Innovating for Global Health through Community-Based Participatory Research:

Design of Mechanical Suction Machines for Rural Health Clinics in Malawi

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ACADEMIC ABSTRACT

Clinicians in low and middle-income countries (LMIC) face many challenges, including high patient-to-staff ratios, limited resources, and inconsistent access to electricity. This research aimed to improve health outcomes in LMIC through an enlightened understanding of challenges associated with healthcare technology. To understand LMIC barriers to acquiring, maintaining, and repairing medical equipment, a community-based participatory study was conducted at three clinical settings in southern Malawi. Thirty-six clinical staff participated in surveys and focus groups to provide information on medical device challenges. Results from the study emphasize the importance of community-based participatory innovation to improve global health. Many clinical staff expressed frustration regarding inability to prevent patient mortality attributed to equipment failure.

Data from the community-based participatory study of medical technology conducted in Malawi revealed key insights for designing for low and middle income countries, and more specifically, for communities in southern Malawi. Specifically, partner communities identified mechanical suction machines as a top priority for design innovation. Working with technical and clinical staff in Malawian communities, a prototype mechanical suction machine was designed and constructed.

This work suggests that engineers working in low and middle income countries face a unique sundry of design requirements that require an intimate understanding of the local community, including community leaders, community beliefs and values, and locally available resources. Technology innovation for global health should incorporate community expertise and assets, and health and technical education efforts should be developed to increase working knowledge of medical devices.

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To my mentors, friends, brothers, and sisters in Malawi
for guiding me with fortitude and compassion.
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forever changing me with your kindness.
I am humbly grateful.

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Chapter 1: Literature Review

Medical professionals in resource-limited clinical settings in low and middle income countries (LMIC) face distinct challenges, including understaffing, an unstable electric grid, and shortage of resources. In recent decades, international leaders in healthcare have placed an unprecedented priority on improving health in LMIC [1]. The following chapter outlines challenges that health systems face in LMIC, the public health significance of medical devices, and a review of recent successful public health interventions in medical devices.

1.1 Health Care System Challenges in Low and Middle Income Countries

Patient-to-staff ratios remain a pressing challenge for health care systems in LMIC. Available data reveals a massive shortage of health personnel in low-income countries, particularly in sub-Saharan Africa (Figure 1). A recent study found that 82,949 physicians in sub-Saharan Africa are responsible for providing care to 660 million people, resulting in a ratio of 13 physicians per 100,000 people [2]. In contrast, the United Kingdom and the United States have ratios of 164 and 279 physicians per 100,000 people, respectively [2].

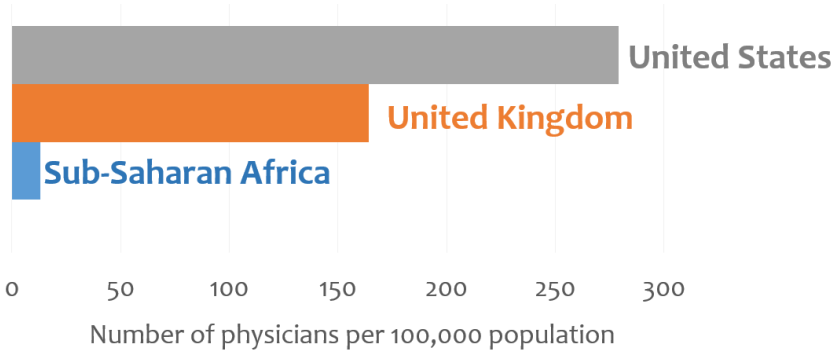


Figure 1. Available data reveals a massive shortage of health personnel in low-income regions, particularly in sub-Saharan Africa. Data source: [2].

Physician-to-patient ratios are exasperated by the 'brain drain', a term which was first used in the 1960s to describe the negative impact of the loss of qualified scholars and personnel from exporting (low income) countries [3], [4], [5]. After clinical training, many physicians from low income countries move to wealthier regions of the world to pursue higher income, better working conditions, and economic prosperity for themselves and their families [2], [4]. After conducting extensive research on the effects of the 'brain drain' on health disparities in low and middle income countries, Padarath et. al conclude the following:

> "The migration flows of health personnel follow a hierarchy of wealth and result in a global conveyor belt of health personnel moving from the remote, rural areas of low income countries via urban areas and/or the private sector in these countries into the under-served areas in high-income countries." [6] [7]

Ultimately, Padarath et. al conclude the migration of health workers accelerates inequities in resource-limited areas [6].

Acknowledging the health disparity the brain drain creates in low and middle income countries, many governments, such as the government of South Africa, have implored the World Health Assembly to prioritize initiatives to prevent the migration of physicians from poor to rich areas. In fact, South Africa set a prominent example for the rest of the world by banning recruitment of physicians from 54 member states of the Africa Union, including many countries in sub-Saharan Africa [2], [3], [8]. Still, the migration of talented health workers continues to occur at alarming rates. A 2004 study found that 5,334 physicians in the U.S. are from sub-Saharan Africa, representing over 6% of the physician workforce practicing in the region at the time of the study [2].

Effects of this migration are not fully understood, partly due to the sparcity of surveillance systems in resource-limited countries. Observing this data gap, the World Bank notes:

> "Quantitative data on the health workforce is notoriously unreliable… in poor countries, government and professional information systems are weak, when they exist at all, and are rarely comprehensive (often there is no information on the private sector) and up-to-date." [2], [9]

Still, as stated previously, available data does confirm a massive deficit of health personnel in LMIC, and without adequate surveillance systems, the issue may be under-realized. By reducing population access to qualified health workers, physician migration intensifies strain on an already stretched system [2]. For sub-Saharan Africa, the life expectancy is 57, and the prevalence of malnutrition (height for age, under five) is 37% [10]. The maternal mortality ratio remains high at 510 maternal deaths per 100,000 live births [10]. The under-five mortality rate for the region, defined by the World Bank as the probability of dying between birth and exactly five years of age, is 92 per 1000 live births, and the infant mortality rate, or the number of infants who die before the age of one year, is 61 per 1,000 live births [10].

Unsatisfactory working conditions, including poor infrastructure and technology, contribute to the brain drain and also present additional barriers to providing health care to patients [2], [3]. Ultimately, energy plays a critical role in the successful delivery of healthcare [11]. Recognizing the importance of energy access in health facilities, the World Health Organization (WHO) is currently devoting resources to scale-up energy access in health facilities, with a particular focus on maternal and child healthcare facilities [11].

Recently, the WHO conducted an international review on the current status of electricity access in health facilities. Nationally representative data was available for only 14 developing countries globally, 11 of which are in sub-Saharan Africa [11], [12]. However, even the scarce amount of data showed alarming results. Of health facilities studied, 25% had no access to electricity. Reliable access, defined as without prolonged interruptions in the past week, was found in only 28% of health facilities and 34% of hospitals [11], [12]. Inconsistent access to electricity remains a key barrier to successful implementation of public health interventions, since many interventions rely on the use of electricity-dependent technology.

1.2 Public Health Significance of Medical Devices in Resource-Limited Settings

In the past half century, both successful and failed global health efforts have shown that medical devices, including their availability, accessibility, and effective use, play a critical role in the quality of healthcare for a population and the realization of healthcare system goals. In the 1970-1980's, international leaders in healthcare placed an unprecedented priority on improving health in LMIC [1]. Several key priorities were identified, including nutrition, birth spacing, control of acute respiratory infections and vector-borne disease, provision of clean water and adequate sanitation, immunization, and oral rehydration [1]. An initiative called "Healthcare for All by the Year 2000" was created, and the efforts to improve access to healthcare worldwide seemed promising.

However, the "Healthcare for All by the Year 2000" initiative made one critical, flawed assumption [13], [14]. The steering delegation for the initiative assumed that technology interventions already existed to aid in the achievement of program goals. Free

summarizes the realization of this flawed assumption, which would ultimately inhibit the success of the initiative:

> "Over the next few years, the experience of implementing primary health care programs in developing countries supported the initial enthusiasm. Where programs were applied with strong political commitment and adequate funding, impressive reductions in infant mortality followed. It became increasingly clear, however, that 'something was wrong'. Infant mortality remained high even in countries with the best programs. Health experts realized that the early optimism that 'technological solutions existed' was naïve. In practically every primary health care program, problems had arisen with the application of technologies." [13], [14]

For example, vaccination programs were unsuccessful after vaccines lost their potency because of lack of refrigeration [14], [1]. A lack of technology to sterilize syringes resulted in transmission of diseases to immunization program participants. Program goals pertaining to water and sanitation were unable to be achieved because pit latrines and water pumps could not be easily maintained in the field [14]. After these failures in the Healthcare for All initiative, it became apparent to health leaders that medical devices play a critical role in improving health outcomes in LMIC [13]–[15], [16], [17]. The World Health Organization now acknowledges that without increasing access to essential medical devices, most current global health goals cannot be achieved [13], [15], [16], [17]. Furthermore, the WHO recently declared that "medical devices provide the foundation for prevention, diagnosis, treatment of illness and disease, and rehabilitation" [17].

In an effort to reduce barriers to accessibility of medical devices in LMIC, extensive research is being undertaken on medical device procurement in LMIC. A recent, large-scale study found that over 95% of medical equipment is imported from developed countries [15], [18]. This is not surprising, given that only 13% of medical device manufacturers are located in LMIC [13], [17]. Due to procurement and manufacturing

issues, among others, a wide technology gap persists in resource-limited clinical environments. It is estimated that 70% of medical technology currently available does not function properly in developing world hospitals [18].

Broadly speaking, innovations in appropriate health technology have been limited to the industrialized world [19], though the largest need for medical devices is found in LMIC [17], [18]. Most equipment in resource-limited environments is donated, often by organizations that fail to adequately understand and consider local needs and design constraints, such as inconsistent access to the electric grid [19]. Ultimately, this cycle results in medical devices often not being used past one year of time of donation [19]. A study of medical device access in Latin America and the Caribbean found that 96% of equipment is non-functioning just five years after donation [15], [18], [20]. An additional 39% are never able to be utilized due to lack of users manuals, training, or spare accessories and consumables [15], [18], [20].

1.3 Successful Public Health Interventions Using Technology

Since the Healthcare for All by 2000 Initiative, funding for health technology for public health initiatives has increased. Organizations such as the Bill and Melinda Gates Foundation, Saving Lives at Birth, Ashoke Changemakers, and NIH Framework have served as critical contributors to funding of global health technologies [21]. As a result of this support, innovation in this arena has seen some notable successes. One of the key leaders in the advancement of global health technologies is the

Figure 2. Disposable syringe jet injectors are a notable global health technology achievement of the PATH Global Health Technologies Coalition. Source: PATH Global Health Technologies Coalition.

Program for Appropriate Technology in Health (PATH) Global Health Technologies Coalition, which strives to accelerate advancement of health technology solutions for low and middle income countries [22]. Through an innovative model, the coalition aims to enable public and private sectors to work symbiotically [18]. Nonprofit corporations, private sector corporations, and universities are partnered to design technologies for public health initiatives in resource-limited environments [18].

Ongoing technology development of the Coalition includes diagnostics, devices, and system and service innovations [22]. One notable success of the coalition is the single-use, disposable-syringe jet injector, a technology developed in response to health threats resulting from reuse and improper disposal of contaminated needles and syringes (Figure 2) [23]. This coalition-developed technology allows medicines and vaccinations to be delivered sans needles, preventing spread of infections among patients [23]. Working with the WHO, PATH has conducted prototype assessments with users in Brazil, China, and India. Ultimately, PATH's pursuit of this technology development may lead to dose sparing, which promises to reduce cost of life-saving vaccines [23].

The PATH Global Health Technologies Coalition partners technology development with advocacy work in public financing of global health research. Additionally, the Coalition serves as a leader in advocating for improved, effective regulatory pathways for licensing of safe technologies [22]. In 2015, the Coalition strongly encouraged the Food and Drug Administration (FDA) to engage in a more comprehensive and tactical approach for global health regulatory issues [24].

The United Nations has also taken a central leadership role in the development of health technologies. Through an initiative of the UN Economic Commission for Africa, the Open Source for Biomedical Engineering (OS4BME) project was created in 2013. In a one-week, intensive course, students from all over the world were exposed to top-quality health design education. Excitingly, the initiative even resulted in the design and assembly of an open source neonatal monitor [13], [25].

Figure 3. Malawian nurse Florence Mwenifumbo cares for a neonate who is receiving treatment from the Pumani bubble CPAP machine at Queen Elizabeth Central Hospital. Source: Rice University, Rice 360°Institute for Global Health Technologies

Several universities in the United States are working towards the successful development of global health technologies. With support from the Lemelson Foundation, Rice University's Department of Bioengineering, the Rice 360° Institute for Global Health Technologies, and the University of Malawi have formed a collaboration to exchange innovative ideas for development of global health technologies. Notably, the collaboration resulted in the development of critical neonatal technologies, including an affordable bubble CPAP machine called Pumani (Figure 3). Preliminary clinical studies in Malawi show remarkable results; the survival rate of infants treated with the Pumani bubble CPAP machine was 71 percent, compared to 44 percent survival rate of infants treated with nasal oxygen from an oxygen concentrator, the current standard of care in Malawi. The cutting-edge technology has been installed at nine hospitals, totaling 22 functioning machines and 354 clinicians who are trained to use them [26]. South Africa, Tanzania, and Zambia will participate in pilot programs in the near future [26].

Duke University sponsors an Engineering World Health Competition for underserved committees. An innovative nonprofit business plan competition provides the opportunity to design a comprehensive approach for development of medical devices for LMIC [14]. The Massachusetts Institute of Technology (MIT) has partnered with the Consortium for Affordable Medical Technologies to lead health technology innovation efforts in India and Uganda [27]. These efforts have resulted in several successful projects, including topics of prevention, monitoring, diagnosis, and treatment of diseases [27].

Partnering with MIT, the non-profit organization Design That Matters has developed a phototherapy device, Firefly (Figure 4), for treating jaundice in resource-limited clinics. To date, the phototherapy device has treated 20,000 newborns in 18 countries [28]. Other technologies created by the non-profit design firm include a portable pulse oximeter, newborn warmer, and a remote-monitoring technology to communicate with rural hospital who need assistance with medical device maintenance or repair [28].

Figure 4. Developed by the nonprofit institution Design that Matters, a collaborator of MIT, the firefly phototherapy device treat jaundice in newborn infants in 18 countries. Source: Design that Matters.

Figure 5. The Embrace Infant Warmer, developed by Stanford University, has been used to prevent hypothermia in 50,000 low birth weight and premature infants in 11 countries. Source: Embrace Infant Warmer.

Out of Stanford University's Design for Extreme Affordability course, a novel infant warming system was born. The "Embrace Infant Warmer" (Figure 5) uses phase change materials to help potentially hypothermic infants maintain fragile body temperatures [29]. Costing around $200, the Embrace Infant Warmer offers revolutionary, life-saving technology that has previously been inaccessible in the developing world. To date, Embrace Infant Warmer has been used to treat 50,000 low birth weight and premature infants in 11 countries [29].

Though these technology developments have had a significant impact on global health, much work still remains to be done. In an effort to encourage appropriate innovations for resource-limited settings, the WHO developed international standards for medical innovations in 2014. These standards resulted from the Priority Medical Devices (PMD) project, which is continuously working to detect accessibility gaps of medical devices [30]. The PMD project aims to address training of medical device users, medical device design, contextual appropriateness of medical devices, and regulatory oversight. Research sponsored by PMD is working to understand barriers to innovation of health technologies for resource-limited settings, as well as catalysts that encourage innovation in LMIC [30].

Chapter 2: Methodology of Community-Based Participatory Needs Assessment Conducted in southern Malawi

During July 2014 and July 2015, an assessment of regional-specific needs for improved access to appropriate health technology was conducted in Malawi. Recognizing the significance of health technology to public health, the needs assessment was conducted to ensure that future design and implementation of health technology incorporates the specific needs of health facilities in Malawi. The methodology used in this assessment was based on the World Health Organization's guidelines for assessing health technology needs in resource-limited settings; these guidelines recommend employing community-based participatory research (CBPR) to assess local needs [31]. Mantzavinou nicely summarizes these WHO guidelines for community-based innovation in health technology:

> "Involvement of the community, local innovators and other stakeholders … is especially critical for the sustainability and acceptance of novel healthcare solutions in resource limited settings. It is imperative that these local partners be involved in the innovation process from the beginning, to identify unaddressed needs, understand resource availability, ask the right questions, seek appropriate feedback, and ultimately develop sensible solutions that will not be thwarted by impenetrable adoption or dissemination barriers." [27]

By working with key stakeholders, interventions aimed towards improving public health can be tailored to the specific needs of the community. The following section briefly outlines 1) the basic premises of CBPR, 2) context of communities in Malawi, and 3) the methodology of the assessment conducted in Malawi health clinics.

2.1 Community-Based Participatory Research

The basic premise of community-based participatory research (CBPR) is to partner community members' practical knowledge and experiences with methodological

and theoretical skills of researchers [32], [33]. In recent years, many public health initiatives have begun to emphasize CBPR in an effort to encourage genuine, collaborative partnerships between researchers and communities [33], [34]. One of the most widely utilized definitions of CBPR was put forth by the W.K. Kellogg Foundation's Community Health Scholars in 2001, defining the research method as:

> "a collaborative process to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community with the aim of combining knowledge and action for social change to improve community health and eliminate health disparities" [33].

To address complex issues of health disparities, CBPR aims to empower community members as agents of change, utilizing and building upon community assets in every phase of the research process [33], [35]. As Cornwall and Jewkes have identified, the paradigm shift in CBPR is embodied by a shift in the attitude of researchers, in addition to the methodological context [33], [36]. CBPR challenges the model of traditional applied research in which a researcher or "expert", most often from outside the community, is solely responsible for making research decisions [33]. These decisions, including research questions to be explored, tools to be used to conduct research, interventions developed and employed, and results analyzed and evaluated, are of critical importance to both long-term and short-term research outcomes [33]. CBPR recognizes the importance of collaborative partnership at every phase of the research process.

Working with colleagues, Barbara Israel, who remains a leading scholar on CBPR, has summarized nine key principles of CBPR, as explained below [35]. These principles serve as a guide for the CBPR process.

1. CBPR acknowledges a community as a unit of identity with both collective and individual components. The unit of identity, such as a family or village, may be described by shared values or social norms, commitment to meeting shared needs, and sense of connection to other community members [35].
2. CBPR identifies and builds upon assets within the participating community. By identifying and strengthening existing strengths and resources of communities, community members and researchers work together to improve community health [35].
3. CBPR is collaborative, meaning that all parties are equal participants in every phase of the research process [35].
4. CBPR involves integration of knowledge and action for mutual benefit of all partners [35].
5. CBPR promotes reciprocal transfer of knowledge by promoting a co-learning environment [35]
6. CBPR is an iterative, cyclical process incorporating research, reflection, and action [35], [37]
7. CBPR employs both positive and ecological perspectives of health. Positive perspectives of health focus on physical, mental, and social wellness, while ecological perspectives of health consider a spectrum of determinants of health including biomedical, social, economic, cultural, historical, and political factors [35]
8. CBPR includes dissemination of results and knowledge gained to all partners in a method that is respectful and understandable for all involved [35]
9. CBPR necessitates long-term commitment from all partners [35], [38]

Limitations of the CBPR methodology certainly exist. Critics of CBPR question whether research methodology can truly be objective when community members are involved [33], [35]. Another key limitation of CBPR is the extensive time investment of the methodology, which often leads to increased research costs. Still, the advantages of CBPR are significant. Arguably the most profound advantage is the mobilization of communities by helping community members realize and build-upon their assets as change-agents and researchers [35]. Additionally, CBPR may produce more sustainable long-term results than traditional methods due to the facilitation of trust relationships between communities and researchers [39].

2.2 Context of Communities in Malawi

Figure 6. Located in sub-Saharan Africa, Malawi is a land-locked country with a population of approximately 16.4 million. Source: Umoyo Orphan Project, 2008.

In order to partner effectively with communities for the CBPR methodology, it is imperative to understand the relevant context of partnering communities. The following sections outline the geography, political history, culture, economy, and health indicators of partnering communities in Malawi.

2.2.1 Geographical Context of Malawian Communities

Located in sub-Saharan Africa, Malawi is a land-locked country bordering Tanzania, Mozambique, and Zambia (Figure 6). In 2016, the population of Malawi was estimated at 17.8 million [40]. Located in central Malawi, Lilongwe serves as the nation's capital, replacing the former capital of Zomba in 1975 [41]. A defining characteristic of the country is Lake Malawi, which forms the eastern boundary between Malawi, Tanzania, and Mozambique. Lying in a deep trough of the Great Rift Valley, it is the third largest lake in Africa [42], [43]. Lake Malawi, with a single outlet of the Shire River, comprises over 20% of Malawi's total land mass [42]

Topographically, Malawi varies significantly by region. Rugged mountains comprise the Northern Region, while the Southern Region consists of low elevations, with

the exception of Mount Mulanje and the Zomba Plateau 3,000 meters and 2,100 meters above sea level, respectively [43]. The Central Region of Malawi houses most of the country's agriculture industry on a plateau at 1,000 meters above sea level [43]. In 2002, the Central Region was connected to the Indian Ocean via a railway line linking central Malawi to Nacala, a port in Mozambique [44], [45].

The Malawian Ministry of Natural Resources, Energy, and Environment classifies the climate as subtropical with three main seasons. From November to April, the country experiences a warm, wet season with humidity levels around 87%. Nearly all (95%) of the country's annual rainfall occurs in warm-wet season, with total ranges from 0.725-2.5 meters. During the winter season from May to August, average temperatures fall between 17-27 °C. The cool, dry winter can bring temperatures as low as 4 °C. From September to October, Malawi experiences a hot, dry season with average temperatures of 25-37 °C and 50% humidity [46].

2.2.2 Political History of Malawi

Malawi gained independence from Britain in the 1960s, but the government was run by an authoritarian leader for the first 30 years of the country's independency [44]. Humanitarian donor interactions with the country, which comprise approximately 40% of the annual national budget, have been strained in recent years as the government of Malawi strives to overcome corruption [44]. A brief history of Malawian politics is useful for understanding community context and international relations.

One of the most influential figures in Malawian history is Victorian explorer Dr. David Livingstone, a Scottish missionary, abolitionist, and physician, who arrived in Malawi in the 1850s [47]. Dr. Livingstone was passionately opposed to slavery and spent

his life advocating for human rights, particularly in sub-Saharan Africa. Dr. Livingstone remains a controversial figure in Malawian history; many argue that he, albeit unwillingly, opened the door to the colonization of Malawi [48]. Dr. John Lwanda, a Malawian historian, reflects on Livingstone's influence in Malawi:

> "Malawians overwhelmingly like David Livingstone. He brought Christianity; he introduced Malawi to the outside world. One of the bad things that he did, when he opened up that part of Africa it led to the scramble for Africa and in the case of Malawi we were left with a small sliver of land, the rest was taken away from us." [48]

Still, Livingstone remains beloved by Malawians, remembered for his relentless fight against the East African Slave Trade. In fact, Blantyre, Malawi's commercial center and oldest city, is named for Dr. Livingstone's birthplace in Blantyre, South Lanarkshire, Scotland [47], [49].

In 1891, nearly 20 years after Livingstone's death, Britain established Nyasaland and District Protectorate in modern-day Malawi [50]. During this time of British colonization, coffee plantations contributed most largely to the economy. For tax incentive purposes, Malawians often worked on these plantations under difficult conditions. Unjust conditions, among other issues, resulted in growing opposition to British rule in the early 1900s to 1950s. In 1953, the conflict reached a pivotal point when Britain combined Nyasaland with modern day Zambia and Zimbabwe, which directly defied the advising of the Nyasaland African Congress [50].

Dr. Hastings Kamuzu Banda, who was studying in the United States and Britain, was outraged by the blatant disregarding of the Congress's wishes. He was compelled to return to Malawi in 1958 to lead the Congress, and from this point on, played a crucial role in working with British government to reform the constitution [50]. In 1961, Nyasaland

became self-governed, and Banda won 94% of the vote to become prime minister. A few years later (1964), Nyasaland officially became the Republic of Malawi, and Banda was declared President for life [50].

Banda faced scrutiny during his political tenure after detaining leaders who opposed the ideas of his party, the single party in the one-party nation of Malawi [44]. Suspecting corruption, the Catholic Church publicly condemned Banda, resulting in many humanitarian organizations withholding aid. Banda later retired from politics and was succeeded in presidency by Bakili Mulizi in 1994. Later, Mulizi would be arrested on corruption charges [50].

In 2004, Bingu wa Mutharika was elected as President of the Republic of Malawi. Tragically, Mutharika succumbed to AIDS in office, resulting in Vice President Joyce Banda assuming the role of President in 2012. Peter Mutharika, the brother of late president Bingu Mutharika, has held the office of the presidency in Malawi since May 2014 [50].

2.2.3 Cultural Considerations in Malawi

Major languages spoken in Malawi include Chichewa and English, aiding communication with English-speaking travelers [44]. In the northern, more rural regions, Chitumbuka is the most common language. Many cultural influences in Malawi reflect Christian values, largely due to the lasting influence of Presbyterian missionary David Livingstone. Christianity comprises 75% of religious preference in Malawi, followed by Islam (20%) and indigenous religions (5%) [51].

Collectivism is central to the culture of Malawi, similar to much of sub-Saharan Africa. Decisions are made collectively, as opposed to many Western cultures where individualism is held paramount [52]. Malawians are notoriously humble, polite, and

inclusive, and tend to prefer indirect communication. In business settings, relationship building should be held as the primary objective. Engaging in small talk with colleagues, such as inquiring about family, health, travel, etc., should proceed formal conversation [53]. Western visitors to the country should note that Malawians may perceive direct communication as rude or insensitive [53], [54].

Family is held paramount in Malawi. The father is the traditional head of the household; Malawi is a historically patriarchal society, with work for men and women clearly defined in societal gender roles [54]. Conceptions of time also differ from conceptions in many Western cultures. In Western cultures, time is linearly defined. Malawians, on the other hand, observe a polychromic definition of time, ensuring that relationships are never compromised to achieve promptness [53]. The polychromic element of Malawian culture often results in delayed meetings, even up to several hours, and should not be viewed by visitors as offensive or disrespectful [53].

2.2.4 Economic Development in Malawi

Despite an estimated growth in GDP of 5.7% in 2014, Malawi's GDP per capita in 2014 was 255 USD, the lowest in the world [55]. An estimated 40% of Malawi's annual budget is donor-funded through NGOs and other humanitarian efforts [56]. At approximately 170 million kilograms per year, Malawi's major export is tobacco [55]. Uranium and Thorium Ore compromise 9.9% of all exports from the country, while tea comprises 6.4% [57]. The currency in Malawi is the Malawian Kwacha (MKW), which in March 2016 was at exchange rate of 1 USD = 715 MKW.

Presence of a strong fishing industry is evident near Lake Malawi, which contains more diversity of fish species than any other lake in the world [54]. However, the economy

of Malawi largely revolves around agriculture. A 2010/2011 Integrated Household Survey estimated that 25% of Malawians live on subsistence farming, and 61.6% of Malawians live below the international poverty line of USD $1.25 per day [58].

2.2.5 Health Indicators in Malawi

Poverty remains a pressing issue in Malawi, compounding issues in the healthcare system. From 1993 to 1997, the World Health Organization conducted an extensive study on the overall efficiency of healthcare systems in member states, including Malawi. At a national level, Malawi ranked 185 of 191 healthcare systems [59]. However, for nearly a decade, the Ministry of Health in Malawi has significantly increased efforts to improve health, with particular focus on improving maternal and child health; their efforts have yielded tremendous progress (Figure 7). In 2015, the infant mortality rate in Malawi was estimated at 46.26 deaths per 1000 live births, down from 72 deaths per 1000 live births in 2006 [60]. In the same time period, the mortality rate for children under five has been nearly cut in half (122 deaths per 1000 children under 5 in 2006 to 64 deaths per 1000 children in 2015). Maternal mortality rate remains alarmingly high and has remained fairly stagnant in the last decade (614 deaths per 100,000 live births in 2006 to 634 deaths per 100,000 live births in 2015) [60]. The average life expectancy in Malawi is 61 years [58].

A shortage of clinical staff remains a pertinent problem in Malawi. The physician to patient ratio is estimated at 1 physician per 53,000 people [61]. Nursing education efforts have increased in recent years, but the ratio of 1 nurse per 3,500 people still presents challenges for providing care to patients [61].

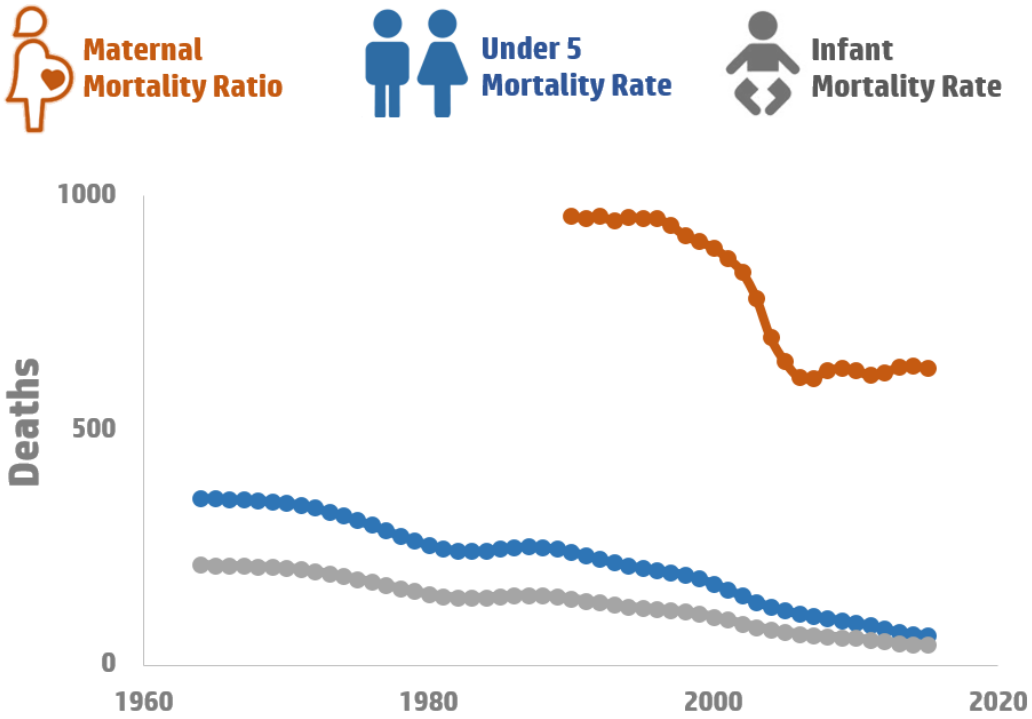


Figure 7. The efforts of the Malawian Ministry of Health have yielded significant improvements in maternal and child health. Both infant mortality rate and mortality rate for children under five have notably decreased in Malawi since 1960. Maternal mortality rate remains alarmingly high in Malawi, and progress has been fairly stagnant since 2000. Original figure. Data source: The World Bank.

2.3 Methodology of Needs Assessment of Clinical Settings in Malawi

The assessment of needs pertaining to medical devices was conducted through a series of focus groups and a survey on medical devices. Cumulatively, the two-year needs assessment had three main objectives:

1) Prioritize community-identified needs for technology intervention in rural Malawi
2) Establish a definition of appropriate technology for rural Malawi
3) Understand the process of repairing and maintaining medical devices in order to ensure the sustainability and longevity of devices in rural Malawi.

The assessment included eight hospitals throughout Malawi, shown in Figure 8 and identified by region and district in Table 1. Focus groups, involving a total of approximately 110 medical personnel, were conducted at all eight hospitals in July 2014. The focus groups provided a wealth of information about barriers to acquiring,

maintaining, and repairing medical equipment in rural Malawi. Nurses and clinicians noted challenges such as inconsistent access to the electric grid and use of outdated equipment. Additionally, focus group participants emphasized the difficulty in repairing and maintaining equipment due to lack of locally available spare parts, lack of user's manuals, and an extreme shortage of maintenance personnel. Several hospitals included in the needs assessment had no maintenance staff on site.

Table 1. Hospitals included in assessment of medical device needs in Malawi
Data source: Census of Malawi

Hospital	Location	Region	District	Regional Population
Domasi Rural Hospital	Domasi	Southern	Zomba District	not available
Mulanje Mission Hospital	Mulanje	Southern	Mulanje District	550,000
Zomba Central Hospital	Zomba	Southern	Zomba District	670,533
Kamuzu Central Hospital	Lilongwe	Central	Lilongwe District	1,897,167
Mzuzu Central Hospital	Mzuzu	Northern	Mzuzu District	128,432
Queen Elizabeth Central Hospital	Blantyre	Southern	Blantyre District	999,491
Embangweni Mission Hospital	Embangweni	Northern	Mzimba District	not available
Ekwendini Mission Hospital	Ekwendini	Northern	Mzimba District	not available

In an attempt to more adequately understand and quantify the issues highlighted in focus groups, a comprehensive survey on medical devices was developed. The survey, developed using the WHO list of Core Medical Equipment [31], provided a formal method of assessing and prioritizing need in rural Malawian hospitals. Survey design included inquiry about specific, commonly used medical devices as well as open-ended questions on hospital infrastructure and device maintenance (Table 2). The research study protocol was approved through both the Virginia Tech Institutional Review Board (IRB) and hospital administrators at each collaborating institution. The comprehensive survey, including IRB documents, can found in Appendices A-D. It is important to note that the data may be subject to response bias due to the nature of survey-based studies. While statistical inferences about larger populations should not be drawn based on this data, the data does provide critical information about community-specific needs in southern Malawi.

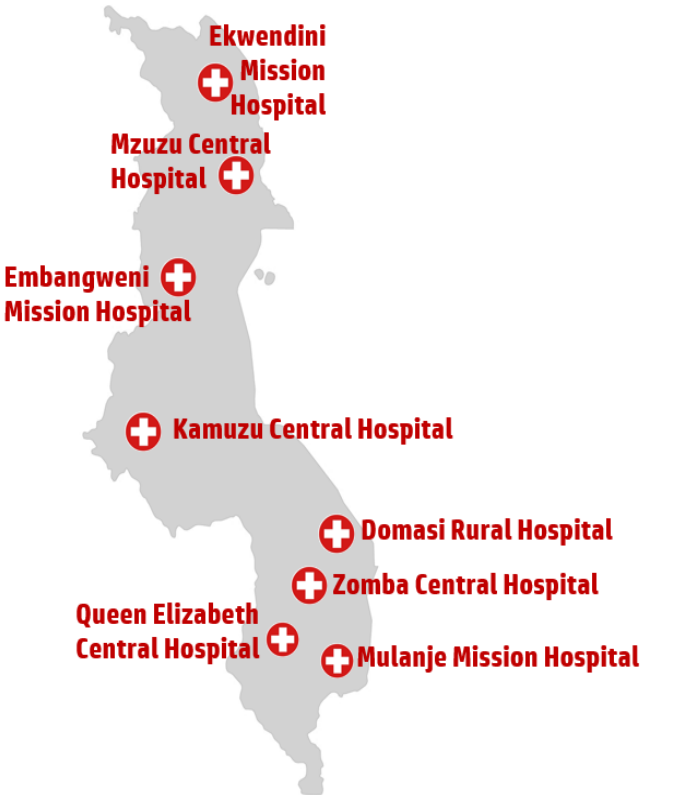


Figure 8. A comprehensive assessment of need for medical devices was conducted in partnership with eight hospitals in Malawi.

Table 2. Questions included in medical device needs assessment survey

1.	[What is] your occupation?
2.	In which setting do you work?
3.	Please list the top five challenges to providing medical care in your clinical setting.

4.	For each of the following [medical] devices, please check all that apply: 1) Hospital has access to device 2) Device is working properly 3) Device is used frequently 4) Comments on device limitations
5.	List the medical devices in your hospital that are in frequent need of repair.
6.	On average, how long does it take to repair a medical device at your hospital?
7.	[What are the] challenges [associated with] repairing equipment?
8.	[What] materials are locally available?
9.	When trying to repair medical devices, are parts difficult to obtain locally?
10.	How often does your hospital have continuous access to electricity?
11.	Does your hospital have access to a backup generator that is functioning properly?
12.	Which of the following problems does your hospital experience? 1) None 2) Daily power outages 3) Power outages 2 or more times per week 4) Power surges
13.	How often does your hospital have continuous access to a safe water supply?
14.	Is the water supply distributed to the entire hospital?
15.	Which of the following problems does your hospital experience with the water supply? 1) No problem 2) Water is contaminated 3) Access to water is unreliable
16.	Is there any other information that you would like to share about challenges that your hospital faces?

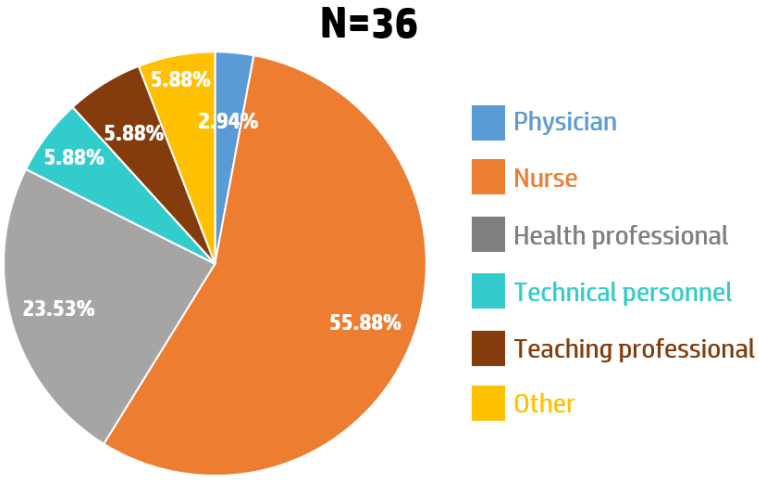


Figure 9. Participants in the needs-assessment survey included clinical personnel in low resource environments. The largest sub-population of personnel who participated in the survey included nurses (56%), followed by health professionals (25%), technical personnel (6%), and teaching professional (6%). Physicians accounted for less than 3% of survey participants, reflecting Malawi's low physician-to-patient ratio.

Surveys were administered to 53 clinical staff at 3 participating hospitals in southern Malawi, and 36 clinical staff completed the survey for a survey response rate of 67.9%. For purposes of anonymity, all personnel

have been de-identified from hospitals in the following data. On average, the survey took approximately 15 minutes for each participant to complete. Surveys were completed anonymously in an attempt to elicit unbiased answers. The survey was completed only once by each clinical staff at a location that was convenient for the respective participant. The survey involved minimal risks and discomfort to participants. There is no physical risk or discomfort associated with the research procedure, and emotional stress of completing the survey was minimized by removing a time limit from the procedures. There are no individual benefits associated with completing the study; however, the study includes the larger societal benefit of helping to develop more appropriate medical devices for use in resource-limited settings.

Figure 9 shows the distribution of occupations of clinical staff who participated in the survey; the largest sub-population of survey participants included nurses (56%), followed by health professionals, including clinical officers (24%). Technical personnel, such as maintenance professionals, accounted for 6% of survey participants. Teaching professionals, such as lecturers at national nursing colleges, comprised an additional 6% of survey participants. Other participants included laboratory technicians. Physicians accounted for less than 3% of survey participants, reflecting Malawi's low physician-to-patient ratio [61]. As shown in Figure 10, 71% of

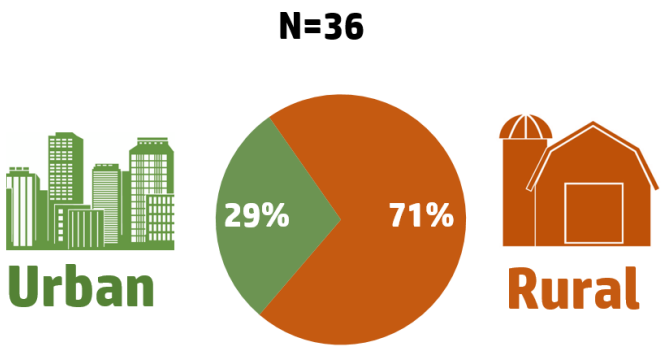


Figure 10. 29% of survey participants reported working in an "urban" setting, while the majority of survey participants (71%) reported working in a "rural" setting.

survey participants identified their clinical setting as “rural”, while 29% identified their setting as “urban”.

In addition to specific questions about availability of electricity, medical device maintenance, and access to specific WHO-recommended equipment, the needs assessment also included open-ended questions about the broad range of challenges facing clinicians. Such questions were designed to elicit unbiased information and provide survey participants with an opportunity to enlighten technology designers on key issues in resource-limited clinical environments.

Following the CBPR model, the survey was developed in collaboration with public health colleagues in Malawi. Furthermore, the survey was piloted with nursing instructors at Mulanje Nursing College as well as maintenance personnel at Mulanje Mission Hospital. Piloting of the survey was conducted in order to ensure that 1) questions were appropriately worded and 2) research topics covered in the survey were appropriate.

Chapter 3: Results and Findings of Community-Based Participatory Needs Assessment

For the purposes of anonymity of hospitals and clinical staff, all data presented in the following section have been de-identified. Some of the most informative data obtained from the survey resulted from asking each participating clinical staff to list his/her greatest challenges to providing medical care (question 3, Appendix A). Thirty-six clinical personnel gave 117 distinct responses to this question, providing extensive insight into the day-to-day challenges of clinicians in low-resource environments. Taylor-Powell and Renner's method for analyzing qualitative data was used to divide the responses into relevant themes, known as thematic analysis [62].

Taylor-Powell and Renner provide two methods of categorizing and interpreting narrative data. One suggested method is to construct preset categories with which to analyze data. In other words, thematic analysis can be accomplished by establishing themes of interest before the data is collected [62]. After the data is collected, the preset categories may be used to search and analyze information. The second method involves forgoing predetermined themes and allowing themes to naturally emerge from the data. Taylor-Powell and Renner refer to this type of categorization as "emergent", and they note that letting themes emerge after the data is collected may expose information not previously considered [62]. For this reason, emergent thematic analysis was chosen to examine responses from clinical staff in Malawi.

Using emergent thematic analysis, the challenges identified by clinical personnel were divided into three general categories: equipment, infrastructure, and human resources (Figure 11). The majority (40.5%) of challenges identified by clinical personnel pertained

to equipment failures or inadequacies. An additional 37.9% of identified challenges referred to issues with healthcare infrastructure, including late reporting of patients to hospitals and an overall fragile infrastructure of hospital systems. The remaining challenges identified in the survey (27.6%) were related to human resources, such as lack of both technical and clinical personnel and high patient-to-staff ratios. The following

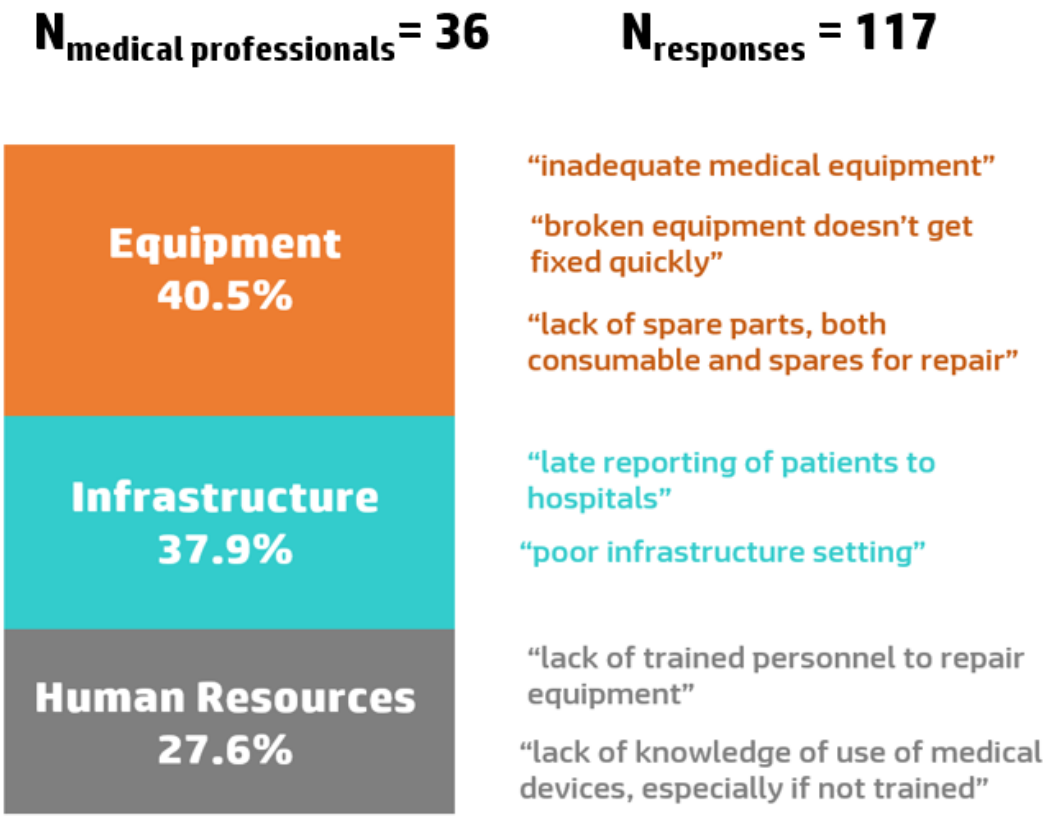


Figure 11. Using thematic analysis, challenges identified by clinical staff were broken into three categories: equipment, infrastructure, and human resources.

sections provide further information on the challenges identified by clinical staff in Malawi.

3.1 Qualitative Data Analysis

3.1.1 Medical Equipment Challenges in Malawi

Inadequate medical equipment was clearly identified as a theme of clinical staff responses, with 40.5% of all data related to this category. A full list of comments on medical equipment may be viewed in Table 3. Clinical staff frequently expressed that often equipment is unavailable or outdated. Many survey participants identified specific pieces of equipment that are lacking, including sphygmomanometers, suction machines, oxygen concentrators, diagnostic equipment such as ultrasound and MRI machines, and autoclaves for sanitation. One participant summed up this information by saying "some *essential* equipment is unavailable", while another participants remarked that the "use of outdated machines" was a barrier for hospital staff. The "lack of funds to procure new equipment" remains a prohibitive barrier to acquiring updated equipment.

Another key barrier identified by this research was the "lack of spare parts available in country" to repair medical equipment. Maintenance personnel commented on the difficulty of obtaining even simple components for repair, stating a "lack of spare parts, both consumables and spares for repair" contribute to equipment sitting idle instead of being properly used. Several clinical staff remarked that "frequent breakdown of laboratory machines" occurs, but "broken equipment doesn't get fixed quickly". Maintenance personnel noted that a "lack of equipment testing tools" contributes to an inability to properly calibrate and maintain machinery. One participant noted that a "lack of preventative maintenance system" contributes to machine malfunction, which another participant echoed by stating "preventative maintenance of equipment is not done timely". Compounding these issues, users manuals are rarely provided for donated equipment,

which makes maintenance of equipment an extremely challenging task. One survey participant, a maintenance manager, noted that “lack of standardization of equipment” makes maintaining and repairing medical equipment a daunting task.

Table 3. Thematic Analysis of Survey Data: Challenges Relating to Medical Equipment

Comments from Clinical Staff relating to Medical Equipment
"broken equipment doesn't get fixed quickly"
"blood pressure machines frequently out of order"
"diagnostic equipment like ultrasound and CBC not available"
"don't have autoclave machines"
"don't have thermometers, BP cuffs, stethoscope"
"expensive spare parts"
"frequent breakdown of laboratory machines, hematological machines"
"in maternity department, do not have life-saving instruments like O2 machines, suction machines, vacuum extractor"
"inadequate equipment"
"inadequate equipment (e.g no MRI, scan, CT scan, etc.)"
"inadequate equipment like blood pressure machines, thermometers, etc."
"inadequate medical equipment and other resources"
"lack of backup equipment, e.g. generators"
"lack of basic equipment"
"lack of equipment"
"lack of equipment testing tools"
"lack of funds to procure most of equipment"
"lack of glucometers"
"lack of medical equipment"
"lack of medical equipment like fluid pump"
"lack of oxygen concentrators, sphygmomanometers (1 for entire hospital)"
"lack of personal protective equipment"
"lack of preventative maintenance system"
"lack of proper equipment"
"lack of spare parts in the country"
"lack of spare parts, both consumables and spares for repair"
"lack of standardization of equipment"
"lack of tools used in repairing equipment"
"maintenance"
"need nebulizing machine"
"need suction machine"

"nonfunctioning autoclave"
"only a few suction machines working"
"only one blood pressure monitor"
"only one suction machine for entire hospital"
"only one suction machine for entire hospital"
"preventative maintenance of equipment not done timely"
"shortage of scale for growth monitoring"
"small table top film processor"
"some essential equipment is unavailable"
"spare parts"
"sphygmomanometer for children inadequate"
"substandard equipment (e.g. sphygmomanometers)"
"suction machine not working properly"
"suction machines break often"
"suction pump not working properly"
"use of outdated machines"

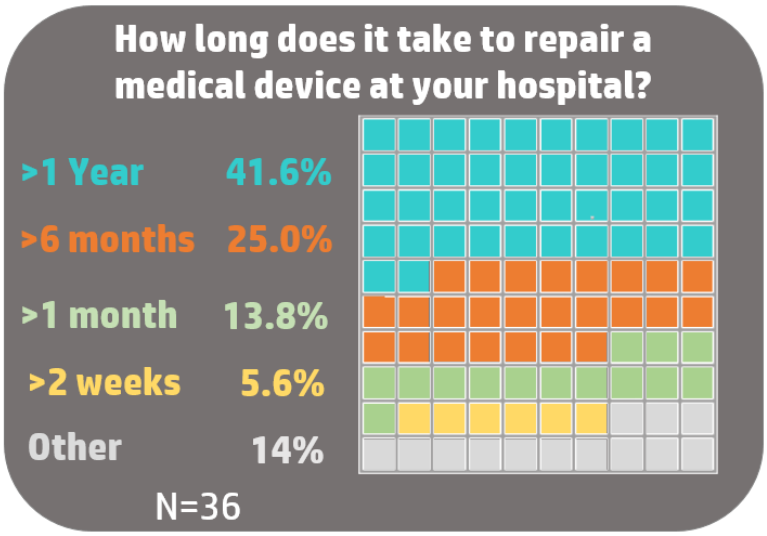


Figure 12. When inquired about time to repair medical equipment at their hospital, 41.6% of clinical staff reported repair takes longer than 1 year.

One goal of the study was to quantify the average time necessary to repair a medical device at each hospital. Figure 12 shows the results from the preliminary study. Alarmingly, 41.6% of clinical staff stated that a single piece of equipment takes longer than 1 year to repair. The next most frequently cited time to repair equipment was six months, at 25% of responses from clinical staff. Only 5.6% of clinical staff reported a time period of two weeks or less to repair a piece of medical equipment. This latent period for medical equipment, in which equipment are non-functioning but unable to be repaired, is a critical issue for clinicians. For instance, several

hospitals participating in the survey had only one suction machine for the entire campus; when the suction machine needs repair, the hospital is without this vital piece of equipment for over 1 year.

To inform technology innovators and organizations who donate medical equipment, participants were asked to identify equipment that most often needs repair.

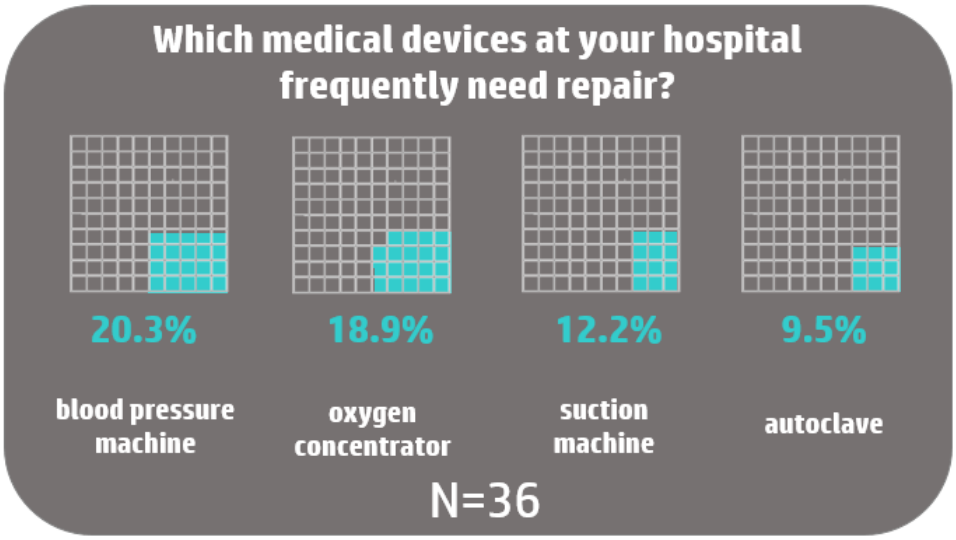


Figure 13. In this study, clinical staff were asked which machines at their hospitals break most frequently. Blood pressure machines were most frequently cited (20.3% of responses), followed by oxygen concentrators (18.9%) and suction machines (12.2%).

Figure 13 shows the top four devices identified from survey results, while Table 4 provides the complete list of medical equipment identified by clinical staff as frequently needing repair. Blood pressure machines were identified as in frequent need of repair, with 20.3% of clinical staff identifying the specific technology as frequently malfunctioning. Oxygen concentrators were also frequently identified (by 18.9% of clinical staff), followed by suction machines (12.2% of clinical staff) and autoclaves (9.5% of clinical staff). A lack of consumables likely contributes to the failure and malfunction of oxygen concentrators, which require a change of filters to maintain proper use. Maintenance personnel identified the lack of replacement sealing for suction machine waste containers as a contributor to suction

machine failure. Many equipment failures are also likely a result of "dirty power", or fluctuations in the electric grid which can damage equipment and render it useless.

Table 4. Thematic Analysis of Survey Data: Challenges Relating to Medical Equipment

Device	% of Responses from Clinical Staff Identifying Device as Frequently Needing Repair ($N_{responses}$ = 117, $N_{medical\ professionals}$ = 36)
Blood pressure machine	20.3%
Oxygen concentrators	18.9%
Suction machines	12.2%
Autoclave	9.5%
Laundry machine	9.5%
Glucometers	4.1%
Incubators/heaters	4.1%
Cooker	4.1%
Film Processor/X-Ray	2.7%
Blood analyzer	2.7%
Ultrasound	2.7%
Stethoscope	1.4%
Thermometer	1.4%
Cryomachine	1.4%
Ventilator	1.4%
Refrigerator	1.4%
Pulse Oximeter	1.4%
Electricity	1.4%

3.1.2 Healthcare Infrastructure Challenges in Malawi

Another key theme identified by thematic analysis was infrastructure instability (Table 5). Just as maintenance personnel expressed difficulties in obtaining spare parts for repair of equipment, nurses expressed difficulties in maintaining supply of medicines for patients. Nurses noted that "frequent drug and supply shortages" occur, and that medical

supplies are “erratic”. An overarching theme of lack of resources was repeatedly identified, with items such as linens, transport for patients, and medicines frequently in short-supply. Nurses noted that “lack of transport … for patients” contributes largely to “late reporting of patients to hospitals”. Patients who are seen late in the progression of a disease may have fewer treatment options or a poorer state of health than a patient who is seen early in disease progression.

Survey participants also commented on limitations of the physical infrastructure, including “limited space for patients” and “not enough beds and mattresses for patients”. Some participants noted the general “poor infrastructure setting”, while other participants noted specific limitations of the facilities in which they worked, such as “shortage of … important wards like surgical/antenatal wards”. Shortage of funds were also identified as a key barrier to obtaining resources and building infrastructure capacity.

Table 5. Thematic Analysis of Survey Data: Challenges Relating to Infrastructure

Comments from Clinical Staff Relating to Infrastructure
"attitude of service users (communities)"
"don't have drug box"
"drug stocks out"
"erratic medical supplies"
"frequent drug and supply shortage"
"funds for maintenance"
"inadequate infrastructure"
"inadequate linen for patients"
"inadequate resources"
"inadequate supplies"
"lack of enough resources"
"lack of linens for beds"
"lack of material resources"
"lack of materials i.e. bedding, linen"
"lack of materials"
"lack of materials"
"lack of money"
"lack of resources"

"lack of resources"
"lack of shelter in community"
"lack of transport e.g. bicycles for patients"
"large number of PPO/clients seeking clinical service"
"late reporting of patients to hospitals"
"limited space for patients"
"not enough beds and mattresses for patients"
"poor infrastructure setting"
"setup at hospital provides little privacy"
"short supplies of laboratory requests"
"shortage of bedding in wards"
"shortage of drugs at times"
"shortage of drugs"
"shortage of other important wards like surgical/antenatal wards"
"shortage of resources"
"shortage of some drugs"
"we don't have attires that can be used by staff"
"we don't have linen"
"working attire (uniforms)"

Perhaps the most notable challenge with infrastructure identified by this survey is the instability of the electric grid at each hospital. Figures 14 and 15 display data relevant to hospital access to electricity. As shown in Figure 14, only 50% of clinical staff reported that their hospital has access to electricity every day. Over 25% of clinical staff reported only having access to electricity 5-6 days per week, while 16% reported having access to electricity 3-4 days per week. The remaining 9% of survey participants answered this question

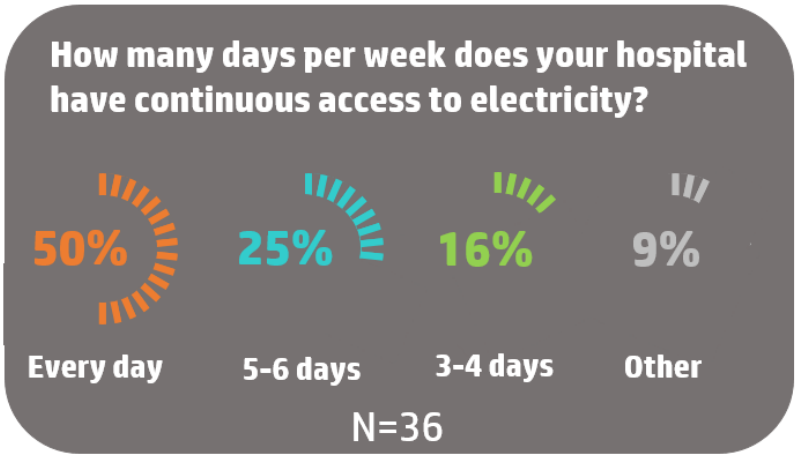


Figure 14. Only half of survey participants (50%) reported having access to electricity every day.

qualitatively, with answers such as “we have power every day except for when we don’t pay the electric bill”.

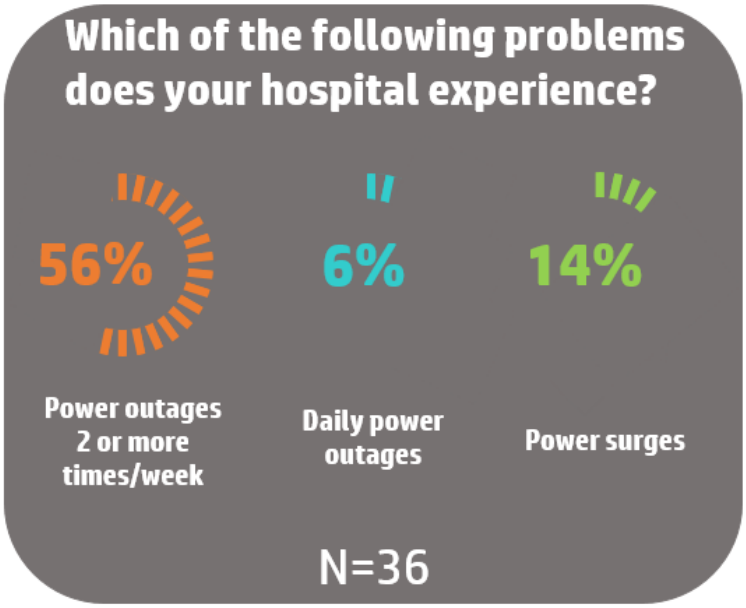


Figure 15. Over half of survey participants (56%) reported experiencing power outages 2 or more times per week. Alarmingly, 6% of survey participants reporting experiencing power outages daily.

As shown in Figure 15, 56% of clinical staff reported that their hospitals experience power outages two or more times per week. Daily power outages were reported by 6% of clinical staff, and power surges were reported by 14% of clinical staff. The data in Figures 4 and 5 provide critical insight for technology development aimed towards improving public health; nearly all equipment currently on the market relies on the electric grid, though the data shows that for hospitals in Malawi, the electric grid is largely unstable. Power surges (cited by 14% of participants in this study) and power outages (cited by 56% of participants in this study) render electricity-dependent equipment useless, contributing to poor health outcomes for patients.

3.1.3 Human Resources Healthcare Challenges in Malawi

The final theme of healthcare challenges identified in this study was issues related to human resources. Table 6 shows a complete list of challenges identified by clinical staff. Broadly, clinical staff cited a general “shortage of human resources” and “understaffing”,

resulting in “overworking”. Staff cited “increased workload” and “work overload” as barriers to delivering appropriate care to patients. Other clinical staff noted the consequences of “low salary payments” on employee motivation, citing “poor motivation for staff” and “lack of career advancement opportunities”.

A critical shortage of maintenance personnel was also identified as a key barrier to providing adequate medical care. “Inadequate engineering personnel” and “lack of medical staff who can repair instruments” were identified by multiple clinical staff as key issues in their hospitals. Shortage of clinical staff was also mentioned, including “lack of well-trained medical expertise” and “increased number of patients to staff”. Additionally, clinical staff recognized the absence of training for proper use of medical equipment, noting that there is a “lack of knowledge on certain procedures, drugs, new equipment (how to use)” and “lack of knowledge of use of medical devices, especially if not oriented”.

Table 6. Thematic Analysis of Survey Data: Challenges Relating to Human Resources

Human Resources
"overworking"
"lack of medical staff who can repair instruments"
"lack of career advancement opportunities"
"lack of trained personnel/specialists"
"shortage of human resources"
"lack of human resources"
"lack of well-trained medical expertise"
"understaffing"
"understaffing"
"lack of resources, both material and human"
"inadequate staff"
"work overload"
"shortage of human resources"
"lack of staff"
"shortage of staff"
"increased workload"
"lack of knowledge on certain procedures, drugs, new equipment (how to use"

"work staffing"
"human resources"
"inadequate engineering personnel"
"increased workload"
"inadequate personnel (staff)"
"increased number of patients to staff"
"lack of medical engineers or equipment technicians/maintenance technicians"
"lack of knowledge on some important medical devices (how to use them)"
"lack of knowledge of use of medical devices, especially if not oriented"
"poor motivation for staff (low salary)"
"low salary payments"
"coordination"
"lack of trained personnel to repair equipment"
"lack of trained/skilled scientists"
"shortage of staff"

3.2 Quantitative Statistical Methods

The following section analyzes four specific variables examined in the study: 1) access to water (days per week), 2) access to electricity (days per week), 3) number of power outages (per week), and 4) time to repair medical equipment (Figure 16). First, the statistical methods will be summarized, follow by analysis results. This section presents the statistical methods used for analyzing these variables.

Figure 16. Variables examined in this quantitative analysis include access to water, access to electricity, number of power outages per week, and time to repair medical equipment.

3.2.1 Statistical Methods: One-way Analysis of Variance

In an effort to prioritize aid for hospitals, one goal of the study was to determine if there is a difference in need at each hospital. Essentially, if it can be shown that there is a difference in need (access

to water, access to electricity, etc.), between hospitals, further research can be done to prioritize efforts towards the hospital(s) with the greatest need. To establish whether or not there are any significant differences between the means of the three independent hospitals, a One-way Analysis of Variance (ANOVA) was used. The model used is shown by equation (1):

$$Y_{ij} = \mu + \tau_i + \epsilon_{ij} \quad (1)$$

Where Y_{ij} represents the j-th observation (j=1,2,…,n) on the i-th treatment (i=1,2,…,k levels), μ represents the common effect for the whole experiment, τ represents the treatment effect, and ϵ represents the random error present. For these tests, the treatment represents the individual hospital.

This test does not show which specific hospitals statistically differ from each other; rather, the one-way ANOVA simply determines whether or not at least two groups are statistically different. Specifically, the one-way ANOVA was conducted to test the following hypotheses shown in Table 7. For the one-way ANOVA testing, it was assumed that the three sets of data constitute independent simple random samples from the three populations (three hospitals). It was also assumed that the three populations of measurements are normally distributed with equal variances. The variance ratio was used as the test statistic. If the null hypothesis is true and assumptions are met, the variance ratio follows the F-distribution with 2 degrees of freedom in the numerator and 30 degrees of freedom in the denominator. For these tests, α=0.05.

Table 7. One-way ANOVA Hypothesis Testing

Question:	Null Hypothesis H_0:	Alternative Hypothesis H_A
Does one hospital yield an average time to repair medical equipment that is different from at least one other hospital?	$\mu_{hospital\ 1} = \mu_{hospital\ 2} = \mu_{hospital\ 3}$	Not all μ's are equal (at least one other hospital yields an average time to repair medical equipment different from the average time to repair equipment at at least one other hospital)
Does one hospital have an average access to electricity (days per week) that is different from at least one other hospital?	$\mu_{hospital\ 1} = \mu_{hospital\ 2} = \mu_{hospital\ 3}$	Not all μ's are equal (at least one other hospital yields an average access to electricity different from the average access to electricity equipment at at least one other hospital)
Does one hospital have an average access to safe water (days per week) that is different from at least one other hospital?	$\mu_{hospital\ 1} = \mu_{hospital\ 2} = \mu_{hospital\ 3}$	Not all μ's are equal (at least one other hospital yields an average access to water different from the average access to water at at least one other hospital)
Does one hospital have an average number of power outages different from at least one other hospital?	$\mu_{hospital\ 1} = \mu_{hospital\ 2} = \mu_{hospital\ 3}$	Not all μ's are equal (at least one other hospital yields an average number of power outages per week different from the average number of power outages per week at at least one other hospital).

If we reject the null hypothesis for the above tests, pairwise t-tests must be used to conduct sample mean pairwise comparisons. However, it is not accurate or sufficient to simply use a t-test twice to look at differences between each hospital, because this increases the probability of making a Type I error. Corrections will be accounted for using Tukey's multiple comparison of means if the null hypothesis is rejected using ANOVA hypothesis testing.

3.2.2 Statistical Methods: Correlation Analysis

In order to understand the degree to which the variables of interest (access to water, access to electricity, and number of power outages) are related to time to repair medical

equipment, correlation analysis was used. We recall that simple linear regression may also be used to understand relationships between two variables, but typically linear regression is used when we fix values of one variable (X) and want to determine corresponding values of another variable (Y). For this study, none of the variables were experimentally manipulated or fixed; rather, all variables were measured. Therefore, correlation analysis is the most appropriate analysis.

To conduct each of the correlation analyses, we assume the following:

1. For each value of X there is a normally distributed subpopulation of Y values
2. For each value of Y there is a normally distributed subpopulation of X values
3. The joint distribution of X and Y is normally distributed
4. Subpopulations of Y have the same variance
5. Subpopulations of X have the same variance [63]

For each correlation analysis, the null hypothesis is that there is no correlation between the two variables ($\rho=0$), and the alternative hypothesis is that there is correlation between the two variables ($\rho\neq0$). Equation (2) shows the test statistic used for testing:

$$t = r\sqrt{\frac{n-2}{1-r*r}} \tag{2}$$

Where t represents the t-statistic of correlation coefficient between the two variables of interest, r represents the sample correlation coefficient, and n represents the sample size. When the null hypothesis is true and the above assumptions are met, the test statistic follows a student's t-distribution with n-2 degrees of freedom. For these tests, $\alpha=0.05$. Three correlation analyses were conducted to analyze the degree to which the following variables are related: 1) time to repair medical equipment and access to electricity, 2) time to repair medical equipment and access to water, and 3) time to repair medical equipment and number of power outages.

3.2.3 Statistical Methods: Single Population Proportion Testing

In order to compare sample statistics to population data from the World Bank, single population proportion testing was used. This testing will better allow us to understand the target population of rural clinicians in southern Malawi from the sample data (N=33). In 2015, the WorldBank reported that 90.2% of Malawi's population has access to an improved water source [64]. We wish to know if we may conclude that fewer than 90.2% of the sampled population has access to a safe (improved) water source.

In order to conduct the single population proportion testing, we assume that the study participants may be treated as a simple random sample from a population of similar participants (clinical staff). Additionally, we assume that the sampling distribution of $\hat{p}$, is approximately normally distributed according to the central limit theorem (n=33 > 30). Accordingly, we use the z test statistic, given by equation (3):

$$z = \frac{\hat{p} - p_0}{\sqrt{\frac{p_0 * q_0}{n}}} \tag{3}$$

Where $\hat{p}$ represents the estimated proportion for the sample, p_0 represents the proportion for the population, $q_0 = (1 - p_0)$, and n is the sample size. For these tests, α=0.05.

3.3 Quantitative Statistical Analysis Results

The following section outlines the results from the aforementioned analyses.

3.3.1 One-way ANOVA

The one-way ANOVA analyses revealed that there is not sufficient evidence to conclude that the hospitals showed any significant differences between the means for 1) access to water, 2) access to electricity, 3) number of power outages per week, and 4) time to repair medical equipment. For each of the four one-way ANOVA tests, we fail to reject the null hypothesis. We therefore were unable to prioritize aid for hospitals based on differences in the mean. Table 8 summarizes the one-way ANOVA tests, while Figures 17a-c display box plots of the analyzed data. A comparison of the p-values for each test (Table 8) shows that for the variables of water and number of power outages, we were very close to falling within the rejection region. Since these tests were completed with a relatively small sample size (n=36), it is recommended that these tests be conducted on data from a larger sample.

Table 8. Summary of One-way ANOVA Hypothesis Testing.

Variable	Critical Value	Test Statistic	Decision	P -value
ELECTRICITY	3.316	2.76	Fail to reject null hypothesis	0.0794
WATER	3.316	3.2	Fail to reject null hypothesis	0.055
OUTAGES	3.316	3.2	Fail to reject null hypothesis	0.055
MEDICAL EQUIPMENT	3.316	0.853	Fail to reject null hypothesis	0.436

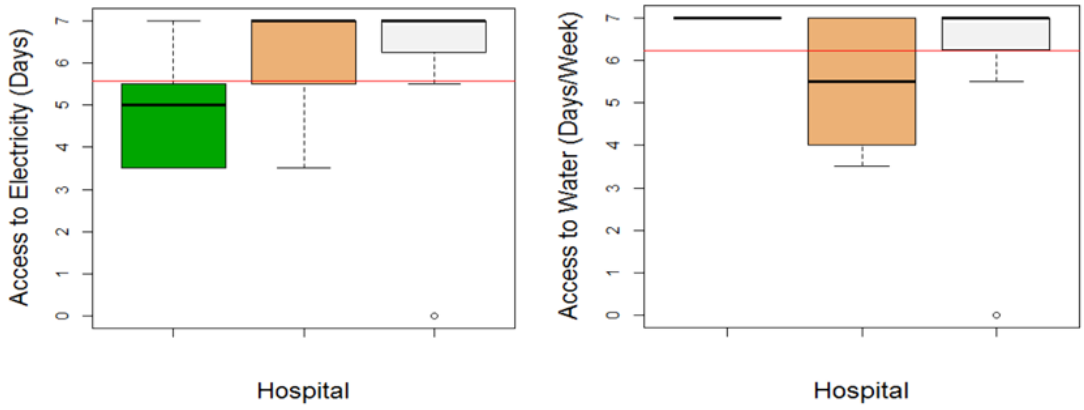


Figure 17a. One-way ANOVA analyses revealed that there is not sufficient evidence to conclude that the hospitals showed any significant differences between the means for 1) access to water, 2) access to electricity. For anonymity, hospitals have been deidentified.

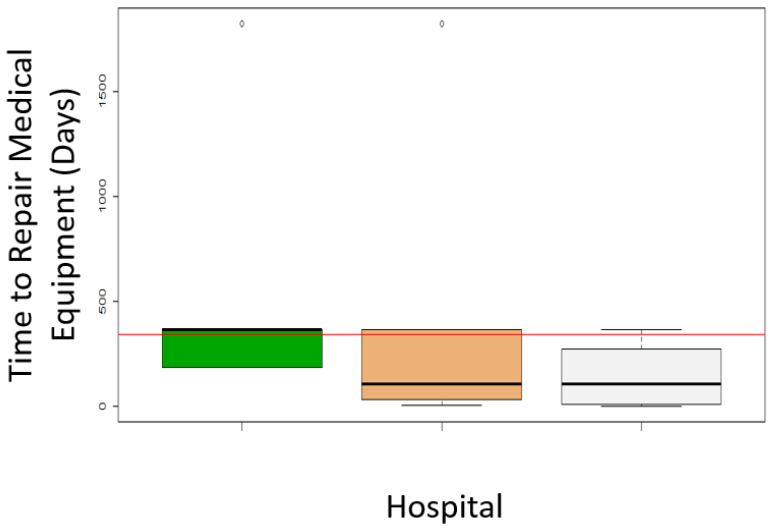


Figure 17b. One-way ANOVA analyses revealed that there is not sufficient evidence to conclude that the hospitals showed any significant differences between the mean time to repair electricity (days) at each hospital. For anonymity, hospitals have been deidentified.

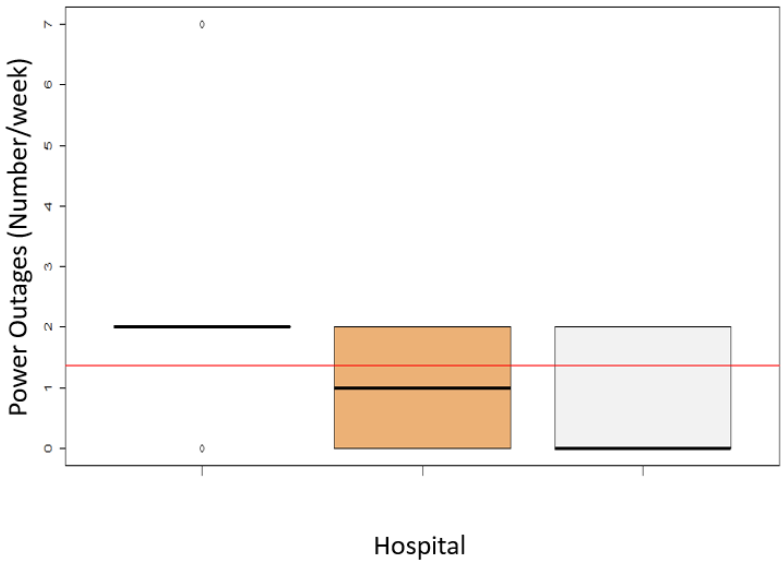


Figure 17c. One-way ANOVA analyses revealed that there is not sufficient evidence to conclude that the hospitals showed any significant differences between the means number of power outages per week at each hospital.

3.3.2 Correlation Analysis

The correlation analysis found no significant relationships between the variables. Specifically, correlation analysis was completed for: 1) access to water and time to repair medical equipment, 2) access to electricity and time to repair medical equipment, and 3)

number of power outages and time to repair medical equipment. Figure 18 displays the analysis plots with the best fit line, while Table 9 displays the calculation of the test

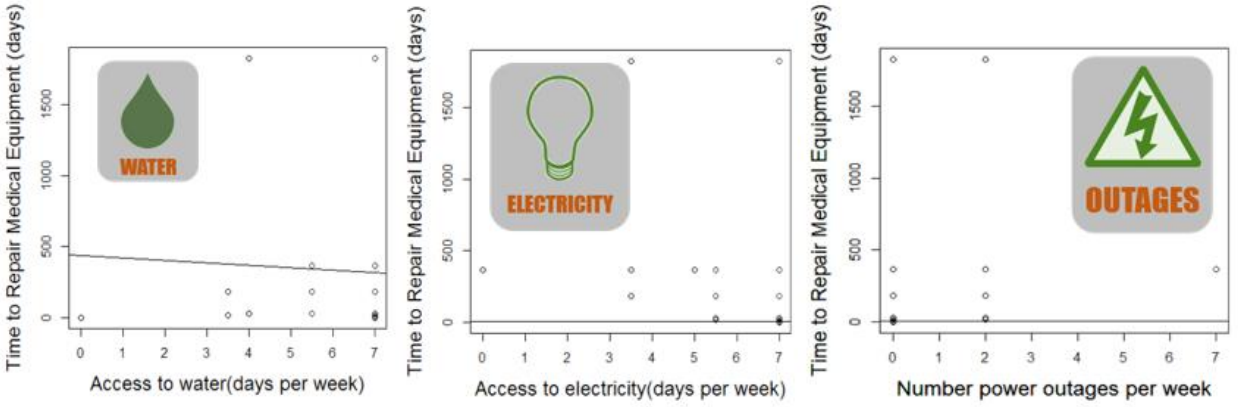


Figure 18. Results from correlation analysis between variables of interest. No statistically significant relationship was found between time to repair medical equipment and 1) access to electricity, 2) access to water, or 3) number of power outages per week.

Table 9: Results from correlation analysis between (top to bottom) 1) access to electricity and time to repair medical equipment, 2) access to water and time to repair medical equipment, and 3) number of power outages and time to repair medical equipment.

Correlation between variables:	Critical Value	Correlation Test Statistic	Multiple R-squared	Decision	P -value
ELECTRICITY MEDICAL EQUIPMENT	1.6955	-0.3318	0.0035	Fail to reject null hypothesis	0.3817
WATER MEDICAL EQUIPMENT	1.6955	0.3871	0.0048	Fail to reject null hypothesis	0.701
OUTAGES MEDICAL EQUIPMENT	1.6955	0.39	0.0049	Fail to reject null hypothesis	0.6992

statistic, p-value, and correlation coefficent for each correlation analysis. Plotting the data reveals a potential issue with the how the data was collected; although the data were intended to be collected as continuous variables, the data appears to be categorical, showing

that humans may tend to inherently put things into categories. Categorical data may not be most appropriate for a correlation analysis. Therefore, future recommendations to the Pediatric Medical Device Institute include designing data collection to collect continuous, objective measurements. Ultimately, it may be challenging to collect truly objective information through surveying clinical staff, since humans are prone to bias. A better study design would be to objectively measure the variables of interest rather than soliciting this information via clinical staff.

3.3.3 Single Proportion Population Testing

From the single proportion population testing, we concluded that in the sampled population of rural hospitals in Malawi, the proportion of hospitals without continuous access to water is less than the proportion projected by the WorldBank (90.2%) [64]. Therefore, we reject the null hypothesis (p-val 0.00037). This is crucial information from a public health perspective; without clean access to water at these clinics, many other medical procedures cannot be performed. Therefore, it is recommended that aid for hospitals is prioritized for access to clean water.

Chapter 4: Development of Suction Machine Design Criteria for Hospitals in Rural Malawi

Data from the community-based participatory study of medical technology conducted in Malawi revealed key insights for designing for low and middle income countries, and more specifically, for communities in southern Malawi. Supporting the broader evidence found in current literature, this study suggests that engineers working in low and middle income countries face a unique sundry of design requirements [18], [65]–[67]. In addition to traditional design considerations, such as physical target metrics and cost constraints, engineering projects in low and middle income countries require an intimate understanding of the local community, include community leaders, community beliefs and values, and locally available resources [18], [65], [66]. Using the community-based participatory framework, community-level design requirements for southern Malawi were intensively explored. Since suction machines were identified by partner communities as a top need for innovation, suction machines were chosen as the design space in which to work. More specifically, the suction machine design criteria in the following section was developed for newborn suction with a target range of 60-80 mm Hg. The following chapter aims to translate the findings from the community-based participatory into engineering design requirements.

4.1 Development of Design Criteria for Medical Equipment

As discussed in Chapter 3, thematic analysis was employed to analyze qualitative data from the community-based focus groups and needs assessments in Malawi. Figure 19 displays the results from thematic analysis; community input and insight on medical device maintenance was broken into three categories: equipment, infrastructure, and human

resources. From these three categories, customer needs (including the needs of patients), clinical staff, and maintenance staff were derived. Over 117 qualitative responses were condensed to the following customer needs, shown visually in Figure 19.

First, the communities emphasized the importance of the device being manufactured and repaired entirely from locally available resources. Spare parts were identified as one of the top challenges to repairing currently available suction machines, and both clinical staff and maintenance staff alike lamented the frustration of not being able to purchase replaceable parts in-country. Community members also emphasized the importance of a user's manual to accompany any device that is designed, so that preventative and tertiary maintenance are clear to both clinical and technical staff. Lastly, clinical staff at several rural locals emphasized the lack of trained technical personnel. This shortage of technical personnel means that devices should be able to be maintained and repaired by non-technical staff with minimal tools. This was a critical insight to the design criteria, since before the findings of this study, the design team had assumed that technical staff were present at every hospital.

Clinical staff also identified the inconsistent electric grid as a key challenge with current suction machines, so it is important that proposed designs for suction machines can operate independently of the electric grid. Next, the communities noted that resources (monetary and otherwise) are often scarce in government and rural hospitals, so the proposed design should be appropriately priced. Lastly, several clinical staff emphasized the limited physical space in the wards, which translates to the need for a compact design. This is imperative during the rainy season when wards have higher patient influx.

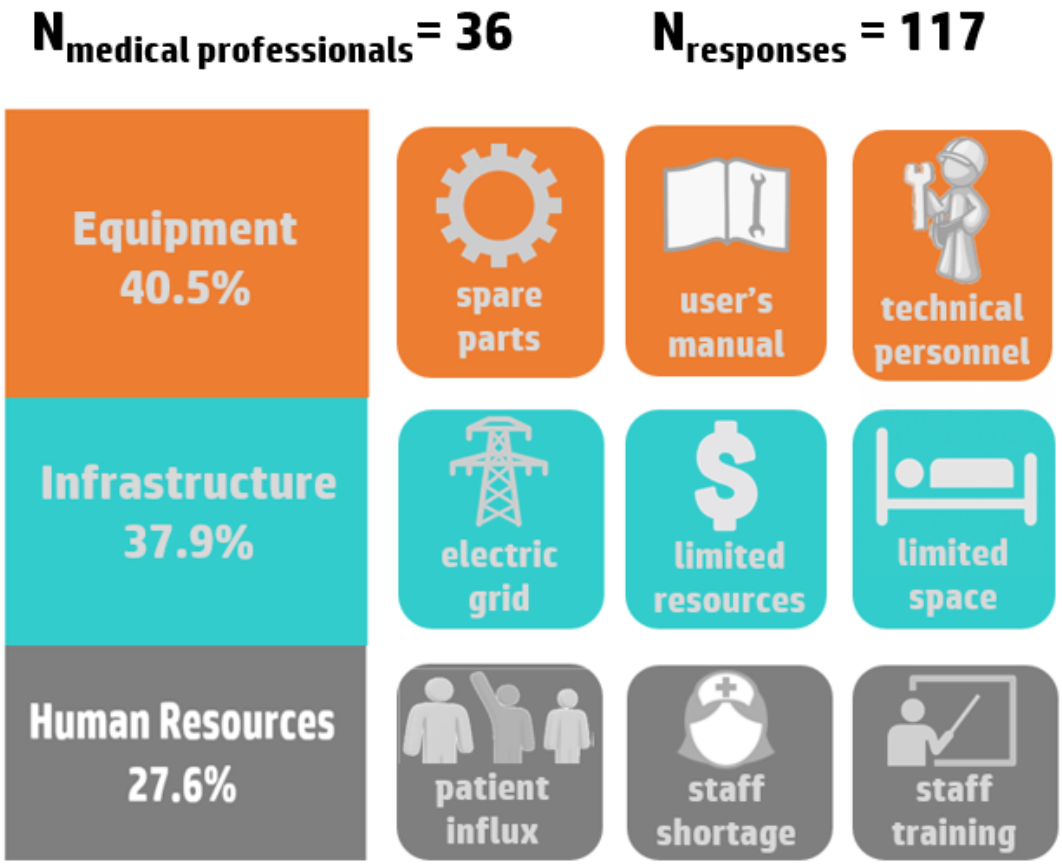


Figure 19. Taylor and Powell's method of thematic analysis was used to gather customer needs from qualitative data obtained during community-based participatory surveys. On the left (above), broad themes including issues relating to equipment, infrastructure, and human resources are identified by the community. On the right, these themes are broken down into more specific themes identified by communities.

Clinical staff also talked openly about the need for staff training on proper utilization, storage, and preventative maintenance of devices. Nurses reported feeling uncomfortable using devices that they had never been trained on. Regarding the design of a new suction machine device, nurses and technical personnel suggested that the manufacturer of the device should conduct a user-training session at the site of the clinic where the device will be implemented. This would allow the staff to interact with the designers and ask questions as needed.

In addition to the design requirements identified by communities in Malawi for suction machines, the World Health Organization has provided recommendations for the

design of suction machines for resource-limited clinical environments [68]. In 2014, the WHO released a draft of *Technical Specifications for Medical Devices* [68]. In this report, the WHO identifies technical specifications for 13 life-saving technological commodities, including suction machines [68]. Therefore, as Figure 20 implies, these technical specifications were incorporated into the target metrics for the proposed suction machine.

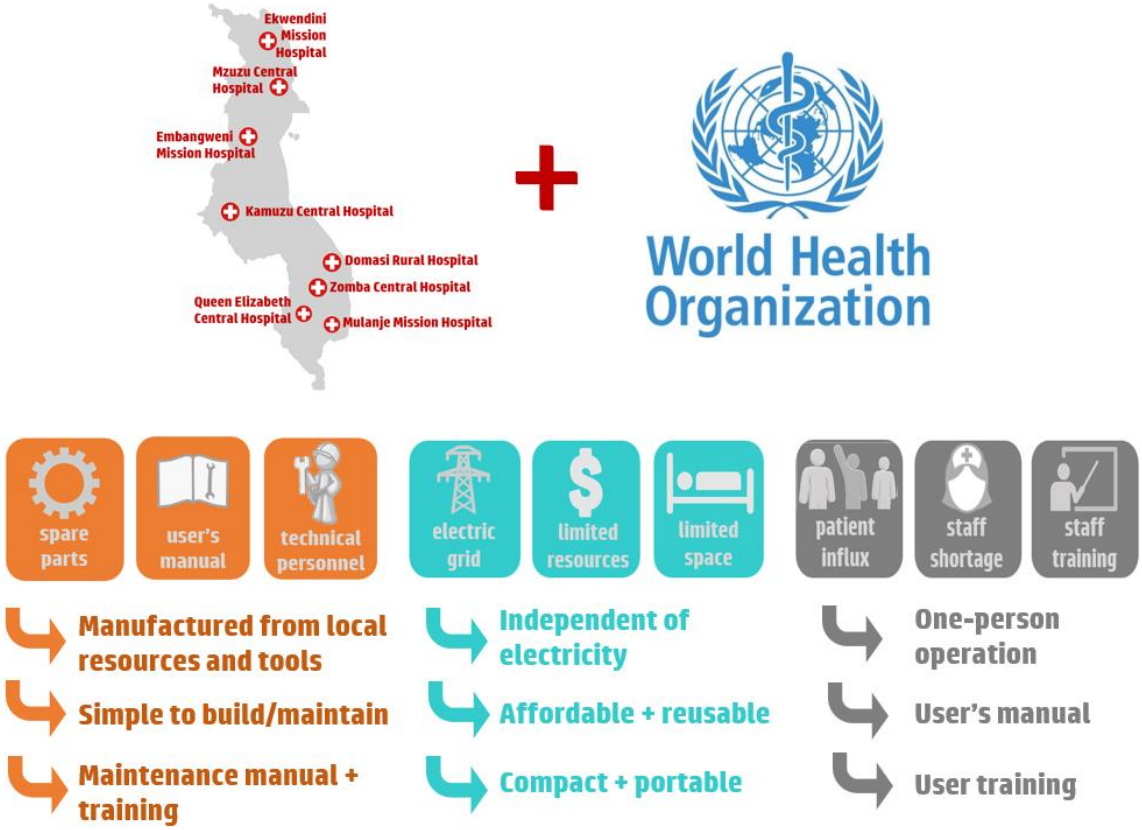


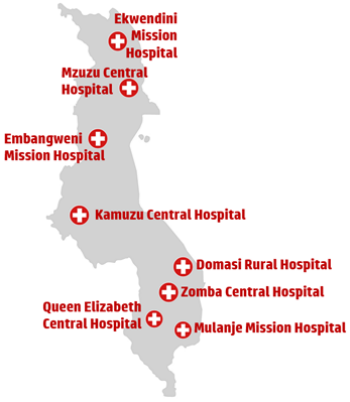
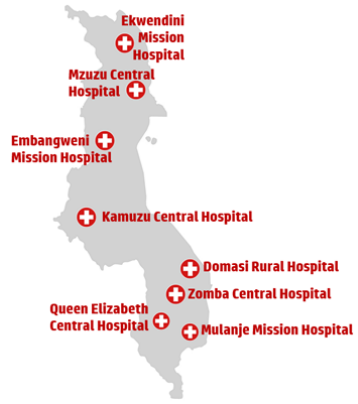
Figure 20. Customer needs and design criteria for suction machines were gathered from both community-identified needs in southern Malawi as well as the World Health Organization's 2014 report on Technical Specifications for Medical Devices.

4.2 Target Design Metrics

Understanding the unique design metrics for clinical communities in Malawi was a top priority of this work. Table 10 displays specifications identified by partner

communities in Malawi and the World Health Organization. Design requirements from the World Health Organization are derived from the WHO 2014 report on Technical Specifications for Medical Devices [68].

Table 10: Design Requirements for Suction Machines Generated by Community Members in Southern Malawi

Requirement Set By	Metric	Units	Threshold	Target
Communities in southern Malawi 	Manufactured from local resources	pass/fail	Pass with 50% local resources	Pass with 100% local resources
	Cost	USD	100	50
	Replaceable parts	pass/fail	Pass with essential parts replaceable	Pass with 100% replaceable parts
	Compact volume	feet^3	2 x 2 x 2	1 x 1 x 1
	Manufactured from locally available tools	pass/fail	Pass	Pass
	Hands free operation	pass/ fail	Pass with hands-free operation of pump	Pass with hands-free operation of pump and hands-free regulation
	Capacity of waste container	liters	0.5	1
	Deployment time	seconds	30	10
	Operates independently of the electric grid	pass/fail	pass	pass
	Portable (easy to move)	pass/fail	pass with 75% of clinical staff deeming portable	pass with 100% of clinical staff deeming portable
	Waste container cutoff	pass/fail	pass with waste container including over-flow protection system	pass with waste container including over-flow protection system

	User operation training	pass/fail	pass with user operation manual included	pass with user operational training curriculum developed AND user operation manual delivered
	Maintenance training	pass/fail	pass with maintenance training manual included	pass with maintenance training manual included AND training curriculum delivered
	Compatible with standard suction catheter/tubing	pass/fail	pass	pass
	Storage temperature	C	0	50
	Operating temperature	C	10	40
	Storage relative humidity	%	15-90%	15-90%
	Operating relative humidity	%	15-90	15-90
	Components can be sterilized in autoclave at 121 C	pass/fail	pass	pass
	Removable parts	pass/fail	pass with essential components of pump able to be disassembled	pass with pump able to be disassembled entirely
	Displayed parameters	pass/fail	pass with pressure gauge displaying suction generated	pass with pressure gauge displaying suction generated

	Corrosion resistant components	pass/fail	pass with 50% corrosion resistant components	pass with 100% corrosion resistant components
	Pump pedal spring loaded	pass/fail	pass with pump returning to 'up' position after each stroke	pass with pump returning to 'up' position after each stroke
	Compatible with standard suction catheter/tubing	pass/fail	pass	pass
	Storage temperature	C	0	50
	Operating temperature	C	10	40

Chapter 5: Concept Generation and Selection

After customer needs and target metrics were established for the design, the concept generation phase was initiated. As shown in Figures 21 and 22, concept maps were generated for the design sub-functions of 1) creating negative pressure and 2) user interface. Concepts for the user interface were constrained to provide hands-free operation of the device, a requirement of the World Health Organization for suction machines. Preliminary sketches for the concept maps below may be seen in Appendix E.

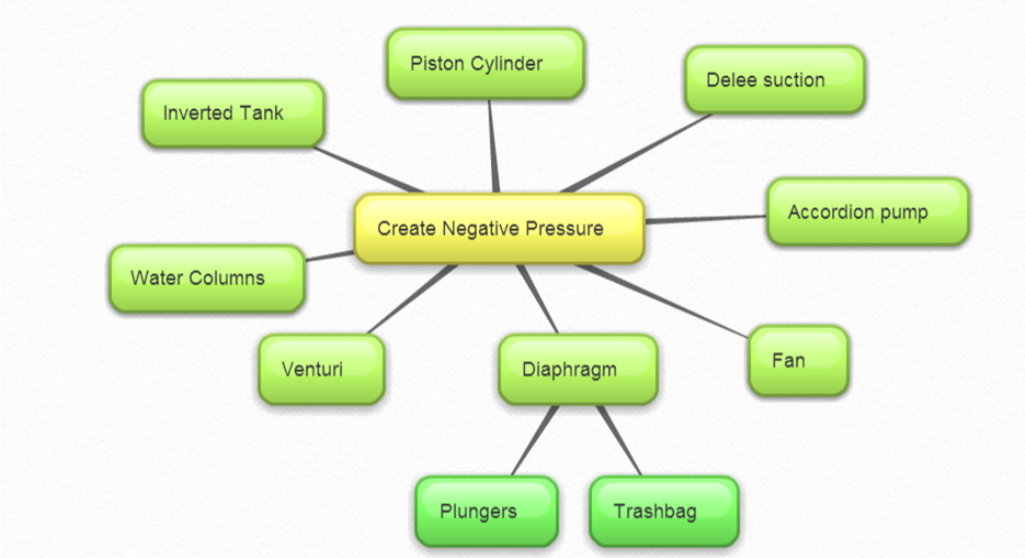


Figure 21. Concept generation map constructed for design sub-function of creating negative pressure.

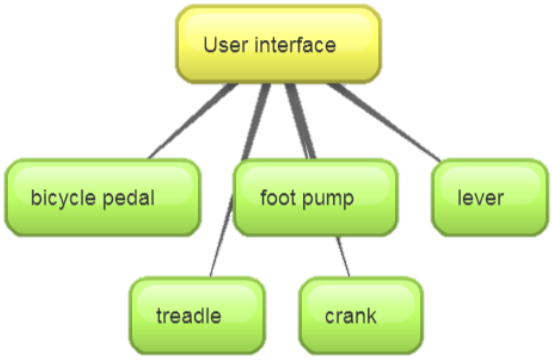


Figure 22. Concept generation map for user interface, or the mechanism to mechanically power the device while providing hands-free operation.

A two stage concept selection methodology was used to narrow the design space for pressure generation. First, Pugh's concept selection was used to improve concepts and to rapidly narrow the number of concepts to be intensely explored [69]. Six selection criteria, developed according to priority needs identified by clinical and maintenance staff in Malawi, were used to screen concepts, as shown in Table 11. Using the Pugh concept selection method, a reference concept must be selected as the "benchmark"; all other designs will be ranked according to the reference. Pugh recommends the reference concept to be an industry standard and familiar concept to the designers [69]. Therefore, for negative pressure generation, piston-cylinder assembly was chosen as the reference concept. Using Pugh's method, each design concept is ranked as better than (+), equal to (0), or worse than (-) the reference design, providing a net score for each design and allowing the design concepts to be ranked accordingly.

Pugh's Concept Screening Matrix significantly narrowed the design space, from 8 concepts to three. Delee suction, fan, water columns, and inverted tank concepts were eliminated from the design space. Three concepts were selected to be evaluated further, including the reference design (piston cylinder), Venturi suction, and diaphragm suction. The following sections outline the physical operating principles and equations for each of the three concepts.

Table 11: Pugh's Concept Screening Matrix for Negative Pressure Generation

	Concepts							
Selection Criteria	**A (Reference) Piston Cylinder**	**B Delee Suction**	**C Accordion Pump**	**D Fan**	**E Diaphragm**	**F Venturi**	**G Water Columns**	**H Inverted Tank**
Ease of fabrication from locally available resources	0	-	-	-	+	+	+	+
Portability	0	+	0	-	0	-	-	-
Ease of use	0	-	0	-	0	+	-	-
Durability	0	-	0	-	+	+	-	-
Affordability	0	+	0	-	+	+	+	+
Ease of Deployment	0	0	0	-	+	-	-	-
Sum +'s	0	1	0	0	4	4	2	2
Sum 0's	6	2	5	0	2	0	0	0
Sum –'s	0	3	1	6	0	2	4	4
Net Score	0	-2	-1	-6	4	2	-2	-2
Rank	3	5 (tie)	4	6	1	2	5 (tie)	5 (tie)
Continue?	Yes	No	No	No	Yes	Yes	No	No

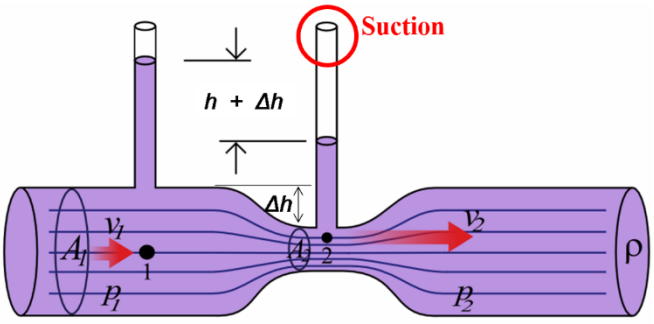


Figure 23. In a Venturi configuration, a pressure drop occurs at area A_2 as fluid is moved from a larger diameter (A_1, v_1) to a smaller diameter. According to Bernoulli's principle, as fluid is moved through the smaller area pipe, the velocity increases ($v_2 > v_1$), resulting in a pressure drop ($p_2 < p_1$). Image source: https://upload.wikimedia.org/wikipedia/commons/5/54/Venturified2.PNG

5.1 Venturi Suction Analysis and Concept Generation

One concept thoroughly explored during the design process was Venturi suction. A Venturi configuration refers to a pipe of large diameter (area A_1) transitioning to a smaller diameter (area A_2). As a fluid is pumped through the Venturi configuration with velocity v_1, a pressure drop ($p_1 - p_2$)

occurs as a result of an increase in velocity ($v_2 > v_1$) at the smaller area (A_2). Venturi suction is an application of Bernoulli's equation. Shown in Equation 5.1, Bernoulli's equation states:

$$P_1 + \frac{1}{2}\rho v_1^2 + \gamma z_1 = P_2 + \frac{1}{2}\rho v_2^2 + \gamma z_2 = \text{constant along streamline} \quad \text{(Eq. 5.1)}$$

Where P_1 represents the pressure at point (1), ρ represents the density of the fluid, v_1 represents the velocity of the fluid at point (1), γ represents the specific gravity of the fluid, z_1 represents the height of the fluid at point (1), P_2 represents the pressure of the fluid at point (2), v_2 represents the velocity of the fluid at point (2), and z_2 represents the height of the fluid at point (2). Bernoulli's equation assumes the following:

1. Points (1) and (2) lie on a streamline
2. Flow is in steady state
3. Flow is inviscid
4. Flow is incompressible

To derive the pressure drop produced by a Venturi suction design, we first assume that the flow is horizontal ($z_1 = z_2$), resulting in Equation 5.2:

$$P_1 + \frac{1}{2}\rho v_1^2 = P_2 + \frac{1}{2}\rho v_2^2 = \text{constant along streamline} \quad \text{(Eq. 5.2)}$$

Assuming a uniform velocity profile at points (1) and (2), the continuity equation may be applied. The principle of the continuity equation is that volumetric flow rate (Q) is conserved (constant) at points (1) and (2). The continuity equation is given in Equation 5.3:

$$Q_1 = Q_2 = A_1V_1 = A_2V_2 \quad \text{(Eq. 5.3)}$$

Where Q represents volumetric flowrate, A represents the area of the pipe, and V represents velocity of the fluid. Solving Equation 5.2 for the pressure drop across the Venturi device yields Equation 5.4:

$$P_1 - P_2 = \frac{1}{2}\rho(v_2^2 - v_1^2) \quad \text{(Eq. 5.4)}$$

Substituting Equation 5.3 into Equation 5.4 and reducing yields Equation 5.5:

$$P_1 - P_2 = \frac{Q^2\rho(1-\frac{A_2}{A_1})^2}{2A_2^2} \quad \text{(Eq. 5.5)}$$

Equation 5.5 was used to conduct analyses on the design space for ideal Venturi devices manufactured from polyvinyl chloride (PVC) pipe, a locally available resource in Malawi. The central component of this concept is a PVC reducing coupling, which seamlessly connects a larger diameter PVC pipe to a smaller PVC pipe. Figure 24 shows an example schematic of a PVC reducing coupling, which reduces nominal pipe size (NPS) 2 to NPS 1 ½. The full concept (Figure 25) was to pump a fluid through a Venturi device, constructed entirely of PVC, in order to harness the pressure drop that occurs at the small diameter, downstream location. Analyses were conducted for water (ρ = 1,000 kg/m^3) to determine the pressure drop produced by combinations of various standard nominal pipe sizes; these analyses may be seen in Figures 26 and 27. As will be discussed in a following section, it is important to note that these analyses employ idealized flow assumptions. Thus, the analyses depend on how similarly the Venturi device follows idealized flow assumptions.

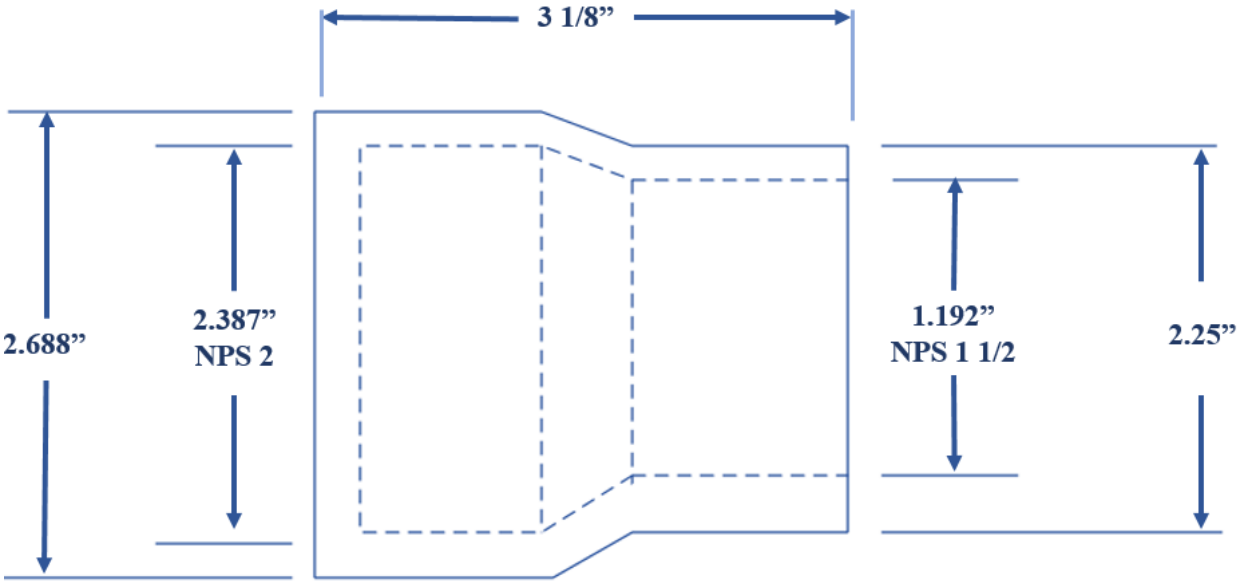


Figure 24. Standard dimensions for polyvinyl chloride reducing coupling from nominal pipe size 2 to nominal pipe size 1 ½. The Venturi design concept hinges on utilizing a PVC reducing coupling to seamlessly transition from a large diameter pipe to a smaller diameter pipe.

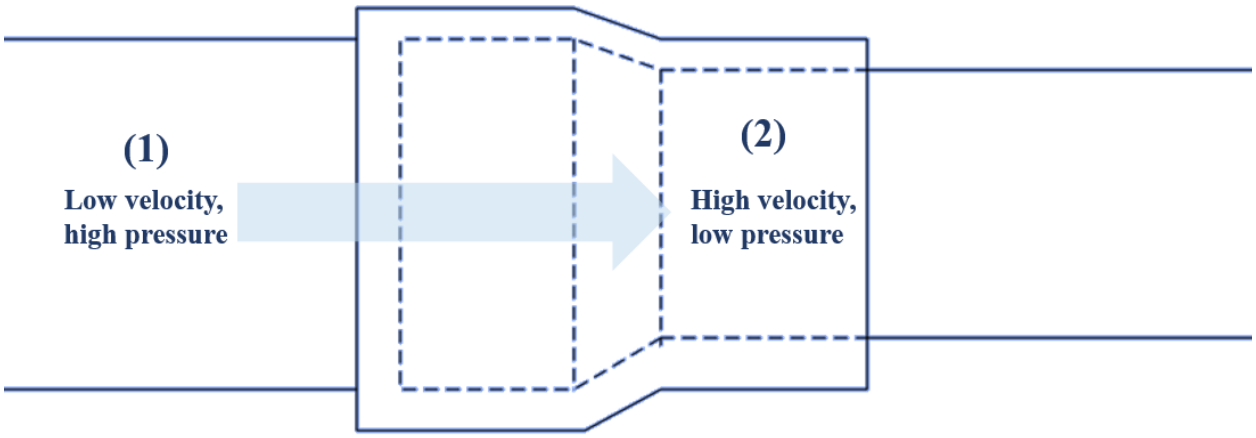


Figure 25. In the proposed Venturi design concept, fluid is pumped from a large diameter section of PVC where velocity is low and pressure is high to a smaller diameter section of PVC where velocity is high and pressure is low. The pressure drop between the two sections, therefore, is a function of the ratio of diameters.

Figures 26 and 27 display results of analyses for the Venturi suction concept. As shown in Equation 5.5, the pressure drop (suction) generated by the Venturi is a function of the inlet fluid velocity as well as the change in diameter between the large diameter, upstream location (point (1), Figure 25) and the smaller diameter, downstream location (point (2), Figure 25).

An inlet velocity of 1 meter per second (m/s) would arguably be difficult to achieve using purely mechanical operations. A more realistic target range for fluid velocity at the inlet of the Venturi is 0.1 – 0.5 m/s. As shown in Figure 26, a Venturi with an inlet velocity of 0.4 m/s with large diameter inlet of NPS 2 and small diameter outlet of NPS ½ would produce a pressure drop of 75 millimeters mercury (mm Hg), which falls within the target range of 60-80 mm Hg for newborn suction.

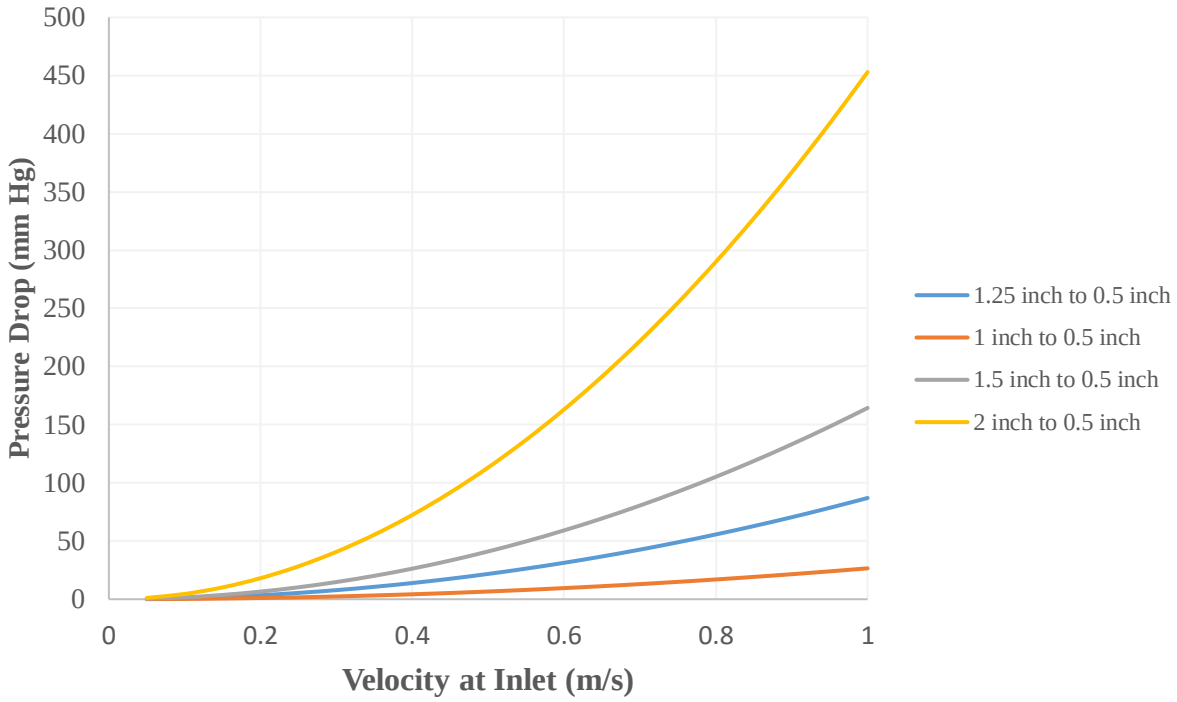


Figure 26. Mathematical analyses of Venturi configurations using Bernoulli's equation with idealized flow assumptions for various inlet diameters reduced to 0.5 inch diameter. The maximum pressure drop increases exponentially as a function of the inlet velocity. The legend on the right displays various reducing sizes, with the numbers denoting the nominal pipe sizes. It is important to note that a realistic target velocity at the inlet is 0.1-0.5 m/s; higher inlet velocities would arguably be difficult to achieve mechanically.

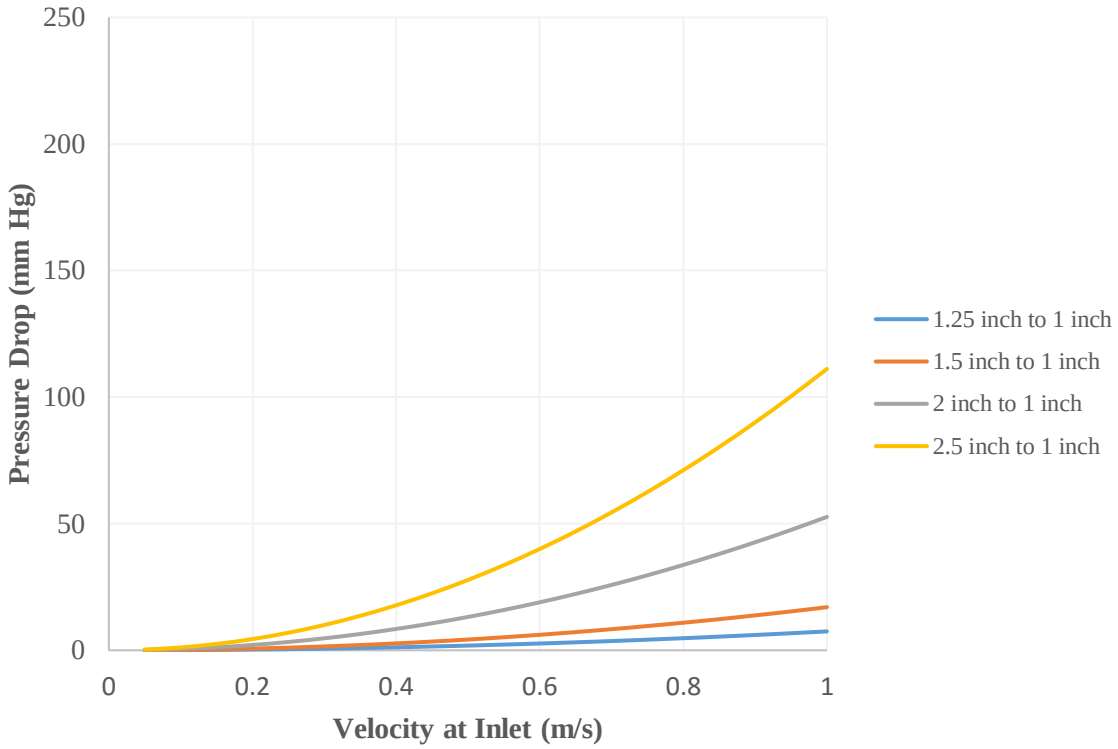


Figure 27. Mathematical analyses of Venturi configurations using Bernoulli's equation with idealized flow assumptions for various inlet diameters reduced to 1 inch diameter. The maximum pressure drop increases exponentially as a function of the inlet velocity. The legend on the right displays various reducing sizes, with the numbers denoting the nominal pipe sizes. It is important to note that a realistic target velocity at the inlet is 0.1-0.5 m/s; higher inlet velocities would arguably be difficult to achieve mechanically.

Another factor to consider is the entry length (l_e) needed for the fluid to fully develop the velocity profile [70]. To determine the entrance length, we first need to understand the Reynold's number for the flow, which is a non-dimensional ratio of inertial forces to viscous forces. The Reynold's number (Re) may be defined by Equation 6.6:

$$Re = \frac{\rho v L}{\mu} \qquad \text{(Eq. 6.6)}$$

Where ρ represents the density of the fluid, v represents the velocity of the fluid, L represents the characteristic length, and μ represents the dynamic viscosity of the fluid.

For a pipe, such as the pipes used to construct the Venturi concept, the characteristic length (L) is the diameter of the pipe. If we assume the velocity at the inlet of the proposed Venturi is 0.4 m/s, inlet diameter is 0.0602 meters (NPS 2), and temperature of the water is 20 °C, the Reynold's number for the proposed Venturi may be calculated:

$$Re = \frac{1000\frac{kg}{m^3} * 0.4\frac{m}{s} * 0.0602\,m}{1.002N\,s/m^2} = 24.0439$$

From this analysis of the flow, we can determine that the flow is laminar (Re <2300). For laminar flow, the entrance length number ($El_{laminar}$), which may be used to calculate the entry length (l_e), may be calculated using Equation 5.7:

$$El_{laminar} = 0.06 * Re \qquad \text{(Eq. 5.7)}$$

Therefore, for the flow conditions mentioned above, the entrance length number may be calculated as:

$$El_{laminar} = 0.06 * 24.04 = 1.442$$

From the entrance length number, the entry length (l_e) may be calculated using Equation 5.8:

$$l_e = d * El_{laminar} \qquad \text{(Eq. 5.8)}$$

Where d represents the diameter of the pipe. Therefore, it is possible to calculate the entry length required for fully developed flow for the conditions above as follows:

$$l_e = 0.0602\,m * 1.442 = 0.0868\,meters$$

Bernoulli's equation in combination with the continuity equation (Eq. 5.5) allow us to analyze a drop in pressure for a fluid as a function of the ratio of the large diameter pipe to the small diameter pipe. Bernoulli's equation does not provide analysis of the convergent or divergent angles, which are defined in Figure 28. The convergent angle, defined by Region 1 in Figure 28, refers to the angle of declination between the inlet and the throat, or small diameter, of the Venturi device. The divergent angle, identified by Region 3 in Figure 28, refers to the angle of inclination between the small diameter and the outlet of the Venturi. As indicated by the velocity profiles (blue) in Figure 27, the divergent and convergent angles in a Venturi device may significantly affect the velocity profile of the fluid and ultimately the operation of the Venturi device.

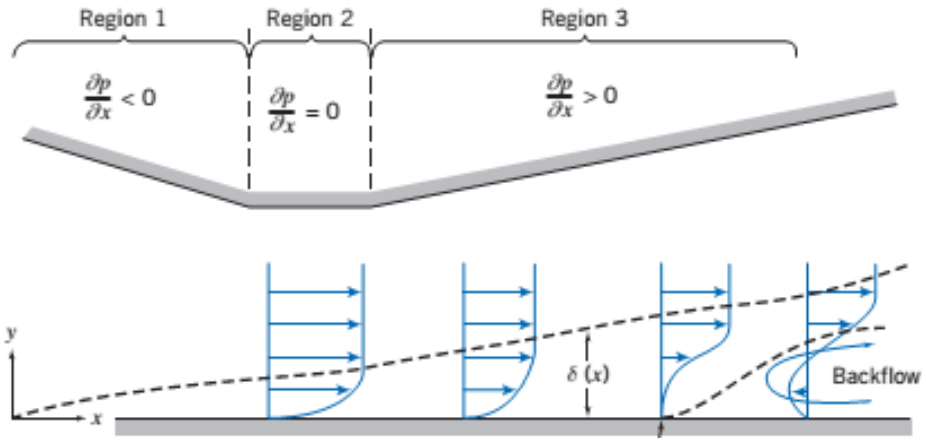


Figure 28. Convergent (region 1) and divergent (region 3) angles of the Venturi assembly significantly affect performance of the device. As indicated by the velocity profiles (blue) in Figure 27, the divergent and convergent angles in a Venturi device may significantly affect the velocity profile of the fluid and ultimately the operation of the Venturi device. Image source: *https://www.quora.com/Why-is-the-length-of-the-diverging-section-in-a-venturi-meter-longer-than-the-converging*

The International Organization for Standardization (ISO 5167-1) has established precise requirements for measurement of fluid flow by differential pressure devices in circular cross sections, including setting recommendations for both the convergent and divergent angles [71]. For divergent angles, the Standard recommends the angle to fall

within 7-8 degrees to avoid separation of the flow [71], [72]. For a Venturi device convergent angle, the Standard recommends 21 degrees.

With these additional design parameters, it becomes apparent that a PVC coupling does not meet the ISO standards for the convergent angle for a Venturi device. A standard PVC reducer from 2 NPS to 1 ½ NPS has a convergent angle of 47.35° [73], which is unacceptable compared to the recommended convergent angle of 21°. Therefore, the proposed design becomes difficult to manufacture, since a standard coupling may not be used. In order to fabricate the proposed design, a lathe would need to be used to manually hollow out a solid piece of cylindrical PVC at 21° for the convergent angle and 7° for the divergent angle. This design parameter becomes significantly more challenging to achieve, especially in a low resource settings where access to power tools (such as the aforementioned lathe) and the electric grid may not be readily available.

5.2 Diaphragm Suction Analysis and Concept Generation

Diaphragm suction was also explored during the ideation and concept generation phase. Diaphragm suction operates under the physical principles of Boyle's Law, which states that pressure and volume are inversely related according to Equation 5.9:

$$P_1 V_1 = P_2 V_2 \qquad \text{(Eq. 5.9)}$$

Where P represents pressure and V represents volume. This relationship is further explained in Figure 29 below. When the volume of a diaphragm (or piston-cylinder assembly, as shown) is compressed at a constant temperature, the pressure inside the diaphragm increases as the gas molecules are compressed into a smaller volume.

Conversely, when the volume of a diaphragm is expanded, the pressure decreases. The fundamental idea of this concept, therefore, was to harness the decreasing pressure as the diaphragm expands, generating suction.

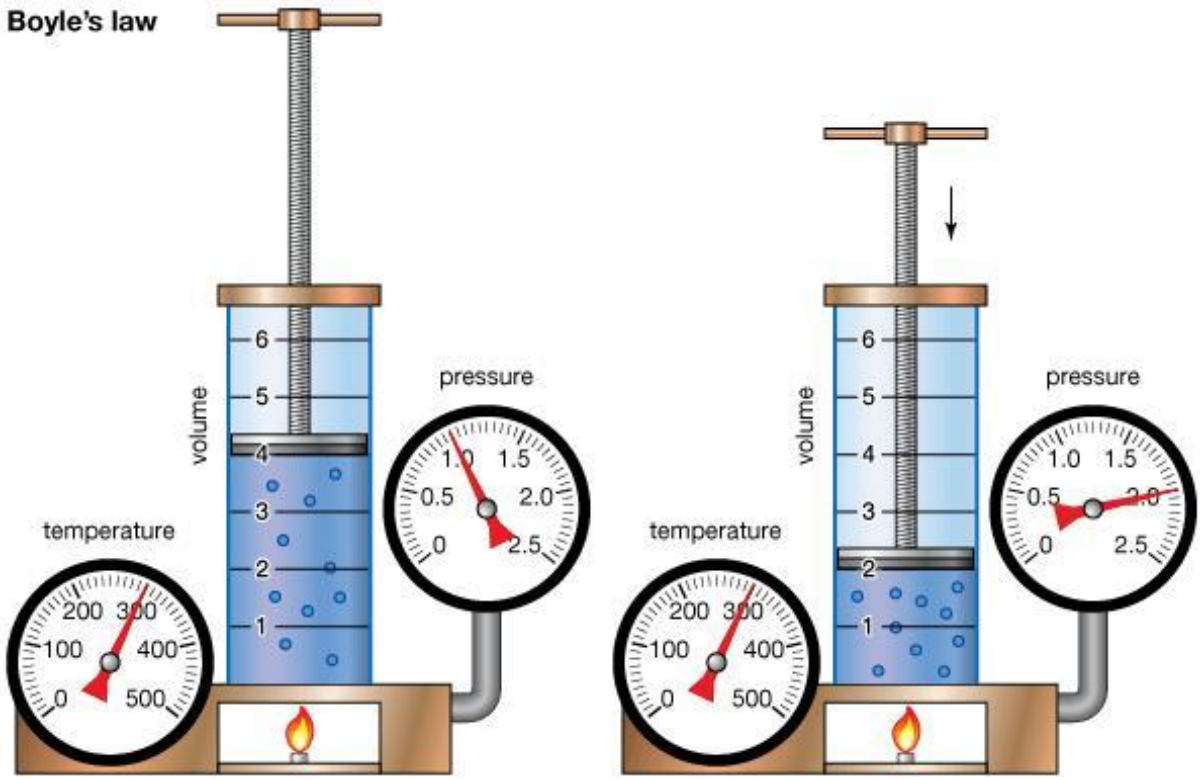


Figure 29. Boyle's Law states that at a constant temperature pressure and volume are inversely related. As volume of an assembly, such as the piston-cylinder assembly above, is expanded, pressure decreases. As the volume of an assembly is decreased (compressed), the pressure in the assembly increases.

Standard toilet plungers, which are comprised of a durable rubber, were explored as a concept for diaphragm suction. Though toilets are not present in many village communities in Malawi, every hardware market documented during this research in southern and central Malawi contained plungers. This is likely due to the prevalence of toilets in hotels and other tourism industries in Malawi.

To evaluate this design concept, a prototype was constructed using a single plunger attached to a 4 inch length of NPS 4 PVC pipe. Pressure measurements were recorded using

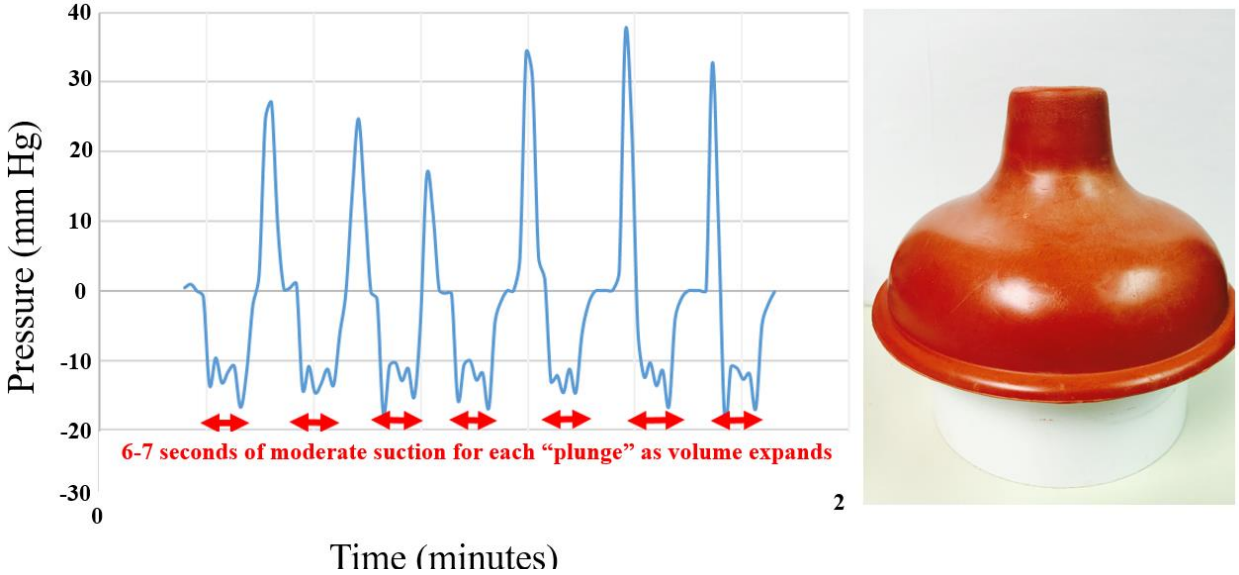


Figure 30. Simple prototype was constructed using a single plunger attached to 4 inch length of NPS 4 PVC pipe. Pressure measurements were recorded using a digital manometer with a sampling rate of 1 Hz.

a digital manometer with a sampling rate of 1 Hertz. With this simple prototype, pressure ranges between -10 and -20 mm Hg were achieved consistently, with a 6-7 second duration for minimum pressure (Figure 30).

Figure 31. Second prototype, constructed with two plungers, produced a suction head of 45 mm Hg.

In an effort to increase the amount of suction generated, a simple prototype was constructed using two plungers acting on the same volume (Figure 31). Using this prototype, a negative pressure head of 45 mm Hg was consistently achieved. However, it became clear upon construction of this prototype that sealing between the plunger and the PVC pipe would be challenging. Additionally, the recharge time between each stroke of the plunger was approximately 10 seconds, which is not ideal in an emergency clinical suction application. Lastly, the plunger displaced only a limited volume of air, resulting in a limited pressure range.

Still, the diaphragm concept showed promise for several reasons. First, the diaphragm does not require precise tolerances, such as the tolerances necessary for a piston-cylinder assembly (described further in Section 5.3). Additionally, rubber plantations are present in Malawi, so a design that incorporates rubber would be incorporating a locally produced product. Lastly, rubber components, such as the plungers tested in the prototypes above, are durable and provide consistent operation over many cycles of use.

5.3 Piston Cylinder Analysis and Concept Generation

The final design concept explored was the reference design used during concept screening: the piston-cylinder assembly. A piston-cylinder assembly also generates suction under the principles of Boyle's Law (Eq. 5.9), similar to the diaphragm concept discussed

in Section 5.2. Piston-cylinder assemblies are used in many pressure-generating applications, including generating a suction head for pumping water from wells, suction pit latrine desludging, and pressure cycling for automobile engines.

Piston cylinder assemblies require a precisely machined seal, usually made of rubber, between the piston and the shaft (cylinder). During exploration of this design concept, it became clear that this level of precision machining would be difficult in a low resource setting. However, when a proper seal is machined, efficiency is high for piston-cylinder assemblies. Ultimately, the high efficiency of a piston-cylinder assembly would allow for a smaller, more compact design, which is an advantage in a low resource setting where physical space in the ward may be limited.

5.4 Selection of Final Design Concept

To assist with differentiation of the final three concepts, a structured concept-scoring matrix was utilized as shown in Table 12. For each selection criteria, each design was ranked on a scale of 1-5, with 5 being optimal. Concepts were scored and ranked according to the weighting system.

Table 12: Concept Scoring Matrix

		Concepts					
		A (Reference) Piston Cylinder		E Diaphragm		F Venturi	
Selection Criteria	**Weight**	**Rating**	**Weighted Score**	**Rating**	**Weighted Score**	**Rating**	**Weighted Score**
Ease of fabrication from locally available resources	35%	4	1.4	5	1.75	4	1.4
Portability	10%	4	0.4	4	0.4	2	0.2
Ease of use	25%	4	1	4	1	2	0.5
Durability	10%	3	0.3	3	0.3	3	0.3
Affordability	10%	3	0.3	4	0.4	3	0.3
Ease of deployment	10%	4	0.4	4	0.4	3	0.3
	Total Score	3.8		4.25		3	
	Rank	2		1		3	
	Continue?	Develop		Develop		No	

Due to the proximity in score of the piston cylinder design concept and the diaphragm design concept, a combination concept was generated, shown in Figure 32. This concept combined the strengths of the piston cylinder, including efficiency, with the manufacturing strengths of a diaphragm. The final concept selected utilizes a trash bag diaphragm in conjunction with a piston cylinder assembly. The trash bag diaphragm serves as the seal between the piston and cylinder, eliminating the need for precise tolerances and expensive machining. The proposed concept operates under the principles of Boyle's Law; as the piston is moved upwards in the cylinder, the bag moves upward, reducing the volume in the cylinder and resulting in an increase in pressure. Consequently, air escapes through the outlet valve. As the piston is moved downward, air enters through the inlet valve, resulting in an increase in volume and corresponding decrease in pressure, generating the desired suction. This combination design concept was used as the foundation for the prototyping phase, described in the next section.

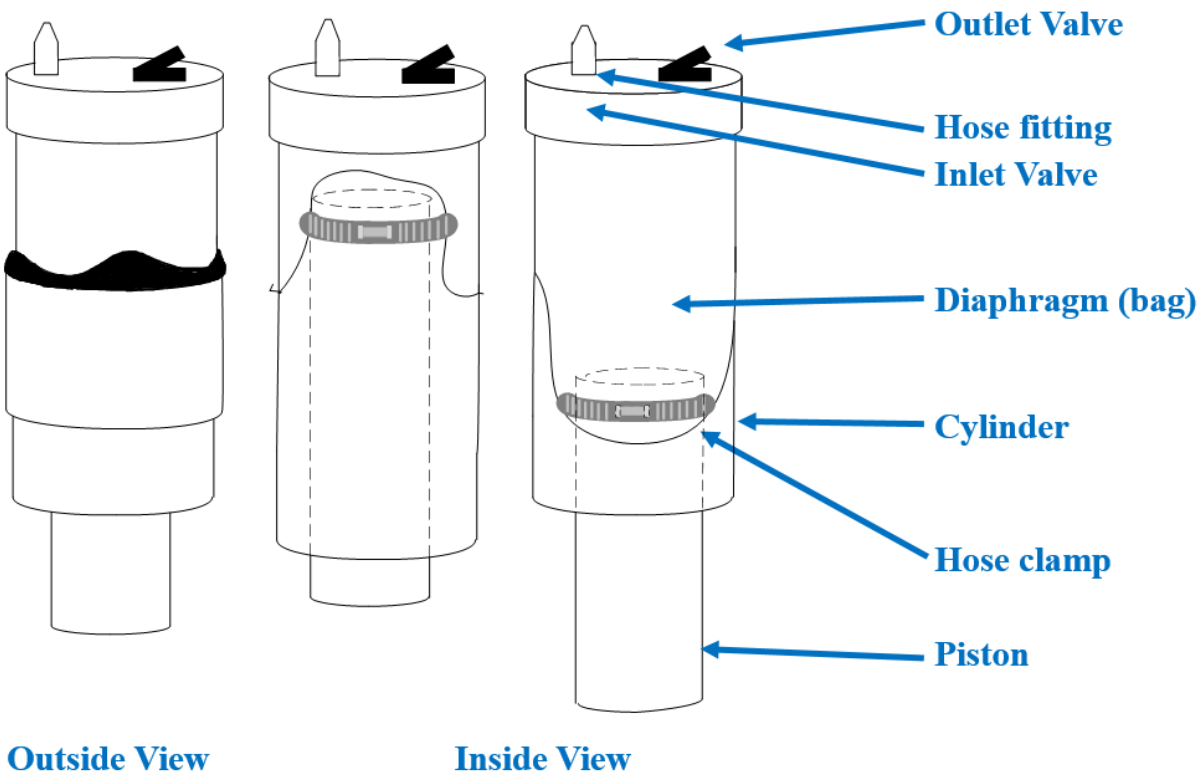


Figure 32. The piston-cylinder and diaphragm concepts were combined to create a new design concept, shown above. The design uses a trash bag diaphragm in conjunction with a piston cylinder assembly. The diaphragm serves as the seal between the piston and cylinder, eliminating the need for precise tolerances and expensive machining.

Chapter 6: Prototyping Suction Machine from Resources Available in Malawi

The following chapter outlines the prototyping process, including assessment of community resources in southern Malawi. This prototype was constructed to exemplify that design of medical devices and other technology is 1) possible utilizing locally available resources and 2) should consider community assets, such as the unique skillsets of local artisans, locally available tools, and locally available resources.

6.1 Mapping Community Assets in Southern Malawi

One of the most critical components of evaluating feasibility of the device in low-resource settings was to fabricate the device entirely from local resources. In order to understand and utilize local community assets, the field research team first mapped distribution points for polyvinyl chloride (PVC) piping in Malawi (Figure 33). Networking with local hardware shop owners in Blantyre, the commercial center for the country, ultimately resulted in collaboration with Polyplast, Inc., a major PVC distributor for Malawi. This connection provided invaluable insight into locally available resources across the entire country, enabling the field research team to redesign and build the device from in-country materials. This connection would likely not have been possible

Figure 33. Map of Polyplast, Inc. PVC distribution points in Malawi. To enable local maintenance and repair, the device was designed from local materials.

without mapping community assets, showing the importance of collaborating with local expertise for community-based engineering solutions [65], [66].

This research prioritized relationship-building with the main PVC distributor of Malawi, Polyplast Inc. The corporation provided prices for components, which can be found in Appendix F. However, it is important to note that prices at individual hardware markets and distribution points may vary. Additionally, management at the corporation established an agreement with this research team that prices would drop significantly for parts ordered in bulk. The corporation also demonstrated the molding process for PVC-components and noted that fabrication of custom parts is possible, though costs would rise according to complexity of the part.

6.2 Suction Machine Prototype

After the final design concept was selected, a full prototype model was constructed as shown in Figure 34. For the pressure generating mechanism, a trash bag of 3 millimeter thickness was used as the diaphragm, with a section of 4-inch diameter section of PVC as the cylinder and a 2-inch diameter section of PVC as the shaft. The diaphragm bag was attached to the 2-inch PVC shaft using a hose clamp lined with rubber to prevent direct contact of the bag with the metal clamp, which could result in early fatigue and tearing of the bag.

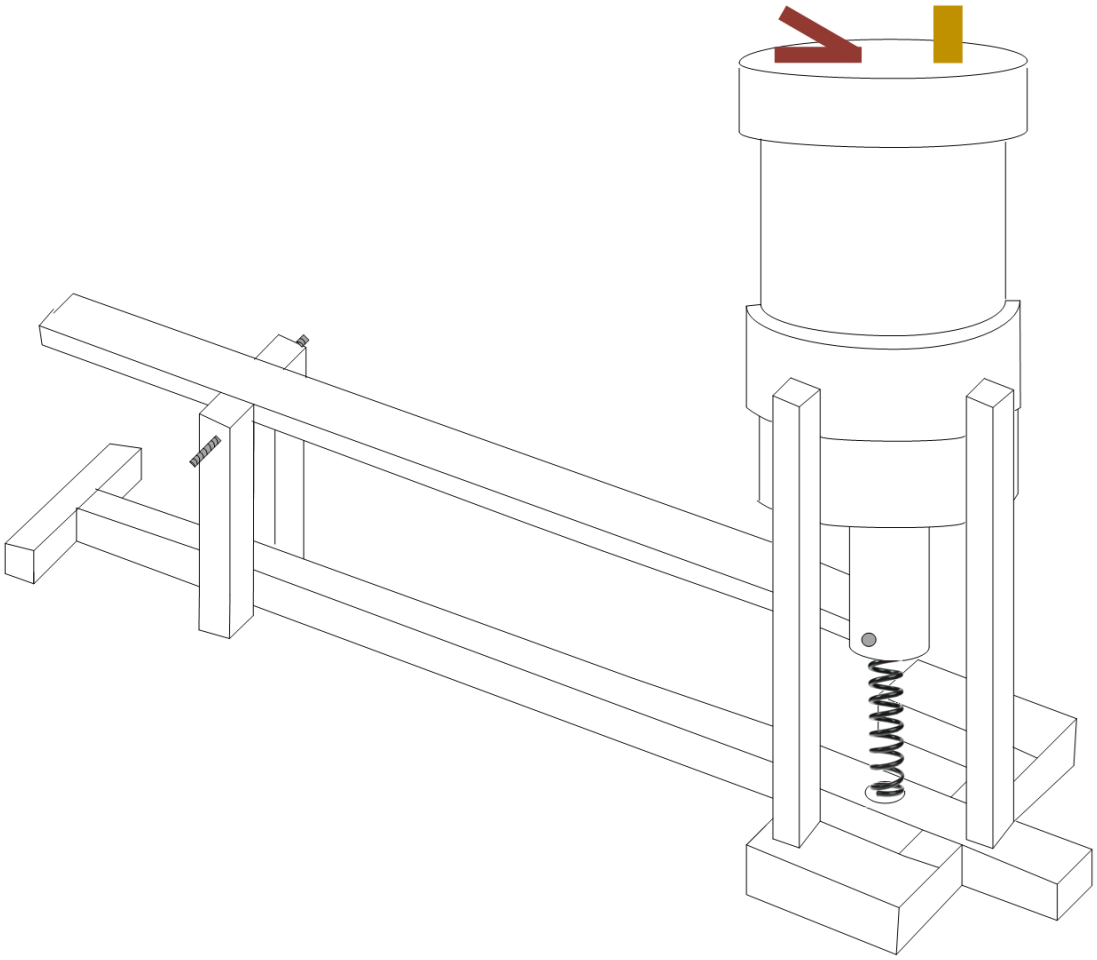


Figure 34. Final design sketch for proposed prototype. The prototype is spring-loaded according to WHO standards. A NPS 2 PVC shaft displaces the trash bag diaphragm in a NPS 4 PVC cylinder. The lever arm and base are constructed from T-Slotted 1-inch 80/20 aluminum.

Kinematic modeling of the system using Matlab software revealed anatomical constraints. Moments acting on the hip and knee joint of the pump user were analyzed using a system dynamics model (Figure [x]). The biomechanical model used for anaylsis was an average female of height 5 feet, 4 inches. For this model, the allowable height for the foot pedal to not exert excessive forces on the user's joint was six inches. Therefore, the lever arm was constrained (at L_1, figure [x]), despite reducing mechanical advantage of the lever, in order to ensure safety of the user. Using this model, spring constants were also analyzed for optimization of both mechanical advantage and user safety. Ultimately, an 8"

spring with spring constant k=3.5 Newtons/meter was chosen for the final prototype.

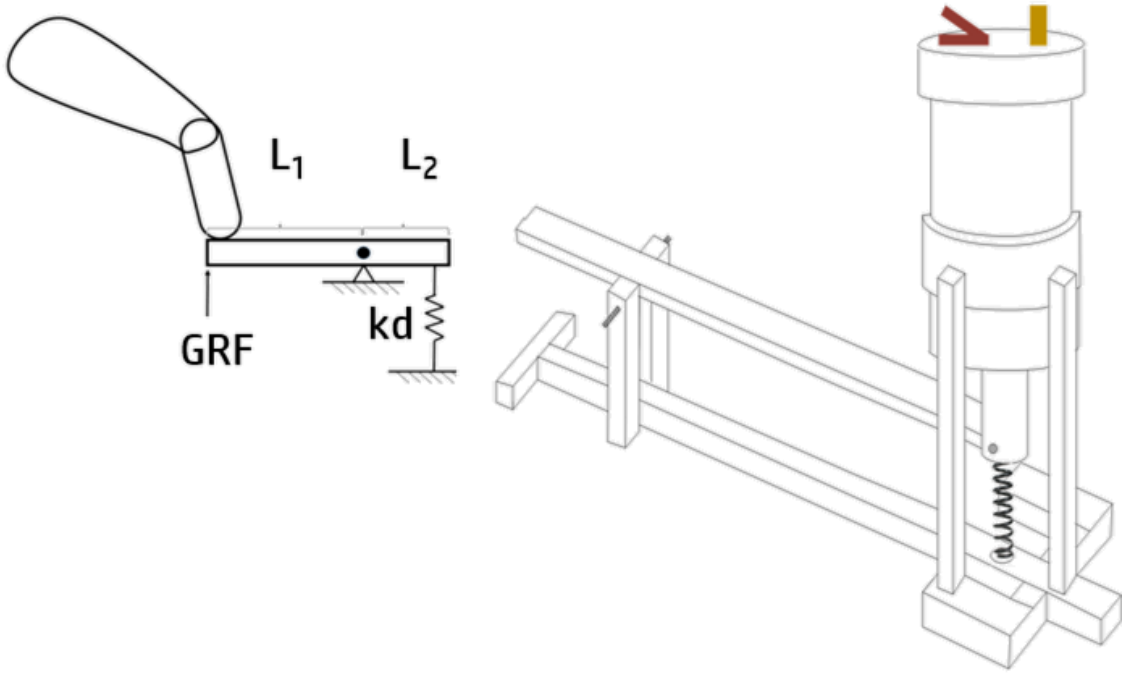


Figure 35. Biomechanical model for kinematic analysis of user-pump interaction. In the figure above, kd represents the spring/mass force, L_1 represents the length from the spring to the fulcrum, L_2 represents the length from the fulcrum to the user's foot, and GRF represents the ground reaction force, or the force exerted on the user.

Various heights were tested for the optimal length of the cylinder assembly. Figures 36-38 show results from pressure testing results for each length of the cylinder. To obtain pressure measurements, the prototype was instrumented with a digital manometer differential pressure sensor. Software was used to collect samples at a sampling frequency of 1 Hz, the maximum sampling frequency of the software. It is important to note that future testing should include sampling at higher frequencies.

The proposed design allows for modification of target pressure range by increasing the volume of the cylinder; this could be achieved by increasing the length of the cylinder device or by increasing the diameter of the PVC. Such modifications could be utilized for

applications such as generating a greater suction head for pit latrine desludging, well pumping, or other clinical applications.

At cylinder length of 8.5 inches, the target pressure of -60 mm Hg was not able to be achieved. Lengthening the cylinder to 12.75 inches resulted in achieving the target pressure range, though results were not consistent. However, a length of 17 inches for the cylinder proved to be awkward for the user to operate and did not yield significantly higher pressures. For these reasons, 12.75 was chosen as the optimal cylinder length.

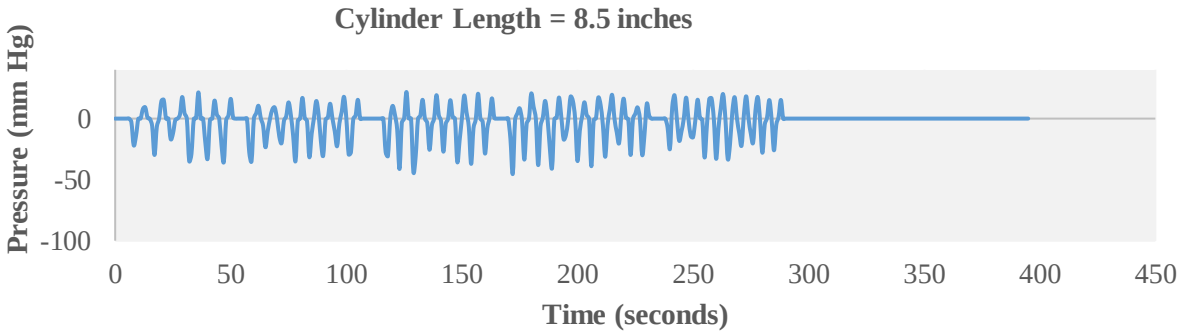


Figure 36. Pressure versus time readings for cylinder of length 8.5 inches.

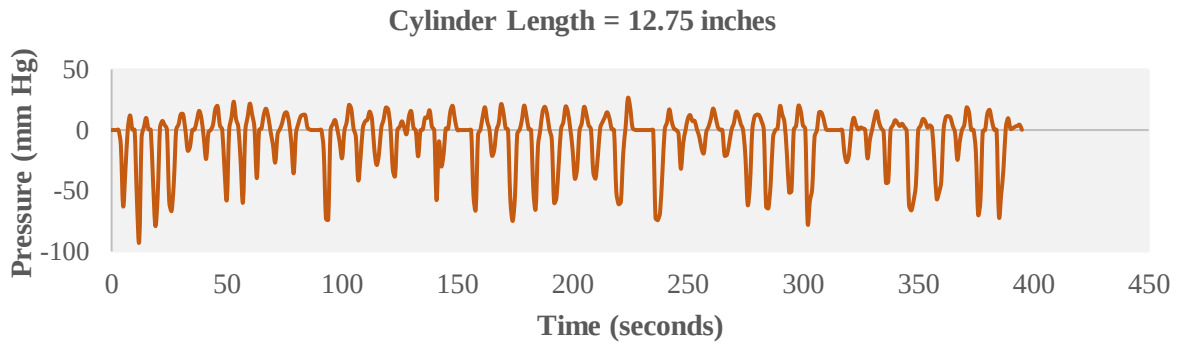


Figure 37. Pressure versus time readings for cylinder of length 12.75 inches.

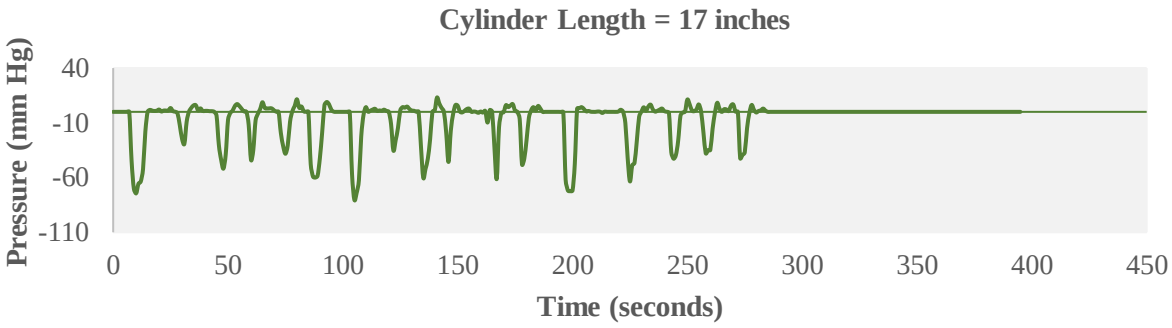


Figure 38. Pressure versus time readings for cylinder of length 17 inches.

Figure 39 shows statistical analyses for minimum pressure achieved by the prototype per stroke of the foot pump. As mentioned previously, increasing the cylinder length to 17 inches did not significantly increase the amount of suction generated, and the longer cylinder assembly was much more cumbersome and difficult to operate. With a median suction pressure of 55 mm Hg (just under target range of 60 mm Hg), 12.75 was chosen as the optimal length for the cylinder. It should be noted that each length chosen for the cylinder is 150% of the previous increment, so according to Boyle's Law, we would expect a 50% increase in pressure. However, due to inefficacies in sealing of the volume as well as user complications with longer length cylinders, we do not see the full 50% increase in pressure.

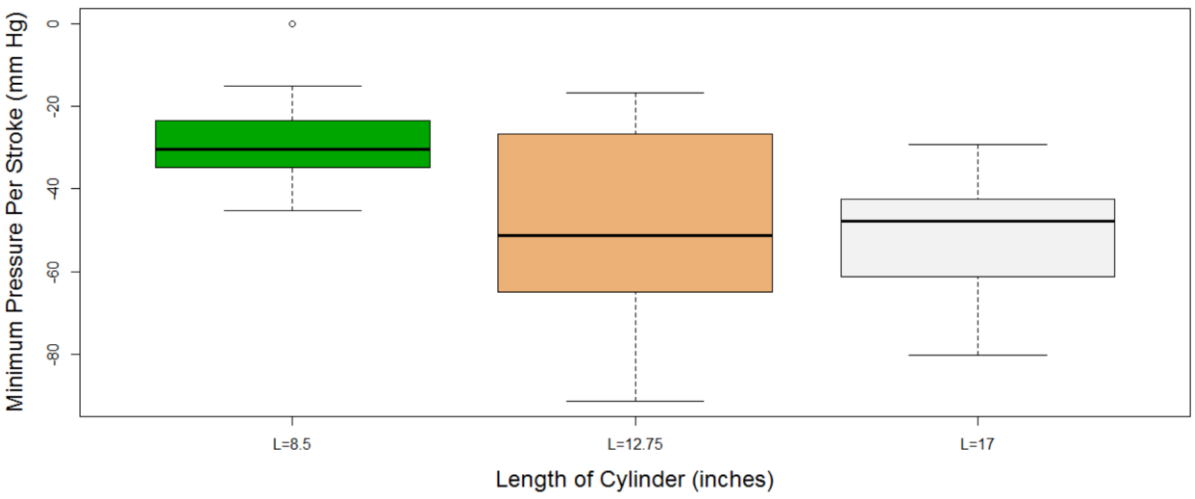


Figure 39. Pressure versus time readings for cylinder of length 12.75 inches.

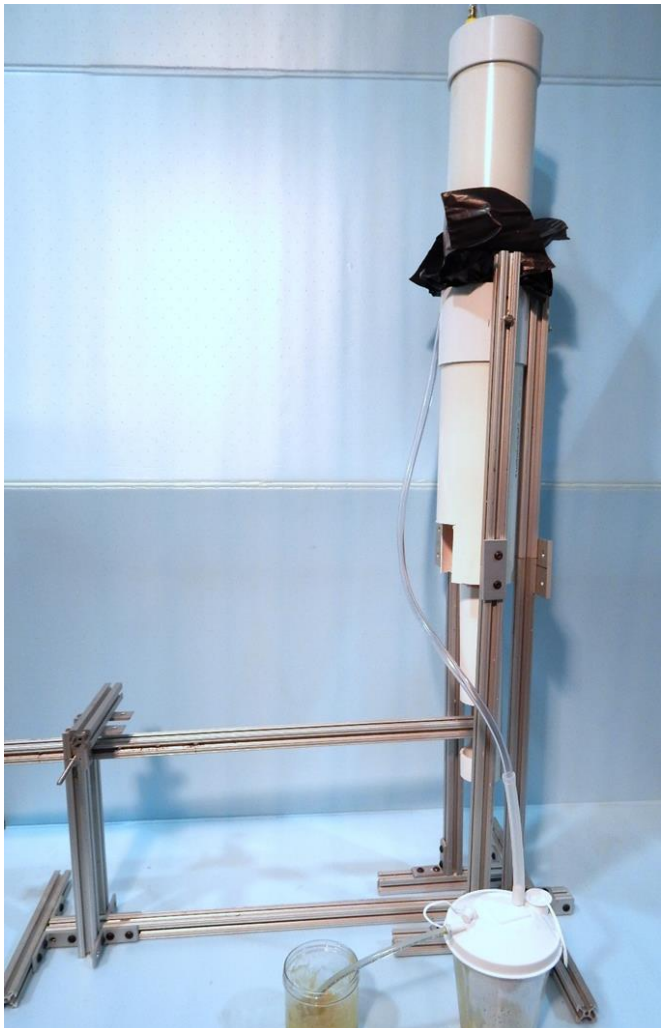


Figure 40. Final prototype suction machine device

Figure 40 shows the constructed prototype, with the base of the prototype and foot pedal mechanism constructed of T-Slotted 80/20 1-inch Aluminum Framing. It is important to note that the frame and foot pedal could easily be substituted with wood, PVC, or another more affordable and locally available material. The lever-arm foot pump mechanism provides hands-free operation for the device.

Construction of the device is possible without the use of advanced machining or power tools, meeting

the target specification of the device being built using locally available tools. A circular saw was used to cut PVC and aluminum to length, with lubricant added to the saw blade to efficiently cut the aluminum framing. However, for the PVC cuts, a simple hand-saw would suffice.

The combination of the trash bag/diaphragm design provides additional manufacturing benefits. The bag is sealed at the open end between a 4-inch PVC coupling and a segment of NPS 4 PVC pipe. This design provides modularity, making maintenance of the device (replacing the diaphragm bag) feasible by not only technical staff, but by clinical staff as well. The merit of this design concept is in the use of locally available resources for the pressure generating mechanism, as well as in the modularity and ease of assembly of the device. For this design, the design philosophy of "make things break the way you want them to break" was employed; in other words, the weakest component of the system is identified (in this case, the trash bag diaphragm), and the designers anticipate this maintenance need by ensuring that replacement of the part is as seamless as possible. Fatigue analysis and cycling of the bag should be conducted in greater detail in future work; however, no noticeable effects of fatigue were observed after 103 iterations of use of the prototype.

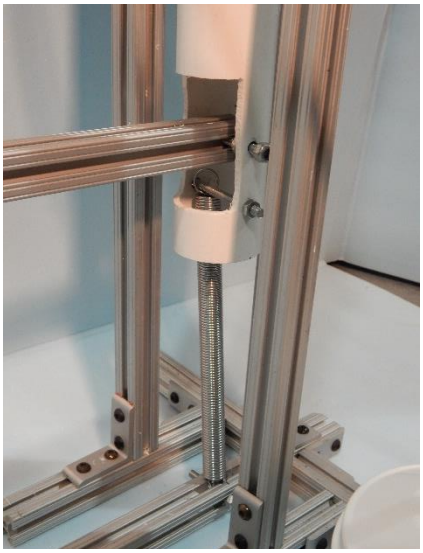


Figure 41. Pressure versus time readings for cylinder of length 12.75 inches.

To counteract the user-supplied input force to the foot pedal, a spring (k=3.5 kN/m) was attached to the shaft (Figure 41). As the user presses the lever down, the piston is moved into the cylinder, stretching the spring. The spring then pulls the piston back to equilibrium for the user to pump the lever again. The spring mechanism ensures that the user only has to input work to move the piston upwards, while system dynamics return the system to the starting position. As shown in Figure 41, the piston is hollowed out to allow the lever to pivot freely. The lever rotates about a standard bot, while the spring is connected to a bolt 1.5 inches below the lever connection.

Figure 42. Brass hose fitting connected to suction tubing

A brass push-on hose fitting was drilled into a flat, 4 inch PVC endcap, creating an airtight seal with the hose-fitting threads (Figure 42). High pressure/vacuum polyethylene tubing was used to connect the suction machine device to the waste container. For this demonstration, a standard suction machine waste container was used. However, other possibilities for locally supplied waste containers that could be sterilized in an autoclave include mason jars, coke bottles, and milk jars.

Valves to control cycling of air into and out of the system were a critical component of the prototyping process. Though several appropriate valves are commercially available, such valves are not available for purchase in Malawi and are prohibitively expensive. Therefore, simple flapper check valves were designed from rubber (Figure 43). Since rubber plantations are located throughout Malawi, the utilization of rubber valves incorporates local resources. Additionally, valves could be constructed from inner tubes or tires, which are also locally available. For valve construction, ethyl-2-cyanoacrylate adhesive, commonly sold under trade names such as "Super Glue" and "Krazy Glue" was used to attach the valves to the PVC and to attach the pieces of rubber to each other. For the flap of the valve, 1/16" sheet rubber was used to allow the flap to open freely. For the base of the valve, 1/8" sheet rubber was used. Pressure results from prototype testing (Figures 36-38) show that the valves should be improved in future work, since minimum positive pressure is read on the digital manometer where only negative pressure should be seen. However, the simple design of the valves does allow for the air to be cycled in and out of the system effectively, and the concept shows promise for locally designed valves.

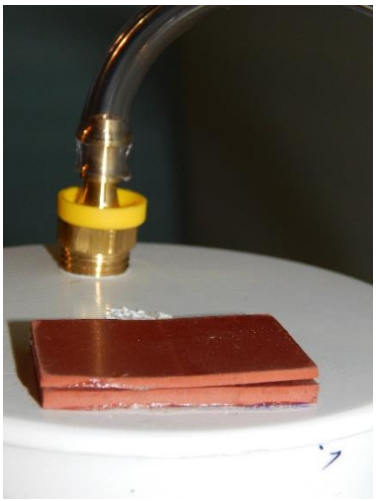
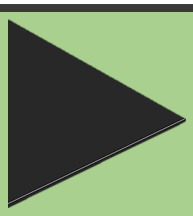
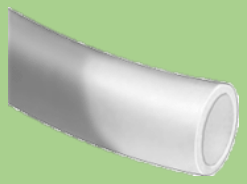
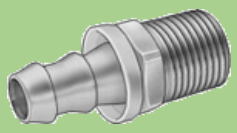


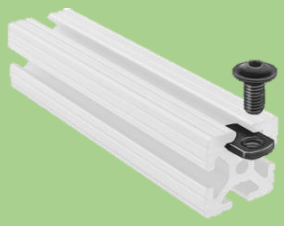
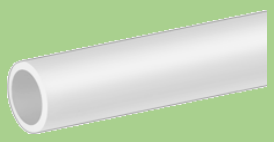
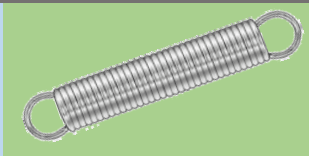
Figure 44. Simple flapper check valves were constructed from rubber, a locally available resource in Malawi.

Table 13 displays the bill of materials for the prototype constructed in Figure 39. The proposed prototype costs a total $124.77 USD. However, it is important to note that 69% of the total cost is in the framing and foot pedal mechanism. This mechanism could easily be redesigned with wood, PVC, or another more affordably-priced material. For the

purposes of this proof-of-concept prototype, T-Slotted Aluminum was used for the framing to recycle parts available at the Unmanned Systems Laboratory and keep prototyping costs to a minimum.

Table 13: Bill of Materials for Suction Machine Prototype

Quantity	Description of Component		Cost
8 square inches	1/16" thickness sheet rubber		**$0.18**
4 square inches	1/8" thickness sheet rubber		**$0.16**
46"	High pressure/vacuum polyethylene tubing 1/4" ID		**$9.66**
1	Brass Push-on Hose Fitting, Adapter for 1/4" Hose ID x 1/4" NPTF Male Pipe		**$1.64**

1	Flexible Fittings for Pipe, Straight, for 4" Pipe Size, 4" Long		**$7.97**
1	Contractor's Bag, 55-60 Gallon, 3 Millimeter Thickness		**$1.40**
19.8 ft	Aluminum 1 inch T-slot Framing (80/20)		**$62.17**
50	Compact End-Feed Fastener, 1/4"-20 Thread for Aluminum T-Slotted Framing Extrusion		**$24.05**
1	4" PVC End Cap		**$1.30**
26"	4" PVC		**$7.24**
29"	2" PVC		
1	8" spring, spring constant 3.5 kN/m		**$9.00**
		Total Cost	**$124.77**

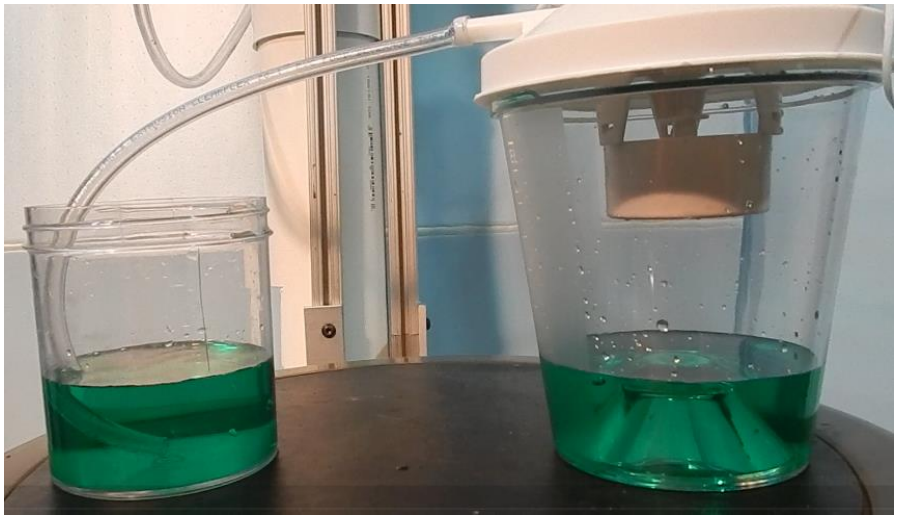


Figure 44. Flow rate was evaluated for suctioning of two fluids: green dyed water (above) and simulated meconium, consisting of a mixture containing 50% water and 50% pea soup.

In addition to the pressure cycling of the prototype, flow rate was evaluated for suctioning of two fluids of varying viscosities. First, the prototype suction machine was used to suction dyed water (Figure 44). As shown in Figure 44, the median flowrate achieved for suctioning water was 3.58 cubic centimetres per second. Additionally, meconium was simulated using literature recommendations of 50% pea soup and 50% water (simulating thin particulate meconium) [74]. For the more viscous fluid (simulated meconium), a median flowrate of 0.74 cubic centimeters per second was achieved. To simulate clinical data, measurements were also taken for time to suction a 50 cubic centimeters (cc) of both water and simulated meconium. Over five trials, the average time to suction 50 cc of water was 13.9 seconds, while simulated meconium required 69.8 seconds to suction 50 cc. Results from the flow rate evaluation trials, which utilized standard suction tubing, are shown in Figures 45 and 47.

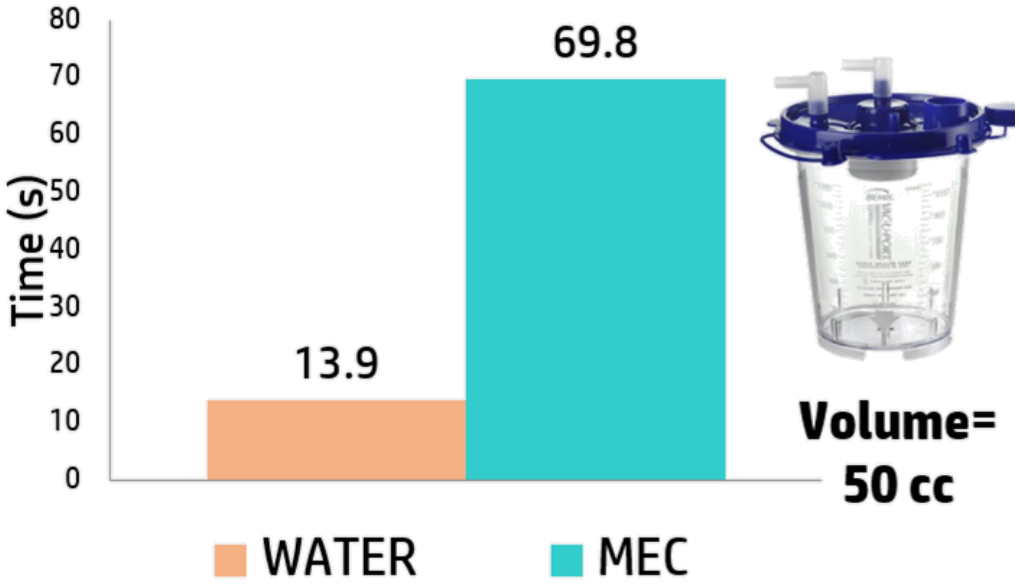


Figure 45. Flow rate was evaluated for suctioning of two fluids: green dyed water (above) and simulated meconium, consisting of a mixture containing 50% water and 50% pea soup.

Further testing was conducted using an 8 French suction catheter, which is routinely used for newborn suction. With the added resistance of the suction catheter, the prototype pump required 59.0 seconds to suction 50 cc of water (Figure 46).

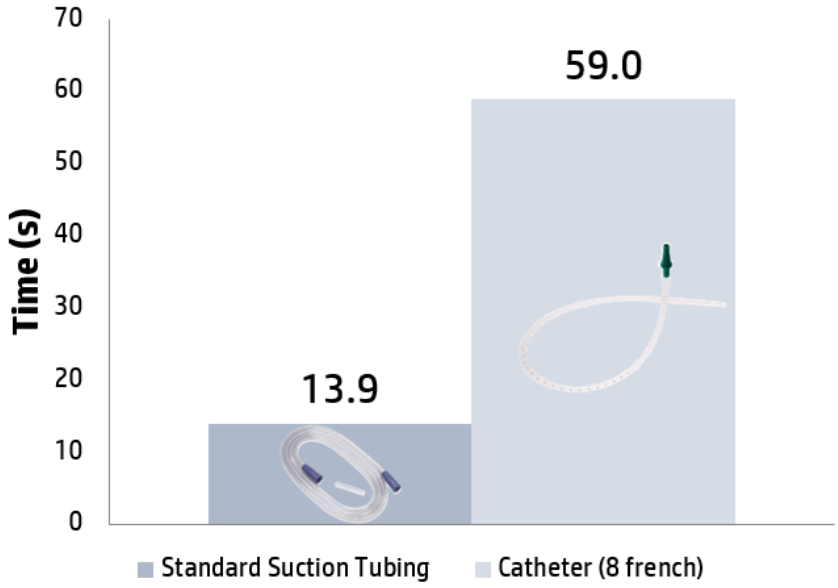


Figure 46. Flow rate was evaluated for suctioning of water using standard suction tubing and an 8 French suction catheter.

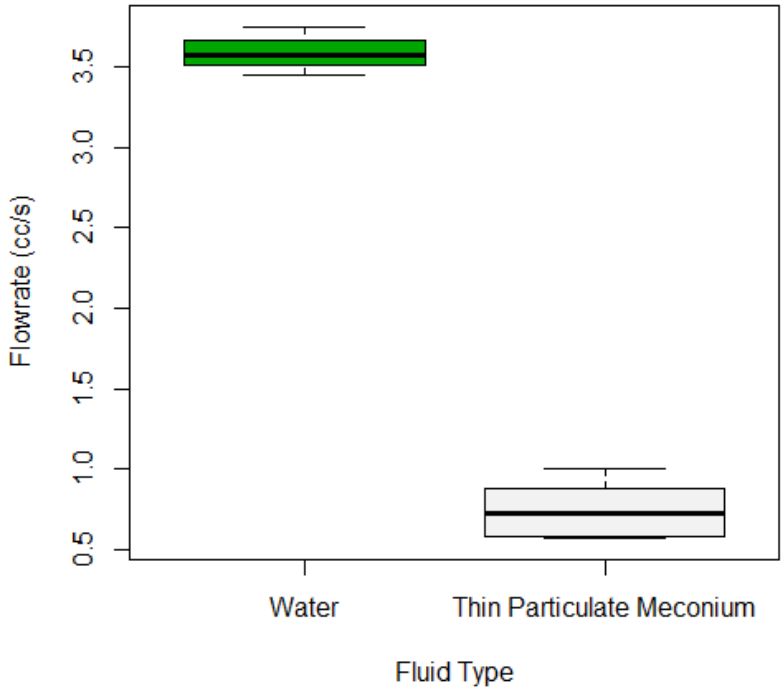


Figure 47. Comparison of prototype flow rate performance for water and simulated thin particulate meconium, consisting of a mixture of 50% pea soup and 50% water.

6.3 Feedback on Prototype from Key Stakeholders in Malawi

General feedback on the design prototype was provided by clinical engineers at Kamuzu Central Hospital in Lilongwe, Malawi. Engineers noted that the design should be made more compact to reduce the amount of space it would occupy in a ward. Clinical engineers appreciated the use of spare parts and echoed the merit of being able to repair the device locally. Other feedback included brainstorming ideas for a cut-off float valve mechanism, which is often missing on donated suction machines and can cause the motor to burn out.

Figure 47. Irreparable electric suction machines at Queen Elizabeth Central Hospital.

At Queen Elizabeth Central Hospital, clinical engineers graciously provided insight into failures of current suction machines. Figure 47 shows suction machines that are non-operable due to fluid being pulled back into the motor, ultimately causing the motor to burn out. Clinical engineers offered innovative ideas about preventative maintenance training workshops on suction machine use for clinical staff, in an effort to increase clinical staff comfort and effectiveness when using suction machines. Interestingly, clinical engineers at Queen Elizabeth Central Hospital noted that clinical staff all but refuse to use mechanical suction machines, even though the electrical ones are consistently broken. This insight emphasizes the importance of community-level work and community-specific needs.

Additionally, the insights provided by Queen Elizabeth Central Hospital pose a critical question to be researched in the future: how is acceptability of technology incorporated into the design process? How do we measure acceptability of technology? For instance, the mechanical suction machines mentioned above meet all design requirements set by the World Health Organization for suction machines; however, these machines are not being utilized due to lack of acceptance. Further research must be conducted to more thoroughly understand the implications of acceptability of

technology, which may hinge on factors that are difficult to quantify for design requirements, such as aesthetics.

Chapter 7: Conclusions and Future Work

Several insights from this work highlight complexities regarding medical device design, use, and maintenance in low resource settings. While this work considers technical specifications for product design and development, it does not consider the larger *system* in which medical devices are used in low resource settings. For instance, incorporating communities into the design process may result in designs that are more sustainable regarding local resources; however, the design process for a product also needs to incorporate day-to-day practices of clinical staff. Notably, education plays a critical role in successful technology use and implementation in resource-limited settings. It is not merely a matter of designing appropriate technology, but rather ensuring that educational efforts are appropriately designed for new *and* existing technologies. Engineering efforts must be focused on systems, not just products.

7.1 Future Design Improvements for Prototype Suction Machine

Several key areas may be improved upon for the existing mechanical suction machine prototype. First, the development of a robust, one-way mechanical valve would significantly improve the functionality of the device. Though the proposed simple rubber flapper valves are effective at cycling air through the cylinder, the valves are not efficient. Due to the inefficiency of air leaking at the valves, suction is not able to be sustained for long durations of time. Additionally, an improved valve design would likely decrease the minimum pressure achieved by the device, allowing the size (volume) of the cylinder to be reduced. Reducing the size of the device is necessary before the device could be implemented, since space is at a premium in wards in low resource settings. The

development of a robust one-way valve, capable of being manufactured and maintained with local resources, would have many medical device applications, including suction machines, CPAP machines, and positive pressure ventilation. Such a valve could also be useful in the water and sanitation arena for applications such as pit latrine desludging and well pumping/drilling.

Secondly, the lever and framing system (user-interface) could be improved. For this prototype, aluminum was used; however, it is imperative to consider constructing the frame/lever system from a resource that is locally available in Malawi. Replacing the framing system with a locally available resource would significantly decrease the cost of the system, making the system more feasible for clinical settings.

7.2 Long-term Sustainability of Design through Community-led Innovation Hubs

One example of successful community-based, community-led design is a passive infant warmer being developed by a team at Virginia Tech. A senior design team worked with faculty and graduate advisors to develop a passive infant warmer to prevent infants from becoming hypothermic in hospitals without electricity. The original pod, shown in Figure [x], was created from PVC pipe, with densely-packed chicken feathers to insulate the pod and prevent heat transfer from the infant. The pod was also lined with vinyl, which can be purchased in Blantyre, to allow the interior of the pod to be cleaned in the event of the infant soiling, etc.

In partnership with the nonprofit group Global Health Educators, based in Roanoke, VA, feedback was obtained in Uganda on the first iteration prototype. In Uganda, mothers

mentioned that the pod looked too “sterile”; they suggested that the pod would be more acceptable if it was wrapped in a bright, colorful, local fabric.

Figure 48. First iteration prototype of passive infant warmer.

After modifying the prototype based on these suggestions, the device was demonstrated in several hospitals in Malawi to obtain qualitative feedback on its functionality. Though the device met an articulated need at several hospitals in Malawi, clinicians warned that the pod closely resembled a coffin. In Malawi, it is the custom to wrap infants in chitenjis, or local fabric; therefore, the addition of the fabric to the pod was completely inappropriate in Malawi.

After this critical insight, an innovation hub was created to re-design the infant warmer in Malawi. Local Malawian entrepreneurs, mothers, and masons were consulted in focus groups to brainstorm design concepts for the passive infant warmer. Remarkably, the innovation hub, led completely by communities in southern Malawi, resulted in the development of a baby pod *basket*, shown in Figure 49. This solution was entirely community-driven, arguably offering a greater probability of long-term sustainability of the design.

Figure 49. Community-led design for passive infant warmer using locally woven baskets.

This case study emphasizes the importance of innovating and iterating through design process *in* the communities where projects will be deployed. Developing devices remotely may be problematic on many levels, including a lack of understanding of cultural norms, cultural values, and even physical assets and resources. Long-term, fostering innovation hubs in low resource settings may lead to sustainable, community-led innovations as well as long-term economic development.

7.3 Increasing Working Knowledge of Medical Device Maintenance

For existing technologies, significant improvements in appropriate use of devices and longevity of device life cycles may benefit greatly from educational efforts. This should be a top priority for future global health work. Designing new and improved devices is alluring, but such efforts require huge investments of time and financial resources. While appropriately designed technologies may improve health outcomes in the long-term, increasing working knowledge of equipment currently on the market through education of technical and clinical staff may be a more productive use of resources in the short-term future.

This research aimed to enlighten understanding of challenges associated with healthcare technology in LMIC. A community-based participatory study was conducted at three clinical settings in southern Malawi. Thirty-six clinical staff participated in surveys and focus groups to provide information on medical device challenges. Results from the study emphasize the importance of community-based participatory innovation to improve global health. Many clinical staff expressed frustration regarding inability to prevent patient mortality attributed to equipment failure. Over 56% of clinical staff reported average time to repair medical equipment as longer than six months. Reported barriers to repairing medical equipment included shortage of maintenance personnel (77.8%), lack of replacement parts (64.7%), lack of proper tools (61.1%), and lack of user's manuals (53%).

Further, this research aimed to provide a starting-point methodology for assessing community-specific design criteria. Data from the community-based participatory study of medical technology conducted in Malawi revealed key insights for designing for low and middle income countries, and more specifically, for communities in southern Malawi.

Specifically, partner communities identified mechanical suction machines as a top priority for design innovation. Working with technical and clinical staff in Malawian communities, prototype mechanical suction machine was designed and constructed. After the concept generation and prototyping stage, feedback on the prototype was obtained from key partners in Malawi.

This work suggests that engineers working in low and middle income countries face a unique sundry of design requirements. In addition to traditional design considerations, such as physical target metrics and cost constraints, engineering projects in low and middle income countries require an intimate understanding of the local community, including community leaders, community beliefs and values, and locally available resources. This work demonstrates that technology innovation for global health must incorporate community expertise and assets. Additionally, it is imperative that design is coupled with health and technical education efforts to increase working knowledge of medical devices.

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Appendix A: Medical Device Needs Assessment

Medical Device Needs Assessment

1. Which of the following best describes your occupation?

- ☐ Medical doctor
- ☐ Nurse/nurse practitioner
- ☐ Other health professional (laboratory scientist, health technical officer, etc.)
- ☐ Organization manager/director
- ☐ Technical professional (engineer, maintenance personnel, designer, etc.)
- ☐ Government/agency official
- ☐ Researcher
- ☐ Teaching professional
- ☐ Other (please specify)

2. In which setting do you work?

- ☐ Urban
- ☐ Rural
- ☐ Transient (slum or refugee camp)

3. Please list the top 5 challenges to providing medical care in your clinical setting:

1.

2.

3.

4.

5.

4. For each of the devices listed below, please check all that apply.

	Hospital has access to device.	Device is working properly.	Device is used frequently.	Comments on device limitations:
Aspirator (suction unit, suction pump)	☐	☐	☐	
Bilirubinometer (jaundice meter)	☐	☐	☐	

	Hospital has access to device.	Device is working properly.	Device is used frequently.	Comments on device limitations:
Blood pressure monitor (vital signs monitoring unit, sphygmomanometer)	☐	☐	☐	
Clinical chemistry analyzer (biochemistry analyzer)	☐	☐	☐	
CPAP machine	☐	☐	☐	
Cryosurgical unit	☐	☐	☐	
Electrocardiograph, ECG	☐	☐	☐	
Electrosurgical unit	☐	☐	☐	
Fetal Heart Detector, Ultrasonic (fetal Doppler)	☐	☐	☐	
Fetal monitor (fetal ECG monitor)	☐	☐	☐	
Glucose analyzer (glucose meter)	☐	☐	☐	
Immunoassay analyzer	☐	☐	☐	
Incubator, infant (infant warmer, neonatal care station)	☐	☐	☐	
Monitoring system, physiologic (vital signs monitor)	☐	☐	☐	
Radiographic, Fluoroscopic System	☐	☐	☐	
Scanning system, ultrasonic (ultrasound, Doppler device)	☐	☐	☐	
Ventilator, intensive care	☐	☐	☐	
Ventilator, intensive care, Neonatal/Pediatric	☐	☐	☐	
Warming Unit, Radiant, Infant	☐	☐	☐	
Whole Blood Coagulation Analyzer (thrombometer)	☐	☐	☐	

5. List the medical devices in your hospital that are in frequent need of repair.

1.

2.

3.

6. On average, how long does it take to repair a medical device at your hospital?

- ○ 1 day
- ○ 1 week
- ○ 2-4 weeks
- ○ >1 month
- ○ >6 months
- ○ >1 year
- ○ Other (please specify)

7. Which of the following are challenges to repairing medical equipment? Check all that apply.

- ☐ Lack of user's manual
- ☐ Shortage of maintenance personnel
- ☐ Lack of proper tools
- ☐ Lack of replacement parts
- ☐ Other (please describe)

8. Which of the following materials are locally available? Check all that apply.

- ☐ Lumber
- ☐ Polyvinyl chloride (PVC)
- ☐ Metals (aluminum, steel, etc.)
- ☐ Concrete
- ☐ Electronic components
- ☐ Other (please describe)

9. When trying to repair medical devices, are parts difficult to obtain locally?

- ○ Yes
- ○ No
- ○ I don't know

10. How often does your hospital have continuous access to electricity?

- ○ 0 days per week
- ○ 1-2 day per week
- ○ 3-4 days per week
- ○ 5-6 days per week
- ○ Every day
- ○ Other (please describe)

11. Does your hospital have access to a backup generator that is functioning properly?

- ○ Yes
- ○ No
- ○ I don't know

12. Which of the following problems does your hospital experience? Check all that apply.

- ☐ None
- ☐ Daily power outages
- ☐ Power outages 2 or more times per week
- ☐ Power surges

13. How often does your hospital have continuous access to a safe water supply?

- ○ 0 days per week
- ○ 1-2 day per week
- ○ 3-4 days per week
- ○ 5-6 days per week
- ○ Every day
- ○ Other (please describe)

14. Is the water supply distributed to the entire hospital?

- ○ Yes
- ○ No
- ○ I don't know

15. Which of the following problems does the hospital experience with the water supply? Check all that apply.

- ☐ No problem
- ☐ Water is contaminated
- ☐ Access to water is unreliable

16. Is there any other information you would like to share about challenges that your hospital faces?

Appendix B: IRB Research Protocol

VirginiaTech

Institutional Review Board
Research Protocol

Once complete, upload this form as a Word document to the IRB Protocol Management System: https://secure.research.vt.edu/irb

Section 1: General Information

1.1 DO ANY OF THE INVESTIGATORS OF THIS PROJECT HAVE A REPORTABLE CONFLICT OF INTEREST? (http://www.irb.vt.edu/pages/researchers.htm#conflict)

☒ **No**
☐ **Yes,** explain:

1.2 IS THIS RESEARCH SPONSORED OR SEEKING SPONSORED FUNDS?

☒ **No,** go to question 2.1
☐ **Yes,** answer questions within table

IF YES
Provide the name of the sponsor [if NIH, specify department]:
Is this project receiving or seeking federal funds? ☐ No ☐ Yes **If yes,** **Does the grant application, OSP proposal, or "statement of work" related to this project include activities involving human subjects that are <u>not</u> covered within this IRB application?** ☐ No, all human subject activities are covered in this IRB application ☐ Yes, however these activities will be covered in future VT IRB applications, these activities include: ☐ Yes, however these activities have been covered in past VT IRB applications, the IRB number(s) are as follows: ☐ Yes, however these activities have been or will be reviewed by another institution's IRB, the name of this institution is as follows: ☐ Other, explain: **Is Virginia Tech the primary awardee or the coordinating center of this grant?** ☐ No, provide the name of the primary institution: ☐ Yes

Section 2: Justification

2.1 DESCRIBE THE BACKGROUND, PURPOSE, AND ANTICIPATED FINDINGS OF THIS STUDY:

The purpose of this study is to assess medical devices in low-resource clinical environments. Specifically, this research aims to understand what devices are currently available and if devices are able to be fully utilized. This research also aims to understand issues associated with maintenance of medical devices,

including access to the electric grid and locally available replacement parts.

2.2 EXPLAIN WHAT THE RESEARCH TEAM PLANS TO DO WITH THE STUDY RESULTS:
For example - publish or use for dissertation

The aim of this research is to acquire understanding from the expertise of clinical personnel who work in these environments daily. This research will be used to improve design of medical devices for low-resource environments, and may be used for publication purposes.

Section 3: Recruitment

3.1 DESCRIBE THE SUBJECT POOL, INCLUDING INCLUSION AND EXCLUSION CRITERIA AND NUMBER OF SUBJECTS:
Examples of inclusion/exclusion criteria - gender, age, health status, ethnicity

The subject pool includes clinical personnel in Malawi, Africa. 40 participants are anticipated.

3.2 WILL EXISTING RECORDS BE USED TO IDENTIFY AND CONTACT / RECRUIT SUBJECTS?
Examples of existing records - directories, class roster, university records, educational records

☒ **No,** go to question 3.3
☐ **Yes,** answer questions within table →

IF YES
Are these records private or public? ☐ Public ☐ Private, describe the researcher's privilege to the records:
Will student, faculty, and/or staff records or contact information be requested from the University? ☐ No ☐ Yes, provide a description under Section 14 (Research Involving Existing Data) below.

3.3 DESCRIBE RECRUITMENT METHODS, INCLUDING HOW THE STUDY WILL BE ADVERTISED OR INTRODUCED TO SUBJECTS:

Recruitment for this research will be conducted in-person in the cities of Blantyre, Mulanje, Domasi, and Zomba in Malawi, Africa. The location of the research will be at clinical settings in the community, and recruitment will occur at a time that is convenient for the subject so as not to cause anxiety or stress

3.4 PROVIDE AN EXPLANATION FOR CHOOSING THIS POPULATION:
Note: the IRB must ensure that the risks and benefits of participating in a study are distributed equitably among the general population and that a specific population is not targeted because of ease of recruitment.

Clinical personnel who work in low-resource environments have critical insights to improving the design of medical devices.

Section 4: Consent Process

For more information about consent process and consent forms visit the following link: http://www.irb.vt.edu/pages/consent.htm

If feasible, researchers are advised and may be required to obtain signed consent from each participant unless obtaining signatures leads to an increase of risk (e.g., the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting in a breach of confidentiality). Signed consent is typically not required for low risk questionnaires (consent is implied) unless audio/video recording or an in-person interview is involved. If researchers will not be obtaining signed consent, participants must, in most cases, be supplied with consent information in a different format (e.g., in recruitment document, at the beginning of survey instrument, read to participant over the phone, information sheet physically or verbally provided to participant).

4.1 CHECK ALL OF THE FOLLOWING THAT APPLY TO THIS STUDY'S CONSENT PROCESS:

- ☐ Verbal consent will be obtained from participants
- ☐ Signed consent will be obtained from participants
- ☒ Consent will be implied from the return of completed questionnaire. Note: The IRB recommends providing consent information in a recruitment document or at the beginning of the questionnaire (if the study only involves implied consent, skip to Section 5 below)
- ☐ Other, describe:

4.2 PROVIDE A GENERAL DESCRIPTION OF THE PROCESS THE RESEARCH TEAM WILL USE TO OBTAIN AND MAINTAIN INFORMED CONSENT:

4.3 WHO, FROM THE RESEARCH TEAM, WILL BE OVERSEEING THE PROCESS AND OBTAINING CONSENT FROM SUBJECTS?

4.4 WHERE WILL THE CONSENT PROCESS TAKE PLACE?

4.5 DURING WHAT POINT IN THE STUDY PROCESS WILL CONSENTING OCCUR?

Note: unless waived by the IRB, participants must be consented before completing any study procedure, including screening questionnaires.

4.6 IF APPLICABLE, DESCRIBE HOW THE RESEARCHERS WILL GIVE SUBJECTS AMPLE TIME TO REVIEW THE CONSENT DOCUMENT BEFORE SIGNING:

Note: typically applicable for complex studies, studies involving more than one session, or studies involving more of a risk to subjects.

☒ Not applicable

Section 5: Procedures

5.1 PROVIDE A STEP-BY-STEP THOROUGH EXPLANATION OF ALL STUDY PROCEDURES EXPECTED FROM STUDY PARTICIPANTS, INCLUDING TIME COMMITMENT & LOCATION:

This study involves administering a brief survey on the functionality of medical devices. Should you agree to participate, you will be asked to review the medical device and provide comments and feedback using the survey. Please note that this research does not involve the use of a medical device on yourself or another person. The survey will only be completed once, and there is no time limit for taking the survey. On average, this survey takes approximately fifteen minutes to complete. The survey may be completed wherever is

most convenient for you.

5.2 DESCRIBE HOW DATA WILL BE COLLECTED AND RECORDED:

Data will be collected and recorded using paper copies of surveys, since access to the electric grid may prohibit electronic data entry in research locations

5.3 DOES THE PROJECT INVOLVE ONLINE RESEARCH ACTIVITES (INCLUDES ENROLLMENT, RECRUITMENT, SURVEYS)?

View the "Policy for Online Research Data Collection Activities Involving Human Subjects" at http://www.irb.vt.edu/documents/onlinepolicy.pdf

☒ **No,** go to question 6.1
☐ **Yes,** answer questions within table →

IF YES
Identify the service / program that will be used: ☐ www.survey.vt.edu, go to question 6.1 ☐ SONA, go to question 6.1 ☐ Qualtrics, go to question 6.1 ☐ Center for Survey Research, go to question 6.1 ☐ Other **IF OTHER:** Name of service / program: URL: This service is… ☐ Included on the list found at: http://www.irb.vt.edu/pages/validated.htm ☐ Approved by VT IT Security ☐ An external service with proper SSL or similar encryption (https://) on the login (if applicable) and all other data collection pages. ☐ None of the above (note: only permissible if this is a collaborative project in which VT individuals are only responsible for data analysis, consulting, or recruitment)

Section 6: Risks and Benefits

6.1 WHAT ARE THE POTENTIAL RISKS (E.G., EMOTIONAL, PHYSICAL, SOCIAL, LEGAL, ECONOMIC, OR DIGNITY) TO STUDY PARTICIPANTS?

The survey involves minimal risks and discomfort. There is no physical risk or discomfort associated with the research procedure, and emotional stress of completing the survey will be minimized by removing a time limit from the procedures.

6.2 EXPLAIN THE STUDY'S EFFORTS TO REDUCE POTENTIAL RISKS TO SUBJECTS:

Emotional stress of completing the survey will be minimized by removing a time limit from the procedures

6.3 WHAT ARE THE DIRECT OR INDIRECT ANTICIPATED BENEFITS TO STUDY PARTICIPANTS AND/OR SOCIETY?

There are no individual benefits associated with this study; however, the study includes the larger societal benefit of helping to develop more appropriate medical devices for use in low-resource clinical settings.

Section 7: Full Board Assessment

7.1 DOES THE RESEARCH INVOLVE MICROWAVES/X-RAYS, OR GENERAL ANESTHESIA OR SEDATION?

☒ **No**
☐ **Yes**

7.2 DO RESEARCH ACTIVITIES INVOLVE PRISONERS, PREGNANT WOMEN, FETUSES, HUMAN IN VITRO FERTILIZATION, OR INDIVIDUALS WITH MENTAL DISORDERS?

☒ **No,** go to question 7.3
☐ **Yes,** answer questions within table →

IF YES
This research involves: ☐ Prisoners ☐ Pregnant women ☐ Fetuses ☐ Human in vitro fertilization ☐ Individuals with a mental disorder

7.3 DOES THIS STUDY INVOLVE MORE THAN MINIMAL RISK TO STUDY PARTICIPANTS?

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily activities or during the performance of routine physical or psychological examinations or tests. Examples of research involving greater than minimal risk include collecting data about abuse or illegal activities. Note: if the project qualifies for Exempt review (http://www.irb.vt.edu/pages/categories.htm), it will not need to go to the Full Board.

☒ **No**
☐ **Yes**

IF YOU ANSWERED "YES" TO ***ANY ONE*** OF THE ABOVE QUESTIONS, 7.1, 7.2, OR 7.3, THE BOARD MAY REVIEW THE PROJECT'S APPLICATION MATERIALS AT ITS MONTHLY MEETING. VIEW THE FOLLOWING LINK FOR DEADLINES AND ADDITIONAL INFORMATION: http://www.irb.vt.edu/pages/deadlines.htm

Section 8: Confidentiality / Anonymity

For more information about confidentiality and anonymity visit the following link: http://www.irb.vt.edu/pages/confidentiality.htm

8.1 WILL PERSONALLY IDENTIFYING STUDY RESULTS OR DATA BE RELEASED TO ANYONE OUTSIDE OF THE RESEARCH TEAM?

For example – to the funding agency or outside data analyst, or participants identified in publications with individual consent

☒ **No**
☐ **Yes,** to whom will identifying data be released?

8.2 WILL THE RESEARCH TEAM COLLECT AND/OR RECORD PARTICIPANT IDENTIFYING INFORMATION (E.G., NAME, CONTACT INFORMATION, VIDEO/AUDIO RECORDINGS)?

Note: if collecting signatures on a consent form, select "Yes."

☒ **No,** go to question 8.3
☐ **Yes,** answer questions within table →

IF YES
Describe if/how the study will utilize study codes:
If applicable, where will the key [i.e., linked code and identifying information document (for instance, John Doe = study ID 001)] **be stored and who will have access?** *Note: the key should be stored separately from subjects' completed data documents and accessibility should be limited.*
The IRB strongly suggests and may require that all data documents (e.g., questionnaire responses, interview responses, etc.) do not include or request identifying information (e.g., name, contact information, etc.) from participants. If you need to link subjects' identifying information to subjects' data documents, use a study ID/code on all data documents.

8.3 HOW WILL DATA BE STORED TO ENSURE SECURITY (E.G., PASSWORD PROTECTED COMPUTERS, ENCRYPTION) AND LIMITED ACCESS?

Examples of data - questionnaire, interview responses, downloaded online survey data, observation recordings, biological samples

Once able, data will be entered electronically into a password protected computer. Paper copies of the surveys will then be destroyed.

8.4 WHO WILL HAVE ACCESS TO STUDY DATA?

Research team

8.5 DESCRIBE THE PLANS FOR RETAINING OR DESTROYING STUDY DATA:

Paper copies of the surveys will be shredded and destroyed

8.6 DOES THIS STUDY REQUEST INFORMATION FROM PARTICIPANTS REGARDING ILLEGAL BEHAVIOR?

☒ **No,** go to question 9.1
☐ **Yes,** answer questions within table

IF YES
Does the study plan to obtain a Certificate of Confidentiality? ☐ No ☐ Yes (Note: participants must be fully informed of the conditions of the Certificate of Confidentiality within the consent process and form) *For more information about Certificates of Confidentiality, visit the following link:* *http://www.irb.vt.edu/pages/coc.htm*

Section 9: Compensation

For more information about compensating subjects, visit the following link: http://www.irb.vt.edu/pages/compensation.htm

9.1 WILL SUBJECTS BE COMPENSATED FOR THEIR PARTICIPATION?

☒ **No,** go to question 10.1

☐ **Yes,** answer questions within table →

IF YES
What is the amount of compensation?
Will compensation be prorated? ☐ Yes, please describe: ☐ No, explain why and clarify whether subjects will receive full compensation if they withdraw from the study? *Unless justified by the researcher, compensation should be prorated based on duration of study participation. Payment must <u>not</u> be contingent upon completion of study procedures. In other words, even if the subject decides to withdraw from the study, he/she should be compensated, at least partially, based on what study procedures he/she has completed.*

Section 10: Audio / Video Recording

For more information about audio/video recording participants, visit the following link: http://www.irb.vt.edu/pages/recordings.htm

☒ **No,** go to question 11.1
☐ **Yes,** answer questions within table →

IF YES
This project involves: ☐ Audio recordings only ☐ Video recordings only ☐ Both video and audio recordings
Provide compelling justification for the use of audio/video recording:
How will data within the recordings be retrieved / transcribed?
How and where will recordings (e.g., tapes, digital data, data backups) be stored to ensure security?
Who will have access to the recordings?
Who will transcribe the recordings?
When will the recordings be erased / destroyed?

Section 11: Research Involving Students

11.1 DOES THIS PROJECT INCLUDE STUDENTS AS PARTICIPANTS?

☒ **No,** go to question 12.1
☐ **Yes,** answer questions within table →

IF YES
Does this study involve conducting research with students of the researcher? ☐ No ☐ Yes, describe safeguards the study will implement to protect against coercion or undue influence for participation: *Note: if it is feasible to use students from a class of students not under the instruction of the researcher, the IRB recommends and may require doing so.*
Will the study need to access student records (e.g., SAT, GPA, or GRE scores)? ☐ No ☐ Yes

11.2 DOES THIS PROJECT INCLUDE ELEMENTARY, JUNIOR, OR HIGH SCHOOL STUDENTS?

☒ **No,** go to question 11.3
☐ **Yes,** answer questions within table →

IF YES
Will study procedures be completed during school hours? ☐ No ☐ Yes **If yes,** **Students not included in the study may view other students' involvement with the research during school time as unfair. Address this issue and how the study will reduce this outcome:** **Missing out on regular class time or seeing other students participate may influence a student's decision to participate. Address how the study will reduce this outcome:**
Is the school's approval letter(s) attached to this submission? ☐ Yes ☐ No, project involves Montgomery County Public Schools (MCPS) ☐ No, explain why: *You will need to obtain school approval (if involving MCPS, click here: http://www.irb.vt.edu/pages/mcps.htm). Approval is typically granted by the superintendent, principal, and classroom teacher (in that order). Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should accompany the approval request to the IRB.*

11.3 DOES THIS PROJECT INCLUDE COLLEGE STUDENTS?

☒ **No,** go to question 12.1
☐ **Yes,** answer questions within table →

IF YES
Some college students might be minors. Indicate whether these minors will be included in the research or actively excluded: ☐ Included ☐ Actively excluded, describe how the study will ensure that minors will not be included:

Will extra credit be offered to subjects?

☐ No
☐ Yes

If yes,

What will be offered to subjects as an equal alternative to receiving extra credit without participating in this study?

Include a description of the extra credit (e.g., amount) to be provided within question 9.1 ("IF YES" table)

Section 12: Research Involving Minors

12.1 DOES THIS PROJECT INVOLVE MINORS (UNDER THE AGE OF 18 IN VIRGINIA)?

Note: age constituting a minor may differ in other States.

☒ **No,** go to question 13.1
☐ **Yes,** answer questions within table

IF YES

Does the project reasonably pose a risk of reports of current threats of abuse and/or suicide?

☐ No
☐ Yes, thoroughly explain how the study will react to such reports:

Note: subjects and parents must be fully informed of the fact that researchers must report threats of suicide or suspected/reported abuse to the appropriate authorities within the Confidentiality section of the Consent, Assent, and/or Permission documents.

Are you requesting a waiver of parental permission (i.e., parent uninformed of child's involvement)?

☐ No, **both** parents/guardians will provide their permission, if possible.
☐ No, **only one** parent/guardian will provide permission.
☐ Yes, describe below how your research meets **all** of the following criteria (A-D):

Criteria A - The research involves no more than minimal risk to the subjects:
Criteria B - The waiver will not adversely affect the rights and welfare of the subjects:
Criteria C - The research could not practicably be carried out without the waiver:
Criteria D - (Optional) Parents will be provided with additional pertinent information after participation:

Is it possible that minor research participants will reach the legal age of consent (18 in Virginia) while enrolled in this study?

☐ No
☐ Yes, will the investigators seek and obtain the legally effective informed consent (in place of the minors' previously provided assent and parents' permission) for the now-adult subjects for any ongoing interactions with the subjects, or analysis of subjects' data? If yes, explain how:

For more information about minors reaching legal age during enrollment, visit the following link:
http://www.irb.vt.edu/pages/assent.htm

*The procedure for obtaining assent from minors and permission from the minor's guardian(s) must be described in **Section 4** (Consent Process) of this form.*

Section 13: Research Involving Deception

For more information about involving deception in research and for assistance with developing your debriefing form, visit our website at http://www.irb.vt.edu/pages/deception.htm

13.1 DOES THIS PROJECT INVOLVE DECEPTION?

☒ **No,** go to question 14.1
☐ **Yes,** answer questions within table →

IF YES
Describe the deception:
Why is the use of deception necessary for this project?
Describe the debriefing process:
Provide an explanation of how the study meets all the following criteria (A-D) for an alteration of consent: Criteria A - The research involves no more than minimal risk to the subjects: Criteria B - The alteration will not adversely affect the rights and welfare of the subjects: Criteria C - The research could not practicably be carried out without the alteration: Criteria D - (Optional) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception): *By nature, studies involving deception cannot provide subjects with a complete description of the study during the consent process; therefore, the IRB must allow (by granting an alteration of consent) a consent process which does not include, or which alters, some or all of the elements of informed consent.*
The IRB requests that the researcher use the title "Information Sheet" instead of "Consent Form" on the document used to obtain subjects' signatures to participate in the research. This will adequately reflect the fact that the subject cannot fully consent to the research without the researcher fully disclosing the true intent of the research.

Section 14: Research Involving Existing Data

14.1 WILL THIS PROJECT INVOLVE THE COLLECTION OR STUDY/ANALYSIS OF EXISTING DATA DOCUMENTS, RECORDS, PATHOLOGICAL SPECIMENS, OR DIAGNOSTIC SPECIMENS?

Please note: it is not considered existing data if a researcher transfers to Virginia Tech from another institution and will be conducting data analysis of an on-going study.

☒ **No,** you are finished with the application
☐ **Yes,** answer questions within table →

IF YES
From where does the existing data originate?
Provide a detailed description of the existing data that will be collected or studied/analyzed:
Is the source of the data public? ☐ No, continue with the next question

☐ Yes, you are finished with this application

Will any individual associated with this project (internal or external) have access to or be provided with existing data containing information which would enable the identification of subjects:

- **Directly** (e.g., by name, phone number, address, email address, social security number, student ID number), or
- **Indirectly through study codes** even if the researcher or research team does not have access to the master list linking study codes to identifiable information such as name, student ID number, etc or
- **Indirectly through the use of information that could reasonably be used in combination to identify an individual** (e.g., demographics)

☐ No, collected/analyzed data will be completely de-identified
☐ Yes,

If yes,

Research will not qualify for exempt review; therefore, if feasible, written consent must be obtained from individuals whose data will be collected / analyzed, unless this requirement is waived by the IRB.

Will written/signed or verbal consent be obtained from participants prior to the analysis of collected data? -select one-

This research protocol represents a contract between all research personnel associated with the project, the University, and federal government; therefore, must be followed accordingly and kept current.

Proposed modifications must be approved by the IRB prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects.

Do not begin human subjects activities until you receive an IRB approval letter via email.

It is the Principal Investigator's responsibility to ensure all members of the research team who interact with research subjects, or collect or handle human subjects data have completed human subjects protection training prior to interacting with subjects, or handling or collecting the data.

----------**END**----------

Appendix C: Recruitment Materials

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Informed Consent for Participants

in Research Projects Involving Human Subjects

Title of Project: Assessment of Medical Device Maintenance Issues in Hospitals in Low Resource Environments

Investigator(s):	**Kevin Kochersberger, Ph.D.**	**kbk@vt.edu/540-231-5589**
	Kerry Redican, Ph.D.	**kredican@vt.edu**
	Lissett Bickford, Ph.D.	**bickford@vt.edu**
	Ashley Taylor, BS	**ashleyt1@vt.edu/276-620-6531**

Recruitment Materials

Recruitment for this research will be conducted in-person in the cities of Blantyre, Mulanje, Domasi, and Zomba in Malawi, Africa. The location of the research will be at clinical settings in the community, and recruitment will occur at a time that is convenient for the subject so as not to cause anxiety or stress.

Suggested recruitment script:

"Hello- my name is _____ and I am a researcher with Virginia Tech. We are working to understand medical device issues in low-resource hospitals. We are administering a survey which asks questions about availability and use of medical devices, as well as maintenance of medical devices. Would you be willing to read over the informed consent document and consider participating in our study?"

Appendix D: Consent Form

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Informed Consent for Participants

in Research Projects Involving Human Subjects

Title of Project: Assessment of Medical Device Maintenance Issues in Hospitals in Low Resource Environments

Investigator(s):	**Kevin Kochersberger, Ph.D.**	**kbk@vt.edu/540-231-5589**
	Kerry Redican, Ph.D.	**kredican@vt.edu**
	Lissett Bickford, Ph.D.	**bickford@vt.edu**
	Ashley Taylor, BS	**ashleyt1@vt.edu**

I. Purpose of this Research Project

The purpose of this study is to assess medical devices in low-resource clinical environments. Specifically, this research aims to understand what devices are currently available and if devices are able to be fully utilized. This research also aims to understand issues associated with maintenance of medical devices, including access to the electric grid and locally available replacement parts. The aim of this research is to acquire understanding from the expertise of clinical personnel who work in these environments daily. This research will be used to improve design of medical devices for low-resource environments, and may be used for publication purposes. The subject pool includes clinical personnel in Malawi, Africa.

II. Procedures

This study involves administering a brief survey on medical devices. Should you agree to participate, you will be asked to provide comments and feedback on medical devices at your hospital using the survey. Please note that this research does not include the use of any medical device on yourself or another person. The survey will only be completed once, and there is no time limit for taking the survey. On average, this survey takes approximately fifteen minutes to complete. The survey may be completed wherever is most convenient for you.

III. Risks

The survey involves minimal risks and discomfort. There is no physical risk or discomfort associated with the research procedure, and emotional stress of completing the survey will be minimized by removing a time limit from the procedures.

IV. Benefits

There are no individual benefits associated with this study; however, the study includes the larger societal benefit of helping to develop medical devices that function more appropriately in low-resource environments. No promise or guarantee of benefits has been made to encourage you to participate.

V. Extent of Anonymity and Confidentiality

Anonymity and confidentiality are paramount for this research. No identifying information will be collected, and survey data will be collected anonymously. Only members of the research team will have access to de-identified data. The Virginia Tech (VT) Institutional Review Board (IRB) may view the study's data for auditing purposes. The IRB is responsible for the oversight of the protection of human subjects involved in research.

VI. Compensation

No compensation is to be earned for involvement in this research.

VII. Freedom to Withdraw

It is important for you to know that you are free to withdraw from this study at any time without penalty. You are free not to answer any questions that you choose or respond to what is being asked of you without penalty.

Please note that there may be circumstances under which the investigator may determine that a subject should not continue as a subject.

VIII. Questions or Concerns

Should you have any questions about this study, you may contact one of the research investigators whose contact information is included at the beginning of this document.

Should you have any questions or concerns about the study's conduct or your rights as a research subject, or need to report a research-related injury or event, you may contact the VT IRB Chair, Dr. David M. Moore at moored@vt.edu or (540) 231-4991.

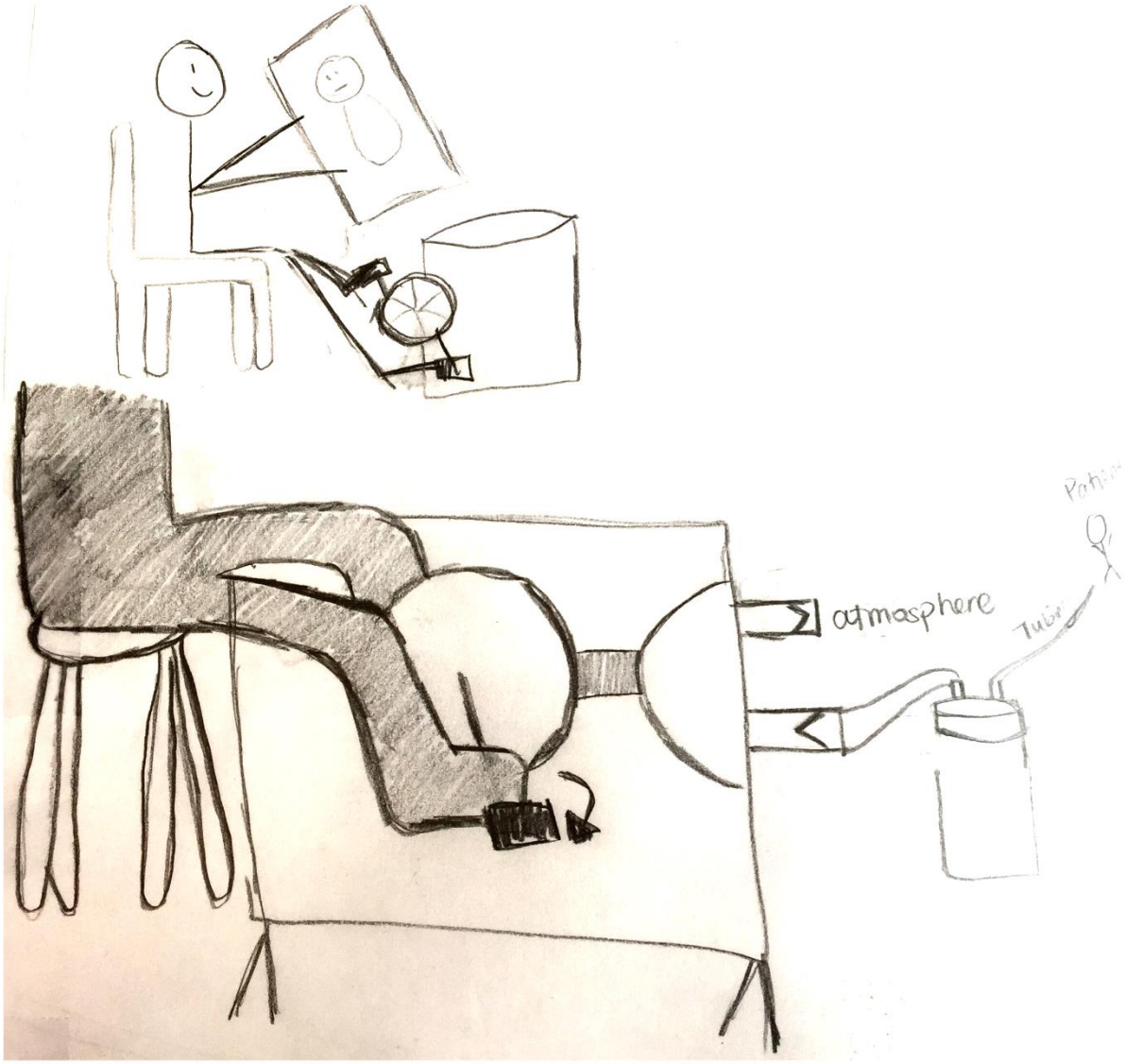
IX. Subject's Consent

I have read the Consent Form and conditions of this project. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent:

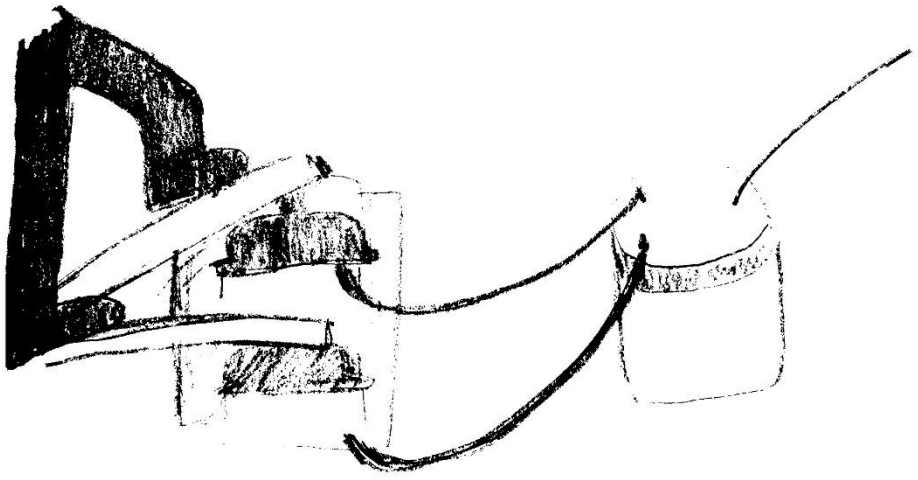
Consent to participate in this study is implied with return of completed questionnaire.

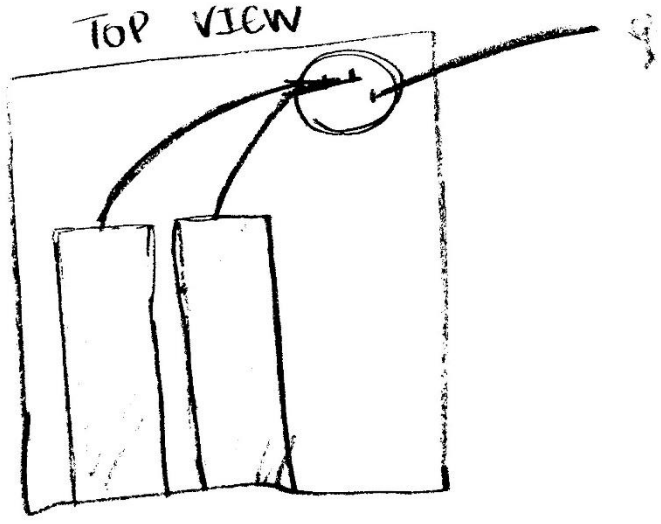
Appendix E: Preliminary Design Concept Sketches

Bicycle-Powered Diaphragm Design Concept

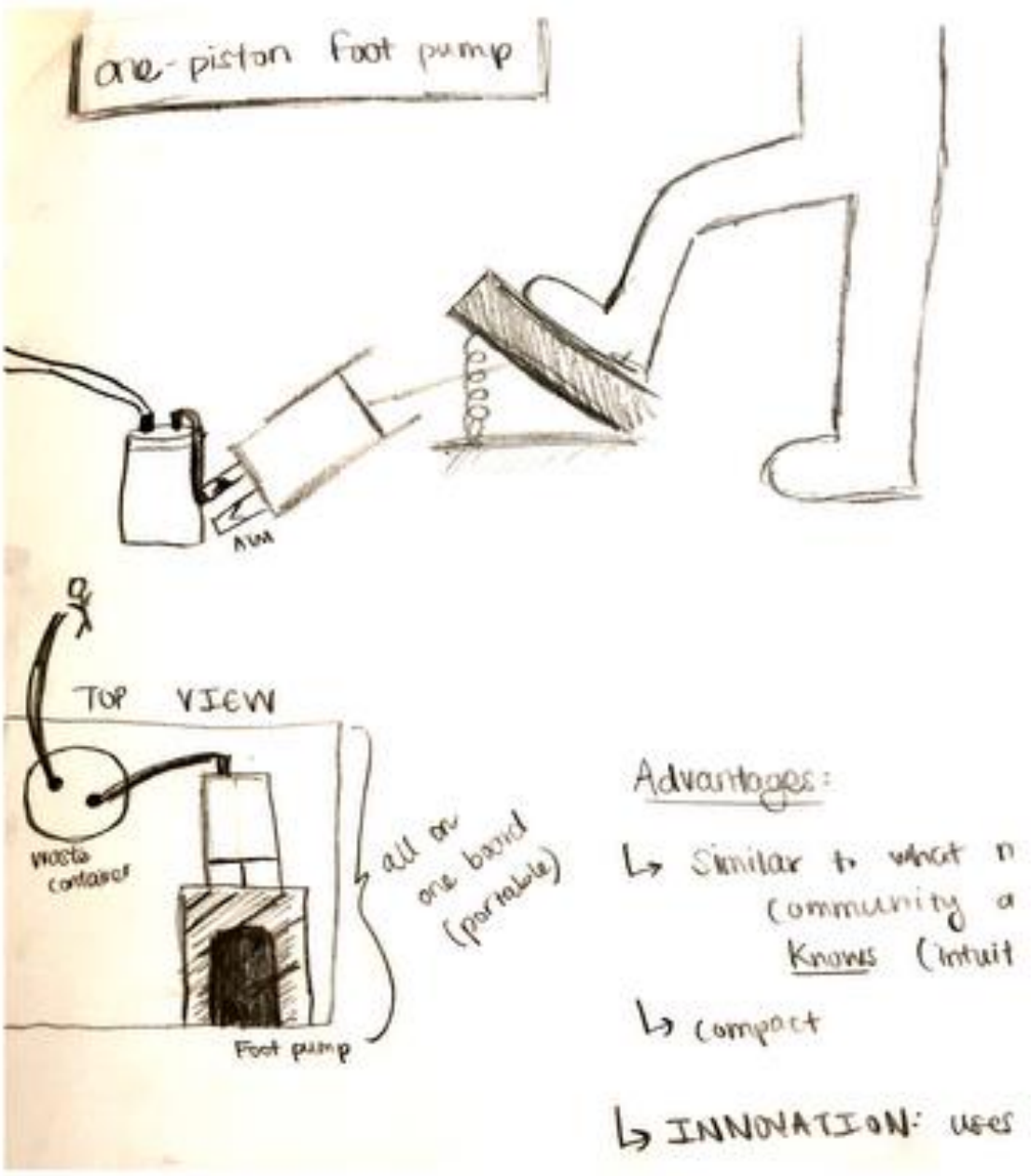


Treadle Diaphragm Initial Concept Sketch

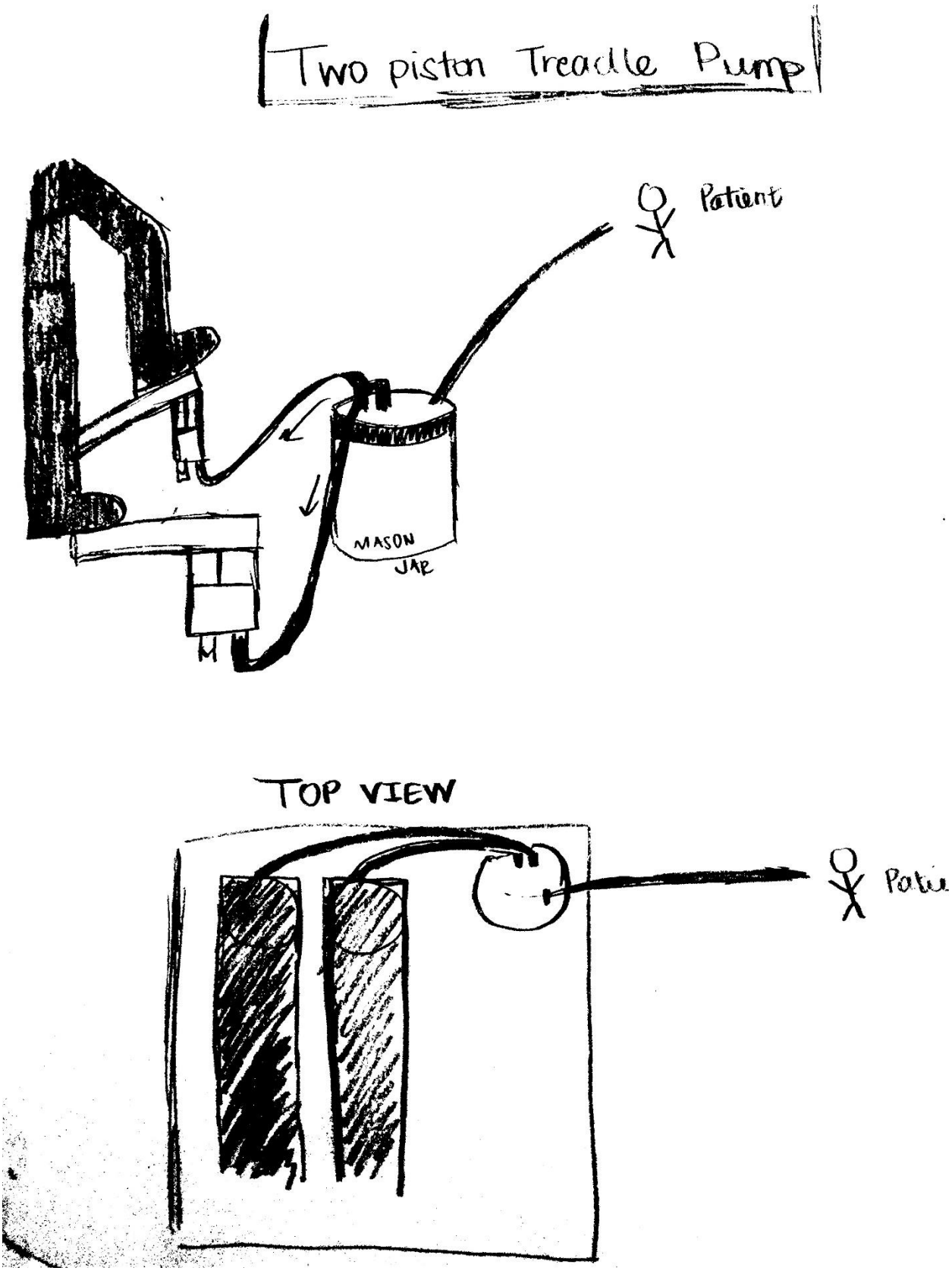




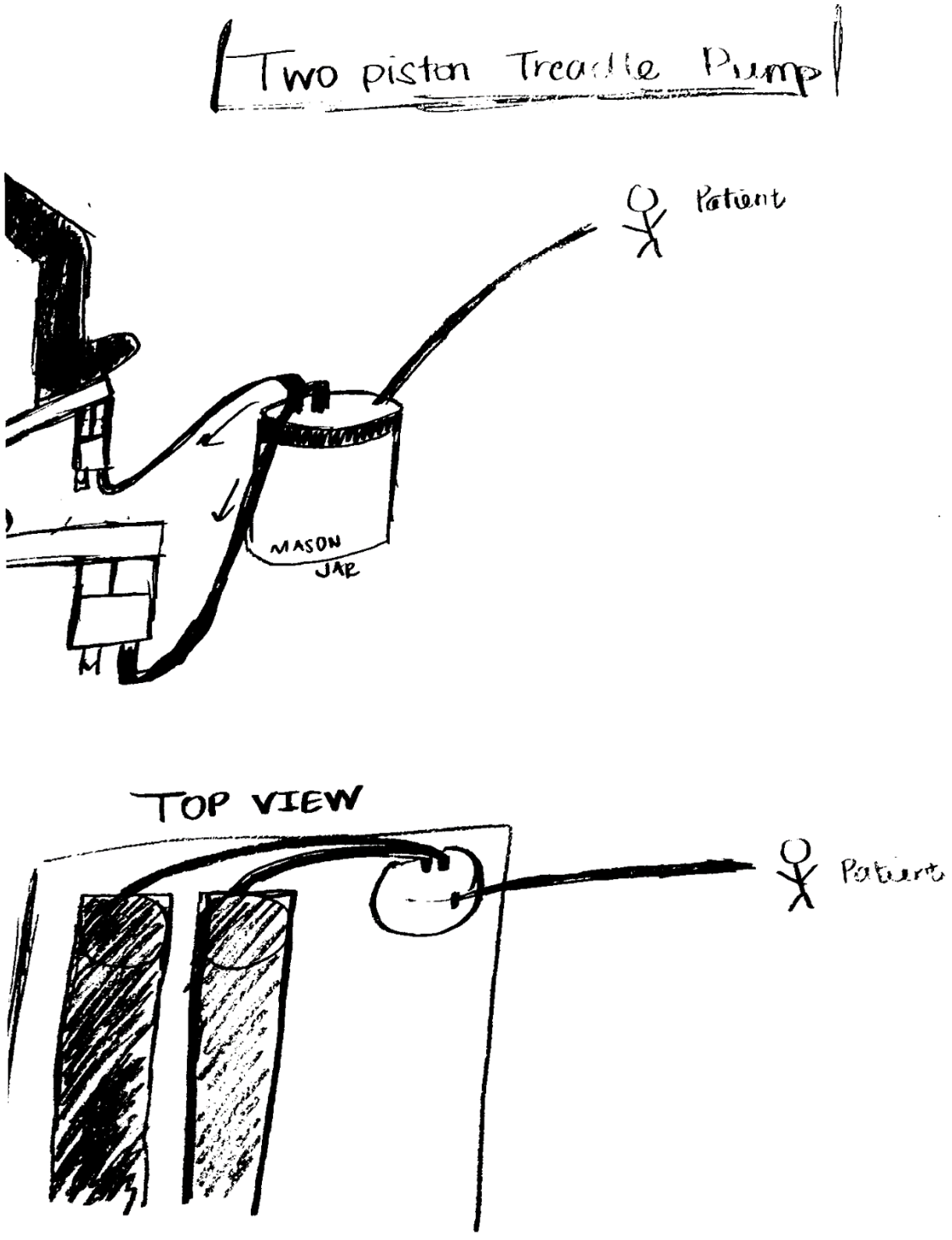
One Piston Foot Pump Initial Design Concept



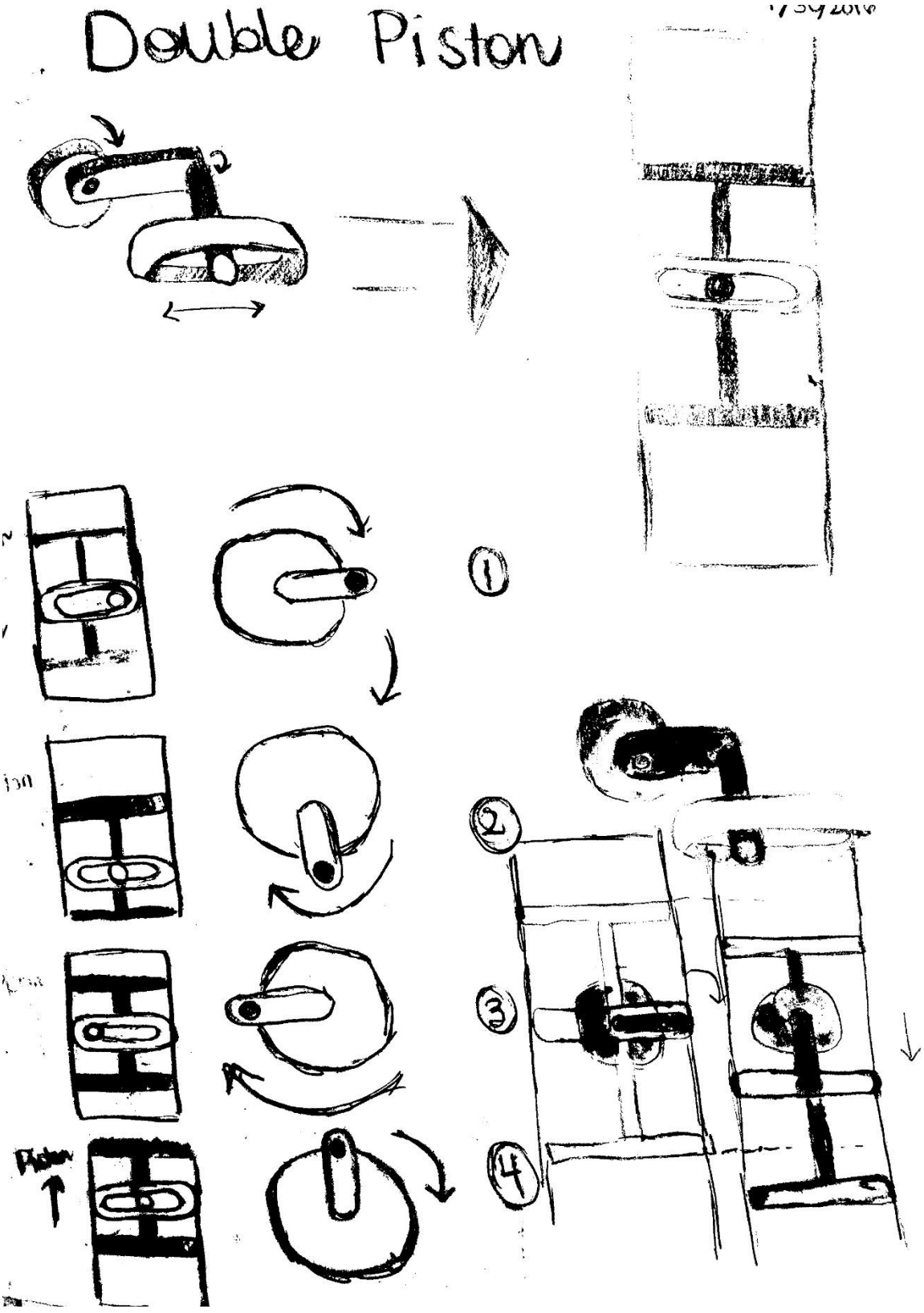
Two Piston Treadle Pump Initial Design Concept



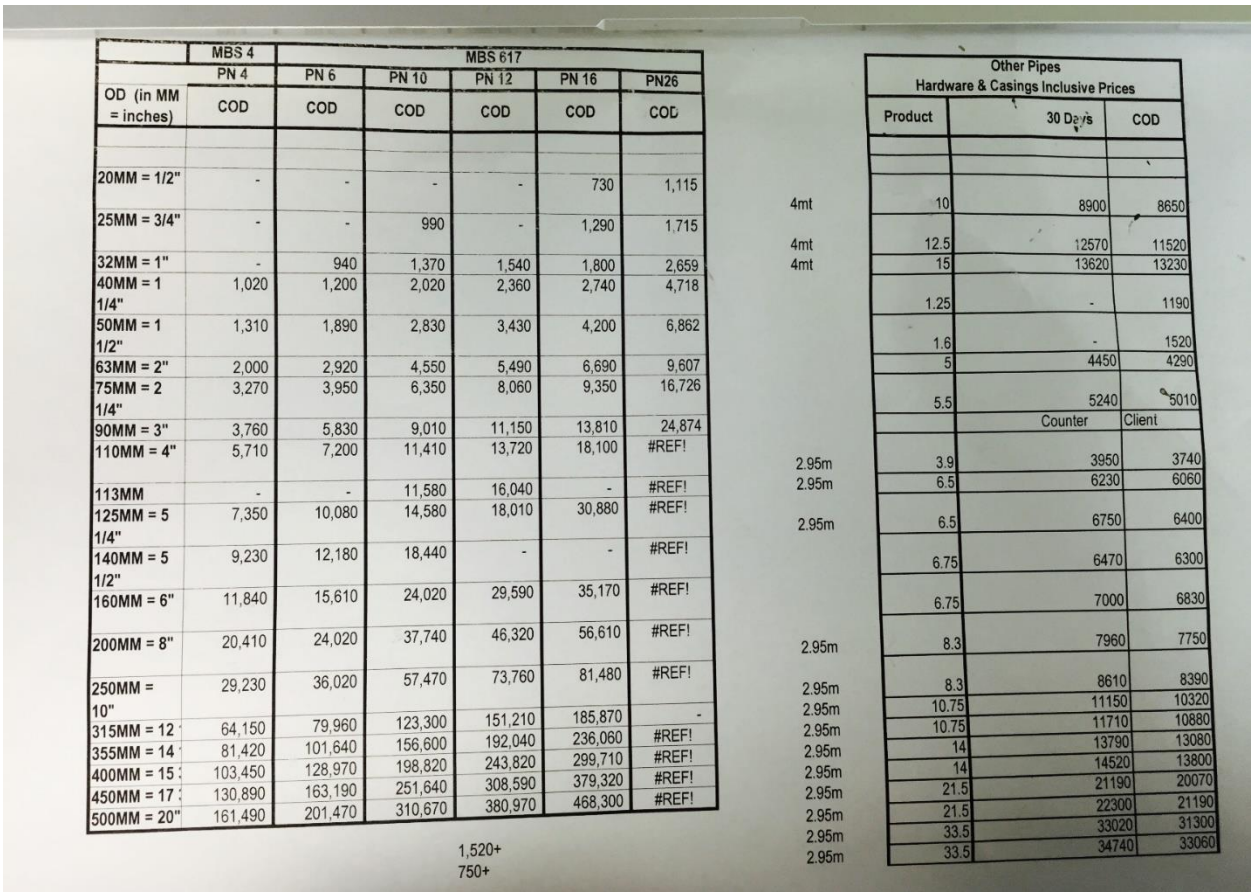
Two Piston Treadle Pump Initial Design Concept



Double-Piston Initial Design Concept



Appendix F: Malawian PVC Distributor Pricing



	MBS 4	MBS 617				
	PN 4	PN 6	PN 10	PN 12	PN 16	PN26
OD (in MM = inches)	COD	COD	COD	COD	COD	COD
20MM = 1/2"	-	-	-	-	730	1,115
25MM = 3/4"	-	-	990	-	1,290	1,715
32MM = 1"	-	940	1,370	1,540	1,800	2,659
40MM = 1 1/4"	1,020	1,200	2,020	2,360	2,740	4,718
50MM = 1 1/2"	1,310	1,890	2,830	3,430	4,200	6,862
63MM = 2"	2,000	2,920	4,550	5,490	6,690	9,607
75MM = 2 1/4"	3,270	3,950	6,350	8,060	9,350	16,726
90MM = 3"	3,760	5,830	9,010	11,150	13,810	24,874
110MM = 4"	5,710	7,200	11,410	13,720	18,100	#REF!
113MM	-	-	11,580	16,040	-	#REF!
125MM = 5 1/4"	7,350	10,080	14,580	18,010	30,880	#REF!
140MM = 5 1/2"	9,230	12,180	18,440	-	-	#REF!
160MM = 6"	11,840	15,610	24,020	29,590	35,170	#REF!
200MM = 8"	20,410	24,020	37,740	46,320	56,610	#REF!
250MM = 10"	29,230	36,020	57,470	73,760	81,480	#REF!
315MM = 12	64,150	79,960	123,300	151,210	185,870	-
355MM = 14	81,420	101,640	156,600	192,040	236,060	#REF!
400MM = 15	103,450	128,970	198,820	243,820	299,710	#REF!
450MM = 17	130,890	163,190	251,640	308,590	379,320	#REF!
500MM = 20"	161,490	201,470	310,670	380,970	468,300	#REF!

1,520+
750+

	Other Pipes Hardware & Casings Inclusive Prices		
	Product	30 Days	COD
4mt	10	8900	8650
4mt	12.5	12570	11520
4mt	15	13620	13230
	1.25	-	1190
	1.6	-	1520
	5	4450	4290
	5.5	5240	5010
		Counter	Client
2.95m	3.9	3950	3740
2.95m	6.5	6230	6060
2.95m	6.5	6750	6400
	6.75	6470	6300
	6.75	7000	6830
2.95m	8.3	7960	7750
2.95m	8.3	8610	8390
2.95m	10.75	11150	10320
2.95m	10.75	11710	10880
2.95m	14	13790	13080
2.95m	14	14520	13800
2.95m	21.5	21190	20070
2.95m	21.5	22300	21190
2.95m	33.5	33020	31300
2.95m	33.5	34740	33060

Pricing of PVC from Polyplast Inc. located in Blantyre, Malawi, July 2015. Note: PN4, PN6, PN10, etc. are "classes" of PVC and refer to the wall thickness of the pipe (see Table, page 7). Prices listed are in Malawian Kwacha (check online for most recent exchange rate, varies from 300-500 MKW per 1 US dollar). Left column is OD in mm. Prices listed are for lengths of 6 meters. Can also buy in lengths of 3 meters.

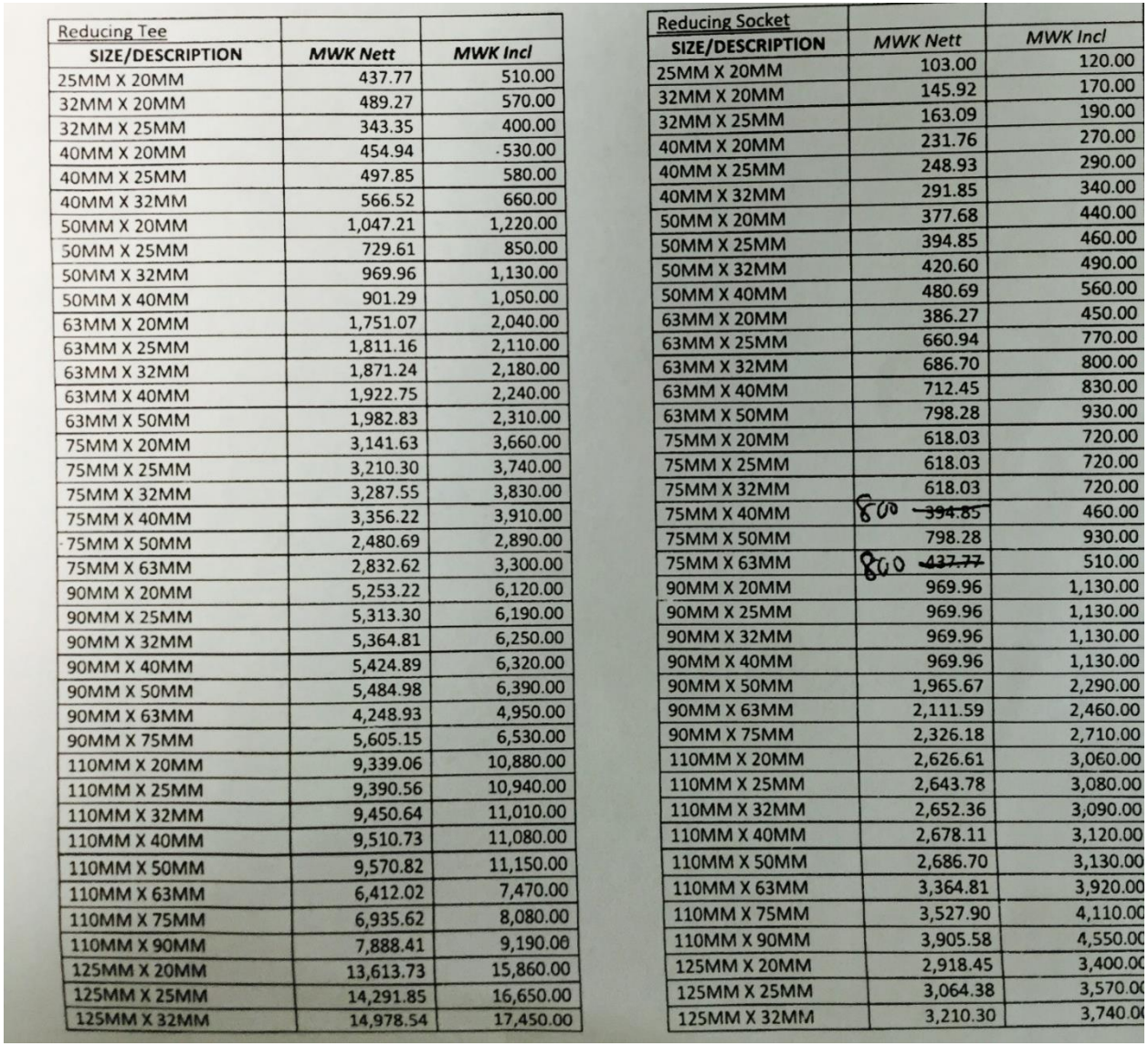
Short Radius Bends		
SIZE/DESCRIPTION	MWK Nett	MWK Incl
20mm	94.42	110.00
25mm	163.09	190.00
32mm	283.26	330.00
40mm	480.69	560.00
50mm	746.78	870.00
63mm	1,364.81	1,590.00
75mm	2,206.01	2,570.00
90mm	3,751.07	4,370.00
110mm	5,347.64	6,230.00
113mm	-	-
125mm	3,888.41	4,530.00
140mm	8,755.36	10,200.00
160mm	18,077.25	21,060.00
200mm	26,257.51	30,590.00
250mm	48,618.03	56,640.00
315mm	108,909.87	126,880.00
355mm	214,909.87	250,370.00
400mm	232,412.02	270,760.00
450mm	-	-
500mm	-	-

Equal Tee		
SIZE/DESCRIPTION	MWK Nett	MWK Incl
20mm	137.34	160.00
25mm	214.59	250.00
32mm	369.10	430.00
40mm	635.19	740.00
50mm	961.37	1,120.00
63mm	1,725.32	2,010.00
75mm	2,901.29	3,380.00
90mm	4,841.20	5,640.00
110mm	8,137.34	9,480.00
113mm	-	-
125mm	9,639.48	11,230.00
140mm	14,240.34	16,590.00
160mm	22,068.67	25,710.00
200mm	34,472.10	40,160.00
250mm	68,686.70	80,020.00
315mm	148,223.18	172,680.00
355mm PN 10	241,502.15	281,350.00
400mm PN 10	252,000.00	293,580.00
450mm PN 10	-	-
500mm PN 10	-	-

MALE Adaptors		
SIZE/DESCRIPTION	MWK Nett	MWK Incl
20mm x 25mm x ½"	103.00	120.00
25mm x 32mm x ¾"	171.67	200.00
32mm x 40mm x 1"	291.85	340.00
40mm x 50mm x 1 1/4"	583.69	680.00
50mm x 63mm x 1 ½"	729.61	850.00
63mm x 75mm x 2"	1,021.46	1,190.00
75mm x 90mm x 2 ½"	1,098.71	1,280.00
90mm x 110mm x 3"	1,313.30	1,530.00
110mm x 125mm x 4"	1,897.00	2,210.00
125mm x 5"	3,888.41	4,530.00
160mm x 5 ½"	5,836.91	6,800.00
200mm x 6"	7,776.82	9,060.00
	11,665.24	13,590.00

1800
2430
4560

FEMALE Adaptors		
SIZE/DESCRIPTION	MWK Nett	MWK Incl
20mm x ½"	137.34	160.00
25mm x ¾"	214.59	250.00
32mm x 1"	343.35	400.00
40mm x 1 1/4"	343.35	400.00
50mm x 63mm x 1 ½"	540.77	630.00
63mm x 75mm x 2"	961.37	1,120.00
75mm x 90mm x 2 ½"	1,304.72	1,520.00
90mm x 110mm x 3"	2,334.76	2,720.00
110mm x 125mm x 4"	3,587.98	4,180.00



Reducing Tee		
SIZE/DESCRIPTION	MWK Nett	MWK Incl
25MM X 20MM	437.77	510.00
32MM X 20MM	489.27	570.00
32MM X 25MM	343.35	400.00
40MM X 20MM	454.94	530.00
40MM X 25MM	497.85	580.00
40MM X 32MM	566.52	660.00
50MM X 20MM	1,047.21	1,220.00
50MM X 25MM	729.61	850.00
50MM X 32MM	969.96	1,130.00
50MM X 40MM	901.29	1,050.00
63MM X 20MM	1,751.07	2,040.00
63MM X 25MM	1,811.16	2,110.00
63MM X 32MM	1,871.24	2,180.00
63MM X 40MM	1,922.75	2,240.00
63MM X 50MM	1,982.83	2,310.00
75MM X 20MM	3,141.63	3,660.00
75MM X 25MM	3,210.30	3,740.00
75MM X 32MM	3,287.55	3,830.00
75MM X 40MM	3,356.22	3,910.00
75MM X 50MM	2,480.69	2,890.00
75MM X 63MM	2,832.62	3,300.00
90MM X 20MM	5,253.22	6,120.00
90MM X 25MM	5,313.30	6,190.00
90MM X 32MM	5,364.81	6,250.00
90MM X 40MM	5,424.89	6,320.00
90MM X 50MM	5,484.98	6,390.00
90MM X 63MM	4,248.93	4,950.00
90MM X 75MM	5,605.15	6,530.00
110MM X 20MM	9,339.06	10,880.00
110MM X 25MM	9,390.56	10,940.00
110MM X 32MM	9,450.64	11,010.00
110MM X 40MM	9,510.73	11,080.00
110MM X 50MM	9,570.82	11,150.00
110MM X 63MM	6,412.02	7,470.00
110MM X 75MM	6,935.62	8,080.00
110MM X 90MM	7,888.41	9,190.00
125MM X 20MM	13,613.73	15,860.00
125MM X 25MM	14,291.85	16,650.00
125MM X 32MM	14,978.54	17,450.00

Reducing Socket		
SIZE/DESCRIPTION	MWK Nett	MWK Incl
25MM X 20MM	103.00	120.00
32MM X 20MM	145.92	170.00
32MM X 25MM	163.09	190.00
40MM X 20MM	231.76	270.00
40MM X 25MM	248.93	290.00
40MM X 32MM	291.85	340.00
50MM X 20MM	377.68	440.00
50MM X 25MM	394.85	460.00
50MM X 32MM	420.60	490.00
50MM X 40MM	480.69	560.00
63MM X 20MM	386.27	450.00
63MM X 25MM	660.94	770.00
63MM X 32MM	686.70	800.00
63MM X 40MM	712.45	830.00
63MM X 50MM	798.28	930.00
75MM X 20MM	618.03	720.00
75MM X 25MM	618.03	720.00
75MM X 32MM	618.03	720.00
75MM X 40MM	800 ~~394.85~~	460.00
75MM X 50MM	798.28	930.00
75MM X 63MM	800 ~~437.77~~	510.00
90MM X 20MM	969.96	1,130.00
90MM X 25MM	969.96	1,130.00
90MM X 32MM	969.96	1,130.00
90MM X 40MM	969.96	1,130.00
90MM X 50MM	1,965.67	2,290.00
90MM X 63MM	2,111.59	2,460.00
90MM X 75MM	2,326.18	2,710.00
110MM X 20MM	2,626.61	3,060.00
110MM X 25MM	2,643.78	3,080.00
110MM X 32MM	2,652.36	3,090.00
110MM X 40MM	2,678.11	3,120.00
110MM X 50MM	2,686.70	3,130.00
110MM X 63MM	3,364.81	3,920.00
110MM X 75MM	3,527.90	4,110.00
110MM X 90MM	3,905.58	4,550.00
125MM X 20MM	2,918.45	3,400.00
125MM X 25MM	3,064.38	3,570.00
125MM X 32MM	3,210.30	3,740.00

EUROAQUA®

PP-R PLUMBING TECHNOLOGY

An ISO 9001:2000 Certified Company

Double Act Plumber

For Operational Life
50 YEARS WARRANTY
For Leak Proof Joints

An Eco friendly Food Grade Plumping System for
Hot and Cold Water Distribution

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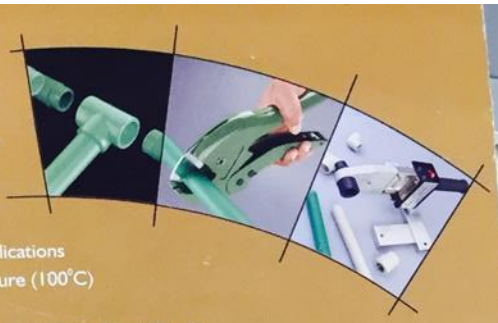
Coupler
Reducer Elbow
End Cap
Female Thread Coupler
Elbow 90°
Male Thread Coupler
Long Elbow
Plastic Union
Female Thread Tee
Reducer Tee
Flange Core
Tee
Male Thread Tee
Cross
Clamp
Reducer
Plug


Female Thread Union
Male Thread Union
Female Thread Elbow
Male Thread Elbow
Plastic Ball Valve
Stop Valve
Double Union Ball Valve
SS Valve
Concealed Valve
Hole Repair Die & Bar
Pipe Cutter
Roller Pipe Cutter
Bye-pass Bend
Welding Device
Welding Device
Bud Weld Machine
Pressure Tester

Features



- Strong, UV Stabilized and Long Lasting
- Hygienic and Non-Toxic
- High Resistance to Acids and Chlorides
- Light Weight and No Maintenance
- Extremely Low Thermal Conductivity
- Easy Installation and Handling
- Insulation is Required for Exterior Applications
- Tolerates High Pressure and Temperature (100°C)
- Negligible Pressure Drop
- Eco-Friendly and Not Harmful to Human Health - Food Grade
- Noice free at High Flow Rates
- Extensive Saving in both Time and Labour during Plumbers
- No Calcification and Sedimentation
- No Rust, No Scaling Down and Resistant to Abrasion - Corrosion
- Widely used in European and Developed Countries
- No Bacterial or Fungal Growth and No Contamination
- Long Life and Competitively Priced
- Approved by Water Quality Institution of 16 Countries across the World

Field of Applications

Potable Water Pipe for Hot & Cold Water Installations
i.e., in Residential Buildings, Hospitals, Hotels, Office and School Buildings

Pipe Networks for Compressed Air Plants

Pipe Networks for Swimming Pool Facilities

Pipe Networks for Solar Plants

Pipe Networks in Agricultural and Horticulture

Pipe Networks for Rainwater Utilization Systems

Ideal in Textile, Sugar and Paper Industries

Ideal for Transportation of Aggressive Fluids like Chemicals, Acids, Lyes etc.

Suitable in Food, Beverage and Dying Industry in place of SS and all Pipes

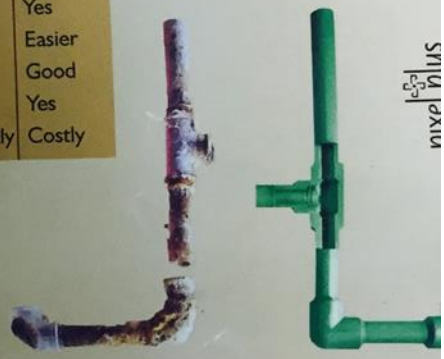
Popular Sizes

OD mm	Wall Thickness mm		
	PN20 kgf/cm²	PN16 kgf/cm²	PN10 kgf/cm²
20	3.4	2.7	1.9
25	4.2	3.5	2.3
32	5.4	4.5	2.9
40	6.7	5.6	3.7
50	8.3	7.0	4.6
63	10.5	8.6	5.8
75	12.5	10.3	6.8
90	15.0	12.2	8.2
110	18.3	14.9	10.0
160	26.6	21.6	14.5

Property and Cost Analysis

Characteristics		CPVC	GI	Copper	S.Steel	PBT Pipe
Light Weight	Yes	Yes	No	No	No	Yes
Rust Proof	Yes	Yes	No	Yes	Yes	Yes
Ease of Joining	Modern Method	Easier	Easier	Easier	Easier	Easier
Thermal Insulation	Good	Poor	Poor	Poor	Poor	Good
Hot Water Application	Yes	Yes	Yes	Yes	Yes	Yes
Cost	Cheap	Costly	Costly	Very Costly	Very Costly	Costly

GI Pipes
After 10 Years



Authorised Distributor / Dealer

POLYPLAST LTD

Water is life, We provide the lifeline

ISO9001:2008
ISO14000

CE AENOR

Healthy green piping system

2013 catalogue

PP-R PIPES

POLYPLAST LTD

PN 16 Suitable for all Cold water applications

CODE	SIZE (mm)
KA201	20x2.8
KA202	25x3.5
KA203	32x4.4
KA204	40x5.5
KA205	50x6.9
KA206	63x8.6

PN 20 Suitable for all Hot water applications

CODE	SIZE (MM)
KA301	20x3.4
KA302	25x4.2
KA303	32x5.4
KA304	40x6.7
KA305	50x8.3
KA306	63x10.5

PP-R FITTINGS

Coupling

CODE	SIZE (mm)
KB001	20
KB002	25
KB003	32
KB004	40
KB005	50
KB006	63

90° Elbow

CODE	SIZE (mm)
KE001	20
KE002	25
KE003	32
KE004	40
KE005	50
KE006	63

Tee

CODE	SIZE (mm)
KC001	20
KC002	25
KC003	32
KC004	40
KC005	50
KC006	63

45° elbow

CODE	SIZE (mm)
KE101	20
KE102	25
KE103	32
KE104	40
KE105	50
KE106	63

Cap

CODE	SIZE (mm)
KD001	20
KD002	25
KD003	32
KD004	40
KD005	50
KD006	63

90° Reducing elbow

CODE	SIZE (mm)
KE601	25x20
KE602	32x20
KE603	32x25
KE604	40x32
KE605	50x40
KE606	50x32
KE607	63x50

Reducing Tee

CODE	SIZE (mm)
KC101	25x20x25
KC102	32x20x32
KC103	32x25x32
KC104	40x20x40
KC105	40x25x40
KC106	40x32x40
KC107	50x20x50
KC108	50x25x50
KC109	50x32x50
KC110	50x40x50
KC111	63x20x63
KC112	63x25x63
KC113	63x32x63
KC114	63x40x63
KC115	63x50x63
KC116	75x20x75
KC117	75x25x75
KC118	75x32x75
KC119	75x40x75
KC120	75x50x75
KC121	75x63x75
KC122	90x32x90
KC123	90x40x90
KC124	90x50x90
KC125	90x63x90
KC126	90x75x90
KC127	110x40x110
KC128	110x50x110
KC129	110x63x110
KC130	110x75x110
KC131	110x90x110
KC132	160x110x160

Reducer

CODE	SIZE (mm)
KB101	25x20
KB102	32x20
KB103	32x25
KB104	40x20
KB105	40x25
KB106	40x32
KB107	50x20
KB108	50x25
KB109	50x32
KB110	50x40
KB111	63x20
KB112	63x25
KB113	63x32
KB114	63x40
KB115	63x50
KB116	75x20
KB117	75x25
KB118	75x32
KB119	75x40
KB120	75x50
KB121	75x63
KB122	90x32
KB123	90x40
KB124	90x50
KB125	90x63
KB126	90x75
KB127	110x40
KB128	110x50
KB129	110x63
KB130	110x75
KB131	110x90
KB132	160x110

Cross

CODE	SIZE (mm)
KF001	20
KF002	25
KF003	32
KF004	40
KF005	50
KF006	63

Plastic union

CODE	SIZE (mm)
KI 001	20
KI 002	25
KI 003	32
KI 004	40
KI 005	50
KI 006	63

Female threaded coupling

CODE	SIZE (mm)
FUB201	20x1/2"
FUB202	20x3/4"
FUB203	25x1/2"
FUB204	25x3/4"
FUB205	32x1/2"
FUB206	32x3/4"

Male threaded coupling

CODE	SIZE (mm)
FUB301	20x1/2"
FUB302	20x3/4"
FUB303	25x1/2"
FUB304	25x3/4"
FUB305	32x1/2"
FUB306	32x3/4"

Female threaded elbow

CODE	SIZE (mm)
FUE201A	20x1/2"
FUE202A	20x3/4"
FUE203A	25x1/2"
FUE204A	25x3/4"
FUE205A	32x1/2"
FUE206A	32x3/4"
FUE207A	32x1"

Female threaded coupling

CODE	SIZE (mm)
FUB207	32x1"
FUB208	40x1¼"
FUB209	50x1½"
FUB210	63x2"
FUB211	75x2½"
FUB212	90x3"
FUB2103	110x4"

Male threaded coupling

CODE	SIZE (mm)
FUB307	32x1"
FUB308	40x1¼"
FUB309	50x1½"
FUB310	63x2"
FUB311	75x2½"
FUB312	90x3"
FUB313	110x4"

Male threaded elbow

CODE	SIZE (mm)
FUE401	20x1/2"
FUE402	20x3/4"
FUE403	25x1/2"
FUE404	25x3/4"
FUE405	32x1/2"
FUE406	32x3/4"
FUE407	32x1"

Female threaded tee

CODE	SIZE (mm)
FUC201	20x1/2"
FUC202	20x3/4"
FUC203	25x1/2"
FUC204	25x3/4"
FUC205	32x1/2"
FUC206	32x3/4"
FUC207	32x1"

Male threaded tee

CODE	SIZE (mm)
FUC301	20x1/2"
FUC302	20x3/4"
FUC303	25x1/2"
FUC304	25x3/4"
FUC305	32x1/2"
FUC306	32x3/4"
FUC307	32x1"

Female threaded elbow w/disk

CODE	SIZE (mm)
FUE301	20x1/2"
FUE302	25x1/2"
FUE303	25x3/4"

Male threaded elbow w/disk

CODE	SIZE (mm)
FUE501	20x1/2"
FUE502	25x1/2"
FUE503	25x3/4"

Type Y filter

CODE	SIZE (mm)
KZ101	20
KZ102	25
KZ103	32

Type Y filter

CODE	SIZE (mm)
KZ001	20
KZ002	25
KZ003	32

★ Product Color: Grey、White、Green、Blue

★ Germany standard:DIN 8077-8078

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POLYPLAST LTD

PP-R FITTINGS

Female saddle

CODE	SIZE (mm)
KB601	63x3/4"
KB602	75x3/4"
KB603	90x3/4"

Threaded union with coupling

CODE	SIZE (mm)
KO001	20x1/2"
KO002	25x1/2"
KO003	25x3/4"

Male threaded union

CODE	SIZE (mm)
KI201	20x1/2"
KI202	25x3/4"
KI203	32x1"
KI204	40x1 1/4"
KI205	50x1 1/2"
KI206	63x2"

Male saddle

CODE	SIZE (mm)
KB701	63x3/4"
KB702	75x3/4"
KB703	90x3/4"

Threaded union with elbow

CODE	SIZE (mm)
KO101	20x1/2"
KO102	25x1/2"
KO103	25x3/4"

Female threaded union

CODE	SIZE (mm)
KI101	20x1/2"
KI102	25x3/4"
KI103	32x1"
KI104	40x1 1/4"
KI105	50x1 1/2"
KI106	63x2"

Flange core

CODE	SIZE (mm)
KK001	40
KK002	50
KK003	63

Coupling M/F

CODE	SIZE (mm)
KB501	25x20
KB502	32x20
KB503	32x25
KB504	40x20
KB505	40x25
KB506	40x32
KB507	50x32
KB508	50x40
KB509	63x32
KB510	63x40
KB511	63x50

Female threaded union

CODE	SIZE (mm)
KI301	20
KI302	25
KI303	32
KI304	40
KI305	50
KI306	63

90° Elbow F/M

CODE	SIZE (mm)
KE901	20x20
KE902	25x25
KE903	32x32

45° elbow F/M

CODE	SIZE (mm)
KE801	20x20
KE802	25x25
KE803	32x32

Tee M/M/F

CODE	SIZE (mm)
KC401	20x20x20
KC402	25x20x25
KC403	25x25x25
KC404	32x20x32
KC405	32x25x32
KC406	32x32x32

Saddle

CODE	SIZE (mm)
KB801	63x32
KB802	75x32
KB803	90x32
KB804	110x32

Plug

CODE	SIZE (mm)
KS001	20
KS002	25

Pipe plug

CODE	SIZE (mm)
KD101	1/2"
KD102	3/4"
KD103	1"
KD104	1 1/4"

Long pipe plug

CODE	SIZE (mm)
KD201	1/2"
KD202	3/4"

Short bypass bend

CODE	SIZE (mm)
KJ101	20
KJ102	25
KJ103	32

Short bypass bend

CODE	SIZE (mm)
KJ201	20
KJ202	25
KJ203	32

Long bypass bend

CODE	SIZE (mm)
KJ001	20
KJ002	25
KJ003	32

Three way elbow

CODE	SIZE (mm)
KC601	20x20x20
KC602	25x25x25
KC603	32x32x32

Pipe clamp

CODE	SIZE (mm)
KG901	20
KG902	25
KG903	32

Low footed pipe clamp

CODE	SIZE (mm)
KG001	20
KG002	25
KG003	32
KG004	40
KG005	50
KG006	63

Metal pipe clamp

CODE	SIZE (mm)
KG301	20
KG302	25
KG303	32
KG304	40
KG305	50
KG306	63

Female Tee W/disk

CODE	SIZE (mm)
KQ001	20*1/2
KQ002	25*1/2

Male Tee W/disk

CODE	SIZE (mm)
KQ101	20*1/2
KQ102	25*1/2

Female elbow W/disk

CODE	SIZE (mm)
KR001	20*1/2
KR002	25*1/2

Male elbow W/disk

CODE	SIZE (mm)
KR101	20*1/2
KR102	25*1/2

Double wall mount

CODE	SIZE (mm)
KY201	20x1/2"
KY202	25x1/2"

Wall mount set

CODE	SIZE (mm)
KY001	20x1/2"
KY002	25x1/2

Wall mount set

CODE	SIZE (mm)
KY301	20x1/2"
KY302	25x1/2"

POLYPLAST LTD

PP-R FITTINGS

Ball valve with brass ball(hot water)

CODE	SIZE (mm)
KHV001	20mm
KHV002	25mm
KHV003	32mm

Ball valve with plastic ball(cold water)

CODE	SIZE (mm)
KH101A	20
KH102A	25
KH103A	32
KH104A	40
KH105A	50
KH106A	63

Ball valve with brass ball(hot water)

CODE	SIZE (mm)
KH701	20
KH702	25
KH703	32
KH704	40
KH705	50
KH706	63

Ball valve with brass ball (hot water)

CODE	SIZE (mm)
KHW201A	20
KHW202A	25

Ball valve with brass ball (hot water)

CODE	SIZE (mm)
KHW301C	20
KHW302C	25

Ball valve with brass ball(hot water)

CODE	SIZE (mm)
KH701A	1/2"x1/2"
KH702A	3/4"x3/4"
KH703A	1"x1"
KH704A	1 1/4"x1 1/4"
KH705A	1 1/2"x1 1/2"
KH706A	2"x2"

Ball valve with brass ball(hot water)

CODE	SIZE (mm)
KH701B	1/2"x1/2"
KH702B	3/4"x3/4"
KH703B	1"x1"
KH704B	1 1/4"x1 1/4"
KH705B	1 1/2"x1 1/2"
KH706B	2"x2"

Ball valve with brass ball(hot water)

CODE	SIZE (mm)
KH801A	20
KH802A	25
KH803A	32

Stop valve

CODE	SIZE (mm)
KHW901A	1/2"x1/2"
KHW902A	3/4"x3/4"

Stop valve

CODE	SIZE (mm)
KH001	20
KH002	25
KH003	32
KH004	40
KH005	50
KH006	63
KH007	75
KH008	90
KH009	110

Stop valve

CODE	SIZE (mm)
KH001A	20
KH002A	25
KH003A	32
KH004A	40
KH005A	50
KH006A	63

Stop valve

CODE	SIZE (mm)
KKW001	20
KKW002	25
KKW003	32

Double union ball cock

CODE	SIZE (mm)
KH201	20
KH202	25
KH203	32
KH204	40
KH205	50
KH206	63

Single union female threaded ball cock

CODE	SIZE (mm)
KH301	20x1/2"
KH302	25x3/4"
KH303	32x1"

Stop valve

CODE	SIZE (mm)
KH401A	20
KH402A	25
KH403A	32

Stop valve

CODE	SIZE (mm)
KH401B	20
KH402B	25
KH403B	32

Concealed valve

CODE	SIZE (mm)
KH501	20
KH502	25
KH503	32

Elbow ball valve

CODE	SIZE (mm)
KHW001	20x1/2"
KHW002	25x1/2"

Coupling ball valve

CODE	SIZE (mm)
KHW101	20x1/2"
KHW102	25x1/2"

PVC PP-R PIPE CUTTER

CODE	SIZE (mm)
KM005	20-32

Water pressure test pump

CODE	SIZE (mm)
KPT003	

PP-R HDPE welding machine

Code:	FUL101
Specification:	16-32mm
Limited power:	220V/50 ± 1Hz
Heat temperature:	260 ± 5°C
Rated power:	600W
PCS/Packagre:	4

PP-R HDPE welding machine

Code:	KL801
Specification/размер/мм:	20-40mm
Limited power:	220V ± 10%/50 ± 1Hz
Heat temperature:	260 ± 5°C
Rated power:	700-1500W
PCS/Packagre:	4

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