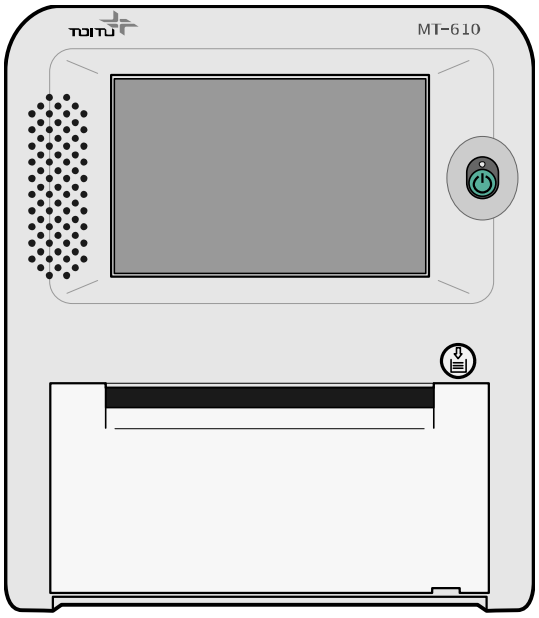
Actocardiograph MT-610

Operation Manual



⚠ CAUTION

- Read the operation manual carefully before use.
- Keep these instructions for future reference.

These are the instructions for use for MT-610 revision name Rev.6.

CE 1639

Manufacturer

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Ver.6.3EU
2023-08-18

Introduction

- This operation manual describes the required method of handling and safety precautions to follow when using the Actocardiograph MT-610.
  Read this operation manual carefully before use for safe operation of the device. All users must read “For Safe and Proper Use” even when they are already familiar with the handling of the device. Any carelessness may result in a serious accident.
  Deviation from this manual may impair the safety of patients or operators, or cause insufficient performance of the device and damage to the device.

- The intended use of the device is to monitor the fetal heart rate and uterine contractions. (Used from mid-pregnancy to delivery.)

- This device is only to be used by doctors and health care workers (such as midwives and nurses) those who were instructed by doctors.

- In order to use the device in the proper condition, proper operation and periodic maintenance are required.
  Only qualified personnel can repair the device.
  In case the device is used in a way not specified in this operation manual or repaired by unqualified personnel, we and our distributor will not have any responsibility for the performance of the device or the safety of patients or operators.

  If this manual is lost or damaged, contact us or our distributor for a new operation manual.

How to read this manual

In this manual, in order to avoid injury to the operator using this device, another person, or nearby object, precautions that must be followed are categorized under "Warning" and "Caution" as follows.

WARNING	Indicates that failure to follow this instruction "may result in death or severe personal injury."
Contraindication	Indicates that the use of this device beyond the performance range, inappropriate method, or to whom other than subjects "may result in death or severe personal injury."
CAUTION	Indicates that failure to follow this instruction "may injure a person or object."
Important	Indicates contents that should be followed upon operation.
Note	Indicates useful information.

The following marks are used in order to indicate different hazards.

	Electrical hazards may cause electric shock or fire.
	Indicates what must be done.
	Indicates what must NOT be done.

Table of Contents

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1. For Safe and Proper Use

1-1. Safety Precautions

Below explains safety precautions those must be followed to use this device safely.

⚠ WARNING

	When using this device in combination with other ME devices, ground them equipotentially so that there is no potential difference between the devices. Patients or operators may receive an electric shock if there is even a small potential difference between chassis.
	Follow the instructions in this operation manual. In case of any abnormality, stop using the device immediately.
	Be sure to inspect the device before use. If you cannot confirm the proper condition during the inspection, turn off the power, and remove the power plug from the outlet. Stop using the device, attach a "Failure" indication, and contact us or our distributor to repair the device immediately.
	If you use two or more of these devices connected to the delivery monitoring cordless system in the same facility, make sure that the receivers and the transmitters are correctly paired before use. Failure to follow this instruction may result in mix-up of patients.
	Do not disassemble or modify the device. Failure to follow this instruction may result in failure or malfunction.
	Do not apply single device to multiple patients. Failure to follow this instruction may result in failure or malfunction.
	For safety, perform electrical safety testing of other medical devices such as cardiac pacemakers, electrical stimulators, and others applied to the patient before using the fetal monitoring device.
	Move the Doppler transducer to the position (optimal position) that provides clear, rhythmic sounds (sounds of heart wall and valves) in response to the fetal movement. If the ultrasound picks up the maternal blood vessel, the maternal heart rate is recorded. Check to make sure the Doppler sound is different from the maternal heart rate on a regular basis.
	If intrauterine fetal death is suspected, perform an additional examination using another method.
	In the event of a fetal heart rate alarm, initiate the appropriate measures under the direction of a physician. Failure to follow this instruction may result in an accident or other deterioration of the fetus.

	Do not use a Doppler transducer which cannot provide the Doppler sound for measurement.
	Carefully watch the surge of the heart rate image. The heart rate can produce incorrect signals because of the change in the number of uterine contractions. In some cases, the displayed and recorded heart rate may be twice as much as the actual heart rate even when it is decreasing, or half as much even when it is increasing.
	Sterilize all equipment that touches the surface of the skin before every use. Failure to follow this instruction may cause infection.
	Do not place heavy objects on the power cord in such a way that the power cord is crushed under the object. Do not damage, forcibly bend, twist, pull, or expose the power cord to heat sources. In case of any damage to the power cord (exposure of core wire or breakage), contact us or our distributor for replacement. Failure to follow this instruction may result in fire or electric shock.
	Be sure to connect to a grounded wall outlet using the provided three-pin plug power cord. Failure to follow this instruction may result in fire or electric shock.
	The accessories connected to the analog or digital interfaces of this device must meet the related IEC or JIS standards (ex: IEC 60950-1 for digital processing devices, CISPR 32 EMC of maltimadia equipments, or IEC 60601-1 for medical devices). In addition, all configurations must conform to IEC 60601-1. Therefore, every person who connects additional devices to this device is responsible for ensuring that the system conforms to the requirements in IEC 60601-1. If you have any questions, contact us or our distributor.
	Supply power from an isolation transformer to non-medical electronic devices used close to expectant and nursing mothers. Failure to follow this instruction may cause electric shock.
	Do not use USB devices with their own power source unless used with an appropriate isolation device. Failure to follow this instruction may cause electric shock.
	Do not perform maintenances in a situation with patient. Failure to follow this instruction may cause electric shock.
	The device may cause radio interference with other devices in the vicinity resulting in poor transmission. Such cases require measures to reduce the interference by using a shield or changing the direction or installation location of the device.
	Do not use this device close to or stacked on top of another device. If the device must be used in such a way, confirm the correct operation in the arrangement to be used.
	Supervise and issue instructions to not bring mobile phones, transceivers, radio controlled toys, and other similar devices into the room where the device is installed or around the antenna installed in the hospital for medical devices.

	Do not use this device in an X-ray room, MRI room, image processing room, or within the strong high-frequency electromagnetic field such as from an electric scalpel. Failure to follow this instruction may result in a malfunction.
	Do not block the heat vent of the device. Failure to follow this instruction may cause fire and device failure.
	Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of tshis equipment and result in improper operation.
	Portable RF communications equipment (including peripherals such as antenna bables and external antennas) should be used no close than 30 cm (12 inches) to any part of the MT-610, including cables specified by the manufacturer. Otherwise, degration of the performance of this equipment could result.

Contraindication

	Do not use in the following places. Failure to follow this instruction may cause an explosion or fire. This device is not explosion-proof. ・Using the device in the hyperbaric oxygen therapy device ・Using the device in the flammable anesthetic gas or high concentration oxygen atmosphere
	This device is not intended to be used with high frequency surgical instrument (electrical scalpel), or while defibrillation and MRI. Remove transducers, sensors, and accessories from patient before such operations.

⚠CAUTION

	When a solution is spilled on the device, stop using the device and contact us or our distributor.
	Check the settings of the alarm periodically. The alarm may not be raised depending on the setting.

1-2. Symbols and Labels Used in this Device

The following warning label is attached to the rear of the device. Be sure to check it before use.

Position of the warning label

The symbols used for this device are as follows.

■ Symbols defined in IEC International Standards and Japanese Industrial Standards

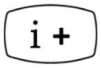
No.	Symbol	Name	No.	Symbol	Name
(1)		Stand-by	(5)	2×T3.15L 250V	Fuse rating
(2)		Supply recording paper	(6)		CAUTION
(3)		Electrostatic sensitive devices	(7)		Type BF applied part
(4)		Alternating current			

■ Our own Symbols

No.	Symbol	Name	No.	Symbol	Name
(8)	Rev.6.3d	Revision name	(10)		Fuse
(9)	I/O	Input/output			

1-3. Meaning of the Screen Indication Symbol Used in this Device

■ Symbols defined in IEC International Standards and Japanese Industrial Standards

No.	Symbol	Name	No.	Symbol	Name
1		Heart mark (heart rate)	9		Menu
2		Alarm sound off	10		Speaker
3		Alarm function off	11		Picture-in Picture selected
4		Alarm suspension	12		Patient information
5		Zero set	13		Time
6		Start action	14		Additional information on the
7		Graphic recorder	15		Zoom-in page
8		Timer			

■ Our own Symbols

No.	Symbol	Name	No.	Symbol	Name
1		Right fetal movement marker	5		Low signal
2		Left fetal movement marker	6		Timestamp
3		Wrong measurement of heart rate	7		Time battery
4		Fetal stimulator			

1-4. EMC Compliance

This device complies with the EMC standard IEC 60601-1-2:2014/ EN 60601-1-2:2015.

Remark:CISPR11:Group 1, Class B

Essential Performance

The Essential Performance for MT-610 is as follows.

- To records a fetus heart rate and labor pains curve in succession

The following phenomena are expected when the Essential Performance is lost or degraded.

- Technical alarm
- No wafeforms and/or numeric values
- Noise is heard in the Doppler sound
- Distinctive waveform distortion on recording paper
- The device has a complete failure

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The MT-610 is intended for use in the electromagnetic environment specified below. The customer or the user of the MT-610 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions CISPR 11	Group 1	The MT-610 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The MT-610 is suitable for use in all establishments other than domestic and those directly connected to the pubulic low-voltage power supply netwark that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not applicable NOTE	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Not applicable NOTE	

Note : This test is not applied (N/A).

Because this device is not connected to the PUBLIC AC MAINS NETWORK.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The MT-610 is intended for use in the electromagnetic environment specified below. The customer or the user of the MT-610 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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 IEC 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 hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line (s) to line (s) ±0.5 kV, ±1 kV, ±2 kV line (s) to earth	±0.5 kV, ±1 kV line (s) to line (s) ±0.5 kV, ±1 kV, ±2 kV line (s) to earth	Mains power quality should be that of a hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T: 0.5 cycle At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º 0% U_T: 1 cycle and 70% U_T: 25/30 cycles Single phase: at 0º 0% U_T: 250/300 cycle	0% U_T: 0.5 cycle At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º 0% U_T: 1 cycle and 70% U_T: 25/30 cycles Single phase: at 0º 0% U_T: 250/300 cycle	Mains power quality should be that of a hospital environment. If the user of the MT-610 requires continued operation during power mains interruptions, it is recommended that the MT-610 be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	Not applicable **NOTE 2**	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.
NOTE 1: U_T is the a. c. mains voltage prior to application of the test level. **NOTE 2:** This test is not applied (N/A). Because this EUT is not magnetically sensitive.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The MT-610 is intended for use in the electromagnetic environment specified below.
The customer or the user of the MT-610 should assure that it is used in such an environment.

Immunity test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V 0.15 MHz-80 MHz The ISM (industrial,scientific and medical) bands between 0.15MHz and 80MHz are 6.765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz. 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 6 V	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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m	

Note : 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.

Test specifications for ENCLOSURE PORT IMMUNITY to RF Wireless communications equipment						
WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MT-610, including cable specified by the manufacturer. Otherwise, deviation of the performance of this equipment could result.						
Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11.b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

1-5. IT network connection

This device can be connected to an IT network to transmit measurement data to our central monitor.

The IT network to which this device is connected must be securely managed with the IT security appropriate for the medical information system.
The IT network configurations include network communication within facilities such as hospitals, and cloud computing via the Internet.

Connecting this device and the other equipment to an IT network may create unacceptable risks to patients, operators, or third parties.
Prior to connection, the connection details should be reviewed with the facility's IT administrator, and risks should be identified, analyzed, evaluated, and controlled.

If the IT network fails, the following risks may occur.

- The central monitor cannot monitor the patient's condition.
- The central monitor cannot monitor the alarms of this device.
- Transmission of measurement data to the central monitor is delayed.
- Measurement data sent to the central monitor is intercepted and falsified.

Additional analysis is required for any subsequent changes to the IT network, as new risks may arise. Examples of changes to the IT network environment are as follows.

- Change to the IT network settings.
- Adding actocardiographs,the central monitors and other equipment to the IT network.
- Removal of actocardiographs, the central monitors and other equipment from the IT network.
- Updating actocardiographs, the central monitors and other equipment connected to the IT network.
- Upgrading other equipment connected to the IT network.

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2. Product Overview

2-1. Features

This device is a fetal monitoring device intended to detect the fetal heart rate and uterine contractions. This device can be used from mid-pregnancy to delivery. The main features are as follows.

- Easy-to-see display
  7-inch color TFT LCD displays large texts and images of the recording paper.
- Touch panel operation
  Touch and hold operation is realized by utilizing resistive touchscreen.
- CTG data storage
  CTG data for up to fifteen hours can be stored in the memory on the device. This data can be printed or stored in a USB memory (not included).
- Battery operation
  The device can operate for 30 minutes when it is disconnected from the power source. (When the battery is fully charged.)
  Although the recorder stops during this period, the CTG recorded (CardioTocoGram) is printed using high-speed printing when connecting the device to the power source.

2-2. Functions

Function Name	Explanation of the Function
Fetal movement monitoring	Monitors and records the fetal movement. (There are two monitoring methods: automatic monitoring using ultrasound and manual recording when the mother recognizes the fetal movement.)
Contraction cycle monitoring	Automatically monitors/displays/prints the contraction cycle.
Twins monitoring (multi-fetuses monitoring)	Monitors the fetal parameters for multiple fetuses by the fetal actocardiograph.
Timer function (recording timer function)	A function to automatically stop the recorder after a configured time. A function to automatically start recording when the configured condition is met. (For more information, see P.41 “6-4 Print the Monitoring Data”)
Monitoring data storage function	A function to store and play the monitoring data to the main unit or a removable media.
Recording/system function	A function to store the monitoring data from this device to central monitoring equipment via an external device or communication device.
Display function	A function to show information such as CTG patterns as an image.

Function Name	Explanation of the Function
Alarm function	A function to alert the operator via alarm sound, alarm indication, and/or record in the case of device failure or if the configured monitoring condition is not met.

2-3. Principle

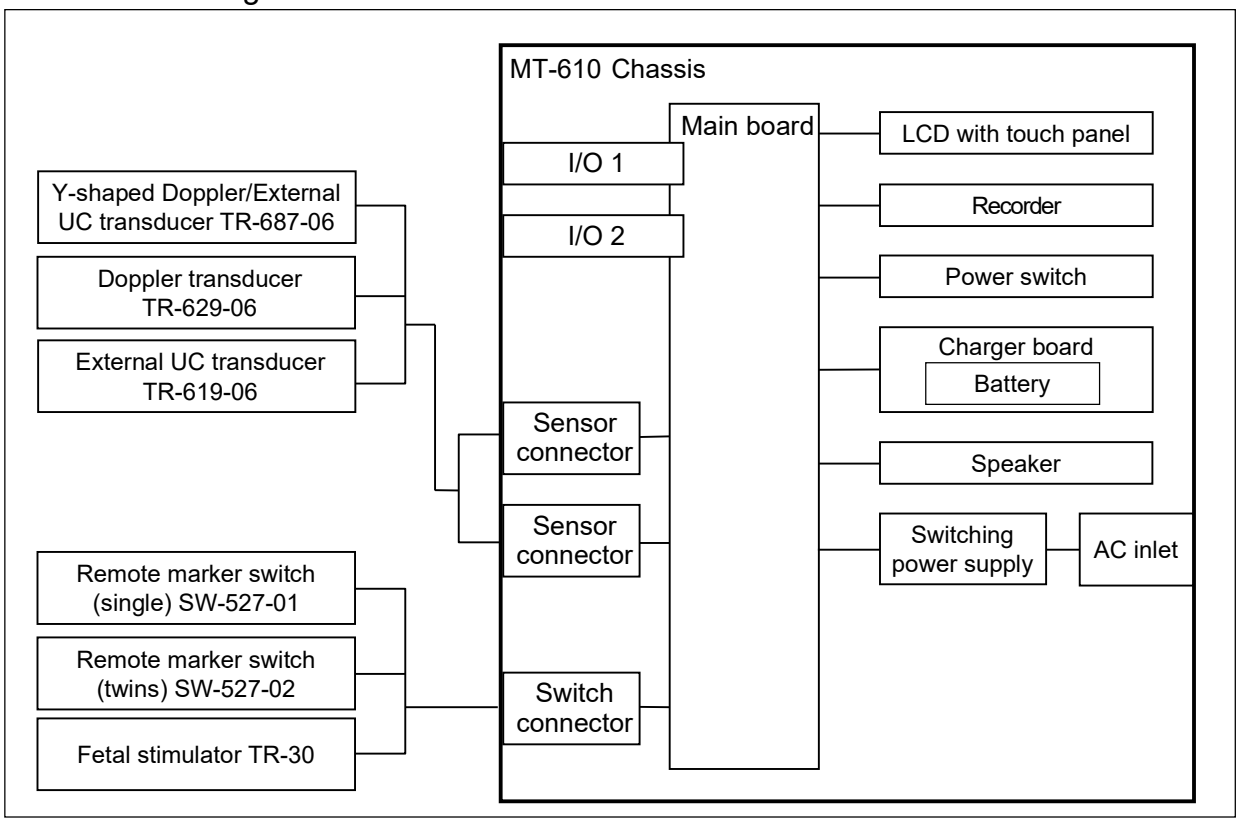
2-3-1. Fetal heart rate

Fetal heart rate is detected by using the ultrasound Doppler method. When high-frequency voltage is applied to the Doppler transducer, the element in it vibrates and emits ultrasound. When this ultrasound is delivered to the heart of the fetus through the maternal abdominal wall, it is reflected by the movement of the heart valve, bloodstream, or movement of the fetus (fetal movement), and then returns to the transducer. The received ultrasound undergoes signal processing, and is separated using the difference in heartbeat signal and fetal movement signal. The heartbeat signal can be heard from the speaker since it is within the range of human audibility.

2-3-2. Uterine contraction

A contraction (uterine contraction) signal is detected by using the strain gauge. When the external UC transducer containing the strain gauge is fixed to the abdominal wall at the uterine fundus, the resistance value changes when a strain is applied to the strain gauge due to the uterine contractions. A contraction (uterine contraction) signal is detected by detecting changes in this resistance.

2-3-3. Block diagram



* Remote marker switch or fetal stimulator is connected to the switch connector.
Either the remote marker switch for single or the one for twins can be connected.

* Three types of sensors can be connected to the sensor connector.
Recommended connection for each case is as follows:

What to Monitor	Connected device 1	Connected device 2
Single monitoring	TR-687-06	
Twins monitoring	TR-687-06	TR-629-06

2-4. Usage Environment

Use the device under the following conditions.

Field	Conditions
Ambient temperature	10 to 40 °C
Relative humidity	30 to 70% (no condensation)
Atmospheric Pressure	700 to 1060 hPa
Other conditions	• Room without the risk of explosion • A place where the provided power cord can be connected to a commercial power outlet in the hospital or clinic building • Stable, flat surface with a space of more than 40 mm at the rear, 30 mm on the right side, and 70 mm on the left side when viewed from the front

2-5. Screen Modes

There are two screen modes on this device. (See P.20 "4-2-1 Monitoring Screen")

For switching mode, contact us or our distributor.

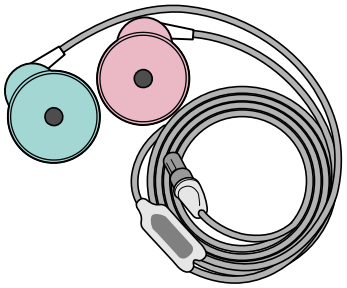
- Extended mode : The mode which includes features such as the history feature.
- Compatible mode : The mode which maintains the compatibility with the screens in the revision name Rev.4 or before.

3. Package Contents

This device consists of the main unit, accessories, and options. Check the package contents before use. The accessories may be included with the main unit or sold separately.

3-1. Accessories

(1)



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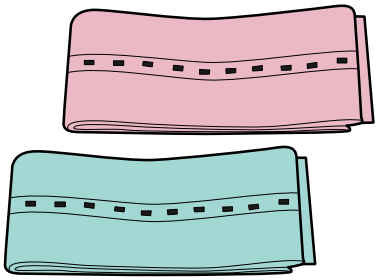

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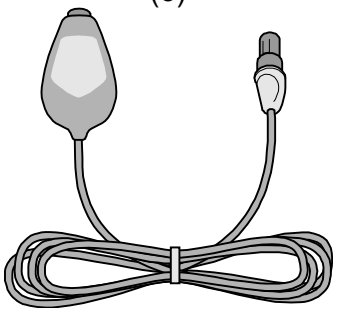

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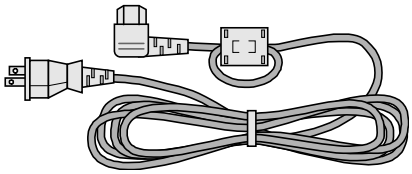

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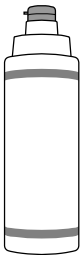

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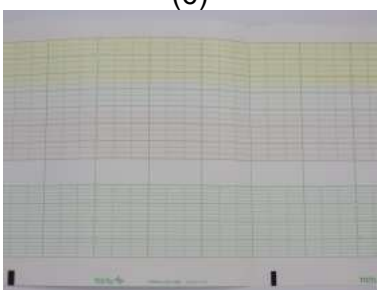
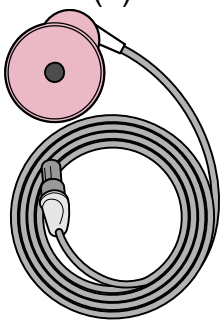


No.	Name	Function and Operation
(1)	Y-shaped Doppler/External UC transducer	Used for monitoring fetal heart rate and external contraction monitoring by ultrasound.
(2)	Transducer belt (pink, green)	Used to affix the transducer to the abdominal wall.
(3)	Remote marker switch (for single fetus)	A hand-held switch used to record maternal perception of fetal movement.
(4)	Power cord	Connects the main unit to a commercial power supply.
(5)	Ultrasound gel	Used to reduce ultrasonic attenuation between the Doppler transducer and the abdominal wall.
(6)	Recording paper	Heat-sensitive paper used to print the monitoring results.
(7)	Operation Manual (This document)	

* For the item number, refer to P.80 “11-2-1 Accessories supplied”.

3-2. Major Options

(1)



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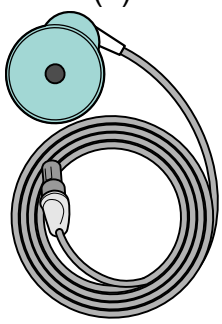

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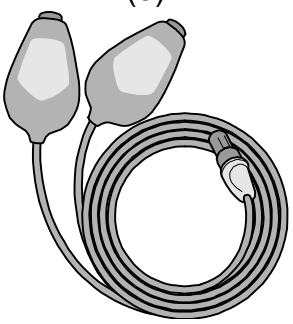


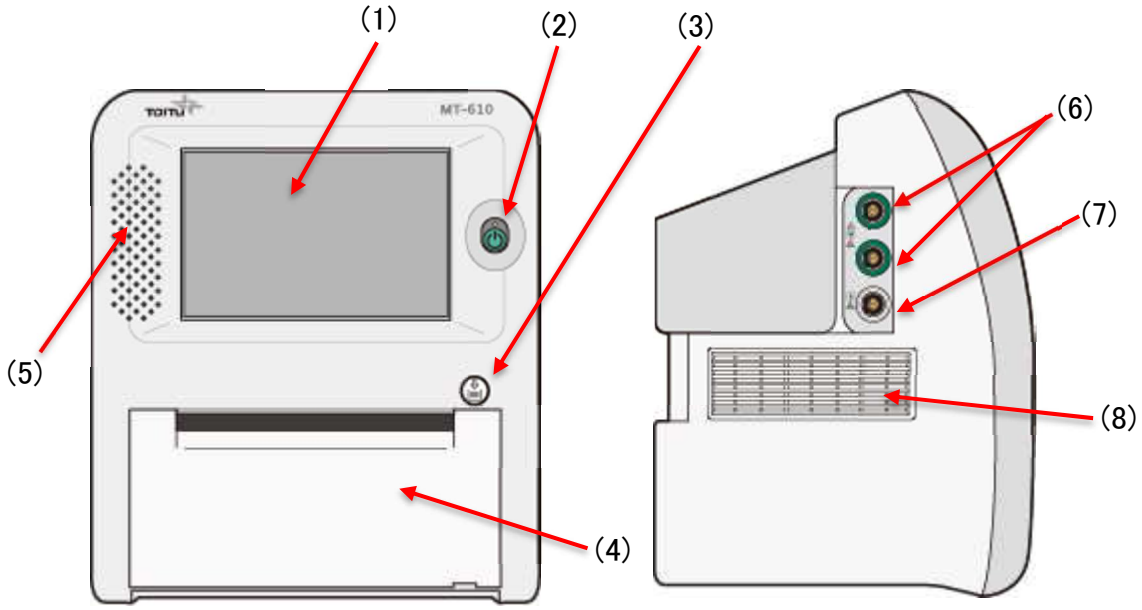
No.	Name	Function and Operation
(1)	Doppler transducer	Used for monitoring fetal heart rate by ultrasound in the case of twins.
(2)	External UC transducer	A transducer used to monitor uterine contraction.
(3)	Remote marker switch (for twin fetuses)	A hand-held switch for twin fetuses used to record maternal perception of fetal movement.

* Refer to P.80 “11-2-2 Options” for item codes and other optional items.

4. Part Names and Functions

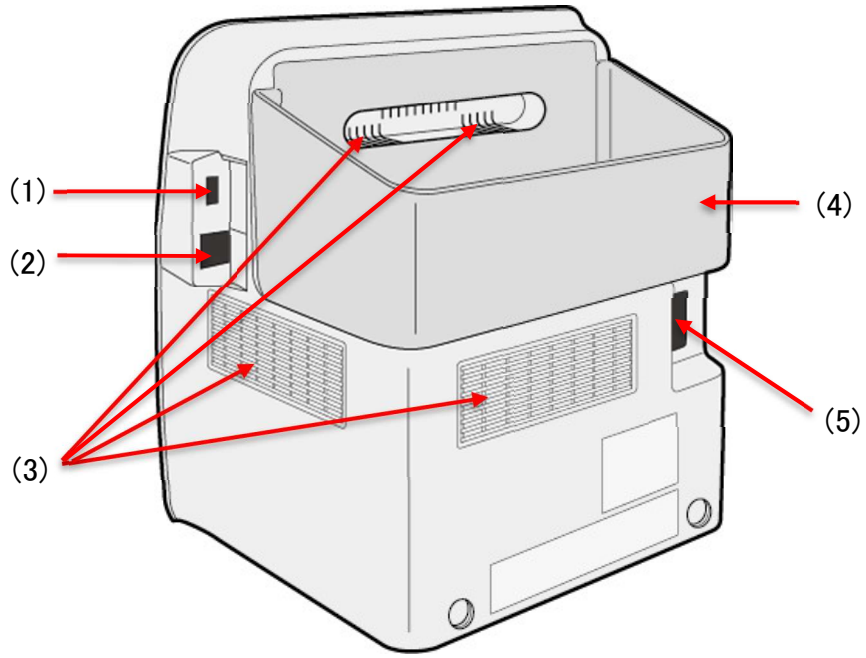
4-1. Body

4-1-1. Front and left side



No.	Part Name	Function and Operation
(1)	LCD screen	Displays the fetal heart rate and can be operated by the touch panel.
(2)	Power switch	Turns the device ON or OFF.
(3)	Recorder cover open button	Opens the recorder cover.
(4)	Recorder	Prints the monitoring data and parameters.
(5)	Speaker	Outputs Doppler sounds and other operating sounds.
(6)	Sensor connectors (green)	Connects the Y-shaped Doppler/External UC transducer, Doppler transducer, and UC transducer.
(7)	Switch connector (white)	Connects the remote marker switch or fetal stimulator.
(8)	Heat vent	Exhausts heat from inside the device.

4-1-2. Back and right side



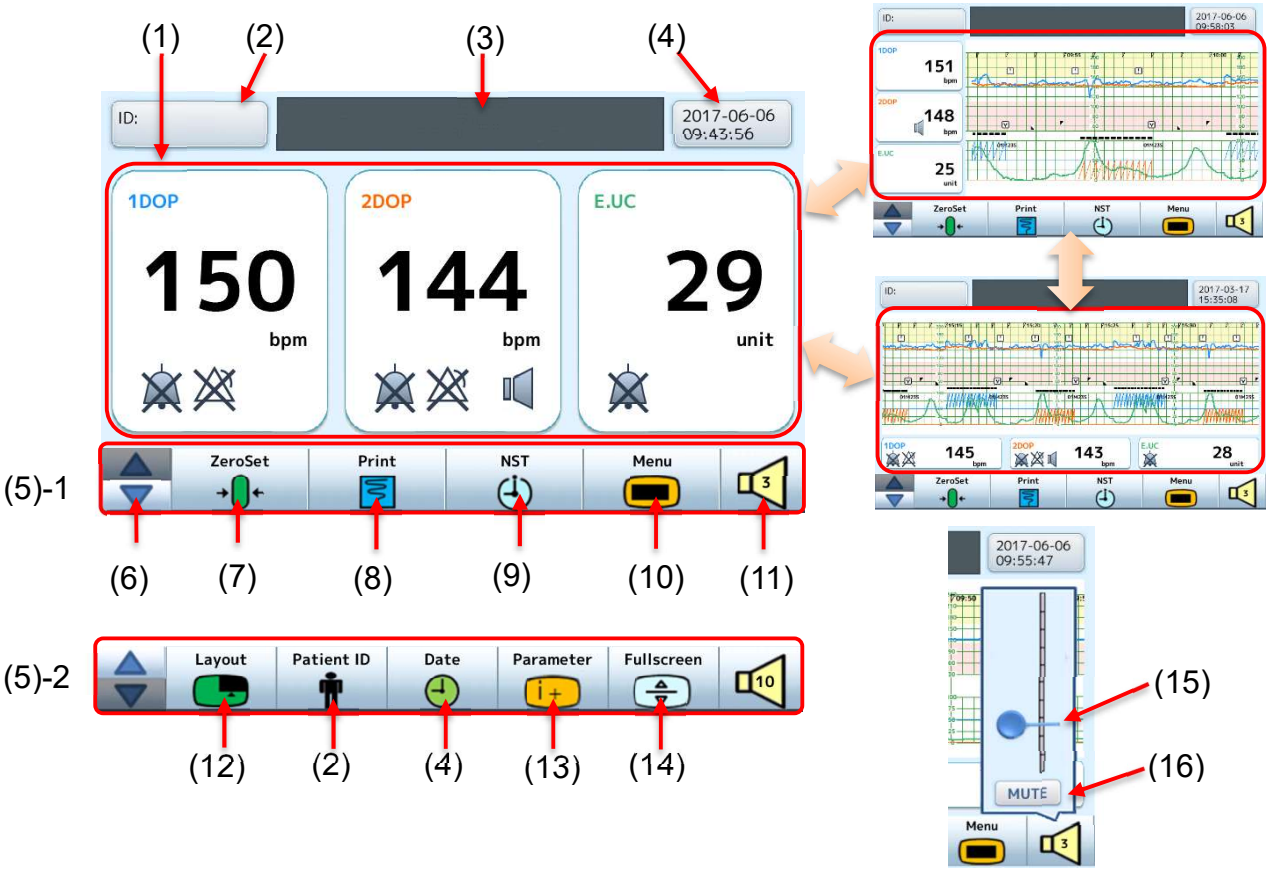
No.	Part Name	Function and Operation
(1)	I/O-1 connector	Connects external devices (e.g. our specified USB memory).
(2)	I/O-2 connector	Connects our Central Monitor.
(3)	Heat vent	Expels heat from inside the device.
(4)	Basket	Holds the accessories.
(5)	Power inlet	Connects to the power cord.

4-2. Screen Display

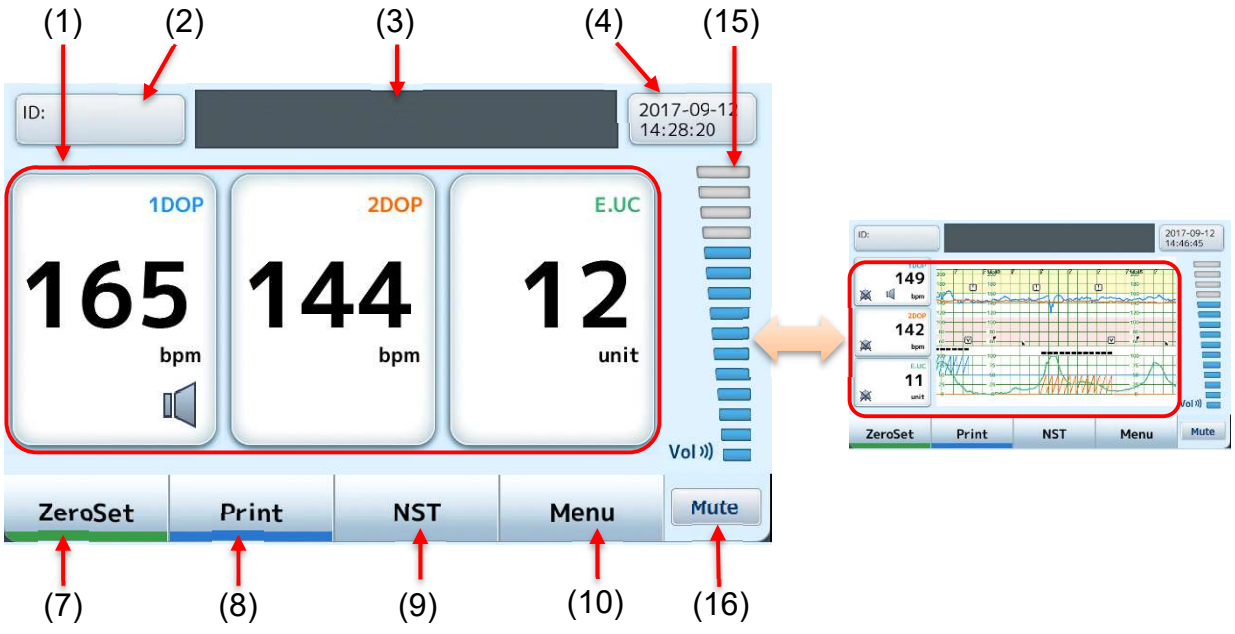
The displayed content may differ depending on "Extended mode" and "Compatible mode".
These instructions are mainly based on the "Extended mode".
For switching modes, contact us or our distributor.

4-2-1. Monitoring Screen

■Extended mode

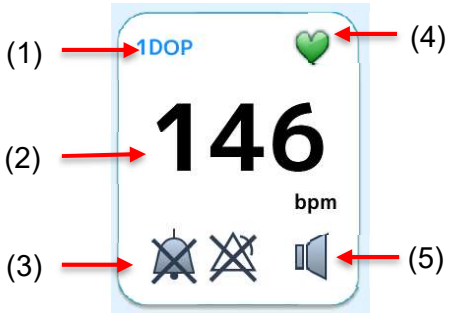


■Compatible mode



No.	Part Name	Function and Operation
(1)	Monitoring value display area	Displays the monitoring values and alarm status. • There are two patterns of display: number-only and number/waveform display. • In number/waveform display, there are two display modes: waveform display mode which shows the number at the left of the screen, and 15-minutes waveform display mode which shows the number below the waveform. • The waveform display mode shows the CTG for the last eight minutes from the latest measurement (on the right edge), and the 15-minutes waveform display mode shows the CTG for the last 15 minutes or more. Older waveform is displayed by pressing and holding the waveform. (See P.23 “4-2-3 History screen”) • You can switch the display using the menu screen or the layout setting screen.
(2)	Patient ID	Configures the patient’s data when the device is interconnected with our central monitor.
(3)	Free space	Displays the status of device operation or the details of alarms.
(4)	Date	Sets the date and time.
(5)	Menu bar	Configures or starts various features. Select <ZeroSet>, <Print>, <NST>, <Menu>, <Layout>, <Patient ID>, <Date>, <Parameter>, or <Full screen>.
(6)	Switching the menu bar	Switch between the first ((5)-1) and second ((5)-2) pages of the menu bar.
(7)	ZeroSet	Sets the contraction value to 12 units. Hold to set to 0 units.
(8)	Print	Starts printing the CTG on the recording paper. • The button changes to <Stop> while printing the CTG. Touch the <Stop> button to stop printing. • Note that printing the CTG is not available during battery operation. In that case, the button turns gray and cannot be used.
(9)	NST	Starts CTG printing which automatically stops after the configured time.
(10)	Menu	Displays the setting menu.
(11)	Speaker	Shows/hides the volume meter. Shows the current volume level.
(12)	Layout	Adds/removes the parameter shown on the screen. (See P.24 “(1) Delete layout screen”)
(13)	Parameter	Displays the setting menu for each parameter.
(14)	Full screen	Displays the waveform for the last 30 minutes or more from the latest measurement (on the right edge), not showing the monitoring value area. (See P.27 “4-2-5 Full screen”)
(15)	Volume meter	Sets the Doppler sound volume.
(16)	Mute	Sets the Doppler sound volume to zero.

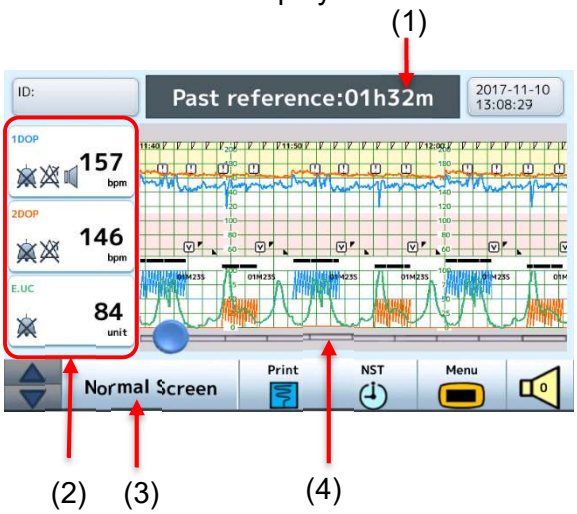
4-2-2. Monitoring value display area



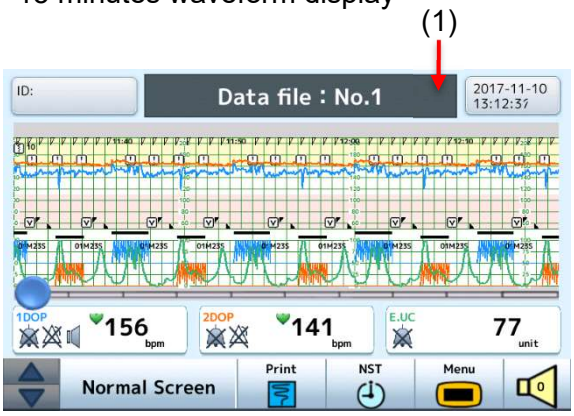
No.	Part Name	Function and Operation
(1)	Heartbeat synchronization symbol	Flashes in synchronization with the heartbeat. The color changes to “green > yellow > red” depending on the state of heart rate input signal. (See P.37 “6-2 (2) Decide on the fitting position”)
(2)	Monitoring value	Displays the monitoring values (heart rate or contraction value).
(3)	Status of alarm setting	Displays the status of alarm setting and alarm. : Displayed when the alarm sound is turned off. : Displayed when one or more conditions of the alarm are turned off. : Displayed when the alarm is off.
(4)	Sensor type	Displays the monitoring sensor type.
(5)	Symbol of choosing the heart beat sound	Displayed when the doppler is selected as speaker output.

4-2-3. History screen

Waveform display



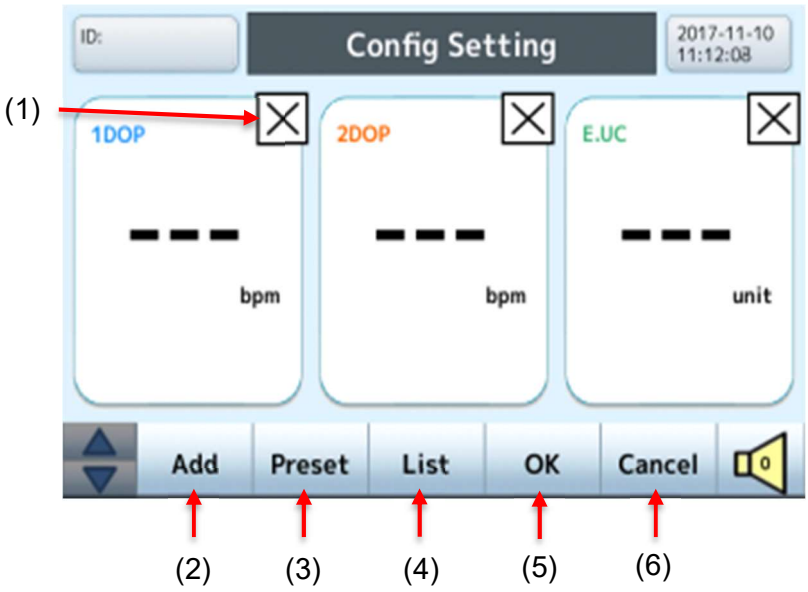
15 minutes waveform display



No.	Part Name	Function and Operation
(1)	Free space	Indicates how old the data is (in minutes). Indicates the data file number when replaying the stored data. (See P.49 “6-5-3 Replaying the stored data (only in the extended mode)”)
(2)	Monitoring value	Shows the current monitoring value.
(3)	Normal Screen	Exits the history screen and return to the monitoring screen.
(4)	Slider	Change the portion of the waveform to display.

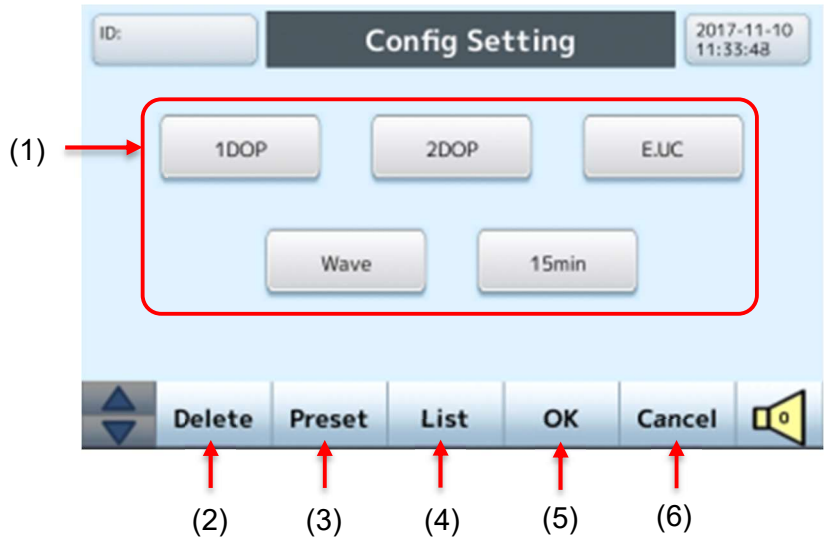
4-2-4. Layout setting screen

(1) Delete layout screen



No.	Part Name	Function and Operation
(1)	☒ (Delete)	Deletes a parameter from monitoring/history screen. If a parameter with display priority is deleted, another parameter with lower display priority may be displayed.
(2)	Add	Displays the Add layout screen. (See P.25 "4-2-4 (2) Add layout screen)
(3)	Preset	Stores/loads the settings for enabled/disabled displays. Short-press: Reverts to the stored display settings. Long-press: Stores the current display settings.
(4)	List	Displays the Layout summary screen. (See P.26 "4-2-4 (3) Layout summary screen")
(5)	OK	Applies the selected settings and goes back to the monitoring screen.
(6)	Cancel	Goes back to the monitoring screen without applying settings.

(2) Add layout screen

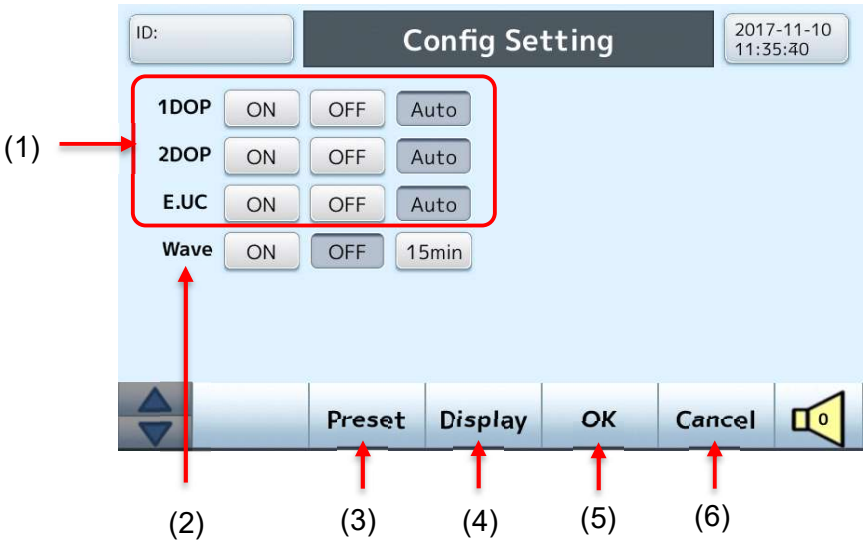


No.	Part Name	Function and Operation
(1)	- (Add)	Adds a parameter to the monitoring/history screen. Parameters that cannot be displayed at the same cannot be selected.
(2)	Delete	Displays the Delete layout screen. (See P.24"4-2-4. (1) Delete layout screen)
(3)	Preset	Stores/loads the settings for enabled/disabled displays. Short-press: Reverts to the stored display settings. Long-press: Stores the current display settings
(4)	List	Displays the Layout summary screen. (See P.26 "4-2-4 (3) Layout summary screen")
(5)	OK	Applies the selected settings and goes back to the monitoring screen.
(6)	Cancel	Goes back to the monitoring screen without applying settings.

(3) Layout summary screen

Important

- When a device in <OFF> status is connected, a message “A device with invalid setting was connected” and relevant device name is displayed.
- For the device in <OFF> status, the data is not shown on the monitoring/history screen, or printed in the recording paper. If you want to show or print the data for the device specified in the message, change the status of the device to <ON> in the layout setting.



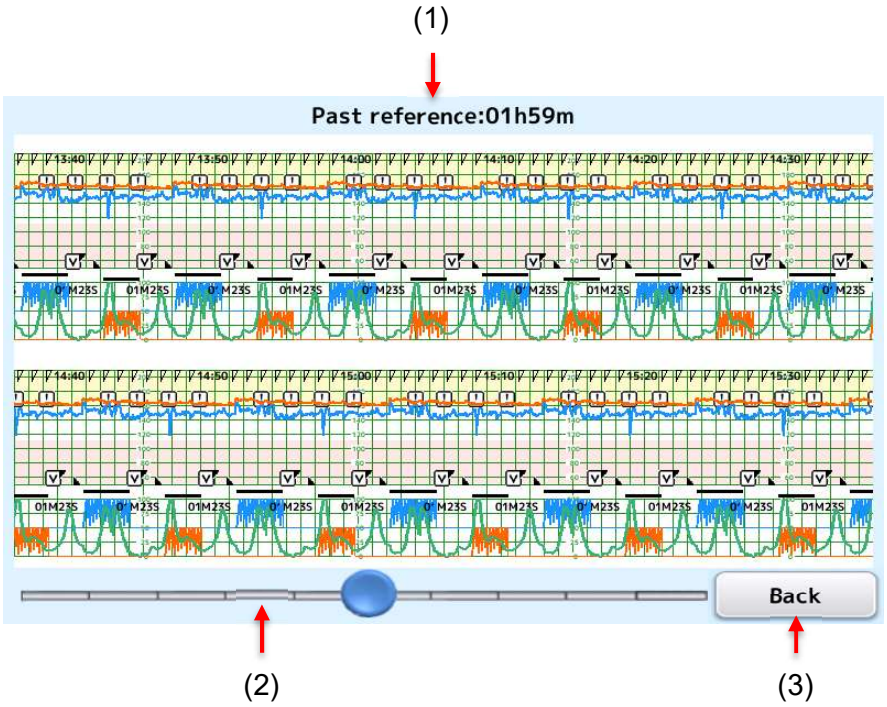
No.	Part Name	Function and Operation
(1)	1DOP 2DOP E.UC	Select either ON/OFF/Auto for each parameters. <ON> : The data is shown on the monitoring/history screen <OFF>: The data is not shown on the monitoring/history screen <Auto>：The data is automatically shown on the monitoring/history screen when the device is connected
(2)	Wave	Selects the waveform display on the monitoring screen <ON> : Waveform display <OFF> : Numeric display <15min> : 15 minutes waveform display
(3)	Preset	Stores/loads the settings for enabled/disabled displays. Short-press : Reverts to the stored display settings. Long-press : Stores the current display settings
(4)	Display	Displays the delete layout screen. (See P.24"4-2-4. (1) Delete layout screen)
(5)	OK	Applies the selected settings and goes back to the monitoring screen.
(6)	Cancel	Goes back to the monitoring screen without applying settings.

4-2-5. Full screen

Displays the waveform for the last 30 minutes or more by not showing the monitoring value area.

Important

The display will go back to the main display when an alarm occurs. Full screen is not available during the occurrence of an alarm.



No.	Part Name	Function and Operation
(1)	Free space	Displays how old the displayed data is in minutes.
(2)	Slider	Moves the displayed position.
(3)	Back	Ends the full screen and goes back to the monitoring screen.

5. Preparations before Use

Our company performs initial installation upon delivery. When relocating the device, disconnect the power plug from the power outlet, and place the device in a location that meets the following conditions. (See P.15 “2-4 Usage Environment”)
Note that the device is not sterilized before shipment. Be sure to clean and sterilize before use. (See P.65 “9-1 Cleaning and Sterilizing”)

Contraindication

	Do not use in the following places. Failure to follow this instruction may cause an explosion or fire. This device is not explosion-proof. ・Using the device in the hyperbaric oxygen therapy device ・Using the device in the flammable anesthetic gas or high concentration oxygen atmosphere
	This device is not intended to be used with high frequency surgical instrument (electrical scalpel), or while defibrillation and MRI. Remove transducers, sensors, and accessories from patient before such operations.

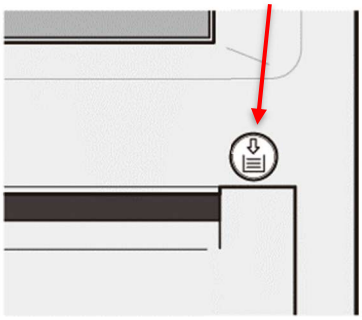
5-1. Setting the Recording Paper

⚠ CAUTION

Do not use any recording paper other than as specified.
An unspecified recording paper may cause a misdiagnosis by incorrect recording of monitoring results.

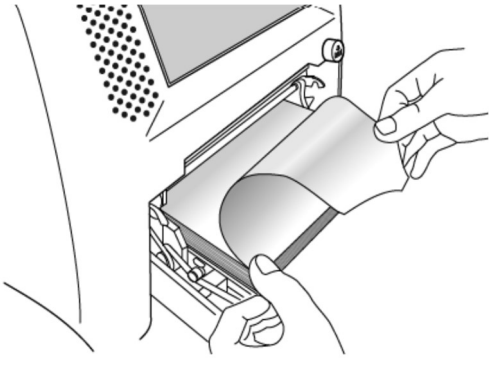
(1) Open the cover
Press the recorder cover open button.
The cover is unlocked and opens towards you.

Recorder cover open button

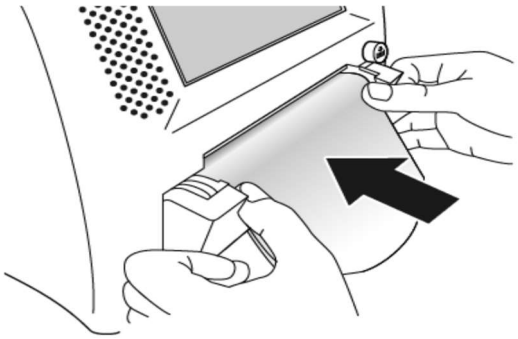


(2) Insert the new recording paper (accessory 0030-026)

1. Remove the paper from the bag and loosen them lightly.
2. Hold the paper with the cut edges facing up, and place them on the cover, then insert them all the way to the end.



3. Pull the top paper out of the cover.



(3) Close the cover

Push the cover back while holding the recording paper.

You will hear a click when it locks into place.

5-2. Connecting Plugs

⚠ WARNING

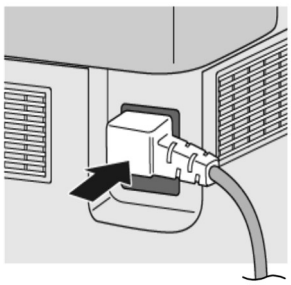
⚡	Do not place heavy objects on the power cord in such a way that the power cord is crushed under the object. Do not damage, forcibly bend, twist, pull, or expose the power cord to heat sources. In case of any damage to the power cord (exposure of core or breakage), contact us or our distributor for replacement. Failure to follow this instruction may result in fire or electric shock.
⚡	Be sure to connect to a grounded wall outlet using the provided three-pin plug power cord. Failure to follow this instruction may result in fire or electric shock.

⚠ CAUTION

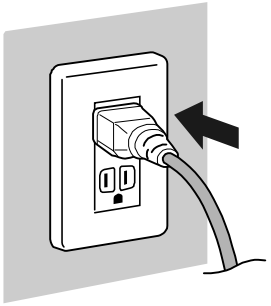
⊘	Use an outlet which you can easily disconnect the power cord and do not place any obstacles around the power outlet.

(1) Connect the power cord

1. Connect the power connector to the power inlet of the main unit.



2. Insert the power plug into a commercial power outlet.



(2) Check the battery charge

Charging automatically starts when the power cord is connected.

Confirm that the power switch LED flashes blue-green.

The power switch LED turns orange when the battery is fully charged.

Charging: Blinks in blue-green

Fully charged: Lights in orange

When the commercial power source is cut off, the power automatically switches to the internal battery. When the power source is recovered, the power reverts back to the commercial power source and continues the operation before cut off.
When the commercial power source is cut off and there is no internal power, all active settings are recovered when the power is back based on each settings stored in the nonvolatile memory.

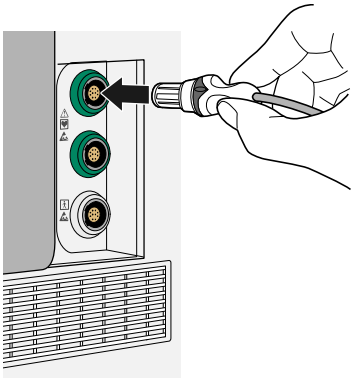
(3) Connect the transducer

CAUTION

	Be sure to use the specified transducer. Failure to follow this instruction may result in monitoring errors or failure.
	Do not drop or excessively bump the transducer.
	Do not remove the sensors while measurement. Measurement display area of the corresponding sensor will become blank and the alarms will be disabled.

Align the sensor connector marks (green) on the plug and on the side of the device, and then insert the plug. Fully insert the plug until it clicks.

- For a single fetus: the Y-shaped Doppler/External UC transducer supplied with the device
- For twin fetuses: the Y-shaped Doppler/External UC transducer supplied with the device, and optional Doppler transducer

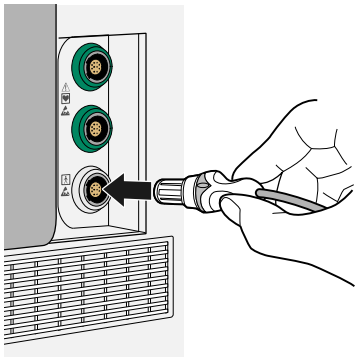


Note

The added Doppler transducer can be used for a single fetus. Using two Doppler transducers (double Doppler) for a single fetus provides a wider range of monitoring since the two signals detected are compared and the one with the highest quality is automatically selected for display and recording (single heart). This monitoring requires a specific mode setting. (See P.62 “8-6 Measurement Setting”)

(4) Connect the remote marker switch

Align the marks on the plug and on the switch connector (white) on the side of the device, and then insert the plug. Fully insert the plug until it clicks.



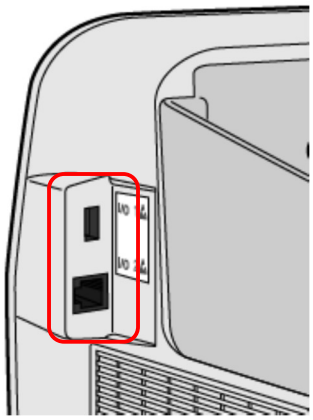
(5) Connect the fetal stimulator

You can connect an optional fetal stimulator to the switch connector (white). In this case, the remote marker switch cannot be used.

(6) Connect the accessories

The information measured by this device can be monitored remotely by connecting below device to the external connectors (I/O-1 connector and I/O-2 connector).

- Central monitor



5-3. Inspections before Use

WARNING

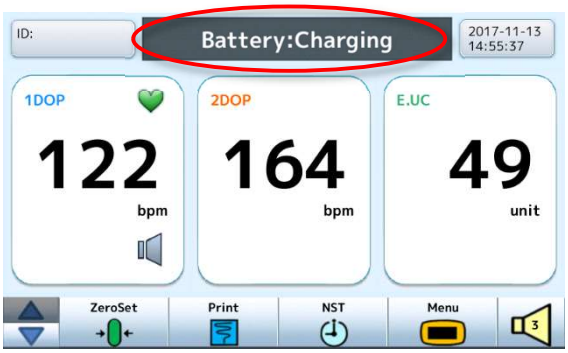
	Be sure to inspect the device before use. If you cannot confirm the proper condition by the inspection, turn off the power, and remove the power plug from the outlet. Stop using the device, attach a "Failure" indication, and contact us or our distributor to repair the device immediately.

CAUTION

	When operating the LCD screen (touch panel), touch the screen using the tip of your finger. Do not operate it using your nails or hard objects such as ballpoint pen or metal, and do not rub or push with excessive force. Failure to follow these instructions may cause a failure.

(1) Confirm startup

1. Press the power switch on the front of the body. The power switch LED turns blue-green.
2. Confirm that the LCD screen displays the startup screen, and shows the charging status on the free space.



Charging: display "Battery:Charging"
Full charge: no display

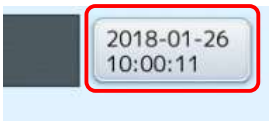
3. Confirm that there are no defective areas on the LCD screen.

(2) Check the time

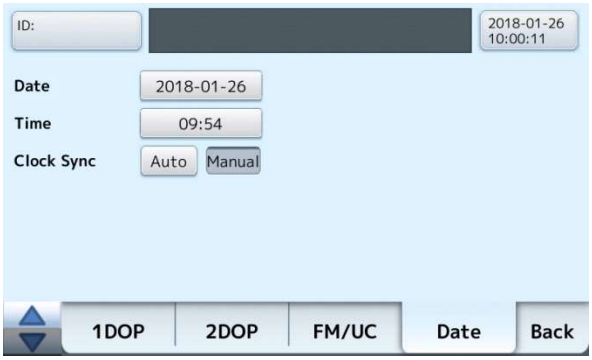
Confirm that the time is correct by comparing it with the correct time.
If there is an error proceeds to (3), be sure to correct the time.

(3) Correct the time (or date)

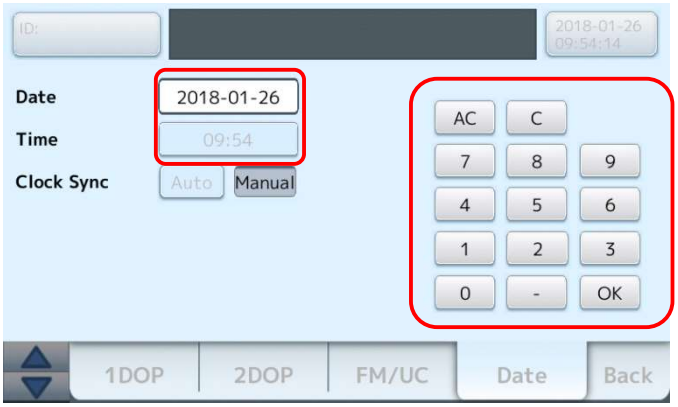
1. Press and hold the area where the time and date is displayed, or touch <Date> on the second page of the menu bar.



The date setting screen is displayed.



2. If the time synchronization is set to <Auto>, touch <Manual>.
3. Touch <Time> (or <Date>) display area.
   A software keypad appears at the right of the screen.

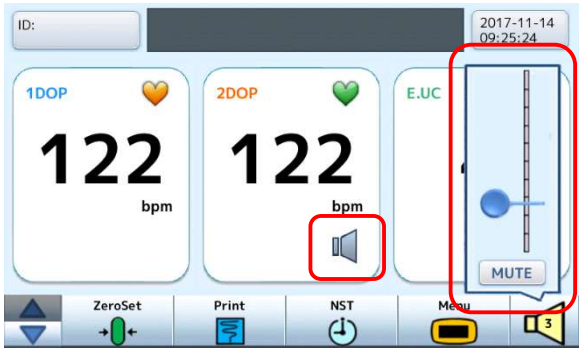


4. Revert back to where the correction is required by pressing <AC> or <C> and enter the correct time (or date).
   You cannot modify the seconds manually. In order to modify the seconds, enter the time with a minute or two minutes ahead and touch <OK> when it reaches 00 seconds of the correct minute.
5. Touch <OK> to save the change.
   To discard the input, touch <AC> or <C> to make the window blank, then touch <OK>.
6. Touch <Back> to go back to the measurement screen.
7. Cycle the power before using the device.

(4) Adjust the Doppler sound volume

When both Y-shaped Doppler/External UC transducer and Doppler transducer are connected, the Doppler sound of either Doppler 1 or Doppler 2 can be heard. You can hear the Doppler sound of the Doppler for which is displayed on the monitoring display area.

1. Touching the area of Doppler 1 or Doppler 2 switches the Doppler sound you can hear.
2. Touch the speaker at the right edge of the menu bar to open the volume meter.
3. Adjust the volume by moving the slider on the volume meter up or down.



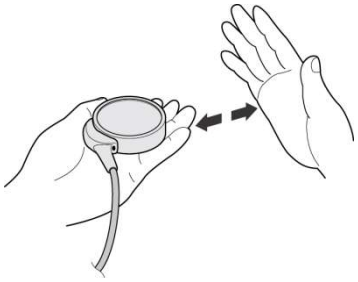
4. Touch <Mute> to set the volume to zero. No Doppler sound can be heard. Touch again to return to the prior level.
5. Touching the speaker again hides the volume meter.

(5) Confirm the Doppler sound

CAUTION

	Do not slap the head of the Doppler transducer hard. Failure to follow this instruction may result in monitoring errors or failure.

1. Hold the Doppler transducer in your hand so that the transmitting and receiving surface faces out.
2. Move the palm of the other hand towards or away from the transmitting and receiving surface.
3. Confirm that the Doppler sound can be heard when the hand is close to the transducer. If it cannot be heard, increase the volume and try again.
4. After confirmation, gently place the transducer avoiding putting pressure on the transmitting and receiving surface.
5. If you cannot confirm the sound, connect a different transducer and try again. If there is no Doppler transducer with which you can confirm the Doppler sound, do not use this device.

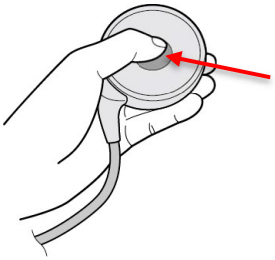


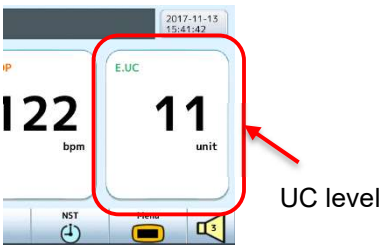
(6) Confirm the contraction level

CAUTION

	Do not exert excessive force on the pressure sensitive part of the UC transducer. Failure to follow this instruction may result in monitoring errors or failure.

1. Lightly press the center of the pressure sensitive part of the UC transducer.
2. Confirm that the UC level increases in proportion to the extent of pressure applied.
3. Once complete, gently place the transducer while avoiding putting pressure to the pressure sensitive part.
4. If you cannot confirm the UC level change, connect a different UC transducer and try again. If there is no UC transducer with which you can confirm the UC level, do not use this device.



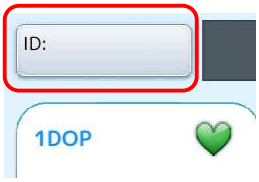


6. How to Use

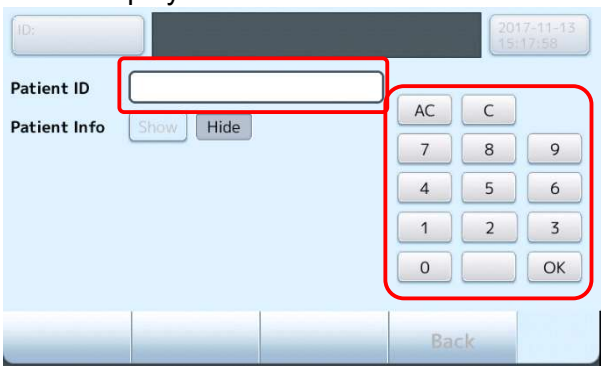
6-1. Register the Patient Information

Patient information can be registered/displayed/recorded if the device is associated with our central monitor. Use the screen to enter the patient ID.

1. Touch <ID:> at the upper-left of the screen or <Patient ID> at the second page of the menu bar.

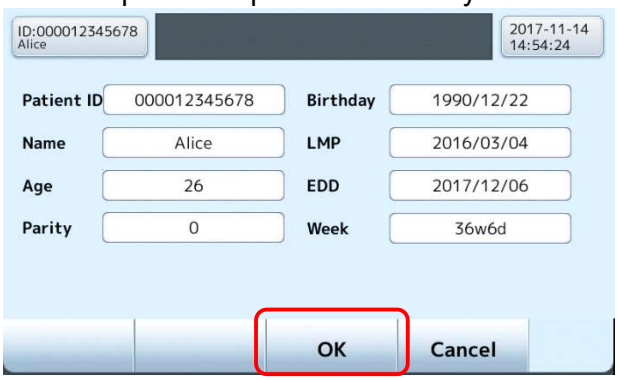


2. Touch the <Patient ID> field.
   The software keyboard is displayed.

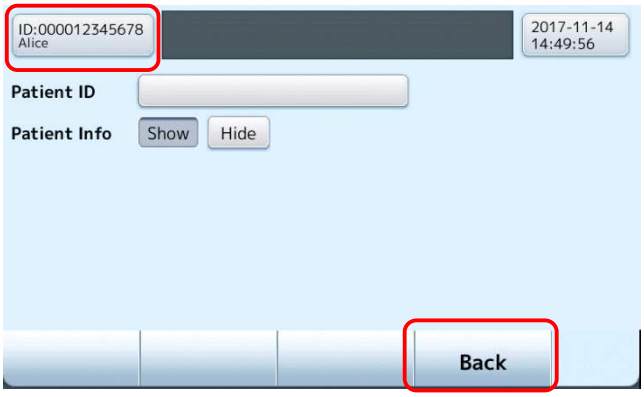


3. Enter the ID number registered with our central monitor and touch <OK>.
4. Confirm that the data shown is what you want to register, and then touch <OK>.

Example of the patient data entry screen



5. Confirm that the patient ID is displayed, and then touch <Back>.
   * When the data display is set to <Show>, the patient's name is displayed on the monitoring screen.



6. Check the data displayed on the monitoring screen.

6-2. Monitor the Doppler Fetal Heart Rate

WARNING

	If intrauterine fetal death is suspected using this method, perform an additional examination using another method. It may cause a misdiagnosis.
	Carefully watch the surge of heart rate image due to any artifacts. The heart rate can be converted to incorrect signals because of the change of uterine contractions. In some cases, the displayed and recorded heart rate may be twice as much as the actual heart rate even when it is decreasing, or half as much even when it is increasing. It may cause a misdiagnosis.
	Move the Doppler transmitter to the position (optimal position) that provides clear, rhythmic sounds (sounds of heart wall and valves) in response to the fetal movement. It may cause a misdiagnosis.

CAUTION

	Do not use any ultrasound gel other than that specified by us. Failure to follow this instruction may result in damage such as failure.
	Confirm that the fetal heart beat is different from the maternal pulse rate. When it is suspected the maternal pulse rate is being recorded, take the maternal pulse and compare with the displayed heart rate.

(1) Apply ultrasound gel

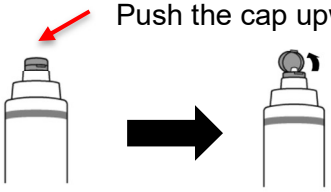
Apply the ultrasound gel to the surface of the maternal abdomen and the transmitting and receiving side of the Doppler transducer.

Important

The amount of the ultrasound gel should be just right and applied thoroughly so that it creates a thin layer.

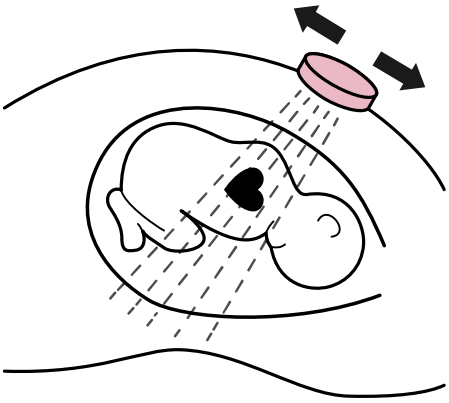
Opening/closing the gel cap

Push the cap upward



(2) Decide on the fitting position

1. Place the transmitting and receiving side of the Doppler transducer so that it is closely attached to the maternal abdominal wall.
2. Slowly move the Doppler transducer to detect the position that provides clear, rhythmic sounds (sounds of heart wall and valves).
3. Check the icon for heartbeat synchronization (♥) on the screen and hold the transducer in the position where the green light is continuously on. The color of the icon is defined as follows depending on the status of the heart rate signals.

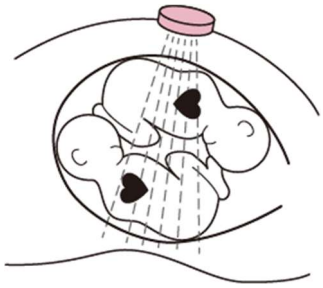


♡ Color	♥ Green	♥ Yellow	♥ Red
Quality of signals	The signal is stable.	There are some noises but the signal can be detected.	The signal is unstable

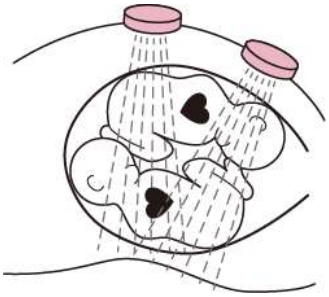
4. In the case of twins, find the position for each fetus.

Important

- In case of twins, position the transducer so that each fetus is measured by the Doppler sound.
  One Doppler transducer may monitor two fetuses, or two transducers may monitor one fetus.



One transducer is monitoring two fetuses

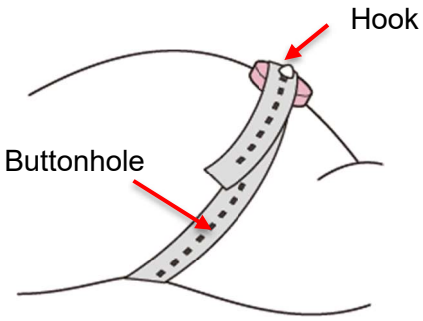


Two transducers are monitoring one fetus

- The Doppler sound switches between the selected Doppler each time you touch the monitoring display area, and is displayed on the monitoring value display area for the active one. Regularly check the fetus with the Doppler sound and adjust the position of the Doppler transducer as required.

(3) Affix the transducer

1. Affix the appropriate buttonhole on one end of the transducer belt applied to the back to the hook of the Doppler transducer while being careful not to move the transducer.
2. Affix the other buttonhole on the other end of the transducer belt to the hook to tighten the transducer belt.
   Drop the end of the transducer belt down to the side.
3. Thoroughly wipe away any excessive ultrasound gel on the abdominal wall.



6-3. Monitor the External UC

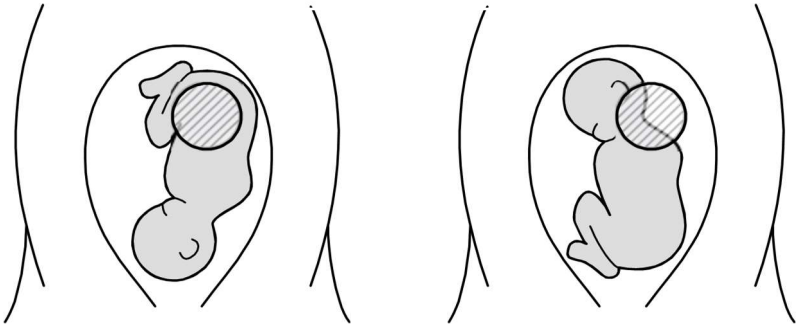
⚠ CAUTION

	Do not apply ultrasound gel to the External UC transducer.
	Do not fasten the transducer belt too tightly. Failure to follow this instruction may result in excessive pressure on the abdominal wall or cause a monitoring error.
	Confirm no redness in the skin when the External UC monitoring transducer is used for a long time. If there is redness, slightly displace the contraction transducer or stop using the monitor device. Failure to follow this instruction may result in contact dermatitis in rare cases.

(1) Decide on the fitting position

Place the External UC transducer slightly above the navel, the center of the abdominal wall that provides the maximum abdominal circumference.

Position of the UC transducer



Around the bottom on the back side of the fetus for a cephalic presentation

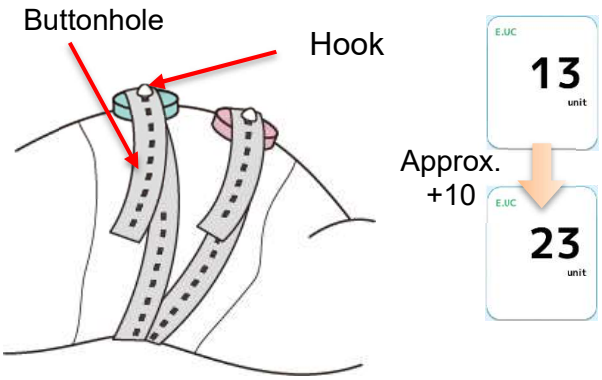
Around the head of the fetus for a breech presentation

Important

- If the transducer is placed below the navel, it cannot monitor correctly due to the mother's breathing.
- The device has a filter to eliminate the effect of breathing.
  If you do not want to use the filter, change the settings. (See P.60 “8-4 Fetal Movement/UC Setting”)

(2) Affix the transducer

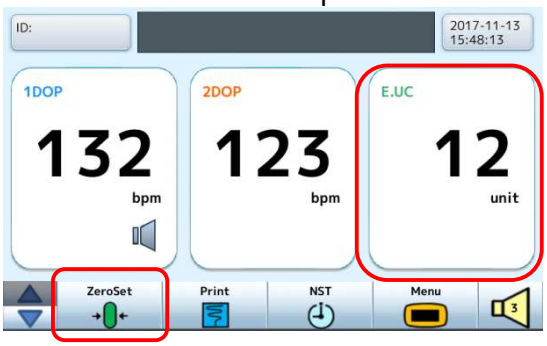
1. Affix the appropriate buttonhole on one end of the transducer belt applied to the back hook of the External UC transducer while being careful not to move the transducer. Fasten the transducer belt so that the UC level is incremented by approximately 10.
2. Drop the end of the transducer belt down to the side.



(3) Set the contraction to zero

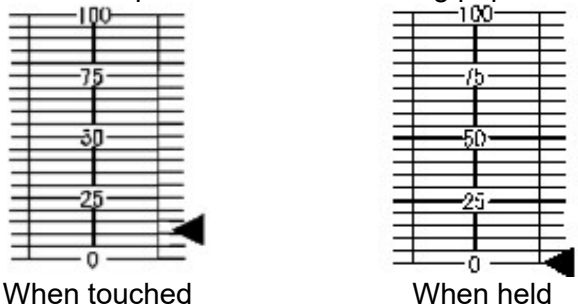
1. After fixing the transducer, touch <ZeroSet> while there is no contraction. The start points of display and record are set to 12 on the scale.

Zero set and sample screen



2. To set the start point to 0, touch and hold <ZeroSet> for about 5 seconds until 0 is displayed.

Example of zero set recording paper



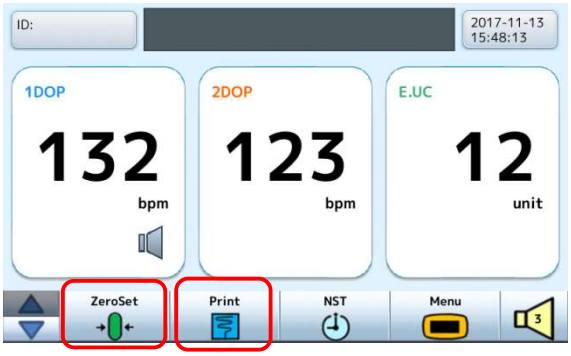
When touched When held

6-4. Print the Monitoring Data

The data can be printed immediately or by setting a timer. The printed information can also be changed.

6-4-1. Print immediately

1. After zero set, touch <Print>.

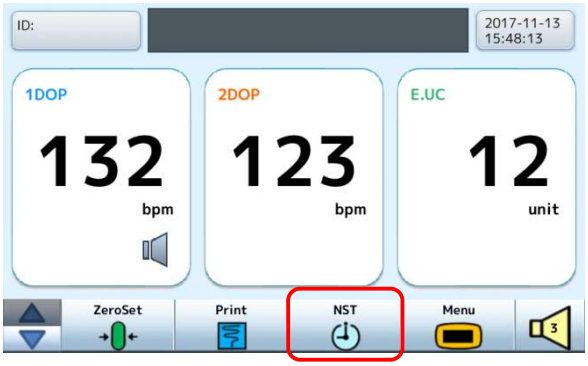


2. After printing the top sheet, the waveform is printed.
   Printing order depends on the settings. (P.64 “8-8 Record Setting”)
   The <Print> button changes to <Stop> while printing.

6-4-2. Print using NST timer

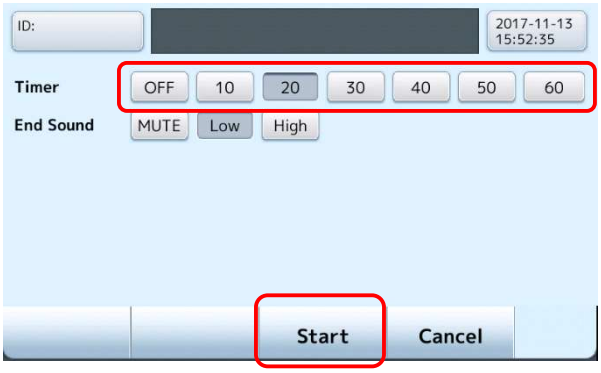
CTG printing starts using the timer function, which automatically stops the recorder after the time set. If the device is in the alarm condition when it reaches the time set, it continues printing until the alarm is released.

1. Touch <NST>.



The timer selection screen is displayed.

2. Touch the time you want to use, and then touch <Start>.



The device returns to the monitoring screen and starts recording.

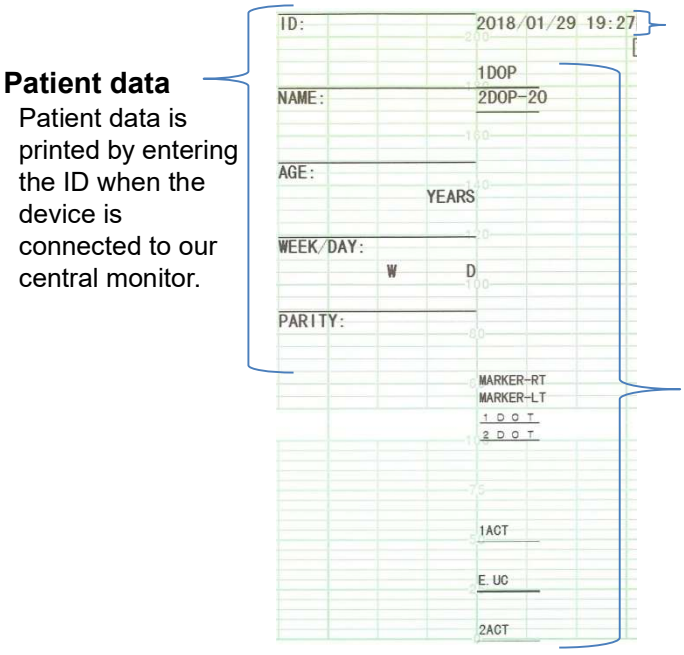
6-4-3. Print using automatic NST timer

When the automatic NST timer is set, CTG printing automatically starts when the fetal heart rate can be stably monitored. The timer setting follows the NST timer setting. (See P.64 “8-8 Record Setting”)

6-4-4. Top sheet and recording item name

Below information is printed as a top sheet when the recording starts.
You can change the settings to skip the top sheet. (See P.64 “8-8 Record Setting”)

Printing example of the top sheet



Patient data
Patient data is printed by entering the ID when the device is connected to our central monitor.

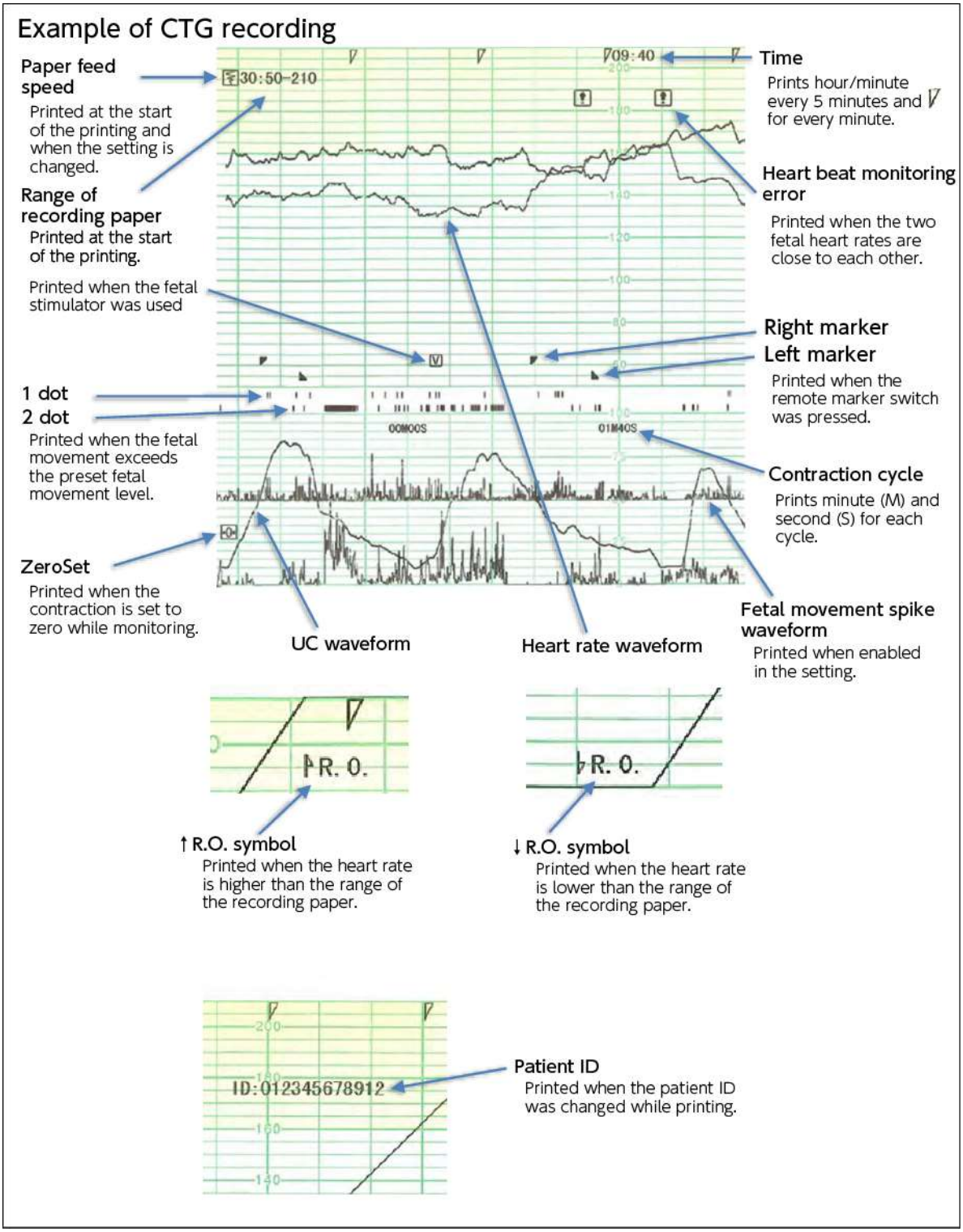
Date and time
Prints the start time of printing.
The date is not printed during monitoring.

The recording mode
Recording items are printed depending on the accessories used or the selected settings.
These are also printed when the recording conditions are changed during monitoring.

■Recording items

1 DOP	Y-shaped Doppler/External UC transducer connection. In the case of double Doppler single heart, Doppler [SH] is shown.
1 DOT	Fetal movement dot of Doppler 1.
1 ACT	Fetal movement spike waveform of Doppler 1.
E.UC	Y-shaped Doppler/External UC transducer connection or external UC transducer connection.
E.UC(HI)	Contraction high-sensitivity setting.
2DOP-20	Printing example when offset -20 is selected in the setting. Offset ±0 or +20 is printed depending on the setting.
MARKER-RT	When the right remote marker switch (twins) was operated, the right marker in "6-4-5. Example of CTG recording" is printed.
MARKER-LT	When the left remote marker switch (twins) was operated, the left marker in "6-4-5. Example of CTG recording" is printed.
2 DOT	Fetal movement dot of Doppler 2.
2 ACT	Fetal movement spike waveform of Doppler 2.

6-4-5. Example of CTG recording



6-4-6. Print the fetal movement mark

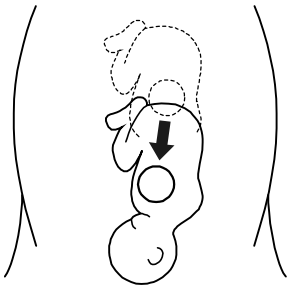
Ask the patient wearing this device to press the remote marker switch when she recognizes the fetal movement. A mark is printed when the switch is pressed.
Use the left and right switches when a switch for twins is used.

6-4-7. Move the position of the Doppler transducer

WARNING

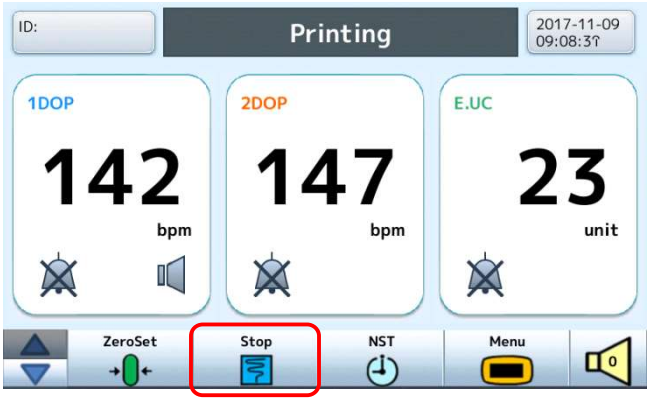
	Move the Doppler transducer to the position (optimal position) that provides clear, rhythmic sounds (sounds of heart wall and valves) in response to the fetal movement. It may cause a misdiagnosis.

Adjust the Doppler transducer in response to the fetal movement. Especially, when recording for twins, periodically check the recording paper, and if ! is printed, be sure to move the position of the Doppler transducer.



6-4-8. Stop printing

1. The recording automatically stops when the timer recording is used.
   Touch <Stop> for manual recording.



   Regardless of the recording speed, the paper is fed to the folding line.
2. Lightly hold the top of the folding line of the recording paper, and then cut the paper downward.

6-5. Print/Restore Past Data

CAUTION

	Use the USB memory specified by us. Failure to follow this instruction may result in an unstable operation.

The monitoring data for the last fifteen hours is stored in the built-in non-volatile memory and can be printed out on the recording paper and backed up to a USB memory device (sold separately).

Old data exceeding fifteen hours is automatically deleted in chronological order. Back up the necessary data before going over the fifteen hours.

Important

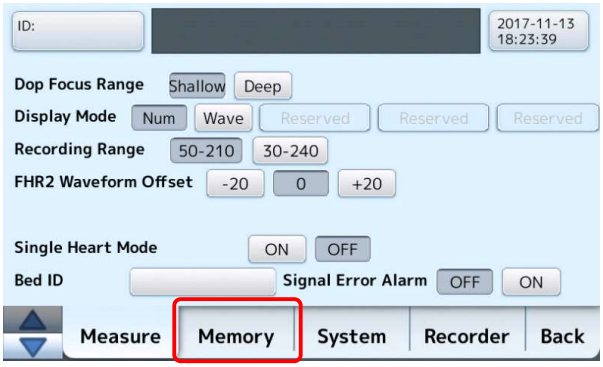
If the recorded data exceeds fifteen hours, old data is removed every minute.

6-5-1. Print the stored data

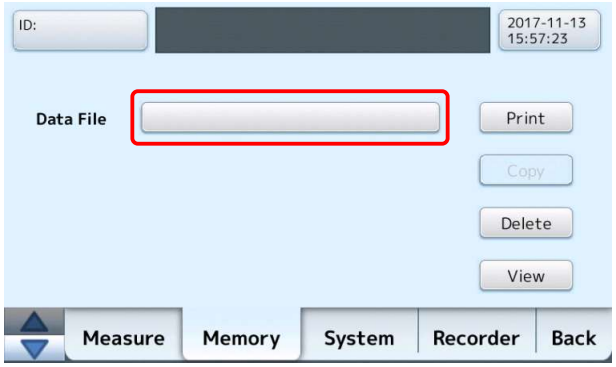
CAUTION

	CTG files should be selected based on the start date and time. This device will not manage CTG files using patient IDs.

1. Touch <Menu> to display the measurement setting screen.
2. Touch <Memory>.

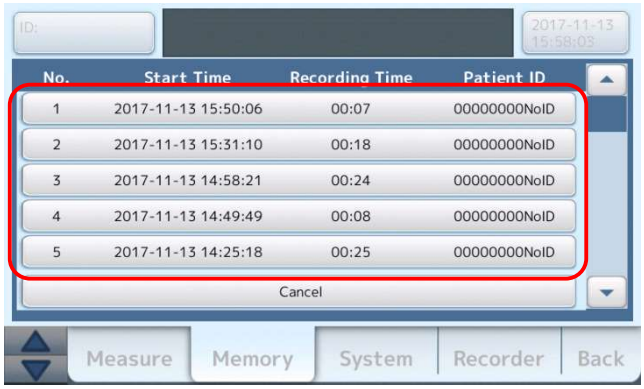


3. Touch the Data File area.

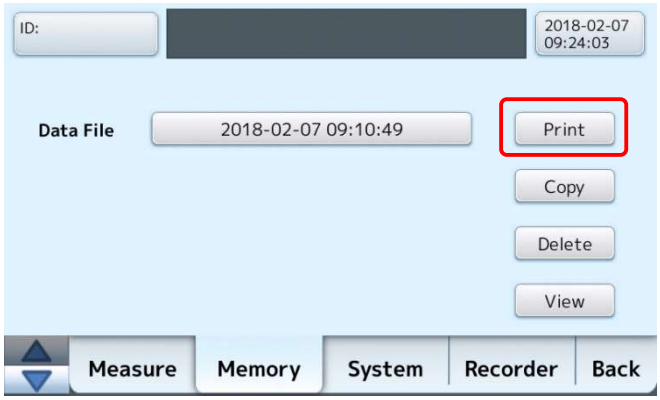


Start Time/Recording Time/Patient ID screen is displayed.

4. Select the data to be printed.

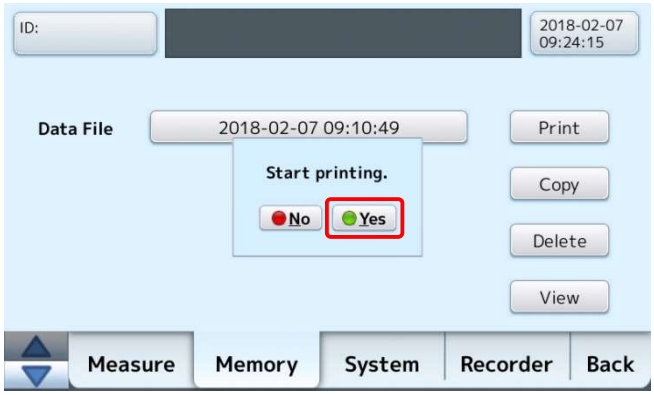


5. Touch <Print>.



A confirmation message is displayed.

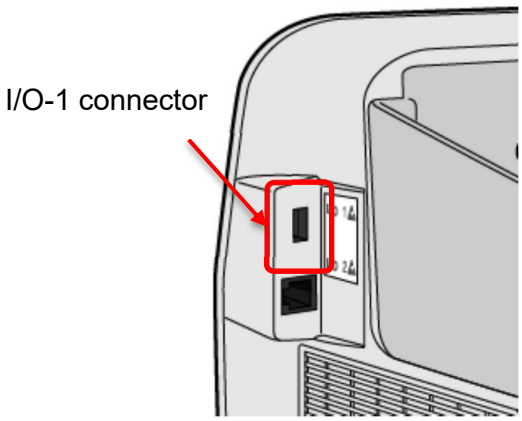
6. Touch <Yes>.



The printing starts.

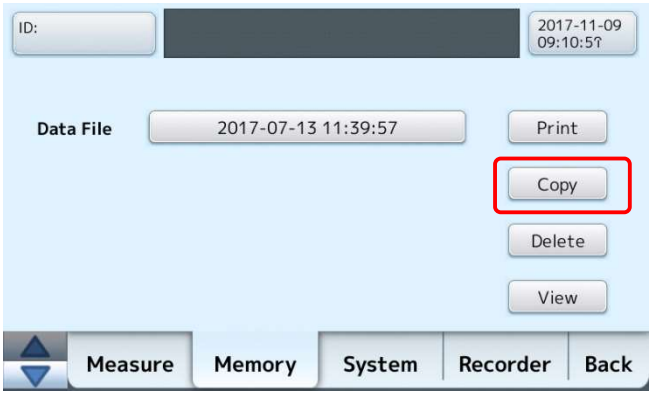
6-5-2. Backup

1. Insert the USB memory into the I/O-1 connector.



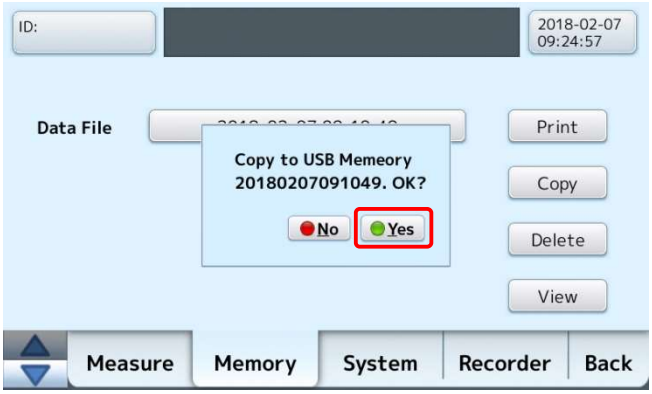
2. Select the data to backup as in the same manner as steps 1 to 4 in 6-5-1.

3. Touch <Copy>.



A confirmation message is displayed.

4. Touch <Yes>.



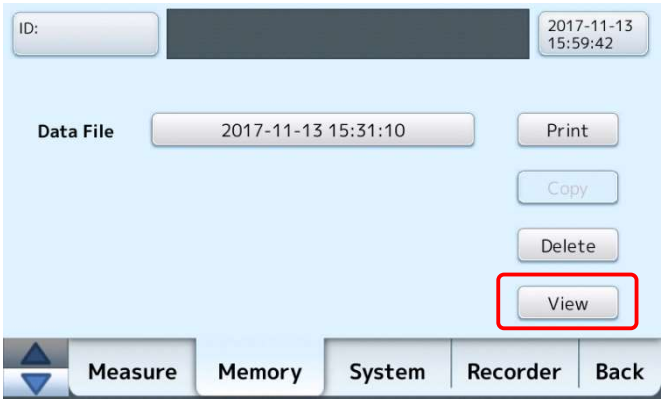
The data is **copied** to the external memory.

Important

In order to backup all data in the internal memory, touch <Copy> before selecting data in Step2.

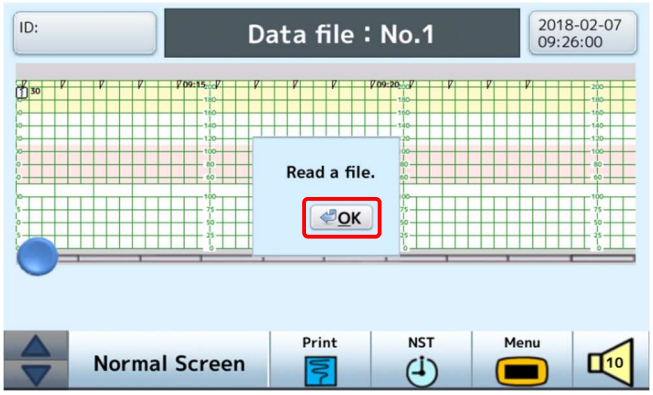
6-5-3. Replaying the stored data (only in the extended mode)

1. If replaying a stored data in an USB memory, connect the USB memory.
2. Select the data to replay as in the same manner as steps 1 to 4 in 6-5-1.
3. Touch <View>.



A confirmation message is displayed.

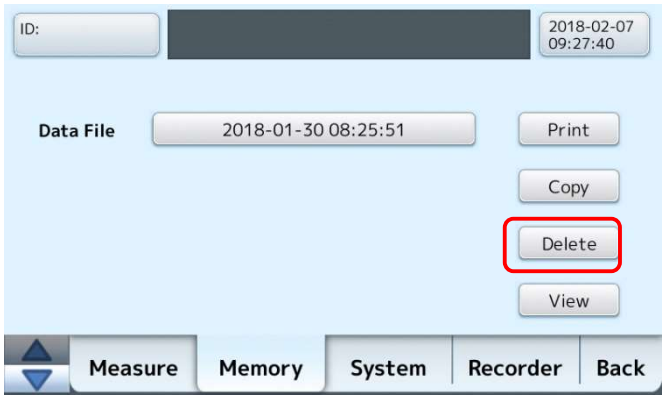
4. Touch <OK>.



The stored data is played. (See P.23 “4-2-3 History screen”)

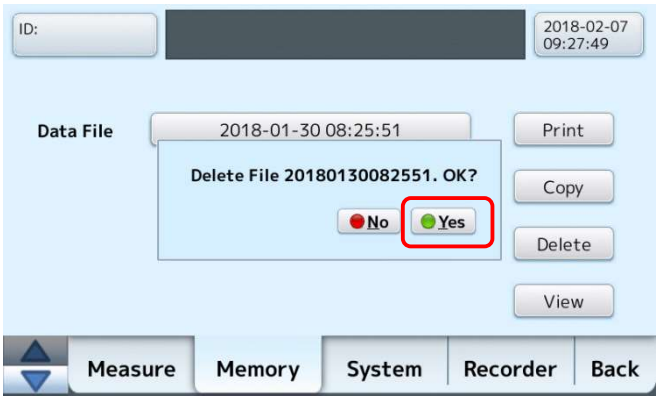
6-5-4. Deleting the stored data

1. Select the data to delete as in the same manner as steps 1 to 4 in 6-5-1.
2. Touch <Delete>.



A confirmation message is displayed.

3. Touch <Yes>.



The data is deleted.

Important

In order to delete all data in the internal memory, touch <Delete> before selecting data in Step1.

6-6. Stop Monitoring

(1) Turn off the power

Press the power switch in front of main body.

The device LCD turns off.

The LED of the power switch will flash while charging even when the power is turned off.

(2) Remove the transducer

1. Detach the transducer belt.
   Remove the transducer from the abdominal wall.
2. Wipe the ultrasound gel on the abdominal wall with tissues or a paper towel.

(3) Sterilize the parts that have touched the surface of the skin

Sterilize the transducer and remote marker switch after each use. (See P.65 “9-1 Cleaning and Sterilizing”)

(4) Disconnect the plugs

Disconnect the connected plugs.

7. Types of Alarm and Corresponding Actions

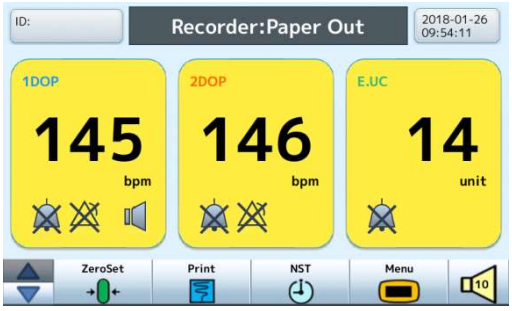
When an alarm is triggered, user is notified by below. Perform actions required.

- Alarm sound is output. (It is not output when the alarm sound is set to <Mute>.)
- Monitoring area flashes. (See below)
- A corresponding alarm message is displayed in the free space.

CAUTION

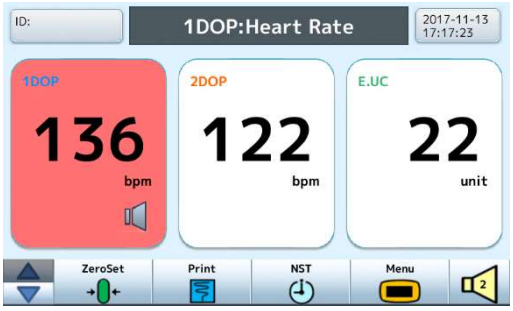
	Pay attention to the change in the screen and recording when performing the monitoring with alarm sound off. Failure to follow this instruction may result in the alarm being missed.
	Check the settings of the alarm periodically. The alarm may not be raised depending on the setting.

Example of alarms other than the heart rate alarm



The monitoring area flashes in yellow every two seconds when an alarm other than the heart rate alarm is issued.

Example of the heart rate alarm



The monitoring area flashes in red every 0.5 seconds only when the heart rate alarm is issued.

7-1. List of Alarms

Message	Reason for the Alarm	Action
1DOP:Heart Rate	The heart rate was higher than the upper limit or lower than the lower limit for more than the delay time.	See P.54 “7-2 Fetal Heart Rate Alarm”
2DOP:Heart Rate		
DOP[SH]: Heart Rate		
Signal Error	The following signal error alarm is issued. • Two transducers may be monitoring the heart rate of the same fetus. • The same heartbeat may be detected for fetal heartbeat and maternal heartbeat.	Move the position of the Doppler transducer.
UC:Check UC Transducer	The UC transducer is not correctly affixed.	Move the position of the UC transducer. Change the way the transducer belt is fastened.
"Recorder: Paper Out" ⇔ "Printing" (displayed alternately)	The recorder cover is open or the recording paper is out.	See P.55 "7-3 Paper Out Alarm"
Recorder:Unit Error	An error has occurred with the recorder.	Stop using the device and contact us or our distributor for repair.
Clock Low Battery	The voltage of the clock battery is low.	Contact us or our distributor for battery replacement. * Be sure to correct the time when you continue the monitoring.
Low Battery	Battery voltage of the main unit is low.	Connect the power cord to charge the battery.
No Multiple transducers	Multiple transducers were connected in combination which is prohibited. Ex.: Two transducers of the same type were connected.	Disconnect either one.
Transducer unavailable	Any abnormality with the transducer.	Use a different transducer.
Transducer unidentifiable	A transducer other than those specified is connected. A transducer which is not supported by the device software is connected.	Connect the specified transducer. Update the software of the device.
Check Transducer	The transducer is not correctly connected.	Reconnect the transducer.

7-2. Fetal Heart Rate Alarm

⚠ WARNING

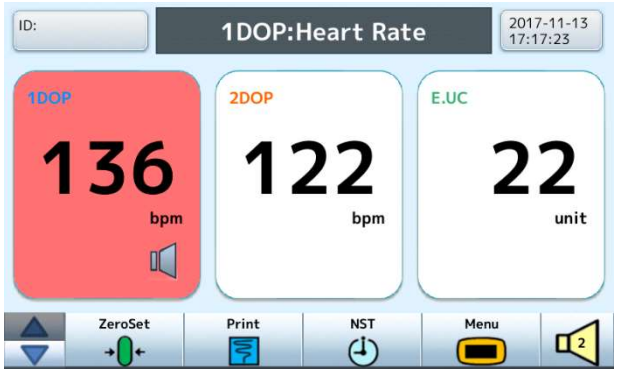
❗	In the event of a fetal heart rate alarm, initiate the appropriate measures under the direction of a physician. Failure to follow this instruction may result in an accident or other deterioration of the fetus.

Important

If the alarm suppression feature is set to <ON>, the fetal heart rate alarm is not activated until five minutes has passed after turning on the power or the transducer was connected, or a good heartbeat signal was monitored for over ten seconds. This is to avoid the frequent occurrence of the fetal heart rate alarm. Pay attention to the condition of the heart rate recorded during the time set.

(1) When a fetal heart rate alarm is issued

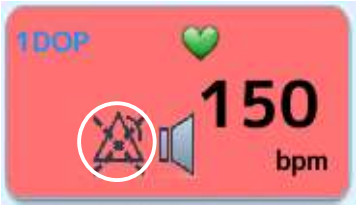
Example of fetal heart rate alarm



- Alarm sound is output. (It is not output when the alarm sound is set to <Mute>.)
- The monitoring area flashes red every 0.5 seconds.
- "1DOP:Heart Rate" (or "2DOP:Heart Rate") appears in the free space.

(2) Confirm the fetal heart rate alarm

1. Touch the monitoring area flashing red.
   Heart rate alarm is suspended.
   The alarm sound stops, the display area turns red, and the alarm suspension icon flashes.



2. Check the fetal and maternal condition and take appropriate measures under the direction of a physician.

(3) Clear the fetal heart rate alarm

The monitoring screen is redisplayed by touching the monitoring area again if the monitored value returns to the configured range while the alarm suspended mark is flashing.

Important

The fetal heart rate alarm is not automatically cleared even if the monitored value returns to the normal range unless the user touches the monitoring area flashing red when it is issued.

7-3. Paper Out Alarm

(1) When a paper out alarm is issued

- Alarm sound is output. (It is not output when the alarm sound is set to <Mute>.)
- The monitoring area flashes yellow every two seconds.
- "Recorder: Paper Out" and "Printing" are displayed alternately in the free space.

(2) Confirm the alarm

1. Touch the monitoring area.
   The alarm is suspended, the alarm sound stops, the display area turns yellow, and the alarm suspension icon flashes.

2. Check the recorder and load new recording paper if it is empty.
   Fully close the cover. (See P.28 “5-1 Setting the Recording Paper”)
   The alarm is automatically cleared when recording paper is loaded and the cover is closed.

(3) Print the recording while printing was suspended

If the paper runs out while printing, monitored data is automatically stored in the memory. When the new recording paper is loaded, up to 30 minutes of monitored data from the time of paper out to when new paper was loaded is automatically printed using high-speed printing.

7-4. Other Alarms

In addition to the fetal heart rate alarm or paper out alarm, there are "Low Battery Voltage", "Unit Error", "Check UC Transducer", and "Signal Error" alarms.

(1) When an alarm occurs

- Alarm sound is output. (It is not output when the alarm sound is set to Mute.)
- The monitoring area flashes yellow every two seconds.
- A corresponding alarm message is displayed in the free space.

(2) Confirm the alarm

1. Touch the monitoring area.
   The alarm is suspended, the alarm sound stops, the display area turns yellow, and the alarm suspension icon flashes.
2. Perform an action in response to the alarm message.
   The alarm is automatically cleared when the condition is remedied.

7-5. Alarm Specifications

(1) Intended position of the operator

The alarms of this device are intended to notify the situation to the personnel in the area where they can see the monitor or the recording paper.

(2) Information delay

There are delays to the alarm signal of this device caused by below processes.

- Delay caused by the heart rate detection algorithm.
- Delay caused by internal communication.

(3) Method and timing for verifying alarm system function

Check periodically that the alarm function of this device operates normally.

- Verification timing: every six months
- Verification method: refer to P.67 “9-2 Inspections to be Conducted by Users”

8. Changing the Configurations

In the setting screen, you can configure the settings of this device or parameters for measuring devices such as a transducer.

8-1. Setting Items List

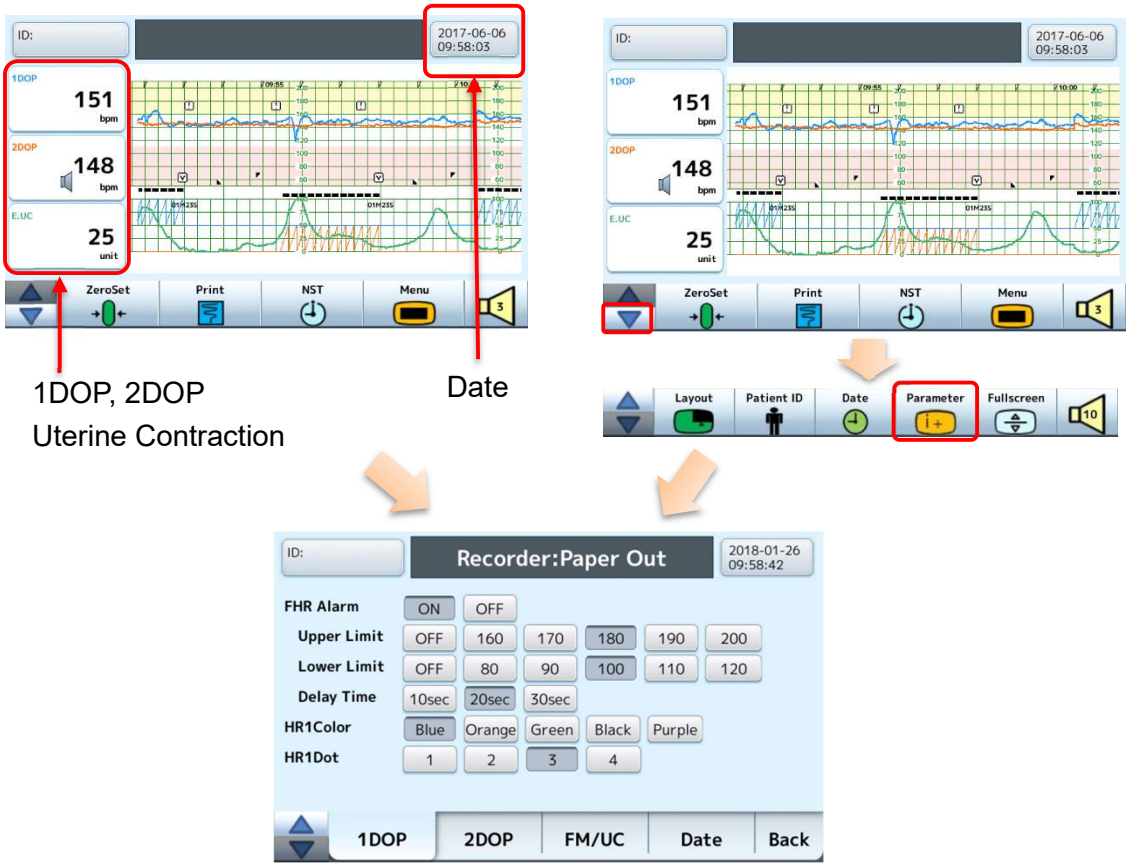
There are two types of setting items. Settings that are set by displaying the settings screen from the measurement screen, and those that are set by displaying the setting screen from <Menu>.

Screen	Setting Items	Refer to
Items shown from the measurement screen		
Heart rate 1 or heart rate 2 setting	FHR Alarm/Upper Limit/Lower Limit/Delay Time/ HR1Color/HR1Dot/HR2Color/HR2Dot	P.59
Fetal movement/UC setting	FM Spike/Dot of FM/UC Sensitivity/UC Filter/UC Color	P.60
Date and time setting	Date/Time/Clock Sync	P.61
Items shown from <Menu>		
Measurement setting	Dop Focus Range/Display Mode/Recording Range/FHR2 Waveform Offset/Single Heart Mode/Bed ID/Signal Error Alarm	P.62
System setting	Alarm Volume/Suspend Time/Alarm Restraint/Key Sound/Print Settings/Brightness/Clock Battery/Initial Settings/Night Mode	P.63
Record setting	REC Speed/Top Sheet/Auto Feed/Auto Print/Auto NST Timer	P.64

8-2. Display Setting Screen

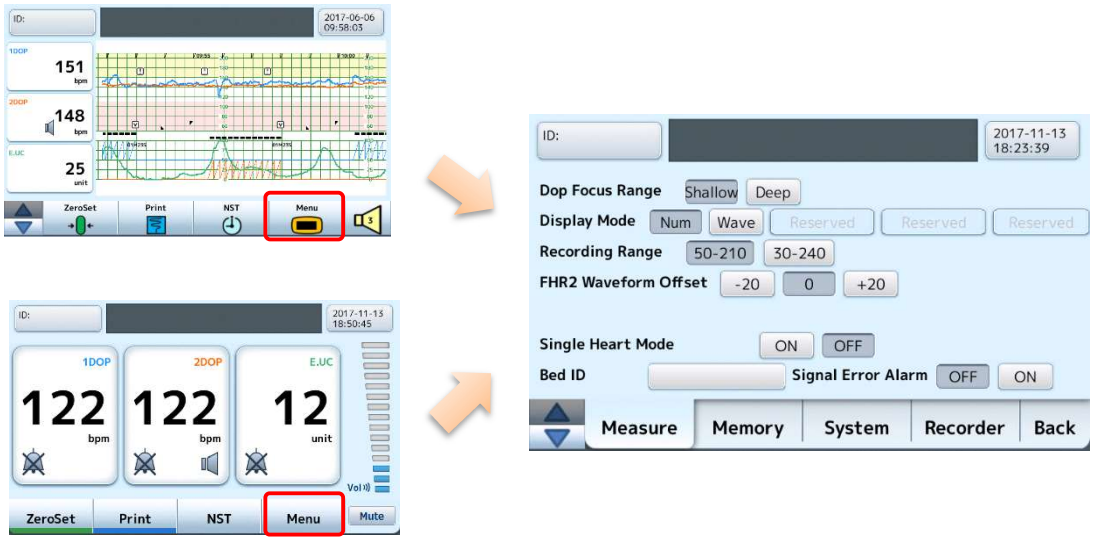
8-2-1. Opening the setting screen from the monitoring screen

Display the settings screen by either holding the display area of the desired item in the measurement screen, or selecting <Parameter> in the menu bar. Three items, "Heart rate setting", "Fetal movement/UC setting", and "Date and time setting" can be set with this method.



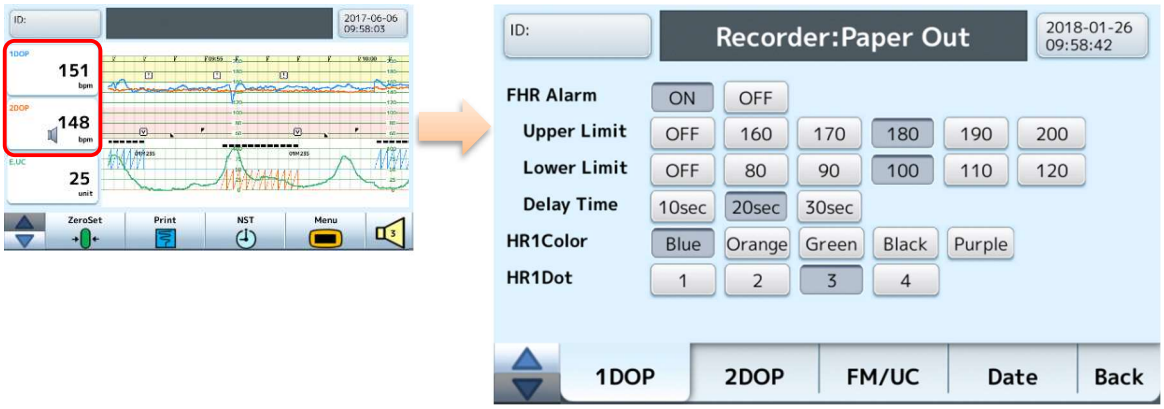
8-2-2. Opening the setting screen from the <Menu>

Display the settings screen by selecting <Menu> in the menu bar. Three items, "Measurement setting", "System setting", "Record setting" can be set with this method.



8-3. Heart Rate 1 or Heart Rate 2 Setting

Press and hold the Doppler 1 (Doppler 2) area to open the heart rate 1 (heart rate 2) setting screen. (When the Doppler transducer is connected.)



Note

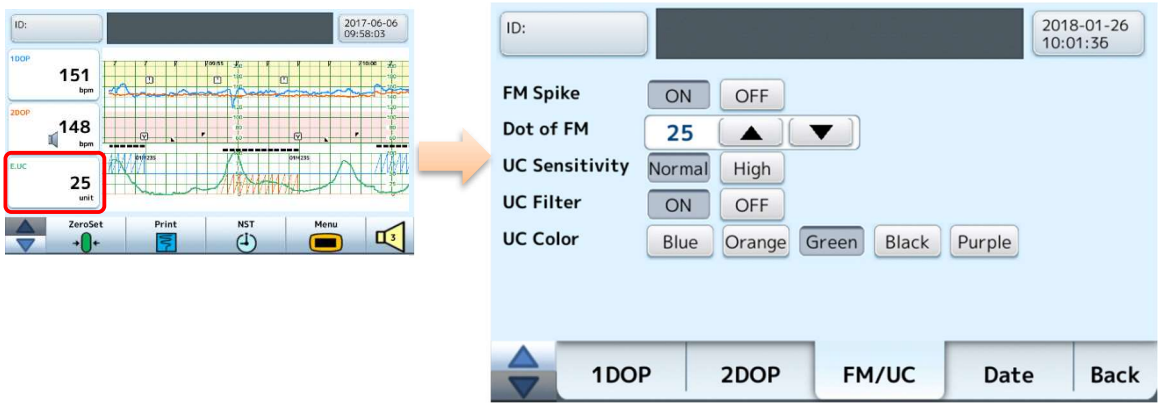
From the monitoring screen, you can also touch <▼>, then <Parameter> to open the heart rate 1 setting screen.

Field	Functions	Default Value
FHR Alarm	Sets whether the fetal heart rate alarm ON or OFF.	ON
Upper Limit	Sets the upper limit of the fetal heart rate alarm.	180
Lower Limit	Sets the lower limit of the fetal heart rate alarm.	100
Delay Time	Sets how long the selected heart rate must remain outside the threshold before the fetal heart rate alarm is issued.	20 sec.
HR1Color	Sets the color of waveforms displayed on the CTG screen.	Blue
HR1Dot	Sets the line weight of waveforms for CTG printing.	3
HR2Color	Sets the color of waveforms displayed on the CTG screen.	Orange
HR2Dot	Sets the line weight of waveforms for CTG printing.	2

* Only the display color and the line weight can be set separately for heart rate 1 and 2. The fetal heart rate alarm criteria can be set from both, but the setting is common. Therefore, if one setting is set and then the other, the first setting is disabled.
Example: Upper limit of heart rate is set to 180 for heart rate 1, and then 190 for heart rate 2.
In this case, 190 are applied for both.

8-4. Fetal Movement/UC Setting

Touch and hold the External Uterine Contraction (EUC) monitoring area to open the fetal movement/contraction setting screen.



Note

The Fetal movement/UC setting screen can also be shown by touching <▼>, <Parameter>, then <FM/UC> from the monitoring screen.

Field	Functions	Default Value
FM Spike	Sets whether or not to record spike waveforms for fetal movement.	ON
Dot of FM	Sets the threshold for recording fetal movement dots.	25
UC Sensitivity	Sets the sensitivity of contraction monitoring.	Normal
UC Filter	Sets the filter function to eliminate the breathing components.	ON
UC Color	Sets the color of waveforms displayed on the CTG screen.	Green

* Set to <OFF> if fetal movement spike waveform recording is not used.

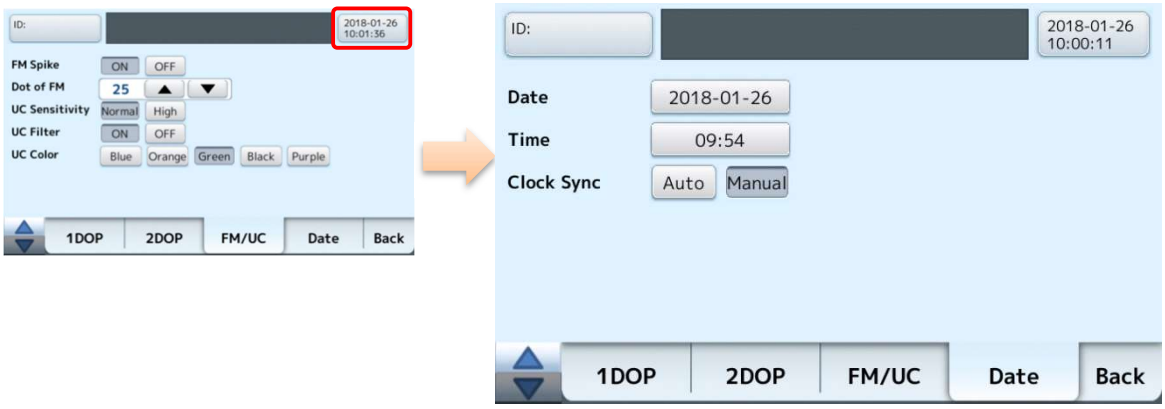
* Fetal movement dot threshold

  In fetal movement dot recording, dots are displayed and printed when the monitored fetal movement level is higher than the setting.

  Touch <▲> or <▼> to change the setting.

8-5. Date and Time Setting

The date and time setting screen is displayed by holding the date and time display area. The software keyboard is displayed by touching the date or time area.



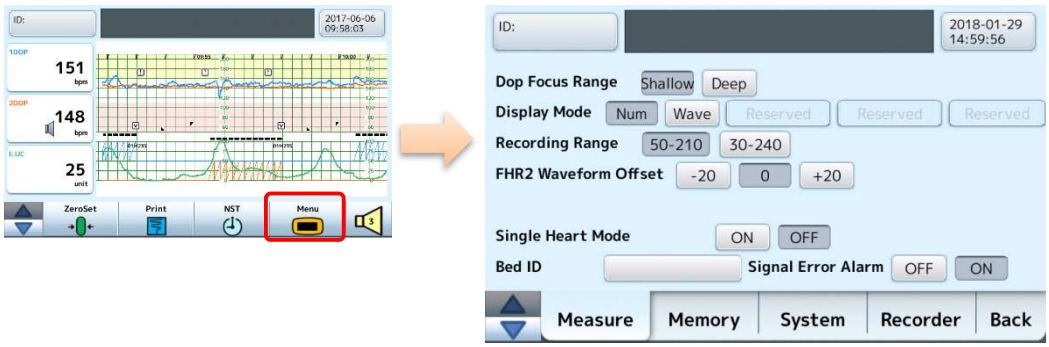
Note

- The date and time setting screen can also be shown by touching <▼>, <Parameter>, then <Date> from the monitoring screen.
- Refer to “(3) Correct the time (or date)” in P.31 “5-3 Inspections before Use” for the method of operation.

Field	Functions	Default Value
Date	Sets the date separated by a hyphen.	-
Time	Sets the time separated by a colon (24-hour notation).	-
Clock Sync	When set to <Manual> the date and time can be manually entered from the LCD of the device. When set to <Auto>, automatic time synchronization is performed with our central monitor.	Manual

8-6. Measurement Setting

The measurement settings screen is displayed when <Menu> in the menu bar is selected.



Field	Functions	Default Value
Dop Focus Range	Sets the range of depth monitored by ultrasound.	Shallow
Display Mode	Sets the display manner of the monitoring results.	Num
Recording Range	Sets the recording paper to be used.	50-210
FHR2 Waveform Offset	Sets the offset of waveform display/printing of heart rate 2.	0
Single Heart Mode	Sets monitoring of a wide range using two Doppler transducers for one fetus.	OFF
Bed ID	Used for device identification when it is connected to our central monitor.	Not set
Signal Error Alarm	The Signal Error Alarm is issued when both doppler transducers are detecting only either heart rate, one of the twins in case of twin fetus, and one of mother's or the fetus' in case of a single fetus.	ON

8-6-1. Double Doppler single heart setting

1. Touch <ON> for the Double Doppler Single Heart Mode.
2. Touch <Back> to return to the monitoring screen. DOP [SH] is displayed on the space for fetal heart rate mode.

Sample double Doppler single heart screen

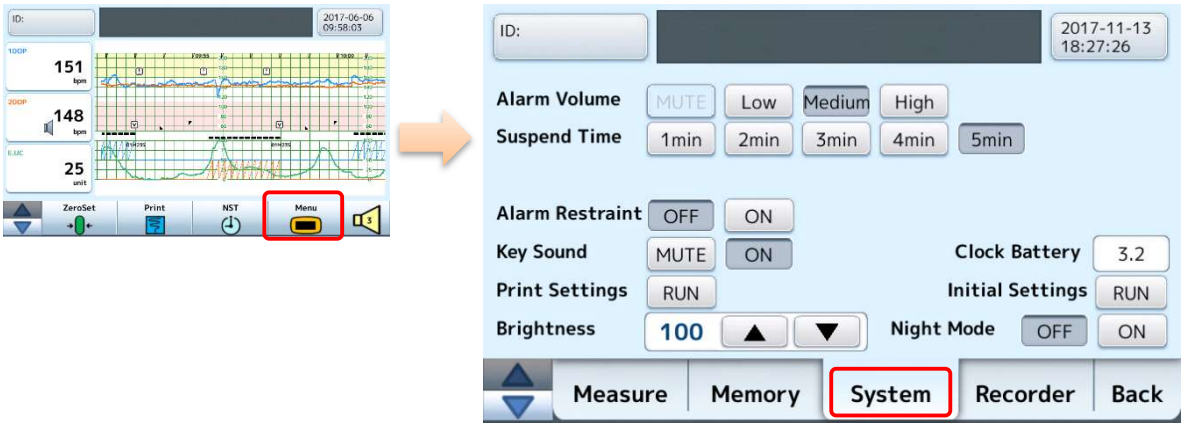
3. Touch <Print> to start printing on the recording paper.
   DOP [SH] is printed on the header of the recording paper.
4. During monitoring, better signals from the two Doppler transducers are automatically selected and recorded.

Important

In order to use the double Doppler single heart setting, you must connect the optional Doppler transducer. (See P.17 “3-2 Major Options”)

8-7. System Setting

The system settings screen is displayed when <Menu>-<System> in the menu bar is selected.

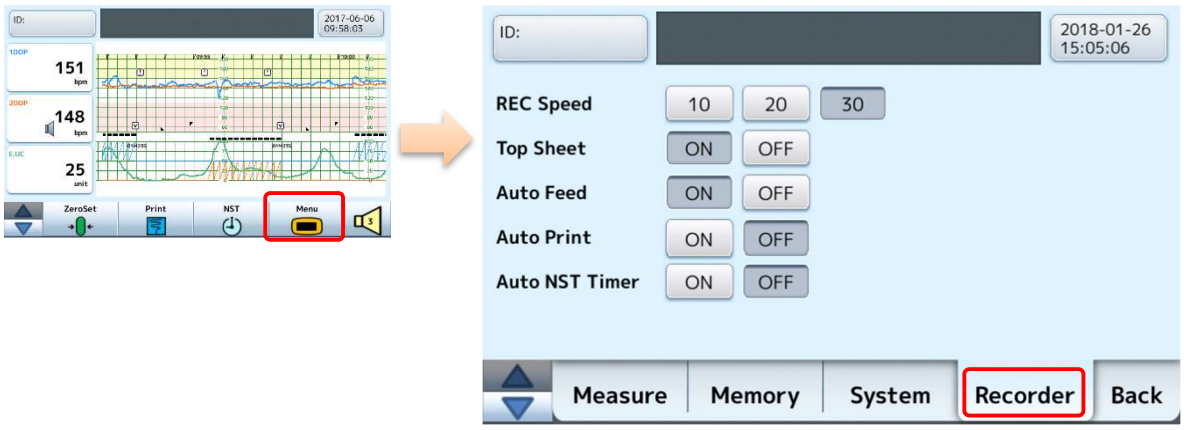


Field	Functions	Default Value
Alarm Volume	Sets the volume of the alarm.	Medium
Suspend Time	Sets the length of alarm suspension period after alarm check.	5 min
Alarm Restraint	Sets if the biological alarm is suppressed at startup.	OFF
Key Sound	Sets the operation sounds to ON or OFF.	ON
Print Settings	Prints the list of settings of the device.	-
Brightness	Sets the brightness of the LCD screen.	100
Clock Battery	Displays the voltage of the battery for the clock.	-
Initial Settings	Restores the settings to the factory defaults.	-
Night Mode	When set to <ON>, sets the brightness of the LCD to 20.	OFF

* Contact us or our distributor when you want to set the alarm volume to <MUTE>.

8-8. Record Setting

The record settings screen is displayed when <Menu>-<Recorder> in the menu bar is selected.



Field	Functions	Default Value
REC Speed	Sets the speed of CTG printing.	30
Top Sheet	Sets whether the top sheet is printed or not.	ON
Auto Feed	Feeds the recording paper to its fold line at the end of recording.	ON
Auto Print	Automatically starts CTG printing when the device is turned on.	OFF
Auto NST Timer	Enables or disables the function to automatically start/stop the printing.	OFF

9. Maintenance and Inspection

9-1. Cleaning and Sterilizing

⚠WARNING

	Sterilize all equipment that touches the surface of the skin before every use. Failure to follow this instruction may cause infection.
	Do not insert or remove the plugs with wet hands. Failure to follow this instruction may result in electric shock.

⚠CAUTION

	The device is not sterilized before shipment. Be sure to sterilize and clean before use.
	For safety reasons, remove the power cord before wiping for safety.
	Do not use chemicals such as sodium hypochlorite, alcohol (ethanol, methanol), thinner, benzine, peracetic acid formulation (Acecide), sodium hydroxide, volatile solvents, or cleanser. Failure to follow these instructions may degrade the material.
	Do not use chemicals other than those specified by us for disinfection or sterilization.
	Do not excessively wipe the head of the transducer. Failure to follow this instruction may damage the sensor or remove the surface coating, preventing smooth movement on the abdominal wall, resulting in the redness in the skin.
	Do not use water to clean, wipe, or disinfect the power cord plug. Failure to follow this instruction may result in corrosion.
	Do not apply or spray disinfectant to the electrical part. Some disinfectants are conductive. Residual liquid may become more conductive by absorbing dust or dirt.
	Perform an inspection using the checklist in Section P.68 "9-2-2 Inspection checklist” after cleaning.
	Do not use the following methods of disinfection or sterilization. ・Disinfection or sterilization at more than 70°C, such as autoclave ・Sterilization by EOG (ethylene oxide gas) or ultraviolet light
	The device body is not waterproof. Do not allow water to get inside the device.
	Although the Doppler transducer and the External UC transducer are IPX7 waterproof, their waterproofness may decrease by immersing into chemicals. Immerse only the applying surface into disinfectants.

	Periodically clean the device to keep it clean. Failure to follow this instruction may spread bacteria that cause a rash.

9-1-1. Sterilizing the accessories which touch the surface of the skin

■ Chemicals that can be used

- Glutaral (STERIHYDE)
- Benzalkonium chloride solution (Osvan)
- Amphoteric surfactant (TEGO 51)

■ Before sterilization

Before sterilization, wipe the ultrasound gel from the Doppler transducer carefully with tissues or a soft cloth.

■ Sterilization

Bacterial sensitivity differs depending on the chemicals being used. Follow the instructions in the documents supplied with each chemical such as the indications, usage, and precautions.

9-1-2. Cleaning the device

Wipe the device with a soft cloth on a regular basis.

Clean tough stains in the following manner.

1. Put a soft cloth in neutral detergent diluted with warm or cold water.
   Wring out the cloth before wiping so that the water does not drip.
2. Wipe the device with the damp cloth.
3. Finally, wipe with a soft dry cloth.

9-2. Inspections to be Conducted by Users

WARNING

	Follow this operation manual. In case of any abnormality, stop using immediately.
	Be sure to inspect the device before use. If you cannot confirm the proper condition by the inspection, turn off the power, and remove the power plug from the outlet. Stop using the device, attach a "Failure" indication, and contact us or our distributor for immediate repairs.
	Do not disassemble or modify the device. Failure to follow this instruction may result in failure or malfunction.
	Do not perform maintenances in a situation with patient. Failure to follow this instruction may cause electric shock.

9-2-1. About inspections

Inspections are required to maintain the function of this device. Some inspections should be performed by the user and some inspections should be performed by our service personnel. The hospital or clinic is responsible for these inspections.
Users should conduct the following inspections.

Inspection		Refer to
Inspection before use	Be sure to conduct before every use.	P.68
Inspection after use	Be sure to conduct after every use.	P.68
Six-month inspection	Conduct a functional inspection every six month.	P.69
Annual inspection	Conduct every year.	P.69

If you cannot confirm the proper action, the device has failed.
Turn off the power, unplug the power cord, and attach a label stating “Failure", and contact us or our distributor to request repairs.

9-2-2. Inspection checklist

Perform the inspection according to the check items. Copy the checklist for your convenience.

■ Inspection before use

Perform before use and after the power is turned on.

Body No.	Date of inspection Year Month Day	Inspected by

No.	Details of inspection	Results
1	The body is correctly installed without the risk of a falling hazard.	Y / N
2	No damage or deformation on the body and power cords.	Y / N
3	No defective areas on the screen.	Y / N
4	The touch panel can be operated.	Y / N
5	The date and time are correct.	Y / N
6	The recording paper is set.	Y / N
7	The volume level is appropriate.	Y / N
8	The top sheet is correctly printed.	Y / N
9	The Doppler transducer correctly operates and the Doppler sound can be heard.	Y / N
10	The display of contraction level changes by pressing the pressure sensitive part of the External UC transducer.	Y / N

■ Inspection after use

Turn off the power before inspection.

Body No.	Date of inspection Year Month Day	Inspected by

No.	Details of inspection	Results
1	Accessories which touch the surface of the skin are sterilized.	Y / N
2	No damage or deformation found on the body and the transducers.	Y / N
3	No dirt or foreign matter is found on the body and transducers.	Y / N

■ Six-month inspection

Connect the transducers to the device and set the recording paper before inspection.

Body No.	Date of inspection Year Month Day	Inspected by

No.	Details of inspection	Results
1	No loose or missing screws in the body and the stand.	Y / N
2	No damage or deformation on the body and power cords.	Y / N
3	The touch panel can be operated.	Y / N
4	No missing accessories.	Y / N
5	No defective areas on the screen.	Y / N
6	The date and time are correct.	Y / N
7	The volume level is appropriate.	Y / N
8	The Doppler transducer correctly operates and the Doppler sound can be heard.	Y / N
9	The display of contraction level changes by pressing the pressure sensitive part of the External UC transducer.	Y / N
10	The remote marker switch operates correctly.	Y / N
11	The fetal heart rate alarm can be correctly activated.	Y / N

■ Annual inspection

Conduct the six-month inspection at the same time.

Body No.	Date of inspection Year Month Day	Inspected by

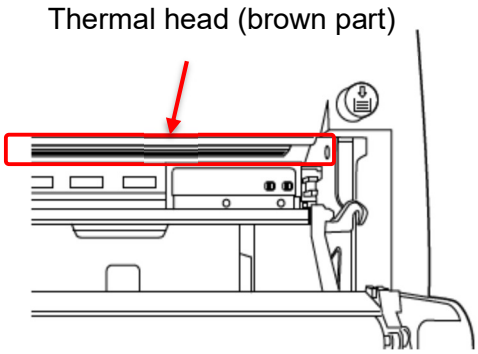
No.	Details of inspection	Results
1	No abnormality is found with the six-month inspection.	Y / N
2	No abnormality in the recorder. No dirt on the thermal head.	Y / N

9-2-3. How to inspect the fetal heart rate alarm

1. Press the power switch to turn on the device, and connect the Doppler transducer.
2. Set <Alarm Restraint> to <OFF>, <Lower limit of heart rate> to 120, and <Delay time> to 10 seconds so that the heart rate alarm can be easily issued.
3. Turn the transmitting and receiving surface up to prevent signal input (“---" is displayed on the screen).
4. Confirm that the alarm is issued after the set delay time.
5. Restore the setting after confirming the alarm.

9-2-4. Inspection of the thermal head

1. Annually check the thermal head of the recorder for dirt.
2. .If it is dirty, clean using thermal head cleaner(commercially available products).



9-3. Inspection by our Service Personnel

In general, contact our service personnel to request inspection once a year.

The service personnel will check that the electronic parts inside the device are operating correctly by using various measurement devices. He/she will visit your site based on the periodic inspection contract. If you need details of the inspection or the service manual, contact our sales representative.

Failure to conduct a periodic inspection may degrade the function of the device, delay the detection of loss, or prevent correct monitoring.

Record the results of these periodic inspections.

9-4. Storage Precautions

⚠ CAUTION

	Do not store the device in the following conditions. Failure to follow this instruction may result in failure. • A place with direct sunlight • Moist (95% or above) or dusty place • Hot place (60°C or above), cold place (-10°C or below) • Unstable place such as under vibration

9-4-1. Storage or transport conditions

- Ambient temperature: -10 to +60°C (excluding freezers)
- Relative humidity: 30-95% (no condensation)
- Atmospheric Pressure: 700-1060 hPa

9-4-2. If the device is not going to be used for a long time

1. Disconnect the power cord from the power outlet.
2. Do not store in a location in which the device could come into contact with water.

Important

- Avoid direct sunlight, high temperature and humidity, slopes, vibrations, and shocks.
- The battery in the device runs out even if the device is not being used. Charge the battery at least once every three months. The battery may become unchargeable if the device is not used for more than three months. We recommend removing the battery when storing the device. Contact us or our distributor to request battery removal.

9-4-3. Storing recording paper

Note the following points when handling and storing under the following conditions. They may cause discoloration.

- Storing in locations subject to high temperature, high humidity, or direct sunlight
- Contact with alcohol or adhesive materials of adhesive tape
- Storing the recording paper in PVC files

Use water-soluble glue to stick the recording paper to medical records.

The recording paper will gradually discolor over time even under optimum storage conditions. In the optimal environment (ambient temperature of 23°C, relative humidity of 50%), the recording paper is readable for approximately five years.

9-4-4. Storing transducer

Avoid subjecting the transmitting and receiving surface of the Doppler transducer and the pressure receiving surface of the External UC transducer to shocks.

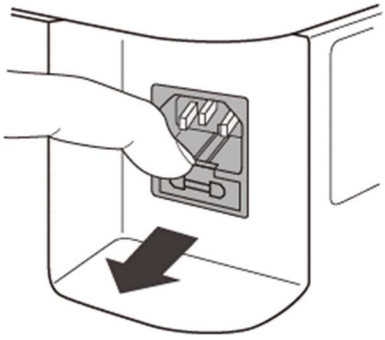
9-5. How to Replace the Fuse

The device incorporates a fuse to prevent damage from transient overcurrent. When the plugs are correctly connected but the power does not turn on, the fuse may have blown. Pull out the fuse holder, check the fuse, and replace it with a new one if the fuse is blown.

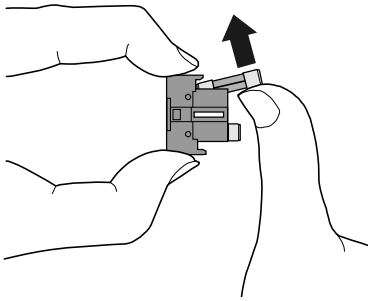
Specified fuse: AC250V 3.15A, Time-lag, Low-breaking capacity, ø5.2×20 mm
(ET3.15A made by SOC)

(1) Turn off the power
1. Press the power switch to turn off the power.
2. Unplug the power cord connector from the power inlet.

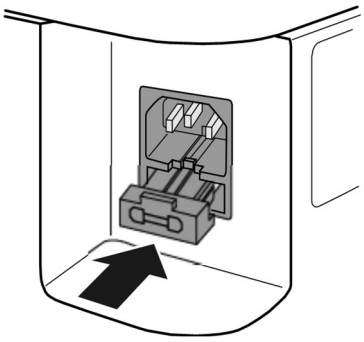
(2) Remove the fuse holder
Pull out the fuse holder from the upper side using your fingernail or a flat screwdriver.



(3) Replace the fuse
1. Push the blown fuse laterally and pull it out.
2. Insert a new fuse.



(4) Return the fuse holder
Turn the fuse holder guide upwards and return the holder to the power inlet.



10. Troubleshooting

WARNING

	Follow this operation manual. In case of any abnormality, stop using immediately.
	Do not disassemble or modify the device. Failure to follow this instruction may result in failure or malfunction.

This section describes the procedures for users to address problems. If there is no improvement after completing the procedures, contact us or our distributor to request repairs since the problem may be caused by a failure or a bad electrical contact. Also, contact us or our distributor if it is necessary to replace the battery for the clock or the lithium-ion battery.

10-1. Errors Displayed in the Free Space

Examples of failure	Possible causes	Action
Clock Low Battery	The voltage of the battery for clock memory is low.	Contact us or our distributor to replace the battery.
Recorder: Paper Out	No recording paper.	Insert new recording paper.
	The recorder cover is open.	Close the cover.
Recorder:Unit Error	The recorder failed.	Contact us or our distributor to request repairs.
UC:Check UC Transducer	The input signal deviates due to a sensor abnormality or for	Check the UC transducer.

10-2. Problems Not Displayed in the Free Space

Examples of failure	Possible causes	Action
The power light does not turn on after switching on the power.	The power cord is unplugged.	Insert the power cord firmly.
	The power fuse is blown.	Replace the fuse. (See P.72 “9-5 How to Replace the Fuse”)
The date and time is not correct	The time setting is incorrect.	Open the date and time setting screen and set them again (See P.32 “(3) Correct the time (or date)”)
The clock is not correct even after setting the time.	The battery of the clock has run out.	Contact us or our distributor to replace the battery.

Examples of failure	Possible causes	Action
No Doppler sound is heard	The volume setting is too low.	Adjust the volume.
	The transducer is not connected correctly to the device.	Connect the transducer firmly to the device.
The Doppler does not work normally	The transducer is not connected correctly to the device.	Connect the transducer firmly to the device.
	The transducer is applied to the inappropriate position.	Adjust the Doppler transducer to the position that provides clear, rhythmic sounds.
	Too small amount of ultrasound gel was applied to the transducer.	Apply a thin, even layer.
	The fetus has an irregular heartbeat or hiccups.	Continue careful monitoring. Use another method of monitoring which does not use this device.
	The transducer failed.	Use a different transducer.
	The fetus or mother frequently moves.	Use another method of monitoring which does not use this device.
	The mother is severely obese.	Use another method of monitoring which does not use this device.
	No signals.	Auscultate the fetal heartbeat.
Static noise in the Doppler	The fetus frequently moves.	Move the position of the transducer.
	Affected by environmental noise.	Keep the sheet and gown away from the transducer. Do not hold the transducer.
	The mother frequently moves.	Stop the mother moving.
	The transducer failed.	Use a different transducer.
 was displayed or printed	Two transducers may be monitoring the heart rate of a single fetus.	Check the fetal position and adjust the transducer.

Examples of failure	Possible causes	Action
The external UC transducer records no contraction	The transducer is inappropriately applied.	Affix the transducer to the uterine fundus of the mother.
	The zero-setting switch is pressed at the time of contraction.	Press the <ZeroSet> switch during a break in contractions.
	The transducer is not connected correctly to the device.	Connect the transducer firmly to the device.
	The transducer failed.	Use a different transducer.
	No Uterine contraction.	Wait for a contraction and monitor for a while.
	The contraction exceeds the reference range.	Loosen the belt. Remove the transducer and fix it again making sure it is not too tight.
CTG is not printed. The <Print> button color is gray	Device is not connected to the power source. (See P.12 “Battery operation”)	Insert the power cord to the power source.

11. Specifications/Parts List

11-1. Product Specifications

11-1-1. Material of the parts which touch the surface of the skin

Name	Material
Y-shaped Doppler/External UC transducer	PC/ABS resin, silicone rubber
Transducer belt	Polyurethane rubber, polyester
Remote marker switch	PC/ABS resin, elastomer material
Doppler transducer	PC/ABS resin
Ultrasound gel	Propylene glycol/carboxypolymethylene sodium/cellulose derivative/purified water

11-1-2. Device category

Category	Description
Classification by protection type to electric shock	Class I
Classification of applied part by protection level to electric shock	Y-shaped Doppler/External UC transducer: Type BF applied part Doppler transducer: BF applied part
Classification by protection level to hazardous entry of water	Main unit: IPX0 Transducer: IPX7 (excluding the connector to the main unit) Remote marker switch: IPX7 (excluding the connector to the main unit)
Classification by actuation (operation) mode	Continuous actuation (operation) device

11-1-3. Electrical rating

Category	Description
Alternating current/direct current	Alternating current
Rated voltage	100-240 V 47 VA (momentary 66 VA)
Frequency	50 Hz /60 Hz

11-1-4. Dimension/weight

Category	Description
Main unit	250±25 mm(W)×265±27 mm(H)×205±21 mm(D)/4.0±0.4 kg (excluding accessories)
Y-shaped Doppler/External UC transducer	66±7 mm(W)×18±2 mm(H)×80±9 mm(D)/240±24 g Length: 2.85±0.1 m
Doppler transducer	66±7 mm(W)×18±2 mm(H)×80±9 mm(D)/170±17 g Length: 2.85±0.1 m
Remote marker switch	73±7 mm(W)×45±5 mm(H)×28±3 mm(D)/100±10 g Length: 2.5±0.3 m

11-1-5. Technical specifications

Category	Details	Description
Fetal heart rate measurement by ultrasound doppler	Ultrasound driving method	Pulse Doppler with autocorrelation processing
	Oscillating frequency	1.108 MHz±10%
	Ultrasound power	Not more than 10 mW/cm^2 TI, MI<1.0
	Heart rate measuring range	50-240 bpm
	Heart rate measuring accuracy	Within ±3 bpm
External UC	UC input	Strain gauge
	Measuring range	0-100 UNIT
	Contraction sensitive mode	1.33 times the normal mode
	Recording sensitivity	30 mm on the recording paper for 100 g load
Measurement function	Double Doppler Single Heart	Two Doppler transducers are used for a single pregnancy to monitor across a wide range.
	NST timer	The function to automatically stop the recorder after the time set.
	Automatic NST	The function to automatically start recording at the beginning of heart rate monitoring and automatically stop after the time set.
	Contraction cycle monitoring	The intervals of contraction peaks are monitored, displayed, and printed.
Print function	Method	Thermal head
	Feeding speed	10, 20, 30 mm/minute
	Range of recording	Heart rate 50-210 bpm/80 mm, or 30-240 bpm/70 mm UC 0-100[UNIT]/40 mm

Category	Details	Description
	Simultaneous recordings	Heart rate area 4 channels, UC area 3 areas, Remote marker switch area 2 channels.
	Applicable recording paper	0030-026(50-210bpm/color) 0030-027(50-210bpm/black and white) 0030-031(30-240bpm/color)
Alarm function	Heart rate and pulse rate alarm	Alarm setting with user-selectable high and low FHR and delay time.
	Wrong heart rate measurement alarm	Alarm of two sensors measuring the same heart rate.
	Device alarm	Alarm regarding the state of the device such as out of paper and low battery.
	Alarm sound pressure level	45 dBA~85 dBA

Category	Description
Fetal movement	Auto measurement of fetal movement spike waveform by Doppler ultrasound system (2 channels).
	Fetal movement spike waveforms and dot recording by thresholds.
	Monitoring of maternal perception by the Remote marker.
FHR sound monitor	Doppler sound.
Display	7-inch TFT LCD panel, resolution: 800 x 480 (WVGA).
External I/O	IO-1: For connecting accessories.
	IO-2: For connecting our central monitor.

11-1-6. Classification by sterilization methods

Dipping method. The following chemicals are used for IEC 60601-1 test.

Name of chemicals	Usage/Amount	Dipping time
STERIHYDE 20 W/V% solution	Carefully measure 100 mL, add it to 900 mL of purified water to make 1 L of 2 W/V% solution, add 5.7 g of buffer agent (powder) to this to make the rattan red solution.	30 minutes
Osvan disinfectant 10%	Used by diluting with purified water. 100 times solution (0.1% solution).	10 minutes
TEGO 51 disinfectant 10%	Used by diluting with purified water. 50 times solution (0.2% solution).	15 minutes

11-1-7. Wiping test

Use undiluted natural detergent for IEC 60601-1 test.

11-2. Accessories/Options List

11-2-1. Accessories supplied

Name	Item code	Standard or Model Name	Cable length	Quantity
Y-shaped Doppler/External UC transducer	GA0128	TR-687-06	2.9 m	1
Remote marker switch (single)	GA1264	SW-527-01	2.9 m	1
Transducer belt	GA0115	Personal belt, 2pcs/set (each 1 pc for Doppler&UC)	-	1
Power cord	JA2222	10A 250VAC, CEE7/7, With ferrite cores	2.9m	1
Ultrasound gel	GA0132	Aquasonic 100 gel, 250ml/bottle	-	1
Recording paper	GA1051	0030-026(50-210bpm/color)	-	1
Operation Manual (This document)	GZ1195	-	-	1

11-2-2. Options

Name	Item code	Standard or Model Name	Cable length
Doppler transducer	GA0129	TR-629-06	2.9 m
External UC transducer	GA0130	TR-619-06	2.9 m
Remote marker switch (twins)	GA1265	SW-527-02	2.9 m
Twins set	GA1770		-
Recording paper	GA1051	0030-026(50-210bpm/color)	-
Recording paper	GA1048	0030-027(50-210bpm/black and white)	-
Recording paper	GA1055	0030-031(30-240bpm/color)	-
Remote marker connection cable	HA1810	For connection of Fetal Stimulator TR-30	2.9 m
USB memory	VB0865		-
Standard cart	AA0174	JC-174	-
Multi-cart	AA0175	JC-175	-

11-3. Service Parts

The usable life of this device is six years after sale. However, the following components are supplied for maintenance since they have shorter usable lives than that of the device.
We will store the parts necessary for repairs for six years after the device is sold. The timing of the replacement will depend on the frequency and the environment of use of the device.
Replace components that fail inspections.
If you have any questions, contact us or our distributor.

Names of the major components	Usable life	Reasons of usable life
Power cord	4 years	Consumable, degradation of external covering of the cord
Power switch	5 years	Degradation with use
Doppler transducer	5 years	Degradation with use
External UC transducer	4 years	Degradation with use
Battery for clock	3 years	Consumption
Lithium ion battery	2 years	Degradation by charge and discharge
Remote marker switch (single/twins)	3 - 4 years	Degradation with use

* The table does not show components that can normally function after the usable life of the device.

12. About Disposal and Warranty

12-1. Usable Life and Disposal

12-1-1. Usable life

The usable life of this device is six years after sale. (Based on our self-certification using in-house data. This applies only when the specified service inspection has been conducted.)

Some components may degrade with age within the usable life. It is necessary to regularly replace the components to maintain the performance of the device during the usable life. Conduct repairs or overhauls depending on the results of inspections as needed.

12-1-2. Disposal

The device is classified as industrial waste. Contact the local authority for disposal. The device has a built-in battery. For disposal of the body, recycle or dispose in accordance with your local authority rules and regulations.

Not complying with regulations may cause environmental pollution.

Contact us or our distributor if disassembly (such as removing the battery) or other support is necessary.

12-2. Warranty

We will repair the device free of charge within the warranty period based on the terms and conditions described in the warranty.

For repairs after the warranty period, we will repair only devices that can be normally used after the repair but the cost is born by the user. We will store the parts necessary for repairs for six years after the device is sold.

Notification to Users

Pursuant to the provisions of the Pharmaceuticals and Medical Devices Etc. Act, we must provide users with information related to the effectiveness and safety of the device and information necessary for proper use of the device. Also, it is required by law that users must cooperate in the collection of information necessary for proper use.
If you encounter any problems, contact us and provide the following information.

(Inform) Toitu Co., Ltd. International Department
1-5-10, Ebisu-Nishi, Shibuya-Ku, Tokyo, 150-0021 Japan
Tel: +81-3-3463-6381
Fax: +81-3-3463-6380

- Address
- Facility name
- Contact person

Device name: Actocardiograph MT-610 Serial number:

Problem description

The contents of this document are subject to change without notice.

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