

Maintenance

To ensure safety reliability and high performance of the HM-800, make sure to perform a daily check according to the Daily Check List on the operation manual of the DS-8500 System.

WARNING

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 module frequently so stains can be removed easily.
- To prevent injury, it is recommended to wear gloves when cleaning the module.
- Do not open the housing.
- Do not allow liquids or cleaning solution to enter the module or connectors.
- 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 module or connectors.
- 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

The specification is as follows.
For the performance of each parameter, refer to the operation manual of the DS-8500 System.

Size
40 (W) x 100 (H) x 135 (D) mm (not including the protrusion)

Weight
0.4kg (not including the accessory)

Environmental Conditions

Operation Temperature	: 10 to 40°C
Operation Humidity	: 30 to 85% (non-condensing)
Operation Ambient Pressure	: 700 to 1060hPa
Transport/Storage Temperature	: -10 to 60°C
Transport/Storage Humidity	: 10 to 95% (at 40°C) (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)
Type of protection against electric shock
Temperature, blood pressure, cardiac output
: Type CF Applied Part
Operation Mode : Continuous Operating Equipment
Waterproof Level : IPX0 (no protection)
Protection against Ignition of Flammable Anesthetic : Not provided

Power Requirements

Voltage : DC 12V
(Supplied from the DSC-8500 series Main Unit via IB-8004 Input Box)

Usable Life
6 years (according to self-certification)

Accessories

Accessories

The standard accessory of this module is as follows:

Item	Qty.
Operation Manual (this manual)	1

Optional Accessories

For optional accessories such as BP relay/conversion cable, Temperature relay cable, CO relay cable, refer to the operation manual of the DS-8500 System.

Electromagnetic Compatibility

The performance of this module under electromagnetic environment complies with EN 60601-1-2 (2007)/IEC60601-1-2 (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.

Operation Manual
HM-800
Multi Module

CE 0086

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CE 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.

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Thank you for purchasing our product.
Read the “Safety Precaution” thoroughly before use to ensure correct and safe use of this module.
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.
⚠ 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 module.

- Users should have a thorough knowledge of the operation before using this module.
- Pay attention to the following when installing and storing the module.
 - Do not install or store in an area where the module 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 module.
 - Place the module 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 module, verify the following items.
 - Check the cable connection and polarity to ensure proper operation of the module.
 - 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 module, verify the following items.
 - Always observe the equipment and patient to ensure safe operation of the module.
 - If any abnormality is found on the module or patient, take appropriate measures such as ceasing operation of the module in the safest way for the patient.
 - Do not allow the patient to come in contact with the module.
- After using the module, 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 module clean to ensure proper operation for the next use.
- If the module is damaged and in need of repair, user should not attempt service. Label the module “OUT OF ORDER” and contact Fukuda Denshi.
- Do not remodel the module.
- Maintenance Check
 - Make sure to periodically check the module, accessories and cables.
 - Before reusing the module that has been left unused for a while, make sure that the module 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.

WARNING

If the HM-800 is used under an environment not fulfilling the specified condition, not only that the module cannot deliver its maximum performance, the module may be damaged and safety cannot be ensured. Do not use the module under condition other than specified.

CAUTION

- Regarding the DS-8500 System Patient Monitor, which the HM-800 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.

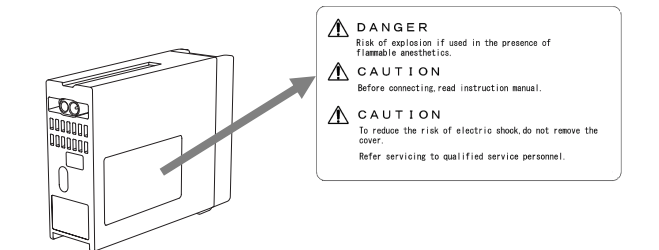
For additional warnings, cautions or contraindications when using the DS-8500 system with the HM-800, refer to the DS-8500 operation manual.

Warning Label

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

CAUTION

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



Graphic Symbols

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

Symbol	Description
	Caution; refer to accompanying documents Indicates the need to refer to related accompanying documents before operation.
	Type CF Applied Part with Defibrillation-Proof Indicates the degree of protection against electric shock which is Type CF Applied Part with defibrillation-proof.
	Year of Manufacture Indicates the manufactured year.
	WEEE (Waste Electrical and Electronics Equipment) Indicates a separate collection for electrical and electronic equipment.

General Description

The HM-800 is an expansion module for the DS-8500 System to extend the measurement parameters of Invasive Blood Pressure, Temperature and Cardiac Output. This module acquires patient’s vital signs and performs signal filtering and measurement processing. The processing results, such as waveforms and measurement data, are displayed on the Patient Monitor screen and each operation is performed on the Patient Monitor.

CAUTION

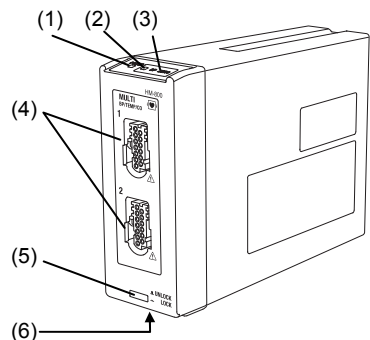
The DS-8500 system is intended for measuring parameters such as ECG, respiration, BP, NIBP, SpO₂, temperature, CO, respiration gas (concentration of CO₂, NO₂, volatile anesthetic agent, O₂), and monitors patient condition by displaying/recording the measurement data on the main screen or central monitor 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

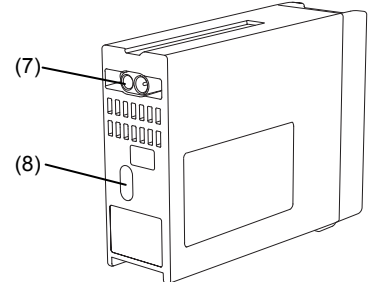
WARNING

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

Front Side



Rear Side



- (1) Power Supply Indicator
Indicates the power status.
Light in green : Power is supplied to the module.
Light Off : When the power of the DS-8500 System is OFF, or the power supply indicator on the display unit is orange (in standby mode).
- (2) BP Zero Balance Indicator
Lights during BP zero balance.
- (3) BP Zero Balance Key
Starts BP zero balance.
- (4) Multiparameter Connector x 2
Connects the input cable for BP, TEMP, or CO.
- (5) Release lock Button
Push in to lock the release lever.
- (6) Release Lever
Press this to remove the expansion modules from the Input Box.
- (7) Power Input Connector
Supplies the power while connected to the Input Box.
- (8) Infrared Communication Port
Communicates with the Input Box via IrDA.

Connection Procedures

This section explains how to install/remove the HM-800 Multi Module to/from the IB-8004 Input Box, and about the power On/Off of the DS-8500 System.

CAUTION

Precautions about the Operating Environment

- The following environmental conditions should be observed when operating the module.
Ambient Temperature : 10 to 40°C
Relative Humidity :30 to 85% (non-condensing)
Ambient Pressure: 700 to 1060hPa
- The power is supplied from the DSC-8500 series Main Unit. Read the operation manual of the DS-8500 System and connect it correctly.
- 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 Turn On the Power

- 1 Turn ON the power supply switch on the DSC-8500 series Main Unit.
The power is supplied to the HM-800 via the IB-8004.
- 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 HM-800 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 HM-800 will also stop.
- 2 To turn off the power of the DS-8500 system, turn OFF the power supply switch on the DSC-8500.

Standby Mode

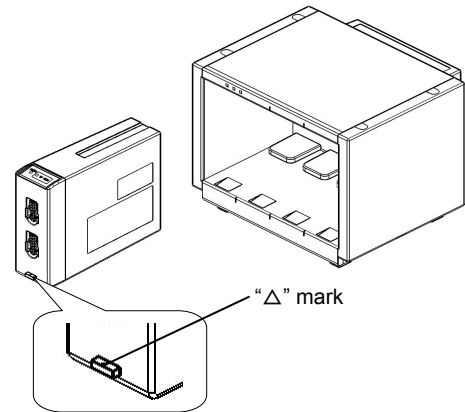
Using the Standby Switch On/Off operation, the power On/Off of the main unit, Super Unit, expansion units, expansion modules and Input Box interlocks. Also, the start/stop of monitoring is available using the Standby Switch. Stopping the monitoring by pressing the Standby Switch will allow resuming the 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 Install/remove the HM-800 Multi Module to/from the Input Box

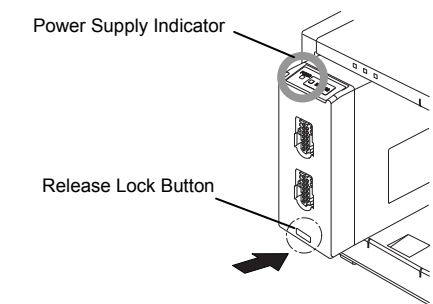
The Input Box has 4 slots to connect the expansion modules.

Insertion of the HM-800

- 1 Insert the HM-800 to one of the slots inside the Input Box.
Insert the HM-800 so that the “△” mark on the release lock button can be seen.

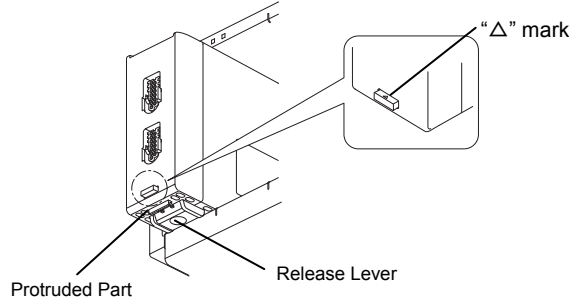


- 2 Press the release lock button until it is fully in.
Check that the power supply indicator on the HM-800 is lit in green.



Removal of the HM-800

- 1 Pull the protruded part on the bottom of the HM-800 until the “△” mark on the release lock button can be seen.



- 2 Pull out the HM-800 while pushing in the release lever.

How to Start Monitoring

By using the HM-800 Multi Module, BP, TEMP, or CO can be additionally monitored.

For monitoring BP, TEMP, or CO, refer to the operation manual of the DS-8500 System.

How to Start BP Monitoring

Connect the BP Relay/Conversion Cable, CJO-P01B-S**** (for 1ch) and CJO-P01B-D**** (for 2ch), to the multiparameter connector for BP monitoring.
(****: the model type varies according to the manufacturer of the BP Transducer and the length of the relay cable.)
With the 2ch BP relay cable/2ch BP conversion cable, one HM-800 allows up to 4 channels of BP monitoring.

How to Start TEMP Monitoring

Connect the temperature probe via the 2ch Temperature Relay Cable, CJO-P01T-DA***, for temperature monitoring.
(***: the model type varies according to the length of the relay cable.)
One HM-800 allows up to 4 channels of temperature monitoring.

How to Start CO Monitoring

Connect the catheter via the Catheter Relay Cable, CJO-P01C-****, for CO monitoring.
(****: the model type varies according to the measurement method of injectate temperature.)

Combination of BP, TEMP, and CO

The HM-800 has 2 multiparameter connectors. Any combination of parameters of BP, TEMP and CO is available with the multiparameter connectors. With the 2ch TEMP relay cable or 2ch BP relay cable/2ch BP conversion cable, one multiparameter connector allows 2 channels of temperature or 2 channels of BP monitoring. The maximum number of channels with combination of BP, TEMP, and CO for one HM-800 is as follows.

Maximum Number of Channels with Combination of BP, TEMP, and CO for one HM-800			
2 Ports	BP	TEMP	CO
Blood Pressure	4ch	—	—
Blood Pressure	(2ch)	—	—
Blood Pressure	2ch	2ch	—
Temperature	(1ch)	—	—
Temperature	—	4ch	—
Temperature	—	—	—
Blood Pressure	2ch	—	1ch
Cardiac Output	(1ch)	—	—
Temperature	—	2ch	1ch
Cardiac Output	—	—	—

* The numbers in parenthesis shows the maximum BP channel’s number when using the 1ch BP relay cable.

In addition, if the HM-800 is connected to the DS-8500 System as an expansion, the measurable parameters and their maximum numbers of channels for one DS-8500 System are as follows.

BP	8ch
TEMP	8ch
CO	1ch

Troubleshooting

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