Conventional Manual CPR

Mechanism of Action

1. How does conventional manual CPR circulate blood in cardiac arrest?

Compression Phase

During the compression phase there are two mechanisms that simultaneously help to circulate blood forward (i.e., create cardiac output). The *Cardiac Pump Theory* contends that forward blood flow is created when the heart is squeezed between the sternum and spine. The *Thoracic Pump Theory* states that the chest becomes like a bellows during both the compression and decompression phases.

Compression Phase

A POSTIVE pressure is created that causes:

- Air to be expelled from the lungs
- Blood to be expelled from the heart
- Intracranial pressure (ICP) to rise

Decompression Phase

In order for CPR to be effective, it is critical that the heart is filled with blood prior to the compression phase. During the chest wall recoil (or decompression) phase of CPR, the opposite occurs; a slight NEGATIVE pressure (or vacuum) is generated that:

- Pulls blood back to the heart (i.e., creates preload)
- Draws air into the lungs
- Lowers ICP

This series of alternating positive and negative pressures helps to empty and then refill the heart.

2. Why is blood flow limited during manual CPR?

Even when performed correctly, manual CPR provides only about 25 – 40% of normal blood flow. This is due to several factors:

- First, as the chest wall recoils, air is drawn in through an open airway and wipes out the vacuum that is needed to fill the heart. As soon as this air comes in, the heart stops filling. This situation is similar to trying to suck fluid into your mouth through a straw that has a hole in it it's not very effective.
- Secondly, the creation of the all-important vacuum is dependent on the chest wall's ability to passively recoil. Incomplete chest wall recoil may occur during CPR for a number of reasons:
 - The chest wall may be stiff or have poor compliance
 - Ribs may be broken, even from CPR that is performed correctly
 - Rescuers may compress too fast, thus not allowing enough time for the chest to recoil
 - Rescuers may fatigue and begin resting on the chest

The ResQCPR™ System is the only product on the market that addresses both of these issues, thus optimizing both the compression and decompression phases.

MCN CRP 1805 0061 Page 1 of 26

ResQPOD ITD 16 - Component of the ResQCPR System

Note: See separate FAQs for the ResQPOD ITD 10.

Mechanism of Action

3. What is the ResQPOD® ITD 16?

The ResQPOD impedance threshold device (ITD) is a simple, non-invasive device that delivers intrathoracic pressure regulation (IPR) therapy during basic or advanced life support CPR to improve perfusion. It lowers intrathoracic pressure during the recoil phase of CPR by selectively restricting unnecessary airflow into the chest. This vacuum increases preload, lowers intracranial pressure (ICP), and improves blood flow to the brain and vital organs. The ResQPOD is a component of the ResQCPR System, which also includes the ResQPUMP® ACD-CPR Device. This device combination provides intrathoracic pressure regulation (IPR) therapy to improve blood flow and increase the likelihood of survival in cardiac arrest. In fact, a large multi-center trial showed a 49% increase in survival to one year in adult patients who received the ResQCPR System.

4. How does the ResQPOD ITD 16 work to improve circulation during cardiopulmonary resuscitation (CPR)?

When used with active compression-decompression CPR (ACD-CPR), the ResQPOD, an impedance threshold device (ITD), selectively impedes airflow into the chest to create a vacuum (negative pressure) during the recoil phase of CPR. This vacuum lowers intrathoracic and intracranial pressures, and draws more venous blood back to the heart. Improved blood return to the heart (preload) and a lowering of ICP result 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 delivers its therapy during chest compressions, specifically during the chest wall recoil phase of CPR.

5. How do upper airway pressure levels during inspiration in a healthy, spontaneously breathing person, compare to those during the decompression phase of various types of CPR?

Studies show the following pressures:

	Approximate Average Negative Intrathoracic Pressures
Healthy, spontaneously breathing person at rest	-1.4 to -4.1 cmH ₂ O
Cardiac arrest patient receiving conventional manual CPR	0 to -2.7 cmH ₂ O*
Cardiac arrest patient receiving active compression decompression (ACD) CPR with the ResQPOD ITD 16	-6.8 to -13.6 cmH ₂ O*

^{*}depending on 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 (ICP). However, it should be noted that excessive negative pressures can be detrimental. The ResQPOD ITD 16 has been specifically designed to safely optimize the degree of negative pressure in order to increase blood flow to the heart and brain.

MCN CRP 1805 0061 Page 2 of 26

6. 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.

7. Does the ResQPOD ITD 16 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 ITD 16 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. Does use of the ResQPOD ITD 16 increase the frequency of stomach regurgitation or aspiration?

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

10. Will the ResQPOD ITD 16 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 -16 cmH₂O) before air will be allowed to enter the device. For this reason, the ResQPOD should be removed immediately from the respiratory circuit when chest compressions are no longer required and breathing should be supported as indicated.

11. What effect does altitude have on function of the ResQPOD ITD 16; i.e., can it be used in aero medical or submarine environments?

Altitude does not have any effect the ResQPOD's performance.

MCN CRP 1805 0061 Page 3 of 26

Research

12. How many studies have evaluated the ResQPOD's efficacy?

Please see the ResQPOD ITD 10 Clinical Summary for research information on the use of an ITD with manual or automated CPR. See also: ResQCPR System FAQs/Research for information about the research on ACD-CPR with an ITD.

Features

13. Where can I find product specifications for the ResQPOD ITD 16?

For a complete list of product specifications, see the instructions for use that are packaged with the product or go to: http://www.zoll.com/medical-products/impedance-threshold-device/resqcpr/literature/

14. Why should the timing assist lights be used?

Ventilating at the proper rate is critical to 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 eliminate 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 every six seconds (10/min), are designed to promote high-quality CPR. A ventilation rate of 10/minute is recommended in the 2015 American Heart Association (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.

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

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

16. Does the ResQPOD ITD 16 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. See also question #30.

17. Can the ResQPOD ITD 16 be reused?

No, the ResQPOD is a single-patient-use product, 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.

MCN CRP 1805 0061 Page 4 of 26

18. Flow rates above 40 lpm can cause gastric distension when using a bag-valve mask. Does the ResQPOD ITD 16 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 each breath to one second, and with enough tidal volume to produce a visible chest rise.

19. How much inspiratory impedance does the ResQPOD ITD 16 provide?

The valving mechanism within the ResQPOD ITD 16 creates a selective resistance to the influx of air until a pressure of approximately -16 cmH₂O (-11.76 mmHg) is reached, at which time the valves open to allow respiratory gases in.

20. When the ResQPOD ITD 16 is in place, how much resistance is there to patient ventilation and exhalation of respiratory gases?

When a positive pressure breath is delivered or when the chest is compressed, respiratory gases pass through the ResQPOD with minimal resistance (<5 cmH₂O).

21. What is the shelf life of the ResQPOD ITD 16?

Four years from the date of manufacture.

22. What is the warranty period on the ResQPOD ITD 16?

The date of first use, or the expiration date on the package, whichever occurs first. See the product packaging insert for complete warranty information.

23. What is the dead space of the ResQPOD ITD 16?

The ResQPOD's dead space is 40.7 ml. For a complete list of product specifications, see the instructions for use that are packaged with the product or go to: http://www.zoll.com/medical-products/impedance-threshold-device/resqcpr/literature/

24. How does the ResQPOD ITD 16 differ from the ResQGARD® ITD 7?

	ResQGARD ITD 7	ResQPOD ITD 16
Provides Therapeutic Benefit During	Inspiratory effort	Chest wall recoil phase of CPR
Intended For	Spontaneously breathing patients	Patients in cardiac arrest
Valve Cracking "Opening" Pressure	-7 cmH₂O	-16 cmH₂O
Valving Mechanism	Partially impedes gases from entering the lungs until a threshold of -7 cmH₂O is reached	Completely impedes gases from entering the lungs until a threshold of -16 cmH ₂ O is reached
Other Features	O ₂ port permits administration of supplemental oxygen	Timing assist lights promote proper ventilation rates.

MCN CRP 1805 0061 Page **5** of **26**

For more information about the ResQGARD, go to http://www.zoll.com/medical-products/impedance-threshold-device/resqgard/

25. What is the difference between the ResQPOD ITD 10 and the ResQPOD ITD 16?

The ResQPOD ITD 10 is cleared to market by the FDA through the 510(k) process as a device to enhance circulation in states of low blood flow. The opening pressure of its check valve is 10 cmH₂O, which is sufficient for providing IPR therapy during conventional manual or automated CPR.

The ResQPOD ITD 16 is approved by the FDA through the pre-market approval (PMA) process as part of a device combination, the ResQCPR System, which has an indication as a CPR adjunct to improve the likelihood of survival in adult, non-traumatic cardiac arrest. The opening pressure of its check valve is 16 cmH₂O, which is more desirable when using an ITD in combination with ACD-CPR.

Use and Compatibility

26. Why do you recommend that the ResQPOD ITD 16 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.

27. I've noticed that the ResQPOD ITD 16 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; that is, to secure the tube well and reassess its location frequently.

28. Can I use the ResQPOD ITD 16 during conventional manual or automated CPR? Isn't that the version that was used with manual CPR in the ROC PRIMED Study, and the one that is sold outside the US?

In the United States (US), use of the ITD 16 is only approved with ACD-CPR. Outside the US, the ITD 16 is approved for use with all types of CPR (i.e., manual, automated, ACD-CPR). The ITD used in the ROC PRIMED Study was the ResQPOD ITD 16.

29. Does the ResQPOD ITD 16 comply with International Standard Organization (ISO) anaesthetic connection standards?

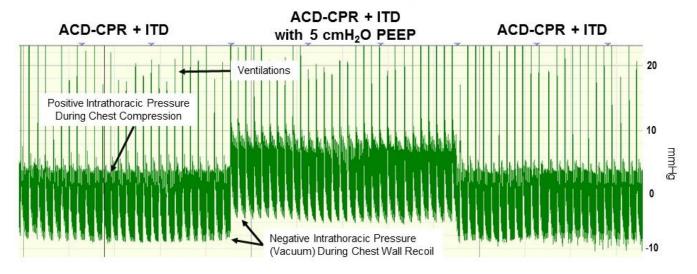
Yes, the ResQPOD is in full compliance of ISO 5356-1, Anaesthetic and respiratory equipment – conical connectors.

MCN CRP 1805 0061 Page 6 of 26

30. What effect does adding a positive end expiratory pressure (PEEP) valve to the ventilation circuit (distal or proximal) have on the ResQPOD ITD 16?

There are no human studies evaluating both the ResQPOD and PEEP to date. In an animal model of ACD-CPR plus the ITD, PEEP (5 cm H_2O) was added for about 3 minutes during ResQCPR (ACD-CPR with an ITD). (NOTE: For intrathoracic pressure, 1 mm H_2O).

Intrathoracic Pressures During ResQCPR ± PEEP



In this example the addition of PEEP reduced the vacuum created during decompression by about 3.75 mmHg, which is equal to the approximate amount of PEEP delivered. This reduction in vaccum has been shown to cause a reduction in cereberal perfusion and preload. We do not recommend the use of PEEP in patients undergoing CPR, with or without the ResQPOD.

31. 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 ResQPOD ITD 16?

CPAP/BiPAP are not compatible with the ResQPOD because it is not possible to lower intrathoracic pressure with them. CPAP/BiPAP are contraindicated during CPR, as they decrease venous blood flow back to the heart. We do not recommend the use of CPAP or BiPAP during the performance of CPR, with or without the ResQPOD.

32. Does the battery in the ResQPOD ITD 16 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.

33. Can I use the ResQPOD ITD 16 with a colormetric end tidal carbon dioxide (EtCO₂) detector in the ventilation circuit to assess endotracheal (ET) tube placement, or with a bag-valve resuscitator that incorporates EtCO₂ detection as a feature?

Yes, the preferred placement of the EtCO₂ detector is between the ResQPOD and the ventilation source, making sure all connections are tight and do not leak.

MCN CRP 1805 0061 Page **7** of **26**

34. Can I use electronic EtCO₂ detection (with sidestream or mainstream gas sampling) in the same ventilation circuit as the ResQPOD ITD 16?

Yes, the preferred location of the EtCO₂ sensor is between the ResQPOD and the ventilation source, and not between the ResQPOD and the airway. This position: 1) gets the ResQPOD into the circuit the quickest; 2) places the ResQPOD closest to the patient; 3) decreases the number of connections between the ResQPOD and the airway adjunct from two to one; and 4) minimizes the potential for loss of vacuum. If the EtCO₂ sensor does not fit above the ResQPOD then it may be placed below with snug connections.

35. Can I use the ResQPOD ITD 16 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?

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.

36. Can I use a drug atomizer with the ResQPOD ITD 16?

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

37. Can the ResQPOD ITD 16 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.

38. Can I use the ResQPOD ITD 16 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 <u>not compatible with the ResQPOD is the Oxylator</u>. In the automatic mode, the Oxylator provides a continuously positive airway pressure to the patient in cardiac arrest, with or without the ResQPOD. This continuously positive airflow interferes with the ResQPOD's ability to create a vacuum (negative pressure).

39. Can the ResQPOD ITD 16 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.

40. Can the ResQPOD ITD 16 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 chest compressions and ventilations, the ResQPOD should

MCN CRP 1805 0061 Page 8 of 26

work effectively. It is the ultimate decision of the prescribing physician to determine what airway adjuncts the ResQPOD should be used with.

41. Does the application of cricoid pressure interfere with ResQPOD ITD 16 performance? No.

42. Can the ResQPOD ITD 16 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 two-handed ventilation technique, as recommended by the American Heart Association, is preferred. A head strap (e.g., ResQSTRAP) may help obtain and maintain a tight face seal.

43. I see that the ResQPOD ITD 16 can be used for mouth-to-mask ventilation, but it doesn't come packaged with a mouthpiece. How can I get one?

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

44. Can the ResQPOD ITD 16 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.

45. Can I use the ResQPOD ITD 16 on a Combitube, laryngeal mask airway (LMA), esophageal obturator airway (EOA), Cobra, King, air-Q_{sp}, or other supraglottic airways?

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.

46. When expiration release pressures are high, minute volume dividers and pressure-cycled resuscitators may respond with a high respiratory rate and low breath volumes. Most EMS ventilators and BVM devices can be fitted with a break valve pressure of between 45 and 60 cmH₂O. Does this affect ResQPOD ITD 16 performance?

This should not alter the performance of the ResQPOD.

47. Is the ResQPOD ITD 16 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.

48. Can the ResQPOD ITD 16 be used during procedures where the chest cavity is open (e.g., open heart surgery, direct heart massage CPR)?

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

MCN CRP 1805 0061 Page **9** of **26**

49. 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 published studies to an 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 intrathoracic pressure regulation (IPR) therapy as impedance threshold devices (ITDs), of which the company manufactures two versions, the ResQPOD® Impedance Threshold Device, and the ResQGARD® Impedance Threshold Device (intended for use in spontaneously breathing applications).

ResQPUMP ACD-CPR Device – Component of the ResQCPR System

Mechanism of Action

50. What is the ResQPUMP ACD-CPR Device?

The ResQPUMP is a hand-held device that allows the rescuer to perform active compression decompression CPR (ACD-CPR). It is a component of the ResQCPR System, which also includes the ResQPOD ITD 16. This device combination provides intrathoracic pressure regulation (IPR) therapy to improve blood flow and increase the likelihood of survival in cardiac arrest. In fact, a large multi-center trial showed a 49% increase in survival to one year in adult patients who received the ResQCPR System. The ResQPUMP is the only device FDA-approved for delivering ACD-CPR with a lifting force of up to 10 kg.

51. How is the ResQPUMP ACD-CPR Device used?

The rescuer attaches the device's suction cup to the middle of the patient's chest and uses it to first compress to approximately two inches, and then to lift up and actively re-expand the chest with up to 10 kg of lift. A force gauge guides compression and lifting forces, while a metronome provides guidance on the proper rate (80/min). See the product insert for complete instructions for use.

52. How does active compression decompression CPR (ACD-CPR) improve circulation during resuscitation?

In order for the heart to circulate blood forward it must first be filled with blood (called preload). Since filling of the heart occurs during the decompression (or recoil) phase of CPR, actively re-expanding the chest helps to optimize and enhance the intrathoracic vacuum. Additionally, in some cases the chest does not recoil well on its own, which can lead to reduced preload and, thus, cardiac output. Recoil may be compromised due to a variety of causes (e.g., poor chest compliance, excessively fast compression rates, rescuers who lean on the chest when they fatigue, broken ribs). ACD-CPR promotes complete and active re-expansion of the chest in all patients, which enhances the all-important vacuum (negative pressure) in the chest when used with the ResQPOD ITD 16. The ResQPUMP is the only device FDA-approved for delivering ACD-CPR with a lifting force of up to 10 kg.

MCN CRP 1805 0061 Page **10** of **26**

53. Is the CardioPump® ACD-CPR Device (ZOLL Medical) the same as the ResQPUMP ACD-CPR Device?

Yes, the only difference is the product name. The CardioPump was formerally available from ZOLL Medical but now all ACD-CPR devices sold by ZOLL Medical are known as the ResQPUMP.

54. How does the ResQCPR System differ from LUCAS 2 device (Physio-Control)?

The LUCAS 2 is a piston-driven mechanical CPR device that does have a suction cup to help return the chest to neutral, but it does not provide ACD-CPR with up to 10 kg of active recoil, nor is it cleared or approved by the FDA to do so. The ResQCPR System is the only CPR adjunct approved by the FDA with an indication for improved likelihood of survival based upon pivotal study data that showed that patients who received ResQCPR had a 49% improvement in one-year survival compared to those who received manual CPR.ⁱⁱ

55. How does the ResQPUMP ACD-CPR Device differ from the CPR RsQ[®] Assist device (AvanTech)?

ZOLL's ResQPUMP ACD-CPR Device allows the user to perform ACD-CPR with up to 10 kg of lift. It is a component of the ResQCPR System, which is approved by the FDA with an indication for improved likelihood of survival. The CPR RsQ Assist device is simply a hand-held device that is placed on the chest as an aid to performing chest compressions. It does not provide ACD-CPR or deliver IPR therapy, nor does it have an indication for improving survival.

Research

56. How many studies have evaluated the efficacy of ACD-CPR alone (without an ITD)?

The use of ACD-CPR <u>alone</u> (without an ITD) has been compared to conventional manual CPR in more than 10 published studies. A couple of these studies demonstrated positive short-term results with ACD-CPR, but most showed that patients who received ACD-CPR had equivalent survival to those receiving manual CPR. These results are predictable given what we now understand. When ACD-CPR is performed <u>without</u> an ITD, the chest compression and decompression phases are optimized, but with an open airway, the body will preferentially move more air (meaning the enhanced vacuum in the chest is not maintained) instead of enhancing blood flow. An ITD is needed with ACD-CPR to enhance the intrathoracic vacuum that improves blood flow and the likelihood of survival. See also: ResQCPR System FAQs/Research section for information about the research on ACD-CPR with an ITD.

Features

57. Where can I find product specifications?

Please see the instructions for use (IFUs) that come packaged with the product. They are also available online at: http://www.zoll.com/medical-products/impedance-threshold-device/resqcpr/literature/

58. Should I use the ResQPUMP's metronome all the time?

Yes! Compression rate is a key CPR quality indicator. The ResQCPR rate of 80/min is not a rate rescuers are used to doing, and research shows that rescuers often go too fast. With ResQCPR the

MCN CRP 1805 0061 Page **11** of **26**

heart needs a little extra time to accommodate the increased blood flow so compressing at the proper rate is very important.

59. Why does the metronome on the ResQPUMP automatically turn off after about ten minutes into our resuscitation effort?

The ResQPUMP has a mechanism built into it that automatically shuts off the metronome after approximately 10 minutes of use. This is in place so that, in the event that the metronome is inadvertently turned on during storage or shipping, it does not completely deplete the battery. If this happens during an actual code, rescuers simply need to press the button to turn it back on; it is not a device malfunction.

60. Do the kg markings on the ResQPUMP's force gauge equate to patient body weight?

No, the force gauge measures the amount of force being applied during the compression and decompression phases.

Compression Phase

The amount of force required to compress the chest 2" will vary depending on how compliant the chest is, but here is a general guide to the approximate amount of force necessary to compress the chest 2 inches:

- Soft, supple chest: ≈30 kg
- Medium/average compliance chest: ≈30 40 kg
- Stiff/rigid chest: ≈50 kg

Once you have determined how much force is required, use that amount of force to guide continued compressions.

Decompression Phase

For all patients, attempt to lift up with no more than 10 kg of force. If the suction cup dislodges before then, lift up on the subsequent decompression with less force.

61. What is the shelf life of the ResQPUMP?

There is no specific shelf life, though it does contain a 10-year battery. The ResQPUMP's metronome has been tested to assure a minimum of 20 service hours, though it may be used for as long as it continues to pass the ResQPUMP Function Testing procedure described in the instructions for use.

62. What is the warranty period on the ResQPUMP?

Twelve months from the date of purchase. See the product packaging insert for complete warranty information.

Use and Compatibility

63. Does ACD-CPR re-expand the chest beyond neutral?

We have done some preliminary evaluation into this question using fluoroscopy in a thawed, fresh frozen cadaveric model. With -10 kg of upward lift, ACD-CPR is able to re-expand the chest beyond neutral but the extent to which it does this will vary based upon the amount of upward lift and the patient's chest compliance.

MCN CRP 1805 0061 Page **12** of **26**

64. Can the ResQPUMP's suction cup be reused?

Yes, there are cleaning procedures listed in the instructions for use. If users have concerns about the ability to adequately clean the suction cup, or would prefer not to, ZOLL does sell replacement suction cups for both the ResQPUMP and CardioPump ACD-CPR Devices.

65. When cleaning the suction cup, do you have to remove the red sternal cushioning pad from the inside of the cup?

It is possible, though not easy, to remove and reinsert the red sternal cushioning pad on the gray ring from the inside of the suction cup. If you determine that it is necessary to remove this piece in order to adequately clean the cup, pay attention to the labeling "Towards Patient" when reinserting it.

66. Does the battery in the ResQPUMP create an environmental disposal issue?

The metronome on the ResQPUMP is powered by a lithium battery and does not pose an overall environmental threat. Check individual country regulations regarding the disposal of lithium batteries.

67. Should I perform ACD-CPR in the back of a moving ambulance?

Studies have shown that performing manual CPR during patient movement or transport is much less effective. In addition, if performed in the back of a moving ambulance, it usually prohibits the use of seat belts, raising safety concerns for rescuers. These same concerns apply to ACD-CPR.

68. Is ACD-CPR harder to do than manual CPR?

The compression phase for ACD-CPR is the same as for manual CPR (for both you push down approximately 2"). For the decompression phase you are actively lifting instead of passively allowing the chest wall to recoil, so in theory it might require more energy, however, remember that the recommended compression rate for manual CPR averages 110/min (range: 100 – 120/min), while the recommended rate for ACD-CPR with an ITD is 80/min, thus, the slower rate does offset that somewhat. We believe that if it does require slightly more effort, the improved hemodynamic benefits justify the additional effort. And we still encourage rescuers to rotate compression duties at least every 2 minutes (or more often if fatigued), just like you should with conventional CPR. With proper technique and a relaxed grip, most rescuers are capable of performing high-quality ResQCPR for several minutes.

69. Does ACD-CPR cause more trauma to the chest than manual CPR?

In studies on humans in cardiac arrest, the rate of chest trauma (fractures and organ damage) have been similar to that of manual CPR, with the exception of superficial bruising or redness to the chest, which occurs in about half of all patients. This complication is not considered clinically significant and is not a reason to discontinue use of the device. If fractures occur, use of the suction cup may facilitate chest wall recoil. Make sure the device is correctly placed on the chest (mid-sternum with suction cup above the xiphoid) and continue using the device to compress to approximately 2 inches.

70. Can I use the ResQPUMP without the ResQPOD ITD 16?

In the United States, the ResQPUMP ACD-CPR Device is only approved for use in combination with the ResQPOD ITD 16. Remember too, that when ACD-CPR is performed without an ITD, the chest compression and decompression phases are optimized, but with an open airway, the body will preferentially move more air (meaning the enhanced vacuum in the chest is not maintained) instead of enhancing blood flow. An ITD is needed with ACD-CPR to optimize the intrathoracic vacuum that improves blood flow and the likelihood of survival. Clinical studies of ACD-CPR alone (without the ITD) MCN CRP 1805 0061

and manual CPR have demonstrated similar results, while animal and clinical studies of the combination of devices have shown consistent benefits.^{ii,iii}

71. Is the ResQPUMP compatible with magnetic resonance imaging (MRI) machines?

No, the ResQPUMP 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.

72. Do you need to shave the chest to achieve good suction?

A normal amount of hair is typically not a problem. If the patient has a large amount of hair that is prohibiting good suction, we recommend quickly shaving the area to remove the bulk of the hair. One agency that we're aware of uses a \$12 battery-operated beard trimmer to rapidly and easily remove the bulk of the hair.

73. Will large breasts create a problem achieving suction?

Most of the time breasts will fall to the side and permit a flat enough surface area to achieve good suction. Sometimes slightly adjusting the upward angle will improve suction in these patients.

74. Sometimes the ResQPUMP migrates away from the middle of the chest while I'm using it. What is causing that?

Compressing in the proper location (middle of the sternum with lip of suction cup above the xiphoid) is important. Once properly placed, some rescuers have used a pen or marker to mark the proper suction cup border so it becomes immediately evident if the location changes. If it does move, immediately lift up the suction cup edge and relocate it to the proper location. If the chest is wet or diaphoretic, make sure to dry it using a towel or the patient's clothing. Check also to make sure the rescuer's shoulders are above the patient's sternum, and that the compression force is being applied straight downward.

75. We use the ZOLL Real CPR Help[®] electrodes (e.g., OneStep[™], Stat-padz[®]), which provide real-time feedback on CPR quality. Can I use the ResQPUMP with these?

At the current time it is not possible to use the ResQPUMP with the OneStep or Stat-padz electrodes.

ResQCPR: Performance of ACD-CPR with an ITD

Physiology

76. What is ResQCPR?

ResQCPR is the performance of active compression decompression CPR (ACD-CPR), utilizing either the ResQPUMP or CardioPump ACD-CPR Devices, combined with the ResQPOD ITD 16.

77. How does ResQCPR improve blood flow during CPR?

The two devices that make up the ResQCPR System work synergistically. The ResQPOD regulates airflow during the chest recoil phase of CPR to enhance the vacuum in the patient's chest. This results in

MCN CRP 1805 0061 Page **14** of **26**

more blood being returned to the heart (preload) and a lowering of intracranial pressure (ICP). The ResQPUMP improves preload even more by actively re-expanding the chest to further enhance negative pressure. The net result is better hemodynamics and vital organ blood flow than either device provides individually.

78. How do I know if ResQCPR is working?

ResQCPR increases 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 how it's impacting perfusion is measuring end tidal carbon dioxide (EtCO₂), an indirect and surrogate measure of circulation. When EtCO₂ is increased, it usually means that more blood is circulating; as blood passes through the lungs, more CO₂ is removed proportionally to the increase in blood flow. One study showed that EtCO₂ increased 46% in patients treated with ResQCPR compared to those receiving ACD-CPR alone. For the best comparison, you should measure EtCO₂ prior to beginning ResQCPR, and then about three minutes later. It may take up to 10 - 15 minutes to achieve maximum EtCO₂ levels once ResQCPR has begun. It is important to note that we do not advise taking time to measure EtCO₂ prior to beginning ResQCPR as it only delays its benefit; however, for those who want to see a difference, this is one way to measure it.

Another indicator of an increase in circulation is the strength of the pulse during ResQCPR.

Two human studies looking at invasive blood pressure during cardiac arrest have demonstrated significantly higher blood pressures when the ResQPOD was added to manual CPR. Pirrallo et al reported that invasive arterial blood pressure increased from 43/15 mmHg in manual CPR to 85/20 mmHg in patients with the ResQPOD. Falsiance et al reported near-normal blood pressures (108/56 mmHg) in patients receiving ResQCPR. In addition, we have heard anecdotal reports of rescuers measuring non-invasive blood pressure during ResQCPR. Keep in mind that how well the ResQCPR System works will vary somewhat from patient to patient as there are other variables that contribute to its effectiveness (e.g., co-morbidities, chest wall compliance, quality of CPR performed, etc).

Note: ZOLL conducts function testing on all ITDs and ACD-CPR devices prior to shipment to assure they are properly functioning.

79. How does ResQCPR lower intracranial pressure (ICP)? Why is that important?

Paravertebral sinuses run along the spinal cord and transmit positive and negative pressures from the chest to the head. 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, resulting in enhanced venous return. It is also transmitted to the head, resulting in a lowering of ICP. Lowered ICP means less resistance to forward blood flow, so cerebral blood is thus enhanced.

80. I've heard there have been reports of patients exhibiting signs of increased levels of consciousness (e.g., eye opening, gagging on tube, gasping/spontaneous breathing, body movement) during ResQCPR. Is this true? Should I continue to use the devices if this happens?

Yes, there have been enough reports of this happening that the instructions for use mention this possibility. What's likely going on is that the patient is receiving such good blood flow to the brain that it's triggering these neurologic signs and symptoms. Don't assume the patient has a pulse; quickly assess to see if a perfusing pulse has returned. If return of spontaneous circulation (ROSC) has occurred, discontinue use of both devices and support the breathing as necessary. If there's no ROSC, continue

MCN CRP 1805 0061 Page **15** of **26**

ResQCPR immediately and consult with your medical control for the best way to manage the patient (e.g., gentle restraint, sedation).

81. Is hyperventilation helpful during ResQCPR?

The natural tendency when performing CPR is to ventilate the patient frequently, either inadvertently or intentionally. Contrary to common practice, <a href="https://hyperventilation.com/hyperventil

82. What if EtCO₂ levels are elevated, either during CPR or right after a pulse has returned? Shouldn't I hyperventilate in those cases?

No, hyperventilation reduces circulation and therefore compromises the elimination of carbon dioxide. Improved circulation (from less ventilation) will tend to correct acid-base imbalance. If EtCO₂ levels are elevated, it can be a sign that cardiac output is improved or that a spontaneous pulse has returned. In the absence of known blood gases, there are no data to support that hyperventilation is good for elevated EtCO₂ levels and plenty of data to suggest that hyperventilation is bad for circulation. If you observe a very low arterial pH after return of spontaneous circulation, then you should consider using sodium bicarbonate rather than increased ventilation rates to help raise the pH, assuming the blood pressure is stable.

83. What other devices optimize the decompression phase of CPR?

We are not aware of any other products on the US market that are designed and intended to optimize the decompression phase of CPR.

84. How does the Boussignac Cardiac Arrest Resuscitation Device (b-card by Vygon) compare to the ResQCPR System?

The ResQCPR System has been shown in numerous animal and clinical studies to improve the likelihood of survival following cardiac arrest, and to improve vital organ blood flow during cardiac arrest. 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. No animal or clinical data supporting the efficacy or safety claims of the b-card could be found during a PubMed search in March 2018. In fact, one pre-clinical study published in 2017 found that using the b-card during CPR resulted in intrathoracic pressures that were always positive during both compression and decompression phases, and at no time was a vacuum created during decompression. The b-card is not approved for use in the US.

MCN CRP 1805 0061 Page **16** of **26**

85. If you significantly lower the negative pressure (i.e., enhance the vacuum) in the chest, isn't there a concern that negative pressure pulmonary edema will develop?

The probability of negative pressure pulmonary edema developing will vary considerably due to differences in patient comorbidities but, in general, it typically does not develop unless the vacuum in the chest reaches -50 to -100 cmH₂O.* The ResQPOD ITD 16 contains a safety check valve that will open and allow air in to limit excursions of negative intrathoracic pressure below -16 cmH₂O. This pressure range has been shown to optimize forward blood flow during CPR.*i

Patients who require CPR already have a relatively high probability of developing pulmonary edema during CPR or post-resuscitation, but it is also a very treatable condition. In the largest clinical trial evaluating ResQCPR (ResQTRIAL), it was observed that more patients receiving ResQCPR had pulmonary edema than patients who received manual CPR, however, a post hoc analysis appeared to demonstrate that the presence of pulmonary edema did not adversely affect effectiveness as measured by survival.

Indications/Contraindications

86. What other CPR devices on the market have an FDA-approved indication to improve the likelihood of survival?

None that we are aware of.

87. Are there any contraindications to use of the ResQCPR System?

Per the ResQCPR System's approved labelling and instructions for use, there are no contraindications to the use of the ResQCPR System in adult patients in non-traumatic cardiac arrest.

88. What warnings should be considered when developing a ResQCPR System protocol for use?

The licensed medical practitioner prescribing the product should review the complete instructions for use (IFUs) and make the final determination about how and when the ResQCPR System is used, keeping in mind these warnings, which include but are not limited to:

- Do not use the ResQPUMP if the patient's chest is not large enough for its suction cup to provide adequate compressions/decompressions during use.
- The ResQPUMP should not be used in patients who have had a recent sternotomy. Use of the ResQPUMP in patients with a recent (within past 6 months) has not been evaluated.

89. What precautions should be considered when developing a ResQCPR System protocol for use?

The licensed medical practitioner prescribing the product should review the complete instructions for use (IFUs) and make the final determination about how and when the ResQCPR System is used, keeping in mind these precautions, which include but are not limited to:

- The safety and effectiveness of CPR using the ResQCPR System have not been assured when used to treat cardiac arrest in patients with a drug/medication overdoes etiology.
- If the patient has a return of spontaneous circulation (ROSC) (e.g., palpable pulse) during the resuscitation effort, the ResQPOD should be immediately removed from the airway circuit, and use of the ResQPUMP should be discontinued. Failure to do so may cause shortness of breath, difficulty breathing and potential pulmonary edema if the patient begins to breathe spontaneously.

MCN CRP 1805 0061 Page **17** of **26**

• The ResQCPR System has not been studied in the setting of in-hospital cardiac arrest, therefore, the safety and effectiveness of the device in this setting are unknown.

- The safety and effectiveness of the ResQCPR System in pregnant women and children under the age of 18 have not been studied in clinical trials.
- The safety and effectiveness of the ResQCPR System in the setting of traumatic injuries (wounds resulting from sudden physical injury) have not been established.

90. Is chest trauma a contraindication for use of the ResQCPR System?

The ResQCPR System is intended for use as a CPR adjunct to improve the likelihood of survival in adult patients with non-traumatic cardiac arrest. Chest trauma is not a contraindication in the product's labeling, but the licensed medical practitioner prescribing the product should review the complete instructions for use (IFUs) and make the final determination about how and when the ResQCPR System is used, keeping in mind all warnings and precautions, which include but are not limited to:

- The ResQPUMP should not be used in patients who have had a recent sternotomy. Use of the ResQPUMP in patients with a recent (within past 6 months) has not been evaluated.
- The safety and effectiveness of the ResQCPR System in the setting of traumatic injuries (wounds resulting from sudden physical injury) have not been established.

91. Can the ResQCPR System be used during resuscitation on patients with an open 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 pneumothoraxes, 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 ResQCPR System should work and should not affect an open pneumothorax.

92. Does the ResQCPR System have any effect on intracranial pressure (ICP) and can it be used in patients with head injuries?

The ResQCPR System is intended for use as a CPR adjunct to improve the likelihood of survival in adult patients with non-traumatic cardiac arrest. In animal models of cardiac arrest, use of an ITD with ACD-CPR 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. Head trauma is not a contraindication in the product's labeling, but the licensed medical practitioner prescribing the product should review the complete instructions for use (IFUs) and make the final determination about how and when the ResQCPR System is used, keeping in mind all warnings and precautions, which include but are not limited to:

• The safety and effectiveness of the ResQCPR System in the setting of traumatic injuries (wounds resulting from sudden physical injury) have not been established.

93. Can I use the ResQCPR System on children?

The ResQCPR System is intended for use as a CPR adjunct to improve the likelihood of survival in adult patients with non-traumatic cardiac arrest. The licensed medical practitioner prescribing the product should review the complete instructions for use (IFUs) and make the final determination about how and when the ResQCPR System is used, keeping in mind all warnings and precautions, which include but are not limited to:

• Do not use the ResQPUMP if the patient's chest is not large enough for its suction cup to provide adequate compressions/decompressions during use.

MCN CRP 1805 0061 Page **18** of **26**

• The safety and effectiveness of the ResQCPR System in pregnant women and children under the age of 18 have not been studied in clinical trials.

94. Will the ResQCPR System be effective in enhancing circulation in an arrested patient who is hypothermic?

We are not able to make a recommendation regarding this because we're not aware of any human studies evaluating ResQCPR in hypothermic cardiac arrest.

95. Can the ResQCPR System be used in conjunction with arrested patients who are being therapeutically cooled?

At present, there are no known human data published on the potential benefit of using the ResQCPR System to therapeutically cool during CPR.

96. Can I use the ResQCPR System on patients with recent sternotomies or chest trauma?

The ResQPUMP should not be used in patients who have had a recent sternotomy. Use of the ResQPUMP in patients with a recent (within past 6 months) has not been evaluated.

97. There are no listed contraindications to ResQCPR but, if it improves blood flow, should I use it in cardiac arrest due to blood loss (e.g., trauma, GI bleed, vaginal bleeding, suspected AAA)?

The ResQCPR System is intended for use as a CPR adjunct to improve the likelihood of survival in adult patients with non-traumatic cardiac arrest. Rescuers should always attempt to control life-threatening bleeding. Use of ResQCPR in hypovolemic blood loss has not been studied. Blood loss is not a contraindication in the product's labeling but the licensed medical practitioner prescribing the product should review the complete instructions for use (IFUs) and make the final determination about how and when the ResQCPR System is used, keeping in mind all warnings and precautions, which include but are not limited to:

- The ResQPUMP should not be used in patients who have had a recent sternotomy. Use of the ResQPUMP in patients with a recent (within past 6 months) has not been evaluated.
- The safety and effectiveness of the ResQCPR System in the setting of traumatic injuries (wounds resulting from sudden physical injury) have not been established.

98. Do the 2015 American Heart Association (AHA) Guidelines recommend ResQCPR?

The 2015 AHA Guidelines gave the combination of ACD-CPR with an ITD a Class II recommendation, stating that "the combination may be a reasonable alternative in settings with available equipment and properly trained personnel". The FDA also reviewed data from the ResQTRIAL and approved the ResQCPR System with an indication for improved likelihood of survival. The primary study that the AHA considered in its review of the data was the ResQTRIAL, which compared patients receiving ResQCPR to those receiving manual CPR. That study published the following results:

- In patients who arrested from cardiac etiology, survival at one year with good neurologic function improved by 49% (6% vs 9%; p=0.03) in those patients receiving ResQCPR.xiii
- In patients who arrested from all non-traumatic etiologies, survival at one year with good neurologic function improved by 39% (5.7% vs 7.9%; p=0.026) in those patients receiving ResQCPR.xiv

MCN CRP 1805 0061 Page **19** of **26**

Research

99. How many studies have evaluated the ResQCPR System's efficacy?

The combination of active compression decompression CPR (ACD-CPR) with an impedance threshold device (ITD) has been extensively evaluated, many with funding support from the National Institutes of Health (NIH) and the US Department of Defense.

Five human studies have been demonstrated that performance of ResQCPR:

- Resulted in a 49% increase in one-year survival following cardiac arrest, compared to manual CPR.
- Resulted in near-normal blood pressures.^{vii}
- Was able to significantly enhance the intrathoracic vacuum with both a facemask and an advanced airway.xv
- Improved short-term survival.xvi,xvii

At least thirty pre-clinical studies have been performed, mostly in porcine models of cardiac arrest. These studies xviii,xix,xx,xxi,viii have shown that:

- Circulation to the heart and brain was consistently higher with ResQCPR versus standard CPR.
- Blood flow to the heart and brain during S-CPR was observed to be approximately 20 30% of normal. By contrast, during ResQCPR blood flow to the heart was approximately 70% of normal and blood flow to the brain was restored to normal values.
- The mechanism of action of the ResQCPR System involves harnessing the body's thoracic pump to lower intracranial pressure during the decompression phase of CPR and to circulate blood to the heart and brain more effectively than standard CPR.
- The improved vital organ blood flow from ResQCPR resulted in a consistently higher likelihood for successful resuscitation and neurological awakening.

See also the ResQCPR Bibliography.

100. Which device combination provides better hemodynamics: manual ACD-CPR with an ITD (ResQCPR), or automated CPR (e.g., AutoPulse®) with an ITD?

We are not aware of any randomized trials that have directly compared these in humans. The ResQCPR System is the only CPR adjunct with an approved indication for improved likelihood of survival and the data show ResQCPR to be more effective than conventional manual CPR (it increased survival to one year by 49% compared to conventional manual CPR alone).ⁱⁱ

Use and Compatibility

101. Our organization has elected to perform chest compression-only CPR for the first few minutes of a resuscitation effort. Can we use the ResQPOD ITD 16 and ResQPUMP during this period?

The AHA guidelines do not recommend chest compression only CPR for the first few minutes of a resuscitation effort for healthcare providers. Regarding the practice of healthcare providers withholding positive pressure ventilations and instead administering passive or no ventilations for a period of time during chest compressions, the 2015 AHA Guidelines state:

• "There is concern that delivery of chest compressions without assisted ventilation for prolonged periods could be less effective than conventional CPR (compressions plus breaths) because the arterial oxygen content will decrease as CPR duration increases."xxii

MCN CRP 1805 0061 Page **20** of **26**

• "We do not recommend the routine use of passive ventilation techniques or during conventional CPR in adults."xxii

• "It is reasonable for healthcare providers to provide chest compressions and ventilation for all adult patients in cardiac arrest, from either a cardiac or noncardiac cause." xxiii

If an organization elects to withhold positive pressure ventilation for a period of time, they should wait to begin ResQCPR until the point that positive pressure ventilations are begun.

102. Proper positioning for ResQCPR requires the compressor to have their shoulders directly over the patient's sternum. What does this mean for shorter rescuers, and for patients who are being resuscitated on stretchers, gurneys or hospital beds?

If the patient is on the floor, shorter rescuers may find it easier to get into proper position if they elevate themselves slightly by kneeling on a ResQPAD™ (ZOLL Medical) or other padding such as a blanket. If the patient is on a stretcher, gurney or hospital bed it should be in the lowest position possible, and rescuers should stand on a sturdy stool next to the patient if needed.

103. The 2015 AHA Guidelines recommend a compression rate for manual CPR of 100 – 120/min. Why isn't the rate for ACD-CPR with an ITD (80/min) consistent with that recommendation?

The AHA recommendation of 100 – 120/min is for <u>conventional manual CPR</u>. The less efficient you are with circulation, the faster you need to go. The better the hemodynamics, the closer you can be to a normal physiologic rate. The AHA did give ACD-CPR with an ITD a Class II recommendation. Their guidelines make no comment on the recommended rate, though they acknowledge that the rate used for ResQCPR in the ResQTRIAL was 80/min compared to 100/min for the conventional manual CPR arm.^{xii} When the FDA approved the ResQCPR System, they approved the instructions for use at the same rate that rescuers were taught to perform it in the ResQTRIAL (which provided the basis for the approval).

104. Can ResQCPR be performed with only one or two rescuers?

As is true with manual CPR, the more rescuers available to rotate duties, the better. If only one rescuer is available initially they should focus on verifying scene safety, assessing the patient, beginning compressions and ventilations (30:2 compression to ventilation ratio), and using the AED as soon as it is available. See also: AHA BLS Healthcare Provider Adult Cardiac Arrest Algorithm. **XIII DO not delay patient care if ResQCPR devices are not readily available. A head strap (e.g., ResQSTRAP by ZOLL Medical) can help hold the facemask and ResQPOD in place. If only two rescuers are available for ResQCPR, we recommend that one focus on maintaining a tight facemask seal with the ResQPOD. When it is time to pause for ventilation, the compressor can reach over with one hand and provide two ventilations before resuming compressions. Rotate duties at least every two minutes to avoid fatigue.

105. Does the fact that the ResQCPR System improves perfusion impact the amount of epinephrine that should be given?

For conventional manual CPR, the 2015 AHA Guidelines recommend giving 1 mg of epinephrine every three to five minutes during CPR to improve systemic blood pressure and coronary perfusion pressure. XXIIII However, prior studies call into question whether epiphrine's ability to increase blood pressure translates into improved cerebral perfusion and survival. XXIIV,XXIV Since ResQCPR has been shown to provide improved hemodynamics and likelihood of surival compared to conventional CPR, it is likely that less epinephrine may be needed. One pre-clinical study showed that both conventional CPR with an ITD and ACD-CPR with an ITD resulted in improved aortic, cerebral and coronary perfusion pressures compared to conventional CPR alone. However, when epinephrine was added to ACD-CPR with an ITD, mean aortic, cerebral and coronary perfusion pressues increased further, but directly measured carotid blood

MCN CRP 1805 0061 Page **21** of **26**

flow and EtCO₂ both significantly decreased following epinephrine administration.^{xxvi} Given the inherent increase in perfusion that ResQCPR offers, it would be reasonable for a medical director to consider adjusting the dosing and/or frequency of epinephrine administration during the performance of ResQCPR.

106. Can I use the ResQPOD ITD 10 with the ResQPUMP?

The ITD that the FDA approved for use with the ResQPUMP as part of the ResQCPR System is the ResQPOD ITD 16.

107. Can I use the ResQPOD ITD 16 with conventional manual or automated CPR?

In the United States (US), use of the ITD 16 is only approved with ACD-CPR. Outside the US, the ITD 16 is approved for use with all types of CPR (e.g., manual, automated, ACD-CPR).

Training

108. How long does it take to get trained on ResQCPR?

Proper initial training in ResQCPR requires both a didactic portion, which takes about 45 minutes, followed by a hands-on skills session, which takes 30 - 45 minutes. This time may vary based upon the instructor-to-student ratio. Frequent refresher training is strongly recommended.

109. What training resources are available for the ResQCPR System?

- The sales representative who sold the product will coordinate training for your organization. ZOLL
 also has Clinical Implementation Specialists and educators who are available to conduct Train the
 Trainer sessions, and to assist with not only training planning and needs, but implementation of the
 ResQCPR System into your system. Please contact your ZOLL sales representative to assist in
 scheduling these.
- Complimentary training resources are available at: http://www.zoll.com/medical-products/impedance-threshold-device/resqcpr/literature/
- Educational videos are available at: http://www.zoll.com/medical-products/impedance-threshold-device/resqcpr/videos/
- A free, online ResQCPR System training video, along with free CME, is available through American CME at: www.AmericanCME.com.
- These additional training tools are available for purchase through your sales representative or by calling 1-978-421-9655:
 - ResQCPR Training Kit (part number: 12-2507-000) a training (not for human use) version of the ResQPUMP and ResQPOD
 - ResQCPR Demo Kit (part number: 12-0869-000) a training aid that includes a ResQMAN Demonstrator, a ResQPOD ITD 16, and a MiniPUMP, and allows you to demonstrate the physiology of both conventional CPR and ResQCPR, as well as the impact of poor quality CPR
 - ManiKIT (part number: 12-2116-000) a training aid that allows many CPR manikins to be adapted for ACD-CPR training
 - ResQPAD (part number: 12-2394-000) a kneeling pad that provides cushioning and rescuer elevation during ResQCPR training and use

MCN CRP 1805 0061 Page **22** of **26**

110. Do you sell a training version of the ResQCPR System?

Yes; please contact your ZOLL sales representative to learn about ResQCPR Systems that are for training use only. If you decide to use a commercially available ResQPOD for training purposes, the ResQPOD's 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 to the OFF position once training is completed; this will preserve battery function for many repeated uses during training.

111. Do I need special CPR manikins to conduct ResQCPR training? Can you train ResQCPR on conventional CPR manikins?

ResQCPR training differs from conventional or automated CPR training in that the upward and active lift of up to 10 kg means that CPR manikins weighing >20 lbs will be lifted off the ground.

Most of the manikins on the market today are not specifically designed for ACD-CPR, which can create more wear and tear (and possibly damage) than manual CPR training. Many customers have successfully adapted their existing CPR manikins using the ManiKIT offered by ZOLL Medical. This is a training tool with a baseboard that contains a variety of straps that can be used to secure many manikins to the board. A hinged wing folds out for the rescuer to kneel on, and their weight keeps the manikin on the floor. It comes with a cushioned kneeling pad (ResQPAD) for rescuer comfort.

One manikin that many customers have reported working well with the ManiKIT for ACD-CPR is the Little Anne made by Laerdal.

We have learned that some manikins do not work well with an ACD-CPR device, and we recommend NOT using them for ACD-CPR; these include (but are not limited to):

- Smaller manikins where the length from the xiphoid process to the sternal notch is not long enough to accommodate the suction cup width
- Professional Adult CPR-AED Training Manikins by Prestan
- Simulation manikins with enclosed electronics

Keep in mind that ACD-CPR can be hard on manikins. If you choose to use the ManiKIT with a traditional CPR manikin for ACD-CPR training, please assess first whether this will cause manikin damage, and keep in mind that ZOLL is not responsible for damage to manikins. Your ZOLL sales rep and our clinical educators are available and happy to provide guidance on this issue.

We are aware of one CPR manikin that is advertised as being intended for active compression decompression CPR (ACD-CPR). It is the Ambu[®] CPR Pal, which can be ordered with an optional ACD-CPR baseboard that attaches to the back of the manikin. The rescuer then kneels on the board and their weight keeps the manikin on the ground.

112. Can I get continuing medical education (CME) credit for ResQCPR training?

Free continuing medical education (CME) is available online for the didactic portion of ResQCPR System training through American CME at www.AmericanCME.com. The initial training curricula outlined on the website (http://www.zoll.com/medical-products/impedance-threshold-device/resqcpr/literature/) is designed to meet the minimal requirements that allow most healthcare disciplines to receive CME credit. It is the responsibility of each student to determine whether this learning module satisfies the requirements for CME credit within their respective healthcare discipline as these requirements vary by state and licensing board.

MCN CRP 1805 0061 Page **23** of **26**

Regulatory

113. Does the ResQCPR System require a prescription for use?

Yes, US federal law restricts the use of the ResQCPR System to sale by or on the order of a licensed medical practitioner.

114. Is the ResQCPR System approved for use by the US FDA?

Yes, the FDA granted a pre-market approval (PMA) order for the ResQCPR System (P110024) in March 2015. It is the only CPR adjunct on the US market with an FDA-approved indication to increase the likelihood of survival."

115. Does the ResQCPR System have the CE mark?

Yes; the ResQCPR System (part number #12-2393-000) does have the CE mark and includes one ResQPUMP ACD-CPR Device (part number #12-0582-000) and two ResQPOD ITD 16s (part number #12-0247-000). The instructions for use are available in 16 languages. The CardioPump ACD-CPR Device does have the CE mark but is no longer available.

Sales

116. How do I buy the ResQCPR System?

Please contact your ZOLL sales representative, or call ZOLL at 1-800-348-9011 or 1-978-421-9655, or go to www.zoll.com.

117. Can I purchase replacement ResQPUMP ACD-CPR Devices or ResQPOD ITD 16s?

Yes; even though the ResQCPR System is a device combination, you may purchase replacements of the individual components separately.

118. Is the ResQCPR System available internationally?

The ResQPUMP ACD-CPR Device (part number 12-0582-000) and the ResQPOD ITD 16 (part number 12-0247-000) are both available internationally. Please contact your ZOLL sales representative or go to our website for worldwide locations: http://www.zoll.com/contact/worldwide-locations/

119. What other accessories are available for ResQCPR?

These additional accessories are available for purchase through your sales representative or by calling 1-978-421-9655.

- ResQCPR Carrying Case (part number: 12-0935-000) a lightweight, zipped case that is designed
 to hold one ResQPUMP, two ResQPODs, and other accessories needed to begin ResQCPR
 immediately (e.g., scissors, facemask, razor, etc.)
- Suction Cup for ACD-CPR Devices (part number: 12-0586-000) a replacement suction cup for either the ResQPUMP or CardioPump ACD-CPR Devices
- ResQSTRAP (part number: 12-0392-000) a disposable, adjustable head strap that can be used to hold a facemask with an ITD in place

MCN CRP 1805 0061 Page **24** of **26**

ResQCPR Demo Kit (part number: 12-0869-000) - a training tool that includes a ResQMAN
Demonstrator, a ResQPOD ITD 16, and a MiniPUMP, and allows you to demonstrate the physiology
of both conventional CPR and ResQCPR, as well as the impact of poor quality CPR

- ManiKIT (part number: 12-2116-000) a training aid that allows many CPR manikins to be adapted for ACD-CPR training
- ResQPAD (part number: 12-2394-000) a kneeling pad that provides cushioning and rescuer elevation during ResQCPR training and use
- ResQCPR Training Kit (part number: 12-2507-000) a training (not for human use) version of the ResQPUMP and ResQPOD

120. Does ZOLL offer financing options?

Yes, please contact your ZOLL sales representative for details.

121. Can ZOLL help with grant writing to assist us in obtaining funding for the purchase of products?

Yes, please contact your ZOLL sales representative for details.

Studies available upon request. Pre-clinical data are not necessarily representative of clinical results. The ResQCPR System is intended for use as a CPR adjunct to improve the likelihood of survival in adult patients with non-traumatic cardiac arrest. Improper use of the ResQCPR System could cause ineffective chest compressions and decompressions, leading to suboptimal circulation during CPR and possible serious injury to the patient. The ResQCPR System should only be used by personnel who have been trained in its use. The ResQPUMP and CardioPump ACD-CPR devices should not be used in patients who have had a recent sternotomy as this may potentially cause serious injury. Improper positioning of the suction cup on the ACD-CPR device may result in possible injury to the rib cage and/or internal organs, and may also result in suboptimal circulation during ACD-CPR. Please see the instructions for use for complete information on how to use.

Citations

MCN CRP 1805 0061 Page **25** of **26**

¹ Andreka P, Frenneaux MP. Haemodynamics of cardiac arrest and resuscitation. Curr Opin Crit Care. 2006;12:198-203.

ii Adult patients in non-traumatic cardiac arrest. ResQCPR System Summary of Safety and Effectiveness Data submitted to FDA; http://www.accessdata.fda.gov/cdrh_docs/pdf11/P110024b.pdf

Wang C-H, Tsai M-S, Chang W-T, et al. Active compression-decompression resuscitation and impedance threshold device for out-of-hospital cardiac arrest: a systematic review and meta-analysis of randomized controlled trials. *Crit Care Med.* 2015;43(4):889-896.

iv Pending publication.

^v Gunaydin YK, Cekmen B, Akilli NB, et al. Comparative effectiveness of standard CPR vs active compression-decompression CPR with CardioPump for treatment of cardiac arrest. *Am J Emerg Med.* 2016;34:542-547.

vi Pirrallo RG, Aufderheide TP, Provo TA, Lurie KG. Effect of an inspiratory impedance threshold device on hemodynamics during conventional manual cardiopulmonary resuscitation. *Resuscitation*. 2005;66:13-20.

vii Plaisance P, Lurie KG, Payen D. Inspiratory impedance during active compression-decompression cardiopulmonary resuscitation: a randomized evaluation in patients in cardiac arrest. *Circulation*. 2000;101(9):989-994.

viii Metzger A, Herman J, McKnite S, et al. Improved cerebral perfusion pressures and 24-hour neurological survival in a porcine model of cardiac arrest with active compression-decompression cardiopulmonary resuscitation and augmentation of negative intrathoracic pressure. *Crit Care Med.* 2012;40(6):1851-1856.

ix Moore JC, Lamhaut L, Hutin A, et al. Evaluation of the Boussingnac cardi ac arrest device (b-card) during cardiopulmonary resuscitation in an animal model. *Resuscitation*. 2017;119:81-88.

^x Bhaskar B, Fraser JF. Negative pressure pulmonary edema revisited: pathophysiology and review of management. *Saudi J Anaesth.* 2011;5(3):308-313.

^{xi} Lurie KG, Nemergut EC, Yannopoulos D, Sweeney M. The physiology of cardiopulmonary resuscitation. *Anesth Analg.* 2015;122(3):767-783.

xii Brooks SC, Anderson ML, Bruder E, et al. Part 6: alternative techniques and ancillary devices for cardiopulmonary resuscitation: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*. 2015;132(suppl 2):S436-S443.

xiii Aufderheide TP, Frascone RJ, Wayne MA, et al. Standard cardiopulmonary resuscitation versus active compression-decompression cardiopulmonary resuscitation with augmentation of negative intrathoracic pressure for out-of-hospital cardiac arrest: A randomized trial. *Lancet*. 2011;377:301-311.

- xiv Frascone RJ, Wayne MA, Swor RA, et al. Treatment of non-traumatic out-of-hospital cardiac arrest with active compression-decompression cardiopulmonary resuscitation plus an impedance threshold device. *Resuscitation*. 2013;84:1214-1222.
- xv Plaisance P, Soleil C, Lurie KG, et al. Use of an inspiratory impedance threshold device on a facemask and endotracheal tube to reduce intrathoracic pressures during the decompression phase of active compression-decompression cardiopulmonary resuscitation. *Crit Care Med.* 2005;33(5):990-994.
- ^{xvi} Wolcke BB, Mauer DK, Schoefmann MF, et al. Comparison of standard cardiopulmonary resuscitation versus the combination of active compression-decompression cardiopulmonary resuscitation and an inspiratory impedance threshold device for out-of-hospital cardiac arrest. *Circulation*. 2003;108(18):2201-2205.
- xvii Plaisance P, Lurie KG, Vicaut E, et al. Evaluation of an impedance threshold device in patients receiving active compression-decompression cardiopulmonary resuscitation for out of hospital cardiac arrest. *Resuscitation*. 2004;61:265-271.
- voil Voelckel WG, Lurie KG, Sweeney M, et al. Effects of active compression-decompression cardiopulmonary resuscitation with the inspiratory threshold valve in a young porcine model of cardiac arrest. *Pediatric Research*. Apr 2002;51(4):523-527.
- xix Lurie KG, Coffeen P, Shultz J, et al. Improving active compression-decompression cardiopulmonary resuscitation with an inspiratory impedance valve. *Circulation*. 1995;91(6):1629-1632.
- xx Lurie K, Zielinski T, McKnite S, Sukhum P. Improving the efficiency of cardiopulmonary resuscitation with an inspiratory impedance threshold valve. *Crit Care Med.* 2000;28(11 Suppl):N207-209.
- xxi Lurie K, Voelckel W, Plaisance P, et al. Use of an inspiratory impedance threshold valve during cardiopulmonary resuscitation: a progress report. *Resuscitation*. 2000;44(3):219-230.
- ^{xxii} Kleinman ME, Brennan EE, Goldberger ZD, et al. Part 5: adult basic life support and cardiopulmonary resuscitation quality: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*. 2015;132(suppl 2):S414-S435.
- Link MS, Berkow LC, Kudenchuk PJ, et al. Part 7: adult advanced life support: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*. 2015;132(suppl 2):S444-S464. Ristagno G, Tang W, Huang L, et al. Epinephrine reduces cerebral perfusion during cardiopulmonary resuscitation. *Crit Care Med*. 2009;37:1408.
- xxv Jacobs IG, Finn JC, Jelinek GA, et al. Effect of adrenaline on survival in out-of-hospital cardiac arrest: a randomized double-blind controlled trial. *Resuscitation*. 2011;82(9):1138-1143.
- xxvi Burnett AM, Segal N, Salzman JG, et al. Potential negative effect of epinephrine on carotid blood flow and ETCO2 during active compression-decompression CPR utilizing an impedance threshold device. Resuscitation. 2012;83:1021-1024.

MCN CRP 1805 0061 Page **26** of **26**