Preface

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

Safety Precautions

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

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

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

⚠CAUTION	Failure to follow this message may cause injury or failure to the equipment.

NOTE	A note is not related to product safety, but provides information about the correct use and operating procedures to prevent incorrect operation and malfunction of the equipment.

Labels Attached to the Unit

Make sure to read the warning labels attached to the unit and comply with these requirements while operating the unit.

⚠CAUTION	Do not damage or erase the warning labels attached to the unit. These warning labels contain descriptions important for handling and operating the unit properly and safely. A damaged label may compromise safe operation.

DS-7100 System

⚠ DANGER

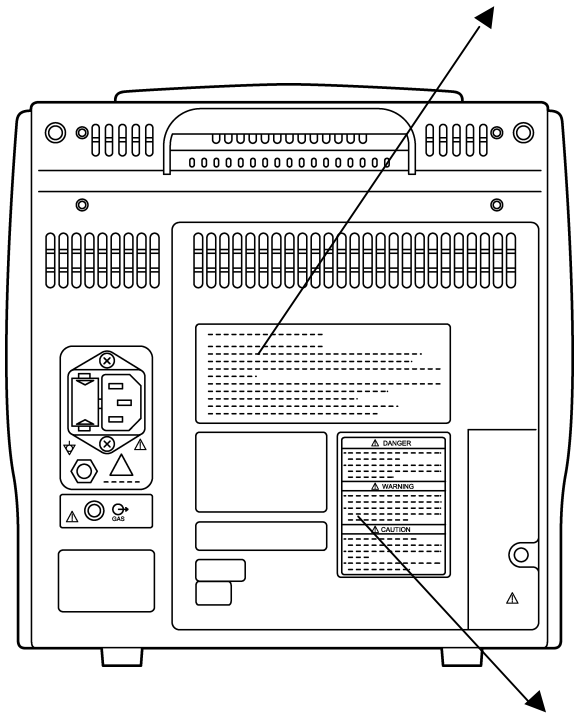
Risk of explosion if used in the presence of flammable anesthetics.

⚠ CAUTION

Before connecting, read instruction manual.

⚠ CAUTION

To reduce the risk of electric shock, do not remove the cover.
Refer servicing to qualified service personnel.



⚠ DANGER

? Use only the batteries specified for this device.
? Do not disassemble or modify the battery. The battery incorporates protection circuitry for safety purposes.

⚠ WARNING

? Installation of the battery should be performed only by our service representative, to avoid any risk of electric shock to the operator or malfunction of the device.

⚠ CAUTION

? The life cycle of the battery is 1 year.
? The battery charges when the power cord is connected to a hospital-grade outlet.
? It takes approximately 2.5 hours to fully charge an empty battery.

Measurement Unit for Each Parameter

The measurement units for this equipment are as follows.

Detail	*Parameter*	*Display*	*Unit*	*Default*
Heart Rate／Pulse Rate *1	ECG	HR	bpm (beats per minute)	
	Invasive Blood Pressure	PR_BP	bpm (beats per minute)	
	SpO_2	PR_SpO_2	bpm (beats per minute)	
ST Level	ECG	ST	mm, mv	mv
VPC	ECG	VPC	beats / hour	
Respiration Rate *2	Impedance Respiration	RR_IMP	Bpm (breaths per minute)	
	CO_2	RR_CO_2	Bpm (breaths per minute)	
Apnea	Impedance Respiration	APNEA	s (second)	
	CO_2	APNEA	s (second)	
Invasive Blood Pressure	Invasive Blood Pressure	BP	mmHg, kpa	mmHg
Non-Invasive Blood Pressure	Non-Invasive Blood Pressure	NIBP	mmHg, kPa	mmHg
Arterial Oxygen Saturation	SpO_2	SpO_2	%	
Temperature	Temperature	TEMP	?C / ?F	?C
End-Tidal CO_2 Concentration	CO_2	EtCO_2	mmHg, kPa, %	mmHg
Inspiratory CO_2 Concentration	CO_2	InspCO_2	mmHg, kPa, %	mmHg

*1 HR/PR will be displayed in the color selected for ECG/HR.
*2 RR will be displayed in the color selected for RESP.

Graphic Symbols

The following symbols are used for this equipment.

DS-7100 System: Main Unit

Symbol	*Description*
	Caution; refer to accompanying documents Indicates the need to refer to related accompanying documents before operation.
	Equipotential Terminal Indicates the terminal to equalize the potential difference when interconnecting the devices.

DS-7100 System: Symbols displayed on the screen

Symbol	Description
	Battery Mark Indicates battery capacity and remaining volume during battery operation.
	Alarm OFF Indicates the alarm is OFF.
	Heart Rate Synchronization Mark This mark flashes synchronizing to the heartbeat.
	Respiration Synchronization Mark This mark flashes synchronizing to the inspiration.
	Event Key Mark Displayed when an alarm generates. ON/OFF of the display can be selected on the ward setup.
	Message Mark Displayed in the parameter key when an alarm message is present for that parameter.

Precautions for Safe Operation of Medical Electrical Equipment

⚠CAUTION	Read the following precautions thoroughly to correctly operate the device. ✍ Users should have a thorough knowledge of the operation before using this system. ✍ Pay attention to the following when installing and storing the equipment. ✍Do not install or store in an area where the equipment will be subject to splashing water. ✍Do not install or store in an area where the environmental conditions, such as atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, sodium, sulfur, will adversely affect the system. ✍Place the equipment on a stable surface where there is no inclination, vibration, or shock (including during transportation). ✍Do not install or store in an area where there are chemical or gasses stored. ✍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. ✍ Before operating the system, verify the following items ✍Verify the power voltage. ✍Check the cable connection and polarity to ensure proper operation of the equipment. ✍Make sure the power system has adequate earth ground. ✍Ensure that all cables are firmly and safely connected. ✍Pay special attention when the device is used in conjunction with other equipment as it may cause erroneous judgement and danger. ✍Ensure all patient connections are proper and secure. ✍ During operation of the system, verify the following items. ✍Always observe the system and patient to ensure safe operation of the equipment. ✍If any abnormality is found on the equipment or patient, take appropriate measures such as ceasing operation of the equipment in the safest way for the patient. ✍Do not allow the patient to come in contact with the device. ✍ After using the system, verify the following items. ✍Unplug all the cables from the patient before turning off the power. ✍When unplugging the cables, do not apply excessive force by pulling on the cord. Pull by the connector part of the cable. ✍Clean the accessories and cables, and keep them together in one place. ✍Keep the unit clean to ensure proper operation of the next use. ✍ If the equipment is damaged and in need of repair, user should not attempt service. Label the unit “OUT OF ORDER” and contact Fukuda Denshi. ✍ Do not remodel the equipment. ✍ Maintenance Check ✍Make sure to periodically check the equipment, accessories and cables. ✍Before reusing the device that has been left unused for a while, make sure that the device works normally and safely. ✍ When using the electrosurgical knives or defibrillator with this equipment, verify proper attachment of patient ground plate, ECG electrode type for the electrosurgical knives, and paste volume, output energy for the defibrillator. Also, verify that proper ground is selected.

Precautions for Safe Operation of Medical Telemetry (DS-7141, DS-7101LT)

⚠CAUTION	Precautions for Safe Operation of Medical Telemetry To operate the device correctly, read the following precautions carefully. ✍ The medical institution (hereinafter referred as “Institution”) must decide the telemetry installation plan for the medical institution in order to prevent interference and interference between transmitters (telemetry based on destination country’s radio law). ✍ 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 medical institution. ✍ When using telemetry which requires zone location, display and identify each prepared zone in the equipment. ✍ When laying receiver antenna for each transmitter, the institution has to be examined so as not to generate electronic interference. ✍ Based on the above examination result, the institution places each receiver antenna as required. In managing, be sure to follow the precautions below. ✍ 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 nominates a person to manage the wireless channels in each zone (a “Zone Manager”). However, when using such telemetry in a local medical institution, one person can perform both functions. ✍ Select a telemetry manager who understands the characteristics and functionality of telemetry systems, and is skilled in operating telemetry. ✍ When installing telemetry, the Overall Manager and the Zone Manager have to understand the precautions for use of the telemetry in advance. ✍ The Overall Manager takes responsibility of wireless channel management and transmitter storage for the whole medical institution by giving proper instruction. ✍ The Overall Manager creates a management log, list of wireless channels, management status for the whole medical institution (hereinafter referred to as the “management log”). When changing a wireless channel, register it in the log and give proper instructions to the zone manager or to the user. ✍ The Zone Manager assumes responsibility for managing the wireless channels, storing, and managing telemetry. ✍ The Zone Manager 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 zone manager 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 zone manager and the overall manager of the problems. The zone manager and overall manager are to deal with the problem properly and/or contact their nearest Fukuda Denshi representative for service.

Precautions about the Maintenance

Safety Inspection and Maintenance

For safe operation of the equipment, regular inspection and maintenance is required. Once a year, check all cables, devices, and accessories for damage, earth impedance, earth and enclosure leakage currents, and all alarm functions. Also, ensure that all safety labels are legible. Maintain a record of these safety inspections.
Immediate maintenance has to be carried out if ;
✍the equipment was subjected to extreme mechanical stress, e.g. after a heavy fall.
✍the equipment was subjected to liquid spill.
✍the monitoring function is interrupted or disturbed.
✍parts of the equipment enclosure are cracked, removed, or lost.
✍an [redacted]ector or cable shows signs of deterioration.

Reference Refer to “10. Maintenance” for details.

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

Maintenance, Modifications, and Repairs

Fukuda Denshi is liable for the safety, reliability, and performance of its equipment only if;
✍Maintenance, modifications, and repairs are carried out by authorized personnel.
✍Components are used in accordance with Fukuda Denshi operating instructions.

A full technical description of the DS-7100 system is available from your local Fukuda Denshi representative.

Precautions about the 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 the cardiac monitoring and diagnostic equipment, 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.) ➲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. [October 14, 1998 (Letter: www .fda.gov/cdrh/safety.html) – FDA]

Non-Explosion Proof

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

Defibrillation Safety

⚠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 directly contact the electrodes or medicament, 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 by the discharged energy. ✍ When defibrillating, do not touch the patient and the metal part of the device or cables. Electric shock may result by the discharged energy.

Electrosurgery Safety

⚠WARNING	The monitoring system contains protection against interference generated by electrosurgical instruments. However, operating conditions, surgery site with respect to the location of ECG electrodes, or the type of instrument used, may cause noise on the ECG. The noise is generated at the tip of an electrical 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 unit 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 the monitor. This will help prevent interference through the power cable. Electrode Placement The amount of 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 a burn at the electrode site.

Precautions about Magnetic Resonance Imaging

⚠WARNING	✍ Do not operate this equipment in magnetic resonance imaging (MRI) environments. ✍ When conducting MRI test, remove the electrodes and sensors connected to the patient (test subject). The local heating caused by the induced electromotive force may cause burn injury to the patient (subject). For details, refer to the operation manual for the MRI testing device.

Precautions about Connections to Peripheral Devices

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

⚠WARNING	For the connector with ⚠ mark, 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	All the peripheral device connectors on the DS-7100 system are isolated from the power supply, but the peripheral devices are not isolated. To prevent danger of electric shock, always position the peripheral devices away from the patient.

When connecting peripheral devices to DS-7100 system, it is the user's responsibility to verify that the overall system complies with IEC 60601-1-1, "Collateral Standard: Safety Requirements for Medical Electrical Systems".

Precautions about the Fuse

⚠DANGER	If the fuse burns out, contact Fukuda Denshi Service Representative. Do not continue using it as internal damage to the equipment may be considered.

Accessories and Optional Accessories

⚠WARNING	Use only the cables specified by Fukuda Denshi. Use of other cables may result in increase in emission or decrease in immunity.

Precautions about the DS-7100 System

⚠DANGER	✍ When connecting to other device, contact Fukuda Denshi service representative. Danger such as electric shock may result to the patient and operator. ✍ When monitoring a patient with wireless telemetry, make sure the patient data is properly received at the central monitor. Pay special attention when channel ID at the bedside monitor is changed.

⚠WARNING	✍ Do not connect unit or cable not authorized by Fukuda Denshi to any I/O connector. If done so by mistake, the DS-7100 system can not deliver its maximum performance and the connected units may be damaged, resulting in a safety hazard. ✍ Use only the accompanying 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 AC 115V outlet. ✍ When using multiple ME equipment simultaneously, perform equipotential grounding to prevent potential difference between the equipment. Even a small potential difference may result in electric shock to the patient and the operator. ✍ The patient type selection influences the precision of the QRS detection and NIBP measurement. Make sure the correct selection is made. ✍ The pacemaker use selection influences the precision of the QRS detection and arrhythmia analysis. Make sure the correct selection is made. ✍ 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 attachment site will rise 2 ~3?C 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 measuring at site with venous pulse ✍Patient with body motion ✍Patient with small pulse ✍ Before the measurement, make sure the patient type (Adult / Child / Neonate) is properly selected. Otherwise, correct measurement can not be performed, and congestion or other injury may result. ✍ Pay attention when measuring the NIBP of patient with bleeding disorders or hypercoagulation. The cuff inflation may cause petechia or circulatory failure by the blood clot. ✍ Use the specified sampling tube and nasal prong manufactured by Oridion. ✍ Always consider the circumference of the intubation tube when using the airway adapter. If inappropriate airway adapter is used for a patient with low ventilation, CO_2 may mix in to the inspired air resulting in incorrect measurement, or apnea detection may become difficult. ✍ When measuring CO_2 concentration of a patient treated with mouth-to-mouth resuscitation, Jackson-Rees circuit, Mapleson D circuit of which CO_2 gas may mix in, the value may be displayed lower than the actual value. ✍ When the system alarm is suspended, all the alarm will be suspended even if the parameter alarm is set to ON. Also, the alarm event will not be stored as recall. ✍ If the upper/lower alarm limit of the parameter is set to OFF, or arrhythmia alarm is set to OFF, alarm will not function even if the system alarm is set to ON. Pay attention when setting them OFF. ✍ If the QRS pace mask function is turned OFF, a decrease in heart rate may not generate HR or ASYSTOLE alarms due to erroneously detected QRS. Turn this function OFF only if you are sure that pacing failure will not occur, or when the patient can be constantly monitored.

⚠WARNING	✍ Objective and constant arrhythmia detection is possible through the fixed algorithm incorporated in this monitor. 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 manual recording, alarm recording and recall waveform for evaluation. ✍ When setting the monitor on a trolley, use 2 fixing screws to ensure safety. Otherwise, the monitor may fall off the trolley, resulting in injury or damage to the monitor. ✍ Use the trolley only with the equipment specified by Fukuda Denshi. Otherwise, the monitor and trolley may fall down, resulting in injury or damage to the monitor. ✍ Be sure to lock both casters when using or storing the trolley. The trolley may move or fall down, resulting in injury or damage to the monitor. ✍ Do not use or store the trolley where it will be subject to inclination of 10 degrees or more. The trolley or defibrillator may fall resulting in injury or damage to the monitor. ✍ Some wireless combinations of telemetry transmitters may generate interference with other devices. ✍ Before selecting the channel, verify it will not interfere with other channels. ✍ Make sure the telemetry manager of your system is aware of any changes to the telemetry channels. ✍ If transmitters are used in a neighboring medical facility, your facility and neighboring facility must make agreements on the setting of telemetry channels to prevent telemetry interference. ✍ The purpose of this respiration alarm is to alert the user to evaluate for the possible occurrence of apnea events by identifying the absence of respiration. It is not intended to be classified as an “Apnea Monitor” and will not identify the condition creating the possible event. (Central, Obstructive or Mixed.)

⚠CAUTION	✍ Systems ✍The monitor should be kept apart at least 20cm from the head of patient or operator. ✍Use only the accessories specified for this device. Otherwise, proper function cannot be executed. ✍For quality improvement, specifications are subject to change without prior notice. ✍The battery deteriorates with the repeated use, which shortens the usable time. ✍The arrhythmia detection level corresponds with the displayed waveform size. Select an appropriate size for monitoring. ✍The display panel utilizes exclusive fluorescent light for the backlight. Since this fluorescent light 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. ✍Always operate the touch screen with fingers or touch screen pen. Do not touch with a pen-point or other hard-edged instruments. Malfunction of the touch screen or damage may result. ✍ ECG Monitoring ✍The indication for continuous use of the electrode is about one day. ✍Replace the electrode if the skin contact gets loosen due to perspiring, etc. ✍When an electrode is attached at the same location for a long time, some patients may develop a skin irritation. Check the patient’s skin condition periodically and change the electrode site as required.

⚠CAUTION	✍The threshold level for arrhythmia detection changes with ECG waveform size. Set a proper waveform size for monitoring. When the waveform size is ?1/4, ?1/2, or ?1, the detection threshold is 250 µV. When the waveform size is ?2 or ?4, the detection threshold is 150 µV. ✍Automatic size/position of the ECG is effective only at the time the AUTO key is pressed. This does not continually adjust size and position. ✍There are some cases when pacemaker pulse can not 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 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 automatic QRS and pacemaker pulse overlap (ex. fusion beat, etc.), QRS detection cannot be performed properly. In this case, the heart rate is degraded. ✍When continuously detecting AC noise artifact as pacemaker pulses, QRS detection stops and heart rate is extremely degraded. Also arrhythmia cannot be detected. ✍ Respiration Monitoring ✍When the following relay cables are used, respiration can not be measured. • Relay Cable CI-700E_3 (Electrosurgery-proof, 3-electrode) • Relay Cable CI-700E_4 (Electrosurgery-proof, 4-electrode) • Relay Cable CI-700E_5 (Electrosurgery-proof, 5-electrode) ✍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 the following lead cables are used, respiration cannot be measured. • Lead Cable #3380.0648.16 (Electrosurgery-proof, 3-electrode) • Lead Cable #3380.0661.16 (Electrosurgery-proof, 5-electrode) ✍ SpO_2 Monitoring ✍If the nail is rough, dirty, or manicured, accurate measurement will not be possible. Change the finger or clean the nail before attaching the probe and sensor. ✍If irritation such as skin reddening or skin fit appears with the sensor use, change the attachment site or stop using the sensor. ✍When fixing the sensor with a tape, do not wind the tape too tight. At the same time, check the blood flow constantly so that congestion is not generated at the peripheral. ✍Even a short duration of attachment may inhibit the blood flow and generate compression necrosis and burn injury ✍Change the sensor attachment site constantly (every 4 hours). As the temperature of sensor attachment site normally rises 2～3?C, compression necrosis and burn injury may generate. ✍As skin for neonate / low birth weight 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. ✍When not performing the measurement, unplug the relay cable and sensor from the SpO_2 connector. Otherwise, the measurement data may be erroneously displayed by the ambient light. ✍ NIBP Monitoring ✍If the air hose is twisted, or weighed down, the cuff air can not be exhausted. Properly arrange the cuff and air hose.

⚠CAUTION

- ✍For the following situation, measurements will be terminated.
  When the measurement time has exceeded 120 seconds for adult, 90 seconds for child, 60 seconds for neonate.
  When the inflation value has exceeded 300mmHg for adult, 200mmHg for child, 150mmHg for neonate.
- ✍If used with the incorrect patient type, 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.
- ✍The 1-minute interval measurement will always start from 00 second. Pressing the [1min start] key will start the measurement from the next 00 second.
- ✍The 1-minute interval measurement will automatically stop after 10 minutes or 20 minutes and returns to the previous interval mode setup. The selection of [10min] / [20min] can be made on the NIBP configuration menu.
- ✍The alarm function will be ineffective for the BP value measured by Quick SYS regardless of the ON/OFF selection of NIBP alarm.

✍ BP Monitoring

- ✍If the SYS value is abnormally high, or DIA is abnormally low, a resonance may be the cause. If the resonance can not be eliminated by adjusting the blood pressure filter, check the BP line and use a thick, short, and hard catheter.
- ✍When the main power is turned ON, the BP value will not be displayed until zero balance is performed. Make sure to perform the zero balance.
- ✍Each time the blood pressure transducer or tubing is replaced, the zero balance procedure is required to ensure accurate measurements.
- ✍The zero balance procedure is required for the following case.
  - ✍When starting the measurement.
  - ✍When the position of the heart has changed due to body movement.
  - ✍When the position of the transducer has changed.
  - ✍When measuring for a long period of time and there is a possibility of measurement error due to change in ambient temperature, etc.
  - ✍When the connector is connected / disconnected, or transducer is replaced.
- ✍If the mean BP display is set to OFF, the mean BP alarm will not be generated. Also, the mean BP will not be displayed on the tabular trend. Be cautious when setting the mean BP display OFF.

✍ CO_2 Monitoring

- ✍Perform calibration after 20 minutes when the main power of the DS-7100 system is turned ON.
- ✍Do not disconnect the sampling tube during calibration.
  If disconnected, calibration will cease.
- ✍Conduct CO_2 calibration for the following case.
  - ✍When 6 months has elapsed from the last calibration date.
  - ✍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.
- ✍CO_2 monitoring will cease when the ventilation connector is covered.
- ✍Use only the specified sampling tube for CO_2 monitoring.

✍ Alarm

- ✍A faint sound will be generated when setting a minimum volume for the alarm sound, but be cautious not to miss any alarm. Adjust the volume to a recognizable level.
- ✍Alarm messages will be displayed according to the priority. (Level 1 → Level 2 → Level 3 → Level 4)
- ✍For the same alarm level, the alarm message for the newer alarm will be displayed.
- ✍The alarm message for the arrhythmia alarm will continue to be displayed for 30 seconds after the alarm is resolved.

	✍While the “LEAD OFF” message is displayed, HR alarm and arrhythmia alarm will not function. Leaving this condition unresolved may result in missing a sudden change of the patient. Promptly check the electrodes when this message is displayed. ✍If the alarm with the higher priority occurs during alarm recording, the recording in process will be ceased and starts the alarm recording with the higher priority. ✍Whether to use the SEC alarm function and its threshold selection should be based on the patient’s clinical indication portent and medical evaluation. ✍If the SpO_2 alarm and SEC alarm setup is set to OFF, the SEC alarm integral value will be set to 0. ✍ System Configuration ✍When performing telemetry transmission, the numeric data corresponding to the waveform should be selected for display. Otherwise, the displayed waveform or numeric data may not be transmitted. ✍If the time/date is not correctly set, or changed during monitoring, erroneous condition may occur to NIBP measurement, periodic recording, trend and NIBP list data. ✍If the time/date is changed during monitoring, patient’s age will not be recalculated. ✍When connected to a wired network, the same time/date with the central monitor will be set. ✍The alarm ON/OFF setup will remain effective even when the power is turned OFF. Be cautious not to miss any important alarm by leaving the alarm silenced. ✍When performing telemetry transmission, the numeric data corresponding to the waveform should be selected for display. Otherwise, the displayed waveform or numeric data may not be transmitted.
⚠CAUTION	✍The setup of channel ID and group ID should be performed only by our service representative. Users should not perform this procedure as malfunction to the equipment may occur. ✍The Bed ID is factory set to 000. If connected to the wired network with the ID unchanged, monitoring on the central monitor will not be possible. ✍When connecting to the wired network, verify that the Bed ID does not duplicate with other bedside monitors. Otherwise, monitoring on the central monitor for both bedside monitors will not be possible. ✍To connect to the wired network, set the Bed ID in the range from 001 to 048. ✍There are following restrictions when connecting the DS-7100 system to the DS-LAN Ⅱ network. ✍ The DS-7100 system is not corresponded to the AU-5500N 8-channel recorder. The data for the DS-7100 system can not be recorded on the AU-5500N. ✍ When the measurement unit of BP is kPa, BP waveform, BP numeric data, NIBP numeric data, NIBP list will not be transmitted. These will be treated as not measured data, and will not be displayed on the central monitor. Also, alarm limit setup on the central monitor can not be performed. ✍ When the temperature unit is ?F, the temperature data will not be transmitted. It will be treated as not measured data, and will not be displayed on the central monitor. Also, alarm limit setup on the central monitor can not be performed. ✍ Arrhythmia alarm of TACHY, BRADY, SLOW_VT, COUPLET, PAUSE will not be transmitted. ✍ For numeric data displayed as “×××”, maximum or minimum value of measurable range will be transmitted. ✍ The numeric data displayed as “———” will be treated as not measured data. ✍For QRS classification, the “S” printed on the built-in recorder will be printed as “N” on the HR-500 Recorder.

⚠CAUTION	✍When DS-5800N/NX/NX^{MB} is used as a central monitor, recall, graphic trend, tabular trend, and ST measurement function will not be displayed. ✍When DS-5700 is used as a central monitor, ST measurement function will not be displayed ✍A delay will occur for the communication with the central monitor. The delay is about 1.5 seconds for the waveform, about 1.5~4.0 seconds for the numeric data, and about 1.5~2.0 seconds for the alarm. ✍When waveform and numeric data display is set to OFF, the alarm generation and tabular/graphic trend will be also set to OFF. ✍ Patient Admit / Discharge ✍If you start monitoring a new patient without performing a discharge procedure for the previous patient, new data will be added to the previous data which will result in inaccuracy. ✍The setup for the alarm mode and display mode remains stored even when the power is turned off or when discharging procedure is performed. Before monitoring, make sure the current monitoring mode is suitable for the patient's condition. ✍Resuming monitoring will resume the alarm in suspension. ✍ Arrhythmia Analysis ✍For proper arrhythmia detection and ECG monitoring, verify proper electrode placement, lead selection, and ECG waveform size. If necessary, turn ON the AC filter. Improper electrode placement, lead selection, and ECG waveform size can cause errors in detection. ✍ IC Card ✍Use only the specified IC card. ✍Restart the system after reading the setup data from the IC card. The setup data will become effective after the system is restarted. ✍ Maintenance ✍Always operate the touch screen with fingers or touch screen pen. Do not touch with a pen-point or other hard-edged instruments. Malfunction of the touch screen or damage may result. ✍Do not clean the touch panel using strong acid ✍A special coating is applied to the surface of the touch panel. Wipe the surface with the soft cleaning cloth provided as optional accessory or with commercially available eyeglass cleaning cloth. ✍Clean the equipment frequently so stains can be removed easily. ✍To prevent injury, it is recommended to wear gloves when cleaning the equipment. ✍Do not allow liquids such as alcohol or cleaning solution enter the monitor or connectors. ✍Do not use organic solvents, thinner, toluene and benzene to avoid damaging the resin case. ✍Do not polish the housing with abrasive or chemical cleaner. ✍When sterilizing the entire room using a spray solution, pay close attention not to have liquids get into the monitor or connectors. ✍Use only neutral detergent to clean the housing. Do not use chemical cloth, scrub brush, abrasive, polishing powder, hot water, volatile solvent and chemicals (cleanser, thinner, toluene, benzine, benzol, and synthetic detergent for house and furniture), or sharp-edged tools. The surface resin coating may be damaged, resulting in discoloration, scratches, and other problems. ✍Do not open the housing. ✍Replace the components periodically as specified.

Precautions for Use of SpO_2 Sensor

⚠DANGER	Burn Risk in Using SpO_2 Sensor In SpO_2 monitoring, always use the sensor/relay cable specified by Fukuda Denshi. 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 for Use of NIBP Cuff

⚠CAUTION	This product contains natural rubber latex which may cause allergic reactions.

Disposing of Equipment, Accessories, or Components

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

Precautions about Transportation

For transporting the DS-7100 system, pack with specified packing materials.

Reference	Refer to “11. Technical Information Specification / Performance” for environmental condition during transportation.

Precautions about RTC or Data Backup

⚠CAUTION	✍ The DS-7100 system is equipped with a built-in clock. When the power of the DS-7100 system 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. ✍ To protect the data during voltage dip, short interruptions and voltage variations on power supply input lines or during short duration of power turned OFF, this monitor performs 5-minute (approx.) data backup using the secondary battery. The data may not be protected if the power is turned off within 30 minutes from power on.

Precautions for Use of Lithium-Ion Battery Pack

⚠DANGER	✍ This battery pack is intended for exclusive use with the DS-7100 system (or other specified equipment). Do not use with other equipment. If charged on unspecified equipment, the performance and life cycle of the battery pack deteriorates or abnormal current flows causing damage, leakage, heating, fuming, explosion, ignition of the battery. ✍ Do not disassemble or remodel the equipment. If the security apparatus or protector inside the battery gets damaged, it may cause heating, fuming, explosion, ignition of the battery. ✍ Do not use the battery if leaked or transformed. If the security apparatus inside the battery is damaged, it may cause heating, fuming, explosion, ignition of the battery. ✍ When installing the battery to the monitor, verify the polarity direction is correct. If not, it may cause leakage, heating, fuming, explosion, ignition. ✍ If the leaked solution of the battery gets into the eyes, do not rub the eyes. Wash thoroughly with clean water and immediately receive medical treatment from the doctor. If not treated soon, it may cause serious injury.

⚠WARNING	✍ If the leaked solution of the battery gets on to the skin or clothes, immediately wash down with rinse water. If not treated soon, it may cause serious injury. ✍ If charging does not complete within the specified charging time, remove the battery and disconnect the power supply cable from the outlet. Otherwise, it may result in leakage or heating of the battery. ✍ Do not throw into fire or heat the battery. The insulator may melt, gas exhaust vent or security apparatus may get damaged, or electrolyte may ignite causing heating, fuming, explosion, ignition of the battery. ✍ Do not connect the (+) and (--) terminals of the battery with a wire or any other metal. Also, do not carry or store the battery with any metal such as necklace, hairpins, etc. The battery may short causing excessive current flow which may result in heating, fuming, explosion, ignition of the battery or heating of the metal (wire, necklace, hairpin, etc.) ✍ Do not solder the battery directly. The heat may melt the insulator or damage the security apparatus which may result in heating, fuming, explosion, ignition of the battery. ✍ Do not put the battery in microwave oven or a pressure cooker. If heated suddenly or if sealed condition breaks, it may result in leakage, heating, fuming, explosion, ignition of the battery. ✍ Do not drive a nail in, hit with a hammer, or step on the battery. The battery may explode and transform causing a short out which may result in heating, fuming, explosion, ignition of the battery. ✍ Do not apply strong impact or throw the battery. This may result in leakage, heating, fuming, breakage, ignition of the battery. Also, if the security apparatus incorporated in the battery gets damaged, the battery charges with abnormal current and voltage which results in leakage, heating, fuming, explosion, or ignition. ✍ Do not get the battery wet with water, sea water or chemicals. If the security apparatus incorporated in the battery gets damaged, it may result in heating, fuming, explosion, ignition of the battery. ✍ Do not connect the battery directly to power outlet or cigarette heater socket in a car. A high voltage application will cause excessive current flow and abnormal chemical reaction inside the battery causing abnormal current flow during discharging. This may result in heating, fuming, explosion, ignition of the battery. ✍ Do not use or leave the battery in a high temperature (80 ?C or over) such as near the fire or heater. If the resin separator gets damaged by heat, the battery shorts causing heating, fuming, explosion, ignition. ✍ If the battery is leaking or generating an abnormal odor, immediately remove the battery away from the fire. The leaked electrolyte may cause heating, fuming, explosion, ignition.

⚠CAUTION	✍ Do not peel off or scratch the exterior tubing. ✍ Do not use or leave the battery in high temperature. It may result in leakage or deterioration of the performance / life cycle of the battery. ✍ Immediately stop using the battery if any abnormality is found during use. ✍ Do not use / store the battery in reach of infants. ✍ If the monitor is expected not to be used for a long time, turn off the power and unplug the power cable from the outlet. Otherwise it may result in battery leakage.

NOTE	Users should not attempt to install or replace the battery pack. For installation and replacement of the battery pack, contact our service representative.

To Prepare for Emergency Use

1. Battery Pack
   (1) The battery self-discharges even when not in use. If there is any possibility to use the battery in emergency, the power cable should be always connected to the power receptacle. To fully charge the empty battery, it takes approximately 2.5 hours when the monitor is not operating, and approximately 13 hours when the monitor is operating.

Reference Refer to “2. Basic Operation To Use with the Battery Pack”

   (2) The performance of the battery deteriorates with the repeated use. To maintain the initial performance, replace the battery at least once a year. It is recommended to indicate the start usage date on the battery so that replacing date can be easily recognized.

2. Accessories / Optional Accessories
   (1) The ECG electrodes are consumables. Always prepare extra supplies of electrodes.
   (2) Check if any wire break on the patient cables once a week.

Electromagnetic Compatibility

The performance of this device under electromagnetic environment complies with IEC60601-1-2 (1993).

Precautions for Safe Operation under Electromagnetic Influence

⚠CAUTION	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. ✍ Cellular Phone The radio wave may cause malfunction to the device. Cellular phones and radio sets should be turned off in the room (building) where medical device is located. ✍ 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. ✍ Lightning ✍A lightning nearby may induce excessive voltage to the equipment. If any danger is suspected, use the uninterruptible power supply system. ✍ 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

This equipment complies with IEC60601-1-2 (1993). However, if portable transmitter or wireless LAN equipment is used extremely nearby, the electromagnetic influence may largely exceed the compliance level and may cause unexpected phenomenon such as noise interference on the waveform, etc. Therefore, this equipment 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 equipment and follow the instruction of the technician.

The following is the information relating to EMC (Electromagnetic Compatibility).
(When using this equipment, verify that it is used within the environment specified below.)

●Compliance to the Electromagnetic Emissions

The DS-7100 system is intended for use in the electromagnetic environment specified below.

Emissions Test	***Compliance***	***Electromagnetic Environment - Guidance***
RF Emissions CISPR 11	Group 1	The equipment uses RF energy that is necessary for the internal functioning of the equipment itself. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	This equipment is suitable for use in all establishments other than domestic and those directly connected to a low-voltage power supply network which supplies buildings used for domestic purposes.

●Compliance to the Electromagnetic Immunity (1)

The DS-7100 system is intended for use in the electromagnetic environment specified below. It should be assured that the DS-7100 system is used in such an environment.

Immunity Test	***IEC60601-1-2 Test Level***	***Compliance Level***	***Electromagnetic Environment - Guidance***
Electrostatic Discharge (ESD) IEC61000-4-2	?3kV contact ?8kV air	?3kV contact ?8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC61000-4-4	?1kV for power supply lines ?0.5kV for input/output lines	?1kV for power supply lines ?0.5kV input/output lines	Power supply quality should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Surge IEC61000-4-5	?2kV: line to ground ?1kV: line to line	?2kV: line to ground ?1kV: line to line	Power supply quality should be at levels characteristic of a typical location in a typical commercial or hospital environment.

●Compliance to the Electromagnetic Immunity (2)

The DS-7100 system is intended for use in the electromagnetic environment specified below. It should be assured that the DS-7100 system is used in such an environment.

Immunity Test	***IEC60601-1-2 Test Level***	***Compliance Level***	***Electromagnetic Environment - Guidance***
Radiated RF IEC61000-4-3	3V/m 26MHz ～ 1.0GHz	3V/m	Recommended Separation Distance d = 1.2$\sqrt{P}$ d = 1.2$\sqrt{P}$ 80MHz～800MHz d = 2.3$\sqrt{P}$ 800MHz～2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1 : At 80Mhz and 800MHz, 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.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast can not be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this monitor.

[b] Over the frequency range 150MHz to 80MHz, field strength should be less than 3V/m.

●Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the DS-7100 System

The DS-7100 system is intended for use in an environment in which radiated RF disturbances are controlled. The electromagnetic interference can be prevented by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DS-7100 system as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	***Separation Distance according to Frequency of Transmitter (m)***		
	26MHz ～ 80MHz d = 1.2 $\sqrt{P}$	80MHz ～ 800MHz d = 1.2 $\sqrt{P}$	800MHz ～ 1GHz 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.

⚠WARNING

FCC Radiation Exposure Statement:

This equipment with a built-in telemeter complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator and your body (excluding extremities: hands, wrists, and feet) and must not be co-located or operated with any other antenna or transmitter.

⚠WARNING

Operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.

⚠CAUTION

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

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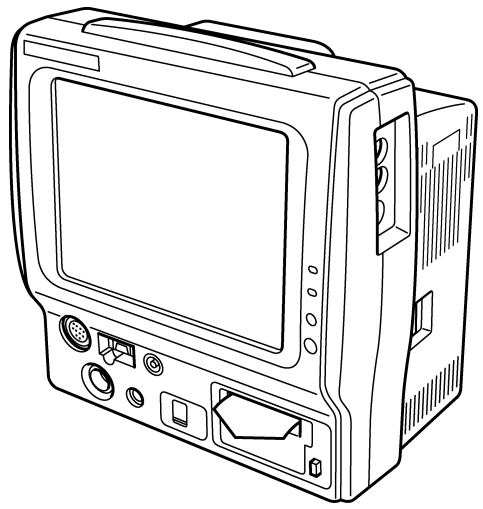
Chapter 1

General Description

This chapter explains the general description of this equipment.

General Description

The DS-7100 system utilizes 8.4-inch color LCD display for monitoring ECG, RESP, SpO_2, BP, NIBP, TEMP measurements. Depending on the model type, CO_2 measurement, telemetry transmission, and Ethernet LAN connection are also possible.



＜DS-7141＞

Model Type	***Function***				
	Basic Measurement	***CO_2 Measurement***	***BP***	***Telemetry Transmission***	***Ethernet LAN***
DS-7141	○	○	2 channels	○	○
DS-7101LT	○	×	2 channels	○	○
DS-7101L	○	×	2 channels	×	○

NOTE	The display illustration on this operation manual includes CO_2 measurement, but note that CO_2 measurement function is not supported for the DS-7101L and DS-7101LT. **DS-7141 is not currently available for sales in the United States.**

Features

✍Completely self-contained, the monitor includes display part, recording part, measuring part in a compact and lightweight package. A battery pack (optional) operation is also possible which allows the monitor to be used as a portable monitor.

✍On the 8.4-inch color LCD display, up to 6 waveforms can be displayed. Also, the numeric data display can be enlarged for easier view.

✍The alarm pole provided as standard indicates the alarm by 9 flashing patterns corresponding to the alarm level.

✍All the operations are performed through the touch screen controls, and up to 4 frequently used keys can be programmed as user key.

✍For the CO_2 measurement, a microstream method is adopted which is less influenced by the anesthetic gas. (DS-7141)

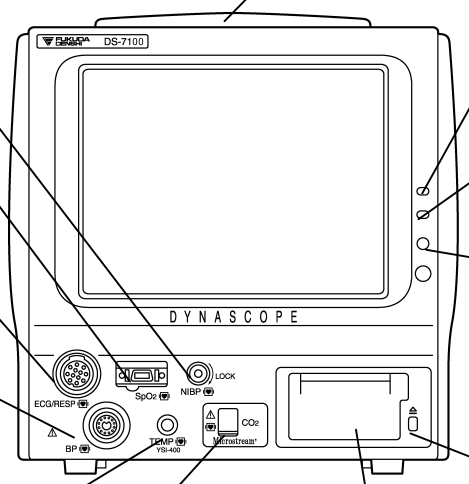
✍Through the use of telemetry transmission unit, a wireless network formation is possible. (DS-7141,DS-7101LT)

✍Through the use of Ethernet LAN unit, a wired network formation is possible. (DS-7141,DS-7101LT,DS-7101L)

✍No cooling fan is used, ensuring clean and quiet monitoring.

Names of Parts and Their Functions

【Front Side】



Alarm Pole
Lights when the alarm generates.

NIBP Cuff Connector
Air hose is connected here.

Power Supply Lamp
Indicates the main power supply.

SpO_2 Input Connector
SpO_2 relay cable (DOC-10) is connected here.

Charge Lamp
Indicates the charge status.
Orange: Charging in process
Green: Charging complete

ECG Input Connector
ECG relay cable is connected here.

Ambient Light Sensor
Detects the ambient light.

BP 2ch conversion Connector
2ch BP conversion cable is connected here.

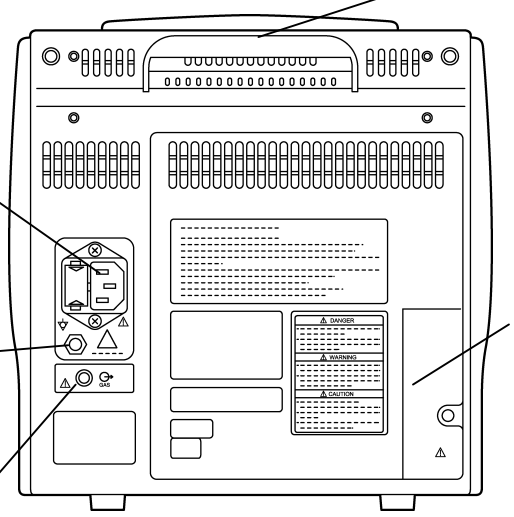
Magazine Release Button
Pressing this button will release the magazine.

Temperature Input Connector
Temperature probe is connected here.

Paper Magazine
Recording paper is installed here.

CO_2 Connector（DS-7141）
CO_2 sampling tube or nasal prong is connected here.

【Rear Side】



Handle
Hold this part when carrying.

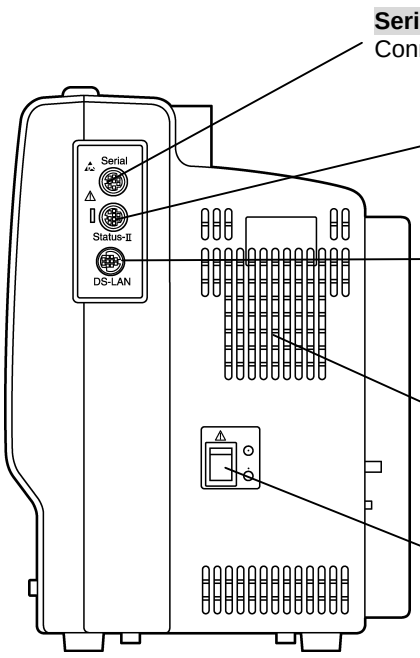
Power Supply Connector (with fuse holder)
Power cable is connected here.
(Fuse is installed in the holder.)

Battery Pack Holder
Battery is installed here.
※We recommend the battery to be replaced annually.

Equipotential Ground Terminal
Equipotential ground terminal is connected here.

Exhaust Connector (DS-7141)
Connects the gas exhausting device and exhausts sampling gas.

【Right Side】



Serial Connector
Connect only the specified device here.

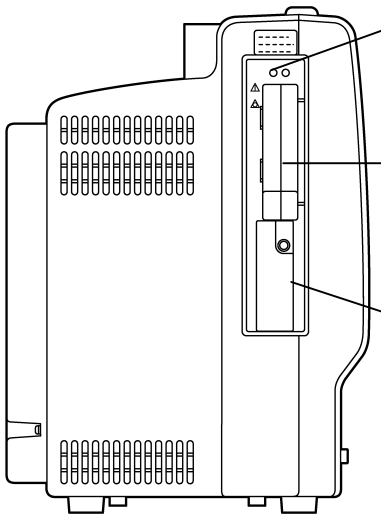
Status Input Connector
Connect only the specified device here.

LAN Connector
Branch cable (CJ-522) is connected here for wired network.

Speaker
Generates synchronous sound, key sound, alarm sound.

Power Supply Switch
Turns the monitor power ON or OFF.

【Left Side】



PC Card Access Lamp
Indicates the PC card access status.

PC Card Slot
Insert only the specified PC card here.

Side Cover (for maintenance)
Do not open this cover. This cover is for maintenance only, which is to be performed by our service representative.

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

NOTE	The display panel utilizes exclusive fluorescent light for the backlight. Since this fluorescent light 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.

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