

RESQGARD IMPEDANCE THRESHOLD DEVICE (ITD) SAMPLE PROTOCOL/SOP

NOTE: This template may be useful in helping your organization write a ResQGARD protocol. It is a guide only and it is the responsibility of each organization's medical director to determine how the ResQGARD will be best used in their organization.

I. Introduction:

1. The ResQGARD is an impedance threshold device (ITD) that provides therapeutic resistance to inspiration in spontaneously breathing patients. During inspiration, a negative pressure (created from expansion of the thorax) draws air into the lungs. When inspiratory impedance is added to the ventilation circuit, it enhances the negative pressure (vacuum) in the chest, which pulls more blood back to the heart, resulting in increased preload and thus, enhanced cardiac output on the subsequent cardiac contraction.
2. The ResQGARD provides therapeutic benefit as soon as it is placed into the circuit and may be helpful in establishing intravenous access.

II. Indications for Use:

1. Spontaneously breathing patients who are experiencing symptoms of low blood circulation (e.g. diaphoresis, tachycardia, weak radial pulses, cold, clammy skin, tachypnea) or hypotensionⁱ (e.g. < 100 mm Hg [adults]; per age & weight and as directed by a physician [children]), which can be secondary to a variety of causes such as;
 - a. Anaphylaxis
 - b. Blood loss (traumatic or medical etiology) or blood donation
 - c. Burns
 - d. Dehydration
 - e. Dialysis
 - f. Drug overdose
 - g. Heat shock
 - h. Orthostatic intolerance
 - i. Pregnancy
 - j. Sepsis/toxins
 - k. Spinal shock
2. Permissive Hypotension: in cases (e.g. hemorrhage due to a trauma-related injury) in which a lower than normal blood pressure (BP) is desired to assist in the blood-clotting process, the ResQGARD may still be a reasonable therapy to help maintain "permissive hypotension."

III. Contraindications:

1. Flail chest
2. Shortness of breath or respiratory insufficiency
3. Chest pain
4. Dilated cardiomyopathy
5. Congestive heart failure
6. Pulmonary hypertension
7. Aortic stenosis

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IV. Precautions

1. The ResQGARD is not recommended for use in patients with a penetrating chest injury that 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. The safety and effectiveness of the ResQGARD in this clinical setting has not been established.
2. Children under 25 lbs may not be cooperative enough to tolerate use of the ResQGARD.
3. The safety and effectiveness in persons suffering from arterial stenosis or asthma has not been established.
4. Prolonged use for more than 30 minutes has not been clinically evaluated.
5. If respiratory distress develops during use of the ResQGARD, immediately discontinue use.
6. If a patient complains of nausea, the ResQGARD should be used with the mouthpiece or facemask without the head strap to allow for easy removal in the event of vomiting.
7. Do not leave the ResQGARD in the hands of untrained healthcare providers.
8. The ResQGARD is single-patient use only.

V. Procedure for Use:

1. Identify the need for ResQGARD application (assess indication for use).
2. Reassure patient and position as appropriate.
3. Obtain baseline vital signs (pulse, respirations, blood pressure and oxygen saturation) and monitor cardiac rhythm.
 - a. A blood pressure may also be estimated rapidly as follows:
 - i. A palpable radial pulse is generally an indication that the systolic BP is at least 90 mmHg.
 - ii. A palpable brachial pulse is generally an indication that the systolic BP is at least 80 mmHg.
 - iii. A palpable femoral pulse is generally an indication that the systolic BP is at least 70 mmHg.
 - iv. A palpable carotid pulse is generally an indication that the systolic BP is at least 60 mmHg.
4. Explain to the patient that the device will make it slightly more difficult to breathe, but that the resistance is what may make them feel better.
5. Apply the ResQGARD:
 - a. Using the ResQGARD on a facemask:
 - i. Gently (but firmly) hold the ResQGARD over the nose and mouth (or have the patient hold), establishing and maintaining a tight face seal with facemask. The head strap (e.g. ResQStrap) may be used if the patient does not want to hold the ResQGARD in place.
 - b. Using the ResQGARD on a mouthpiece:
 - i. Place the mouthpiece into the patient's mouth and have them make a tight seal with their lips.
 - ii. Apply the nose clip if necessary to discourage inspiring through nose.

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6. Have patient breathe in slowly (over 2 - 3 seconds) and deeply; exhale normally. Breathe at a rate of 10 – 16/minute.
7. If supplemental oxygen is used, attach the tubing to the oxygen port on the ResQGARD and deliver up to 15 lpm, but do not exceed 15 lpm.
8. If end tidal carbon dioxide (ETCO₂) monitoring is desired, attach the sensor to the exhalation port of the ResQGARD.
9. Reassess vital signs often (every 3 - 5 minutes).
10. Once the patient's blood pressure has stabilized and risen to an acceptable level it is recommended that you continue ResQGARD treatment for approximately 5 minutes before discontinuing its use. Reapply if necessary if the blood pressure drops again.
11. Document ResQGARD therapy on patient care report (e.g. time initiated and discontinued, vital sign response).

VI. Special Patient Considerations:

1. In a patient without intravenous (IV) access, applying the ResQGARD may make it easier to establish an IV because of the improvement in blood pressure.
2. The ResQGARD may be used in conjunction with other indicated treatments for hypotension (e.g. fluids, vasopressors, patient positioning).
3. In cases where the rate of blood loss is unclear, the recommendation is to use the ResQGARD as you would a fluid challenge in the field (i.e. if a fluid challenge is indicated, then the ResQGARD may be too). Since the use of an ITD may be fluid sparing and can be discontinued immediately, a trial application of the ResQGARD may be considered. If it is believed that the administration of fluids would worsen bleeding, then the ResQGARD should not be used.
4. Some patients who are claustrophobic will tolerate ResQGARD use on a mouthpiece better than on a facemask.

Effective Date: [insert date]

APPROVED BY:

Signature of Medical Director

Approval Date

ⁱ Eastridge et al. Hypotension begins at 110 mmHg: redefining "hypotension" with data. J Trauma 2007;63:291-299