# SAFETY AND PERFORMANCE INFORMATION NIHON KOHDEN



## **Defibrillation Pads** P-511X

#### General

The P-511X defibrillation pads can be used with the following defibrillators to deliver defibrillation shocks to the patient.

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

### 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**

Do not use the defibrillation 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 defibrillation pads only when you will immediately use them. Otherwise, the defibrillation 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 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.

#### **⚠ WARNING**

Do not use the defibrillation 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 defibrillation pad, the operator may receive electrical shock.

#### **⚠ WARNING**

When medicine, patch or electrode is on the patient skin where the defibrillation pads are to be attached, remove them and wipe any medicine off the skin before attaching the defibrillation 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 defibrillation pads and the connector. Also, keep the pads away from any metal objects contacting the patient. The operator may receive electrical shock.

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

#### **⚠ WARNING**

When using the defibrillation 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 injury and damage the defibrillator.

#### **⚠ WARNING**

Do not perform pacing while using an ESU. Before using the ESU, turn the defibrillator power off and remove defibrillation 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.

#### **⚠** CAUTION

Only connect the pads to the specified defibrillator 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 defibrillation pads.

#### **↑** CAUTION

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

#### ⚠ CAUTION

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

#### **⚠** CAUTION

Always have the spare pads ready.

#### ⚠ CAUTION

Replace the defibrillation 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 defibrillation 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

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

For infants less than 1 year old, use the P-513 disposable pads.

#### **⚠** CAUTION

If the patient is a small child 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.

#### **⚠** CAUTION

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.



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1st Edition: 27 May 2019 2nd Edition: 30 May 2023

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