

# Telemetry Transmitter Module

(TM XMTR Module)

# HLX-801(G)

Ver. 01

## Operation Manual



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



**This operation manual is for the HLX-801(G) Ver. 01.**

** 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.
- 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.

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

## Safety Precautions

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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.

 <b>DANGER</b>	Failure to follow this message may cause immediate threat of death or serious injury.
 <b>WARNING</b>	Failure to follow this message may result in death or serious injury.
 <b>CAUTION</b>	Failure to follow this message may cause injury or failure to the equipment.
<b>NOTE</b>	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(G).

### Precaution from Fukuda Denshi

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






- Maintenance, modifications, and repairs are carried out by authorized personnel or organization.
- 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(G)

<i>Symbol</i>	<i>Description</i>
	<u>Follow operating instructions (Information)</u> Indicates the need to refer to related accompanying documents before operation.
	<u>Year of Manufacture</u> Indicates the manufactured year.
	<u>Serial Number</u>
	<u>WEEE (Waste Electrical and Electronics Equipment)</u> Indicates a separate collection for electrical and electronic equipment.
	<u>Non-ionizing radiation</u> Indicates the including RF transmitter.

## Precautions for Safe Operation of Medical Electrical Equipment

Cautions described here are regarding the general instructions for safety use to the patient and users. Precautions unique to this device are detailed throughout the manual.



### CAUTION

1. Users should have a thorough knowledge of the operation before using this equipment.
2. Pay attention to the following when installing or storing the equipment.
  - Do not install or store in an area where the unit will be subject to splashing water.
  - Do not install or store in an area where the environmental conditions, such as atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, sodium, sulfur, will adversely affect the equipment.
  - Place the equipment on a stable surface where there is no inclination, vibration, or shock (including during transportation).
  - Do not install or store in an area where chemicals are stored or gasses are evolved.
3. Before operating the equipment, verify the following items.
  - Check the cable connection and polarity to ensure safe and proper operation of the equipment.
  - Ensure that all cables are firmly 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. During operation of the equipment, verify the following items.
  - Do not operate the equipment beyond the time period required for diagnosis and medical care.
  - Do not pick up and/or swing the equipment pulling/grabbing the probe (sensor) or cable part. It may damage the equipment and lead to measurement error.
  - Always observe the equipment 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.
  - Do not allow the patient to come in contact with the equipment.

## CAUTION

5. After using the device, verify the following items.
  - 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 is damaged and in need of repair, ensure patient safety by immediately turning the equipment off and remove the electrodes and/or probe from the patient. Label the unit "OUT OF ORDER" and contact 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 electrosurgical knives or defibrillator with this equipment, take care of the following.
  - To prevent patient from burn injury, verify proper attachment of patient ground plate, ECG electrode type when using the electrosurgical knife, and verify paste volume, output energy when using the defibrillator.
  - Some types of equipment 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 operate the equipment in the presence of flammable anesthetics or high concentration of oxygen. It may cause an explosion or fire.
- Never operate the equipment inside a hyperbaric chamber. It may cause an explosion or fire.
- Never operate 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. And 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. Otherwise, the HLX-801(G) cannot deliver its maximum performance and may be damaged, resulting in a safety hazard.

## Precautions about Output Signal

### WARNING

Do not use the output signal of the monitor that receives radio wave signal from the HLX-801(G) as the trigger signal for IABP, MRI, echocardiographic, or defibrillator for the following reasons. It may lead to a delay of operating timing due to the delay time of waveform transmission. A trigger signal unrelated to the heart rate may be generated due to the interfusion of spike noise at weak electric field.

## Precautions about 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.

## Precautions about Cleaning and Disinfection

### CAUTION

- Wipe using gauze or absorbent cotton etc. that has been soaked in alcohol, or a weak acidic, weak alkaline, or neutral detergent and wrung. 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, wipe using a gauze or absorbent cotton soaked in antiseptic soap or alcohol and wrung. At this time, do not immerse the connector parts of the equipment in any chemical solution. Doing so may cause contact failure.
- Sterilizing in high-temperature by using gas sterilization or autoclave equipment will damage this product, and should therefore not be used.
- When sterilizing the entire room using a spray solution, pay close attention not to have liquids get into the equipment or 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(G) transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.
- This equipment complies with FCC/IC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines and RSS-102 of the IC radio frequency (RF) Exposure rules. This equipment should be installed and operated keeping the radiator at least 20cm or more away from person's body
- Operation of HLX-801(G) 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(G) 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

- Regarding introduction, make sure of the following precautions.
  - The medical institution (hereinafter referred to as the "Institution") must decide the telemetry installation plan for the medical department in order to prevent interference and interference between transmitters (telemetry based on destination country's radio law). When telemetry has already been installed and been used, radio format, frequency, and antenna power are required to be examined to prevent interference.
  - When laying receiver antenna for each transmitter, the Institution has to examine the installation so that electronic interference does not occur.
  - Based on the above examination result, the Institution should install each receiver antenna as required.

### 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.
  - The telemetry user verifies operation of the transmitter/receiver before use.

# Electromagnetic Compatibility

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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 IEC 60601-1-2 (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(G) system is intended for use in the electromagnetic environment specified below.

<i>Emissions Test</i>	<i>Compliance</i>	<i>Electromagnetic Environment - Guidance</i>
RF Emissions CISPR 11	Group 1	The HLX-801(G) 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(G) is suitable for use in all establishments other than domestic buildings and those directly connected to a low-voltage power supply network which supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	NA	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	NA	

## ● Compliance to the Electromagnetic Immunity (1)


The HLX-801(G) is intended for use in the electromagnetic environment specified below. It is recommended that the HLX-801(G) be used in such an environment.

<i>Immunity Test</i>	<i>IEC60601-1-2 Test Level</i>	<i>Compliance Level</i>	<i>Electromagnetic Environment - Guidance</i>
Electrostatic Discharge (ESD) IEC 61000-4-2	±2,4,6kV: Contact ±2,4,8kV: Air	±2,4,6kV: Contact ±2,4,8kV: 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 IEC 61000-4-4	±2kV power supply lines ±1kV input/output lines	±2kV power supply lines ±1kV input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC E61000-4-5	±1kV: differential mode ±2kV: common mode	±1kV: differential mode ±2kV: common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% UT*(>95% dip in UT) for 0.5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 sec.	<5% UT*(>95% dip in UT) for 0.5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HLX-801(G) requires continued operation during power mains interruptions, it is recommended that the HLX-801(G) is powered from an uninterruptible power supply.
Power Frequency (50/60Hz) Magnetic Field IEC 61000-4-8	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(G) is intended for use in the electromagnetic environment specified below.

It is recommended that the HLX-801(G) be used in such an environment.

<i>Immunity Test</i>	<i>IEC60601-1-2 Test Level</i>	<i>Compliance Level</i>	<i>Electromagnetic Environment - Guidance</i>
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3Vrms 150kHz to 80MHz</p> <p>3V/m 80MHz to 2.5GHz</p>	<p>3Vrms</p> <p>3V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the HLX-801(G), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended Separation Distance</p> $d = 1.2 \sqrt{P}$ <p><math>d = 1.2 \sqrt{P}</math> 80MHz to 800MHz  <math>d = 2.3 \sqrt{P}</math> 800MHz to 2.5GHz</p> <p>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<sup>a)</sup>, should be less than the compliance level in each frequency range<sup>b)</sup>. Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Note 1 : At 80MHz and 800MHz, the higher frequency range is applied.</p> <p>Note 2 : These guidelines may not apply in all situations.                      Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p><sup>a)</sup> 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(G) is used exceeds the applicable RF compliance level above, the HLX-801(G) 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(G).</p> <p><sup>b)</sup> Over the frequency range 150kHz to 80MHz, field strength should be less than 3V/m.</p>			

## ● Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the HLX-801(G)

The HLX-801(G) 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(G) 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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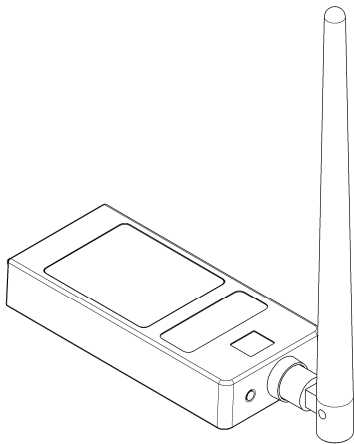
# 1. General Description

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The HLX-801(G) is a transmitter module to wirelessly transmit vital signal waveforms and numeric data which are monitored on the DS-8100 series bedside 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(G), also read the operation manuals of the patient monitor and central monitor thoroughly.

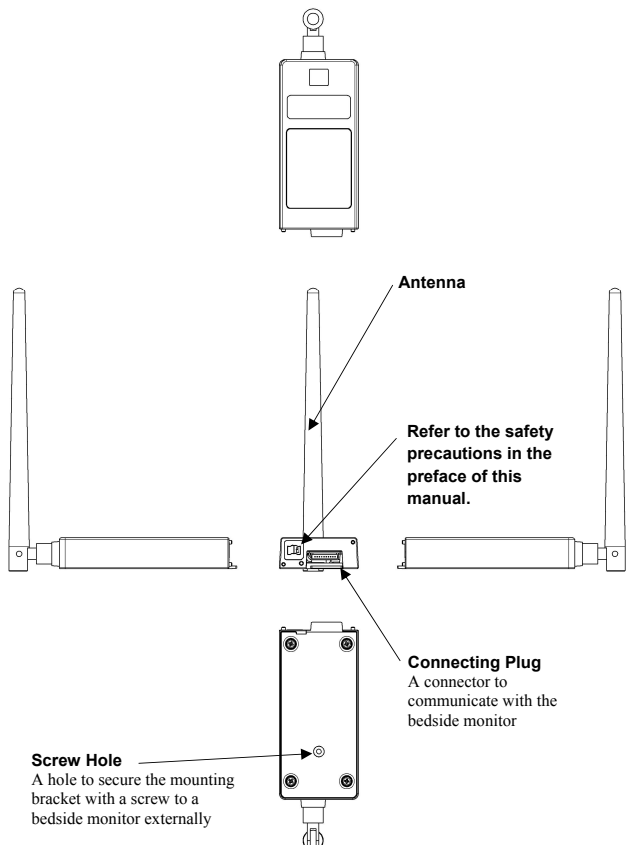
## External appearance





## 2. Name of Parts and Their Functions

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### 3. Preparation

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#### ■ 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(G) 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(G) 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(G), verify that the power of the bedside monitor is OFF before the procedure.
- After installation, make sure it operates normally.

## 4. Operation

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### ■ Operation Procedure

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

### ■ Changing the Transmitter Channel

The HLX-801(G) 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.

### ■ Changing the Group ID

The HLX-801(G) 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.


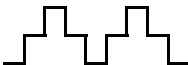
#### CAUTION

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.

## 5. Troubleshooting

If the measurement waveform is not properly displayed on the central monitor, check the following items.

If the phenomenon cannot be improved, contact your local Fukuda Denshi service representative.

<i>Pattern on the central monitor</i>	<i>Cause</i>		<i>Solution</i>
	The radio waves are not transmitted.	The connection is not properly set.	Check the connection between the HLX-801(G) 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(G).
			Check the antenna of the central monitor.
Transmitter malfunction	Contact Fukuda Denshi representative.		
	Noise is interfering.	The channel number arrangement is not appropriate.	Follow the instruction of the telemetry manager and set the appropriate channel.
		The group ID is not corresponded with the central monitor.	Follow the instruction of the telemetry manager and set the correct group ID.





## 6. Cleaning and Disinfection

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Clean and disinfect the HLX-801(G) as shown below.

### CAUTION

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

#### ■ Cleaning

Clean the HLX-801(G) using squeezed gauze or an absorbent cotton cloth dampened with alcohol or a neutral detergent.

### 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(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.
- 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, benzene, 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, wipe using gauze or absorbent cotton soaked in antiseptic soap or alcohol and wrung.

### CAUTION

- Do not immerse the connector parts of the HLX-801(G) 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.



## 7. Maintenance Check

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Periodic check must be performed. When reusing the HLX-801(G) 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(G) 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 Type: HLX-801(G) Serial No. \_\_\_\_\_ Date of Purchase \_\_\_\_\_

<i>Item</i>	<i>Check Details</i>	<i>Criteria</i>	<i>Judgement</i>
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 be properly 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
Periodic Check	Check the date of the previous periodic check.	Should be within 1 year.	OK/NG

Comment

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## 8. Accessories

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### WARNING

Use only the accessories specified by Fukuda Denshi for the HLX-801(G). Otherwise, the HLX-801(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

<i>No.</i>	<i>Item</i>	<i>Model Type</i>	<i>Q'ty</i>	<i>Note</i>
(1)	Operation Manual		1	This manual



## 9. Specification

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### ■ Specification



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

### Standard Specification

<b>Size:</b>	41(W) × 93(D) × 16(H) mm (excluding the antenna, protrusion, and option unit)
<b>Weight:</b>	Approx. 70g

### Communication method

<b>Modulation method:</b>	F1D
<b>Frequency:</b>	1395MHz to 1400MHz, 1427MHz to 1432MHz
<b>Transmitter Channel</b>	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
<b>Oscillation method:</b>	PLL Synthesizer method by crystal control
<b>Channel spacing:</b>	25.0kHz
<b>Occupied frequency bandwidth:</b>	Within 16.0kHz
<b>Frequency deviation:</b>	Within ±2.5ppm
<b>Adjacent channel power ratio:</b>	-42dBc or below
<b>Effective radiated power:</b>	Within 5mW ±2dB
<b>Transmission antenna:</b>	1/2 wavelength Sleeve antenna Gain 2.14dBi or below

## Safety

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

## Operating Environment

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

## Transport and Storage Environment

- Temperature:** -10°C to 60°C
- Humidity:** 10% to 95% (non-condensing)
- Atmospheric Pressure:** 70kPa to 106kPa



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# **FUKUDA DENSHI CO.,LTD.**

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3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan  
Tel: +81-3-5684-1455 Fax: +81-3-3814-1222  
<http://www.fukuda.com>

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