SAFETY AND PERFORMANCE INFORMATION NIHON KOHDEN



Disposable Pads for Infant P-513

General

The P-513 disposable pads are for the infant less than 1 year old. These disposable pads are used with the following defibrillators to deliver defibrillation shocks to the patient.

- TEC-7600 series defibrillator
- TEC-7700 series defibrillator
- TEC-5500 series defibrillator
- TEC-5600 series defibrillator
- TEC-8300 series defibrillator
- EMS-1052 defibrillator

Safety Information

CAUTION

WARNING 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.

WARNING

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.

WARNING

Open the package of the disposable pads only when you will immediately use them. Otherwise, the disposable pads deteriorate and cause insufficient energy discharge and skin burn.

WARNING

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.

WARNING

If the package of the disposable pads is punctured, do not use the disposable pads. 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

If the pad or connector is wet, wipe the pad or connector thoroughly before use. If you perform defibrillation using a wet disposable pad, the operator may receive electrical shock.

WARNING

When medicine, patch or electrode is on the patient skin where the disposable pads are to be attached, remove them and wipe any medicine off the skin before attaching the disposable pads. Failure to follow this warning causes skin burn or poor energy discharge to the heart.

WARNING

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

WARNING

When charging energy or performing defibrillation, do not touch the disposable pads and the connector. Also, keep the pads away from any metal objects contacting the patient. The operator may receive electrical shock.

WARNING

When using the disposable pads for long term pacing, replace them every hour. When performing defibrillation after pacing, press the pads firmly to the patient skin before defibrillation. Failure to follow this warning may cause skin burn or insufficient energy discharge and pacing current to the heart.

WARNING

Do not touch the patient, pads or connectors during pacing. It may cause electrical shock.

WARNING

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 in jury and damage the defibrillator.

WARNING

Do not perform 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 burn, shock or other injury. It also damages the defibrillator.

WARNING

Do not use the P-513 disposable pads for the patient age one or more. P-513 disposable pads cannot be used for discharge of more than 100 J. Use the P-511 disposable pads for the patient age one or more.

CAUTION

Only connect the pads to the specified pad adapter. Otherwise, the connector pin is bent or deformed.

CAUTION

Do not get the pad connector wet. The connector pin may get rusted.

CAUTION

Do not reuse disposable pads.

CAUTION

Do not put a heavy object on the disposable pads and do not bend the disposable pads. The disposable pads are damaged and it may cause insufficient energy discharge and skin burn to the patient.

CAUTION

Replace the disposable pads with new ones if a message or the status indicator indicates pad error.

CAUTION

Always have the spare pads ready.

CAUTION

Replace the disposable pads with new ones every 24 hours when monitoring ECG for a long time. The discharged energy may be insufficient and it may cause skin burn to the patient.

CAUTION

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. Poor skin pad contact may cause poor energy discharge to the heart.

CAUTION

When you monitor ECG that is acquired with the disposable pads, check the polarity of the pads before attaching them on the patient. If the pad polarity is incorrect, the waveform appears upsidedown and this may cause incorrect judgment by the operator and delay of treatment.

CAUTION

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, correct ECG cannot be acquired and the discharged energy may be insufficient and it may cause skin burn to the patient.

CAUTION

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.

CAUTION

After connecting the pads, make sure to push the connector of the pads all the way into the pad adapter connector. If the connector is not properly connected, correct ECG cannot be acquired or the energy might not be discharged.

CAUTION

The used disposable pads are medical waste. Immediately dispose of the used disposable 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.



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