6. SpO_2 Monitoring

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

⚠WARNING

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

⚠CAUTION

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

■Preparation for Monitoring

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

⚠WARNING

- For SpO_2 monitoring, always use the sensor specified by Fukuda Denshi. Also, check the probe before usage to make sure that it is the specified probe. If unspecified probe is used, not only that the equipment cannot deliver its maximum performance, the equipment may be damaged and safety cannot be ensured.
- As with all medical equipment, carefully route cables to reduce the possibility of patient entanglement and strangulation.
- Do not place this equipment or accessories in any position that might cause it to fall on the patient.
- Do not start or operate this equipment unless the setup was verified to be correct.
- Do not operate this equipment in magnetic resonance imaging (MRI) environments.

6. SpO_2 Monitoring

⚠WARNING

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

⚠WARNING

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

⚠CAUTION

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

⚠CAUTION

the active irradiation period.

- Variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.
- Do not submerge this equipment in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage this equipment.
- Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked in compliance with IEC 60601-1. When an event such as a component drop or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.
- Disposal of product - Comply with local laws in the disposal of the equipment and/or its accessories.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to this equipment.
- Replace the sensor when a <Bad Sens> message is consistently displayed while monitoring patients even after following the troubleshooting steps explained in this manual.

NOTE

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

NOTE

- Precautions about the Masimo Sensors

  A technology called X-Cal for patient safety and reinforcement of efficiency in a clinical site is implemented for Masimo sensors. X-Cal is designed to address the following three common factors that can impact measurement accuracy and patient safety due to reliability risks.
  1) Imitation Masimo sensors
  2) Sensors used far beyond their expected life
  3) Third-party reprocessed pulse oximetry sensors

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

- About the Expected Life of Masimo Sensors

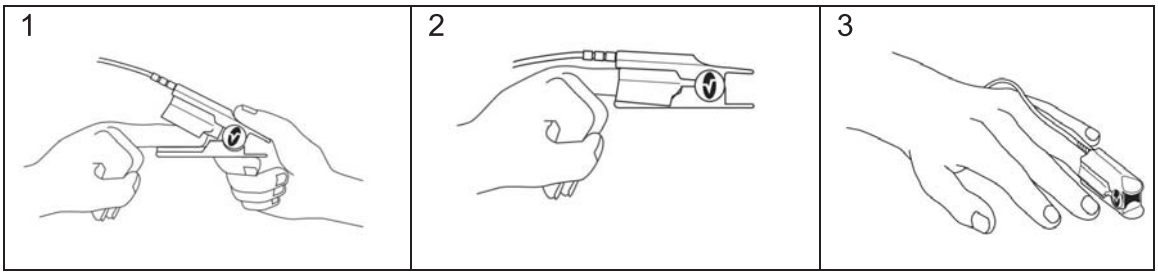
  The X-Cal function automatically monitors the Active Monitoring Time (actual time of SpO_2 monitoring) for each sensor. If the sensors are used beyond the expected life, <Bad Sens> or an icon will be displayed. The monitoring can be continued after <Bad Sens> is displayed, but after 12 hours (disposable sensor)/72 hours (reusable sensor), one of the following operation will make the sensor unusable.
  1) Sensor is detached from the patient for 2 hours or more.
  2) Probe is disconnected from the equipment.
  3) The power of the equipment is turned OFF.

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

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

●Applying the LNCS DCI, RD SET DCI

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



Precautions for Using the LNCS DCI, RD SET DCI

⚠CAUTION

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

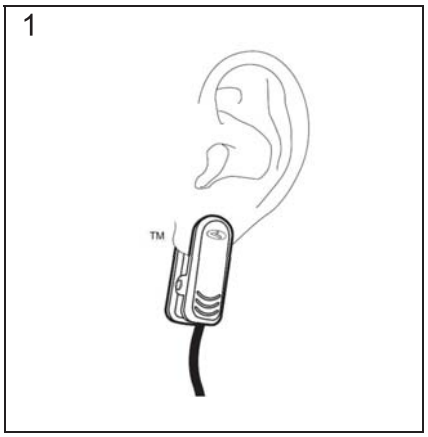
⚠CAUTION

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

•Applying the LNCS TCI

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

1



Precautions for Using the LNCS TCI

⚠CAUTION

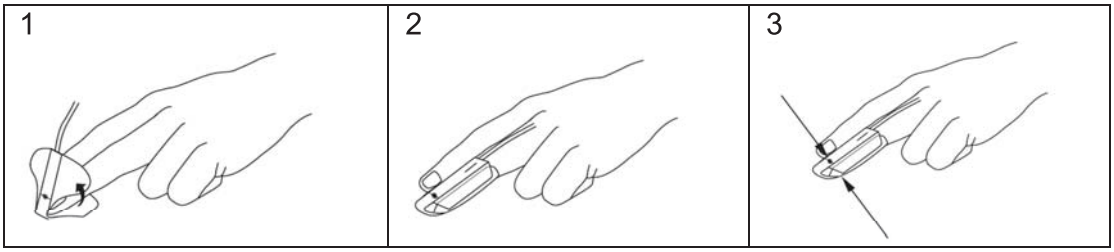
- Do not immerse the connector on the LNCS TC-I cable in any liquid solution.
- Do not sterilize by irradiation, steam autoclave or ethylene oxide.
- Do not use undiluted bleach (5%-5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the sensor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

⚠CAUTION

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

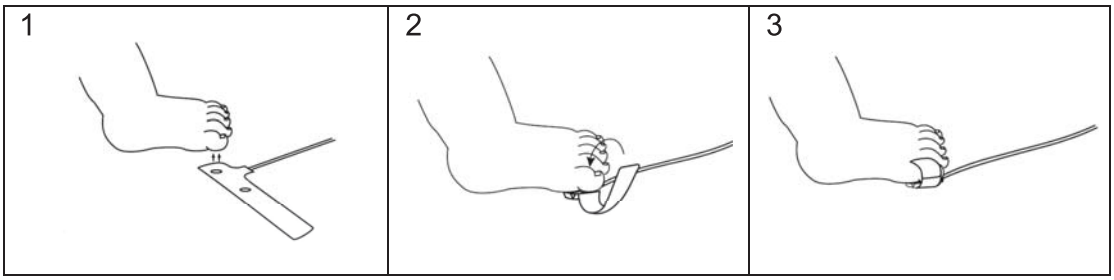
●Applying the LNCS Adtx, LNCS Pdtx, RD SET Adt, RD SET Pdt

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



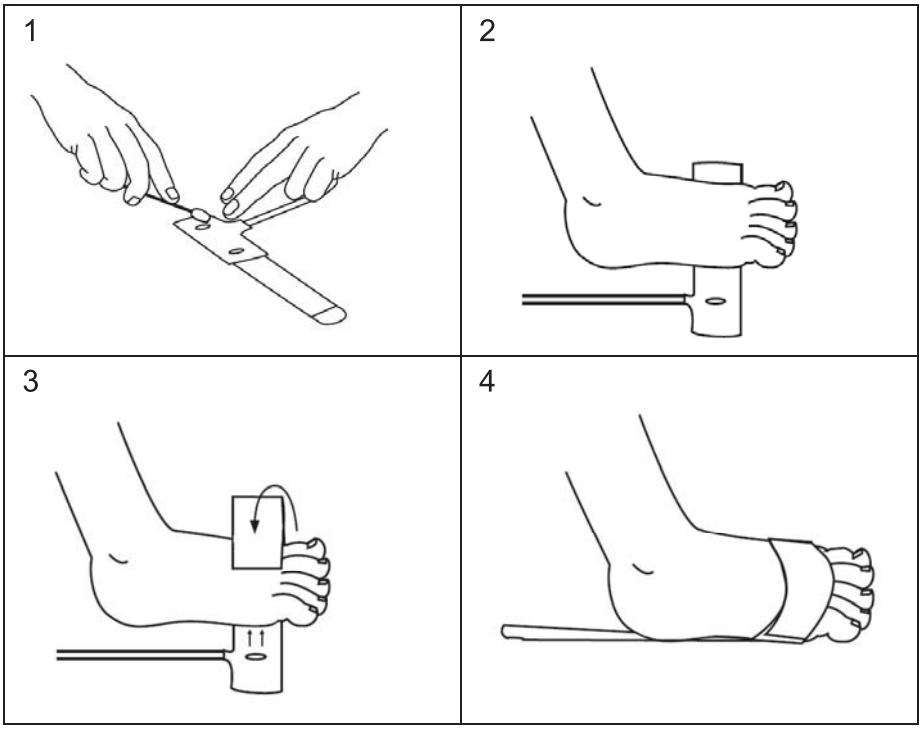
●Applying the LNCS inf-L, LNCS inf-3, RD SET Inf

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



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

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



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

⚠CAUTION

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

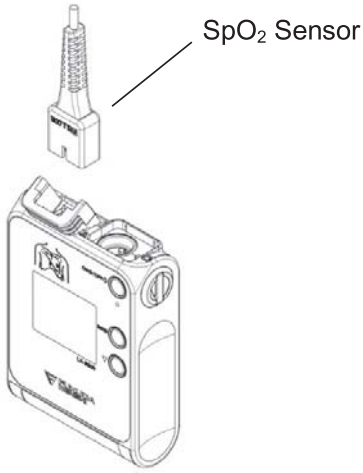
6. SpO_2 Monitoring

⚠CAUTION

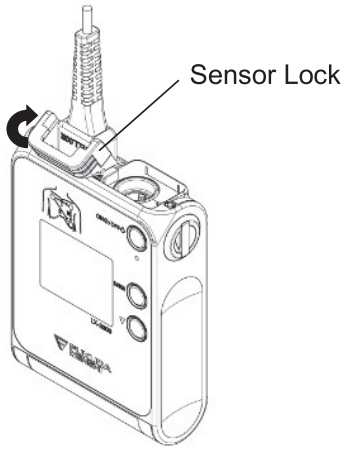
- Intravascular dyes or externally applied coloring (such as nail polish) may lead to inaccurate SpO_2 measurements.
- Sensors applied too tightly or that become tight due to edema will cause inaccurate readings and can cause pressure necrosis.
- Venous congestion may cause under reading of actual arterial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

■Connecting the SpO_2 sensor to the LX-8300M/LX-8300M(G)

1. Insert the SpO_2 sensor into the SpO_2 input connector on the LX-8300M /LX-8300M(G).



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



6. SpO_2 Monitoring

7. Measurement

Turn ON the power and the measurement starts.

■Monitoring Screen

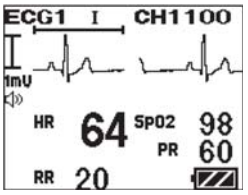
ECG waveform (1 channel when using 3-electrode lead cable, 2 channels when using other lead cable), heart rate, pacemaker marker, respiration waveform, respiration rate, pulse wave, SpO_2 measurement value, remaining battery level, and various messages are displayed.

⚠CAUTION

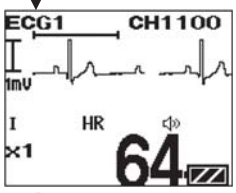
- The LX-8300M/LX-8300M(G) does not have a diagnostic function. Check the diagnostic function on the receiving monitor.
- The LX-8300M/LX-8300M(G) does not have an alarm function. Check the alarm function on the receiving monitor.
- The ECG waveform size and sweep speed settings displayed on the display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

●Switching the Display

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

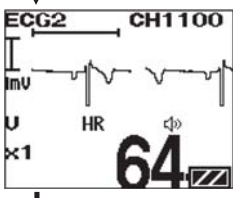


Press the [▽] button.



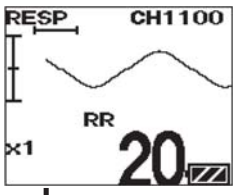
Press and hold the [ENTER] button for 2 seconds.
→ Move onto ECG1 setup display.

Press the [▽] button.



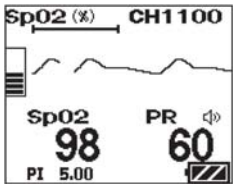
Press and hold the [ENTER] button for 2 seconds.
→ Move onto ECG2 setup display.

Press the [▽] button.



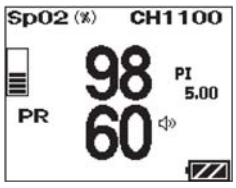
Press and hold the [ENTER] button for 2 seconds.
→ Move onto RESP setup display.

Press the [▽] button.



Press and hold the [ENTER] button for 2 seconds.
→ Move onto SpO_2 setup display.

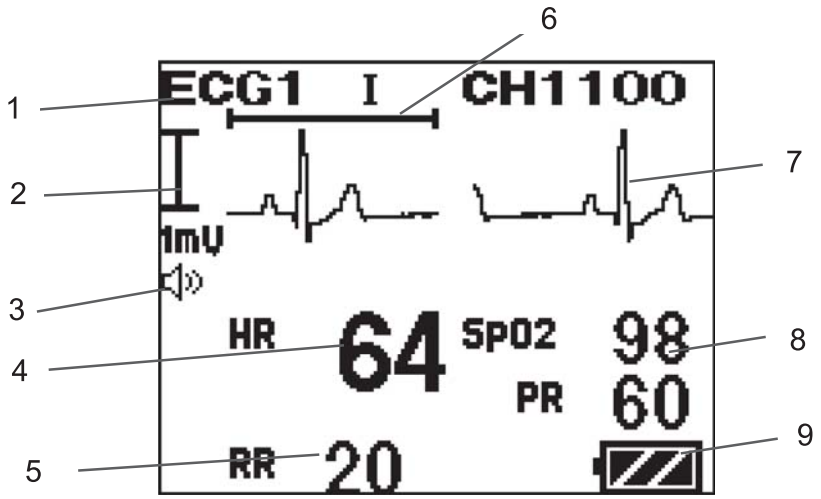
Press the [▽] button.



Press and hold the [ENTER] button for 2 seconds.
→ Move onto SpO_2 setup display.

●All Data Display

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



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

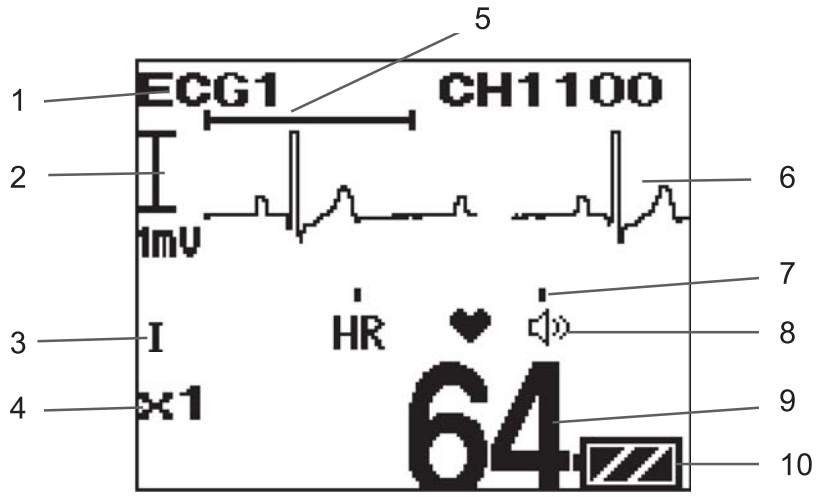
For details of the displayed messages and icons, refer to “11. Troubleshooting”.

●ECG Display

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

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

The descriptions of the displayed contents are as follows.



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

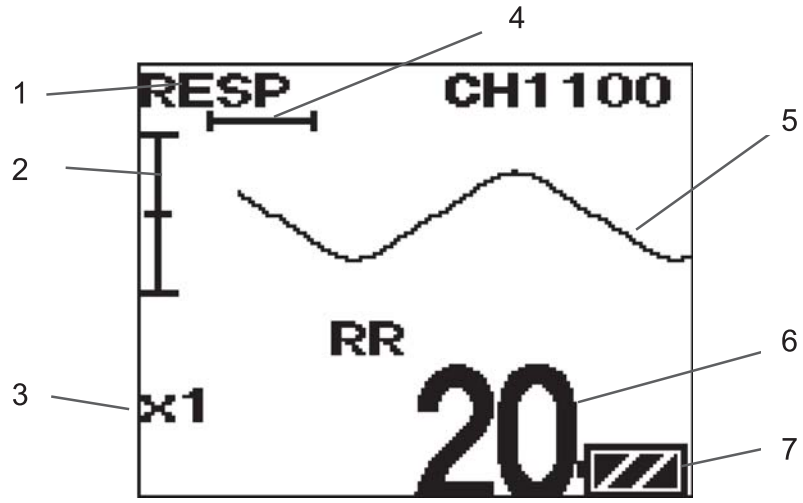
For details of the displayed messages and icons, refer to “11. Troubleshooting”.

⚠CAUTION

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

●Respiration Display

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



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

⚠CAUTION

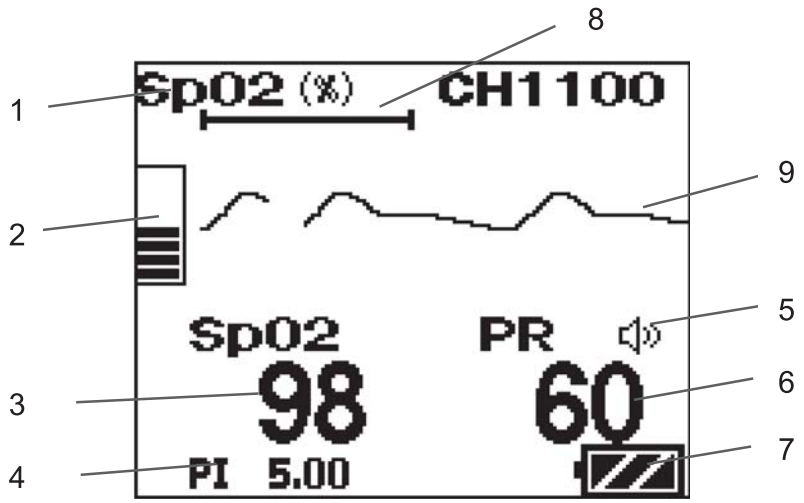
- The displayed respiration waveform size setting does not interact with the one displayed on the receiving monitor.
  If the respiration waveform size displayed on the receiving monitor is changed, follow the instruction in the operation manual of the receiving monitor.
- If RR is outside the display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

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

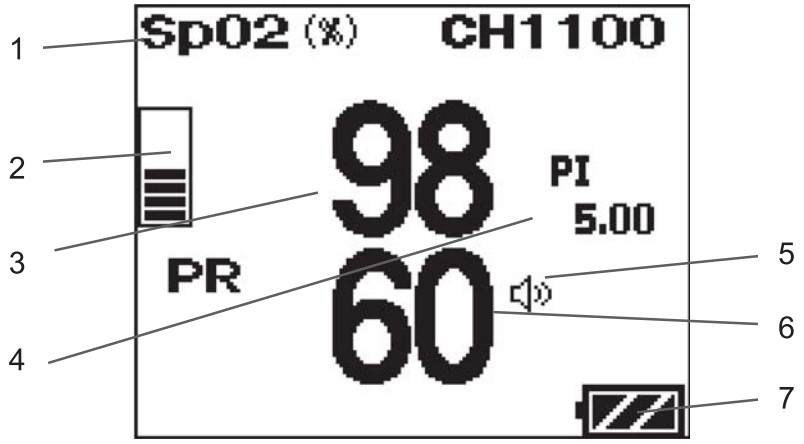
●SpO_2 Display

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

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



SpO_2 Standard Display



SpO_2 Enlarged Display

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

For details, refer to “8. Operation”.

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

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

⚠CAUTION

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

NOTE

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

8. Operation

■Setup Mode

To Enter Setup Mode

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

To Terminate Setup Mode

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

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

Setup Items

The following settings can be perfomred.

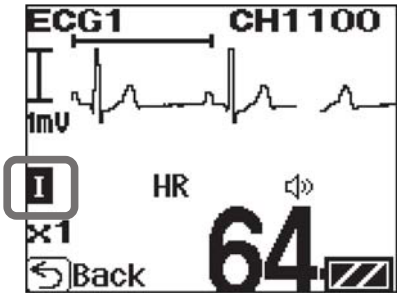
Items	Selection	Default	Backup
ECG Lead	I, II, III	II	Yes
Display Size of ECG (1)	×1, ×1/2	×1	Yes
Display Size of ECG (2)	×1, ×1/2	×1	Yes
Display Size of RESP	×1, ×1/2	×1	Yes

■ECG Setup

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

Switching Lead

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

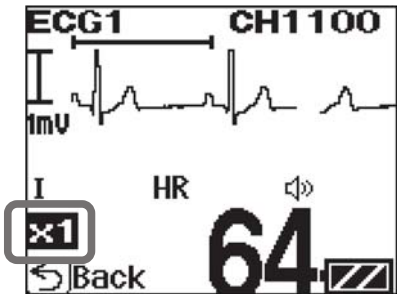


Press the [▽] button to highlight the lead indication.

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

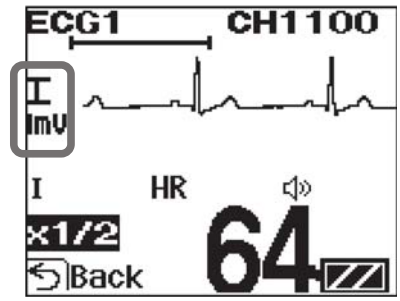
NOTE
The lead cannot be changed for ECG2 display.

Changing the ECG Waveform Size



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

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



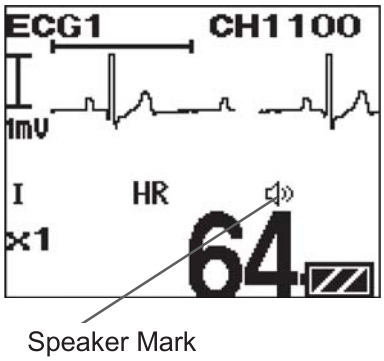
When the waveform size is changed, the ECG scale will also change.
For the example shown on left, the scale between -2mV and +2mV can be selected.

⚠CAUTION

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

Generating a Synchronized Tone

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

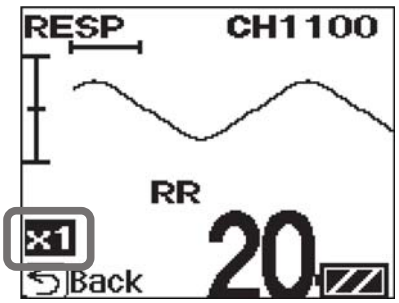


Press and hold the [ENTER] and [▽] button for 2 seconds to display the speaker mark. Press and hold the [ENTER] and [▽] button again for 2 seconds to clear the speaker mark and synchronized tone. This setting will be applied to ECG1, ECG2, and SpO_2 display.

■Respiration Setup

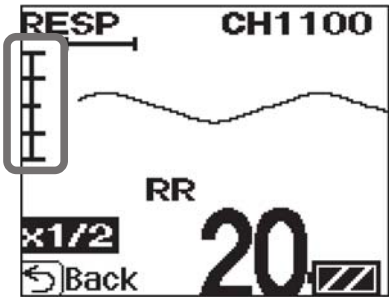
In the respiration display, the respiration waveform size can be changed.

Changing Respiration Waveform Size



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

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



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

⚠CAUTION

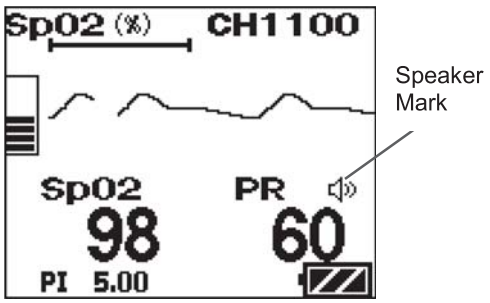
The waveform size displayed on the LX-8300M/LX-8300M(G) does not interact with the one displayed on the receiving monitor.
To change the waveform size of the receiving monitor, follow the instruction in the operation manual of the receiving monitor.

■SpO_2 Setup

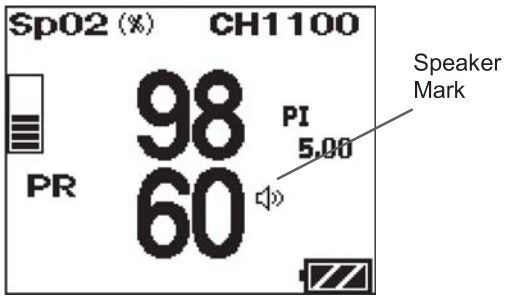
In the SpO_2 display, the synchronized tone and ON/OFF of SpO_2 measurement can be set.

Generating a Synchronized Tone

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



SpO_2 Standard Display

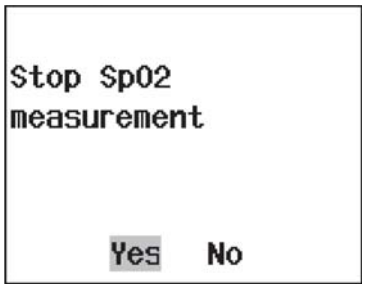


SpO_2 Enlarged Display

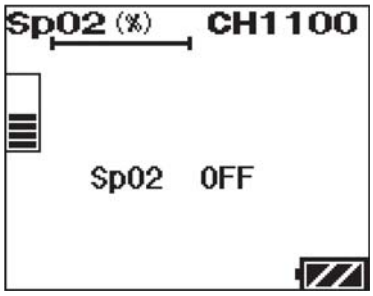
Press and hold the [ENTER] and [▽] button for 2 seconds to display the speaker mark.
Press and hold the [ENTER] and [▽] button again for 2 seconds to clear the speaker mark and synchronized tone. This setting will be applied to ECG1, ECG2, and SpO_2 display.

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

Turning OFF the SpO_2 measurement



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



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

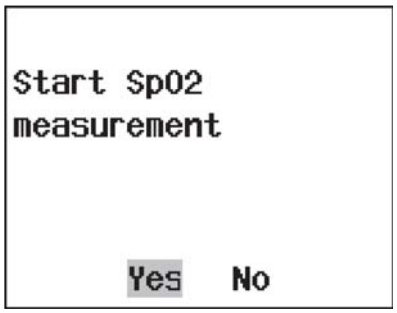
⚠CAUTION

When the SpO_2 measurement is turned OFF, “Check SpO_2 Sensor” or “SpO_2 Disconnected” is displayed on the receiving monitor. The displayed message differs depending on the receiving monitor type.

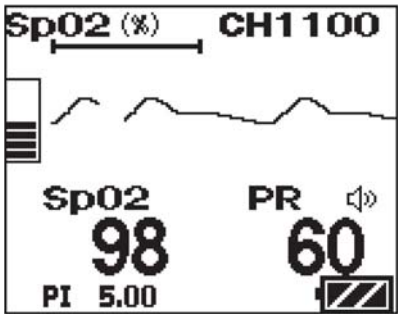
NOTE

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

Turning ON the SpO_2 measurement



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



The SpO_2 measurement will resume.

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

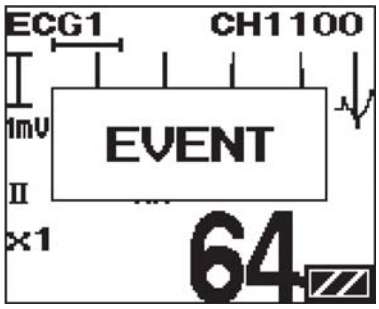
■Restarting the Display

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

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

■Pressing the [EVENT] Button

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



9. Other Setting Items

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

Items	Selection	Default	Backup
Time Constant	0.4 sec, 0.1 sec	0.4 sec	Yes
Detection Sensitivity of Pacemaker Pulse (Pace Sens.)	Low, Mid, High	Mid	Yes
QRS Detection (QRS Width)	Wide, Narrow	Wide	Yes
Respiration Detection Signal (Display)	ON, OFF	ON	Yes
Display Brightness (Brightness)	8 levels	5	Yes
Turn Off Display Time (Display OFF)	1 min, 3 min, 10 min, OFF	3 min	Yes
Sound (Sound)	ON, OFF	ON	Yes
Displayed Color of SpO_2 (Color)	Yellow, Blue	Yellow	Yes
Transmit PI Information (PI Data Send)	ON, OFF	ON	Yes
LX-8300M Transmitter Channel (CH)	One from the following channels. 0801 to 0879 0900 to 0979 1000 to 1079 1100 to 1179 1200 to 1279 1300 to 1379	1379	Yes
LX-8300M(G) Transmitter Channel (CH)	One from the following channels. 9501 to 9539 9600 to 9639 9700 to 9739 9800 to 9839 9900 to 9938 2701 to 2739 2800 to 2839 2900 to 2918 2921 to 2939 3000 to 3039 3100 to 3118	3118	Yes
Group ID	One from 00 to 63	00	Yes

■Time Constant

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

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

⚠CAUTION

- The threshold level for HR detection of this equipment and the receiving monitor changes with ECG waveform size. Set a proper waveform size for monitoring.
- When changing the time constant to “0.1 second”, the lower frequency characteristic becomes 1.6 Hz ± 25%. This setup does not meet IEC 60601-2-27 standard. It may lead to a change in the ECG waveform and the ST measurement value may be especially affected. Fukuda Denshi recommends “0.4 seconds” setting in normal use.
- The display screen in normal use does not indicate the selection of time constant. Make sure to take measures, such as marking on the LX-8300M/LX-8300M(G), to distinguish whether the selection of time constant has changed.

■Detection Sensitivity of the Pacemaker Pulse

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

Detection/Rejection of Pacemaker Pulse:

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

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

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

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

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

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

⚠CAUTION

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

■QRS Detection

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

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

⚠CAUTION

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

■Respiration Detection Signal ON/OFF

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

⚠WARNING

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

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

⚠CAUTION

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

■Display Brightness

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

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

■Display Timeout Duration

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

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

■Sound ON/OFF

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

- ECG Lead Off
- SpO_2 probe Off

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

■Displayed Color of SpO_2

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

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

■Transmit PI Information

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

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

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

9. Other Setting Items

10. Changing the Transmitter Channel and Group ID

■Transmitter Channel

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

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

⚠WARNING

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

■Group ID

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

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

⚠CAUTION

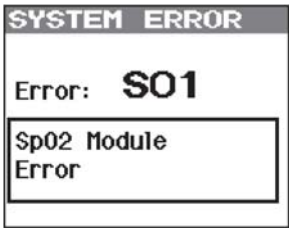
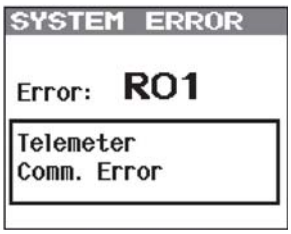
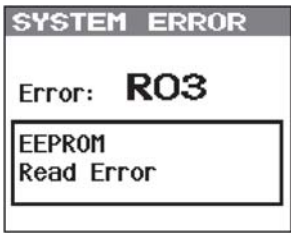
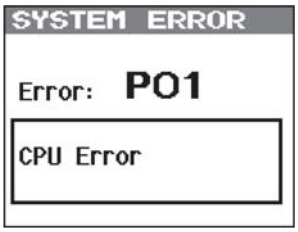
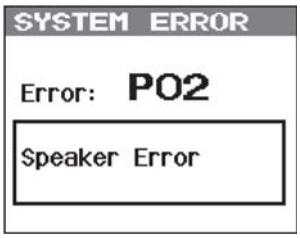
Possible causes of interference other than radio telemetry from neighboring hospital's transmitter, are the proximity of mobile phone, amateur radio station, radio taxi, and illegal citizens band, which may be a cause of interference. In such case, the situation should be carefully observed to find the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

10. Changing the Transmitter Channel and Group ID

11. Troubleshooting

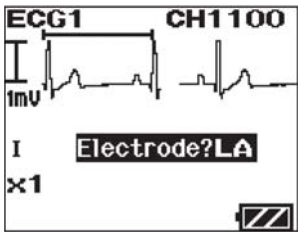
Make sure of the following. However, if there is no improvement in the situation, contact your local Fukuda Denshi service representative.

Transmitter

Message	Cause	Solution
	Faulty SpO_2 module.	Contact your local Fukuda Denshi service representative.
	Failed to transmit waveform and value.	
	Faulty EEPROM.	
	Failed to initialize CPU.	
	Faulty Speaker.	

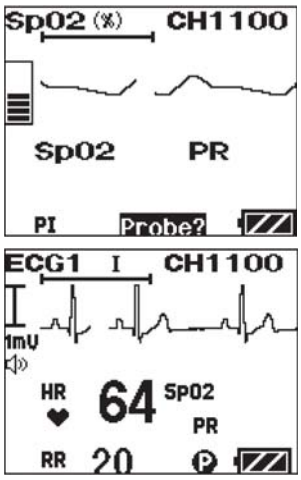
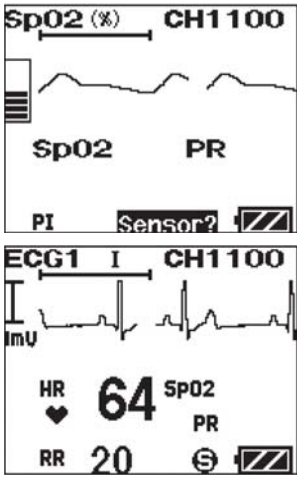
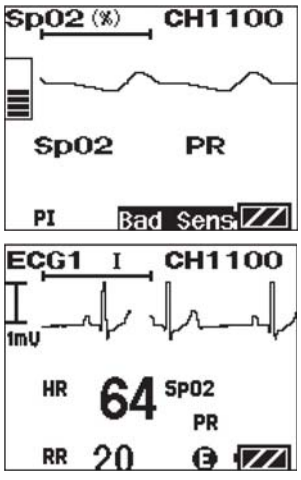
Situation	Cause	Solution
Nothing is displayed on the display when the power switch is turned ON.	No batteries or wrong polarity.	Install the batteries correctly.
	Battery level is empty.	Replace the batteries with new ones.
The system restarts.	Battery level is empty.	Replace the batteries with new ones.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

ECG

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

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

SpO_2

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