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DS-X Series ECG, Respiration and SpO_2 Transmitter DS-X1

DS-X1M/DS-X1N

FUKUDA DENSHI

Ver.01

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⚠ 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 DS-X1 Version 01

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.
- The information contained in this document is subject to change without prior notice for quality improvement purposes.
- This product and its accessories are subject to change without prior notice for quality improvement purposes.

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Preface

Thank you for purchasing our product.

This manual provides instructions essential for operating this device and includes important safety precautions to be observed.

Please be sure to read this 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 Use of this Device

This device continuously transmits biometric data wirelessly such as patient ECGs, respiratory waveforms, arterial oxygen saturation (SpO_2), and pulse waveforms to a monitoring unit in operating rooms in medical facilities, intensive care units, wards, and treatment rooms.

- For the specifications and limitations of this device, refer to "14 Specifications (P.14-1)".

⚠ WARNING

- This device is intended to be used by healthcare professionals. Users should have a thorough knowledge of the functions and operations before using this device.
- Maintenance of this device should be performed by skilled personnel who have received training in possible hazards and measures to avoid those hazards. Any local regulations that are applicable to operation and care of this device must also be followed. The following hazards may occur if this device is used for any purpose other than what is intended for, or if the user does not follow proper safety protocols.
  - 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.

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⚠ 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.

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 configured as intended.

In addition, record the setting information periodically so that the device settings can be reconfigured if needed. (For details on setting values, see "10.2 Admin. Setup (P.10-3)".)

Users should manage device settings, patient information, and alarm settings, ensuring that all information is correctly configured before use.

In addition, record the setting information periodically so that the various settings can be reconfigured if needed. (For details on setting values, see "10 Setup (P.10-1)".)

Recovery

Contact your local Fukuda Denshi service representative. The Fukuda Denshi service representative will perform reinstallation if the product is no longer operating normally. After the work is completed, the product will be returned to you following an operational check.

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Reconfiguring the Device Settings

For devices returned by a Fukuda Denshi service representative, users should follow the procedure described in 3.6 Setup Menu Basic Operations (P.3-6) and reconfigure the device settings with reference to the information recorded for reconfiguration.

In addition, the device administrator or Fukuda Denshi service representative should reconfigure the network settings and administrator settings by referring to the reconfiguration records.

Interfaces Capable of Communicating Externally

This device is equipped with the following interfaces:

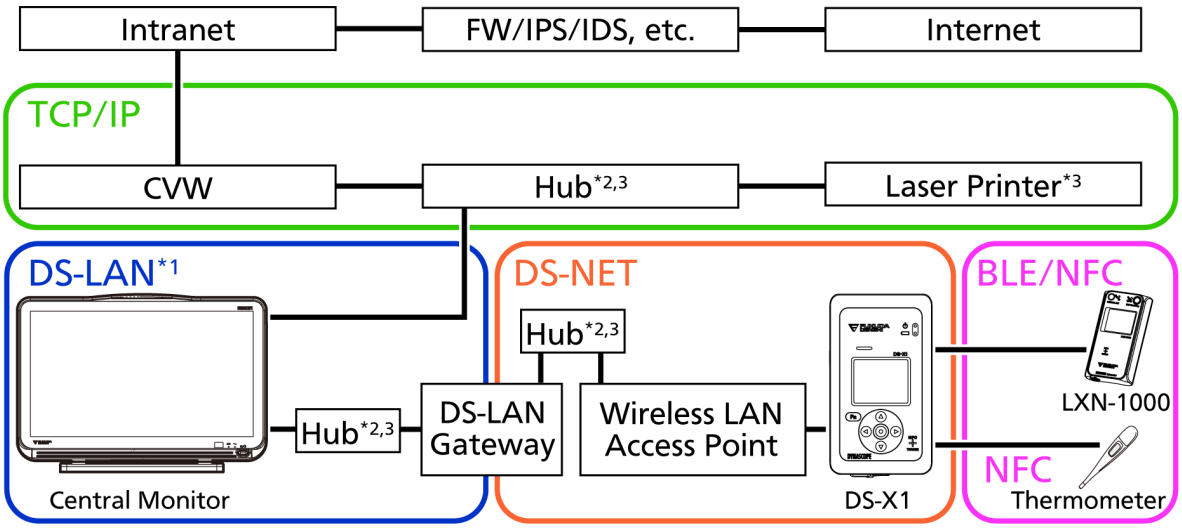
- Function Key
- Operation / Set Key
- NFC antenna
- Standby Switch
- BLE communication area
- Wireless LAN communication area

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.

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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
	Caution, see the appendix 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 the standby switch or pilot lamp.
	Indicates the type and direction of the battery.
	Indicates the model and polarity of the lithium-ion battery.
	Indicates that the device generates non-ionizing radiation.

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Graphic Symbols	Description
	Date of Manufacture Indicates the date of manufacture.
IPX8	Degree of protection against ingress of water
NFC	Indicates short-range wireless communication.
SN	Indicates the manufacturer's serial number.
LOT	Indicates the manufacturer's lot number.

Graphic Symbols on the Display

Graphic Symbols	Description
	Synchronized Mark Flashes synchronizing to the heartbeat
	Indicates the battery level.
N P A	Indicates the patient classification. N: Neonate P: Child A: Adult
	Indicates the status of pairing with LXN-1000.
	Indicates the signal condition of wireless LAN.
SusPend Alarm	On this device, this graphic symbol indicates an interruption in notification sounds, while on the central monitor, it indicates an interruption in alarm sounds.

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.

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⚠ 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.
  - 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.
- 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 polarity of the batteries are correct.
  - Do not charge the alkaline batteries.
- 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 allow the patient to come in contact with other devices.
  - Do not assess the patient's condition based solely on the information from this device. Clinical judgments based on information from this device should be made by a physician who fully understands its functions, and only in conjunction 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 inspect the device and parts. (It is recommended to sign 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 defibrillators 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.

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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:
  - Installation 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.
  - Power supply position
    The electrocautery equipment should be powered from a medical outlet located as far away as possible from the power supply outlet used for this device. This will help reduce interference through the power supply line.
  - Electrode Placement
    The amount of noise interference is considerably different depending on the electrode position and surgery site. Place the ECG electrodes as far away as possible from the surgery site and the ground plate. Do not place electrodes in the path between the surgery site and the ground plate. If the electrodes are placed in this path, the amount of interference will be quite large. Position (+) and (-) electrodes as close as possible to each other.
  - Ground Plate:
    When using electrosurgical instruments, make sure the contact between the patient and the ground plate is secure. If the connection is incomplete, the patient may suffer from burn at the electrode site.
- 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 patient cable. If unspecified patient 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.

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⚠ WARNING

- 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.
- 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 the 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.)
- 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.

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

Precautions for Using This 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.
- 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 wrap the cable around the device. It may damage the cable.
- 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.

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- The waterproof performance of this product is based on our internal test conditions (immersion in water at a depth of 1.5 meters for 30 minutes) and does not guarantee that the product will remain undamaged or free from malfunction under all conditions.

⚠ CAUTION

- To maintain the waterproof performance, replace the battery compartment lid periodically. Otherwise, the quality of the lid will deteriorate and cannot keep the waterproof performance. For periodic replacement, contact your local service representative.
- When the 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 SpO_2 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 SpO_2 connector.
- If the device gets wet, dry it thoroughly before use. Then, verify its operation using a simulator and confirm that ECG and SpO_2 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 our service 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 patient cable and patient monitor, pay attention that the metal part of the electrode does not get in touch with any metal parts of the bed or any conductive parts. Also, the operator should not touch any conductive parts with bare hands. Otherwise, it may cause electric shock to the patient and/or operator due to excessive leakage current.
- The indication for continuous use of the electrode is about one day.
- Replace the electrode if the skin contact gets 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 patient 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 contamination by hum noise, etc., QRS detection will not be properly displayed. Also, arrhythmia will not be detected.
- The threshold level for arrhythmia detection changes with ECG waveform size. Set a proper waveform size for monitoring.
  - When the ECG waveform size is x1/4, x1/2, or x1, the arrhythmia detection level is 250 µV.
  - When the ECG waveform size is x2 or x4, the arrhythmia detection level is 150 µV.
- The leads for arrhythmia detection, central monitor display, printing are fixed as ECG1 and ECG2. Set the most appropriate leads with high QRS for ECG1 and ECG2 for arrhythmia detection, for both normal heartbeat and arrhythmia. If the QRS amplitude of the set lead is low, it may result in falsely detecting or failures to detect arrhythmia.
- When a spontaneous QRS and pacemaker pulse overlap (ex. fusion beat, etc.), QRS detection cannot be performed properly. In this case, the heart rate is degraded.

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Precautions about ST Monitoring

⚠ CAUTION

- For the lead which the electrode is detached, the reference waveform cannot be set. Check if the electrode is securely attached, and perform the setup again.

Precautions about SpO_2 Monitoring

⚠ WARNING

- For SpO_2 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 be 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 SpO_2 probe is disconnected from the device, the SpO_2 measurement/waveform will not be displayed on the receiving monitor. Also, the alarm will not be generated. Make sure that the SpO_2 probe is securely connected to this device.
- When not measuring, unplug the SpO_2 probe from the connector. Otherwise, the outside light may affect it and cause it to falsely display the measurements.
- Check the sensor attachment site constantly every 4 hours when probes or reusable sensor are used, and at least every 8 hours when single patient use sensors are used. Be especially careful of a patient with bad perfusion. If the sensor attachment position is not changed constantly, skin irritation or skin necrosis due to compression may be developed. For the patient with bad perfusion, check the sensor attachment position at least every 2 hours.
- As the skin for neonates and premature infants is immature, change the sensor attachment site more frequently depending on the condition.
- When measuring the SpO_2 of patient with high fever or peripheral circulatory insufficiency, check the sensor attachment periodically and change the attachment site. Due to heat generated by the SpO_2 probe, the temperature at the attachment site may reach up to 42.4°C under the maximum operating environment temperature of 40°C.
- Even attachment for a short duration may inhibit the blood flow and generate compression necrosis. Also, blood flow inhibition may prevent correct measurements.
- Direct sunlight to the sensor area can cause a measurement error. Place a black or dark cloth over the sensor if using in direct sunlight.
- The pulse wave is normalized for SpO_2 measurement, and does not indicate perfused blood volume. Check proper sensor attachment by observing the pulse wave.
- Precautions for Reusable Sensors
  The light-emitting part of the sensor should be over the root of the fingernail or as instructed per the related sensor instruction manual. Do not insert the finger too far into the sensor as it may hurt the patient. For details, refer to the instruction manual of the SpO_2 probe.
- 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 instruction manual of the SpO_2 probe.
- 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

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⚠ CAUTION

- 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 cables and SpO_2 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 peripheral device connection

To use the equipment safely and to ensure maximum performance of the equipment, connection of other manufacturer's equipment to this equipment is not authorized, unless the connection is explicitly approved by Fukuda Denshi. It is the user's responsibility to contact Fukuda Denshi to determine the compatibility and warranty status of any connection made to another manufacturer's device.

⚠ WARNING

- Connect peripheral devices specified by us with the given procedure. Use of an unspecified device may cause electric shock to the patient and/or operator due to excessive leakage current.

Precautions about Batteries

⚠ WARNING

- Install the batteries and lithium-ion 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.

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Precautions about alkaline batteries

⚠ WARNING

- Please use new AA alkaline batteries before the recommended expiration date.
- Do not charge AA alkaline batteries. Charging the batteries may cause liquid leak or damage.
- When using alkaline batteries, do not connect the AC adapter to the USB connector. Doing so may cause leakage 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.
- When using nickel metal hydride batteries, do not connect the AC adapter to the USB connector. Doing so may cause leakage or damage.

Precautions about the lithium-ion battery

⚠ WARNING

- The lithium-ion battery can only be charged in the specified operating temperatures of the device. For details, refer to the operation manual of the lithium-ion battery.
- Do not use a battery other than the lithium-ion battery specified by us.
- For instructions on battery installation and replacement, refer to this manual. Incorrect installation or replacement may cause battery leakage, overheating, smoke, rupture, or fire.

⚠ CAUTION

- If not using the equipment for a long period, remove the lithium-ion battery.

Precautions about Disposing of Device, Accessories, or Components

⚠ CAUTION

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

Precautions about Disposing of Battery

⚠ CAUTION

- Follow the local municipal rule to dispose the used dry cell battery.
- Recycling is recommended for used nickel metal hydride batteries. For details, refer to the manual attached to the battery.
- Recycling is recommended for used nickel metal hydride batteries. For details, refer to the manual attached to the battery. Follow the local municipal rule to dispose nickel metal hydride batteries.
- When disposing of the lithium-ion battery, separate it from other wastes and contact your nearest service representative.

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Precautions about the Wireless Network

Wireless Communications Module

⚠ CAUTION

- The wireless LAN of this device uses the frequencies specified in Article 2, Paragraph 1, Item 19 of the Radio Law Certification Regulations. In the frequency band used by this device, industrial, scientific, and medical equipment such as microwave ovens, other similar radio stations, on-site radio stations for mobile vehicle identification used in factory production lines, etc., and specified low power radio stations not requiring a license and amateur radio stations, etc. (hereinafter abbreviated as "other radio stations") are operating.
- Before using this device, make sure that no “other radio stations" are operating nearby.
- In the unlikely event of radio interference between this device and "other radio stations," immediately change the location of use or stop using the product (stop transmitting radio waves).
- If you encounter any other problems, such as cases of radio interference, please contact us.

Precautions for Using the External Input and Output Function

⚠ CAUTION

- You can input external biometric data 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 IEC 60601-1-2:2014+A1:2020, the 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 a medical facility (except inside the shield room of MRI device), and satisfies the immunity level for professional healthcare facility environments stipulated in IEC 60601-1-2:2014+A1:2020.
- Excessive magnetic disturbance may degrade the HR and SpO_2 measurement accuracy (refer to 14 Specifications (P.14-1)), which is the essential function 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 12 Maintenance (P.12-1))

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.
- 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.

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⚠ 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.
  - Cellular Phone
    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 a portable transmitter or wireless LAN equipment is used extremely nearby, the electromagnetic influence may largely exceed the compliance level and may cause unexpected phenomena such as noise interference on the waveform, etc.

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

If any unexpected noise interference on the waveform or failure to the peripheral device occurs, stop using the device and follow the instruction of the technician.

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 A
Harmonic Emissions IEC 61000-3-2	Not applicable
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Not applicable

⚠ CAUTION

- The emission performance of this equipment is suitable for use in industrial environment and hospital environment (CISPR 11 Group 1 Class A). Do not use in home environment (generally, CISPR 11 Group 1 Class B is required).

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
Radiated RF EM Fields IEC 61000-4-3	3 V/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.

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The EMC Standard or Test Level	Immunity test level
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	PM, 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 460, 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)		
	150kHz to 80MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	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
10	3.8	3.8	7.3
100	12	12	23

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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 80MHz and 800MHz, 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.

Maintenance, Repair, Replacement

Fukuda Denshi is liable for the safety, reliability, and performance of its device only if;

- Maintenance, modifications, and repairs are carried out by personnel or organizations authorized by Fukuda Denshi.
- Components are used in accordance with Fukuda Denshi operating instructions.

A full technical description of this device is available from your local Fukuda Denshi sales representative.

Contact

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

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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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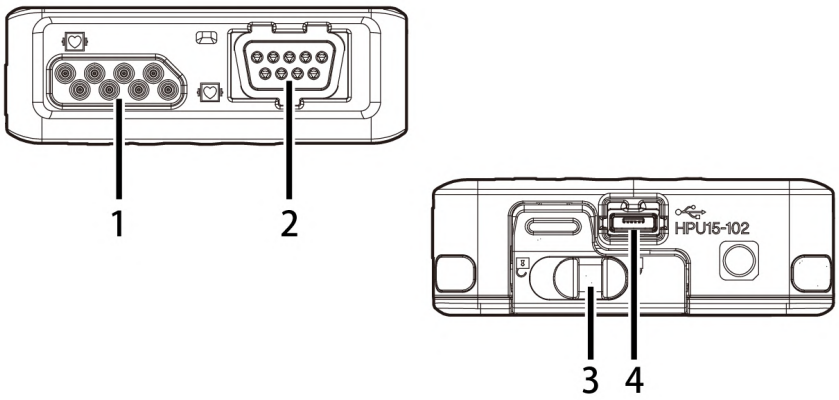
Chapter 1: General Description

This device is a wireless transmitter used to measure ECG, respiratory waveform, SpO_2 (arterial oxygen saturation), and pulse waveform.

- This device can perform bidirectional communication of biometric and device information with the central monitor via wireless LAN.
- This device displays ECG, respiratory waveform, SpO_2, and pulse waveforms being measured, as well as the battery level, ECG electrode status, SpO_2 probe status and other information.
- You can use this device as a transmitter for ECG and respiration measurements without measuring SpO_2 or as a transmitter for SpO_2 measurements without measuring ECG and respiration waveforms.
- BP values measured with the LXN-1000 portable sphygmomanometer can be received via wireless communication and displayed. Received BP values can be sent to the receiving monitor.
- The device can operate on the dedicated lithium-ion battery, AA alkaline battery or AA nickel-hydrogen battery.
- The DS-X1M is equipped with MASIMO's SpO_2 measurement module and the DS-X1N with Medtronic's SpO_2 measurement module.

1.1: Names of Parts and Their Functions

Top and Bottom Sides



1. ECG Connector
   Install the patient cables for measuring ECG and respiratory waveforms
2. SpO_2 Connector
   Install the probe for measuring SpO_2.
3. Lock Lever
   Locks the battery cover.
4. USB Connector
   Charging terminal for use with an AC adapter. (Only for the dedicated lithium-ion battery)

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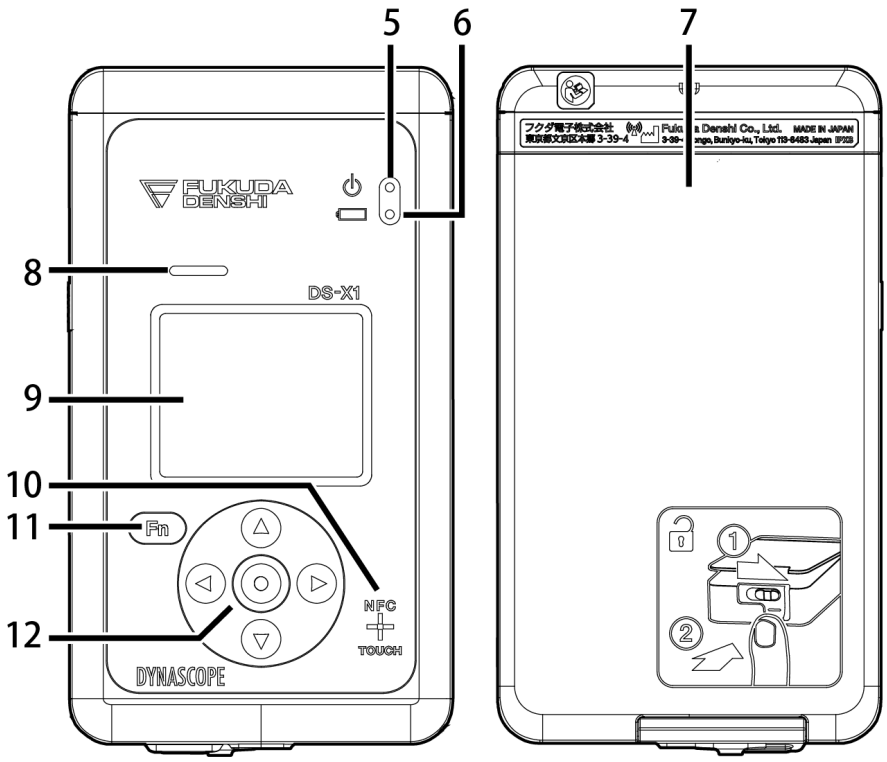
Front and Rear Sides



5. Pilot Lamp
   Indicates the operation status of this device by the color of the indicator light.
   Green (lit): Operating
   Light off: Power off
6. Charging LED
   Indicates the battery charging status by the lighting color.
   Green (lit): Charging complete
   Orange (lit): Charging
   Orange (blinking): Charging error
   Light off: Charging stopped
7. Battery Cover / Battery Cover Unit
   Protection cover for the battery. (In the image, the battery cover is attached.)
8. Alarm Indicator
   Lights up or blinks while the alarm is sounding.
9. Display Area
   Displays measured waveforms and information of the device.
10. NFC Mark
    A marker indicating the location of the antenna for NFC.
11. Function Key
    Used to send event information and switch status messages.
12. Operation / Set Key
    Use the up, down, left, and right keys and the center key to configure settings.

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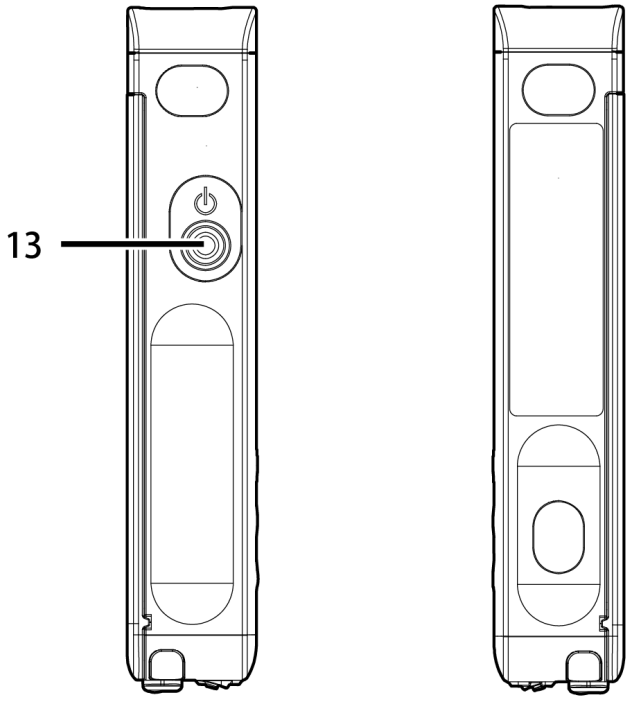
Left and Right Sides



13. Standby Switch
    Turns the power on/off.

⚠ CAUTION

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

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Chapter 2: Preparation Before Use

This section outlines the setup procedures and preparations required after purchasing the device and before use.

2.1: Installing Batteries

This device can be used with dedicated lithium-ion batteries, AA alkaline batteries or AA nickel metal hydride batteries.

The installation procedure varies depending on the battery type, so please confirm the battery type and install by following the correct procedure.

2.1.1: Lithium-ion Battery

- When using a lithium-ion battery, ensure it has sufficient charge before use.
- When using a lithium-ion battery, set the battery setting of this device to "Li-ion" before use. (Refer to 10.2.5 Changing the Battery Settings (P.10-4))

Designated Batteries

Type	Product name	Note
Lithium-ion Battery	RRC1130	Rated voltage: 3.8 V Rated capacity: 3.81 Ah

⚠ DANGER

- The specified lithium-ion battery is designed for exclusive use with equipment designated by Fukuda Denshi. Please refrain from using it with any other devices. Using it with other devices may affect the performance and lifespan of the battery, as well as lead to potential issues such as leakage, overheating, smoke emission, rupturing, or ignition.
- If electrolyte leaks from the lithium-ion battery and enters the eyes, avoid rubbing. Immediately rinse with clean water and seek medical attention immediately. Leaving it unattended can lead to eye damage due to the leaked liquid.
- If the internal battery fluid comes into contact with the skin or clothing, promptly rinse with water to prevent potential skin irritation.
- To mitigate the risks of overheating, ignition, rupturing, or leakage, please adhere to the following precautions.
  - Ensure the orientation of the connector is correct and it is securely attached when connecting the lithium-ion battery to the device.
  - Do not use a battery other than the specified lithium-ion battery.
  - Charge the battery only using the designated device.
  - Avoid short-circuiting, altering, or disassembling the electrodes or terminals.
  - Do not expose to fire, heat, or high-temperature conditions, or attempt to charge in such conditions.
  - Do not store alongside metallic items like clips or pins.
  - Lithium-ion batteries have a limited lifespan. Do not use degraded batteries.
  - Avoid puncturing, striking with a hammer, stepping on, removing the outer casing of, or causing any damage to the lithium-ion battery.
  - Avoid using or leaving the lithium-ion battery in high-temperature areas (above 60°C).
  - Do not place the lithium-ion battery in a microwave or a high-pressure container.

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⚠ WARNING

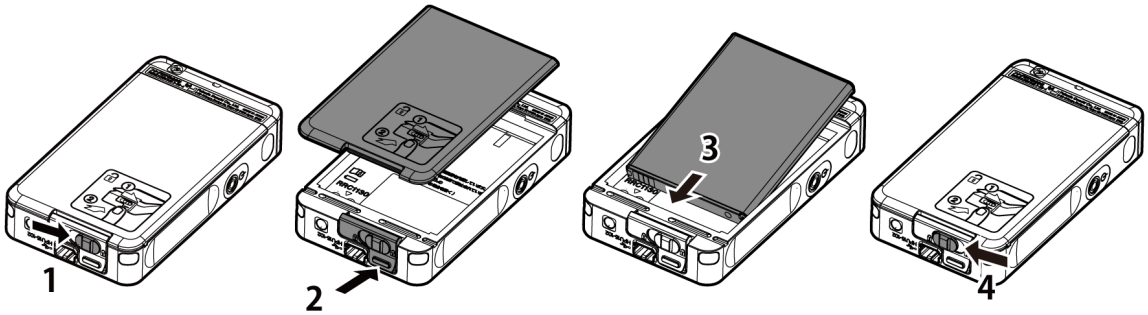
- Refrain from subjecting the lithium-ion battery to strong impacts or being thrown.
- Do not sterilize the lithium-ion battery.
- Use and store the lithium-ion battery in places that infants and toddlers cannot access.
- If you observe any abnormalities while using the lithium-ion battery, cease use immediately.
- If the charging process does not end after the specified charging duration has elapsed, immediately remove the battery from the device and discontinue use.
- If any abnormality is found on the device, immediately turn off the power, and disconnect the AC adapter from the outlet.
- Install this device in a place where the AC adapter can be easily disconnected.
- When removing the lithium-ion battery, always disconnect the AC adapter from the device first.

⚠ CAUTION

- If the "Low Battery" message appears, switch to AC power.
- For older lithium-ion batteries, the device may stop working within less than a minute after the "Charge the battery" message is displayed.
- When storing the device with a lithium-ion battery installed, always ensure that the battery is fully charged and store in a cool place.
- If storing the device for more than 90 days, remove the charged lithium-ion battery from the device and store it in a cool place.
- If not using the device for an extended period, remember to charge it at least once every two months.
- Replace the periodic replacement parts at the specified times.

Installation Procedure

1. **Unlocks the battery cover.**
2. **While pressing the protruding part at the bottom of the lock, remove the battery cover.**
3. **Install the lithium-ion battery.**
4. **Attach the battery cover and lock it in place.**



⚠ CAUTION

- Make sure that no hair or other foreign objects are stuck in the battery cover and that no dust or chemicals are on the lid. Foreign objects may degrade the waterproof performance and flood the battery compartment.

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⚠ CAUTION

- Do not leave the cover unlocked. The battery cover may open unexpectedly and the battery may pop out.
- When installing the battery, insert it by firmly pressing the battery terminals onto the corresponding terminals on the device. Incorrect installation may deform the terminals, potentially causing damage to the battery or the device.

Lithium-ion Batteries

- Even if the lithium-ion battery is not in use, the remaining capacity decreases due to self-discharge. Regularly check the remaining battery level.
- The performance of the lithium-ion battery deteriorates with repeated use. To maintain the performance, replace it with a new one within the period specified in 12.3.3 Periodic Replacement Parts (P.12-4).

2.1.2: Alkaline Batteries, Nickel Metal Hydride Batteries

This transmitter operates with three AA alkaline batteries or three AA nickel metal hydride batteries.

If you use alkaline batteries or nickel metal hydride batteries, please use the DS-X1 battery cover unit (OAT-X1A) designed for DS-X1.

Designated Batteries

Type	Product name
AA Alkaline Battery	LR6 (XJ)
AA Nickel-Metal Hydride Battery	eneloop® BK-3MCD

⚠ WARNING

- 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 polarity (+) (-).
- Do not charge AA alkaline batteries. Charging the batteries may cause liquid leak 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.
- Remove used batteries 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.

⚠ CAUTION

- When storing used or unused batteries, keep their terminals away from other batteries or metal.
- If a nickel metal hydride battery is used in the alkaline battery setting, the level 1 symbol of the battery level appears later than usual. In addition, the operating time becomes shorter than usual after the level 1 symbol of the battery level appears.
- When alkaline batteries are used in the rechargeable battery setting, the level 1 battery symbol appears earlier than usual. In addition, the operating time becomes longer than usual after the level 1 symbol of the battery level appears.
- Precautions about Nickel Metal Hydride Batteries

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⚠ CAUTION

- Use fully charged batteries. Do not mix fully charged and discharged batteries.
- Charge the three batteries at the same time.
- Read the manual accompanying the battery and charger to fully understand precautions regarding them 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 two years, the specified operating time 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.

How to Install Batteries

⚠ WARNING

- Use new AA alkaline batteries or fully charged AA nickel metal hydride batteries.
- Replace the three 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.
- 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.
- Always unplug the patient cable when opening the battery cover of a transmitter used for a patient. Opening the battery cover with the patient cable connected may cause a patient leakage current in excess of the allowable value.

⚠ CAUTION

- Use alkaline or nickel metal hydride batteries specified by Fukuda Denshi.
- Use the type of battery selected in the battery settings of the device. If a battery that does not match the setting is used, the device will not display the correct battery level.
- Turn off the power when opening the battery cover.
- Do not exchange the batteries with wet hands.

1. **Unlock and remove the battery cover unit.**
2. **While pressing the protruding part at the bottom of the lock, remove the battery cover unit.**
3. **While paying attention to polarity, install the batteries into the battery cover unit.**
4. **Attach the battery cover unit to the device and lock it.**

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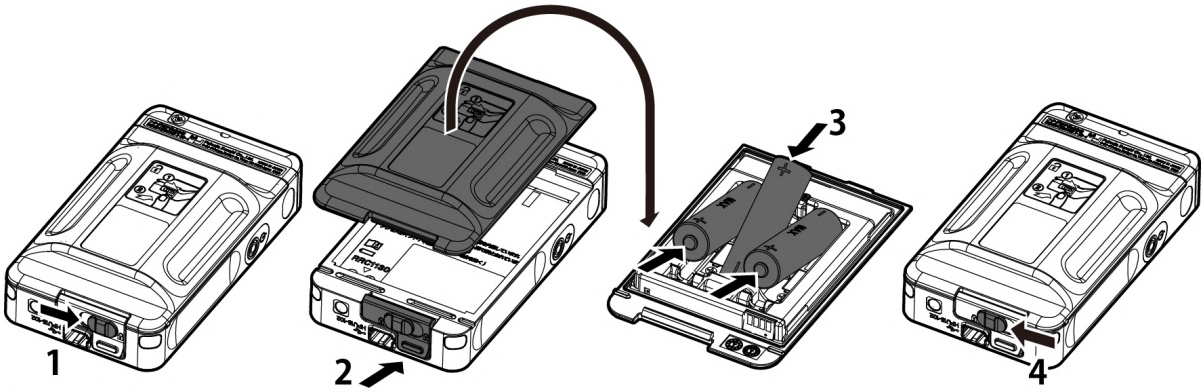


⚠ CAUTION

- Make sure that no hair or other foreign objects are stuck in the battery cover unit and that no dust or chemicals are on the lid. Foreign objects may degrade the waterproof performance and flood the battery compartment.
- Do not leave the cover unlocked. The battery cover unit may detach unexpectedly and the batteries may pop out.
- When installing the batteries, insert them by pressing the "-" terminal onto the spring. Incorrect installation may deform the springs, potentially causing damage to the batteries or the device.

2.2: Power Operations and Screen Display

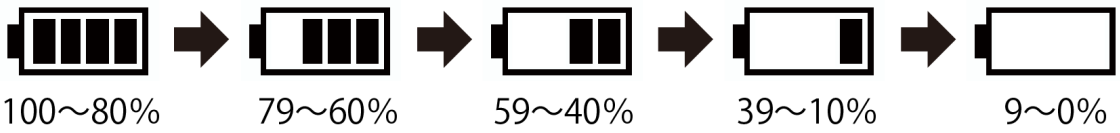
2.2.1: Turning on the power

1. **Press and hold the standby switch for at least one second.**
   A buzzer sounds and the alarm indicator lights up. The opening screen then appears, the device starts up, and measurement begins.

- For details of the screen display, refer to 3.2 How to Interpret the Screen (Common) (P.3-1).
- The liquid crystal display will automatically turn off after the set duration has passed.

2.2.2: Checking the battery level

During use, you can check the battery level through the icon displayed on the home display.



- The icon will blink while charging.

If the battery level falls below 3%, the following screen will display, and the device will turn off. Promptly recharge or replace the battery.

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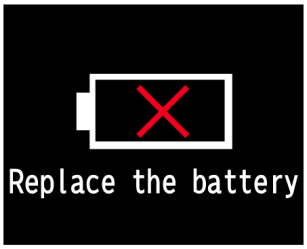
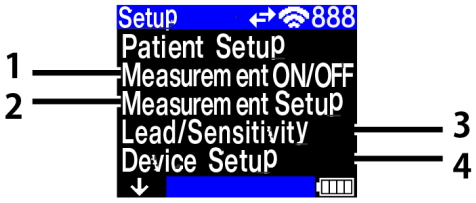


2.2.3: Turning off the power

1. **Press and hold the standby switch for at least two seconds.**
2. **Select [Yes] and press the Set key when the confirmation screen appears.**

2.3: Setting Patient Information

1. **Select [Patient Setup] from the Setup menu.**
   (For information on the basic operations of the Setup menu, refer to 3.6 Setup Menu Basic Operations (P.3-6).)
2. **Enter the patient information as indicated below.**



1. [Bed ID]
   Sets the Bed ID of the patient.
2. [Patient]
   Select from [Adult] / [Child] / [Neo.].
3. [Pacemaker]
   Sets whether a pacemaker is in use. For details, refer to 10.1.1 Patient Setup (P.10-1).
4. [Pace. Sens.]
   Select the pacing detection sensitivity for the pacemaker from three levels.

- To use the alarm function, refer to 4 Alarm Function (P.4-1) for instructions on configuring the alarm.

2.4: Checking the Wireless LAN Connection

Before performing wireless communication using a wireless LAN, check the communication status from the icon on the screen.

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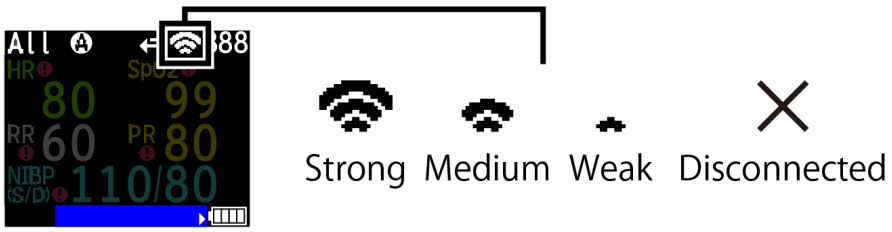


You can check the wireless LAN connection settings stored in the device from [Network Setup]. (For details, refer to 10.1 Setup (P.10-1).)

- If you want to change the wireless LAN connection settings, contact our service representative.

2.5: Bluetooth Settings

This device and LXN-1000 can send and receive blood pressure data wirelessly using Bluetooth.

To receive blood pressure data measured by LXN-1000 on this device, perform device registration (pairing) between the devices in advance.

2.5.1: Pairing

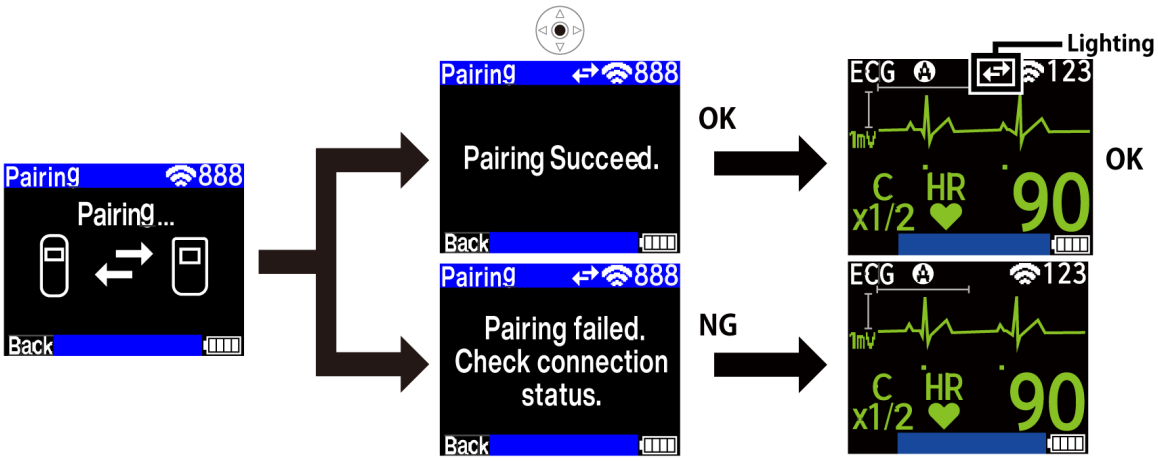
1. **Hold down the Up key for at least two seconds on the measurement screen.**

- If the NIBP measurement setting is off, pairing will not be performed.
- If the device is already paired with LXN-1000, a screen to cancel the pairing will appear. In that case, cancel the pairing first and then pair again to reconnect with LXN-1000.

2. **Place LXN-1000 near the pairing settings screen of the device.**

3. **Confirm that the pairing icon is lit at the top of the screen, then press the Set key to return to the measurement screen.**

- If the pairing 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.



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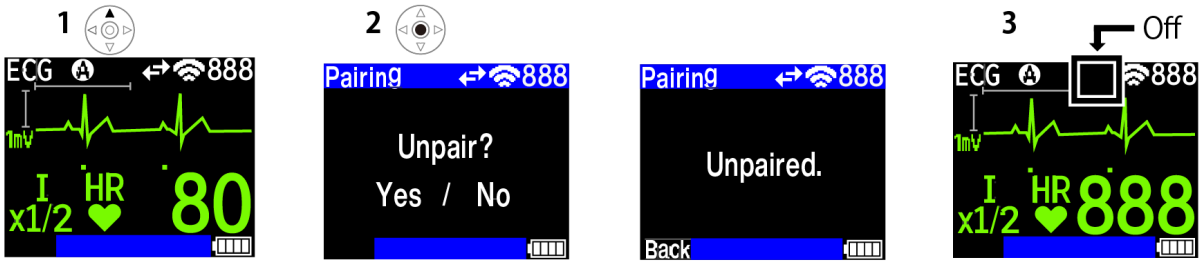
2.5.2: Cancel Pairing

If you have already paired a device and want to pair another device, first cancel the current pairing.

1. **Hold down the Up key for at least two seconds on the measurement screen.**
2. **Select [Yes] and press the Set key.**
3. **When the unpairing message appears, press the Set key.**
4. **Confirm that the icon at the top of the screen is no longer displayed.**



2.6: 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 batteries from falling out.

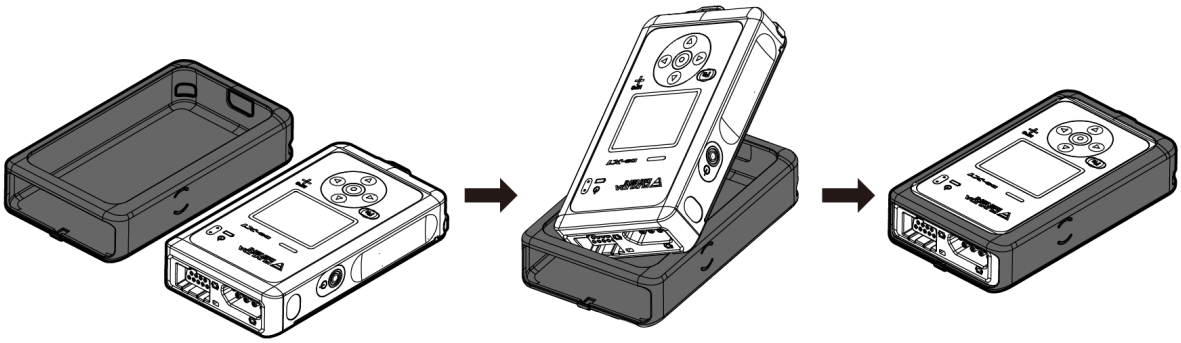
⚠ CAUTION

- Caution is advised, as patient contact with a detached battery or battery terminal may result in a patient leakage current that exceeds permissible limits.

2.7: Attaching and Using the Silicone Cover

To protect the main device against scratches and dirt, a silicone cover (ABT-X1C) 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.

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⚠ CAUTION

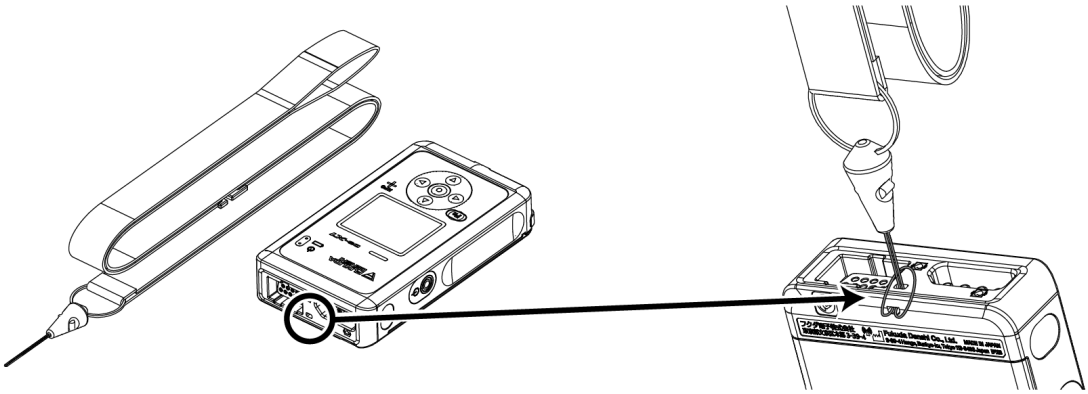
- For patients who are at risk of swallowing the silicone cover accidentally, use the device without attaching the silicone cover.

2.8: 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 batteries from falling out.

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



⚠ CAUTION

- Caution is advised, as patient contact with a detached battery or battery terminal may result in a patient leakage current that exceeds permissible limits.
- 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.

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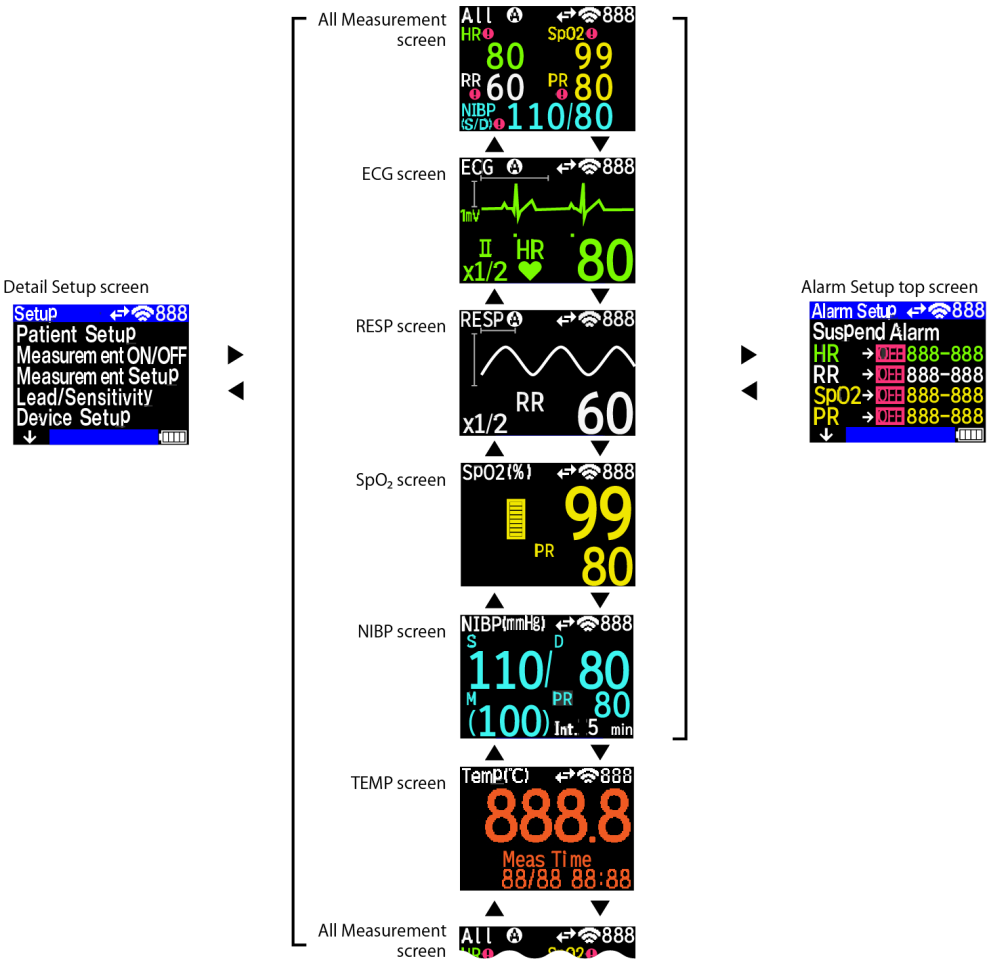
Chapter 3: Basic Operations

3.1: Switching the Screen Display

This product allows switching between multiple screens based on the parameters being measured. Use the Up, Down, Left, and Right keys to select screens.



- When the operation lock is enabled, a password input screen will be displayed when transitioning to the detail setup screen or the alarm setup screen.
- If no operation is performed for a certain period of time, the screen will automatically turn off.
  For instructions on how to display a screen that has been turned off, refer to 3.4 How to redisplay the screen (P.3-6).
- If the device is not paired with LXN-1000, NIBP measurement values will not be shown on the All Measurements screen. The NIBP screen will also not be displayed.

3.2: How to Interpret the Screen (Common)

Basic information is displayed on all screens.

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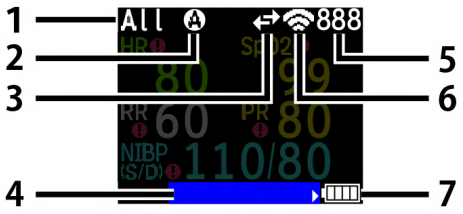


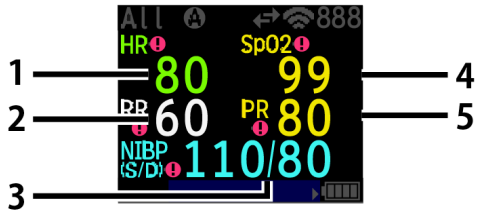
1. Screen name
   The name of the screen that is currently displayed
2. Patient
   Displays the patient classification as follows.
   Adult: A / Child: P / Neonate: N
3. Pairing icon
   Displays the pairing status with LXN-1000.
   On: Connected / Off: Not Connected / Flashing: Communication error or communication in progress
4. Status message
   Displays alarm information or device-related notifications.
   If there are multiple messages, pressing the function key will display the next message.
5. Bed ID
6. Signal strength icon
   Displays the signal strength of the wireless LAN.
   3 bars: Strong / 2 bars: Medium / 1 bar: Weak / x: Communication error
7. Battery level

3.3: Waveform/Numeric Data Display Screen

⚠ CAUTION

- 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.
- This transmitter is not equipped with a diagnostic function. Please be sure to use the receiving monitor to receive the signal.

3.3.1: All Measurement screen



1. Heart rate
2. Respiration rate
3. Non-Invasive blood pressure (S/D)
4. Oxygen saturation
5. Pulse rate

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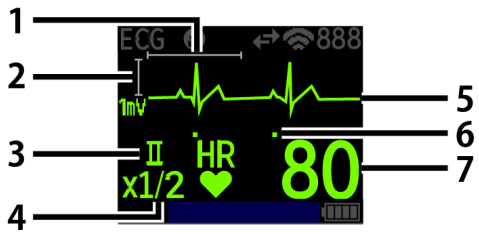
- Refer to 11 Troubleshooting (P.11-1) for the messages and icons that appear.

3.3.2: ECG Screen

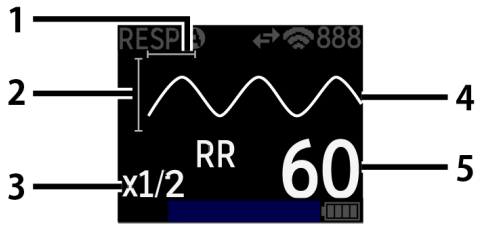


1. Lateral scale of ECG
   Equivalent to 1 second per scale
2. Vertical scale of ECG
   Equivalent to 1 mV per scale Example screen can display up to ±1mV.
3. Lead name
4. Display sensitivity
5. ECG waveform
6. Pacemaker pulse
   Displays at the position where the pacemaker pulse is detected.
7. Heart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

⚠ CAUTION

- The sensitivity displayed on the indicator of this device is not the sensitivity displayed on the receiving monitor. The sensitivity displayed on the receiving monitor cannot be changed with this device. To change the display sensitivity of the receiving monitor, follow the operation manual of the receiving monitor.

3.3.3: 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 ±1Ω.
3. Display sensitivity
4. Respiration Waveform
5. Respiration rate

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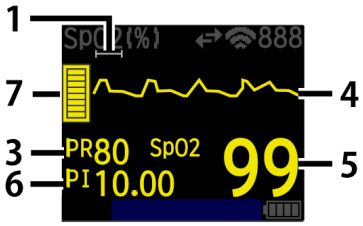
⚠ CAUTION

- The sensitivity displayed on the indicator of this device is not the sensitivity displayed on the receiving monitor. The sensitivity displayed on the receiving monitor cannot be changed with this device. 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 the 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.

3.3.4: SpO_2 Screen

DS-X1N



DS-X1M

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 DS-X1M.
  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 critical condition of a patient 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 11 Troubleshooting (P.11-1) 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.

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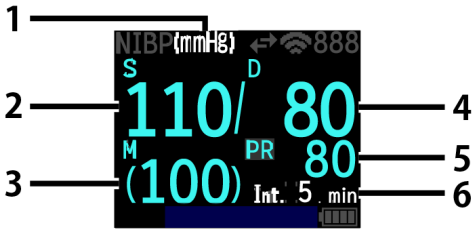
- The DS-X1 display provides a visual indicator Signal IQ and an alert when the displayed values are not based on adequate Signal IQ. The Low SIQ visual alert occurs when the sensor may be compromised. When the Low SIQ alarm occurs, proceed with caution and do the following:
  - Assess the patient.
  - Check the sensor and ensure proper sensor application. The sensor must be well secured to the site for the DS-X1 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.

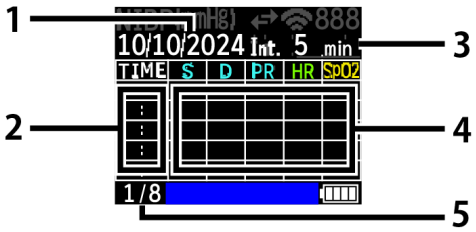
3.3.5: NIBP Display Screen



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

3.3.6: NIBP List Display

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



1. Date of measurement
2. Measurement time
3. Measurement interval

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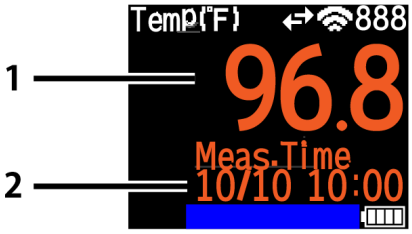
4. Numeric data
5. Page
   Displays "Current Page Number/Total Pages".

- Pressing the Set key switches to the NIBP screen.

3.3.7: TEMP Screen



1. Temperature
2. Measurement time
   Displays the timestamp of when the data was fetched from the thermometer.

- The measurement time inside the measurement value box indicates the time read from the thermometer. Please note that it may not reflect the exact time the temperature was taken with the thermometer.

3.4: How to redisplay the screen

The screen display automatically turns off after there is no activity for the time set in the screen-off time.

If you press any key while the screen is off, the screen will turn on and the all measurement screen will be displayed.

3.5: Send Event Notifications to Monitors

- To enable sending event information, set the [Function Setup] item in the [Central Comm.] Settings to [Print] or [Alarm Suspend] from the Setup menu.

Hold down the function key for two seconds to send event information to the receiving monitor.

Event information can be used for remote recording or alarm sound muting based on the settings of the receiving monitor.

For detailed instructions on configuring the operation of the receiving monitor based on event information, refer to the operation manual of the receiving monitor.

3.6: Setup Menu Basic Operations

From the Setup menu, you can adjust settings related to individual waveform screens, such as waveform display sensitivity or toggling the HR synchronized tone.

1. **Press the Left key on the home display to open the Setup menu.**
2. **Use the Up and Down keys to select a setting item from the menu, then press the Set key.**

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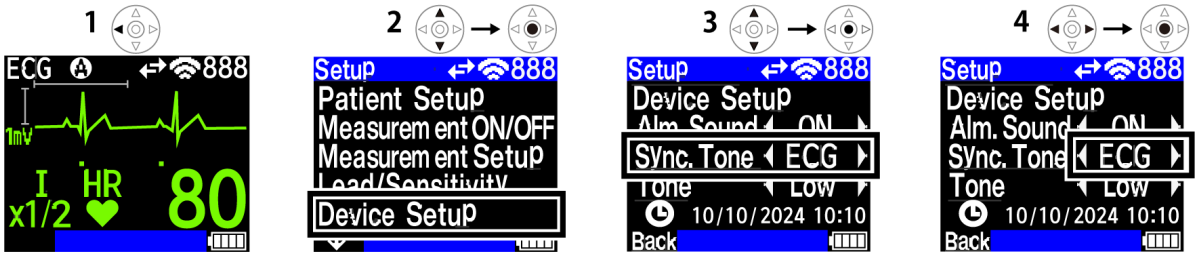
3. Select the desired item and press the Set key.

4. Use the Left and Right keys to change the setting value, and press the Set key to confirm.



⚠ CAUTION

- If you continue to use the device with the setting screen on, you may accidentally change the settings. Always remember to return to the waveform/numeric data display screen before using the device.
  Even while the Setup screen is displayed, the display unit will automatically turn off after the set period of inactivity has elapsed.

- For details on the settings that can be changed, refer to 10.1 Setup (P.10-1).

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Chapter 4: Alarm Function

This device generates an alarm when the waveform or numerical data of biometric information reaches or exceeds preset conditions.

You can set and stop alarms from the device, and this information is shared with the central monitoring system.

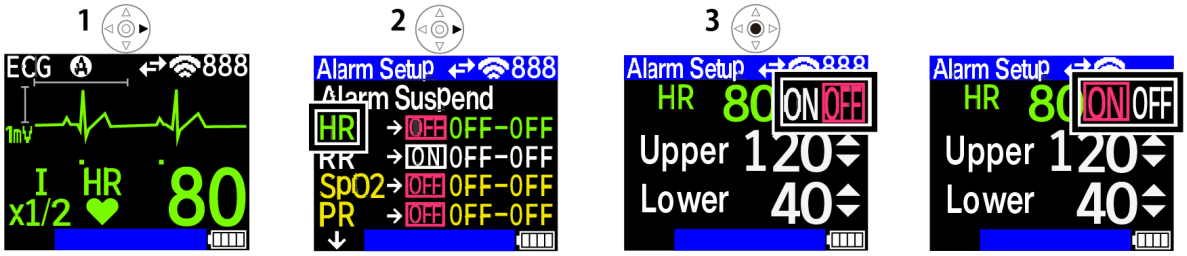
- In addition to vital alarms triggered by changes in biometric information, there are device alarms that occur based on the device status.

4.1: Switching the Alarm ON/OFF

1. **Hold down the Right key on the measurement screen.**
   (If operation lock is enabled, enter the password.)

2. **Select the ON/OFF switching parameter on the Alarm Setup top screen, then press the Right key.**

3. **With ON/OFF selected, press the Set key to switch the alarm between ON and OFF.**

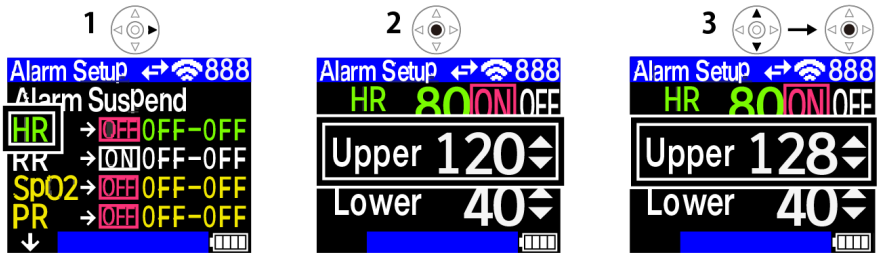


4.2: Alarm Threshold Settings

1. **Select the threshold changing parameter on the Alarm Setup top screen, then press the Right key.**

2. **Select the threshold item and press the Set key.**

3. **Select the value and press the Set key.**



- When changing the threshold value, holding down the Up or Down key for at least two seconds will accelerate the rate of change.

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4.3: Suspending the Alarm and Mute Notification

There are two ways to stop an alarm from sounding: Suspend Alarm and Mute Notification

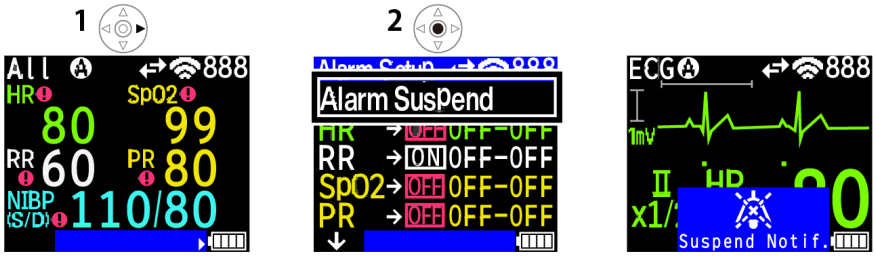
- The Suspend Alarm function temporarily suspends the alarm sound.
  The alarm will resume after a certain period of time.
- The Mute Notification function turns off the sound of all alarms.

⚠ WARNING

- The notification sound may not be audible depending on the usage status of the device. Pay attention not to miss any important alarm by simultaneously monitoring the patient on the central monitor or other monitors.
- The notification sounds generated by this device are intended to prompt the user to check alarm details on the central monitor.
- This device does not comply with the IEC 60601-1-8 alarm standard. Always use this device with a central monitor.

4.3.1: Suspend Alarm

1. **Hold down the Right key on the measurement screen while an alarm is sounding.**
2. **Select [Alarm Suspend] and press the Set key.**
3. **The Suspend Alarm function is enabled and the icon flashes on the home display.**



Precautions about Silencing the Alarm

- The alarm silence function is effective for each parameter. Once the alarm cause is resolved, the suspend alarm condition for that parameter will be canceled.
- If the "Suspend Alarm" key is pressed for the alarm of another parameter which occurred during the suspend alarm condition, the suspend alarm duration for the first alarm will not be extended.
- The suspend alarm condition for each parameter will be canceled in the following cases.
  - When the alarm cause is resolved for that parameter.
  - When the alarm silence time for the parameter is completed.
  - When the alarm is turned off for each parameter.

4.3.2: Mute Notification

1. **Press the Left Key on the Home Display.**
2. **Select [Device Setup] and press the Set key.**
3. **Select [Notif. Sound], change the setting value and press the Set key.**

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⚠ WARNING

- When the notification sound is turned off, the notification sound will not sound even if an alarm is generated. Pay attention not to miss any important alarm by simultaneously monitoring the patient on the central monitor or other monitors.

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Chapter 5: ECG Monitoring

When this transmitter is used without the SpO_2 probe attached, it can be used as an ECG and respiration transmitter.

This transmitter is available with a variety of patient cables and electrodes as options.

For available electrodes and patient cables, refer to "13 System Components (P.13-1)."

⚠ WARNING

- Use electrodes and patient cables designated by Fukuda Denshi. 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 patient cable alone, turn off the SpO_2 measurement of the receiving monitor to prevent false alarms.

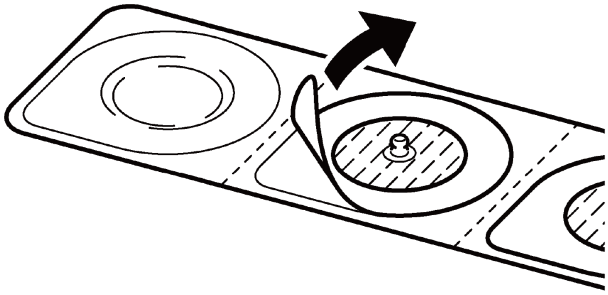
5.1: Attaching Electrodes

⚠ CAUTION

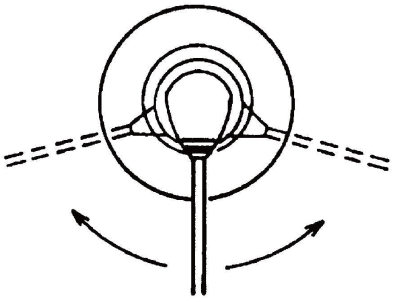
- Make sure to use the same type of electrodes. If different types of electrodes are used at the same time, the ECG may not be measured due to polarization voltage.
- The electrode is disposable. Do not reuse it.

1. **Clean the skin at the electrode sites with alcohol wipes or a similar item. If necessary, shave the electrode sites to remove excess 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 patient 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.**



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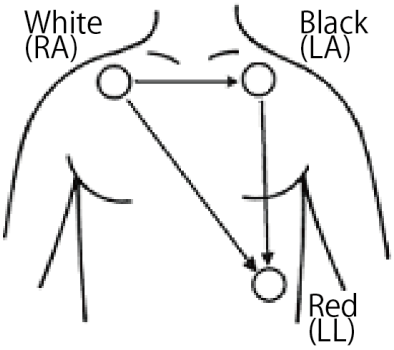
5.2: Attaching the Patient Cable

When using a 3-electrode patient cable

The limb lead can be measured by selecting either lead I, II, or III according to the settings of the main unit.



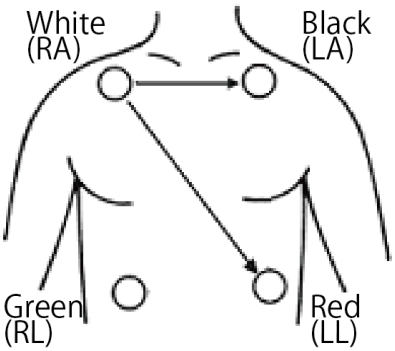
Limb lead

When using a 4-electrode patient cable

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

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

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



Limb lead

When using a 5-electrode (chest) patient cable

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

The limb lead can be measured by selecting either lead I, II, or III 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.

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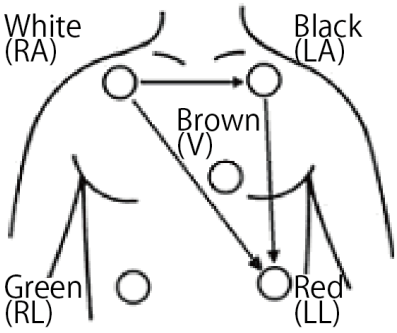
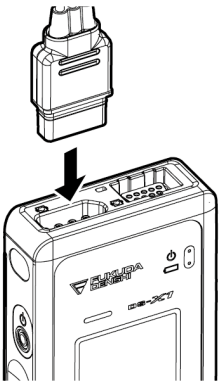


Limb lead and chest lead

5.3: Connecting the Patient Cable to the Device

Insert the patient 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; this 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 patient 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 wired monitoring systems of Fukuda Denshi, 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.
- Promptly replace electrodes when the contact conditions have deteriorated 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 patient cable, hold the sides of the device. Applying excessive pressure on the screen may cause the device to malfunction.

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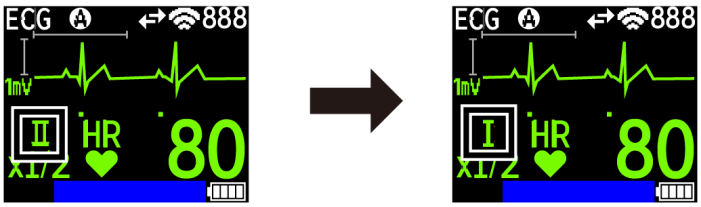
⚠ CAUTION

- 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 patient 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.

5.4: ECG-Related Settings

5.4.1: Switching the ECG Lead

You can select the lead with the highest wave height value while checking the waveform when using a 3-electrode patient cable or a 5-electrode chest patient cable.

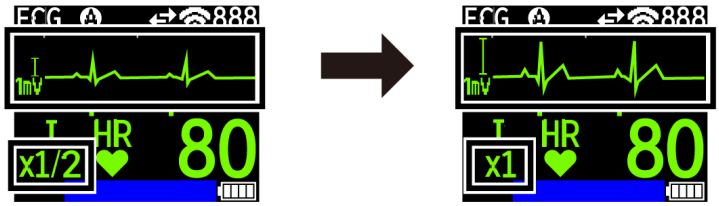


You can change the settings from [Lead/Sensitivity] in the Setup menu.

- Leads for 2ch and beyond cannot be switched from this device. Please change them on the central monitor.
- For details of the Setup menu, refer to 10.1 Setup (P.10-1).

5.4.2: Changing the ECG Display Sensitivity

By changing the ECG display sensitivity setting, you can enlarge/reduce the vertical axis scale of the ECG waveform.



You can change the settings from [Lead/Sensitivity] in the Setup menu.

- Sensitivity settings for 2ch and beyond cannot be switched from this device. Please change them on the central monitor.
- For details of the Setup menu, refer to 10.1 Setup (P.10-1).

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5.4.3: Playing the HR Synchronized Tone

By setting the synchronized sound to ECG, the HR synchronized tone can be played along with the display of the synchronized mark.

You can change the settings from "Device Setup" in the Setup menu.

- For details of the Setup menu, refer to 10.1 Setup (P.10-1).

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Chapter 6: Respiration monitoring

Preparing according to 5 ECG Monitoring (P.5-1) enables respiratory monitoring using the impedance method.

The electrodes for respiration detection are shared with those for ECG.

⚠ WARNING

- When patient monitor and diagnostic equipment is connected to a patient with an implanted cardiac pacemaker that incorporates a minute volume (MV) sensor, the MV sensor of the cardiac pacemaker may overreact, causing inappropriate pacing rates, such as reaching the maximum rate. The patient monitor and diagnostic equipment may possibly send the 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, polarization voltage may be generated by the ECG electrodes due to the high voltage, which may cause interruption of monitoring for a few seconds.

6.1: Respiration-Related Settings

6.1.1: Switching the Respiration Lead

You can select the lead with the highest wave height value while checking the waveform when using a 3-electrode patient cable or a 5-electrode chest patient cable.

You can change the settings from [Lead/Sensitivity] in the Setup menu.

- For details of the Setup menu, refer to 10 Setup (P.10-1).

6.1.2: Changing the Respiration Display Sensitivity

By changing the respiration display sensitivity setting, you can enlarge/reduce the vertical axis scale of the respiration waveform.

You can change the settings from [Lead/Sensitivity] in the Setup menu.

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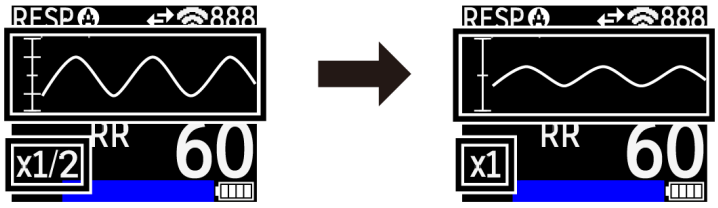

With a display sensitivity of 1/2, it can display a change of up to ±4Ω.

- For details of the Setup menu, refer to 10.1 Setup (P.10-1).

Chapter 7: SpO_2 Monitoring

When this device is used without an ECG patient cable attached, it can also be used as a SpO_2 transmitter.

The DS-X1N is equipped with Medtronic's SpO_2 module and the DS-X1M with MASIMO's SpO_2 module.

⚠ WARNING

- When the SpO_2 probe is disconnected from the device, the SpO_2 measurement/waveform will not be displayed on the receiving monitor. Also, the alarm will not be generated. Make sure that the SpO_2 probe and each connector of the main unit are firmly plugged in.

⚠ CAUTION

- When using the SpO_2 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 SpO_2 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 SpO_2 probes that can be used with this device, depending on its purpose and application. Select and install the appropriate one for your applications. (For details, refer to 13 System Components (P.13-1).)

7.1: Precautions about SpO_2 Measurement (DS-X1N)

This is a note on SpO_2 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 be 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 SpO_2 values.
- When removing the probe, do not hold and pull on the cable.
- Do not lift the device by holding the probe. The probe may come off and the device may fall.

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⚠ CAUTION

- 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 SpO_2 probes. Accurate measurement may not be possible.
- Do not resterilize for use.

⚠ CAUTION

- The accuracy of SpO_2 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 SpO_2 and pulse rate measurements.
  - Low perfusion
  - Excessive body motion (patient's motion)
  - Pigment injected in the patient for the exam
  - If measuring during CPR
  - Sphygmomanometer cuff, SpO_2 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
  - External light (direct sunlight, fluorescent, light therapy equipment, surgical light, infrared heat ramp, etc.)

- 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 SpO_2 value. In such cases, either re-install the sensor or change the attachment site and use a Nellcor sensor appropriate for the site.

7.2: Attaching SpO_2 OXISENSOR III OXIMAX I-20

SpO_2 OXISENSOR III OXIMAX I-20 is an adhesive SpO_2 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.

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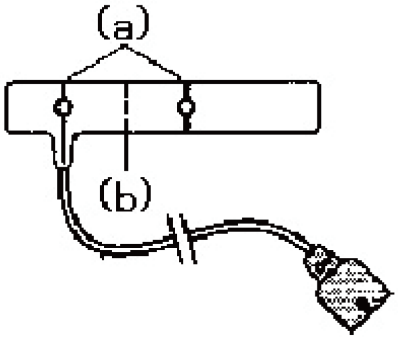
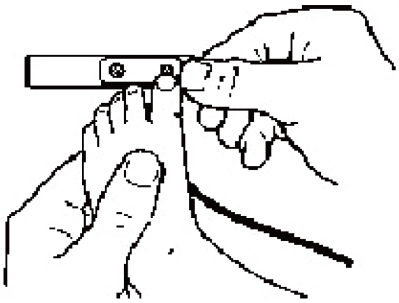
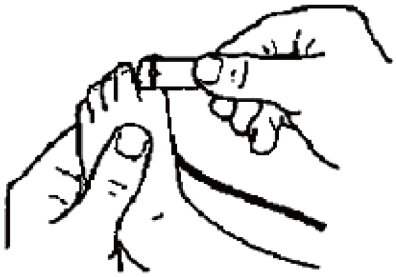


2. Attach the sensor on the foot or finger. The window on the side where the cable comes out should be placed toward the ball of the thumb and the cable should be placed toward the heel.

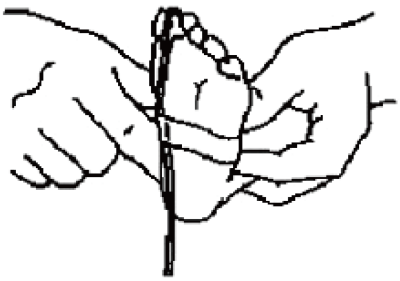


- The best site for attachment is the thumb of the toe. However, it can be attached to other small fingers such as the thumb.
- When choosing a site for the sensor, place it on the side of the foot or finger that is not connected to an arterial catheter, blood pressure cuff, or infusion line.

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).

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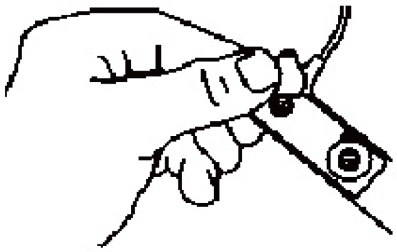
Reattaching

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.

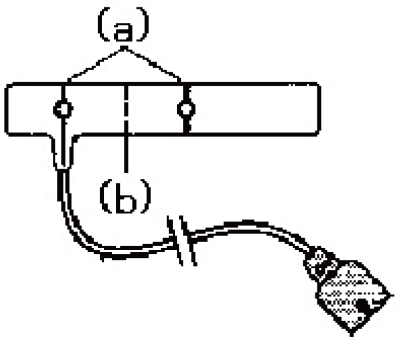
⚠ CAUTION

- 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 SpO_2 readings.

7.3: Attaching MAXI

MAXI is an adhesive SpO_2 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.



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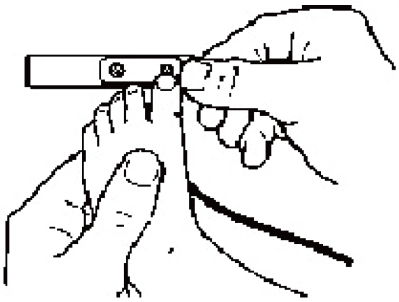
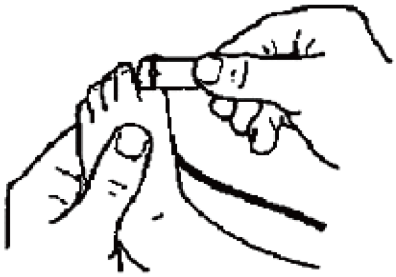
2. Attach the sensor on the foot or finger. The window on the side where the cable comes out should be placed toward the ball of the thumb and the cable should be placed toward the heel.

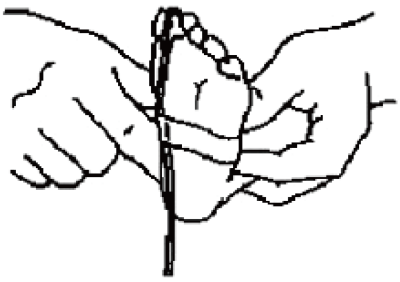


- The best site for attachment is the thumb of the toe. However, it can be attached to other small fingers such as the thumb.
- When choosing a site for the sensor, place it on the side of the foot or finger that is not connected to an arterial catheter, blood pressure cuff, or infusion line.

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.

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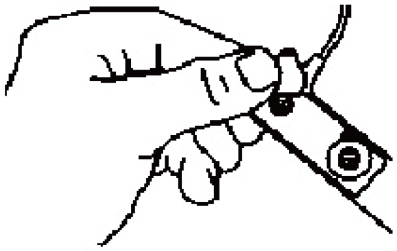


2. **Remove the release paper from the dots.**
   It is now ready to be fitted to the same patient. Do not peel off the previously applied tape, but apply the tape on top of the tape as it is.

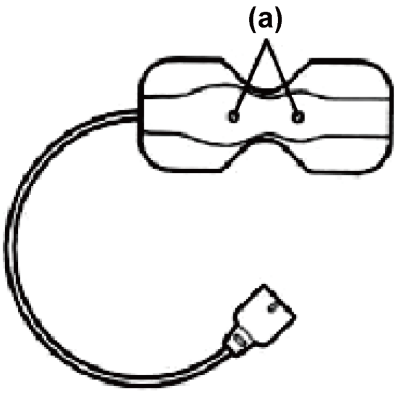
⚠ CAUTION

- 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 SpO_2 readings.

7.4: Attaching MAXP, MAXA, MAXAL

MAXP, MAXA, MAXAL is a sensor for adhesive SpO_2 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.

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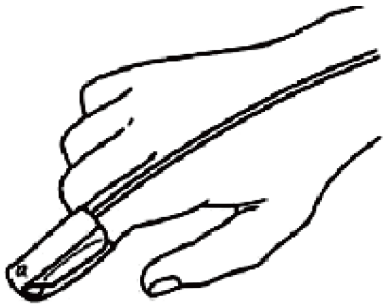
3. **Attach the adhesive flap on the side without the cable to your finger. Ensure that the cables are on the upper side of the limbs.**

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).**

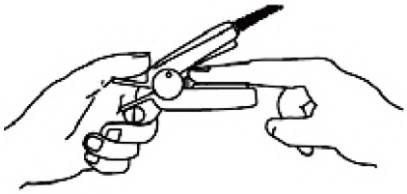
⚠ CAUTION

- 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 SpO_2 readings.

7.5: Attaching DS100A

DS100A is reusable sensor for SpO_2 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.**



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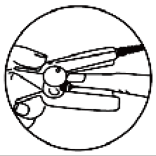
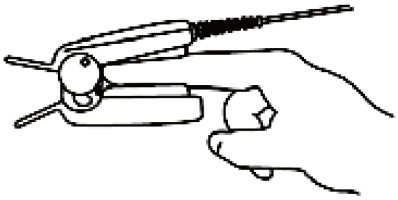
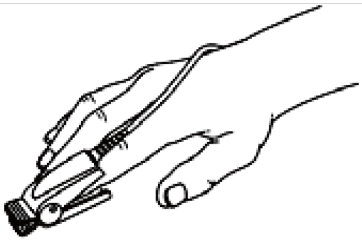
- If the index finger cannot be correctly attached, attach it to another thin finger or use a different Nellcor OXISENSOR III. Do not use this product on thumbs, toes, or the limbs of children.
- When choosing a site for the sensor, place it on the side of the foot or finger that is not connected to 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 Nellcor OXISENSOR III (OXIMAX D-25, OXIMAX D-25L, OXIMAX N-25).
- Do not apply tape over the top to secure it in place. Venous pulsation may occur, resulting in inaccurate oxygen saturation measurements.
- Never use radiation sterilization, high-pressure steam sterilization, or ethylene oxide gas sterilization. There is a risk of sensor damage.

7.6: Attaching MAXR

MAXR is an adhesive SpO_2 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.**

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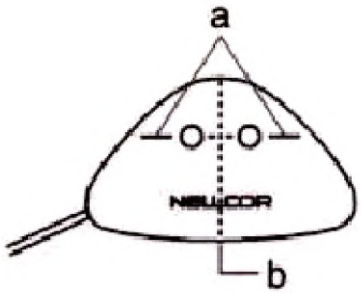
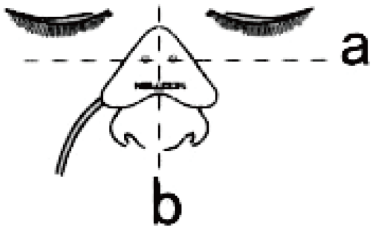
There are two transparent windows on the adhesive side, and the optics are located under these windows. The non-adhesive side has a relative alignment mark (a) and a dotted line (b) in the middle of the two.



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.

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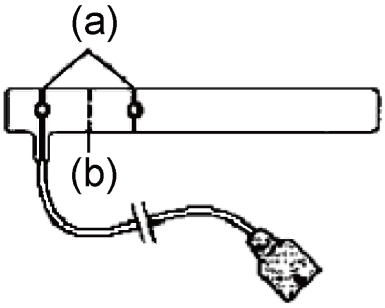
⚠ CAUTION

- 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.

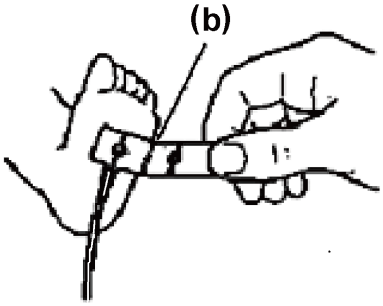
7.7: Attaching MAXN

MAXN is an adhesive SpO_2 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.

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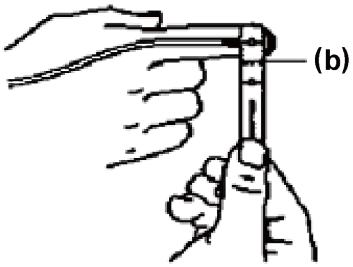


- When choosing a site for the sensor, place it on the side of the foot or finger that is not connected to an arterial catheter, blood pressure cuff, or infusion line.

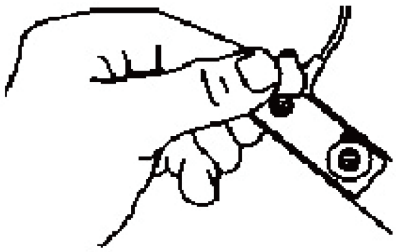
2. **Wrap tightly around the foot or toe, but not too tightly. Make sure the two windows are relative to each other at this time.**

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 SpO_2 readings.

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7.8: MAXFAST

MAXFAST is an adhesive SpO_2 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 SpO_2 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 fontanels 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 MAX-FAST
  - 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).

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⚠ CAUTION

- 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 SpO_2 measurements due to static pulsation. Patients in the supine position may have venous retention, which may result in inaccurate measurements.

7.9: Precautions about SpO_2 Measurement (DS-X1M)

The following is a note on SpO_2 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 be 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.
  - 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 SpO_2 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 SpO_2 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

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⚠ WARNING

- 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 SpO_2 data to monitor apnea condition.
- This device may be used during defibrillation, but this may affect the accuracy or availability of the SpO_2 parameters and measurements.
- This device may be used during electrocautery, but this may affect the accuracy or availability of the SpO_2 parameters and measurements.
- The SpO_2 data cannot be used for arrhythmia analysis.
- SpO_2 is 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

- SpO_2 probe for LX-8300 cannot be used.
- The probe is not waterproof or splashproof. Keep water and chemicals away from the probe.
- Do not lift the device by holding the probe. The probe may come off and the device may fall.
- 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 SpO_2 probes. Accurate measurement may not be possible.
- 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. SpO_2 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.

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⚠ CAUTION

- 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 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.
- 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).

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⚠ CAUTION

- 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 SpO_2 accuracy.
- If an intense light source (e.g., pulsed strobe light) directed toward the sensor, it may not be possible to read the SpO_2.
- 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 SpO_2 even if used with X-Cal compatible devices. In addition, even when using MASIMO sensors or sensors specified by us, SpO_2 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 SpO_2 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 12 hours or 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.
    1. Leaving the sensor off the attachment site for more than two hours
    2. Removing the probe from the main unit of the device
    3. 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 before the status message indicating that sensor's expiration date is approaching appears in the parenthesis.

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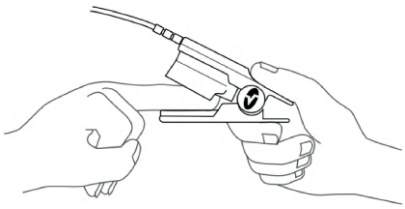
Sensor	Predicted service life for patient measurement	Actual Time of SpO_2Monitoring: 24 hours/day	Actual Time of SpO_2Monitoring: 12 hours/day	Actual Time of SpO_2Monitoring: 8 hours/day
Single Patient Use SpO_2 L Sensor	336 hours (Approx. 302 hours)	14 days (Approx. 12 days)	28 days (Approx. 25 days)	42 days (Approx. 37 days)
Single Patient UseSpO_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)

7.10: Attaching LNCS DCI

LNCS DCI and RD DCI are reusable sensors for SpO_2 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.

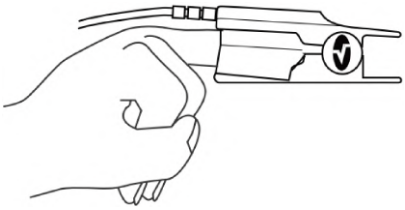
1. **Before attaching the sensor, wipe off any dust or dirt from the attachment site and dry it well.**

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.

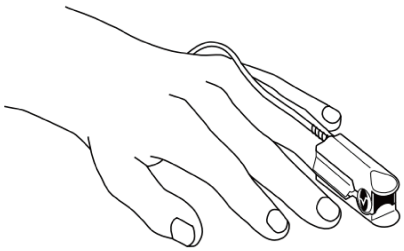


- The ring finger on the opposite side of the dominant hand is the recommended attachment point. Other fingers and toes on the opposite side of the dominant hand can also be used, as long as the sensor receiver can be completely covered.

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).**

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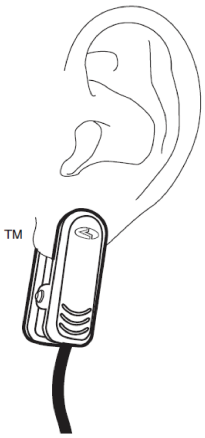
⚠ CAUTION

- 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.

7.11: Attaching LNCS TC-I

LNCS TC-I are reusable sensors for SpO_2 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 to 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.

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⚠ CAUTION

- 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.

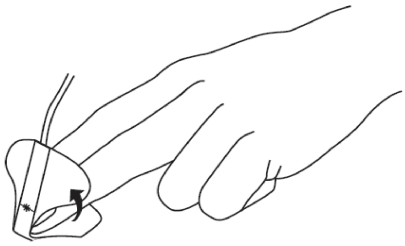
7.12: Attaching LNCS Adtx, LNCS Pdtx, RD Adt and Rd Pd

LNCS Adtx, LNCS Pdtx, RD Adt, and Rd Pdt are adhesive sensors for SpO_2 measurement.

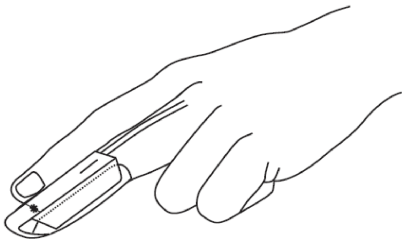
LNCS Adtx and RD Adt are sterilizable sensors for adult patients weighing more than 30 kg, and LNCS Pdtx and RD Pdt are sterilizable sensors for pediatric patients weighing 10 to 50 kg, and cannot be used on patients with significant body motion or for prolonged use.

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

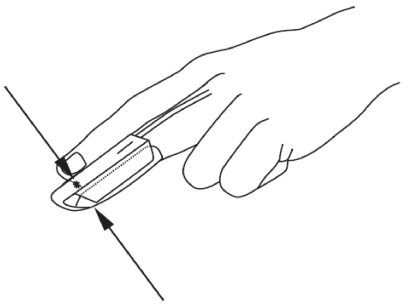
2. **Place the tip of the finger on the dotted line so that the sensor's light-receiving area is completely covered. Attach the adhesive flap on the side without the cable to your finger. At this time, place the cable above the limbs.**



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.**



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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.

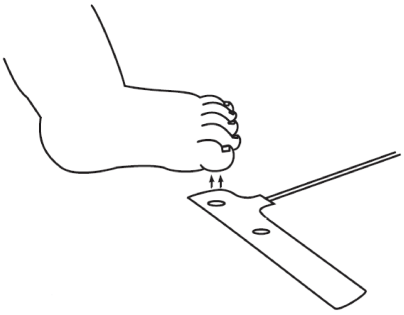
7.13: Attaching LNCS inf-L, LNCS inf-3 and RD Inf

LNCS inf-L, LNCS inf-3, and RD Inf are sensors for adhesive SpO_2 measurement.

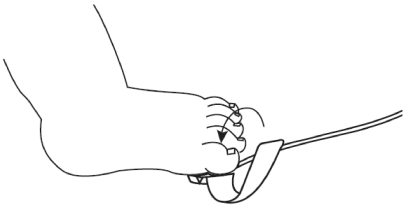
These are sterilizable sensors for use on infants weighing 3 to 20 kg, and not for use on patients with significant body motion or for prolonged periods of time.

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 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.

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⚠ CAUTION

- 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.

7.14: Attaching LNCS Neo-L, LNCS NeoPt-L, LNCS NeoPt3, RD Neo and RD NeoPt

LNCS Neo-L, LNCS NeoPt-L, LNCS NeoPt3, RD Neo, and RD NeoPt are adhesive sensors for SpO_2 measurement.

LNCS Neo-L and RD 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 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.

7.15: Attaching LNCS TFA-1

LNCS TFA-1 is an adhesive SpO_2 measurement sensor.

The LNCS TFA-1 is a transmissive reflective frontal disposable sensor for use on adult and pediatric patients weighing 10 kg or more.

1. **Before mounting the sensor, wipe off any dust or dirt from the mounting area and dry it well. Avoid attaching it on palpable sites with pulsation.**

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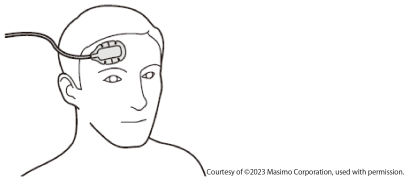
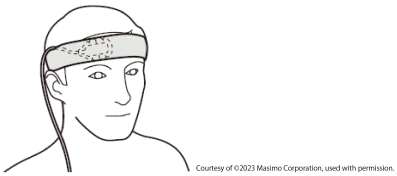
2. Attach the sensor on the patient's forehead. Place it just above the eyebrows, with the centerline aligned with the center of the eyeball.



3. Cover the sensor completely with the headband and attach it securely so that light pressure applies.

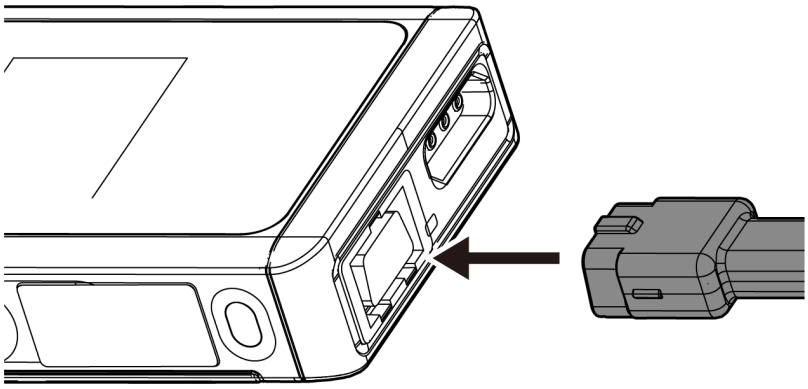
4. Wire above the headband while making sure that the cable will not compress the skin or pull on the sensor.



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).

7.16: Connecting the Transmitter and SpO_2 Probe

1. Connect the SpO_2 probe to the SpO_2 connector of the device.



7.17: Settings on the SpO_2 Display Screen

7.17.1: Playing the Pulse Rate Synchronized Sound

The device can sound the pulse wave synchronization sound in conjunction with the pulse wave level.

1. Press the Left Key on the Home Display.

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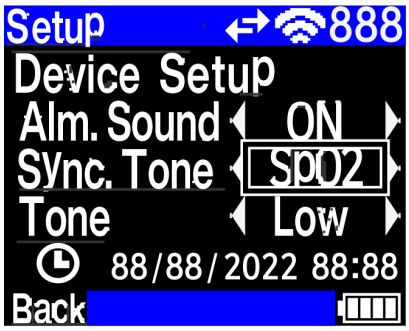
2. In the setting menu, use the Up/Down keys to select [Device Setup] and press the Set key.

3. When the Device Setup screen appears, set "Sync. Tone" to "SpO_2".



7.17.2: Changing the SpO_2 display color

You can change the display color of SpO_2-related parameters. (The initial value is set to "Yellow".)

1. Press the Left Key on the Home Display.

2. In the Setup menu, select [Display Setup] and press the Set key.

3. Change "SpO_2 Color" to the specified color.

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Chapter 8: Monitoring NIBP

BP values measured with the LXN-1000 portable sphygmomanometer can be received via wireless communication using this transmitter to be displayed. Received BP values can be sent to the receiving monitor.

To monitor NIBP, you must pair (initial registration) this device with LXN-1000 in advance.

For instructions on pairing, refer to 2.5.1 Pairing (P.2-7).

⚠ CAUTION

- When pairing is set up, the continuous operation time of the device becomes shorter. If you do not wish to monitor NIBP, cancel the pairing setting.
  For instructions on how to cancel pairing, refer to 2.5.2 Cancel Pairing (P.2-8).
- 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.

While referring to the operation manual of LXN-1000 for settings and procedures related to NIBP measurements, perform the measurements using LXN-1000.

8.1: NIBP Alarm Information Display

If a problem occurs with LXN-1000, such as low battery level or poor communication status, an alarm will be notified to the device.

For details, refer to 11 Troubleshooting (P.11-1).

⚠ CAUTION

- The following receiving monitors are supported.
  - DS-1700: V01-01 and later versions
  - DS-1800: V01-01 and later versions
- For setting instructions, refer to 8.1 NIBP Alarm Information Display (P.8-1).

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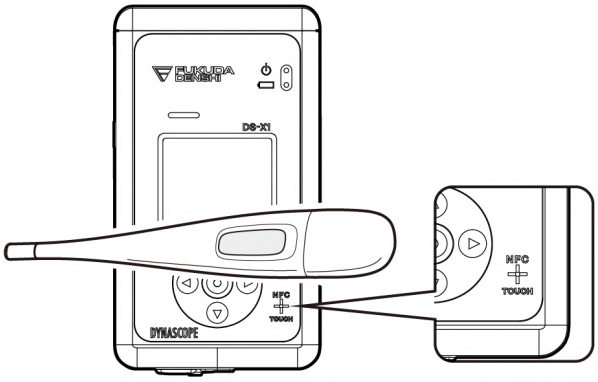
Chapter 9: Monitoring Temperature

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

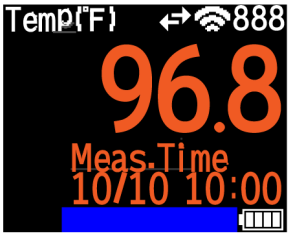
9.1: Acquiring Body Temperature Data

1. **Measure the body temperature using an electronic thermometer specified by Fukuda Denshi. For instructions on measuring body temperature, refer to the operation manual of the electronic thermometer that is used.**

2. **While displaying the waveform/numerical data display screen, position the NFC antenna of the electronic thermometer to touch the NFC antenna of DS-X1.**



3. **When the reading is successful, the measurement value and reading time will be displayed along with a single beep sound.**



4. **If reading fails, several beep sounds will be heard.**

- When touching the thermometer, touch it so that the NFC antenna of the thermometer is aligned with the NFC antenna mark.
- For the location of the NFC antenna of the electronic thermometer specified by Fukuda Denshi, refer to the instruction manual of the thermometer.
- If a thermometer that has already been read is touched again, the value will not be read, and the status message will display [Loaded]. It will not read the value again until a new measurement is taken.
- If the reading fails, the status message will display [Load Failed]. If the reading fails, touch the thermometer again. If the issue persists, contact your nearest service representative.
- The measured body temperature is transmitted to the central monitor for five minutes. After transmission, the acquired value will be reset.

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⚠ 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.

Chapter 10: Setup

For information on how to operate the Setup menu, refer to 3.6 Setup Menu Basic Operations (P.3-6).

10.1: Setup

10.1.1: Patient Setup

The following settings can be changed in Patient Setup.

Item	Description	Setting value	Default	Backup
[Bed ID]	Displays the Bed ID.	001 to 999	000	Yes
[Patient]	Sets the patient classification.	[Adult], [Child], [Neo.]	[Adult]	Yes
[Pacemaker]	Sets whether to use a pacemaker.	[Used], [Unused]	[Unused]	Yes
[Pace. Sens.]	Sets the pacemaker pulse detection sensitivity.	[Low] / [Mid.] / [High]	[Mid.]	Yes

⚠ CAUTION

- The pacemaker sensitivity setting is not available on the screen that is normally used. Devices with changed pacemaker sensitivity should be identifiable by labeling or other means.

Precautions about Pacemaker Sensitivity Setting

When the pacemaker sensitivity setting of the device is set to "Mid.," pacemaker pulses specified in the IEC 60601-2-27:2011, section 201.12.1.101.13 (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 noise, 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 noise.

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 noise. The "Low" setting reduces the detection sensitivity and therefore cannot detect pacemaker pulses as specified in IEC 60601-2-27:2011, section 201.12.1.101.13.

10.1.2: Measurement ON/OFF Setting

The following settings can be changed in the Measurement ON/OFF setting.

Item	Description	Setting value	Default	Backup
[ECG]	Sets the ECG measurement to be ON/OFF.	[ON] / [OFF]	[ON]	Yes

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Item	Description	Setting value	Default	Backup
[RESP]	Sets the RESP measurement to be ON/OFF.	[ON] / [OFF]	[ON]	Yes
[SpO_2]	Sets SpO_2 measurement to be ON/OFF.	[ON] / [OFF]	[ON]	Yes
[NIBP]	Sets the NIBP measurement to be ON/OFF.	[ON] / [OFF]	[ON]	Yes

10.1.3: Measurement Setup

The following settings can be changed in Measurement Setup.

Item	Description	Setting value	Default	Backup
[Arrhythmia Learn]	Configures settings for relearning arrhythmia learning.	[Learn] / [Done]	-	×
[AC Filter]	A filter that removes power line noise from the ECG waveform.	[ON] / [OFF]	[ON]	Yes
[Drift Filter]	A filter that removes only noise without distorting the ECG waveform.	[ON] / [OFF]	[OFF]	Yes
[HR Calc.]	Displays the heart rate calculation method according to the arrhythmia analysis setting in the Admin. Setup.	[Average] / [Arrhythmia]	[Arrhythmia]	Yes
[SpO_2 Mode]*1	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.	[Normal] / [Active]	[Normal]	Yes

*1 This item can only be set for DS-X1N.

10.1.4: Lead/Sensitivity Settings

The following settings can be changed in the Lead/Sensitivity setting.

Item	Description	Setting value	Default	Backup
[ECG Lead]	Sets the ECG display waveform monitoring lead.	[I] / [II] / [III] / [aVR] / [aVL] / [aVF] / [C(V)]	[II]	Yes
[ECG Sens.]	Sets the ECG display waveform sensitivity.	[x4] / [x2] / [x1] / [(x1/2)] / [(x1/4)]	[x1]	Yes
[RESP Lead]	Sets the RESP display waveform monitoring lead.	[I] / [II]	[II]	Yes
[RESP Sens.]	Sets the RESP display waveform sensitivity.	[x1] / [x(1/2)]	[x1]	Yes

10.1.5: Device Setup

The following settings can be changed in Device Setup.

Item	Description	Setting value	Default	Backup
[Notif. Sound]	Sets whether to enable the notification sound.	[ON] / [OFF]	[ON]	Yes
[Sync. Tone]	Sets the waveform that triggers the synchronized sound.	[ECG] / [SpO_2] / [OFF]	[OFF]	Yes
[Tone]	Sets the tone of the synchronized sound.	[Low] / [Mid.] / [High]	[Mid.]	Yes
Time Mark	Sets the time/date of the device.	MM/DD/YYYY 88:88	01/01/2022 00:00:00	Yes

10.1.6: Display Setup

The following settings can be changed in Display Setup.

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Item	Description	Setting value	Default	Backup
[Brightness]	Sets the brightness of the device.	1 to 8	5	Yes
[Disp. OFF]	Sets the time it takes for the screen to turn off when no operation has been performed.	[1min] / [3min] / [10min] / [None]	[3min]	Yes
[SpO_2 Display Color]	Sets the SpO_2 display color.	[Yellow] / [Blue]	[Yellow]	Yes

10.1.7: Central Comm.

The following settings can be changed in Central Comm.

Item	Description	Setting value	Default	Backup
[Function Setup]	Sets the function to assign to the function key.	[None] / [Print] / [Alarm Suspend]	[None]	Yes
[Link Alarm Suspend]	Sets whether to link the Notification Sound OFF function with the Suspend Alarm function of the central monitor.	[ON] / [OFF]	[OFF]	Yes
[NW ID]	Sets the network ID.	0 to 999	-	Yes

10.1.8: Network Setup

The following settings can be changed in Network Setup.

Item	Description	Setting value	Default	Backup
[Auto Get IP]	Sets whether to obtain an IP address automatically.	[ON] / [OFF]	[ON]	Yes
[Registered SSID]	Displays the registered SSID.	-	-	-
[Encryption Key]	Displays the encryption key.	-	-	-
[Security]	Displays the security information.	-	-	-
[IP Address]	Displays the IP address assigned to the device.	-	-	-
[Subnet Mask]	Displays the subnet mask setting value.	-	-	-
[Default Gateway]	Displays the default gateway settings.	-	-	-
[MAC Address]	Displays the MAC address of the device.	-	-	-

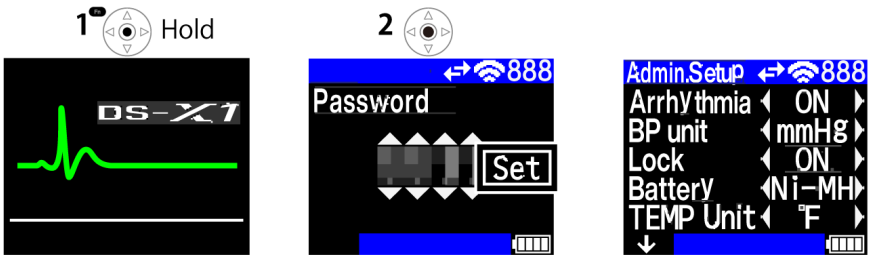
- If you want to change these settings, please speak to our service representative.

10.2: Admin. Setup

In the Admin. Setup, important settings related to device operations such as setting initialization and password setup are performed.

To access Admin. Setup, perform the following steps.

1. **Press and hold the Set key and function key at the same time immediately after powering on.**
2. **Enter your password when the password entry screen appears.**



Admin. Setup includes the following items.

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Item	Description	Setting value	Default	Backup
[Arrhythmia]	Sets whether to perform arrhythmia analysis.	[ON] / [OFF]	[ON]	Yes
[BP unit]	Sets the blood pressure display unit.	[mmHg] / [kPa]	[mmHg]	Yes
[Lock]	Sets whether to require a password when switching screens.	[ON], [OFF]	[ON]	Yes
[Battery]	Sets the type of battery that is used.	[AA] / [Ni-MH] / [Li-ion]	[Li-ion]	Yes
[TEMP Unit]	Sets the body temperature display unit.	[°C] / [°F]	[°C]	Yes
[Region]*1	This is a setting function for service representatives.	-	-	Yes
[AC Freq.]	Sets the AC power frequency.	[50 Hz] / [60 Hz]	[50 Hz]	Yes
[Change Password]	Changes the password of the device.	4 digits	*2	Yes
[Version]*1	This is a setting function for service representatives.	-	-	Yes
[Initialize Meas. Data]	Initializes full disclosure waveform data.	-	-	-
[Initialize Network]	Initializes network settings.	-	-	-
[Initialize Setup]	Initializes the setting data.	-	-	-
[Factory Default]	Initializes all data on the device.	-	-	-

*1 Please refrain from making adjustments as these settings do not require any customer input.

*2 Contact your nearest service representative.

- If you want to change these settings, please speak to our service representative.

10.2.1: Arrhythmia Settings

You can set whether to perform arrhythmia analysis.

⚠ CAUTION

- When enabling arrhythmia analysis, please update the admission and discharge processes on the receiving monitor to refresh the information.

10.2.2: BP Unit Settings

Select the blood pressure display unit from "mmHg" and "kPa".

10.2.3: Body Temperature Unit Settings

Select the display unit for body temperature from "°C" and "°F".

10.2.4: Lock

You can set whether to display the password entry screen when transitioning to the settings screen or alarm setting screen.

10.2.5: Changing the Battery Settings

Set the type of battery used to calculate remaining battery power.

The initial value is set to "Li-ion"

⚠ CAUTION

- Use the same type of battery as set in the battery settings. If a battery that does not match the battery setting is used, the device will not display the correct battery level.
- When using a battery different from the one set in the battery settings, the indication for battery level 1 may appear sooner or later than usual. In addition, the operating time becomes shorter or longer than usual after the level 1 symbol of the battery level appears.

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- The notation displayed in the setting items and the types of batteries are as follows.
  - Alkaline battery: AA
  - Nickel metal hydride battery: Ni-MH
  - Lithium-ion battery: Li-ion

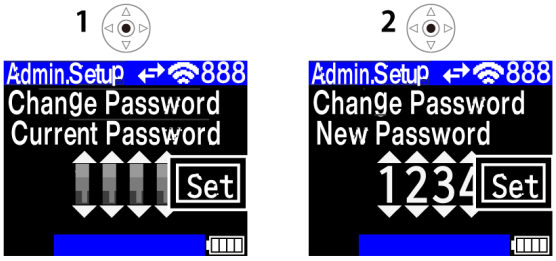
10.2.6: AC Filter Settings

By setting the AC frequency according to the environment in which this device is used, noise originating from the commercial power source can be reduced.

10.2.7: Change Password

You can change the password set on the device.

1. **After entering the current password, select [Set] and press the Set key.**
2. **After entering the new password, select [Set] and press the Set key.**



10.2.8: Initialize Meas. Data

Initializes full disclosure waveform data stored in the device.

10.2.9: Initialize Network

Initializes network settings set in the device.

10.2.10: Initialize Setup

Initializes the setting data of the device.

10.2.11: Factory Default

Initializes all data stored on the device.

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Chapter 11: Troubleshooting

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

11.1: Abnormality of the device itself

Phenomenon	Measure
Nothing is displayed on the indicator when the power is turned on	• Check the condition of the batteries and attach them correctly. 2.1 Installing Batteries (P.2-1) • 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	• Check the status of the wireless LAN. 2.4 Checking the Wireless LAN Connection (P.2-6) • If you do not have a wireless LAN connection, check the wireless LAN settings. 10.1 Setup (P.10-1)
Poor reception	• Check the setup environment of the wireless LAN access point and consider repositioning or expanding its coverage. • Device failure is likely. Contact our service representative.

⚠ CAUTION

- If an abnormality is detected in the device, the following system error message will be appear. Stop using the device and contact your nearest service representative.

Message	Measure
[Chk. NIBP Comm.]	• Please check the status of connection with LXN-1000. • Device failure is likely. Contact our service representative.
[Chk. Central]	• If this message appears, the device may be malfunctioning. Contact our service representative.
[Battery Error]	• Check if you are using the specified battery. • If this message appears while the device is using the specified battery, it may be malfunctioning. Contact our service representative.
[NW Error(XXX)]	• Device failure is likely. Contact our service representative.
[Error(XXX)]	• Device failure is likely. Contact our service representative.

11.2: 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.

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If an abnormality is detected in the electrode attachment, the following message appears on the screen.

Message	Measure
Lead OFF	• Referring to the electrode guide screen, check the condition of the electrodes and attach them correctly. • Check the connection between the patient cable and the device. • Check the connection between the patient cable and the electrode. • Replace with a new patient cable. • Replace with a new electrode.

11.3: Abnormal SpO_2

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.
[Probe OFF] appears.	• Check the probe attachment status. • Use the specified probe. • Replace the probe.
[Chk. Sensor] [No Pls. Detect] appears.	• Check the sensor attachment status. • Block out ambient light to prevent outside light from entering. • Use the specified probe. • Replace the probe.
[Near Sens. Life] appears.	• Replace the probe.
[Replace Sensor] appears.	• Replace the probe.
[Chk. Cable] appears.	• Check the connection status with the relay cable. • Replace the relay cable.
[Near Cable Life] appears.	• Replace the relay cable.
[Replace Cable] appears.	• Replace the relay cable.
[Moving] appears.	• Maintain a resting posture.
[Low Perfusion] appears.	• Check that the LED light emitting and receiving parts of the sensor are aligned in a straight line.
[Pls. Search] appears.	• Maintain a stable posture.
[Low SIQ] appears. (Only DS-X1M)	• Check the sensor attachment status. • Maintain a stable posture.

11.4: Abnormal NIBP

Message	Measure
[Chk. NIBP Comm.] appears.	• Please check if pairing with LXN-1000 is established. • Communication with LXN-1000 has failed. Please check the status of communication.
[Chk. NIBP Batt.] appears.	• Please check the battery level of LXN-1000. • Replace the battery of LXN-1000.

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Message	Measure
[Chk. NIBP Stat.] appears.	• There is a measurement error on LXN-1000. Please check LXN-1000.
The pairing icon blinks	• The pairing icon blinks during pairing with the LXN-1000 and when a communication error occurs. When communication is stable, it will switch to the lit state.

11.5: 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 SpO_2 probe, but clean the device with them attached. After cleaning, wipe off moisture well and remove the cardiac patient cable and SpO_2 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.

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Chapter 12: Maintenance

12.1: Charging Batteries

Charging Lithium-ion Batteries

When charging lithium-ion batteries, use the designated AC adapter for charging.

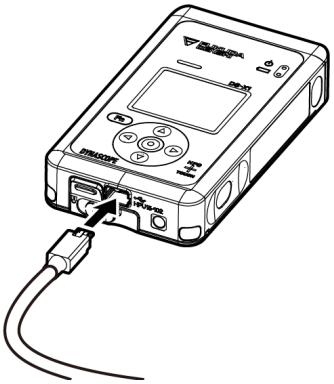
While charging, the device's charging LED lights up orange. When charging is complete, it lights up green.

⚠ CAUTION

- If charging is attempted without the battery installed, the charging LED will blink orange. Stop charging, install the battery, and then try charging again.

⚠ WARNING

- If the charging LED blinks orange even when a battery is properly installed, or if any abnormality is found on the device, immediately turn off the power, and disconnect the AC adapter from the outlet.
- Do not charge the device if the main unit or USB connector is wet.
- Install this device in a place where the AC adapter can be easily disconnected.



- The optional battery charger (RRC-SCC1130) allows you to charge spare batteries or batteries removed from the device.
  For details, please refer to the battery charger's operation manual.

Charging Nickel Metal Hydride Batteries

When charging nickel metal hydride batteries, ensure you have detached the battery from the device and use a charger specifically designed for nickel-metal hydride batteries.

⚠ WARNING

- When using nickel metal hydride batteries, do not connect the AC adapter to the USB connector. Doing so may cause leakage or damage.

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12.2: Cleaning/Disinfecting

Clean and disinfect the device, ECG cable, and SpO_2 probe as follows.

⚠ CAUTION

- This device, ECG cables, and SpO_2 probes are not sterilizable and should not be sterilized in any way.
- Before cleaning or disinfecting, remove the device from the patient and ensure that the battery is removed. Failure to do so may cause malfunction.

12.2.1: 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 SpO_2 probe, but clean the device with them attached. After cleaning, wipe off moisture well and remove the cardiac patient cable and SpO_2 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.

12.2.2: 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, they 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.

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12.2.3: 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 the residue cannot be removed by wiping, use a commercially available air duster or adhesive cleaner to remove it.

⚠ 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.

12.2.4: Cleaning the Silicon Cover

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

12.2.5: 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 let it 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.

12.3: 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 technical information on this product, 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.

12.3.1: Daily Inspection

Perform daily inspections according to the daily inspection list.

12.3.2: Periodic Inspection

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

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Periodic inspection may be performed by the medical institution or by a third party by concluding a maintenance contract.

Contact our service representative for details.

12.3.3: Periodic Replacement Parts

To maintain the safety, functionality, and reliability of this device, there are components that need periodic replacement.

When replacing them, contact your nearest service representative.

Item	Model Type	Replacement Period
DS-X1 Battery cover unit	OAT-X1A	1 year (to maintain waterproof performance, IPX8)
Battery Cover	OAT-10X1A	1 year (to maintain waterproof performance, IPX8)
Lithium-ion Battery	RRC1130	300 charges/discharges or one year of usage, whichever comes first

⚠ CAUTION

- The periodic replacement parts must be replaced at the specified period.

12.3.4: Daily Check Items and Procedures

Make sure to perform a daily check.

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 12.2 Cleaning/Disinfecting (P.12-2).	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	Battery compartment	Visually check the condition of the battery cover or battery cover packing.	There should be no scratches, kinks, loose parts, or debris.
		Visually check the inside of the main unit, the battery, and each battery terminal.	Ensure there are no deformities in the battery, any deformation, warping, corrosion, etc., in each battery terminal.

3. Operation

No.	Check Items	Check Procedure	Criteria
01	Power Supply	Turn the power switch ON/OFF and check the operation of the switch.	The display should light when the power is turned on.
02	ECG connector	Visually inspect the main unit and the plug part of the patient cable.	There should be no defects or chips. There should be no debris.
03	Patient cable	Visually check the wire coating part of the patient 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.

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No.	Check Items	Check Procedure	Criteria
05	Charging (during battery usage)	Install the battery into the main unit, and check the charging operation.	Check that the battery charging LED is lit. While charging: Orange, Fully charged: Green, Charging stopped: Off
06	Alarm Indicator	Check the lighting operation of the alarm indicator from the "Maintenance screen".	It should light with the color of each level.
07	Notification Sound	Check the generation of the notification sound from the "Maintenance screen".	The alarm sound should be generated from the buzzer.
08	Send/Receive 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.
		Switch the lead/sensitivity on the receiving monitor and check the operation with this device.	The lead/sensitivity switches. (Revert the settings after changing the sensitivity)
09	Display function	Turn on the device and check the SpO_2 value, bar graph, and various display conditions.	The display for each display item should be normal for the corresponding condition.

4. Other

No.	Check Items	Check Procedure	Criteria
01	Periodic Replacement Parts	Check the service life of the battery cover or cell cover.	Should be within one year.
		Check the number of charging/discharging times or the first usage date of the RRC1130 lithium-Ion battery.	The number of charging/discharging times should not exceed 300 times, or usage duration should not exceed 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.	Accompanying documents (operation manual, etc.) are available for prompt reference.

12.3.5: Periodic Inspection Items and Procedures

Periodic inspections should be conducted at specified intervals.

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 12.2 Cleaning/Disinfecting (P.12-2).	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	Label	Visually check the rating label of the device.	There should be no peeled, stained or unclear areas.
03	Battery compartment	Visually check the condition of the battery cover or battery cover packing.	There should be no scratches, kinks, loose parts, or debris.
		Visually check the inside of the main unit, the battery, and each battery terminal.	Ensure there are no deformities in the battery, any deformation, warping, corrosion, etc., in each battery terminal.
04	Cables	Check that none of the cables have damage or broken wires.	There should be no damaged or broken wires.
		Check that the connection is smooth and secure.	Should be securely connected.
05	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

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No.	Check Items	Check Procedure	Criteria
01	Power Supply	Turn the power switch ON/OFF and check the operation of the switch.	The display should light when the power is turned on.
02	Charging (during battery usage)	Install the battery into the main unit, and check the charging operation.	Check that the battery charging LED is lit. Fully charged: Green (lit), Charging: Orange (lit), Charging error: Orange (blinking), Charging stopped: Off
03	Battery operation (when using batteries)	After charging the battery, unplug the AC adapter, and change to battery operation.	Check that the battery-operating condition is as specified on the operation manual.

4. Display/Operation/Sending/Receiving

No.	Check Items	Check Procedure	Criteria
01	Operation, Switch	Confirm by operating the keys.	Should operate correctly.
02	LCD	Check that the home display is displayed on the LCD.	Characters and waveform should be clear. The display should be clearly displayed with sufficient brightness.
03	Alarm Indicator	Check if the alarm indicator lights when the power is turned on.	Should light when the power is turned on.
04	Notification Sound	Confirm by performing a notification sound test from the maintenance screen.	The volume should be appropriate and there should be no beat noise.
05	Display Date	Hold the Down key to check the year, month, day, and time on the display.	The year, month, day, and time should be correctly displayed.
06	Bluetooth Communication (when using LXN-1000)	Pair using LXN-1000.	The measurement screen of LXN-1000 should be displayed on this device.
07	Sending 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.
08	Receiving Function	Switch the lead/sensitivity on the receiving monitor and check the operation with this device.	The lead/sensitivity should switch (revert the settings after changing the sensitivity)

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 main unit with a waveform size of x1.	The amplitude of the displayed waveform should be within 10 mm ± 1 mm.
02	Heart Rate Display Accuracy	Set the heart rate to 60 bpm on the simulator, and check the displayed heart rate on the main unit.	The displayed heart rate should be within 60 bpm ± 3 bpm.
03	Lead OFF	Remove each electrode from the simulator and check that "Lead OFF" message is displayed.	The "Lead OFF" message for the removed electrode should be displayed. ること。

6. Respiration (impedance measurement)

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 main unit. Baseline Impedance:1500Ω, Detection Lead: II (LL), Respiration Waveform: Normal, Amplitude: 1 Ω	The displayed RR should be within 20 bpm ±3 bpm.

7. SpO_2

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 main unit.	The displayed oxygen saturation value should be within 90% SpO_2 ± 2%.

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No.	Check Items	Check Procedure	Criteria
02	Pulse Rate Display Accuracy	Input the pulse rate signal of 60 bpm from the simulator, and check the displayed HR value on the main unit.	The displayed heart rate should be within 60 bpm ± 3 bpm.

8. Periodic Replacement Parts

No.	Check Items	Check Procedure	Criteria
01	Battery Cover	Check the service life of the battery cover and the cell cover.	Should be within one year
02	Lithium-ion Battery	Check the number of charging/discharging times or the first usage date of the RRC1130 lithium-Ion battery.	The number of charging/discharging times should not exceed 300 times, or usage duration should not exceed one year.

9. Electrical Safety Test

No.	Check Items	Check Procedure	Criteria
01	Contact Current (NC)	Measure the contact current under normal conditions using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	Contact Current (NC) ≦ 100 μA
02	Patient Leakage Current (NC)	Measure the patient leakage current under normal conditions using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	[AC/DC] Type CF Applied Part Patient Leakage Current (NC) ≦ 10 μA
03	Patient Leakage Current (SFC)	Measure the patient leakage current under single fault conditions using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	Type CF Applied Part Patient Leakage Current (SFC) ≦ 50 μA
04	Total Patient Leakage Current (NC)	Measure the total patient leakage current under normal conditions using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	[AC/DC] Type CF Applied Part Patient Leakage Current (NC) ≦ 50 μA
05	Total Patient Leakage Current (SFC)	Measure the total patient leakage current under single fault conditions using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	Type CF Applied Part Patient Leakage Current (SFC) ≦ 100 μA
06	Patient Auxiliary Current (NC)	Measure the patient auxiliary current (NC) under normal conditions using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	[AC/DC] Patient Auxiliary Current (NC) ≦10 μA
07	Patient Auxiliary Current (SFC)	Measure the patient auxiliary current (SFC) under a single fault condition using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	Patient Auxiliary Current (SFC) ≦ 50 μA

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Chapter 13: 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.

13.1: Medical Device

Device Name	Model	Type
DS-X Series ECG, Respiration and SpO_2 Transmitter DS-X1System	DS-X1	DS-X1N
		DS-X1M

13.2: Accessories

Device Name	Model	Note
Battery Cover Unit for DS-X1	OAT-X1A	-
Silicone Case for DS-X1	ABT-X1C	-
Neck Strap	OAT-03A	-
Disposable Portable Case	ABT-720D	-
AC Adapter	HPU15-102	-
Lithium-ion Battery	RRC1130	Periodic replacement parts Nominal capacity:3.81 Ah Periodic replacement:Every two years
Battery Charger	RRC-SCC1130	-
DSLAN GW	DSLAN GW	-

ECG Sensors

Device Name	Model	Note
Patient Cable CMO-N series	CMO-03NTG-0.9A	For 3-electrode
	CMO-04NTG-0.9A	For 4-electrode
	CMO-05NTG-0.9A	For 5-electrode
ECG Relay Cable CIO-13DIN series	CIO-13DIN3-2.7A	For 3-electrode

13.3: The other medical device

SpO_2 Sensors （Medtronic）

Device Name	Model	Remark	Attachment 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
Pediatric SpO_2 Sensor	MAXP	Children (weighing 10 to 50kg)	Finger	45cm

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Device Name	Model	Remark	Attachment site	Cable Length
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

SpO_2 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 50kg Masimo PN:1860	Finger, toe	Approx. 45cm
Pulse Oximeter Adhesive Sensor	LNCS Inf-L	Infants weighing 3 to 20kg 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 20kg 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 the DS-X1M.

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 50kg Masimo PN:4001	Finger, toe
Pulse Oximeter Adhesive Sensor	RD SET Inf	Infants weighing 3 to 20kg Masimo PN:4002	Thumb, thumb toe
Pulse Oximeter Adhesive Sensor	RD SET Neo	Neonates weighing less than 3kg Masimo PN:4003	Hands, feet

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Device Name	Model	Remark	Attachment site
		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

Blood Pressure Monitor

Device Name	Model	Remark	Length
LX-1000 Series Non-Invasive Blood Pressure Monitor LXN-1000	LXN-1000	LXN-1000	-

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	-

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Chapter 14: Specifications

⚠ CAUTION

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

14.1: Basic specifications

Main Unit

Item	Specifications
External dimensions (not including the protrusion)	68 (W) × 120 (H) × 23 (D) mm
Weight (not including the battery)	Approx.150 g
Transmitting Waveform	ECG 5ch (selected by patient cable), respiratory waveform, SpO_2 value, pulse waveform
Applicable ECG Patient Cable	3-electrode, 4-electrode, 5-electrode (limb, chest), insert the patient cable for automatic recognition
Transmission status data	ECG electrode misalignment, low battery voltage, event key, pacemaker, SpO_2, vital alarm, equipment status alarm
Display Unit	160×128 dot
Dust proof/waterproof performance	IPX8 (annual periodic maintenance required)
Power Supply	The device can operate on the dedicated lithium-ion battery, 3 AA alkaline batteries or 3 AA nickel-hydrogen batteries. DC5V (when using the dedicated AC adapter)
Continuous use time*1	DS-X1M: 20 hours
	DS-X1N: 20 hours
Operation mode	Continuous operation
Service life	6 years (according to self-certification)

*1 The continuous use time assumes using the new, fully charged specified AA alkaline battery, new, fully charged AA nickel-hydrogen batteries, or new, fully charged lithium-ion batteries.
Usage conditions: ECG measurement, RESP measurement, SpO_2 measurement, pairing off, equipment settings in default state, operating environment temperature at 23°C (operating time may be shorter depending on usage environment).

AC Adapter

Item	Specifications
Power Supply	Voltage: AC100 - 240V
	Frequency: 47 - 63Hz
	Input current: 0.4 - 0.2A
	Output voltage: 5V ±5%
	Output Current: 2.4A
Safety	Dust proof/waterproof performance: IP22
	Expected Service Life: 6 years (according to self-certification)

14.2: ECG

Item	Specifications
Number of lead electrodes	3-electrode, 4-electrode, 5-electrode (limb+ chest)
Number of input channels	5ch (depending on the number of electrodes in the patient cable)
Accuracy of sensitivity	Satisfies IEC 60601-2-27:2011 section 201.12.1.101.1 (within ±20% or 100 µV, whichever is greater)
Cardiac input impedance	Satisfies IEC 60601-2-27:2011 201.12.1.101.3 (2.5 MΩ or higher)

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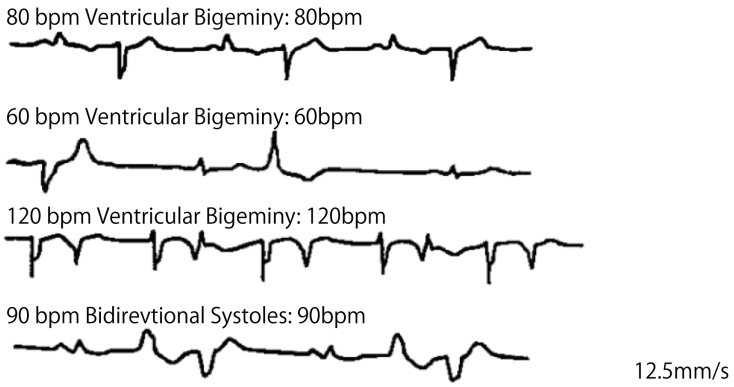
Item	Specifications
Input dynamic range and offset voltage	Satisfies IEC 60601-2-27:2011 201.12.1.101.2 (Input dynamic range: 10 mVp-p) (Offset voltage: ±825mV)
Common Mode Rejection Ratio	Satisfies IEC 60601-2-27:2011 201.12.1.101.10 (90 dB or higher)
Detecting heart rate	Satisfies IEC 60601-2-27:2011 201.12.1.101.15 (Heart rate measurement accuracy: ±10% or ±5 bpm, whichever is greater or less. However, the heart rate measurement range and heart rate measurement accuracy are as follows) Patient Category of Adult and Pediatric periods: 0.12 to 300 bpm Patient Category of neonate period: 0.30 to 300 bpm
Heard Rate Display Range	Patient Category of Adult and Pediatric periods: 0, 12 to 300 bpm (1 bpm steps) Patient Category of neonate period: 0, 30 to 300 bpm (1 bpm steps)
Frequency Characteristic	Patient Category of Adult and Pediatric periods: 0.5 to 40 [Hz] Patient Category of neonate period: 1.6 to 40 [Hz]
Pacemaker Pulse Detection	Compliant with IEC 60601-2-27:2011 201.12.1.101.13 (0.1 to 2 ms width, ±2 to ±700 mV amplitude pulse width, applicable only to pacemaker pulses with no overshoot/undershoot)
Defibrillation Proof	Satisfies the requirements of IEC 60601-2-27
Time Constant	Within 0.4 seconds ±25%
Lead-off detection current	1 uA or less
Average Heart Rate	Patient Category of Adult and Pediatric periods: Heart rate over 6 seconds Patient Category of neonate period: Heart rate over 4 seconds
Response time of heart rate meter to change in heart rate	HR change from 80 bpm to 120 bpm: Range 6 to 11 seconds HR change from 80 bpm to 40 bpm: Range 6 to 11 seconds
T-wave rejection capability	1.2 mV T-wave can be rejected when tested according to IEC 60601-2-27.
Sweep Speed	12.5 mm/s
Heart rate meter accuracy and response to irregular rhythm	

- This device does not comply with IEC 60601-2-27:2011, clause 201.12.1.101.8.

14.3: Respiration (Impedance method)

Item	Specifications
Accuracy of sensitivity	10 mm / within 1Ω ±2 mm (at a basic impedance of 480Ω)
Respiration rate display range	0,4 to 150 bpm
Respiration rate display error	Within 3 bpm
Measured Current of Respiration	100 µA or less (35 kHz to 56 kHz)

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14.4: SpO_2

Medtronic SpO_2 Unit

- The accuracy of the SpO_2 measurement is determined based on the mean square of the difference between the CO-oximeter measurements taken simultaneously in healthy adult volunteers. Since SpO_2 measurements are statistically distributed, a measurement accuracy of ±2% means that approximately 68% of people fall within ±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.)

Item	Specifications
SpO_2 measurement range:	1% 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 (±1SD)
MAXI	Within ±2% SpO_2
MAXP	Within ±2% SpO_2
MAXA	Within ±2% SpO_2
MAXAL	Within ±2% SpO_2
DS100A	Within ±3% SpO_2
MAXR	Within ±3.5% SpO_2
MAXN	Within ±2% SpO_2
MAXFAST	Within ±2% SpO_2

(When SpO_2 is 70% to 100%. Not specified for values less than 70%)

Item	Specifications
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

Item	Specifications
Measurement value update rate	1 sec.
Measurement response time	4 to 7 seconds (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.

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Masimo SpO_2 Unit

- SpO_2 Clinical Trials
  - The SpO_2 and pulse rate measurement accuracy have been validated for each range by testing on healthy adult male and female volunteers against a laboratory CO-Oximeter.
    The SpO_2 accuracy has been validated for the range from 70% to 100% by testing on healthy adult male and female volunteers with light to dark skin pigmentation. Without body motion, the standard deviation is ±2% which encompasses 68% of the population. With body motion, the standard deviation is ±3% which encompasses 68% of the population. 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.

Item	Specifications
SpO_2 measurement range:	1% to 100% SpO_2
Resolution	1% SpO_2
Measurement accuracy	Without body motion • Adults and children: ±2% SpO_2 or less at 70-100% SpO_2 • Neonates: ±3% SpO_2 or less at 70-100% SpO_2 With body motion • Adults and children: ±2% SpO_2 or less at 70-100% SpO_2 • Neonates: ±3% SpO_2 or less at 70-100% SpO_2
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)

14.5: Pulse rate

Medtronic SpO_2 Unit

Item	Specifications
Pulse Rate Measurement Range	20 bpm to 250 bpm
Measurement accuracy	Without body motion: ±3 bpm With body motion: ±5 bpm

Masimo SpO_2 Unit

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

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14.6: PI (perfusion index)

Masimo SpO_2 Unit

Item	Specifications
Measurement Range	0.02% to 20.00%
Measurement Resolution	0.01%

14.7: Communication method, etc.

Item	Specifications
Supported Standards	WLAN (IEEE802.11a/b/g/n/ac) BlueTooth (Bluetooth 4.2) NFC (Protocols: NFCIP1, NFCIP-2, NFC-A, NFC-B, NFC-F, NFC-V) (Reader/writer mode: Type 1 to 5) (Card emulation mode: T4T-ISO/IEC 14443A, T4T-ISO/IEC 14443B, NFC FORUM-T3T)
Frequency	2412 MHz to 2472 MHz (WLAN) 2402 MHz to 2480 MHz (Bluetooth) 5150 MHz to 5250 MHz (WLAN) Not available for outdoor use 5250 MHz to 5350 MHz (WLAN) Not available for outdoor use 5470 MHz to 5725 MHz (WLAN) Available for outdoor use 13.56 MHz (NFC)
Aerial power	WLAN: 18 dBm (Max.) Bluetooth: 10 dBm (Max. for Class1 BR)
Laws and regulations	FCC Part 15 Subpart C FCC Part 15 Subpart E FCC Part 2.1093 UDI Directive

14.8: Federal Communications Commission (FCC) Statement

15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

15.19

This device complies with Part 15 of the FCC Rules.

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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.

15.21

You are cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. For portable operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines.

14.9: Safety

Item	Specifications
General Safety Standard	ANSI/AAMI ES 60601-1: 2005/A2: 2021 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance)
EMC Standard	IEC 60601-1-2 Edition 4.1:2020 Medical electrical equipment - part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - requirements and tests.
Protection against electrical shock	Class II Equipment (when using AC adapter) Internally Powered Equipment (when using battery)
Classification of attachment sites by degree of protection against electric shocks	Type CF application site

14.10: Operating Environment

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

The primary purpose is to continuously transmit biometric data wirelessly such as patient ECGs, respiratory waveforms, arterial oxygen saturation (SpO_2), and pulse waveforms to a monitoring unit in operating rooms in medical facilities, intensive care units, wards, and treatment rooms.

Do not use in an MRI environment or in a home-care setting.

The power source should fulfill the following condition.

- Verify the power voltage and frequency before connecting to an AC power source.

Pay attention to install or store the device in a proper location. Do not install or store in the following locations.

- Where chemicals are stored or gas may be generated
- Where the device will be subject to splashing water or humidity from a nebulizer or vaporizer
- Where the device will be subject to direct sunlight
- An unstable place e.g., where there is inclination, vibrations, or shocks

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⚠ WARNING

- If the device is used in an environment that does not fulfill the above conditions, not only will the device be unable to deliver its maximum performance, it may also be damaged and safety cannot be ensured.
  If using it in an environment other than as specified above, contact your nearest service representative.

14.11: Transport and storage environment

Item	Specifications
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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