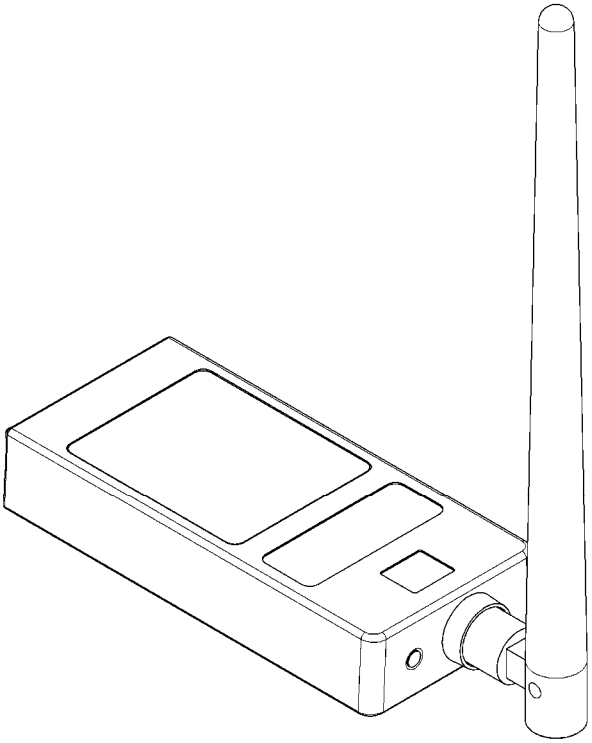
TM XMTR Module HLX-801

Operation Manual



- **Before using this device, read this manual thoroughly.**
- **Store this manual near the deivce where it can be always referred.**

FUKUDA DENSHI

⚠CAUTION

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

⚠CAUTION

Users are advised to periodically contact the FCC or specified frequency coordinator and determine if other or your transmitter frequencies that may cause interference.

⚠CAUTION

The manufacturers, installers and users of Wireless Medical Telemetry System equipment are cautioned that the operation of this equipment could result in harmful interference to other nearby medical devices.

CAUTION:

- **This equipment for sale by or on the order of a physician.**
- **The company and product names used in this manual are trademarks or registered trademarks.**
- **If this manual has pages missing or out of order, contact Fukuda Denshi for replacement.**
- **Only physician or persons instructed by physicians are allowed to use the equipment.**
- **The information contained in this document is subject to change without notice due to improvement in the equipment.**

Printed in Japan

Thank you for purchasing the HLX-801 telemetry transmission module from Fukuda Denshi. Before use, read this operation manual thoroughly for correct handling and operation.

Safety Precautions

The safety precautions shown in this manual contain important details on the safe use of this product, and must be obeyed. Make sure to follow the precautions indicated below, as these are important messages related to safety.

⚠DANGER	Failure to follow this message may cause immediate threat of death, serious injury, or complete failure of the equipment.

⚠WARNING	Failure to follow this message may result in death or serious injury, or complete failure of the equipment.

⚠CAUTION	Failure to follow this message may cause injury or failure of the equipment.

NOTE	A note is not related to product safety, but provides information about the correct use and operating procedures to prevent incorrect operation and malfunction of the HLX-801.

Precaution from Fukuda Denshi

Fukuda Denshi is liable for the safety, reliability, and performance of its equipment. Maintenance, modifications, and repairs are carried out by authorized personnel. Components are used in accordance with Fukuda Denshi operating instructions.

If the equipment is used incorrectly and become unusable, Fukuda Denshi is not liable for the malfunction. Use the equipment only for the purpose specified in this manual.

Graphic Symbols

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

Symbols indicated on the main unit of the HLX-801

Symbol	*Description*
	Caution; refer to accompanying documents Indicates the need to refer to related accompanying documents before operation.
	Refer to accompanying documents Indicates the need to refer to related accompanying documents before operation.
	Year of Manufacture Indicates the manufactured year.
	WEEE (Waste Electrical and Electronics Equipment) Indicates a separate collection for electrical and electronic equipment.

Precautions for Safe Operation of Medical Electrical Equipment

Cautions described here are regarding the general instructions for safety use to the patient and users. For cautions about the HLX-801, refer to the following pages.

⚠CAUTION

1. Do not use the equipment unless you are familiar with its operation.

2. Pay attention to the following when installing or storing the equipment.

- Install or store in a place where the equipment will not be exposed to splashing water.
- Store in a place where the device will not be adversely affected by atmospheric pressure, temperature, humidity, ventilation, sunlight, dust or atmosphere containing salt or sulfur.
- Prevent inclination, vibration, or shock (including during transportation).
- Do not install or store in an area where chemicals are stored or gasses are evolved.

3. Precautions before Operation

- Check the cable connection and polarity to ensure safe and proper operation of the equipment.
- Make sure that all cables are correctly and safely connected. Especially, recheck the attachment and connection condition of electrodes and transducers.
- Pay special attention when the equipment is used in conjunction with other equipment because it may cause erroneous judgment and danger.
- Check the remaining battery level.
  When replacing the battery, make sure that the battery polarity is correct. Do not charge the battery.

4. Precautions during Operation

- Make sure the time required for diagnosis, or medical care is not exceeded.
- Do not pick up or swing the equipment pulling the probe or cable. It may damage the equipment and lead to measurement error.
- Always observe the device and patient to ensure safe operation of the equipment.
- If any abnormality is found on the equipment or patient, take appropriate measures such as ceasing operation of the equipment or detaching the sensor or electrode in the safest way for the patient.
- Prevent patients from touching the equipments or other electric apparatus.

⚠CAUTION

5. Cares after Operation

- Return all operating switches or knobs to the position before using the equipment, and then switch off the power.
- When unplugging the cables, do not apply excessive force by pulling on the cable. Pull from the connector part of the cable.
- Clean the accessories and cables, and keep them together in one place.
- Keep the equipment clean to ensure proper operation for the next use.
- Make sure to remove the batteries if the equipment is not used for a long time. The leakage from the batteries may damage the equipment, or an explosion from the batteries may occur.

6. If the equipment gets out of order, immediately turn off the equipment and ensure patient safety by disconnecting electrodes and cables from the patient.
Label the equipment "OUT OF ORDER" and contact your nearest Fukuda Denshi representative.

7. Do not disassemble or remodel the device.

8. Maintenance check

- Make sure to periodically check the equipment and accessories. (Maintenance contract is recommended.)
- Before reusing the equipment that has been left unused for a while, make sure that the equipment works normally and safely.

9. When using an electrosurgical unit or defibrillator in conjunction with this equipment, take care of the following.

- To prevent patient from burn injury, verify proper attachment of patient ground plate and ECG electrode type when using the electrosurgical knife, and verify paste volume and output energy when using the defibrillator.
- Devices other than the above may cause accidental hazards to the patient and operator due to the conditions of the equipment. Read the operation manual attached to each device and understand the precautionary instructions prior to use.

Non-Explosion Proof

⚠DANGER

- Never use the equipment in the presence of flammable anesthetics or high concentration of oxygen. It may cause an explosion or fire.
- Never use the equipment inside a hyperbaric chamber.
  It may cause an explosion or fire.
- Never use the equipment where flammable gas or fluid such as anesthetic, oxygen, and hydrogen are used.
  It may cause an explosion or fire.

Precautions about Magnetic Resonance Imaging (MRI)

⚠WARNING

- Do not use this equipment in magnetic resonance imaging (MRI) environments. This equipment may be pulled towards the MRI device. The local heating by the induced electromotive force may cause burn injury to the patient or deteriorate the performance of this equipment. For details, refer to the operation manual for the MRI testing device.

Precautions about the installation of the equipment

⚠WARNING

- This equipment is a module dedicated to the bedside monitor manufactured by Fukuda Denshi Co., Ltd. The use of the power separated from the commercial power guarantees the safety.
- Do not connect this equipment to a device other than the bedside monitor manufactured by Fukuda Denshi Co., Ltd. The equipment may be damaged or leakage current increases and the safety of the patient and operator cannot be guaranteed.

Precautions about Accessories and Optional Accessories

⚠WARNING

Use only the accessories and optional accessories specified by Fukuda Denshi. Or the equipment can not only deliver maximum performance but also may be damaged and then the safety may not be guaranteed.

Precautions about Output Signal

⚠WARNING

Do not use the output signal of the monitor that receives radio wave signal from this equipment as the cardiac synchronization signal for the IABP, MRI, echocardiograph, or defibrillator. A trigger signal unrelated to the heart rate may be generated by the operating timing delay caused by the delay of waveform transmission and the interfusion of spike noise at weak electric field.

Precautions about Alarm

⚠CAUTION

- The alarm generation may be delayed between the bedside monitor and the central monitor depending on the communication specification (wired or wireless) between the bedside monitor and central monitor. Read the operation manual thoroughly and set the alarm.
- The Alarm System is different between the bedside monitor and central monitor depending on the communication specification (wired or wireless). Read the operation manual thoroughly and set the alarm.
- When a parameter monitored on a bedside monitor is in a connector-off condition, the numeric data and waveform for the parameter will not be displayed on the central monitor. In addition, the alarm for the parameter will not generate. Make sure that the connector is securely connected.
- When the "Alarm Mute" (Hospital Setup) is set ON, all the alarm will not be generated. Read the operation manual thoroughly and set the alarm.

Precautions about Cleaning and Disinfection

⚠CAUTION

- Soak a piece of gauze or absorbent cotton in alcohol or a weak acidic or alkaline or neutral detergent, wring the gauze or cotton, and wipe the equipment using it. At this time, make sure the chemicals do not enter the connectors or equipment. Do not use organic solvents, thinner, toluene and benzene to avoid damaging the resin case.
- If there is a fear of contagion, soak a piece of gauze or absorbent cotton in antiseptic soap or alcohol, wring the gauze or cotton, and wipe the equipment using it. At this time, do not immerse the connector parts of the equipment in any chemical solution. Contact failure may occur.
- Do not sterilize using an autoclave apparatus because it may damage the equipment.
- When performing simultaneous disinfection inside the ward or room using chemical sprays, make sure that the chemicals do not enter the equipment or come into contact with the connectors.

Precautions about Disposing of Equipment, Accessories, or Components

⚠CAUTION

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

Precautions for Safe Operation of Medical Telemetry

⚠ WARNING

- The HLX-801 transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.
- The HLX-801 complies with FCC radiation exposure limits set forth for a controlled environment and meets the FCC radio frequency (RF) Exposure Guidelines in Supplement C to OET65. The HLX-801 has been confirmed to comply with maximum permissive exposure evaluation (MPE). But it should be installed and operated keeping the radiator at least 20cm or more away from person's body (excluding extremities: hands, wrists, feet and ankles).
- Operation of HLX-801 requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.
- This radio frequency device is susceptible to interference from outside sources. Interference may prevent the monitoring of patients connected to this equipment. If a problem exists, contact your local service representative.
- The HLX-801 transmits vital signs to the receiving monitor using radio wave signal. Under unstable radio wave signals, the receiving monitor will not generate any alarms. This situation may miss sudden change in the patient's condition and may cause a serious accident. Under unstable radio wave signals, check the patient status consistently under this situation. To get stable radio wave signals, make sure to have a proper telemetry installation.

⚠ CAUTION

- For installation, make sure the following.
  - The medical institution (hereinafter referred to as the "Institution") must decide the telemetry installation plan for the medical department in order to prevent interference and interference between transmitters (telemetry based on destination country's radio law). When telemetry has already been installed and been used, radio format, frequency, and antenna power are required to be examined to prevent interference.
  - When using telemetry, which requires zone location, the Institution is to set up the zones as an operation unit for each transmitter to prevent electronic interference between telemetry throughout the Institution.
  - When using telemetry, which requires zone location, display and identify each prepared zone in the equipment.
  - When laying receiver antenna for each transmitter, the Institution has to examine the installation so that electronic interference does not occur.
  - Based on the above examination result, the Institution should install each receiver antenna as required.

⚠ CAUTION

- For management, make sure to follow the precautions below.
  - The Institution should appoint a person (hereinafter referred to as the “Overall Manager”) to manage the wireless channels for the whole Institution.
  - And when using telemetry, which requires zone location, the Institution should nominate a person (hereinafter referred to as the “Zone Manager”) to manage the wireless channels in each zone. However, when using such telemetry in a local Institution, one person can perform both functions.
  - The Overall Manager and Zone Manager must be selected from people who understand the characteristics and functionality of telemetry systems, and are skilled in operating telemetry.
  - When installing telemetry, the Overall Manager and the Zone Manager have to understand the precautions for use of telemetry in advance.
  - The Overall Manager is responsible for maintenance of wireless channel and storage and maintenance of telemeter in the overall medical facilities to give proper instructions to the Zone Manager when using telemetry needing zone alignment, and to the telemetry user when using telemetry not-needing zone alignment.
  - The Overall Manager should create a management log (hereinafter referred to as the “log”), which contains a list of the management status of the wireless channels for the whole Institution. When changing a wireless channel, register it in the log and give proper instructions to the Zone Manager or to the user.
  - The Zone Manager assumes responsibility for managing the wireless channels, storing, and managing telemetry.
  - The Zone Manager assigns the transmitter to the user, and provides enough education for use inside the zone.
  - The telemetry user verifies operation of the transmitter/receiver before use.
  - The telemetry user, if using the telemetry in a zone location, follows the instructions of the Zone Manager for the zone and gives instructions to the patient if required.
- When interference or breakdown occurs in telemetry communication, the user is required to inform the Zone Manager and the Overall Manager of the problems. The Zone Manager and Overall Manager are to deal with the problem properly and/or contact their nearest Fukuda Denshi representative for service.

Electromagnetic Compatibility

The performance of this device under electromagnetic environment complies with IEC60601-1-2 (2007).

Precautions for Safe Operation under Electromagnetic Influence

⚠ CAUTION

If any sorts of electromagnetic wave, magnetic field, or static electricity exist around the equipment, noise interference or malfunction of the device may occur. If any unintended malfunction or noise occurs in monitoring, check the magnetic influence and take appropriate countermeasures
The following are examples of the common cause and countermeasures.

- **Cellular Phone**

  The radio wave may cause malfunction to the device.
  Cellular phones and radio sets should be turned off in the room (building) where a medical device is located.

- **Static Electricity**

  In a dry environment (room), static electricity is likely to occur. Take the following countermeasures.

  - Both operator and patient should remove any static electricity before entering the room.
  - Humidify the room.

EMC Guidance

This equipment complies with IEC60601-1-2 (2007). However, if portable transmitter or wireless LAN equipment is used extremely nearby, the electromagnetic influence may largely exceed the compliance level and may cause unexpected phenomenon such as noise interference on the waveform.
Therefore, this equipment should be used in a location specified by each medical institution.
If any unexpected noise interference on the waveform or failure to the peripheral device occurs, stop using the equipment and follow the instruction of the technical engineer.

The following is the information relating to EMC (Electromagnetic Compatibility). (When using this equipment, verify that it is used within the environment specified below.)

●Compliance to the Electromagnetic Emissions

The HLX-801 system is intended for use in the electromagnetic environment specified below.

Emissions Test	***Compliance***	***Electromagnetic Environment - Guidance***
RF Emissions CISPR 11	Group 1	The HLX-801 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The HLX-801 is suitable for use in all establishments other than domestic buildings.

●Compliance to the Electromagnetic Immunity (1)

The HLX-801 is intended for use in the electromagnetic environment specified in below tables. It should be assured that the HLX-801 is used in such an environment.

Immunity Test	***IEC60601-1-2 Test Level***	***Compliance Level***	***Electromagnetic Environment - Guidance***
Electrostatic Discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2kV Power supply lines ±1kV for input/output lines	±2kV Complies ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60Hz) Magnetic Field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

●Compliance to the Electromagnetic Immunity (2)

The HLX-801 is intended for use in the electromagnetic environment specified below. It should be assured that the HLX-801 is used in such an environment.

Immunity Test	*IEC60601-1-2 Test Level*	*Compliance Level*	*Electromagnetic Environment - Guidance*
			Portable and mobile RF communications equipment should be used no closer to any part of the HLX-801, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance
Conducted RF IEC61000-4-6	3Vrms 150kHz to 80MHz	3Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	$d = 1.2\sqrt{P}$ 80MHz~800MHz $d = 2.3\sqrt{P}$ 800MHz~2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a)], should be less than the compliance level in each frequency range[b)]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1 : At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
Note 2 : These guidelines may not apply in all situations.
Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note[a)] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast can not be predicted theoretically with accuracy.
To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered.
If the measured field strength in the location in which the HLX-801 is used exceeds the applicable RF compliance level above, the HLX-801 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the HLX-801.

[b)] Over the frequency range 150kHz to 80MHz, field strength should be less than 3V/m.

●Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the HLX-801

The HLX-801 is intended for use in an environment in which radiated RF disturbances are controlled. The electromagnetic interference can be prevented by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HLX-801 as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	***Separation Distance according to Frequency of Transmitter (m)***		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

Note 2 :These guidelines may not apply in all situations.
Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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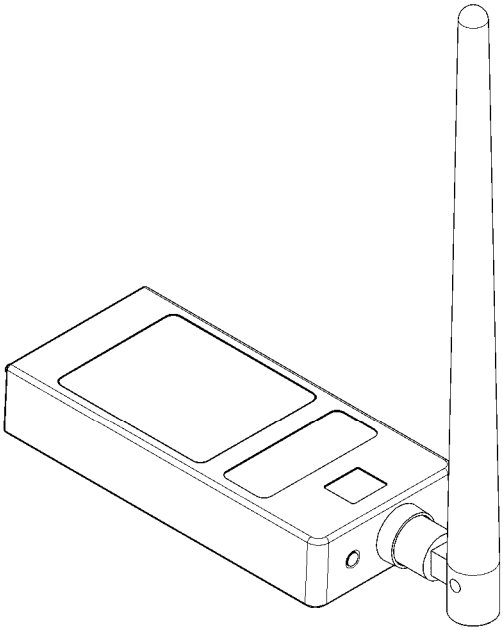
1. General Description

The HLX-801 is a transmitter module to wirelessly transmit vital signal waveforms and Numeric Data which are monitored on the DS-8000 series bed side monitors. A telemetry monitoring system is constructed in combination with a central monitor such as DS-7700 system.
A telemetry channel can be set with an arbitrary channel on the bedside monitor.
Before using the HLX-801, also read the operation manuals of the patient monitor and central monitor thoroughly.

External appearance



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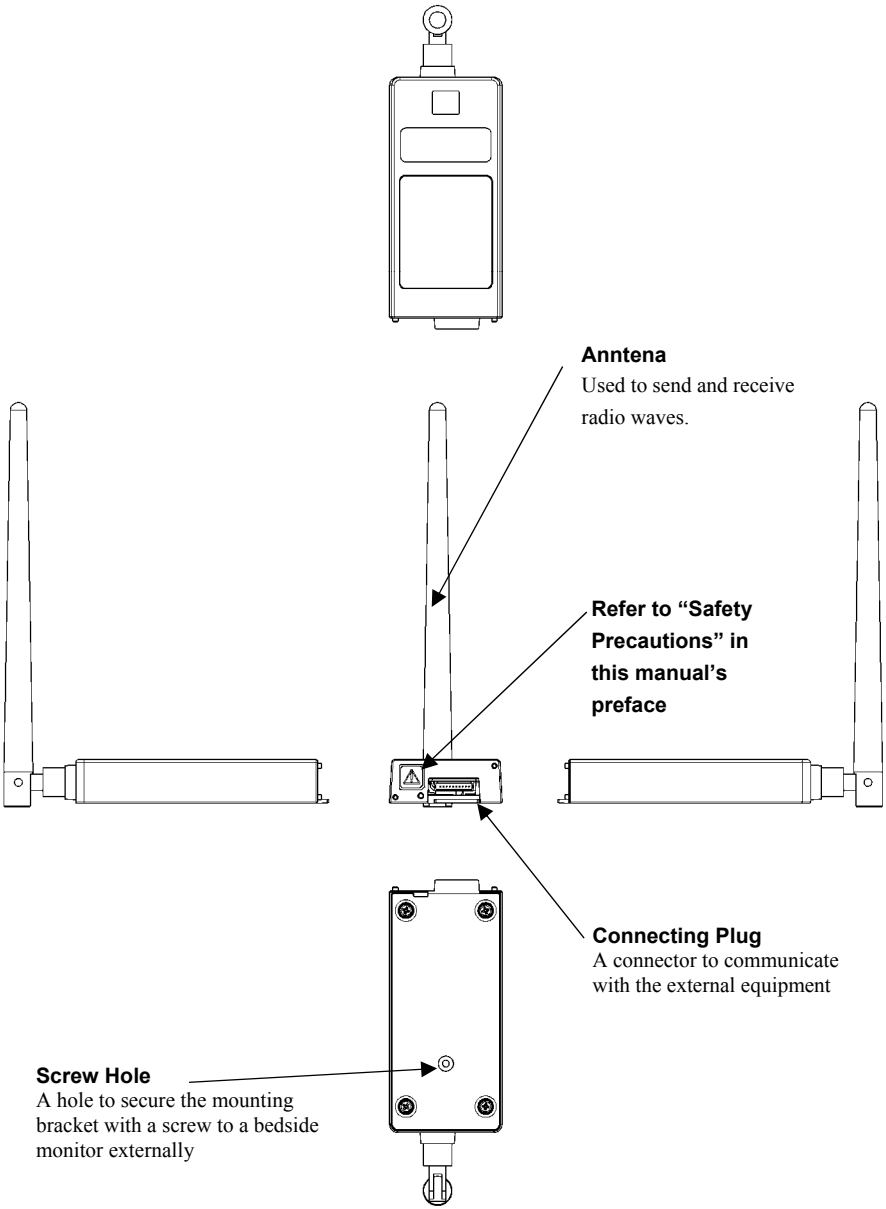
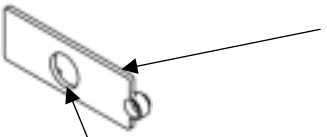
2. Name of Parts and Their Functions





Attachment cover
To fix the HLX-801 to the monitor.

A hole to run the HLX antenna through this cover

3. Preparation

■ Installation to the Bedside Monitor

For procedure to install to the bedside monitor, refer to the operation manuals of the bedside monitor and optional mounting bracket.

⚠WARNING

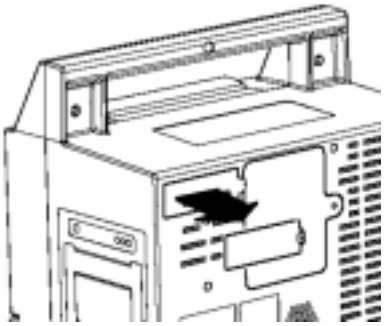
- The HLX-801 is a module dedicated to the bedside monitor manufactured by Fukuda Denshi Co., Ltd. The use of the power separated from the commercial power guarantees the safety.
- Do not connect the HLX-801 to a device other than the bedside monitor manufactured by Fukuda Denshi Co., Ltd. The equipment may be damaged or leakage current increases and the safety of the patient and operator cannot be guaranteed.

⚠CAUTION

- When installing the HLX-801, verify that the power of the bedside monitor is OFF before the procedure.
- After installation, make sure it operates normally.

■ Installation to the Patient Monitor DSL-8001

① Loosen the screw on the rear of the DSL-8001 and remove the maintenance cover.



The removed maintenance cover is not used when the HLX-801 is installed. Make sure to store the cover because it is needed when the HLX-801 is removed.

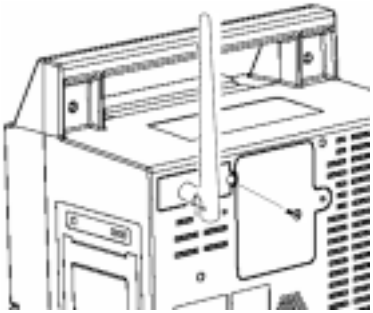
② Connect the connection cable of the DSL-8001 maintenance part to the HLX-801 connector.

Pay attention to the connector orientation and connect the connector.

After connection, insert the HLX-801 in the maintenance part of the DSL-8001. At this time, insert it paying attention to the following precautions.

- Make sure that the connection cable is not caught.
- Pay attention to the orientation of the HLX-801. Make sure that the Rating Label is facing upward.

③ Use the attachment cover supplied with the HLX-801 and attach it, instead of the maintenance cover which was removed in ①.



Run the HLX-801 antenna through the cover and attach it on the rear side of the DSL-8001 using the screw removed in ①.

Bend the antenna vertically.

4. Operation

■ Operation Procedure

For operation procedure, refer to the operation manual of the bedside monitor to which the-HLX-801 is connected.

■ Changing the Transmitter Channel

The HLX-801 is a synthesizer type transmitter module which the transmitter channel can be changed. It can be set up with an arbitrary channel among the channels assigned by the Telemetry Laws (according to each country). For details on the setting procedure, see the operation manual of the bedside monitor.

⚠WARNING

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

■ Changing the Group ID

The HLX-801 transmits its group ID to prevent interference with neighboring hospital's transmitter. The central monitor checks whether the incoming group ID is the same as the programmed one that the central monitor has and displays the waveform.
The transmitter group ID can be changed if there is interference with a neighboring hospital's transmitter. For details on the setting procedure, see the operation manual of the bedside monitor.

⚠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 a case, the situation should be carefully observed to find the cause of interference.

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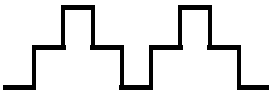
5. Troubleshooting

If the measurement waveform is not properly displayed on the central monitor, check the following items.
If the phenomenon cannot be improved, refer to your local Fukuda Denshi service representative.

Pattern on the central monitor	Cause		Solution
	The radio waves are not transmitted.	The connection is not properly set.	Check the connection between the HLX-801 and bedside monitor.
		The power of the bedside monitor is turned OFF.	Check if the power on the bedside monitor is turned ON.
		The channel numbers between the transmitter and the receiving monitor are not the same.	Make sure that the channel number of the bedside monitor and central monitor is the same.
		Poor transmission	Check the antenna of the HLX-801.
			Check the antenna of the central monitor.
		Transmitter malfunction	Contact Fukuda Denshi representative.
	Interference with radiowave of other wireless device	Other wireless device uses the same channel nearby, (If the transmitter module is turned ON, the central monitor is in the receiving condition.	Follow the instruction by the person in charge of radio telemetry channel in your facility and set the HLX-801 with the correct channel setting.
		Interference	Follow the instruction by the person in charge of radio telemetry channel in your facility and set the HLX-801 with the correct channel setting.

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6. Cleaning and Disinfection

Clean and disinfect the HLX-801 as shown below.

⚠CAUTION

Do not sterilize the HLX-801 in any manners since it is not ready for sterilization.

■ Cleaning

Soak a piece of gauze or absorbent cotton in alcohol or a neutral detergent, wring the gauze or cotton, and wipe the HLX-801 using it.

⚠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 liquids or cleaning solution to enter the equipment or connectors.**
- **The HLX-801 cannot be sterilized.**
- **Do not use organic solvents, thinner, toluene and benzene to avoid damaging the resin case.**
- **Do not polish the housing with abrasive or chemical cleaner.**
- **Use only neutral detergent to clean the housing. Do not use chemical cloth, scrub brush, abrasive, polishing powder, hot water, volatile solvent and chemicals (cleanser, thinner, toluene, benzine, benzol, and synthetic detergent for house and furniture), or sharp-edged tools. The surface resin coating may be damaged, resulting in discoloration, scratches, and other problems.**

■ Disinfection

If there is a fear of contagion, soak a piece of gauze or absorbent cotton in antiseptic soap or alcohol, wring the gauze or cotton, and wipe the HLX-801 using it.

⚠CAUTION

- **Do not immerse the connector parts of the HLX-801 in any chemical solution. Contact failure may occur.**
- **When performing simultaneous disinfection inside the ward or room using chemical sprays, make sure that the chemicals do not enter the equipment or come into contact with the connectors.**

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7. Maintenance Check

Periodic check must be performed. When reusing the HLX-801 which was left unused for a while, always check that the unit operates properly and safely before use.
In this section, the maintenance check items that must be performed for the HLX-801 are explained. To ensure safety, reliability, and high performance, a “Daily Check” and “Periodic Check” must be performed. Be aware that Fukuda Denshi is not liable for any accidents arising from the lack of maintenance check.

⚠ CAUTION

- **Do not open the housing.**
- **Avoid alcohol or other liquids from getting into the equipment.**

■ Daily Check

Perform the daily check according to the “Daily Check List”.

■ Periodic Check

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

■ Periodic Replacement

No periodic replacement parts.

Daily Check List

No.

Checked Date **Checked by** **Location**

Model: HLX-801 **Serial No.** **Date of Purchase**

Item	Check Details	Criteria	Judgement
External appearance	Visually inspect for damage, cracks, breaks,and chips of the exterior, peeling label, and loose screws.	No remarkable abnormalities should be found.	OK/NG
Transmitting function	Connect to the bedside monitor, operate under normal operating conditions, and check the communication function and operation on the central monitor.	The waveform and numerical value should properly be received.	OK/NG
Telemetry Channel	Check if the Transmitter Channel and Group IDs are as specified by the telemetry channel administrator.	It should conform to the telemetry channel checklist.	OK/NG
Zone location	Visually check the color and location of the zone location label and make sure that they are as specified by the telemetry channel administrator.	It should conform to telemetry the channel checklist.	OK/NG
Periodic Check	Check the date of the previous periodic check.	Should be within 1 year.	OK/NG

Comment

8. Accessories / Optional Accessories

⚠WARNING

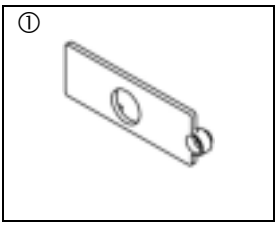
Use only the accessories specified by Fukuda Denshi for the HLX-801. Otherwise, the HLX-801 cannot deliver its maximum performance and may be damaged, resulting in a safety hazard.

⚠CAUTION

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

■ Standard Accessories

No.	Item	Model Type	Q'ty	Note
①	Attachment cover		1	
②	Operation Manual		1	This manual



■ Optional Accessories (sold separately)

The following accessories are available as optional for the HLX-801. Purchase them as required.
In order to satisfy product performance requirements, always use the accessories specified by Fukuda Denshi. When ordering spare parts, inform Fukuda Denshi of the Model Type.

Mounting Bracket

Item	Model Type	Note
HLX-801 mounting bracket (For DS-8500)	OAT-8185A	A mounting bracket to fix the HLX-801 to the DS-8500 and the cable to connect the HLX-801 to the DS-8500

9. Specification

■ Specification

⚠CAUTION

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

Standard Specification

Size:	42(W)×93(D)×16(H) mm (not including the antenna, protrusion, and option unit)
Weight:	Approx. 60g

Communication method

Modulation method:	F1D
Frequency:	608MHz to 614MHz
Oscillation method:	PLL Synthesizer method by crystal control
Channel spacing:	12.5kHz
Occupied bandwidth:	Within 8.5kHz
Frequency deviation:	Within ±2.5ppm
Adjacent channel power ratio:	-40dBc or below
Effective radiated power:	Within 1mW ±2dBm
Transmission antenna:	1/4λwhip Gain 2.14dBi or below

Safety

General Standard:	IEC 60601-1: 1988 +Am1:1991 +Am2:1995 (Medical Electrical Equipment- Part 1: General Requirements for Safety)
EM Standard:	IEC 60601-1-2:2007 (Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral standard: Electromagnetic compatibility – Requirements and tests)

Operating Environment

Temperature:	10 to 40°C
Humidity:	30 to 85%RH (non-condensing)
Vibration/Shock:	Comply with IEC60068-2-64：2008, IEC60068-2-32 Ed.2:1975 Amd.1:1982 Amd.2:1990, IEC60068-2-6：2007, IEC60068-2-27：2008

Transport and Storage Environment

Temperature:	-10 to 60°C
Humidity:	10 to 95% (non-condensing)

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