects may be identified in the future remains. It is therefore deemed desirable by medical and other scientific authorities in this field that exposure to ultrasound should be limited to the duration and intensity appropriate for the clinical objective. Because fetal tissue could be more sensitive to biological effects by reason of pregnant subjects be kept to a minimum. At present, there is a clear consensus that the benefits to patients of prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present.

AngelSounds JPD-100S is a portable battery operated detector designed for the detection of fetal life and confirmation of continued life during pregnancy.

Minimizing patient exposure
Acoustic output of the AngelSounds JPD-100S is internally controlled and cannot changed by the operator in the course of the examination. The duration of sure is, however, fully under the control of the operator. Mastery of the techniques described in the operating instructions will facilitate limit the maximum amount of diagnostic information with the minimum of exposure.

Acoustic output data
The acoustic output of the AngelSounds JPD-100S transducer has been measured in water using a calibrated hydrophone at Authorized Laboratory. Normalized values, which estimate the maximum 'in-situ' dosage to tissue at the point of highest intensity in the beam path have been calculated.
These data are presented in the following tables.

Table 1 Maximum acoustic output measured in water

Parameter of AngelSounds JPD-100S transducer	
Operating mode	Continuous Doppler
Frequency	3.3 MHz
Intended use	Fetal heart detection
Intended for fetal use	Yes
Control settings	None
Acoustic intensity:	
I_{SPTA}*(mW/cm^2)	＜10mW/cm^2
Peak negative pressure	＜1 Mpa
Output beam intensity	＜20 mW/cm^2

*I_{SPTA}=Spatial peak, Temporal Average

Table 2 Estimation of maximum normalized 'in-situ'

Intensity in tissue estimate the 'in-situ' value in tissue at the point of examination, where:
I_T=Spatial peak intensity 'in-situ' (tissue)
I_W=Spatial peak intensity in water
F=Ultrasound frequency(MHz)
Z=Distance from the face of the transducer to the point of measurement (cm)
then:
$I_T = I_W$ exp.(-0.069f.z.)
For example; at a typical point of measurement using the AngelSounds JPD-100S the following value of maximum intensity is obtained:

Parameter of AngelSounds JPD-100S transducer	
Typical measurement Depth in tissue(cm)	4.8
Maximum intensity I_{SPTA} in tissue(mW/cm^2)	0.8

This also conforms to the requirements of IEC1157 (details on request).

AngelSounds®