SAFETY AND PERFORMANCE INFORMATION

NIHON KOHDEN

Defibrillator
TEC-1021, TEC-1031

General

This device is a defibrillator that ends ventricular fibrillation or pulseless ventricular tachycardia by delivering a short-duration high-current electrical shock to the heart. This defibrillator can measure ECG and perform asynchronous defibrillation as well as synchronized cardioversion to treat atrial flutter.

In addition, a model with transcutaneous pacing function (TEC-1031) can be used to treat temporary bradycardia.

Safety Information

⚠ **CONTRAINDICATION**	A contraindication alerts the user to a situation in which the device should not be used because the risks of using it are clearly greater than the expected benefits.
⚠ **DANGER**	A danger alerts the user to a hazardous situation which causes death or serious injury.
⚠ **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.

⚠ CONTRAINDICATION

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

⚠ CONTRAINDICATION

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

⚠ CONTRAINDICATION

Do not bring the defibrillator (including components and accessories) into an MR examination room. It may cause stick, malfunction and damage to the MR equipment and skin burns on the patient. For details, follow the instruction in the manual for the MR equipment.

⚠ DANGER

Failure to observe any of the following may cause battery pack malfunction, overheating, explosion, fire or skin burn.

- Do not immerse the battery pack in liquid or get it wet.
- Do not leave the battery pack near a heat source such as a stove.
- Do not charge the battery pack on unspecified instruments.
- Do not charge the battery pack in conditions outside the specified environment. (Over 40°C (104°F))
- Do not put the battery pack into fire or heat it.
- Do not short-circuit the + and – terminals on the battery pack.
- Do not give strong impact to or deform the battery pack.
- Do not disassemble or modify the battery pack.
- Do not charge the battery pack in a high temperature place such as near a stove or in sun-heated cars.

⚠ WARNING

When the defibrillator is used with an electrosurgical unit (ESU), firmly attach the entire area of the ESU return plate. Otherwise, the current from the ESU flows into the electrodes of the defibrillator, causing electrical burns where the electrodes are attached. For details, refer to the ESU manual.

⚠ WARNING

Do not perform transcutaneous pacing while using an ESU. Before using the ESU, turn the defibrillator power off and remove disposable pads from the patient. Otherwise, high frequency energy from the ESU causes abnormal current to flow into the patient and causes electrical burns, shock or other injury. It also damages the defibrillator.

⚠ WARNING

Before discharging energy to the patient, check that the electrodes and sensors attached to the patient are properly connected to the defibrillator. Touching the metal parts of the disconnected cords and cables may cause electrical shock or injury by discharged energy.

⚠ WARNING

Before discharging energy to the patient, remove from the patient all electrodes and sensors connected to sockets that do not have a "♥" or "⍓" mark. Otherwise, the operator may receive electrical shock.

⚠ WARNING

When discharging energy to the patient, discharge the energy as far as possible from electrodes, patches and any gel, cream or medicine on the patient. If there is a possibility that the paddles or disposable pads could touch these foreign substances, remove them from the patient. If the paddles or disposable pads directly contact these foreign substances, the discharged energy may be insufficient and may cause skin burn to the patient.

⚠ WARNING

When using another defibrillator instead of this defibrillator, remove the disposable pads or electrodes connected to this defibrillator from the patient. If paddles or disposable pads of another defibrillator contact these objects, the discharged energy may be insufficient and may cause a skin burn to the patient or damage to the defibrillator.

⚠ WARNING

When discharging energy to the patient, all persons must keep clear of the bed and must not touch the patient, equipment or cables connected to the patient, or bed, stretcher or the like on which the patient is lying. Failure to follow this warning may cause electrical shock or injury.

⚠ WARNING

Use the provided power cord and connect it to a 3-pin AC outlet which is properly grounded. If this is not possible, operate the defibrillator on battery power. Otherwise, the patient and operator may receive electrical shock or injury.

⚠ WARNING

If an electrode is removed from the patient after attaching electrodes to the patient and connecting them to the patient cable and defibrillator, do not touch the metal part of the electrode with bare hands or let a metal part of the electrode contact a metal part of a bed or any other conductive parts. Failure to follow this warning may cause electrical shock or injury to the patient.

⚠ WARNING

Connect only the specified devices to the defibrillator 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

- When using the TL-201T finger probe, do not fasten the probe and cable to the finger by wrapping with tape. This may cause burns, congestion or skin problems from poor blood circulation.
- When using probes other than the TL-201T finger probe, to avoid poor circulation, do not wrap the tape too tight. Check the blood circulation condition by observing the skin color and congestion at the skin peripheral to the probe attachment site. Even for short-term monitoring, there may be burns or skin problems from poor blood circulation, especially on neonates or low birth weight infants whose skin is delicate. Accurate measurement cannot be performed on a site with poor peripheral circulation.

⚠ WARNING

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

⚠ WARNING

If the battery pack is damaged and the substance inside the battery pack contacts the eyes, wash immediately and thoroughly with water and see a physician. Never rub your eyes, because you may lose your eyesight.

⚠ WARNING

- When you start using a new battery pack, write the date of first use on the labels on the battery pack and defibrillator.
- Replace the battery pack every 2 years.

⚠ WARNING

If the package of the disposable pads is punctured, dispose of the pads without using them. Failure to follow this warning may cause insufficient energy discharge or skin burn.

⚠ WARNING

Never discharge energy to a person or object other than the patient or discharge test equipment (test electrode plate or defibrillator analyzer). Failure to follow this warning may result in electrical shock.

⚠ WARNING

Apply contact gel only to the electrode plates of the external paddles. Otherwise, it may cause electrical shock to the operator.

⚠ WARNING

Do not hold the paddle handles if the hands are wet or have contact gel on them. This may cause electrical shock to the operator.

⚠ WARNING

Before using an ESU, remove the paddles or disposable pads from the patient. Otherwise, high frequency energy from the ESU causes abnormal current to flow in the patient and may cause unexpected discharge and damage to the defibrillator.

⚠ WARNING

Do not use the disposable pads if they are past the expiration date. Failure to follow this warning may cause insufficient energy discharge or skin burn.

⚠ WARNING

Do not touch the disposable pads or the area around the pads during transcutaneous pacing. Failure to follow this warning may cause electrical shock.

⚠ WARNING

Confirm that there is no noise in the ECG. Noise may be misrecognized as QRS complex and discharge might not synchronize with the patient's QRS.

⚠ WARNING

Confirm that there is no noise in the ECG. Noise may be misrecognized as QRS complex and correct transcutaneous pacing cannot be performed.

⚠ WARNING

When performing synchronized cardioversion, check that the vertical dotted line appears on the rising slope of every QRS wave (between the Q and R points). If the dotted line is not appear on the rising slope, synchronized cardioversion may cause ventricular fibrillation. To make the dotted line appear on the rising slope of every QRS wave:

- Change the sensitivity (amplitude of the ECG waveforms).
- Change the ECG lead.
- Change the electrode position.

⚠ WARNING

If any disposable pad or connector gets wet, wipe it thoroughly before use. If a wet pad or connector is used for transcutaneous pacing, it may cause electrical shock to the operator.

⚠ WARNING

Turn Pacing Reject to Off when monitoring a child. With Pacing Reject On, narrow width QRS of a child cannot be detected correctly and the defibrillator may miscount QRS.

⚠ WARNING

When performing basic check, make sure that the disposable pads are not attached to the patient. Failure to follow this warning may cause electrical shock to the patient.

⚠ WARNING

When performing the defibrillation check using the external paddles, keep the paddles in the paddle holders. Failure to follow this instruction may result in electrical shock.

⚠ WARNING

Do not move the defibrillator when any charged energy is in the defibrillator. If the defibrillator receives any impact, such as from falling, it may discharge energy and cause electrical shock.

⚠ WARNING

Do not press the shock button with the internal paddles in the air. This may cause electrical shock to the operator or damage the defibrillator.

⚠ WARNING

When charging or discharging energy, do not touch the pad or connectors. If the pad or connectors are touched, the operator receives an electrical shock.

⚠ WARNING

When charging or discharging energy, grip the internal paddles between the cable and the guard at the top of the handle. If the internal paddles are gripped between the electrode and the guard, the operator may receive an electrical shock.

⚠ WARNING

When charging or discharging energy, do not touch anything other than the paddle handles. If any other part of the defibrillator is touched during charging or discharging energy, the operator receives an electrical shock.

⚠ WARNING

The defibrillator must only be operated by medical personnel who understand how to use it and have received appropriate training (such as basic life support and advanced life support training).

⚠ WARNING

Do not use 12 lead ECG interpretation results and measured values from the Mason-Likar modification for diagnosis because the limb electrode placement is not the same as the standard 12 lead ECG. This may cause wrong diagnosis since 12 lead ECG interpretation of this defibrillator is based on the standard 12 lead ECG.

⚠ WARNING

Do not use the defibrillator near RF devices, such as a microwave oven, bluetooth device, cordless phone, RFID tag, high frequency heating machine, or hyperthermia and microwave surgical device. The electromagnetic radiation from the devices may interfere with the radio communication of the defibrillator.

⚠ WARNING

The only oxygen cannula that can be used with YG-122T is #1103 manufactured by Hudson RCI. Do not use any other oxygen cannula. Other oxygen cannulas cannot be attached and oxygen cannot be delivered to the patient through the nostrils.

⚠ WARNING

Check that the oxygen cannula tube is not bent, broken, or blocked by the nasal tube. If the ends of the oxygen cannula tube turn too far up or down, it causes insufficient O_2 supply or the CO_2 value may be incorrect.

⚠ WARNING

Only use Nihon Kohden specified parts and accessories, such as cables, electrodes, paddles and probes, with the defibrillator. Otherwise, defibrillator protection cannot be guaranteed and the patient may receive electrical shock. The defibrillator may also malfunction and monitoring may stop.

⚠ WARNING

Be careful when measuring NIBP on a patient with known bleeding disorders or coagulation. After NIBP measurement, there may be dot hemorrhage, or circulatory disorder by thrombus where the cuff is attached.

⚠ WARNING

During NIBP measurement, check the cuff attachment site and confirm that the cuff does not affect the blood circulation of the patient.

⚠ WARNING

Do not attach the NIBP cuff on a wounded area. It may make the wound worse.

⚠ WARNING

Do not attach the NIBP cuff on a limb which is being used for intravascular access or therapy, or an arterio-venous (A-V) shunt. It may cause reflux of blood or medicinal solution or block injection of medicinal solution due to poor blood circulation.

⚠ WARNING

Do not attach the NIBP cuff on an arm which is on the same side of the body as a mastectomy or axillary lymph node dissection. It may cause circulatory disorders, such as swelling caused by poor blood circulation.

⚠ WARNING

During NIBP measurement, other medical devices attached to the same limb as the cuff might stop measuring temporarily.

⚠ WARNING

Do not bend the cuff tube during measurement. This may cause the cuff to interfere with circulation and cause congestion. If the cuff keeps receiving pressure, skin problems may occur at the measurement site.

⚠ 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

Check the circulation condition by observing the skin color at the measurement site and pulse waveform. Change the measurement site every 8 hours for disposable probes and every 4 hours for reusable probes (every 8 hours for TL-630T3/ TL-631T3 probe). The skin temperature may increase at the attached site by 2 or 3°C (4 or 5°F) and cause a burn or skin problems. When using the probe on the following patients, take extreme care and change the measurement site more frequently according to symptoms and degree.

- Elderly patient
- Unconscious patient
- Patient with a fever
- Patient with insufficient peripheral circulation
- Neonate or low birth weight infant with delicate skin

⚠ WARNING

When monitoring SpO_2 of a patient who is receiving photodynamic therapy, the light from the finger probe sensor may cause a burn. Photodynamic therapy uses a photosensitizing agent that has a side effect of photosensitivity.

⚠ WARNING

SpO_2 measurement may be incorrect in the following cases.

- When the patient's carboxyhemoglobin or methemoglobin increases abnormally.
- When dye is injected in the blood.
- When using an electrosurgical unit.
- During CPR.
- When measuring at a site with venous pulse.
- When there is body movement.
- When the pulse wave is small (insufficient peripheral circulation).

⚠ WARNING

When using the airway adapter or nasal adapter on a patient with low ventilatory volume, the CO_2 may mix in the inspiration due to the airway adapter's or nasal adapter's dead space, resulting in inaccurate measured values or difficulty in detecting no breath. Perform ventilation taking into consideration the dead space of the adapters. If that dead space is too much for this patient, appropriate ventilation might be impossible.

⚠ WARNING

After use, clean the reusable SpO_2 probe. Failure to follow this warning may cause cross infection.

⚠ WARNING

Do not judge the patient condition based on only on alarms generated by the defibrillator. If alarms are set to off, critical changes in 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

While the “All Alarms Suspended” message is displayed on the defibrillator, all alarm sounds are turned off and the indicator does not light or blink. Keep the patient under close observation.

⚠ WARNING

When not measuring SpO_2, disconnect the SpO_2 connection cord from the defibrillator. Otherwise, noise may interfere with measurement and cause an incorrect result to be displayed.

⚠ WARNING

While the defibrillator is analyzing the patient’s ECG, stop CPR and do not move or shake the patient’s body. Otherwise, the defibrillator cannot analyze the patient’s ECG correctly.

⚠ WARNING

Use the disposable pads as soon as possible after opening the package. Failure to follow this warning may cause skin burn or insufficient energy discharge to the heart.

⚠ WARNING

Do not use the disposable pads if the gel has become dry or if the gel has become abnormal, such as when the gel has become liquid or is coming off the edges of the pads. Failure to follow this warning may cause insufficient energy discharge or skin burn.

⚠ WARNING

Do not use the disposable pads if the gel is dark brown or dark brown gel is on the protective sheet. Failure to follow this warning may cause insufficient energy discharge or skin burn.

⚠ WARNING

Pay careful attention to the selected energy when using the pediatric electrode plates. Applying high energy with the pediatric electrode plates can cause skin burn because the electrode plates are small.

⚠ WARNING

Do not use the same defibrillator for more than one patient at the same time. Do not connect sensors from multiple patients to the same defibrillator.

⚠ WARNING

Never use a battery pack which is damaged, discolored or has leakage. It may cause overheating, explosion or fire.

⚠ WARNING

Remove the battery pack from the defibrillator when it is not going to be used for a long time (about 1 year). Otherwise the battery may leak.

⚠ WARNING

Install all network devices including 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

Do not leave the SD card near the patient or in reach of children. This may lead to an accident such as the patient or child swallowing the SD card.

⚠ WARNING

Turn Pacing Reject to On when monitoring a pacemaker patient. Otherwise the pacemaker pulse is not rejected. However, even when Pacing Reject 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 Pacing Reject 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

- When you use YG-122T together with an oxygen cannula, check that the oxygen cannula is correctly attached on the patient by referring to other parameters and by observing the patient periodically.
- If arterial oxygen partial pressure does not increase, immediately stop using the oxygen cannula with the CO_2 sensor kit and select another way to supply oxygen.

⚠ WARNING

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

⚠ WARNING

Assign a system administrator to supervise operation of the wireless LAN system. The system must be used under the supervision of the system administrator according to the facility protocol.

⚠ WARNING

Do not reuse disposable pads. Failure to follow this warning may cause insufficient energy discharge or skin burn.

⚠ WARNING

When using the disposable pads for long term transcutaneous pacing, replace them with new ones at the specified interval. Failure to follow this warning may cause skin burn or insufficient energy discharge to the patient.

⚠ WARNING

Before discharging energy to the patient, confirm that the internal paddles are firmly pressed against the heart. Failure to follow this warning may cause skin burn or poor energy discharge to the heart.

⚠ WARNING

Before discharging energy to the patient, confirm that the paddles or disposable pads are firmly pressed against the chest wall. Failure to follow this warning may cause skin burn or poor energy discharge to the heart.

⚠ WARNING

When the patient is a child (age 6 or younger), use the AED mode (Child mode). Attach the disposable pads very carefully so that the two pads do not touch each other.

⚠ WARNING

Use the AED mode (Child mode) only for a child (age 6 or younger). If the AED mode (Child mode) is used for an adult, the discharged energy may be insufficient.

⚠ WARNING

Use the AED mode (Child mode) when discharging energy to a patient age 6 or younger. Discharging energy to a patient age 6 or younger using Adult mode might cause damage to the patient's cardiac muscle due to the high energy.

⚠ WARNING

Before using the defibrillator, check that synchronized cardioversion occurs within 60 ms of the peak of the ECG's R wave with the defibrillator and an external monitor connected. Otherwise synchronized cardioversion may be ineffective and may cause ventricular fibrillation.

⚠ 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

A physician must be within the range where he/she can hear the alarm sound of the defibrillator while monitoring a patient on the defibrillator. If the physician cannot hear the alarm sound, critical changes in the patient condition may be overlooked.

⚠ WARNING

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

⚠ WARNING

For arrhythmia monitoring, set arrhythmia analysis on the System Setup window to ON. Otherwise, there is no sound or indication for arrhythmia alarms (except for ASYSTOLE).

⚠ WARNING

Check the software versions of the Nihon Kohden devices before connecting them to the network. Different software versions have different communication methods. Using more than one communication method in a network may cause communication failure.

⚠ WARNING

Check the alarm settings when starting monitoring of a new patient and whenever the patient condition changes, and change the alarm settings if necessary. The alarm settings return to the settings in Alarm Master in the System Setup screen when 30 minutes elapse after the defibrillator power is turned off.

⚠ WARNING

When measuring NIBP in Inflate Mode, use a cuff specified by Nihon Kohden. If an unspecified cuff is used, correct NIBP measurement might not be performed.

⚠ WARNING

NIBP value may be affected by measurement conditions, measurement site, exercise, or physiological conditions of the patient. NIBP measurement may be incorrect in the following situations.

- When using an ESU
- Body movement
- Small pulse wave
- Too many arrhythmias
- Shaking from an external source
- Rapid blood pressure change
- During CPR
- Slow pulse
- Low blood pressure
- Small pulse pressure
- Cuff is too tight or too loose
- Cuff does not fit the arm
- Cuff is wrapped over thick clothing
- Cuff is deteriorated

⚠ WARNING

When connecting the paddles or pad adapter, firmly insert the connector into the paddle connector on the defibrillator. Check the connection and confirm that the tab of the paddle connector lock is in the locked position.
After the paddles or the pad adapter are replaced, do a discharge test and confirm that the defibrillator operates normally.
Incorrect cable connection may result in troubles such as failure to display the “CONNECT PADDLES/PAD” message, accidental removal of the cable, or failure to discharge energy to the patient.

⚠ CAUTION

Before discharging energy to the patient, check that the patient is not in electrical contact with any metal part of a bed, stretcher, or other equipment directly or via blood or chemical solution on the patient. The current may flow into unwanted pathways and the discharged energy may be insufficient.

⚠ CAUTION

Before connecting or disconnecting instruments, make sure that each instrument is turned off, the power cord is disconnected from the AC socket, and the battery pack is not installed. Otherwise, the patient or operator may receive electrical shock or injury.

⚠ CAUTION

If the battery pack is damaged and the substance inside the battery pack contacts the skin or clothes, wash immediately with clear water. The skin may get irritated.

⚠ CAUTION

Do not leave the battery pack within reach of the patient.

⚠ CAUTION

Do not touch the thermal head inside the recorder module. 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

To keep the battery fully charged, always keep the power cord connected to the AC outlet even when the defibrillator is not used. Otherwise, the battery may discharge and become unusable.

⚠ CAUTION

When inserting or removing the battery pack, disconnect the power cord from the defibrillator. Otherwise, the operator may receive electrical shock.

⚠ CAUTION

Sterilize the internal paddles before use. Failure to sterilize the paddles may cause serious infection.

⚠ CAUTION

To prevent skin burn on the patient, apply contact gel evenly to the electrode plates of the external paddles.

⚠ CAUTION

Do not discharge the energy to the patient if the paddles or disposable pads overlap each other or are shorted to each other by a conductive substance such as contact gel. This may cause skin burn or insufficient energy discharge.

⚠ CAUTION

If the patient’s body is wet, thoroughly wipe the moisture off the skin so that the paddles or disposable pads do not short to each other. Otherwise, the discharged energy may be insufficient.

⚠ CAUTION

When performing synchronized cardioversion, confirm that “Sync Mode” is displayed on the defibrillator screen. Depending on the setting made on the System Setup screen, the defibrillator automatically changes to asynchronous defibrillation mode.

⚠ CAUTION

Do not perform synchronized cardioversion with the PADDLE lead unless it is absolutely necessary. In synchronized cardioversion with the PADDLE lead, noise may be misrecognized as QRS and discharge might not synchronize with the patient’s QRS.

⚠ CAUTION

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

⚠ CAUTION

When using internal paddles, be careful of the selected energy. High energy may cause critical damage to the cardiac muscle.

⚠ CAUTION

Have another defibrillator ready in case of defibrillator failure.

⚠ CAUTION

Only use Nihon Kohden specified CO_2 sensor kit. If an unspecified CO_2 sensor kit is used, maximum safety and performance from the defibrillator might not be achieved.

⚠ CAUTION

- The defibrillator automatically analyzes ECG. The ECG automatic interpretation is performed for acquired ECG waveforms only and does not reflect all conditions of the patient. The results of the analysis might not correspond to the judgement of a physician.
- Overall judgement must be performed by the physician, referring to the analysis result, clinical findings, and other examination results. After the physician's overall judgement, the analysis results should be signed or initialed by the physician.

⚠ CAUTION

Do not twist or give strong impact to the internal paddle while holding the electrode. This damages the electrode.

⚠ CAUTION

The TG-920P CO_2 sensor kit does not adjust the measurement value to compensate for different atmospheric pressure. Be careful when reading the value from the CO_2 sensor kit at high altitudes because the measurement value may be inaccurate.

⚠ CAUTION

Supply adequate oxygen when measuring CO_2 partial pressure of a patient connected to a Jackson Rees, Mapleson D or any other respiration circuit where CO_2 gas may be present during inspiration. The semi-quantitative method measures CO_2 partial pressure based on the assumption of no CO_2 gas in the inspired air; it measures the CO_2 partial pressure of the expiration of every respiration. If the inspired air contains CO_2 gas, the displayed CO_2 value is lower than the actual value.

⚠ CAUTION

When measuring CO_2 partial pressure of a patient with an oxygen mask, set the oxygen supply to 5 L/min or more. If CO_2 gas remains in the oxygen mask and mixes with the inspired air, the measured value may be lower than the actual value.

⚠ CAUTION

Only use Nihon Kohden specified electrodes and electrode leads. If other type of electrodes or electrode leads are used, the "Check Electrodes" message may appear and ECG monitoring may stop.

⚠ CAUTION

Do not reuse disposable parts and accessories.

⚠ CAUTION

When the "Adapter Failure" or "Sensor Failure" 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 defibrillator relearn the patient's ECG and check that the dominant QRS is appropriate. Otherwise, an important arrhythmia may be overlooked.

⚠ CAUTION

Do not wrap the cuff on an arm or thigh which is used for injection. NIBP measurement on an arm or thigh which is used for injection may cause reflux of blood and stop injection.

⚠ CAUTION

Do not wrap the cuff too tight. It may cause poor blood circulation and congestion. If the cuff is wrapped too loosely, the NIBP value may increase.

⚠ CAUTION

Do not perform a venous puncture on the same arm where NIBP is measured. This may cause an infusion backflow or internal hemorrhage at the puncture.

⚠ CAUTION

Do not replace any parts on the cuff. If parts are replaced with other parts, correct NIBP measurement cannot be performed.

⚠ CAUTION

If the attachment site is dirty with blood or bodily fluids, clean the attachment site before attaching the probe. If there is nail polish on the attachment site, remove the polish. Otherwise, the amount of transmitted light decreases, and measured value may be incorrect or measurement cannot be performed.

⚠ CAUTION

When measuring SpO_2 under strong light such as surgical light or sunlight, cover the measuring site with a blanket to block the light. Otherwise measurement accuracy may be affected.

⚠ CAUTION

When a mobile phone or small wireless device interferes with the defibrillator, move the defibrillator as far as possible or turn off the mobile phone or small wireless device. Radio wave from the mobile phone or small wireless device may be mistaken for ECG or pulse waves and the displayed data may be incorrect.

⚠ CAUTION

Nihon Kohden disposable cuffs are not sterilized. Sterilizing the cuffs is not recommended. For details, refer to the operator's manual provided with the disposable cuffs.

⚠ 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 turning on the power or periodically, check that one "bong" sounds and the alarm indicator blinks in red, yellow and cyan.

⚠ CAUTION

After the defibrillator power is turned on, parameter-related alarms do not function until the parameters are monitored.

⚠ CAUTION

The defibrillator may judge that it is not necessary to discharge energy to the patient even if it is actually necessary. Also in very rare cases, the defibrillator may judge that it is necessary to discharge energy to the patient even if it is not necessary. When the defibrillator judges that it is not necessary to discharge energy to the patient, it provides instructions for performing CPR.

⚠ CAUTION

If a pacemaker or ICD (Implantable Cardioverter-Defibrillator) is implanted in the patient, note the following.

- Do not attach the disposable pads on top of the pacemaker or ICD bulge.
- If energy was discharged to a patient who has an implanted ICD or pacemaker, check the pacing system of the ICD or pacemaker at a medical facility.
- If the patient has an ICD that is delivering shocks, wait 30 to 60 seconds for the ICD to complete the treatment cycle before attaching the disposable pads. The analysis and shock cycles of the automatic ICD and the AED may conflict.
- When the width of the pacemaker pulse is wide, analysis might be incorrect.

⚠ CAUTION

Do not locate the air hose connector (defibrillator side) near a magnetic card or magnetic recording media. The data on the magnetic card or magnetic recording media may be damaged by magnetic interference from the air hose connector.

⚠ CAUTION

Before ECG analysis in AED mode or discharging energy to the patient, confirm that the patient is unconscious and has no respiration and no pulse.

⚠ CAUTION

The ECG of a patient with an implanted pacemaker cannot be analyzed correctly. In that case, follow the physician's instructions.

⚠ CAUTION

Asystole is not judged to be a shockable rhythm.

⚠ CAUTION

The network must be managed by the network administrator. Make sure that each network instrument in the network has a different IP address. Otherwise, data communication cannot be performed properly and it causes incorrect monitoring. Before connecting the server to an already operating network, set the IP address.

⚠ CAUTION

When a message indicates a faulty probe or faulty SpO_2 connection cord, replace the probe or SpO_2 connection cord with a new one.

⚠ 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

At the start of ECG monitoring, check that the dominant QRS is appropriate. Otherwise arrhythmia monitoring may be inaccurate.

⚠ CAUTION

When using the defibrillator with an ESU, locate the defibrillator and ESU appropriately and ground devices properly. Otherwise noise from the ESU may interfere with the ECG and the heart rate and arrhythmia analysis may be incorrect.

⚠ CAUTION

Only connect the air hose to the cuff and NIBP socket on the defibrillator. Do not connect the air hose, especially the air hose for neonate, to other parts, such as an infusion line. It may cause thrombus.

⚠ CAUTION

Firmly connect the air hose to the NIBP socket on the defibrillator until it clicks. If not connected properly, the cuff type cannot be identified. At the start of NIBP measurement, check if the cuff type corresponds to the type displayed on the monitoring screen.

⚠ CAUTION

When too much pressure is applied to the cuff, or the hose is bent or squeezed, the “NIBP Safety Circuit Running” message appears on the screen and NIBP monitoring may be stopped. Remove the cause, wait 40 seconds, check that the message disappears, then measure again.

⚠ CAUTION

The defibrillator cannot measure the $ETCO_2$ value and respiration rate during high frequency oscillation (HFO).

⚠ CAUTION

Follow the CAUTION label on the CO_2 gas cylinder.

⚠ CAUTION

Do not put heavy objects on the disposable pads or bend the pads. The pads may be damaged and deteriorated, resulting in skin burn on the patient.

⚠ CAUTION

After attaching the disposable pads to the patient, replace them with new ones every 24 hours. Otherwise the gel dries even if the pads are not used for monitoring and the performance of the pads is impaired.

⚠ CAUTION

Store the disposable pads in the environment described on the pads package. If stored in an environment other than specified, the pads become unusable.

⚠ CAUTION

Do not attach a disposable pad over another pad. It may cause skin burn to the patient.

⚠ CAUTION

During transcutaneous pacing, always check that the pacing pulse is effective by observing the ECG on the screen.

⚠ CAUTION

Select the airway adapter or nasal adapter taking into consideration the patient weight and ventilation volume. If an inappropriate airway adapter or nasal adapter is used, the resistance in the respiratory circuit may increase and it may cause incorrect measurement value.

⚠ CAUTION

The measured value may be incorrect when the operating temperature changes greatly.

⚠ CAUTION

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

⚠ CAUTION

The CO_2 data may be inaccurate when monitoring a patient with an extremely high respiration rate or irregular respiration. Read the measured values carefully.

⚠ 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

Do not leave the battery pack in direct sunlight or high temperatures such as in a sun-heated car. This may cause leakage of the battery pack, degrade its performance and make it unusable.

⚠ CAUTION

When using an anesthetic instrument with a volatile anesthetic agent, the CO_2 measurement may be inaccurate.

⚠ CAUTION

While a patient is on medication which causes vasodilation, the pulse waveform may change and in rare cases the SpO_2 value might not be displayed.

⚠ CAUTION

When using the YG-121T or YG-122T nasal adapter on the patient, observe the patient condition all the time. The mouth guide touches the mouth and may cause pressure sores.

⚠ 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 removing an SD card, turn the defibrillator off. Otherwise, data on the SD card will be lost or data cannot be saved on the card because of static electricity.

⚠ 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

When using a wireless LAN system, be aware that signal loss may occur because of multipath cancellation.

⚠ CAUTION

When using a DFS supported channel, fully understand the access point operation when the access point detects radar waves and construct the wireless LAN system accordingly. Otherwise, the wireless communication may be interrupted when radar waves are detected.

⚠ CAUTION

For handling and precautions on options and consumables such as electrodes, sensors, probes and transducers, refer to the manual of the option or consumable.

⚠ CAUTION

Enter the age and gender when performing the 12 lead ECG interpretation. Otherwise:

- gender is male.
- age is 35 years old.

⚠ CAUTION

When monitoring ECG with disposable pads, check the polarity of the pads before attaching them on the patient. If the pad polarity is incorrect, the waveform appears upside-down and this may cause incorrect judgment by the operator and delay of treatment.

⚠ CAUTION

Be careful when using the defibrillator to measure SpO_2 without measuring ECG. Because arrhythmia is not analyzed when ECG is not measured, arrhythmia alarms such as Asystole, VF or VT are not generated. Also, SpO_2 upper and lower limit alarms are not generated when the patient's pulse cannot be detected because of asystole or other condition. If the patient requires ECG monitoring, measure the ECG.

⚠ CAUTION

- When using the defibrillator to measure SpO_2 without measuring ECG, turn on the upper and lower limit alarms for PR and SpO_2. Even when the limit alarms are turned on, SpO_2 upper and lower limit alarms are not generated if the patient has no pulse. In that case, a technical alarm ("Cannot Detect Pulse" or "Check Probe") occurs instead of an SpO_2 limit alarm.
- Noise from probe movement may be misjudged as a pulse and cause an incorrect PR or SpO_2 value to be displayed.

⚠ CAUTION

Some data and operations on the defibrillator 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

Observe all terms and conditions of the information security policy for the defibrillator. Otherwise, there is a risk that personal information and other data stored on the defibrillator may be leaked or misused. In order to protect the security of personal information and maintain the essential functionality of the defibrillator, it is necessary to implement a comprehensive, multi-layered security strategy (including policies, processes and security controls) to protect against internal and external cybersecurity threats.

⚠ CAUTION

Use the defibrillator in a securely managed environment.

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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