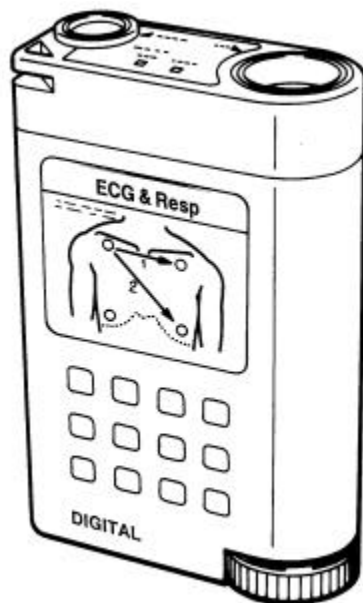


EXHIBIT D: User Manual

FCC ID DV8LX5160

ECG & Respiration Transmitter
LX-5160
Operation Manual



Before using the LX-5160 you must first thoroughly read this manual.

Remember to keep this operation manual in an easily accessible place near the unit for future reference.

— Important Information —

Only a physician or a person under the guidance of a physician can use this product.

The information contained in this document is subject to change without notice due to improvement in the equipment.



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.

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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 devices. If a problems exists, contact your local service representative.

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 replace the battery.

CAUTION

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

Thank you for purchasing this instrument from Fukuda Denshi. Familiarize yourself with the correct operation of this instrument prior to operation.

PRECAUTIONS FOR SAFE OPERATION AND HAZARD PREVENTION

Installation and Storage

- Install or store the instrument where it is free from moisture, splashed water, excessive dust, salt and direct sunlight.
- Avoid excessive vibration and shock during operation or transport.
- Do not store near chemicals, where gases are generated, or in a highly sulfuric atmosphere.

Precautions before Operation

- Do not operate this instrument in the presence of flammable gases.
- Ensure the instrument is operating normally and safely.
- When using the instrument in conjunction with another instrument, follow the appropriate instructions for both instruments.

Caution during Operation

Observe the instrument and patient for any abnormality. If abnormal operation occurs, remove the instrument from use and have it checked by the biomedical engineering department or contact your nearest Fukuda Denshi service representative.

Cautions after Operation

- Turn off the power switch when operation is complete.
- Disconnect cables properly by holding the plug and pulling it out gently.
- Clean the instrument prior to storing.

Non-explosion-proof

The instrument is not designed for operation in areas in which there is a risk of explosion.

Be sure to perform a periodical inspection of the instrument and all accessories.

CLEANING AND DISINFECTION

Electrodes and electrode cables

For disinfection, the electrodes and electrode cables should be rubbed with a swab or cloth moistened with a formaldehyde solution, such as Cidex 5%.

Under no circumstances may the electrode cables be immersed in any cleaning fluid, nor may they be subjected to heat sterilization with water, steam, or air, or be subjected to ether sterilization.

Transmitter

The transmitter cabinet may be cleaned and disinfected in the following manner.

Cleaning:

Rub the unit with a cleaning cloth moistened with water to which an ordinary household cleaning agent can be added if necessary. But never use ether or benzene.

Disinfection:

Thoroughly spray the cabinet with a 5% Cidex or a similar product.

Any and all modifications must be performed by an authorized Fukuda Denshi service representative.

 **CAUTION**

Some pacemaker pulses are difficult or not possible to detect. This is dependent on the amplitude and width of the pacemaker pulse in addition to the type of pacemaker and lead type used (unipolar, bipolar, etc.).

 **CAUTION**

QRS detection allows for detection of low amplitude ECG. But if excessive artifact is present on the ECG waveform, the noise may be detected as QRS in error.

 **CAUTION**

**Make sure each receiving telemetry channel corresponds to that of the transmitter worn by the patient.
Instruct the patient wearing a telemetry transmitter to remain within the range of the antenna system.
To avoid interference from other transmitters in the adjacent area or hospital, make sure the proper channel identification and group codes are used.
Refer system settings to your Fukuda Denshi service representative.**

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| 1. GENERAL DESCRIPTION | 1 |
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| 3. PREPARATION & OPERATION | 4 |
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| 7. MAINTENANCE AND INSPECTION | 13 |
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1. GENERAL DESCRIPTION

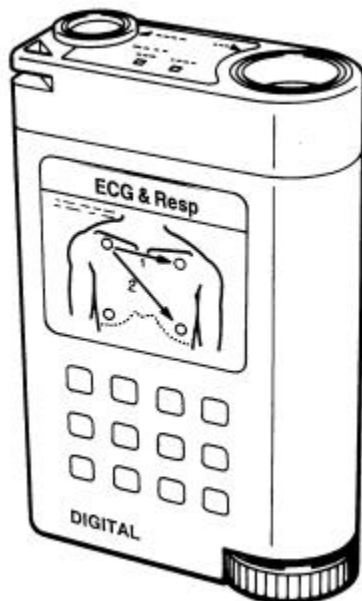
The LX-5160 is a radio telemetry transmitter designed for monitoring the ECG and Respiration. The transmitter will operate 5 continuous days from one "AA" size alkaline battery. On the top panel, battery and electrodes status displays are provided.

The LX-5160 is transmitting a digitized code that includes the transmitting channel number and group codes to prevent interference by other radio apparatus. Read the receiver and display unit operation manual before using this transmitter.

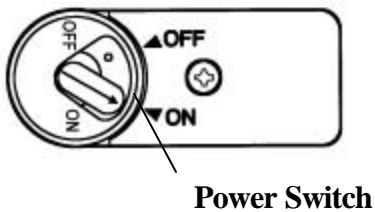
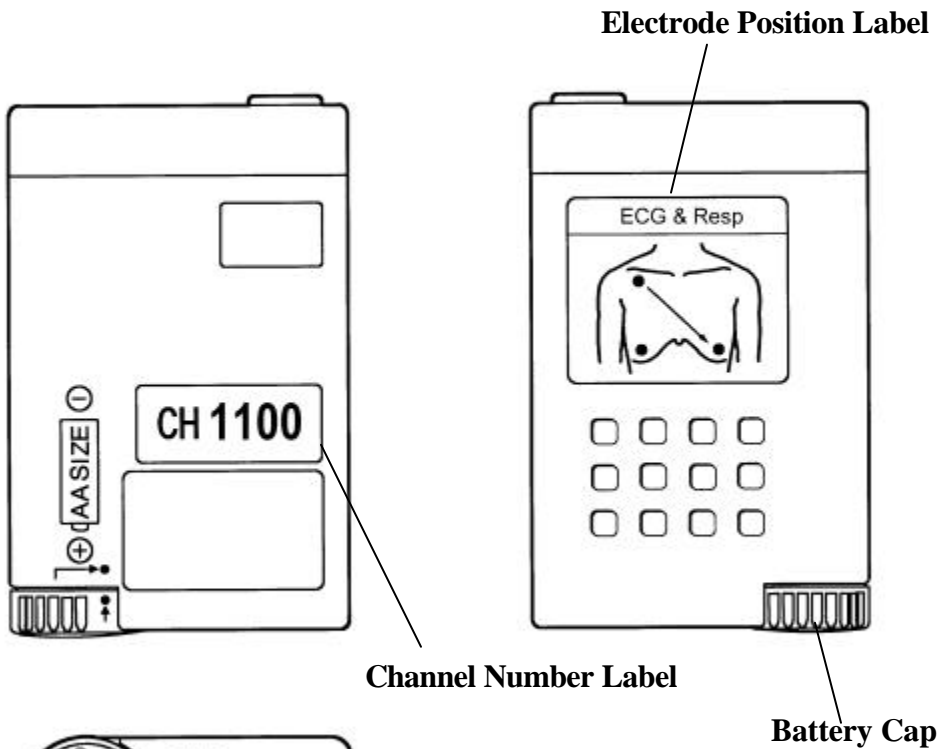
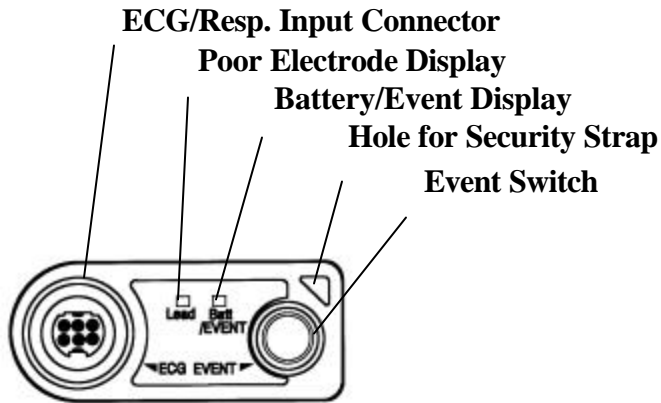
WARNING

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



ECG/Resp. Input Connector

Connect the accessory patient cable.

Poor Electrode Display

This lamp will light for two minutes when the electrodes are making poor contact or the patient cables are broken or disconnected.

Battery/Event Display

When the power switch is turned on, the battery check lamp will light for about 10 seconds. If the battery is low, the lamp will not light after turning on the power switch. The battery should be replaced with a new one.

Also, when the Event switch is pressed, this lamp will light.

Hole for Security Strap

Attach the accessory security strap to prevent the transmitter from dropping. Adjust the length of the strap to the appropriate length for the patient.

Event Switch

When this switch is pressed, this function will be activated at the receiver. This can be designated on or off at the receiver.

Channel Number label

The transmitter channel number is printed on this label. Select the receiver channel to correspond to this channel number.

Battery Cap

This is the battery compartment cap. To close the battery compartment, align the mark on the cap and arrow mark on the lower part of the transmitter, then push and turn the cap clockwise to align the dot-marks with each other.

Electrode Position Label

Typical electrode positions are shown on this label.

Power Switch

This is the power switch. When the switch is turned to the ON position, the "Batt." lamp will be lit for about 10 seconds.

If the battery is weak or has no power, the "Batt." lamp will not light even when the switch is turned to the ON position.

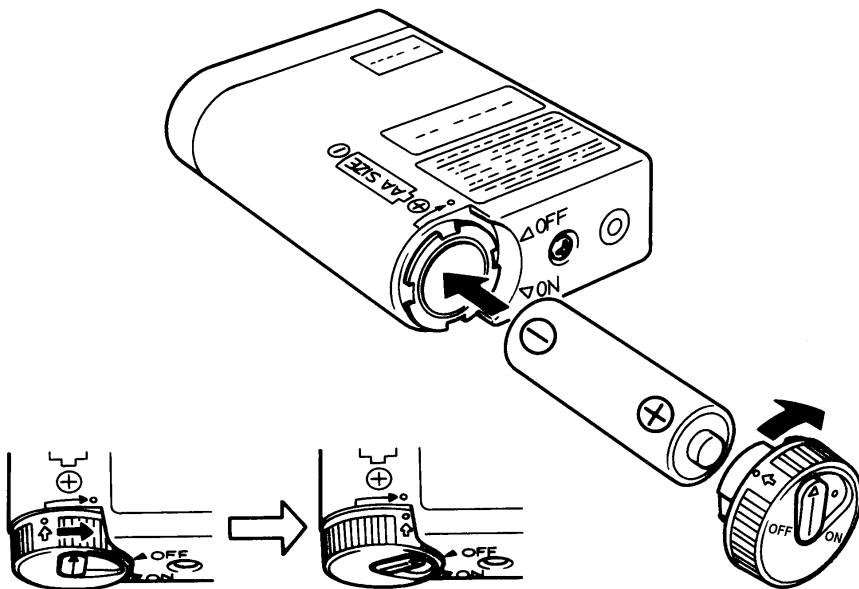
3. PREPARATION & OPERATION

Loading a battery

The LX-5160 uses one "AA" size alkaline cell (LR-6) for its power source.

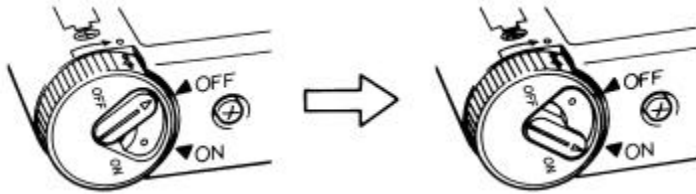
When installing a battery taking note of the polarity. To close the battery compartment, align the mark (yellow) on the cap and the mark (yellow) on the lower part of the transmitter, then gently push in and turn the cap clockwise to the mark (white) on the transmitter to align the dot-marks (white & yellow) with each other.

If the transmitter is not in use for a long period of time, remove the battery and store in an appropriate place.



Turn the power switch to "ON"

Turn the power switch, which is located at the bottom of the transmitter, on the battery cap, to the "ON" position.



The battery life will be approximately 5 days of continuous operation.



CAUTION

Do not use in high humidity or in areas of high oxygen concentration.

Attaching the electrodes

Wipe the skin at the electrode site with alcohol. Then detach the electrode from the electrode mount and attach it to the electrode site. Color coding of the electrode positions are shown below.

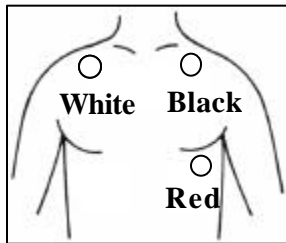
Adhesive tape should be used to tape the electrode wire to the skin to prevent the lead wire from moving on the electrode.

With the LX-5160 impedance measurements are used for respiration monitoring. There is a possibility that a large amplitude ECG signal will not always provide a large respiration signal. In general, lead CC5, as illustrated below, will provide the best respiration waveform.

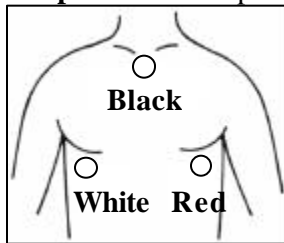
EXAMPLE OF ELECTRODE POSITIONS

For single lead ECG and respiration monitoring, use the CM-85B for AHA color code or CM-86B for IEC color code patient cable (three electrodes). AHA color code is applied in U.S.A. and IEC color code is applied in Europe.

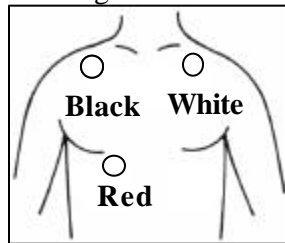
AHA color code electrode position Respiration sensing : White and Red



LEAD I

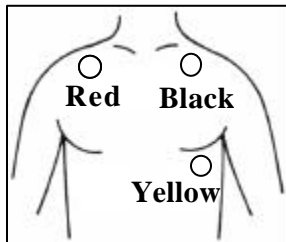


LEAD CC5

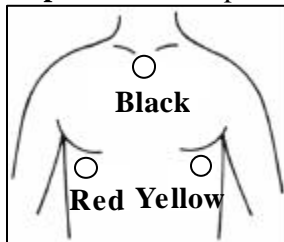


LEAD MCL1

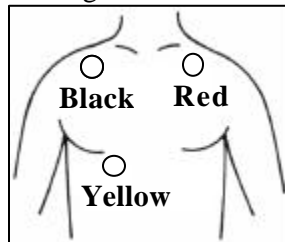
IEC color code electrode position Respiration sensing : Red and Yellow



LEAD I



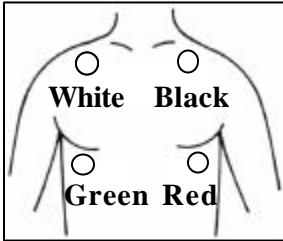
LEAD CC5



LEAD MCL1

For two lead ECG and respiration monitoring, use the CM-85C for AHA color code or CM-86C for IEC color code patient cable (four electrodes).

AHA color code electrode position



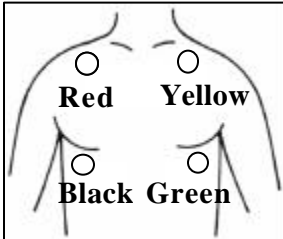
CH 1 $\left(\begin{array}{l} + : \text{Black} \\ - : \text{White} \end{array} \right)$ LEAD

CH 2 $\left(\begin{array}{l} + : \text{Red} \\ - : \text{White} \end{array} \right)$ LEAD

LEAD and LEAD

Reference : Green
Respiration sensing : White and Red

IEC color code electrode position



CH 1 $\left(\begin{array}{l} + : \text{Yellow} \\ - : \text{Red} \end{array} \right)$ LEAD

CH 2 $\left(\begin{array}{l} + : \text{Green} \\ - : \text{Red} \end{array} \right)$ LEAD

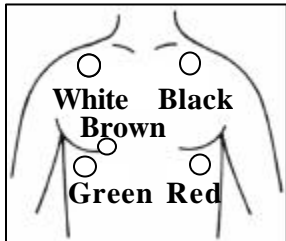
LEAD and LEAD

Reference : Black
Respiration sensing : Red and Green

| |
|--|
| CAUTION |
| <p>The CM-85 and CM-86 series patient cable are designed for ECG and Respiration monitoring. Other patient cables will not measure the respiration signals.</p> |

For dual channel ECG and respiration monitoring, use the CM-85D for AHA color code or CM-86D for IEC color code patient cable (five electrodes).

AHA color code electrode position



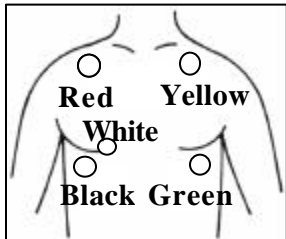
CH 1 $\left. \begin{array}{l} + : \text{Red} \\ - : \text{White} \end{array} \right\}$ LEAD

CH 2 $\left. \begin{array}{l} + : \text{Brown} \\ - : \text{Black} \end{array} \right\}$ LEAD

LEAD and LEAD MCL 1

Reference : Green
Respiration sensing : White and Red

IEC color code electrode position



CH 1 $\left. \begin{array}{l} + : \text{Green} \\ - : \end{array} \right\}$ LEAD

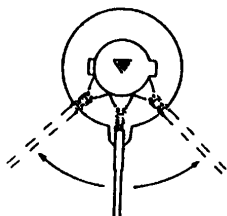
CH 2 $\left. \begin{array}{l} + : \text{White} \\ - : \text{Yellow} \end{array} \right\}$ LEAD MCL

LEAD and LEAD MCL 1

Reference : Black
Respiration sensing : Red and Green

Connect the lead wires to the electrode.

Connect the tip of lead wire to the center of the electrode and gently swing it right and left as shown below.



Connect the lead wire set firmly to the transmitter.



Connect the patient cable firmly to the ECG/Resp. input connector of the transmitter.

When disconnecting the patient cable, do not disconnect the lead wire set by pulling on the wires.



CAUTION

Confirm the direction of the keyed plug to match the transmitter's guide key on the connector. Improper connection will cause damage to the transmitter, patient cable, and will not provide proper monitoring.

4. SET THE GROUP CODE

The LX-5160 transmits a digitized code which includes the transmitting channel number and group code to prevent interference from other radio apparatus or a neighboring hospital's transmitter.

There are 64 group codes. Zero ("0") is set for factory adjustment.

The receiver is required to set the group code to match the transmitter's group code (The receiver group code's factory adjustment is "0").

The receiver is continuously checking the incoming channel number and group code versus the number and code programmed to the receiver. If the transmitter's group code is required to be changed, please contact Fukuda Denshi.

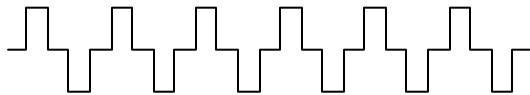
NOTE: The system function to prevent interference will not work if the receiver does not incorporate this function.

5. SELECT THE CORRESPONDING RECEIVER CHANNEL

Select the receiver channel at the patient monitor to correspond to the telemetry transmitter. The channel number will be displayed on the screen display. If the receiver channel and transmitter channel do not match, the monitor will display a caution and the unique waveform shown below. This function will prevent telemetry channel interference from other transmitters or external sources.

NOTE: This function will only be active if this has been incorporated into the receiver.

Example of the DS-5800N telemetry patient's display when interference is present.



This unique waveform will also be displayed when a group or channel number mismatch occurs.

6. CLEANING AND DISINFECTION

Clean the transmitter and patient cable with gauze or sanitary cotton dampened with alcohol or inert soap. Be sure not to get cleaning liquid into the patient lead connector and battery compartment.

Do not use cleaner containing organic solution, thinners, toluene, benzene. Do not autoclave or heat the unit and patient cable above 60°C.

When the room is disinfected by spraying, take proper measures so the chemical solution does not get on the connector or enter into the inside of the enclosure.

7. MAINTENANCE AND INSPECTION

Items in this section include routine daily and periodic checks of the equipment to ensure it is operating properly.

It is recommended that to maintain the safety and reliability of functions and performance of the unit, the daily and periodical checks given in this section be followed.



CAUTION

Do not open the unit or attempt service. Refer service to Fukuda Denshi.

Do not allow excessive moisture or cleaning agents into the connectors or the inside of the housing.

Daily Check

Perform daily checks in accordance with the recommended daily check list.

Periodical Check

Periodical checks of the equipment for safety and performance of medical equipment is normally required by every institution at least once or twice per year. Contact Fukuda Denshi for recommended periodic maintenance.

Daily Check List

No. _____

Date _____ Checker _____ Installation Place _____

Unit LX-5160 _____ S/No. _____ Purchase Date _____

| Items | Details of the Check | Criteria | Judgement |
|---------------------|---|---|-----------|
| Appearance | Visually check for any damage, cracks, chink, chips and peeled nameplate on the outer enclosure. | No abnormality. | OK NG |
| Battery Compartment | Visually check the connecting spring on the inside of the device and battery cap. | No spring transformed, deformed or rusted. | OK NG |
| Power | Turn ON/OFF power to verify proper switch operation. | With battery in, the Batt. lamp will be illuminated for about 10 seconds. | OK NG |
| ECG Connector | Visually check for plug connector of main unit and patient cable. | No scratch and chips. No dust attached. | OK NG |
| Patient Cable | Visually check for wire coating of patient cable. | No cracks, kinks, or damage. | OK NG |
| Wireless Channel | Visually verify the transmit channel, and group No. Follow instructions of the wireless channel manager for the receiver. | Must correspond with wireless channel check list. | OK NG |
| Function | Turn on the power and make sure operation is normal. | Waveform is received without any problem. | OK NG |
| Periodic Check | Check the dates of previously performed periodic checks. | Should be within one month. | OK NG |

8. SPECIFICATIONS

| | |
|-----------------------------|---|
| Parameters | : 1 or 2 channel ECG and respiration |
| ECG input impedance | : More than 50 Meg-ohms |
| ECG max. input range | : ± 5 mV |
| ECG freq. response | : 40 Hz (refer to the receiver filter also) |
| ECG time constant | : 0.8 seconds (1.5 seconds for option) |
| Resp. measurement | : Impedance pneumography |
| Resp. max. input range | : ± 5 ohms |
| Resp. meas. electrodes | : RA & LL, ECG channel 1 |
| Resp. freq. response | : 0.3 to 3 Hz (refer to the receiver filter also) |
| Defibrillator protection | : By protection circuit in the patient cable |
| Status information | : Electrode fail, Low battery (below 1 volt), Event switch, Pacemaker detection, Channel ID, 64 kinds of Group code |
| Transmission freq. | : 608~614 MHz |
| RF output power | : 1.0 mW ± 2 dB |
| Channel spacing | : 12.5 kHz |
| Occupied band width | : 8.5 kHz |
| Modulation mode | : Digital, Frequency shift keying |
| Power source | : One 1.5 V AA size alkaline battery |
| Battery polarity protection | : Mechanical reverse polarity protection |
| Battery life | : 5 days min. |
| Water immersion degree | : Per IP-66 |
| Weight | : Approx. 110 g (including battery) |
| Dimensions | : 54(W) \times 86(H) \times 22(D) mm |
| Operating temperature | : 10 to 40 °C |
| Operating humidity | : 30 to 85 % RH (no dew condition) |
| Storage temperature | : -10 to 60 °C |
| Storage humidity | : 10 to 95 % RH |



**CAUTION: Specifications are subject to change
without prior notice.**

9. ACCESSORIES

Standard Accessories

- Patient cable : One CM-85B or CM-86B, three electrodes type or CM-85C or CM-86C, four electrodes type. The type of the cable depends on the destination.
- Pouch : Two AB-95, disposable pouch
- Security Strap : One OB-25 belt kit
- Battery : One LR-6, 1.5 V alkaline AA battery
- Instruction manual : One



Patient cable
CM-85B(AHA color code)
CM-86B(IEC color code)



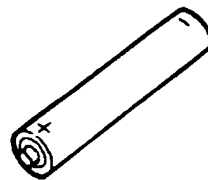
Patient cable
CM-85C(AHA color code)
CM-86C(IEC color code)



Pouch AB-95



Security Strap
OA-25



Battery
LR-6

Optional Accessories

CM-85B or CM-86B, Patient cable for single ECG lead and respiration.

CM-85C or CM-86C, Patient cable for two ECG lead , and respiration.

CM-85D or CM-86D, Patient cable for dual ECG for any two channel differential ECG and Respiration, five electrode type.



Patient cable
CM-85B(AHA color code)
CM-86B(IEC color code)



Patient cable
CM-85C(AHA color code)
CM-86C(IEC color code)



Patient cable
CM-85D(AHA color code)
CM-86D(IEC color code)

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