

Jumper®

Fetal Heart Detector


JPD-100S


AngelSounds®

INSTRUCTION MANUAL

Symbols

Transport and storage conditions


 Temperature: from -10°C to 60°C


 Humidity: from 0% to 95%

 Air Pressure: from 500hpa to 1060hpa


 Upward

 Water-proof

 Non-hook


 Layer limit 15

CE Mark

 0197 This CE mark on a product denotes conformity with the European Council Directive 93/42/EEC (MDD) concerning medical devices


Authorised representative in the European community:

Retail-therapy.com Limited
2 Hillside Cottages, Harley Lane, Heathfield, East Sussex,
TN21 8AQ




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

 Date of Manufacture

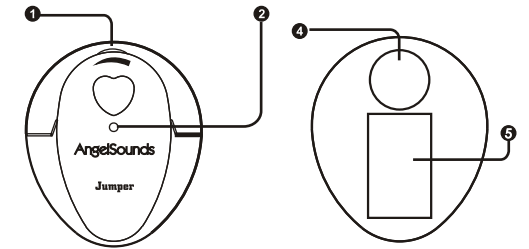
 Caution, See instructions for use






 Manufacturer
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Warning

 Device is sealed and 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.

Controls and indicators

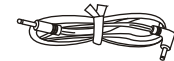


 On/off/volume key
 Working indicator light
 Headset socket (two)
 Transducer
 Battery compartment cover

Accessories



Headset



Recording cable

Introduction

The AngelSounds JPD-100S is a single-hand device for detection of the fetal heart.

The fetal heart may be detected from early pregnancy, and more easily from pregnancies greater than 12 weeks. The AngelSounds JPD-100S is suitable for use in the antenatal.

Every AngelSounds JPD-100S is supplied with 1 dry-cell battery. Dry-cell battery must NOT be placed in a re-charging device and must NOT be disposed of by burning.

The AngelSounds JPD-100S operates at a nominal frequency of 3.3MHz, using Doppler ultrasound.

There is an 'on/off/volume key' (1), it's easy to operate. And working indicator light (2) shows working condition.

A headset and an audio line are available.

The AngelSounds JPD-100S is lightweight and designed to fit comfortably in hand.

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Operation procedure

Insert the headset jack securely into the socket(3).
Apply a small amount of acoustic coupling gel to the examination site. Or put some of gel, oil or water on the top of the transducer(4).
Switching on 'On/off/volume key'(1)
'On/off/volume key'(1)' is used to select either high or low volume level, too.
Hold the AngelSounds JPD-100S.
The AngelSounds JPD-100S is now ready for use.

Examination

Place the transducer on the examination site and move it around slowly until a good signal is obtained. This will sound like 'galloping horses'. It may be necessary to angle the transducer slightly to obtain the optimum signal.

Use of audio line

Insert one jack of the audio line into the main unit's headset socket (anyone of the two), put another plug into the recorder, then the fetal heart beat can be recorded by recorder.

Move the transducer to pregnant woman's left chest to record her heart beat and play the mother's heart beat to the baby after the baby is born, this can calm the baby.

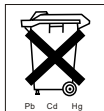
To switch off turn 'on/off/volume key'(1).

Battery fitting or replacement

To fit or replace the battery on the AngelSounds JPD-100S:
Remove the rear battery compartment cover(5) carefully. Remove the old battery. Fit the new battery (IEC6F22 9V alkaline). Then off the battery cover.

Use only the specified battery type and insert the battery according to polarity instruction

Always dispose of empty batteries in accordance with regulations. Do not dispose together with household garbage



New alkaline battery will give more than 500 one minute examinations.
Battery should be removed if the unit is not in regular use.

After use, the AngelSounds JPD-100S should be dried thoroughly with a soft cloth.
If AngelSounds JPD-100S is soiled after use, follow the cleaning, and disinfection procedure detailed in the preventive maintenance section.

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:
1 The AngelSounds JPD-100S has not been damaged by misuse, mishandling or attempted repair.
2 The 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°C. 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 ELECTRICAL 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 ELECTRICAL EQUIPMENT.

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

Warning:

Operation of the EQUIPMENT 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

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 being 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 be changed by the operator in the course of the examination. The duration of use 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)	<10 mW/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_s = 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:

$$I_s = I_w \exp(-0.069f.z.)$$

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	4.8
Depth in tissue (cm)	
Maximum intensity I_{SPTA} in tissue (mW/cm ²)	0.8

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

For technical data, please contact: European Representative

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