



ADVANCED CIRCULATORY SYSTEMS, INC.

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



ResQPOD®

Key Studies

A Systems-Based Approach

Lick CJ, Aufderheide TP, Niskanen RA, et al. Take Heart America: a comprehensive, community-wide, systems-based approach to the treatment of cardiac arrest. *Crit Care Med*. 2011;39(1):26-33.

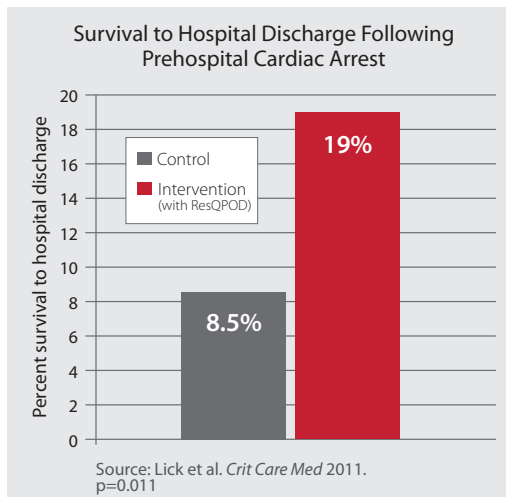


In this prospective, observational study involving more than 350 prehospital cardiac arrest patients, **overall survival to hospital discharge more than doubled following adoption of a systems-based approach** and implementation of the most highly recommended American Heart Association (AHA) CPR guidelines,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

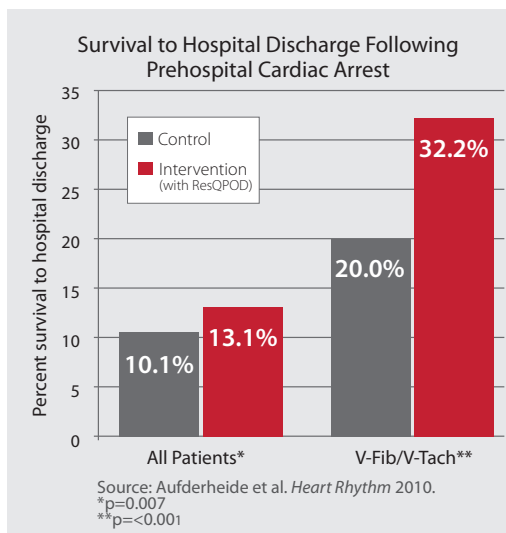
Aufderheide TP, Yannopoulos D, Lick CJ, et al. Implementing the 2005 American Heart Association guidelines improves outcomes after out-of-hospital cardiac arrest. *Heart Rhythm*. 2010;9(10):1357-1364.



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

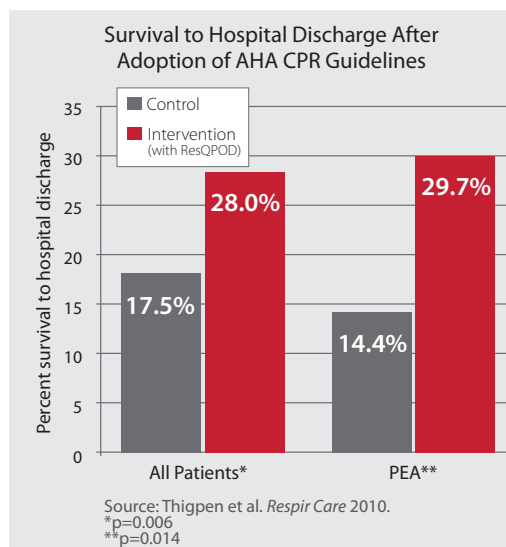
Thigpen K, Davis SP, Basol R, et al. Implementing the 2005 American Heart Association guidelines, including use of an impedance threshold device, improves hospital discharge rate after in-hospital cardiac arrest. *Respir Care*. 2010;55(8):1014-1019.



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%.



Wake County, NC, Experience

Hinchey PR, Myers JB, Lewis R, et al, for the Capitol County Research Consortium. Improved out-of-hospital cardiac arrest survival after the sequential implementation of the 2005 AHA guidelines for compressions, ventilations and induced hypothermia: the Wake County experience. *Ann Emerg Med.* 2010;56(4):358-361.

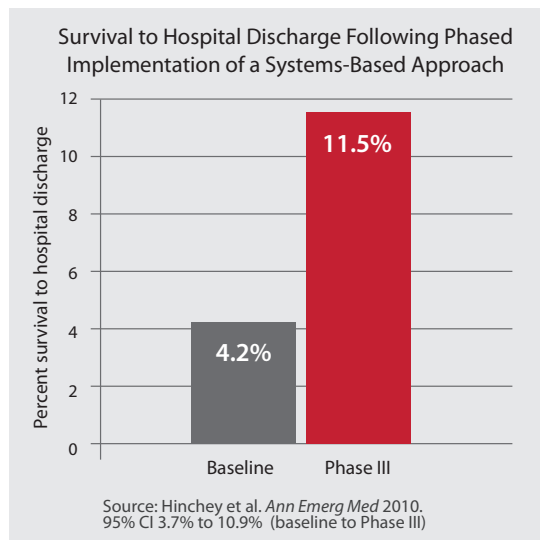


This observational study of prehospital QI data compared survival in 1,365 patients between phased, sequential implementation of a systems-based approach that included use of the ResQPOD.

Survival to hospital discharge increased by 274% from baseline to Phase III.



Throughout the study, 75% of patients survived to hospital discharge with favorable neurologic function.



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

Aufderheide TP, Frascone RJ, Wayne MA, et al. Standard cardiopulmonary resuscitation versus active compression-decompression cardiopulmonary resuscitation with augmentation of negative intrathoracic pressure for out-of-hospital cardiac arrest: a randomised trial. *Lancet.* (ResQTRIAL) 2011;377(9762):301-311.

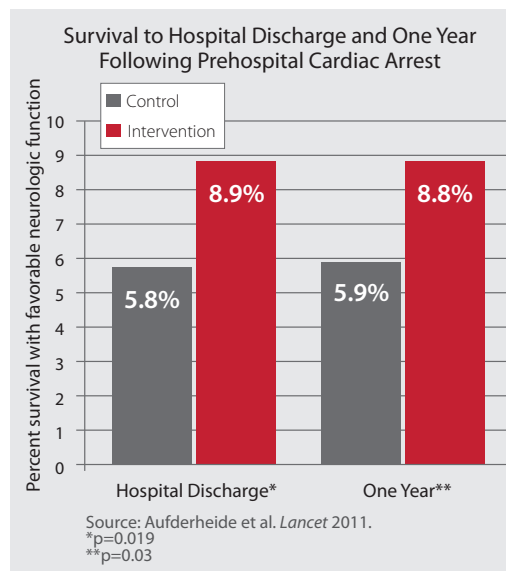
A prospective, randomized, controlled trial comparing the ResQPOD and ResQPUMP ACD-CPR devices (ResQCPR) to conventional manual CPR in >1600 patients found that:



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.



ROC PRIMED Study: New positive results pending

The Resuscitation Outcomes Consortium (ROC) PRIMED Study was a prospective, multicenter, randomized, placebo-controlled, prehospital clinical trial comparing an active ITD and sham ITD in >8,700 patients.¹ As originally published, the study results were neutral, showing no survival difference between an active and sham ITD. ROC investigators presented Epistry data at the 2011 American Heart Association (AHA) Resuscitation Symposium* showing that two-thirds of the patients did not

receive the proper chest compression rate (rates ranged from 50 - 240/min). Improper chest compression rates were associated with poor outcomes.² The manufacturer analyzed the complete data set, and when CPR was performed per AHA guidelines (e.g., compression rates of 90 - 110/min), the active ITD demonstrated the anticipated benefit of improved survival with good neurologic function. It is anticipated that these data will be published in late 2012.

*Data on file at Advanced Circulatory Systems, Inc.

- ¹Aufderheide TP, Nichol G, Rea TD, et al, for the Resuscitation Outcomes Consortium (ROC) Investigators. A trial of an impedance threshold device in out-of-hospital cardiac arrest. *N Engl J Med* 2011;365:798-806.
- ²Idris AH, Guffey D, Pepe PP, et al, for the Resuscitation Outcomes Consortium Investigators. The relationship of chest compression rate and survival during out-of-hospital cardiopulmonary resuscitation at Resuscitation Outcomes Consortium (ROC) regional sites. *Circulation* 2011;124:A289.

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.



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