Patient Monitor

DYNASCOPE 1000 Series
BDS-1001 System

Ver. 02

Operation 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 02.

⚠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.

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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

Indications for Use

- Intended Users
  Medical doctor or qualified healthcare professionals under instruction by medical doctor.
- Intended Patient Population
  - Age: Adult, Child, Infant, Neonate
  - Gender: Male, Female
- Application (Medical Conditions)
  - Patient selection criteria
    Patients whose designated electrodes and sensor can be physically used.
  - Indications
    This device is intended for measuring parameters such as ECG, respiration, NIBP, pulse rate, SpO_2, CO_2 and monitors patient condition by displaying/printing the measurement data on this device or central monitor and generates alarm as required. This device is intended for monitoring one patient, and it is not intended for monitoring multiple patients.
  - Contra-indications
    - Use with other medical devices
      - Do not use this device in magnetic resonance imaging (MRI) environments. 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.
      - Never use this device in hyperbaric oxygen therapy device. It may cause an explosion or fire.
    - How to Use
      Never use this device in an atmosphere containing flammable anesthetic gas or high oxygen concentration. It may cause an explosion or fire.
  - Warnings
    See WARNING in this manual.

Clinical Benefits

The clinical benefits of the BDS-1001 system include:

- Measuring and displaying the patient's vital signs and generating the alarms if necessary to enable the medical professionals to be aware of changes in the patient's condition.
- Recording and displaying measurement data and alarm results to be useful for the patient follow-up.

Copyright

(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.

(1) Fukuda Denshi Co., Ltd., Head Office

3-39-4 Hongo, Bunkyo-ku, Tokyo 113-8483 Japan
Tel: +81-3-5684-1455 Fax: +81-3-3814-1222
E-mail: info@fukuda.co.jp
Website: https://fukuda.com/

(2) Fukuda Denshi USA, Inc.

17725-C NE 65th Street Redmond, WA 98052 USA
Toll Free: +1-800-365-6668
Local: +1-425-881-7737
Fax: +1-425-869-2018

- 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.

Cybersecurity

❑Problem Occurrence

- Fukuda Denshi periodically checks the vulnerability of this device.
- If you notice any issue, contact (☞"Contact" P iii).

❑How to Respond upon Detection of a Vulnerability or Incident

- Backup Data Management
  The administrator of this device should check that the device settings are correct. Also, backup the device settings and patient information periodically by following the procedure explained in the operation manual of this device.
  Before backup, use the antivirus software to make sure that the storage media (USB memory device, SD card, etc.) is not infected with a virus.
  After backup, use the antivirus software again to make sure that the storage media (USB memory device, SD card, etc.) is not infected with a virus.
- Recovery
  For more details, contact your local Fukuda Denshi service representative. Fukuda Denshi will return the device to the customers after verifying the operation.
- Restoring from the Backup Data
  The administrator of this device should restore the settings from backup data saved on the storage media by following the procedure explained in the operation manual of this device.
  Before restoring, use the antivirus software to make sure that the storage media (USB memory device, SD card, etc.) is not infected with a virus.

❑Interfaces Capable of Communicating Externally

There are following interfaces on this device.

- NFC Antenna (Unsupported function)
- Serial Connector (COM)
- SpO_2 Connector
- ECG Connector (Only for model with ECG optional function)
- NIBP Connector
- $EtCO_2$ Connector (Inside $EtCO_2$ cover)
- Recorder Connector (Inside recorder cover, For optional recorder unit)
- USB Connector (USB1 to USB3)
- Status Input/Output Connector
- SD Card Slot (Inside maintenance cover)

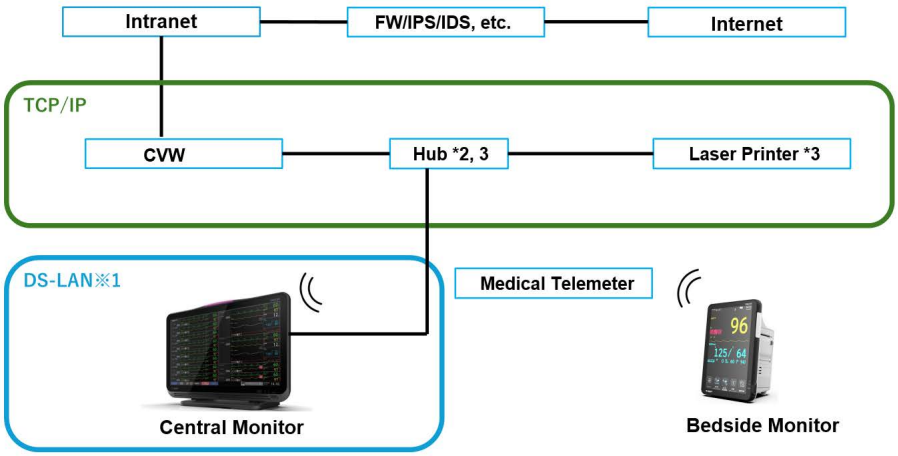
For details, see ☞"Names of Parts and Their Functions" P2-1.

❑Inquiries Regarding Cybersecurity

Refer also to “Customer Security Documentation” of this device. For details, contact your nearest service representative.

❑Recommended Operating Environment

The following network configuration is recommended. For details, refer to “Security Enhancement” and “Instructions for Connecting to a Network” described below.



*1: Do not directly connect to the Internet, and use the properly set FW/IPS/IDS, etc.
*2: Locate the hub in the locked room or distributing board. To prevent improper connection, cover and lock the unused LAN ports.
*3: Use the device recommended by Fukuda Denshi.

❑Security Enhancement

- On the hospital network (wired LAN network inside the hospital), medical devices of various manufacturers, hospital PC, servers, printers, etc. are connected with TCP/IP packets. To prevent unauthorized connection or operation of the connected devices such as hubs, make sure to take sufficient security measures of the server room.
- To prevent intrusions from the Internet into the hospital LAN, it is strongly recommended to install a firewall or IPS/IDS device between the hospital LAN and the Internet.

❑Instructions for Connecting to a Network?

- The PCs connected to the hospital network should always install a security software after updating to the latest software version. If a PC is infected with malware (malicious software), it may lead to attacks not only on the PCs in the hospital network, but also on surrounding network-connected devices, including this device.
- For more secure communications, consider implementing encrypted communications in the closed network within the hospital where this device is installed. If encrypted communications are implemented, an encryption device is installed between this device and the opposing device. For installing an encryption device, contact your local Fukuda Denshi service representative.
- The communication functions that are not used should be set to default settings under [Menu > Setup > Initial Settings > External Device] and [Menu > Setup > Initial Settings > System]. ☞Maintenance Manual "Initial Settings (External Device)" P6-5, ☞Maintenance Manual "Initial Settings (System)" P6-6
  When constructing a network, check again the settings.
- When using a DS-LAN or TCP network, physically block unused HUB ports with a port lock (with key) to prevent unintended device connections.

❑Security Related Residual Risks

- If residual risks related to the cybersecurity of this device is identified, you will be contacted by Fukuda Denshi.

❑Stopping Use

- When stopping use of this device, contact your nearest service representative in order to clear the internal memory and initialize the configuration information. When you decide to stop using this device, cut off all

communications with external devices.

❑Security Updates

- When security updates become available for this device, you will be notified by Fukuda Denshi.

About This Manual

Expression Used in This Manual

❑Trademarks

- SD : SD Logo is a trademark of SD-3C, LLC.
- Other company and product names used in this manual are trademarks or registered trademarks of respective companies.

❑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, 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.
	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

- Contact your local Fukuda Denshi service representative if this device packaging is damaged, unintentionally opened or exposed to environmental conditions outside of those specified.
- 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.
- When defibrillating, pay attention that the thermometer connected to this device does not touch the patient.
- 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.
- 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.

- 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. 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.
- The alarm operation differs between the bedside monitor and central monitor. Refer also to the operation manual of the central monitor, and set the alarm correctly.

⚠ 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 Thermometer

⚠ CAUTION

- When connecting a thermometer to this device, use only the thermometer and connection cable specified by Fukuda Denshi.
- Check that this device and the thermometer are connected properly.
- When connecting the cable, make sure that the power of this device and the thermometer are turned 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.

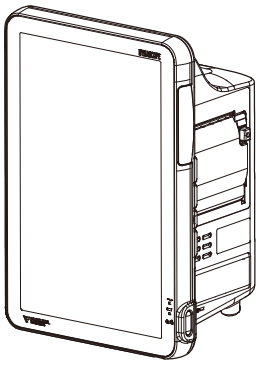
Note 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

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 General Description of the Device

Composition of the System

Depending on the SpO_2 unit type and telemetry function availability, there are following model types for the BDS-1001 system.
Option units can be also used.



Model Type	Fixed Parameter	ECG/Impedance Respiration	SpO_2 Unit	Telemeter
BDS-1001EN	NIBP, Respiration	Yes	Medtronic	-
BDS-1001ENT		Yes	Medtronic	Yes
BDS-1001EM		Yes	Masimo	-
BDS-1001EMT		Yes	Masimo	Yes
BDS-1001N		-	Medtronic	-
BDS-1001NT		-	Medtronic	Yes
BDS-1001M		-	Masimo	-
BDS-1001MT		-	Masimo	Yes

The last 3 digits of the model type indicates the following.

BDS-1001□□□
(1) (2) (3)

(1)	ECG Function	Yes: E
(2)	SpO_2 Type	Medtronic: N / Masimo: M
(3)	Telemetry Function	Yes: T

Optional Gas Unit

Model Type	Item	Note
HCP-110	CO_2 Gas Unit	NanoMediCO$_2$ (CO_2 I/F connection, all-in-one type)

Option Unit

Model Type	Item	Note
HR-110	Recorder Unit	50 mm roll paper, 3 waveforms printing

The BDS-1001N (N/EN/NT/ENT), BDS-1001M (M/EM/MT/EMT) models are collectively called "BDS-1001N"

and "BDS-1001M".

Measuring Parameters of SpO_2 Units

Model Type (Generic Name)	SpO_2 Unit	Measuring Parameters
BDS-1001N	Medtronic	SpO_2, PR
BDS-1001M	Masimo	SpO_2, PR, PI

Features

- Various displays such as trend and ventilator can be selected according to monitoring conditions. The operation can be performed with the touch panel. Also, frequently used keys can be programmed as user key.
- The vertical design is space-saving, and the high-resolution WXGA (1280 x 800) LCD enables smooth waveform display.
- The alarm indicator notifies the alarm with different flashing patterns corresponding to the alarm level so that the users can easily identify the alarm level of the generating alarm.
- The device can be operated with a battery (optional).
- 3ch recorder unit (optional) can be additionally used.
- By connecting the specified thermometer to the general purpose serial connector, temperature measurement can be monitored.
- 28 types of arrhythmia can be analyzed.
- This system uses pulse oximetry to measure and display functional oxygen saturation in the blood. There are model types with different built-in SpO_2 modules, which are Medtronic, Masimo.
- By connecting the CO_2 Gas Unit (HCP-110), CO_2 concentration can be measured.
- SI (Shock Index) and RPP (Rate Pressure Product, Double Product) can be displayed. RPP is an index to evaluate the condition of cardiac function.
- EWS (Early Warning Score) which is a diagnostic support function useful for predicting sudden changes in patients is provided.
- Inflationary NIBP measurement allows short and less stressful measurement.

Menu Configurations

The menu configuration of this device is as follows.

❑Menu Screen

There are 2 types of menu display for this device, menu list and quick menu.

- Menu List

The menu list is displayed when quick menu display is OFF.
The menu screen is a group of shortcut keys to jump to each menu.
The menu is composed of the following 5 groups and can be accessed from the menu screen.

Function Groups	Displayed Menu
Patient Admit/Discharge	Admit/Discharge
Alarm	Alarm Setup: Basic, Arrhy., ST, Detail Setup

Function Groups	Displayed Menu
Parameter	Parameter Setup: ECG, RESP, NIBP, SpO_2, TEMP, CO_2, Scoring, RPP, SI
Function	Function Setup: Graphic Trend, Tabular Trend, Recall, Full Disclosure, Zoom Wave, MPDR, Alarm History
Setup	System Configuration Setup: Display Config., Manual Printing, Auto Printing, Tone/Volume, Time/Date, Color, Brightness, Night Mode, Initial Settings, Maintenance

REFERENCE

- The items to be displayed on the menu screen can be customized by groups. However, the items for "Initial Settings" and "Maintenance" cannot be customized.

- Quick Menu (☞"Quick Menu" P3-15)

The quick menu is displayed when quick menu display is ON.
The quick menu is a group of shortcut keys to jump to each window. 5 shortcut keys can be set.
The [Menu List] key display is fixed. Pressing the [Menu List] key will display the menu list explained above.

REFERENCE

- 5 items to be displayed on the quick menu can be customized.
- 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.

❑Patient Admit/Discharge

Admit/Discharge	Mode Selection
	ID, Name, Class., Sex, Birth Date, Age, Blood (ABO, Rh), Pacemaker, Admit Date/Time, Height, Weight, BSA
	Monitor Suspend
	Discharge

❑Alarm

Basic	The parameters to be displayed are selectable.
	Alarm Suspend, Mode Select, Resume All Alarm Sound
Arrhythmia	Alarm setup for each arrhythmia
ST	Alarm, Update Ref. Wave, Reference Point, Measurement Point
Detail Setup	Suspend Time, Silence Time, Alarm Silence, Alarm Sound Suspend, Status Alarm Control

❑Parameter

ECG	Arrhy. Learn, Arrhythmia Alarm Setup, ST Setup, Alarm Setup (HR, Ext Tachy/Ext Brady)
	Lead/Size, Optimize Size, Alarm Assist, HR/PR, Display ON/OFF
	Detail Setup Filter, Pacemaker Pulse, ECG Drift Filter, Synchronized Mark/Tone, Pace Pulse Mask Time, AC Filter, Pacemaker, ECG Waveform Display during Lead-OFF, Pacemaker Sens. Setting
RESP	Size, Common Setup (RR Synchronized Mark, RR Alarm/APNEA Source), Alarm Setup (RR, APNEA), Alarm Assist, Display ON/OFF
	Detail Setup Impedance Measurement, Impedance Detection Lead, Impedance Detection Level

NIBP		NIBP Auto Mode, Alarm Setup (NIBP S, M, D), Alarm Assist, Cancel Error, Oscill. Print, DynaAlert
		Detail Setup Patient Classification, PR Display, NIBP Erase Time, Measure at Alarm, Quick Measurement, Sight Inflation, End Tone, Auto Mode with Start/Stop Key, Time Display, Periodic Measurement Starting Time, Oscill. Print, Target Inflation Value, Measurement Mode, MAP, Dyna Alert
SpO_2		Size, Alarm Setup (SpO_2, ExtSpO_2, PR_SpO_2), Alarm Assist, HR/PR, Display ON/OFF
	BDS-1001N	Detail Setup Alarm during NIBP, Synchronized Mark/Tone, Second Alarm, SpO_2 Averaging
	BDS-1001M	Detail Setup Alarm during NIBP, Synchronized Mark/Tone, SpO_2 Averaging, Pulse Sensitivity, FAST SAT, PI Display, Signal IQ Wave
CO_2		Scale, CO_2 Calibration, Alarm Assist, Display ON/OFF, Suspend, Alarm Setup (InspCO_2, EtCO_2)
		Detail Setup EtCO_2 Peak Duration
Scoring		Score Calculation, History, Setup
RPP		HR/PR, Alarm Setup (RPP)
SI		HR/PR, Alarm Setup (SI)
TEMP		TEMP Erase Time

❑Function

Graphic Trend	Latest Data, Alarm Review, Setup, Print, Range
Tabular Trend	Latest Data, Alarm Review, Setup, Print, Interval
Recall	Latest Data, Display Selection, Setup, Delete Sel.
Full Disclosure Waveform	Latest Data, Alarm Review, Search, Alarm Display, Setup, Print
Zoom Wave	Latest Data, Alarm Review, Meas., User Selection, Print, Setup, Delete
Alarm History	Latest Data, Display Selection, Print
MPDR	Patient List, Search

❑Setup

Display Configuration	Meas. (Change, Alarm Limit Display), Wave (Change, Sweep Speed, Grid, Thickness), User Key
Manual Printing	Waveform Selection, Print Duration, Delay Time Common (QRS Classific., Speed, Print Calibration, Print NIBP Data, Print after NIBP Meas., Print Simple List, Auto Print List Data)
Auto Printing	Periodic Printing (Periodic Printing, Waveform Selection, Timer/Interval, Print Duration)
Tone/Volume	Alarm Sound (Vital, Status, Ventilator), Sync. Tone, Key Sound, Other
Time/Date	Time, Date
Color	Waveform/Numeric Data, User Key
Brightness	Brightness
Night Mode	Night Mode, Detail Setup (Volume, Display, Alarm Indicator)

❑Initial Settings

Alarm	-	Alarm System, Asystole, VF, VT Alarm, Suspend Arrhy. Analysis during Noise Interference, Lower Limit for Alarm Volume, Alarm Mute, Alarm Mute Reminder, Alarm Threshold Limit, Alarm Indicator, Alarm Level
Measurement	Unit	CO_2, BP, TEMP, ST, Height/Weight

	Other	NIBP Start 5min.early, MAP Calculation (NIBP), Synchronized Mark/Tone, HR/PR Source Priority, Score Mode
User I/F	Display/Print	Date Format, Printer Message Display, Waveform Size Display, Night Mode Cancel, Patient Name on the Information Display Area, Monitor Suspend Label, Monitor Suspend Timer
	Power ON/ Discharge	Check Discharge at Power ON, Discharge Mode, NIBP Resume Auto Mode by Manual Meas., Backup Setting at Power ON/Discharge
	Key Mask	Items not to be displayed on the menu screen can be selected, or all selections can be canceled.
	Operation	Auto Hide Window
	Quick Menu	Menu 1 to 5, Quick Menu, Menu Color, Selection
External Device	Sync. Sig Output	Sync. Signal Output, Signal Output, Output Logic, Pulse Width
	Magnetic Card	Data digits for each patient information
	COM Setup	COM Setup (Status II, COM)
	Status Output	Alarm Output: Alarm Level, Output Logic
System	Telemeter	Telemeter ON/OFF, Channel/Group ID, Telemetry Wave, CO_2(mmHg) Upper Limit of Transmission
	Bed Name	Room ID, Bed ID
	Other	AC Frequency, Search Patient ID
User Mode Registration		Registering/Changing/Initializing the User Mode, Link with Patient Classification
Administrator Setup	Key Lock	Key lock for each function can be set.
	Password Setup	Password for each administrator level can be registered/changed.

❑Maintenance

Maintenance	Program Version, External Media, Parts Usage Time, Install, Module Install, Test Menu

Chapter 2 Names of Parts and Their Functions

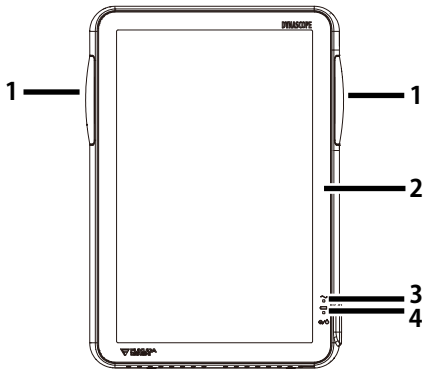
Names of Parts and Their Functions

WARNING

- Do not connect any device or cable not authorized by Fukuda Denshi to any I/O connector. If unspecified device or cable is connected, not only that this device cannot deliver its maximum performance, the device may be damaged and safety cannot be ensured.

Main Unit: BDS-1001

❑Front Side



1 Alarm Indicator
Lights or flashes when the alarm generates.

2 NFC Antenna (Unsupported function)
By holding the NFC compatible device near the antenna, communication can be performed.

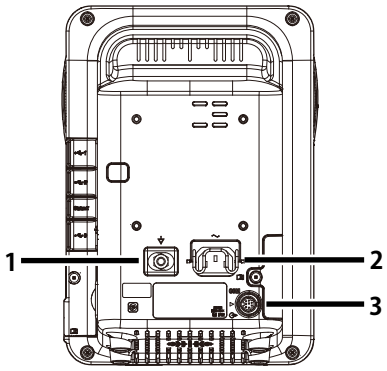
3 Power Supply LED
Indicates the power supply status. Light will be off when the AC power is not supplied to the monitor.
Orange: Standby mode
Green: In normal operation
Light Off: During battery operation (power cable is disconnected.)

4 Charge Status LED
Indicates the battery charging status.
Orange: Charging
Green: Charging is complete
Light Off: During battery operation, or when battery is not installed, or when battery charging is ceased (due to temperature, etc.)
Flash: Battery charging error (Orange)

NOTE

- If the battery charging LED flashes, battery charging error is occurring. Remove the battery and install it again. If the error persists, contact your nearest service representative.
- If the voltage inside the cell is high, charging may cease to protect the battery. In this case, battery charging LED will turn off. <Reinstall the battery.> will not be displayed. The battery can be continuously used, but if the periodic replacement period is expired, replace the battery.

❑Rear Side

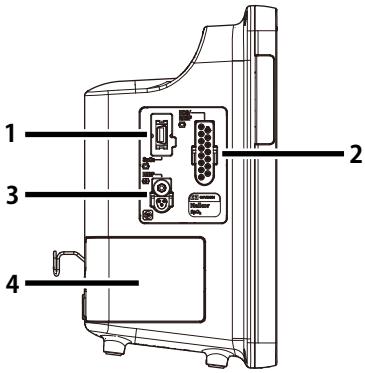


1 Potential Equalization Terminal
For equipotential connection.

2 Power Supply Connector
Connects the power supply cable.

3 Serial Connector (COM)
Connects the specified device.

❑Left Side



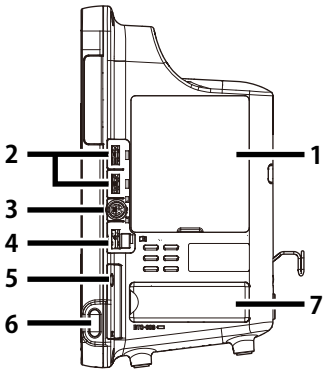
1 SpO_2 Connector
Connects the SpO_2 sensor, or relay cable (patient cable).

2 ECG Connector (Only for the model type with optional ECG function)
Connects the specified ECG relay cable.

3 NIBP Connector
Connects the NIBP air hose.

4 $EtCO_2$ Cover
Connects the optional CO_2 Gas Unit (HCP-110).

❑Right Side



1 Recorder Cover
Attaches the optional recorder unit (HR-110).

2 USB Connector (USB1/USB2)
Connects the USB memory.

3 Status Input/Output Connector (Status II)
Connects the specified device.

4 USB Connector (USB3)
Connects the USB memory for backup.

5 Maintenance Cover

⚠ CAUTION

- The full disclosure waveform data is saved on the SD card. When using with this device, insert the SD card and format it. If the SD card is not inserted, the full disclosure waveform data cannot be saved.

6 Standby Switch
Sets ON/OFF of the standby condition.

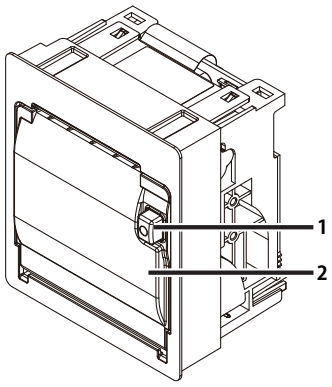
7 Battery Cover
Stores the specified lithium-ion battery (BTO-008).

Recorder Unit HR-110

❑Front Side

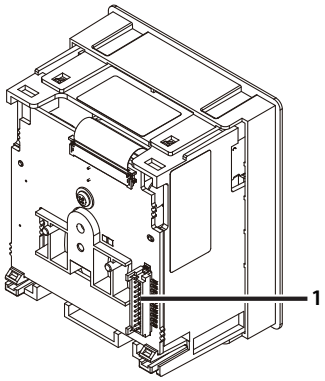
1 Open/Close Lever
Press the lever to open the paper holder.

2 Paper Case
Stores the printing paper.



❑Rear Side

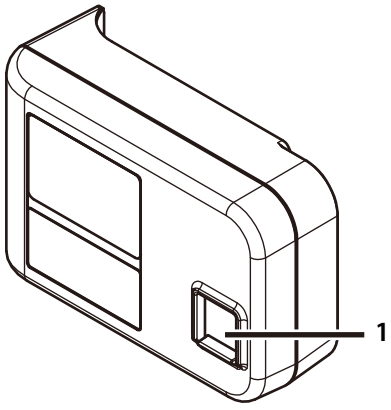
1 Recorder I/F Connector
Connects the BDS-1001.



CO_2 Gas Unit HCP-110

❑Front Side

1 Sampling Line Connector
Connects the sampling line.



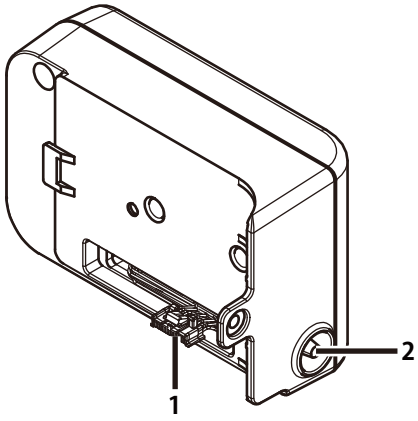
❑Rear Side

1 CO_2 I/F Cable

Connects to the BDS-1001.

2 Exhaust connector

Connects the gas exhaust system and exhausts sampling gas.



⚠ CAUTION

- Do not block the outlet as it may cause damage to the device.

Chapter 3 Operation Procedure and Screen Examples

Operation Procedure

Operations on this device are performed through the touch keys.

CAUTION

- Do not attach film to the touch panel. This may result in malfunction or failure.

Touch Key

❑General Key Control

1 Pressing the [Menu] key will switch the display with a pip sound.

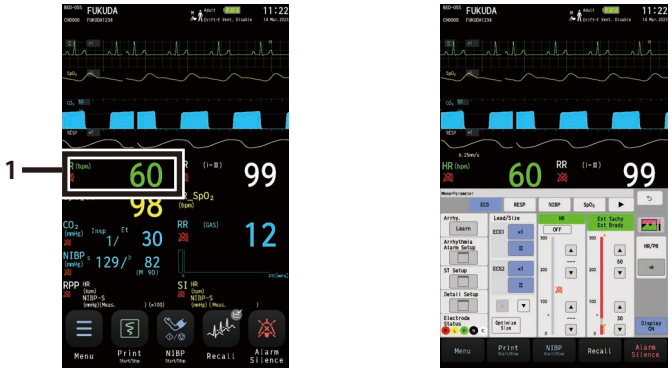
2 The touch key will respond by pressing any part of the key.

3 When [Menu] or patient data area, waveform area, numeric data area is pressed during displaying a window display such as menu display, the display will return to the home display.

REFERENCE

- The above is an example of the screen. (☞"To Configure the Display" P10-2)

❑Key Control for Each Parameter



1 Press the numeric data area. The setup window will be displayed.
The touch key will respond by pressing any part of the numeric data area.

2 When [Menu] or patient data area, waveform area, numeric data area is pressed during displaying a window display such as menu display, the display will return to the home display.

REFERENCE

- Frequently used touch keys can be programmed as user key. (☞"For Easier Use" P3-14)

Home Display

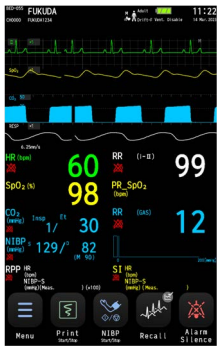
About the Home Display

The display can be configured according to the monitoring purpose.

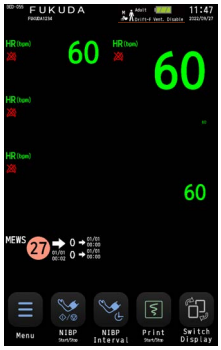
REFERENCE

- The display layout can be configured/registered according to the monitoring waveform and numeric data as necessary.
(☞"To Configure the Display" P10-2)

Display Example:



Waveform+Numeric



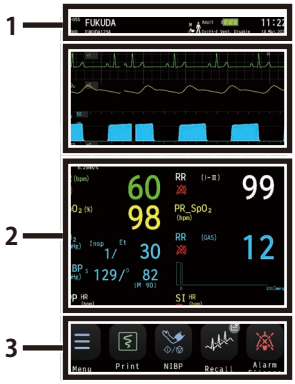
Numeric Only

On this system, 3 monitor modes and 3 display mode can be preprogrammed according to the monitoring purpose. By registering the configuration to each mode, the display configuration setups at admittance of patient can be simplified by just selecting one of the modes.
(☞"To Select the User Mode" P5-5)
It is recommended to program the display mode in rough classification such as patient's condition or monitoring purpose (ICU or ward), and if necessary, make specific setup for each patient.

Displayed Items

Other than waveforms and numeric data, patient name, alarm message, status message, etc. will be displayed on the screen.

❑Numeric Data, Waveform, Patient Name, etc.



1 Information Display Area

Room/Bed ID, Patient Name, Patient Class., current time, messages, etc., will be displayed.

2 Waveform/Numeric Data Area

3 User Key Area

❑Information Display Area

1 Telemetry Channel (For model types with a built-in telemeter transmission module.)

Displays the telemetry channel ID.

2 Room/Bed ID

Displays the 3-digit Room ID and 3-digit (000–999) Bed ID.

3 Patient ID

The patient ID set on the "Admit/Discharge" menu will be displayed.

4 Patient Name

The patient name set on the "Admit/Discharge" menu will be displayed.

5 Pacemaker Usage

When [Used] is set for "Pacemaker" on the "Admit/Discharge" menu, a pacemaker icon will be displayed.

6 Sex

"M" (Male) or "F" (Female) will be displayed.

7 Patient Classification

The patient classification (Adult, Child, Neonate) set on the "Admit/Discharge" menu will be displayed.

Adult **Child** **Neonate**

8 Set Mode

The currently selected monitor mode will be displayed.

9 Drift Filter

When "ECG Drift Filter" is set to [ON], <Drift-F> will be displayed.

10 Power Supply/Battery

The power supply status and battery charging status (when battery is installed) will be displayed.

11 Ventilator Connection Status

Displays the connection status of the ventilator.
<Vent. Comm.>: Communication with the ventilator is in progress.
<Vent. Offline>: Communication with the ventilator is interrupted.
<Vent. Disable>: Communication with the ventilator is disabled.

12 Date/Time

The current date (year, month, day) and time (hour, minute) will be displayed.

13 Message Area

When an alarm generates, a message will be displayed.

By pressing the message display area, the alarm message history can be verified.

⚠ CAUTION

- The actual battery operation time differs depending on the optional unit composition, NIBP measurement interval, recorder operating condition, etc. When <Charge the battery.> message is displayed, charge the battery.

❑Waveform Area

1 ECG

2 ECG Lead

3 ECG Size

The waveform size display of ECG, RESP, SpO_2 can be selected from [Numeric]/[Bar]/[Bar (10 mm)].
(☞Maintenance Manual "Display/Print Setup" P5-9)

4 ECG Filter, Filter Mode Display

AC: AC Filter ON,
DF: Drift Filter ON,
M: Monitor Mode, E: ESIS Mode,
D: Diagnosis Mode

5 SpO_2 Pulse Waveform

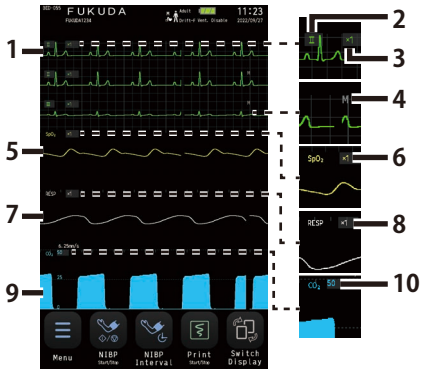
6 SpO_2 Pulse Waveform Size

7 Respiration Waveform

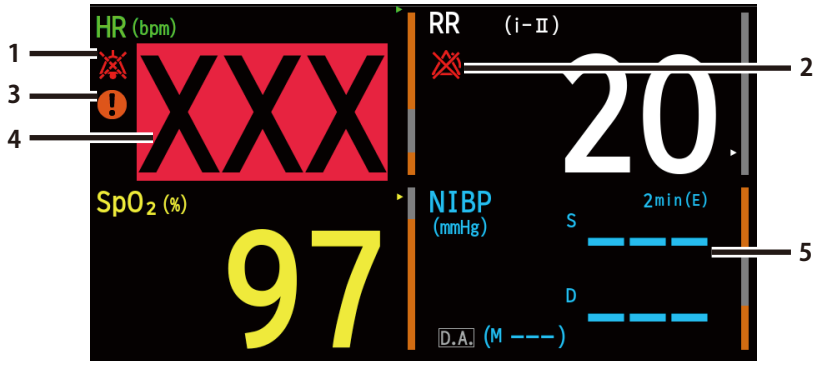
8 Respiration Waveform Size

9 CO_2 Waveform

10 CO_2 Waveform Scale



❑Numeric Data Box Display (for all parameters)



1 Alarm Silence Mark

Indicates that the alarm is silenced.

2 Alarm OFF Mark

Indicates that the alarm is set to OFF.

3 Message Icon

Indicates that an alarm message is present for that parameter.

4 Out of Measurement Range (XXX)

Indicates that the measurement is out of range.

5 Measurement Error (---)

Displayed when the measurement could not be performed due to causes such as ECG lead off, SpO_2 sensor off, and NIBP measurement error.

❑ Numeric Data Box Display (for each parameter)

REFERENCE

- The following numeric data box is displayed when the corresponding parameter is selected on the "Numeric Data Selection" window under "Display Config.". (☞"Numeric Data Selection" P10-1)

HR, HR/PR

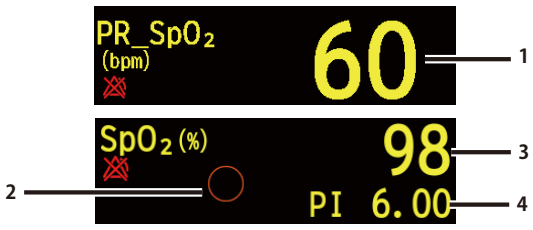
1 HR/PR Synchronization Mark

When HR or PR according to the setting of "Synchronized Mark/Tone" is detected, HR/PR synchronized mark will be displayed inside the corresponding numeric data box.

2 HR/PR Value

The HR/PR value will be displayed. When the value exceeds the measurable range, "xxx" will be displayed.

SpO_2



1 Pulse Rate

The pulse rate is displayed. When the value exceeds the measurable range, "xxx" will be displayed.

2 Second Alarm Indicator (Medtronic Only)

When the second alarm is set, the second alarm indicator is displayed.

3 SpO_2 Value

The arterial oxygen saturation will be displayed.

4 PI Value (Masimo)

The perfusion index will be displayed.

VPC

1 VPC (1 min)

The VPC rate for the last 1 minute will be displayed. <---> will be displayed during arrhythmia learning.

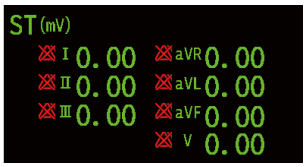
2 Pace Beats (1 minute) / Total Beats (1 minute)

Pace beats and total beats for the last 1 minute will be displayed. <---> will be displayed during arrhythmia learning.

ST

ST Level

The ST value for each lead can be displayed in the ST data box.
For the following case, "---" will be displayed.



- Learn
- During lead-off condition
- When "N" or "S" is not detected for QRS within 30 seconds.
- When reference waveform is not set for ST measurement.

Respiration

1 RR Source

The RR measurement source will be displayed. A detection lead (I/II) will also be displayed for the impedance measurement.

2 RR Synchronized Mark

When the respiration of the set RR source is detected, a synchronized mark will be displayed inside the corresponding numeric data box.

3 Respiration Rate

The respiration rate will be displayed. When the value exceeds the measurable range, "xxx" will be displayed.

When the impedance measurement is set to OFF, impedance RR will not be displayed.

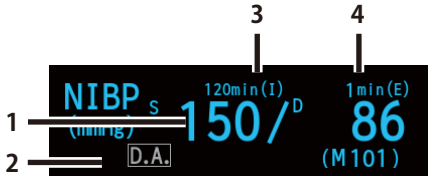
NIBP

1 NIBP Value/Cuff Pressure

The NIBP measurement value (SYS / DIA / MAP) will be displayed.

The mean NIBP display can be set to ON or OFF on the NIBP setup menu. The value will be displayed as "---" when the preprogrammed NIBP erase time has elapsed.

During measurement, a cuff pressure (CP) will be displayed.



2 Dyna Alert Message (BDS-1001N only)

This message will be displayed when the Dyna Alert is effective.
The detailed message will be displayed on the NIBP setup screen.

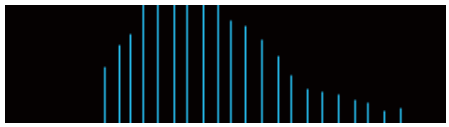
3 NIBP Measurement Interval

The NIBP measurement interval will be displayed.

4 Elapsed Time/Measured Time

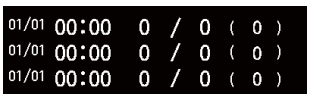
The elapsed time or measured time will be displayed.
The display can be selected under [Menu > Parameter > NIBP > Detail Setup > Time Display].

5 Oscillation Graph



The horizontal axis in the graph shows the cuff pressure, and vertical axis shows the pulse amplitude with reference to maximum pulse amplitude.

6 NIBP List



The NIBP list of the latest 3/6/9/12/18 data and measured date/ time will be displayed. The number of displaying data depends on the size of numeric data box.

Temperature

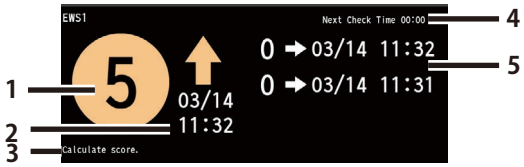
The temperature value measured by the specified electronic thermometer will be displayed. The time which the temperature data was acquired from the thermometer will be also displayed. The measurement data will be erased after the set duration. The measurement unit can be selected from °C /°F under [Menu > Menu List > Setup > Initial Settings > Meas. > Unit].

$EtCO_2$ / $InspCO_2$

$EtCO_2$ / $InspCO_2$ Value

The end-tidal CO_2 concentration and inspiratory CO_2 concentration measurement value will be displayed. The measurement unit can be selected from mmHg / kPa / % under the "Initial Settings" menu.

Scoring



1 Aggregate Score

The aggregate score will be displayed.

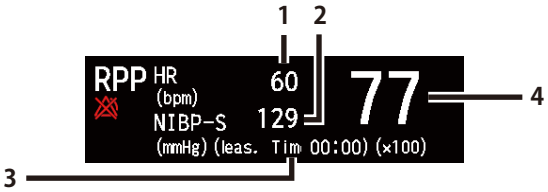
2 Calculated date/time of the score will be displayed.

3 Messages will be displayed.

4 The estimated date for recalculating this score will be displayed.

5 History of the score will be displayed.

RPP



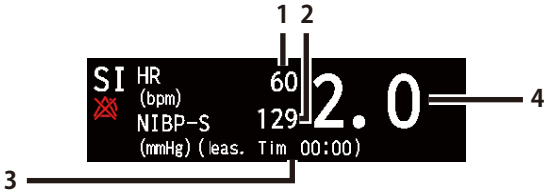
1 HR/PR value at the calculated time of RPP will be displayed.

2 Systolic blood pressure value at the calculated time of RPP will be displayed.

3 Calculated time of RPP will be displayed.

4 Calculated value of RPP will be displayed.

SI



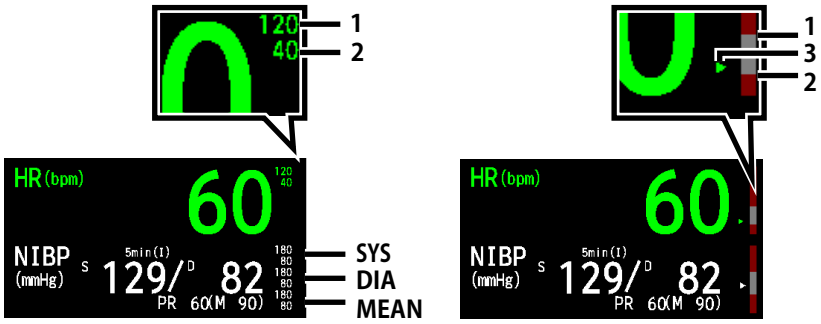
1 HR/PR value at the calculated time of SI will be displayed.

2 Systolic blood pressure value at the calculated time of SI will be displayed.

3 Calculated time of SI will be displayed.

4 Calculated value of SI will be displayed.

❑Alarm Limit Display



The alarm limit can be displayed beside each numeric data. The display type can be selected from [Graph] / [Numeric] / [OFF] for "Alarm Limit Display" under [Menu > Menu List > Setup> Display Config.].

If ON is selected for the individual alarm, the alarm limit will be displayed.

The upper and lower limit will be displayed at upper and lower row respectively.

For NIBP, each alarm limit of systolic BP (SYS), diastolic BP (DIA), mean BP (MAP) will be displayed from the top.

1 Upper Alarm Limit

2 Lower Alarm Limit

3 Current Measurement Value (SYS)

NOTE

- The alarm limit for the parameter with the alarm turned OFF will not be displayed regardless of this setup.
- If the alarm limit display for BP is [Graph], systolic value will be displayed.
- Depending on the numeric data box type, alarm limit may not be displayed.
- The alarm limit for the parameter with the alarm turned OFF will not be displayed regardless of this setup.

❑Displayed number of waveform and numeric data

Maximum Displayed Waveforms	Display Duration (25 mm/s)	Maximum Displayed Numeric Data Boxes
7	5.4 sec.	18

Numeric data and waveform can be displayed in desired location on the display area (9 rows x 2 columns). Up to 7 waveforms and 18 numeric data can be displayed. Refer to *** 'Display Configuration' on page 1 *** for display configuration setting.

Description of the Display

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

Graphic Symbols	Description
	Alarm OFF Indicates the alarm is OFF.
	Alarm Suspend Indicates the alarm is suspended.

Graphic Symbols	Description
	Alarm Mute Indicates the alarm is muted.
	Alarm Silence Indicates the alarm is silenced.
	Heart Rate Synchronization Mark Flashes synchronizing to the heartbeat.
	Respiration Synchronization Mark Flashes synchronizing to the inspiration.
	Message Icon Indicates that an alarm message is present for that parameter. Whether or not to display this icon can be selected under "Initial Settings".
	Key Lock Mark Indicates that the item requires a password to change the setting.
	Key Unlocked Mark Indicates that the key is unlocked.
	Indicates the remaining battery level. This icon (full green) indicates that the battery is fully charged. While charging, the corresponding battery level icon flashes.
	This icon (2/3 green) indicates that the battery is less than full, but still usable.
	This icon (1/3 yellow) indicates that the battery level is low and needs to be charged. The battery needs to be charged. Technical alarm will generate.
	This icon (1/3 Red) indicates that the battery is less than full. This icon flashes to indicate that the battery needs to be charged. Needs to be charged immediately. Technical alarm will generate.
	This icon (Red frame) indicates that the battery is almost empty. This icon flashes to indicate that the battery needs to be charged. Make sure to charge the battery immediately when this icon appears. Technical alarm will generate.
	This icon (Black frame with a slash) indicates that the battery is not installed. If AC power cable is disconnected during this state, power will not be supplied to the device. Pay attention when disconnecting the AC power cable.

Messages and Sound

This section explains about the message displayed on the home display.

There are vital alarm message and device status alarm message which will be displayed at the top of the home display.

The alarms are classified to Level S (top priority), Level H (high priority, urgent), Level M (medium priority, caution), Level L (low priority, status), and Level N, and the message will be displayed according to the priority of Level S > Level H > Level M > Level L > Level N.

The displayed messages will flash in red and white for Level S, red for Level H, yellow for Level M, blue for Level L, and white for Level N.

Alarm Priority, Level		Description	Color of Text/Background
Top Priority	S	Top Priority Alarm	Red, White/White, Red
High Priority	H	Life Threatening Alarm	White/Red
Medium Priority	M	Cautionary Alarm	White/Yellow
Low Priority	L	Status Alarm	White/Blue
Notification	N	Notification Alarm	White/Gray

⚠ CAUTION

- S alarm can be selected only when "Fukuda Tone" is selected.

Alarm sound can be selected from either "IEC Tone" or "Fukuda Tone". Each alarm sound will operate as follows.

IEC tone

Alarm Priority, Level		Description	Burst Interval
High Priority	H	Life Threatening Alarm	About 2.5 sec.
Medium Priority	M	Cautionary Alarm	About 4.5 sec.
Low Priority	L	Status Alarm	About 15.5 sec.

IEC tone complies to IEC60601-1-8.

Fukuda tone

Alarm Priority, Level		Description	Burst Interval
Top Priority	S	Top Priority Alarm	About 2.5 sec.
High Priority	H	Life Threatening Alarm	About 2.5 sec.
Medium Priority	M	Cautionary Alarm	About 4.5 sec.
Low Priority	L	Status Alarm	About 15.5 sec.

❑Vital Alarm Message

The vital alarm message is generated when a measurement exceeds the alarm limit, or when arrhythmia is detected.

1 Numeric Data Alarm Message

2 Arrhythmia Alarm Message

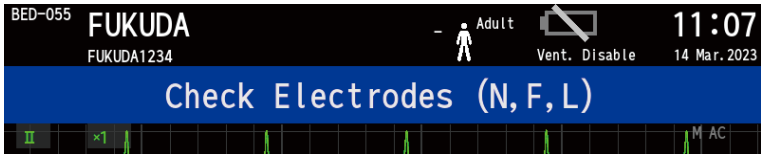
There are 2 types of vital alarm messages; numeric data alarm and arrhythmia alarm. If both alarms occur at the same time, the numeric alarm message and arrhythmia alarm message will be displayed alternately in 2-seconds intervals. The alarm messages will be displayed according to the priority. If the priority level is the same, the newer alarm message will be prioritized.

⚠ CAUTION

- 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.

❑Device Status Alarm Message

The device status alarm message will be displayed when proper monitoring cannot be performed.
The alarm messages will be displayed according to the priority. If the priority level is the same, the newer alarm message will be prioritized.



⚠ CAUTION

- If vital alarm and status alarm occur at the same time, the vital alarm will be displayed on the left and status alarm will be displayed on the right.

❑Numeric Data Box Message

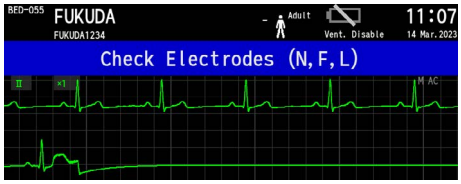
The measurement status of each parameter will be displayed inside the corresponding numeric data box.

❑Lead-Off Message

If the ECG electrodes used for HR measurement orarrhythmia analysis are detached, the status will be notified.

⚠ WARNING

- When <Lead Off> is displayed, HR alarm or arrhythmia alarm will not generate. 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.



❑Ventilator Alarm Message

When a ventilator is connected to this device, ventilator alarm and connection status alarm will be displayed on the device status alarm message area.

The alarm message with the higher alarm level will be displayed.

⚠ WARNING

- The ventilator alarm sound is set to OFF (factory default).
- The alarm sound can be turned ON under [Menu>Tone/Volume]. (☞"Tone/Volume" P10-7)

❑Ventilator Alarm Factor Message

For SERVO-i/s, SERVO-U/n/air, ventilator alarm factor if specified will be notified and displayed on the central monitor.

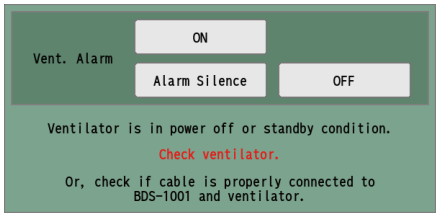
⚠ CAUTION

- Depending on the central monitor type and software version, ventilator alarm factor may not be displayed. For details of the central monitor type and software version, refer to your nearest service representative.
- The ventilator alarm factors are displayed only on the central monitor. These will not be

displayed on the bedside monitor.

❑Ventilator Disconnected Confirmation Window

A confirmation window will be displayed when a ventilator cable is disconnected from the device, or when the power of the ventilator is turned OFF.



[ON] will continue communication with the ventilator during ventilator alarm condition. Check the ventilator power and cable connection.

[Alarm Silence] will silence the ventilator alarm for 2 minutes. If the ventilator alarm condition remains after 2 minutes, the alarm will generate again.

[OFF] will disable the ventilator alarm until the ventilator connection status recovers.

⚠ CAUTION

- Check occasionally the communication status of this device and the ventilator.
- Verify that a ventilator alarm is not generated, and that the <Vent. Comm.> message is displayed.
  This confirmation window will be displayed until the displayed key is pressed or proper communication with the ventilator is resumed. When the communication is resumed, the window will automatically close.
  When disconnecting the ventilator and this device, make sure to select [OFF] on the confirmation window which will be displayed when the power of the ventilator is turned OFF, or when the cable is disconnected.

Window Display

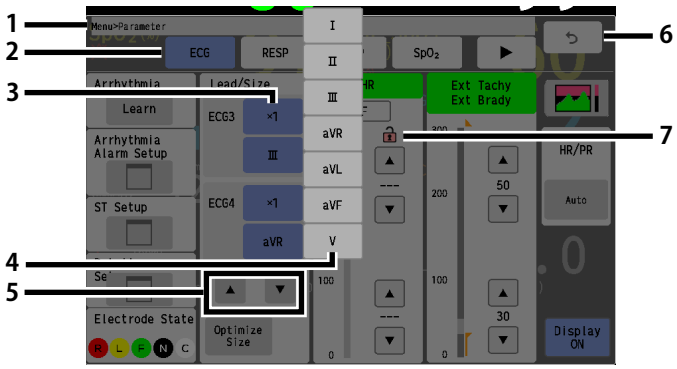
About the Window Display

The setup window will be displayed during the operation of this device.

To display the setup window, select from the menu, or press the numeric data area or user key.

Display

The common items on the window are explained below.



1 Hierarchical Level Display

The hierarchical level of the current window is displayed. The level is expressed using the ">" symbol.

2 Tab Display Area

These are the tabs to display the screens under the same menu level. The screens under the same menu level can be switched by one-touch operation of these tabs without returning to the main menu.

For example, to change the blood pressure scale after changing the ECG waveform size, it is not necessary to return to the main menu.
For the review screens, the date/time of each review data are linked which allows to switch the display of the tabular trend, graphic trend, waveform of the same date/time in one-touch operation.

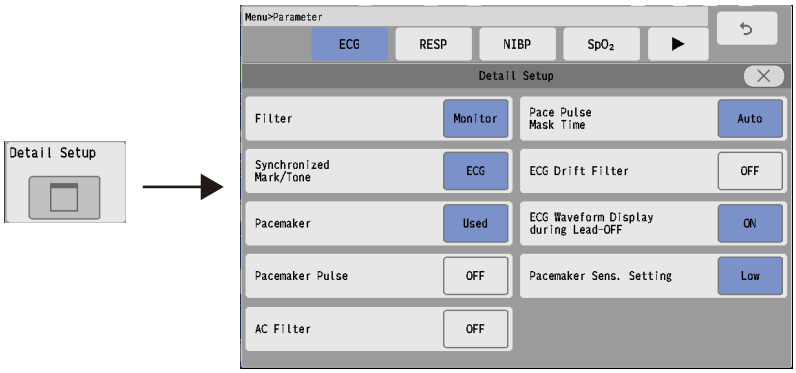
3 Setup Item

Most of the setups can be performed by selecting from the dropdown list.
The dropdown list will automatically close when a selection has been made.
Pressing the item again or selecting a different item will also close the dropdown list.

Some menu may display a subwindow to perform the setup.
To close the subwindow, press either the (X) key, [Home] or return key.

Pressing the key with the "[□]" icon will display another window. To return to the original display, press the (↩) key.

- Example of an item which displays another screen



4 Dropdown List

Select one from the displayed selection list.

5 Page Switch Key

This key will appear when the setup items or display data are on multiple pages.

6 Previous Display

Pressing this key will return the display to the previous window.

7 Key Lock Icon

Key lock icon will be displayed for the setup item that is locked.

To unlock the setup item, enter the password.

It will return to locked condition after 30 seconds if no key operation is performed.

- : Locked
- : Unlocked

NOTE

- The color of each key lock icon indicates its administrative level, and a higher level password must be entered to unlock it.

Operation Restriction

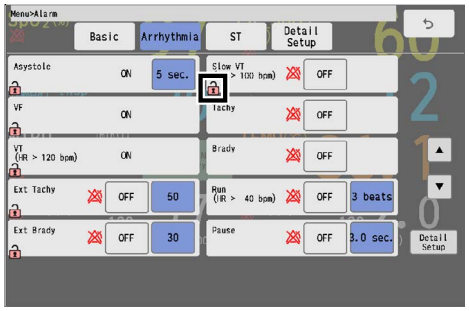
To restrict the operator to change the setup items, key lock function can be used.
(☞Maintenance Manual "Key Lock" P5-2)

For the items that are key locked, the settings cannot be changed unless the password is entered.

The unlocked condition will return to locked condition if operation has not been performed for about 30 seconds.

For the key locked item, 🔒 icon will be displayed.

When the password is entered and key is unlocked, the icon will change to 🔓.



NOTE

- There are 3 key lock levels.
- The level is distinguished by the color of 🔒 which are "Red (Manager) > "Yellow (Administrator)" > "Green (User)", and the upper level password can unlock the lower level key lock.

Procedure to Return the Display

❑To Return to Home Display

Press the waveform/numeric data area to return to the home display.

❑To Return to Upper Level Menu

The display will return to menu list by pressing the ⮌ key displayed on each setup window.

For Easier Use

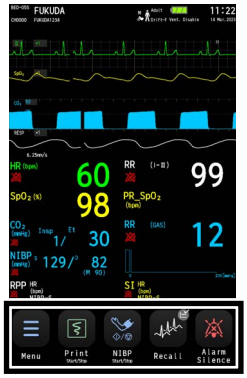
The user keys and menu can be customized according to the monitoring purpose.

REFERENCE

- From the preprogrammed user mode, the display configuration and alarm settings can be selected according to the monitoring purpose.
  (☞Maintenance Manual "User Mode Registration" P5-16)

User Key

The user keys can be customized according to the monitoring purpose.
(☞"To Configure the Display" P10-2)
Maximum of 5 user keys can be set.

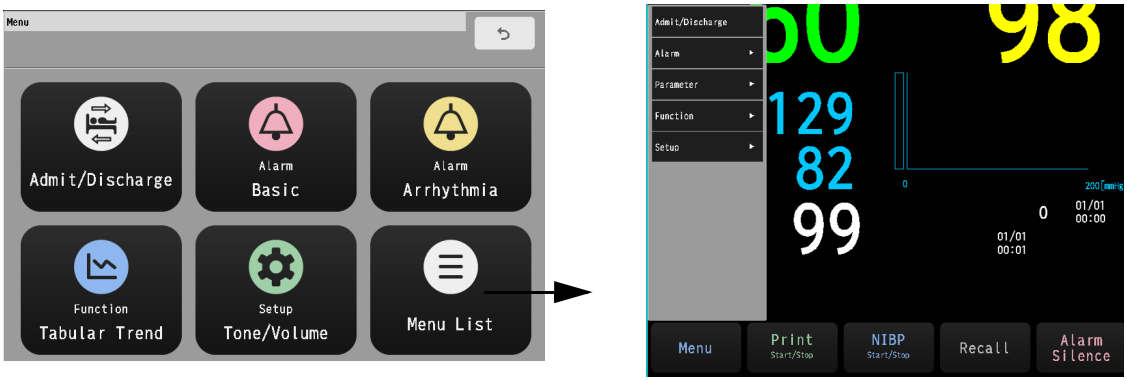


NOTE

- [Menu] position is fixed and cannot be changed.

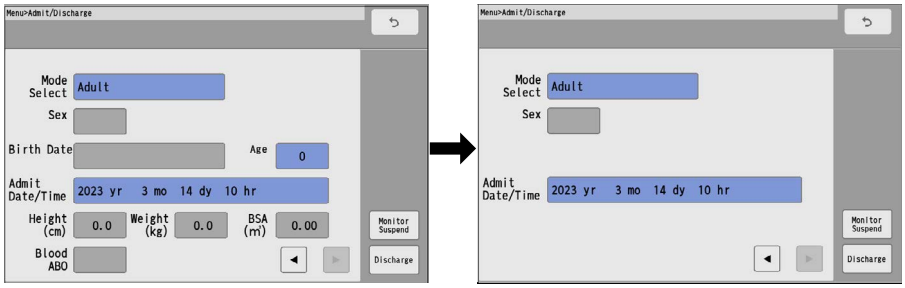
Quick Menu

5 frequently used menu keys can be displayed large with icons.
ON/OFF of Quick Menu to be displayed can be set under [Menu>Setup>Initial Settings>User I/F>Quick Menu].
(☞Maintenance Manual "Display/Print Setup" P5-9) The menu keys to be displayed on the Quick Menu can be set on the "Initial Settings" .
(☞Maintenance Manual "Quick Menu Setup" P5-15)
Pressing the [Menu List] key will display the menu list.



To Delete the Unnecessary Keys (Key Mask)

Unused keys, items, tabs can be masked.
(☞Maintenance Manual "Key Mask" P5-13)



Example on "Admit/Discharge" Screen

Chapter 4 Preparation

Daily Inspection

Before using the device, perform the daily inspection.
Take necessary measures for the items with the "NG" judgment, and use the device only if the judgments for all the items are "OK".

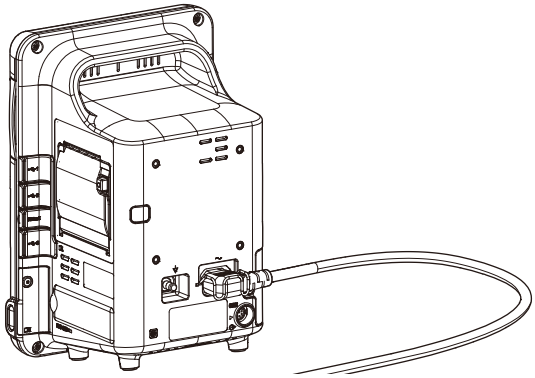
To Start Monitoring

This section explains about the procedure to turn the power ON and start monitoring.

⚠ CAUTION

- If not using the device for a long period, disconnect the power cable and lithium-ion battery pack.
- During transportation, firmly grasp the handle and make sure that the device does not fall. The operator may be injured or the device may be damaged.

1 If operating with AC power supply, verify that the power supply cable is properly connected to the main unit.
If operating with battery, verify that the lithium-ion battery (BTO-008) is properly installed in the main unit.
(☞Maintenance Manual "Installing the Lithium-Ion Battery Pack (BTO-008)" P1-4)



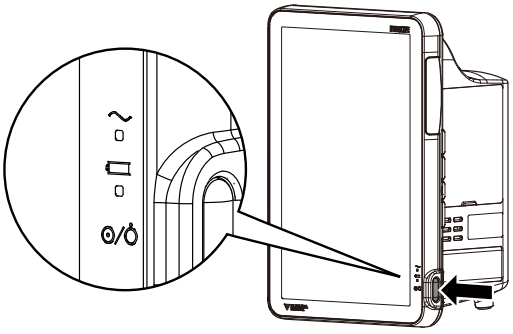
- When connected to the AC power source with battery installed, charging will automatically start.
  1 Rapid Charge (when the device is not in operation): within 6 hours
  2 Normal Charge (when the device is operating): within 12 hours

⚠ WARNING

- Do not connect a battery other than the lithium-ion battery (BTO-008).

2 Turn ON the standby switch on the main unit.

- The system will turn ON and monitoring will start.
- The power supply LED on the front side of the main unit will light.
  1 Power Supply LED
  Green: Power ON
  Orange: Standby Mode
  Light Off: During battery operation
  2 Battery Charging LED
  Green: Charging is complete
  Orange: Charging



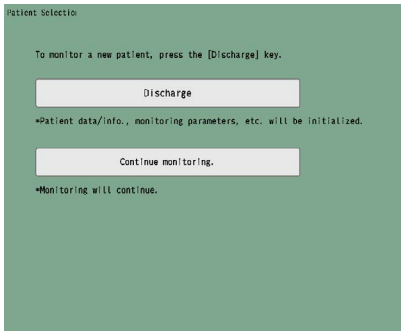
Light Off: During battery operation, when battery is not installed, or when battery charging is ceased (due to temperature, etc.)
Flash:Battery charging error

NOTE

- If the battery charging LED flashes, battery charging error is occurring. Remove the battery and install it again. If the error persists, contact your nearest service representative.
- If the voltage inside the cell is high, charging may cease to protect the battery. In this case, battery charging LED will turn off. <Reinstall the battery.> will not be displayed. The battery can be continuously used, but if the periodic replacement period is expired, replace the battery.
- 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.

Check Discharge When Start Monitoring a New Patient

The full disclosure waveform, graphic trend, tabular trend, recall, ST measurement data will be stored even after the monitoring is ceased by pressing the standby switch. If the previous data is remained when the monitoring is started by pressing the standby switch, a discharge confirmation window will be displayed.



❑Check Discharge

1 Select from [Discharge] / [Continue monitoring].

- [Discharge]: The previous data will be deleted.
- [Continue monitoring]: The monitoring will start with the previous data retained.

NOTE

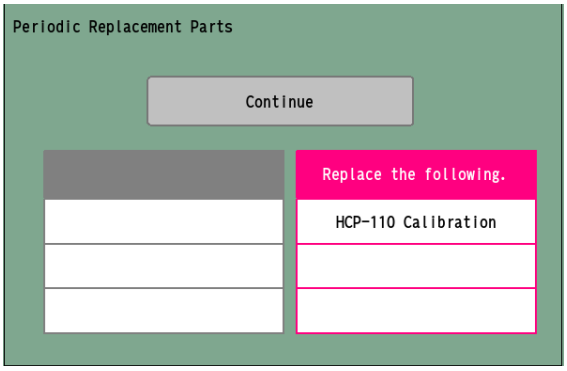
- If the standby switch was turned OFF for less than 30 seconds, the discharge confirmation screen will not be displayed. To perform the discharge procedure, press the [Discharge] key on the "Admit/Discharge" screen.
  (☞"Discharge" P5-4)
- To start monitoring a new patient, select [Discharge] and enter the new patient information on the "Admit/Discharge" screen.

REFERENCE

- Whether or not to display the discharge confirmation window can be selected.
  (☞Maintenance Manual "Power ON/Discharge" P5-10)

❑Periodic Replacement Message

When the periodic replacement period approaches for each part, a message will be displayed on the discharge confirmation window to notify the user.



REFERENCE

- The parts which the replacement periods are notified on the discharge confirmation window are NIBP unit and CO_2 Gas Unit (HCP-110).
  (☞Maintenance Manual "Periodic Replacement" P7-1)
- Even if the discharge confirmation window display is set to OFF, it will be displayed when the replacement period approaches.

To Stop Monitoring

This section explains about the procedure to stop monitoring.

1 Turn OFF the standby switch on the main unit.

▸ A standby confirmation message will appear.

2 Press [Standby].

3 The display will turn OFF and monitoring will stop.

⚠ CAUTION

- When ceasing the monitoring, set to standby mode, and then disconnect the power cable/ battery. If the power cable/ battery is disconnected in monitoring status, it may cause failure to the device.
- If the remaining battery capacity becomes extremely low during battery operation, monitoring will automatically stop.
- If not using the device for a long period, disconnect the power cable and battery.

NOTE

- If the power cable is disconnected, graphic trend, tabular trend, recall and ST display data will not be protected.

Clock Setup

This section explains about the time/date setup procedure.

⚠ CAUTION

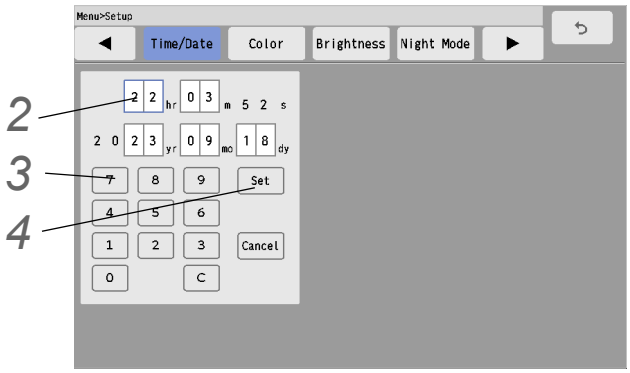
- If the time/date is not correctly set, or changed during monitoring, malfunction may occur

with the NIBP measurement, periodic printing, graphic/tabular trend 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.

1 Press [Menu > Menu List > Setup > Time/Date]. Or, press the time/date on the information display area at the upper part of the screen.

- The Time/Date setup window will be displayed.



2 Press on the area to perform the setup.

3 Use the numeric keys to enter the numerics.

4 Enter the current time/date and press the [Set] key.

- The entered time/date will be set. The number of seconds will be set to "00" sec.
- Press [Cancel] to cancel the time/date setup.

Installing the Recording Paper

⚠ CAUTION

♦Recording paper

- Use only "OP-050-02DR" for the recording paper.
  If the surface treatment and thickness of the recording paper are different, it may result in poor print quality.

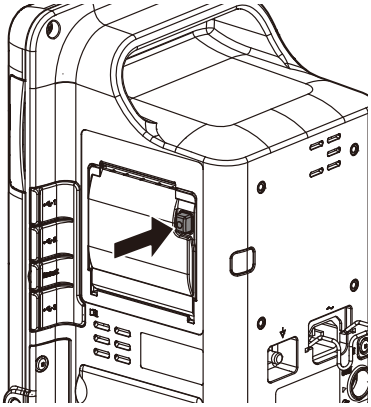
- Storing the Recording Paper
  Since the recording paper is thermal type, inappropriate storage may change the quality of the printed content, and make it illegible.
  When storing the recording paper, follow the precautions below.
  - Store in a place where light is shut off and avoid direct sunlight.
  - 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 superpose the papers until the diazo copy is completely dried.
  - Do not expose the paper to alcohol, hydrochloric acid, or ester ketone.
  - Avoid using adhesive agents other than water based glue.
- Installing the Recording Paper
  - When installing the recording paper, pay attention not to touch the thermal head or sensor. The temperature of those parts rises immediately after printing and may cause burn injury. Also, it may cause failure to the thermal head and sensor.
  - Do not operate the device with wet hands. Doing so may short the thermal head.
  - Do not touch the metal part of the recorder. Do not touch the patient while replacing the

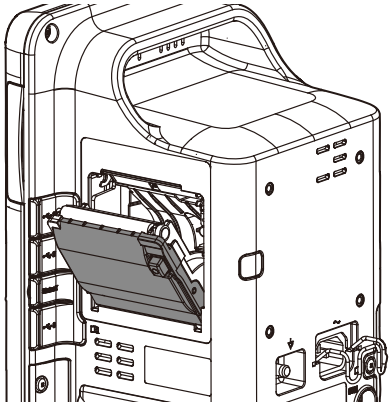
recording paper.

Install the recording paper with the following procedure.

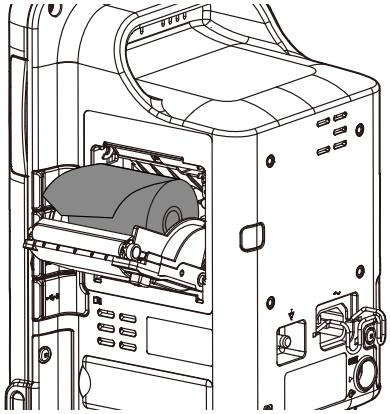
1 Press the paper holder open/close button.

▸ The paper holder will open.

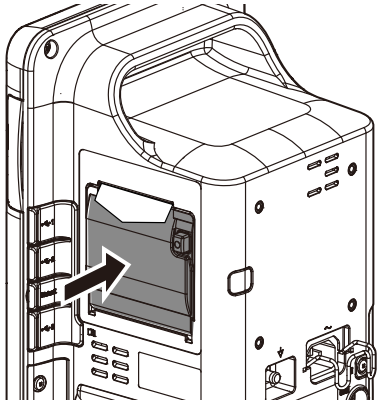




2 Set the paper. The outside surface of the paper is heat-sensitive.
Place the paper so that the "FUKUDA DENSHI" logo is outside and facing up.



3 Close the paper holder.



NOTE

- Push until it locks into place with a click sound.

Chapter 5 Admit/Discharge

On the "Admit/Discharge" menu, patient admit/discharge process and monitoring suspend setup can be performed.

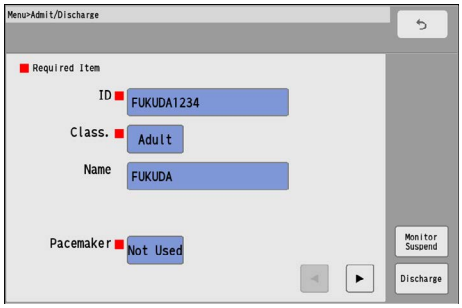
CAUTION

- 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.

To Display the "Admit/Discharge" Screen

1 Press [Menu > [Admit/Discharge].
Or, press the patient information area (patient ID, patient name, patient classification) on the upper part of the home display.

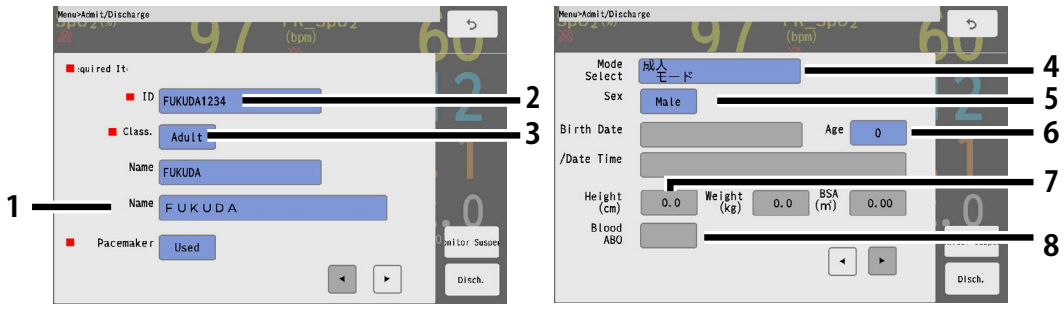
▸ The "Admit/Discharge" window will be displayed.



Admit

This section explains the admit procedure.
This menu allows entering of patient's name, ID, age, and selection of patient classification (adult, child, neonate) and pacemaker usage (used, not used) which affects the monitoring accuracy.

Entering the Patient Information



1 Patient Name
Up to 16 characters of alphabets, numbers, or symbols can be used. The entered name will be displayed on the home display.

2 Patient ID

Up to 20 characters of alphabets, numbers, or symbols can be used. After entering the ID, press the [Set] key.
If the [Set] key is not pressed, the entered ID will not be finalized.

3 Patient Classification

- The selected patient classification and icon will be displayed on the home display.

Adult  **Child**  **Neonate** 

- The patient classification affects the accuracy of NIBP measurement, HR measurement, and RR measurement. It also affects the delay time to generate the measurement data alarm.
- The alarm delay time is the function to prevent frequent generation of the measurement data alarm by holding the alarm generation for the duration of each delay time.
  The alarm delay occurs for HR/PR, RR, SpO_2, $EtCO_2$/$InspCO_2$, Tachy, Brady, Ext Tachy, Ext Brady.

		Adult	Child	Neonate
NIBP Measurement Range	SYS	30 mmHg to 280 mmHg	30 mmHg to 180 mmHg	30 mmHg to 130 mmHg
	MAP	15 mmHg to 235 mmHg	15 mmHg to 160 mmHg	15 mmHg to 100 mmHg
	DIA	10 mmHg to 200 mmHg	10 mmHg to 150 mmHg	10 mmHg to 90 mmHg
Heart Rate		0 bpm, 12 bpm to 300 bpm		0 bpm, 30 bpm to 300 bpm
Filter Mode	Monitor	0.5 Hz to 40 Hz		1.6 Hz to 40 Hz
	ESIS	1.6 Hz to 15Hz		1.6 Hz to 15Hz
	Diagnosis	0.05 Hz to 150 Hz		
Impedance Respiration		0.1 Hz to 1.5 Hz		0.1 Hz to 2.5Hz
Alarm delay time		5 sec.		0 sec.

⚠ WARNING

- The patient classification selection influences the precision of the QRS detection and NIBP measurement. Make sure the correct selection is made.
- The NIBP air hose corresponded to the set patient classification must be used to perform NIBP measurement. (However, if the patient classification is child, NIBP air hose for adult can be used.)

⚠ CAUTION

- When "Link with Patient Class." is set to [ON], and patient classification is changed, the monitor mode will change to the selected mode on the "Link Settings". (☞Maintenance Manual "To Program the User Mode" P5-17)

4 Monitoring Mode

Select the preconfigured monitoring mode.
(☞"User Mode" P5-5)

5 Sex

Select [Male] or [Female].

6 Age

There are two ways to enter the patient's age. One is to enter the birth date which will automatically calculate the age, and the other is to directly enter the age using the numeric keypad. If [Neonate] is selected for patient classification, age will be displayed in days.

7 Height/Weight

The BSA (Body Surface Area) will be automatically calculated from the height and weight.

8 Blood Type

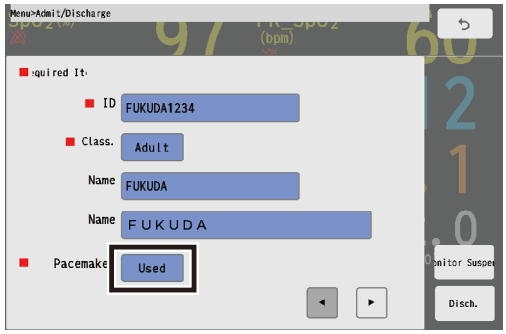
❑When Pacemaker is Used

WARNING

- The pacemaker usage setting influences the precision of the QRS detection and arrhythmia analysis. Make sure the correct selection is made.

If [Used] is selected for "Pacemaker", the monitor will detect the pacing pulse (pacemaker pulse) to perform the following process.

- The artificial pacemaker pulse will be displayed.
- When pacing waveform does not appear (pacing failure), erroneously detecting the pacemaker pulse as QRS will be prevented.
- The arrhythmia analysis will detect pacing beat as P (Pacemaker Beat) or F (Fusion Beat) to prevent erroneous judgment of VPC.



1 Press the key for "Pacemaker", and select from [Used]/[Not Used].

▸ When [Used] is selected, a pacemaker icon will be displayed on the home display.

Entering Patient Information from the Magnetic Card

By using the magnetic card reader, patient information can be entered from the magnetic card. The admittance process will speed up compared to manually entering each information.

NOTE

- To automatically enter the patient information from the magnetic card or barcode, it is necessary to perform the setup in advance.
  (☞Maintenance Manual "Using the Magnetic Card Reader" P4-9)

1 Read the data from the magnetic card or barcode.

▸ The acquired data will be displayed.

2 Press the [Change only patient info.]/[Cancel] key.

- [Change only patient info.] : Replaces the current patient information with the newly acquired information.
- [Cancel] : Cancels the acquired information.

NOTE

- Make sure the patient is discharged before replacing the patient information.
- The item which the information was not acquired from the magnetic card or barcode will be left blank. For the blank item, manually enter the information.

Discharge

This section explains about the discharge process.
This procedure will erase the patient name, ID, age, and past measurement data such as tabular / graphic trend, and recall.

Discharging Procedure

⚠ CAUTION

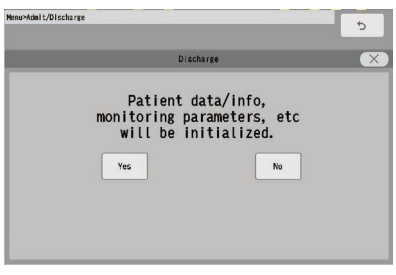
- If monitoring of new patient is started without discharging the previous patient, the measurement data of the previous and new patient will become mixed up on the recall and trend data.
- When the discharge process is performed, patient data such as recall and trend will be initialized. The parameter and alarm settings will be reset according to the settings made under [Menu > Menu List > Setup > 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 of the central monitor.
  (☞Maintenance Manual "Power ON/Discharge" P5-10)
- If the power is turned OFF or if the system enters into standby mode soon after the discharge procedure, the patient may not be discharged on the central monitor.
  If it is necessary to turn OFF the power or enter into standby mode after the discharge procedure, select [Standby] for "Discharge Mode".

NOTE

- Depending on the setting made for "At Discharge" under [Power ON/Discharge], some items may not be initialized.
  (☞Maintenance Manual "Power ON/Discharge" P5-10)
- The monitoring condition after discharge can be set on "Discharge Mode" under [Power ON/Discharge].

1 Press the [Discharge] key on the "Admit/Discharge" screen.

- The discharging confirmation message will be displayed.
- To cancel the discharge process, press the [No] key or close the discharge confirmation window.



2 Press the [Yes] key.

▸ The patient data, patient information will be initialized.

Data	Description
Patient Data	Data for graphic trend, tabular trend, recall and ST measurement will be erased. The settings for recall, tabular trend, graphic trend, vigilance list will remain.
Patient Information	Erases the data of patient name, ID, sex, age. The patient classification will not be initialized.
Measurement Condition	The learned arrhythmia waveform data will be deleted. The NIBP target inflation value will be initialized to the default value of each patient classification.

User Mode

This section explains about the user mode selection.
From the preprogrammed user mode, an appropriate user mode can be selected according to the monitoring purpose.

⚠ CAUTION

- The selected user mode will be stored even after the power is turned OFF or discharge process is performed.
  Before monitoring, make sure the current user mode is suitable for the patient's condition.
  (☞Maintenance Manual "User Mode Registration" P5-16)

REFERENCE

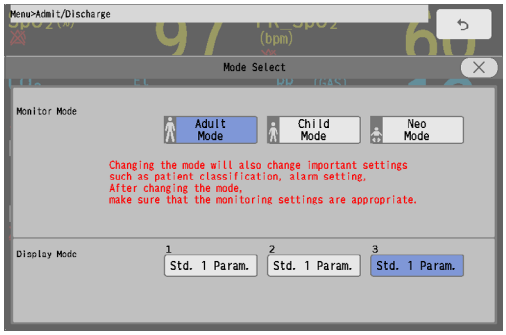
- For the user mode, up to 3 monitor modes of different alarm settings and display configurations according to the patient's age and monitoring purpose can be registered. Also, for temporarily changing the display configuration, 3 display modes of display configuration can be registered.
  (☞Maintenance Manual "User Mode Registration" P5-16)

To Select the User Mode

1 Press [Menu > Admit/Discharge > Mode Select (Adult, etc.)] Or, press the mode key on the information display area at the upper part of the screen.

▸ The "Mode Select" window will be displayed. (shown on right)

2 Select the monitor mode or display mode appropriate for the patient.



⚠ WARNING

- After changing the mode, make sure that the monitoring setting is appropriate.
  When the mode is changed, patient classification, alarm settings, etc. will be changed.

REFERENCE

- The selected user mode will be stored even after the power is turned OFF. If a new patient is admitted without changing the user mode, the monitoring will start with the previous user mode.

- The mode after the discharge process can be set under the [Menu > Menu List > Setup > Initial Settings > User I/F > Power ON/Discharge].
- Refer to "Setup Item/Default Value" for the default setting of each mode. (☞Maintenance Manual "User Mode Registration" P5-16)

Suspend Monitoring

This section explains about the monitoring suspend/resume function.
Monitoring suspend function can be used when a patient temporarily leaves the bed. If the monitoring is ceased by turning the power OFF, recall and ST data will be erased.
By using the monitoring suspend function, measurement, alarm, printing will be suspended but data and settings will remain, which allows to resume monitoring smoothly.
By using the monitor suspend label function, different labels in different colors according to the patient's destination can be displayed during the monitoring suspended condition.
To remind the user to resume monitoring, alarm will generate after the preprogrammed duration (15 min./30 min./1 hr/1.5 hr/2 hr) for "Monitor Suspend Timer".

REFERENCE

- The monitor suspend label can be set on the Initial Settings menu. (☞Maintenance Manual "Display/Print Setup" P5-9)

To Suspend Monitoring

❑When "Monitor Suspend Label" is not set:

1 Press the [Menu], "Admit/Discharge" icon, [Monitor Suspend] keys.

- The monitor suspend confirmation window will be displayed.
- If [Cancel] is pressed, monitoring will not be suspended and the confirmation window will close.

2 Press [OK].

- The screen will automatically return to the home display with "Monitoring is suspended" message and [Resume] key.
- On the home display, numeric data and waveform display will be suspended.

REFERENCE

- When the monitoring is suspended, telemetry transmission will cease. Note that the square wave will be displayed on the central monitor indicating the too far condition of the telemetry.
- The setting can be changed even when the monitoring is suspended.

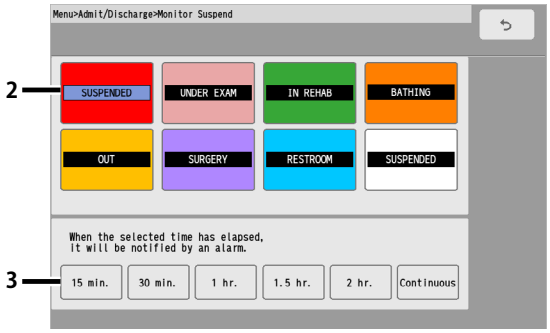
❑When Both "Monitor Suspend Label" and "Monitor Suspend Timer" are set

1 Press the [Menu], "Admit/Discharge" icon, [Monitor Suspend] keys.

- The "Suspend" screen will be displayed.

2 Select the label to be displayed during the monitoring suspended condition.

- The monitoring suspend duration selection will be displayed after selecting the monitoring suspend label.

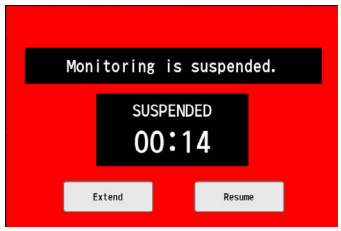


3 Select the monitoring suspend duration from [15Min.]/[30Min.]/[1Hr.]/[1.5Hr.]/[2Hr.]/[Continuous].
[Continuous] will start to suspend monitoring without setting the duration.

- Confirmation window to suspend monitoring will be displayed. (shown on right)
- Pressing the [Suspend] key will suspend the monitoring.

4 Verify that the monitoring is suspended on the home display.
The selected label with the set color will be displayed on the home display.

- On the home display, the time will start counting for the set duration.
- When the set duration completes, alarm sound will generate and the alarm indicator will light.



REFERENCE

- To extend the monitoring suspended duration, press [Extend] to display the timer selection.

❑When "Monitor Suspend Label" is set, but "Monitor Suspend Timer" is not set:

1 Press the [Menu], "Admit/Discharge" icon, [Monitor Suspend] keys.

- The "Suspend" screen will be displayed.

2 Select the label to be displayed during the monitoring suspended condition.

- A confirmation window will be displayed.
- Pressing the [Suspend] key will suspend the monitoring.
- The selected monitor suspend's message with the set color will be displayed on the home display.

To Resume Monitoring

⚠ CAUTION

- Resuming monitoring will also resume the suspended alarm.

1 Press the [Resume] key.

Chapter 6 Alarm Function

Alarm

To Set the Arrhythmia Alarm

The arrhythmia alarm can be turned ON or OFF, and arrhythmia detection level can be set.

WARNING

- Set the appropriate upper and lower alarm limit for each parameter according to the monitoring condition.
- When the system alarm is suspended, all the alarms 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.

1 Press [Menu > Menu List > Alarm > Arrhy.].

▸ The arrhythmia alarm setup screen will be displayed.

2 Set ON/OFF of each arrhythmia.

▸ [ON]: Arrhythmia alarm will generate.

▸ [OFF]: Alarm will not generate.

NOTE

- <Arrhythmia alarm OFF> will be displayed when the Asystole, VF, VT, Slow_VT, Tachy, Brady, Ext Tachy, Ext Brady, or HR alarm is OFF.
- If the patient classification is "Child" or "Neonate", Afib cannot be detected.

REFERENCE

- The arrhythmia detection level for tachycardia (Tachy), bradycardia (Brady), extreme tachycardia (Ext Tachy), extreme bradycardia (Brady) alarms link with the upper and lower alarm limit for HR/PR.
  - The tachycardia (Tachy) alarm generates when the value exceeds the HR/PR upper alarm limit. When the upper alarm limit is OFF, alarm will not generate.

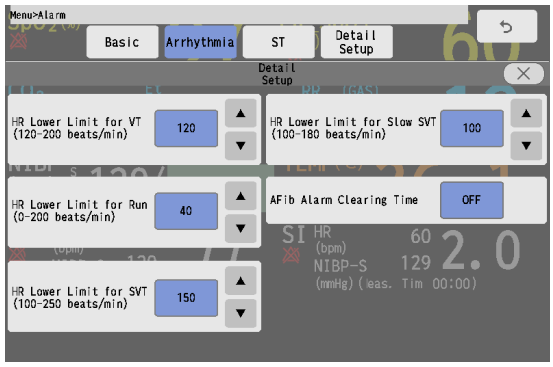
- For the Ext Tachy alarm, the alarm threshold level cannot be set below that of Tachy alarm.
- The bradycardia (Brady) alarm generates when the value exceeds the HR/PR lower alarm limit. When the lower alarm limit is OFF, alarm will not generate.
- For the Ext Brady alarm, the alarm threshold level cannot be set above that of Brady alarm.

3 Select the level to detect each arrhythmia.

Item	Description
Asystole	3 sec. to 10 sec.
Run	2 beats to 8 beats
Pause	1.5 sec. to 5 sec.
Frequent	1 bpm to 50 bpm/ min.
Ext Tachy	22 bpm to 300 bpm
Ext Brady	20 bpm to 295 bpm

Item	Description
R on T	200 ms to 600 ms
SVT	2 beats to 10 beats
Irregular RR	10, 15, 20%
S Frequent	1 bpm to 50 bpm
Pacer Not Capture	80 ms to 480 ms
Pacer Not Pacing	20 bpm to 200 bpm
AFib	1 - 100%

4 Press the [Detail Setup] key, and set HR Lower Limit for VT, HR Lower Limit for RUN and HR Lower Limit for SVT.



1 "HR Lower Limit for VT"

- If the HR is same or above the set value, VT alarm will generate.

2 "HR Lower Limit for RUN"

- If the HR is same or above the selected value, RUN will generate.

3 "HR Lower Limit for SVT"

- If the HR is same or above the set value, SVT alarm will generate.

4 " HR Lower Limit for Slow VT"

- If the HR is same or above the set value, Slow VT alarm will generate.

5 "AFib Alarm Clear Time"

- When the set time has elapsed, the alarm level of the AFib alarm changes to N (Notification Alarm).

SpO_2 Second Alarm Setup

The SpO2 second alarm function is available only for the BDS-1001N.

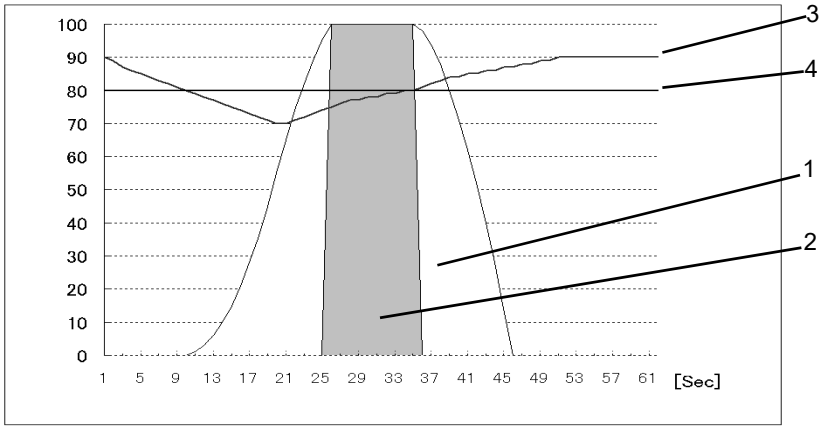
When the SpO_2 value is unstable around the lower alarm limit, the frequently generated alarm may be bothersome. The second alarm function controls these frequent alarms.

This function generates the alarm only when the integral value (the accumulation of difference between the alarm limit and SpO_2 value at every second) reaches the preprogrammed second alarm threshold value.

NOTE

- The SpO_2 SEC alarm function utilizes SatSeconds™ technology of Medtronic. SatSeconds™ is a trademark of Medtronic.

The integral value of the second alarm is calculated as follows.



1 Integral Value

2 Alarm Generation

3 SpO_2 Value

4 Alarm Limit

On this graph, the second alarm threshold value is set as 100.

The SpO_2 value begins to fall below the alarm limit from approximately 10 seconds. At the same time, the integral value begins to increase. (Alarm limit) – (SpO_2 value) is accumulated each second.

At approximately 25 seconds, the integral value reaches 100 and the alarm is generated.

The SpO_2 value begins to fall below the alarm limit at approximately 36 seconds. At the same time, the integral value begins to decrease. [(Alarm limit) – (SpO_2 value)]x 2 is subtracted each second.

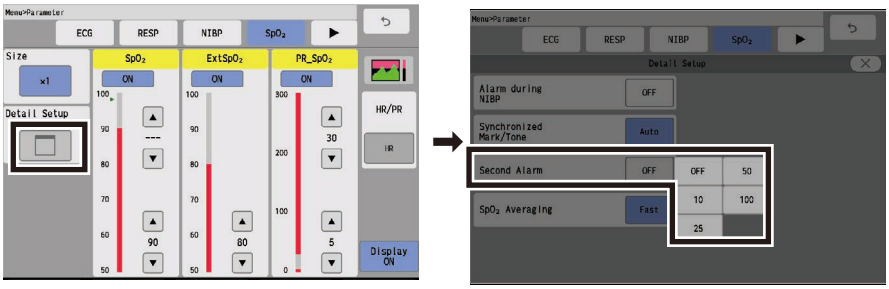
Also, there is a safety net when setting the second alarm function. This safety net is for the case when the SpO_2 value frequently falls below the alarm limit but does not last long enough to reach the second alarm threshold.

If the SpO_2 value falls below the limit 3 times or more during the last 60 seconds, an alarm will be generated even if the second alarm threshold is not reached.

CAUTION

- Whether to use the 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.

1 Press [Menu > Menu List > Parameter > SpO_2] to display the SpO_2 parameter setup screen.



2 Set [Detail Setup > Second Alarm].

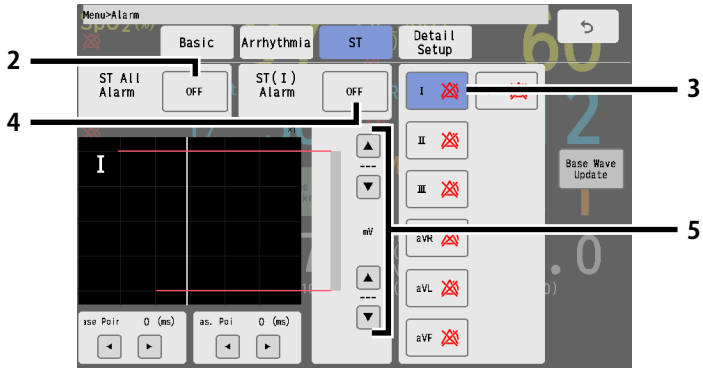
- [10]/ [25]/ [50]/ [100]: A circular second alarm indicator will be displayed inside the numeric data box.
  As the integral value increases, the indicator will begin to fill, and when it is completely filled, an alarm will be generated.

▸ [OFF]: Second alarm indicator will not be displayed.

ST Alarm Setup

Set the ST upper limit and lower limit for the reference waveform.
The upper and lower limit can be set in 1 mm/0.1 mV increments.
The alarm setup for ST will be saved respectively.

1 Press [Menu > Menu List > ST].



▸ The ST alarm setup screen will be displayed.

2 Select [ON]/[OFF] for "ST All Alarm" .

▸ [OFF]: Alarms will not generate even if the alarm for each lead is set to ON.

3 Select [ON]/[OFF] of ST alarm for each lead.

▸ The selected lead will be displayed large at the left.

4 Press [▲]/[▼] keys and set the upper, lower limit (±20 mm / ±2.0 mV).

▸ Alarm will be set to OFF if the value -20 mm / +2.0 mV or lower is selected.

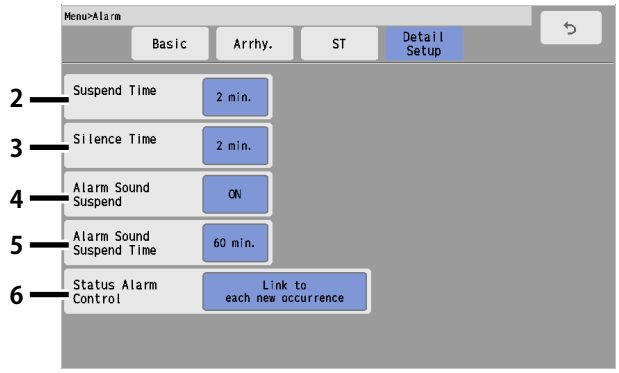
▸ Alarm will be set to OFF if the value +20 mm / +2.0 mV or above is selected.

Detail Setup

The alarm-related setup such as alarm suspend time and alarm silence time can be performed.

1 Press [Menu > Menu List > Alarm > Detail Setup].

- The alarm detail setup screen will be displayed.



2 Suspend Time

- Select from [1 min.] / [2 min.].

3 Silence Time

- Select from [1 min.] / [2 min.].

4 Alarm Sound Suspend

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

5 Alarm Sound Suspend Time

- Select from [1min] / [2min] /[5min] / [10min] / [30min] /[60min] /[90min] / [120min] /[240min] / [360min].

6 Status Alarm Control

REFERENCE

- The alarm silence time for the level L device status alarm ("Check electrodes", "NIBP Check patient type, air hose", etc.) can be set.
  (☞"Device Status Alarm Message" P11-4)

- [Link to Alarm Silence Time]: When the [Alarm Silence] key is pressed at occurrence of device status alarm, alarm will be silenced for fixed amount of time set for "Silence Time".
  If the alarm factor still remains at completion of silence time, the alarm sound will generate again.
  If the same alarm occurs during the alarm silence time, the alarm sound will not generate.
  If a new alarm occurs during the alarm silence time, the alarm sound for the new alarm will generate.
- [Link to each new occurrence]: When the [Alarm Silence] key is pressed at occurrence of device status alarm, the alarm will be silenced as long as the alarm factor remains regardless of the "Silence Time" setting.
  While the same device status alarm is generated, the alarm will remain silenced.
  If the alarm factor is resolved during the alarm silence time, the alarm will be canceled.
  If the same alarm generates again during the alarm silence time, the alarm sound will generate.

Alarm Limit Setup

This section explains the procedure to enable/suspend the system alarm, and to set the upper/lower alarm limit for each parameter.

On this system,3 modes can be preprogrammed according to the monitoring purpose. By preprogramming the alarm setting to each mode, the alarm setups at admittance of patient can be simplified by just selecting a mode. It is recommended to program the mode in rough classification such as patient's age, monitoring purpose (ICU or ward), and if necessary, perform unique setup for each patient.

To Set the System Alarm (ON or Suspend)

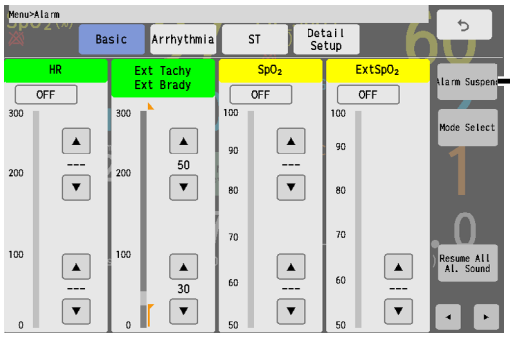
The system alarm can be enabled or suspended.
The system alarm enabled condition is when the alarm suspended condition is canceled, and alarm limit and alarm ON/OFF setting for each parameter are effective. The system alarm cannot be disabled.

WARNING

- When the system alarm is suspended, all the alarms 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.

1 Press [Menu > Menu List > Alarm > Basic].

▸ The alarm setup screen will be displayed.



2 Select whether to enable or suspend the alarm.

1 To suspend the alarm, press the [Alarm Suspend] key.

▸ The key will change to blue.

▸ The alarm will suspend temporarily.

▸ <Alarm Suspend (xxx sec.)> will be displayed. <xxx s> indicates the remaining time. The system alarm will be enabled when the suspended time completes.

2 To set the alarm ON, press the [Alarm Suspend] key while in alarm suspended condition.

▸ The key will change to gray.

▸ The alarm limits and ON/OFF settings for each parameter will become effective.

▸ The alarm suspended condition will be canceled.

To Silence or Suspend the System Alarm Sound

The alarm sound can be suspended for fixed amount of time. There are two ways to suspend the alarm sound, which are "Alarm Silence" and "Alarm Sound Suspend".
The "Alarm Silence" function suspends the alarm sound for fixed amount of time (1 min. / 2 min.).
The "Alarm Sound Suspend" function suspends the alarm generation in advance when the alarm generation is expected. Alarm monitoring will continue even while the alarm sound is suspended. The alarm sound suspend duration can be selected from 1 min, 2 min, 5min, 10min, 30min, 60min, 90min, 120min, 240min, 360min.

1 To silence the alarm, press the [Alarm Silence] key (user key).

- The alarm sound will be silenced for fixed amount of time.
- If the alarm factor still remains at completion of silence time, the alarm sound will generate again.

2 To suspend the alarm sound, press the [Alarm Silence] key (user key) for more than 3 seconds.

- The alarm sound will be suspended for fixed amount of time.
- During the alarm sound suspended duration, the alarm sound will not generate.

NOTE

- If the [Alarm Silence] key is pressed while the alarm sound is generated, it will bring the system to "Alarm Silence" condition and not the "Alarm Sound Suspend" condition.

❑Precautions about Silencing the Alarm

The alarm silence function is effective for each parameter. Once the alarm cause is resolved, the alarm silence condition for that parameter will be canceled.

When [Fukuda Tone] is set for "Alarm System" under [Menu>Setup>Initial Settings], and if another alarm with the lower priority occurs during the alarm silence duration, alarm sound will not generate. The recall will function.

When [Fukuda Tone] is set for the "Alarm System" and device status alarm is silenced, the alarm sound for the lower priority numeric and arrhythmia alarm will generate.

When [IEC Tone] is set for the "Alarm System" and if another alarm with lower priority occurs, the alarm sound will generate.

If the [Alarm Silence] key is pressed for the alarm of another parameter which occurred during the alarm silence condition, the alarm silence duration for the first alarm will not be extended.

The alarm silence condition for all parameters will be canceled for the following case.

- When the power is turned ON.
- When the system alarm status (enable/suspend) is changed.
- When the monitoring is suspended on the "Admit/Discharge" screen.
- When the user mode is changed.
- When the patient is discharged.
- When [Resume All Al. Sound] key on the alarm setup screen is pressed.

The alarm silence condition for each parameter will be canceled for the following case.

- When the alarm cause is resolved for that parameter.
- When the alarm silence time for the parameter is completed.
- When the alarm is turned OFF for the parameter.

If [Link to each new occurrence] is set for "Status Alarm Control" (Menu>Alarm>Detail Setup), the alarm sound will not generate until the alarm condition changes even the set alarm silence duration completes.

❑Precautions about Suspending the Alarm Sound

During the alarm sound suspended duration, recall will function.

The alarm sound suspended condition will cease in the event of any of the following.

- Discharge
- When OFF is set for "Alarm Sound Suspend".
- When the ventilator alarm is generated.
- When resumed from monitor suspend condition.
- When the [Alarm Silence] key is pressed.

❑About the Alarm Mute Function

When "Alarm Mute" is set to [ON], all the alarms will be silenced.

- "Alarm Mute" function can be turned ON/OFF under the "Initial Settings" menu. (☞Maintenance Manual "Alarm Related Setup" P5-4)
- By using the "Alarm Mute Reminder" function, a reminder sound can be generated after preprogrammed duration. When ON is set for "Alarm Mute" , <Alarm is silenced.> will keep being displayed .
- During the alarm mute duration, recall will function.

⚠ 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.

Alarm Limit Setup for Each Parameter

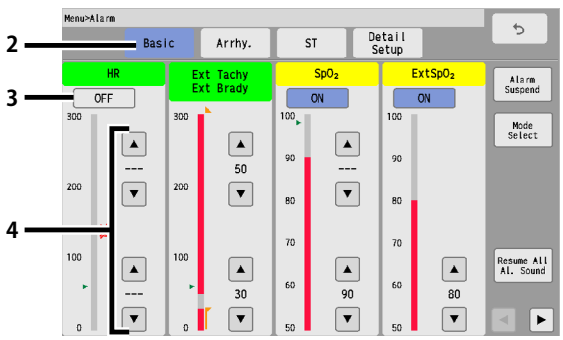
The alarm for each parameter can be turned ON or OFF, and upper and lower alarm limit can be set.

⚠ WARNING

- Set the appropriate upper and lower alarm limit for each parameter according to the monitoring condition.
- When the system alarm is suspended, all the alarms 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 alarm for that parameter is set to ON. Pay attention when setting them OFF.

1 Press [Menu > Menu List > Alarm > Basic].

▸ The alarm setup menu will be displayed.



2 Select the parameter group from the tab.

REFERENCE

- The standard parameters will be displayed on the Menu screen. The parameters to be displayed here are selectable.
  (☞Maintenance Manual "Alarm Related Setup" P5-4)

3 Select ON/ OFF for the individual alarm.

- [ON]: Alarm of the corresponding parameter will generate.
- [OFF]: Alarm of the corresponding parameter will not generate.

4 Press ▲ / ▼ to set the upper/lower limit.

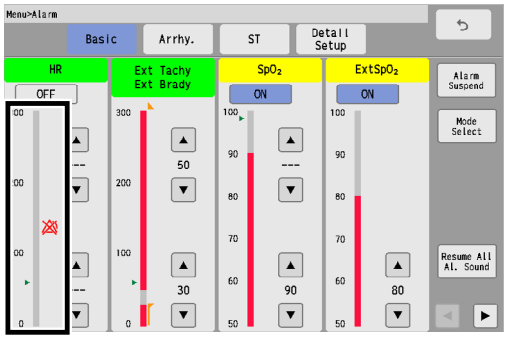
- Also, the upper/lower limit can be set by sliding the boundary of the alarm threshold.

REFERENCE

- To maintain the alarm setting even after the power is turned OFF or after the discharge procedure, store the setting to the mode, or select "Backup" for [Power ON/Discharge > Alarm].
  (☞Maintenance Manual "Display/Print Setup" P5-9)

About the Alarm Threshold Limit

By setting the alarm threshold limit ("Initial Settings") in advance, the alarm threshold can be limited within the preprogrammed range. When the alarm threshold limit function is enabled, threshold limit will be displayed beside the alarm bar.
(☞Maintenance Manual "Alarm Related Setup" P5-4)



Above is an example of alarm threshold limit setting where HR is set to [Enable], and upper and lower limits are set to 180 bpm and 40 bpm respectively.

NOTE

- The alarm threshold limit can be set for each parameter. When enabling this function, make sure the upper and lower limits are set appropriately.

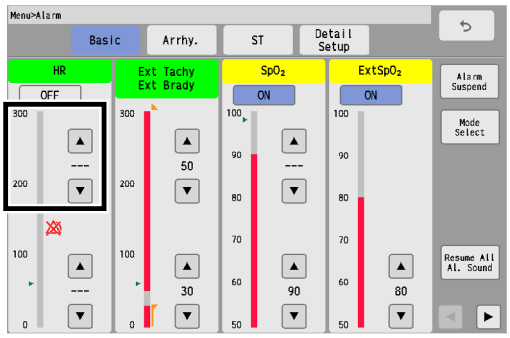
❑Limit Deactivating Mode

Even when the alarm threshold limit function is enabled, the alarm threshold outside the limit can be temporarily set. This is called the "Limit Deactivating Mode."

By pressing the up arrow key ▲ for 2 seconds at the upper threshold limit, the limit can be deactivated. The arrow keys will turn to blue indicating that the upper threshold limit can be exceeded.

In the same way, by pressing the down arrow key ▼ for 2 seconds at the lower threshold limit, the limit can be deactivated. The arrow keys will turn to blue indicating that the lower threshold limit can be exceeded.

When the alarm threshold is set within the limit range, the limit deactivating mode will end.



Above is an example of HR upper threshold limit being deactivated. The upper limit keys are turned to blue indicating that the upper limit 180 bpm can be exceeded.

NOTE

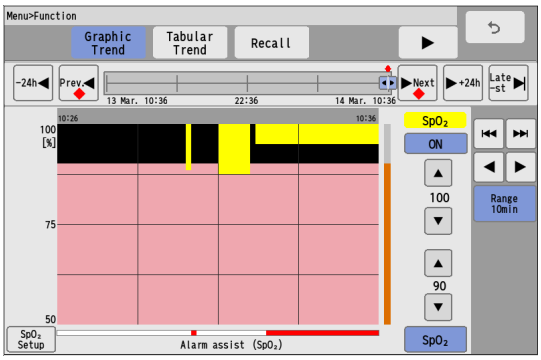
- If the alarm threshold set on the central monitor exceeds the threshold limit set on this device, the alarm threshold set on the central monitor will be applied. Make sure to check the alarm setting on the device as the alarm threshold limit status will be changed to "Limit Deactivating Mode".
- If the 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".

Alarm Assist Screen

On the alarm assist screen, maximum of 24 hours of trend data for the corresponding parameter will be displayed. Alarm limit can be set by using the past trend data as reference.

1 To display the alarm assist screen, press [Menu], select a parameter, and press [ ] on the corresponding parameter setup screen.
Or, press the numeric data box on the home display, and press [ ] on the corresponding parameter setup screen.

▸ The alarm assist screen will be displayed.



2 Select the time range on the time bar.

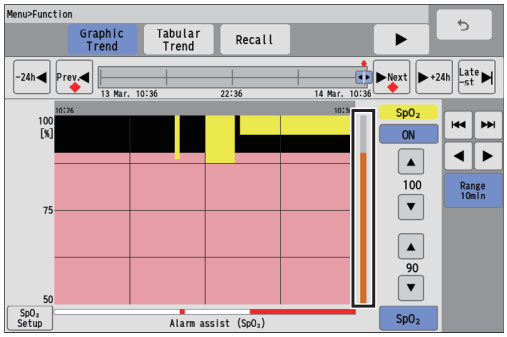
▸ Dragging the slider to the right will display newer data, and dragging it to the left will display older data.

▸ Pressing [24h] will switch the display by 24 hours.

3 Set the upper and lower alarm limit.

1 Use the ▲/▼ keys on the right side of the bar to set the alarm.

▸ Alarm zone will be displayed on the trend.



▸ The displayed alarm zone will slide by sliding the boundary.

2 Set the alarm limit by using the alarm trend as reference.

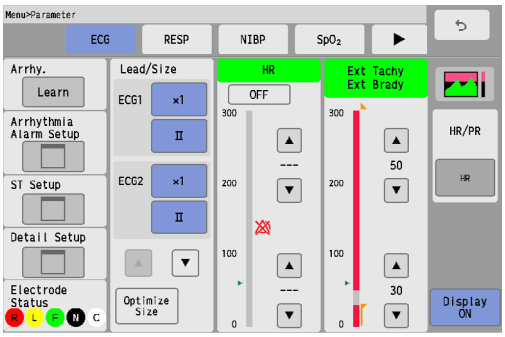
Chapter 7 Monitoring

To Display the Parameter Setup Screen

This section explains how to display the setup window of monitoring parameters.

1 Press [Menu > Menu List > Parameter] and then select the parameter to perform the setup.

▸ The parameter setup window will be displayed.



NOTE

- Pressing the numeric data box on the home display will also display the parameter setup window.

ECG

This section explains the procedure for ECG measurement preparation and monitoring condition setup.

Before Attaching the Electrodes

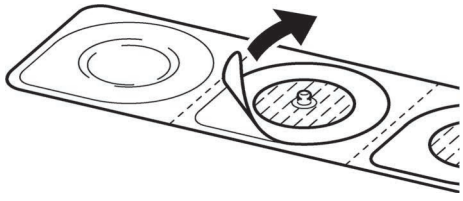
⚠ CAUTION

- Do not use different types (materials) of electrodes at the same time.
  The difference between the polarization potential from each electrode may interfere monitoring.
- ECG measurement part is Type CF applied part, but it is not intended to directly apply on patient's heart.

1 If necessary, shave the electrode sites to remove excessive hair.

2 Clean the electrode sites with alcohol wipes or other skin preparation.

3 After opening the package, peel off the backing of electrode, and attach to the patient.



NOTE

- After opening the package, pay attention not to touch the electrode gel.

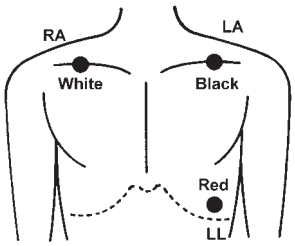
Electrode Placement

Depending on the lead cable type, 3-electrode/4-electrode/5-electrode placements are available. Using the 4-electrode or 5-electrode application allows simultaneous monitoring of 2 ECG waveforms, and high accuracy of arrhythmia analysis can be attained. (1 to 7 waveforms can be displayed depending on the number of electrodes.) Also, the displayed lead type can be changed.

❑For 3-electrode lead cable (1 waveform monitoring)

Lead Type: [I]/[II]/[III]

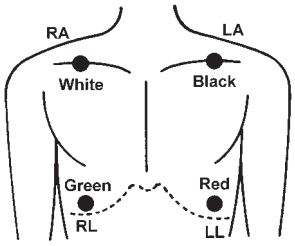
Symbol	Color	Electrode Site
RA	White	On the right infraclavicular fossa
LA	Black	On the left infraclavicular fossa
LL	Red	On the left midclavicular line, near the supracrestal line.



❑For 4-electrode lead cable (Maximum 6 waveforms monitoring)

Lead Type: [I]/[II]/[III]/[aVR]/[aVL]/[aVF]

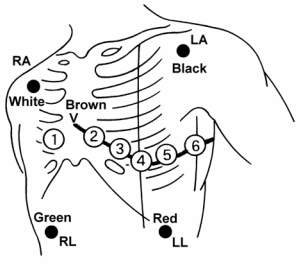
Symbol	Color	Electrode Site
RA	White	On the right infraclavicular fossa
LA	Black	On the left infraclavicular fossa
LL	Red	On the left midclavicular line, near the supracrestal line.
RL	Green	On the right midclavicular line at the same height as LL.



❑For 5-electrode lead cable (Maximum 7 waveforms monitoring)

Lead Type: [I]/[II]/[III]/[aVR]/[aVL]/[aVF]/[V]

Symbol	Color	Electrode Site
RA	White	On the right infraclavicular fossa
LA	Black	On the left infraclavicular fossa
LL	Red	On the left midclavicular line, near the supracrestal line.
RL	Green	On the right midclavicular line at the same height as LL.
V	Red/Brown	Chest Lead (V1 to V6)



Type of Electrodes and Lead Cable

There are various types of disposable electrodes for ECG measurement depending on the connection method with the lead cable and materials which the electrodes are made of. Make sure to use the appropriate electrodes which will make full use of the characteristics.
Do not reuse/resterilize the disposable electrodes.
For details of usable lead cables, refer to ☞"ECG Accessory" P13-2.

Connection to the Patient Monitor

⚠ CAUTION

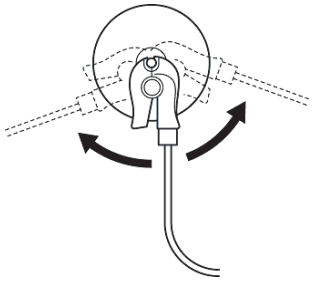
- The indication for continuous use of the electrode is about one day.
- Replace the electrode if the skin contact gets loosen due to perspiration, etc.
- When an electrode is attached to the same location for a long period, some patients may develop skin irritation. Check periodically and change the electrode site as required.
- 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.

NOTE

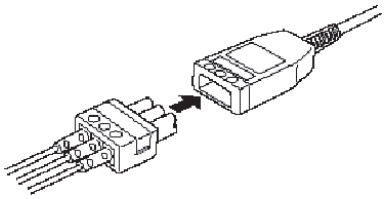
- Use only the specified relay cables, lead cables, and electrodes.
- The conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact other conductive parts including earth.

1 Clip on the lead cable end to the electrode convex part.

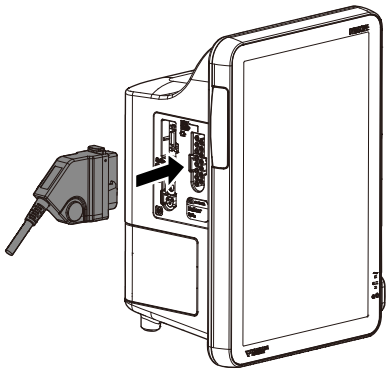
2 Turn right and left to verify that it is securely connected.



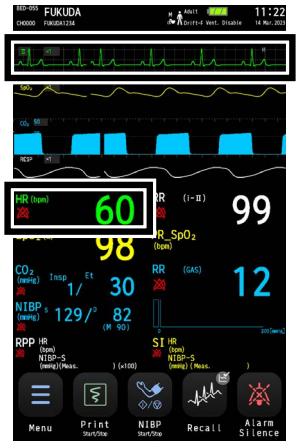
3 Connect the lead cable to the relay cable.



4 Plug in the relay cable to the ECG input connector (green) of the BDS-1001.



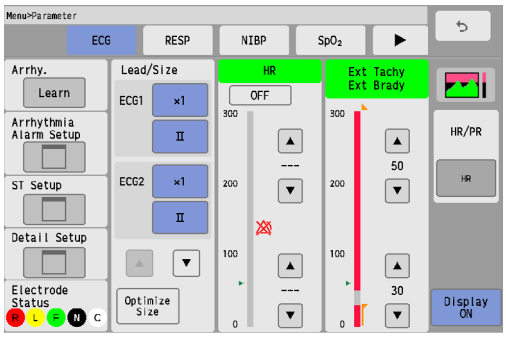
▸ ECG waveform and HR data will be displayed on the monitor.



5 Adjust the waveform size and position, and change the monitoring lead as necessary.
(☞"ECG Parameter Setup" P7-5)

ECG Parameter Setup

Press [Menu > Menu List > Parameter > ECG] to display the ECG parameter window.



❑Waveform size can be adjusted.

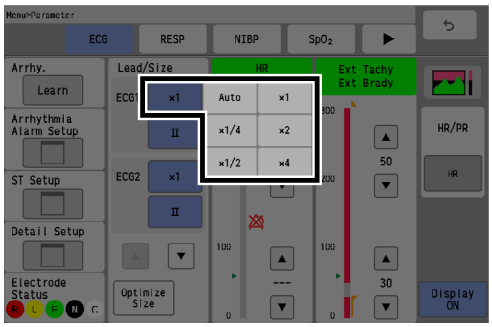
⚠ CAUTION

- 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 setting is not possible if the waveform is not displayed. Refer to ☞"To Configure the Display" P10-2 and change the display configuration.

1 Press the key for "ECG1" to "ECG7".

2 Select the waveform size for displaying/printing.

- [Auto]: ECG amplitude will be automatically adjusted to 10 mm. The automatic adjustment is effective only when the [Auto] key is pressed.



Waveform Size	x1/4	x1/2	x1	x2	x4
Voltage (10 mm)	4 mV	2 mV	1 mV	500 µV	250 µV

3 If the waveform is difficult to see due to ECG amplitude, press ▲/▼ and set the baseline position to 0 mV.

❑Lead Selection

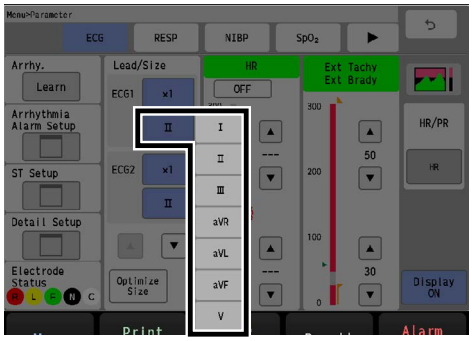
Set the monitoring lead.

⚠ CAUTION

- 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 for arrhythmia detection.
- The alarms for HR, Tachy, Brady, Ext Tachy, Ext Brady will not be generated when the electrode for ECG1 or ECG2 lead is detached, and for 30 seconds after the electrode is reattached.

1 Press the key for "ECG1" to "ECG7".

2 Select the ECG monitoring lead.



❑HR Alarm Setup

Set the HR alarm.
(☞"Alarm Limit Setup for Each Parameter" P6-8)

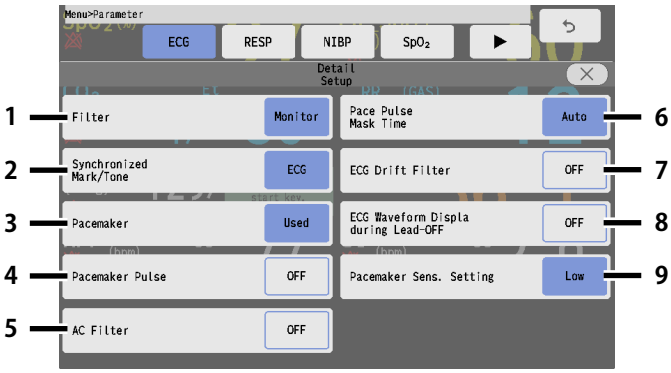
NOTE

- When Ext Tachy or Ext Brady alarm is ON, alarm threshold of Ext Tachy, Ext Brady will be displayed on the HR alarm bar. To change the threshold, press the alarm bar and display the alarm setup window.
- Set the upper limit in the range of 22 bpm to 300 bpm. The upper limit alarm will become OFF if the value exceeds 300 bpm.
- Set the lower limit in the range of 20 bpm to 295 bpm. If a value below 20 bpm is set, the lower alarm will turn OFF.
- Ext Tachy alarm threshold cannot be set below HR upper alarm limit, and Ext Brady alarm threshold cannot be set above HR lower alarm limit.

❑Arrhythmia Alarm Setup

Set the arrhythmia alarm.
(☞"To Set the Arrhythmia Alarm" P6-1)

❑Detail Setup



1 Set the filter mode.

- Select from [Monitor]/[ESIS]/[Diag.]. Each mode has different frequency characteristic.
- The selected filter mode will be printed along with other data.
- On the waveform area, "M" (Monitor), "E" (ESIS), or "D" (Diagnosis) will be displayed.

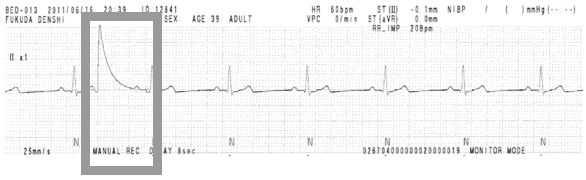
⚠ CAUTION

- The ESIS mode cannot completely reduce the electrical noise.
  Even if used with ESIS mode, it may erroneously detect the pacemaker spike.
- The ESIS mode should be selected only when a high frequency noise largely affects the HR measurement.

Monitor Mode (Frequency Characteristic: Adult/Child 0.5 Hz to 40 Hz, Neonate 1.6 Hz to 40 Hz)	This is the standard mode for ECG monitoring. The highest frequency is set to 40 Hz to reduce the artifact caused by EMG, etc.
ESIS Mode (Frequency Characteristic: Adult/Child/Neonate 1.6 Hz to 15 Hz)	When using the electrosurgical knife or electric blanket, select this mode. The noise can be largely reduced.
Diagnosis Mode (Frequency Characteristic: Adult/Child/Neonate 0.05 Hz to 150 Hz)	Select this mode when performing ST measurement or high frequency ECG monitoring. As the lowest frequency is set to 0.05 Hz, ST level can be accurately measured.

NOTE

- When the filter mode is changed, a notch will appear on the ECG waveform due to the change in frequency characteristic as shown below.



2 Set the "Synchronized Mark/Tone".

- [OFF]: Synchronized mark will not be displayed.
- [Auto]: The priority will be according to the setting of "Synchronized Mark/Tone Priority" under [Menu>Setup>Initial Settings>Meas.>Other].
  (☞Maintenance Manual "Other Setup" P5-7)
  [ECG]: The synchronized mark will be displayed in the priority of ECG > SpO_2. Also, the synchronized tone

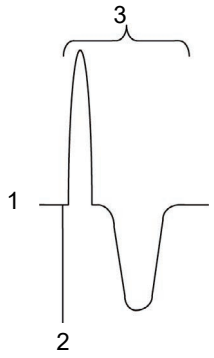
will be set to ON.
[SpO_2]: The synchronized mark will be displayed in the priority of SpO_2>ECG. Also, the synchronized tone will be set to ON.

- [ECG]: HR synchronized mark will be displayed on the HR numeric data area. Also, the synchronized tone will be set to ON.
- [SpO_2]: PR_SpO_2 synchronized mark will be displayed inside the PR_SpO_2 numeric data area. Also, the synchronized tone will be set to ON.

3 Select [Used]/[Not Used] for "Pacemaker".

- [Used]: Pacemaker pulse will be detected and pace pulse mask function will be performed for set duration.
- [Not Used]: Pacemaker pulse will not be detected.

4 Set the "Pacemaker Pulse".



1 ECG Signal Input
ECG signal will be input.

2 Pacemaker Pulse Detection and Suspension of QRS Detection
Detects the high frequency and large amplitude signal as pacemaker pulse. When pacemaker pulse is detected, QRS detection will be suspended for fixed amount of time to avoid erroneous detection of pacemaker pulse as QRS.

3 Canceling of Arrhythmia Detection
Arrhythmia detection of the waveform following the pacemaker pulse will be canceled.

⚠ CAUTION

- Precautions about Pacemaker Pulse Detection
  - 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. Also, arrhythmia will not be detected.

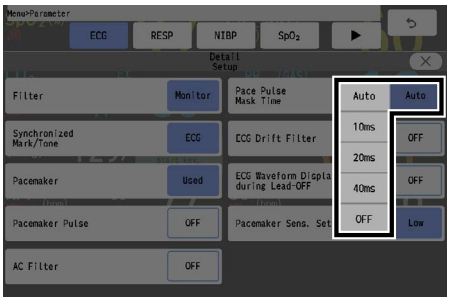
- [ON]: The pacemaker artificial pulse will be displayed overlapping to the ECG waveform with a different color. It will be automatically set to [ON] when [Used] is selected for "Pacemaker" on the "Admit/Discharge" screen.
- [OFF]: The pacemaker artificial pulse will not be displayed.

5 Set the "AC Filter".

- If the ECG waveform is interfered with AC noise, the AC filter cuts off the frequency component (50 Hz/60 Hz).
- [ON]: AC filter which attenuates the AC noise of 50 Hz to 60 Hz will be set. "AC" will be displayed in the waveform area.
- [OFF]: AC filter will not be set.

6 Set the "Pace Pulse Mask Time".

- Select the mask time depending on the pace spike amplitude or presence of fusion beat.
- [Auto]: Pace pulse mask time will be automatically set according to the pace pulse amplitude.
- [OFF]: Pace pulse mask time will be set to 0 ms.

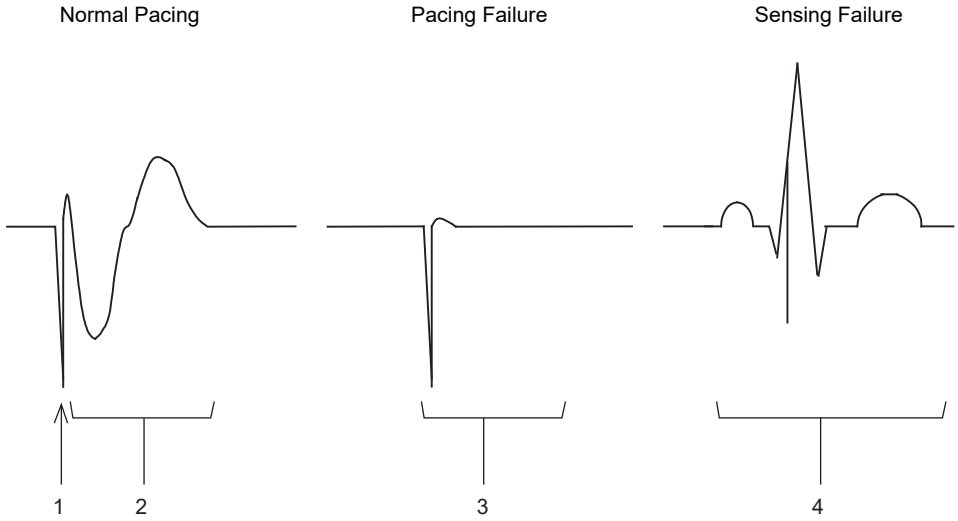


WARNING

- When [10ms]/[20ms]/[OFF] is set for "Pace Pulse Mask Time" , the pace pulse may be erroneously detected as a QRS complex, and even when the patient's HR is decreasing, HR or asystole alarms may not generate. 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.

REFERENCE

- For the patients using pacemakers, there are cases when the pacing waveform may not occur in spite of the pacing stimulus. This condition is called "pacing failure". To avoid detecting pacemaker pulses as a QRS complex, this monitor has a function to mask the pace pulse for a fixed amount of time starting from the detection of the pacing stimulus. This function is called "pace pulse mask".
  But if the pacemaker does not detect the patient's spontaneous heartbeat (sensing failure), and the pacing stimulus is applied at the same timing as QRS, this pace mask function may erroneously mask the QRS and cause the heart rate measurement to decrease.
  To avoid this, QRS pace pulse mask function can be set to [OFF]/[10ms]/[20ms] for correct measurement of the heart rate. (Default: Auto)

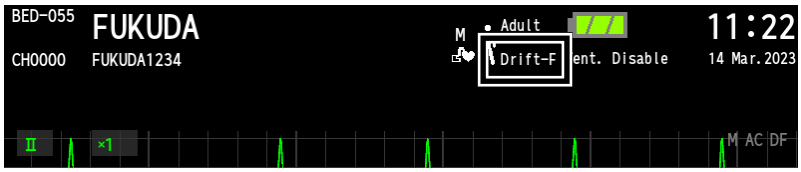


1 Pacemaker Pulse
2 Pacing waveform caused by pacemaker pulse
3 No waveform in spite of pacing stimulus
4 Pacemaker pulse and spontaneous heartbeat occurring at the same time

7 Set the "Drift Filter".

- [ON]: Only the amplitude with frequency component under 1 Hz will be attenuated to prevent the ECG

baseline drift.
The patient signal display will delay about 0.5 seconds.
On the home display, "Drift-F" will be displayed in the information area, and "DF" will be displayed in the waveform area.



- [OFF]: ECG drift filter will not be set.

8 Set the "ECG Waveform Display during Lead-OFF".
When the lead-OFF condition is detected, whether or not to display the waveform for detached lead can be selected.

- [ON]: The input waveform will be displayed even during lead-off condition.
- [OFF]: Baseline will be displayed during lead-off condition.

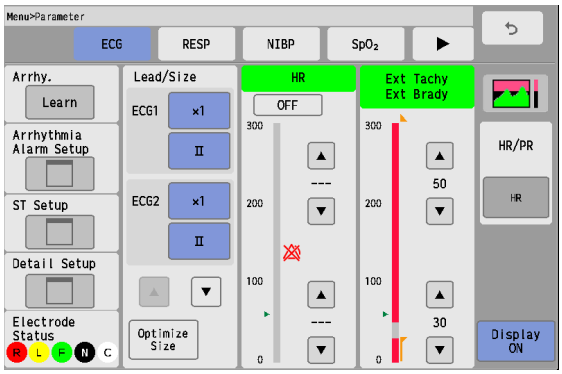
9 Set the Pacemaker Sens.
Select from [Top] / [High] / [Med.] / [Low] depending on the pacemaker detection conditions.

❑ON/OFF of Parameter Display

Select ON/OFF for parameter display.

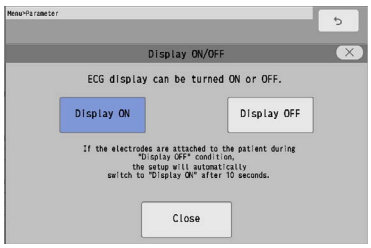
⚠ CAUTION

- When the waveform and numeric data display is set to OFF, the alarm generation and tabular trend input will also cease.



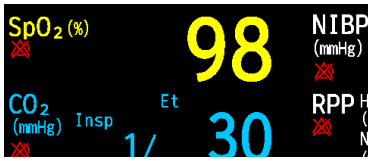
1 Press [Disp. ON].

- The "Display ON/OFF" confirmation window will be displayed.

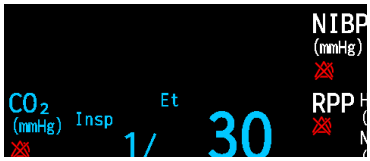


2 Select from [Display ON] or [Display OFF].

- [Display ON]: Waveform and numeric data will be displayed.
- [Display OFF]: Waveform and numeric data will not be displayed.



Display ON (SpO_2)



Display OFF (SpO_2)

- When ECG electrodes are attached to the patient with the ECG display set to OFF, the ECG waveform and numeric data will be automatically displayed after 10 seconds.

Respiration

This section explains about the respiration measurement and the measurement condition settings.

CAUTION

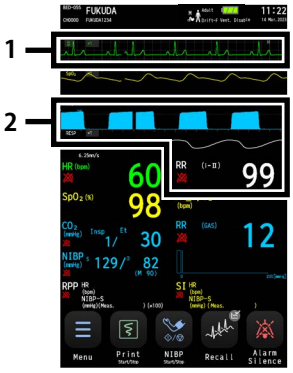
- When a defibrillator is used during respiration monitoring, a large offset voltage will be placed on the ECG electrodes, which may cause interruption of monitoring for a few seconds.
- When using the electrosurgery-proof type ECG relay cable, the impedance respiration cannot be measured, and its numeric 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.

Respiration Monitoring (Impedance Method)

The respiration waveform is detected from lead II or lead I of ECG explained in the previous section. Therefore, a stable ECG waveform is necessary to acquire respiration waveform.

1 Verify that the ECG waveform is stable, and respiration waveform and respiration rate are displayed.

2 If the waveform is difficult to see due to impedance waveform amplitude, set the baseline position to 0 Ω.
The keys to adjust the size and baseline position will be displayed on the waveforms. Press ▼/▼ to adjust the baseline position.



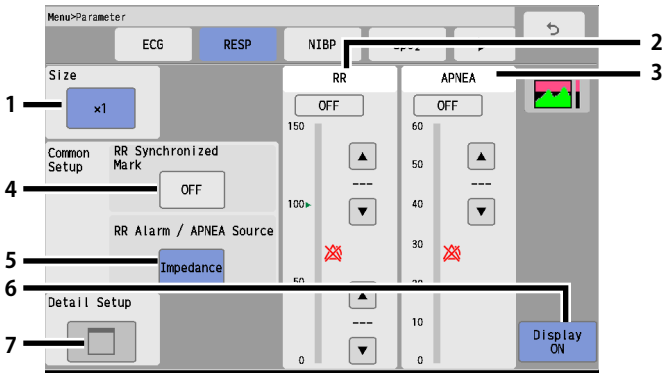
NOTE

- Adjust the detection lead, waveform size, baseline position, and sweep speed for optimum waveform display. (☞"To Configure the Display" P10-2)

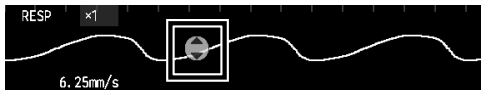
RESP Parameter Setup

Press [Menu>RESP] to display the "RESP" setup window.

❑RESP Parameter Setup



1 Press the key for "Size", and set the waveform size.



- Select from [x1/4] / [x1/2] / [x1] / [x2] / [x4].
- If the waveform is difficult to see due to impedance waveform amplitude, set the baseline position to 0 Ω. Use ▲/▼ to adjust the baseline position.

2 Set the RR alarm.

(☞"Alarm Limit Setup for Each Parameter" P6-8)

NOTE

- The same RR alarm setting will be applied for impedance and CO_2 waveform.
- For RR measured from CO_2 waveform, alarm will not generate unless 2 or more respiration is detected within 30 seconds after the power is turned ON, monitoring is resumed, CO_2 unit is connected, or a patient is discharged.
- Set the upper limit within the following range for each patient classification.
  Adult: 10 Bpm to 150 Bpm
  Child/ Neonate: 4 Bpm to 150 Bpm
  The upper limit alarm will turn OFF if the value above 150 Bpm is set.
- Set the lower limit within the following range for each patient classification.
  Adult: 5 Bpm to 145 Bpm
  Child/ Neonate: 2 Bpm to 148 Bpm
  If a value below 5 Bpm / 2 Bpm is set, the lower alarm will turn OFF.
- For the impedance respiration, RR alarm will not generate when the electrode of detection lead is detached and for 30 seconds after the electrode is reattached.

REFERENCE

- The adjustable increment for upper and lower limit is 5 Bpm for adult and 2 Bpm for child/ neonate.

3 Set the APNEA alarm.

(☞"Alarm Limit Setup for Each Parameter" P6-8)

NOTE

- The same APNEA alarm setting will be applied for impedance and CO_2 waveform

measurement.

- In case of CO_2 waveform measurement, APNEA alarm will not generate unless 2 or more respiration is detected within 30 seconds after the power is turned ON, monitoring is resumed, CO_2 unit is connected, or a patient is discharged.
- Set the upper limit in the range numeric of 10 sec. to 60 sec. The upper limit alarm will turn OFF if a value above 60 seconds is set.
- For the impedance respiration, apnea alarm will not generate when the electrode of detection lead is detached and for 30 seconds after the electrode is reattached.

REFERENCE

- The upper limit can be set in 1 second increment. There is no lower limit.

4 Set the "RR Synchronized Mark".

- [ON]: The mark synchronized to impedance respiration or CO_2 waveform will be displayed.
- [OFF]: Synchronized mark will not be displayed.

5 Set the "RR Alarm/APNEA Source".

The parameter to display the RR synchronized mark and to generate the RR/APNEA alarm can be selected from Impedance, CO_2, Auto.

WARNING

- 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 parameter set as the RR/APNEA alarm source.

- [Impedance]: RR alarm will be generated based on the impedance respiration curve. The RR synchronized mark based on impedance respiration will be displayed.
- [CO_2]: RR alarm will be generated based on the RR measured by the HCP-110. The RR synchronized mark based on CO_2 waveform will be displayed.
- [Auto]: The measurable parameter will be automatically selected in the priority of CO_2>impedance, and generates the alarm if the corresponding numeric data box is displayed on the home display.

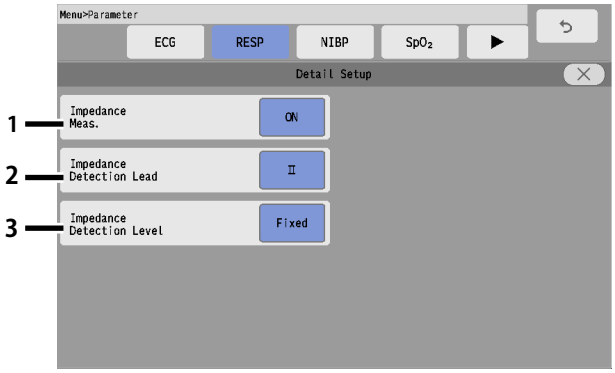
6 Select ON/OFF for parameter display.

(☞"ECG Parameter Setup" P7-5)

7 Set the details.

❑Detail Setup

Press [Detail Setup] on the "RESP" menu to display the "Detail Setup" menu.



1 Set the "Impedance Measurement".

- [ON]: Standard impedance respiration measurement will be performed.
- [OFF]: Impedance respiration measurement will not be performed and impedance respiration waveform and RR data will not be displayed. A high-frequency current which is a measurement signal will not be conducted.

2 Set the "Impedance Detection Lead".

Select the respiration detection lead from [I] or [II].

3 Set the "Impedance Detection Level".

- [Fixed]: The respiration detection level will be set according to the displayed waveform size. By increasing the displayed waveform size, low amplitude will become more detectable.
- [Auto]: The respiration detection level will be automatically set according to the current respiration amplitude.

Non-Invasive Blood Pressure

The procedure of NIBP measurement and measurement condition setup are explained.

⚠ CAUTION

- For the following situation, measurements will be terminated.
  - When the measurement time has exceeded 160 seconds for adult and child, and 80 seconds for neonate.
  - When the inflation value has exceeded 300 mmHg for adult, 210 mmHg for child, and 150 mmHg for neonate.
- If used with the incorrect patient classification, it will cause erroneous measurement, and also the inflating level for the adult may be applied to child or neonate causing dangerous situation to the patient.

Lineup of Cuffs

REFERENCE

- According to the AHA (American Heart Association) guideline, the appropriate cuff width is

40% of the arm circumference. Prepare an appropriate cuff for the patient. For details of the usable cuffs, refer to ☞"NIBP Accessory" P13-3.

NIBP Monitoring

⚠ WARNING

- Before the NIBP measurement, make sure the patient classification ([Adult]/[Child]/[Neonate]) is properly selected on the "Admit/Discharge" menu. Otherwise, correct measurement cannot be performed, and congestion or other injury may result.

⚠ CAUTION

- Correct NIBP measurement cannot be performed if oxygenator is used or if the pulse is difficult to detect.
- Pay attention when measuring the NIBP of patient with bleeding disorders or hypercoagulation. The cuff inflation constricting the arm may cause petechia or circulatory failure with blood clot.
- Do not apply the cuff to the arm or thigh where vein is secured. The blood may backflow causing the chemical injection to cease.
- Properly arrange the cuff and air hose.
- Check the condition of cuff-applied part on the patient during measurement so that the blood circulation will not be blocked over long period of time by the squashed or bent cuff hose.
- Check the patient's condition constantly while measuring over a long period of time with interval of 2.5 minutes or less. Also, periodically check the blood circulation while performing periodic measurement over a long period of time. Congestion or rash may occur at the measuring site.
- When the cuff is not applied to the patient, pay attention not to leave the cuff unattended. If periodic measurement is set, the cuff will automatically inflate and may cause the rubber bag inside the cuff to burst. When not performing the NIBP measurement, set the NIBP measurement interval OFF and disconnect the air hose from the NIBP connector.
- The following factors may affect the NIBP value.
  - Body motion, arrhythmia, convulsion, low perfusion
  - Continuous noise such as cardiac massage
  - Periodic electromagnetic noise
- If the cuff inflation may adversely affect the patient's blood flow or wound, attach the cuff to an appropriate position under physician's instruction.
- Do not apply the NIBP cuff to the arm of the mastectomized side. It may cause swelling or other circulatory failure.
- Do not perform NIBP measurement to patient who is pregnant including preeclampsia. Accurate measurement may not be possible.
- Before measurement, make sure the following conditions are not applied to the patient. Otherwise accurate measurement may not be possible.
  - Peripheral circulatory insufficiency, very low BP, or hypothermia (poor blood flow of the measurement part)
  - An aneurysm is developed.
  - Body motion such as convulsion, venous pulse, or trembling
- Do not apply the cuff in the following areas.

- The part receiving IV drips or blood transfusions.
  The blood may backflow affecting the treatment.
- The part attaching the SpO_2 sensor or IBP catheter.
  It may affect the measurement value.
- The part where a shunt is created for the hemodialysis therapy.
  The shunt may be damaged and affect the patient's condition.

- Pay special attention to neonates and children as they are not able to express their intention. Otherwise this may result in an accident or trouble.

NOTE

- When the [NIBP Start/Stop] key is pressed or when the NIBP measurement interval is changed, the standby mode will be canceled and the NIBP periodic measurement will start.

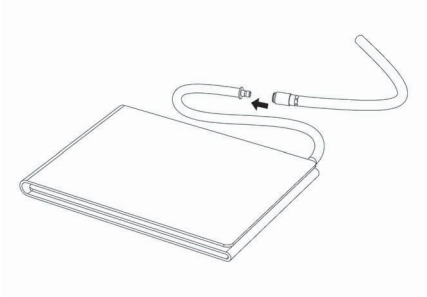
1 Select the appropriate cuff type for the patient.

(☞"NIBP Accessory" P13-3)

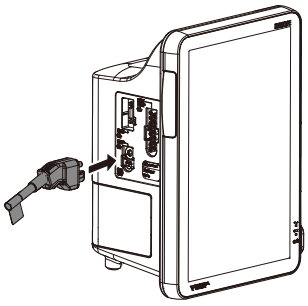
⚠ CAUTION

- Select the appropriate cuff size which best fits the arm circumference.
  If the cuff size is inappropriate, it may cause measurement error.
- When larger cuff is used, the BP value will be indicated lower than actual value. When smaller cuff is used, the BP will be indicated higher than actual value.
- Do not use a cuff which is worn out or damaged on the exterior.
  The cuff may burst during inflation.
- When using to multiple patients or the patient who has infectious diseases, follow the specified procedure of the medical facility. This may result in infectious diseases.
- Only use cuffs and air hoses specified by Fukuda Denshi to connect to the device. This may result in malfunction or failure.

2 Connect the cuff to the air hose.



3 Connect the air hose to the NIBP connector.



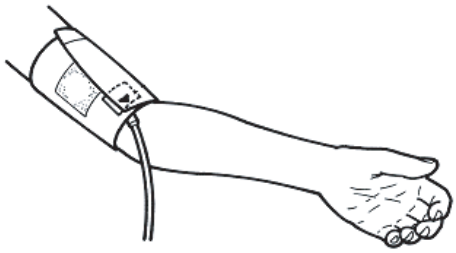
⚠ CAUTION

- Make sure that the cuff hose connection is secure.
  If there is any air leakage, correct NIBP measurement cannot be performed.

NOTE

- The neonate cuff should be connected to air hose for neonate. Other cuffs should be connected to air hose for general use. The BDS-1001 automatically determines the patient classification (neonate or adult/child) according to the connected air hose. If the air hose is not connected to the cuff connector, the measurement will not start.

4 Apply cuff to the patient.

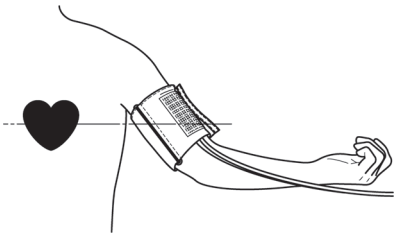


NOTE

- Position the ARTERY▼ mark over the artery on the patient's arm and wrap the cuff around.
- One or two fingers should just fit in between the cuff and arm.

REFERENCE

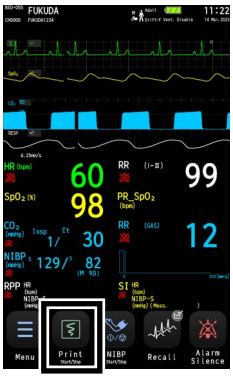
- Align the cuff height and heart position to eliminate an error caused by the blood weight. It is most appropriate to measure with the patient lying down and arms naturally extended.



- Before and during measurement, make sure the following conditions are not observed. It may cause incorrect measurements.
  - The attachment position of the cuff is higher or lower than the patient's heart. (If the cuff is applied on the location that is 10 cm higher or lower than the heart location, the BP value may change up to 7 mmHg to 8 mmHg.)
  - The patient is moving or talking during the measurement.
  - The cuff is applied over thick clothes.
  - The measurement part is compressed due to rolled-up clothes.

5 Press [NIBP Start/Stop] key.

- Cuff inflation and measurement will start.
- Upon completion, the measured value will be displayed inside the NIBP numeric data box.



REFERENCE

- About the Oscillometric Method
- The oscillometric method measures the blood pressure by detecting the pulse oscillation change by the cuff pressure. The cuff connects to the NIBP cuff connector on the monitor via the air hose. The air pressure inside the cuff is converted to voltage by the pressure sensor, converted to digital signal (A/D conversion), and transmitted to the CPU.
  The deflation measurement is performed with the following process.
  - The cuff inflates to the set value and inhibits the arterial blood flow at the measured site.
  - The cuff gradually deflates.
  - The arterial blood flow of the patient will return when the cuff pressure is decreased sufficiently.
  - The oscillation (pulse signal) caused by the restricted blood circulation is transmitted to the pressure sensor via the air hose, and converted to an electric signal.
  - From the pulse signal and cuff pressure detected at the pressure measurement circuit, the systolic, diastolic, average blood pressure and pulse rate will be measured at the CPU.
- The systolic, diastolic, mean blood pressure will be displayed on the monitor. The measurement will start with the following factor.
  - When the [NIBP Start/Stop] key (User Key) is pressed.
  - At the selected measurement interval.
  - If "NIBP Measurement at Alarm Occurrence" is set ON, and the set parameter generates an alarm.
  - When the change in patient's circulation condition is detected from the time difference of ECG and SpO_2 waveform.

Inflation Mode Setup

The maximum inflation value and measurement duration needs to be changed according to the patient classification. The inflation mode will automatically change according to the patient classification setting. Set the appropriate patient classification on "Admit/Discharge" menu or "Detail Setup" menu under NIBP parameter setup.

The NIBP measurement on this device is provided with forced exhaust system for safety purpose. When the maximum inflation value is reached or when the fixed measurement duration is exceeded, the system will automatically start to exhaust. The maximum inflation value, maximum measurement duration, initial inflation value, measurement range, and alarm limit range for this exhaust system is set according to the patient classification

setting. These values will be set when selecting the patient classification or setting the target inflation value.

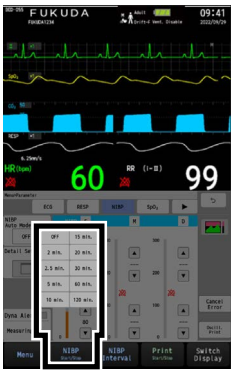
Patient Classification	Initial Inflation Value	Maximum Inflation Value	Maximum Measurement Duration
Adult	180 mmHg	300 mmHg	160 sec.
Child	140 mmHg	210 mmHg	160 sec.
Neonate	100 mmHg	150 mmHg	80 sec.

NIBP Auto Mode Setup

Non-invasive blood pressure can be measured automatically at selected time intervals.

1 Press the [NIBP Auto Mode] key on the home display.

▸ The "NIBP Auto Mode" window will be displayed.



2 Select the measurement interval from [2 min.] to [120 min.], [OFF].

⚠ CAUTION

- When "Auto Mode with Start/Stop Key" is set to [ON], the auto mode measurement needs to be started manually.

NOTE

- When the NIBP auto mode interval is [2min]/[2.5min]/[5min], NIBP measurement cannot be started from the central monitor.
- When the [NIBP Start/Stop] key is pressed or when the NIBP measurement interval is changed during the standby status, the auto mode measurement will start.

▸ The measurement will automatically start at selected interval.

▸ The selected interval will be displayed inside the numeric data box.

REFERENCE

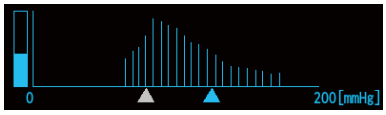
- Select [OFF] if not performing the auto mode measurement.
- The measurement starting point can be selected from [Time] (start from 0 min.) or [Meas.] (start from actual measured time).
  (☞"NIBP Parameter Setup" P7-23)
- When [60min]/[120min] is selected for the measurement interval when "NIBP Start 5 min. early" is set to [ON], the measurement will start 5 minutes before the set time. 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.
[Menu>Menu List>Setup>Initial Settings>Meas.>Other]

- On the "Initial Settings", whether or not to backup the NIBP measurement interval at discharge/power ON can be selected.
  (OFF / Backup / OFF→2.5 min. / OFF→5 min. / 2.5 min. / 5 min.)

Oscillation Graph Display

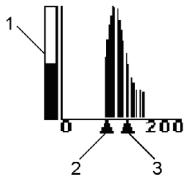
When [NIBP Graph] is selected to be displayed for numeric data, oscillation graph can be displayed.



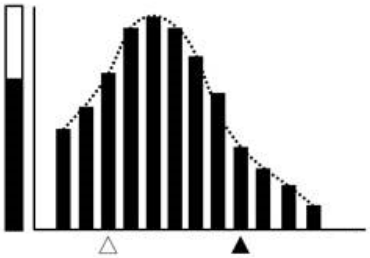
The description of the oscillation graph is as follows.

The horizontal axis shows the cuff pressure, and vertical axis shows the pulse amplitude with reference to maximum pulse amplitude.
The bar graph shown at left indicates the size of maximum pulse amplitude compared with the reference value.
For example, if the maximum pulse amplitude is 1/2 of the reference value, the bar graph will be half Fill in.

1 Bar Graph
2 DIA Value
3 SYS Value

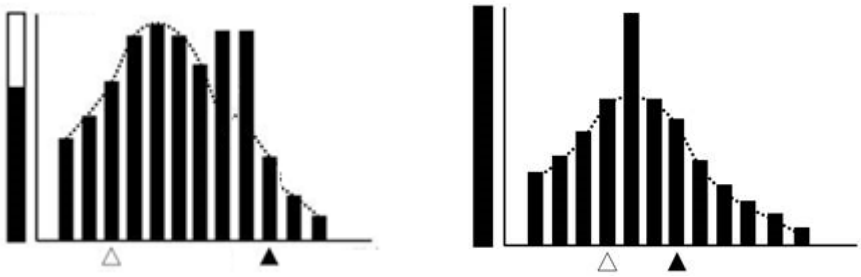


▸ Oscillation Graph (When NIBP is correctly measured.)



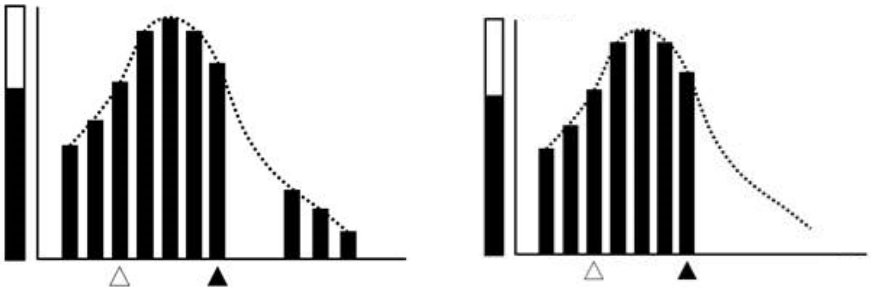
▸ Oscillation Graph (When NIBP measurement is unreliable.)
When NIBP measurement is unreliable, the measurement value will not be displayed correctly.

When noise interferes in the measurement



When noise interferes, the amplitude will be measured higher than actual value and the measurement value may not be displayed correctly.

When pulse is not detected.



When pulse is not detected and amplitude value is skipped, the measurement value may not be displayed correctly.

Dyna Alert Function Status

The Dyna Alert function is a technology to prevent accidents which may occur by sudden BP change during the non-measured duration by estimating the variation of circulatory dynamics.

This function is available for the BDS-1001N with the Medtronic SpO_2 module.

When [ON] is selected for "Dyna Alert", NIBP measurement will automatically start when the Dyna Alert estimated value exceeds the alarm limit. The function will activate with the following condition.

(☞"Dyna Alert" P7-27)

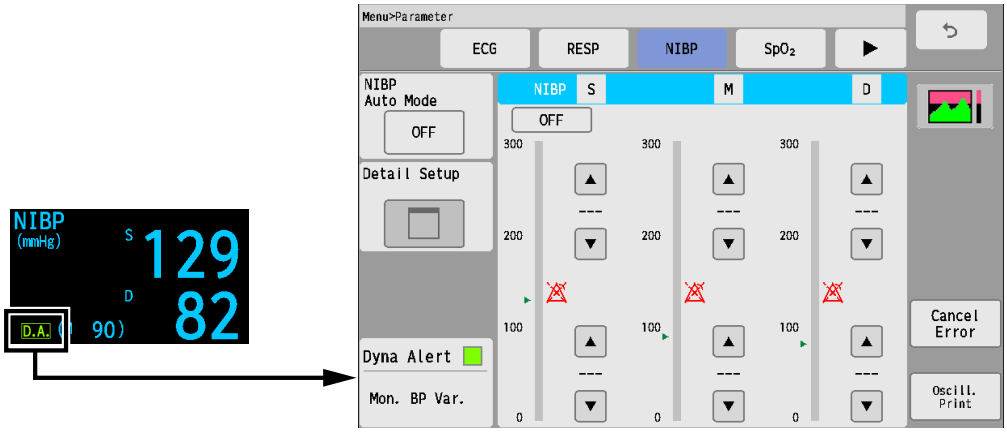
- Patient Classification: Adult (20 kg or above)
- Cuff Applied Site: Upper Arm
- SpO_2 Sensor Attachment Site: Fingertip
- NIBP Measurement Interval: 5 minutes to 60 minutes

⚠ CAUTION

- When the SpO_2 sensor is applied to the toe or forehead, the circulatory dynamics variation monitoring by the Dyna Alert may not properly function.
- This function is available only for the BDS-1001N with the Medtronic SpO_2 module.

A mark indicating the status of the Dyna Alert function will be displayed inside the NIBP numeric data box, and a

message will be displayed in the NIBP setup window.



D.A. Color of Mark	Message	Device Status	Dyna Alert Function Status*1
Gray	DA Setup: OFF	Dyna Alert (DA) is set to OFF.	Disable
	Patient: Child	NIBP measurement is performed on child.	Disable
	Patient: Neonate	NIBP measurement is performed on neonate.	Disable
	Pacemaker: ON	Pacemaker setting is set to ON.	Disable
	Interv.: <5min.	NIBP interval is set to 2min or 2.5min.	Suspended
	Interv.: >60min.	NIBP interval is set to 120min.	Suspended
	Interv.: OFF	NIBP interval is set to OFF.	Suspended
Yellow	Measure NIBP	Initialization of Dyna Alert is complete, and the NIBP measurement has not been performed since the power is turned ON.	Suspended
	Poor ECG Signal	ECG signal failure due to lead-off, noise, etc.	Disable
	Poor PTG Signal	PTG (Photoplethysmograph) signal failure due to sensor off, noise, severe low perfusion, etc.	Disable
	DA-NIBP Suspended	Within 2.5 minutes from previous Dyna Alert NIBP measurement.	Suspended
	Measuring NIBP	NIBP measurement other than Dyna Alert is in progress.	Disable
	Initializing	Waiting for stable signal after starting Dyna Alert.	Disable
Green	PTG Low Perfusion	PTG amplitude is 200 unit or above, and below 800 unit.	Enable
	Mon. BP Var.	Dyna Alert is properly monitoring circulatory dynamics variation.	Enable
Pink	Measuring DA-NIBP	Dyna Alert NIBP measurement is in progress.	Disable

*1: Disable: Circulatory dynamics variation is not monitored.

Suspended: Circulatory dynamics variation is monitored. But the display suspends the measurement when NIBP measurement is requested. When the suspending factor is resolved, the measurement will resume as quickly as possible.

Enable: Circulatory dynamics variation is monitored. The display control software responds to NIBP measurement request as quickly as possible.

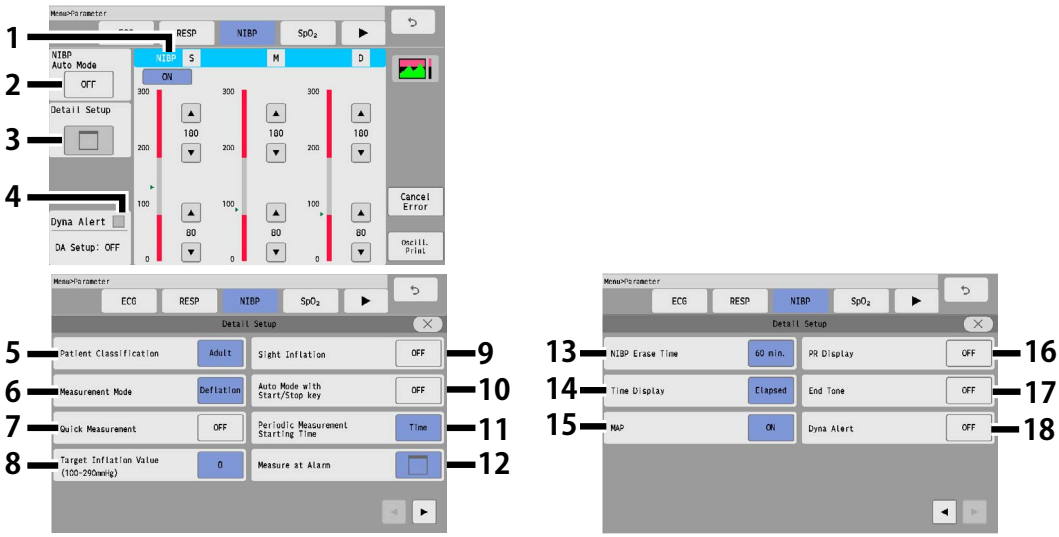
*2: "Measuring BP" indicates the status when IBP (BP1 or ART) measurement is possible and can be displayed on the monitor.

⚠ CAUTION

- When using the Dyna Alert function, be aware of these risks and do not increase the NIBP interval time by relying only on the Dyna Alert function.
- After the Dyna Alert NIBP measurement, the next Dyna Alert NIBP measurement cannot be performed for 2.5 minutes.
- The Dyna Alert will not properly function for the following cases.
  - If peripheral circulatory insufficiency or very low BP is developed.
  - If highly-frequent arrhythmia is generated.
  - If an oxygenator is used.
  - If a large noise from body movement or electric surgery equipment is interfering.
  - If autonomic nerve or circulatory dynamics is largely affected by medication.

NIBP Parameter Setup

Press [Menu > Menu List > Parameter > NIBP] to display the NIBP parameter window.



1 NIBP Alarm

(☞"Alarm Limit Setup for Each Parameter" P6-8)

NOTE

- Set the upper limit in the range of 15 mmHg to 300 mmHg/2.0 kPa to 40.0 kPa. Setting a value above 300 mmHg/40.0 kPa will turn OFF the alarm.
- Set the lower limit in the range of 10 mmHg to 295 mmHg/1.5 kPa to 39.5 kPa. The alarm will turn OFF if a value below 10 mmHg/1.5 kPa is set.

REFERENCE

- Set ON/OFF of NIBP alarm, upper and lower alarm limits of systolic (S), diastolic (D), mean (M) NIBP.
- The alarm limit should be set for each unit (mmHg/kPa).
- The upper/lower limit can be set in 5 mmHg / 0.5 kPa increment.

2 Set the measurement interval.

3 "Detail Setup" window will be displayed.

4 DynaAlert status will be displayed.

5 Patient Classification

The patient classification setting is linked with that on the "Admit/Discharge" screen. The inflation value and measurement duration will differ according to the patient classification setting.

(☞"Inflation Mode Setup" P7-18)

⚠ WARNING

- The patient classification selection influences the precision of the QRS detection and NIBP measurement. Make sure to select the correct patient classification.
- If the set patient classification and the connected NIBP air hose do not match, NIBP measurement can not be performed. However, if the patient classification is child, NIBP air hose for adult can be used.

6 Measurement Mode

Select [Deflation] or [Inflation].

- [Deflation]: The BP value will be determined during the cuff deflation.
- [Inflation]: The BP value will be determined during the cuff inflation.

NOTE

- During the inflation measurement mode, the sight inflation function cannot be used.
- During the inflation measurement mode, the quick measurement function cannot be used.
- When the patient classification is neonate, [Inflation] can not be selected and deflation measurement will be performed.

7 Quick Measurement

[ON]: NIBP measurement will be performed in duration of about 20 seconds to 25 seconds in case of adult patient.

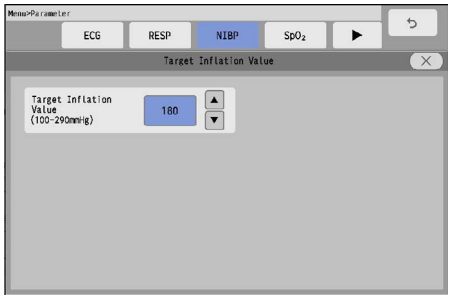
NOTE

- The quick measurement setting will be effective only when the patient classification is adult or child. If the patient classification is neonate, standard NIBP measurement will be performed regardless of the quick measurement setting.

8 Target Inflation Value

The window to set the target inflation value will be displayed.
Set the target inflation value using the up/down keys. The indication of target inflation value is SYS + 40 mmHg

for adult/child, SYS + 30 mmHg for neonate.



Patient Classification	Target Inflation Value	Maximum Inflation Value	Maximum Measurement Duration
Adult	100 mmHg to 290 mmHg (Default: 180 mmHg)	300 mmHg	160 sec.
Child	100 mmHg to 200 mmHg (Default: 140 mmHg)	210 mmHg	160 sec.
Neonate	100 mmHg to 140 mmHg (Default: 100 mmHg)	150 mmHg	80 sec.

For the following case, the target inflation value will be automatically set to the default value of each patient classification.

- At Discharge
- When the patient classification is changed

CAUTION

- When the "Sight Inflation" is [OFF], the target inflation value after the first periodic measurement will be automatically set based on the previous measurement value.
- When the "Sight Inflation" is [ON], the target inflation value after the first periodic measurement will be set based on the sight inflation function.

9 Sight Inflation

- [ON]: Sight inflation function will turn ON.
  The inflation target level will be automatically estimated during the inflation, and starts to deflate after the target level is reached.
  If [ON] is selected for "Sight Inflation", the target inflation value will be increased in case such as sudden increase of blood pressure to prevent the re-inflation.
- [OFF]: Sight inflation function will turn OFF.
  It will inflate to the target level set according to the previous measurement result.

NOTE

- The sight inflation function can be used only during the NIBP auto mode measurement.
- The sight inflation function cannot be used when the patient classification is "Neonate".
- When performing manual measurement/measurement at alarm occurrence, it will inflate to the target inflation value.

10 Auto Mode with Start/Stop Key

NIBP measurement will be performed automatically at selected time intervals.

- [OFF]: When the power is turned ON, NIBP auto mode will resume even after the patient is discharged regardless of whether the next patient is admitted or not.

- [ON]: When the power is turned ON, NIBP auto mode will resume by starting a manual measurement for the newly admitted patient. Until the NIBP auto mode is resumed or the interval is changed, "Standby" will be displayed inside the NIBP numeric data box.

NOTE

- When the [NIBP Start/Stop] key is pressed or when the NIBP measurement interval is changed, the standby mode will be canceled and the NIBP periodic measurement will start.

11 Periodic Measurement Starting Time

The starting time of periodic measurement can be set.

- [Time]: The periodic measurement will start from the integral multiple of the selected interval starting from 0min.
- [Meas.]: The periodic measurement will start from the actual starting time.

	Measurement time when [Time] is selected:	Measurement time when [Meas.] is selected:
When the interval is [15min.] and the measurement is started on 15:11:15	15:11:15 15:15:00 15:30:00 15:45:00	15:11:15 15:26:15 15:41:15 15:56:15
When the interval is changed to [30min.] on 15:58	16:00:00 16:30:00 17:00:00	16:26:15 16:56:15 17:26:15

NOTE

- When [Periodic Measurement Starting Time] is set to [Time], and [Auto Mode with Start/Stop Key] is set to [ON], the interval between the first and second NIBP measurement may be less than 30 seconds..

12 Measure at Alarm

NIBP measurement will start at alarm generation.

Select [ON] for "NIBP Measurement at Alarm Occurrence", and select the alarm factor to start the NIBP measurement. Multiple parameters can be selected.

⚠ CAUTION

- If the NIBP measurement has not been performed since the power was turned ON, NIBP measurement at alarm occurrence will not be performed.

13 NIBP Erase Time

NIBP data will be erased after the set duration (5min/10min/30min/60min/120min).

14 Time Display

The time for the NIBP measurement will be displayed.

- [Elapsed]: The elapsed time from the previous NIBP measurement will be displayed.
- [Meas.]: The NIBP measured time will be displayed.

15 MAP

[ON]: Mean BP (MAP) value will be displayed.

CAUTION

- If the mean BP (MAP) value is not displayed, the mean BP (MAP) alarm will not be generated.

16 PR Display

[ON]: PR will be displayed.

NOTE

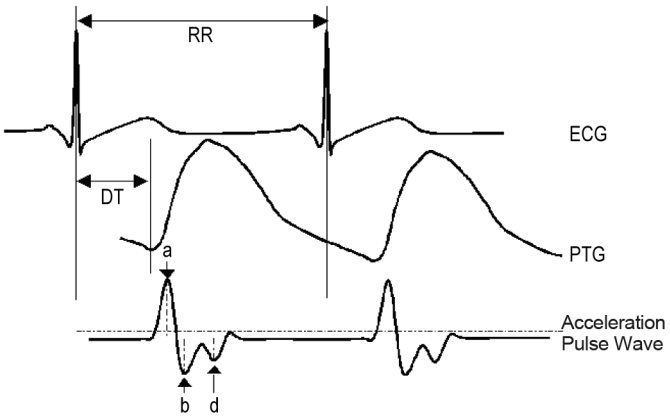
- PR will be displayed only. It will not generate an alarm, or be displayed for the tabular trend.

17 End Tone

[ON]: A buzzer tone will be generated when the NIBP measurement completes.

18 Dyna Alert

[ON]: Dyna Alert function will turn ON when BDS-1001N is used.



Parameters used for Dyna Alert Function

CAUTION

- When the PTG (SpO_2) sensor is applied to the toe or forehead, the circulatory dynamics variation monitoring by the Dyna Alert may not properly function.
- The circulatory dynamics variation monitoring by the Dyna Alert is effective only on the BDS-1001N with the Medtronic SpO_2 module.

REFERENCE

- About the Dyna Alert: Using a cuff allows to measure the blood pressure non-invasively, but on the other hand, there is a disadvantage of not being able to perform the measurement continuously. Therefore, there is always a risk of sudden blood pressure change in between the periodic measurements.

Pulse Oximetry

This section explains the procedures and settings of SpO_2 measurement.

SpO_2 Monitoring

WARNING

- Explosion hazard: Do not use the pulse oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- Do not adjust, repair, open, disassemble, or modify the pulse oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse oximeter for servicing if necessary.
- 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 may not be possible.
  - Patient with excessive abnormal hemoglobin (HbCO, 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.
- Do not connect any sensor or cable not authorized by Fukuda Denshi to any I/O connector. The device cannot deliver its maximum performance, the device may be damaged and safety cannot be ensured.
- If any measurement seems questionable, first check the patient's vital signs by alternate means and then check this device for proper functioning.
- For the following case, accurate measurement of SpO_2 may not be possible.
  - Improper sensor application
  - Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO_2. Therefore, when elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
  - Elevated levels of bilirubin
  - Elevated levels of dyshemoglobin
  - Vasospastic disease, such as Raynaud's, and peripheral vascular disease
  - Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
  - Hypocapnic or hypercapnic conditions
  - Severe anemia

- Very low arterial perfusion
- Extreme motion artifact
- Abnormal venous pulsation or venous constriction
- Severe vasoconstriction or hypothermia
- Arterial catheters and intra-aortic balloon
- Intravascular dyes, such as indocyanine green or methylene blue
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
- Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.

- Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
- The SpO_2 data should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.
- Do not use the SpO_2 data to monitor apnea condition.
- This device may be used during defibrillation, but this may affect the accuracy or availability of the SpO_2 parameters and measurements.
- This device may be used during electrocautery, but this may affect the accuracy or availability of the SpO_2 parameters and measurements.
- The SpO_2 data cannot be used for arrhythmia analysis.
- SpO_2 data is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

⚠ CAUTION

- When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.
- Do not place the pulse oximeter on electrical equipment that may affect the device, preventing it from working properly.
- To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse oximeter is used.
- Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.
- Do not submerge the pulse oximeter in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximeter.
- Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse oximeter.
- If irritation such as skin reddening appears with the sensor use, change the attachment site or stop using the sensor.
- When attaching the sensor with tape, do not wrap the tape too tight. Also check the blood flow constantly so that congestion is not generated at the peripheral.
- 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.

- If SpO_2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.
- If the <SpO_2 Low Perfusion> message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and if indicated, verify oxygenation status through other means.
- Change the application site or replace the sensor and/or patient cable when a <Replace Sensor>, <Replace Cable>, <Low Signal IQ> is displayed on the monitor. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.
- Replace the cable or sensor when a <Replace Sensor> or <Low Signal IQ> message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.
- If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.
- The device must be configured to match your local power line frequency to allow for the cancelation of noise introduced by fluorescent lights and other sources.
- Check the sensor attachment site constantly 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 the skin for neonate and 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.
- If "– – –" is displayed for the numeric data, the sensor may not be properly attached. Check the attachment condition.
- Before bathing the patient, make sure to remove the sensor and device from the patient.

NOTE

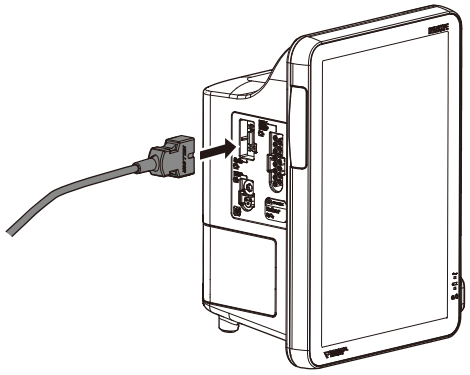
- A functional tester cannot be used to assess the accuracy of the pulse oximeter.
- PI is a parameter which can be measured only on the BDS-1001M, BDS-1001F.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow this device to obtain SpO_2 readings.
- Do not wrap the cables around the device. It may damage the cables.
- Additional information specific to the Masimo sensors compatible with this device, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use.
- Cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the directions for use for the cables or sensors for the specified duration of the patient monitoring time.

1 Prepare an appropriate probe or sensor for the patient.

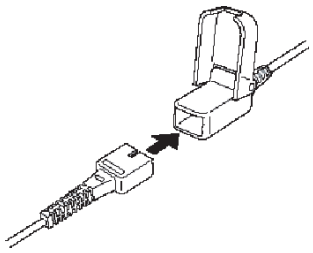
2 Connect the sensor to BDS-1001.

In Case of Medtronic Unit:

1 Connect the DOC-10 SpO_2 Relay Cable to the SpO_2 connector on the BDS-1001N.



2 Insert the sensor into the SpO_2 relay cable connector, and lock it with the transparent cover.



In Case of Masimo Unit:

1 Connect the SpO_2 patient cable (LNOP®, LNCS®) to the SpO_2 connector on the BDS-1001M.

2 Connect the SpO_2 patient cable and the sensor.
Face the metallic side of the sensor upward and align the logo with that of the patient cable. Then, insert the sensor connector to the patient cable until a click sound is heard.

⚠ CAUTION

- The SpO_2 patient cables (LNOP®, LNCS®, M-LNCS™) are intended for Masimo SET sensors only. Connect them only to BDS-1001M. If connected to other device, it will not function properly.

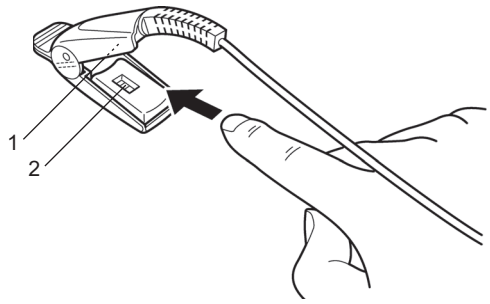
NOTE

- Pull the connector slowly to ensure it is securely connected.
- If necessary, secure the cable to the patient.

Probe Type

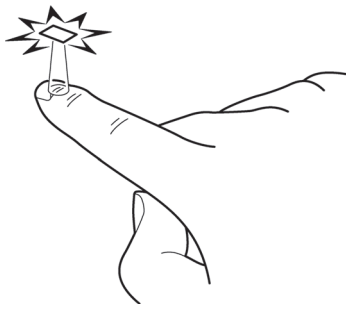
1 As shown below, the probe cable should be on the nail side.

1 Light Emitting Part
2 Light Receiving part

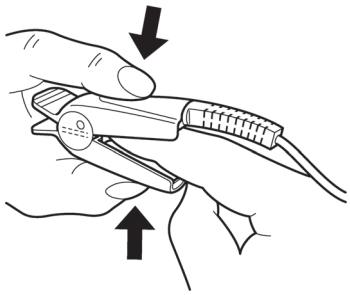


2 Adjust the sensor so that the light-emitting part (on cable side) touches the root of the nail, and close the

probe.



3 Press the probe lightly so that the finger and the rubber cover are appressed. This is to stabilize the probe, and to avoid ambient light.



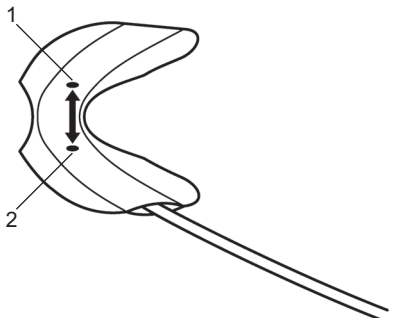
Single-Patient-Use Type

1 Clean the attachment site with alcohol, etc.

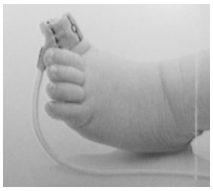
2 Align the light emitting element and light receiving element of the sensor with the measuring site in between when attaching the sensor to patient.

1 Light Emitting Element

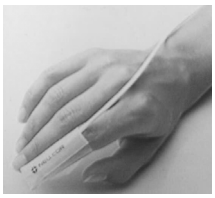
2 Light Receiving Element



3 Secure the cable with surgical tape so that the sensor does not come off when the cable is pulled.

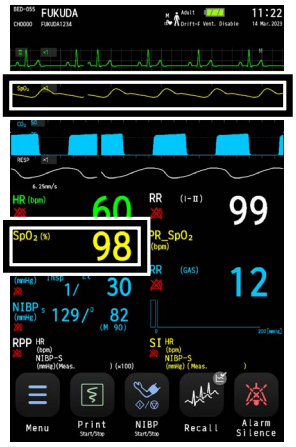


Attachment to the toe



Attachment to the finger

3 Verify that the SpO_2 measurement and SpO_2 waveform are displayed on the home display.



Precautions about the Masimo Sensors and Cables

A technology called X-Cal for patient safety and reinforcement of efficiency in a clinical site is implemented for Masimo sensors and cables.
X-Cal is designed to address the following three common factors that can impact measurement accuracy and patient safety due to reliability risks.

1 Imitation Masimo sensors and cables

2 Cables and sensors used far beyond their expected life

3 Third-party reprocessed pulse oximetry sensors

If a sensor or cable that does not support X-Cal is used with an X-Cal enabled device, SpO_2 measurement will not be available.
Even if Masimo sensors or specified sensors and cables are used, SpO_2 measurement may not be available if the sensors and cables are used beyond their expected life.

❑About the Expected Life of Sensors and Cables

- The X-Cal function automatically monitors the Active Monitoring Time (actual time of SpO_2 monitoring) for each sensor and cable.If the sensors and cables are used beyond the expected life, the message, <Replace Cable> or <Replace Sensor> will be displayed.
- The measurement will not cease until it is completed even if the cable or sensor has reached end of life during the measurement.
- When a measurement with cable or sensor that has reached end of life is suspended for certain amount of time, and resumed with the same cable or sensor, a message to replace the sensor or cable will be displayed.
- The sensor or cable that has reached end of life needs to be replaced before resuming monitoring.
- The following table shows the expected life of cable and sensor. The indication of usage hours per day (24 hours/12 hours/8 hours) are also shown.

Active Monitoring Time (actual time of monitoring)

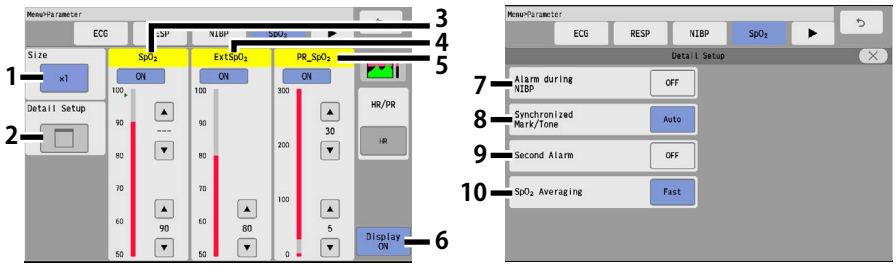
Sensors or Cables	Expected Life	When monitoring 24 hours/day	When monitoring 12 hours/day	When monitoring 8 hours/day
Single Patient Use SpO_2 "L" Sensor with replaceable tape	336 hours	14 days	28 days	42 days
Single Patient Use SpO_2 Sensor	168 hours	7 days	14 days	21 days

Active Monitoring Time (actual time of monitoring)

Sensors or Cables	Expected Life	When monitoring 24 hours/day	When monitoring 12 hours/day	When monitoring 8 hours/day
Reusable SpO_2 Sensor (DCI, DCIP, YI, TF-I, DBI)	8,760 hours	12 months	2 years	3 years
Patient Cable	17,280 hours	24 months	4 years	6 years

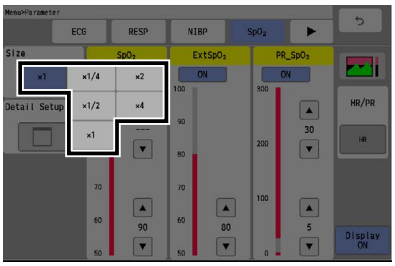
SpO_2 Parameter Setup (Medtronic)

This section explains the measurement procedure when using the BDS-1001N.
Press the [Menu], [Parameter], [SpO_2] keys to display the "SpO_2" setup screen.



1 Press the key for "Size", and set the waveform size.

- Select from [x1/4] / [x1/2] / [x1] / [x2] / [x4].



2 Open the "Detail Setup" window.

3 Set the SpO_2 alarm.
(☞"Alarm Limit Setup for Each Parameter" P6-8)

NOTE

- Whether to use the second alarm function and its threshold selection should be based on the patient's clinical indication portent and medical evaluation.
- Set the upper limit in the range of 51%SpO_2 to 100%SpO_2. If a value above 100%SpO_2 is set, the upper alarm will turn OFF.
- Set the lower limit in the range of 50%SpO_2 to 99%SpO_2. If a value below 50%SpO_2 is set, the lower alarm will turn OFF.

REFERENCE

- Also, when the SpO_2 value is unstable around the lower alarm limit, the frequently generated alarm can be corrected by setting the second alarm function.
(☞"SpO2 Second Alarm Setup" P6-2)
- The upper/lower limit can be set in 1%SpO_2 increment.
- The following delay occurs for the SpO_2 alarm depending on the patient classification and

second alarm setting. (In Case of Medtronic)

	Second Alarm Setup	Patient Classification	
		Adult/Child	Neonate
SpO_2 Alarm Condition Delay	For all settings	About 7 sec. to 9 sec.	About 7 sec. to 9 sec.
SpO_2 Alarm Signal Delay	OFF	About 5 sec.	0 sec.
	10	About 5 sec. to 7 sec.	About 5 sec. to 7 sec.
	25	About 11 sec. to 13 sec.	About 11 sec. to 13 sec.
	50	About 19 sec. to 22 sec.	About 19 sec. to 22 sec.
	100	About 36 sec. to 38 sec.	About 36 sec. to 38 sec.

4 Set the ExtSpO_2 alarm.
(☞"Alarm Limit Setup for Each Parameter" P6-8)

NOTE

- Set the lower limit in the range of 50%SpO_2 to 98%SpO_2. If a value below 50%SpO_2 is set, the lower alarm will turn OFF.
- When the ExtSpO_2 alarm is ON, the lower limit of SpO_2 cannot be set below ExtSpO_2.
- The SEC alarm function cannot be used for ExtSpO_2.

REFERENCE

- The lower limit can be set in 1%SpO_2 increment.
- ▶ indicates the current measurement value.
- The following delay occurs for the ExtSpO_2 alarm depending on the patient classification and second alarm setting. (For Medtronic)

	Patient Classification	
	Adult/Child	Neonate
SpO_2 Alarm Condition Delay	About 7 sec. to 9 sec.	About 7 sec. to 9 sec.
SpO_2 Alarm Signal Delay	About 5 sec.	0 sec.

5 Set the PR alarm.
(☞"Alarm Limit Setup for Each Parameter" P6-8)

NOTE

- Set the upper limit in the range of 22 bpm to 300 bpm. The upper limit alarm will become OFF if the value exceeds 300 bpm.
- Set the lower limit in the range of 20 bpm to 295 bpm. If a value below 20 bpm is set, the lower alarm will turn OFF.

REFERENCE

- The upper and lower limit can be set in 5 bpm increments.
  It can be set in 1 bpm increment for 25 bpm and below.
- The following delay occurs for the PR alarm depending on the patient classification. (In Case of Medtronic)

- PR Alarm Condition Delay: <Adult/Child/Neonate> About 5 sec. to 6 sec.
- PR Alarm Signal Delay: <Adult/Child> About 5 sec., <Neonate> 0 sec.

6 Select ON/OFF for parameter display.
(☞"ECG Parameter Setup" P7-5)

⚠ CAUTION

- When the waveform and numeric data display is set to OFF, the alarm generation and tabular/graphic trend input will also cease.
- When the waveform and numeric data display is set to OFF, the pulse rate measured by SpO_2 will not be displayed either.

REFERENCE

- When SpO_2 sensor is attached to the patient with the SpO_2 display set to OFF, and SpO_2 is measured for 10 seconds, the pulse wave and numeric data will be automatically displayed.

7 Set the "Alarm during NIBP". This setup can be used when the SpO_2 sensor and the NIBP cuff is placed on the same limb for measurement.

NOTE

- During the NIBP measurement, the cuff inflation restricts the blood flow which disables the correct detection of the SpO_2 and PR, and may generate an improper alarm.
- Selecting [OFF] will not generate the SpO_2, Ext SpO_2, PR alarm until the NIBP measurement is complete.

▸ [ON]: Alarm will be generated even during NIBP measurement.

▸ [OFF]: SpO_2/PR alarm will not be generated during NIBP measurement.

8 Set the "Synchronized Mark/Tone".
(☞"Set the "Synchronized Mark/Tone"." P7-7)

9 Set the "Second Alarm".
(☞"SpO2 Second Alarm Setup" P6-2)

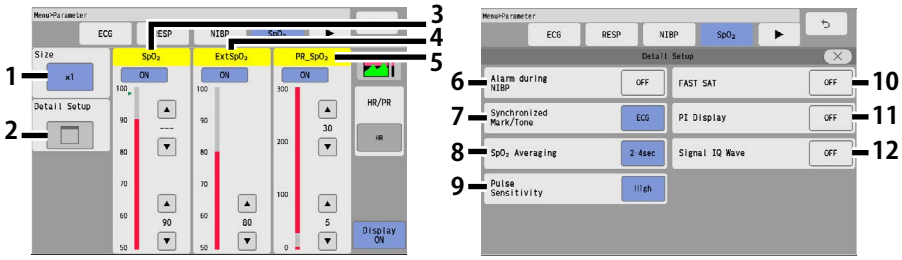
10 Set the "SpO_2 Averaging".

▸ [Fast]: Used for comparatively still patients. This should be used for most clinical procedures.

▸ [Normal]: Used for patients with a comparatively large amount of movement. SpO_2 measurements are less affected by movement, but the response time is slower.

SpO_2 Parameter Setup (Masimo)

This section explains the measurement procedure when using the BDS-1001M. Press [Menu > Menu List > Parameter > SpO_2] to display the SpO_2 parameter window.



1 Set the waveform size.
(☞"SpO2 Parameter Setup (Medtronic)" P7-34)

2 Open the "Detail Setup" window.

3 Set the SpO_2 alarm.
(☞"SpO2 Parameter Setup (Medtronic)" P7-34)

REFERENCE

- The following delay occurs for the SpO_2 alarm depending on the patient classification and SpO_2 averaging duration setting. (For Masimo)

	SpO_2 Averaging	Patient Classification	
		Adult/Child	Neonate
SpO_2 Alarm Condition Delay	For all settings	About 7 sec. to 9 sec.	About 7 sec. to 9 sec.
SpO_2 Alarm Signal Delay	For all settings	About 5 sec.	0 sec.

4 Set the ExtSpO_2 alarm.
(☞"Alarm Limit Setup for Each Parameter" P6-8)

NOTE

- Set the lower limit in the range of 50%SpO_2 to 98%SpO_2. If a value below 50%SpO_2 is set, the lower alarm will turn OFF.
- The lower limit of ExtSpO_2 cannot be set above the lower limit of SpO_2.

REFERENCE

- The lower limit can be set in 1%SpO_2 increment.
- ▶ indicates the current measurement value.
- The following delay occurs for the ExtSpO_2 alarm depending on the patient classification and second alarm setting.

	Patient Classification	
	Adult/Child	Neonate
SpO_2 Alarm Condition Delay	About 7 sec. to 9 sec.	About 7 sec. to 9 sec.
SpO_2 Alarm Signal Delay	About 5 sec.	0 sec.

5 Set the PR alarm.

(☞"SpO2 Parameter Setup (Medtronic)" P7-34)

REFERENCE

- The following delay occurs for the PR alarm depending on the patient classification. (For Masimo)
  - PR Alarm Condition Delay: <Adult/Child> About 8 sec. to 10 sec. <Neonate> About 7 sec. to 9 sec.
  - PR Alarm Signal Delay: <Adult/Child> About 5 sec., <Neonate> 0 sec.

6 Set the "Alarm during NIBP".

(☞"SpO2 Parameter Setup (Medtronic)" P7-34)

NOTE

- Selecting [OFF] will not generate the SpO_2, PR alarm until the NIBP measurement is complete.

7 Set the "Synchronized Mark/Tone".

(☞"Set the "Synchronized Mark/Tone"." P7-7)

8 Set the "SpO_2 Averaging".

⚠ WARNING

- The displayed SpO_2 value is the average value for the duration selected for "SpO_2 Averaging". As the alarm is based on the displayed SpO_2 value, the alarm occurring condition depends on the averaging duration. Therefore, alarm may not occur if the SpO_2 value changes transiently. Be very careful when changing the averaging duration.

▸ Select from [2-4sec.]/[4-6sec.]/[8sec.]/[10sec.]/[12sec.]/[14sec.]/[16sec.].

9 Set the pulse sensitivity.

▸ Select from [High] /[Normal]/[APOD].

⚠ CAUTION

- If [High] is selected for pulse sensitivity, probe-off detection will become somewhat inaccurate.

NOTE

- To improve the low perfusion condition, or to perform fast tracking when the oxygen saturation value changes abruptly, select [High].
- For standard use, select [Normal].
- If there is a high possibility of sensor getting disconnected, select [APOD].
- When the pulse detection sensitivity is set to [High], performance of the "Sensor Off" detection may be compromised. If the device is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.

10 Set the "FAST SAT".

- [ON]: Abrupt change of the SpO_2 value can be monitored.
- [OFF]: FAST SAT mode will turn OFF.

11 Set the "PI (Perfusion Index) Display".

NOTE

- The perfusion index is calculated by pulsatile signal divided by apulsatile signal times 100, and indicates patient's circulation condition at the monitoring site.
- This can be used to find a good perfusion site to attach the sensor. Also, it can be used as diagnosis index to predict the patient's critical condition when at low perfusion.

- [ON]: PI will be displayed.

- [OFF]: PI will not be displayed.

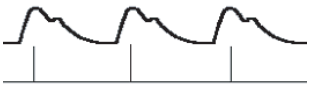
12 Select [ON]/[OFF] for "Signal IQ Wave".

NOTE

- The signal IQ wave cannot be printed.

REFERENCE

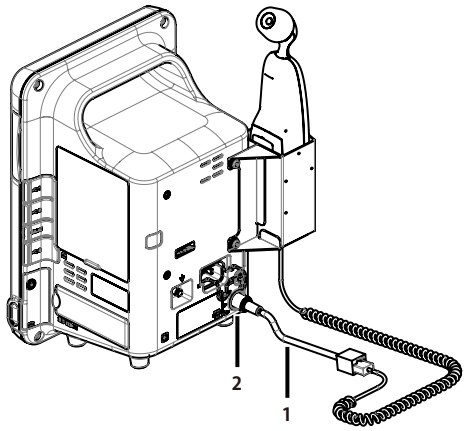
- The signal IQ wave indicates the signal confidence and pulse beat. The vertical length indicates the signal confidence. A low vertical line indicates a lower signal confidence.



Temperature

This section explains the procedure to monitor the temperature data measured by the specified thermometer (TAT-5000S-RS232-QR).

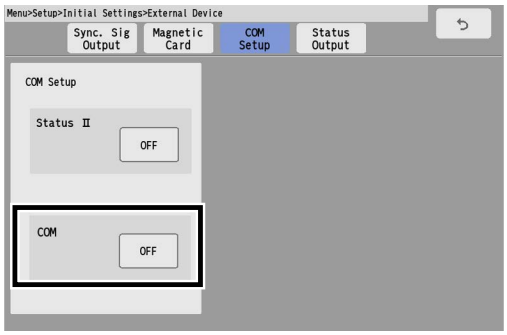
1 Connect the thermometer connection cable (CJO-32RS0.1) to the serial connector (COM) of the BDS-1001.
(☞Maintenance Manual "Connecting the Thermometer" P4-5)



1 Thermometer Connection Cable (CJO-32RS0.1)

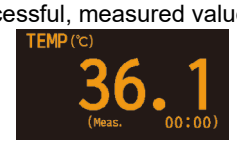
2 Serial Connector (COM)

2 Press [Menu > Menu List > Setup > Initial Settings > External Device > COM Setup].
Select [TEMP] for “COM”.



3 Measure the temperature using the specified thermometer.
For measurement procedure, refer to the operation manual of the thermometer.

- When the reading is successful, measured value and read time will be displayed with a success sound.



- When the reading fails, a failure sound will generate.

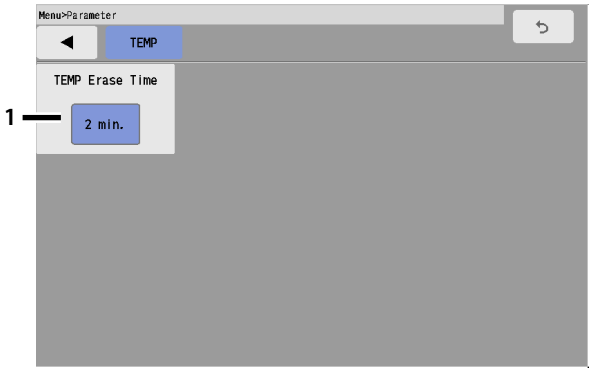
NOTE

- The temperature data will be input to scoring and tabular trend function. But, it will not generate an alarm, or be input to graphic trend.
- If an error message is displayed on the thermometer, refer to the operation manual of the thermometer.
- If reading of measured data has failed, measure the temperature again. If reading of

measured data still fails, contact your local Fukuda Denshi service representative.

TEMP Parameter Setup

Press [Menu > Menu List >Parameter > TEMP] to display the TEMP parameter window.



1 TEMP Erase Time

- TEMP data will be erased after the set duration (2 min./5 min.).
- The erased data will not be transmitted to the central monitor.

NOTE

- During the set duration, data input to the BDS-1001 tabular trend and data transmission to the central monitor will be performed.

CO_2 Concentration (Sidestream Method)

The HCP-110 is a CO_2 Gas Unit which measures CO_2 concentration. The HCP-110 CO_2 Gas Unit incorporates Microstream technology from Medtronic for $EtCO_2$ (End-tidal CO_2 concentration) and $InspCO_2$ (Inspiratory CO_2 concentration) measurement. This section explains about the procedure and setup of the CO_2 concentration measurement of the HCP-110.

⚠ WARNING

- 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.
- Loose or damaged connections 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), <CO_2 Check Sample Line> will appear in the message area. Replace the sampling line when this message appears.
- Carefully route the sampling line to reduce the possibility of patient entanglement or strangulation.
- Do not lift the device by holding the sampling line. 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, ambient environmental conditions, and patient conditions.

- If uncertain about the accuracy of any measurement, first check the patient's vital signs by alternate means, and then make sure the HCP-110 is functioning correctly.
- The device should not be used as an apnea monitor.
- Do not place this device in any position that might cause it to fall on the patient.
- The use of accessories and cables other than those specified may result in increased emission and/or decreased immunity of the device and/or system.
- HCP-110 is a prescription medical device. Only qualified healthcare professionals can use this device.
- If the calibration is not performed as instructed, the calibration of HCP-110 may not be proper. Without proper calibration, accurate results cannot be attained.
- Do not modify this device without authorization of the manufacturer.
- Do not silence the audible alarm on the monitor if patient safety cannot be ensured.
- Always respond immediately to a system alarm since the patient may not be monitored during certain alarm conditions.
- Before each use, verify that the alarm limits are appropriate for the patient being monitored.
- When using the HCP-110 with anesthetics, nitrous oxide or high concentrations of oxygen, connect the gas outlet to a scavenger system.
- The FilterLine may ignite in the presence of O_2 when directly exposed to laser, ESU devices, or high heat. When performing head and neck procedures involving laser, electrosurgical devices or high heat, use with caution to prevent flammability of the FilterLine or surrounding surgical drapes.
- Do not use the monitor with nuclear spin tomography (MRT, NMR, NMT) as the function of the monitor may be disturbed.
- When using a sampling line for intubated patients with suction system, do not such a way as to avoid 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 and that the airway adapter is not damaged during suction. Damage of the airway adapter may harm the patient.
- Check CO_2 and O_2 tubing regularly during use to ensure that no kinks are present. Kinked tubing may cause inaccurate CO_2 sampling or affect O_2 delivery to patient.
- Inaccurate CO_2 readings or ineffective O_2 delivery may occur if the patient has clogged nares.
- Use the sampling lines with oxygen of maximum 5L/min or as indicated in the directions for use of the sampling lines. At higher levels of oxygen provision, dilution of CO_2 readings may occur, leading to lower CO_2 values.
- This device is compatible only with MVPNO, MVPO, MVPOL, MVPOH, MVPOHL, MVPNOH, MVPN, MVP and ZMVPO. This product may be exposed to chemicals such as DINP that are recognized as carcinogenic by the State of California. For details, refer to the following. www.P65Warnings.ca.gov.
- Do not use the MVIIH, MVIIHH, MVIIHL or ZMVIIH together with products that have protruding internal connectors (Hamilton flow sensor, etc.), as they may damage the airway adapter.
- When using an upper endoscopy sampling line, respiratory gases may be measured incorrectly if the oral cavity prong is not correctly inserted in the channel of the bite block. The oral cavity prong needs to be inside the channel during treatment.

⚠ CAUTION

- 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.

- 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.
- Replace the sampling line according to hospital protocol or when a blockage is indicated on the device. Excessive patient secretions or a buildup of liquids in the airway tube may occlude the sampling line, requiring more frequent replacement.
- In high-altitude environments, $EtCO_2$ values may be lower than values observed at sea level, as described by Dalton's law of partial pressures. When using the monitor in high-altitude environments, it is advisable to take this into account and to consider adjusting $EtCO_2$ alarm settings accordingly.
- Read values may decrease and the waveform may become rounded when the oral RAE tube is partially blocked to align the endoscope or during suction. This becomes more pronounced at higher oxygen supply levels.

NOTE

- When connecting a sampling line to the HCP-110, screw the sampling line clockwise into the connector firmly to avoid inaccurate measurement which may be caused by gas leak from the connection point.
- When the sampling line connected to the HCP-110 is blocked, <CO_2 Check Sample Line> will be displayed, and the CO_2 pump will stop delivering the patient's respiration to the monitor. In such cases, refer to the "Troubleshooting" section. First, disconnect and reconnect the sampling line. If the message still appears, disconnect and replace the sampling line. Once a working sampling line is attached, the CO_2 pump will automatically resume operation.
- After connecting the CO_2 sampling line to the HCP-110 and patient, check that CO_2 values appear on the monitor.
- The $EtCO_2$ accuracy is checked according to the test method of ISO 80601- 2-55: 2018 (Medical electrical equipment-Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors).
- The waveform sampling rate is 20 samples per second.
- When using the HCP module with a ventilator, and when the pressure exceeds 10 kPa (100 cmH_2O), the module may enter into a blockage mode in order to protect the module from damage.
- Respiration rate accuracy is verified by changing respiration rate input to the module within the measurement range using a circuit that generates square wave that simulates breath by switching nitrogen gas and calibration gas for test.
- Regarding drift, please note that the periodic auto zero function compensates for drifts between components, changes in ambient temperature, and barometric conditions. This automatic process eliminates variances that might otherwise cause measurement drift.
- After connecting the CO_2 sampling line to the monitor and patient, check that CO_2 values appear on the monitor.
- Sampling lines with H in their names include a moisture reduction component (Nafion® or its equivalent) for use in higher humidity environments where long duration use of CO_2 sampling is required.
- Any serious incident that may occur related to the device usage should be reported immediately to the manufacturer, the local competent authority, and any other regulators as required.
- Before use, make sure the airway adapter can be easily attached and removed from the sampling line.
- During spraying, cleaning or suction, stop the CO_2 pump according to the operation manual

of the monitor to prevent water from accumulating and blocking the sampling line. If the CO_2 pump cannot be stopped, remove the connector of the sampling line from the CO_2 port of the HCP-110.

- When using an upper endoscopy sampling line, 100% of O_2 enters the patient's nares when the O_2 luer is not connected between the sampling line and bite block. When the O_2 luer is connected between the sampling line and bite block (recommended), O_2 enters the patient's nares and mouth simultaneously. O_2 flow is distributed so that 80% enters the patient's mouth and 20% enters the nares.
- A longer delay results in a longer response time, which causes a decrease in frequency response when using the Filter Line MRI XI.
- All Biocompatibility Reports for the sampling lines are kept in Medtronic (Covidien Jerusalem) AGILE PLM system, doc # DR0025, and will be available upon request.

REFERENCE

- Medtronic Recommended Default Alarm/Alarm Threshold

Parameter	Adult	Child	Infant/Neonate	Alarm/Warning Range
$EtCO_2$ High	60	60	50	5 to 99
$EtCO_2$ Low	15	15	20	0 to 94
$InspCO_2$ High	8	8	5	2 mmHg to 98 mmHg
RR High	30	40	65	5 bpm to 150 bpm
RR Low	5	10	25	0 bpm to 145 bpm*
No Breath Detected	30	20	15	10 sec to 60 sec

* RR=0 is not a valid RR. Pay attention that an alarm will not occur with this value.

Patient Application and Display

The CO_2 concentration can be measured by using the HCP-110 CO_2 Gas Unit.

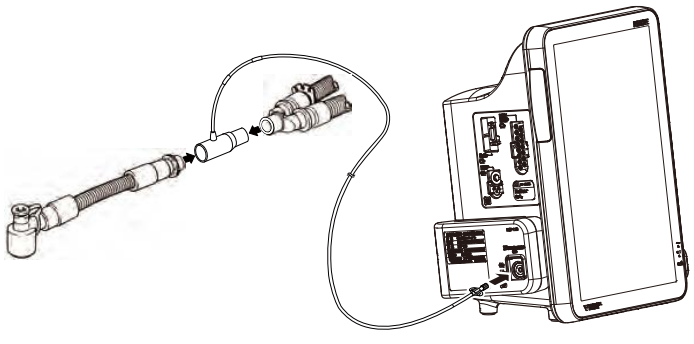
NOTE

- Accurate CO_2 concentration measurement can be acquired after 40 seconds from turning the power ON.

1 Connect the HCP-110 CO_2 Gas Unit to the BDS-1001.

2 Attach the airway adapter or nasal prong to the patient.

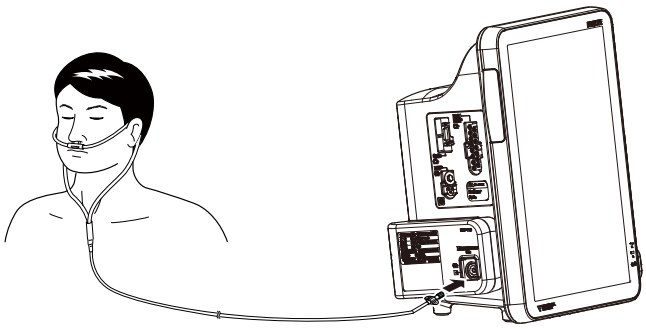
For intubated patient



1 Attach the airway adapter to respiration circuit.

2 Connect one end of the sampling line to the connector on the HCP-110. Verify that all the tubes are properly connected.

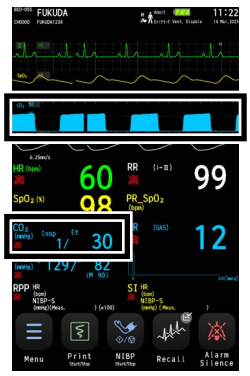
For patient using the nasal prong



1 Attach the nasal prong to the patient.

2 Connect the nasal prong connector to the connector on the HCP-110. Verify that all the tubes are properly connected.

3 Start the CO_2 concentration measurement.



▸ Verify that the CO_2 waveform, $EtCO_2$ value, $InspCO_2$ value are displayed.

CAUTION

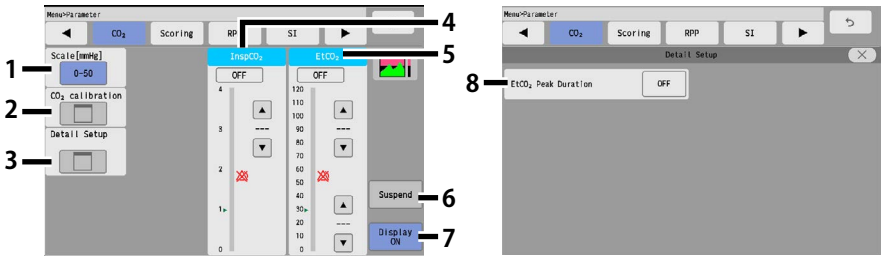
- If the power supply is interrupted due to power failure, etc., HCP-110 will be initialized even if the power interruption was within 30 seconds.

NOTE

- Connecting a sampling line or nasal prong to the HCP-110 will automatically start the sampling pump. To prevent the pump from deteriorating, disconnect the sampling line and nasal prong from the HCP-110 when not measuring the CO_2 concentration.
- Set the scale, measurement unit, alarm, etc. as necessary.
- When ambient temperature or atmospheric pressure changes significantly, auto zeroing will function. During auto zeroing, "---" will be displayed inside the CO_2 numeric data box and CO_2 measurement cannot be performed.

CO_2 Parameter Setup

Press [Menu > Parameter > CO_2] to display the CO_2 setup window.



1 Scale

Select from [0- 50]/[0- 100] if the measurement unit is mmHg, and from [0- 4]/[0- 8]/[0- 10] if the unit is kPa or %.

2 CO_2 Calibration

CO_2 calibration can be performed.

(☞Maintenance Manual "CO2 Calibration (HCP-110)" P9-8)

3 The "Detail Setup" window will be displayed.

4 InspCO_2 (Inspired Carbon Dioxide)

(☞"Alarm Limit Setup for Each Parameter" P6-8)

NOTE

- InspCO_2 alarm will not generate unless 2 or more respiration is detected within 30 seconds after power ON or after discharge.
- Set the upper limit in the range of 1 mmHg to 4 mmHg/0.1 kPa to 0.4 kPa/0.1% to 0.4%.
  Setting a value above 4 mmHg/0.4 kPa/0.4% will turn OFF the alarm.

REFERENCE

- The alarm limit should be set for each unit (mmHg/kPa/%).
- The upper limit can be set in 1 mmHg/0.1 kPa/0.1% increment. There is no lower limit.

5 EtCO_2 (End-tidal Carbon Dioxide)

(☞"Alarm Limit Setup for Each Parameter" P6-8)

NOTE

- EtCO_2 alarm will not generate unless 2 or more respiration is detected within 30 seconds after power ON or after discharge.
- Set the upper limit in the range of 3 mmHg to 100 mmHg/0.3 kPa to 13.3 kPa/0.3% to 13.3%.
  Setting a value above 100 mmHg/3.3 kPa/13.3% will turn OFF the alarm.
- Set the lower limit in the range of 1 mmHg to 98 mmHg/0.1 kPa to 13.1 kPa/0.1% to 13.1%.
  Setting a value below 1 mmHg/0.1 kPa/0.1% will turn OFF the alarm.

REFERENCE

- The alarm limit should be set for each unit (mmHg/kPa/%).
- The upper/lower limit can be set in 1 mmHg/0.1 kPa/0.1% increment.

6 Suspend

[Suspend]: The pump operation will stop, and waveform and numeric data display will disappear.

[Resume]: Resumes CO_2 monitoring. The [Resume] key will be displayed when the measurement is suspended.

⚠ CAUTION

- When the measurement is suspended, the alarm generation and trend input will be also suspended.
- The measurement suspended condition will be canceled after 15 minutes has elapsed, or when the filter line is disconnected.

7 Display ON/OFF

(☞"ECG Parameter Setup" P7-5)

⚠ CAUTION

- When the waveform and numeric data display is set to OFF, the alarm generation and tabular trend input will also cease.
- When the waveform and numeric data display is set to OFF, the respiration rate measured by CO_2 will not be displayed either.

REFERENCE

- When the filter line is applied to the patient during the "Display OFF" condition, the waveform and numeric data will be automatically displayed when 2 or more respirations are detected in 30 seconds.

8 $EtCO_2$ Peak Duration

[10sec]/[20sec]: Maximum $EtCO_2$ value, minimum $InspCO_2$ value for the selected duration will be displayed.

[OFF]: $EtCO_2$ value, $InspCO_2$ value for each respiration will be displayed.

NOTE

- As the $EtCO_2$ value display is updated each second, $EtCO_2$ value for each respiration cannot be displayed if respiration rate is 60 Bpm and above.

CO_2 Calibration

This section describes about the procedure of CO_2 gas calibration.

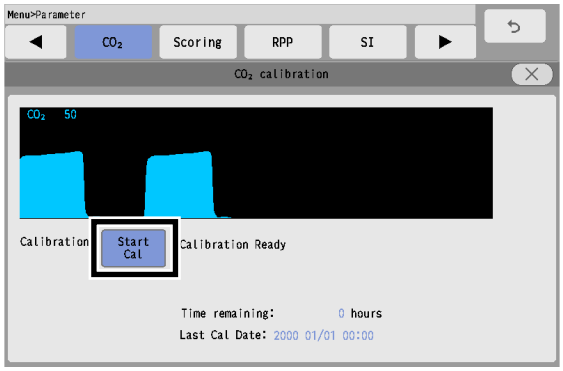
Perform calibration for the following case.

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 [Menu > Menu List > Parameter > CO_2 > CO_2 calibration] to display the CO_2 calibration window.



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

3 <Feed Cal. Gas> will be displayed. Press the injection button and inject the calibration gas.

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

5 <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 [Cal Complete] to end the calibration.

⚠ CAUTION

- Perform the calibration 5 minutes after turning ON the power on the HCP-110.
- Do not disconnect the sampling line during calibration. If the sampling line 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, "HCP-110 Replacement" or "HCP-110 Calibration" is displayed at power ON.
- Dispose of calibration gas according to the regulation of each medical institution.

Scoring Function

As an index to assist predicting possible sudden health changes for a patient, a score can be calculated based on the patient's medical history, biometric measurements, and the observations performed by the medical professional.

The following score modes can be used. The score mode can be customized by changing the parameters and score thresholds.

- NEWS2
  Improved scoring system of NEWS (National Early Warning Score) which is a scoring system released by NHS (National Health Service) on 2012.
- qSOFA (quick-Sequential Organ Failure Assessment)
  Scoring system to predict organ failure caused by sepsis, etc.

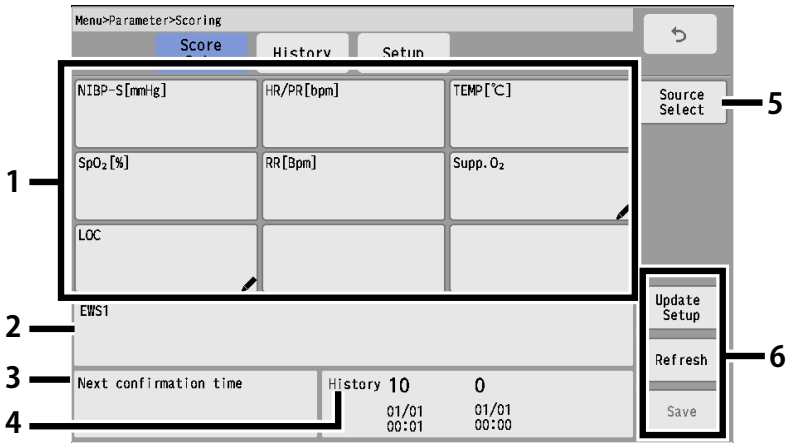
⚠ CAUTION

- A diagnosis should not be made based solely on a patient's score. A comprehensive diagnosis should be performed taking into consideration all of the patient's clinical signs and symptoms.
- NEWS2 cannot be used for patients under the age of 16.

Description of the Scoring Display

Press [Menu > Menu List > Parameter > Scoring > Score Calc], or press the Scoring numeric data box to display the Scoring window.

❑Score Calculation Display



1 Maximum of 9 parameters and scores (0 to 3) will be displayed.

▸ Pressing the parameter display area with ✎ mark will allow to enter the values manually.

2 The aggregate score (0 to 27) and calculated date/time will be displayed.
It will be displayed only if measurement data for all parameters are entered.

REFERENCE

- The background color of the score will differ depending on the score value.
- On the right side of the score, an arrow comparing with the previous score will be displayed.
  ↑: Increased from the previous score.

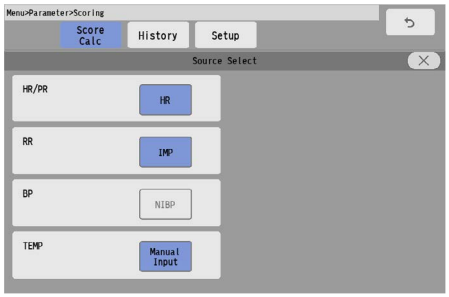
→: Same with the previous score.
↓: Decreased from the previous score.

3 The time to check the next score will be displayed. (☞"Scoring Setup" P7-51)

4 3 scores (aggregate score and date/time) will be displayed.

5 Press [Source Select] to display the setup window.

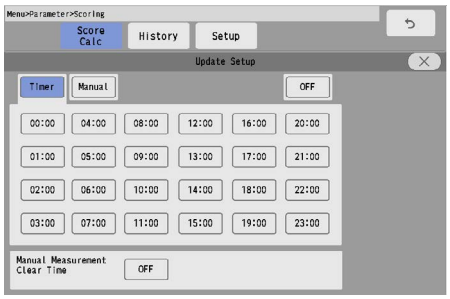
- Select the measurement source for HR/PR, RESP, BP, TEMP.



6 Description of Each Key

1 [Update Setup]: The score update timing can be set. (Timer/Manual/OFF)

- [Timer]: Select the time to automatically update. (More than one selection is possible.)
  In addition, select "Manual Measurement Clear Time". The manually entered data will be deleted after the set time.
- [Manual]: The data will be updated according to the setting of "Time Interval until Next Check". (☞"Scoring Setup" P7-51)

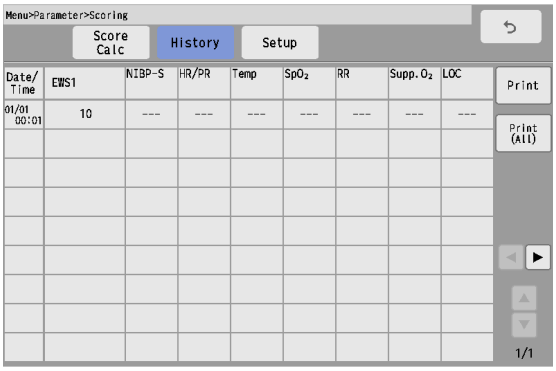


2 [Refresh]: Aggregate score, individual parameter score, manually entered data will be displayed blank.

3 [Save]: Numeric data box, score list will be updated.
It will not be displayed when [OFF] is set for [Update Setup].

❑Score List Display

Press [Menu > Parameter > Scoring > List] to display the score history list.



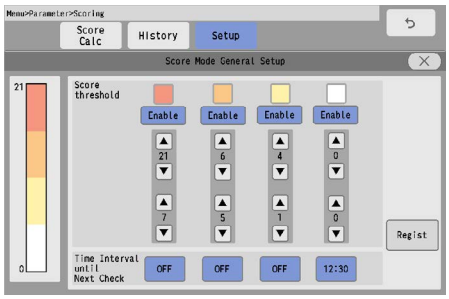
Scoring Setup

Press "Setup" to display the setup window. Score mode, parameters, score range can be set.

NOTE

- For the score mode 4 (NEWS2), parameters and score thresholds cannot be changed.

1 Press the score mode display area to display the setup window.

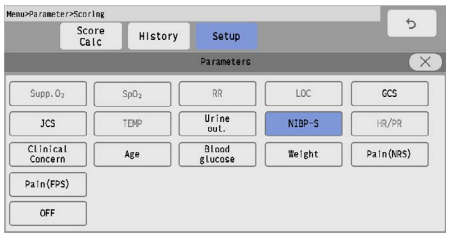


- Set the thresholds for score level 1 to 4, and the time interval of next check time.

- When the score mode is set to "NEWS 2" , the thresholds for score level and interval until next check will be set as follows and these settings cannot be changed.

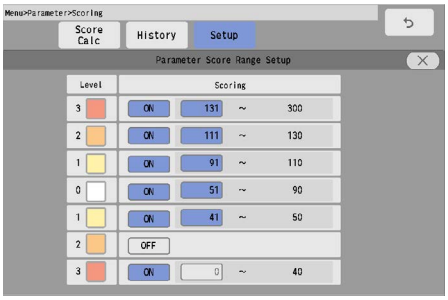
Aggregate Score Level	4 (Red)	3 (Orange)	2 (Yellow)	1 (White)
Score Threshold	7 to 21	5 to 6	3 in Single Parameter	0 to 4
Time Interval until Next Check	15 min.	1 hour	1 hour	12 hours

2 Press the parameter display area to display the parameter selection window.



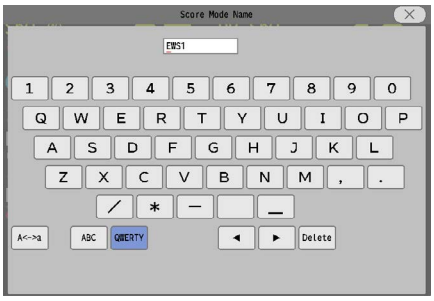
- Select the parameters to be used.

3 Press the score range display area to display the threshold setup window.



- The setup window differs depending on the selected parameter.
  The example shown on right is when setting ON/OFF and threshold for each level of scoring.
  Other than the example shown on right, the setup window which allows to select the level or Yes/No from the dropdown list may be displayed.

4 Press [Change Name] to change the score mode name.



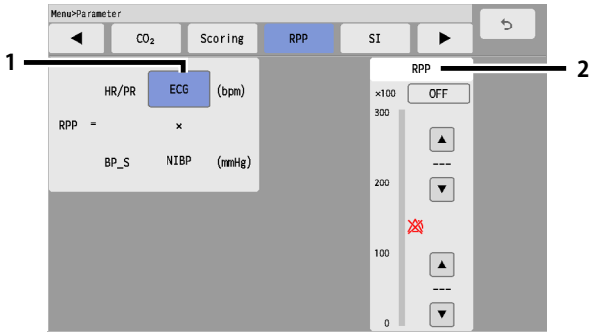
Double Product RPP (Rate Pressure Product)

This section explains the measurement method and condition for RPP.
RPP calculation formula:
RPP = HR (bpm) x Systolic Blood Pressure (mmHg)

NOTE

- When the NIBP erase time has elapsed and NIBP numeric data is erased, RPP will be also erased.
- When the NIBP measurement ends erroneously, RPP will not be calculated.
- When HR/PR or BP_S are not measured or out of range, RPP will not be calculated.
- If the BP unit is "kPa", the data is converted to "mmHg" for calculation.
- RPP is displayed with a supplementary unit of x100.

Press [Menu > Menu List > Parameter > RPP] to display the RPP parameter window.



1 HR/PR Source

Select the parameter for RPP calculation from [ECG], [SpO_2].

2 RPP Alarm

(☞"Alarm Limit Setup for Each Parameter" P6-8)

NOTE

- Set the upper limit in the range of 20 to 300, lower limit in the range of 10 to 290. If a value outside this range is set, the alarm will turn OFF.

REFERENCE

- The upper/lower limit can be set in 10 increments.

SI (Shock Index)

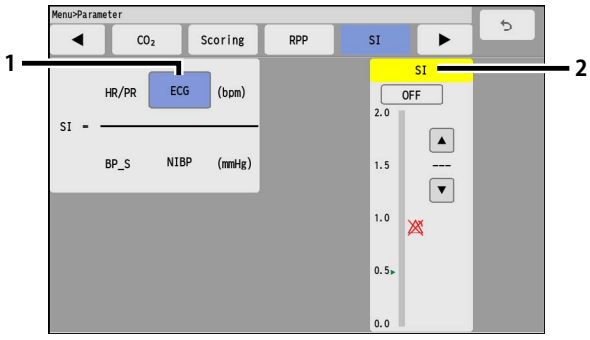
This section explains the measurement method and condition for SI.
SI calculation formula:

$$\text{SI (Shock Index)} = \frac{\text{HR [bpm]}}{\text{Systolic Blood Pressure [mmHg]}}$$

NOTE

- When the NIBP erase time has elapsed and NIBP numeric data is erased, SI will be also erased.
- When the NIBP measurement ends erroneously, SI will not be calculated.
- When HR/PR or BP_S are not measured or out of range, SI will not be calculated.
- If the BP unit is "kPa", the data is converted to "mmHg" for calculation.

Press [Menu > Menu List > Parameter > SI] to display the SI parameter window.



1 HR/PR Source

Select the parameter for SI calculation from [ECG], [SpO_2].

2 SI Alarm

(☞"Alarm Limit Setup for Each Parameter" P6-8)

NOTE

- Set the upper limit in the range of 0.5 to 2.0. The upper limit alarm will turn OFF if a value above 2.0 is set.

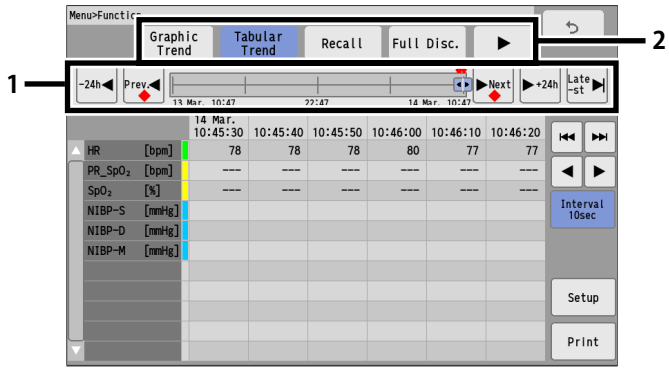
REFERENCE

- The upper limit can be set in 0.1 increments.

Chapter 8 Review Function

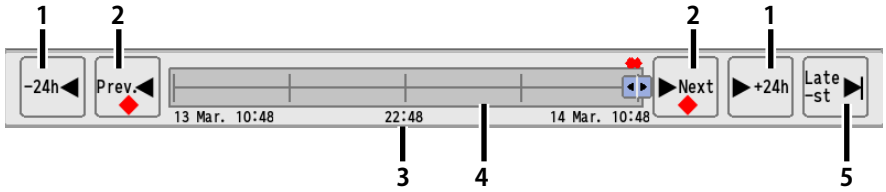
Common Operation

The common operations for all the review screens are explained below.



1 Time Bar

- Changing the time span, scrolling the time, displaying the latest data can be performed.



1 The display can be switched in 24 hours interval.

2 The previous/next alarm event will be displayed.

3 The time zone for the whole data is shown. A diamond shape mark indicates the alarm occurrence point.
The lower row shows the time zone for the displayed data.
Pressing the time bar will display the data at pressed time.

4 Indicates the displayed time range with the bar length.
Dragging the slider to the right will display newer data, and dragging it to the left will display older data.

5 The latest data will be displayed.

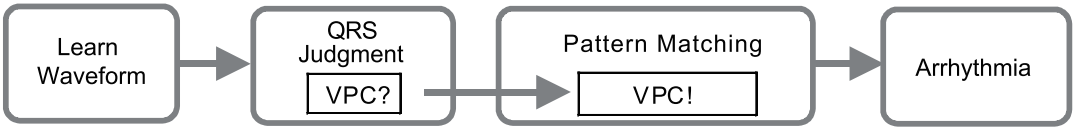
2 Displays other review data of the same time.

- With the displayed date/time, the review data display can be switched.
  Other review data (graphic/tabular trend) can be displayed without moving the current cursor time.

Arrhythmia Analysis

This section explains about the arrhythmia analysis.

Arrhythmia Definition



The arrhythmia detection is performed by learning the normal waveform of the patient, and determines the VPC by comparing the waveform (QRS pattern) and R-R interval for each heartbeat.
The parameters such as QRS amplitude, QRS width, QRS polarity, RR interval are compared with the normal waveform to extract the abnormal QRS.
Then, the QRS with suspected VPC is pattern matched. The noise and VPC are distinguished to determine the VPC, and generates the arrhythmia alarm.

WARNING

- 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 by closely checking the data obtained by printing and recall waveform.

CAUTION

- 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.
- When HR, arrhythmia or QRS is misjudged, perform arrhythmia learning. Performing arrhythmia learning will recover the original analyzing accuracy.

❑Arrhythmia Type

With the QRS judgment, the following arrhythmia alarm will be generated.

Arrhythmia	Description	Detection Criteria
Asystole (Cardiac Arrest)	ON 3 sec to 10 sec., 1 sec. increments	Cardiac arrest is detected for more than preprogrammed time.
VF (Ventricular Fibrillation)	ON	A random, rapid electrical activity of the heart is detected.
VT (Ventricular Tachycardia)	ON	9 or more continuous VPC beats are detected.* 1
Slow VT	ON	9 or more continuous VPC beats are detected.* 2
Run (Consecutive VPC)	ON, OFF 2 beats to 8 beats, 1 beat increments	Continuous VPC exceeding the preprogrammed value (2 beats to 8 beats) is detected.* 3
Couplet (Couplet SVPC)	ON, OFF	2 continuous VPC beats are detected.
Pause	ON, OFF 1.5 sec. to 5.0 sec.,0.5 sec. increments	Cardiac arrest exceeding the preprogrammed duration is detected.
Bigeminy (Ventricular Bigeminy)	ON, OFF	QRS pattern of V-x-V-x-V-x is detected.* 4
Trigeminy (Ventricular Trigeminy)	ON, OFF	QRS pattern of x-x-V-x-x-V is detected.* 4
Frequent (Frequent VPC)	ON, OFF 1 beats to 50 /min. beats, 1 beat increments	VPC exceeding the preprogrammed value is detected within 1 minute.
Tachy (Tachycardia)	ON, OFF	The upper HR alarm limit is exceeded.
Brady (Bradycardia)	ON, OFF	The lower HR alarm limit is exceeded.
Ext Tachy (Extreme Tachycardia)	ON, OFF 22 beats to 300 beats/ min. 22 bpm to 60 bpm, 1 beat increments 60 bpm to 300 bpm, 5 beat increments	The upper alarm limit of extreme tachycardia is exceeded.
Ext Brady (Extreme Bradycardia)	ON, OFF 20 beats to 295 beats/ min. 20 bpm to 60 bpm, 1 beat increments 60 bpm to 295 bpm, 5 beat increments	The lower alarm limit of extreme bradycardia is exceeded.
R on T (R on T VPC)	ON, OFF 200 ms to 600 ms, 8 ms increments	VPC is detected within the preprogrammed RR interval (200 ms to 600 ms).
Multiform (Multiform VPC)	ON, OFF	2 different forms of VPC beats are detected within 4 minutes.
Vent Rhythm (Ventricular Rhythm)	ON, OFF	Continuous VPC beats with HR below the set value for "HR Lower Limit for Run" (0 bpm to 200 bpm), and same or above value of the set beats for Run (2 beats to 8 beats) are detected.
SVT (Supraventricular Tachycardia)	ON, OFF 2 beats to 10 beats, 1 beat increments	Continuous SVPC exceeding the preprogrammed value (2 beats to 10 beats) is detected.
AFib (Atrial Fibrillation)	ON, OFF 1% to 100%, 1% increments	The variation of the RR interval above the set value continues for fixed amount of time and learned P wave cannot be detected.* 5
Irregular RR (Irregular RR Interval)	ON, OFF 10% to 20%, 5% increments	RR interval variability exceeding the preprogrammed value (10% to 20%) is detected.
Prolonged RR (Prolonged RR Interval)	ON, OFF	RR interval of 1.75 times longer than the normal RR interval is detected.
Pacer Not Capture (Non-Capture)	ON, OFF 80 ms to 480 ms, 8 ms increments	HR is not detected from the pacing pulse within the set duration.
Pacer Not Pacing (Oversensing)	ON, OFF 20 beats to 200 beats/ min., 5 beat increments	Pacing pulse and HR are not detected during the set instant HR.

Arrhythmia	Description	Detection Criteria
Triplet (Triplet VPC)	ON, OFF	3 continuous VPC beats are detected.
S Frequent (Frequent SVPC)	ON, OFF 1 beat to 50 beats /min., 1 beat increments	SVPC exceeding the preprogrammed value is detected within 1 minute.
S Couplet (Couplet SVPC)	ON, OFF	2 continuous SVPC beats are detected.
VPC (Ventricular Extrasystole)	ON, OFF	VPC is detected.
SVPC (Supraventricular Extrasystole)	ON, OFF	SVPC is detected.

*1: HR of 120 bpm to 200 bpm (increments of 10ms)

*2: HR of 100 bpm to 180 bpm (It should not exceed the value of HR Lower Limit for Slow VT -20 bpm.)

*3: HR of same or above the set value of "HR Lower Limit for RUN" (0 bpm to 200 bpm)

*4: * indicates N, P, F, ?.

*5: AFib can be detected only when the patient classification is “Adult”. If the patient classification is "Child" or "Neonate", AFib cannot be detected.

Arrhythmia Alarm Setup

Arrhythmia alarm setup procedure is explained below.
ON/OFF of arrhythmia alarm and arrhythmia detection level can be set.
When the measured value exceeds the set arrhythmia detection level, arrhythmia alarm will generate.

Arrhythmia Detection Level Setting

Item	Description
Asystole	3 sec. to 10 sec.
Run	2 beats to 8 beats
Pause	1.5 sec. to 5 sec.
Frequent	1 bpm to 50 bpm/ min.
Ext Tachy	22 beats to 300 beats
Ext Brady	20 beats to 295 beats

Item	Description
R on T	200 ms to 600 ms
SVT	2 beats to 10 beats
Irregular RR	10, 15, 20%
S Frequent	1 beats to 50 beats
Pacer Not Capture	80 ms to 480 ms
Pacer Not Pacing	20 bpm to 200 bpm
AFib	1 - 100%

1 Press the [Menu], [Arrhy.] ("Alarm") key.

- The arrhythmia alarm setup screen will be displayed.

2 Set the detection level.
Set using the dropdown list, numeric keys, or displayed key selection.

3 Select ON/OFF for the alarm.

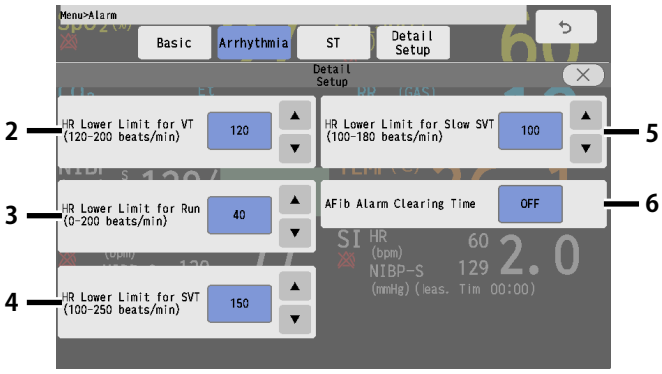
- [ON]: Alarm will generate.
- [OFF]: Alarm will not generate.

NOTE

- If the patient classification is "Child" or "Neonate", AFib cannot be detected.

❑Arrhythmia Alarm Detail Setup

On the "Detail Setup" of arrhythmia alarm, HR Lower Limit for VT, RUN, and SVT can be set.



1 Press the [Menu], [Arrhy.] ("Alarm"), [Detail Setup] key.

- The "Detail Setup" window for arrhythmia alarm will be displayed.

2 Set the "HR Lower Limit for VT" .

- Set the VT analyzing condition for the arrhythmia analysis.
  VT alarm will generate if the HR is same or above the set value.
- Press the [▲]/[▼] keys for "HR Lower Limit for VT to set the HR in the range from 120 bpm to 200 bpm.

3 Set the "HR Lower Limit for RUN" .

- Set the Run analyzing condition for the arrhythmia analysis. Run alarm will generate if the HR is same or above the set value.
- Press the [▲]/[▼] keys for "HR Lower Limit for Run" to set the HR in the range from 0 bpm to 200 bpm.

4 Set the "HR Lower Limit for SVT" .

- Set the SVT analyzing condition for the arrhythmia analysis. SVT alarm will generate if the HR is same or above the set value.
- Press the [▲]/[▼] keys for "HR Lower Limit for SVT" to set the HR in the range from 100 bpm to 250 bpm.

5 Set the "HR Lower Limit for Slow VT" .

- Set the Slow VT analyzing condition for the arrhythmia analysis. If the HR is the same or above the selected value, Slow VT will be detected.
- Press the [▲]/[▼] keys for "HR Lower Limit for Slow VT" to set the HR in the range from 100 bpm to 180 bpm.
- The upper limit can be set up to 20 bpm lower than the HR Lower Limit for VT.

6 Set the "AFib Alarm Clear Time" .

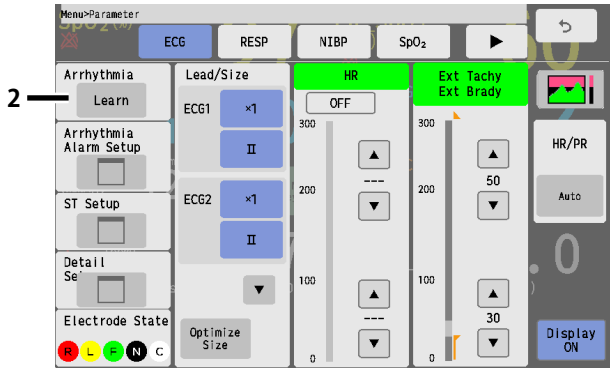
- Set the AFib alarm analyzing condition for the arrhythmia analysis. When the set time has elapsed, the alarm level of the AFib alarm changes to N (Notification Alarm). When [OFF] is selected, the alarm level of the AFib alarm will not change to the notification alarm.

Arrhythmia Learn

Learning the normal ECG largely affects the accuracy of arrhythmia analysis.
If any error occurs in arrhythmia detection and QRS judgment, performing arrhythmia learning will recover the original analyzing accuracy.
Arrhythmia learning will be performed for about 20 beats for the normal ECG, but it may take longer if the heartbeat is unstable.
During arrhythmia learning, arrhythmia alarm other than Asystole, VF, Tachy, Brady, Ext Tachy, Ext Brady will not generate.

1 Press [Menu > Menu List > Parameter > ECG].
Or, press the HR numeric data box.

- The ECG setup screen will be displayed.



2 Press the [Learn] key while displayed in gray.

- The key will change to blue.
- Arrhythmia learning will start.
- During arrhythmia learning, a message will be displayed.

NOTE

- If [Used] is selected for "Pacemaker", the [Learn] key will not change to blue and <LEARN> will not be displayed, but the learning process will be performed.
- Pressing the key while arrhythmia learning is in process will not stop the process.

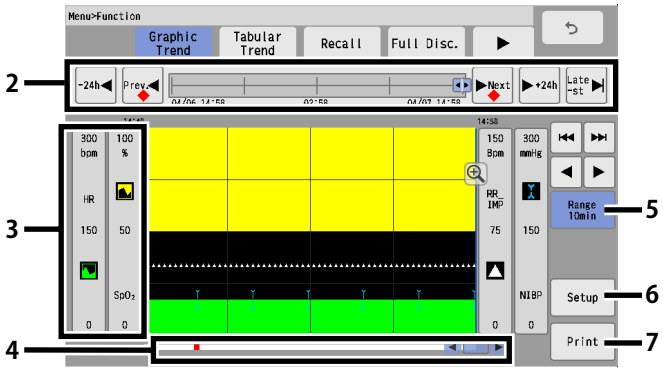
Graphic Trend

This section explains the graphic trend function and printing procedure.
If the numeric data is displayed on the home display, data will be automatically stored and displayed as trend data.

Graphic Trend Setup

1 Press [Menu > Function > Graphic Trend].
Or, press the [Graphic Trend] key on the user key area.

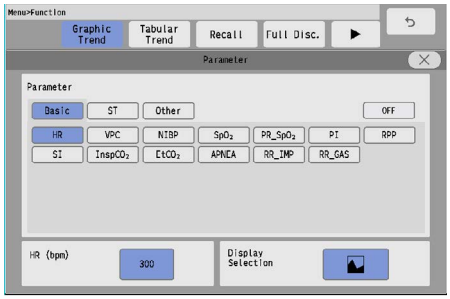
▸ The graphic trend will be displayed.



2 Changing the displayed time, scrolling the time, updating the data (☞"Common Operation" P8-1)

3 Press the scale area for each parameter, and set the displayed parameter.

1 Press the key for "Parameter", and select the parameter to be displayed.



NOTE

- The APNEA duration will be stored when it exceeds the upper alarm threshold level. If lower than the alarm threshold level, it will be stored as "0 (zero)".

4 Move the cursor.

1 Pressing the center part of ◀ ▶ will display the trend data at the cursor position.

2 The cursor will move to left and right by dragging ▭.

3 Press ◀ / ▶ to adjust the cursor position.

▸ The data display at cursor position will be automatically erased after fixed duration.

4 Press 🔍+ to display the 10-minute trend data before and after the cursor position.

5 Press 🔍− to return the display to the previous time range.

5 Set the display range.

REFERENCE

- The displayed data is compressed as follows depending on the display interval.
  VPC: Maximum value within the display interval
  APNEA: Maximum value within the display interval
  Other than above: Latest value within the display interval
  For example, if the 24-hour trend for the parameter with minimum resolution of 1 minute is displayed, one mark will be displayed for the 12-minute (720-second) data.
- If the display resolution is higher than the minimum resolution of the data, the same data is repeated to match the display resolution. Refer to the following table for resolution. The data resolution differs according to the parameter.

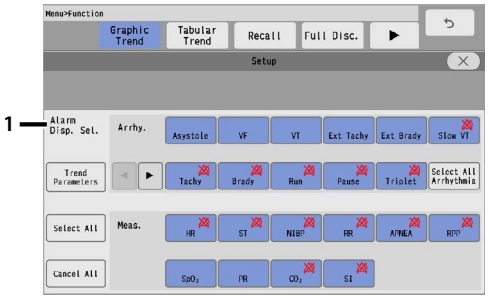
Display Resolution

Time Span	Minimum Resolution	
	Line Display	Mark Display
	10 sec. Sample	10 sec. Sample
10 min.	10 sec.	10 sec.
1 hours	10 sec.	30 sec.
2 hours	10 sec.	60 sec.
4 hours	20 sec.	120 sec.
8 hours	40 sec.	240 sec.
12 hours	60 sec.	360 sec.
16 hours	80 sec.	480 sec.
24 hours	120 sec.	720 sec.

6 Perform the setup for the graphic trend display.

1 Alarm Display Selection

Select the alarm display status.
If the alarm for the selected arrhythmia, parameter is generated during the displayed time range, it will be indicated in red at the alarm status display area.



- [Trend Parameters]: The displayed trend parameters will be selected.
- [Select All]: All parameters including arrhythmia will be selected.
- [Cancel All]: All selections will be canceled.
- [Select All Arrhythmia]: All arrhythmia will be selected.
- Each parameter key: Each time the key is pressed, selected/unselected status will change.

7 Press [Print].

- To print the trend data, press the [Print] key, select the parameter, and press the [Enter] key.

Description for Each Parameter

Numeric Data	Description	Scale	Unit
HR	Heart Rate	300	bpm
VPC	VPC Counts	100	-
ST (I, II, III,aVR, aVL, aVF, V)	ST Level	±20.0 ±2.0	mm mV
SpO_2	SpO_2 Value	0 to 100	%SpO_2
PR_SpO_2	SpO_2 Pulse Rate	300	bpm
NIBP	Non-Invasive Blood Pressure	300 40	mmHg kPa
SI	Shock Index	3.0	-
RR_IMP	Impedance Respiration Rate	150	Bpm
Apnea	Apnea Duration (Impedance, CO_2, Ventilator)	30	sec
$EtCO_2$, $InspCO_2$	Gas Unit CO_2 Concentration	100 100	mmHg kPa, %
PI	Perfusion Index	20	%
RPP	Double Product	900	-
RR_GAS	Gas Unit Respiration Rate	150	Bpm

NOTE

- The APNEA duration will be stored when it exceeds the upper alarm threshold level. If lower than the alarm threshold level, it will be stored as "0 (zero)".

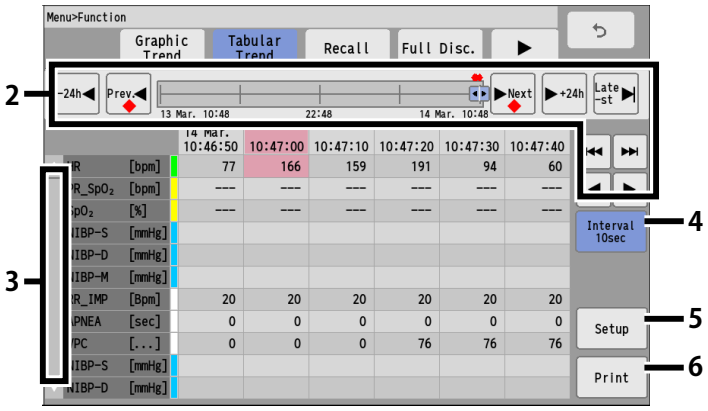
Tabular Trend

This section explains the tabular trend function and printing procedure.
If the numeric data is displayed on the home display, data will be automatically stored and displayed.

To Display/Print the Tabular Trend

1 Press the [Menu > Function > Tabular Trend] keys.
Or, press the [Tabular Trend] key on the user key area.

▸ The tabular trend will be displayed.



2 Changing the displayed time, scrolling the time, updating the data (☞"Common Operation" P8-1)

3 The list will be scrolled up or down to display other parameters.

4 Select the display interval.

[NIBP]: The tabular trend display interval will be according to the NIBP measurement time.

NOTE

- If the display resolution is higher than the minimum resolution of the data, the same data is repeated to match the display resolution.
- Maximum 336 hours of data will be stored regardless of the time bar display range.

5 Set the parameters for the tabular trend.

(☞"Parameter Setup for Tabular Trend" P8-10)

6 Press [Print].

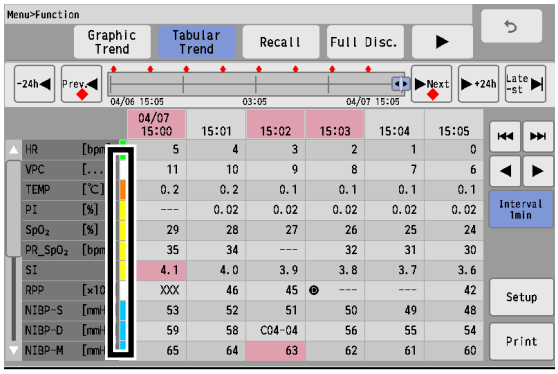
▸ The currently displayed tabular trend will be printed.

The Description of the Display

If the measured data is not displayed on the home display, the data will be displayed as "---".
The alarm generated data will be displayed with red background.
The date column of alarm generated data will be also displayed with red background.

NOTE

- The red background will be displayed for the alarm generated parameter.
  The alarm display for the expiratory and inspiratory parameter such as $EtCO_2$ and $InspCO_2$ will be the same.
  For example, if the alarm is generated for NIBP-S, the background color of NIBP-S, NIBP-M, NIBP-D will be displayed in red.

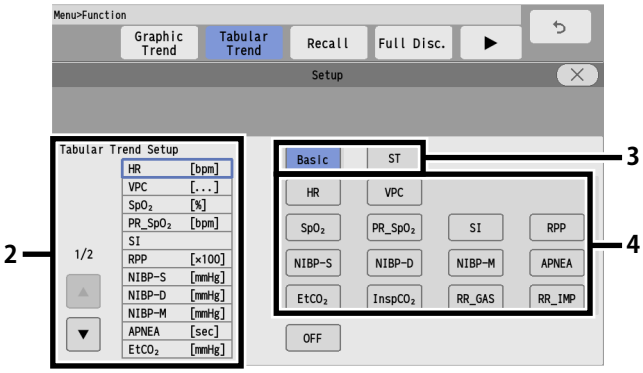


On the right side of the parameter, the color assigned for the corresponding parameter will be displayed.

Parameter Setup for Tabular Trend

1 Press the [Menu], [Function], [TabularTrend], [Setup] keys.

▸ The tabular trend setup screen will be displayed.



2 Select the display location for the parameter.

▸ The selected location will be indicated with blue frame.

▸ To change the displayed page, press the [▲]/[▼] keys on the left.

3 Select the category of the parameters to be displayed on the tabular trend.

▸ [Basic]/[ST]: The parameters for the corresponding category will be displayed.

Parameters for each Category

Basic	HR, VPC, TEMP, PI, SpO_2, PR_SpO_2, SI, RPP, NIBP-S, NIBP-D, NIBP-M, APNEA, $EtCO_2$, $InspCO_2$, RR_GAS, RR_IMP
ST	ST (I) to ST (V)

NOTE

- The APNEA duration will be stored when it exceeds the upper alarm threshold level. If lower than the alarm threshold level, it will be stored as "0 (zero)".

4 Select the parameters to be displayed in the blue frame.

Recall

This section explains about the recall function and the setup procedure.

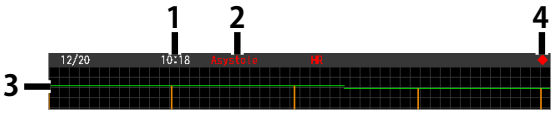
To Display the Recall Waveform

1 Date/Time at Alarm Occurrence

2 Recall Factor

3 Recall Waveform (Compressed: 12 sec.)

4 ◆Mark

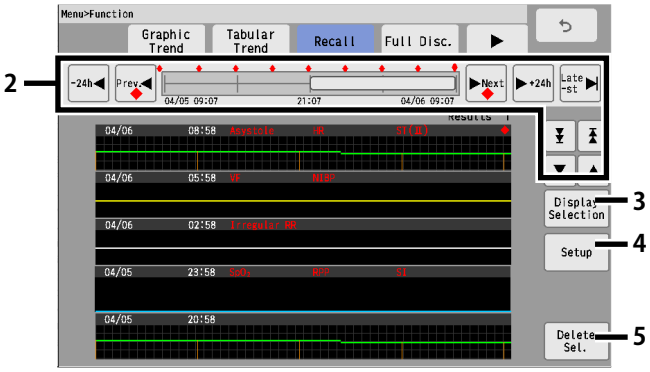


When the alarm for the specified recall factor occurs, waveforms (max. 2 waveforms/12 seconds) and numeric data for each recall factor will be stored up to 300 data.
On the display selection menu, the data to be displayed can be selected from the stored recall data.
5 compressed recall waveforms will be displayed.
Pressing the waveform area will display the enlarged waveform. When using the full disclosure waveform function,

an enlarged full disclosure waveform will be displayed.
If the recall data exceeds 300, the data will be erased from the oldest one.
The recall waveform will be acquired from the point prior to alarm occurrence so that alarm-generated point will be displayed at 7 to 8 seconds point on the 12-seconds recall waveform.
◆mark indicates the alarm generated point.

1 Press the [Menu], [Function], [Recall] keys.

- Recall screen will be displayed.
- 5 compressed waveforms (12 sec. per each waveform) will be displayed.
- The alarm occurrence time, the recall factor occurred at the same time, and the compressed waveform of recall waveform 1 will be displayed.



- The time bar display interval is fixed as 24 hours.

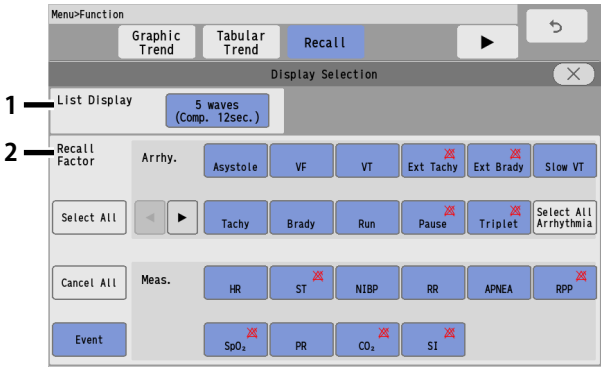
2 Changing the displayed time, scrolling the time, updating the data (☞"Common Operation" P8-1)

3 Select the recall factor to display on the recall screen.

1 The quantity of displayed waveforms is fixed as 5 waveforms.

2 Select the recall factor.

- The key will turn blue when pressed to indicate that it is selected as the recall factor.
- [Select All]: All parameters including arrhythmia will be selected.
- [Select All Arrhythmia]: All arrhythmia will be selected.
- [Cancel All]: All selections will be canceled.



4 Set the storing condition for recall data.
(☞"Recall Setup" P8-13)

5 Deleting All Recall Waveform

1 Press [Delete Sel.], and select [Select] or [Select All].
[Select]: Selects the waveform to delete. For the selected waveform, "x" will be displayed.
[Select All]: Selects all displayed waveforms.
To cancel the selection, select again the parameter with "x" mark. "x" mark will be cleared indicating that it has been removed from the deleting parameter selection.

2 Press [Delete] > [Delete OK] to delete the waveforms with "x" mark.

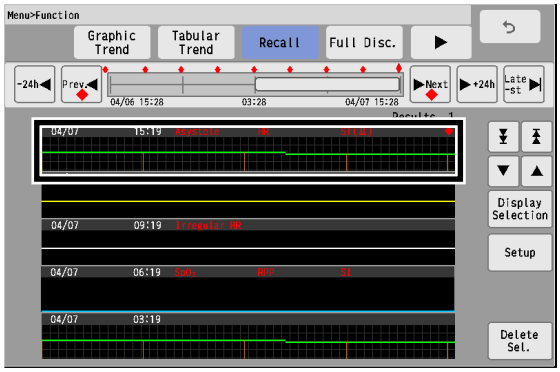
NOTE

- Deleting the recall factor will not delete the full disclosure waveform.

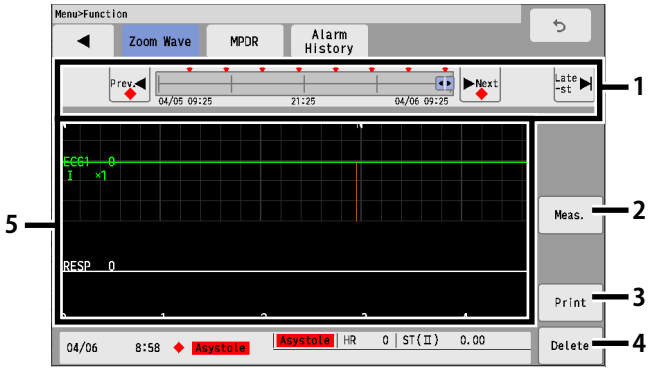
To Display/Print the Enlarged Recall Waveform

On the enlarged recall waveform display, the recall waveform will be displayed in 25 mm/s, and by using the cursor, the data before and after the alarm occurrence can be checked.

1 Press the waveform display area on the recall screen.



▸ The enlarged recall waveform will be displayed.



1 Shifts the recall waveform display.

2 Numeric Data

Numeric data can be checked.

3 Printing the Recall Waveform

The displayed enlarged waveform and measurement data will be printed. (☞"Printing Setup" P9-1)

4 Deleting the Recall Waveform

The displayed recall waveform will be deleted.

5 Recall Waveform

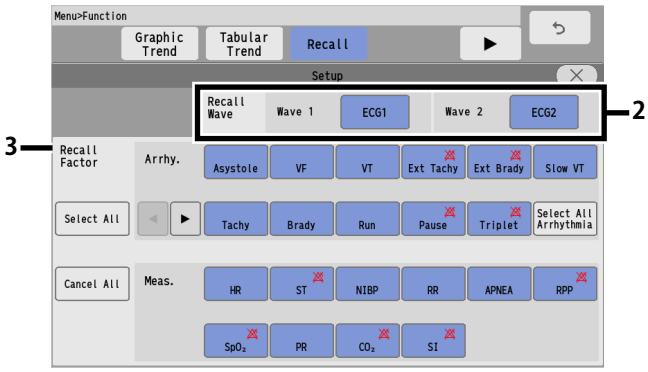
The waveform can be scrolled by dragging the waveform area to left and right.

Recall Setup

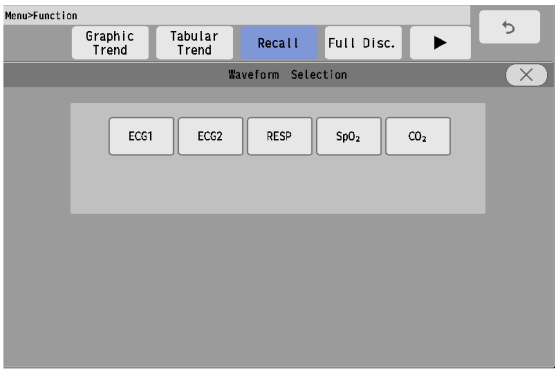
The storing condition at alarm occurrence can be set for the recall function.
The recall waveform and recall factor (numeric data, arrhythmia) can be selected.

1 Press the [Setup] key on the recall screen.
(☞"To Display the Recall Waveform" P8-11)

▸ The "Setup" window will be displayed.



2 Select the recall waveform. Up to 2 waveforms can be selected for recall waveform.



3 Select the recall factor.
(☞"To Display the Recall Waveform" P8-11)

NOTE

- The recall waveform will start with the following delay time tracing back from the alarm occurrence.

	Adult	Child	Neonate	
			Numeric Data Alarm	Arrhythmia Alarm
Delay Time	12 sec.	12 sec.	8 sec.	12 sec.

Full Disclosure Waveform

By using the optional SD card (SD-16G), 336 hours of full disclosure waveform data can be saved.
Maximum of 6 waveforms can be displayed. The alarm event and time will be also saved which allows to search the waveform by each factor.

⚠ CAUTION

- Use only the specified SD card.
- Turn OFF the power before removing the SD card.
- To turn OFF the power of the main unit, use the standby function.
- The full disclosure waveform card can be used only on the device where it was formatted.
- It will take about 3 minutes to format the full disclosure waveform card. Do not format the card during monitoring as all operation will not be possible during the format process.
- The SD card formatted for the central monitor full disclosure waveform data cannot be used on the device.

NOTE

- When the full disclosure waveform data exceeds the capacity of the SD card, the data will be deleted from the old one.
- To delete the full disclosure waveform data, perform the discharge procedure.
(☞"Discharge" P5-4)

Formatting the SD Card

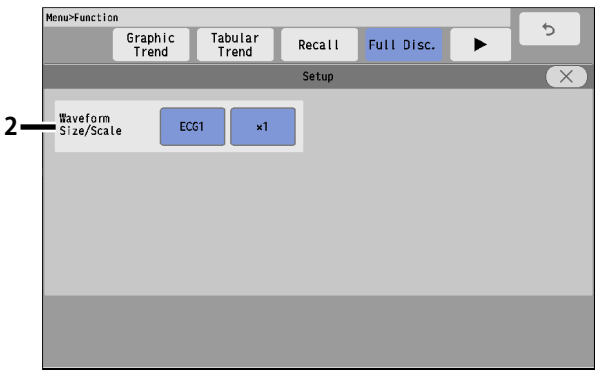
REFERENCE

- To save the full disclosure waveform, the SD card needs to be formatted for the full disclosure waveform.
(☞Maintenance Manual "Formatting the Full Disclosure Waveform Card" P3-1)

Waveform Setup

1 Press the [Menu], [Function], [Full Disc.], [Setup] keys.

▸ The "Setup" window for full disclosure waveform will be displayed.

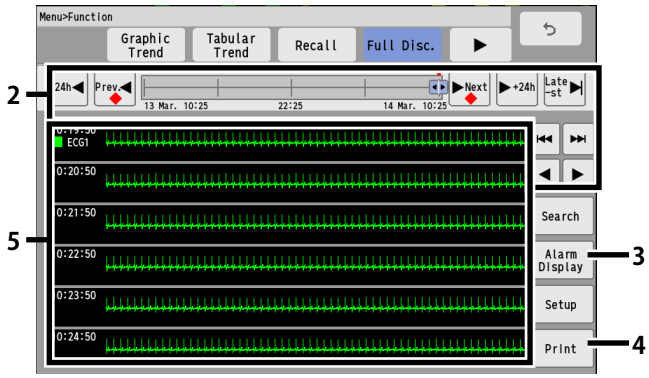


2 Select the waveform and size to display/print.

Description of the Full Disclosure Waveform Display

1 Press the [Menu], [Function], [Full Disc.] keys.

▸ The full disclosure waveform will be displayed.



2 Changing the displayed time, scrolling the time, updating the data (☞"Common Operation" P8-1)

3 Press the [Alarm Display] key.

▸ The background color of the waveform at alarm occurrence can be changed.

NOTE

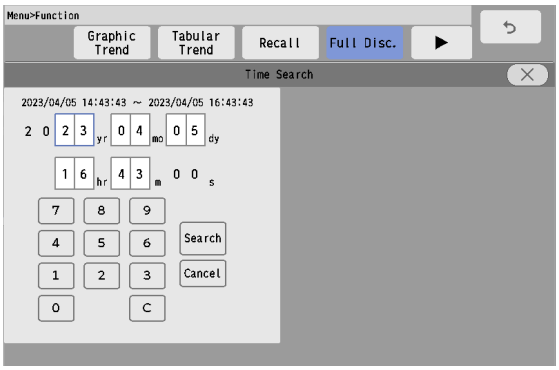
- On the full disclosure waveform display, the arrhythmia occurrence point will be displayed 7 seconds before the actual arrhythmia occurrence.

4 Press [Print].

▸ The currently displayed waveform will be output on the printer.

To Search by Time

The full disclosure waveform of the specified time can be displayed.



1 Press the [Search] key on the full disclosure waveform display.

▸ The "Time Search" window will be displayed.

2 Enter the searching date/time using the numeric keys and press the [Search] key.

- Searching will start.
- The searched waveform will be displayed on the full disclosure waveform display.

Zoom Wave

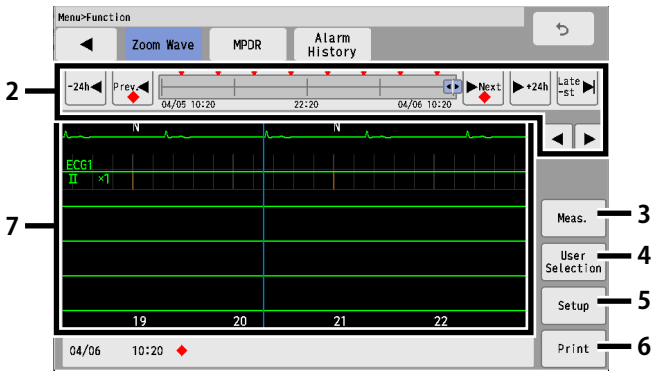
This section explains about the "Zoom Wave" window. (When the SD card is inserted.)
Maximum of 6 waveforms (5 seconds each) can be displayed.

REFERENCE

- When the SD card is not inserted, the latest enlarged recall waveform will be displayed.
- The "Zoom Wave" window can be also displayed by pressing the waveform area on the "Full Disc." window. The enlarged waveform of the pressed time will be displayed.
- Pressing the [Recall] key will also display the enlarged waveform.

1 Press the [Menu], [Function], [Zoom Wave] keys.

- The "Zoom Wave" window will be displayed.
- When the enlarged waveform is displayed by pressing the recall waveform, the last part of recall waveform (after 12 seconds) will be displayed at the center.
  By swiping the enlarged waveform from left to right, the waveform will shift rightwards, and the alarm occurrence point can be checked by shifting the waveform.



2 Changing the displayed time, scrolling the time, updating the data (☞"Common Operation" P8-1)

3 The numeric data of the displayed time will be displayed.

4 Switch the waveform to display.
[Limb]: Limb lead ECG waveform will be displayed.
[Chest]: Chest lead ECG waveform will be displayed.
[User Selection]: The waveform selected at procedure 5 will be displayed.

5 When [User Selection] is set at procedure 4, select the waveforms to be displayed.

6 The currently displayed waveform will be printed.

7 The waveform can be scrolled by dragging the waveform area to left and right.

MPDR

This section explains the operation and printing procedure of MPDR display.
The MPDR (Multiple Patient Data Review) is a function to monitor the data of current/discharged patients saved on the SD card.
By using the optional SD card (SD-16G), 336 hours of review data for the current/discharged patients can be saved.
Refer to ☞"Using the External Media" P3-1 for procedure to use the SD card.

⚠ CAUTION

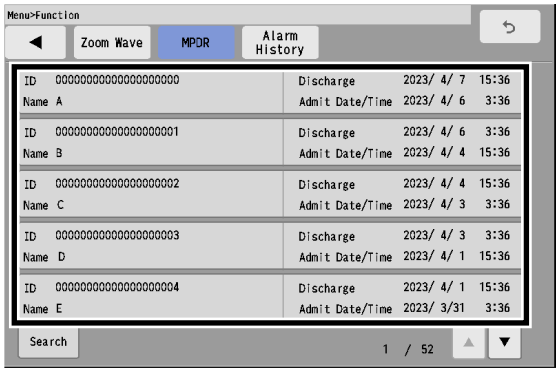
- This function may display the data of the patient other than the currently monitored patient.
- When using this function, make sure to discharge the previous patient before monitoring. Otherwise, the data cannot be distinguished between the previous patient and the current patient.
  Do not use the MPDR function if monitoring the current patient data. The latest data cannot be monitored.
- When <Reading Data> is displayed, MPDR data may not be displayed. To review the MPDR data, check that <Reading Data> is not displayed.
- If the discharge process is performed after the SD card is removed, and if the same SD card is inserted again, the previous and current patient data may become combined. If the SD card for full disclosure waveform data is used for monitoring, make sure to perform the discharge process before removing the SD card.

MPDR Data List (Patient Selection)

Select the patient data to display for the MPDR function.

1 Press the [Menu], [Function], [MPDR] keys.

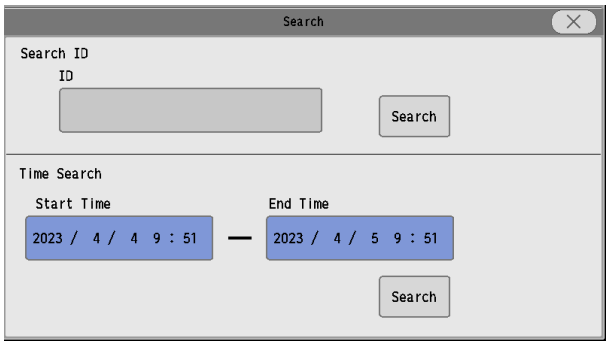
- The MPDR data list will be displayed.
- On the MPDR data list, the patient data saved on the SD card are listed by the date/time of admittance and discharge.



2 On the data list, maximum of 256 data (5 data/1page) can be displayed.

- The data of discharged patient will be displayed.
- Pressing the patient data area will display the review data selection screen. (☞"Review Data Display" P8-19)

3 The patient data can be searched within the saved time on the SD card.



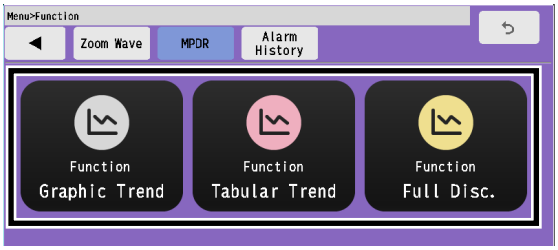
- The patient data can be searched using the patient ID or time range.
- The searched result will be displayed on the MPDR data list.

1 Search Patient ID
Only exact match can be searched.
A wild card cannot be used.
If searched without entering the ID, the patient data with no patient ID will be searched.

2 Time Search
If the data is present for the specified time range, the searched result will be displayed. The data cannot be searched for the time range outside the saved time range on the SD card.

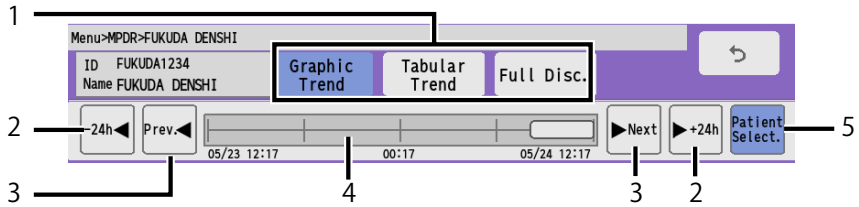
Review Data Display

Pressing the patient data area on the MPDR data list will display the review data selection screen.
The displaying review data can be selected from graphic trend, tabular trend, and full disclosure waveform.



❑Common Operation on the MPDR Display

The common operations on the MPDR display are explained below.



1 The display will switch to graphic trend/tabular trend/full disclosure waveform for the currently selected patient.

2 The display can be switched in 24 hours interval.

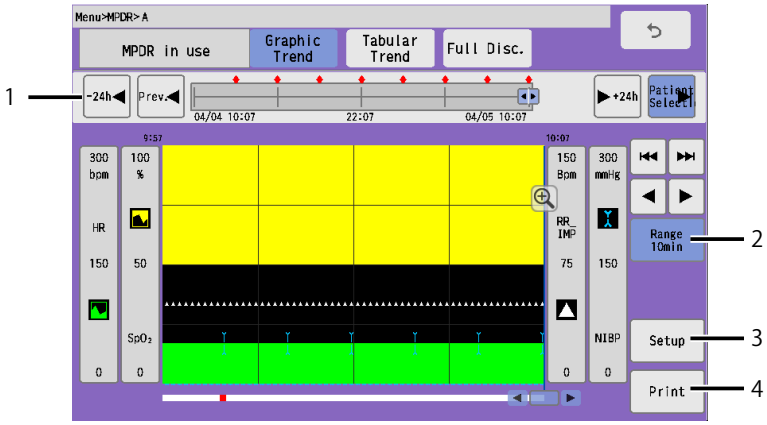
3 The next patient data on the MPDR data list will be displayed.

4 Indicates the displayed time range with the bar length.

5 The "Patient Selection" window will be displayed.

❑Graphic Trend (MPDR)

The MPDR graphic trend display is explained below.



1 Changing the displayed time, scrolling the time, updating the data (☞"Common Operation on the MPDR Display" P8-19)

2 Set the display range.

3 Perform the setup for the graphic trend display.

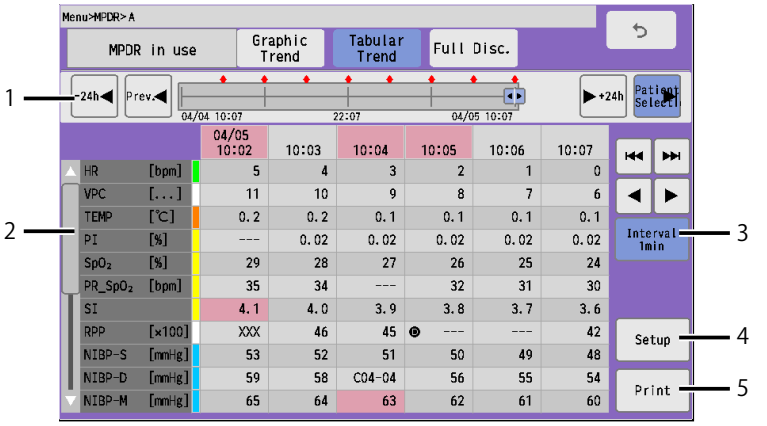
REFERENCE

- The operation procedures for the display range, trend group, trend display setup are the same with that of the standard graphic trend display. (☞"Graphic Trend Setup" P8-6)

4 To print the trend data, press the [Print] key, select the parameter, and press the [Enter] key.

❑Tabular Trend (MPDR)

The MPDR tabular trend display is explained below.



1 Changing the displayed time, scrolling the time, updating the data (☞"Common Operation on the MPDR Display" P8-19)

2 Scroll to display other parameters.

3 Select the display interval.

[NIBP]: The tabular trend display interval will be according to the NIBP measurement time.

4 Set the parameters for the tabular trend.

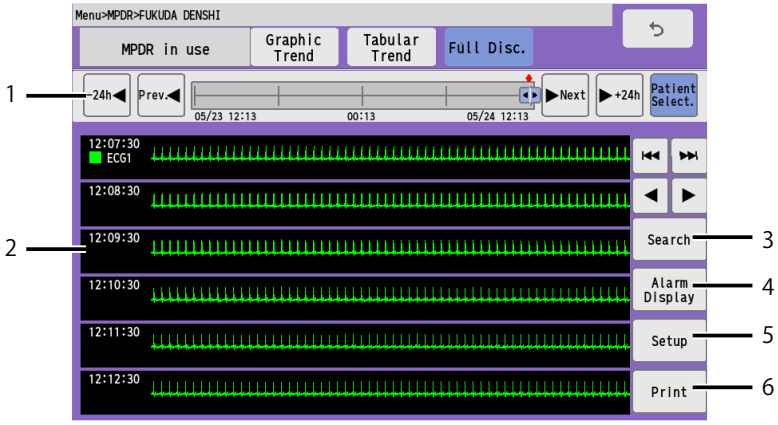
REFERENCE

- The operation procedures for the display interval, trend group, parameter selection are the same with that of the standard tabular trend display. (☞"To Display/Print the Tabular Trend" P8-9)

5 The currently displayed tabular trend will be printed.

❑Full Disclosure Waveform (MPDR)

The MPDR full disclosure waveform display is explained below.



1 Changing the displayed time, scrolling the time, updating the data (☞"Common Operation on the MPDR Display" P8-19)

2 The enlarged waveform (MPDR) will be displayed.

REFERENCE

- The operation procedure for the enlarged waveform is the same with that of the standard enlarged waveform. (☞"Full Disclosure Waveform" P8-15)

3 The full disclosure waveform of the specified time can be displayed by using the time search function.

⚠ CAUTION

- The data will be searched within the admittance period of the patient selected on the MPDR data list.
  To search from the whole data range, use the search function on the MPDR data list display.

4 The background color of the waveform at alarm occurrence can be changed.

5 Set the displaying waveform and waveform size/scale.

REFERENCE

- The operation procedures for the time search, alarm display, display setup are the same with that of the standard full disclosure waveform display. (☞"Full Disclosure Waveform" P8-15)

6 The currently displayed waveform will be output on the printer.

Alarm History

This section explains the alarm history function and printing procedure.
The alarm generation of numeric data, arrhythmia, device status and change in alarm settings can be stored as alarm history. Maximum of 1599 data can be stored.

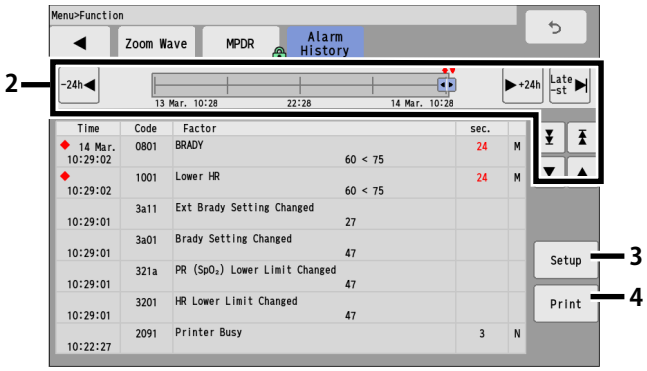
NOTE

- When the alarm history exceeds 1599 data, the data will be deleted from the oldest one.

Alarm History Setup

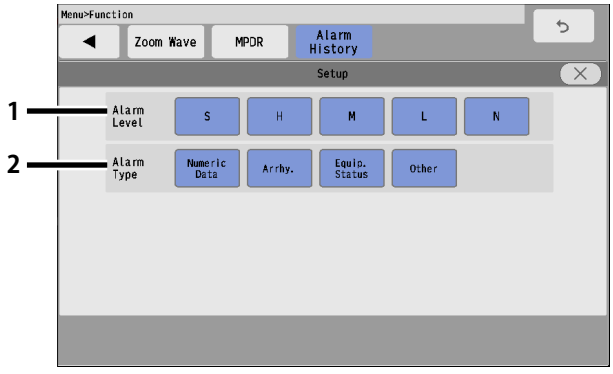
1 Press [Menu > Function > Alarm History].

▸ The alarm history screen will be displayed.



2 Changing the displayed time, scrolling the time, updating the data (☞"Common Operation" P8-1)

3 Set the alarm history display.



1 Select the alarm level to be displayed.
The selected item will be displayed in blue.

2 Select the alarm type to be displayed.
The selected item will be displayed in blue.

4 Press [Print].

▸ The currently displayed alarm history will be printed.

Description for Each Item

The descriptions of each item are as follows.

Item	Description
Time	The alarm generated time or alarm setting changed time will be displayed.
Code	The hexadecimal code related to alarm generation or alarm setting change will be displayed.
Factor	The factor for alarm generation and alarm setting change will be displayed.
	In case of numeric data/arrhythmia alarm, the numeric data and alarm setting at alarm generation will be also displayed.
	In case of device status alarm, a detailed code may be also displayed.
	In case of alarm setting change, the changed value will be also displayed.
sec.	The duration of numeric data/arrhythmia/device status alarm generation, alarm suspend, night mode will be displayed in seconds. The maximum displayable value is 99999 seconds. It will not be displayed for the alarm setting change.

Chapter 9 Printing

Printing Setup

This section describes the procedure for printing.
The following type of printing/recording can be performed.

- Manual Printing
- Auto Printing (Periodic Printing)
- Graphic Printing (Graphic Trend, NIBP Oscillation Graph, etc.)
  (☞"Review Function" P8-1)

REFERENCE

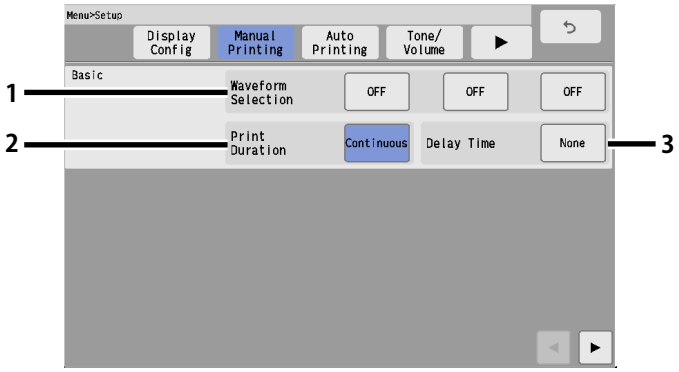
- The printed HR/PR data depends on the ECG/SpO_2 selection for "Synchronized Mark/Tone" under [Menu>Parameter>ECG/ SpO_2]. (☞"Synchronized Mark/Tone" P7-7)
- Under the following condition, the amplitude value will be printed for the ECG calibration waveform.
  *[Bar (10mm)] is set for "Waveform Size Display" under [Initial Settings > User I/F > Display/ Print].
  *[ON] is set for "Print Calibration" under [Setup > Manual Printing >Common Setup]

1 Press [Menu > Setup > Manual Printing] or [Auto Printing] keys.

▸ The manual printing or automatic printing setup screen will be displayed.

Manual Printing (Basic)

The manual printing can be set to start from the time the key is pressed, or 8 sec./16 sec. prior to the time the key is pressed.
Also, the printing can be set to automatically stop after 24 seconds, or continue to print until the "Print Start/Stop" key is pressed again.



1 Waveform

On the "Waveform Selection" window, 3 waveforms can be selected for printing.
The key for the selected waveform will be displayed in blue.

2 Print Duration

[24sec.]: Printing will automatically stop after 24 seconds.
[Continuous]: Printing will continue until the [Print Start/Stop] key is pressed again or until paper runs out.

3 Delay Time

[None]: Printing will start from the point the [Print Start/Stop] key is pressed.
[8 sec.] / [16 sec.]: Printing will start 8 sec. or 16 sec. prior from the point the [Print Start/Stop] key is pressed.

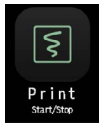
NOTE

- If [None] is selected for the manual printing delay time, QRS classification symbol will not be printed. To print the QRS symbol, set the delay time to [8 sec.] or [16 sec.].

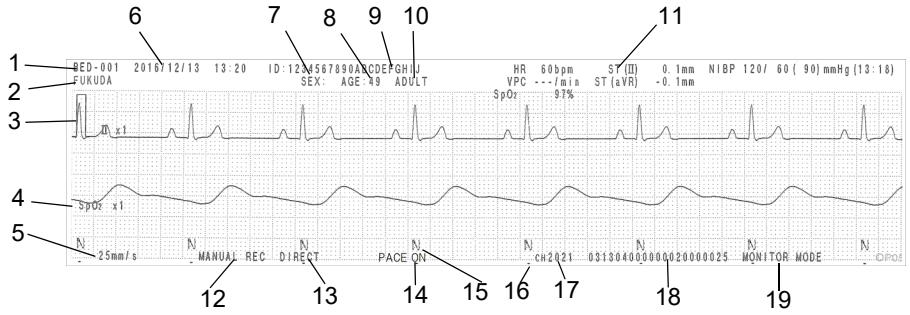
❑To Start/Stop the Printing

1 Press [Print Start/Stop] of the user key.

- Pressing this key during periodic printing, graphic printing, or recall printing will cease the printing in process.



❑Example of Manual Printing



1	Bed ID
2	Patient Name
3	Waveform Type, Lead, Size
4	Waveform Type, Scale
5	Paper Speed
6	Print Duration
7	Sex
8	Age
9	Patient ID
10	Patient Classification

11	Numeric Data (Value at the beginning of the waveform)
12	Printing Mode
13	Delay Time
14	Pacemaker
15	QRS Classification
16	R Wave Trigger Mark
17	Telemetry Channel
18	Device Setting ID (Refer to the next table.)
19	Filter Mode

The 21-digit number printed at the bottom of the paper indicates the settings of the device. At the 14th digit from the left, filter setting (AC filter, drift filter) is printed in hexadecimal number.

0 0 0 0 0 0 0 0 0 0 0 0 0 **0** 0 0 0 0 0 0 0

0	
1	
2	AC Filter ON
3	AC Filter ON
4	
5	

8		Drift Filter ON
9		Drift Filter ON
A	AC Filter ON	Drift Filter ON
B	AC Filter ON	Drift Filter ON
C		Drift Filter ON
D		

6	AC Filter ON
7	AC Filter ON

E	AC Filter ON	Drift Filter ON
F	AC Filter ON	Drift Filter ON

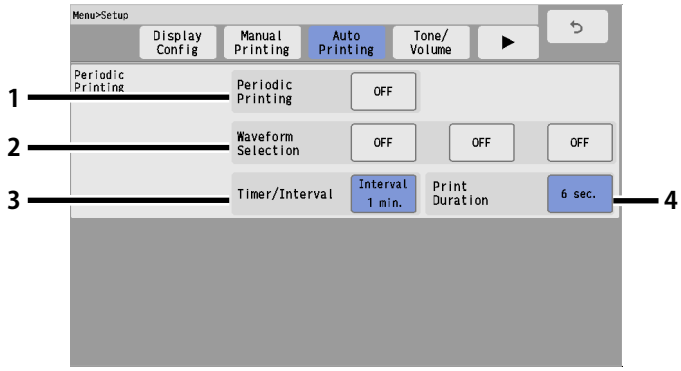
Filter setting is OFF for the numbers in blank.

Automatic Printing (Periodic Printing)

The printing will be automatically performed with the selected interval.

NOTE

- If the periodic printing is interrupted due to paper out, etc., the latest periodic printing will be performed when the printing is resumed.
- QRS classification symbol will not be printed for periodic printing.



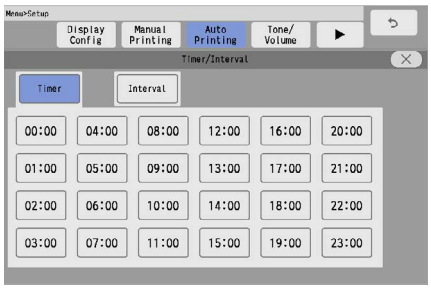
1 Periodic Printing

[ON]: Printing will automatically start at fixed interval.

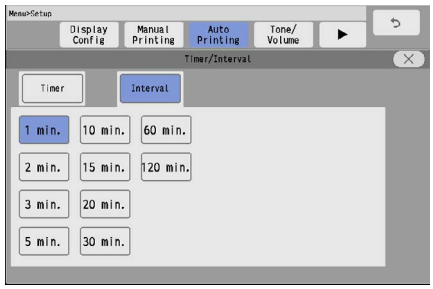
[OFF]: Turns OFF the periodic printing function.

2 Waveform (☞"Manual Printing (Basic)" P9-1)

3 Timer/Interval for Periodic Printing



Timer Window



Interval Window

[Timer]: Printing will automatically start at selected time.

[Interval]: Printing will automatically start at selected interval.

REFERENCE

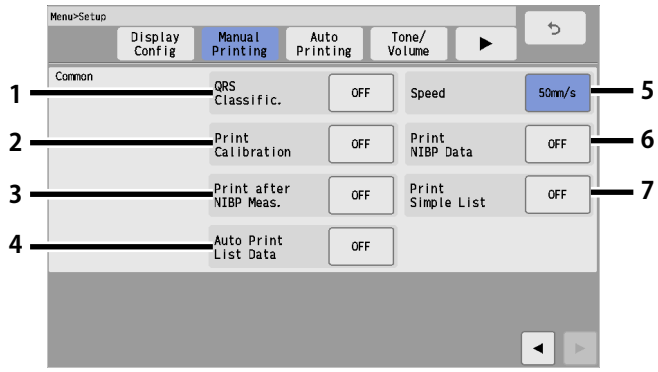
- If [5 min.] is selected for [Interval], the time will be displayed in real time such as 10:00, 10:05, ...10:25. If [60 min.] is selected, it will be displayed as 10:00, 11:00, 12:00.

4 Print Duration

The printing will automatically stop after the selected duration.

Common Setup for Printing

The printing condition common for manual printing and automatic printing can be set.
Press the [Menu > Setup > Manual Printing] ▶ keys to display the setup screen.



1 QRS Classification

[ON]: QRS classification symbol will be printed with the ECG waveform.

Symbol	Description
N (Normal)	Normal QRS beat
V (VPC)	Ventricular extrasystole
S (SVPC)	Supraventricular extrasystole
P (Pacing Beat)	Pacing beat
F (Fusion Beat)	Fusion beat of pacing and spontaneous beat
? (Undetermined Beat)	Learning arrhythmia, or unmatched beat

[OFF]: QRS classification symbol will not be printed.

NOTE

- For manual printing when delay time is set to [None] or for periodic printing, the QRS symbol cannot be printed. To print the QRS symbol, set the delay time to [8 sec.] or [16 sec.] on the "Manual Printing" menu.

2 Print Calibration

[Top]: Calibration waveform will be printed at the beginning of the waveform.
[Each Page]: Calibration waveform will will be printed on each page.
[OFF]: Calibration waveform will not be printed.

3 Print after NIBP Meas.

[ON]: NIBP data will be printed after the NIBP measurement.
[OFF]: NIBP data will not be printed after the NIBP measurement.

4 Auto Print List Data

[ON]: Tabular trend data stored on the device will be automatically printed according to the set display interval.
[OFF]: Tabular trend data will not be printed.

5 Speed

[25 mm/s]: The printing speed will be set to 25 mm/s.

[50 mm/s]: The printing speed will be set to 50mm/s.

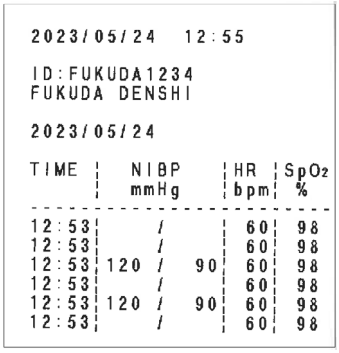
6 Print NIBP Data

[ON]: NIBP measurement data will be printed.

[OFF]: NIBP measurement data will not be printed.

7 Print Simple List

[ON]: Simple list will be printed for tabular trend printing and NIBP measurement printing.



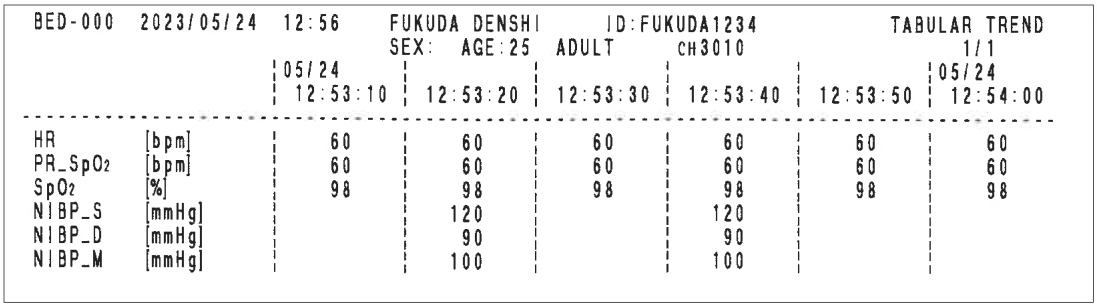
2023/05/24 12:55

ID:FUKUDA1234
FUKUDA DENSHI

2023/05/24

TIME	NIBP mmHg	HR bpm	SpO2 %
12:53	/	60	98
12:53	/	60	98
12:53	120 / 90	60	98
12:53	/	60	98
12:53	120 / 90	60	98
12:53	/	60	98

[OFF]: Simple list will not be printed for tabular trend printing and NIBP measurement printing.



BED-000 2023/05/24 12:56 FUKUDA DENSHI ID:FUKUDA1234 TABULAR TREND
SEX: AGE:25 ADULT CH3010 1/1

		05/24 12:53:10	12:53:20	12:53:30	12:53:40	12:53:50	05/24 12:54:00
HR	[bpm]	60	60	60	60	60	60
PR_SpO2	[bpm]	60	60	60	60	60	60
SpO2	[%]	98	98	98	98	98	98
NIBP_S	[mmHg]		120		120		
NIBP_D	[mmHg]		90		90		
NIBP_M	[mmHg]		100		100		

Chapter 10 System Configuration

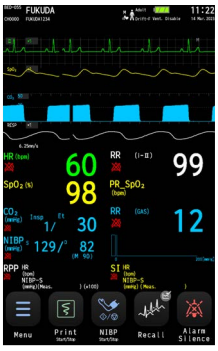
Display Configuration

This section describes about the display configuration type and the procedure to configure the display.
The waveform/numeric data display can be configured according to the monitoring purpose.
When ECG cascade or block cascade is selected, a full disclosure waveform can be displayed.

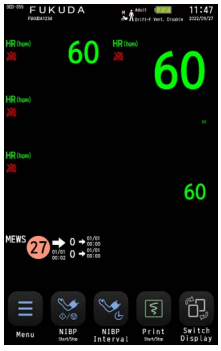
⚠ CAUTION

- The display configuration set on this menu will not be registered on the display mode. When the display mode is changed, the display will change to the configuration registered on the display mode. To apply the set display configuration using the [Display] key on the user key area, it needs to be registered on the display mode.
  (☞Maintenance Manual "User Mode Registration" P5-16)

❑Example on DS-1001



Waveform+Numeric

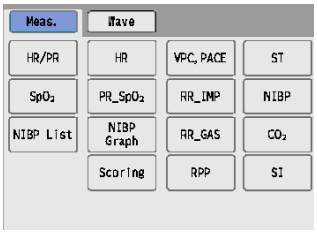


Numeric Only

On this system, 3 monitor modes and 3 display mode can be preprogrammed according to the monitoring purpose. By registering the configuration to each mode, the display configuration setups at admittance of patient can be simplified by just selecting one of the modes.
(☞"User Mode" P5-5)
(☞Maintenance Manual "User Mode Registration" P5-16)
It is recommended to program the display mode in rough classification such as patient's condition or monitoring purpose (ward or emergency room), and if necessary, make specific setup for each patient.

Numeric Data Selection

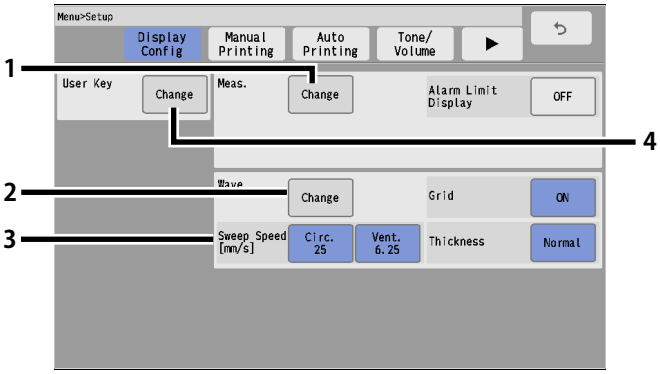
The numeric data to be displayed can be selected on the "Meas." window.
The parameters of the "Meas." window can be assigned to the numeric data box on the home display.
(☞"Displayed Items" P3-3)



To Configure the Display

1 Press the [Menu], [Setup], [Display Config.] keys.

▸ The display configuration menu will be displayed.



1 Numeric Data
(☞"Changing the Displayed Numeric Data" P10-2)

2 Waveform
(☞"Changing the Displayed Waveform" P10-3)

3 Sweep Speed
(☞"Sweep Speed" P10-4)

4 User Key
(☞"User Key Setup" P10-4)

❑Changing the Displayed Numeric Data

The displayed numeric data can be changed with the following procedure.

⚠ CAUTION

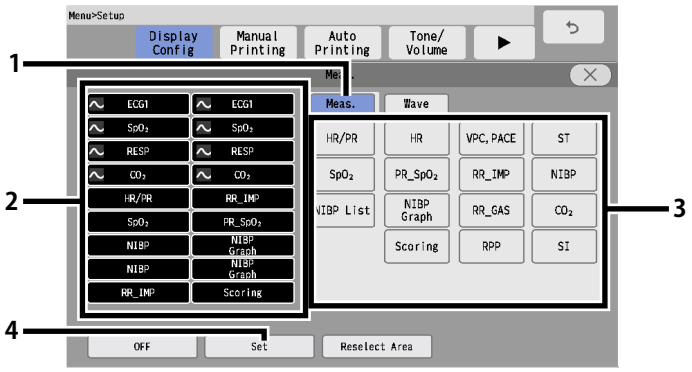
- When performing the telemetry transmission, configure the display so that the numeric data corresponding to the waveform is displayed. If not, the displayed waveform or numeric data may not be transmitted.

NOTE

- For HR/PR data, an alarm will be generated only for the current parameter displayed in the HR/ PR numeric data box. The Parameter alarm will not be generated unless the data is displayed.
  The parameter for the HR/PR numeric data box can be selected by pressing the key for "HR/PR" on the ECG, BP, SpO_2 parameter setup window or by pressing the [HR/PR] key on the user key area.

1 Press the [Meas.] key.

▸ The display will change to numeric data selection mode.



2 Press the display area to change the parameter.

▸ By pressing the selected area again, the selection will be canceled.

▸ Waveforms cannot be set on the bottom two rows as they are specified for numeric data display area.

CAUTION

- Waveforms which are not set on the numeric data display area will not be displayed.

REFERENCE

- On the display item selection screen, a wavy line is displayed in front of the parameter that indicates the waveform. (The parameters without a wavy line are numeric data.)
- To start again from the beginning, press the [Reselect Area] key.
- Adjust the size of the selected area which is indicated by blue box.

3 Select the parameter on the "Numeric Data Selection" window.

4 Press the [Setup] key.

▸ The setup will be finalized.

REFERENCE

- The selected parameter may not be displayed depending on the combination of the parameters and size.
  In such case, the same parameter will be separately located. Adjust the size or change the parameter.

❑Changing the Displayed Waveform

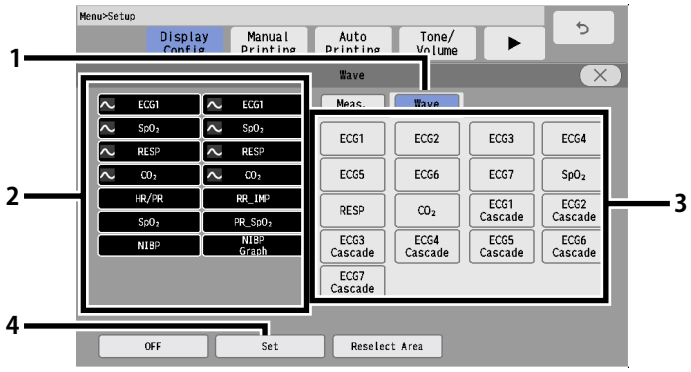
The displayed waveform can be changed with the following procedure.

CAUTION

- When performing the telemetry transmission, configure the display so that the numeric data corresponding to the waveform is displayed. If not, the displayed waveform or numeric data may not be transmitted.

1 Press the [Wave] key.

▸ The display will change to waveform selection mode.



2 Press the waveform display area to change the parameter.

▸ By pressing the selected area again, the selection will be canceled.

REFERENCE

- On the display item selection screen, a wavy line is displayed in front of the parameter

that indicates the waveform. (The parameters without a wavy line are numeric data.)

- To start again from the beginning, press the [Reselect Area] key.
- Adjust the size of the selected area which is indicated by blue box.

3 Select the parameter on the "Waveform Selection" window.

4 Press the [Set] key.

▸ The setup will be finalized.

❑Sweep Speed

The sweep speed can be set with the following procedure. A different sweep speed can be set for circulatory system and respiratory system.

1 Select the circulatory sweep speed from [6.25] / [12.5] / [25] / [50].

2 Select the respiratory sweep speed from [6.25] / [12.5] / [25].

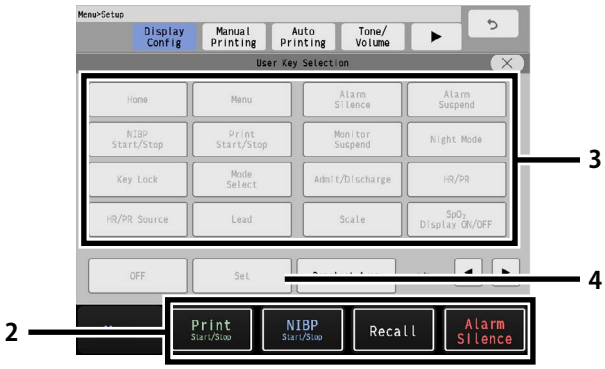
❑User Key Setup

The user key can be set with the following procedure.

1 Press the [Change] key for "User Key".

▸ The display will change to user key selection mode.

▸ The "User Key Selection" window will be displayed.



2 Select the area to change the user key.

▸ By pressing the selected area again, the selection will be canceled.

NOTE

- To start again from the beginning, press the [Reselect Area] key.
- Relocate the selected area which is indicated by blue box.

3 Select the function to assign to the user key on the "User Key Selection" window.

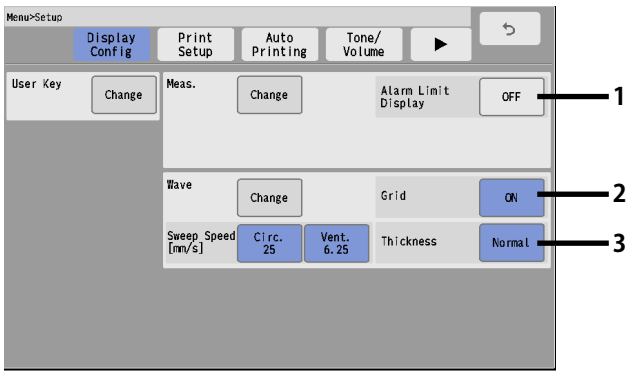
NOTE

- Press the ◀/ ▶ keys to switch the user key selection. (☞"User Key Selection" P10-6)

4 Press the [Setup] key.

▸ The setup will be finalized.

❑Other Setup



1 Set each item.

1 Alarm Limit Display

The alarm limit can be displayed inside the numeric data box.

[Graph]: Alarm limit will be displayed in bar graph.
[Numeric]: Alarm limit will be displayed in numeric format.
[OFF]: Alarm limit will not be displayed.

2 Grid

The ECG waveform can be displayed on the grid.

[ON]: Grid will be displayed.

[OFF]: Grid will not be displayed.

3 Thickness

The thickness of the displayed waveforms can be selected from [Normal] / [Thick].

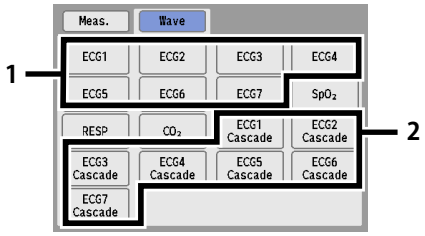
2 Check the display configuration set on the home display.

NOTE

- After configuring the display, make sure to verify the configured display on the home display.
- To maintain the configured display even after the power is turned OFF or after the discharge procedure, store the configuration to one of the user modes, or select [Backup] for "Display Configuration" under Initial Settings>User I/F>At Power ON/At Discharge. (☞"To Select the User Mode" P5-5)

Waveform Selection

The waveform to be displayed can be selected on the "Waveform Selection" window.
This section explains the details of the displayed waveforms.



1 ECG1 to ECG7

The ECG waveform of the specified channel will be displayed.

2 ECG1 to ECG7 Cascade

The ECG waveforms of the specified channel will be displayed in cascade. Minimum of 2 blocks are required to display in cascade.

Other than the waveforms explained above, the selected waveform on the "Waveform Selection Window" will be displayed.

User Key Selection

The user keys can be set on the "User Key Selection" window.
This section explains the function for each user key.

Example (Page.1)

Page 1

OFF	Blank key will be displayed.
Home	The display will return to the home display. The [Home] key is also available as fixed key.
Menu	The menu screen will be displayed. The [Menu] key is also available as fixed key.
Alarm Silence	Alarm sound will be suspended for fixed amount of time. The [Alarm Silence] key is also available as fixed key. By pressing the key for more than 3 seconds while the alarm is not generated, it will bring the system to "Alarm Sound Suspend" condition.
Alarm Suspend	Alarm (sound and display) will be suspended for fixed amount of time.
NIBP Start/Stop	NIBP measurement will start/stop.
Print Start/Stop	Manual printing will start/stop.
Monitor Suspend	Confirmation window to suspend monitoring will be displayed.
Night Mode	Night mode will turn ON/OFF.
Key Lock	The touch key operation will turn ON/OFF. It can be used when cleaning the display.
Mode Select	User mode selection screen will be displayed.
Admit/Discharge	Admit/Discharge screen will be displayed.
HR/PR	The HR/PR numeric data box will be switched between HR and PR.
HR/PR Source	The parameter for HR/PR source will be switched.
Lead	List of lead groups will be displayed, and selecting a lead group will display the lead selection window.
Scale	The home display will change to scale selection mode.
SpO_2 Display ON/OFF	SpO_2 display will turn ON/OFF.

Page 2

CO_2 Display ON/OFF	CO_2 display will turn ON/OFF.
CO_2 Suspended	CO_2 measurement suspend status will switch.
Graphic Trend	The graphic trend will be displayed.
Tabular Trend	The tabular trend will be displayed.
NIBP List	NIBP list will be displayed.
Recall	Recall screen will be displayed.
Alarm History	Alarm history will be displayed.
Full Disc.	The full disclosure waveform will be displayed.
Tone/Volume	The "Tone/Volume" menu will be displayed.
NIBP Auto Mode	NIBP Auto Mode window will be displayed.
Alarm Setup (Basic)	Alarm settings for basic parameters will be displayed.
Print Setup	Manual printing setup screen will be displayed.
Display Config.	The display configuration window will be displayed.
MPDR	MPDR (multiple patient data review) list will be displayed.
Display	The home display will be changed.
Event	Event selection list will be displayed. The selected event will be saved as recall waveform.

Page 3

Monitor Mode 1	"Monitor Mode 1" will be set for "Admit/Discharge".
Monitor Mode 2	"Monitor Mode 2" will be set for "Admit/Discharge".
Monitor Mode 3	"Monitor Mode 3" will be set for "Admit/Discharge".

WARNING

- After changing the mode, make sure that the monitoring setting is appropriate.
  When the mode is changed, patient classification, alarm settings, etc. will change to the settings of the selected mode.

Tone/Volume

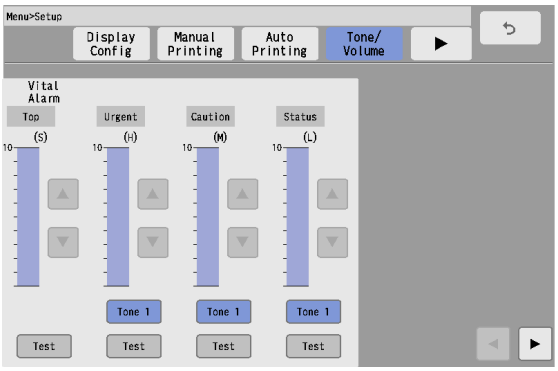
This section explains the tone/volume setup procedure for alarm sound, HR synchronized tone, key sound, and boot/shutdown sound. The tone/volume setup screen also allows to turn OFF the ventilator alarm sound.
The volume of the sound which notifies the completion of NIBP measurement can be adjusted on "Other" setting.

NOTE

- HR synchronized tone can be set. The tone for SpO_2 synchronized sound will change according to the SpO_2 value. The tone will increase as the SpO_2 value increases, and vice versa.

1 Press the [Menu], [Setup], [Tone/Volume] keys.

▸ The "Tone/Volume" menu will be displayed.



2 Set the volume.

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.
- When using this device, the operator should stay in a distance close enough to recognize an alarm sound. Do not move too far away from the device where an alarm sound cannot be recognized.

CAUTION

- Pay attention not to set the alarm volume too low to avoid missing any important alarms.
- When [IEC Tone] is set for the "Alarm System", the alarm volume and tone for the ventilator alarm and device status alarm will be the same with that of the vital alarm.

▸ Press [▲]/[▼] to set the volume.

REFERENCE

- The order of alarm priority is Urgent (H) > Caution (M) > Status (L).
  The volume is also set according to the alarm priority.
  The volume for high priority alarm cannot be set lower than the lower priority alarm, and vice versa.
- The volume above the set minimum volume can be set.
  (☞Maintenance Manual "Alarm Related Setup" P5-4)

3 Set the tone for the alarm sound, key sound.

4 Press the [Test] key to check the set volume/tone.

5 Set the "Sync. Tone".

▸ [Selected Tone]: The HR synchronized tone of ECG will be generated.

▸ [Sync. with SpO_2 Value]: The HR synchronized tone will be generated with the same tone with the SpO_2 synchronized tone. If the SpO_2 value is invalid, the HR synchronized tone of ECG will be generated.

6 For "Ventilator Alarm", select [ON]/[OFF] of ventilator alarm sound.Ventilator Alarm Sound.

❑Alarm System

Alarm System	Fukuda Tone (1) Tone 1 to 4 (2) Tone 5 to 8	IEC Tone
Sound: Physiological Alarm		
Level H	(1) Continuous melodic tone (2) Continuous single tone	Continuous single tone
Level M	(1) Melodic tone in 4.5 seconds interval (2) Single tone in 4.5 seconds interval	Single tone in 4.5 seconds interval
Level L	(1) Melodic tone in 15.5 seconds interval (2) Single tone in 15.5 seconds interval	Single tone (twice) in 15.5 seconds interval
Sound: Device Status Alarm		
Level H	(1) Continuous melodic tone (2) Continuous single tone	Continuous single tone
Level M	(1) Melodic tone in 4.5 seconds interval (2) Single tone in 4.5 seconds interval	Single tone in 4.5 seconds interval
Level L	(1) Melodic tone in 15.5 seconds interval (2) Single tone in 15.5 seconds interval	Single tone (twice) in 15.5 seconds interval
Volume Setup		
Level H, M, L	The volume for low level alarm cannot be set higher than the higher level alarm.	
Tone Setup		
Level H	Physiological Alarm: Setup can be performed. Device Status Alarm: Setup can be performed.	Physiological Alarm: Setup cannot be changed. Device Status Alarm: Setup cannot be changed.
Level M		
Level L		
Setup other than above		
Ventilator Alarm Sound	Sound: Continuous single tone Tone: Cannot be changed. Volume: Can be adjusted.	Continuous single tone

Color

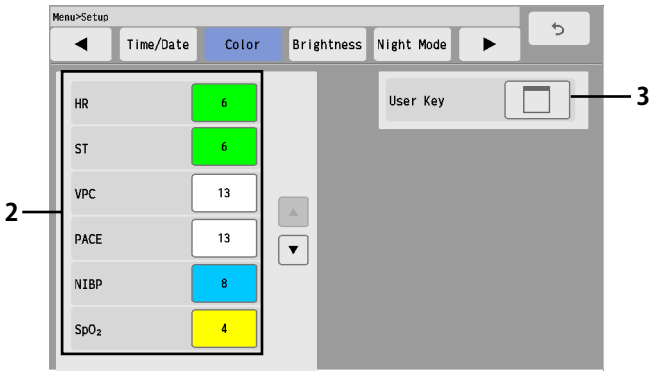
In this section, setup procedure for the color of background, numeric data, waveform is explained.

The colors of the background, numeric data, waveform color, user key color can be customized.

The colors can be customized according to the various monitoring scene such as recognizable colors from a far distance or colors which will not strain your eyes by the long time monitoring.

1 Press the [Menu], [Setup], [Color] keys.

▸ The "Color" selection window will be displayed.



2 Set the color of the numeric data and waveforms

The color can be set for each parameter. 12 colors (+white) are selectable.

1 Press the key for the parameter to change the color.

2 Select a desired color from the pull-down menu.

▸ The selected color for the parameter will be applied to the waveform, numeric data, graphic trend, and tabular trend.

3 Set the color of the user key.

1 Pressing the key for "User Key" will display the "User Key Color" window.

2 Press ◀/▶ to switch the page.

3 Select the user key to change the color.

▸ Pressing the key again will cancel the selection.

4 Select from the 5 colors displayed below.

▸ The color of the user key will change.

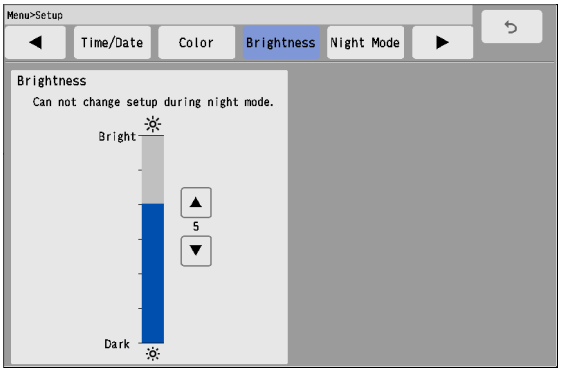
Brightness

In this section, brightness adjustment of the monitor display is explained.

⚠ CAUTION

- 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.

1 Press the [Menu], [Setup], [Brightness] keys to display the "Brightness" menu.



2 Press ▼/▲.

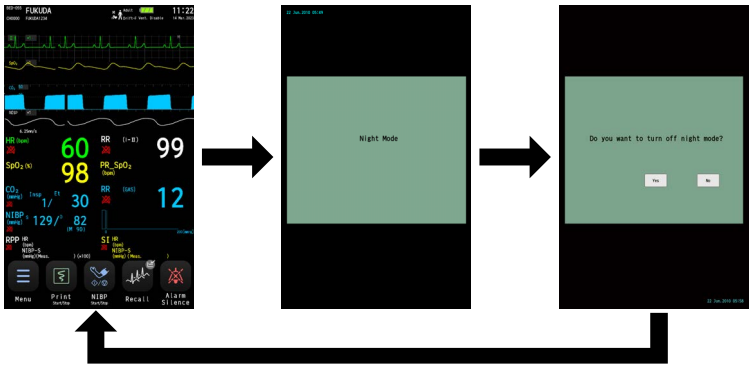
▸ The brightness will be adjusted.

Night Mode

This section explains about the night mode setup procedure.
The night mode is a function to preset the screen brightness and alarm volume when turning OFF the light of the ward or when the patient is asleep, etc.
The night mode can be manually set to ON, or automatically set to ON by preprogramming the time to turn ON/OFF the night mode.

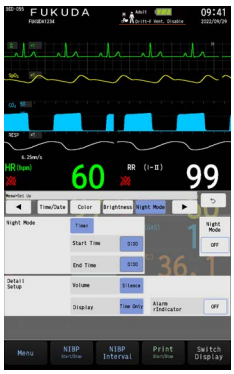
❑Operation flow when the night mode is set to "Timer"

During the night mode, touching the screen will display the window which allows to turn off the night mode.



❑Operation flow when the night mode is set to [Darker] or [Dark]

1 To manually set the night mode, select [ON] for "Night Mode" or press the [Night Mode] key on the user key area.



- During the night mode, "Night Mode" message will be displayed.

NOTE

- When the timer is set, the night mode will automatically start at the set "Start Time".

2 Cancel the night mode.

- There are two ways to cancel the Night Mode, which can be selected on the "Initial Settings" menu. (☞Maintenance Manual "Display/Print Setup" P5-9)
- [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.

NOTE

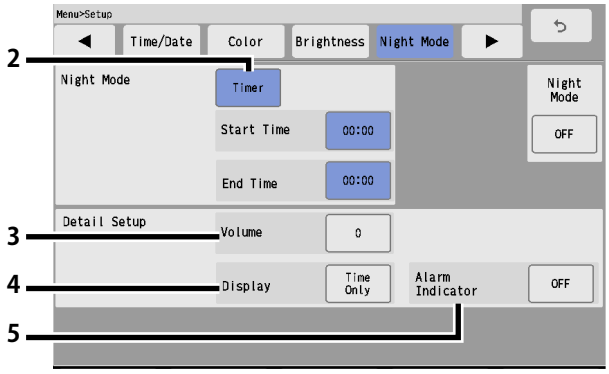
- The night mode can be manually turned ON from the menu or user key even when the night mode is set to automatically turn ON. The night mode will automatically turn OFF at the set "End Time".
- The night mode cannot be set when the ventilator alarm is generated.
- The night mode cannot be set during the battery operation. If switched to battery operation during the night mode, the night mode will be canceled.

Night Mode

The time to start and end the night mode, and the night mode display can be set.

1 Press the [Menu], [Setup], [Night Mode] keys.

▸ The "Night Mode" menu will be displayed.



2 Set the "Start Time" and "End Time" for the night mode.

▸ [Manual]: The night mode can be turned ON or OFF manually using the user key.

▸ [Timer]: The night mode will automatically turned ON or OFF at the preprogrammed time. The night mode can be manually turned ON from the user key even when the [Timer] is set.

When [Timer] is selected:

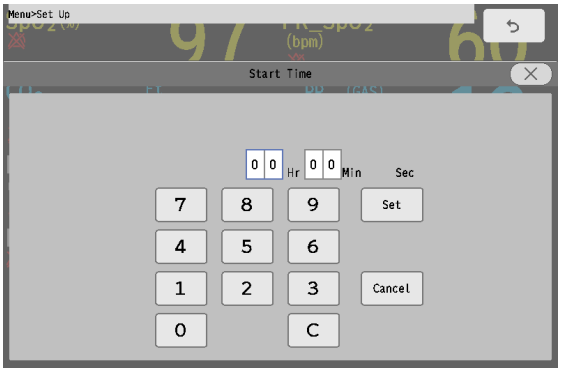
1 Press the key for "Start Time".

▸ The "Start Time" window will be displayed.

2 Use the numeric keys to enter the time.

3 Press the [Set] key.

4 Set the "End Time" with the same procedure from step 2 to 3.



3 Set the volume.

WARNING

- When selecting [0], pay attention not to miss any important alarm by simultaneously monitoring the bed on other monitors such as central monitor.

▸ [No Change]: Standard volume will be set.

▸ [3]: Third level from the minimum volume will be set. It will not change if the tone below the third level from minimum is set.

▸ [1]: Minimum volume will be set.

▸ [0]: Sound will be silenced.

4 Set the brightness.

WARNING

- When selecting [Time Only], pay attention not to miss any important alarm by simultaneously monitoring the patient on other monitors such as central monitor.

- [No Change]: Brightness will not change
- [Dark]: The display will become dark during the night mode.
- [Darker]: The display will become darker (than [Dark]) during the night mode.
- [Time Only]: Only the time will be displayed. The message will disappear after 1 minute from starting the night mode.

5 Set the alarm indicator operation.

- [ON]: The alarm indicator will light even during the night mode.
- [OFF]: The alarm indicator will not light during the night mode.

Chapter 11 Troubleshooting

Message List

For the vital alarm message, there are numeric data alarm and arrhythmia alarm, and the delay time are as follows.

	Delay Time	
	Adult / Child	Neonate
HR Upper / Lower Limit Tachy / Brady Ext Tachy / Ext Brady	None (0 sec.)	None (0 sec.)
RR Upper / Lower Limit	5 sec.	0 sec. to 5 sec. (It is variable depending on the setting / Increment: 1 sec.)
SpO_2 Upper / Lower Limit		
Numeric data alarm other than above	5 sec.	None (0 sec.)
Arrhythmia alarm other than above	None (0 sec.)	None (0 sec.)

REFERENCE

- The alarm delay time can be changed under [Initial Settings > Alarm > Alarm Level > Setup > Delay Time].
  (☞Maintenance Manual "Alarm Related Setup" P5-4)

Vital Alarm Message

⚠ CAUTION

- 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.
- The alarm level shown below is the standard level set by Fukuda Denshi.
- The alarm level can be changed under [Initial Settings > Alarm Setup > Alarm Level].

❑Top Priority Alarm (Alarm Level S)

This level can be selected only when [Fukuda Tone] is selected under [Menu> Setup>Initial Settings>Alarm System].
It cannot be selected when the "Alarm System" is [IEC Tone].

❑Life Threatening Alarm (Alarm Level H)

Measuring Parameters	Message
Respiration (Impedance, CO_2)	<Apnea>
Arrhythmia	<Asystole>
	<VF>
	<VT>
	<Ext Tachy>
	<Ext Brady>
SpO_2	<Lower Ext SpO_2 Alarm>
Shock Index (PI)	<Upper SI Alarm>

❑Cautionary Alarm (Alarm Level M)

Measuring Parameters	Message
Heart Rate	<Lower HR Alarm>
	<Upper HR Alarm>
SpO_2	<Lower SpO_2 Alarm>
	<Upper SpO_2 Alarm>
Pulse Rate (SpO_2)	<Lower PR Alarm>
	<Upper PR Alarm>
Non-Invasive Blood Pressure	<Lower NIBP Alarm>
	<Upper NIBP Alarm>
Respiration (Impedance, CO_2)	<Lower RR Alarm>
	<Upper RR Alarm>
CO_2	<Lower CO_2-E Alarm>
	<Upper CO_2-E Alarm>
	<Upper CO_2-I Alarm>
Arrhythmia	<Tachy>
	<Brady>
	<Slow VT>
	<Run>
	<Pause>
	<AFib Detected>
ST1 to 7	<Lower ST(Lead Type) Alarm>
	<Upper ST(Lead Type) Alarm>
RPP	<Lower RPP Alarm>
	<Upper RPP Alarm>

❑Treatment Needed Alarm (Alarm Level L)

Measuring Parameters	Message
Arrhythmia	<Couplet>
	<Bigeminy>
	<Trigeminy>
	<Frequent>
	<Triplet>
	<R on T>
	<Multiform>
	<Vent Rhtm>
	<SVT>
	<Ireg RR>
	<Prolong RR>
	<S Frequent>
	<S Couplet>
	<VPC>
	<SVPC>
	<Not Capt>
	<Not Pace>

❑Notification Alarm

Measuring Parameters	Message
All Alarm	<Alarm Suspend (xxx sec.)>
Alarm Sound Suspend	<Alarm Silence (xxx min.)>
Alarm Mute	<Alarm is silenced.>
Scoring Function	<Calculate score.>
Arrhythmia	<ECG Learn>
	<ARRHY. OFF>
	<AFib>

NOTE

- (xxx sec) of the <Alarm Suspend (xxx sec)> message indicates the remaining time of alarm suspended duration.
- (xxx min.) of the <Alarm Silence (xxx min.)> message indicates the remaining time of alarm sound suspended duration.
- The <ARRHY OFF> message will be displayed when the Asystole, VF, VT, Slow VT, Tachy, Brady, Ext Tachy, Ext Brady and HR alarm is OFF.
- The notification alarm “Afib” will be displayed when the Afib alarm has occurred after the “Afib Alarm Clear Time”.

Device Status Alarm Message

❑Top Priority Alarm (Alarm Level S)

Item	Message	Delay Time (sec.)
Ventilator	<Vent. Alarm>	1
	<VENT_COMM>	1

❑Life Threatening Alarm (Alarm Level H)

Item	Message	Delay Time (sec.)
Main Unit	<Main Unit Failure>	10
	<ECG Unit Error>	5
	<NIBP Meas. Error (xxx-xxx)>*1	10 or 3
	<Check SpO_2>	5 or 1
	<Charge the battery>	10
	<Telemeter Failure>	3
CO_2 (HCP-110)	<CO_2 Check Sample Line>	1
	<CO_2 Check Exhaust Port>	1
	<CO_2 Unit Failure>	1
	<CO_2 Cal. Required>	1

*1: # indicates an error code.

❑Cautionary Alarm (Alarm Level M)

Item	Message	Delay Time (sec.)
NIBP	<NIBP meas. failed. (###-##)>*1	1
Main Unit	<Check Long-Term Battery>	10
	<Out of Operating Temp. Range>	3
	<Charge the battery>	10
	<Replace the battery.>*2	120
	<Remove the Battery. (Error Temp.)>	120
Monitor Suspend	<Monitor Suspend Timer>	1

*1: On "Initial Settings" menu, the alarm level can be selected from Level M, L, N (Notification). (Default: Level M)
If [Alarm Silence] key is pressed during Level M/L alarm generation, the alarm level will change to Level N (notification). # indicates an error code.

*2: When charging a battery which has not been charged for a long time, <Replace the battery.> may be displayed. If the message disappears during charging, the battery can be used, but if the message remains to be displayed, replace the battery.

❑Treatment Needed Alarm (Alarm Level L)

Item	Message	Delay Time (sec.)
ECG	<Check Electrodes (#, #, #)>*1	3
	<ECG Check Electrodes Attachment.>	3
	<Cannot Analyze>	1
	<ECG Pacing Detection Error>	1

Item	Message	Delay Time (sec.)
SpO_2 (Masimo Unit)	<SpO_2 Check Sensor Attach.>	3
	<SpO_2 Replace Sensor>	1
	<SpO_2 Low Perfusion>*2	1
	<SpO_2 Pulse Search>	1
	<SpO_2 Noise Interference>	1
	<SpO_2 Check Sensor>	1
	<SpO_2 Replace Cable>	3
	<SpO_2 Check Cable>	3
	<SpO_2 Disconnected>	3
	<SpO_2 only mode>	1
	<SpO_2 Check Cable, Sensor>	1
SpO_2 (Medtronic Unit)	<SpO_2 Check Sensor Attach.>	3
	<SpO_2 Replace Sensor>	1
	<SpO_2 No Pulse Detected>	1
Non-Invasive Blood Pressure	<Check NIBP cuff, hose>*3	3
	<NIBP Check patient type, air hose>	3
Cable Disconnected	<ECG Disconnected>	3
	<SpO_2 Disconnected>	3
Main Unit	<Check Main Unit>	10
	<Out of Operating Temp. Range>	10
	<Check the Battery.>	3
	<Charge the Battery.>	10
	<Reinstall the battery.>	3
Full Disclosure Waveform	<Wrong card for full disclosure.>	1
	<Failed to read full disclosure from the card.>	1
	<Failed to write full disclosure to the card.>	1
	<Check card for full disclosure.>	1

*1: # indicates an electrode type.

*2: On "Initial Settings" menu, the alarm level can be selected from Level L, N (Notification). (Default: Level L)

*3: On "Initial Settings" menu, the alarm level can be selected from Level M, L, N (Notification). (Default: Level L)
If [Alarm Silence] key is pressed during Level M/L alarm generation, the alarm level will change to Level N (notification).

NOTE

- < NIBP meas. failed>, <Check NIBP cuff, hose>, <Connector Off>, <Check xx Conn.>, alarms will be canceled when [Alarm Silence] key is pressed. Pay attention not to cancel the important alarm.

❑Notification Alarm

Item	Message	Delay Time (sec.)
Operation	<Key Locked (xx sec.)> (Key Unlock/Hold 2 sec.)*1	1
	<Night Mode>	1
ECG	<ECG Low Amplitude>	3
	<ECG Artifact>	3
	<Check Electrodes (##, ##, ##)>*3	3

Item	Message	Delay Time (sec.)
	<ECG Artifact>	3
SpO_2 (Masimo Unit)	<SpO_2 Initializing>	1
	<SpO_2 Check Sensor Attach.>*3	3
	<SpO_2 Cable Near Expiration>	3
	<SpO_2 Sensor Near Expiration>	3
SpO_2 (Medtronic Unit)	<SpO_2 Motion Artifact>	1
	<SpO_2 Check Sensor Attach.>*3	1
Temperature	<TEMP read error>	5
Non-Invasive Blood Pressure	<Initializing NIBP>	3
	<Check NIBP cuff, hose>	3
CO_2 (HCP-110)	<CO_2 Suspended>	1
	<CO_2 Zeroing>	1
Recorder Unit	<Check Printer>*2	3
	<Check Paper>*2	3
	<Printer Busy>*2	1
	<Check Cassette>*2	3
Main Unit	<Check Rotary SW>	1
	<Check DIPSW>	1
	<Reading data.>	1
	<Parameters not displayed due to layout.>*4	3
	<Battery Charge Suspended.>	120
	<Replace the battery.>	120
System Configuration	<Check System Conn.>	3

*1: ## indicates the remaining time.

*2: The alarm generation can be inhibited depending on the setting.

*3: Displayed when lead-off or sensor-off condition remains after the power is turned ON, monitoring is resumed, or a patient is discharged.

*4: On "Initial Settings" menu the alarm level can be selected from Level L / N (Notification) / OFF. (Default: Notification)

Numeric Data Box Message

❑CO_2 (When HCP-110 is used)

Message
<Initializing>
<Check Sample Line>
<Zeroing>
<Check the Exhaust Port>
<Perform calibration.>
<GAS Unit I/F Failure>
<Suspended>

Ventilator Alarm Message

❑Top Priority Alarm (Alarm Level S)

Item	Message
Ventilator	<Vent. Alarm>
Ventilator	<VENT_COMM>

⚠ WARNING

- The ventilator alarm sound is set to OFF (factory default).
- The alarm sound can be turned ON on the "Tone/Volume" menu. (☞"Tone/Volume" P10-7)

Troubleshooting

This section explains the troubleshooting for each case.

ECG

❑<Check Electrodes> or <LEAD OFF> is displayed.

Cause 1

The electrode is detached, or is not making good electrical contact with the skin.

Solution

Check if the electrodes are properly attached.
Replace the electrodes.
Make sure that the lead cable or relay cable is not defective (wire break, etc.).
(☞"Before Attaching the Electrodes" P7-1)
(☞"Electrode Placement" P7-2)

❑<ECG Low Amplitude> is displayed.

Cause 1

The ECG amplitude is 0.25 mV or below for the waveform size of x1, x1/2, x1/4, and 0.15 mV or below for the waveform size of x2, x4.

Solution

Change the electrode site, or select a lead with higher QRS amplitude.

NOTE

- Using 4-electrode or 5-electrode instead of 3-electrode allows more accurate QRS detection.

Cause 2

The electrode contact is poor.
Electrical blanket or other noise source is near the patient.

Solution

Attach the electrodes firmly. Or, replace the electrodes.

- If the lead cable or relay cable is defective (wire break, etc.), replace it.

- If any noise source is near the patient, move it away from the patient as far as possible.

❑<ECG Artifact> is displayed.

Cause 1

The electrode contact is poor.
Electrical blanket or other noise source is near the patient.

Solution

Attach the electrodes firmly.

- If the lead cable or relay cable is defective (wire break, etc.), replace it.
- If any noise source is near the patient, move it away from the patient as far as possible.

Cause 2

EMG is interfering.

Solution

- Change the electrode site to a location where the myoelectricity will be less likely to interfere.
- Select ESIS for the filter mode.

⚠ CAUTION

- Selecting ESIS for the filter mode will decrease the QRS amplitude and may result in not counting the heart rate.

❑The ECG waveform is in the baseline position.

The lead-off condition may have occurred by the following causes.

Cause 1

Electrode is detached.

Solution

Place the electrodes again. If the electrode contact is poor, replace the electrode.
(☞"Before Attaching the Electrodes" P7-1)
(☞"Electrode Placement" P7-2)

Cause 2

The lead cable is disconnected from the electrode terminal.

Solution

Securely connect the lead cable.

REFERENCE

- If the error persists, wire break of the lead cable or relay cable can be considered. Contact your nearest service representative.

❑<Check Electrodes Attachment> is displayed.

Cause 1

The electrode contact with the skin is poor. There is substantial contact resistance between the electrodes.

Solution

Replace all the electrodes. Make sure to use the same type of electrodes.
(☞"Before Attaching the Electrodes" P7-1)

(☞"Electrode Placement" P7-2)

❑<ECG Unit Failure> is displayed.

Cause

A communication error has occurred between the ECG measuring unit.

Solution

A failure of the ECG unit can be considered. Contact your nearest service representative.

❑The measurement data is displayed as "xxx".

Cause

The heart rate is outside the measurement range.

Solution

- Check if the electrodes are properly attached.
  (☞"Before Attaching the Electrodes" P7-1)
  (☞"Electrode Placement" P7-2)
- Replace the electrode, or check the lead cable and relay cable.

❑Heart rate is not counted. Heart rate is low.

Cause

The ECG waveform amplitude is below the QRS detection level (0.3 mV).

Solution 1

Change the electrode site, or select a lead with higher QRS amplitude.

⚠ CAUTION

- Using 4-electrode or 5-electrode instead of 3-electrode allows more accurate QRS detection.
- Also, if large amount of noise is interfering, the noise may be erroneously detected as QRS. Change the electrode site and increase the ECG amplitude.

Solution 2

Increase the waveform size. By increasing the waveform size, small QRS wave will become detectable. However, noise may be also detected.

❑Heart rate is not counted, and <LEAD OFF> is displayed.

Cause 1

The electrode of the displayed lead type is detached, or is not making good electrical contact with the skin.

Solution

- Check if the electrodes are properly attached.
  (☞"Before Attaching the Electrodes" P7-1)
  (☞"Electrode Placement" P7-2)
- Replace the electrode, or check the lead cable and relay cable.

❑Artificial pacemaker pulse is not displayed.

Cause 1

[Not Used] is selected for "Pacemaker" on the "Admit/Discharge" menu.

Solution

Select [Used] for "Pacemaker".

Cause 2

"Pacemaker Pulse" is set to [OFF] (ECG Parameter Setup).

Solution

Select [ON] for "Pacemaker Pulse"..

Cause 3

The electrode attachment site is not appropriate.

Solution

Check the electrode attachment site.
(☞"Before Attaching the Electrodes" P7-1)
(☞"Electrode Placement" P7-2)

❑<ECG Pacing detection error> is displayed.

Cause

The pacemaker pulse is detected 16 pulses or more per second.

Solution 1

- Check if the electrodes are properly attached.
  (☞"Before Attaching the Electrodes" P7-1)
  (☞"Electrode Placement" P7-2)
- Replace the electrode, or check the lead cable and relay cable.
- If any noise source is near the patient, move it away from the patient as far as possible.

Solution 2

If the patient is not using a pacemaker, select [Not Used] for "Pacemaker" ("Admit/Discharge").

❑<ECG Disconnected> is displayed.

Cause

While monitoring the ECG, the relay cable was unplugged.

Solution 1

To cease monitoring, press the [Alarm Silence] key. The message will disappear, and the alarm will be silenced.

Solution 2

To continue monitoring, plug in the ECG relay cable. The message will disappear, and the alarm will be silenced.

❑<Cannot analyze> is displayed.

Cause

"Suspend Arrhy, Analysis during Noise Interference" ("Initial Settings") is set to ON, and arrhythmia analysis is suspended for more than 30 seconds due to continuous noise or EMG interference.

Solution

Check the electrode attachment, and remove the noise source.

- Check the electrode attachment, lead cable and relay cable.
- If the electrode, lead cable, or relay cable is defective, replace them.
- If any noise source is near the patient, move it away from the patient as far as possible.
  If EMG is interfering, change the electrode site to a location where EMG will less likely to interfere.

❑Arrhythmia cannot be detected. It is judged as "?" .

Cause 1

The amplitude of ECG1 or ECG2 is below the QRS detection level (250 μV and below).

Solution

Change the electrode site, or select a lead with higher QRS amplitude for both ECG1 and ECG2. When the electrode site is changed, perform the arrhythmia learn process.

Cause 2

The shapes of normal heartbeat and arrhythmia are similar.

Solution

Change the electrode site or select a lead which shows a clear difference between a normal heartbeat and arrhythmia. When the electrode site is changed, perform the arrhythmia learn process.

Cause 3

Noise is interfering with the ECG.

Solution

Check the electrode attachment, and remove the noise source.

- Check the electrode attachment, lead cable and relay cable.
- If the electrode, lead cable, or relay cable is defective, replace them.
- If any noise source is near the patient, move it away from the patient as far as possible.
  If EMG is interfering, change the electrode site to a location where EMG will less likely to interfere.

Respiration

❑"0" is displayed for respiration rate, or apnea alarm is generated.

Cause

The amplitude of the respiration waveform is too low.

Solution 1

Change the electrode site, or select a lead with higher QRS amplitude.

Solution 2

Increase the waveform size.

❑The measurement data is displayed as "xxx".

Cause

The respiration rate is outside the measurement range.

Solution

- Check if the electrodes are properly attached.
  (☞"Before Attaching the Electrodes" P7-1)
  (☞"Electrode Placement" P7-2)
- Replace the electrode, or check the lead cable.
- Change the lead for respiration measurement.

SpO_2 Measurement (Medtronic)

❑<SpO_2 Check Sensor Attach.> is displayed.

Cause

The sensor is detached from the patient.

Solution 1

Check if the sensor is properly attached to the patient.

Solution 2

Check that the light emitting and receiving parts of the sensor LED are aligned.

❑<SpO_2 Pulse Search> is displayed.

Cause 1

The amplitude of the pulse waveform is too low, or the sensor is not positioned correctly.

Solution

Check that the light emitting and receiving parts of the sensor LED are aligned.

Cause 2

The sensor has not been attached long enough to obtain stable measurement.

Solution

After the sensor attachment, wait and see for about one minute until the waveform stabilizes.

❑<SpO_2 No Pulse Detected> is displayed.

Cause

The amplitude of the pulse waveform is too low, or the sensor is not positioned correctly.

Solution

Check that the light emitting and receiving parts of the sensor LED are aligned.
Avoid the sensor from exposure to ambient light.

❑<SpO_2 Motion Artifact> is displayed.

Cause

There is excessive body motion from the patient.

Solution

Relocate the sensor to which body motion will have less influence.

❑The pulse waveform is not displayed, or interrupted.

Situation: <SpO_2 Check Sensor Attach.> is displayed.

Cause 1

The amplitude of the pulse waveform is too low, or the sensor is not positioned correctly.

Solution

Check that the light emitting and receiving parts of the sensor LED are aligned.

Cause 2

The sensor is defective.

Solution

Replace the sensor.

Cause 3

SpO_2 sensor is not firmly connected to the connector.

Solution

Make sure the SpO_2 sensor is firmly connected.

Cause 4

Sensor is exposed to light.

Solution

Place a black or dark cloth over the sensor to avoid direct sunlight. When not using the sensor for measurement, avoid placing the sensor in light or unplug the sensor from the connector.

❑SpO_2 value is unstable.

Cause 1

There is excessive body motion from the patient which disables correct measurement.

Solution 1

Have the patient lie still.

Solution 2

Relocate the sensor, or change the sensor to which the body motion will have less influence.

Cause 2

The probe size is not appropriate.

Solution

Select a probe size which is appropriate for the patient.

Cause 3

Sensor is exposed to light.

Solution

Place a black or dark cloth over the sensor to avoid direct sunlight.

❑<Check SpO_2> is displayed.

Cause 1

The sensor is defective.

Solution

Replace the sensor.

Cause 2

Communication error has occurred with the SpO_2 unit.

Solution

A defective cable or SpO_2 unit failure can be considered.
Contact your nearest service representative.

Cause 3

The system was started with the sensor and cable connected.

Solution

Disconnect the SpO_2 cable and sensor from this device, and press the standby switch to enter into standby mode. Then, press the standby switch again to cancel the standby mode, and when the monitoring screen is displayed,

connect the cable and sensor.

❑<SpO_2 Replace Sensor> is displayed.

Cause 1

The sensor is not connected securely.

Solution

Connect the sensor securely.

Cause 2

The sensor is defective.

Solution

Replace the sensor.

Cause 3

A wrong sensor is used.

Solution

Replace the sensor.
For details of the usable sensors, refer to your nearest service representative.

❑<SpO_2 Disconnected> is displayed.

Cause

The SpO_2 relay cable is disconnected during SpO_2 monitoring.

Solution 1

To cease monitoring, press the [Alarm Silence] key. The message will disappear, and the alarm will be silenced.

Solution 2

To continue monitoring, plug in the SpO_2 relay cable. The message will disappear, and the alarm will be silenced.

SpO_2 Measurement (Masimo)

❑<SpO_2 Replace Sensor> is displayed.

Cause 1

The sensor is not connected securely.

Solution

Connect the sensor securely.

Cause 2

The sensor is defective.

Solution

Replace the sensor.

Cause 3

A wrong sensor is used.

Solution

Replace the sensor.

(☞"Pulse Oximetry Measurement (Manufactured by Masimo)" P13-4)

Cause 4

The sensor is used beyond its expected life.

Solution

Replace the sensor.

NOTE

- The X-Cal function automatically monitors the Active Monitoring Time (actual time of SpO_2 monitoring) for each sensor and cable.
- Even if the sensor is used beyond its expected life, the measurement will not cease unless the power is turned OFF, sensor is disconnected from the cable, cable is disconnected from the monitor, or the sensor is reattached.
- When a measurement with a sensor that has reached its end of life is suspended for certain amount of time, and resumed with the same sensor, a message to replace the sensor will be displayed.
- Depending on the device, some sensors may not be recognized.

❑<SpO_2 Check Sensor Attach.> is displayed.

Cause 1

The sensor is detached from the patient.

Solution 1

Check if the sensor is properly attached to the patient.

Solution 2

Check that the light emitting and receiving parts of the sensor LED are aligned.

Cause 2

The sensor is exposed to too much ambient light. The detecting part of the sensor is not covered appropriately.

Solution 1

Turn down or turn off the light.

Solution 2

Avoid the sensor from exposure to ambient light.

Solution 3

Relocate the sensor position.

❑<SpO_2 Low Perfusion> is displayed.

Cause

The amplitude of the pulse waveform is too low, or the sensor is not positioned correctly.

Solution

Check that the light emitting and receiving parts of the sensor LED are aligned.

❑<Low Confidence> is displayed.

Cause

The amplitude of the pulse waveform is too low, or the sensor is not positioned correctly.

Solution

Check that the light emitting and receiving parts of the sensor LED are aligned.

❑<SpO_2 Pulse Search> is displayed.

Cause 1

The amplitude of the pulse waveform is too low, or the sensor is not positioned correctly.

Solution

Check that the light emitting and receiving parts of the sensor LED are aligned.

Cause 2

The sensor has not been attached long enough to obtain stable measurement.

Solution

After the sensor attachment, wait and see for about one minute until the waveform stabilizes.

❑<SpO_2 Noise Interference> is displayed.

Cause

External signal or energy is interfering with the measurement.

Solution

Remove the external interference or apply ambient shielding.

❑<SpO_2 Check Sensor>, <SpO_2 Replace Cable>, or <SpO_2 Check Cable> is displayed.

Cause 1

Unrecognizable sensor is connected.

A wrong patient cable is used.

When attached to the patient, the sensor was exposed to high-intensity light which lead to false recognition.

Solution

Reattach the SpO_2 sensor and patient cable.

Replace with a Fukuda Denshi specified patient cable and sensor.

(☞"Pulse Oximetry Measurement (Manufactured by Masimo)" P13-4)

Cause 2

The cable is used beyond its expected life.

Solution

Replace the patient cable.

NOTE

- The X-Cal function automatically monitors the Active Monitoring Time (actual time of SpO_2 monitoring) for each sensor and cable.
- Even if the cable is used beyond its expected life, the measurement will not cease unless the power is turned OFF or the cable is reconnected.
- When a measurement with a cable that has reached its end of life is suspended for certain amount of time, and resumed with the same cable, a message to replace the cable will be displayed.
- Depending on the device, some cable may not be recognized.

❑<Check SpO_2> is displayed.

Cause

Communication error has occurred with the SpO_2 unit.

Solution

A cable disconnection or SpO_2 unit failure can be considered. Contact your nearest service representative.

❑<SpO_2 Disconnected> is displayed.

Cause

The SpO_2 relay cable is disconnected during SpO_2 monitoring.

Solution 1

To cease monitoring, press the [Alarm Silence] key. The message will disappear, and the alarm will be silenced.

Solution 2

To continue monitoring, plug in the SpO_2 relay cable. The message will disappear, and the alarm will be silenced.

❑<Low Signal IQ> is displayed.

Cause

There is excessive body motion, or sensor attached position is not appropriate.

Solution 1

Check that the light emitting and receiving parts of the sensor LED are aligned.

Solution 2

Relocate the sensor to which body motion will have less influence.

Non-Invasive Blood Pressure

❑The cuff is not inflated although the pump is operating.

Cause 1

The air hose is not firmly connected, and the air is leaking.

Solution

Check if the air hose is properly connected.

Cause 2

The cuff size does not match the selected patient type.

Solution

Use the cuff with correct size for the selected patient type.

❑The pump is not operating.

Cause

The air hose is disconnected from the NIBP connector.

Solution

Check if the air hose is properly connected.

❑The measurement data is displayed as "---" .

Cause 1

The measurement accuracy is not reliable due to body motion artifact.

Solution

During the measurement, have the patient stay still.

Cause 2

The pulse is too small to acquire reliable measurement accuracy.

Solution

Check if the cuff application is proper, and if the cuff size corresponds with the selected patient type.

Cause 3

The air hose is disconnected.

Solution

Check if the air hose is tightly connected, and then measure again. If the same message is displayed again, air leakage inside the BDS-1001 can be considered.
Contact your nearest service representative.

❑<Check NIBP cuff, hose> is displayed.

Cause 1

The connection between the cuff and air hose or the air hose and NIBP connector is loose or disconnected.

Solution

If the connection is loose or disconnected, securely connect it and perform the measurement again.

If the same message is displayed again, internal air leakage can be considered. Cease the measurement, and contact your nearest service representative.

Cause 2

The cuff is compressed.

Solution

Make sure that the cuff is not subjected to compression, and measure with the patient arms extended as much as possible.

If the same message is repeatedly displayed, air system may be clogged. Cease the measurement, and contact your nearest service representative.

Cause 3

The cuff size is not suitable for the patient.

Solution

Check that the cuff size is appropriate for the patient, and that the cuff is properly attached, and measure again.

Cause 4

The cuff size and the patient classification setting do not match.

Solution

Make sure that the appropriate cuff size is used according to the patient classification setting.

❑<NIBP measurement failed (Cxx-xx)> is displayed.

Error code condition (phenomenon, or situation) and its cause are indicated below.

C01-xx Could not inflate to the specified pressure.

Cause 1

The air hose is not firmly connected, and the air is leaking.

Solution

Check if the air hose is properly connected.

Cause 2

The cuff size does not match the selected patient type.

Solution

Use the cuff with correct size for the selected patient type.

C02-00 When "Quick Measurement" is [OFF], the data could not be measured.

Cause 1

The blood pressure may not be correctly measured due to the patient's condition.

Solution

Check the patient's condition, and measure again.

Cause 2

The cuff application has become loose.

Solution

Check that the cuff size is appropriate for the patient, and then measure again after attaching the cuff properly.

C02-01 When "Quick Measurement" is [ON], the data could not be measured.

Cause 1

The blood pressure may not be correctly measured due to the patient's condition.

Solution

Check the patient's condition, set "Quick Measurement" to OFF, and measure again.

Cause 2

The cuff application has become loose.

Solution

Check that the cuff size is appropriate for the patient, and then measure again after attaching the cuff properly.

C02-02 The air hose was disconnected from the NIBP connector during the measurement.

Cause

The air hose was disconnected from the NIBP connector during the measurement.

Solution

Connect the air hose to the NIBP connector, and then measure again.

C03-xx The exhaust ventilation has ceased, or the target deflation speed was not achieved.

Cause 1

During measurement, an artifact such as body motion may have interfered.

Solution

Keep the patient still as much as possible, and measure while the patient is not moving. When performing the measurement during surgery, avoid artifact caused by the surgery.

Cause 2

During the measurement, air hose was bent or occluded by the compression.

Solution

Make sure that the air hose is not bent or compressed before the measurement.

If the error persists and C03-xx error is frequently displayed, contact your nearest service representative and notify the error code.

C04-00 to C04-03 The cuff inflation was insufficient for the patient's blood pressure.

Cause

The blood pressure has significantly increased from the previous measurement.

Solution

Check the cuff application and size and perform the manual measurement.

C04-04 Switched to the deflation measurement. (Data could not be measured by the inflation measurement.)

Cause 1

The pulse signal could not be detected, and the blood pressure may not be correctly measured.

Solution 1

Check whether the cuff for the inflation measurement is applied, or the cuff application or size.

Solution 2

Measure by the deflation measurement.

C05-xx The pulse signal detected during the measurement was unreliable.

Cause 1

There was shivering or body motion during measurement.

Solution

Measure while the patient keeps calm and does not shiver or move as much as possible. In addition, measure while taking steps to prevent artifacts caused by the measurement environment.

Cause 2

Arrhythmia occurred frequently during measurement.

Solution

Correct measurement is not possible when arrhythmia is frequent. Measure while there is no arrhythmia as much as possible.

Cause 3

The cuff size is not appropriate or the cuff is not wrapped properly, and the detected pulse is too small.

Solution

Check that the cuff size is suitable for the attachment site or the way the cuff is wrapped is appropriate.

Cause 4

The air hose is loose, and air is leaking.

Solution

Check the cuff and the air hose connection state, and perform measurement again. If the problem is not resolved, contact your local Fukuda Denshi service representative.

C06-xx The pulse signal detected during the measurement was unstable.

Cause 1

During the measurement, the patient has trembled or moved.

Solution

Keep the patient still as much as possible, and measure while the patient is not trembling or moving.

Cause 2

Arrhythmia has frequently occurred during the measurement.

Solution

If arrhythmia occurs many times, correct measurement cannot be performed.Measure when arrhythmia is not frequently occurring.

C07-00 The measurement time has exceeded the allowable time.

Cause

Measurement is automatically repeated due to body motion or insufficient inflation.

Solution

Check the cuff application and size, and measure while keeping the patient still as much as possible.

C08-00 The detected PR value was abnormal.

Cause

The patient has trembled or moved.

Solution

Keep the patient still as much as possible, and measure while the patient is not moving.

C09-00 The inflation value has exceeded the allowable maximum value.

Cause

The cuff was subjected to compression.

Solution

Make sure that the cuff is not subjected to compression, and measure with the patient arms extended as much as possible.

C11-00 Neonate cuff is detected with adult mode.

Cause

The cuff size does not match the selected patient type. (Neonate cuff is used in adult mode.)

Solution

Use the cuff with correct size for the selected patient type.

C11-01 Infant cuff is detected with adult mode.

Cause

The cuff size does not match the selected patient type. (Infant cuff is used in adult mode.)

Solution

Use the cuff with correct size for the selected patient type.

C11-02 Neonate cuff is detected with child mode.

Cause

The cuff size does not match the selected patient type. (Neonate cuff is used in child mode.))

Solution

Use the cuff with correct size for the selected patient type.

❑The time of measurement disappears and the numeric data is displayed as " - - - ".

Cause

The preprogrammed time to clear the NIBP data has elapsed.

Solution

The "NIBP Erase Time" can be selected from [5 min.], [10 min.], [30 min.], [60 min.], [120 min.], and after the set duration, the NIBP data will be displayed as "---".
Select the appropriate time which best fits the monitoring purpose.

❑The NIBP periodic measurement is ceased.

Cause

<NIBP Meas. Error (Exx-xx)> is displayed during the measurement.

Solution

When <NIBP Meas. Error (Exx-xx)> is displayed, the NIBP periodic measurement will be canceled. To resume the measurement, press the [NIBP Start/Stop] key and check that the measurement is properly performed.

❑<NIBP Unit Error (E**-**)> is displayed.

Cause

An error has occurred on the NIBP unit.

E08-01: Communication Error (Sub CPU)
E08-02: WatchDog Timeout
E08-03: Pressure Offset Error
E08-04: Pressure Comparison Error
E08-05: Sub CPU Power Supply Failure
E08-06: Pressure Sensor 2 Power Supply Failure
E08-07: Pressure Sensor 1 A/D Reference Power Voltage Failure
E08-08: Rapid Exhaust Error
E08-09: Air Hose Identification Error
E09-A: Exceeded Maximum Cuff Pressure
E09-B: Inflation Timeout
E09-C: Quick Mode Timeout
E09-D: Measurement started during the long pause
E09-E: Measurement Timeout
E09-F: Main CPU Pressure Data Transmission Timeout
E09-G: Pressure Sensor 1 +5V Power Supply Failure
E09-H: Zero Calibration Timeout
E09-I: ROM Test Error

E09-J: RAM Test Error
E09-L: Clock Transmission Ceased
E09-M: Communication Failure at Power ON
E09-N: Pressure Comparison Error
E09-O: Maximum Inflation Timeout
E09-Q: Measurement was started before zero calibration
E09-R: Zeroing Error
E09-S: WatchDog Timeout
E09-T: +5V Digital Power Supply Failure
E09-U: Main CPU Power Supply Failure
E09-V: Pump Control Signal Failure
E09-W: Quick Exhaust Valve Control Signal Failure
E09-X: Sub CPU Constant Exhaust Valve Control Signal Failure
E09-Y: Main CPU Constant Exhaust Valve Control Signal Failure

Solution 1

These errors can be cleared by pressing the [Cancel Error] on the NIBP setup menu or [NIBP Start/Stop] key (User Key).If the same message is repeatedly displayed, a failure of the device can be considered. Cease the measurement, and contact your nearest service representative.

Solution 2

When <NIBP Unit Error (Exx-xx)> is displayed, make sure that the congestion is not generated, and remove the cuff if necessary.

CO_2 (HCP-110)

❑<CO_2 Check Sample Line> is displayed.

Cause

The sampling tube is clogged.

Solution

Replace the sampling tube.

❑<Initializing> displayed inside the numeric data box does not disappear.

Cause

An error has occurred during the initialization at power ON.

Solution

The CO_2 unit failure can be considered.

❑<CO_2 Unit Failure> is displayed.

Cause

Communication error has occurred with the CO_2 unit.

Solution

A cable disconnection or CO_2 unit failure can be considered. Contact your nearest service representative.

❑There is substantial measurement error.

Cause 1

20 minutes have not yet elapsed since the power is turned ON.

Solution

For 20 minutes from turning ON the power, there will be a substantial measurement error.

Cause 2

The CO_2 calibration value is not appropriate.

Solution

Perform the CO_2 calibration again.

❑<CO_2 Disconnected> is displayed.

Cause

When the filter line is disconnected during CO_2 monitoring, this message will be displayed.

Solution 1

To cease monitoring, press the [Alarm Silence] key to clear the message and silence the alarm.

Solution 2

To continue monitoring, plug in the filter line. This will clear the message and silence the alarm.

❑<Check CO_2 Exhaust Port> is displayed.

Cause

The exhaust port of the HCP-110 is clogged.

Solution 1

After removing the occlusion by checking the exhaust port and gas exhaust system connection, press the [Resume Meas.] key on the CO_2 setup menu for 2 seconds. If the message is still displayed, CO_2 unit failure can be considered. Contact your nearest service representative.

Temperature

❑<TEMP read error> is displayed.

Cause

The communication has failed between the BDS-1001 and thermometer.

Solution

Check if the thermometer connection cable is properly connected, and then measure again.

REFERENCE

- If the message is displayed repeatedly, contact your local Fukuda Denshi service representative.

❑The temperature data is not displayed on the BDS-1001 even though the temperature is measured.

Cause 1

[OFF] is selected for “COM” under [Menu > Menu List > Setup > Initial Settings > External Device > COM Setup].

Solution

Select [TEMP] for “COM”.

Cause 2

The temperature data is not set to be displayed under [Menu > Menu List > Setup > Display Configuration].

Solution

Set the display configuration so that the temperature data will be displayed. (☞"Changing the Displayed Numeric Data" P10-2)

Cause 3

The thermometer connection cable is disconnected, or the wire is broken.

Solution

Check if the thermometer connection cable is properly connected, and then measure again.

Cause 4

An error message is displayed on the thermometer.

Solution

Refer to the operation manual of the thermometer.

REFERENCE

- If the data is still not displayed, contact your local Fukuda Denshi service representative.

❑The temperature value displayed on the BDS-1001 and thermometer does not match.

Cause

The temperature measurement unit differs between the BDS-1001 and the thermometer.

Solution

Make sure that the same measurement unit is set on the BDS-1001 and the thermometer.
If different measurement unit is set, the value will be converted and displayed with the measurement unit set on the BDS-1001.
For the BDS-1001, the measurement unit can be set under [Menu > Menu List > Setup > Initial Settings > Meas. > Unit].
For the measurement unit of the thermometer, refer to the operation manual of the thermometer.

Recorder

❑<Check Paper> is displayed, and printing cannot be performed.

Cause

There is no paper in the printer.

Solution

Set the paper in the paper holder.

❑<Check Cassette> is displayed, and printing cannot be performed.

Cause

The paper holder is open.

Solution

Firmly close the paper holder.

❑Although the paper is fed, printing is not performed.

Cause

The paper is not correctly installed. The front and backside of the paper is set oppositely.

Solution

Set the paper in the paper holder so that the logo, FUKUDA DENSHI CO., LTD appears on the upper surface.

❑The second and third waveforms are not printed.

Cause

The second and third waveforms are not set on the printing setup screen.

Solution

Set the second and third waveform on the corresponding printing setup screen.

❑<Check Printer> is displayed and printing cannot be performed.

Cause 1

The paper is jammed.

Solution

Open the paper holder and properly set the paper.

Cause 2

The thermal head temperature has increased or other failure exists.

Solution

Damage to the thermal head or other failure can be considered. Contact your nearest service representative.

Telemeter

❑The data cannot be received at the telemetry center.

Cause

The channel ID or group ID is not corresponded with the telemetry receiver.

Solution

Set the correct channel ID and group ID.

❑The impedance respiration waveform cannot be received at the telemetry center.

Cause

[CO_2] is selected for "RR Alarm / APNEA Source".

Solution

Select [Impedance] for "RR/APNEA Alarm Source" on the RESP setup menu.

❑<Telemeter Failure> is displayed.

Cause

Communication failure has occurred with the telemeter.

Solution

The telemeter unit failure can be considered. Contact your nearest service representative.

General

❑The data is initialized each time the power is turned ON.

Cause

The internal switch setting is incorrect.

Solution

The internal switch setting needs to be changed. Contact your nearest service representative.

❑The display is dark, or cannot be seen clearly.

Cause 1

The night mode is set.

Solution

Cancel the night mode.

Cause 2

The display brightness is not adjusted.

Solution

Due to the LCD characteristic, the visible range is limited.
Adjust the brightness on the "Brightness" menu.

❑The system does not start although the standby switch is pressed.

Cause 1

The power cable is not connected.

Solution

Plug in the power cable to this device. Plug in the power cable to a hospital grade outlet.

Cause 2

Incorrect SD card is inserted.

Solution

Remove the SD card, turn OFF the power, and turn ON the power again.

Cause 3

The control board is in the disabled state.

Solution

Press the standby switch for about 7 seconds to restart the system.

Cause 4

The battery was installed too soon after it was removed, and the system could not detect the standby switch condition.

Solution

After removing the battery, wait for 3 to 4 seconds before installing the battery. Then, press the standby switch to properly restart the system.

Cause 5

The battery is almost empty.

Solution

Connect to the AC power source, or replace with fully charged battery.

❑<Check Standby> is not displayed although the standby switch is pressed.

Cause

The control board is in the disabled state.

Solution

Press the standby switch for about 7 seconds to restart the system.

❑The clock is often delayed.

Cause

The battery for the backup memory is depleted.

Solution

Check if the time is delayed when the power is turned OFF.
The battery needs to be replaced. Contact your nearest service representative.

❑The touch panel does not function properly.

Cause

A scratch on the touch panel surface or foreign object entering the touch panel junction is causing misdetection of the key area.

Solution

The touch panel needs to be replaced. Contact your nearest service representative.

❑<Check Main Unit> is displayed.

Cause

A hardware failure has occurred.

Solution

Immediately turn OFF the power and cease the operation. Contact your nearest service representative.

❑<Out of Operating Temp. Range> is displayed.

Cause 1

The device is used outside the specified operating temperature range.

Solution

Make sure the ambient temperature is within 10°C to 40°C.

Cause 2

The device has been stored in an environment below the specified operating temperature before the usage.

Solution

Warm up the device until the alarm message disappears.

Cause 3

The vent hole is clogged.

Solution

Relocate the device. For installation location of the device, refer to ☞Maintenance Manual "Precautions for Installing the Device" P1-1.

Cause 4

A hardware failure has occurred.

Solution

If error persists, the device failure can be considered. Immediately turn OFF the power and cease the operation. Contact your nearest service representative.

❑<Check Rotary SW> is displayed.

Cause

The rotary switch setting is incorrect.

Solution

If the rotary switch is not set to "0", the device will not function properly.
Immediately turn OFF the power and cease the operation. Contact your nearest service representative.

❑<Check Long-Term Battery> is displayed.

Cause

The battery is depleted or malfunctioning.

Solution

The battery needs to be replaced. Contact your nearest service representative.

Ventilator

❑<Vent. Alarm> is displayed.

Cause

The following alarm has generated on the ventilator.

- Parameter alarm such as AWP, MV, FiO_2
- Technical alarm such as battery replacement of the ventilator

Solution

Check the alarm cause of the ventilator, and take appropriate action.

❑<Vent. Offline> is displayed.
<VENT COMM> is displayed on the monitor and the ventilator.

Cause 1

The cable between the device and ventilator is disconnected or not securely connected.

Solution

Make sure the cable is properly connected.

Cause 2

The power of the ventilator is turned OFF.

Solution

Turn ON the power of the ventilator.

Cause 3

The ventilator is in standby mode.

Solution

Start the ventilation on the ventilator.

Cause 4

The network setting of the monitor does not match with the ventilator.

Solution

Make sure that the network setting of the connecting devices are as follows.

[SERVO-i/SERVO-s]

- No network setting.

[SERVO-U/n/air]

- No network setting.

[VELIA, ASTRAL, VS ULTRA]

- No network setting.

[PB-740/760/840]

- Baud Rate: 9600 bps
- Parity Bit: None
- Stop Bit: 1
- Data Bit: 8

[Evita4/2dura/XL]

- Communication Protocol: Medibus
- Baud Rate: 19200 bps
- Parity Bit: Even
- Stop Bit: 1

PC Communication

❑<Check System Conn.> is displayed.

Cause 1

The cable is not properly connected. The connection cable is disconnected. The power of the communication conversion port is turned OFF.

Solution

Connect the serial connection cable securely. Check if the power is supplied to the communication port by checking the communication indicator.

Cause 2

Communication with the system is not performed. Communication is ceased.

Solution

Start the communication with the system again. Communication timeout is approximately 1 minute.

Magnetic Card Reader/Barcode Reader

❑The magnetic card reader or barcode reader does not function.

Cause

The magnetic card reader or barcode reader is not properly connected.

Solution

Connect again the magnetic card reader, barcode reader to the USB connector.

External Media

❑USB Memory/SD Card Slot: There is no card in the slot.

Cause

USB memory/SD card is not inserted or not correctly set in the USB memory/SD card slot.

Solution

Set the USB memory/SD card into the USB memory/SD card slot.

❑Error has occurred during loading the data. Model type or software version is not compatible, or the file is damaged. Do you want to read only the common data?

Cause 1

There is no data on the USB memory.

Solution

Check if the USB memory is readable. Or, check if the data exists on the USB memory. Pressing "Yes" will not start reading the compatible data. <Media access error.> will be displayed.

Cause 2

Error is detected during the read process.

Solution

The data may not be correctly written on the USB memory. Format the USB memory again on the used device and try the write/read process again. Pressing "Yes" will not start reading the compatible data.

❑An error has occurred.

Cause 1

There is not enough capacity on the USB memory to write the data.

Solution

Check the remaining capacity on the USB memory.

Format the USB memory again on the used device and try the write/read process again.

Cause 2

Error is detected during the write process.

Solution

Make sure that the USB memory is properly inserted and try the write process again.

Format the USB memory again on the used device and try the write/read process again.

Cause 3

Unspecified USB memory is used.

Solution

Use the specified USB memory.

❑No data on the CF card.

Cause

There is no data on the USB memory.

Solution

Check if the USB memory is readable. Or, check if the data exists on the external media.

❑<Wrong card for full disclosure.>, <Failed to read FD from the card.>

Cause

Specified SD card is not used.
The SD card is unformatted.
The data stored in the SD card is damaged. The full disclosure waveform card used on other device is inserted.

Solution 1

Use the specified SD card.
Disconnect and connect the full disclosure waveform card again to make sure that it is properly inserted.
Format the card on the used device. (All previous data will be deleted.)

Solution 2

If the error persists, contact your nearest service representative.

❑<Card not supported.>

Cause

Specified SD card is not used.

Solution 1

Use the specified SD card. Disconnect and connect the full disclosure waveform card to make sure that it is properly inserted.

Solution 2

If the error persists, contact your nearest service representative.

Battery

❑<Reinstall the battery.> is displayed.

Cause

The battery is not firmly installed and battery status cannot be detected. Or, charging of the battery is ceased.

Solution

Reinstall the battery. If the message is still displayed, replace the battery.

❑<Check the battery.> is displayed.

Cause

The communication with the battery is unstable. Or, battery is almost empty.

Solution

If the battery level is low, charge the battery. The battery level decreases even when not in use such as during storage. If the battery level is sufficient, reinstall the battery. If the error persists, contact your nearest service representative.

❑<Battery Charge Suspended.> is displayed.

Cause

Battery charge is temporarily suspended because the temperature of the battery is out of range for charging.

Solution

Wait until the battery is back to chargeable temperature. The battery may not be fully charged. When operating with battery, check the battery icon and operable time on the screen.

❑<Replace the battery.> (Alarm Level M) is displayed.

Cause 1

The battery is deteriorated and cannot be charged and discharged.

Solution

Replace the battery.

Cause 2

The battery has not been charged for a long time.

Solution

If the message disappears during charging, the battery can be used. If the message is still displayed, replace the battery.

❑<Replace the battery.> (Notification) is displayed.

Cause

The battery is deteriorating.

Solution

The battery can be continuously used, but prepare to replace with a new battery as it may soon fail to operate properly.

❑<Remove the Battery.(Error Temp.)> is displayed.

Cause

The temperature of the battery is out of range for charging/discharging.

Solution

Remove the battery from the main unit, and wait until the temperature returns to the chargeable/dischargeable level. Pay attention when touching the battery, as it may be hot.

❑Battery charging ceases before completion, and charging LED turns off.

Cause

The voltage inside the battery is high.

Solution

If this condition continues, replace the battery.

Chapter 12 Setup Item/Default Value

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.

Patient Admit / Discharge

Item	Description	Default	At Power ON	At Discharge
ID	Numeric, Alphabet, Symbol (20 characters)	Blank	Backup	Initialize
Classification	Adult, Child, Neonate	Adult	Depends on the "Patient Classification" setting under [Setup > Initial Settings > User I/F > Power ON/ Discharge].	
Name	Numeric, Alphabet, Symbol (16 characters)	Blank	Backup	Initialize
Pacemaker	Used, Not Used	Not Used	Depends on the setting under [Setup>Initial Settings>User I/F>Power ON/Discharge].	
Mode Select	Monitor Mode 1 to 3	Adult	Depends on the "Monitor Mode" setting under [Setup > Initial Settings > User I/F > Power ON/Discharge].	
	Display Mode 1 to 3	DISPLAY1	Depends on the "Display Mode" setting under [Setup > Initial Settings > User I/F > Power ON/Discharge].	
Sex	Male, Female	Blank	Backup	Initialize
Birth Date	Birth Date	Blank	Backup	Initialize
Age	0 year to 150 years or 0 day to 999 days	0 year	Backup	Initialize
Admit Date/Time	Year, Month, Day, Time	Blank	Backup	Initialize
Height	0.0 inch to 118.1 inch	0.0 inch	Backup	Initialize
Weight	0.0 lbs to 771.6 lbs	0.0 lbs	Backup	Initialize
BSA	0.00 m to 9.99 m^2	0.00 m^2	Backup	Initialize
Blood Type	A, B, O, AB (Rh +/-)	Blank	Backup	Initialize

Alarm

REFERENCE

- Setup for "Power ON/Discharge" depends on "Monitor Mode" setting under [Setup > Initial Settings > User I/F > Power ON/Discharge]. If "Monitor Mode" setting is [Backup]; Depends on the "Alarm" setting under [Setup > Initial Settings > User I/F > Power ON/Discharge].

Item	Description	Default
HR	ON/OFF, 20 bpm to 300 bpm 5 bpm increments (60 bpm and below: 1 bpm increments)	ON, 40 bpm to 120 bpm

Item	Description	Default
Ext Tachy	ON/OFF, 22 bpm to 300 bpm 5 bpm increments (60 bpm and below: 1 bpm increments)	OFF, 150 bpm
Ext Brady		OFF, 30 bpm
SpO_2	ON/OFF, 50%SpO_2 to 100%SpO_2, 1%SpO_2 increments	ON, 90%SpO_2 to OFF
ExtSpO_2	ON/OFF, 50%SpO_2 to 98%SpO_2, 1%SpO_2 increments	ON, 80%SpO_2
PR_SpO_2	ON/OFF, 20 bpm to 300 bpm, 5 bpm increments (25 bpm and below: 1 bpm increments)	ON, 40 bpm to 120 bpm
NIBP (mmHg)	ON/OFF, 10 mmHg to 300 mmHg, 5 mmHg increments	ON SYS: 80 mmHg to 180mmHg DIA: OFF to OFF MAP: OFF to OFF
NIBP (kPa)	ON/OFF, 1.5 kPa to 40.0 kPa, 0.5 kPa increments	ON SYS: 10.0 to 24.0 kPa DIA: OFF to OFF MAP: OFF to OFF
RR	ON/OFF, 5 bpm to 150 bpm, 5 bpm increments Child/Neonate: 2 bpm to 150 bpm, 2 bpm increments	ON, 5 bpm to 30 bpm
Apnea	ON/OFF, 10 sec. to 60 sec., 1 increments	ON, 15 sec.
InspCO_2 (mmHg)	ON/OFF, 1 mmHg to 4 mmHg, 1 mmHg increments	OFF
InspCO_2 (kPa)	ON/OFF, 0.1 kPa to 0.4 kPa, 0.1 kPa increments	OFF
InspCO_2 (%)	ON/OFF, 0.1% to 0.4%, 0.1% increments	OFF
EtCO_2 (mmHg)	ON/OFF, 10 mmHg to 100 mmHg, 5 mmHg increments	OFF
EtCO_2 (kPa)	ON/OFF, 0.1 kPa to 13.3 kPa, 5 mmHg increments	OFF
EtCO_2 (%)	ON/OFF, 0.1% to 13.3%, 5mmHg increments	OFF
RPP	ON/OFF, 10 to 300 (x100), 10 increments	OFF
SI	ON/OFF, 0.5 to 2.0, 0.1 increments	OFF
Asystole	ON, 3 sec. to 10 sec., 1 sec. increments	ON, 5 sec.
VF	ON	ON
VT	ON	ON
Slow_VT	ON/OFF	ON
Tachy	ON/OFF	ON
Brady	ON/OFF	ON
Run	ON/OFF, 2 beats to 8 beats, 1 beat increments	ON, 3 beats
Pause	ON/OFF, 1.5 sec. to 5 sec., 0.5 sec. increments	OFF, 3.0 sec.
Triplet	ON/OFF	OFF
Couplet	ON/OFF	OFF
R on T	ON/OFF, 200 ms to 600 ms, 8 ms increments	OFF, 320 ms
Multiform	ON/OFF	OFF
Vent Rhythm	ON/OFF	OFF
Bigeminy	ON/OFF	OFF
Trigeminy	ON/OFF	OFF
Frequent	ON/OFF, 1 bpm to 50 bpm, 1 bpm increments	OFF, 10 bpm
SVT	ON/OFF, 2 beats to 10 beats, 1 beat increments	OFF, 6 beats

Item	Description	Default
AFib	ON/OFF, 1% to 100%, 1% increments	OFF, 10%
Irregular RR	ON/ OFF, 10% to 20%, 5% increments	OFF, 10%
Prolonged RR	ON/OFF	OFF
S Frequent	ON/OFF, 1 bpm to 50 bpm, 1 bpm increments	OFF, 10 bpm
S Couplet	ON/OFF	OFF
VPC	ON/OFF	OFF
SVPC	ON/OFF	OFF
Pacer Not Capture	ON/OFF, 80 ms to 480 ms, 8 ms increments	OFF, 320 ms
Pacer Not Pacing	ON/OFF, 20 bpm to 200 bpm, 5 bpm increments	OFF, 50 bpm
HR Lower Limit for VT	120 bpm to 200 bpm	120 bpm
HR Lower Limit for RUN	0 bpm to 200 bpm, 10 bpm increments (50 bpm and above: 5 bpm increments)	40 bpm
HR Lower Limit for SVT	100 bpm to 250 bpm, 5 bpm increments	150 bpm
HR Lower Limit for Slow VT	100 bpm to 180 bpm, 10 bpm increments	100 bpm
AFib Alarm Clear Time	OFF, 30 sec., 60 sec.	30 sec.
ST (I) to ST (V) (mm)	ST All Alarm ON/OFF, Individual Alarm ON/ OFF, ±20 mm, 1 mm increments	ST All Alarm OFF, Individual Alarm OFF, OFF to OFF
ST (I) to ST (V) (mV)	ST All Alarm ON/OFF, Individual Alarm ON/ OFF,±2.00mV, 0.1 mV increments	ST All Alarm OFF, Individual Alarm OFF, OFF to OFF

Item		Description	Default
Alarm (Detail Setup)	Suspend Time	1 min., 2 min.	2 min.
	Alarm Silence Time	1 min., 2 min.	2 min.
	Alarm Sound Suspend	ON/OFF	ON
	Alarm Sound Suspend Time	[1min] / [2min] /[5min] / [10min] / [30min] / [60min] /[90min] / [120min] /[240min] / [360min]	2 min.
	Status Alarm Control	Link to alarm silence time, Link to each new occurrence	Link to each new occurrence

Parameter

ECG

Item	Description	Default (with ECG)	Default (without ECG)	At Power ON	At Discharge
Lead	I, II, III, aVR, aVL, aVF, V	ECG1: II ECG2: aVR ECG3: I ECG4: III ECG5: aVL ECG6: aVF ECG7: V		*1	
Size	Auto, x1/4, x1/2, x1, x2, x4	ECG1 to ECG7 x1		*1	

ECG

Item	Description	Default (with ECG)	Default (without ECG)	At Power ON	At Discharge
Filter Mode	Monitor, Diagnosis, ESIS	Monitor		Backup	Backup
Synchronized Mark/Tone	ECG, SpO_2, Auto, OFF	Auto	SpO_2		
Pacemaker	*Same with "Patient Admit/Discharge" section.				
Pacemaker Pulse	ON, OFF	OFF		Backup	Backup
AC Filter	ON, OFF	ON		Backup	Backup
Pace Pulse Mask Time	Auto, 10 ms, 20 ms, 40 ms, OFF	Auto		Backup	Initialize
ECG Drift Filter	ON, OFF	OFF		Backup	Backup
ECG Waveform Display during Lead-OFF	ON, OFF	OFF		Backup	Backup
Pacemaker Sens. Setting	Top, High, Middle, Low	Middle		Backup	Backup

*1: It depends on the "Monitor Mode" setting under [Initial Settings>User I/F>Power ON/Discharge].
However, if "Monitor Mode" setting is [Backup], it depends on the "ECG1, ECG2 Lead", "ECG1, ECG2 Size" setting under [Setup>Initial Settings>User I/F>Power ON/Discharge].

RESP

Item	Description	Default (with ECG)	Default (without ECG)	At Power ON	At Discharge
Size	x1/4, x1/2, x1, x2, x4	x1		Backup	Initialize
RR Synchronized Mark	ON, OFF	ON		Backup	Backup
RR/APNEA Alarm Source	Auto, Impedance, CO_2	Auto	CO_2		
Impedance Meas.	ON, OFF	ON		Depends on the setting under [Setup>Initial Settings>User I/F>Power ON/Discharge].	
Impedance Detection Lead	I, II	II			
Impedance Detection Level	Fixed, Auto	Fixed			

NIBP

Item	Description	Default	At Power ON	At Discharge
NIBP Auto Mode	OFF, 2 min, 2.5 min, 5 min, 10 min, 15 min, 20 min, 30 min, 60 min, 120 min	OFF	*1	
Patient Classification	*Same with "Patient Admit/Discharge" section.			
Measurement Mode	Inflation, Deflation	Inflation	Backup	Backup
Quick Measurement	ON, OFF	ON	Backup	Backup
Target Inflation Value	Adult: 100 mmHg to 290 mmHg Child: 100 mmHg to 200 mmHg Neonate: 100 mmHg to 140 mmHg	Adult: 180 mmHg Child: 140 mmHg Neonate: 100 mmHg	Backup	Backup
Sight Inflation	ON, OFF	OFF	Backup	Backup
Auto Mode with Start/Stop Key	ON, OFF	ON	Backup	Backup
Periodic Measurement Starting Time	Time, Meas.	Time	Backup	Backup
NIBP Measurement at Alarm Occurrence	ON, OFF	OFF	Backup	Backup

NIBP

Item	Description	Default	At Power ON	At Discharge
Arrhythmia	Asystole, VF, VT, Ext Tachy, Ext Brady, Slow VT, Tachy, Brady, Run, Pause, Triplet, Couplet, R on T, Multiform, Vent Rhtm, Bigeminy, Trigeminy, Frequent, SVT, Ireg RR, Prolong RR, S Frequent, S Couplet, VPC, SVPC, Not Capt, Not Pacing, AFib	No Selection		
Meas.	HR, ST, RR, APNEA, SpO_2, PR, CO_2	No Selection		
NIBP Erase Time	5 min., 10 min., 30 min., 60 min., 120 min.	120 min.	Backup	Backup
Time Display	Elapsed, Meas.	Elapsed Time	Backup	Backup
MAP	ON, OFF	ON	Backup	Backup
PR Display	ON, OFF	OFF	Backup	Backup
End Tone	ON, OFF	ON	Backup	Backup

*1: Depends on the "Monitor Mode" setting under [Setup > Initial Settings > User I/F > Power ON/Discharge].
If "Monitor Mode" setting is [Backup] ; Depends on the "NIBP Auto Mode" setting under [Setup > Initial Settings > User I/F > Power ON/Discharge].

SpO_2 (General)

Item	Description	Default	At Power ON	At Discharge
Waveform Size	x1/4, x1/2, x1, x2, x4	x1	Backup	Initialize
Synchronized Mark/Tone	*Same with ECG setting.			
Alarm during NIBP	ON, OFF	ON	Backup	Backup

SpO_2 (Medtronic)

Item	Description	Default	At Power ON	At Discharge
Second Alarm	OFF, 10, 25, 50, 100	OFF	Backup	Backup
SpO_2 Averaging	Fast, Normal	Fast	Backup	Backup

SpO_2 (Masimo)

Item	Description	Default	At Power ON	At Discharge
SpO_2 Averaging	2-4sec., 4-6 sec., 8 sec., 10 sec., 12 sec., 14 sec., 16 sec.	8 sec.	*1	
Pulse Sensitivity	Normal, High, APOD	Normal	Initialize	Initialize
FAST SAT	ON, OFF	OFF		
PI Display	ON, OFF	ON		
Signal IQ Wave	ON, OFF	OFF		

*1: Depends on the "Monitor Mode" setting under [Setup > Initial Settings > User I/F > Power ON/Discharge].
If "Monitor Mode" setting is [Backup] ; Depends on the "SpO_2 Averaging" setting under [Setup > Initial Settings > User I/F > Power ON/Discharge].

CO_2 (Medtronic/HCP-110)

Item	Description	Default	At Power ON	At Discharge
Scale	0 to 50, 0 mmHg to 100 mmHg	0 to 50	*1	
	0 to 4, 0 to 8, 0 to 10 kPa	0 to 4		
	0 to 4, 0 to 8, 0% to 10%	0 to 4		
$EtCO_2$ Peak Duration	10 sec, 20 sec, OFF	10 sec.	*2	

*1: Depends on the "Monitor Mode" setting under [Setup > Initial Settings > User I/F > Power ON/Discharge]. If "Monitor Mode" setting is [Backup] ; Depends on the "CO_2 Scale" setting under [Setup>Initial Settings>User I/F>Power ON/Discharge].

*2: Depends on the "Monitor Mode" setting under [Setup > Initial Settings > User I/F > Power ON/Discharge]. If "Monitor Mode" setting is [Backup] ; Depends on the "$EtCO_2$ Peak Duration" setting under [Setup>Initial Settings>User I/F>Power ON/Discharge].

Scoring

Item	Description	Default	Setting at Discharge
Score Calculation			Default
Parameter Selection	Supp.O2, SpO_2, RR, LOC, GCS, JCS, TEMP, Urine volume, NIBP-S, HR/PR, Clinical Concern, Age, Blood Glucose, Weight, Pain (NRS), Pain (FPS), OFF	NIBP-S, HR/PR, TEMP, SpO_2, RR, Supp.O2, LOC	
Source Select			
HR/PR	HR, PR_SpO_2	With ECG: HR Without ECG: PR_SpO_2	
RR	IMP, CO_2, Manual Input	IMP	
BP	NIBP	NIBP	
TEMP	TEMP, Manual Input	TEMP	
Update Setup	Timer, Manual, OFF	OFF	
Score Mode General Setup			
Score Threshold	Level 0 to 3: 0-27	Level 0: 0 Level 1: 1-4 Level 2: 5-6 Level 3: 7-21	
Time Interval until Next Check	Level 0 to 3: OFF, 00:01 to 24:00	Level 0 to 3: OFF	

RPP

Item	Description	Default (with ECG)	Default (without ECG)	Setting at Discharge
HR/PR	ECG, SpO_2	ECG	SpO_2	Default

SI

Item	Description	Default (with ECG)	Default (without ECG)	Setting at Discharge
HR/PR	ECG, SpO_2	ECG	SpO_2	Default

TEMP

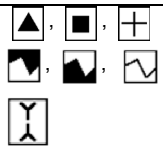
Item	Description	Default	Setting at Discharge
TEMP Erase Time	2 min., 5 min.	5 min.	Default

Data Review

Graphic Trend

Item	Description	Default (with ECG)	Default (without ECG)	At Power ON	At Discharge
Graphic Trend	Basic: HR, VPC, NIBP, SpO_2, PR_SpO_2, PI, RPP, SI, InspCO_2, EtCO_2, APNEA, RR_IMP, RR_GAS ST: ST (I to V)	HR, SpO_2, RR_IMP, NIBP	PR_SpO_2, SpO_2, NIBP	Backup	Backup
Range	10min, 1h, 2h, 4h, 8h, 12h, 16h, 24h	4 hours		Backup	Backup

Graphic Trend

Item	Description	Default (with ECG)	Default (without ECG)	At Power ON	At Discharge
Display Selection					
Scale, Display Selection	HR, PR_SpO_2	300 bpm		Backup	Backup
	VPC	100 beats		Backup	Backup
	NIBP	300 mmHg 40 kPa		Backup	Backup
	SpO_2	0- 100%SpO_2		Backup	Backup
	PI	0- 20%		Backup	Backup
	CO_2 ($InspCO_2$, $EtCO_2$)	100 mmHg		Backup	Backup
		10.0 kPa			
		10.0%			
	Apnea	30 sec.		Backup	Backup
	RR_IMP, RR_GAS	150 Bpm		Backup	Backup
	ST	± 2.0 mV, ± 20.0 mm		Backup	Backup
	RPP	900		Backup	Backup
	SI	3.0		Backup	Backup

Tabular Trend

Item	Description	Default (with ECG)	Default (without ECG)	At Power ON	At Discharge
Interval	10 sec., 30 sec., 1 min., 2 min., 2.5 min., 5 min., 10 min., 15 min., 30 min., 60 min., NIBP	5 min.		Backup	Backup
Parameter Selection	<Basic> OFF, HR, VPC, TEMP, PI, SpO_2, PR_ SpO_2, SI, RPP, NIBP-S/D/M, APNEA, $EtCO_2$, $InspCO_2$, RR_GAS, RR_IMP, OFF <ST> ST (I to V)	HR, PR_SpO_2, SpO_2, NIBP-S,D,M	PR_SpO_2, SpO_2, NIBP-S,D,M	Backup	Backup

Recall

Item	Description	Default (with ECG)	Default (without ECG)	At Power ON	At Discharge
Recall Wave	ECG1, ECG2, SpO_2, RESP, CO_2	ECG1, ECG2	SpO_2, OFF	Backup	Backup
Recall Factor	Asystole, VF, VT, Ext Tachy, Ext Brady, Slow VT, Tachy, Brady, Run, Pause, Triplet, Couplet, R on T, Multiform, Vent Rhtm, Bigeminy, Trigeminy, Frequent, SVT, Ireg RR, Prolong RR, S Frequent, S Couplet, VPC, SVPC, Not Capt, Not Pacing, AFib HR, ST, NIBP, RR, APNEA, RPP, SpO_2, PR, CO_2, SI	All ON		Backup	Backup
List Display	5 Waves (Compressed: 12 sec.)	5 Waves (Compressed: 12 sec.)		Backup	Backup

Recall

Item	Description	Default (with ECG)	Default (without ECG)	At Power ON	At Discharge
Recall Factor	Asystole, VF, VT, Ext Tachy, Ext Brady, Slow VT, Tachy, Brady, Run, Pause, Triplet, Couplet, R on T, Multiform, Vent Rhtm, Bigeminy, Trigeminy, Frequent, SVT, Ireg RR, Prolong RR, S Frequent, S Couplet, VPC, SVPC, Not Capt, Not Pacing, AFib HR, ST, NIBP, RR, APNEA, RPP, SpO_2, PR, CO_2, SI	All ON		Backup	Backup

Full Disc.

Item	Description	Default	At Power ON	At Discharge
Waveform	ECG1, ECG2, I, II,III, aVR, aVL, aVF, V, SpO_2, RESP, CO_2, OFF	ECG1	Backup	Backup
Size/Scale	x1/4, x1/2, x1, x2, x4 (When CO_2 label is set: 0 to 50, 0 to 100)	x1	Backup	Backup

MPDR

Item	Description	Default	At Power ON	At Discharge
Graphic Trend	(Same as graphic trend settings)		Backup	Backup
Tabular Trend	(Same as tabular trend settings)		Backup	Backup
Full Disc.	(Same as full disclosure waveform settings)		Backup	Backup

Alarm History

Item	Description	Default	At Power ON	At Discharge
Alarm Level	S, H, M, L, N	Select All	Backup	Backup
Alarm Type	Numeric Data, Arrhy, Equip. Status, Other	Select All	Backup	Backup

System Configuration

Display Config.

Item	Description	Default (with ECG)	Default (without ECG)	At Power ON	At Discharge
User Key	OFF, Home, Menu, Alarm Silence, Alarm Suspend, NIBP Start/Stop, Print Start/Stop, Monitor Suspend, Night Mode, Key Lock, Mode Select, Admit/Disch., HR/PR, HR/PR Source, Lead, Scale, SpO_2 Display ON/OFF, CO_2 Display ON/OFF, CO2 Suspended, Trend, Tabular Trend, NIBP List, Recall, Alarm History, Full Disc., Tone/Volume, NIBP Auto Mode, Alarm Setup (Basic), Print, Monitor Mode 1, Monitor Mode 2, Monitor Mode 3, Display Config., MPDR, Display, Event	Menu, Print Start/Stop, NIBP Start/Stop, Recall, Alarm Silence		Backup	Backup
Meas.	HR/PR, HR, VPC PACE, ST, SpO_2, PR_SpO_2, RR_IMP, NIBP, NIBP List, NIBP Graph, RR_GAS, CO_2, TEMP, Scoring, RPP, SI	HR/PR, SpO_2, NIBP, NIBP Graph, RR_IMP, Scoring	SpO_2, NIBP, NIBP Graph, NIBP List, Scoring		
Alarm Limit Display	Graph, Numeric, OFF	Graph			
Wave	ECG1 to ECG7, SpO_2, RESP, CO_2, ECG1 to EEG7 Cascade	ECG1, SpO_2, RESP, CO_2	SpO_2		
Sweep Speed	Circ.: 6.25, 12.5, 25, 50 Vent: 6.25, 12.5, 25	Circ.: 25 Vent: 6.25			
Grid	ON, OFF	ON			
Thickness	Normal, Thick	Normal			

Manual Printing

Item		Description	Default	At Power ON	At Discharge
Basic	Waveform Selection	OFF, ECG1, ECG2, ECG3, SpO_2, RESP, CO_2	With ECG: ECG1 Without ECG: SpO_2	Backup	Backup
	Print Duration	24 sec., Cont.	24 sec.	Backup	Backup
	Delay Time	None, 8 sec., 16 sec.	8 sec.	Backup	Backup
Common	QRS Classification	ON, OFF	ON	Backup	Backup
	Print Calibration	ON, OFF	OFF	Backup	Backup
	Print after NIBP Meas.	ON, OFF	OFF	Backup	Backup
	Auto Print List Data	ON, OFF	OFF	Backup	Backup
	Speed	50 mm/s, 25 mm/s	25 mm/s	Backup	Backup
	Print NIBP Data	ON, OFF	OFF	Backup	Backup
	Print Simple List	ON, OFF	OFF	Backup	Backup

Auto Printing

Item	Description	Default	At Power ON	At Discharge
Periodic Printing	ON, OFF	OFF	Backup	Backup
Waveform Selection	OFF, ECG1, ECG2, ECG3, SpO_2, RESP, CO_2	With ECG: ECG1 Without ECG: SpO_2	Backup	Backup

Auto Printing

Item	Description	Default	At Power ON	At Discharge
Timer/Interval	Interval, Timer	Timer	Backup	Backup
Interval	1, 2, 3, 5, 10, 15, 20, 30, 60, 120 min.	120 min.	Backup	Backup
Timer	0:00 to 23:00 (1:00 interval)	None	Backup	Backup
Periodic Printing	6, 12, 24 sec.	12 sec.	Backup	Backup

Tone/Volume

Item	Description		Default	At Power ON	At Discharge
Vital Alarm Sound	Urgent	Volume: 11 levels	4	Depends on the "Monitor Mode" setting under [Setup > User I/F > Power ON/ Discharge].	
	Caution	Volume: 11 levels	4		
	Status	Volume: 11 levels	4		
Ventilator Alarm Sound	ON/OFF		OFF		
	Volume: 11 levels		4		
Status Alarm Control Alarm Sound	Urgent	Volume: 11 levels	4		
	Caution	Volume: 11 levels	4		
	Status	Volume: 11 levels	4		
Sync. Tone	Volume: 11 levels		2		
	Sync. Tone: Selected Tone, Sync. with SpO_2 Value		Selected Tone		
Key Sound	Volume: 11 levels		4		
Other	Volume: 11 levels		4		

Other Setup

Item		Description	Default	At Power ON	At Discharge
Color	HR	12 colors + White	6	Backup	Backup
	ST		6	Backup	Backup
	VPC		White	Backup	Backup
	PACE		White	Backup	Backup
	NIBP		8	Backup	Backup
	SpO_2		4	Backup	Backup
	CO_2		8	Backup	Backup
	RESP		White	Backup	Backup
	TEMP		2	Backup	Backup
	RPP		White	Backup	Backup
	SI		4	Backup	Backup
User Key Color	Home	Gray (Light), Gray (Dark), Blue, Pink, Green	Blue	Backup	Backup
	Menu		Blue	Backup	Backup
	Alarm Silence		Pink	Backup	Backup
	Alarm Suspend		Pink	Backup	Backup
	NIBP Start/Stop		Blue	Backup	Backup
	Print Start/Stop		Green	Backup	Backup
	Monitor Suspend		Gray (Light)	Backup	Backup

Other Setup

Item		Description	Default	At Power ON	At Discharge
	Night Mode		Gray (Light)	Backup	Backup
	Key Lock		Gray (Light)	Backup	Backup
	Mode Select		Gray (Light)	Backup	Backup
	Admit/Discharge		Gray (Light)	Backup	Backup
	HR/PR		Gray (Light)	Backup	Backup
	HR/PR Source		Gray (Light)	Backup	Backup
	Lead		Gray (Light)	Backup	Backup
	Scale		Gray (Light)	Backup	Backup
	SpO_2 Display ON/ OFF		Gray (Light)	Backup	Backup
	CO_2 Display ON/ OFF		Gray (Light)	Backup	Backup
	CO_2 suspended		Gray (Light)	Backup	Backup
	Graphic Trend		Gray (Light)	Backup	Backup
	Tabular Trend		Gray (Light)	Backup	Backup
	NIBP List		Gray (Light)	Backup	Backup
	Recall		Gray (Light)	Backup	Backup
	Alarm History		Gray (Light)	Backup	Backup
	Full Disc.		Gray (Light)	Backup	Backup
	Tone/Volume		Gray (Light)	Backup	Backup
	NIBP Auto Mode		Blue	Backup	Backup
	Alarm Basic		Pink	Backup	Backup
	Manual Printing		Gray (Light)	Backup	Backup
	Display Config.		Gray (Light)	Backup	Backup
	MPDR		Gray (Light)	Backup	Backup
	Display		Gray (Dark)	Backup	Backup
	Event		Gray (Light)	Backup	Backup
	Monitor Mode 1		Gray (Light)	Backup	Backup
	Monitor Mode 2		Gray (Light)	Backup	Backup
	Monitor Mode 3		Gray (Light)	Backup	Backup
Brightness	Brightness	7 levels	4th from top	Backup	Backup
Night Mode	Mode	Manual, Timer	Manual	Backup	Backup
	Start Time	00:00 to 23:59	21:00	Backup	Backup
	End Time	00:00 to 23:59	07:00	Backup	Backup
	Volume	No Change, 3, 1, 0	1	Backup	Backup
	Display	No Change, Dark, Darker, Time Only	Darker	Backup	Backup
	Alarm Indicator	ON, OFF	OFF	Backup	Backup

Chapter 13 System Components

Medical Device

The following model types are available.

Model	ECG Unit	SpO_2 Unit	Telemeter
BDS-1001EN	Yes	Medtronic	-
BDS-1001ENT	Yes	Medtronic	Yes
BDS-1001EM	Yes	Masimo	-
BDS-1001EMT	Yes	Masimo	Yes
BDS-1001N	-	Medtronic	-
BDS-1001NT	-	Medtronic	Yes
BDS-1001M	-	Masimo	-
BDS-1001MT	-	Masimo	Yes

Accessories

The following products are available as accessories for the BDS-1001 System.
Purchase them as necessary.

⚠ CAUTION

- Use only the accessories specified for this device. If unspecified products are used, proper function cannot be executed.
- Products for single use are intended to use to single patient only. Make sure to not reuse. After using, dispose it properly.
- For quality improvement purposes, specifications may be subjected to change without prior notice.

Accessory

Device Name	Model	Note
CO2 Gas Unit	HCP-110	
Recorder Unit	HR-110	
GCX Attachment for Monitor	OAO-116A	
Trolley Attachment for Monitor	OAO-118A	
Bed Mount for Monitor	OAO-119A	
Thermometer Holder	OAO-125A	
Trolley (S)	OTO-16S	
Power Cable	CS-34	
Detachable Attachment for Patient Monitor	OAO-1000	
Recording Paper	OP050-02TDR	

Device Name	Model	Note
Rechargeable Lithium-ion Battery Pack	BTO-008	
SD Card	SD-16G	
Earth Wire	CE-01A	
Relay Cable	CJ-402RI-70SVi	
PB700/800 serial interface cable	CJ-403RI-70PB	
Thermometer Connection Cable	CJO-32RS0.1	

ECG Accessory

Device Name	Model	Note
ECG Relay Cable	CIO-05CTP-3NU	3-electrode (standard type)
	CIO-05CTP-4NU	4-electrode (standard type)
	CIO-05CTP-5NU	5-electrode (standard type)
	CIO-08CTP-3EU	3-electrode (electrosurgery-proof type)
	CIO-08CTP-5EU	5-electrode (electrosurgery-proof type)
	CIO-07CTP-3NA	3-electrode (standard type) for FA
	CIO-07CTP-4NA	4-electrode (standard type) for FA
	CIO-07CTP-5NA	5-electrode (standard type) for FA
	CMO-07FT-3NAB	3-electrode (standard type) for FA
	CMO-07FT-4NAB	4-electrode (standard type) for FA
	CMO-07FT-5NAB	5-electrode (standard type) for FA
	CIO-09CTP-3NA	3-electrode for DIN type
	CIO-09CTP-4NA	4-electrode for DIN type
	CIO-09CTP-5NA	5-electrode for DIN type
Patient Cable Adapter	CIZ-173DIN-3-U	
Patient Cable Adapter	CIZ-173DIN-5-U	
ECG Clip Type Lead Cable 3-electrode	CMF-700-3	
ECG Clip Type Lead Cable 4-electrode	CMF-700-4	
ECG Clip Type Lead Cable 5-electrode	CMF-700-5	
Limb-5lead For 10 electrode ECG	CMF-702-5	
Limb-5lead For 10 electrode ECG	CMF-703-5	
3 electrode ECG	CMC-700-3	
4 electrode ECG	CMC-700-4	
5 electrode ECG	CMC-700-5	
10 electrode ECG Limb-5lead	CMC-702-5	
10 electrode ECG Limb-5lead	CMC-703-5	

NIBP Accessory

Device Name	Model	Note
Air Hose	OA-80APS1.5-S	1.5 m, General
	OA-80APS3.5-S	3.5 m, General
	OA-80NE1.5-S	1.5 m, Neonate
	OA-80NE3.5-S	3.5 m, Neonate
All Purpose Blood Pressure Cuff	CUF-1000-XS	Adult Cuff (XS size) Latex-free, Arm Circumference 12 cm to 17 cm
All Purpose Blood Pressure Cuff	CUF-1000-S	Adult Cuff (S size) Latex-free, Arm Circumference 17 cm to 22 cm
All Purpose Blood Pressure Cuff	CUF-1000-M	Adult Cuff (M size) Latex-free, Arm Circumference 22 cm to 32 cm
All Purpose Blood Pressure Cuff	CUF-1000-L	Adult Cuff (L size) Latex-free, Arm Circumference 32 cm to 42 cm
All Purpose Blood Pressure Cuff	CUF-1000-XL	Adult Cuff (XL size) Latex-free, Arm Circumference 42 cm to 50 cm
Soft Cuff, APC	CUF-8503	Adult Cuff (small)
Soft Cuff, APC	CUF-8504	Adult Cuff (medium)
Soft Cuff, APC	CUF-8505	Adult Cuff (large)
Soft Cuff, APC	CUF-8506	Adult Cuff (thigh)

The Other Medical Devices

The other medical devices to be used in combination with this device as system are as follows.

Central Monitor/Central Telemetry Receiver (Manufactured by Fukuda Denshi)

Device Name	Model	Note
DYNASCOPE 1000 Series DS-1800 System	DS-1800 System	Central Monitor
DYNASCOPE 7000 Series DS-7700 System	DS-7700 System	Central Monitor
DYNASCOPE 8000 Series DS-8900 System	DS-8900 System	Central Monitor
Central Telemetry Receiver LW-1000	LW-1000	Central Telemetry Receiver

Pulse Oximetry Measurement (Manufactured by Medtronic)

Device Name	Model	Note
Adult SpO_2 Sensor Reusable	DS100A	
Adult SpO_2 Sensor	MAXA	
Adult SpO_2 Sensor	MAXAL	
Pediatric SpO_2 Sensor	MAXP	
Infant SpO_2 Sensor	MAXI	

Device Name	Model	Note
Neonatal-Adult SpO_2 Sensor	MAXN	
Adult SpO_2 Nasal Sensor	MAXR	
Forehead SpO_2 Sensor	MAXFAST	
SpO_2 Relay Cable	DOC-10	

Pulse Oximetry Measurement (Manufactured by Masimo)

Device Name	Model	Note
Pulse Oximeter Adhesive Sensor	LNCS Adtx	PN:1859
Pulse Oximeter Adhesive Sensor	LNCS Pdtx	PN:1860
Pulse Oximeter Adhesive Sensor	LNCS Inf-L	PN:1861
Pulse Oximeter Adhesive Sensor	LNCS Neo-L	PN:1862
Reusable Finger Clip Sensor	LNCS DCI	PN:1863
Reusable Ear Sensor	LNCS TC-I	PN:1895
Reusable Forehead Sensor	LNCS TF-I	PN:1896
Pulse Oximeter Adhesive Sensor	LNCS NeoPt-L	PN:1901
Pulse Oximeter Adhesive Sensor	LNCS Inf-3	PN:2319
Pulse Oximeter Adhesive Sensor	LNCS NeoPt-3	PN:2321
Disposable Transflectance Sensor	LNCS TFA-1	PN:3858
LNCS Patient Cable	LNC-4	PN:2017
LNCS Patient Cable	LNC-10	PN:1814
Reusable Finger Clip Sensor	RD SET DCI	PN:4050
Pulse Oximeter Adhesive Sensor	RD SET Adt	PN:4000
Pulse Oximeter Adhesive Sensor	RD SET Pdt	PN:4001
Pulse Oximeter Adhesive Sensor	RD SET Inf	PN:4002
Pulse Oximeter Adhesive Sensor	RD SET Neo	PN:4003
Pulse Oximeter Adhesive Sensor	RD SET NeoPt	PN:4004
Reusable Ear Sensor	RD SET TC-I	PN:4053
Reusable Forehead Sensor	RD SET TF-I	PN:4055
RD SET Series Patient Cable	RD SET MD14-05	PN:4080
RD SET Series Patient Cable	RD SET MD14-08	PN:4108
RD SET Series Patient Cable	RD SET MD14-12	PN:4081

CO_2 Concentration Measurement (Manufactured by Medtronic)

For Short Term Use

Device Name	Model	Note
Microstream™ Advance Adult Oral-Nasal CO2 Filter Line with O2 connector	MVA	Adult, with O2 male connector
Microstream™ Advance Adult Oral-Nasal CO2 Filter Line with O2 connector	MVAL	Adult, with O2 male connector, long
Microstream™ Advance Adult Oral-Nasal CO2 Filter Line with O2 Tubing	MVAO	Adult, with O2 tubing-female connector

Device Name	Model	Note
Microstream™ Advance Adult Oral-Nasal CO2 Filter Line with O2 Tubing	MVAOL	Adult, with O2 tubing-female connector, Long
Microstream™ Advance Pediatric Oral-Nasal CO2 Filter Line	MVP	Pediatric
Microstream™ Advance Pediatric Oral-Nasal CO2 Filter Line with O2 Tubing	MVPO	Pediatric, with O2 tubing-female connector
Microstream™ Advance Pediatric Oral-Nasal CO2 Filter Line with O2 Tubing	MVPOL	Pediatric, with O2 tubing-female connector, Long
Microstream™ Advance Adult Nasal CO2 Filter Line	MVAN	Adult
Microstream™ Advance Adult Nasal CO2 Filter Line with O2 Tubing	MVANO	Adult, with O2 tubing-female connector
Microstream™ Advance Adult Nasal CO2 Filter Line with O2 Tubing	MVANOL	Adult, with O2 tubing-female connector, Long
Microstream™ Advance Pediatric Nasal CO2 Filter Line	MVPN	Pediatric
Microstream™ Advance Pediatric Nasal CO2 Filter Line with O2 Tubing	MVPNO	Pediatric, with O2 tubing-female connector
Microstream™ Advance Adult-Intermediate Bite Block CO2 Filter Line with O2 Tubing	MVABO	O2 tubing-female connector
Microstream™ Advance Adult-Intermediate Bite Block CO2 Filter Line with O2 Tubing	MVABOL	O2 tubing-female connector,,Long
Microstream™ Advance Adult-Intermediate Bite Block CO2 Filter Line with O2 connector	MVAB	O2 male connector

For Long Term Use

Device Name	Model	Note
Microstream™ Advance Adult Oral-Nasal CO2 Filter Line with O2 Tubing	MVAOH	Adult, with O2 tubing-female connector
Microstream™ Advance Adult Oral-Nasal CO2 Filter Line with O2 Tubing	MVAOHL	Adult, with O2 tubing-female connector, Long
Microstream™ Advance Pediatric Oral-Nasal CO2 Filter Line with O2 Tubing	MVPOH	Pediatric, with O2 tubing-female connector
Microstream™ Advance Adult Nasal CO2 Filter Line	MVANH	Adult
Microstream™ Advance Adult Nasal CO2 Filter Line with O2 Tubing	MVANOH	Adult, with O2 tubing-female connector
Microstream™ Advance Pediatric Nasal CO2 Filter Line with O2 Tubing	MVPNOH	Pediatric, with O2 tubing-female connector
Microstream™ Advance Adult-Pediatric Intubated CO2 Filter Line	MVAIHH	Adult-pediatric, High humidity
Microstream™ Advance Adult-Pediatric Intubated CO2 Filter Line	MVAIH	Adult-pediatric
Microstream™ Advance Adult-Pediatric Intubated CO2 Filter Line	MVAIHL	Adult-pediatric, Long
Microstream™ Advance Neonatal-Infant Intubated CO2 Filter Line	MVIIHH	Neonatal-infant, High humidity
Microstream™ Advance Neonatal-Infant Intubated CO2 Filter Line	MVIIH	Neonatal-infant
Microstream™ Advance Neonatal-Infant Intubated CO2 Filter Line	MVIIHL	Neonatal-infant, Long

Thermometer for Exergen (Manufacturer: Exergen Corporation)

Device Name	Model	Note
Temporal Scanner	TAT-5000S-RS232-QR	

Chapter 14 Specification

Specification

This section states the specification of this device.

Main Unit: BDS-1001

Size (not including the protrusion)

178(W) mm x 252(H) mm x 133.5(D) mm

Weight (not including the accessory)

1.9 kg

Environmental Conditions

Operating Temperature	10°C to 40°C
Operating Humidity	30% to 85% (non-condensing)
Operating Atmospheric Pressure	70 kPa to 106 kPa
Transport/Storage Temperature	-10°C to 60°C
Transport/Storage Humidity	10% to 95% (at 40°C, non-condensing)
Storage Atmospheric Pressure	70 kPa to 106 kPa

Safety

General Safety Standard	IEC 60601-1 Ed. 3.2: 2020 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance)
EMC Standard	IEC 60601-1-2: 2014+A1: 2020 (Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests)
Type of protection against electric shock	Class I Equipment (During AC power operation) Internally Powered Equipment (During battery operation)
Degree of protection against electric shock	ECG/RESP, SpO_2: Type CF Applied Part NIBP: Type BF Applied Part
Operation Mode	Continuous Operation
Waterproof/Dustproof	BDS-1001 Main Unit: IP32 Only when I/O cover, battery cover, $EtCO_2$ cover (or HCP-110), or recorder cover (or HR-110) is attached.
Usage in the Presence of Flammable Gas	This device cannot be used in the presence of air or flammable anesthetic gas or oxygen or nitrous oxide and flammable anesthetic gas.
Use in environment with high concentration of oxygen	Never operate the device in an environment with a high concentration of oxygen.

Power Supply

Voltage	100-240 V AC DC 14.8 V (when using the battery)

Power Consumption	During AC power operation: 90VA and below During battery operation: 43VA and below
Battery Operation Time	2.5 hours or more
Battery Charging Time	Rapid Charge (when the device is not operating): 6 hours, Normal Charge (when the device is operating): 12 hours

Expected Service Life

6 years	According to self-certification (☞Maintenance Manual "Periodic Replacement" P7-1)

Recorder Unit: HR-110

Size

82.2 (W) mm x 94.9 (H) mm x 59 (D) mm (not including the protrusion)

Weight

0.2 kg (not including the accessory)

Environmental Conditions

Operating Temperature	10°C to 40°C/50°F to 104°F
Operating Humidity	30% to 85% (non-condensing)
Operating Atmospheric Pressure	70 kPa to 106 kPa
Transport/Storage Temperature	-10°C to 60°C/14°F to 140°F
Transport/Storage Humidity	10% to 95% (40°C/104°F) (non-condensing)
Storage Atmospheric Pressure	70 kPa to 106 kPa

Safety

General Safety Standard	IEC 60601-1 Ed. 3.2: 2020 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance)
EMC Standard	IEC 60601-1-2: 2014+A1: 2020 (Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance Collateral standard: Electromagnetic compatibility Requirements and tests)
Type of protection against electric shock	Class I Equipment (During AC power operation)/Internally Powered Equipment (During battery operation)

Power Supply

Voltage	DC 12 V (Supplied from main unit)

Expected Service Life

6 years	According to self-certification (☞Maintenance Manual "Periodic Replacement" P7-1)

CO_2 Gas Unit: HCP-110

Size

104 (W) mm x 64 (H) mm x 33 (D) mm (not including the connector part and protrusion)

Weight

0.2 kg (not including the accessory)

Environmental Conditions

Operating Temperature	10°C to 40°C/50°F to 104°F
Operating Humidity	30% to 85% (non-condensing)
Operating Atmospheric Pressure	70 kPa to 106 kPa
Transport/Storage Temperature	-10°C to 60°C/14°F to 140°F
Transport/Storage Humidity	10% to 95% (40°C/104°F) (non-condensing)
Storage Atmospheric Pressure	70 kPa to 106 kPa

Safety

General Safety Standard	IEC 60601-1 Ed. 3.2: 2020 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance)
EMC Standard	IEC 60601-1-2: 2014+A1: 2020 (Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests)
Type of protection against electric shock	Class I equipment (BDS-1001 system)/Internally Powered Equipment (BDS-1001 system)
Degree of protection against electric shock	CO_2 : Type BF Applied Part
Usage in the Presence of Flammable Gas	This device cannot be used in the presence of air or flammable anesthetic gas or oxygen or nitrous oxide and flammable anesthetic gas.

Power Supply

Voltage	DC 12 V (Supplied from main unit)

Expected Service Life

6 years	According to self-certification (☞Maintenance Manual "Periodic Replacement" P7-1)

Performance

This section states the performance of the BDS-1001 system. The EMC essential performance is indicated with ※.

Display Unit

Display Device	10.1 inch color LCD
Resolution	1280 pixel × 800 pixel
Function Control	Touch Screen Method
Waveform Trace	Stationary Trace
Sweep Speed	ECG/SpO_2 (6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s) RESP/CO_2 (6.25 mm/s, 12.5 mm/s, 25 mm/s)

Operation

Touch Panel	Capacitive Touch Panel
Fixed Key	1 (power supply switch)

Sound Pressure

Alarm Sound (IEC Tone)	High Priority Maximum: 78 dBA, Minimum: 64 dBA
	Medium Priority Maximum: 75 dBA, Minimum: 61 dBA
	Low Priority Maximum: 72 dBA, Minimum: 58 dBA
Alarm Sound (IEC Tone, When trolley is used.)	High Priority Maximum: 71 dBA, Minimum: 56 dBA
	Medium Priority Maximum: 70 dBA, Minimum: 53 dBA
	Low Priority Maximum: 69 dBA, Minimum: 50 dBA
HR Synchronized Tone	Maximum: 74 dBA, Minimum: 24 dBA
HR Synchronized Tone (When trolley is used.)	Maximum: 64 dBA, Minimum: 21 dBA
SpO_2 Synchronized Tone	Maximum: 75 dBA, Minimum: 34 dBA
SpO_2 Synchronized Tone (When trolley is used.)	Maximum: 65 dBA, Minimum: 29 dBA
Measurement Radius	1.0 m
Measurement Radius (When trolley is used.)	2.0 m

Clock Accuracy

	±2 min. per year (25°C)

Alarm

Alarm Function	For each alarm level, the respective alarm sound generates, and the alarm indicator flashes.
Alarm Indicator	Visual check is possible from 4m distance.
Alarm Display	Visual check is possible from 1 m distance.

ECG

Lead Type	Wired 3, 4, 5-electrode
Frequency Characteristic	150 Hz / 40 Hz / 15 Hz
Input impedance	2.5 MΩ or above

Maximum Input Voltage	10 mVp-p
Polarization Voltage	±825 mV or above
Common Mode Rejection Ratio	90 dB or above
HR Measurement Range	Adult: 0, 12 bpm to 300 bpm Neonate: 0, 30 bpm to 300 bpm
※ HR Measurement Accuracy	±3 bpm

NOTE

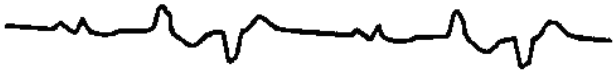
- In the test according to IEC 60601-2-27 201.12.1.101.15, non-detection performance of QRS complex is satisfied under the following condition. The QRS complex of 1.0 mV, 10 ms is not detected when patient classification is adult, filter mode is ESIS, and waveform size is x1, x1/2, x1/4.

HR Display Response Time	Adult/Child: 6 sec., Neonate: 3 sec.
Waveform Size	1/4, 1/2, 1, 2, 4
Defibrillation Proof	Provided Resuming time is 5 seconds when tested according to IEC 60601-2-25: 2011 and IEC 60601-2-27: 2011 201.8.5.5.1.
Heart rate meter accuracy and response to irregular rhythm	80 bpm Ventricular Bigeminy: 80 bpm

60 bpm Ventricular Bigeminy: 60 bpm

120 bpm Ventricular Bigeminy: 120 bpm

90 bpm Bidirectional Systoles: 90 bpm



Response time of heart rate meter to change in heart rate	HR change from 80 bpm to 120 bpm: Range 8 sec. to 10 sec., Average 9 sec. HR change from 80 bpm to 40 bpm: Range 8 sec. to 10 sec., Average 9 sec.
Time to ALARM for tachycardia	Ventricular Tachycardia 1 mVpp, 206 bpm: Range 9 sec. to 11 sec., Average 10 sec.

Ventricular Tachycardia 1 mVpp, 206 bpm:
Range 8 sec. to 10 sec., Average 9 sec.

Ventricular Tachycardia 0.5 mVpp, 206 bpm:
Range 13 sec. to 16 sec., Average 14 sec.

Ventricular Tachycardia 2 mVpp, 195 bpm:
Range 9 sec. to 11 sec., Average 10 sec.

Ventricular Tachycardia 4 mVpp, 195 bpm:
Range 8 sec. to 10 sec., Average 9 sec.

	Ventricular Tachycardia 1 mVpp, 195 bpm: Range 10 sec. to 12 sec., Average 11 sec.
Tall T-wave Rejection Capability	The following T-wave can be removed when tested according to IEC 60601-2-27 201.12.1.101.17. ・For adult and child, T-wave of 1.2 mV can be removed. ・For neonate, T-wave of 0.5 mV can be removed.
Transient Characteristic	3.2 sec, 0.32 sec, 0.1 sec (time constant can be changed)

NOTE

- The impulse response satisfies the test according to IEC 60601-2-27 201.12.1.101.8 when the ECG filter is set to Diagnosis Mode.

Rejection of Pacemaker Pulse	a) Pacemaker Pulse without Over/Undershoot Capable to reject pulses of pulse width 0.1 ms to 2 ms, amplitude±2 mV to±700 mV b) Pacemaker Pulse with Over/Undershoot Rejection is not possible. c) Pacer Pulse Detector Rejection of Fast ECG Signals Slew Rate 3.2V/S
Lead-off Detection Current	100 nA and below

Respiration

Method	Impedance Method
Frequency Characteristic	1.5 Hz (adult, child) / 2.5 Hz (neonate)
Current	100 µA and below (at 33.3 kHz ±5%)
Measurement Range	0, 4 bpm to 150 bpm
Measurement Accuracy	±3Bpm

SpO_2 (Arterial Oxygen Saturation)

Measurement Value Update Rate	1 sec.

Medtronic Unit

Measurement Method	2 Wavelength Pulse Wave Method Wavelength: Approx. 660nm (Red light) Approx. 890nm (Infrared light) Output: 15 mW and below
Measurement Range	1%SpO_2 to 100%SpO_2
Resolution	1%SpO_2
※ Measurement Accuracy	±2 [digit] (70%SpO_2 to 100%SpO_2) At low perfusion: ±2 [digit] (70%SpO_2 to 100%SpO_2) With body motion: ±3 [digit] (70%SpO_2 to 100%SpO_2) At low oxygen saturation level: ±3 [digit] (60%SpO_2 to 80%SpO_2)
PR Measurement Range	20 bpm to 250 bpm
※ PR Accuracy	± 3 bpm when 20 bpm to 250 bpm
Measurement Response Time	6 sec. to 7 sec.

Masimo Unit

Measurement Method	2 Wavelength Pulse Wave Method Masimo LNCS/M-LNCS/RD Sensor Wavelength: Approx. 660nm (Red light) 905nm (Infrared light) Output: 15 mW and below
SpO_2	
Measurement Range	1%SpO_2 to 100%SpO_2
Resolution	1%SpO_2
※ Measurement Accuracy	Without body motion Adult: ±2%SpO_2 when 70%SpO_2 to 100%SpO_2 Neonate: ±3%SpO_2 when 70%SpO_2 to 100%SpO_2 With body motion Adult: ±3%SpO_2 when 70%SpO_2 to 100%SpO_2 Neonate: ±3%SpO_2 when 70%SpO_2 to 100%SpO_2
PI (Perfusion Index)	
Measurement Range	0.02% to 20.0% (when disposable sensor is used) / 0.05% to 20.0% (when reusable sensor is used)
Minimum Display Unit	0.01%
Pulse Rate	
Measurement Range	26 bpm to 239 bpm
※ Measurement Accuracy	± 3 bpm when 26 bpm to 239 bpm (without body motion)
Measurement Response Time	7 levels: 2 to 4 sec., 4 to 6 sec., 8 sec., 10 sec., 12 sec., 14 sec., 16 sec. (averaging duration)

NOTE

- The SpO_2 measurement accuracy is determined based on the values of the root-mean-square (rms) difference between SpO2 readings of the pulse oximeter device and values of SaO2 determined with a CO oximeter, by healthy adult volunteers. The pulse oximeter device measurements are statistically distributed; ±2% measurement accuracy means that only about two-thirds of pulse oximeter device measurements can be expected to fall within ±2% of the value measured by a CO-oximeter.

NIBP (non-invasive blood pressure)
(AAMI SP10: 2002+A1:2003+A2:2006 +(R)2008 Manual, electronic or automated sphygmomanometers) (ISO81060-2:2013 Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type)

Measurement Method	Oscillometric Method
Measurement Range	0 mmHg to 300 mmHg
Resolution	1 mmHg
Pressure accuracy	±3 mmHg
BP Measurement Error according to the Clinical Performance Test	
Mean Error	Within ±5 mmHg
Standard Deviation of Error	8 mmHg and below
Error of Cuff Pressure Display	Within ±3 mmHg
※ Measurement Error (including simulator)	±10 mmHg
PR Measurement Range	40 bpm to 240 bpm

Rated Cuff Pressure	Adult: 300 mmHg Pediatric: 210 mmHg Neonate: 150 mmHg
PR Accuracy	±5%
Deflation Speed	5±1 mmHg/sec. (Quick Measurement OFF) 10±2 mmHg/sec. (Quick Measurement ON)
Safety Mechanism	Adult: 300 mmHg and below Pediatric: 210 mmHg and below Neonate: 150 mmHg and below

CO_2 (Carbon Dioxide Concentration)

Medtronic Unit

Measurement Method	Infra-Red Solid-State Method, SidestreamMethod
CO_2, $EtCO_2$, $InspCO_2$ Measurement Range	0 mmHg to 99 mmHg
※ Measurement Accuracy	0 mmHg to 38 mmHg: ±2 mmHg 39 mmHg to 99 mmHg: ± {5% x CO_2 Reading + 8% x (CO_2 Reading - 39 mmHg)}

NOTE

- Above values are related to maximum of 80 bpm of respiration rate and maximum of 55ºC of the module temperature.
- When the respiration rate exceeds 80 bpm, the accuracy will be maximum 4 mmHg or reading ±12%, whichever higher. This accuracy complies to FilterLine™ P/N 006324.
- If the module temperature exceeds 55°C, the nominal CO_2 measurement accuracy might decrease to maximum 1 mmHg or 2.5% of the CO_2 reading, whichever higher.

CO_2 Waveform Resolution	0.1 mmHg
$EtCO_2$, $InspCO_2$ Resolution	1 mmHg
CO_2 measurement accuracy when interference gas is present	
	0 mmHg to 38 mmHg: ± (2 mmHg + 0.04 x displayed value) 39 mmHg to 99 mmHg: ± { 0.09 x displayed value + 0.08 x (displayed value - 39 mmHg)}
RR Measurement Range	0 bpm to 150 bpm
RR Measurement Accuracy	0 bpm to 70 bpm: ±1 bpm 71 bpm to 120 bpm: ±2 bpm 121 bpm to 150 bpm: ±3 bpm
Flow Rate	50 ±5 mL/min Measured by airway volume.
Waveform Sampling	20 samples/ sec
Turn On Time	30 sec. (Fixed, including activating and initializing time)
Calibration Interval	Calibrate after 1200 hours of operation for the first time, then calibrate once a year or after 4000 hours of operation, whichever earlier.

NOTE

- Do not perform the first calibration before operating 720 hours. If the first calibration is performed before operating 720 hours, the module will be reset to after 1200 hours to perform next calibration instead of after 4000 hours.

System Response Time	4.5 sec.: 2 m When FilterLine™ is used. 6.0 sec.: 4 m When FilterLine™ is used.
Delay Time	4.0 sec.
Rise Time	190 msec.: 2 m When FilterLine™ is used. 210 msec.: 4 m When FilterLine™ is used.

Compensation	BTPS (Standard compensation used in Microstream capnography during measurement of temperature, pressure and saturation.)
Drift	Periodical zero calibration function compensates the drift of the component, change of the ambient temperature and atmospheric pressure. This automatic process eliminates variances that might otherwise cause measurement drift. So, the capnography module does not indicate the drift of the measurement accuracy.

NOTE

- This accuracy complies to FilterLine™ Model 006324.

Recording (Recorder Unit)

Printing Speed	50 mm/s, 25 mm/s (Error: within ±5%)
Resolution	Head Direction: 8 dots/mm Feed Direction: 40 lines/mm (at printing speed of 25 mm/s)
Printing Waveforms	3 waveforms
Printing Type	Waveform, List, Graphic
Detection	Paper out, printhead temperature
Protective Circuit	Provided

Telemeter

Modulation Mode	F1D
Frequency	608 MHz to 614 MHz
Oscillation Method	PLL synthesizer method by crystal control
Channel Spacing	12.5 kHz
Occupied Frequency Bandwidth	Within 8.5 kHz
RF Output Power	1 mW (within +20%/-50%)

QRS Synchronization Output

Output Waveform	Square Wave (Positive/negative logic can be selected.)
Output Voltage	+4.3 V to +5.0 V (High Level) +0.3 V and below (Low Level)
Synchronized Signal Width	100 ms/ 60 ms/ 20 ms (Selectable)
Delay Time	35 ms and below (when the diagnosis mode for adult is set)
Output Impedance	Open Collector Output (with +5 V 1kΩ pull-up resistor)

NOTE

- The delay time of QRS synchronization output depends on the filter setting and the input waveform type. For details, refer to your nearest service representative.
- The QRS synchronized signal is not intended to be used as synchronized signal for defibrillator. When using the QRS synchronized signal, refer to your nearest service representative.

Measurement Unit for Each Parameter

The measurement units of the displayed numeric data for this device are as follows.

Description	Parameter	Display	Unit	Default Unit
HR/PR Value	ECG	HR	bpm (beats per minute)	
	SpO_2	PR_SpO_2	bpm	
ST Level	ECG	ST	mm, mv	mm
VPC	ECG	VPC	beat/minute	
		PACE	beat/minute	
Respiration Rate	Impedance	RESP	Bpm (breaths per minute)	
	CO_2	RR_CO_2	Bpm	
Apnea Duration	Impedance	Apnea	s (second)	
	CO_2	Apnea	s (second)	
Non-Invasive Blood Pressure	Non-Invasive Blood Pressure	NIBP	mmHg, kPa	mmHg
Arterial Oxygen Saturation	SpO_2	SpO_2	%	
Perfusion Index	Perfusion Index	PI	%	
Double Product	RPP	RPP	-	
Shock Index	SI	SI	-	
End Tidal CO_2 Concentration	CO_2	$EtCO_2$	mmHg, kPa, %	mmHg
Inspiratory CO_2 Concentration	CO_2	$InspCO_2$	mmHg, kPa, %	mmHg
Temperature	Temperature	TEMP	°C, °F	°F

Alarm Limit Range for Each Parameter

The alarm can be set in the following range.

Item	Adjustable Range	
	Lower Limit	Upper Limit
	Adjustable Increments	
HR	20 bpm to 295 bpm	22 bpm to 300 bpm
	60 bpm and below: 1 bpm increments 60 bpm and above: 5 bpm increments	
ST	-2.0 mV to +1.8 mV	-1.8 mV to +2.0 mV
	0.1 mV increments	
	-20 mm to + 18 mm	-18 mm to + 20 mm
	1 mm increments	
Ext Tachy	-	22 bpm to 300 bpm
	60 bpm and below: 1 bpm increments 60 bpm and above: 5 bpm increments	
Ext Brady	20 bpm to 295 bpm	-
	60 bpm and below: 1 bpm increments 60 bpm and above: 5 bpm increments	

Item	Adjustable Range	
	Lower Limit	Upper Limit
	Adjustable Increments	
RR (Adult)	5 Bpm to 145 Bpm	10 Bpm to 150 Bpm
	5 Bpm increments	
RR (Child/Neonate)	2 Bpm to 148 Bpm	4 Bpm to 150 Bpm
	2 Bpm increments	
Apnea	-	10 sec. to 60 sec.
	1 second increments	
NIBP	10 mmHg to 295 mmHg	15 mmHg to 300 mmHg
	5 mmHg increments	
	1.5 kPa to 39.5 kPa	2.0 kPa to 40.0 kPa
	0.5 kPa increments	
SpO_2	50% to 99%	51% to 100%
	1% increments	
Ext SpO_2	50% to 98%	
	1% increments	
$EtCO_2$	1 mmHg to 98 mmHg	3 mmHg to 100 mmHg
	1 mmHg increments	
	0.1 kPa to 13.1 kPa	0.3 kPa to 13.3 kPa
	0.1 kPa increments	
	0.1% to 13.1%	0.3% to 13.3%
	0.1% increments	
$InspCO_2$		1 mmHg to 4 mmHg
	1 mmHg increments	
		0.1 kPa to 0.4 kPa
	0.1 kPa increments	
		0.1% to 0.4%
	0.1% to 3.0%	
PR	20 bpm to 295 bpm	22 bpm to 300 bpm
	60 bpm and below: 1 bpm increments 60 bpm and above: 5 bpm increments	
SI		0.5 to 2.0
	increments of 0.1	
RPP	10 to 290	20 to 300
	increments of 10	

*: If the value exceeds the adjustable range, the limit within the range will be set.

About the SpO_2 Clinical Test

❑Covidien Unit

The SpO_2 and pulse rate measurement accuracy have been validated for each range by testing on healthy adult male and female volunteers against a laboratory CO-Oximeter.

The SpO_2 accuracy has been validated for the range from 70% to 100% by testing on healthy adult male and female volunteers (age: 22 to 46 years old) with light to dark skin pigmentation. Without body motion, the standard deviation is ±2% which encompasses 68% of the population. With body motion, the standard deviation is ±3% which encompasses 68% of the population. For the validation, frictional or contact motion of 1 cm to 2 cm, and random vibration of 1 Hz to 4 Hz were tested.
The validation has been also performed for the low oxygen saturation level (60% to 80%), and the standard deviation was ±3% which encompasses 68% of the population.

The pulse rate accuracy has been validated for the range from 70% to 100% by testing on healthy adult male and female volunteers (age: 22 to 46 years old) with light to dark skin pigmentation The standard deviation is ±3 bpm which encompasses 68% of the population.

These clinical test data are disclosed based on the data provided from Covidien.

❑Masimo Unit

The SpO_2 and pulse rate measurement accuracy have been validated for each range by testing on healthy adult male and female volunteers against a laboratory CO-Oximeter.

SpO_2 accuracy have been validated by testing on 16 neonatal NICU patients ranging in age from 7 days to 135 days old and weighing between 0.5 kg to 4.25 kg. Seventy-nine (79) data samples were collected over a range of 70% to 100% SpO_2 and 0.5% to 2.5% HbMet with a resultant accuracy of 2.9% SpO2 and 0.9% SpMet.

The SpO_2 accuracy has been validated for the range from 70% to 100% by testing on healthy adult male and female volunteers (age: 21 to 36 years old) with light to dark skin pigmentation. Without body motion, the standard deviation is ±2% which encompasses 68% of the population. With body motion, the standard deviation is ±3% which encompasses 68% of the population. For the validation, frictional or contact motion of 1 cm to 2 cm, and random vibration of 1 Hz to 5Hz were tested.

The pulse rate accuracy has been validated for the range from 70% to 100% by testing on healthy adult male and female volunteers (age: 24 to 37 years old) with light to dark skin pigmentation The standard deviation is ±3 bpm which encompasses 68% of the population.

These clinical test data are disclosed based on the data provided from Masimo.

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