LX-8000 series
ECG, Respiration and SpO_2 Transmitter

LX-8300M

Ver. 01

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 Version 01.

⚠ 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.

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If this manual has pages missing or out of order, contact Fukuda Denshi for replacement.

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

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.
ON⊙/OFF Ȯ	Indicates the power ON/OFF status.
PUSH	Indicates the point to close the battery compartment lid.
LR6/AA	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 (“LR06” 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 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.
- 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 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 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 distrubances 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 is intended for use in the electromagnetic environment specified below.
The customer or the user of the LX-8300M 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.

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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 7

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 13

5. Respiration Monitoring 15

6. SpO_2 Monitoring 17
- ■Preparation for Monitoring 17
- ■Connecting the SpO_2 sensor to the LX-8300M 29

7. Measurement 31
- ■Monitoring Screen 31
- ●All Data Display 33

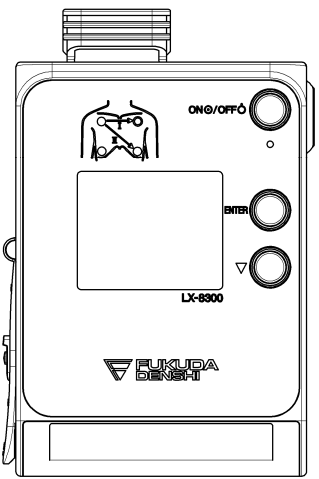
8. Operation 39

■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 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

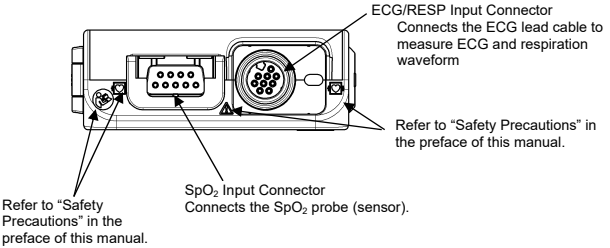
1. General Description

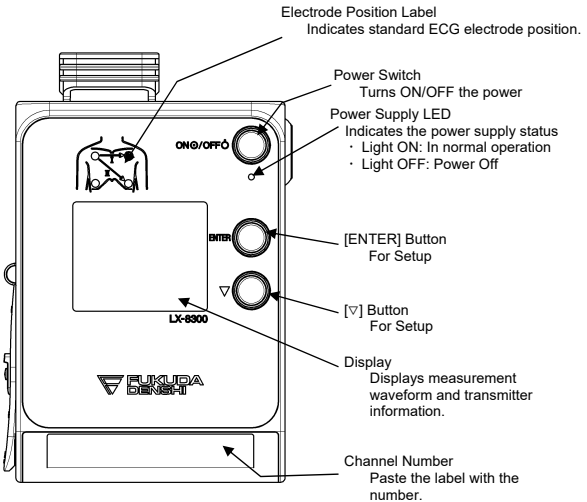
The LX-8300M is a radio telemetry transmitter designed to measure the ECG, respiration waveform, SpO_2 (functional oxygen saturation of arterial hemoglobin), pulse waveform with two “AA” size (“LR06” size) alkaline batteries.
Information such as ECG measurements, respiration waveform, SpO_2 measurements, 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 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, read also the operation manual of the patient monitor at the receiving side thoroughly.

External Appearance



2. Names of Parts and Their Functions





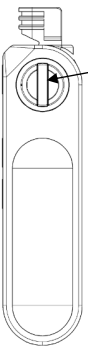
2. Names of Parts and Their Functions

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

- 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“.

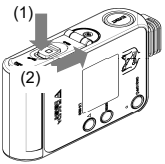
However, continuous operating time may be shorter than the above mentioned time depending on the application of the SpO_2 probe (sensor).

⚠WARNING

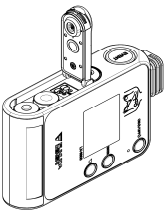
- Unplug the ECG lead cable when the battery compartment lid is opened. Otherwise, patient leakage current beyond the allowable value may occur.
- Use new "AA" size (“LR06” size) alkaline batteries.
- Do not short out the (+) and (-) terminals. It may result in exothermic heat and fire, the leakage from 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

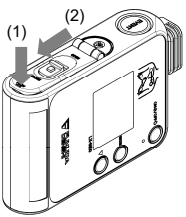
- Use only alkaline battery (AA). Other battery will shorten the continuous operating time.
- Once the power switch is on the OFF position, then open the battery compartment lid.
- Do not replace the batteries with wet hands.
- In case of storing the used or unused batteries, make sure that the terminals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



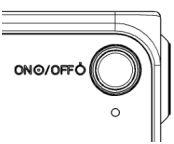
After installing the batteries, lock the battery compartment lid by sliding the open/close lever towards CLOSE while pressing over “PUSH” on the lid.

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”



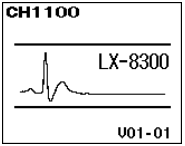
Press the power switch.

Display screen turns ON and measurement starts.

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

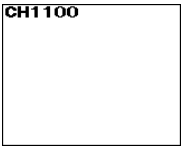
Starting Screen

When the power is turned ON, the channel number configured on the LX-8300M 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 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.

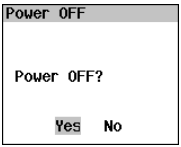
Battery Symbol

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.

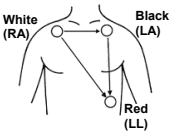
⚠CAUTION
When using the transmitter with only the ECG lead cable, SpO_2 measurements on the receiving monitor shall be turned off to prevent an erroneous alarm.

■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.

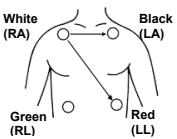
For 3-electrode lead cable



Limb leads

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

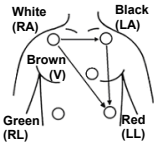
For 4-electrode lead cable



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.

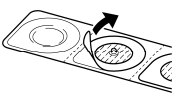
■Attaching the Electrodes

⚠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.

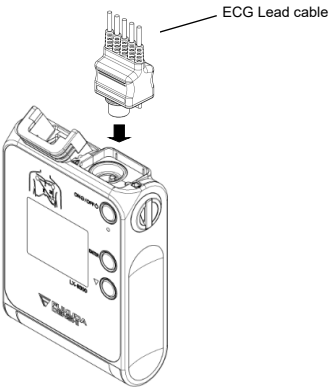
Peel off the disposable electrode



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

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.

6. SpO_2 Monitoring

When the transmitter is used without the ECG lead cable, it will measure only SpO_2.

⚠WARNING

When the SpO_2 probe (sensor) is in a connector-off condition, the SpO_2 alarm will not be generated on the receiving monitor regardless of the SpO_2 measurement ON/OFF status. Make sure that the SpO_2 probe (sensor) is securely connected. If the SpO_2 waveform/numeric data is not displayed, check the patient's condition and pay attention not to miss the connector-off condition.
If the display is OFF, SpO_2 measurement will not start even when the SpO_2 probe is connected. In such case, turn ON the display. SpO_2 measurement will automatically start regardless of the ON/OFF status of SpO_2 measurement.

⚠CAUTION

- When using the transmitter with only the SpO_2 sensor cable, ECG and respiration measurements on the receiving monitor shall be turned off to prevent an erroneous alarm.
- The pulse wave and level meter are normalized for SpO_2 measurement. It does not indicate perfused blood volume. Check proper probe attachment by observing the pulse wave.

■Preparation for Monitoring

Select the proper SpO_2 sensors depending on the purpose and application sites defined in the sensors directions for use.
For details of the usable SpO_2 sensors, refer to "14. Standard and Optional Accessories".

⚠WARNING

- For SpO_2 monitoring, always use the sensor specified by Fukuda Denshi. Also, 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.
- As with all medical equipment, carefully route cables to reduce the possibility of patient entanglement and strangulation.
- Do not place this equipment or accessories in any position that might cause it to fall on the patient.
- Do not start or operate this equipment unless the setup was verified to be correct.
- Do not operate this equipment in magnetic resonance imaging (MRI) environments.

⚠WARNING

- Do not use this equipment if it appears or is suspected to be damaged.
- Explosion hazard: Do not use this equipment in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- To ensure safety, avoid stacking multiple devices or placing anything on the instrument during operation.
- To protect against injury, follow the directions below:
  - Avoid placing the equipment on surfaces with visible liquid spills.
  - Do not soak or immerse the equipment in liquids.
  - Do not sterilize the equipment.
  - Use cleaning solutions only as instructed in this operation manual.
  - Do not attempt to clean the equipment while monitoring patient.
- To protect from electric shock, always remove the sensor and completely disconnect this equipment before bathing the patient.
- If any measurement seems questionable, first check the patient's vital signs by alternate means and then check this equipment for proper functioning.
- Inaccurate SpO_2 readings can be caused by the following.
  - Improper sensor application
  - Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO_2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (co-oximetry) of a blood sample should be performed.
  - Intravascular dyes, such as indocyanine green or methylene blue
  - Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
  - Elevated levels of bilirubin
  - Severe anemia
  - Very low arterial perfusion
  - Extreme motion artifact
  - Elevated levels of dyshemoglobin
  - Vasospastic disease such as Raynaud's
  - Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
  - Hypocapnic or hypercapnic conditions
  - Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.
  - Pigment disorder
- Inaccurate SpO_2 readings can be caused by the following. (Continued)
- Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
- This equipment is intended only as a supplementary equipment for patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.
- Do not use the SpO_2 data to monitor apnea condition.
- This equipment may be used during defibrillation, but this may affect the accuracy or availability of the SpO_2 parameters and measurements.

⚠WARNING

- This equipment may be used during electrocautery, but this may affect the accuracy or availability of the SpO_2 parameters and measurements.
- The SpO_2 data cannot be used for arrhythmia analysis.
- SpO_2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- Do not adjust, repair, open, disassemble, or modify this equipment or accessories. Injury to personnel or equipment damage could occur. Return this equipment for servicing if necessary.

⚠CAUTION

- SpO_2 sensors are not waterproof. Keep away from liquids.
- Do not pick up the equipment pulling the sensor or cable part. It may get disconnected from the equipment and the equipment may be dropped.
- “SpO_2 OFF” is displayed when the SpO_2 measurement is turned OFF.
- A message is displayed when the SpO_2 sensor is disconnected from the equipment.
- A message is displayed when the equipment detects that the SpO_2 sensor is disconnected from the patient. Properly attach the SpO_2 sensor to the patient.
- Do not reuse the single-use SpO_2 sensor. It may cause incorrect measurements.
- Read through the instruction of the SpO_2 sensor as well.
- Do not place this equipment where the controls can be changed by the patient.
- Electrical shock and flammability hazard: Before cleaning this equipment, make sure to turn off the power.
- When patients are undergoing photodynamic therapy, they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.
- Do not place this equipment on electrical equipment that may affect the operation, preventing it from working properly.
- If the measurements indicate hypoxemia, a laboratory blood sample should be taken to accurately assess the patient’s condition.
- If the <LowPerf.> message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.
- Change the application site or replace the sensor when a < Bad Sens > is displayed on the monitor. This messages may indicate that patient monitoring time is exhausted on the patient sensor.
- If using this equipment during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the equipment might read zero for the duration of the active irradiation period.
- Variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient’s clinical

⚠CAUTION

status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.

- Do not submerge this equipment in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage this equipment.
- Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked in compliance with IEC 60601-1. When an event such as a component drop or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.
- Disposal of product - Comply with local laws in the disposal of the equipment and/or its accessories.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to this equipment.
- Replace the sensor when a <Bad Sens> message is consistently displayed while monitoring patients even after following the troubleshooting steps explained in this manual.

NOTE

- A functional tester cannot be used to assess the SpO_2 accuracy.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow this equipment to obtain SpO_2 readings.
- When using the maximum sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the equipment is in this setting and the sensor becomes disconnected from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.
- Do not loop the patient cabling into a tight coil or wrap around the equipment, as this can damage the patient cabling.
- Additional information specific to the sensors compatible with this equipment, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use.

NOTE

- Precautions about the Masimo Sensors

  A technology called X-Cal for patient safety and reinforcement of efficiency in a clinical site is implemented for Masimo sensors. X-Cal is designed to address the following three common factors that can impact measurement accuracy and patient safety due to reliability risks.

  1) Imitation Masimo sensors
  2) Sensors used far beyond their expected life
  3) Third-party reprocessed pulse oximetry sensors

  If a sensor that does not support X-Cal is used with an X-Cal enabled equipment, SpO_2 measurement will not be available. Even if Masimo sensors or specified sensors are used, SpO_2 measurement may not be available if the sensors are used beyond their expected life.

- About the Expected Life of Masimo Sensors

  The X-Cal function automatically monitors the Active Monitoring Time (actual time of SpO_2 monitoring) for each sensor. If the sensors are used beyond the expected life, <Bad Sens> or an icon will be displayed. The monitoring can be continued after <Bad Sens> is displayed, but after 12 hours (disposable sensor)/72 hours (reusable sensor), one of the following operation will make the sensor unusable.

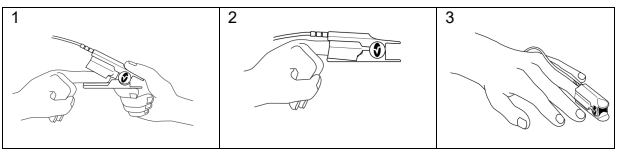
  1) Sensor is detached from the patient for 2 hours or more.
  2) Probe is disconnected from the equipment.
  3) The power of the equipment is turned OFF.

  The following table shows the expected life of sensor. The indication of usage hours per day (24 hours/12 hours/8 hours) are also shown.
  The time inside the brackets are indication of time until the ⚠ icon is displayed.

Sensor	Expected Life	Actual Time of SpO_2 Monitoring: 24 hours/day	Actual Time of SpO_2 Monitoring: 12 hours/day	Actual Time of SpO_2 Monitoring: 8 hours/day
Single Patient Use SpO_2 L-Shape Sensor	336 hours (Approximately 302 hours)	14 days (Approximately 12 days)	28 days (Approximately 25 days)	42 days (Approximately 37 days)
Single Patient Use SpO_2 Sensor	168 hours (Approximately 151 hours)	7 days (Approximately 5 days)	14 days (Approximately 12 days)	21 days (Approximately 18 days)
Reusable Sensor (DCI, TC-I, TF-I)	8,760 hours (Approximately 7,884 hours)	12 months (Approximately 328 days)	2 years (Approximately 657 days)	3 years (Approximately 985 days)

●Applying the LNCS DCI, RD SET DCI

1. Open the sensor by pressing on hinge tabs. Place the selected digit over the sensor window of the LNCS DCI or DCIP. The fleshiest part of the digit should be covering the detector window in the lower half of the sensor. The top half of the sensor is identified by the cable. On finger sites, the tip of the finger should touch the raised digit stop inside the sensor. If the fingernail is long, it may extend over and pass the finger stop (Fig. 1).
2. The hinged tabs of the sensor should open to evenly distribute the grip of the sensor along the length of the finger. Check position of sensor to verify correct positioning. Complete coverage of the detector window is needed to ensure accurate data (Fig. 2).
3. Orient the sensor so that the cable will be running towards the top of the patient's hand (as shown in Fig. 3). Connect the sensor connector to a patient cable.



Precautions for Using the LNCS DCI, RD SET DCI

⚠CAUTION

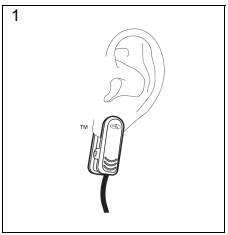
- Do not sterilize by irradiation, steam autoclave or ethylene oxide.
- Before using the sensor, ensure that the sensor is physically intact, with no broken or frayed wires or damaged parts.
- Do not immerse the sensor or connector in any liquid solution.
- With smaller digits, in order to completely cover the detector window, the digit might not need to be pushed all the way to the stop. The sensor is not intended for use on the thumb or across a child's hand or foot.
- The site must be checked or changed at least every four hours to ensure adequate adhesion, circulation, skin integrity and correct optical alignment.
- Exercise extreme caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when the sensor is not frequently moved. Assess site at least every two (2) hours with poorly perfused patients.
- During low perfusion, the sensor site needs to be assessed frequently for signs of tissue ischemia, which can lead to pressure necrosis.
- With very low perfusion at the monitored site, the readings may read lower than core arterial oxygen saturation.
- Sensors applied too tightly may cause erroneously low readings.
- Circulation distal to the sensor site should be checked routinely.
- Misapplied sensors or sensors that become partially dislodged may cause either over or under reading of actual arterial oxygen saturation.

⚠CAUTION

- Do not use tape to secure the sensor to the site; this can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage or damage the sensor.
- The sensor should be free of visible defects. Never use a damaged sensor or one with exposed electrical circuitry.
- To prevent damage, do not soak or immerse sensor in any liquid solution. Do not attempt to sterilize the sensor.
- Carefully route cable and patient cable to reduce the possibility of patient entanglement or strangulation.
- Intravascular dyes or externally applied coloring (such as nail polish) may lead to inaccurate SpO_2 measurements.
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO_2 measurements.
- Elevated levels of Methehemoglobin (MetHb) may lead to inaccurate SpO_2 measurements.
- Failure to apply the sensor properly may cause incorrect measurements.
- Do not use the sensor during MRI scanning.
- If using pulse oximetry during full body irradiation, keep the sensor out of the irradiation field. If sensor is exposed to the irradiation, the reading might be inaccurate or the unit might read zero for the duration of the active irradiation period.
- Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.
- The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify patient's pulse rate against the ECG heart rate.
- Do not modify or alter the sensor in any way. Alterations or modification may affect performance and/or accuracy.
- Venous congestion may cause under reading of actual arterial 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).
- Venous pulsations may cause erroneous low SpO_2 readings (e.g. tricuspid value regurgitation).

•Applying the LNCS TCI

1. To improve perfusion to the ear, rub the earlobe vigorously for 25-30 seconds. The ear lobe can also be rubbed with rubefacient cream (10-30% methylsalicylate and 2-10% menthol).
2. Clip the sensor onto the ear lobe (Fig. 1) or pinna. Orient the cable so that it runs down the neck toward the body. If the LNCS TC-I sensor does not fit properly on the ear, consider using an LNCS adhesive sensor or LNCS reusable finger clip on another measuring site.



Precautions for Using the LNCS TCI

⚠CAUTION

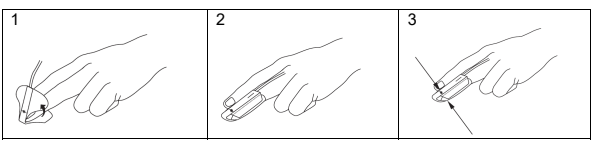
- Do not immerse the connector on the LNCS TC-I cable in any liquid solution.
- Do not sterilize by irradiation, steam autoclave or ethylene oxide.
- Do not use undiluted bleach (5%-5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the sensor may occur.
- Do not immerse the connector on the LNCS TC-I cable in any liquid solution.
- The site must be changed every four hours.
- Circulation distal to the sensor site should be checked routinely.
- Exercise caution with poorly perfused patients; skin erosion and/or pressure necrosis may occur.
- During low perfusion, the sensor site needs to be assessed frequently for signs of tissue ischemia, which can lead to pressure necrosis.
- With very low perfusion at the monitored site, the readings may read lower than core arterial oxygen saturation.
- Do not use tape to secure the sensor to the site; this can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage or damage the sensor.
- Do not use the LNCS TC-I on any site other than the ear lobe or pinna. This may result in inaccurate readings due to tissue thickness.
- If supplemental tape is used, venous congestion/pulsations may occur causing erroneous readings.
- Misapplied sensors or sensors that become partially dislodged may cause either over or under reading of actual arterial oxygen saturation.

⚠CAUTION

- If the sensor is damaged in any way, discontinue use immediately.
- Carefully route cable and patient cable to reduce the possibility of patient entanglement or strangulation.
- Intravascular dyes may lead to inaccurate SpO_2 measurements.
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO_2 measurements.
- Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO_2 measurements.
- Failure to apply the LNCS TC-I properly may cause incorrect measurements.
- Do not use the LNCS TC-I during MRI scanning.
- If using pulse oximetry during full body irradiation, keep the sensor out of the irradiation field. If sensor is exposed to the irradiation, the reading might be inaccurate or the unit might read zero for the duration of the active irradiation period.
- The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify patient's pulse rate against the ECG heart rate.
- Venous pulsations may cause erroneous low readings (e.g., tricuspid value regurgitation, Trendelenberg position).
- Do not modify or alter the sensor in any way. Alterations or modification may affect performance and/or accuracy.

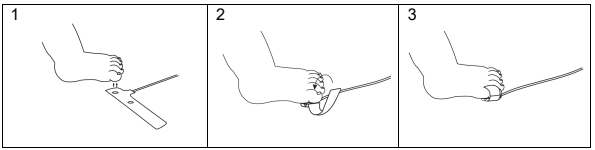
●Applying the LNCS Adtx, LNCS Pdtx, RD SET Adt, RD SET Pdt

1. Open the pouch and remove the sensor. Remove the backing from the sensor, if present.
2. Orient the sensor cable so that the detector can be placed first. Place the tip of the finger on the dashed line with the fleshy part of the finger covering the detector window (Fig 1). Press the adhesive wings one at a time onto the finger (Fig 2). Complete coverage of the detector window is needed to ensure accurate data.
3. Fold the sensor over the finger with the emitter window (red star) positioned over the fingernail. Secure the wings down one at a time around the finger. When properly applied, the emitter and detector should be vertically aligned (Fig 3).
   Verify correct positioning and reposition if necessary (the black lines should align).



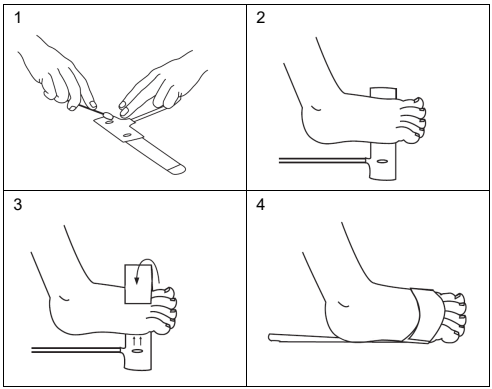
●Applying the LNCS inf-L, LNCS inf-3, RD SET Inf

1. Open the pouch and remove the sensor. Remove the backing from the sensor, if present.
2. Direct the sensor cable so that it either points away from the patient or runs along the bottom of the foot. Position the detector onto the fleshy part of the great toe (Fig 1). Complete coverage of the detector window is needed to ensure accurate data.
3. Wrap the adhesive wrap around the toe and ensure that the emitter window (red star) aligns on the top of the toe directly opposite the detector (Fig. 2).
   Verify correct positioning and reposition if necessary (Fig. 3).



●Applying the LNCS Neo-L, LNCS NeoPt-L, LNCS NeoPt3, RD SET Neo, RD SET NeoPt

1. Open the pouch and remove the sensor. Remove the backing from the sensor, if present.
2. For fragile skin, the stickiness of the medical grade adhesive can be diminished or eliminated by daubing the adhesive areas with a cotton ball or with gauze (Fig. 1).This step does not apply to the NeoPt 500.
3. Direct the sensor cable so that it either points away from the patient or runs along the bottom of the foot. Apply the detector onto the fleshy part of the lateral aspect of the sole of the foot aligned with the fourth toe (Fig. 2). Alternatively, the detector may be applied to the top of the foot (not shown). Complete coverage of the detector window is needed to ensure accurate data.
4. Wrap the adhesive/foam wrap around the foot and ensure that the emitter window (red star) aligns directly opposite of the detector. Be careful to maintain proper alignment of the detector and emitter windows while attaching adhesive/foam wrap to secure the sensor (Fig. 3).
   Verify correct positioning and reposition if necessary. (Fig. 4).



Precautions for Using the LNCS Adtx, LNCS Pdtx, RD SET Adt, RD SET Pdt, LNCS inf-L, LNCS inf-3, RD SET Inf, LNCS Neo-L, LNCS NeoPt-L, LNCS NeoPt3, RD SET Neo, RD SET NeoPt

⚠CAUTION

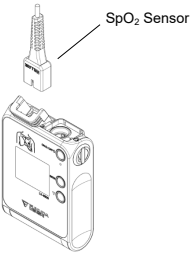
- The site must be checked frequently or per clinical protocol to ensure adequate adhesion, circulation, skin integrity and correct optical alignment.
- Circulation distal to the sensor site should be checked routinely.
- Exercise caution with poorly perfused patients; skin erosion and/or pressure necrosis can be caused when the sensor is not frequently moved. Assess site as frequently as every 1 hour with poorly perfused patients and move the sensor if there are signs of tissue ischemia.
- During low perfusion, the sensor site needs to be assessed frequently for signs of tissue ischemia, which can lead pressure necrosis.
- Do not use tape to secure the sensor to the site; this can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage or damage the sensor.
- Misapplied sensors or sensors that become partially dislodged may cause either over or under reading of actual arterial oxygen saturation.
- With very low perfusion at the monitored site, the readings may read lower than core arterial oxygen saturation.
- Failure to apply the sensor properly may cause incorrect measurements.
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO_2 measurements.
- Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO_2 measurements.
- Elevated levels of Total Bilirubin may lead to inaccurate SpO_2 measurements.

⚠CAUTION

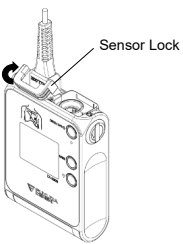
- Intravascular dyes or externally applied coloring (such as nail polish) may lead to inaccurate SpO_2 measurements.
- Sensors applied too tightly or that become tight due to edema will cause inaccurate readings and can cause pressure necrosis.
- Venous congestion may cause under reading of actual arterial 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).
- The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify patient's pulse rate against the ECG heart rate.
- Venous pulsations may cause erroneous low readings (e.g. tricuspid value regurgitation).
- The sensor should be free of visible defects. Never use a damaged sensor or one with exposed electrical circuitry.
- Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.
- Carefully route cable and patient cable to reduce the possibility of patient entanglement or strangulation.
- If using pulse oximetry during full body irradiation, keep the sensor out of the irradiation field. If sensor is exposed to the irradiation, the reading might be inaccurate or the unit might read zero for the duration of the active irradiation period.
- To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.
- Do not use the sensor during MRI scanning.
- To prevent damage, do not soak or immerse the sensor in any liquid solution.
- Do not modify or alter the sensor in any way. Alterations or modification may affect performance and/or accuracy.
- Do not attempt to reprocess, recondition or recycle Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to patient harm.
- High oxygen concentrations may predispose a premature infant to retinopathy. Therefore, the upper alarm limit for the oxygen saturation must be carefully selected in accordance with accepted clinical standards.

■Connecting the SpO_2 sensor to the LX-8300M

1. Insert the SpO_2 sensor into the SpO_2 input connector on the LX-8300M.



2. Attach the sensor lock as shown in the following illustration to prevent the SpO_2 sensor to be disconnected.



7. Measurement

Turn ON the power and the measurement starts.

■Monitoring Screen

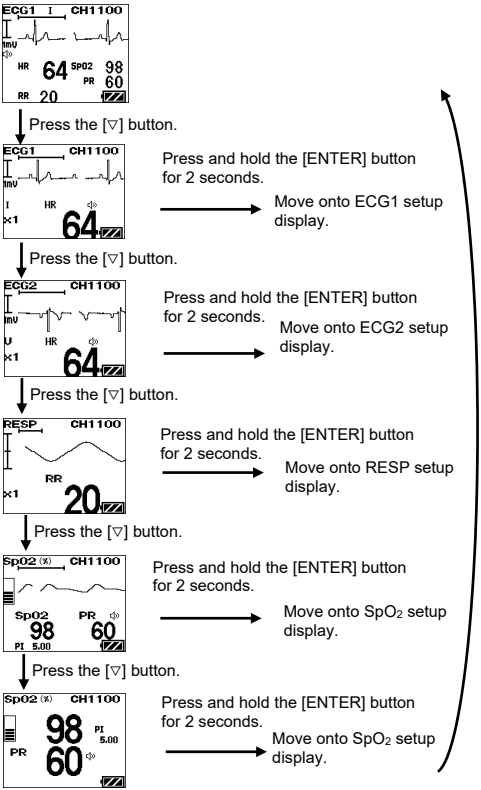
ECG waveform (1 channel when using 3-electrode lead cable, 2 channels when using other lead cable), heart rate, pacemaker marker, respiration waveform, respiration rate, pulse wave, SpO_2 measurement value, remaining battery level, and various messages are displayed.

⚠CAUTION

- The LX-8300M does not have a diagnostic function. Check the diagnostic function on the receiving monitor.
- The LX-8300M does not have an alarm function. Check the alarm function on the receiving monitor.
- The ECG waveform size and sweep speed settings displayed on the display of the LX-8300M do not interface with the ones displayed on the screen of the receiving monitor.
- The heart rate and respiration rate displayed on the display of the LX-8300M may be different from the ones displayed on the receiving monitor because the algorithm of the ECG and respiration rate is different.

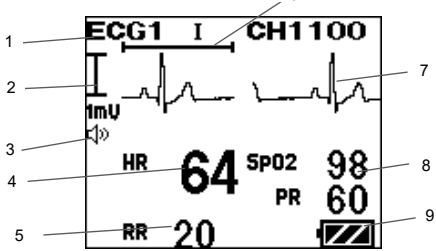
●Switching the Display

The screen (e.g. ECG) can be switched to other screens (respiration, pulse, or SpO_2, etc.)
The screen automatically turns itself OFF after preprogrammed duration if no operation is done. For procedure to restart the display, refer to “8. Operation”.
When the display is active, press the [▽] button to move onto the next screen.
The screen will switch in the following order.



●All Data Display

ECG1 waveform and all other measured data (heart rate, respiration rate, pulse rate, SpO_2 value) pacemaker marker, remaining battery level, electrode check message, and SpO_2 OFF status are displayed.
The displayed contents are as follows.



1. Indicates that ECG1 waveform is displayed.
2. Indicates the vertical scale of the displayed ECG.
   One scale corresponds to 1 mV. For the above display example, the display range is ±1mV.
3. Displays the speaker mark when the synchronized tone is active.
   For details, refer to “8. Operation”.
4. Displays the heart rate.
5. Displays the respiration rate.
6. Indicates the horizontal scale of the displayed ECG.
   One scale corresponds to 1 second.
7. Displays the measured waveform.
8. Displays the SpO_2 value, pulse rate.
   “SpO_2 OFF” is displayed when the SpO_2 measurement is set to OFF.
9. Indicates the remaining battery level.
   For details, refer to “7. Measurement/Battery Level”.

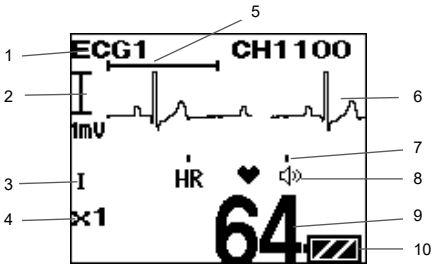
For details of the displayed messages and icons, refer to “11. Troubleshooting”.

●ECG Display

ECG1/ECG2 waveform, heart rate, pacemaker mark, remaining battery level, and electrode check message are displayed.

NOTE
If 3-electrode lead cable is used, ECG2 display will not appear.

The descriptions of the displayed contents are as follows.



1. Indicates ECG1 or ECG2.
2. Indicates the vertical scale of the displayed ECG waveform.
   One scale corresponds to 1 mV.
3. Indicates the measuring lead.
4. Indicates the ECG waveform size displayed on the display.
5. Indicates the horizontal scale of the displayed ECG waveform.
   One scale corresponds to one second.
6. Displays the ECG waveform.
7. Displays the detection marker when a pacemaker pulse is detected.
8. Displays the speaker mark when synchronized tone is active.
   For details, refer to “8. Operation”.
9. Displays the heart rate.
   ♥ is displayed in synchronization with the heart rate.
10. Indicates the remaining battery level.
    For details of the battery level, refer to “3. Preparation”.

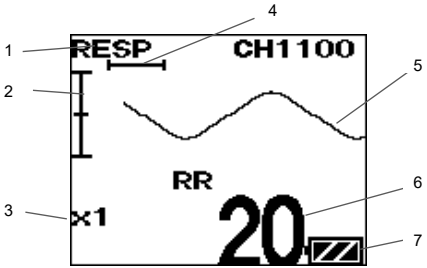
For details of the displayed messages and icons, refer to “11. Troubleshooting”.

⚠CAUTION

- The displayed ECG waveform size setting does not interact with the one displayed on the receiving monitor.
  If the ECG waveform size displayed on the receiving monitor is changed, follow the instruction in the operation manual of the receiving monitor.
- When “Wide” is selected in the “QRS Detection” and if HR is outside the display range (12 bpm to 300 bpm), 0 bpm will be displayed if 11 bpm and below is measured and 300 bpm will be displayed if 300 bpm and above is measured.
- When “Narrow” is selected in the “QRS Detection”, and if HR is outside the display range (30 bpm to 300 bpm), 0 bpm will be displayed if 29 bpm and below is measured and 300 bpm will be displayed if 300 bpm and above is measured.

●Respiration Display

Respiration waveform, respiration rate, remaining battery level, and electrode check message are displayed.
The descriptions of the displayed contents are as follows.



1. Indicates the respiration waveform display screen.
2. Indicates the vertical scale of the displayed respiration waveform.
   One scale corresponds to 1Ω.
   For the above display example, it can display between -1Ω and +1Ω.
3. Indicates the respiration waveform size displayed on the display.
4. Indicates the horizontal scale of the displayed respiration waveform.
   One scale corresponds to one second.
5. Displays the respiration waveform.
6. Displays the respiration rate.
7. Indicates the remaining battery level.
   For details of the battery level, refer to “3. Preparation”.

⚠CAUTION

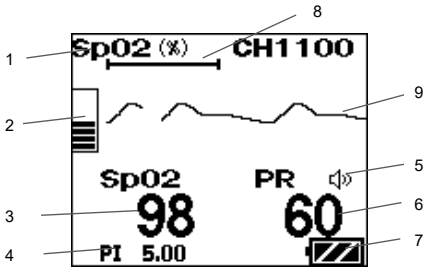
- The displayed respiration waveform size setting does not interact with the one displayed on the receiving monitor.
  If the respiration waveform size displayed on the receiving monitor is changed, follow the instruction in the operation manual of the receiving monitor.
- If RR is outside the display range (4 Bpm to 150 Bpm), 0 Bpm will be displayed if 3 Bpm and below is measured, and 150 Bpm will be displayed if 150 Bpm and above is measured.

For details of the displayed messages and icons, refer to “11. Troubleshooting”.

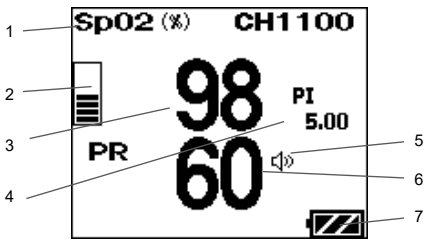
●SpO_2 Display

Pulse wave, pulse rate, SpO_2 measurement value, PI measurement value, remaining battery level, probe condition, and SpO_2 OFF status are displayed. The descriptions of the displayed contents are as follows.

NOTE
The following display example is when the SpO_2 measurement is set to ON. When the SpO_2 measurement is set to OFF, “SpO_2 OFF” is displayed.



SpO_2 Standard Display



SpO_2 Enlarged Display

1. Indicates the SpO_2 display.
2. Indicates the amplitude level of the pulse wave in 8 steps.
3. Displays the SpO_2 measurement value.
4. Displays the PI measurement value.
5. Displays the speaker mark when the synchronized tone is active.

For details, refer to “8. Operation”.

6. Displays the pulse rate.
7. Indicates the remaining battery level.
   For details of the battery level, refer to “3. Preparation”.
8. Indicates the horizontal scale of the displayed SpO_2 waveform.
   One scale corresponds to one second.
9. Displays the pulse wave.
   The waveform size is adjusted automatically.

For details of the displayed messages and icons, refer to “11. Troubleshooting”

⚠CAUTION

To display the PI value on the receiving monitor, the receiving monitor needs to be compatible with the PI value display function. For details, refer to the operation manual of the receiving monitor.

NOTE

The perfusion index (PI) is calculated by pulsatile signal divided by apulsatile signal times 100, and indicates patient’s circulation condition at the monitoring site.
This can be used to find a good perfusion site to attach the sensor. Also, it can be used as diagnosis index to predict the patient’s critical condition when at low perfusion.
(Reference)
Perfusion Index (PI) is a relative assessment of the pulse strength at the monitoring site. It is a ratio of the pulsatile and the non-pulsatile blood flow at the monitoring site. It can be used to find the most appropriate sensor application site by finding the site with the highest PI. Perfusion Index (PI) is displayed in the range from 0.02% to 20%, and the recommended value is 1% or above.

■Setup Mode

To Enter Setup Mode

Press and hold the [ENTER] button for 2 seconds.

To Terminate Setup Mode

Press the [▽] button to highlight [↩], and press the [ENTER] button.

⚠CAUTION
Make sure to terminate the setup mode after the setting to prevent the settings to be changed by unintended operation.

Setup Items

The following settings can be perfomred.

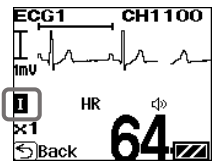
Items	Selection	Default	Backup
ECG Lead	I, II, III	II	Yes
Display Size of ECG (1)	×1, ×1/2	×1	Yes
Display Size of ECG (2)	×1, ×1/2	×1	Yes
Display Size of RESP	×1, ×1/2	×1	Yes

■ECG Setup

In the ECG display, the waveform size and lead can be changed and the synchronized tone can be set.

Switching Lead

ECG lead can be switched when 3-electrode lead cable or 5-electrode (Chest) lead cable is used.
Select an appropriate lead by checking the ECG waveform on the display.

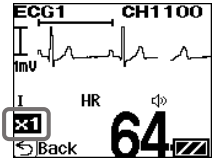


Press the [▽] button to highlight the lead indication.

Press the [ENTER] button to sequentially change the lead in the order of I → II → III → I.

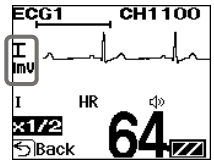
NOTE
The lead cannot be changed for ECG2 display.

Changing the ECG Waveform Size



Press the [▽] button to highlight the size indication.

Pressing the [ENTER] button will sequentially change the size in the order of ×1 → ×1/2 → ×1



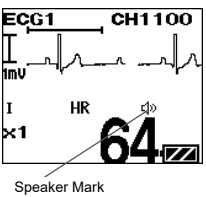
When the waveform size is changed, the ECG scale will also change.
For the example shown on left, the scale between -2mV and +2mV can be selected.

⚠CAUTION

The ECG waveform size displayed on the LX-8300M does not interact with the one displayed on the receiving monitor.
To change the waveform size of the receiving monitor, follow the instruction in the operation manual of the receiving monitor.

Generating a Synchronized Tone

When the speaker mark is displayed, a synchronized tone will generate along with the mark.

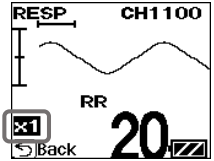


Press and hold the [ENTER] and [▽] button for 2 seconds to display the speaker mark. Press and hold the [ENTER] and [▽] button again for 2 seconds to clear the speaker mark and synchronized tone. This setting will be applied to ECG1, ECG2, and SpO_2 display.

■Respiration Setup

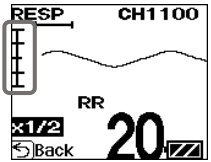
In the respiration display, the respiration waveform size can be changed.

Changing Respiration Waveform Size



Press the [▽] button to highlight the size indication.

Press the [ENTER] button to sequentially change the waveform size in the order of ×1 → ×1/2 → ×1.



When the waveform size is changed, the respiration scale will also change.
In the example shown on left, up to 4Ω change can be displayed.

⚠CAUTION

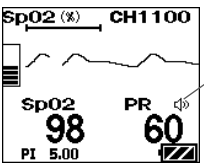
The waveform size displayed on the LX-8300M does not interact with the one displayed on the receiving monitor.
To change the waveform size of the receiving monitor, follow the instruction in the operation manual of the receiving monitor.

■SpO_2 Setup

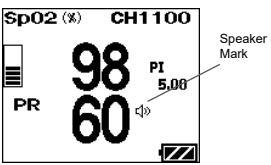
In the SpO_2 display, the synchronized tone and ON/OFF of SpO_2 measurement can be set.

Generating a Synchronized Tone

When the speaker mark is displayed, a synchronized tone will generate along with the mark.



SpO_2 Standard Display

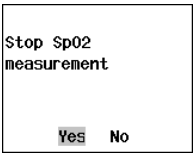


SpO_2 Enlarged Display

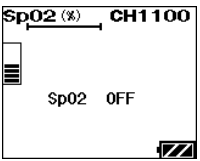
Press and hold the [ENTER] and [▽] button for 2 seconds to display the speaker mark.
Press and hold the [ENTER] and [▽] button again for 2 seconds to clear the speaker mark and synchronized tone. This setting will be applied to ECG1, ECG2, and SpO_2 display.

The synchronized tone changes with the SpO_2 value.
The tone is highest when the SpO_2 value is 100%, and decreases in 1% step until 80% which is the lowest tone.

Turning OFF the SpO_2 measurement



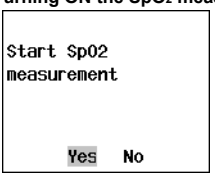
While the SpO_2 display is shown, disconnect the SpO_2 probe and press the [ENTER] button for 2 seconds.
A confirmation screen will be displayed.
Select [Yes], and press the [ENTER] button.



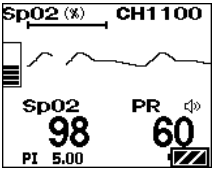
The SpO_2 measurement will stop, and “SpO2 OFF” will be displayed.

NOTE
● If no selection is made for 10 seconds on the confirmation screen, the display will automatically return to SpO_2 display without changing the ON/OFF status of SpO_2 measurement. ● While the SpO_2 probe is connected to the transmitter, SpO_2 measurement cannot be turned OFF. Before turning OFF the SpO_2 measurement, disconnect the SpO_2 probe from the transmitter.

Turning ON the SpO_2 measurement



While the “SpO2 OFF” is displayed, press the [ENTER] button for 2 seconds.
A confirmation screen will be displayed.
Select [Yes], and press the [ENTER] button.



The SpO_2 measurement will resume.

NOTE
● If no selection is made for 10 seconds on the confirmation screen, the display will automatically return to SpO_2 display without changing the ON/OFF status of SpO_2 measurement. ● Connecting the SpO_2 probe while the display is ON will also resume the SpO_2 measurement.

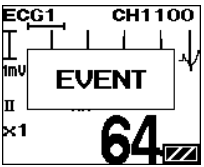
■Restarting the Display

The display automatically turns itself OFF after the preprogrammed duration if no operation is performed.
Press the [ENTER] button or press and hold the [▽] button to restart the display.
The starting screen with the telemetry channel number appears, and then the waveform display screen appears.
The display timeout duration can be changed. For details, refer to “9.Other Settings”.

⚠CAUTION
The heart rates and respiration rates are not measured during display OFF. Therefore, HR, RR value may not be accurate right after restarting the display.

■Pressing the [EVENT] Button

Press and hold the [EVENT] button for 2 seconds to activate the function assigned on the receiving monitor. The following message appears on the display while the “EVENT” is transmitted.
After the transmission is completed, the monitoring display appears.
“EVENT” operation is available as a remote recording.
For details of the receiving monitor operation and settings related to the “EVENT” function, refer to the operation manual of the receiving monitor.



9. Other Setting Items

The following settings are available for the LX-8300M depending on the usage and condition of the patient. For details of the settings, contact your local Fukuda Denshi service representative.

Items	Selection	Default	Backup
Time Constant	0.4 sec, 0.1 sec	0.4 sec	Yes
Detection Sensitivity of Pacemaker Pulse (Pace Sens.)	Low, Mid, High	Mid	Yes
QRS Detection (QRS Width)	Wide, Narrow	Wide	Yes
Respiration Detection Signal (Display)	ON, OFF	ON	Yes
Display Brightness (Brightness)	8 levels	5	Yes
Turn Off Display Time (Display OFF)	1 min, 3 min, 10 min, OFF	3 min	Yes
Sound (Sound)	ON, OFF	ON	Yes
Displayed Color of SpO_2 (Color)	Yellow, Blue	Yellow	Yes
Transmit PI Information (PI Data Send)	ON, OFF	OFF	Yes
Transmitter Channel (CH)	One from the following channels. 0801 to 0879 0900 to 0979 1000 to 1079 1100 to 1179 1200 to 1279 1300 to 1379	1379	Yes
Group ID	One from 00 to 63	00	Yes

■Time Constant

The default setting of the time constant is “0.4 second”.
If a stable monitoring is difficult with excessive change in the baseline due to excessive body motion of the patient or an interference noise, such as AC frequency, by changing the time constant to “0.1 second”, the monitoring may become relatively stable.

For details of the setting, contact your local Fukuda Denshi service representative.

⚠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.
- When changing the time constant to “0.1 second”, the lower frequency characteristic becomes 1.6 Hz ± 25%. This setup does not meet IEC 60601-2-27 standard. It may lead to a change in the ECG waveform and the ST measurement value may be especially affected. Fukuda Denshi recommends “0.4 seconds” setting in normal use.
- The display screen in normal use does not indicate the selection of time constant. Make sure to take measures, such as marking on the LX-8300M, to distinguish whether the selection of time constant has changed.

■Detection Sensitivity of the Pacemaker Pulse

The default setting of pacemaker pulse detection sensitivity is “Mid”.
The “Mid” setting can detect and reject the following pacemaker pulse specified in IEC 60601-2-27 standard.

Detection/Rejection of Pacemaker Pulse:

a) Pacemaker Pulse without Over/Undershoot:
Capable to detect pulses of pulse width 0.1 ms to 2 ms, amplitude ±2 mV to ±700 mV.
b) Pacemaker Pulse with Over/Undershoot:
Rejection is not possible.

Fukuda Denshi recommends the “Mid” setting in normal use.

There may be some cases when the pacemaker pulse cannot be detected depending on the pacemaker type, pulse voltage, pulse width, electrode lead type (unipolar, bipolar). In this case, change the lead or the position of the electrodes to be able to detect the pacemaker pulse.
Nonetheless, if the detection is still undetectable, change the setting to “High” in order to increase the detection sensitivity. So that smaller pacemaker pulse can be detected. However, the “High” setting may lead to erroneous detection due to interference noise, such as AC frequency.

If erroneous detections occur due to interference noise, such as AC frequency, turn OFF the setting of the pacemaker pulse detection in the receiving monitor. If erroneous detections occur due to interference noise, such as AC frequency, while monitoring a patient with a pacemaker and the setting of the pacemaker pulse detection cannot be turned OFF, replace the electrodes or change the lead to remove the interference noise, such as AC frequency.

Nonetheless, if erroneous detections still occur, change the setting to “Low” in order to decrease the detection sensitivity. It makes the LX-8300M less likely to be interfered by noise, such as AC frequency.
The “Low” setting decreases the detection sensitivity. Therefore, it cannot detect the pacemaker pulse specified in IEC 60601-2-27 standard.

For details of the setting, contact your local Fukuda Denshi service representative.

⚠CAUTION

The display screen in normal use does not indicate the setting status of the pacemaker pulse detection. Make sure to take measures, such as marking on the LX-8300M, to distinguish whether the setting of the pacemaker pulse detection has changed.

■QRS Detection

The QRS detection mode of the LX-8300M is initially set as “Wide”. The setting can be changed to “Narrow” if it cannot detect the heart rates due to narrow QRS amplitude.

For details of the setting, contact your local Fukuda Denshi service representative.

⚠CAUTION

- This setting is effective only for the LX-8300M and it is not reflected in the QRS detection setting of the receiving monitor.
  To change the QRS detection in the receiving monitor, refer to the operation manual of the receiving monitor.
- The display screen in normal use does not indicate the setting status of the QRS detection mode such as ”Wide/Narrow”. Make sure to take measures, such as marking on the LX-8300M, to distinguish whether the setting of the QRS detection mode has changed.

■Respiration Detection Signal ON/OFF

The default setting of the respiration detection signal is “ON”.
The respiration waveform can be detected when the setting of the respiration detection signal is turned “ON”.

⚠WARNING

If the LX-8300M is used with minute ventilation rate-adaptive implantable pacemaker, the respiration detection signal may cause the pacemaker to pace at its maximum programmed rate. If such event occurs, change the setting to “OFF” to prevent an occurrence of erroneous pacing rate.

For details of the setting, contact your local Fukuda Denshi service representative.

⚠CAUTION

- The respiration waveform cannot be measured if the setting of the respiration detection signal is turned “OFF”.
- Make sure to turn OFF the respiration measurement function on the receiving monitor to prevent an erroneous detection of the respiration alarm (on the receiving monitor side)
- The display screen in normal use does not indicate the setting status of the respiration detection signal ON/OFF. Make sure to take measures, such as marking on the LX-8300M, to distinguish whether the setting of the respiration detection signal ON/OFF has changed.

■Display Brightness

The display brightness of the LX-8300M can be changed in 8 levels.

For details of the setting, contact your local Fukuda Denshi service representative.

■Display Timeout Duration

The time to automatically turn OFF the display while not in operation can be selected from 1 min, 3 min, 10 min or OFF (The display will not turn off).
The default setting is “3 min”.

For details of the setting, contact your local Fukuda Denshi service representative.

■Sound ON/OFF

When the sound setting is “ON”, alarm will generate in the following situation.

- ECG Lead Off
- SpO_2 probe Off

The default setting is “ON”.
Alarm will not generate with Display OFF status.
For details of the setting, contact your local Fukuda Denshi service representative.

■Displayed Color of SpO_2

The displayed color for SpO_2 related parameters can be selected from yellow or blue.

The default setting is “Yellow”.
When changing the settings, contact your local service representative.

■Transmit PI Information

The PI value can be transmitted to the receiving monitor by setting to “ON”.

The default setting is “OFF”.
When changing the settings, contact your local service representative.

⚠CAUTION
To display the PI value on the receiving monitor, the receiving monitor needs to be compatible with the PI value display function. For details, refer to the operation manual of the receiving monitor.

10. Changing the Transmitter Channel and Group ID

■Transmitter Channel

The LX-8300M is a transmitter of PLL synthesizer type, and its transmitter channel can be programmed. It can be set up with an arbitrary channel among the channels assigned by the Telemetry Laws (according to each country).

For details of the setting, contact your local Fukuda Denshi service representative.

⚠WARNING

- If the transmitter channel is changed, follow the instruction of the person in charge of the radio telemetry channel in your facility. Mismanagement may result in a serious accident, such as interference and mixing up patients.
- Replace promptly with new channel label if the transmitter channel has been changed.

■Group ID

The LX-8300M transmits its group ID, which it belongs to, to prevent interference with neighboring hospital's transmitter.
The receiving monitor checks whether the incoming group ID is the same as that of the receiving monitor. There are 64 group codes available. The default setting is “00”.
The transmitter group ID can be changed if there is interference with a neighboring hospital's transmitter.

For details of the setting, contact your local Fukuda Denshi service representative.

⚠CAUTION

Possible causes of interference other than radio telemetry from neighboring hospital's transmitter, are the proximity of mobile phone, amateur radio station, radio taxi, and illegal citizens band, which may be a cause of interference. In such case, the situation should be carefully observed to find the cause of interference.

11. Troubleshooting

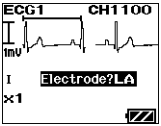
Make sure of the following. However, if there is no improvement in the situation, contact your local Fukuda Denshi service representative.

Transmitter

Message	Cause	Solution
SYSTEM ERROR Error: S01 Sp02 Module Error	Faulty SpO_2 module.	Contact your local Fukuda Denshi service representative.
SYSTEM ERROR Error: R01 Telemeter Comm. Error	Failed to transmit waveform and value.	
SYSTEM ERROR Error: R03 EEPROM Read Error	Faulty EEPROM.	
SYSTEM ERROR Error: P01 CPU Error	Failed to initialize CPU.	
SYSTEM ERROR Error: P02 Speaker Error	Faulty Speaker.	

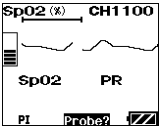
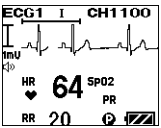
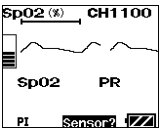
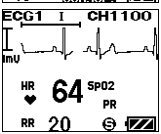
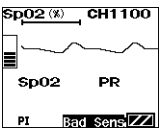
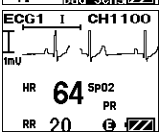
Situation	Cause	Solution
Nothing is displayed on the display when the power switch is turned ON.	No batteries or wrong polarity.	Install the batteries correctly.
	Battery level is empty.	Replace the batteries with new ones.
The system restarts.	Battery level is empty.	Replace the batteries with new ones.
Nothing is displayed on the receiving screen.	The channel number between the transmitter and the receiving monitor do not match up.	Set the same channel number for the transmitter and the receiving monitor.
Transmission problem.	Same channel number is already used.	Make sure to not duplicate channel numbers. Follow the instruction by the person in charge of radio telemetry channel in your facility and use the transmitter with the correct channel setting.
	Channel interference.	Follow the instruction by the person in charge of radio telemetry channel in your facility and use the transmitter with the correct channel setting.
	Transmitter failure.	Contact your local Fukuda Denshi service representative.

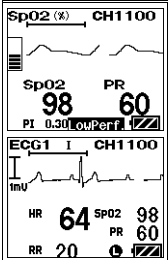
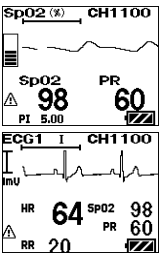
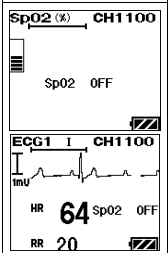
ECG

Message/Icon	Cause	Solution
 The displayed character string indicates the detached electrode position. For details, refer to “Details of the “Electrode” Message”.	Electrode is off.	Check the electrode condition.
	Lead cable is off.	Check the connection between the lead cable and this equipment.
		Check the connection between the lead cable and the electrode.
	Faulty Lead cable.	Replace the ECG cable with a new one.
	Electrode is peeling off.	Replace the electrode with a new one.
	Polarization potential of the electrode is too high.	Replace the electrode with a new one.

Situation	Cause	Solution
ECG waveform contains noise.	Electrode gel is dry	Replace the electrode with a new one.
	Electrode is peeling off.	
	Electric blanket is used.	Cover the electric blanket with a shield cover.
	AC filter setting of the receiving monitor is OFF.	Set the AC filter up as ON.
Respiration waveform cannot be measured.	Electrode gel is dry	Replace the electrode with a new one.
	Electrode is peeling off.	
	The positions of the electrodes are improper.	Attach the electrodes where the respiration waveform can be measured appropriately.

SpO_2

Message/Icon	Cause	Solution
 	The probe is disconnected.	Verify that the probe is properly attached.
	The probe is damaged.	Replace the probe.
 	SpO_2 is not measured correctly.	Verify that the sensor is properly attached.
		Avoid exposure to ambient light.
	Unspecified probe is used.	Replace the probe.
 	The probe is damaged, or the usable life of the sensor is expired.	Replace the probe. For the expiration date of the sensor, refer to “6. SpO_2 Monitoring/About the Expected Life of Masimo Sensors”.

Message/Icon	Cause	Solution
	The amplitude of the pulse waveform is too low, or the sensor is not positioned correctly.	Check that the light emitting and receiving parts of the sensor LED are aligned.
	The expiration date of the sensor is approaching.	Replace the probe. For the expiration date of the sensor, refer to “6. SpO_2 Monitoring/About the Expected Life of Masimo Sensors”.
	The SpO_2 measurement is turned OFF.	To turn ON the SpO_2 measurement, refer to “Turning ON the SpO2 measurement”.

Situation	Cause	Solution
SpO_2 value is unstable.	The probe size is improper.	Use a probe, which fits properly.
	The probe is peeling off or is affected by the outside light due to the poor condition	Attach the probe properly following the instruction.
	Transmitting and measuring LEDs sensor are dirty.	Clean both LED sensors from dirt.

Details of the “Electrode” Message

The following “Electrode?” messages are displayed depending on the selected lead cable and lead.

Check Position	3-electrode Lead I display	3-electrode Lead II display	3-electrode Lead III display
LL	Electrode?	Electrode?LL	Electrode?LL
RA	Electrode?RA	Electrode?RA	Electrode?
LA	Electrode?LA	Electrode?	Electrode?LA
Several Position Simultaneously	Electrode?	Electrode?	Electrode?

Check Position	4-electrode	5-electrode (Chest)
LL	Electrode?LL	Electrode?LL
RA	Electrode?RA	Electrode?RA
LA	Electrode?LA	Electrode?LA
RL	Electrode?	Electrode?
V		Electrode?V
Several Position Simultaneously	Electrode?	Electrode?

■In Case of Dropping the LX-8300M into Water

In case of dropping the LX-8300M into water containing disinfectant, pick up the LX-8300M as soon as possible.
In case of dropping the equipment into dirty water, clean it without disconnecting the ECG lead cable and SpO_2 probe (sensor), and make sure that the battery compartment lid is locked. After cleaning, wipe off any moisture thoroughly before removing the ECG lead cable, SpO_2 probe (sensor), or batteries.

⚠CAUTION

- Do not use a dryer. The LX-8300M shape may change or be broken.
- When rinsing the LX-8300M with running water, make sure to close the battery compartment lid.
- In case of dropping the equipment into dirty water, it is recommended to contact Fukuda Denshi or your nearest service representative.
- If it is difficult to clean the connector part, or if an inadequate contact occurs, contact Fukuda Denshi or your nearest service representative.

12. Cleaning and Disinfection

The cleaning and disinfection of the LX-8300M, ECG lead cable, and SpO_2 probe (sensor) shall be performed as follows.

⚠CAUTION
Do not sterilize the LX-8300M, ECG lead cable, and SpO_2 probe (sensor) in any manners, such as radioactive rays, steam, or ethylene oxide.

■Cleaning the Housing

1. Clean the equipment using squeezed gauze or an absorbent cotton cloth dampened with alcohol or a neutral cleanser. When cleaning, do not allow any solution to enter the equipment or connectors. Also, do not use organic solvents, thinner, toluene and benzene to avoid damaging the resin case.
2. In case of dropping the equipment into dirty water, clean it without disconnecting the ECG lead cable and SpO_2 probe (sensor), and make sure that the battery compartment lid is locked. After cleaning, wipe off any moisture thoroughly before removing the ECG lead cable, SpO_2 probe (sensor), or batteries.

⚠CAUTION
● Clean the equipment frequently so stains can be removed easily. ● To prevent injury, it is recommended to wear gloves when cleaning the equipment. ● Do not allow any chemical solution to enter the LX-8300M or connectors. ● The LX-8300M cannot be sterilized. ● Do not use organic solvents, thinner, toluene and benzene to avoid damaging the resin case. ● Do not polish the housing with abrasive or chemical cleaner. ● Use only neutral detergent to clean the housing. Do not use chemical cloth, scrub brush, abrasive, polishing powder, hot water, volatile solvent and chemicals (cleanser, thinner, benzine, benzol, and synthetic detergent for house and furniture), or sharp-edged tools. The surface resin coating may be damaged, resulting in discoloration, scratches, and other problems.

■Cleaning the Connector

Do not wipe the ECG connector and SpO_2 connector with a swab, gauze, or absorbent cotton.
Use an air duster to clean the dust and dirt in the connector.

⚠CAUTION

If a swab, gauze, or cotton is used to clean the connector, dust or cotton fibers may enter the connector causing inadequate contact. Also, chemical solution may enter the connector causing inadequate contact. If it occurs, correct measurement cannot be performed and the alarm may not be generated. If cleaning the connector is needed, contact Fukuda Denshi or your nearest service representative.

■Disinfection

If there is a possibility of being infected, clean the LX-8300M using a squeezed gauze or an absorbent cotton cloth dampened with alcohol or invert soap.

⚠CAUTION

- Do not immerse the connector parts of the LX-8300M in any chemical solution to prevent connection failure.
- When disinfecting the entire room using a spray solution, pay close attention not to have liquids get into the LX-8300M or connectors.

■Cleaning the ECG lead cable

After using the cable, clean it with neutral detergent or 70% isopropyl alcohol.

⚠CAUTION

- Do not use thinner, toluene, or other organic solvents to clean the cables.
- Do not pull the cable and do not hold the connector part when cleaning. (It may degrade the cable coating and result in damage. Particularly organic solvents and antiseptic solution such as cresol soap solution will degrade the cable coating.)
- After cleaning, dry it completely before usage.
- Do not use high temperature sterilization such as steam or EOG method.

13. Maintenance and Inspection

This section explains the daily checks and periodic checks of the LX-8300M. To ensure safety, reliability, and high performance, a “Daily Check” and “Periodic Check” must be performed. We are not liable for any accident arising from lack of maintenance. A full technical description of the LX-8300M is available from your local Fukuda Denshi representative.

⚠CAUTION
● Do not open the housing. ● Do not allow excessive moisture or cleaning agents into the connectors or inside the equipment.

■Daily Check

Perform daily checks using the “Daily Check List” on the next page.

■Periodic Check

Periodic check of medical electronic equipment is mandatory to prevent failures and accidents, and to ensure safety and reliability.
Periodic maintenance may be performed by the medical institution or by a third party by concluding a “Maintenance Contract”.
For more details, contact your local Fukuda Denshi service representative.

Perform Periodic check using the “Periodic Check List”.
The periodic check should be performed once a year.
If there is an item with “Fail” judgement, the overall judgement will be “Fail”.
Make sure to take countermeasures for the “Fail” item.
Use the equipment only if the judgements of all the items are “Pass”.

■Periodic Replacement Parts

The “Battery Compartment Lid (Waterproof)” is the only periodic replacement part.
To ensure the reliability of waterproof (IPX8) performance of the LX-8300M, replace it once a year.
Contact your local Fukuda Denshi service representative for replacement.
The reliability of water resistance (IPX8) performance will not be ensured without yearly replacement.

⚠CAUTION
The periodic replacement parts must be replaced at specified period.

Daily Check List

No. _____

Inspected Date _____ Inspected by _____ Location _____

Device Type _____ S/No. _____ Date of Purchase _____

Items	***Details***	***Criteria***	***Judgment***
Appearance	Visually check for any damage, cracks, chip, peeled label, and loosen screw on the housing.	No abnormality should be found.	□OK/ □NG
Battery Compartment	Visually check for the ring condition of the battery compartment lid.	No damage, kink, floating, and adhesion of dust should be found.	□OK/ □NG
	Visually check for the contact springs, inside the LX-8300M, to the battery and the lock lever of the battery compartment lid.	No deformation, cracks, and rust should be found.	□OK/ □NG
Power Supply	Turn the power ON/OFF to verify proper switch operation.	With batteries installed, the LCD should turn ON.	□OK/ □NG
ECG Connectors	Visually check the connectors of the cable and the LX-8300M.	No damage, chip, and adhesion of dust should be found.	□OK/ □NG
ECG Lead cable	Visually check each lead for damages.	No crack and damage should be found.	□OK/ □NG
SpO_2 Sensor (Probe)	Visually check the cable, optical receiver, LED, and connector for damages.	No crack, chip, damage, and adhesion of dust should be found.	□OK/ □NG
Wireless Channel	Verify whether the transmitting channel and group ID are the same with the receiving monitor.	Must match the wireless channel check list.	□OK/ □NG
Transmission Function	Turn the power ON and make sure the information is displayed on the receiving monitor.	Waveforms and values should be received without any problem.	□OK/ □NG
Display Function	Turn the power ON and verify each display condition, such as SpO_2 value and bar graph.	All data should be properly displayed.	□OK/ □NG
Periodic Check	Check the date of the previous periodic check.	Should be within one year.	□OK/ □NG

Comment

■Periodic Check

The periodic maintenance check is intended to check the medical equipment used daily in a medical institution to prevent failures and accidents and to ensure safety and reliability.
The check procedures are described for daily and periodic checks. Each check item must be performed according to the described check procedure.
The consignee can select the check items according to the product quality, frequency of usage, and maintenance check period. However, electrical safety items must also be performed.
For details of the electrical safety check procedure, refer to IEC 60601-1.

●Periodic Check Items

The periodic check items are as follows.

No.	Check Item
1	External Appearance
2	Power Supply Switch
3	Display / Operation
4	ECG
5	Respiration
6	Arterial Oxygen Saturation (SpO_2)
7	Speaker
8	Electrical Safety

No.	Check Item	Check Procedure	Criteria
1. External Appearance, Accessories			
01	Appearance	Visually check the exterior for scratches, cracks, deformation, and rust.	No abnormality should be found.
02	Cables	Visually check all cables for any damage or being disconnected.	No damage should be found.
03	Operation Manual	Check if the operation manual and other accompanying documents are stored in the specified places.	Should be stored in the specified place.

No	Check Item	Check Procedure	Criteria
2. Power Supply Switch			
01	Power Supply Switch	Turn ON/OFF the power switch.	Should turn ON/OFF the power switch properly.

No	Check Item	Check Procedure	Criteria
3. Display, Operation			
01	Labels	Visually check the labels, caution labels, etc.	Should be clean, clear and firmly attached.
02	Operation, Switches and keys	Check by operating the switches and keys.	Should operate properly.
03	Display	Check that the characters and waveforms appear on the display.	The characters and waveforms should be clearly displayed. The brightness should be sufficient.

No	Check Item	Check Procedure	Criteria
4. ECG			
01	Input Impedance*	According to test procedure of IEC 60601-2-27: 2011 201.12.1.101.3	Should be 2.5 MΩ or above.
02	Suppression Characteristic of Common-Mode Signal*	According to test procedure of IEC 60601-2-27: 2011 201.12.1.101.10	Should be 10 mmp-p or below for standard sensitivity (sensitivity 1).
03	Transient Characteristic*	With comprehensive tester, apply standard voltage of 1 mV, and check the time the amplitude natural logarithmically drops and becomes 37% of the waveform of 0.04 sec. after the application of standard voltage.	Should be 0.4 ± 0.1 seconds. (When the time constant is set to 0.4 seconds.)
04	Frequency Characteristic*	With comprehensive tester, apply sinusoidal voltage. Measure the frequency characteristic at test voltage of 40 Hz. According to test procedure of IEC 60601-2-27: 2011 201.12.1.101.8	Should be 40 Hz (-3 dB) or above.
05	Heart Rhythm Detection*	With comprehensive tester, input both positive and negative polarity of 0.3 mV and 3 mV with sensitivity 1. According to test procedure of IEC 60601-2-27: 2011 201.12.101.15	The heart beat rhythm should be detected with sensitivity 1 according to the peak-to-peak signal of 0.3 mV and 3 mV.

No	Check Item	Check Procedure	Criteria
06	ECG Sensitivity	With comprehensive tester, apply 1mV voltage and measure the displayed amplitude. According to test procedure of IEC 60601-2-27: 2011 201.12.1.101.1	Wave form size on the receiving monitor should be within 0mm ±10% at sensitivity 1.
07	Heart Rate Accuracy*	With ECG simulator, test heartbeat 60, 180 beats/min., and check the displayed HR value. According to test procedure of IEC 60601-2-27: 2011 201.12.101.15	For reference heartbeat signal of 60, 180 beats/min., error of the displayed HR value should be within ±3 beats/min.
08	ECG Lead Switch	With ECG simulator, check that each lead is displayed properly. (Check for 3-electrode, and 4-electrode, 5-electrode.)	For each lead cable, lead should be correctly switched, and waveform should be correctly displayed.
09	Lead-Off Indication	Remove each electrode, and check that lead-off message is displayed.	Lead-Off message for the corresponded lead should be displayed.
10	ECG Lead Cable Recognition	Switch the ECG lead cable or switch the setup of lead cable.	Should correctly recognize the connected lead cable.

* As these functions are dependent on the design or software, these items are not mandatory for periodic checks. Perform the test as necessary.

No	Check Item	Check Procedure	Criteria
5. Respiration			
01	Respiration Waveform Sensitivity	With comprehensive tester or reference respiration signal generator, input sinusoidal waveform of 0.5 Hz with base resistance of 1.5 kΩ / 1 Ω change.	The amplitude displayed on the receiving monitor screen should be within 10 mm ± 2 mm.
02	Respiration Rate Accuracy*	Input reference respiration signal to comprehensive tester or respiration simulator, and check the respiration rate display. Test with the respiration reference load signal of 60, 120/min.	Error should be within ±5 Bpm.
03	Frequency Characteristic*	With comprehensive tester or reference respiration signal generator, input 0.5 Hz and 1.5 Hz or 2.5 Hz, and measure the frequency characteristic.	The crest value at 1.5 Hz should be more than 70% of the crest value at 0.5 Hz input.

* As these functions are dependent on the design or software, these items are not mandatory for periodic checks. Perform the test as necessary.

No	Check Item	Check Procedure	Criteria
6. Arterial Oxygen Saturation (SpO_2)			
01	SpO_2 Accuracy	Measure the error at 75%, 90% using a SpO_2 simulator.	Error should be within ±2% for SpO_2 of 70–100%.
		Prepare other reference device, perform measurement on healthy subject, and compare the value.	Error between the 2 devices should be within ±4%.
02	Pulse Rate Accuracy	Input 60, 200bpm using the SpO_2 simulator, and measure the error.	Error should be within ±3bpm (20-250bpm)
		Prepare other reference device, perform measurement on healthy subject, and compare the value.	Error between the 2 devices should be within ±6%.
03	SpO_2 Probe-Off Detection	Check the display by disconnecting the probe.	Waveform and numeric data should disappear from the display.

No	Check Item	Check Procedure	Criteria
7. Speaker			
01	Generation	Generate synchronized tone and check the sound.	Generating synchronized tone.

No	Check Item	Check Procedure	Criteria
8. Electrical Safety			
01	Contact current	Measure the leakage current that runs through the ground from the enclosure of the device under normal condition using a leak measurement safety tester. According to test procedure of IEC 60601-1 8.7.4	From the enclosure to the ground (NC) ≤0.1mA.
02	Patient leakage current that runs through the ground from the patient connecting part (NC)	Measure the patient leakage current that runs through the ground from the patient connecting part using a leak measurement safety tester. According to test procedure of IEC 60601-1 8.7.4	[AC/DC] From the patient connecting part to the ground (NC) ≤0.01mA.

No	Check Item	Check Procedure	Criteria
03	Leakage current when external voltage is applied to the patient connection in the Type F attaching part (SFC)	Measure the leakage current when external voltage is applied to the patient connection in the Type F attaching part using a leak measurement safety tester. According to test procedure of IEC 60601-1 8.7.4	Leakage current when external voltage is applied to the patient connection in the Type F attaching part. (SFC) ≤0.05mA.
04	Total patient leakage current that runs through the ground from the total patient connecting part. (NC)	Measure the total patient leakage current that runs through the ground from the patient. According to test procedure of IEC 60601-1 8.7.4	[AC/DC] From the patient connecting part to the ground (NC) ≤0.05mA.
05	Leakage current when external voltage is applied to the patient connection in the Type F attaching part (SFC)	Measure the leakage current when external voltage is applied to the patient connection in the Type F attaching part using a leak measurement safety tester According to test procedure of IEC 60601-1 8.7.4	Leakage current when external voltage is applied to the patient connection in the Type F attaching part. (SFC) ≤0.01mA.
06	Patient auxiliary current (NC)	Measure the patient auxiliary current (NC) using a leak measurement safety tester According to test procedure of IEC 60601-1 8.7.4	Patient auxiliary current (NC) ≤0.01mA.

No	Check Item	Check Procedure	Criteria
8. Electrical Safety (*) Perform the following check item as appropriate. Check these items when you have disassembled the equipment to check/ replace the boards or units.			
07	Withstand Voltage Test (the enclosure – isolated connecting part)	Apply AC 1500V for 1 minute between the enclosure and a connecting part. Note: The voltage differs depending on the internal protective circuit composition of the equipment. According to test procedure of IEC 60601-1 8.8.3	Should withstand applied voltage.

Periodic Check List

Telemetry Transmitter Periodic Check Report

Check Date

Location		Delivery Date		Periodic Check Contract ☐Yes ☐No Month Check
		Customer Code		
Model Name	Serial No.:	Product Code		Next Check Date
Requested Item			Acceptance Date	

No.	Check Item	Judge	Check
1	**Exterior, Accessories**		
01	Exterior	OK NG	
02	Cables	OK NG	
03	Operation Manuals	OK NG	
2	**Power Supply Switch**		
01	Power Supply Switch	OK NG	
3	**Display, Operation**		
01	Labels	OK NG	
02	Operation Switch/Key	OK NG	
03	LCD	OK NG	
4	**ECG**		
01	Input Impedance	OK NG	
02	Suppression Characteristic of Common-Mode Signal	OK NG	
03	Transient Characteristic	OK NG	
04	Frequency Characteristic	OK NG	
05	Heart Rhythm Detection	OK NG	
06	ECG Sensitivity	OK NG	
07	Heart Rate Accuracy	OK NG	
08	ECG Lead Switch	OK NG	
09	Lead-Off indication	OK NG	
10	ECG Lead Cable Recognition	OK NG	

No.	Check Item	Judge	Check
5	**Respiration**		
01	Respiration Waveform Sensitivity	OK NG	
02	RR Accuracy	OK NG	
03	Frequency Characteristic	OK NG	
6	**SpO_2**		
01	SpO_2 Accuracy	OK NG	
02	PR Accuracy	OK NG	
03	SpO_2 Probe-Off Detection	OK NG	
7	**Speaker**		
	Synchronized Tone	OK NG	

No.	Check Item	Judge	Check
7	**Electrical Safety**		
01	From the patient connecting part to the ground NC (　　) mA	OK NG	
02	Patient leakage current that runs through the ground from the patient connecting part NC (　　) mA	OK NG	
03	Leakage current when external voltage is applied to the patient connection in the Type F attaching part. SFC (　　) mA	OK NG	
04	Total patient leakage current that runs through the ground from the total patient connecting part. NC (　　) mA	OK NG	
05	Leakage current when external voltage is applied to the patient connection in the Type F attaching part. SFC (　　) mA	OK NG	
06	Patient auxiliary current NC (　　) mA	OK NG	
07	Withstand Voltage Test	OK NG	

Description

レ	Check	A	Adjustment
×	Replacement part	C	Cleaning
／	Not covered	R	Repair

The check result is as follows:

☐Normal Operation ☐Malfunctioning. ☐Needs to be repaired.

(Details of malfunction and repair)

Company

Inspector

Person in charge

Replacement parts

Classification

☐On-site ☐Taking-over

☐Holiday ☐Night

■Repairing the Equipment

This equipment is basically repaired at Fukuda Denshi factory.
If detailed information about the repair is needed, contact Fukuda Denshi.

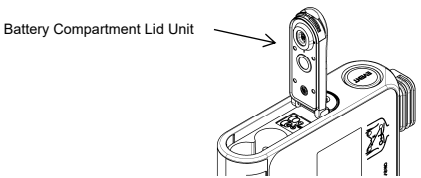
On-site repair is possible for the following parts.
- Replacing the battery compartment lid

⚠CAUTION
Make sure to replace the parts correctly. Otherwise, it may cause damage and heat generation of the equipment.

■ Replacing the Battery Compartment Lid Unit

●Life of the Battery Compartment Lid Unit

Life of the waterproof battery compartment lid unit is one year. If this unit is used for more than a year, the waterproof (IPX8) performance cannot be guaranteed. Replace the battery compartment lid unit to maintain its waterproof performance.



⚠CAUTION
● The battery unit must be replaced at specified period. ● Even if the LX-8300M is used less than one (1) year, the unit may be damaged from high impact. If the LX-8300M is dropped or is subjected to a high impact, make sure that the unit is not damaged.

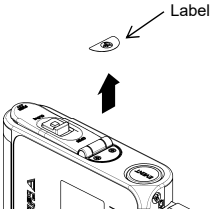
●Tools

- Phillips screwdriver (#0)

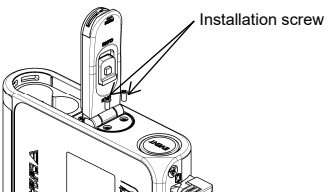
●Assembly and Disassembly

Follow the procedure below to remove the battery compartment lid unit.

1. Remove the label.

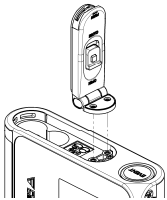


2. Remove the 2 installation screws, then remove the battery compartment lid unit.

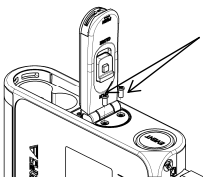


Follow the procedure below to attach the battery compartment lid unit.

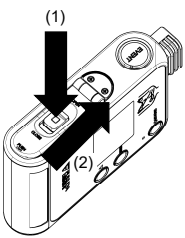
1. Set the battery compartment lid unit adjusting to the front case.



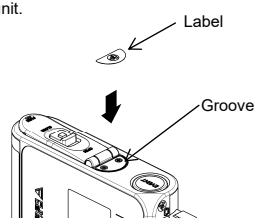
2. Secure the battery compartment lid unit with new 2 installation screws. Make sure that the screws are securely tightened.



3. Make sure that the battery compartment lid unit opens/closes smoothly.



4. Attach the label firmly aligning with the groove of the battery compartment lid unit.



14. Standard and Optional Accessories

⚠WARNING

Use only the accessories specified by Fukuda Denshi for the LX-8300M. Otherwise, the LX-8300M cannot deliver its maximum performance and may be damaged, resulting in a safety hazard.

⚠CAUTION

For quality improvement, specifications are subject to change without prior notice.

■Standard Accessories

Item	Model Type	Q'ty	Remarks
4-electrode ECG lead cable	CMT-02CTH-0.8DA	1	AHA color code, Clip Type, Limb Lead (2CH)
Operation Manual		1	

■Optional Accessories

The following optional accessories are available for the LX-8300M.
Purchase them as required.

ECG Lead Cables

Item	Model Type	Remarks
Clip Type Lead Cable	CMT-01CTH-0.8DA	3-electrode (White, Black, Red) Limb Lead (1ch)
Clip Type Lead Cable	CMT-02CTH-0.8DA	4-electrode (White, Black, Green, Red) Limb Lead (2ch)
Clip Type Lead Cable	CMT-03CTH-0.8DA	5-electrode (White, Black, Green, Red, Brown) Limb Lead (1ch) + Chest (1ch)

SpO_2 Sensors

• LNCS Sensor

Model Type	Remarks	
LNCS DCI 1863	Adult (weight of 30kg and over)	Finger, Toe Reusable
LNCS TC-I 1895	Adult (weight of 30kg and over)	Lobe or Pinna of the Ear Reusable
LNCS TF-I 1896	Adult (weight of 30kg and over)	Forehead Reusable
LNCS Adtx 1859	Adult (weight of 30kg and over)	Finger, Toe Single-Patient-Use
LNCS Pdtx 1860	Pediatric (weight of 10 to 50kg)	Finger, Toe Single-Patient-Use
LNCS Inf-L 1861	Infant (weight of 3 to 20kg)	Thumb, Great toe Single-Patient-Use
LNCS Neo-L 1862	Neonate (weight of less than 3kg) Adult (weight of 40kg and over)	Neonate: Hand, Foot Adult: Finger, Toe Single-Patient-Use
LNCS NeoPt-L 1901	Preterm (weight of less 1kg)	Hand, Foot Single-Patient-Use
LNCS Inf-3 2319	Infant (weight of 3 to 20kg)	Thumb, Great toe Single-Patient-Use
LNCS NeoPt3 2321	Preterm (weight of less than 1kg)	Hand, Foot Single-Patient-Use

The LNCS Sensors can be directly connected to the LX-8300M.

• RD SET Sensor

Model Type	Remarks	
RD SET DCI 4050	Adult (weight of 30kg and over)	Finger, Toe Reusable
RD SET Adt 4000	Adult (weight of 30kg and over)	Finger, Toe Single-Patient-Use
RD SET Pdt 4001	Pediatric (weight of 10 to 50kg)	Finger, Toe Single-Patient-Use
RD SET Inf 4002	Infant (weight of 3 to 20kg)	Thumb, Great toe Single-Patient-Use
RD SET Neo 4003	Neonate (weight of less 3kg) Adult (weight of 40kg and over)	Neonate: Hand, Foot Adult: Finger, Toe Single-Patient-Use
RD SET NeoPt 4004	Preterm (weight of less 1kg)	Hand, Foot Single-Patient-Use

When using the RD SET Sensor, the following conversion cables are required.

Types of Conversion Cable	Length
RD to LNCS adapter cable 4089	3 ft.
RD to LNCS adapter cable 4105	1.5 ft

Other Item

Item	Model Type	Remarks
Disposable Portable Case	ABT-720D	5 pieces/pack

15. Specification

■Specification

⚠CAUTION
For quality improvement, specifications are subject to change without prior notice.

General

Size:	72.0(W) mm x 27.0(D) mm x 102.0(H) mm (not including the protrusion)
Weight:	Approximately 190 g (with batteries)
Transmitting Waveform:	ECG 1CH or 2CH (selectable from the ECG lead cable), Respiration waveform, pulse waveform (with SpO_2 value)
ECG Lead Cable Type:	3-electrode, 4-electrode, or 5-electrode (Limb+Chest) lead cable. Automatically detect the type by inserting the lead cable.
Transmitting Status Data:	Electrode Off, Low Battery, Event Switch, Pacemaker, SpO_2 Sensor Off
LCD:	Built-in
Waterproof:	IPX8 (If periodic replacements are performed) / IPX5 IPX5: Protection from water. IPX8: Protection from submerge
Power Supply:	DC: Two 1.5 V “AA” size (“LR06” size) alkaline batteries
Continuous Operating Time: (Standard Operation)	Two “AA” size (“LR6” size) alkaline batteries Approximately 2.5 days with MX1500 (DURACELL) Conditions: When measuring ECG, RESP, SpO_2 with default settings, operating temperature 23°C
Continuous Operating Time: (During SpO_2 OFF Status)	Two “AA” size (“LR6” size) alkaline batteries Approximately 6.5 days with MX1500 (DURACELL) Conditions: When measuring ECG, RESP with default settings, SpO_2 measurement OFF, operating temperature 23°C
Operation Mode:	Continuous operation

*Continuous operating time is based on when using new ”AA” size (“LR6”size) alkaline batteries specified by Fukuda Denshi.

ECG

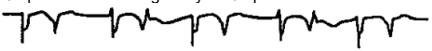
Numbers of Lead Electrode:	3-electrode, 4-electrode, or 5-electrode (Limb+Chest) lead cable
Numbers of Input Channel:	1CH (3-electrode) or 2CH
Accuracy of Sensitivity:	Complies with IEC 60601-2-27: 2011 and 201.12.1.101.1 (±20% or 100uV, whichever is greater.)
ECG Input Impedance:	Complies with IEC 60601-2-27: 2011 and 201.12.1.101.3 (2.5MΩ and above)
Input Dynamic Range and Offset Voltage:	Complies with IEC 60601-2-27: 2011 and 201.12.1.101.2 (Input dynamic range: ±5 mV Offset voltage: ±300 mV Change of amplitude caused by offset voltage: Within ±10%)
Common Mode Rejection Ratio:	Complies with IEC 60601-2-27: 2011 and 201.12.1.101.10 (Less than 1mVp-p (RTI))
HR Measurment Detection:	Complies with IEC 60601-2-27: 2011 and 201.12.1.101.15 (HR Measurement Accuracy: Less than ±10% or ± 5bpm, whichever is greater HR measurement range and accuracy are as follows. HR measurement range: 0, 12 bpm to 300 bpm)
HR Display Range:	QRS Detection Wide: 0, 12 bpm to 300 bpm (1bpm increment) QRS Detection Narrow: 0, 30 bpm to 300 bpm (1 bpm increment)
Frequency Characteristic:	0.5 Hz to 40 Hz (within -3dB)
Time Constant:	0.4 sec ± 25% Can be switched to 0.1 sec ± 25%
Rejection of Pacemaker Pulse:	a) Pacemaker Pulse without Over/Undershoot Capable to reject pulses of pulse width 0.1 ms to 2 ms, amplitude ±2 mV to ±700 mV b) Pacemaker Pulse with Over/Undershoot Rejection is not possible.
Protection to Defibrillation:	Complies with IEC 60601-2-27
Lead-off Detection Current:	100 nA and below
Tall T-wave Rejection Capability:	1.2 mV T-wave can be removed when tested according to IEC 60601-2-27
Average of Heart Rate:	HR measured from 6 seconds of heartbeat for setting QRS width: wide, and 4 seconds of heartbeat for setting QRS width: narrow.
Response time of heart rate meter to change in heart rate:	HR change from 80 bpm to 120 bpm: Range 6 sec. to 11 sec. HR change from 80 bpm to 40 bpm: Range 6 sec. to 11 sec.
Sweep speed:	12.5 mm/s

Heart rate meter accuracy and response to irregular rhythm:

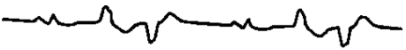
80 bpm Ventricular Bigeminy: 80 bpm

60 bpm Ventricular Bigeminy: 60 bpm

120 bpm Ventricular Bigeminy: 120 bpm



90 bpm Bidirectional Systoles: 90 bpm



Respiration (Impedance Method)

Accuracy of Sensitivity:	10 mm/1Ω ± 2 mm (When standard Impedance is 480Ω.)
Resp. Display Range:	0, 4 Bpm to 150 Bpm
Display Error of Respiration Rate:	±3 Bpm
Measured Current of Respiration:	Below 100μA (42kHz)

SpO_2

NOTE

About the SpO_2 Clinical Test

The SpO_2 and pulse rate measurement accuracy have been validated for each range by testing on healthy adult male and female volunteers against a laboratory CO-Oximeter.
The SpO_2 accuracy has been validated for the range from 70% to 100% by testing on healthy adult male and female volunteers with light to dark skin pigmentation. Without body motion, the standard deviation is ±2% which encompasses 68% of the population. With body motion, the standard deviation is ±3% which encompasses 68% of the population. For the validation, frictional or contact motion of 1 cm to 2 cm, and random vibration of 1 Hz to 5 Hz were tested.
The pulse rate accuracy has been validated for the range from 70% to 100% by testing on healthy adult male and female volunteers with light to dark skin pigmentation The standard deviation is ±3 bpm which encompasses 68% of the population.
These clinical test data are disclosed based on the data provided from Masimo.

NOTE

The SpO_2 measurement accuracy is determined based on the values of the root-mean-square (rms) difference between SpO_2 readings of the pulse oximeter equipment and values of SaO_2 determined with a CO-oximeter, by healthy adult volunteers. The pulse oximeter equipment measurements are statistically distributed; ±2% measurement accuracy means that only about two-thirds of pulse oximeter equipment measurements can be expected to fall within ±2% of the value measured by a CO-oximeter.

Measurement Method	2 Wavelength Pulse Wave Method Wavelength: Approx. 660 nm (red light) Approx. 905 nm (infrared light) Output: 15 mW and below
SpO_2 Measurement Range:	1%SpO_2 to 100%SpO_2
Resolution:	1%SpO_2
Measurement Accuracy:	Without body motion Adult: ±2%SpO_2 when 70%SpO_2 to 100%SpO_2 Neonate: ±3%SpO_2 when 70%SpO_2 to 100%SpO_2 With body motion Adult: ±3%SpO_2 when 70%SpO_2 to 100%SpO_2 Neonate: ±3%SpO_2 when 70%SpO_2 to 100%SpO_2
Measurement Value Update Rate:	1 sec.
Averaging Time:	8 sec.

Pulse Rate

Measurement Range:	26 bpm to 239 bpm
Measurement Accuracy:	Without body motion: ±3bpm With body motion: ±5bpm

PI

Measurement Range:	0.02% to 20.00%
Resolution:	0.01%

Transmission Method

Modulation Mode:	Digital, Frequency shift keying
Frequency:	608 MHz to 614 MHz
Oscillation Method:	PLL Synthesizer method by crystal control
Channel Spacing:	12.5 kHz
Occupied Frequency Bandwidth:	Within 8.5 kHz
RF Output Power:	1 mW ± 2 dB
Transmitting Antenna:	ECG lead cable and/or SpO_2 Probe

Safety

General Standard:	ANSI / AAMI ES 60601-1: 2005(R)2012 and A1:2012, C1:2009(r)2012 and A2: 2010(r)2012 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance)
EMC Standard:	IEC 60601-1-2: 2014 (Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests)
The class of protection against electric shock:	Internally Powered Equipment
The type of protection against electric shock:	ECG/RESP: Type CF Applied Part SpO_2: Type CF Applied Part

Operating Environment

Temperature:	10°C to 40°C / 50°F to 104°F
Humidity:	30% RH to 85% RH (non-condensing)
Atmospheric Pressure:	70 kPa to 106 kPa

Transport / Storage Environment

Temperature:	-10°C to 60°C / 14°F to 140°F
Humidity:	10% RH to 95% RH (40°C / 104°F, non-condensing)
Atmospheric Pressure:	70 kPa to 106 kPa

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