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Final Report: Summary of Findings and Recommendations for Suction Devices for Management of Prehospital Combat Casualty Care Injuries.

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Executive Summary

Suction is a critical component of airway management, which is the second leading cause of preventable battlefield death. Current commercially available portable suction devices have not been scientifically validated for key performance measures relevant to prehospital care, let alone tactical combat casualty care. Current portable suction devices are not endorsed for combat casualty care and are considered too large and heavy to carry onto the battlefield anyway. As a result, the performance of suction itself is subsequently omitted as a care practice under current tactical combat casualty care (TCCC) treatment guidelines. It can be presumed that if a small, lightweight and effective device were available, the guidelines would change to reflect it.

There are commercially available manual and powered suction devices on the market, and several are specifically advertised for use in prehospital tactical or combat environments. However, a review of the manufacturers information, user reviews, and the limited literature on performance, combine to suggest that no device on the market meets even the most basic requirements of being small, lightweight, rugged, and demonstrating adequate suction performance. A fresh approach is needed, one that entails evidence-based requirements and specifications combined with engineering design and manufacture specially geared towards prehospital combat use.

Fortunately, existing guidelines, regulations and the literature do inform some aspects of prehospital suction relevant to tactical combat casualty care. This includes parameters for size and weight, suction performance, and robustness to survive the harsh battlefield environment. However, the data also expose significant gaps in knowledge and standards. While simple measures such as larger suction tip and tubing diameter improves suction performance, there are no standards for required vacuum pressures, flowrates or even the type of fluid and particulate matter that must be suctioned. Recommendations can be inferred from the literature, but the quality of supporting evidence is limited and subject to future research. In the interim, this report provides preliminary conclusions and recommendations regarding specific aspects of suction device performance and safety.

This report synthesizes the available information and proposes a series of findings and recommendations to improved airway management in the prehospital combat environment. The key findings and recommendations are listed in the appendices along with the complete list of observations and recommendations. The net result should be the establishment of a military program to establish clinically- and militarily-relevant standards for suction devices used in prehospital and combat casualty care environments. The device specifications outlined in this report should be adopted as a starting point for the development and engineering of a future prehospital combat

suction device. In turn, the services should support the advanced development of a future prehospital combat suction device and ensure robust, evidence-based design and testing. The ultimate goal is the establishment of a comprehensive military medical acquisition requirement and program to procure suction devices intended for prehospital combat care.

Executive Summary Points

- Airway obstruction is the second leading cause of preventable battlefield death.
- Suction is integral to airway management, which is given a high priority in TCCC guidelines.
- Suction was recently added as an intervention by the CoTCCC but remains deemphasized in textbooks and articles on prehospital combat casualty care.
- Despite the recent inclusion in the guidelines, the recommendation for suction remains nonspecific and subject to availability of equipment; presumably it is because effective suction devices are not generally available in far-forward combat casualty care areas.
- A DoD research agenda for the implementation and use of suction in the prehospital combat environment has not been established.
- If available in a lightweight, portable package, medical suction could save lives and improve airway management.
- Field users prioritized portability, strong suction, and ease of use as the key characteristics of a prehospital suction device. They also identified training is a gap area identified by users in using portable suction.
- Current commercially available hand-powered devices have insufficient performance to be recommended. Powered units offer better performance at prohibitive size and weight.
- There are no studies or expert opinions regarding the appropriate performance and size and weight of portable suction devices intended for prehospital combat care.
- Current standards and guidelines are intended for civilian use, and the supporting evidence is weak.

- Standard have not been validated clinically or operationally, and may be inadequate for emergency and prehospital care, and there is a lack of combat-relevant specifications.
- The military health system has not established a requirement for medical suction in the prehospital combat environment.

Executive Recommendations

- The CoTCCC should further emphasize the need for far-forward suction capability on their list of priorities.
- Combat medical providers should receive additional training beyond what is currently available in the manuals pertaining to airway securement and suction
- Textbooks and articles focused on combat casualty care should address suctioning of the airway.
- Establish clinically- and militarily-relevant standards for suction devices used in prehospital and combat casualty care environments.
- The DoD should establish a research and development agenda for suction that includes a capabilities gap and research priorities.
- Adopt the device specifications outlined in this report as a starting point for the development and engineering of a future prehospital combat suction device.
- Support the advanced development of a future prehospital combat suction device and ensure robust, evidence-based design and testing.
- Establish a military medical acquisition requirement and program to procure suction devices intended for prehospital combat care

Objective of the Report

This final report integrates, synthesizes, and articulates the key requirements and considerations of a suction device intended for use on pre-hospital combat casualties. This document summarizes the results of six prior reports (listed in appendix) and proposes future steps toward the development of a pre-hospital combat medical suction device. This project was intended primarily a requirements-based analysis derived primarily from combat data and supplemented with physiologic data, medical literature and industry standards. The appendix outlines the technical approach of this report.

Background

Tactical airway management often determines survival in both trauma and medical patients. Skilled interventions often make the critical difference in survival for patients with actual or impending airway compromise. Managing airways in the tactical environment presents an additional level of unique and complex challenges for any emergency provider. Hazardous or confined spaces and hostile action inherently limit the ability to intervene with an artificial airway or assisted ventilation. Loss of patient airway in tactical and combat environments commonly occurs. The proximate cause can be direct trauma to the airway structures or indirectly from traumatic shock or brain injury and the subsequent loss of airway protective reflexes.

In the Vietnam War, 6% of all soldiers killed in action only had an airway obstruction. More recent conflicts, notably Operation Iraqi Freedom (OIF), have shown an increase in primary injuries to the airway. In OIF, 27% of wounded in action suffered injuries only to the head, neck or airway structures.¹ This increase in airway trauma is likely due to the excellent torso protection of body armor and a subsequent diversion of injuries towards less armored areas such as the neck and face. The Registry of Emergency Airways at Combat Hospitals study (REACH) shows that prehospital cricothyrotomies are performed ten times more often on the battlefield as compared to civilian trauma systems. (5.8% vs. 0.5%).¹ A recent study highlights the high incidence of combat airway injury in combat maxillofacial trauma.² In these and other trauma cases, airway management requires a low threshold for airway stabilization to include tracheal intubation and cricothyrotomy or tracheostomy. A major reason for this dramatically higher rate of surgical airways is poor visualization of the injured airway with current inadequate suction devices available on the battlefield.

Aspiration of as little as 25 mL (approximately ¼ mouthful) of vomitus can cause significant pulmonary aspiration injury, and a massive aspiration carries a mortality as high as 70%.^{3,4} Delays in suction can presumably increase the risk of aspiration,

obstruction-related hypoxia, and make visualized intubation of the trachea impossible, so the availability and performance of suction can be viewed as essential. Despite this, there is a paucity of high-quality evidence on the techniques of suction. A 2009 Cochrane review on suctioning of patients revealed limited scope of data.⁵ Practice guidelines from 2001 on hyperoxygenation, hyperinflation, use of a ventilator circuit adaptor and subglottic suctioning were validated. In the review, new evidence was identified with respect to indications for suctioning, open suction versus closed suction systems, use of medications and infection control. Virtually all of the data was focused on in-hospital suctioning of primarily mechanically ventilated patients. There were no high-quality reports focusing on prehospital or emergency care in the Cochrane review.

The combat experience of the last dozen years clearly demonstrates that airway obstruction is the leading cause of preventable combat casualty deaths behind only hemorrhagic shock. Between 6-10% of battlefield deaths could have been prevented with adequate airway management.⁶ Because of vastly improved body armor and the enemy's shift towards direct fire and improvised explosive devices, the injury pattern today is much different than in previous wars. Airway management in this austere environment is notoriously difficult for many reasons but especially because of inadequate airway equipment.

In comparison to the advances in many areas of prehospital equipment, the current suction devices on the market have not achieved the level of performance required in civilian prehospital care, let alone battlefield care. It is telling that a recent 5 page review article on an advances in technology and concepts in tactical combat casualty care, there was no mention of suction and only this to say about airway management advances in general:⁷

Airway Protection: A skill common to all physicians deploying on the MERTE Medical Emergency Response Team (MERT)] is that they must be proficient at airway assessment and competent to definitively secure an airway if required. Generally, this takes the form of a rapid sequence induction using direct laryngoscopy. Several rescue devices are also available as alternatives or for use in a failed intubation such as supraglottic airways, optical laryngoscopes, and cricothyroidotomy.

Perhaps reflecting the perceived lack of effectiveness of prehospital suction devices, Kozak reported on a survey of paramedics carrying suction equipment to the scene of medical aid calls less than 25% of the time, and once on scene, suction equipment was utilized on only 50% of advanced airway procedures.⁸ It seems the available off-theshelf devices do not possess the proper balance of tradeoffs between portability, effectiveness and cost to be effective in tactical care.

There is limited information on the types, if any, of portable suction units carried by combat medics in the far-forward combat area. Anecdotal information suggests that powered suction devices are simply too heavy to be carried in the combat medic's aid kit. Manual powered devices, while lightweight, offer limited capability and require the use of a hand or foot to operate, limiting efficiency of the provider. Fielding data from military logistics agencies on the number and types of suction units employed in the field is not available, and prior experience suggests even if obtained, the data shows only total purchases and not where and when fielded.

Existing portable suction standards are civilian-oriented, lack a detailed base of evidentiary support, and in any case do not satisfy the critical needs of combat casualty care. We propose a set of performance standards that meet the needs of prehospital combat casualty care that could support a future development of a portable suction design that meets all of the combat medic's needs.

Combat Casualty Care and Suction

Over the past 15 years of wars, between 5-10% of the combat casualty population required emergency airway management and 6% of casualties arrived at a combat support hospital (CSH) without a definitive airway despite needing one.¹ Ten percent of combat deaths had airway compromise as the primary cause of death.⁶

Gunshot wounds (GSWs) and explosions were the most common mechanism of injury causing death in the recent wars.⁹ Most potentially survivable deaths due to airway obstruction were caused by GSWs to the upper airway structures.^{9,10} In the civilian setting, GSWs to the face require emergency airway management 35% of the time.^{11,12}

Since the end of the Vietnam War, there have been significant changes in protective equipment, weaponry, and tactics increasing the proportion of injuries to the face and neck. Data from US military casualties treated by US naval personnel between 2004 and 2010 revealed 23% of all injured casualties had combat-related maxillofacial injuries, with 4% of total casualties having severe maxillofacial injuries.² Of those with severe injuries, 51% required intubation prior to reaching a Role III Military treatment facility, and 19% underwent eventual tracheotomy reflecting the severity of anatomical disruption.²

Maxillofacial trauma can cause airway obstruction and loss of airway protection by multiple mechanisms including prolapse of the tongue base or maxillary structures, edema of the pharyngeal tissues, or hematoma formation. Bleeding into the airway from open wounds of the face, head, and oropharyngeal area will likely be copious, owing to the rich vascular supply of the head and face. Bleeding from the neck can be brisk, given the large vessels located there, and can easily pool in the upper airway. Hemoptysis from pulmonary injury can further increase the rate and amount of bleeding into the upper airway. Although clinical data is not available, it is easily conceivable that 200-400 mL/min of blood can hemorrhage into the airway from major vessel disruption. Vomiting can introduce significant volumes of fluid and partially digested food into the airway. While there is wide variation, the typical human adult stomach has a 1 liter capacity, most of which can be emptied through emesis. While the nondistended adult pharynx is considerably smaller, averaging 23 mL and the oral cavity averages 40 mL, repeated bouts of emesis can refill these cavities.^{13,14} Others report a mouthful to represent 90 mL.³ Distension of these structure might nearly double the volume to approximately 100 mL.

Importantly a combat casualty is likely to have concomitant shattering of bones, broken teeth, and avulsed tissue fragments. and introduction of mud, gravel and other debris mixed in with the blood and secretions. Failure to rapidly clear the fluids and particulates from the casualty's upper airway will likely lead to rapid and severe morbidity or death.

Combat Versus Civil Sector Out-of-Hospital Care

The "Fundamentals of Combat Casualty Care" chapter in the US Army Borden Institute textbook *Combat Casualty Care: Lessons Learned from Operation Enduring Freedom and Operation Iraqi Freedom* provides the following explanation for the key differences between combat casualty care and civilian prehospital care.¹⁵

While some similarities exist, out-of-hospital emergency care in combat or other military deployment settings often radically differs from civil sector practice in the United States. Beyond the challenges of individual patient care, harsh weather conditions, and austere settings, combat casualty care providers providing out-of-hospital care face unique tactical challenges.

For example, in civilian sector EMS, a common accident scene might include an ambulance crew routinely consisting of two or even three emergency medical technicians (EMTs), with at least one being an EMT-Paramedic. Often, firefighters will be present, bringing additional capability. Their ambulance, in most cases, will be stocked with a generous selection of basic and advanced life

support devices, monitors, and pharmaceuticals. This will generally include battery-powered "luggable" (the size of a small suitcase) suction units. While first responders often operate in harsh weather and austere settings, they do not typically encounter hostile fire while providing care. Thus, civilian sector out-ofhospital emergency care practitioners are able to fully focus on patient care and will have ready access to relatively heavy, battery-powered equipment including suction devices.

In contrast, a combat medic or other combat casualty care provider typically has a far more restricted ability to carry equipment and supplies. In many cases all available medical equipment is carried on the medic's person, in a rucksack, or otherwise harnessed to them. In some situations a vehicle or forward-operating medical unit (e.g., battalion aid station) is nearby and this may increase the availability of bulky and heavy equipment. In any event, there is likely to be only one medic, but there may be many patients, often severely wounded by highexplosive ordnance, vehicle fires, or small arms fire. The medic is appropriately focused on patient care, but must also be cognizant that the overarching priorities are the unit's integrity and mission. While working, the medic may become the target of hostile fire, and may have to return fire.

As highlighted above, tactical combat casualty care poses additional unique challenges compared to civilian practice. Combat casualty care providers are more likely to encounter mass casualty incidents and patients with catastrophic wounds. The epidemiology of wounding in OEF and OIF reveals a high incidence of penetrating trauma and blast-related mechanisms of injury.¹⁶ Casualty evacuations will tend to be longer in distance, duration and complexity, often necessitating longer duration of patient care. This latter aspect has been codified into doctrine and now termed "prolonged field care." Implicit in this concept is the requirement to care for severely injured casualties for a prolonged length of time (e.g., 72 hours) with limited availability of trained personnel, equipment and supplies. Prolonged field care is a particular condition of special operations missions that have a small footprint of personnel and materiel often occur in remote corners of the globe, far from logistical centers and without rapid evacuation capabilities.

In addition to the individual challenges of combat casualty care, several systemic issues pose significant obstacles to the optimization of combat casualty care in the modern battlespace. The most pressing of these issues is a lack of effective clinical data collection in the forward setting. Outcomes research in EMS is sparse in both the civilian sector and combat settings. Randomized, controlled,

prospective trials are the exception rather than the rule.¹⁷ Much of what is available comes in the form of case reports or series, focusing on single aspects of out-of-hospital combat casualty care or case series resulting from individual engagements.^{18,19} This is also true of data and information on suction devices.

Key Mechanics of Suction

The Hagen–Poiseuille equation relates flow, pressure and the viscosity of a fluid. For a Newtonian (linear mechanics) fluid, flow rate is proportional to pressure and viscosity.

$$\frac{\mathrm{dP}}{\mathrm{dx}} = \frac{8\mu LQ}{\pi r4} = \frac{128\mu LQ}{\pi \,\mathrm{d4}} \cong \Delta P$$

Where

 $\frac{dP}{dx}$ and ΔP are the pressure change [dP/dx]

L is the length of tubing

μ is the dynamic viscosity,

Q is the volumetric flow rate,

r is the pipe radius,

d is the diameter

 π is the mathematical constant pi.

Thus, for a given length of suction tubing and diameter, flowrate is proportional to the pressure and inversely proportional to the fluid viscosity. For a given pressure, flowrate is proportional to the tube length and the 4th power of radius or diameter. This latter fact underscores the importance of tube diameter to flowrate and small increases in tube cross section can result in large changes to flowrate.

Viscosity is the resistance to flow due to neighboring particles in a fluid. That is it is the "thickness" of the fluid. For example, water has a reference viscosity of 1 centipoise (cP) and blood typically 3-6 times as viscous at 37° C. Air, of course, is two orders of magnitude less viscous than water or nearly 74 times less viscous than blood. Thick mucus secretions can be 100-150 times as thick as the thickest blood.²⁰ Increased viscosity has the net effect of proportionally reducing flow rates for any given tubing diameter and length.

Figure: Flow of water compared to SAE 40 motor oil (simulating very thick mucus secretions) at different settings of the pressure regulator.

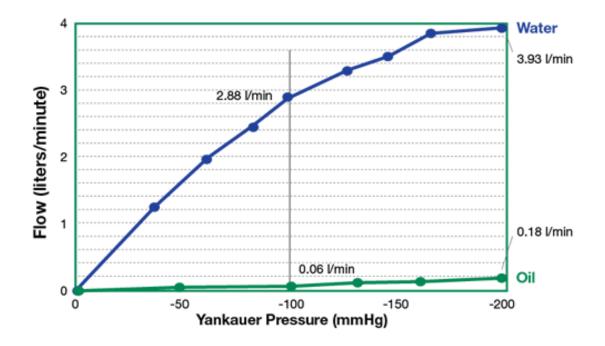


Photo Credit: Paulsen, AW: Are There Guidelines For Anesthesia Suction? APSF Newsletter, February 2015. Volume 29, No. 3, 41-64. Anesthesia Patient Safety Foundation, Indianapolis, IN. <u>http://www.apsf.org/newsletters/html/2015/February/pdf/Feb2015.pdf</u> COPYRIGHTED FIGURE – NOT FOR REPRODUCTION OR DISTRIBUTION Table: Viscosity of various substances that may require suctioning during an anesthetic compared to the viscosity of SAE 40 motor oil.

Substance	Viscosity, cP at room Temp	Reference	
Air	0.081	http://hyperphysics.phy- astr.gsu.edu/hbase/tables/viscosity.html	
Water	1.0	http://hyperphysics.phy- astr.gsu.edu/hbase/tables/viscosity.html	
Whole Blood	3.6 - 6.0	http://ltd.aruplab.com/tests/pub/0020054	
Gastric Mucus	75 - 230	Curt JRN, Pringle R. Viscosity of gastric mucus in duodenal ulceration. Gut 1969;10: 931-934.	
SAE 40 Motor Oil	650 -900	http://www.vp-scientific.com/Viscosity_Tables.htm	
Sputum	148 – 15,000	Picot R, Das I, Reid L. Pus, deoxyribonucleic acid, and sputum viscosity. Thorax 1978;33:235-242, & Jenssen AO. Scanning of viscosity in sputum. Scand J Respir Dis 1976;57:31-36.	

Adapted from Paulsen, AW: Are There Guidelines For Anesthesia Suction? APSF Newsletter, February 2015. Volume 29, No. 3, 41-64. Anesthesia Patient Safety Foundation, Indianapolis, IN.<u>http://www.apsf.org/newsletters/html/2015/February/pdf/Feb2015.pdf</u> COPYRIGHTED FIGURE – NOT FOR REPRODUCTION OR DISTRIBUTION

Interestingly, there is no mention in the manufacturing standards or in other documents for a standard reflecting particulate matter. A combat casualty is likely to have severe injuries, with shattered bones, broken teeth, mud, gravel and tissue debris mixed in with the blood and secretions.

Tiered Organization of Military Healthcare Delivery

An internationally-recognized textbook on emergency medical services and prehospital care entitled *EMS: A Practical Global Guidebook* provides in the "Military EMS Systems" chapter an adapted description of the tiered organization of medical care on the battlefield.²¹ Tiered layers of care is an important doctrinal concept when discussing the

employment of combat medical providers and fielding of medical equipment is the "role" of the medical provider or unit.

The military Roles of Care (formerly referred to as "Levels of Care," and before that "echelons") system describes a graduated hierarchy of combat medical care and facilities Treatment capabilities are roughly standardized for each role of care across the services, in compliance with the Joint Chiefs of Staff doctrinal directives.

Role 1 is located closest to the fighting, and thus, Role 1 care is austere and its elements are light and mobile. It includes four distinct levels of care: (1) self- and buddy-aid, (2) combat lifesaving, (3) combat medic care, and (4) "aid station care." Generally speaking, tactical combat casualty care is the primary responsibility of these role 1 medical providers and facilities. Self- and buddy-aid is the care rendered by the casualty himself or by his compatriot. It is essentially first aid. Combat lifesaver care is care by specially trained combatants who have advanced first aid training. Combat medic care is rendered by the first-line medical provider. This individual can, in addition to advanced first aid, initiate intravenous fluids, insert thoracostomy needles, and insert basic and advanced airways. The combat medic is also the first provider in the line to possess formal training on the use of suction devices.

For the U.S. Army and Marines, the battalion aid station is the first medical "facility" casualties will encounter, and may be staffed by physicians or physician assistants. It is austere and highly mobile, with advanced trauma life support capabilities, including endotracheal intubation, tube thoracostomy, intravenous medication and other physician-directed medical care. The equipment list for a battalion aid station generally does include a powered suction device. Navy ships have a rough equivalent in various satellite "battle dressing stations" located remotely from the primary shipboard medical department.

Role 2 is a divisional level "clearing station" that is staffed by a medical company of physicians, nurses, and medics. Casualties are examined to determine treatment needs and evacuation triage priority. Emergency medical treatment, including initial comprehensive resuscitation, is provided, and is supported by limited radiographic, dental, and laboratory services with whole-blood transfusion capacity. Portable suction units are standard equipment in these units. The "clearing station" provides limited duration patient-holding capability for sick or injured personnel, roughly at the "general ward" level. Ship medical departments approximate this capability, as do the Marine Fleet Surgical Support Groups. Role 2 units can be supplemented with surgical capabilities such as a Forward Surgical Team

Role 3 is the first true "full service" medical facility that a casualty will encounter on the battlefield. At present, this is a U.S. Army "combat support hospital", the Air Force Theater Hospitals or Expeditionary Medical Support (EMEDS) facilities, the Navy fleet hospitals, and the major amphibious assault ships medical departments, if augmented by surgical support teams. Role 3 hospitals provide comprehensive resuscitative surgery and medical care. Medical providers at them include general surgeons, and both surgical and medical sub-specialists, with comprehensive anesthesia and nursing support. Patients who are unlikely to return to duty are evacuated as soon as possible from these facilities after stabilization. Several types of suction units are present in Role 3 facilities including hand-portable and cartable devices for emergency care and bedside use, larger non-portable suction devices for use in surgical operations.

Role 4 has been traditionally represented by comprehensive theater hospitals variously designated as General, Field, Theater Area, or Station Hospitals. These large and generally poorly mobile facilities are mostly obsolete. Exceptions include the Navy's two 1,000-bed hospital ships (USNS Mercy and USNS Comfort), Landstuhl Regional Medical Center in Germany, and any host nation hospitals with which the services may have developed official relationships. As in any modern hospital, an array of suction devices is available for use in all emergency, acute and critical care locations.

Role 5 represents fixed hospitals located outside the theater of operations in the continental United States. These are primarily military medical facilities, augmented within the United States by Veteran's Administration, and civilian hospitals as part of the National Defense Medical System. Definitive and rehabilitative care of all types are found in role 5 facilities, and most have extensive medical education training programs.

Summary of the Background Sections

- Airway obstruction is the second leading cause of preventable battlefield death
- Suction is integral to management of airway obstruction.
- The nondistended volume of the human oropharynx is limited, approximately 65 mL. Distension might increase this volume to 100 mL.
- Up to 400 mL/min of blood and a total of 1 L of emesis can contaminate the upper airways.

- Airway secretions and blood will likely be mixed with bone fragments, broken teeth and other solids, making suctioning imperative.
- Powered suction is not available in far-forward combat casualty care areas.
- Limited information suggests manual suction devices are not carried or used by medics because of limited capability to evacuate secretions.
- The large size and heavy weight of existing powered portable suction units precludes their carry by combat medics.
- Flowrate is proportional to the pressure and inversely proportional to the fluid viscosity.
- Flowrate is proportional to the tube length and the 4th power of radius or diameter of the tube.
- Flowrate standards based on free flow of air are unlikely to be relevant to the suctioning of secretions and blood.

Recommendations of Background Section

- Suction devices for prehospital combat casualty care should be capable of evacuating up to 1L of blood or emesis as well as debris such as bone fragments.
- Detailed fielding data on the types of suction in current use in far-forward combat environments would establish a clear baseline of current availability of suction devices.
- Combat casualty care provider (e.g., medic) user feedback would establish a clear baseline of prime user preferences.
- Flowrate performance should be measured using a fluid that has been shown to mimic the secretions and blood anticipated in a combat casualty.

Tactical Combat Casualty Care (TCCC) Guidelines

The inadequacy of applying a civilian trauma model to tactical situations has long been recognized.^{18,22} The Tactical Combat Casualty Care (TCCC) program was initiated by the Naval Special Warfare Command in 1993, and later continued by the U.S. Special Operations Command (USSOCOM). This effort developed a set of tactically appropriate battlefield trauma care guidelines that provide combat casualty care providers with trauma management strategies that combine good medicine with good small-unit tactics.²² TCCC guidelines recognize that trauma care in the tactical environment has three goals: (1) treat the casualty; (2) prevent additional casualties; and (3) complete the mission.

The overarching goal of the TCCC initiative was the combination of good tactics with good medicine. As the name implies, TCCC is practiced during combat missions. TCCC was originally conceived as comprising three phases: (1) care-under-fire; (2) tactical field care and (3) tactical evacuation care. Prolonged field care, while not a separate phase, can be conceived as a merging of tactical field care and tactical evacuation in the context of a long time duration, typically many hours to several days.

Current TCCC guidelines were recently updated and now mention, and the otherwise relevant sections state in part:²³

Care Under Fire Guidelines

Casualty with airway obstruction or impending airway obstruction:

- Allow a conscious casualty to assume any position that best protects the airway, to include sitting up.
- Use a chin lift or jaw thrust maneuver
- Use suction if available and appropriate
- Nasopharyngeal airway or
- Extraglottic airway (if the casualty is unconscious)
- Place an unconscious casualty in the recovery position..

Tactical Field Care Guidelines

Casualty with airway obstruction or impending airway obstruction:

- Allow a conscious casualty to assume any position that best protects the airway, to include sitting up.
- Use a chin lift or jaw thrust maneuver
- Use suction if available and appropriate
- Nasopharyngeal airway or
- Extraglottic airway (if the casualty is unconscious)
- Place an unconscious casualty in the recovery position.

If the previous measures are unsuccessful, assess the tactical and clinical situations, the equipment at hand, and the skills and experience of the person providing care, and then select one of the following airway interventions:

- Endotracheal intubation or
- Perform a surgical cricothyroidotomy using one of the following...

Summary of the Tactical Combat Casualty Care (TCCC) Guidelines Section

• Airway management is emphasized as a high priority in TCCC guidelines.

- Management of secretions is emphasized with simple maneuvers such as recovery position emphasized.
- Suction was recently added as an intervention by the CoTCCC but remains deemphasized in textbooks and articles on prehospital combat casualty care.
- TCCC guidelines place a premium on small, lightweight and effective implements that can easily be carried by the combat casualty care provider; presumably current suction devices do not meet this threshold.

Recommendations of the Tactical Combat Casualty Care (TCCC) Guidelines Section

• The Committee on Tactical Combat Casualty Care (CoTCCC) should expand guidance on the use of suction

Suction in the Prehospital Combat Environment

Combat Casualties Requiring Suction

According to Kotwal et al., airway obstruction is one of three leading causes of preventable battlefield death²⁴. This is attributed to improper identification and assessment of the need for airway securement. Even if the initial need for airway securement is recognized, follow-up assessments to keep airways unobstructed are frequently not conducted. Lack of knowledge and improper use of suction devices or intubation could also lead to more serious injuries. Clearing the airway is important for several reasons: 1) it allows for improved visualization for intubation or needed advanced airway intervention; 2) it can also improve visualization to find and control bleeding in airway passages.

A review of civilian EMT and paramedic textbooks as well as a select sample of textbooks in the fields of respiratory therapy, anesthesia, and emergency medicine reveals a paucity of safety information relevant to suctioning in tactical combat casualty care. Even the authoritative and comprehensive tome *Benumof & Hagberg's Airway Management* invests less than two pages (out of 1,141) on suction technique and virtually no content on suction devices or catheters.²⁵

One notable exception is Roberts and Hedges' *Clinical Procedures in Emergency Medicine*²⁶. It describes suction devices and catheters and notes several points related to avoidance of adverse effects in the performance of suction:

- There are no contraindications to suctioning, however prolonged (>15s) suctioning can lead to hypoxia.
- To avoid hypoxia, consider supplemental oxygen during suctioning, or hyperventilate with oxygen before suction.
- Suction only under direct vision as blind suction can cause tissue damage or convert a partial obstruction to a complete one.

There are several injury types and subsequent conditions that result in the need for suction devices. These can range anywhere from airway obstruction to burn injuries. Airway obstruction occurs when build-up of bodily fluids (vomit, blood, saliva, bile, etc.) and debris (broken teeth, fracture bones, etc.) accumulate at the oropharynx and/or nasopharynx block airway passages and prevent ventilation. As much as a fourth of a mouthful of vomitous fluid (about 0.4 mL/kg) is enough to cause serious airway obstructions.²⁷ Hypoxia occurs when the amount of oxygen reaching the blood is reduced due to airway obstructions, and hypercarbia results from a build-up of carbon dioxide due to the reduced oxygen levels reaching the blood stream⁴. Burn injuries can cause swelling of airways due to inflammation from burns or inhalation of a large amount of smoke or gas.²⁸ The leading cause of airway deaths on the battlefield is maxillofacial injuries.²⁹ Due to deformed facial features from injuries such as fractures, swollen tongues, or debris blocking the airway, suctioning and intubation can be difficult. These atypical presentation scenarios are challenging for combat medics, who receive relatively limited training related to intubation. Suction devices may be needed in other instances as well, such as for tracheal suction for intubated patients, gastric suctioning for patients with nasogastric or orogastric tubes, or build-up of fluids in the pleural cavities of the chest.

Review of Textbooks in Prehospital Combat Casualty Care

In care-under-fire, combat medical personnel and their units are presumed to be under effective hostile fire, and the care they are capable of providing is very limited. In the tactical field care phase, medical personnel and their casualties are no longer under effective hostile fire, and more extensive care can be provided. In the tactical evacuation phase, casualties are transported to a medical facility by an aircraft, ground vehicle, or boat and there is an opportunity to provide additional medical personnel and equipment to further increase the level of care rendered.

Because the large size and heavy weight of battery powered suction units has generally precluded them from being included in the kit carried by ground combat medics, the use of powered suction devices has generally been omitted from standard texts and resources for TCCC. The sentinel 1999 textbook Tactical Emergency Care made reference to the management of secretions from a combat casualty through use of the recovery (lateral recumbent) position.³⁰ More recently, textbooks for the combat medic provide only slightly more detail on the use of portable powered suction equipment. For example, the 2012 US Army publication entitled *Tactical Combat Casualty Care: Lessons and Best Practices* makes no mention of suction and has just three paragraphs relevant to clearance of the airway:³¹

In the tactical field care phase, direct initial management to the evaluation and treatment of the casualty's airway once all hemorrhage problems have been addressed. Intervention should proceed from the least invasive procedure to the most invasive. Do not attempt any airway intervention if the casualty is conscious and breathing well on his own. Allow the casualty to assume the most comfortable position that best protects his airway, to include sitting upright.

Unconscious casualty without airway obstruction. If the casualty is unconscious, the most likely cause is either hemorrhagic shock or head trauma. In either case, an adequate airway must be maintained. If the unconscious casualty does not exhibit signs of airway obstruction, the airway should first be opened with a chin lift or a jaw-thrust maneuver. As in the care under fire phase, cervical spine immobilization is generally not required, except in the instance of significant blunt trauma.

If spontaneous respirations are present without respiratory distress, an adequate airway in the unconscious casualty is best maintained with a nasopharyngeal airway (NPA). An NPA is preferred over an oropharyngeal airway because it is better tolerated if the casualty regains consciousness and is less likely to be dislodged during casualty transport. After inserting the NPA, place the casualty in the recovery position to maintain the open airway and prevent aspiration of blood, mucous, or vomit.

Another recent textbook focusing on the combat medic and tactical combat casualty care provides one of the few references to suction. It is a 2009 edition entitled *68W Advanced Field Craft: Combat Medic Skills.*³² In the section on airway management, it describes the technique of suctioning a casualty's oropharynx. However, on careful review the information differs little from that provided in standard civilian-style emergency medical technician (EMT) textbooks from which it appears to be derived. That is, the suction technique described is exactly the same as civilian EMT textbooks with adjustments made to photos to reflect military uniforms on the providers and casualties. No detail is provided on the equipment or performance requirements of the suction devices.

Figure: Technique of suctioning a casualty as detailed in a combat medic textbook.

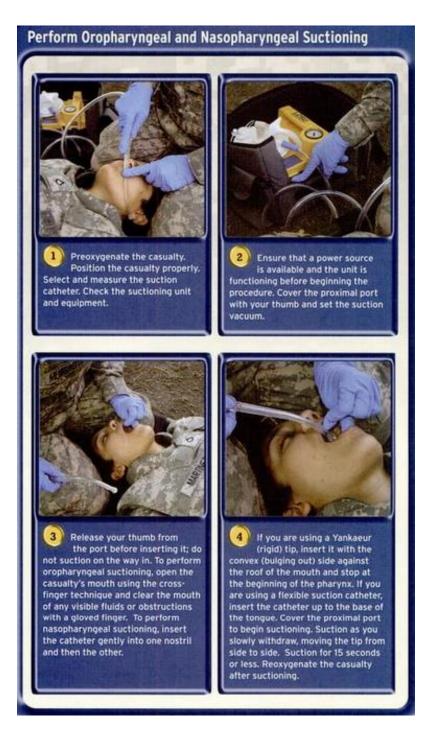


Photo Credit: US Army. 68W Advanced Field Craft: Combat Medic Skills 1st ed. Jones & Bartlett Learning; 1 edition, 2009, Burlington, MA. COPYRIGHTED FIGURE – NOT FOR REPRODUCTION OR DISTRIBUTION

A review of civilian EMT and paramedic textbooks as well as a select sample of textbooks in the fields of respiratory therapy, anesthesia, and emergency medicine reveals a paucity of information relevant to suctioning in tactical combat casualty care. One notable exception is Roberts and Hedges' Clinical Procedures in Emergency Medicine.²⁶ It notes several points related to the performance of suction:

- A large bore dental-type tip should be used because it allows clearing of vomitus, hemorrhage, and secretions.
- 5/8 inch suction tubing should be used as larger diameters are more effective.
- Clogging is a common problem and devices such as traps can mitigate.
- Equipment that is always ready and is rapidly deployable from the stored state is essential.

Review of Peer-Reviewed Journals

There is limited peer-reviewed literature on the optimal suction performance characteristics related to vacuum suction flow rates, pressure, and the fluid viscosity and anticipated particle size that must be suctioned. There are no randomized controlled trials or other high-quality evidence that addresses the issues; nevertheless there is meaningful data that can be extracted from the non-clinical studies, narrative reviews case reports, and expert opinion in the literature.

Tubing and Tips

Vandenberg and Vinson in 1999 published a case series entitled *the inadequacies of contemporary oropharyngeal suction* in which they describe the general state of suction devices available for clinical use in the emergency department:²⁷ It is unclear if the situation has improved since then as follow-up reports have not been published. The Vandenberg and Vinson paper primarily focuses on the tubing and tip diameter, noting that Hagen–Poiseuille equation strongly favors larger diameters. Vandenberg also criticizes the commonly used Yankaeur suction tip as not being designed for precision suctioning during tonsillectomies and other surgeries and not for the rapid evacuation of large quantities of obscuring fluids. He notes there are potentially better designs on the market and advocates for their use.

In two very similar follow-up papers, Vandenberg, et al studied the suction of various fluids simulating vomitus from human volunteers.^{3,33} Not surprisingly, they showed fluid evacuation times were 10 times faster using large bore (5/8 inch tip and ³/₄ inch tubing) versus small (standard Yankauer tip and ¹/₄ inch tubing) systems. Unfortunately, Vandenberg, et al's experimental setup used the wall suction available in hospital

emergency departments so his results may not be applicable to the prehospital environment where battery or manually powered devices are the norm.

Larger tip diameters not only increase flow rates they likely reduce clogging. Kozak, et al described in 1997 that 62% of Los Angeles County paramedics surveyed reported clogging as a significant problem.⁸ Recently, Kei and Mebuster described an improvised setup including an 8mm endotracheal tube and infant meconium aspirator and showed in the laboratory that it reduced clogging when compared to the Yankauer suction tip.³⁴ While it can be assumed that clogging is a potential pitfall of current suction devices, there are no scientific studies available that describe the clogging problem in specific terms.

Portable Suction Devices

There have been several reports comparing the suction performance of portable manual and battery powered suction devices intended for prehospital use. Rossi, et al were among the first and in 1992 evaluated several suction devices on the market at the time.³⁵ Sizes were modest (typically 20x10x20 cm) and weighed between 1-2 kg. Vacuum pressure ranged between 375 and 600 mm Hg. Water and salad oil were used as test fluids and water flow rates were measured between 7 and 67 L/min, a variation spanning nearly and order of magnitude. Simon, et al conducted a similar evaluation in 1993.³⁶ While all the devices tested are no longer commercially available, his report is instructive in that he did not establish performance standards based on clinical data or physiological inference.

Calkins, et al in 2002 evaluated manual and portable suction devices for use in prehospital combat casualty care.³⁷ They examined three commercially available devices, one modified device, a syringe, and two prototypes. He concluded that all were capable of generating suction pressure, but there were no controlled measurements of flow rates. Nevertheless they identified one device as superior in terms of size, weight, and performance. Like Vandenberg, et al before them, Calkins et al did not establish performance standards based on clinical data or physiological inference.

Arnstein in 1996 evaluated four manual (3 hand- and 1 foot-) powered suction devices.³⁸ Weights ranged between 0.2-1.9 kg and sizes were nominally 25x16x6 cm. He used volunteers to power the devices and performance testing was limited to vacuum pressure (range 197-525 mm Hg) and air flow (20-106 L/min). Similar to other suction device evaluations, an effort to establish performance standards based on clinical data or physiological inference was not completed.

While size and weight are important for portability and have big impact on combat casualty care providers who must often carry all of their gear, there is no literature describing the range of acceptable dimensions and weight. In articles that do report size and weight the inference is the user (or agency) purchasing and using the device will decide.

Fluid Viscosity and Particle Size

There are no clinical studies examining the viscosity and particle size of the fluids that are aspirated during prehospital or emergency care suctioning procedures for airway management. Data on the viscosity of human blood, gastric mucus and sputum is available (see table in the *Suction Devices for Emergency and Combat Casualty Care* section). There is no equivalent data for emesis. Given the significate range of foodstuffs and broad physiologic and circumstance differences between humans, there is probably no "typical" emesis and it may even be difficult to estimate a range of viscosities. This fact has not prevented investigators from devising their own version of test fluids, which generally range from water to commercially available condensed soups.^{3,27,36} Other fluids include charcoal suspended in sorbitol, salad oil, motor oil, and porcine blood.^{20,33,34,35}

Even less well studied is the particulate matter that can be mixed with the fluid. Partially digested food, broken teeth, shattered bone, avulsed tissue and gravel are all potential components of the material to be suctioned from a casualty. As mentioned, several authors have simulated this using commercially available condensed soups. One enterprising investigator used a coarsely blended mixture of a hamburger, French fries, and a soda to simulate emesis. The authors report the final mixture was primarily liquid in consistency with scattered solid food particles throughout.³⁴ While readily available and inexpensive, this substance is not validated nor standardized, and this remains an area in need of exploration. The issue is important as particulate matter can be particularly difficult to remove from the oropharynx with a suction device, and the particles can easily clog the inner workings of a machine, rendering it useless (at least until cleared). Trap devices can mitigate this problem, but like a collection container, they can fill and require emptying or replacement.

Other Performance Characteristics

The effluent container capacity defines the volume of secretions that can be suctioned before the container must be emptied or changed. Portable devices generally have

small containers; there is not a recommendation based on clinical evidence. Rossi, et al recommend 200-300 mL, but give no justification.³⁵ Others report a range of capacity from 140-1000 mL, suggesting a lack of consensus on the appropriate capacity.^{36,38} Given the potential volume of blood, vomitus, secretions, mud and other fluids that can potentially befall a casualty, there is a need for data to better estimate the minimum capacity of portable suction devices.

Reliability and battery life are obvious and important performance characteristics for a portable device intended for prehospital use. There is no literature on toughness, lifespan, or battery life. Some testing for aviation has been reported but this is limited to electromagnetic interference and vibration testing. There is one report surveying suction device failures in EMS. In 2013 Risavi, et al reported on inspections of suction units in a rural regional EMS system.³⁹ They reported that over a two-year period, 9,631 suction unit inspections were completed and there were 233 failures (2.4%). The majority (126, 54.1%) were due to battery failure. Seventy-three units failed due to other reasons (not recorded, switch failure, battery not seated). Ten inspections failed due to incorrect assembly, 19 due to defects with the suction canister and 5 due to kinked or disconnected suction tubing. This report underscores that reliability and fail-safe mechanisms of suction devices requires attention.

Of note, the literature does not shed light on the ergonomics and human factors aspects of suction devices. Factors such as balance, setup, controls, ease of use, and cleanup are important for all prehospital providers. Combat casualty care providers have the added requirements for noise and light abatement, owing to the tactical risk of giving up their position to the enemy, as well as more stringent requirements for size, weight and ruggedness.

Summary of the Suction in the Prehospital Environment Section

- Airway obstruction could lead to death in survivable cases.
- Clearing the airways is important for improved visualization.
- Suction devices could be needed in several cases including, but not limited to, obstructed airways, ventilatory failure, hypoxia, hypercarbia, burn injuries, and maxillofacial injuries.
- Military and tactical combat casualty care textbooks generally omit suction as a topic.
- Select civilian medical textbooks make pertinent recommendations relevant to suction performance and characteristics.
 - Large bore tips and tubing improve suction performance.
 - Prolonged suctioning can lead to hypoxia.

- Hypoxia can be avoided with supplemental oxygen or pre-hyperventilation with oxygen.
- Clogging is a frequent problem but can be mitigated with traps.
- Direct visualization is important as blind suctioning can worsen airway obstruction.
- Equipment should be readily deployable for patient use.
- There are no studies or expert opinions regarding the appropriate size and weight of portable suction units intended for prehospital care.
- Similarly, there is no data on vacuum suction pressure or flow rates.
- The Yankauer tip and small diameter tubing is ineffective for emergency care suction.
- Large bore tips and tubing improve suction performance.
- There is not a standardized fluid viscosity to test suction performance but investigators have used a range of simulated emesis fluids. There are no standards on particulate matter but experts opine that removal capacity is an important attribute of suction devices.
- Container capacity is not studied but ranges from 140 1000 mL.
- Reliability of suction machines may be inadequate; there is no data on ergonomics.
- There is no information on the specific needs of the tactical environment including ruggedness, and light and noise abatement.

Recommendations of the Suction in the Prehospital Environment Section

- Combat medics should receive additional training beyond what is currently available in the manuals pertaining to airway securement and suction
- Textbooks focused on combat casualty care should address suctioning
- Recommendations from select civilian medical textbooks are relevant to tactical combat casualty care and should be considered for adoption
- Standards should be established relevant to combat casualty care for
 - Size and weight of portable suction machines
 - Suction tip and tubing diameter
 - o Minimum performance especially flowrates of validated simulated emesis t
 - Effluent container capacity
 - o Reliability, ruggedness, and ease of use, and ergonomics
 - Noise and light abatement

Considerations in Suctioning Safety

Anatomic Considerations

Suction is the employment of negative pressure through a catheter directed into the upper airway of a casualty. The catheter can be passed through the oral or nasal cavity into the pharynx and supraglottic region. If advanced further, it can pass either into the upper esophagus or through the glottis and into the trachea. In most cases of combat casualty care the suction catheter will remain in the upper airways, as clearance of this structure is the primary goal. Advancing the suction catheter beyond the glottis is not considered desirable when performing upper airway suction and may be detrimental by stimulating a gag reflex. In selected clinical situations, there is a need to perform tracheal suction through an endotracheal tube or similar airway device. This procedure is generally reserved for casualties undergoing lengthy evacuation as may occur in prolonged care situations. Gastric suctioning is not considered a prehospital procedure and is unlikely to be performed by a combat medic in role 1; however, it is a procedure expected in role 2 and role 3, and possibly during prolonged care.³⁰

The tissues exposed to suctioning include all of the structures of the oro- and nasopharynx, glottis structures, trachea, and esophagus. This aerodigestive tracts has multiple functions and varied structures, each with unique characteristics relevant to suction safety. When intact and healthy, these structures have reasonable resistance to the forces generated during ordinary suctioning. Solid structures such as the teeth are impervious to the effects, while softer, mucous-membrane covered tissues can be affected. Vascularity of the aerodigestive tract likewise varies, with most soft tissue structures well supplied by superficial capillaries; larger vessels lie deeper but can also be exposed.

Since the technique of oropharyngeal suction is ideally visually guided, anatomy plays a role in creating pockets of visual obstruction. The nasal vestibule, lateral cheeks, subungual space and of course, deeper structures of the hypo- and posterior pharynx are all difficult to visualize. Large amounts of secretions and debris (often the reason for needing suction in the first place) can obscure sensitive tissues. Deeper structures such as the traches and esophagus are commonly cannulated blindly and this has additional safety implications.

Damaged or injured tissue presents additional concern as the local resistance to the forces applied can convert marginally viable to dead tissue. In rare cases avulsed tissues can be inadvertently be amputated by suctioning and exposed blood vessels can perforate, causing significant hemorrhage. Damage from trauma can also expose

deeper structures to damage, and in extreme cases, result in profound iatrogenic injury. Insertion of a suction cannula into the cranium through a large basilar skull or cribiform plate fracture is one rare but serious example.

Physiologic Considerations

The activity of suctioning can have local and systemic physiologic effects. On a microscopic level, suctioning can induce tissue changes that are readily observed in pathological specimens:⁴⁰ "The vacuum effect of a surgical suction tip can induce significant artifactual alterations in the connective tissue of specimens removed for diagnostic or therapeutic purposes. The alterations... [are] characterized by the formation of numerous, pleomorphic vacuoles that, on casual microscopic examination, resemble the morphology of traumatized adipose tissue. This artifact occurs when a vacuum draws air into connective tissue and mobilizes connective tissue mucins (acid mucopolysaccharides) that localize within the vacuoles that are formed."

If continuously applied for many minutes to hours, suction can cause local tissue ischemia and necrosis. This is a potential problem in nasogastric suctioning (gastric mucosa) and tracheobronchial suctioning (tracheal mucosa).⁴¹,⁴² This was a common complication of gastric suctioning until techniques and devices became common to limit suction duration, so called intermittent-suctioning techniques.

Locally, suctioning can cause an increase in secretions secondary to tactile stimulation. Generally, this effect is mild. Stimulation of sensitive tissues can result in a reflex arc such as sneezing (nasal cavity), gagging (posterior tongue), coughing (trachea), or bronchospasm (bronchi). ⁴³ Additional reflexes include vagal stimulation with bradycardia and hypotension, and tachycardia. Elevations in intracranial pressure can also occur. Hypoxia can be the result of coughing, bronchospasm, reflex hypopnea, or the direct effect of the cannula (airway obstruction) or the evacuation of therapeutically hyperoxygenated air and its replacement with room air.

In the awake patient, suctioning can range from mildly uncomfortable to painful. Catheter stiffness, force applied and suction strength are among the factors that determine the degree of patient discomfort.⁴³

Arguably the most important physiologic effect of suctioning relevant to prehospital combat care is the development of hypoxia, either directly by evacuating oxygenenriched air from the airway, or indirectly through reflex mediated cough, laryngospasm, gagging or other mechanism.⁴³ Limiting the duration of suctioning, the depth of catheter insertion, and avoidance of suction airflow during periods when not in contact with fluid or debris can limit these effects.⁴³

Suction in the prehospital combat casualty can be used to evacuate fluids for other than airway clearance. It can be used in virtually any part of the body. Evacuating blood for better visualization of a bleeding site is one example; evacuating skin and soft tissue abscesses is another. In these circumstances the physiologic response to suction is related to the anatomic area affected, with the most likely response being pain and discomfort. In any event, the focus of this report is on oropharyngeal suctioning for airway clearance.

Peer-Reviewed Literature on Suction Safety

There is limited peer-reviewed literature on the adverse effects of suction and related safety concerns. There are no randomized controlled trials or other high-quality evidence that addresses the issues; nevertheless there is meaningful data that can be extracted from the non-clinical studies, narrative reviews case reports, and expert opinion in the literature.

Adverse Effects

Pathophysiologically, there are several potential adverse effects of oropharyngeal and tracheobronchial suctioning,⁴⁴ and they include:

- Atelectasis
- Hypoxemia
- Pulmonary hemorrhage
- Local trauma, both from catheter and from vacuum-pressure aspiration of tissue
- Negative pressure pulmonary edema

Ashurst similarly summarizes the potential clinical adverse effects of airway suctioning in her review article (Table 1).⁴³

Table 1 Adverse Effects of Suction, Adapted
from Ashurst ⁴³
Discomfort and pain
Local trauma and injury
Irritation and abrasion
Hemorrhage
Perforation

Table 1 Adverse Effects of Suction, Adapted	
from Ashurst ⁴³	
Pneumothorax	
Bronchospasm	
Cough and sneeze	
Gagging and emesis	
Atelectasis	
Hypoxemia	
Tachycardia	
Bradycardia	
Hypotension	
Elevated intracranial pressure	
COPYRIGHTED FIGURE – NOT FOR REPRODUCTION	OR DISTRIBUTIO

Tracheal Suctioning

Arbon, in his thesis, comprehensively summarizes the risks of endotracheal suctioning, as occurs during mechanical ventilation of a tracheal-intubated patient in a critical care unit.⁴⁴ He summarizes his position by noting that suction pressures of 150 mm Hg (with flowrates of 10-15 L air) are adequate for most clinical situations and pressures above this level have increased adverse event rates. It is critical to note that this thesis focuses on suction catheters passed through the tracheal tube and into the tracheobronchial tree. The report does not address oropharyngeal suctioning, and indeed, this latter clinical entity is vastly different than tracheobronchial suctioning through a tracheal tube.

Gastric Suctioning

Gastritis is a frequent complication of nasogastric tube insertion.⁴⁵ Pressure and irritation of the stomach by the tip of the tube have been implicated, as opposed to the action of aspirated tissue by the induced vacuum.⁴⁶ In any event frequent changing of the tip position and use of intermittent suction should minimize incidence of gastritis in patients with nasogastric tubes in place. Regardless of the recommendations, the implication for prehospital oropharyngeal suctioning is not clear.

Suction Vacuum Pressure Levels

Carroll, in 2003, noted: "There is little research to guide the clinician in selecting appropriate level of negative pressure for various suctioning procedures. For example, a review of published (but not referenced) guidelines for airway suctioning found

suggested levels of 50 to 100 mm Hg for infants, 80 to 120 mm Hg for children, and 100 to 150 mm Hg for adults. However, none of these recommendations are evidencebased.⁴⁷ Additionally, these generic recommendations do not take into account the type of suctioning (e.g., tracheobronchial or oropharyngeal), the clinical indication, or the particular catheter used or flowrates desired. To date there has not been significant additions to the literature base on this topic.

A review of civilian EMT and paramedic textbooks as well as a select sample of textbooks in the fields of respiratory therapy, anesthesia, and emergency medicine reveals a paucity of safety information relevant to suctioning in tactical combat casualty care. One notable exception is Roberts and Hedges' Clinical Procedures in Emergency Medicine.²⁶ It notes several points related to avoidance of adverse effects in the performance of suction:

- There are no contraindications to suctioning, however prolonged (>15s) suctioning can lead to hypoxia.
- To avoid hypoxia, consider supplemental oxygen during suctioning, or hyperventilate with oxygen before suction.
- Suction only under direct vision as blind suction can cause tissue damage or convert a partial obstruction to a complete one.

Summary of the Considerations in Suction Safety Section

- Anatomic consideration in suction include
 - Prehospital suctioning generally involves the aerodigestive tract
 - Structures involved include the nasal and oral cavities, naso- and oropharynx, glottic structures, trachea, bronchi, and esophagus.
 - Anatomic locations with limited visualization are at greater risk of inadvertent cannulation and local trauma.
 - Pre-existing injury or trauma can increase the risk of anatomic disruption by suctioning.
- Physiologic considerations in suction include
 - Local stimulation from suctioning can increase local secretion production
 - Reflex responses can range from sneezing (nasal cavity), gagging (posterior tongue), coughing (trachea), or bronchospasm (bronchi).
 - More serious responses include vagal-mediated bradycardia, hypotension, hypoxia, and elevated intracranial pressure.
- Prolonged oropharyngeal suctioning can lead to hypoxia.

- Hypoxia can be avoided with supplemental oxygen or pre-hyperventilation with oxygen.
- Direct visualization is important as blind suctioning can worsen airway obstruction.
- There are no studies or expert opinions regarding the adverse effects or safety of suction units intended specifically for prehospital oropharyngeal suctioning.
- There is limited information to support the premise that rigid catheters are more likely to cause local tissue trauma than flexible catheters.
- There is no data to guide the maximal vacuum pressure or flow rates that can be safely applied for prehospital oropharyngeal airway suctioning.
- There is expert opinion on maximal vacuum pressure ranges for tracheal suctioning.
- Reports on gastric suctioning vacuum pressure maximums and duration of suction application have limited translation to prehospital airway clearance and may be misleading.

Recommendations of the Considerations in Suction Safety Section

- Training of prehospital combat casualty care providers should include the fundamentals of anatomy and physiology as they relate to the safety effects of upper airway suctioning.
- Standards should be established relevant to the safety of prehospital combat casualty care suctioning including:
 - \circ $\,$ Suction duration and necessity of adequate visualization of the catheter tip $\,$
 - Suction catheter rigidity and ability to cause trauma to airway structures
 - Maximal suction flow rate
 - Maximal vacuum pressure

Commercial Suction Devices for Emergency and Combat Casualty Care

Commercial Suction Device Categories

Suction devices for use in emergency and combat casualty care can generally be divided into three categories:

- 1. Manually powered devices
- 2. Electrically powered devices (usually battery powered)

3. Fixed vacuum system devices that rely on piped wall suction

For purposes of this report, the focus will be on the first two categories, as fixed systems are not relevant to the mobile needs of far-forward combat casualty providers. Suction units can also be subdivided into the following two categories based on the location of intended use:

- 1. Field devices that are intended to be carried by the individual prehospital provider. These devices are relatively lightweight and compact.
- 2. Portable or "luggable" devices that are intended to be carried in a transport vehicle or used a stationary machine in a temporary facility such as an aid station.

The following figures depict typical current examples of portable suction units.

Figure: Example medical suction devices, for use in the prehospital environment. From left, SSCOR QuickDraw Jr. Laerdal V-Vac and Ambu Rescue Pump.



Photo Credit: SSCOR, Sun Valley, <u>www.sscor.com</u>; Laerdal, Wrappinggers Falls, NY, <u>www.laerdal.com</u>; Ambu, Ballerup, Denmark, <u>www.ambu.com</u> COPYRIGHTED FIGURE – NOT FOR REPRODUCTION OR DISTRIBUTION Figure: Example medical suction devices, for use in transport or other emergency care environments. From the left, Laerdal Suction Unit, Spencer Jet Compact, S-SCCOR VX-2.



Photo Credit: Laerdal, Wrappinggers Falls, NY, <u>www.laerdal.com</u>; Spencer USA, <u>www.spencer.it/en</u>; SSCOR, Sun Valley, <u>www.sscor.com</u> COPYRIGHTED FIGURE – NOT FOR REPRODUCTION OR DISTRIBUTION

Manufacturing Standards for Suction Devices

A review of the available literature reveals no standards, either proposed, validated or accepted for the performance of a portable suction device for use in combat casualty care. Similarly, there are no accepted standards to guide the performance suction for use in prehospital or emergency care. There are, however some sources that inform the discussion.

ISO 10079-1 Medical Suction Equipment

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. ISO normally focuses on technical and engineering aspects of a machine and in general, they do not address medical standards, *per se*. ISO is generally used by manufacturers seeking to document they have produced products that have met certain standardization guidelines. ISO is not normally considered applicable to the actual practice of patient care in the clinical environment.

ISO 10079 is a standard with the most recent available date of 2014-15 (the range reflects the different subparts of the ISO document).^{48,49,50} Compliance with ISO is voluntary but generally expected since unless a governmental body (e.g., Food and Drug Administration) requires it.

It is important to recognize that ISO 10079 covers suction devices in general, that is, it encompasses the universe of all medical suction devices. Suction devices for use in prehospital care are just a subset and not all of ISO 10079 is relevant to this environment, let alone combat. In fact, much of the ISO standard represents good manufacturing practice, safety standards, and design implications that would all likely be transparent to the clinician. Nevertheless, the standard contains a number of relevant design and performance requirements for portable suction devices that may or may not apply to the combat casualty care environment. A select list of characteristics follows; readers are referred to the full ISO document for additional details.

- Dimensional Characteristics
 - Size: Device, including any carrying case or frame shall pass through a rectangular opening having dimensions of 600 mm × 300 mm (23.6 x 11.8")
 - \circ Weight < 6kg (13.2 lb)
 - Effluent container > 300mL for field use, > 500 mL for transport use
 - Minimum inside diameter of suction tubing 6mm
- Performance Characteristics
 - Vacuum pressure: > 60 kPa (450 mm Hg)
 - Flow rate: > 20 L/min of air
 - Battery power: operate > 20 min @ free air flowrate > 20 L/min and a vacuum > 40 kPa (300 mm Hg)
 - Noise maximum 70 dBA

The test standard for pharyngeal suctioning for electrically powered devices is described:⁴⁸

Prepare the simulated vomitus by dissolving 10 g of food grade xanthan gum in 1 I of distilled water and adding 100 g of 1 mm diameter glass beads having a specific gravity of approximately 2,55. Benzoic acid 0,1 % (mass fraction) can be added as a preservative. Use a graduated cylinder having a capacity of at least 300 ml with graduations no more than 50 ml apart. Agitate the simulated vomitus to disperse the glass beads immediately before testing. Pour 250 ml at ambient temperature into the graduated cylinder. Attach the suction tubing to the suction equipment and operate the equipment with the level of the simulated vomitus at the same horizontal level as the top of the collection container. Place the suction tubing into the graduated cylinder and record the time taken to evacuate 200 ml of the simulated vomitus.

Thick mucus secretions can be 100-150 times as thick as the thickest blood. Yet the ISO standard is for the free flow of air. The graph in the previous section shows the effect of different fluids on the flow rate. The net result is a dramatic decrease in the effective flow rate to the order of 180 mL/min, which is likely to be inadequate in the case of copious fluids.

Interestingly, there is also no mention in the ISO standards or in other documents for a standard reflecting particulate matter. A combat casualty is likely to have severe injuries, with shattered bones, broken teeth, mud, gravel and tissue debris mixed in with the blood and secretions. Thus, it is unclear if devices that meet the ISO standard would be effective in battlefield medicine.

The key performance standards of vacuum pressure and flowrate are similarly not validated against the clinical needs of prehospital and combat casualty care. In this fashion, an interesting commentary on the performance standards can be found in a newsletter from Anesthesia Patient Safety Foundation.⁴⁸

ISO 10079 represents a minimum standard for portable manual and electrically powered suction devices. There is little indication in the standard that these minimums are satisfactory for either prehospital or combat casualty care use. Of note, the size and weight standards are far above that expected to be hand-carried by a combat medic.

On a historical note, a previous standard from the American Society for Testing and Materials (ASTM) provides the following consensus recommendation for oral-nasal-tracheal suctioning of 0-160 mm Hg static vacuum pressure and 40 L/min air flow rate.⁵¹ Since this recommendation covers both oropharyngeal and tracheal (and presumably, bronchial) suctioning, and the two techniques have very different needs and safety parameters, it can no longer be considered state-of-the-art. In any event, ISO has superseded ASTM in many applications including suction devices.

Manufacturer Guidance

A major manufacturer of in-hospital and portable suction units published a monograph that provides some general guidance on desired suction characteristics.⁴⁶ It provides the following general guidance:

Portable pumps can also be used to produce vacuum, particularly for hospital areas not served by the wall system. Negative pressure generated by this equipment may be comparable to wall vacuum when the portable pump is new or well maintained. However, flow rates on some pumps may be lower (assuming equal service life and maintenance) than central systems. Users should identify pressures and flow specifications when evaluating portable units.

The monograph is also informative on the issue of clogging. In part it states:⁴⁶

Clogging results from four major causes:

- 1. The normal passage of lint-laden room air through the mechanism when regulators remain attached to the outlet and are left on when not in use.
- 2. The accumulation of aerosols during normal suction procedures.
- 3. Flooding which follows accidental overflow of aspirated fluids due to shut-off failures or connection errors.
- 4. Aspiration of smoke and debris during surgical procedures.

All of these risks can be reduced or eliminated by proper use of effective shut-off valves in collection canisters, properly installed over-flow safety traps on vacuum regulators and disposable particulate filters. Filters, however, become more restrictive to air flow as they clean the air that passes through them and accumulate particulate matter.

Of note, this description regards in-hospital wall suction systems and not portable devices. Nevertheless, the concern of clogging is relevant and can be translated as a specification calling for a device that is clog-resistant or easy to clear.

Food and Drug Administration Regulations

The Food and Drug Administration (FDA) classifies medical devices according to their hazard risk.⁵² Devices are classified into one of three categories—Class I, Class II, and Class III. Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. Class II devices are higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness. Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control. Class III devices must typically be approved by FDA before they are marketed. Class II devices are subject to much more stringent regulations that that of a Class I device.

Powered suction devices are considered a class II device by the FDA. Below are the several devices related to emergency suction devices and their classification.

Device Nomenclature	Regulation Number	Class
Patient care suction apparatus	870.5050	II
Catheter and tip, suction	880.6740	П

Class II devices are medical devices which pose a higher level of risk to a patient and as such require additional regulation to ensure the safety and effectiveness of the device. Class II medical devices are devices, which if they fail, can cause injury but not death to a patient who uses them. The regulatory controls that are put into place include a premarket authorization, post market analysis, and adherence to national and international performance standards.

There are no specific FDA guidelines or regulations regarding emergency suction devices.

Summary of the Manufacturing Standards for Suction Devices for Use in Combat and Emergency Care Section

- Suction devices are FDA class II
- ISO 10079 provides detailed minimal standards for suction devices intended for use in emergency and prehospital care. They do not address combat casualty care.
- The evidence supporting minimum performance standards for suction devices is not strong. No standard has been validated clinically or operationally, and may be inadequate for emergency and prehospital care.
- The standards are not specific to battlefield medicine and are unlikely to be applicable to combat casualty care environments

Recommendations of the Manufacturing Standards for Suction Devices for Use in Combat and Emergency Care Section

- Establish clinically-relevant standards for suction use in prehospital and farforward combat casualty care environments.
 - Validate key performance characteristics such as suction flow rates and vacuum pressure.
 - Use test procedures reflecting real-world conditions in key areas such as the use of simulated vomit in volumes and consistencies that have been validated.

Overview of Currently Available Suction Pump Devices

There are currently several suction pump devices available for use. Many of these devices are used in hospital settings or ambulances; however, their use in combat situations is not feasible due to a variety of limitations including, but not limited to, limited operating temperatures, heavy weight, bulky dimensions, or short battery life. This document consists of a compiled list of some of these devices. To see a comparison table of all devices with more performance variables such as canister size; or to read about the method of approach in finding these devices; or to see a list of website photo credits, please see the Appendices. *The following figures may be copyrighted and are not for reproduction or distribution.*

Compilation of Suction Pump Devices



1. Aeros Tote-L-Vac Suction Unit

Weight	15.5 lbs
Dimensions	8 x 12 x 9.5 in
Flow Rate	36 LPM
Vacuum Pressure	Up to 550 mmHg
Battery Life	30 minutes, rechargeable

Consumer reviews were not found. The manufacturer claims that this device can provide high enough vacuum pressure and flow rates to perform airway clearance procedures despite its compact size. Due to the battery power and portability, the Tote-L-Vac could be used for EMS, home health, hospital patient transport, and wherever battery power is a requirement. Performance reviews were not available and there is no summary recommendation on the product.

2. Ambu Res-Cue Manual Suction Pump

	Weight	0.507 lbs
A c hanner	Dimensions	7.28 x 2.52 x 6.61 in
	Flow Rate	>20 LPM
	Vacuum Pressure	225 to 450 mmHg
Concumer reviews for this	Battery Life	Hand-powered

Consumer reviews for this

device were found on Amazon. Overall, the Ambu Res-Cue Manual Suction Pump received 4.0/5.0 stars. Reviewers claim this device is compact and easy to assemble. It would not be recommended for dedicated EMS use as the suction power is not guaranteed, but it is recommended for emergencies in which battery-powered devices are not available.

3. Curaplex Manual Suction Unit

Weight	0.6 lbs
Dimensions	7.09 x 8.66 x 3.15 in
Flow Rate	>20 LPM
Vacuum Pressure	450 mmHg
Battery Life	Hand-powered

Consumer reviews for this device were found on Amazon. The Curaplex Manual Suction Unit received 2.4/5.0 stars. Several reviewers claim the device they received suctions very little, if at all, while other reviewers claim they could use this device in non-emergency settings. This product has potential but the execution could not be verified.

SPAT.	Weight	3.8 lbs
	Dimensions	9 x 7 x 8 in
	Flow Rate	27 LPM
C	Vacuum Pressure	80 to 550 mmHg
	Battery Life	60 min, rechargeable

4. DeVilbiss 7305D Series Homecare Suction Unit

Consumer reviews for this device were found on Vitality Medical. The DeVilbiss 7305D received 3.5/5.0 stars. Every single reviewer claims this device is too loud. One reviewer stated that the noise outweighed any of the positive aspects; however, all other reviewers stated it did clear airways despite the loud noise. It follows performance standards stated in ISO 10079-1.

5. Drive Medical VacuMax Suction Machine with Rechargeable Battery

and a	Weight	5 lbs
4 °	Dimensions	12.4 x 9.8 x 8.1 in
	Flow Rate	25 LPM
	Vacuum Pressure	150 to 530 mmHg
	Battery Life	50 min, rechargeable

Consumer reviews for this device were found on Drive Medical. The VacuMax Suction Machine received an average of 3.5/5.0 stars from two reviewers. One reviewer claims the device is poorly designed and does not take into consideration ease of use for wheelchair patients. Both reviewers stated the device has good suction ability and works well.

6. EM Innovations Suction Easy Pump

	Weight	0.419 lbs
	Dimensions	10 5/8 x 11 7/8 in
200	Flow Rate	Not specified
	Vacuum Pressure	100 mmHg
	Battery Life	Hand-powered

Only one consumer review was found on Amazon. The EM Innovations Suction Easy Pump received 3.0/5.0 stars. The reviewer claimed that the device is useful but not for ambulances and that the bulb was hard to squeeze. The manufacturer claims this device is an inexpensive solution for training purposes and is a must have in first responder airway kits because it is easy, disposable, and compact.

7. Emergency Aspirator from Vitalograph



Weight	0.882 lbs
Dimensions	6.5 x 6.5 x 3.43 in
Flow Rate	4.56 LPM
Vacuum Pressure	120 to 450 mmHg
Battery Life	Hand-powered

Consumer reviews were not

found. The manufacturer claims this hand-powered device is widely used in hospital and military settings. The Emergency Aspirator conforms to EN ISO 10079-2 and is made from tough polycarbonate to withstand serious shocks. It is also easy to disassemble for cleaning and has a unique overflow design. Performance reviews were not available and there is no summary recommendation on the product.



8. Eurovac AC Suction Unit

Weight	17.6 lbs
Dimensions	16.9 x 8.66 x 14.6 in
Flow Rate	45 LPM
Vacuum Pressure	575 mmHg
Battery Life	110 V on request

Consumer reviews were not found. The manufacturer

claims that this device has low maintenance costs and has built in mechanical overflow safety as well as an electronic acoustic alarm. The Eurovac is used on hospital crash carts, during patient transfers, long-term home care, by tracheostomy, and by EMS. Performance reviews were not available and there is no summary recommendation on the product.

9. EuroLite Suction Device

	Weight	9.92 lbs
	Dimensions	11.8 x 5.51 x 13 in
	Flow Rate	12 LPM
Kanyasa	Vacuum Pressure	600 mmHg
	Battery Life	110 V on request

Consumer reviews were not found. The manufacturer claims that this device has low maintenance costs and has built in mechanical overflow safety as well as an electronic acoustic alarm. The EuroLite is used in nursing, obstetrics, and neonatal and pediatrics. Performance reviews were not available and there is no summary recommendation on the product.

10. Gomco OptiVac AC/DC Portable Aspirator Model G180



Weight	11.4 lbs
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Dimensions	16.8 x 7.5 x 9.4 in
Flow Rate	>30 LPM
Vacuum Pressure	25 to 550 mmHg
Battery Life	3 hours, rechargeable

Only one consumer review

was found for this product in which the reviewer states that the Gomco OptiVac G180 is portable and dependable. The manufacturer claims this device can operate for 3 hours when fully charged and has a rugged go-anywhere design. It was tested to UL 60601-1 standards. Performance could not be verified, as there are no relevant reviews available.

11. INSTAD Suction Pump



Weight	8.82 lbs
Dimensions	15.4 x 8.7 x 8.7 in
Flow Rate	25 LPM
Vacuum Pressure	700 mmHg
Battery Life	110 V on request

Consumer reviews were not found. The manufacturer claims that this device has low maintenance costs and has built in mechanical overflow safety. The INSTAD is used on hospital crash carts, during patient transfers, long-term home care, by tracheostomy, and by EMS. Performance reviews were not available and there is no summary recommendation on the product.

12. John Bunn Vacutec 800 EV2 Portable Aspirator Suction Unit



Weight	11.6 lbs
Dimensions	4.9 x 15.3 x 10 in
Flow Rate	0 to 40 LPM
Vacuum Pressure	0 to 560 mmHg
Battery Life	115 VAC

Consumer reviews were found on 4MD Medical. The

John Bunn Vacutec 800 EV2 received 5.0/5.0 stars from 8 reviewers. All reviewers claim this product does exactly what it advertises. One reviewer stated that it is dependable and may be a good option for field medical or dental applications. It complies with EN60601 standards.

13. Laerdal Compact Suction Unit LCSU 4 (300 mL) RTCA Certificate



Consumer reviews were not found. The manufacturer

Weight	3.375 lbs
Dimensions	7.3 x 10.3 x 3.2 in
Flow Rate	30 LPM
Vacuum Pressure	50 to 550 mmHg
Battery Life	45 min, no-tools-necessary field changeable

claims this product has a rugged and lightweight design that exceeds international performance standards, which makes it an essential tool for first responders. It also has an overflow shutoff feature for the canister. This product is certified for use in aircrafts. Performance reviews were not available and there is no summary recommendation on the product.



14. Laerdal Suction Unit

Weight	8.9 lbs
Dimensions	12.4 x 13 x 6.3 in
Flow Rate	>30 LPM
Vacuum Pressure	80 to 500 mmHg
Battery Life	45 minutes, no-tools-necessary field changeable

Consumer reviews were not found. The manufacturer claims the Laerdal Suction

Unit is effective at improving patient safety because it is powerful and effective and exceeds international standards. This product is in compliance with the Council Directive 93/42/EEC Medical Device Directive. Performance reviews were not available and there is no summary recommendation on the product.

15. Laerdal V-Vac Starter Kit



Weight	0.644 lbs
Dimensions	13.5 x 2.5 x 4.8 in
Flow Rate	70 LPM
Vacuum Pressure	170 to 380 mmHg
Battery Life	Hand-powered

Consumer reviews were not

found. The manufacturer claims the disposable suction tip is built to prevent tube occlusions. The handle for this device is reusable and can be cleaned with warm, soapy water between uses. This product is in compliance with the Council Directive 93/42/EEC. Performance reviews were not available and there is no summary recommendation on the product.

16. LSP Advantage Emergency Portable Suction Unit

	Weight	10.6 lbs
	Dimensions	16.8 x 9.4 x 7.5 in
	Flow Rate	30 LPM
	Vacuum Pressure	25 to 550 mmHg
	Battery Life	75 min, rechargeable

Consumer reviews were not found. The manufacturer claims this product is built to be used in the field, ambulances, and helicopters. The LSP Advantage Emergency Portable Suction Unit will operate at full power when plugged in and for 75 minutes when fully charged. This product also claims to have a versatile vacuum range, from 25 to 550 mmHg. Performance reviews were not available and there is no summary recommendation on the product.

17. Medela Basic Aspirator



Weight	20.5 lbs
Dimensions	8.3 x 12 x 14.8 in
Flow Rate	30 LPM
Vacuum Pressure	675 mmHg
Battery Life	US AC plug

Consumer reviews were not

found. The manufacturer claims the Medela Basic Aspirator is built to perform in hospitals, clinics, and medical practices. It cannot operate unless plugged in. Performance reviews were not available and there is no summary recommendation on the product.

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	Weight	20.5 lbs
	Dimensions	8.3 x 12 x 14.8 in
	Flow Rate	40 to 60 LPM
-	Vacuum Pressure	713 mmHg
	Battery Life	Plug into wall

18. Medela Dominant Flex Aspirator

Consumer reviews were not found. The manufacturer claims the Medela Basic Aspirator is built to perform in hospitals, clinics, and medical practices. It cannot operate unless plugged in. Performance reviews were not available and there is no summary recommendation on the product.

19. Medline Vac-Assist Portable Aspirator Suction Machine



Weight	12.1 lbs
Dimensions	14.8 x 9.8 x 6.8 in
Flow Rate	>40 LPM
Vacuum Pressure	0 to 560 mmHg
Battery Life	AC 115 VAC

Consumer reviews were not found. The manufacturer

claims the Medline Vac-Assist has a rugged design for frequent use and is designed for home or hospital use. This product can handle oral, nasal, and tracheal suction. It has a quiet motor, at only 58 dB, and is easy to clean. Performance reviews were not available and there is no summary recommendation on the product.

20. MedSource Manual Suction Pump

	Weight	1 lb
Matheway	Dimensions	8.8 x 7.1 x 3.2 in
	Flow Rate	>20 LPM
	Vacuum Pressure	450 mmHg
	Battery Life	Hand-powered

Consumer reviews were not found. The manufacturer claims the Medsource Manual Suction Pump can be powered using only one hand. It is simple to operate during emergency situations. The pump is reusable while the canister and tubing are disposable and meant for single use. Performance reviews were not available and there is no summary recommendation on the product.

21. Morgan Suction Pump



Weight	1 lb
Dimensions	3.15 x 2.75 x 1.4 in
Flow Rate	>20 LPM
Vacuum Pressure	550 mmHg
Battery Life	Hand-powered

Consumer reviews were not

found. The manufacturer states that the Morgan Suction Pump is an FDA registered class 1 medical suction kit. This product should be able to prevent back-flow and is completely disposable. It was designed for use by hospice field nurses. Performance reviews were not available and there is no summary recommendation on the product.

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Weight	0.46 lbs
Dimensions	9.75 x 3.75 x 3 in
Flow Rate	Not specified
Vacuum Pressure	100 mmHg
Battery Life	Hand-powered

22. North American Rescue (NAR) Tactical Suction Device

Two consumer reviews were

found on Rescue Essentials. The NAR Tactical Suction Device is said to be highly effective, especially for EMS and military medical settings. One reviewer claims this is the only manual suction product that works. The manufacturer claims this device can be used with one hand.

23. Portable Vacuum Absorb Pump Phlegm Suction Unit Suction Machine SXT-5A



Weight	8.82 lbs
Dimensions	16.1 x 8.1 x 16.5 in
Flow Rate	>20 LPM
Vacuum Pressure	150 to 600 mmHg
Battery Life	110 VAC

Consumer reviews were not

found. The manufacturer claims that the SXT-5A is used for treatment in hospitals, first aid stations, or centers of social medical service. It is designed to aspirate highly viscous secretions such as mucus and phlegm from infants to adults. This product has overflow protection and is autoclavable. Performance reviews were not available and there is no summary recommendation on the product.

24. Precision Medical PM66AC EasyGoVac Portable Aspirator Suction Machine

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Weight	3.25 lbs
Dimensions	8.6 x 6.3 x 8.02 in
Flow Rate	>20 LPM
Vacuum Pressure	51 to 533 mmHg
Battery Life	2 hours, rechargeable

Consumer reviews were not found. The manufacturer claims that lithium batteries provide fast 2 hour recharge. The PM66AC EasyGoVac can come with either a disposable 800 mL canister or a reusable 1200 mL canister. Performance reviews were not available and there is no summary recommendation on the product.

25.Res-Q-Vac



Weight	0.5 lbs
Dimensions	4.49 x 7.1 x 2.15 in
Flow Rate	20 LPM
Vacuum Pressure	>600 mmHg
Battery Life	Hand-powered

Consumer reviews were not

found. The Res-Q-Vac is built for EMS operators and technicians, hospitals, nursing homes, home care, and the military. The manufacturers claim that this product can be customizable for use with infants through adults. This product is made with molded ABS plastic, which is rugged and durable. This product can only operate in temperatures that range from 0 to 140 °F. Performance reviews were not available and there is no summary recommendation on the product.



Weight	5.7 lbs
Dimensions	14.3 x 6.9 x 8.3 in
Flow Rate	28 LPM
Vacuum Pressure	550 mmHg
Battery Life	30 minutes, rechargeable

26. Roscoe Medical Heavy-Duty Aspirator Suction Machine

Consumer reviews were not

found. The manufacturer claims this product is easy to handle and transportable due to its light weight. It has built-in overflow protection and is easy to clean. This product also claims to have an anti-vibration vacuum gauge setting. Performance reviews were not available and there is no summary recommendation on the product.

27. SAM E.P.S. Portable Suction Unit



Consumer reviews were not found. The manufacturer

Weight	10.4 lbs
Dimensions	13.7 x 13 x 6.65 in
Flow Rate	32 LPM
Vacuum Pressure	0 to 600 mmHg
Battery Life	125 min full power, rechargeable

claims that this device is ideal for use by emergency services because it is lightweight and can be recharged within 2.5 hours. This product also has a 90° rotating canister vessel, which allows the device to be laid flat even on uneven terrain. Due to its BioCloak coating, it is ideal for outside use. Performance reviews were not available and there is no summary recommendation on the product.

28. SSCOR QUICKDRAW Alkaline Powered Portable Suction, Olive Drab



Weight	2.6 lbs
Dimensions	10.5 x 4.5 x 4.35 in
Flow Rate	>30 LPM
Vacuum Pressure	80 to 500 mmHg
Battery Life	Up to 3 hours, 10 AAA batteries

Consumer reviews were not

found. This product was designed specifically for field use, which can be seen due to its light weight and changeable AAA batteries. The manufacturer claims that alkaline batteries have a long shelf life, which means this product does not require constant charging and can be stored in aid bags with minimal degradation. It is not specified the range of temperatures the Olive Drab Quickdraw can operate in. This product conforms to ISO 10079-1, UL 60601-1, IEC 60601-1, EN 60601-1-2 standards. Performance reviews were not available and there is no summary recommendation on the product.

29. SSCOR VX-2



Weight	8.6 lbs
Dimensions	17 x 9 x 5.25 in
Flow Rate	>30 LPM
Vacuum Pressure	50 to 525 mmHg
Battery Life	45 min, rechargeable

Consumer reviews were not

found. The manufacturer claims this device is "Firefighter" tough, portable, and powerful. It meets state, national, and international standards for portable suction equipment. This product has a built-in battery maintenance system to prevent overcharges and deep discharges of the battery. It is compliant with SAE J3043 standards. Performance reviews were not available and there is no summary recommendation on the product.

30. S-SCORT 9 Suction



Weight	8 lbs
Dimensions	9.5 x 7 x 14 in
Flow Rate	>30 LPM
Vacuum Pressure	120 or 525 mmHg
Battery Life	30-45 min, rechargeable

Consumer reviews were not

found. The manufacturer claims this product is quiet and is "Firefighter-proof" tough, being the most durable, economic, and high-performance suction pump available. It is suited for pre-hospital healthcare environments due to its durability and ease of cleaning. Performance reviews were not available and there is no summary recommendation on the product.

31. S-SCORT II Portable Suction Unit



Consumer reviews were not found. This product is designed to fit LifePak 5, 10,

Weight	10 lbs
Dimensions	7 x 7 x 14 in
Flow Rate	>30 LPM
Vacuum Pressure	120 or 525 mmHg
Battery Life	20 min on each battery, supplied by user

and 12 defibrillators and is not rechargeable. The manufacturer claims the device is covered by vinyl coated nylon for easy wipe down and disinfection. Performance reviews were not available and there is no summary recommendation on the product.



32.	S-SCORT	III Portable	Suction Unit
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Weight	7 lbs
Dimensions	8 x 7 x 11 in
Flow Rate	>30 LPM
Vacuum Pressure	120 or 525 mmHg
Battery Life	30 to 45 min, rechargeable

Consumer reviews were not found. The manufacturer

claims this product is durable, reliable, and an economical EMS suction device. It provides power and versatility while being relatively light weight. Performance reviews were not available and there is no summary recommendation on the product.

33. S-SCORT Ten



Consumer reviews were not found. The manufacturer

Weight	10 lbs
Dimensions	9.5 x 7 x 14 in
Flow Rate	>30 LPM
Vacuum Pressure	120 or 525 mmHg
Battery Life	45 min, rechargeable

claims the linear polyethylene rotational molded exterior of the S-SCORT Ten makes it virtually indestructible. The power can be adjusted in this device between full power and lower vacuum settings for pediatric aspiration. It also has a built-in battery maintenance system to automatically disconnect the battery when the battery is depleted in order to avoid deep discharge. Performance reviews were not available and there is no summary recommendation on the product.

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Weight	3.37 lbs
Dimensions	7.25 x 7.25 x 6.75 in
Flow Rate	27 LPM
Vacuum Pressure	50 to 500 mmHg
Battery Life	Up to 60 min, rechargeable

Consumer reviews were not found. The manufacturer claims the Vacu-Aide is the smallest and strongest suction unit of its kind. This product is ideal for home and hospital use. It complies with ISO 10079-1 standards. Performance reviews were not available and there is no summary recommendation on the product.

Summary of the Overview of Currently Available Suction Pump Devices

- There are a variety of suction pump devices on the market; however, very few of them claim to be useful for combat casualty care.
- This list is an overview of different types of suction pump devices that can be found through a web-based search for portable devices.

Recommendations of the Overview of Currently Available Suction Pump Devices

- There are few suction pump devices that state they can be used for prehospital combat use.
- Suction devices that do claim a prehospital combat use require independent validation and need to be adjusted for operability in a wider range of conditions with smaller dimensions and lighter weights.

Military Requirements for Suction Devices

There are no set military standards for medical suction devices. Tactical Combat Casualty Care (TCCC) guidelines are updated annually, which means military requirements are changing regularly. There are also different medical personnel with various needs, which render it difficult to standardize requirements. For example, medics working in the front-line will require a lightweight, compact suction device design that is easy to carry. Medics working from ambulances can carry heavier or larger equipment, and also have more options for power supply. Because of these different needs, there is no single standard or list of specifications that can be recommended. Any currently listed specifications should remain flexible to the various combat medic roles and changing TCCC guidelines. With these in mind, there are some important performance measures that should be taken into account including weight, dimensions, portability, sterilization, air flow and vacuum pressure, collection canister volume, and whether the pump is battery operated.

Combat situations can be stressful with many confounding mission, field, and environmental variables such as extreme temperatures, different tactical situations, difficult terrains, and combat search and rescue (CSAR) operations. Airway suction device performance under various environmental parameters should be assessed, such as altitude, vibration, temperature, and humidity. Furthermore, device suction should be assessed when the device itself is wet or in a strong electric field. In high casualty scenarios, a suction device that can be operated without any prior medical training is highly preferred.²⁸ Because of these variables, there are several military requirements for airway suction devices to be suitable for field use. Due to the diverse terrains and tactical situations, the device must be durable, easy to transport, and easy to sterilize.⁵³ Tubing for the suction device must be clear to allow for constant monitoring of the suction process and any clogging of the device. Large-bore tubing is preferred to smaller tubing, as the latter can only be used to suction low viscosity fluids with little to no debris.³⁵ Similar suction efficacy should be available to combat medics as in civilian clinical settings which eliminates the use of manual, unpowered suction devices. Manually-powered suction devices do not provide as much flow rate their electricaldriven counterparts, although they may be more lightweight and portable. In addition, combat-ready suction devices must differ from their civilian counterparts by being compact, rugged, and quiet (reduced IR/noise signatures).⁵⁴ The maximum weight for a military suction device should ideally be as light as possible; a realistic weight for a battery-operated, rugged device is a kilogram or less. Because of sterility issues on the field, it may be easier to have disposable tubing and collection chambers.

There are currently no suction devices specifically designed for regular military field use. A surgical suction pump currently used at aid stations and hospitals is manufactured by Impact Instrumentation Inc. and is called Impact 326M Portable Continuous/Intermittent Surgical Suction Pump Aspirator. This suction device has the ability to work continuously when plugged into an AC/DC power supply or for a limited number of hours on battery power, which is rechargeable by plugging into an AC/DC power source. It is lightweight, versatile, compact, and can hold 2000 mL fluid per canister. This device is too heavy (12 lbs) and bulky (11.5" x 9.5" x 4.87") for a field medic to carry. Additionally, the range of operating temperatures (-4 °F to 120 °F) does not cover extreme cases. Another device that is currently employed in ambulances is also manufactured by Impact Instrumentations Inc. and is called Impact 325M Portable Suction Unit with Gauge/Regulator. This device also comes with a compact carry unit but is heavier. It can be operated in a range of extreme temperatures and runs on AC/DC power supplies. Due to the heavy weight (13 lbs), bulky dimensions (10" x 13.5" x 6.125"), and limited battery-power (60 minutes on high power) before requiring recharging, this device is also not feasible for medical field use.

Summary of the Military Requirements for Suction Devices Section

- There are no set military standards for suction units; however, there are important performance standards that need to be maintained when manufacturing a device, including weight, dimensions, portability, sterilization, air flow and vacuum pressure, collection canister volume, and whether the pump is battery operated.
- Suction devices must be built for use on different terrains and extreme weather situations. They should be rugged with an extended battery life that is easy to change without the need of a power supply for recharge.
- There are currently no devices built for use on the field specifically. The device used at aid stations and in hospitals is the Impact 326M, which is unsuitable for field use because it is heavy, bulky, and inoperable in extreme temperatures. The device used in ambulances is 325M, which is unsuitable for field use because it is heavy bulky, and has a short battery life.

Recommendations of the Military Requirements for Suction Devices Section

- Standards should be established relevant to universal use for military personnel with different needs. Some important design concepts to consider are:
 - Size, weight, and ergonomics
 - Vacuum pressure similar to that in clinical use
 - Battery operated and easily replaceable batteries
 - o Rugged
 - Extreme weather conditions

Proposed Specifications for a New Suction Device

This section proposes specifications for a suction device specifically intended for use in prehospital combat casualty care. This information is derived from proprietary work conducted by the institution and its collaborative partners.

Methodology

Survey of Users and Experts

A survey of experts and users was conducted to establish priorities in portable suction characteristics relevant to prehospital care. A team of two engineers and a business professional conducted 102 interviews with relevant medical personnel in the Texas and National Capitol regions of the U.S. Included in those interviews were paramedics, EMT's, supply chain personnel, manufacturing representatives, FDA consultants, emergency medicine doctors, military special forces, and police officers. Additionally, informal interviews with subject matter experts in military prehospital care were obtained and incorporated into the results. From the user interviews, it was possible to determine that the customer segment that has the highest need was in the paramedic segment. Paramedics working field calls are typically encumbered with over 80 lbs of equipment that is separated into three cumbersome packages. As such, the development of a lightweight and portable technology is key in reducing the amount of weight and space that their equipment takes up. By reducing the size and weight, it then makes it possible for paramedics to be better equipped for more situations without adding to the already heavy load they carry.

Qualitative results of the user survey demonstrate the following four areas as high priority (mentioned most frequently by participants), in order:

- 1. Portability
- 2. Strong suction
- 3. Ease of use
- 4. Training support for using device optimally

Other items that are important but mentioned less frequently are, in order:

- 5. Include a light for visibility
- 6. Indicator to show remaining battery life
- 7. Shape of catheter to get into mouth easier
- 8. Larger diameter tubing to prevent clogging
- 9. Longer tube for reaching patient
- 10. Small and less bulky effluent container
- 11. Use specific (design by setting)
- 12. Able to perform oronasogastric suctioning
- 13. Controls and device visible in the dark

- 14. Different size tips like a drill bit kit
- 15. Backup to battery power

Specification Development

Taking the user feedback and expert opinion, combined with a synthesis of available literature, a set of specifications is proposed. As a baseline, off-the-shelf manufacturer's specifications list categories were utilized. Specifications are divided into physical characteristics, performance characteristics, and selected engineering and functional specifications. Where appropriate, ranges of values are provided to imply that different uses and designs may benefit from different specification values.

Proposed Specification

Specification Criteria

Specifications (Proposed) for a portable suction device for use in prehospital combat casualty care.

	Statement
Physical Specifications	
Weight Range (overall device)	<1 Kg, <0.5kg for man-pack version.
Dimensions overall device (length, height, depth), including canister	30 x 10 x 10 cm
Canister Capacity (mL), Volume markings on canister?	1000 mL, 500 mL for man-pack version
Performance Specifications	
Directional performance	Functions in all orientations
Vomit Flowrate (removal)	3 L/min
Vacuum pressure range (measured at catheter tip)	0-550 Hg mm
Device Operation Time (under no load, under maximum load)	5 min, 3 min

Values or

Specification Criteria

Values or Statement

Device operational temperature, humidity, moisture exposure range	Based on Mil Std pertinent for medical devices
Device operational atmospheric pressure range	Airworthy/safe to fly based on Mil Std
Device durability	Mil Std
Device carry-ability	Handles or straps to allow easy carry by a person
Engineering Design Specifications	
External AC/DC input power range	120 VAC/12-24 VDC nominal
Battery Type (rechargeable or disposable)	Both
Battery Cell Chemistry	Per Design
Max noise level (dB), overall device	≤ 69 dBA
Suction Tube Diameter	0.5-0.75 in ID
Suction Tube Length	3 feet nominal
Suction Tube Material	Flexible in hot/cold environments, not collapsible under max vacuum, lightweight, and coilable/packable

Specification Criteria

Values or Statement

Device Case	Resistant to scratches, dents, and protect internal parts from shock, vibration, moisture, and dust.
Infection control	Easily disinfected with disposable components that contact the patient
Functional Requirements	
Pressure display	Not necessary
Variable vacuum pressure controller	Yes
Low battery display	Yes

Summary of the Proposed Specifications Section

- Users prioritized portability, strong suction, and ease of use as the key characteristics of a prehospital suction device.
- Training is a gap area identified by users in using portable suction.
- Physical, performance, engineering and functional specifications can be described for a suction unit designed for the prehospital combat environment.

Recommendations of the Proposed Specifications Section

• A suction device for prehospital combat use should be portable, powerful, and easy to use.

- Training of users should be included in the fielding and employment of prehospital suction.
- Physical, performance, engineering and functional specifications specific to combat casualty care should be incorporated in military service requirements for device design of prehospital suction.

Proposed Suction Design Concept

Brief Design Considerations

A portable suction device is a medical device intended to maintain a human's airway clear of any obstructions (refer to Figure). Said obstructions include vomit, debris, and fragmentation. This medical device is intended to be used in a military environment.

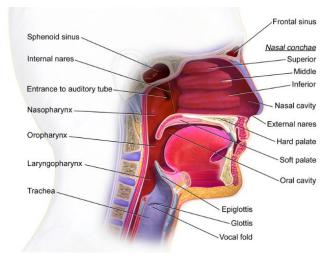


FIGURE: Upper Respiratory Tract

Photo Credit: Blausen.com staff (2014). "Medical gallery of Blausen Medical 2014". WikiJournal of Medicine 1 (2). DOI:10.15347/wjm/2014.010. ISSN 2002-4436. COPYRIGHTED FIGURE – NOT FOR REPRODUCTION OR DISTRIBUTION

Theoretical Pump and Vacuum Concepts

Pumps

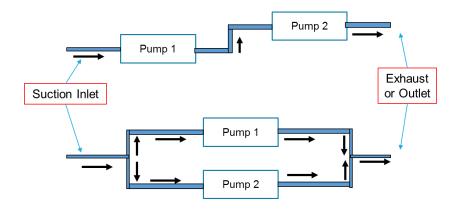
- Mechanical devices used to suction, increase pressure or move liquids or gases.
- Pumps can be configured for vacuum, pressure and vacuum-pressure purposes.

Pumps in Series

- Pressure head doubles when compared to one operating pump.
- \circ $\;$ Flow rate remains the same when compared to one operating pump.
- Pumps in Parallel

- Flow rate doubles when compared to one operating pump.
- Pressure head remains the same when compared to one operating pump.

Figure: Pumps in series and parallel



Note: Pump 1 and 2 are Identical Pumps

Flow and Vacuum Relationship

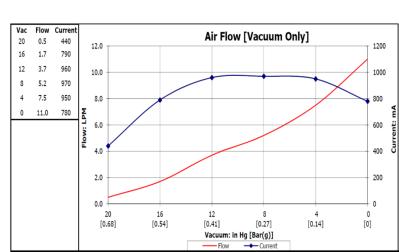


Figure: Pressure – Flow Relationship

Therefore :

$$Pressure_{vacuum} \propto \frac{1}{Flow Rate}$$

- As Vacuum increases flow rate decreases

The current concept design is depicted in the figure. This design utilizes a pump as the mechanism to suction obstructions out of a person's airway, an inline hydrophobic filter and a collection canister. The inline hydrophobic filter is intended to protect the pump from any contaminants and also restricts the passage of any fluid to the air pump. Inherently, this makes the pump reusable while the filter, canister and tubing require replacement after usage. The concept design also has an on/off switch, a low battery LED and a potentiometer to regulate the pumping power. The control system of the device is composed of an Arduino Leonardo and a motor shield. Two power sources are used to power the entire device; a 12V

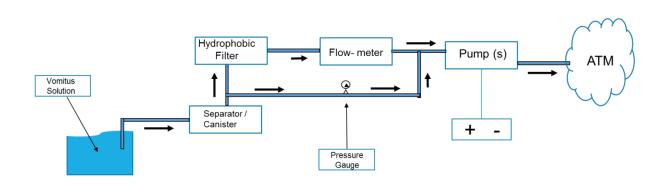


Figure: Prototype

battery is solely dedicated for the pump and a 9V battery powers the Arduino board. After examining the design concept it was determined that the device had the following deficiencies:

- Low suction; higher suction is desired
- Large footprint and heavy; smaller portable device is desired
- A large canister which gives it a large footprint
- Requires two separate batteries to operate
- Utilizes a hydrophobic filter which provides a large pressure drop and restricts flowrate

Figure: Concept design, with setup for bench testing.



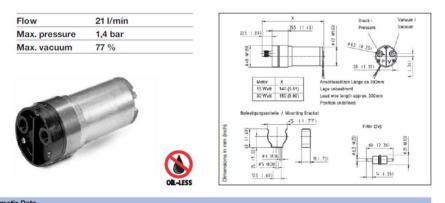
Specifications and Functional Requirements

A detailed review of the functional requirements for improvement is described in this section.

Prime Mover (Pump) Options

Commercial off-the-shelf rotary pumps are available in a variety of sizes and configurations. Two representative examples are shown.

Rotary Vane Pump G 07



Pneumatic Data			
Description	G 12/07-15 Watt	G 24/07-15 Watt	G 24/07-30 Watt
Part number	50336	50218	50221
Max. flow	17,0 l/min	17,5 l/min	21,0 l/min
Max. intermittent pressure	1,3 bar	1,0 bar	1,4 bar
Max. continuous pressure	0,3 bar		0,2 bar
Max. intermittent vacuum	76 %	75 %	77 %
Max. continuous vacuum	30 %		20 %
Electrical Data			
Motor type	Permanent magnet	Permanent magnet	Permanent magnet
Nominal voltage	12 V DC	24 V DC	24 V DC
Min. current consumption	1,9 A	1,1 A	1,9 A
Max. current consumption	3,2 A	1,6 A	2,5 A
Protection class	IP40	IP40	IP40
Motor bearing	Ball bearing	Ball bearing	Ball bearing
General Data			
Ambient temperature	-10 to 40 °C	-10 to 40 °C	-10 to 40 °C
Weight	0,6 kg	0,6 kg	0,7 kg
Direction of rotation	CW	CW	CW

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WOB-L Piston Vacuum Pump 8006ZV DC

Flow		31,0 l/min			
Max.	vacuum	80 %		46 (159) 17.50	
			Dimensions in rm (inch)		
Pneumatic Data					
Description		8006ZV/30/4,5/V/DC			
art number	12 V DC	80060131			
	24 V DC	80060135			
Max. flow	24 V DC	80060135 31,0 l/min			
	24 V DC				
Max. flow		31,0 l/min			
Max. flow Max. vacuum		31,0 l/min 80 %			
Max. flow Max. vacuum Max. restart vacu		31,0 l/min 80 %			
Max. flow Max. vacuum Max. restart vacu Electrical Data		31,0 //min 80 % Ambient pressure Direct current 12 V/24 V DC			
Max. flow Max. vacuum Max. restart vacu Electrical Data Aotor type Jominal voltage Jominal speed	um	31,0 I/min 80 % Ambient pressure Direct current 12 V/24 V DC 2800 rpm			
Aax. flow Aax. vacuum Aax. restart vacuu Electrical Data Aotor type Jominal voltage Jominal speed Power consumpti	um	31,0 //min 80 % Ambient pressure Direct current 12 //24 V DC 2800 rpm 60 W			
Max. flow Max. vacuum Max. restart vacu Electrical Data Aotor type Jominal voltage Jominal speed	um	31,0 I/min 80 % Ambient pressure Direct current 12 V/24 V DC 2800 rpm			
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Aax. flow Aax, vacuum Aax, restart vacuu Electrical Data Actor type Jominal voltage Jominal speed Jominal speed Jower consumpt Actor insulation c General Data mbient temperal	um on class	31,0 Umin 80 % Ambient pressure Direct current 12 V/24 V DC 2800 rpm 60 W E 10 to 40 °C			
Aax. flow Aax. vacuum Aax. restart vacuu Electrical Data Aotor type Jominal speed Yower consumpti Aotor insulation o General Data whibient temperatu	um on class	31.0 //min 80 % Ambient pressure Direct current 12 //24 / DC 2800 rpm 60 W E 10 to 40 °C 10 to 60 °C			
Aax. flow Aax. restart vacuum Aax. restart vacuu Electrical Data Aotor type Jominal voltage Jominal speed Power consumpti Aotor insulation of General Data mbient temperatur Veight	um on class	31,0 //min 80 % Ambient pressure Direct current 12 //24 V DC 2800 rpm 60 W E 10 to 40 °C 10 to 60 °C 0,93 kg			
Aax. flow Aax. vacuum Aax. restart vacuu Electrical Data Aotor type Jominal speed Yower consumpti Aotor insulation o General Data whibient temperatu	um on class	31.0 //min 80 % Ambient pressure Direct current 12 //24 / DC 2800 rpm 60 W E 10 to 40 °C 10 to 60 °C			

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Another pump option is provided at:

<u>http://www.micropump.com/product_detail.aspx?ProductID=71</u>.It has a removable impeller which means you could potentially use this pump without the filter; thus, providing an alternative design concept.

Power Source (Battery) Selection Criteria

Batteries containing the required power requirements and smaller in physical size will need to be obtained for the design concept. There are a wide variety of commercial off-the-shelf battery packs that can be used. If there is no generic power sources that meet the specified requirements under load, a custom-made batteries need to be considered.

Criteria of information needed:

- What is device's input voltage? (V)
- What is its power consumption (W)
- What is Maximum current drain (A)

- Decide Battery pack's Capacity (mAh or Ah)
- Calculation : (Ah) = Device's Wattage (W) x Time to run (Hours) / Battery Voltage (V)

A representative example of a commercial battery pack is shown.

Polymer Li-Ion Battery Pack: 14.8v 3650mAh (54.02 Wh, 7.0A rate) with PCM (4.38)

Your Price: \$80.95
In Stock
Product ID # 5878 Part Number: PL-5545135S4-WR
Lead Time: 5 Business Days
Quantity: 1 Buy
Add to a new shopping list
Email this page to a friend
y of P 🛛 🛨

*Important Shipping Regulation	This pack is for testing (prototype) only. It has not been UN38.3 tested yet. Read more
Packing	 Made by 4 <u>Polymer Li-ion 3.7V3650 mAh (PL- 5545135-2C)</u> Wrapped by heavy duty heat shrink tube Optional for 1 pc <u>A Fire Retardant Bag: 295mmx230mmx75mm Reduce the chance of damage if caught fire</u> This Fire Retardant Bag (Li-Ion Safer Bag) is intended to reduce the chance of damage in the event of catching fire. Must locate & seal the battery pack in the bag while charging / leaving without any attention
Voltage	14.8V (working) 16.8V (peak) 11.0V (cut-off)
Capacity	Nominal: 3650 mAh (54.02Wh)
Protection	 One <u>PCM with balance function</u> (10A max.) is installed with the battery pack to protect battery from Over-charging beyond 4.25V/cell Over-discharging below 2.75V/cell Over-drain beyond 10A Must wait min of 30 minutes after battery is fully charged to allow the pcm to perform balance function on all the cells within the pack. <u>7 Amp polyswitch</u> installed to limit max. discharging current and to protect wrong polarity
Pre-wired	6" wire with 18 AWG
Max. Discharging Rate	7 Amp limited by polyswitch (lower rate available upon request)
Dimensions(LxWxH)	5.8"(148mm) x 2.3"(58mm) x 1.7"(46mm)
Detail Data Sheet	Please click here to download the specification
Weight	12.7oz. (360grams)

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Electronics and Controller Criteria

Printed Circuit Board

A Printed Circuit Board (PCB) could replace the current state of the design concept which is composed of routed wires and electronic components; this will provide a more compact solution and will inherently enhance the manufacturing process. The following image illustrates the proposed design concept.

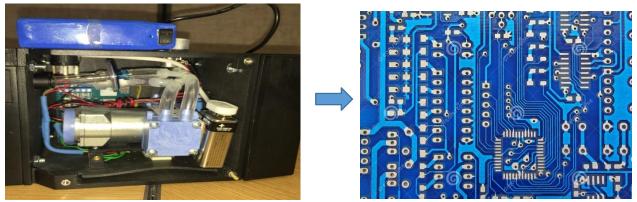
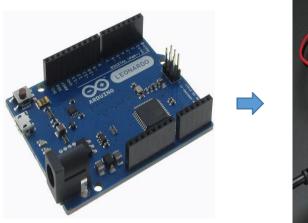


Figure: Printed Circuit Board

Micro-controller and Motor-controller

A relative large size micro- controller and motor-controller are currently used in the design concept. These components can be replaced by much smaller components such as the Adafruit-feather micro controller and motor shield. By implementing the suggested improvement, the resulting prototype will be lighter and compact in size. The power requirements of the device will also be decreased since the proposed micro-controller requires a much smaller and lighter power source. The following images represent the aforementioned improvements.



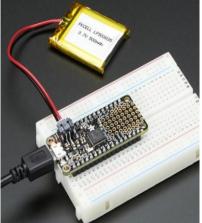


Figure: Micro Controllers

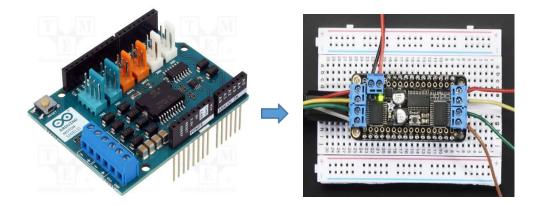


Figure: Motor Controllers

Miscellaneous Considerations

Miscellaneous areas of design consideration

- Pneumatic fittings to ensure vacuum is maintained
- Fluid lines to use with vacuum systems
- Pressure sensors and flow-rate sensors
- Solenoid valves
- Check valves
- Mufflers to reduce noise
- Other ways to obtain a strong vacuum (i.e. vacuum generators)



Prior Art

Intellectual Property and Patent Overview

A preliminary review of the United States Patent and Trademark Office (USPTO) database produced a list of 35 patents which are in the realm of intellectual property that deals with the portable airway device. Of those 35 patent and patent applications, 4 include claims concerning the portability of the device.

Three patents of particular interest are detailed below:

Patent US 4,930,997 (Bennett, 1990) which is granted for a portable medical suction device. This patent claims generation of a portable suction device that utilizes a power supply, motor, hydrophobic vent, housing, and vacuum generation apparatus. These claims all cover the development of a basic device which will generate suction via a portable device.

Patent US 7,063,688 (Say, 2006) which is granted for a portable battery powered aspirator. This device claims to have developed a battery powered device that will generate suction and have the ability to transport fluid into a removable storage container. This device is primarily designed to be an all in one aspiration device.

Patent US 5,776,119 (Bilbo, 1998) was granted for a portable suction unit. This device is design for removal of mucus, sputum, and bodily fluids.

Looking at the current state of the art research, development of portable suction devices is a well-developed area, the problem lies in the fact that there is still a significant gap in the implementation of technology to assist emergency responders to help save lives.

General Information and Device Usability

For the purposes of illustration of the current state-of-the-art in commercial portable suction devices, the Laerdal Compact Suction Unit® 4 (LCSU® 4) is described. This device is intended to maintain a person's airway through the use of medical vacuum or suction. The versatile design shown in Figure 3 displays a 300 mL and 800 mL reservoir configuration. Depending on the emergency, the pump and electronics housing can be attached to the desired fluid storage capacity container. Both containers are disposable and enclose a hydrophobic



Figure: LCSU 4

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filter which prevents any unwanted fluids from entering the main housing.

Pressure display and Suction Adjustment

By adjusting the dial, the device provides a variable flow rate/suction feature. Suction can be varied from 50 to 550 mmHg, in 50 mmHg increments.

Performance

Pump

A maximum flow rate of 30 LPM (liters per minute of air) can be provide by the pump under no load. The maximum vacuum the pump can provide is 550 mmHg, although the flow rate at this stage was not specified.

Power Consumption and Display

This device displays significantly low efficiency in power consumption. Specifications state that the device can run for 45 minutes under no load (free flow). Therefore, the run time under maximum vacuum should be relatively low (not specified). Battery consumption is displayed in a control panel which provides low battery alert, external power indicator and fully charged alert features.

Specification Comparison

The following table was developed based on the specifications that were used to develop the design concept.* Unless otherwise specified, specifications stated for the Laerdal Compact Suction Device were obtain from the Laerdal website <u>www.Laerdal.com</u>.

Table 1: Specification	Comparison
------------------------	------------

Specification	Concept Design Suction Device	Laerdal Compact Suction Device
Pump Flow Rate	3 L/min (vomitus)	30 Liters/ Minute (air flow)
Suction Performance	Vacuum Range: 0-550 mmHg	Vacuum Range: 50 -550 mmHg
Weight	< 1kg (2.2 lbs)	@ 300 mL configuration, 3.3 lbs.
		@500 mL configuration,4.3 lbs.
Hose Diameter	5/8 in diameter tubing.	3/16 in diameter tubing.
Noise Level	≤ 70 dB.	≤ 70 dB
Fluid Storage	1000 mL.	300 mL and 500 mL configurations available
Power	12V rechargeable power source.	12V rechargeable power source.
Control	Device allows for adjustment of flow rate/ suction through the use of a dial.	Device allows for adjustment of flow rate/ suction through the use of a dial.
Foot Print	30 x 10 x 10 cm	@ 300 mL, 7.3" x 10.3" x 3.2"
		@ 500 mL, 9.3" x 7.5" x 9.3"
Pressure display	None	Provides pressure values

Cost and Current Use

The listed price for the 300 mL and 800 mL is \$553 and \$675 respectively as of 2017. This includes the single body (pump & electronics housing), reservoir, filter and a standardized suction line. The canister (fluid storage) and tubing are listed at \$14.45 and \$28.90 for the 300 mL and 800 mL respectively. It was found that LCSU® 4 is currently in use by fire departments in North America. The Laerdal Co. possesses distribution cells in 23 countries around the world, concentrating most resources and personnel in North America.

Prior Art Conclusion

Based on the analyzed information, it was determined that the LCSU® 4 represents the typical unit used in the commercial prehospital care environment. This medical device is a reasonable benchmark for further design development.

Relevant ISO Standard (ISO 10079-1)

ISO 10079-1 is a standard specifically for electrically powered suction equipment for hospital and emergency care use.⁴⁸ It specifies minimum safety and performance requirements for medical and surgical suction equipment for healthcare facilities such as hospitals, for domiciliary care of patients and for field and transport use. It is recommended that you review this standard for guidance in the development of this device.

Pump Performance and Suction Rate

The pump suction shall comply with ISO 10079-1 in that the suction equipment shall develop a vacuum of at least 40kPa below atmospheric pressure within 10 seconds.

Weight

In accordance with ISO 10079-1 the mass of the handheld suction device shall not exceed six kilograms.

Hose Assembly

In accordance with ISO 10079-1, the tubing diameter must be a minimum of 6 millimeters.

Noise Level

In accordance with ISO 10079-1, the acoustic energy cannot exceed 80 dbA for a cumulative exposure of 24 hours. A peak level of 140 dbC for acoustic noise is the maximum value for non-exposure values. The testing of the medical equipment is to be operated under it "worst case" normal condition. The test room is to be semi-reverberant with a hard reflecting floor and the distance between any wall or object and surface is not be less than 3 meters. In accordance with ISO 10079-1, the vibration of the device should not exceed 2.5 m/s² over a time interval of 8 hours.

Power Supply

According to ISO 10079-1, the power supply shall not exceed 250 V for a handheld device. The frequency must be less than or equal to 1 kHz.

Display and Indicators

In accordance with 10079-1, the vacuum indicator for analog displays shall have graduations not less than 2 mm apart. For digital displays, the medical device shall display vacuum at intervals of not greater than 2 % of the full-scale value. The maximum vacuum for which the equipment is designed shall be marked prominently on the display case or immediately adjacent to it.

Operation and Storage Conditions

In accordance with ISO 10079-1, the device shall be operable in a temperature range of -18 to 50 (\pm 2) °C. In addition, the device shall also be capable of being stored in temperatures ranging from -40 to 60 (\pm 2) °C.

Suction Rate

The suction device shall remove 200 mL of vomitus solution in less than 10 seconds (Section 59.9)

Summary and Conclusions

Suction is a critical component of airway management, which is the second leading cause of preventable battlefield death. Current commercially available portable suction devices have not been scientifically validated for key performance measures relevant to prehospital care, let alone tactical combat casualty care. Current portable suction devices are not endorsed for combat casualty care and are considered too large and heavy to carry onto the battlefield anyway. As a result, the performance of suction itself is subsequently omitted as a care practice under current tactical combat casualty care (TCCC) treatment guidelines. It can be presumed that if a small, lightweight and effective device were available, the guidelines would change to reflect it.

There are commercially available manual and powered suction devices on the market, and several are specifically advertised for use in prehospital tactical or combat environments. However, a review of the manufacturers information, user reviews, and the limited literature on performance, combine to suggest that no device on the market meets even the most basic requirements of being small, lightweight, rugged, and demonstrating adequate suction performance. A fresh approach is needed, one that entails evidence-based requirements and specifications combined with engineering design and manufacture specially geared towards prehospital combat use.

Fortunately, existing guidelines, regulations and the literature do inform some aspects of prehospital suction relevant to tactical combat casualty care. This includes parameters for size and weight, suction performance, and robustness to survive the harsh battlefield environment. However, the data also expose significant gaps in knowledge and standards. While simple measures such as larger suction tip and tubing diameter improves suction performance, there are no standards for required vacuum pressures, flowrates or even the type of fluid and particulate matter that must be suctioned. Recommendations can be inferred from the literature, but the quality of supporting evidence is limited and subject to future research. In the interim, this report provides preliminary conclusions and recommendations regarding specific aspects of suction device performance and safety.

This report synthesizes the available information and proposes a series of findings and recommendations to improved airway management in the prehospital combat environment. The key findings and recommendations are listed in the appendices along with the complete list of observations and recommendations. The net result should be the establishment of a military program to establish clinically- and militarily-relevant standards for suction devices used in prehospital and combat casualty care environments. The device specifications outlined in this report should be adopted as a starting point for the development and engineering of a future prehospital combat

suction device. In turn, the services should support the advanced development of a future prehospital combat suction device and ensure robust, evidence-based design and testing. The ultimate goal is the establishment of a comprehensive military medical acquisition requirement and program to procure suction devices intended for prehospital combat care.

Dedication and Acknowledgements

This report is dedicated to the brave young men and women who selflessly serve on and off the battlefield as combat medics, corpsman, medical technicians, and other tactical medical providers. They and their patients deserve the best medical suction equipment that can be designed and optimized for the harsh, unforgiving environment in which they conduct the best possible medical care.

The author wishes to acknowledge the administrative and editorial skill, tireless effort, and patience of Heather Wantuch, MPA; and the technical advice, support and background information of Bruce Adams, MD.

Disclaimers

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Appendix A – Key Summaries and Recommendations

Executive Summary Points

- Airway obstruction is the second leading cause of preventable battlefield death.
- Suction is integral to airway management, which is given a high priority in TCCC guidelines.
- Suction was recently added as an intervention by the CoTCCC but remains deemphasized in textbooks and articles on prehospital combat casualty care.
- A DoD research agenda for the implementation and use of suction in the prehospital combat environment has not been established.
- Despite the recent inclusion in the guidelines, the recommendation for suction remains nonspecific and subject to availability of equipment; presumably it is because effective suction devices are not generally available in far-forward combat casualty care areas.
- If available in a lightweight, portable package, medical suction could save lives and improve airway management.
- Field users prioritized portability, strong suction, and ease of use as the key characteristics of a prehospital suction device. They also identified training is a gap area identified by users in using portable suction.
- Current commercially available hand-powered devices have insufficient performance to be recommended. Powered units offer better performance at prohibitive size and weight.
- There are no studies or expert opinions regarding the appropriate performance and size and weight of portable suction devices intended for prehospital combat care.
- Current standards and guidelines are intended for civilian use, and the supporting evidence is weak.
- Standard have not been validated clinically or operationally, and may be inadequate for emergency and prehospital care, and there is a lack of combat-relevant specifications.

• The military health system has not established a requirement for medical suction in the prehospital combat environment.

Executive Recommendations

- The CoTCCC should further emphasize the need for far-forward suction capability on their list of priorities.
- Combat medical providers should receive additional training beyond what is currently available in the manuals pertaining to airway securement and suction
- Textbooks and articles focused on combat casualty care should address suctioning of the airway.
- Establish clinically- and militarily-relevant standards for suction devices used in prehospital and combat casualty care environments.
- The DoD should establish a research and development agenda for suction that includes a capabilities gap and research priorities.
- Adopt the device specifications outlined in this report as a starting point for the development and engineering of a future prehospital combat suction device.
- Support the advanced development of a future prehospital combat suction device and ensure robust, evidence-based design and testing.
- Establish a military medical acquisition requirement and program to procure suction devices intended for prehospital combat care

Appendix B – All Section Summaries and Recommendations

Summary of the Background Sections

- Airway obstruction is the second leading cause of preventable battlefield death.
- Suction is integral to management of airway obstruction.
- The nondistended volume of the human oropharynx is limited, approximately 65 mL. Distension might increase this volume to 100 mL.
- Up to 400 mL/min of blood and a total of 1 L of emesis can contaminate the upper airways.
- Airway secretions and blood will likely be mixed with bone fragments, broen teeth and other solids, making suctioning imperative.
- Powered suction is not available in far-forward combat casualty care areas.
- Limited information suggests manual suction devices are not carried or used by medics because of limited capability to evacuate secretions.
- Large size and heavy weight of existing powered portable suction units precludes their carry by combat medics.
- Flowrate is proportional to the pressure and inversely proportional to the fluid viscosity.
- Flowrate is proportional to the tube length and the 4th power of radius or diameter of the tube.
- Flowrate standards based on free flow of air are unlikely to be relevant to the suctioning of secretions and blood.

Recommendations of Background Section

- Suction devices for prehospital combat casualty care should be capable of evacuating up to 1L of blood or emesis as well as debris such as bone fragments.
- Detailed fielding data on the types of suction in current use in far-forward combat environments would establish a clear baseline of current availability of suction devices.

- Combat casualty care provider (e.g., medic) user feedback would establish a clear baseline of prime user preferences.
- Flowrate performance should be measured using a fluid that has been shown to mimic the secretions and blood anticipated in a combat casualty.

Summary of the Tactical Combat Casualty Care (TCCC) Guidelines Section

- Airway management is given a high priority in TCCC guidelines.
- Management of secretions is emphasized with simple maneuvers such as recovery position emphasized.
- Suction is not mentioned as an intervention and the rationale for this is not specified.
- TCCC guidelines place a premium on small, lightweight and effective implements that can easily be carried by the combat casualty care provider; presumably current suction devices do not meet this threshold.

Recommendations of the Tactical Combat Casualty Care (TCCC) Guidelines Section

- Specifically query the Committee on Tactical Combat Casualty Care (CoTCCC) for their guidance on the use of suction.
- Specifically petition the CoTCCC to place the need for far-forward suction capability on their list of priorities.

Summary of the Suction in the Prehospital Environment Section

- Airway obstruction could lead to death in survivable cases.
- Clearing the airways is important for improved visualization.
- Suction devices could be needed in several cases including, but not limited to, obstructed airways, ventilatory failure, hypoxia, hypercarbia, burn injuries, and maxillofacial injuries.
- Military and tactical combat casualty care textbooks generally omit suction as a topic.
 - Select civilian medical textbooks make pertinent recommendations relevant to suction performance and characteristics.

- Large bore tips and tubing improve suction performance.
- Prolonged suctioning can lead to hypoxia.
- Hypoxia can be avoided with supplemental oxygen or pre-hyperventilation with oxygen.
- Clogging is a frequent problem but can be mitigated with traps.
- Direct visualization is important as blind suctioning can worsen airway obstruction.
- Equipment should be readily deployable for patient use.
- There are no studies or expert opinions regarding the appropriate size and weight of portable suction units intended for prehospital care.
- Similarly, there is no data on vacuum suction pressure or flow rates.
- The Yankauer tip and small diameter tubing is ineffective for emergency care suction.
- Large bore tips and tubing improve suction performance.
- There is not a standardized fluid viscosity to test suction performance but investigators have used a range of simulated emesis fluids. There are no standards on particulate matter but experts opine that removal capacity is an important attribute of suction devices.
- Container capacity is not studied but ranges from 140 1000 mL.
- Reliability of suction machines may be inadequate; there is no data on ergonomics.
- There is no information on the specific needs of the tactical environment including ruggedness, and light and noise abatement.

Recommendations of the Suction in the Prehospital Environment Section

- Combat medics should receive additional training beyond what is currently available in the manuals pertaining to airway securement and suction
- Textbooks focused on combat casualty care should address suctioning
- Recommendations from select civilian medical textbooks are relevant to tactical combat casualty care and should be considered for adoption
- Standards should be established relevant to combat casualty care for
 - Size and weight of portable suction machines
 - Suction tip and tubing diameter
 - o Minimum performance especially flowrates of validated simulated emesis t
 - Effluent container capacity
 - Reliability, ruggedness, and ease of use, and ergonomics
 - Noise and light abatement

Summary of the Considerations in Suction Safety Section

- Anatomic consideration in suction include
 - Prehospital suctioning generally involves the aerodigestive tract
 - Structures involved include the nasal and oral cavities, naso- and oropharynx, glottic structures, trachea, bronchi, and esophagus.
 - Anatomic locations with limited visualization are at greater risk of inadvertent cannulation and local trauma.
 - Pre-existing injury or trauma can increase the risk of anatomic disruption by suctioning.
- Physiologic considerations in suction include
 - Local stimulation from suctioning can increase local secretion production
 - Reflex responses can range from sneezing (nasal cavity), gagging (posterior tongue), coughing (trachea), or bronchospasm (bronchi).
 - More serious responses include vagal-mediated bradycardia, hypotension, hypoxia, and elevated intracranial pressure.
- Prolonged oropharyngeal suctioning can lead to hypoxia.
- Hypoxia can be avoided with supplemental oxygen or pre-hyperventilation with oxygen.
- Direct visualization is important as blind suctioning can worsen airway obstruction.
- There are no studies or expert opinions regarding the adverse effects or safety of suction units intended specifically for prehospital oropharyngeal suctioning.
- There is limited information to support the premise that rigid catheters are more likely to cause local tissue trauma than flexible catheters.
- There is no data to guide the maximal vacuum pressure or flow rates that can be safely applied for prehospital oropharyngeal airway suctioning.
- There is expert opinion on maximal vacuum pressure ranges for tracheal suctioning.
- Reports on gastric suctioning vacuum pressure maximums and duration of suction application have limited translation to prehospital airway clearance and may be misleading.

Recommendations of the Considerations in Suction Safety Section

• Training of prehospital combat casualty care providers should include the fundamentals of anatomy and physiology as they relate to the safety effects of upper airway suctioning.

- Standards should be established relevant to the safety of prehospital combat casualty care suctioning including:
 - Suction duration and necessity of adequate visualization of the catheter tip
 - Suction catheter rigidity and ability to cause trauma to airway structures
 - Maximal suction flow rate
 - Maximal vacuum pressure

Summary of the Commercial Suction Devices for Emergency and Combat Casualty Care Section

- Suction devices can generally be divided into three categories based on their power source: manual, electrical (battery) and fixed vacuum systems.
- Flowrate is proportional to the pressure and inversely proportional to the fluid viscosity.
- Flowrate is proportional to the tube length and the 4th power of radius or diameter of the tube.
- Flowrate standards based on free flow of air are unlikely to be relevant to the suctioning of secretions and blood.

Recommendations of the Commercial Suction Devices for Emergency and Combat Casualty Care Section

• Flowrate performance should be measured using a fluid that has been shown to mimic the secretions and blood anticipated in a combat casualty.

Summary of the Manufacturing Standards for Suction Devices for Use in Combat and Emergency Care Section

- Suction devices are FDA class II
- ISO 10079 provides detailed minimal standards for suction devices intended for use in emergency and prehospital care. They do not address combat casualty care.
- The evidence supporting minimum performance standards for suction devices is not strong. No standard has been validated clinically or operationally, and may be inadequate for emergency and prehospital care.

• The standards are not specific to battlefield medicine and are unlikely to be applicable to combat casualty care environments

Recommendations of the Manufacturing Standards for Suction Devices for Use in Combat and Emergency Care Section

- Establish clinically-relevant standards for suction use in prehospital and farforward combat casualty care environments.
 - Validate key performance characteristics such as suction flow rates and vacuum pressure.
 - Use test procedures reflecting real-world conditions in key areas such as the use of simulated vomit in volumes and consistencies that have been validated.

Summary of the Overview of Currently Available Suction Pump Devices

- There are a variety of suction pump devices on the market; however, very few of them claim to be useful for combat casualty care.
- This list is an overview of different types of suction pump devices that can be found through a web-based search for portable devices.

Recommendations of the Overview of Currently Available Suction Pump Devices

- There are few suction pump devices that state they can be used for prehospital combat use.
- Suction devices that do claim a prehospital combat use require independent validation and need to be adjusted for operability in a wider range of conditions with smaller dimensions and lighter weights.

Summary of the Military Requirements for Suction Devices Section

 There are no set military standards for suction units; however, there are important performance standards that need to be maintained when manufacturing a device, including weight, dimensions, portability, sterilization, air flow and vacuum pressure, collection canister volume, and whether the pump is battery operated.

- Suction devices must be built for use on different terrains and extreme weather situations. They should be rugged with an extended battery life that is easy to change without the need of a power supply for recharge.
- There are currently no devices built for use on the field specifically. The device used at aid stations and in hospitals is the Impact 326M, which is unsuitable for field use because it is heavy, bulky, and inoperable in extreme temperatures. The device used in ambulances is 325M, which is unsuitable for field use because it is heavy bulky, and has a short battery life.

Recommendations of the Military Requirements for Suction Devices Section

- Standards should be established relevant to universal use for military personnel with different needs. Some important design concepts to consider are:
 - Size, weight, and ergonomics
 - o Vacuum pressure similar to that in clinical use
 - o Battery operated and easily replaceable batteries
 - Rugged
 - Extreme weather conditions

Summary of the Proposed Specifications Section

- Users prioritized portability, strong suction, and ease of use as the key characteristics of a prehospital suction device.
- Training is a gap area identified by users in using portable suction.
- Physical, performance, engineering and functional specifications can be described for a suction unit designed for the prehospital combat environment.

Recommendations of the Proposed Specifications Section

- A suction device for prehospital combat use should be portable, powerful, and easy to use.
- Training of users should be included in the fielding and employment of prehospital suction.
- Physical, performance, engineering and functional specifications should be incorporated in requirements for device design of prehospital suction.

Appendix C – Key Task of the Report

Prepare a final report that integrates and articulates all the deliverables into a report summarizing the results and proposing future steps toward the development of a prehospital combat medical suction device. This is a requirements-based analysis derived primarily from combat data and supplemented with physiologic data, medical literature and industry standards.

Appendix D – Prior Reports in This Series

Contract Number: W81XWH-17-P-0022: Support the (TCCCR) Task Area for Research and Development of Medical Equipment to Clear and Maintain a Combat Airway

- 1. A Report on Deliverable One: Determine Required Performance Characteristics [of Suction] for Management Of Prehospital Combat Casualty Care Injuries. Report Author: Robert A. De Lorenzo, 22 February 2017
- 2. A Report on Deliverable Two: *Determine Safety Parameters [of Suction] (Primarily Maximum Vacuum Strength) That Will Not Injure Tissue.* Report Author: Robert A. De Lorenzo, 4 September 2017
- 3. A Report on Deliverable Three: *Determine a Standard Performance Test for Military Suction Device Use.* Report Authors: Priya Jain, R. Lyle Hood, Robert A. De Lorenzo, 20 September 2017
- 4. A Report on Deliverable Four: *Develop a specifications list for a portable, lightweight prehospital suction device*. Report Author: Robert A. De Lorenzo, 14 September 2017
- 5. A Report on Deliverable Five: *Evaluate Current Commercially Available Suction Pump Devices for Use in Prehospital Combat Care.* Report Authors: Priya Jain, R. Lyle Hood, Robert A. De Lorenzo, 20 September 2017
- A Report on Deliverable Six: Develop a Concept Design for a Ruggedized, Lightweight, Portable, Powered Handheld Suction Device. Report Authors: Ricardo Pescador, Michael Lasch, Yusheng Feng, Robert A. De Lorenzo, 27 September 2017

Appendix E – Technical Approach

Existing and projected (future) military medical requirements relevant to the expected combat and operational scenarios (such as prolonged field care) are identified. The required performance characteristics of a suction unit intended for prehospital combat casualty care is ascertained based on these anticipated operational scenarios. The key characteristics searched include vacuum suction flow rate, pressure, and capacity to evacuate the expected fluid/particle viscosity/size (e.g., saliva, blood, vomitus, mud, gravel, broken teeth) for management of prehospital Combat Casualty Care injuries. Source documents were extracted from 1980-present and analyzed for title content. If relevant, the article was reviewed in detail. Secondary references prior to 1980 were selectively searched based on the title and the likelihood of topical relevance. Specific sources searched include but are not limited to:

- Committee on Combat Casualty Care (CoTCCC)
- Medical literature using Medline or equivalent with search terms including
 - \circ Suction
 - o Vacuum
 - o Aspiration
 - o Airway, airway management
 - o Airway obstruction
 - o Modifier terms including safety, efficacy, and performance
- Engineering literature using Academic Search (EBSCO), or equivalent using similar search terms as above
- Defense Technical Information Center (DTIC)
- Retrievable information from conferences and meetings focused on combat casualty care, prehospital care, and airway management.
- Government standards including FDA
- Industry and government standards clearinghouses including ISO
- User surveys
- Informal feedback from subject matter experts

• Detailed review of web-based information, to include user reviews, of commercial suction device manufacturer websites

Where necessary to fill in information gaps, existing requirements were supplemented with proposed requirements vetted against local expert military and civilian medical consultations. UT Health San Antonio maintains a robust panel of US military experts in emergency medicine and prehospital care that can be consulted. Additionally, UT Health San Antonio is in close proximity to and maintains a healthy relationship with JBSA-Fort Sam Houston which is the US military's key hub of combat casualty care and trauma training, and UT Health San Antonio retains the ability to consult with the organizations and personnel within this installation as well as other US military installations worldwide.

The available information is organized, critically appraised, and synthesized into a narrative report that summarizes the performance characteristics for management of prehospital combat

Appendix F – Proposed Research Protocol to Test Suction Performance

PROTOCOL TITLE: Prehospital Upper Airway Suctioning Testing Methods – A Guideline for Performance Testing for Field-Use Military Suction Devices

BACKGROUND

Study Aim: The primary goal of this study is to explore key performance requirements regarding suction devices for military use in a prehospital combat casualty care environment. For purposes of this protocol, the following parameters and assumptions are established:

- Scope is limited to the clinical application of suctioning the oronasopharyngeal airway for purposes of airway clearance for basic life support in preparation for advanced airway procedures such as orotracheal intubation.
- Mechanisms of potential injury will focus on local trauma as a result of catheter mechanics and/or vacuum pressure effects and flowrates.
- Not examined are systemic or distant effects such as hypoxemia or atelectasis.

Background and Review of the Literature: Tactical airway management often determines survival in both trauma and medical patients. Skilled interventions often make the critical difference in survival for patients with actual or impending airway compromise. Managing airways in the tactical environment presents an additional level of unique and complex challenges for any emergency provider. Hazardous or confined spaces and hostile action inherently limit the ability to intervene with an artificial airway or assisted ventilation. Loss of patient airway in tactical and combat environments commonly occurs. The proximate cause can be direct trauma to the airway structures or indirectly from traumatic shock or brain injury and the subsequent loss of airway protective reflexes.

In the Vietnam War, 6% of all soldiers killed in action only had an airway obstruction. More recent conflicts, notably Operation Iraqi Freedom (OIF), have shown an increase in primary injuries to the airway. In OIF, 27% of wounded in action suffered injuries only to the head, neck or airway structures ¹⁴. This increase in airway trauma is likely due to the excellent torso protection of body armor and a subsequent diversion of injuries towards less armored areas such as the neck and face. The Registry of Emergency Airways at Combat Hospitals study (REACH) shows that prehospital cricothyrotomies are performed ten times more often on the battlefield as compared to civilian trauma systems. (5.8% vs. 0.5%)². A recent study highlights the high incidence of combat airway injury in combat maxillofacial trauma ¹⁴. In these and other trauma cases, airway management requires a low threshold for airway stabilization to include tracheal intubation and cricothyrotomy or tracheostomy. A major reason for this dramatically higher rate of surgical airways is poor visualization of the injured airway with current inadequate suction devices available on the battlefield.

Aspiration of as little as 25 mL (approximately ¼ mouthful) of vomitus can cause significant pulmonary aspiration injury, and a massive aspiration carries a mortality as high as 70%^{15,16}. Delays in suction can presumably increase the risk of aspiration, obstruction-related hypoxia, and make visualized intubation of the trachea impossible, so the availability and performance of suction can be viewed as essential. Despite this, there is a paucity of high-quality evidence on the techniques of suction. A 2009 Cochrane review on suctioning of patients revealed limited scope of data¹⁷. Practice guidelines from 2001 on hyperoxygenation, hyperinflation, use of a ventilator circuit adaptor and subglottic suctioning were validated. In the review, new evidence was identified with respect to indications for suctioning, open suction versus closed suction systems, use of medications and infection control. Virtually all of the data was focused on in-hospital suctioning of primarily mechanically ventilated patients. There were no high-quality reports focusing on prehospital or emergency care in the Cochrane review.

The combat experience of the last dozen years clearly demonstrates that airway obstruction is the leading cause of preventable combat casualty deaths behind only hemorrhagic shock. Between 6-10% of battlefield deaths could have been prevented with adequate airway management¹⁸. Because of vastly improved body armor and the enemy's shift towards direct fire and improvised explosive devices, the injury pattern today is much different than in previous wars. Airway management in this austere environment is notoriously difficult for many reasons but especially because of inadequate airway equipment.

Nonhuman primates are considered the standard model for the human airway, but these species are not available for study. Large animals such as swine approximate adult human cardiorespiratory physiology, but lack anatomic correlation. Smaller animals such as cats and ferrets have anatomy similar to small children, but this is not the population of interest. Given the overall experimental situation, the most pragmatic compromise is a young swine. It is available, cost-effective, and offers reasonable local tissue similarity in the areas of interest.

Significance: In comparison to the advances in many areas of prehospital equipment, the current suction devices on the market have not achieved the level of performance required in civilian prehospital care, let alone battlefield care. It is telling that a recent 5 page review article on an advances in technology and concepts in tactical combat casualty care, there was no mention of suction and had only this to say about airway management advances in general:

Airway Protection: A skill common to all physicians deploying on the MERT Medical Emergency Response Team (MERT)] is that they must be proficient at airway assessment and competent to definitively secure an airway if required. Generally, this takes the form of a rapid sequence induction using direct laryngoscopy. Several rescue devices are also available as alternatives or for use in a failed intubation such as supraglottic airways, optical laryngoscopes, and cricothyroidotomy. Perhaps reflecting the perceived lack of effectiveness of prehospital suction devices, Kozak reported on a survey of paramedics carrying suction equipment to the scene of medical aid calls less than 25% of the time, and once on scene, suction equipment was utilized on only 50% of advanced airway procedures. It seems the available off-theshelf devices do not possess the proper balance of tradeoffs between portability, effectiveness and cost to be effective in tactical care.

To help answer questions regarding suction device performance in the prehospital combat environment, a series of laboratory testing methods are proposed to test selected performance measures.

Literature Sources Searched: Literature review was completed with the assistance of Dr. DeLorenzo as well as database searches. The databases searched included: the Google Scholar database system, Pub Med/Medline, and the UTSA library database system.

Key Words of Search: Suction; Vacuum; Airway; Oropharyngeal; Nasopharyngeal, Tracheal; Performance Test; Obstruction; Intubation. Boolean combinations and fuzzy logic were used as allowed by the search engines.

Results of Search: The literature search revealed two published sources referring to military testing of suction devices. These methods are not standardized, and each source focused on a different subset of testing: mechanical, electrical, and environmental.

OBJECTIVE: Research and review current test methods outlined in ISO 10079 and published journal articles. Suggest improved methods to aid in suction devices meeting military requirements for field use in prehospital combat casualty care.

MILITARY RELEVANCE:

There is limited information on the types, if any, of portable suction units carried by combat medics in the far-forward combat area. Anecdotal information suggests that powered suction devices are simply too heavy to be carried in the combat medic's aid kit. Manual powered devices, while lightweight, offer limited capability and require the use of a hand or foot to operate, limiting efficiency of the provider. Fielding data from military logistics agencies on the number and types of suction units employed in the field is not available, and prior experience suggests even if obtained, the data shows only total purchases and not where and when fielded.

Existing portable suction standards are civilian-oriented, lack a detailed base of evidentiary support, and in any case do not satisfy the critical needs of combat casualty care. We propose a set of performance standards that meet the needs of prehospital combat casualty care that could support a future development of a portable suction design that meets all of the combat medic's needs.

MATERIALS AND METHODS

Experimental Design and General Procedures

<u>Materials</u>: Suction pumps already on the market 6 lbs or lighter that are batterypowered with the option to be recharged will be selected for performance testing to establish and standardize laboratory testing. If determined feasible, data collected during laboratory testing will be used to test and hypothesize suction pump use on the field.

Experimental Methodology: Record initial measurements such as weight, vacuum pressure, suction tubing diameter, and battery power before each performance test for each suction device. Record measurements after conducting each performance test as well for data analysis.

<u>Drop test for durability:</u> Drop each pump from a height of 2 m onto concrete, gravel, and uneven rocky surfaces. The laboratory personnel conducting the drop tests should remain constant for all test. Test each airway suction device n=3 times, recording measurements after each drop, to account for human error.

<u>Battery life test:</u> Run each device at minimum and maximum flow rate until the battery dies; record the run time. Record the length of time required to recharge the device to maximum battery power. Conduct this test n=30 times at minimum and maximum flow rate to account for battery wear time.

<u>Flow rate test:</u> Test different using different concentrations of food grade xanthan gum in 1 L of distilled water. Dissolve 3 g, 7 g, 10 g, and 15 g of xanthan gum in 1 L of water. A mixture of 15 g of 1 mm, 5 mm, 10 mm, and 20 mm beads each will be added to each mixture of xanthan gum to replicate the variety of debris sizes that could be found in vomitus fluids for maxillofacial injuries. To replicate the variety of hardness found in debris, a mixture of 20 g of corn kernels and 20 g of diced mushrooms will be added to each mixture of xanthan gum as well. The flow rate will be tested at the low and high vacuum pressures identified by the manufacturer for each suction device. Repeat each test n=3 times to verify how fast the flow rate is for each viscosity.

Environmental and electrical test methods including altitude, vibration, extreme temperature, and electric field tests will be conducted as discussed in Bruckart et al.⁵⁵ These testing methods are briefly laid out in the Suction Device Testing Methods Found in Literature subsection of the Manufacturing Standards for Suction Test Methods section of this document (page 10):

Environmental testing was conducted through wet suctioning of 550 ml of water under a variety of different conditions including altitude, vibration, temperature, and humidity. Altitude testing was conducted using a Tenney Engineering model 64S altitude chamber simulating 15,000 ft above sea level. Vibration testing was conducted using an Unholts-Dickey model TA115-40/CSTA system to determine how the device would work on a rotary wing aircraft during CSAR. Extreme temperature (-46 °C -71 °C) and humidity (0-20%) testing was conducted using a

Tenney Engineering model ZWUL-10107D Walk-in Controlled Environment Chamber. Another series of tests were conducted inside an electromagnetic interference chamber, wherein the device suctioned fluid while subjected to electric field strengths up to 10 V/m produced by radiotransmission emitters.

ISO 10079-1 guidelines will be followed for all other suction pump tests such as noise testing, overfill capability testing, and suction tubing degree of collapse⁹.

Data Analysis: This investigation is limited to laboratory testing. Data analysis will be calculated by comparing initial measurements taken for each device to the average measurements taken in each performance test.

STUDY PERSONNEL QUALIFICATIONS AND TRAINING:

All investigators / research personnel involved in this study should familiarize themselves with ISO 10079-1 test methods and should have laboratory access. At least one laboratory member is needed to conduct all drop tests for uniformity.

BIOHAZARD/SAFETY: All personnel participating in this protocol are currently enrolled in an Occupational Health and Safety Program, have received a risk assessment relative to protocol related hazards, and have been cleared to conduct all proposed activities listed. This is considered minimal risk because all tests will be conducted in a laboratory setting. All lab personnel must wear proper personal protective equipment (PPE) at all times. Because xanthan gum may cause irritation and is slippery when wet, PPE will include gloves and non-slip shoes.

Appendix G – Consumer Style Comparison Table of Suction Pump Devices

Suction Device Name	Weight	Dimensions	Flow Rate	Vacuum Pressure	Canister capacity	Price, \$	One time use?	Extra information	Website	
Aeros Tote-L- Vac Suction Unit	15.5 lbs	8 x 12 x 9.5 in	36 LPM	up to 550 mmHg	800 cc	599.99	Disposable waste container, tubing, suction tip		https://www.ohiomedical.com/literature/550150%20toteLvac%20Rev10.pdf	
Ambu Res-Cue Manual Suction Pump	0.507 Ibs	7.28 x 2.52 x 6.61 in	>20 LPM	225 to 450 mmHg	300 mL	61.37	Disposable waste container	overfill protection	http://www.ambu.com/corp/products/emergency_care/product/res- cue_pump-prod875.aspx	
Curaplex Manual Suction Unit	0.6 lbs	7.09 x 8.66 x 3.15 in	>20 LPM	450 mmHg	300 ml	61.99	Disposable waste container	Similar to the Laerdal V-Vac & Ambu Res-Que Pump	http://www.liveactionsafety.com/curaplex-manual-suction- unit/?gclid=CjwKEAjwytLKBRCX547gve7EsE4SJAD3IZV6y1LB5iYa2Qg4W QyZCOrRi8NAZGXhCP5Tj3sEGusrxBoCcLrw_wcB	
DeVilbiss 7305D Series Homecare Suction Unit	3.8 lbs	9 x 7 x 8 in	27 LPM	80-550 mmHg	800 or 1200 mL	467.99	800 ml canister disposable, 1200 ml reusable	tested to ISO 10079-1: 1999 standards	http://www.devilbisshealthcare.com/products/suction-therapy/homecar suction-unit	
Drive Medical VacuMax Suction Machine with Rechargeable Battery	5 lbs	12.4 x 9.8 x 8.1 in	25 LPM	150-530 mmHg	800 cc	408.06	No, clean with warm water; filter needs to be replaced if it gets wet		http://cdn.drivemedical.com/media/files/1701/18610_18615_Manual_V 30.pdf	
EM Innovations Suction Easy Pump	0.419 Ibs	10 5/8 x 11 7/8 in	not specified	100 mmHg	>1000 cc	35.22	yes		http://www.eminnovations.com/assets/images/Suction%20Easy%20Techr al%20Bulletin.pdf	
Emergency Aspirator from Vitalograph	0.882 Ibs	6.5 x 6.5 x 3.43 in	4.56 LPM	120-450 mmHg	240 ml	199.24	no, clean with cold liquid, ResusBag can be single-use	follows performance standards ISO 10079-2	https://vitalograph.co.uk/product/162440/aspirator	
Eurovac AC Suction Unit	17.6 lbs	16.9 x 8.66 x 14.6 in	45 LPM	575 mmHg	1 x 2 L	197.00	no, autoclave		http://www.narang.com/suction-machines-units/portable-suction- units/SU03a.php	
EuroLite Suction Device	9.92 lbs	11.8 x 5.51 x 13 in	12 LPM	600 mmHq	1 x 1 L	114.45	no, autoclave		http://www.aticomedical.com/suction-unit.html	
Gomco OptiVac AC/DC Portable Aspirator Model G180	11.4 lbs	16.8 x 7.5 x 9.4 in	>30 LPM	25-550 mmHg	1500 mL	692.00	disposable tubing, waste canister, and hydrophobic bacteria filters	tested to UL 60601-1	http://www.alliedhpi.com/images/z21-00-0001.pdf	
INSTAD Suction Pump	8.82 lbs	15.4 x 8.7 x 8.7 in	25 LPM	700 mmHg	1 x 1 L	203.20	no, autoclave	mechanical overflow safety	http://www.narang.com/suction-machines-units/portable-suction- units/SU47c.php	
John Bunn Vacutec 800	11.6 lbs	4.9 x 15.3 x 10 in	0-40 LPM	0-560 mmHg	800 cc	139.00	disposable waste canister	complies with EN60601	https://www.ventureresp.com/productcart/pc/John-Bunn-Vacutec-800-EV2- Portable-Aspirator-Suction-Unit-JB0112-016-p3175.htm	

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Suction Device Name	Weight	Dimensions	Flow Rate	Vacuum Pressure	Canister capacity	Price, \$	One time use?	Extra information	Website
EV2 Portable Aspirator Suction Unit								standards, automatic shut off	
Laerdal Compact Suction Unit LCSU 4 (300 mL) RTCA Certified	3.375 Ibs	7.3 x 10.3 x 3.2 in	30 LPM	50 to 550 mmHg	300 mL	590.00	disposable waste canister	certified for use in aircraft	http://www.laerdal.com/us/products/medical-devices/airway- management/laerdal-compact-suction-unit-lcsu-4/
Laerdal Suction Unit	8.9 lbs	12.4 x 13 x 6.3 in	>30 LPM	80-500 mmHg	1000 and 1200 mL	995.00	disposable waste canister and tubing		http://www.laerdal.com/us/products/medical-devices/airway- management/laerdal-suction-unit-lsu/
Laerdal V-Vac Starter Kit	0.644 lbs	13.5 x 2.5 x 4.8 in	70 LPM	170-380 mmHg	425 ml	125.00	Everything except handle		http://www.laerdal.com/us/products/medical-devices/airway-management/v- vac-manual-suction-unit/
LSP Advantage Emergency Portable Suction Unit	10.6 lbs	16.8 x 9.4 x 7.5 in	30 LPM	25-550 mmHg	800 cc	1,095.00	disposable tubing, waste canister, and hydrophobic bacteria filters	designed for use by emergency medical personnel in the field, within ambulances, and helicopters	http://www.alliedhpi.com/images/z90-00-0005.pdf
Medela Basic Aspirator	20.5 lbs	8.3 x 12 x 14.8 in	30 LPM	675 mmHg	5000 cc	2,626.50	no, sterilize		http://www.medela-healthcare.us/healthcare/products/surgical-suction/basic
Medela Dominant Flex Aspirator	20.5 lbs	8.3 x 12 x 14.8 in	40 to 60 LPM	713 mmHg	1000 to 5000 L	3,146.65	no, sterilize		http://www.medela-healthcare.us/healthcare/products/surgical- suction/dominant-flex
Medline Vac- Assist Portable Aspirator Suction Machine	12.1 lbs	14.8 x 9.8 x 6.8 in	>40 LPM	0-560 mmHg	800 ml	239.95	disposable waste canister		https://www.medline.com/product/Vac-Assist-Suction- Aspirator/Aspirators/Z05-PF01963#mrkSpec
MedSource Manual Suction Pump	1 lb	8.8 x 7.1 x 3.2 in	>20 LPM	450 mmHg	300 ml	51.98	disposable waste canister and tubing		https://www.4mdmedical.com/catalog/product/view/id/389307/?CAWELAID= 120141310000056386&utm_source=google&utm_medium=cpc&adpos=101 5&scid=scplpMSIMS-001PMP≻_intid=MSIMS- 001PMP&gclid=CjwKEAjwytLKBRCX547gve7EsE4SJAD3IZV60e83Od1mH VNijgSz2ZcVBmg4Rxlu86VJ46APYS6MMRoCNerw_wcB
Morgan Suction Pump	1 lb	3.15 x 2.75 x 1.4 in	>20 LPM	550 mmHg	300 mL	40.00	disposable waste container and tubing		http://morgansuctionpump.com/product-overview/
North American Rescue (NAR) Tactical Suction Device	0.46 lbs	9.75 x 3.75 x 3 in	not specified	100 mmHg	>1000 mL	37.99	yes		https://www.narescue.com/nar-tactical-suction-device
Portable Vacuum Absorb Pump Phlegm Suction Unit Suction Machine SXT-5A	8.82 lbs	16.1 x 8.1 x 16.5 in	>20 LPM	150-600 mmHg	1000 mL	224.00	no, autoclave		https://lifescienceequipment.science/phlegm-suction-unit-vacuum-absorb- pump-sxt-5a-new-potable-v-332187562446.html
Precision Medical PM66AC EasyGoVac Portable	3.25 lbs	8.6 x 6.3 x 8.02 in	>20 LPM	51-533 mmHg	800 or 1200 cc	399.99	800 cc disposable waste canister, 1200 cc reusable canister		http://www.precisionmedical.com/node/1677

UT Health San Antonio

Suction Device Name	Weight	Dimensions	Flow Rate	Vacuum Pressure	Canister capacity	Price, \$	One time use?	Extra information	Website
Aspirator Suction Machine									
Res-Q-Vac	0.5 lbs	4.49 x 7.1 x 2.15 in	20 LPM	>600 mmHg	300 mL	100.00	disposable waste canister		http://www.rmsmedicalproducts.com/products/medical-suction/res-q-vac/
Roscoe Medical Heavy-Duty Aspirator Suction Machine	5.7 lbs	14.3 x 6.9 x 8.3 in	28 LPM	550 mmHg	1000 cc	352.25	disposable waste canister		https://www.roscoemedical.com/wps/portal/c/products/!ut/p/a1/hc6xDoIwEA bgZ2Fg5a4aibp1IChg1EnoYsDUgiktKRVe32pcTBRv- y_fnztgkANT5dCl0jZalfKZWXl0stVxk8YE48NuhtskjkJCU4J7dKBwAH8MxX _9E7BJguQNJk4kwITU1evdgqpqvhTADL9yw01wN25dW9v1ax99HMcxEFo LyYOLbn38Vq1byH_INC1Od4Wcsio5z0AV0mA6g!!/dl5/d5/L2dBISEvZ0FBI S9nQSEh/?itemNumber=50004#.WXaUFljytEY
SAM E.P.S Portable Suction Unit	10.4 lbs	13.7 x 13 x 6.65 in	32 LPM	0 to 600 mmHg	1000 cc	1,010.00	autoclavable or disposable waste canister	can rotate collection canister up to 90 degrees for uneven terrain	http://www.mgeworldwide.com/Medical/SAMeps.htm
SSCOR QUICKDRAW Alkaline Powered Portable Suction, Olive Drab	2.6 lbs	10.5 x 4.5 x 4.35 in	>30 LPM	80 to 500 mmHg	300 cc/mL	679.00	disposable tubing and suction tip	designend specifically for military field use	http://www.sscor.com/quickdraw od portable suction.html
SSCOR VX-2	8.6 lbs	17 x 9 x 5.25 in	>30 LPM	50 to 525 mmHg	1200 cc/ml	1,175.00	disposable tubing and suction tip	compliant with SAE J3043 standards	http://www.sscor.com/S-SCORT_VX2_specs.html
S-SCORT 9 Suction	8 lbs	9.5 x 7 x 14 in	>30 LPM	120 or 525 mmHg	1200 cc/mL	829.00	disposable tubing and suction tip		http://www.sscor.com/S-SCORT_9_suction_unit.html
S-SCORT II Portable Suction Unit	10 lbs	7 x 7 x 14 in	>30 LPM	120 or 525 mmHg	1200 cc/mL	749.95	disposable tubing and suction tip		http://www.sscor.com/S-SCORT_II_specs.html
S-SCORT III Portable Suction Unit	7 lbs	8 x 7 x 11 in	>30 LPM	120 or 525 mmHg	1200 cc/mL	607.00	disposable tubing and suction tip		http://www.sscor.com/S-SCORT_III_suction_unit.html
S-SCORT Ten	10 lbs	9.5 x 7 x 14 in	>30 LPM	120 or 525 mmHg	1200 cc/mL	1,143.00	disposable tubing and suction tip		http://www.sscor.com/S-SCORT_10_specs.html
Vacu-Aide Portable Compact Suction Unit	3.37 lbs	7.25 x 7.25 x 6.75 in	27 LPM	50-500 mmHg	725 ml	540.00	reusable, autoclave	meets ISO 10079-1:1999 standards	http://www.devilbisshealthcare.com/files/LT-2016_RevF_Vacu- Aide_Compact_FINAL_100114_Web.pdf

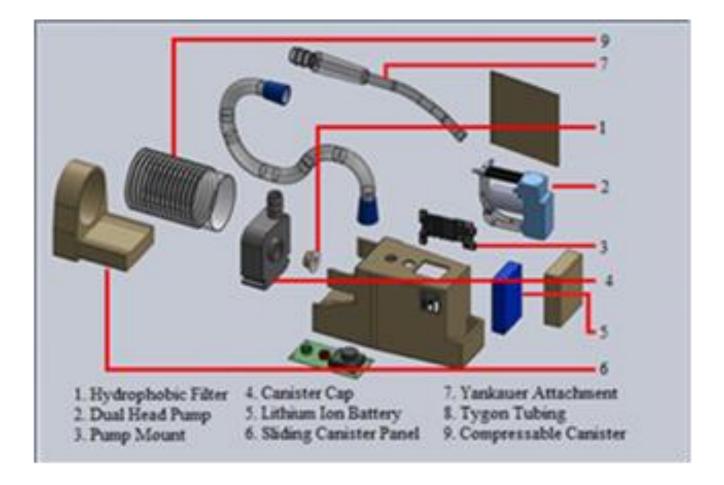
Appendix H – Web Links for Images for Consumer-Style Report

- 1. Aeros Tote-L-Vac Suction Unit <u>https://d2ch1jyy91788s.cloudfront.net/buyemp/images/product/Tote-L-Vac-Suction-Unit-18117903-400_300.png</u>
- Ambu Res-Cue Manual Suction Pump <u>https://d1xxg88b45bl3b.cloudfront.net/Files/Billeder/Product%20Images/Rescue</u> <u>PumpLarge.jpg</u>
- 3. Curaplex Manual Suction Unit http://d1xwdusrophmb1.cloudfront.net/btm/265/10369.jpg
- 4. DeVilbiss 7305D Series Homecare Suction Unit http://www.devilbisshealthcare.com/images/products/homecare-suction1.jpg
- Drive Medical VacuMax Suction Machine with Rechargeable Battery <u>https://smhttp-ssl-</u> <u>51929.nexcesscdn.net/media/extendware/ewimageopt/media/inline/15/b/vacuma</u> <u>x-suction-machine-with-rechargeable-battery-efd.jpg</u>
- EM Innovations Suction Easy Pump <u>http://d1xwdusrophmb1.cloudfront.net/btm/265/590412.jpg</u>
- 7. Emergency Aspirator from Vitalograph <u>https://vitalograph.com/imageLibrary.axd?2827</u>?
- 8. Eurovac AC Suction Unit <u>http://www.narang.com/suction-machines-units/portable-suction-units/images/suction-unit-eurovac-su03a.jpg</u>
- EuroLite Suction Device https://www.hospytek.com/images/phpThumb.php?src=1919.jpg
- 10. Gomco OptiVac AC/DC Portable Aspirator Model G180 <u>https://cdn2.bigcommerce.com/server3500/55fb4/products/17722/images/15004/</u> <u>url__97343.1365872019.1280.1280.jpg?c=2</u>
- 11.INSTAD Suction Pump <u>http://www.narang.com/suction-machines-units/portable-suction-</u> units/images/suction-unit-instad-ac-su47c.jpg

- 12. John Bunn Vacutec 800 EV2 Portable Aspirator Suction Unit https://www.ventureresp.com/productcart/pc/catalog/jb0112-016copy_263_general.jpg
- 13. Laerdal Compact Suction Unit LCSU 4 (300 ml) RTCA Certified <u>https://ds5cvxtqu2rt0.cloudfront.net/media/catalog/product/cache/1/image/265x/9</u> <u>df78eab33525d08d6e5fb8d27136e95/5/7/57931_w.jpg</u>
- 14. Laerdal Suction Unit <u>https://cdn0.laerdal.com/cdn-4aeced/globalassets/images--</u> <u>blocks/products/therapy-products/lsu/_bro0184.jpg?w=705&h=396&mode=crop</u>
- 15. Laerdal V-Vac Starter Kit http://www.laerdal.com/images/S/ACYITLZX.jpg
- 16.LSP Advantage Emergency Portable Suction Unit https://images.mooremedical.com/450x450/74031.jpg
- 17. Medela Basic Aspirator <u>https://cdn.shopify.com/s/files/1/1046/1086/products/medela-basic-aspirator_grande.jpg?v=1485538643</u>
- 18. Medela Dominant Flex Aspirator <u>https://cdn.shopify.com/s/files/1/1046/1086/products/medela-dominant-flex-aspirator_grande.jpg?v=1478027543</u>
- 19. Medline Vac-Assist Portable Aspirator Suction Machine <u>https://www.medline.com/media/catalog/CA05/CA05_09/CA05_09_02/PF01963/</u> <u>PF01963_PRI03.JPG</u>
- 20. MedSource Manual Suction Pump <u>https://smhttp-ssl-</u> <u>51929.nexcesscdn.net/media/extendware/ewimageopt/media/inline/c6/a/manual-</u> suction-pump-15c.jpg
- 21. Morgan Suction Pump <u>http://morgansuctionpump.com/wp-content/uploads/2014/12/morgan-pump-new-</u> <u>web-300x197.jpg</u>
- 22. North American Rescue (NAR) Tactical Suction Device <u>https://www.narescue.com/media/catalog/product/cache/1/image/1200x1200/9df</u> <u>78eab33525d08d6e5fb8d27136e95/1/0/10-0018_a_1.jpg</u>

- 23. Portable Vacuum Absorb Pump Phlegm Suction Unit Suction Machine SXT-5A https://i.ebayimg.com/images/g/rmUAAOSw1vIUwNDx/s-I300.jpg
- 24. Precision Medical PM66AC EasyGoVac Portable Aspirator Suction Machine <u>http://www.precisionmedical.com/sites/www.precisionmedical.com/files/images/P</u> <u>M66/pm66lir.left.png</u>
- 25. Res-Q-Vac https://www.quadmed.com/prodimage/ProductImage/800/ea0779a4-8f20-452ab896-f2bd505a2557.jpg
- 26. Roscoe Medical Heavy-Duty Aspirator Suction Machine <u>https://www.rehabmart.com/include-mt/img-resize.asp?path=/imagesfromrd/ros-</u> <u>cf608.jpg&newwidth=650&product_name=Roscoe%20Medical%20Heavy-</u> <u>Duty%20Aspirator%20Suction%20Machine</u>
- 27. SAM E.P.S. Portable Suction Unit <u>http://www.mgeworldwide.com/Medical/Pictures/SAM%20eps%20outside%20em</u> <u>ergency%20portable%20suction.jpg</u>
- 28.SSCOR QUICKDRAW Alkaline Powered Portable Suction, Olive Drab http://www.sscor.com/images/Q8010-Quickdraw-OliveDrab-Black-Cap-400px.jpg
- 29. SSCOR VX-2 http://www.sscor.com/images/VX-2-7700-400px.jpg
- 30. S-SCORT 9 Suction http://www.sscor.com/images/NINE-7855-400px-white.jpg
- 31.S-SCORT II Portable Suction Unit http://www.sscor.com/images/II-7792-400px.jpg
- 32.S-SCORT III Portable Suction Unit http://www.sscor.com/images/III-7824-white-400px.jpg
- 33.S-SCORT Ten http://www.sscor.com/images/TEN-main-7856-400px.jpg
- 34. Vacu-Aide Portable Compact Suction Unit http://www.devilbisshealthcare.com/images/products/vacuaide1.jpg

Appendix I – Concept Design Schematic Drawing



Appendix J – Parts List for Design Concept

end Comp	pany	Miscelane	eous parts					
Amazo	zon	Item No.	Part Number	Description	Quantity	Price/ par	t Tof	tal Price Web lin
Spark	(fun	1	N/A	Soldering Station: X-Tronic Model #3020-XTS Digital LED Display	1	\$ 49.8	0\$	49.80 https://v
Adafri	ruit	2	N/A	SE MZ101B Helping Hand with Magnifying Glass	2	\$ 6.2	6\$	12.52 https://v
Mouse	ser Electronics	3	N/A	uxcell® 900M-T-LI 0.8mm Point Diameter Soldering Solder Iron Tips 5 Pcs	3	\$ 4.3	1\$	12.93 https://v
McMa	aster Carr	4	N/A	Rosin Paste Flux #135 in a 2 oz Jar	1	\$ 10.1	1\$	10.11 https://v
		5	N/A	Sywon 1.0mm 100g Lead Free Solder Wire Tin Reel with Rosin Core, Sn 99% Ag 0.3% Cu 0.7%	1	\$ 25.9		25.99 https://v
		6	N/A	Fluke 179/TPAK True RMS Digital Multimeter with TPAK Meter Hanging Kit, 50 Megaohm Resistance, 1000V AC/DC Voltage, 10A AC/DC Current	1	\$ 404.5	0 5	404.50 https://v
		7	N/A	Feedback Sports Table Top Digital Gram Scale (Red, 3-Kilogram)	1	\$ 45.5		45.58 https://v
		8	N/A	Lock&Lock 41.6-Cup 338-Fluid Ounce Rectangular Container with Handle and Tray, Tall	2	\$ 41.0		82.00 https://v
		9	N/A	Elence 350 Piece Pre-formed Jumper Horn Kink (Win Kit	2	\$ 14.4		28.98 https://v
		10	N/A	Remington Industries 2010L0075TRKITULI00720 AWG Gauge Stranded Hook-Up Wire Kit, 300V, 0.0320" Diameter, 25', 3" Length		\$ 26.3		26.31 https://v
		10	N/A	Remington Industries 20ULID075TRKIT ULID0722 AVG Gauge Strander Hook up Wire Kit, 300V, 0.0253" Diameter, 25, 5" Length	1	\$ 20.6		20.61 https://v
		11	N/A	Remingion muscries zzelecen za work dauge stranded note op wrie kit, soor, duzs channeler, zs, s tengui	1	\$ 26.9		26.99 https://v
		12	N/A	Paravise Moder 21 Julio 1 Minister Vise CRIMPING PLERS 10° by INVIN MFrantho 2078310	1	\$ 18.7		18.77 https://
						7 -0		1 1 1 1
		14 15	N/A	IRVIN VISE-GRIP Multi-Tool Wire Stripper/Crimper/Cutter, 2078309	1			15.58 https://
			N/A	URBEST* 530 Pcs 2:1 Heat Shrink Tubing Tube Sleeving Wrap Cable Wire 5 Color 8 Size	1	+		10.29 https://
		16	N/A	Darius 480 Pcs Premium Quality Assorted Insulated Electrical Wire Terminals Crimp Connectors Spade Set	1	\$ 23.0		23.00 https://
		17	N/A	Hakko CHP-170 Micro Soft Wire Cutter, 1.5mm Stand-off, Flush Cut, 2.5mm Hardened Carbon Steel Construction, 21-Degree Angled Jaw, 8mm Jaw Length, 16 Gauge Maximum Cutting Capacity	1	\$ 5.9		5.99 https://
		18	N/A	Kuman 120pcs Breadboard Jumper Wires For Arduino Raspberry Pi 40pin Male to Female, 40pin Male to Male, 40pin Female to Female Ribbon Cables Kit Multicolored Pack K45	1	\$ 9.9		9.99 https://
		19	N/A	CO RODE 300pcs 3mm 5mm Assorted Color 2pin Diffused LED Light Emitting Diodes Electronic Parts with 5 Colors	1	\$ 14.9		14.99 https://
		20	N/A	E-Projects EPC-103 16 Value Resistor Kit, 10 Ohm - 1M Ohm (Pack of 400)	1	\$ 11.3		11.33 https://
		21	N/A	100 pcs Rectifier Diode Tape kit,1N4148 1N4007 1N5819 1N5399 FR107 FR207 1N5408 1N5822	1	\$ 2.7		2.71 https://
		22	N/A	Sunkee S9012 S9013 S9014 A1015 C1815 S8050 S8550 2N3904 2N3906 A42 A92 A733,17valuesX10pcs=170pcs,Transistor Assorted Kit	1	\$ 9.9	9 \$	9.99 https://
		23	N/A	10 pcs UA741 LM741 17741 IC OP AMP COMPENSATED DIP-8	1	\$ 6.5	8 \$	6.58 https://
		24	N/A	uxcell 60 Pcs 8 Pin 2.54mm Pitch DIP IC Sockets Adaptor	1	\$ 3.3	4 \$	3.34 https:/
		25	N/A	50 Pcs 5mm Round Head Common Cathode RGB Light LED Emitting Diodes	1	\$ 2.5	6 \$	2.56 https:/
		26	N/A	Leather / Vinyl Restorers (ORGANIZER, PORTABLE, 15X11X3IN) 1 Each / Each	1	\$ 53.9	5 \$	53.95 https:/
		27	N/A	VISHAY SFERNICE P16NP103KAB15 POTENTIOMETER CERMET, 10KOHM 10% 1W	2	\$ 17.0	0 \$	34.00 https:/
		28	N/A	Energizer Ultimate Lithium Battery, 2 Count	4	\$ 12.9	7 \$	51.88 https:/
		29	N/A	Sics Replacement Double Wire Lead 9V Battery Box Case Holder Connector		\$ 6.6		19.80 https://
		30	N/A	uxcell* 10 Pcs Faux Leather Housing T Type Clip Connector for 9V Battery	-	\$ 4.0		4.04 https://
		31	N/A	Dirmail 57 XW DC-DC Adjustable Step-down Module with Voltmeter		\$ 7.9		15.98 https:/
		32	N/A	Lavota BYSK Octoberagistaale Stephoomi moude while outline effective and a state of the stephoomi moude while outline effective and the stephoomi moute while outline effectiv	1	\$ 76.4		76.49 https:/
		33	N/A	Levon to 23 Sona to Mingraber Set			9 \$	
		34	1				9 \$ 6 \$	
			N/A	Elence Banana to Banana Test Lead Set				6.46 https:/
		35	N/A	Elenco Electronis TL-16 Banana to Large Alligator Test Lead Set		\$ 6.9		6.99 https:/
		36	PRT-00112	Breadboard - Classic	-	\$ 9.9		9.95 https:/
		37	PRT-12614	Breadboard - Giant		\$ 19.9		19.95 https:/
		38	PRODUCT ID: 321	Large Alligator Clip Test Lead (set of 10)		\$ 4.9		4.95 https:/
		39	PRODUCT ID: 1008	Small Alligator Clip Test Lead (set of 12)		\$ 3.9		3.95 https:/
		40	PRODUCT ID: 1359	SMD Component Testing Tweezers	1	\$ 27.9		27.95 https:/
		41	PRODUCT ID: 1597	Professional Silicone-Tip Solder Sucker		\$ 17.5		17.50 https:/
		42	PRODUCT ID: 422	Fine tip curved tweezers - ESD safe - 120mm	1	\$ 3.9		3.95 https:/
		43	PRODUCT ID: 807	Dual H-Bridge Motor Driver for DC or Steppers - 600mA - L293D	3	\$ 2.9	5\$	8.85 https:/
		44	PRODUCT ID: 2203	IC Socket - for 16-pin 0.3" Chips - Pack of 3	1		5\$	0.95 https:/
		45	PRODUCT ID: 421	Fine tip straight tweezers - ESD safe - 135mm	1	\$ 3.9	5\$	3.95 https:/
		46	PRODUCT ID: 723	Adafruit Perma-Proto Mint Tin Size Breadboard PCB	2	\$ 5.9	5 \$	11.90 https:/
		47	PRODUCT ID: 591	Adafruit Perma-Proto Super Pack!	1	\$ 34.9	5\$	34.95 https:/
		48	PRODUCT ID: 1214	Adafruit Perma-Proto Small Mint Tin Size Breadboard PCB - 3 pack	1	\$ 7.9	5 \$	7.95 https:/
		49	71-CMF5038K300FHEB	Metal Film Resistors - Through Hole 1/4W 38.3Kohms 1%	10	\$ 0.4		4.60 http://
		50	576-0313002.HXP	Inclaim reasons mough for 2 years and a second se	4	\$ 1.0		4.08 http://
		51	11355T84	Durable Nylon Extra-Grip Barbed Tube Fitting, Straight for 1/2" Tube ID x 3/8 Male Pipe Size, packs of 10		T	6 \$	4.76 http://
		52	5372K118	Durable Myton Extra-Grip Barbed Tube Fitting Straight for 3/8" Tube IDX 3/8 Male Pipe Size, Packs of 30 Durable Myton Extra-Grip Barbed Tube Fitting Straight for 3/8" Tube IDX 3/8 Male Pipe Size	1	\$ 4.7 \$ 4.7		4.76 http://
		52	5372K118					4.71 http://
				Durable Nylon Extra-Grip Barbed Tube Fitting Straight for 1/2" Tube ID x 1/4 Male Pipe Size	1			
		54	5372K117	Durable Nylon Extra-Grip Barbed Tube Fitting Straight for 3/8" Tube ID x 1/4 Male Pipe Size	1	\$ 4.5		4.54 http://
		55	5195T78	Abrasion-Resistant Polyurethane Tubing for Water, 1/2 " ID, 3/4" OD 25 ft	1	\$ 76.2		76.25 http://
		56	5195T82	Abrasion-Resistant Polyurethane Tubing for Water, 3/4 " ID, 1" OD 10 ft	1	\$ 30.7		30.70 http://
		57	53055K145	Sanitary White PVDF Barbed Tube Fitting Reducing Straight for 3/4" x 1/2" Tube ID	1	\$ 4.1	.9 \$	4.19 http:/

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