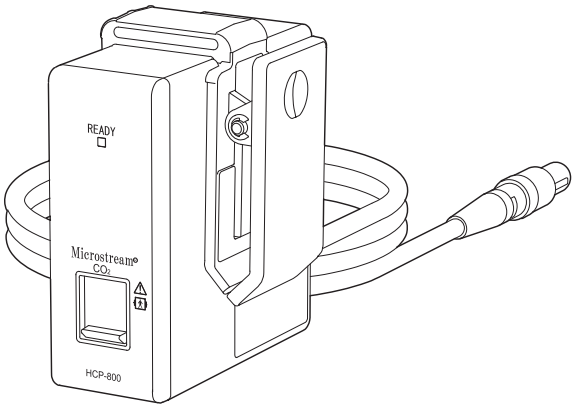
CO_2 Gas Unit

HCP-800

Service Manual



- Before setting up/maintenance, please read this “Service Manual” thoroughly.
- After reading, keep this manual for future reference.

FUKUDA DENSHI

Service manual Delivery Notice

Service Manual (No.): Q'ty 1

Please confirm your receipt of the above service manual by filling in and sending us back this sheet by return.

Delivery of Service Manual

Please note that this service manual is a confidential document and needs to be kept with an utmost care under person in charge. If the technical drawing in the service manual is unreadable, you can request it to us by specifying a page or a part.

When you have received this service manual, verify that there is no paging disorder or missing page. You are requested to kindly fill the underlined area below in this sheet and send it back to us after verification. Please be noted that photocopying of this manual is strictly prohibited.

Also, for improvement of the future service manual, your comment and request will be appreciated. If you have any comment or request on usability, viewability, readability, or if you notice anything hard to understand on this service manual, please inform it to us.

Fukuda Denshi Co., Ltd.
Development & Production Support Dept.
2-35-8 Hongo Bunkyo-ku, Tokyo, 113-8420 Japan

Received by _____
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on the day of _____

Revision History

Model Names: HCP-800 Service Manual			
Edition	Revised Items	Reason of the Revision	Revised Date
1	—	New Edition	2011.8

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Preface

Thank you for purchasing this product.
Before using this product, read the following precautions to make sure the product is used correctly and safely.

Safety Precautions

- Read the “Safety Precautions” thoroughly before use to ensure correct and safe use of the product.
- Make sure to follow the precautions indicated below, as these are important messages related to safety.

⚠DANGER	Failure to follow this message may cause immediate threat of death or serious injury, or complete failure of the equipment.

⚠WARNING	Failure to follow this message may result in death or serious injury, or complete failure of the equipment.

⚠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

Refer following for the meaning of the symbols indicated on the equipment.

Symbol used in the Unit

Symbol	*Description*
	Caution; refer to accompanying documents Indicates the need to refer to related accompanying documents before operation.
	Type BF Applied Part with Defibrillation-Proof Indicates the degree of protection against electric shock which is Type BF Applied Part with defibrillation-proof.
	GAS Input Indicates the position where it inputs the sampling gas.
	GAS Output Indicates the position where it exhausts the sampling gas.
	Year of Manufacture Indicates the manufactured year.
	WEEE (Waste Electrical and Electronics Equipment) Indicates a separate collection for electrical and electronic quipment.

Precautions for Safe Operation of Medical Electrical Equipment

⚠CAUTION	Read the following precautions thoroughly to correctly operate the device. ● Users should have a thorough knowledge of the operation before using this system. ● 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 system. • 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 there are chemical or gasses stored. ● Before operating the system, verify the following items. • Check the cable connection to ensure proper operation of the unit. • Ensure that all cables are firmly and safely connected. • Pay special attention when the device is used in conjunction with other equipment as it may cause erroneous judgment and danger. • Ensure all patient connections are proper and secure. ● During operation of the system, verify the following items. • Always observe the system 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 device. ● After using the system, verify the following items. • When unplugging the cables, do not apply excessive force by pulling on the cord. Pull by the connector part of the cable. • Clean the accessories and cables, and keep them together in one place. • Keep the unit clean to ensure proper operation of the next use. ● If the equipment is damaged and in need of repair, user should not attempt service. Label the unit “OUT OF ORDER” and contact our service representative. ● Do not remodel the equipment. ● Maintenance Check • Make sure to periodically check the equipment, accessories and cables. • Before reusing the device that has been left unused for a while, make sure that the device works normally and safely.

Precautions about the Maintenance

Safety Inspection and Maintenance

For safe operation of the equipment, regular inspection and maintenance is required. Once a year, check all cables, devices, and accessories for damage, earth impedance, earth and leakage currents, and all alarm functions. Also, ensure that all safety labels are legible. Maintain a record of these safety inspections.

Immediate maintenance has to be carried out if ;

- the equipment was subjected to extreme mechanical stress, e.g. after a heavy fall.
- the equipment was subjected to liquid spill.
- the monitoring function is interrupted or disturbed.
- parts of the equipment enclosure are cracked, removed, or lost.
- any connector or cable shows signs of deterioration.

Refer to “8. Maintenance” for details.

⚠WARNING	Never open the housing while the equipment is in operation or connected to hospital grade outlet as it may result in electric shock.

Maintenance, Modifications, and Repairs

Fukuda Denshi is liable for the safety, reliability, and performance of its equipment only if;

- Maintenance, modifications, and repairs are carried out by authorized personnel.
- Components are used in accordance with Fukuda Denshi operating instructions.

Precautions about Connections to Devices

In the interest of safe and sufficient performance of this equipment, the connection of other manufacturers’ equipment to this equipment is not authorized, unless the connection is explicitly approved by Fukuda Denshi. It is the user’s responsibility to contact Fukuda Denshi to determine the compatibility and warranty status of any connection made to another manufacturer’s equipment.

⚠WARNING	This Unit cannot be connected to unspecified devices. Use of an unspecified device may cause electric shock to the patient and/or operator due to excessive leakage current.

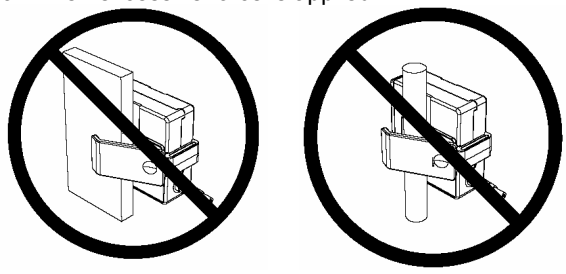
Accessories and Optional Accessories

⚠WARNING	Use only the sampling line specified by Fukuda Denshi. We cannot assure the performance of this unit when other products are used.

Precautions about the HCP-800 System

⚠DANGER	This Unit is intended for use in connection to specified devices. Do not connect this unit to unspecified devices. Danger such as electric shock may result to the patient and operator.

⚠WARNING	● If this unit is used under the condition where operating environment is not satisfied, this unit can neither deliver its maximum performance nor ensure safety such as damage to this unit. ● Always consider the circumference of the intubation tube when using the airway adapter. If an inappropriate airway adapter is used for a patient with low ventilation, CO_2 may mix in to the inspired air resulting in incorrect measurement, or apnea detection may become difficult.

⚠CAUTION	● CO_2 Monitoring • When using the MGU-800 series Multigas Unit, CO_2 measurement with this unit cannot be performed. • The sampling line should be opened just before use. • Do not reuse the sampling line. ● Maintenance • To prevent injury, it is recommended to wear gloves when cleaning the equipment. • 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 monitor or connectors. • Use only neutral detergent to clean the housing. Do not use chemical cloth, scrub brush, abrasive, polishing powder, hot water, volatile solvent and chemicals (cleanser, thinner, toluene, benzine, benzol, and synthetic detergent for house and furniture), or sharp-edged tools. The surface resin coating may be damaged, resulting in discoloration, scratches, and other problems. • Do not open the housing. • Avoid alcohol or other liquids from getting into the device. • If you accidentally wet the device, dry it completely and verify it operates safely before usage. ● Handling the clip Do not attach the clip to a pole or plate arranged vertically. The unit may fall off when excessive force is applied. 

Disposing of Equipment, Accessories, or Components

⚠CAUTION	When disposing of this product, accessories, or components, use an industrial waste distributor. Do not dispose of as ordinary waste.

Precautions about Transportation

When transporting this equipment, pack it with specified packing materials.

Reference Refer to “2. Specification” for Environmental Conditions during transportation.

Contents

Preface

Chapter 1 General Description

Chapter 2 Specification

Chapter 3 Names of Parts and Their Functions

Chapter 4 Operational Description

Chapter 5 Spare Parts List

Chapter 6 Assembly Diagram

Chapter 7 Troubleshooting

Chapter 8 Maintenance

Chapter 9 Periodic Check

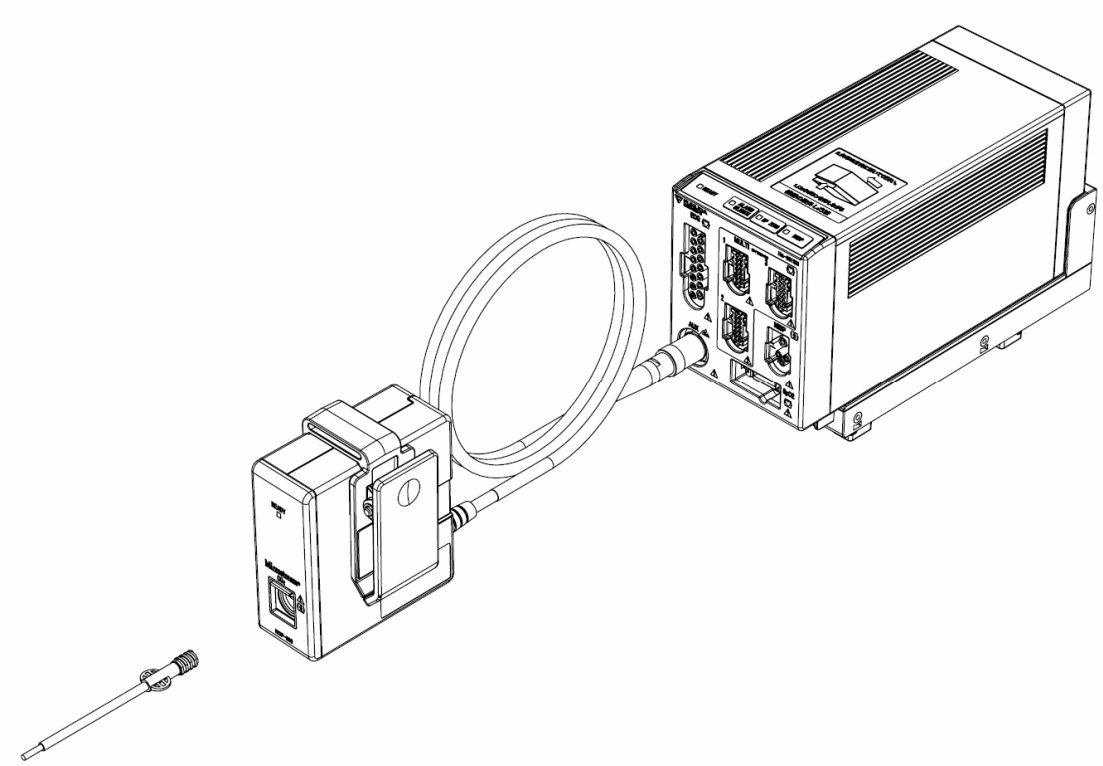
Chapter 1

General Description

This chapter describes the outline of this equipment.

General Description

The HCP-800 is a CO_2Gas Unit which measures CO_2concentration by connecting to the AUX Connectors of the HS-8000 series Super Unit and DS-8000 series monitor.
The HCP-800 CO_2 Gas Unit incorporates the Microstream® technology of Oridion Medical 1987 Ltd. for CO_2 concentration measurement.



＜Connecting the CO_2 Gas Unit HCP-800 and Super Unit HS-8000＞

For the details on CO_2 concentration measurement, refer to the operation manuals of the “DS-8500 Bedside Monitor” and “HS-8000 series Super Unit”.

Chapter 2
Specification

Specification/ Performance

This chapter states the specification and performance of this equipment.

Specification

Dimensions

36(W) × 91(H) × 87(D) mm (not including the connector part and protrusion.)

Cable Length

2800mm ±100mm

Weight

0.4kg (not including the accessory)

Environmental Conditions

Operational Temperature ：10 to 40°C
Operational Humidity ：30 to 85% (non-condensing)
Atmospheric Pressure ：700 to 1060hPa
Transport / Storage Temperature ：-10 to 60◦C
Transport / Storage Humidity ：10 to 95% (within absolute humidity of 0◦C/90%RH) (non-condensing)
Transport / Storage Atmospheric Pressure：700 to 1060hPa

Safety (when DS-8500 is connected)

General Standard (CE): EN 60601-1:1990+A1:1993+A2:1995
(Medical Electrical Equipment- Part 1: General Requirements for Safety)

EN 60601-1-1:2001
(Medical Electrical Equipment- Part 1-1: General Requirements for Safety - Collateral standard: Safety Requirements for Medical Electrical Systems)

EMC Standard (CE) : EN 60601-1-2 Ed. 3.0:2007
(Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance Collateral standard: Electromagnetic compatibility – Requirements and tests)

General Standard :IEC 60601-1:1998+A1:1991+A2:1995
(Medical Electrical Equipment- Part 1: General Requirements for Safety)

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 :IEC 60601-1-2 Ed. 3.0:2007
(Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance Collateral standard: Electromagnetic compatibility – Requirements and tests)

Classification (when DS-8500 is connected)

Class of protection against electric shock : Class I equipment
Degree of protection against electric shock : Respiratory gas concentration: Type BF Applied Part
Waterproof Level : IPX0 (no protection)
Sterilization and Disinfection : Only Cleaning
Usage in Presence of Flammable Gas : Equipment inappropriate to use in presence of air/flammable anesthetics, or oxygen or nitrous oxide/flammable anesthetics.
Operation Mode : Continuous operation equipment

Power Requirements

HCP-800 : Maximum 4.0W
(Supplied from the AUX connector on the HS-8000 series)

Usable Life

6 years : According to self-certification.
Refer to “Chapter 8 Maintenance” for the usable life of periodic replacement parts

Performance

CO_2 Concentration

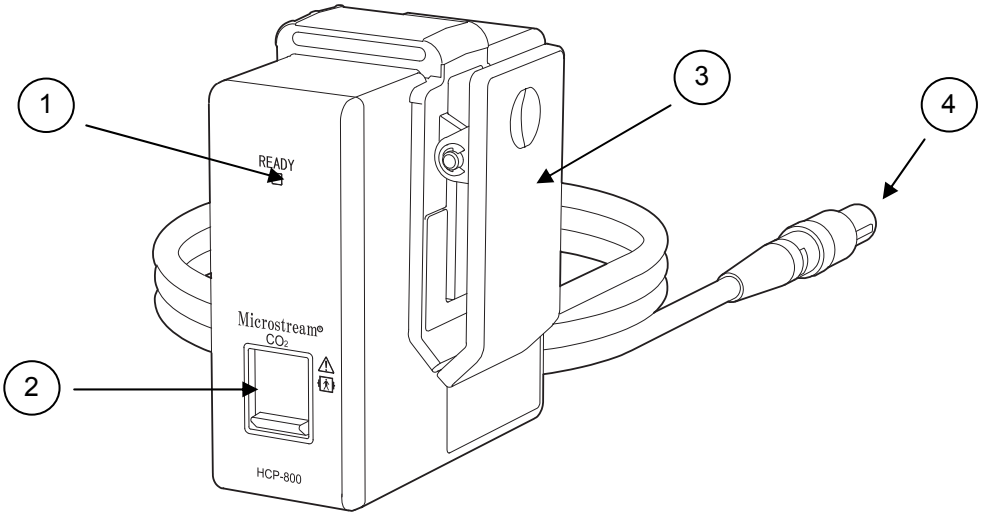
Incorporates MicroMediCO_2 module developed by Oridion Medical 1987 Ltd.

Measurement Method	: Microstream™ Method (Sidestream Method)		
CO_2 Measurement Range	: 0 to 99mmHg		
CO_2 Measurement Accuracy	: 0 to 38mmHg	: ±2mmHg	
	39 to 99mmHg	: ±[5 + 0.08 × (displayed value – 39)]%	
		: (RR Value 80Bpm or less)	
		: The larger of ±4mmHg or ±12%	
	:	(RR: over 80Bpm)	
RR Measurement Range	: 0 to 150Bpm		
RR Measurement Accuracy	: 0 to 70Bpm	: ±1Bpm	
	71 to 120Bpm	: ±2Bpm	
	121 to 150Bpm	: ±3Bpm	
Flow Rate	: 50mL/min +15, -7.5mL/min		
Response Time	: 4.2 sec. (When connecting to DS-8500 system HS-8000)		
Delay Time	: 4.0 sec. (When connecting to DS-8500 system HS-8000)		
Rise Time	: 0.2 sec.		

Chapter 3
Names of Parts and Their Functions

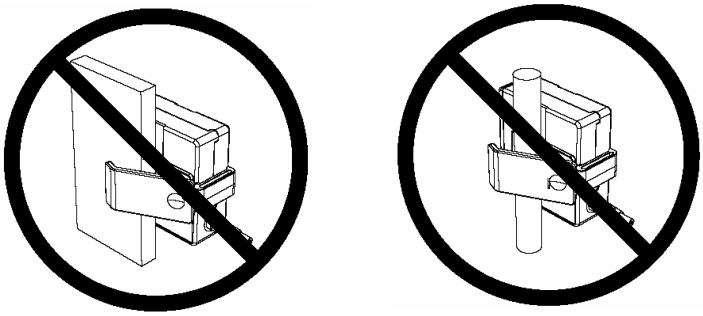
Name of Parts and Their Functions

HCP-800



	Item	Descriptions
1.	Power Supply Indicator	Indicates the power status. It will light in green while the power is ON.
2.	Sampling Tube Connector	Connects the sampling tube manufactured by Oridion®.
3	Clip	By clipping a bedside rail or head board, the unit can be installed at bedside.
4	AUX Connector	Connects to the AUX connector of the HS-8000.

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

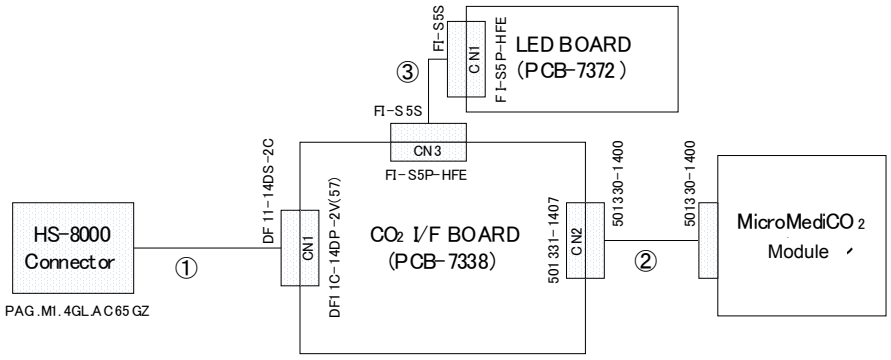
⚠CAUTION	Handling the clip Do not attach the clip to a pole or plate arranged vertically. The unit may fall off when excessive force is applied. 

Chapter 4
Operational Description

CO_2 Gas Unit I/F HCP-800

This section explains the block diagram of the HCP-800 and its function.

HCP-800 Block Diagram

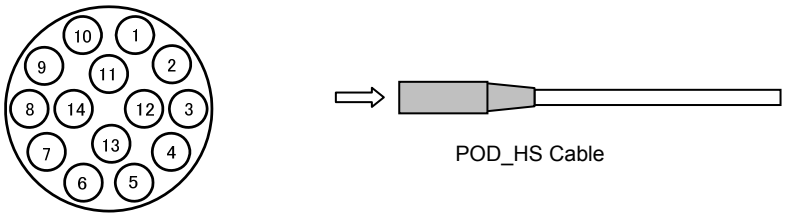


The list of Connection Cable in HCP-800 Block Diagram is as follows:

No	Item Code	Item Name
1	1M0102100	POD_HS Cable (Same as the HPD-800)
2	1M0102470	MicroMediCO$_2$ I/F Cable
3	1M0102340	HPD-800 LED Cable (Same as the HPD-800)

POD_HS Cable　HS-8000 Connector (PAG.M1.4GL.AC65GZ)

(Pin configuration：viewed from the HS-8000)

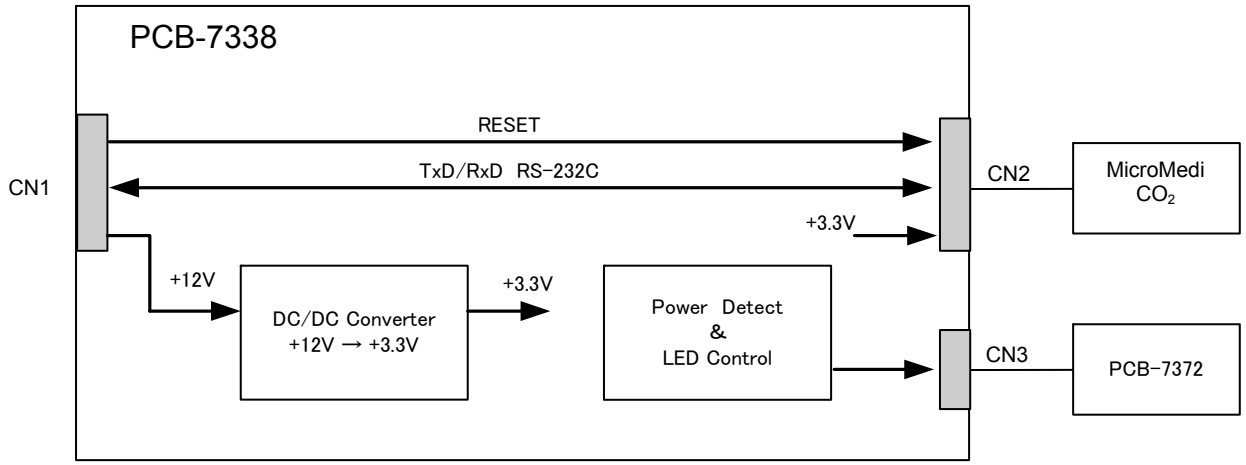


No.	*Signal Type*	*Description*	*Note*
1	+12V	12V Power Supply from HS-8000	
2	+12V	12V Power Supply from HS-8000	
3	GND_P	GND	
4	GND_P	GND	
5	+5V	5V Power Supply from HS-8000	
6	+5V	5V Power Supply from HS-8000	
7	GND	GND	
8	GND	GND	
9	RXD	Serial Data Input from HS-8000	RS-232C
10	TXD	Serial Data Output to HS-8000	RS-232C
11	_RESET	MicroMediCO$_2$ Reset Signal Output	+5V TTL Negative Logic
12	POD_ON	GAS Unit I/F Detection Signal	
13	POD_DETECT	GAS Unit I/F Information Signal	
14	RESET	Reserved	

CO_2 I/F BOARD Block Diagram

Block Diagram

CO_2 I/F BOARD Block Diagram is as follows:



DC/DC Converter

Using +12V supplied from HS-8000, +3.3V Power Supply that drives MicroMediCO_2 Module is generated.

Power Detect & LED Control

Detecting +3.3V power voltage, the power supply status controls LED lighting on the PCB-7372 (LED board).

PCB-7372

READY LED board installed in front of the HCP-800 (same as HPD-800)

Internal Connector

POD_HS Cable Connector CN1

No.	*Signal Type*	*Description*	*Note*
1	+12V	12V Power Supply from HS-8000	
2	+12V	12V Power Supply from HS-8000	
3	GND_P	GND	
4	GND_P	GND	
5	+5V	5V Power Supply from HS-8000	Unused
6	+5V	5V Power Supply from HS-8000	Unused
7	GND	GND	
8	GND	GND	
9	RXD	Serial Data Input from HS-8000	RS-232C
10	TXD	Serial Data Output to HS-8000	RS-232C
11	_RESET	Reset Signal to MicroMediCO_2	+5V Lo Active.
12	POD_ON	Gas Unit I/F Detection Signal	Unused
13	POD_DETECT	Gas Unit I/F Information Signal	Unused
14	RESET	Reserved	Unused

MicroMediCO$_2$ Interface Connector CN2

No.	*Signal Type*	*Description*	*Note*
1	RESERVE	Reserved pin	
2	RESERVE	Reserved pin	
3	RESERVE	Reserved pin	
4	RESERVE	Reserved pin	
5	RESERVE	Reserved pin	
6	_RESET	Reset Signal to MicroMediCO$_2$	+5V Lo Active
7	CO$_2$_RXD	Serial Transmission Data to MicroMediCO$_2$	RS-232
8	CO$_2$_TXD	Serial Receive Data from MicroMediCO$_2$	RS-232
9	GND	GND	
10	+3.3V	Driving power supply of MicroMediCO$_2$	
11	GND	GND	
12	GND	GND	
13	+3.3V	Driving power supply of MicroMediCO$_2$	
14	+3.3V	Driving power supply of MicroMediCO$_2$	

LED Interface Connector CN3

No.	*Signal Type*	*Description*	*Note*
1	VDD_GREEN	Power Supply for LED	
2	VDD_RED	Power Supply for LED	
3	LED_GREEN	Green control signal in 2-color LED	
4	LED_RED	Red control signal in 2-color LED	
5	GND	GND	

Chapter 5

Spare Parts List

The spare parts in this chapter mainly include electrical parts and cables inside equipment.

HCP-800 Main Unit Block Spare Parts

HCP-800 Main Unit Block Spare Electrical Parts are as follows:

Item Code	Item Name	Model Type	Note
9F0103230	MicroMediCO$_2$ Module	—	—
9F0101450	CO$_2$ I/F BOARD	PCB-7338 SAS	—
9F0102610	LED BOARD	PCB-7372 SAS	—

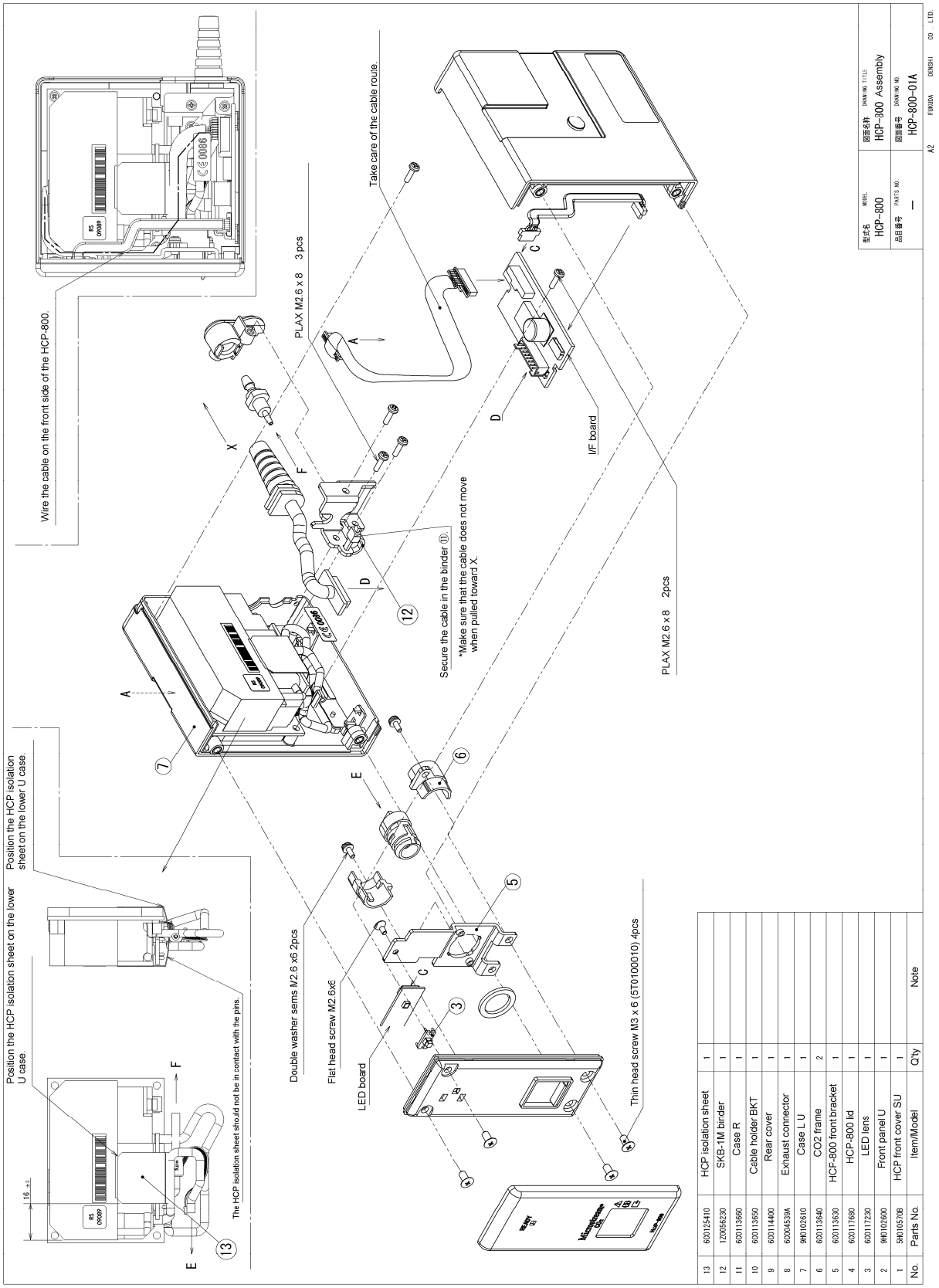
The spare parts cables of the HCP-800 Main Unit Block are as follows:

Item Code	Item Name	Note
1M0102470	MicroMediCO$_2$ I/F cable	—
1M0102340	HPD_LED cable	—
1M0102100	POD_HS cable	—

Chapter 6

Assembly Diagram

HCP-800 Assembly HCP-800-01A



No.	Parts No.	Item/Model	Q'ty	Note
13	600125410	HCP isolation sheet	1	
12	120056230	SKB-1M binder	1	
11	600113660	Case R	1	
10	600113650	Cable holder BKT	1	
9	600114400	Rear cover	1	
8	60004539A	Exhaust connector	1	
7	9W0102610	Case L U	1	
6	600113640	CO2 frame	2	
5	600113630	HCF-800 front bracket	1	
4	600117680	HCP-800 lid	1	
3	600117230	LED lens	1	
2	9W0102600	Front panel U	1	
1	5W0105708	HCP front cover SU	1	

型式名 MODEL	図面名称 DRAWING TITLE
HCP-800	HCP-800 Assembly
品目番号 PARTS NO.	図面番号 DRAWING NO.
—	HCP-800-01A

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Chapter 7

Troubleshooting

CO_2 Concentration

The "Check Sample Line" message is displayed on the monitor.

Cause ：Check if the sampling line is clogged or bent.

Solution ：Replace the sampling tube.

The "Check CO_2 Exhaust Port" message is displayed on the monitor.

Cause ：The exhaust port is clogged.

Solution ：Check if the exhaust port is clogged.
：Make sure that the exhaust line is not clogged or bent.

The "Gas Unit I/F Failure" message is displayed on the monitor.

Cause ：There is a communication error with the CO_2 unit.

Solution ：A broken wire or CO_2 unit failure can be considered.

The "Check CO_2 unit" message is displayed on the monitor.

Investigation ：When the "Check CO_2 unit" message is displayed, more details will be displayed by pressing Test Menu>CO_2>Service Mode.

・Check calibration
Cause ：Calibration has not been performed.
Solution：→Perform a calibration.

・Check flow
Cause ：The exhaust port is clogged.
Solution：Check if the exhaust port is clogged.
Make sure that the exhaust line is not clogged or bent.

・Occlusion in gas input line
Cause ：The inhale port is clogged.
Solution：Check if the sampling line is clogged or bent.
Make sure that the internal inhale line is not clogged or bent.

・Replace Main Board
Cause ：The Main Board needs to be replaced.
Solution：Replace the MicroMediCO_2 module.

・Check CO_2 Sensor or Main Board
Cause ：The CO_2 sensor or Main Board needs to be replaced.
Solution：Replace the MicroMediCO_2 module.

・Replace Scrubber + Pump
Cause ：The scrubber (CO_2 absorbent) and pump need to be replaced.
Solution：Replace the MicroMediCO_2 module.

・Change CO_2 Sensor The message prompts the replacement of the CO_2 sensor.
Cause ：The CO_2 sensor needs to be replaced.
Solution：Replace the MicroMediCO_2 module.

・12V-Voltage out of range　The message prompts the inspection of the power supply.
Cause：The power supply to MicroMediCO$_2$ module error.
Solution：Replace the MicroMediCO$_2$ module.

The "CO$_2$ Disconnected" message is displayed on the monitor.

Cause　：If the HCP-800 is disconnected during CO$_2$ monitoring, the message will be displayed.
*Depending on the software version, the message will be also displayed when the sampling line is disconnected.

Solution 1　：Check if the HCP-800 is firmly connected.

Solution 2　：To continue monitoring, plug in the HCP-800 again. This will clear the message and silence the alarm. Pressing the [Alarm Silence] key will clear the message and silence the alarm.

The "Sample Line Disconnected" message is displayed on the monitor.

Cause　：If the sampling line is disconnected during CO$_2$ monitoring, the message will be displayed.
*Depending on the software version, "CO$_2$ Disconnected" may be indicated.

Solution 1　：Check if the sampling line is firmly connected.

Solution 2　：When the sampling line is replaced or monitoring is suspended, press the [Alarm Silence] key. The message will disappear, and the alarm will be silenced.

The "Calibrating CO$_2$" message is displayed on the monitor.

Cause　：The zero calibration automatically starts if the temperature or atmospheric pressure change.

Solution 1　：There is no problem since this specification is for the MicroMediCO$_2$ module.

READY LED does not light.

Cause 1　：The HS-8000 does not supply power since a fuse inside the HCP-800 is melting or the POD_HS cable is disconnected.

Solution　：Inspect the fuse mounted on the CO$_2$ I/F board (PCB-7338). Refer to the pin assignments shown in "4. Operational Description" and inspect the POD_HS cable.

READY LED lights in red.

Cause　：The power of the CO$_2$ unit inside HCP-800 is reduced.

Solution　：Measure the voltage between IT2 and TP3 on the CO$_2$ I/F board (PCB-7338) and check that the voltage value is within 3.3V±0.1V.

There is substantial measurement error.

Cause　：The calibration is not properly performed.

Solution　：Perform CO$_2$ calibration again.

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Chapter 8

Maintenance

Test Menu

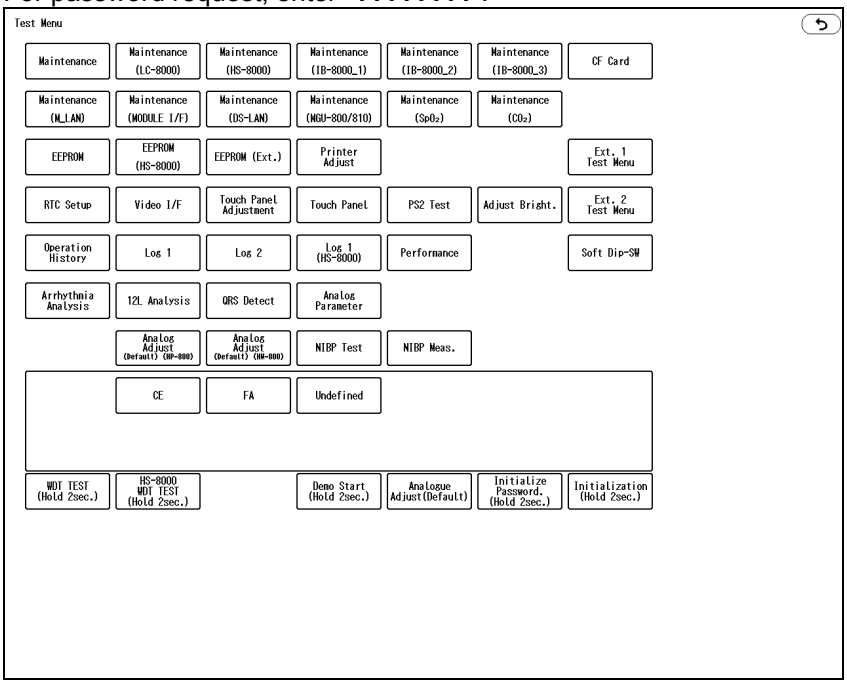
This section explains the test menus related to the HCP-800. For the test menus of other devices and whole system, refer to the DS-8500 service manual.
The HCP-800 test menu is operated from the display of the DS-8500 system main unit.

How to display Test Menu

<To display "Maintenance Menu" window>

Menu → **Maintenance** → **Test Menu** →**(Password)**

For password request, enter "**11111111**".



NOTE	The Test Menu screen may differ according to the software version.

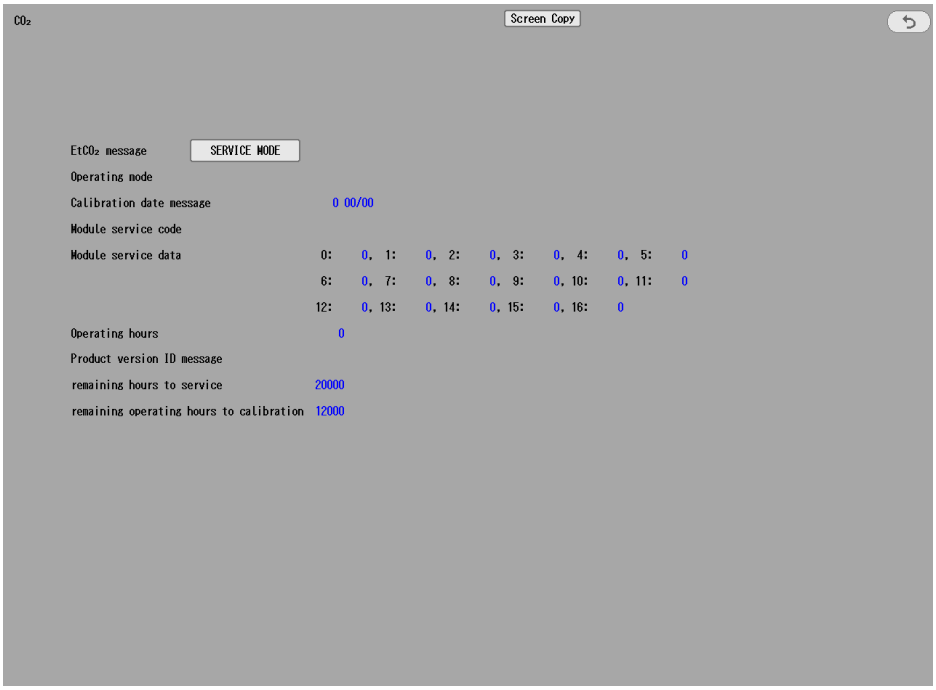
Test Menu Description

Maintenance (CO_2) : Condition of the MicroMediCO$_2$ module is displayed. When measurement interference occurs, write down the Service Code and contact our service representative.
Pressing the Measurement mode key and switching to Service Mode, integrated time of EtCO_2 measurement is displayed in Operating Hours section. If this operation is performed, make sure to turn ON/OFF the power supply and restart the equipment.

Test Menu Details

This section describes the HCP-800 test menu items.

●CO_2



Condition of the CO_2 module is displayed.

Every time the [Service mode] key is pressed, Service Mode and Measurement Mode are switched.

Operating Mode

Current Operation Mode is displayed.
Operating Mode has Power-up Mode, Measurement Mode, Standby Mode, Calibration Mode, Service Mode, and Download Mode.

Calibration Date Message

Latest calibration date is displayed.

Module Service Code

In Service Mode, failure information of module is displayed.
Displayed items are as follows. For troubleshooting, refer to “Chapter 7 Troubleshooting”.

- Check calibration
- Check flow
- Occlusion in gas input line
- Replace Main Board
- Check CO_2 Sensor or Main Board
- Replace Scrubber + Pump
- Change CO_2 Sensor

・12V-Voltage out of range

Module Service Data

The data used for failure analysis is displayed.

Operating Hours

Integrated operation time is displayed.
If MicroMediCO$_2$ module is replaced, integrated time is automatically cleared.

Product Version ID Message

Information of the MicroMediCO$_2$ module is displayed.

Remaining hours to service

Replacement period (the amount of remaining period) of MicroMediCO$_2$ module is displayed.

Remaining operating hours to calibration

The remaining time until the next calibration is displayed.

CO_2 Calibration

This section explains CO_2 calibration of the HCP-800.
The HCP-800 CO_2 calibration is operated on the display of the DS-8500 system main unit.

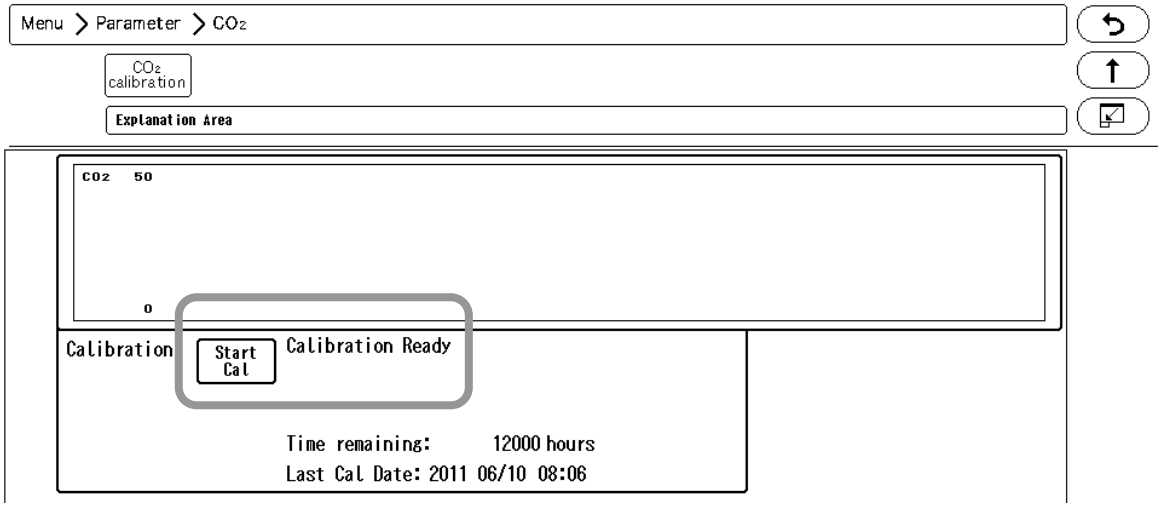
CO_2 Calibration Step

Perform CO_2 calibration using Calibration Gas (Calibration Kit 03046530RFBD).

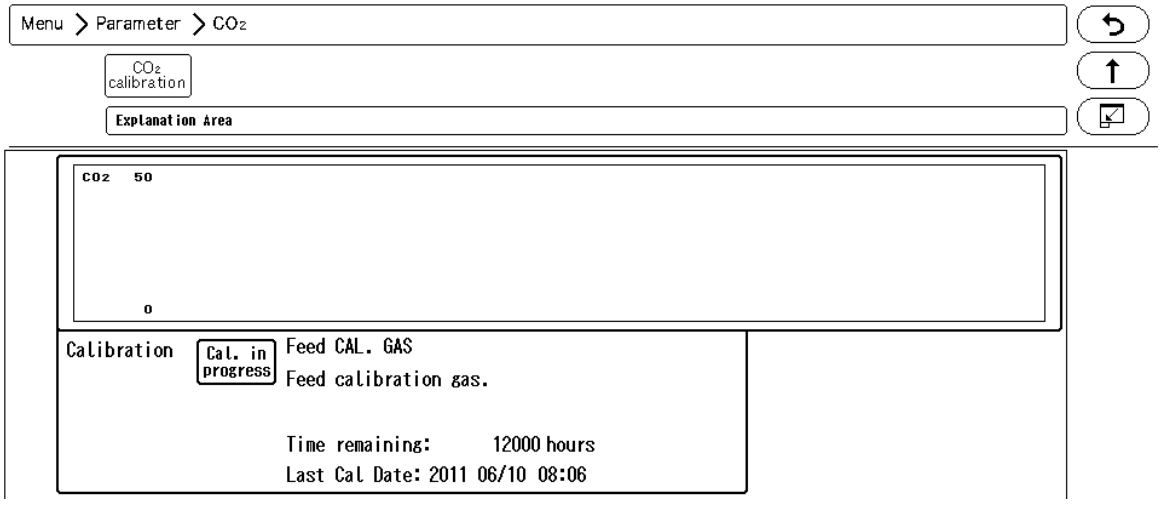
NOTE	Calibrate after 5 minutes or more once the power of HCP-800 is turned ON.

1 Press the following keys [Menu] → [CO_2] → [CO_2 Cal.].

2 Check that "Calibration Ready" is displayed and press the [Start Cal.] key.



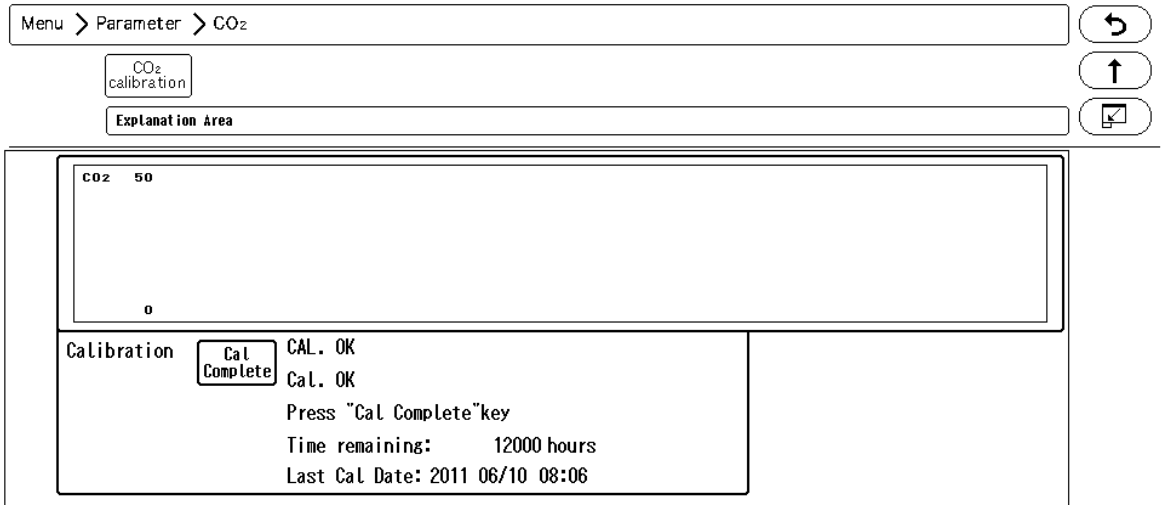
3 When "Feed calibration gas." is displayed, continue to inject Calibration Gas until the message disappears.



4 When “Measuring- Remove Gas.” is displayed, stop injecting Calibration Gas.

5 When “Cal. OK” is displayed, check that the calibration date is updated and press the Cal Complete key.

If calibration is not displayed as OK, check the connection between the Calibration Gas and HCP-800 again and calibrate again from the beginning.



After the calibration is completed, measure CO_2 Concentration and check that Numeric Data is within 38 mmHg±2 mmHg.

Storage

This section explains how to store the equipment.

Storing the Equipment

- Store in a place where the equipment will not be exposed to splashing water.
- Store in a place where the equipment will not be adversely affected by atmospheric pressure, temperature, humidity, ventilation, sunlight, dust or atmosphere containing salt or sulfur.
- Place the equipment on a stable surface where there is no inclination, vibration, or shock (including during transportation).
- The following environmental conditions should be observed when storing the equipment.

  Storage Temperature：—10 to 60°C

  Storage Humidity：10 to 95% (at 60°C)

  Storage Atmospheric Pressure：700 to 1060hPa

Cleaning of Housing and Cables

This section explains about the cleaning of the equipment.

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. ● Do not allow liquids or cleaning solution to enter the equipment or connectors. ● Do not use organic solvents, thinner, toluene and 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. Do not use chemical cloth, scrub brush, abrasive, polishing powder, hot water, volatile solvent and chemicals (cleanser, thinner, toluene, benzine, benzol, and synthetic detergent for house and furniture), or sharp-edged tools. The surface resin coating may be damaged, resulting in discoloration, scratches, and other problems.

Handling the Sampling Tube

⚠WARNING	Sampling tube is for single-patient-use only. Do not reuse it.

Chapter 9

Periodic Check

This section explains the daily check and periodic check items of the equipment.

About the Periodic Check

Periodic inspection must be performed. When reusing the equipment which was left unused for a while, always check that the device operates properly and safely before use.

Following maintenance check items are for this equipment. To ensure safety, reliability, and high performance, a “Daily Check” and “Periodic Inspection” must be performed. Please be aware that Fukuda Denshi is not liable of any accidents arising from lack of maintenance check.

⚠CAUTION	Do not open the housing. Avoid alcohol or other liquids from getting into the equipment.

●Daily Check

Perform daily inspection using the “Daily Check List”.

●Periodic Check

Periodic inspection of medical electronic equipment is mandatory to prevent failures and accidents and to ensure safety and reliability.
Periodic maintenance may be performed by each medical institution or by a third party by concluding a “Maintenance Contract”.

Periodic Replacement

To ensure reliability of safety, function, and performance of this equipment, the following parts must be replaced periodically.

MicroMediCO$_2$ Module Periodic Replacement Period: 30,000 hours

⚠CAUTION	Replace the periodic replacement parts periodically as specified.

Daily Check

●Daily Check Procedure

No.	Check Item	Check Procedure	Criteria
1 External Appearance, Accessories			
01	External Appearance	Visually check the exterior for scratches, cracks, deformation, and rust.	No scratches, cracks, deformation, and rust should be found on the exterior.
02	Installation	Check whether the equipment is installed on a level surface.	The unit should be levelled and stable.
		Check whether the equipment is installed in a place susceptible to adverse environment.	The environmental condition (e.g. temperature, humidity) of the installed place should be as specified. The equipment should not be subjected to splashing water.
03	Cables	Check that neither damage nor broken wire is found in all cables.	Neither damage nor broken wire should be found.
04	Periodic Check	Check the date of the previous periodic inspection.	Should be within 1 year.

No.	Check Item	Check Procedure	Criteria
2 Operation			
01	Function	Connect the cable to the Super Unit AUX Connector and check that it functions properly.	READY LED should light in green, and waveform and numeric data should be displayed on the Home Display of the Main Unit.

●Daily Check List

Daily Check List

No. _____

Inspected Date _____ Inspected by _____ Location _____

Device Type _____ Serial No. _____ Purchased Date _____

Item	*Details*	*Criteria*	*Judgment*
Appearance	Visually check the exterior for scratches, cracks, deformation, and rust.	No abnormality should be found.	☐OK / ☐NG
Installation	Check if the unit is leveled.	The unit should be levelled and stable.	☐OK / ☐NG
	Check if the unit is installed in a place not susceptible to adverse environment.	The environmental condition (ex. temperature, humidity) of the installed place should be as specified. The unit should not be subjected to splashing water.	☐OK / ☐NG
Functions	Turn ON the monitor, and check if it operates normally.	READY LED should light in green, and waveform and numeric data should be displayed on the Home Display of the Main Unit.	☐OK / ☐NG
Cables	Visually check all cables for any damage.	No damage should be found.	☐OK / ☐NG
Periodic Inspection	Check the date of previous periodic inspection.	Should be within 1 year.	☐OK / ☐NG

Comment

Periodic Check

●Introduction

The periodic maintenance check is intended to check the medical equipment used daily in a medical institution to prevent failures and accidents and to ensure safety and reliability.
As these are general check procedures covering the whole monitoring equipment, perform the check procedure for the corresponded function of the equipment.
The check procedures are described for daily check and periodic check. Each check items must be performed according to the described check procedure.
The consignee can select the check items according to the product quality, frequency of usage, and maintenance check period. However, electrical safety items must also be performed.
For details of the electrical safety check procedure, refer to IEC 60601-1, EN60601-1.

●Service tools/Measurement Device

The measurement devices used for this periodic check are as follows.

Name	Model Type	Reference
Leakage Measurement Safety tester	3155/3156 or equivalent	HIOKI
	Patient Leakage Current I/III	

Purchase following devices as required.

Name	Model Type	Reference
Withstand Voltage Tester	3173 or equivalent	HIOKI
	Withstand Voltage Test(B-a) Withstand Voltage Test(B-d)	

⚠CAUTION	The measurement device must be properly calibrated.

●Periodic Check Item

The periodic check items are as follows.

No.	Check Item
1	External Appearance
2	Power Supply Part
3	Display/Operation
4	CO_2 Concentration
5	Electrical Safety

●Periodic Check Procedure

⚠CAUTION	Before the check procedure, back up the setup data, patient data, etc. on a CF card.

No.	Check Item	Check Procedure	Criteria
1 External Appearance, Accessories			
01	Appearance	Visually check the exterior for scratches, cracks, deformation, and rust	No abnormality should be found.
02	Cables	Check that neither damage nor broken wire is found in all cables.	Neither damage nor broken wire should be found.
03	Operation Manual	Check that accompanying documents such as Operational Manual are stored in specified location.	Should be stored in a specified place.

No	Check Item	Check Procedure	Criteria
2 Power Supply Part			
01	READY LED Display	Connect the cable to the Super Unit AUX Connector and check that READY LED Display.	REDAY LED should light in green.

No	Check Item	Check Procedure	Criteria
3 Display, Operation, Printing			
01	Check Labels	Visually check the Rating Label and Caution Label of this equipment.	Should be neither peeled nor stained nor unclear.
02	Check the shutter	Operate the shutter up and down.	Should operate correctly.

No	Check Item	Check Procedure	Criteria
4 CO_2 Concentration			
01	Check calibration expiry date	Check the remaining time until the next calibration on the Test Menu (CO_2) screen. If the remaining time is zero or significantly little, perform a calibration using 5% Calibration Gas.	After calibration, CO_2 Concentration should be within 38mmHg±2mmHg.
02	CO_2 Concentration Display	Measure CO_2 Gas Concentration using 5% Calibration gas. If CO_2 zero calibration is performed in Check Item 01, this inspection is unnecessary.	Should be within 38mmHg±2mmHg.
03	Detect disconnected sampling line	Remove the sampling line from the HCP-800.	The "CO_2 Disconnected" message should be displayed.*

*Expression differs depending on the software version.

No	Check Item	Check Procedure	Criteria
5 Electrical Safety			
01	Patient Leakage Current-I（NC）	Measure the patient leakage current-I of normal condition using a leak measurement safety tester. Perform the check procedure as the DS-8500 system. According to test procedure of IEC 60601-1 19.	【DC】 Patient Leakage Current-I（NC） ≦0.01mA 【AC】 Patient Leakage Current-I（NC） ≦0.1mA
02	Patient Leakage Current-I（SFC）	Measure the patient leakage current-I of single failure condition using a leak measurement safety tester. Perform the check procedure as the DS-8500 system. According to test procedure of IEC 60601-1 19.	【DC】 Patient Leakage Current-I（SFC） ≦0.05mA 【AC】 Patient Leakage Current-I（SFC） ≦0.5mA
03	Patient Leakage Current-III（SFC）	Measure the patient leakage current-III of single failure condition using a leak measurement safety tester. Perform the check procedure as the DS-8500 system. According to test procedure of IEC 60601-1 19.	Patient Leakage Current-III（SFC） ≦5mA

No	Check Item	Check Procedure	Criteria
5 Electrical Safety (*) Perform the following check item as appropriate. Check these items when you have disassembled the equipment to check / replace the boards or units.			
04	Withstand Voltage Test (B-a)	Apply AC3000V for 1 minute between primary power source and applied part (B-a). According to test procedure of IEC 60601-1 20.	Should withstand applied voltage
05	Withstand Voltage Test (B-d)	Apply AC1500V for 1 minute between the exterior and applied part (B-d). According to test procedure of IEC 60601-1 20.	Should withstand applied voltage

●Periodic Check List

Patient Monitor Periodic Check Report

Check Date

Location		Delivery Date		Periodic Check Contract ☐Yes ☐No Month
		Customer Code		
Model Name	Serial No.:	Product Code		Next Check Date
Requests			Acceptance Date	

No.	Check Item	Judge	Check
1	Exterior/Accessories		
01	Exterior	OK NG	
02	Cables	OK NG	
03	Operation Manual	OK NG	
2	Power Supply		
01	Ready LED	OK NG	
3	Display/Control/Record		
01	Labels	OK NG	
02	Check the shutter	OK NG	
4	CO_2 Concentration		
01	Check calibration expiry date	OK NG	
02	CO_2 Gas Calibration	OK NG	
03	Check CO_2 Concentration	OK NG	
04	Disconnected sampling line	OK NG	

No.	Check Item	Judge	Check

No.	Check Item	Judge	Check
5	Electrical Safety		
01	Patient Leakage Current-I (DC)NC( )mA	OK NG	
01	Patient Leakage Current-I (AC)NC( )mA	OK NG	
02	Patient Leakage Current-I (DC)SFC( )mA	OK NG	
02	Patient Leagage Current-I (AC))SFC( )mA	OK NG	
03	Patient Leagage Current-III SFC( )mA	OK NG	
5	Electrical Safety (*)		
04	Withstand Voltage Test (B-a)	OK NG	
05	Withstand Voltage Test (B-d)	OK NG	

Description of Symbols

✓	Check	A	Adjust/Lubricate
×	Replace	C	Clean
／	Not applicable	R	Repair

We would like to report the result of the checks.
☐Normal Operation ☐The device is malfunctioning. ☐Needs to be repaired.
(Details of malfunction and repair)

Corporate name

Checked by:

Consignee:

Periodic Replacement Parts

Operational classification
☐On-site ☐Taking-over
☐Holiday ☐Night

⚠CAUTION	FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

CE 0086 This device bears the CE label in accordance with the provisions of Medical Device Directive 93/42/EEC.

THE PERSONS RESPONSIBLE FOR PLACING DEVICES ON THE EC MARKET UNDER MDD 93/42/EEC

EC REP FUKUDA DENSHI UK
13 WESTMINSTER COURT, HIPLEY STREET OLD WOKING, SURREY GU22 9LG, U.K.

CAUTION: This device is for sale by or on the order of a physician.

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- Only physician or persons instructed by physicians are allowed to use the equipment.
- The information contained in this document is subject to change without notice due to improvement in the equipment.

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