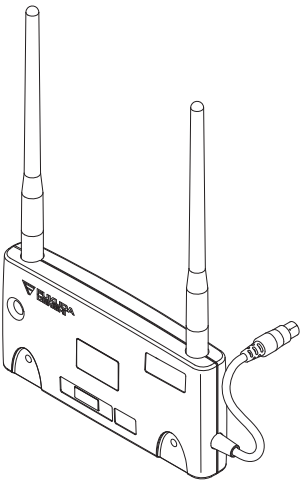
Bidirectional Wireless Communications Module

(TCON)
HTC-702
Instruction Manual



- Before using this device, read this “Instruction Manual” thoroughly.
- After reading, keep this manual near the device for future reference.

FUKUDA DENSHI

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

CAUTION:

- 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 this product.
Before using this product, please read through this “Instruction Manual” to make sure the product is used correctly and safely. Even if you are familiar with our devices, there are certain handling procedures that are unique to this device. Therefore, please make sure you read this manual thoroughly before use.

Safety Precautions

The safety precautions shown in this manual contain important details on the safe use of this product, and must be obeyed. Symbols and their meanings are shown below. Be sure to understand the contents below before reading the rest of the manual.

⚠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 equipment.

Precautions for Safety and Hazard Prevention

This section contains general information on how to handle this device for safety use.
Precautions unique to this device are detailed throughout the manual.

⚠CAUTION

1. Users should have a thorough knowledge of the operation before using this device.

2. Pay attention to the following when installing and storing the device.
   - Do not install or store in an area where the equipment will be subject to splashing water.
   - Do not install or store in an area where the environmental conditions, such as humidity, ventilation, sunlight, and air containing dust, salinity, or sulfur, will adversely affect the system.
   - 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 device, verify the following items.
   - This equipment is not designed to prevent explosions etc. due to flammable anesthetics or oxygen etc. Therefore, do not use this equipment in a flammable atmosphere.
   - Check that the device is operating normally and safely.
   - Ensure that all cables are firmly and safely connected.
   - Pay special attention when this device is used in conjunction with other devices, as it may cause erroneous judgment and danger.

4. During operation of the device, verify the following items.
   - Make sure the time required for diagnosis, observation, and treatment is not exceeded.
   - Always observe the device and patient to ensure safe operation of the equipment.
   - If any abnormality is found on the device or patient, take appropriate measures such as ceasing operation of the device in the safest way for the patient.
   - Do not allow the patient to come into contact with the device or electronic components.

5. After using the device, verify the following items.
   - Return all operating switches, knobs etc 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 by the connector part of the cable.
   - Clean the accessories and cables, and keep them together in one place.
   - Keep the unit clean to ensure proper operation of the next use.

⚠CAUTION

6. If the device is damaged and in need of repair, users should not attempt to service the device themselves. 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 device and accessories.
- Before reusing a device that has been left unused for a while, make sure that the device works normally and safely.

⚠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.

Precautions for Use of Bidirectional Wireless Communications (TCON)

⚠CAUTION

■To operate the device correctly, read the following precautions carefully.

- The medical institution (hereinafter referred to as “Institution”) must execute investigation required to prevent interference including types of radio waves, frequencies, and antenna power if wireless equipment is already installed and being used in the facility.
- Even if this device is installed within the range of radio communication, the communication may not be possible due to noise or multi-path phasing etc. Always consider this thoroughly before use.
- Do not install this device in an area where it will be subject to splashing water. Water entering the equipment may cause the equipment to malfunction or be damaged.

■In managing, be sure to follow the precautions below.

- The Institution should appoint a person (hereinafter referred to as the “Overall Manager”) to manage the wireless devices for the whole facility.
- When installing TCON, the Overall Manager has to receive an explanation of the precautions for use of the TCON from the manufacturer or sales representative.
- The Overall Manager is responsible for the maintenance and storage of the equipment.
- 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 facility. When assigning or changing wireless channels, register it in the log, and give proper instructions to the TCON user.
- The user needs to verify operation of the transmitter/receiver before use.
- If interference or breakdown occurs in the communication, the TCON user is required to stop using TCON and to inform the Overall Manager of the problem. The Overall Manager is to deal with the problem properly and/or contacts the nearest Fukuda Denshi representative for service.

⚠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

■Precautions for Use

The Bidirectional Wireless Communications Module (TCON) uses radio waves to transmit data. Therefore, the necessary precautions need to be taken for the characteristics and difficulties of using the device that emits radio waves. The TCON user should fully understand these precautions beforehand, and use the TCON device safely.
Furthermore, situations in which interference may occur are outlined below. In such cases, pay special attention to the condition of the patient connecting to the bedside monitor, and eliminate the cause of the interference.

1. The patient's data may become mixed with a different patient's data due to Interference.
   - When there are multiple TCON communication devices set to the same channel and group (ID).
2. When symptoms such as being unable to communicate, unstable communication, or poor reception may occur.
   - When the radio communication is bad because there are metal, concrete, or other such obstacles between the Bidirectional Wireless Communications Modules (TCON).
   - When a different wireless device is using the same frequency (or the same channel).
   - When there are other TCON devices nearby using different channels or groups.
   - When a cell telephone or other wireless device is being used nearby.
   - When citizens broadcast bands such as amateur radio or truck radios are used in the vicinity of the TCON operating area.
   - When a computer or word processor, or electrical device that has an internal computer, is used near the TCON device antenna.
   - When the TCON device is installed or moved to a location that is outside the radio communication range.
   - If a nearby different group is set with a TCON channel frequency that is too close to the channel frequency set for the current TCON group.

FCC Radiation Exposure Statement

⚠WARNING

- This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.
- This equipment complies with FCC radiation exposure limits set forth for an controlled environment and meets the FCC radio frequency (RF) Exposure Guidelines in Supplement C to OET65. This equipment has very low levels of RF energy that it deemed to comply without maximum permissive exposure evaluation (MPE). But it is desirable that 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 this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.

Contents

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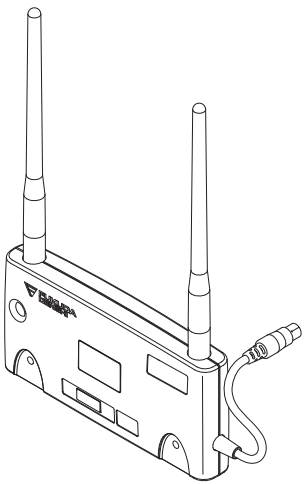
1. Overview

This device is a Bidirectional Wireless Communications Module (HTC-702) used for wirelessly communicating vital signs data monitored by the DS-7000 series patient monitor. This device can be used in combination with a wireless central monitor such as the DS-7600 to construct a patient monitoring system with a medical telemetry and the Bidirectional Wireless Communications (TCON) system.

For details on compatibility with other patient monitors, contact Fukuda Denshi representative.

[External Appearance]



HTC-702

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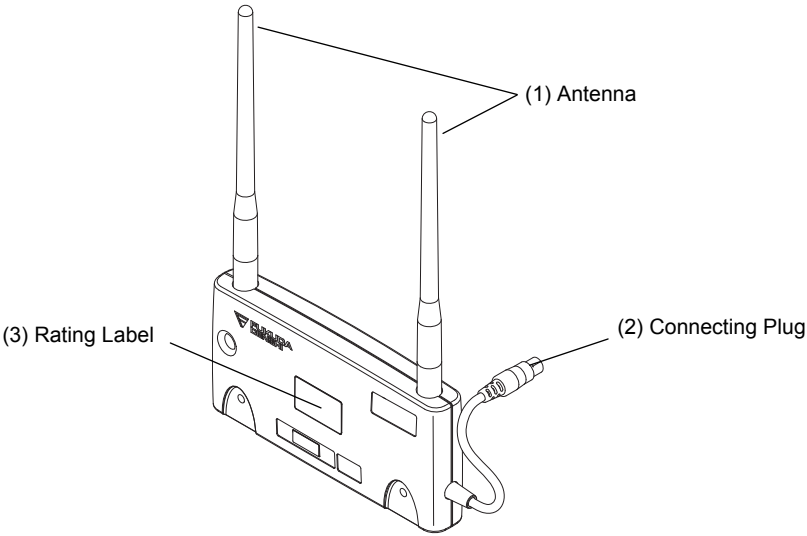
2. Names of Parts and Their Functions

■HTC-702



(1) Antenna

Used to send and receive radio waves.

(2) Connecting Plug

Used to connect the HTC-702 with the patient monitor.
Connect to the “COM1 to 3 port” or “F-LINK” connector on the patient monitor.

(3) Rating Label

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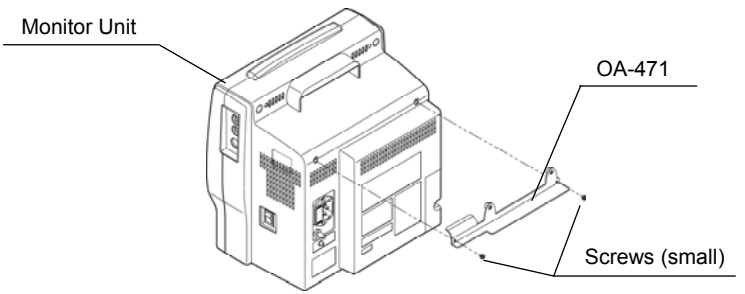
3. Installation to the Patient Monitor

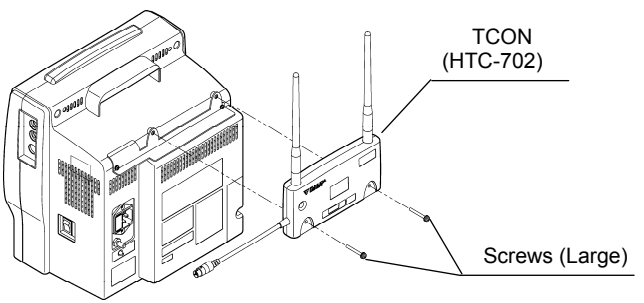
⚠ **CAUTION**
Before starting the installation work, switch the patient monitor main power switch OFF, and remove the power plug from the socket.

■Example Installation of HTC-702 to Bedside Monitor, DS-7100

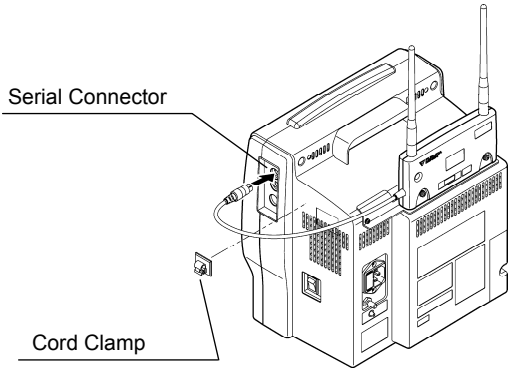
1 On the rear side of the monitor unit (DS-7100 series), fix the OA-471 (Optional TOCN Installation Bracket for Patient Monitor) in place in 2 locations using the screws (small), which are included in the OA-471 accessories.



2 Fix the TCON (HTC-702) to the OA-471 in 2 places using the screws (large), which are included in the OA-471 accessories.



3 Attach the Connecting Plug of the HTC-702 cable to the Serial Connector on the right side of the monitor unit.
Attach the Cord Clamp, which is included in the HTC-702 accessories, to the monitor unit, and pass the connecting cable through the clamp.



4 Switch the DS-7100 power on, and set the TCON channel and ID in the TCON Setup screen.
For details on the setting procedure, see the DS-7100 operation manual.

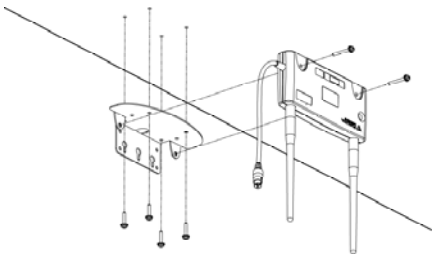
⚠CAUTION

- Follow the instructions of the Overall Manager for the wireless channel when setting the TCON channel or ID to prevent interference within the same institution.
- Select TCON OFF on the TCON Setup screen if the TCON is connected when the TCON channel or ID is changed. Otherwise, the TCON may communicate with a different group.

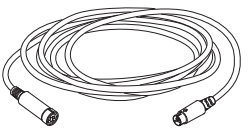
■Example Installation of HTC-702 to Central Monitor, DS-7600

NOTE

The recommended connection procedure for the HTC-702 and DS-7600 is to use the optional OA-702 and CJ-702 to install the HTC-702 in a high location on a wall or on the ceiling in the corridor.
However, if the DS-7600 is to be moved during use, install it to the rear side of the DS-7600. In this case, the TCON communication range is smaller than when installed on the ceiling or wall.

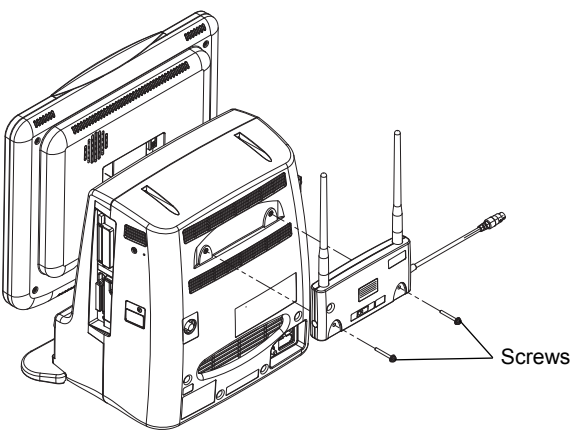


OA-702

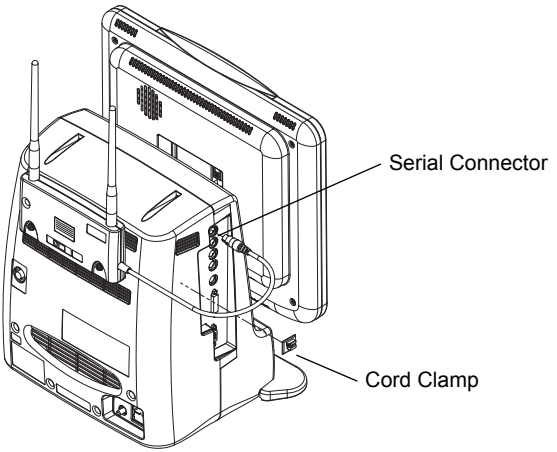


CJ-702

1 Fix the HTC-702 to the back of the DS-7600 using the screws, which are included in the HTC-702 accessories.



2 Attach the Connecting Plug of the HTC-702 cable to the Serial Connector on the left side of the DS-7600.
Attach the Cord Camp, which is included in the HTC-702 accessories, to the DS-7600, and pass the connecting cord through the clamp.



3 This completes the installation.

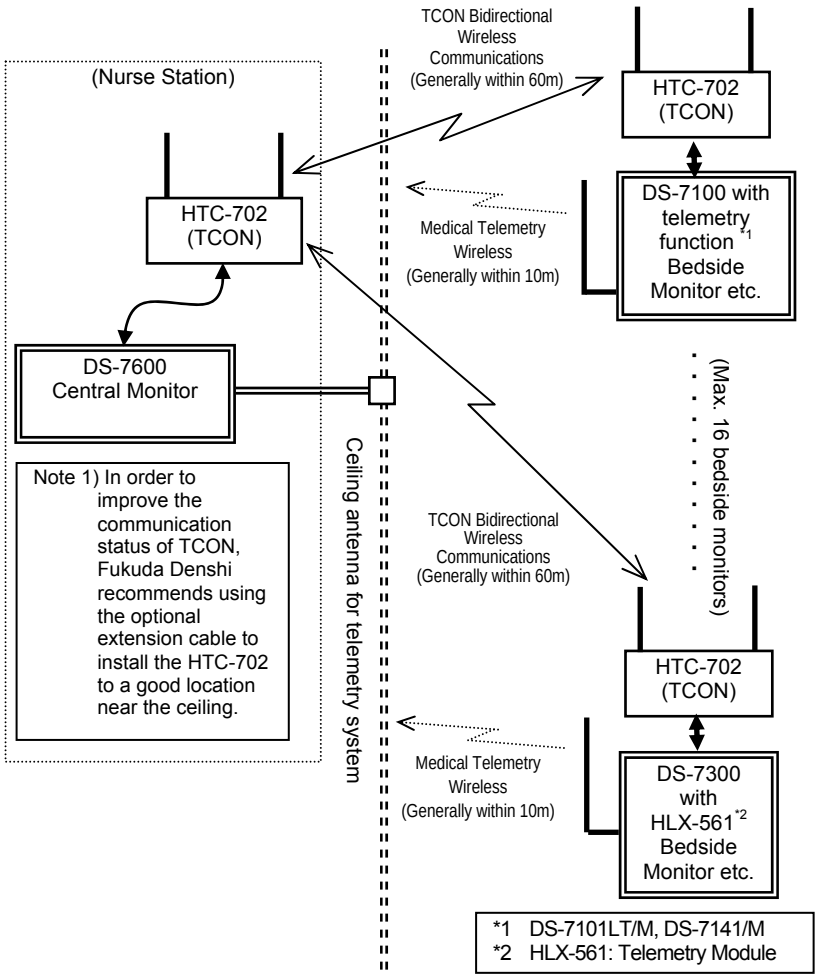
4 Switch the DS-7600 power on, and set the TCON channel and ID in the TCON Setup screen.
For details on the setting procedure, see the DS-7600 operation manual.

⚠CAUTION

- Follow the instructions of the Overall Manager for the wireless channel when setting the TCON channel or ID to prevent interference within the same institution.
- Select TCON OFF on the TCON Setup screen if the TCON is connected when the TCON channel or ID is changed. Otherwise, the TCON may communicate with a different group.

4. System Configuration Example

<Medical telemetry with TCON System Configuration Example>



Note 3) •In the configuration above, set the same TCON channel for the bedsides and central monitor.
•Set the TCON ID as “1 to 16” for the bedside monitors, and “1” for the central monitor.

NOTE

If the TCON is installed in a location that exceeds the TCON communication range (within 60m) in the TCON system on the previous page, it is possible to use the system by installing a “TCON Repeater”. Certain installation conditions and limitations apply to the “TCON Repeater”. For details, contact 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.

5. Cleaning, Disinfection, and Sterilization

Clean, disinfect, and sterilize the module unit and connecting cords as shown below.

■Cleaning

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 inside the connectors or main unit.
Furthermore, do not use detergents that include organic solvents, thinners, toluene or benzine, as these solvents may damage the resin used in the unit.

■Disinfection and Sterilization

- If there is a fear of contagion, wipe using gauze or absorbent cotton soaked in antiseptic soap or alcohol and wrung. At this time, do not soak or wipe inside the connector using the chemical. Doing so may cause contact failure.

- Sterilizing in high-temperature by using gas sterilization or autoclave equipment will damage this device, and should therefore not be used.
  When performing simultaneous disinfection inside the ward or room using chemical sprays, be sure that the chemicals do not enter the equipment or come into contact with the connectors.

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6. Maintenance Check

In order to use this equipment safely and to maintain the functions, performance and reliability of this equipment, the “Daily Check” and “Periodic Inspection” must be performed.
Fukuda Denshi is not liable for accidents arising from lack of maintenance.

⚠CAUTION

- Do not open the main unit housing.
- Make sure that alcohol and other liquids do not enter inside the device.

■Daily Check

Perform the following daily check according to the “Daily Check List” on the next page.

■Periodic Inspection

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

Daily Check List

No. _____

Checked Date _____ Checked by _____ Installation Location _____

Device Type HTC-702 Serial Number _____ Date of Purchase _____

Item	Check Details	Criteria	Judgment
External appearance	Visually inspect for damage, cracks, breaks, chips, loose label, loose screws, installation condition or bending of the connecting connector and antenna.	No remarkable abnormalities should be found.	OK • NG
Functions	Connect to the monitor, operate under normal operating conditions, and check the communication function and operation.	Measurement values etc. should be transmitted correctly.	OK • NG
Periodic Inspection	Check the date of the previous periodic inspection.	Within 1 year of the current date.	OK • NG

7. Specifications

Communication Parameters (Depends on the patient monitor used)

: Bedside monitor measurement values, alarm limits, NIBP control, etc.

Communication Channel : Max. 60 channels

Interface

Communication method	: RS-232C Serial Interface
Synchronization	: Start-stop synchronization

Wireless communication section

FCC regulation	: FCC part 95 Subpart H Wireless Medical Telemetry Service (WMTS)
Type of emission	: F1D
Modulation	: Frequency shift keying
Field strength	: <740 mV/m (at 3 meter)
Effective radiated power	: 20mW (35mW eirp)
Transmission frequency range	: 1395.5125MHz to 1396.9875MHz
Channel spacing	: 25KHz
Occupied bandwidth	: <16KHz
Antenna	: Half wave length dipole for transmission Two of Half wave length dipole for diversity receiving

Power Supply

Within DC+5V 0.75W (within 150mA) from the patient monitor

Dimensions and Weight

Dimensions	: 160(W) x 27(D) x 76 (H) mm (excluding the antenna and connecting cables)
Weight	: Approx. 270g

Environmental Conditions

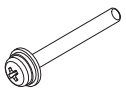
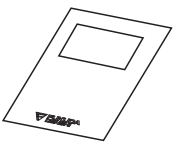
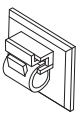
Operating Temperature	: 10 to 40ºC
Operating Humidity	: 30 to 85% RH (with no condensation)
Storage Temperature	: -10 to 60ºC
Storage Humidity	: 10 to 95% RH (with no condensation)

8. Accessories

In order to satisfy product performance requirements, always use the accessories specified by Fukuda Denshi.

■Standard Accessories

No.	Item	Model Type	Quantity	Notes
(1)	Installation Screw for Patient Monitor	W sems M4x30	2	
(2)	Instruction Manual (this manual)		1	
(3)	Cord Clamp	CKN-05	1	

(1) 	(2) 	(3) 

■Optional Accessories

The following items are available as optional accessories. Purchase them as required separately.

No.	Item	Model Type	Notes
(4)	Wall mount & tabletop stand for HTC-702	OA-702	
(5)	Extension Cable	CJ-702	5m
(6)	TOCN Installation Bracket for Patient Monitor	OA-471	
(7)	TCON Repeater Box	CJ-703	

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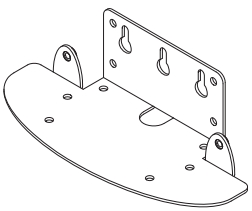

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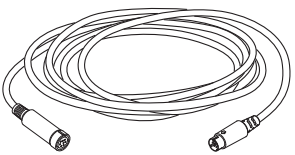

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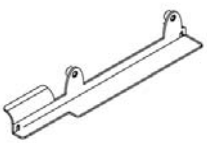

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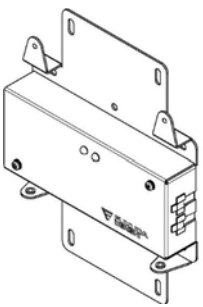

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