Stat-padz®II Multi-function

Instructions for Use

OPERATING TEMPERATURE: 0°C to 50°C (32°F to 122°F)
SHORT TERM STORAGE TEMPERATURE: -30°C to 65°C (-22°F to 149°F)
LONG TERM STORAGE TEMPERATURE: 0°C to 35°C (32°F to 95°F)

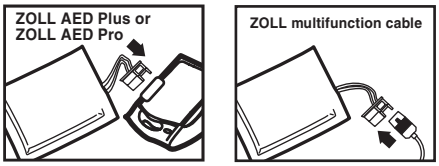
Rx ONLY 0° C 32° F 50° C 122° F IPX2 MD MR NON STERILE LATEX NOT MADE WITH NATURAL RUBBER LATEX. CE 0123

February 2022
R2001-67-50 Rev. 02

Intended Purpose: To deliver defibrillation, cardioversion, non-invasive pacing therapy to the heart and provide ECG monitoring.

Indications for use: For use on adult patients with ZOLL® AED Pro®, AED Plus®, AED 3®, AED 3® BLS, R Series®, X Series®, X Series® Advanced and Propaq® MD by trained personnel including Physicians, Nurses, Paramedics, Emergency Medical Technicians and Cardiovascular Laboratory Technicians. The Stat-padz electrodes are not indicated for use on a patient less than 8 years of age or weighing less than 55lbs (25kg).

Preconnecting the Electrodes (Optional)



1. Do not open until ready to use.
2. Periodically inspect electrode packaging for integrity & expiration date.
3. Attach to ZOLL AED Plus, ZOLL AED Pro, or to ZOLL multifunction cable.

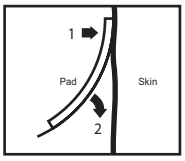
SKIN PREPARATION

Instructions

1. Remove excess chest hair. Clip if necessary to maximize gel to skin contact. Clipping is recommended since shaving can leave tiny microabrasions that can lead to patient discomfort during pacing.
2. Ensure skin is clean and dry under electrode. Remove any debris, ointments, skin preps, etc. with water (and mild soap if needed). Wipe off moisture/diaphoresis with dry cloth.

⚠ Excessive hair can inhibit good coupling (contact), which can lead to the possibility of arcing and skin burns.

ELECTRODE APPLICATION



Instructions

1. Apply one edge of the pad securely to the patient.
2. "Roll" the electrode smoothly from that edge to the other. Be careful not to trap any pockets of air between the gel and skin.

⚠ Poor adherence and/or air under the electrodes can lead to the possibility of arcing and skin burns.

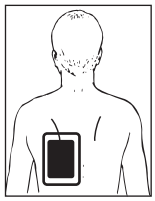
ELECTRODE PLACEMENT

Anterior-Posterior

Recommended for defibrillation, non-invasive pacing, ventricular cardioversion, and ECG monitoring. Optimal for non-invasive pacing because it increases patient tolerance and decreases capture thresholds.

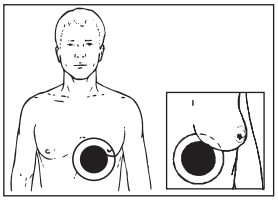
Posterior:
Grasp the Posterior electrode at the red tab and peel away from the plastic liner. Place to the left of the spine just below the scapula at the heart level.

⚠ Always apply Posterior electrode first. If Anterior electrode is already in place when patient is being maneuvered for placement of the Posterior, the Anterior may become partially lifted. This could lead to arcing and skin burns.


POSTERIOR

Anterior Apical:
Grasp the Anterior Apical electrode at the red tab and peel away from the plastic liner. Apply over cardiac apex with the nipple under adhesive area on a male patient. Position under breast on a female patient.

⚠ Avoid any contact between nipple and gel treatment area. Skin of the nipple area is more susceptible to burning.


ANTERIOR APICAL

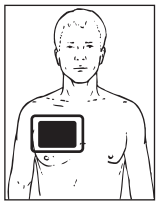
Anterior-Anterior

Recommended for defibrillation and ECG monitoring only.

⚠ Not optimal for non-invasive pacing. Non-invasive pacing with this configuration can lead to decreased patient tolerance and increased capture thresholds.

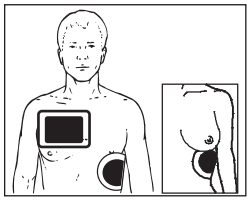
Anterior Sternal:
Grasp the Anterior Sternal electrode at the red tab and peel away from the plastic liner. Apply on the patient's upper right torso.

⚠ Avoid any contact between nipple and gel treatment area. Skin of the nipple area is more susceptible to burning.


ANTERIOR STERNAL

Anterior Lateral:
Grasp the Anterior Lateral electrode at the red tab and peel away from the plastic liner. Apply so that the top of the gel treatment area lines up with the bottom of the pectoral muscle on a male patient. Position electrode under the breast on a female patient.

⚠ Placement of Anterior Lateral electrode varies slightly in anterior-anterior configuration. The more lateral placement increases the likelihood that more of the heart musculature will be within the current pathway.


ANTERIOR LATERAL

CARDIOVERSION

Elective cardioversion may cause visible reddening under the surface of a defibrillation / pacing / monitoring electrode. This effect is likely caused by hyperemia (excess blood) under the surface of the skin and is probably not a "burn".

During cardioversion, in contrast to a standard defibrillation, the patient is normally perfused. The impact of the energy passing through engorged capillaries under the skin's surface can cause blood to diffuse out, creating an effect that often looks
like a burn or rash. The reddening typically goes away within a few days.

Among the factors that contribute to this phenomenon are:
1) high energy settings
2) multiple, successive shocks
3) skin integrity
4) patient age
5) certain antiarrhythmic drugs

Blistering and/or sloughing do not typically result from cardioversion and should be considered an indication of burning due to other factors.

⚠ WARNINGS

1. After patient movement due to muscle contraction or patient repositioning, press pads to skin to ensure good coupling between pads and skin.
2. Do not conduct chest compressions through the pads. Doing so may cause damage to the pads that could lead to the possibility of arcing and skin burns.
3. Transcutaneous pacing may cause burns to the skin. Periodically check the electrode site to ensure that the electrodes are well adhered to the skin.
4. During transcutaneous pacing, do not exceed the maximum pacing settings of 1 hour of pacing (140 mA/180 ppm) or 8 hours of pacing (100 mA/100 ppm). Doing so can increase the possibility of skin burns.
5. Replace electrodes after 24 hours of skin contact or 8 hours of pacing to maximize patient benefit.
6. Do not use if gel is dry. Dried out gel can lead to skin burning. Do not open until ready to use. Do not use electrodes past the expiration date printed on the pouch label.
7. To avoid electrical shock, do not touch the pads, patient, or bed when defibrillating.
8. Do not discharge standard paddles on or through electrodes or place separate ECG leads under pads. Doing so could lead to arcing and/or skin burning.
9. Always apply electrodes to flat areas of skin. If possible, avoid folds of skin such as those underneath the breast or those visible on obese individuals.
10. Avoid electrode placement near the generator of an internal pacemaker, other electrodes or metal parts in contact with the patient.
11. Some current generated by electrosurgical units (ESU) may concentrate in the conductive gel of pacing / defibrillation electrodes, especially if an ESU grounding pad other than that recommended by the ESU manufacturer is used. Consult the ESU operator's manual for further details.
12. Do not fold the electrodes or packaging. Any fold in or other damage to the conductive element could lead to the possibility of arcing and/or skin burns.
13. During prolonged pacing greater than 30 minutes, periodically examine the patient's skin for irritation.
14. Use only with ZOLL Pacemaker/Defibrillator products.
15. Device disposal should follow hospital protocol.
16. Do not use electrodes in the presence of oxygen-rich environment or other flammable agents. Doing so could cause explosion.
17. If any serious incident has occurred in relation to the device, the incident should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
18. If repositioning of the electrodes is needed, consider replacement with a new electrode.

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