SAFETY AND PERFORMANCE INFORMATION

Defibrillation Pads for Adult P-531

General

The P-531 defibrillation pads are disposable and for adult use.

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 or Installation Guide.

WARNING

- Open the package of the defibrillation pads only when you will immediately use them. Otherwise, the defibrillation pads deteriorate and cause burn to the skin. The defibrillation pads are disposable and single use only. If you use the defibrillation pads more than once, it may cause skin burn.
- 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.
- If the package of the defibrillation pads is punctured, do not use the defibrillation 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 skin burn or insufficient energy discharge.
- 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.
- 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 defibrillator cannot analyze the ECG and the discharged energy may be insufficient and it may cause skin burn to the patient.
- Before attaching the defibrillation pads, remove everything including electrodes, patches and gel from the site where the pads will be attached. If the defibrillation pads contact any gel or object on the patient's chest, the discharged energy may be insufficient and cause skin burn.
- If the pad or connector is wet, wipe the pad or connector thoroughly before use. If you perform defibrillation using a wet defibrillation pad, the operator may receive electrical shock.
- 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.

- When performing defibrillation, do not touch the defibrillation pads and keep defibrillation 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 operator may receive electrical shock.
- When using an ESU, remove the defibrillation 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.
- This defibrillation pad cannot be used for pacing.

CAUTION

- When you connect the defibrillation pads to the defibrillator, insert the defibrillation pad connector into the defibrillator socket and make sure that it is locked. If the defibrillation pads are not connected properly, the defibrillator cannot analyze the ECG and defibrillation is not performed.
- The defibrillator cannot analyze and perform defibrillation if defibrillation pads are put on the patient body with the defibrillation pads still in the package. To perform defibrillation, follow the instruction in this manual to attach the defibrillation pads.
- When you attach defibrillation pads to the patient skin, remove the protection sheets from the defibrillation pads.
- 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.
- 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, 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.
- When you monitor ECG that is acquired with the defibrillation 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.
- If voice instruction, pad placement indicator or self-test result indicates abnormality of the pads, replace the pads immediately.
- Replace the defibrillation pads with new ones every 24 hours when you continuously use the defibrillator for more than 24 hours. Otherwise, the discharged energy may be insufficient and it may cause skin burn to the patient.
- Store the defibrillation pads in the conditions which are described on the package of the defibrillation pads. Otherwise, the defibrillation pads deteriorate and maximum performance cannot be guaranteed.
- Do not put a heavy object on the defibrillation pads and do not bend the defibrillation pads. The metal foil of the defibrillation pads may break, the discharged energy may be insufficient and it may cause skin burn to the patient.
- The used defibrillation pads are medical waste. Immediately dispose of the used defibrillation pads according to your local laws.

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.



EC REP European Representative NIHON KOHDEN EUROPE GmbH Raiffeisenstrasse 10, D-61191 Rosbach, Germany Phone +49 6003-827-0 Fax +49 6003-827-599

1-31-4 Nishiochiai, Shinjuku-ku, Tokyo 161-8560, Japan Phone +81 3-5996-8041 https://www.nihonkohden.com/

NIHON KOHDEN CORPORATION