FC1400

(English) Product Manual
(Deutsch) Bedienungsanleitung
(Français) Manuel du produit
(Italiano) Manuale del prodotto
(Español) Manual del producto
(Português) Manual do produto
(Nederlands) Producthandleiding
(Dansk) Produktmanual
(Svenska) Produktmanual
(Suomi) Tuotemanuaali
(Polski) Instrukcja produktu
(Čeština) Manuál produktu
(Slovenčina) Manuál produktu
(Magyar) Termék kézikönyv
(Română) Manualul produsului
(Български) Ръководство за продукта
(Ελληνικά) Εγχειρίδιο προϊόντος
(Eesti) Tootejuhend
(Latviešu) Produkta rokasgrāmata
(Lietuvių) Produkto vadovas
(Slovenščina) Priročnik za izdelek
(Hrvatski) Priručnik proizvoda
(Malti) Manwal tal-prodott
(Gaeilge) Lámhleabhar táirge

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Model: FC1400
Manufacturer: Bionet Co., Ltd.

SRN:
KR-MF-000013439
Conformity assessment procedure:
Annex. II excluding 4 (MDD)
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bionet

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1. Introduction

1.1. Product Overview

FC1400 is a fetal monitoring system used to measure the Fetal Heart Rates (FHR), degree of maternal uterine contraction (UA: Uterine Activity), and fetal movements (FM). Its ultrasounds into the abdomen of the patient and extracts Doppler frequencies from the signals returned after being reflected by the heart of the fetus. The Doppler frequencies vary with the movements of the fetal heart and the changes in the heartbeats of the fetus are output as sounds, which is analyzed to detect the heart rates and movements of the fetus. In addition, it detects the degrees of uterine contraction of the patient using a pressure sensor. It shows the fetal heart rates, maternal uterine activity, and fetal movements on its LCD screen as figures and numeric values and saves the data in its memory.

1.2. Intended Purpose

FC1400 detects and displays single or twins Fetal Heart Rate (FHR), Fetal Movement (FM), and Uterine Activity (UA) in real-time, and provides the fetal heartbeat sound with internal speaker.

1.3. Indication

FC1400 is suitable for use when there is a need to monitor the following physiological applications:

- Single or twins fetal heart rates by means of ultrasound
- Uterine activity - externally sensed
- Fetal movement - maternally sensed and externally via ultrasound

1.4. Contraindications

Stop using or do not use the device in following situations:

1. Patient who has allergic reactions (skin rashes, itching, swelling, or respiratory distress) to following materials:

- Methanol, ethanol, isopropanol alcohol, or any other alcohol-based products
- Mineral oils
- Iodine
- Lotions
- Lanolin
- Aloe vera
- Olive oil
- Methyl or ethyl parabens (para hydroxybenzoic acid)
- Dimethyl silicone

2. Patient who is undergoing defibrillation, electro surgery, or magnetic resonance imaging (MRI).
3. Patient who is in intensive care units, operating room, or their house.

1.5. Clinical Benefit

The device emits ultrasound waves to the mother's abdomen, allowing for monitoring of the fetal heart rate within a margin of error of ±2 BPM, increasing the detection and aiding in the diagnosis of fetal health conditions such as abnormal heart rates, fetal hypoxia, metabolic acidosis, and predicting preterm labor with uterine contractions during third trimester in gestation.

1.6. Undesirable Side Effect

These can be rarely occurred through wrong control of the device:

- Serious burn
- Electric shock
- Injury
- Wrong diagnosis
- Skin rash

1.7. Intended User

This device is for use only by trained medical professionals such as Obstetricians / Gynecologists regarding the following:

- In the use of fetal heart rate (FHR) monitors
- In the interpretation of FHR traces

- Familiar with using medical devices and with standard fetal monitoring procedures

1.8. Intended patient target group

Pregnant women from the 28th week of gestation.

1.9. Precautions

The transducers and patient modules are sensitive instruments. Handle them with care.
Keep your monitor, transducers, patient modules, cables and accessories free of dust and dirt. After cleaning and disinfection, check the equipment carefully. Do not use if you see signs of deterioration or damage. If you need to return any equipment to Bionet, always decontaminate it first before sending it back in appropriate packaging.

Observe the following general precautions:

1. Always follow carefully and retain the instructions that accompany the specific cleaning and disinfecting substances you are using
2. The product must work in a clean environment, should avoid areas where moisture, direct sunlight, or a heater is near the product; that are frequently exposed to vibration; that are too dusty or are not properly ventilated; or where chemicals or gases are present
3. Do not place anything on top of the instrument
4. Always dilute according to the manufacturer's instructions or use lowest possible concentration
5. Do not allow liquid to enter the case
6. Do not immerse the monitor in liquid. Protect it against water sprays or splashes
7. Do not pour liquid onto the system
8. Never use abrasive material (such as steel wool or silver polish)
9. Never use bleach
10. The product shall be repaired by professional recognized by Bionet Co., Ltd. only after which it can be re-used.
11. Do not use FC1400 to directly monitor patients during water births, in whirlpool or submersion water baths, during showers, or in any other situation where the mother is immersed in water. Doing so may result in electrical shock hazard
12. FC1400 Fetal Monitoring system is not intended for use in intensive care units, operating rooms or for home use
13. Use a commonly used ultrasound scan gel. However, gels containing these ingredients should not be used as they may cause probe damage:

- Methanol, ethanol, isopropanol alcohol, or any other alcohol-based products
- Mineral oils
- Iodine
- Lotions
- Lanolin
- Aloe vera
- Olive oil
- Methyl or ethyl parabens (para hydroxybenzoic acid)
- Dimethyl silicone

1.10. Significant residual risks

We identified the risks through risk management and implemented risk control measures, thereby reducing all risks to acceptable levels. However, the following risks are considered as improbable probability but critical severity:

- Respiratory arrest
- Heart paralysis
- Explosion
- Decreased consciousness

1.11. Product Characteristics

1. FC1400 measures fetal heart rates and fetal movements simultaneously.
2. By using the US probe for twin fetuses, twin fetal FHR and movements can be measured. (optional specification)
3. Measured data can be saved and identified on the LCD. Thus, the condition of the fetus can be efficiently monitored during labor without wasting recording sheets.
4. While reviewing the saved data, any data that should be kept in recording sheets can be printed at high speeds.
5. With ultrasound Doppler probes having high durability even against noise, clear sounds of the heartbeats of the fetus and accurate FHR can be detected.
6. The 7 ultrasonic sensors driven at 1Mhz are used to minimize broken FHR waveforms even if the fetus or the patient moves.
7. The fetal movement is automatically detected by the analysis of the Doppler signal, and the intensity and duration are displayed on screen or printed as spike waveforms.
8. Universal communication interfaces including LAN are provided for connection with the central parturition monitoring system.
9. Rechargeable batteries are used; thus, parturition conditions can be continuously monitored even during a power failure. (optional specification

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Warning

- Using accessories not supplied by Bionet may cause signal distortion or noise. Always use genuine Bionet accessories.

1.12. Safety Symbol

The International Electro Technical Commission (IEC) has established a set of symbols for medical electronic equipment which classify a connection or warn of any potential hazards. The classifications and symbols are shown below:

Manufacturing date

The manufacturer’s name and address are provided.

Safety Sign: It indicates that you should read the operation manual. Read this operation manual before starting work or operating the equipment.

Consult Instructions for Use: This symbol advises the reader to consult the operating instructions for information needed for the proper use of the equipment.

Protection against vertically falling water drops (IEC 60529) Water Protection Specification Level 0, Level 1 and Level 7.

IPX0, IPX1
and IPX7

Non-ionizing electromagnetic radiation

Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

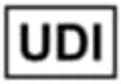
This way up

Use no hooks

Fragile

Keep dry

Unique Device Identification (UDI): Every system has a unique marking for identification



Indicates that the product is in compliance with all relevant European Directives and under surveillance by Notified Body 2265.

This equipment is a medical device.

Power Adapter connection

External Signal IN/OUT Port

IEC 60601-1 Type BF applied part

Power Standby

USB Port for external signal

USB Connector

Conductor provides a connection between the equipment and the potential equalization bus bar of the electrical installation

Video Out

2. Safety

To prevent damage of the equipment or injury to yourself or others, read the following safety instruction before using FC1400.

2.1. Definition of Warning, Caution, Mandatory Action and Note

The following terms are used throughout this manual to emphasize important and critical information. You must read these statements to help ensure safety and to prevent product damage.
The manufacturer or the product distributor is not liable for any loss or damage to the product caused by incorrect use or negligence in product maintenance.

Warning

- Failure to follow this message may cause severe injuries, casualty or physical damage to patients.

Caution

- Failure to follow this message may cause in non-life-threatening injury or damage to the equipment.

Mandatory

- Mandatory Action messages are directions you must follow for safe operation and maintenance of the equipment.

Note

- Note messages indicate some important information and tips, which are not dangerous, about installation, operations and maintenance.

2.2. Electrical Safety

Please note the following precautions before using the product:

- Is the power supply cord proper? (100 - 240V AC)
- Is every cord connected properly to the product?
- Is the product fully grounded? (Otherwise, noise may occur.)

- Is there any damage - which may affect the monitoring or safety of the patients — to any of the product or accessories?

Note

- You should not place this equipment in the vicinity of electric generator, X-ray, broadcasting apparatus or portable wires to eliminate electric noise during operation. Otherwise, it may cause incorrect results. Isolated power line and stable grounding are important requirements for use of this equipment. Using same power source with other electric equipment may cause incorrect results.
- FC1400 is classified as listed below:
    - As for protection against electric shock, it is a Class 2 type and has type-BF degree.
    - Do not use it in the vicinity of flammable anesthetics and solvents.
- It fulfills the level A according to IEC/EN 60601-1-2 (Electromagnetic Compatibility Requirements).
- Doctors and patients in hospitals are exposed to the risk of uncontrollable currents. These currents are caused by a potential difference between this equipment and conductive objects, which may come into it. To solve this problem, make sure that the auxiliary equipment connected to this equipment satisfies EN60601-1-1.
- If a multiple socket outlet is used for AC power input, it must be a grounding- type.
- Avoid contact with the connector pin of this equipment and the patient at the same time while it is in use.
- Do not connect or remove the power cable with wet hands.
- In case the medical equipment does not operate normally, or if it has been damaged, do not use it on any patient; Contact the medical equipment technician in your hospital or the equipment supplier.

Warning

- DO NOT make contact with patient during defibrillation. Otherwise, severe injury or death could result. To avoid the risk of serious electrical burn, shock, or other injury during defibrillation, all persons must keep clear of the bed and must not touch the patient, or any devices connected to the patient.
- Devices for fetal heartbeat sound measurements using ultrasonic (US) waves or uterine contraction measurements (TOCO) performed from outside of the uterus are not designed for use during any electric operation, defibrillation, or defibrillator discharge.
- This equipment has not been designed for use with other types of monitoring equipment apart from those devices permitted to use together with it in this manual.
- Do not touch signal input, signal output or other connectors, and this equipment simultaneously.
- Do not connect or remove the power cable with wet hands.
- This equipment is not designed for use with devices that generate high electromagnetic fields, such as high frequency surgery machines. Therefore, measurements may be affected in the presence of strong electromagnetic sources such as electrosurgery equipment.
- Electromagnetic Interference - Do not use mobile phones nearby in the process of monitoring.

- Electromagnetic Interference - Fetal parameters, especially ultrasound are sensitive measurements involving small signals, and the monitoring equipment contains very sensitive high gain front-end amplifiers. Immunity levels for radiated RF electromagnetic fields and conducted disturbances induced by RF fields are subject to technological limitations. To ensure that external electromagnetic fields do not cause erroneous measurements, it is recommended to avoid the use of electrically radiating equipment in close proximity to these measurements.
- Electromagnetic Interference - The monitor should not be used adjacent to, or stacked with, other equipment unless otherwise specified.
- Electromagnetic interference is not unique to the monitor but is characteristic of fetal patient monitoring equipment in use today. This performance is due to very sensitive high gain front end amplifiers required to process the small physiological signals from the patient. Among the various monitoring systems already in clinical use, interference from electromagnetic sources is rarely a problem.
- Electromagnetic Interference - Ensure that the environment in which the monitor is installed is not subject to any source of strong electromagnetic interference, such as CT, radio transmitters, mobile phone base stations, etc. Even though other devices are in accordance with national standard radiation requirements, the monitor may be interfered.

2.3. Mechanical Safety

Warning

- Please do not drop the probe.
- Do not use if shaking the ultrasound probe produces a sound of loose cells inside.
- Do not apply excessive force to the sensing portion of the UC Probe.

2.4. Cyber Security

In case of equipment theft or loss, report it immediately to hospital officials or the manufacturer. Upon receiving the report, the hospital network administrator should take measures to prevent the equipment from accessing the hospital network.
If a cyber security threat is detected while using the equipment, disconnect the equipment from the network immediately and contact hospital officials or the manufacturer.

※ Please refer to the manufacturer's contact information index for contact details.

2.5. Biological Safety

When used as intended, the parts of this equipment described in this operation manual, including accessories that come in contact with the patient during the Intended Purpose, fulfill the biocompatibility requirements of the applicable standards. If you have questions about this matter, please contact Bionet or its representatives.

2.6. Electromagnetic Emission

Guidance and manufacturer’s declaration – electromagnetic emissions:
FC1400 is designed for use in the electromagnetic environment specified below. Customers or users of FC1400 must ensure that it is used in such an environment.

- Emission Test: Mains terminal disturbance voltage CISPR 11
  - Compliance limit: Group 1, Class A
  - Electromagnetic environment - guidance: The EMISSIONS characteristics of FC1400 make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Emission Test: Radiated disturbance CISPR 11
  - Compliance limit: Group1, Class A
  - Electromagnetic environment - guidance: The EMISSIONS characteristics of FC1400 make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Emission Test: Harmonics IEC 61000-3-2
  - Compliance limit: Class A
  - Electromagnetic environment - guidance: The FC1400 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
    Warning

    This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the FC1400 or shielding the location
- Emission Test: Voltage fluctuations/Flicker IEC 61000-3-3
  - Compliance limit: Complies
  - Electromagnetic environment - guidance: The FC1400 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
    Warning

    This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may

be necessary to take mitigation measures, such as re-orienting or relocating the FC1400 or shielding the location

2.7. Electromagnetic Immunity

Manufacturer’s declaration - electromagnetic immunity

Guidance and manufacturer’s declaration – electromagnetic immunity:
FC1400 is designed for use in the electromagnetic environment specified below. Customers or users of FC1400 must ensure that it is used in such an environment.

- Immunity Test: Electrostatic Discharge (ESD) IEC 61000-4-2
  - IEC 60601 test level:
    - ±8 kV/Contact
    - ±2, ±4, ±8, ±15 kV/Air
  - IEC 60601 Compliance level:
    - ±8 kV/Contact
    - ±2, ±4, ±8, ±15 kV/Air
  - Electromagnetic environment - guidance: Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
- Immunity Test: Radiated RF Electromagnetic Field IEC 61000-4-3
  - IEC 60601 test level:
    - 3V/m
    - 80 MHz - 2.7 GHz
    - 80% AM at 1 kHz
  - IEC 60601 Compliance level:
    - 3V/m
    - 80 MHz - 2.7 GHz
    - 80% AM at 1 kHz
  - Electromagnetic environment - guidance: FC1400 is suitable to use in professional healthcare environment. RF communication equipment is used no closer than 30 cm to any part of the FC1400, including cables specified by Bionet Co., Ltd.
- Immunity Test: Immunity to Proximity Fields from RF wireless Communications Equipment IEC 61000-4-3
  - IEC 60601 test level:
    - 28 V/m Max.
    - 385-5785 MHz in according to table 9 in IEC 60601-1-2
  - IEC 60601 Compliance level:
    - 28 V/m Max.
    - 385-5785 MHz in according to table 9 in IEC 60601-1-2
  - Electromagnetic environment - guidance: FC1400 is suitable to use in professional healthcare environment. RF communication equipment is used no closer than 30 cm to any part of the FC1400, including cables specified by Bionet Co., Ltd.
- Immunity Test: Electrical Fast Transient /Burst IEC 61000-4-4
  - IEC 60601 test level:
    - 100 kHz repetition frequency

        - ± 2 kV for power supply lines
        - ± 1 kV for input/output lines
    - IEC 60601 Compliance level:
        - 100 kHz repetition frequency
        - ± 2 kV for power supply lines
        - ± 1 kV for input/output lines
    - Electromagnetic environment - guidance: The quality of supplied power should be suitable for general business site or hospital environment.
- Immunity Test: Surge IEC 61000-4-5
    - IEC 60601 test level:
        - Line to Line ±0.5 kV, ±1 kV
        - Line to Ground ±0.5 kV, ±1 kV, ±2 kV
    - IEC 60601 Compliance level:
        - Line to Line ±0.5 kV, ±1 kV
        - Line to Ground ±0.5 kV, ±1 kV, ±2 kV
    - Electromagnetic environment - guidance: The quality of supplied power should be suitable for general business site or hospital environment.
- Immunity Test: Conducted Disturbances Induced by RF fields IEC 61000-4-6
    - IEC 60601 test level:
        - 3 V, 0.15 MHz - 80 MHz
        - 6 V in ISM bands between 0.15 MHz and 80 MHz
        - 80% AM at 1 kHz
    - IEC 60601 Compliance level:
        - 3 V, 0.15 MHz - 80 MHz
        - 6 V in ISM bands between 0.15 MHz and 80 MHz
        - 80% AM at 1 kHz
    - Electromagnetic environment - guidance: The strength of RF field in the frequency range higher than 150 kHz - 80 MHz, the strength of the RF field is smaller than 3 V.
- Immunity Test: Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8
    - IEC 60601 test level:
        - 30 A/m, 50 & 60 Hz
    - IEC 60601 Compliance level:
        - 30 A/m, 50 & 60 Hz
    - Electromagnetic environment - guidance: Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, residential or Home Health Care environment.
- Immunity Test: Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11*
    - IEC 60601 test level:
        - 0% UT: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
        - 0% UT: 1 cycle and 70% UT: 30 cycles — single phase: at 0°
        - 0% UT: 250/300 cycles
    - IEC 60601 Compliance level:
        - 0% UT: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
        - 0% UT: 1 cycle and 70% UT: 30 cycles — single phase: at 0°
        - 0% UT: 250/300 cycles

    - Electromagnetic environment - guidance: Mains power quality should be that of a typical residental or hospital environment. If the user of the FC1400 requires continued operation during power mains interruptions, it is recommended that the FC1400 be powered from an uninterruptible power supply or a battery be used with the system power source.
- Immunity Test: Radiated fields in close proximity IEC 61000-4-39
    - IEC 60601 test level:
        - 65 A/m Max
        - 30 kHz - 13.56 MHz in according to table 11 in IEC 60601-1-2
    - IEC 60601 Compliance level:
        - 65 A/m Max
        - 30 kHz - 13.56 MHz in according to table 11 in IEC 60601-1-2
    - Electromagnetic environment - guidance: FC1400 is suitable to use in professional healthcare environment.Portable radio frequency (RF, RFID) communication devices can interfere with the medical electrical device. Therefore, do not use your mobile phone in a medical office or hospital environment.

[Note] UT is the AC voltage of the power before using test level

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Recommended separation distances between portable and mobile RF communications equipment and the FC1400:
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 FC1400 including cables specified by the manufacturer. If the distance is closer than 30 cm (12 inches), performance of the FC1400 may decrease.

- Immunity test: Proximity fields from RF wireless communications equipment
    - Band: 380-390 MHz
        - Service: TETRA 400
        - Modulation: Pulse modulation 18 Hz
        - IEC 60601 test level: 27 V/m
        - Compliance level: 27 V/m
    - Band: 430–470 MHz
        - Service: GMRS 460, FRS 460
        - Modulation: FM, ± 5 kHz deviation, 1 kHz sine
        - IEC 60601 test level: 28 V/m
        - Compliance level: 28 V/m
    - Band: 704-787 MHz
        - Service: LTE Band 13, 17
        - Modulation: Pulse modulation 217 Hz
        - IEC 60601 test level: 9 V/m
        - Compliance level: 9 V/m
    - Band: 800-960 MHz
        - Service: GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5
        - Modulation: Pulse modulation 18 Hz
        - IEC 60601 test level: 28 V/m
        - Compliance level: 28 V/m
    - Band: 1700-1990 MHz
        - Service: GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS

        - Modulation: Pulse modulation 217 Hz
        - IEC 60601 test level: 28 V/m
        - Compliance level: 28 V/m
    - Band: 2400-2570 MHz
        - Service: Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7
        - Modulation: Pulse modulation 217 Hz
        - IEC 60601 test level: 28 V/m
        - Compliance level: 28 V/m
    - Band: 5100-5800 MHz
        - Service: WLAN 802.11 a/n
        - Modulation: Pulse modulation 217 Hz
        - IEC 60601 test level: 9 V/m
        - Compliance level: 9 V/m

[Note] These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) For some services, only the uplink frequencies are included.

Warning

- 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 this equipment and result in improper operation.

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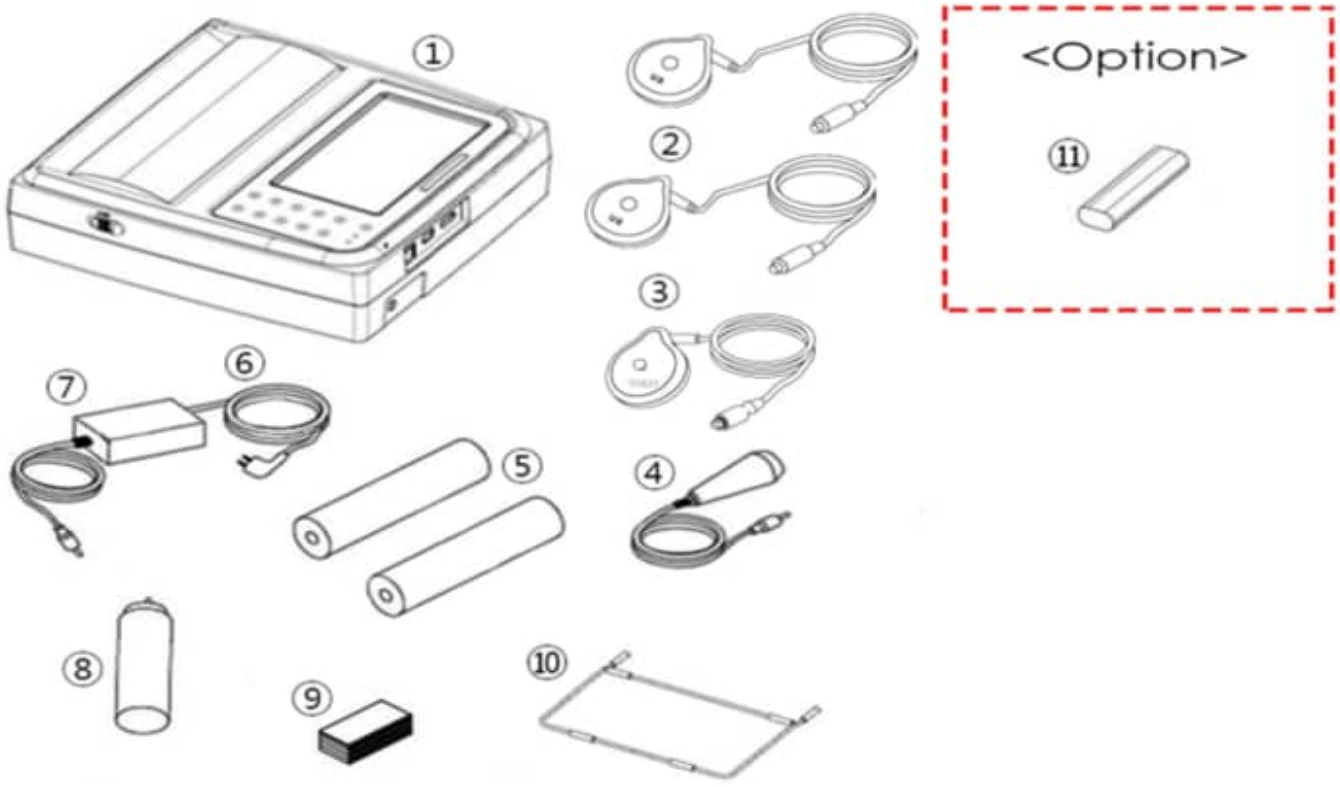
3. Preparing for Use

FOR YOUR PROTECTION, please read safety instructions completely before turning the power on.

3.1. Composition of Products

The FC1400 Fetal Monitoring System consists of the following components. Open the packaging box and check that all items below are included. In addition, please check the monitor and the components for any

damage).



- Basic Composition and Accessories:

1. Monitor
2. US probe(2)
3. UC probe(1)
4. Event Marker(1)
5. Fetal Paper(2)
6. Power cord(1)
7. Adaptor(1)
8. Ultrasound gel(1)
9. Belt(3)
10. FC1400 Stand(1)

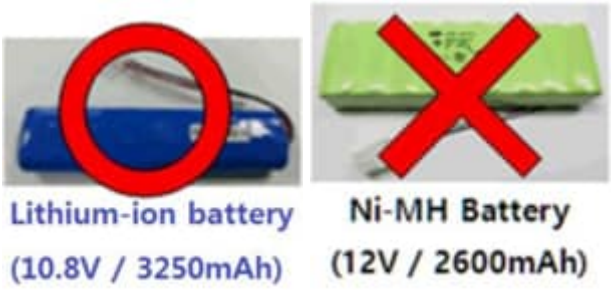
- Optional specification

11. Battery(1)

Warning

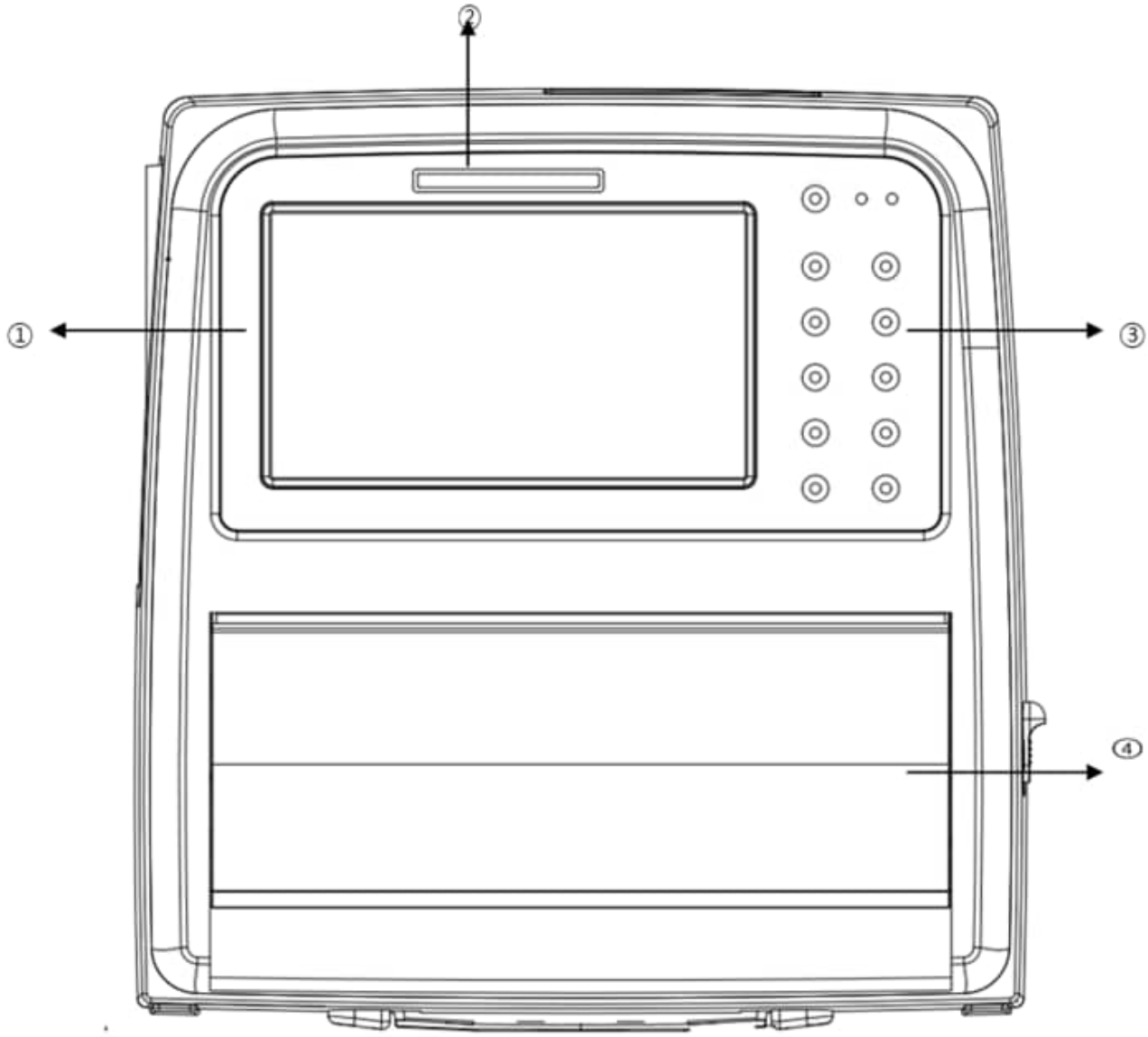
- How to replace battery: Please make sure you use the right battery(Lithium-ion battery) as shown here. Otherwise, Bionet is not liable for any damages and/or explosion caused by the wrong battery. Make

sure to use the genuine battery recommended by Bionet.



- Do not subject the probe to physical shocks or excessive pressure.
- Shock and excessive pressure on the probe may damage the internal sensor.
- Impact or excessive pressure on the center of the probe may cause damage.
- Bionet is not liable for probes damaged as a result of these actions.

- Top View



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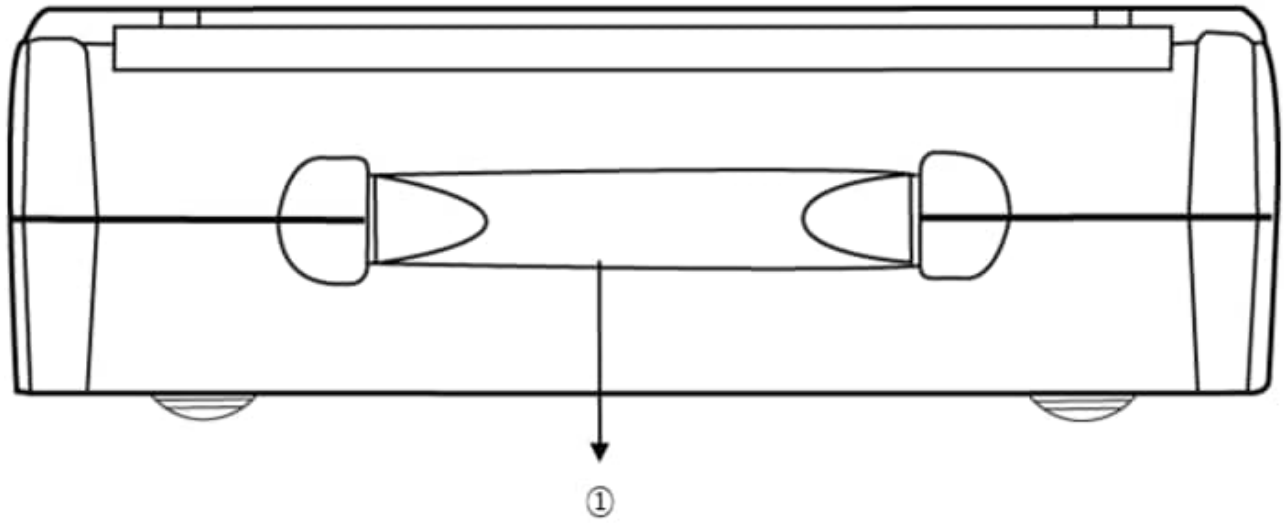
1. Graphic display window: Displays the measuring items and condition of FC1400.
2. Alarm LED: Displays the state of alarm.
3. Control panel: Controls the functions.
4. Printer door: Opens for replacing recording paper.

Warning

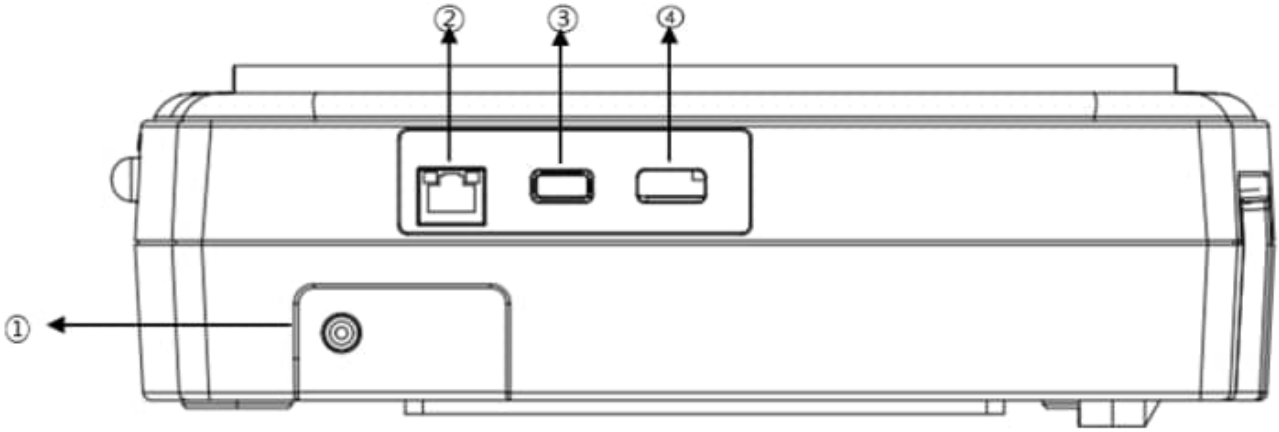
- To avoid high-voltage electric shock, DO NOT disassemble the monitor. If any of the probes has been damaged, stop using them to prevent electric shock and contact Bionet or its representative for the replacement of the probe. Disassembling the monitor should be done only by the service representative authorized by Bionet.

- Front View



1. Hand Grip: Use it when lifting and moving the monitor.

- Rear View

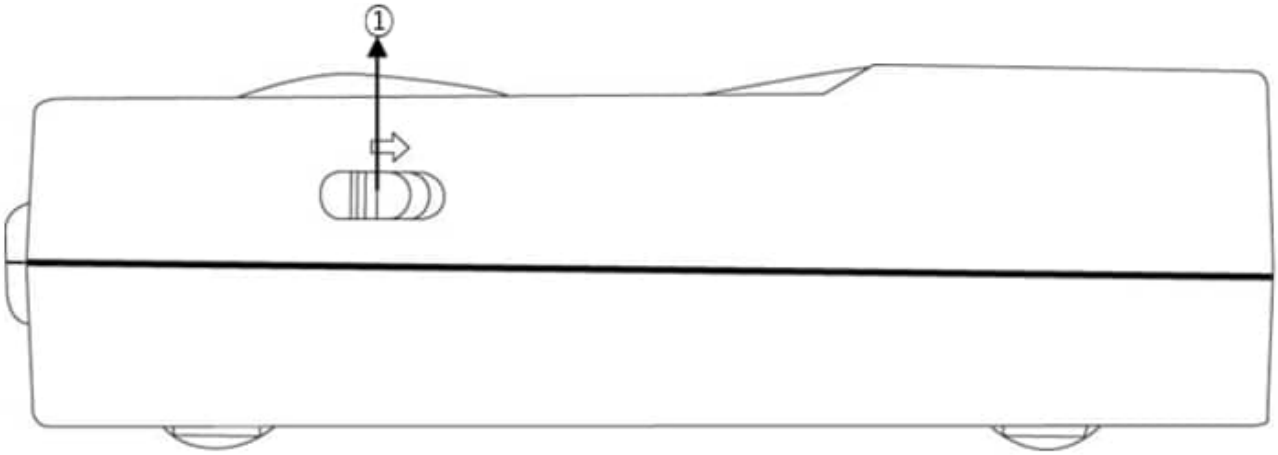


1. Power adaptor connector: Connect a power adaptor of 18V, 2.8A.
2. LAN Port: A terminal for LAN communication
3. USB1 Port: A terminal for USB communication
4. USB2 Port: A terminal for USB communication

Mandatory

- DO NOT remove the USB storage device until it is recognized completely.

- Right Side



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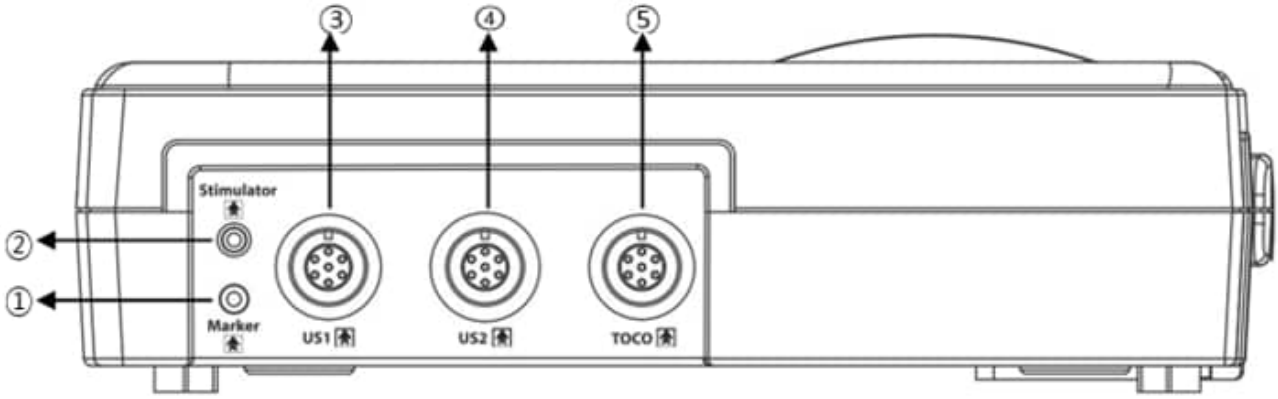
1. Printer door release lever: Slide it to open the printer door.

- Left Side



---

1. Marker jack connection terminal: Connect the marker jack cable.
2. Stimulator jack connection terminal: Connect the stimulator cable.
3. US probe connection terminal 1: A terminal to connect a US probe
4. US probe connection terminal 2: A terminal to connect a US probe to measure twin fetal
5. UC Probe connection terminal: A terminal to connect the UC Probe.

Mandatory

- Avoid contact with both the USB or LAN port area and the patient simultaneously.
- RISK OF ELECTRICAL SHOCKS - DO NOT OPEN THE MONITOR: Monitor disassembly is only authorized to individuals with Bionet service authorization.

3.2. Cautions in installation

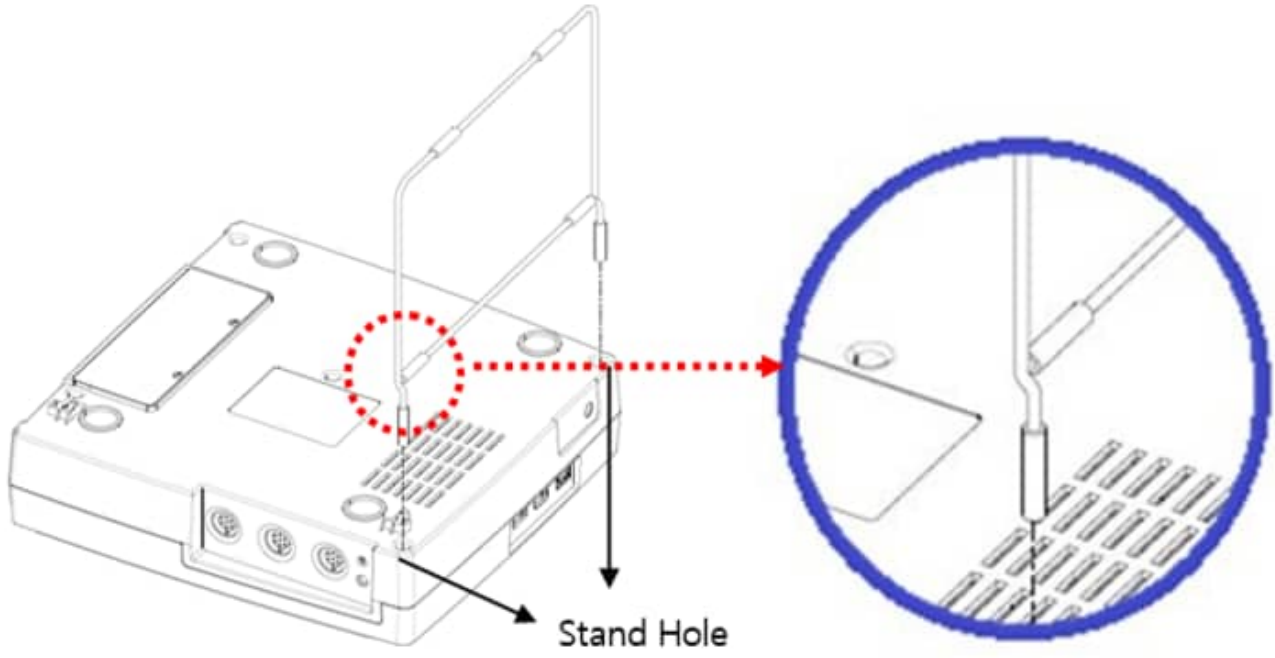
Preparations before use:

- Be sure to use FC1400 in dry condition at normal temperatures (temperature: 10 ~ 40℃, humidity: 30 ~ 85%).
- Be sure to use an outlet away from any equipment that may generate electric noise (room heating/cooling equipment using a large motor, etc.).
- Installing recording paper: Open the printer cover by pushing back the Printer cover open lever on the right side of the monitor. Load paper with printable side up and close the cover.
- Put the adaptor into the connection site at the back of the monitor to connect AC power. At this time, check if the power cord has been installed properly.

- Operating Environment
  - Ambient Temperature: 10 °C ~ 40 °C
  - Humidity: 30 % ~ 85 %
  - Atmospheric Pressure: 70 kPa (700 mbar) ~ 106 kPa (1060 mbar)
- Transportation/Storage Environment
  - Ambient Temperature: -20 °C ~ 60 °C (-4 °F ~ 140 °F)
  - Humidity: 10 % ~ 95 % (without condensation)
  - Atmospheric Pressure: 50 kPa (500 mbar) ~ 106 kPa (1060 mbar)

Installing FC1400 stand:

- Insert the FC1400 stand to the stand hole on the underside of the monitor.



Operating procedure:

- Press the power switch on the front side of the monitor for 2 seconds when power has been turned off; on the other hand, press the power switch on the for 3 seconds when power has been turned on.
- Put some ultrasound gel on the US probe, find heartbeat of the fetus and attach the probe around the abdomen of the patient using a fixing belt.
- Fix the UC Probe on Fundus which is located 10 cm above the belly button of the maternal abdomen using a fixing belt.
- Determine a usage mode and use FC1400 accordingly.

If a problem occurs with FC1400, press and hold the power key for more than 6 seconds to force shutdown.

How to store and manage FC1400 after use:

- Turn off the power switch and unplug the power cord.
- When the operation has been completed, clean the monitor and accessories to prevent malfunction.

3.3. Cautions in use

Installation and storage:

- Avoid moisture, high temperature, dust in the air, salt, and sulfuric materials including places that are under direct sunlight or not well-ventilated.
- Avoid vibrations or mechanical impacts.
- Avoid places exposed to chemicals or at risk of gas leakage.
- FC1400 should be used with the voltage and frequency indicated.

Before operation:

- FC1400 should be properly grounded.
- Connect all cords accurately and safely.
- When using an optional battery, please charge it for at least four hours.
- Any part directly connected to the patient should be double-checked.
- Use FC1400 within the range of operating temperatures.

During operation:

- The patient should not come into contact with any metal parts of FC1400, such as the chassis or case. DO NOT touch the patient and FC1400 at the same time.
- If any abnormality has been found, turn off power and unplug the power cord.
- DO NOT use any sharp or pointed object to press the LCD or any touch key.
- DO NOT confuse demo data with patient data.

After use:

- Turn off the power switch and unplug the power cord.
- Take off the probes connected to the patient.
- When the operation has been completed, clean the monitor and accessories to prevent malfunction.

Periodic Inspection:

- Keep the monitor and the measuring probes clean by wiping them off with soft cloth wet with alcohol at least once a month. DO NOT use lacquer, thinner, ethylene, or oxidizing substances.

- Keep the cables free of dust or dirt. Clean them with cloth wet with tepid water (40˚C/104˚F) after use and at least once a week, wipe them off with clinical alcohol.
- Inspect FC1400 periodically once a year.
- FC1400 should be serviced only by the service representative authorized by Bionet.

4. Basic operations

4.1. Getting Started

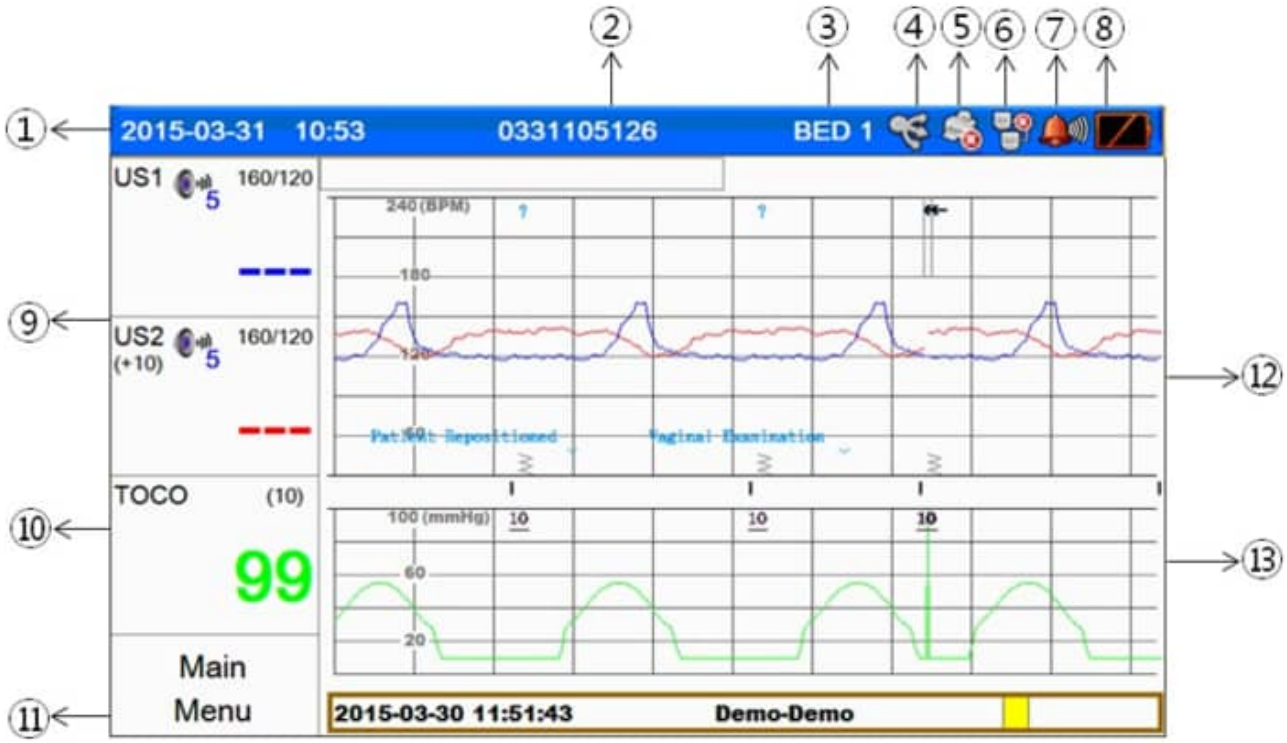
Press the power switch on the monitor for 2 seconds; it turns on and home screen appears.

4.2. Shutting Down

Hold down the power switch for 3 seconds to turn off the monitor. If it does not turn off when you press the power switch for 3 seconds, press and hold the power switch for 6 seconds or more.

4.3. Graphic Display

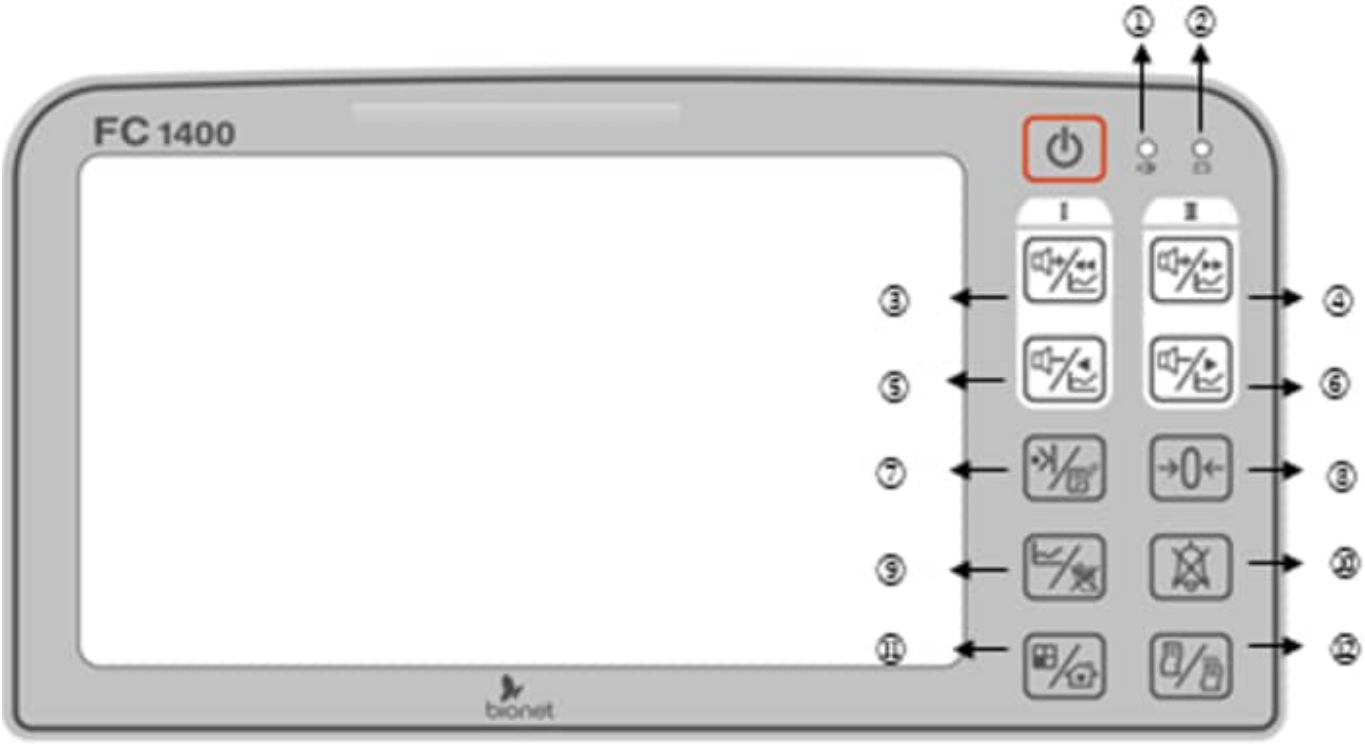
- Monitoring screen



1. Date and Time
2. Patient name or ID
3. Bed ID
4. USB terminal connection
5. Print state
6. Network connection
7. Alarm volume, size, and setting state
8. Battery capacity
9. Fetal heart rate parameters

10. Uterine contraction parameters
11. Main Menu
12. The trends of fetal heart rates
13. The trends in the real-time degrees of uterine contraction and fetal movements

4.4. Control Panel



1. AC power indicator LED: AC power connection state
2. Battery indicator LED: State of battery charges
3. US1 volume up/1 min forward key in Trace mode:
    - Short key: US1 Volume up or forwarding 1 minute in trace mode
    - Long key: Return US1 volume back to the Pre-Mute stage
4. US2 volume up/1 min backward key in Trace mode:
    - Short key: US2 volume up or backwarding 1 minute in Trace mode
    - Long key: Return US2 volume back to the Pre-Mute stage
5. US1 volume down/6 sec forward key in Trace mode:
    - Short key: US1 volume down or forwarding 6 seconds in Trace mode
    - Long key: US1 volume mute
6. US2 volume up/6 sec backward key in Trace mode:
    - Short key: US2 volume down or backwarding 6 seconds in Trace mode
    - Long key: US2 volume mute
7. Clinical Mark and Note Bottom:
    - Short key: Used by doctors or nurses to mark the current location
    - Long key: Used by doctors or nurses to record the statements frequently used
8. Zero calibration uterine contraction: Zero calibration of UC Probe
9. Trace entry:
    - Short key: Used to view trace data

    - Long key: Enable or disable the screen touch lock
10. Alarm silence key: used to change alarm state. The alarm circulates: alarm on -> alarm silence -> pause -> alarm off -> alarm on.
11. HOME key: You can swap Graphic screen and Text mode. Pressing it in the sub menu moves you to the main menu.
12. Print start/stop key and Paper feeding key:
    - Short key: Used to print data on the recording paper in real time or in Trace mode.
    - Long key(Paper feeding key): Used to feed papers while printing is stopped.

4.5. Menu

Selecting menu:
To go to a menu, touch the main menu or parameter window on the screen.

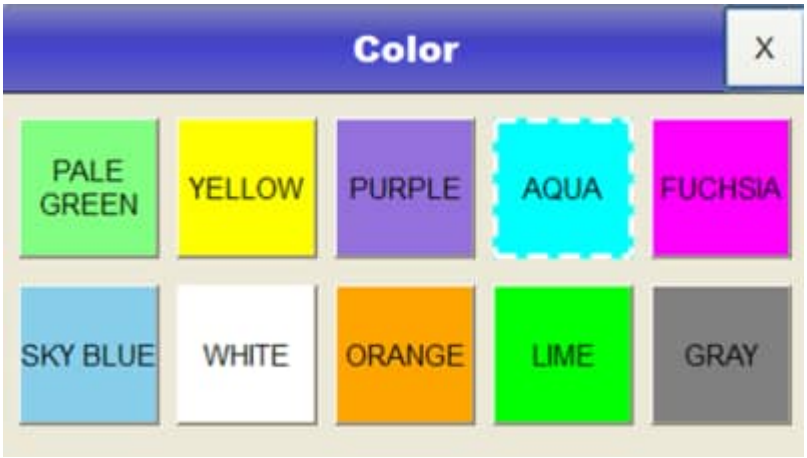
Entering a letter:
To enter a letter, touch the key for that character. To clear all entered characters, touch and hold the [<-] key for at least 1 second.

Entering value:
To enter a value, touch the selection key or the screen. If the previously entered value remains, press [CLEAR]

key or use [BS] to clear them.

Selecting color:

To select the color of a line or a numerical value, touch the selection key or color on the screen.



4.6. Connecting Power

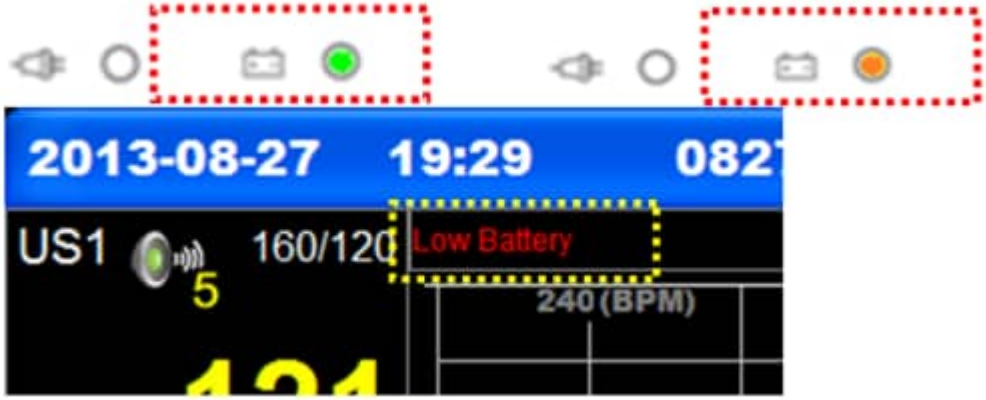
AC power:

If the monitor is connected to AC power, the Power LED on the front side of the monitor lights green; if a battery has been installed, the power mode is automatically changed to automatic charging mode, and the battery is charged.

Battery power(optional):

If you turn on the monitor with the AC power supply being cut off, it is powered by the battery and the battery indicator lights orange in its front. When it is mounted with the battery and connected to the AC power, the battery is charged in automatic charging mode. When the battery is fully charged, the battery indicator LED lights green.

If the battery is low, alarm occurs with Battery low being displayed on the LCD screen a few minutes before the monitor is automatically turned off. In this case, connect it to AC power.



For a new battery:

- Charging time: Minimum of 4 hours
- Continuous use time: Maximum 2 hours

Changes in the screen in relation to the state of battery connection:
The battery state is displayed on the screen as follows depending on the connection status of the battery and AC power, and the condition of the battery;

No battery(AC power connection only)

Battery only but with little or no power

 : 2 images are toggled.

Battery only and its state

 : Low

 : Medium

 : Full

---

AC and Battery: Level of battery being charged.

 : Low

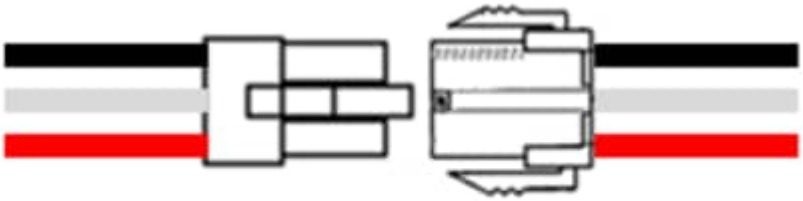
 : Medium

 : Full

---

Replacing the battery: When replacing the battery, use the same type of battery.

- Type: CMICR18650 F9, Lithium Ion rechargeable Battery Pack(10.8V/3250mV)
- When to replace: When the monitor is connected to a power source, the battery is charged automatically. The battery can be recharged about 300 times and replace it if you cannot use it for longer than 20 minutes even after full charge. In case the battery is damaged or leaks, replace it immediately. Do not use a damaged battery on the monitor.
- How to: Connect the connector as shown in the following image(Connector cannot be plugged inversely).



(Connecting a battery)

Warning

- Pay attention to the polarity when replacing the battery.
- Be sure to install and remove the battery with the AC power off.
- To protect the environment, do not carelessly dispose of wastes or residues such as the components of FC1400 after their lifetime; instead, ask the biomedical engineering department of the hospital to dispose of them in the designated places following appropriate procedures.
- If the installation or arrangement of the external grounding wire is doubtful, operate FC1400 with internal power. If it is not used for a certain period, remove the battery to avoid any safety hazard.

The effect of lithium-Ion technology on the battery:
Find out about lithium-ion battery technology here.
The battery is discharged naturally even when not installed in the monitor. Discharging is caused by the current demanded by the lithium-ion battery integrated circuit. Battery is self- discharged due to the nature of lithium-ion cells.
Battery retention loss is greater at higher temperatures. As the battery ages, it may not be fully charged, or not charged at all. As a result, the total charge capacity used for saving and using gradually decreases.

- Conditioning Guidelines: Check battery performance by fully charging and completely discharging it every 6 months.
- Storage Guidelines: Store the battery between 20°C and 25°C(68°F and 77°F) when it is set aside separately. When the battery is installed in the monitor being connected to AC power, the temperature of the battery increases by 15°C to 20°C(59°F to 68°F) at room temperature, which shortens the life of the battery. When a battery is installed in the monitor with AC power being connected, normally the battery does not use its battery power. Battery life may be less than 12 months. Store the battery along

with the monitor to prevent being lost and stolen, and take out the battery from the monitor when moving it around.

4.7. Definition of Groups

Users of FC1400 are divided into three types, and the authority varies according to each group. User passwords are group specific.

- Administrator: Can set preset and note items(default password: 1234)
- Factory: Factory setting. Authorized users at head office and AS representatives
- General user: Can change the settings for the current patient.

5. Patient Management

Learn how to store the basic information for patient identification.

5.1. Registering a New Patient

Register a new patient with this menu.
When you turn on the monitor, a random ID is created with the current date and time.
To change the user's ID to the current ID or to register the changed patient with a different ID, use New function. If the records of the patients measured before are left in the list of the recent 99 patients, use Search function.

< Registering a new patient >

1. Touch [Patient] on the menu. (It is not available in Demo mode.)
2. Select [New] to register a new patient.
3. Touch the ID, first name, last name, and gestational-age respectively to enter the text in the input window, then press [OK] to enter the items.
4. Enter the ID, first name, last name, and gestational-age and press [OK].
5. To register the patient with the default values of date and time, touch the [Default] button.
6. Information on the currently registered patient appears at the patient information tap on top of the screen.

< Registering a patient using Search >

1. Touch [Patient] on the menu.
2. Select [Search] to register a recently measured patient.
3. Referring to the ID, first name, last name, and gestational-age on the patient list, touch and select the patient you want to register.
4. ☑ button to maintain the current information.

Note

- You can enter patient information using a barcode reader. Place the cursor on each item in the patient information screen and scan the barcode. Information is entered automatically.

Basically, you can use any kind of barcode reader. However, since the default setting of the input method of each product may be different, check the method supported by Bionet before using them.

- Entry methods supported by Bionet products: International standard and USB.
- The products that have been tested by being connected to Bionet equipment are listed below.

1. Manufacturer: Data Logic, Product Name: DL6000
2. Manufacturer: ZEBEX, Product Name: Z-3190
3. Manufacturer: Techscan, Product Name: TSK-2000

Caution

- Each barcode reader has a product-specific initialization code. Be sure to read the user manual of the product and check the entry method before initializing it.

5.2. Editing a Patient

Change the information of the currently set patient.

1. Touch [Patient] on the menu.
2. Select [Edit].
3. Edit a patient information except the ID.
4. When you click the item, a text box where you can enter text. Press [OK] to register the items.
5. Information on the currently registered patient is shown in the patient information tab on top of the screen.

Note

- Patient list saves up to 99 patients that have been entered so far.
- If the number of patients exceeds 99, the oldest patient in the list is removed.
- The patient information which has been entered or modified in the monitor does not synchronize with those in the FC central.

6. Measuring FHR Using US

FHR is measured by obtaining the heartbeat sounds of the fetus using ultrasonic Doppler effects and subsequently calculating and saving the heart rate per minute in real-time. Since ultrasounds are reduced considerably in the air, apply sufficient amounts of ultrasonic gel to the surface of US probe to remove any air layer before using it.
FC1400 fetal monitoring device adjusts the volume automatically according to the amount of input data. When no input is detected while probe is connected, the noise will increase. When not measuring while FC1400 is running, mute it by pressing and holding the volume down key. Then when measuring, press and hold the volume up key to return back to the previous setting for the measurement.

6.1. Measuring FHR

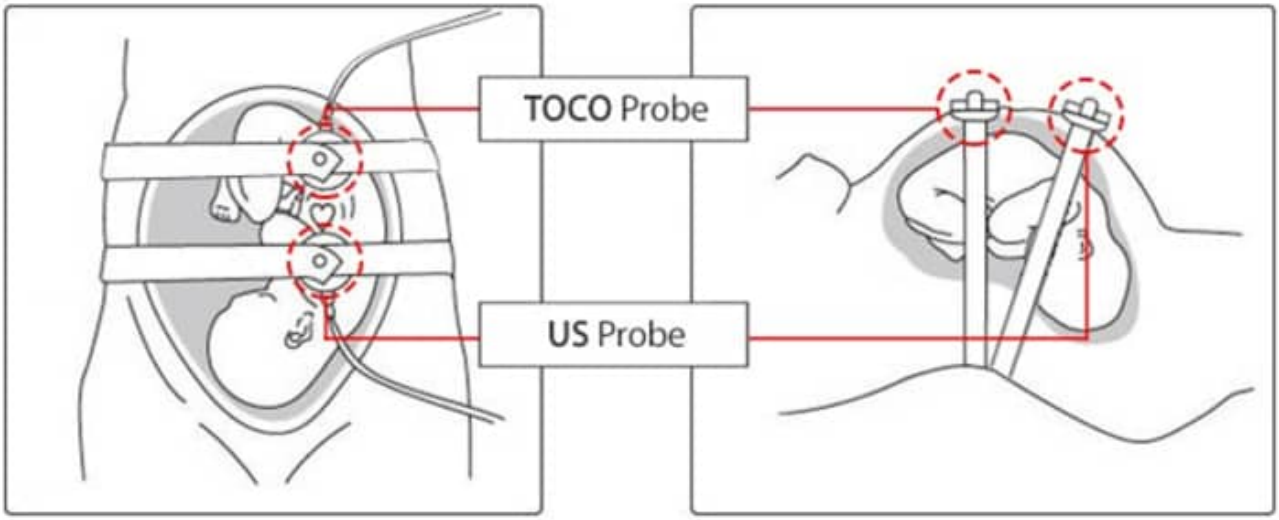
Connecting the US probe:
Connect the US probe to the US1 and US2 connection terminals on the left side of the monitor.

US probe:

Basic operations following a US probe connection:
When the US Probe is not connected to the monitor, nothing is displayed in FHR area, while " --“ is displayed if only the US probe is connected. When you connect the US probe to the US1 connection terminal and place it to heart position of the fetus, a numerical value is displayed in the FHR display area.

How to measure FHR:

1. Place a fixing belt below the waist of the patient.
2. To remove air bubbles between the abdomen of the patient and the surface of the US probe, apply a sufficient amount of ultrasonic gel to the US probe.
3. Feel the abdomen of the patient to find the back side of the fetus and place the US probe there. If the fetus faces laterally, place the US probe on the position shown in the figure below.



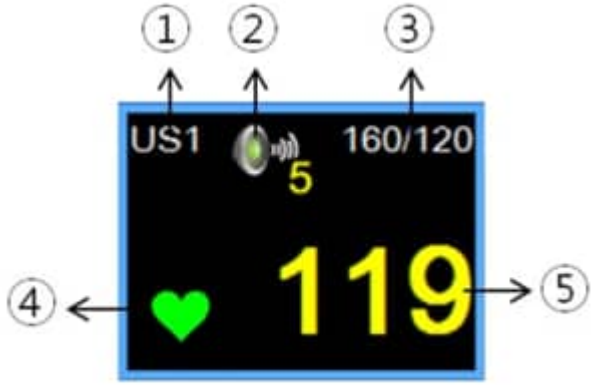
4. Move the US probe little by little around the patient's abdomen to place the US probe in a position where: the sounds from the heart of the fetus are heard relatively loud and clear; the heart shape in the FHR display area turns green; and it blinks according to the heartbeats of the fetus. adjust the speaker volume so that the sounds from the heart of the fetal becomes appropriately louder.
5. Put the button on the upper part of the US probe into the hole in the fixing belt to fix it to prevent slipping down.
6. Put the button on the upper part of the US probe into the hole in the fixing belt to fix it so that it does not slip.
7. It takes around 2~8 seconds for FHRs to be calculated and displayed.

Note

- Care should be taken not to scan over a wound or incision to avoid contamination and infection.
- If the US Probe is placed on the side of the chest of the fetus instead of the back side, ultrasounds will not be accurately shot to the heart of the fetus; thus, the heartbeat sounds of the fetus may be frequently missed.
- If you fix the probe cable toward the patient's head, you can prevent damage to the cable and also prevent the probe from moving or shaking.

6.2. US screen

The US area on the screen consists of the following:



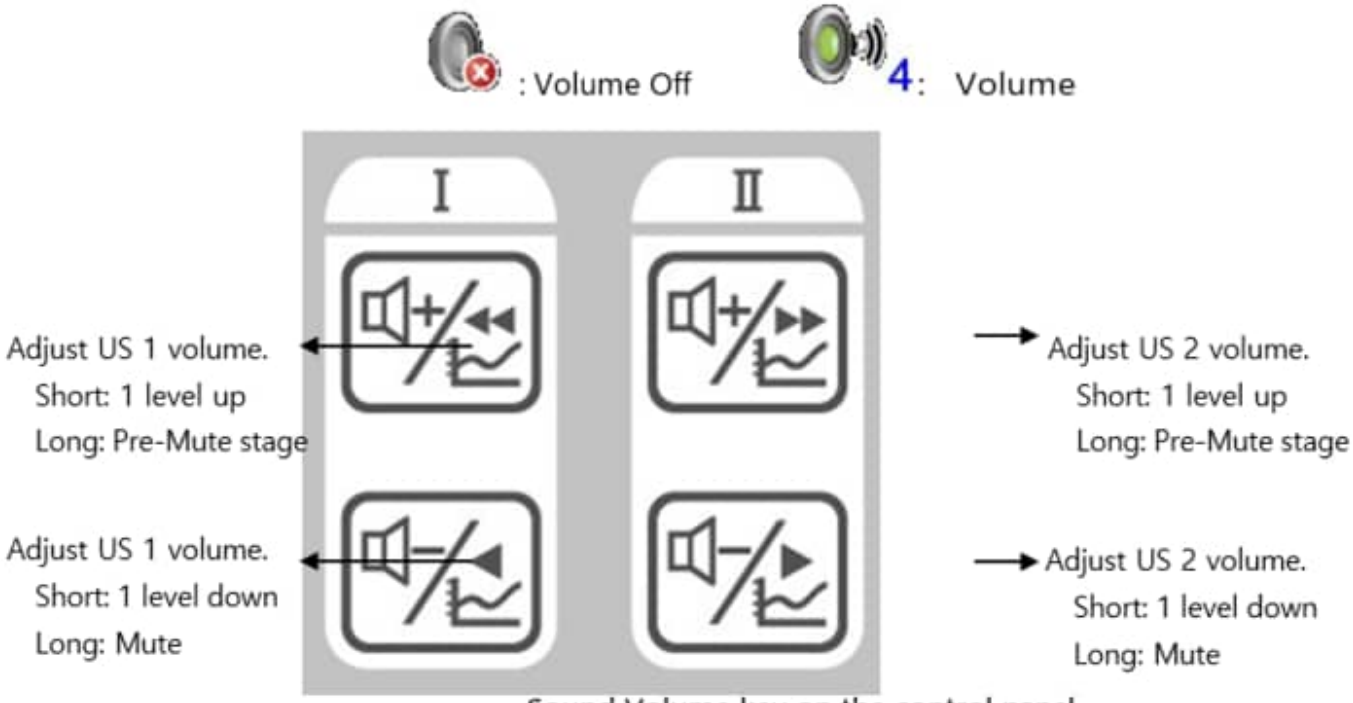
1. Probe No.
2. FHR Volume Icon: The current state of the Volume
3. Alarm range: The alarm ranges of parameters
4. Beat indicator: When FHR is detected as beats, the heart icon blinks
5. FHR value: FHR indicator

6.3. Setup

If you select and touch the US area on the screen, the following selection window pops up. Touch the US1 area or US2 area to setup US1-related items and US2-related items, respectively.

Adjusting sound volume:
Touch the [Sound Volume] menu. Select the value to set from Off or at levels 1~9. You can use the control panel to adjust the FHR sounds. Touch the [Sound Volume] button and select a volume from the popup window.

Also, you can directly go to the Sound Volume window using the speaker icon in the US area.

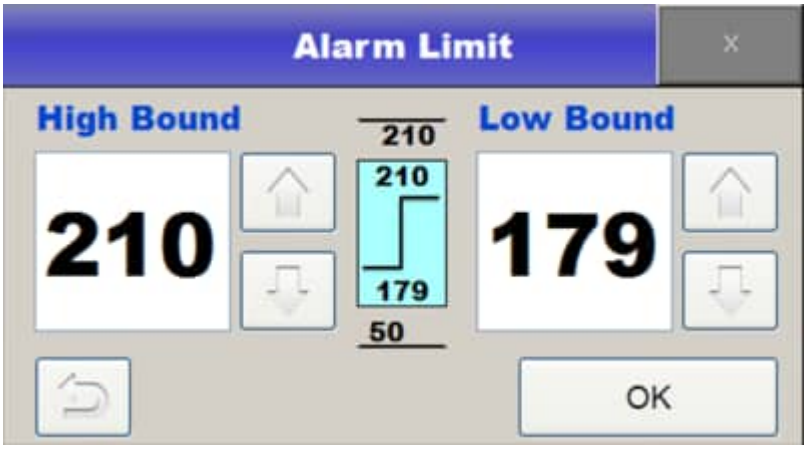


Sound Volume key on the control panel

Alarm:
You can adjust the FHR alarms for US1 and US2 separately. Set whether to use FHR alarms.

Alarm Level:
Set the alarm levels for FHR. You can set the alarms for patient condition alarms to Medium and Low. Refer to the alarm section for details.

Alarm limit:
Touch [Alarm Limit] within FHR setting menu to set the alarm range of FHR. Enter numbers or touch the arrow keys to set the limit.



Alarm delay:
Set this function to prevent alarms from ringing when FHR values exceed the alarm range but only for a short time. To set up an alarm delay, touch the [Alarm Delay] in the FHR setting menu. To not to use this function, select Off.

Color:
Set the FHR values and Trace line colors.

Offset:
To make it easy to distinguish when the twin fetal FHR values are similar to each other, in Trace mode and printing, the US2 value is displayed at a position where the offset value is added.

Signal loss alarm:
Set whether to occur an alarm when the fetal heart rate is not detected. Refer to the alarm section for details.

7. Measuring the Uterine Contractio n Externally

Use external attachment-type pressure sensors to measure UA. When you attach a TOCO probe to the abdomen of the patient, it measures the relative pressures that vary with the uterine contraction of the patient, thereby recording the uterine activity.

7.1. Measuring Uterine Contraction

Connecting the UC Probe:
Connect a UC Probe to the TOCO connection terminal on the left side of the monitor.

UC Probe:

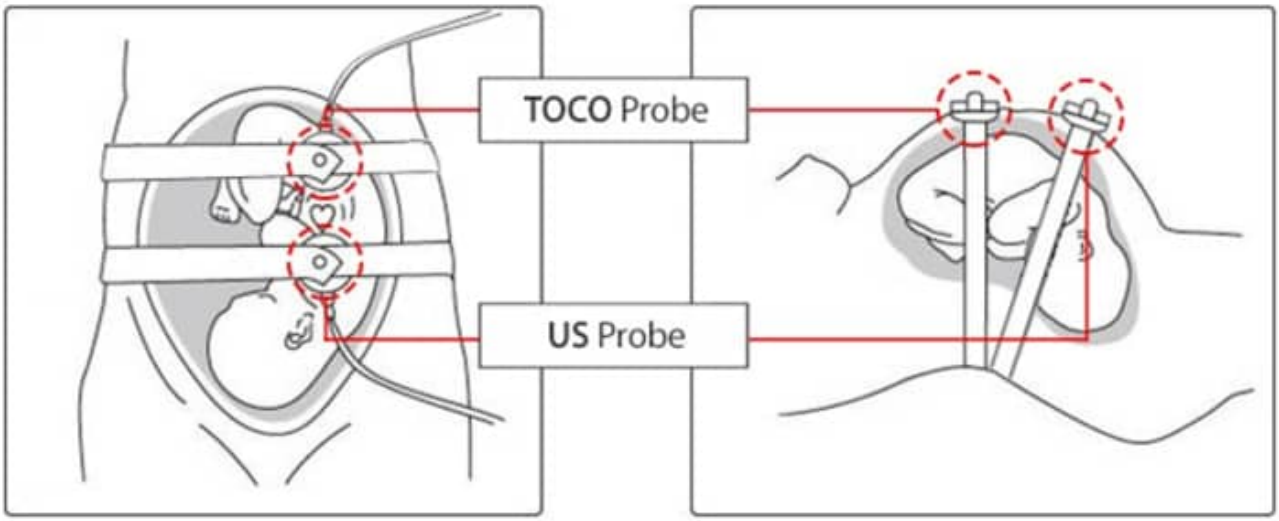

: NEW PROBE

Basic operations with UC Probe connection:
When there is no UC Probe connected to the monitor, "---" is displayed in the UC display. When you connect a UC Probe to the monitor, a numerical value is displayed, indicating that it is ready to measure uterine activities. When you view FMs (Fetal Movements), "TOCO+FM" is displayed.

Measuring UA:

1. Place a fixing belt below the back of the patient.
2. Place the TOCO probe on the highest peak of the abdomen of the patient(Fundus: located around 10cm above the umbilicus) or the place that hardens first in the abdomen of the patient.
3. Put the fixing button protruding on top of the TOCO probe into the hole of the fixing belt to fix the TOCO probe. At this time, the degree of tightening with the belt should be between 20 and 90 TOCO value.

4. Perform Zero calibration to set up a reference value.

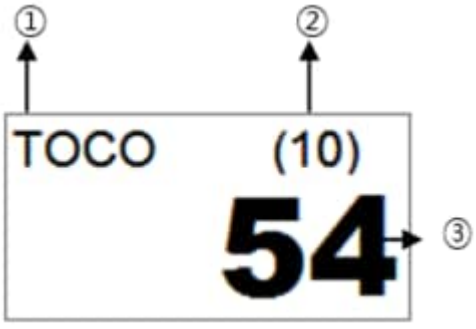


Note

- If a TOCO probe is connected to the monitor but not used, unreliable values may appear in the TOCO display area.
- If the type of probe(Gray or White) is not identical to the value set in FC1400, the TOCO value is not be measured. To change the probe type, check the TOCO New probe setting first.

7.2. UC screen

The TOCO area on the screen consists of the following:

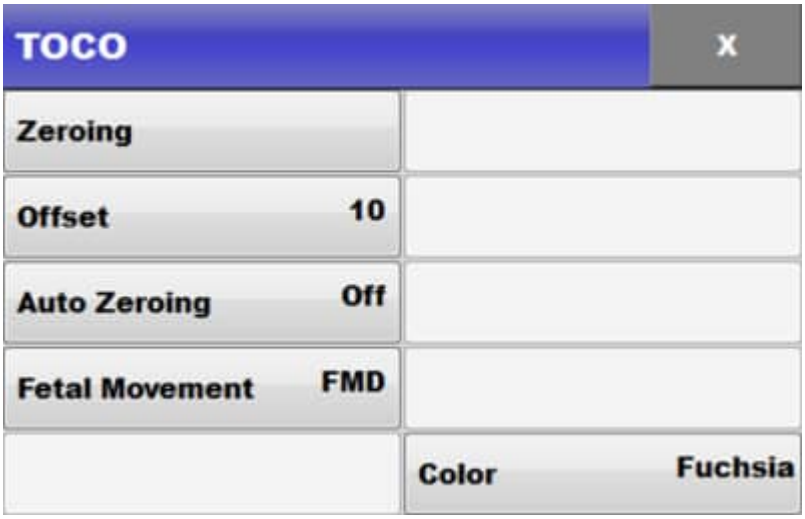


---

1. Title:
    - TOCO: Displays only uterine contraction but not fetal movements.
    - TOCO + FM: Displays both fetal movements and uterine contraction at the same time.
2. UC Zero value: Displays the reference value that appears when Zeroing has been done.
3. UC: The degrees of uterine contraction

7.3. Setup

If you select and touch the UC area on the screen, the following selection window pops up.



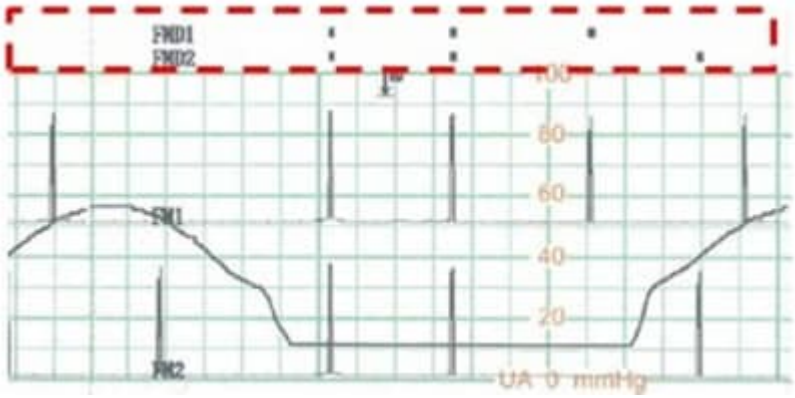
Zeroing:
Adjust the zero point of UC. If you touch it, the UC value at the moment is set as Offset value.

Offset:
Set a reference value to use when adjusting the zero point of UC among 0, 10, and 20.

Auto zeroing:
Initiate automatic adjustment of the zero point when a UC value is maintained below 0 for longer than 10 seconds.

Fetal movement:
Set whether to output fetal movement-related graphs to the screen or through the printer. If the value is FMD+FM or FMD, the title of UC is shown as TOCO+FM(if Off, TOCO).

Fetal movements are automatically detected and shown as Fetal Movement graph, and as FMDs in the form of points.



UC Color:
Set the colors of UC values and Trace.

8. Measuring Fetal Movement

Fetal Movements can be measured in two methods: one that is automatically detected from the data input by ultrasound and one that is measured when the patient presses the marker jack when she feels the fetal movement.

8.1. How to use marker jack

The marker jack records the moment of fetal movement by the patient pressing it when she feels it. When the patient presses the marker jack, "|" is displayed in the FHR waveform display area. It is printed as ↑ on the recording paper.

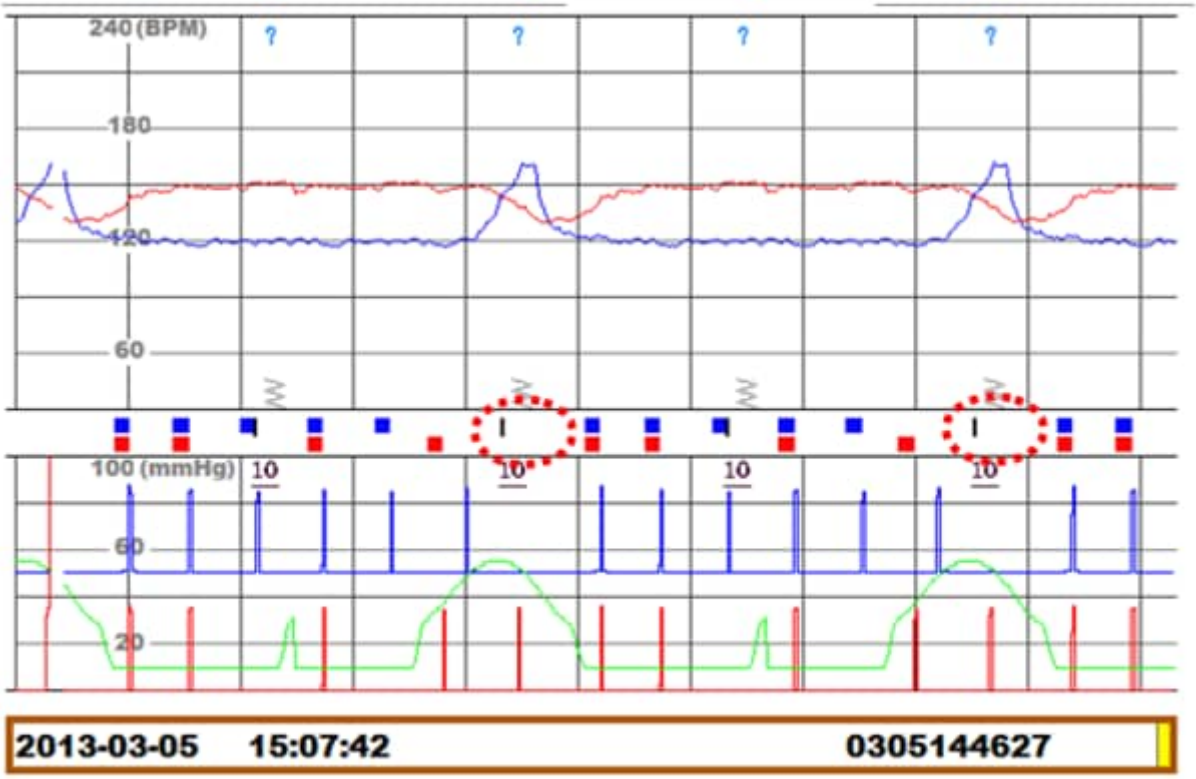
Marker jack:

8.2. Automatic measuring of fetal movements

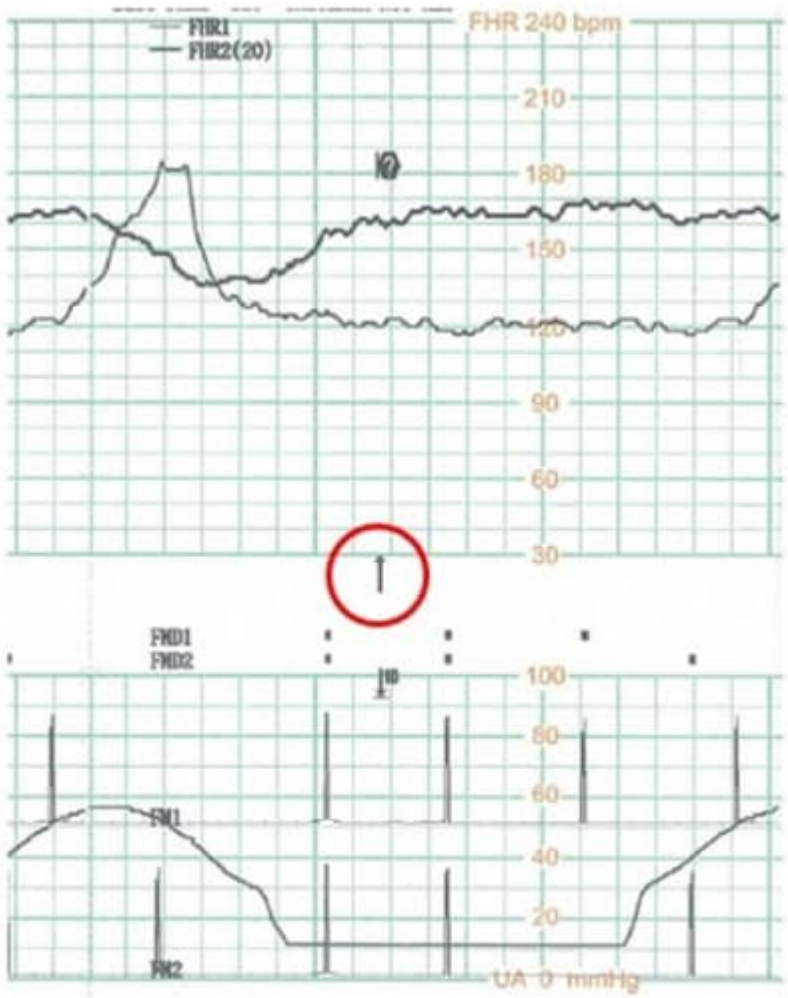
The automatic fetal movement measurements extract information in proportion to the sizes and durations of fetal movement from the received ultrasonic Doppler signals and display the data along with uterine contraction information. In addition, if any of the obtained values is larger than the size threshold of fetal movements that has been set, the values are marked as points in the UC waveform display area. Refer to 6. Measuring the Uterine Contraction Externally on how to set up the threshold.

8.3. Setting the marker jack sound

To turn On/Off the sound of pressing Marker jack, touch the Main Menu -> System -> Marker Sound.



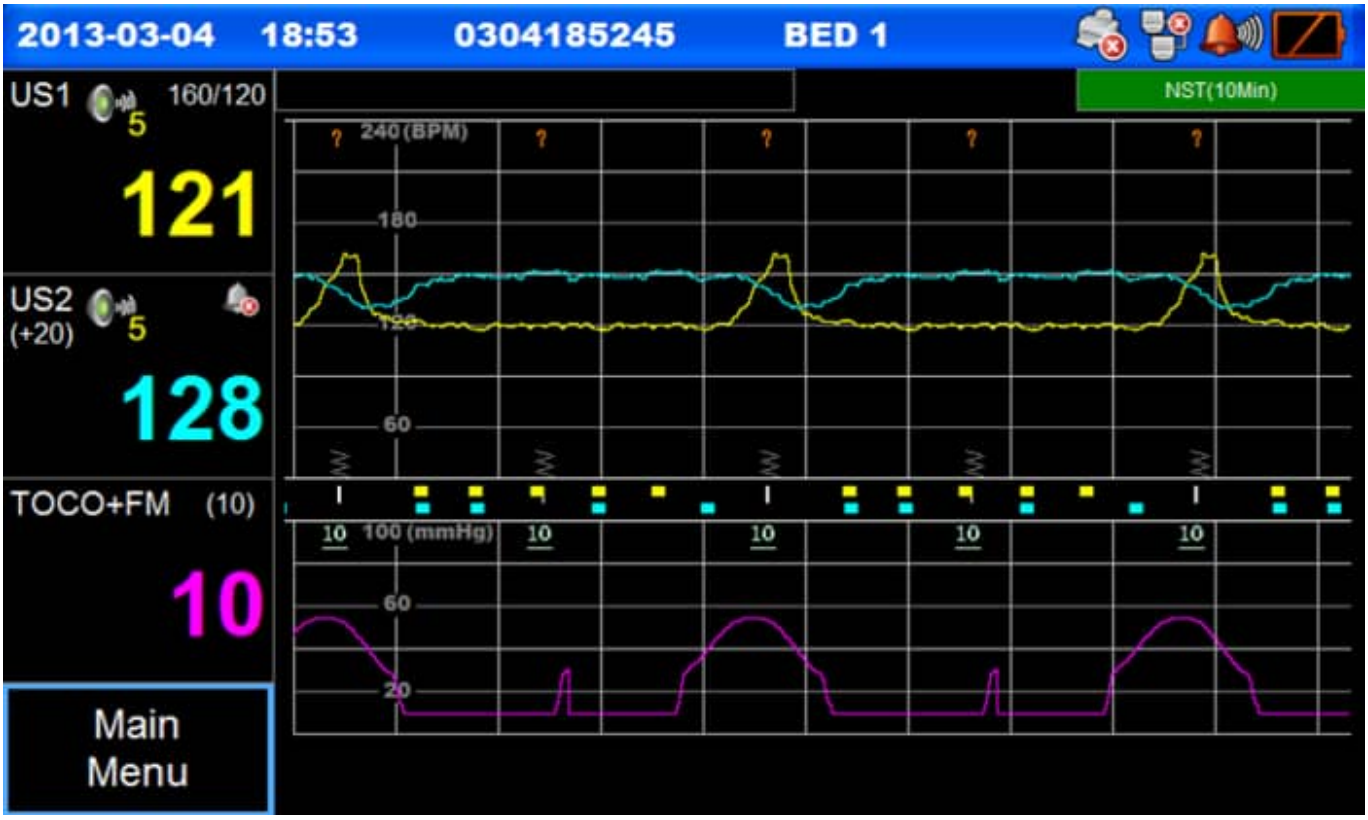
< LCD Display >



< Print out >

9. Connecting the Stimulator

When you connect the stimulator to the connecter and press it, a stimulator symbol appears on the screen.



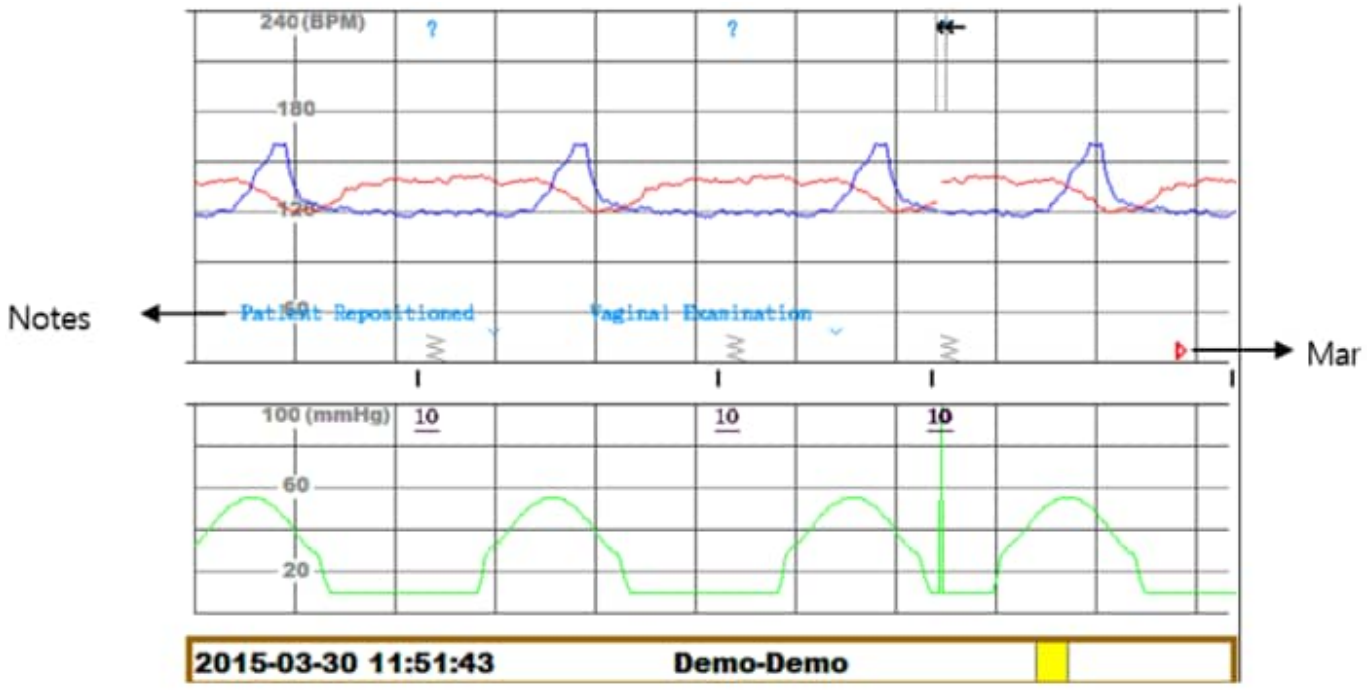
Warning

- The stimulator is not a part of the Fetal Monitoring System. If you wish to use the stimulator, you must use either GE products or GE-compatible products whose stability has been confirmed.

10. Clinical Marks and Notes

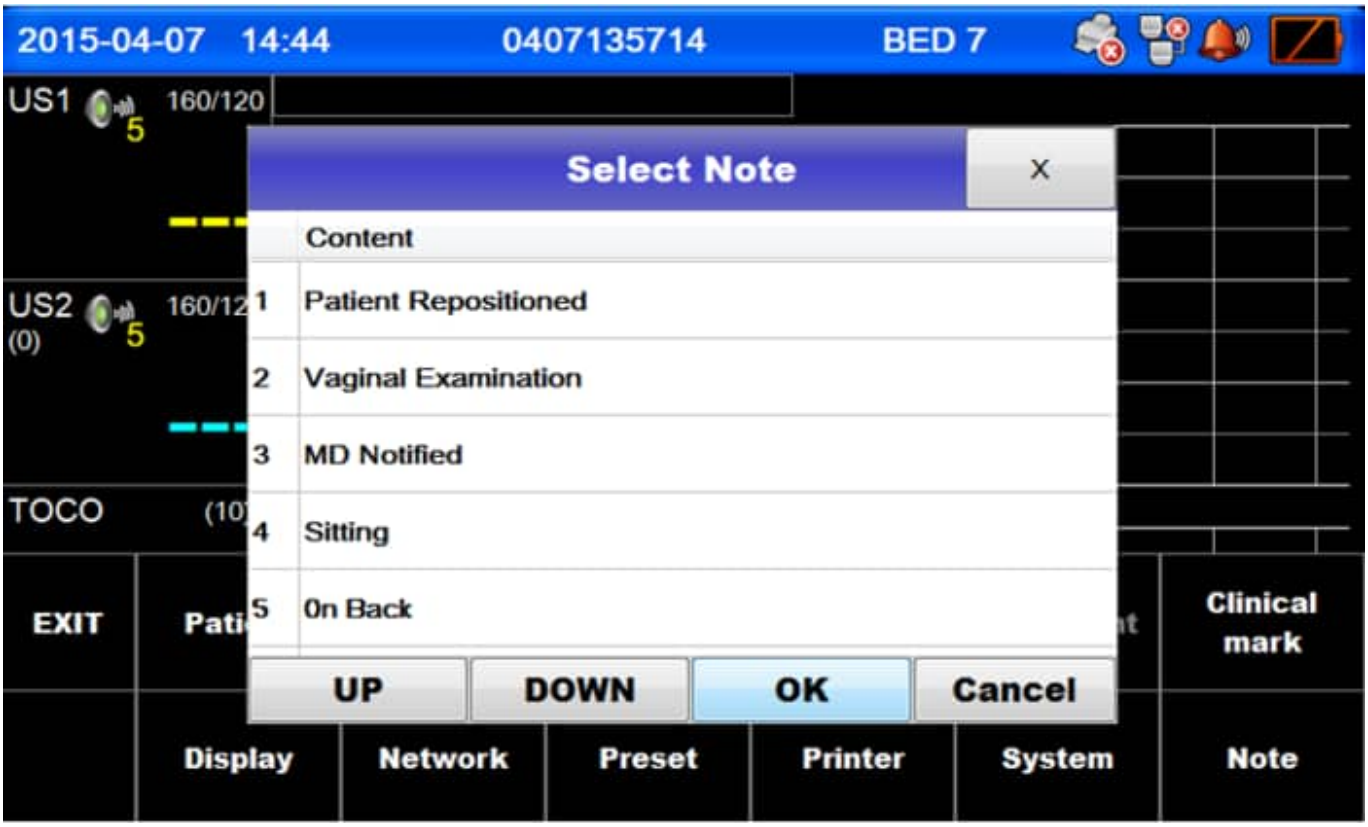
To record clinical mark or notes in real-time, use [Clinical Mark] key. Press the [Clinical Mark] key shortly to display the mark on screen or include it in Trace range printing or real-time printing. The Clinical mark is displayed in Orange triangle on screen as well as in print out.
When you press the [Clinical Mark] key long, Note window pops up. Select one of the lists to include the related information in Trace printing and real-time printing.


: Clinical Mark Key



Entering notes:

When you press the [Clinical Mark] key long, Note window pops up. Touch the applicable item from the list and press [OK] to output the Note text in Trace printing and real-time printing.



Adding notes:

Note lists can be added and edited only by users having Administrator rights. Touch the Main Menu -> System -> Edit Note, enter the admin password, and then use the New/Modify/Delete buttons to set the note to suit your environment.

You can only save up to 100 additional Notes, with up to 40 characters in one Note. If you try to add more than 100 Notes, an error message saying that it cannot be entered is displayed.

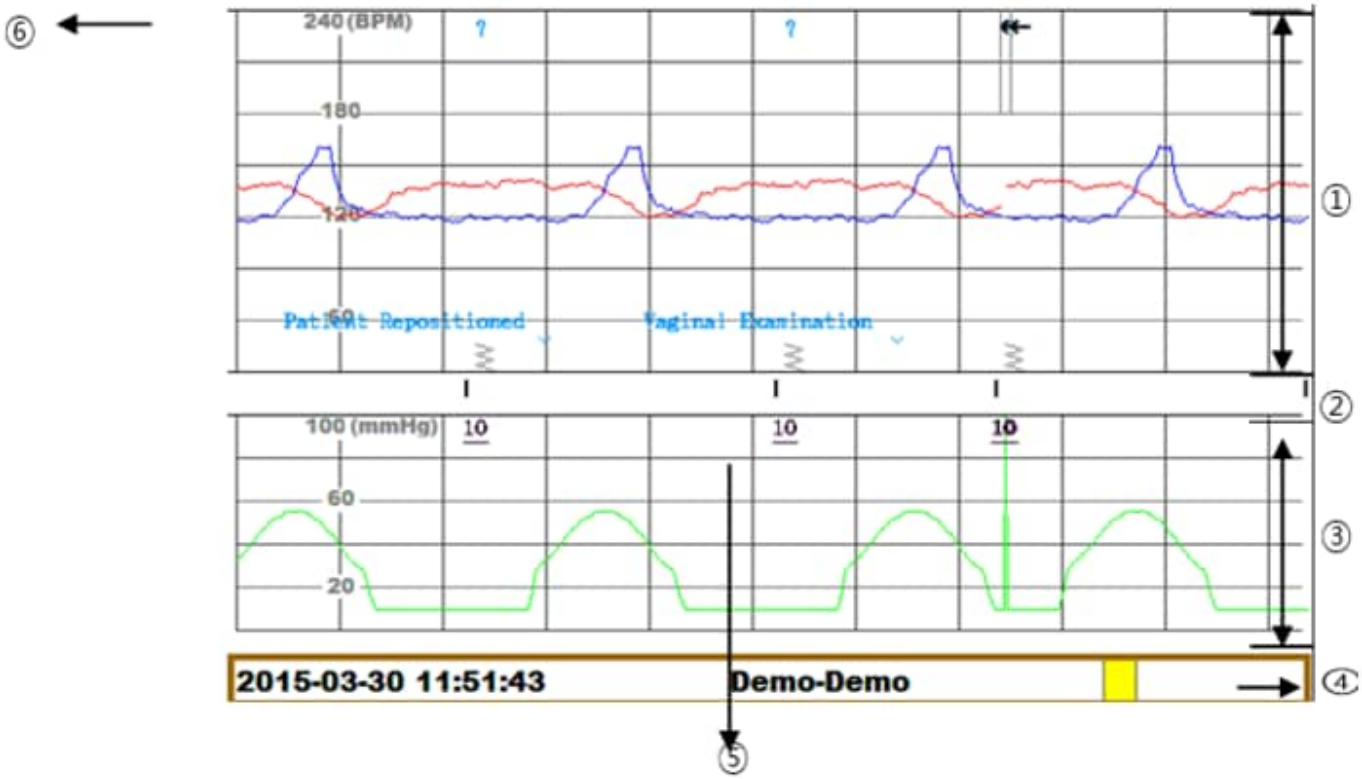
Note

- The preset 15 lists cannot be edited nor deleted.
- For preset password, refer to Chapter 12, Alarm and Preset.

11. Trace

View the saved measurement results using the Trace function. Data measured for 72 hours are saved.

11.1. Trace Area



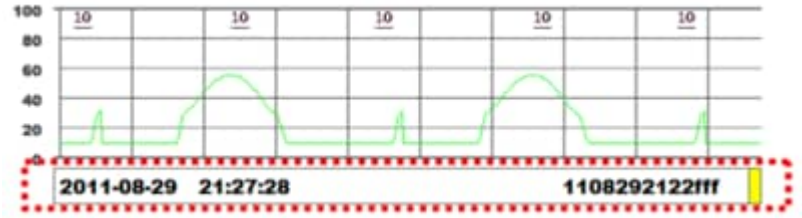
1. This is data in the range of 30 to 240 bpm, and displays the Trace of the heart rate of the fetus.
2. FMD: Automatically detected fetal movements are displayed.
3. TOCO of 0~99 units is displayed. Also, a graph of fetal movement detected by the US is displayed.
4. Scroll bar: Use it to move the Trace point. To navigate, touch the scroll bar or use the volume control key.
5. UC zeroing: It indicates that UC zeroing is done. The number above is the zeroing number.
6. Grid: Grid criteria

11.2. Trace

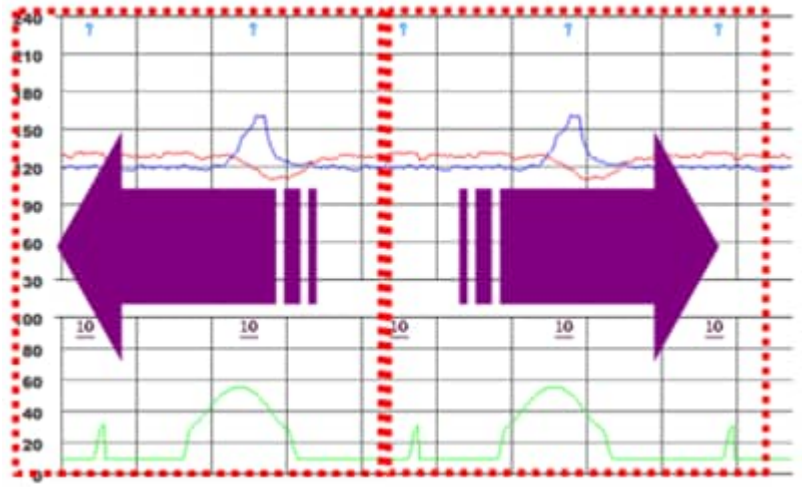
Trace:
To view Trace data, touch [Trace] on the main menu or press the [Trace] key.


: Trace Key

Changing the trace time:
To change the time of the Trace data, move the scroll bar of the Trace, touch the left or right side of the Trace data on the LCD, or use the volume control keys. At the bottom of the Trace screen, date information and patient name of the first Trace are displayed. If there is a Start marker within 30 seconds, the next patient's information is displayed.



By using the Volume UP key, if you press the US1 Volume UP key, the view is moved to 1 min earlier; if you press the US2 Volume UP key, the view is moved to 1 min behind. Also, by using the Volume Down key, if you press the US1 Volume Down key, the view is moved to 6 sec earlier; if you press the US2 Volume Down key, the view is moved to 6 sec behind.



You can drag or touch the LCD screen to move as shown in the arrow above. It moves by one page (approximately 10 minutes) when touched.

Exiting the trace screen:
To view real-time data in Trace screen, touch the [Main Home] in the Trace menu or the [Screen Switching and Function] key on the control panel.


: Screen Switching and Function key

11.3. Trace Menu

Touch the menu in the Trace screen. The Trace menu appears.

EXIT				Data Save	Print Start	Main Home

Saving data:
Save a certain period of data from the Trace to the USB storage device. If you insert a USB storage device into the slot on the back of the monitor, a USB device recognition icon is shown on top of the screen. Once a USB storage device is recognized, the [Data Save] button is activated when you touch the main menu in the Trace.

When you touch the [Data Save] button, data is saved to USB. The first position of the Trace is saved as data image up to 3 hrs within one page. Duration depends on the print speed, 30 min for 3cm/min, 60 min for 2cm/min and 90 min for 1cm/min. If the patient is changed in the meantime, saving is suspended. If there is a Start marker within the first 30 seconds of the first position of the Trace, data is saved from that position. The following window appears, and when the progress bar reaches the end after about 10 seconds, saving is completed and the window automatically disappears.
You can find the data in the \NewFC1400\data path of the recognized storage device. The name of the save file is: `{Patient ID}_{Patient Name}_({Gestational-age})_{Year Month Day Hour Minute Second}.jpg`

Note

- If the patient's ID or name contains special characters, images cannot be created.

Warning

- Remove the USB storage device from the slot only after data saving is completely finished and the Saving data window disappears.
- Do not remove the USB device from the monitor during the data transfer.

Printing:
You can print a certain time of the Trace. Up to 1 hour of data is printed from the Trace position on the current screen. If the patient is changed in the meantime, data until the patient change is printed. If there is a Start marker within the first 30 seconds of the Trace, data is saved from that position.
You can also touch the [Print] key on the control panel to perform the same feature.

Main home:
The Trace mode is terminated, and data is shown on screen in real-time.

Warning

- Trace data is saved periodically by every 1 minute. Thus, up to 1 minute from the end of data may not be saved.
- Additionally, no data is saved if you turn off the monitor within 1 minute of powering on.
- Trace data may be erased after the SW upgrade.

---

12. Printing

FC1400 fetal monitoring device offers 2 kinds of printing: real-time printing and Trace printing. In the printing process, print icon is seen on the right top. There are 2 types of Print icons:
Printing and Not printing.

 : Printing

 : Not Printing

To start or stop print, press the following [Print] key.
To start or stop normal printing, press the key shortly. To accelerate the printing, keep pressing the key. If you take your hand off the key during the accelerated printing, the maximum of 2.5 cm is printed more and

printing stops.


: Print start/stop key

12.1. Real-time printing

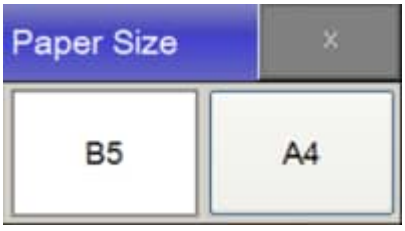
To print currently inputted data, press the [Print] key or touch the [Print Start] in the menu. If any printing is in progress, a print icon is displayed on the upper right side of the screen. To stop printing, press the [Print] key again or touch the [Print Stop] in the menu. When printing in real-time has been stopped, paper is fed in a certain length to facilitate cutting.
Printing in real-time is done in any of three speeds: 1, 2, 3 cm/min.

Changing the speed of real-time printing:
To change FC1400's speed of real-time printing, touch the Main Menu -> Printer. Touch the [Print Speed] in the menu and select the desired speed to change the speed.
Printing speeds is not changed while the real-time printing is in progress. To change the speed, stop the printing first, change the speed, and then resume printing.

Changing the type of printing paper:
To change the type of paper, touch the Main Menu -> Printer. Touch [Scale] in the menu and select the desired type of paper.

Changing the intensity of line:
To change the intensity of print line of paper, touch the Main Menu -> Printer. Touch [Print line] in the menu to change the line intensity.

Changing the size of printing paper:
To change the size of printing paper, touch the Main Menu -> Printer. Touch [Size] in the menu and select the desired size of printing paper between B5 and A4 in the following menu.



Printing the grid line:
To print grid line on the fax paper, touch the Main Menu -> Printer -> Grid. Set the Grid to On to print the grid on the paper.

12.2. Printing the Trace

To print the Trace data, move to the point from which you want to print on the Trace window and press the [Print] key or touch the [Print Start] in Trace menu. The Trace is printed up to the next measurement or up to 1 hour. The Trace printing speed is 30cm/min(when NST print speed is 2cm/min or 3cm/min) or 20cm/min(when NST print speed is 1cm/min).

12.3. Loading the Paper

If there is no paper during printing, No paper alarm occurs. In that case, load paper or press [Alarm silence] key to release the alarm. To load the pater, open the printer cover by pushing back the Printer cover open lever on the right side of the monitor, and load paper with printable side up and close the cover.

12.4. Registering hospital name

To register hospital name on printing paper, touch the Main Menu -> Printer -> Hospital.

13. Alarm and Preset

Alarms are largely divided into patient condition alarms and product condition alarms(INOP Alarms).

13.1. Patient Condition Alarms

Patient condition alarm occurs when the value exceeds the maximum and minimum limit values for alarms.
There are two levels of alarms: Medium and Low, which differ in terms of the order of ringing and volume.
Medium alarms are shown as ** on the alarm list when they occur, and Low alarms, as *.
The FHR alarm occurs when the value is out of the normal range during the set Alarm Delay time.
If more than one alarm sounds, alarm messages appear successively on the alarm condition window.
If two or more alarms occur, the alarm at the highest level will sound. If an alarm has already occurred, it will sound at the previous level even if you change its level. To immediately apply the alarm to the changed level, turn it off and on to trigger the alarm again.

MEDIUM	A low-pitched sound will be repeated three times and paused for a while.
LOW	A low-pitched sound will be repeated two times and paused for a while.

13.2. Product Condition Alarms

Product condition alarms are used to indicate that FC1400 is not operating properly and its capability of detecting the dangerous conditions of the patient is not reliable.
Alarms include those related to connector connection and technical alarms such as FHR disappearing, No paper, and Battery Low.

"Ding-dong"	When the connector is being disconnected
Technical Alarm	A low-pitched sound is repeated one time and paused for a while.

Alarm Level	Volume	Alarm Interval	Beep Rate	Sound Pressure level[dB]
Medium Level	1 step	Every 8 sec	3 beeps	46.2 ~ 53.1
Low Level	1 step	Every 8 sec	2 beeps	46.1 ~ 53.0
Medium Level	5 steps	Every 8 sec	3 beeps	63.4 ~ 68.2
Low Level	5 steps	Every 8 sec	2 beeps	63.1 ~ 67.6

Note

- High-priority alarms indicate that immediate operator response is required. Low-priority alarms indicate that operator awareness is required.

13.3. Visual Alarms

Alarm messages appear in the Alarm State window on the screen. If more than one alarm occur, messages are changed every 2 seconds. The * marks of the alarm messages match the level of the alarm. Medium Alarms are marked with **, Low Alarms with *, and product condition alarms with none.
When a patient condition alarm occurs, the color of the numerical value in the numeral window is changed to red.
Visual Alarms are maintained even after you change the alarm state into Alarm Silence or Alarm Pause.
No Paper and Battery Low alarms are displayed in the alarm state window.

Visual alarm		
Alarm priority		LED Flashing Duty Cycle
PATIENT CONDITION	MEDIUM	** Indicates Medium Alarms
		Yellow LED; Flickers once a second
	LOW	* Indicates Low Alarms
		Yellow LED; Stay on
PRODUCT CONDITION		Green LED; Alarm occurs due to technical alarm and stays on.

13.4. Alarm LED

There are two types of Alarm LED around the exterior of the monitor to help checking the alarm condition from a distance.

- Yellow LED: An alarm occurs due to patient condition.
  - Medium Alarm: Flickers once every second.
  - Low Alarm: Stays on.
- Green LED: An alarm occurs due to Technical Alarm and stays on.

13.5. Audible Silence and Pause

When various alarms occur during the operation, use this function to silence or pause them to verify the message.
Press the [Alarm Silence] key once to sound off(Silence) for 1 minute. If a new alarm occurs during the Silence operation, alarm sound will ring again.
Press the [Alarm Silence] key twice to make the alarm in pause state for 5 minute. In Pause state, no alarm will sound even if a new alarm is generated.
If you press the [Alarm Silence] key 3 times, sound alarms are turned off and no sound will be made even if a new alarm occurs. Visual alarms are displayed until the situation is resolved. To mute the alarm, touch [Alarm Silence] key on the operational panel.

 : Alarm Silence key

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Warning

- When monitoring patient conditions, do not rely solely on audible signals. Reducing or turning off the volume of audible signals may endanger the patients.

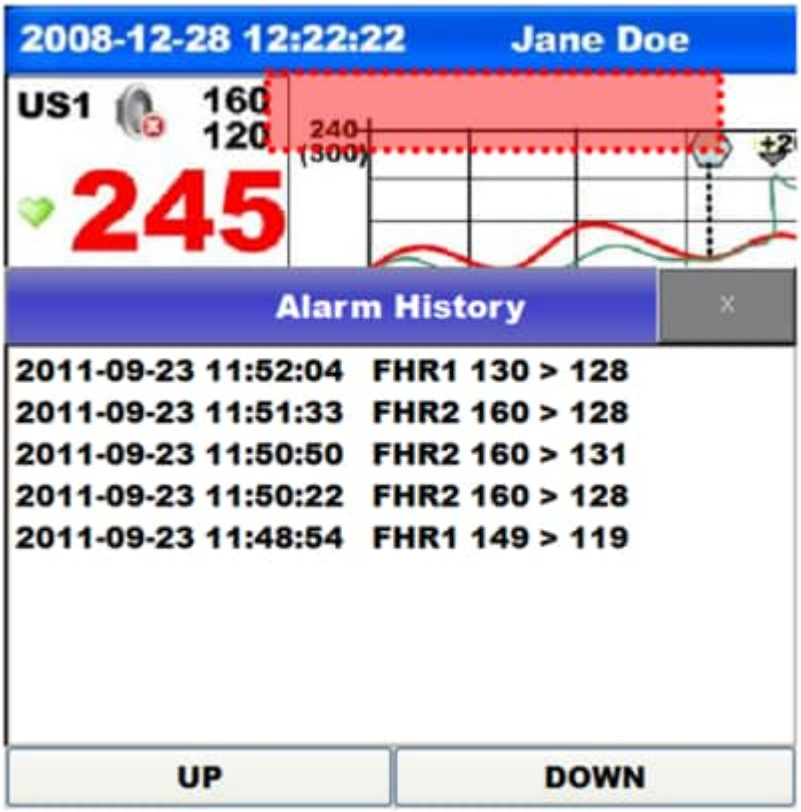
13.6. Alarm Latching

Audible alarms continue to ring until you take an appropriate action and the situation is resolved. Once you take measures and the alarm situation is over, both audible and visual alarm disappear.

13.7. Alarm History

You can check the history of alarms that occurred to the patients. Touch the Main Menu -> Alarm History in the alarm message area to view the alarm history window. If you admit a new patient or change to another

patient, the Alarm History is cleared.



13.8. Preset

Preset values are those loaded by default on system rebooting, which can only be changed by an administrator. Volume adjusting applies to current patient only, and when you restart FC1400 or use it for another patient, it operates using the preset values. However, if you turn it on within 30 seconds after abnormal shutdown, the previous setting value is maintained assuming that it is still registered with the same patient.
Preset consists of alarm volume, alarm function usage, alarm range, alarm level, alarm delay time, US1 Volume, and US2 Volume.
To set Preset, touch the Main Menu -> Preset.
As Preset is accessible only by an administrator, you need a password in order to enter the menu.

Warning

- The initial Preset password in Factory mode is 1234. Change the Preset password after installing FC1400 to avoid unauthorized access. To change the Preset password, touch the Main Menu -> System -> Change PW and enter password.
- Be aware, when the changed password is lost, the only way to reuse FC1400 is initializing it to factory mode. On initializing, all data will be removed. Make sure to keep the password safe.

13.9. Adjusting Alarm Volume

You can adjust the Audible Alarms volume to 1 ~ 5 levels or Off.

1. Touch the Main Menu->Preset->Alarm Volume.
2. Select the desired volume on the popup window.

3. Check if the current alarm volume is displayed on the alarm icon on the screen.


: Alarm Volume condition icon Off, levels 1 ~ 5


: Alarm off icon. Turn off the alarm(Off).


: Alarm Silence


: Alarm Pause

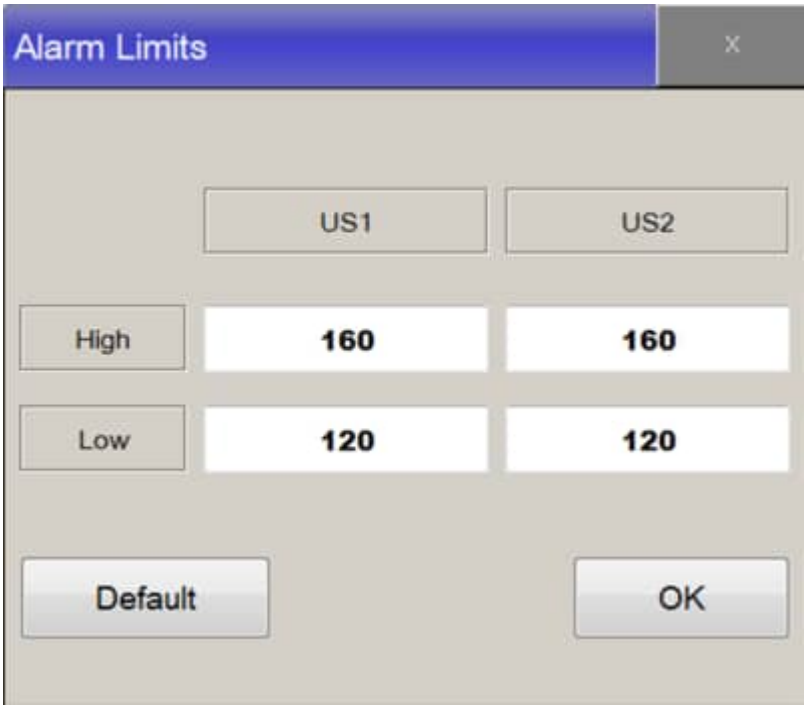
13.10. Setting All Alarms ON/OFF

You can activate or deactivate alarm for each parameter. Touch the Main Menu -> Preset-> Alarm On/Off and set the condition by pressing the button in Alarm Parameter window. To apply default values, select the [Default] button and press [OK]. For default values, see 19. Product Specifications.

13.11. Setting Ranges of All Alarms

You can set the alarm range for each parameter. Touch the Main Menu->Preset->Alarm Limit and set the alarm range for each parameter in the Alarm Limit window. To apply default values, select the [Default] button

and press [OK].



13.12. Setting Levels of All Alarms

You can set the alarm level for each parameter. Touch the Main Menu->Preset->Alarm Level and set the alarm level for each parameter in the Alarm level window. To apply default values, select the [Default] button and press [OK].

13.13. Default Setting

You can set default values in Alarm Parameter, Alarm Limit and Alarm Level. Touch the Main Menu -> Preset -> Default Setting to apply default values in the Preset settings. For default values, see 19. Product Specifications.

Note

- When using the monitor through FC central, all setting values are synchronized once you are out of the main menu and parameter window.

13.14. Signal Loss Alarm

Signal Loss Alarm occurs when FHR is lost for a certain period.

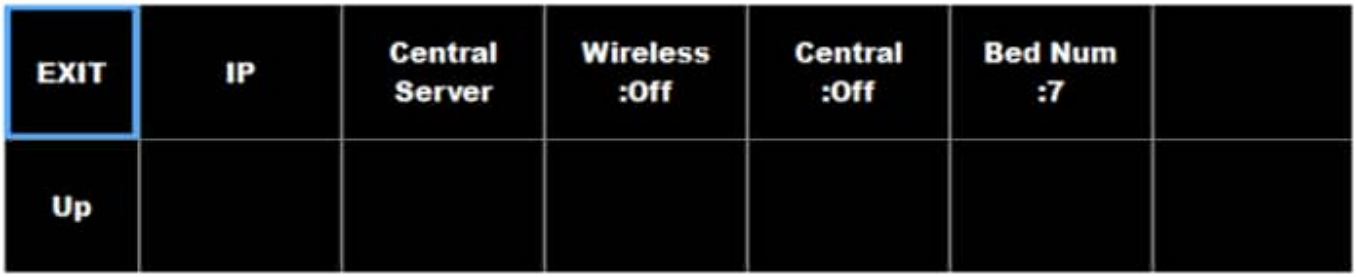
- 100 % Signal loss: Absent FHR for last 75 seconds.
- 70 % Signal loss: Less than 30% acceptable FHR for last 5 minute.
- 65 % Signal loss: Less than 35% acceptable FHR for last 10 minute.

The alarm is displayed as a Product condition alarm.
The signal loss alarm is enabled/disabled on the US1 and US2 menu.

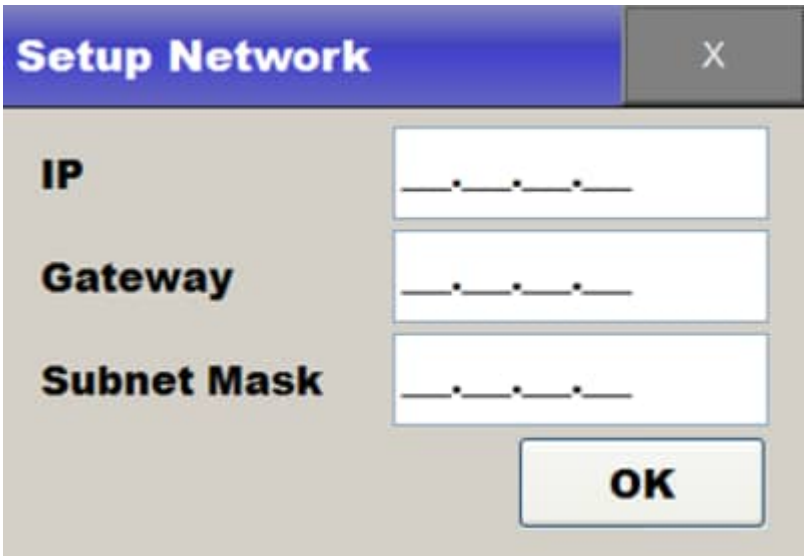
14. Network

14.1. Setting Network

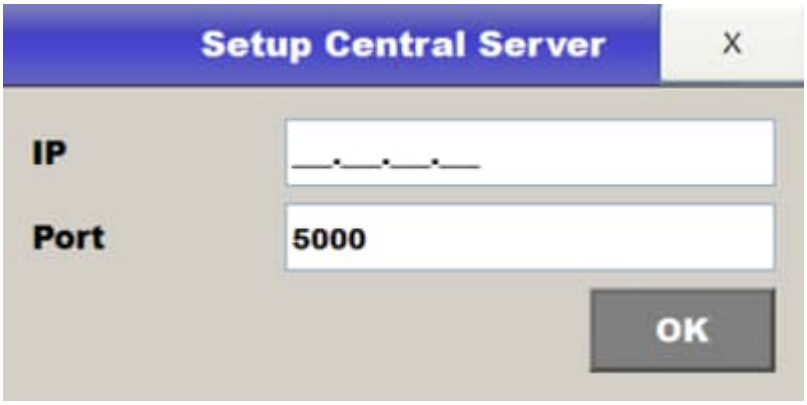
To set up a network, touch the Main Menu -> Network. There are 5 setting criteria.



IP: Monitor network information



Central IP: Central server information



Enter the IP of the PC where the remote PC(central) program is installed, with fixing the Port to 5000.

Wireless setting:
If using the Wireless LAN, insert the wireless LAN module into the USB slot on the rear side, and touch the Wireless menu to set it to On. Set Central to ON. When the both menu above are set to ON, the wireless LAN function is activated and network menu configuration looks different that appears when you touch the IP button. When the wireless is Off, the network is connected using wired LAN configuration. For more information about FC Central network configuration using wireless, refer to the FC Central Installation Guide.

Setting Central:
If setting Central to On, you can connect the monitor to the Central. If you set it to Off, the connection is terminated.

Warning

- Before setting the Wireless and Central to ON, check the Wireless LAN module is properly installed in the monitor. Wireless is not selectable unless it is well recognized.
- VLAN Network:
  - If data is exchanged within a single network, an independent VLAN network for the clinical information system must be established.
  - A network system that detects and defends against denial-of-service attacks must be established through the installation of equipment dedicated to DDos defense.
  - When using wireless, ensure a proper AP security; if it not available, a wired connection is recommended.

Mandatory

- DO NOT remove the USB storage device until it is recognized completely.

Changing the bed number:
To change the bed number, which is required for monitor identification, touch Bed No. in the setting menu.
You can select the number from 1 ~ 16

Note

- Wireless AP's ID are recognized only if it consists of alphanumeric characters.

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15. General Settings

Go to System in the main menu to define the general settings.

The menu of the system is as follows:

15.1. Changing the Date

To set up a date, touch System -> Date.

15.2. Changing the Time

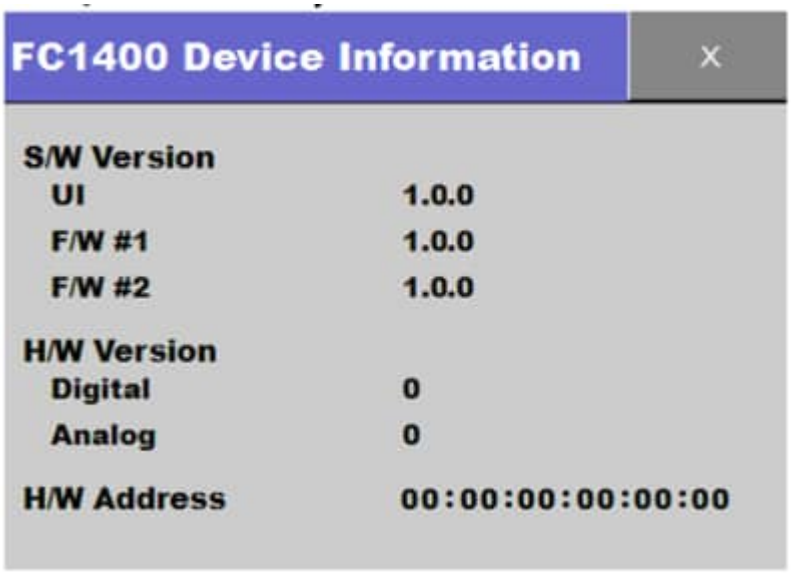
To set up time, touch System -> Time.

15.3. Changing the Language

To set up language, touch System -> Language.

15.4. Checking the System Version

To check the version of the system, touch System -> Version.



- S/W Version: Software Version
  - UI: Version of UI software
  - F/W #1 : Version of fetal module firmware
  - F/W #2 : Version of printer module firmware
- H/W Version: Hardware Version
  - Digital : Digital board version
  - Analog : Analog board version
- H/W Address : Mac Address

15.5. Changing the Touch Tone

To change the volume of touch sound, touch System -> Touch Tone. Set Off or select 1 ~ 5.

15.6. Demo Operation

To operate FC1400 in the demo mode, touch System -> Demo and set it to On.

15.7. Editing Note

Touch it for New/Edit/Delete of Note list. This function can be only used by an administrator. When correct Preset password is inserted, setting window pops up. For more information, see 9. Clinical Marks and Notes.

15.8. Marker Sound

Touch it to turn On/Off the sound when clicking a Marker. For more information, see 7. Measuring Fetal Movement.

15.9. Factory Mode

Only the administrator can enter the Factory mode. In order to change the item, request for a service to Bionet Headquarter or its representative.

15.10. Changing Admin PW

Change Admin password in this menu.
At first, enter the current Admin password correctly. Once it is confirmed, you can proceed to change it by entering a new and confirm password.
The default Admin password is 1234.

Warning

- Admin password cannot be recovered after a change. If password is lost, reset to Factory mode is the only way to reuse FC1400, and all the measured data and set values will be lost.
- Make sure to keep the password safe.

15.11. Volume Range

Use this menu to change volume range. 7 is the loudest and 0 is the quietest volume.

15.12. Screen Output Mode

The screen supports two output modes: Graphic Mode and Text mode. To change a screen output mode, touch the [screen switching and function] key on the control panel in the main menu.

 : Home and function key

15.13. Protocol Version

Set the version of protocol according to the version of FC Central. To use Note function in FC1400 and have it synced to FC Central, select protocol version 1.2 and FC central version 1.2.2 or higher.

16. Non Stress Test(NST)

The Non-Stress Test Timer measures the NST time that passed. You can print the only the data measured during a certain period of time.

16.1. Measuring NST

Starting NST:
Press the [Print] key to start NST. When the set NST time has passed, alarms will sound to indicate the NST is over. To mute the NST ending alarm, touch the [Alarm Silence] key on the control panel.

Ending NST:
Press the [Print] key again to stop the NST even if the NST measurement time is not over. The printing stop as well.

16.2. Setting NST

Touch the Main Menu -> Setting -> Printer-> NST causes the following setting window to pop up.

NST Duration:
Set the NST duration. Select OFF, 10, 20, 30, 40, 50, 60, and 90 min.

17. CTG

CTG is FC1400 fetal monitoring device' interpretation about the Cardio-TOCO Gram. The analysis begins with the data collected from that moment when you press the [Printer] button.

17.1. Setup

Setting CTG:
Touch the Main Menu -> Printer -> CTG. Set the CTG Print to On to print out the CTG result.

Turning off CTG:
Touch the Main Menu -> Printer -> CTG. Set the CTG Print to Off.

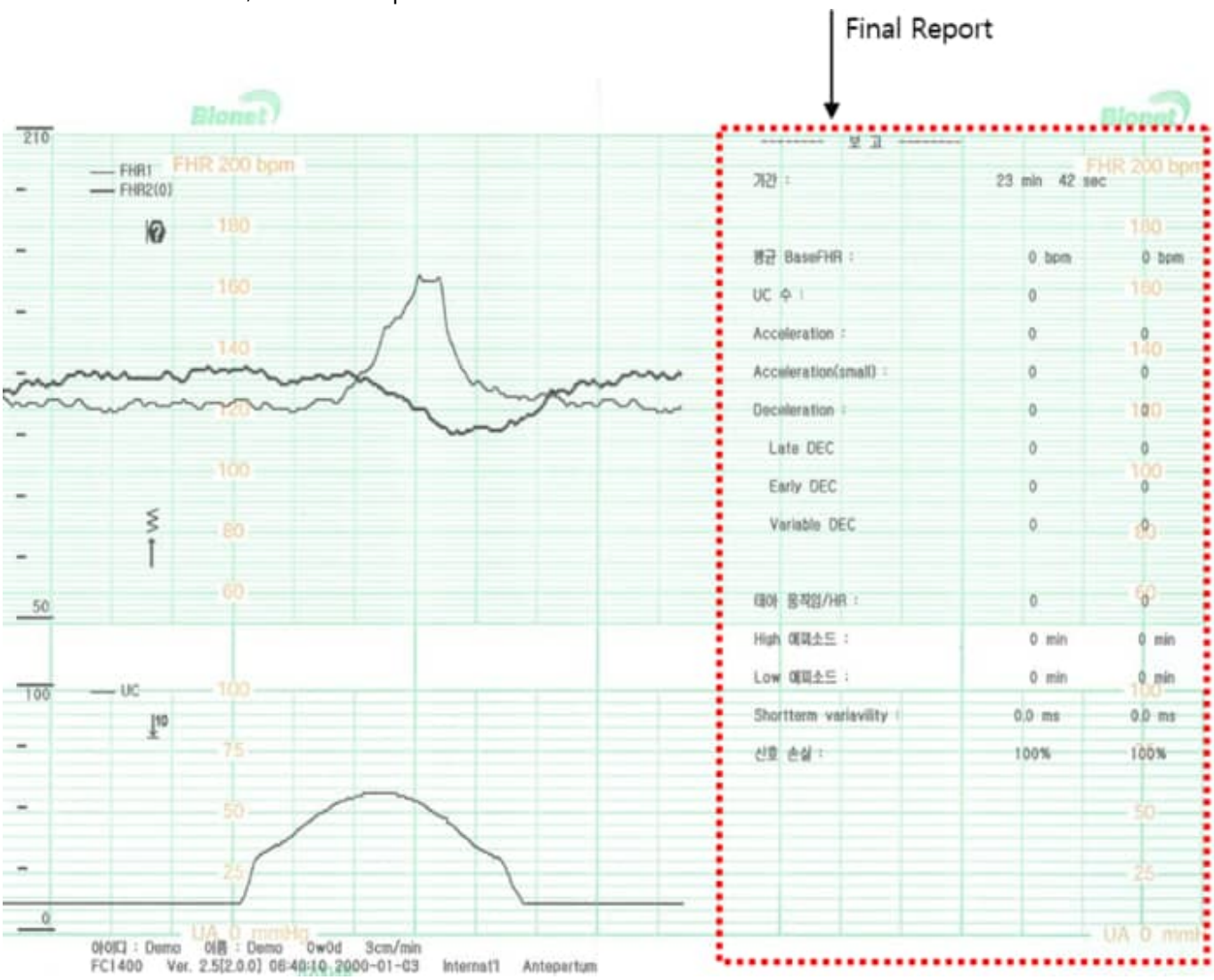
17.2. Printing CTG

Starting CTG:
CTG analysis starts when you start the real-time printing. The CTG analysis result requires equal to or more than 10 minutes printing.

Stopping CTG:
When you stop the real-time printing, the CTG final result is printed after 5 seconds. To print out CTG final result, you have to measure data at least 10 minutes.

17.3. CTG Measurement results

After CTG is measured, the result is printed out as below.



17.4. Glossary of CTG Terms

Base FHR/Average BaseFHR:
Excluding constant or irregular FHR, significantly changed FHR, or sections where the difference from the baseline exceeds 25 bpm, it must run over 2 minutes in increments of 5 bpm with an average FHR value over 10 minutes.

Number of UC:
It is number of uterus contractions during measurement.

High Episode/Low Episode:
If the changing width of the last 5 minutes is less than 30msec, it is a Low Episode, and if it is more than 32ms, it is a High Episode.

Short Term Variability:
Short Term Variability(STV) is the beat-to-beat differences between consecutive heart beats. If the value of STV is 2.6 ms or less, carefully monitor the condition of the fetus and perform additional tests if the fetus is judged to be in critical condition.

Acceleration:
It is visually apparent increase(onset to peak is < 30sec) of FHR above baseline. Peak is ≥ 15 bpm. Duration is

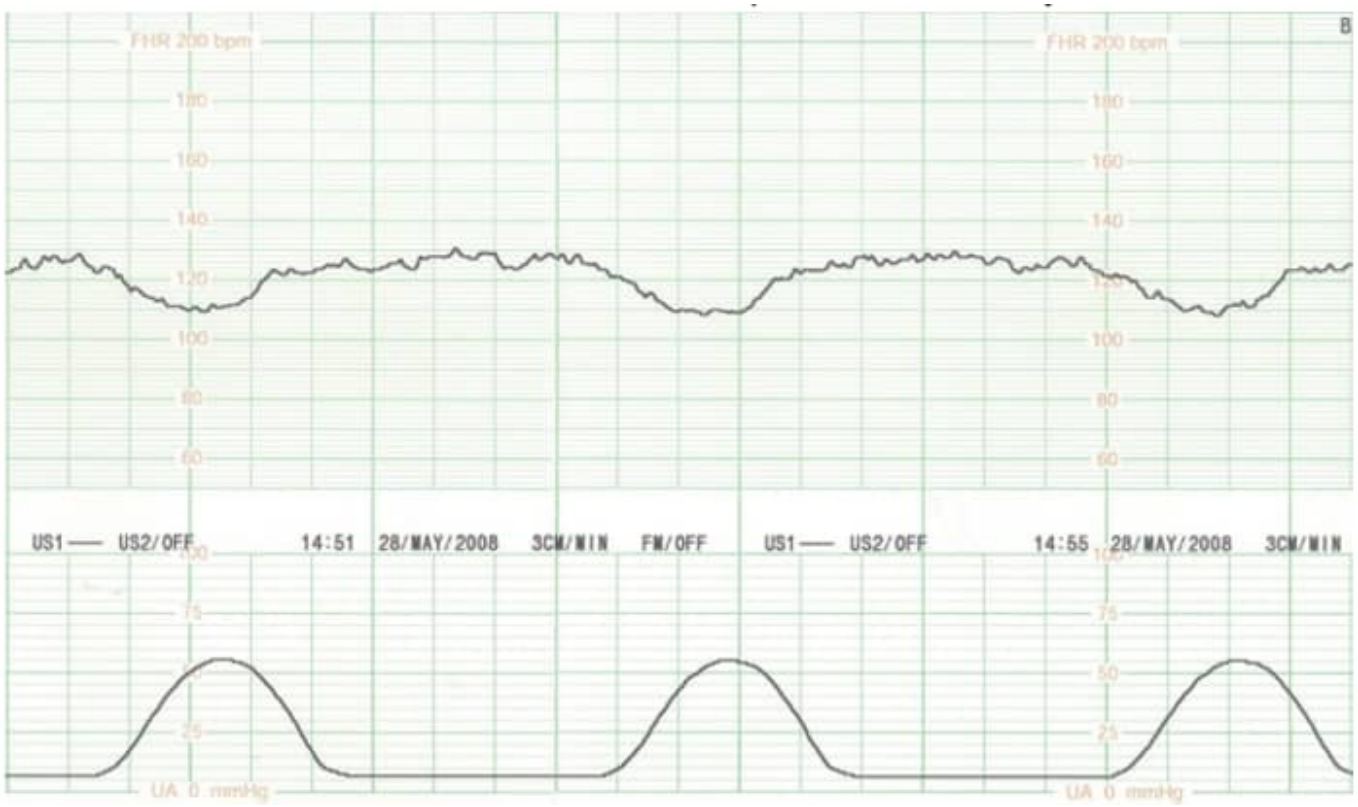
≥ 15 sec and < 2 min.

Smaller Acceleration:
It is visually apparent increase(onset to peak is < 30sec) of FHR above baseline. Peak is ≥ 10 bpm and < 15 bpm. Duration is ≥ 15 sec and < 2 min.

Late Deceleration:
It is visually apparent gradual decrease(onset to nadir is ≥ 30 sec.) of FHR below baseline. Return to baseline is associated with a uterine contraction. Nadir of deceleration occurs after the peak of the contraction. Generally, the onset, nadir and recovery of the deceleration occur after same time as the onset, peak, and recovery of the contraction.

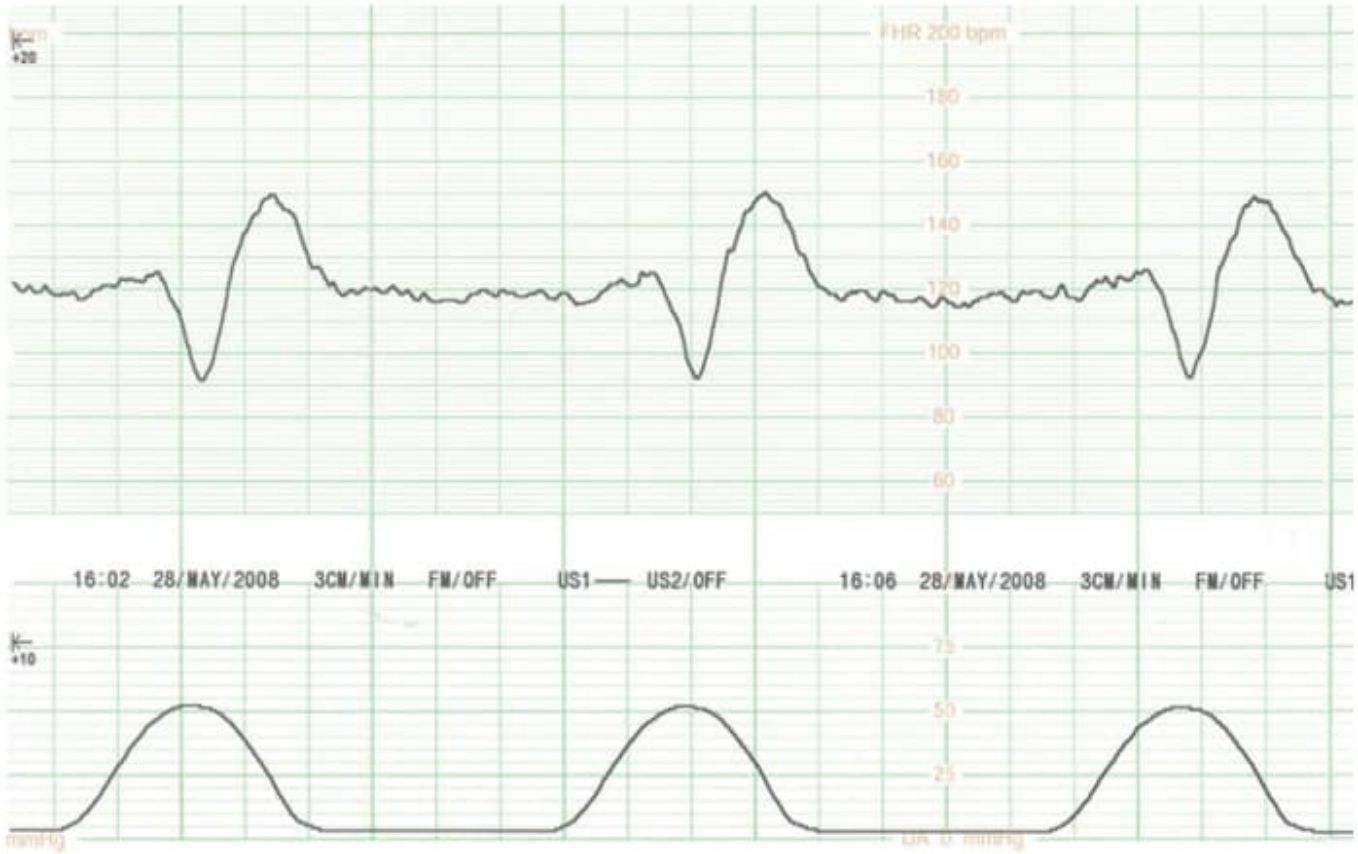
Early Deceleration:
It is visually apparent gradual decrease(onset to nadir is ≥ 30 sec.) of FHR below baseline. Return to baseline is associated with a uterine contraction. Nadir of deceleration occurs at the same time as the peak of the contraction. Generally, the onset, nadir, and recovery of the deceleration occur at the same time as the onset,

peak and recovery of the contraction.



Variable Deceleration:

It is visually apparent abrupt decrease(onset to nadir is < 30sec) in FHR below baseline. Decrease is ≥ 15 bpm. Duration is ≥ 2 min and < 10 min.



Fetal Movement per Hour:

Fetal movement - Indicates the fetal movement as a number of times per hour.

18. Message List

18.1. Patient Alarms

Short Msg	Figure Msg	From
FHR* Medium	FHR* xxx < yyy	FHR*
FHR* LOW	FHR* xxx>yyy	FHR*

18.2. Technical/INOP Alarms

Short Msg	Figure Msg
No Paper	Main
Low Battery	Main
Signal Loss	FHR* 100% Signal Loss FHR* 70% Signal Loss FHR* 65% Signal Loss

19. Maintenance

19.1. Troubleshooting and Solutions

1. If the probe comes off during operation, a “---” sign is displayed, and a “Ding” sound is heard. In that case, check the probe's connection condition and connect it again.
2. If paper has run out during operation, a No Paper sign is displayed on the LCD screen In this case, open the printer, check if the recording sheets have run out, replenish the record sheets, and close the printer.

Warning

- If Touch is not calibrated properly, FC1400 may not operate properly. You must calibrate the touch input as written in the operation manual.

19.2. Performing Periodic Inspections

Just like all kinds of medical equipment, conduct safety inspections on FC1400 periodically(once a year). Refer to the service manual provided by Bionet for inspection items.

19.3. Cyber Security Issues

If equipment is stolen or lost, immediately report it to the hospital staff or manufacturer. Upon receipt of a report, the hospital network administrator must take measures to prevent the equipment from accessing the

hospital network.
If a cyber security threat is detected while using the equipment, immediately disconnect it from the network and contact the hospital staff or manufacturer.
※ For manufacturer contact information, refer to the table of contents of How to Contact Us.

19.4. Maintenance, Cleaning and Equipment Connection

Although FC1400 fetal monitoring system and its accessories can be cleaned in many ways, please use the methods recommended below to avoid unnecessary damage to or contamination of them.
If any dangerous material other than those designated for cleaning has been used, the resulting contaminated or damaged monitor or accessories will not be repaired free of charge even during the warranty period.
Make sure that the monitor, probe, cable, and accessories are free of dirt or dust. Carefully check them after each cleaning or disinfection. If degeneration or damage has been found, do not use the them.
Please take note of the following:

- Be sure not to leave any cleaning/disinfecting chemical residue on the surface of the monitor and accessories. After allowing sufficient time for the chemical to work, wipe off all residues with a cloth damp with water.
- Prevent any fluid from seeping into the monitor, module, or accessories.
- The monitor, module, or accessories should not be soaked in any fluid; protect them from water drops or prevent water from being splashed on them.
- Never use any abrasive material (steel wool or silver polish).
- Never use any bleaching agent.
- Do not use any kind of drying equipment such as heater, oven (including microwave oven), hair dryer, or heating lamp.

Note

- After cleaning, carefully check the monitor and the probe.

Cleaning Components – Probe, electric cables ,and lead wires

Note

- Do not use acetone or ketone solvents for cleaning.
- Do not use an autoclave or steam cleaner.
- Do not mix the cleaner with any disinfecting solution as toxic gases may be produced.
- Turn off the power before cleaning; do not pour water into the components being cleaned.

All probes must be cleaned and disinfected before and after each use. Use a soft cloth or appropriate cleaning sheet, lightly dampened with Isopropyl alcohol (or proper cleaner), to remove any foreign substances left on the probe, the edges, corners, and curved parts of the probes. Dry the probe with a clean, soft cloth. Alternatively, dampen a soft cloth in a glutaraldehyde-based hospital disinfectant solution such as Cidex. Wipe the probe with a dampened cloth. If still wet or left with a stain, wipe with a clean water-dampened cloth. Before use, dry the probe completely with clean, soft cloth.
Event marker should be cleaned and disinfected before and after each use. Use a soft cloth or appropriate cleaning sheet, lightly dampened with Isopropyl alcohol (or proper cleaner), to remove any foreign substances left on the switch and handle of event marker.
Electric cables and lead wires can be wiped off or cleaned with towels wet with lukewarm water, neutral soap, or isopropyl alcohol. Using ethylene oxide for intensive disinfection (almost complete sterilization) is allowed. Note, however, that it will reduce the lifetime of cables or lead wires. Clean the belt using soap and water while making sure that the water temperature does not exceed 60°C.

Note

- The decision to sterilize must be made per your institution's requirements with an awareness of the effect on the integrity of the cable or lead wires.
- FC1400 needs safety inspection once a year. Refer to this operation manual or service manual for inspection items.

After cleaning, carefully inspect the monitor and sensors. Do not use them if they have been damaged or deteriorated.
Clean the exterior of the monitor at least once a month using soft cloth wet with tepid water or alcohol. Do not use lacquer, thinner, ethylene, or any oxidizing agent that may cause damage to it. After verifying that there is no dust or contamination on the cables and accessories, wipe them off with soft cloth wet with 40˚C/104˚F water. Wipe them at least once a week using clinical alcohol.

Note

- There is back-up battery on board inside FC1400.
- Please dispose of it according to all local regulations.

Warning

- Before changing battery, remove the AC power and check the electrodes of the battery.

If the installation or arrangement of the external grounding wire is doubtful, operate FC1400 with internal power.
If FC1400 is not used for a certain period, remove the backup battery to avoid any safety hazard.

Note

- Annual Servicing:
    - For continued safety and performance of FC1400, it is recommended that its calibration, accuracy, and electrical safety be verified on an annual basis by a Bionet Service Representative.
- Daily Testing:
    - It is essential that FC1400 and its accessories be inspected every day. It is recommended practice to initiate its self-test feature at the beginning of each monitoring session; follow the instructions in 1 and 2.

Mechanical hazard

Warning

Ultrasound probes are highly sensitive medical instruments that can easily be damaged by improper handling. Use with care when handling and protect from damage when not in use.

- DO NOT use a damaged or defective probe.
- DO NOT drop the probes or subject them to other types of mechanical shock or impact. A defective probe or excessive force can cause patient injury or probe damage:
- Observe depth markings and do not apply excessive force when inserting or manipulating intercavitary probes.
- Inspect probes for sharp edges or rough surfaces that could injure sensitive tissue.
- DO NOT apply excessive force to the probe connector when inserting into the probe port. The pin of a probe connector may bend.

Biological hazard

Warning

To avoid the risk of disease transmission:

- Must use protective barriers (gloves and probe sheaths). Follow sterile procedures when appropriate.

- Thoroughly clean probes and reusable accessories after each patient examination and disinfect or sterilize as needed.
- Follow all infection control policies established by your office, department or institution as they apply to personnel and equipment.

Electrical hazard

Warning

- In case Gel contacts internal electronic device, defective probe may cause electrical shock.
- Prior to each use, visually inspect the probe lens and case area for cracks, cuts, tears, and other signs of physical damage.
- DO NOT use a probe which appears to be damaged until you verify functional and safe performance.
- Perform a more thorough inspection, including the cable, and connector, each time you clean the probe.
- DO NOT kink, tightly coil, or apply excessive force on the probe cable. Insulation failure may result.
- To avoid risk of electric shock, this equipment must only be connected to a supply main with ground
- Do not modify this equipment without authorization of the manufacturer
- If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- Do not touch signal input, signal output or other connectors, and the patient simultaneously.
- Refer servicing to qualified personnel of Bionet Co., Ltd.
- Power supply is specified as a part of ME Equipment.

Probe acoustic output hazard

Warning

- Ultrasound can produce harmful effects in tissue and potentially result in patient injury. Always minimize exposure time and keep ultrasound levels low when there is no medical benefit.

Probe head: Waterproof

Mandatory

- From US probe bottom to 2~3 cm, waterproof IPX is possible. Do NOT immerse the probe bottom into any liquid beyond 2~3 cm from probe bottom. Never immerse the probe connector into any liquid.

19.5. General Precautions on Environment

DO NOT store or operate the equipment in the places listed below:

- A place exposed to moisture(DO NOT touch the equipment with wet hands).

- A place in areas with highly fluctuating temperatures.

- A place with excessive humidity rise or poor ventilation.

- A place exposed to chemicals or at risk of gas leakage.

- DO NOT disjoint or disassemble the equipment(Bionet is not liable for broken products caused by attempted disassembly).

- A place under direct sunlight.

- A place in the vicinity of Electric heater.

- A place with sources that cause excessive shock or vibration.

- Avoid the invasion of small objects/ particles such as dust, and especially avoid metallic material.

- DO NOT connect power until the product is completely installed. It may cause damage to the product.

19.6. CAUTIONS

Before Installation:
Compatibility is critical to safe and effective use of this equipment. Please contact your local sales or service representative prior to installation to verify equipment compatibility.

Defibrillator Precautions:
The patient signal inputs labeled with the CF and BF symbols are protected against damage resulting from defibrillation voltages. To ensure proper defibrillator protection, use only the recommended cables and lead wires. Proper placement of defibrillator paddles in relation to the electrodes is required to ensure successful defibrillation.

Disposables:
Disposable devices are intended for single use only. They should not be reused as performance could degrade or contamination could occur.

Existing Device Disposal

1. Products bearing this symbol (X-marked wheeled bins) are subject to European Directive 2002/96/EC.
2. All electrical and electronic products must be disposed of separately from municipal waste at the collection facility designated by government or local authorities.
3. Proper disposal of old devices helps prevent potential adverse consequences against environmental and human health.
4. For more information on the disposal of existing devices, contact City Hall, Waste Disposal Service Center, or the store where you purchased the product.

Warning

- This equipment contains a chemical known to the State of California to cause cancer, birth defects, or other reproductive harm.

Electrocute Precautions:
To prevent skin burns, apply electrocute electrodes as far as possible from all other electrodes. A distance of at 15 cm/6 in. is recommended.

EMC:
Magnetic and electrical fields are capable of interfering with the proper performance of this equipment. For this reason, make sure that all external devices operated in its vicinity comply with the relevant EMC requirements. X-ray equipment or MRI devices are possible source of interference as they may emit higher levels of electromagnetic radiation. Also, keep cellular phones to other telecommunication equipment away from it.

Instruction for Use:
To continue using this equipment safely, it is necessary that you follow the instructions. However, instructions listed in this manual in no way supersede established medical practices concerning patient care.

Loss of Data:
Should this equipment at any time temporarily lose patient data, the potential exists that active monitoring is not being done. Close patient observation or alternate monitoring devices should be used until the monitoring function is restored. If this equipment does not automatically resume operation within 60 seconds, power cycle it using the power on/off switch. Once monitoring is restored, you should verify correct the monitoring state and alarm function.

Maintenance:
Regular technical inspections should be carried out annually to meet any requirements specific to your country.

MPSO:
The use of a multiple portable socket outlet (MPSO) for this equipment result in current leakage in it. DO NOT use MPSO as much as possible.

Negligence:
Bionet Co., Ltd. does not assume responsibility for damage to this equipment caused by improper or faulty power or incorrect placement.

19.7. NOTES

Power Requirements:
This equipment uses DC adapter of 100-240VAC / 18VDC 2.8A. Be sure to use the adapter provided by Bionet.

Restricted Sale:
U.S.A federal law restricts this equipment to sale by hospital or on the order of a physician.

Supervised Use:
This equipment is intended for use under the direct supervision of a licensed health care practitioner.

Installation Requirements:
Set up this equipment in a location which affords sufficient ventilation(The ambient conditions specified in the technical specifications must be ensured at all times.) Put this equipment in a location where you can easily see the screen and access the operating controls.

19.8. Contact

If you have any questions or comments relating to our products or purchasing, please contact the telephone numbers or E-mail below. You can talk to our sales people. Bionet always welcomes your enquiries. Please contact us.

Korea Headquarters (HQ)
Bionet Co., Ltd.:
5F, 61 Digital-ro 31 gil, Guro-gu, SEOUL
08375, REPUBLIC OF KOREA

Tel: +82-2-6292-6410
Fax: +82-2-6499-7789
Email: sales@ebionet.com
Website: www.ebionet.com

U.S. Sales & Support Office
Bionet America, Inc.:
2691, Dow Ave, Suite B
Tustin, CA 92780 U.S.A.
Toll Free: 1-877-924-6638
Fax: 1-714-734-1761
Email: support@bionetus.com
Website: www.bionetus.com

European Sales & Support Office
Bionet Europe GmbH
Bessemerstr. 51
12103 Berlin
GERMANY

Tel : +49 30 240 374 52
E-mail : info@bionet-europe.com
Website: bionet-europe.com

European Representative
CMC Medical Devices & Drugs S.L.:
C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel +34-951-214-054/Fax +34-952-330-100
E-mail: info@cmcmedicaldevices.com
Website: www.cmcmedicaldevices.com

※ In the event of a malfunction or failure, contact Service Dept. Of Bionet Co., Ltd. along with the model's name, serial number, date of purchase and explanation of failure.
※ Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Appendix A. Product Specifications

1. General specification

- Dimension: 296(W) × 305.5(H) × 97.5(D) (Approx. 2.9 kg)
- Display: 7" Wide (800 × 480)
- Recorder
    - Method: Thermal Array Print
    - Type: Roll type

- Print speed:
  - 1, 2, 3 cm/min (Real time)
  - 30 cm/min (Trace, 2, 4 cm/min setting)
  - 20 cm/min (Trace, 1 cm/min setting)
- Paper feeding function

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2. Performance Specification

- Fetal Heart Rate:
  - Input Signal: Ultrasound pulsed Doppler
  - FHR detection method: Autocorrelation
  - FHR range: 50 ~ 210 bpm
  - FHR accuracy: 120 ~ 160 bpm : ±1 bpm | Except 120 ~ 160 bpm : ±2 bpm
- Ultrasound Transducer:
  - Operating mode: PWD Mode
  - Transducer Type: 9-crystal
  - Ultrasound frequency: 1.0 MHz
  - Pulse Repetition Frequency: 3125 Hz
  - Spatial-Peak Temporal Average Intensity: <10 mW/cm^2
- Uterine Contraction:
  - Input Source: External Transducer
  - Reference Control: One-touch switch
  - Auto zeroing
  - Measurement range: 0 ~ 99
- Auto CTG Analysis:
  - Average Baseline FHR
  - Number of TOCO
  - Number of Acceleration
  - Number of Deceleration: Late, Early, Variable
  - High/Low Episode
  - Short-term Variability
  - Signal Loss

    ※ CTG Analysis results are printed out every 10 minutes
- Data Storage: Storage for 72 hours

---

4. Power Specification

- Power:
  - DC Input: 18V , 2.8A
  - Adaptor “USE THE ONLY Bridge Power Corp BPM050S18F02”
- Battery(Option):
  - Li-ion: 4 hours (charging), 2 hours(discharging)
- External Link: LAN, Wi-fi, USB

---

5. Default Alarm Setting

Alarm Parameter	US1/US2	ON	
Alarm Limit	US1/US2	160	120
Alarm Level	US1/US2	Medium	

6. Wi-Fi dongle appendix

- Additional Specification
  - Wireless Function (TL-WN725N):
    - Wireless Standard: IEEE 802.11b, IEEE 802.11g, IEEE 802.11n
    - Frequency: 2.400-2.4835GHz
    - Signal Rate:
      - 11b: Up to 11Mbps (dynamic)
      - 11g: Up to 54Mbps (dynamic)
      - 11n: Up to 150Mbps (dynamic)
    - Reception Sensitivity:
      - 130M: -68dBm@10% PER
      - 108M: -68dBm@10% PER
      - 54M: -68dBm@10% PER
      - 11M: -85dBm@8% PER
      - 6M: -88dBm@10% PER
      - 1M: -90dBm@8% PER
    - Transmission Strength: <20dBm
    - Wireless Modes: Ad-Hoc / Infrastructure Mode
    - Wireless Security: Supports 64/128 WEP, WPA/WPA2, WPA- PSK/WPA2-PSK (TKIP/AES), supports IEEE 802.1X
    - Modulation Technology:
      - DBPSK, DQPSK, CCK, OFDM, 16-QAM, 64-QAM

The operating distance between the device and the intended communication companion is greatly influenced by the performance of the wireless dongle, the output of the AP, and the installation location. We generally recommend that the distance between the device and the intended communication companion be within 10 meters.

Appendix B. Ultrasound Power
Use of Diagnostic Ultrasound:
The American Institute of Ultrasound in Medicine (AIUM) has published a document entitled "Medical Ultrasound Safety".
This three-part document covers Bioeffects and Biophysics, prudent Use and Implementing ALARA.
Ultrasound users should read the AIUM documents to become more familiar with Ultrasound safety. A copy of this document is included as part of the documentation package (Document 2163920-100).

AIUM
14750 Sweitzer Lane
Suite 100

Laurel, MD, USA 20707-5906
telephone 1-800-638-5352.

In accordance with US FDA Guidelines, the overall maximum acoustic SPTA intensity for the product is limited to 100 mW/cm^2 and MI is limited to 1.0.

1. Measurement Precision and Uncertainty

	Center Frequency	Acoustic Power	Peak Rarefractional Pressure	Acoustic Intensity
Measurement Uncertainty	± 2 %	±5%	±15%	± 25%

2. Maximum Output Summary

Operating Mode	DOP Probe
Pulsed Doppler Mode	O

3. Maximum Probe Temperature (Degrees C)

Probe	Max Temperature		
	With TMM Phantom	In Air	Mode
US	33.2	21.6	PWD Mode

Lens temperature monitored for 30 min.
Measurement uncertainty: +-0.5-degree C.
Ambient temperature: 22.1 degree C

4. Table Key

IEC	FDA	Meaning IEC60601-2-37 / FDA&NEMA UD2,UD3
α	a	Acoustic Attenuation Coefficient / Derating factor (usually 0.3 dB/cm-MHz)
Aaprt	Aaprt	-12db Output Beam Area / Active aperture area
CMI	-	Normalizing Coefficient
Deq	Deq	Equivalent Aperture Diameter
d-6	d-6	Pulse Beam Width / Beam diameter at –6 dB
deq	deq	Equivalent Beam Diameter
*f*awf	fc	Acoustic Working Frequency / Center frequency
Ipa	Ipa	Pulse-Average Intensity
Ipa,α	Ipa.3	Attenuated Pulse-Average Intensity
Ipi	PII	Pulse-Intensity Integral
Ipi,α	PII.3	Attenuated Pulse-Intensity Integral
Ita(z)	ITA	Temporal-Average Intensity
Ita,α(z)	ITA.3(Z)	Attenuated Temporal-Average Intensity at depth z
Izpta(z)	ISPTA(Z)	Spatial-Peak Temporal-Average Intensity
Izpta,α(z)	ISPTA.3(Z)	Attenuated Spatial-Peak Temporal-Average Intensity
MI	MI	Mechanical Index
P	Wo	Output Power / Time average acoustic power at the source
Pα	W.3(Z)	Attenuated Output Power / Time average acoustic power derated to depth z
P1	Wo1	Bounded Output Power / Power emitted from the central 1cm of aperture
pi	PII	Pulse Pressure Squared Integral / Pulse intensity integral
pr	pr	Peak-Rarefactional Acoustic Pressure
prα	pr.3	Attenuated Peak-Rarefactional Acoustic Pressure
prr	PRF	Pulse Repetition Rate / Pulse repetition frequency
TI	TI	Thermal Index
TIB	TIB	Bone Thermal Index
TIC	TIC	Cranial-Bone Thermal Index
TIS	TIS	Soft-Tissue Thermal Index

td	PD	Pulse Duration
X, Y	x-12,y-12	-12 dB Output Beam Dimensions
Z	Z	Distance from the Source to a Specified Point
Zb	Zsp	Depth for TIB / Depth at which the relevant index is maximum
Zbp	Zbp	Break-Point Depth
Zs	Zsp	Depth for TIS / Depth at which the relevant index is maximum

5. Acoustic Output Tables

MC65R1S – Pulsed Doppler Mode

Index				MI	TIS			TIB	TIC
					scan	Non-scan		Non-scan	
						Aaprt<= 1	Aaprt > 1		
Global Maximum : Index Value				0.0164842	-	0.00168143	-	0.0130577	0.00869565
	IEC	FDA	Unit						
Associated Acoustic Parameter	pra	pr.3	(MPa)	0.0164807					
	p	Wo	(mW)		-	0.4		0.4	0.4
	min of [Pα(zs), Ita,α(zs)]	min of [(W.3(Z1), ITA.3(z1)]	(mW)				-		
	Zs	z1	(cm)				-		
	zbp	zbp	(cm)				-		
	zb	zsp	(cm)	1.8				1.8	
	z at max. Ipi,α	zsp	(cm)						
	deq(zb)	deq(zsp)	(cm)					1.0865	
	ƒawf	fc	(MHz)	0.999572	-	0.999572	-	0.999572	0.999572
	Dim of Aaprt	X	(cm)		-	0.4	-	0.4	0.4
		Y	(cm)		-	0.4	-	0.4	0.4
Other Information	td	PD	(μsec)	59.9647					
	prr	PRF	(Hz)	3906					
	pr at max. Ipi	pr@PIImax	(MPa)	0.0175374					
	deq at max. Ipi	deq@PIImax	(cm)					1.0865	
	Focal Length	FLX	(cm)		-	2	-		2
		FLY	(cm)		-	2	-		2
	Ipa,α at max. MI	IPA.3@MImax	(W/cm^2)	0.00154839					
Operating Control Conditions	Frequency		(MHz)	1.0	-	1.0	-	1.0	1.0

Appendix C. Abbreviation and Symbol

Abbreviation and Symbol of manual or system operation is arranged in alphabetical order.

Abbreviations:

AC: alternating current

C: Celsius

cm, CM: centimeter

DC: direct current

EMC: electromagnetic compatibility

EMI: electromagnetic interference

F: Fahrenheit

g: gram

HR: heart rate, hour

Hz: hertz

Inc: incorporated

kg, KG: kilogram

L: liter, left

lbs, LBS: pounds

LCD: liquid crystal display

LED: light emitting diode

M: mean, minute m: meter

MIN: min, minute MM, mm: millimeters

MM/S: millimeters per second

MMHG, mmHg: millimeters of mercury

mV: millivolt

sec: second

Temp, TEMP: temperature

V: volt

X: multiplier when used with a number(2X)

Symbols:

&: and

°: degree(s)

> : greater than
> <: less than
> –: minus
> #: number

> %: percent
> ± , +/-: plus, or minus