SAFETY AND PERFORMANCE INFORMATION

Disposable Pads P-730K

General

The P-730K disposable pads are used with the following defibrillators to deliver defibrillation shocks to the patient to treat ventricular fibrillation and ventricular tachycardia.

- AED-2100K
- AED-2150K • AED-2152K
- AED-2151K
- TEC-5500 series TEC-5600 series
- TEC-7600 series TEC-7700 series
- TEC-8300 series

Safety Information

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

- · Never use the disposable pads in the presence of any flammable anesthetic gas or high concentration oxygen atmosphere. Failure to follow this warning may cause explosion or fire.
- When performing MRI test, remove these disposable pads from the patient. Failure to follow this warning may cause skin burn on the patient. For details, refer to the MRI manual
- Do not use the pads if they are past the expiration date on the package. Failure to follow this warning may cause skin burn or insufficient energy discharge.
- · Open the package of the disposable pads only when you will immediately use them. Otherwise, the disposable pads deteriorate and it causes insufficient energy discharge and skin burn.
- Do not reuse disposable pads. If you use the disposable pads more than once, it may cause skin burn and cross infection.

- If the package of the disposable pads is punctured or the disposable pads are deformed or damaged, do not use the disposable pads. The discharged energy may be insufficient and it may cause skin burn to the patient.
- 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.
- Do not use the disposable pads if the gel has become dry or if the gel has become abnormal (the gel has become liquid or is coming off the edges of the pad, etc). Failure to follow this warning may cause insufficient energy discharge and skin burn.
- When medicine, patch, electrode, sweat or paste is on the patient skin where the disposable pads are to be attached, remove or wipe them off the skin before attaching the disposable pads. Failure to follow this warning causes insufficient energy discharge and skin burn
- Attach the disposable pads firmly so that there are no air bubbles between the pads and patient skin. If the pads are not attached properly, the discharged energy may be insufficient and it may cause skin burn to the patient.
- Do not remove the package from the pad cable. It may damage the cable and cause electrical shock to the patient or operator. If the package is in the way, roll the package around the cable and fasten the cable with tape.
- If the cable is not long enough, you can get more cable length by slowly separating the two wires of the cable. When separating the cable, do not use too much force. If the cable breaks, the operator may receive electrical shock.
- If the pad or connector is wet, wipe the pad or connector thoroughly before use. If water gets into the pad connector, do not use the pads. If defibrillation is performed using a wet disposable pad, the operator may receive electrical shock. Also, the discharged energy may be insufficient and it may cause skin burn to the patient.

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 defibrillator.

A WARNING

- Do not perform defibrillation or cardioversion in a wet place. Before defibrillation or cardioversion, move the patient and defibrillator to a dry place. Otherwise the operator may get electrical shock.
- When charging energy or performing defibrillation, do not touch the disposable pads, the connector or the patient. The operator may receive electrical shock.
- Do not perform defibrillation using an external paddle pressed against the disposable pads on the patient's chest. The discharged energy may be insufficient.
- Before discharging, confirm that the pads are firmly pressed against the chest wall. Otherwise, the discharged energy may be insufficient and it may cause skin burn to the patient.
- If the patient's body is wet, thoroughly wipe the moisture off the skin so that the paddles do not short to each other. Otherwise, the discharged energy may be insufficient.

- Do not touch the patient, pads or connectors during pacing. It may cause electrical shock.
- When using the disposable pads for long term pacing, replace them every hour. Failure to follow this warning may cause skin burn, insufficient energy discharge and insufficient pacing current to the heart.
- Before performing defibrillation after pacing, press the pads to the patient's skin to ensure good contact. If the pads are not attached correctly, the discharged energy may be insufficient and it may cause skin burn to the patient.

- These disposable pads are not sterilized.
- Never autoclave or perform EOG gas sterilization on the pads. It damages the pads.
- Do not disinfect the pads with alcohol.
- Connect the pads only to the specified defibrillator or pad adapter. Otherwise, defibrillation might not be performed or the operator may receive electrical shock. Confirm the defibrillator model before using the pads.
- Periodically check the expiration date of the disposable pads. Dispose of expired disposable pads. The discharged energy may be insufficient and it may cause skin burn to the patient.
- Always have spare pads ready.
- Do not use disassembled or modified disposable pads. The defibrillator cannot acquire correct ECG. Also, fracture of the cable may cause insufficient energy discharge and skin burn.
- When you connect the disposable pads to the defibrillator, check the direction of the connector pins, insert the connector into the defibrillator socket or pad adapter and make sure that it is locked.

- Only connect the disposable pads to the specified defibrillator socket or pad adapter. Confirm the connector shape when inserting the pads. Otherwise, connector pins may be deformed or damaged.
- Dispose of the pads if the side with the gel gets dirty. The discharged energy may be insufficient and it may cause skin burn to the patient.
- If pads are accidentally attached to an incorrect position, remove them and use other pads. Do not reuse them even for the same patient. Reattached pads cause insufficient energy discharge and skin burn.
- Do not attach a disposable pad over another disposable pad. The discharged energy may be insufficient and it may cause skin burn to the patient.
- If you performed chest compressions against the pads and the pads are damaged, replace the pads. Damaged pads may cause skin burn and poor energy discharge to the heart.
- If the defibrillator indicates abnormality of the pads, replace the pads immediately.
- Replace the disposable pads with new ones every 24 hours when you continuously use the defibrillator for more than 24 hours. Otherwise, the gel on the pads gets dry and it may cause insufficient energy discharge and skin burn.
- Do not use pads if the cable has a lot of tension. The cable may break or the pads may get detached from the patient.
- Do not put strong pressure on the package. The package is damaged and the adhesive gel on the pads gets dry and the discharged energy may be insufficient and it may cause skin burn to the patient.
- Do not step on the disposable pads and do not give strong impact to the pads. Do not put a heavy object on the pads and do not bend the pads. If you did these actions, confirm that the pads are not damaged. The skin gets irritated or redness appears from deformed or abnormal pads.
- 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.
- When detaching the pads from the patient's skin, slowly remove the pads from the edge.
- When using adhesive remover, refer to the accompanying documents for the remover.
- Do not use the disposable pads if the electrode is rusted. The discharged energy may be insufficient.
- If the gel on the pad is removed when removing protection sheet from the pad, dispose of the pads. The discharged energy may be insufficient and it may cause skin burn to the patient.
- Do not attach the pads on skin which has a wound or rash. The skin may get irritated or redness appears on the pad attachment sites.
- When the disposable pads are used for a long time, redness may appear on the skin depending on the patient's constitution.
- Do not heat the pads before attaching them to the patient. The pads may deteriorate and the skin may get irritated or redness appears on the pad attachment sites.

- Do not use a cutter to open the package. The pads or cable may get damaged.
- After removing the disposable pads from the patient, make sure that no gel remains on the patient skin. If gel is left on the skin, the skin may get irritated or redness may appear on the skin.

▲ CAUTION

When using an ESU, do not perform pacing using the pads. 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 defibrillator.

- When attaching the disposable pads, remove clothing and attach the disposable pads directly to the patient skin so that there is no space between the disposable pads and patient skin. If the disposable pads are not attached properly, the defibrillator cannot analyze the ECG and the discharged energy may be insufficient and it may cause skin burn to the patient.
- When using the disposable pads on a patient with delicate skin, redness on the skin or skin erosion may occur. Also, the mark of the redness or erosion may remain.

- Do not discharge if the pads overlap each other or are shorted to each other by anything conductive such as contact gel. This may cause skin burn and poor energy discharge to the heart.
- If the disposable pads are not attached to the patient's skin properly because of the patient's chest hair, firmly press the pads against the skin. If the skin pad contact is not good enough, remove the hair. If there are spare pads, remove the hair using the already attached pads and use the spare pads for defibrillation. To remove the hair using the pads, press the already attached pads to the chest skin and pull them off quickly. If the skin pad contact is poor, the discharged energy may be insufficient and it may cause skin burn to the patient.
- If the patient's body is small and the disposable pads contact each other, attach the disposable pads on the patient's chest and back instead of on the upper right and left side of the chest. If the disposable pads contact each other, discharged energy may be insufficient and cause skin burn.
- After changing the position of the patient who is attached disposable pads, press the pads firmly to the patient skin and confirm that pads are not detached from the patient. Detached pads may cause insufficient energy discharge and skin burn.

- Long-term pacing may cause redness or itching on the skin.
- After pacing, check the ECG using the electrocardiograph. The ECG acquired by the pads may be unstable after pacing.
- After a long term external pacing, ECG analysis in the AED mode might not be correctly performed. The ECG acquired by the pads may be unstable after pacing.

Store the pads in a dry and cool place avoiding high temperature and direct sunlight.

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.

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.

Manufacture

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