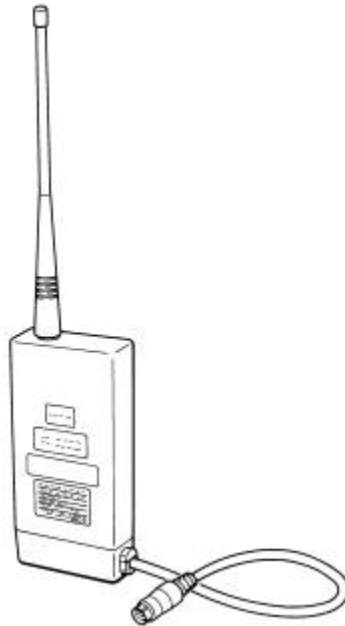


EXHIBIT D: User Manual

FCC ID DV8HLX561

Telemetry Transmitter Module
HLX-561
Operation Manual



**Read this manual prior to use of the HLX-561.
Store this operation manual in an easily accessible place near the
unit for future reference.**

**FUKUDA
DENSHI**



CAUTION

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

NOTE: Only a physician or a person under the guidance of a physician can use this device.

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Printed in Japan

Telemetry Precautions

For proper management of the telemetry installation, consult your Fukuda Denshi representative concerning the following:

- Plan the installation of your telemetry system taking into account your entire medical facility needs and plant requirements.
- Be sure the antenna system installed meets the facility and plant requirements.

WARNING

This Radio Frequency device is susceptible to interference from outside sources. Interference may prevent the monitoring of patients connected to this device. If problems exist contact your local service representative.

NOTE : This device operates in the 600MHz UHF band. The exact frequency of operation depends on designation, and each individual county's wireless service regulation.

To assure safe and reliable operation, observe the following precautions:

- Be sure that no other devices are using the frequency assigned to this transmitter.
- This device is susceptible to interference from electrosurgical knives and other computerized equipment. If problems occur contact your local Fukuda Denshi service representative.
- Any obstruction such as reinforced concrete or large metallic surfaces between the receiver and the transmitter can affect reception. If problems occur contact your local Fukuda Denshi service representative.
- When the low battery alarm is present at the central monitor, charge the battery in the patient monitor.



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.

Thank you for purchasing the HLX-561 telemetry transmission module from Fukuda Denshi. Before use, read this operation manual thoroughly for correct handling and operation. If you are familiar with a similar type of product, it is recommended this operation manual be read and understood since the HLX-561 has unique operation and handling methods.

Safety Information and Messages

Be sure to observe the warning and cautionary messages related to important safety information. These instructions are described under the following message headings. Understand the meaning of the different types of messages while reading this operation manual.

 WARNING	Erroneous operation by failure to observe instructions when this message is printed may result in death or serious injury to the patient, operator, or create a fire hazard.
 CAUTION	Erroneous operation by failure to observe instructions when this message is printed may result in injury to the patient or operator, or may cause damage to the HLX-561 and/or related instruments.
NOTE	A NOTE is not a warning instruction but offers information for correct use of the HLX-561 to avoid erroneous operation.

Safety Considerations in Using Medical Electrical Equipment

Contents described here are general safety considerations to be taken for proper operation of medical electrical equipment and for the safety of both the patient and operator. Safety considerations specific to the use of the HLX-561 telemetry transmission module are described on the next page.



CAUTION

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

2. Observe the following when installing or storing the equipment:

- Select a place where the equipment may not be contaminated with splashing water.
- Consider the atmospheric pressure, temperature and humidity and provide adequate ventilation. Avoid direct sunlight. The equipment should not be installed or stored in a location where it may be adversely affected by air containing dust, saline or sulfur.
- Avoid inclination, vibration and shock, even during transport to ensure stable operating conditions.
- Do not install or store the equipment where chemicals are stored or gases are generated.

3. Precautions before Operation

- The equipment is not designed to be explosion-proof. Do not use the equipment in the presence of flammable gasses or anesthetics.
- Make sure the equipment is operating safely and normally at all times.
Ensure that all cords and cables are correctly connected.
- Improper use of multiple instruments simultaneously may result in erroneous information or lead to a hazardous accident. (Refer to the Section 9.)



CAUTION

4. Precautions during Operation

- Do not to operate the equipment beyond the time period necessary that is required for diagnosis, monitoring or treatment.
- Observe the equipment and patient constantly for any abnormality.
- If the equipment or patient indicates any abnormality, stop the equipment from operating or take proper measures (e.g. disconnect transducers and electrodes) to ensure patient safety.
- Instruct the patient not to contact the equipment.

5. Cares after Operation

- Disconnect cords and cables by holding the connector plugs. Do not apply excessive force to cords and cables by pulling to disconnect.
- Keep the equipment clean in preparation for the next use.

6. If the equipment gets out of order, ensure patient safety by immediately turning the equipment off and disconnecting electrodes and or transducers from the patient. Contact your nearest Fukuda representative and label the device as "OUT OF ORDER".

7. Do not disassemble or attempt service on the equipment. Contact your nearest Fukuda Denshi representative for service.

8. Maintenance and Inspection

- Be sure to perform periodic inspection of the equipment and accessories.
- Before operating the equipment which has not been used for a long period of time, make sure that the equipment operates normally and safely.



CAUTION

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

- The high-frequency energy produced by electrosurgery equipment may result in burns to the patient or possible damage to the equipment. Be sure to observe the precautionary instructions described in the operation manual of the electrosurgical unit.
- Some types of equipment may be damaged by the energy discharged by a defibrillator. Ensure a thorough understanding of the precautionary instructions described in the operation manual of the equipment before using a defibrillator.
- Some types of equipment other than electrosurgical units and defibrillators may cause accidental hazards to the patient and operator when operated under adverse conditions. Read the operation manual attached to each individual unit and understand the precautionary instructions prior to use.

Contents

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Safety Considerations in Using Medical Electrical Equipment	iv
1. General Description	1
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6. Maintenance and Inspection	12
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1. General Description

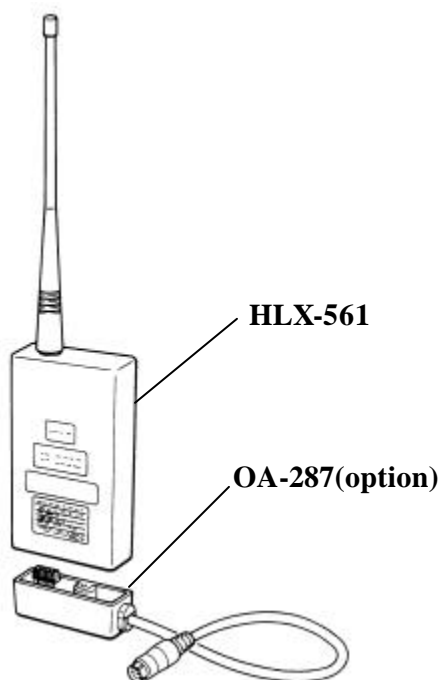
The HLX-561 is a telemetry transmission module to transmit physiological parameters monitored by a bedside monitor in the DS-5000 series via wireless technology. Thus, the HLX-561 allows the user to configure an integrated telemetry patient monitoring system in combination with a central telemetry receiver and central monitor such as the DS-5800N.

For compatibility with monitors other than DS-5000 series, contact your Fukuda Denshi representative.

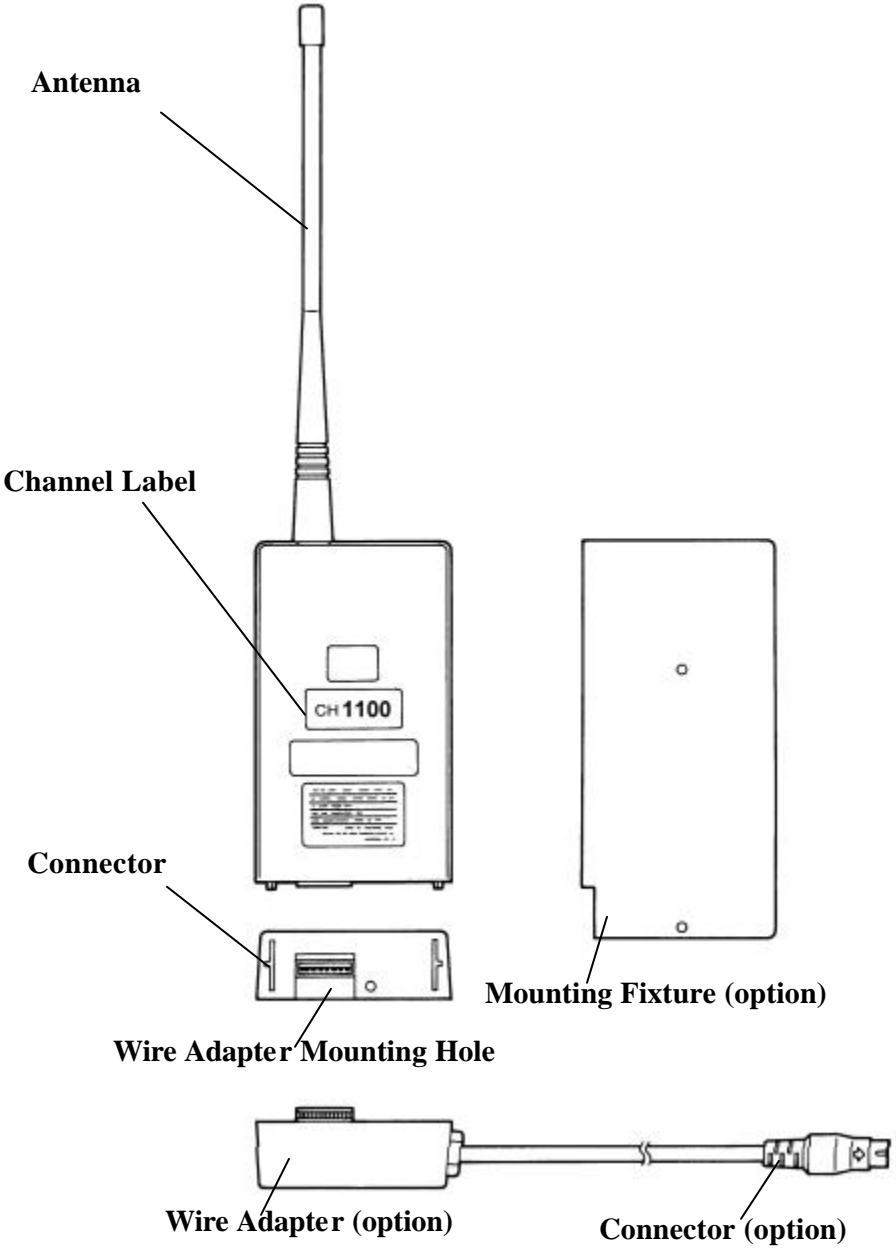
WARNING

Operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.

External Appearance



2. Controls and Indicators



Antenna

Transmitting antenna for the physiological parameters.

Channel Label

Contains the channel identification number of the transmitter. The receiver must be set to the same channel number. If the channel number is changed, the channel label must be replaced.

Connector

Connects to the bedside monitor.

Wire Adapter Mounting Hole

Connects to the optional wire adapter OA-287.

Wire Adapter OA-287 (option)

Allows for mounting the HLX-561 onto a bedside monitor.

Connector (option)

Allows for external connection of the HLX-561 to the bedside monitor. Connect to the F-LINK connector of the bedside monitor.

Mounting Fixture (option)

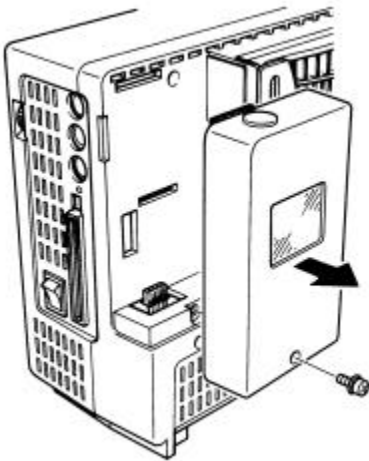
For mounting the HLX-561 into the bedside monitor. The illustration shows the method for mounting to the DS-5300.

3. Mounting the HLX-561 to the Bedside Monitor

Described here are the procedures for mounting the HLX-561 to the DS-5100 and DS-5300 as typical bedside monitors. If the radio channel is changed, it is recommended the channel label be changed in advance.

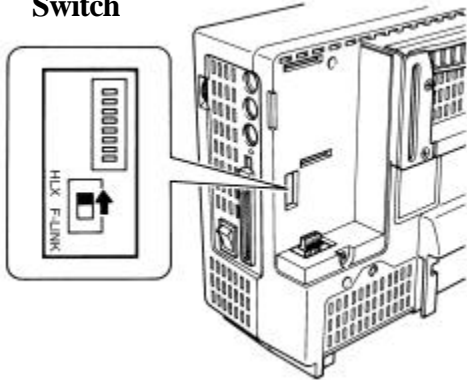
Mounting to the DS-5100

NOTE: Before starting the mounting work, turn the main power switch on the DS-5100 OFF and disconnect the power cable from the wall outlet.



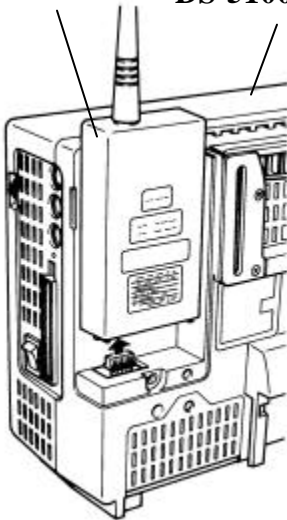
The transmission module housing is located at the upper left of the DS-5100 as viewed from the rear. Remove the screw that holds the cover in place and remove the cover as shown.

F-LINK/HLX Switch

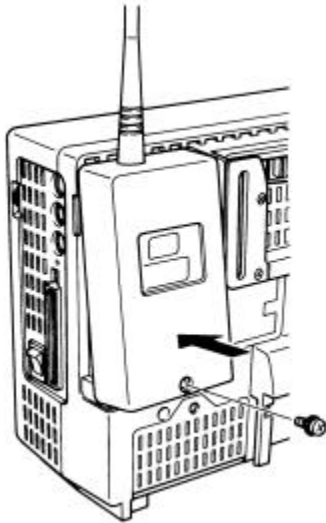


The F-LINK / HLX switch is now accessible. Switch to the HLX position to effect internal communication (Setting this switch to the HLX position disables the external F-LINK connector.)

HLX-561 DS-5100 Rear panel



Connect the cable from the bottom of the module housing to the connector at the bottom of the HLX-561. Remove the cap which covers the antenna hole in the top of HLX-561 transmission module housing cover. Place the HLX-561 into the housing, taking care not to jam the cable in the inside.



Place the cover back in its original position while at the same time inserting the antenna into the antenna hole. Replace the cover onto the DS-5100 by replacing the screw at the bottom.

Reconnect the power cord and turn the DS-5100 ON. Set the telemetry channel from the telemetry set-up display on the DS-5100.

For details in selecting the telemetry channel, refer to the operation manual for the DS-5100.

 **WARNING**

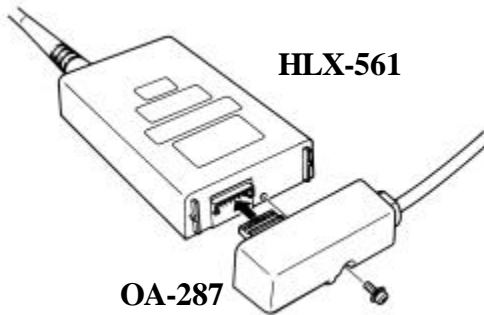
Operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.

To check the system, and verify proper transmission from the HLX-561 to the telemetry receiver, check the central receiver and monitor to ensure the waveforms and alphanumeric data are properly displayed.

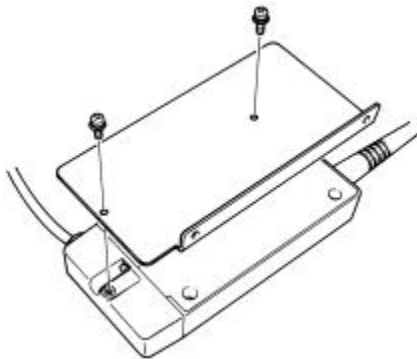
The wireless network system is now functioning properly.

Mounting into the DS-5300

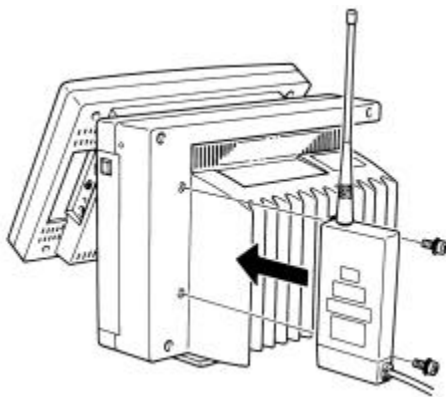
NOTE: Before starting, be sure to turn the main power switch of the DS-5300 OFF and disconnect the power cable from the wall outlet.



Connect the optional OA-287 adapter to the HLX-561, connector to connector. Attach the adapter to the HLX-561 with the accessory screw (M2.6 x 8).

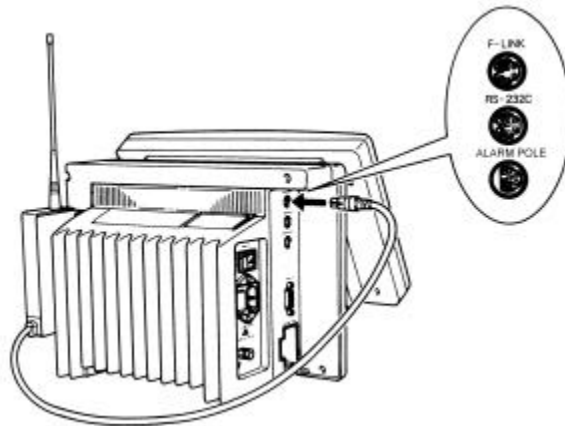


Attach the optional mounting fixture onto the HLX-561 with two accessory screws (M2.6 x 6).



Attach the assembly consisting of the HLX-561, OA-287 and mounting fixture, to the DS-5300 with the two accessory screws (M3 x 6).

Connect the cable from the OA-287 to the F-LINK connector of DS-5300.



Reconnect the power cord and turn the DS-5300 ON. Select the telemetry channel from the telemetry set-up display on the DS-5300.

For details on the telemetry channel set-up procedure, refer to the operation manual for to the DS-5300.

! WARNING

Operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.

! WARNING

Setting or changing the telemetry channel may cause interference with another telemetry system. Be sure to consult engineering for telemetry channels to select the proper radio channel which does not cause interference.

To check the system, and verify proper transmission from the HLX-561 to the telemetry receiver, check the central receiver and monitor to ensure the waveforms and alphanumeric data are properly displayed.

The wireless network system is now functioning properly.

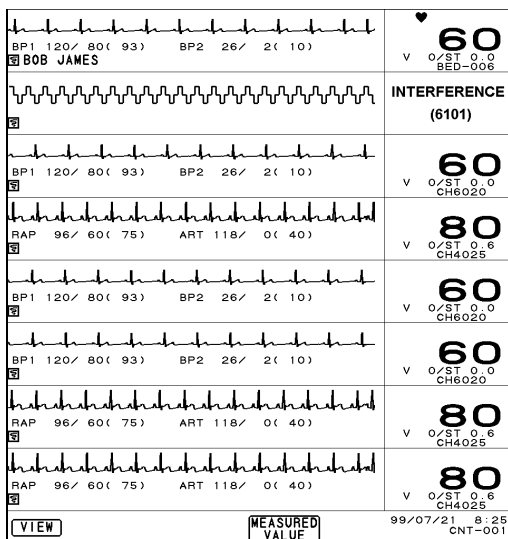
4. Setting the Receiving Channel of the Monitor

Select the telemetry receiver channel to match that of the telemetry transmission module. The monitor will display the channel number. If the transmission module has a different group code than that of the receiver, set the telemetry receiver group code to correspond to the telemetry transmission module. (For details on selecting the channel and group code, refer to the operation manual for the appropriate monitor.)

If the selected channel number does not correspond to the frequency that is actually received, an alarm waveform will be displayed to alert the staff to interference (see example below).

NOTE: The interference prevention function is not effective unless the receiver has the interference detection function.
Verify the receiver has the interference detection function and the proper channel number set.

Example of display on the DS-5800NX central monitor



**INTERFERENCE
message with alarm**

5. Cleaning, Sterilization and Disinfection

Clean, sterilize and disinfect the HLX-561 and accessories as follows.

Cleaning

Use a clean, soft cloth dampened with alcohol or a weak acid/alkalescent/neutral cleanser. Clean the HLX-561 and accessories with the dampened cloth, taking care that the cleaning solution does not enter into any connectors or get inside the HLX-561.

Do not use cleaning agents containing organic solutions, thinner, toluene and benzene. Such chemical solutions may damage the resin casing.

Sterilization and Disinfection

For Disinfection, wipe the HLX-561 and accessories using a gauze or sanitary cotton moistened with inert soap or alcohol. Do not moisten allow moisture inside of the connector to avoid contact failure.

For sterilization, use a gas sterilization method. Sterilization methods utilizing high temperatures such as an autoclave will damage the HLX-561 and accessories.

If sterilizing the room utilizing spray chemical solution methods, take proper measures to ensure the chemical solution will not contact the inside of the HLX-561 and connectors.

6. Maintenance and Inspection

To maintain the safety and reliable functionality and performance of the HLX-561, it is preferable to perform routine and periodic inspections before use. A recommendation is described in this section. Failure to perform routine maintenance and inspection may void the responsibility of Fukuda Denshi.



CAUTION

Persons other than your authorized Fukuda Denshi service representative must not remove the external casing of the HLX-561.

Always take care to avoid spilling alcohol or any other liquids inside of the HLX-561.

Routine Inspection

It is recommended that a routine inspections be performed daily. A sample Routine Inspection Record is provided on the next page.

Periodical Inspection

Periodic inspections are necessary to prevent trouble and accidents and to maintain the safety and efficacy of medical electrical equipment.

Ensure normal operation of the equipment by correcting adverse environmental conditions, if any, and by keeping the equipment in good repair. Periodic inspection becomes a part of the maintenance and inspection to ensure the equipment operates properly, efficiently, and safely.

Periodic inspection may be conducted by either the user or an authorized Fukuda Denshi service representative.

For details, contact your Fukuda service representative.

Routine Inspection Record

No. _____

Inspection Date: _____ **Inspected by:** _____ **Location:** _____

Model: HLX-561 _____ **Serial No.:** _____ **Purchase Date:** _____

Items	Inspection	Judgement criteria	Judgement
External appearance	Check the external appearance for scratches, breaks, cracks, loose screws, or labels. Check the antenna for bends or breaks.	No abnormalities	Pass/Fail
Function	Under normal operating conditions, check the functions at the central monitor.	Waveforms and data received in normal manner.	Pass/Fail
Periodic Inspection	Check the data of the most recent inspection.	Periodic Inspections should be performed per the institutions standard operating procedures.	Pass/Fail

7. Specifications

Transmitting Information (will depend on bedside monitor used)

Waveforms	: ECG × 1, 5 additional waveforms (e.g. Respiration, pulse, 2 blood pressure waveforms)
Numeric Parameters	: NIBP, SpO ₂ , Temp 1, Temp 2, BP1, BP2, Heart Rate, Respiration Rate, etc.
Status Information	: Low Battery, Electrode fail, Group code (64 types), Alarm, Alarm suspend, Remote record, Model ID number, Transmitter channel No.

Interface

Communications Method: RS-232C Serial Interface

Radio Frequency Specification

Modulation Method	: Digital, Frequency Shift Keying (FSK)
RF Output Power	: -15 dBm Standard, 0 dBm MAX
Transmission Frequency	: 608~614 MHz
Channel spacing	: 12.5 kHz

Power Requirements : +5 V, 60 mA supplied from the bedside monitor

Dimensions and Weight

Dimensions : 61.5(W) × 108.5(H) × 20.5(D) mm
Weight : Approximately 100 grams

Environmental Conditions

Operating Temperature : 10 to 40 °C
Operating Humidity : 30 to 85 %R.H. no dew condensation
Storage Temperature : -10 to 60 °C
Storage Humidity : 30 to 95 %R.H.(at 60 °C)

Specifications subject to change without notice

8. Accessories

To ensure the HLX-561 will perform to its published specifications, use only those accessories specified by Fukuda Denshi. When ordering spare parts or accessories, specify the part name and model number.

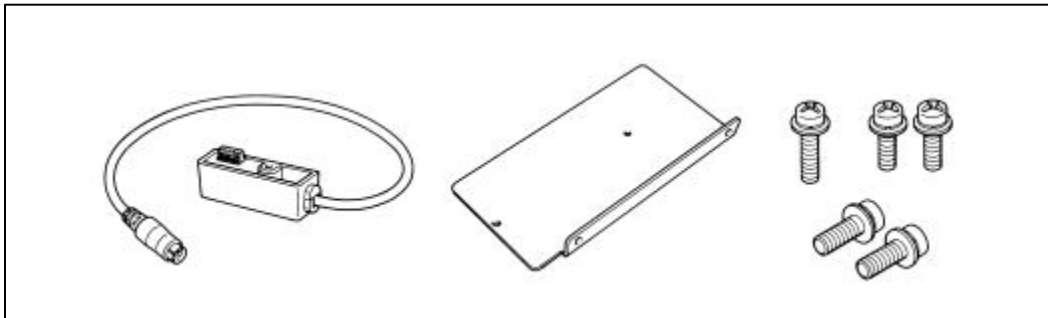
Standard Accessories

No.	Item	Model	Q'ty	Remarks
	Operation Manual		1	

Optional Accessories

The following item is not included in standard accessories. Purchase it separately.

No.	Item	Model	Remarks
	Wire Adapter	OA-287	Comes complete with the mounting fixture for the DS-5300 and mounting screws (M2.6x6 : 2 pcs. And M3x6 : 2 pcs, all with washer)





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