OneStep™ Pediatric Electrodes

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

R2027-07 Rev. G

Defibrillation Noninvasive Pacing Cardioversion ECG monitoring

For use on pediatric patients with ZOLL® defibrillators, such as R Series®, by trained personnel including physicians, nurses, paramedics, emergency medical technicians and cardiovascular laboratory technicians. OneStep Pediatric electrodes are indicated for use on patient less than 8 years of age or weighing less than 55lbs (25kg).

Use of R Series with adult electrodes or pediatric electrodes other than OneStep Pediatric Electrodes can result in adult oriented shock advisory outcome and the delivery of adult energies to pediatric patients.

Pediatric energy levels must be manually set to site-specific clinical protocols when using OneStep Pediatric Electrodes on defibrillators other than R Series. Refer to defibrillator operator's manual.

PRECONNECTING THE ELECTRODES



- 1. Do not open until ready to use.
- 2. Periodically inspect electrode packaging for integrity & expiration date.
- 3. Attach electrode connector to ZOLL OneStep cable or Multi-Function cable.
- Open electrode package by pulling apart at yellow arrow.
- Self test connection disengages after the electrode has been removed from the liner.

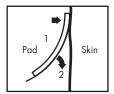
SKIN PREPARATION



Instructions

- 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.

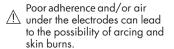
Excessive hair can inhibit good coupling (contact), which can lead to the possibility of arcing and skin burns.



Instructions

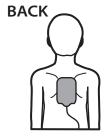
ELECTRODE APPLICATION

- 1. Apply one edge of the pad securely to the patient.
- 2. "Roll" the pad smoothly from that edge to the other. Be careful not to trap any pockets of air between the gel and skin.
- 3. Connect electrodes to Defibrillator/Pacer cable.
- 4. Connect ECG leads for demand pacing



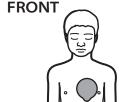
ELECTRODE PLACEMENT (ANTERIOR-POSTERIOR)

Recommended for defibrillation, noninvasive pacing, cardioversion, and ECG monitoring of pediatric patients.



Grasp the Back/Sternum electrode at the bottom and peel from the plastic liner. Apply electrode centered along spine of patient.

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



Grasp the Apex/Front electrode at the bottom and peel from the plastic liner. Apply over cardiac apex with the nipple alongside adhesive area.

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

WARNINGS

- 1. Use of R Series with pediatric electrodes other than OneStep Pediatric Electrodes can result in adult oriented shock advisory outcome, and the delivery of adult energies to pediatric patients.
- 2. Pediatric energy levels must be manually set to site-specific clinical protocols when using OneStep Pediatric Electrodes on defibrillators other than R Series. Refer to defibrillator operator's manual.
- 3. 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 the electrodes past the expiration date printed on the pouch label.
- 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.
- 5. After patient movement due to muscle contraction or patient repositioning, press pads to skin to ensure good coupling between pads and skin.
- Continuous pacing of patients could cause burns. Periodic inspection of the underlying skin, at least every 30 minutes during pacing, is strongly advised.

- Electrodes should be replaced after 24 hours of use or 1 hour of pacing.
- These electrodes are recommended for patients weighing less than 55lbs (25kg). For patients over 55lbs (25kg), adult electrodes are recommended. Do not delay therapy to determine actual weight of patient during emergency.
- 9. U.S. Federal law restricts this device to use by or on the order of a physician.
- 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 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
- 12. To avoid electrical shock, do not touch the pads, patient, or bed when defibrillating.

- 13. 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.
- 14. Use only with ZOLL pacemaker/defibrillator products.
- 15. Device disposal shall follow hospital protocol.





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