# Operation Manual IB-8004 Input Box

(€ 0086

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#### € 0086

This device bears the CE label in accordance with the provisions of Medical Device Directive 93/42/EEC.

This device bears the CE label in accordance with the provisions of RoHS Directive 2011/65/EU.

EC REP

Fukuda Denshi UK Unit 7, Genesis Business Park, Albert Drive, Woking, Surrey GU21 5RW, United Kingdom

Thank you for purchasing our product.

Read the "Safety Precautions" thoroughly before use to ensure correct and safe use of the equipment.

Please also refer to the operation manual of the DS-8500 System Patient Monitor.

# Safety Precautions

Make sure to follow the precautions indicated below, as these are important messages related to safety. The followings are descriptions and graphic symbols of the safety and precaution messages used in this manual.

| ⚠DANGER          | Failure to follow this message may cause immediate threat of death or serious injury.   |
|------------------|---|
| ⚠WARNING         | Failure to follow this message may result in death or serious injury.   |
| <b>∆</b> CAUTION | Failure to follow this message may cause injury or failure to 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. |

# **∆**CAUTION

Precautions for Safe Operation of Medical Electrical Equipment Read the following precautions thoroughly to correctly operate the equipment.

- Users should have a thorough knowledge of the operation before using this equipment.
- Pay attention to the following when installing and storing the equipment.
  - 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 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.
- Before operating the equipment, verify the following items.
  - Check the cable connection and polarity to ensure proper operation of the equipment.
- Ensure that all cables are firmly and safely connected.
- Pay special attention when the equipment is used in conjunction with other equipment as it may cause erroneous judgment and danger.

# **∴**CAUTION

- During operation of the equipment, verify the following items.
- 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 in the safest way for the patient.
- Do not allow the patient to come in contact with the equipment.
- After using the equipment, verify the following items.
- 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.
- If the equipment is damaged and in need of repair, user should not attempt service. Label the equipment "OUT OF ORDER" and contact Fukuda Denshi
- Do not remodel the equipment.
- Maintenance Check
- Make sure to periodically check the equipment, accessories and cables
- Before reusing the equipment that has been left unused for a while, make sure that the equipment works normally and safely

# **⚠**DANGER

Connect this equipment only to the specified patient monitor. Otherwise, danger such as electric shock may result to the patient and operator.

# **MARNING**

- If the IB-8004 is used under an environment not fulfilling the specified condition, not only that the equipment cannot deliver its maximum performance, the equipment may be damaged and safety cannot be ensured. Do not use the equipment under condition other than specified.
- When mounting to trolley, make sure to attach the IB-8004 to an adaptor beforehand. Otherwise, the equipment may fall from the trolley, resulting in injury to the operator or damage to the Input Box.

# CAUTION

- Regarding the DS-8500 System Patient Monitor, which the IB-8004 is connected to;
  - Use only the optional accessories specified for the system.
     Otherwise, proper function of the system cannot be executed.
  - For quality improvement, specifications are subject to change without prior notice.
- The system is not able to monitor multiple patients at one time.
- The installation of the system should be performed by our service representative or a person who is well acquainted with the system.
- If it is not used for a long period, make sure to turn OFF the power of the main unit.

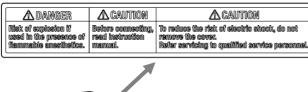
For additional warnings, cautions or contraindications when using the DS-8500 system with the IB-8004, refer to the DS-8500 operation manual.

#### Warning Label

Make sure to read the warning label attached to the equipment and comply with the requirements while operating the equipment.

## **∴** CAUTION

- Do not damage or erase the warning label attached to the equipment.
- The warning label contains important descriptions for handling and operating the equipment properly and safely. A damaged label may compromise safe operation.





# **Graphic Symbols**

The following are the symbols and their meaning indicated on the equipment.

| Symbol      | Description  |
|-------------|--|
| $\triangle$ | Caution; refer to accompanying documents Indicates the need to refer to related accompanying documents before operation.   |
| ~~          | Year of Manufacture Indicates the manufactured year.   |
| Z           | WEEE (Waste Electrical and Electronics Equipment) Indicates a separate collection for electrical and electronic equipment. |

# **General Description**

The IB-8004 Input Box allows connecting expansion modules to measure additional parameters for the DS-8500 System if measurement parameters with the Super Unit HS-8000 series are lack.

Any combination of the expansion modules, which are inserted to the Input Box, will be available according to the parameters required for the patient monitoring.

Up to two Input Boxes can be connected to one DS-8500 system.

# **∆** CAUTION

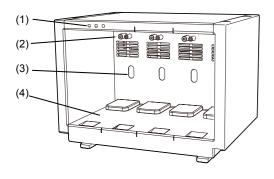
The DS-8500 System is intended for measuring parameters such as ECG, respiration, BP, NIBP,  $\text{SpO}_2$ , temperature, CO, respiration gas (concentration of  $\text{CO}_2$ ,  $\text{NO}_2$ , volatile anesthetic agent,  $\text{O}_2$ ), and monitors patient condition by displaying/recording the measurement data on this equipment or central monitor and generates alarm as required. Direct use in MRI environment, hyperbaric oxygen therapy chamber, outdoors, home-care, or ambulance vehicle is not permitted.

#### Name of Parts and Their Functions

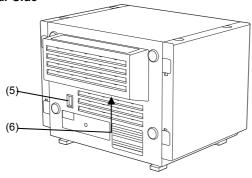
# **MARNING**

Do not connect a unit or cable not authorized by Fukuda Denshi to any I/O connector. If done so by mistake, the equipment cannot deliver its maximum performance and the connected units may be damaged, resulting in a safety hazard.

#### **Front Side**



# Rear Side



- (1) LAN-ID Setting Indicator Indicates the assigned LAN-ID.
- (2) Power Output Connector Supplies power to the expansion module.
- (3) Infrared Communication Port Communicates with the expansion module via IrDA.
- (4) Expansion Module Connection Slot Connects 4 expansion modules at maximum in SLOT1 to 4.
- (5) LAN-ID Setting Dial Uses to assign LAN-ID.
- (6) module-LAN Connector x 3 Connects to the DSC-8500 series Main Unit, IB-8004 Input Box or HSA-80 HS Adapter.

### **Connecting Procedures**

This section explains how to connect the HSA-80, HS-8000 series, and DSC-8500 series Main Unit.

# **∴** CAUTION

Precautions about the Operating Environment

- The following environmental conditions should be observed when operating the equipment.
   Ambient Temperature: 10 to 40°C
   Relative Humidity: 30 to 85% (non-condensing)
   Ambient Pressure: 700 to 1060hPa
- The power is supplied from the DS-8500 series Main Unit. Read the operation manual of the DS-8500 System and connect properly.
- Make sure to install the Input Box (IB-8004) leveled onto a flat surface. If installed in the incorrect direction, water or chemicals may enter the equipment and cause damage.

# How to Connect to the DSC-8500 series Main Unit

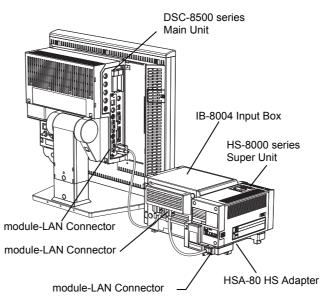
Connect the DSC-8500 series Main Unit and the IB-8004 Input Box with the module connection cable (CJO-08SSxx). And connect the HSA-80 HS Adapter to the Main Unit via the Input Box.

The following cables are available depending on the installation.

| Model       | Length |
|-------------|--------|
| CJO-08SS0.3 | 0.3m   |
| CJO-08SS1.5 | 1.5m   |
| CJO-08SS3.5 | 3.5m   |
| CJO-08SS5   | 5m     |
| CJO-08SS10  | 10m    |

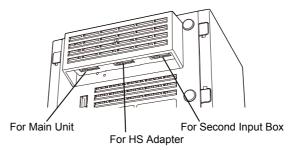
2

1 Connect the IB-8004 with the module connection cable (CJO-08SSxx) to the module-LAN connector on the left side of the DSC-8500 series Main Unit.

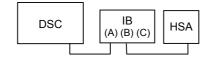


2 Connect the module connection cable to the module-LAN connector on the rear side of the IB-8004.

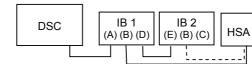
There are 3 module-LAN connectors on the rear side of the Input Box. Connect each cable to the module-LAN Connectors on the left, center, and right side to connect the Main Unit, HS Adapter, and the second Input Box respectively.



#### When using one Input Box



# When using two Input Boxs



- (A) Connects to the Main Unit.
- (B) Connects to the HS Adapter.
- (C) Not Used
- (D) Connects to the second Input Box.
- (E) Connects to the first Input Box.

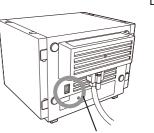
# **△ CAUTION**

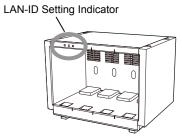
- Make sure that the power of the DSC-8500 Main Unit is turned OFF when connecting/disconnecting the connection cable.
- When connecting with the connection cable, make sure to secure the connector with screws.
- If the HSA-80 is connected to the DSC-8500 series Main Unit via the IB-8004 Input Box with the connection cables, make sure that the total length of the connection cables are within 10m between the DSC-8500 series Main Unit and the HSA-80.

#### Setting the LAN-ID

A maximum of 2 Input Boxes can be connected to the DS-8500 System. When connecting 2 Input Boxes, change the LAN-ID using the setting dial on the rear side of the Input Box.

- 1 Select 1 or 2 for the LAN-ID which is not duplicated with the second Input Box.
- 2 Verify that the correct ID is set by checking the LAN-ID Setting Indicator on the front side.





LAN-ID Setting Dial

| LAN-ID Setting<br>Dial | Input Box ID* | LAN-ID Setting<br>Indicator |  |
|------------------------|---------------|-----------------------------|--|
| 1                      | IB1           | "1" is lighted.             |  |
| 2                      | IB2           | "2" is lighted.             |  |
| 3                      | (Not Used)    |                             |  |

<sup>\*</sup>The Input Box ID corresponds to the following displayed messages IB1: "IB-8000-1" or "IB1"

### How to Turn On the Power

1 Turn ON the power supply switch on the DSC-8500 series Main Unit

The power will be supplied to the IB-8004.

The LAN-ID Setting Indicator changes to lighting from flashing when communication with the DSC-8500 is established.

Check that the LAN-ID Setting Indicator set in the above procedure "Setting the LAN-ID" lights properly.

2 Press the Standby Switch on the Display Unit.

When the DS-8500 System is in standby mode, the system will resume by pressing the Standby Switch, then the power will be supplied to the IB-8004 also.

# How to Turn Off the Power

1 To set the system in standby mode, press the Standby Switch on the Display Unit.

A standby confirmation message will appear. Pressing the [OK] key will turn the display OFF and monitoring will stop. The operation of the Input Box will also stop.

2 To turn off the power of the DS-8500 System, turn OFF the power supply switch on the DSC-8500 series Main Unit.

3

IB2: "IB-8000-2" or "IB2"

#### Standby Mode

Using the Standby Switch On/Off operation, the power On/Off of the main unit, Super Unit, expansion units, expansion modules and Input Box interlocks. Also, the start/stop of monitoring is available using the Standby Switch. Stopping the monitoring by pressing the Standby Switch will allow resuming the system in a short span by pressing the

Standby Switch again. If not monitoring for a long period of time, the power supply switch of the main unit should be turned OFF.

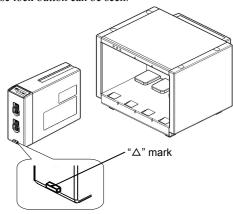
#### How to Insert/Remove an Expansion Module

The Input Box has 4 slots to connect expansion modules.

#### **Insertion of an Expansion Module**

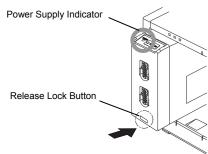
1 Insert the expansion module to one of the slots inside the Input Box.

Insert the expansion module so that the " $\triangle$ " mark on the release lock button can be seen.



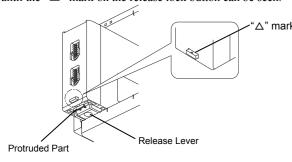
The inserted expansion module can be used by setting the parameter on the Unit Module Setup menu. By performing this setup, the expansion module can be used regardless of the slot position of the Input Box.

2 Press the release lock button until it is fully in. Check that the power supply indicator on the expansion module is lit in green.



#### Removal of an Expansion Module

1 Pull the protruded part on the bottom of the expansion module until the " $\Delta$ " mark on the release lock button can be seen.



2 Pull out the expansion module while pushing in the release lever.

#### Troubleshooting

For troubleshooting, refer to the operation manual of the DS-8500 System.

#### Maintenance

To ensure safety reliability and high performance of the IB-8004, make sure to perform a daily check according to the Daily Check List on the operation manual of the DS-8500 System.

#### MARNING

Please be aware that Fukuda Denshi is not liable of any accidents arising from lack of daily check.

#### Cleaning

#### Cleaning the Housing

- 1 Wipe the housing using tightly squeezed cloth that is soaked with a neutral liquid detergent or water.
- 2 Clean using a cloth dampened with alcohol.
- 3 Wipe the housing using a smooth cloth and then dry it completely.

# **♠**CAUTION

- Clean the equipment frequently so stains can be removed
- To prevent injury, it is recommended to wear gloves when cleaning the equipment.
- Do not open the housing.
- Do not allow liquids or cleaning solution to enter the equipment
- Do not use organic solvents, thinner, toluene or benzene to avoid damaging the resin case.
- Do not polish the housing with abrasive or chemical cleaner.
- When sterilizing the entire room using a spray solution, pay close attention not to have liquids get into the equipment or
- Use only neutral detergent to clean the housing. The surface resin coating may be damaged, resulting in discoloration, scratches, and other problems.

Do not use chemical cloth, scrub brush, abrasive, polishing powder, hot water, volatile solvent and chemicals (cleanser, thinner, benzine, benzol, and synthetic detergent for house and furniture), or sharp-edged tools.

#### Specification

184(W) x 129(H) x 164(D) mm (not including the protrusion)

# Weight

1.3kg (not including the accessory)

# **Environmental Conditions**

Operational Temperature : 10 to 40°C

Operational Humidity : 30 to 85% (non-condensing)

Operation Ambient Pressure : 700 to 1060hPa Transport/Storage Temperature : -10 to 60°C : 10 to 95% (at 40°C) Transport/Storage Humidity

(non-condensing) Storage Ambient Pressure : 700 to 1060hPa

### Safety

General Standard (with DS-8500 System):

EN 60601-1: 1990+A1: 1993+A2: 1995

IEC 60601-1: 1988+A1: 1991+A2: 1995

(Medical electrical equipment - Part 1: General requirements

for safety)

EN 60601-1-1: 2001

IEC 60601-1-1: 2000

(Medical electrical equipment - Part 1-1:General

requirements for safety- Collateral standard: Safety

requirements for medical electrical systems)

EMC Standard (with DS-8500 System):

EN 60601-1-2: 2007

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)

Class of protection against electric shock

: Class I Equipment (with DS-8500 System)

Operation Mode : Continuous Operating Equipment

Waterproof Level : IPX0 (no protection)

Protection against Ignition of Flammable Anesthetic

: Not provided

#### **Power Requirements**

Voltage : DC 18V

(Supplied from the DSC-8500 series Main

Unit.)

#### **Usable Life**

6 years (according to self-certification)

#### Accessories

The standard accessory of this equipment is as follows:

| Item                           | Qty. |
|--------------------------------|------|
| Operation Manual (this manual) | 1    |

#### **Electromagnetic Compatibility**

The performance of this equipment under electromagnetic environment complies with EN 60601-1-2 (2007)/IEC 60601-1-2 (2007) (When using with the DS-8500 system).

For the precautions for safe operation under electromagnetic influence and EMC guidance, refer to the operation manual of the DS-8500 System.