Pro-padz® Cardiology Specialty, Pro-padz® Liquid Gel Radiolucent, Adult MFE and Cath Lab

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)













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INDICATIONS FOR USE

Defibrillation Noninvasive Pacing Cardioversion ECG monitoring

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

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 excess moisture/diaphoresis with dry cloth.

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

Instructions

ELECTRODE APPLICATION

- 1. Apply the electrode securely to the patient.
- 2. Press electrode FIRMLY to the skin, moving any air pockets to the outer edges.

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

ELECTRODE PLACEMENT

Anterior-Posterior (Apex/Front-Back)

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

Grasp the Back/Sternum electrode at the red tab, peel from the package liner. Place to the left of the spine just below the scapula at the heart level.



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

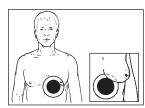


Apex / Front:

Grasp the Apex/Front electrode at the red tab, peel from the package liner and apply over cardiac apex with the nipple under adhesive area on a male patient. Position under breast on a female



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



APEX / FRONT

Anterior-Anterior (Apex/Lateral-Sternum)

Recommended for defibrillation and ECG monitoring only.

Not recommended for noninvasive pacing. Noninvasive pacing with this configuration can lead to decreased patient tolerance and increased

Sternum:

Grasp the Back/Sternum electrode at the red tab, peel from the package liner. Apply on the patient's upper right torso.



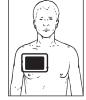
Avoid any contact between nipple and gel treatment area. Skin of the nipple area is more susceptible to burning.

Apex / Lateral:

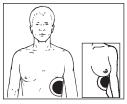
Grasp the Apex/Front electrode at the red tab, peel from the package liner. Apply so that the top of the gel treatment area lines up with the bottom of the pectoral muscle on a male patient. Position electrode under the breast on a female patient.



Placement of Apex 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.



STERNUM



APEX / LATERAL

WARNINGS

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
- multiple, successive shocks
- 3) skin integrity
- patient age
- certain antiarrythmic drugs

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

GENERAL WARNINGS

- After patient movement due to muscle contraction or patient repositioning, press pads to skin to ensure good coupling between pads and skin.
- 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. Electrodes should be replaced after 24 hours of use or after 8 hours of continuous pacing (2 hours pacing for Radiolucent) to maximize patient benefit.
- Do not use if gel has escaped from the electrode into the packaging.
- Do not use if gel is dry. Dried out gel can lead to skin burning. Do not open pouch until ready to use. Do not use electrodes past the expiration date printed on the pouch label.
- To avoid electrical shock, do not touch the pads, patient, or bed when defibrillating.
- 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.
- 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.
- Avoid electrode placement near the generator of an internal pacemaker, other electrodes or metal parts in contact with the patient.

- 10. 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.
- 11. 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.
- 12. During prolonged pacing greater than 30 minutes, periodically examine the patient's skin for irritation.
- 13. Use only with ZOLL pacemaker/defibrillator products.
- 14. Device disposal should follow hospital protocol.





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