Fetal Monitor

Fetal Actocardiograph MT-516

Japan Medical Products License Number 21300BZZ00393000

Operation Manual

CAUTION

This equipment is for medical use. Only doctors and their trained staff ***should*** use this equipment.
Read the operation manual carefully before use.
Use this equipment only according to the instructions in this manual.
Improper operation may cause accidents.
Keep this manual in a safe and accessible place for easy future reference.

Manufacturer **Distributor**

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Multiple Notes

This operation manual is written for specifications, functions, operations and maintenance of the MT-516 that has a twin monitoring capability in Fetal Monitor MT-510 series.

This equipment is used for the purpose of monitoring fetal status and doing non-stress testing to estimate the health condition of the fetus from the middle stage of pregnancy through labor.

To use this equipment properly, please operate according to instructions and perform periodical maintenance. Only a trained and qualified service engineer should repair the equipment.

Our company and our representatives are not responsible for the safety of users and for the performance of the equipment due to operation that is not described in this operation manual.

This equipment is not specified or intended for operation during the use of defibrillators or during defibrillator discharge.

This equipment is not specified or intended for use in the presence of electro surgical equipment.

This equipment is not specified or intended for use in conjunction with any other type of monitoring equipment except the specific devices identified for use in this book.

Perform safety testing in accordance with local legal requirements to ensure proper patient safety.

The TOITU quality management system complies with the international standards ISO9001:2008, ISO13485:2003, EN ISO13485:2003, and the Council Directive on Medical Devices 93/42/EEC Annex II.

The specifications of the equipment are subject to change without notice for product improvements. Therefore, specifications may differ from your equipment.

Please contact us if you have any questions regarding technical issues or the contents of this operation manual. To contact us, please refer to our addresses on the last page of the manual.

SAFETY CAUTIONS ON THE USAGE OF MEDICAL ELECTRIC EQUIPMENT

Written on the basis of Notice No.495 Health Policy Bureau, Japanese Ministry of Health, Labor and Welfare.

1. Only well-trained and qualified persons should use this equipment.
2. Pay attention to the following when you install the equipment;
   (1) Install it at a place free from moisture.
   (2) Install it in a place free from the effects of air, temperature, humidity, wind, sunshine, dust, salt, sulfurous air, etc.
   (3) Make sure stable statuses are maintained, such as without inclination, vibration, or shock (including during transportation).
   (4) Do not install near chemicals and gas storage.
   (5) Make sure the power supply, frequency, voltage and electric current allowances (or electric consumption) are correct.
   (6) Properly ground the unit.
3. Pay attention to the following before using the equipment:
   (1) Be sure the equipment is function properly by checking the connection of switches, polarity, dial setting and meters.
   (2) Be sure that the unit is properly grounded.
   (3) Be sure that all cables are properly connected and they are not broken.
   (4) Do not use two pieces of equipment on the patient at the same time. Doing so may cause errors in diagnosis.
   (5) Check external circuits and electric circuits that connect directly to patients.
   (6) Do not use more than one patient for one piece of equipment.
4. Pay attentions to the followings while using the equipment:
   (1) Watch continually and be sure that no abnormality exists in either the equipment or with the patient.
   (2) In case an abnormality in the equipment or patient is found, discontinue use of the equipment until safe operation can be resumed.
   (3) In case the equipment is turn off since the supply mains is interrupted, the equipment backs to the same condition as 'Start Up'.
   (4) Do not allow the patient to touch the equipment.

5. Pay attention to the following after using the equipment:
   (1) Turn off all operating switches and dials to the before use position according to procedures. Then turn off the power supply switch.
   (2) When disconnecting cables, do not use excessive force.
   (3) For storage:
      a. Store it in a place free from water.
      b. Store it in a place free from changes in air, temperature, humidity, wind, sunshine, dust salt, sulfurous air, etc.
      c. Make sure stable statuses are maintained, such as without inclination, vibration, or shock (including during transportation).
      d. Do not store near chemicals or gas.
6. When the equipment is not functioning correctly, do not attempt to repair without our permission.
7. Do not alter the equipment.
8. Ongoing maintenance
   (1) Make periodic checks of the equipment and the parts.
   (2) When the equipment has not been used for a while, be sure the equipment is functioning properly and safely before use.
9. Confirm other operational notifications in the operation manual for this equipment.

Notes for Safe and Correct Operation

To prevent injury of operators or others and property damage, you must observe the following Symbols that are divided into two groups.

WARNING

This s natters that may lead to death.

This s natters that may lead to injury or physical damage.

The list ls is shown below.

WARNING

1. To prevent explosion
   * Do not use the equipment in an environment where there is an explosion hazard such as in the presence of flammable anesthetic gas. The equipment does not have explosion proof construction.
2. To prevent accidents or the deterioration during convalescence
   * Check the status of the recording and alarm message at least every 20 to 30 minutes during monitoring.
   * Take countermeasures according to the instructions of the doctor when the the heart rate alarms issue.
3. To prevent wrong diagnosis
   * Check the equipment before starting to use. If the equipment is not functioning properly, it may have a failure. Turn off the switch and disconnect the power cable. Call for repair.
   * Do not use a transducer from which the Doppler sound or UC level cannot be conformed.
   * The equipment may record twice the real heart value that is coming down or half of what is going up, because of incorrect signal conversion due to the change in uterine contraction.
   * Fix the transducer to the most suitable position based on the current fetal position.

⚠ WARNING

When the ultrasound is aimed strongly at the blood vessel of the maternal body, the equipment records maternal heart rate. Make sure to record the fetal heart rate instead of the maternal heart rate by comparing the Doppler sound with maternal heart rate.

* If the accuracy of any value displayed on the monitor, central station, or printed on a graph strip is questionable, determine the patient's vital signs by alternative means. Verify that all equipment is working correctly.

4. To prevent fire and electrical shock
   * The device must be connected to a properly installed power outlet with protective earth contacts only.
   * Use the 3 prong outlets with an earth ground. Do not use 2 prong outlets. A 2 prong outlet is not grounded.
   * This equipment is suitability for connection to public mains as defined in CISPR11
   * 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.
   * Do no attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.
   * Use only patient cables and transducers supplied with the monitor. Use of any other patient cables may result in out-of-specification performance and possible safety hazards.
   * Route all cables away from patient's throat to avoid possible strangulation.

⚠ WARNING

* Devices may only be interconnected with each other or to parts of the system when it has been determined by qualified biomedical engineering personnel that there is no danger to the patient, the operator, or the environment as a result. In all cases, safe and proper operation should be verified with the applicable manufacturer's instructions for use, and system standards IEC 60601-1-1/EN 60601-1-1 must be complied with.
* When interfacing with other equipment, a test for leakage current must be performed by qualified biomedical engineering personnel before using with patients.
* Do not attempt to disassemble or modify the equipment.

5. To prevent the equipment from slipping or falling down
   * Do not place the equipment on unstable surfaces.
   * Take care to position the monitor securely when overhead. Avoid insecure positioning.
   * Do not route cables in a way that they may present a stumbling hazard. For devices installed above the patient, adequate precautions must be taken to prevent them from dropping on the patient. For device installed with carrier, certain fixation to the carrier must be taken to prevent them from dropping on the operator or patient.
6. To prevent the influence to equipment from electromagnetic waves and radio waves
   * Do not allow cellular phones, transceivers or radio-controlled toys, etc, in the room where this equipment is installed.

Warning display

The warning label shown below is especially important and is attached to the side of the main body. **Read the label before using.**

WARNING

TO AVOID 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.

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.

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.
3. Installation
   * Compatibility is critical to safe and effective use of this device. Please contact your local sales or service representative prior to installation to verify equipment compatibility.
   * Before connecting the device to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the unit's label.
   * When installing the unit into a cabinet, allow for adequate ventilation, accessibility for servicing, and room for adequate visualization and operation.

CAUTION

4. 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 cleanliness instructions.
   * Do not immerse the transducer connectors during any stage of the cleanliness process.
   * Dispose of the packaging material, observing the applicable waste control regulations and keeping it out of children's reach.
5. 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.

Classification

Equipment components are classified, according to IEC 60601-1, as:

Type of protection against electrical shock	Class I	
Degree of protection against electrical shock	Type BF	
Degree of protection against harmful ingress of water	Equipment	Ordinary Equipment (enclosed equipment without protection against ingress of water)
	Doppler/UC Transducer (without connector)	IPX4 (EN60529: protected against water sprayed from all directions – limited ingress permitted)
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	
Method(s) of sterilization or disinfections recommended by the manufacturer	Applicable (Refer to 8. Cleanliness)	
Mode of operation Continuous operation	Continuous operation	

Symbolic marks and meanings of terms

Symbolic marks

This equipment uses the following Symbolic marks.

1. Symbolic marks on the base are IEC standards or Japanese Industrial Standards

	Heart mark (Heart Rate synchronized)
	Speaker
	Graphic Recorder
	Timer
	Electrical Screen (Operating display screen for electrical display device)
	“0” Setting
	Stopping Alarm
	Recording Sheet Paper Feeder
	Power Supply ON
	Power Supply OFF
	Hand switch (Marker switch)
	Bell (Alarm)
	Input
	Alternating Current
	Fuse
	BF type equipment

2. Our original Symbolic marks

	Uterine Contraction
	Select (Fix)

Meanings of terms

The following abbreviations are used:

1. IEC Standard and JIS

2×TIL250V	Two pieces of Time delay Fuse 1A Type250V

2. Our original abbreviations

RT	Right	LT	Left
1DOP	1st Doppler	2DOP	2nd Doppler
UC	Uterine Contraction	RCD	Recording Chart Paper Drive Speed
ACT	Fetal Movement	ALM	Alarm

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 MT-516 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.

Warning
ESD warning symbol
A warning that pins of connectors identified with the ESD warning symbol should not be touched and that connections should not be made to these connectors unless ESD precautionary procedures are used.
Staff must be made aware that accessible pins of connectors identified with the ESD warning symbol should not be touched with the fingers or with a hand-held tool unless proper precautionary procedures have been followed;
—discharging one's body to the frame of the MT-516 or to earth or a large metal object;
—bonding oneself by means of a wrist strap to the MT-516 or to earth.
Staff that could touch connectors identified with the ESD warning symbol should receive this explanation and training. This includes clinical/biomedical engineering and health-care staff.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The MT-516 is intended for use in the electromagnetic environment specified below. The customer or the user of the MT-516 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions EN 55011	Group 1	The MT-516 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 A	The MT-516 is suitable for use in all establishments other than domestic 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 A	
Voltage Fluctuations/ Flicker Emissions EN 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The MT-516 is intended for use in the electromagnetic environment specified below. The customer or the user of the MT-516 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 MT-516 requires continued operation during power mains interruptions, it is recommended that the MT-516 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 MT-516 is intended for use in the electromagnetic environment specified below. The customer or the user of the MT-516 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 MT-516

The MT-516 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MT-516 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MT-516 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.
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, transducers 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-686-05S	Transducer (Doppler, UC)	1.9 m
TR-627-05S	Transducer (Doppler)	2.0 m
SW-524	Remote Marker Switch	2.8 m
NOTE: Any supplied accessories that do not affect EMC compliance are not included.		

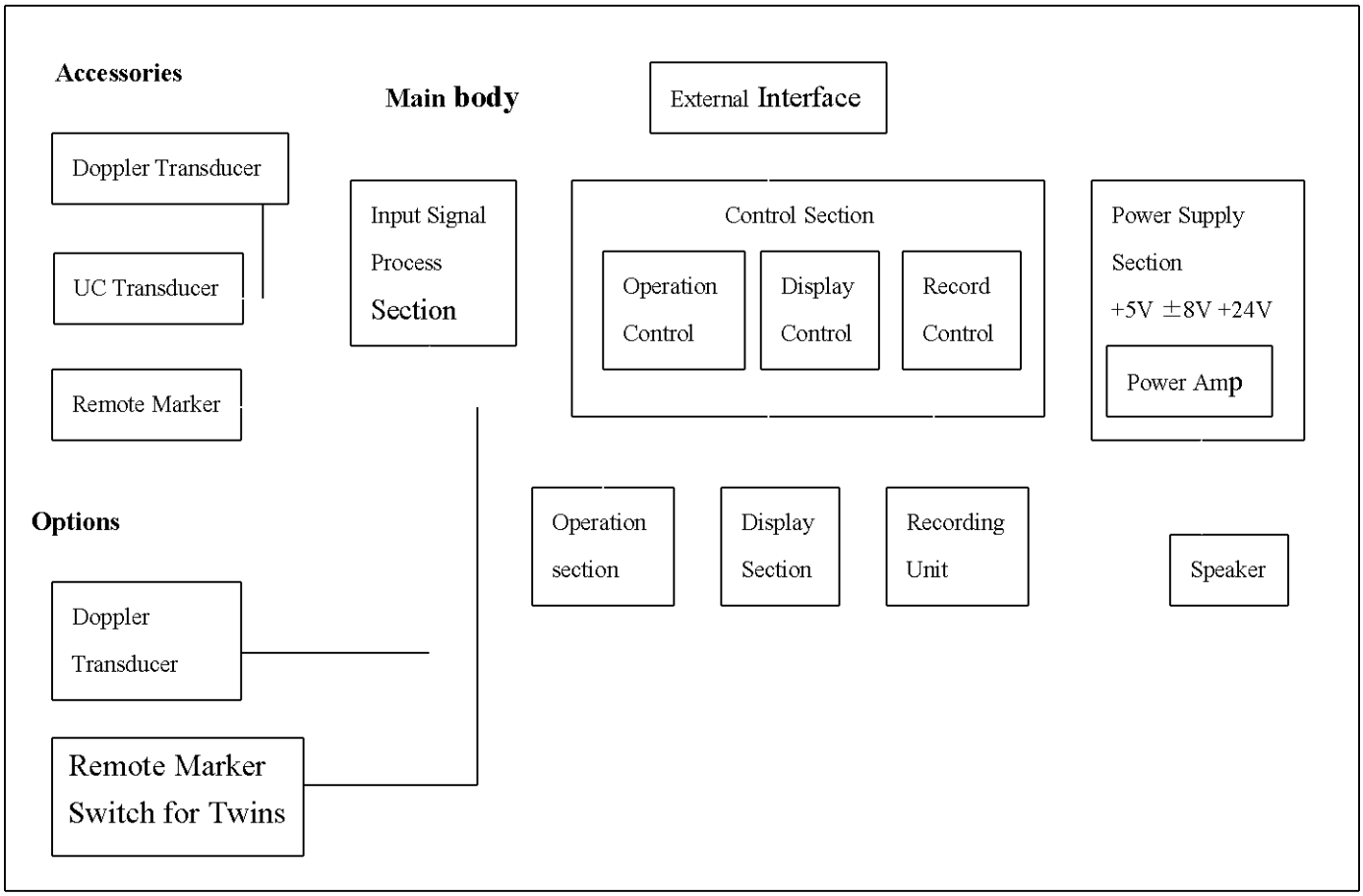
Table of Contents

1. Overview

1.1 Components

This equipment is composed of the MT-516 main body, accessories, and options.
The body has an input signal process section, a control section, an operation section, a display section, a recording unit, an external interface, a power supply section and a speaker.
Outside output terminal connectors are built-in and can be connected to the external recorder, data recorder, etc., to record fetal heart rate and uterine contraction. The unit can also be connected to a personal computer, a central station monitor, etc., to analyze the data.
The standard accessories like transducers are listed on P.39.
Options are listed bellow;

Standard Cart	JC-167
Additional options for twins	Doppler transducer
	Doppler transducer belt
	Remote marker switch for twins



Equipment Block Diagram

1.2 Product Technology

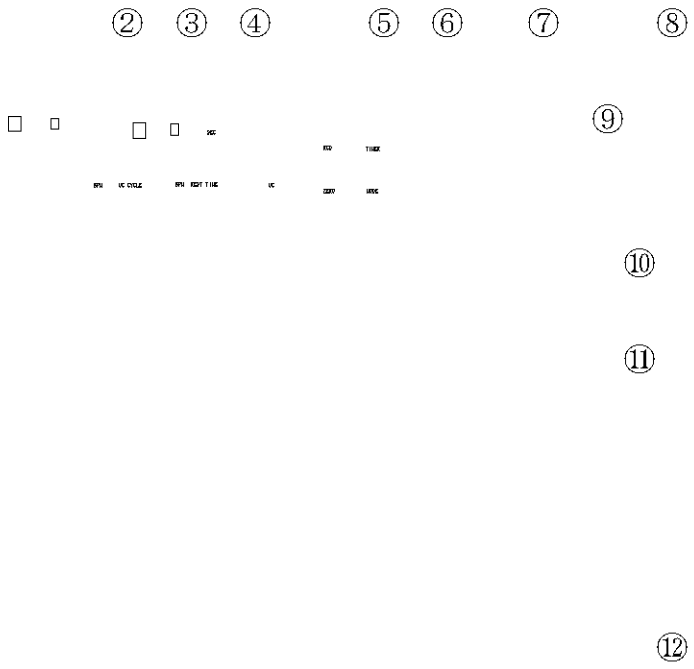
The Doppler transducer and External UC transducer is attached to the maternal *abdominal wall. The Doppler transducer detects fetal heart rate beats by ultrasound doppler* technology and the External UC transducer detects displacement caused by tension of the abdominal wall while uterus is contracting. The detected information will be transmitted to the main unit where the signals will be processed corresponding to their characteristics and will display heart rate and UC level on the display board.

The equipment will record heart rate and UC waveforms and fetal movement information on the recording chart paper simultaneously.

The heart rate alarm will visually alert on the display board and audibly sound an alarm when the heart rate beats go over the upper limit of the heart rate preset in memory or go under the preset lower limit and continues longer than the delay time.

2. Names of each Unit and Functions

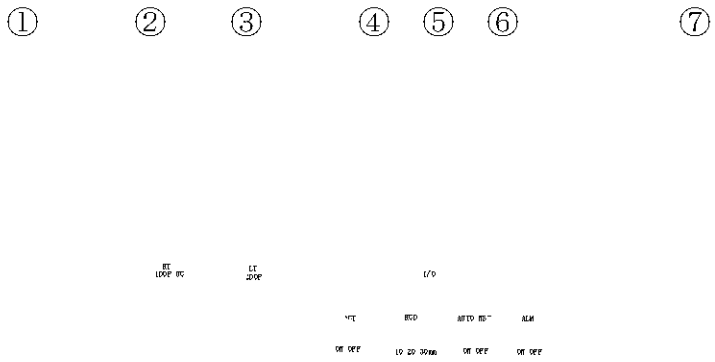
2.1 Front panel



Number	Names	Outlines of functions
1	Display board	Display measurement data, setup items and values
2	Alarm Silence Lamp	Audible alarm OFF. Lamp on when audible alarm is off.
3	Recorder Lamp	Lamp on while recorder is functioning.
4	Recorder Switch	ON/OFF recorder
5	Zero Set Switch	UC recording position zero setting
6	Timer Switch	Record only the set period of time.
7	Mode Switch	Select Measurement Mode or Setting Mode.
8	Dial Switch	Selects setting items/ values and controls volume of doppler sound.
9	Setting Switch	Fixes the setting items/values and selects the doppler sound for twins.
10	Recorder Button	Press and open the cover of the recorder
11	Recorder	Records the various data on recording chart paper
12	Power Switch	Power Supply turning ON (I)/OFF (O)
13	Speaker	Available to hear Doppler Sound and Alarm Sound

2. Names of each Unit and Functions

2.2 Rear panel



Number	Names	Outline of functions
1	1 DOP/UC Socket	Connects Y-shape transducer.
2	2 DOP Socket	Connects Doppler transducer.
3	Marker Jack	Connects a plug to the remote marker switch or the fetal vibration stimulator (optional)
4	Fetal Movement Spike Shape Waveform Recording Switch	Selects ON/OFF for recording fetal movement spike shape waveform.
5	Recording Speed Switch	Selects recording chart paper drive speeds
6	Outside Output Connector	Connects to other external equipment (Central Station Monitor, Data Recorder)
7	Auto NST Switch	Selects ON/OFF of auto NST
8	Alarm Sound Switch	Selects ON/OFF of heart rate alarm. Alerts by sound or silence.
9	Spare Fuses	Spare fuses
10	Power Supply Input Socket	Connects the attached power cable
11	Fuse Holder	Contains a fuse.

3. Preparation

3.1 Installation

Please observe the following conditions when installing or operating the equipment.

Environmental Temperature : +10~+40℃

Pressure : 700~1060hPa

Humidity : 30~75%

WARNING

To prevent explosion

Do not use in an environment where there is an explosion hazard such as in the presence of flammable anesthetic gas. The equipment does not have explosion proof construction.

CAUTION

To prevent the damage from slipping down or falling down

Do not place the equipment on unstable places such as on a loose base or an inclined place.

3.2 Connecting plugs

WARNING

To prevent fire and electric shock

Use a grounded 3-prong outlet for the power supply. Do not use a 2-prong outlet, as it is not grounded.

CAUTION

Please use the specified Transducers. A shock such as dropping may cause errors in measurements or breakdowns.

Connecting AC Power Cable

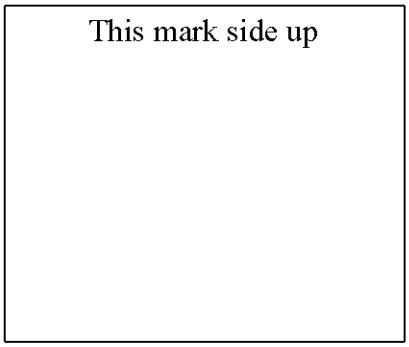
Insert the plug to the socket of the Main body and connect the Power cable to a grounded 3 prong wall outlet.

A grounded 3 prong wall outlet

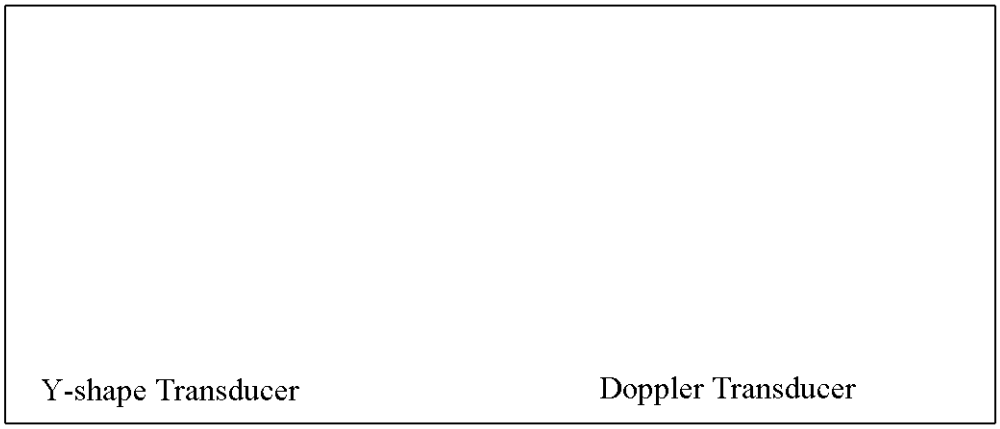
3. Preparation

Connecting Transducers

Hold the plug logo mark side up and insert in the same color socket. Insert firmly.



Remarks: There are two kinds of transducers.
One is both a doppler and for uterine contraction. The other is only a doppler.



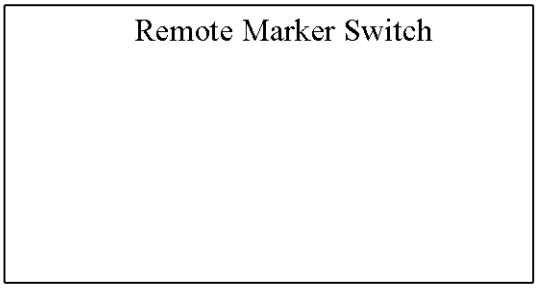
① For single fetus, use the Y letter shape transducer that has two cables for the doppler and uterine contraction

② For twin fetuses, add and connect the second doppler transducer(optional)

③ In the case of a single fetus, adding the second doppler transducer to the 2DOP socket will give a more stable measurement and wider monitoring.

Connecting Remote Marker Switch

Insert the plug into the jack.



3. Preparation

Connecting External Equipment

Each of the following equipment may be connected to the external output connector of the MT-516. Operation of this equipment may also be monitored remotely.

Central Station Monitor
Wireless Monitoring System Transmitting Unit
Remote Wire Monitoring Set
Remote Wireless Monitoring Set

3.3 Setting of Recording Paper

Use only our specified recording paper 0030-026 for fetal monitor.

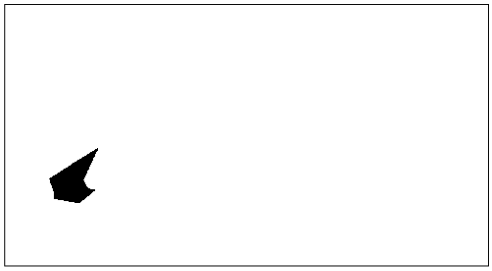
Other paper may cause incorrect recording or damage to the recorder.

Opening Cover

Press the recorder button.
Unlock and the cover will automatically
open to front.

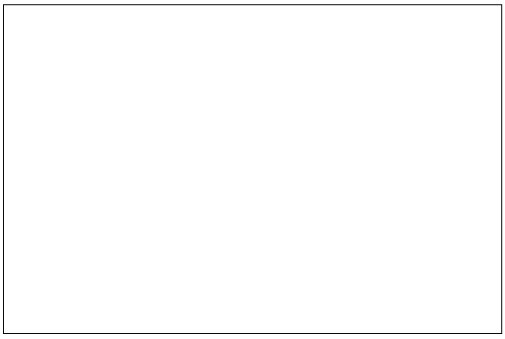
Loading of Recording Paper

① Remove from the plastic cover and soften slightly.
② Hold the cut corner side up and place into the cover, inserting to the end.
③ Take out one sheet from the top of the stack.



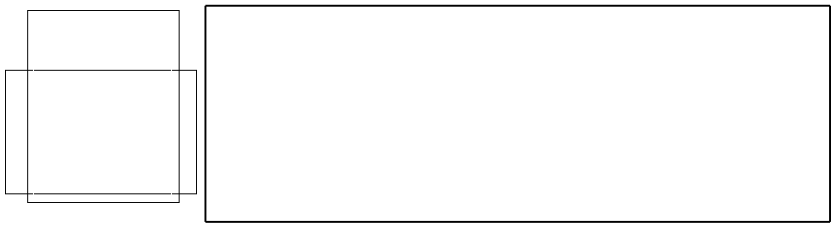
Closing Cover

Close the cover, holding the recording chart paper.
A click sound will be heard indicating the cover is closed.



3.4 Selecting Switches on the Rear Panel

Slide the switch with a finger right and left for item selection.



Selecting ON/OFF for recording fetal movement spike shape waveform

Select ON or OFF on the recording switch (ACT) on the fetal movement spike shape waveform.

ON : Recording the 1st fetus movement waveform upper side of the External UC waveform and the 2nd fetus movement waveform lower side of the UC waveform.

OFF : No recording

Fetal Movement Spike Shape Waveform

External UC Waveform

Selection of Recording Speed

Note : The fetal heart rate waveform shape differs according to the recording speeds.

Select the speed for the recording paper at millimeter per minute.

The 10-unit value records 10mm/minute, 20 records 20mm/minute and 30 records 30mm/minute.

Remarks: Select the speed before recording and do not change while recording. The speed determines the shape of FHR waveform.

Record waveform for 1 minute at 10 mm wide

Record waveform for 1 minute at 30 mm wide

3. Preparation

Selection of recording start methods

Select how to start recording of data with AUTO NST switch.

ON : Automatically starts, when the input signal of heart rate gets stable.

OFF : Manual Start.

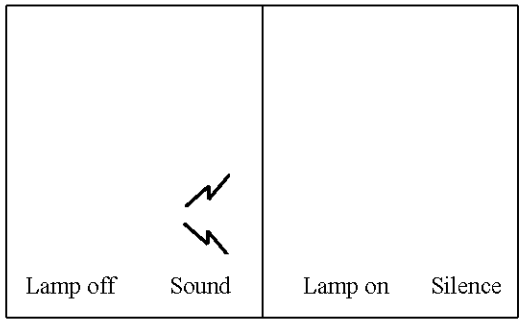
start automatically start by pushing or

Select alarm ON/OFF

You can select audible sound or silent alerting of the heart rate alarm.

ON : Audible Alarm Sound

OFF : Silence The silence display Lamp of the front panel is on, when power supply switch is turned on.



CAUTION

When monitoring with the audible alarm sound off, watch closely any changes on the display board and recording. You may overlook the alarm of the heart rate.

3.5 Checking before starting

Check the equipment before starting to use, and make sure the equipment is functioning correctly.

CAUTION

Always check the equipment before starting use. If the equipment is not functioning properly, turn off the switch, disconnect the power cable, and discontinue use. Call your authorized representative for repair.

Confirming start up

① Press the "**I**" power switch, and turn on the power supply.
The equipment automatically checks the circuit and the LED display.

② Confirm the LED Display shows no error.

3. Preparation

Examples of displayed numeric values (88 sign automatically appears while checking display functions).

1 DOP Heart rate	Heart Rate synchronizing	Doppler Sound output	* 1	AUTO NST (Lamp on)

AUTO

UC Level

BPM BPM UC

*1: Automatically alternates display items corresponding to monitoring conditions.

MIN SEC UC CYCLE The cycle of Uterine Contraction *2	□ BPM 2 DOP Heart Rate	REST TIME Remaining Time

*2 Measurement starts when UC continued over 20 seconds.
Initialized when one cycle goes over 59 minutes, 59 seconds or UC Level gets to 0 and the level continues over 20 seconds.
The cycle of UC may not be measured when tonus comes up.

③ Display Time

The 3.cl sign is blinking quickly when verifying time operation.

Quick blink: Waiting verification

Verifying Time

CAUTION

Confirm the time before starting to monitor and adjust if needed.

Check the correct time and verify that there is no difference in time.

① Press the Set Switch after verification.

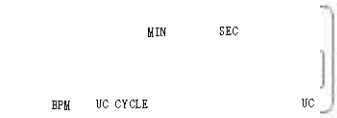
Time Display disappears on the display board

and the display changes to Measurement Mode.

② If a difference is found, adjust it.

Remarks: the accuracy of the clock built-in is 50 seconds/month.

Adjust once every 2 or 3 months



Measurement Model

Adjusting Time (Hours/Minutes)

① Press the mode switch. Blinking will become slow and time digits display for hour and minute turn red indicating the mode has changed to time adjusting mode. After changing to time adjust mode, if the next operation is not started in 10 seconds, the display returns to the measurement mode automatically.

② Press the set switch. Hour digits will blink. (Go to ④ skipping ③, to adjust the hour, and adjust hours in the same way as minutes.)

③ Press the set switch again. Minute digits will blink.

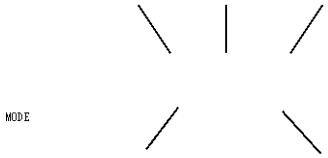
④ Turn the dial switch, and the minute digits will change click by click.

⑤ Display the correct digits and press the set switch. Minute digits will stop blinking and be fixed; the 3cl sign will blink slowly.

With the 3cl sign blinking, turning the dial switch will change the digits, and pressing set switch will fix the digits.

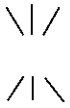
⑥ To return to the measurement mode, press the mode switch.

Example: Adjust 9 o'clock 24 minutes to 25 minutes

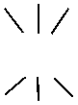


Blinking slowly red

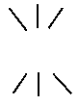
Hours blink

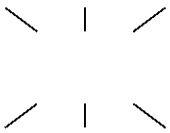


Minutes blink



25 appears





3. Preparation

Adjusting Years/Months/Days

① When the 3cl sign is blinking, turn the dial switch and adjusting items as follows:

Adjusting Items		Meanings of items and adjustable values
1.cl	2001	Years: 2000～2099 Read measure year printed in recording chart paper
2.cl	10.01	Months/Days: 01～12/01～31 Read measure month and day printed in recording chart paper
3.cl	09.01	Hours/Minutes: 00～23/00～59 Read measure hour and minute printed in recording chart paper

② Adjust as needed, same as minutes.

With item sign blinking, turning dial switch will change the digits, and pressing set switch will fix the digits.

③ To return to the measurement mode, press the mode switch.

Confirming the sound volume level

CAUTION

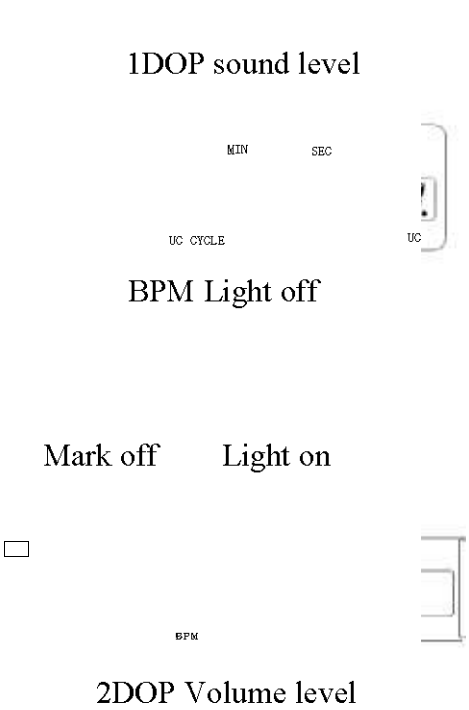
After turning on the power supply, confirm that the volume level is comfortable. Sudden loud sounds may frighten mothers and their fetuses.

① Turn the dial switch lightly. The display board will show the two red numerical letters instantly. The numerical value is the sound volume level and shows it when turning the dial switch. When turning is stopped, the board displays the measurement mode.

② Confirm the sound value level is between 15 and 20.

③ To adjust again, turn the dial switch. The sound value can be changed from 0 to 30. Keep it between 15 to 20 for both dopplers.

④ For twins, one at a time can be heard. Every press of the set switch will change from 1DOP and 2DOP alternately. Either of the marks that are audible will light up.



Remarks: Only the sound volume of the doppler sound can be changed. The alarm sound volume and the operation confirming sound cannot be changed.

3. Preparation

Confirming Doppler Sound

① Hold the transducer on the palm, Transmitting and receiving surface side up.

② Place the palm of the other hand on the transmitter surface with a grasping motion.

③ Confirm that the doppler sound can be heard. If not, turn the sound up.

④ After confirmation, treat and place the transducer carefully, not to add any pressure on the transmitting and receiving surface.

⑤ Do not use the transducer when the doppler sound cannot be confirmed.

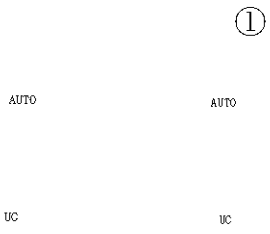
Confirming UC Level

CAUTION

Do not press the pressure sensing part of the UC transducer strongly. It may cause failure.

① Press the pressure detector lightly on the receiving pressure surface of the transducer as pictured.

② Confirm that the stronger the press, the higher the UC level.



The stronger the press, the higher the level.

4. Measuring Operation

4.1 Measurement Preparation

Preparing Accessories

Ready transducer belts and Gel (CG for Monitoring).

Placing Transducer Belts

Place 2 belts around the maternal abdomen for a single fetus and 3 belts for twin fetuses.

4.2 Doppler Method

Transducer Gel

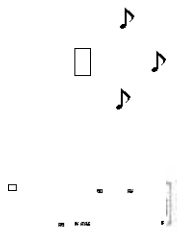
Place gel on the surface of the maternal abdomen and on the surface of the transmitting and receiving part of the transducer.

Remarks: Gel can be squeezed out without taking off the cap.
When the cap is removed, gel will flow out too freely.

Turn the top	Open upside	Close downside
① Turn the top counterclockwise, then the top comes up and gel can be pushed out little by little from the top end.		② To close, turn clockwise until it comes to a stop.

Positioning

① Place the transmitting and receiving surface of the transducer on the wall of the maternal abdomen.
② Search for a position where crisp and rhythmical sound can be heard (sound from heart wall and valve)
③ Watching the display screen, stop at a position where the green light is on continuously. According to the status of inputted heart rate signals, the display changes its colors as at right.



Green	Orange
Good	Mixing Noise

④ In case of twins, look for each fetus. Press the set switch and set 2DOP for doppler sound.

light off

□

CAUTION

Place transducers to the most appropriate position of each fetus. Make sure not to measure the same fetus with both transducers. When it is likely that one fetus is being measured by both transducers, the ! warning mark will be printed on the recoding chart paper. In that case, change position of the transducers .

1 transducer for 2 fetus. 2 transducers for 1 fetus

Placement

① Place and fix the transducer at the position decided upon with the belt under the mother's back. Hook a buttonhole of the end of the belt to the hook of the transducer.
② To tighten appropriately, hook a buttonhole of the other end of the belt to the hook. Hang the remaining belt end over to the side of the maternal body.
③ Wipe off excess gel from the abdomen.

CAUTION

Do not tighten the transducer belt too tightly. It may press the maternal body or cause miss-reading.
Do not add gel to the External UC transducer.
It may cause failure.

4.3 External Uterine Contraction Method

Positioning

Place the external transducer on the most projecting wall of the abdomen.

Example: In case of cephalic presentation, place on the fetal back a little to the hip.
In case of breech presentation, place on and around a fetal head.

Remarks: If placed on the maternal navel, the influence of maternal respiration will prevent correct measurement.

Fastening

CAUTION

Do not tighten the transducer belt too tightly. It may press the maternal body or cause miss measuring.

① Place and fix the transducer on the found position with a belt under the mother's back. Hook the buttonhole at the end of the belt to the hook of the transducer.

② Tighten the belt to get the UC level to 22 value and hook the buttonhole of the other end of the belt. Hang the remaining belt end over the side of the maternal body.

Remarks: In using the transducer for a long time, be careful that no inflammation of the skin is seen on the maternal abdomen.
UC transducer seldom causes skin inflammation.

4.4 Recording

Using Timer Functions

① When the auto NST switch is on, the equipment starts to record automatically after the input signal of the heart rate becomes stable.

Automatic Start

Automatic Stop

② When the auto NST switch is off, push the time switch and confirm the time on the timer and start recording.

TIMER

Manual Start

Automatic Stop

For the timer function, please refer to Page 22.

Not using Timer Functions (Auto NST Switch OFF)

① Setting the UC zero set.
Press the zero set switch while there is not uterine contraction.
Press slightly, the 12 value appears on the display and start position of the recording comes to 12.5 value on the paper scale.
To set the staring value to "0" scale, press continuously until "0" shows on the display board and "0" shows on the scale.

Push lightly

ZERO

UC

Push a little bit longer

ZERO

UC

② Press the recorder switch.
The recorder lamp lights up and recording starts after printing the headings on the top sheet.

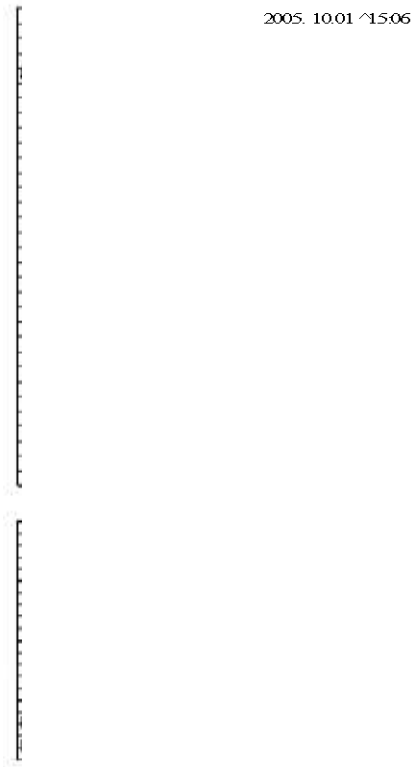
Manual Start, Manual Stop

RCD

4. Measuring Operation

Heading

Write name, gestational age. etc., by hand



Year/Months/Day/Time

The ^mark before time shows the difference between real time and the place where it is printed. Because the date is printed first, the place of time stamp may differ slightly .

Recording speed of Recording paper

Type Mark for the equipment

Modes for recording

Various items may be printed according to the accessories used, the switches selected on the rear panel and setting values.

The names of recording items will be printed at every change according to the changes of recording conditions.

Print out the preset value of the heart rate alarm and fetal movement level.

HR.HI=Upper Limit of FHR, HR,LO=Lower Limit of FHR

DLY.T=Delay Time, ACT.L=Fetal Movement Level

List of names of recording items

1DOP	Connecting Y-shape Transducer
Marker RT	Remote marker Switch (Single), printing when connecting only 1DOP
1 DOT	Dot of Fetal Movement of 1DOP
1FM	Fetal Movement Spike Shape Waveform of 1DOP
External UC	Connecting Y-shape Doppler/External UC Transducer
2DOP	Transducer only for Doppler
2DOP0	Setting and selecting Offset 0
2DOP+20	Setting and selecting Offset level +20
2DOP-20	Setting and selecting Offset level –20
DOP[S.HR]	Setting and selecting Single Heart ON
Marker RT LT	Remote Maker Switch (twin), Printing when connecting 2DOP.
2DOT	Dot of Fetal Movement of 2DOP
2FM	Fetal movement Spike Shape Waveform of 2DOP.

4. Measuring Operation

Printing Fetal Movement

① Let the patient press the remote marker switch when she feels fetal movement. Marks are printed out on the recording chart paper.

② In case of twins, let the patient use the Y-shape marker in order to press the right and left separately.

Changing positions

WARNING

To prevent missed diagnosis

Fix the transducer to the most suitable position according to changing position of the fetus.

If the ultrasound aims strongly toward the blood vessel of the maternal body, the equipment will record the maternal heart rate. Be careful not to record the maternal heart rate, but to record fetal heart rate. It is recommended that you compare the doppler sound of the fetal heart rate and the maternal heart rate periodically.

Reposition according to changing position of fetus. Especially when ! mark is shown, reposition is inevitable (Refer to P.15).

Example of Single Fetus Recording

Time stamp
Printing hour and minute every 5-minute at 30 mm/minute speed and every 10-minute at 10 mm/minute speed printing▽ mark every one minute.

1DOP Heart Rate Waveform

Marker RT
Printed out when the Marker Switch is pressed.

1DOT
Printing a thin dot when Fetal Movement goes over preset level.

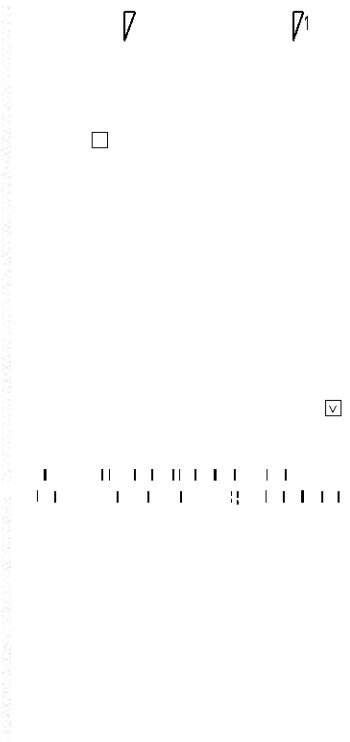
Cycle of Uterine Contraction
Printing minute /second every one cycle.

Measurement starts when UC continues over 20seconds.
Initialized when one cycle goes over 59 minutes, 59seconds or UC level gets to 0 and UC continues over 20 seconds.
The cycle of the UC may not be measured when tone comes up.

External UC Waveform

Zero Set
Printing out Zero set mark when setting zero set while recording

Example of Twin Fetus Recording



External UC Waveform

Time stamp

Alarm of signal error
When most likely measuring one fetus with two transducers, this mark will be printed.

1DOP Heart Rate Waveform

2DOP Heart Rate Waveform

Offset
Printed offsetting waveform to the selected and specified direction.

Vibration Stimulating Marker (Option)
Printed when using Vibration Stimulator.

Marker RT

Marker LT
Printed when pressing the left Remote Marker Switch.

1DOT

2DOT
Printed dots when the Movement of the second fetus goes over preset level.

1DOP Fetal Movement Spike Shape Waveform
Printed when selecting the ON switch of rear panel.

2DOP Fetal Movement Spike Shape Waveform

Stop Recording

① Recorder stops automatically in timer recording mode. In the manual recording mode, press recorder switch to stop.

② When the equipment comes to a stop, the recording lamp blinks and the paper fast-forwards until the next fold regardless of any chosen speeds. After fast-forward, recorder stops and lamp turns off.

③ To stop fast-forwarding, press recorder switch again.

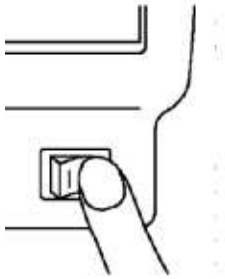
④ Press the fold of the chart paper lightly and cut

Auto stop	Manual stop
	RCD

The paper forwards fast until meeting to the next fold

4.5 Finishing Measurement

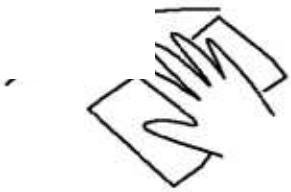
① Press the O mark of the power supply switch and turn off power supply.



② Take off transducer belts. Remove transducers from the abdomen.

③ Wipe off gel from the abdomen with tissue papers.

Wipe off gel



④ For cleaning of equipment and accessories, refer to P. 29.

5. NST Timer

5.1 Timer Functions

Starting Timer Functions is different according to the selection of the auto NST switch on the rear panel.

NST Switch	Starting Conditions	UC Zero Set	Timer Functions
ON	Automatically starts when the input signal of the heart rate becomes stable.	Automatically set to the 12.5 value	①Record only the selected time span.(*1) ②Remaining time appears every 5 seconds. ③The end sign blinks when Timer ends. The recording paper fast-forwards and stops automatically.(*2)
OFF	Press the timer switch twice to start		

*1 If the heart rate alarm sounds near the auto end, the recorder continues recording.

*2 Setting end (refer to p.28), end alarm will sound.

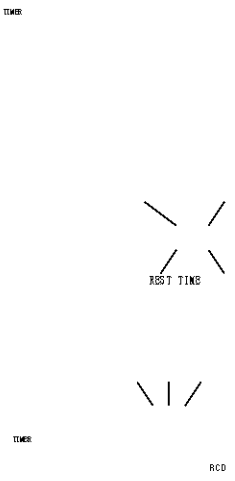
5.2 Timer Setting Mode

Selecting Timer Setting Mode

① Press timer switch. Display will change to timer mode (minutes). The dot next to the digits blinks and solicits confirmation of timer time. If the next operation is not started within 10 seconds after the setting mode was set or when the paper run out alarm occurs while operating, the mode returns to the measurement automatically.

② When the display time is correct, press timer switch again. The display returns to the measurement mode and timer starts to function. The recorder lamp turns on and recorder starts recording after printing the headings on the top sheet.

③ To extend or shorten the recording time, change the setting.

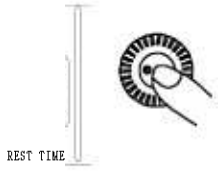


5. NST Timer

Changing Time Mode Time (Setting)

① Turn the dial switch while the dot next to the digits is blinking. Every click changes 10 minutes on the display.

When 00 is set, time will not count. Recorder continues until the recorder switch is pressed and recording is stopped.



② When the desired time span is displayed, press the set switch.

③ To change the recording time while timer recording, press the timer switch and change in the same way. The timer will be changed and the waveform will be continuously recorded without interruption.

④ To change back to the measurement mode, press the timer switch.

Stopping recording

To stop recording, press the recorder switch.

6. Alarms

6.1 Fetal Heart Rate Alarm

WARNING

To prevent accidents

For safety, when heart rate alarm occurs, consult the doctor.

CAUTION

When monitoring in audible alarm sound off mode, monitor changes on the display board and recording. Overlooking of the alarm of the heart rate may occur.

Heart Rate Alarm Alert

Alarm alerts when the heart rate beats go over the upper limit of heart rate preset in memory or go under the preset lower limit and continues longer than the delay time.

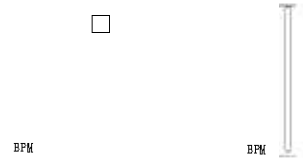
Remarks: 5 minutes after the power supply is turned off or after calling off the alarm, the heart rate alarm function does not work.

Example

Settings	Starting Conditions
Heart Rate Upper Limit **180**	When heart rate goes over 180 and does not come down in 20 seconds.
Heart Rate Lower Limit **100**	When heart rate goes below 100 and does not go up in 20 seconds.
Delay Time **20**	

① Audible alarm sounds.
When the OFF switch is selected, keeps silent.

② Visual alarm will alert by blinking the **A** (alarm) sign and heart rate value alternately on the display board.



Stopping

① Press either the recorder switch, zero set switch, timer switch, mode switch or set switch. The alarm sound stops and the display returns to the measurement mode. Even if the condition recovers, the alarm does not stop automatically.

② Confirm the patient's situation and take appropriate measures according to the doctor's instructions.

③ Pay close attention to the transition of recording. After stopping the alarm for 5 minutes alarm will not alert regardless of preset conditions.

6.2 Paper Run-Out Alarm

CAUTION

While monitoring, when the recording chart paper is close to the end, load a new paper.

The transition of the heart rate waveform will be interrupted and it may cause actual events to be overlooked.

Paper End Alarm Alert

An alert is sounded when the end of the recording chart paper is detected, or when the recorder cover is opened while recording.

①An audible alarm sounds. The alarm sounds even if the OFF switch is selected.

②A visual alarm will alert by blinking the **PAPER** sign on the display board.

③The recorder lamp blinks in red for 5 seconds.

Stopping

①Press either the recorder switch; zero set switch, timer switch, menu switch or set switch. The alarm sound stops and the display returns to the measurement mode.

②When the cover is opened, close it. When the recording chart paper is running out, load a new paper pack. (Refer to P.7)

6.3 No Plugs Alarm

No Plugs Alarm Alert

No plugs alarm alerts when the plug of the transducer is disconnected.

①An audible alarm sounds. The alarm sounds even if the OFF switch is selected.

②A visual alarm will alert by blinking the **nc** (No Connection) sign on the display board.

③The alarm cannot be stopped by switching operations. Insert the plug into the socket. The alarm silences. The display will return to the measurement mode.

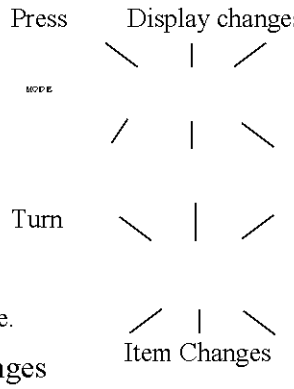
7. Settings

7.1 Setting Fetal Heart Rate

Changing to Setting Mode

①Press the mode switch continuously. The **0.dp**, **2.oFF.** sign appear and the setting of the heart rate and the related mode is selected. The sign blinks and indicates readiness for the next step.

If you do not proceed to the next step within 10 seconds after pressing the mode switch, the mode returns to measurement mode.



②Turn the dial switch clockwise slightly. Every click changes the signs of items from **0.dp** to **1dp** and as to the following.

Setting Items	Factory value	Meanings of Items and Setting Value
0.dp	**2.oFF**	**Setting of Offset mode of 2 DOP** Please select **On** or **OFF** at Power supply on
1.dp	**1.oFF**	**Single Heart Mode of 1 DOP: On** or **OFF** On: Two Transducers for Single Fetus Off: Two Transducers for each of Twins
2.dp	**F. 0**	**2nd Doppler Waveform Offset : 0 +20 -20 (bpm)** In case two Doppler, 2nd waveform is printed offsetting upward or downward. Please select the numbers
3.hr	**H.180**	**Heart Rate Upper Limit: OFF 160 170 180 190 200 (bpm)** Heart rate Alarm upper limit values.
4.hr	**L.100**	**Heart Rate Lower Limit: OFF 80 90 100 110 120 (bpm)** Heart Rate Alarm lower limit values.
5.hr	**d. 20**	**Alarm Delay Time: 10 20 30 (Seconds)** Judging time to alert Heart Rate Alarm

Changing Settings

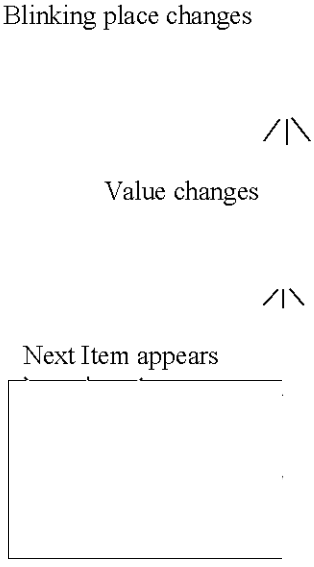
Example: Changing HR lower limit from 100(bpm) to 120(bpm)

①Display the item you want to change and press the set switch. The blinking of setting item changes to light on and the dot next to the set value blinks.

②Turn the dial switch and the set value changes.

③Select and indicate the set value desired and press the set switch.

While the dot is blinking, turn the dial switch and the set value changes. Press the set switch to set the value.



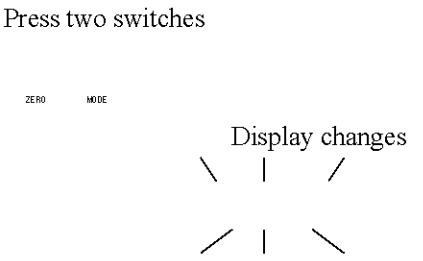
Finishing Settings

Press the mode switch to turn back to measurement mode.

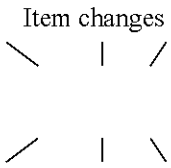
7.2 Setting Uterine Contraction and Related Settings

Changing to the Uterine Contraction Mode

① Press the zero set switch and the mode switch simultaneously.
The **0.FC** **0.on** sign appear, set uterine contraction.
The blinking shows the changeable status.
If the next step is not started within 10 seconds after changing the setting mode, the sign turns back to measurement mode.



② Turn clockwise the dial switch slightly.
Every click changes setting items from **0.FC** to **9** 「」 as follows and the Setting Item blinks.



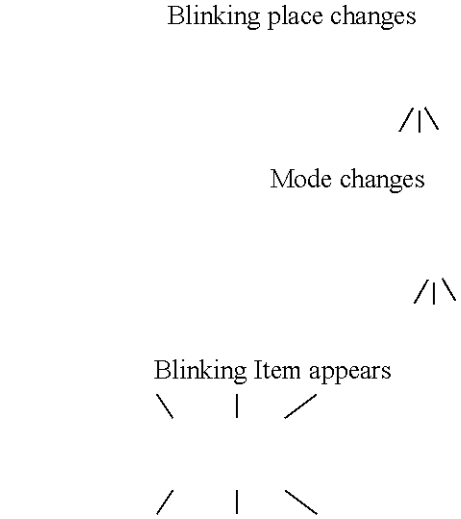
Setting Items	Factory Set Value	Meanings of Items and Setting Values
0.FC	0.on	Default Value : ON OFF When the power switch is turned on, the value returns to the factory set values.
1.AC	L.25	Fetal Movement Value: OFF 05 10 15 20 25 30 35 40 45 Level records fetal movement DOT
2.uc	F.on	UC Filter: ON OFF Subtracts the respiratory waveform from the uterine contraction waveform.
3.uc	H. on	UC Sensitivity: ON OFF Makes more sensitive than normal UC recording.
4.uc	d.on	Displaying the Cycle of UC: ON OFF Displays the cycle of UC as on or off.
5.uc	r.on	Recording the Cycle of UC: ON OFF Records the cycle of UC as on or off.
6.AL	A.on	Signal Error Alarm : ON OFF When most likely recording one fetus in the case of twins, the ⚠warning mark will be printed on the recoding chart paper.
7.bE	P.on	Beep Sound : ON OFF Confirms sound will sound or be silent when pressing switches
8. n⌐	E.on	NST End Sound : ON OFF When NST ends, sounds or be silent
9. 「」	.on	Printing Headings on top sheet: ON OFF Prints heading on the top sheet or not

7. Settings

Changing the setting Values

① To change, display the item and press the set switch.
Blinking of the setting item changes to light on and the dot next to the set value blinks.
② Turn the dial switch to change set values.
③ Select and indicate the set value wanted and press the set switch.
While the dot is blinking, turn the dial switch and the set value will change. Press the set switch to fix the value.

Ex.: Change the UC filter from on to off



Finishing Settings

Press the mode switch, and the sign turns back to the measurement mode.
The set value newly changed is memorized automatically.

7.3 Changing Settings while Recording

While recording, a change of setting will cause all setting conditions to be printed out.
While recording conditions are being printed, the normal recording is interrupted.

7.4 Default Settings

FHR HI : 180bmp
FHR LO: 100bmp
DLY : 20sec

8. Cleanliness

8.1 Accessories Contact to Skin

Accessories in contact with skin such as, transducers, remote marker switches and belts should be cleaned before and after use.

CAUTION

Detach them from the main body before cleanliness.
Do not strongly wipe the transmitting and receiving surface of transducers.
It may cause failures.
Do not use chlorhexidine, gluconate, sodium hypochlorite, volatile solvent (ethanol, benzene and etc.) or cleanser for cleaning.
It may cause deterioration of materials.
Do not clean or wipe off with water or liquid the connecting plugs of power cables.
It may cause electrical damage

The transducers of the MT-516 are water resistant with IPX4. However, connecting plugs is not water resistant.

Usable Chemical Liquid

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

Before cleanliness

Wipe off gel on transducers with tissue papers or paper towels.

Cleanliness

①Dip a clean cloth in the chemical liquid and squeeze it. Wipe the surface of accessories that have contact to skin.
②Dip a clean cloth in the sterile distilled water and squeeze it.
Wipe the surface of accessories again in order to take off any remaining drops of the chemical liquid.
③Wipe them dry with a clean dry cloth or paper towels.

8.2 Main body

Clean the main body after turning off the power switch and disconnecting the power cable from the outlet. Wipe the main body lightly with a dry cloth periodically.

①Put a soft cloth in a neutral detergent diluted with warm water.
After squeezing the cloth well, wipe off the main body.

②Again wipe the main body with a damp clean cloth.

③Dry with a clean dry cloth.

9. Maintenance and Checks

9.1 Maintenance

To maintain the function of this device, maintenance is needed. Maintenance operations are to be done by users or the manufacturer or its representatives. Both cases are under the control of hospitals.

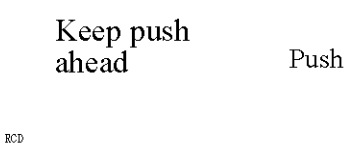
Maintenance Types		Operator	Contents
Before use	Every time before using the device	User	Refer to P9[3.5 Checking before starting]
After use	Every time after using the device	User	Turn off power supply, Cleaning, Disinfection, Confirming no damage of the device
Every 6 months	Check the functions every 6 months	User	See below
Every year	1time every year	User	See below

9.2 Twice yearly Check

Check the device every 6 months as follows;

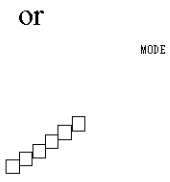
Check the printing of the recorder

① Turn on the power supply switch.
While pushing the recorder switch, turn on the power supply switch.
The checking mode is ready and .o1 is displayed on the display board



② Turn the dial switch clockwise and display .02 on the display board
The print checking mode is ready.

③ Printing
Push the setting switch or the mode switch and the display turns to .02 run ■ marks are printed like a ladder. After ■ marks are printed for a while, printing stops automatically.
Then turn off the power supply switch.



④Confirming
Confirm there are no printing faults on the recording paper.

Check the heart rate alarm

① After turning on the power supply switch, push the setting switch and make mode to the measurement.

② Set the heart rate lower limit 120, and the delay time to10 seconds in order to issue the heart rate alarm easily.

③ Put the Doppler transducer on your pulse and make arrange to keep the green digital on the display board for over 20 seconds.

④Confirm that heart rate alarm sounds 5 minutes after power supply switch turned on.

⑤ Confirm the heart rate alarm can be turned off after pushing one of the recorder /timer/zero set/mode/setting switches.

Finishing the twice yearly check

① Turn off the power supply switch.

② If you cannot confirm the ordinary operation, there may be some faults. Contact our distributor to repair the device.

CAUTION

If you cannot confirm the ordinary operation of the device at your 6 months check, the device may have faults. Please turn off the power switch, disconnect from the outlet, indicate the device has faults and make us or our representatives to repair it.

9.3 Yearly Maintenance

Check the thermal head of the recorder every year.
If the head is stained, remove stains from the head, tracing it slightly with the attached thermal head cleaner after removing the cap, touching the felt to the thermal head.

Thermal head (Brown)

9.4 Component Parts

For maintenance we supply the following component parts. The time to change them is subject to the frequency and circumstances of using them. Please change them if it's needed. If the changing time is not clear, please ask our distributor.

Main component parts	The life of parts	Reason	
Power supply cord	3~4 years	Deterioration of the cable coating	
Buttery for a clock memory	4 years(Using 8 hours/day)	Decline of the buttery capacity	
Power supply switch	5 years	Deterioration of machinery durability	
External UC Transducer	4 years	Deterioration of the pressure sensor	Deterioration of the connecting point of the transducer
Doppler transducer	5 years	Deterioration of the ceramic glueing	
Recorder	6 years(Using 8 hours/day)	Deterioration with age	

The component parts of which durability is longer than the device durability are not shown.

9.5 Check lists

Check before use

Serial No.	Date	Checker	
	Check items	Results of checks	
1.	Are there any damages or deformation on the main body or cables?	OK	NO
2	Are there any display faults during the circuit and the LED display self-check?	OK	NO
3	Does the clock keep good time?	OK	NO
4	Is the sound volume proper?	OK	NO
5	Is the Doppler sound heard, when the transducer is brought near a hand?	OK	NO
6	Does the UC level display change, when the pressure sensing part of the UC transducer is pressed?	OK	NO

Check after use

Serial No.	Date	Checker	
	Check items	Results of checks	
1	Did you disinfect the accessories that contacted patient's skin?	OK	NO
2	Are there any damages or deformation on the main body or cables?	OK	NO
3	Is there any dust on the electronic parts?	OK	NO

6 months check

Serial No.	Date	Checker	
	Check items	Results of checks	
1	Is the recorder printing clear?	OK	NO
2	Does the heart rate alarm work properly?	OK	NO

9.6 Changing a Fuse

In order to protect the equipment from temporary surges of electric current, a fuse is built in. The fuse may be broken when electric power is not supplied although plugs are connected properly. Confirm by taking out the fuse from the holder. If it is broken, install a new one.

① Disconnect from power.
② Hold the fuse by the fingers and push the latch with a fingernail. The latch comes off and the head of the holder will pop out a little. Pull out the holder.
③ Extract the broken fuse.
④ Insert a new fuse in the holder. Use 1A, 250V, time delay fuse.
⑤ Replace the holder.

Extract a broken fuse from a holder.

9.7 Supplementation of expendables

Gel for Doppler sound and Color recording chart papers are expendables.
Please check your stock and order us or our distributor, if they are needed.

9.8 Storage

Storing Place

Keep the equipment and accessories (excluding recording chart paper) in the following conditions:

Temperature	−10～+60℃
Humidity	30～95% (Non-condensing)
Pressure	700～1060hPa

Main body

When not in use for an extended period, disconnect the power cable plug from the outlet.

Transducer

Store the transducer so that the transmitting and receiving surface of the doppler transducer and the pressure-sensing surface of the uterine contraction transducer are protected from shock.

9. Maintenance and checks

Recording Chart Paper

The paper can turn yellow and the color can fade under the following environmental conditions.

①Preservation under high temperature, high humidity and direct sunlight.

②Contact with the alcohol and the adhesive material such as adhesive tape.

③Keeping the recorded data in the polyvinyl chloride.

Please be certain to use the soluble paste when you paste the chart.

The color begins to fade by degrees after the recording is done.

The recording paper lasts approx. 5 years under the temperature 23℃ and humidity 50% RH circumstances.

10. Troubleshooting

10.1 Possible Malfunctioning

Possible malfunctions are listed below. If after following the recommendations, the equipment still does not work well, failure of the equipment should be suspected. Contact our distributor.

Example of mal-functioning	Possible causes	Solutions
You cannot light the power lamp on, even if you turn on the power supply switch.	Power cable may be disconnected.	Connect the power cable tightly.
	Fuses may be broken.	Change fuses.
You can not hear Doppler Sound	Volume of sound is too low.	Turn the volume clockwise and volume up.
Doppler does not function correctly.	The transducer has not been placed properly.	Find the position where you can hear the crispy and rhythmical sound and attach there again.
	More ultrasound gel is needed.	Be sure the transducer face is covered with a thin coat of gel.
	Fetus has arrhythmia or hiccupping	Continue monitoring carefully
Uterine Contraction is not recorded	Position of the transducer is not correct.	Attach it over the uterine body and stabilize.
	When Uterine contraction occurred, you pressed the Zero Set Switch.	Press Zero Set Switch while there is no uterine contraction.
b.LO appears on the display See chapter 10.2	Battery voltage is going low.	Call our distributor
Err. and numbers appear 002	The circuit may be damaged.	Stop operating the equipment. Please contact our distributor

10.2 Low Battery Voltage

①Display

When battery voltage goes between 2.64V and 2.6V, the **b.LO** sign and voltage value appear on the LED display for 20 seconds after starting the routine. The display cannot be reset.

Battery Voltage displays 20 sec.

②When continue to use

After notification of the low battery voltage, the equipment displays the time as usual, but there may be a time error. Adjust the time(Refer to Page 11).

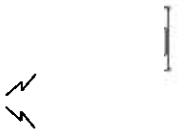
Please correct time.

Remarks: Even if the battery voltage is low, the clock keeps the time correctly while the equipment is connecting to the AC power supply.

③ Alarm Sound

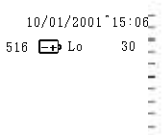
After several weeks, if you continue to use without changing the battery, after 1 or 2 weeks the battery voltage goes to under 2.59V, and the b.LO sign and voltage value appear on the display for 40 seconds. The audible sound can also be heard for 40 seconds. You cannot stop the alarm sound.

Battery voltage



④ Printing Mark

When the battery voltage goes under 2.6V, the equipment prints the LO mark on the recording paper.



LO

11. Specifications

11.1 Specifications

Standard Compliance		Medical Device Directive 93/42/EEC EN60601-1:1990+A1:1993+A2:1995 +A13:1996/IEC60601-1:1988+A2:1995 EN60601-1-2:2007
Power supplies		AC100V,110V,115V,120V AC220V,230V,240V 50Hz/60Hz 26VA
Electrical Isolation		Class Ⅰ Type BF (Parts contacting to skin)
Heart Rate Measurement Mode	Heart Rate Signal Input	2 Channels Doppler Ultrasound Technique
	Measuring Technique	Quick Autocorrelation Processing
	Heart Rate Count Range	50～210 bpm
	Heart Rate Display Range	50～210 bpm
	Alarm	User-selectable, FHR Upper Limit/FHR Lower Limit/ Delay Time
Fetal Movement Mode	Measuring Technique	Auto-measurement by Doppler Ultrasound.
	Recording	Printing Spike shape waveform on the UC column. Printing a dot corresponding to the big spike waveform on print column.
Uterine Contraction Measurement	Uterine Contraction signal Input	External Measurement (Strain Gauge)
Recording by recorder	Recording Method	Line Thermal Head
	Recording Speeds	10, 20, 30 mm/minute
	Recording Width	Fetal Heart Rate 80mm(50～210 bpm) Uterine Contraction 40mm
	Printing	Headings on top sheet, Time Stamp, Auto-printing Input Modes, Event Mark. Manual printing Fetal Movement Mark.
	Recording Paper	High Sensitive Thermal Paper
Ultrasound Transducer	$I_{(sata)}$ at the transducer face	4.1mW/cm^2 maximum
	Entrance Beam Dimensions	7.6cm^2 , circular
	Ultrasonic Power	31.2mW maximum
Dimensions/Weight		240(W)×250(H: including Legs) × 200(D)mm / 4.5kg

11.2 Environmental Conditions

	Operating Environment	Transfer and Storage Environment
Temperature	+10～+40℃	－10～+60℃
Humidity	30～75%	30～95%(Non-condensing)
Pressure	700～1060hPa	700～1060hPa

11.3 Accessories

Names	Standards/Type Number		Pieces
Y-shape (DOP/UC) Transducer	TR-686-05S		1
Transducer Belt	External 58×1300 mm	Green	1
		Orange	1
Gel for Ultrasound *	CG250mL for Monitor		1
Remote Marker Switch (Single)	SW-524-01		1
Socket Cap	335B-25-01		1
Color Recording Paper *	0030-026		2
Thermal Head Cleaner Pen *	Y011		1
Rubber Fuse Holder (B Type)	0310-412		1
Time Delay Fuse	250V1A		2
Power Cord	P-0014U(L)2.4m		1
Basket	For MT-516		1
Quick Operation Guide	For MT-516		1
Operation Manual	For MT-516		1

The * mark goods are expendable supplies. Please order our distributor or us to fill up

11.4 Options

Names		Standards/Type Number
Standard Cart for MT-516		JC-167
Twin Set	Doppler Transducer	TR-627-05S
	Transducer Belt	External 58 × 1300mm Orange
	Remote Marker Switch (Twin)	SW-524-02

11.5 Repair

During the warranty period, repairs are available according to the terms of the warranty policy free of charge. After the warranty period, we will repair the equipment, with charge, only when we think the repairs will make it work properly. We keep repair parts for 6 years after discontinuation of the equipment.

11.6 Durable Years

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

11.7 Scrapping

This equipment corresponds to the industrial waste when scrapped. The industrial waste is restricted to scrap by law. The law depends on each local government. Please contact the appropriate governmental entity and scrap it according to their instructions.