Operation Manual
HS-8000
Super Unit

CE 0086

FUKUDA DENSHI CO.,LTD.
3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan
Phone:+81-3-5684-1455 Fax:+81-3-3814-1222

Printed in Japan 4L010668B 201402

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 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.
⚠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.

⚠WARNING

If the HS-8000 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 HS-8000 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 HS-8000, refer to the DS-8500 operation manual.

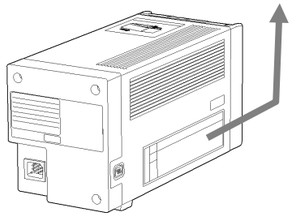
Warning Label

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.

⚠DANGER
Risk of explosion if used in the presence of flammable anesthetics.
⚠CAUTION
Before connecting, read instruction manual.
⚠CAUTION
To reduce the risk of electric shock, do not remove the cover.
Refer servicing to qualified service personnel.



Graphic Symbols

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

Symbol	Description
	Caution; refer to accompanying documents Indicates the need to refer to related accompanying documents before operation.
	Electrostatic Sensitive Part Directly touching this connector part with hands should be avoided.
	Type CF Applied Part with Defibrillation-Proof Indicates the degree of protection against electric shock which is Type CF Applied Part with defibrillation-proof.
	Type BF Applied Part with Defibrillation-Proof Indicates the degree of protection against electric shock which is Type BF Applied Part with defibrillation-proof.
	Signal Output Indicates the connector which outputs signals (analog, and QRS sync.).
	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 HS-8000 series Super Unit is a multiparameter measurement unit. It is connected to the DS-8500 System Patient Monitor. This unit allows measuring multiple parameters such as ECG, Resp., NIBP, SpO_2, BP, Temperature, and CO. It 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.

For measuring the arterial oxygen saturation (SpO_2), there are 2 types of Super Units depending on the built-in SpO_2 module, COVIDIEN® /Nellcor™ or MASIMO®.

In addition, the multiparameter connectors allow measuring the parameters of TEMP, BP, and CO.

Lineup of Super Unit

Model Type	Fixed	SpO_2 module	Multiparameter Measuring Items	CO_2 *1	BISx *4
HS-8312N	ECG (10 electrodes) x max. 12-leads RESP x 1 NIBP x 1 SpO_2 x 1	Nellcor™	3 ports TEMP x 6 (max.) IBP x 6 (max.) CO x 1 (max.)	Yes	Yes
HS-8312M*3	ECG (10 electrodes) x max. 12-leads RESP x 1 NIBP x 1 SpO_2 x 1 SpCO*2 x 1 SpMet*2 x 1 SpHb*2 x 1	MASIMO®			

*1: For CO_2 measurement, HCP-800 CO_2 Gas Unit or HPD-800 Gas Unit I/F (both external option unit) is necessary.
*2: Available only with HS-8312M. SpCO, SpMet, and SpHb are optional.
*3 The HS-8312M allows to display the measurement condition such as PI (Perfusion Index), PVI (Pleth Variability Index), Signal IQ. Note that PVI is optional.
*4: For BISx measurement, HBX-800 BIS I/F Unit (external option unit) is necessary.

Features

- With the multiparameter connectors, any combination of parameters (BP, TEMP, and CO) is available depending on the patient condition.
- The equipment is provided with Alarm Silence, BP Zero Balance, and NIBP Start/Stop keys.
- The equipment also has an analog output connector to output analog signal (1ch ECG waveform, 2ch BP waveform) and QRS SYNC signal.
- By connecting the HPD-800 Gas Unit I/F or HCP-800 CO_2 Gas Unit (both external option unit) to an AUX connector, CO_2 measurement is possible.
- By connecting the HBX-800 BISx I/F Unit (external option unit) to an AUX connector, BISx measurement is possible.

⚠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 equipment cannot deliver its maximum performance and the connected units may be damaged, resulting in a safety hazard.
- Do not connect an external output cable not specified for the HS-8000 series to the analog output connector. If done so by mistake, the equipment cannot deliver its maximum performance and the connected equipments may be damaged, resulting in a safety hazard.

Type of protection against electric shock
: Class I Equipment (with DS-8500 System)
Degree of protection against electric shock
ECG/Resp (Impedance), SpO_2/SpCO*/SpMet*/SpHb*, Temp, BP, and Cardiac Output : Type CF Applied Part
* HS-8312M only
NIBP : Type BF Applied Part
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

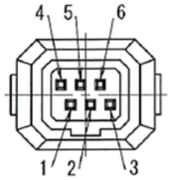
Power Supply

Voltage : DC 12V
(Supplied from the DSC-8500 series Main Unit via HSA-80 HS Adapter.)

Usable Life

6 years (according to self-certification)
Refer to the above "Maintenance Periodic Replacement" for parts requiring periodic replacement.

External Connection



Analog Output Signal Connector on HS-8000

No.	Signal Name	Notes	Signal Spec.
1	ECG OUT	ECG Output Signal	1V/mV±10%
2	IBP1 OUT	BP Output Signal 1	1V/100mmHg±10%
3	IBP2 OUT	BP Output Signal 2	1V/100mmHg±10%
4	QRS OUT	QRS SYNC Output Signal	TTL Level (logic – or + can select)
5	GND	GND	——
6	Don't use	Non-usable	——

*The ECG OUT signal outputs the lead set on the main unit.
*The IBP1, 2 OUT signal outputs the BP signal set on the main unit.
*The output logic of the QRS SYNC Output Signal can be set in positive or negative logic according to the setting on the main unit.

⚠WARNING

- The analog signal has a delay output according to the filter mode setting on the main unit. (For ECG waveform, the delay is 35msec and below, and for BP waveform, it is 35ms and below when wave filter is 40Hz.)
  When connecting to any equipment that uses a vital signal as a trigger signal, for instance, IABP, make sure that the delay time of the HS-8000 series meets the specification of such equipment.
- The delay time varies depending on the types of waveform, or caused interference.
- The QRS SYNC signal has a delay output (the delay time is 35ms and below during Monitor Mode, Diagnosis Mode). The delay time varies depending on the filter mode setting on the main unit or type of the waveform input.
- When the QRS SYNC signal is input to any external devices, make sure that the delay time of the HS-8000 series is within the acceptable range of such device.
- 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.

External Output Box

The External Output Box (CJO-C01Q-SJ0.3) is a special product that phone plugs can be inserted to extract the analog output from the HS-8000 Super Unit. By using this product, the above-described ECG (1ch), BP (2ch), and the QRS synchronized signal can be output. For details, refer to the operation manual of the External Output Box.

For details of connecting to external equipments, refer to our service representative.

Accessories

Accessories

The standard accessory of this equipment is as follows:

Item	Qty.
Operation Manual (this manual)	1
Parts Replacement Label	1
Channel Label	1

Optional Accessories

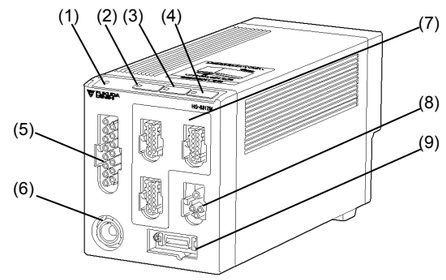
The following products are available as optional accessories. Purchase them as required.
For optional accessories such as ECG lead cable, NIBP cuff, refer to the operation manual of the DS-8500 System.

Item	Model Type	Notes
SD Card	SD-1G	
Module Connection Cable	CJO-08SS0.3	module-LAN Cable 0.3m
	CJO-08SS1.5	module-LAN Cable 1.5m
	CJO-08SS3.5	module-LAN Cable 3.5m
	CJO-08SS5	module-LAN Cable 5m
	CJO-08SS10	module-LAN Cable 10m
External Output Box	CJO-C01Q-SJ0.3	For analog signal output
HS Fixing Base	OAO-52A	Mounts the equipment to a shelf.
HS Suspended Base	OAO-49A	Suspends the equipment to a rail or shelf.
HS Attachment Spacer	OAO-46A	Attaches the HSA-80 to the IB-8004.
HS Rail Clamp	OAO-48A	Attaches the HSA-80 to a medical rail.
HS Pole Clamp	OAO-50A	Attaches the HSA-80 to a pole (φ19mm to φ38mm).

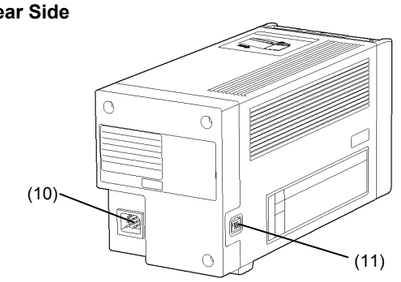
Electromagnetic Compatibility

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.

Front Side



Rear Side



(1) Power Supply Indicator
Indicates the power status.
Light in green: Power is supplied to the Super Unit.
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) Alarm Silence Key with Indicator
Silences the Alarm. The indicator lights during the alarm silence condition.

(3) BP Zero balance Key with Indicator
Performs BP zero balance. The indicator lights during BP zero balancing.

(4) NIBP Start/Stop Key with Indicator
Starts/stops NIBP measurement. The indicator lights during NIBP measurement.

(5) ECG Connector
Connects the ECG cable.

(6) AUX Connector
Connects the HPD-800 Gas Unit I/F, HCP-800 CO_2 Gas Unit, or HBX-800 BISx I/F Unit.

(7) Multiparameter Connector x 3
Connects the relay cable for BP, TEMP, or CO.

(8) NIBP Input Connector
Connects the NIBP air hose.

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

(10) HS Adapter Connector
Connects the HSA-80 HS Adapter.

(11) Analog Output Connector
Outputs the ECG and BP waveforms.

Connection Procedures

Use the HSA-80 HS Adapter to connect the HS-8000 series Super Unit to the DSC-8500 series Main Unit.

⚠CAUTION

Precautions about the Operating Environment

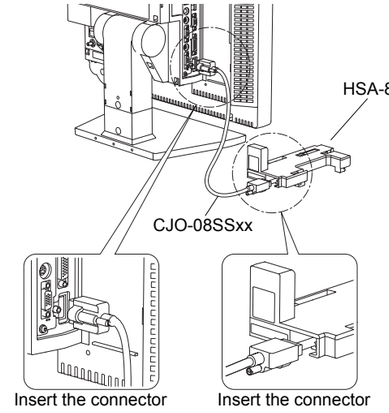
- The following environmental conditions should be observed when operating the equipment.
  Ambient Temperature: 10 to 40°C
  Relative Humidity: 30 to 85% (non-condensing)
- The power is supplied from the DSC-8500 series Main Unit. Read the operation manual of the DS-8500 System and connect properly.

How to Connect the DSC-8500 Main Unit and HSA-80

1 Connect the HSA-80 with the module connection cable (CJO-08SSxx) to the module-LAN connector on the left side of the DSC-8500 series Main Unit.

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

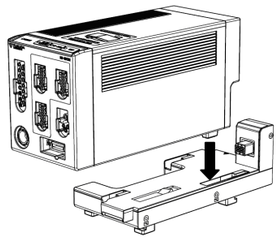


⚠CAUTION

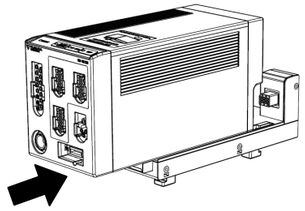
- Make sure that the power of the DSC-8500 Main Unit is turned OFF when connecting/disconnecting the connection cable.
- When connecting with the connection cable, make sure to secure the connector with screws.
- If the HSA-80 is connected to the DSC-8500 series Main Unit via the IB-8004 Input Box with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

How to Connect the HS-8000 series Super Unit

1 Align the HS-8000 leg position with the slots on the HSA-80.

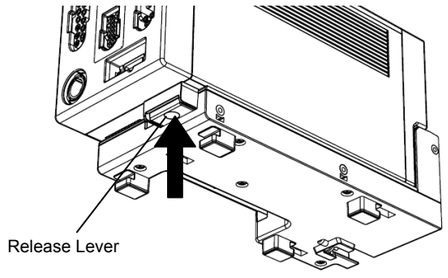


2 Slide the HS-8000 backward until it locks with a click sound.

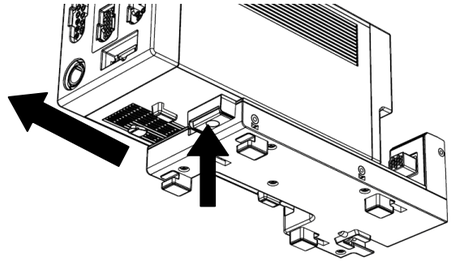


How to Remove the HS-8000

1 Press the release lever on the bottom of the HSA-80.



2 While pressing the release lever, pull out the HS-8000.



How to Connect to the Patient

For more details, refer to the operation manual of the DS-8500 system.

Combination of BP, TEMP, and CO

The Super Unit has 3 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 measurable parameters and their maximum number of channels with the multiparameter connectors are as follows;

BP 6ch
TEMP 6ch
CO 1ch

Maximum Number of Channels with Combination of BP, TEMP, and CO

3 Ports	BP	TEMP	CO
BP BP BP	6ch (3ch)	—	—
BP BP TEMP	4ch (2ch)	2ch	—
BP TEMP TEMP	2ch (1ch)	4ch	—
TEMP TEMP TEMP	—	6ch	—
BP TEMP CO	2ch (1ch)	2ch	1ch
BP BP CO	4ch (2ch)	—	1ch
TEMP TEMP CO	—	4ch	1ch

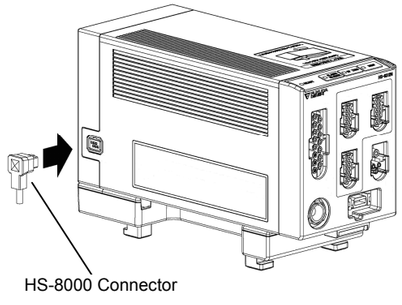
* The numbers in parenthesis shows the maximum number of BP channels when using the 1ch BP relay cable.

Analog Signal Output

It is possible to output analog waveform and QRS SYNC signal of ECG (1ch) and BP (2ch) from the analog output connector.

Cable Connection

1 Connect the HS-8000 connector plug of the External Output Box (CJO-C01Q-SJ0.3) to the analog output connector on the HS-8000.



Regarding the external output box (CJO-C01Q-SJ0.3), refer to the “External Output Box” in the “External Connection”.

Output Waveform and Size

ECG
An analog waveform of ECG (1ch) can be output.
The ECG lead of output waveform is specified on the main unit.
The frequency characteristic synchronizes with the filter mode set on the main unit (Monitor/ ESIS / DIAG), and the size is fixed to 1V/mV.

BP
An analog waveform of BP (2ch) can be output.
The waveform to output is specified on the main unit.
The frequency characteristic synchronizes with the wave filter set on the main unit (6/8/12/40 Hz), and the size is fixed to 1V/100mmHg.

Size and Output Range of the Analog Signal

	Output Size	Input Range
ECG	1V/mV	-4.5 to +4.5mV
BP	1V/100mmHg	-50 to +300mmHg

⚠CAUTION

- The output waveform of ECG and BP includes an offset voltage of below ±0.1V.
- The analog output frequency range of the ECG is roughly restricted as follows according to the different setting on the main unit such as filter mode or patient classification;
  - ・Diagnosis Mode:
    0.05 to 100Hz
    (with 3-electrodes, for adult/child/neonate)
    0.05 to 150Hz
    (with 4, 5, or 10-electrodes, for adult/child/neonate)
  - ・Monitor Mode: 0.5 to 40Hz (for adult/child),
    1.6 to 40Hz (for neonate)
  - ・ESIS Mode: 1.6 to 15Hz (for adult/child/neonate)
- The AC filter of the ECG analog output is set to ON or OFF according to the setting on the main unit.
- The frequency range of the BP analog output is restricted according to the filter setting on the main unit.

Output of the QRS SYNC Signal

The QRS SYNC signal can be output (TTL level) in a negative or positive logic according to the setting on the main unit.
For the setting of the output logic, refer to the DS-8500 System operation manual.

Troubleshooting

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

Maintenance

Maintenance Check

To ensure safety reliability and high performance of the HS-8000 series, 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.

Periodic Replacement

To ensure reliability of safety, function, and performance of this equipment, the following component must be replaced periodically. When replacing, contact our service representative.

NIBP Unit 100,000 times of measurement

⚠CAUTION

Replace the periodic replacement parts periodically as specified.

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

Size
85(W） x 100(H) x 200(D) mm (not including the protrusion)

Weight
1.2kg (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)