

FREQUENTLY ASKED QUESTIONS

Mechanism of Action

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

During normal inhalation the chest expands and the diaphragm moves down, creating a slight negative pressure (or vacuum) inside the chest (approx -1.5 cmH₂O). This vacuum pulls air into the chest and helps return some blood back to the heart. During exhalation, the chest comes in and the diaphragm moves up, creating a slight positive pressure (approx 0.5 cmH₂O) that forces air out of the chest. When shock develops, eventually the body is no longer able to compensate and the blood pressure drops. The ResQGARD optimizes the relationship between the respiratory, circulatory and nervous systems to enhance circulation during states of poor perfusion by creating a slight amount of therapeutic resistance only while the patient inhales. This enhanced vacuum:

- Draws more blood back to the heart. When preload is increased, it results in improved cardiac output on the subsequent contraction of the heart.
- Lowers intracranial pressure (ICP), which decreases resistance to forward blood flow to the brain, and results in increased cerebral blood flow.

The net result of both of these mechanisms is improved blood flow to the vital organs. 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. How do the upper airway pressure levels found during inspiration in a healthy, spontaneously breathing person compare 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;
- Healthy, spontaneously breathing person at rest during EXHALATION are ~ +0.5 cmH₂O;
- Spontaneously breathing person using the ResQGARD during INSPIRATION are ~ -7.0 cmH₂O; and
- 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 and manufactured 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 a similar 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. How do negative and positive pressures within the lungs influence pressure inside the head (intracranial pressure) and blood flow to the brain?

The transfer of intrathoracic pressures in the closed cranium has been long recognized, but the mechanism of the immediate pressure transfer is not yet well understood. Studies with the ResQGARD have demonstrated that a positive pressure ventilation with positive intrathoracic pressure results in an increase in intracranial pressure (ICP), while negative pressure deflections in intrathoracic pressure are instantaneously transferred to the ICP as well. Guerci et al have tried to identify the main route of pressure transfer during cardiopulmonary resuscitation and have shown that pressure is transferred through the thoracic spine to the cerebrospinal fluid and the nonvalvular veins around the spinal cord.⁵

Research has also demonstrated that pressure transfer was eliminated with exsanguination, pointing out that circulating blood volume is a critical component in this physiologic relationship. Restricting blood flow (ligation) in the carotids and jugular veins did not have a significant effect. Generation of negative intrathoracic pressure by indirectly increasing inspiratory effort or by applying direct airway vacuum between positive pressure ventilations resulted in a remarkable decrease in ICP by a direct transfer of pressure and increasing venous drainage, as it can be seen by the immediate pressure changes of the ICP correlating with the changes in airway pressures. The effect seems to be mediated by a mechanical process

through the venous channels of the paraspinal plexuses (a bed of intersecting veins near the spinal column) and the increase of venous return by the jugular veins. The increase of venous return is very well documented with the generation of negative intrathoracic pressure and is especially pronounced in low volume states. It is unlikely that changes in autonomic nervous system activity underlie these changes in pressures, but further research is needed to fully understand the operative mechanisms.²⁸

Cerebral perfusion pressure is the net pressure gradient causing blood flow to the brain (brain perfusion). Cerebral perfusion pressure is equal to the mean arterial blood pressure (MAP) minus the intracranial pressure. Since the ResQGARD works to both increase MAP and lower ICP, the net effect is an improvement in blood flow to the brain.

7. 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.⁷

When a hypotensive person breathes 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 nerve activity causing the arteries to relax. This can be seen in the lower body negative pressure study sympathetic nerve measurements studies by Ryan et al when a person is hypotensive and breathing through the ResQGARD.³⁵ Separate human studies on rate variability show a similar shift away from the sympathetic to the parasympathetic side of the system.³³⁻³⁵ 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.

8. How will I know if the ResQGARD is working? How much of an effect will it have?

The easiest way to know if the ResQGARD is working is to ask the patient if they feel more resistance during inhalation. You can also measure blood pressure before and during 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 every three to five minutes thereafter. The ResQGARD has been evaluated in over 30 animal and clinical studies. These studies have demonstrated increases in systolic and diastolic blood pressures of up to 30%.⁴¹⁻⁴⁶

9. How soon does the ResQGARD begin working?

This length of time it takes for patients to respond can vary and is dependent upon the severity of the shock state, the etiology, the age and physical condition of the patient, other underlying medical conditions, concurrent therapy and environmental factors. Many patients report feeling better within several minutes of

breathing through the ResQGARD, and blood pressure differences have been reported within 5 to 10 minutes of breathing through the ResQGARD.

10. How much does the ResQGARD raise the blood pressure of a spontaneously breathing, hypotensive patient?

The ResQGARD has been evaluated in over 30 clinical trials and animal studies. These studies have shown that the ResQGARD:

- Increases systolic and diastolic BP up to 30%⁴¹⁻⁴⁶
- Increases MAP by 5 – 27%^{11,20,21,25,26,36,42}
- Increases stroke volume and cardiac output^{16,17,35,42}
- Increases cerebral blood flow^{10,25,28,33,34,42}
- Lowers ICP during inspiration^{10,28,42}
- Reduces orthostatic symptoms^{18,19,22}
- Is well tolerated^{13,14,30,41,42,45}
- Does not compromise oxygen saturation^{29,42,43}
- “Buys time” and extends the “window of opportunity” during shock^{8,16,17,26,36,42}

11. What effect will the ResQGARD 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, an increase in middle cerebral artery blood flow,²⁵ a slightly slower respiratory rate but larger tidal volume, and a slight decrease in peripheral vascular resistance.^{13,14,25} 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.

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

The purpose of the ResQGARD is to provide a slight therapeutic resistance during inspiration in order to enhance circulation. The amount of resistance is dependent upon ventilation rate and volume. One study in humans, which evaluated the imposed power of breathing through the ResQGARD, found that there were no differences in heart rate, respiratory rate, tidal volume and minute volume with and without inspiratory impedance.³⁰ 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 joules/min of power. In contrast, the -7 cmH₂O ITD requires about 12 - 16 joules/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.

13. The instructions for use recommend breathing through the ResQGARD at a rate of 10 - 16 times per minute. What if a patient is breathing more rapidly than that (e.g. due to pain or shock)? What are the hemodynamic effects of that?

Patients in shock may breathe more rapidly as part of the reflex related to low blood pressure but this hard to sustain. This is often noted in people and in pigs during hypovolemic stress. Breathing more rapidly while using the ResQGARD can enable the patient to get the same hemodynamic benefit with less work since the ResQGARD can help restore blood pressure and blood flow to the brain over time by providing a mechanical aid to circulation.

For example, an athlete who has run a hard race will pant in the end to maintain blood pressure and perfusion. If this athlete were to put the ResQGARD on at the end of a race it will not be helpful and will feel unnatural and make it harder to breathe through because the body has already initiated its own attempt at lowering intrathoracic pressure to enhance circulation. But, if you have persistent hypotension because of dehydration after a marathon or hypotension due to other causes (e.g. blood loss, heat shock, orthostatic hypotension) and you cannot stand up secondary to a fixed loss of fluids or a shift in your body's nervous system function, then the ResQGARD can be helpful by providing circulatory assistance to a tired body.

Timing is everything; blood loss begets hypotension that begets the inability to think clearly and get out of harm's way. Use of the ResQGARD, once bleeding has been controlled or in the setting of severe dehydration, can help the body's own defense system and buy time until fluids can be given or the body restores itself.

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

There is no significant accumulation of ETCO₂ when the ResQGARD is used on a standard facemask.

15. 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.

16. 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 valves are coated to reduce stickiness and have been tested under extreme temperature/humidity conditions; they remain functional as indicated in the product's labeling.

17. 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.⁶ • Trendelenburg 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. • Trendelenburg can cause changes in the lung ventilation to perfusion match as there is an increase in diaphragmatic pressure on the lungs. • Trendelenburg can also cause esophageal reflux.
Intravenous Fluids (IVs)	<ul style="list-style-type: none"> • ResQGARD may be initiated in situations where establishing an IV is not practical or possible (e.g. battlefield, entrapped patient). • ResQGARD may assist in making it easier to establish an IV. • ResQGARD can be initiated faster than establishing an IV. • Fluids hemodilute clotting factors and the oxygen-carrying capacity of the blood. The ResQGARD may be fluid sparing for situations when administering fluids is not desirable (e.g. dialysis) or ideal (e.g. trauma). • Fluids are often the longer-term solution whereas the ResQGARD 'buys

Hypotension Therapies	ResQGARD Advantages Over Therapy
	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"> ResQGARD may be initiated and discontinued instantly; it is difficult to immediately discontinue the effects of medications already given. 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). Unlike vasopressors, the ResQGARD has no direct effect on heart rate.
Pneumatic Anti-Shock Garments (PASG)	<ul style="list-style-type: none"> ResQGARD can be initiated faster. ResQGARD is less cumbersome. Use of MAST is controversial.

18. How does the therapy provided by the ResQGARD compare to CPAP?

In general, positive pressure in the chest drives fluid and air away from it, and tends to lower blood pressure, while negative pressure (a vacuum) in the chest draws fluid and air towards it, and tends to raise blood pressure. Thus, the ResQGARD and continuous positive airway pressure (CPAP) therapies are intended for very different patient populations and conditions.

	CPAP	ResQGARD
DIFFERENCES Between Therapies		
Therapy	Delivers continuous POSITIVE airway pressure to help force fluid out of the lungs	Optimizes the NEGATIVE airway pressure to enhance blood flow
Effect on Blood Pressure	Tends to lower blood pressure	Tends to increase blood pressure
Intended Patient Population	Patients who would benefit from DECREASED preload (e.g. CHF)	Patient who would benefit from INCREASED preload
SIMILARITIES Between Therapies		
How Administered	May be administered with facemask and supplemental oxygen	
Patient Coaching	Therapy will make it a little harder for the patient to breathe in order to feel better. Coaching the patient prior to application will help.	
Cost of Therapy	Similar	
Treatment Approach	Non-invasive approach preferred over invasive approach	

Features

19. 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 oxygen may interfere with the valving mechanism.

20. What is the fraction of inspired oxygen (FiO₂) when supplemental oxygen is administered with the ResQGARD?

The FiO₂ will vary from patient to patient and is dependent upon the ventilation rate, condition and size of the patient, and tidal volume, but when a healthy, non-smoking adult breathes normally through the

ResQGARD with the facemask or the mouthpiece, and has supplemental oxygen delivered via the O₂ port, FiO₂s are approximately as follows:

FiO ₂ (%) During Supplemental Oxygen Administration (lpm)								
Configuration	0 lpm	2 lpm	4 lpm	6 lpm	8 lpm	10 lpm	12 lpm	15 lpm
Facemask	21%	25%	32%	38%	46%	49%	55%	64%
Mouthpiece	20%	23%	28%	33%	38%	41%	49%	57%

Theoretically, a patient receiving high concentration supplemental oxygen with poor perfusion will benefit more from the ResQGARD even though the FiO₂ may be slightly lower because the enhanced circulatory effects of the ResQGARD may result in more oxygenated blood being delivered to the tissues.

21. 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. 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.

22. 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.

23. 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.

24. What is the ResQGARD’s shelf life?

Four years from the date of manufacture.

25. What is the dead space of the ResQGARD?

The ResQGARD’s dead space is 14 ml.

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

	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 ₂ O	-10 or -16 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 or -16 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.

27. Can the ResQGARD and ResQPOD be used interchangeably?

No. The mechanics and valving mechanisms for each device are different and the devices are powered by different physiologic mechanisms (inspiratory effort vs. chest wall recoil). In addition, the expiratory port on the ResQGARD is not designed to accommodate a resuscitation bag. Finally, the ResQGARD, unlike the ResQPOD, is not designed to impede the influx of ambient air during CPR.

Indications/Contraindications

28. The ResQGARD is indicated for which patients? How do I know which patients I SHOULD use the ResQGARD on?

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. Low blood flow and poor circulation 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. In general, because the ResQGARD increases preload, any patient who would likely benefit from increasing preload or having fluids administered, will likely benefit from the ResQGARD as well. This may include patients experiencing hypotension from a variety of medical and traumatic causes: blood loss, blood donation, dehydration, early sepsis, renal dialysis, orthostatic intolerance, drug overdose, heat shock, anesthesia and analgesia.

29. The ResQGARD is contraindicated in which patients? How do I know which patients I SHOULD NOT use the ResQGARD on?

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

PRECAUTION: The ResQGARD is not recommended for use in patients with a penetrating chest injury who have on-going, uncontrolled blood loss. The ResQGARD may be prescribed for use as a tool to treat low blood pressure in patients with a non-thoracic penetrating injury and ongoing blood loss, similar to prescribing fluid resuscitation for the same patient population, but the safety and effectiveness of the ResQGARD in this clinical setting has not been established. Any patient who may become worse by significantly increasing preload or receiving fluid challenges should not be treated with the ResQGARD; for example: patients in acute congestive heart failure, and patients who are not able to tolerate breathing through increased resistance (e.g. short of breath). The prescribing physician should make the final determination about when the ResQGARD is used.

30. 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 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. In animals with normal pulmonary artery pressure, inspiration through the ResQGARD lowers pulmonary artery pressures during inspiration.

31. 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, as seen in right-sided heart failure. It may also be beneficial for patients with a history of left-sided congestive heart failure who are hypotensive from over-diuresis or other non-cardiac causes, but close physician supervision is advised. It should not be used in patients with acute left-sided heart failure as it may decrease left ventricular filling and increase left ventricular diastolic pressures.

32. When should I apply the ResQGARD?

You should always refer to your organization'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 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

33. 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.

34. 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.

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

The ResQGARD is indicated 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 battlefield setting, where BP measurement equipment may not be available, this means that if a patient has a strong 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 and indicated.

36. 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.

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

The ResQGARD should not be used in patients with a flail chest. Since the ResQGARD is used to enhance circulation, the device also should not be used in patients with uncontrolled bleeding from a penetrating thoracic injury. The ResQGARD may be prescribed for use as a tool to treat low blood pressure in patients with a non-thoracic penetrating injury and ongoing blood loss once a clinical decision has been made to treat the patient with fluid resuscitation; however, the safety and effectiveness of the ResQGARD in this clinical setting has not been established.

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

In animal models, 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.²⁸ There are no current data on use of the ResQGARD in humans with head injuries or cranial insult though studies are planned. We caution against using the ResQGARD in patients with known or suspected intracranial bleeding.

39. 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 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 breathing through an ITD safely and significantly enhances hemodynamic parameters (e.g. systolic blood pressure, cardiac index and stroke volume index).¹⁷ Anecdotal data suggest that the ResQGARD can be used safely in infants and children but its benefit is dependent upon the child's ability 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.

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

In the setting of hypotension the ResQGARD should increase circulation to the fetus as it increases circulation to all vital organs in the mother. While the ResQGARD has not been studied specifically in pregnancy, the manufacturer is aware of positive anecdotal results in pregnant women, as well as one published report where it was shown to provide benefit.⁴⁶

41. 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 increase the patient's blood pressure. It may also make it easier to establish an IV because of the improvement in blood pressure. The ResQGARD may 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.

In one prehospital evaluation, after the ResQGARD was removed, the blood pressure in about one third of the patients remained stable upon arrival to the emergency department, in one third the blood pressure increased slightly, and in the final third of patients the blood pressure began dropping again.⁴¹ The response in each patient following discontinuation of the ResQGARD will vary based upon patient condition, underlying etiology and the hemodynamic status of the patient. Reassess the patient for symptoms and the vital signs frequently. If they begin to decompensate, the ResQGARD may be re-applied and additional therapies should be considered.

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) organization 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.

42. 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.

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

Generally no. 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 are breathing adequately on their own (10 – 30/min in adults) and do not require assisted ventilation,
2. Showing no signs of respiratory distress (e.g. use of accessory muscles, low oxygen saturation, abnormal ETCO₂ levels, respiratory rates <10 or > 30 in adults), and
3. It is not otherwise contraindicated.

44. Can I use the ResQGARD for an unconscious patient who is hypotensive but spontaneously breathing?

Yes, as long as the patient is:

1. Breathing adequately on their own (10 – 30/min in adults) and do not require assisted ventilation,
2. Showing no signs of respiratory distress (e.g. use of accessory muscles, low oxygen saturation, abnormal ETCO₂ levels, respiratory rates <10 or > 30 in adults), and
3. It is not otherwise contraindicated.

45. 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 do not require assisted ventilation,

2. Showing no signs of respiratory distress (e.g. use of accessory muscles, low oxygen saturation, abnormal ETCO₂ levels, respiratory rates <10 or > 30 in adults), and
3. It is not otherwise contraindicated.

46. 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 may 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.

47. 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). In some situations (e.g. battlefield, during EMS transport, patient with poor veins) the establishment of intravenous access can be problematic and the ResQGARD can be easily initiated. It also complements a "permissive hypotension" approach to fluid management in trauma. 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. From this perspective, fluids and the ResQGARD have been shown to work together synergistically to increase blood pressure and reduce symptoms.⁴¹⁻⁴⁵

Compatibility with Other Adjuncts/Procedures

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

The ResQGARD's inspiratory port is in full compliance of *ISO 5356-1, Anaesthetic and Respiratory Equipment – Conical Connectors*.

49. 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.

50. 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. 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.

51. Can I use a colormetric 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.

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

Potentially; 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.

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

Yes, as long as the mask and healthcare provider are able to maintain a tight facemask seal. A head strap (e.g. ResQSTRAP™ made by Advanced Circulatory) may help obtain and maintain a tight face seal.

Regulatory Questions

54. Does the ResQGARD require a prescription for use?

Yes.

55. Has the American Heart Association made any recommendations on the ResQGARD for treatment of patients with hypotension?

Not at this time.

56. 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.

57. Does the ResQGARD have the CE mark?

Yes; the ResQGARD is labeled to Article 12 of the Medical Device Directive for Procedure Packs.

Sales

58. How do I buy the ResQGARD?

Please call Advanced Circulatory at 651-403-5600 or 1-877-737-7763, or go to www.AdvancedCirculatory.com for help determining the distributor or sales representative for your organization.

59. How does the ResQGARD come packaged?

The ResQGARD is available in a variety of configurations:

Product #	Description	Comments
12-0707-000	ResQGARD® FM Kit Includes: ResQGARD ITD, facemask, oxygen tubing, and ResQSTRAP in clamshell packaging	Most commonly used configuration
12-0705-000	ResQGARD® MP Kit Includes: ResQGARD ITD, mouthpiece, nose clip in re-sealable package	
12-0706-000	ResQGARD® Military Kit - Domestic Includes: ResQGARD ITD, 3-port facemask, mouthpiece, nose clip, ResQSTRAP, lanyards, and quick reference card in clamshell packaging	Intended for US military use only; the NSN# is 6515-01-575-8173
12-0752-000	ResQGARD® Military Kit - International Includes: ResQGARD ITD, facemask, mouthpiece, nose clip, ResQSTRAP, lanyards, and quick reference card in clamshell packaging	Intended for military use outside the US
12-0708-000	ResQGARD® ITD 7 Includes: ResQGARD ITD only in re-sealable package	
12-0392-000	ResQSTRAP™ Includes: ResQSTRAP only in re-sealable package	

For more details, please contact your local distributor.

60. What other products are available from Advanced Circulatory?

Product #	Description	Comments
12-0242-000	ResQPOD® ITD 10	Currently available only in the US
12-0247-000	ResQPOD® ITD 16	Currently available only outside the US
12-0582-000	CardioPump® ACD-CPR Device with Metronome Hand-held device placed on the patient's chest and used to perform active compression decompression (ACD) cardiopulmonary resuscitation (CPR).	Currently available only outside the US
12-0483-000	CardioPump® ACD-CPR Device without Metronome Hand-held device used to perform ACD-CPR.	Currently available only outside the US
12-0392-000	ResQSTRAP™ Uniquely designed head strap to help maintain a tight facemask seal during ITD use or ventilation	
12-0869-000	ResQCPR™ Demo Kit 1 Includes: ResQMAN™ Demonstrator, one ResQPOD, training materials	Available at www.AdvancedCirculatory.com
12-0906-000	ResQCPR™ Demo Kit 3 Includes: ResQMAN™ Demonstrator, three ResQPODs, training materials	Available at www.AdvancedCirculatory.com

61. Does the ResQGARD have a reimbursement code?

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

Company

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

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), or simply Advanced Circulatory.

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

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. Advanced Circulatory 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[®] ITD 10 and 16, intended for use in assisted ventilation applications (e.g. cardiac arrest), and 2) ResQGARD[®] ITD 7, intended for use in spontaneously breathing applications.

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

Advanced Circulatory is the only manufacturer of ITDs because the technology is patent protected.

Training

65. My organization has just purchased ResQGARDs. What product training resources are available?

Each organization that purchases ResQGARDs will receive complimentary training resources to train users on the product, including a CD of product inservice files and DVD. To obtain these materials, please contact your sales rep, go to www.AdvancedCirculatory.com to download the training files, or call Advanced Circulatory at 1-877-737-7763.

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

Currently, no.

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The generally cleared indication for the ResQGARD is for a temporary increase in blood circulation during emergency care, hospital, clinic and home use. Research is ongoing to evaluate the benefit of the ResQGARD for indications related to specific etiologies. The studies listed here are not intended to imply specific outcome-based claims not yet cleared by the US FDA.