


WARRANTY CARD	
Model No.:.....	Lot No.:.....
Invoice No.:.....	Date of Purchase:.....
Purchased By:.....	Contact No.:.....
Address:.....	
Dealer's Name:.....	
Dealer's Sign & Stamp	Register your product to claim warranty 

* Terms & Conditions apply



Fetal Doppler

MODEL NO. - OFD105

INSTRUCTION MANUAL



Passim Lifesciences Ltd. warrants this units free of any defect in material, workmanship and operation, under normal use, for a period of one year from the date of purchase. If any part become defective during the warranty period Passim Lifesciences Ltd. will repair or replace (if not repairable) the same, free of cost. This shall not apply to any parts that are considered as expandible or deteriorable in the course of normal use. Passim Lifesciences Ltd. shall be relieved of any liability and warranty shall cease to apply if :

- This is not used in accordance with the instructions in the operational manual.
- It is used with any equipment not complying with the specification of this unit.
- It is not regularly maintained.
- The unit is disassembled, repaired or operated by person not authorized by Passim Lifesciences Ltd.
- Damage caused due to negligency.
- The unit is operated in corrosive materials or in the harmful atmosphere.
- The warranty card is not filled completely and produced at the time of warranty claim.

Symbols

-  Medical Device
  Refer Instructions Manual
  Lot No.
  Keep Away From Sunlight
  Warning/Caution
  Serial NO.
-  No Trash
  Manufactured By
  Manufacturing Date
  Must not be exposed in rain or excessive moisture
  Do not use if Package damaged

Manufactured by:

Passim Lifesciences Ltd

Plot No. 45, Ind. Area, Phase-II, Panchkula - 134113, Haryana-INDIA
 Mfg. Lic. No.: MFG/MD/2022/000633
 For any complaint/Suggestion please contact :
 Customercare Number : 1800 309, Timing : 9am - 7pm, Mon. - Sat.
 Email ID : customercare@droidin.in, Website : www.droidin.in

Marketed by:

Odin Healthcare Pvt. Ltd.

Plot No. 45, Ind. Area, Phase-II,
 Panchkula -134113, Haryana- INDIA

IM/OFD/119-00

Please read instruction manual before use

1. Intended Use :-

This device is used to check baby's heartbeat during pregnancy.

2. Manufacturer's responsibility :-

Our company is only responsible for the safety, reliability and performance of equipment under the following circumstances. Namely : Assembly operation, expansion, modification and maintenance are carried out by personnel approved by our company and the equipment is operated according to the user manual.

⚠ Warning :-

The intended use of this equipment is fetal heart rate detection and cannot be used for treatment. If you have doubts about the health of the fetus after using this equipment, please use other methods for further examination immediately, such as stethoscope for verification.

Warranty :-

This equipment cannot be repaired by users themselves and all maintenance treatment should be carried out by technicians approved by the company. The warranty scope of this equipment covers all equipment failures caused by failure of materials and equipment or production process. During the warranty period, all faulty parts can be repaired and replaced free of charge (except warning part). Man-made damage is not covered by the warranty.

The annotation of this manual.

3. Safety Guide :-

This equipment is an internal power supply equipment and the electric shock protection type is B application part. Type B application parts are equipment with specific degree of protection against electric shocks. Type B protection means that the equipment connection shall comply with ICE 60601-1 for permission leakage current and dielectric strength. This equipment conforms to GB/t 14710-2009 climate Environment Group II and Mechanical Environment Group II.

In order to avoid possible injury, please observe the following safety instructions when operating this equipment :

⚠ Warning :-

Do not use in places with combustible gases such as paralytic agents, which may cause explosion.

⚠ Warning :-

Do not throw the battery into the fire to avoid explosion. Waste shall be disposed of according to relevant national regulations.

⚠ Warning :-

Do not touch the signal input or output connector and the patient at the same time.

⚠ Warning :-

Do not use with high frequency surgical equipment.

⚠ Warning :-

Accessory equipment connected to analog and digital interfaces must be verified against their respective IEC standards (e.g. Medical equipment Standard IEC 60601-1) and all configurations should conform to the valid version of IEC 60601. Therefore, personnel who

connect accessory equipment to signal input connectors or signal output connectors should ensure that the system meets the requirements of the valid version of IEC 60601-1 when configuring the medical system. If in doubt, please consult our technical service department or your local agent.

⚠ Warning :-

Fetal Doppler (hereinafter referred to as "Fetal Doppler") is a hand-held fetal heart rate examination tool and cannot replace standard fetal monitoring.

ⓘ Caution :-

If the equipment is not used for a long time, please turn off the power in time.

ⓘ Caution :-

The equipment must be stored in a cool and dry environment.

ⓘ Caution :-

This equipment should be returned to the manufacturer for recycling or disposal according to local regulations after its effective life.

When cleaning the equipment :

ⓘ Caution :-

Do not use string solvents such as acetone.

ⓘ Caution :-

Do not use abrasive materials (such as steel wire or silver polish).

ⓘ Caution :-

Do not let any liquid into the casing and do not invade any part of the equipped into the liquid.

ⓘ Caution :-

Do not liquid into the equipment during cleaning.

ⓘ Caution :-

Do not let any cleaning liquid remain on the surface of the equipment.

When disinfecting the equipment :

ⓘ Caution :- Do not sterilize the equipment or probe by high and low temperature, steam or other methods.

Not :- See the random file.

4. Product Instruction :-

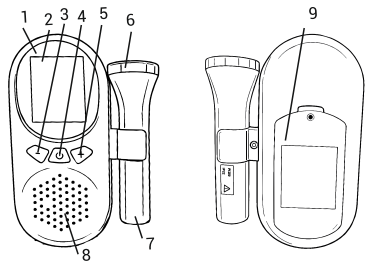
1 Structural composition :- This product consists of a main and an external ultrasonic probe. The main unit includes a display unit, a signal processing unit, an audio output unit and a button input unit. The ultrasonic probe includes an ultrasonic transducer and a micro-signal processing processing unit.

2. Scope of application :- This product is suitable for measuring and monitoring fetal heart rate.

3. Expected uses :- This product is for pregnant women to detect fetal heart rate, for medical staff who have received relevant professional training or pregnant women to use in hospitals, clinics, communities and families.

4. This Product can be used from 16 Weeks onwards.

5. Appearance :-



- 1. Main Unit
- 2. Display Mode
- 3. Volume down button
- 4. On/off button
- 5. Volume up button
- 6. Probe
- 7. Probe connection cable
- 8. Speaker
- 9. Battery cover

6. Display Content and Interpretation :-

1		Fetal heart signal. It twinkles with fetal heart beat
2	bpm	Fetal heart rate unit, byte per minute
3		Battery level
4		No FHR value, it indicates the probe does not connect well with main unit or there is not fetal heart signal
5		Sound level

7. Control button function:-

7.1. Power Switch button:-

Function: Control the power supply on/off

Startup: In the shutdown state, press the power switch button to start the equipment.

Shutdown: In the startup state, press the power switch button 3s for a long time to shut down the equipment. Press the power switch button, can quickly exit the menu or storage playback interface, back to the main interface.

7.2. Volume Up/Down button :-

When the equipment is turned on or working, if the sound is to low, press the volume increase button to increase the volume. If the sound is to high, press the volume decrease button to decrease the volume.

7.3. Menu Setting :-

When the device is power on, Press key can switch Mode and Menu items.

History Curve Mode :- In the boot state, the default is digital mode . Click the button condition. If it is not in good condition, please stop using the equipment and contact the manufacturer immediately, and keep the packaging materials for later transportation or storage.

8. Using Batteries :- Installing battery Turn over the equipment, hold the body with one hand, press and hold the battery compartment with the other finger , slide along the arrow direction, remove the battery cover, load the battery correctly according to the direction indicated by the battery, and close the battery cover after the battery is loaded.

9. Recommended Battery Type :- AA Alkaline Battery (AA R6 1.5 V) Note: If the positive and negative electrodes of the battery are installed incorrectly, the equipment will not run normally.

1. Remove battery Open the battery cover and remove the battery.
2. Battery low charge detection When working normally, the LCD screen displays power information, the number of squares in the battery icon indicates the amount of remaining power, and when the number of squares is zero, it indicates that the battery power is very low.

10 . Probe operation :-

Hold the upper end of the probe first and pull it out.

10.1. Fetal heart rate detection :-

10.2. Fetal heart rate detection steps :-

1. Maintain a Jennifer mood and take a supine position. The recommended measurement time is 30 minutes after getting up, 30-60 minutes after lunch, and half an hour before going to bed. The length of a single measurement is 1-2 minutes.
2. Coating a proper amount of coupling agent on the probe surface of the fetal sound equipment;
3. Press the power switch-on button to start up;
4. Press the probe close to the abdominal wall, and move the probe within the position of the fetus to find it. The probe should not move too fast, but should stay for more than 5 seconds. After finding the best auscultation position, adjust the volume and select the best volume gear until you hear clear and rhythmic fetal heart sounds and have a stable fetal heart rate value.

10.3. Method of finding fetal heart position

1. Refer to the fetal heart position recently found by the doctor, and slowly find it near this position.
2. Because the fetus moves in the abdomen at any time, the position of fetal heart may also change:-
Before 6 months, the fetal heart rate was often located in the middle or both sides of the umbilicus
6-8 months, as the fetus grows up, the position of fetal heart rate will also move up. The loudest position of fetal heart sounds is on the back of fetus. Fetal movement is usually the fetus
The hands and feet are moving. If the right side feels frequent fetal movement, the fetal heart rate is generally on the left side; When the left side feels frequent fetal movement, the fetal heart rate is generally on the right side
If you don't hear the fetal heart, you can patiently look near the fetus
If you find that you can't hear the fetal sound suddenly at the original position, but you can feel the fetal movement, it means that the fetal position has changed, so you can find it slowly near the original position. If the fetal movement is not obvious, please go to the hospital immediately.
When the fetal heart rate is normal, it fluctuates in the range of 120-160 times per minute. If it is confirmed that it is more than 160 times per minute or less than 120 times per minute, you should go to the hospital for treatment



Early-term of pregnancy
(16-24weeks)



Mid-term of pregnancy
(24-32 weeks)



Later-term of pregnancy
(32-40 weeks)

Precautions:-

1. Before use for the first time, please open the battery cover of the fetal sound equipment and install the alkaline dry battery that meets the requirements.
2. Do not move the probe all the time during use, but stay the probe for about 5s. If the fetal heart rate is not found, move the probe to continue measuring.
3. Don't mistake the sound of mother's heart rate and umbilical blood flow for fetal heart sounds.
4. Put the probe close to the abdominal wall, with a little softness, not just tiptoe on the belly to prevent the noise caused by air between the probe and the belly.
5. In actual use, please do not press hard so as not to cause abdominal muscle tension, which will weaken fetal heart sounds and affect auscultation effect.
6. Better detection results can only be obtained by placing the probe in the best

position, and do not place the probe in a place where strong placental sounds or umbilical cord blood pulsation can be heard.

7. It is impossible to detect fetal heart rate unless audible fetal heart sounds are obtained.

11. Method for determining fetal heart rate :- At the moment of hearing fetal heart sounds, you can't read immediately, and the number displayed after the probe is relatively fixed for 5 seconds is accurate. At the same time, the heart rate displayed by the equipment will change with the change of fetal heart rate. Usually, fetal heart rate is normal at 120-160 beats/min, and critical at 100-120 beats/min and 160-180 beats/min, which should be paid attention to.

12. End of fetal heart test :- After the fetal heart test, please turn off the fetal sound equipment first, then wipe the coupling agent left on the probe surface of the fetal sound equipment and the abdomen of pregnant women with paper towel, and put the probe into the probe card to protect the probe.

13. Frequently Asked Questions :-

Where is the fetal heart rate generally?

Before the 24th week of pregnancy, the fetal heart rate is usually located in the middle or both sides under the umbilicus, between the navel and pubis, and sometimes it is necessary to move the probe to point close to the pubis.

13.1. How to find fetal heart rate?

Apply a proper amount of coupling agent on the surface of the probe. When looking for fetal heart rate, the probe must move the probe slowly and in a small amplitude (about 1 cm), stay for 5 seconds after selecting the position and search patiently. After hearing the fetal heart sound, continue to move the probe around to find a clear, loud any rhythmic position and keep the probe still after finding it. The fetal heart rate displayed after 3-5 seconds is the accurate fetal heart rate.

13.2. After finding the fetal heart rate, it will disappear for a while. What's the matter?

Because the fetus will move in the abdomen at any time, the position of fetal heart will change accordingly, so if you can't hear the clear fetal heartbeat or the heartbeat sound is weak, you should immediately move the position of the probe to find the best position again.

13.3. How to judge the sound fetal heart rate?

Fetal heart sound is like horseshoe sound, which is a continuous rhythmic sound. After hearing the rhythmic sound, the value displayed on the screen is 110-160 (it may exceed 160 before 20 weeks, and the more careful the gestational age, the faster the rate). The stable fluctuation number is the current effective heart rate value of the baby.

13.4. Why is there a numerical display when you first open?

Under normal circumstances, there is no numerical display on the boot, only display--, the boot has a numerical value may be the user in the boot touched the probe position, or shaking the equipment caused. The value at this time is not the true fetal heart rate.

13.5. Why is there noise when measuring?

The fetal sound equipment can sense any sound vibration, including air vibration.

Therefore, there will be noise after starting up, which is a normal phenomenon. In the measurement process, noise will be generated due to fetal movement and probe movement. At the same time, if the user does not find the correct position, fetal movement, amniotic fluid, pregnant woman's body movement, cord blood flow, pregnant woman's breathing, cough and other factors will also lead to noise. Coated with coupling agent, the probe presses the skin slightly, which can effectively reduce the noise.

13.6. How often do you test it? Will it affect your children if you test it too much?

All indicators such as electromagnetic radiation of fetal sound equipment meet the national standards, so daily fetal heart rate detection can be carried out with confidence. Under normal circumstances, it is recommended to measure it 2-3 times a week for 1-2 minutes each time. Older pregnant women and pregnant women with abortion history can appropriately increase the frequency of use.

13.7. How many weeks can I start listening to my baby's fetal heart?

It is recommended to find fetal heart after 16 weeks.

14. Technical indicators

Product name:	Fetal Doppler
Product model:	OFD105
Software release version:	V2.0

15. Electrical Safety :-

Type of electric shock protection	Internal power supply equipment
Degree of resistance to electric shock	Type B application part
Power connection conditions	AA Battery = DC 3v
Degree of liquid inlet prevention	Probe protection level IPX1
Safety degree with combustible gas	It is not suitable for use in the environment with combustible gas
Operating mode	Continuous work
Electromagnetic compatibility	Group 1 Class B

16. Physical Properties

Dimensions	125x50x25mm
Weight	240g(with battery)

17. Performance Parameters

Ultrasound Intensity	2MHz
Fetal heart rate range	50-230bpm
Error of fetal heart rate measurement	Not more than 2bpm
Comprehensive sensitivity	Not less than 90dB (probe surface distance 200mm)

18.

Working environment	Temperature: + 5 °C ~ + 40 °C Humidity: 25% ~ 80% Atmospheric pressure: 70kPa ~ 106kPa
Transportation and storage	Temperature: -25 °C ~ + 70 °C Humidity: ≤ 93% Atmospheric pressure: 50kPa ~ 106kPa Transportation conditions: fall-proof, earthquake-proof and moisture-proof Storage conditions: dry, clean and normal temperature

19. Maintenance and Troubleshooting

19.1. Maintenance

The device is precision equipment, and the probe acoustic surface is frangible, you need to handle the device especially probe with enough care. Gel and dirt must be wiped from the probe after using. These precautions will prolong the life of the unit and keep the examination precision.

Before using, the user must check that the equipment does not have visible evidence of damage that may affect patient safety or device capability. The recommended inspection interval is once per month or shouter time. If damage is evident, reparation is recommended before use.

19.2. Troubleshooting

When using, if it appears following problems, please treat by following instruction. If fail to treat, please contact local distributor or manufacturer.

19.3. No Sound

Main reasons: (1) The battery volume is serious insufficient; (2) The equipment is damaged; (3) The battery connection line is damaged.

Solution: (1) Charge the battery or change battery; (2) Inspect the device; (3) Contact dealer or manufacturer.

19.4. Weak Sound

Main reasons: (1) Voice volume is too low; (2) Battery volume is too low; (3) Without or insufficient gel.

Solutions: (1) Adjust higher voice volume; (2) Change or charge the battery; (3) Add sufficient gel on probe inspecting surface.

19.5. Noise

Main reasons: (1) Probe is too near from the main unit; (2) Disturbance from the outside signal; (3) Battery volume is too low.

Solutions: (1) Keep the probe far enough from main unit; (2) Be away from the outside signals; (3) Change or charge the battery.

19.6. Low Sensitivity

Main reasons: (1) Probe position is incorrect; (2) Without or insufficient gel.

Solutions: (1) Keep the probe at right position; (2) Daub sufficient gel.

20. Equipment Maintenance

If the equipment is not used for a long time, please take out the battery and store it.

1. Preservation :-

Prevent water or other liquids from immersing in the equipment and probe, and keep it in a dry and clean place.

After the equipment is used, if the shell is dirty, it can be scrubbed with neutral detergent.

2. Precautions :-

1. The inside of the equipment is a precision electronic circuit, please do not open it without authorization
2. Do not collide with the probe surface, so as not to cause damage to the chip.
3. The appearance of the equipment can be wiped and cleaned with non-corrosive detergent. Do not disinfect at high temperature or clean with corrosive detergent. The probe can be wiped and disinfected with a small amount of alcohol.
4. After each monitoring, clean and disinfect with cloth or paper towel.
5. The equipment is forbidden to collide to avoid damage.
6. Please pay attention to waterproof and moisture-proof equipment.
7. After each use, the power should be turned off to prolong the use time monitoring
8. When the external ultrasonic probe reaches its service life, please replace the probe of the same type in our company in time in order to make the more accurate.

21. Maintenance, Cleaning and Disinfection

1. Maintenance :- Fetal Doppler is a precision equipment, which must be handled with care. The excess coupling agent on the probe must be wiped off after the equipment is used.

These maintenance measures will prolong the service life of the equipment.

Before use, the user must check that the equipment is free of obvious damage that may affect patient safety or equipment performance. The recommended inspection cycle is once a month or less. If obvious damage is found, it is recommended to replace the damaged parts before use.

The equipment shall be periodically inspected to ensure leakage current insulation, including leakage current measurement.

The recommended test cycle is once every two years or according to the regulations formulated or inspected by public institutions.

The accuracy of fetal heart rate is controlled by hand equipment and cannot be adjusted by user. If fetal heart rate results are not credible, use other methods, such as using a stethoscope for verification, or contact your local agent or manufacturer for assistance.

2. Cleaning :- Please turn off the equipment before cleaning.

Keep the appearance of the fetal sound equipment clean, free of dust and dirt, and clean the outer surface of the casing (including LCD display) with a dry and soft cloth.

Wipe off the excess coupler on the probe with a soft cloth.

ⓘ **Caution :** Do not use strong solvents such as acetone.

ⓘ **Caution :** Do not use abrasive materials (such as steel wool or polishing agent).

ⓘ **Caution :** Do not let any liquid into the casing, and do not immerse any part of the equipment in liquid.

ⓘ **Caution :** Do not pour liquid into the equipment during cleaning.









ⓘ **Caution :** Do not let any cleaning liquid remain on the surface of the equipment.

Note :- The probe surface can be wiped with 70% alcohol, air-dried naturally or cleaned with a clean and dry cloth.

3. Disinfect :- Clean the equipment surface and probe as described above, and then wipe the probe surface with 70% alcohol. Wipe the probe with a dry, soft cloth to remove liquid substances remaining on its surface.

ⓘ **Caution :** Do not sterilize the equipment or probe by high and low temperature, steam or other methods.

22. Symbolic Information and Interpretation

S/N	Symbol	Description
1		Note that refer to the attached document
2		Important information about operation and product safety.
3		Afraid of wet, this symbol also means "keep dry".
4		The upper and lower temperature limits should be marked near the upper and lower horizontal lines.
5		Humidity limits should be shown near the upper and lower horizontal lines.
6		DescAtmospheric pressure limits should be shown near the upper horizontal line and the lower horizontal line. iption
7		This symbol indicates that the mesh atomizer cannot be discarded as domestic garbage. Please hand over the old or unused mesh atomizer to the waste disposal station for electronic waste disposal or to your hearing care specialist for disposal. Reasonable treatment will protect the environment and health.
8		Type B application part