LX-8000 series
ECG, Respiration and SpO_2 Transmitter

LX-8300M
LX-8300M(G)

Ver. 02

Operation Manual

* Before using the product, please read this manual thoroughly.
* Store this manual where it can be always referred to.

FUKUDA

This manual is for the LX-8300M, LX-8300M(G) Version 02.

⚠ CAUTION	Federal Law restricts this device to sale by or on the order of a physician.

CAUTION

- Only physician or persons instructed by physicians are allowed to use the equipment.
- The information contained in this document is subject to change without notice due to improvement in the equipment.

Thank you for purchasing our product.
Before using this product, read this operation manual thoroughly for correct handling and operation.

In this manual, the operation procedure of LX-8300M/LX-8300M(G) is explained using the illustration and screen of the LX-8300M as examples.

Safety Precautions

The safety precautions shown in this manual contain important details on the safe use of this product, and must be obeyed. Symbols and their meanings are shown below. Make sure to understand the following before reading the rest of the manual.

⚠DANGER	Indicates a potentially hazardous situation which, if not avoided, will result in death, serious injury, or fire.

⚠WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠CAUTION	Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury, or property damage.

NOTE	A note is not related to product safety, but provides information about the correct use and operating procedures to prevent incorrect operation and malfunction of the equipment.

Precaution from Fukuda Denshi

Fukuda Denshi is liable for the safety, reliability, and performance of its equipment only if; Maintenance, modifications, and repairs are carried out by authorized personnel. Components are used in accordance with Fukuda Denshi operating instructions.
If the equipment is used incorrectly and become unusable, Fukuda Denshi is not liable for the malfunction. Use the equipment only for the purpose specified in this manual.

Intended Use of this Equipment

This equipment is designed for the following <Intended Use>.

<Intended Use>
This equipment is intended for patient monitoring in surgery room, ICU, ward, emergency room in the medical facility by measuring ECG, respiration and SpO_2 and transmitting the measured data by wireless network to the central monitor continuously.

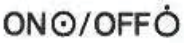
This equipment is intended to be used by healthcare professionals. Users should have a thorough knowledge of the function and operation before using this equipment. The maintenance of this equipment should be performed by skilled personnel who received a training of possible hazards and measures to avoid those hazards. Also, your local regulation must be followed. If this equipment is used for the purpose other than intended, or if the user does not follow the safety instructions, the following hazard may result.

- Hazard to the Life and Health of the Patient or the User
- A Problem Related to Medical Practice
- Damage to the Equipment

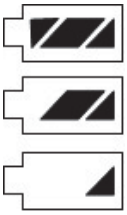
Graphic Symbols

The following symbols are used for this equipment.

Symbols indicated on the main unit

Symbol	Description
	Warning (indicated in yellow)
	Follow operating instructions (Warning); (indicated in blue) Indicates that the failure to follow operating instructions could place the patient or operator at risk.
	Follow operating instructions (Information); Indicates the need to refer to the related accompanying documents before operation.
	Type CF Applied Part with Defibrillation-Proof Indicates that the degree of protection against electric shock is Type CF Applied Part with defibrillation-proof.
	Indicates the power ON/OFF status.
	Indicates the point to close the battery compartment lid.
	Indicates the battery type and direction.
	Indicates that the alarm function is not provided.
	Date of Manufacture Indicates the date of manufacture.
	Non-ionizing electromagnetic radiation Indicates the radio transmitting device.

Symbols displayed on the screen

Symbol	Description
	HR Synchronized Mark This mark flashes synchronizing to the heartbeat.
	Indicates the remaining battery level.
	Indicates that the expiration date of the SpO_2 sensor is approaching.

The following icons are displayed only on the all data display.

	Indicates that probe is disconnected or damaged.
	Indicates that sensor check, etc. is required.
	Indicates that the amplitude of the pulse waveform is too low, or the sensor is not positioned correctly.
	Indicates that the probe is damaged, or the usable life of the sensor has expired.

Precautions for Safe Operation of Medical Electrical Equipment

This section contains general information on how to handle this equipment safely for the patient and users. The precautions specific to this equipment are described afterwards.

⚠CAUTION

1. User should have a thorough knowledge of the operation before using the equipment.
2. For installation and storage of the equipment, pay attention to the following.
   - Install or store in a place where the equipment will not be exposed to splashing water.
   - Install or store in an area where environmental conditions such as atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, sodium, and sulfur will not adversely affect the system.
   - Place the equipment on a stable surface where there is no inclination, vibration, or shock (including during transportation).
   - Do not install or store in an area where chemicals are stored or gases are evolved.
3. Before operating the equipment, verify the following items.
   - Check the cable connection, polarity, etc. to ensure safe and proper operation of the equipment.
   - Ensure that all cables are firmly and safely connected. Especially, make sure to check the attachment and connection condition of electrodes and transducers.
   - Pay special attention when the equipment is used in conjunction with other equipments as it may cause erroneous judgment and dangerous situation.
   - Check the remaining battery level.
   - When replacing the batteries, make sure that the batteries polarity are correct. Do not charge the batteries.
4. During operation of the system, verify the following items:
   - Do not operate the equipment beyond the time period required for diagnosis and medical care.
   - Do not hold the probe or cable part to pick up the equipment. It may damage the equipment and lead to measurement error.
   - Always observe the equipment and patient to ensure safe operation.
   - If any abnormality is found on the equipment or patient, take appropriate measures such as ceasing operation of the equipment and/or detaching the probe (sensor) and/or electrode, in the safest way for the patient.
   - Do not allow the patient to come in contact with other equipments.

⚠CAUTION

5. After using the equipment, verify following items.
   - Return all operating switches, knobs etc to the position before using the equipment, and then switch off the power.
   - When unplugging the cables, make sure to pull from the connector part of the cable to avoid excessive force on the cable.
   - Clean the accessories and cables, and keep them together in one place.
   - Keep the equipment clean to ensure proper operation for the next use.
   - Make sure to remove the batteries if the equipment is not used for a long time. The leakage from the batteries may damage the equipment, or an explosion from the batteries may occur.
6. If the equipment is damaged, do not attempt service. Ensure patient safety by immediately turning off the power and removing the electrodes and cables from the patient. Label the unit “OUT OF ORDER” and contact your nearest service representative.
7. Do not disassemble or remodel the equipment.
8. Maintenance and Inspection
   - Make sure to periodically check the equipment and parts. (It is recommended to conclude a maintenance contract.)
   - Before reusing the equipment that has been left unused for a while, make sure that the equipment operates properly and safely.
9. When using electrosurgical knives or defibrillator with this equipment, follow the precautions below.
   - To prevent patient from burn injury, verify proper attachment of patient ground plate, ECG electrode type when using the electrosurgical knife, and verify paste volume, output energy when using the defibrillator.
   - Some types of equipment other than the above may cause accidental hazards to the patient and operator due to the conditions of the equipment. Read the operation manual attached to each equipment and fully understand the precautions prior to use.

Non-Explosion Proof

⚠DANGER

- Never operate the equipment in the presence of flammable anesthetics, high concentration of oxygen. It may cause an explosion or fire.
- Never use the equipment in the hyperbaric oxygen therapy chamber. It may cause an explosion or fire.
- Never operate the equipment where flammable gas or fluid such as anesthetic, oxygen, and hydrogen are used. It may cause an explosion or fire.

Precautions about Magnetic Resonance Imaging (MRI)

⚠WARNING

- Do not use this equipment in magnetic resonance imaging (MRI) environments.
- When conducting MRI test, remove the electrodes and sensors connected to the patient. The local heating caused by the induced electromotive force may cause burn injury to the patient. For details, refer to the operation manual for the MRI testing device.

Electrosurgery Safety

⚠WARNING

The monitoring system contains protection against interference generated by electrosurgical instruments. However, depending on the operating conditions, surgery site with respect to the location of ECG electrodes, ground plate attachment condition, or the type of instrument used, it may cause burn injury at the electrode site or noise on the ECG. The noise is generated at the tip of the electrosurgical knife and is difficult to completely eliminate because of the frequency components of the ECG. To reduce electrosurgical interference, take the following precautions:

Location:

Locate the electrosurgical unit as far as possible from this equipment and the patient cable. This will help reduce interference on the ECG through the monitor or cables.

Electrode Placement:

The amount of noise interference is considerably different depending on the electrode position and surgery site. Place the ECG electrodes as far away as possible from the surgery site and the ground plate. Do not place electrodes in the path between the surgery site and the ground plate. If the electrodes are placed in this path, the amount of interference will be quite large. Position (+) and (–) electrodes as close as possible to each other.

Ground Plate:

When using electrosurgical instruments, make sure the contact between the patient and the ground plate is secure. If the connection is incomplete, the patient may suffer from burn at the electrode site.

Precautions about Using with the Defibrillator

⚠WARNING

- When using this equipment with a defibrillator, use only the specified lead cable. If unspecified lead cable is used, it may damage the equipment and safety cannot be ensured.
- When defibrillating, keep away from the electrodes or medicament applied to the patient chest. If this is not possible, remove the electrodes or medicament before defibrillating.
  If the defibrillator paddles directly touch the electrodes or medicament, an electrical shock may result by the discharged energy.
- When defibrillating, do not touch the patient and the metal part of the equipment or cables. Electric shock may result from the discharged energy.

Precautions about the Pacemaker

⚠WARNING

- Minute ventilation rate-adaptive implantable pacemakers can occasionally interact with certain cardiac monitoring and diagnostic equipment, causing the pacemakers to pace at their maximum programmed rate. The cardiac monitoring and diagnostic equipment may possibly send wrong information.
  If such event occurs, disconnect the cardiac monitoring and diagnostic equipment, or follow the procedures described in the operation manual of the pacemaker.
  (For more details, contact FUKUDA DENSHI personnel, your institution's professionals, or your pacemaker distributors.)
- Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms. Keep pacemaker patients under close surveillance.

➔Reference
"Minute Ventilation Rate-Adaptive Pacemakers"
FDA alerts health professionals that minute ventilation rate-adaptive implantable pacemakers can occasionally interact with certain cardiac monitoring and diagnostic equipment, causing pacemakers to pace at their maximum programmed rate.
[October 14, 1998 – FDA]

Precautions for Using This Equipment

⚠WARNING

- Do not connect cables not authorized by Fukuda Denshi to any I/O connector. If unspecified cable is connected, not only that the equipment cannot deliver its maximum performance, the equipment may be damaged and safety cannot be ensured.
- Do not use this equipment with multiple patients simultaneously.

⚠CAUTION

Do not hold the cable part and hang or swing the transmitter. It may cause wire break, injury, or damage to the surrounding equipment.

Precautions about Waterproof

⚠CAUTION

- To maintain the waterproof performance, replace the battery compartment lid periodically. Otherwise, the quality of the lid will deteriorate and cannot keep the waterproof performance. For periodic replacement, contact your local service representative.
- When the equipment is subjected to high impact, the damage to the enclosure or lid may degrade the waterproof performance. In such case, contact your local service representative to check the waterproof performance.
- The SpO_2 probes are not waterproof. Do not take a bath with the probes attached, and keep them away from liquids.
- Do not use the transmitter when it is wet. Wipe the transmitter with a soft cloth and dry it thoroughly before use.

Precautions about ECG Monitoring

⚠CAUTION

- When removing electrodes from the patient, remove them carefully and slowly. Do not apply excessive force to remove them. Otherwise, it may damage the skin.
- If any electrodes get detached from the patient after being connected to the lead cable and patient monitor, pay attention that the metal part of the electrode does not get in touch with any metal parts of the bed or any conductive parts. Also, the operator should not touch any conductive parts with bare hands. Otherwise, it may cause electric shock to the patient and/or operator due to excessive leakage current.
- The indication for continuous use of the electrode is about one day.
- Replace the electrode if the skin contact gets loosen due to perspiration, etc.
- When an electrode is attached to the same location for a long period, some patients may develop skin irritation. Check the patient's skin condition periodically and change the electrode site as required.
- For stable ECG monitoring, verify proper electrode placement, lead, and waveform size. If not properly selected, it may cause erroneous detection.
- There are some cases when the pacemaker pulse cannot be detected depending on the pacemaker type, pulse voltage, pulse width, electrode lead type (unipolar, bipolar), or electrode placement which causes the pacemaker pulse amplitude to decrease, and disables the pacemaker pulse detection.
- If signals similar to a pacemaker pulse are present, such as electric blanket noise or excessive AC frequency noise, these may be erroneously detected and displayed as a pacemaker pulse. In such case, check the condition of the electrodes and lead cables to resolve the cause or turn off the pacemaker detection setting on the receiving monitor.
- If a pacemaker pulse is continuously detected due to AC frequency interference, QRS detection will not be properly displayed.

Precautions about SpO_2 Monitoring

⚠WARNING

- For SpO_2 monitoring, use only the specified probe. Check the probe before usage to make sure that it is the specified probe. If unspecified probe is used, not only that the equipment cannot deliver its maximum performance, the equipment may be damaged and safety cannot be ensured.
- If the nail is rough, dirty, or manicured, accurate measurement will not be possible. Change the finger or clean the nail before attaching the sensor.
- If irritation such as skin reddening appears with the sensor use, change the attachment site or stop using the sensor.
- Do not use a tape to attach the sensor.
- When the SpO_2 probe is disconnected from the equipment, the SpO_2 measurement/waveform will not be displayed on the receiving monitor. Also, the alarms will not be generated. Make sure that the SpO_2 probe is securely connected to this equipment.
- When not measuring, unplug the SpO_2 probe from the connector. Otherwise, the outside light may affect to falsely display the measurements.
- Check the sensor attachment site constantly every 4 hours when probes or reusable sensor are used, and at least every 8 hours when single patient use sensors are used. Be especially careful of a patient with bad perfusion. If the sensor attachment position is not changed constantly, skin irritation or skin necrosis due to compression may be developed. For the patient with bad perfusion, check the sensor attachment position at least every 2 hours.
- As skin for neonate, premature infant is immature, change the sensor attachment site more frequently depending on the condition.
- When measuring the SpO_2 of patient with high fever or peripheral circulatory insufficiency, check the sensor attachment periodically and change the attachment site. The temperature of the attachment site will rise due to the sensor heat which may result in burn injury.
- Even attachment for a short duration may inhibit the blood flow and generate compression necrosis. Also, blood flow inhibition may prevent correct measurements.
- Direct sunlight to the sensor area can cause a measurement error. Place a black or dark cloth over the sensor if using in direct sunlight.
- The pulse wave is normalized for SpO_2 measurement, and does not indicate perfused blood volume. Check proper sensor attachment by observing the pulse wave.
- Precautions for Reusable Sensors
  The light-emitting part of the sensor should be over the root of the fingernail or as instructed per the related sensor instruction manual. Do not insert the finger too far into the sensor as it may hurt the patient. For details, refer to the SpO_2 sensor instruction manual.
- Precautions for Single-Patient-Use Type Sensors
  The sensor can be reused on the same patient as long as the adhesive tape attaches without slippage. Do not reuse on other patients to avoid

⚠WARNING

cross contamination. It is intended for single patient use only. For details, refer to the operation manual of the SpO_2 sensor.

- Measuring on a limb with NIBP cuff, arterial catheter, or intracatheter may result in incorrect measurement.
  Venous congestion may cause under reading of actual oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should not be below heart level (e.g. sensor on hand of a patient in a bed with arm dangling to the floor).

⚠CAUTION

For the following case, accurate measurement may not be possible.

- Patient with excessive abnormal hemoglobin (COHb, MetHb)
- Patient with the pigment injected to the blood
- Patient receiving CPR treatment
- When a probe is applied to a limb with NIBP cuff, arterial catheter, or intracatheter
- When measuring at position with venous pulse
- Patient with body motion
- Patient with small pulse
- Excessive body motion (patient's motion)
- Excessive light (direct sunlight, fluorescent, light therapy equipment, surgical light, infrared heat ramp, etc.)
- External colorant such as nail polish
- Abnormally low or high hemoglobin concentration

Precautions about Output Signal

⚠WARNING

Do not use the output signal of the monitor that receives radio wave signal from this equipment as the trigger signal for MRI, echocardiographic, or defibrillator. It may lead to a delay of operating timing due to the delay time of waveform transmission. A trigger signal unrelated to the heart rate may be generated due to the interfusion of spike noise at weak electric field.

Precautions about Accessories and Optional Accessories

⚠WARNING

Use only the specified disposable electrodes, lead cable, SpO_2 probes, etc. Otherwise, this equipment cannot deliver its maximum performance and may be damaged, resulting in a safety hazard.

⚠CAUTION
● Do not reuse disposable products. ● Store the disposable products properly as mentioned in their user manuals.

Precautions about the Alkaline Batteries

⚠WARNING
● Use new "AA" size (“LR6” size) alkaline batteries which is within the expiration date. ● Install the batteries with the correct polarity. ● Do not charge the batteries. Any attempt to charge the batteries may cause them to leak or break. ● Do not short the (+) and (-) terminals. It may result in exothermic heat and fire. ● Do not use different types of batteries at the same time. The leakage from the batteries may damage the equipment, or an explosion from the batteries may occur.

Precautions about Disposing of Equipment, Accessories, or Components

⚠CAUTION
● When disposing of the equipment, accessories, or components, use an industrial waste distributor. Do not dispose of as ordinary waste. ● Used disposal items (ECG electrodes, etc.) shall be discarded as medical waste.

Precautions about Disposing of Battery

⚠CAUTION
Obey the local municipal rule to dispose the used dry cell battery.

Precautions for Use of Medical Telemeter

⚠WARNING

- The LX-8300M/LX-8300M(G) transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.
- For the receiving monitor of the LX-8300M transmitter, make sure to use the Fukuda Denshi products with the receiving range of 608 MHz-614 MHz.
- For the receiving monitor of the LX-8300M(G) transmitter, make sure to use the Fukuda Denshi products with the receiving range of 1395 MHz-1400 MHz and 1427 MHz-1432 MHz.
- This equipment complies with FCC/IC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines and RSS-102 of the IC radio frequency (RF) Exposure rules. This equipment has very low levels of RF energy that are deemed to comply without testing of specific absorption rate (SAR).
- Operation of LX-8300M/LX-8300M(G) requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.
- This radio frequency device is susceptible to interference from outside sources. Interference may prevent the monitoring of patients connected to this equipment. If a problem exists, contact your local service representative.
- The LX-8300M/LX-8300M(G) transmits vital signs to the receiving monitor using radio wave signal. Under unstable radio wave signals, the receiving monitor will not generate any alarms. This situation may miss sudden change in the patient's condition and may cause a serious accident. Under unstable radio wave signals, check the patient status consistently under this situation. To get stable radio wave signals, make sure to have a proper telemetry installation.

⚠CAUTION

- For installation, make sure to follow the precautions below.
  - The medical institution (hereinafter referred to as the “Institution”) must decide the telemetry installation plan for the medical department in order to prevent interference and interference between transmitters (telemetry based on destination country’s radio law). When telemetry has already been installed and been used, radio format, frequency, and antenna power are required to be examined to prevent interference.
  - When laying receiver antenna for each transmitter, the Institution has to examine the installation so that electronic interference does not occur.
  - Based on the above examination result, the Institution should install each receiver antenna as required.

⚠CAUTION

- For management, make sure to follow the precautions below.
  - The Institution should appoint a person (hereinafter referred to as the "Coordinator") to manage the wireless channels for the whole Institution.
  - The Coordinator must be selected from people who understand the characteristics and functionality of telemetry systems, and are skilled in operating telemetry.
  - When installing telemetry, the Coordinator has to understand the precautions for use of the telemetry in advance.
  - The Coordinator is responsible for maintenance of wireless channels and storage and maintenance of telemeter in the overall medical facilities to give proper instructions to the telemetry users.
  - The Coordinator should create a management log (hereinafter referred to as the "log"), which contains a list of the management status of the wireless channels for the whole Institution. When changing a wireless channel, register it in the log and give proper instructions to the user.
  - The telemetry user verifies operation of the transmitter/receiver before use.
  - When interference or breakdown occurs in telemetry communication, the user is required to inform the Coordinator of the problems. The Coordinator is to deal with the problem properly and/or contact their nearest Fukuda Denshi representative for service.

Electromagnetic Compatibility

This equipment complies with IEC 60601-1-2 (2014), safety standard regarding the electromagnetic disturbances of medical electrical equipment. To ensure maximum performance against the electromagnetic disturbances, make sure to follow the precautions for installation and usage described in this manual.

- This equipment is intended for use in the medical facility (except inside the shield room of MRI device), and satisfies the immunity level for professional healthcare facility environment stipulated in IEC 60601-1-2.

- An excessive magnetic disturbance may degrade the HR and SpO_2 measurement accuracy (refer to “15. Specification”), which is the essential performance of this equipment, and may cause delay in treatment or inaccurate diagnosis.

- When using this equipment, interference with other medical electrical equipments or non-medical electrical equipments may occur. Make sure that no interference is present before usage.

- To ensure basic safety and essential performance related to electromagnetic disturbances during the expected service life of this equipment, “Daily Check” and “Periodic Check” must be performed.
  (refer to “13. Maintenance and Inspection”)

Precautions for Safe Operation under Electromagnetic Influence

⚠CAUTION

If any sorts of electromagnetic wave, magnetic field, or static electricity exist around the equipment, noise interference or malfunction of the equipment may occur. If any unintended malfunction or noise occurs during monitoring, check the magnetic influence and take appropriate countermeasures.

The followings are examples of the common cause and countermeasures.

●Mobile Phone

The radio wave may cause malfunction to the equipment.
Mobile phones and radio sets should be turned off in the room (building) where medical device is located.

●Static Electricity

In a dry environment (room), static electricity is likely to occur. Take the following countermeasures.

- Both operator and patient should remove any static electricity before entering the room.
- Humidify the room.

⚠CAUTION

- If this equipment is installed close to, or stacked with other equipment, malfunction may occur. Make sure to verify that the equipments operate properly in a used location.
- Use of accessories, probes, or cables other than specified may cause increase in electromagnetic emission or decrease in electromagnetic immunity resulting in malfunction of the equipment.
- The portable RF communications equipment (including antenna cable and peripheral equipment such as external antenna) with the specified cable should be used in a location at least 30 cm apart from any part of this equipment. Otherwise, it may result in performance degradation of this equipment.

EMC Guidance

This equipment complies with IEC 60601-1-2 (2014). However, if portable transmitter or wireless LAN equipment is used extremely nearby, the electromagnetic influence may largely exceed the compliance level and may cause unexpected phenomenon such as noise interference on the waveform, etc.
Therefore, this equipment should be used in a location specified by each medical institution. If any unexpected noise interference on the waveform or failure to the peripheral device occurs, stop using the equipment and follow the instruction of the technician.

The following is the information relating to EMC (Electromagnetic Compatibility).
(When using this equipment, verify that it is used within the environment specified below.)

●Compliance to the Electromagnetic Emissions

This equipment complies with the following emission standard.

Emission test	Compliance
RF Emission CISPR 11	Group 1 Class A

⚠CAUTION

The emission performance of this equipment is suitable for use in industrial environment and hospital environment (CISPR 11 Class A). To use in home environment (generally, CISPR 11 Class B is required), this equipment may not be properly protected from wireless frequency communication service. It may be necessary to take measures such as changing the installation location or equipment orientation.

●Compliance to the Electromagnetic Immunity

The LX-8300M/LX-8300M(G) is intended for use in the electromagnetic environment specified below.
The customer or the user of the LX-8300M/LX-8300M(G) should assure that it is used in such an environment.

Basic EMC standard or test method	Immunity test levels
Electrostatic discharge IEC 61000-4-2	±8 kV　contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 1 kHz　80%AM
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Refer to the following table.
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 1 kHz　80%AM 6 V 0.15 MHz to 80 MHz (in ISM bands between 0.15 MHz and 80 MHz) 1 kHz 80%AM
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m 60 Hz

Immunity test specifications for RF wireless communications equipment

Test frequency (MHz)	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
710, 745, 780	PM, 217 Hz	0.2	0.3	9
810, 870, 930	PM, 18 Hz	2	0.3	28
1720, 1845, 1970	PM, 217 Hz	2	0.3	28
2450	PM, 217 Hz	2	0.3	28
5240, 5500, 5785	PM, 217 Hz	0.2	0.3	9

IEC 61000-4-3: Proximity fields from RF wireless communications equipment

Since TETRA 400 is a service in Europe and this product for the US does not emit close proximity, the test frequency of 385 MHz is not implemented.

GMRS 460, FRS 460 are general and leisure radios and have a test frequency of 450 MHz because they are not radiated in close proximity with this product, which is intended for use on a patient in a professional healthcare environment. Not implemented.

Contact

If you need more information, please contact the following.

(1) Fukuda Denshi Co., Ltd., Head Office

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Tel: +81-3-5684-1455　Fax: +81-3-3814-1222
E-mail: info@fukuda.co.jp
Home Page: http://www.fukuda.com

(2) Sales Representative

Write the name, address, phone, fax number of your local sales representative.

(Name of Sales Representative, Address, Phone/Fax)

Contents

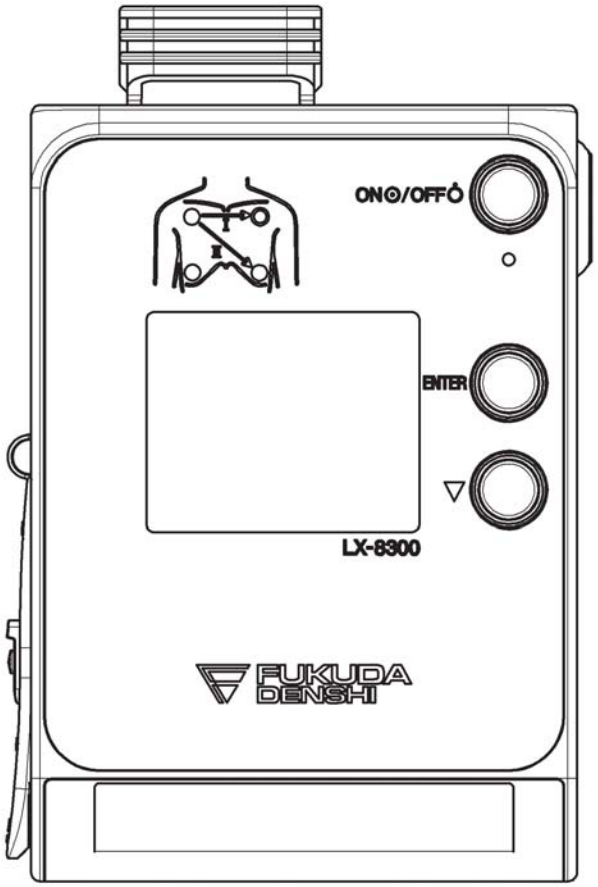
Safety Precautions i
Precaution from Fukuda Denshi i
Intended Use of this Equipment ii
Graphic Symbols iii
Precautions for Safe Operation of Medical Electrical Equipment v
Non-Explosion Proof vi
Precautions about Magnetic Resonance Imaging (MRI) vii
Electrosurgery Safety vii
Precautions about Using with the Defibrillator viii
Precautions about the Pacemaker ix
Precautions for Using This Equipment ix
Precautions about Waterproof x
Precautions about ECG Monitoring x
Precautions about SpO_2 Monitoring xi
Precautions about Output Signal xii
Precautions about Accessories and Optional Accessories xii
Precautions about the Alkaline Batteries xiii
Precautions about Disposing of Equipment, Accessories, or Components xiii
Precautions about Disposing of Battery xiii
Precautions for Use of Medical Telemeter xiv
Electromagnetic Compatibility xv
Precautions for Safe Operation under Electromagnetic Influence xvi
EMC Guidance xvii
Contact xix
1. General Description 1
2. Names of Parts and Their Functions 3
3. Preparation 5
1) Installing the Batteries 5
2) Operating the Power Switch 8
4. ECG Monitoring 11
■Connecting the ECG Lead Cable and Electrodes 11
■Attaching the Electrodes 12
■Connecting the ECG Lead Cable to the LX-8300M/LX-8300M(G) 13
5. Respiration Monitoring 15
6. SpO_2 Monitoring 17
■Preparation for Monitoring 17
■Connecting the SpO_2 sensor to the LX-8300M/LX-8300M(G) 29
7. Measurement 31
■Monitoring Screen 31
●All Data Display 33
8. Operation 39

■Setup Mode 39
■ECG Setup 39
■Respiration Setup 41
■SpO_2 Setup 41
■Restarting the Display 43
■Pressing the [EVENT] Button 44
9. Other Setting Items 45
■Time Constant 46
■Detection Sensitivity of the Pacemaker Pulse 46
■QRS Detection 47
■Respiration Detection Signal ON/OFF 48
■Display Brightness 48
■Display Timeout Duration 48
■Sound ON/OFF 49
■Displayed Color of SpO_2 49
■Transmit PI Information 49
10. Changing the Transmitter Channel and Group ID 51
■Transmitter Channel 51
■Group ID 51
11. Troubleshooting 53
■In Case of Dropping the LX-8300M/LX-8300M(G) into Water 59
12. Cleaning and Disinfection 61
■Cleaning the Housing 61
■Cleaning the Connector 62
■Disinfection 62
■Cleaning the ECG lead cable 62
13. Maintenance and Inspection 63
■Daily Check 63
■Periodic Check 63
■Periodic Replacement Parts 63
■Periodic Check 65
■Repairing the Equipment 71
■ Replacing the Battery Compartment Lid Unit 71
14. Standard and Optional Accessories 75
■Standard Accessories 75
■Optional Accessories 75
15. Specification 79
■Specification 79

1. General Description

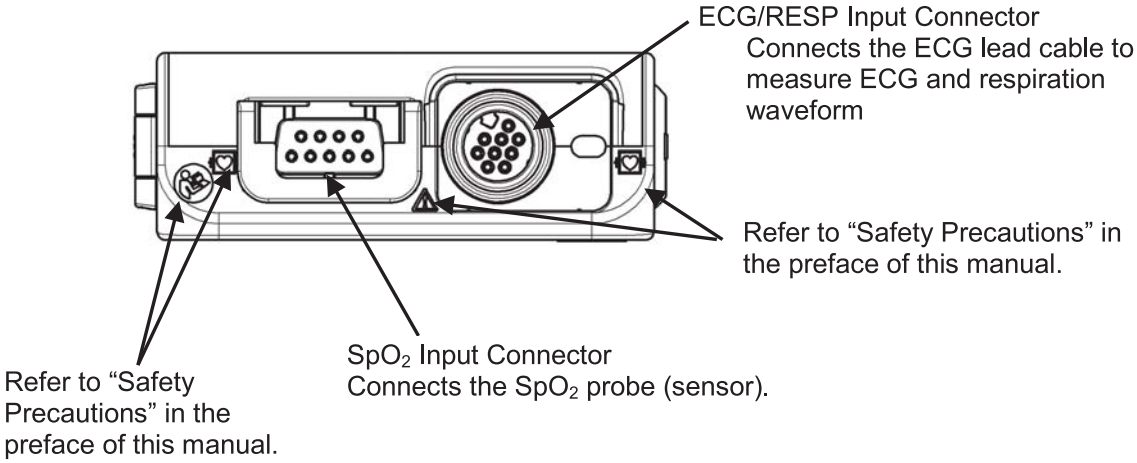
The LX-8300M/LX-8300M(G) is a radio telemetry transmitter designed to measure the ECG, respiration waveform, SpO_2 (functional oxygen saturation of arterial hemoglobin), pulse waveform with two “AA” size (“LR6” size) alkaline batteries.
Information such as ECG measurements, respiration waveform, SpO_2 measurements, pulse waveform, battery level, and the conditions of the ECG electrodes and SpO_2 probe (sensor) are displayed on the front panel.
ECG lead selection is available using the two buttons ([ENTER] and [▽]) on the front panel (In case of using a 3-electrode lead cable or a 5-electrode chest lead cable).
The LX-8300M/LX-8300M(G) can also function as a transmitter to measure only the ECG/Respiration without SpO_2 or to measure only the SpO_2 without ECG/Respiration.
Before using the LX-8300M/LX-8300M(G), read also the operation manual of the patient monitor at the receiving side thoroughly.

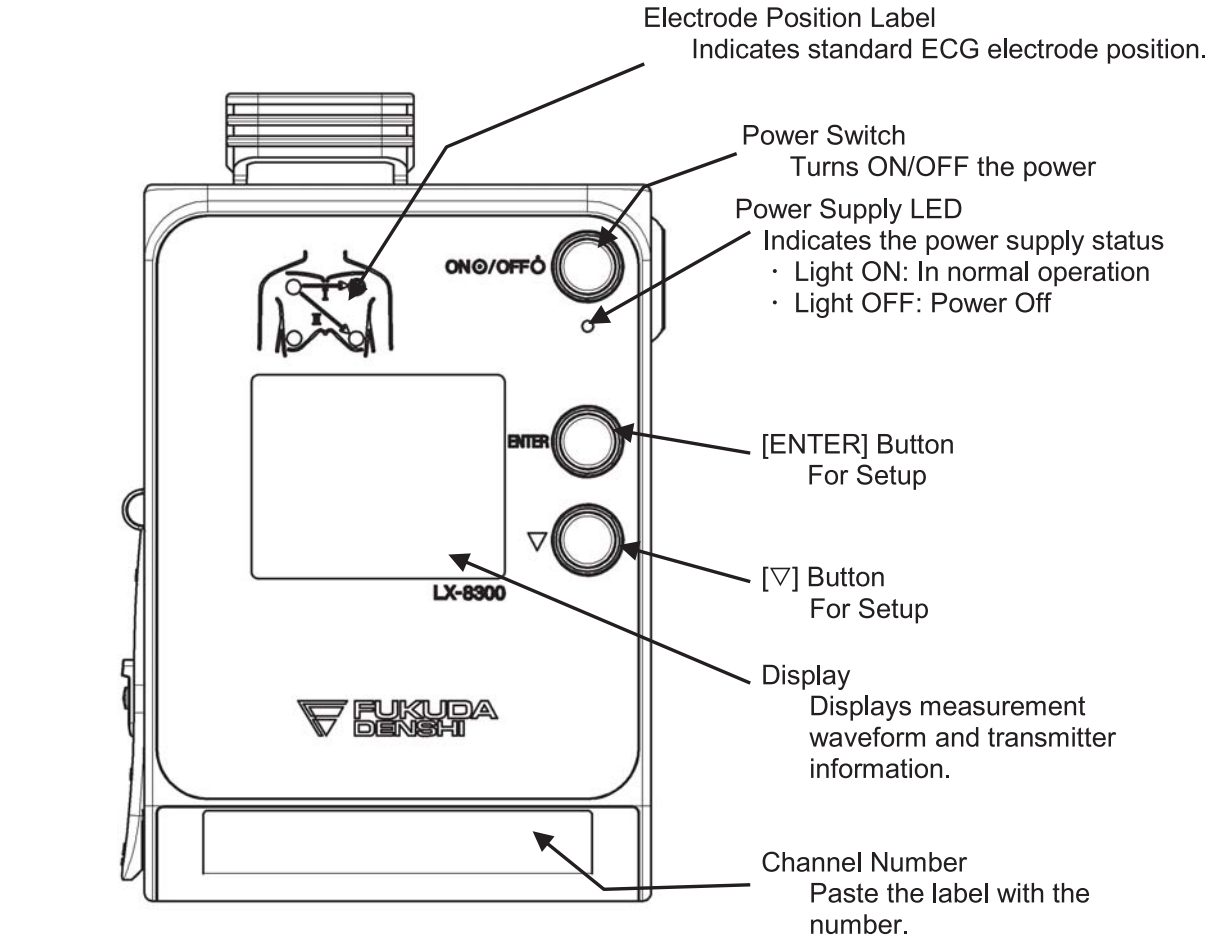
External Appearance



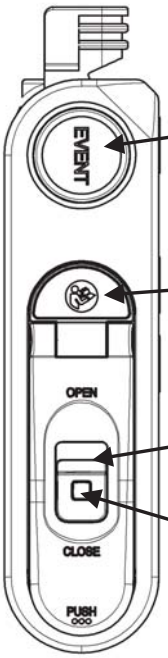
1. General Description

2. Names of Parts and Their Functions





2. Names of Parts and Their Functions

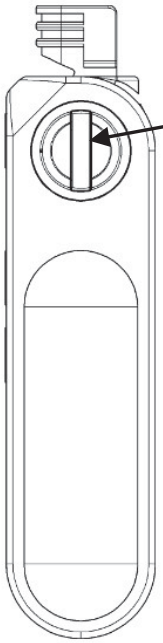


[EVENT] Button
Transmits EVENT Information

Refer to “Safety Precautions” in the preface of this manual.

Battery Compartment Lid Open/Close Lever
To open/close the battery compartment lid, slide this lever up/down.

Battery Lid Lock Button
Unlocks the battery compartment lid.



Strap Hole
Attaches the strap.

3. Preparation

1) Installing the Batteries

The LX-8300M/LX-8300M(G) functions with two “AA” size (“LR6” size) alkaline batteries.
The battery operation time of LX-8300M/LX-8300M(G) is as follows.

LX-8300M

- When SpO_2 measurement is ON: Approximately 2.5 days (new batteries)
  Conditions: When measuring ECG, RESP, SpO_2 with default settings, operating temperature 23°C
- When SpO_2 measurement is OFF: Approximately 6.5 days (new batteries)
  Conditions: When measuring ECG, RESP with default settings, SpO_2 measurement OFF, operating temperature 23°C
  *Disconnecting the SpO_2 probe does not satisfy the above condition. It is necessary to set the SpO_2 measurement to OFF. Refer to “Turning OFF the SpO2 measurement“.

LX-8300M(G)

- When SpO_2 measurement is ON: Approximately 1.5 days (new batteries)
  Conditions: When measuring ECG, RESP, SpO_2 with default settings, operating temperature 23°C
- When SpO_2 measurement is OFF: Approximately 2.5 days (new batteries)
  Conditions: When measuring ECG, RESP with default settings, SpO_2 measurement OFF, operating temperature 23°C
  *Disconnecting the SpO_2 probe does not satisfy the above condition. It is necessary to set the SpO_2 measurement to OFF. Refer to “Turning OFF the SpO2 measurement“.

However, continuous operating time may be shorter than the above mentioned time depending on the application of the SpO_2 probe (sensor).

⚠WARNING

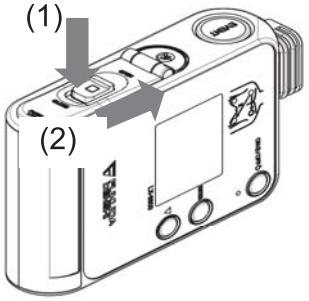
- Unplug the ECG lead cable when the battery compartment lid is opened. Otherwise, patient leakage current beyond the allowable value may occur.
- Use new "AA" size (“LR6” size) alkaline batteries.
- Do not short out the (+) and (-) terminals. It may result in exothermic heat and fire, the leakage from the batteries may damage the equipment, or an explosion from the batteries may occur.
- Install the batteries with the correct polarity.
- Do not charge alkaline batteries. Any attempt to charge the batteries may cause them to leak or break.
- Do not use a disassembled or a damaged battery due to drop or shock. The leakage from the batteries may damage the equipment, or an explosion from the batteries may occur.
- Do not use different types of batteries at the same time. The leakage from the batteries may damage the equipment, or an explosion from the

batteries may occur.

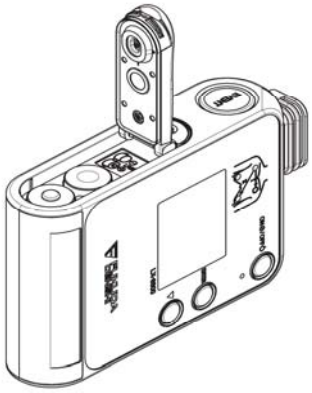
- Remove the exhausted batteries immediately. The leakage from the batteries may damage the equipment, or an explosion from the batteries may occur.
- If the equipment is not in use for a long period of time, remove the batteries and store the equipment in an appropriate place. If the batteries are left in the equipment for a long period of time, the leakage from the batteries may damage the equipment or an explosion from the batteries may occur.
- Make sure to replace the two batteries simultaneously. If a new and used battery are mixed, a leakage from the batteries may damage the equipment or an explosion from the batteries may occur.

⚠CAUTION

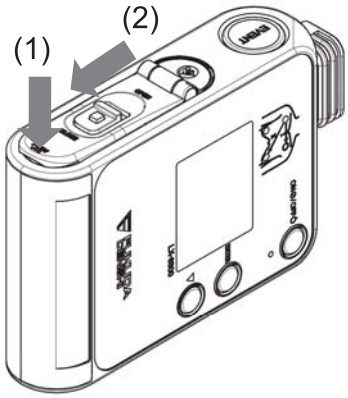
- Use only alkaline battery (AA). Other battery will shorten the continuous operating time.
- Once the power switch is on the OFF position, then open the battery compartment lid.
- Do not replace the batteries with wet hands.
- In case of storing the used or unused batteries, make sure that the terminals are not touching other batteries or metal parts.



Unlock and open the battery compartment lid by sliding the open/close lever towards OPEN while pressing the lock button.



Install new batteries according to the polarity indication inside the battery compartment.



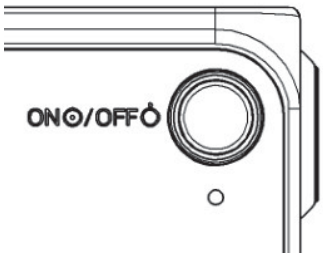
After installing the batteries, lock the battery compartment lid by sliding the open/close lever towards CLOSE while pressing over “PUSH” on the lid.

Make sure that the battery compartment lid is locked. (If you can still see red, then it is not locked properly.)

⚠CAUTION
● Make sure that any foreign particles, such as hairs, are not held on the battery compartment lid and dust is not adhered to the edge of the lid to prevent water entering into the battery compartment area. ● Do not keep the compartment lid unlocked as the batteries may unexpectedly get out from the compartment.

2) Operating the Power Switch

Turning the power switch to “ON”



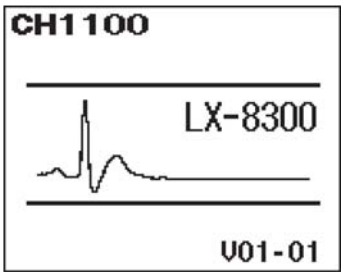
Press the power switch.

Display screen turns ON and measurement starts.

The display screen automatically turns itself OFF after the preprogrammed duration.

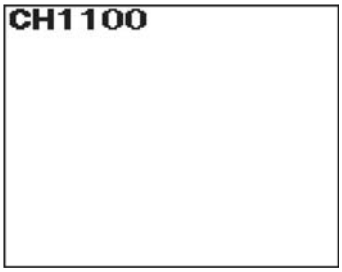
Starting Screen

When the power is turned ON, the channel number configured on the LX-8300M/LX-8300M(G) is displayed at the top of the display.



Make sure that the channel number on the display matches the channel number indicated on the label of the LX-8300M/LX-8300M(G) and the channel number configured on the receiving monitor.

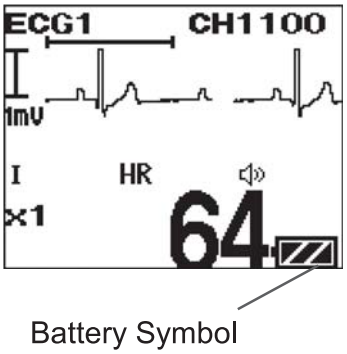
Channel Display Screen



This display is automatically displayed after the starting screen and moves on to the waveform display screen.

Battery Level

After the power is turned ON, make sure to check the remaining battery level on the display screen.
Refer to the following symbol to check the remaining battery level.



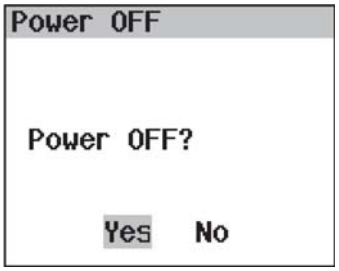
Battery Symbol

Battery Symbol	Remaining Battery Level
	Full
	Getting low but still available
	Nearly empty Replace the batteries. A message that prompts the battery check appears on the screen of the receiving monitor.

NOTE

- When ON/OFF status of SpO_2 measurement is changed, the displayed battery level may change.
- When the SpO_2 measurement is turned OFF, the remaining operation time from the point the lowest battery symbol is displayed will be longer than when the SpO_2 measurement is turned ON.

Turning the power switch to “OFF”



Press the power switch for two seconds, then display screen displays as the left illustration to confirm. Choose “Yes” and press the [ENTER] button.

4. ECG Monitoring

When the transmitter is used without the SpO_2 probe (sensor), it will measure only ECG and respiration.

⚠CAUTION

When using the transmitter with only the ECG lead cable, SpO_2 measurements on the receiving monitor shall be turned off to prevent an erroneous alarm.

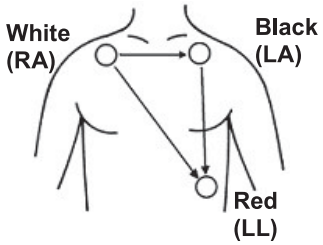
■Connecting the ECG Lead Cable and Electrodes

⚠WARNING

Use only the specified lead cable by Fukuda Denshi. Otherwise, proper monitoring may not be performed, and also defibrillation may fail or cause a malfunction of the equipment when the equipment is used with a defibrillator. For details of the usable lead cables, refer to “14. Standard and Optional Accessories”.

The relations between the attached electrode positions and lead method are as follows. Attach the electrodes to monitor proper waveform.

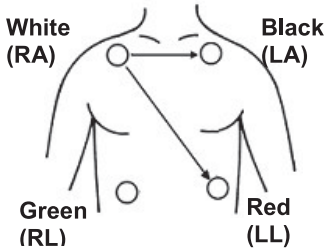
For 3-electrode lead cable



Limb leads

Standard Limb leads can be selected from lead I, lead II, or lead III.
Refer to “8. Operation”.

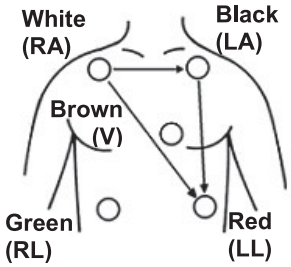
For 4-electrode lead cable



Limb leads

Two leads such as lead I and II can be measured. Lead III, aVR, aVL, and aVF can be also displayed from the setting on the receiving monitor. For details, refer to the operation manual of the receiving monitor

For 5-electrode (chest) lead cable



Limb Lead
+Chest

One limb lead and one chest lead (brown) measurements are available.
Standard Limb leads can be selected from lead I, lead II, or lead III.
Refer to “8. Operation”.
The chest lead waveform is measured from the chest lead (brown) positioned on the chest.

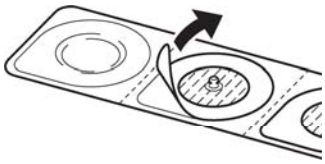
■Attaching the Electrodes

⚠CAUTION

- Always use the same type of electrodes. If different types of electrodes are used at the same time, the difference between the polarization potential from each electrode may interfere with monitoring.
- Do not reuse the disposable electrodes. It is intended for single patient use only.

Clean the electrode sites with alcohol wipes or other skin preparation. If necessary, shave the electrode sites to remove excessive hair.

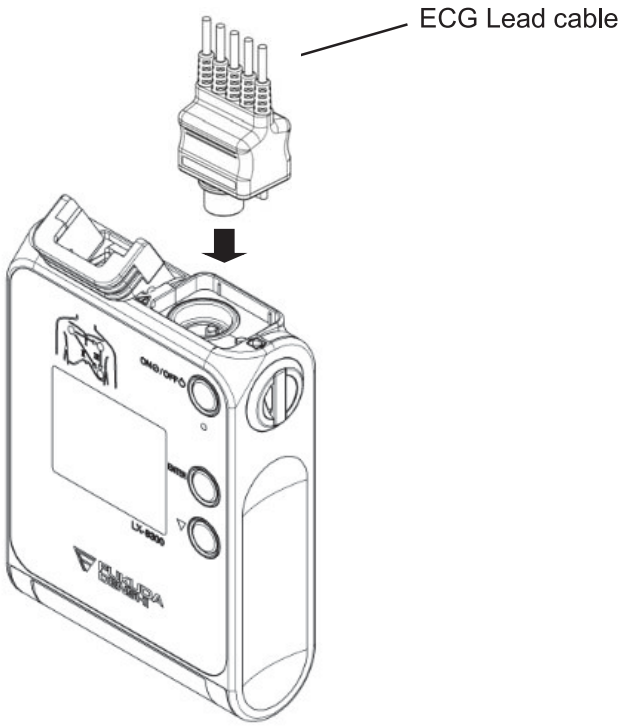
Peel off the disposable electrode



Pay attention not to touch the electrode gel.
Attach the lead cable end to the electrode (convex part).
Turn right and left to verify that it is securely attached.

■Connecting the ECG Lead Cable to the LX-8300M/LX-8300M(G)

Insert the ECG lead cable firmly into the ECG/RESP input connector matching the transmitter's connector guide and the direction of the notched part on the connector.



⚠CAUTION

- The threshold level for HR detection of this equipment and the receiving monitor changes with ECG waveform size. Set a proper waveform size for monitoring.
- There are some cases when pacemaker pulse cannot be detected depending on the pacemaker type, pulse voltage, pulse width, electrode lead type (unipolar, bipolar), electrode placement, or lead method which causes the pacemaker pulse amplitude to decrease and disables pacemaker pulse detection.
- If signals similar to a pacemaker pulse are present, such as electric blanket noise or excessive AC frequency noise, these may be erroneously detected and displayed as a pacemaker pulse. In this case, check the condition of the electrodes and ECG lead cable to resolve the cause or turn off the pacemaker detection setting on the receiving monitor.
- Time constant of this equipment is shorter than Fukuda Denshi monitors (direct ECG connection). Therefore, there is a difference in the ST measurement value between them. Pay attention to the difference when monitoring a patient from a transmitter or a monitor.
- When an electrode is attached on the same location for a long time, some patients may develop skin irritation. Check the patient's skin condition periodically and change the electrode position as required.
- The indication for continuous use of an electrode is about one day.
- Replace the electrode if the skin contact gets loosen due to perspiring, etc.
- Make sure to use new disposable electrodes. Otherwise, the waveform quality may become poor and it may fail to perform correct monitoring
- When "Check Electrode" message is displayed on the screen of the receiving monitor or the display of this equipment, check the condition of the electrodes and ECG lead cable to resolve the cause.
- When removing electrodes from the patient, remove them carefully and slowly. Do not apply excessive force to remove them. Otherwise, it may damage the skin.
- A correct measurement may not be performed depending on the attached position of the electrodes. Attach the electrodes on the patient referring to "■Connecting the ECG Lead Cable and Electrodes" and make sure that the correct waveform is measured on the display.

5. Respiration Monitoring

Follow the procedure explained in “4. ECG Monitoring” to perform the respiration monitoring.

This respiration monitoring is performed with impedance method.
The ECG electrodes are also used for detecting the respiration. Each lead cable specifies the electrodes to detect the respiration. For 3-electrode and 5-electrode (chest) lead cable, the electrodes to detect the respiration are fixed as follows. Even if lead method is switched, they are no changes.

Lead Cable	Color of Electrode
3-electrode	White (RA) and Red (LL)
4-electrode	White (RA) and Red (LL)
5-electrode (Chest)	White (RA) and Red (LL)

⚠WARNING

Minute ventilation rate-adaptive implantable pacemakers can occasionally interact with certain cardiac monitoring and diagnostic equipment, causing the pacemakers to pace at their maximum programmed rate. The cardiac monitoring and diagnostic equipment may possibly send wrong information.

If such event occurs, please disconnect the cardiac monitoring and diagnostic equipment, or follow the procedures described in the operation manual of the pacemaker.

(For more details, contact FUKUDA DENSHI personnel, your institution’s professionals, or your pacemaker distributors.)

➲Reference
“Minute Ventilation Rate-Adaptive Pacemakers”
FDA alerts health professionals that minute ventilation rate-adaptive implantable pacemakers can occasionally interact with certain cardiac monitoring and diagnostic equipment, causing pacemakers to pace at their maximum programmed rate.
[October 14, 1998 – FDA]

⚠CAUTION

- Even if the electrodes are attached on the proper positions for ECG monitoring, it may not be always the proper ones for respiration monitoring as well.
- When a defibrillator is used during respiration monitoring, a large offset voltage will be placed on the ECG electrodes, which may cause interruption of monitoring for a few seconds.

5. Respiration Monitoring