Service Manual

Prefense™

Early Detection and Notification System™

EDNS-9001

Revision K

NIHON KOHDEN

MUMG 023 [B] - CO-0692

CONTENTS

1. GENERAL HANDLING PRECAUTIONS 1

2. WARRANTY POLICY 3

3. EMC RELATED CAUTION 4

4. CONVENTIONS USED IN THIS MANUAL AND INSTRUMENT 5

5. PREFENSE COMPOSITION 6

6. NETWORK COMPOSITION 7

7. INSTALLATION 8

7.1 INSTALLATION CONDITIONS 8
7.2 INSTALLATION FLOWCHART 9
7.3 IMPORTANT SAFETY INFORMATION FOR INSTALLATION 11
7.4 CO_2 DEVICE INSTALLATION 14

8. EDNS-9001 MAIN UNIT 21

8.1 FRONT PANEL 21
8.2 REAR PANEL 22

9. EDNS-WSXX LCD 23

9.1 EDNS-WSXX LCD FRONT 23
9.2 EDNS-WSXX LCD BACK 23
9.3 OSD LOCK SETTINGS 24

10. LASER PRINTER 25

11. UPS 28

12. MOUNT EDNS-9001 TO LCD DISPLAY 29

13. INSTALLING PREFENSE EDNS-9001 31

13.1 CONNECTION DIAGRAM 32
13.2 INSTALLING THE UPS 33
13.3 CONNECTING EACH INSTRUMENT POWER CORD TO THE UPS 35
13.4 CONNECTING EXTERNAL INSTRUMENTS TO THE EDNS-9001 MAIN UNIT 36

14. SYSTEM STARTUP 38

14.1 POWER ON FLOWCHART 38
14.2 TURNING THE UPS POWER ON 38
14.3 TURNING THE EDNS-WSXX LCD POWER ON 38
14.4 TURNING THE EDNS-9001 MAIN UNIT POWER ON 39
14.5 CHECK AFTER INSTALLATION AND CONNECTION 39

15. SHUTTING THE SYSTEM DOWN 40

16. SERVICING THE PREFENSE EDNS-9001 43

16.1 General Information on Servicing 43
16.2 Service Policy, Service Parts and Patient Safety Checks 45
16.3 Important Safety Information for Servicing 46

17. LOGIN ACCOUNTS 49

17.1 Prefense Account 49
17.2 Biomed Account 49

18. BACKUP/RESTORE PREFENSE SYSTEM SETTINGS 50

18.1 Backup System Settings 50
18.2 Restore System Settings 53

19. TROUBLESHOOTING 55

19.1 System 55
19.2 Network 55
19.3 Measurement Value 56
19.4 Alarm 56
19.5 Home Screen 57
19.6 Admitting/Discharging 57
19.7 Vital Signs Review Screen 58
19.8 Waves and Events Screen 58
19.9 Power Problem 59
19.10 Display Problem 59
19.11 Sound Problem 60
19.12 Keyboard Problem 60
19.13 Mouse Problem 60
19.14 Hard Disk Problem 60

20. EDNS-9001 SPECIFICATION 62

21. STANDARD ACCESSORIES 64

21.1 Prefense™ - EDNS-9001 System 64
21.2 Prefense™ PC Main Unit Accessories 64
21.3 Prefense™ LCD Unit Accessories 64

22. GENERAL REQUIREMENTS FOR CONNECTING MEDICAL ELECTRICAL SYSTEM 65

1. General Handling Precautions

This instrument is intended for use only by qualified medical personnel. Use only Nihon Kohden approved products with this instrument. Use of non-approved products or in a non-approved manner may affect the performance specifications of the instrument. This includes, but is not limited to, batteries, recording paper, pens, extension cables, electrode leads, input boxes, and AC power.

Please read these precautions thoroughly before attempting to operate the instrument.

1. To safely and effectively use the instrument, its operation must be fully understood.

2. When installing or storing the instrument, take the following precautions:

1) Avoid moisture or contact with water, extreme atmospheric pressure, excessive humidity and temperature, poorly ventilated areas, and dust, saline or sulfuric air.
2) Place the instrument on an even, level floor. Avoid vibration and mechanical shock, even during transport.
3) Avoid placing in an area where chemicals are stored or where there is danger of gas leakage.
4) The power line source to be applied to the instrument must correspond in frequency and voltage to product specifications, and have sufficient current capacity.
5) Choose a room where a proper grounding facility is available.

3. Before Operation

1) Check that the instrument is in perfect operating order.
2) Check that the instrument is grounded properly.
3) Check that all cords are connected properly.
4) Pay extra attention when the instrument is in combination with other instruments to avoid misdiagnosis or other problems.
5) All circuitry used for direct patient connection must be doubly checked.
6) Check that battery level is acceptable and battery condition is good when using battery-operated models.

4. During Operation

1) Both the instrument and the patient must receive continual, careful attention.
2) Turn power off or remove electrodes and/or transducers when necessary to assure the patient's safety.
3) Avoid direct contact between the instrument housing and the patient.

5. **To Shutdown After Use**
   1) Turn power off with all controls returned to their original positions.
   2) Remove the cords gently; do not use force to remove them.
   3) Clean the instrument together with all accessories for their next use.

6. **The instrument must receive expert, professional attention for maintenance and repairs. When the instrument is not functioning properly, it should be clearly marked to avoid operation while it is out of order.**

7. **The instrument must not be altered or modified in any way.**

8. **Maintenance and Inspection:**
   1) The instrument and parts must undergo regular maintenance inspection at least every 6 months.
   2) If stored for extended periods without being used, make sure prior to operation that the instrument is in perfect operating condition.
   3) Technical information such as parts list, descriptions, calibration instructions or other information is available for qualified user technical personnel upon request from your Nihon Kohden distributor.

9. **When the instrument is used with an electrosurgical instrument, pay careful attention to the application and/or location of electrodes and/or transducers to avoid possible burn to the patient.**

10. **When the instrument is used with a defibrillator, make sure that the instrument is protected against defibrillator discharge. If not, remove patient cables and/or transducers from the instrument to avoid possible damage.**

2. Warranty Policy

Nihon Kohden NKUS Lab* (NKUS Lab) shall warrant its products against all defects in materials and workmanship for one year from the date of delivery. However, consumable materials such as recording paper, ink, stylus and battery are excluded from the warranty.

NKUS Lab or its authorized agents will repair or replace any products which prove to be defective during the warranty period; provided these products are used as prescribed by the operating instructions given in the operator's and service manuals.

No other party is authorized to make any warranty or assume liability for NKUS Lab's products. NKUS Lab will not recognize any other warranty, either implied or in writing. In addition, service, technical modification or any other product change performed by someone other than NKUS Lab or its authorized agents without prior consent of NKUS Lab may be cause for voiding this warranty.

Defective products or parts must be returned to NKUS Lab or its authorized agents, along with an explanation of the failure. Shipping costs must be pre-paid.

This warranty does not apply to products that have been modified, disassembled, reinstalled or repaired without Nihon Kohden NKUS Lab's approval or which have been subjected to neglect or accident, damage due to accident, fire, lightning, vandalism, water or other casualty, improper installation or application, or on which the original identification marks have been removed.

In the USA and Canada other warranty policies may apply.

CAUTION

United State law restricts this device to sale by or on the order of a physician.

* NKUS Lab is a subsidiary of Nihon Kohden Corporation.

3. EMC Related Caution

During the operation of the equipment and/or system, if there is any undesired deviation from its intended operational performance, you must avoid, identify and resolve the adverse electromagnetic effect before continuing to use the equipment and/or system.

The following describes some common interference sources and remedial actions:

1. **Strong electromagnetic interference from a nearby emitter source such as an authorized radio station or cellular phone:**
   Install the equipment and/or system at another location if it is interfered with by an emitter source such as an authorized radio station. Keep the emitter source such as cellular phone away from the equipment and/or system.

2. **Radio-frequency interference from other equipment through the AC power supply of the Equipment and/or system:**
   Identify the cause of this interference and if possible remove this interference source. If this is not possible, use a different power supply.

3. **Effect of direct or indirect electrostatic discharge:**
   Make sure all users and patients in contact with the equipment and/or system are free from direct or indirect electrostatic energy before using it. A humid room can help lessen this problem.

4. **Electromagnetic interference with any radio wave receiver such as radio or television:**
   If the equipment and/or system interferes with any radio wave receiver, locate the equipment and/or system as far as possible from the radio wave receiver.

If the above suggested remedial actions do not solve the problem, consult your Nihon Kohden representative or distributor for additional suggestions.

4. Conventions Used in this Manual and Instrument

Warnings, Caution, and Notes
Warnings, cautions, and notes are used in this manual to alert or signal the reader to specific information.

WARNING

A warning alerts the user to possible injury or death associated with the use or misuse of the instrument.

CAUTION

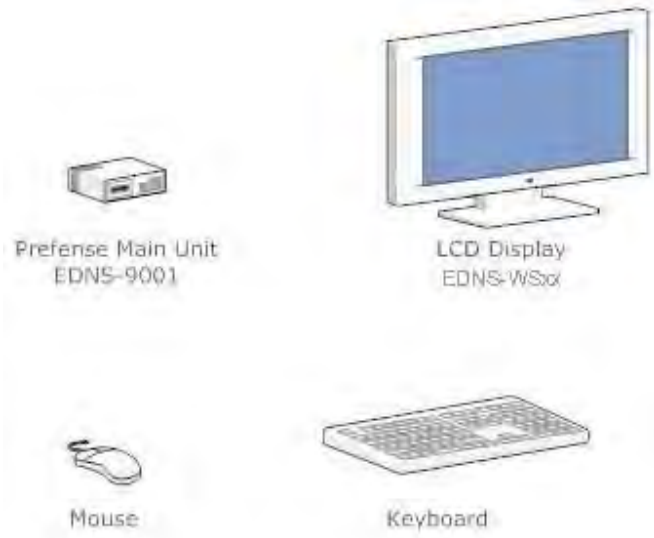
A caution alerts the user to possible injury or problems with the instrument associated with its use or misuse such as instrument malfunction, instrument failure, damage to the instrument, or damage to other property.

NOTE

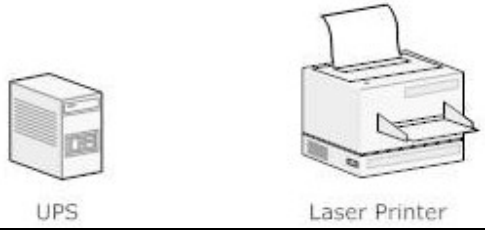
A note provides specific information, in the form of recommendations, requirements, alternative methods or supplemental information.

5. Prefense Composition

STANDARD SYSTEM



OPTIONS



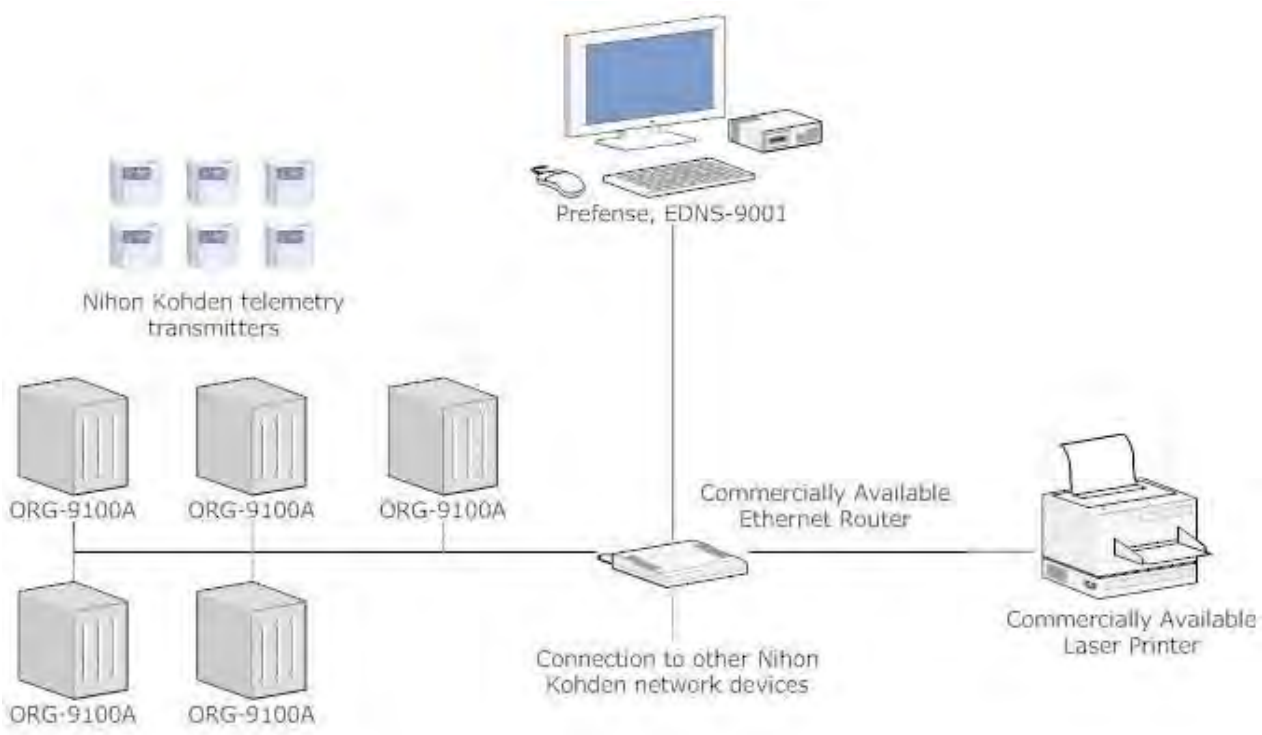
ACCESSORIES

ORG-9000 Series Multiple Patient Receiver and NTX Transmitter

OLG-2800 CO_2 Monitor

6. Network Composition

Prefense can display data for up to 40 patients on a single screen, with each patient connected to one transmitter. The patient data is transmitted through the wireless network to Prefense.



A laser printer can be networked with Prefense for printing stored information.

Alarm limits and other transmitter settings can be set or changed remotely from Prefense.

Please read this manual and the operator's manual thoroughly before operation in order to obtain full use of Prefense. Also read the manuals for the transmitters and multiple patient receivers.

NOTE

Use Nihon Kohden parts and accessories to assure maximum performance from your instrument.

WARNING

Prefense does not work with CNS-9300 series central monitors and CNS-9701 revision 01-66 or earlier. Prefense should not overview beds whose data are stored on these devices. Do not transfer patients to/from these devices.

7. Installation

This installation guide describes how to install the Prefense EDNS-9001. Follow the instructions to correctly install Prefense. If Prefense is not properly installed, monitoring data may not be correctly managed.

7.1 Installation Conditions

Put Prefense on a stable and flat surface in a suitable location where the screen is easy to see and does not reflect light.

WARNING

- **Never use Prefense in the presence of any flammable anesthetic gas, concentrated oxygen or hyperbaric oxygen. Failure to follow this warning may result in explosion.**
- **Never use Prefense in a high-pressure oxygen medical care tank. Failure to follow this warning may cause explosion or fire.**
- **Install the Prefense system and external instruments outside the patient environment (IEC 60601-1-1 2.202). If they are installed inside the patient environment, the patient or operator may receive electrical shock or injury. For installation, contact your Nihon Kohden representative.**

CAUTION

- **Do not install the Prefense system where it will be exposed to water or chemical solutions. Avoid direct sprinkling, spray or moist air from the nebulizer or humidifier. These cause malfunction and shorten the life of the device.**
- **Avoid exposing the Prefense system to direct sunlight. Otherwise, the temperature rises and it causes malfunction and shortens the life of the device.**
- **Avoid locations where the Prefense system may receive strong electromagnetic interference such as radio or TV stations, cellular phone or mobile two-way radios.**
- **Make sure that there is enough space between the Prefense system and the wall for adequate ventilation. Otherwise the internal temperature of the Prefense system may rise, which leads to inaccurate operation and shortens the device life.**
- **Leave more than 5 cm of space between the wall and vent holes of the Prefense system.**
- **When the Prefense system is surrounded, leave more than 10 cm of space above the Prefense system for ventilation. Do not let the surrounding temperature exceed 35°C during operation.**
- **If PC Main Unit is not mounted to LCD, lay unit on a table or other surface so that its vent holes are not covered.**
- **Do not place blankets or cloth over the Prefense system. It may affect monitoring.**
- **Do not install the Prefense system in a dusty area.**
- **Connect the power cord to an AC outlet that can supply sufficient AC current to the Prefense system. The Prefense system cannot function properly with low current. Also the breaker trips and it causes electric power failure.**
- **When there is any problem with the Prefense system, turn off the power immediately and disconnect the power cord from the AC outlet. Take the Prefense system out of service and check for damage.**
- **Do not move the EDNS-WSxx LCD unit with the display facing down. The display may tip over.**

7.2 Installation Flowchart

1. **Install UPS.**
2. **Connect the power cord of the following units to the UPS.**
    - **EDNS-9001 main unit**
    - **EDNS-WSxx LCD unit**
3. **Connect the laser printer power cord to an AC outlet on the wall. (Optional)**
4. **Connect the following units to the EDNS-9001 main unit.**
    - **EDNS-WSxx LCD unit**
    - **Keyboard**
    - **Mouse**
5. **Connect the Prefense EDNS-9001, ORG-9000 series multiple patient receivers, and laser printer to a network.**
6. **Power on EDNS-WSxx LCD unit.**
7. **Power on EDNS-9001 main unit.**
8. **The Prefense program will automatically start.**
9. **After the Home (All Beds) screen is displayed, press CTRL+ALT+DEL on the keyboard.**
10. **Log Off the Prefense account.**
11. **Wait for Prefense program to exit.**
12. **Wait for the Log On to Windows prompts.**
13. **Log On using user name Biomed, default password is 1234.**

WARNING

Do not initialize the Security Platform state. Ignore the following message if it pops up. "The Security Platform state is "Not initialized". Click here to initialize now."

14. **Assign a name to Prefense by setting the "computer name" to a unique ASCII string that is <u>10 characters or less</u>. This name will appear in your Prefense's Device/Channel column at the Revision Information and Alarm Volume screen. Do not restart the PC yet.**
15. **Assign the Prefense an IP address. If prompted, you can go ahead and restart the PC.**
    a. **A persistent route must be added to Windows 7 if the Prefense subnet mask does not match the value corresponding to the IP address Class from the following table:**

Network Class	Subnet Mask
Class A (0.0.0.0 to 127.255.255.255)	255.0.0.0
Class B (128.0.0.0 to 191.255.255.255)	255.255.0.0
Class C (192.0.0.0 to 223.255.255.255)	255.255.255.0

To add a persistent route, open a Command Prompt and use the "route –p" command as follows:

For a Class A IP address of the form W.X.Y.Z add a persistent route to W.255.255.254 with a 31-bit (255.255.255.254) subnet mask.

Example: The Class A IP address is 10.11.12.13.

route –p ADD 10.255.255.254 MASK 255.255.255.254 10.11.12.13

For a Class B IP address of the form W.X.Y.Z add a persistent route to W.X.255.254 with a 31-bit (255.255.255.254) subnet mask.

Example: The Class B IP address is 172.16.17.18.

route –p ADD 172.16.255.254 MASK 255.255.255.254 172.16.17.18

For a Class C IP address of the form W.X.Y.Z add a persistent route to W.X.Y.254 with a 31-bit (255.255.255.254) subnet mask.

Example: The Class C IP address is 192.168.9.10.

route –p ADD 192.168.9.254 MASK 255.255.255.254 192.168.9.10

16. **If the PC hasn't restarted, do the following: click on Windows Start button / Shutdown / Restart.**
17. **(Optional) Add a printer by logging back into Biomed account. Please reference Laser Printer section. Restart PC.**
18. **PC will restart using the Prefense account and automatically execute the Prefense software.**
19. **Click on the Date and Time area to display the Revision Information and Alarm Volume screen.**
20. **Enter default password 1234.**
21. **Verify that the Computer Name and IP Address you set up are displayed on the first line of the Revision Information table.**
22. **If the date and time are not correct, change it by going to the Maintenance screen, click on Date & Time button to display the Windows Date and Time dialog box.**
    - **Click on Time Zone tab.**
    - **Select your time zone.**
    - **Click Apply.**
    - **Click on Date & Time tab.**
    - **Modify date and/or time if they are not correct. Note that changing the date and time affects the entire Nihon Kohden network.**
    - **Click OK.**
23. **Go to System Configuration screen to assign a Group to Prefense.**
24. **At System Configuration screen, select Fixed or Floating Bed Assignment Mode.**
25. **If Bed Assignment Mode is Fixed, select the devices to monitor on Prefense at the Device Configuration screen. This is described in detail in the Prefense Operator's Manual.**
26. **If Bed Assignment Mode is Floating, create a list of transmitter channel numbers at the System Configuration screen, then go to the Admit/Discharge screen to monitor and admit devices on Prefense. This is described in detail in the Prefense Operator's Manual.**
27. **Start monitoring.**

WARNING

The date and time must only be modified from Prefense's Maintenance screen. Do not attempt to modify the date and time outside of the Prefense software.

7.3 Important Safety Information for Installation

General

WARNING

- **Never use Prefense in the presence of any flammable anesthetic gas or high concentration oxygen atmosphere. Failure to follow this warning may cause explosion or fire.**
- **Never use Prefense in a hyperbaric oxygen chamber. Failure to follow this warning may cause explosion or fire.**
- **Do not install or run any software not specified by Nihon Kohden in Prefense. Nihon Kohden does not warrant normal operation of the Prefense system program if unspecified software is installed or used.**
- **Do not install the Prefense system software in a personal computer which is not specified by Nihon Kohden and use it for monitoring.**
- **If the personal computer does not satisfy the performance specifications that are required by Nihon Kohden, the system software might not function normally.**
- **If the personal computer does not satisfy the safety standards that are required by Nihon Kohden, the patient and operator may receive electrical shock through another instrument in the network.**
- **While Prefense is on, do not attach CD or floppy disk drives nor insert any CD-ROM or floppy disk into it. Nihon Kohden does not warrant the normal operation of Prefense if an application or software installation starts automatically.**

CAUTION

- **While Prefense is on, do not touch unused sockets. Failure to follow this instruction may damage Prefense by static electricity and cause malfunction.**
- **If any liquid might have gotten into Prefense, stop using Prefense and contact your Nihon Kohden representative. The Prefense system must be disassembled, cleaned and dried. Then it must be checked for safety, functions and performance.**

Installation

WARNING

Install Prefense and external instruments outside the patient environment (IEC 60601-1-1 2.202). If they are installed inside the patient environment, the patient or operator may receive electrical shock or injury. For installation, contact your Nihon Kohden representative.

CAUTION

- **Only use the provided power cord. Using other power cords may result in electrical shock or injury to the operator.**
- **Before connecting or disconnecting instruments, make sure that each instrument is turned off and the power cord is disconnected**

from the AC socket. Otherwise, the patient or operator may receive electrical shock or injury.

- **Connect only the specified instrument to Prefense and external instruments and follow the specified procedure. Failure to follow this instruction may result in electrical shock or injury to the operator, and cause fire or instrument malfunction.**
- **Do not let connection cables stick out; run them along the floor or wall. If people trip over the cable, the monitor may tip over and cause injury.**

UPS (Uninterruptible Power Supply)

WARNING

- **Install the UPS outside the patient environment (IEC 60601-1-1 2.202). If it is installed inside the patient environment, the safety standards which are required by Nihon Kohden are not satisfied, and it may cause electrical shock to the patient or operator.**
- **Use a UPS that satisfies the safety standards specified by IEC and UL. Otherwise, lack of safety may cause electrical shock to the patient or operator.**
- **Periodically check the life of the UPS battery. Replace the battery when the lifetime expires. If the battery is used beyond its lifetime, liquid leakage, smoke, fire or explosion may occur.**
- **Only connect Prefense's main unit and LCD display to the UPS.**
- **Make sure that there is enough space between the UPS and the wall for adequate ventilation.**

CAUTION

- **Make sure that the UPS is properly grounded. Otherwise the operator may receive electrical shock.**
- **To assure an uninterrupted power supply, we recommend using the specified UPS. A sudden loss of power supply can damage Prefense and delete stored data.**

Network

WARNING

- **Connect Prefense to the network as specified in the Service Manual. Otherwise the patient and operator may receive electrical shock or injury. For assistance on how to connect the network, contact your Nihon Kohden representative.**
- **Check the software version number of the Prefense system before connecting it to the network. Different software versions have different communication methods. More than one communication method in a network may cause communication failure.**
- **Install all external instruments, including printer and hubs, outside the patient environment (IEC 60601-1-1 2.202). If they are installed inside the patient environment, the patient or operator may receive electrical shock or injury. For installation, contact your Nihon Kohden representative.**

CAUTION

- **Network settings and Windows Operating System settings must only be set by qualified service personnel. Contact your Nihon Kohden representative.**
- **The network must be managed by the network administrator. Make sure that each device in the network has a different IP address. Otherwise, data communication cannot be performed properly. When adding a device to an already operating network, set the IP address on the device before connecting the device to the network.**

Turning Power On/Off

WARNING

- **Do not turn off the LCD display to which the Prefense Main Unit is connected. There will be no alarm sound.**
- **Do not mute or decrease the sound volume of the LCD display. If you decrease the volume, you might not hear the sound.**

CAUTION

- **Follow the specified procedure to turn off Prefense, otherwise patient data may be corrupted and the hard disk may be damaged.**
- **Confirm that there is a test sound from the speaker on the LCD display when the Prefense starts.**
- **Periodically check LCD signal indicator. When LCD has no power its power light is off and when no signal is received the LCD power light is orange. Normal condition is blue.**

Admission, Discharge and Changing the Receiving Channel

WARNING

- **After admitting a patient, confirm that Prefense starts monitoring the patient.**
- **When you change the receiving channel to monitor a new patient, first delete all data of the previous patient. Otherwise, the data of the previous patient and new patient will be mixed together and cause misunderstanding of the patient history.**
- **Do not use the same transmitter on more than one patient at the same time. Do not connect different sensors on different patients to the same transmitter.**
- **Do not use transmitters of adjacent channels in a hospital. Otherwise, radio waves from one transmitter affect the receiver of the adjacent channel's transmitter and there may be interference.**

NOTE

- **To prevent interference between channels, assign a channel administrator in the hospital and only he or she should manage channel assignment.**
- **Use Nihon Kohden parts and accessories to assure maximum performance from your instrument.**
- **For stable signal reception, it is recommended to use a diversity antenna system on the receiving monitor. Otherwise, spike noise from transient fading of electric field strength (for example, people moving) may interfere with the transmitter signal and may be mistaken as an arrhythmia on the receiving monitor.**
- **NIBP cannot be measured on a neonate (ECG, respiration and SpO2 can be monitored on a neonate).**
- **For details on the receiving monitor and upgrade information, contact**

your Nihon Kohden representative.

CAUTION

- **When connecting a new patient to the monitoring device, first discharge the previous patient which archives or deletes all data of the previous patient, then admit the new patient. Otherwise, the data of the previous patient and new patient will be combined together and it will cause confusion in the patient history.**

Alarm

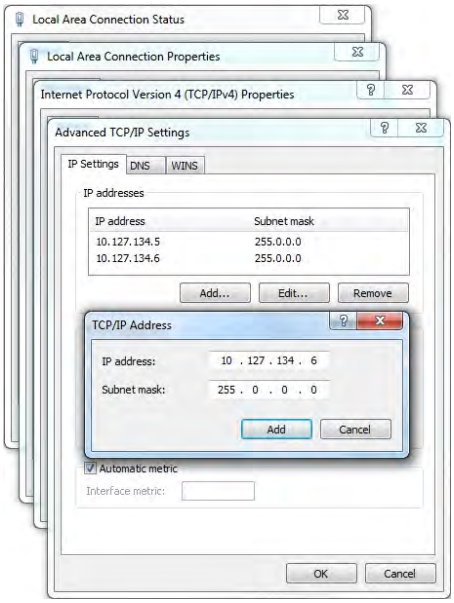
WARNING

- **Securely connect the display cable. There is no sound if the cable comes off.**
- **Do not plug headphones into headphone jack. Alarm sounds are redirected to headphones instead of the speakers.**
- **Do not adjust the sound volume at the display unit. If you decrease the display unit volume to the minimum, there is no alarm sound.**
- **Changing the alarm settings on a CO_2 monitor does not affect the CO_2 alarm limits on the Prefense (and vice-versa).**

7.4 CO_2 Device Installation

Prefense can display and store CO_2 wave and vital sign data from a Nihon Kohden CO_2 monitor. This is accomplished by performing the following steps:

1. **Press Ctrl-Alt-Del and logout of the Prefense account, then login as Biomed (the default password is 1234).**
2. **Assign a second IP address to the Prefense PC for the CO_2 device(s) to use. If the Prefense PC already has two IP addresses then skip this step.**
    a. **To set a second IP address, first open the dialog normally used to set the IP address from the Windows Control Panel (Start -> Control Panel -> Network and Sharing Center -> Local Area Connection - > Properties -> Internet Protocol Version 4 (TCP/IPv4) Properties).**
    b. **Press the Advanced… button.**
    c. **Press the Add… button for IP addresses.**
    d. **Enter the second IP address and subnet mask (the second subnet mask will always be the same as the first subnet mask), then press the Add button.**



e. The second IP address must be unique and compatible with the existing patient monitoring network. If possible, simply use the same values as the first IP address but increase or decrease the last number by 1 (the last number must not be 0 or 255).

f. Close all open dialogs by pressing OK or Close as needed.

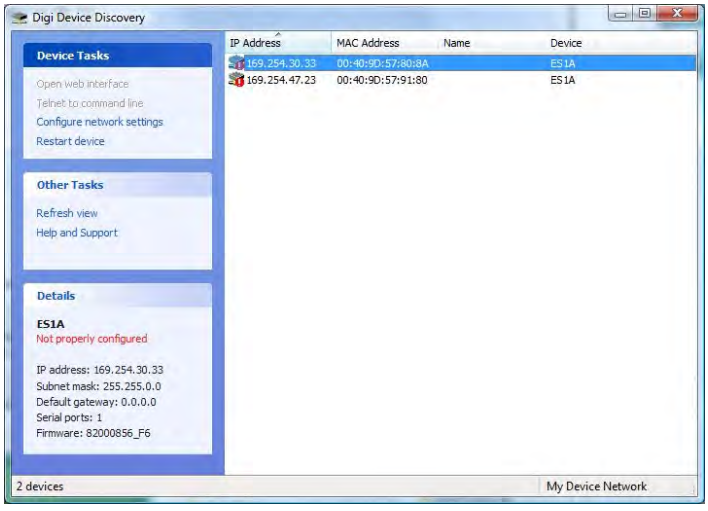
3. Connect the CO_2 monitor serial-to-Ethernet converter to the patient monitoring network.

4. Go to the Windows Control Panel and temporarily turn off the Windows Firewall.

5. Set the IP Address of the serial-to-Ethernet converter attached to the CO_2 monitor.

a. Start the Digi Device Discovery program from the Start menu, All Programs, Digi.

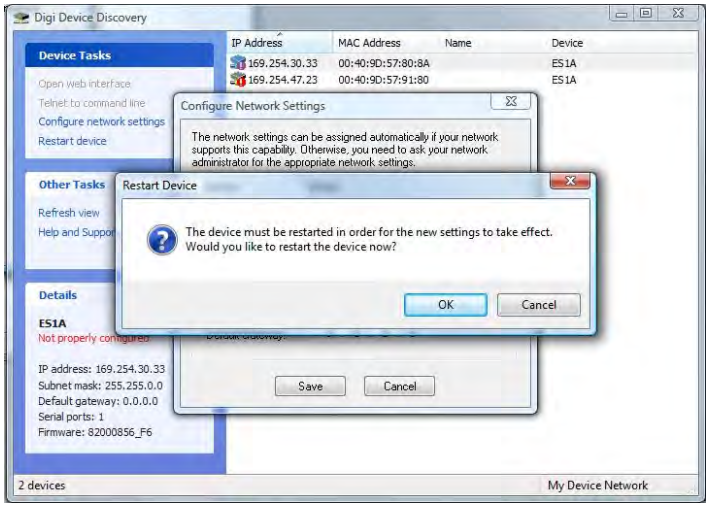
b. Select a serial-to-Ethernet converter by its MAC Address.



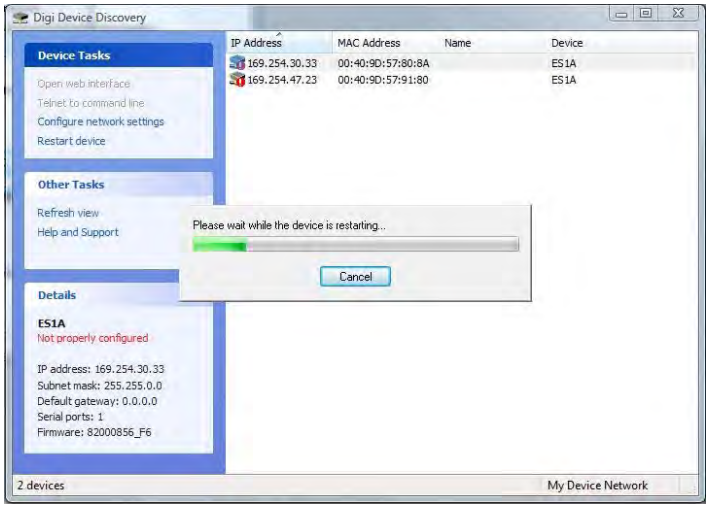
c. Click on "Configure network settings" under Device Tasks.

d. Enter the desired manual network settings and press Save.

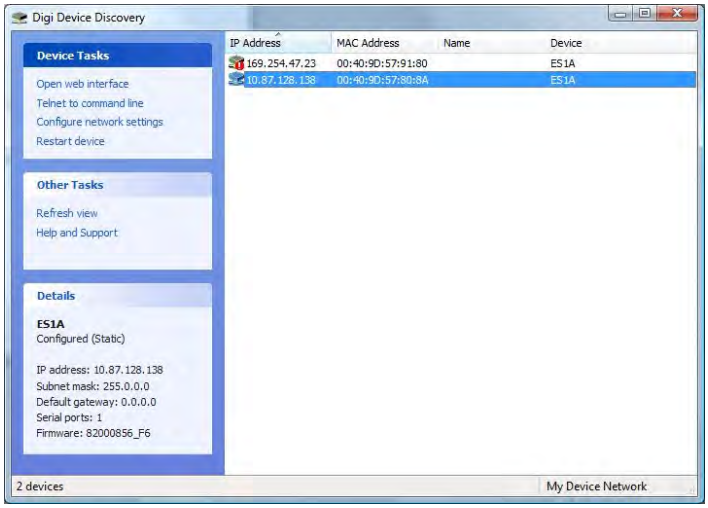
e. Press OK when prompted to confirm restarting the device.



f. Wait for the device to restart.

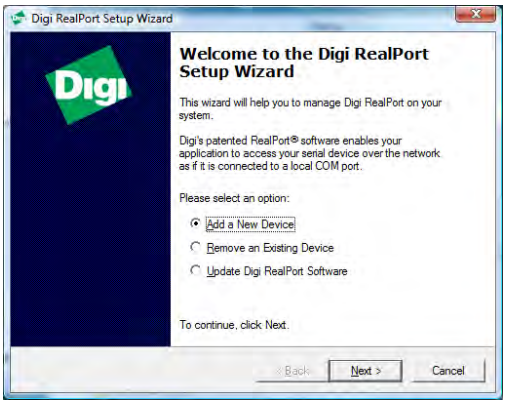


g. Confirm that the device has the correct network settings.

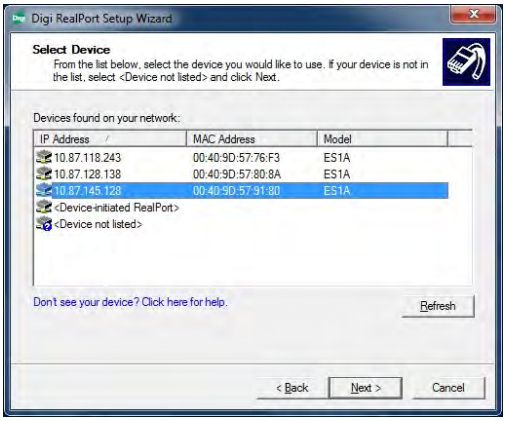


6. **Go to the Windows Control Panel and turn the Windows Firewall back on.**
7. **Launch the RealPort driver installation program from the shortcut on the desktop. If the RealPort software is not already installed you will first see this screen so go ahead and press the Next button.**

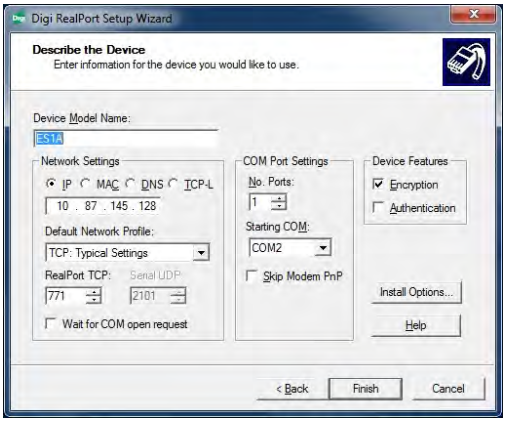
8. **Select "Add a New Device" and press the Next button.**



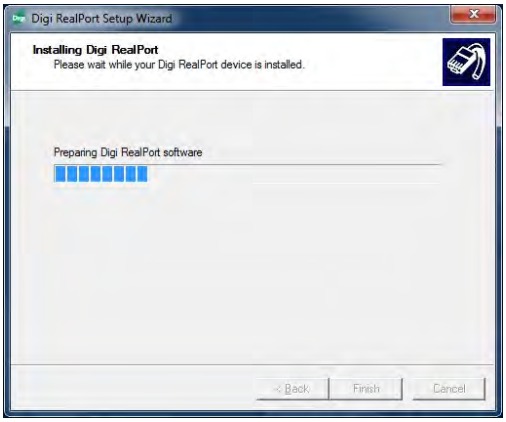
9. **Select the device from the list and press the Next button.**



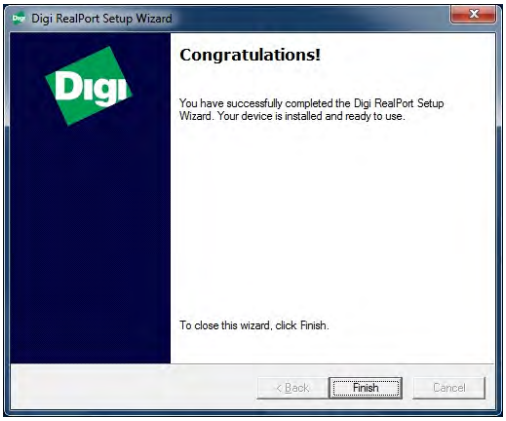
10. Keep the default settings and press the Finish button.



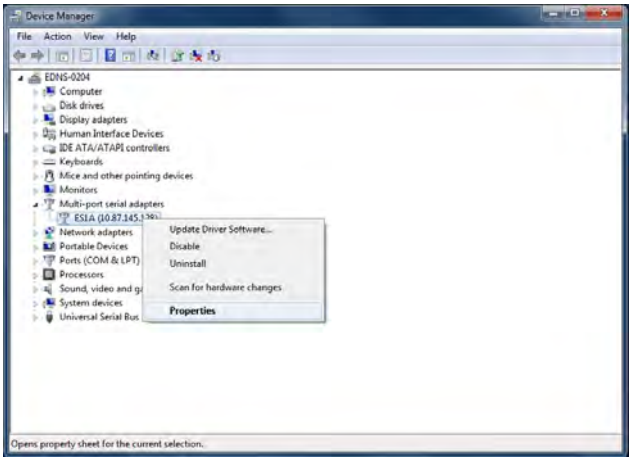
11. Wait for the installation to complete.



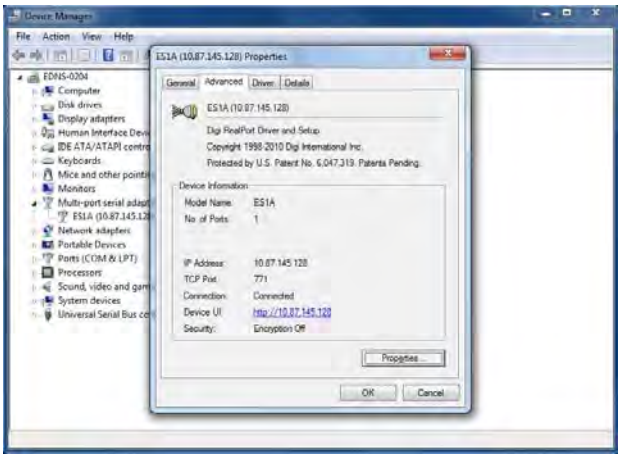
12. Press the Finish button to close the installer.



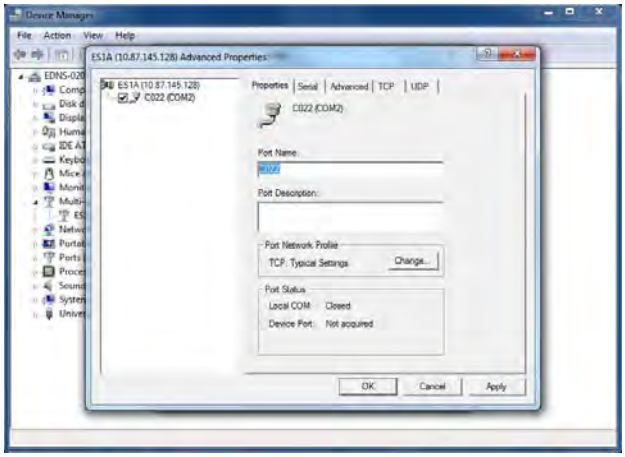
13. **Repeat steps 7 through 12 for each additional CO_2 device to be added.**
14. **Open Device Manager by clicking Start, Control Panel, Device Manager and open the Properties page for the Multi-port serial adapter that was just installed.**



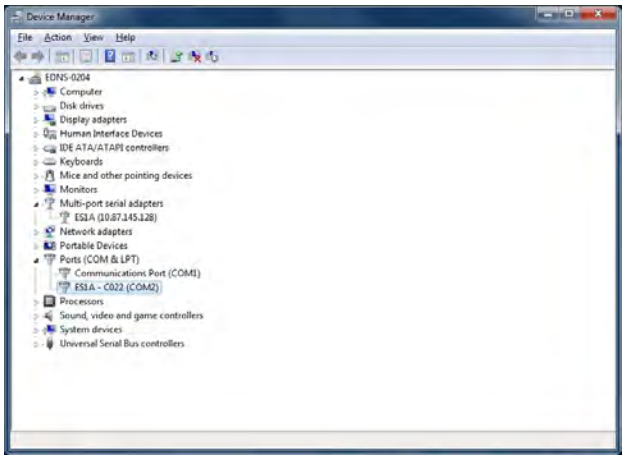
15. **Select the Advanced tab and press the Properties button.**



16. **Select the COM port (not the ES1A) and enter a "virtual channel number" as the Port Name. This value must be a system-wide unique hexadecimal number in the range C000 to C0FE.**



17. **Press OK and close the Properties page. The port name will appear with the device under the Ports section of the Device Manager.**



18. **The CO_2 device must send data in the appropriate serial format. Power off the CO_2 device, then press and hold the orange alarm silence button while turning the CO_2 device back on in order to enter the System Setup screens.**
19. **Press the menu button (just below the alarm silence button) twice to go to the third System Setup (3/3) screen.**
20. **Use the down arrow to select the Serial Out item and then press the menu button to select the setting and the arrow buttons to change the value to NET-9CNV. Then press the menu button again to set the new value. Press the orange alarm silence button to exit the setup screens and then press the menu button to save the new setting and restart the CO_2 device.**
21. **Restart the Prefense PC. The CO_2 device should now appear in the patient monitoring network.**

8. EDNS-9001 Main Unit

8.1 Front Panel

CAUTION

While Prefense is on, do not touch unused sockets. Failure to follow this caution damages the Prefense system by static electricity and causes malfunction.

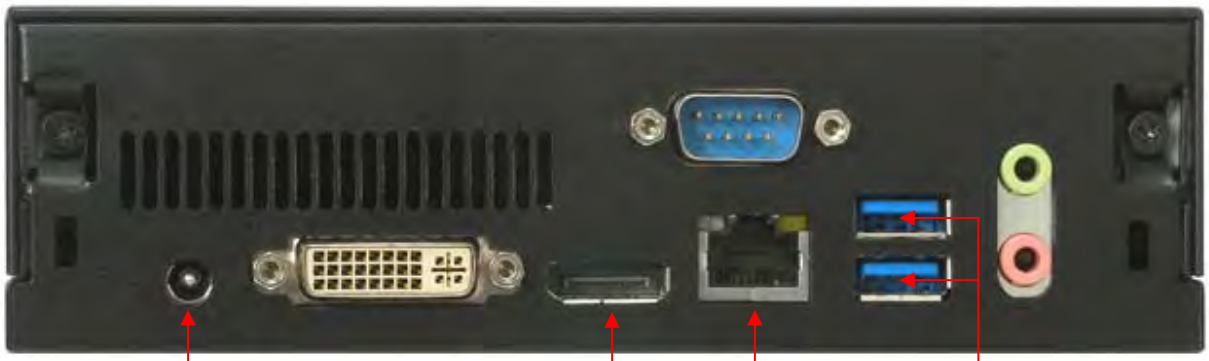
Power button
Turns the EDNS-9001 main unit on or off.

USB Ports
Use to back up EDNS-9001 system settings or updating EDNS-9001 software.

8.2 Rear Panel

CAUTION

Do not touch unused sockets on the rear panel of the EDNS-9001 main unit. Failure to follow this instruction may damage the EDNS-9001 main unit by static electricity and cause malfunction



AC Power Connector
Connects to a UPS via the power cord provided with the EDNS-9001 main unit.

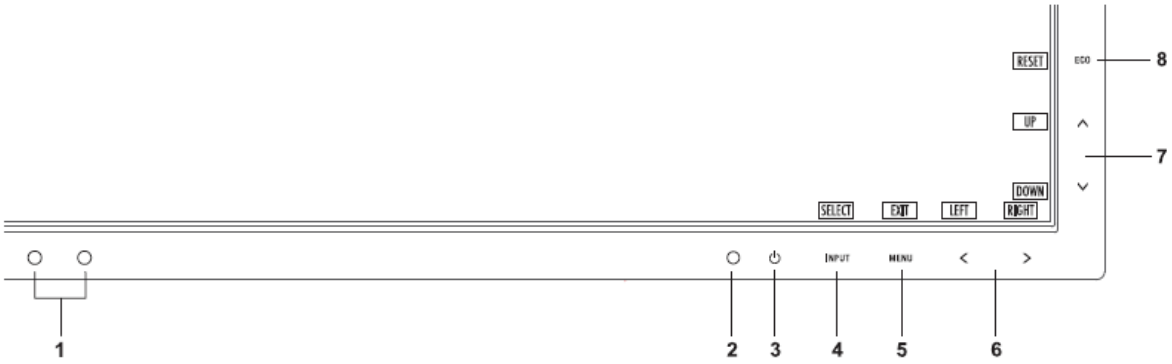
USB Ports
Connects the provided USB keyboard and mouse to the EDNS-9001 main unit.

Ethernet Connector
Connects the EDNS-9001 main unit to the monitoring network.

Display Connector
Connects the EDNS-9001 main unit to the EDNS-WSxx LCD.

9. EDNS-WSxx LCD

9.1 EDNS-WSxx LCD Front



1 Ambibright Sensor Human Sensor	Detects the level of ambient lighting, allowing the monitor to make adjustments to various settings resulting in a more comfortable viewing experience. Do not cover this sensor.
2 LED	Indicates that the power is on or off.
3 Power	Turns the monitor on and off.
4 INPUT/SELECT	Enters the OSD Control menu. Enters OSD sub menus. Changes the input source when not in the OSD Control menu.
5 MENU/EXIT	Accesses OSD menu. Exits the OSD sub menu. Exits OSD Control menu.
6 LEFT/RIGHT	Navigates to the left or right through the OSD Control menu. You can adjust the BRIGHTNESS directly while the OSD menu is off*.
7 UP/DOWN	Navigates up or down through the OSD Control menu. You can adjust the VOLUME directly when not in the OSD Control menu*.
8 RESET/ECO	Resets the OSD back to factory settings in the OSD control menu. Switches among ECO MODE settings. Activates Auto Adjust function if held for 3 seconds while the OSD menu is off (Analog input only)*.

* When Hot Key function is OFF, this function is disabled.

9.2 EDNS-WSxx LCD Back

DisplayPort or HDMI Connector (use the type of cable that came with your Prefense)
Connects the EDNS-WSxx LCD to the EDNS-9001 main unit.

9.3 OSD Lock Settings

The EDNS-WSxx LCD on-screen display (OSD) is locked to prevent unauthorized access to volume control and other settings.

WARNING

If the OSD becomes unlocked, then it must be re-locked.

OSD Lock Out completely locks out access to all OSD control functions except for Brightness, Contrast and Volume.

- Lock OSD: Press MENU button. Push RIGHT button until the Menu Tools menu is displayed. Push DOWN CONTROL button until the OSD Lock Out control is displayed. Press SELECT button and RIGHT button simultaneously until OSD Menu displays the Brightness menu with only the Brightness and Contrast settings in the menu.

- Unlock OSD: Press MENU button. Push RIGHT button until the Information menu is displayed. Press SELECT button and LEFT button until OSD Menu displays the Brightness menu with Brightness, Contrast, Eco Mode and DV Mode settings in the menu.

WARNING

If the Hot Key setting changes to on, then it must be reset to off.

When Hot Key is off, the brightness and volume settings cannot be directly adjusted using the front keys.

- Before changing Hot Key setting, unlock OSD as described above.

- Set Hot Key Off: Press MENU button. Push RIGHT button until the Menu Tools menu is displayed. Push DOWN button until the Hot Key control is displayed. Push LEFT button until Hot Key is set to OFF.

- Set Hot Key On: Press MENU button. Push RIGHT button until the Menu Tools menu is displayed. Push DOWN button until the Hot Key control is displayed. Push RIGHT button until Hot Key is set to ON.

- After changing Hot Key setting, lock OSD as described above.

WARNING

Do not mute or decrease the sound volume of the LCD display.
If you decrease the volume, you might not hear the sound.

10. Laser Printer

Use the laser printer that Nihon Kohden recommends. Read the printer manual thoroughly. Please contact your Nihon Kohden representative when you locally purchase a laser printer.

NOTE

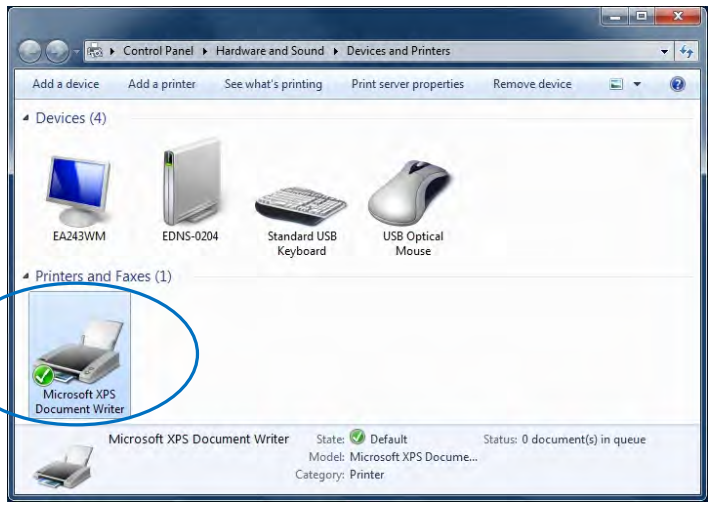
- **This procedure describes how to install a Hewlett Packard LaserJet 4100n, 4200n, 4250n or P4015n.**
- **When more than one central monitor uses a single printer, set the following settings on each central monitor.**
- **Connect the printer to each central monitor as a local printer, not as a network printer.**

1) Power on EDNS-WSxx LCD unit.
2) Power on EDNS-9001 main unit.
3) The Prefense program will automatically start.
4) After the Home (All Beds) screen is displayed, press CTRL+ALT+DEL on the keyboard.
5) Log Off the Prefense account.
6) Wait for Prefense program to exit.
7) Log On using user name Biomed, default password is 1234.

Removing Unnecessary Printers

Remove unnecessary printers, such as the Microsoft XPS Document Writer or a printer which has the same IP address as the printer that you want to install.

1) Click the Windows Start button then select “Devices and Printers” to open the Devices and Printers window.
2) If there is an existing printer, click the printer icon and press “Remove device” or the keyboard Delete key. The confirmation message appears. Click the Yes button.



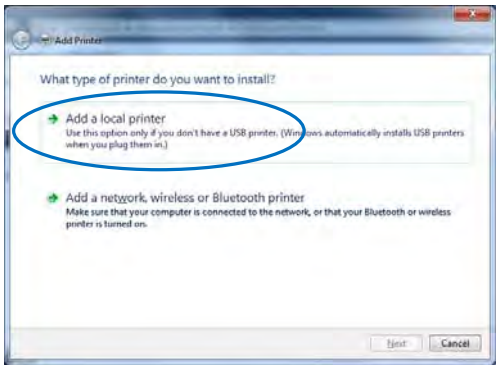
3) Close the Devices and Printers window.

Installing the Network Printer

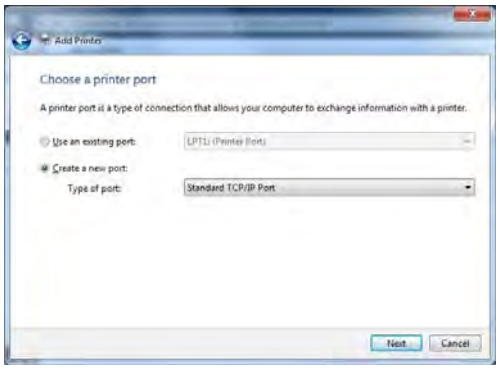
Install the printer to be used by Prefense.

1) Click the Windows Start button then select “Devices and Printers” to open the Devices and Printers window.

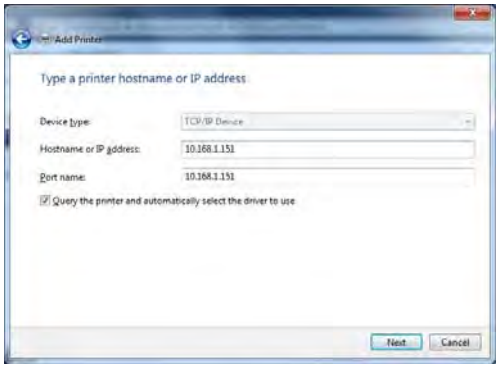
2) Click “Add a printer”, then choose “Add a local printer” and click Next.



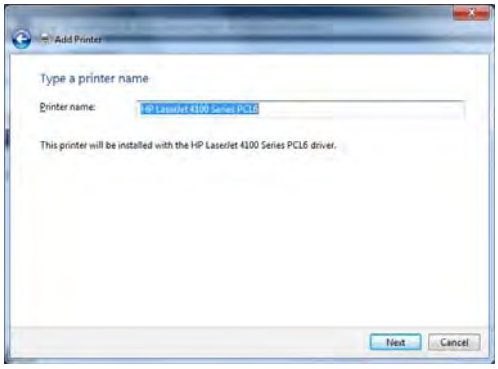
3) Select “Create a new port” and set the Type of port to “Standard TCP/IP Port” and click Next.



4) Enter the IP address of the printer. Click Next.



5) Click Next to accept the default printer name.

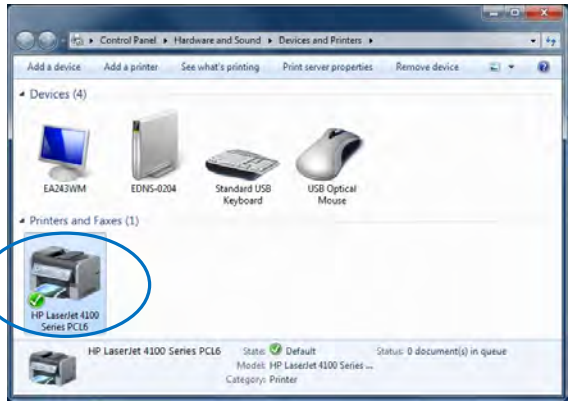


6) Click Finish to complete the installation.

NOTE

Even if more than one central monitor uses one printer, do not share this printer. You can use the printer with two or more monitors connected.

7) On the Devices and Printers window, confirm that an icon for the newly created printer is added with a check mark to indicate that it is the default printer.



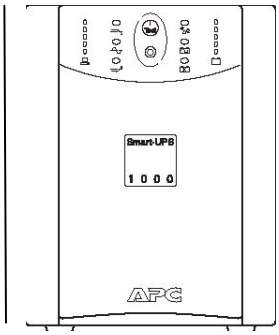
8) Close the Devices and Printers window.

11. UPS

WARNING

- **Periodically check the lifetime of the UPS battery. Replace the battery when the lifetime expires. If the battery is used beyond its lifetime, liquid leakage, smoke, fire or explosion may occur.**
- **Make sure that the UPS is properly grounded. Otherwise the operator may receive electrical shock.**

Recommended UPS: American Power Conversion, Smart UPS



The recommended model may be changed without notice. Contact your Nihon Kohden distributor or representative when you locally purchase a UPS.

Read the UPS manual thoroughly.

We suggest using the recommended UPS. However, if the recommended UPS cannot be acquired, use a UPS which satisfies the following specifications.

- It has an equipotential grounding terminal.
- The output wave is a sine wave. (When the output wave is a square wave, the AC voltage may become lower due to the AC filter.)
- Inverter type. (With a switch type, noise may interfere when the power changes from AC to battery.)
- An alarm sound is generated at the power failure and the alarm cannot be turned off.

12. Mount EDNS-9001 to LCD Display

The EDNS-9001 main unit can be mounted to the back of the LCD display to save desk space.
To mount the EDNS-9001 main unit to the back of the LCD display, perform the following steps:

1) Slide the main unit into the mounting bracket as shown. Attach the main unit to the bracket using 4 of the 8 small black screws included with the Prefense but do not tighten completely at this time.

2) Use the remaining 4 small black screws for the opposite side of the bracket. Completely tighten all 8 of the screws only after all screws have been inserted.

3) Attach the cables to the main unit and then gently slide the completed assembly onto the back of the LCD mounting arm as shown.

13. Installing Prefense EDNS-9001

WARNING

Install Prefense and external instruments outside the patient environment (IEC 60601-1-1 2.202). If they are installed inside the patient environment, the patient or operator may receive electrical shock or other injury. For installation, contact your Nihon Kohden distributor or representative.

CAUTION

- **Connect only the specified instruments to Prefense and external instruments by following the specified procedure. Otherwise electrical leakage current may harm the patient and operator.**
- **Before connecting or disconnecting instruments, turn each instrument off and disconnect each power cord from the AC socket. Failure to follow this caution may cause electrical shock. Also, instruments may get damaged.**
- **Only use the provided power cord. Using other power cords may result in electrical shock or other injury to the operator.**
- **Do not let connection cables stick out; run them along the floor or wall. If people trip over the cable, the monitor may tip over and it may cause injury.**

NOTE

While Prefense is on, do not touch unused sockets. Failure to follow this caution damages the Prefense system by static electricity and causes malfunction.

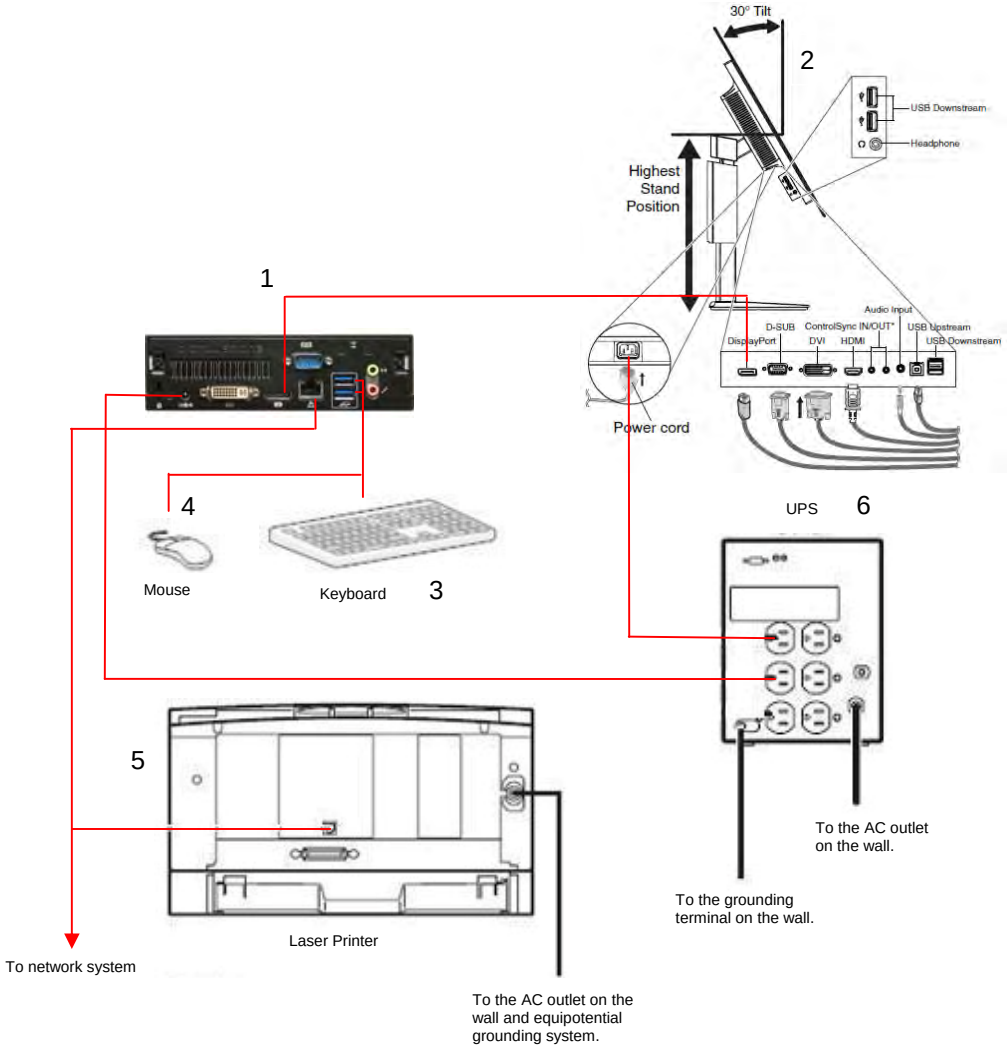
WARNING

The date and time must only be modified from Prefense's Maintenance screen. Do not attempt to modify the date and time outside of the Prefense software.

13.1 Connection Diagram

This section describes how to install the following instruments.

1) EDNS-9001 Main Unit
2) EDNS-WSxx LCD Display
3) USB Keyboard
4) USB Mouse
5) Laser Printer (optional)
6) UPS



13.2 Installing the UPS

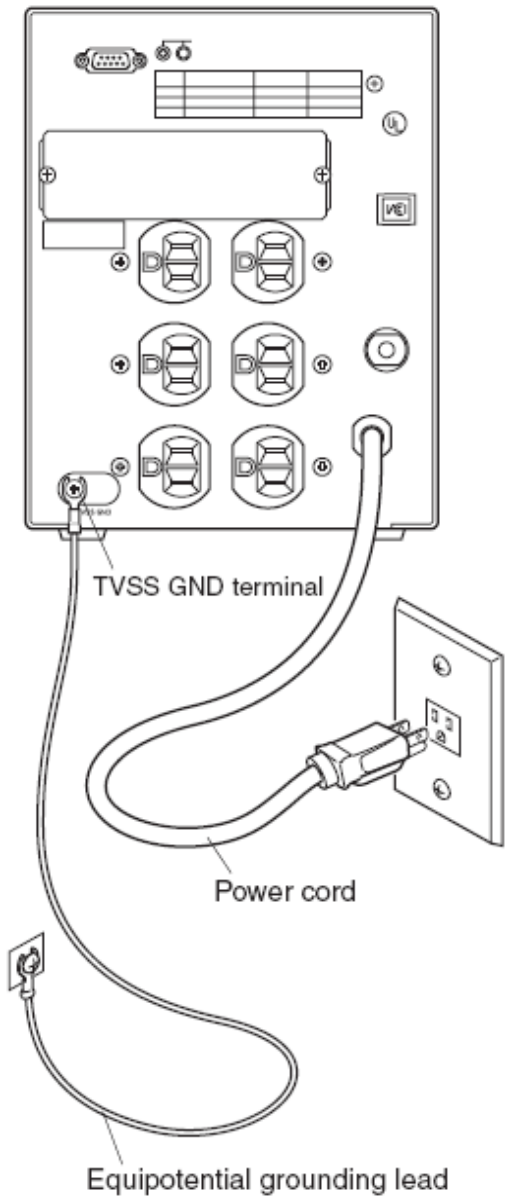
A sudden loss of power supply or an extreme power surge can damage the EDNS-9001 and delete stored data. To assure an uninterrupted power supply, we recommend using the specified UPS. Follow the instructions in this guide and the UPS manual.

WARNING

- **Install the UPS as specified in this guide and UPS manual. Otherwise the installation may not satisfy safety standards.**
- **Make sure that the UPS is properly grounded. Otherwise the operator may receive electrical shock.**
- **Periodically check the lifetime of the UPS battery. Replace the battery when the lifetime expires. If the battery is used beyond its lifetime, liquid leakage, smoke, fire or explosion may occur.**

NOTE

- **The battery lifetime of the UPS may be shortened when the environmental temperature rises. Install the UPS as described in the UPS manual and make sure that the vent holes of the UPS are not obstructed. Install the UPS where it is easy to periodically check the UPS.**
- **Install the UPS where the alarm sound can be heard. If the alarm cannot be heard, the battery may become dead without anyone's notice and result in data loss and instrument damage.**
- **Do not exceed the capacity of the UPS. Otherwise the UPS may not operate properly when there is a power failure.**
- **When there is a power failure, immediately shut down Prefense system and turn Prefense power off. Otherwise data may be lost or the instrument may be damaged when the battery lifetime of the UPS expires.**
- **We recommend using the specified UPS. However, if the recommended UPS cannot be acquired, use a UPS which satisfies the following specifications.**
    - **It has an equipotential grounding terminal.**
    - **The output wave is a sine wave. (When the output wave is a square wave, the AC voltage may become lower due to the AC filter.)**
    - **Inverter type. (With a switch type, noise may interfere when the power changes from AC to battery.)**
    - **An alarm sound is generated at the power failure and the alarm cannot be turned off.**



1. Connect the UPS power cord to the 3-prong AC outlet on the wall.

CAUTION

Do not connect the power cord of the laser printer to the UPS which Prefense main unit is connected to. An extreme power surge may be caused by the laser printer which may interfere with the UPS operation and turn off the system. Connect the power cord of the laser printer to the AC outlet on the wall.

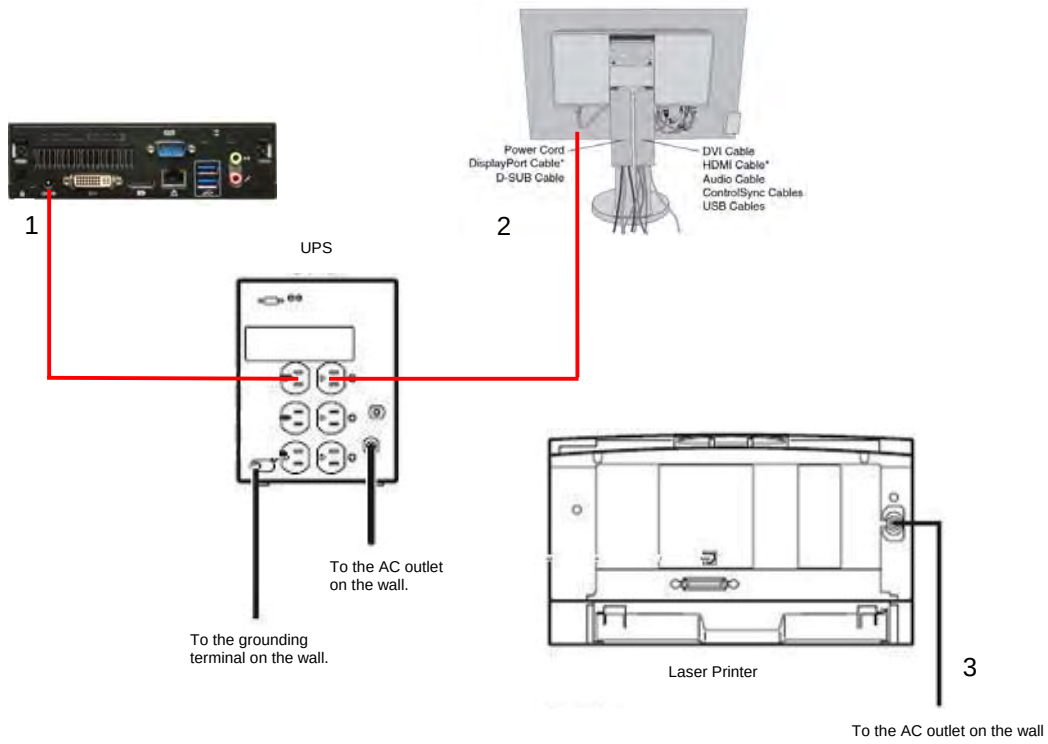
2. Connect the equipotential grounding lead of the UPS (optional) to the TVSS GND terminal on the UPS and to the equipotential grounding terminal on the wall.

WARNING

Make sure that the UPS is properly grounded. Otherwise the operator may receive electrical shock.

13.3 Connecting Each Instrument Power Cord to the UPS

1) Connect the power adapter from the power brick to the EDNS-9001 main unit and the power cord of the power brick to an open socket on the UPS.
2) Connect the power cord of the EDNS-WSxx LCD display to an open socket on the UPS. Loop the power cord through the securing hooks on the back of the LCD stand.
3) Connect the power cord of the laser printer to the AC outlet on the wall and the AC source socket on the rear panel of the laser printer



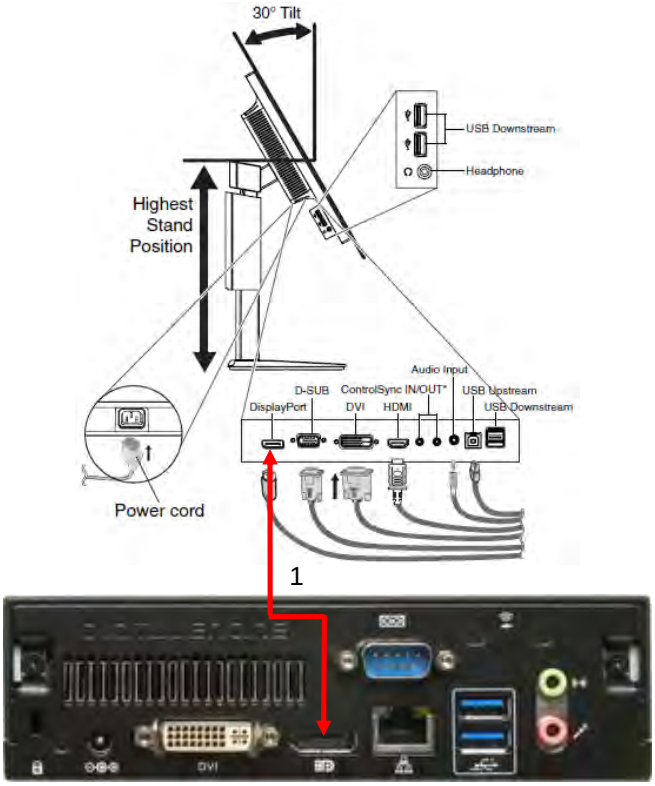
13.4 Connecting External Instruments to the EDNS-9001 Main Unit

CAUTION

- **Before connecting or disconnecting instruments, turn each instrument off and disconnect each power cord from the AC socket. Failure to follow this caution may cause electrical shock. Also, instruments may get damaged.**
- **Connect only the specified instruments to Prefense and external instruments by following the specified procedure. Otherwise, electrical leakage current may harm the patient and operator.**

13.4.1 Connecting EDNS-WSxx LCD display to EDNS-9001 main unit

1) For easier access to the connectors on the EDNS-WSxx LCD display, place a hand on each side of the monitor to tilt the LCD display to a 30-degree angle and lift up the monitor to its highest position. Connect one end of the display cable to the EDNS-WSxx LCD display and the other end to the EDNS-9001 main unit.



WARNING

- **Do not turn off the display which the main unit is connected to. Otherwise there is no alarm sound.**
- **Do not adjust the sound volume at the display unit. If you decrease the display unit volume to the minimum, there is no alarm sound.**
- **Do not plug headphones into headphone jack. Alarm sounds are redirected to headphones instead of the speakers.**

13.4.2 Connecting USB Keyboard and Mouse to EDNS-9001 Main Unit

1) Connect the USB keyboard to a USB port on the rear panel of the EDNS-9001 main unit.
2) Connect the USB mouse to another USB port on the rear panel of the EDNS-9001 main unit.

13.4.3 Connecting the EDNS-9001 Main Unit to the Network System

The network installation must comply with IEC 60601-1-1 “Safety Requirements for Medical Electrical Systems”. Consult with a biomedical engineer or Nihon Kohden distributor.

The connection method and grounding method depends on the location where the Prefense EDNS-9001 is installed and the types and installation locations of the other instruments. When the network system is composed of two instruments, connect these two instruments with a cross cable. When the network system is composed of more than two instruments, connect the instruments to the hub with a straight cable.

WARNING

Do not use a damaged network cable. Otherwise patient or operator may get an electrical shock when the damaged part is touched.

CAUTION

Before connecting or disconnecting instruments, turn each instrument off and disconnect each power cord from the AC socket. Failure to follow this caution may cause electrical shock. Also, instruments may get damaged.

NOTE

Make sure that the correct cable is used for connecting the instruments. Otherwise communication between the instruments cannot be performed properly.

14. System Startup

14.1 Power On Flowchart

Turn on the power of the instruments in the following order.

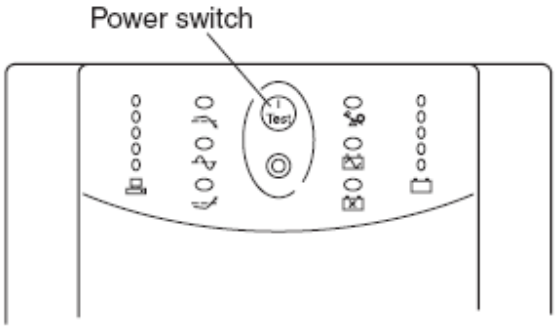
1) UPS
2) EDNS-WSxx LCD Display
3) EDNS-9001 Main Unit

The following instruments can be turned on at any time.

- Laser printer
- Multiple patient receivers
- Transmitters

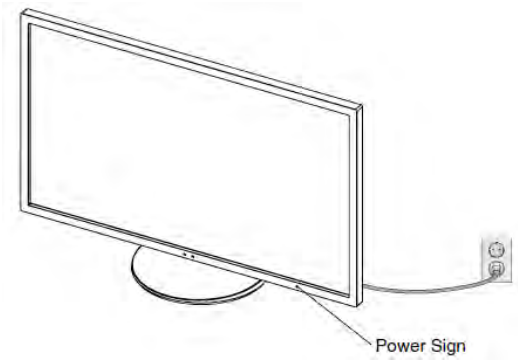
14.2 Turning the UPS Power On

Press the power switch on the front panel to turn the power on. Also read the UPS manual.



14.3 Turning the EDNS-WSxx LCD Power On

Press the power button on the front panel to turn the power on. The power LED will emit a blue glow when the power is on.



NOTE

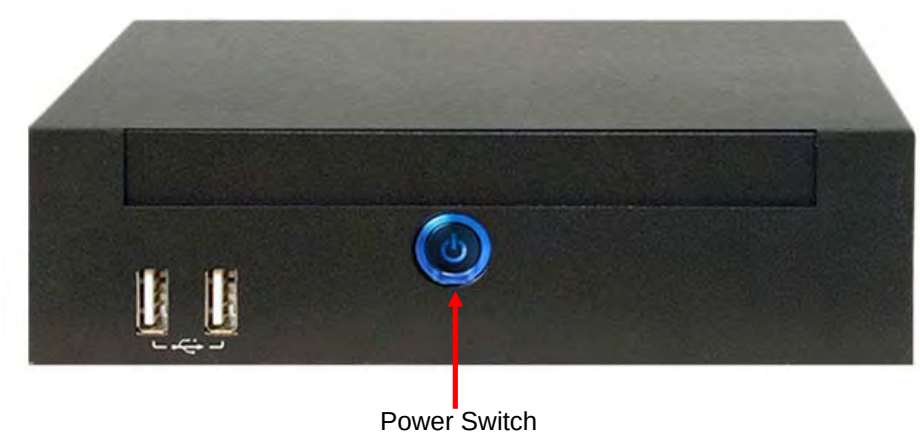
- **If the power switch does not emit a blue glow, check the power cord connection. The power switch does not emit a blue glow if no power is supplied to the instrument.**
- **It may take a few minutes for the LCD screen to reach full brightness.**
- **The shadow of the previous screen may remain for a few minutes after changing screens.**

CAUTION

- **Periodically check LCD signal indicator. When LCD has no power its power light is off and when no signal is received the LCD power light is orange. Normal condition is blue.**

14.4 Turning the EDNS-9001 Main Unit Power On

Press the power switch on the front panel to turn the power on. The power switch will emit a blue glow when the power is on. The Prefense monitoring system starts automatically when the EDNS-9001 main unit is turned on.



Power Switch

NOTE

If the power switch does not emit a blue glow, check the power cord connection. The power switch does not emit a blue glow if no power is supplied to the instrument.

14.5 Check After Installation and Connection

After you finished installation and connection of Prefense EDNS-9001 and other instruments, turn the power of all the instruments on to start the system and check the following items. If there are any problems, confirm that all installation and connection are done correctly.

- After turning the power on, the Prefense system starts automatically and the Home screen is displayed.
- No error message is displayed on the Prefense screen.
- The keyboard, mouse, and switches operate properly.

15. Shutting the System Down

Turn the power off in the following order.

1) EDNS-9001 Main Unit
2) EDNS-WSxx LCD Display
3) Other instruments

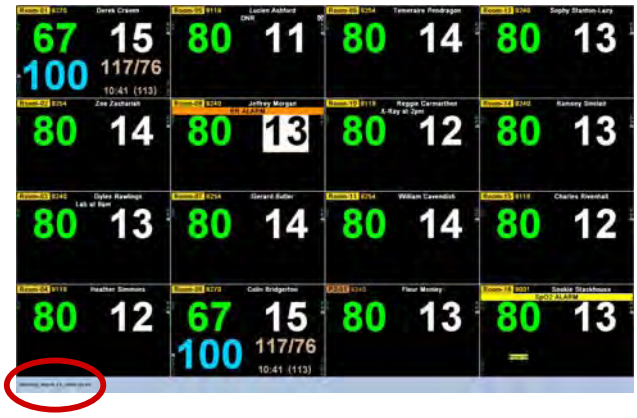
CAUTION

The Prefense EDNS-9001 power must be turned off in the specified order. Otherwise, patient data will be deleted and other data in the hard disk or the hard disk may be damaged.

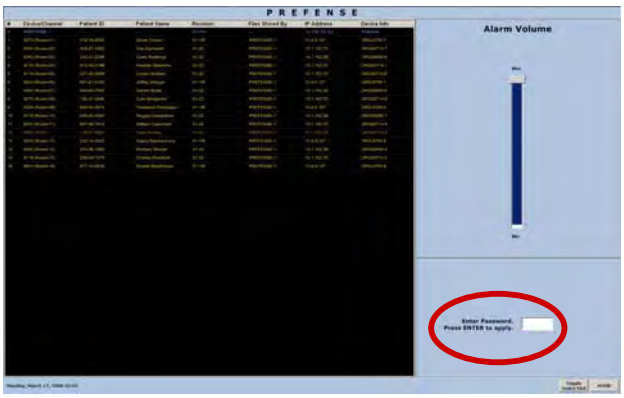
NOTE

- **When the patient is transferred from one central monitor to another, the data before the patient transfer is stored on the first central monitor. If this first central monitor power is turned off, the data before the patient transfer cannot be displayed on the second central monitor.**
- **Leave the power of the UPS and multiple patient receiver on.**

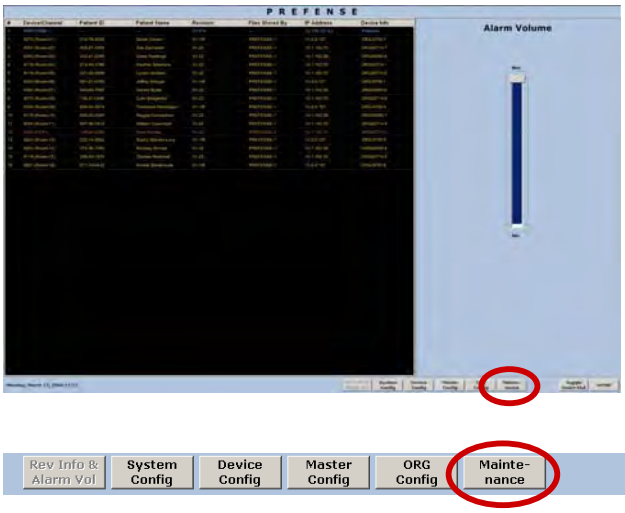
1. Shut down the Prefense monitoring system.
   1) Click on the Date and Time in the lower left corner of the Prefense Home screen.



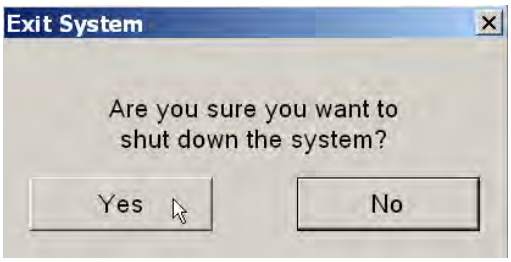
   2) Enter the password at the Revision Information and Alarm Volume screen, default is **1234**.



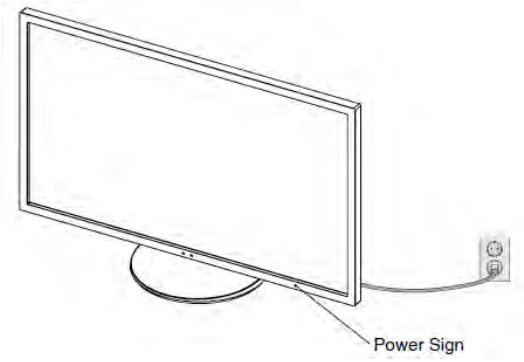
3) Click on the Maintenance button from the configuration menu.



4) In the Maintenance screen, click on the Exit System button in the upper right corner. Click Yes in the confirmation dialog box that appears. The EDNS-9001 main unit power turns off automatically.



2. Turn the EDNS-WSxx LCD display power off.



3. Turn the laser printer power off, if necessary.

16. Servicing the Prefense EDNS-9001

This service guide provides useful information to qualified service personnel to understand, troubleshoot, service, maintain, and repair the Prefense EDNS-9001. It is important for service personnel to thoroughly read the operator's manual and service manual before starting to troubleshoot, service, maintain or repair the Prefense EDNS-9001. This is because service personnel need to understand the operation of the Prefense system in order to effectively use the information in the service manual.

16.1 General Information on Servicing

WARNING

To avoid the possibility of injury to yourself or damage to the Prefense system, do not install or remove any component while the power is on. When disassembling, make sure that the Prefense system is turned off and the power cord is disconnected from Prefense and AC outlet. There is a high voltage circuit on the power unit.

CAUTION

Safety

- **There is the possibility that the outside surface of the Prefense system, such as the operation keys, could be contaminated by contagious germs so disinfect and clean the Prefense system before servicing it. When servicing the Prefense system, wear rubber gloves to protect yourself from infection.**
- **There is the possibility that when the lithium battery or LCD unit is broken, a solvent could flow out or a toxic substance inside it could come out. If the solvent or toxic substance contacts the eyes or skin, wash immediately and thoroughly with water and see your physician. Never rub your eyes; otherwise you may lose your eyesight.**
- **To avoid accidental electrostatic discharge which could damage the components of the Prefense system, use a grounded wrist strap when installing or removing any component of the Prefense system.**
- **Use a pair of clean cotton gloves when replacing the LCD unit. If it is damaged, your hand may get injured.**

Liquid Ingress

The Prefense system is not waterproof, so do not install the Prefense system where water or liquid can get into or fall on the Prefense system. If liquid accidentally gets into the Prefense system or the Prefense system accidentally falls into liquid, disassemble the Prefense system, clean it with clean water and dry it completely. After reassembling, do the patient safety checks and function/performance checks to verify that there is nothing wrong. If there is something wrong with the Prefense system, contact your Nihon Kohden representative for repair.

Environmental Safeguards

Depending on the local laws in your community, it may be illegal to dispose of the lithium battery in the regular waste collection. Check with your local officials for proper disposal procedures.

Disinfection and Cleaning

To disinfect the outside surface of the Prefense system, wipe it with a nonabrasive cloth moistened with any of the disinfectants listed below. Do not use any other disinfectants or ultraviolet rays to disinfect the Prefense system.

- **Chlorohexidine gluconate solution: 0.5%**
- **Benzethonium chloride solution: 0.2%**
- **Glutaraldehyde solution: 2.0%**
- **Benzalkonium chloride: 0.2%**
- **Hydrochloric alkyl diaminoethylglycine: 0.5%**

Only clean LCD with water on a soft cotton cloth.

Transport

- **Use the specified shipment container and packing material to transport the Prefense system. If necessary, double pack the LCD display. Also, put the LCD display into the shipment container after packing so that the buffer material does not get inside the display.**
- **When transporting a board or unit of the Prefense system, be sure to put it in a conductive bag. Never use an aluminum bag to transport a board or unit. Also, never use a styrene foam or plastic bag which generates static electricity to wrap the board or unit of the Prefense system.**

Handling the LCD

- **Because the outside surface of the LCD display is made of resin, the outside surface of the LCD is easily damaged. So when handling the LCD, remove clutter from around the LCD and be careful to not damage the LCD or get it dirty.**
- **Because most of the boards in the LCD are multilayer boards with surface mount electrical devices (SMD), a special tool is required to remove and solder the electrical devices on it. To avoid damaging other electrical components, do not remove and solder SMD components yourself.**

Measuring and Test Equipment

Maintain the accuracy of the measuring and test equipment by checking and calibrating it according to the check and calibration procedures.

Lithium Battery

- **Before disposing of the battery, check with your local solid waste officials for details in your area for recycling options or proper disposal. The battery is recyclable. At the end of its useful life, under various state and local laws, it may be illegal to dispose of this battery into the municipal waste stream.**

16.2 Service Policy, Service Parts and Patient Safety Checks

Service Policy

Our technical service policy for the Prefense system is to replace the faulty unit, board or part or damaged mechanical part with a new one. Do not perform electrical device or component level repair of the multilayer board or unit. We do not support component level repair outside the factory for the following reasons:

- Most of the boards are multilayer boards with surface mount electrical devices, so the mounting density of the board is too high.
- A special tool or high degree of repair skill is required to repair the multilayer boards with surface mount electrical devices.

As background knowledge for repair, pay special attention to the following:

- To reduce the repair time, consider the problem before starting repair.
- To clarify the source of the troubles, use the information described in the troubleshooting section.

Service Parts

NOTE

When ordering parts or accessories from your Nihon Kohden representative, please quote the product name and part number which is listed in this service manual, and the name or model of the unit in which the required part is located. This will help us to promptly attend to your needs. Always use parts and accessories recommended or supplied by Nihon Kohden to assure maximum performance from your monitor.

Maintenance Equipments and Tools

Test equipment

When repairing or calibrating the Prefense system, the following test equipment is required.

- Digital voltmeter: standard type (An oscilloscope can be used instead of the digital voltmeter.)

16.3 Important Safety Information for Servicing

Discharge and Receiving Channel Change

WARNING

- **Confirm that the channel number of the appropriate transmitter is displayed on the Prefense screen. If the channel number on the screen is different from the transmitter channel, data of a different patient will be monitored or no signal will be received by Prefense.**
- **Do not use the same channel for different patients. Otherwise two patients' data will be lost due to mutual modulation interference or another patient's data may appear on the Prefense system screen.**
- **When you change the receiving channel to monitor a new patient, first delete all data of the previous patient. Otherwise, the data of the previous patient and new patient will be mixed together and cause misunderstanding of the patient history.**

Pause

WARNING

- **When a paused patient returns, resume monitoring for the patient. During Pause, there is no display of measurement values, no alarm function and no data saving.**

Patient Transfer

CAUTION

- **Keep the source multiple patient receiver and the destination multiple patient receiver powered on and connected to the network until the patient transfer is complete. Otherwise the patient transfer fails and the data is lost. After transferring the patient, confirm that the data before the patient transfer can be displayed at the destination bed.**
- **When the patient is transferred more than eight times between different devices in the network, the data on the first device is deleted.**

Alarm

WARNING

- **When the SUSPEND key on the transmitter is pressed (when the alarms are suspended at the transmitter), all alarm functions for the patient are turned off.**
- **For arrhythmia monitoring, set Arrhythmia Analysis on the Parameter Settings screen to ON. Otherwise, there is no sound or indication for arrhythmia alarms.**
- **When admitting a new patient, confirm alarm settings. For a bed monitored via ORG-9000 series multiple patient receiver, the alarm settings become the Alarm Master selected at the Admit/Discharge screen.**
- **Securely connect the display cable. There is no alarm sound if the cable is not connected.**
- **Do not plug headphones into headphone jack. Alarm sounds are redirected to headphones instead of the speakers.**
- **When the communication loss alarm is set to OFF, there will be no**

communication loss alarm. When the communication loss alarm is set to OFF, pay careful attention to the communication status of the bed.

CAUTION

- **When the alarm limit is set to OFF, there will be no alarm for that limit. Be careful when you set the alarm limit to OFF.**
- **When the alarm is turned OFF for an arrhythmia, there will be no alarm for that arrhythmia type. There is no message or mark to indicate that a certain arrhythmia alarm is turned off. Therefore, be careful when an arrhythmia alarm is turned off.**
- **When the communication loss alarm in the confirmation mode is silenced, an alarm for the same alarm condition does not occur again while communication is still lost. In confirmation mode, always pay careful attention to the communication status.**
- **Changing the alarm settings on a CO_2 monitor does not affect the CO_2 alarm limits on the Prefense (and vice-versa).**

ECG Monitoring

CAUTION

- **If there is any doubt about the arrhythmia analysis, make Prefense relearn the patient's ECG and check that the dominant QRS is appropriate. Otherwise, an important arrhythmia may be overlooked.**
- **The Prefense has a time delay of approximately several seconds because of network connection.**
- **When "ECG Measurement" on the Parameter Settings screen is set to OFF, there will be no ECG related alarms even when the alarms are set to ON.**
- **Turn the pacing detection to ON when monitoring a pacemaker patient. Otherwise QRS and pacemaker spike might not be distinguished and pacing failure might not be recognized.**

Respiration Measurement

CAUTION

- **When measuring respiration by impedance method and "Impedance Respiration Measurement" on the Parameter Settings screen is set to OFF, there will be no respiration related alarms even when the alarms are set to ON.**

NIBP Measurement

WARNING

- **When performing long term measurement at intervals less than 2.5 minutes, observe the state of the patient, blood vessels and limb for adequate circulation.**
- **Congestion may occur at the measurement site. When performing periodic measurement for a long term, periodically check the circulation condition.**

CAUTION

- **Do not disassemble or repair Prefense. Disassembly and repair must be performed by qualified service personnel. When there is any abnormality, contact your Nihon Kohden representative.**
- **Before maintenance, cleaning or disinfecting, turn Prefense power off and disconnect the power cord from the AC socket. Failure to follow this instruction may result in electrical shock and Prefense malfunction.**
- **During maintenance and inspection, patients monitored by Prefense must be monitored by alternate instruments such as CNS-9701A or bedside monitors.**
- **Software upgrade must only be done by qualified service personnel. If upgrade is not done correctly, Prefense may malfunction.**
- **Do regular inspection according to the cycle specified by Nihon Kohden. Otherwise, the decrease and loss in function are overlooked and it results in incorrect monitoring.**
- **Restart Prefense once every three months. Otherwise operation may become unstable and monitoring may stop. While restarting, patients monitored by Prefense must be monitored by alternate instruments such as CNS-9701A or bedside monitors.**
- **Replace the hard disk once every two years. If the hard disk is damaged, monitoring is incorrect and all data saved in Prefense is lost.**
- **Follow your hospital regulations to handle blood or bodily fluids on the display.**
- **Be careful not to let any liquid get inside the display.**

17. Login Accounts

There are two types of login accounts available on the Prefense EDNS-9001 - the Prefense account and the Biomed account.

17.1 Prefense Account

The Prefense account is only used to run the Prefense program. The account name is **Prefense** and the default password is **1234**. No Windows system settings changes can be made from this account. All Windows system settings changes must be made from the Biomed account. The Prefense registration program prompts for the *Prefense* account's password.

17.2 Biomed Account

The Biomed account has administrative privileges that will allow Biomed personnel to make changes to the Windows system settings. The account name is **Biomed** and the default password is **1234**. The Biomed account should be used to change the IP address, computer name, update the Prefense software, change the default password for the Biomed account, and register the Prefense program. The Prefense registration program prompts for the *Prefense* account's password.

CAUTION

If you change the account name or default password for the Biomed account, please make sure that other Biomed personnel have access to the new account name and password.

17.2.1 Logging Into the Biomed Account

To log into the Biomed account, perform the following steps:

1) While the Prefense program is running, go to the Home screen (All Beds), press Ctrl + Alt + Delete on the keyboard, then log off the Prefense account.
2) Log on to the Prefense EDNS-9001 using the account name **Biomed**. The default password is **1234**.
3) Make any necessary changes, then log off the Biomed account.
4) Either a) restart the PC or b) log on to the Prefense EDNS-9001 using the account name **Prefense** to start the Prefense program. The default password is **1234**.

WARNING

Do not initialize the Security Platform state. Ignore the following message if it pops up. "The Security Platform state is "Not initialized". Click here to initialize now."

18. Backup/Restore Prefense System Settings

Prefense system settings can be backed up to a removable USB storage device to ensure that the settings are preserved when an existing Prefense system is being replaced with a new one, the existing Prefense software is being updated with new software, or to set up multiple Prefense systems with the same system settings. To set up multiple Prefense systems with the same settings, configure the desired system settings on one Prefense, backup the settings to the removable USB storage device *before* any devices are selected, and then restore those settings on different Prefense systems.

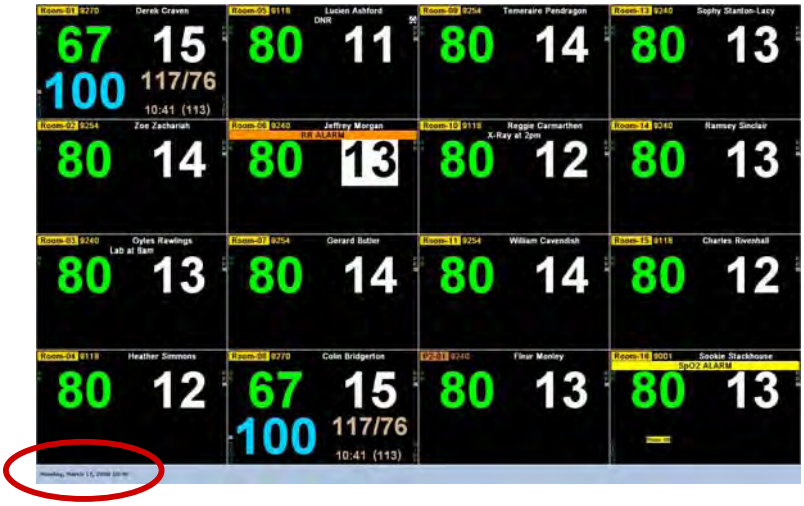
Please reference the Operator's Manual for the list of Prefense settings that are backed up and restored.

18.1 Backup System Settings

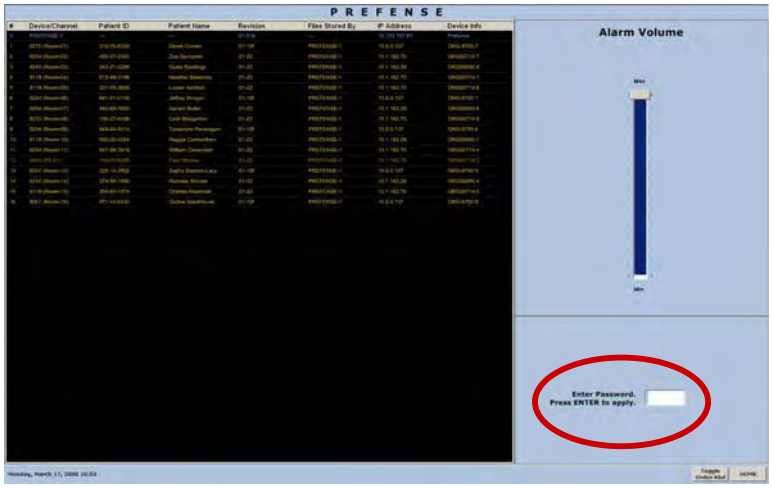
To backup the system settings, perform the following steps:

1) While the Prefense program is running, insert a removable USB storage device into one of the two USB ports on the front panel of the EDNS-9001 main unit.

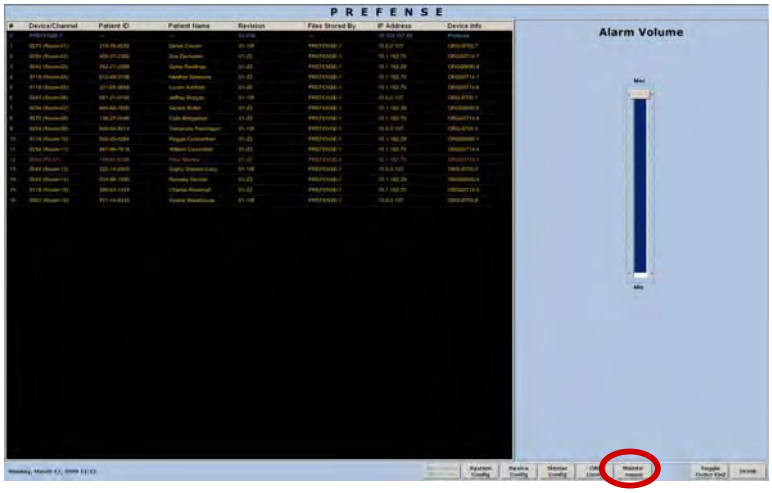
2) Click on the Date and Time in the lower left corner of the Prefense Home screen.



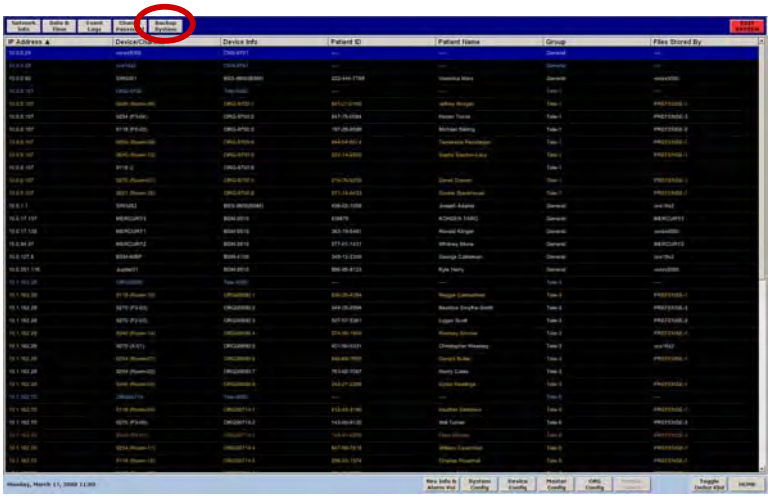
3) Enter the password at the Revision Information and Alarm Volume screen, default is **1234**.



4) Click on the Maintenance button from the configuration menu.



5) Click on the Backup System button at the top of the Maintenance screen.



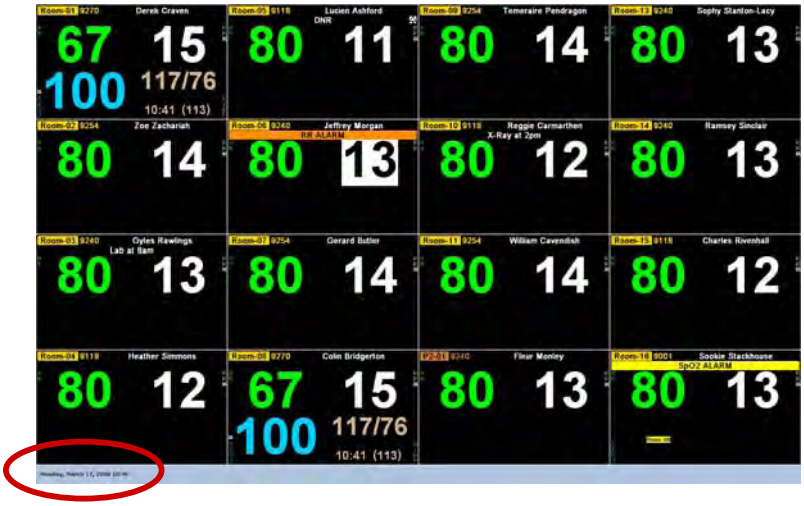
The following window will be displayed when the backup finishes.

18.2 Restore System Settings

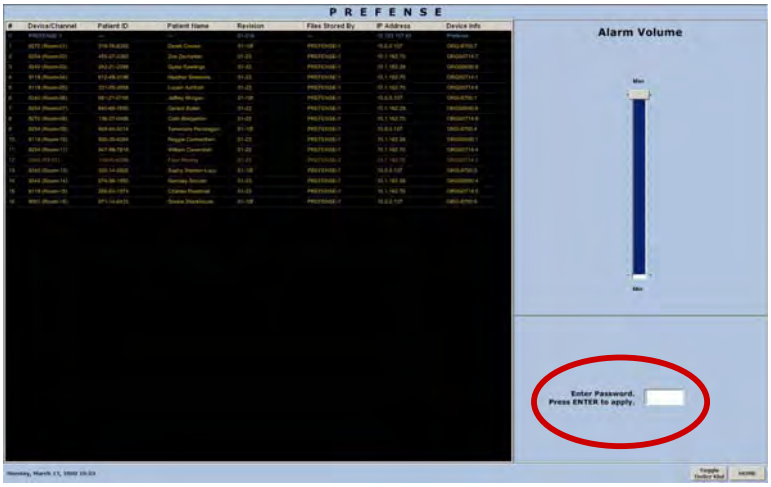
To restore the system settings, perform the following steps:

1) While the Prefense program is running, insert a removable USB storage device containing the backup file (Prefense.hiv) into one of the two USB ports on the front panel of the EDNS-9001 main unit.

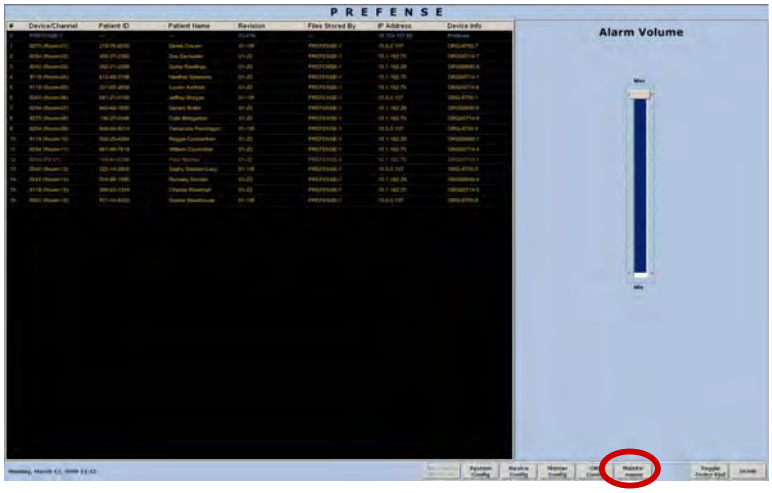
2) Click on the Date and Time in the lower left corner of the Prefense Home screen.



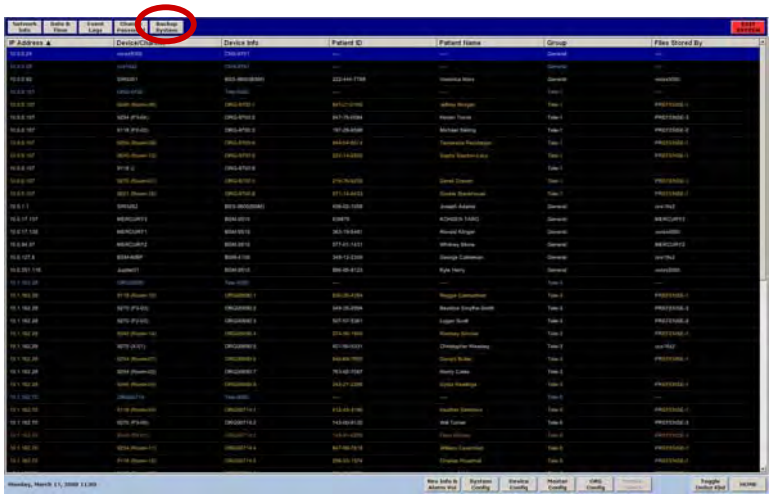
3) Enter the password at the Revision Information and Alarm Volume screen, default is **1234**.



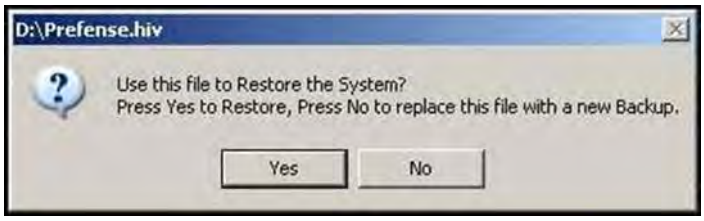
4) Click on the Maintenance button from the configuration menu.



5) Click on the Backup System button at the top of the Maintenance screen.



6) Click “Yes” to restore the system settings.



19. Troubleshooting

How to use the troubleshooting table

1. Determine which troubleshooting table to use.
2. In the “Problem” column, find the trouble item that matches the problem.
3. Do the action recommended in the “Action” column.
4. If the problem is not solved, do the action for the next possible cause or criteria.
5. If none of the actions solve the problem, contact your Nihon Kohden representative.

NOTE

Before contacting your Nihon Kohden representative for technical support, please provide additional detailed information on the problem. This will allow your Nihon Kohden representative to provide you with the best support.

19.1 System

Problem	Possible Cause/Criteria	Action
Data is deleted when Prefense power is turned off.	Faulty hard disk.	Contact your Nihon Kohden distributor or representative. The Prefense EDNS-9001 may lose its function as a monitor.
The system crashes when trying to review the past data.		
The system crashes periodically such as once a day.		
Incorrect date and time.	Clock error	Contact your Nihon Kohden distributor or representative.
	If the clock becomes incorrect after adjusting the clock and turning Prefense EDNS-9001 power on again, the back-up battery is weak.	
• Slow operation. • It takes time to read out the saved data. • Malfunction	Windows is unstable.	Shut down the Prefense EDNS-9001 system program and restart it. For a stable operation, restart the Prefense EDNS-9001 system program once every three months.

19.2 Network

Problem	Possible Cause/Criteria	Action
A desired bed is not displayed in the selected group.	The multiple patient receiver for that bed is turned off.	Turn on the multiple patient receiver.
	The desired bed belongs to another group.	On the Device Configuration screen, check other groups to find the desired bed. Check group names of each multiple patient receiver.

Problem	Possible Cause/Criteria	Action
The light near the network socket on the main unit does not light and the main unit cannot communicate with any instrument connected to the network.	The network cable is loose at the socket.	Check that the network cable and its connectors at both ends have no damage and check the continuity. After these checks, firmly connect the cable between the main unit and hub.
	The hub connected to the main unit through the network cable has a failure.	Replace the hub with a new one.
The Prefense time does not match the other patient monitoring equipment.	The IP address used requires a persistent route to be added to Windows 7.	Use the instructions in Step 15 of the Installation Flowchart.

19.3 Measurement Value

Problem	Possible Cause/Criteria	Action
Heart rate is not counted correctly.	Waveform too large or too small.	Adjust the QRS detection sensitivity by modifying the real-time ECG waveform display sensitivity at the Waves and Events screen.
	QRS detection threshold was changed.	
	QRS and pacemaker spikes are not distinguished.	Turn pacing detection ON.
	QRS detection is set to “Manual”.	Set QRS detection to “Auto” by modifying the real-time ECG waveform display sensitivity at the Waves and Events screen.
Arrhythmia is not measured correctly.	ECG learning is not correct.	Relearn patient’s ECG.
	The arrhythmia analysis is set to OFF on the Parameter Settings screen.	Turn the arrhythmia analysis to ON on the Parameter Settings screen.
Heart rate and arrhythmia are not measured correctly.	ECG lead that is inappropriate for analysis is selected.	Change the ECG lead use for analysis.
Noise on the ECG waveform	Hum interference on the ECG waveform.	Set the hum filter to ON.
Respiration is not measured correctly.	Waveform too large or too small.	Set the proper sensitivity.
	Respiration sensitivity was changed.	
	Respiration measurement is set to OFF.	Turn respiration measurement ON.

19.4 Alarm

Problem	Possible Cause/Criteria	Action
No alarm.	Each alarm setting in the Alarm Settings screen is set to OFF.	Turn the alarms ON for the bed.

Problem	Possible Cause/Criteria	Action
	The arrhythmia analysis is set to OFF on the Parameter Settings screen.	Turn the arrhythmia analysis to ON on the Parameter Settings screen.
All alarms for a bed cannot be turned ON/OFF together.	---	This operation is not available at the Prefense EDNS-9001.

19.5 Home Screen

Problem	Possible Cause/Criteria	Action
Numeric data and messages disappear for a moment.	The display is refreshed. This is normal.	---
Numeric data is not displayed.	The parameter of the numeric data is not selected as the displayed parameter.	None. Heart rate or pulse rate, SpO2, respiration rate and NIBP are automatically displayed if they are being measured.
	The label of the currently measured numeric data is different from the label to be displayed.	Confirm the setting so that the label of the currently measured numeric data matches the label to be displayed.
The desired parameter cannot be displayed.	The parameter is a parameter that cannot be displayed.	None. Prefense only supports vital signs for non-invasive parameters ECG, NIBP, SpO_2 and Respiration.

19.6 Admitting/Discharging

Problem	Possible Cause/Criteria	Action
Cannot transfer a patient's data.	You are trying to do this operation on a Prefense EDNS-9001 where the patient's data is not saved.	Do this on the Prefense EDNS-9001 where the patient's data is saved.
Cannot change the receiving channel.		
Cannot admit/discharge a patient.	You are trying to do this operation on a Prefense EDNS-9001 where the patient's data is not saved.	Do this on the Prefense EDNS-9001 where the patient's data is saved.
	The multiple patient receiver is turned off.	Turn on the multiple patient receiver.
Cannot select a bedside monitor as a transfer destination bed.	The bedside monitor is turned off.	Turn on the bedside monitor.
The patient's data before patient transfer is lost.	The patient was transferred to different beds more that 8 times.	To save the patient's data in the first Prefense EDNS-9001, do not transfer the patient more than 8 times.
The patient's data before patient transfer cannot be reviewed.	The Prefense EDNS-9001 where the patient's data is saved is turned off.	Turn on the Prefense EDNS-9001 where the patient's data before the patient transfer is saved.

Problem	Possible Cause/Criteria	Action
The message “Transferring” is displayed on the screen but it does not change to “Completed”.	During patient transfer, the Prefense EDNS-9001 was turned off or there was a problem on the network and the transfer failed.	The lost data cannot be restored.
All patient’s data was lost after patient transfer.		
“All receivers are currently in use” error message is displayed when you try to start monitoring a bed in floating bed assignment mode.	Prefense Group is incorrect.	Go to System Configuration screen and set up Prefense Group.
	No receivers available in your Prefense Group with the necessary channel band.	Confirm this by going to the Device Configuration screen and check that all the beds in your group and channel range have a non-blank “Files Stored By” column, thus indicating they all have a Master Storage Device.
		Discharge a patient then try monitoring the channel again.

19.7 Vital Signs Review Screen

Problem	Possible Cause/Criteria	Action
Trend data is not displayed.	Prefense that is storing the bed’s data is turned off.	Turn on Prefense where the bed’s data is saved.
Trend data is not saved.	Prefense where the bed’s data is saved was turned off during measurement.	Trend data is not created when Prefense where the bed’s data is saved is turned off.

19.8 Waves and Events Screen

Problem	Possible Cause/Criteria	Action
Alarm History data is not displayed.	The EDNS-9001 that is monitoring the bed is not storing the data.	Re-select the device and be its master storage device.
The “Real Time Waves”, “Expanded MultiWv”, “Compressed MultiWv”, and “Compressed Single Wv” buttons are not displayed.	The EDNS-9001 that is monitoring the bed is not storing the data.	Re-select the device and be its master storage device.
Waveform is not displayed.	The bed is discharged.	Admit the patient.
	The bed is set to temporary discharge (paused).	Resume monitoring.
	The multiple patient receiver is turned off.	Turn on the multiple patient receiver.

Problem	Possible Cause/Criteria	Action
	The currently measured lead/label is different from the lead/label to be displayed on the screen.	Confirm the setting so that the currently measured lead/label matches the lead/label to be displayed on the screen.
	The waveform is not selected as the displayed waveform.	None. ECG, SpO_2 and respiration are automatically displayed if they are being measured.
	The bed is not registered as a monitored bed.	Select the device at the Device Configuration screen.
	Network is disconnected.	Confirm the network connection.
The desired waveform cannot be displayed.	The waveform is a waveform that cannot be displayed.	None. Prefense only supports waveforms for non-invasive parameters ECG, SpO_2 and Respiration.

19.9 Power Problem

Problem	Possible Cause/Criteria	Action
- When the main unit is turned on, the power lamp on the front panel does not light. - When the display unit is turned on, the LCD does not light. - The main unit or display unit frequently turns itself off.	AC power is not obtained from the power cord.	Check that the AC power is obtained from the AC outlet on the facility wall.
	The power cord is loose between the AC outlet and AC inlet of the main unit or display unit.	Disconnect the power cord between the AC outlet and AC inlet of the main unit or AC adapter, and connect the power cord between them again.
	The power brick for the main unit or power supply for the display unit has a failure.	Replace the power brick of the main unit or replace the power supply for the display unit with a new one.
In power failure, the UPS does not cover the power requirement of Prefense.	The battery in the UPS is completely discharged.	Replace the battery with a new one.
	UPS has a failure.	Replace the UPS with a new one.

19.10 Display Problem

Problem	Possible Cause/Criteria	Action
The “No Signal” message appears on the display unit.	The video cable is improperly connected from the main unit to the LCD display.	Firmly connect the video cable from the main unit to the LCD display.
	The main unit is not turned on.	Turn on the main unit.
	The video signal is not output from the display connector.	Replace the main unit and/or display with a new one.
A “No boot device” message appears.	The hard disk is damaged.	Replace the main unit with a new one.
	The hard disk is not recognized due to incorrect BIOS setting.	Set the BIOS setting correctly.

19.11 Sound Problem

Problem	Possible Cause/Criteria	Action
The main unit intermittently generates a beep sound.	A key on the keyboard is pressed and held.	Release the key.
No alarm sounds.	Poor contact of the display cable.	Firmly connect the cable from the main unit to the LCD display.
	Failure of the speakers in the LCD display.	Replace the display with a new one.
	Failure of the audio out port on the main unit.	Replace the main unit with a new one.
	Monitor is powered off.	Power on monitor.
	Volume level is low or muted.	Increase volume level at Revision Information and Alarm Volume screen.
		Unmute volume. Reference Service Manual for details.
	Display cable is disconnected.	Ensure that the display cable is securely plugged into PC and into LCD.
	Headphones are plugged into headphone jack.	Unplug headphones so sound is directed to speakers.

19.12 Keyboard Problem

Problem	Possible Cause/Criteria	Action
No keyboard keys work.	The keyboard is not connected properly to the main unit.	Connect the keyboard cable firmly to the USB port on the main unit.
	The keyboard cable is damaged.	Replace the main unit and/or keyboard with a new one.
Some keyboard keys do not work.	Failure of the key switches.	Replace the main unit and/or keyboard with a new one.

19.13 Mouse Problem

Problem	Possible Cause/Criteria	Action
The cursor does not move when the mouse is moved.	The mouse cable is loose at the USB port on the main unit.	Connect the mouse cable firmly to the USB port on the main unit.
	Mouse failure.	Replace the main unit and/or mouse with a new one.

19.14 Hard Disk Problem

Problem	Possible Cause/Criteria	Action
A “No boot device” message appears.	The hard disk is damaged.	Replace the main unit with a new one.
	The hard disk is not recognized due to incorrect BIOS setting.	Set the BIOS setting correctly.
Metallic sound from the hard disk.	The bearing for the spindle motor in the hard disk is worn out.	Replace the main unit with a new one.

20. EDNS-9001 Specification

Display	Number of patients on the display	40 patients max
	Number of transmitters	40 transmitters max
	Display type	Widescreen LCD with 1920 x 1200 resolution
	Waveform display method	Non-fade, fixed method
	Number of waveforms	3 waveforms max (ECG, SpO_2, Respiration or CO_2)
	Sweep speed	Approximately 25 mm/s
Waveform display items	ECG, SpO_2, Respiration or CO_2	
Alphanumeric display items	Heart rate or pulse rate, respiration rate, SpO_2, $EtCO_2$, NIBP	
Sound	Alarm sound	Crisis, Warning, Advisory
	Modes	Nihon Kohden, IEC
Alarm Function	Alarm decision is done at each bedside monitor (except for CO_2 monitors) or multiple patient receivers. Prefense only displays the alarm and generates sound by receiving the alarm information from bedside monitors and multiple patient receivers.	
	Alarm type	Crisis, Warning, Advisory
	Alarm items	Vital Sign: Heart rate, respiration rate, apnea, SpO2, pulse rate, NIBP (sys, dias, mean), $EtCO_2$ Arrhythmia: Asystole, V. Fib, V. Tachy
	Alarm display	Highlighted numeric display, highlighted message for arrhythmia
	Alarm occurrence	Alarm occurs when any of the bedside monitor or telemetry beds the Prefense is monitoring generates an alarm for a supported alarm parameter.
	Alarm silence	Available
	Alarm recording	Not available
Vital Signs Review (Trend)	Trend parameters	Heart rate, respiration rate, SpO_2, pulse rate, NIBP (sys, dias, mean), $EtCO_2$
	Trend display times	1, 8, 12, 24, 48, 72 hours

	Trend display formats	Trendgraph and tabular trend
	Events related to trendgraphs	Asystole, V. Fib, V. Tachy, Off/Noise
Waveform Sensitivity	ECG display sensitivity	Auto, x1/4, x1/2, x3/4, x1, x3/2, x2, x4
	SpO_2 display sensitivity	Auto, x1/8, x1/4, x1/2, x1, x2, x4, x8
	Respiration curve sensitivity	Auto, x1/4, x1/2, x3/4, x1, x3/2, x2, x4
	CO_2 display scale	Auto, 0-20, 0-40, 0-80 mmHg or Auto, 0-3.0, 0-6.0, 0-12.0 kPa
Remote Setting	Alarm setting of multiple patient receivers and CO_2 devices. Individual setting of multiple patient receivers. Channel setting of multiple patient receivers.	
Full Disclosure	Only waveforms associated with an event can be viewed.	
File Saving	Vital Signs Review (trend)	72 hours
	Events (alarm history)	1000 events
	Event Waveforms (full disclosure)	72 hours
Power Requirement	Prefense Main Unit	
	Line Voltage	AC 100 to 240 V ± 10 %
	Line Frequency	50 or 60 Hz
	Adapter	90W (20V, 4.5A) AC Adapter
	LCD Unit	
	Line Voltage	AC 100 to 240 V ± 10 %
	Line Frequency	50 or 60 Hz
Environment	Operating temperature	5~35°C (41~95°F)
	Storage temperature	-10~60°C (14~140°F)
	Relative Humidity	80% RH (50°C non-condensing)
Dimensions	Main Unit	165 x 160 x 48 (mm) 6.5 x 6.3 x 1.9 (in) 1.45 kg (2.4 lb)
	LCD Unit	558.6 x 437-547 x 272.4 (mm) 22 x 17.2-21.5 x 10.7 (in) 10.5 kg (23.1 lb)

21. Standard Accessories

21.1 Prefense™ - EDNS-9001 System

Description	Part Number
Prefense™ PC Main Unit Mini-PC with Prefense software installed.	EDNS-9001-PC
Prefense™ LCD Unit Widescreen LCD with 1920 x 1200 resolution.	EDNS-WSxx, where xx = diagonal size of monitor in inches

21.2 Prefense™ PC Main Unit Accessories

Description	Quantity	Part Number
Power Brick and Cable	1	---
Keyboard	1	EDNS-9001-002
Mouse	1	EDNS-9001-003
Mounting Bracket	1	EDNS-9001-016
Screws (mounts PC to bracket)	8	EDNS-9001-018
Operator's Manual	1	EDNS-9001-VSC-DHF-011
Service Manual	1	EDNS-9001-VSC-DHF-012
Assembly Guide for DE7000	1	---
Windows CD	1	---

21.3 Prefense™ LCD Unit Accessories

Description	Quantity	Part Number
Display Cable	1	---
Power Cable	1	---
NEC Setup Manual	1	---

NOTE

When ordering parts or accessories from your Nihon Kohden representative, please quote the product name and part number which is listed in this service manual, and the name or model of the unit in which the required part is located. This will help us to promptly attend to your needs. Always use parts and accessories recommended or supplied by Nihon Kohden to assure maximum performance from your monitor.

22. General Requirements for Connecting Medical Electrical System

When more than one electrical instrument is used, there may be electrical potential difference between the instruments. Potential difference between instruments may cause current to flow to the patient connected to the instruments, resulting in electrical shock (micro shock). Therefore, electrical instruments must be appropriately installed as specified in IEC 60601-1-1.

The following is an extract from IEC 60601-1-1 “Medical electrical equipment Part 1: General requirements for safety”. For details, refer to IEC 60601-1-1 and consult with a biomedical engineer.

Examples of combinations of MEDICAL ELECTRICAL EQUIPMENT and non-medical electrical equipment.

Situation No.	Equipment A	Equipment B	Solution
1	IEC 60601/X		OK
1a	IEC XXXXX		OK, if ENCLOSURE LEAKAGE CURRENT is less than 0.5 mA. If the ENCLOSURE LEAKAGE CURRENT is more than 0.5 mA: Solution *Q* (separating transformers).
2a	IEC 60601/X	IEC 60601/B	OK
2b	IEC 60601/F	IEC XXXXX	for B any one of *P*, *Q*, *R*
2c	IEC 60601/B	IEC XXXXX	for A solution *P* for B any one of *P*, *Q*, *R*
3a	IEC 60601/X	IEC 60601/B	OK
3b	IEC 60601/F	IEC XXXXX	OK
3c	IEC 60601/B	IEC XXXXX	for A solution *P*
4	See 3a, 3b, 3c		
5a	IEC 60601/X	IEC 60601/B	for A solution *P* or *S* (groundloop possible)
5b	IEC 60601/X	IEC XXXXX	for A solution *P* or *S* (groundloop possible)
6a	IEC 60601/X	IEC 60601/X	OK (with *S*)
6b	IEC 60601/X	IEC XXXXX	OK (with *S*)

IEC 60601/B = IEC 60601-1 EQUIPMENT of TYPE B with PATIENT connection

IEC 60601/F = IEC 60601-1 EQUIPMENT of TYPE BF or TYPE CF (or TYPE B without PATIENT connection)

IEC 60601/X = IEC 60601-1 EQUIPMENT of TYPE B or TYPE BF or TYPE CF

IEC XXXXX = Equipment complying with e.g. IEC 348, IEC 950 etc.

P: additional protective earth
Q: additional separating transformer
R: floating power supply
S: separation

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EDNS-9001-VSC-DHF-012

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