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Abstract
Most developing world hospitals do not possess operating suction machines; yet, they are required for many procedures. The main problems are the lack of available parts, the cost of a replacement unit, and dependence on consistent electricity. We designed an aspirator that uses a water jet eductor, constructed with low cost, locally available materials, that produces suction when connected to a garden hose and water line. We achieved maximum vacuum pressure of 58 KPa (gauge) and pulled maximums of 20 lpm of air or 3.2 lpm of water.

Background Information
Aspirators are used in a clinical setting to remove blood, mucus, and other bodily fluids from patients. Aspirators are common and critical tools in the operating room. By removing fluids they allow surgeons to see what they're working on. The key components of an aspirator are a disposable collection tip and a removable collection container. United States hospitals use wall suction, where tubing and a collection chamber are connected to a wall outlet powered by a large central vacuum pump.

Most aspirator applications require high suction, such as the removal of mucus and blood. However, there exist a few special cases where low flow rates and suction are required. Gentle intermittent suction is required for the removal of gastrointestinal obstructions, since powerful suction would pull the coelom wall and block the aspirator tip. Another procedure requiring low-suction is meconium aspiration, when the earliest stool of an infant is removed to prevent meconium aspiration syndrome. Meconium aspiration syndrome (MAS) occurs when infants take meconium into the lungs before or during delivery and causes the infant to develop pneumonia, so low levels of suction are required to remove this health risk while avoiding suction of fragile fetal tissue. So while high suction is needed in most procedures, variable power controls are common in order to accommodate these special low-suction procedures.

This project is a special case for the design of an aspirator. The purpose of the project is to make instructions for the construction of an aspirator from materials which would be locally available in a developing world country. The electrical power for these hospitals is produced by generators which are unstable and frequently malfunction. Trained medical staff is also limited, so it is important the device is simple to use even by untrained personnel. Aspirators are usually powered by 120 VAC outlets, batteries, or a combination of both.

Engineering World Health (EWH) is a non-profit organization of engineers which evaluates the needs of hospitals in developing world countries, then accommodates them in providing them with refurbished medical equipment. They also help in training the medical staff in the use and maintenance of the equipment in order to improve the capabilities of the hospital for years to come (“Engineering World Health,” 2008).

Project Specifications
In order for this device to be relevant for a clinical setting in the developing world, the design must follow several criteria. First and foremost, the device must safely remove fluid from the surgical field. Additionally, the device must be constructed and maintained by locally available materials. Specifically, there are several technical benchmarks which this design will have to achieve. The device must reach an adjustable suction of up to -550 mmHg (gauge). Also, the device must be able to evacuate 15 L/min through the suction tip. These two standards bring an important facet of the design into focus. The suction strength of the design will determine whether or not the pressure benchmark is reached, while the rate at which it can replenish the vacuum will determine the flow through the tip. In order to achieve the vacuum required, some sort of energy transducer (i.e. pump) will need to be used. As a

reliable power grid is not available in the developing world, the device must run off of a 12 VDC battery. Since surgeries can last for up to eight hours, the energy drawn from the device must not exceed the energy rating of the battery. Although the device will be designed to last for an entire surgery, a superior design will include a mechanism to create a vacuum in the event of power loss.

Since the device will be implemented in the developing world, the materials from which the device will be built must be "locally available." For the purpose of this design, locally available materials will be limited to salvaged car parts, UW-SWAP materials, and basic hardware store purchases. Also, the ergonomics of this design will be important since it will be used in an operating room. The operating room environment requires a low profile device which does not introduce pollutants into the air. While no specific size or weight restrictions are imposed on the device, the device should not interfere with operating room use. Preference is for a device that takes up minimal floor space, resulting in it likely being taller than it is wide. If the device weights more than 10 kg, it should include some means for movement inside the hospital such as wheels. The device should include an autoclavable collection vessel and suction tip.

These criteria define significant restraints for the design process, but will ultimately produce a practical and safe device to use within the clinics of the developing world. The device, if chosen by EWH, will be used in surgeries to save countless lives.

Current Devices

Ignoring irrelevant large wall suction units due to low-power requirements of this project, there are a handful of portable aspiration units. The aspirator in **Figure 1** is made by Supreme Enterprises. It has a capacity of -710 mmHg (gauge) ± 10 at 25-30 L/min. It is a 180 watt device which runs on 110 V AC. Although it is small and portable it still requires wall power ("Portable suction units," 2008). **Figure 2** is a 12 VDC battery operated suction pump. It is a diaphragm type pump and can produce a variable vacuum between 50-525 mmHg (gauge) and achieve airflow rates as high as 30 L/min. However the unit costs $700 ("Portable vacuum aspirator," 2008). SSCOR also produces less powerful models as inexpensive as $300, still well outside of the proposed materials price of $100 set by Engineering World Health. These aspirators are inaccessible to developing world countries because of their price, and they are difficult to maintain since specialty spare parts are hard to obtain when the devices fail. In these situations, advanced circuitry and specialty parts make these devices practically irreparable.

Figure 1. Portable suction unit from Supreme Enterprises. ("Portable suction units," 2008)

Figure 2. Battery operated portable suction unit manufactured by SSCOR. ("Portable vacuum aspirator," 2008)

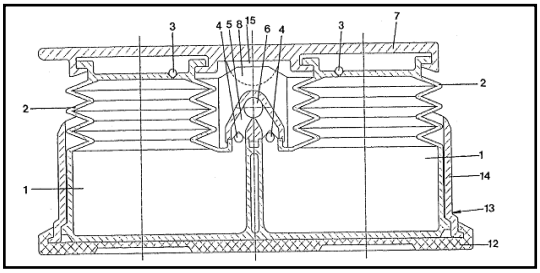

Figure 3. *(U. S. Patent No. 5,934,888) "Aspirator Pump"* This design makes use of a bellows-style design to create suction in both chambers, labeled "1."

In a search for patents, one seemed the most applicable to this project. U.S. Patent No. 5,934,888 describes a human powered aspirator pump as shown in **Figure 3**. It functions by alternating the compression and expansion of the two chambers by stepping on them, and creating a vacuum with the help of one way valves. The two spaces are connected through a common manifold with a connection for the suction tube of a catheter. One way valves at the entrance of each large hollow space close when the pressure in the hollow space is greater than the pressure in the common manifold. This design is relevant because it produces suctions without the need for electric power. However the goal of this project is to create an aspirator from salvaged or locally available materials. A device like this would need to be custom manufactured.

Previous Design

Developing suction system intended for the developing world has actually been an ongoing project for the Biomedical Engineering Department at the University of Wisconsin-Madison. Last semester's device was a piston-based design using an adapted car heater fan, as shown in **Figure 4**. The fan is powered by a standard 12V battery and is connected to the piston using a pin connection, which uses two rigid coat hanger arms to convert the radial motion of the fan motor into linear motion. One arm rotates with the motor while the other moves back and forth along a straight slot, cut through a piece of wood, which is dimensioned to be the stroke length corresponding to the diameter of the fan motor (**Figure 5**). Through the linear motion of the piston, air is alternately drawn and expended through two check valves at either end of a PVC pipe. The valves are oriented such that when the piston is pushing air in one direction, one valve opens while the other is pulled shut. The inlet check valve connects to a collection chamber and an autoclavable suction tip.

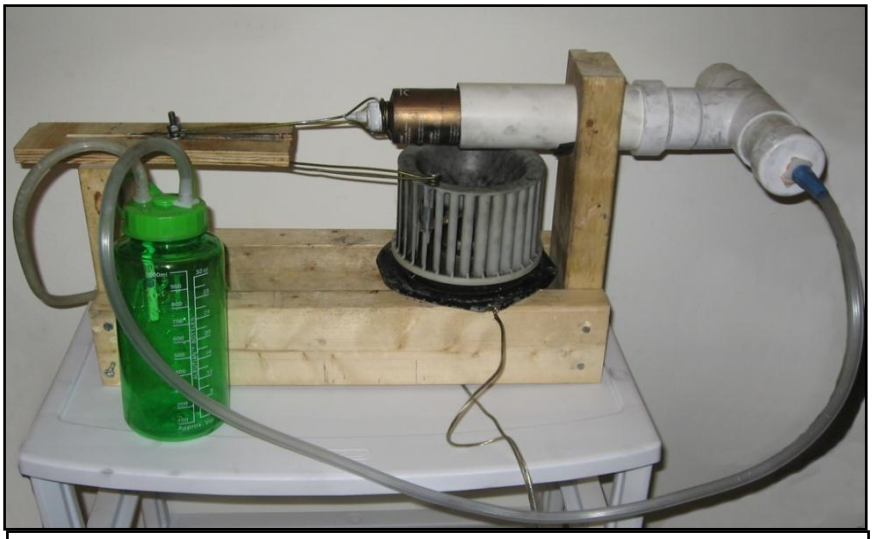

Figure 4. The image above displays the final design, including the fan motor, piston arrangement, and collection flask.

The advantages of the design were that it was very cost-effective, compact, and used locally-available materials. However, testing results indicated it was unable to draw sufficient volumes of fluid or air to meet product specifications nor could it generate sufficient vacuum pressure. Air flow was tested using a clinical flow meter and was found to be approximately 12 L/min, while liquid flow was tested by measuring water displacement over time and the average value was approximately 1.51 L/min. A pressure test revealed the device was capable of drawing 76 mmHg instead of the requisite 550 mmHg, leaving room for improvement in a new design.

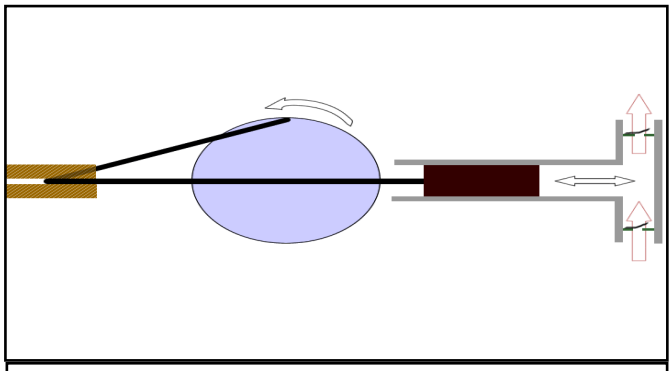

Figure 5. As the fan motor rotates, it forces the motion of a pin-connected rod along a wooden slot. This linear motion along the slot actuates the piston, which alternately suctions and expels air through a section of PVC pipe.

Specific features that contributed to the inefficiency of the design included the leaky one-way valves, which were made from pieces of flimsy inner-tube rubber and tin can lids, in addition to the power inefficiency, which was largely caused by the necessity for radial to linear motion conversion rather than one type of motion. Finally, the utility of the piston was limited by its failure to fit snugly in the PVC tubing, despite the use of a graphite lubricant. The lubricant itself was messy and was unable to maintain a uniform seal around the piston walls. In our survey of the design, we realized that it would be difficult to modify the existing components, so we chose to pursue significantly different design approaches.

Final Design

Several potential mechanisms were considered to overcome the shortcomings of the previous design, and they are more clearly outlined in **Appendix B**. Ultimately, we developed a water jet educator to accomplish the design requirements, with several important components to allow for its functionality. A water jet eductor was created to remove air from the system and create a vacuum. The two most important factors in the design of the aspirator were the force with which it removes water from the system (the vacuum pressure) and the rate at which the air is removed (free air flow rate). Next, there will be a description of each component in the aspirator system.

Collections vessel

The collection vessel is a modified one liter Nalgene bottle, into which two holes have been cut. Tubing barbs were then attached into the holes. One barb connects to 3⁄8" suction tubing from the collection vessel to the vacuum source. The other connects to the suction tip. Inside the bottle, a short section of 3⁄8" tube comprises part of the one-way valve for the effluent coming from the patient. At the bottom of this tube, a surgical glove finger is attached with a small hole cut into it. The glove finger is flexible enough to expand and allow suction to occur under vacuum conditions, but when positive pressure is introduced into the vessel the glove collapses, covering the hole and prevents fluid backflow to the patient – an important aspect to patient safety. Since the bottle is made from polycarbonate it is extremely durable and can be autoclaved. **Figure 6** shows the collection vessel assembly.

Figure 6. The assembly of the collection vessel with the inclusion of the one-way valve.

Suction tip

The suction tip was fashioned by assembling a 5 mL and a 1 mL pipette tips, both of which have been modified. **Figure 7** shows an exploded view of the suction tip assembly. The narrow end of the tip has been removed, and the larger tip is fenestrated. When assembled, the smaller suction tip is inserted into the larger, and both are

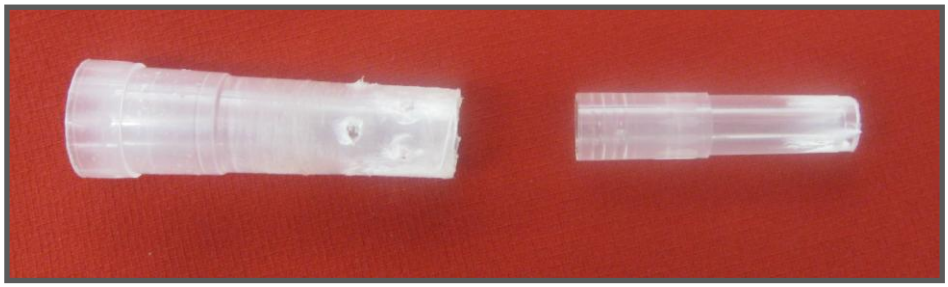

Figure 7. The portion of the tip assembly on the righthand side fits on within the portion on the left. Aspirate flows through the pores in the tip component on the right.

attached to the suction tubing, since one fits inside the tubing and one fits outside of it. The fenestrations prevent soft tissue from being exposed to the full vacuum. If the full vacuum force (60 kPa) was concentrated on one area, tissue damage would likely occur. The fenestrations allow either air or fluid to be aspirated while a portion of the tip is occluded.

Water Jet Eductor

The source of the vacuum for this apparatus is a water jet eductor. This is fashioned from a garden hose spray nozzle, a PVC Tee, and a several connectors. A more precise list of components and associated costs can be found in **Appendix C**. The spray-nozzle is epoxied to the ¾" PVC Tee, such that the jet is directed into the tee (**Figure 8**).

Figure 8. The nozzle is inserted so that the jet portion is located at the interior of the tee.

Figure 9. The water bottle has been manipulated to ensure that the educator assembly is perpetually submerged in water.

The side outlet of the tee is threaded and connected to a ⅜" barb, which connects to the intermediate tubing. The outlet of the tee has two adaptors, which connect to ½" PVC. It is important that the outlet tube be completely filled with water to prevent air entrainment from the outlet of the PVC Tee instead of the suction port. In commercially available eductors this is not an issue because custom fabrication permits specific geometries to be calculated such that the fluid adheres to the wall of the tube as it exits the educator, keeping it completely filled. In our design, a disposable plastic bottle is modified to attach to the outlet tubing by cutting a hole in the top of the bottle and making a large window in the side of the bottle. The window's lower edge must be higher than the outlet tubing, as in **Figure 9**.

The assembly functions by forcing water through the nozzle at high pressure, which accelerates the fluid according to the continuity equation. This high velocity fluid has a Reynold's number of 143,000. This is well

above the boundary for turbulent flow for water. Turbulent flow is characterized by the formation of eddies and pools of chaotic flow velocities. When the turbulent flow is injected into a vessel of stagnant air, the air is entrained into the water and air flow begins to occur from the tube. The effect of entrainment by turbulent jets is well studied in the literature (Ricou & Spalding 1960, Schlicting 1955, and Pai 1954).

The vacuum created by the jet educator evacuates the collection vessel, which elicits aspiration at the fenestrated tip. The overall performance of this device is a function of the line pressure, which we validated by our testing as outlined in the following section.

Design Testing

The performance of the device was evaluated at a variety of water line pressures to correlate the performance of the device to the water line pressure available. Specifically, vacuum pressure, air intake flow rate, and water intake flow rate were measured as a function of the water line pressure. The water line flow (and ultimately pressure) was varied by partially opening the water faucet coming from the wall. The water line pressure was measured at the head of the water jet educator with a pressure gauge connected to the opposing end of a Tee junction.

Poiseuille's law regarding fluid flow is: $\Delta P = \frac{8\mu L Q}{\pi r^4}$

where ΔP is the pressure drop, L is the length of the pipe, μ is the viscosity, Q is the volumetric flow rate, r is the radius, and d is the diameter (Pfitzner, 1976). All other things constant, a reduction in the fluid flow rate from the wall Q results in a corresponding decrease in line pressure P. An analogous electronic circuit for fluid flow is well defined (**Figure 10**), and can be considered a voltage source (the line pressure) in series with a variable resistor (the faucet valve), and in series with another resistor (the eductor) then connected to ground (the atmosphere). We monitor the voltage (pressure) across the resistor (eductor). When we vary the resistance of the valve at the source, we affect the flow through the circuit, as well as the pressure drop across the eductor.

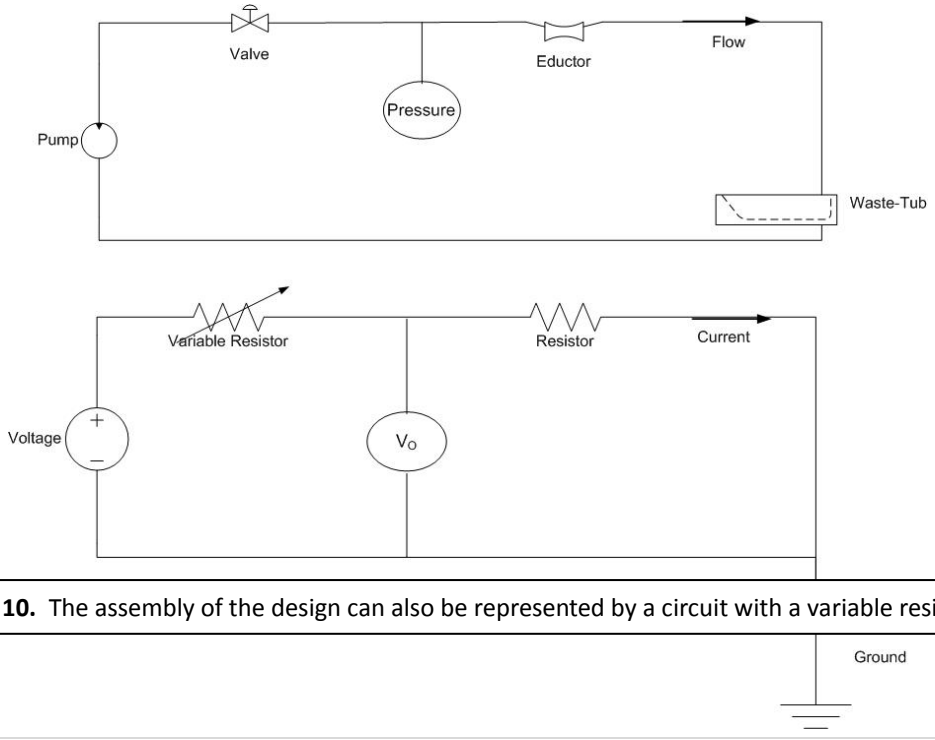

Figure 10. The assembly of the design can also be represented by a circuit with a variable resistor.

Vacuum Pressure

The vacuum pressure of the device was measured by sealing off the air intake with a vacuum pressure gauge. Measurements were taken at four different line pressures, each corresponding to the pressure drop across the device. We varied the line pressure by adjusting the valve on the water faucet. The results of this experiment are shown below.

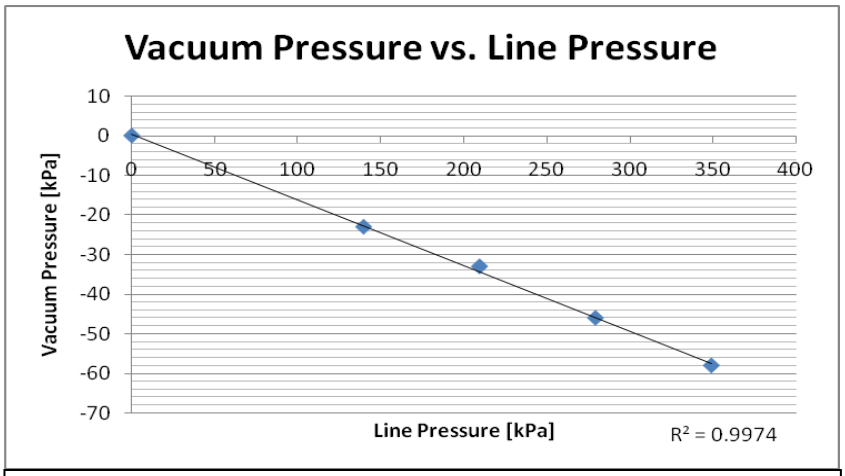

Figure 11. This graph shows the vacuum pressure (kPa) produced by the prototype as a function of the line pressure (kPa).

As can be seen in

1, the goal of creating 60 kPa gauge suction was nearly reached when a pressure drop of 350 kPa was applied across the water jet educator. This corresponds to a "high vacuum" rating according to the ISO standards for electrically powered suction equipment (ISO 10079-3:1999). "Medium suction" is a vacuum pressure between 25 and 50 kPa, and this device meets this range with water pressure drops of 150 to 300 kPa across the water jet. The previous aspirator project group obtained 10 kPa (gauge) suction, so there was almost a 50 kPa improvement when the prototype was receiving optimal water flow.

Air Flow Rate

The air flow rate was measured by using a bubble trap to measure the volume of air entrained in the water by the device. This was accomplished by directing the water jet effluent with a U-shaped tube to the mouth of an inverted one-liter graduated cylinder filled with water. Explicitly, the amount of water

displaced from the graduated cylinder in 5 seconds was measured. The results of this experiment are shown below (**Figure 12**).

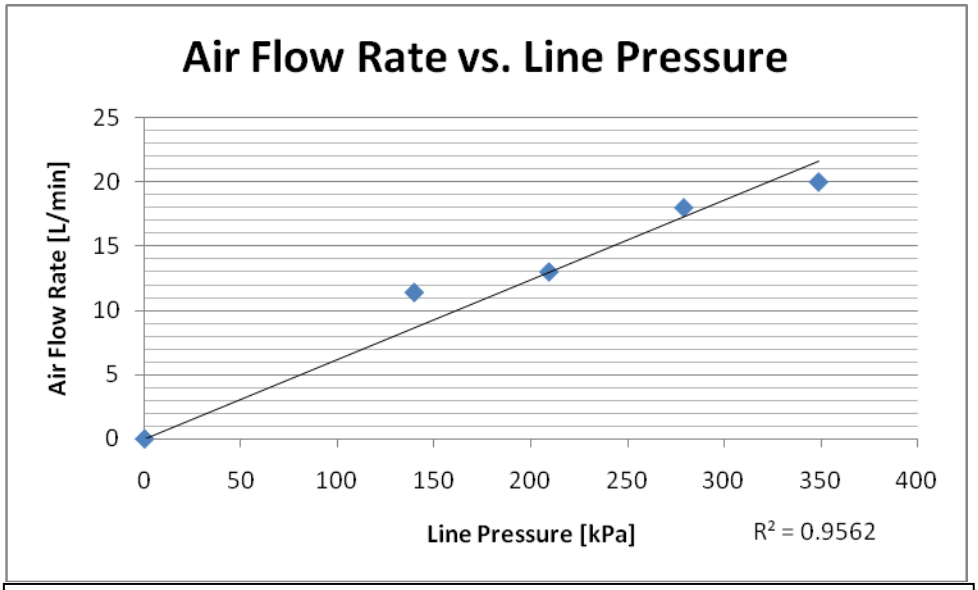

Figure 12. This graph shows the rate the prototype aspirates air [L/min] as a function of the line pressure [kPa] powering it.

The goal for air flow rate was 10 L/min. This was exceeded at all line pressures. The ISO standard for high flow (17 L/min) was met at a line pressure of 300 kPa. Below this pressure, the device is given a "low flow" rating (ISO 10079-3:1999). This method, however, reported underestimates of the air flow rate since not all of the bubbles were caught, yet it only took 3 seconds to empty one liter of air. The system could be refined by increasing the percentage of bubbles caught and using a larger graduated cylinder. The results could also be more accurate by measuring the air flow rate into the system directly using an appropriate flowmeter.

Water Flow Rate

The water flow rate was simply measured by timing the aspiration of one liter of water. The results of this experiment are shown below (**Figure 13**).

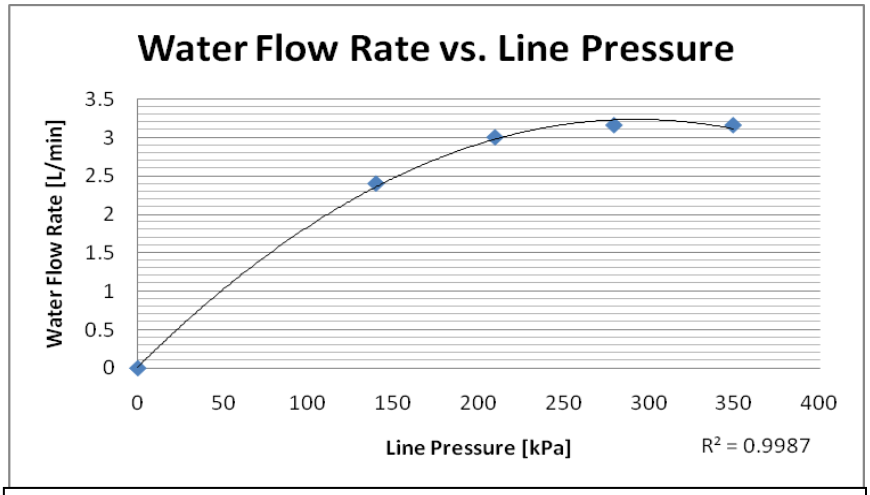

Figure 13. This graph shows the rate the prototype aspirates water [L/min] as a function of the line pressure [kPa] powering it.

For the higher pressure drops across the prototype, the aspiration remained fairly constant around 3 L/min. However, once the supplied line pressure was below 200 kPa the water flow rate began to drop off. Overall, the aspiration rate with this device approximately doubled the flow rate obtained by the previous design team.

Viscosity

Finally, the device was used to suction a viscous solution of polyethylene glycol and it was able to aspirate it at a rate between 2 and 3 L/min. Afterwards the viscosity of this solution was measured to be 73.5 times the kinematic viscosity of water.

Potential Product Markets

In many instances within the developing world, advancing infrastructure (e.g. building roads or supplying electricity) and advancing the quality of health care (administering vaccines and offering additional incentives to train doctors) are treated as mutually exclusive (World Health Organization, 2005). However, many experts argue that delivering appropriate treatments demands a certain level of adequacy in each area, (Global Health Council, 2005) as is the case in our aspirator design. Since the use of our aspirator in health care requires the presence of a water source in its infrastructure, we can presume that our device could be used in a setting where a community is considered underdeveloped but shows signs of some level of infrastructure. To substantiate this claim, we performed a literature search to assess several requirements for appropriate implementation of our technology. The main limitation is, of course, is the availability of water in the developing world since water is required for the operation of our device. However, the effect the product will have on improving health care is also contingent on the following items:

- Extent of medical services offered
    - Doctor to patient ratio
    - Use of operating rooms
    - Availability of modern medical equipment
- Health care usage
- Access to electricity

Definitions of access

The following technologies were included in the assessment as representing "improved" water supply and sanitation:

Water supply	Sanitation
Household connection	Connection to a public sewer
Public standpipe	Connection to septic system
Borehole	Pour-flush latrine
Protected dug well	Simple pit latrine
Protected spring	Ventilated improved pit latrine
Rainwater collection	

The following technologies were considered "not improved":

Water supply	Sanitation
Unprotected well	Service or bucket latrines (where excreta are manually removed)
Unprotected spring	Public latrines
Vendor-provided water	Latrines with an open pit
Bottled water[2]	
Tanker truck-provided water	

[2] Considered as "not improved" because of concerns about the quantity of supplied water, not because of concerns over the water quality.

Availability of Community Water

The World Health Organization has established different classifications for a community's ability to meet daily requirements for water supply and sanitation using data collected from thousands of household surveys and assessment questionnaires. The surveys identified adequate water supply and sanitation in communities based on a standard list (Figure 14) of types of supply technology capable of delivering at least 20 liters per person per day within 1 kilometer of the user's dwelling (World Health Organization, 2000). According to this system, a community that would likely have a pressurized water source present at their hospital would use what is known as an improved water supply.

Figure 14. The technologies listed under "water supply" draw distinctions between improved water sources versus non-improved water sources.

Figures 15 and **16** illustrate the percentage of people in the least developed countries and developing countries, respectively, with access to improved drinking water sources as a improved water supply. Although 58% of the population in the least developed countries has access to improved drinking water, there is a strong distinction between urban and rural access (World Health Organization and UNICEF, 2006). By contrast, in developing countries, 80% of the population has access to improved drinking water, with a larger proportion of rural dwellers receiving access to water, according to the 2004 statistics. This percentage is significantly higher than the statistics for the least developed countries.

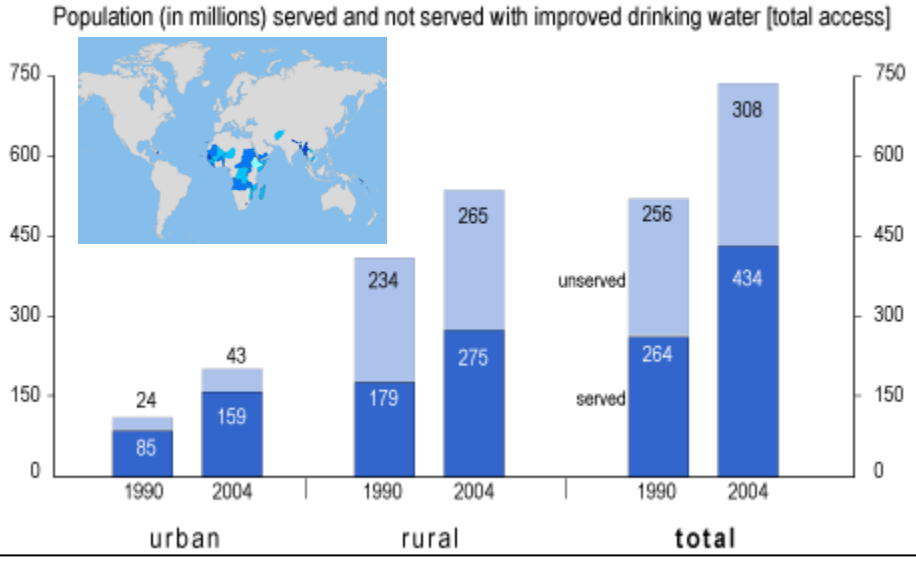

Figure 15. This figure illustrates the availability of improved water access in the least developed countries. Approximately 58% of the population in these communities has access to an adequate water source (World Health Organization, 2000).

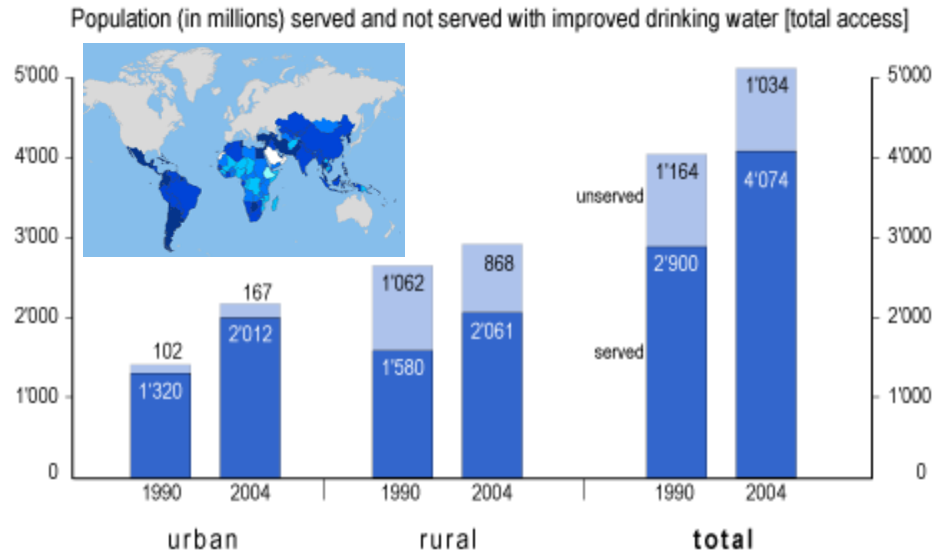

Figure 16. This figure illustrates the availability of improved water access in the developing countries. Approximately 80% of the population in these communities has access to an adequate water source (World Health Organization, 2000).

One caveat of these data is that these data is useful for estimating the availability of water for the entire community, but the access in clinics is not specifically defined and may likely be higher than for rural areas. Therefore, we predict that our aspirator device could be useful in urban settings with improved water sources as well as a substantial number of rural clinical settings. However, we require additional information to determine whether or not our technology could be supported in the communities that do not meet the requirements for improved water access in the above data.

Availability of Hospital Water Access

Limited concrete data exists to describe the level of water access in medical clinics. However, we used an online content service provider and electronic African news distributor, AllAfrica.com, to reflect three case studies of communities in Sub-Saharan Africa. The stories illustrate the disparities present in water access for health care providers, from least accessible to most accessible.

FREETOWN, SIERRA LEONE (UN INTEGRATED REGIONAL INFORMATION NETWORKS, 2008)

Prolonged civil war in Sierra Leone has ruined its once stable economy and has seriously impacted the health system. The Freetown clinic is a remote hospital with a failing infrastructure. The state run hospital has no modern surgical equipment and limited diagnostic tools, is only capable of prescribing pharmaceuticals for diarrhea and malaria, and is disconnected from the populous surrounding community. Thirty years ago, Sierra Leone was in second place in the UN Development Programme's annual Human Development Index, but since then the quality of life has been drastically reduced and the water crisis is only part of the problem. According to the article, “running water in the first floor of Princess Christian Maternal Health Hospital is only on for an average of one hour every day, hospital staff said - usually in the dead of night.” To compensate, they fill buckets to serve as the daily supply. In this community, neither the infrastructure nor the health care is capable of sustaining a technology like ours. Instead, they require much more basic improvements to their clinic.

KAWOLO HOSPITAL, UGANDA (OGWANG, 2008)

The hospital is located on a major thoroughfare and has been in operation since 1967. According to the Mukano District Council, the hospital is "one of the busiest hospitals in Uganda." Aside from the typical ailments and injuries that the hospital treats, it deals with frequent trauma cases from victims of traffic accidents on the nearby Kampala-Jinja highway. Although the hospital is wired for electricity, it cannot afford to pay the bills, and it cannot afford to provide more than four doctors, who handle 300 outpatients and 150 in-patients daily. The article describes the water situation as follows.

"Until recently, there were two sources of water at the hospital - the piped water supplied by Lugazi water project and harvested rainwater. Because of insufficient security (there are only three guards at the hospital), however, water pipes are frequently vandalised. The resulting water shortage means patients have to buy water from vendors at between sh300 and sh500 a jerrycan."

The infrastructure is present, but the hospital cannot support it. This type of hospital could only make use of our device if they were able to regain control of their water supply.

OSHAKATI, NAMIBIA (MBANGULA, 2007)

In October of 2007, the mayor of Namibia announced a plan to commence several major renovation projects in the Oshakati area. Along with several industrial, residential, and commercial construction projects, he announced the "informal settlements of Evululuko, Uupindi and Kandjengedi will be provided with water and electricity, and the gravel roads will be upgraded." Furthermore, an N$1,8 million water tower will be built in Uupindi, and the community will also gain a private hospital with a landing strip for helicopters. This example is touted as "ambitious," and indeed it serves as one of the only examples of a rapidly industrializing community as far as recent literature shows.

As shown in these case studies, a hospital may have access to a water line, even if it may not be in use. This disparity is due to other limiting factors caused by missing infrastructure elements or health services offered. In theory, each of these examples would be able to support our technology, although only in the last example is the device truly feasible.

Extent of medical services offered

Another factor in assessing the implementation of this technology lies in its overall need in the clinical setting, relative to the extent of patient care provided. Many hospitals in the third world are constrained by the number of clinicians available, the presence of surgical facilities, and the use of other medical equipment. Hospitals with limited staff or space will be less able to perform surgical procedures that might require an aspirator; however, hospitals that have the capacity to use medical equipment like CT scanners would most likely be able to use an electrically-powered, commercial aspirator device. The following statistics shed light on the global situation.

DOCTOR TO PATIENT RATIO

Generally, a reduced number of health professionals corresponds to a reduction in the quality of care as and the opportunity to offer advanced treatments in clinics. According to **Table 1** below, there is a serious global shortage. However, reports indicate that these practitioners offer as many services as the hospital infrastructure may permit, so the doctor shortage should not limit the target market for the aspirator device. Nonetheless, these staggering statistics do place added merit on our specific design, since it only requires the labor from one health care worker, opposed to other manual designs, which may require multiple people to operate the device.

Table 1. The data shown in the table below illustrates the severe health care worker shortage that currently exists throughout the world, especially in Africa (World Health Organization, 2006).

WHO region	Number of countries		In countries with shortages		
	Total	With shortages	Total stock	Estimated shortage	Percentage increase required
Africa	46	36	590 198	817 992	139
Americas	35	5	93 603	37 886	40
South-East Asia	11	6	2 332 054	1 164 001	50
Europe	52	0	NA	NA	NA
Eastern Mediterranean	21	7	312 613	306 031	98
Western Pacific	27	3	27 260	32 560	119
World	192	57	3 355 728	2 358 470	70

NA, not applicable.

USE OF OPERATING ROOMS

Since most applications for aspirators take place in the operating room, we found it pertinent to investigate how frequently patients require the use of an operating room in the developing world as well as to investigate crude estimates for the ability to perform surgeries. The 2006-2007 World Alliance for Patient Safety Forward Programme estimates that 63 million people a year require surgical treatment for traumatic injuries, 31 million for malignancies, and 10 million for obstetric complications. This value represents approximately 10% of all annual deaths. However, in East Africa, for example, there are only 400 surgeons available to serve over 200 million people. (University of Toronto, 2004). The implementation of functional aspirators could be extremely beneficial to all health practitioners, be they certified surgeons or not, since emergency care and basic surgeries are an inevitable part of practicing medicine in the third world.

AVAILABILITY OF MODERN MEDICAL EQUIPMENT

Finally, the utility of our low-tech aspirator design can be evaluated by determining the level of medical technology present in most clinical settings. According to a publication by Robert Malkin, PhD (2007), more than 95% of medical equipment in public hospitals is imported, with "essentially no local production of medical equipment." The imported products insufficiently meet the needs of the patients and clinics. The paper also references a study of donations to Colombia, which revealed that "96% of foreign-donated equipment was not working just 5 years after donation" and "39% never worked owing to lack of training, manuals, or accessories." Applying engineering principles and implementing technologies such as the one we have developed could bridge this gap in servicing the world's poorest with more appropriate technology translation and an outcome of better patient care.

Health Care Usage in the Developing World

Insufficient infrastructure and unsatisfactory medical services ultimately impact the distance individuals are willing to go to visit a clinic. When the health care system is not effective or if it is too costly for individuals to receive appropriate treatment, these people cease to go to clinics to receive care. As the chart below shows (**Figure 17**), 53% of the world's poor do not seek care outside the home. Thus, at the most, 470 million people can benefit from a technology such as ours, by this factor alone.

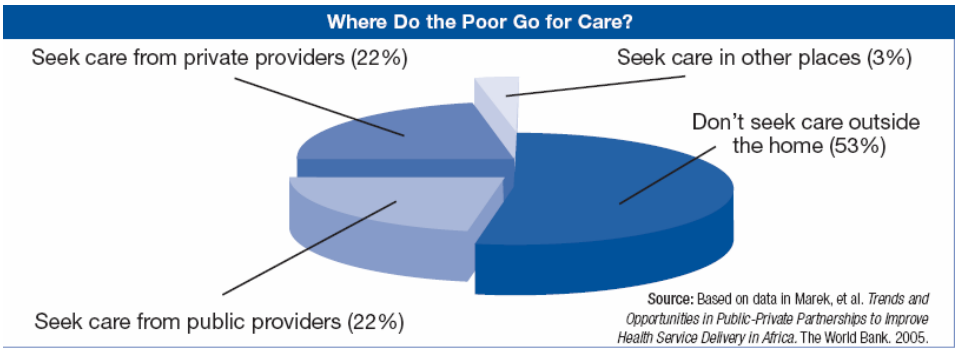

Figure 17. This chart shows a breakdown of primary care providers for the world's poorest. This demographic represents approximately one billion people globally.

Access to Electricity

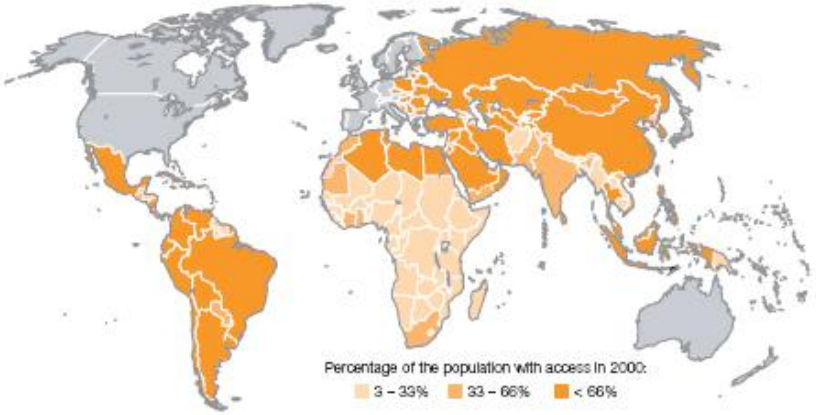

Figure 18. Many portions of the world lack reliable access to electricity. Target areas especially include sub-Saharan Africa and parts of

Finally, the ability to utilize a manually-powered aspirator design must be leveraged against the availability of reliable electricity. Globally, the United Nations has identified that at least 25% of people do not have access to electricity, and 80% of these people live in rural areas of the developing world (The Energy Challenge for Achieving the MGDs, 2005). It also predicts that if these trends continue, 1.5 billion people will still lack access to electricity in 2030. In the map below (Figure 18), it shows that in the developing world, less than 66% of people have access to electricity, with many countries at much lower levels. Thus, any medical technology that does not rely on electricity is, realistically, the only type of technology that can benefit the largest margin of the global population.

Conclusions

In the above discussion, we may conclude that the feasibility of implementing our aspirator design requires the consideration of several factors, which reflect the ability for a community's infrastructure to support quality medical care and the availability of appropriate health care resources. As discussed, most modern medical equipment has no use in the developing world, largely due to the fact that at least 34% of the developing world is without electricity, and in many of these countries, over 70% of communities do not have access. By contrast, only 20% of the developing world is without an improved water source, and in many clinics this percentage could be even less. Thus, a water-powered design like ours would be more feasible than an electricity-powered design. An added advantage of our design is that, compared to other commercially-available technologies, only one person is required to operate our device, which may be helpful in light of the doctor shortage. The greatest barrier to implementation, according to our analysis, is the lack of clinic visits by patients who require care but may be discouraged by current quality of provided services, in terms of the number of people who would not benefit from our technology compared to the other parameters. However, with appropriate technologies, individuals

may be more apt to seek the care they need. Despite this limitation in reaching individuals who are unable to visit the clinic, at least 470 million people may be able to benefit from this technology, especially those living in urban settings with an improved water supply and access to clinics with the required staff and services to perform surgeries.

Patient Safety and Design Ethics

Since our design will ultimately be considered a medical device for use in a full array of clinical settings, we paid special care to evaluate each design component based on its ease of construction, reliability in meeting ISO standards, ability to be sterilized, and its incorporation of safety factors in case of inappropriate use. Since the device will be manufactured *in situ,* its assembly must be straightforward and adaptable to other materials that may be more readily available. Thus, we reduced the components required and developed a system that was not completely dependent on pre-fabricated parts, specific dimensions, or flawlessly watertight seals. Instead of the components determining peak performance, the water pressure is the main variable, and the clinician should be able to accurately and easily adjust the degree of suction with a manual water shutoff valve. The design is, therefore, much safer to use regardless of the materials available locally. Furthermore, the final construction should be able to fulfill ISO standards for manually operated suction systems, provided that a pressurized water source is available.

Another feature of our design is that it may be sterilized for repeated use in the clinic. The eductor components themselves may be autoclaved repeatedly at 121°C, 15 psi (gauge) for at least 15 minutes each time (Autoclaving, 2008). The standard pipette tips, Nalgene water bottle, and Tygon tubing that comprise the rest of the design may also be autoclaved under the same conditions. This design feature further reduces the cost of the overall product and makes it more feasible for use in the developing world.

Finally, we installed two other safety features to protect the patient while the device is in use. The suction tip we developed is a simplified version of the fenestration-style tip commonly used in the United States. As described earlier, this tip pulls in fluid from smaller pores on the side of the tip rather than at the base. This design prevents a patient's delicate tissue from being drawn up, due to the smaller surface area of each pore compared to the base of the tip. We also developed a one-way valve from a portion of a rubber glove by cutting a hole in the tip of one of the fingers. By connecting the valve to the tubing connection within the collection flask that leads to the aspirator tip, we were able to prevent backflow of the aspirate to the patient. We also assessed the risk of aspirate being drawn up into the other tubing connection and determined that a valve would not be necessary under standard pressure conditions. In general, these design conditions allow us to more safely and effectively meet the needs of our target population.

Future Work

Moving forward, there are two issues to address with this device. First of all, a system needs to be developed to recycle the water that flows through the aspirator. This is not critical to device function but would eliminate much of the wasted water the device produces. One option would be for the water collected from the aspirator to be put back into the hospital's water supply, which would completely eliminate wasted resources arising from aspirator use. Alternatively, if some sort of pump, either automatic or manually powered, such as a treadle pump, were employed and could produce enough water pressure it would allow the water to be pumped in a cycle through the aspirator and not to be wasted at all.

The second issue to address with the aspirator is to test it in a clinical setting. Preliminary testing and device characterization was carried out outside the clinical setting using water and simulated blood. The aspirator was never tested in a clinical setting for actual medical aspiration applications. There are several reasons why clinical testing is needed for the aspirator. First, it would allow identification of any unforeseen safety issues that need resolution. Second, clinical testing would determine exactly what medical applications this aspirator is sufficient for. Third, it is critical to know that the aspirator holds up against actual bio-fluids as opposed to the simulated blood that was used for preliminary testing. Once these issues are resolved, this aspirator design will be ready for implementation in the developing world. Finally, we are awaiting feedback from EWH regarding the efficacy of our design, based on our description of its performance along with an operator's manual (See **Appendix D**).

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Appendix A: Product Design Specifications (PDS)

Engineering World Health Aspirator (May 11, 2008)

Claire Flanagan - Team Leader
Adam Rieves - Communications
Michael Socie - BWIG
Justin Lundell – BSAC

Problem Statement
Most developing world hospitals do not possess operating suction machines. The main problems are the lack of available spare parts, the cost of a replacement unit, and dependence on consistent electricity. The objective of this project is to design and develop a medical grade aspirator that can be manufactured inexpensively from locally available materials. Along with the device, an instruction manual will be produced to allow for proper usage and care in the future.

Client Requirements:
• Device should run on 12 V batteries with manual back-up.
• Device should provide the broadest range of applications possible, with a high setting for adult applications and anesthesia and a low setting for neonatal applications and gastrointestinal work.
• Device must include autoclavable suction tips and collection flask.
• Device must be completely manufactured from locally available materials for under $100.

Design Requirements

1. **Physical and Operational Characteristics**
   a. *Performance requirements:* 0-60 kPa vacuum (gauge), 0-10 L/min flow of air

   b. *Safety:* Entire device must be easily disinfected for use in a surgical setting. Aspirator tips and collection vessel should be autoclavable. Usage should be possible for sustained duration, preferably over eight hour intervals. Power source and motorized elements should be enclosed to minimize patient/user risk. Also, measures need to be taken to prevent aspirate from regurgitating towards patient from collection vessel.

   c. *Accuracy and Reliability:* If included, pressure and flow adjustment dials must be able to be calibrated prior to use. Device must be able to provide reliable suction throughout an entire surgery or operation (up to 8 hours). Minimal maintenance should be required. If included, manual backup should provide reliable service.

   d. *Life in Service:* 5 years

   e. *Shelf Life:* 5 years

   f. *Operating Environment:* Must be able to be stored and function under temperatures ranging from 0 to 40 degrees Celsius and variable humidity.

g. *Ergonomics:* Aspirator should have minimal steps to turn on and begin use. Device, including manual backup power and suction attachments, should be self-contained to create more space in the operating room.

h. *Size:* There are no specific size restrictions on the device. However, the device will be implemented in the operating room and therefore should take up as little floor space as possible to avoid interfering with the medical staff's ability to navigate the room. A taller device is preferable to a device with a wide base. Collection flask should be approximately 1-3 L.

i. *Weight:* There are no specific weight restrictions on the device. For movement inside hospital, if the device weights more than 10 kg, it should include means for movement such as wheels.

j. *Materials:* Completely manufactured using locally available parts.

k. *Aesthetics, Appearance, and Finish*: Moving parts, sharp edges, etc. need to be shielded from clinical environment. Device components must be able to be sterilized for implementation in operating room.

2. Production Characteristics

a. *Quantity:* Device should be able to be widely implemented in a third world community.

b. *Target Product Cost*: < $100 per device using locally available materials.

3. Miscellaneous

a. *Standards and Specifications:* The ISO maintains standards for both manual and electrically powered medical suction devices and suction tips (ISO 8836:1997).

b. *Customer:* EWH-affiliated medical professionals and institutions in developing communities. Instruction manual should be sensitive to language barriers.

c. *Competition:* Discarded medical aspirators from developed nations and alternative manually powered aspirators.

Appendix B: Design Concepts

An apparent dichotomy exists between our two primary design constraints of creating high levels of negative partial pressure while minimizing electric current from an external battery source, so we generated designs that primarily aimed to achieve a balance between these two parameters. Our four designs described in the following sections illustrate how common techniques for generating suction can be applied in ways that overcome many of the limitations posed by the unique environment of a third world medical clinic.

Each of the designs would be connected to a collection flask and suction tip. The suction tip will be autoclavable, and its purpose is to draw up any patient waste or fluids. This matter enters the tube, passes through a section of flexible tubing, and is stored in the collection flask. We have learned that the collection flask must be at least 2 L in volume to meet standard hospital regulations.

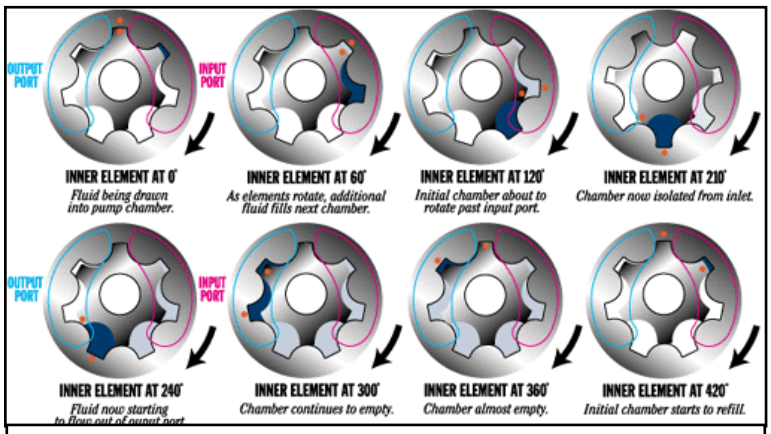


Figure 1. This figure shows the cycle of a gerotor pump and demonstrates how it generates vacuum through angular motion. http://www.irisengineering.com/about.html

Positive Displacement Pump

A positive displacement pump is defined as a pump which physically traps a substance and transfers it to a different location. The previous semester's design is an example of such a pump, although the previously listed design flaws limit its functionality. However, the concept of a positive displacement pump provides an effective mechanism to generate vacuum pressure. Since air is physically removed from the system, this configuration will be efficient if properly sealed. There are several different pumps which fall into the category of positive displacement. The gerotor pump is one such design. It consists of two gears; the outer has N teeth, and the inner has N+1 teeth. This set configuration can be seen in **Figure 1**.

As the inner gear rotates a volume of air is drawn through a port and into an expanding chamber, creating a vacuum. The volume of air expands to a maximum point, and then becomes sealed by the junction of two rotor teeth. Finally the volume of air begins to contract and is forced through an outlet port. The gerotor pump can be found in the oil pumps and power steering units of a car and are normally driven off of the crank shaft. This type of pump has the benefit of being internally sealed, thus eliminating the need to create one way valves.

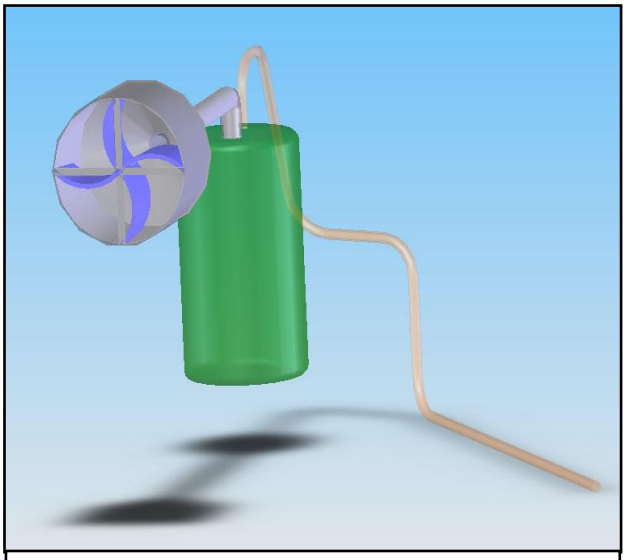


Figure 2. Schematic representation of a turbine driven aspirator. As shown, the turbine itself is connected to the aspirator collection flask, which draws suction using the rpm of the turbine motor.

Turbine

This design uses a turbine or fan pump to move air and create suction. As shown in **Figure 2**, a rotating fan creates a region of reduced pressure behind the fan blades. As an example, a one horse-power Shop-Vac has an airflow rate of 120 ft^3/min with a pressure of 101 mmHg (gauge). The fan of a turbine pump functions similar to the propeller of airplane. The most efficient setup is a large diameter fan blade, but the efficiency can be compensated for by running the propeller at higher speeds. In the case of a fan driven pump in an operating room, a small fan would need to be used to keep a small footprint. Consequently, the fan would need to be run at high speeds.

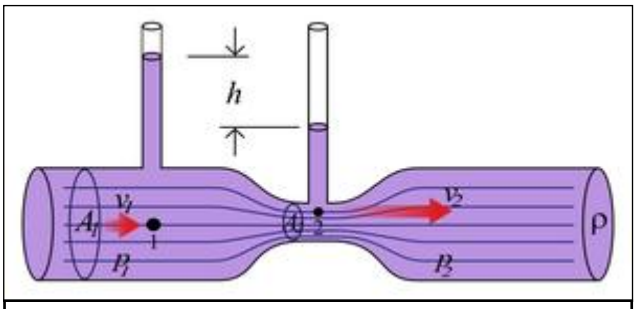


Figure 3. Classically, a venturi tube's geometry resembles the one in this figure, where fluid enters in a region of wider diameter and passes into a region of smaller diameter. This elicits a pressure drop.

Venturi Tube Design

A venturi tube is used to form partial vacuums for a diverse array of fluid and gaseous applications, from spray atomizers to carburetors and, additionally, they can be used as sensors for fluid flow measurements. This diversity of applications lends itself toward a wide range of materials and sizes available for venturi tubes. However, all venturi tubes are grouped together by a common geometry as shown in **Figure 3**.

Fluid flow through the chambers of the tube is a function of the inner diameter. This is governed by the Bernoulli Principle and the continuity equation, which describe that as the diameter of a vessel decreases the fluid velocity increases to maintain conservation of volume while the pressure decreases to maintain conservation of energy within the system.

In a venturi tube, a tap is placed in the narrower portion, since this region is of lower pressure and is capable of drawing suction. The tap draws air, which then mixes with the fluid passing through the tube, and this mixture flows into a wider portion of the tube where pressure is elevated to atmospheric pressure once more as it passes out of the tube. The key feature of venturi tubes is to create appropriate dimensions of the different chambers in order to effect appropriate changes in pressure. As shown in the Bernoulli equation, the fluid velocity entering the tube and the tube's elevation are also contributors in determining the pressure at the tap.

The venturi system design provides a constant supply of fluid to pass through the venturi tube. As shown in the diagram (**Figure 4**), the fluid leaves a lower reservoir and is pumped upward by a motorized pump into another collection reservoir. Then, the fluid is gravity-fed through the venturi tube and back into the lower reservoir. The open system

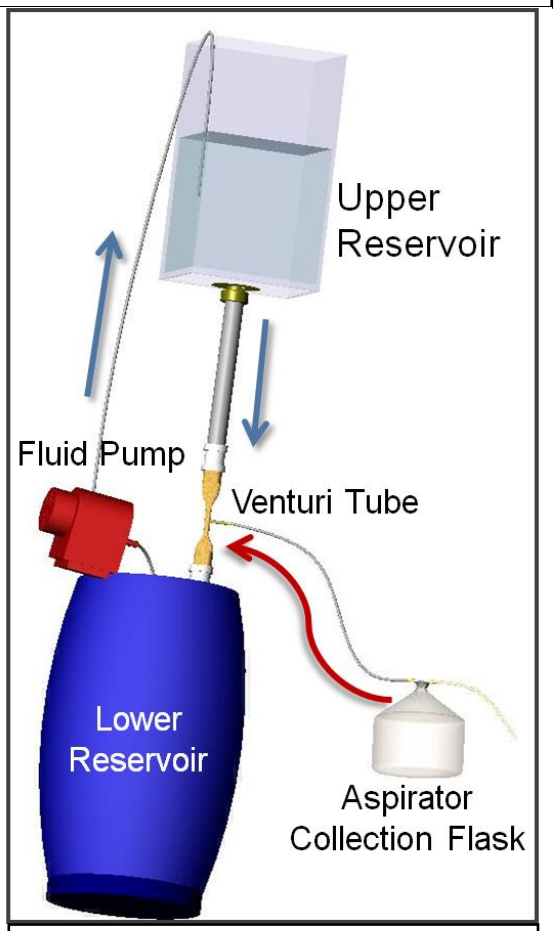


Figure 4. The venturi tube design would require an arrangement shown in this figure. The blue arrows indicate the direction of fluid flow, while the red arrow indicates air flow.

allows any air drawn into the tube to escape downstream from the tap.

Water Piston

This design is based around negative pressure created by evacuating tanks of water in a closed system. The water level in each tank mimics the activity of a piston head, giving this design its name. As the water level is lowered, negative pressure is created in the top of the tank, drawing air in. This effect is equivalent to using a mechanical piston to create negative pressure (as in the previous semester's design). However, using water instead of a mechanical piston has some advantages as far as sealing, which will be discussed later. **Figure 5** shows the layout of the design.

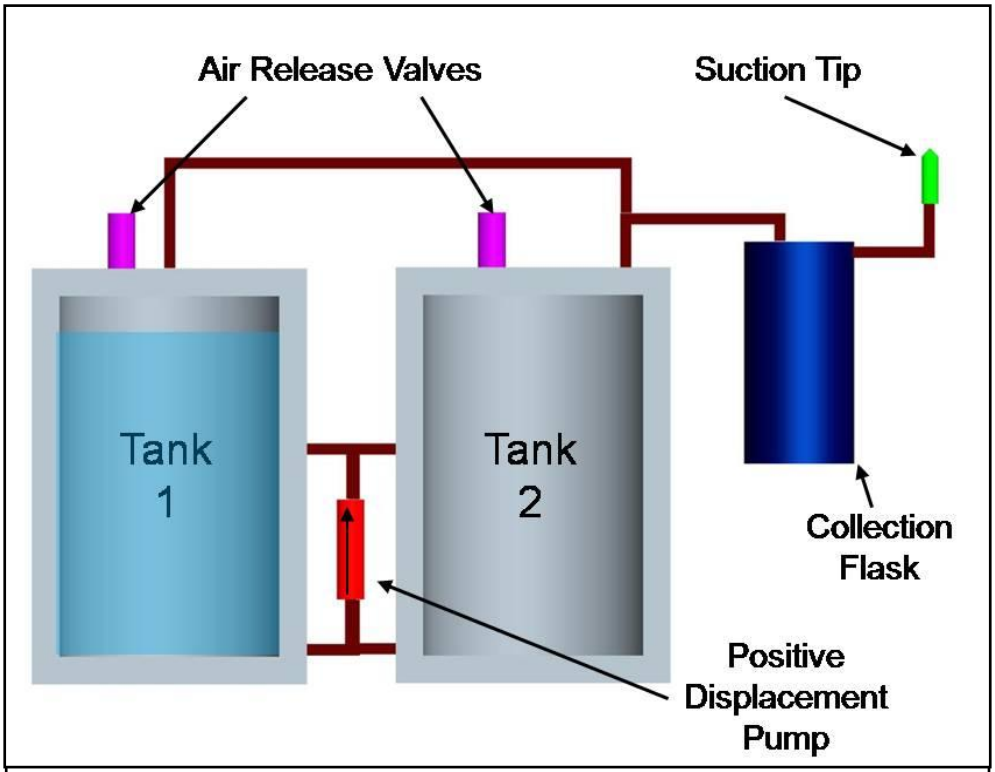


Figure 5. This picture demonstrates the components required for the water piston design. The water is completely located in Tank One, which indicates that it is at the beginning of the vacuum cycle.

During operation, water is evacuated out of tank 1 into tank 2 by means of a positive displacement fluid pump. Valves a and c are closed while valves b and d remain open during this phase to permit water movement in only the desired direction. Also at this time, the one way valve on tank 2 opens to allow air to escape while water fills the tank. As tank 1 is evacuated, air is drawn through the tubing, collection flask, and suction tip, producing aspiration. One-way valves at the tubing-tank connection ensure air can only move into the tanks and not out via the tubing.

Once all the water in tank 1 has been removed, the flow direction must be changed manually. To do so, the pump must be disengaged while valves a and c are opened and valves b and d are closed, switching the direction of water flow from tank 2 back to tank 1. Once all valves have been properly set, the pump may be turned on again, now creating negative pressure in tank 2 that pulls air and creates aspiration through the suction tip.

Decision Matrix

Table 1. We organized our preferences for each design into a decision matrix and ranked several criteria to quantitatively determine which design was the most feasible.

	Category weight	Positive Displacement	Turbine	Venturi	Water Piston
Materials feasibility	20	14	18	17	12
Power Efficiency	15	11	10	13	12
Manual backup compatibility	5	3	4	5	1
Maintenance	10	3	8	9	8
Safety	5	3	4	5	5
Pressure/Flow	20	16	10	18	14
OR Integration (ergonomics)	5	4	4	2	2
Assembly	15	8	11	12	10
Cost	5	2	3	4	3
Total:	100	64	72	85	67

Table 1 above is the decision matrix used to evaluate the four design alternatives in order to select one to proceed to prototyping with. The designs were evaluated based on nine criteria carrying different weightings according to their importance to a successful design. The highest weighted criteria are Pressure/Flow and Materials Feasibility, each receiving a weighting of 20 out of 100. Pressure/Flow refers to the potential for a design to meet the pressure and flow requirements outlined in the design specifications. Materials Feasibility is an indication of how likely it is that all of the parts required for a design will be available in a developing nation.

The two criteria with the next highest weightings were Power Efficiency and Assembly, each receiving 15 out of 100. Power efficiency refers to how efficient energy use in the device is as well as how fast the device would drain a 12 VDC source. Assembly refers to the ease of construction of the design for someone who may or may not have technical expertise. This is an important element to our final design because a superior design that requires a great deal of technical background to put together is, most likely, unfeasible for implementation in the developing world.

Other notable design constraints relevant to our design matrix included maintenance, which refers to how often and how involved maintenance for a design would be required. Maintenance received a weighting of 10 out of 100. Also, compatibility with a manual backup, safety, OR integration (how feasible a design is to implement in the operating room), and cost each received a weighting of 5 out of 100. In the case of safety and cost, their low weighting is not a reflection of how important they are to the design (both are vital to a successful design), but instead reflect the ability to distinguish between the four designs. Since all of the designs must be safe and must be produced within budget, giving those criteria a high weighting would result in similarly high scores for each design.

With a total score of 85 out of 100, the venturi tube design was the highest rated design. For this reason, the venturi tube design concept was pursued for prototyping and testing phase. The basis for

this decision included preliminary experimental evidence that a venturi tube system can produce over 600 mmHg of negative pressure, exceeding our base requirements. Furthermore, at most, the venturi tube design employs only one pump and has no need to convert energy from one motion to another, making it power efficient. Also, the venturi tube design does not require specialty parts, which we were able to capitalize on in our final design.

Appendix C: Budget

The final design met all cost constraints that were outlined by Engineering World Health Organization. The table below provides an item-by-item list of the components involved in building our prototype. In the third world, many of these items would be available by recycling discarded parts, so these values may become irrelevant. Nonetheless, they serve as a good parameter of the overall cost of the device.

Part Description	Cost	US Source	Third World Source
3/4'' PVC Tee slip sockets by 1/2'' FPT (1)	$0.61	Home Depot	plumbing
Water hose jet nozzle w/ ¾'' MPT (1)	$2.97	Home Depot	garden
1/2'' X 3/8" brass barbed fitting, spigot by MPT (1)	$2.49	Home Depot	plumbing
3/4" spigot x 1/2" FPT PVC reducer bushing	$0.18	Home Depot	plumbing
½'' PVC pipe, 8'' long (1)	$1.05	Home Depot	plumbing
1/2" MPT x 1/2" coupling (1)	$0.48	Home Depot	plumbing
Eductor Subtotal	**$7.78**		
Y Brass shut-off valve w/ ¾'' FPT (1)	$7.87	Home Depot	garden
Medical tubing (as needed)	$1.09/0.3 m x 1.8 m = $6.54	medicalsupplyco.com	hospital clinic
Barbed Fittings with Reducing Connector (2)	pack of 12 = $12.50 two fittings = $2.08	Fischer Scientific Cat. No. 22-235-739	hospital clinic
20 oz thin plastic bottle (1)	$1.00	vending machine	household
1 L Nalgene water bottle (1)	$4.00	Wal-Mart	household
5 ml plastic pipette (1)	box of 500 = $46.20 one tip = $0.09	Fischer Scientific Cat. No. S317183A	hospital lab
1 ml plastic pipette (1)	box of 1000 = $34.50 one tip = $0.04	Fischer Scientific Cat. No. S63213	hospital lab
Disposable vinyl exam glove (1)	box of 100 = $13.80 one glove = $0.14	Fischer Scientific Cat. No. 19-041-190E	hospital clinic
Duct tape	$2.74	Ace Hardware	household
Teflon Tape	$0.79	Ace Hardware	plumbing
Epoxy	$2.97	Home Depot	household
Total	**$36.84**		

Appendix D: Construction and Operation Manual

Resources

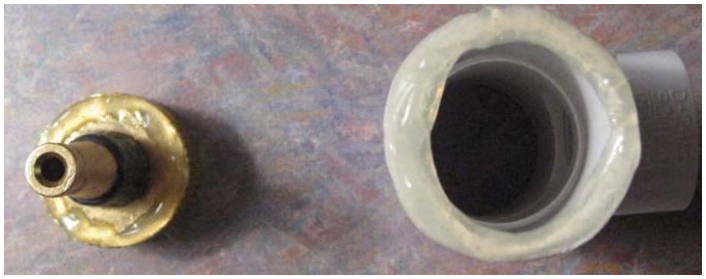
Access to running water with line pressure is required for device operation

Parts required (quantity):

- 3/4'' PVC Tee with 3/8'' threaded side inlet (1)
- Water hose jet nozzle with 3/4'' threaded connection (1)
- 3/8'' threaded pipe to soft hose adapter (1)
- 1/2'' PVC pipe, 8'' long (1)
- PVC 3/4'' to 1/2'' adapter (1)
- 3/8'' medical tubing (as needed)
- Rubber medical tubing connector (2)
- 20 oz. thin plastic bottle (1)
- 1 L autoclavable plastic container with lid (1)
- 5 ml plastic pipette (1)
- 1 ml plastic pipette (1)
- Rubber glove (1)
- Duct tape
- Teflon tape
- PVC cement

Assembly

1 Spread a ring of PVC cement around one of the ends of the PVC Tee and the base of the water jet nozzle, as shown.



2 Connect water jet nozzle and PVC Tee as shown and allow PVC cement to dry.

3 Screw 3⁄8’’ threaded connector into side inlet of PVC Tee after wrapping the threading with Teflon tape.

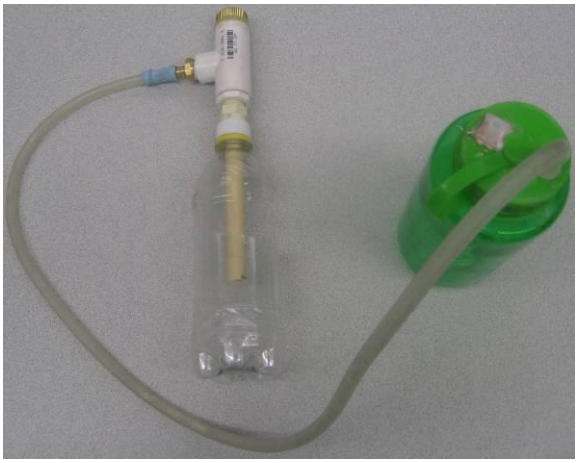
4 Attach 3⁄4’’ to 1⁄2’’ PVC connector to remaining port of PVC Tee.

5 Attach 1⁄2’’ PVC pipe to the 1⁄2’’ port just installed.

6 Cut 2'' by 3'' rectangular hole in side of 20 oz. plastic bottle, near the top, and a 1/2'' hole in the lid such that it fits snugly around PVC pipe.

7 Connect 20 oz. plastic bottle to PVC pipe as shown.

8 Connect desired length of medical tubing to the barbed port on the side of the PVC Tee at one end using a rubber tubing connector and to the 1 L autoclavable container, using PVC cement to seal connection to container.



9 Cut off finger of rubber glove 2'' from fingertip and cut 1/4'' hole in the fingertip.

10 Place broad end of glove piece around the distal end of a new piece of tubing that will eventually go to aspirator tip, using duct tape to secure in place.

11 Connect this medical tubing, with glove attached, to 1 L autoclavable container such that tubing runs into container by 6-7''. Again, use PVC cement to seal connection.

12 Cut out 2'' section from the middle of 5 ml and 1 ml plastic pipette tips for aspirator tip construction. Poke a number of small holes around the smaller end of the 5 ml pipette section.

14 Connect 1 ml and 5 ml pipette sections to open end of medical tubing using rubber tubing connector. Insert 1 ml pipette section to inner diameter and fit 5 ml pipette section around outer diameter. Seal connection with duct tape.

15 Final product.

Operation

To operate aspirator, connect hose from running water source to water jet nozzle port on the aspirator. Aspirator must be mounted vertically inside of a reservoir to catch water such as a large sink, drain, or tank. When the water is turned on and water runs through aspirator, suction is created at suction tip.