SAFETY AND PERFORMANCE INFORMATION

NIHON KOHDEN

Central Monitor
CNS-2101

General

The central monitor is a central monitoring device designed to support medical personnel to provide medical care to multiple patients at the same time. It acquires vital sign data from multiple monitoring devices such as bedside monitors and displays the acquired data such as ECG and pulse rate on the screen in an appropriate format as well as generating alarms. The central monitor is designed to be installed in a location outside the patient environment such as a nurses station for central monitoring.

Safety 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.

Pay attention to all safety information in the Operator's Manual.

⚠ WARNING

Never use the central monitor in the presence of any flammable anesthetic gas or high concentration oxygen atmosphere. Failure to follow this warning may cause explosion or fire.

⚠ WARNING

Never use the central monitor in a hyperbaric oxygen chamber. Failure to follow this warning may cause explosion or fire.

⚠ WARNING

When several medical instruments are used together, ground all instruments, including battery-powered ones, to the same one-point ground. Any potential difference between instruments may cause electrical shock to the patient and operator.

⚠ WARNING

Connect only the specified instruments to the central monitor and follow the specified procedure. Failure to follow this warning may result in electrical shock or injury to the patient and operator, and cause fire or instrument malfunction.

⚠ WARNING

After attaching electrodes and sensors to the patient, check that there are no error messages and that the waveforms and numeric data are appropriately displayed on the screen of the central monitor. If there is an error message, or if waveforms or numeric data are not appropriate, check the attachment of the electrodes and sensors, patient condition and settings on the central monitor and remove the cause.

⚠ WARNING

Check that the channel number of the transmitter corresponds to the receiving channel (the channel displayed on the monitor screen). Otherwise, the central monitor monitors a different patient.

⚠ WARNING

Do not disassemble or modify the central monitor. Disassembly or modification may cause skin burn, fire, electrical shock or injury.

⚠ WARNING

When performing long term measurement at intervals less than 2.5 minutes, perform measurements while observing the state of the patient, blood vessels and limb to ensure adequate circulation. Congestion may occur at the measurement site. When performing periodic measurement for a long time, periodically check the circulation condition.

⚠ WARNING

Do not diagnose a patient based on only the alarm information of the central monitor. An alarm may not be indicated due to alarm level or alarm on/off setting and critical changes on the patient may be overlooked.

⚠ WARNING

When an alarm is generated, check the patient condition and secure the patient safety. Depending on the generated alarm, perform appropriate treatment and remove the cause of alarm. If there is a problem on the alarm setting, change it to an appropriate setting.

⚠ WARNING

When an alarm is suspended on the transmitter, all alarms are turned off so keep the patient under close observation when you suspend the alarm.

⚠ WARNING

When the patient of the paused bed returns to the bed and monitoring is resumed, check that the pause condition is ended and monitoring is resumed at the central monitor. While monitoring is paused, measurement data is not displayed and alarms do not occur.

⚠ WARNING

After admitting a patient at a bedside monitor, confirm that the patient is also admitted at the central monitor and that the central monitor starts monitoring the patient.

⚠ WARNING

When the bed is set to automatically resume monitoring after pause, check that monitoring is resumed at the central monitor when the pause condition is ended. Monitoring might not resume if there is network failure.

⚠ WARNING

Do not monitor the patients over the number of receivers in a multiple patient receiver (up to 8 patients) by changing the channels. The patient's data will be mixed together. It can only monitor the patients who are set at the receiving channels in the central monitor. You cannot know the information if there is a sudden change in condition of a patient who is not set in the central monitor.

⚠ WARNING

Connect the central monitor to the network as specified. Otherwise, the patient or operator may receive electrical shock or injury, the central monitor may malfunction or stop, or the stored data may be damaged. To connect the network, contact your Nihon Kohden representative.

⚠ WARNING

Install all network devices, including a printer and hubs, outside the patient environment. 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.

⚠ WARNING

Install the central monitor outside the patient environment. If it is installed inside the patient environment, the patient or operator may receive electrical shock or injury. For installation, contact your Nihon Kohden representative.

⚠ WARNING

Do not use a damaged network cable. When the damaged part is touched, the patient or operator may receive electrical shock.

⚠ WARNING

Turn the pacing pulse detection [1] to [ON] when monitoring a pacemaker patient. Otherwise the pacemaker pulse is not rejected. However, even when the pacing pulse detection is set to [ON], the pacemaker pulse might not be rejected. When the pacemaker pulse is not rejected, the pacemaker pulse is detected as QRS and false heart rate may be indicated or critical arrhythmia such as asystole may be overlooked. Keep pacemaker patients under close observation.

⚠ WARNING

Even when the pacing pulse detection is set to ON, the pacemaker pulse can be overlooked or detected as QRS. You cannot confirm the pacemaker operation only from the detected pacemaker pulse.

⚠ WARNING

Do not diagnose a patient based only on data acquired by the central monitor. Overall judgement must be performed by a physician who understands the features, limitations and characteristics of the central monitor and by reading the biomedical signals acquired by other instruments.

⚠ WARNING

The following actions must be taken to properly receive the transmitter signal of the correct patient on the receiving instrument. Otherwise, there may be signal loss or signals may mix causing a serious accident, such as monitoring a different patient.

- Assign a channel administrator in the hospital and only he or she should manage channel assignment.
- The channel administrator must manage the channels in the facility so that there is no signal interference.
- When the transmitter channel is changed, the channel administrator must check that the channel on the receiving monitor is also changed and the signal is properly received.
- The channel administrator must replace the channel number label on the transmitter with the new one after changing the channel.

⚠ WARNING

All medical electrical equipment used together in the same facility must have the same default alarm settings (alarm master). Otherwise, equipment with different alarm masters will have different alarm settings after initialization, and alarms in the facility cannot be appropriately managed. If different areas or wings in the facility use different alarm masters, be careful to thoroughly understand the differences so that alarms can be managed appropriately.

⚠ WARNING

Do not diagnose a patient based on alarm information of an instrument which can view the data by setting [Extended Network] to ON. There is a time delay. Confirm the alarm information on this central monitor.

⚠ WARNING

A well trained medical staff must be within the range where she/he can hear the alarm sound of the central monitor while monitoring a patient on the central monitor. If the medical staff cannot hear the alarm sound, critical changes on the patient may be overlooked.

⚠ WARNING

If the alarm sound volume is quieter than the surrounding sound, frequently check the patient and central monitor. Otherwise, the alarm sound might not be heard and changes in the patient and central monitor may be overlooked. Set the appropriate alarm sound volume according to the environment where the central monitor is used.

⚠ WARNING

To prepare for a voltage drop or power failure, connect the secondary display to an uninterruptible power supply which meets IEC 60601-1 requirements or to the emergency power system in the hospital.

⚠ WARNING

While the central monitor is operating, do not connect a USB flash drive or any other device to the central monitor. Nihon Kohden does not warrant the normal operation of the central monitor if an application or software installation starts automatically.

⚠ WARNING

Do not install or run any software not specified by Nihon Kohden in the central monitor. Nihon Kohden does not warrant normal operation of the central monitor if unspecified software is installed or used.

⚠ WARNING

For arrhythmia monitoring, set ARRHYTHMIA ANALYSIS to ON. Otherwise, there is no sound or indication for arrhythmia alarms other than ASYSTOLE.

⚠ WARNING

Check the software version of the Nihon Kohden monitoring device 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. For details, refer to the Network and System Installation Guide.

⚠ WARNING

Check the alarm settings when admitting a new patient and whenever the patient condition changes and change the alarm settings if necessary.
When using a multiple patient receiver, the alarm settings return to the alarm master 1 when:

- a patient is discharged
- patient data is deleted
- patient data is deleted when the receiving channel is changed

⚠ WARNING

When using the transport function:

- Do not connect or disconnect the network cable from the bedside monitors and central monitor.
- Do not perform the following operations on the bedside monitor which is being monitored and whose data is saved by the central monitor. Patient data may be mixed together or lost in the following cases:
  - Removing the input unit while the bedside monitor power is off.
  - Using transport function and wireless LAN at the same time.

⚠ CAUTION

Only use the provided power cord and connect it to a 3-pin AC outlet which is properly grounded. Otherwise, it may result in electrical shock or injury to the operator.

⚠ CAUTION

Before connecting or disconnecting instruments, make sure that each instrument is turned off and the power cord is disconnected from the AC outlet. Otherwise, the patient or operator may receive electrical shock or injury, data may be lost or the instrument may malfunction.

⚠ CAUTION

Do not touch the thermal head inside the recorder unit. The thermal head may be damaged by static electricity or become dirty and cause printing failure.

⚠ CAUTION

When the “CHECK ELECTRODE” message is displayed, ECG is not monitored properly and the ECG alarm does not function. Check the electrode, its leads and connection cord to remove the cause of the alarm.

⚠ CAUTION

When the “NOISE” or “CANNOT ANALYZE” message is displayed, ECG data and alarm are not reliable. Remove the cause by checking the electrodes, electrode leads, patient’s body movement, EMG and peripheral instruments grounding. Also make sure that an electric blanket is not used.

⚠ CAUTION

When the “CONNECTOR OFF” message appears on the screen, check that the connection cords are connected to the sockets properly. The patient cannot be monitored and the alarm does not function while this message is displayed.

⚠ CAUTION

While the “SIGNAL LOSS” message is displayed, parameters are not monitored and the alarms do not function. Check the transmitter and communication status and remove the cause.

⚠ CAUTION

Before maintenance, cleaning or disinfection, turn the central monitor power off and disconnect the power cord from the AC socket. Failure to follow this instruction may result in electrical shock or central monitor malfunction.

⚠ CAUTION

Never disassemble or repair the central monitor. If there is any problem with the central monitor, contact your Nihon Kohden representative.

⚠ CAUTION

When the “CHECK SENSOR” message is displayed, check the CO_2 sensor kit and replace it if necessary. CO_2 cannot be monitored while the message is displayed.

⚠ CAUTION

If there is any doubt about the arrhythmia analysis, make the monitor relearn the patient’s ECG and check that the dominant QRS is appropriate. Otherwise, an important arrhythmia may be overlooked.

⚠ CAUTION

Keep the cable out of the way by running it along the floor or wall. Otherwise people may trip over it, causing the instrument to fall and injure the patient and operator.

⚠ CAUTION

When the alarm limit is set to OFF, there will be no alarm for that limit. Keep the patient under close observation when you set the alarm limit to OFF.

⚠ CAUTION

When the central monitor is turned on and periodically during operation, check that the red, yellow and cyan alarm indicator lamps light and sound is generated.

⚠ CAUTION

When admitting 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 it will cause misunderstanding of the patient history.

⚠ CAUTION

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 it will cause misunderstanding of the patient history.

⚠ CAUTION

The network must be managed by the network administrator. Make sure that each monitor in the network has a different IP address. Otherwise, data communication cannot be performed properly. When adding a monitor to an already operating network, set the IP address on the monitor before connecting the monitor to the network.

⚠ CAUTION

When the probe is attached on an appropriate site with sufficient circulation and an error message about probe attachment repeatedly appears, the probe may be deteriorated. Replace it with a new one.

⚠ CAUTION

If fluids are accidentally spilled into the central monitor, take the central monitor out of service and contact your Nihon Kohden representative. The central monitor must be disassembled, cleaned, dried and tested for safety and function.

⚠ CAUTION

When receiving temperature data through a ZB-800P, ZB-900P or ZS-900PA/PG transmitter, measurement values below 5°C (41°F) and above 45°C (113°F) are not transmitted and the value is not displayed on the central monitor.

⚠ CAUTION

When receiving CO_2 data from a bedside monitor through a ZB-800P, ZB-900P or ZS-900PA/PG transmitter, if a measured value is out of the range of the central monitor, only the maximum value of the central monitor is displayed. Be careful when reading the value.

⚠ CAUTION

When receiving data from a transmitter connected to the bedside monitor or from a transmitter which has a display, the measurement data and waveforms may be different on the central monitor depending on the detection setting and display timing. Be aware of this when reading the measurement data and waveforms.

⚠ CAUTION

Do not carry the central monitor by the filter cover. The cover may be detached, resulting in the central monitor to fall off and the operator to get injured.
Hold the bottom panel of the central monitor to support it while mounting the central monitor to a stand, wall mount or other devices.

⚠ CAUTION

- Although the ST algorithm has been tested for accuracy of the ST analysis result, the significance of the ST level changes need to be determined only by a physician.
- The ECG from the transmitter other than ZM series is not processed by a 3.2 second time constant filter. Therefore, the ST level measurement is not designed to be accurate enough for diagnosis. Do not rely on this ST level measurement.

⚠ CAUTION

Before you remotely start and stop NIBP measurement from the central monitor, confirm the state of the patient at the bedside monitor. Carefully start and stop NIBP measurement from the central monitor.

⚠ CAUTION

Do the regular inspection twice a year. Otherwise, a decrease and loss in function will not be noticed and this results in incorrect monitoring.

⚠ CAUTION

The sync sound at the central monitor has a time delay of 1 to 3 seconds because of network connection.

⚠ CAUTION

The central monitor does not perform ECG analysis. Therefore, the QRS sync sound at the central monitor might not synchronize with the patient's actual QRS during pacing or when complicated arrhythmias occur.

⚠ CAUTION

The central monitor CPU may be reset when there is unit failure, considerable static electricity or noise. If this occurs, there is a 5-beep alarm sound for 5 seconds and monitoring stops for about 3 minutes. To secure patient safety, carefully observe the patients and alarm information from the instruments which are connected to the patients. After the central monitor is reset, check that it is working properly.

⚠ CAUTION

When the monitor is connected to a central monitor network, set the Bed Name (Bed ID)/CNS Name and Group Name on the monitor. Otherwise, the default settings are used for the names and the bed may be incorrectly identified on the central monitor.

⚠ CAUTION

Connect the AC power cord to an AC outlet which can supply sufficient power to the instrument. If the power supply is unstable or the power capacity is insufficient, it may cause power failure or momentary power loss.

⚠ CAUTION

The network must be managed by the network administrator. Only the network administrator can change the network settings on the central monitor and connect the central monitor to the network. Incorrect settings or connection may cause failure of the network system and instrument.

⚠ CAUTION

While the central monitor is on, do not touch unused sockets or cables connected to the sockets. Failure to follow this instruction may damage the central monitor by static electricity and cause malfunction.

⚠ CAUTION

Keep the source bedside monitor and the destination bedside monitor power on and connected to the network until the patient transfer or bed exchange is complete. Otherwise, the patient transfer or bed exchange fails and the data is lost. After transferring the patient or exchanging the bed, confirm that the data before the patient transfer or bed exchange can be displayed at the destination bed.

⚠ CAUTION

Keep the current bedside monitor and the new bedside monitor power on and connected to the network until the monitor is changed. Otherwise the patient data is lost. After changing the monitor, confirm that the data and settings before changing the monitor are displayed in the new monitor.

⚠ CAUTION

When transferring a patient, confirm the destination bed by the message on the screen. If you select the wrong destination bed, the patient data of the destination bed gets overwritten and cannot be recovered.

⚠ CAUTION

After patient transfer, settings other than patient information and alarm settings are returned to the default settings. Change the settings if necessary.

⚠ CAUTION

If the monitoring bed is changed to a different monitor on a central monitor other than a CNS-2101 or CNS-6201, the monitoring bed does not change on this central monitor. Register the bed again on this central monitor. Otherwise, the patient data might not be displayed or data of a different patient may be displayed on this central monitor.

⚠ CAUTION

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 you turn off an arrhythmia alarm.

⚠ CAUTION

When the impedance respiration measurement functionality is turned off while using the impedance method for respiration measurement, respiration alarms do not occur even if each respiration alarm item is set to ON.

⚠ CAUTION

When the ECG measurement is OFF, ECG alarms do not occur even if each ECG alarm item is set to ON.

⚠ CAUTION

The system should be used in a closed network to prevent computer viruses and unexpected software updates.

⚠ CAUTION

The central monitor communicates with specified systems using the HL7 protocol via the hospital network.

When transmitting medical information containing personal information from the central monitor to an external facility over a network using the HL-7 protocol, security measures such as encryption must be used to prevent leakage of confidential information or alteration of data. In addition, security measures must be employed to protect the route between the institutions exchanging data, such as using a closed IP network or other closed network.

When using the HL7 protocol for data communication, use the central monitor in a securely managed environment.

⚠ CAUTION

When receiving bedside monitor data through the ZB-800P, ZB-900P or ZS-900PA/PG transmitter, check the alarm, arrhythmia and monitoring settings on the bedside monitor and central monitor. The alarm, arrhythmia and monitoring setting information of the bedside monitor is not transmitted.

⚠ CAUTION

During maintenance and servicing, patients monitored by the central monitor must be monitored by alternate instruments such as bedside monitors.

⚠ CAUTION

Restart the central monitor once every six months. Otherwise operation becomes unstable and monitoring may stop. While restarting, patients monitored by the central monitor must be monitored by alternate instruments such as bedside monitors.

⚠ CAUTION

The sensitivity of the pulse waveform measured by a ZM-930P transmitter is automatically changed by the transmitter. When the sensitivity is changed, the waveform becomes flat for about one second.

⚠ CAUTION

If there are too many patient transfers, old review data might not be displayed on the central monitor.

⚠ CAUTION

Follow the specified procedure to turn off the central monitor. Otherwise, patient data will be deleted and the storage device and data in the storage device may be damaged.

⚠ CAUTION

If the patient requires respiration monitoring, monitor the respiration. Oxygen saturation (SpO_2) is measured by pulse oximetry which cannot be used for respiration monitoring.

⚠ CAUTION

When monitoring SpO_2 only (without ECG monitoring), turn on both the upper and lower limit alarms for PR and SpO_2. If the patient's pulse is not detected during asystole or other condition, a "CANNOT DETECT PULSE" or "SpO_2 CHECK PROBE" alarm occurs instead of an SpO_2 limit alarm. Furthermore, if the patient has no pulse, noise from probe movement could be misjudged as a pulse and cause an incorrect PR or SpO_2 value to be displayed.

⚠ CAUTION

When monitoring SpO_2 only, detection of arrhythmia and asystole is not available and arrhythmia alarms such as ASYSTOLE, V FIB or V TACHY are not available. If the patient requires ECG monitoring, monitor the ECG.

⚠ CAUTION

When admitting a new patient, check that the patient information is entered correctly.

⚠ CAUTION

At the start of ECG monitoring, check that the correct patient type (Adult, Child or Neonate) is set for QRS Detection Type. If an inappropriate patient type is set, heart rate cannot be counted accurately and noise or P waves may be counted as QRS and cardiac arrest may be overlooked.

⚠ CAUTION

Dispose of Nihon Kohden products according to your local laws and your facility's guidelines for waste disposal. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, dispose of it as medical waste according to your local laws and your facility's guidelines for medical waste. Otherwise, it may cause infection.

⚠ CAUTION

When installing, connecting and assembling the central monitor, only use specified instruments and parts and follow the specified procedure. Otherwise, the operator may receive electrical shock or injury.

⚠ CAUTION

Do not remove the input unit from the bedside monitor while the central monitor is receiving data from the bedside monitor. The data may be lost.

⚠ CAUTION

To ensure the cybersecurity of the central monitor, implement the following network security measures under the supervision of the information security manager of the medical facility.

1. When a device in the network (LS-NET, HIS, etc.) is connected to an external network including the internet, access to sensitive information is protected by firewalls and ACL (access control lists).
2. When a device in an LS-NET network is connected to a network with a different protocol (HIS, etc.), access control is implemented on routers and switches to restrict communication to the designated source and destination devices only.

⚠ CAUTION

Some data and operations on the central monitor can be set, changed or managed only by a user with administrator privileges. Set a password for the administrator that is difficult to guess and store it securely to prevent security breaches.

⚠ CAUTION

Comply with the "User Agreement with Relation to the Information Security of the Central Monitor" below. In order to protect personal information stored on the central monitor or the PC on which optional software of the central monitor is installed from being leaked or misused, and to maintain the functionality of the central monitor, implement a comprehensive and multifaceted security strategy, including information security management standards, operating procedures and safety measures, to protect against internal and external threats.

⚠ CAUTION

Use the central monitor in a securely managed environment.

⚠ CAUTION

Check that no error messages related to the backup battery are displayed and that the central monitor operates normally. If the battery is deteriorated, the central monitor might not shutdown properly when there is a sudden power failure.

This Safety and Performance Information is an extract from the general and safety information sections of the most recent edition of Operator's Manual or Installation Guide. Therefore, the contents of your Operator's Manual or Installation Guide may differ from those of this Safety and Performance Information. For detailed operating procedures, follow the instructions of your Operator's Manual or Installation Guide.

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