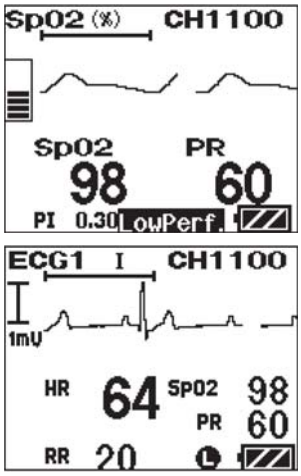
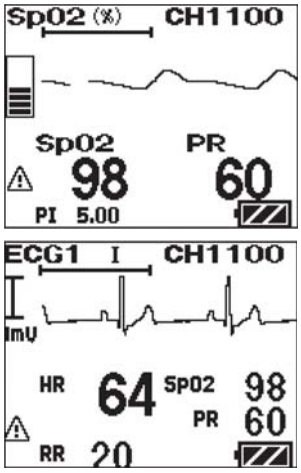
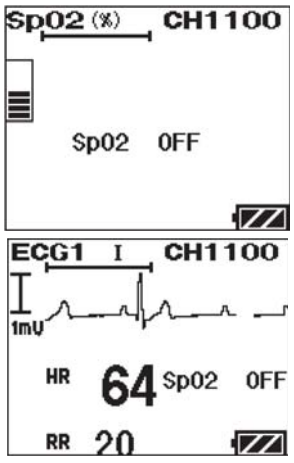
Message/Icon	Cause	Solution
	The amplitude of the pulse waveform is too low, or the sensor is not positioned correctly.	Check that the light emitting and receiving parts of the sensor LED are aligned.
	The expiration date of the sensor is approaching.	Replace the probe. For the expiration date of the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

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

Details of the “Electrode” Message

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

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

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

■In Case of Dropping the LX-8300M/LX-8300M(G) into Water

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

⚠CAUTION

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

12. Cleaning and Disinfection

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

⚠CAUTION

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

■Cleaning the Housing

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

⚠CAUTION

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

■Cleaning the Connector

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

⚠CAUTION

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

■Disinfection

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

⚠CAUTION

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

■Cleaning the ECG lead cable

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

⚠CAUTION

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

13. Maintenance and Inspection

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

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

■Daily Check

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

■Periodic Check

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

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

■Periodic Replacement Parts

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

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

Daily Check List

No. _____

Inspected Date _____ Inspected by _____ Location _____

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

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

Comment

■Periodic Check

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

●Periodic Check Items

The periodic check items are as follows.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Periodic Check List

Telemetry Transmitter Periodic Check Report

Check Date

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

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

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

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

Description

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

The check result is as follows:
☐Normal Operation ☐Malfunctioning. ☐Needs to be repaired.
(Details of malfunction and repair)

Company

Inspector

Person in charge

Replacement parts

Classification
☐On-site ☐Taking-over
☐Holiday ☐Night

■Repairing the Equipment

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

On-site repair is possible for the following parts.

- Replacing the battery compartment lid

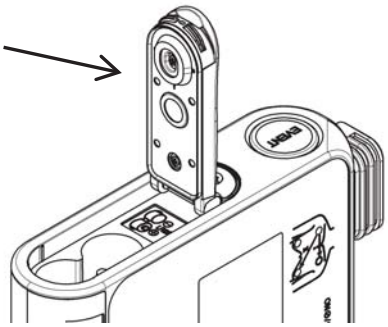
⚠CAUTION
Make sure to replace the parts correctly. Otherwise, it may cause damage and heat generation of the equipment.

■ Replacing the Battery Compartment Lid Unit

●Life of the Battery Compartment Lid Unit

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

Battery Compartment Lid Unit



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

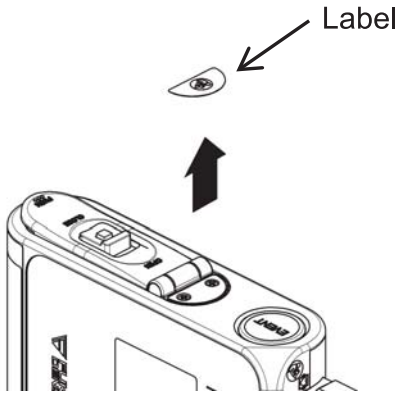
●Tools

- Phillips screwdriver (#0)

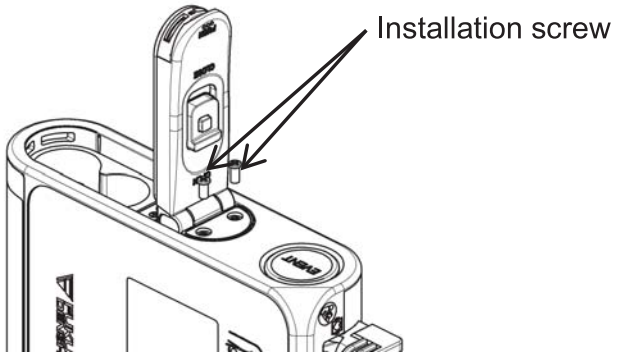
●Assembly and Disassembly

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

1. Remove the label.

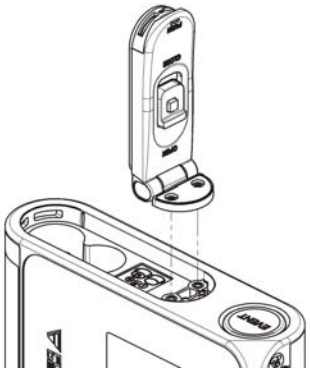


2. Remove the 2 installation screws, then remove the battery compartment lid unit.

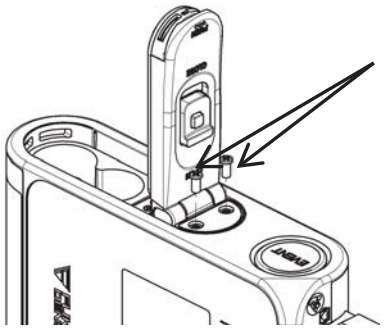


Follow the procedure below to attach the battery compartment lid unit.

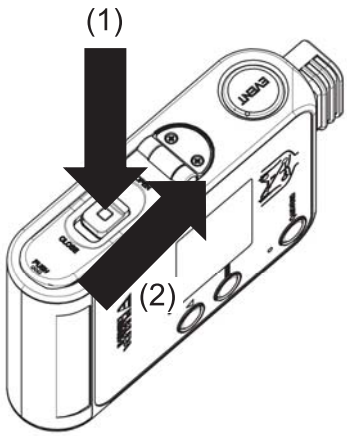
1. Set the battery compartment lid unit adjusting to the front case.



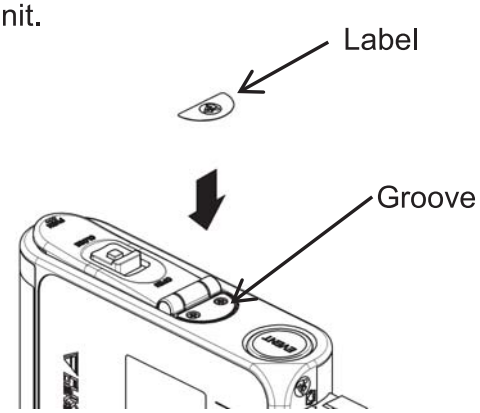
2. Secure the battery compartment lid unit with new 2 installation screws. Make sure that the screws are securely tightened.



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



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



14. Standard and Optional Accessories

⚠WARNING

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

⚠CAUTION

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

■Standard Accessories

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

■Optional Accessories

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

ECG Lead Cables

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

SpO_2 Sensors

- **LNCS Sensor**

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

The LNCS Sensors can be directly connected to the LX-8300M/LX-8300M(G).

- **RD SET Sensor**

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

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

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

Other Item

Item	Model Type	Remarks
Disposable Portable Case	ABT-720D	5 pieces/pack
SpO_2 Cap	OAT-05A	10 pieces/pack
ECG Cap	OAT-06A	10 pieces/pack

14. Standard and Optional Accessories

15. Specification

■Specification

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

General

Size:	72.0(W) mm x 27.0(D) mm x 102.0(H) mm (not including the protrusion)
Weight:	Approximately 190 g (with batteries)
Transmitting Waveform:	ECG 1CH or 2CH (selectable from the ECG lead cable), Respiration waveform, pulse waveform (with SpO_2 value)
ECG Lead Cable Type:	3-electrode, 4-electrode, or 5-electrode (Limb+Chest) lead cable. Automatically detect the type by inserting the lead cable.
Transmitting Status Data:	Electrode Off, Low Battery, Event Switch, Pacemaker, SpO_2 Sensor Off
LCD:	Built-in
Waterproof:	IPX8 (If periodic replacements are performed) / IPX5 IPX5: Protection from water. IPX8: Protection from submerge
Power Supply:	DC: Two 1.5 V “AA” size (“LR6” size) alkaline batteries
LX-8300M Continuous Operating Time: (Standard Operation)	Two “AA” size (“LR6” size) alkaline batteries Approximately 2.5 days with MX1500 (DURACELL) Conditions: When measuring ECG, RESP, SpO_2 with default settings, operating temperature 23°C
LX-8300M Continuous Operating Time: (During SpO_2 OFF Status)	Two “AA” size (“LR6” size) alkaline batteries Approximately 6.5 days with MX1500 (DURACELL) Conditions: When measuring ECG, RESP with default settings, SpO_2 measurement OFF, operating temperature 23°C
LX-8300M(G) Continuous Operating Time: (Standard Operation)	Two “AA” size (“LR6” size) alkaline batteries Approximately 1.5 days with MX1500 (DURACELL) Conditions: When measuring ECG, RESP, SpO_2 with default settings, operating temperature 23°C
LX-8300M(G) Continuous Operating Time: (During SpO_2 OFF Status)	Two “AA” size (“LR6” size) alkaline batteries Approximately 2.5 days with MX1500 (DURACELL) Conditions: When measuring ECG, RESP with default settings, SpO_2 measurement OFF, operating temperature 23°C
Operation Mode:	Continuous operation

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

ECG

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

Sweep speed: 12.5 mm/s

Heart rate meter accuracy and response to irregular rhythm:

80 bpm Ventricular Bigeminy: 80 bpm

60 bpm Ventricular Bigeminy: 60 bpm

120 bpm Ventricular Bigeminy: 120 bpm

90 bpm Bidirectional Systoles: 90 bpm

Respiration (Impedance Method)

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

SpO_2

NOTE

About the SpO_2 Clinical Test

The SpO_2 and pulse rate measurement accuracy have been validated for each range by testing on healthy adult male and female volunteers against a laboratory CO-Oximeter.

The SpO_2 accuracy has been validated for the range from 70% to 100% by testing on healthy adult male and female volunteers with light to dark skin pigmentation. Without body motion, the standard deviation is ±2% which encompasses 68% of the population. With body motion, the standard deviation is ±3% which encompasses 68% of the population. For the validation, frictional or contact motion of 1 cm to 2 cm, and random vibration of 1 Hz to 5 Hz were tested.

The pulse rate accuracy has been validated for the range from 70% to 100% by testing on healthy adult male and female volunteers with light to dark skin pigmentation The standard deviation is ±3 bpm which encompasses 68% of the population.

These clinical test data are disclosed based on the data provided from Masimo.

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

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

Pulse Rate

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

PI

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

Transmission Method of LX-8300M

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

Transmission Method of LX-8300M(G)

Modulation Mode:	Digital, Frequency shift keying
Frequency:	1395 MHz to 1400 MHz, 1427 MHz to 1432 MHz
Oscillation Method:	PLL Synthesizer method by crystal control
Channel Spacing:	25.0 kHz
Occupied Frequency Bandwidth:	Within 16 kHz
RF Output Power:	5 mW ± 2 dB
Transmitting Antenna:	Dielectric Antenna

Safety

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

Operating Environment

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

Transport / Storage Environment

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

15. Specification

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