ResQPOD™ Impedance Threshold Device Key Study Summary

The ResQPOD, or an earlier version of the impedance threshold device (ITD), has been the subject of over 65 published clinical trials, animal studies and review articles. Based upon the multiple positive human and animal studies, the *2005 American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care* gave an ITD (e.g. ResQPOD) a Class IIa recommendation.[45] The AHA recommendation means that there is strong evidence to demonstrate that the ResQPOD enhances circulation, improves hemodynamics and increases the likelihood of resuscitation in patients in cardiac arrest. This level of AHA recommendation is higher than any other device or drug (e.g. epinephrine, vasopressin, amiodarone) used in the treatment of patients in cardiac arrest. Since 2005, more than 20 additional articles and studies have been published in support of that recommendation (bibliography on other side).

Human Clinical Trials

The ResQPOD has been evaluated in 15 human clinical trials during both
Conventional, standard manual CPR:
1,2,3,46,52,53,57,63,65,66,67; and in
Active compression decompression (ACD) CPR:
4,5,6,7,57.

These studies have shown that the ResQPOD:

- **Improves hemodynamics**
  - Systolic BP during cardiac arrest nearly doubled (2)
  - Mean coronary perfusion pressure improved by 70% (5)
- **Improves short and/or long-term survival from prehospital cardiac arrest:**
  - Survival to ED admission improved by 50% (3)
  - Survival to 24 hours in PEA patients more than doubled (1)
  - Survival to 24 hours in all patients improved 45 - 68% (4,6)
  - ROSC rates improved 31 - 80% (5, 46)
  - Survival to hospital discharge improved 80 - 98% (52,65)
  - Meta-analysis shows a more than doubling of favorable neurologic outcomes (57)
- **Improves short and/or long-term survival from inhospital cardiac arrest:**
  - Survival to hospital discharge rates improved 62-73% with adoption of AHA guidelines (including ITD) (53,67)
- **Provides benefit in non-V-fib cardiac arrest rhythms:**
  - Survival to 24 hours in PEA patients more than doubled (1)
  - Survival in patients presenting in asystole tripled (3)
- **Works effectively on a variety of airway adjuncts** (7)
- **Is clinically and cost effective** (66)

Animal Studies

The ResQPOD has been evaluated in 19 animal studies during both:
Conventional, standard manual CPR:
16,17,18,19,20,23,43,49,50,55,63,64; and in
Active compression decompression (ACD) CPR:
8,9,11,12,13,20,23,44,47,49.

These studies have shown that the ResQPOD:

- **Improves hemodynamics and vital organ blood flow** (8,9,11,12,16,17,18,19,20,43,44,47,49,55,63,64)
  - **Increases cardiac output** (43), **coronary perfusion pressure** (9,11,12,18,19,43,44,47,49,63) **and blood flow to the heart** (17,18,12 & 20 [doubles])
  - **Increases cerebral perfusion pressure** (43,47,49,50,63) **and blood flow to the brain** (11,18,12 & 17 [≥50%],43,47,50,55,63)
  - **Raises aortic blood pressure** (8,9,11,12,16,19,49)
  - **Lowers intracranial pressure during decompression phase of CPR** (50,63)
- **Improves survival** (9,16,44,64) **and neurologically intact survival** (16,47)
- **Improves cerebral metabolism** (8) **and hemodynamics** (8,11) **during hypothermic cardiac arrest, and induces cerebral hypothermia more rapidly after ROSC** (44)
- **Increases the likelihood of successful defibrillation** (9) **or the total energy required for successful defibrillation** (44,64)
- **Circulates drugs more effectively** (11)
- **Improves hemodynamics in a pediatric model of cardiac arrest** (50,63)
- **Optimizes and compliments current AHA CPR recommendations** (43,55)

Finally, the best outcomes following cardiac arrest will be achieved with a continuum of care and therapies, not a single drug or device.[48] Advanced Circulatory Systems supports the approach taken by the Take Heart America™ Demonstration Project (www.takeheartameria.org), which promotes a full spectrum of optimal therapies including public recognition, widespread bystander CPR, performance of high-quality CPR with an ITD, and definitive care at Level One Cardiac Arrest Centers[66,67] offering state-of-the-art post-resuscitation care to optimize neurologic recovery (e.g. therapeutic hypothermia).

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The generally cleared indication for the ResQPOD is for a temporary increase in blood circulation during emergency care, hospital, clinic and home use. Studies are on-going 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 outcome-based claims not yet cleared by the US Food and Drug Administration.