

RESQPOD[®] ITD FREQUENTLY ASKED QUESTIONS

MECHANISM OF ACTION IN PATIENTS REQUIRING ASSISTED VENTILATION, FOR EXAMPLE, DURING CPR

1. How does the ResQPOD improve circulation during cardiopulmonary resuscitation (CPR)?

The ResQPOD, an impedance threshold device (ITD), utilizes the interdependence of the body's respiratory and circulatory systems to create a vacuum (negative pressure) within the chest during the recoil phase of CPR, which follows each chest compression. The ResQPOD regulates 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 heart (preload) results in improved blood flow out of the heart (cardiac output) during the subsequent compression. Thus, despite its placement into the ventilation circuit, the ResQPOD is a circulatory enhancer device that works during chest compressions, specifically during the chest wall recoil phase of CPR.

2. What are the upper airway pressure levels found during inspiration in a healthy, spontaneously breathing person compared to the decompression phase of CPR in a cardiac arrest patient receiving standard CPR alone and to a patient receiving CPR in conjunction with the ResQPOD?

Average negative intrathoracic pressures:

In a healthy, spontaneously breathing person at rest are approximately -1 to -3 mmHg;

In a cardiac arrest patient who is receiving standard CPR, varies between approximately 0 to -2 mmHg; and

In a cardiac arrest patient who is receiving CPR with the ResQPOD varies between approximately -3 to -8 mmHg depending upon the elastic recoil properties of the chest.

The greater the negative intrathoracic pressure (vacuum), the more blood that returns to the heart. In addition, the lower intrathoracic pressure causes a decrease in intracranial pressure. However, it should be noted that excessive negative pressures can be detrimental. The ResQPOD has been specifically designed to safely optimize the degree of negative pressure in order to increase blood flow to the heart and brain.

3. How do negative and positive pressures within the lungs influence blood flow within the thoracic cavity?

The impedance threshold device (ITD) physiology is based on the principle that changes in intrathoracic pressure are transmitted rapidly to the heart and other organs in the chest. This physiology was initially discovered by Mueller, who showed that when someone takes a breath or inspires against a closed glottis (Mueller Maneuver), this results in an abrupt and marked decrease in pressure within the plural space, which is instantaneously transmitted to the right heart. This results in a marked enhancement in venous return back to the heart.

Although initially contra-intuitive, using an ITD during CPR is based upon the same principle; that is, when the chest wall recoils the pressure inside the lungs (and the thorax across the board) decreases to sub-atmospheric pressure, thus creating a vacuum relative to the rest of the body. This negative pressure is immediately transmitted to the right heart, just as in the Mueller Maneuver, and venous return is enhanced. Intracranial pressure is also instantaneously lowered because of the connection between the thorax and paravertebral sinuses along the spinal cord. This can be seen in the pig video (produced by ACSI) at the point in the video where the narrator points out how low the right atrial pressure goes when the ITD is added to the circuit. Lowered intrathoracic pressures translate into lowered right atrial pressures, resulting in an enhanced venous return and greater coronary perfusion pressures.

4. How do I know if the ResQPOD is working?

The ResQPOD works by increasing circulation. All ResQPODs are 100% tested prior to shipment to assure they are properly functioning. Measurements of blood flow and circulation must be made indirectly, especially in a patient undergoing CPR. The best and most rapid way to know the device is working is to measure end tidal carbon dioxide (ETCO₂), an indirect measure of circulation. When ETCO₂ is increased, it usually means that more blood is circulating; as blood passes through the lungs, more CO₂ is removed proportionally to the

increase in blood flow. Typically, ETCO₂ increases by about 30% in a patient treated with the ResQPOD. This equates to a near doubling of blood flow to the heart. For the best comparison, you should measure ETCO₂ prior to placement of the ResQPOD, and then about 3 minutes later. It sometimes takes up to 15 minutes to achieve maximum ETCO₂ levels once the ResQPOD is in place. It is important to note that we do not advise taking time to measure ETCO₂ prior to use of the ResQPOD as it only delays the benefit to the device. However, for those who want to see a difference, and thus know the ResQPOD is working, this is one way to measure it.

Another indirect way to assess the increase in circulation is to look at survival rates. Since relatively few patients actually live for 24 hours after an out-of-hospital cardiac arrest and fewer survive to discharge, you would need to look at a large number (hundreds to thousands) of cardiac arrests before you will see a statistically significant increase in survival rates. Several studies have demonstrated improvements in survival rates. For example, in the emergency medical services (EMS) setting, a study by Lick et al showed that overall survival to hospital discharge more than doubled (from 8.5% to 19%) when the ResQPOD was implemented as part of systems-based approach.ⁱ In the in-hospital setting, a study by Thigpen et al showed a 60% improvement in survival to hospital discharge (from 17.5% to 28%) when a 571-bed, acute care hospital implemented the ResQPOD as part of their adoption of the AHA CPR guidelines.ⁱⁱ

Yet another way to see the increase in circulation is to measure blood pressure or the strength of the pulse. The invasive blood pressure should be significantly higher with the ResQPOD and in general, rescuers report feeling a stronger pulse with the ResQPOD.

Finally, how well the ResQPOD works can vary somewhat from patient to patient as there are other variables that contribute to the ResQPOD's effectiveness (e.g. chest wall compliance, quality of CPR performed, etc.).

5. Is the ResQPOD effective with standard and active compression decompression (ACD) CPR? What about mechanical CPR devices (e.g. LUCAS Device [PhysioControl], AutoPulse [ZOLL])?

The combination of animal and human studies have shown statistically significant improvements in blood pressure, vital organ circulation and survival rates from cardiac arrest and normal neurological function when an ITD is used in conjunction with standard and ACD-CPR (see Key Study Summary). It can also be used with any method of automated mechanical CPR.

6. What effect will the ResQPOD have if used during the performance of continuous chest compressions without ventilations (e.g. compression-only CPR)?

ACSI is aware that some EMS agencies have elected to perform compression-only (or "hands-only") CPR with ventilations withheld for a period of time. The American Heart Association recommends this CPR method only for lay rescuers who are not confident in their ability to perform ventilations. ACSI endorses the concepts of applying chest compressions rapidly and with minimal interruptions but does not support having trained rescuers or healthcare providers withhold ventilations due to the deleterious effects that low or no ventilations can have on hemodynamics during CPR. One recent study, which compared 10 breaths/minute vs. 2 breaths/minute in a porcine model of cardiac arrest found that "... during the first five minutes of CPR, 2 breaths/minute resulted in significantly lower carotid blood flow and brain-tissue oxygenation than did 10 breaths/minute. Subsequent addition of an impedance threshold device significantly enhanced carotid flow and brain-tissue oxygen tension, especially in the 10 breaths/minute group."ⁱⁱⁱ If an organization elects to provide compression-only CPR, they should not use the ResQPOD during the period of time when ventilations are withheld as atelectasis will occur over time, the patient will not receive supplemental oxygen, and will thus suffer from anoxia. When ventilations are resumed, the ResQPOD can be added. ACSI recommends that when the ResQPOD is used during CPR, positive pressure ventilations of at least 8 - 10/min should be provided.

7. Does the ResQPOD interfere with the patient's ability to exhale?

No, the ResQPOD provides insignificant resistance to patient exhalation. Expired air leaves the patient through the ventilation port.

8. Does the ResQPOD limit the rescuer's ability to ventilate the patient?

No, the patient may be freely ventilated, at whatever compression to ventilation ratio and tidal volume the situation dictates.

9. I've heard there have been reports of patients in cardiac arrest exhibiting signs of an increased level of consciousness (e.g. eye opening, gagging on tube, spontaneous breathing, purposeful and non-purposeful movement of extremities) during the performance of CPR with the ResQPOD in place. What's going on? Should I continue to use the ResQPOD?

What's most likely going on is that the patient is receiving such good blood flow to the brain during CPR that it's triggering neurologic signs. Don't be fooled by these. Quickly assess to see if a perfusing pulse has returned. If there's no pulse, continue CPR immediately with the ResQPOD and gently restrain the patient, if necessary, from interfering with care (e.g. trying to pull on the tube). Consider sedation if your local protocol permits it.

10. Does use of the ResQPOD increase the frequency of stomach regurgitation or aspiration?

No; there have been no human studies suggesting that the ResQPOD increases the likelihood of regurgitation or aspiration.

11. Is hyperventilation helpful during CPR?

The natural tendency when performing CPR is to ventilate the patient frequently, either inadvertently or intentionally. Contrary to common practice, hyperventilation is very detrimental during CPR and in the newly resuscitated patient. Each extra breath interferes with the development of negative intrathoracic pressure created during the chest wall recoil (or decompression) phase. The 2010 American Heart Association (AHA) guidelines state "*Excessive ventilation can be harmful because it increases intrathoracic pressure, decreases venous return to the heart and diminishes cardiac output and survival.*"^{iv} Thus, hyperventilation (ventilation more often than 10 times/minute), markedly reduces the efficiency of all methods of CPR, with or without the ResQPOD. Hyperventilation, with or without the ResQPOD, inhibits blood flow back to the heart by preventing the development of the intrathoracic vacuum and venous return to the heart during the decompression phase of CPR. This is a fundamental point that must be heavily emphasized when training rescuers on how to perform any method of CPR and use the ResQPOD.

12. What if ETCO₂ levels are elevated, either during CPR or right after a pulse has returned? Shouldn't I hyperventilate in those cases?

No, hyperventilation reduces circulation and therefore compromises the elimination of carbon dioxide. Improved circulation (from less ventilation) will tend to correct acid-base imbalance. If ETCO₂ levels are elevated, it can be a sign that cardiac output is improved or that a spontaneous pulse has returned. In the absence of known blood gases, there are no data to support that hyperventilation is good for elevated ETCO₂ levels and plenty of data to suggest that hyperventilation is bad for circulation. If you observe a very low arterial pH after return of spontaneous circulation, then you should consider using sodium bicarbonate rather than increased ventilation rates to help raise the pH, assuming the blood pressure is stable.

13. Will the ResQPOD hinder patients who begin to breathe spontaneously?

Patients who begin to breathe on their own will have to overcome the "opening pressure" of the ResQPOD's resistance regulation system (approx. -10 cmH₂O) before air will be allowed to enter the device. For this reason, the ResQPOD should be removed immediately from the respiratory circuit when chest compressions are no longer required and the breathing should be supported as indicated.

14. What effect does altitude have on the ResQPOD's function; i.e. can it be used in aero medical or submarine environments?

No effect. Altitude does not effect on the ResQPOD's performance.

15. What effect will breath stacking (delivering a series of breaths without compressions in between) have on the ResQPOD's function?

Breath stacking will increase pressures in the chest, inhibit venous return, and when performed with the ResQPOD, will delay the effect of the ResQPOD, as the pressure within the chest is higher after breath stacking. It is for that reason that the 2010 AHA guidelines recommend a 30:2 compression to ventilation ratio for patients with an unsecured airway (e.g. facemask). Breaths should be delivered over 1 sec for both unsecured (e.g. facemask) and secured airways (e.g. ET tube). In intubated patients, we recommend a 10:1 compression to ventilation ratio (equivalent to 10 ventilations/minute at the AHA-recommended compression rate of 100/min), which is consistent with AHA Guidelines.

FEATURES

16. I've been doing CPR on the job for years, why should I use the timing assist lights?

Ventilating at the proper rate is critical to the success during CPR, with or without the ResQPOD. Even among experienced rescuers, 10 breaths/minute seems slow as there is a natural tendency to ventilate patients too frequently during cardiac arrest. While proper ventilation is important, hyperventilation diminishes the opportunity for the ResQPOD to be effective, because each time you give a breath, you destroy the vacuum that is being created in the chest during chest compressions. Studies have shown that even the most experienced healthcare providers perform proper CPR only about 20% of the time and that devices that provide rate guidance lead to a significant improvement in technique. The timing assist lights, which flash at 10/min, are designed to promote high quality CPR. A ventilation rate of 10/minute is recommended in the 2010 AHA guidelines for patients with a secured airway. Proper chest compression is also critically important. Rescuers should compress the chest 10 times for each light flash (10 compressions every 6 seconds = 100 compressions/min). The timing light function is not linked in any way to the device's inspiratory impedance feature, so, if for some reason the timing lights fail to blink, the device still provides inspiratory impedance.

17. If the timing assist lights flash at 10/min (at 6 second intervals), how do I use them during CPR with an unsecured airway?

The timing assist lights are really intended to promote the proper rate during ventilation with a secured airway, where it is recommended that compressions and ventilations are performed asynchronously (independent of each other). During CPR with a facemask, rescuers are encouraged to perform CPR with the ResQPOD in place but without using the timing assist lights to guide ventilations. Minimal interruptions in chest compression result in enhanced circulation. The person performing chest compressions should count out loud to 30, then pause compressions to allow 2 ventilations. Ventilations more often than every 30 compressions are NOT recommended.

18. Does the battery in the ResQPOD create an environmental disposal issue?

The timing assist lights on the ResQPOD are powered by a lithium battery and do not pose an overall environmental threat. When you are through using the ResQPOD, leave the timing lights on to drain the battery then dispose of the ResQPOD as you would lithium batteries. Check individual country regulations regarding disposal.

19. Does the ResQPOD provide positive end expiratory pressure (PEEP)?

No, and we do not recommend the use of PEEP in patients undergoing CPR, with or without the ResQPOD.

20. Can the ResQPOD be reused?

No, the ResQPOD is a single patient use product and is marked with the ISO international symbol for single use. The number of parts and their tight specifications, along with the various material components do not allow the ResQPOD to be disassembled, disinfected and reassembled for reuse.

21. It has been demonstrated that flow rates above 40 lpm can cause gastric distension when using a bag-valve mask. Does the ResQPOD limit ventilation flow rates to less than 40 lpm?

No, there is no significant airflow resistance through the ResQPOD during ventilation by the rescuer. Care must be taken to avoid high pressures during rescuer-assisted ventilations and to limit the duration of the breath to 1 second/breath (until chest rise).

22. How much inspiratory impedance does the ResQPOD provide?

The valving mechanism within the ResQPOD creates a selective resistance to the influx of air until a pressure of approximately -10 cmH₂O (-7.36 mmHg) is reached, at which time the valves open to allow respiratory gases in.

23. What is the ResQPOD's shelf life?

Four years from the date of manufacture.

24. What is the dead space of the ResQPOD?

The ResQPOD's dead space is 40.7 ml.

25. What should we do if the patient starts gasping?

Gasping represents a primitive brainstem reflex that draws air into the lungs, venous blood back to the heart, and lowers intracranial pressures. Continue to use the ResQPOD if the patient is gasping as long as the patient requires CPR (i.e. severe hypotension).

26. Can the ResQPOD be used with one or two-person CPR?

Yes, the key to success with the ResQPOD in an unintubated patient is using it with a good facemask seal. With two rescuers, one should focus solely on maintaining a good seal with the ResQPOD in place while the other person compresses the chest. Either the chest compressor or the person holding the facemask can squeeze the bag. A facemask head strap can be used with either one or two-person CPR to also help maintain the seal.

27. How does the ResQPOD differ from the ResQGARD®, also an ITD made by Advanced Circulatory Systems?

	ResQGARD ITD 7	ResQPOD ITD 10
Provides Therapeutic Benefit During	Inspiration	Chest wall recoil phase of CPR
Intended For	Spontaneously breathing patients	Apneic patients (e.g. cardiac arrest)
Valve Cracking "Opening" Pressure	-7 cmH ₂ O	-10 cmH ₂ O
Valving Mechanism	Partially impedes gases from entering the lungs until a threshold of -7 cmH ₂ O is reached	Completely impedes gases from entering the lungs until a threshold of -10 cmH ₂ O is reached
Other Features	O ₂ port permits administration of supplemental oxygen	Timing assist lights promote proper ventilation and chest compression rates.

For more information about the ResQGARD go to www.advancedcirculatory.com.

INDICATIONS/CONTRAINDICATIONS

28. The ResQPOD is contraindicated in dilated cardiomyopathy, congestive heart failure, pulmonary hypertension, aortic stenosis, flail chest, chest pain and shortness of breath. What does this mean for patients in cardiac arrest?

Patients in cardiac arrest do not have enough blood pressure to support life. Regardless if they have a prior history of other medical conditions (e.g. heart failure or hypertension), when in cardiac arrest they have only one major medical problem that must be corrected or they will die. Blood flow and circulation during cardiac arrest are known to be poor. For patients who are in need of circulatory support because they are in cardiac arrest and receiving CPR, you can use the ResQPOD as a circulatory enhancer. The ResQPOD is not contraindicated in patients in cardiac arrest receiving CPR. These patients have an 80 - 90% or more chance of dying secondary to low circulation due to cardiac arrest, which is their primary medical problem. One can use the ResQPOD to help treat this primary problem. Once that problem has been effectively treated, then the ResQPOD may no longer be indicated or appropriate in view of other medical conditions, such as the listed contraindications; thus, we recommend removing it when not performing CPR, once a pulse has been obtained. Since the ResQPOD is used to enhance circulation, the device also should not be used in patients with ongoing uncontrolled hemorrhage. The prescribing physician should make the final determination about when the ResQPOD is used.

29. Is chest trauma a contraindication for use of the ResQPOD?

The only trauma-related contraindication to ResQPOD use is a flail chest. Since the ResQPOD is used to enhance circulation, the device also should not be used in patients with ongoing uncontrolled hemorrhage.

30. What effect will the ResQPOD have during resuscitation on patients with an open or closed pneumothorax?

Any “leak” in the chest cavity will interfere with the generation of negative pressures. In patients with open pneumothoraces, rescuers are taught to cover the wound with a one-way seal that allows air to escape from the chest but not to enter. Assuming there is a one-way flap in place, the ResQPOD will not affect an open pneumothorax. In a closed pneumothorax, positive pressure ventilation is dangerous, but we are not aware of any mechanism by which the ResQPOD could significantly worsen a closed pneumothorax.

31. Does the ResQPOD have any effect on intracranial pressure and are there any specific recommendations for patients with head injuries?

In animal models of cardiac arrest, use of an ITD lowers intracranial pressure with each chest wall recoil and results in overall improvement in cerebral perfusion pressures by increasing forward blood flow and lowering resistance.^v The ResQPOD has not been specifically tested in patients with head injuries, the manufacturer is not aware of any contraindications for use in patients with head injuries.

32. Can I use the ResQPOD on children?

There are no specific age limitations in the ResQPOD’s product labelling. The AHA guidelines recommend adult CPR procedures for patients reaching puberty and above. The ResQPOD should be effective in patients of all ages; however, it has only been tested clinically in adults ages 18 years and above. Animal studies in a pediatric model of cardiac arrest, have demonstrated that the ResQPOD very effectively enhances circulation in 10 kg piglets in cardiac arrest.^{vi} Anecdotal data suggest that the ResQPOD can be used safely in children \geq 20 lbs (10 kg). As long as there is an adequate seal within the ventilation circuit during chest compressions, the ResQPOD should work effectively. It is the ultimate decision of the prescribing physician to determine in what ages of patients the ResQPOD should be used.

33. I've noticed that the ResQPOD adds some height and weight to the ventilation circuit. If my patient is intubated, should I be concerned at all about the tube dislodging?

The ResQPOD does add some height and weight to the ventilation circuit. For this reason, ACSI strongly recommends that the rescuer use a commercially available tube restraint device when using the ResQPOD. We do not advocate using tape for this purpose. Prior to attaching the ResQPOD, the tube's placement should be confirmed. The same care should be taken with the ResQPOD as when using a resuscitator bag alone: secure the tube well and reassess tube placement frequently.

34. The instructions for use state that prolonged use for more than 30 minutes is not recommended. Why is this?

The ResQPOD is a 510(k) cleared device with an intended use for patients who can benefit from an increase in blood circulation. This includes patients with low blood pressure who may need assisted ventilation, such as those in cardiac arrest, as well as patients with low blood pressure who are spontaneously breathing, such as those suffering from severe dehydration. Although it has a broad indication for use, the ResQPOD is optimized for use in patients who require assisted breathing. A different ACSI product, the ResQGARD, which has the same regulatory clearance and utilizes similar technology, is optimized for use in patients who are spontaneously breathing.

The reference to prolonged use in the instructions for use is intended to ensure that if a spontaneously breathing patient does use the ResQPOD, the patient does not become fatigued during use. Patients using the ResQPOD with assisted ventilation, such as cardiac arrest patients, will not tire from use of the ResQPOD after 30 minutes as they are not breathing on their own.

35. Why do you recommend that the ResQPOD be removed immediately after the return of spontaneous circulation in cardiac arrest patients?

While cardiac arrest patients may be able to breathe on their own through the ResQPOD upon return of spontaneous circulation, the work of breathing may be too much for them to tolerate given their fragile state immediately after the return of spontaneous circulation. In addition, once a pulse returns and CPR is no longer being performed, the device has served its purpose for a cardiac arrest patient.

36. Will the ResQPOD be effective in enhancing circulation in an arrested patient who is hypothermic?

The ResQPOD has been studied in a porcine model of hypothermic cardiac arrest using a combination of active compression decompression (ACD) CPR and the ResQPOD, compared to standard, conventional CPR.^{vii} This study showed that ACD CPR with the ResQPOD resulted in markedly improved common carotid blood flow compared with standard CPR alone. To our knowledge, use of the ResQPOD alone in the clinical setting of hypothermic cardiac arrest has not been studied.

COMPATIBILITY WITH OTHER ADJUNCTS/PROCEDURES

37. Does the ResQPOD comply with International Standard Organization (ISO) anaesthetic connection standards?

Yes, the ResQPOD is in full compliance of ISO 5356-1, Anaesthetic and respiratory equipment – conical connectors.

38. What effect does adding a PEEP valve to the ventilation circuit (distal or proximal) have on the ResQPOD?

There are no human studies evaluating both the ResQPOD and PEEP to date. We do not recommend the use of PEEP in patients undergoing CPR, with or without the ResQPOD.

39. What effect does adding continuous positive airway pressure (CPAP) to the ventilation circuit (distal or proximal) have on the ResQPOD?

CPAP is not compatible with the ResQPOD because it is not possible to lower intrathoracic pressure with CPAP. CPAP is contraindicated during CPR as it decreases venous blood flow back to the heart. CPAP should not be used during the performance of CPR, with or without the ResQPOD.

40. What effect does adding bi-level positive airway pressure (BiPAP) to the ventilation circuit (distal or proximal) have on the ResQPOD?

BiPAP is not compatible with the ResQPOD because any continuous positive airway pressure ventilation negates most of the effects of the ResQPOD during cardiac arrest.

41. Can I use the ResQPOD with a colormetric end tidal carbon dioxide (ETCO₂) detector in the ventilation circuit to assess endotracheal (ET) tube placement or with a bag-valve resuscitator that incorporates ETCO₂ detection as a feature (e.g. Capno-Flo [Mallinkrodt])?

Yes, place the ETCO₂ detector between the ResQPOD and the ventilation source, making sure all connections are tight and do not leak.

42. Can I use electronic ETCO₂ detection (with sidestream or mainstream gas sampling) in the same ventilation circuit as the ResQPOD?

Yes, the preferred location of the ETCO₂ sensor is between the ResQPOD and the ventilation source and not between the ResQPOD and the airway. This position: 1) gets the ResQPOD into the circuit the quickest; 2) places the ResQPOD closest to the patient; 3) decreases the number of connections between the ResQPOD and the airway adjunct from two to one; and 4) minimizes the potential for loss of vacuum. If the ETCO₂ sensor does not fit above the ResQPOD then it may be placed below with snug connections.

43. Can I use the ResQPOD with bag-valve resuscitators that have an integrated "mediport" (feature that permits administration of medications via a metered dose inhaler) or to administer medications endotracheally (e.g. Medibag, Ambu)?

Yes, the ResQPOD should not affect the delivery of the medication and the medication should not affect the performance of the ResQPOD; however, this has not been clinically tested and may depend upon the medication used. If you are delivering endotracheal medications without a mediport, the manufacturer recommends that you disconnect the ResQPOD from the endotracheal (ET) tube, administer the medications directly into the ET tube, and then reconnect the ResQPOD.

44. Can I use a drug atomizer with the ResQPOD?

The ResQPOD does not need to be removed when the atomizer is securely connected between the ResQPOD and the ET tube.

45. Can the ResQPOD be used with a bag-valve resuscitator with a feature that limits flow rates (and thus airflow pressures) during ventilation (e.g. SMART BAG)?

Yes. This feature will not affect the ResQPOD's function.

46. Can I use the ResQPOD with automatic (transport or other) ventilators?

Yes, the ResQPOD can be used with most automatic ventilators. The only brand that we are aware of that is not compatible with the ResQPOD is the Oxylator. In the automatic mode, the Oxylator provides a continuously positive airway pressure that is harmful for the patient, with or without the ResQPOD. This continuously positive airflow interferes with the ResQPOD's ability to create a vacuum (negative pressure).

47. Can the ResQPOD be used on a patient with a tracheostomy or stoma?

A patient with a stoma could have an endotracheal tube placed into the stoma for airway management. If there is not a good seal between the airway device and the lungs, the ResQPOD may be less effective. As long as there is an adequate seal during positive pressure ventilation, the ResQPOD should work effectively. It is

the ultimate decision of the prescribing physician to determine whether the ResQPOD should be used in these types of patients.

48. Can the ResQPOD be used on an uncuffed endotracheal tube?

If there is not a good seal between the airway device and the lungs, the ResQPOD may be less effective. As long as there is an adequate seal during positive pressure ventilation, the ResQPOD should work effectively. It is the ultimate decision of the prescribing physician to determine what airway adjuncts the ResQPOD should be used with.

49. Does the application of cricoid pressure interfere with ResQPOD performance?

No.

50. Can the ResQPOD be used in conjunction with arrested patients who are being therapeutically cooled?

One study in pigs evaluated how well a rapid, ice-cold saline flush, combined with active compression decompression (ACD) CPR and the ResQPOD could cool brain tissue compared with standard CPR during cardiac arrest.^{viii} In this study, the device combination (ACD CPR & ResQPOD), combined with a cold saline bolus during cardiac arrest induced cerebral hypothermia more rapidly immediately following return of spontaneous circulation than standard CPR with a cold saline bolus. Moreover, survival rates were significantly higher with ACD CPR and the ResQPOD. At present, there are no data published on the potential benefit of using the ResQPOD with manual CPR to increase the circulation of cold saline during CPR. ACSI recommends, as does the American Heart Association, that patients who remain unconscious following cardiac arrest be considered for early therapeutic cooling following a return of spontaneous circulation in a effort further improve upon survival to hospital discharge rates with good neurologic recovery.

51. Can the ResQPOD be used with any standard facemask?

Yes; however, the manufacturer strongly recommends that the user consider the quality of the facemask to use it with. Obtaining and maintaining an adequate seal during facemask ventilation is critically important to the generation of the all-important vacuum. Many standard facemasks purchased today are selected primarily based upon cost, not mask quality. ACSI recommends that anyone who is going to use the ResQPOD on a facemask use one with excellent face-sealing qualities. A 2-handed ventilation technique, as recommended by the American Heart Association, is preferred. A head strap may help obtain and maintain a tight face seal.

52. I see that the ResQPOD can be used for mouth-to-mask ventilation, but the ResQPOD doesn't come packaged with a mouthpiece. How can I get one?

Most mouthpieces with a standard 22 mm OD adaptor will work.

53. Can I use the ResQPOD on a Combitube, laryngeal mask airway (LMA), esophageal obturator airway (EOA), Cobra, King or other advanced airways?

The ResQPOD is cleared for use on airway adjuncts used during assisted ventilation. The ResQPOD will fit on these advanced airway devices and should be effective as long as there is a sufficient seal within the ventilation circuit.

54. Has the ResQPOD been tested with semi-open anesthetic circuits (e.g. Bain, McGill, Lack) as these are used in emergency resuscitation rooms connected to resuscitation machines?

The ResQPOD has not been tested in semi-open anesthetic circuits; however, there is no known reason that the ResQPOD should not work with these machines.

55. Has the ResQPOD been tested with Soda Lime Absorber "Closed Circuit" anesthetic systems, which are also used in resuscitation areas?

The ResQPOD has not been tested in closed circuit anesthetic systems; however, there is no reason to believe that the ResQPOD would not work.

56. When expiration release pressures are high, minute volume dividers and pressure-cycled resuscitators may respond with a high respiratory rate and low breath volumes. Most EMS ventilators and BVM devices can be fitted with a break valve pressure of between 45 and 60 cmH₂O. Does this affect ResQPOD performance?

This should not alter the performance of the ResQPOD.

57. Is the ResQPOD compatible with magnetic resonance imaging (MRI) machines?

No; the ResQPOD contains stainless steel, which means that it can not be used in an MRI. If a patient arrests during an MRI, they should be taken to a magnetic field safe zone so that defibrillators and other rescue devices can be effectively deployed.

REGULATORY

58. Does the ResQPOD require a prescription for use?

Yes.

59. Has the AHA made any recommendations on the ResQPOD?

Yes, an impedance threshold device (e.g. ResQPOD) is recommended with a Class IIb level recommendation in the recently released 2010 AHA guidelines for CPR and emergency cardiac care.^{ix} The timing light feature, which promote proper compression and ventilation rates, have a Class IIa recommendation.^x

60. Does the ResQPOD have 510(k) clearance from the FDA?

Yes; the ResQPOD is indicated for home, hospital, clinic and emergency care use, for the temporary increase in blood circulation as directed by a physician or licensed practitioner. The ResQPOD can be used in patients requiring assisted ventilation, for example, patients receiving CPR. It is contraindicated in dilated cardiomyopathy, congestive heart failure, pulmonary hypertension, aortic stenosis, flail chest, chest pain and shortness of breath. It can be used with a facemask, endotracheal tube or other appropriate airway adjunct used for assisted ventilation.

61. Does the ResQPOD have the CE mark?

Yes.

SALES

62. Are there other impedance threshold devices on the market?

ACSI is the only manufacturer of ITDs because the technology is patented.

63. How do I buy the ResQPOD?

Please call Advanced Circulatory Systems, Inc. at 651-403-5600 or 1-877-RESQPOD (737-7763) for help determining the sales representative for your agency. You can also find a list of distributors at:

<http://www.advancedcirculatory.com/Distributors.htm>.

64. What other products are available from Advanced Circulatory Systems?

ResQCPR™ Demo Kits – contain ResQMAN Demonstrator, training ResQPOD(s), training DVD and CD with electronic files. Available at: <http://www.advancedcirculatory.com/DemoKit.htm>.

CardioPump® - a hand-held device placed on the patient's chest and used to perform active compression decompression (ACD) cardiopulmonary resuscitation (CPR). This product is currently only available outside the United States.

ResQGARD® – an impedance threshold device that provides a slight therapeutic resistance when used in hypotensive patients who are spontaneously breathing to enhance circulation.

COMPANY

65. I've seen references to CPRx and ResQSystems. Are these the same company as Advanced Circulatory Systems?

Yes, the company, when founded in 2000, was named CPRx LLC. In 2002, the name changed to ResQSystems, and in 2003 the company incorporated and assumed the current name, Advanced Circulatory Systems, Inc. (ACSI).

66. I've seen the term impedance threshold valve (ITV) and other names for this product. Are they the same?

Yes, you may see references in the studies that have been published to impedance threshold valve (ITV), Resuscitator Valve, Resusci-Valve, and ResQValve. These are essentially earlier versions of the same product with the same functionality. ACSI currently generically refers to devices that provide inspiratory impedance as impedance threshold devices (ITDs), of which the company manufactures two versions with the brand names: 1) ResQPOD® Impedance Threshold Device, intended for use in assisted ventilation applications, and 2) ResQGARD® Impedance Threshold Device, intended for use in spontaneously breathing applications.

67. I've heard that ACSI also manufactures a product called the ResQPUMP. Where can I get one?

The ResQPUMP is a hand-held device used to perform active-compression decompression (ACD) CPR. A large clinical trial (ResQTRIAL) involving the use of the ResQPUMP and ResQPOD (ResQCPR System) began in the Fall of 2005 and concluded in 2010.^{xi} Data from that study is currently under review by the Food and Drug Administration (FDA) and the company is anticipating approval for sale in the United States (US) sometime in 2012. Another hand-held ACD CPR device, the CardioPump®, can be purchased for use outside the US by calling 651-403-5600 or go to: <http://www.advancedcirculatory.com/IDistributors.htm>.

TRAINING

68. My agency has just purchased ResQPODs. What product training resources are available?

Each agency that purchases ResQPODs receives a complimentary Customer Inservice Kit that contains all the materials needed to train users of the ResQPOD. Please ask your sales representative to provide this to you.

The sales representative who sold the product is available as a training resource.

A free, online ResQPOD learning module is available at www.advancedcirculatory.com.

A free ResQPOD storyboard, designed to fit a 36" (h) x 48" (w) cardboard display board, is available from your sales representative.

The ResQCPR Demo Kit is available at: <http://www.advancedcirculatory.com/DemoKit.htm>.

69. Do you sell a training version of the ResQPOD?

Currently no; however, the battery will usually power the lights on the device for many hours or even days if the battery is properly preserved. If you use a ResQPOD for training, be sure to replace the clear plastic tab that secures the ON-OFF switch in the OFF position once training is completed. This will preserve battery function for many repeated uses during training. ResQPODs that are used for training purposes should not be used on real patients.

70. Can I get continuing education credit for ResQPOD training?

The initial training curricula outlined in the Customer Inservice Kit is designed to meet the minimal requirements that allow most healthcare disciplines to receive 1 hour of continuing education unit (CEU) credit. It is the responsibility of each student to determine whether this learning module satisfies the requirements for CEU credit within their respective healthcare discipline as these requirements vary by state and licensing board. This same learning module is now available online at www.advancedcirculatory.com.

The generally cleared indication for the ResQPOD available for sale in the United States (US) 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 US. Research is ongoing in the US 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 FDA.

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- i Lick et al. Crit Care Med 2010;39(1):26-33.
 - ii Thigpen et al. Resp Care 2010;55(8):1014-1019.
 - iii Lurie et al. Resp Care 2008;53(7):862-70.
 - iv 2010 AHA Guidelines for CPR and ECC. Circulation 2010;112:S72.
 - v Yannopoulos D et al. Resuscitation 2004;(61):75-82.
 - vi Voelckel WG et al. Pediatr Res 2002;51(4):523-7.
 - vii Raedler et al. Anesth Analg 2002;95:1496-1502.
 - viii Srinivasan et al. J Am Coll Cardiol 2006;47:835-41.
 - ix 2010 AHA Guidelines for CPR and ECC. Circulation 2010;2005:S722.
 - x 2010 AHA Guidelines for CPR and ECC. Circulation 2010;2005:S697.
 - xi Aufderheide et al. Lancet 2011;377(9762):301-311.