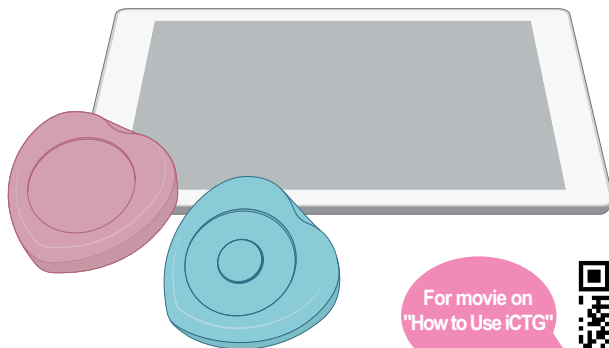


Instrument 21 Equipment for examinations of built-in function  
Managed medical equipment Cardiocography JMDN 37796000  
Specific maintenance managed medical equipment



Cardiocography  
MI1001A

# Operation manual



For movie on  
"How to Use iCTG"



## Caution

- For the safe and proper use of this equipment, be sure to read this manual and the accompanying documentation before use.
- After reading, keep the manual and documentation in a safe accessible place for future reference. Contact our company if the manual and documentation is damaged or lost.



Melody International

---

## Medical device authentication number, manufacturer and distributor

Authentication number: 230AFBZX00024000

Manufacturer and distributor: Melody International Ltd.

304 Next Kagawa, 2217-44 Hayashi, Takamatsu,  
Kagawa, Japan 761-0301

TEL: 087-813-7362 FAX: 087-813-7361

Manufacturer:

Melody International Co., Ltd.

Phytronics Co., Ltd.

Technical Conformity Mark:



® 007-AF0148

---

## Trademark

- Windows is a registered trademark or trademark of Microsoft Corporation, America in the United States and other countries.
- iOS is a trademark or registered trademark of Cisco in the US and other countries, and it is used under license.
- Bluetooth is a registered trademark or trademark of Bluetooth SGI Inc. in the United States.
- All other company and product names mentioned in this document are the trademarks or registered trademarks of their respective companies.

# Introduction

Thank you for purchasing the cardiotocography device iCTG.

This is a cardiotocography device that detects fetal heart rate by ultrasound Doppler method and uterine contraction by a strain gauge from the middle pregnancy period to delivery.

This manual describes the precautions for use, maintenance and inspection methods, and operation methods. Make sure to fully understand the contents of this manual and use the device effectively.

If you have any questions or concerns about this device (See back cover), please contact our company or distributor.

---

## Intended medical use

The device measures fetal heart rate and maternal labor pain (uterine contractions) and is designed to be used for the following applications.

- NST (Non-stress test)

To find out the status of the fetus at a prenatal checkup at more than 32 weeks' gestation (all expectant mothers). Over-term pregnancies, high-risk pregnancies and CST application, etc.

- Monitoring during labor

Transient tachycardia, base line fluctuation disappearance, tachycardia, bradycardia, early deceleration bradycardia, fluctuation transient bradycardia, late transient bradycardia and transient bradycardia, etc.



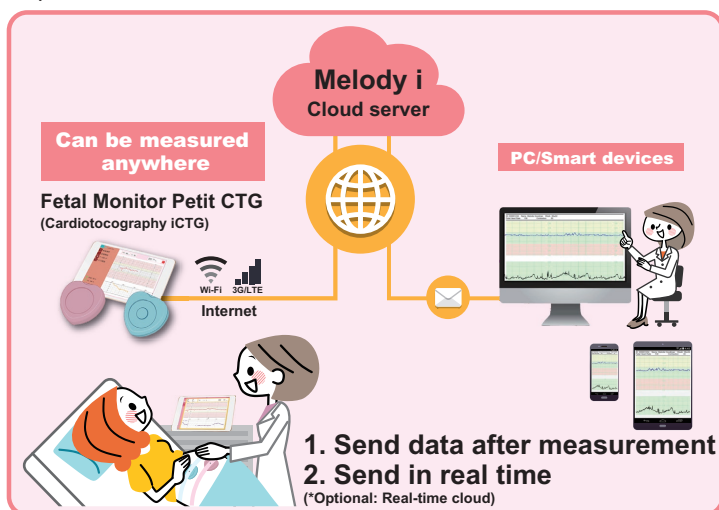
### Caution

- Do not use this device for purposes other than its intended use.
-

## System Summary

The device (FHR Transducer and UC Transducer) is placed on the abdomen of an expectant mother during pregnancy and delivery to perform measurements.

The measurement data is sent to the tablet (display and data management device) in real time, and the user and expectant mother can view the measurements and cardiocograph on the tablet screen. In addition, the measurement data is sent from the tablet to the hospital server or data center. Doctors from outside the hospital can browse the data by accessing the hospital server or data center.



- Bluetooth is used for data communication between the device (transducer) and tablet.
- Internet is used for data communication between the tablet and data server, SIM connection is used for mobile data communication, and Wi-Fi connection via the hospital's LAN for data communication between the tablet and hospital server.

### **i** Important

- The Internet connection settings are preset at the factory. To change the settings, contact our company or distributor.

# Table of contents

<b>1</b>	<b>To Use the Device Safely .....</b>	<b>6</b>
1.1	Symbols Used in this Manual .....	6
1.2	Label Symbols .....	7
1.3	General Precautions .....	8
1.4	Precautions for Usage .....	10
1.5	Caution for Maintenance and Inspection .....	11
1.6	Precautions During Storage and Shipment .....	11
1.7	Disposal .....	12
1.8	Service life .....	12
1.9	Disclaimer .....	12
<b>2</b>	<b>Overview of the Device.....</b>	<b>13</b>
2.1	Device Configuration .....	13
2.1.1	Packing Content .....	13
2.2	Name and Function of Each Part.....	15
2.2.1	FHR Transducer .....	15
2.2.2	UC Transducer .....	16
2.2.3	Tablet.....	17
<b>3</b>	<b>Before Measurement.....</b>	<b>18</b>
3.1	Charging Transducers .....	18
3.2	Charging the Tablet.....	21
3.3	Registration of Patient (Expectant Mother) Information.....	22
3.4	Various Settings.....	27
<b>4</b>	<b>Measurement.....</b>	<b>29</b>
4.1	Start Measurement .....	29
4.1.1	Turn the Power ON.....	29
4.1.2	Expectant Mother (Patient) Selection .....	32
4.1.3	Wearing FHR Transducer.....	35

## Table of contents

---

4.1.4	Wearing the UC transducer .....	37
4.1.5	Start Measurement .....	39
4.2	Finish measurement .....	41
4.2.1	Automatic termination due to elapse of measuring time.....	41
4.2.2	Cancel measurement .....	43
4.2.3	Removing the Transducers.....	44
4.3	Check the Measurement Data .....	45
4.3.1	Display past data .....	45
4.3.2	Resend data .....	47
4.3.3	Delete the Data.....	48
<b>5</b>	<b>Description of Screen .....</b>	<b>49</b>
5.1	Main Screen.....	50
5.1.1	Menu bar .....	51
5.1.2	Header.....	53
5.1.3	Graph (Cardiotocograph).....	54
5.2	Patient List/Information Screen.....	55
5.2.1	Patient list .....	55
5.2.2	Patient information.....	56
5.3	Data List Screen .....	58
5.4	FHR Transducer1 Information screen.....	60
5.5	UC Transducer Information Screen .....	60
5.6	Setting Screen .....	61
5.6.1	Information.....	61
5.6.2	General.....	62
5.6.3	Line.....	63
5.6.4	Hospital.....	64
5.6.5	Pairing .....	65
<b>6</b>	<b>Troubleshooting.....</b>	<b>66</b>
6.1	When a problem occurs.....	66
6.2	Message List.....	70





<b>7</b>	<b>Maintenance and Inspection.....</b>	<b>71</b>
7.1	Maintenance and Inspection List .....	71
7.2	Cleaning the Transducers.....	72
<b>8</b>	<b>Technical Data.....</b>	<b>73</b>
8.1	Specifications.....	73
8.2	Principle .....	77
8.2.1	Fetal heart rate measurement .....	77
8.2.2	Uterine contraction measurement .....	77

# 1 To Use the Device Safely

This chapter describes the warnings and precautions for the safe use of the device.

## 1.1 Symbols Used in this Manual




The following symbols are used in this manual and quick operation manual for important information.

Symbol	Description
 <b>Warning</b>	Indicates that failure to follow the instructions could result in death or serious injury to a person.
 <b>Caution</b>	Indicates that failure to follow the instructions could result in a possible injury to a person or may cause only property damage.
 <b>Important</b>	Indicates the precautions to be taken when operating the device. Be sure to read the precautions.
 <b>Reference</b>	Provides reference information relating to the device operations.



## 1.2 Label Symbols

The symbols in the labels affixed on the main units (FHR transducer and UC transducer) have the following meanings.

Symbol	Meaning/Description
	Classification by type: Type BF applied part This device is only for application to the surface of a human body (fitting part). However, it is connected to multiple devices at same time, and it is protected against electric surge from other equipment. The fitting part is designed such that the patient who is between different equipment is not subject to electrical shock.
	Follow the operation manual Use the device after reading the accompanying documents and operation manual carefully.
	EMC compliance IEC60601-1-2:2007
<b>IPX2</b>	Waterproofing indication drip-proof II type Waterproof to the extent that there is no harmful effect from water droplets falling in the range of 15 degrees from the vertical

## 1.3 General Precautions



### Warning

- This device should be used under the supervision of a physician or trained health care professional.
  - This device does not support measurement of fetal heart rate in the case of multiple pregnancies. Do not use this device for measurement in expectant mothers with multiple pregnancies.
  - Before using this device, be sure to read this manual and other accompanying documents carefully to ensure proper use. Failure to follow the handling method and cautions may result not only in incorrect measurements, but also malfunction and accidents.
  - Do not disassemble, repair or modify this device. If the device is required to be repaired, contact our company or distributor.
  - Do not touch this device with wet hands. Not following the above instruction may subject the user to an electrical shock.
  - When charging, use only the charger (cord and adapter) that has been provided. Not following the above instruction may cause a fire or subject the user to an electric shock.
  - Do not plug the charger into an outlet that is not within the range of input voltage specification. Not following the above instruction may cause a fire or subject the user to an electric shock.
  - Make sure that the cord of the supplied charger is not damaged due to placing of heavy objects or by pulling the cord. Not following the above instruction may result in a fire or electric shock to the user due to a short circuit or wire getting cut.
  - In the case of emission of abnormal smell, or smoke from the device, stop using the device immediately and contact our company or distributor.
  - If battery fluid leaks from the device, stop using the device immediately and contact our company or distributor.
  - Do not install other software on the tablet.
-



### Caution

- To protect this device from impact, make sure not to drop the device or hit against any object.
  - Be careful when handling patient information (such as disclosure of information, mistakes in measurement values).
  - In the unlikely event that battery fluid leaked from this device enters your eyes, rinse thoroughly with clean water such as tap water, without rubbing, and seek immediate medical attention. If left untreated, the fluid can cause damage to the eyes.
  - In the unlikely event that battery fluid leaked from this device comes in contact with your skin or clothing, rinse it off immediately with clean water such as tap water. Not following this instruction may cause skin irritation.
- 



### Important

- Do not sterilize this device.
  - Do not immerse the device in water (Waterproof and drip-proof specification – IPX2). If the device is submerged in water, contact our company without drying with a dryer.
  - Do not touch this device while it is charged with static electricity. Not following the above instruction may cause device failure.
-

## 1.4 Precautions for Usage

---

 **Warning**

- Do not use this device in the following places. There is a possibility of explosion of the device.
- Places where gases (corrosive, flammable) are present
- Places where there is a fire
- Do not determine fetus condition with only the measurement results\* of this device. The measured values may be different from the intended value depending on the environment and various conditions.
- Do not charge the device when it is attached to the body of a person. Not following the above instruction may subject the user to an electrical shock.

---

\* The FHR transducer does not always clearly distinguish between the fetal and maternal heart rates. The ultrasonic waves may pick up signals from the mother's umbilical cord or other blood vessels. Measure the heart rate of the mother with an SpO<sub>2</sub> pulse oximeter or any other device, and always make sure that the value you are measuring is the fetal heart rate.

---

 **Caution**

- Do not use this device in the following places. There is a possibility that this device may not operate or function properly in such places.
  - Places that do not meet the specified (See “8.1 Specifications”) environmental conditions
    - Places exposed to direct sunlight
    - Places where liquids such as water splashes
    - Places where temperature changes suddenly
  - Take care not to carry cell phones, walkie-talkies, radio-controlled toys, etc. into the room where this device is being used. There is a possibility that data communication may be interrupted due to electromagnetic interference.
  - When using multiple sets of this device, be careful not to mix up the transducers and tablets.
-

## 1.5 Caution for Maintenance and Inspection

---

 **Caution**

- Carry out maintenance and inspection of the device in accordance with the maintenance and inspection list (“7.1 Maintenance and Inspection List”).
  - When using disinfectants such as alcohol, follow the respective handling precautions.
- 

## 1.6 Precautions During Storage and Shipment

---

 **Important**

- Clean the device and make sure that there is no adhesion contaminants such as gel, before storing the device.
  - Do not store this device in the following places.
    - Places that do not meet the storage (See “8.1 Specifications”) environmental conditions
    - Places exposed to direct sunlight
    - Places where liquids such as water splashes
    - Places where temperature changes suddenly
    - Places with dirt and dust
    - Places where gases (corrosive, flammable) are present
    - Places where there is a fire
  - Store and transport with the power of the device turned OFF.
  - Make sure that during transportation, the storage environment conditions (See “8.1 Specifications”) are within the specified range, and the device is not subject to excessive shocks.
-

## 1.7 Disposal

Dispose this device, including the accessories, in an appropriate manner complying with the local laws and regulations stipulated for the disposal of electronic components, electronic devices and lithium-ion batteries \*. If you have any questions, contact our company.

\* Lithium-ion batteries are installed in the FHR transducer, UC transducer and tablet.

## 1.8 Service life

The service life of this device is as follows:

<b>Transducer</b>	5 years

- This is valid only when the cautions described in this manual are followed and the device is used correctly.
- When replacing the transducer, the connection setting must be changed on the tablet.

## 1.9 Disclaimer

Our company cannot take any responsibility for damages in the event of harm to human body, life and property, caused by any of the following.

- Malfunction or failure due to usage by a method that is different from, or under usage conditions that deviate from those described in this manual and accompanying documents.
- Malfunction or failure caused by maintenance or repairs by other companies or companies not approved by our company.
- Malfunction or failure of this device caused by the use of accessories other than those supplied with this device.
- Malfunction or failure caused when products that are non-compliant with JIS standards (JIS T0601-1, JIS T0601-1-2) or peripheral devices that do not meet the equivalent standards are used with this product.
- The contents of this document are subject to change without prior notice.

## 2 Overview of the Device

This chapter describes the device components and an overview of the functions.

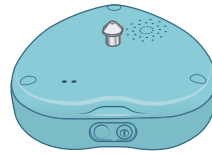
### 2.1 Device Configuration

#### 2.1.1 Packing Content

After opening the package, please make sure that the following items have supplied.

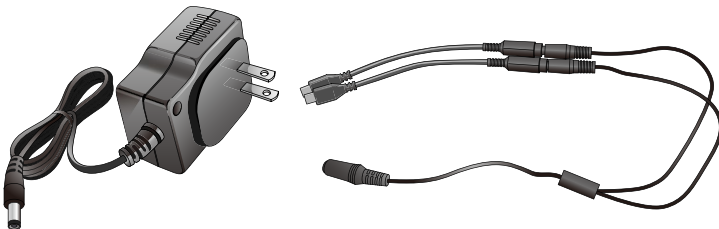
#### Devices

- FHR Transducer (Pink)
- UC Transducer (Blue)



#### Accessories

- AC adapter for charging the device, branch cable for charging and conversion adapter for charging



### **Accessories** (continued)

- Controlling software \*
- Operation manual
- Quick operation manual
- Accompanying documents

\* Controlling software is installed on the tablet.

### **Option products**

- Tablet



#### **Important**

#### **Tablet operating environment**

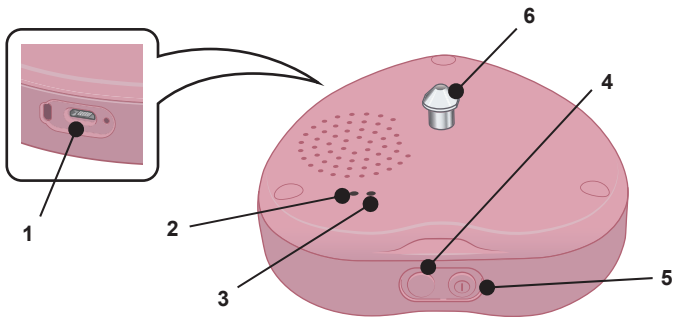
- The following operating environment is required for the tablet.
    - Storage space: 100 MB or more of free space
    - Memory: 2 GB or higher
    - Bluetooth chip manufactured by the company Broadcom should be installed
    - The chip should be IEC60950-1 or IEC60601-1 certified
    - The chip should be EMC:CISPR22/CISPR24/CISPR32 or VCCI compliant
-



## 2.2 Name and Function of Each Part

This section describes the names and functions of each part of the device.

### 2.2.1 FHR Transducer

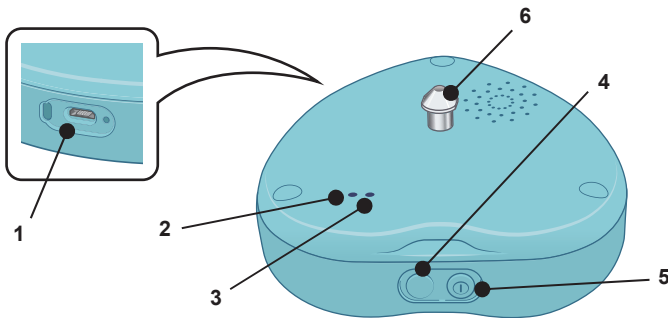


1	Power connector	Uses to connect the included charger when charging.
2	LED1	Green: Fully charged Orange: Charging
3	LED2	Green: Power ON Red (flashing): Battery level low
4	Volume adjusting button	This button is used to adjust the volume.
5	Power button	Turns the device ON/OFF. Press and hold for at least 3 seconds to turn OFF the device.
6	Hook	Used to fasten the buttonhole on the belt when securing it to expectant mothers.

## Volume adjustment of FHR Transducer

- Each time you press the volume adjusting button on the FHR transducer, the volume switches as given below.  
High → Medium → Low (→ High: Repeat)
- Press and hold the volume adjusting button on the FHR transducer for more than 3 seconds to mute the device.
- You can also adjust the volume from the tablet. For the operation method, see “5.1.2 Header”.

## 2.2.2 UC Transducer



1	Power connector	Uses to connect the included charger when charging.
2	LED1	Green: Fully charged Orange: Charging
3	LED2	Green: Power ON Red (flashing): Battery level low
4	Zero-set button	The reference value is set to uterine contraction measurement when this button is pressed. Zero-set is also possible from the tablet. (Using the tablet for zero-set is recommended as the measured value may change when the button is pressed.)

5	Power button	Turns the device ON/OFF. Press and hold for at least 3 seconds to turn OFF the device.
6	Hook	Used to fasten the buttonhole on the belt when securing it to expectant mothers.

### 2.2.3 Tablet

For an overview of the tablet and its operations, refer to the operation manual of the tablet.

## 3 Before Measurement

This section describes how to charge the device and register patient information before starting the measurements.

### 3.1 Charging Transducers

The transducers should be charged before use.



#### Caution

- Do not charge the transducers when it is attached to the body of a person. Not following the above instruction may cause electric shock to the person or failure of the device.
- Do not charge the transducer near a fire or in a vehicle during hot weather. Not following the above instruction may cause overheating, rupture, or ignition.
- Do not charge the transducers if there is a risk of lightning. Also, be sure to pull out the power plug from the power outlet.



#### Important

- Measurements are not possible while charging the transducer.
- Be sure to use the supplied charger.
- Battery cannot be replaced. Contact our company or distributor for any repairs.

#### 1. Place the tablet, FHR and UC transducers in the following locations.

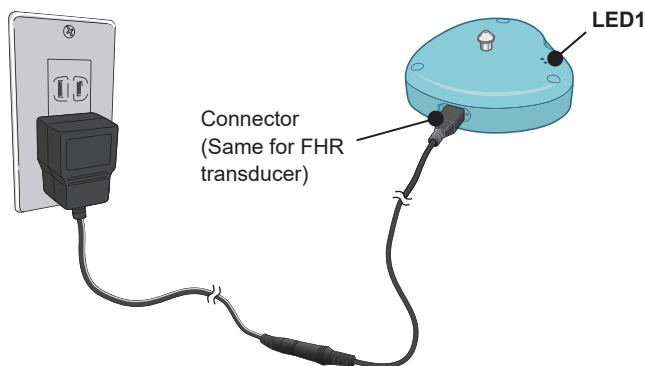
- Places that are flat and stable
- A place where the AC adapter reaches the commercial power source and the plug can be plugged in and removed from the outlet easily

**2. Connect the dedicated charger (AC adapter for charging device + branch cable for charging + conversion adapter) to the FHR and UC transducers.**

Remove the waterproof cover and ensure that the micro USB connector is plugged in.

**3. Connect the power plug of the charger into an electric outlet.**

LED1 on the respective transducer will be lit in orange.



The device will be fully charged in approximately 1 hour. LED1 changes to green on completion of charging.

**Caution**

- If the device is not charged in a few hours, stop charging. If you continue to charge, there is a risk of overheating, explosion, or catching fire. (Charging stops after 9 hours.)

**Reference**

- You can check the battery level on the screen when the transducer and tablet are turned ON. For details, see “5.1.1 Menu bar”.
- The device can measure for about 6 hours on a full charge. Charging the device after the completion of measurements of each day is recommended.

**4. Disconnect the charger from each transducer and power outlet and store after completion of charging.**



**Caution**

- Be sure to pull out the power plug of the charger from the power outlet when the device is not being used for charging.
-

## 3.2 Charging the Tablet

Charge the tablet's battery using the cable and USB power adapter supplied with the tablet. Use and charge the tablet after reading the operation manual that was provided with the tablet.

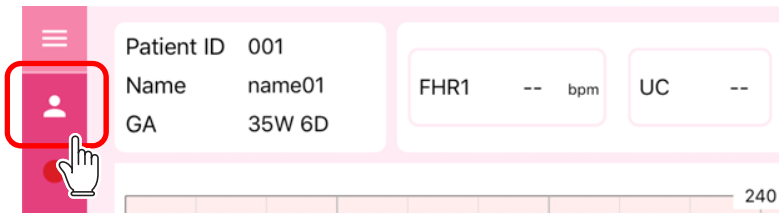
### 3.3 Registration of Patient (Expectant Mother) Information

When an expectant mother is taking the measurements for the first time, she needs to register patient information on the tablet.

#### 1. Turn ON the tablet to display the main screen.

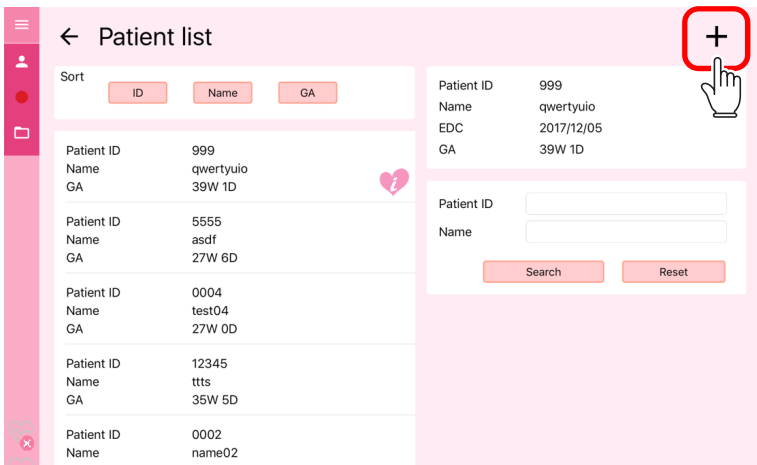
If the main screen is not displayed even after the tablet is switched ON, launch the app.

#### 2. Tap on the icon.



The patient list screen is displayed.

#### 3. Tap on the icon.



The patient information screen is displayed.



#### 4. Enter the patient information.

- Tap to select the item you want to enter, and then enter with the keyboard.
- Enter the [Patient ID] with alphanumeric characters only. Double-byte characters, Hiragana, Katakana, Kanji, or special symbols cannot be used.
- Select the [Number of Fetus] by tapping on [Single Pregnancy].  
([Number of Fetus] is a setting for future development and measurement of twins is not possible at present. Selecting [Twins] does not affect the measurement.)
- Select [EDC] from the calendar displayed by tapping on the calendar icon in the entry field. When you set EDC, GA is calculated and displayed.

← Patient information

Mother information

ID  
(only half-width alphanumeric characters or symbols)

Name

Age

Remarks

Pregnancy information

Number of fetus  
 Single  Twins

GA  
40W 0D

EDC  
07/03/2020

#### 5. Tap on the icon.

##### Important

- After registering the patient information, patient ID cannot be changed. Check again to confirm that you have entered the correct information before saving.

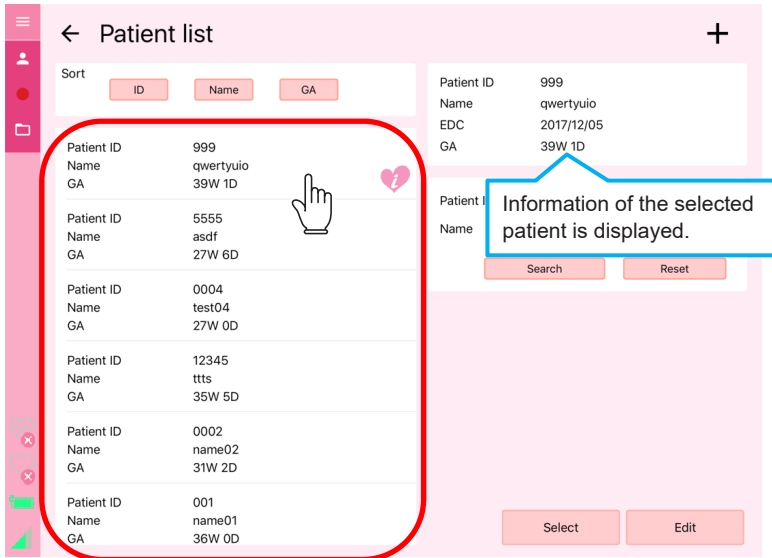


The entered information will be saved, and the display returns to the previous screen.

## Changing the patient information

This section describes how to modify the patient information.

1. From the list on the Patient List screen, tap to select the patient whose information you want to modify.



### Reference

- You can change the order in the patient list and filter by patient ID or name. For information on how to operate, see “4.1.2 Expectant Mother (Patient) Selection”.

2. Tap on [Edit].

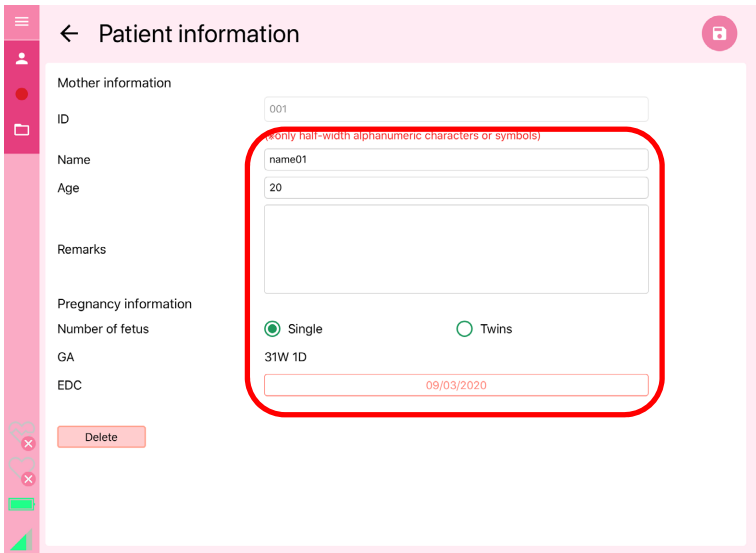


The patient information screen for the selected patient is displayed.

### 3. Changing the patient information.

**Important**

- Patient ID cannot be modified.
- To modify a patient ID, register with a new patient ID and then delete the patient information of the old patient ID. Note that measurements performed with the old patient ID are also deleted when the patient information is deleted.



### 4. Tap on the icon.



The patient is registered and the display returns to the patient list screen.

## Delete patient information

This section describes how to delete the patient information.



### Caution

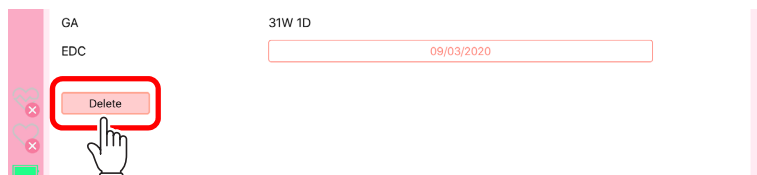
- When you delete patient information, measurement data of that patient is also deleted. Deleted data cannot be retrieved.

### 1. Select the patient whose information you want to delete on the Patient List screen, and then tap Edit.

The patient information screen for the selected patient is displayed.

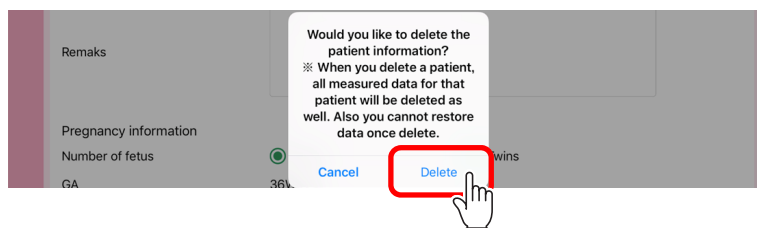
### 2. Check if the information is of the patient you want to delete.

### 3. Tap on [Delete].



A confirmation message is displayed.

### 4. Tap on [Delete].



Patient information and measured data are deleted.

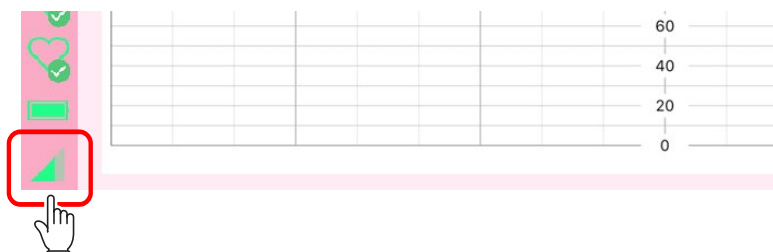
## 3.4 Various Settings

You can change the display format of the graph that is displayed during the measurement.

Main settings that can be changed	Overview
Display language	English, Japanese or Thai can be selected.
Vertical and horizontal scales of the graph	Vertical and horizontal scales of the graph can be selected from the specified sizes.
Warning area on the graph	A threshold value to indicate areas on the graph that are outside the normal range of measured values can be set.
Lines in the graph	Color and thickness of the lines in the graph can be set.
Hospital information	Hospital information of the user. Do not change this information.

The steps to change the settings is shown below, using the example of changing the color of the graph line. For information on other settings, see “5.6 Setting Screen”.

### 1. Tap on the icon.



The setting screen is displayed.

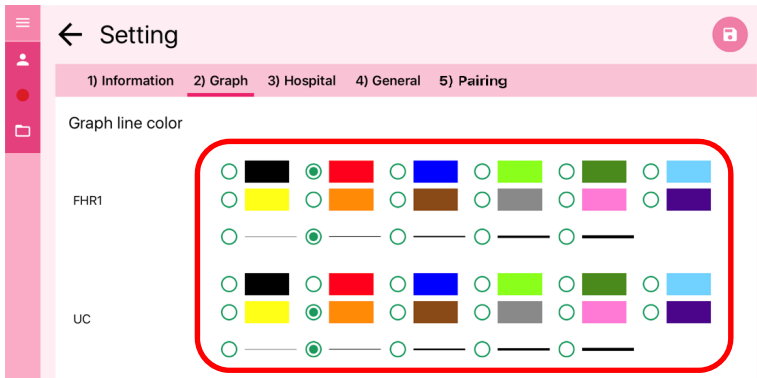
## 2. Tap on the category to set.

Tap on the [3] Line] category for graph line color.



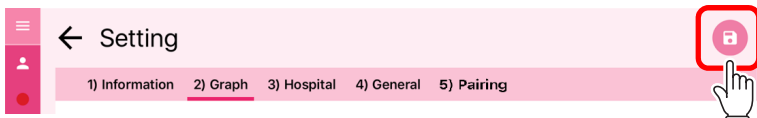
Setting items of category that is tapped are displayed.

## 3. Select the line color and thickness by tapping.



Some settings require a value to be entered.

## 4. Tap on the icon.



Returns to the previous screen and the settings are applied.

To return to the previous screen without applying the changes, tap on .

## 4 Measurement

This chapter describes the series of operating procedures, from turning ON each device to performing measurements and turning OFF each device.

### 4.1 Start Measurement

This section describes the steps from turning ON each device to performing measurements.

#### 4.1.1 Turn the Power ON

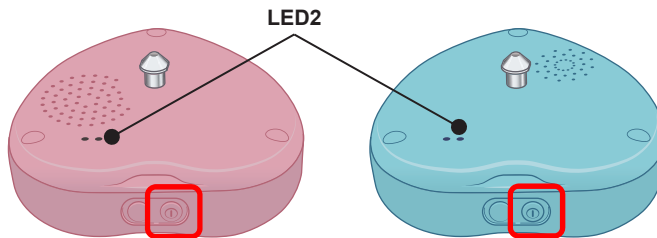
Turn on the power of the tablet and each transducer.

##### 1. Turn ON the tablet to display the main screen.

If the main screen is not displayed even after the tablet is switched ON, launch the app.

##### 2. Turn on the power of each transducer.

Press the respective power button. Press and hold the power button until a beep is heard.



When the power is turned ON, the respective LED 2 lights up.

### 3. Check the status of the device with the icon (indicator) on the menu bar.

For information on how to read the icons, see “5.1.1 Menu bar”.



- Each transducer must be connected to the tablet

If the transducer is not connected, wait for some time or turn OFF and then turn ON the transducer. To turn OFF the transducer, press and hold the power button until a beep is heard (about 3 seconds).

- Each device must have sufficient battery level

Measurements are not possible if the battery level of the transducer is not sufficient.

The tablet can be used to record while it is charging.

- Internet connection should be available

If the Internet connection is unstable, record the data without the connection, and send the data at a place where you can connect by referring to “4.3.2 Resend data”.

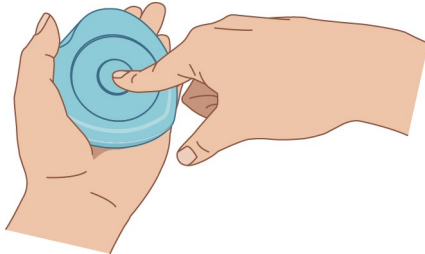


**4. Make sure that each transducer is functioning properly.**

- A sound should be heard from the speaker when the hand is placed near the measuring surface of the FHR transducer



- The graph should respond when the sensor of the UC transducer is pressed



## 4.1.2 Expectant Mother (Patient) Selection

Select an expectant mother (patient) for performing measurements.

1. Confirm that the information of the expectant mother to be recorded is displayed in the patient column of the main screen.



If information of a different expectant mother is displayed, follow the procedure given below.

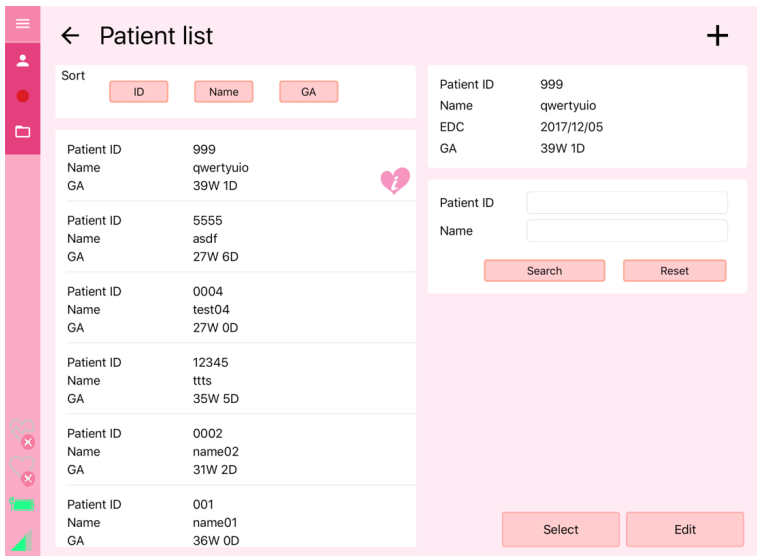
### Important

- To measure data of an expectant mother who is not registered in the patient information register, please register first. For information on how to register, see “3.3 Registration of Patient (Expectant Mother) Information”.

2. Tap on the  icon.



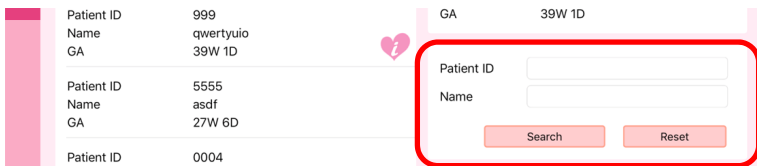
The patient list screen is displayed.



For information on each item and function of the patient list screen, see “5.2.1 Patient list”.

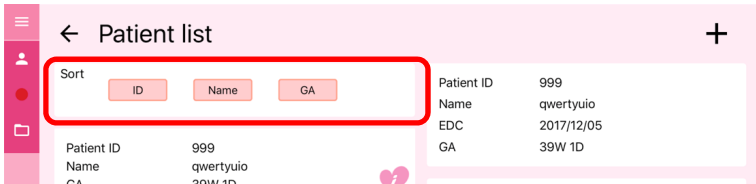
**3. To filter the list, enter a patient ID or part of the patient name and tap on [Search].**

Tap on [Reset] to clear the filter.

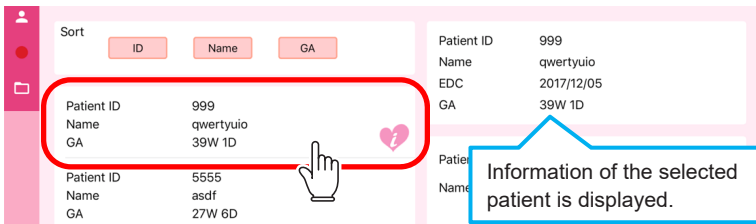


### Sort the list

Tap the button in the [Sort] field to sort the list in the order shown. Tap the same button to switch between ascending and descending order.



### 4. Tap and select the expectant mother for performing measurements.

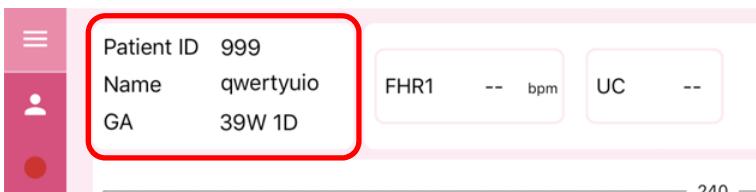


### 5. Tap on [Select].



Returns to the main screen.

The expectant mother selected is displayed on the patient column.

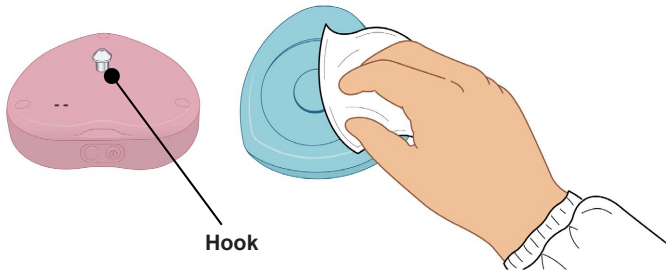


### 4.1.3 Wearing FHR Transducer

Attach the FHR transducer (pink) to the expectant mother.

#### 1. Check the status of each transducer.

- Hook should not be loose  
If the hook is loose, tighten it by hand.
- Device should be free of dirt  
Clean the device if it is dirty.



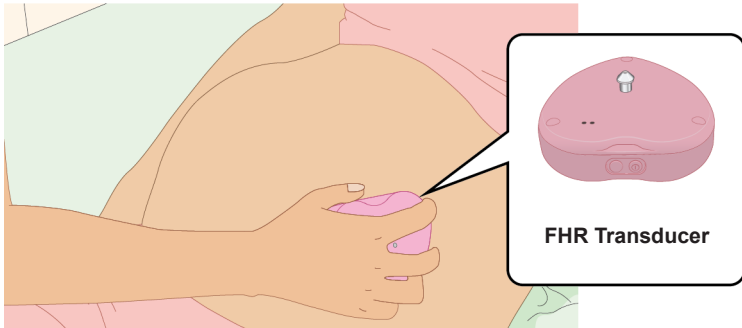
#### 2. A belt (total 2 numbers) is passed around the waist of the expectant mother to secure each transducer.

#### 3. Apply gel for the FHR transducer.

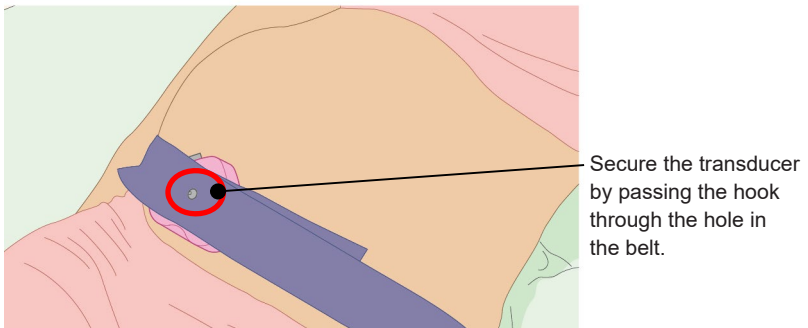


#### 4. Place the FHR transducer on the fetal heart.

Check the fetal heart position while listening to the heartbeat sound from the heart rate monitor.



#### 5. Secure the FHR transducer with a belt.



#### Important

- To prevent the FHR transducer from moving to either side, fix the FHR transducer while pulling the belt with equal force on the left and right. Do not tighten more than necessary.

## 6. Adjust the sound volume of the FHR transducer in consultation with the expectant mother.

To adjust the sound volume using the buttons on the FHR transducer, see “2.2.1 FHR Transducer”.

To adjust the sound volume on the tablet, see “5.1.2 Header”.

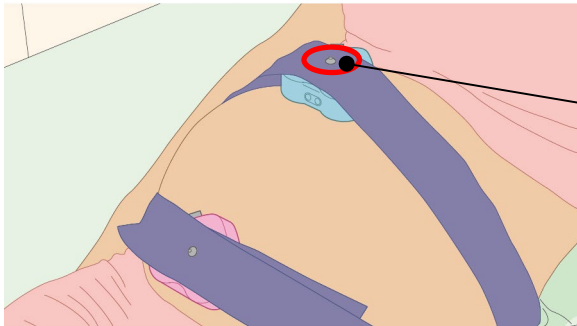
### 4.1.4 Wearing the UC transducer

Attach the UC transducer (blue) to the expectant mother.

#### 1. Place the UC transducer in the correct position and secure it with the belt.

##### Important

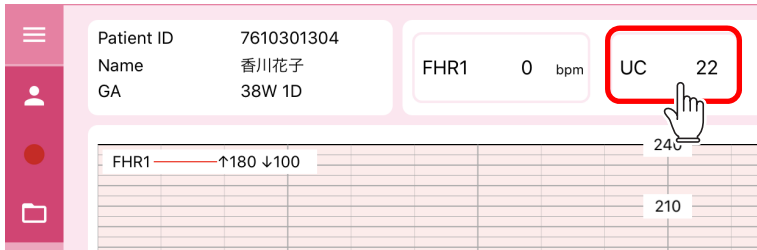
- Do not apply gel for the UC transducer.
- To prevent the UC transducer from moving to either side, fix the UC transducer while pulling the belt with equal force on the left and right. Do not tighten more than necessary.



Secure the transducer by passing the hook through the hole in the belt.

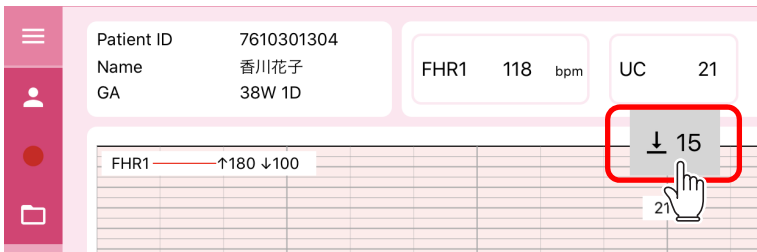
#### 2. Cover the expectant mother with a blanket, etc. to keep her belly from getting cold.

### 3. Tap on the contraction measurement field.



The icon ( ↓ 15 ) for preset is displayed (process to make the current contraction measurement a reference value).

### 4. Tap on the ↓ 15 icon.



The measured value of contraction is corrected to 15 (reference value).



## 4.1.5 Start Measurement

Start the measurements once the FHR and UC transducers have been fitted.

---

### Reference

- When the transducer is turned ON, each device starts measuring. The start of measurement indicates that recording of the measured value starts, for example, by saving it to a tablet.
- 

### 1. Tap on the icon.



The dialog box to select the measurement time is displayed.

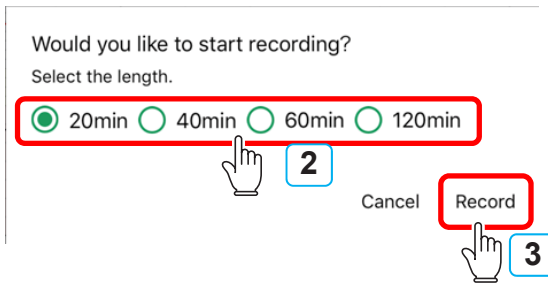
### 2. Tap and select the measurement time.

---

### Caution

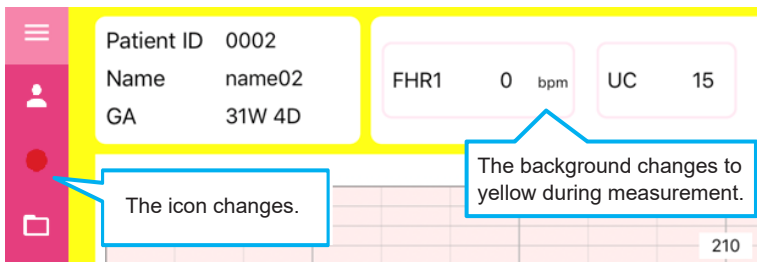
- The physician should decide the measurement time to be used.
-

### 3. Tap on the [Record] icon.



The measurement starts.

During measurement, the screen display changes as follows.



### 4. Place the tablet in a stable location.



#### Caution

- Place the tablet in a location where it will not be subject to impact or knocked down due to vibrations.
- Adjust the touchscreen and touch pad opening angle to ensure a stable installation.

## 4.2 Finish measurement

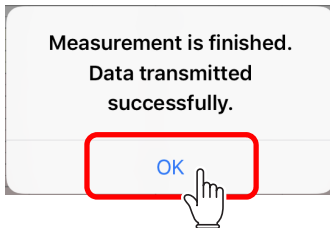
This section describes the procedure from the completion of measurement to turning OFF and storage of each device.

### 4.2.1 Automatic termination due to elapse of measuring time

When the recording duration has elapsed, an end tone is played, recorded data is saved and communication is terminated. A confirmation message is then displayed.

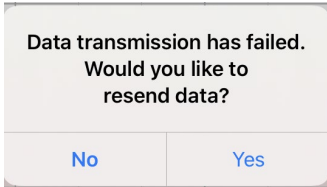
To finish without waiting for the measurement time to elapse, see “4.2.2 Cancel measurement”.


#### 1. Tap on the [OK] icon.



## If a data transmission error occurs

The following inquiry message is displayed at the completion of measurement.



Check  in the menu bar to see if the tablet has an active Internet connection.

### When the tablet is connected

Tap on [Resend].

### When the tablet is not connected

Tap on [Close].

Move to a different place and try or resend the data when the tablet is connected.

To resend data, see "4.3.2 Resend data".

## 4.2.2 Cancel measurement

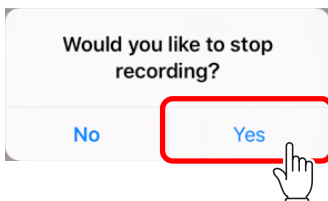
To exit without waiting for the measurement time to elapse, perform the operations given below.

### 1. Tap on the icon.



A confirmation message is displayed.

### 2. Tap on [Yes].

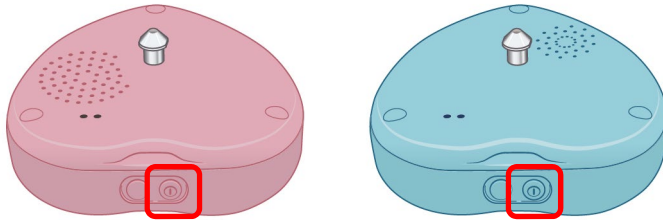


This completes the measurement and a confirmation message is displayed. The subsequent operations are the same as “4.3.1 Display past data”.

### 4.2.3 Removing the Transducers

Remove the transducers from the expectant mother and clean up.

1. Remove the transducers and belts from the expectant mother.
2. Wipe off the gel on the expectant mother.
3. Power off the transducers by pressing the power button (about 3 seconds) until you hear a sound.



#### 4. Clean and store the transducers.

- For information on how to clean the transducers, see “7.2 Cleaning the Transducers”.
- For information on inspection during storage, see “7.1 Maintenance and Inspection List”.

## 4.3 Check the Measurement Data

The measurement results saved on the tablet can be viewed while the measurement is not in progress.

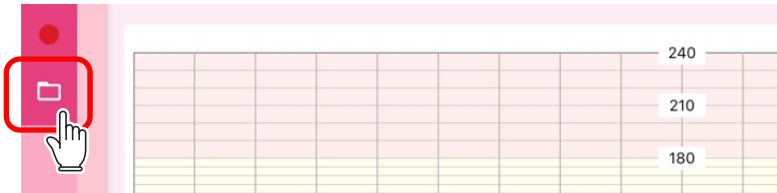
This section describes how to view past measurement data and how to resend measurement data that was not sent.

### 4.3.1 Display past data

#### 1. Select the patient.

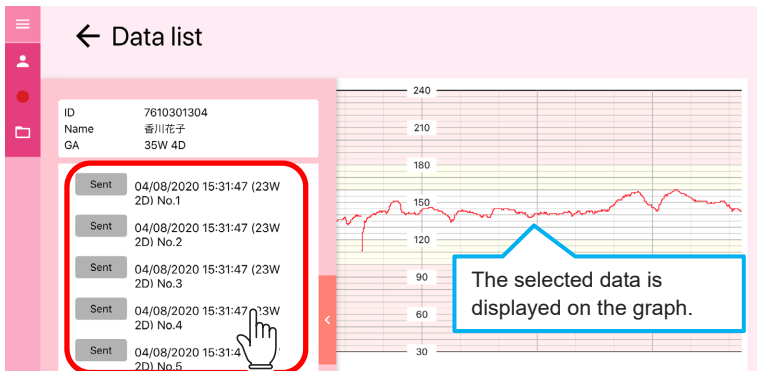
For information on how to operate, see “4.1.2 Expectant Mother (Patient) Selection”.

#### 2. Tap on the icon.

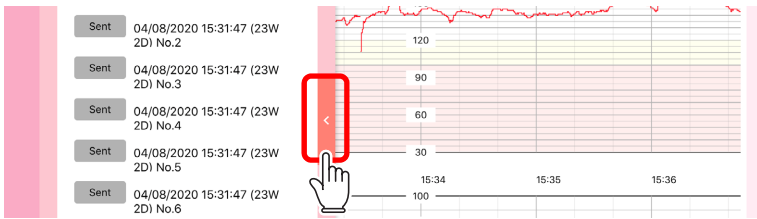


The data list screen is displayed and the list of past measurement data for the selected patient is displayed.


#### 3. Tap and select the data to browse.



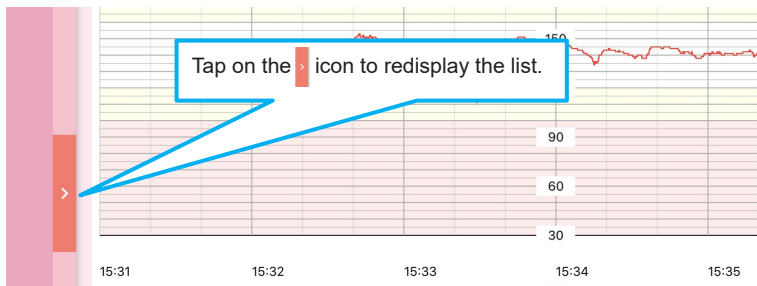
4. Tap on the < icon.



The list closes.

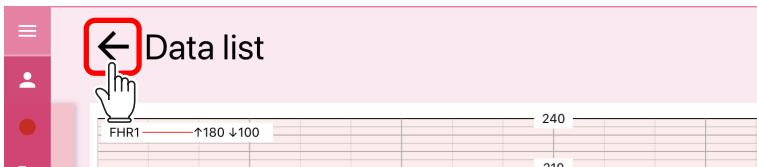
 **Reference**

- You can also close the list by tapping on the graph.



For information on each item and function of the data list screen, see “5.3 Data List Screen”.

5. Tap on the ← icon when you finish checking.

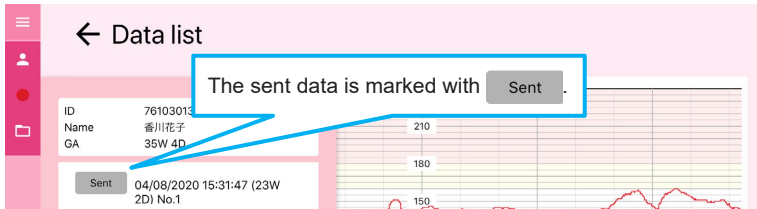


Returns to the previous screen.

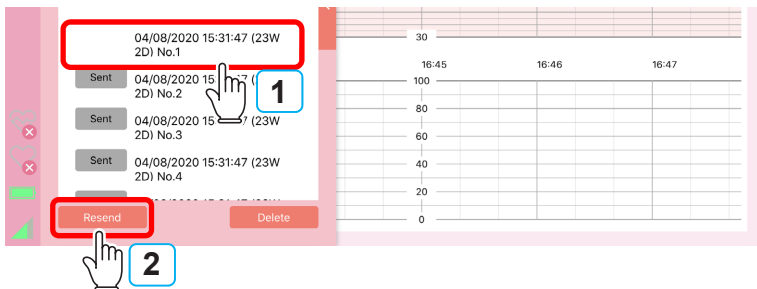


## 4.3.2 Resend data

If the data has not been sent to the data center, it will be resent.

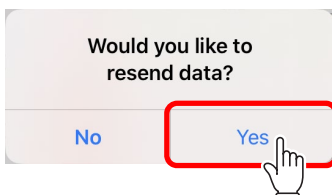


1. Tap and select the data to be sent.
2. Tap on [Resend].



A confirmation message is displayed.

3. Tap on [Yes].



The data selected is sent.

When send is complete, a message is displayed.

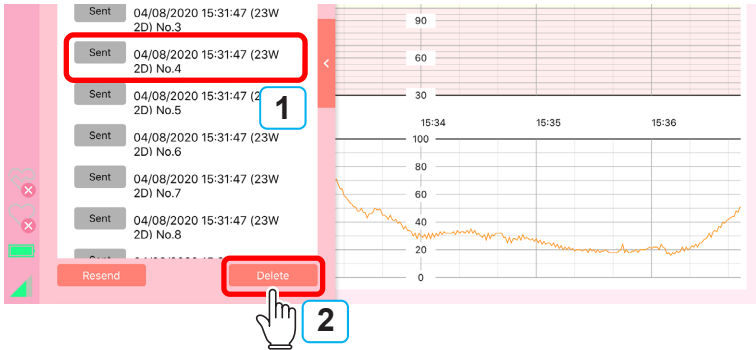
### 4.3.3 Delete the Data

Deletes unnecessary measurement data.

 **Caution**

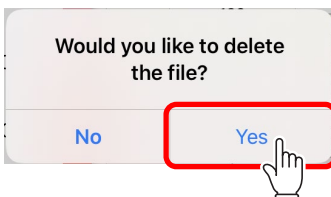
- Deleted data cannot be retrieved.

1. Tap and select the data to be deleted.
2. Tap on [Delete].



A confirmation message is displayed.

3. Tap on [Yes].



The selected data is deleted.

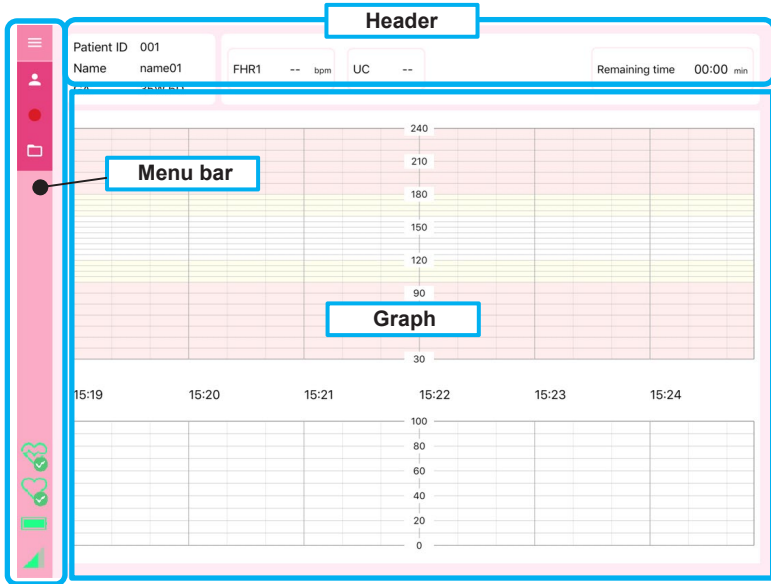
## 5 Description of Screen

This chapter describes the items and functions of the screen.

Screen title	Reference
(Initial screen)	"5.1 Main Screen"
Patient list	"5.2.1 Patient list"
Patient information	"5.2.2 Patient information"
Data list	"5.3 Data List Screen"
FHR transducer1 information	"5.4 FHR Transducer1 Information screen"
UC transducer information	"5.5 UC Transducer Information Screen"
Setting	"5.6 Setting Screen"

## 5.1 Main Screen


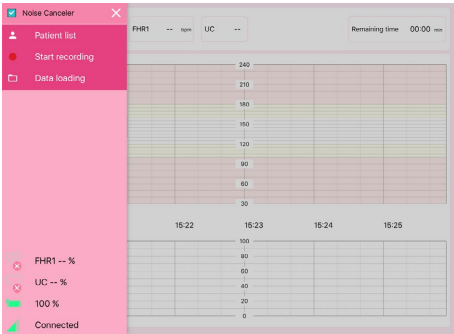





This screen is displayed when you turn on the tablet. This screen is used to perform measurements.


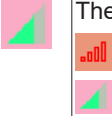




Menu bar	The menu bar has icons and indicators to switch between screens and check the device status. For more information, see “5.1.1 Menu bar”.
Header	Displays the information or measurement values of the selected patient. For more information, see “5.1.2 Header”.
Graph (cardiotocograph)	Graph of the fetal heart rate is displayed at the top and graph of the fetal uterine contraction measurement at the bottom. For more information, see “5.1.3 Graph (Cardiotocograph)”.

## 5.1.1 Menu bar

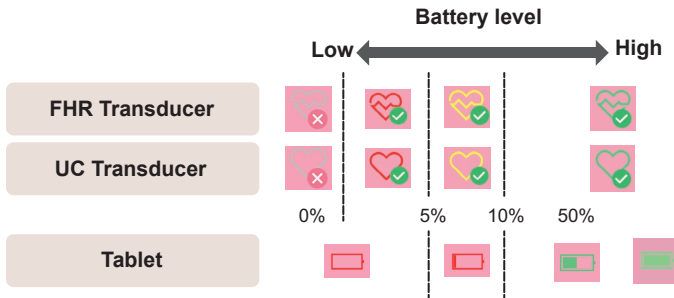
The menu bar contains icons and indicators to switch between screens and to check the device status. The menu bar will always be displayed even if you switch screens.

	<p>Tap to expand the menu as shown below. Tap on the icon again to collapse the menu.</p>  <ul style="list-style-type: none"> <li>• Expanding the menu does not change the function of each icon or indicator.</li> <li>• You can check the numerical value for the battery related information of the indicator.</li> </ul>
	<p>Tap to display the patient list screen. For information on patient list screen, see “5.2 Patient List/Information Screen”.</p>
	<p>Tap to start the measurement. For more information, see “4.1.5 Start Measurement”.</p>
	<p>Tap to display the data list screen. For information on the data list screen, see “5.3 Data List Screen”.</p>
	<p>When connected to a transducer, the color changes to show the battery level of each transducer. For more information, see “Indicator</p>
	<p>display and device status”that is described later. Tap to display the transducer information. The upper indicator corresponds to FHR Transducer and lower to UC Transducer.</p>

	Indicates the battery level of the tablet. For more information, see “Indicator (icon) display and device status” that is described later.
	The connection status with the Internet is indicated with color.  (Red): Not connected  (Green): Connected Tap to display the setting screen. For information on the setting screen, see “5.3 Data List Screen”.

## Indicator (icon) display and device status

Indicator that represents the battery level changes as follows:

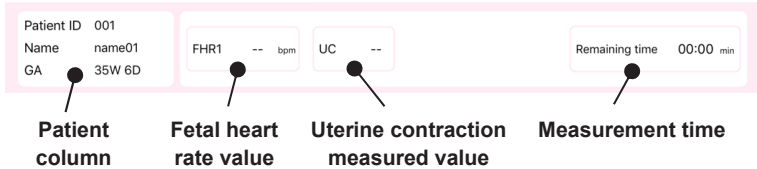



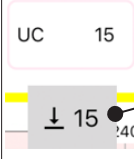
- If the transducer is not recognized by the tablet, the battery life is displayed as 0%.
- When power is supplied to the tablet a power plug symbol is displayed.



## 5.1.2 Header

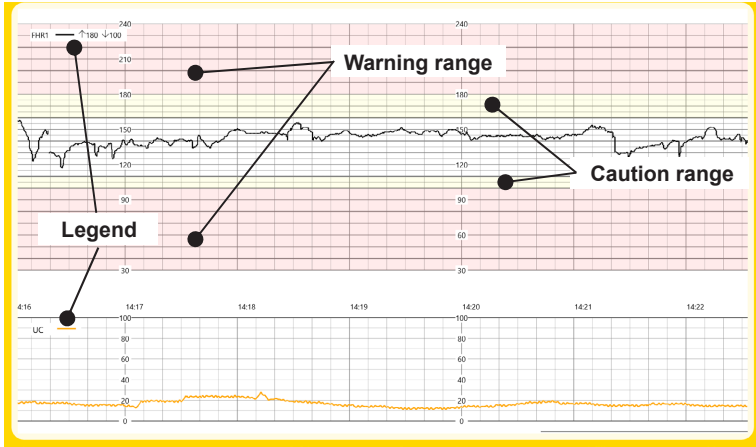
Displays the information or measurement values of the selected patient.



<p>Patient column</p>	<p>The information of the selected expectant mother is displayed when measurements are performed or past data is viewed.</p> <p>For information on how to select an expectant mother(patient), see "4.1.2 Expectant Mother (Patient) Selection".</p>
<p>Fetal heart rate value</p>	<p>Displays the fetal heart rate value.</p> <p>Tap this field to display a menu for adjusting the sound volume of the FHR transducer.</p>  <p>Sound is muted.</p> <p>Sound increases by one level.</p> <p>Sound decreases by one level.</p>
<p>Uterine contraction measured value</p>	<p>Displays the measured value of uterine contraction.</p> <p>When you tap on this field, an icon will appear to perform a zero reset.</p>  <p>When tapped, the contraction measurement value at that time is corrected to 15 (reference value).</p>
<p>Measurement time</p>	<p>The current time is shown in the upper section, and elapsed time and elapsed time since the start of measurement are shown in the lower section.</p>

### 5.1.3 Graph (Cardiotocograph)

Graph of the fetal heart rate is displayed at the top and graph of the uterine contraction measurement at the bottom.




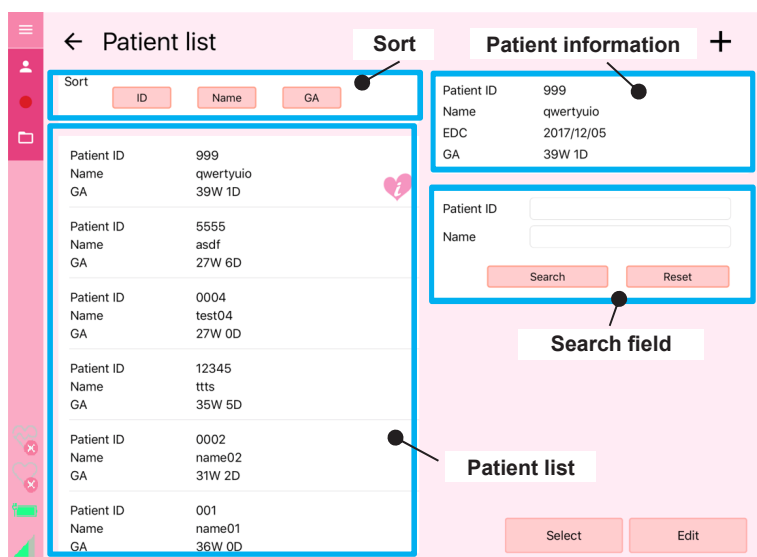
<p>Graph</p>	<p>The graph automatically scrolls to the right as time passes.</p> <p>To see the hidden part of the graph on the left, swipe to scroll the graph to the left. When the graph has been scrolled manually, the graph returns to the position corresponding to the current time after a certain period.</p> <p>The scale of the graph can be changed from the settings (general) screen. The thickness and color of the lines can be changed from the settings (line) screen.</p>
<p>Legend</p>	<p>Describes the line type of each chart.</p> <p>The legend in the upper part of the graph shows the threshold values that fall into the warning range.</p>
<p>Warning range, caution range</p>	<p>The background is set to 3 colors to help identify whether the measured value falls in danger range.</p> <p>The threshold that separates each range can be changed from the settings (general) screen.</p>






## 5.2 Patient List/Information Screen

### 5.2.1 Patient list


This screen displays a list of expectant mothers (patients). This option is used to select an expectant mother for measurement. Tap on  of the menu to display the patient.

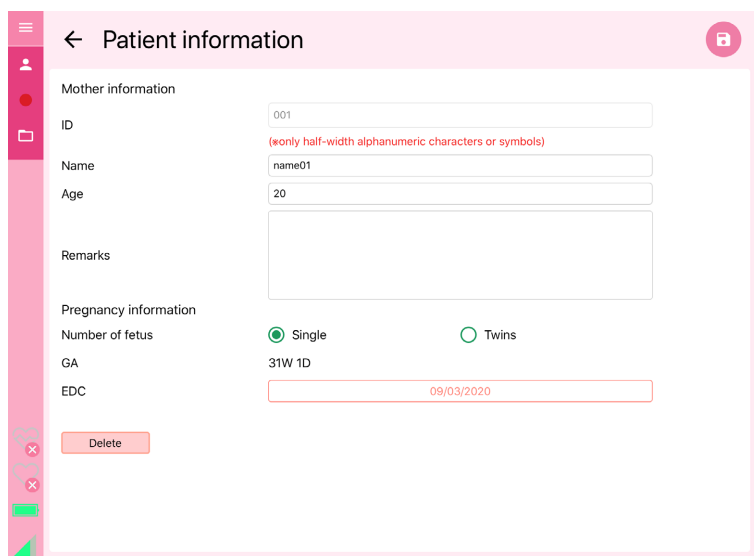


Sort	Tap the button to sort the patient list in the order shown by the buttons. Tap the same button to switch between ascending and descending order.
Patient list	List of registered patients will be displayed on the tablet. The  icon is displayed next to the selected patient. Tap on the icon to select the patient to be processed (display or edit).
Patient information	Displays information of the patient selected in the list.

Search field	Use this option to filter the patients to be displayed. Enter a patient ID or part of the patient name and tap on [Search] to display only the patients who match the value entered. Tap on [Reset] to clear the filter.
[Select]	When you tap on [Select], the patient in the list is selected as the patient to perform the measurements. This changes the display of the patient column on the main screen.
[Edit]	Tap to display the patient information screen to edit information of the selected patient.
	Tap to return to the previous screen.
	Tap to display the patient information screen for registering a new patient.

## 5.2.2 Patient information

This screen is used to edit the patient information. The screen is displayed when you tap on  in the patient list screen or tap on [Edit] after selecting the patient.



**← Patient information**

**Mother information**

ID: 001  
(only half-width alphanumeric characters or symbols)

Name: name01

Age: 20

Remarks:

**Pregnancy information**



Number of fetus:  Single  Twins

GA: 31W 1D

EDC: 09/03/2020


Delete

The above figure shows the screen when editing a registered patient.

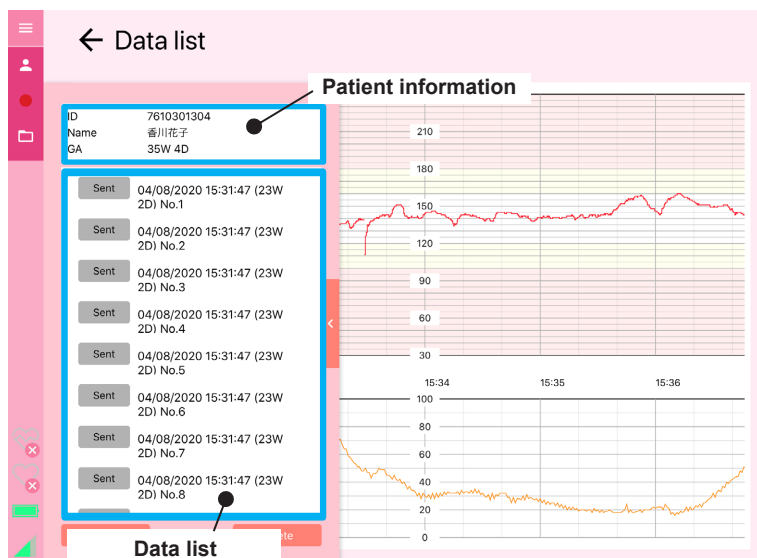
Patient ID*	Enter the patient ID of an expectant mother at the time of new registration. The ID cannot be changed after registration. The ID can include only half-width alphanumeric characters or symbols.
Name*	Enter the name of the expectant mother.
Age*	Enter the age of the expectant mother.
Remarks	Enter any additional information.
Number of fetus	This setting is for future development and measurement of twins is not possible at present. Selecting [Twins] does not affect the measurement.
EDC*	Select from the calendar displayed by tapping on the calendar icon in the entry field. When you set EDC, GA is calculated and displayed.
[Delete]	Tap to delete the patient information that is displayed. (A confirmation message is displayed before execution.)
	Tap to return to the previous screen.
	Tap to register patient information with the information that you have entered.


\* are mandatory items.




## 5.3 Data List Screen

This screen is used to browse the measurement results stored on the tablet. Tap on  of the menu to display the patient.


Select a patient (expectant mother) and then display this screen. A measurement data list of the selected patient is displayed. When you select data from the list, a graph of that data is displayed on the right.



Patient information	Information of the selected patient is displayed.
Data list	The list of the selected patient's data stored on the tablet is displayed. The data that has been sent to the data center is marked with  . Tap here to select the data to process (view, send, or delete).

[Resend]	Tap to send the data you have selected in the list. (A confirmation message is displayed before execution.) For more information, see “4.3.2 Resend data”.
[Delete]	Tap to delete the data selected in the list. (A confirmation message is displayed before execution.) For more information, see “4.3.3 Delete the Data”.
	Tap to close the list and expand the graph. Tap on the  icon to redisplay the list.
Graph	Displays the graph for the data selected in the list. To see the hidden part of the graph, swipe to scroll the graph to the left or right. Tap on the graph when the list is displayed to close the list.
	Tap to return to the previous screen.


## 5.4 FHR Transducer1 Information screen

This screen displays information of the FHR transducer. Tap on  of the menu to display the patient.

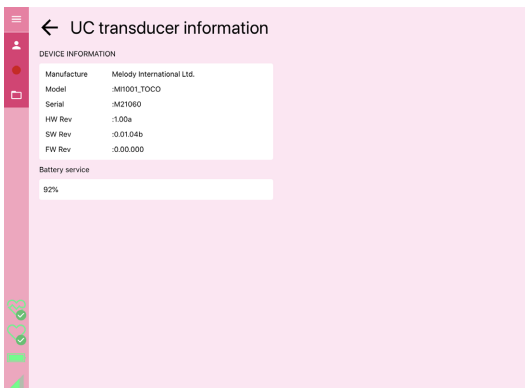
Cannot be displayed when the tablet is not connected to the FHR transducer.




## 5.5 UC Transducer Information Screen

This screen displays information of the UC transducer. Tap on  of the menu to display the patient.

Cannot be displayed when the tablet is not connected to an UC transducer.



## 5.6 Setting Screen

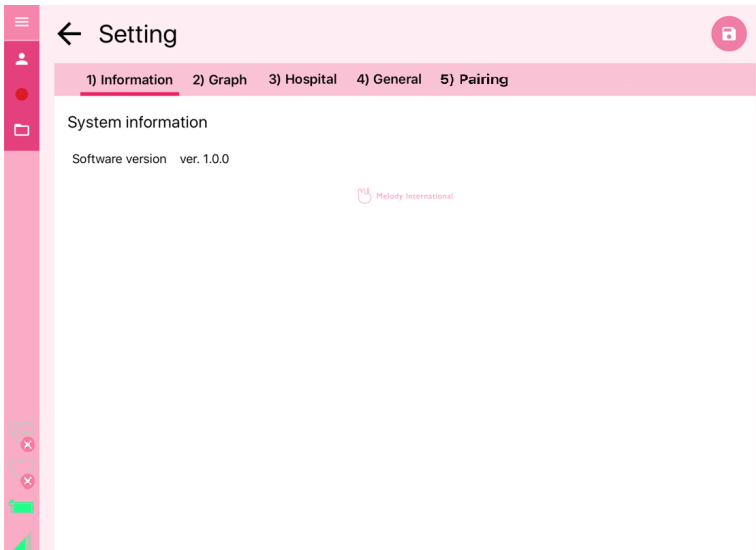
This screen is used to configure various settings. Tap on  of the menu to display the patient.

Tap on a setting category at the top of the screen to display the corresponding settings.



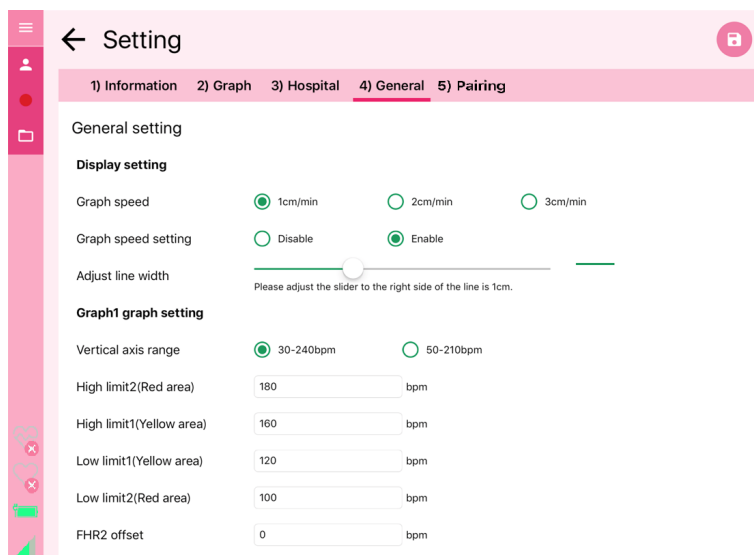
### 5.6.1 Information



Displays the version of the iCTG software.



Tap to return to the previous screen.

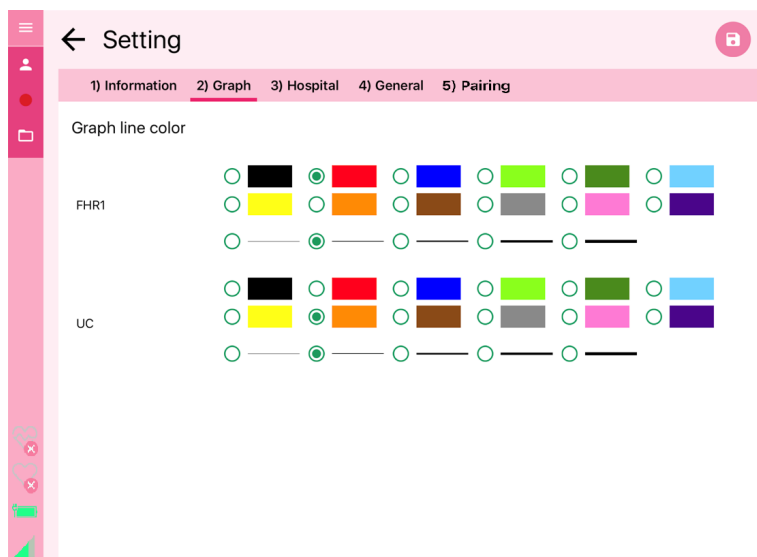
## 5.6.2 General





Language	Select the display language.
Display	Select the type of screen for the measurement. Graph: Displays a graph. Numeric value only: Stops the graph display and displays the measured value in a larger size.
Graph speed	Select the scale of the horizontal axis of the graph (length per measured minute).
Vertical axis range	Select the vertical axis range for the top graph (FHR graph).
High limit, low limit	Enter a threshold value for the warning area (yellow: Caution, red: Warning) for the top graph (FHR graph).
FHR2 offset	Not used.
	Tap to return to the previous screen.
	Tap to save the settings.






## 5.6.3 Line

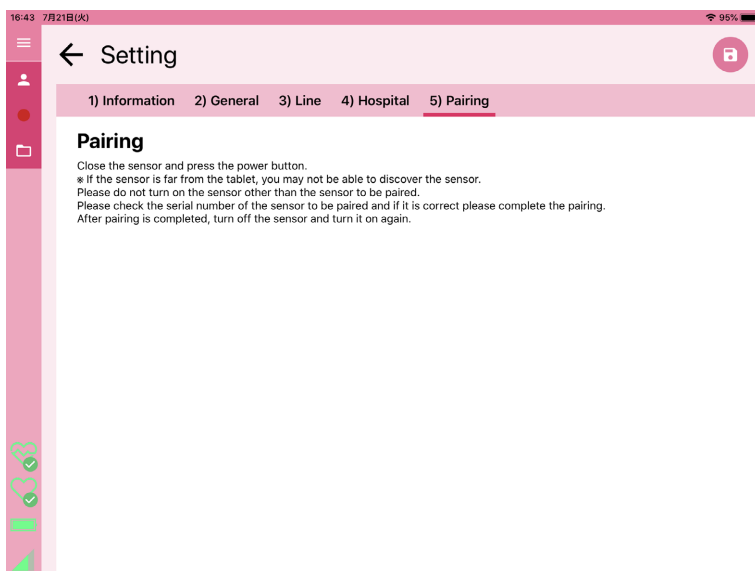


Top graph line color/ thickness	Select the color and thickness of the lines in the graph.
Bottom graph line color/ thickness	
	Tap to return to the previous screen.
	Tap to save the settings.

## 5.6.4 Hospital

Hospital ID	 <b>Caution</b> <ul style="list-style-type: none"> <li>Do not change the value. The ID is used when sending information to the data center, if the value is changed, the data will be sent as the examination information of a different hospital.</li> </ul>
Hospital name	This is not a mandatory input item. Arbitrary number of characters can be input.
Address	
Telephone	
	Tap to return to the previous screen.
	Tap to save the settings.


## 5.6.5 Pairing



Follow the instructions to pair the transducer with the tablet.

### Important

- When the serial number of the sensor to be paired is displayed, tap the serial number. A check mark is added to the right of the serial number after completion of pairing.

	Tap to save the settings.
---	---------------------------

# 6 Troubleshooting

This chapter describes the steps to be taken when a problem occurs in the device.

## 6.1 When a problem occurs

This section describes the possible problems and solutions. For information on the operations when messages are displayed during screen operations, see “6.2 Message List”.

If the problem is not listed below, or if the solutions that are mentioned do not solve the problem, contact our company.

### Important

- If the damage is caused due to wrong usage method, you may be charged for repair or replacement.

### Transducer

Problem	Solution
Tablet cannot be turned ON	<ul style="list-style-type: none"> <li>• Check if the power button has been pressed. (See section 4.1.1)</li> <li>• Press and hold the power button for a few seconds until you hear a beep.</li> <li>• Try to turn ON after fully charging the device (Charging method: See See paragraph 3.1)</li> </ul>
Device was dropped and subject to impact	<ul style="list-style-type: none"> <li>• If the following problems are observed in the device, do not use the device and contact our company.               <ul style="list-style-type: none"> <li>- Tablet is damaged</li> <li>- Device cannot be turned ON.</li> <li>- Tablet emits a strange noise</li> <li>- Measurements are not accurate</li> </ul> </li> </ul>
Device was washed.	<ul style="list-style-type: none"> <li>• Do not use the device and contact our company.</li> </ul>

**Tablet**

Problem	Solution
Tablet cannot be turned ON	<ul style="list-style-type: none"> <li>• Check if the tablet is charged.</li> <li>• Check if the power button has been pressed. (See section 4.1.1)</li> <li>• Press and hold the power button for about 3 to 5 seconds until the touchscreen (monitor) lights up.</li> </ul>
Tablet was dropped	<ul style="list-style-type: none"> <li>• If the following problems are observed in the device, do not use the device and contact our company.               <ul style="list-style-type: none"> <li>- Tablet is damaged</li> <li>- Tablet not start</li> <li>- Tablet emits a strange noise</li> <li>- Measurements are not accurate</li> <li>- Tablet cannot be operated normally</li> </ul> </li> </ul>

**Communication**

Problem	Solution
Transducer cannot connect to tablet	<ul style="list-style-type: none"> <li>• Check the connection status. (See section 4.1.2)</li> <li>• Turn on the transducer after the main screen is displayed on the tablet. (See section 4.1.1)</li> <li>• Move the tablet closer to the transducer.</li> <li>• Check if there are other devices in the vicinity that use the 2.4 GHz band. If such devices are present, move away or turn OFF the devices. Also, do not use microwave ovens in the vicinity.</li> </ul>

**Measurement**

Problem	Solution
Unable to start the measurement.	<ul style="list-style-type: none"> <li>• Check if the measurement start icon has been pressed. (See section 4.1.5)</li> <li>• Turn OFF the tablet (See paragraph 4.4) and then turn it back ON again. If the transducer cannot be connected, turn OFF the transducer and then again turn it ON.</li> </ul>
Fetal heart rate cannot be measured properly	<ul style="list-style-type: none"> <li>• Confirm that the device is FHR transducer (pink) (See section 2.2.1)</li> <li>• Check if the FHR transducer is turned ON. (See section 2.2.1)</li> <li>• Check if the FHR transducer is connected to the tablet. (See section 5.1.1)</li> <li>• Check if the FHR transducer is accurately capturing the fetus position.</li> <li>• Check if the belt that secures the FHR transducer loose.</li> <li>• Check if the maternal heart rate is being measured.</li> <li>• Check if gel has been applied.</li> </ul>
Uterine contraction cannot be measured properly	<ul style="list-style-type: none"> <li>• Check if the device is the UC transducer (blue). (See section 2.2.2)</li> <li>• Check if the UC transducer is turned ON. (See section 2.2.2)</li> <li>• Check if the UC transducer is connected to the tablet. (See section 5.1.1)</li> <li>• Check if the UC transducer is correctly placed over the base of the uterus.</li> <li>• Check if the belt that secures the UC transducer loose.</li> <li>• Check if zero-set completed. (See section 4.1.5)</li> </ul>

Problem	Solution
Measurement data is not saved	<ul style="list-style-type: none"><li>• Check if pairing with the tablet complete. (See section 4.1.2)</li><li>• Check if the graph is being drawn.</li></ul>

### Accessories

Problem	Solution
Device is damaged	<ul style="list-style-type: none"><li>• Do not use the device and contact our company.</li></ul>
Device is lost	<ul style="list-style-type: none"><li>• Contact our company or distributor.</li></ul>

## 6.2 Message List

Message	Description
Enter Patient ID, Name, Age, and EDC.	One of the items displayed in the message is missing. Enter all fields before registering (saving).
Would you like to start recording? Select the recording length. <input type="radio"/> 20min <input type="radio"/> 40min <input type="radio"/> 60min <input type="radio"/> 120min	To start the measurement, select the measurement time determined by the physician, and then tap Start Measurement. (See section 4.1.5)
Would you like to stop recording?	Tap on [Yes] to end the measurement without waiting for the measurement time to elapse. Tap [No] to continue the measurement. (See section 4.2.2)
Measurement is finished. Data transmitted successfully.	Indicates that the measurement was completed and data transmission was successful.
Delete this file?	Tap on [Yes] to delete the selected measurement data. Tap [No] to cancel the delete operation.
Do you want to shut down?	Tap on [Yes] to shut down the tablet. Tap on [No] to cancel the shutdown operation.
Data transmission has failed.	Indicates that data transmission was not successful. Perform the data transmission operation if necessary. (See section 4.3.2) Measurement data can be viewed on the tablet even if the data has not been sent.
The battery level is very low	Indicates that the battery level of the tablet is low. Charge the battery. (See section 3.2)



# 7 Maintenance and Inspection

This chapter describes the maintenance and inspection method.

## 7.1 Maintenance and Inspection List

Cycle	Details
Before measurement	Perform the following inspections for the transducers. <ul style="list-style-type: none"> <li>• Device should be free of dirt</li> <li>• Battery level that is required for the measurement should be available</li> <li>• Hook should not be loose</li> <li>• The FHR transducer must operate normally (check that the speaker beeps by moving your hand closer to the measuring surface)</li> <li>• The UC transducer must operate normally (press the sensor to confirm that the graph responds)</li> </ul>
After measurement	Clean the transducers. (See paragraph 7.2)
During storage	Perform the following inspections for the transducers. <ul style="list-style-type: none"> <li>• Power should be OFF (check that both LEDs 1 and 2 are turned OFF)</li> <li>• Device should be free of gel adhesion and dirt</li> <li>• Hook should not be loose</li> </ul>
Annual inspection	Our company or distributor will arrange for an inspection.

## 7.2 Cleaning the Transducers

Turn OFF the power and wipe the transducer dry with a soft cloth or paper towel while it is not charging.

Wipe off any gel or stains with a soft cloth or paper towel moistened with water, warm water, or alcohol.

---

**i Important**

- Do not use organic solvents such as thinner, or povidon iodine. If organic solvents or disinfectants other than those permitted are used, it may result in damage, discoloration, or malfunction of the device. Wiping with povidone-iodine may cause the dye to stick to the device surface.
-

## 8 Technical Data

This chapter describes technical documentation, including specifications.

### 8.1 Specifications

#### Physical specifications

##### Transducer

Measurement method (FHR Transducer)	Transmission and reception method: Continuous wave Doppler method Detection signal: Heartbeat signal Fetal heartbeat screening method: Frequency band filter
Measurement method (UC Transducer)	Amplifier: Differential amplifier Uterine contraction detection method: Strain gauge type Sensitivity: Equivalent to 50 on the display scale when weighted at 200 g Zero setting: Equivalent to 15 on the display scale
Material of the part in contact with the body	ABS-PC
Power supply rating	DC 5 V / 1 A or more (when measured and at maximum charging current)
Degree and type of protection	Internal power supply device, BF type mounting part
External dimensions	Approx. 96 mm × Approx. 93 mm × Approx. 29.5 mm
Weight	FHR Transducer: Approx. 166 g UC Transducer: Approx. 137 g

Operation duration	Approximately 6 hours (depends on temperature and battery age)
Charging time of battery	Approximately 1 hour (charging stops after 9 hours)
Battery life	500 charge/discharge cycles (battery cannot be replaced.)
AC Adapter rated input power	AC100 - 240 V
Connection to tablet	Bluetooth 4.0LE (Cypress Semiconductor CYW20737S)
Maximum connection distance with tablet	5 m or less (differs depending on the environment)
EMC compliance	IEC60601-1-2:2007, JISC61000-3-2:2011
Storage environment	Temperature: -15 to 70°C Relative humidity: 10 to 95% (non-condensing) Pressure: 700 to 1060 hPa
Operating environment	Temperature: 15 to 40°C Relative humidity: 20 to 80% (non-condensing) Pressure: 700 to 1060 hPa

**Tablet (display and data management device)**

Measured data display	Scroll speed: Can be switched between 1 cm, 2 cm and 3 cm/min Display range: Heart rate 30 to 250 bpm / 50 to 210 bpm Labor pain 0 to 100 scale
Operation	Key board, touch panel
Power adapter	Rated output 5.2 V 2 A (Normal Mode) 7 V or 9 V or 12 V 2 A (Quick Charge Mode)

## Performance

### Ultrasonic probe

Drive frequency	1.00 MHz $\pm$ 10%
-----------------	--------------------

### Heart rate measurement

Step change	$\pm 2$ heart beats within 5 mm of recorded progress
Temporary upward change	<ul style="list-style-type: none"> <li>• Maximum fetal heart rate: Maximum value recorded within 3 heart beats</li> <li>• Fluctuation range of the inclined straight line is within 1.5 mm</li> <li>• Recorded length from rise to the end of fall is <math>\pm 0.5</math> mm of the recorded length at input time</li> </ul>
Temporary downward change A	<ul style="list-style-type: none"> <li>• Minimum fetal heart rate input + minimum value within 3 heart beats is recorded</li> <li>• Fluctuation range of the inclined straight line is within 1.5 mm</li> </ul>
Temporary downward change B	<ul style="list-style-type: none"> <li>• Fluctuation range of the inclined straight line is within 1.5 mm</li> <li>• The original constant heart rate <math>\pm 2</math> heart beats within 5 mm of progress after returning to a constant value</li> </ul>
Temporary downward change C	<ul style="list-style-type: none"> <li>• Fluctuation range of the inclined straight line is within 1.5 mm</li> <li>• Recording the start of linear rise within 5 mm of the recorded progress from the instantaneous fall</li> </ul>
Temporary downward change D	<ul style="list-style-type: none"> <li>• The original constant heart rate <math>\pm 2</math> heart beats within 5 mm of recorded progress from the instantaneous fall</li> <li>• Original constant fetal heart rate <math>\pm 2</math> heart beats within 5 mm of the recorded progress from the instantaneous rise and return to the original constant value</li> </ul>

Minute fluctuation responsiveness	<ul style="list-style-type: none"> <li>• Fluctuation range of the inclined straight line is within 1.5 mm</li> <li>• The fluctuation amplitude for reciprocating fluctuation of 2 to 8 times/min is input fluctuation amplitude <math>\pm 3</math> heart beats</li> <li>• The fluctuation amplitude for reciprocating fluctuation of 12 times/min is 1/2 or more of the input fluctuation amplitude</li> </ul>
-----------------------------------	--

**Tocodynamometer**

Sensitivity	A band for detecting uterine contractions by external measurement that must have the required sensitivity 0 to 100 units
Temperature drift	Within $\pm 20\%$ of the full scale recorded on paper for 30 minutes after the temperature is raised by $10^{\circ}\text{C}$

## **8.2 Principle**

### **8.2.1 Fetal heart rate measurement**

The fetus heart beat is detected by the Continuous Doppler method that uses ultrasonic waves emitted from a FHR transducer, and converts them into electrical signals to measure the heart rate.

### **8.2.2 Uterine contraction measurement**

A strain gauge inside the UC transducer mounted on the abdomen of the mother detects changes in uterine contraction pressure, and converts the pressure into electrical signals to measure the intensity of labor pain.

---

If you have any questions about repairs or any other inquiry about the product, contact our distributor or at the address given below.

## Melody International Ltd.

Medical device manufacturer registered, Second-class marketing license for medical devices granted, Medical device sales/lease business license granted, PrivacyMark certified

304 Next Kagawa, 2217-44 Hayashi, Takamatsu, Kagawa, Japan  
761-0301

TEL: 087-813-7362 FAX: 087-813-7361

EMAIL: [e-support@melody.international](mailto:e-support@melody.international)

---