



Development of an Electrically Powered Medical Suction Device for Clinical Applications in Developing Countries

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ABSTRACT

In clinical settings, the process of suction is the removal of biological fluids using vacuum technology. This study sought to design and develop an inexpensive suction device for the facilitation of airway management in patients under emergency or critical care. The suction device was fabricated based on the design specifications. The device was designed to be able to aspirate biological samples at low (70 mmHg), medium (90 mmHg), and high (120 mmHg) pressures using catheters of 9.4 mm and 3.3 mm diameters. These pressures were selected to enable the device to be useful for infants and elderly patients. The developed device passed the required electrical safety tests using the standard electrical safety analyzer by Fluke. For example, the leakage AC and DC were 0.1 μ A AC and 0.0 μ A DC, respectively, suggesting that the device is safe for use on patients. We are confident that the introduction of this inexpensive device (<USD 65) to rural healthcare centers will be able to address the critical shortage of suction devices for trauma and critical care.

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INTRODUCTION

In clinical settings, a suction device is vital in airway management. This device is pertinent as an obstruction in the respiratory airways can prevent air from entering the lungs partially or completely, resulting in minor or life-threatening conditions that may require urgent medical intervention [1]. This is especially the case for patients under emergency care, and for those whose body fluid requires removal during and after surgery. This clinical challenge of effective airway management is one of the leading causes of death, especially in emergency care during resuscitation [2]. Therefore, effective suctioning is a critical component of oral and respiratory airway clearance to facilitate seamless respiration and prevent potential aspiration tendencies [3, 4]. As a result of these, facilitating the clearance of the airways by technology is important. A medical suction device is widely recognized and accepted for this purpose [5-7]. However, due to the low healthcare budgets, this

device is usually in inadequate supply in most hospitals, especially in developing countries. The direct consequence of this may lead to inefficient patient management [8] and a high mortality rate.

There have been limited research efforts in the design and development of the suction device [3]. The reported research efforts are generally directed toward improving the existing designs [9, 10] and/or widening the scope of the existing design for effective and emergency airway clearance [11]. These efforts are majorly useful for developed economies where maintenance and spare parts for this device are readily available. By implication, these efforts are not solving the problem of the critical shortage of suction devices in developing countries. Although manual suction devices are generally inexpensive and light in weight, the need for human intervention and strength in their operation often make their application unreliable and limited [12]. Alternatively, the major limitation of a wall-mounted suction device is its immobility and thus

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limited application in attending to patients, not within the vicinity of the device.

Therefore, portable suction devices have been promoted as the most widely used alternative as they can be used in various clinical settings. Based on this background, this study sought to present the development of an inexpensive, portable and electrically powered suction device using available materials in developing countries. Specifically, the suction device's compartment will be fabricated using a galvanized iron sheet, and other components including the suction pump which will be selected based on the design specifications. Ease of use, portability and availability of materials for local production of this device and its maintenance were our priority and

these conform to the criteria to be fulfilled by a clinically useful suction device.

MATERIAL AND METHOD

Materials

A multi-criteria decision-making approach [13] as applied to engineering design was used to determine if the choice of the material used for the development of this device was appropriate. Table 1 describes the importance of the materials used and the rationale for the material selection. In this study, our priority was cost and material availability within the country. Table 2 presents the cost analysis of the selected materials.

Table 1: Importance and rationale for material selection

| S/N | Materials | Importance | Rationale |
|-----|---|---|---|
| 1 | Suction pump Thomas compressor and vacuum pump. Model no: 2107V, D18-0146, 220V, 50Hz, 1.3A. | An electric motor that generates a vacuum for suctioning | Low power consumption, and low noise. It is thermally protected. |
| 2 | Bacterial filter Disk AM-BF Model | Prevent suction pump contamination | Low cost, lightweight, and availability |
| 3 | Vacuum pressure gauge Size 50 mm, ¼ connection size | Display the reading of pressure to monitor the suctioning operation | Product compatibility, accuracy, cost, easy mounting method |
| 4 | Yankauer suction catheter | For extraction of biological secretions | Availability and flexibility in reaching hidden anatomical locations like the oropharyngeal airway |
| 5 | 2.5 litres glass medical suction canister | Temporarily stores secretions removed from the body before disposal | Hygiene and human waste are better maintained in glass materials, and suctioned human secretions are easily removed |
| 6 | Continuous pressure regulator. Size 1. | Controls the pressure of fluids to the desired value | Availability, smart design, and inexpensive |
| 7 | Galvanized iron sheet | Strong enough to support and protect the device | Durability, corrosion resistance, and low maintenance cost |

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Table 2: Cost analysis of the suction machine

| S/N | Item | Description | Quantity | Unit price (USD) | Total price (USD) |
|--------------|-------------------------|------------------------------------|----------|------------------|-------------------|
| 1 | Vacuum pump (AC motor) | 220VAC, 50 Hz | 1 | 15 | 15 |
| 2 | Negative pressure gauge | - | 1 | 5 | 5 |
| 3 | Regulator | - | 1 | 4 | 4 |
| 4 | Suction canister | 2.5 litres | 1 | 8 | 8 |
| 5 | Bacterial filter | ABS plastic | 1 | 2 | 2 |
| 6 | Power cord | 220-240VAC, 50Hz, 3A | 1 | 0.5 | 0.5 |
| 7 | Compartment | 30.4 x 31.6 x 37.8 cm ³ | 1 | 20 | 20 |
| 8 | Catheter | 9.4 mm & 3.3 mm | 2 | 2 | 4 |
| 9 | Miscellaneous | | Lot | 5 | 5 |
| TOTAL | | | | | 63.5 |

System Design

The construction of this design followed a series of stages. The first stage was the pre-construction where the material selections were considered, the SolidWorks (Waltham, MA 02451, USA) design was performed, and all other necessary procedures that were required before the device's construction was carried out. Next to this stage was the construction stage, where the actual fabrication of the machine was carried out. This stage included all the marking out and measurement to ensure accurate dimensions in

the device's design based on the SolidWorks specification as shown in Figure 1. This stage was immediately followed by the assembling stage as shown in Figure 2. The assembling stage included the procedure for mounting the pump onto the compartment made from galvanized iron sheets and connection of the peripherals including tubing and cables. Finally, the last stage was the packing, where the completely fabricated machine was well packaged with the canister installed as shown in Figure 3.

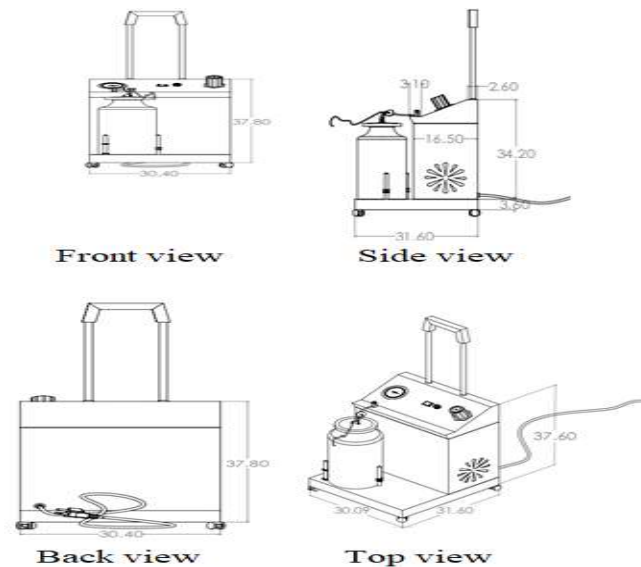


Figure 1: 3D views of the suction machine

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Specifically, the galvanized iron sheet was cut according to the specifications in the SolidWorks design of the device with a measuring tape. The galvanized iron sheet was cut into pieces. These pieces were bent as required and were joined. The device was sprayed in blue and silver as shown in Figure 3. As required, holes were drilled for the placement of the pump. The suction pump was fixed to the base of the compartment using bolts and nuts to hold the pump firmly in place. The power cord, suction pump, fuse, and switch were, thereafter, connected. The electrical connection points were

insulated with insulating tape to prevent electric leakages and shock. The base and body of the compartment were then screwed together. Then, the pressure gauge, fuse, switch, and regulator were fixed to the positions marked out for them, respectively. A T-junction tube connects the pressure gauge and regulator to the regulator. The top of the compartment was screwed to the body of the compartment, and then the iron rod was fixed. A filter was placed from the outlet to the collection bottle. Figures 2 and 3 present the device during the assembling stage and final stage, respectively.

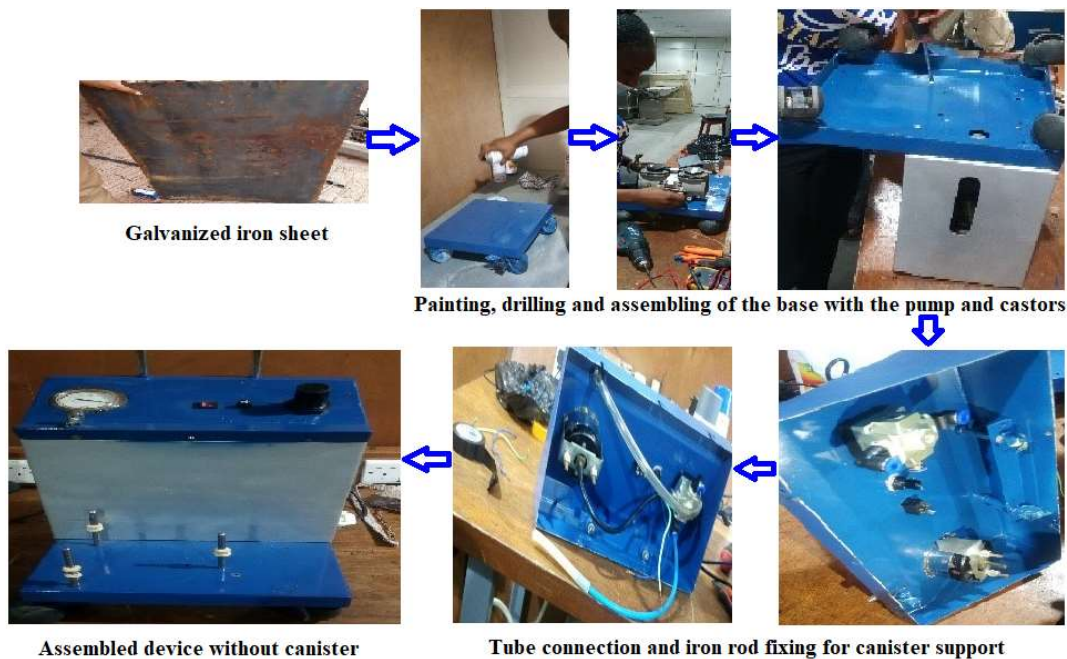


Figure 2: Assembling stage

The classical work of Rosen & Hillard (1960) [14] on the concept of negative pressure, as “the pressure lower than the atmospheric pressure”, guided our design and consideration for the flow in the suction machine’ tube in the case of smooth or turbulent fluid flow [15]. The governing equations could be found as follows. For lamina flow:
 Fluid flow $\propto \Delta P$ between the tube ends [1]
 Once the turbulence surfaces, the relationship in equation [1] becomes:

Fluid flow $\propto \sqrt{(\Delta P)}$ [2]
 However, for turbulence flow, the increase of flow due to an increase in the pressure difference (ΔP) is significantly lower than that of the lamina flow. The relationship become:
 Fluid flow $\propto \frac{1}{Resistance}$
 Where the tube resistance depends on the tube’s diameter and its length and the density of the fluid.

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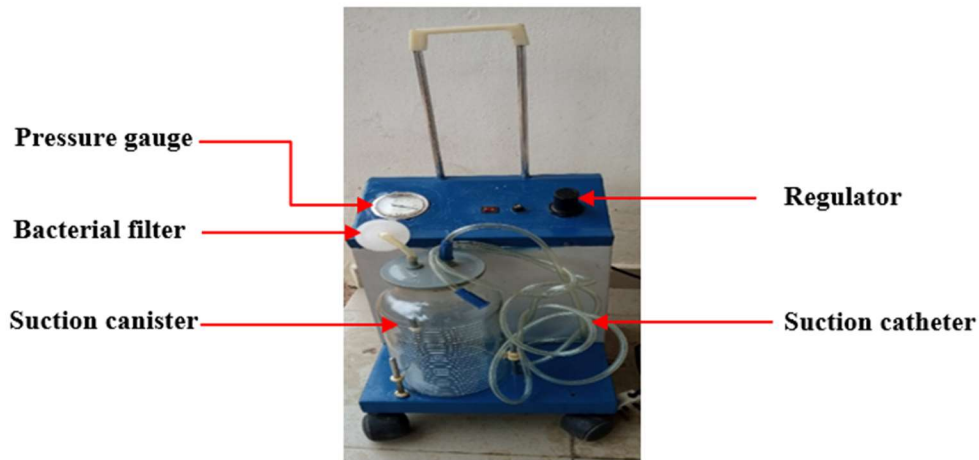


Figure 3: Finishing stage

Description of Operation

Here we describe the operation of the device when the device is powered up. An electrically powered motor used in the device is meant to create a negative pressure [14], which sucks air from a collection canister. The components are connected by plastic tubing, resulting in an open-ended system that continuously takes biological fluids from the patient via a tube by the reduced pressure in the collection canister. The gauge allows the user to set a safe suction limit, evaluate the vacuum pump's performance, and detect blockage. Using negative pressure here is important as it facilitates airway suction [3]. The flow of fluid through a tube

is the principle that governs the properties of a suction device.

The suction machine was designed and developed in such a way that it could be regulated to 70 mmHg for low, 100 mmHg for medium, and 120 mmHg for high. These values complied with the standard (i.e., the maximum occluded suction pressure should be limited to 80-150 mmHg for adults and 80-100 mmHg for neonates and paediatrics [16]). These values were within the range for infants and elderly requiring airway clearance or other suction care. This was also to ensure that the reading of the machine was accurate at the point of delivery to a patient. The Basic technical specification of the developed suction machine is as presented in Table 3.

Table 3: Basic technical specification of the developed suction machine

| Characteristics | Value | Unit |
|----------------------------|-------------------|--------------|
| Voltage | 220 - 240 | V |
| Frequency | 50 | Hz |
| Dimension | 31.60x30.40x37.80 | cm × cm × cm |
| Mass | 9.3 | Kg |
| Equipment Current | 0.9 | A |
| Suction/ Canister capacity | 2.5 | Litre |

Electrical Safety Analysis

To confirm that the developed device is safe for use on human, standard electric safety tests were carried out. An electrical safety

analyzer (Fluke ESA620, 6920 Seaway Boulevard Everett, WA, 98203, USA) that complied with international standards was used to carry out a current leakage test, a voltage test, and a

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resistance test. According to the IEC 60601-1:2005 Medical Electrical Equipment Standard [17], the acceptable safe level for leakage current is 10 μA , while 0.5 - 1.1 mA represents a range where current could be noticeable when applied to the fingertips. For a class II medical device, where suction machine belongs according FDA [18], the

equipment current is 0.1 A with voltage of 230V AC.

The objective of the current leakage test was to verify that the product does not leak excessive current when in contact with the user and patients. The experimental setup for electrical safety analysis of the developed equipment is as shown in Figure 4.



Figure 4: Electrical safety test arrangement

RESULTS AND DISCUSSION

Here we report and discuss the results of the electrical safety analysis (Figure 4) carried out on the developed device. Specifically, the leakage AC and DC were 0.1 μA AC and 0.0 μA DC, respectively as shown in Figure 4, meaning that the effects of electric current in the human body were negligible and were not perceptible. According to IEC 60038:2009, the standard voltage values are 230V (50Hz). The mains voltage of the developed suction device for Live to Earth was 227.8V AC, Neutral to Earth was 0V AC, and Live to Neutral was 228.0V AC, accessible voltage of 0.1V AC. With these, the developed suction device can be adjudged safe for clinical deployment.

CONCLUSION

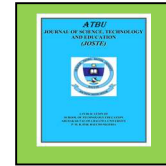
Inexpensive and readily available materials were used in fabricating the portable suction device described in this study. Hence, the device is affordable and useful in hospitals in low-resource settings. The results of the electrical safety analysis carried out on the developed device showed that this device would certainly function safely in clinical settings as its operation and maintenance are made to be seamless. The low cost of production and ultimately, procurement of the device (<USD 65) will also make it attractive to clinicians in developing countries and promote its use for their routine clinical services. Specifically, this device will make oral and respiratory waste removal seamless for critically ill patients being managed in rural healthcare settings. In the future, the performance of the device using fluids with different viscosities similar

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to the biological fluids will be performed subject to the ethics approval.

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