CE 0598

tenovi

User Manual
Fetal Doppler

Model: TE-BFDG-A1

Manual Version: 3.0
Issuing Date: 2024.4

Thank you for purchasing the Fetal Doppler made by Tenovi. Before using the product, read this manual carefully and operate the product as specified in this manual.

SECTION 1: INTRODUCTION

1.1 PACKING LIST

Main unit×1;
Battery AA×2;
Coupling agent×2
User manual×1.

1.2 PRODUCT DESCRIPTION

The product is mainly used to detect the sound of the fetal heartbeat (SFH). Fetal heart rate (FHR) is important basis for checking whether a fetus is healthy. Recording the changes in FHR helps detecting signs of fetal hypoxia, fetal distress, fetal umbilical cord around neck, and so on. Fetal monitoring at home mainly includes listening to fetal heartbeat and checking FHR changes, which help greatly increase fertility safety.

1.3 OPERATING PRINCIPLE

Using Doppler's principle, a 3.0MHz ultrasonic probe detects fetal heart signals from the abdomen of a pregnant woman. The backend circuit processes these signals, outputs them to speakers for audio playback, and wirelessly transmits the data via its built-in Bluetooth module. A smartphone connected to the device receives the data, calculates the fetal heart rate using dedicated mobile software, and displays the result.

SECTION 2: SAFETY GUIDANCE

2.1 INTENDED USE

The Fetal Doppler TE-BFDG-A1 is a hand-held, battery powered audio Doppler device used for detecting fetal heartbeats. The patient is an intended operator.

2.2 INDICATIONS FOR USE

The product is normally applied to fetus above 12 weeks growth, difference in pregnant mater.

- Listen to SFH: Operator can listen to the sound of fetal heartbeat from the speaker.
- Audio record: The sound of fetal heartbeat can be recorded by APP.

CAUTION: It should not be used in life supporting or life sustaining applications.

2.3 CONTRAINDICATIONS FOR USE

The device has no side-effects if administered correctly and residual risk is acceptable.

2.4 NOTE FOR HOME USE

This device cannot replace a professional fetal monitor. If the fetal heart rate is abnormal or cannot be located by using this monitor, pregnant woman should immediately go to the hospital to seek the doctor's help. If fetal movement is not felt by the pregnant woman, immediately go to the hospital to seek the doctor's help.

2.5 SAFETY TERMS AND CONDITIONS

The signal words shown below left, identify the potential hazard categories. The definition of each category is as follows:

DANGER: This alert identifies hazards that will cause serious personal injury or death.

WARNING: This alert identifies hazards that may cause serious personal injury or death.

CAUTION: This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

2.6 SAFETY ALERT DESCRIPTIONS

The following is a list of product safety alerts that appear in this section and throughout this manual. You must read, understand, and pay heed to these safety alerts before attempting to operate the product.

DANGER: Fire and Explosion Hazard
Do not operate the product in the presence of flammable gases to avoid possible explosion or fire hazard.

WARNING: Strangulation resulting from baby or child entanglement in monitoring cables.

WARNING: Do not modify this equipment without authorization of the manufacturer.

WARNING: Dust, light may affect the safety and performance of the instrument.

WARNING: Degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems.

WARNING: The effects caused by pets, pests or children

WARNING: Use only Approved Equipment
Do not use batteries, gel, cables, or optional equipment other than those approved by manufacturer which may cause the product to function improperly during a rescue.

WARNING: Adjacent and/or Stacked Equipment
The Product should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Product should be observed to verify normal operation in the configuration in which it will be used.

CAUTION: Check that the equipment does not have visible evidence of damage that may affect personnel's safety or examining capability before use. If damage is detected, replacement is recommended.

CAUTION: The surface of the probe in contact with the patient may cause discomfort due to biocompatibility issues. The coupling agent may cause skin allergies in users. If the patient experiences any discomfort or allergic reactions, usage should be immediately discontinued and medical attention sought if necessary.

CAUTION: Do not wrap the probe wire to avoid suffocation.

CAUTION: Don't touch patient, power port ,and probe at the same time.

CAUTION: This product is not recommended for use on ships and aircraft.

CAUTION: Please keep the Fetal Doppler and batteries out of the reach of children to prevent them from playing with them. In the event that a child accidentally swallows a battery, seek immediate medical attention.

CAUTION: Temperature/Humidity/Pressure extremes
Exposing the Product to extreme environmental conditions outside of its operating parameters may compromise the ability of the Product to function properly.

CAUTION: Battery Disposal
Recycle or dispose of the battery in accordance with the local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

CAUTION: Possible Radio Frequency (RF) Susceptibility
RF susceptibility from cellular phones, CB radios and FM 2-way radio may cause interference with the product. Do not operate wireless radiotelephones in the vicinity of the Product – turn power OFF to the radiotelephone and other like equipment near the Product.

CAUTION: Systems Statement
Equipment connected to the product must be certified to the respective IEC Standards (IEC 60601-1 for medical equipment).

CAUTION: Case Cleaning Solutions
When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

CAUTION: Environment of use
The product is designed for indoor use. Operator must confirm that the environment of use meets the required operating environmental specifications before using.

CAUTION: Cold Environments
If the product is stored in an environment with a temperature below the operating temperature, the unit should be allowed to warm up to the needed operating temperature before using.

CAUTION: Do not use the device with HF surgical equipment.

2.7 SYMBOL DESCRIPTIONS

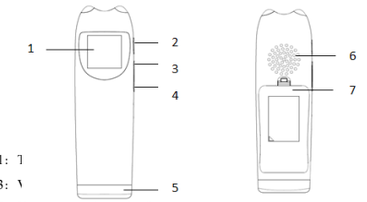
The following symbols may appear in this manual, on the product, or on its accessories. Some of the symbols represent standards and compliances associated with the product and its use.

	Consult instructions for use of the product and/or its accessories.
MD	Medical Device
	Warning Information.
EC REP	Authorized Representative in the European Community.
	This product complies with the Regulation (EU) 2017/745 requirements.
	Date of manufacture.
	Manufacturer information.
	type BF applied part
SN	Specifies serial number of the Product
LOT	Batch code
5	The environmental protection use period is 5 years.
IP22	Degree of protection against ingress of water and particulate matter.
	It indicates that the equipment should be sent to the special agencies according to local regulation for separate collection after its useful life.
	Storage Temperature
%	Humidity
	Atmospheric Pressure

SECTION 3: USING THE PRODUCT

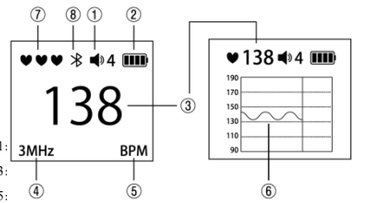
This section provides the description for operation.

3.1 PRODUCT STRUCTURE



1：
3：
5：Ultrasonic probe 6：Speaker
7：Battery compartments

3.2 INTERFACE DISPLAY



7：FH Signal 8：Bluetooth

3.2.1 Power on/off

Power on: Press and hold ⏻button for about 2s and the screen lights up, and the device is powered on. In power on state, short press⏻button to switch the display mode.

Power off: In the power-on state, press and hold ⏻ button for about 2s, the screen goes out, and the device is powered off.

3.2.2 Volume adjustment button

While monitoring, the volume increases by press "+" button, and the volume decreases by press "-" button. There are 7 volume levels.

3.2.3 Icons

: In curve mode, when a fetal heartbeat is detected, the heartbeat symbol will light up and flash with the heart rate. In value mode, this symbol signifies the quality of the detected fetal heart signal. Three heart symbols represent the best signal quality, while zero heart symbol indicate that no fetal heartbeat signal was detected. It is important to follow the correct method to locate the optimal fetal heart position.

: The number next to the volume symbol indicates the volume and can be adjusted from 0-7.

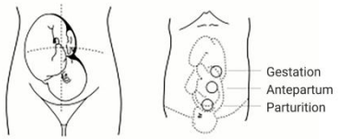
: When the icon displays in red , it means that the battery is about to run out and needs to be replaced in time.

: The Bluetooth icon is green when the Bluetooth is connected, and is white when disconnected.

3.3 USING PRODUCT TO DETECT

Locate the position of the fetus by hand touching, firstly to find out the best direction to the fetal heart. Place the panel of probe at the best position for detecting fetal heartbeat. Adjust the transducer to obtain an optimum audio signal ideally by angling the transducer around. Generally, the site of heart of fetus is 1/3 below of navel line at its earlier stage, it then moves upward with increasing of gestational period, and the site of heart of fetus will be a little deviation to left or right with different fetuses. Please make sure that the surface of the probe should be fully contacted with the skin. After the sound become clear, it is the proper functioning. If no coupling gel, water can be used.

Note: The normal range of fetal heart rate is 110 bpm-160 bpm. During measurement, values are displayed in white within the normal range and in red when they are out of range.



SECTION 4: MAINTENANCE & CLEANING AND DISINFECTION

4.1 MAINTENANCE

4.1.1 The transducer acoustic surface is frangible and must be handle with care .Gel must be wiped off from the transducer after use. These precautions will prolong the life of the unit.

4.1.2 To ensure the product is always functional when required, the following maintenance shall be performed.

- Visual Inspection
- Clean the product and its accessories
- Check the battery fuel gauge
- Test product performance
- Remove the battery if it is not used for a long time.
- The product requires no calibration.

Note: No service and maintenance while the equipment is in use.
Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions ,or other information that will assist to service personnel in parts repair.

4.2 CLEANING PRODUCT AND ACCESSORIES

The following cleaning products may be used to clean the exterior surfaces of the product.

- Isopropyl alcohol (70% solution in water)
- Mild soap and water
- Sodium hypochlorite (chlorine bleach) (3% solution in water).
- Quaternary ammonium compounds (such as Lysol) (10% solution in water).

WARNING: Do not use abrasive cleaners or strong solvents such as acetone or acetone-based cleaners.

WARNING: Do not use mixing disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.

WARNING: Do not use acid, alkaline, or corrosive detergent.

WARNING: Do not clean electrical contacts or connectors with bleach.

4.3 CLEANING INSTRUCTIONS

1. Before cleaning the product, turn off the product.

2.Before cleaning, remove all adherent soil (tissue, fluids, etc.) and wipe thoroughly with a cloth dampened with water before applying the cleaning solution.

3.When cleaning, do not immerse. Keep the exterior surface of the device clean and free of dust and dirt, clean exterior surface of the unit with a dry, soft cloth, if necessary, clean it with a soft cloth soaked in a solution of soap and wipe dry with a clean cloth immediately. Wipe the transducer body with soft cloth to remove any remaining coupling gel .Clean with soap only.

CAUTION: To prevent damage to the product, do not clean any part of the Product or Accessories with phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not steam, autoclave, or gas-sterilize the Product or accessories.

CAUTION: Cleaning liquids: do not submerge the product in liquids or pour cleaning liquids over, into or onto the product.

4.4 DISINFECTION

Cleaning the unit surface and the transducer as the above mentioned, then wipe the surface of transducer with 75% ethanol or alcohol, clean the transducer surface with a dry, soft cloth.

WARNING: Don't use low temperature steam sterilization or other way to sterilize.

WARNING: Don't use high temperature sterilizing process.

After cleaning or disinfection, check if the Doppler function well. If any problem is detected, please contact the manufacturer for service before reusing them.

Visual Check：Check if the Doppler probe and host are damaged；

Function Check：

1.Check if the Doppler can be switched on or off properly;

2.Check if the TFT works normally;
3.Rub the surface of the probe with your hand to check if the Doppler is producing sound properly

SECTION 5: SPECIFICATIONS & TROUBLESHOOTING

This section presents the specifications and safety standards of the Product.

5.1 SPECIFICATIONS

Note: The following specifications are subject to change and are only noted as a point of reference.

Technical Specifications

Acoustic working frequency: 3.0MHz±5%
Overall sensitivity (200 mm off the probe surface): not lower than90 dB
Spatial-peak temporal-peak acoustic pressure: < 0.1 Mpa
Ultrasound output power: ≤ 20mW
FHR display range: 50 – 210 bpm
Resolution: 1 bpm
Precision: ± 2 bpm
Curve display range: 90 – 190 bpm
Battery: AAx2
Work mode: continuous (The device can work continuously for over 4 hours)
Dimension: 142.6mm x 40.5mm x 42.5 mm
Weight: 130± 5 g
Ultrasound coupling agent requirement: density = 1.0g/cm2; speed ≤1.7m/s; impedance ≤1.7×10^5g/cm2.s; attenuation ≤0.02dB/mm
P_ < 1MPa; Iob < 20 mW/cm2; Ispta < 100mW/cm2
Manufacturing date: See the label.
Device life expectancy: 5 years
Waterproofing grade: IP22
Safety type: Internally powered equipment, type BF applied part
Software version:1.0
Operation conditions: Temperature: 5°C to 40°C; Humidity ≤80%RH; non-condensing Atmospheric pressure:70kpa to 106kpa
Transportation & Storage conditions: Temperature: -20°C to 55°C; Humidity:10%RH – 93%RH; non-condensing Atmospheric pressure:50kpa to 106kpa; indoor ventilated place that has no corrosive gas

Equipment heating time

-the time required for the equipment to warm from the minimum storage temperature between uses until it is ready for intended use: 30min.
-the time required for the equipment to cool from the maximum storage temperature between uses until it is ready for intended use: 30min.

5.2 Troubleshooting

Symptom	Possible cause	Troubleshooting
Power-on failure	Low battery	Charge the instrument
No sound	Low volume Low power	Increase the volume Replace the battery
Fetal heart cannot be found	Low volume The coupling agent is not coated	Increase the volume Coat the coupling agent or water
Low sensitivity	Incorrect probe location The coupling agent is not coated	Adjust the probe location Coat a proper amount of coupling agent
Bluetooth connection failed	Bluetooth on phone is not turned on	Manually turn on the Bluetooth function of the mobile phone

EMC Information

1* WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally."

2* WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

3* WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

Table 1

declaration - electromagnetic emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable

Table 2

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

Table 3

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	Not applicable
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m

Table 4

declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.					

FCC Statement

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.
changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
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 cause 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.
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

SECTION 6: CONTACT INFORMATION

6.1 Ultrasound Intensity and Safety

6.1.1 Ultrasound in Medicine

The use of diagnostic ultrasound has proved to be a valuable tool in medical practice. The ultrasound output of the device is controlled internally and cannot be changed by the user during the inspection process. Although no confirmed bioeffects on patients caused by exposure from present diagnostic ultrasound equipment have ever been reported, the potential exists that such bioeffects may be identified in the future. Therefore, the ultrasound should be used prudently. High levels of acoustic output and long exposure time should be avoided while acquiring necessary clinical information.

6.1.2 Explanation of MI/TI

6.1.2.1 MI (Mechanical Index)

When ultrasound waves penetrate and contact tissues, cavitation effects may occur, causing local instantaneous high temperatures. The occurrence of this effect depends on various factors and has a threshold phenomenon. Currently, there are no reports of harmful mechanical effects from human use of ultrasound diagnostic equipment, and the threshold for cavitation effects is unclear. As the peak sound pressure of ultrasound waves increases, the occurrence rate of mechanical effects increases, but decreases with increasing frequency. The American Institute of Ultrasound in Medicine and the National

Electrical Manufacturers Association have established the Mechanical Index (MI) to characterize the probability of ultrasound mechanical effects.

6.1.2.2 TI (Thermal Index)

Heating of tissues is caused by absorption of ultrasound when the ultrasound energy is applied. The temperature rise is determined by the acoustic intensity, exposed area and thermophysical properties of the tissue.
According to different thermophysical properties of the tissue, TI is divided into three kinds: TIS, TIB and TIC.
TIS (Soft Tissue Thermal Index): It provides an estimate of potential temperature rise in soft or similar tissues.
TIB (Bone Thermal Index): It provides an estimate of potential temperature rise when the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.
TIC (Cranial Bone Thermal Index): It provides an estimate of potential temperature rise in the cranial bones or superficial bones.

6.1.3 Ultrasonic output limitation

The acoustic output parameter meets the provision freedom from publication in IEC 61157 Requirement for the declaration of the acoustic output of medical diagnostic ultrasonic equipment: Pr<1MPa; the output power divided by the 12dB output beam area is not less tan 20mW/cm2; Ispta<100mW/cm2.
Note: For all equipment settings, the thermal index and mechanical index are less than 1.0.

6.2 Statement:

The lay operator or lay responsible organization should contact the manufacturer or manufacturer's representative on the following issues:
Assistance in setting up, using, or maintaining the equipment or system when needed.
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authorities of your Member State.

6.3 Manufacturer

Manufactured for Tenovi Co.
1 Cate Street, STE 100,
Portsmouth, NH 03801