DYNASCOPE 1000 Series
Patient Monitor

BDS-1001 System

Ver. 01

Maintenance Manual

＊ Before using the product,
please read this manual thoroughly.

＊ Store this manual where it can be
always referred to.

FUKUDA DENSHI

This manual is for the BDS-1001 System Version 01.

⚠ CAUTION	Federal Law restricts this device to sale by or on the order of a physician.

CAUTION

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

If this manual has pages missing or out of order, contact Fukuda Denshi for replacement.

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Preface

Introduction

Thank you for purchasing this product. Read the "Safety Precautions" thoroughly before use to ensure correct and safe use of the product.

Before using or installing this product, read this manual thoroughly.

Important Notice

For Safe Operation of the Device

(1) Before using this device, read this manual.

(2) Fukuda Denshi cannot predict all the dangers which may be caused by misusage of this product or environmental condition.

(3) For using this device, there are many items that "should be performed", "should not be performed", and "cannot be performed". It is not possible to cover all these items in this manual or warning labels. Therefore, it is necessary to also follow the general safety precaution other than the items described in this manual.

(4) To prevent accidents, usage other than intended, or usage, cleaning, and maintenance not described in this manual should not be performed.

(5) When using this device, follow the respective regulation to minimize the probability of accidents.

Intended Purpose of this Device

This device is designed for the following intended purpose.

Intended Purpose

This device intends to measure the vital signs to monitor patient condition by displaying and printing the measurement data on this device or central monitor and to generate alarm when necessary.

The vital signs are electrocardiogram, heart rate, respiration rate, arterial oxygen saturation (SpO_2), pulse rate, non-invasive blood pressure, and CO_2 concentration.

REFERENCE

- For specification of this device, refer to "Chapter 14 Specification" of the operation manual.

WARNING

- This device is intended to be used by healthcare professionals. Users should have a thorough knowledge of the function and operation before using this device. The maintenance of this device should be performed by skilled personnel who received a training of possible hazards and measures to avoid those hazards. Also, your local regulation must be followed. If this device is used for the purpose other than intended, or if the user does not follow the safety instructions, the following hazard may result.

*Hazard to the Life and Health of the Patient or the User
*A Problem Related to Medical Practice
*Damage to the Device

Copyright

(1) The copyright of this manual is owned by Fukuda Denshi. No part of this document may be copied or transmitted in any form without the prior written permission of Fukuda Denshi Co., Ltd.

(2) This manual includes the description for the optional devices that can be connected.

(3) The illustration in this manual may differ with the actual device.

(4) If you lose or damage this manual, contact your nearest sales representative. Using the device without this manual may cause accidents.

(5) When handing over this device, make sure to also pass this manual to the next owner.

Maintenance, Repair, Replacement

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

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

A full technical description of the BDS-1001 system is available from your local Fukuda Denshi sales representative.

Contact

If you need more detailed information or information about security risk, please contact following.

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- If a serious incident has occurred in relation to this device, please report it to the manufacturer and to the competent authority of the country where the user and/or the patient is established.
- In case you need the contact information for your national competent authority, please ask the manufacturer or the distributor from whom you purchased the device.

About This Manual

Expression Used in This Manual

❑Meaning of the Symbols

Type of Precaution	Description
⚠ 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 device.
NOTE	"Note" is used to emphasize important information.
REFERENCE	"Reference" is used to provide useful information.
☞	Indicates the reference page for the procedure and precaution.
*	Used in a table which indicates that there is detailed explanation outside the table.

❑Indications for the Screens and Keys

The keys displayed on the monitor screen are indicated by [ ].
(Ex.: [Display Config.], [Manual Printing], etc.)

The expressions displayed on the monitor screen are indicated by " " .
(Ex.: "Volume", "Admit/Discharge", etc.)

The messages displayed on the screen are indicated by < >.
(Ex: <Searching>, <Alarm Suspend>, etc.)

REFERENCE

- There are 2 types of menu display for this device, menu list and quick menu.
  (☞"Menu Configurations" P1-2)
- In this manual, the operation procedure is explained for the case when menu list is displayed (when quick menu display is OFF).
  If quick menu is displayed, press [Menu] > [Menu List] to display the menu list and follow the procedure explained in this manual.

Composition of This Manual

The operation manual is composed of the following chapters.

Chapter Title	Description
Preface	Outline and purpose of this manual (Important Notice, About This Manual)
Safety	Warning, Precautions for Safety
1 General Description of the Device	Composition, features, menu configuration of this device
2 Names of Parts and Their Functions	Name and function of each part, external appearance
3 Operation Procedure and Screen Examples	Operation procedure, home display, window, procedure to return the display, user key setup
4 Preparation	Daily inspection, power ON/OFF, time/date, installing the recording paper
5 Admit/Discharge	Entering patient information (name, age, etc.) at admittance, discharging the patient, user mode selection, suspend monitoring
6 Alarm Function	General description of alarm function, alarm-related setups
7 Monitoring	Measurement condition setup of the monitoring parameters, size/scale setup, etc.
8 Review Function	Arrhythmia analysis, trend, tabular trend, ST measurement, alarm history, full disclosure waveform, MPDR
9 Printing	Recorder output function
10 System Configuration	Display configuration, tone/volume, color, brightness, night mode
11 Troubleshooting	Message list, maintenance and troubleshooting of this device
12 Setup Item/Default Value	Setup item and default value
13 System Components	List of accessories and optional accessories of this device
14 Specification	Specification and performance of this device

The maintenance manual is composed of the following chapters.

Chapter Title	Description
Preface	Outline and purpose of this manual (Important Notice, About This Manual)
Safety	Warning, Precautions for Safety
1 Installation of the Unit	Precautions about the operating environment, system construction, power source and ground connection.
2 Network System Construction	Network connection and setup
3 Using the External Media	Procedure to use the USB memory and SD card.
4 Connection to the External Devices	External device connection/setup, magnetic card reader usage
5 Initial Settings	Initial setup, administrator setup, alarm/measurement setup, user I/F, user mode registration
6 Setup Item/Default Value	Default and backup of setup items
7 Replacement Parts	Precautions about the periodic replacement parts, consumable parts
8 Cleaning/Disinfecting/Storing	Procedure to handle, clean, store this device
9 Maintenance Check	Daily and periodic inspections, self-diagnosis function, software version, software install

Safety

About the Safety Precautions

The Meaning of Each Safety Precaution

Read this manual thoroughly before use to ensure correct and safe use of the product.
Be sure to follow the precautions indicated below, as these are important messages related to safety.

Type of Precaution	Description
DANGER	Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.
WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

Graphic Symbols

Refer to the following for the meaning of the symbol indicated on the device.

Graphic Symbols	Description
	Follow operating instructions (Warning). Indicated in blue. Failure to follow operating instructions could place the patient or operator at risk.
	Follow operating instructions (Information). Indicates the need to refer to the related accompanying documents before operation.
	General Precaution
	Caution
	Potential Equalization Terminal Indicates the terminal to equalize the potential difference when interconnecting the devices.
	Protective Earth Indicates the protective earth inside the device.
	Alternating Current (Main Power Input Indicator)
	Indicates that the device is in normal operation.
	Indicates that the device is in standby mode.
	Type CF Applied Part with Defibrillation-Proof Indicates that the degree of protection against electric shock is Type CF Applied Part with defibrillation-proof.
	Type BF Applied Part with Defibrillation-Proof Indicates that the degree of protection against electric shock is Type BF Applied Part with defibrillation-proof.
	RS-232C Connector Connects the related device.

Graphic Symbols	Description
	Indicates prohibited actions. Refer to the instruction stated near the symbol.
	Indicates mandatory or instructed actions. Refer to the instruction stated near the symbol.
	Battery
IP32	Dustproof (IP3X): Protection against ingress of solid objects more than φ2.5mm. Waterproof (IPX2): Protection against water drops falling vertically over 15 degrees range. Only when I/O cover, battery cover, $EtCO_2$ cover (or HCP-110), or recorder cover (or HR-110) is attached.
	Alarm Silence
	NIBP Start/Stop
	NIBP Periodic Measurement
	Lock
	Unlock
	Gas Input Part
	Gas Output Part
	Signal Input/Output Indicates the connector which inputs/outputs the signals.
	USB Connector Indicates the USB connector.
NFC	Indicates that the communication is Near Field Communication (NFC). (Unsupported function)
	Name and Address of Manufacturer / Date of Manufacture Indicates the name and address of manufacturer, and date of manufacture.
	WEEE (Waste Electrical and Electronics Equipment) Indicates a separate collection for electrical and electronic equipment.

Precautions for Safe Operation of Medical Device

WARNING

- Do not disassemble or remodel the device.
- Do not operate this device until the setup is verified to be correct.
- If any damage of the device is suspected, do not use the device.

CAUTION

- Users should have a thorough knowledge of the operation before using this device.
- Do not use the device in an environment where protective earth and wiring is questionable.

❑Precautions about the Location of Installation and Storage of the Device

- Set the monitor to the user's intended position where the user can easily recognize the visual and audible monitoring conditions. Normally it is recommended to set at a distance of one (1) m from the user.
- Install or store in a place where the device will not be exposed to splashing water.
- Install or store in an area where environmental conditions such as atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, sodium, and sulfur will not adversely affect the system.
- Place the device 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 gases are evolved.
- Verify the power frequency, voltage and allowable current (or power consumption).
- Ensure the grounding is proper by connecting the accompanying power cable to the hospital grade outlet.
- Make sure to secure the device using a trolley or stand.
- Do not place this device or accessories in any position that might cause it to fall on the patient.
- Do not place this device where the controls can be changed by the patient.
- Do not place this device on electrical device that may affect the device.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to this device.

❑Precautions Before Using the Device

- Verify the power voltage. When operating the system with the battery pack, make sure that the battery pack is fully charged.
- Check the cable connection and polarity to ensure proper operation of the device.
- Ensure that all cables are firmly and safely connected.
- Pay special attention when the device is used in conjunction with other devices as it may cause erroneous judgment and dangerous situation.

❑Precautions during Operation of the Device

- Always observe the device and patient to ensure safe operation.
- If any abnormality is found on the device or with the patient, take appropriate measures under the safe conditions, such as ceasing operation of the device.
- Do not allow the patient to come in contact with the device.
- On start-up of the system, verify that the start-up tone generates and alarm indicator lights.
- For the connectors which are not Type BF, CF applied part, do not touch them and the patient at the same time.
- Do not touch the patient while operating the device.

❑Precautions After Using the Device

- Unplug all the cables from the patient before turning off the power.
- When unplugging the cables, make sure to pull from the connector part of the cable and avoid applying excessive force.
- Clean the accessories and cables, and keep them together in one place.
- Keep the device clean to ensure proper operation for the next use.
- Before cleaning, be sure to turn off the power and unplug from all the power cables.

❑Precaution when Device Failure Occurs

- If the device is damaged and in need of repair, the user should not attempt service. Label the unit "OUT OF ORDER" and contact your nearest service representative.

❑Precaution about Disassembling/Remodeling the Device

- If water or other liquids enter the device, cease using the device and contact your nearest service representative.

❑Precautions about Maintenance Check

- Make sure to periodically check the device, accessories, and cables.
- Before reusing the device that has been left unused for a while, make sure that the device operates normally and safely.

❑Precautions when Using with Other Device

- To prevent patient from burn injury, verify proper attachment of patient ground plate, ECG electrode type when using the electrosurgical knife, and verify paste volume, output energy when using the defibrillator. Also, verify that each device is properly grounded.

Precautions about the Maintenance

⚠ WARNING

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

⚠ CAUTION Precautions about Safety Check

- For safe operation of the device, regular inspection and maintenance are 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 for the following case.
  - When the device was subjected to extreme mechanical stress, e.g. after a heavy fall.
  - When the device was subjected to liquid spill.
  - When the monitoring function is interrupted or disturbed.
  - When parts of the device enclosure are cracked, removed, or lost.
  - When any connector or cable shows signs of deterioration.

Precautions about the Network System

Medical Telemetry

⚠ CAUTION Precautions about the Installation

- The medical institution (hereinafter referred as "Institution") must decide the telemetry installation plan for the medical institution in order to prevent interference between transmitters (telemetry based on destination country's radio law). When telemetry has already been installed and been used, radio format, frequency, and antenna power are required to be examined to prevent interference.
- When using telemetry which requires zone location, the institution is to set up the zones as an operation unit for each transmitter to prevent electronic interference between telemetry throughout the Institution.
- When using telemetry which requires zone location, display and identify each prepared zone in the device.
- When laying receiver antenna for each transmitter, the Institution has to examine the installation so that electronic interference does not occur.
- Based on the above examination result, the Institution should place each receiver antenna as required.

CAUTION Precautions about the Management

- The institution appoints a person to manage the wireless channels for the whole medical institution. And when using telemetry which requires zone location, the Institution should nominate a person to manage the wireless channels in each zone (a "Coordinator"). However, when using such telemetry in a local medical institution, one person can perform both functions.
- Select a telemetry coordinator who understands the characteristics and functionality of telemetry systems, and is skilled in operating telemetry.
- When installing telemetry, the Coordinators have to understand the precautions for use of the telemetry in advance.
- The Coordinator takes responsibility of wireless channel management and transmitter storage for the whole Institution by giving proper instruction.
- The Coordinator should create a management log (hereinafter referred to as the "log"), which contains a list of the management status of the wireless channels for the whole Institution. When changing a wireless channel, register it in the log and give proper instructions to the user.
- The Coordinator assumes responsibility for managing the wireless channels, storing, and managing telemetry.
- The Coordinator assigns the transmitter to the user, and provides enough education for use inside the zone.
- The telemetry user verifies operation of the transmitter/receiver before use.
- The telemetry user, if using the telemetry in a zone location, follows the instructions of the Coordinator for the zone and gives instructions to the patient if required.
- When interference or breakdown occurs in telemetry communication, the user is required to inform the Coordinators of the problems. The Coordinators are to deal with the problem properly and/or contact their nearest Fukuda Denshi representative for service.

Precautions when Using with Other Device

Pacemaker

WARNING

- Minute ventilation rate-adaptive implantable pacemakers can occasionally interact with certain cardiac monitoring and diagnostic equipment, causing the pacemakers to pace at their maximum programmed rate. The cardiac monitoring and diagnostic equipment may possibly send wrong information. If such event occurs, please disconnect these devices, or follow the procedures described in the operation manual of the pacemaker. For more details, contact FUKUDA DENSHI personnel, your institution’s professionals, or your pacemaker distributors.
- Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms. Keep pacemaker patients under close surveillance.

Reference

"Minute Ventilation Rate-Adaptive Pacemakers"
FDA alerts health professionals that minute ventilation rate-adaptive implantable pacemakers can occasionally interact with certain cardiac monitoring and diagnostic equipment, causing pacemakers to pace at their maximum programmed rate.
[Based on a safety bulletin issued by FDA Center for Devices and Radiological Health on October 14, 1998]

Non-Explosion Proof

DANGER

- Never operate the device in the presence of flammable anesthetics, high concentration of oxygen, or inside hyperbaric chamber. Also, do not operate the device in an environment in which there is a risk of explosion. Explosion or fire may result.

Defibrillator

WARNING

- When defibrillating, keep away from the electrodes or medicament applied to the patient chest. If this is not possible, remove the electrodes or medicament before defibrillating.
  If the defibrillator paddles are directly in contact with the electrodes or medicament, an electrical shock may result by the discharged energy.
- When defibrillating, make sure that the electrodes, sensor cables, or relay cables are firmly connected to the device.
  Contacting the metal part of the disconnected cable may result in electrical shock from the discharged energy.
- When defibrillating, do not touch the patient and the metal part of the device or cables.
  Electric shock may result from the discharged energy.
- This device will return to standard operating mode within 10 seconds after defibrillating. However, when in diagnosis mode, it may require 10 seconds or more after defibrillation to display the normal ECG waveform as the time constant setting is large.
  The stored data will not be affected. The measurement accuracy will temporarily decrease during defibrillation, but it will not compromise the safety of patient and the device.
- The QRS synchronized signal is not intended to be used as synchronized signal for defibrillator.

Electrosurgical Instrument

WARNING

- The monitoring system contains protection against interference generated by electrosurgical instruments. However, depending on the conditions, such as operating environment, surgery site, ground plate attachment condition, or the type of instrument used, it may cause burn injuries at the electrode sites or noise on the ECG. The noise is generated at the tip of the electrosurgical knife and is difficult to completely eliminate because of the frequency components of the ECG. To reduce electrosurgical interference, take the following precautions:

  Location:

  Locate the electrosurgical unit as far as possible from this device and the patient cable. This will help reduce interference on the ECG through the monitor or cables.

  Power Supply:

  Connect the electrosurgical unit to a power supply that is different from that of this device. This will help prevent interference through the power cable.

  Electrode Placement

  The amount of noise interference is considerably different depending on the electrode position and surgery site. Place the ECG electrodes as far away as possible from the surgery site and the ground plate. Do not place electrodes in the path between the surgery site and the ground plate. If the electrodes are placed in this path, the amount of interference will be quite large. Position (+) and (–) electrodes as close as possible to each other.

  Ground Plate

  When using electrosurgical instruments, make sure the contact between the patient and the ground plate is secure. If the connection is incomplete, the patient may suffer from burn at the electrode site.
- The stored data will not be affected. The measurement accuracy will temporarily decrease during electrosurgery, but it will not compromise the safety of patient and the device.

- When using the electrosurgery-proof type ECG relay cable, the impedance respiration cannot be measured, and its numeric data and waveform will not be displayed. When measuring in an environment where electrosurgery is not performed, make sure to use the standard ECG relay cable.
- As this device utilizes capacitive touch panel, the energy from the electrosurgical knife may pass through the cable to the touch panel causing unintentional touch panel control. Locate the cables as far away as possible from the touch panel.

MRI (Magnetic Resonance Imaging)

WARNING

MR Unsafe-Keep away from magnetic resonance imaging (MRI) device.

- Do not use this device in magnetic resonance imaging (MRI) environments.
- When conducting MRI test, remove the electrodes and sensors connected to the patient (test subject).
  This device may be pulled towards the MRI device. Also, the local heating caused by the induced electromotive force may cause burn injury to the patient or performance degradation, failure, damage of this device.
  For details, refer to the operation manual for the MRI testing device.

Precautions about Connections to Peripheral Devices

To use the device safely and to ensure maximum performance of the device, connection of other manufacturer's device to this device 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 device.

WARNING

- When multiple devices are connected to the patient, it may be necessary to take measures for connection (use of separation device), power supply (use of isolation power), grounding (additional protective earth). If these measures are not properly taken, a leakage current may flow between the devices, or the total amount of leakage current may exceed the limit specified on IEC 60601-1-1.
- Only the peripheral devices specified by Fukuda Denshi should be connected with the given procedure. Use of an unspecified device may cause electric shock to the patient and/or operator due to excessive leakage current.

CAUTION

- Although the peripheral device connectors on the BDS-1001 system are, with some exceptions, isolated from the power supply, the connecting peripheral devices should comply with IEC 60601-1. It is the user's responsibility to verify that the overall system complies with IEC 60601-1-1.
- To prevent danger of electric shock, always position the peripheral devices away from the patient.
- Network device including printer and hub should be located outside the "Patient Environment". If located inside the "Patient Environment", it may result in electric shock to the patient or the operator.
- Combinations of medical device with non-medical device must comply with IEC 60601-1-1 or IEC 60601-1. Never use a multiple portable socket-outlet or extension cable when connecting the devices unless it is supplied specifically for use with that device.

Precautions for Using the Device

This System

DANGER

- When connecting to other devices, contact your nearest representative.
  Danger such as electric shock may result to the patient and operator.

WARNING Warnings about the System

- Do not connect any device or cable not authorized by Fukuda Denshi to any I/O connector. Also, do not connect any damaged device or cable. If done so by mistake, not only that the device cannot deliver its maximum performance, the device may be damaged and safety cannot be ensured.
- If the device is used under an environment not fulfilling the specified condition, not only that the device cannot deliver its maximum performance, the device may be damaged and safety cannot be ensured. If using the device under condition other than specified, contact your nearest representative.
- Use only the supplied 3-way AC power cable. Use of other cables may result in electric shock to the patient and the operator.
- The power cable must be connected to a hospital grade outlet.
- The lithium-ion battery can only be charged in the specified operating temperatures of the device. For details, refer to the operation manual of the lithium-ion battery (BTO-008).
- When using multiple medical devices simultaneously, pay attention not to touch multiple devices at the same time. Even a small potential difference between the devices may result in electric shock to the patient and the operator.
- Pay special attention to connect the cables. Carefully route the cables to avoid patient entanglement and strangulation.
- When lifting this device, hold the bottom part and the handle.
- When using this device, the operator should stay in a distance close enough to recognize an alarm sound. Do not move too far away where a sound cannot be recognized.
- To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
- To protect against injury, follow the directions below.
  - Avoid placing the device on surfaces with visible liquid spills.
  - Do not soak or immerse the device in liquids.
  - Do not sterilize the device.
  - Use cleaning solutions only as instructed in this operation manual.
  - Do not disinfect the device while monitoring patient.

WARNING Warnings about the monitoring

- The patient classification selection influences the precision of the QRS detection and NIBP measurement. Make sure the proper selection is made.
- The pacemaker usage setting influences the precision of the QRS detection and arrhythmia analysis. Make sure the correct selection is made.
- If the QRS pace mask function is set to [OFF], [10ms] / [20 ms], the pace pulse may be erroneously be detected as a QRS complex and HR alarm or asystole alarm may not generate due to incorrect HR (counting pace pulse as QRS complex). Set this function to [OFF]/[10ms]/[20ms] only if you are sure that pacing failure will not occur, or when the patient can be constantly monitored.
- Before bathing the patient, make sure to remove the sensor and device from the patient.

- 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 due to the sensor heat which may result in burn injury.
- For the following case, accurate measurement of SpO_2 may not be possible.
  - Patient with excessive abnormal hemoglobin (COHb, MetHb)
  - Patient with the pigment injected to 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
- When a patient is receiving a photodynamic therapy, measuring SpO_2 on a same site for a long duration may cause blisters from the irradiation light of the SpO_2 sensor. Make sure to periodically change the sensor attachment site.
- Before the measurement, make sure the patient classification (Adult/Child/Neonate) is properly selected. Otherwise, correct measurement cannot be performed, and congestion or other injury may result.
- When the system alarm is suspended, all the alarm will be suspended even if the parameter alarm is set to [ON]. Also, the alarms will not be stored as recall events.
- If the upper/lower alarm limit of the parameter is set to [OFF], or if , arrhythmia alarm is set to [OFF], alarm will not function even if the system alarm is enabled. Pay attention when setting them [OFF].
- Objective and constant arrhythmia detection is possible through the fixed algorithm incorporated in this unit. However, excessive waveform morphology change, motion artifact, or the inability to determine the waveform pattern may cause an error, or fail to make adequate detection. Therefore, physicians should make final decisions using printing and recall waveform for evaluation.
- The RR/APNEA alarm will not be generated unless the numeric data box corresponded to the selected RR/APNEA alarm source is displayed. Make sure to display the numeric data box for the RR/APNEA alarm source.
- When selecting [0] for "Volume" or [Timer] for "Display" for the Night Mode, pay attention not to miss any important alarm by simultaneously monitoring the patient on central monitor or other monitors.
- When the alarm sound is suspended, the alarm sound will not generate for the fixed amount of time. Pay attention not to miss any important alarm by simultaneously monitoring the patient on central monitor or other monitors.
- If the safety of the patient cannot be ensured, do not suspend the alarm or decrease the alarm volume.

WARNING Warnings about the CO_2 Monitoring (HCP-110)

- Only one HCP-110 can be connected.
- When using a sampling line for intubated patients with a closed suction system, do not place the airway adapter between the suction catheter and endotracheal tube. This is to ensure that the airway adapter does not interfere with the functioning of the suction catheter.
- To prevent cross-infection, do not allow the sampling gas to return to the breathing system.
- To protect the hospital staffs from unnecessary anesthetic agent when using the HCP-110, it is strongly recommended to connect the exhaust hole to the gas exhaust system in the hospital.
- Loose or damaged connections of the sampling line may compromise ventilation or cause an inaccurate measurement of respiratory gases. Securely connect all components and check connections for leaks according to standard clinical procedures.
- Do not cut or remove any part of the sampling line. It could lead to erroneous readings.
- If too much moisture enters the sampling line (i.e., from ambient humidity or breathing of unusually humid air) when using the HCP-110, <Check Sample Line> will be displayed in the message area. Replace the sampling

line once this message is displayed.

- Carefully route the sampling line to reduce the possibility of patient entanglement or strangulation.
- Do not lift the HCP-110 by the sampling line, as the sampling line could disconnect from the device, causing the device to fall on the patient.
- CO_2 readings and respiratory rate can be affected by sensor application errors, certain ambient environmental conditions, and certain patient conditions.

CAUTION Precautions for Installing the Monitor

- Make sure to secure the device using a specified trolley or stand. Otherwise, the device may fall down, resulting in injury to the operator or damage to the device.

CAUTION Precautions about the Trolley

- When attaching the monitor to the specified trolley, make sure that it is securely fixed on. Otherwise, the device may fall off from the trolley, resulting in injury to the operator or damage to the device.
- The trolley is intended to be used with specified device. If the trolley is used with unspecified device, the trolley may fall down, resulting in injury to the operator or damage to the device. Do not use with any unspecified device.
- When using or storing the trolley, make sure that the casters are locked. Otherwise, the trolley may fall down, resulting in injury to the operator or damage to the device.
- Do not use or store the trolley where it will be subject to inclination of 10 degrees or more. The trolley or device may fall resulting in injury to the operator or damage to the device.

CAUTION Precautions about the System

- Do not assess the patient's condition only with the information from this device. A clinical judgment based on the information from the device should be made by a doctor who fully understands functions of the device, in a comprehensive manner combined with clinical findings and other test results.
- Do not assess the patient's condition only by the alarm generated on this device. When the alarm is set to OFF or if the alarm priority is low, a sudden change of the patient may not be noticed.
- If an alarm generates, check the patient's condition first and ensure the safety. Depending on the alarm, take appropriate measures to remove the problem. If the problem lies with the alarm setting, set the alarm properly.
- When measuring for a long period of time, make sure not to compress the patient with the lead cables and the electrodes. Compressing the same site for a long duration may inhibit the blood flow and generate compression necrosis and burn injury.
- Use only the products specified for this device. If unspecified products are used, proper function cannot be executed.
- Do not attach film to the touch panel. This may result in malfunction or failure.
- For quality improvement purposes, specifications may be subjected to change without prior notice.
- This device utilizes LED for the backlight. Since this LED deteriorates by the life cycle, the display may become dark, scintillate, or may not light by the long term use. In such case, contact your nearest service representative.
- This device is intended to be used for only one patient.
- The installation of this device should be performed by our service representative or a person who is well acquainted with this device.
- If not using the device for a long period, disconnect the power cable and lithium-ion battery.

CAUTION Precautions about the ECG Monitoring

- If any electrodes get detached from the patient after being connected to the lead cable and patient monitor, pay attention that the metal part of the electrode does not get in touch with any metal parts of the bed or any conductive parts. Also, the operator should not touch any conductive parts with bare hands. Otherwise, it may cause electric shock to the patient and/or operator due to excessive leakage current.
- The indication for continuous use of the electrode is about one day.

- Replace the electrode if the skin contact gets loosen due to perspiration, etc.
- When an electrode is attached to the same location for a long period, some patients may develop skin irritation. Check the patient's skin condition periodically and change the electrode site as required.
- For stable arrhythmia detection and ECG monitoring, verify proper electrode placement, lead, waveform size, and filter mode selection. If not properly selected, it may cause erroneous detection.
- The threshold level for arrhythmia detection changes with ECG waveform size. Set a proper waveform size for monitoring.
  - When the ECG waveform size is x1/4, x1/2, or x1, the arrhythmia detection level is 250 μV.
  - When the ECG waveform size is x2 or x4, the arrhythmia detection level is 150 μV.
- The leads for arrhythmia detection, central monitor display, printing are fixed as ECG1 and ECG2. Set the most appropriate leads with high QRS for ECG1 and ECG2, especially for arrhythmia detection. If the QRS amplitude for the set lead is low, it may cause erroneous arrhythmia detection.
- In ESIS Mode, artifacts such as electrosurgical noise or EMG can be largely reduced, but QRS amplitude attenuation, waveform distortion, or ST segment change may occur compared with other filter modes.
- The ESIS mode cannot completely reduce the electrical noise, and may erroneously detect the pacemaker spike. This mode should be selected only when a high frequency noise largely affects the HR measurement.
- There are some cases when the pacemaker pulse cannot be detected depending on the pacemaker type, pulse voltage, pulse width, electrode lead type (unipolar, bipolar), or electrode placement which causes the pacemaker pulse amplitude to decrease, and disables the pacemaker pulse detection.
- If signals similar to a pacemaker pulse are present, such as electric blanket noise or excessive AC frequency noise, these may be erroneously detected and displayed as a pacemaker pulse.
- When a spontaneous QRS and pacemaker pulse overlap (ex. fusion beat, etc.), QRS detection cannot be performed properly. In this case, the heart rate is degraded.
- If a pacemaker pulse is continuously detected due to AC frequency interference, QRS detection will be suspended and the heart rate will be reduced. Arrhythmia will not be detected either.

⚠ CAUTION Precautions about the ST Measurement

- The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes need to be determined by a clinician.
- For the lead which the electrode is detached, the reference waveform setup cannot be performed. Check if the electrode is appropriately attached, and perform the setup again.

⚠ CAUTION Precautions about the SpO_2 Monitoring

- Use only the sensor/relay cable specified by Fukuda Denshi. Otherwise, it may cause measurement error.If the sensor is damaged, stop using it.
- 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.
- Do not apply the sensor too tight. At the same time, check the blood flow constantly so that congestion is not generated at the peripheral site.
- Do not use tape to attach the sensor.
- Even attachment for a short duration may inhibit the blood flow and generate compression necrosis or burn injury. Also, blood flow inhibition may prevent correct measurements.
- Check the sensor attachment site constantly in every 4 hours when probes or reusable sensor are used, and at least every 8 hours when single patient use sensors are used. Be especially careful of a patient with bad perfusion. If the sensor attachment position is not changed constantly, skin irritation or skin necrosis due to compression may be developed. For the patient with bad perfusion, check the sensor attachment position at least every 2 hours.

- As skin for neonate, premature infant is immature, change the sensor attachment site more frequently depending on the condition.
- Direct sunlight to the sensor area can cause a measurement error.Place a black or dark cloth over the sensor if using in direct sunlight.
- When not measuring, unplug the relay cable and sensor from the SpO_2 connector. Otherwise, the outside light may affect to falsely display measurements.
- The pulse wave is normalized for SpO_2 measurement, and does not indicate perfused blood volume. Check proper probe attachment by observing the pulse wave.
- Precautions for Reusable Sensors
  The light-emitting part of the sensor should be over the root of the fingernail or as instructed per the related sensor instruction manual. Do not insert the finger too far into the sensor as it may hurt the patient. For details, refer to the SpO_2 sensor instruction manual.
- Precautions for Single-Patient-Use Type Sensors
  The sensor can be reused on the same patient as long as the adhesive tape attaches without slippage. But do not reuse on other patients to avoid cross contamination. It is intended for single patient use only. For details, refer to the SpO_2 sensor instruction manual.
- If "---" is displayed for the SpO_2 numeric data, make sure that the sensor is properly attached.
- Measuring on a limb with NIBP cuff, arterial catheter, or intracatheter may result in incorrect measurement.
- Venous congestion may cause under reading of actual oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should not be below heart level (e.g. sensor on hand of a patient in a bed with arm dangling to the floor).

⚠ CAUTION Precautions about the NIBP Monitoring

- Do not apply the NIBP cuff to site of injury. An injury may be worsened by the measurement.
- Do not apply the NIBP cuff to the arm on side treated axillary lymph nodes dissection. It may lead to lymphatic edema by the cuff pressure.
- Measuring on a limb with SpO_2 sensor, arterial catheter, or intracatheter may result in incorrect measurement.
- An operator must not get away from a patient during the NIBP measurement. However, when getting away from the patient is necessary, do not activate the Alarm Suspend and Silence functions in order not to miss any sudden changes in the patient's condition.
- Pay attention when measuring the NIBP of patient with bleeding disorders or hyper coagulation. The cuff inflation may cause petechia or circulatory failure by the blood clot.
- For the following situation, measurements will be terminated.
  - When the measurement time has exceeded 160 seconds for adult and child, 80 seconds for neonate.
  - When the inflation value has exceeded 300mmHg for adult, 210mmHg for child, and 150mmHg for neonate.
- If used with the incorrect patient classification, it will not only cause erroneous measurement, but the inflating level for the adult may be applied to child or neonate causing dangerous situation to the patient.
- If the mean MAP display is set to OFF, the MAP alarm will not be generated. Also the MAP data will not be displayed for the tabular trend or the NIBP list.

⚠ CAUTION Precautions about the CO_2 Monitoring (HCP-110)

- Conduct CO_2 calibration for the following case.
  If the CO_2 gas calibration is not performed at a specified interval, CO_2 measurement accuracy may be affected and also subsequent gas calibration may not be possible.
  - When the accumulated measurement time exceeds 1,200 hours from the first use.
    However, if the first calibration was performed before the accumulated measurement time reaches 720 hours, another calibration is required when the accumulated measurement time exceeds 1,200 hours from the first calibration.
  - When 12 months has elapsed or the accumulated measurement time has exceeded 4,000 hours from the

previous calibration.

- When $EtCO_2$ measurement is not stable or accuracy is degraded compared with other measuring device.
- When the patient monitor was not used for a while, or when $EtCO_2$ was not measured for a while.

- Perform the calibration 5 minutes after turning ON the power on the HCP-110.
- Do not disconnect the sampling tube during calibration. If the sampling tube is disconnected, calibration will cease.
- Dispose of calibration gas according to the regulation of each medical institution.
- The Microstream™ $EtCO_2$ sampling lines are designed for single patient use, and are not to be reused. Do not attempt to clean, disinfect, sterilize or flush any part of the sampling line as this can cause damage to the monitor. It may cause crass-infection.
- Dispose of sampling lines according to standard operating procedures or local regulations for the disposal of contaminated medical waste.
- Before use, carefully read the Directions for Use for the Microstream™ $EtCO_2$ sampling line.
- Use only the Microstream™ $EtCO_2$ sampling line to ensure proper function of the monitor.

⚠ CAUTION Precautions about the Alarm

- Alarm messages will be displayed according to the priority. (Level S > Level H > Level M > Level L> Level N)
- For the same alarm level, the alarm message for the newer alarm will be displayed. However, arrhythmia alarm will be displayed according to the arrhythmia priority.
- The arrhythmia alarm message other than Tachy, Brady, Ext Tachy, Ext Brady will continue to be displayed for 30 seconds after the alarm is resolved.
- When "LEAD OFF", "Check Electrodes" is displayed, HR alarm or arrhythmia alarm will not function. If this condition is left unresolved, a sudden change of the patient may not be noticed. Take prompt action when the lead-off condition is detected.
- When CO_2 is measured on the HCP-110, the upper $EtCO_2$alarm will not generate if the upper limit is set to 100 mmHg/13.4 kPa and above as the measurement range is 0 to 99 mmHg / 0 to 13.3 kPa.
- Whether to use the SpO_2 second alarm function and its threshold selection should be based on the patient's clinical indication/portent and medical evaluation.
- If the second alarm setup is set to [OFF], the second alarm integral value will be set to 0.
- Pay attention not to set the alarm volume too low to avoid missing any important alarms.
- If the same or similar devices with different alarm settings are used in the same facility or same department, pay attention not to misjudge the alarms.
- To ensure that the alarm setup is appropriate for the patient being monitored, check the setup each time this device is used.

⚠ CAUTION Precautions about the System Setup

- When the waveform and numeric data display for each parameter is set to OFF, the alarm and trend input will be also suspended.
- If the HR/PR source is set to [SpO_2], and if SpO_2 waveform/numeric data is set to [Disp. OFF], the PR value will not be displayed.
- If the RR source is set to [CO_2/GAS], and if CO_2 waveform/numeric data is set to [Disp. OFF], the RR value will not be displayed.
- If the time/date is not correctly set, or changed during monitoring, malfunction may occur with NIBP measurement, periodic printing, trend, NIBP list data, and age calculation from the birth date.
- If the time/date is changed, the time/date for all the saved patient data (trend, list, recall, etc.) will also change. The printed time/date before changing and the displayed time/date after changing will differ. Also, the data transmitted to the central monitor before the time/date is changed will be displayed on the central monitor with the previous time/date.

CAUTION Precautions about the Patient Admit/Discharge

- Make sure to discharge the previous patient before admitting a new patient. Otherwise, monitoring data of new patient will be added to that of the previous patient which will result in inaccurate monitoring.
- The user mode setting (alarm/display configuration) will remain effective even when the power is turned OFF or when the patient is discharged. Before monitoring, make sure the current user mode is suitable for the patient's condition.
- Resuming monitoring will also resume the alarm in suspension.

CAUTION Precautions about the External Media

- Use only the specified external media.
- Use only the external media formatted on this device.
- Make sure to power cycle the system after the setup data is read from the external media.
  By power cycling the system, the read data will become effective.
- Reading the patient data from the external media will erase all previous patient data stored in the patient monitor.

CAUTION Precautions about the Maintenance

- When cleaning the touch panel, never use strong-acidic cleaning solution.
- To clean the touch panel, use an optional cleaning cloth, eyeglass cleaning cloth, soft cotton cloth, or non-woven cloth (pulp, rayon, polyethylene, etc.).
- Clean the device frequently so stains can be removed easily.
- To prevent injury, it is recommended to wear gloves when cleaning the device.
- Pay attention not to allow chemical solution to enter the device or connectors.
- Do not use organic solvents, thinner, toluene or benzene to avoid damaging the resin case.
- Do not polish the device with abrasive or chemical cleaner.
- When disinfecting the entire room using a spray solution, pay close attention not to get any solution into the device or connectors.
- Use only neutral detergent to clean the device. The surface resin coating may damage, resulting in discoloration, scratches, and malfunction.
  Example:
  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
- Do not open the housing.
- Do not allow alcohol or other liquids to enter the device.
- Replace the periodic replacement parts periodically as specified.

Wireless Network System

DANGER

- When monitoring a patient using wireless telemetry, make sure the patient data is properly received at the central monitor. Pay special attention when the channel ID at the bedside monitor is changed.

WARNING

- A password can be set to access the channel ID setup menu to allow only the telemetry channel administrator to change the channel ID.
- Some type of wireless combinations may generate interference with other telemetry.
- Before selecting a channel, verify it will not interfere with other channels.
- Inform the supervisor of the use of telemetry channels to avoid interference with other telemetry.
- If transmitters are used in a neighboring medical facility, your facility and the neighboring facility must make agreements on the setting of the telemetry channels to prevent telemetry interference.

CAUTION Precautions about the Telemetry

- When performing telemetry transmission, configure the display so that the numeric data corresponded to the waveform is displayed. If not, the displayed waveform or numeric data may not be transmitted.
- The setup of channel ID and group ID should be performed only by the telemetry channel administrator or our service representative. Users should not perform this procedure as malfunction may occur.
- If the "RR/APNEA Alarm Source" setting is other than [Impedance] (or, if [Auto] selects a setting other than [Impedance]), the RESP waveform will not be transmitted on a wireless network.
- When the BP measurement unit is kPa, the corresponding numeric data will not be transmitted. When using the wireless network, the BP measurement unit should be set to "mmHg".

RTC and Data Backup

CAUTION

- This device is equipped with a built-in clock.When the power of this device is turned OFF, this clock is backed up by a lithium primary battery.If incorrect time is displayed when turning ON the power, a low battery may be the cause. In such case, contact Fukuda Denshi service representative for replacing the battery.

Precautions about the Ventilator Monitoring

WARNING

- The ventilator alarm sound is set to OFF (factory default).
  The alarm sound can be turned ON on the Tone/Volume setup screen.
- If the BDS-1001 system does not generate an alarm even though the ventilator is generating an alarm, or if any other malfunction occurs, immediately check the ventilator, this device, cable, and replace the cable if necessary. If the malfunction persists, stop using the device.
- The alarm generation on the BDS-1001 system is not guaranteed if the alarm other than the specified one generates at the ventilator.
  (☞Maintenance Manual "Ventilator Alarm Input" P4-1)

⚠ CAUTION

- The ventilator operation should be performed by well-trained and authorized personnel.
- When connecting this device and a ventilator, use only the specified connection cable.
- Verify that this device and the ventilator are properly connected.
- When connecting the cable, verify that the main power of this device and the ventilator are OFF.

Precautions about the SpO_2 Sensor

⚠ DANGER Danger of Burn Injury Caused by the SpO_2 Sensor

- When monitoring SpO_2, make sure to use only the specified sensor/relay cable. If any other sensor/relay 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 use for SpO_2 measurements of this device, please contact Fukuda Denshi service representative.

Precautions about the NIBP Cuff

⚠ CAUTION

- Some of the NIBP cuffs used for this device contain natural rubber latex which may cause allergic reactions. (FDA: Medical Alert on Latex Products, "Allergic Reactions to Latex-Containing Medical Devices", Food & Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 1991.)

Precautions about Disposing of the Device, Accessories, or Components

⚠ CAUTION

- When disposing of this device, accessories, or components, use an industrial waste distributor. Do not dispose of as ordinary waste.
- When disposing of the battery, separate it from other wastes and contact your nearest service representative.

Precautions about Transportation

⚠ CAUTION

- When transporting this device, pack it with specified packing materials.
  Also, transport it under appropriate environment condition.
  (☞Operation Manual "Specification" P14-1)

Monitoring after Power Failure

When the power failure is less than 30 seconds, monitoring will resume with the display mode and patient information unchanged. When the power failure is 30 seconds or more, monitoring will resume with the default display mode set by the user, or the display mode which was last set.

HCP-110 will start up from the warm-up mode. The warm-up time differs for each unit.

To Prepare for Emergency Use

Accessories/Optional Accessories

- The ECG electrodes are consumable products. Always prepare extra supplies of electrodes.
- Verify that there is no wire break on the patient cable once a week.

Battery Pack

- Even if the battery pack is not in use, the remaining capacity decreases due to self-discharge.Make sure to verify once a week that the battery pack is fully charged.
- To fully charge the empty battery pack, it takes 12 hours during operation, and 6 hours when the power is OFF and AC cable is connected.
- The performance of the battery deteriorates with repeated use. To ensure performance of the battery, it is recommended to replace it once a year.

Electromagnetic Compatibility

This device complies with IEC 60601-1-2: 2014+A1: 2020, safety standard regarding the electromagnetic disturbances of medical electrical equipment. To ensure maximum performance against the electromagnetic disturbances, make sure to follow the precautions for installation and usage described in this manual.

- This device is intended for use in the medical facility (except in the vicinity of MRI device), and satisfies the immunity level for professional healthcare facility environment stipulated in IEC 60601-1-2: 2014+A1: 2020.
- When using this device, interference with other medical electrical equipments or non-medical electrical equipments may occur. Make sure that no interference is present before usage.
- This device is a medical device which intentionally receives RF energy of specific reception frequency. RF electromagnetic radiation from other device for the intended specific reception frequency band may cause radio interference. Make sure that the reception is properly made in the used environment.
- To ensure basic safety and essential performance related to electromagnetic disturbances during the expected service life of this device, "Daily Inspection" and "Periodic Inspection" must be performed.
  (Refer to "Chapter 9 Maintenance Check" of the Maintenance Manual.)

⚠ CAUTION

- Do not use any unauthorized device or cables as they may not comply with the EMC standard.

Precautions for Safe Operation under Electromagnetic Influence

If any sorts of electromagnetic wave, magnetic field, or static electricity exist around the device, noise interference or malfunction of the device may occur. If any unintended malfunction or noise occurs during monitoring, check the magnetic influence and take appropriate countermeasures.

The following are examples of the common cause and countermeasures.

⚠ DANGER Static Electricity

In a dry environment (room), static electricity is likely to occur. Take the following countermeasures.

- Both operator and patient should remove any static electricity before entering the room.
- Humidify the room.

⚠ WARNING Cellular Phone

- The radio wave may cause malfunction to the device.
  Mobile phones and radio sets should be turned off in the room (building) where medical device is located.

WARNING Lightning

A lightning nearby may induce excessive voltage to the device. If any danger is suspected;

- Use the uninterruptible power supply system.
- Use the battery.

CAUTION High frequency noise interference from other device through the power outlet

- Check where the noise is originated and remove it using filtering device, etc.
- Stop using the device that is originating the noise.
- Use other power outlet.

EMC Guidance

WARNING

- If portable transmitter is used in a place closer than 30 cm from the device, the electromagnetic influence may largely exceed the compliance level and may cause unexpected phenomenon such as noise interference on the waveform, etc.
- If this device is installed close to, or stacked with other device, malfunction may occur. Make sure to verify that the device operates properly in a used location.
- This device should be used in a location specified by each medical institution.

If any unexpected noise interference on the waveform or failure to the peripheral device occurs, stop using the device and follow the instruction of the technical engineer.

The following is the information relating to EMC (Electromagnetic Compatibility).

(When using this device, verify that it is used within the environment specified below.)

This device complies with IEC 60601-1-2: 2014+A1: 2020 for the following system configuration.

- Main Unit: BDS-1001
- Recorder Unit: HR-110
- CO_2 Gas Unit: HCP-110
- Lithium-ion Battery: BTO-008

❑Compliance to the Electromagnetic Emissions

The BDS-1001 system is intended for use in the electromagnetic environment specified below. The customer or the user of the BDS-1001 system should assure that it is used in such an environment.

Emission Test	Compliance
Mains Terminal Disturbance Voltage CISPR 11	Group 1 Class A
Electromagnetic Radiation Disturbance CISPR 11	Group 1 Class A
Harmonic Emissions IEC 61000-3-2	Class A
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies

CAUTION

- The emission performance of this equipment is suitable for use in industrial environment and hospital environment (CISPR 11 Group 1 Class A). Do not use in home environment (generally, CISPR 11 Group 1 Class B is required).

❑Compliance to the Electromagnetic Immunity

The BDS-1001 system is intended for use in the electromagnetic environment specified below. The customer or the user of the BDS-1001 system should assure that it is used in such an environment.

The EMC Standard or Test Level	Immunity test level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV Contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM Fields IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz 2 Hz 80%AM
Immunity test specifications for RF wireless communications IEC 61000-4-3	Refer to the following table.
Electrical fast transient/burst IEC 61000-4-4	±2 kV AC Mains ±1 kV output lines Repetition frequency 100 kHz
Surge IEC 61000-4-5	±0.5 kV, ±1 kV (normal mode) (Phase Angle 0°, 90°, 180°, 270°) ±0.5 kV, ±1 kV, ±2 kV Common mode (Phase Angle 0°, 90°, 180°, 270°)
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 2 Hz 80%AM 6 V 0.15 MHz to 80 MHz (ISM bands) 2 Hz 80%AM
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz, 60 Hz
Voltage dips, Voltage Interruptions and Voltage Fluctuations IEC 61000-4-11	0% U_T 0.5 cycles (Phase 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) 0% U_T; 1 cycle, 70% U_T; 25 cycles (Phase 0°) 0% U_T 250 cycles
Proximity magnetic fields IEC 61000-4-39	Refer to the following table.

⚠ CAUTION

- The electromagnetic disturbances test evoked from the radiated RF electromagnetic field and RF electromagnetic field is performed with 2 Hz modulation frequency which is close to the frequency component of the vital parameter.

Immunity test specifications for RF wireless communications equipment

Test Frequency (MHz)	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
710, 745, 780	PM, 217 Hz	0.2	0.3	9
810, 870, 930	PM, 18 Hz	2	0.3	28
1720, 1845, 1970	PM, 217 Hz	2	0.3	28
2450	PM, 217 Hz	2	0.3	28
5240, 5500, 5785	PM, 217 Hz	0.2	0.3	9

⚠ CAUTION

- The assumed service TETRA 400 of the test frequency of 385 MHz is a service in Europe, and this product, which is intended for use in the United States, has not been tested as it will not be radiated in close proximity.

- The assumed service GMRS 460, FRS 460 of the test frequency of 450 MHz is a wireless device for general and leisure use, and this product, which is intended for use in a professional healthcare facility environment, has not been tested as it will not be radiated in close proximity.

Immunity test specifications for proximity magnetic fields

Test Frequency	Modulation	Immunity Test Level (A/m)
134.2 kHz	PM, 2.1 kHz	65
13.56 MHz	PM, 50 kHz	7.5

The test frequency of 30 kHz is for home healthcare environment, and this product, which is intended for use in a professional healthcare facility environment, has not been tested as it will not be radiated.

❑Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the BDS-1001 system

The customer or the user of the BDS-1001 system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BDS-1001 system as recommended below, according to the maximum output power of the communications equipment.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the BDS-1001 system			
Rated Maximum Output Power of Transmitter (W)	Separation Distance according to Frequency of Transmitter (m)		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations.
Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Chapter 1 Installation of the Unit

Precautions for Installing the Device

This section describes the environmental condition to use this device.

⚠ CAUTION

- The installation of this device should be performed by our service representative or a person who is well acquainted with this device.
- Avoid stacking multiple devices or placing anything on the device during operation.
- Do not soak or immerse the device in liquids.
- If any abnormality is found on the device, immediately turn OFF the power, and disconnect the power supply cable from the outlet. Install this device in a place where power supply cable can be easily disconnected.
- Install this device in a place where the device will not be exposed to liquids.

Operating Environment

- The following environmental conditions should be observed when using the device.
  - Surrounding Temperature: 10°C to 40°C
  - Relative Humidity: 30% to 85% (non-condensing)
  - Atmospheric Pressure: 70 kPa to 106 kPa

- This device is intended for patient monitoring in ER, ICU, ward, or treatment room.
  Do not use in MRI environment or in a home-care setting.

- The power source should fulfill the following condition.
  - Use a hospital grade outlet (3-pin grounded outlet).
  - Verify power voltage and frequency before connecting to an AC power source.
  - Use the power source that can provide adequate power to the device.
    Refer ☞Operation Manual "Specification" P14-1 for power voltage, frequency, and power consumption.

- Pay attention to install or store the device in proper location. Do not install or store in the following locations.
  - where chemicals are stored or gas may generate
  - where the device will be subject to splashing water or humidity from a nebulizer or vaporizer
  - where the device will be subject to direct sunlight
  - Unstable place with inclination, vibration, or shock

- Ensure proper ventilation to cool the device.
  - A minimum space of 5 cm is required between vents on the rear side of the device and the wall. If the device is embedded in a wall or surrounded by a wall, a minimum space of 10 cm is required on the top side.
- Install the device with the specified direction. If installed in incorrect direction, water or chemicals may enter the device and cause damage. For the recorder unit, it may also cause paper jam.

WARNING

- If the device is used under an environment not fulfilling the above condition, not only that the device cannot deliver its maximum performance, the device may be damaged and safety cannot be ensured.
  If using in an environment other than specified above, contact your nearest service representative.

CAUTION

- Equipotential Grounding
  - When connecting multiple devices, electrical potential difference may be generated between the devices. This may result in electric shock to the patient connected to these devices. Pay special attention for use in operating room, ICU, CCU, cardiac catheter laboratory, and cardiovascular X-ray room. To avoid such electrical potential difference, use the ground cable to connect each device's potential equalization terminal to the same ground terminal. This is called equipotential grounding.

System Construction

This section describes the connection procedure of this device.
The following products can be connected to the BDS-1001.

- AC Power Cable
- SD Card

Power Source and Ground Connection

This section explains about the power connection.

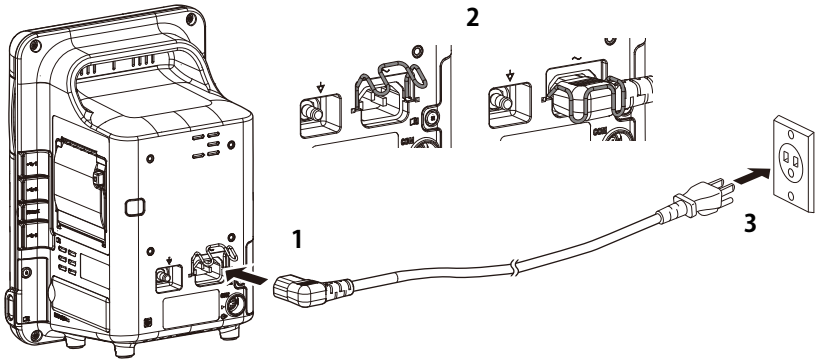
Power Connection of the Main Unit

WARNING

- Use only the supplied 3-way AC power cable. Use of other cables may result in electric shock to the patient and the operator.
- The power cable must be connected to a 100 V hospital grade outlet.
- When using multiple ME devices simultaneously, perform equipotential grounding to prevent potential difference between the devices. Even a small potential difference between the devices may result in electric shock to the patient and the operator.

1. Connect the power supply cable to the main unit of the BDS-1001.
   1. Connect the power cable (CS-34) to the rear side of the main unit of the BDS-1001.
   2. Hook the cable lock on the power supply connector to lock.

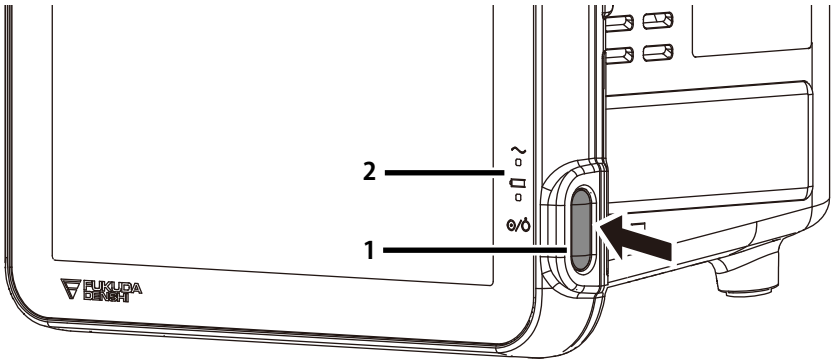
3 Connect the power cable to a hospital grade outlet (3-pin grounded outlet).



- To disconnect the power cable, unplug one end from the outlet, and the other end from the connector on the rear side of the main unit after releasing the hook of the cable lock.

2 Turn ON the power switch on the main unit.

AC power will be supplied and the power supply LED on the front side of the main unit will light.



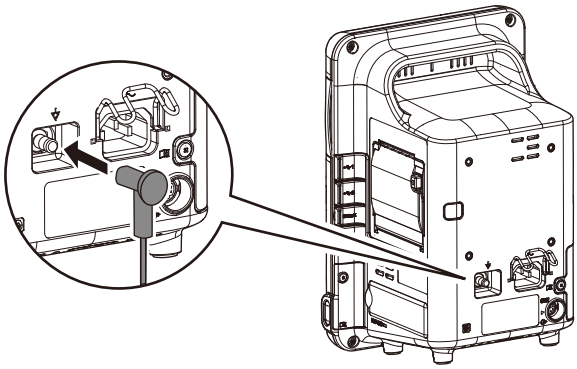
1 Power Supply LED
Green: In normal operation
Orange: Standby Mode
Light Off: During battery operation

2 Battery Charging LED
Green: Charging is complete
Orange: Charging
Light Off: During battery operation, or when battery is not installed, or when battery charging is ceased (due to temperature, etc.)

Equipotential Grounding

When connecting multiple devices, electrical potential difference may be generated between the devices. This may result in electric shock to the patient connected to these devices. Pay special attention for use in operating room, ICU, CCU, cardiac catheter laboratory, and cardiovascular X-ray room. To avoid such electrical potential difference, a ground cable is used to connect each device's potential equalization terminal to the same ground terminal. This is called equipotential grounding.

The ground cable is a connector which can be connected/disconnected manually without using tools.

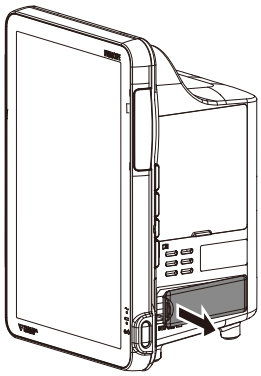


Installing the Lithium-Ion Battery Pack (BTO-008)

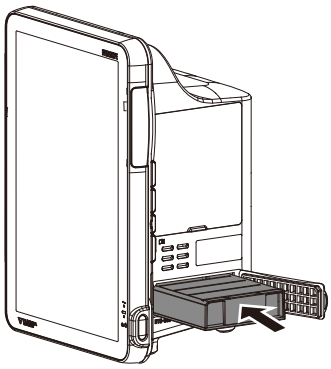
WARNING

- When replacing the battery while monitoring, make sure to supply power by connecting the power cable.

1 Remove the battery cover located on the right side.



2 Insert the BTO-008 to the main unit and close the battery cover.



NOTE

- Make sure to insert the battery in a correct direction.

Chapter 2 Network System Construction

CAUTION

- Configure the network as specified by Fukuda Denshi. If the device of different network type is connected, malfunction may occur to the whole network system.

Wireless Network

In this section, connection and setup procedure for wireless network is explained.
By constructing a wireless network using the optional telemetry unit, the data on this monitor can be transmitted to the central monitor.

WARNING

- On a wireless network, the alarm generated on the bedside monitor will be output to the network with a maximum delay of 2 seconds, and to the central monitor with a total delay of 3 seconds to 12 seconds.
- Some type of wireless combinations may generate interference with other telemetry.
- Before selecting a channel, verify it will not interfere with other channels.
- Make sure the telemetry manager of your system is aware of any changes to the telemetry channels.
- If transmitters are used in a neighboring medical facility, your facility and the neighboring facility must make agreements on the setting of the telemetry channels to prevent telemetry interference.

Example of Wireless Network Construction

CAUTION

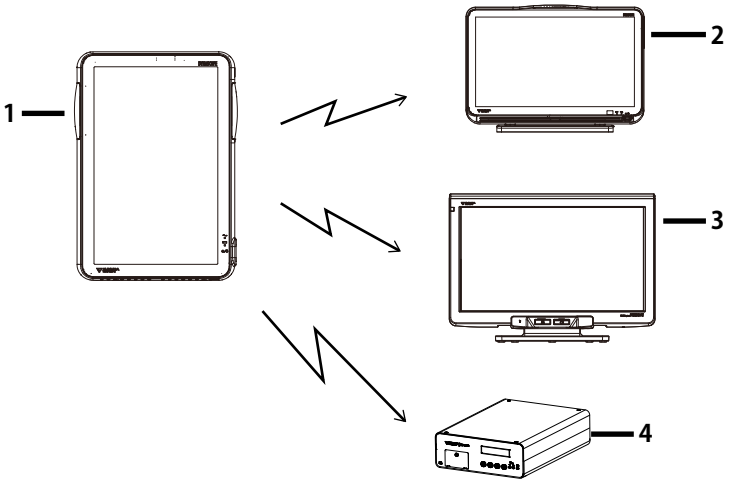
- The setup of channel ID and group ID should be performed only by our service representative. Users should not perform this procedure as malfunction may occur.

1 Bedside Monitor: BDS-1001 system

2 Central Monitor: DS-1800 System

3 Central Monitor: DS-8900 System

4 Central Telemetry Receiver: LW-1000 System



Channel ID and Telemetry Wave Setup

In this section, channel ID and telemetry wave setup when using the telemetry is explained.
Once the transmitting channel ID and group ID are set, these will be retained even after the main power is turned OFF.

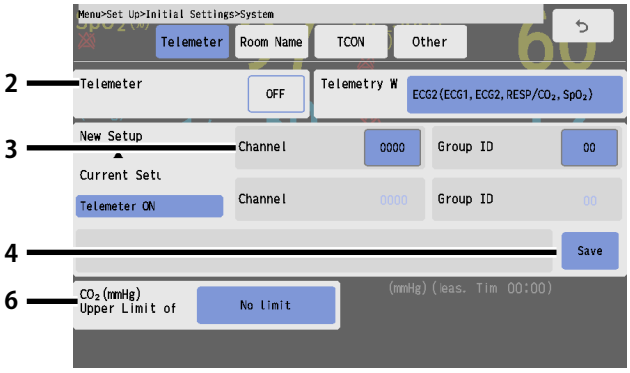
WARNING

- A password can be set to restrict access to the channel ID setup menu. Only the telemetry channel administrator should change the channel ID.
- Some type of wireless combinations may generate interference with other telemetry.
- Before selecting the wireless channel, verify it does not cause interference.
- Inform the supervisor of the use of telemetry channels to avoid interference with other telemetry.
- If transmitters are used in a neighboring medical facility, your facility and the neighboring facility must make agreements on the setting of the telemetry channels to prevent telemetry interference.

NOTE

- To change the setting, enter the password.
  (☞"Administrator Setup" P5-1)

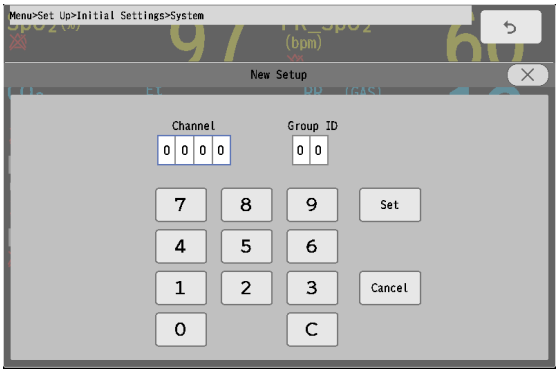
1 Press [Menu > Menu List > Setup > Initial Settings > System > Telemeter] keys to display the telemeter setup menu.



2 Perform setup for the telemetry transmission.

- [ON]: Telemetry transmission will be performed.
- [OFF]: Telemetry transmission will not be performed. In this case, channel ID will not be displayed on the home display.

3 Set the channel ID and group ID.

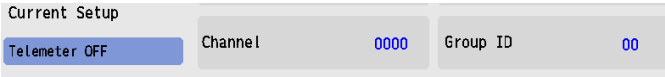


1. Press the key for "Channel" or "Group ID", and display the numeric keypad.
2. Enter the 4-digit medical telemetry channel ID, and the group ID in the range of 00 to 63.
3. Press the [Set] key.

4 Press the [Save] key to save the channel ID and group ID.

- The channel ID and group ID will be saved.
- <Complete> will be displayed.
- The set channel ID will be displayed on the upper left of the home display.
- If an error is found on the password, channel ID, or group ID, <Invalid Data> will be displayed. (Ex. The entered channel ID or group ID is outside the allowable range.)
  Enter the ID within the range and press the [Save] key.

5 Check the stored channel ID and group ID.



NOTE

- If the numeric data is displayed as "xxx" (out of measurement range) on this monitor, maximum or minimum value of measurable range will be transmitted to the central monitor.

	Value Outside the Measurement Range	Central Monitor Display
Heart Rate	301 bpm or above	Calculated on the central monitor based on ECG waveform.
Respiration Rate	151 bpm or above	150 bpm In case of impedance respiration, it is calculated on the central monitor.
PR (Masimo Unit)	240 bpm or above 25 bpm or below	239 bpm 26 bpm
PR (Medtronic Unit)	251 bpm or above	254 bpm

REFERENCE

- The waveform not displayed on the home display can not be transmitted.

6 Set the "CO_2 (mmHg) Upper Limit of Transmission".

CAUTION

- If the measurement unit of CO_2 concentration is mmHg and [99 mmHg] is selected for "CO2(mmHg) Upper Limit of Transmission" under [Initial Settings>System>Telemeter], the CO2 value of 100 mmHg or above will be transmitted as 99 mmHg.
- When using the Medtronic unit, the PR value of 255 bpm or above will be transmitted to the central monitor as 254 bpm.

REFERENCE

- The waveform not displayed on the home display can not be transmitted.

Chapter 3 Using the External Media

Formatting the Full Disclosure Waveform Card

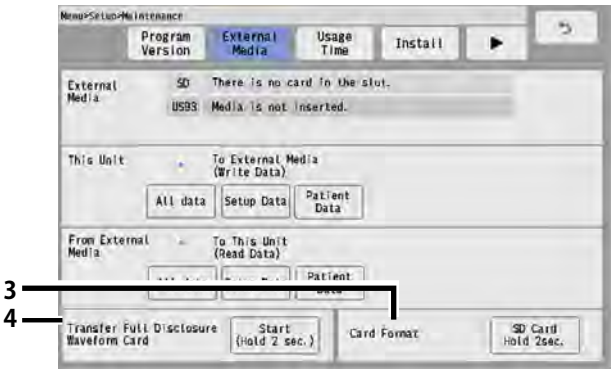
In this section, formatting of SD Card to be used for storing the full disclosure waveform is explained.

By formatting the specified SD Card for full disclosure waveform, the card can be used for storing the full disclosure waveform data. By inserting the formatted SD Card to the SD Card slot, storing of the full disclosure waveform data will automatically start, and reviewing of the full disclosure waveform will become possible.

⚠ CAUTION

- The full disclosure waveform card formatted on other bedside monitors and central monitors cannot be used on this device.
- The full disclosure waveform card formatted on this device cannot be used on other bedside monitors and central monitors.
- Make sure that the full disclosure waveform card is inserted in the SD Card slot when formatting.
- While saving the data to the full disclosure waveform card, avoid removing/inserting the SD Card.
  Remove or insert the full disclosure waveform card while in standby or while the full disclosure waveform card is prepared for data transfer (while "Remove the SD card" is displayed).
- It will take about 5 minutes to format the full disclosure waveform card. During the format process, do not turn OFF the power, enter into standby mode, or remove the card. It may damage the card.

1 Press [Menu > Menu List > Setup > Maintenance > Tabular Trend > External Media].



2 Format the full disclosure waveform card.

1. Make sure that the SD Card is inserted, and "SD" on "External Media" is unformatted or is for the full disclosure waveform data.
2. Press the [SD Card HOLD 2sec.] key on "Card Format" for 2 seconds.
3. Wait until the format completes. The popup "SD card slot: Full Disc. Wave Format in progress." will be displayed during the format.
   It will take about 5 minutes to format. Do not remove the SD Card or turn off the power during the format process. It may cause the SD Card to malfunction.
4. When the format completes, the "Full Disc. Wave Format in progress." will disappear and the name of the full disclosure waveform card will appear in the "SD" area.

Data Backup/Copy Using a USB Memory

This section explains about the backup and copy procedure of the setup data using a USB memory.

Setting all the monitors in the same ward to the same alarm settings and display configuration may take large amount of time. This process can be simplified by performing the setup on one monitor, and copying the data to other monitors using a USB memory.

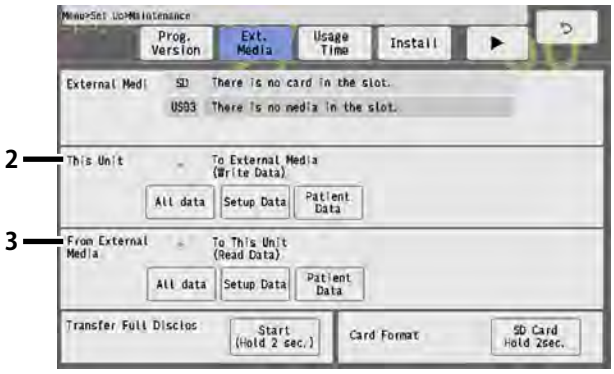
CAUTION

- Make sure to use the specified USB memory.
- To backup/copy the data, use a FAT32 formatted USB memory.

REFERENCE

- For details of the data which can be backed up, refer to "Data that can be Backed Up/ Copied".

1 Press [Menu > Menu List > Setup > Maintenance > External Media].



2 Write the data to the USB memory. (Backup)

1. Make sure that the USB memory is inserted to USB3 connector.
2. Press [Setup Data] on "This Unit → To External Media (Write Data)"
   On the displayed window, press the [Start] key.
   However, full disclosure waveform data cannot be saved.

3 Read the data from the USB memory. (Copy)

1. Make sure that the USB memory is inserted to USB3 connector.
2. Press [Setup Data] on "From External Media→To This Unit (Read Data)" .
   On the displayed window, press the [Start] key.
   However, full disclosure waveform data cannot be read.

CAUTION

- During access to the USB memory, all keys will become inoperative until the process is complete.
- Make sure to power cycle the system after the setup data is read from the USB memory. By power cycling the system, the read data will become effective.

NOTE

- If read/write is incorrectly selected, the data on the USB memory may be unintentionally overwritten with the data on the patient monitor. Make sure to check that the selection is correct before pressing [Yes].
- The display will return to the home display when the reading process is completed.
- When the backup/copy process is complete, and the data is no longer necessary, format the card to erase the data.

❑Data that can be Backed Up/Copied

The setup data such as monitoring condition, alarm setting, and patient data such as graphic trend and tabular trend can be backed up/copied.

- Backup: Select [All Data], [Patient Data], or [Setup Data] on "This Unit→To External Media (Write Data)".

  [All Data]: Setup data and patient data are both backed up.

  [Setup Data]: Setup data is backed up.

  [Patient Data]: Patient data is backed up.
- Copy: Select [All Data], [Patient Data], or [Setup Data] on "From External Media→To This Unit (Read Data)"
  .

  [All Data]: Setup data and patient data are both backed up.

  [Setup Data]: Setup data is backed up.

  [Patient Data]: Patient data is backed up.

NOTE

- On the USB memory, full disclosure waveform data cannot be saved.

Setup Data

Data Item		Description
Parameter Setup		Stores the monitoring condition (size, lead, etc.) for all the monitoring parameters.
Alarm Setup		Stores the alarm threshold level.
Setup Data	Basic Setup	Stores the current setup.
	Alarm Setup	Stores the alarm ON/OFF and alarm limit settings.
	Parameter Setup	Stores the monitoring condition (size, lead, etc.) for the parameter.
	Data Review/Waveform Review/ Calculation	Stores the settings for each review data.
	Initial Settings	Stores the current setup.

Patient Data

Data Item	Description
Patient Information	Stores the patient information such as name, ID, age, sex, pacemaker usage, patient classification.
Trend Data	Stores 24 hours of graphic trend data. Not restored when using a full disclosure waveform card.
Tabular Trend Data	Stores 24 hours of tabular trend data. Not restored when using a full disclosure waveform card.
Recall	Stores 300 recall data. Not restored when using a full disclosure waveform card.

The following items will not be backed up/copied.

- Setup Data
  - Time/Date
  - Telemetry setup
    (The settings are saved in the connected telemetry transmitter module.)

Chapter 4 Connection to the External Devices

Ventilator Alarm Input

Ventilator can be connected to the BDS-1001 system using the Status II connector.
By connecting a ventilator, ventilator alarm monitoring can be centralized on the patient monitor.
Also, ventilator alarm can be notified to the central monitor via wireless network.
This section describes the procedure to connect the BDS-1001 system and ventilator.

Ventilator	Connection Cable
	For Status II Connector
Servo Ventilator 300/300A	CJ-401RI-70SV3 (x1)
Servo Ventilator SERVO-i/SERVO-s/SERVO-U/SERVO-n/ SERVO-air	CJ-402RI-70SVi (x1)
PURITAN-BENNETT Ventilator 740/760	CJ-403RI-70PB (x1)
PURITAN-BENNETT Ventilator 840	CJ-403RI-70PB (x1)
Drager Medical Ventilator Evita 2dura/Evita 4/Evita XL	CJ-402RI-70SVi (x1)

When connecting a ventilator, check the corresponding software version of the ventilator.

Ventilator	Corresponding Software Version
Servo Ventilator 300/300A	Not specified
Servo Ventilator SERVO-i	v1.5/v2.0/v3.0
Servo Ventilator SERVO-s	v2.0/v3.0
Servo Ventilator SERVO-U/SERVO-n/SERVO-air	v1.0
PB740	M
PB760	H
PB840	K
Evita 2dura	04.14
Evita 4	04.14
Evita XL	05.10

WARNING

- If the BDS-1001 system does not generate an alarm even though the ventilator is generating an alarm, or if any other malfunction occurs, immediately check the ventilator, this device, cable, and replace the cable if necessary.
- The alarm generation on this system is not guaranteed if the alarm other than the following generates at the ventilator.
  - SV-300:
    Airway pressure upper limit alarm, high continuous pressure alarm, O2 concentration lower limit alarm, expiratory minute volume upper/lower limit alarm, apnea alarm, gas supply alarm, air supply alarm, O2 supply alarm, battery alarm, limited battery alarm, no battery alarm, overrange alarm
  - SERVO-i:
    Airway pressure upper limit alarm, high continuous pressure alarm, O2 concentration

lower limit alarm, expiratory minute volume upper/lower limit alarm, apnea alarm, gas supply (air supply) alarm, O2 supply alarm, battery alarm, limited battery alarm, no battery alarm, overrange alarm, expiratory cassette disconnected alarm, backup ventilation alarm, regulation pressure limited alarm, respiratory rate alarm, PEEP low alarm, $EtCO_2$ upper limit alarm, $EtCO_2$ lower limit alarm

- SERVO-s:
  airway pressure upper limit alarm, high continuous pressure alarm, O2 concentration lower limit alarm, expiratory minute volume upper/lower limit alarm, apnea alarm, gas supply alarm, air supply alarm, O2 supply alarm, backup ventilation alarm, respiratory rate alarm, PEEP low alarm
- PB740/PB760/P 840:
  The PB740/PB760/PB840 acquires alarm information from the nurse call port. The ventilator alarm that cannot be acquired from the nurse call port is not guaranteed. For corresponding alarm, refer to the service representative of the ventilator manufacturer.

- This device is not compatible to the following alarms generated on the Evita 2 dura/Evita 4/ Evita XL.
  - O_2 monitoring disabled alarm, CO_2 alarm disabled alarm, Oximeter alarm disabled alarm, Neo. volume measurement inoperable alarm, Minute volume alarm disabled alarm, Minute volume alarm low off alarm, Tidal volume alarm high off alarm, Apnea alarm off alarm, Nebulizer active alarm
- When the Evita 2 dura/Evita 4/Evita XL is connected, there is a communication delay of 3 seconds between the BDS-1001 system and the Evita ventilator. Therefore, if the alarm generated at the ventilator is resolved within 3 seconds, the ventilator alarm may not be generated at the BDS-1001 system.

⚠ CAUTION

- The ventilator operation should be performed by well-trained and authorized personnel.
- When connecting the BDS-1001 system and the ventilator, use only the specified connection cable.
- Make sure that the ventilator is connected to the specified connector on the BDS-1001 system.
- When connecting the cable, make sure that the main power of this system and the ventilator is OFF.

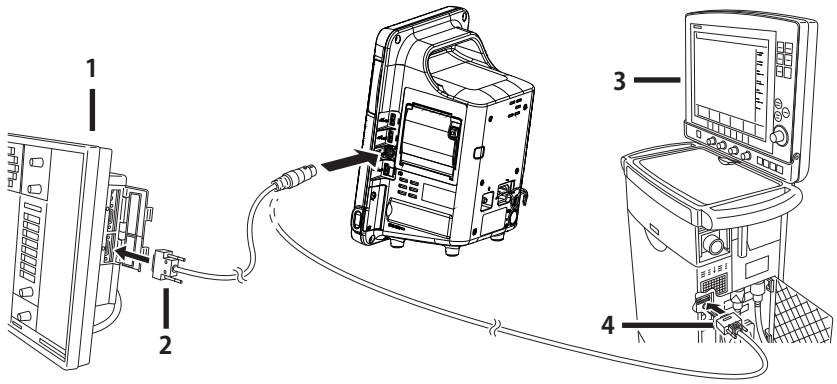
Connecting the Ventilator

⚠ CAUTION

- Only one ventilator can be connected to each device. Do not connect more than one ventilators.

❑In Case of SV-300, SERVO-i/s

1 Connect the SV-300 or SERVO-i/s to the Status II connector on the BDS-1001.



1 SV-300

2 CJ-401RI-70SV3

3 SERVO-i/ s

4 CJ-402RI-70SVi

❑In Case of SERVO-U/SERVO-n/SERVO-air

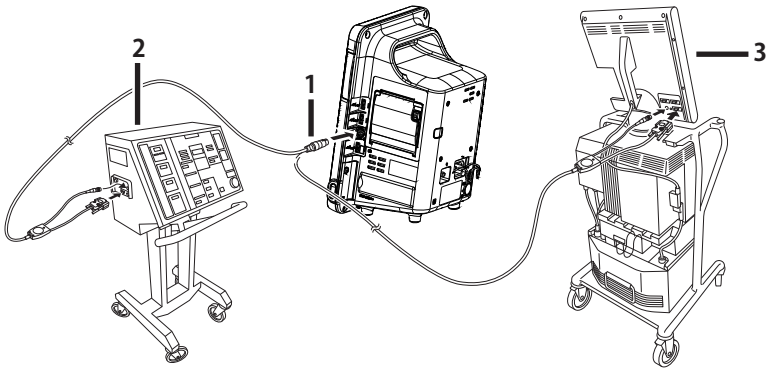
1 Connect the SERVO-U, SERVO-n, SERVO-air to the Status II connectors on the BDS-1001.

❑In Case of PB740/760/840

⚠ CAUTION

- When connecting the PURITAN-BENNETT ventilator, follow the precautions below. The serial port (RS-232C) of the ventilator should be set as follows. Refer to the service representative of the ventilator manufacturer.
  Baud Rate: 9600 bps
  Data Bit: 8bit
  Parity Bit: None
  (Stop Bit): (1bit)
- This system detects the "ventilator alarm" when the nurse call port on the ventilator outputs the alarm signal.
  For details of ventilator setup and alarm signal output condition from the nurse call port, refer to the service representative of the ventilator manufacturer.

1 Connect the PB740/760/840 to Status II connector on the BDS-1001.



1 CJ-403RI-70PB

2 PB740/760

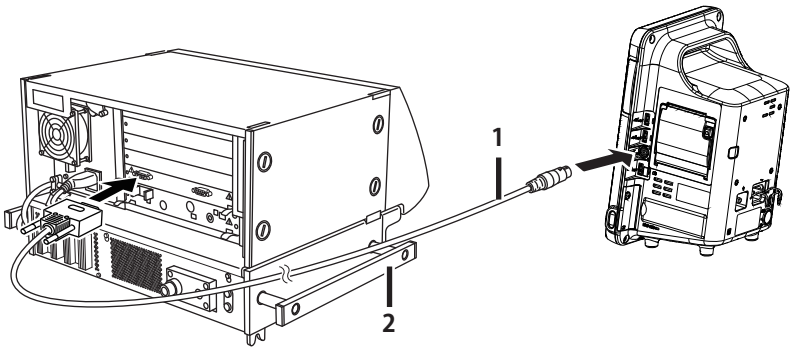
3 PB840

❑In Case of Evita

⚠ CAUTION

- When connecting the Evita 2 dura/Evita 4/Evita XL ventilator, the serial port (RS-232C) setup of the ventilator should be as follows. Refer to the service representative of the ventilator manufacturer.
- In Case of Evita 2 dura/Evita 4/Evita XL
  Protocol: Medibus
  Baud Rate: 19200 bps
  Data Bit: 8bit
  Parity Bit: Even
  Stop Bit: 1bit

1 Connect the Evita 2 dura/Evita 4/Evita XL to Status II connector on the BDS-1001.



1 CJ-402RI-70SVi

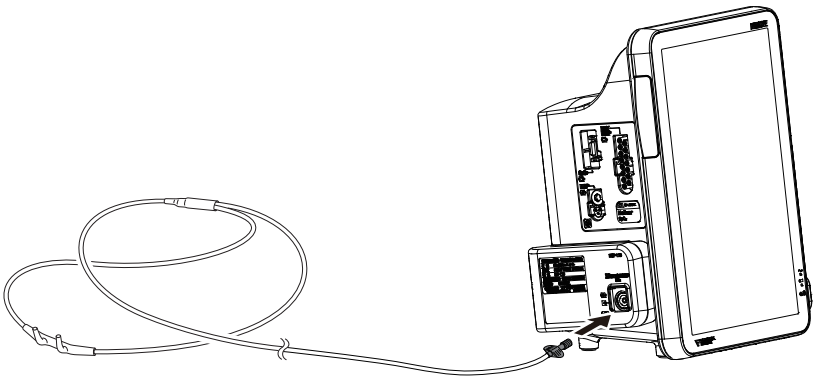
2 Evita 2dura

CO_2 Concentration Data Input

By connecting the CO_2 gas unit (HCP-110), waveform and numeric data of CO_2 concentration can be monitored on the device.

Connecting the Sampling Line (Medtronic)

By connecting the FilterLine CO_2 sampling line series using the CO_2 Gas Unit HCP-110, CO_2 concentration measured by intubation or non-intubation can be monitored.



Sidestream Method
(Incorporates Microstream technology developed by Covidien)

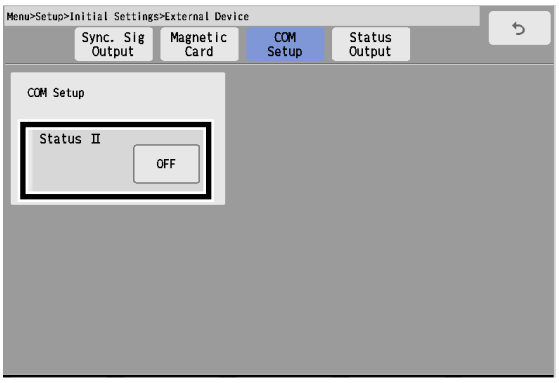
Setup for the External Device Connection

This section explains about the external device connection setup.

External Device Setup

1 Press [Menu > Menu List > Setup > Initial Settings > External Device > COM Setup].

2 Select the connecting device from the "Status II" display.



Selectable External Device for Each Port

Port	Selectable External Device
Status II	SV-300, SERVO i/s, SERVO-U/n/air, PB, Evita, Velia, Ultra, Astral, PC Comm, OFF

NOTE

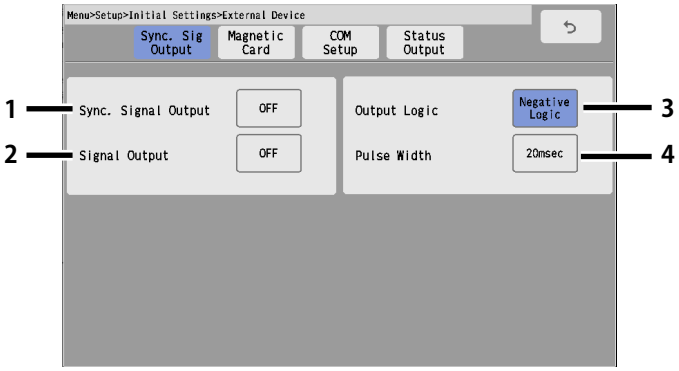
- When connecting the cable, make sure that the power of this system and the external device is turned OFF.
- When the external device setup is changed, make sure that this system and the external device is properly communicating.
- If communication with the external device is already established through the corresponding port, it is necessary to disconnect the communication in order to change the selection on this menu.

Synchronized Signal Output

This device is capable to output the synchronized signal (HR, RR) from the Status II connector.

1 Press [Menu > Menu List > Setup > Initial Settings > External Device > Sync. Sig Output].

2 Set the following items for the synchronized signal.



1 "Sync. Signal Output"

- [ON]: Synchronized signal will be output.
- [OFF]: Synchronized signal will not be output.

2 "Signal Output"

- [HR]: HR synchronized signal will be output.
- [RR]: Synchronized signal based on RR source (impedance) will be output.

3 "Output Logic"

- [Positive Logic]: Positive synchronized signal will be output.
- [Negative Logic]: Negative synchronized signal will be output.

4 "Pulse Width"

- [20 msec]: Synchronized signal will be output with 20 msec.
- [60 msec]: Synchronized signal will be output with 60 msec.
- [100 msec]: Synchronized signal will be output with 100 msec.

NOTE

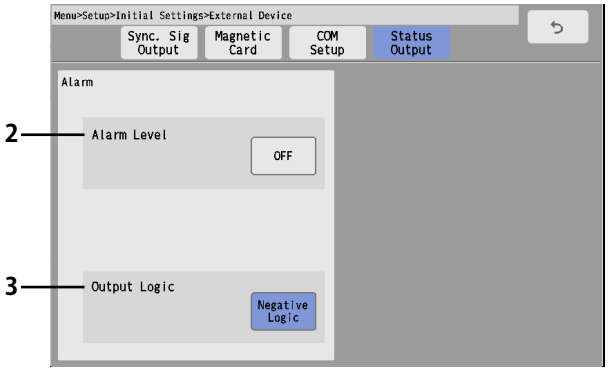
- The QRS synchronized signal is a delay output. (35 msec or less during Monitor/ Diagnosis Mode)
  The delay time varies depending on the filter mode setting and input waveform type.
- When the QRS synchronized signal is input to the external device, make sure that the delay time is within the acceptable range of the connected device.

Status Output Setup

The alarm can be output from the status input/output connector or I/O connector (optional) on the device.

1 Press [Menu > Menu List > Setup > Initial Settings > External Device > Status Output].

- The "Status Output" setup menu will be displayed.



2 Select the alarm to output.

- [Level H]: Level H alarm will be output.
- [Level H,M]: Level H, M alarm will be output.
- [Level H,M,L]: Level H, M, L alarm will be output.
- [APNEA]: Apnea alarm will be output.
- [OFF]: Alarm will not be output.

3 Set the Output Logic.

- [Positive Logic]: Positive synchronized signal will be output.
- [Negative Logic]: Negative synchronized signal will be output.
- [Pulse]: A square wave of 440 ms cycle will be output.

NOTE

- Refer to "Status I/O Signal (Status II Connector)" P6-8 for connector pin assignments of the alarm output.
- The device status alarm will be output as level L. To output the device status alarm, select [Level H,M,L].

Using the Magnetic Card Reader

This section explains the connection and setup procedure for the magnetic card reader.
By using the magnetic card reader, patient information can be automatically entered from the magnetic card at patient admittance.
(☞Operation Manual "Entering Patient Information from the Magnetic Card" P5-3)

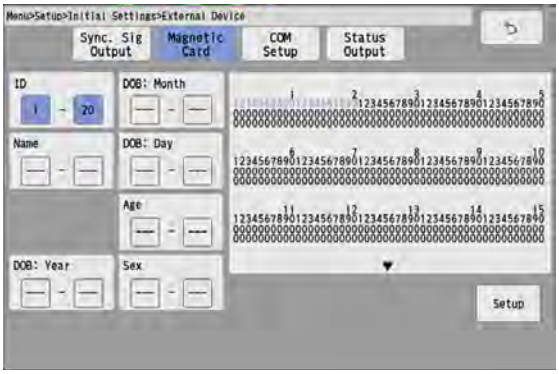
Connecting the Magnetic Card Reader

1 Connect the cable of the magnetic card reader to the USB connector.

Magnetic Card Reader Setup

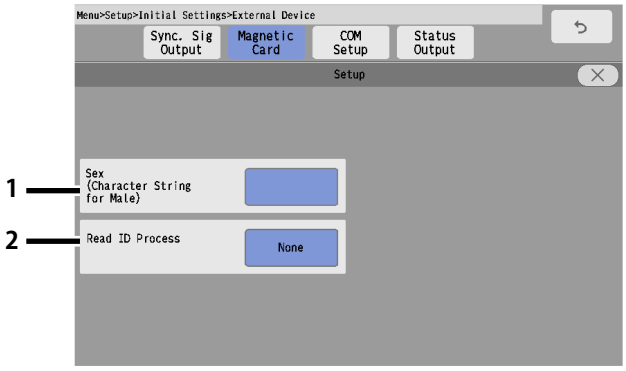
The initial settings for the magnetic card reader can be performed.

1 Press [Menu > Menu List > Setup > Initial Settings > External Device > Magnetic Card].



Since the data formats of magnetic card vary for each institution, it is necessary to set the digit location of each information.
For the items that needs to be read, perform the setup following the procedure. This setup is not necessary for the items not required to be read.

2 Press the [Setup] key to preconfigure the magnetic card reader.
The character strings to indicate birth date, sex, etc., can be set.



1. Press the key for "Sex" to display "Character String for Male" window. Enter the character string for male (max. 3 characters) used on the magnetic card.
2. Set the "Read ID Process".

- [None]: The whole patient ID will be read as the patient ID.
- [Numeric]: Only the numerics will be read as the patient ID.
- [Alphanumeric]: The numerics and alphabets will be read as the patient ID.

3 Analyze the starting and ending digit of the data (patient ID, etc.) read from a magnetic card.

NOTE

- The procedure to analyze the data read from the magnetic card is explained below.
- If not analyzing the data on the magnetic card, proceed to next step.

REFERENCE

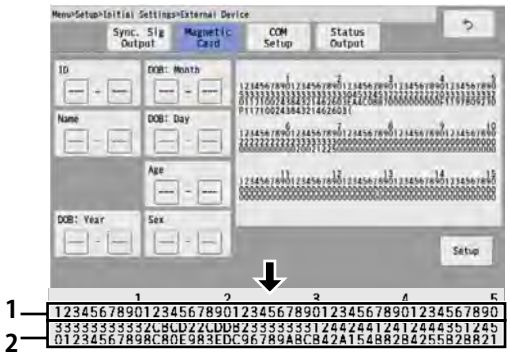
- On the "Magnetic Card Reader" setup menu, starting and ending digit of each data such as [ID], [DOB: Year] can be set.
  - From: Starting digit number of the data to be read from the magnetic card
  - To: Ending digit number of the data to be read from the magnetic card.

REFERENCE

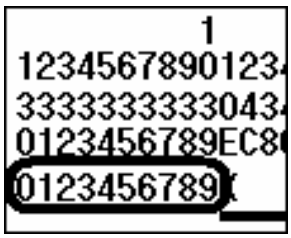
- The analyzing procedure is explained using the example of patient data below.
  Patient ID: 0123456789
  Patient Name: FUKUDA DENSHI
  Date of Birth: Jan. 1, 1980
  Sex: Male

1 While the first page of the "Magnetic Card Reader" setup menu is displayed, scan the magnetic card.

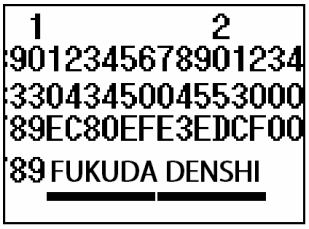
- At the first and second row, the data read from the card will be displayed in hexadecimal. At the third row, the characters converted from the data will be displayed.



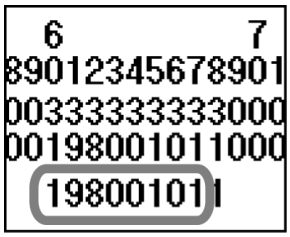
2 From the displayed result, specify the data position.



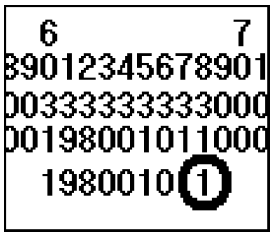
The patient ID, "0123456789" is displayed with the 1st to 10th characters.



The name, "(Fukuda) (Denshi)", is displayed with the 11th to 22nd characters.
"( )" should be also included in the digit range.



The date of birth, "19800101" is displayed at 27th to 34th digit.



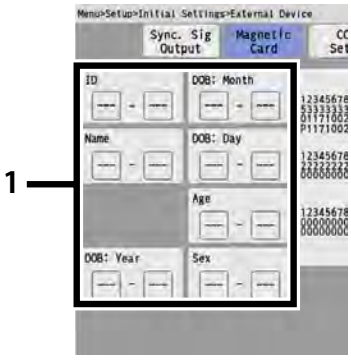
"1" which is displayed at the 68th digit can be estimated as the character string for male.
It will be more definite if compared with the data of female.

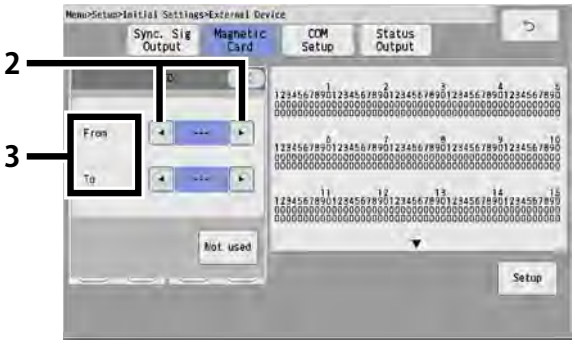
3 The setup will be performed with the analyzed result.

NOTE

- After the setup, check if the data of other patient's card can be correctly read.

4 Enter the starting digit and ending digit for each data.





1 Select the item to enter from the list displayed at left.

2 Enter the starting digit or ending digit in the range of 1 to 255 using the left or right button.

3 Press the [1] key for "From" or the [20] key for "To".

REFERENCE

- If the data is not present on the magnetic card, enter [Not Used] for both starting and ending digit.

4 Repeat step 1 to 3.

PC Communication

This section explains about the PC communication setup procedure.
By using the PC communication function, vital data measured on the bedside monitor can be transmitted to PC.

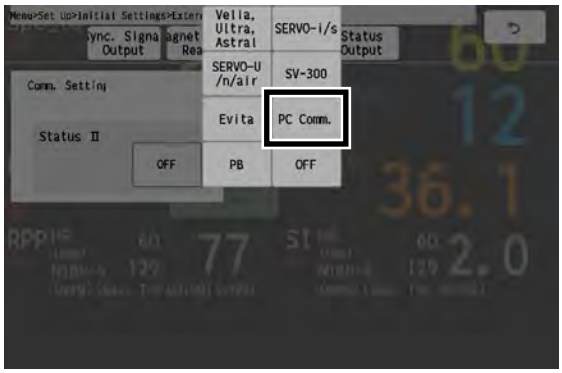
Connection with the System

1 Connect the accessory cable to the Status II connector on the device.

External Device Setup

To transmit the data to PC, "External Device" setup is required.

1 Press [Menu > Menu List > Setup > Initial Settings > External Device > COM Setup].



2 Select "PC Comm." from the "Status II" display.

NOTE

- If the PC communication is disconnected, <Check System Conn.> will be displayed.

Chapter 5 Initial Settings

Initial Settings

This section explains about the "Initial Settings" menu.
Under "Initial Settings" menu, there are 7 setup categories which are Alarm, Measurement, User I/F, External Device, System, User Mode Registration, and Administrator Setup.

Description for Each Category

Category	Subcategory	Description
Alarm	-	Alarm-related settings, alarm indicator settings, etc.
Measurement	Unit	Measurement unit settings for CO_2, BP, TEMP, ST, Height/Weight
	Other	Measurement related setup
User I/F	Display/Print	Display and print settings such as date format, etc.
	Power ON/ Discharge	Settings such as backup status at "Power ON" and "Discharge", etc.
	Key Mask	Key mask settings for unnecessary keys
	Operation	Auto Hide Window
	Quick Menu	Settings for quick menu items and colors
External Device Connection	Synchronized Signal Output	Settings for the synchronized signal output of HR or RR
	Magnetic Card Reader	Settings for magnetic card reader
	Communication Setup	Settings for the status II connector
	Status Output	Alarm Output Setup
System	Telemeter	Settings for the telemetry channel, transmitting waveform, etc.
	Bed Name	Settings for the bed name
	Other	Settings for AC filter, search patient ID
User Mode Registration	-	Registration of 3 types of monitor modes and 3 types of display modes
Administrator Setup	Key Lock	Settings of key lock level for display and setting
	Password Setup	Settings for password and administrator

Administrator Setup

This section explains about the "Administrator Setup" menu.
The "Administrator Setup" is composed of [Key Lock] and [Password Setup].

NOTE

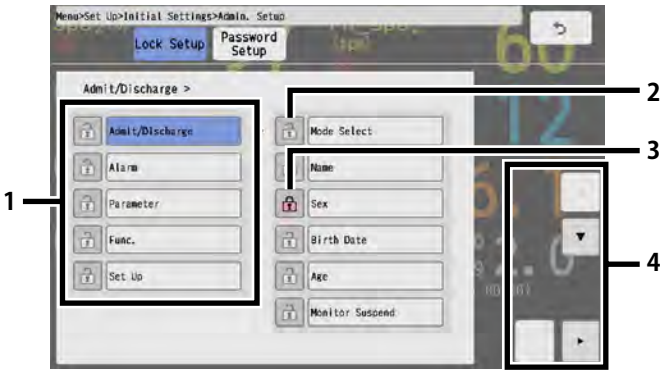
- To display the administrator setup menu, a password is required. There are 3 levels of password with different operation authorization. With higher level password, the lower level settings can be changed.
- For details of the password, refer to your nearest service representative.

Key Lock

1 Press [Menu > Menu List > Setup > Initial Settings > Admin. Setup > Key Lock].

2 Enter the password.

▸ The "Key Lock" menu will be displayed.



1 The setup items will be displayed.

2 This indicates unlocked item. It is displayed in white.

3 This indicates locked item. To change the setting, an authorized password is required.
There are 3 levels of password which are distinguished by the color of the icon.
The level is in the order of red>yellow>green. For example, the following operation is possible.
Red: Manager > Yellow: Administrator > Green: User

4 The page will switch.

REFERENCE

- Maximum of 3 types of password can be set for the administrator which can individually lock the setting with each password.
- The items that can be protected by password will be displayed in a tree format.

Password Setup

This section explains how to change the password and how to enter the administrator name.

⚠ CAUTION

- Do not forget the password.
- The password should be strictly controlled.

NOTE

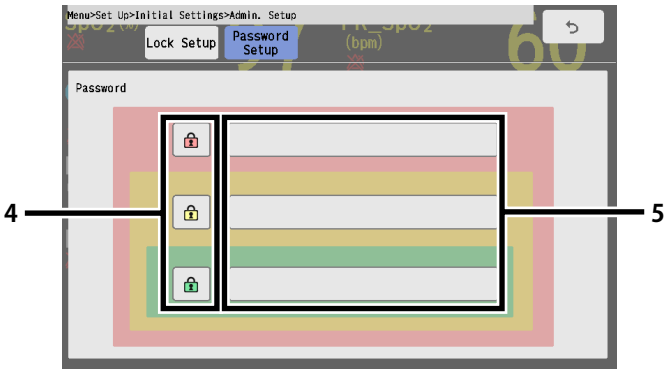
- The default passwords are set as follows.
  Red: 11111111
  Yellow: 22222222
  Green: 33333333
- Before using the device, make sure to change the password.
- For details of the password, refer to your nearest service representative.

1 Press [Menu > Menu List > Setup > Initial Settings > Admin. Setup > Password Setup].

2 Enter the password.

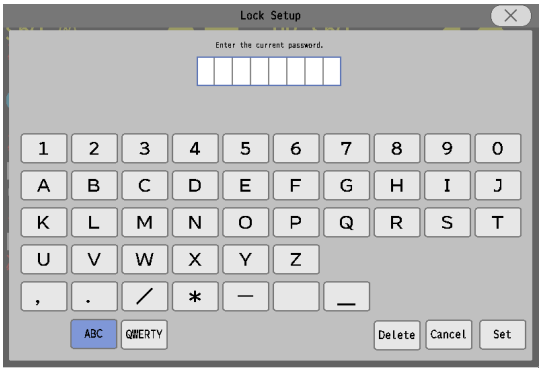
3 Press the [Password Setup] key.

▸ The password setup window will be displayed.



4 Enter the password.

Depending on the password, the operation authorization will differ. With higher level password, the lower level settings can be changed.



1 By pressing the key for the level to change the password, "Edit Password" window will be displayed.

2 Enter the current password using the keyboard.

3 Press [Set].

4 Enter the new password using the keyboard. Maximum of 8 digits can be set for the password.

NOTE

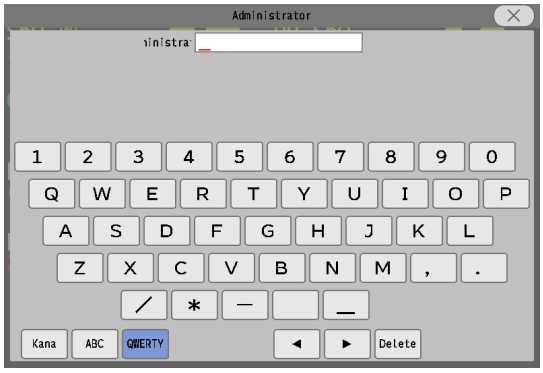
- As the authorization level is distinguished by the password, the password cannot be duplicated.

5 For confirmation, enter the new password again.
There are 3 levels of password which are distinguished by the color of the icon.
The level is in the order of red>yellow>green and are distinguished by the entered password to display the "Admin. Setup" menu.

5 Set the administrator name.

Depending on the password, the operation authorization will differ. With higher level password, the lower level

settings can be changed.



1 Press the key for the level to change the administrator name.

- The "Administrator" window will be displayed.

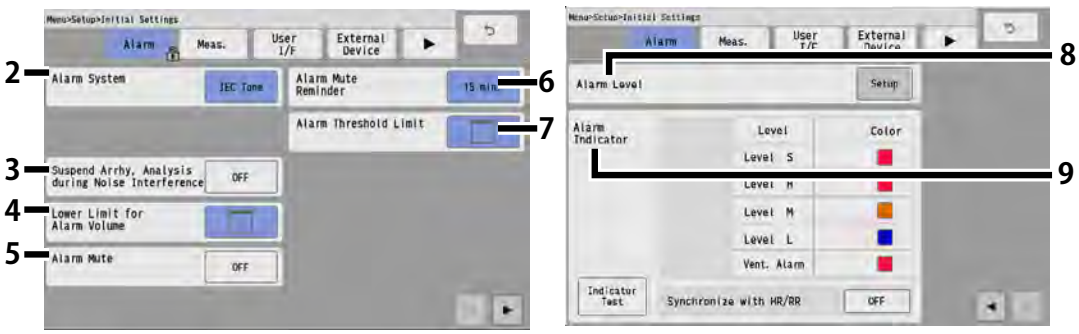
2 Enter the administrator name using the alphanumeric keys. Maximum of 8 characters can be set for the administrator name.

Alarm Related Setup

On the alarm setup menu, alarm related setup can be performed.

1 Press [Menu > Menu List > Setup > Initial Settings > Alarm].

- The alarm setup menu will be displayed.



2 Set the "Alarm System".

WARNING

- Changing the setting for "Alarm System" (Initial Settings > Alarm) will also change the alarm volume and tone setting. Make sure to check the volume and tone when the setting is changed.

- [Fukuda Tone]: The alarm tone common to DS-7000 series bedside monitor will be set.
- [IEC Tone]: The alarm tone complied to the IEC standard will be set.

3 Set the "Suspend Arrhy. Analysis during Noise Interference" .

- [ON]: Arrhythmia analysis will be suspended for fixed duration (5 sec.) when a noise is continuously interfering.

- [OFF]: Arrhythmia analysis will not be suspended even when a noise is continuously interfering.

CAUTION

- If "Suspend Arrhy. Analysis during Noise Interference" is set to [ON], the <Cannot analyze> alarm will generate when analysis is suspended for 30 seconds and longer.

4 Set the "Lower Limit for Alarm Volume".

Set the lower limit of alarm volume for "Vital Alarm", "Ventilator Alarm", "Status Alarm".

WARNING

- Changing the setting for "Alarm System" (Initial Settings > Alarm) will also change the alarm volume and tone setting. The "Lower Limit for Alarm Volume" setting may also change with this setting. Make sure to check the volume and tone when the setting is changed.

- The lower limit of adjustable alarm volume range on the "Tone/Volume" setup menu will be set. It is limited in the order of Urgent > Caution > Status.
- [Test]: The test sound will be generated with the set volume.

5 Set "Alarm Mute".

- [ON]: The alarm mute function will turn ON.
- [OFF]: The alarm mute function will turn OFF.

WARNING

- During the alarm mute duration, alarm sound will not generate. Pay attention not to miss any important alarm by simultaneously monitoring the patient on central monitor or other monitors.

6 Set "Alarm Mute Reminder".

- A reminder message/sound can be displayed/generated after preprogrammed duration to remind the alarm mute condition.
- Select from [15 min.] / [30 min.] / [60 min.] / [120 min.].
- [OFF]: A reminder message/sound will not be displayed/generated.

7 Set the "Alarm Threshold Limit".

- The alarm threshold range for each parameter can be set.
- For the parameter which is set to [Enable], the alarm threshold level outside the set range cannot be set.

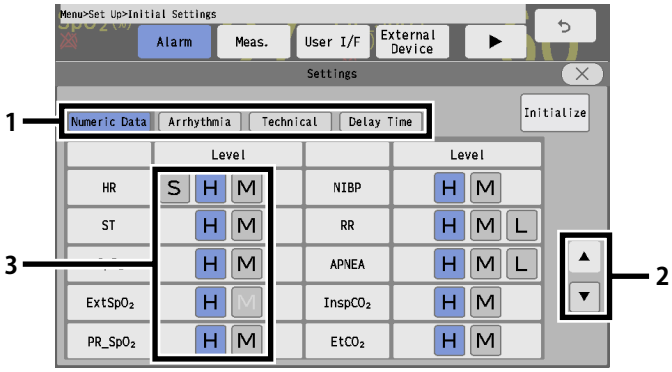
NOTE

- If the alarm threshold set on the central monitor exceeds the threshold limit set on this device, the alarm threshold set on the central monitor will be applied. Make sure to check the alarm setting on the device as the alarm threshold limit status will be changed to limit deactivating mode.
- If the alarm threshold of "At Discharge" settings exceeds the alarm threshold limit, the exceeded alarm threshold will be applied. Since the alarm threshold limit status will be changed to limit deactivating mode, make sure to check the alarm setting at patient admittance/discharge.
- If the monitor mode is changed, and the alarm threshold of the current monitor mode

exceeds the threshold limit, this alarm setting will be applied. Make sure to check the alarm setting on the device as the alarm threshold limit status will be changed to limit deactivating mode.

- Depending on the model type and software version of the network administrator connected with a wired network, the alarm threshold limit setting on the network administrator will be applied to this device.

8 Set the "Alarm Level".



The alarm level for numeric data alarm, arrhythmia alarm, technical alarm can be set. The alarm level can be selected from S, H, M, L, OFF according to the priority.
("S" is the highest priority alarm.)
Press the [Setup] key to display the alarm level setup window.

1. Select [Numeric Data]/[Arrhythmia]/[Technical] to set the alarm level.
2. Press [▲]/[▼] to switch the page.
3. Select the alarm level from [S] / [H] / [M] / [L] / [OFF] for each parameter.

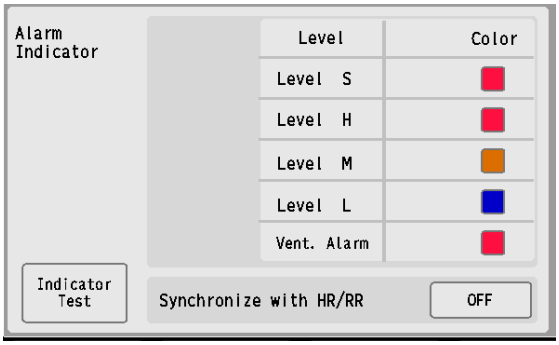
NOTE

- Only the displayed alarm level can be selected.
- Press the [Initialize] key to initialize the alarm level setting.

⚠ CAUTION

- If [OFF] is set for the alarm level, alarm will not be generated.

9 Set the alarm indicator operation.



1. "Synchronize with HR/RR"
   - [Sync. to HR]: The alarm indicator will be lit in green synchronizing to HR.
   - [Sync. to Resp.]: The alarm indicators will be lit in green synchronizing to RR.

▶ [OFF]: The alarm indicator will not light.

2 Press [Indicator Test] to test the alarm indicator operation.

NOTE

- If asystole alarm generates while [Sync. to HR] is selected, the green LED of the alarm indicator will remain lit. When PR synchronized mark is displayed, the LED on the alarm indicator will not flash.
- When [Sync. to Resp.] is selected and RR synchronized mark other than impedance is displayed, the alarm indicator will not flash.

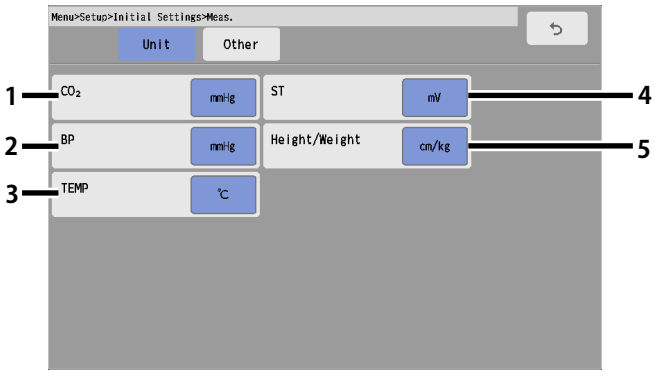
Measurement Related Setup

Measurement Unit

The measurement unit can be set on the "Unit" menu.

1 Press the [Menu > Menu List > Setup > Initial Settings > Meas. > Unit].

▶ The "Unit" menu will be displayed.



2 Select the unit for each parameter.

1 Select the CO_2 measurement unit from [mmHg]/[kPa]/[%].

2 BP
Select the NIBP measurement unit from [mmHg]/[kPa].

3 TEMP
Select the temperature measurement unit from [°C]/ [°F].

4 ST
Select the ST measurement unit from [mV]/[mm].

5 Height/Weight
Select the height/weight measurement unit from [cm\kg]/[in/lb].

NOTE

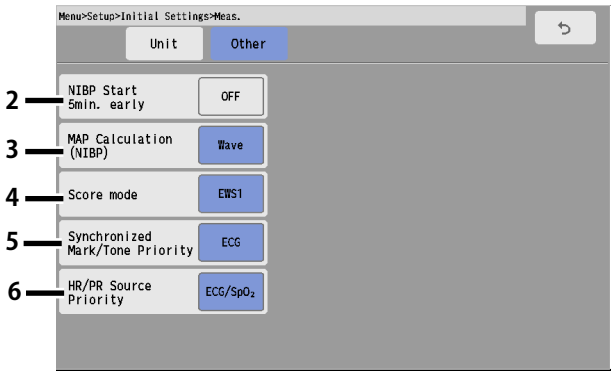
- Changing the BP unit will erase the tabular trend data and graphic trend data. Also, when the unit is changed, it is necessary to perform the alarm setup for the new measurement unit.

Other Setup

On the "Other" menu, other measurement related settings can be performed.

1 Press the [Menu > Menu List > Setup > Initial Settings > Meas. > Other].

▸ The "Other" menu will be displayed.



2 NIBP Start 5 min. early

If outputting the data to PC or other external device using the PC communication function of this system, an error may be generated to the NIBP measurement time depending on the input interval of the external device. This system outputs the data at completion of NIBP measurement, and if the external device inputs the data at 60 minutes interval, 60 minutes time lag will occur. By starting the measurement 5 minutes early, this time lag between the external device can be minimized.

[ON]: When [60min]/[120min] is selected for the measurement interval, the measurement will start 5 minutes before the set time.

NOTE

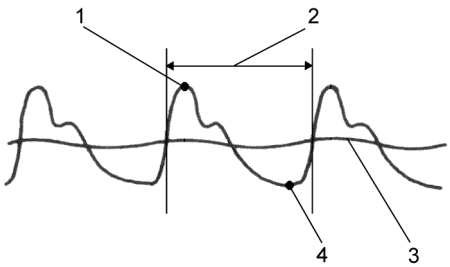
- This setting will be disabled when [Meas.] is set for "Periodic Measurement Starting Time" on the NIBP setup menu.

3 MAP Calculation (NIBP)

The mean blood pressure (MAP) value of NIBP can be selected to be measured from the waveform or from calculation.

[Calc.]: Calculates the mean BP from the following calculation. Mean BP (MAP) = (Systolic BP + Diastolic BP x 2) / 3

[Wave]: The following measurement will be performed.



1: Systolic BP

2: HR interval

3: Mean Value (MAP)

4: Diastolic BP

4 Score Mode

Select the score mode from EWS1, EWS2, qSOFA, NEWS2.

5 Synchronized Mark/Tone

Set the priority of the synchronizing parameter when [Auto] is selected for "Synchronized Mark/Tone" .

[ECG]: The synchronized mark will be displayed in the priority of ECG > SpO_2. Also, the synchronized tone will be set to ON.

[SpO_2]: The synchronized mark will be displayed in the priority of SpO_2>ECG. Also, the synchronized tone will be set to ON.

6 HR/PR Source Priority

Set the display priority of the parameter to be displayed inside the HR/PR numeric data box.

This priority setting will be applied when [Auto] is selected for "HR/PR", or when [HR/PR] user key is used to switch the HR/PR source.

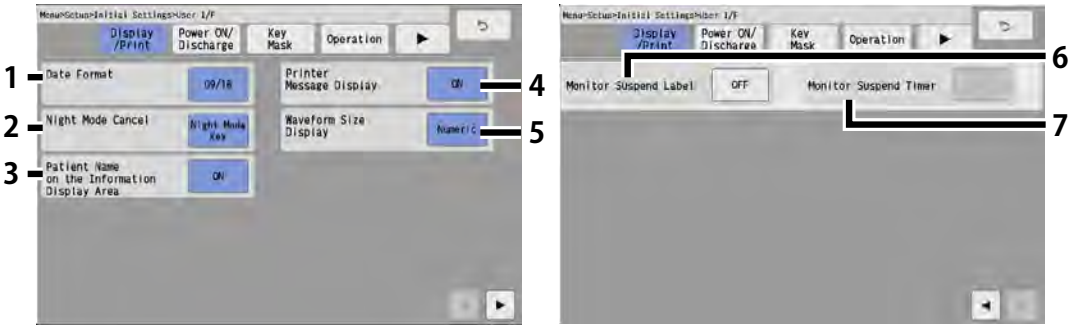
Select the priority order from the dropdown list.
For example, if [ECG/SpO_2] is selected, HR/PR source will be set in the priority of ECG>SpO_2.

User I/F

Display/Print Setup

The initial settings for displaying/printing can be performed.

1 Press [Menu > Menu List > Setup > Initial Settings > User I/F > Display/Print].



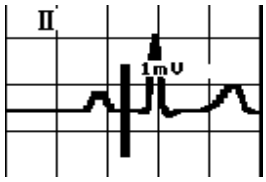
1 Date Format
The selected format will be applied to display and printing.

2 Select the procedure to cancel the night mode when [No Change]/[Dark]/[Darker] is set.
[Any Key]: The night mode can be canceled by pressing any key on the screen.
[Night Mode Key]: The night mode can be canceled by pressing the [Night Mode] key on the user key area or on the menu.

3 Patient Name on the Information Display Area
[ON]: Patient name will be displayed on the information display area.
[OFF]: Patient name will not be displayed on the information display area.

4 Printer Message Display
[ON]: The printer status will be displayed on the home display.
[OFF]: The printer status will not be displayed.

5 Select the display type of the waveform size.
[Numeric]: The waveform size for the ECG, RESP, SpO_2 will be displayed in numerics.
[Bar]: The waveform size will be indicated by a bar.
[Bar (10mm)]: The waveform size will be indicated by a 10 mm bar. The amplitude voltage value of the corresponding waveform size will be displayed beside the bar. (shown on right)



6 Monitor Suspend Label
[ON]: Monitor suspend label will be displayed.
[OFF]: Monitor suspend label will not be displayed.

7 Monitor Suspend Timer
[ON]: Timer will be displayed during the monitor suspended duration.

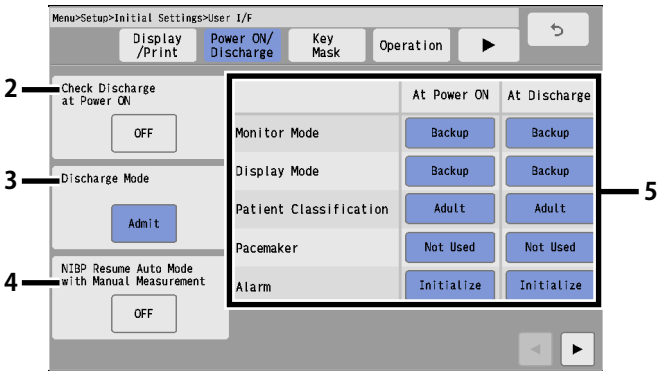
[OFF]: Timer will not be displayed during the monitor suspended duration.

Power ON/Discharge

On this menu, monitoring operation when the power is turned ON or when a patient is discharged can be performed.

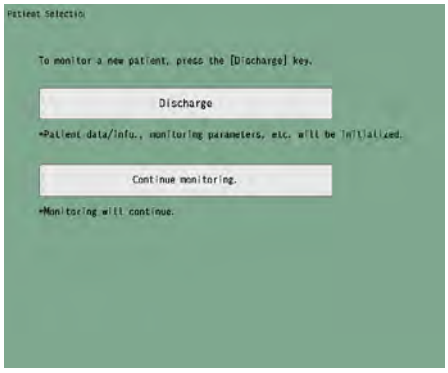
1 Press [Menu > Menu List > Setup > Initial Settings > User I/F > Power ON/Discharge].

▸ The "Power ON/Discharge" setup menu will be displayed.



2 Check Discharge at Power ON

The trend data and tabular trend data will be stored even when the power is turned OFF using the standby switch. To start monitoring a new patient, it is necessary to perform discharge procedure on the "Admit/Discharge" menu, and clear the data of previous patient. When the power has been turned OFF for 30 seconds or more, whether or not to display the discharge confirmation window can be selected.



[OFF]: The discharge confirmation window will not be displayed and monitoring will be immediately started.

[ON]: The discharge confirmation window will be displayed at power ON if the power has been turned OFF for 30 seconds or more.

3 Discharge Mode

The monitoring condition after the patient has been discharged can be set.

[Admit]: Monitoring will continue even after the discharge operation has been performed.

[Monitor Suspend]: Monitoring will be suspended after the discharge operation. The numeric data display will be cleared, and alarm generation, NIBP periodic measurement, periodic printing will not be performed.

Monitoring Suspended Display

4 NIBP Resume Auto Mode with Manual Measurement

[OFF]: NIBP auto mode will resume at power ON and at discharge. NIBP auto mode will resume even after the patient is discharged regardless of whether the next patient is admitted or not.

[ON]: At power ON and at discharge, NIBP auto mode will resume by starting a manual measurement. When the previous patient is discharged and the next patient is admitted, starting a manual measurement for the next patient will resume NIBP auto mode measurement.

Until the NIBP auto mode is resumed or the interval is changed, "Standby" will be displayed inside the NIBP numeric data box.

5 The backup status when the power is turned ON and when the patient is discharged can be set for each item.

[Backup]: The setting will be backed up.

[Initialize]: Initializes the settings. The initialized settings are as follows.

Selection other than Backup

Item	Setup	Power ON/Discharge
Monitor Mode	Monitor Mode 1 to 3	The setting will be initialized to the selected mode.
Display Mode	Display Mode 1 to 3	The setting will be initialized to the selected mode.
Patient Classification	Adult, Child, Neonate	The setting will be initialized to the selected patient classification.
Pacemaker	OFF	"Not Used" will be set for "Pacemaker".
Alarm Setup	Initialize	The setting will be initialized with the currently selected mode.
Display Configuration	Initialize	The setting will be initialized with the currently selected mode.
ECG1, ECG2 Lead	Initialize	The setting will be initialized with the currently selected mode.
ECG1, ECG2 Size	Initialize	The setting will be initialized with the currently selected mode.
Impedance Mode ON/OFF	Initialize	The setting will be initialized with the currently selected mode.
NIBP Auto Mode	OFF	NIBP auto mode will be turned OFF.
	OFF->2.5 min.	If NIBP Auto Mode is OFF, 2.5 min. interval will be set.
	OFF->5 min.	If NIBP Auto Mode is OFF, 5 min. interval will be set.
	2.5 min.	NIBP auto mode will be set to 2.5 min. interval.
	5 min.	NIBP auto mode will be set to 5 min. interval.
SpO_2 Averaging	Initialize	The setting will be initialized with the currently selected mode.
CO_2 Scale	Initialize	The setting will be initialized with the currently selected mode.
$EtCO_2$ Peak Duration	10 sec.	$EtCO_2$ peak picking duration will be set to 10 sec.

⚠ CAUTION

- When the discharge process is performed, patient data such as recall and trend will be initialized. The parameter and alarm settings will be reset according to the settings made under [Initial Settings>User I/F>Power ON/Discharge].
  When the discharge process is performed on the central monitor, alarm will be reset according to the setting on "Admit Setup" of the central monitor.

NOTE

- The operation after the power is turned ON will be according to the setting made on [Initial Settings > User I/F > Power ON/Discharge]. However, if the power was turned OFF for

less than 30 seconds, the setting before the power was turned OFF will remain.

- If the "Main Mode" setting is other than [Backup], only the following settings can be made. Patient Classification, Alarm, Display Configuration, ECG1/ECG2 Lead, ECG1/ECG2 Size, Impedance Mode ON/OFF, NIBP Auto Mode, SpO_2 Averaging, CO_2 Scale, $EtCO_2$ Peak Duration, Pacemaker
- If the alarm threshold of "At Discharge" settings exceeds the alarm threshold limit, the exceeded alarm threshold will be applied. Since the alarm threshold limit status will be changed to limit deactivating mode, make sure to check the alarm setting at patient admittance/discharge.

6 When "Link with Patient Class." is set to [ON], the operation will differ depending on the "Monitor Mode" setting under "Power ON/Discharge". (☞"To Program the User Mode" P5-17)

- If [Backup] is set for "Monitor Mode" under "Power ON/Discharge", the settings will be as follows. When "Link with Patient Class." is set to [ON], it is recommended to set [Initialize] for "Alarm" under "Power ON/Discharge".

Power ON/Discharge		Operation	
Patient Classification	Alarm Setup		
Backup	Backup	Patient Classification:	Current patient classification will be maintained.
		Alarm Settings:	Current alarm settings will be maintained.
	Initialize	Patient Classification:	Current patient classification will be maintained.
		Alarm Settings:	Alarm settings of the main mode selected for "Link with Patient Class."
Adult	Backup	Patient Classification:	Patient classification will be set to "Adult".
		Alarm Settings:	Current alarm settings will be maintained.
	Initialize	Patient Classification:	Patient classification will be set to "Adult".
		Alarm Settings:	Alarm settings of the main mode selected for "Link with Patient Class."
Child	Backup	Patient Classification:	Patient classification will be set to "Child".
		Alarm Settings:	Current alarm settings will be maintained.
	Initialize	Patient Classification:	Patient classification will be set to "Child".
		Alarm Settings:	Alarm settings of the main mode selected for "Link with Patient Class."
Neonate	Backup	Patient Classification:	Patient classification will be set to "Neonate".
		Alarm Settings:	Current alarm settings will be maintained.
	Initialize	Patient Classification:	Patient classification will be set to "Neonate".
		Alarm Settings:	Alarm settings of the main mode selected for "Link with Patient Class."

- If settings other than [Backup] is set for "Monitor Mode" under "Power ON/Discharge", the selected main mode settings will be applied regardless of the ON/OFF setting of "Link with Patient Class.".

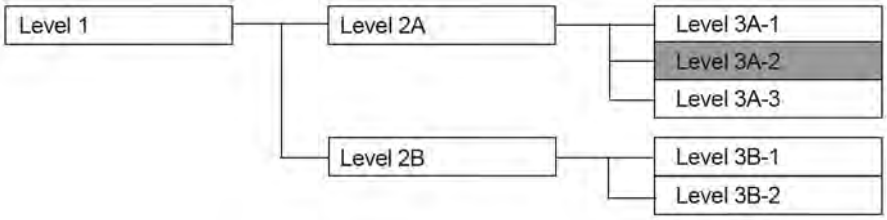
Key Mask

On the "Key Mask" setup, unnecessary keys and tabs can be masked.

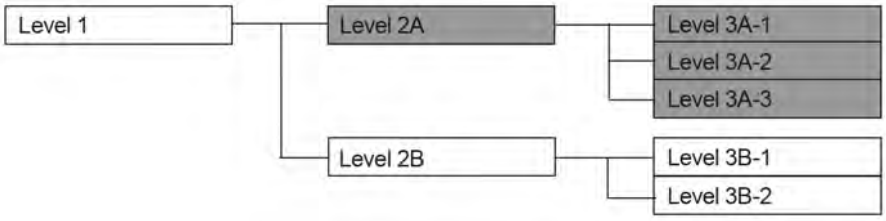
NOTE

- The masked key operation will be disabled on this system, but the operation from the central monitor can be performed and the setting can be changed from the central monitor. The settings will be applied to this device.

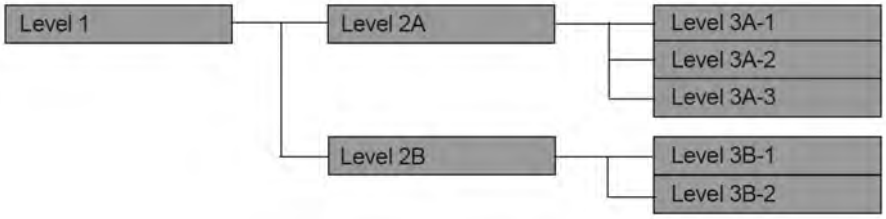
The setup items are in tree structure.
If the upper level key is masked, the lower level key will be also masked.
For the following tree structure, if "Level 3A2" is masked, only this item will be masked.



If "Level 2A" is masked, the masked items will be as follows.



If "Level 1" is masked, the masked items will be as follows.



1 Press [Menu > Menu List > Setup > Initial Settings > User I/F > Key Mask].

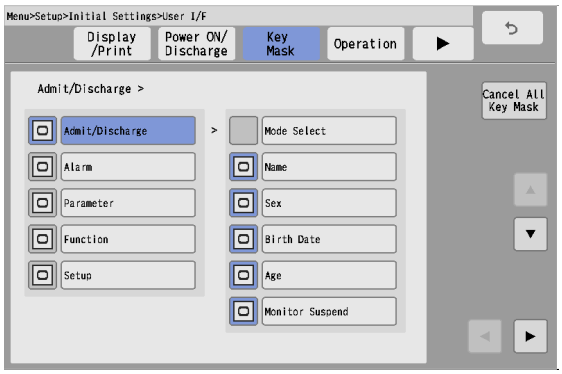
▸ The "Key Mask" menu will be displayed.

2 Select the item to perform the setting.

NOTE

- If there are no lower level items for the selected item, the display will not change.

▸ The lower level items will be displayed.



3 Press [ ] for the item to mask.

NOTE

- Only the [ ] items displayed with blue frame can be masked. The items with white frame cannot be set. Select the lower level items to perform the mask setting.
- Even if "Initial Setting" is masked, [Key Mask] setting cannot be masked.

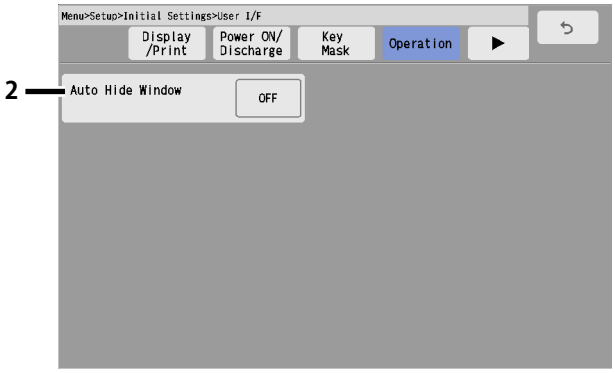
4 Press [ ] for the item to display.

Operation Related Setup

The initial settings for the operation can be performed.

1 Press [Menu > Menu List > Setup > Initial Settings > User I/F > Operation].

▸ The "Operation" menu will be displayed.



2 Whether or not to automatically close the window after fixed duration can be set.
[OFF]: The window will not automatically close.
[5] to [60]: If no operation was performed for the set duration, the window will automatically close. However, the windows for "Data Review", "Waveform Review", "Calculation", "Initial Settings" will not automatically close.

Quick Menu Setup

The function menu to be displayed and its displayed color on the quick menu can be set.
(☞Operation Manual "Quick Menu" P3-15)

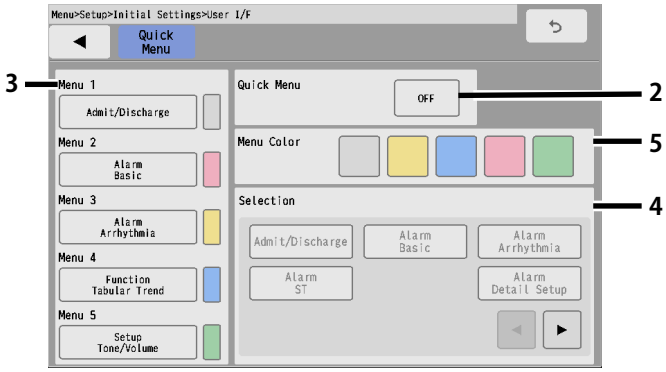
1 Press the [Menu], [Setup], [Initial Settings], [User I/F], [Quick Menu] keys to set the quick menu display.

2 Select whether or not to display the quick menu.

3 Press the key for "Menu 1" to "Menu 5" to perform the setup.

4 Select the function menu from the "Selection" list.

5 Set the color of the function menu.

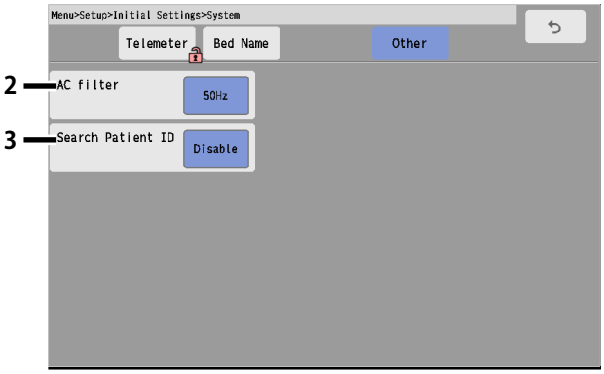


System Setup

On the "System" menu, system related setup can be performed.

1 Press [Menu > Menu List > Setup > Initial Settings > System > Other].

- The system setup menu will be displayed.



2 Select [50Hz]/[60Hz] for "AC Filter".

3 Set the "Search Patient ID".

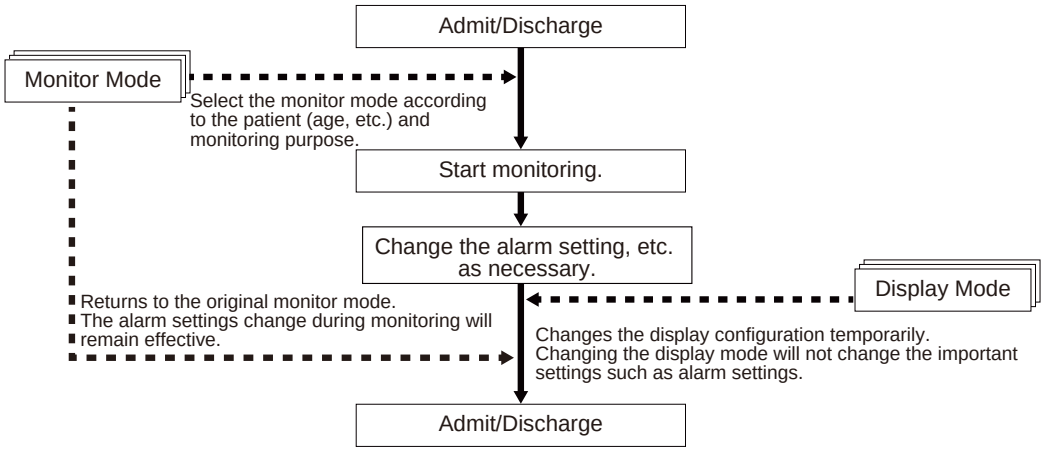
- [Enable]: Patient data can be searched on the patient data server using the patient ID.
- [Disable]: Patient data will not be searched on the patient data server.

User Mode Registration

This section explains about the user mode registration.

About the User Mode

For the user mode, up to 3 monitor modes of different alarm settings and display configurations according to the patient's age and monitoring purpose can be registered. Also, for temporarily changing the display configuration, 3 types of display modes can be registered.
By registering monitor modes, the alarm and display configuration settings at admittance can be simplified by just selecting the registered monitor mode. It is recommended to program the monitor mode in rough classification such as patient’s age and monitoring purpose (ICU or surgery). The settings can be changed for each patient if necessary. The display modes can be used when temporarily changing the display configuration such as when checking the ECG.



❑Items that can be registered for the Monitor Mode

The following items can be registered for the monitor mode.

- Mode Name
- Patient Classification
- Alarm Setup
- Display Configuration
- Manual Printing
- Auto Printing
- Tone/Volume
- Color
- Brightness
- Night Mode Setup
- Parameter Setup
- Graphic/Tabular Trend Display
- Synchronized Mark/Tone
- RR Alarm / APNEA Source

❑Items that can be registered for the Display Mode

The following items can be registered for the display mode.

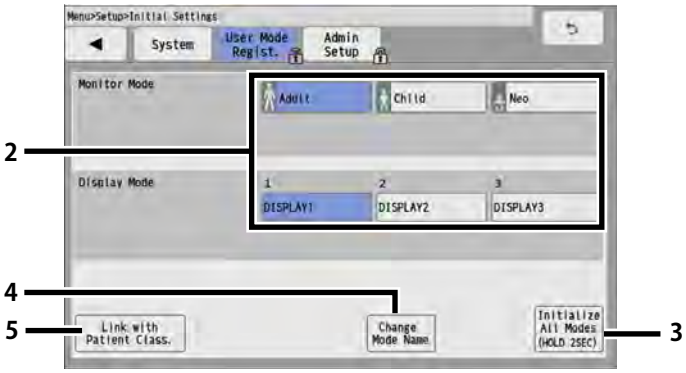
- Mode Name
- Display Configuration

To Program the User Mode

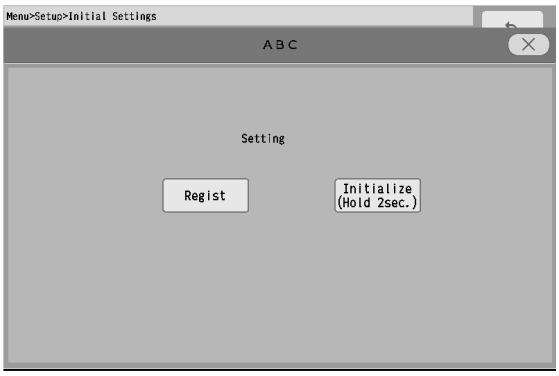
This section explains how to register/change the user mode.

1 Press [Menu > Menu List > Setup > Initial Settings > User I/F > User Mode Regist.].

▸ The "User Mode Regist." menu will be displayed.



2 By pressing the key for each user mode, the selection window will be displayed.



▸ [Regist]: The current monitoring settings will be registered to the selected key.

▸ [Initialize]: The settings for the selected key will be initialized.

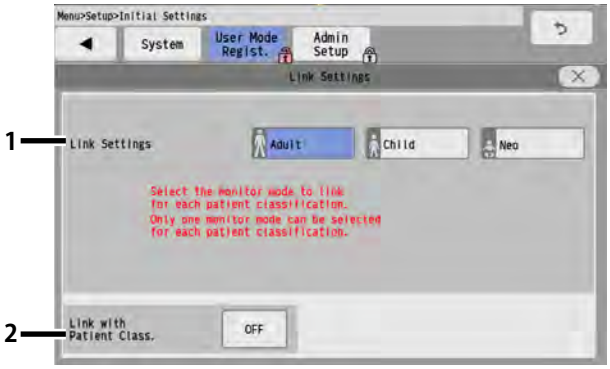
NOTE

- When a user mode is registered or initialized, the monitoring mode will change to the selected user mode. The alarm settings of the selected alarm system will be applied.

3 All user modes will be initialized.

4 To change the user mode name, press the [Change Mode Name] key, and then select the key for the corresponding user mode.

5 By pressing [Link with Patient Class.], the monitor mode to link with the patient classification can be set.



- The patient icon indicates the patient classification registered for each monitor mode.
  When the monitor mode is linked with the patient classification, the patient icon will change to yellow.

1 Link Settings

- Select the monitor mode to link with each patient classification. One monitor mode per each patient classification can be set.

NOTE

- When [Regist] or [Initialize] key is pressed on the monitor mode setup window, the link setting for that monitor mode will be canceled.
- When [Initialize All Modes] key is pressed, link settings for all monitor modes will be canceled, and "Link with Patient Class." will be set to OFF.

2 ON/OFF of "Link with Patient Class."

- [ON]: The monitor mode will change when the patient classification is changed.
- [OFF]: The monitor mode will not change when the patient classification is changed.

NOTE

- When selecting [ON] for "Link with Patient Class.", set the following in advance.
  *On the "Link Settings", select the monitor mode to link with each patient classification.
  *Set the appropriate alarm limits for the linked monitor mode.
  *Check the settings for "Power ON/Discharge". (☞"Power ON/Discharge" P5-10)

Chapter 6 Setup Item/Default Value

Setup Item

This section lists selection, default setting, and backup status for each setup item.
The following indicates the selection, default setting and backup status for each setup item.

Initial Settings

❑Initial Settings (Alarm)

Item		Description	Default	Backup
Alarm System		Fukuda Tone, IEC Tone	IEC Tone	Yes
Suspend Arrhy. Analysis during Noise Interference		ON, OFF	OFF	Yes
Lower Limit for Alarm Volume	Vital Alarm: Urgent	11 levels	0	Yes
	Vital Alarm: Caution		0	
	Vital Alarm: Status		0	
	Ventilator Alarm		0	
	Status Alarm: Urgent		0	
	Status Alarm: Caution		0	
	Status Alarm: Status		0	
Alarm Mute		ON, OFF	OFF	Yes
Alarm Mute Reminder		OFF, 15 min., 30 min., 60 min., 120 min.	15 min.	Yes
Alarm Threshold Limit	Parameter	HR, Ext Tachy, Ext Brady, SpO_2, Ext SpO_2, PR-SpO_2, NIBP-S, RR, APNEA, $EtCO_2$	All Disable	Yes
	Setting Range	(Standard alarm setting range will be applied.)		
Alarm Indicator	Level S*1	Always ON	ON	Yes
	Level H		ON	Yes
	Level M		ON	Yes
	Level L		ON	Yes
	Ventilator Alarm		ON	Yes
	Synchronize with HR/RR	Sync. to HR, Sync. to Resp., OFF	OFF	Yes
Numeric Data	HR	S, H, M	M	Yes
	ST	H, M	M	Yes
	SpO_2	H, M	M	Yes
	Ext SpO_2	H, M	H	Yes
	PR_SpO_2	H, M	M	Yes
	NIBP	H, M	M	Yes
	$InspCO_2$	H, M	M	Yes
	$EtCO_2$	H, M	M	Yes
	RR	H, M, L	M	Yes
	Apnea	H, M, L	H	Yes

Item		Description	Default	Backup
	RPP	S, H, M	M	Yes
	SI	S, H, M	H	Yes
Arrhythmia	Asystole	S, H	H	Yes
	VF	S, H	H	Yes
	VT	S, H	H	Yes
	Ext Tachy	S, H	H	Yes
	Ext Brady	S, H	H	Yes
	Slow VT	H, M	M	Yes
	Tachy	S, H, M	M	Yes
	Brady	S, H, M	M	Yes
	Run	H, M	M	Yes
	Pause	H, M	M	Yes
	Triplet	H, M, L	L	Yes
	Couplet	H, M, L	L	Yes
	R on T	H, M, L	L	Yes
	Multiform	H, M, L	L	Yes
	Vent Rhythm	H, M, L	L	Yes
	Bigeminy	H, M, L	L	Yes
	Trigeminy	H, M, L	L	Yes
	Frequent	H, M, L	L	Yes
	SVT	H, M, L	M	Yes
	Irregular RR	H, M, L	L	Yes
	Prolonged RR	H, M, L	L	Yes
	S Frequent	H, M, L	L	Yes
	S Couplet	H, M, L	L	Yes
	VPC	L	L	Yes
	SVPC	L	L	Yes
	Pacer Not Capture	H, M, L	L	Yes
	Pacer Not Pacing	H, M, L	L	Yes
	AFib	H, M, L	M	Yes
Technical	SpO_2 Low Perfusion	L, N	L	Yes
	Check NIBP cuff, hose	M, L, N	L	Yes
	NIBP meas. failed.(*****)	M, L, N	M	Yes
	RR meas. range is exceeded.	L, N	N	Yes
	Check System Conn.	L, N	N	Yes
	Check Electrodes	H, M, L	L	Yes
	SpO_2 Check Sensor Attach.	H, M, L	L	Yes
	Parameters not displayed due to layout.	L, N, OFF	N	Yes

*1: This setting is selectable only when [Fukuda Tone] is set for "Alarm System".

❑Initial Settings (Measurement)

Unit

Item	Description	Default	Backup
CO_2	mmHg, kPa, %	mmHg	Yes
BP	mmHg, kPa	mmHg	Yes
TEMP	°C, °F	°F	Yes
ST	mm, mV	mV	Yes
Height/Weight	cm/kg, in/lb	in/lb	Yes

Other

Item	Description	Default	Backup
NIBP Start 5 min. early	ON, OFF	OFF	Yes
MAP Calculation (NIBP)	Wave, Calc.	Wave	Yes
Score Mode	EWS1, EWS2, qSOFA, NEWS2	EWS1	Yes
Synchronized Mark/Tone	ECG, SpO_2	ECG	Yes
HR/PR Source Priority	ECG/SpO_2, SpO_2/ECG	ECG/SpO_2	Yes

❑Initial Settings (User I/F)

Display/Print

Item		Description	Default	Backup
Date Format		07/19, Jul.19, 19 Jul	Jul.19	Yes
Night Mode Cancel		Any Key, Night Mode Key	Any Key	Yes
Patient Name on the Information Display Area		ON, OFF	ON	Yes
Printer Message Display		ON, OFF	ON	Yes
Waveform Size Display		Numeric, Bar, Bar (10 mm)	Numeric	Yes
Monitor Suspend Setup	Monitor Suspend Label	ON, OFF	OFF	Yes
	Monitor Suspend Timer	ON, OFF	OFF	Yes
	Label 1	Fixed	SUSPENDED/Red	Yes
	Label 2		UNDER EXAM/Pink	Yes
	Label 3		IN REHAB/Green	Yes
	Label 4		BATHING/Orange	Yes
	Label 5		OUT/Light Orange	Yes
	Label 6		SURGERY/Violet	Yes
	Label 7		RESTROOM/Light Blue	Yes
	Label 8		SUSPENDED/White	Yes

*: When blank, "Group n" will be displayed.

Power ON/Discharge

Item		Description	Default	Backup
Check Discharge at Power ON		ON, OFF	ON	Yes
Discharge Mode		Admit, Monitor Suspend	Admit	Yes
NIBP Resume Auto Mode with Manual Measurement		ON, OFF	ON	Yes
At Power ON Backup/Initialize	Monitor Mode	Backup, Current Mode, Adult, Child, Neonate	Backup	Yes

Power ON/Discharge

Item		Description	Default	Backup
	Display Mode	Backup, Layout 1, Layout 2, Layout 3	Backup	Yes
	Patient Classification	Backup, Adult, Child, Neonate	Backup	Yes
	Pacemaker	Backup, Not Used	Backup	Yes
	Alarm Setup	Backup, Initialize	Backup	Yes
	ECG1, ECG2 Lead	Backup, Initialize	Backup	Yes
	ECG1, ECG2 Size	Backup, Initialize	Backup	Yes
	Impedance Mode ON/ OFF	Backup, Initialize	Backup	Yes
	NIBP Auto Mode	Backup, OFF, OFF->2.5 min., OFF->5 min., 2.5 min., 5 min.	Backup	Yes
	SpO_2 Averaging	Backup, Initialize	Backup	Yes
	CO_2 Scale	Backup, Initialize	Backup	Yes
	$EtCO_2$ Peak Duration	Backup, 10 sec.	Backup	Yes
At Discharge Backup/Initialize	Monitor Mode	Backup, Current Mode, Adult, Child, Neonate	Backup	Yes
	Display Configuration	Backup, Adult, Child, Neonate	Backup	Yes
	Patient Classification	Backup, Adult, Child, Neonate	Backup	Yes
	Pacemaker	Backup, Not Used	Not Used	Yes
	Alarm Setup	Backup, Initialize	Initialize	Yes
	ECG1, ECG2 Lead	Backup, Initialize	Initialize	Yes
	ECG1, ECG2 Size	Backup, Initialize	Initialize	Yes
	Impedance Mode ON/ OFF	Backup, Initialize	Initialize	Yes
	NIBP Auto Mode	Backup, OFF, OFF->2.5 min., OFF->5 min., 2.5 min., 5 min.	OFF	Yes
	SpO_2 Averaging	Backup, Initialize	Initialize	Yes
	CO_2 Scale	Backup, Initialize	Initialize	Yes
	$EtCO_2$ Peak Duration	Backup, 10 sec.	10 sec.	Yes

Key Mask

Item		Description	Default	Backup
Key Mask	Admit/Discharge Items	ON/OFF	All ON	Yes
	Alarm	ON/OFF	All ON	Yes
	Parameter	ON/OFF	All ON	Yes
	Function	ON/OFF	All ON	Yes
	Setup	ON/OFF	All ON	Yes

Operation (Touch Panel, etc.)

Item	Description	Default	Backup
Auto Hide Window	OFF, 5, 10, 20, 30, 60 sec.	60 sec.	Yes

Quick Menu

Item		Description	Default	Backup
Quick Menu		ON, OFF	ON	Yes
Menu Setup	Menu 1	Admit/Discharge, Basic Alarm, Arrhythmia Alarm, ST Alarm, Alarm Detail Setup, ECG, RESP, NIBP, SpO_2, CO_2, Scoring, RPP, ST, Graphic Trend, Tabular Trend, Recall, Full Disc., Zoom Wave, Alarm History, MPDR, Display Config., Manual Printing, Auto Printing, Tone/Volume, Time/Date, Color, Brightness, Night Mode	Admit/Discharge	Yes
	Menu 2		Basic Alarm	Yes
	Menu 3		With ECG: Arrhythmia Alarm Without ECG: Graphic Trend	Yes
	Menu 4		Tabular Trend	Yes
	Menu 5		Tone/Volume	Yes
Menu Color	Menu 1	Gray, Yellow, Blue, Red, Green	Gray	Yes
	Menu 2		Yellow	Yes
	Menu 3		Blue	Yes
	Menu 4		Red	Yes
	Menu 5		Green	Yes

❑Initial Settings (External Device) ON, OFF

Synchronized Signal Output*

Item	Description	Default	Backup
Synchronized Signal Output	ON, OFF	ON	Yes
Signal Output	HR, RR	HR	Yes
Output Logic	Positive Logic, Negative Logic	Negative Logic	Yes
Pulse Width (msec)	100, 60, 20	100	Yes

Magnetic Card Reader

Item		Description	Default	Backup
Starting Digit / Ending Digit	Patient ID	Entering using left/right arrow keys	1- 20	Yes
	Patient Name		OFF-OFF	Yes
	Birth Year		OFF-OFF	Yes
	Birth Month		OFF-OFF	Yes
	Birth Day		OFF-OFF	Yes
	Age		OFF-OFF	Yes
	Sex		OFF-OFF	Yes

Communication Setup

Item		Description	Default	Backup
Communication Setup*	Status II	Veria/Ultra/Astral, SERVO-i/s, SERVO-U/n/air, SV-300, Evita, PC Comm., PB, OFF	OFF	Yes

Status Output

Item		Description	Default	Backup
Alarm Output*	Alarm Level	OFF, APNEA, Level H, Level H,M, Level H,M,L	OFF	Yes
	Output Logic	Positive Logic, Negative Logic, Pulse	Negative Logic	Yes

NOTE

- For the item with *mark, the setting is backed up. Performing F-start (turning the power ON with the rotary switch set to F) will not initialize the setting.

❑Initial Settings (System)

Item		Description	Default	Backup
Telemeter	Usage	ON, OFF	ON	Yes
	Channel	1001 to 1080, 2001 to 2120 3001 to 3040, 4001 to 4080 5001 to 5080, 6001 to 6080	Depends on the telemeter	Yes
	Group	00 to 63	00	Yes
	Transmitting Waveform	ECG1 (ECG1, RESP, CO_2, SpO_2), ECG2 (ECG1, ECG2, RESP/CO_2, SpO_2)	ECG1 (ECG1, RESP, CO_2, SpO_2)	Yes
	CO_2 (mmHg) Upper Limit of Transmission	99 mmHg, No limit	99 mmHg	Yes
Bed Name	Room ID	3 alphanumeric characters	BED	Yes
	Bed ID	3 numerics	000	Yes
Other	AC filter	50 Hz, 60 Hz	60 Hz	Yes

NOTE

- For the item with *mark, the setting is backed up. Performing F-start (turning the power ON with the rotary switch set to F) will not initialize the setting.

❑Initial Settings (User Mode Registration: Monitor Mode)

Item		Description	Default	Backup
Monitor Mode	Mode Name	8 characters	Adult Mode	Yes
			Child Mode	
			Neonate Mode	

The following settings can be registered for the monitor mode. Other than display configuration setting, the default settings will be applied to all modes.

*Patient Classification *Manual Printing *Auto Printing

*Tone/Volume *Night Mode *Alarm

*Settings for Each Parameter

*Settings for Review Data (Trend, Tabular Trend, Recall, Zoom Wave, Full Disc. Wave)

❑Initial Settings (User Mode Registration: Display Mode)

Item		Description	Default	Backup
Display Mode	Mode Name	8 characters	DISPLAY1	Yes
			DISPLAY2	
			DISPLAY3	

The following settings can be registered for the display mode. Other than display configuration setting, the default settings will be applied to all modes.

*Display Configuration *Color *Brightness

*Display Mode (Layout 1)

Item		Default	Backup
Item		DISPLAY1	Yes
Numeric Data		With ECG: HR/PR, SpO_2, NIBP, NIBP Graph, RR_IMP, Scoring Without ECG: SpO_2, NIBP, NIBP Graph, NIBP List, Scoring	
Waveform		With ECG: ECG1, SpO_2, RESP, CO_2 Without ECG: SpO_2	
User Key		Menu, NIBP Start/Stop, Recall, Print Start/Stop, Alarm Silence	
Detail Setup (Numeric Data)	Alarm Limit Display	Graph	
Detail Setup (Waveform)	Grid	ON	
	Thickness	Normal	

*Display Mode (Layout 2)

Item		Default	Backup
Item		DISPLAY2	Yes
Numeric Data		With ECG: HR/PR, SpO_2, NIBP, NIBP Graph Without ECG: SpO_2, PR_SpO_2	
Waveform		With ECG: None Without ECG: SpO_2	
User Key		Menu, NIBP Start/Stop, Recall, Print Start/Stop, Alarm Silence	
Detail Setup (Numeric Data)	Alarm Limit Display	Graph	
Detail Setup (Waveform)	Grid	ON	
	Thickness	Normal	

*Display Mode (Layout 3)

Item		Default	Backup
Item		DISPLAY3	Yes
Numeric Data		With ECG: HR/PR, NIBP Without ECG: NIBP, NIBP Graph, NIBP List	
Waveform		With ECG: ECG1 Cascade Without ECG: None	
User Key		Menu, NIBP Start/Stop, Recall, Print Start/Stop, Alarm Silence	
Detail Setup (Numeric Data)	Alarm Limit Display	Graph	
Detail Setup (Waveform)	Grid	ON	
	Thickness	Normal	

❑Initial Settings (Link with Patient Classification)

Item		Description	Default	Backup
Link Settings	Adult	Monitor Mode1 to 3	OFF	Yes
	Child		OFF	
	Neonate		OFF	
Link with Patient Class.		ON, OFF	OFF	

External Connection (Pin Assignments)

This section lists the connector pin assignments.

Serial Connector Output Signal

No.	Signal Name	Note	Signal Level
1	RESET	Reset	Open Collector Output (Internal Pull-Up Resistor)
2	NC	Not connected	
3	TxD	Serial Transmission Data Output	RS232C
4	GND_ISO	GND	
5	RxD	Serial Reception Data Input	RS232C
6	+5V	+5V Power Supply Output	+5V Power Supply (100mA)
7	NC	Not connected	
8	NC	Not connected	

Status I/O Signal (Status II Connector)

No.	Signal Name	Note	Signal Level
1	QRS_SYNC	QRS Synchronization Output Signal	Open Connector (Internal Pull-Up)
2	ALARM_OUT2+	Alarm Output2+ (Isolation)	Photo MOS Relay Contact
3	TxD	Serial Transmission Data Output	RS232C
4	RxD	Serial Reception Data Input	RS232C
5	ALARM2_IN+	Alarm Input 2 (Isolation)	Logic Input
6	ALARM2_IN-	Alarm Input 2 Return (Isolation)	
7	+5V	+5V Power Supply Output	+5V Power Supply (100mA)
8	ALARM_OUT2-	Alarm Output 2- (Isolation)	Photo MOS Relay Contact
9	GND_ISO	Isolation Ground	

If isolation is necessary, use the alarm input 2 and output 2.

Chapter 7 Replacement Parts

Periodic Replacement

To ensure reliability of safety, function, and performance of this device, the following parts must be replaced periodically.
When replacing, contact your nearest service representative.

CAUTION

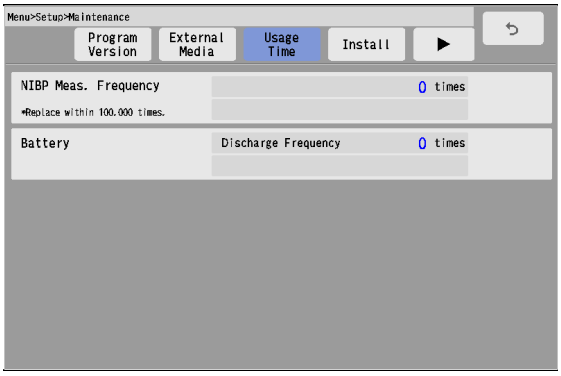
- Replace the periodic replacement parts periodically as specified.
- This device utilizes LED for the backlight. Since this LED deteriorates by the life cycle, the display may become dark or may not light by the long term use. In such case, contact your nearest service representative.

Periodic Replacement Parts	Periodic Replacement Period
NIBP Unit	30,000 times of measurement
Lithium-Ion Battery Pack: BTO-008	300 times of charge/discharge or 1 year of usage whichever earlier
CO_2 Gas Unit HCP-110	30,000 hours

To Check the Periodic Replacement Period

The usage hours for the part which requires periodic replacement can be displayed.
It can be used as an indication of replacement period for each part.

1 Press [Menu > Menu List > Setup > Maintenance > Usage Time].



- The Usage Time window will be displayed.
- The usage period or NIBP measurement frequency for each part will be displayed.

2 After the part is replaced, press the [Reset] key.

- The displayed value will reset.

CAUTION

- To replace the parts, contact your nearest service representative.

Disposing the Device

CAUTION

- When disposing of the device, accessories, follow the regulations of local authority or each institution. Do not dispose of as ordinary waste.
- When disposing of the battery, separate it from other wastes and contact your nearest service representative.
- If there is risk of infection, dispose of as infectious waste according to the regulations of local authority or each institution.

Chapter 8 Cleaning/Disinfecting/Storing

After Usage/Handling the Device

This section explains about how to handle the device.

After Using the Device

- When unplugging the cables, make sure to pull from the connector part of the cable and avoid applying excessive force.
- Clean the device, accessories, and cables, and keep them together in one place for next use.
- Always check for adequate supply of ECG electrodes, and other disposable accessories. If any shortage is found, contact your nearest service representative.

Display

- The display (touch panel) is made of glass. Do not apply strong impact.
- As the display panel is vulnerable, do not scratch or rub it with a hard item.
- If the display panel cracks, or the internal part of the device gets exposed due to any accident, do not touch the display panel or the exposed part. It may cause electric shock or injury to the operator. Contact your nearest service representative.

Storing the Device and Recording Paper

This section explains how to store the device and recording paper.

Device

- Store in a place where the device will not be exposed to splashing water.
- Store in an area where the environmental conditions, such as atmospheric pressure, temperature, sunlight, dust, sodium, sulfur, will not adversely affect the system.
- Store in a level area where the device is not exposed to vibration and shock (including during transportation).
- Store in an area which meets the following environmental conditions.
  - Storage Temperature: -10°C to 60°C/14°F to 140°F
  - Storage Humidity: 10% to 95% (at 40°C/104°F, non-condensing)
  - Atmospheric Pressure: 70 kPa to 106 kPa

Recording Paper

The recording paper is thermal type. Storage over an extended period of time at a high temperature may change the quality of the printed content, and make it illegible. When storing, follow the precautions below.

- Store in a place where light is shut off and avoid direct sunlight.
- Do not leave the paper in a high temperature (50 °C/122 °F and above).

- Do not store the paper in a polyvinyl chloride bag.
- Do not expose the paper to alcohol, hydrochloric acid, or ester ketone.
- Avoid using adhesive agents other than water based glue.

Cleaning the Device and Sensors

This section explains how to clean/disinfect the device and sensors.

CAUTION

- Do not sterilize the device.
- Do not disinfect the device while monitoring patient.

Touch Panel

Since the display panel uses a touch panel, finger prints and other stains are likely to appear on the touch panel. Follow the procedure below to clean the touch panel while monitoring. For disinfecting procedure, refer to the next section, "Housing".

CAUTION

- Never use strong-acidic cleaning solution.
- To clean the touch panel, use an optional cleaning cloth, eyeglass cleaning cloth, soft cotton cloth, or non-woven cloth (pulp, rayon, polyethylene, etc.).

1 Press the [Key Lock] key on the Home Display for more than 2 seconds.

NOTE

- Assign the [Key Lock] key to the user key area in advance.
  (☞Operation Manual "To Configure the Display" P10-2)
- If the touch panel is not touched for 30 seconds, the key lock condition will be automatically canceled. When the key lock condition is canceled, press the [Key Lock] key again.

▸ <Key Locked> will be displayed.

▸ While this message is displayed, the touch panel key will be deactivated.

▸ If <LEAD OFF> or other message is displayed, the key lock message will not be displayed.

2 Wipe the touch panel using a cleaning cloth.

3 Press again the [Key Lock] key for more than 2 seconds.

▸ The message will disappear, and the key locked condition will be canceled.

Housing

❑Cleaning

Wipe using a tightly squeezed gauze or an absorbent cotton dampened with alcohol (ethanol, isopropyl alcohol). Then wipe with a dry cloth. Then, wipe with a dry cloth.

Usable Cloth:

*Soft cloth (cotton)

*Soft non-woven cloth (pulp, rayon, polyethylene, etc.)

⚠ CAUTION

- If cleaning solution is left on the device, wipe with a dry cloth. It may damage the surface resin coating, resulting in discoloration, scratches, malfunction, and deterioration.
- Do not wipe the metal part inside the connector.

❑Disinfection

Wipe with a cloth dampened with one of the following chemicals. Then, wipe off with dry cloth.

Chemicals:

*Disinfectant Alcohol (ethanol, isopropyl alcohol)

*Benzalkonium Chloride 0.2%

*Benzethonium Chloride 0.2%

*Alkyldiaminoethylglycine Hydrochloride 0.5%

Usable Cloth:

*Soft cloth (cotton)

*Soft non-woven cloth (pulp, rayon, polyethylene, etc.)

⚠ CAUTION

- Clean the device frequently so stains can be removed easily.
- To prevent injury, it is recommended to wear gloves when cleaning the device.
- When cleaning or disinfecting, do not allow chemical solution to enter the device or connectors.
- Do not use organic solvents, thinner, toluene or benzene to avoid damaging the resin case.
- Do not polish the device with abrasive, chemical cleaner, alkaline or acidic detergent. The surface resin coating may damage, resulting in discoloration, scratches, and malfunction.
- For the precautions for storing and handling the chemicals, refer to the instruction manual for the respective chemical.

NIBP Cuff and Air Hose

To clean the cuff shell, remove the bladder and wash it using neutral detergent. Make sure that the cuff is dry before placing back the bladder inside.

For procedure to clean/disinfect the reusable cuff, refer to the instruction manual for the respective cuff.

Do not reuse/resterilize the disposable cuff.

⚠ CAUTION

- After washing, ensure the size indication on the bladder and cuff shell match. Make sure that the cuff hose is threaded through one of the hose openings in the cuff.

SpO_2 Sensor

Disinfect the SpO_2 sensor according to the manufacturer's guidelines. Do not reuse/resterilize the disposable type SpO_2 sensor.

❑Medtronic Sensor

- Do not soak the sensor in water or antiseptic solution.
- Wipe the DURASENSOR with disinfectant such as 70% alcohol. Do not sterilize by irradiation, steam, or ethylene oxide.
- OxiMax is a single-patient use type sensor. Do not reuse or resterilize.

❑Masimo Sensor

- Do not soak the sensor or patient cable in water or antiseptic solution.
  (Sensors and connectors are not water-proof.)
- Do not sterilize the sensors and cables by irradiation, steam, or ethylene oxide.
- The Masimo disposable 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.
  For most of the sensors, the adhesiveness will return by cleaning the sensor with alcohol and completely drying it before applying it to the patient. For details of the cleaning procedure, refer to the instruction manual of the sensor.
- Disinfect the Masimo reusable sensor and patient cable according to the manufacturer's guidelines.
- When cleaning the Masimo reusable sensor and patient cable, disconnect them from the main unit, and follow the procedure below.

1 Wipe the sensor and cable using 70% isopropyl alcohol cotton.

2 Dry it completely with air before reusing.

Chapter 9 Maintenance Check

Daily and Periodic Inspection

Maintenance Check

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

In this section, the maintenance check items that must be performed for this device are explained. Make sure to perform "Daily Inspection" and "Periodic Inspection" described in this section to maintain functionality, performance and reliability. Fukuda Denshi is not liable for any accidents arising from lack of maintenance.

Contact your nearest service representative for information on basic performance.

For additional information required by the service and technical engineers to service the device, refer to your nearest service representative.

⚠ CAUTION

- Do not open the housing.
- Do not allow alcohol or other liquids to enter the device.

❑Daily Inspection

Perform the daily inspection using the "Daily Inspection List".

❑Periodic Inspection

Periodic inspection 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.

Check the essential performance and basic safety when performing periodic inspection. Refer to ☞"Periodic Inspection Items and Procedures" P9-3 for check items and procedures.

Daily Inspection Items and Procedures

Make sure to perform the daily inspection.

- If the device fails any check item on the daily inspection list, the general judgment will be "Fail". Repair the device so that it passes all the check items.
- Use the device only if the judgments for all the items are "OK".

No.	Check Items	Check Procedure	Criteria
1. Cleanness, Cleaning (Note: Turn OFF the power, and disconnect the power cable and battery before cleaning.)			
01	Cleanness	If contamination is found, perform proper disinfection before the daily inspection.	No contamination should be found.
02	Cleaning	Visually check the exterior, and perform proper cleaning. For details, refer to "Chapter 8 Cleaning/ Disinfecting/Storing" of Maintenance Manual.	It should be clean.

No.	Check Items	Check Procedure	Criteria
2. External Appearance			
01	External Appearance	Visually check the exterior for scratches, cracks, and rust.	No abnormality should be found.
02	Cables	Check that the cables are intact and firmly connected.	The cables should be intact and firmly connected.
03	Installation	Check whether the device is installed on a level surface.	The installation area must be level and free from vibration and shock.
04	Installation	Check whether the device is installed in a place susceptible to adverse environment.	The temperature and humidity of the installation area must be as specified. The device should not be subjected to splashing water or chemicals.

No.	Check Items	Check Procedure	Criteria
3. Operation			
01	Function	Turn ON the power, and check that the device operates normally.	The home display should appear, and the power supply LED should light.
			The date and time should be correct.
02	Function	Turn ON the power, and check that the device operates normally.	Pressing the NIBP Start/Stop key should inflate the NIBP cuff.
			Connecting the SpO_2 sensor should light the sensor LED.
03	Function (When HCP-110 is used)		The home display should appear, and the power supply LED should light.
			When the sampling tube is connected, "0" should be displayed in the numeric data box.
04	CO_2 Calibration (When HCP-110 is used)	Check the date of the previous calibration. (Refer to the following caution.)	Should be within one year.
		Check the remaining time until the next calibration. [Menu > Menu List > Parameter] > CO_2 > CO_2 Cal.]	Should not be 0 hrs.
05	Alarm Indicator	Check the alarm indicator operation by pressing the [Indicator Test] key.	It should light with the color of each level.
06	Alarm Sound	Check the alarm sound by pressing the [Test] key.	The alarm sound should be properly generated from the speaker.

No.	Check Items	Check Procedure	Criteria
07	Recorder (When HR-110 is used)	Visually check the installed condition of the paper.	The paper should be correctly installed.
			Neither damage nor discoloration should be found.
		Check if the printing operation is smooth, and no abnormal sound is occurring.	The operation should be smooth and no abnormal sound should occur.

No.	Check Items	Check Procedure	Criteria
4. Other Items			
01	Periodic Replacement Parts	Check the number of measurements of the NIBP unit.	It should not exceed 30,000 times.
		Check the number of charging/discharging times or the first usage date of the BTO-008 Lithium-Ion Battery Pack.	The number of charging/discharging times should not exceed 300 times, or usage duration should not exceed one year.
		Check the operation hours of the CO_2 gas unit (HCP-110).	It should not exceed 30,000 hours.
02	Periodic Inspection	Check the date of the previous periodic inspection.	Should be within one year.
03	Operation Manual	Check that accompanying documents (operation manual, etc.) are available for prompt reference.	Accompanying documents (operation manual, etc.) are available for prompt reference.

⚠ CAUTION

- If the CO_2 gas calibration is not performed at a specified interval, CO_2 measurement accuracy may be affected and also subsequent gas calibration may not be possible.

Periodic Inspection Items and Procedures

Perform the periodic inspection according to the following list.

- The periodic inspection should be performed once a year.
- If the device fails any check item on the periodic inspection list, the general judgment will be "Fail". Repair the device so that it passes all the check items.
- Use the device only if the judgments for all the items are "OK".
- Check the damage, earth impedance, leakage current, and accuracy for all cables, devices, and accessories.
- For details about the essential performance and basic safety, contact your nearest service representative.

⚠ CAUTION

- Before the check procedure, back up the setup data and patient data on the USB memory.
- Some models of commercially available bench top functional testers and patient simulators can be used to verify the proper functionality of SpO_2 monitoring system, sensors, cables, but they are incapable of properly evaluating the SpO_2 measurement accuracy. SpO_2 measurement accuracy can only be evaluated by comparing measurement data with SaO_2 measurements obtained from simultaneously sampled arterial blood using a laboratory Co-oximeter.

No.	Check Items	Check Procedure	Criteria
1. Preparation, Cleaning			
01	Data Backup, etc.	Before the check procedure, back up the setup data and patient data on the SD card or USB memory. If backup is not possible, write down the setting information, etc. before the check procedure, and restore the settings to original state after the check procedure.	The data should be properly backed up. Or, the setting information, etc. should be written down.
02	Cleanness	If contamination is found, perform proper disinfection before the daily inspection.	No contamination should be found.
03	Cleaning	Visually check the exterior, and perform proper cleaning. For details, refer to "Chapter 8 Cleaning/Disinfecting/Storing" of Maintenance Manual.	It should be clean.

No.	Check Items	Check Procedure	Criteria
2. 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	Label	Visually check the rating label and caution label of the device.	Should be neither peeled nor stained nor unclear.
03	Cables	Check that neither damage nor broken wire is found in all cables. Check that the connection is smooth and secure.	Neither damaged nor broken wire should be found. Should be securely connected.
04	Printing Paper	Visually check the installed condition. Check that extra printing paper is stored.	The paper should be correctly installed. No discoloration should be found. Extra printing paper should be stored.
05	Operation Manual	Check that accompanying documents (operation manual, etc.) are available for prompt reference.	Accompanying documents (operation manual, etc.) are available for prompt reference.

No.	Check Items	Check Procedure	Criteria
3. Power Supply			
01	Standby Switch	Check by connecting the power cable to AC and turning the power ON/OFF using a standby switch.	Check that the power supply LED lights. ON: Green, OFF: Orange
02	Battery-Charging Operation (When a battery is installed)	Install the battery, and check the charging operation.	Check that the battery charging LED lights. While charging: Orange, Fully charged: Green, Charging ceased: Light Off
03	Battery Operation (When a battery is installed)	After charging the battery, unplug the power cable, and change to battery operation.	Check that the battery-operating condition is as specified on the operation manual.
04	Battery Replacement (When a battery is installed)	Check the battery replacement date.	Should be within one year from start of usage.

No.	Check Items	Check Procedure	Criteria
4. Display/Operation/Print			
01	Operation, Switch	Check by operating the control switches and keys on the touch panel.	Should operate correctly.
02	LCD	Check that the home display is displayed on the LCD.	Characters and waveform should be clear. The display should be clearly displayed with sufficient brightness.
03	Alarm Indicator	Check if the alarm indicator lights when the power is turned ON.	Should light when the power is turned ON.
04	Alarm Sound/ Operating Sound	On the "Tone/Volume" menu, check the alarm sound.	Alarm sound should generate with proper volume. There should be no beat noise.
05	Date/Time	Check the year, month, day, and time on the display.	The year, month, day, and time should be correctly displayed.
06	Printing Status	Perform test printing on the maintenance menu. Visually check the printing condition and also if there are thin or missing points.	The printed characters should be clear and legible.
07	Printing Speed	Perform test printing on the maintenance menu. Check by measuring the length of printed grid.	Error should be within ±3% for 25 mm/sec and 50 mm/sec waveform traces.
08	Telemetry Transmission	Perform telemetry transmission, and check the reception condition and waveform on the receiver side.	Correct waveforms and numeric data should be displayed and receiving condition should be stable.

No.	Check Items	Check Procedure	Criteria
5. ECG			
01	ECG Display Size	Input square wave of 1 mV amplitude from the simulator, and check the displayed waveform on the monitor with a waveform size of x1.	The amplitude of the displayed waveform should be within 10 mm ± 1 mm.
02	Heart Rate Display Accuracy	Set the heart rate to 60 bpm on the simulator, and check the displayed heart rate on the monitor.	The displayed heart rate should be within 60 bpm ± 3 bpm.
03	Lead OFF	Remove each electrode from the simulator and check that "Lead OFF" message is displayed.	The "Lead OFF" message for the removed electrode should be displayed.

No.	Check Items	Check Procedure	Criteria
6. Respiration (Impedance Measurement)			
01	Respiration Rate Display Accuracy	Input the respiration signal of 20 Bpm with the following setting from the simulator, and check the displayed RR value on the monitor. Baseline Impedance: 1500Ω Detection Lead: II (LL), Respiration Waveform: Normal, Amplitude: 1 Ω	The displayed RR should be within 20 Bpm ± 3 Bpm.

No.	Check Items	Check Procedure	Criteria
7. SpO_2			
01	Oxygen Saturation Display Accuracy	Input the oxygen saturation signal of 90%SpO_2 from the simulator, and check the displayed oxygen saturation value on the monitor.	The displayed oxygen saturation value should be within 90%SpO_2 ± 2%.
02	Pulse Rate Display Accuracy	Input the pulse rate signal of 60 bpm from the simulator, and check the displayed HR value on the monitor.	The displayed heart rate should be within 60 bpm ± 3 bpm.

No.	Check Items	Check Procedure	Criteria
8. NIBP			
01	NIBP Test	Connect the 500 ml tank, and perform the NIBP test under the test menu.	All the test results should be "OK".
02	BP Measurement Error	Set the simulator to 120 mmHg for SYS, 80 mmHg for DIA, 90 mmHg for MAP, and perform the NIBP measurement.	The displayed BP value should be within 120 mmHg ± 10 mmHg for SYS, 80 mmHg ±10 mmHg for DIA, 90 mmHg ±10 mmHg for MAP.
03	Pulse Rate Measurement Error	Set the pulse rate to 60 bpm on the simulator, and perform the NIBP measurement.	The displayed pulse rate should be within 60 bpm ± 3 bpm.

No.	Check Items	Check Procedure	Criteria
9. CO_2 Concentration (Optional)			
01	CO_2 Concentration Calibration (HCP-110)	Perform calibration according to the procedure explained in "Chapter 9 Maintenance Check"(Maintenance Manual).	The calibration should complete without error.
02	CO_2 Concentration Measurement	Perform measurement with 5% calibration gas, and check the displayed CO_2 concentration value on the monitor.	The displayed CO_2 concentration value should be within 38 mmHg ± 2 mmHg.

No.	Check Items	Check Procedure	Criteria
10. Periodic Replacement Parts, Aftertreatment			
01	NIBP Unit	Check the number of measurements.	It should not exceed 30,000 times.
02	Lithium-Ion Battery Pack: BTO-008	Check the number of charging/discharging times or the first usage date.	The number of charging/discharging times should not exceed 300 times, or usage duration should not exceed one year.
03	CO_2 Gas Unit (When HCP-110 is used)	Check the usage hours.	It should not exceed 30,000 hours.
04	Restore Backup Data	After the check procedure, restore the setup data from the USB memory. If the settings have been written down, restore the settings to original state as written.	The settings should be properly restored to original state.

No.	Check Items	Check Procedure	Criteria
Electrical Safety			
01	Earth Leakage Current (NC)	Measure the earth leakage current under normal condition using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	Earth Leakage Current (NC) should be 5 mA or less.
02	Earth Leakage Current (SFC)	Measure the earth leakage current under single fault condition using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	Earth Leakage Current (SFC) should be 10 mA or less.
03	Contact Current (NC)	Measure the contact current under normal condition using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	Contact Current (NC) Should be 100μA or less
04	Contact Current (SFC)	Measure the contact current under single fault condition using a leak measurement safety tester. Test according to the test method of IEC 60601-1.	Contact Current (NC) Should be 500μA or less
05	Patient Leakage Current (NC)	Measure the patient leakage current under normal condition using a leak measurement safety tester. Test according to the test method of IEC 60601- 1.	[AC/DC] Type CF Applied Part Patient Leakage Current (NC) Should be 10μA or less
06	Patient Leakage Current (SFC)	Measure the patient leakage current under single fault condition using a leak measurement safety tester. Test according to the test method of IEC 60601- 1.	[AC/DC] Type CF Applied Part Patient Leakage Current (SFC) Should be 50 μA or less

07	Total Patient Leakage Current (NC)	Measure the total patient leakage current under normal condition using a leak measurement safety tester. Test according to the test method of IEC 60601- 1.	[AC/DC] Type CF Applied Part Patient Leakage Current (NC) Should be 50μA or less
08	Total Patient Leakage Current (SFC)	Measure the total patient leakage current under single fault condition using a leak measurement safety tester. Test according to the test method of IEC 60601- 1.	[AC/DC] Type CF Applied Part Patient Leakage Current (SFC) Should be 100 μA or less
09	Patient Auxiliary Current (NC)	Measure the patient auxiliary current (NC) under normal condition using a leak measurement safety tester. Test according to the test method of IEC 60601- 1.	Patient Auxiliary Current (NC) Should be 10 μA or less
10	Patient Auxiliary Current (SFC)	Measure the patient auxiliary current (SFC) under single fault condition using a leak measurement safety tester. Test according to the test method of IEC 60601- 1.	Patient Auxiliary Current (SFC) Should be 50 μA or less

Handling and Storage of Lithium-Ion Battery Pack (BTO-008)

This section describes the handling and storage of the BTO-008 battery pack. Refer also to the BTO-008 Operation Manual.

❑Handling the Battery

- For uninterrupted monitoring, charge the battery when the battery level is low.
- When the battery operation time becomes short even after it is fully charged, the battery needs to be replaced.
- The battery should be charged at room temperature (10°C to 30°C/50°F to 86°F).
- The lithium-ion battery can only be charged in the specified operating temperatures of the device. Refer to the operation manual of the lithium-ion battery (BTO-008) for details.
- When using the battery for the first time, or using after leaving it for a while, make sure to charge the battery before use.

❑Storing

To take advantage of the characteristic of the battery pack, pay attention to the following when storing.

Storage Temperature and Humidity for the Battery

- Store in an environment specified below without corrosive gas.

Storage Period	Storage Temperature	Storage Humidity
Within 30 days	-20°C to 60°C/-4°F to 140°F	20% to 85% (non-condensing)
Within 90 days	-20°C to 45°C/-4°F to 113°F	
Within 1 year	-20°C to 20°C/-4°F to 68°F	

- Do not store in an environment outside the specified temperature range or excessive high humidity. This may result in leakage caused by expansion/contraction inside the battery or rusting of the metal part.

❑Long-Term Storage

- If the battery is left installed in the monitor without use for a long period of time, the capacity recovery after storage may be degraded.
  When storing the monitor for a long period, remove the battery from the monitor.

CO_2 Calibration (HCP-110)

This section describes about the procedure of CO_2 gas calibration.

Perform calibration for the following case.

When the measurement time exceeds 1,200 hours from the first use.

When 1 year has elapsed from the last calibration; or the accumulated $EtCO_2$ measurement time exceeds 4,000 hours, whichever comes earlier.

When error occurs to the measurement reading.

1 Press the [Menu > Menu List > Parameter > CO_2 > CO_2 calibration] to display the CO_2 calibration screen.

2 Press the [Start Cal] key and conduct calibration according to the displayed messages.

3 The message, <Feed calibration gas.> will be displayed. Press the injection button and inject the calibration gas.

4 The message, <Measuring- Remove Gas.> will be displayed. Stop pressing the injection button to cease the injection.

5 The message, "Cal. OK" will be displayed. "Last Cal Date" will be updated to the current date.

- If any of the following messages is displayed, start the procedure again from step 2. <Sensor Cal. Error>, <Cal. Gas Error>, <Auto Zero Cal. Failed.>, <Wrong Gas.>, <Cal. Failed>

6 Press the [Cal Complete] key to end the calibration.

⚠ CAUTION

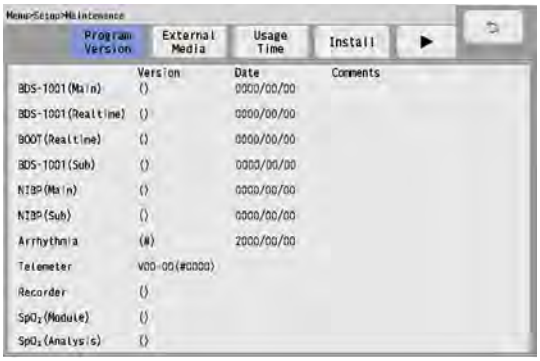
- Perform the calibration 5 minutes after turning ON the power on the HCP-110.
- Do not disconnect the sampling tube during calibration. If the sampling tube is disconnected, calibration will cease.
- Conduct CO_2 calibration for the following case.
  - When the accumulated measurement time exceeds 1,200 hours from the first use. However, if the first calibration was performed before the accumulated measurement time reaches 720 hours, another calibration is required when the accumulated measurement time exceeds 1,200 hours from the first calibration.
  - When 12 months has elapsed or the accumulated measurement time has exceeded 4,000 hours from the previous calibration.
  - When $EtCO_2$ measurement is not stable or accuracy is degraded compared with other measuring device.
  - When the patient monitor was not used for a while, or when $EtCO_2$ was not measured for a while.
  - When a message, "Calibrate the CO_2 unit (HCP-110)" or "The periodic calibration of the CO_2 unit (HCP-110) is approaching" is displayed at power ON.
- Dispose of calibration gas according to the regulation of each medical institution.

Program Version

On the program version screen, software version of the main unit and modules can be verified.

1 Press [Menu > Menu List > Setup > Maintenance > Program Version].

- The software version screen will be displayed.



- The software version, boot version, date, comment installed on the device will be displayed.

NOTE

- Depending on the construction of the device such as without recorder type, version for some items will not be displayed.

Software Install

The software can be updated on the install screen.

1 Press [Menu > Menu List > Setup > Maintenance > Install].

- The software install screen will be displayed.

NOTE

- Users cannot perform the software update process.
  Refer to your nearest service representative.

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