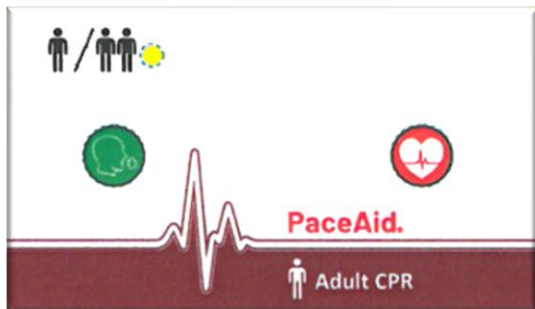




**PaceAid**

Improving the Quality of the Life You Save



**PaceAid PA04 - Adult  
1-MAN / 2-MAN  
VISUAL CPR GUIDANCE DEVICE**

**Device Name:** PaceAid

**Model Number:** PA04

**Classification:** Class 1, 510(k)-exempt

**Sterility Status:** Nonsterile

**Single-use/Reusable:** Single-Use

**Material Disclosures:** Latex-free

**Intent for Use:** **PaceAid PA04** 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 adult patients during CPR, in any setting where CPR may be required.

**Contraindications:** Do not use PaceAid PA04 in situations where visual guidance is not appropriate or the device cannot be observed by the rescuer.

**Do not use PaceAid PA04 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 PA04:**

- 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.

**Mode:**

- 1-Man CPR/2-Man CPR (30 compressions: 2 rescue breaths)

**LED Signal Indicators:**

- Red Light (Heart Icon): Compression needed
- Green Light (Head Icon): Deliver breath

**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.



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Exclusively for:  
**OCEANA**  
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MD Medical Device



**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.

**Website:** [www.paceaid.com](http://www.paceaid.com)



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