ResQPOD®

FREQUENTLY ASKED QUESTIONS

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FREQUENTLY ASKED QUESTIONS

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

The ResQPOD, an impedance threshold device (ITD), impedes airflow into the chest to create a vacuum (negative pressure) during the recoil phase of CPR, which follows each chest compression. This vacuum lowers intrathoracic and intracranial pressures 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) and to the brain during the subsequent compression. Thus, despite its placement into the ventilation circuit, the ResQPOD is a circulatory enhancement 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 conventional manual CPR alone, and to a patient receiving CPR in conjunction with the ResQPOD?

Studies show the following pressures:

	Approximate Average Negative Intrathoracic Pressures
Healthy, spontaneously breathing person at rest	-1 to -3 mmHg
Cardiac arrest patient receiving conventional manual CPR	0 to -2 mmHg*
Cardiac arrest patient receiving conventional manual CPR with the ResQPOD ITD 10	-2 to -6 mmHg*
Cardiac arrest patient receiving active compression decompression (ACD) CPR with the ResQPOD ITD 16	-5 to -10 mmHg

*depending upon passive recoil and the elastic 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, however, 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 pleural space, which is instantaneously transmitted to the right heart. This results in a marked enhancement in venous return back to the heart.

Although initially counterintuitive, 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 (ICP) is also instantaneously lowered because of the connection between the thorax and paravertebral sinuses along the spinal cord. 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. 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 ($ETCO_2$), an indirect measure of circulation. When $ETCO_2$ is increased, it usually means that more blood is circulating; as blood passes through the lungs, more CO_2 is removed proportionally to the increase in blood flow. Typically, $ETCO_2$ increases by about 30% in a patient treated with the ResQPOD and high-quality CPR. This equates to a near doubling of blood flow to the heart.

For the best comparison, you should measure $ETCO_2$ prior to placement of the ResQPOD, and then about 3 minutes later. It sometimes takes up to 15 minutes to achieve maximum $ETCO_2$ levels once the ResQPOD is in place. It is important to note that we do not advise taking time to measure $ETCO_2$ 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 indicator of an increase in circulation is the strength of the pulse, rescuers have reported feeling a stronger pulse with the ResQPOD in place.

Two human studies looking at invasive blood pressure during cardiac arrest have demonstrated significantly higher blood pressures when the ResQPOD was added. Pirrallo et al reported that invasive arterial blood pressure increased from 43/15 mmHg in conventional manual CPR to 85/20 mmHg in patients with the ResQPOD.[i] Plaisance et al reported near-normal blood pressures (108/56 mmHg) in patients receiving the ResQPOD with ACD-CPR.[ii]

An 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.[iii] A study by Yannopoulos et al found that when an active ITD is used in conjunction with high-quality CPR, use of an active ITD resulted in a 75% improvement in survival to hospital discharge.[iv] In the 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 American Heart Association (AHA) CPR Guidelines.[v]

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.).

Note: All ResQPODs are 100% tested prior to shipment to assure they are properly functioning.

5. Is the ResQPOD effective with conventional manual CPR? What about automated CPR devices (e.g., LUCAS Device [PhysioControl], AutoPulse [ZOLL])?

The combination of animal and human studies has shown statistically significant improvements in blood pressure, vital organ circulation and survival rates from cardiac arrest when an ITD is used in conjunction with high-quality conventional manual and ACD-CPR (see Clinical Summary). In addition, data from the Resuscitation Outcomes Consortium (ROC) PRIMED Study showed that the highest survival rates trended highest when the ITD was used at AHA-recommended compression rates.[vi] Yannopoulos et al showed that when an ITD was used with high-quality CPR, survival increased by as much as 75% compared to standard high-quality CPR alone.[iv]

The ResQPOD ITD can also be used with any method of automated CPR, and this being one option for promoting high-quality CPR (e.g., correct compression rate, depth and fraction). There have been several studies published demonstrating the synergy between the ResQPOD and automated CPR devices. Please contact ZOLL for these studies.

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

ZOLL is aware that some caregivers have elected to perform compression-only (or "hands-only") CPR with ventilations withheld for a period of time. Currently, the AHA recommends this CPR method *only* for lay rescuers who are not confident in their ability to perform ventilations. While applying chest compressions rapidly and with minimal interruptions can help to ensure high-quality compressions at the right rate, withholding ventilations can have deleterious effects 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."[vii] As a result, ZOLL recommends that patients be ventilated at 8-10 breaths/minute as recommended by the AHA.

If an organization elects to provide compression-only CPR during the first few minutes of CPR, they should not use the ResQPOD during the period of time when ventilations are withheld, as it will restrict passive oxygenation. When ventilations are resumed, the ResQPOD can be added. ZOLL 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 occurring 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 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*."[viii] 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. Since the ResQPOD ITD helps enhance negative intrathoracic pressure, hyperventilating can impact its performance. The ResQPOD is designed to assist rescuers in avoiding hyperventilation and includes timing lights that flash 10 times per minute to guide ventilations.

12. What if $ETCO_2$ 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 $ETCO_2$ 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 $ETCO_2$ levels, but 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 (approximately -10 or -16 cmH_2O depending on model) 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 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 affect 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 10/min, which is consistent with AHA Guidelines.

16. What effect does chest compression rate have on the effectiveness of the ResQPOD?

It is very important to get compression rates right – not too fast and not too slow. Data from the ROC PRIMED study showed that CPR compression rates impact survival rates from cardiac arrest, whether or not

an ITD is used.[ix] Survival rates trended highest when an active ITD was used at the AHA-recommended compression rate vs. a sham ITD at the same rate. In order to help rescuers, get the right rate, depth and fraction ZOLL recommends the use of CPR feedback technologies. A further post hoc analysis of the ROC PRIMED study demonstrated that when the ITD was used with high-quality CPR (i.e., correct rate, depth and fraction) led to a significant (75%) increase in survival over doing high-quality CPR alone.

Features

17. 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. 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.

18. 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, whereas 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.

19. 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.

20. 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.

21. 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.

22. 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).

23. How much inspiratory impedance does the ResQPOD provide?

The valving mechanism within the ResQPOD ITD 10 creates a selective resistance to the influx of air until a pressure of approximately -10 cmH_2O (-7.36 mmHg) is reached, at which time the valves open to allow respiratory gases in. For the ResQPOD ITD 16 this "cracking" pressure is approximately -16 cmH_2O (11.76 mmHg).

24. What is the ResQPOD's shelf life?

Four years from the date of manufacture.

25. What is the dead space of the ResQPOD?

The ResQPOD's dead space is 40.7 ml.

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

Gasping is a good sign during cardiac arrest and 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).

27. 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.

28. How does the ResQPOD differ from the ResQGARD®, an ITD also made by ZOLL?

	ResQGARD ITD 7	ResQPOD ITD 10 or 16
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_2O	-10 and -16 cmH_2O
Valving Mechanism	Partially impedes gases from entering the lungs until a threshold of -7 cmH_2O is reached	Completely impedes gases from entering the lungs until a threshold of -10 or -16 cmH_2O is reached
Other Features	O_2 port permits administration of supplemental oxygen	Timing assist lights promote proper ventilation rates.

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

Indications/Contraindications

29. The ResQPOD is contraindicated in dilated cardiomyopathy, congestive heart failure, pulmonaryhypertension, 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 should also not be used in patients with ongoing uncontrolled hemorrhage. The prescribing physician should make the final determination about when the ResQPOD is used.

30. 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 should also not be used in patients with ongoing uncontrolled hemorrhage.

31. What effect will the ResQPOD have during resuscitation on patients with an open or closed pneumothorax? What if there are chest tubes in place?

Any "leak" in the chest cavity will interfere with the generation of negative pressures. In patients with open pneumothoraces, caregivers are taught to cover the wound with a one-way seal that allows air to escape from the chest but not to enter, or to place a chest tube. Assuming there is a one-way flap or chest tube in place with no leaks, the ResQPOD will work and should 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.

32. 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.[x] 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.

33. 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.[xi] 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.

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 ZOLL 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. 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, ZOLL 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.

36. 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.

37. 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.[xii] 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

38. Does the ResQPOD comply with International Standard Organization (ISO) anaesthetic connectionstandards?

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

39. What effect does adding a positive end expiratory pressure (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.

40. 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.

41. 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.

42. Can I use the ResQPOD with a colormetric end tidal carbon dioxide ($ETCO_2$) detector in the ventilation circuit to assess endotracheal (ET) tube placement or with a bag-valve resuscitator that incorporates $ETCO_2$ detection as a feature (e.g. Capno-Flo [Mallinkrodt])?

Yes, the preferred placement of the $ETCO_2$ detector is between the ResQPOD and the ventilation source, making sure all connections are tight and do not leak.

43. Can I use electronic $ETCO_2$ detection (with sidestream or mainstream gas sampling) in the same ventilation circuit as the ResQPOD?

Yes, the preferred location of the $ETCO_2$ 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 $ETCO_2$ sensor does not fit above the ResQPOD then it may be placed below with snug connections.

44. 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.

45. 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.

46. 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.

47. 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).

48. 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.

49. 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.

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

No.

51. 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.[xiii] 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. ZOLL 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 an effort further improve upon survival to hospital discharge rates with good neurologic recovery.

52. 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. ZOLL 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.

53. 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.

54. Can the ResQPOD be used with the NuMask Intraoral Mask (IOM)?

The ResQPOD fits on the NuMask IOM and should work as long as the IOM and the rescuer's hands are sealing the mouth and nose well during compressions, though this has not been tested in animals or humans.

55. Can I use the ResQPOD on a Combitube, laryngeal mask airway (LMA), esophageal obturatorairway (EOA), Cobra, King, air-Q_{sp}, or other supraglottic 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 during chest compressions.

56. 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. If positive end expiratory pressure (PEEP) is provided by the device, the therapeutic effect of the ITD may be lessened.

57. 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. If positive end expiratory pressure (PEEP) is provided by the device, the therapeutic effect of the ITD may be lessened.

58. 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 60cmH_2O. Does this affect ResQPOD performance?

This should not alter the performance of the ResQPOD.

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

No; the ResQPOD contains stainless steel, which means that it cannot 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.

60. Can the ResQPOD be used during procedures where the chest cavity is open (e.g. open heartsurgery, direct heart massage CPR)?

No. An open chest will not allow negative pressures to form and the ResQPOD will not be effective.

Regulatory

61. How does the Boussignac Cardiac Resuscitation Device (b-card by Vygon) compare to the ResQPOD?

The ResQPOD has been shown in numerous animal and clinical studies to improve blood flow and hemodynamics. It does this by significantly enhancing the intrathoracic vacuum during the decompression phase of CPR. According to Vygon's website the b-card works on the principle of a virtual valve generated by the acceleration of a flow of oxygen passing through micro-jets that supposedly maintain positive intrathoracic pressure during the thoracic compression phase of chest compressions, and a negative intrathoracic pressure during the decompression phase of chest compressions. These variations then, theoretically, impact venous return and hemodynamics. No animal or clinical data supporting the efficacy or safety claims of the b-card could be found during a PubMed search in March 2016, and the b-card is not approved for use in the US.

62. Does the ResQPOD require a prescription for use?

Yes.

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

Use of the ITD with standard CPR has been reclassified to a newly defined Class III recommendation (Class III: No Benefit) in the 2015 American Heart Association Guidelines.[xiv] The change is a result of the evidence evaluation process and the addition of this new Class III category. Use of the ITD still carries a Class IIb recommendation in the Guidelines when used with Active Compression Decompression CPR (ACD-CPR).[xiv]

The AHA 2015 Guidelines changed the previous definition of a Class III recommendation by dividing it into two categories: 1) "Class III: No Benefit" and 2) "Class III: Harm." Based on the neutral findings of the ROC PRIMED study, the reviewers gave the ITD a Class III: No Benefit recommendation. The timing lights on the ITD that guide ventilations still carry a Class IIa recommendation While we are disappointed in the AHA's recommendation, we are not surprised by the change in classification for the ITD with standard CPR. There are two key reasons for this:

- The recommendation for the ITD was based on one study designed to assess survival, the ROC PRIMED study which was published in 2011 by Aufderheide et al. and showed a neutral result[2]. You have likely been familiar with this study for years and have already made the decision to continue using the ITD.
- What was not considered was a paper by Yannopoulos et al. published in Resuscitation in 2015 showing that CPR quality was a major confounder in the ROC PRIMED study and that when AHA Guidelines-quality CPR was performed the ITD showed a significant survival benefit compared to AHA Guidelines-quality CPR alone[3]. This paper was published after the evidence evaluation was completed. In addition, data previously considered in the AHA evidence evaluation process that resulted in a Class II recommendation for the ITD in 2010 was not considered in the 2015 recommendation. You can obtain a copy of these studies by contacting your ZOLL representative or by contacting us at www@zoll.com/IPRinfo

64. 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.

65. Does the ResQPOD have a CE mark?

Yes.

Sales

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

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

67. How do I buy the ResQPOD?

Please contact your ZOLL sales representative, or call ZOLL at 1-800-348-9011, or go to www.zoll.com.

68. What other Intrathoracic Pressure Regulation (IPR) Therapy products are available from ZOLL?

ResQCPR System – CPR adjunct consisting of two synergistic devices - the ResQPOD ITD 16 and the ResQPUMP® ACD-CPR Device. Used together, these devices improve blood flow to the brain and vital organs and have been shown to increase the likelihood of survival.[xvi]

ResQCPR Demo Kit – contains a ResQMAN Demonstrator, training ResQPOD, and training DVD. Available at www.zoll.com or through your sales representative.

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

69. I've seen reference to CPRx, ResQSystems, ACSI, and Advanced Circulatory. Are these are the same company as ZOLL?

Advanced Circulatory, when founded in 2000, was named CPRx LLC. In 2002, the name changed to ResQSystems, and in 2003 the company incorporated and assumed the legal name, Advanced Circulatory Systems, Inc. (ACSI), but the company commonly refered to itself as "Advanced Circulatory." In early 2015 ZOLL Medical acquired Advanced Circulatory and it became a wholly owned subsidiary.

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

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. ZOLL 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.

61. I've heard that ZOLL also manufactures a product called the ResQPUMP or CardioPump. 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.[xvi] This study demonstrating a 49% increase in survival to one year in adult cardiac arrest patients who received the ResQCPR System.[xvii] The Food and Drug Administration (FDA) has approved the ResQCPR System for sale in the US. The ResQCPR System is

the only CPR device with an FDA-approved indication to improve the likelihood of survival from cardiac arrest. Another hand-held ACD-CPR device, the CardioPump®, can be purchasedfor use outside the US by calling ZOLL at 1-800-348-9011.

Training

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

- Each agency that purchases ResQPODs is eligible to receive complimentary training resources (e.g. videos, PowerPoint presentations) that contain materials needed to train users of the ResQPOD. Please ask your sales representative to provide these, or they can be found at www.zoll.com.
- The sales representative who sold the product is available as a training resource, and ZOLL has clinical educators who are available to assist with training planning and needs.
- A free, online ResQPOD learning module is available on the ZOLL website.
- The ResQCPR Demo Kit is available for purchase on the ZOLL website.

63. 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 turn 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.

Studies available upon request. The generally cleared indication for use for the ResQPOD ITD 10 available for sale in the United States (U.S.) is for a temporary increase in blood circulation during emergency care, hospital, clinic, and home use. The studies referenced here are not intended to imply specific outcomes-based claims not cleared by the U.S. FDA.

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