



Pocket Fetal Doppler User Manual

Model: AF-706/AF-706-L



Thank you for purchasing the Pocket Fetal Doppler AF-706/AF-706-L. Please read this user manual thoroughly before using the device. Please keep for future reference. Please note all the pictures in the user manual are references.

1. Safety Guidance

The unit is internally powered equipment; the degree of electric shock protection is type BF applied part.
Type BF applied part protection means that patient connections will comply with permitted leakage currents and dielectric strengths of IEC60601-1.

The degree of water proofing provided by the ultrasound probe is IP21.

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.

- ⚠ This device is not explosion-proof and cannot be used in the presence of flammable anesthetics.
- ⚠ Do not throw batteries into fire as this may cause them to explode.
- ⚠ This equipment can be used just for one patient only at one time.
- ⚠ Do not use the device in the area the HF surgical equipment, MRI, or CT scanner existing, or in the oxygen rich environment.
- ⚠ The device must be serviced only by the engineers approved by the manufacturer
- ⚠ The device is designed for continuous operation. Be care to avoid to immerse in any liquid.
- ⚠ Keep the device clean. Avoid vibration.
- ⚠ Do not use high temperature sterilization and E-beam or gamma radiation sterilization.
- ⚠ Electromagnetic interference ----- Ensure that the environment in which the device is operated is not subject to any source of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc. Keep them far away.
- ⚠ The user must check that the equipment does not have visible evidence of damage that may affect patient's 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.
- ⚠ 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 equipment 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.

- ⚠ After the service life, please return the products to the manufacturer or dispose the products according to local regulations.
- ⚠ The batteries must be properly disposed according to local regulation after their use.
- ⚠ The hand-held device is a tool to aid the healthcare professionally and should not be used in place of normal fetal monitoring.
- ⚠ It is suggested that in the premise of clinical needs, ultrasonic irradiation time should be as little as possible.
- ⚠ The device shall only be used when the battery cover is closed.

1.2 Scope of Application

Applicable to fetal heart rate measurement.

2. Introduction

2.1 Overview

Pocket Fetal Doppler is a hand-held obstetrical unit. It is applicable for department of gynaecology and obstetrics, clinic, and home.

Table 1 Display screen and function

Function \ Display screen	Digital display	Curve display
LCD	✓	-
TFT	✓	✓

2.2 Features

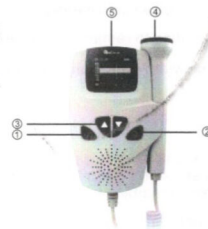
- ★ Optional: Bicolor LCD screen or color TFT screen ;
- ★ Calculating FHR with DSP techniques as used in fetal heart monitor, ensure the FHR accuracy and reliability;
- ★ High sensitive probe, low ultrasound power, more safety to the fetus;
- ★ Friendly interface, easy to operate;
- ★ Built-in speaker and audio output;
- ★ Optional Bluetooth transmission;
- ★ Alkaline batteries and rechargeable lithium batteries are optional according to demand;
- ★ Auto power-off after 1 minute of inactivity.

2.3 Configuration

Mainframe ----- 1 set
User manual ----- 1 pc

3. Outlook

3.1 Front Panel



The model has two types of screen to choose.

LCD screen TFT screen

Keys and ports:

- ① Power button: Press the button once to power on. press down the button and hold 3 seconds to power off.

- ② Menu button: Digital/ Curve display switch on TFT screen; as mute function button on LCD screen.
- ③ Volume button: Triangle up means to increase the volume, while triangle down means to reduce the volume.
- ④ Ultrasound probe: To receive fetal heartbeat signal.
- ⑤ Headphone socket.

3.2 Display

3.2.1 FHR Inspection Interface

Insert the ultrasound probe into the cable connector to enter the FHR display interface. Interfaces are slightly different on different display screens. Normal FHR range is 110bpm-160bpm.

LCD screen: The LCD display is as shown in Figure 1.
TFT screen: The curve display is as shown in Figure 2.



Figure 1 LCD screen – FHR value display



Figure 2 TFT screen - curve display

3.2.2 Symbols

♥ or ♥: Fetal heart signal symbol (i.e. signal strength and FHR speed).

LCD screen: When there is a fetal heart rate signal, the symbol will flash. It flashes fast with high heart rate and slowly with low heart rate. When there is no fetal heart rate signal, the symbol is motionless.

TFT screen: When there is no fetal heart rate signal or the signal is weak, TFT screen displays hollow heart-shaped symbol. When clear FHR signal is detected, it displays solid symbol.

⑦: There are 8 grades for volume adjusting which displayed from 0 to 7. '0' means that the volume is turned off; '7' means that the volume is maximum. Press the volume button to turn up or turn down the sound.

🔋: There are 5 statuses of battery power, namely, 0, grid 1, grid 2, grid 3, full. When the symbol flashes, batteries need to be replaced; otherwise it will influence fetal heart sound. The device will shut off automatically after several minutes.

FHR: Current FHR value.

bpm: FHR unit, beat per minute.

143or 158: FHR value.

[Note]

When FHR value exceeds normal range, the LCD screen color switches from green to orange, while the color of FHR value for the 1.77-inch TFT switches from blue-green to orange, please pay attention to the change of FHR.

4. General Operation

4.1 Power On/Off

Power on: Press the power button to power on. The LCD is lighted up to enter the working status.

Power off: Press and hold the power button for 3 seconds to power off. The device can be shut off after releasing the button.

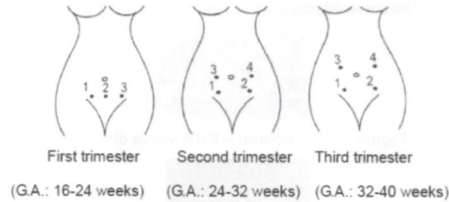
4.2 Volume Adjusting

The device volume ranges from grade 0 to grade 7. "7" means that the volume is maximum. Press UP key to increase the volume, while press DOWN key to reduce the volume.

4.3 FHR Detection

Turn on the mainframe and locate the position of the fetus by hand to find out the best direction to the fetal heart. Apply the ultrasonic gel to the faceplate of the probe; place the faceplate of the probe at the best position for detecting fetal heart. Adjust the probe to obtain an optimum signal (i.e. clear sound, less noise). Adjust the volume according to requirements. Generally, the fetal heart position is 1/3 below the pubis-umbilicus line at its earlier stage, it then moves upward with increasing of gestational period, and the fetal heart position will be a little deviation to left or right with different fetus position. Make sure that the probe surface should be fully contacted with the skin. After hearing regular fetal heart sound, the FHR value will display on the screen in real time. If no Ultrasound gel, water can be used.

The fetal heart position reference of fetal heart for different G.A. (gestational age) is shown as follows:



4.4 Changing TFT Interface

Customers can select digital interface and curve interface according to requirements. Press the menu button to switch between the two interfaces.

4.5 Replacing Alkaline Batteries

- ① Taking out batteries: First slide open the battery compartment in the direction of the arrow, then take out the batteries from the battery compartment.
- ② Replacing batteries: First put two AA batteries into the battery compartment (as for the direction of the batteries, please refer to the instruction inside the battery compartment); Then close the battery compartment.

[Note] The batteries must be taken out from the battery compartment if the device will not be used for a long time.

4.6 Charging Lithium Batteries

- ① Use 5V, 1A adapter for charging.
 - ② The charging symbol is displayed on LCD interface. The symbol will be full-grid when the batteries are fully recharged. On TFT screen, the interface displays the charging symbol and corresponding percentage. When the symbol is full-grid, the percentage is 100%, charging completed.
- ⚠ When charging, do not use the device.

5. Product Specifications

Product name: Pocket Fetal Doppler

Classification:

Anti-electric shock type: Internally powered equipment
Anti-electric shock degree: Type BF applied part
Liquid proof degree: Ordinary equipment (without water proof)
Degree of safety in presence of flammable gases: Not suitable for use in presence of flammable gases
Working system: Continuous running
EMC: Group I Class B

Size: 150 (Length) × 96 (Width) × 38 (Height) mm
Weight: 170g±5g (excluding batteries)

Working environment:

Temperature: +5℃~+40℃
Humidity: 15%~85%
Atmospheric pressure: 86kPa ~ 106kPa

Transport and storage environment:

Temperature: -10℃~ +55℃,
Humidity: 10%~93%
Atmospheric pressure: 86kPa ~ 106kPa

FHR performance:

Integrative sensitivity: ≥90db
FHR measuring range: 50 ~210BPM (BPM: beat per minute)
Accuracy: ±2BPM,
Speaker power: 0.5W
Battery type: Two pieces of AA batteries or lithium battery pack(3.7V-800mAh)

Ultrasound probe:

Degree of liquid protection provided by sealed equipment: IP21
Working frequency: 2.5MHz±15%
Working mode: Continuous wave doppler
Spatial-peak temporal-peak intensity: < 21.7 kPa
Ultrasonic output intensity: < 10mW
Effective radiating area of transducer: 157mm²±15%

This product is in line with the regulation of the products exempted from publish, the following acoustic parameters of which:

I_{OB}: < 20mW/cm²
P₋: < 1MPa
I_{SPTA}: < 100mW/cm²

6. Maintenance

6.1 Maintenance

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

The user must check that the equipment does not have visible evidence of damage that may affect patient safety or device performance before use. The recommended inspection interval is once per month or less. If damage is evident, replacement is recommended before use.

The equipment should undergo periodic safety testing to insure proper patient isolation from leakage currents. This should include leakage current measurement. 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 equipment and cannot be adjusted by user. If the FHR result is distrustful, please use other methods such as stethoscope to verify immediately or contact local distributor or manufacturer to seek help.

6.2 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 (including display screen) 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 a soft cloth to remove any remaining ultrasound coupling gel. Clean the probe with soap and water only.

- ⚠ 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 part of the device into any liquid.
- ⚠ Do not pour liquids into the device while cleaning.
- ⚠ Do not allow any cleaning solution to remain on the surface of the device.
- ⚠ Wipe the surface of the probe with 70% ethanol or isopropyl alcohol, self-air dry, or clean with a clean dry cloth.

6.3 Disinfecting

Clean the equipment surface and probe as mentioned above, and then wipe the probe surface with 70% ethanol or isopropyl alcohol. Wipe the probe with a clean, dry cloth to remove any remaining liquid substance.

- ⚠ Never try to sterilize the equipment or the probe with low temperature steam or other methods.
- ⚠ The device cannot be repaired by users themselves. All services must be done by technical persons authorized by the manufacturer. This user manual includes proprietary information which is under protection of copyright law. All rights reserved. No part of this document can be photocopied, reproduced or translated to another language without prior written consent of the manufacturer.

In case of modifications and technical upgrades, the information contained in this manual is subject to change without notice.

7. Storage and Transport

Storage: Ambient temperature: -10℃ ~+55℃, relative humidity 10%~93%, no corrosive gases, well-ventilated.

Transportation: Allow transporting by air, ship, truck and rail. Avoid impact, violent vibration and damp during transport.

Label Explanation

⚠ You should know the information to avoid the potential hurt to the patient and doctor.

⚠ You should know this information about how to protect the equipment.

Note: You should know this important information.

📖 Refer to the user manual.

Appendix: Essentiality of Fetal Monitoring

1. Modern medicine proves that the asphyxia, fetal distress and umbilical cord around neck (25% of pregnant has such situation) will affect the normal growing development of fetal, sometimes there will be dangerous to the fetus, even to the mother, and these symptoms will make the FHR changed abnormally, so the FHR gives an indication of fetal well-being.
2. Fetal monitoring tests FHR changes by listening to fetal heart sound mainly; the normal value of FHR is 110-160 bpm.
3. Fetal monitoring is a powerful guarantee to improve generational safety.
4. Pregnant women should listen to the fetal heart sound for 1-2 minutes per time, three times per day (in the morning, at noon, in the evening).
5. Note: Ultrasound gel, water or edible oil must be daubed on the probe while using, and the probe must be placed directly on the abdominal skin.

Using Pocket Fetal Doppler:

If condition is permitted, the pregnant should listen to the fetal heart beating and get FHR three times per day, 1-2 minutes per time. The normal FHR range is 110-160 bpm. When abnormal FHR or abnormal fetal heart beating is got, please contact your doctor immediately.

Morning: Within 30 minutes before pregnant women have breakfast;
Noon: Within 60 minutes after pregnant women have lunch;
Evening: Within 30 minutes before pregnant women go to bed.

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