



DOPPLER FETUS DETECTOR

Model FD-380

Operation Manual

This equipment is for medical use. Only Doctors and their trained staff **SHOULD** use this equipment.

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.

CE
0120

Manufacturer

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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.

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 classing 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.



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.

LIST OF WARNINGS

Before using the unit, all personnel, who will be working with it, should read and thoroughly understand the contents of WARNING and other entire descriptions the manual.

WARNING

1. 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.



2. 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.

3. TO AVOID THE FIRE AND ELECTRIC SHOCK HAZARD

- When it happened to drop the unit down or damage the panel, turn the power switch off and remove the battery, 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, forcedly bent, twist, pull or heat the cords of probe and earphone.
- When the cord for probe or earphone was injured (exposure of the core, or snapping of the wire), contact the representative or manufacturer for the replacement.
- 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.
- This equipment is not specified or intended for use in the presence of electro surgical equipment.
- Avoid the physically strong shock that cause damage of the probe and the probe connector. It leads to immerse liquids, and cause of troubles.

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-380 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-380 is intended for use in the electromagnetic environment specified below. The customer or the user of the FD-380 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions EN 55011	Group 1	The FD-380 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-380 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	Not applicable	
Voltage Fluctuations/ Flicker Emissions EN 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity


The FD-380 is intended for use in the electromagnetic environment specified below.
The customer or the user of the FD-380 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	N/A	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	N/A	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% U_t (>95% dip in U_t) for 0.5 cycles <40% U_t (>60% dip in U_t) for 5 cycles <70% U_t (>30% dip in U_t) for 25 cycles <5% U_t (>95% dip in U_t) for 5 s	N/A	FD-380 runs only on battery power.
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: U_t is the AC mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The FD-380 is intended for use in the electromagnetic environment specified below.
The customer or the user of the FD-380 should assure that it is used in such an environment.

Immunity test	EN 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
<p>Conducted RF EN 61000-4-6</p> <p>Radiated RF EN 61000-4-3</p>	<p>3 Vrms 150 KHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>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.</p> <p>Recommended separation distance</p> <p>$d = 1.2\sqrt{P}$</p> <p>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>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).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>

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-380

The FD-380 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FD-380 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FD-380 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.

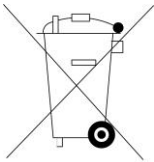
Compliant Cables and Accessories

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
TR-201	Probe (Doppler)	N/A

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



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.



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1-1 Description

Doppler Fetus Detector that is used for monitoring fetus heartbeat during pregnancy.

Doppler Fetus Detector is used to confirm the fetal well-being. Instantaneous display of FHR (fetal heart rate) and audible Doppler sounds are obtained by Doppler reflection at fetal heart or blood flow of placenta through maternal abdomen.

1-2 Intended OPERATOR (OPERATOR PROFILE)

Doctors and their trained staff(has equal qualification of midwife)

1-3 Specifications

Ultrasonic frequency	: 2.5 MHZ
Ultrasonic output	: 10 mW/cm ² or less
TI, MI	: <1.0
FHR measurement range	: 50-210 bpm
FHR display range	: 50-210 bpm
Audible output	: 600 mW
Speaker	: 57 mm diameter
Power source	: Alkaline dry battery (9V, 006P)
Continuous operation time	: 7 hours approx.
Classification of protection	: Internally powered equipment
Type of applied part	: TypeB †
Outer dimensions	: 85(W) x 160(H) x 33(D) mm
Weight	: 270 g approx. (including battery)

1-4 Environmental Requirements

	Operating Range	Transport/Storage range
Ambient Temperature	10 ~ 40°C	-10 ~ 60°C
Relative Humidity	75%	30 ~ 80%
Atmospheric Pressure	70 ~ 106kPa	70 ~ 106kPa

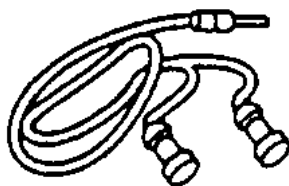
1. OUTLINE

1-5 Standard Accessories

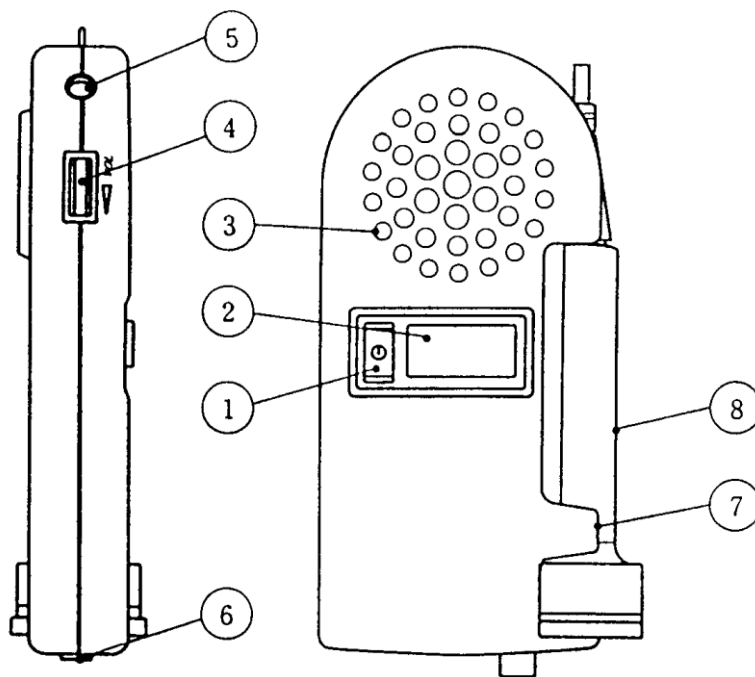
Standard probe, TR-201	1
Ultrasonic scanning gel SG, 250 ml	1
Alkaline dry battery (9V, 006P)	1
Strap	1
Operation manual	1

1-6 Optional Accessory

Binaural earphone



2-1 Description and function of each section



- ① Power switch : The switch is used to turn power ON or OFF.
- ② 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 🔋 .
- ③ Speaker : To emit Doppler original sound of fetal heart.
- ④ Sound adjusting volum : Turning upward makes the sound larger.
- ⑤ Earphone jack : To connect the plug for earphone.
- ⑥ Probe connector : To connect the plug for probe.
- ⑦ Probe holder : Probe is rested when the unit is not operated.
- ⑧ Probe : By emitting ultrasonic wave, it obtains Doppler sound.

3. PREPARATION

3-1 Preparation

Fit the accessories on main unit.

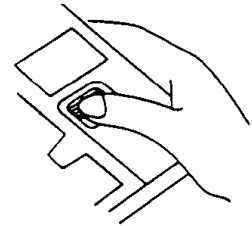


CAUTION

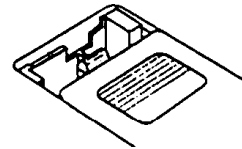
- Correctly insert battery with attention to the polarity "+ -". Don't use other type dry battery than designated and described in the manual.
 - There would be the case of a cause for fire, wound or surrounding corruption by heat generation or leakage of liquid from battery. -

1. Dry battery

- ① Put the battery into the main unit.
 - a. Open the lid by first pushing down the ditch portion on the "▽" marked plate of the rear case and then drawing it.
 - b. Correctly put the battery at correct direction of polarity "+ -".

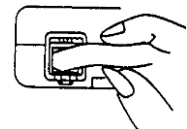


- ② Close the lid by matching with grooves.



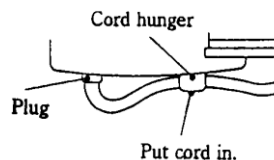
2. Standard probe

- ① Connect the plug to main unit
 - a. Match direction of plug with the connector located at bottom of the unit.
 - b. Keep in pushing until the click sound emits.



Push deep until
The click sound
emits

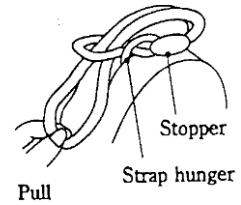
- ② Put the cord in cord hunger.



3. Strap


Fit it with main unit by followings:

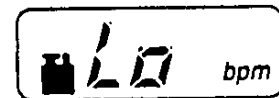
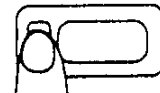
- ① Pass the thin loop through strap hunger.
- ② Pass the thick loop through the thin loop which is passed through the strap hunger already.
- ③ Pass through the stopper, and then pull firmly.

3-2 Operational Inspection

The inspection is to confirm that the unit is operative.

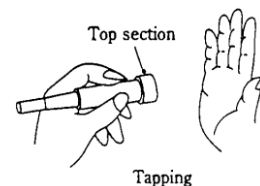
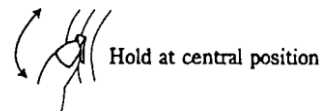
1. Power source

- ① Press power switch.
- ② Right side figure is displayed on LCD display unit, and then the display changes to no-signal display " - - - ".
- ③ Lighting of the mark  indicates the lowering of battery capacity.
 - a. Replace with the new battery.
 - b. If continued to use without replacement, the right display appears and the power turns OFF.



2. Standard probe

- ① Turning the sound volume up and down, hold it at central position.
- ② Verify that sound emits through speaker, by tapping the palm of hand with probe's top (transmitting and receiving surface).

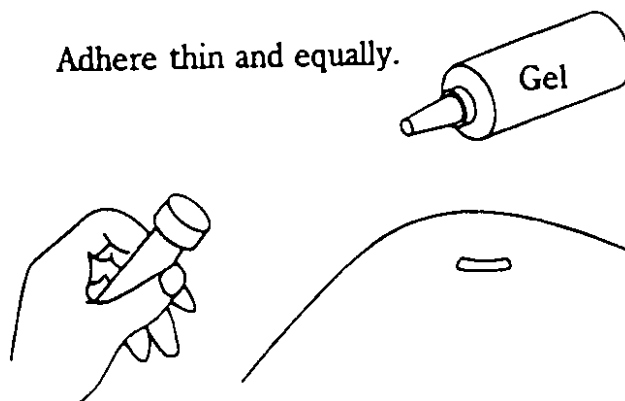


3. PREPARATION

3-3 Application of gel

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

- ① Adhere the supplied gel (ultrasonic scanning gel SG), equally to have thin membrane, on maternal abdomen and probe's top.



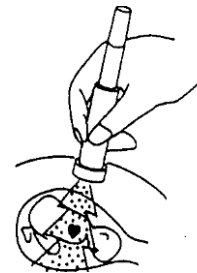
4-1 Fetal Heart Beats**WARNING**

1. 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.

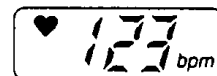
1. Doppler sound

- ① Put the probe vertically on maternal abdomen.
Adjust the volume to suitable sound.
- ② Change the angle and position of probe slowly until the clear and rhythmical sound (sound of heart wan or valve) is detected.
- ③ There is a case of Doppler's smaller sound in early stage of pregnancy.
It will be easily audible to use an optionally supplied binaural earphone.



2. FHR (fetal heart rate) display

- ① FHR is displayed when the signal is input.
- ② Signal input from placenta or blood flow does not have stable display.
Try to find the most suitable position corresponding to movement of fetal position.



4. METHOD OF OPERATION

3. In case 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.

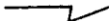
4-2 Detection for Locations of Placenta and Umbilical Cord

Audible sounds are different according to blood flows.

1. 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.

Placenta
" GOH "


2. 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.

Umbilical cord
"HYUH " "HYUH "


4-3 Power Saving Function


① Power supply turns OFF automatically 5 minutes after turned the power ON, or when no-signal condition " - - - " continues for 1 minute.



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




5-1 Cleaning



CAUTION

- Don't strongly wipe the top (transmitting and receiving surface) of probe.
 - There would be the case as a cause of wrong measurement or trouble. -
- Don't use the volatile solvent such as alcohol, thinner or benzene, or cleanser.
 - There would be the case as a cause for damage of the material or change of color. -
- To prevent cross-contamination:
Clean and disinfect the monitor and the probe (including patient cables) after each use.



The probe of the FD-380 is water resistant with IPX1.
IPX1: Protected against vertically foreign water drops.

1. Cleaning before use

- ① Lightly wipe the main unit and probe with 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.

2. Cleaning after use

- ① Wipe off the gel on the probe completely:
 - a. Immerse the soft cloth into (warm) water.
 - b. Well wring the cloth and wipe off.
 - c. Finally wipe with other dry and soft cloth.
- 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.
 - b. Wringing the cloth well, wipe off the stains a little strongly.
 - c. Then, wipe with the cloth wetted with fresh water and well wrung.
 - d. Finally wipe with dry cloth.

5-2 Maintenance

1. Operational caution

 **CAUTION**

- Don't give the physically strong shock to the unit by Dropping the probe down, hitting the unit or others.
 - There would be the case as a cause of trouble. -
- Don't use a portable/hand-carry telephone or other devices, which emits electromagnetic waves, near the unit.
 - There would be the case as a cause of wrong measurement. -
- Don't use other gels than the gel (ultrasonic scanning gel SG) designated by us.
 - There would be the case as a cause of signal deterioration or damage of probe.
- Battery should not be disassembled, heated, electrically shorted or put into fire.
 - There would be the case as a cause of the human injury or surrounding corruption by battery's explosion. -

2. Verification

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

Probe	Whether there would be a damage on the appearance, or rust/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?
Appearance of main unit	Whether there would be the rust or adhered remains of leaked liquid?

3. 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 service department or sales representative /dealer for the inspection, repair or adjustment if needed.
- ③ Even through there would be no trouble for operation, the inspection once a year to check out the correct performances is recommended.

4. Storage



CAUTION

- Don't put the unit:
 - * under direct sunshine
 - * in dusty or higher humid (80%RH or more) or colder (-10 °C or less) room
 - * on unstable and shaky place.
 - There would be the case as a cause of trouble (wrong performance, change of color, blot and etc.). -
- Remove the battery from the unit when don't use for long period.
 - Otherwise, there would be the case as a cause of fire, human injury or surrounding corruption by heating caused with electric short, or leakage of liquid. -

- ① Store the probe by putting into probe holder.

5-3 Primary Malfunctions and Correspondences

Malfunctions	Causes thinkable	Correspondences
Electric power doesn't	Battery is not put in	Put battery in
	Polarity (+ -) of battery is put adversely	Relocate the polarity correctly
Sound doesn't emit or is low	Sound volume is set at low position	Reset the volume
	Battery capacity has lowered	Replace with the new battery
FHR is not displayed	Probe is not located on suitable position	Relocate the probe on position where clean and rhythmical sound is detected
	Battery capacity has lowered	Replace with the new battery

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

5-4 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.

5-5 Disposal

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

6-1 On the Body



6-2 On the Probe

