



BT-220

Operation Manual



BT-220

Keep this manual for future reference

P/N: 220-ENG-OPM-EUR-R03

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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 Operation Manual.
- Do not operate the BT-220 Doppler if it fails to pass the power on procedure.

**WARNING**

A hazard of serious injury or death

**CAUTION**A hazard of minor injury or damage to the system.

1.2 Warnings

**WARNING**

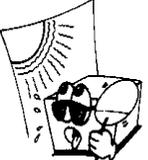
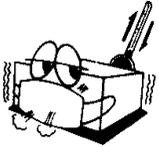
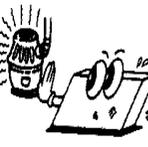
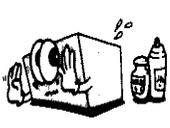
- EXPLOSION HAZARD - Do not use the BT-220 in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.
 - SHOCK HAZARD - BT-220 does not have protection against the burn injury caused by RF surgical equipment. Do not use this product along with RF surgical equipment.
-

1.3 Cautions

-
-  **CAUTION**
-
- The relevant law restricts this device to sale by or on the order of a physician.
 - 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 ultrasound transmission gel and other substances.
-

General Precaution on Environment

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

	<p>Avoid placing in an area exposed to moisture. Do not touch the equipment with wet hand.</p>		<p>Avoid exposure to direct sunlight</p>
	<p>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%.</p>		<p>Avoid in the vicinity of Electric heater</p>
	<p>Avoid placing in an area where there is an excessive humidity rise or ventilation problem.</p>		<p>Avoid placing in an area where there is an excessive shock or vibration.</p>
	<p>Avoid placing in an area where chemicals are stored or where there is in danger of gas leakage.</p>		<p>Avoid dust and especially metal material into the equipment.</p>
	<p>Do not disjoint or disassemble the equipment. BISTOS Co., Ltd. does not take responsibility of it.</p>		<p>Power off when the equipment is not fully installed. Otherwise, the equipment could be damaged.</p>

1.4 Definitions of Symbols

Symbol	Description
	Power On/Off Button
	This symbol identifies a caution. Ensure you understand the function of this control before using it. Control function is described in the operation manual.
	Type BF Equipment
IPX7	IPX7 Waterproof
	When disposing of some components, do not dispose as general wastes. Adhere to all applicable laws regarding recycling.

 **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 heart 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 ultrasound 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.

2.3 Product Features

The BT-220 is a microprocessor-based fetal Doppler, which 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

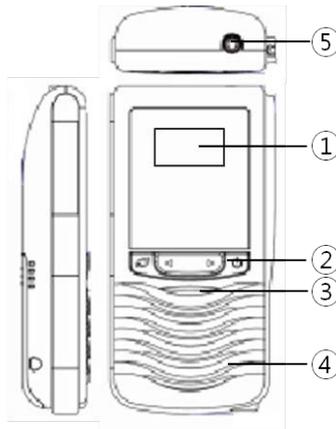
BT-220 consists of the followings. Unpack the package and check out the following items. Also be sure to check any damage of main body, probe and accessories.

- ① BT-220 main body and probe
- ② 1.5V Battery (2EA)
- ③ Ultrasound transmission gel (1EA)
- ④ Quick guide (1EA)

2.5 Exterior Component Designation

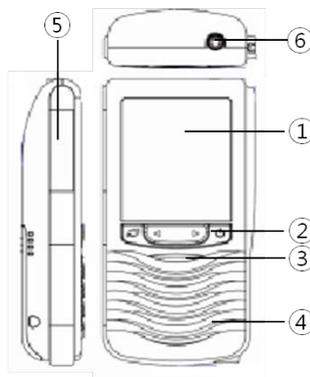
◎ Front View, Top View & Right View

◇ BT-220L



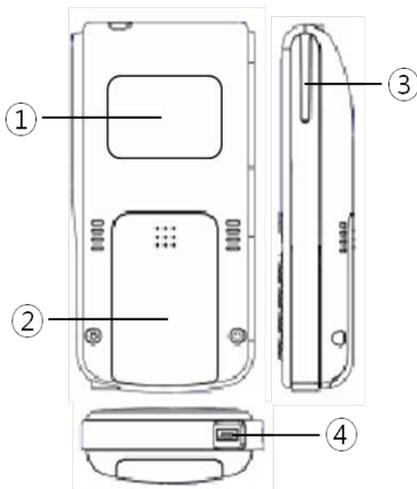
- ① Custom Mono LCD
- ② Power and Mode Button, Speaker test and Up/Down Button
- ③ Charging Indicator LED
- ④ Built-in speaker
- ⑤ Ear Phone Jack

◇ BT-220C



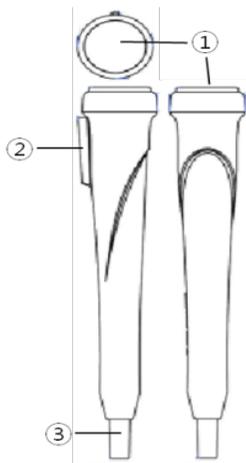
- ① TFT Color LCD
- ② Power and Mode Button, Speaker test and Up/Down Button
- ③ Charging Indicator LED
- ④ Built-in speaker
- ⑤ Electrode Plate
- ⑥ Ear Phone Jack

◎ 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
	Speaker test On/Off
	Volume Down
	Volume Up
	Power On/Off

◇ BT-220C

Button	Description
	Mode change or menu select
	Volume Down, Speaker teste on and data value decrease
	Volume Up, Speaker test off and data value increase
	Power On/Off

3.1.2 Symbols and Description

◇ BT-220C

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

3.1.3 Mode and Description

◇ BT-220C

Symbol	Description	
	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
	BMI calculation	This mode displays the BMI
	BMI trend	This mode displays saved data of BMI
	Unit setting	This mode set the unit of height, weight, and start mode.

3.1.4 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 replace with AA type 1.5V battery.

If you want to use the rechargeable battery, please use AA type, 1.2V, Ni-MH battery. To charge the battery, connect your computer's USB to probe connection and charging jack (see the bottom view on page 11 of this manual).

Indicator

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

Charging time

General(2000mAh)	Under approx. 400 minutes
------------------	---------------------------

* During the charging the device does not operating.

3.1.5 Automatic Shutdown

If the device is not used for 1 minute, it stops the heart sound with "beep" sound, and shutdown in 3 minutes with another "beep" sound.

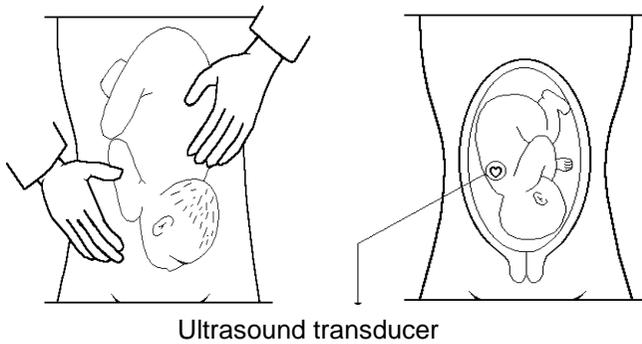
If the battery voltage is dropped or the device being charged during the use, the device will shut down automatically.

3.1.6 Use of Probe

Apply a moderate 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.

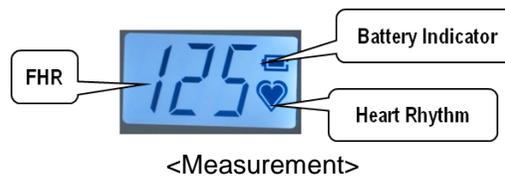


Search for the position which can get the clearest sound.

3.2 Operation of BT-220

3.2.1 LCD Display

◇ BT-220L



When the 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 the input signal is not stable, only the outline of 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. In this case, the unit will not functional correctly and the batteries should be replaced.



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

◇ BT-220C

BT-220C has totally four modes. You can select the mode by pressing  button for a short time.



FHR Number mode



FHR Graph mode



BMI mode

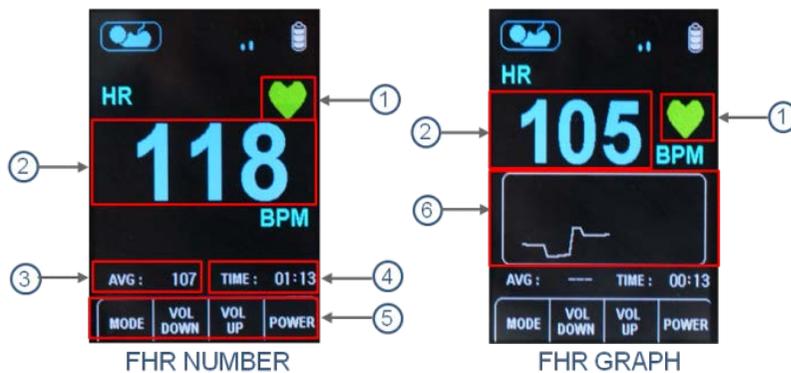


BMI trend mode

3.2.2 FHR(Fetal Heart Rate) Mode

When the input signal is good and stable, FHR will appear on the screen and the solid heart rhythm indicator will flash as shown in Figure.

1) Mode change (FHR Number → FHR Graph): Press the mode button [].



- ① Heart rhythm indicator
- ② Heart rate (HR) value
- ③ Average HR value
- ④ Operating time of FHR
- ⑤ Function of button
- ⑥ Graph of HR

When the input signal is not stable, only the outline of heart rhythm indicator will flash. 'AVG' represents the average value of the stable heart rate and 'TIME' represents listening time of heat beat.

The bold lines in graph region represent the stable heart rate.

2) To control the volume: Press the  button to adjust volume (1 ~ 4 levels). The current volume setting is displayed by icon on the upper right corner of screen.



3) Speaker test operation (FHR graph → AST): Press the  button shortly.



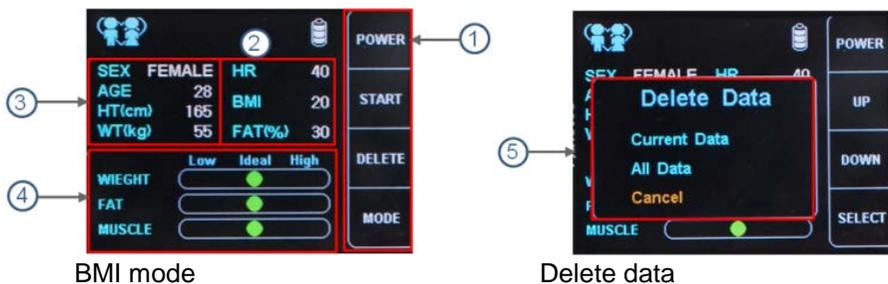
<AST Operation>

Use the  button for generating sound. The sound is generated only at speaker. AST1 has 75 Hz and AST2 has 100 Hz frequency.

3.2.3 BMI(Body mass index) Mode

BT-220 displays BMI(Body Mass Index) using the weight and height.

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



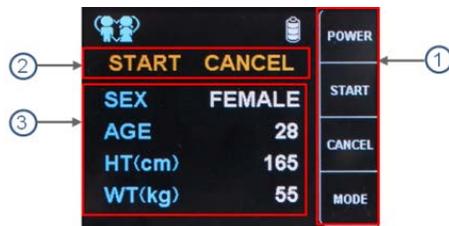
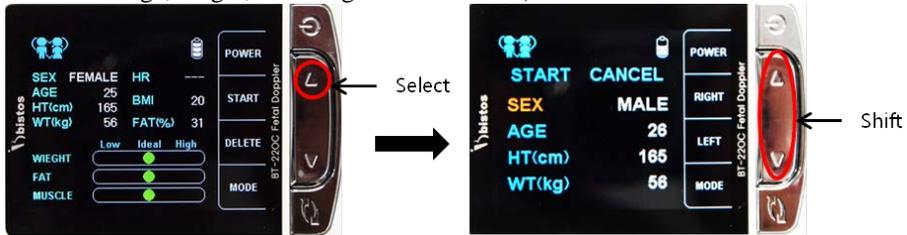
- ① Function of button
- ② Last measured data
- ③ Entered information
- ④ Body composition graph
- ⑤ Pop-up window for deleting data

2) Information Setting: Press the  button to enter the start menu.

Item Select: Press the  button to select item (Sex, Age, HT, WT)

Change Value : Use the   button to change the value.

(Information of age, height, and weight is not cleared)

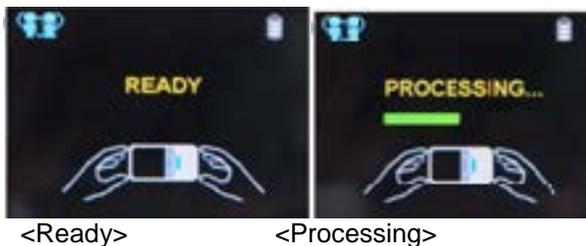


- ① Function of button
- ② Start/Cancel
- ③ Entered information

If all information has been modified or changed press mode button  to select [START/CANCEL] menu.

3) Start Measurement: when the cursor is on [START CANCEL], press the  button to start measurement or press the  button to cancel (return to BMI mode).





<Ready> <Processing>

After pressing start, touch the metal electrode on the left side on main body with both thumbs. 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 delete data. Use the button to select the menu and press button to select the operation.



3.2.4 BMI TREND



- ① Function of button
- ② Measured data
- ③ Last entered information
- ④ Graph of stored data

1) Mode Change: Press the button shortly to change the mode to FHR numeric mode

2) Stored Data Review: Press the button to see the stored data.

3.2.5 UNIT Setting



① Unit set value

② Function of buttons

- 1) To enter unit setting menu, press down the  button about 2 seconds.
- 2) Item select: Press the  button shortly
- 3) Value Change: Press the   button.
- 4) The following items can be changed:
 - DISP: Default display when power ON. Dop(N): Doppler Normal, Dop(G): Doppler Graph, Bmi(M): Bmi measurement, Bmi(T): Bmi trend.
 - HT: The unit of height for BMI. cm/ft
 - WT: The unit of weight for BMI. kg/lb
- 5) To exit unit setting and return to the current operating mode, press down the  button about 2 seconds.

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°C / 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 battery. It could be the cause of breakdown.
-

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 fetal Doppler is complies with IEC 60601-1 and IEC 60601-1-2. And the ultrasound Doppler system complies with IEC 60601-2-37.

General	
Ultrasound Frequency	2MHz, 3Mhz
Intensity	Less than 10mW/cm ²
Heart rate counting range	50 ~ 240 bpm(BT-220L)/ 30 ~ 240 bpm(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)132mm×(H)66mm×(D)27.6mm
Probe	(L)162mm×(H)29.3mm×(D)27.8mm
Weight (Main body and probe)	190 g(BT-220L) / 200 g(BT-220C)

Safety classification	
Protection against electric shock	Internal powered equipment
Protection level against electric shock	Type BF
Mode of operation	Continuous operation
Protection against ingress of water	Probe: IPX7 Main body: IPX0

Power	
Battery	AA type 1.5V X 2 About 240 minutes (continuous use)

Environment	
Operating Temperature	10 °C (50°F) to 40 °C (104°F)
Operating Humidity	30% ~ 85% non-condensing
Operating Atmospheric Pressure	79.051 kPa ~ 101.325kPa
Storage Temperature	Main body: IPX0
Storage Humidity	-10 °C (14°F) to 60 °C (131°F)
Storage Atmospheric Pressure	79.051 kPa ~ 101.325kPa

Section 6 Declaration on EMC

6.1 Electromagnetic emissions

The BT-220 is intended for use in the electromagnetic environment specified below. The customer or the user of BT-220 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The BT-220 uses RF energy only for its Internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The BT-220 is suitable for use in all establishments by using a battery.
Harmonic emission IEC61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC61000-3-3	Not applicable	

6.2 Recommended separation distances between portable and mobile RF communications equipment and the BT-220

The BT-220 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BT-220 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and the BT-220 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter[M]		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

6.3 Electromagnetic immunity

The BT-220 is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-220 should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC 61000-4-2	±6 kV Contact ±8 kV air	±6 kV Contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (<95% dip in U_T) for 5s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BT-220 image intensifier requires Continued operation during power mains interruptions, it is recommended that the BT-220 image. Intensifier be powered from a battery.
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

<p>The BT-220 is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-220 should assure that it is used in such an environment.</p>			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
<p>Conducted RF IEC 61000-4-6</p>	<p>3 V_{rms} 150 kHz ~ 80 MHz</p>	<p>3 V/m</p>	<p>Portable mobile RF ommunications equipment should be used no closer to any part of the BT- 220, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p>
<p>Radiated RF IEC 61000-4-3</p>	<p>3 V/m 80 MHz ~ 2.5 MHz</p>	<p>3 V/m</p>	<p>Recommended separation distance:</p> $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P} \quad 80 \text{ MHz} \sim 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 800 \text{ MHz} \sim 2.5 \text{ GHz}$ <p>where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a, should be less than the compliance level in each frequency range ^b. Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1) At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2)These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BT-220 is used exceeds the applicable RF compliance level above, the BT-220 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BT-220.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

6.4 Immunity and Compliance Level

[Probe : AY-2MHZDOP-220C (2 Hz, Vertical)]

Image at Frequency of Interest	Frequency of Interest** [MHz]	Actual Immunity Level
 Radiated RF IEC 61000-4-3	160.54 MHz	3 V/m
	201.82 MHz	3 V/m
* Voltage Level at which the RF Induced Noise is No Longer Discernable from the system ambient background noise. ** Between 80 MHz ~ 158.95 MHz, 162.14 MHz ~ 199.82 MHz and 203.84 MHz ~ 2.5 GHz the level of Immunity is 3 V/m.		

Frequency of Interest [MHz]	F1 = 160.54	F1 = 201.82
Image at Frequency of Interest		
Voltage Level at which the RF Induced Noise is No Longer Discernable from the System Ambient Background Noise	1.6 V/m	2.6 V/m

Probe : AY-2MHZDOP-220C (2 Hz, Horizontal)]

Image at Frequency of Interest	Frequency of Interest** [MHz]	Actual Immunity Level
 Radiated RF IEC 61000-4-3	82.42 MHz	3 V/m
	152.74 MHz	3 V/m
	216.38 MHz	3 V/m
* Voltage Level at which the RF Induced Noise is No Longer Discernable from the system ambient background noise. ** Between 80 MHz ~ 81.60 MHz, 83.24 MHz ~ 151.23 MHz, 154.27 MHz ~ 214.24 MHz and 218.54 MHz ~ 2.5 GHz the level of Immunity is 3 V/m.		

Frequency of Interest [MHz]	F1 = 82.42	F1 = 152.74	F1 = 216.38
Image at Frequency of Interest			
Voltage Level at which the RF Induced Noise is No Longer Discernable from the System Ambient	2.4 V/m	1.6 V/m	2.8 V/m

[Probe : AY-3MHZDOP-220C (2 Hz, Vertical)]

Image at Frequency of Interest	Frequency of Interest** [MHz]	Actual Immunity Level
	116.76 MHz	3 V/m
	120.30 MHz	3 V/m
Radiated RF IEC 61000-4-3		
<p>* Voltage Level at which the RF Induced Noise is No Longer Discernable from the system ambient background noise. ** Between 80 MHz ~ 115.60 MHz, 117.92 MHz ~ 119.10 MHz and 121.50 MHz ~ 2.5 GHz the level of Immunity is 3 V/m.</p>		

Frequency of Interest [MHz]	F1 = 116.76	F1 = 120.30
Image at Frequency of Interest		
Voltage Level at which the RF Induced Noise is No Longer Discernable from the System Ambient Background Noise	2.4 V/m	2.8 V/m

[Probe : AY-3MHZDOP-220C (2 Hz, Horizontal)]

Image at Frequency of Interest	Frequency of Interest** [MHz]	Actual Immunity Level
 Radiated RF IEC 61000-4-3	157.37 MHz	3 V/m
	229.69 MHz	3 V/m
	277.49 MHz	3 V/m

* Voltage Level at which the RF Induced Noise is No Longer Discernable from the system ambient background noise.

** Between 80 MHz ~ 155.81 MHz, 158.95 MHz ~ 227.42 MHz, 231.99 MHz ~ 274.75 MHz and 280.27 MHz ~ 2.5 GHz the level of Immunity is 3 V/m.

Frequency of Interest [MHz]	F1 = 157.37	F1 = 229.69	F1 = 277.49
Image at Frequency of Interest			
Voltage Level at which the RF Induced Noise is No Longer Discernable from the System Ambient	1.4 V/m	2.2 V/m	2 V/m

Product Warranty

Product Name	Fetal Doppler
Model Name	BT-220
Serial No.	
Warranty Period	1 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 “**Framework Act on Consumers**” noticed by Fair Trade Commission of Republic of Korea.

Service Telephone and Fax. Numbers

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