

# **OPERATOR'S MANUAL**

**Disposable Pads P-740K** 

### General

The P-740K disposable pads are used with the following defibrillators to deliver defibrillation shocks to the patient.

• AED-2150K

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

The disposable pads can also acquire ECG. The pads can be used for external pacing when connected to a defibrillator which has an external pacing function.

The pads are intended to be used in a hospital, ambulance and outdoors. The pads are for single use only. The pad materials are less affected by baseline drift during CPR than the conventional Nihon Kohden disposable pads. The pads are not made with natural rubber latex. The pads are designed so the distance between the pads and operator is 50 cm.

NOTE: There may be a slight baseline drift because the materials of the pads cannot completely prevent baseline drift.

## **Description of Parts**



#### AED-3100 • TEC-5600 series

# • TEC-7600 series

#### Expiration date . LOT

**Symbols** 

Symbol

(3)

Background

color: blue

	Lot number
$\otimes$	Do not reuse
NON	Not sterilized at factory
-5	Temperature limits
*	Keep away from sunlight
CE	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.

The following symbols are used with the disposable pads. The

Description

description of each symbol is shown in the table below.

Follow instructions for use

# **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 this operator's manual.

#### General

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- 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.
- · 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.

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#### A WARNING

- 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.
- 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.
- 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.

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- 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.
- Do not use the disposable pads if the electrode is rusted. The discharged energy may be insufficient.
- 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.
- 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.
- · Always have spare pads ready.
- Do not use a cutter to open the package. The pads or cable may get damaged.
- 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.

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- If the defibrillator indicates abnormality of the pads, replace the pads immediately.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- When using adhesive remover, refer to the accompanying documents for the remover.
- 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.

NOTE: The right and left pads are connected with the same label but it can be divided by tearing along the dotted line on the label.

### Defibrillation

#### A WARNING

- 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 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.
- Do not perform defibrillation using an external paddle pressed against the disposable pads on the patient's chest. The discharged energy may be insufficient.

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- 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.
- 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 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.

### Pacing

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

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- 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.

### Using with ESU

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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.

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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.

### Storage

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

- NOTE The electrode and the gel on the pads might become yellow if you store the pads at high temperature for a long time, but this does not affect the performance.
  - Do not store the pads where they may get wet with water or chemical solution or exposed to toxic gases.
  - Store the disposable pads in the conditions which are described on the package. Otherwise, the disposable pads may become unusable for rescue.

### Disposal

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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.

# Attaching the Pads to the Patient

- 1. Insert the connector of the pads into the pad connector of the defibrillator until it locks with a click.
- 2. Remove all clothing from the patient's chest and wipe the patient skin.
- 3. Tear the package along the dotted line and take the pads out. Do not remove the package from the pads cable.

If the package is in the way, wind the package around the cable and fasten the cable with tape.



4. Hold the tab of the protection sheet (blue sheet) and slowly peel away the protection sheet from the cable side.



5. Attach the disposable pads as shown below and press them so that there is no space between the pads and the patient's skin. The position of the pads depends on whether the patient is an adult or child and the size of the child's body.



each other.

## **Disposing of the Pads**

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

- 1. After use, slowly remove the pads from the patient's chest.
- 2. Disconnect the connector of the pad from the defibrillator.
- 3. Put the pads in the package and dispose of the pads.

## Specifications

Operating Environment				
Temperature: -5	5 to +50°C (23 to 122°F)			
Humidity: 5	to 95% (noncondensing)			
Atmospheric pressure: 54	0 to 1060 hPa			
Storage Environment				
Temperature: Within 1 v	week: $-30 \text{ to } +65^{\circ}\text{C}$			
	(-22 to +149°F)			
More than	1 week: $-5$ to $+50^{\circ}$ C			
	(23 to 122°F)			
Humidity:	5 to 95% (noncondensing)			
Atmospheric pressure:	540 to 1060 hPa			
Expiration date:	32 months from the date of			
1	nanufacture			
Cable length:	about 1.5 m			
Performance				
Electrode pair voltage:	$\leq 100 \text{ mV}$			
	$\leq$ 850 mV (after pacing)			
Electrode pair impedance:	$s \leq 3 \text{ k}\Omega \text{ (at 10 Hz)}$			
	$\leq$ 5 $\Omega$ (at 30 kHz)			
Defibrillation impedance:	$\leq$ 3 k $\Omega$ (monophasic discharge at			
	360 J)			
Offset voltage deviation and internal noise:				
	$\leq$ 100 µVp-p for 5 minutes (0.5 to			
	40 Hz)			
Recovery after defibrillation (monophasic discharge at 360 J				
	$\leq$ 400 mV (4 s after discharge)			
	$\leq$ 850 mV (after pacing)			
	$\leq 300 \text{ mV} (60 \text{ s after discharge})$			
т 1	$\leq$ 850 mV (after pacing)			
Impedance	Patrice node > 7.2 W DC			
	Between paus. $\geq 7.2$ kV DC			
	(1 mm) Retween conductive part and other			
	part: $> 7.2 \text{ kV DC} (1 \text{ min})$			
Pacing duration	$\leq 1 \text{ hr (at 200 mÅ 180 nnm)}$			
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