How to Start Monitoring

For monitoring the arterial oxygen saturation, refer to the operation manual of the DS-8500 System.

Troubleshooting

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

Maintenance

To ensure safety reliability and high performance of the HG-810/HG-820, 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.
- The surface resin coating may be damaged, resulting in discoloration, scratches, or other problems.
  Do not use a 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.

Cleaning and Disinfecting Sensors

MASIMO® Sensor for HG-810

- Do not soak the sensor or patient cable in water or antiseptic solution.
- Do not sterilize the sensor and cable by irradiation, steam, or ethylene oxide.
- Clean the Masimo reusable sensor (LNOP® DCI) and patient cable using the following procedure.
  1. Remove the sensor from the patient. Disconnect the patient cable from the sensor.
  2. Disconnect the sensor from the HG-810.
  3. Wipe the sensor and cable using 70% isopropyl alcohol cotton.
  4. Dry the sensors and cables before reusing.
- The Masimo single-patient-use type sensor can be reused on the same patient if the light emitting and receiving part is clean, and if it is still adhesive to the skin.
  The adhesiveness will return by completely drying the sensor after cleaning with alcohol. Do not resterilize it.

NELLCOR™ Sensor for HG-820

- Do not soak the sensor in water or antiseptic solution.
- Wipe the Durasensor™ (DS-100A) with disinfectant such as 70% alcohol. Do not sterilize by applying radioactive rays, steam, or ethylene oxide.
- The OxiMax™ is a sterilized product which can be reused on the same patient as long as it is still adhesive to the skin. Do not resterilize and reuse it on other patient. It is intended for single patient only.

Specification

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

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)
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)
Type of protection against electric shock
: Class I Equipment (with DS-8500 System)
Degree of protection against electric shock
SpO_2/SpCO*/SpMet*/SpHb*: Type CF Applied Part
* HG-810 only
Protection against defibrillation discharge: Provided
Operation Mode : Continuous Operating Equipment
Degree of protection against ingress of water
: IPX0 (no protection)
Protection against ignition of flammable gas
: Not provided

Power Supply
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:
- Operation Manual (this manual): Qty 1

Optional Accessories

For optional accessories, such as SpO_2 sensors and relay cables, for SpO_2 monitoring, 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
HG-810/HG-820
SpO_2 Module

CE 0086

FUKUDA DENSHI CO.,LTD.
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Printed in Japan 4L010674B 201403

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.

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 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.

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.
- Burn Risk in Using SpO_2 Sensor
  In SpO_2 monitoring, always use the sensor/relay cable (patient cable) specified by Fukuda Denshi. If any other sensor/relay cable (patient cable) is used, a high temperature rise of the sensor may place the patient in danger of burns. If there are any questions regarding the sensor/relay cable (patient cable) use for SpO_2 measurements on this module, please contact Fukuda Denshi service representative.

⚠WARNING

If the HG-810/HG-820 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 HG-810/HG-820 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.
- Do not connect a unit or sensor/cable not authorized by MASIMO® or NELLCOR™ to any I/O connector. If done so by mistake, Fukuda Denshi shall not be liable for any trouble of the module.

For additional warnings, cautions or contraindications when using the DS-8500 system with the HG-810/HG-820, refer to the DS-8500 operation manual.

⚠WARNING

- When measuring the SpO_2 of patient with high fever or peripheral circulatory insufficiency, check the sensor attachment periodically and change the attachment site. The temperature of the attachment site will rise 2 to 3°C due to the sensor heat which may result in burn injury.
- For the following case, accurate SpO_2 measurement may not be possible.
  - Patient with excessive abnormal hemoglobin (HbCO, MetHb)
  - Patient with dyes injected into the blood
  - Patient receiving CPR treatment
  - When a sensor is applied to a limb with NIBP cuff, arterial catheter, or intracatheter
  - When measuring at site with venous pulse
  - Patient with body motion
  - Patient with small pulse

⚠CAUTION

Precautions about the SpO_2 Monitoring

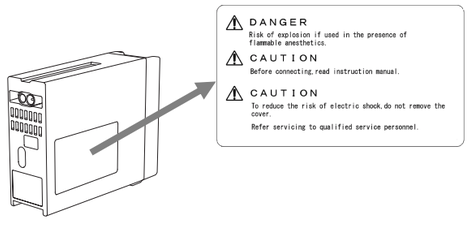
- If the nail is rough, dirty, or manicured, accurate measurement will not be possible. Change the finger or clean the nail before attaching the sensor.
- If irritation such as skin reddening appears with the sensor use, change the attachment site or stop using the sensor.
- When fixing the sensor with a tape, do not wrap the tape too tight. At the same time, check the blood flow constantly so that congestion is not generated at the peripheral.
- Even a short duration of attachment may inhibit the blood flow and generate compression necrosis and burn injury.
- Change the sensor attachment site at regular time interval, which is specified for each SpO_2 sensor. The temperature of attachment site will rise 2 to 3°C due to the sensor heat which may result in compression necrosis and burn injury.
- As skin for neonate/ low birth weight infant is immature, change the sensor attachment site more frequently depending on the condition.
- Excessive light may cause inaccurate measurements. In such cases, cover the sensor with opaque material.
- When not performing the measurement, unplug the relay cable and sensor from the SpO_2 connector. Otherwise, the measurement data may be erroneously displayed by the ambient light.
- Measuring on a limb with NIBP cuff, arterial catheter, or intracatheter may result in incorrect measurement.
- Regarding the additional warnings, cautions or contraindications for reusable and single-patient-use type SpO_2 sensors, when using the sensors with HG-810 Masimo® model or HG-820 Nellcor™ model, refer to each SpO_2 sensor instruction 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.
- This 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 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 HG-810/HG-820 is an expansion module for the DS-8500 System to extend the measurement parameters of Arterial Oxygen Saturation (SpO_2).

Model Type (built-in module)	Parameters
HG-810 SpO_2 Module M (Masimo®)	SpO_2, SpCO*, SpMet*, SpHb*, PR
HG-820 SpO_2 Module N (NELLCOR™)	SpO_2, PR

* SpCO (carboxyhemoglobin saturation), SpMet (methemoglobin saturation), and SpHb (total hemoglobin concentration) are available as option.

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.

Features

- Using with the Super Unit, up to 2 channels of SpO_2 monitoring is available.
- A SpO_2 plethysmographic waveform can be additionally displayed on the monitor screen.
- The HG-810 allows the display of measurement condition such as PI (Perfusion Index), PVI (Pleth Variability Index), Signal IQ. Note that PVI is available as an option.

⚠CAUTION

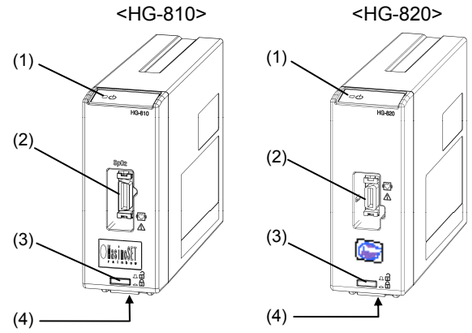
The DS-8500 system is intended for measuring parameters such as ECG, respiration, BP, NIBP, SpO_2, temperature, CO, respiration gas (concentration of CO_2, NO_2, volatile anesthetic agent, O_2), and monitors patient condition by displaying/recording the measurement data on the main screen or central 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

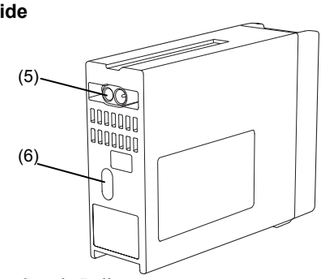
⚠WARNING

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 in orange (in standby mode).

(2) SpO_2 Connector
Connects the SpO_2 sensor, or relay cable (patient cable).

(3) Release Lock Button
Push in to lock the release lever.

(4) Release Lever
Press this to remove the modules from the Input Box.

(5) Power Input Connector
Supplies the power while connected to the Input Box.

(6) Infrared Communication Port
Communicates with the input box via IrDA.

Connection Procedures

This section explains how to install/remove the HG-810/HG-820 SpO_2 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)
- The power is supplied from the DSC -8500 series main unit. Read the operation manual of the DS-8500 Series 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 HG-810/HG-820 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 HG-810/HG-820 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 HG-810/HG-820 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.

Standby Mode

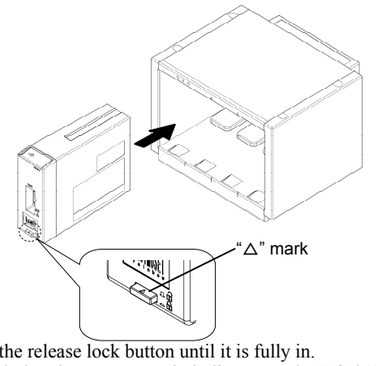
Using the Standby Switch On/Off operation, the power On/Off of the main unit, Super Unit, expansion units, expansion modules and Input Box interlocks. Also, the start/stop of monitoring is available using the Standby Switch.
Stopping the monitoring by pressing the Standby Switch will allow resuming the 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 HG-810/HG-820 SpO_2 Module to/from the Input Box

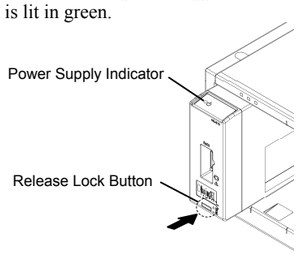
The Input Box has 4 slots to connect the expansion modules.

Insertion of the HG-810/HG-820

1 Insert the HG-810/HG-820 to one of the slots inside the Input Box.
Insert the HG-810/HG-820 so that the "△" mark on the release lock button can be seen.

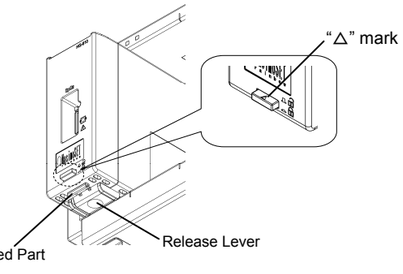


2 Press the release lock button until it is fully in.
Check that the power supply indicator on the HG-810/HG-820 is lit in green.



Removal of the HG-810/HG-820

1 Pull the protruded part on the bottom of the HG-810/HG-820 until the "△" mark on the release lock button can be seen.



2 Pull out the HG-810/HG-820 while pushing in the release lever.