DOPPLER FETUS DETECTOR

FD-390

Operation Manual

The manual describes about the application, operation and maintenance of Doppler Fetus Detector.
All personnel, who operate the unit, have to read and thoroughly understand the manual before the application.
Keep the manual nearby where the operation is done so as to be able to refer to when desired.

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Manufacturer **Distributor**

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INTRODUCTION

The unit is used to confirm the fetal well- being as well as the location of placenta/umbilical cord.
Instantaneous display of **FHR** (fetal heart rate) and emission of different audible Doppler sounds are done by Doppler signals obtained by reflection at fetal heart or blood flow of placenta through maternal abdomen with probe.

We are not responsible for the accident (s) caused by trouble or damage by different operation and maintenance than descriptions in this manual, or by repair and modifications done by others than us.
Contact us for your technical questions.

OPERATING PRECAUTIONS TO MAINTAIN SAFETY AND TO PREVENT DANGER ON USE OF MEDICAL ELECTRONIC INSTRUMENTS

1. The instrument must be operated only by qualified personnel.

2. When installing the instrument, observe the following notes:
   (1) Install the instrument in an area free from splashes of water.
   (2) Install the instrument in an area not adversely affected by atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, salt and sulphur, etc.
   (3) Be careful not to tilt, vibrate or shock the instrument (during transfer).
   (4) Do not install the instrument in an area where chemicals are stored or gases are generated.
   (5) Verify that the power frequency, power voltage and allowable current value (or power consumption) are proper.
   (6) The instrument must be properly grounded.
   (7) This equipment is not specified or intended for using in the presence of electro surgical equipment.

3. Before using the instrument, observe the following notes:
   (1) Check the contact conditions of switches, polarity, dial settings and displays, etc. to to verify that the instrument functions properly.
   (2) Verify that the instrument is properly grounded.
   (3) Verify that all cables are properly and safety connected.
   (4) When the instrument is to be used with other equipment, utmost care must be taken as as this might lead to failure in proper diagnosis or danger.
   (5) Recheck the outside circuit which is to be directly connected to the patient.

4. While the instrument is in use, observe the following notes:
   (1) Watch both the entire system and the patient at all times to verify that they are in normal conditions.
   (2) If any abnormality has been detected in the instrument or the patient, stop the instrument from operating or take other proper steps to secure the patient.
   (3) The instrument must on no account be handed by the patient.

5. After using the instrument, observe the following notes:
   (1) After returning the control switches and dials, etc., to their preoperative original positions in accordance with the predetermined procedures, turn off the power to the instrument.
   (2) When removing the cables, care must be taken not to exert too much pressure on the cables. The cables must be removed by holding their plugs.

(3) To store the instrument, observe the following notes:
   I Store the instrument in an area free from splashes of water.
   II Store the instrument in an area not adversely affected by atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, salt and sulphur, etc.
   III Be careful not to tilt, vibrate or shock the instrument (during transfer).
   IV Do not store the instrument in an area where chemicals are stored or gases are generated.
(4) Clean the accessories, cables and electrodes, etc., and put them in order.
(5) Clean the instrument without fail for later use.

6. Should the instrument malfunction, note the proper indication without attempting to tamper with the instrument and refer servicing to qualified service personnel.

7. Do not perform any unauthorized modification to the instrument.

8. Maintenance
   (1) Periodically check out the instrument and its parts without fail.
   (2) When the instrument, which has not been used for some time, is to be used again, verify without fail that the instrument functions properly and safety before use.

9. Observe other operating precautions provided in the instruction manual of this instrument.

FOR SAFE AND CORRECT APPLICATION OF THE UNIT

The WARNING and CAUTION described along with Symbols in this manual are the must to follow and keep before, after or during operation of the unit, by classifying the contents according to dangerous or hazardous conditions.
Read the manual through well understanding the following contents:

WARNING To call attention to:
if erroneously operate the unit by ignoring the descriptions, there would be a possibility for personal heavy injury or death of the operator or patient.

CAUTION To call attention to:
if erroneously operate the unit by ignoring the descriptions, there would be a possibility for personal injury of the operator or patient, or material damages.

SYMBOLS

The symbol is to advise that there are contents to call attention (at Warning or Caution) to the operator.

The symbol is to advise the prohibited operation or action for the unit.

The symbol is to advise the limited action or indicated contents.

Examples

Caution against electric shock

Prohibition of disassembly

To pull out plug by holing it

INDICATION OF WARNING

Warning label below is selected to specially important matter and put on the rear of main unit. Read and thoroughly understand the contents before using the unit.

Location of label

WARNING

TO AVOID THE EXPLOSION HAZARD
Don't use in the environment where explosion hazard exists (such as in the presence of flammable anesthetic gas).

The unit is not made by explosion-proof structure.

LIST OF WARNINGS

The undermentioned are list of warning described in this manual.
Read and thoroughly understand the contents by following them.

⚠ WARNING

TO AVOID WRONG DIAGNOSIS

- Relocate the probe to most suitable position corresponding to movement of fetal position.
  Maternal heart will be detected if the probe is strongly put on maternal blood vessel.
- When the intrauterine fetal death (IUFD) is doubted by this examination method, try to verify it with other method.
- If accuracy of any value displayed on the monitor is questionable, determine the patient's vital signs by alternative means. Verify that all equipment is working correctly.

TO AVOID THE FIRE AND ELECTRIC SHOCK HAZARD

- Apply the 3P socket with protective earth as the power source, but don't use 2P socket.
  Don't use the table tap, too.
  [Application of 2P socket cut off the earthing to ground, and table tap causes not only the cutting of earth but the drop-down of voltage, detachment of plug and noise.]
- When it happened to drop the unit down or damage the panel, turn the power and operation switches off, and then contact the representative or manufacturer.
- Protect the unit from water to splash on the unit.
  Contact the representative or manufacturer in case when water flowed into the unit.
- Don't injure, process, bent, twist, pull or heat the probe or power cord.
- When the probe or power cord was Insured (exposure of the core, or snapping of the wire), contact the representative or manufacturer.

⚠ WARNING

- Don't insert other plug into the plug connector than the plug for standard probe.
- Don’t open the outer case by removing screws or disassemble the unit.
- Liquids must not be allowed to enter the device. If liquids have entered a device, take it out of service and have it checked by a service technician before it is used again.
- A test for leakage current should be performed periodically.
  GND leakage current: Single fault < 1mA
  Patient leakage current: Single fault < 0.5mA

TO PREVENT THE INFLUENCE TO EQUIPMENT FROM ELECTRO-MAGNETIC WAVES AND RADIO WAVES

- Do not allow cellular phones, transceivers or radio-controlled toys, etc. in the room where this equipment is installed.

⚠ CAUTION

1. Accessories
   ＊ To ensure patient safety, use only parts and accessories manufactured or recommended by TOITU. Parts and accessories used must meet the requirements of the applicable IEC 60601 series safety standards and essential performance standards, and/or the system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard.
2. EMC
   ＊ Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

⚠ CAUTION

3. Maintenance
   * Regular preventive maintenance should be carried out annually. You are responsible for any requirements specific to your country.
   * Never use sharp or pointed objects to operate the front-panel switches.
   * Do not autoclave or gas sterilize the monitor or any accessories. Follow cleaning instructions.
   * Do not immerse the probe connectors during any stage of the cleaning process.
   * Dispose of the packaging material, observing the applicable waste control regulations and keeping it out of children's reach.
4. Biocompatibility
   * When used as intended, the parts of the product described in this operator manual, including accessories that come in contact with the patient during the intended use, fulfill the biocompatibility requirements of the applicable standards. If you have questions about this matter, please contact TOITU or its representatives.

SUPPLEMENTAL EXPLANATION

INTERRUPTION OF LARGE SOUND

Large sound emits when gel is spread on the probe or when probe is moved on maternal abdomen, and then the sound goes away soon.

This is not by trouble.

It is because the unit, FD-390, is installed with a built-in Mute-Circuit which shuts off the circuit immediately when a large signal is input.

In relation to detection of audible sound area, there are two (2) types at Toitu Doppler fetus detectors:

- Detector which detects the sound of heart valve as main purpose by eliminating low sound area.
  Detector which detects low sound area, too, by stabilizing the detection ratio from heart wall and others.

As FD-390 detects the low sound area, the unnecessary sound for examination is harshly felt as large noise. In order to reduce the noise, the unit (FD-390) is designed for the large sound to be interrupted soon when large signal is input.

Electromagnetic Compatibility (EMC)

MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document.

Warning
Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

Warning
The FD-390 should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The FD-390 is intended for use in the electromagnetic environment specified below. The customer or the user of the FD-390 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions EN 55011	Group 1	The FD-390 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 EN 55011	Class B	The FD-390 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions EN 61000-3-2	Class B	
Voltage Fluctuations/ Flicker Emissions EN 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The FD-390 is intended for use in the electromagnetic environment specified below. The customer or the user of the FD-390 should assure that it is used in such an environment.			
Immunity test	**EN 60601 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) EN 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 EN 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	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 EN 61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycles <40% Ut (>60% dip in Ut) for 5 cycles <70% Ut (>30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 s	<5% Ut (>95% dip in Ut) for 0.5 cycles <40% Ut (>60% dip in Ut) for 5 cycles <70% Ut (>30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FD-390 requires continued operation during power mains interruptions, it is recommended that the FD-390 be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic Field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: Ut is the AC mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The FD-390 is intended for use in the electromagnetic environment specified below.
The customer or the user of the FD-390 should assure that it is used in such an environment.

Immunity test	EN 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Conducted RF EN 61000-4-6 Radiated RF EN 61000-4-3	3 Vrms 150 KHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should not be used closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d 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: 

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 reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment.

[b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the FD-390

The FD-390 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FD-390 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FD-390 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 metres (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.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Compliant Cables and Accessories

WARNING
The use of accessories, probes and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.

Model Name	Description	Maximum Lengths
YA0014	AC Power Cable	3.3 m
TR-202	Probe (Doppler)	N/A

NOTE: Any supplied accessories that do not affect EMC compliance are not included.

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1. OUTLINE

1-1 Specifications

Ultrasound Transducer	: Frequency: 2.5MHz
	: I_{sata} at the transducer face: 10mW/cm^2 maximum Entrance Beam Dimensions: 2.5cm^2 Ultrasonic Power: 21.3mW maximum
TI, MI	: <1.0
FHR measurement range	: 50 -210 bpm
Audible output	: 1W
Speaker	: 120mm diameter
Power source	: AC …. Voltage as specified, 50-60 Hz 9.5VA (25VA during charge) or DC …. Built-in Nickel-hydrogen rechargeable Charging time: 1.5 hours approx.
Continuous working time by battery	: 5 hours approx. (when no signal is provided)
Classification of protection	: Class I (when AC power is applied) Internally powered equipment (when Rechargeable battery is applied)
Type of protection	: Type B
External dimensions	: 220 (W) x 210 (H) x 120 (D) mm
Weight	: 2.4kgs approx. (including battery)
Applicable environment	: Temperature 10 ～ 40℃ Humidity 30 ～ 75% RH Atmospheric pressure 70 ～ 106 kPa

1-2 Environmental Requirements

	Operating Range	Transport/Storage Range
Ambient Temperature	10 ～ 40℃	-10 ～ 60℃
Relative Humidity	30 ～ 70%	30 ～ 80%
Atmospheric Pressure	70 ～ 106 kPa	70 ～ 106 kPa

1-3 Standard Accessories

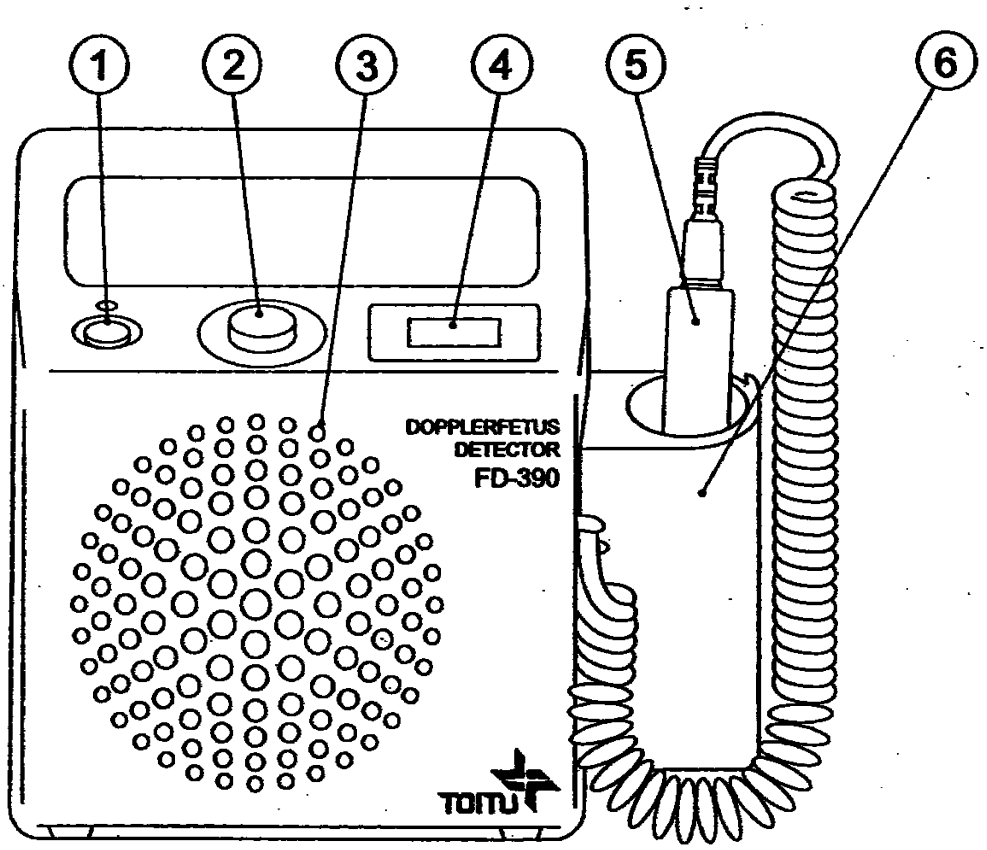
Standard probe	1
Ultrasonic scanning gel SG, 250ml	1
Power cord	1
Operation manual	1

1-4 Optional Accessories

Binaural earphone

2. DESCRIPTION AND FUNCTION OF EACH SECTION

2-1 Front View



① Operation switch : To switch the operation ON or OFF.

② Sound control volume : To control volume of Doppler original sound.

③ Speaker : Doppler original sound emits.

④ LCD display unit : FHR is displayed.
The mark ♥ is displayed too, in blinking by synchronizing with fetal heart beats.
Further, the lowering of battery capacity is displayed in lighting of the mark .

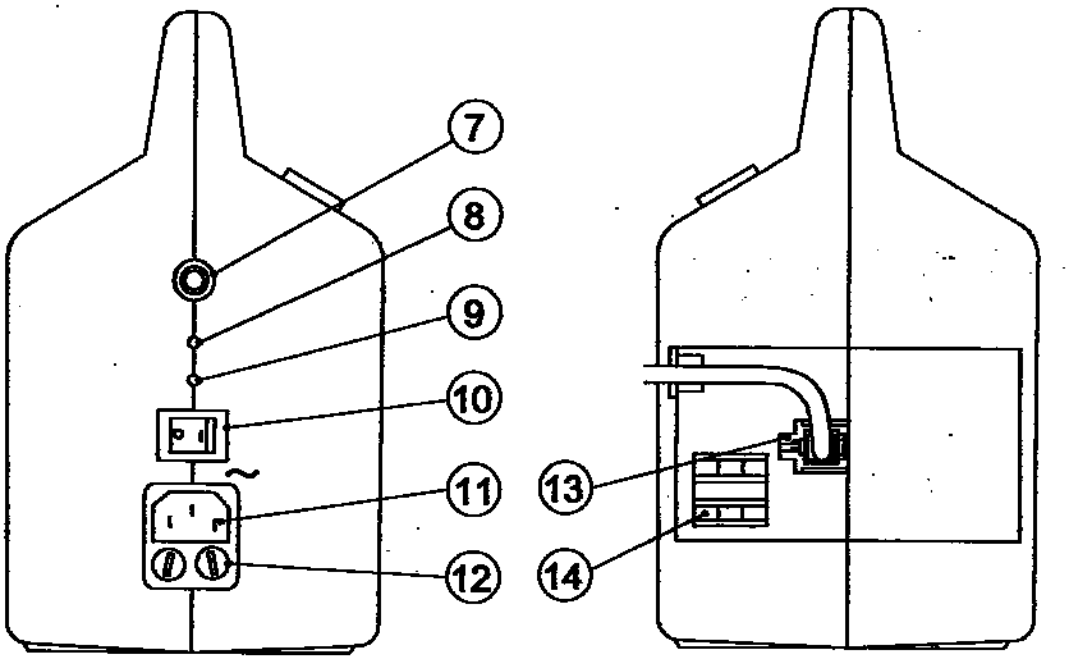
⑤ Standard probe : To obtain Doppler signals.

⑥ Holder : Probe is received at front side and gel tube at at other side.

2-2 Side Views

Left side

Right side
(View through moving holder)



⑦ Earphone jack : To plug earphone into the jack.

⑧ Charging indication lamp : Blinking of the lamp indicates the in-charge of battery, and it lights when charging is completed.

⑨ Power lamp : It lights when power switch is turned ON.

⑩ Power switch : Supply of AC power is switched ON (I) or OFF (O).

⑪ Power socket : To connect power cord.

⑫ Fuse holder : Fuses (0.5A) are located in the holder.

⑬ Connector for Doppler : To plug the probe in the connector.

⑭ Spare fuse : Spare fuses are located.

3. PREPARATION

3-1 Preparation

Following caution is for the room and place where to be operated:

⚠ CAUTION

DON'T USE THE UNIT:

- under direct sunshine
- in dusty or high humid room
- in warmer room (40℃ or more)
- in colder room (10℃ or less)
- on unstable or shaky place

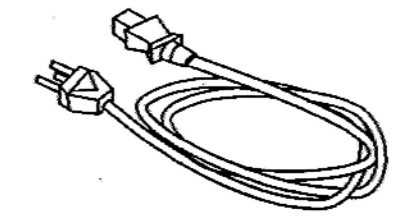
[There would be the case to be as a cause of trouble (wrong performance, change of color, blot or others).]

When hand-carry the unit, receive the probe into probe holder beforehand.

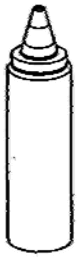
3-2 Accessories

Take out and verify the accessories which are packed together with the main unit. If they are short or damaged, immediately contact the representative or to us.

Power Cord



Gel (ultrasonic scanning gel, SG)



3-3 Charging Battery

Though the battery has been charged before shipment, it discharges during transportation, and it may completely discharge out if the unit would not be used for a long period.

Connect the power cord.

⚠ WARNING

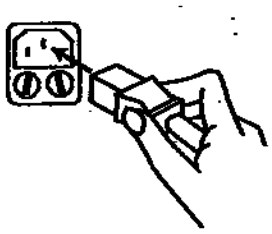
TO AVOID THE FIRE AND ELECTRIC SHOCK HAZARD

- Apply the 3P socket with protective earth as the power source, but don't use 2P socket.
  Don't use the table tap, too.

  [Application of 2P socket cut off the earthing to ground, and table tap causes not only the cutting of earth but the drop-down of voltage, detachment of plug and noise.]

- Heavy articles should not be put on power cord.
  Don't injure, process, forcedly bent, twist, pull or heat heat the power cord.
  When the cord was injured (exposure of core, or snapping of wire), contact the representative or us.

Inserting power cord into power source connect, plug it to 3P socket with protective earth for main unit.

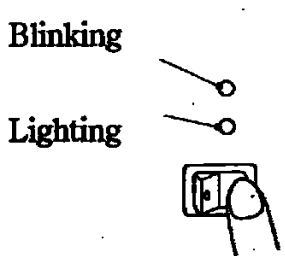


Charging battery

① Press the “I” side of power switch.

② Power lamp lights and the charging automatically starts.

③ Charging indication lamp blinks during charging and changes to lighting when it is completed.



4. OPERATIONAL CHECKOUT

4-1 Turning Power Switch On

Verify that there is not any abnormality in the unit.

⚠ WARNING

- Adjust by turning to the lower sound volume before before switching the power on.

  [There might be the cause to threaten pregnant woman or fetus by suddenly large sound.]

Volume

① Turn the volume for smaller sound.
(Sound emits even though turning to the smallest position.)

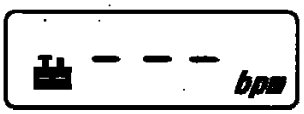
② Press the operation switch slowly.
Sound emits from speaker after the switch makes the click sound.

LCD Display Unit

① The unit displays as the right figure, and then immediately changes to the non-signal display " - - - bpm ".

Battery Charging Capacity

① Lighting of the battery mark indicates that charged capacity of battery dropped down.



② Operate the unit through connecting to AC power for charging battery.

③ Battery's operation power runs out in about 10 minutes if continues to use without charging.

4-2 Standard Probe

Check the signal detection.

⚠ WARNING

TO AVOID WRONG DIAGNOSIS

- Don't use the probe, which can't verify the Doppler's original sound, for monitoring.

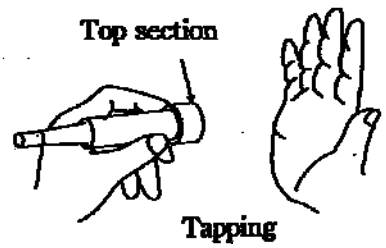
⚠ CAUTION

- Don't strike the transmitting and receiving surface surface for probe strongly.
  [It may become the cause of wrong diagnosis or trouble.]

① Tap the palm of hand with probe's top (transmitting and receiving surface) .

Replace it several times.

② Verify that sound emits through speaker.



5. MEASURING OPERATION

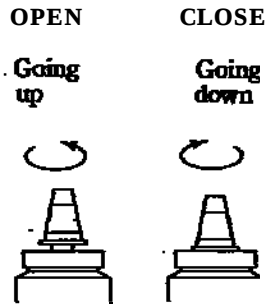
5-1 Application of Gel

The application closely adheres the probe and maternal abdomen, and reduces ultrasonic attenuation.

Open Cap

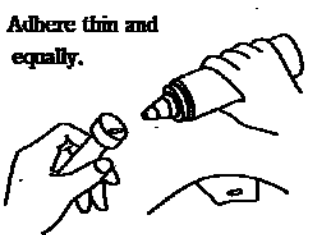
① Cap slightly moves upward when its upper section is turned and gel can be gradually flowed out from top of cap.

Note: It's not necessary to turn cap's lower section.



Apply Gel

① Adhere the supplied gel, equally to have thin membrane on maternal abdomen and probe's top.



Close Cap

① Turn the upper cap.

② Receive gel tube into holder by putting the cap down.

5-2 Fetal Heart Beats

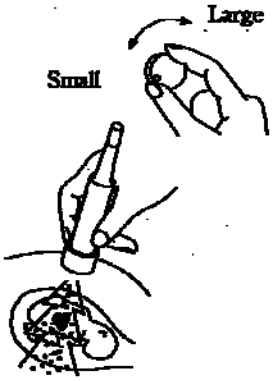
WARNING

TO AVOID WRONG DIAGNOSIS

- Relocate the probe to most suitable position corresponding to movement of fetal position.
  [Maternal heart will be detected if the probe is strongly put on maternal blood vessel.]
- When the intrauterine fetal death (IUFD) is doubted by this examination method, try to verify it with other method.

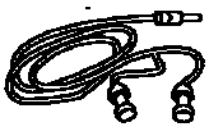
Doppler sound

① Put the probe vertically on maternal abdomen.
Adjust the volume to suitable sound.
Turning clock-wise makes the sound large.



② Change the angle and position of probe slowly until the clear and rhythmical sound (sound of heart wall or valve) is detected.

③ There is a case of Doppler's smaller sound in early stage of pregnancy.
It will be easily audible by using optionally supplied binaural earphone.



FHR (fetal heart rate) Display

① FHR is displayed when the signal is input.

② Signal input from placenta or blood flow doesn't have stable display.
Try to find the most suitable position corresponding to movement of fetal position.

When it's difficult to detect better signal . .

① In early stage of pregnancy
   a. Start to find at position two fingers breadth from upper margin of pubic symphysis on the median line.
   b. Or, the detection will be easily done if location of the uterus is confirmed beforehand by palpation.

② In intermediate and last stages of pregnancy
   The knowledge on the Traube's stethoscope is applicable for the detection.

   EXAMPLE:
   In case of cephalic presentation, start from the point one- third outside of the naval - spine line of fetal back side.
   If the fetal signal can't be detected there, try at the point three fingers from upper margin of pubic symphysis on median line.

5-3 Detection for Locations of Placenta and Umbilical Cord

Audible sounds are different according to blood flows.

Blood Flow Sound of Placenta

The sound is said as a continuous sound " GOH ".
When the position of placenta is on back wall, possibility for detection is said to be lower than the case that it is on anterior wall.

Blood Flow Sound of Umbilical Cord

The sound " HYUH " " HYUH " is said from the blood flow of umbilical cord in synchronization with fetal heart beats.

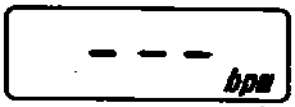
5-4 Power Saving Function

It prevents from the lowering of battery's charged capacity.
The release is done when the operation switch is pressed.

To Save Power

① Power supply automatically turns off, even during its operation, 10 minutes after the operation switch is once pressed, or when no signal condition " - - - " continues for 2 minutes.

Light of display is put out and sound doesn't emit.



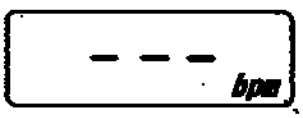
Note: When the unit is operated while battery is charged, the charging continues until battery is fully charged or power switch is turned off by pressing its "O" side.

② Press the power switch again if continuously use the unit.

Not To Save Power

① Keep the pressing of operation switch for about 5 seconds.

② The right display " - - 888 - - " appears on display unit, and then changes to no-signal display " - - - " immediately.



The display " - - 888 - - " appears again and power saving function doesn't work.

6. CLEANING AND MAINTENANCE

6-1 Cleaning

Power Source

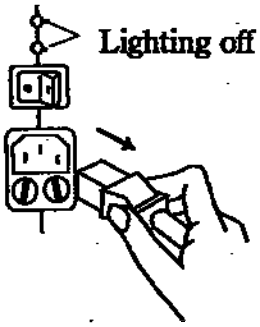
⚠ CAUTION

- Start cleaning after remove the power source plug for safety.
- Don't plug in or out with a wet hand.

  [It may cause electric shock.]

① Verify that both of power and operation switches are turned off.

② Remove the power plug from socket.



⚠ CAUTION

- Don't strongly wipe the probe's top (transmitting and receiving surface) .
  Don't splash water on the unit.

  [It may cause wrong measurement or trouble.]
- Don't use volatile solvent such as alcohol, thinner, benzine, cleanser or scrub brush.
  [It may cause damage of material or change of color.]

The probe of the FD-390 is water resistant with IPX1.

Cleaning before Use

① Lightly wipe the main unit and probe with paper towel, soft cloth or gauze.

② Every time you apply a probe to a new patient, clean it with a clean soft cloth or gauze. Please be sure to use chemical solutions mentioned the following Usable Chemical Liquid.

Usable Chemical Liquid

Glutaraledehyde (Cidex, Sterihyde, etc.)
Benzalkonium Chloride (Osavan, etc.)
Amphoteric Surfactants (Hypal, etc.)
Each chemical liquid has a different efficacy for germs. Observe and use according to the statement of virtues, usages and notices of each chemical liquid.

Wipe the top toward one-side.

Immersing other clean soft cloth or gauze with sterile distilled water and then well wrung, wipe off the remains of the agents or soap on the top of probe.

Finally wipe the top with paper towel or other dry soft cloth or gauze.

Cleaning after Use

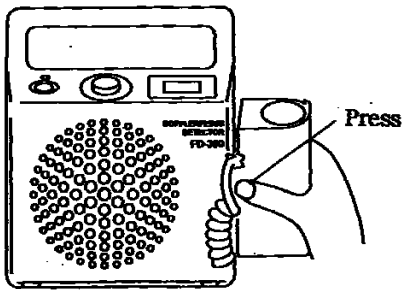
① Wipe off the gel on the probe well by immersing soft cloth or gauze into (warm) water and wringing well.

Finally wipe the top with paper towel or other dry and soft cloth or gauze.

② Lightly wipe the main unit and probe.
When it is difficult to remove the stains, clean the unit by followings:

a. Immerse the soft cloth with neutral detergent made thin by (tepid) water and then wringing well, wipe off the stains a little strongly.
b. Wipe with the cloth or gauze wetted with fresh water and well wrung.
c. Finally wipe with dry cloth or gauze.

③ Removing the holder by pressing its front section, wash it with fresh water.



6-2 Maintenance

The descriptions are of the cautions to maintain the performance level of the unit.

Operational Cautions

⚠ CAUTION

- Don't shut the vent for the unit.
  [There would be a case as the cause of fire by the remained heat inside the unit.]
- Don't give the physically strong shock by dropping the probe down, hitting the unit or others.
  [It may cause the trouble.]
- Don't use a portable/hand-carry telephone or such other devices, which emits electromagnetic waves, near the unit.
  [It may cause the wring measurement.]
- Don’t use other gels than the gel (ultrasound scanning gel SG) designated by us.
  [It may cause the signal deterioration or damage of probe.]

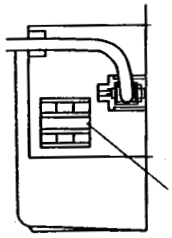
Checkout

Verify the followings for the whole unit before and after operation:

Standard probe	whether there would be a damage on the appearance, rut/stains on the top of probe ?
Appearance of main unit	whether there would be a damage or crack on outer cases ?
Cord	whether there would be a damage of the mantle, snapping of wire or hardening ?

Fuse

To prevent the trouble by temporary over current, the fuses, 0.5A, are used. If failed in supply of power source into the unit, verify whether it is disconnected or not by removing the fuse holder. If disconnected, replace with spare fuse.

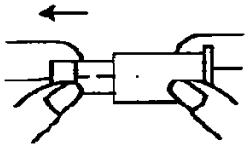


Spare fuses

Take out by removing the receiving holder

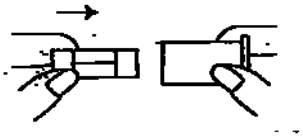
① Loosen by turning with a minus (－) driver, and then the head of fuse holder Jumps out.

② Take out the head with fingers.



③ Remove the old fuse.

④ Insert the new fuse.



⑤ Return the fuse holder and screw it with the minus driver.

Storage

⚠ CAUTION

- **DON'T PUT THE UNIT:**

* under direct sunshine
* in dusty or higher humid (800% or more) room
* in warm room (60 ℃ or more)
* in colder room (- 10 ℃ or less)
* on unstable or shaky place

[There would be the case as a cause of trouble (wrong performance, change of color, blot and others).]

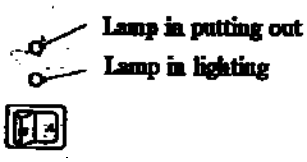
① Store the probe by putting into the holder.

Charging Type Battery

① Charging type battery will deteriorate during the repeats of changing and discharging.

Request the replacement of battery in the following cases to the representative:

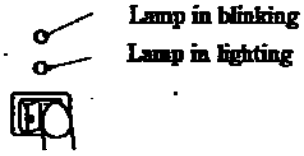
a. Charging indication lamp is in putting out although AC power source is used.



b. Charging indication lamp continues in blinking although AC power source is for many hours.

Until when the charging Continues??

c. Battery mark "  " often appears in display although battery has been fully charged.

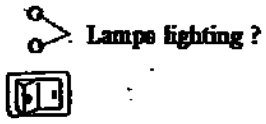


② The capacity already charged will become empty by self-discharge if the unit is not used for a long period.

There will be such case that, when try to charge the battery which became empty, the charging will stop before fully charged by the over current prevention.

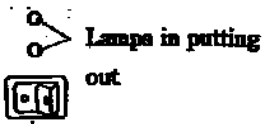
a. Verify for about first 10 minutes that the charging lamp is blinking.

Fully charged already?



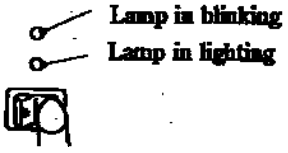
b. If the indication lamp is in lighting, once turn power source off and then turn on again.

Turn off



c. Start the charging again.
It takes about 1.5 hours for full charge.

Turn on for restart of charge



6-3 Primary Malfunction and Correspondences

Malfunction	Causes presumed	Correspondences
Nothing is displayed	Charged capacity of battery not remain	Charge the battery
	Fuse is disconnected	Replace fuse
FHR display is unstable	Location of probe is not suitable	Relocate it on the place where clear and rhythmical sound can be obtained
	Gel adhered on probe is not sufficient	Adhere gel sufficiently and equally
	Charged capacity of battery has lowered	Charge the battery
Sound not emit or low	Sound volume is set at low position	Reset the volume
	Charged capacity has lowered	Charge the battery

If the malfunction can't be solved by above correspondences or the troubles are others are others than above malfunctions, immediately contact the representative or the manufacturer.

6-4 Inspection and Repair

① No direct inspection or repair should be done, as the touch inside the unit may cause new or other troubles.

② Contact the servicing department or sales representative for the inspection, repair or inspection, repair or adjustment if needed.

③ Although there would be no trouble for operation, the inspection once a year to check out the correct performance is recommended.

6-5 Durable Years

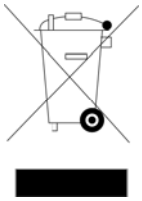
The lifetime of this equipment is 6 years. After this time, even if the equipment properly, the equipment should be inspected to prevent failures.

6-6 Disposal

When to dispose of this device, make contact with your local government, because it may be correspond to industrial waste.

7. LABELING

7-1 On the Body



This symbol indicates that this product comes under the provisions of EU Directive 2002/96/EC on waste electrical and electronic equipment (WEEE) and that this unit was placed on the market after 12 August 2005.
This directive covers EOL (end-of-life) disposal.

7-2 On the Probe

MEMO