

REQUEST FOR TRIAL STUDY APPROVAL

ALAMEDA COUNTY EMS AGENCY

With

ALAMEDA COUNTY FIRE DEPARTMENT / HAYWARD FIRE DEPARTMENT

Proposed Trial Study

CONVENTIONAL MANUAL CPR compared to CONVENTIONAL MANUAL CPR with
an IMPEDANCE THRESHOLD DEVICE (ResQPOD Circulatory Enhancer)

ANTICIPATED START DATE: APRIL 1, 2007

LOCAL EMS AGENCY: Alameda County Emergency Medical Services

PROVIDER AGENCY: Alameda County Fire Department / Hayward Fire Department

PROCEDURE / EQUIPMENT: Res Q POD Circulatory Enhancer

METHOD: Prospective Non-randomized (Conventional Manual CPR with ResQPOD)
compared to Historic Controls / Database (Conventional Manual CPR)

1. Description of procedure, device or medication requested:

The ResQPOD Circulatory Enhancer is classified as an Inspiratory Impedance Threshold Device (ITD).

The ResQPOD is a valve device that is placed between the bag valve and mask of a BVM, between a bag valve and a tracheal tube, or between a bag valve and another rescue airway such as a Combitube. The device is intended to be used when performing CPR.

The ResQPOD utilizes the impedance of the body's respiratory and circulatory systems to create a vacuum (negative pressure) in the chest during the recoil phase of CPR, which follows each chest compression. The ResQPOD prevents the influx of respiratory gases into the chest during the chest wall recoil (relaxation or decompression phase), which lowers the intrathoracic pressure and draws more venous blood back to the heart. Improved blood return to the right side of the heart (preload) results in improved blood flow to the lungs, and out of the left side of the heart (cardiac output) during subsequent compressions.

2. Description of the medical conditions for which the procedure / medication / device will be utilized:

The Alameda County Fire Department and Hayward Fire Department Paramedics will provide conventional CPR with the ResQPOD to **ALL non-traumatic cardiopulmonary arrest patients that are presumed to be 12 years of age or older.** All patients must meet Alameda County criteria for resuscitation efforts. Special attention will be directed to meeting the current 2005 American Heart Association standards for number and volume of ventilations and number and depth of chest compressions for CPR. The Auto Pulse or any other CPR adjuncts will **not** be used for the study patients.

Paramedics will intubate the cardiac arrest patient as per Alameda County protocol. Intubations will be confirmed by colorimetric capnometer or waveform capnography, and the esophageal detection device. Medics will perform conventional CPR according to current 2005 AHA Guidelines and will attach the ResQPOD circulatory enhancement device between the bag valve and mask, bag valve and tracheal tube or bag valve and Combitube.

3. Alternatives (disadvantages / disadvantages)

There is one alternative to the proposed Impedance Threshold Device (ResQPOD): conventional manual CPR.

Conventional Manual CPR:

- Advantages = none
- Disadvantages = lower blood flow, lower perfusion pressures

4. An estimate of frequency of utilization:

The Alameda County Fire Department attempts resuscitation on approximately 200+ medical cardiopulmonary arrests per year. The Hayward Fire Department attempts resuscitation on approximately 100+ non-traumatic cardiopulmonary arrests per year. Combined, the two departments, over a six month period should utilize the ResQPOD approximately 150 times. The non-traumatic cardiac arrest survival rates for Alameda County and Hayward Fire Departments collectively, and specifically regarding ventricular fibrillation / pulseless ventricular tachycardia are: 2005 = 13.1%, and 2006 = 15.0%.

5. Other factors or exceptional circumstances:

The following are contraindications for the use of the ResQPOD:

Dilated cardio myopathy, congestive heart failure, pulmonary hypertension, flail chest, aortic stenosis, chest pain, shortness of breath. Obviously, the patients may not be able to provide a history of these conditions. The device should not be used if family members or friends provide a history of any of the above conditions. The device should be removed upon the return of spontaneous circulation (ROSC). While it is probably acceptable for breathing patients, it is not designed to do so. The device may / should be reapplied if the patient subsequently loses pulses.

6. Any supporting data, including relevant studies and medical literature:

See attachment #1 for documentation

7. Recommended policies / procedures to be instituted regarding: See attachment #2 for documentation

- **Use:** (Protocol)
- **Medical Control:** (Protocol)
- **Treatment Protocols:** (Protocol)

- **Quality assurance of procedure / medication / device:** (Protocol)

Each Fire Department will complete a data summary sheet with the following data points: estimated downtime, estimated time to CPR, estimated time to defibrillation (if applicable), initial rhythm, changes in rhythm, initial colorimetric capnometry or capnography values and any changes in the course of the cardiac arrest, return of spontaneous circulation (ROSC) at scene, ROSC at hospital, and survival to discharge from hospital; this will be obtained by the EMS agency monthly. See attached documentation (Data sheet)


8. Description of the training and competency testing required to implement the procedure / medication / device: See attachment #3 for documentation (protocol and training materials)

9. Copy of the local EMS System Evaluation and Quality Improvement Program plan for this request: See attachment #4 for documentation

The ResQPOD trial study will be reviewed and evaluated by following applicable Administrative policies under Section 1000 and Policy # 2251 established by Alameda County Emergency Medical Services: (ALCO EMS Administrative Manual / Policies)

- Trail Study Process (Admin. # 1000)
- Emergency Medical Oversight Committee (EMOC) (Admin. # 1000)
- Research Committee (Admin. # 1000)
- Quality Council (QC) (Admin. # 1000)
- Quality Improvement Responsibilities – EMS (QIR # 2250 / 2251)

Please refer to the attached ResQPOD Protocol for specifics regarding process, procedure, data collection and medical oversight.


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ResQPOD Circulatory Enhancer[®]

Circulatory Enhancer
Technology Overview

Product Features

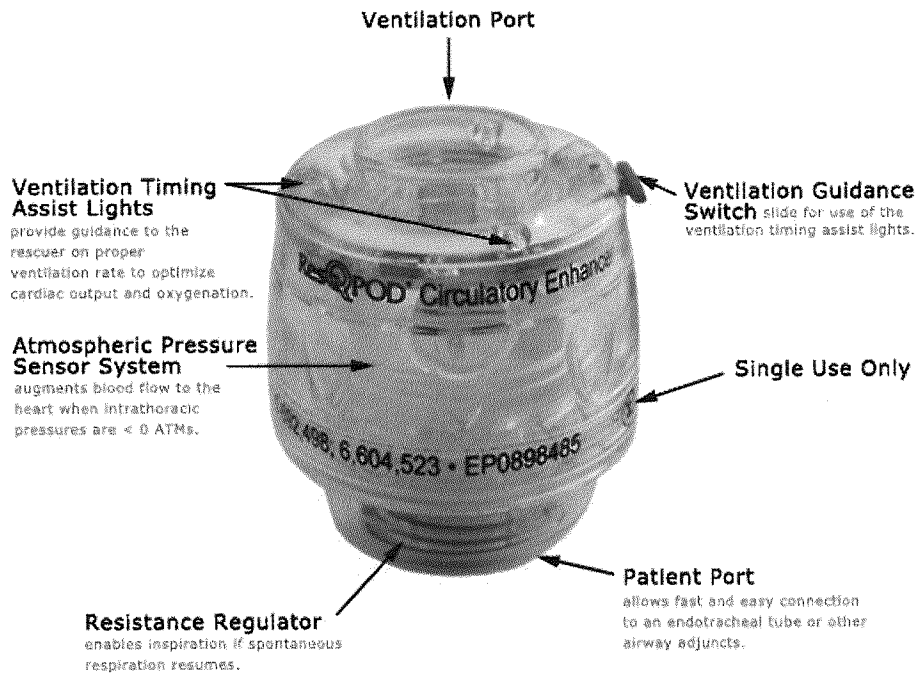
The ResQPOD is placed between a ventilation source (e.g., bag-valve or demand-valve resuscitator) and an airway adjunct. The ResQPOD is designed with a series of features to aid rescuers in enhancing circulation for patients receiving assisted ventilation, such as those receiving CPR.

ResQPOD Circulatory Enhancer

- Product Features
- Technology
- FAQs
- Published Articles
- Clinical Information
- American Heart Association Guidelines
- Circulatory Enhancement Applications
 - Sudden Cardiac Arrest
 - Hypotension
 - Blood Loss
- Instructions for Use
- Product Literature and Video
- ACSI Circulatory Enhancer

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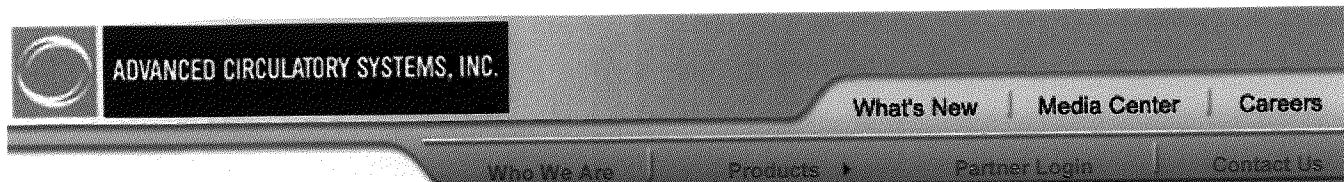
Advanced Circulatory Systems, Inc.
7615 Golden Triangle Drive, Suite A
Eden Prairie, MN 55344
877-RESQPOD
1-877-737-7763
www.advancedcirculatory.com



The generally cleared indication for the ResQPOD is a temporary increase in blood circulation during emergency care, hospital, clinic and home use. [Click here to review the Instructions for Use.](#) Studies are ongoing in the United States to evaluate the long-term benefit of the ResQPOD for indications related to patients suffering from cardiac arrest, hypotension during dialysis and severe blood loss.

For more information on completed clinical studies [click here](#). The references on this website are not intended to imply specific outcome-based claims not yet cleared by the US Food and Drug Administration.

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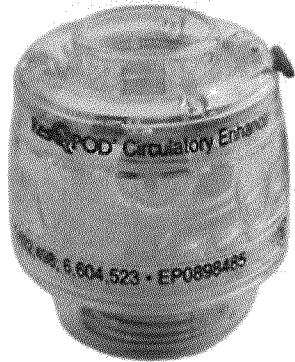
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ACSI Circulatory
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Introducing the most advanced device for enhancing circulation in patients requiring assisted ventilation, such as those receiving Cardiopulmonary Resuscitation (CPR)

The ResQPOD Circulatory Enhancer

- Increases blood flow to the heart and brain during assisted ventilation
- Increases the opportunity for survival and normal neurological outcome
- Is effective with standard CPR or other methods of CPR (i.e., active compression decompression - ACD)
- Works in conjunction with all standard resuscitation techniques and equipment
- Recommended as a circulatory enhancer for the treatment of cardiac arrest by the AHA.

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