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Section 1
Safety

1.1 Instructions for the Safe Operation and Use of the BT-220 Doppler

- Examine the Doppler and any accessories periodically to ensure that the cable and batteries do not have visible evidence of damage that may affect patient safety or performance. Do not use the Doppler if there is any visible sign of damage.
- Do not attempt to service the BT-220 Doppler. Only qualified service personnel by Bistos Co.,Ltd. should attempt any needed internal servicing.
- The BT-220 is not specified or intended for operation during the use of defibrillators or during defibrillator discharge.
- The BT-220 is not specified or intended for operation in the presence of electrosurgical equipment.
- The BT-220 is not specified or intended for operation in conjunction with any other type of monitoring equipment except the specific devices that have been identified for use in this Operator's Manual.
- Do not operate the BT-220 Doppler r if it fails to pass the power on procedure.

CAUTION: Be informed that it may cause no harm in life but lead to injury against the "Caution" sign.

NOTE: Be informed that it may cause a potential hazardous situation which, if not avoided, may result in minor or moderate injury.

1.2 Warnings

WARNING: EXPLOSION HAZARD — Do not use the BT-220 in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

WARNING: SHOCK HAZARD — BT-220 doesn't have protection against the burn injury caused by RF Surgical equipment. Do NOT use this product along with RF Surgical equipment.

1.3 Cautions

CAUTION: The relevant law restricts this device to sale by or on the order of a physician.

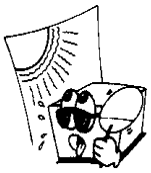
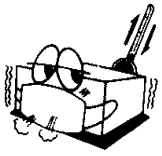
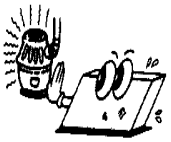
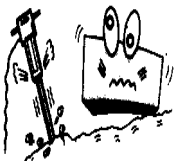
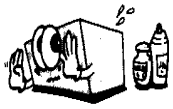
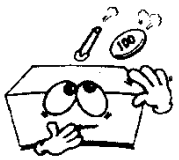
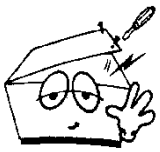
CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity. The unit should be kept clean and free of transducer gel and other substances.

CAUTION: If the equipment use in area where the integrity of the external protective conductor in the installation or its arrangement is in doubt, equipment shall be operated from its internal electrical source when the optional battery is selected.

CAUTION:
-The equipment conforms to Class A according to IEC/EN 60601-1(Safety of Electric Medical Equipment)
- This equipment conforms to Level B according to IEC/EN 60601-1-2 (Electromagnetic Compatibility Requirements)

General Precaution on Environment

- Do not keep or operate the equipment under the environment listed below.

	Avoid placing in an area exposed to moisture. Do not touch the equipment with wet hand.		Avoid exposure to direct sunlight
	Avoid placing in an area where there is a high variation of temperature. Operating temperature ranges from 10°C to 40°C. Operating humidity ranges from 30% to 85%.		Avoid in the vicinity of Electric heater
	Avoid placing in an area where there is an excessive humidity rise or ventilation problem.		Avoid placing in an area where there is an excessive shock or vibration.
	Avoid placing in an area where chemicals are stored or where there is in danger of gas leakage.		Avoid dust and especially metal material into the equipment.
	Do not disjoint or disassemble the equipment. BISTOS Co., Ltd. does not take responsibility of it.		Power off when the equipment is not fully installed. Otherwise, the equipment could be damaged.

1.4 Definitions of Symbols

Symbol	Description	Requirements
	Power On/Off Button	IEC TR 60878
	This symbol identifies a safety note. Ensure you understand the function of this control before using it. Control function is described in the operator's manual.	IEC 60601-1
	Type BF Equipment	IEC60601-1
IPX7	IPX7 Waterproof	IEC60529
	When disposing of some components, do not dispose as general wastes. Adhere to all applicable laws regarding recycling.	Directive 2002/96/EC & EN50419

※ According to IEC 60601-1-6 General requirements for basic safety and essential performance – Collateral Standard : Usability, the definition and using these symbols is adjusted.

> ***CAUTION***: Federal law restricts this device to sale by or on the order of a physician.

Section 2
Introduction

2.1 Product Overview

BT-220 is a pocket-size fetal Doppler that measures the fetal heat rate and outputs the fetal heart sound through built-in speaker. By measuring fetal heart rate(FHR), you are able to predict fetal well-being. BT-220 irradiates fetal wave to the abdomen of a pregnant woman to detect the Doppler frequency signal and analyze, and displays the heart rate on screen. The device also provides the heart sound from the heart of fetus.

2.2 Intended Use

The BT-220 is a potable fetal Doppler that measures the fetal heart rate and outputs the fetal heart sound through a built-in speaker. Measuring the fetal heart rate(FHR) gives an indication of fetal well-being. This data is intended to aid in assessing the well being of the fetus (Non-Stress Test). This device is for use only by trained medical personnel located in hospitals, clinics, doctor's offices and in the patient's home

2.3 Product Features

The BT-220 is a microprocessor-based fetal Doppler, which does display and output the fetal heart rate and sound for antepartum testing.

① Compact (Pocket size) and light
② Easy to use
③ Low Power consumption
④ Long time use
⑤ High quality sound

2.4 Product Configuration

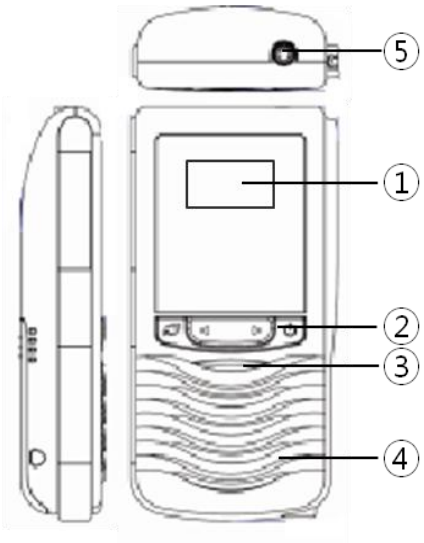
BT-220 consists of the following. Unpack the package and check out the following items. Also be sure to check any damage of main body, probe and accessories.

① BT-220 main body and probe
② 1.5V Battery(2EA)
③ Ultrasound gel (1EA)
④ User's manual (1EA)

2.5 Exterior Component Designation

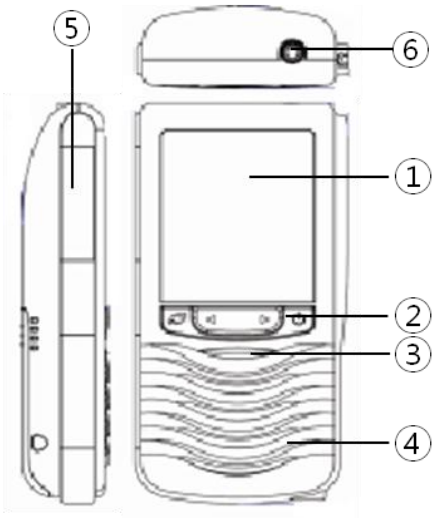
◎ Front View, Top View & Right View

◇ BT-220L



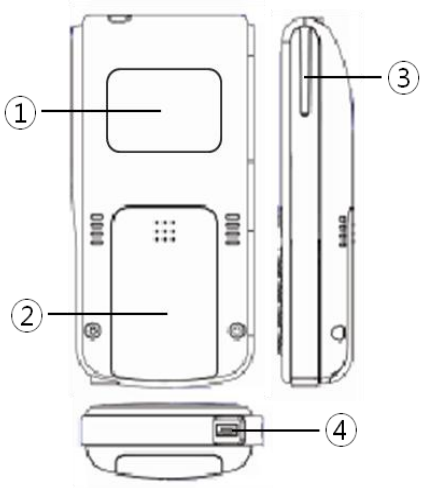
① Custom Mono LCD
② Power and Mode Button & AST and Up/Down Button
③ Charging Indicator LED
④ Sound Output
⑤ Ear Phone Jack

◇ **BT-220C**



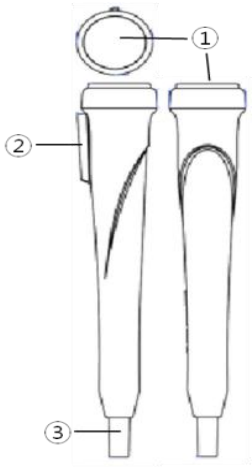
① TFT Color LCD
② Power and Mode Button& AST and Up/Down Button
③ Charging Indicator LED
④ Sound Output
⑤ Electrode Plate
⑥ Ear Phone Jack

◎ Rear View, Bottom View & Left View



① Product Label
② Battery Compartment
③ Probe Groove Joint
④ Probe Connection and Charging Jack

◎ Probe



① Sensor
② Probe Groove Joint
③ Probe Connector

Section 3
Operation

3.1 Controls and Indicators

3.1.1 Button and Description

◇ **BT-220L**

Button	Description
	It has the function of AST On/Off.
	It has the function of Volume Down
	It has the function of Volume Up
	It has the function of power on and power off

◇ **BT-220C**

Button	Description
	According to display, it has the function of mode change and menu select.
	According to display, it has the function of AST on, volume down and data value down.
	According to display, it has the function of AST off, volume up and data value up.
	It has the function of power on and power off.

3.1.2 Symbols and Description

◇ **BT-220C**

Symbol	Description
	Battery indicator
	Doppler volume indicator
MUTE	Doppler volume mute indicator
	Low battery indicator
	Battery charge indicator

3.1.3 Mode and Description

◇ **BT-220C**

MODE	DESCRIOTION
 FHR NUMBER	This mode displays fetal heart rate and heart rhythm with heart sound
 FHR GRAPH	This mode displays fetal heart rate, heart rhythm and change of Heart rate with heart sound
 BIA CHECK	This mode measures and displays body fat percentage and Heart rate
 BIA TREND	This mode displays saved data of body fat percentage and Heart rate
 UNIT SETTING	This mode set the Unit of height, weight, and start mode

3.1.3 Battery Charging

If the voltage level of battery is lower than the required level, the low battery indicator will appear on middle of screen. In this case, the unit will not functional correctly and the batteries should be replaced.
Please use AA type 1.2V Ni-MH rechargeable battery.
To charge the battery, connect your computer's USB to charging jack (probe connection).

Indicator

charging	*Completing the charging.*
Blue LED is OFF.	Blue LED is ON.

Charging time

General(2000mAh)	Under approx. 400 minutes

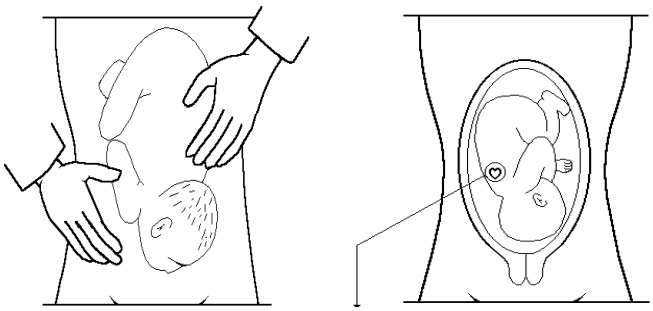
* If the unit is charging, it does not working.

3.1.4 Automatic Shutdown

If the device is not in use for 1 minute, it stops the heart sound with "beep" sound, and shutdown itself in 3 minutes with another "beep" sound.
If the battery voltage is dropped or being charged during the use, the device will shut down itself automatically**.**

3.1.5 Use of Probe

Apply a liberal amount of ultrasound gel to the face of the end of the probe.
Place the probe directly against the measuring position.
Search for the fetal heart by slowly moving the probe around until the fetal heart sounds are heard.



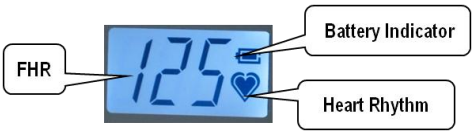
Ultrasound transducer

Search for the position which can get the clearest sound.

3.2 Operation of BT-220

◇ BT-220L

3.2.1 LCD Display



<Measurement>

When Input signal is good and stable, FHR will appear on the screen and the solid heart rhythm indicator will flash as shown in Figure.
When Input signal not stable, the outline heart rhythm indicator will flash.
If the voltage level of battery is lower than the required level, the battery low message ”bat Lo” will appear as shown in Figure. In this case, the unit will not functional correctly and the batteries should be replaced.



<Volume Level>

Press the volume up/down button to adjust the volume level (1~4).

◇ BT-220C

BT-220 is consists of four modes totally. You can shift each mode by pressing  button for a short time.



FHR Number Mode



FHR Graph Mode



BIA Mode

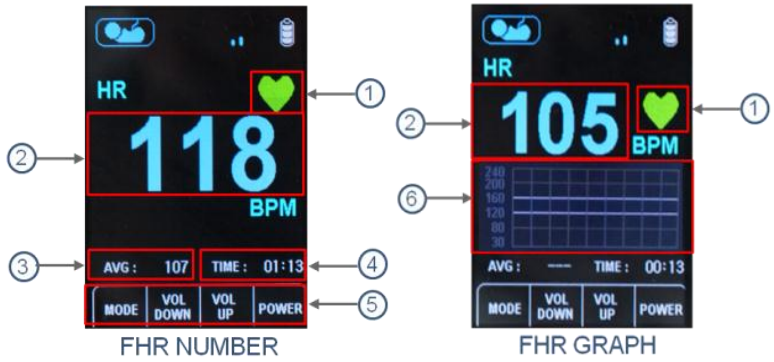


BIA TREND Mode

3.2.2 FHR(Fetal Heart Rate) Mode

When Input signal is good and stable, FHR will appear on the screen and the solid heart rhythm indicator will flash as shown in Figure. Refer to 2.1.6 for using probe.

1) Mode Change(FHR Number →FHR Graph) : Press the button for a short time.



FHR NUMBER FHR GRAPH

① Heart Rhythm Indicator ② Herat rate(HR) Value
③ Average of HR Mode ④ Operating Time of FHR
⑤ Function of Button ⑥ Graph of HR

When Input signal not stable, the solid heart rhythm indicator will flash.
'AVG' represents the average value of the stable status of heart rate and 'TIME' represents listening time of heat beat.
The bold lines of the graph region means a stable heart rate interval.

2) Volume Level Control : Press the button to adjust the volume level (1~4). It is displayed by icon of upper screen.



3) AST Operation(FHR Graph →AST) : Press the button for a short time.



<AST Operation>

Use the ◄ ► for generating sound. AST1 has 75Hz and AST2 has 100Hz.

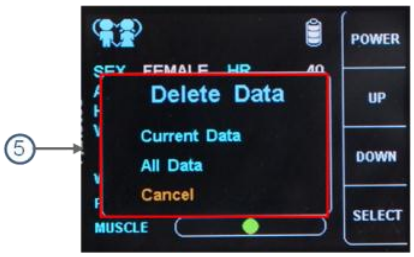
3.2.3 BIA(Body Impedance Analysis) Mode

BT-220 displays BMI(Body Mass Index) and FAT(Body Fat) using the body impedance.

1) Mode Change(FHR mode → BIA mode) : Press the button for a short time.



BIA CHECK



Delete Data

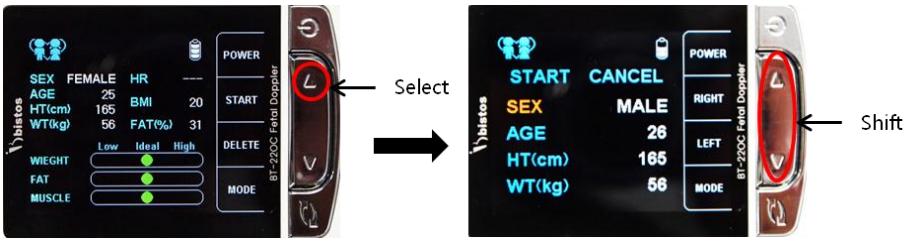
① Function of Button
② Last Measurement Data
③ Body Setting Value
④ Body Composition graph
⑤ Pop-up window for deleting data

2) Information Setting : Press the ◄ button and ⟳ button Continuously.
Change Value : Use the ◄ ► button
Item Saving : Press the ⟳ button
(Information of age, height, and weight is not cleared)



Data Setting & Start

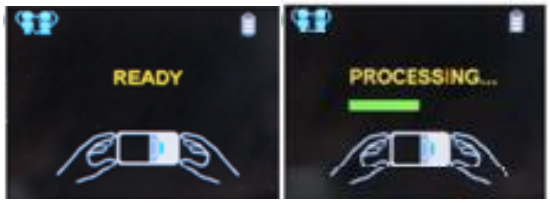
① Function of Button ② Start / Cancel Select Item
③ Body Setting Value



If the modification or change of all of the values and items is complete, the first screen appears.

3) Start Measurement : if the cursor is on START CANCEL, Press the ▲ button.
Return(BIA mode): Press the ▼ button.



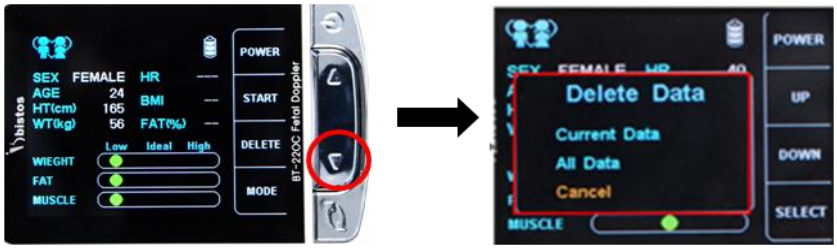


<Ready> <Processing>

After starting, both of thumb are touched on sensor. Then measurement begins automatically. If the contact area is small, the measurement may be inaccurate

Information of setting age, height, weight will be saved automatically.
Automatically measured HR, BMI, FAT is stored (up to 10).

4) Delete Data : Press the button to return Information Setting and use the button and button.



3.2.4 BIA TREND



BIA TREND

① Function of Button ② Selected Measurement Data
③ Body Setting Value ④ Graph of Stored Data

1) Mode Change : Press the button for a short time.

2) Stored Data Review : Press the button.

3.2.5 UNIT Setting



UNIT SETTING

① Unit Setting Value ② Function of Button

1) Mode Change(UNIT Setting) : Press the button about 2 seconds.

2) Item Saving : Press the button for a short time.

3) Value Change : Press the button.

Section 4
Maintenance & Cleaning

This chapter contains instructions for the care and cleaning of the BT-220 unit and its accessories.

The BT-220 requires proper care and preventive maintenance. If you use the material that is not approved, it may cause any damage to the product. In this case, the product will not be guaranteed even within the warranty period.

4.1 Main Body & Probe

To keep the device clean, apply alcohol on a soft cloth and scrub the body and the probe once a month. Do not use lacquer, thinner, ethylene, or the oxidizing substance. Keep the probes from dust or stain.
Do not soak the main body and the probe into any liquid or detergent. Keep the main and the probe away from any liquid.

> ***CAUTION***: Check the main body and the probe thoroughly after cleaning.

4.2 Cable

Wipe the cable with a soaked cloth that is wet with warm water (40℃ / 104˚F), and with the clinical alcohol once a week.

> ***CAUTION***: Do not autoclave. Do not gas sterilize.

4.3 Battery Disposal and Handling

> ***NOTE***: 1.5V x 2(AA Type) Batteries are used for the system power. Do not use the other type of batter. It could be the cause of breakdown.

The battery is consumables. Therefore the operation time by the battery can be decreased. If the operation time is not long enough, please change the battery. If this system is used with not sufficient operating time by the internal battery, it is possible to be shut down the system because of the lack of the internal battery's capacity. This situation can cause not intended stop of measuring function.

4.4 Request a service for general problems

If the main body or accessories are damaged by excessive mechanical forces, narrow cracks or separation of ultrasonic sensor can be happened. These can be checked through visible or auditory decision. These can cause malfunction some times. But these do not cause unacceptable risks. If the BT-220 does not work properly, please contact us and change the corresponding parts. Note that the replacement costs can be occurred.

Section ***5***
Specifications

BT-220 Doppler Specifications:

General
Ultrasound Frequency : 2MHz, 3MHz
Intensity : <10mW/cm^2
Heart Rate Counting Range : 50~240bpm(BT-220L) / 30~240bpm(BT-220C)
FHR Accuracy : ±2% of range
Sensitivity : 10~12 Weeks Onward
PC Interface : Sound Card(using by BCM200 S/W)

Physical Characteristics

Main body : (L)132㎜×(H)66㎜×(D)27㎜
Probe : (L)162㎜×(H)29.5㎜×(D)27.3㎜
Weight(Main Body and Probe) : 190g(BT-220L) / 200g(BT-220C)g

Safety

Complies with EN60601-1, EN60601-1-2
Ultrasound Doppler system according to IEC 60601-2-37
Internal Powered Equipment
Continuous Operation
Type BF applied parts
Probe Waterproof Level : IPX7 / IPX0

Power

Battery	1.5V x 2(AA Type)
	About 240minutes (Continuously use)

Environmental

Operating Temperature : 10℃(50˚F) to 40℃(104˚F)
Operating Humidity : 30% ~ 85% non-condensing
Operating Atmospheric Pressure : 79.051 ㎪ ~ 101.325㎪
Storage Temperature : -10℃(14˚F) to 60℃(131˚F)
Storage Humidity : 20% ~ 95% non-condensing
Storage Atmospheric Pressure : 79.051 ㎪ ~ 101.325㎪

Product Guarantee

Product Name	Fetal Doppler
Model Name	BT-220
Approval No.	
Approval Date	
Serial No.	
Warranty Period	2 Years (Probe excluded)
Date of Purchase	
Customer	Hospital: Address: Name: Telephone:
Sales Agency	
Manufacture	Bistos Co., Ltd.

※ Thank you for purchasing BT-220.

※ This product is manufactured and passed through strict quality control and inspection.

※ Compensation standard concerning repair, replacement, refund of the product complies with "**Consumer's protection law**" noticed by Economic Planning Dept.

Service Telephone and Fax. Numbers

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