

Defibrillation Pads P-511X

General

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

- AED-2100K automated external defibrillator
- AED-2150K automated external defibrillator
- AED-2151K automated external defibrillator
- AED-2152K automated external defibrillator
- TEC-5500 series defibrillators
- TEC-5600 series defibrillators
- TEC-7600 series defibrillators
- TEC-7700 series defibrillators
- TEC-8300 series defibrillators

The pads, cables and electrodes are made of radiotransparent materials. The pads are intended for use in the hospital but outdoor or ambulance use is also possible. The connector is outside the package so you can store the defibrillation pads while they are connected to the defibrillator.

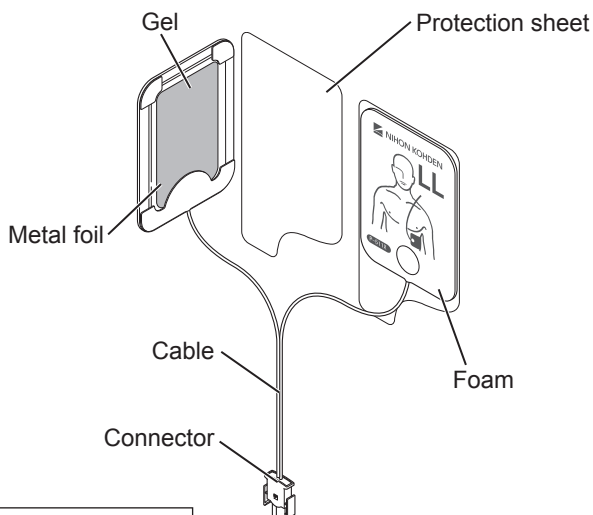
These pads can also be used for external pacing. The pads can also acquire ECG when used for pacing.

One of the following pad adapters is required to connect the defibrillation pads to the defibrillators.

- JC-765V pad adapter: TEC-5500/TEC-7600/TEC-7700 series defibrillators
- JC-865V pad adapter: TEC-5600/TEC-8300 series defibrillators

The defibrillation pads are not made with natural rubber latex.








Description of Parts





Printed:

Symbols

The following symbols are used with this defibrillation pads. The description of each symbol is shown in the table below.

Symbol	Description
	Caution
	Expiration date
	Do not reuse
	Non-sterile
	Temperature limits
	Keep away from sunlight
	The CE mark is a protected conformity mark of the European Community. Products marked with this symbol comply with the requirements of the Medical Device Directive 93/42/EEC.

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 this Operator's Manual.

General

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.

⚠ CAUTION

Only connect the pads to the specified defibrillator pad adapter or AED. 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.

- NOTE
- These defibrillation pads cannot be sterilized.
 - 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.

Defibrillation

⚠ 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.

⚠ 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.

NOTE: If the package on the cable prevents operation, remove the package.

Pacing

⚠ 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.

Using with ESU

⚠ 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.

Using Defibrillation Pads on Child

⚠ 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.

Storage

⚠ 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.

- NOTE
- Though the gel on the pads might become yellow if you store the pads at high temperature for a long time, the yellowish gel does not affect the performance.
 - Store the defibrillation pads in the conditions which are described on the package and this manual. Otherwise, the defibrillation pads becomes unavailable for rescue.

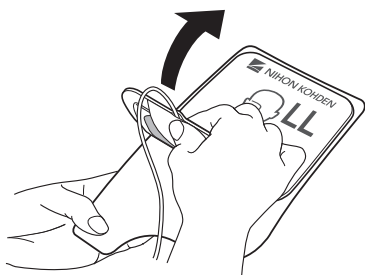
Disposal

CAUTION

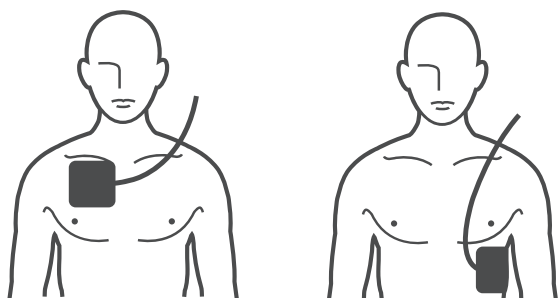
The used defibrillation pads are medical waste. Immediately dispose of the used defibrillation pads according to your local laws.

Attaching the Pads to the Patient

1. Connect the defibrillation pads to the defibrillator pad adapter or AED so that the defibrillation pads connector is locked.
2. Remove all clothing from the patient's chest and clean the patient skin to remove oil, moisture and dirt, and thoroughly dry the skin.
3. Tear the package along the dotted line and take the pads out.
4. Hold the tab of the protection sheet and slowly peel away the protection sheet. If you peel from the opposite edge, the gel might come off.



5. Attach the defibrillation pads as shown on the package and press them so that there is no space between the pads and the patient's skin.

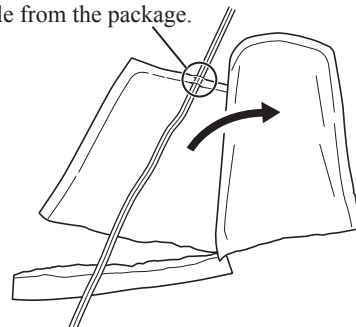


Removing the Package

If the package on the cable prevents operation, remove the package.

1. Hold both sides of the package opening and tear it open.

Remove the cable from the package.



2. Remove the cable from the package.

Disposing of the Pads

Used defibrillation pads are medical waste. Follow your local laws when disposing the defibrillation pads.

1. After the rescue or treatment, slowly remove the pads from the patient's chest.
2. Disconnect the defibrillation pads from the pad adapter.
3. Put the defibrillation pads in the package. If you removed the package from the cable, put the pads in a plastic bag to prevent cross infection.
4. Dispose of the pads by following your local laws.

Specifications

Operating Environment

Temperature: 0 to 45°C (32 to 113°F)

Humidity: 30 to 95% (noncondensing)

Atmospheric pressure: 700 to 1060 hPa

Storage Environment

Temperature: 0 to 35°C (32 to 95°F)

Humidity: 15 to 95% (noncondensing)

Atmospheric pressure: 500 to 1060 hPa

Expiration date: 24 months from the date of manufacture

Performance

Electrode pair voltage (electrode offset voltage):

≤ 100 mV

≤ 1200 mV (after pacing)

Electrode pair impedance: ≤ 3 kΩ (at 10 Hz)

≤ 5 Ω (at 30 kHz)

≤ 10 Ω (at 30 kHz after pacing)

Defibrillation impedance: $\leq 3 \Omega$ (discharge at 360 J)

$\leq 5 \Omega$ (discharge at 360 J after
pacing)

Offset voltage deviation and internal noise:

$\leq 100 \mu\text{Vp-p}$ (0.5 to 40 Hz)

Recovery after defibrillation:

$\leq 400 \text{ mV}$ (4 s after discharge at
360 J)

$\leq 1200 \text{ mV}$ (4 s after discharge at
360 J, after pacing)

$\leq 300 \text{ mV}$ (60 s after discharge at
360 J)

$\leq 1100 \text{ mV}$ (60 s after discharge at
360 J, after pacing)

Copyright Notice

The entire contents of this manual are copyrighted by Nihon Kohden.
All rights are reserved.



Manufacturer

NIHON KOHDEN CORPORATION

1-31-4 Nishiuchi, Shinjuku-ku,

Tokyo 161-8560, Japan

Phone +81 3-5996-8036 Fax +81 3-5996-8100

<http://www.nihonkohden.com/>



European Representative

NIHON KOHDEN EUROPE GmbH

Raiffeisenstrasse 10, D-61191 Rosbach, Germany

Phone +49 6003-827-0 Fax +49 6003-827-599

**SHANGHAI KOHDEN MEDICAL ELECTRONIC
INSTRUMENT CORP.**

567 Huancheng Bei Road

Shanghai Comprehensive Industrial Development Zone
Shanghai 201401, China

NIHON KOHDEN AMERICA, INC.

15353 Barranca Parkway, Irvine, CA 92618, U.S.A.

Toll-free +1-800-325-0283

Phone +1 949-580-1555 Fax +1 949-580-1550

1st Edition: 08 Jan 2015

2nd Edition: 28 Aug 2015

