Instruction Manual
HBX-800 BISx I/F UNIT
(Bispectral Index, BISx Module Interface）

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No part of this document may be copied or transmitted in any form without the prior written permission of
Fukuda Denshi Co., Ltd.
● Thank you for purchasing this product.
● Before using this product, read through this manual and also refer to the DS-8500 System operation manual.
● After reading, keep this manual near the unit for future reference.

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
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For details on how to set the monitoring condition, refer to the operation manual of the DS-8500 System or other equipment which the HBX-800 is connected to.

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.

⚠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.

Graphic Symbols

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

| Symbol	Description
📖	Follow operating instructions (Information).
⚕	Type BF Applied Part with Defibrillation-Proof Indicates the degree of protection against electric shock which is Type BF eApplied Part with defibrillation-proof.
⚠	Electrostatic Sensitive Part Directly touching this connector part with hands should be avoided.
⊖→	Signal Input/Output
∿	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 HBX-800 is an interface unit between the AUX connector of the HS-8312N/HS-8312M (or other equipment which the HBX-800 is connected to) and the BISx Module to measure the BIS, SQI, SR and EMG.

The HBX-800 is provided with a serial communication connector which connects the BISx Module (optional).

＜HS-8312N/HS-8312M and HBX-800＞
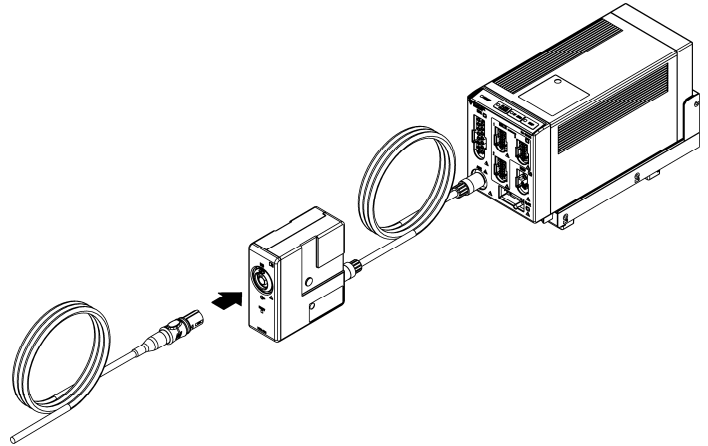
Name of Parts and Their Functions
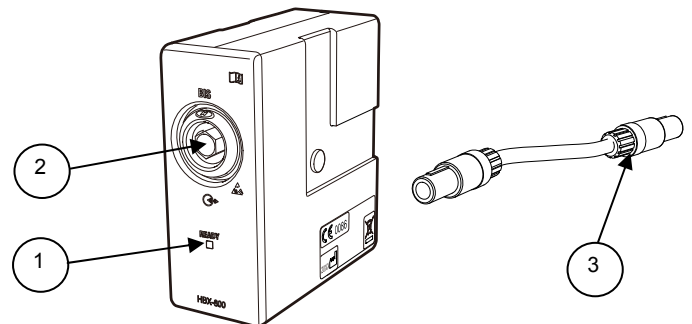
	Item	Function
1	Power Supply Indicator	Indicates the power ON/OFF status. When the power is turned ON and BISx Module is not connected, it will light in orange. When the BISx Module is connected, it will light in green.
2	Serial Communication Connector (BISx Input)	Connects the BISx Module (Covidien).
3	AUX Connection Cable	Connects to the AUX connector of the HS-8312N/HS-8312M.

⚠ CAUTION

If the indicator does not light or lights red when connected to the patient monitor, disconnect it and cease using the equipment. Contact your nearest service representative.

Maintenance

Cleaning the Housing
Clean the housing using tightly squeezed gauze or an absorbent cotton cloth dampened with alcohol or a neutral cleanser.

> ⚠ CAUTION
>
> - Clean the equipment frequently so stains can be removed easily.
> - To prevent injury, it is recommended to wear gloves when cleaning the equipment.
> - When sterilizing the entire room using a spray solution, pay close attention not to have liquids get into 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, chemical cleaner, alkaline or acidic detergent. Otherwise, the surface resin or paint coating may be damaged, resulting in discoloration, scratches, and other problems.

Cleaning and Disinfecting the BISx Module
- Clean any spillage of blood or solutions on BISx as soon as possible.
- Use lint-free absorbent towels for spill cleanups.
- Dampen the towel with detergent and lukewarm water to aid in cleaning.
- After cleaning, wipe the PIC connector ends with alcohol and allow to dry completely
- Residual moisture inside the connector may affect BISx performance.
- Use lint-free absorbent towels dampened with a 10% bleach solution, or a commercial disinfectant.

> ⚠ WARNING
>
> - Clean the equipment frequently so stains can be removed easily.
> - Universal Precautions shall be observed to prevent contact with blood or other potentially infectious materials.
> - Place contaminated materials in regulated waste container.
> - Whenever an event such as spillage of blood or solutions occurs, re-test leakage current before further use.
> - Do not mix disinfecting solutions (e.g., bleach and ammonia) as hazardous gases may result.

> ⚠ CAUTION
>
> Do not autoclave the BISx Module or HBX-800. Autoclaving will seriously damage both components.
> Avoid liquid ingress to the patient interface cable. Contact of fluids with the PIC sensor connectors can interfere with PIC performance.

Daily Check
Conduct the following daily check.
- Check if the cables are properly connected.

Periodic Check
The safety check conformed to IEC 60601-1 must be performed at least once a year for this equipment.
Periodic check of medical electronic equipment is mandatory to prevent failures and accidents and to ensure safety and reliability.
Periodic inspection may be performed by the medical institution or by a third party by concluding a "Maintenance Contract". For more details, contact your nearest service representative.

> NOTE
>
> If any damage is found, contact your nearest service representative.

Troubleshooting

For troubleshooting, refer to the operation manual of the DS-8500 System or other equipment which the HBX-800 is connected to.
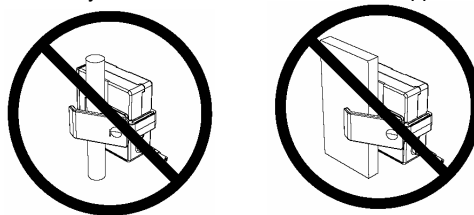
Accessories

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

No.	Item	Q'ty
1	Operation Manual (this manual)	1
2	Clip	1

> ⚠ CAUTION
>
> - Handling the clip
>   Do not attach the clip to a pole or board arranged vertically.
>   The unit may fall off when excessive force is applied.

Optional Accessories
The following products are available as optional accessories. Purchase them as required. For more details, refer to our product catalogue or contact your nearest service representative.

No.	Item	Parts Number
1	BISx	185-0145-AMS
2	Patient Interface Cable	186-0107
3	BIS Extended Use Sensor	186-0160
4	BIS Pediatric Sensor	186-0200
5	BIS Quatro Sensor	186-0106
6	CJO-15RR0.65 AUX Connection Cable	551024870
7	CJO-15RR1.5 AUX Connection Cable	551024880
8	CJO-15RR3 AUX Connection Cable	551024890

Specification

The following is the specification for this equipment.
For the performance of each parameter, refer to the operation manual of the DS-8500 System or other equipment which the HBX-800 is connected to.

Size/Weight
Size : 36(W) × 87(D) × 91(H) mm±10mm
Weight : 0.20kg±0.05kg
    *not including the connector part and protrusion.

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%
    (within absolute humidity of 0℃/90%RH) (non-condensing)

Safety
Type of protection against electric shock: Class I Equipment
    (Depends on the connected equipment)
Degree of protection against electric shock:
    Type BF Applied Part (BIS Measurement)

Power Supply
Voltage : DC+12V (Supplied from the connected equipment)