ResQPOD® Impedance Threshold Device
Clinical Summary

The ResQPOD® impedance threshold device (ITD) enhances circulation during basic or advanced life support CPR. Attached to a face mask or other airway adjunct, the ResQPOD selectively prevents air from re-entering the lungs during chest wall recoil. This enhances the vacuum needed to pull blood back into the heart. As a result, more blood is circulated to vital organs until the heart can be restarted.

The ResQPOD has been evaluated in more than 50 animal and clinical studies using both conventional CPR and ACD-CPR. Research shows that use of the ResQPOD can increase survival with favorable neurologic outcomes by 25% or more, giving rescuers the opportunity to return more people to a full life after sudden cardiac arrest.

Following is a summary of five key ResQPOD studies, highlighting improved survival to hospital discharge, favorable neurologic outcomes, and demonstrated cost effectiveness. Each is indicated with a symbol as shown in the key below.

Key:

- Improved survival to hospital discharge
- Favorable neurologic outcomes
- Demonstrated cost effectiveness
A Systems-Based Approach

In this prospective, observational study involving more than 350 prehospital cardiac arrest patients, overall survival to hospital discharge more than doubled following adoption of a systems-based approach and implementation of the most highly recommended American Heart Association (AHA) CPR guidelines, which included the use of an ITD.

Despite the costs of implementing a systems-based approach, the receiving hospital had average direct margin* of more than $20,000 if the patient survived to hospital discharge, and more than $3,000 if the patient later died in the hospital.

* Margin after direct costs subtracted

Multi-System Impact

This prospective, observational study of more than 3,000 prehospital cardiac arrest patients from five US communities (MN, TX, NE, FL, NC) found that survival to hospital discharge improved nearly 30% following implementation of the most highly recommended AHA CPR guidelines, which included use of an ITD. The effect of the new interventions was most pronounced in patients initially presenting with V-Fib or V-Tach, with an almost 62% increase in survival to hospital discharge after implementation of the AHA CPR guidelines.

Survival to hospital discharge with favorable neurologic function improved more than 75% at three sites that tracked these outcomes (p=0.038).

In-Hospital Cardiac Arrest

In a prospective, observational study involving more than 500 in-hospital cardiac arrest patients, survival to hospital discharge increased by 60% following adoption of the AHA CPR guidelines, including ResQPOD use.

The greatest benefit of the intervention was in patients presenting with pulseless electrical activity (PEA), the most common initial arrest rhythm during in-hospital arrests. In these patients, survival improved 106%.
Conventional CPR vs. CPR with the ResQPOD


The Resuscitation Outcomes Consortium (ROC) PRIMED Study was a prospective, multicenter, randomized, placebo-controlled, prehospital clinical trial comparing an active ITD (ResQPOD) and sham ITD in >8,700 patients.1 As originally published in 2011, the study results were neutral, showing no survival difference between an active and sham ITD. In late 2011, ROC investigators presented additional data at the American Heart Association (AHA) Resuscitation Science Symposium (ReSS) showing that two-thirds of the patients did not receive the proper chest compression rate (rates ranged from 50 - 240/min)* and that survival declined when chest compression rates were either too slow or too fast.2

At the 2012 AHA ReSS, ROC investigators presented additional data showing that:

- The highest overall survival rates with favorable neurologic outcome were observed when the ResQPOD was used as intended (i.e. with chest compressions at ≈100/min).
- The highest observed survival rates for CPR with the ResQPOD were higher than for those with conventional CPR, which required a faster rate (=118/min) for peak survival; thus, use of the ResQPOD allowed rescuers to achieve the highest survival rates at lower chest compression rates.

Conventional CPR vs. Active Compression-Decompression (ACD) CPR


A prospective, randomized, controlled trial comparing the ResQPOD and ResQPUMP ACD-CPR devices (ResQCPR) to conventional manual CPR in >1600 patients found that:

- ResQCPR resulted in a 53% increase in survival to hospital discharge with favorable neurologic function.
- A survival benefit of 49% persisted out to one year for those patients receiving ResQCPR.

![Graph showing survival to hospital discharge and one year following prehospital cardiac arrest](image)


*Data on file at Advanced Circulatory Systems, Inc.

*p=0.019

**p=0.03
The generally cleared indication for the ResQPOD available for sale in the United States is for a temporary increase in blood circulation during emergency care, hospital, clinic and home use. The version of the ResQPOD used in the ROC PRIMED Study and ResQTRIAL is not yet approved for sale in the United States. Research is ongoing in the United States to evaluate the long-term benefit of the ResQPOD for indications related to patients suffering from cardiac arrest. The studies listed here are not intended to imply specific outcomes-based claims not yet cleared by the US FDA.
