

Automated External Defibrillator

AED-3100

General

The AED-3100 automated external defibrillator is a compact automated external defibrillator.

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.
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 AED in the presence of any flammable anesthetic gas or high concentration oxygen atmosphere. Failure to follow this instruction may cause explosion or fire.

CONTRAINDICATION

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

CONTRAINDICATION

Do not take the AED into an MR examination room. The AED is not designed to be used during MR examinations.

WARNING

When using an ESU, remove the disposable pads from the patient. High frequency energy from the ESU causes abnormal current to flow in the patient and unexpected discharge. This may cause burn or injury and damage the AED.

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 and the connected instrument may be damaged.

WARNING

Before attaching the disposable pads to the patient, remove everything including electrodes, patches and any gel, cream or medicine from the site where the pads will be attached. If the pads contact these foreign substances, the discharged energy may be insufficient and cause skin burn to the patient.

WARNING

Before discharging energy to the patient, make sure that no one is in contact with either the patient or any metal part of any equipment or cables which supports or is connected to the patient. Failure to follow this warning causes serious electrical shock or injury.

WARNING

When discharging energy to the patient, do not touch the disposable pads and keep disposable pads away from the electrode or instrument connected to the patient and any other metal objects contacting the patient such as a bed frame or stretcher. Otherwise the discharged energy may be insufficient and cause skin burn.

WARNING

If the liquid leaked from the battery pack contacts the eyes, mouth, or skin, do not rub. Flush with plenty of clean water and see a physician immediately.

WARNING

Never do the following. The following may cause leak, overheating, explosion and fire.

- Giving an impact to the battery pack by dropping or throwing.
- Charging, short-circuit, disassembly, deformation, overheating, dropping into fire, or immersing in water.

WARNING

Install the battery pack correctly. If there is no battery pack in the AED, self test is not performed and the AED condition is not maintained.

WARNING

If the package of the defibrillation pads is punctured, dispose of the pads without using them. The discharged energy may be insufficient and it may cause skin burn to the patient.

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 use the AED when the patient's body is wet. If the patient's body is wet with water, sweat or oil, wipe the patient's body before discharging energy to the patient. If the patient body is wet, the discharged energy may be insufficient and the operator may receive electrical shock, or defibrillation pads cannot be attached to the patient.

WARNING

If the AED gets wet, wipe it thoroughly before use. Otherwise, the operator may receive electrical shock.

WARNING

To use the AED properly and effectively, it is recommended that first aid training including CPR and usage of this AED is performed.

WARNING

Do not use the wireless communication function within 15 cm of an implanted pacemaker or ICD. The radio frequency energy from the AED might affect the pacemaker or ICD.

WARNING

Do not use the wireless communication function in an airplane. The radio frequency energy from the AED might affect critical instruments on the plane.

WARNING

Do not disassemble or modify the AED. Disassembly or modification may cause overheating, fire, electrical shock or injury. The maximum performance from the AED cannot be guaranteed.

WARNING

Before pressing the shock button to discharge energy, make sure that all electrodes, transducers and connection cords of all medical instruments other than this AED are connected to the instrument. If they are disconnected, the operator receives electrical shock.

WARNING

The effectiveness of defibrillation depends on the patient conditions such as height, weight, patient history, current medications, combination of symptoms, and how soon the CPR and defibrillation are performed after collapse.

WARNING

While the AED is analyzing the patient's ECG, stop CPR and do not move or shake the patient's body. If the patient is in a car, stop the car. Otherwise, the AED cannot analyze the patient's ECG correctly.

WARNING

Only open the package of the disposable pads when you will immediately use them. If you use pads that have been opened and left out of the package for a period of time, or use pads more than once, the discharged energy may be insufficient and it may cause skin burn to the patient.

WARNING

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

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 pad. Failure to follow this warning may cause skin burn or insufficient energy discharge.

WARNING

Do not use the disposable pads if the gel peels off while removing the protection sheet or if the foam is peeled off and the metal part is exposed. Failure to follow this warning may cause skin burn or insufficient energy discharge.

WARNING

Do not use the battery pack if it is wet. Too much electricity might be discharged and the battery pack gets damaged.

WARNING

Do not use a broken or deformed battery pack. It may explode or cause fire.

WARNING

Do not use defibrillation pads which have already been used. The discharged energy may be insufficient and it may cause skin burn to the patient.

WARNING

When attaching the defibrillation pads, remove clothing and attach the defibrillation pads directly to the patient skin so that there is no space between the defibrillation pads and patient skin. If the defibrillation pads are not attached properly, the AED cannot analyze the ECG and the discharged energy may be insufficient and it may cause skin burn to the patient.

WARNING

When the patient is age 8 or older, use the adult mode. If child mode is selected, the discharged energy may be insufficient.

WARNING

When the patient is a child age 0 to 7, use the child mode. Discharging energy in the adult mode may damage the patient's cardiac muscle.

WARNING

If the patient's body is small and the defibrillation pads contact each other, attach the defibrillation pads on the patient's chest and back instead of on the upper right and left side of the chest. If the defibrillation pads contact each other, discharged energy may be insufficient and cause skin burn.

WARNING

Do not use or leave the battery pack in direct sunlight or high temperatures such as in a car in hot weather or in front of a stove. It may cause leakage of the battery pack and degrade the performance and lifetime of the battery pack.

WARNING

Do not use training pads for defibrillation. The AED cannot discharge energy to the patient if training pads are used.

CAUTION

Before discharging energy to the patient by pressing the shock button, 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

Attach the disposable pads firmly so that there are no air bubbles between the pads and patient skin. Otherwise energy discharge might burn the patient skin where the defibrillation pads are attached.

CAUTION

Only use Nihon Kohden specified battery pack. If unspecified battery pack is used, maximum safety and performance from the AED might not be achieved.

CAUTION

Only use the specified accessories and options. Otherwise, the AED might not operate correctly and the maximum performance from the AED cannot be guaranteed.

CAUTION

Do not install the AED near equipment which emits strong electromagnetic waves such as microwave therapy instruments. The AED might not operate for resuscitation.

CAUTION

Install the AED in a place which has the following conditions. Otherwise, the AED might not operate correctly.

- Temperature: -5 to $+50^{\circ}\text{C}$ (23 to 122°F)
- Humidity: 5 to 95% (noncondensing)
- Atmospheric pressure: 540 to 1060 hPa

CAUTION

Make sure that there is more than 30 cm of space between mobile phones and the AED. For other wireless devices, make sure that there is more than the space of "Recommended separation distances: d*" in this manual. Radio waves from these devices may affect the AED. Depending on the radio waves, noise may be superimposed on the ECG and analysis may be incorrect.

* The recommended separation distance is calculated from the equation in the "Recommended separation distances between portable and mobile RF communications equipment and the AED-3100" in the operator's manual.

CAUTION

The AED 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 AED may judge that it is necessary to discharge energy to the patient even if it is not necessary. When the AED 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

Before using the AED, check the following.

- The patient is unconscious.
- The patient is not breathing.
- No pulse (Only for medical personnel)

CAUTION

Energy is not discharged when asystole occurs. Follow the voice instruction and perform CPR.

CAUTION

Do not put heavy objects on the disposable pads or bend the pads. The discharged energy may be insufficient due to damage to the wires, resulting in skin burn on the patient.

CAUTION

When the disposable pads are used for more than 24 hours, replace them with new ones every 24 hours. Otherwise the discharged energy may be insufficient and it may cause skin burn to the patient.

CAUTION

Store the disposable pads in the conditions described on the pads package. Otherwise the disposable pads deteriorate and maximum performance cannot be guaranteed.

CAUTION

Do not attach a defibrillation pad over another defibrillation pad. The discharged energy may be insufficient and it may cause skin burn to the patient.

CAUTION

If the defibrillation pads are not attached to the patient's skin properly because of the patient's chest hair, maximum performance from the AED cannot be guaranteed. In this case, firmly press the pads against the skin. If the pads placement indicators are still lit and there are spare pads, press the already attached pads to the chest skin, pull the them off quickly to remove hair and then attach the spare pads for rescue. If there is a shaver, shave the chest hair.

CAUTION

Follow the instructions in this manual to attach the disposable pads. The AED cannot analyze the patients ECG and discharge energy to the patient if disposable pads are put on the patient body while the pads are still in the package.

CAUTION

Before attaching the disposable pads to the patient skin, completely remove the protection sheets from the disposable pads. Failure to follow this instruction may cause poor energy discharge to the heart.

CAUTION

When turning the AED on, check that the proper mode (child or adult) is selected. Otherwise, the discharged energy may be insufficient or too much.

CAUTION

When connecting the disposable pads to the AED, insert the disposable pad connector into the slot and make sure that it is locked. If the disposable pads are not connected properly, the AED cannot analyze the ECG and cannot discharge energy to the patient.

CAUTION

When disposing of the AED,

- Remove the battery pack from the AED.
- Follow your local laws.

CAUTION

When disposing of the battery pack, follow your local laws.

CAUTION

The used disposable pads are medical waste. Dispose of the disposable pads according to your local laws.

CAUTION

Store the battery pack in the following conditions. Otherwise, the battery pack might deteriorate.

- Temperature: -20 to $+70^{\circ}\text{C}$ (-4 to $+158^{\circ}\text{F}$)
- Humidity: 5 to 95% (noncondensing)

CAUTION

In the following cases, the life of the battery pack may become shorter than 4 years.

- Turning the AED on and off too frequently for purposes other than rescue or inspection.
- Turning the AED power on for a long time, such as during training or inspection.
- Discharging energy too many times for testing.
- Leaving the AED without stopping an alarm.

CAUTION

This AED is medical equipment. For installation and usage of this AED, assign a manager.

CAUTION

Check the remaining battery power periodically.

CAUTION

Create a security policy for the facility to manage the AED in accordance with the laws and regulations of the country in which the facility is located. Use the AED in an environment in which personal data is securely protected.

⚠ CAUTION

Observe all terms and conditions of the user agreement related to the information security of the AED. In order to protect personal information and the essential functionality of the defibrillator from internal and external threats, it is necessary to implement a comprehensive, multi-layered security strategy (including policies, processes and security controls).

⚠ CAUTION

The Bluetooth function is used when communicating with a PC with the QP-551VK defibrillation report viewer software. Since this involves connecting the AED to a network, appropriate network security measures should be implemented under the supervision of the information security manager of the medical facility.

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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