

OCT BABY

iFM-10B Series Fetal Doppler

User Manual

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1 Safety Guide

This device is internally powered equipment, and the degree of protection against electric shock is Type B applied part. It is IPX1 transducer.

Before use it, please check its lifetime. Its lifetime is 5 years and manufacturing date is labeled at the bottom side of device.

1.1 Important Notice

To avoid the potential harm, please make sure operating complies with follows:

Warning: It is not suitable for using in the environment with flammable gas, such as anesthesia gas, to avoid exploding.

Warning: Do not put the battery into the fire, it will cause exploding.

Warning: Use on one patient only at the same time.

Warning: It is not against defibrillation devices. Do not use it if there is high frequency surgical unit operating, MRI checking. It will do harm to operator and patient.

Warning: The efficient working distance is 5 meters.

Caution: This instrument must be maintained by qualified engineers.

Caution: This instrument is designed to work continuously, and water drop proof type, and be care to avoid to be splashed.

Caution: Avoid vibrating; keep it clean

Caution: Do not sterilize it in high-temperature environment, or use electronic beam or γ beam.

Caution: Before using the instrument, please check if there is any damage of equipment that may affect the patient's safety or the instrument performance. The recommended check period is one month or shorter. If an obvious damage is found, it should be solved before use.

Caution: Following safety check needs to be done by qualified, experienced personnel about every 2 years or follow local

government regulations:

- ✧ Check if there is mechanical or functional damage
- ✧ Check if safety labels are clear
- ✧ Check its function works in compliance with user manual.

Caution: When the device is out of its lifetime, follow local laws to return to manufacturer for recycling.

Caution: The battery should get properly treatment according to local rules after the capability of battery run out.

Caution: This instrument is a hand-held FHR checking device; it can't replace the standard fetal monitoring. End user needs to get professional personals guidance before 1st time using.

Caution: We recommend using minimum monitoring time after meeting clinical monitoring need.

Caution: Do not use the device before battery is well installed.

2 Product Introduction

2.1 General Information

iFM-10B series Fetal Doppler is hand-held monitoring devices. It is made of main unit including battery, transducer and APP software. It is applicable for monitoring of fetal heart rate.

Model No.	Connection between transducer and mobile phone
iFM-10B	Bluetooth

2.2 Features

- ❖ Use same DSP technology as fetal monitors to monitor fetal heart rate, ensure its accuracy and reliability.
- ❖ Very sensitive transducer, the ultrasound power is far lower than Industrial standard, is safe to the fetus.
- ❖ User-friendly interface, easy to use.

- ❖ Fetus Heart Sound output through mobile phone
- ❖ App software features with review, share and antenatal training music.

2.3Configurations

USB cable1piece

Audio cable.....1piece

Ultrasound transducer.....1 piece

User Manual, Warranty Card..... 1set

3 Transducer and software

3.1 Transducer

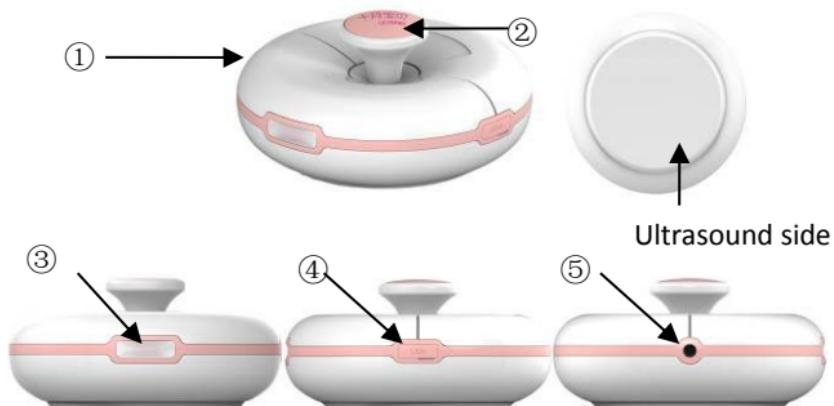


Fig 3-1 Transducer Appearance

- ① Transducer: Receive fetal heart signal
- ② FHR and power indicator
 - FHR (110bpm-160bpm), green
 - FHR(less than 110bpm, over 160bpm), yellow
 - Power recharge: orange flashing

Power recharge finished: Green

③ On/off switch

Press it for 5 seconds for power on and off the device, the Bluetooth function on/off during the device on/off.

④ Mini USB port: connect USB cable

⑤ Audio output

3.2 Software

3.2.1 Software Introduction

This software runs at front-page of the smart phone. It can be interrupted if shift to other software. Do not shift to other software during working.

Name: OCT Baby; Version: 1.0; Platform: Android 2.3 or higher version.

Note: There is no time limit for software running.

This software does not rely on other software and will not affect other software(if there is Android upgrade notice, new version No. will replace old version No.), if delete something, operating system

will give confirmation notice.

Initial Version No. is 1.0; Luckcome provide hardware maintenance only; Any software issue, go to Android website for upgrade; Any software issue does not damage SD card; before upgrade, user need to backup information on SD card as the mother information is stored there. Then connect USB cable to computer for data copy or backup. One smart phone can only be used on one mother only at the same time. Before using, user need to input own information, the mother can monitor fetal heart rate at any place at any time and can store sound and data. It is very convenient for using and storage of precious memory.

This software complies with China Food and Drug Administration 25000.51-2010 regulations.

3.2.2 Software download

Visit www.luckcome.com, download software package. Then install the software as per installation guidance. Before installation, ensure Android system version is 2.3 or higher, Smart phone display

resolution is 1280*720 or higher.

SD card space is over 50M space .

3.2.3 Software Interface

Click  , enter software. New user will see following interface:

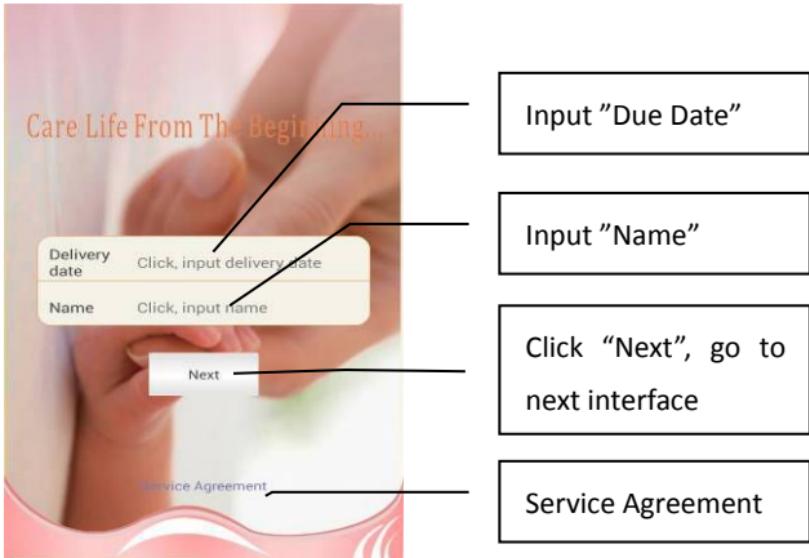


Fig 3-2 1st Interface

1) Please check and review “Service Agreement” firstly, understand related service terms, then input “Due Date” and “Name”. After input, see following interface:



Fig 3-3 Input “Due Date”

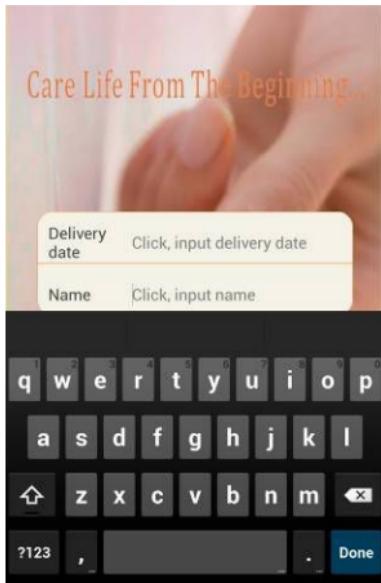


Fig 3-4 Input “Name”

Note: It is a must to input “Due Date”, because all the monitoring data are named by gestation week; gestation week come from Due Date.

2) Click “Next”, if user do not input “Due Date” and “Name”, it will prompt following interface: “Input “Due Date and Name”



Fig3-5 Input “Due Date” indication Fig 3-6 Input “Name” indication

3) After input “Due Date” and “Name”, click “next”, see “Bluetooth connection” interface. Click  to activate communication:



Fig 3-7 Bluetooth Connection

All wireless devices have distance limitation to ensure stable data communication. Blue tooth distance limitation is less than 10meters; we recommend less than 5 meters between this device and smart

phone. Longer than 5 meters, sound output may become non-continuous and will be interfered by other Bluetooth devices. That is normal situation, not device failure.

When log in OCT Baby software, Bluetooth function at smart phonies not on, it prompt “Connection failed”; During testing, if smart phone run out of power, or is at far distance or user turn off Bluetooth function, after 20 seconds, it will prompt “Bluetooth device disconnected”; This software can only connect with Luckcome Fetal Doppler. User can login again after exit of APP.

This APP software and fetal Doppler connect by Bluetooth, Bluetooth delay is less than 1.5 seconds; if hardware is not connected, software can not go to monitoring status; if smart phone platform system error, OCT BABY software will suggest exit to re-activate the system.

4) If connected, it will go to monitoring interface automatically.

If no response, system will give message “Network error”.

Click  to store the data; click again to stop storage.



Fig 3-8 Monitoring Interface

5) Click “Record”, go to record interface to view the record.

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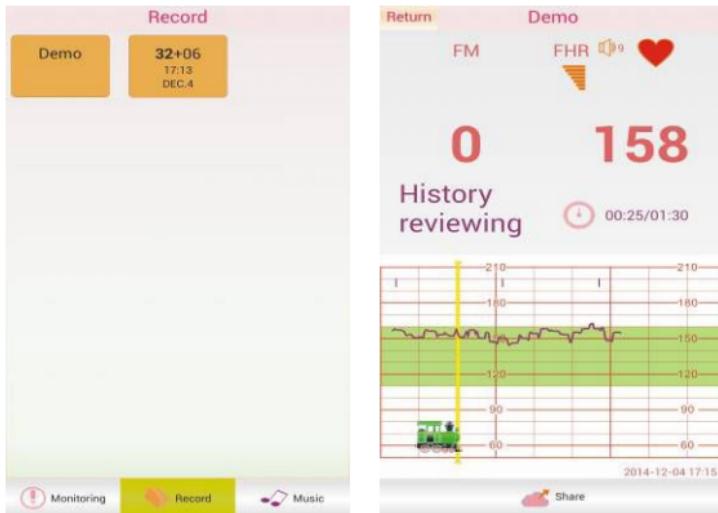


Fig 3-9 Record Review

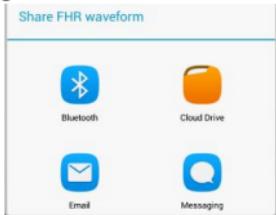


Fig 3-10 Share

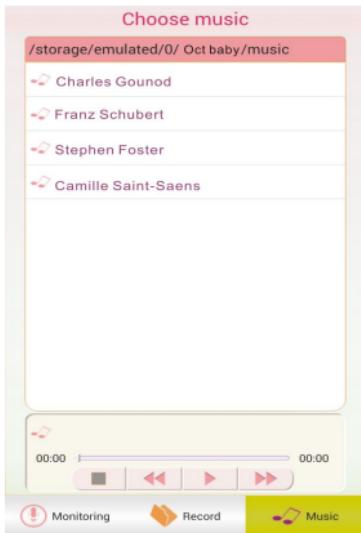
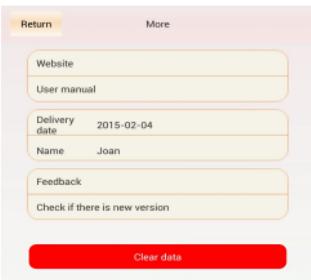


Fig 3-11 Antenatal Training Music

- 6) Click  , go to music interface (see Fig 3-11). User can listen to built in music; or copy favorable music to this folder for listening.
- 7) At monitoring interface, Click  , go to “More”:

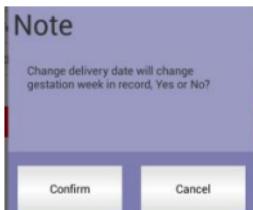


Return----Go back to monitoring interface

Website----Go to www.luckcome.com

User Manual---Open User Manual(PDF format)

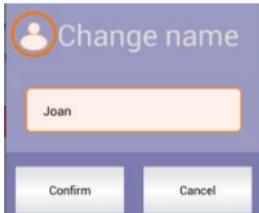
Delivery Date---- Display preinput delivery date, clickitif you want to revise the delivery date.



After delivery, gestation week at history record will change.

Name: Display pre input name; click it if you want to revise the

name.



Feedback --- Go to email interface to write email.

Check and update --- Check software version. If there is new software, message prompt to remind user for update software.

Click “Yes” to update software. After updating, smart phone will auto reactivate the new software; if user does not want to update, click “cancel”.

Clear the data ----- Delete history data(Name, Delivery Date, Record)



4 Device Operations

4.1 FHR Monitoring

Press on the transducer, activate the software. For 1st time use, user need to input “Due Date” & “Name”. If connection succeed, it will go to monitoring interface automatically.

Note: If user forget to press on the transducer, or the transducer power is not enough, it cannot process normal monitoring.



Fig 4-1 Monitoring Interface

Interface Introduction:

Gestation week will be counted automated by this software according to “Due Date”.

 Click , start monitoring, click again, stop monitoring.

 Fetal Movement Marker button

 01:06 Monitored time

 Flashing during monitoring

 Fetal Heart signal status(strong or weak signal)

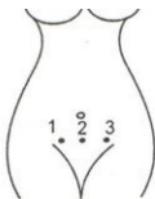
4.2 Fetal Heart Positioning

By touch, find position where heart beats is strong; then put the belt around the abdomen. Put appropriate gel on the surface of ultrasound probe and put it near the fetal heart, adjust the probe to get good fetal heart signal (the sound is clear and with less noise). User can adjust the sound volume as per clinical requirement.

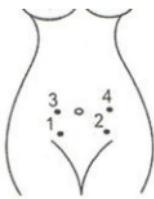
Usually, for the earlier gestational weeks, the fetal heart position is always at 1/3 between navel and pubis, as the fetus grows up, the position will move up, and will be at left or right slightly due to different fetus position. When using the probe, please make sure it touch the skin completely.

Usually, when probe is at the back side of fetus left shoulder, the signal is best. Regular fetal heart sound can be heard, the FHR value will be on display continuously. Then tie the probe here. If probe change its place during monitoring, adjust it to get best signal.

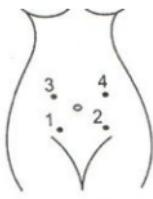
Fetal Heart Position, for reference.



Phase I



Phase II



Phase III

Phase I: Gestation week: 16-24

Phase II: Gestation week: 23-32

Phase III: Gestation week: 32-40

After regular fetal heart beating is heard, click  , start monitoring.

4.3 Fetal Movement

During monitoring, if mother feel fetal movement, click  , this software will make the icon  at the horizontal level of FHR210. At horizontal level of FHR200, the purple bar indicates fetal movement; the length of the bar indicates fetal movement time duration.

4.4 Record

Click “Record” button, go to record list interface. Click the record for review.



During review, user can drag the FHR waveform to left or right.

Click  , waveform will move, and accompany with sound output. Click  , stop wave movement and sound output.

 01:06/01:30 Total display time/Total time.

Click "Return" go back to record list.

Click  , go to share interface. User can share the reviewing record with others.



4.5 Power recharge

This fetal Doppler is equipped with rechargeable Li-Ion battery. If battery is running out of power, please recharge it as per following instructions:

- 1) Connect USB cable, one end to USB port of fetal Doppler; the other end of computer. It starts charging.
- 2) During charging, status indicator is green; power charging

indicator is orange flashing; after finish charging, power charging indicator turns to green.

Note: User can not open the device to take out battery without permit.

Note: If the device is not in use for a long time, please take out the battery to extend battery lifetime.

Note: During charging, the transducer cannot work. After charging, switch on the machine, it can work. If you use charging device instead of computer, the battery charger needs to be CE certified.

5 Technical Data

Product Name: Fetal Doppler

Model: iFM-10B

Classify: Protection against electric shock: internal power supply, type B: ;

Protection against liquid: normal device, (Probe IPX1), do not have waterproof ability;

Protection against flammable gas: not suitable for using in the environment with flammable gas;

Working mode: continuous;

Electromagnetic compatibility: Class I Type B.

Physical Characteristics

Size: 80 mm (Diagram)*43 mm (height))

Weight: 75g ± 10g (include battery)

Working environment: Temperature: +5 °C - +40 °C

Humidity: ≤ 80%

Atmospheric pressure: 86kPa - 106kPa

Transport and storage: Temperature: -10 °C - +55 °C

Humidity: < 93%

Atmospheric pressure: 86kPa - 106kPa

Capability of fetal heart rate:

Measurement range: 50 ~ 210bpm

Accuracy: ± 2 bpm

Speaker power: 1W

Battery: 3.7V rechargeable Li-Ion battery

Ultrasonic probe:

Working mode: Continuous Doppler

Waterproof: IPX1

Acoustic-working frequency: 2.5MHz $\pm 15\%$

Ultrasonic output power: ≤ 10 mW/ cm²

This product is exempted from publishing the following acoustic parameters:

P₀: < 1MPa

I_{ob}< 20mW/cm²

I_{spta}<100mW/ cm²

Effective ultrasound sending area: 245 mm² $\pm 15\%$

6 Maintenance

6.1 Maintenance

The acoustics of ultrasonic probe is a precise instrument that we should handle them gently. Washing the Gel left on transducer after using is very useful for extending the service life of this instrument.

Before using, ensure the device has no obvious damage of device function and which may be harmful to patient. Recommended checking period is one month or shorter. Once there is obvious damage, please replace it.

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 decided by machine itself and can not be adjusted. If you are suspicious of accuracy of result, you can verify it through other devices like a stethoscope; also you can contact local distributors or manufacturers for help.

Only qualified technicians who are certificated by LUCKCOME can repair machine, anyone can't repair machine without special permit. Accessories needed are offered by LUCKCOME only.

6.2 Cleaning

Keep the instrument clean without dust, use a dry and soft cloth to mop outside. If necessary, only a cloth wet with clean water or soapy water can be used.

Do not use strong solvents such as acetone .

Caution: Forbid to use friction material (such as steel wool and silver polishing agent)

Caution: Do not immerse instrument in any liquid

Caution: Do not splash any liquid into the instrument when cleaning

Caution: Do not leave any cleaning liquid on the surface

Note: The probe surface may be use 70% alcohol or Isopropyl alcohol to wipe, dry it in natural air or clean it by a clean, soft cloth.

6.3 Disinfection

As above mentioned way to clean the instrument appearance and transducer, then use the alcohol which density is 70% or isopropyl alcohol to clean the transducer surface. Then use a dry and soft cloth to clean the liquid left on the instrument. No other ways are allowed.

7 Warranty

All maintenances of this instrument should be operated by professional technical persons. The warranty period is 1 year (from the purchased date). All the failures caused by the material failure or production problem are within the warranty range. And all the failed parts are free replaced and repaired. The warranty does not apply if the product:

- has been damaged from improper operation (misuse).
- has been damaged because of improper connection to other equipment.
- has been damaged by accident.
- has been modified without written authorization of the Company.

Note: The information contained in this publication is carefully checked and is believed to be correct. Our company

assumes no responsibility for errors contained herein or for any damage to the user resulting from accidents or any other reasons during operation of the user's unit according to this material.

Note: This User Manual contains special files which are protected by related laws. Without prior written notice, nobody is allowed to copy, photographing, translating any part of this files.

Note: Specifications are subject to change without prior notice.

8 Storage and Transportation

Storage: It cannot be stored in a room with erosive air or bad ventilation.

Transportation: Avoid shock, impact, violent vibration and damp. Explaining the label:

Warning: you should know the information to avoid the potential

hurt to the patient and doctor.

Caution: you should know this information about how to protect the instrument.

Note: you should know this important information.

 Refer to User Manual

 B type applied part

 Waste Electrical and Electronic Equipment Directive 2002/96/EC (WEEE Directive).

Contact information

Shenzhen Luckcome Technology Inc, Ltd

Address: 201, 2F, No.1 Zhongjian Industrial Building, No, 18 Yanshan Road, Shekou, Nanshan District, Shenzhen, Guangdong, China 518067

Tel: +86-755-26853526

Fax: +86-755-26853526

Email: info@luckcome.com

<http://www.luckcome.com>

Tips for 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 growth and life of fetus, sometime it endangers the life of mother. These symptoms will make the FHR changed abnormally, so the FHR gives an indication of fetal well-being.
2. Fetal Monitoring mainly use device to calculate fetal heart rate, check if it is within normal range (110-160bpm)
3. Fetal Monitoring is an important part of ante-partum monitoring
4. Mother should monitor fetus heart rate 3 times a day, morning, noon, night; each time last 1-2 minutes and make record for doctor's reference.

 Morning: Within 30 minutes before breakfast

 Noon: Within 60 minutes after lunch

 Supper: Within 30 minutes before sleeping

5. Note: Add coupling gel before use and put transducers closely to the abdomen skin

Remark: The applicant will display the detail FCC ID label in the formal user's manual of the product. That will be show:

FCC ID:2AG9TLKNIFM10B

Made in China

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may caus

e harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

You are cautioned that changes or modifications not expressly approved by the party responsible for compliance could void your authority to operate the equipment.

In order to protect your right for repair service, please take a few moments to fill out the warranty card below:



Warranty Card

Product		
Model No.		
Serial No.		
Date of Purchase		
Warranty Period		
Customer	Name	
	Tel	
	Fax	
	Address	
Information Resource	<input type="checkbox"/> Network <input type="checkbox"/> Exhibition <input type="checkbox"/> Magazine <input type="checkbox"/> Sales Recommendation <input type="checkbox"/> Other _____	
Comment		