



RESQGARD® IMPEDANCE THRESHOLD DEVICE 7.0 FREQUENTLY ASKED QUESTIONS

Mechanism of Action

1. How does the ResQGARD Impedance Threshold Device (ITD) improve circulation in a patient who is hypotensive?

The ResQGARD, an impedance threshold device (ITD), harnesses the body's respiratory and circulatory systems to create a vacuum (negative pressure) within the chest with each inspiration. The ResQGARD provides a slight therapeutic resistance during inspiration, which lowers the intrathoracic pressure and draws more venous blood back to the heart. Improved blood return to the heart (preload) increases blood flow out of the heart (cardiac output) to the brain and other vital organs. Each inspiration through the ResQGARD also lowers intracranial pressures slightly, thereby increasing forward flow to the brain. Thus, despite its placement into the respiratory circuit, the ResQGARD increases circulation using the patient's inspiratory effort to drive the process.

2. How prevalent are hypotensive episodes?

Hypotension and shock are extremely prevalent. Hypotensive episodes are common in patients presenting to emergency departments with one study reporting non-traumatic hypotension in 19% of emergency department patients admitted to the hospital. Hypotension accounts for nearly 10% of all hospital admissions from the emergency department.(1) Inside the hospital, postoperative orthostatic intolerance is common (incidence ~50%) following surgery, and general anesthesia may be a major cause of orthostatic hypotension.(2) Hemorrhage contributes to 50% of current combat fatalities and up to 80% of civilian trauma fatalities.(3) In addition, a symptomatic reduction in blood pressure during or immediately following dialysis occurs in approximately 20 – 30% of dialysis sessions.(4)

3. Why are hypotensive episodes dangerous?

Hypotension is a common precursor to death, since low blood pressure results in a decrease in organ perfusion that can lead to a lethal downward spiral. One large study of emergency department (ED) patients found that patients with hypotensive episodes were 2.5 times more likely to die in the hospital and were 10 times more likely to have sudden and unexpected death compared to patients who did not become hypotensive in the ED.(1) In addition, review of a National Trauma Data Bank of hundreds of thousands of patients found that mortality increased by 4.8% for every 10 mmHg drop in systolic blood pressure.(3) Likewise, intradialytic hypotension and orthostatic hypotension following dialysis are significant and independent risk factors affecting mortality in dialysis patients.(4)

4. What are the upper airway pressure levels found during inspiration in a healthy, spontaneously breathing person compared to levels in a patient breathing through a ResQGARD?

Average intrathoracic pressures:

- In a healthy, spontaneously breathing person at rest during INSPIRATION are ~ -1.0 cmH₂O;
- In a healthy, spontaneously breathing person at rest during EXHALATION are ~+0.5 cmH₂O;
- In a spontaneously breathing person using the ResQGARD during INSPIRATION are ~-7.0 cmH₂O; and
- In a spontaneously breathing person using the ResQGARD during EXHALATION are ~+0.5 cmH₂O.



When someone is panting after exercise, for example at the end of a hard run, the intrathoracic pressures are similar to those observed with the ResQGARD. The greater the negative intrathoracic pressure (vacuum), the more blood that returns to the heart. This is part of the way the body responds to stress. 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 ResQGARD has been specifically designed to safely optimize the degree of negative pressure in order to increase blood flow to the heart and brain.

5. 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 is based upon the same principle; that is, as the chest wall expands during inspiration the pressure inside the lungs (and the thorax across the board) decreases to sub-atmospheric pressure, thus creating a slight 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. Lowered intrathoracic pressures translate into lowered right atrial pressures, resulting in an enhanced venous return and greater coronary perfusion pressures.

6. What effect does the ResQGARD have on the autonomic (sympathetic and parasympathetic) nervous system?

The sympathetic nervous system plays a key role in blood pressure regulation. The sympathetic side of the autonomic nervous system revs the body up, as the response is mediated by adrenalin and adrenalin-like neurotransmitters. It mobilizes energy reserves to deal with crisis, and stimulation of the sympathetic nervous system is associated with increased heart rate, increased mean arterial blood pressure, bronchodilation and constriction (alpha) or dilation (beta) of blood vessels. On the other hand, the parasympathetic side of this process revs the body down, for example, when we sleep. The two sides of the autonomic nervous system have opposing functions, but under normal conditions, they balance each other out.(5)

When breathing through the ResQGARD, the higher cardiac output and blood pressure causes the balance between these two aspects of the nervous system to shift towards the parasympathetic side of the autonomic system. These adjustments, which occur instantaneously, are thought to be triggered by the carotid baroreflexes in the neck; the higher the blood pressure, the more the body adjusts with less sympathetic activity or tone causing the arteries to relax. This can be seen in the lower body negative pressure study sympathetic nerve measurements studies by Ryan et al in relation to changes in blood pressure when the subject is hypotensive and breathing through the ResQGARD.(6) Separate human studies on rate variability show a similar shift away from the sympathetic to the parasympathetic side of the system.(6,7,8) This mechanism is fundamental as the body is able to maintain a higher blood pressure with less sympathetic nervous system activity, thereby saving the sympathetic nervous system energy for when it is needed more. Furthermore, the lower sympathetic nervous system activity results in less constriction of arteries and therefore greater blood flow to organs and tissue beds. This is a big benefit for patients with low blood pressure. These are some of the unique features of the ResQGARD technology.

**7. How do I know if the ResQGARD is working? How soon does it begin working?**

The ResQGARD works by increasing circulation. The easiest and most rapid way to know the device is working is to ask the patient if they feel more resistance during inspiration. You can also measure blood pressure and/or cardiac output before, during and after use for comparison. Other indicators of perfusion, such as oxygen saturation, pulse strength, skin color and end tidal carbon dioxide (ETCO₂) (an indirect measure of circulation), will likely improve as well. For the best comparison, you should measure blood pressure prior to placement of the ResQGARD, and then about 3 – 5 minutes later.

8. What effect will the ResQPOD have on a patient who is normotensive (normal blood pressure)?

This has been studied in normal human subjects who are either lying down or sitting up. Use of the ResQGARD in someone who has normal blood volume and normal blood pressure results in an increase in cardiac output of about 1-1,5 liters/minute, a slight increase (5-10 mmHg) in systolic and diastolic blood pressure, a slight increase in heart rate (5-10 bpm), a slightly slower respiratory rate but larger tidal volume and a slight decrease in peripheral vascular resistance.(9,10) This is essentially what happens when a person takes a deep breath or sigh. In addition, there is an immediate increase in cerebral blood flow.

9. How hard is it to breathe through the ResQGARD?

The purpose of the ResQGARD is to provide a slight therapeutic resistance during inspiration to order to enhance circulation. The amount of resistance is dependent upon ventilation rate and volume. One study in humans, which compared the imposed power of breathing through an active impedance threshold device set to open at -7 cmH₂O with a sham (non-functional placebo) device, found that there were no differences in heart rate, respiratory rate, tidal volume and minute volume with and without inspiratory impedance.(11) The study found that it was more difficult to breathe through an active vs. sham device but that the increased amount of work was well-tolerated. For the purpose of comparison, *“moderate exercise requires approximately 80 J/min of power. In contrast, the -7 cmH₂O ITD requires about 12-16 J/min of power, which should be well tolerated by most people with normal respiratory function.”* It is important to tell patients about the slight resistance before placing the device, and coaching them through the first few minutes may make them feel more at ease as well. When patients have a hard time, it is usually because they do not like a facemask on their face, which can be claustrophobic for some. These patients may prefer the mouthpiece instead.

10. Does ETCO₂ build up if the ResQGARD is used on a facemask?

No, and the custom facemask that comes with the ResQGARD is uniquely designed with exhalation ports to facilitate the exit of gases from inside the mask.

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

No effect. Altitude does not have any effect on the ResQGARD’s performance.

12. Silicone valves are known to stick when they become warm and wet – especially diaphragm valves. Does the ResQGARD remain functional in extreme temperatures and humidity?

Yes, the ResQGARD has been tested under extreme temperature and humidity conditions and remains functional as indicated in the product’s packaging and labeling.



13. What are the benefits of the ResQGARD over other therapies that are used to treat hypotension?

Hypotension Therapies	ResQGARD Advantages Over Therapy
Trendelenburg Positioning	<ul style="list-style-type: none"> • There is a general paucity of data supporting use of the Trendelenburg position and its use has been controversial and linked to adverse effects on pulmonary function and intracranial pressure.(12) • It may increase blood flow back to the heart transiently but also increases intracranial pressure. Blood pressure may increase and blood flow to the brain may increase but venous blood drainage out of the brain is decreased with the net effect being an increase in intracranial pressure which, in the end, is harmful. • This position can cause changes in the lung ventilation to perfusion match as there is an increase in diaphragmatic pressure on the lungs. • It can also cause esophageal reflux.
Intravenous Fluids (IVs)	<ul style="list-style-type: none"> • May be initiated in situations where establishing an IV is not practical or possible (e.g. battlefield) • May assist in making it easier to establish an IV • Can be initiated faster than establishing an IV • Fluid sparing for situations when administering fluids is not desirable (e.g. dialysis) • Fluids are often the longer-term solution whereas the ResQGARD ‘buys time’. They are synergistic and it is likely that less fluid is needed to increase circulation and blood pressure (the ResQGARD is fluid-sparing) in many clinical situations.
Vasopressors	<ul style="list-style-type: none"> • May be initiated and discontinued instantly • Vasopressors will increase blood pressure but not blood flow back to the heart. Some cause an increase in heart rate as well. Vasopressor effects can be positive or negative (ischemia, infarction, renal function deterioration, limb ischemia, etc).
Medical Anti-Shock Trousers (MAST)	<ul style="list-style-type: none"> • Can be initiated faster • Is less cumbersome • Use of MAST is controversial



Features

14. Can I administer supplemental oxygen to a patient while using the ResQGARD?

Yes; the ResQGARD has an ISO standard supplemental oxygen port that allows caregivers to administer up to 15 lpm of supplemental oxygen. Using >15 lpm supplemental oxygen may interfere with the inspiratory impedance feature.

15. Does the ResQGARD interfere with the patient’s ability to exhale or provide PEEP?

No, the ResQGARD provides insignificant resistance (<-1.2 cmH₂O) to patient exhalation. A unique facemask, designed specifically for use with the ResQGARD, has three exhalation ports that reduce positive end expiratory pressure (PEEP) to essentially zero. If it is desirable to add PEEP so that the patient both inspires and expires through low levels of resistance, then a standard facemask without exhalation ports could be used.

16. Can the ResQGARD be reused?

The ResQGARD 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 ResQGARD to be disassembled, disinfected and reassembled for reuse. There are anecdotal reports of multiple uses over many days by the same patient but it is unknown if the benefits of the ResQGARD will persist over multiple uses and the cleanliness of the product cannot be assured.

17. How much inspiratory impedance does the ResQGARD provide?

The valving mechanism within the ResQGARD creates a selective resistance to the influx of air until a pressure of approximately -7 cmH₂O is reached, at which time the valve opens to allow respiratory gases in.

18. How does the ResQGARD differ from the ResQPOD, also an impedance threshold device?

	ResQGARD ITD 7.0	ResQPOD ITD 10.0
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.

19. What is the ResQGARD’s shelf life?

Four years from the date of manufacture.

**20. What is the dead space of the ResQGARD?**

The ResQGARD's dead space is 14 ml.

Indications/Contraindications

21. The ResQGARD is contraindicated in which patients?

There are no clinical data demonstrating harm of the ResQGARD in any hypotensive patient population. The FDA-recommended contraindications in the product labeling are based upon theoretical physiological concerns. The ResQGARD is contraindicated in dilated cardiomyopathy, congestive heart failure, pulmonary hypertension, aortic stenosis, flail chest, chest pain and shortness of breath. Also, since the ResQGARD 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 ResQGARD is used.

22. What is the physiological basis for the ResQGARD being contraindicated in pulmonary hypertension?

The contraindication of pulmonary hypertension was not proposed by the manufacturer and the potential benefits of the ResQGARD in these patients have not been studied. The Food and Drug Administration (FDA) requested that it be included in the labeling due to a theoretical concern that increasing blood flow to the pulmonary arteries could worsen the condition, but the manufacturer is not aware of any clinical data to support this concern.

23. The ResQGARD is contraindicated in congestive heart failure, but might it not provide benefit in patients who are hypotensive due to right-sided heart failure?

The ResQGARD increases venous preload and should be of benefit in patients with decreased preload from all causes, including patients with a history of left-sided congestive heart failure who are hypotensive from over-diuresis, but close physician supervision is advised. It should not be used in patients with left-sided heart failure as it may decrease left ventricular filling and increase left ventricular diastolic pressures.

24. The ResQGARD is indicated for which patients?

The ResQGARD is indicated for the temporary increase in blood circulation in people who suffer from states of poor circulation and low blood flow that may be reflected in low blood pressure (hypotension). Patients experience hypotension for a variety of reasons including, but not limited to: dialysis, blood donation/loss, orthostatic intolerance, dehydration, sepsis, excessive heat, drug overdose and spinal cord injury.

25. When should I apply the ResQGARD?

You should always refer to your agency's protocol for use; but in general, the ResQGARD should be applied when a patient develops signs and symptoms associated with low blood pressure. It's important to realize that there is not a single, non-invasive vital sign that is a reliable indicator of the presence of hypoperfusion; rather, it is essential to look for a variety of signs and symptoms and how they change over time. Early signs of low central blood volume include (but are not limited to): tachypnea, tachycardia, delayed capillary refill, pallor and confusion. Late signs include (but are not limited to): hypotension, decreased cardiac output, cold temperature, cyanosis, combativeness or unconsciousness. A recent paper published by Eastridge et al suggests that the practice of defining shock as a systolic blood pressure < 90 mmHg in adults, likely underdetects the presence of shock and may delay treatment because "*compensatory mechanisms allow significant reductions in*



circulating blood volume, stroke volume and cardiac output to occur well before changes in arterial blood pressure”. The authors concluded that using a “systolic blood pressure of ≤ 110 mmHg is a more clinically relevant definition of hypotension and shock than 90 mmHg.”(3)

26. How does mean arterial pressure correlate to systolic blood pressure?

Mean arterial pressure (MAP) is equal to: $\frac{(2 \times \text{diastolic BP}) + \text{systolic BP}}{3}$

Diastole counts twice as much as systole because 2/3 of the cardiac cycle is spent in diastole. For example, a blood pressure of 90/50 translates into an MAP of 63.3 mmHg. An MAP of about 60 is necessary to perfuse coronary arteries, brain, kidneys. The usual range is: 70 – 110 mmHg.

27. Is there a way to estimate systolic blood pressure in the absence of a BP cuff and stethoscope?

Yes, this will vary somewhat among individuals but:

- A palpable radial pulse is generally an indication that the systolic BP is at least 90 mmHg.
- A palpable brachial pulse is generally an indication that the systolic BP is at least 80 mmHg.
- A palpable femoral pulse is generally an indication that the systolic BP is at least 70 mmHg.
- A palpable carotid pulse is generally an indication that the systolic BP is at least 60 mmHg.

28. Question: Can the ResQGARD be used prophylactically to prevent hypotensive episodes in patients who are prone to them (e.g. dialysis patients)?

Specifically, if a patient is not hypotensive but could become hypotensive, for example someone puts the device on a dialysis patient thinking that they could prevent a hypotensive episode but at the time they use the device the patient is NOT hypotensive, then when the ResQGARD is removed the patient may become hypotensive. The device takes some of their hypotensive fighting power and banks it for another time, but if the patient is then in an exposed situation (e.g. when fluids are being removed during dialysis), then taking the ResQGARD off leaves them without their external preload pump and without as much sympathetic tone, which may lead to hypotension. By modulating the balance between the sympathetic side of the nervous system that revs us up with adrenalin and the parasympathetic system that revs us down, the ResQGARD should only be used once the patient has become hypotensive and not before they are hypotensive. Once the blood pressure has risen to an acceptable level it may be removed and the patient monitored closely. It should be reapplied if the blood pressure again drops.

In the battle field, where BP measurement equipment may not be available, this means that if a patient has a good pulse and when the ResQGARD is removed the pulse becomes weak and thready, then the ResQGARD should be put back on and the soldier should get more fluids if available.

29. Can I use the ResQGARD in patients who are hypotensive due to bradycardia (slow heart rate) or tachycardia (fast heart rate)?

Yes, if it is not otherwise contraindicated, but the cause of the slow or fast heart rate should be treated simultaneously.

30. Is chest trauma a contraindication for use of the ResQGARD?

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



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

In animal models of hypotension, use of an ITD lowers intracranial pressure with each inspiratory effort and results in overall improvement in cerebral perfusion pressures by increasing forward blood flow and lowering resistance.(13) There are no current data on use of the ResQGARD in animals or humans with head injuries or cranial insult though studies are planned. We would caution against using the ResQGARD in patients with known or suspected intracranial bleeding.

32. Can I use the ResQGARD on children?

There are no specific age limitations in the product labelling. The ResQGARD should be effective in patients of all ages and it has been studied extensively in 10 – 15 kg piglets with identical physiological effects as have been reported in adults; however, it has only been tested clinically in adults ages 18 years and above. The mask that comes packaged with the ResQGARD is an adult-sized mask that may fit older children as well, or a standard pediatric facemask may be used instead. An animal study in a pediatric model of hypovolemia, demonstrated that ITD-assisted breathing safely and significantly enhances hemodynamic parameters (e.g. systolic blood pressure, cardiac index and stroke volume index).(14) Anecdotal data suggest that the ResQGARD can be used safely in children \geq 25 lbs but its benefit is dependent upon the child's willingness to cooperate with its use. It is the ultimate decision of the prescribing physician to determine in what ages of patients the ResQGARD should be used.

33. Can the ResQGARD be used on pregnant women? What effect will it have on the fetus?

Yes, in the setting of hypotension it should increase circulation to the fetus as it increases circulation to all vital organs in the mother but this has not been clinically evaluated at present.

34. I've applied the ResQGARD to my hypotensive patient and their blood pressure and symptoms have improved. When should the ResQGARD be removed? When should it be re-applied?

In a patient without intravenous (IV) access, applying the ResQGARD may make it easier to establish an IV because of the improvement in blood pressure. The ResQGARD should be used in conjunction with other indicated treatments for hypotension (e.g. fluids, vasopressors, patient positioning). Once the patient is feeling better and the blood pressure has stabilized and risen to an acceptable level (e.g. >110 mmHg in adults), we recommend you continue ResQGARD treatment for approximately 5 minutes before discontinuing it. Reassess the patient for symptoms and the vital signs frequently. If they begin to decompensate, the ResQGARD should be re-applied. The objective in treating a patient with the ResQGARD is not to ignore the underlying cause of the hypotension, but rather to buy time and help preserve vital organ blood flow during a hypotensive crisis until the etiology can be determined and treated. If the ResQGARD has been applied by an emergency medical services (EMS) agency and they transport the patient to a hospital that is not familiar with the ResQGARD, then the ResQGARD should not be left in the hands of untrained healthcare providers.

35. The instructions for use state that prolonged use for more than 30 minutes is not recommended.

Why is this?

The ResQGARD is a 510(k) cleared device with an intended use for patients who can benefit from an increase in blood circulation. The reference to prolonged use in the directions is intended to ensure that patients do not become fatigued during use.

36. Are there any indications for ResQGARD application to an endotracheal tube in a spontaneously breathing patient?

Most non-arrested patients who are intubated require some form of paralytic or sedation in order for the patient to tolerate the tube. Patients who have been chemically paralyzed would not be



appropriate candidates for ResQGARD application because it requires an inspiratory effort in order to be effective. Most spontaneously breathing patients who are intubated are intubated because of respiratory failure or concern over the patient being able to manage their own airway. The ResQGARD should only be used on a hypotensive, intubated patient if:

1. They were breathing adequately on their own (10 – 30/min in adults), and
2. Showing no signs of respiratory distress (e.g. use of accessory muscles, low oxygen saturation, abnormal end tidal carbon dioxide (ETCO₂) levels, respiratory rates <10 or > 30 in adults), and
3. Not otherwise contraindicated.

37. Some cardiac arrest patients, following a return of spontaneous circulation, remain hypotensive. Would it be appropriate to place the ResQGARD for this type of patient?

Most patients following a return of spontaneous circulation are in a tenuous state in regards to their cardiac and respiratory systems and often require continued ventilatory assistance. Because the purpose of the ResQGARD is to provide a therapeutic resistance to inspiration, it will be slightly more difficult for the patient to inspire and will increase the work of breathing. It may be appropriate to use the ResQGARD in a newly resuscitated, hypotensive patient if:

1. They were breathing adequately on their own (10 – 30/min in adults), and
2. Showing no signs of respiratory distress (e.g. use of accessory muscles, low oxygen saturation, abnormal end tidal carbon dioxide (ETCO₂) levels, respiratory rates <10 or > 30 in adults), and
3. Not otherwise contraindicated.

38. The ResQGARD may be beneficial in patients who are hypotensive due to hypovolemia but should not be used in cases where life-threatening bleeding has not been controlled. What if my patient has internal bleeding due to blunt trauma or other medical causes (e.g. gastrointestinal or vaginal bleeding, abdominal aortic aneurysm) and I'm not sure if it's been controlled?

In a situation where life-threatening bleeding is not under control, the ResQGARD may accelerate the bleeding. For this reason it's important to have bleeding under control before applying the ResQGARD. In cases where this is unclear, the manufacturer recommends that you use the ResQGARD as you would a fluid challenge; i.e. if a fluid challenge is indicated, then the ResQGARD would be too. If it's believed that the administration of fluids will worsen bleeding and "permissive hypotension" is desired, then the ResQGARD should not be used. Since the use of an ITD may be fluid-sparing and can be discontinued immediately, a trial application of the ResQGARD may be considered but should be done at the discretion of the physician in charge of the patient's care.

39. Are there any advantages to treating a hypotensive patient with inspiratory impedance as opposed to fluids?

The ResQGARD may increase the blood pressure quicker than fluids and can help to maintain vital organ perfusion during that crisis. The ResQGARD works by redistributing the patient's own fluid and can help prevent over-hydrating the patient, which is desired in certain types of patients (e.g. dialysis). Also, in some situations (e.g. battlefield, during EMS transport, patient with poor veins) the establishment of intravenous access is problematic and the ResQGARD can be easily initiated. The objective in treating a patient with the ResQGARD is not to ignore the underlying cause of shock, but rather to buy time and help preserve vital organ blood flow during a hypotensive crisis until the etiology can be determined and treated.



Compatibility with Other Adjuncts/Procedures

40. How does the ResQGARD come packaged?

Currently, the ResQGARD is available as a kit that contains: 1) ResQGARD, 2) ResQStrap, 3) custom facemask with expiratory ports, 4) mouthpiece, 4) oxygen tubing and 5) nose clip. Other product configurations will be available in the near future.

41. Does the ResQGARD comply with International Standard Organization (ISO) anaesthetic connection standards?

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

42. What effect does adding a positive end expiratory pressure (PEEP) valve to the ventilation circuit (distal or proximal) have on the ResQGARD Circulatory Enhancer?

PEEP can reduce pulmonary interstitial fluid and pulmonary edema. The use of PEEP with the ResQGARD has only been evaluated in animal models. Low levels of PEEP may be of benefit when used in conjunction with the ResQGARD if not otherwise contraindicated. If it is desirable to add PEEP so that the patient both inspires and expires through low levels of resistance, then a standard facemask without exhalation ports could be used.

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

The ResQGARD should be used in hypotensive patients. There may be a theoretical benefit to using CPAP or BiPAP but this has not yet been evaluated. If a patient is getting CPAP or BiPAP, they are typically having a problem with oxygenation or are being treated for congestive heart failure, in which the ResQGARD should not be used. If a 100% non-rebreather mask is inadequate to maintain adequate oxygen saturation, then they may need to be intubated. The ResQGARD should be promoted and used for hypotensive patients for whom fluids or vasopressor agents are not yet available or for whom such therapies cannot be given or are contraindicated. With positive pressures from CPAP or BiPAP of ≤ 5 cmH₂O, there might be a small to modest benefit. At > 7.5 cmH₂O CPAP or BiPAP there will likely be no benefit as the threshold valve would be open all of the time.

44. Can I use a colormetric end tidal carbon dioxide (ETCO₂) detector or electronic ETCO₂ detection (with sidestream or mainstream gas sampling) with the ResQGARD?

Yes. The colormetric test results may be more positive with the ResQGARD in place. Place the colormetric ETCO₂ detector on the expiratory port of the ResQGARD. Some electronic ETCO₂ sensors (depending on brand) may not fit into the ventilation circuit above the ResQGARD without a 15/22 mm adaptor. One inexpensive source for these is: Tri-anim (www.tri-anim.com; 1-800-874-2646); part name: Connector, 22 mm OD x 15 mm OD; part #: 963-S6260.

45. Can the ResQGARD be used on a patient with a tracheostomy or stoma?

Yes. 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 ResQGARD may be less effective. As long as there is an adequate seal during inspiration, the ResQGARD should work effectively. It is the ultimate decision of the prescribing physician to determine whether the ResQGARD should be used in these types of patients.



46. Can the ResQGARD be used with any standard facemask?

Yes; however, the facemask that comes with the ResQGARD has been uniquely designed to optimize use of the ResQGARD by including three expiratory ports that serve to 1) reduce PEEP (which can decrease preload), 2) reduce the work of breathing, and 3) decrease the opportunity for carbon dioxide retention. A head strap (e.g. ResQStrap™ made by Advanced Circulatory Systems, Inc.) may help obtain and maintain a tight face seal.

Regulatory Questions

47. Does the ResQGARD require a prescription for use?

Yes.

48. Has the AHA made any recommendations on the ResQGARD for treatment of patients with hypotension?

Not at this time.

49. Does the ResQGARD have 510(k) clearance from the FDA?

Yes; the ResQGARD 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.

50. Does the ResQGARD have the CE mark?

The company is in the process of getting the CE mark for the ResQGARD.

Sales

51. How do I buy the ResQGARD?

Please call Advanced Circulatory Systems, Inc. at 952-947-9590 or 1-877-737-7763 for help determining the distributor or sales representative for your agency.

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

ResQPOD® - an impedance threshold device (ITD) that enhances circulation in patients who are apneic (e.g. cardiac arrest)

ResQStrap™ - a uniquely designed head strap to help maintain a tight face seal during facemask ventilation

ResQReady Kit™ - designed with the first responder in mind, comes with a ResQGARD, ResQStrap, high quality facemask and mouthpiece, all in a handy carrying case, for those who are likely to be a situation where mouth-to-mask is indicated.

ResQTrainer™ Kit – extensive training materials for educating caregivers about the ResQPOD

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.

53. Does the ResQGARD have a reimbursement code?

No, typically medical supply items do not have their own reimbursement code.



Company

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

Yes, the company, when founded in 1997, 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).

55. 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 ResQPOD, with similar functionality to the ResQGARD. 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 10.0, intended for use in assisted ventilation applications (e.g. cardiac arrest), and 2) ResQGARD™ Impedance Threshold Device 7.0, intended for use in spontaneously breathing applications.

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

ACSI is the only manufacturer of ITDs because the technology is patent protected.

Training

57. My agency has just purchased ResQGARDs. What product training resources are available?

Each agency that purchases ResQGARDs will receive complimentary training resources to train users on the product. Please contact your sales rep for these materials; in addition, the sales rep is available as a training resource.

58. Do you sell a training version of the ResQGARD?

Currently, no.

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