PaceAid®

Improving the Quality of the Life You Save

PaceAid PA01 – Infant/Pediatric
1-MAN / 2-MAN / EMERGENCY AIRWAY
VISUAL CPR GUIDANCE DEVICE

Device Name: PaceAid
Classification: Class 1, 510(k)-exempt
Single-use/Reusable: Single-Use

Model Number: PA01
Sterility Status: Nonsterile
Material Disclosures: Latex-free

Intent for Use: PA02 is a visual guidance device designed to aid anyone performing CPR in emergency situations by offering real-time visual prompts for chest compressions and rescue breaths, aligned with established CPR guidelines, including those published by the American Heart Association (AHA).

Indications for Use: For use on infants and pediatric patients during CPR, in any setting where CPR may be required.

Contraindications: Do not use **PaceAid PA01** in situations where visual guidance is not appropriate or the device cannot be observed by the rescuer.

Do not use PaceAid PA02 in MRI environments. The device is NOT MRI SAFE and must be removed before any MRI procedures.

Warnings

- **Contains a button battery. If swallowed, seek immediate medical attention.**
- **PaceAid is an aid and does not replace CPR training.**
- **Survival depends on multiple factors beyond device use.**

FDA: PaceAid is a Class 1 medical device registered and listed with the FDA. FDA registration means the manufacturer has provided required information to the FDA, but the FDA has not reviewed or approved this product for safety to current good manufacturing practices (CGMPs).

INFORMATION FOR USE CONTINUED:

Directions for Use

Activating PaceAid:
- Locate the overhanging liner at the bottom of the device; activation is automatic.

Applying the Device:
- Place on victim's upper chest, shoulder, arm, or any area within rescuer's direct line of sight. Ensure secure placement before starting CPR.

Adjusting the Mode:
- Use the toggle button to switch between modes:
  - 1-Man CPR (30 compressions: 2 rescue breaths)
  - 2-Man CPR (15 compressions: 2 rescue breaths)
  - Advanced Airway (110 compressions/min, rescue breaths every 2.5 seconds).

LED Signal Indicators:
- Red Light (Heart Icon): Compression needed
- Green Light (Head Icon): Deliver breath
- Yellow Light: Current operational mode.

Default Mode:
- Device defaults to 1-Man/2-Man CPR mode when activated. Use toggle to switch modes as needed.

Device Description
- Visual CPR guidance device for adults
- Does not provide clinical decision-making.
- Contains LED indicators for real-time prompts.
- Materials: Latex-free, contains button battery

Storage & Handling: Store in a cool, dry place. Avoid exposure to extreme temperatures.

Disposal Instructions: Dispose of as per local regulations for single-use medical devices and batteries.

Lot Number / Tracking Information: Refer to packaging for lot number and tracking details.

Adverse Event Reporting: Report adverse events to FDA MedWatch.

Additional Information:
- PaceAid can be used alongside AED; shock can be delivered without removing.
- May remain in place during transport or follow-up care if victim remains unstable.

MD Medical Device

www.paceaid.com

MADE IN USA

NON STERILE — Single Use Only   MR Unsafe   Button Battery

WARNING! This product contains a button battery. If swallowed, a lithium button battery can cause severe or fatal injuries within 2 hours. Keep batteries out of reach of children. If you think battery may have been swallowed or placed inside any part of the body, seek immediate medical attention.