

ECG, Respiration and SpO₂ Transmitter

LX-1000 Series ECG, Respiration and SpO₂ Transmitter LX-1300

LX-1300N/LX-1300M/LX-1300E





CAUTION

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

- Before using the product, please read this manual thoroughly.
- This manual is for the LX-1300 Version 02

CAUTION

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

Preface

Thank you for purchasing our product.

Please be sure to read this instruction manual before use to ensure correct and safe use.

Notes from Us

For Safe Operation of the Device

- Before using this device, please read this operation manual.
- Fukuda Denshi cannot predict all the dangers which may be caused by misuse of this product or due to mistakes in settings or due to environmental conditions.
- For using this device, there are many items that "should be performed", "should not be performed", and "cannot be performed". It is not possible to cover all these items in this manual or warning labels. Therefore, it is necessary to also follow the general safety precaution other than the items described in this manual.
- To prevent accidents, usage other than the intended use, or usage, cleaning, and maintenance not described in this manual should not be performed.
- Activities to prevent accidents should be implemented in an organized manner and after preparing an appropriate procedure manual based on the following regulations.
 1. "Guidelines for Occupational Health and Safety Management Systems"
 2. PP (Prerequisite Program) or HACCP (Hazard Analysis and critical control Point) system
- Not only health care professionals, but also those in charge of management should participate in activities to ensure safety, including sanitation, in an integrated manner to prevent disasters.
- When using this device, follow the respective regulation to minimize the probability of accidents.

Intended Purpose of this Device

This device is designed for the following <Intended Purpose>.

Intended Purpose

This device intends to continuously transmit the vital signs to a specified monitor by wireless network.

The measurable vital signs are electrocardiogram, respiration waveform, arterial oxygen saturation (SpO₂) and pulse waveform.

WARNING

This device is intended to be used by healthcare professionals. Users should have a thorough knowledge of the function and operation before using this device. The maintenance of this device 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 device 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 Device

About the Safety Precautions

The safety precautions are classified as follows which indicate the extent of injury or damage that may result from incorrect handling of the product.

DANGER

- Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

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.



- A note is not related to product safety, but provides information about the proper usage methods to prevent incorrect operation and malfunction.

Clinical Benefits

The clinical benefits of the LX-1300 include:

- measuring and transmitting wirelessly the patient's ECG, respiration and SpO₂ to the central monitor, where display vital signs and alarm generation enable the medical professionals to be aware of changes in the patient's condition.

Cybersecurity

This device complies with Clauses 4 to 9 of IEC 81001-5-1:2021.

This applies only to the maintenance and support of this device.

Problem Occurrence

Fukuda Denshi periodically checks the vulnerability of this device.

If a problem related to the cybersecurity of this device is identified, you will be contacted by Fukuda Denshi.

If you notice any issues, please contact us using the information provided in the Contact section.

How to Respond upon Detection of a Vulnerability or Incident

Management of Device Settings

The administrator of this device should check that the device settings are as intended.

For details on each setting value, refer to the Preset Settings section.

Also, users should periodically record the settings to allow for reconfiguration if needed.

Recovery

Contact your local Fukuda Denshi service representative. Fukuda Denshi will return the device to the customer after verifying the operation.

Reconfiguring the Device Settings

A Fukuda Denshi local service representative will reconfigure the device by referring to the recorded configuration data.

Interfaces Capable of Communicating Externally

This device is equipped with the following interfaces:

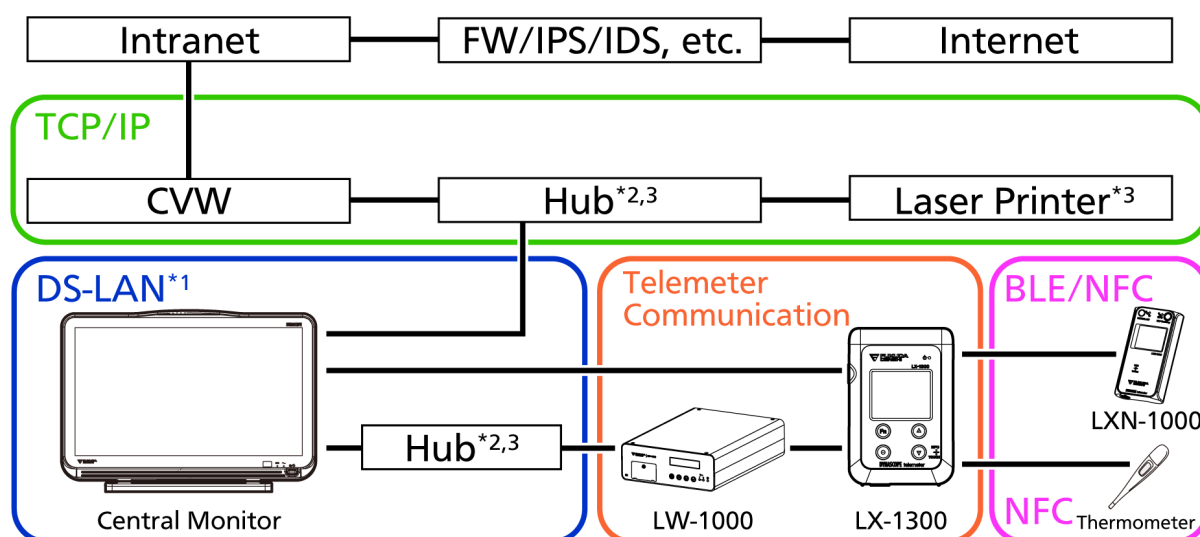
- Function Key
- Operation / Set Key
- NFC antenna
- Standby switch
- BLE communication area

Inquiries Regarding Cybersecurity

Refer also to "Customer Security Documentation" of this device. For details, contact your nearest service representative.

Recommended Operating Environment

The following network configuration is recommended. For details, refer to "Security Enhancement" and "Instructions for Connecting to a Network" described below.



*1 Do not connect to the Internet.

*2 Connect only the recommended devices to the hub within the DS-LAN network, and ensure that all unused ports are locked.

*3 Use devices specified by Fukuda Denshi.

Security Enhancement

- On the hospital network (wired LAN network inside the hospital), medical devices of various manufacturers, hospital PC, servers, printers, etc. are connected with TCP/IP packets. To prevent unauthorized connection or operation of the connected devices such as hubs, make sure to take sufficient security measures of the server room.
- To prevent intrusions from the Internet into the hospital LAN, it is strongly recommended to install a firewall or IPS/IDS device between the hospital LAN and the Internet.
- Although BLE and NFC communications are restricted based on device information, please thoroughly check the surrounding area to ensure there are no suspicious communication devices nearby.

Instructions for Connecting to a Network

- The PCs connected to the hospital network should always install a security software after updating to the latest software version.
- If a PC is infected with malware (malicious software), it may lead to attacks not only on the PCs in the hospital network, but also on surrounding network-connected devices, including this device.
- When using a DS-LAN or TCP network, physically block unused hub ports with a port lock (with key). This helps prevent unauthorized or unintended device connections. In particular, ensure that only recommended devices are connected to hubs within the DS-LAN network.

Security-related Residual Risks

If residual risks related to the cybersecurity of this device are identified, Fukuda Denshi will notify you.

Stopping Use

Before discontinuing use of this device, the internal memory must be erased and the configuration settings initialized. Please contact your local service representative to perform this procedure.

Once you decide to stop using this device, do not power it on.

Security Updates

When security updates become available for this device, you will be notified by Fukuda Denshi.

Graphic Symbols

Refer to the following for the meaning of the symbol indicated on the device.

Graphic Symbols on the Main Unit

Graphic Symbols	Description
	Refer to the operation manual and follow the instructions (Warning). Indicated in blue. Failure to follow operating instructions could place the patient or operator at risk.
	Refer to the operation manual (Information); Indicates the need to refer to the related accompanying documents before operation.
	Type CF Applied Part with Defibrillation-Proof Indicates that in terms of the degree of protection against electric shock, it is Type CF Applied Part with defibrillation-proof.
	Indicates absence of an alarm function. (Only for LX-1300N, LX-1300M)
	Indicates that the device generates non-ionizing radiation.
IPX8	Degree of protection against ingress of water

Graphic Symbols	Description
	Indicates short-range wireless communication.
	Indicates the standby switch or pilot lamp.
	Date of Manufacture Indicates the date of manufacture.
	Name and Address of Manufacturer / Date of Manufacture Indicates the name and address of manufacturer, and date of manufacture.
	Indicates the manufacturer's serial number.
	Indicates a carrier that contains unique device identifier information.

Graphic Symbols on the Display

Graphic Symbols	Description
	Synchronized Mark Flashes synchronizing to the heartbeat
	Indicates the battery level.
	Indicates that the SpO ₂ sensor's expiration date is approaching. (Only LX-1300M)

Precautions for Safe Operation

Precautions for Safe Operation of Medical Device

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

CAUTION

- User should have a thorough knowledge of the operation before using the device.
- For installation and storage of the device, pay attention to the following.
 - Install or store in a place where the device 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.

⚠ CAUTION

- Place the device 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.
- Contact your local Fukuda Denshi service representative if this device packaging is damaged, unintentionally opened or exposed to environmental conditions outside of those specified.
- Before operating the device, verify the following items.
 - □Check the cable connection, polarity, etc. to ensure safe and proper operation of the device.
 - 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 device is used in conjunction with other devices 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 dry cell batteries.
 - The operator should not touch the device's battery terminals and the patient at the same time. Doing so may cause electric shock.
- During operation of the system, verify the following items:
 - Do not operate the device beyond the time period required for diagnosis and medical care.
 - Do not hold the probe or cable part to pick up the device. It may damage the device and lead to measurement error.
 - Always observe the device and patient to ensure safe operation.
 - If any abnormality is found on the device or patient, take appropriate measures such as ceasing operation of the device and/or detaching the probe (sensor) and/or electrode, in the safest way for the patient.
 - Do not repair or perform maintenance while the device is used on a patient.
 - Do not allow the patient to come in contact with other devices.
 - Do not assess the patient's condition only by the information generated on this device. A clinical judgment based on the information from the device should be made by a doctor who fully understands the functions of the device, in a comprehensive manner combined with clinical findings and other test results.
- After using the device, verify following items.
 - Restore the device to the state before it was used and turn 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 device clean to ensure proper operation for the next use.
 - Make sure to remove the batteries if the device is not used for a long time. The leakage from the batteries may damage the device, or an explosion from the batteries may occur.
- If the device 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.
- Do not disassemble or remodel the device.
- Maintenance and Inspection
 - Make sure to periodically check the device and parts. (It is recommended to conclude a maintenance contract.)
 - Before reusing the device that has been left unused for a while, make sure that the device operates properly and safely.
- When using electrosurgical knives or defibrillator with this device, 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 device other than the above may cause accidental hazards to the patient and operator due to the conditions of the device. Read the operation manual attached to each device and fully understand the precautions prior to use.

Non-Explosion Proof

DANGER

- Never operate the device in the presence of flammable anesthetics, high concentration of oxygen. It may cause an explosion or fire.
- Never use the device in the hyperbaric oxygen therapy chamber. It may cause an explosion or fire.
- Never operate the device 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 device 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 device 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. Whenever possible, place the electrodes as far apart as possible between the two points and position the (+) 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.
- The stored data will not be affected. The measurement accuracy will temporarily decrease during surgical procedures using an electrosurgical instrument, but it will not compromise the safety of the patient and the device.

Precautions about Using with the Defibrillator

WARNING

- When using this device with a defibrillator, use only the specified lead cable. If unspecified lead cable is used, it may damage the device 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 device or cables. Electric shock may result from the discharged energy.
- This device will return to standard operating mode within 10 seconds after defibrillating. However, while in the diagnosis mode, the time constant is set bigger, so it may take 10 seconds or longer for the ECG waveform to return to normal after defibrillation is performed.

⚠ WARNING

- The stored data will not be affected. The measurement accuracy will temporarily decrease during defibrillation, but it will not compromise the safety of patient and the device.

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 patient monitor and diagnostic equipment may possibly send wrong information. If such event occurs, please disconnect these devices, 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]
- 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.

Precautions for Using This Device

Please have patients carry this device by placing it in a chest pocket of their clothing or in a pouch designed for transmitters. When a patient is lying in bed, place and use the device in a stable position near the patient, such as next to the bed.

This device is not intended to be worn directly on the patient's skin.

When operating the device, hold it in your hand and perform operations in a position where the screen can be easily seen.

⚠ WARNING

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

Waterproof mechanism

- This device has waterproof capabilities equivalent to IPX8.
- The waterproof capabilities are based on internal test conditions by Fukuda Denshi (immersion in water at a depth of 1.5 m for 30 minutes). However, this does not guarantee that the product will remain undamaged or function properly in all conditions.

⚠ CAUTION

- To maintain the waterproof performance, replace the battery cover periodically. Otherwise, the quality of the lid will deteriorate and cannot keep the waterproof performance. For periodic replacement, contact your local service representative.

CAUTION

- When the device 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 SpO₂ probe and patient cable 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. In particular, ensure that no moisture remains inside the ECG connector and SpO₂ connector.
- If the device gets wet, dry it thoroughly before use. Then, verify its operation using a simulator and confirm that ECG and SpO₂ measurements remain accurate before using the device.
- Make sure that no hair or other foreign objects are stuck in the battery cover and that no dust or chemicals are on to the lid.
- Check the battery cover gasket for any cracks, scratches, or damage. If any cracks or scratches are found, the waterproof performance may be compromised. Please contact your local Fukuda Denshi sales representative for support.

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 a duration of one day.
- Replace the electrode if the skin contact gets loosened 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 sensitivity. If they are 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 cases, 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 SpO₂ Monitoring

WARNING

- For SpO₂ monitoring, use only the probe specified by us. Check the probe before use to make sure that it is the specified probe. If unspecified probe is used, not only will it cause the device to be unable to deliver its maximum performance, but also the device may get damaged and the safety cannot be ensured.
- If the nails of the patient are 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 SpO₂ probe is disconnected from the device, the SpO₂ measurement/waveform will not be displayed on the receiving monitor. Also, the alarm will not be generated. Make sure that the SpO₂ probe is securely connected to this device.
- When not measuring, unplug the SpO₂ probe from the connector. Otherwise, the outside light may affect it and cause it to falsely display the measurements.

⚠ WARNING

- 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 the skin for neonates and premature infants is immature, change the sensor attachment site more frequently depending on the condition.
- When measuring the SpO₂ 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 SpO₂ 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 SpO₂ 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 cross contamination. It is intended for single patient use only. For details, refer to the operation manual of the SpO₂ 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 signals from this device as the trigger signal for IABP, MRI, echocardiography, 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 our genuine or specified products for disposable electrodes, electrode cords and SpO₂ probes. Otherwise, this device 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 Batteries

WARNING

- Install the batteries with the correct (+) (-) direction.
- Do not short-circuit between the (+) and (-) terminals. It may cause a fire due to overheating.
- Do not use different types of batteries at the same time. The leakage from the batteries may damage the device, or an explosion from the batteries may occur.
- Do not throw the battery into fire. It may explode.

Precautions about alkaline/lithium batteries

WARNING

- Please use new AA alkaline/lithium batteries before the recommended expiration date.
- Do not charge AA alkaline/lithium batteries. Charging the batteries may cause liquid leak or damage.

Precaution about Nickel Metal Hydride Battery

WARNING

- Use "AA" size ("HR6" size) fully charged nickel metal hydride batteries.
- Read the manual of the battery, charger and accessories prior to use.
- Do not mix fully charged and discharged batteries.
- If the operating time of the device is short or the battery level indicator decreases quickly, the condition may be improved by repeating the charge and discharge cycle two to three times.

Precautions about Disposing of Device, Accessories, or Components

CAUTION

- When disposing of the device, accessories, or components, use our service representative you purchased them from or 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

- Follow the local municipal rule to dispose the used battery.
- Recycling is recommended for used nickel metal hydride batteries. For details, refer to the manual attached to the battery. When disposing, follow the local municipal rule.

Precautions about FCC

CAUTION

- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the device.
- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Precautions for Operating the Medical Telemetry

WARNING

- The device must not be co-located or operated in conjunction with any other antenna or transmitter.
- For the receiving monitor of the device, make sure to use the Fukuda Denshi products with the receiving range of 608 MHz to 614 MHz.
- Operation of the device 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 device. If a problem exists, contact your local service representative.
- The device 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.
- 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.

⚠ CAUTION

- 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.

Precautions about RF Exposure Compliance

⚠ CAUTION

- The available scientific evidence does not show that any health problems are associated with using low power wireless devices. There is no proof, however, that these low power wireless devices are absolutely safe. Low power wireless devices emit low levels of radio frequency energy (RF) in the microwave range while being used. Whereas high levels of RF can produce health effects (by heating tissue), exposure of low-level RF that does not produce heating effects causes no known adverse health effects. Many studies of low-level RF exposures have not found any biological effects. Some studies have suggested that some biological effects might occur, but such findings have not been confirmed by additional research.
LX-1300 has been tested and found to comply with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines.

Precautions for Using the External Input Function

⚠ CAUTION

- You can input external vital sign in this device via Bluetooth. The external input feature will not operate properly if the communication condition is unstable, so check the communication condition before use.
- If the communication condition is unstable, keep an eye on the patient's condition.

Electromagnetic Compatibility

This device complies with the IEC 60601-1-2:2014+A1:2020 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 device is intended for use in medical facilities (except inside the shield room of an MRI device), and satisfies the immunity level for professional healthcare facility environments stipulated in IEC 60601-1-2:2014+A1:2020.
- An excessive magnetic disturbance may degrade the HR and SpO₂ measurement accuracy, which is the essential performance of this device, and may cause delay in treatment or inaccurate diagnosis.
- When using this device, interference with other medical electrical equipments or non-medical electrical equipments may occur. Make sure that no interference is present before use.
- This device is a medical device which intentionally sends and receives RF energy of specific frequency. RF electromagnetic radiation from other device for the intended specific frequency band may cause radio interference. Make sure that the device sends and receives the energy properly in the used environment.
- To ensure basic safety and essential performance related to electromagnetic disturbances during the expected service life of this device, "Daily Inspection" and "Periodic Inspection" must be performed. (Refer to "Maintenance")

Precautions for Safe Operation under Electromagnetic Influence

⚠ WARNING

- If this device is installed close to, or stacked with other device, malfunction may occur. Make sure to verify that the device operates 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 device.

⚠ WARNING

- 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 device. Otherwise, it may result in performance degradation of this device.

⚠ CAUTION

If any sorts of electromagnetic wave, magnetic field, or static electricity exist around the device, noise interference or malfunction of the device 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.

- Impact of Mobile Phone use:
The radio wave may cause malfunction to the device.
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.

EMC Guidance

This device complies with IEC 60601-1-2:2014+A1:2020. 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.

This device should be used in a location range specified by each medical institution.

The following is the information relating to EMC (Electromagnetic Compatibility).

(When using this device, verify that it is used within the environment specified below.)

Compliance to the Electromagnetic Emissions

This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.

Emission Test	Compliance
Mains Terminal Disturbance Voltage CISPR 11	Not applicable
Electromagnetic Radiation Disturbance CISPR 11	Group 1 Class B
Harmonic Emissions IEC 61000-3-2	Not applicable
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Not applicable

⚠ CAUTION

- The emission characteristics of this device are compliant with CISPR11 Group 1 Class B to provide improved performance, however its use is limited to medical facilities and it should not be used in residential environments.

Compliance to the Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.

The EMC Standard or Test Level	Immunity test level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV Contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air

The EMC Standard or Test Level	Immunity test level
Radiated RF EM Fields IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz 2 Hz 80%AM
Immunity test specifications for 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 2 Hz 80%AM 6 V 0.15 MHz to 80 MHz (ISM bands) 2 Hz 80%AM
Power Frequency Magnetic Field IEC 61000-4-8	30 A/m 50 Hz, 60 Hz
Proximity Magnetic Fields IEC 61000-4-39	Refer to the following table.

⚠ CAUTION

- The electromagnetic disturbances test evoked from the radiated RF electromagnetic field and RF electromagnetic field is performed with 2 Hz modulation frequency which is close to the frequency component of the vital parameter.

Immunity test specifications for RF wireless communications equipment

Test Frequency (MHz)	Modulation	Immunity Test Level (V/m)
810, 870, 930	Pulse modulation, 18 Hz	28
1720, 1845, 1970	PM, 217 Hz	28
2450	PM, 217 Hz	28
5240, 5500, 5785	PM, 217 Hz	9

⚠ CAUTION

- The assumed service, TETRA 400, of the test frequency 385 MHz is a service in Europe, and this product, which is intended for use in the United States, has not been tested as it will not be radiated in close proximity.
- The assumed services, GMRS 460 and FRS 4600, of the test frequency 450 MHz is a wireless device for general and leisure use, and this product, which is intended for use in a professional healthcare facility environment, has not been tested as it will not be radiated in close proximity.

Immunity test specifications for proximity magnetic fields

Test frequency	Modulation	Immunity test level (A/m)
134.2 kHz	PM, 2.1 kHz	65
13.56 MHz	PM, 50 kHz	7.5

The test frequency of 30 kHz is for home healthcare environments, and this product, which is intended for use in professional healthcare facilities, has not been tested in this frequency range as it does not emit radiation.

Recommended Separation Distance between Portable and Mobile RF Communications Equipment and this Device

This device is intended for use in an environment in which radiated RF disturbances are controlled. The user of this device can help prevent electromagnetic disturbance by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

Recommended Separation Distance between Portable and Mobile RF Communications Equipment and this Device

Maximum Output Power of the Transmitter (W)	Separation Distance based on the Frequency of the Transmitter (m)		
	150 kHz to 80 MHz $d=1.2 \sqrt{P}$	80 MHz to 800 MHz $d=1.2 \sqrt{P}$	800 MHz to 2.7 GHz $d=2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3

Maximum Output Power of the Transmitter (W)	Separation Distance based on the Frequency of the Transmitter (m)		
	150 kHz to 80 MHz $d=1.2 \sqrt{P}$	80 MHz to 800 MHz $d=1.2 \sqrt{P}$	800 MHz to 2.7 GHz $d=2.3 \sqrt{P}$
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Absorption and reflection from buildings, objects, and people affect the propagation of electromagnetic waves.

Contact

For information on security risks, it is recommend to refer to the customer security documentation.

If you need more detailed information or information about security risk, please contact following.

Fukuda Denshi Co., Ltd., Head Office

3-39-4 Hongo, Bunkyo-ku, Tokyo 113-8483 Japan

Tel: +81-3-5684-1455 Fax: +81-3-3814-1222

E-mail: info@fukuda.co.jp

Website: <https://fukuda.com/>

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17725-C NE 65th Street Redmond, WA 98052 USA

Toll Free: +1-800-365-6668

Local: +1-425-881-7737

Fax: +1-425-869-2018

If a serious incident has occurred in relation to this device, please report it to the manufacturer and to the competent authority of the country where the user and/or the patient is established.

In case you need the contact information for your national competent authority, please ask the manufacturer or the distributor from whom you purchased the device.

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Chapter 1: General Description

This device is a telemeter transmitter used to measure ECG, respiratory waveform, SpO₂ (arterial oxygen saturation), and pulse waveform. (The LX-1300E is not equipped with any functions related to SpO₂ measurement.)

- You can use this device as a transmitter for ECG and respiration measurements without measuring SpO₂ or as a transmitter for SpO₂ measurements without measuring ECG and respiration waveforms.
- BP values measured with the LXN-1000 Non-Invasive Blood Pressure Monitor can be received via wireless communication and displayed. Received BP values can be sent to the receiving monitor.
- This device is designed for use in operating rooms, intensive care units, hospital wards, and treatment rooms.
- The SpO₂ module and functions differ depending on the model. For details, refer to the following table.

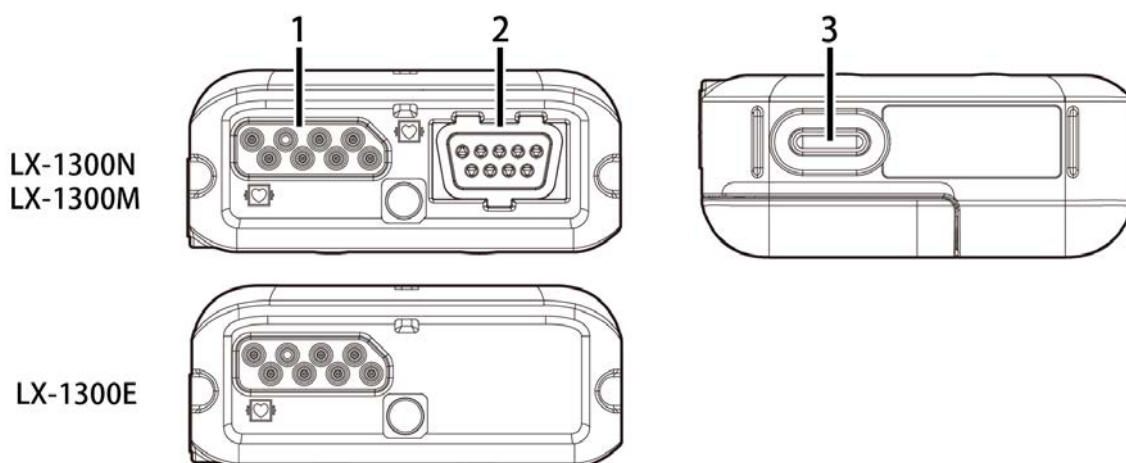
	LX-1300N	LX-1300M	LX-1300E
SpO ₂ module	Manufactured by Medtronic	Manufactured by Masimo	Not equipped
Heart rate measurement (ECG)	Yes	Yes	Yes
Respiratory rate measurement (RESP)	Yes	Yes	Yes
Oxygen saturation measurement (SpO ₂)	Yes	Yes	No
Non-Invasive blood pressure (NIBP) ^{*1}	Yes	Yes	Yes
Battery life ^{*2}	Approx. 1.5 days	Approx. 1.5 days	Approx. 4 days

^{*1} Wireless communication with the LXN-1000 enables measurement data to be acquired.

^{*2} When using alkaline batteries, if the LX-1300E is not paired with the LXN-1000, SpO₂ measurement is not performed. For other models, the values reflect those during SpO₂ measurement.

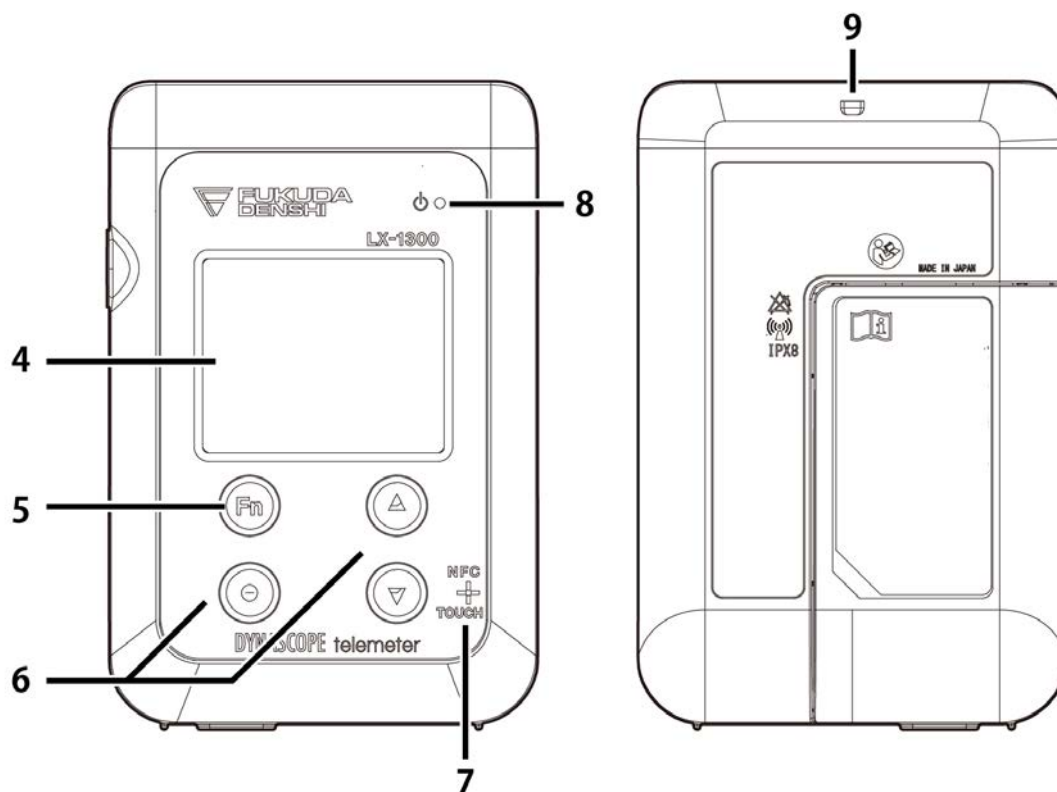
1.1: Names of Parts and Their Functions

Top and Bottom Sides



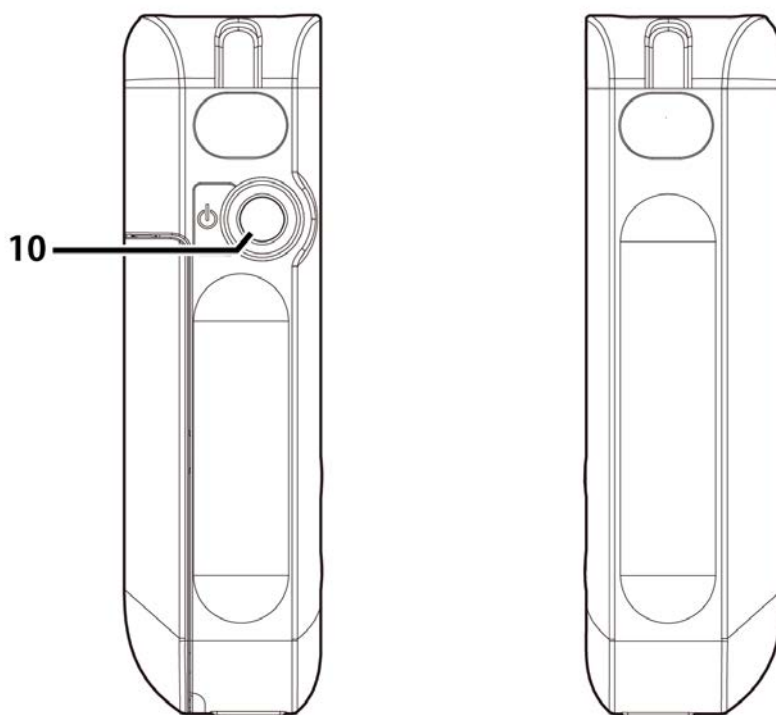
1. ECG Connector
2. SpO₂ Connector
(SpO₂ connector is not equipped on the LX-1300E.)
3. Battery Cover Unlock Key

Front and Rear Sides



- 4. Display Area
- 5. Function Key
- 6. Operation / Set Key
- 7. NFC Mark
A marker indicating the location of the antenna for NFC.
- 8. Pilot Lamp
- 9. Strap Attachment Hole

Left and Right Sides



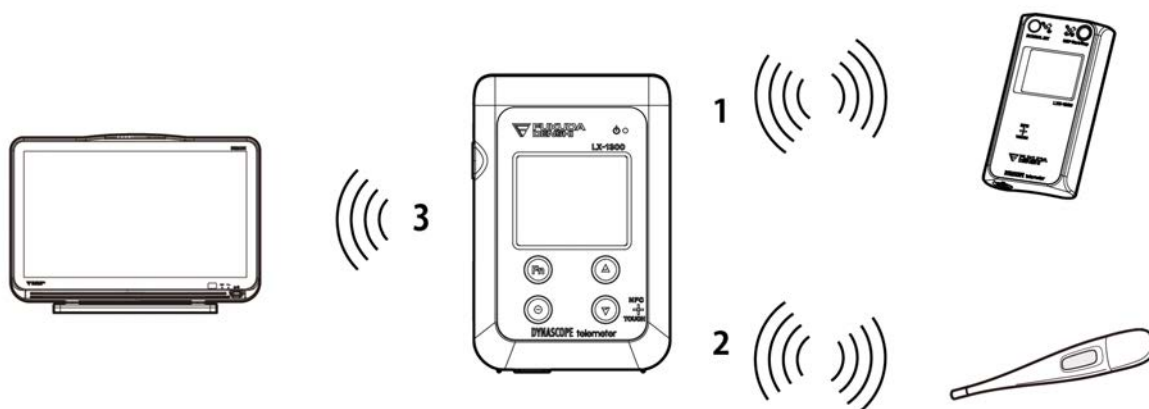
10. Standby Switch.

⚠ CAUTION

- Always operate the standby switch, operation/set key, function button, and battery cover unlock key with your fingers.
- Using anything other than your fingers may damage the switches or buttons.

1.2: System Configuration Example

Below is an example of the system configuration, including this device and its peripheral equipment.



1. NIBP measurement values and status information are received wirelessly from the portable blood pressure monitor (LXN-1000).
Communication is carried out using Bluetooth or NFC.
2. Body temperature measurements are received wirelessly from an NFC thermometer.
3. Measurement values, waveforms, and status information obtained by this device are transmitted to the receiving monitor via communication with a telemeter. (Data received from the blood pressure monitor and thermometer is also transmitted.)

The following receiving monitors are compatible with this device.

- Dynascope 1000 Series - DS-1800 System
- Central Telemetry Receiver - LW-1000 System

Chapter 2: Preparation Before Use

2.1: Install Batteries

Designated Batteries

Type	Product name	Manufacturer
AA Alkaline Battery	LR6 (XJ)	Panasonic
AA Nickel-Metal Hydride Battery	eneloop® BK-3MCD	Panasonic
AA Lithium Battery	L91	Energizer

WARNING

- Always unplug the lead cable when opening the battery cover of a transmitter used for a patient. Opening the battery cover with the lead cable connected may cause a patient leakage current in excess of the allowable value.
- Please use new AA alkaline batteries, AA nickel metal hydride batteries or AA lithium batteries.
- Do not short-circuit the + and - terminals of the battery. Overheating of the battery may cause fire, malfunction due to leakage of liquid, or rupture.
- Install the batteries with the correct (+) (-).
- Do not charge AA alkaline batteries or lithium batteries. Charging the batteries may cause liquid leakage or damage.
- Do not use batteries that have been disassembled or damaged by dropping or impact. The leakage from the batteries may damage the device, 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 device, or an explosion from the batteries may occur.
- Remove the used battery as soon as possible. The leakage from the batteries may damage the device, or an explosion from the batteries may occur.
- Make sure to remove the batteries if the device is not used for a long time. The leakage from the batteries may damage the device, or an explosion from the batteries may occur.
- Replace the two batteries at the same time. Mixing new batteries with old batteries that have been used before may cause malfunctions or rupture due to battery leakage.

CAUTION

- Please use alkaline batteries, nickel metal hydride batteries or lithium batteries specified by Fukuda Denshi.
- Turn OFF the power when opening the battery cover. If you open the battery cover without turning off the power, information about the device's power-off will not be sent to the receiving monitor.
- Do not exchange the batteries with wet hands.
- When storing used or unused batteries, keep their terminals away from other batteries or metal.
- Use batteries that match the battery setting. If a battery that does not match the battery setting is used, the correct battery level will not appear.

⚠ CAUTION

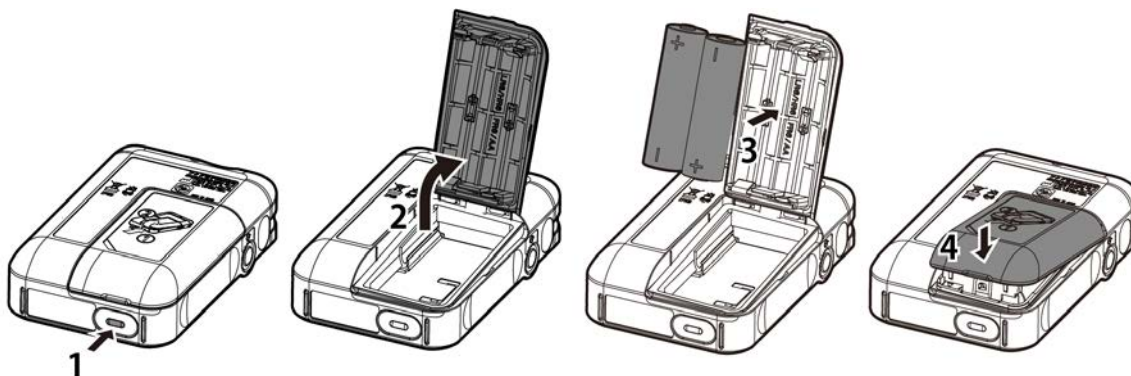
- If a nickel metal hydride battery is used when battery type is set to alkaline batteries, the  symbol will appear later than usual. In addition, the operating time will become shorter than usual after the  symbol appears.
- When an alkaline battery is used when the battery type is set to rechargeable batteries, the  symbol appears earlier than usual. In addition, the operating time will become longer than usual after the  symbol appears.
- Precaution about Nickel Metal Hydride Battery
 - Use fully charged batteries. Do not mix fully charged and discharged batteries.
 - Charge the two batteries at the same time.
 - Read the manual of the battery, charger and accessories prior to use.
 - Nickel metal hydride batteries deteriorate with their life cycle. Do not use batteries that have exceeded the number of charge/discharge cycles specified by the manufacturer.
 - Replace the nickel metal hydride batteries within the number of charge/discharge cycles specified by the manufacturer and after two years of use. If the number of charge/discharge cycles specified by the manufacturer is exceeded or the product is used for more than 2 years, the operating time specified by us may become shorter. However, the operating time will vary depending on battery usage, temperature, and storage conditions.
 - If the operating time of the device becomes shorter even with a fully charged battery, replace the battery with a new one.
 - If the operating time of the device is short or the battery level indicator decreases quickly, the condition may be improved by repeating the charge and discharge cycle two to three times.



Refer to "[13.1 Basic Specifications \(P.13-1\)](#)" for the operating times of each battery.

How to install batteries

1. Push the battery cover unlock key.
2. Open the battery cover.
3. Insert new batteries. Make sure to insert the batteries in the correct direction.
4. Close the battery cover. Push the battery cover until it clicks.



⚠ CAUTION

- Make sure that no hair or other foreign objects are stuck in the battery cover and that no dust or chemicals are on to the lid. Foreign objects may degrade the waterproof performance and flood the battery compartment.
- When installing the alkaline batteries, insert them by pressing the negative terminal of the batteries against the terminal on the battery cover. Forcing the battery in from the positive terminal side may deform the battery terminal, potentially causing damage to the batteries or the device.
- Do not swing the device while holding the battery cover. It may damage the device.

2.2: Power Operations and Screen Display

2.2.1: Turning ON the Power

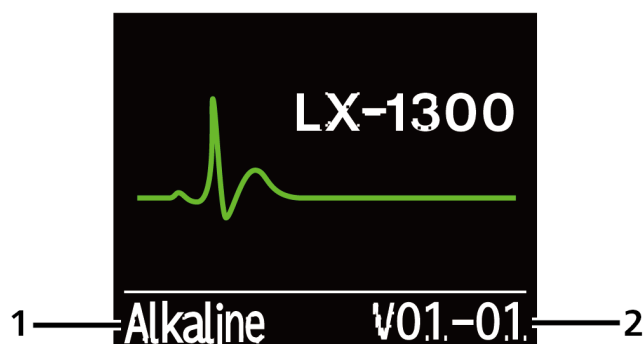
1. Press the standby switch.

The opening screen appears, the device starts up and measurement begins.



- For details of the screen display, refer to "[3 Basic Operation \(P.3-1\)](#)".
- The liquid crystal display will automatically turn off after the set duration has passed.

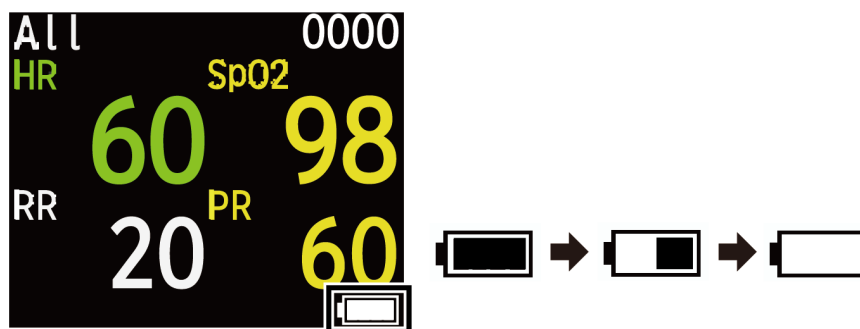
2.2.2: How to See the Opening Screen



1. Battery setting
Please make sure that the display matches the batteries in use. If it does not match, change the battery setting ([9.5.4 Changing the Battery Settings \(P.9-5\)](#)).
2. Software version

2.2.3: Check the Battery Level

During use, you can check the battery level with battery level symbol.



The following is information on the battery level marks.

- : The battery level is sufficient.
- : The battery level is decreasing but still usable.
- : The battery level is very low. Replace the battery.

If a low battery level is detected at startup, the following screen will be displayed. Please replace the battery with a new alkaline battery or a fully charged nickel metal hydride battery.



CAUTION

- Use batteries that match the battery setting. If a battery that does not match the battery type setting is used, the correct battery level cannot be determined.

2.2.4: Turning OFF the Power

1. Press and hold the standby switch for two seconds.
The Power OFF confirmation screen appears.



2. Select [Yes] and press the  key.

2.3: Preparing for NIBP Monitoring

This device receives blood pressure values measured by the LXN-1000 via Bluetooth or NFC for monitoring purposes.

Before performing NIBP monitoring, complete the preparation steps below based on the selected communication method.

2.3.1: Configuring Bluetooth Settings

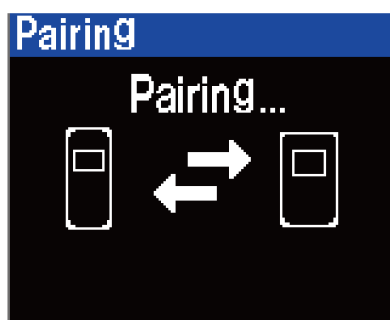
If you are using Bluetooth communication, you must pair this device with the LXN-1000 in advance.

⚠ CAUTION

- When the pairing setting is changed, telemeter transmission will stop for a few seconds, and the receiving monitor will display a waveform that is too far away.

Pairing

1. Press and hold the  key for 2 seconds.
2. Press and hold the interval switch key of LXN-1000 for 5 seconds.
When the pairing screen appears on both this product and LXN-1000, the pairing will automatically begin.



3. The following screen appears when pairing succeeds. Select [Back] and exit.



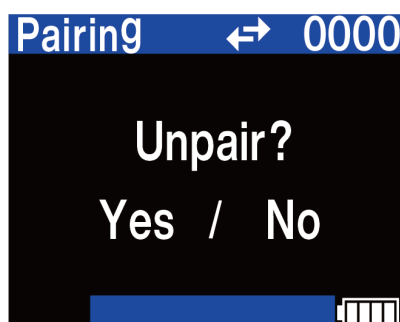
4. Confirm that the icon is displayed on the screen.



- If the icon is flashing, the connection has not been successfully established. Check the settings of the device and LXN-1000, as well as the communication environment.

Cancel the Pairing

1. With pairing established, press and hold the  key for two seconds.
2. When the pairing screen appears, wait 5 seconds without doing anything.
3. Select [Yes] if the screen below appears.



2.3.2: Configuring NFC Settings

NFC communication cannot be used while a Bluetooth pairing is established.

To use NFC, make sure to unpair the LXN-1000 from Bluetooth in advance. ([2.3.1.2 Cancel the Pairing \(P.2-6\)](#))

2.4: Carrying in the Pouch

To make it easier to carry the main device, a pouch (ABT-720D) is available (sold separately).

When carrying around the device, place it inside the pouch. This will prevent potential damage from unexpected drops and keep the battery cover from falling off.



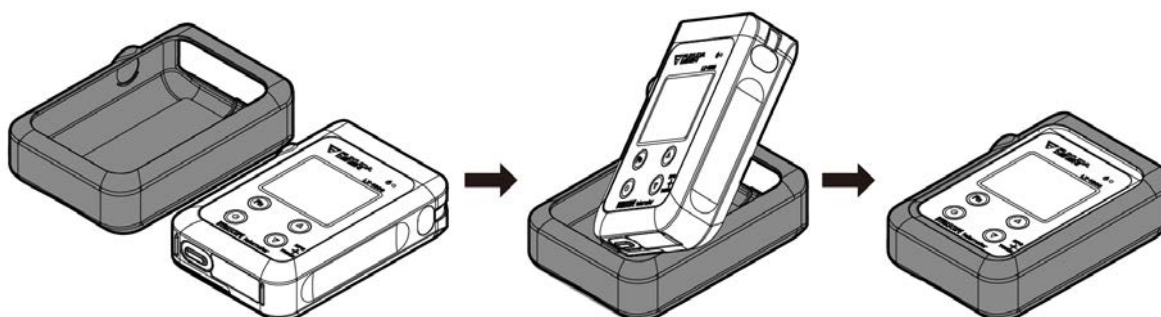
CAUTION

- If a patient touches the battery terminals, there is a risk of electric shock.

2.5: Attaching and Using the Silicone Cover

To protect the main device against scratches and dirt, a silicone cover (ABT-1300C) is available (sold separately).

When attaching the case, disconnect the cables connected to the device and follow the instructions in the diagram below.



⚠ CAUTION

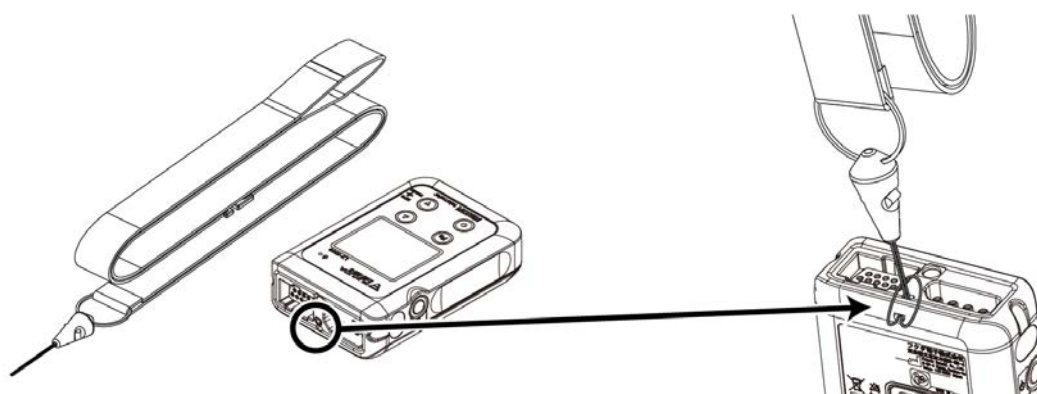
- Be careful to prevent the silicone cover being in contact with the patient's skin for a prolonged time.
- Do not use the device if the silicone cover is damaged.
- For patients who are at risk of swallowing the silicone cover accidentally, use the device without attaching the silicone cover.

2.6: Attaching and Using the Strap

To make it easier to carry the device, a strap (OAT-03A) is available (sold separately).

When carrying the device, please attach the strap. This will prevent potential damage from unexpected drops and keep the battery cover from falling off.

Attach and use the strap as shown in the image below.



⚠ CAUTION

- If a patient touches the battery terminals, there is a risk of electric shock.
- Be careful to prevent the device being in contact with the patient's skin for a prolonged time. While in operation, the device temperature may rise by 2°C to 4°C, which may cause burns at the attachment site.

⚠ CAUTION

- This transmitter is not equipped with a diagnostic function. Please be sure to use the receiving monitor to receive the signal.
- This transmitter does not have an alarm function. Please be sure to use the receiving monitor to receive the signal.
- The display sensitivity and sweep speed of the waveform on the indicator of this transmitter are different from those of the monitor.
- The values of the heart rate and respiratory rate may be different from those on the receiving monitor.

3.2: How to Interpret the Screen

3.2.1: How to Interpret the Screen (Common)

Basic information is displayed on all screens.



1. Screen name
The name of the screen that is currently displayed
2. Patient
Displays the patient classification as follows.
Adult: A / Child: P / Neonate: N
3. Pairing icon
Displays the pairing status with LXN-1000.
On: Communication in progress / Off: Not Connected / Flashing: Communication error or attempting to connect
4. Status message
Displays alarm information or device-related notifications.
5. Telemetry channel number
6. Battery level

3.2.2: All Measurement Screen

This screen displays all parameters that can be monitored by the product. This is suitable for monitoring multiple parameters at the same time.



1. Heart rate
2. Respiration rate
3. SpO₂ value
4. Pulse rate
5. Non-invasive blood pressure (S/D)



- Refer to [10 Troubleshooting \(P.10-1\)](#) for the messages and icons that appear.

3.2.3: ECG Screen



1. Lateral scale of ECG
Equivalent to 1 second per scale
2. Vertical scale of ECG
Equivalent to 1 mV per scale Example screen can display up to ± 1 mV.
3. Lead name
4. Display sensitivity
5. ECG waveform
6. Pacemaker pulse
Displays at the position where the pacemaker pulse is detected.
7. Heart rate

CAUTION

- The sensitivity displayed on the indicator of this transmitter is not the sensitivity displayed on the receiving monitor. The sensitivity displayed on the receiving monitor cannot be changed with this transmitter. To change the display sensitivity of the receiving monitor, follow the operation manual of the receiving monitor.
- If the QRS detection mode is set to [Wide] and a heart rate is measured outside the heart rate display range (12 bpm to 300 bpm), the display will show 0 bpm if the heart rate is 11 bpm or lower and 300 bpm if the heart rate is 300 bpm or higher.
- When the QRS detection mode is set to [Narrow] and the heart rate is measured outside the heart rate display range (30 bpm to 300 bpm), the display will show 0 bpm if the heart rate is 29 bpm or lower and 300 bpm if the heart rate is 300 bpm or higher.



- Refer to [10 Troubleshooting \(P.10-1\)](#) for the messages and icons that appear.

3.2.4: RESP Screen



1. Lateral scale of respiration
Equivalent to 1 second per scale
2. Vertical scale of respiration
Equivalent to change of 1Ω per scale. In the example screen, it corresponds to a change of $\pm 1\Omega$.
3. Display sensitivity
4. Respiration waveform
5. Respiration rate

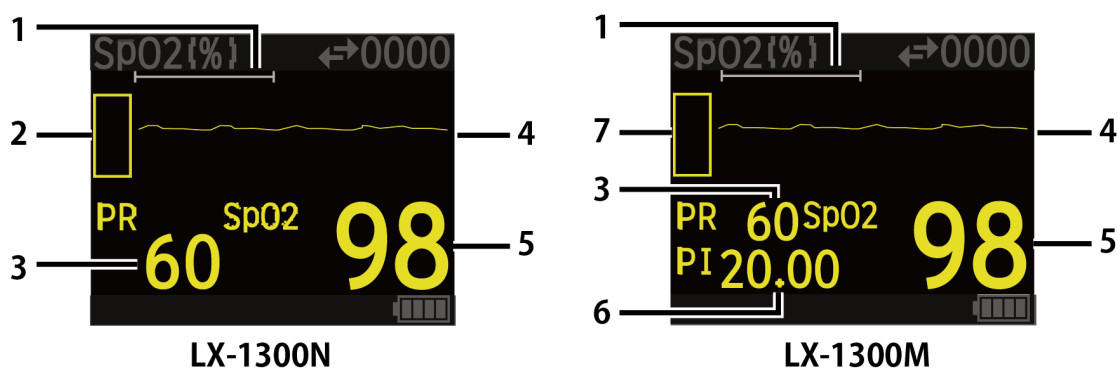
⚠ CAUTION

- The sensitivity displayed on the indicator of this transmitter is not the sensitivity displayed on the receiving monitor. The sensitivity displayed on the receiving monitor cannot be changed with this transmitter. To change the display sensitivity of the receiving monitor, follow the operation manual of the receiving monitor.
- If the respiratory rate is measured outside the displayed range of respiratory rate (4 bpm to 150 bpm), the display will show 0 bpm if the respiratory rate is 3 bpm or lower, and 150 bpm if the respiratory rate is 150 bpm or higher.



- Refer to [10 Troubleshooting \(P.10-1\)](#) for the messages and icons that appear.

3.2.5: SpO₂ Screen



1. Lateral scale of waveform size
Equivalent to 1 second per scale
2. Pulse wave level meter
Displays pulse wave amplitude levels in 8 levels.
3. Pulse rate
4. Pulse waveform
The display sensitivity is automatically adjusted
5. Oxygen saturation
6. PI value

⚠ CAUTION

- For the display of PI values on the receiving monitor, the receiving monitor must support displaying of PI values. For details, refer to the operation manual of the receiving monitor.



- The PI value can only be displayed on LX-1300M.
The perfusion index (PI) is calculated by a pulse rate signal divided by a pulse rate 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.
- Perfusion Index (PI) is a relative assessment of the pulse strength at the monitoring site. It is a ratio of the pulse rate and the non-pulse rate 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. The perfusion index (PI) ranges from 0.05% to 20%, with 1% or more being the preferred value.
- Refer to [10 Troubleshooting \(P.10-1\)](#) for the messages and icons that appear.

7. SIQ Bar

The Signal I.Q. (SIQ) provides an indication of the quality of the acquired signal. The height of the SIQ bar indicates the quality of the signal.



- The LX-1300 display provides a visual indicator Signal IQ and an alert when the displayed values are not based on adequate Signal IQ. The Low SIQ visual alert occurs when the sensor may be compromised. When the Low SIQ alarm occurs, proceed with caution and do the following:
 - Assess the patient.
 - Check the sensor and ensure proper sensor application. The sensor must be well secured to the site for the LX-1300 to maintain accurate readings. Also, misalignment of the sensor's emitter and detector can result in smaller signals.
 - Determine if an extreme change in the patient's physiology and blood flow at the monitoring site occurred, (e.g. an inflated blood pressure cuff, a squeezing motion, sampling of an arterial blood specimen from the hand containing the pulse oximetry sensor, severe hypotension, peripheral vasoconstriction in response to hypothermia, medications, or a spell of Raynaud's syndrome.)
 - With neonates or infants, check that the peripheral blood flow to the sensor site has not been interrupted. For example, as may occur while lifting or crossing their legs during a diaper change.
- After performing the above, if the "Low SIQ" visual alert occurs frequently or continuously, obtaining an arterial blood specimen for CO-Oximetry analysis may be considered to verify the oxygen saturation value.

3.2.6: NIBP Displayable Screen



- Measurement unit

2. NIBP SYS value
3. NIBP MEAN value
4. NIBP DIA value
5. Pulse rate
6. Measurement interval



- Refer to [10 Troubleshooting \(P.10-1\)](#) for the messages that appear.

3.2.7: NIBP List Display

Press and hold the  key on the NIBP screen to display the NIBP list screen.



NIBP(mmHg)		←→0000	
10/10/2024			
TIME	S	D	HR SpO2 RR
12:00	37	95	83 98 16
11:00	31	95	84 98 15
10:00	30	95	82 98 14
09:00	32	95	81 98 16
08:00	32	95	82 98 12
Int. 2 min 1/1			

1. Date of measurement
2. Measurement time
3. Measurement interval
4. Numeric data
5. Page
Displays "Current Page Number/Total Pages".



- Pressing the  key switches to the NIBP screen.

3.2.8: Temperature Screen



1. Temperature

3.3: How to Redisplay the Screen

The screen display automatically turns off after a certain period of inactivity.

The screen can be redisplayed by pressing the , , or  key.

The time it takes for the screen to turn off can be changed by the setting.



- Measurement of the heart rate and respiratory rate in the device is suspended while the device screen is off. Therefore, accurate heart rate and respiratory rate may not appear immediately after the screen is redisplayed.

3.4: Send Event Notifications to Monitors

Press and hold the function key for two seconds to send an event notification to the central monitor.

The functions available for event notifications are as follows.

Event	Description
Alarm Suspend	Temporarily suspends the alarms on the central monitor.
Monitor Suspend	Temporarily suspends monitoring on the central monitor.
Call	Displays a call-out message on the central monitor screen for a certain period of time.
Print	Records the vital sign transmitted from the device on the central monitor.

1. Press and hold the function key for two seconds.

2. Make sure that the selection screen for the event to be notified is displayed.



- If the displayed event selection screen is different from the intended one, press the function key to switch the event type.
- The event type displayed immediately after pressing and holding the function key can be set as desired.
(For details, refer to [9.7.2 Function Setting \(P.9-6\)](#).)

3. Select [Yes] and press the  key.



- If the call-out notification is used for [Print], etc., settings on the receiving monitor are required. For details, refer to the operation manual of the receiving monitor.

Chapter 4: ECG Monitoring

When this transmitter is used without the SpO₂ probe attached, it can be used as an ECG and respiration transmitter.

⚠ WARNING

- Use electrodes and lead cables designated by us. Otherwise, accurate monitoring may be impossible. If an undesignated device is used, energy will be transferred to the device when it is used with a defibrillator, resulting in failure of defibrillation or device malfunction.

⚠ CAUTION

- When using the ECG lead cable alone, turn off the SpO₂ measurement of the receiving monitor to prevent false alarms.



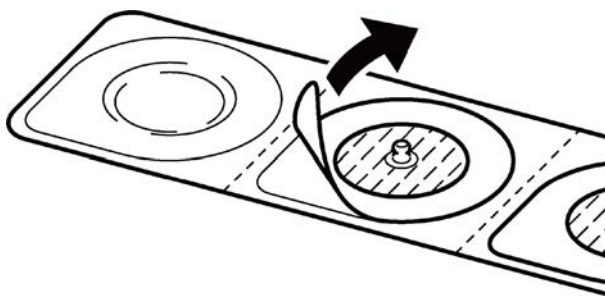
This transmitter is available with a variety of lead cables and electrodes as options. For available electrodes and patient cables, refer to "[12 System Components \(P.12-1\)](#)".

4.1: Attach Electrodes

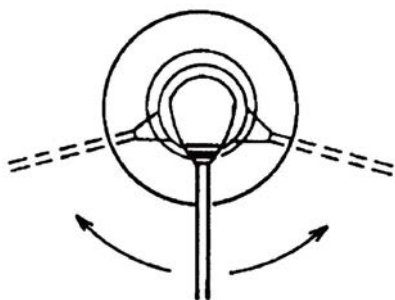
⚠ CAUTION

- Make sure to use the same type of electrodes. If different types of electrodes are used at the same time, the ECG may not be measured due to polarization voltage.
- The electrode is disposable. Do not reuse it.

1. Clean the electrode sites with alcohol wipes or other skin preparation. If necessary shave the electrode sites to remove excessive hair.
2. Peel off the release paper of the disposable electrode and affix it. After opening the package, pay attention not to touch the electrode gel.



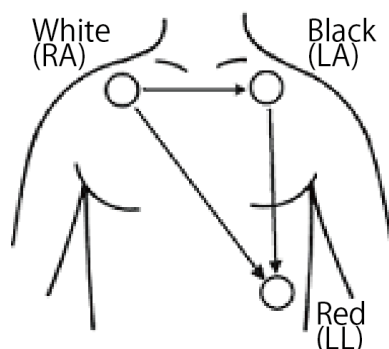
3. When using a magnet-type lead cable, snap the magnetic part at the end into the center of the electrode and turn it several times to the left and right to confirm that it is securely connected.



4.2: Attach the Lead Cable

When using a 3-electrode lead cable

Limb lead can be measured by selecting one of I, II, and III leads according to the settings of the main unit.



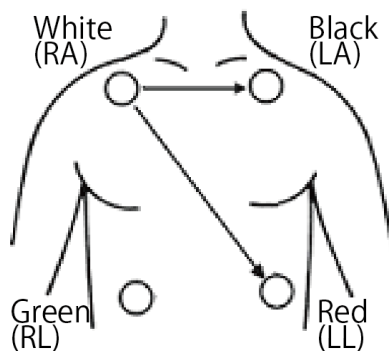
Limb lead

When using a 4-electrode lead cable

Two leads, I lead and II lead, can be measured.

On the receiving monitor side, two leads can be selected from I, II, III, aVR, aVL, and aVF leads to display by setting.

For how to configure the setting, refer to the operation manual of the receiving monitor.



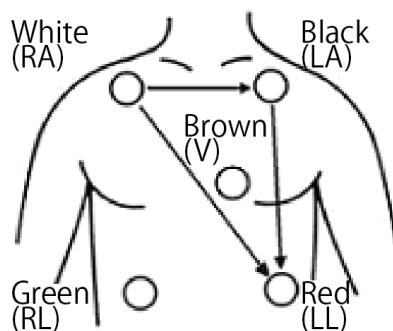
Limb lead

When using an 5-electrode (chest) lead cable

One limb lead and one chest lead (brown) can be measured.

Limb lead can be measured by selecting one of I, II, and III leads according to the settings of the main unit.

By affixing the brown electrode to any part of the body, a thoracic inductive waveform can be obtained.



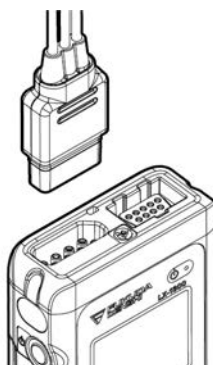
Limb lead and chest lead



- For instructions on switching the lead, refer to "[4.4 Switching the Lead \(P.4-4\)](#)".

4.3: Connecting the Lead Cable to the Device

1. Insert the lead cable straight into the connector, aligning it with the notch in the connector section.



⚠ CAUTION

- 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), electrode placement or lead, which 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 cases, check the condition of the electrodes and lead cables to resolve the cause or turn off the pacemaker detection setting on the receiving monitor.
- Please note that the time constant of the ECG is shorter than that of our wired monitors, resulting in differences in ST measurements.
- 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.
- The indication for continuous use of the electrode is about one day.

⚠ CAUTION

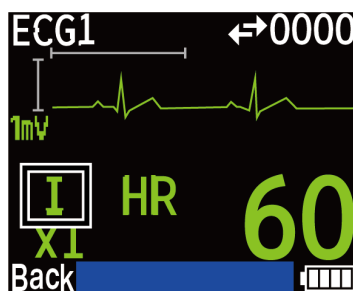
- Promptly replace electrodes that have deteriorated contact conditions due to perspiration or misalignment.
- Always use new disposable electrodes. Waveform quality may deteriorate and incorrect monitoring may occur.
- When removing the patient cable, do not hold and pull on the cable.
- Do not lift the device with the patient cable. The patient cable may detach and the device may fall.
- When removing the probe, hold the sides of the device. Applying excessive pressure on the screen may cause the device to malfunction.
- If a message indicating electrode confirmation appears on the receiver monitor screen or on the main unit display, check the condition of the electrodes and lead cable and remove 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.
- Accurate measurement may not be possible depending on the position where the electrode is attached. Refer to this chapter to attach the electrode and check that the waveform is accurately measured on the main unit display.

4.4: Switching the Lead

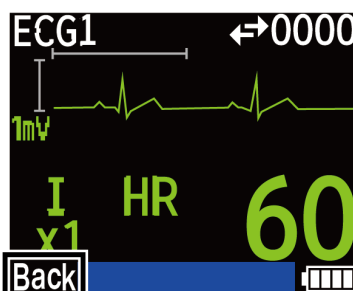
You can switch the lead being measured in the ECG when using a 3-electrode lead cable or a 5-electrode chest lead cable.

The waveform can be checked on the display unit of this transmitter to select a lead with a large wave height value.

1. In the ECG screen, press and hold the  key for two seconds.
2. Press the  key to switch the lead. Each time you press the key, the display switches between lead I, II, and III.



3. Select [Back] and exit.



⚠ CAUTION

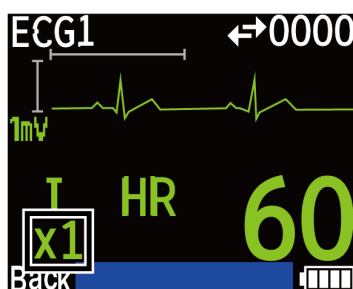
- When you have finished changing settings, be sure to select [Back]. If you continue to use the device with the setting screen on, you may accidentally change the settings.



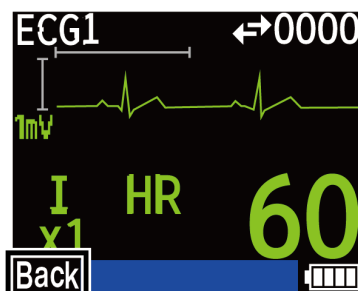
- You can't switch the lead on the 2ch ECG display screen (ECG2 Screen).

4.5: Changing Display Sensitivity (ECG Screen)

- In the ECG screen, press and hold the  key for two seconds.
- Press  to select the sensitivity of the display unit.



- Press  to switch the sensitivity of the display unit.
- Select [Back] and exit.



⚠ CAUTION

- Changing the sensitivity of the transmitter does not change the display sensitivity of the receiving monitor. To change the display sensitivity of the receiving monitor, follow the receiving monitor's operation manual.
- When you have finished changing settings, be sure to select [Back]. If you continue to use the device with the setting screen on, you may accidentally change the settings.



- By changing the sensitivity of the display unit, you can change the scale of ECG.

Chapter 5: Respiration Monitoring

Preparing according to [4 ECG Monitoring \(P.4-1\)](#) enables respiratory monitoring.

Respiration measurement for this device is performed by the impedance method.

The electrodes for respiration detection are shared with those for ECG. Each lead code has a specific electrode used for respiration detection.

When using 3-electrodes and 5-electrode (chest), the electrode that detects respiration does not change even if the lead is switched.

Lead cable	Color of electrode
3-electrode	White (RA) and Red (LL)
4-electrode	White (RA) and Red (LL)
5-electrode (for 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 patient monitor and diagnostic equipment may possibly send wrong information. If such event occurs, please disconnect these devices, 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.

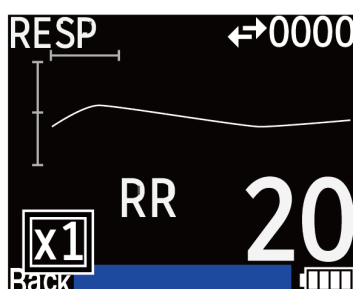
[October 14, 1998 – FDA]

⚠ CAUTION

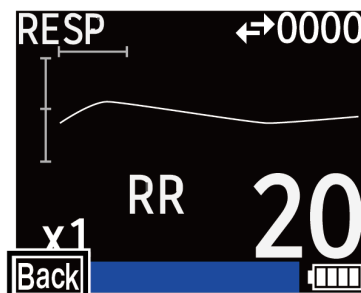
- If an electrode is affixed in a position suitable for ECG monitoring, that affixing position may not always be appropriate for respiration monitoring.
- When a defibrillator is used during respiration monitoring, a large offset voltage will be placed on the ECG electrodes, which may cause interruption of monitoring for a few seconds.

5.1: Changing Display Sensitivity (RESP Screen)

- Press and hold the  key for 2 seconds.
- Press the  key to switch the display sensitivity.



3. Select [Back] and exit.



CAUTION

- Changing the sensitivity of the transmitter does not change the display sensitivity of the receiving monitor. To change the display sensitivity of the receiving monitor, follow the receiving monitor's operation manual.
- When you have finished changing settings, be sure to select [Back]. If you continue to use the device with the setting screen on, you may accidentally change the settings.



- By changing the sensitivity of the display unit, the scale of the respiration waveform also changes.

Chapter 6: SpO₂ monitoring

When this device is used without an ECG lead cable attached, it can also be used as a SpO₂ transmitter. (excluding LX-1300E).

The LX-1300N is equipped with Medtronic's SpO₂ module and the LX-1300M with MASIMO's SpO₂ module.

WARNING

- When the SpO₂ probe is disconnected from the device, the SpO₂ measurement/waveform will not be displayed on the receiving monitor. Also, the alarm will not be generated. Make sure that the SpO₂ probe and each connector of the main unit are firmly plugged in.

CAUTION

- When using the SpO₂ probe alone, turn off the ECG and respiration measurements of the receiving monitor to prevent false alarms.
- Pulse wave amplitude and pulse wave level meter magnitudes are normalized for SpO₂ measurement. The pulse wave does not indicate perfused blood volume. Check the probe's fit by measuring the pulse wave amplitude and the size of the pulse wave level meter.

There are various SpO₂ probes that can be used with this device, depending on its purpose and application. Select and use the appropriate one according to your usage ([12 System Components \(P.12-1\)](#)).

6.1: Precautions about SpO₂ Measurement (LX-1300N)

This is a note on SpO₂ monitoring using Medtronic sensors.

WARNING

- Use only our specified probe. Check the probe before use to make sure that it is the specified probe. If unspecified probe is used, not only will it cause the device to be unable to deliver its maximum performance, but also the device may get damaged and the safety cannot be ensured.
- Pay special attention to connect the cables like all other medical devices. Carefully route the cables to avoid patient entanglement and strangulation.

CAUTION

- If the sensor is not installed correctly, the measurement may be inaccurate.
- If the probe is not connected to the device, a message is displayed.
- If the device detects that the probe is off the patient, it displays messages. Attach the probe correctly on the patient.
- It is designed to minimize the effect of external to the extent possible, but excessive external light can cause inaccurate measurements. In such cases, cover the mounting area with a material that does not allow light to penetrate.
- If the patient's body motion is significant, the measurement accuracy may be reduced. If this occurs, the patient should be placed at rest or reattach the probe.
- Contamination or pigmentation from nail polish, pigment deposits, colored creams, etc. may affect SpO₂ values.
- When removing the probe, do not hold and pull on the cable.

⚠ CAUTION

- Do not lift the main device by the probe. The probe may come off and the device itself may fall.
- When removing the probe, hold the sides of the device. Applying excessive pressure on the screen may cause the device to malfunction.
- Do not use if the package does not seal properly. Always check the package and product for cracks or damage before use. If any abnormality is found, do not use the product.
- Do not soak the sensor in water or antiseptic solution.
- The probe is not waterproof or splashproof. Keep water and chemicals away from the probe.
- Do not reuse disposable type SpO₂ probes. Accurate measurement may not be possible.
- Do not resterilize for use.

⚠ CAUTION

The accuracy of SpO₂ can be affected by abnormal hemoglobins such as carbon monoxide hemoglobin (COHb) and methemoglobin. It may also be affected by CARDIOGREEN and INTRAVASCULAR DYES.

In addition, the following may also affect the accuracy of SpO₂ and pulse rate measurements.

- External light (direct sunlight, fluorescent, light therapy equipment, surgical light, infrared heat ramp, etc.)
- Low perfusion
- Excessive body motion (patient's motion)
- Pigment injected in the patient for the exam
- If measuring during CPR
- Sphygmomanometer cuff, SpO₂ probe on the side with the arterial catheter should be attached
- External colorant such as nail polish
- Abnormally low or high hemoglobin concentration
- Static pulse rate motion
- Electrosurgical instrument
- Effect of electromagnetic radiation from other electronic devices
- Strong signal from cell phones



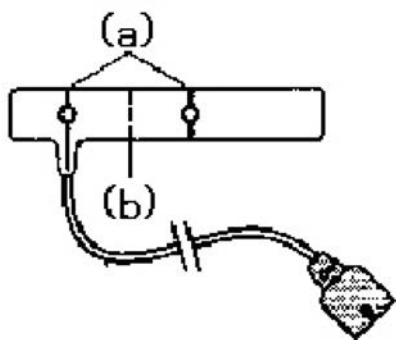
If the sensor attachment site is not appropriate, if the attachment site is too thick or too thin, or if pigmentation, nail polish, colored cream, or other pigments that interfere with light transmission or adherence of pigments may affect the SpO₂ value. In such cases, either re-install the sensor or change the attachment site and use a Nellcor sensor appropriate for the site.

6.2: Attaching MAXI

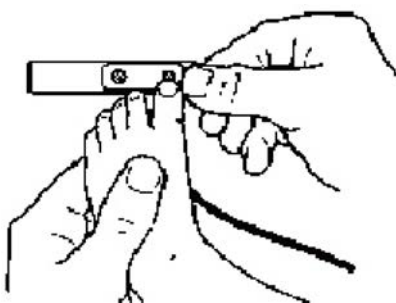
MAXI is an adhesive SpO₂ measurement sensor. Can be used repeatedly on the same patient until the adhesive part loses adhesiveness.

1. Remove from the release paper.

There are two transparent windows on the adhesive side, and the optics are located inside these windows. The non-adhesive side has a relative alignment mark (a) and a dotted line (b) in the middle of the two.



2. Attach the sensor on the foot or finger. The window on the side where the cable comes out should be placed toward the ball of the thumb and the cable should be placed toward the heel.

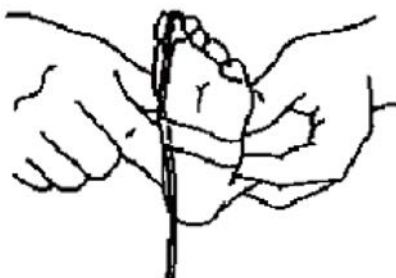


- A great toe is the preferred location. Alternatively, apply the sensor to another digit of similar size, for example, a thumb.
- When choosing a site for the sensor, place it on the side of the foot or finger that is not connected to an arterial catheter, blood pressure cuff, or infusion line.

3. Wrap tightly around the foot or toe, but not too tightly. At this point, make sure the two windows are relative to each other.



4. Wrap the remaining tape loosely around the cable and lightly fasten the cable to the back of the foot with the other tape included. Make sure not to impede blood flow at this time.

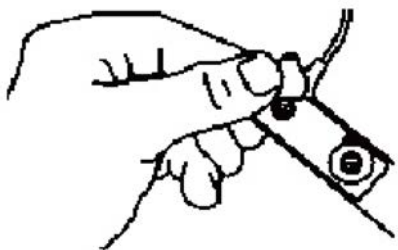


5. Connect to this product and confirm that it is operating properly as described in the operation manual (for this product and the receiving monitor).

Reattaching

For the same patient, the sensor can be reattached as long as the adhesiveness of the sensor part is not compromised.

1. **Attach the supplied circular double-sided tape (dots) to each of the two windows.**



2. **Remove the release paper from the dots.**

It is now ready to be fitted to the same patient. Do not peel off the previously applied tape, but apply the tape on top of the tape as it is.

⚠ CAUTION

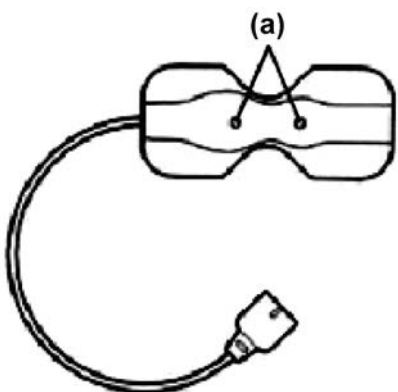
- Do not use on more than one patient as this is a sterile product that can only be used on the same patient.
- Peripheral blood flow to the site of application should be checked periodically. Check the wearing area to ensure that it is in the correct condition, that the skin is in good condition, and that the light is emitted and received correctly. Please read the probe's accompanying documentation for the approximate duration of continuous use. If there is any abnormality in the skin tissue, or if the position of the light emitter or receiver is misaligned, please reattach it on a different part of the body.
- Do not use on patients allergic to adhesive tape.
- If the tape is wound too tightly, or if another tape is wrapped over the top, venous pulsation may occur, resulting in inaccurate SpO₂ readings.

6.3: Attaching MAXP, MAXA, MAXAL

MAXP, MAXA, MAXAL is a sensor for adhesive SpO₂ measurement. Can be used repeatedly on the same patient until the adhesive part loses adhesiveness.

1. **Remove the release paper from the dots.**

There are two transparent windows on the adhesive side, and the optics are located inside these windows.



2. Place the sensor against your finger so that the dotted line in the center between the two windows (a) is at the tip of your finger.



- The index finger is the most suitable site for attachment, but it can also be attached to other fingers of the hand or the thumb of the foot.
- When choosing a site for the sensor, place it on the side of the foot or finger that is not connected to an arterial catheter, blood pressure cuff, or infusion line.

3. Attach the adhesive flap on the side without the cable to your finger. Ensure that the cables are on the upper side of the limbs.



4. Fold the adhesive part of the cable side and affix it to your finger. At this point, make sure the two windows are relative to each other. Wrap the adhesive flap tightly enough to avoid finger pressure.



5. Connect to this product and confirm that it is operating properly as described in the operation manual (for this product and the receiving monitor).

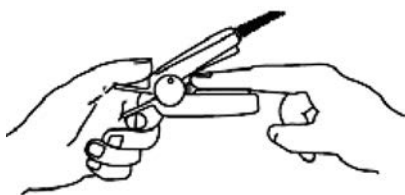
⚠ CAUTION

- Do not use on more than one patient as this is a sterile product that can only be used on the same patient.
- Peripheral blood flow to the site of application should be checked periodically. Check the wearing area to ensure that it is in the correct condition, that the skin is in good condition, and that the light is emitted and received correctly. Please read the probe's accompanying documentation for the approximate duration of continuous use. If there is any abnormality in the skin tissue, or if the position of the light emitter or receiver is misaligned, please reattach it on a different part of the body.
- Do not use on patients allergic to adhesive tape.
- If the tape is wound too tightly, or if another tape is wrapped over the top, venous pulsation may occur, resulting in inaccurate SpO₂ readings.

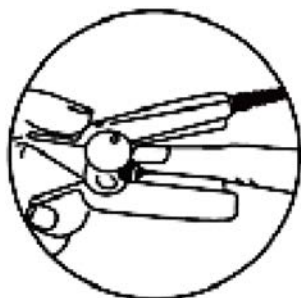
6.4: Attaching DS100A

DS100A is reusable sensor for SpO₂ measurement. This unsterilized sensor is used on patients weighing more than 40 kg and cannot be used on patients with significant body motion or for prolonged periods of time.

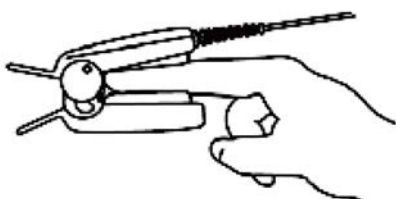
1. Attach it to the patient's index finger with the finger over the window of the product and the fingertip touching the stopper.



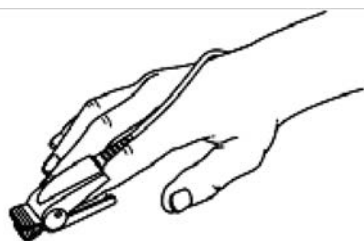
- If the index finger cannot be correctly attached, attach it to another thin finger or use a different Nellcor OxySensor III. Do not use this product on thumbs, toes, or the limbs of children.
- When choosing a site for the sensor, place it on the side of the foot or finger that is not connected to an arterial catheter, blood pressure cuff, or infusion line.
- If the nails are long, place them over the stopper.



2. Open the tabs at the rear of the product so that the force is distributed across the entire pad.



3. When attaching the sensor, the cable should be on the back of the hand.



4. Connect to this product and confirm that it is operating properly as described in the operation manual (for this product and the receiving monitor).

⚠ CAUTION

- Do not use on thumb or toe. You may not be able to take accurate measurements.
- Do not use for long periods of time. Please read the probe's accompanying documentation for the approximate duration of continuous use.
- If the skin color changes, immediately reattach it to another area. If prolonged monitoring is required, use MAXA, MAXAL, MAXN.
- Do not apply tape over the top to secure it in place. Venous pulsation may occur, resulting in inaccurate oxygen saturation measurements.

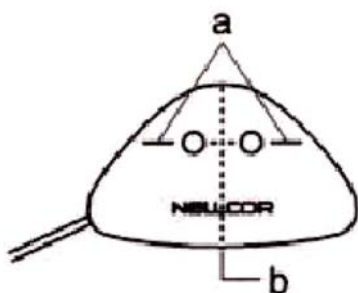
⚠ CAUTION

- Never use radiation sterilization, high-pressure steam sterilization, or ethylene oxide gas sterilization. There is a risk of sensor damage.

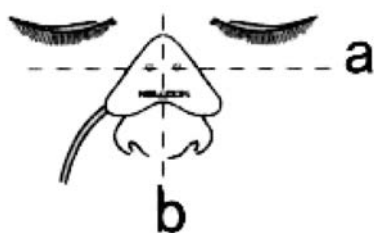
6.5: Attaching MAXR

MAXR is an adhesive SpO₂ measurement sensor. Use for an adult nasal, when measurement on the finger is not possible, due to unstable finger pulsation, etc.

1. **Cleanse the nasal bridge with alcohol or other substance. At this time, make sure to keep the chemical solution away from the patient's eyes.**
2. **Remove the release paper from the dots.**
There are two transparent windows on the adhesive side, and the optics are located under these windows. The non-adhesive side has a relative alignment mark (a) and a dotted line (b) in the middle of the two.



3. **Place the sensor over the nose with the cable coming to the patient's right side. Align the center line of the mark (a) with the midline of the nose, so that the alignment mark (b) is at the nasal midline.**



4. **Press down for about 10 seconds so that it completely adheres to the nose. Make sure it is firmly affixed. Take extra care so that cables do not become entangled with the patient.**



5. Connect to this product and confirm that it is operating properly as described in the operation manual (for this product and the receiving monitor).

⚠ CAUTION

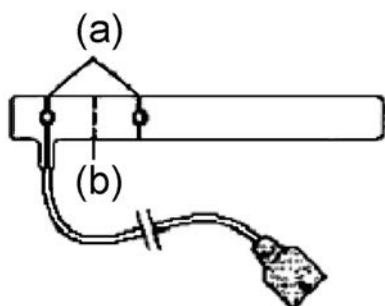
- Do not use on more than one patient as this is a sterile product that can only be used on the same patient.
- Inspect the attachment site periodically to ensure that there are no skin problems, that it is in the correct position, and that there are no problems with the adhesiveness of the sensor.
- Please read the probe's accompanying documentation for the approximate duration of continuous use.
- Do not use on patients allergic to adhesive tape.
- When wiping off the attachment site, make sure to keep the cleaning solution (acetone/alcohol, etc.) away from the patient's eyes.
- When peeling off, take cautions to damage facial tissues by the adhesive.
- Do not use on patients wearing oxygen or anesthesia masks.

6.6: Attaching MAXN

MAXN is an adhesive SpO₂ measurement sensor. Can be used repeatedly on the same patient until the adhesive part loses adhesiveness.

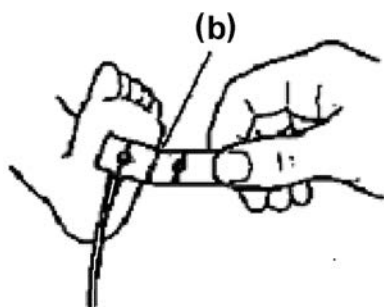
1. Remove the release paper from the dots.

There are two transparent windows on the adhesive side, and the optics are located inside these windows. The non-adhesive side has a relative alignment mark (a) and a dotted line (b) in the middle of the two.

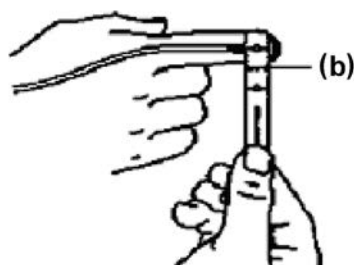


2. Attach the sensor on the foot or finger. The dotted line (a) should be on the outside of the attachment site.

- Neonates: The suitable site for attachment is the feet, but can also be used on the hands. The window on the side where the cable comes out should be on the back side of the foot or palm side.



- Adults: The index finger is the most suitable site for attachment, but it can be attached to other fingers. Attach the sensor so that the window on the side where the cable comes out is at the end of the first joint on the nail side. Do not attach to joints. The cable should be on the back of the hand.



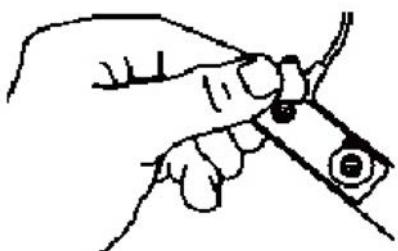
- When choosing a site for the sensor, place it on the side of the foot or finger that is not connected to an arterial catheter, blood pressure cuff, or infusion line.

2. Wrap tightly around the foot or toe, but not too tightly. Make sure the two windows are relative to each other at this time.
3. Connect to this product and confirm that it is operating properly as described in the operation manual (for this product and the receiving monitor).

Reattaching

For the same patient, the sensor can be reattached as long as the adhesiveness of the sensor part is not compromised.

1. Attach the supplied circular double-sided tape (dots) to each of the two windows.



2. Remove the release paper from the dots.

It is now ready to be fitted to the same patient. Do not peel off the previously applied tape, but apply the tape on top of the tape as it is.

⚠ CAUTION

- Do not use on more than one patient as this is a sterile product that can only be used on the same patient.
- Peripheral blood flow to the site of application should be checked periodically. Check the wearing area to ensure that it is in the correct condition, that the skin is in good condition, and that the light is emitted and received correctly. Please read the probe's accompanying documentation for the approximate duration of continuous use. If there is any abnormality in the skin tissue, or if the position of the light emitter or receiver is misaligned, please reattach it on a different part of the body.
- Do not use on patients allergic to adhesive tape.
- If the tape is wound too tightly, or if another tape is wrapped over the top, venous pulsation may occur, resulting in inaccurate SpO₂ readings.

6.7: Attaching MAXFAST

MAXFAST is an adhesive SpO₂ measurement sensor. Can be used repeatedly on the same patient until the adhesive part loses adhesiveness.

1. **Wipe the attachment site with alcohol or other liquids to remove sebum.**
2. **Peel off the release paper to reveal the first of three layers of adhesive pads.**



- This product has three layers of adhesive pads with tabs for easy removal. To reattach the product on the same patient, remove the old adhesive pad by the tab to reveal the new pad.

3. **Place on the patient's frontal, flat and hairless site, just above their eyes.**
If the patient is lying down, place it over the eyes at the patient's side head so that it does not touch the bed. After making sure that the entire surface of the adhesive pad is in contact with the skin, press firmly for 10 seconds to fix the product in position.
4. **If necessary, the cable of the product can be secured to the patient's clothing or other objects using the clip on the cable. Pinch both sides of the clip ring to open, and release to close.**
5. **Connect to this product and confirm that it is operating properly as described in the operation manual (for this product and the receiving monitor).**



- If the sensor is not attached on the appropriate site and the attachment site is too wrinkled, contamination or pigmentation from colored cream and other pigments that block light may affect the SpO₂ value. In such cases, reinstall the sensor or use a Nellcor sensor that is mounted on something other than the forehead.

6. **Put on the headband if necessary.**

When putting on the headband, be sure to read and follow the instruction manual and accompanying documents for the headband.

⚠ WARNING

- The headband should not be used for children under 24 months of age.
- The headband should not be used on children whose fontanelles are not closed.

⚠ CAUTION

- Precautions for headband use
 - If the headband is worn too loosely or too tightly, you may not be able to take accurate measurements. Make sure the headband is worn in a way the same pressure applies to the entire sensor. Ensure that the sensor is completely covered by the headband.
- Precautions for use of MAXFAST
 - Do not use on more than one patient as this is a sterile product that can only be used on the same patient.
 - Peripheral blood flow to the site of application should be checked periodically. Inspect the attachment site periodically to ensure that there are no skin problems, that it is in the correct position, and that there are no problems with the adhesiveness of the sensor. Please read the probe's accompanying documentation for the approximate duration of continuous use.
 - Do not use on patients who are allergic to the adhesive pad part, patients who perspire excessively, or patients in the Trendelenburg position (head lower than the chest).
 - Do not use the tape to secure. Using other tapes or different types of adhesives may cause skin damage.
 - Do not wrap the headband tightly around the head as you may not be able to take accurate SpO₂ measurements due to static pulsation.
 - Patients in the supine position may have venous retention, which may result in inaccurate measurements.

6.8: Precautions about SpO₂ Measurement (LX-1300M)

The following is a note on SpO₂ monitoring using MASIMO sensors.

⚠ WARNING

- Use only our specified probe. Check the probe before use to make sure that it is the specified probe. If unspecified probe is used, not only will it cause the device to be unable to deliver its maximum performance, but also the device may get damaged and the safety cannot be ensured.
- Pay special attention to connect the cables like all other medical devices. Carefully route the cables to avoid patient entanglement and strangulation.
- Use the utmost caution to make sure that the cable will not become entangled with the patient's body or neck, compromising the patient's safety.
- Do not place this device and accessories in any place where it might fall on the patient.
- Do not start monitoring until you are sure it is set correctly.
- Do not use this device during an MRI examination or in an MRI environment.
- Do not use this device if there is a risk of damage.
- Explosion hazard: Do not use this device in an environment where air, highly concentrated oxygen, or nitrous oxide is mixed with flammable anesthetic gases or flammable materials.
- To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
- To protect against injury, follow the directions below.
 - Do not place the device in wet areas.
 - Do not soak or immerse the device in liquids.
 - Do not sterilize the device.
 - Use the cleaning solution specified in this manual.

⚠ WARNING

- Do not clean the device during patient monitoring.
- To prevent electric shock, always remove the sensor and this device completely from the patient when bathing the patient.
- If you doubt that the measurements are accurate, check the patient's vital signs by other means to check if the device is functioning properly.
- Inaccurate SpO₂ measurements may be due to the following reasons.
 - Improper sensor attachment
 - Elevated levels of COHb or MetHb: The COHb or MetHb levels may be elevated even when the SpO₂ measurement is seemingly normal. When you suspect elevated levels of COHb or MetHb, perform analysis (co-oximetry) of a blood sample.
 - Intravascular dyes, such as indocyanine green or methylene blue
 - External colorants such as nail polish, acrylic artificial nails, and glitter
 - Elevated levels of bilirubin
 - Severe anemia
 - Abnormal venous pulsation or venous constriction
 - Severe vasoconstriction or hypothermia
 - Arterial catheters and intra-aortic balloon.
 - Very low arterial perfusion
 - Extreme motion artifact
 - Elevated levels of dyshemoglobin
 - Raynaud's and other vasospastic diseases
 - 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.
 - Skin pigmentation abnormalities
- Interference substance: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous measurements.
- This device is intended only as a supplementary device for patient assessment. It should not be used as the sole basis for clinical decisions. It must be used in conjunction with clinical signs and symptoms.
- Do not use the SpO₂ data to monitor apnea condition.
- This device may be used during defibrillation, but this may affect the accuracy or availability of the SpO₂ parameters and measurements.
- This device may be used during electrocautery, but this may affect the accuracy or availability of the SpO₂ parameters and measurements.
- The SpO₂ data cannot be used for arrhythmia analysis.
- SpO₂ is adjusted based on functional arterial blood oxygen saturation data from healthy adult volunteers with normal carboxyhemoglobin (COHb) and methemoglobin (MetHb) levels.
- Do not adjust, repair, open, disassemble, or modify this device or accessories. This may damage the device or cause injury. Request repair service if necessary.

⚠ CAUTION

- SpO₂ probe for LX-1300N cannot be used.
- The probe is not waterproof or splashproof. Keep water and chemicals away from the probe.
- Do not lift the main device by the probe. The probe may come off and the device itself may fall.

⚠ CAUTION

- When removing the probe, hold the sides of the device. Applying excessive pressure on the screen may cause the device to malfunction.
- If the probe is not connected to the device, a message is displayed.
- If the device detects that the probe is off the patient, it displays messages. Attach the probe correctly on the patient.
- Do not reuse disposable type SpO₂ probes. Accurate measurement may not be possible.
- Please also refer to the attached document for the SpO₂ probe.
- Do not place this device in a location where a patient can operate it.
- Electrical shock and flammability hazard: Before cleaning this device, make sure to turn off the power.
- When patients are undergoing photodynamic therapy, they may be sensitive to light sources. SpO₂ may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.
- Do not install on top of any electronic equipment that may affect this device and interfere with its proper operation.
- If a patient shows a tendency toward oxygen deprivation, analyze a blood sample to accurately assess the patient's condition.
- If the Low Perfusion message frequently appears, find a better perfused monitoring site. In the interim, assess the patient and if indicated, verify oxygenation status through other means.
- Change the measurement point or replace the sensor if the [Replace Sensor] message appears on the screen. This message may indicate that patient monitoring time on the sensor has expired.
- If using the device 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 device might read zero.
- Variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. If you get any results exhibiting inconsistency with the patient's clinical condition, repeat the measurement and supplement with additional test data. Analyze the blood samples should to accurately understand the patient's condition.
- Do not submerge this device, sensor and connector in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage this device.
- Risk of electric shock: Perform periodic testing to ensure that the leakage current of the patient-worn part and the system is within the permissible limits specified in the safety standard. Test the total leakage current and comply with IEC 60601-1. If the device is dropped or blood or other liquid is spilled, stop using the device and perform a safety inspection. Injury may occur.
- Product disposal: Follow local government regulations when disposing of devices and accessories.
- To minimize radio interference, do not place electrical equipment transmitting radio communications near this equipment.
- Replace the sensor if the [Replace Sensor] message stays on the screen while monitoring patients after completing the troubleshooting steps provided in this manual.
- To prevent damage to the sensor or the main unit of the device, remove the sensor from the main unit when re-attaching the sensor or changing the attachment site.
- Before using the sensor, make sure that the wire is physically complete, free of scratches, wear, or damaged parts.

⚠ CAUTION

- Use extreme caution with hypoperfused patients. If the sensor is not moved frequently, skin sores, necrosis due to pressure, etc. may occur. For patients with low perfusion, check the attachment site at least every 2 hours.
- If the sensor is mounted too tightly, it may result in incorrect, low measurements.
- Check the blood flow at the end of the sensor attachment site periodically.
- If the sensor is nearly disconnected for improper attachment, the measurement may be higher or lower than the actual arterial oxygen saturation.
- Do not use the tape to secure the sensor to the measurement site. This may restrict the blood flow, resulting in inaccurate measurements. Using additional tape may damage skin or sensors.
- Make sure that the exterior of the sensor is free from defects. Do not use a sensor that is damaged or has exposed electronic circuitry.
- Avoid attaching the sensor to the tip of the site where an arterial catheter or blood pressure measuring cuff is attached.
- Support by the intra-aortic balloon adds to the pulse rate displayed on the oximeter. Verify the patient's pulse rate by comparing it with the ECG heart rate.
- Arterial blood oxygen saturation readings may be lower than actual if there is intravenous congestion. Therefore, check for normal venous perfusion from the monitored site. The sensor should not be mounted lower than the heart (e.g., on the hand of a patient in bed with the arm hanging to the floor).
- Venous pulsation may cause false low readings (e.g., tricuspid regurgitation, Trendelenburg position).
- Do not modify the product as this will affect its performance and accuracy.
- Strong ambient light such as no-shadow lamps (especially xenon lamps), bilirubin lamps, fluorescent lamps, infrared lamps, and direct sunlight can interfere with sensor performance.
- To avoid obstruction by ambient light, make sure the sensor is properly attached and cover it with an opaque object if necessary. Failure to implement this precaution against strong ambient light may result in incorrect measurements.
- Premature infants may be more susceptible to retinopathy when the oxygen levels are high. Therefore, upward warning limits for oxygen saturation should be carefully established based on accepted clinical standards.



- Do not use the Functional Tester to evaluate SpO₂ accuracy.
- If an intense light source (e.g., pulsed strobe light) directed toward the sensor, it may not be possible to read the SpO₂.
- When set to the maximum sensitivity, the performance of sensor outlier detection may be degraded. If the device is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.
- Do not wrap the cable around the device. This may damage the cable.
- Additional information specific to the sensors compatible with this device, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use.
- Precautions about MASIMO sensors
Masimo's sensors utilize a technology called X-Cal to ensure patient safety and promote efficiency in the clinical site. X-Cal is designed to address the following three issues affecting measurement accuracy and patient safety
 1. Using imitations of MASIMO sensors
 2. Loss of measurement accuracy caused by using the sensor beyond the expected service life

3. Using sensors reprocessed by other companies

Sensors that do not support X-Cal cannot measure SpO₂ even if used with X-Cal compatible devices. In addition, even when using MASIMO sensors or sensors specified by us, SpO₂ measurement may not be possible if the sensor has passed its predicted service life.

Predicted Service Life of MASIMO Sensors

The X-Cal function automatically monitors the Active Monitoring Time (actual time of SpO₂ monitoring) for each sensor. If the sensor has passed its predicted service life, the message <Replace Sensor> appears. Monitoring can be continued even after the sensor has passed its predicted service life, but when 12 hours and 72 hours after the [Replace Sensor] message appears for the disposable sensors and reusable sensors, respectively, the sensor becomes unusable by one of the following operations.

- Leave the sensor off the attachment site for more than 2 hours
- Remove the probe from the main unit of the device
- Turn OFF the main unit

The following table shows the predicted service lives of the sensors. The table also shows the approximate use times per day (24 hours / 12 hours / 8 hours). It also shows the approximate time in parentheses it takes for the  mark to appear, indicating that the sensor is nearing its expiration date.

Sensor	Patient Measurement Predicted service Life	Actual Time of SpO ₂ is 24 hours/day	Actual Time of SpO ₂ is 12 hours/day	Actual Time of SpO ₂ is 8 hours/day
Single Patient Use SpO ₂ L Sensor	336 hours (Approx. 302 hours)	14 days (Approx. 12 days)	28 days (Approx. 25 days)	42 days (Approx. 37 days)
Single Patient Use SpO ₂ Sensor	168 hours (Approx. 151 hours)	7 days (Approx. 5 days)	14 days (Approx. 12 days)	21 days (Approx. 18 days)
Reusable Sensors (DCI, TC-I, TF-I)	8,760 hours (Approx. 7,884 hours)	12 months (Approx. 328 days)	2 years (Approx. 657 days)	3 years (Approx. 985 days)

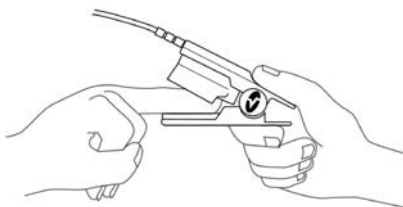
MASIMO Patent Information

- Masimo Patents:
Patents: www.masimo.com/patents.htm
- No Implied License:
"Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device."

6.9: Attaching LNCS DCI, RD SET DCI

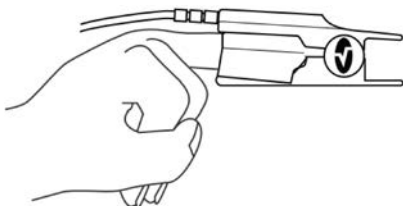
LNCS DCI and RD SET DCI are reusable sensors for SpO₂ measurement. This unsterilized sensor is for use on adult patients weighing more than 30 kg and is not for use on patients with significant body motion or for prolonged periods of time.

1. Before attaching the sensor, wipe off any dust or dirt from the attachment site and dry it well.
2. Press the hinge tab to open the sensor and place your chosen finger on the sensor receiver. Make sure that your fingertips touch the inner stopper part of the sensor.
At this time, if the fingernail is long, the nail may exceed the top of the finger stop.

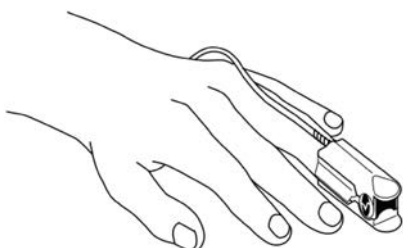


The ring finger on the opposite side of the dominant hand is the recommended attachment point. Other fingers and toes on the opposite side of the dominant hand can also be used, as long as the sensor receiver can be completely covered.

3. Make sure that the light-receiving part of the sensor is well covered.



4. Attach the sensor cable so that it runs across the back of the patient's hand.



5. Connect to this product and confirm that it is operating properly as described in the operation manual (for this product and the receiving monitor).



CAUTION

- If the patient has small fingers, you may not need to push their finger all the way down to the finger stop to completely cover the receiver window. The sensors are not intended for use on thumbs or children's hands or feet.
- Check the attachment site should at least every 4 hours to ensure good adhesion, check the skin condition, if the attachment position is correct, etc.
- Use extreme caution with hypoperfused patients. If the sensor is not moved frequently, skin sores, necrosis due to pressure, etc. may occur. For patients with low perfusion, check the attachment site at least every 2 hours.
- If the sensor is mounted too tightly, it may result in incorrect, low measurements.

6.10: Attaching LNCS TC-I

LNCS TC-I are reusable sensors for SpO₂ measurement. This unsterilized sensor is for use on patients weighing more than 30 kg and is not for use on patients with significant body motion or for prolonged periods of time.

1. Before mounting the sensor, wipe off any dust or dirt from the mounting area and dry it well.
2. Wear on the earlobe or ear wing.



Choose an area with good blood circulation and wear the sensor so that the sensor receiver is completely covered (rubbing the earlobe vigorously for 25-30 seconds or applying a reddening cream can help improve ear circulation).

3. Connect to this product and confirm that it is operating properly as described in the operation manual (for this product and the receiving monitor).

⚠ CAUTION

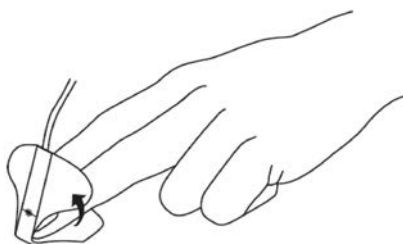
- Do not allow the patient to be in a position where external pressure applies to the measurement site of the sensor.
- Do not use strong vasodilator creams such as nitroglycerin paste to improve circulation.
- Discontinue using the ear sensor if the sensor slips or moves from the earlobe or earwing attachment site due to loss of spring tension in the clip.
- Do not pull on the cable when removing the sensor from the patient's ear.
- Do not immerse the connectors of the LNCS TC-I cable in liquid.
- Change the attachment site every 4 hours.
- Check the blood flow at the end of the sensor attachment site periodically.
- Use particular caution with hypoperfused patients. Skin sores, necrosis due to pressure, etc. may occur.
- Do not use on earlobes or any area other than ear wings. Other areas may have inaccurate readings due to thicker tissue.
- Use of supplementary tapes may result in erroneous readings due to static pulse/congestion.

6.11: Attaching LNCS Aadx, LNCS Padx, RD SET Adt, RD SET Pdt

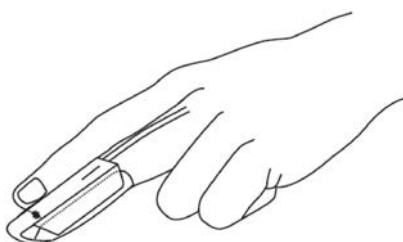
LNCS Aadx, LNCS Padx, RD SET Adt, and RD SET Pdt are adhesive sensors for SpO₂ measurement. LNCS Aadx and RD SET Adt are sterilizable sensors for adult patients weighing more than 30 kg, and LNCS Padx and RD SET Pdt are sterilizable sensors for pediatric patients weighing 10 to 50 kg, and cannot be used on patients with significant body motion or for prolonged use.

1. Before mounting the sensor, wipe off any dust or dirt from the mounting area and dry it well.

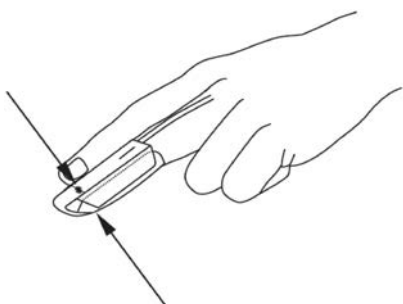
2. Place the tip of the finger on the dotted line so that the sensor's light-receiving area is completely covered. Attach the adhesive flap on the side without the cable to your finger. At this time, place the cable above the limbs.



3. Fold the adhesive part of the cable side one side at a time and affix it. At this time, make sure that the light-receiving area is completely covered, and wrap the adhesive flap tightly enough while avoiding pressuring the finger.



4. Wrap it around the finger so that the light-emitting part window (red star) is at the top of the fingernail. At this time, the windows of the light emitter and receiver should be relative to each other.



5. Connect to this product and confirm that it is operating properly as described in the operation manual (for this product and the receiving monitor).

CAUTION

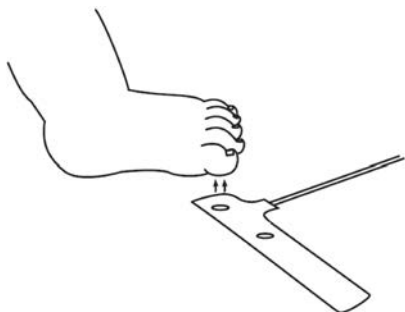
- The LNCS sensor should not be used on patients who are allergic to foam rubber products or adhesive tape.
- Check the attachment site frequently or according to your healthcare provider's protocol to ensure good adhesion, check the blood flow, skin condition, and if the optical sensor is positioned correctly.
- Use particular caution with hypoperfused patients. If the sensor is not reapplied frequently, skin damage or pressure necrosis may occur. For hypoperfused patients, examine the attachment site every hour and reattach the sensor if there are signs of ischemia.

6.12: Attaching LNCS inf-L, LNCS inf-3 and RD SET Inf

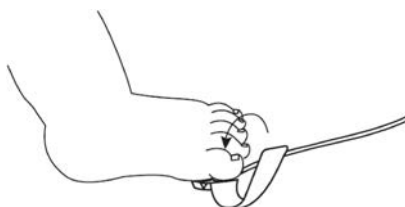
LNCS inf-L, LNCS inf-3, and RD SET Inf are adhesive sensors for SpO₂ measurement.

These are sterilizable sensors for use on infants weighing 3 to 20 kg, and not for use on patients with significant body motion or for prolonged periods of time.

1. Before mounting the sensor, wipe off any dust or dirt from the mounting area and dry it well.
2. Attach the sensor cable so that it faces away from the patient and the side of the ball of the toe thumb covers the light-emitting part. At this time, make sure that the light-receiving area is completely covered.



3. Wrap the adhesive wrap part around the thumb (Fig. 2) so that the light-emitting part window (red star) is at the top of the thumb. At this time, the windows of the light emitter and receiver should be relative to each other.



4. Connect to LX-1300M and confirm that it is operating properly as described in the instruction manual (for this product and the receiving monitor).

⚠ CAUTION

- The LNCS sensor should not be used on patients who are allergic to foam rubber products or adhesive tape.
- Check the attachment site frequently or according to your healthcare provider's protocol to ensure good adhesion, check the blood flow, skin condition, and if the optical sensor is positioned correctly.
- Use particular caution with hypoperfused patients. If the sensor is not reapplied frequently, skin damage or pressure necrosis may occur. For hypoperfused patients, examine the attachment site every hour and reattach the sensor if there are signs of ischemia.

6.13: Attaching LNCS Neo-L, LNCS NeoPt-L, LNCS NeoPt3, RD SET Neo, and RD SET NeoPt

LNCS Neo-L, LNCS NeoPt-L, LNCS NeoPt3, RD SET Neo, RD SET NeoPt are adhesive sensors for SpO₂ measurement.

LNCS Neo-L and RD SET Neo are sterilizable sensors for use on neonates weighing less than 3 kg or adult patients weighing more than 40 kg, and LNCS NeoPt-L and RD SET NeoPt are sterilizable sensors for use on premature babies weighing less than 1 kg, and should not be used on patients with significant body motion or for prolonged periods of time.

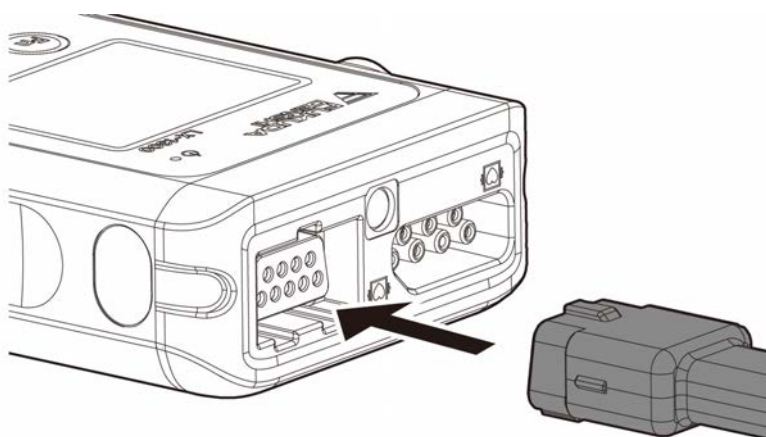
1. Before mounting the sensor, wipe off any dust or dirt from the mounting area and dry it well. For patients with sensitive skin, you can make the medical adhesive bandage less adhesive by pressing cotton or gauze onto its adhesive side.
2. Install the sensor cable so that the sensor cable runs along the sole of the foot and the thick part of the sole on the extension of the ring finger covers the light-receiving area. The light-receiving area can also be attached on the instep.
3. Wrap the adhesive wrap part around the foot so that the light-emitting part window (red star) is directly above the foot.
4. Connect to this product and confirm that it is operating properly as described in the operation manual (for this product and the receiving monitor).

⚠ CAUTION

- The LNCS sensor should not be used on patients who are allergic to foam rubber products or adhesive tape.
- Check the attachment site frequently or according to your healthcare provider's protocol to ensure good adhesion, check the blood flow, skin condition, and if the optical sensor is positioned correctly.
- Use particular caution with hypoperfused patients. If the sensor is not reapplied frequently, skin damage or pressure necrosis may occur. For hypoperfused patients, examine the attachment site every hour and reattach the sensor if there are signs of ischemia.

6.14: Connecting the SpO₂ Connector to the Product

1. Connect the SpO₂ sensor to the SpO₂ input connector on the main unit of the transmitter.

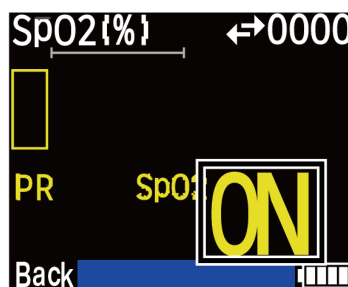


6.15: Turning ON/OFF SpO₂ Measurement

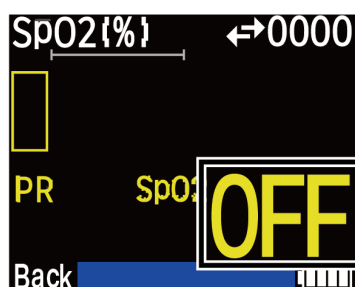
Set SpO₂ measurement to OFF

1. Remove the SpO₂ probe on the SpO₂ display screen.
2. Press and hold the  key for two seconds.

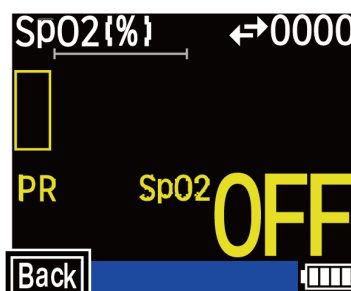
3. Select [ON] on the measurement value area and press the  key.



4. Confirm that the measurement setting has been changed to OFF.



5. Select [Back] and press the  key.



CAUTION

- If SpO₂ measurement is set to OFF, the receiving monitor displays [Confirm SpO₂ sensor] or [SpO₂ connector disconnected]. The message depends on the type of receiving monitor.
- When the SpO₂ measurement setting is changed, telemeter transmission stops for a few seconds, and the receiving monitor shows a too-far waveform.

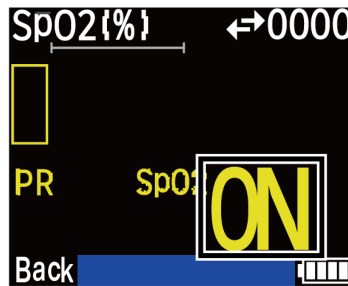


- If no selection is made within 10 seconds on the confirmation screen, the measurement feature is not switched to ON/OFF and the device automatically returns to the SpO₂ display screen.
- You cannot turn off SpO₂ measurement while the SpO₂ probe is connected to the transmitter. Disconnect the SpO₂ probe from the transmitter before turning off the SpO₂ measurement.

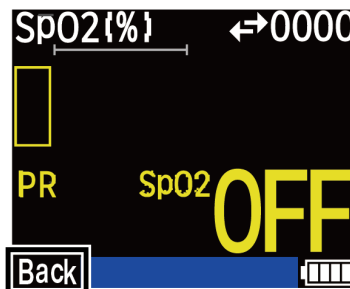
Set SpO₂ measurement to ON

1. While [OFF] is displayed in the measurement value area, press and hold the  key for two seconds.

2. Select [OFF] on the measurement value area and press the  key.
3. Confirm that the measurement setting has been changed to ON.



4. Select [Back] and press the  key.



- If no selection is made within 10 seconds on the confirmation screen, the measurement feature is not switched ON/OFF and the device automatically returns to the SpO₂ display screen.

Chapter 7: Monitoring NIBP

BP values measured with the LXN-1000 Non-Invasive Blood Pressure Monitor can be received via wireless communication using this transmitter to be displayed. Received BP values can be sent to the receiving monitor.

Blood pressure values are received via Bluetooth or NFC. If you need to obtain continuous NIBP readings, use Bluetooth communication. With NFC communication, only the most recent measurement result can be received.

7.1: Receiving NIBP Measurement Values

7.1.1: Receiving Blood Pressure Values via Bluetooth

When using Bluetooth to monitor NIBP, please set up pairing with the LXN-1000 first.

Once pairing is complete, blood pressure measurement values taken with the LXN-1000 will be automatically transmitted to this device. For instructions on pairing, refer to [2.3.1.1 Pairing \(P.2-5\)](#).

CAUTION

- If the icon is flashing, the device is not communicating with the LXN-1000. Confirm that the LXN-1000 is powered on and that the channel of this device is displayed.
- With the pairing set up, the device's continuous operation time becomes shorter. If you do not wish to monitor NIBP, please deactivate the pairing setting.
For instructions on how to cancel pairing, refer to [2.3.1.2 Cancel the Pairing \(P.2-6\)](#).
- When pairing, set the target device in a pairing mode. Pairing will not succeed if the target device is not in pairing mode. Please refer to the operation manual of the target device for the pairing mode.

7.1.2: Receiving Blood Pressure Values via NFC

WARNING

- This product is an NFC device that uses radio waves. Do not use the communication part (antenna mark part) of this product within 22 cm of implanted medical devices. It may affect medical electronic devices.

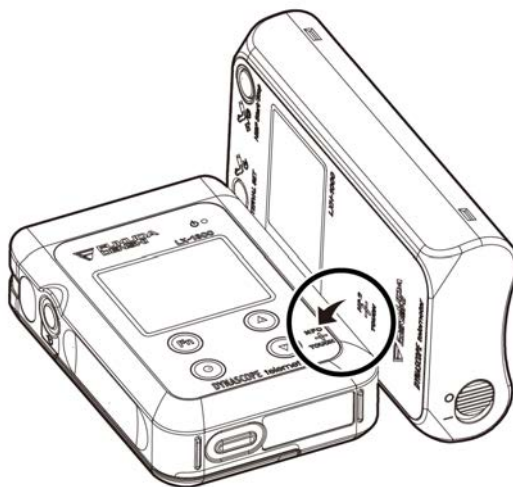
CAUTION

- When receiving blood pressure values via NFC, always measure the blood pressure of the patient wearing this device before communicating with the LXN-1000. If you receive blood pressure values via NFC after measuring another patient, there is a risk of associating the data with the wrong patient.



- NFC communication cannot be used while a Bluetooth pairing is established. To use NFC, make sure to unpair the LXN-1000 from Bluetooth in advance. ([2.3.1.2 Cancel the Pairing \(P.2-6\)](#))
- The acquired blood pressure values are retained only while the screen is displayed and are transmitted to the receiving monitor. If the [Disp. OFF] setting is set to [OFF], the values are retained for only 10 minutes after acquisition and are transmitted to the receiving monitor.

1. Measure the patient's NIBP using the LXN-1000. For details, refer to the operation manual of the LXN-1000.
2. While displaying the waveform/numerical data display screen, position the NFC antenna of the LXN-1000 to touch the NFC antenna of this device.



- If NFC communication is carried out while the LXN-1000 is still paired via Bluetooth, a confirmation screen for unpairing will appear. If you select [Yes], the Bluetooth pairing will be canceled and the blood pressure values will be acquired. If you select [No], the pairing will be maintained and the received data will be discarded.



3. When data acquisition is successful, a confirmation tone ("beep") will sound and the blood pressure values will be displayed.



- The acquired blood pressure values will be retained and transmitted to the receiving monitor until this device is powered off.

4. If data acquisition fails, several beep sounds will be heard.



- Once a blood pressure value has been read, it cannot be acquired again by touching the LXN-1000 to this device again.

- If blood pressure value acquisition fails, remeasure the blood pressure and then try reading it again. If repeated attempts to read the value fail, contact your local Fukuda Denshi service representative.

7.2: Check NIBP Values in the List View

The NIBP List screen provides a list view of NIBP values received from the LXN-1000.

NIBP(mmHg) ↔ 0000					
10/10/2024					
TIME	S	D	HR	SpO2	RR
12:00	137	95	83	98	16
11:00	131	95	84	98	15
10:00	130	95	82	98	14
09:00	132	95	81	98	16
08:00	132	95	82	98	12
Int. 2 min 1/1 					

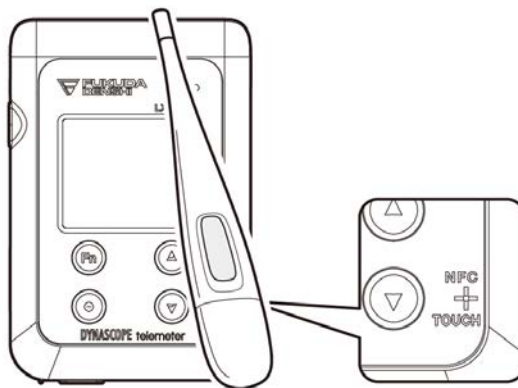
Display the NIBP list

1. While the NIBP screen is displayed, press and hold the  key for two seconds.
2. Press and hold the  key again for two seconds to return to the NIBP screen.

Chapter 8: Monitoring Temperature

This section explains how to display body temperature values measured with supported electronic thermometers.

8.1: Acquiring Body Temperature Data



For information on how to obtain temperature data, please contact our service representative.

Chapter 9: Preset Setting

Detailed settings of the device can be adjusted from the following menu items in the preset settings screen.

If you want to change the preset setting, contact your nearest service representative.

Channel

Item	Description	Default	Backup
[Channel] (Transmission channel)	Select from 479 channels	—	Yes
[Group] (Group ID)	1 of 00 to 63	00	Yes

ECG

Item	Description	Default	Backup
[Time Constant]	[0.4S], [0.1S]	[0.4S]	Yes
[Pace.Sens.]	[Low], [Mid], [High]	[Mid]	Yes
[QRS detection]	[Wide], [Narrow]	[Wide]	Yes

RESP

Item	Description	Default	Backup
[Measurement setting]	[ON], [OFF]	[ON]	Yes

SpO₂

Item	Description	Default	Backup
[SpO ₂ Color]	[Yellow], [Blue]	[Yellow]	Yes
SpO ₂ Mode ^{*1}	[Normal], [Active]	[Active]	Yes

^{*1} Some models may not allow you to change the setting.

Device

Item	Description	Default	Backup
[Notif.Sound]	[ON], [OFF]	[ON]	Yes
[Brightness]	8 levels	5	Yes
[Disp.OFF]	[1 min], [3 min], [10 min], [None]	[3 min]	Yes
[Battery]	[Alkaline], [Ni-MH], [Lithium]	[Alkaline]	Yes

Unit

Item	Description	Default	Backup
[BP unit]	[mmHg], [kPa]	[mmHg]	Yes
[TEMP Unit]	[°C], [°F]	[°C]	Yes

Admin

Item	Description	Default	Backup
[Password]	0000-9999	-	Yes
[Function Setup]	[Print], [Alarm Suspend], [Monitor Suspend], [Call]	[Print]	Yes

9.1: Channel Setting

9.1.1: Changing the Transmission Channel

This device is a PLL synthesizer type transmitter with changeable transmission channels.

It can be set to any of the channels allocated by the radio laws of the respective country.

If you need to change the settings, please contact your nearest Fukuda Denshi service representative.

WARNING

- Change transmission channels in accordance with the instructions of the facility's radio channel administrator. Improper operation can lead to serious accidents such as loss of monitoring due to interference or mistaken patient identification.

9.1.2: Changing Group ID

This transmitter sends its group ID in order to prevent interference between adjacent medical institutions.

The receiving monitor confirms that this group ID is the same as the group ID set for the receiving monitor itself and displays the waveform. There are 64 different group IDs, with the number 00 set in the standard shipment.

If there is a possibility of interference between adjacent medical facilities, you can change the group ID of the transmitter.

If you want to change the setting, contact your nearest service representative.

CAUTION

- Other sources of telemetry interference include adjacent medical facilities, as well as cellular phones, amateur radio, cab radio, and illegal citizen radio in close proximity, which can also become interference under certain circumstances. In such cases, it is important to observe the occurrence of interference in detail and determine the cause of the interference.

9.2: ECG Setting

9.2.1: Changing Time Constant

The time constant of this transmitter is initially set to [0.4 s].

When the baseline fluctuates too much and cannot be monitored stably due to the patient's severe body motion or AC frequency or other noises, set the time constant to [0.1 s] to monitor relatively stably.

CAUTION

- When the time constant is set to [0.1 s], the low frequency response is 1.6 Hz $\pm$ 25%. This setting does not meet the IEC60601-2-27 standard. The shape of the waveform also changes, and in particular, the effect on ST measurements changes significantly. For normal use, it is recommended to use a time constant of [0.4 s].
- The time constant setting is not visible on the screen normally used. Transmitters with changed time constants should be identified by marking or other means.

9.2.2: Changing Pacemaker Pulse Sensitivity

The pacemaker sensitivity of this transmitter is initially set to [Mid].

In the [Mid] setting, pacemaker pulses specified in the ANSI/AAMI EC13 standard (0.1 to 2 ms width, ± 2 to ± 700 mV amplitude pulse width, applicable only to pacemaker pulses with no overshoot/undershoot) can be detected. The [Mid] setting is recommended for normal use.

Depending on the type of pacemaker used, the voltage and pulse width of the output pulse, and the type of electrode lead (unipolar or bipolar), it may not detect pacemaker pulses. In this case, either change the lead to detect the pacemaker pulse or change the position of the electrode attachment.

If the device still cannot detect it, set the device to [High] to increase the detection sensitivity, thereby enabling it to detect small pacemaker pulses. However, in the [High] setting, false positives are more likely due to AC frequency and other noise effects.

If pacemaker pulses are mis-detected due to AC frequency or other noises, turn off the pacemaker detection on the receiving monitor.

If you get a false detection in a patient with a pacemaker due to noise and cannot turn off the pacemaker detection feature on the receiving monitor, replace the electrode with a new one or change the lead to remove the effect of AC frequency and other noises.

If you still get a false detection, use the [Low] setting to reduce the detection sensitivity. This makes the device less susceptible to AC frequency and other noises. The [Low] setting reduces the detection sensitivity and therefore cannot detect pacemaker pulses as specified in the ANSI/AAMI EC13 standard.

CAUTION

- The Pacemaker Pulse Sensitivity setting is not available on the screen normally used. Transmitters that have changed pacemaker pulse sensitivity should be identifiable by labeling or other means.

9.2.3: Changing the QRS Detection Mode

The QRS detection mode of this transmitter is initially set to [Wide]. If the device cannot detect the heart rate due to narrow QRS width, use the [Narrow] setting.

CAUTION

- This setting is valid only for the display screen of the transmitter and is not reflected in the QRS detection setting of the receiving monitor. To change the QRS detection mode on the receiving monitor, please refer to the operation manual of the receiving monitor.
- The [Wide]/[Narrow] setting of the QRS detection mode is not visible on the screen normally used. Transmitters with the QRS detection mode changed to [Wide]/[Narrow] setting should be identifiable by labeling and other means.

9.3: RESP Setting

9.3.1: Measurement Setting

The initial value for the respiratory carrier of this transmitter is set to [ON]. The respiratory waveform can be measured when the respiratory carrier setting is [ON].

WARNING

- When using this device on a patient with an implanted cardiac pacemaker with a built-in minute volume (MV) sensor, the respiratory carrier may cause the MV sensor of the cardiac pacemaker to overreact and reach its maximum rate, resulting in an inappropriate pacing rate. In such cases, set the respiratory carrier to [OFF].

CAUTION

- When the respiratory carrier is set to [OFF], the device cannot measure the respiratory waveform and the RESP screen will not be displayed.
- Be sure to set the parameter monitoring on the receiving monitor to OFF to prevent false detection of respiratory alarms.
- The ON/OFF settings of the respiratory carrier are not visible on the screen normally used. Transmitters with the respiratory carrier setting changed to ON/OFF should be identifiable by labelling or other means.

9.4: SpO₂ Setting

9.4.1: Changing the SpO₂ Display Color

You can choose the display color of SpO₂-related parameters from [Yellow] and [Blue].
The default value is set to [Yellow].

9.4.2: Changing the SpO₂ Mode

You can select the SpO₂ measurement operating mode from [Normal] or [Active].

The initial value is set to be [Active].

If measurement is unstable in patients with low perfusion, setting it to [Active] can provide relatively stable monitoring. However, please note that the continuous use time will be shorter compared to the [Normal] setting.

CAUTION

- This setting can only be changed on the LX-1300N.
- The continuous use time varies depending on the settings. For details, refer to "Basic Specifications".

9.5: Device Setting

9.5.1: Changing ON/OFF of Notification Sound

When set to [ON], a notification tone will sound in the following cases.

- ECG lead detached
- SpO₂ probe detached

The initial value is set to be [ON]

9.5.2: Changing Brightness

You can change the display brightness of the transmitter to 8 levels.

9.5.3: Changing the Time until the Screen Turns OFF

You can set the time until the display unit turns off when it is left unoperated to [1 min], [3 min], [10 min] or [OFF] (the screen stays on).

The default value is set to [3 min].

9.5.4: Changing the Battery Settings

You can select the battery type from Alkaline (alkaline batteries), Rechargeable (nickel metal hydride batteries), and Lithium (lithium batteries). The default value is set to [Alkaline].

⚠ CAUTION

- Use batteries that match the battery setting. If a battery that does not match the battery setting is used, the correct battery level will not appear.

9.6: Unit Setting

9.6.1: BP Unit

You can change the unit of the blood pressure that is displayed. The initial value is set to be [mmHg].

⚠ CAUTION

- This setting only affects the display on the transmitter. Configure the display settings on the receiving monitor.

9.6.2: TEMP Unit

You can change the unit of the temperature that is displayed. The initial value is set to be [°C].

⚠ CAUTION

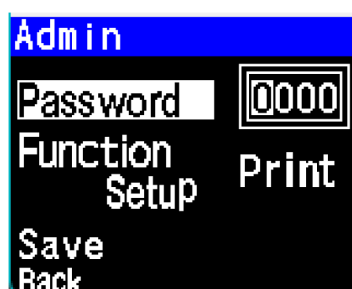
This setting only affects the display on the transmitter. Configure the display settings on the receiving monitor.

9.7: Administrator Setting

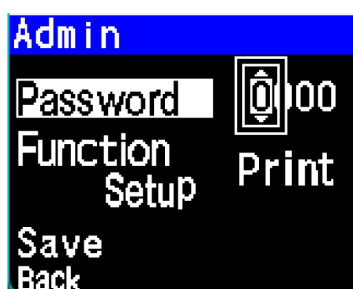
9.7.1: Password

You can change the password to access the preset settings.

1. Select [Password] on the Admin preset screen.
2. Select the menu option with ▲▼ and press ● to edit the value.



3. Switch the value using   and press  to confirm.



4. After selecting [Save], press  to save the setting.

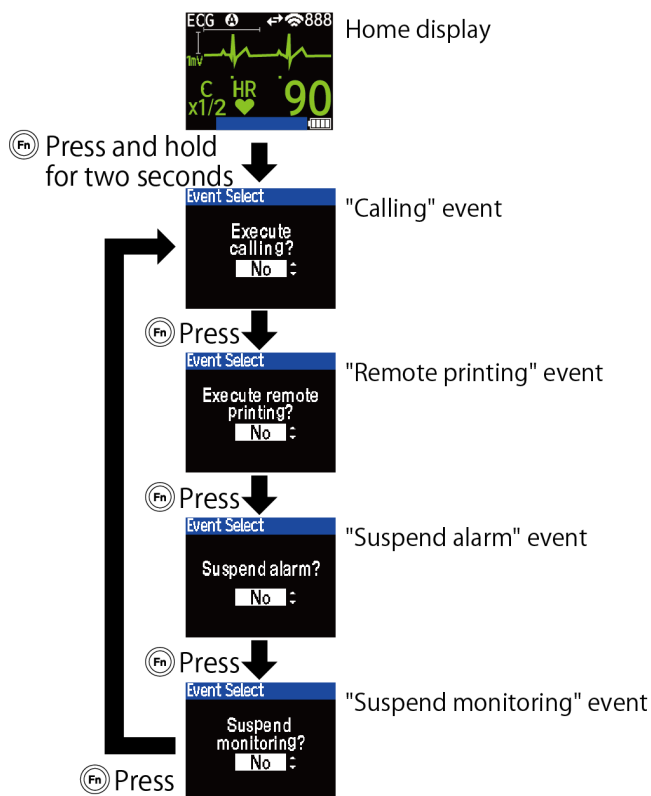
⚠ CAUTION

- Do not forget the password.
- Keep your password strictly confidential, and do not allow it to be known to anyone other than authorized personnel.
- When setting a password, avoid numbers that are easily guessable, such as consecutive numbers or birthdays.

9.7.2: Function Setting

You can set the function of the event selection screen displayed when pressing and holding the function key. The default value is set to [Print].

After the event selection screen is displayed, you can switch between functions each time you press the function key. (The following is an example when setting the function to [Call].)



- If you set this option to [OFF], event notifications will be disabled, and the event selection screen will not be displayed.

Chapter 10: Troubleshooting

If the problem persists after checking the following items, please contact our service personnel.

10.1: Abnormality of the Device Itself

Phenomenon	Measure
Nothing is displayed on the indicator when the power is turned on	• Make sure that the battery is installed correctly and insert the battery correctly. • Charge the battery or replace it with a new one.
Device reboots on its own.	• Make sure you are not mixing new and old batteries. • Charge the battery or replace it with a new one.
Nothing appears on the receiver even when you turn on the device	• Set the transmitter and receiver so that their channels match.
Poor receiving	• Since the receiving monitor is most likely still receiving even when the transmitter is turned off, please follow the instructions of the radio channel administrator and use a transmitter that is set to the correct channel. • Follow the instructions of the radio channel administrator and use a transmitter that is set to the correct channel. • Device failure is likely. Contact our service representative.
A main unit error message appears	• A device failure is likely. Contact a Fukuda Denshi service representative.

10.2: Abnormal ECG/Error Messages

Abnormal ECG

Phenomenon	Measure
Noise is interfering with the ECG.	• Replace with a new electrode. • Cover the electric blanket with a shield cover. • Turn [ON] the AC Filter setting.
The device cannot stably measure respiratory waveform.	• Replace with a new electrode. • Change the electrode attachment position to a site where the device can obtain a larger respiratory waveform.

ECG error messages

Message	Measure
[Lead OFF]	- The position of the electrode at which an abnormality is detected may appear, as in [Lead OFF RA] or [Lead OFF V]. - Check the condition of the electrodes and attach them correctly. - Check the connection between the lead cable and the device. - Check the connection between the lead cable and the electrode. - Replace with a new lead cable. - Replace with a new electrode.

10.3: Abnormal SpO₂/Error Messages

Abnormal SpO₂

Phenomenon	Measure
Unstable SpO ₂	- Make sure to use the probe with appropriate size. - Follow the procedure to properly attach the probe. - Clean the measurement site.

SpO₂ error message

Message	Measure
[Detached probe]	- Check the probe attachment status. - Replace the probe.
[Check the sensor] [Pulse timeout]	- Check the sensor attachment status. - Block out ambient light to prevent outside light from entering. - Replace the probe.
[Replacing sensor]	Replace the probe.
[Body motion] [Pulse search]	Maintain a resting posture.
[Low perfusion]	Check that the LED light-emitting and light-receiving parts of the sensor are aligned.
[Low SIQ] (Only LX-1300M)	- Check the sensor attachment status. - Maintain a resting posture.
 icon (Only LX-1300M)	It is time to replace the probe. Replace the probe. For the expiration date of the sensor, refer to "Predicted Service Life of MASIMO's Sensors" in "Precautions for SpO₂ Measurement (LX-1300M)."

10.4: Abnormal NIBP/Error Messages

Error message on the NIBP screen

Message	Measure
[Measurement error]	There is an error on LXN-1000. Please check the status of LXN-1000.
[NIBP error]	
[Chk. NIBP Batt.]	Please check the battery level of LXN-1000.
[Chk. NIBP Comm.]	- Please check the status of communication with LXN-1000. - Please check if pairing with LXN-1000 is established.

10.5: If Submerged in Water

If the entire device needs to be cleaned due to immersion in sewage, etc., do not remove the ECG cable and SpO₂ probe, but clean the device with them attached. After cleaning, wipe off moisture well and remove the ECG lead cable and SpO₂ probe.

CAUTION

- Do not use a hair dryer to dry the product. The main unit may be deformed or damaged.
- When rinsing with tap water, do so with the battery cover closed.
- We recommend that you have your device inspected by our service representative when it is immersed in sewage or other water.
- If the connector part is heavily soiled or if poor contact occurs, have it inspected by our service representative.

Chapter 11: Maintenance

11.1: Cleaning/Disinfecting

Clean and disinfect the device, ECG cable, and SpO₂ probe as follows.

CAUTION

- This device, ECG cables, and SpO₂ probes are not sterilizable and should not be sterilized in any way.
- Before cleaning or disinfecting, remove the transmitter from the patient and ensure that the battery is removed. Failure to do so may cause malfunction.

11.1.1: Cleaning the Main Unit

- When cleaning, soak a gauze or cotton ball with rubbing alcohol (ethanol or isopropyl alcohol) and wring it out well.
- When cleaning the inside of the battery compartment, gently clean it with a cotton swab or similar. After cleaning, wipe it dry with a soft cloth.
- If the entire device needs to be cleaned due to immersion in sewage, etc., do not remove the ECG cable and SpO₂ probe, but clean the device with them attached. After cleaning, wipe off moisture well and remove the cardiac lead cable and SpO₂ probe.

CAUTION

- Clean the device frequently so stains can be removed easily.
- To prevent injury, it is recommended to clean with gloves on.
- Be careful not to allow chemicals to enter the inside of this device or connector parts.
- This device cannot be sterilized.
- We recommend that you have your device inspected by our service representative when it is immersed in sewage or other water.
- If the connector part is heavily soiled or if poor contact occurs, have it inspected by our service representative.
- Do not use organic solvents, thinner, toluene or benzene to avoid damaging the resin case.
- Do not polish the housing with abrasive or chemical cleaner.
- Do not clean the housing with chemical cloth, scrub brush, abrasive, polishing powder, hot water, volatile solvent and chemicals (cleanser, thinner, benzine, benzol, and synthetic detergent for house and furniture), sharp-edged tools, etc. The surface resin coating may damage, resulting in discoloration, scratches, and malfunction.
- For the precautions for storing and handling the chemicals, refer to the instruction manual for the respective chemical.

11.1.2: Cleaning the Connector

Do not wipe-clean the connector section.

If dust or debris is noticeable on the connector, clean it periodically with a commercially available air duster, and do not use cotton swabs, gauze, or cotton wool.

 CAUTION

- If cotton swabs, gauze, or cotton pads are used to clean the connector, dust and other contaminants can enter the connector, and fibers from the cotton swabs, gauze, or cotton pads can also enter the connector, causing connection failures. Also, if liquid or chemicals enter the connector section, it may cause connection failures. If a connection failure occurs, not only the device may not be able to perform measurement correctly but also the alarm may not go off. To clean the connector section, contact our service representative.

11.1.3: Cleaning the Battery Cover

For cleaning the battery cover exterior and battery compartment, refer to cleaning instructions for the main unit.

For the gasket area, ensure that no dust or foreign particles are on the gasket or its contact surface. If any foreign matter is found, soak a lint-free clean cloth with rubbing alcohol, wring it out thoroughly, and wipe the surface clean.

If foreign particles cannot be removed by wiping, use a commercially available air duster or adhesive cleaner to remove them.

 CAUTION

- Check the battery cover gasket for any cracks, scratches, or damage. If any cracks or scratches are found, the waterproof performance may be compromised. Please contact our service representative for support.

11.1.4: Cleaning the Silicon Cover

Clean it using the same procedure as you would for cleaning the device.

11.1.5: Disinfection

For disinfection, soak a gauze or cotton ball with rubbing alcohol (ethanol or isopropyl alcohol) and wring it out well.

 CAUTION

- Do not immerse the connector part in or adhere to a chemical solution. It may result in connection failures.
- When disinfecting a room simultaneously by spraying chemicals, etc., please be careful not to get the chemicals on the inside of the device or connectors.
- For the precautions for storing and handling the chemicals, refer to the instruction manual for the respective chemical.

11.2: Maintenance and Inspection

To ensure safety, reliability, and high performance of this device, a "Daily Inspection" and "Periodic Inspection" must be performed. Fukuda Denshi is not liable for any accidents arising from lack of maintenance.

For information on basic performance and technical information on this product, please contact our service representative.

For details on the information required by our service and technical engineers to help service the device, please contact our service representative.

⚠ CAUTION

- Do not open the housing.
- Be careful not to allow alcohol or other liquids to enter the interior of the device.

11.2.1: Daily Inspection

Perform daily inspection according to the Daily Inspection list.

11.2.2: Periodic Inspection

Periodic inspection of medical electronic equipment is mandatory to prevent failures and accidents and to ensure safety and reliability.

Periodic inspection may be performed by the medical institution or by a third party by concluding a "Maintenance Contract".

Please conduct basic performance and basic safety checks in conjunction with period checks. Refer to "Daily Check Items and Procedures" for the items to be verified and instructions.

Contact our service representative for details.

11.2.3: Periodic Replacement Parts

The battery cover is a periodic replacement part. To maintain its waterproof performance (IPX8), replace it each year.

For replacement, contact our service representative for details. Continued use without replacement will result in loss of waterproof performance (IPX8).

⚠ CAUTION

- The periodic replacement part must be replaced at specified period.

11.2.4: Daily Check Items and Procedures

Make sure to perform the daily check.

1. External Appearance

No.	Check Items	Check Procedure	Criteria
01	External Appearance	Visually inspect the exterior for scratches, cracks, splits, chips, stripped nameplates, etc.	There should be no significant abnormality.
02	Battery cover	Visually check the condition of the battery cover packing.	There should be no scratches, kinks, floaters, or debris.
		Visually check the battery terminal.	The battery terminal should not be deformed, distorted, or rusted.

2. Operation

No.	Check Items	Check Procedure	Criteria
01	Power Supply	Turn the standby switch ON/OFF and check the operation of the switch.	The display should light up when the power is turned on.
02	ECG Connector	Visually inspect the main unit and the plug part of the lead cable.	There should be no defects or chips. There should be no debris.
03	Lead cable	Visually check the wire coating part of the lead cable.	There should be no cracks, splits, or scratches.
04	SpO ₂ probe	Visually check the wire coating part, light-receiving sensor part, LED part, and connector part of the probe.	There should be no cracks, splits, scratches, chips, and debris.
05	Wireless channel	Verify on the receiving monitor that the transmission channel and group ID are as specified by the radio channel administrator.	Should conform to the radio channel checklist.

No.	Check Items	Check Procedure	Criteria
06	Transmission function	Turn on the device and check the function and operation of the device on the receiving monitor.	The device should be able to properly receive data such as waveforms and numerical values.
07	Display function	Turn on the device and check the values, bar graph, and various display conditions.	Display for each display item should be normal for the corresponding condition.

3. Others

No.	Check Items	Check Procedure	Criteria
01	Periodic Replacement Parts	Check the date the battery cover was last replaced.	Should be within one year.
02	Periodic Inspection	Check the date of the previous periodic inspection.	Should be within one year.
03	Operation Manual	Check that accompanying documents (operation manual, etc.) are stored in specified location.	Should be stored in specified location.

11.2.5: Periodic Inspection Items and Procedures

Perform periodic inspections according to the following list.

- Perform periodic inspections once a year.
- Check all cables, devices, and accessories for damage, earth impedance, earth and leakage currents, and accuracy.
- For information on basic performance and basic safety, please contact our service representative.

Tools and measuring instruments used

The measuring instruments used for maintenance and inspection are as follows.

Name	Model - Items to be inspected are enclosed in brackets	Note
Simulator	Prosim 8 or equivalent [ECG, RESP, SpO ₂]	Fluke Biomedical
Leak measurement safety tester	ST5540 or equivalent [Contact current (between external surfaces), patient leakage current, patient auxiliary current]	HIOKI
Dielectric strength tester	3174 or equivalent [Dielectric strength test (between applied part and external surface)]	HIOKI
Receiving monitor	DS-1800 or equivalent	Fukuda Denshi

CAUTION

- Please use measuring instruments that have been properly calibrated.

Check Items

1. Cleaning status, cleaning

No.	Check Items	Check Procedure	Criteria
01	Check Cleaning Status	If contamination is found, perform proper disinfection before the daily check.	No contamination should be found.
02	Cleaning	Visually check the exterior, and perform proper cleaning. For details, refer to "Daily Check Items and Procedures."	It should be clean.

2. External Appearance

No.	Check Items	Check Procedure	Criteria
01	External Appearance	Visually inspect the exterior for scratches, cracks, splits, chips, stripped nameplates, loose screws, etc.	There should be no significant abnormality.
02	Cables	Check that none of the cables have damage or broken wires.	There should be no damaged or broken wires.
03	Operation Manual	Check that accompanying documents (operation manual, etc.) are available for prompt reference.	Accompanying documents (operation manual, etc.) are available for prompt reference.

3. Power Supply

No.	Check Items	Check Procedure	Criteria
01	Power Supply	Turn on the power and verify its functionality.	Check that the power turns on and off correctly.

4. Display/Operation/Recording

No.	Check Items	Check Procedure	Criteria
01	Check Labels	Visually check the rating label and caution label of the device.	There should be no peeling or dirt, and it should be clearly visible.
02	Operation, Switches	Operate and check the operating switches and operating keys.	Ensure that they operate properly.
03	Display Unit	Check that the home display is displayed on the display unit.	Characters and waveform should be clear. The display should be clearly displayed with sufficient brightness.

5. ECG

No.	Check Items	Check Procedure	Criteria
01	ECG Display Size	Input square wave of 1 mV amplitude from the simulator, and check the displayed waveform on the receiving monitor at a display sensitivity of $\times 1$.	The waveform amplitude is displayed as $10 \text{ mm} \pm 1 \text{ mm}$ on the receiving monitor at a display sensitivity of $\times 1$.
02	Heart Rate Display Accuracy	Set the heart rate to 60 bpm on the simulator, and check the displayed heart rate on the receiving monitor.	The displayed heart rate should be within $60 \text{ bpm} \pm 3 \text{ bpm}$ on the receiving monitor.
03	Lead OFF check	Remove each electrode and check that the "Lead OFF" message is displayed.	The "Lead OFF" message should be displayed.
04	ECG Patient Cable Recognition Check	Switch between different ECG patient cable and verify recognition.	The connected patient cable is correctly recognized.

6. Respiration

No.	Check Items	Check Procedure	Criteria
01	Respiration Rate Display Accuracy	Input the respiration signal of 20 bpm with the following setting from the simulator, and check the displayed RR value on the receiving monitor. - Waveform: Normal - Amplitude: $1 \text{ } \Omega$ - Lead: LL - Base impedance: $500 \text{ } \Omega$	The displayed RR should be within $20 \text{ bpm} \pm 3 \text{ bpm}$.

7. SpO₂

No.	Check Items	Check Procedure	Criteria
01	Oxygen Saturation Display Accuracy	Input the oxygen saturation signal of 90% SpO ₂ from the simulator, and check the displayed oxygen saturation value on the receiving monitor.	The displayed oxygen saturation value should be within $90\% \text{ SpO}_2 \pm 2\%$
02	Pulse Rate Display Accuracy	Input the pulse rate signal of 60 bpm from the simulator, and check the displayed HR value on the receiving unit.	The heart rate should be within $60 \text{ bpm} \pm 3 \text{ bpm}$.
03	SpO ₂ Probe Disconnection Detection	Insert and remove the probe to check the display.	The display and values disappear when the probe is disconnected.

8. Speaker

No.	Check Items	Check Procedure	Criteria
01	Sound	When the ECG cable or SpO ₂ cable is disconnected, check for a warning sound.	A warning sound should be heard.

9. Wireless External Input Function

No.	Check Items	Check Procedure	Criteria
01	Communication Function	Turn on the power and verify its functionality.	*Wireless module communication error* does not occur.

10. ID Transmission Function

No.	Check Items	Check Procedure	Criteria
01	ID Transmission Function	Turn on the power and verify its functionality.	The signal can be received by the receiving monitor.

11. Electrical Safety

No.	Check Items	Check Procedure	Criteria
01	Contact Current	Measure the leakage current from the exterior to ground under normal conditions using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	Exterior to ground (NC) ≤ 0.1 mA
02	Patient leakage current from patient connection point to ground (NC)	Measure the patient leakage current from the patient connection point to ground using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	[AC/DC] Patient connection to ground (NC) ≤ 0.01 mA
03	Patient leakage current (SFC) when applying external voltage to the Type F applied part at the patient connection point	Measure the patient leakage current when applying external voltage to the Type F applied part at the patient connection point using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	Patient leakage current (SFC) when applying external voltage to the Type F applied part at the patient connection point ≤ 0.05 mA
04	Patient leakage current from the connected patient connection point to ground (NC)	Measure the total patient leakage current from the patient connection point to ground using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	[AC/DC] Patient connection to ground (NC) ≤ 0.05 mA
05	Total patient leakage current (SFC) when applying external voltage from the Type F applied part at the patient connection point	Measure the total patient leakage current (SFC) when applying external voltage to the Type F applied part at the patient connection point using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	Patient leakage current (SFC) when applying external voltage from the Type F applied part at the patient connection point ≤ 0.1 mA
06	Patient Auxiliary Current (NC)	Measure the patient auxiliary current (NC) using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	Patient Auxiliary Current (NC) ≤ 0.01 mA

Please conduct the following inspection items as needed.

If disassembly is required for inspection, replacement of internal boards and units, etc., please proceed accordingly.

No.	Check Items	Check Procedure	Criteria
07	Dielectric strength test (between exterior and insulated connection part)	Apply AC 1500 V for one minute between the exterior and connection part. Test according to the test method of IEC 60601-1. Note: Depending on the internal protective circuit configuration of the device, the test voltage may vary.	It should withstand the applied voltage.

Chapter 12: System Components

⚠ CAUTION

- Be sure to use our genuine or specified accessories and optional items. Otherwise, this device cannot deliver its maximum performance and may be damaged, resulting in a safety hazard.



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

12.1: Medical Device

Device Name	Model	Type
LX-1000 Series ECG, Respiration and SpO ₂ Transmitter LX-1300	LX-1300	LX-1300N
		LX-1300M
		LX-1300E

12.2: Accessories

Device Name	Model	Note
Battery Cover Unit for LX-1300	OAT-1300A	Periodic replacement parts
Disposable Portable Case	ABT-720D	
Silicone Cover for LX-1300	ABT-1300C	
Neck Strap	OAT-03A	

ECG Sensors

Device Name	Model	Note
Patient Cable CMO-N series	CMO-03NTG-0.9A	3-electrode Usable Life: 2 years(According to self-certification)
Patient Cable CMO-N series	CMO-04NTG-0.9A	4-electrode Usable Life: 2 years(According to self-certification)
Patient Cable CMO-N series	CMO-05NTG-0.9A	5-electrode Usable Life: 2 years(According to self-certification)
ECG Relay Cable CIT-13 DIN series	CIT-13DIN3-0.3A	Usable Life: 2 years(According to self-certification)

12.3: The Other Medical Device

SpO₂ Sensors (Medtronic)

Device Name	Model	Remark	Attachm ent site	Cable Length
Adult SpO ₂ Sensor Reusable	DS100A	Reusable, Adults (weighing more than 40kg)	Finger	Approx. 90cm
Adult SpO ₂ Sensor	MAXA	Adults (weighing more than 30kg)	Finger	45cm
Adult SpO ₂ Sensor	MAXAL	Adults (weighing more than 30kg)	Finger	90cm

Device Name	Model	Remark	Attachment site	Cable Length
Pediatric SpO ₂ Sensor	MAXP	Children (weighing 10 to 50 kg)	Finger	45cm
Infant SpO ₂ Sensor	MAXI	Children (weighing 3 to 20kg)	Toe	90cm
Neonatal-Adult SpO ₂ Sensor	MAXN	Adults (weighing more than 40kg)	Finger	90cm
		Neonates (weighing less than 3kg)	Instep	90cm
Adult SpO ₂ Nasal Sensor	MAXR	Adults (weighing 50kg or more)	Nose	45cm
Forehead SpO ₂ Sensor	MAXFAST	Children, adults (weighing more than 10kg)	Forehead	70cm

SpO₂ Sensors (Masimo)

Masimo LNCS Sensor

Device Name	Model	Remark	Attachment site	Cable Length
Pulse Oximeter Adhesive Sensor	LNCS Adtx	Adults or children weighing 30kg or more Masimo PN:1859	Finger, toe	Approx. 45cm
Pulse Oximeter Adhesive Sensor	LNCS Pdtx	Children or adults weighing 10 to 50 kg Masimo PN:1860	Finger, toe	Approx. 45cm
Pulse Oximeter Adhesive Sensor	LNCS Inf-L	Infants weighing 3 to 20 kg Masimo PN:1861	Thumb, thumb toe	Approx. 90cm
Pulse Oximeter Adhesive Sensor	LNCS Neo-L	Neonates weighing less than 3kg Masimo PN:1862	Hands, feet	Approx. 90cm
		Adults weighing 40kg or more Masimo PN:1862	Finger, toe	Approx. 90cm
Reusable Finger Clip Sensor	LNCS DCI	Adults or children weighing 30kg or more Masimo PN:1863	Finger, toe	Approx. 90cm
Reusable Ear Sensor	LNCS TC-I	Adults or children weighing 30kg or more Masimo PN:1895	Ear	Approx. 90cm
Reusable Forehead Sensor	LNCS TF-I	Adults or children weighing 30kg or more Masimo PN:1896	Forehead	Approx. 90cm
Pulse Oximeter Adhesive Sensor	LNCS NeoPt-L	Premature babies weighing less than 1kg Masimo PN:1901	Hands, feet	Approx. 90cm
Pulse Oximeter Adhesive Sensor	LNCS Inf-3	Infants weighing 3 to 20 kg Masimo PN:2319	Thumb, thumb toe	Approx. 90cm
Pulse Oximeter Adhesive Sensor	LNCS NeoPt-3	Neonates weighing less than 1kg Masimo PN:2321	Hands, feet	Approx. 90cm
Disposable Transflectance Sensor	LNCS TFA-1	Adults or children weighing 10kg or more Masimo PN:3858	Forehead	Approx. 1m

The Masimo LNCS sensor can be directly connected to LX-1300M.

Masimo RD SET Sensor

Device Name	Model	Remark	Attachment site
Reusable Finger Clip Sensor	RD SET DCI	Adults or children weighing 30kg or more Masimo PN:4050	Finger, toe
Pulse Oximeter Adhesive Sensor	RD SET Adt	Adults or children weighing 30kg or more Masimo PN:4000	Finger, toe
Pulse Oximeter Adhesive Sensor	RD SET Pdt	Children or adults weighing 10 to 50 kg Masimo PN:4001	Finger, toe
Pulse Oximeter Adhesive Sensor	RD SET Inf	Infants weighing 3 to 20 kg Masimo PN:4002	Thumb, thumb toe

Device Name	Model	Remark	Attachment site
Pulse Oximeter Adhesive Sensor	RD SET Neo	Neonates weighing less than 3kg Masimo PN:4003	Hands, feet
		Adults weighing 40kg or more Masimo PN:4003	Finger, toe
Pulse Oximeter Adhesive Sensor	RD SET NeoPt	Premature babies weighing less than 1kg Masimo PN:4004	Hands, feet
Reusable Ear Sensor	RD SET TC-I	Adults or children weighing 30kg or more Masimo PN:4053	Ear
Reusable Forehead Sensor	RD SET TF-I	Adults or children weighing 30kg or more Masimo PN:4055	Forehead

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

Device Name	Model	Remark	Length
RD to LNC adapter cable	RD to LNC adapter cable	Masimo PN:4089	Approx. 90cm

Central monitor / Central telemetry receiver

Device Name	Model	Type	Note
DYNASCOPE 1000 Series DS-1800 System	DS-1800	DS-1812	
		DS-1812R	
		DS-1812RE	
		DS-1800L	
		DS-1800LR	
		DS-1800LRE	
Central Telemetry Receiver LW-1000	LW-1000	LW-1080	

Blood Pressure Monitor

Device Name	Model	Type	Note
LX-1000 Series Non-Invasive Blood Pressure Monitor LXN-1000	LXN-1000	LXN-1000	

Chapter 13: Specifications

CAUTION

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

13.1: Basic Specifications

Item	Specifications
External dimensions (not including the protrusion)	64 (W) x 96 (H) x 27 (D) mm
Weight (not including the battery)	Approx.110 g
Transmitting waveform	ECG 1CH or 2CH (selected by lead cable), respiratory waveform, SpO ₂ value, pulse waveform
Applicable ECG Patient Cable	3-electrode, 4-electrode, 5-electrode (limb, chest), insert the lead cable for automatic recognition
Transmission status data	ECG electrode misalignment, low battery voltage, event key, pacemaker, SpO ₂
Display Unit	Yes
Waterproof capability	IPX8 (annual periodic maintenance required)
Power Supply	DC: AA alkaline batteries, AA nickel metal hydride batteries or AA lithium batteries x 2
Operation mode	Continuous operation
Service life	6 years (according to self-certification)

Continuous Use time (LX-1300N^{*1}/LX-1300M)

	Not paired with LXN-1000	Paired with LXN-1000
AA Alkaline Battery	Approx. 1.5 days	Approx. 1.0 day
AA Nickel Metal Hydride Battery	Approx. 1.0 day	Approx. 1.0 day
AA Lithium Battery	Approx. 2.0 days	Approx. 2.0 days

*1: When SpO₂ mode is set to [Normal]

Continuous Use Time (LX-1300N^{*2})

	Not paired with LXN-1000	Paired with LXN-1000
AA Alkaline Battery	Approx. 1.5 days	Approx. 1.0 day
AA Nickel Metal Hydride Battery	Approx. 1.0 day	Approx. 1.0 day
AA Lithium Battery	Approx. 2.0 days	Approx. 2.0 days

*2: When SpO₂ mode is set to [Active]

Continuous use time (LX-1300E)

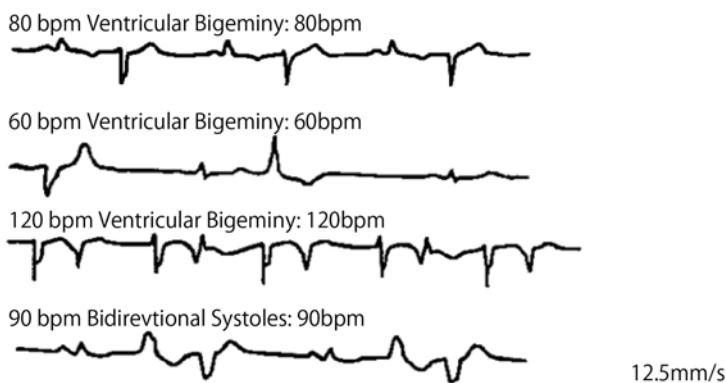
	Not paired with LXN-1000	Paired with LXN-1000
AA Alkaline Battery	Approx. 4.0 days	Approx. 3.5 days
AA Nickel Metal Hydride Battery	Approx. 3.0 days	Approx. 2.5 days
AA Lithium Battery	Approx. 6.0 days	Approx. 5.0 days



Continuous use time is based on the following conditions

- Temperature of the operating environment 23°C
- When using new batteries designated by us

13.2: ECG

Number of lead electrodes	3-electrode, 4-electrode, 5-electrode (limb+ chest)
Number of input channels	1CH (3-electrode) or 2CH
Accuracy of sensitivity	Satisfies IEC60601-2-27:2011 201.12.1.101.1 ($\pm 20\%$ or $100 \mu\text{V}$, whichever is greater or less)
ECG input impedance	Satisfies IEC60601-2-27:2011 201.12.1.101.3 ($2.5 \text{ M}\Omega$ or above.)
Input dynamic range and Offset voltage	Satisfies IEC60601-2-27:2011 201.12.1.101.2 (Input dynamic range: $\pm 5 \text{ mV}$ Offset voltage: $\pm 300 \text{ mV}$ Amplitude variation due to offset voltage: within $\pm 10\%$)
Common mode rejection ratio	Satisfies IEC60601-2-27:2011 201.12.1.101.10 clause (1 mVp-p (RTI) or less)
Heart rate detection	Satisfies IEC60601-2-27:2011 201.12.1.101.15 (Heart rate measurement accuracy: $\pm 10\%$ or $\pm 5 \text{ bpm}$, whichever is greater or less. However, the heart rate measurement range and heart rate measurement accuracy are as follows) Adults: 0, 12 bpm to 300 bpm Neonates: 0, 30 bpm to 300 bpm
Heart Rate Display Range	QRS detection mode at wide: 0, 12 bpm to 300 bpm (1 bpm steps) QRS detection mode at narrow width: 0, 30 bpm to 300 bpm (1 bpm steps)
Frequency Characteristic	0.5 Hz to 40 Hz (within -3dB)
Time Constant	Within 0.4 seconds $\pm 25\%$, switchable within 0.1 second $\pm 25\%$
Pacemaker Pulse Detection	Conforms to ANSI/AAMI EC13 Pacemaker pulse rejection capability (Applicable only for pacemaker pulses with a width of 0.1 ms to 2 ms, amplitude of ± 2 to $\pm 700 \text{ mV}$, and no overshoot/undershoot)
Defibrillation Proof	Equipped The recovery time is 5 seconds when tested in accordance with IEC60601-2-27:2011 201.8.5.5.1
Lead-off Detection Current	100 nA and below.
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.
Tall T-wave Rejection Capability	1.2-mV T-wave can be removed when tested according to IEC60601-2-27.
Sweep Speed	12.5 mm/s
Heart rate meter accuracy and response to irregular rhythm:	 80 bpm Ventricular Bigeminy: 80bpm 60 bpm Ventricular Bigeminy: 60bpm 120 bpm Ventricular Bigeminy: 120bpm 90 bpm Bidirectional Systoles: 90bpm 12.5mm/s

13.3: Respiration (Impedance Method)

Accuracy of sensitivity	10 mm / within $1\Omega \pm 2 \text{ mm}$ (at a basic impedance of 480Ω)
Respiration rate display range	0, 4 bpm to 150 bpm
Respiration rate display error	Within 3 bpm
Measured Current of Respiration	$100 \mu\text{A}$ or less (42kHz)

13.4: SpO₂

Medtronic SpO₂ Unit



- The accuracy of the SpO₂ measurement is determined based on the mean square of the difference between the CO-oximeter measurements taken simultaneously in healthy adult volunteers. Since SpO₂ measurements are statistically distributed, a measurement accuracy of $\pm 2\%$ means that approximately 68% of people fall within $\pm 2\%$ of the difference between the measured value and the CO-oximeter. (Simulators that generate pseudo test signals can be used to verify equipment operation, but not to evaluate measurement accuracy.)

SpO ₂ measurement range:	1% SpO ₂ to 100% SpO ₂
Resolution	1% SpO ₂
Measurement accuracy	Measurement accuracy with the SpO ₂ probe is as follows

SpO ₂ probe	Measurement accuracy ($\pm 1S$)
MAXI	Within $\pm 2\%$ SpO ₂
MAXP	Within $\pm 2\%$ SpO ₂
MAXA	Within $\pm 2\%$ SpO ₂
MAXAL	Within $\pm 2\%$ SpO ₂
DS100A	Within $\pm 3\%$ SpO ₂
MAXR	Within $\pm 3.5\%$ SpO ₂
MAXN	Within $\pm 2\%$ SpO ₂
MAXFAST	Within $\pm 2\%$ SpO ₂

(When SpO₂ is 70% - 100%. Not specified for values less than 70%)

Measurement accuracy	The accuracy of the measurement is measured by controlling the inhaled oxygen to produce a steady-state stable period at five different target saturations for 11 healthy subjects and comparing the results with the CO-oximeter measurements.
Study population	The study population is as follows:

Type	Classification	Total
Sex	Male	5
	Female	6
Race	Caucasian	8
	Hispanic	2
	African American	1
	Asian	0
Age	-	19 to 48
Weight (lbs)	-	108 to 250
Skin pigmentation	Very bright	2
	Olive brown	5
	Dark olive brown/medium dark	3
	Very dark/dark indigo	1

Measurement Value Update Rate	1 sec.
Measurement Response Time	4 sec. to 7 sec. (averaging time)
Wavelength	Approx. 660 nm (Red light), 900 nm (Infrared light)
Output	15 mW and below
US Patents Covered by one or more of the following U.S. patents and foreign equivalents :	5,485,847; 5,676,141; 5,743,263; 6,035,223; 6,226,539; 6,411,833; 6,463,310; 6,591,123; 6,708,049; 7,016,715; 7,039,538; 7,120,479; 7,120,480; 7,142,142; 7,162,288; 7,190,985; 7,194,293; 7,209,774; 7,212,847; 7,400,919.

Masimo SpO₂ Unit



- SpO₂ Clinical Trials

- The SpO₂ 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 SpO₂ 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 $\pm 2\%$ which encompasses 68% of the population. With body motion, the standard deviation is $\pm 3\%$ which encompasses 68% of the population. The validation involved frictional and light tapping movements with an amplitude of 1 cm to 2 cm (2 Hz to 4 Hz) and random vibrations with an amplitude of 2 cm to 3 cm (1 Hz to 5 Hz). 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 trial data are disclosed based on data provided by MASIMO.

SpO ₂ measurement range	1% SpO ₂ to 100% SpO ₂
Resolution	1% SpO ₂
Measurement accuracy	- Without body motion - Adults: $\pm 2\%$ SpO₂ at 70%-100% SpO₂ - Neonates: $\pm 3\%$ SpO₂ at 70%-100% SpO₂ - With body motion - Adults: $\pm 3\%$ SpO₂ at 70%-100% SpO₂ - Neonates: $\pm 3\%$ SpO₂ at 70%-100% SpO₂
Measurement method	Two-wavelength pulse wave method
Wavelength	Approx. 660 nm (Red light), 905 nm (Infrared light)
Output	15 mW and below
Measurement Value Update Rate	1 sec.
Measurement Response Time	8 sec. (averaging time)



- The SpO₂ measurement accuracy is determined based on the values of the root-mean-square (rms) difference between SpO₂ readings of the pulse oximeter equipment and values of SaO₂ determined with a CO-oximeter, by healthy adult volunteers.
- The pulse oximeter equipment measurements are statistically distributed; $\pm 2\%$ measurement accuracy means that only about two-thirds of pulse oximeter equipment measurements can be expected to fall within $\pm 2\%$ of the value measured by a CO-oximeter.

13.5: Pulse Rate

Medtronic SpO₂ Unit

Pulse Rate Measurement Range	20 bpm to 250 bpm
Measurement accuracy	Without body motion: ± 3 bpm

Masimo SpO₂ Unit

Pulse Rate Measurement Range	26 bpm to 239 bpm
Measurement accuracy	Without body motion: ± 3 bpm With body motion: ± 5 bpm

13.6: PI (Perfusion Index)

Masimo SpO₂ Unit

Measurement Range	0.02% to 20.00%
Measurement Resolution	0.01%

13.7: Communication Method, etc.

Modulation method:	Digital, frequency shift keying
Frequency:	608 MHz to 614 MHz
Oscillation method:	PLL synthesizer method with crystal control
Channel interval:	12.5 kHz
Occupied frequency bandwidth:	Within 8.5 kHz
RF Output Power	5 mW $\pm$ 2 dB or 2 mW $\pm$ 2 dB

13.8: Wireless Standard

Supported Standards	Bluetooth 5.0 NFC (Protocols: NFCIP1, NFCIP-2, NFC-A, NFC-B, NFC-F) (Reader/writer mode: Type 1 to 5) (Card emulation mode: T4T-ISO/IEC 14443A, T4T-ISO/IEC 14443B, NFC FORUM-T3T)
Frequency	2402 MHz to 2480 MHz (Bluetooth) 13.56 MHz (NFC)
Aerial power	$\leq$ +5 dBm (Bluetooth) $\leq$ +4 dBm (NFC)
Laws and regulations	FCC 47 CFR Part2 Subpart J (Equipment Authorization Procedure) FCC 47 CFR Part15 Subpart C (Intentional Radiator) FCC 47 CFR Part 95 Subpart H (Wireless Medical Telemetry Service) UDI Directive

13.9: Safety

General Safety Standard	ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012 A2:2021 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance)
EMC Standard	IEC 60601-1-2:2014+A1:2020 (Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests)
Protection against electrical shock	Internally Powered Equipment
Classification of attachment sites by degree of protection against electric shocks	Type CF applied part

13.10: Operating Environment

Temperature	10°C to 40°C
Humidity	30%-85%RH (non-condensing)
Atmospheric Pressure	700 hPa to 1060 hPa

13.11: Transport and Storage Environment

Temperature	-10°C to 60°C
Humidity	10% to 95% (at 40°C) (non-condensing)
Atmospheric Pressure	700 hpa to 1060 hpa

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