REDESIGN OF NEONATAL RESUSCITATOR FOR THE LOW-RESOURCE SETTINGS: AN APPLICATION OF QFD-BASED UCD APPROACH

BY

GAMADA ABARA GUDINA

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ADDIS ABABA INSTITUTE OF TECHNOLOGY
ADDIS ABABA UNIVERSITY

MAIN ADVISOR: DAWIT ASSEFA HAILE, PhD
CO-ADVISOR: ROBERT FLEISIG, PhD

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DEDICATION

This Master's Thesis is dedicated in memory of Ayantu Kebena Jigi (sister-in-law) and my lovely little queen (Twin B), who both passed away during the course of this thesis work.

DECLARATION

I am the author of the thesis entitled, "***Redesign of Neonatal Resuscitator for the Low-Resource settings: An Application of QFD-Based UCD Approach***". All the materials used from other sources are acknowledged appropriately. This work or any part of this work has not been published before submission.

I certify that I am the student named below and that the information provided in the paper is correct.

Full name: Gamada Abara Gudina

Signature: _____

Date: _____

This MSc. thesis has been submitted for examination with my approval as an advisor.

_____

Dr. Dawit Assefa Haile

Addis Ababa Institute of Technology
Centre of Biomedical Engineering
Addis Ababa, Ethiopia

APPROVAL PAGE

SUBMITTED BY

Gamada Abara Gudina	_____	_____
Student name	Signature	Date

APPROVED BY

Dr. Dawit Assefa Haile	_____	_____
Advisor	Signature	Date
_____	_____	_____
Postgraduate Coordinator	Signature	Date
Dr. Dawit Assefa Haile	_____	_____
Centre Head	Signature	Date
_____	_____	_____
Postgraduate Director	Signature	Date

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SCHOOL OF GRADUATE STUDIES

CERTIFICATE OF EXAMINATION

This is to certify that the thesis prepared by ***Gamada Abara Gudina*** entitled "***Redesign of Neonatal Resuscitator for the Low-Resource settings: An Application of QFD-Based UCD Approach***" submitted in partial fulfilment of the requirements for the degree of Masters of Science in Biomedical Engineering (Bioinstrumentation and Imaging) complies with the regulation of the university and meets the accepted standards with respect to originality and quality.

Signed by the examining committee

External Examiner_____Signature_____ Date_____

Internal Examiner_____Signature_____ Date_____

Adviser_____Signature_____ Date_____

_____

Chief of Department or Graduate Program Coordinator

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ABSTRACT

Introduction: *Neonatal resuscitation is a delicate procedure which assists newborns with respiratory problems. Regardless of the life-saving potential of this assistance, numerous complications have been identified in the use of the neonatal resuscitators. Thus, the resuscitation outcomes are poor because of the procedure induced complications. These challenges are significantly apparent in low-income countries. Worldwide popular neonatal resuscitator is Ambu self-inflating bag due to its simplicity and low price. The resuscitation using Ambu is performed by two caregivers and is tiresome procedure. The genuine resuscitation can be performed by well-trained caregivers using well-equipped tool kits to mitigate the challenges. Nevertheless, there are great challenges to do so in low-resource settings because of poor facilities, lack of internationally accepted standards and lack of well-trained staff. Hence, neonatal resuscitation with the existing Ambu bag needs thoughtful attention.*

Objective*: This thesis aimed to figure out the challenges of neonatal resuscitators and later designed an improved neonatal resuscitator to ameliorate patient outcomes and ease work for hospital staff.*

Methods: *The study was conducted in Jimma University Medical Centre from October 10 - December 08/2019. The Quality Function Deployment-based User Centred Design approach was employed to describe the design problem systematically. The qualitative semi-structured interviews were conducted with the hospital staff to investigate voice of the customers. The identified customers' requirements were to get a resuscitator which controls tidal volume, flow pressure and flow rate and is safe. They were identified as study variables and important inputs in the design process to improve the device features, thereby improving patient outcomes. The identified customers' needs formed a basis for the development process.*

Results: *The result from the study revealed demand for a new resuscitator with improved features. The device was designed conceptually by using 3 dimensional AutoCAD software. Arduino based electrical simulation was developed. Finally, flow scheme in the NEOVENT™ was modelled mathematically.*

Conclusion: *The final design was expected to be better and more effective than existing solutions. However, further research should be done to ensure the safety for the neonates before launching the final product.*

Key words: *Ambu Bag, Neonatal Resuscitation, Quality Function Deployment, User Centred Design, Voice of Customers.*

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ABBREVIATIONS/ACRONYMS

AHA	American Heart Association
APGAR	Appearance, Pulse, Grimace, Activity and Respiration
SBA	Skilled Birth Attendant
BPM	Beat per Minute/Breath per Minute
BVM	Bag Valve Mask
CFD	Computational Fluid Dynamics
COPD	Chronic Obstruction Pulmonary Diseases
CA	Conjoint Analysis
CmH2O	Centimetres of Water
CPAP	Continues Positive Airway Pressure
CPR	Cardiopulmonary Resuscitations
EMS	Emergency Medical Service
HoQ	House of Quality
JUMC	Jimma University Medical Centre
KE	Kansei Engineering
LCD	Liquid Crystal Display
LPM	Litre per Minute
NICU	Neonatal Intensive Care Unit
PEEP	Positive End Expiratory Pressure
PICU	Paediatrics Intensive Care Unit
PIP	Positive Inspiratory Pressure
PVP	Positive Ventilation Pressure
QFD	Quality Function Deployment
RD	Resuscitation Device
SIB	Self-inflating Bag
SPO_2	Arterial Oxygen Saturation
UCD	User Centred Design
WHO	World Health Organization

CHAPTER ONE

INTRODUCTION

1.1. Background of the Study

Respiratory and cardiovascular associated problems are the leading cause of mortality and morbidity on the globe. In order of total number of lives loss, the highest worldwide cause of death are related with three issues: 1) Cardiovascular which include coronary heart disease and stroke 2) respiratory which encompasses chronic obstructive pulmonary disease(COPD) and lower respiratory infections and 3) neonatal conditions-which constitutes birth asphyxia, birth trauma, neonatal sepsis, infections and preterm birth complications (WHO 2020). All the above mentioned diseases can bring breathing difficulty or total breathing loss to patients. Human tissues can survive for a very short period of time without respiration. Hence, if there is breathing difficulty, irregular gasping or total respiration loss because of some of the above mentioned cases or other diseases, urgent artificial respiration (commonly known as resuscitation) should be given. To resuscitate patients, there are different types of lifesaving device available worldwide. The devices are known as resuscitators as they assist patients to revive and relief from their respiratory distresses. Most commonly used are the manual resuscitators: Bag valve mask (BVM) (a.k.a self-inflating bag (SIB) or Ambu bag), flow-inflating bag, T-Piece resuscitator. And the automatic devices used to supply airflow and/or oxygen to a victim who insufficiently or unable to breath include: Continuous positive airway pressure (CPAP) machine to help air sacs stay open and transport ventilators used during pre-hospital emergency and transporting patients from one hospital to another (CADTH 2010) and for new-borns who do not cry on their own after birth (Mathai, Adhikari and Rajeev 2015, ANZCOR 2018). The Ambu SIB is the most common solution that it is simple, cheap technique, not necessarily needs oxygen source, can deliver accurate target pressures (Tracy, et al. 2016) and avoids neonatal resuscitation oxygen toxicity, especially when used without reservoir (Thió, et al. 2013).

1.2. Problem Statements

The neonates' lungs are very soft and premature to withstand uncontrolled ventilation pressure and volume flow caused by using manual resuscitators if not given by highly skilled and passionate caregivers using appropriate tool kits. These tool kits assist to sustain life before

patients get appropriate medication and/or therapy. The commonly used devices along with the tool kits are manually operating air supply devices such as self-inflating bag (Ambu SIB), flow-inflating bag and T-piece resuscitator. The latter two are safer and recommended by different experts due to their consistency in peak inflation pressures and sustained inflation (ANZCOR 2018). However, they need to be used with manometer and need external sources. The NeoPuff^{MT} T-piece resuscitator, for example, addresses the problem of effectiveness as it allows for a sustained inspiratory breath of 1-2 seconds which keeps the lungs safe from collapsing and also pressure controlling issue does not depend on the skill of the professional. The device fixes the pressures to insure consistent breaths which limit the risk of excessive pressures. However, this device is expensive and also depends on having pressurized oxygen sources. It requires a lot of training because of the complexity and number of adjustments possible (Mauricio, et al. 2007). Hence, it cannot be sufficiently available and used in low-resource settings of poor healthcare facilities. On the contrary, the Ambu SIB is simplest supportive device with variety of levels and does not need external sources. So, it is commonly used worldwide.

The other device is mechanical ventilator which is advanced and safest lifesaving equipment for ventilation of patients with breathing difficulty and unconscious patients who are unable to breathe. Its working principles do not exactly overlap with that other manual resuscitators, but are similar in its function on providing safer ventilation. It is automatic in its function and can supply oxygen efficiently and reliably. It is preferred for sustaining patients who have breathing difficulty, although it can bring threat to patients such as pneumonia, pneumothorax and oxygen toxicity. On the other hand, it depends on external oxygen sources such as cylinders/tanks and highly sophisticated device. It is a highly expensive lifesaving medical equipment which needs high level training, maintenance issues and thus, cannot be sufficiently available everywhere, even in the developed countries. The global high demand of mechanical ventilators is apparently revealed during the COVID-19 pandemic. The developed world themselves could not provide the machine to their healthcare facilities for assisting patients breathing due to corona virus disease.

Many clinics across the world, however, do not have access to resuscitation equipment and rely on mouth to mouth resuscitation. Where resources exist, the most commonly used device is the Ambu SIB. It is relatively cheap and simple, but there are many challenges of using it. There is no way to know how much pressure to give. Each breath is different because it depends on

the squeezing flow pressure developed by hands of users (Pérez, et al. 2017). Too little pressure can result in ineffective resuscitation and cause death or brain damage. Too much pressure can result in damage to healthy lung cells. This technique relies on the proper use by the nurse (Mauricio, et al. 2007). The other risks related with the usage of these devices are barotraumas, pneumothorax, chronic lung disease in the preterm (Tracy, et al. 2019) and volutrauma (alveolar damage by excess tidal volume) (Chua 2009). Other limitations including the fact that it does not assist users to detect the mask leak, inconsistent peak inflation pressures (may be very high), delivers no peak end expiratory pressure (PEEP) or CPAP and it cannot deliver sustained inflation (ANZCOR 2018). The risks associated with using Ambu for resuscitating neonates become highly apparent than when using for paediatrics and adults. These possible associated risks come from different factors such as uncontrolled parameters (flow pressure, flow rate, SIB compression speed and distances (Tracy, et al. 2019) and flow speed) and complicated conditions and underdeveloped lung physiology of the new-borns. The Ambu SIBs in resource-limited settings like Ethiopia often lack the training and equipment necessary to offer appropriate intervention (UNICEF 2014). The Ambu SIB in the limited centres of neonatal care lack appropriate guideline on the way and know-how of its usage especially on the volume of air to be pushed in. This on the other hand indicates that appropriate control of volume, pressure and flow rate of air to be given are the most important points to deal with. This is the gap that initiated the current thesis project. Keeping the Ambu SIB simplicity as it is, it should be redesigned so that it will be dependable, cheap, easy to monitor, and different power driven, thereby mitigate the higher percentage of neonatal loss. Therefore, it was found mandatory to design appropriate device that can fill this gap by taking users need into account through quality function deployment approach.

1.3. Objectives of the Study

The general objective was to redesign the neonatal resuscitator with improved features resulting in improved resuscitation outcomes for the low-resource settings by using the concept of Quality Function Deployment-based User Centered Design approach.

The specific objectives were:

- To verify the demand for an improved resuscitator
- To investigate problems with existing technologies and analyse
- To design a solution that meets the settled specifications based on the QFD approach
- To model the flow scheme between the designed Neovent™ and neonates

1.4. Significance of the Study

This study indicated the problems that new-borns face starting from first minute of their lives. It lit light on the challenges of physiological, technological and information gaps concerning neonatal resuscitators - due to which millions of babies have been losing their life annually, especially in the developing world. Respiratory support through cardiopulmonary resuscitation (CPR) needs careful considerations, serious commitment and profound experience as it is emergency intervention which takes place, most of the times, in chaotic and uncomfortable situations in ICU of healthcare settings and emergency department. Appropriate tool kits which are designed depending on the users experience and context of use are desirable to improve resuscitation outcomes. After implementation of the current design solution, it will surely ease work for staff, help neonates breathe effectively and increases patients' recovery outcomes by reducing therapy induced injuries to healthy lung tissues. The research findings from the current study and the efforts made for finding design solutions will initiate other researchers and designers to work on this area for better design solutions.

1.5. Scope of the Study

Even though many different efforts have been made to complete the thesis, the following limitations were set for this study. A design solution was presented, however, a physical prototype was not produced. The design was not intended for the adult ICU and emergency room where volume and pressure ranges variations may be compromised, but only for NICU and PICU wards where very slight changes in flow rate and pressure can significantly affect patient recovery outcomes. Furthermore, the interview materials used in this study are based on research done at Jimma University Medical Centre.

1.6. Operational Definitions

In order to create a common understanding between the researcher and various readers of the research paper, conceptual definition of some words and phrases are presented:

- **Ambu bag**- bag valve mask (BVM), sometimes known by the proprietary name Ambu bag or generically as a manual resuscitator or "self-inflating bag", is a hand-held device commonly used to provide positive pressure ventilation to patients who are not breathing or not breathing adequately.

- **Asphyxia:** a condition arising when the body is deprived of oxygen, causing changes in mental status or death; suffocation. A neonatal asphyxia or perinatal asphyxia is the medical condition resulting from deprivation of oxygen to a new-born infant that lasts long enough during the birth process to cause physical harm, usually to the brain.
- **Barotrauma**: It is lung injury induced by high inspiratory airway pressure ventilation.
- **Oxygenation:** is the process of delivering oxygen from the alveoli to the tissues in order to maintain cellular activity.
- **Pneumothorax**: is an abnormal collection of air or gas in the pleural space that separates the lung from the chest wall and then collapse lungs.
- **Resuscitation:** a medical procedure involving repeated cycles of compression of the chest and artificial respiration, performed to maintain blood circulation and oxygenation in a person who has suffered cardiac arrest. Resuscitation can also be defined as giving positive pressure ventilation when the heart rate of the neonate is in normal range
- **Ventilation:** is the delivery system that presents oxygen-rich air to the lung/alveoli.
- **Volutrauma**: refers to the local over distention of normal alveoli due to excessively high tidal volume ventilation and result in lung injury.

1.7. The Thesis Organization

This thesis has been divided into five chapters. The first chapter gives a brief introduction, background about the research work conducted and problem statements. Also objectives of the study, significance of the study and scope of the study were explained here. Chapter 2 discusses about the historical background of resuscitation instigation. This chapter also presents overview of respiration resistance, neonatal airway anatomy and physiology, neonatal global statistical data, neonatal resuscitation, Ambu resuscitator and associated risks. Chapter 3 discusses about the methodology used in detail. The user centred design (UCD) approach and quality function deployment (QFD) were broadly elaborated in this chapter. The ideation and concept generation were also explained in this chapter. The chapter 4 gives details on the thesis result and discussion. Detailed and step by step of QFD decision making matrix also explained here. The geometrical modelling, system electrical simulation and mathematical model were also discussed in this chapter. The final chapter 5 presented conclusion, the research limitation, recommendations and future works.

CHAPTER TWO

LITERATURE REVIEW

This chapter presents about the historical background of how resuscitation started a long time ago and gave detailed explanation on the respiratory system and mostly focused on conditions in developing countries. Also it provides how the situation needs attention to alleviate the suffering of the new-borns. Finally, the literature review was transformed into the appropriate conceptual framework of the study.

2.1. Evolution of Neonatal Resuscitation

The understanding of death of newborns from respiratory failure, asphyxia, was recognized very long time ago. The report on increased mortality among premature infants was as old as the report indicated in Eber's Papyrus in Egypt since 1552 BC and accounts of resuscitation found in the Old Testament of Holy Bible (O'Donnell, Gibson and Davis 2006). In Chinese also, it was noted between 2698–2599 BC that this occurred more commonly among infants born prematurely (Wiswell and Gibson. 2005). In 1949 and 1950, advances in artificial respiration for adults occurred in which Archer Gordon evaluated the most popular methods of respiratory support (arm lift and chest pressure). Then, in 1960s and 1970s, the flood of new technologies and methods of care for acutely ill adults and children were seen (O'Donnell, Gibson and Davis 2006). In 1992 the International Liaison Committee on Resuscitation (ILCOR) was formed to provide a forum for liaison between resuscitation organisations in the developed world and published the first advisory statement summarizing international consensus on resuscitation of the newly born infant at the time (Kattwinkel, Niermeyer and Nadkarni 1999). Thus, through these long evolutions and beyond, formal teaching programs have started over the last 20 years and these days, it is generally recognized that the neonatal resuscitation is among the most important and commonly performed medical interventions worldwide (O'Donnell, Gibson and Davis 2006).

2.2. The Overview of Respiratory System Resistance

The term respiratory system resistance can be explained as a combination of resistance to gas flow in the airways and resistance to deformation of tissues of both the lung and chest wall. This may be common to all peoples due to variety of reasons (Chovancová and Elcner 2014).

When it comes to infants, this most commonly occurs when the infant still has fluid in their airway (WHO 2016). Thus, this phenomenon that occurs when a newborn is unable to breathe enough in the first few minutes of life is generally called as birth asphyxia. Removing the fluid and clearing the airway to decrease respiratory resistance through suction is therefore important. However, this is only recommended in cases the newborn has obvious airway obstruction that prevents spontaneous breathing like when newborn has meconium-stained amniotic fluid or when either the mouth or nose is blocked with secretions (WHO 2016). Approximately, one quarter of overall neonatal deaths is attributed to birth asphyxia, the failure to initiate and uphold breathing at birth. This is because transition from in utero to an independent ex utero state can be complicated by failure to establish adequate respiration with bradycardia or asystole. Therefore, appropriate care including effective neonatal resuscitation which can prevent such high number of neonatal deaths is in dispensable. Thus, resuscitation is a common emergency procedure during the time of birth. Administering of the intervention by trained skilled birth attendants (SBAs) and quality devices can decrease mortality by up to 30% as elaborated in report previously (UNICEF 2014). As further elaborated, UN Commission recognized neonatal resuscitation as one of the most important, strategic, cost-effective interventions that can prevent and decrease child death and has supported activities to progress both overall and facility-level availability of resuscitation devices. For the neonatal resuscitation procedures to be performed by a SBA, resuscitators and suction devices are required. The resuscitators are hand-operated devices to provide positive pressure ventilation (PPV) to patients that need support to breathe (UNICEF 2014).

2.3. Neonatal Airways Anatomy and the Respiratory System

Understanding of the anatomy of airways is utmost important in performing the appropriate resuscitation for the victim during emergency in hospital or pre-hospital. Performing the procedure with clear understanding of the physiological and physical arena leads to greater success rate during the procedure. The upper airway of the human respiratory system includes mouth, nostrils, pharynx and larynx while the lower airways consists the subglottic, the trachea, bronchi and alveoli (air sacs). As illustrated on Figure 2.1, it is a complicated system that transmits filtered warm air to the lungs through the trachea and at the same time permits passage of solids and liquids to the oesophagus. However, if a food particle or liquid enters the airway, a complete system of reflexes will be activated to protect its integrity (Alsheikhly and Subhy 2018).

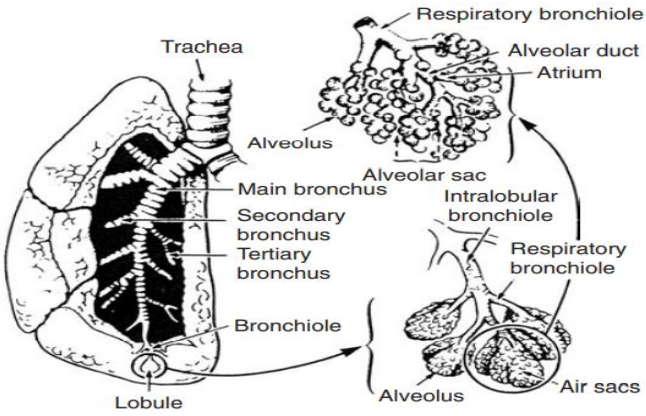

Figure 2.1: Functional anatomy of the lung *(Waite and Fine 2007)*.

Lungs are made up of spongy like, pinkish-gray tissue and constitute two cone-shaped organs. These cone shaped organs are classified as right and left lungs. The right lung has three lobes while the left lung has two lobes. During development of baby's lungs, the most important is the production of surfactant-substance made in small airways (lung tissues) by cells later during pregnancy once the lungs are fully developed. The substance keeps neonatal alveoli open that it will be ready for respiration and can easily exchange gases. Premature babies/preterm born before due date with low birth weight often will not have sufficient surfactant in their lung tissues. That is why most of preterm and low birth weight babies have difficulty breathing immediately after birth. These neonates need serious care and get resuscitation procedure with full toolkits and by well-trained caregivers (see also Figure 2.3).

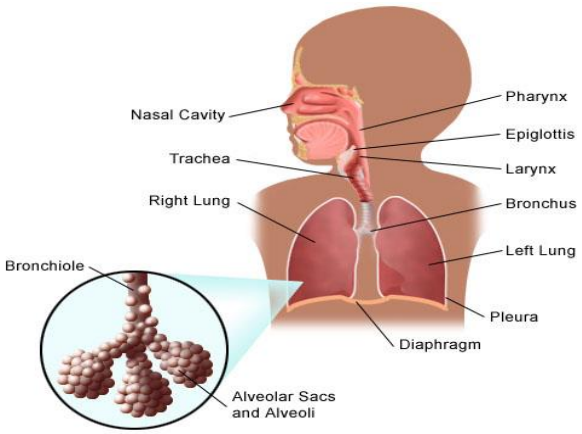

Figure 2.2: Respiration system in New-borns *(Lucile Packard 2020)*.

The term respiration refers to the act of breathing air into (inhalation) and out (exhalation) of lungs through the respiratory system. This respiration system is made of different organs that take part in exchanging gas between the environment and lungs. These organs include: Nostrils,

mouth, pharynx, larynx, trachea, bronchi, bronchioles and alveoli (air sacs). During inhalation (breathe in), oxygen come in and utilized by tissues. Figure 2.2 depicts these different organs that take part in the exchange of gases. When breathing out (exhalation), carbon dioxide comes out of the body (Lucile Packard 2020, Waite and Fine 2007).

2.4. Neonatal Resuscitation and Artificial Ventilation

Different scholars came up with different solutions to resuscitate patients during emergency of variety of conditions. There are different options starting from easiest to sophisticated devices. However, all of them have different drawbacks in spite of their unique advantages.

Positive pressure which occurs during the artificial ventilation in lungs and thoracic cavity is quite different from normal physiological conditions. That means, though it has therapeutic advantages in creating such as PEEP and intrinsic PEEP, it poses critical risks to patients. The governing parameters seem to be mean alveolar pressure and mean intrathoracic pressure (Lumb 2000). One risk to the patient is barotrauma that may appear after long high airway pressure ventilation. Also volutrauma - alveolar damage by excess volume can occur as a result of intrinsic PEEP as alveoli can safely enlarge only to certain volume (Hamdan et al 2002). On the other hand, a wise application of moderate PEEP reduces the risk of barotrauma (Lumb 2000). These both pathophysiology conditions become serious and immediately kill when occur in the very sensitive and immature lungs of new born babies.

From the total of the world new-born babies each year, around 10 million are not be able to breathe immediately at birth. The fatality of this problem becomes much magnified in the low resource settings, where the effectiveness and affordability capacity for helping the babies is very poor (WHO 2016, Stephen Wall, et al. 2009). Neonates pass through different and complex physiological conditions to adapt when leaving from the warm and dark environment of inner uterine to outside environment where they get exposed to different external stimuli such as light, cold, noise and transitioned from depending on placental oxygenation to spontaneous self-breathing. In most cases, such transition happens without difficulty. However, underlined mother diseases and foetal perinatal conditions may hinder the smooth transition and needs immediate interventions. From this, approximately six million of them require basic neonatal resuscitation (Marissa de Ungria 2004, Alsheikhly and Subhy 2018, WHO 2016). As a result of this, a well-trained health professional that has passion to help

babies should be present during every delivery with ready essential equipment in the room (Marissa de Ungria 2004).

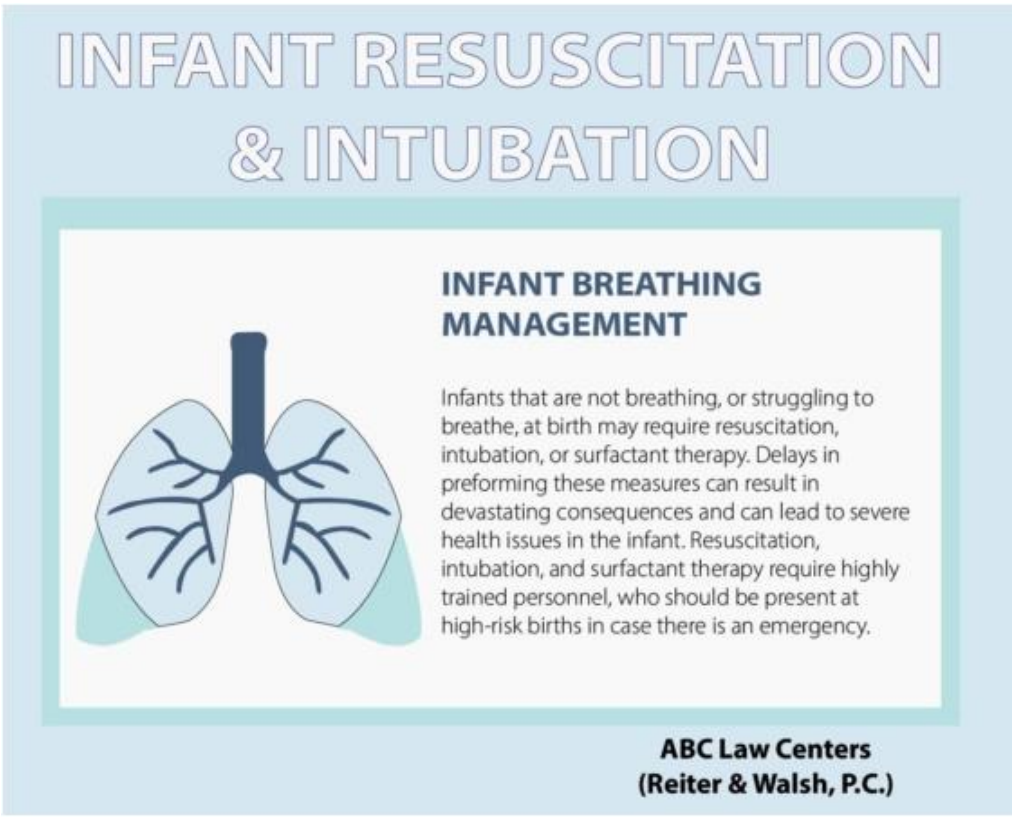

Figure 2.3: Infant Resuscitation management *(American and Child 2010)*

Approximate numbers regarding world-wide statistics of neonates that go through resuscitation at birth have been depicted in Figure 2.4. Fortunately, a high percentage of neonatal deaths can be prevented by genuine neonatal resuscitation along with other thorough cares and effective follow-ups. Nevertheless, lack of equipment is one of the leading problems in healthcare in low-resource settings (WHO 2016). Figure 2.5 shows algorithm for neonatal resuscitation prepared by WHO. Application of air ventilation to young patients is more than just pushing the air in and out of the body; proper flow rate, right tidal volume and proper pressure of the air should be monitored so that it will not cause ventilation induced injuries such as volutrauma and barotrauma to immature lungs (WHO 2016, LeCroy, CRTT and EMT 2014).

According to the WHO, there is lack of international standards for life-saving devices, specifically mask sizes and bag sizes, difference between existing standards and professional association guidelines and lack of information and research regarding essential critical medical devices. Despite that the essential parameters of air flow to patients are to be monitored in terms of amount of flow per minute, tidal volume and pressure, the currently available devices

are being calibrated in terms of pressure alone which is very risky and can result in volutrauma and ineffective ventilation (WHO 2016). Most clinicians have been taught proper respiratory rates for paediatric patients. However, many clinicians have no idea what the proper tidal volume (TV) is for neonates (5mL/kg to 8mL/kg), and have been taught to watch for chest rise. Watching chest rise may be the only choice to determine TV. Most clinicians lack the experience to properly ventilate a neonate without causing injury to the lungs, which may include chronic lung disease, pneumothorax (*presence of air or gas in the cavity between the lungs and the chest wall, causing collapse lung alveoli*) or even death (LeCroy, CRTT and EMT 2014, Tracy, et al. 2019). Such cases become more serious when it comes to developing countries with limited trained man power and low resources in health care facilities

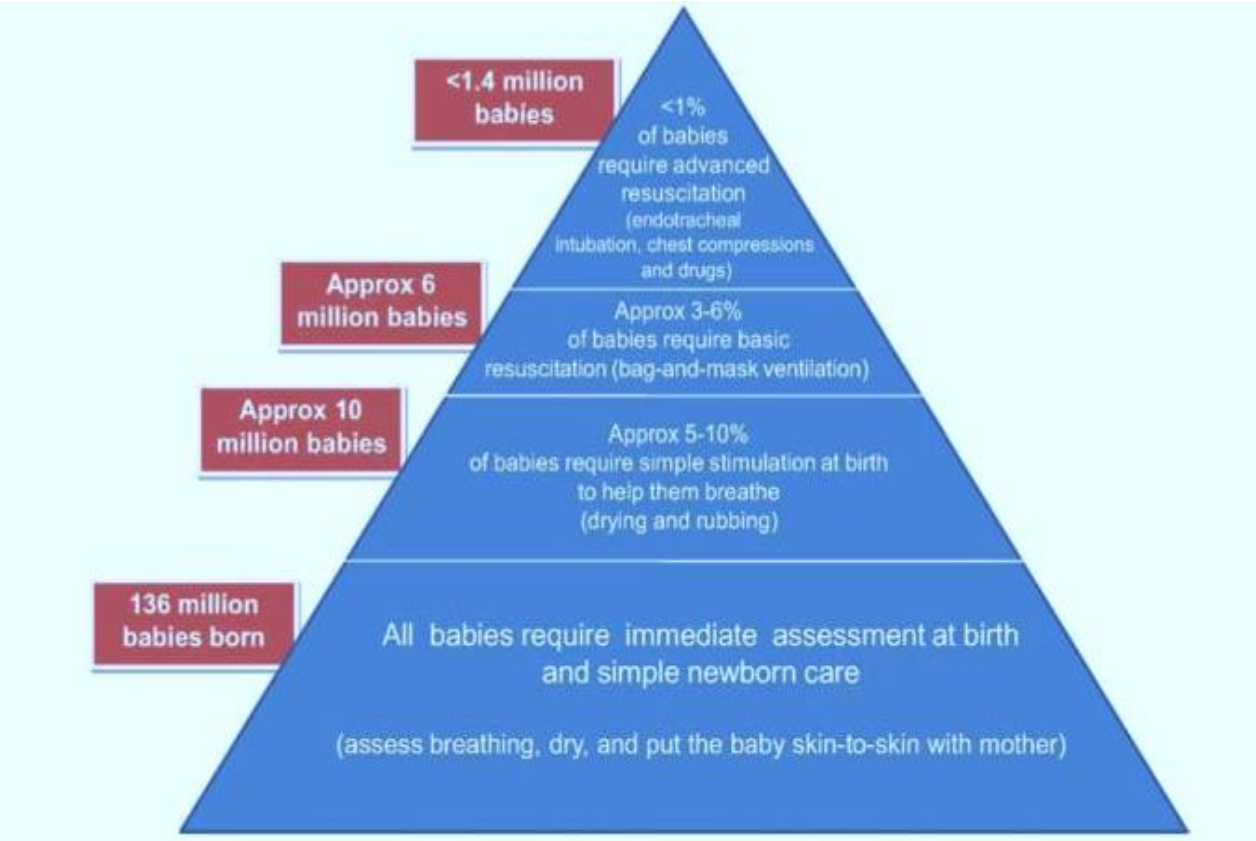

Figure 2.4: Approximations of world-wide statistics of neonates that go through resuscitation at birth. (Stephen Wall, et al. 2009).

2.5. Efficacy of the Ambu SIB Resuscitators

There are different devices most commonly used for providing manual positive pressure ventilation for new-borns in need of resuscitation at delivery. The self-inflating bags (SIB), flow-inflating or anaesthetic bags (AB), and T-piece resuscitators are the most commonly used

resuscitators. Different authors might have different stands on the efficacy of different resuscitators.

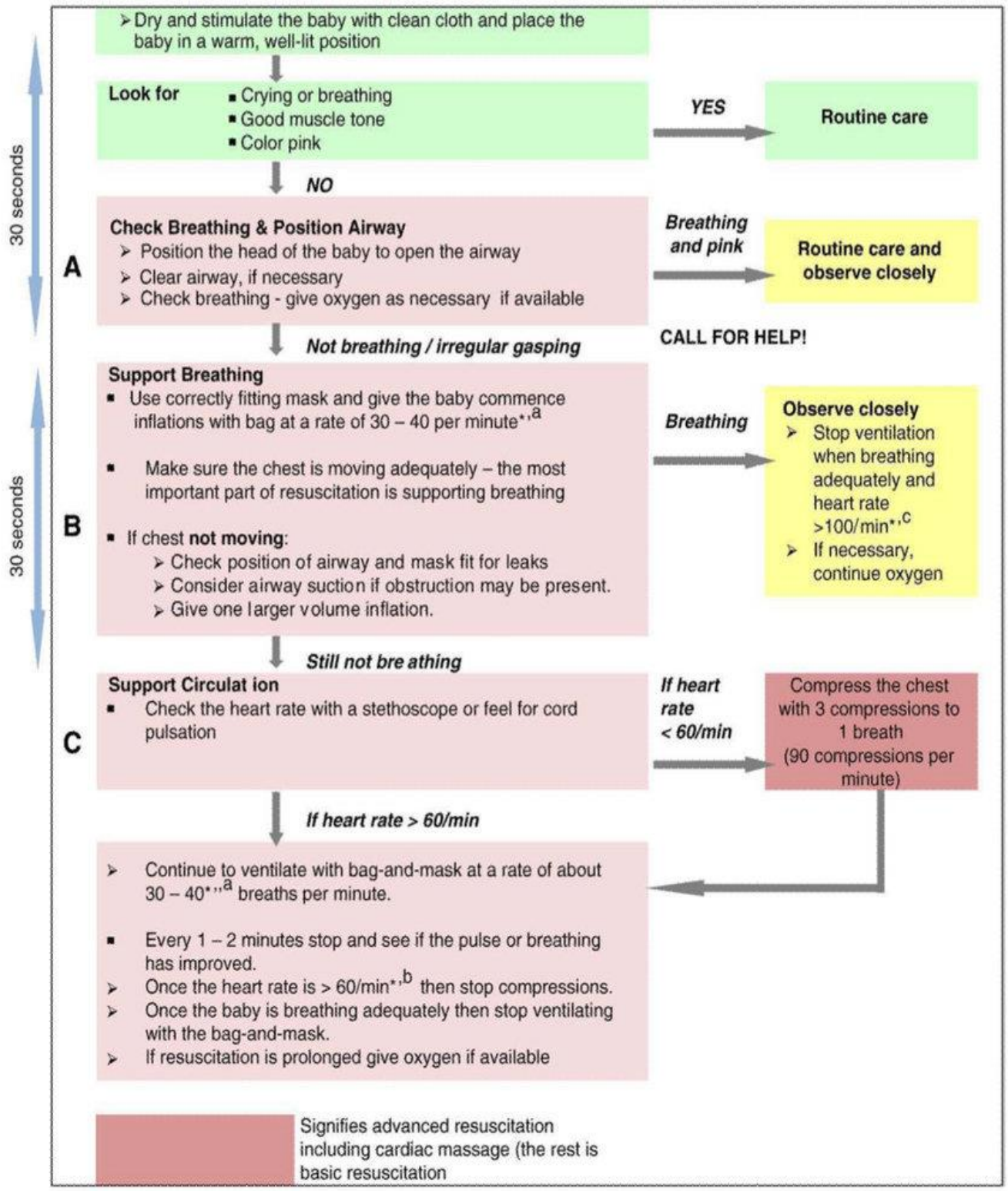

Figure 2.5 : Neonatal Resuscitation diagram based on WHO Pocketbook of Hospital Care for Children and updated with ILCOR 2005 Recommendation. (Stephen Wall, et al. 2009).

There are different studies in favour of T-piece for providing reliable and consistent pressures though a previous study (Jayaram, et al. 2013) indicated no significant differences in effectiveness of resuscitation by the T-piece and SIB. On the other hand, the T-piece resuscitator supplies the most reliable pressures and is most effective as compared to the others as reported in other literature (Nimbalkar, et al. 2015). Other authors also reported T-piece as the most accurate and consistent neonatal resuscitation device after comparing it with the two devices stated above (Dawson, et al. 2011). These authors also elaborated that the T-piece resuscitator protected against barotraumas as evidenced by the lower maximum pressure delivered than the two devices indicated above. The flow-inflating bag on the other hand had been reported of having the highest variation and leak by different scholars (Dawson, et al. 2011, Jayaram, et al. 2013).

There are supporters for each device, with locally practiced guidelines stating which device is used. However, as it is indicated by different researchers, self-inflating bags and T-pieces are the most widely used neonatal resuscitation devices (Dawson, et al. 2011). The T-pieces resuscitator is expensive as compared to SIB as indicated in literatures (Thio, et al. 2015, Jayaram, et al. 2013). The self-inflating bag is the most commonly used device for neonatal resuscitation in most countries (WHO 2016). A study in tertiary hospitals in Australia and New Zealand for example indicated that 76% of centres in these countries use this self-inflating bag (Donnell and C.J. 2004). The same is true for middle and low income countries including Ethiopia that the use of this self-inflating bag for neonatal resuscitation is the most common one due to its efficacy per price (UNICEF 2014).

In Ethiopia as stated above, the Ambu self-inflating bag (Ambu bag) is the most commonly used resuscitator for resuscitation of neonates in need (Mirkuzie, et al. 2014, UNICEF 2014). Despite the availability of these reasonably priced devices and training across the world, SIBs in resource-limited settings like Ethiopia often lack the training and equipment necessary to offer appropriate intervention (UNICEF 2014). The existing equipment (Ambu bag) in limited centres of neonatal care lack appropriate guideline on the way and know-how of its usage especially on the volume of air to be pushed in. This on the other hand indicates that appropriate control of volume, pressure and speed of air to be given are the most important points to deal with. Therefore, it was found mandatory to design appropriate device that can fill this gap by taking users need into account using quality function deployment approach.

2.6. The Situation in Low-income Settings

As it is stated above, almost all (99%) of birth asphyxia occur in countries which range from low to middle in terms of income. A study in Vietnam, for example, indicated that there was no adequate equipment for neonatal resuscitation in a substantial proportion of hospitals in the country (Lawn, et al. 2014). In fact, it is still obvious that, a baby born in rural Africa or South Asia has a very small chance of being resuscitated at birth if they do not breathe (Stephen Wall, et al. 2009). This is in harsh contrast to the careful attention paid to avoiding injuries at the time of birth for a baby born in high-income countries. A study done in Ethiopia also pointed out that, infrastructure, medical equipment, staff education concerning care providers' knowledge scores on diagnosis and management of labour, bleeding after childbirth, birth asphyxia and skill scores on neonatal resuscitation are all still key points for improving the quality of maternal and neonatal care in the country (Mirkuzie, et al. 2014). Thus, these facts are therefore the indication that much is expected in these low and medium income countries in this regard.

In general, there is lack of capacity in low-resource settings where the burden of intrapartum events is the greatest to provide resuscitation for neonate. In South Africa for instance, there is the lowest of skilled birth attendance from the lowest in the world (UNICEF 2014). Furthermore, there is also lack of training for staff and non-availability of equipment for the new-born babies in hospitals. This situation, however, is not limited to South Africa, but also true in many of the developing world countries. From the assessment conducted in six countries in Africa, for example, only 2% to 12% of professionals conducting births were trained in neonatal resuscitation and only 8%–22% of facilities had equipment for resuscitation (Stephen Wall, et al. 2009). The data imply that, less than one-quarter of babies born in facilities would have access to resuscitation because of the fact that only about half of births are in facilities and one-eighth of babies who require resuscitation may receive it in Africa. Therefore, major increase in coverage is required for the resource constrained countries including facilities, basic resuscitation in facility settings, equipment and competent personnel training.

In line with global perspectives, approximately one quarter of neonatal deaths and unknown number of intrapartum stillbirths are caused by birth asphyxia in Ethiopia (Haile-Mariam, et al. 2012, Hayelom and Berhe 2017). According to the findings of these authors, there exist barriers to performing neonatal resuscitation which essentially is attributed to lack of equipment and inadequately trained staff. Thus, different authors and organizations responsible

for the issues are recommending that there should be pre-service and in-service training and availability of appropriate equipment to perform neonatal resuscitation should also be ensured (Mekasha, et al. 2014, Haile-Mariam, et al. 2012, Gebreegziabher, Aregawi and Getinet 2014).

There are considerable differences in terms of anatomical and physiological aspects between pediatric patients and that of adults. This fact on the other hand can impact the techniques and tools that the anesthesiologist might choose to provide safe and effective control of the airways (Harless, R. and S.M. 2014). As further elaborated, there are also a number of pathological processes, typically seen in the pediatric population, which present unique anatomical or functional difficulties in airway management. In addition to that, the neonatal air way management in low and middle resource settings is still in need of improvement specially in terms of infrastructure, medical equipment, staff education concerning care providers' knowledge scores on diagnosis and management of labour, bleeding after childbirth, birth asphyxia and the like (Mirkuzie, et al. 2014). As literatures imply, the major focus of basic neonatal resuscitation guidelines for low- and middle-income countries has been on providing immediate drying, stimulation, maintaining open airway, and bag and mask ventilation (Shukla, Mwenechanya M and Carlo WA 2019).

Despite of the incredible progress that has been made in neonatal care in low and middle resource setting, much remains to be achieved due to the fact that these countries still contribute disproportionally high to the global neonatal mortality (Shukla, Mwenechanya M and Carlo WA 2019). Significant portion (approximated to 25%) of these deaths is due to birth asphyxia, the failure to spontaneously initiate breathing at birth (WHO 2016). The lack of trained birth attendants and effective basic neonatal resuscitation device are the redundantly indicated reasons for this problem in literatures (Shukla, Mwenechanya M and Carlo WA 2019, Enweronu-Laryea, et al. 2015, Stephen Wall, et al. 2009). This indicates that still much has to be done specially in lower resource settings for saving life of neonates. Thus, designing of appropriate resuscitator that takes the need of the users into consideration is very important in minimizing such problems. Designing of such equipment might not have taken into consideration the desire of the end users before. Therefore, the current thesis project was designed to assess the need of the users to designing of neonatal resuscitator and improving patient outcomes for low resource settings.

2.7. Ambu Neonatal Resuscitation and Associated Risks

It is indicated in literatures that the use of bag and mask was easier. Researchers concluded that the bag and mask device was more acceptable to providers, and potentially more effective at saving lives (LeCroy, CRTT and EMT 2014). That is why the self-inflating bag and mask device remain the standard of care. Although the self-inflating bag and mask devices used in high-income countries are expensive, there are affordable versions now available in many low income settings. The device is designed to be reusable and easily cleaned for safe reuse (Stephen Wall, et al. 2009). According to these authors, the midwives also preferred this self-inflating bag and mask device for ease of use, due to their belief in greater efficacy and safety with regard to transmission of infections (LeCroy, CRTT and EMT 2014).

However, many of the emergency medical service (EMS) systems still use the most dangerous method to ventilate a neonate by a self-inflating bag without a manometer. Such practices are dangerous because they are almost impossible to maintain a safe pressure by observing chest rise alone. However, the neonatal resuscitation program supported by the American Heart Association (AHA) and the American Academy of Pediatrics recommends that the starting peak inspiratory pressure (the highest pressure level) applied to the lungs during inhalation should be 20 centimeters of water pressure (cmH2O) and positive end-expiratory pressure (PEEP) resistance on expiration should be 5 centimeters of water pressure (cmH2O) to prevent lung damage and to open airways respectively (LeCroy, CRTT and EMT 2014). The Ambu SIB size is also less than 500 cubic centimeters and should be consisted of a bag, reservoir, oxygen tubing, pressure pop-off valve, a mask and, in some cases, a PEEP valve and a pressure manometer. Therefore, the management of volume, pressure, and speed of air is determinant and need control during neonatal resuscitation. Unless and other wise, barotrauma and volutrauma could occur even when low levels of PIP are given during positive pressure ventilation (LeCroy, CRTT and EMT 2014). The risk of infections could also be another issue to consider during designing of self-inflating bags (Ariawan, et al. 2011, Ogunlesi, et al. 2008, Zaichkin, Thomas and Wiswell 2002). These problems are even harder attributing to the number of pathological processes, typically seen in the neonatal population, which present unique anatomical or functional difficulties in airway management (Harless, R. and S.M. 2014).

2.8. Conceptual Framework

In this section, the literature review was transformed into a theoretical model. The research study conceptualized out on five major categories of independent variables was suggested to redesign neonatal resuscitator (Figure 2.6). The dependent variables in this study are neonatal resuscitation outcomes improvement and easy of work for hospital staff.

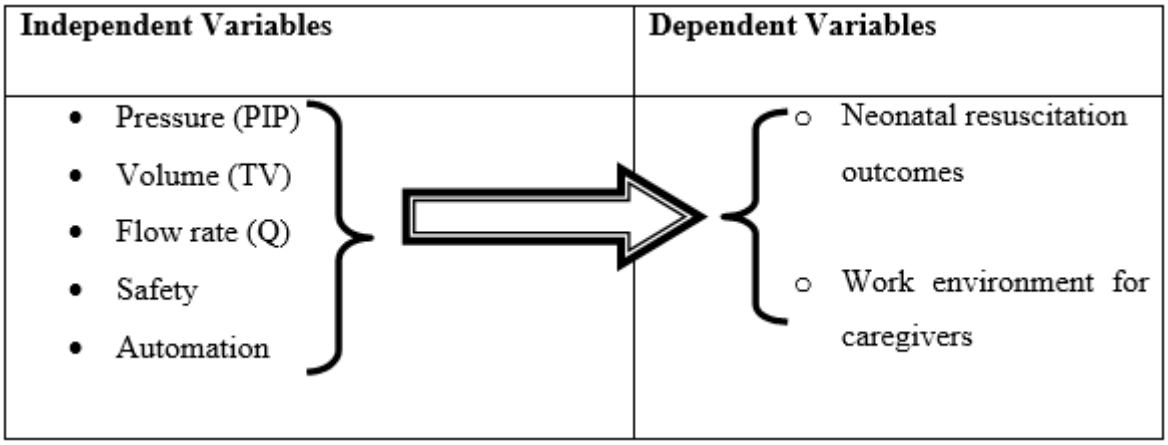

Figure 2.6: Conceptual framework of the study

CHAPTER THREE

RESEARCH METHODOLOGY

This chapter presents the research approaches and methodologies employed in this study to acquire the necessary information in achieving the study objectives. Furthermore, topics related to method of data collection, materials, and interpretation tools are included in this chapter.

3.1. The Study Setting and Approach

The research aimed to evaluate the performance of neonatal resuscitators and related factors that affect resuscitation outcomes in low-resource settings. The study was conducted in the South-Western Ethiopia in Jimma zone at Jimma University Medical Centre in the selected wards including neonatal intensive care unit (NICU), paediatric intensive care unit (PICU), labour and delivery ward and adult ICU during the period of October 10 - December 08/2019.

3.2. Sampling Technique and Size

The purposeful qualitative sampling technique was employed to investigate in-depth and detailed information about the resuscitation devices and pathophysiology of the newborns after births. Twelve participants were selected to respond to the semi-structured research questions (See also Appendix A). The interview respondents were two neonatologist nurses (BSc), two midwives (BSc), three nurses (BSc), two doctors (MD), and three biomedical engineers (BSc) as well. Creswell (1998) recommends for the phenomenological studies that 5 – 25 sample size is sufficient for qualitative semi-structured/in-depth interview while Morse (1994) suggests at least six (Townsend 2013).

3.3. Data Sources, Collection Methods and Analysis

The data used as inputs in the study were collected through semi-structured interviews, observations of the procedures in the hospital wards and small focused group discussions. There are both primary and secondary data sources. The primary data sources were collected directly from the users in the wards via semi-structured interviews and perceived via observations. The secondary data were brought from online materials and monthly reports both in NICU and PICU wards at JUMC. The analysis was done in accordance with the facts

identified as global norms, limited resource settings in general and in the context of use at the JUMC in particular.

3.4. The Study Variables

The research variables in the study were classified as independent variables and dependent variables. The independent variables were factors affecting output of the resuscitator, thereby affecting patient outcomes. These variables are velocity, volume and pressure of the flow. These are the major variables that need to be controlled to positively affect the resuscitation outcomes and increase the safety of the device. These can be achieved through different approaches. The independent variables were explicitly: tidal volume, pressure, flow rate, automation and safety. All these variables have their own contributions to the improvements of the design along with the other factors. The other variable which can affect the patient outcome is training of hospital staff. However, this variable was not controlled in this study and the issue needs awareness creation at national level by policy making authorities. The dependent variables are meant to improve neonatal resuscitation and ease of use for the hospital staff so that the patient outcomes would be improved. The same was explained in the conceptual framework section of this study in chapter 2. The basis for the implementation is the QFD-based UCD approach.

3.5. Quality Function Deployment

The utmost important but challenging part of design development is to identify and define costumers' experience and their needs along with environments or context of use. Nowadays, there are many different types of rationale methodologies to identify customers' requirements and contexts of uses, and one of them is Quality Function Deployment (QFD). QFD is an efficient customer requirement development tool and is based on identifying the customer and ensuring that the engineering team has thoroughly understood the problems. It translates the requirements into measurable parameters and includes an evaluation of the competition. This method was developed in the mid-1970s in Japan and the Japanese automotive manufacturer Toyota improved the quality of their new car model while reducing their development time by one third and their development costs by 60% by using this method (QFD 2019). The QFD based methodology for User Centred Design (UCD) is employed in the current design. First of all, the problems with the current airflow devices were identified. To investigate demands and needs of users with existing airflow delivering devices, qualitative semi-structured interviews

were conducted individually with Jimma University Medical Centre staffs that have experiences with the devices. Biomedical engineers of the hospitals were also included in the interviews. Depending on the requirements identified, engineering quantitative specifications were produced and incorporated in each and every steps of the design.

3.6. User-Centred Design Method

User-centred design (UCD) is a general term that illustrates design developments in which end-users of products manipulate how a design takes nature (Abras, Maloney-Krichmar and Preece 2004). It is a project method that puts the intended users of a system at the centre of its design and development. It does this by talking directly to the users at key points in the project to make sure the system will deliver upon their requirements. The stages are carried out in an iterative fashion, with the cycle being repeated until the project's usability objectives have been attained. This makes it critical that the participants in these methods accurately reflect the profile of actual users (Teoh 2006). The following are the four essential phases in a UCD process (Teoh 2006):

1. Requirements gathering - Understanding and specifying the context of use.
2. Requirements specification - Specifying the user and organizational requirements.
3. Design solutions - Producing designs and prototypes.
4. Evaluation - Carrying out user-based assessment of the system.

When it comes to UCD, it is very general term and could not able to provide quantitative specifications when used alone. The best UCD tool for analysing the needs and demands in systematic and scientific way is Quality Function Deployment (QFD) methodology.

The main intention of UCD is to engage end users in the progress of the system in a way that the model and designs, and finally the products would meet the wants and requirements of the users. The work of UCD is multidisciplinary that it joins together the expertise of different stakeholders. In the iterative UCD process, the main principles of UCD are user involvement throughout the process, iteration of design solutions, and cross-functional teamwork (Heinilä and Netta 2005). UCD in the whole product development cycle is an iterative process where feedback from end users is brought into design in different stages of the development cycle.

The concept of UCD which involves focusing on the user’s needs, carrying out an activity/task analysis as well as a general requirements analysis, carrying out early testing and evaluation,

and designing iteratively start to coming to fore since 1980s (Ritter, Baxter and Churchill 2014.). The term user-centered design was told by scholars to be originated in Donald Norman's research laboratory at the University of California San Diego (UCSD) in the 1980s (Abras, Maloney-Krichmar and Preece 2004). These days, the rational roots of UCD, sometimes called User-Centered System Design (UCSD), evolve and developed in several areas of basic and applied sciences including cognitive and social psychology, linguistics, mathematics, computer science, engineering, human factors and ergonomics, socio-technical systems design, scientific management, work, industrial, and occupational psychology, human relations, organizational behaviour and the like (Ritter, Baxter and Churchill 2014.).

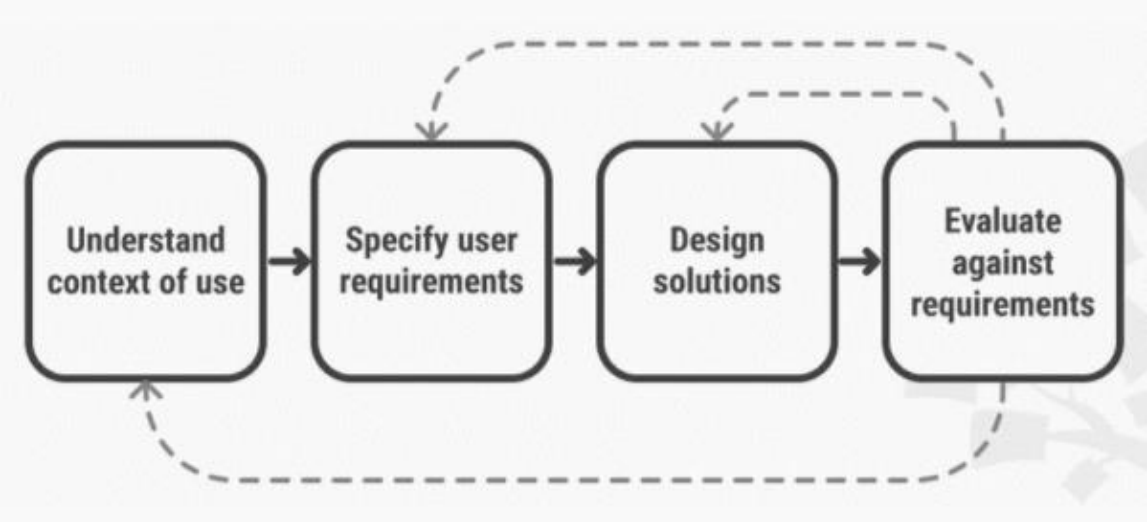

Figure 3.1: The Iterative User-Centered Design Process (Soegaard 2002).

As its name implies, UCD is the design process which involves consideration of the user at every stage of the engineering design. The UCD process starts at the concept generation step. Once users of the design have been identified, a detailed investigation of their needs is performed to recognize the intended use and goal of the design. Following the investigation of the users' needs, translation of these needs into a set of functional requirements and design guidelines is performed. Then, following these stages, initial prototypes and usability test will follow (McCurdie T., et al. 2012, Usability.gov 2016). The basics of the UCD process are depicted in Figure 3.1 while Figure 3.2 presents a more detailed processes involved in the UCD approach.

It has been recommended that patients be concerned while designing and testing of health technologies. However, few research based information describe how to include patients in systematic and meaningful ways to ensure that the designs are customized to meet their needs

(Dabbs, et al. 2009). The UCD is an engineering design approach that involves users all through the development process so that technology support tasks are easy to operate, and are of importance to users.

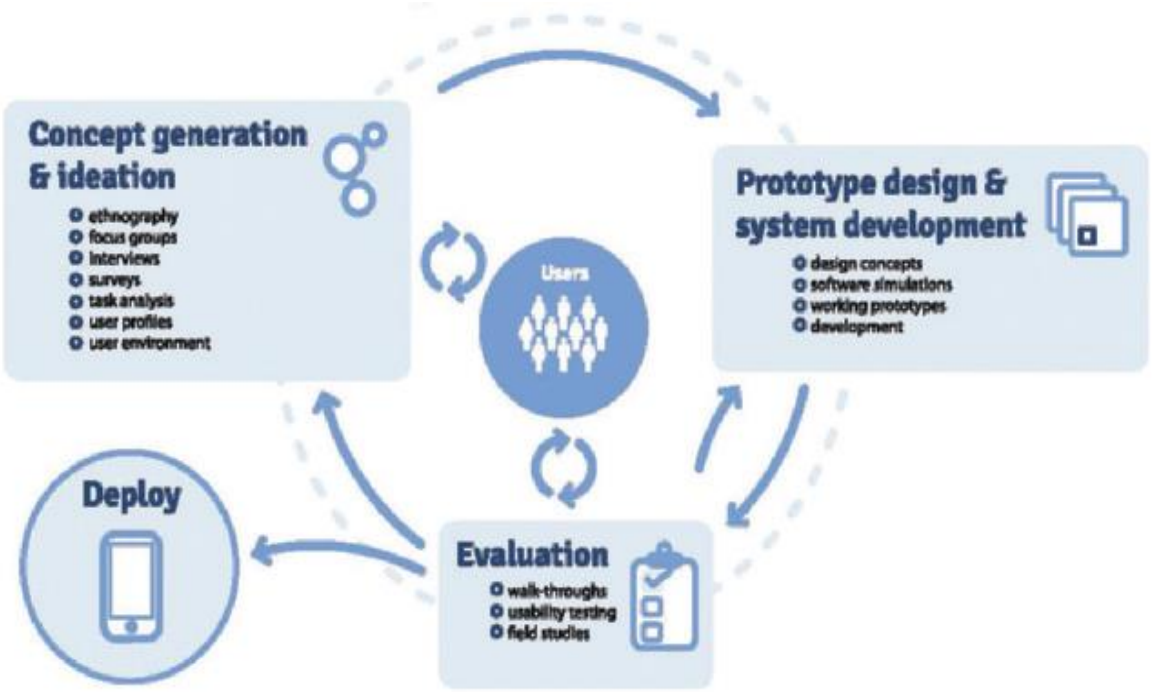

Figure 3.2: User-Centered Design Process Details *(McCurdie T., et al. 2012).*

Mainly, designing of medical devices comprise the product development team to balance the requirements of different participants: the customer, regulatory organizations, and the designing institution itself (Hagedorn *et al*., 2016). This is because of the fact that in designing of such devices, additional consideration must be given for a much more complex user-base. This is why emerging and developing concepts like UCD which play pivotal role in the product design process (Smith *et al*., 2012) are important. It was farther elaborated that only few projects exist that consider design domain concepts, such as aspects of a detailed design, a detailed view of various stakeholders and their capabilities, along with the UCD approach taking the inherent challenge discussed above into account.

The UCD therefore is an important approach that matches designs to user needs as its name implies and thus could play pivotal role in the engineering product design. It is important in matching the given designs to needs of the users through improving overall product quality, customer satisfaction, product success and other product functions. Nonetheless, the matching

process is inherently not very easy and in some cases can be inaccurate also. Thus, matching accuracy is generally very low and that is why most the designs still do not match user needs.

3.7. Approaches of User-Centered Design

There are three approaches of UCD used by engineering designers in matching designs to the needs of user. These UCD approaches are discussed hereunder with more emphasize on quality function deployment approach which is focal point of study in this review.

3.7.1 Quality Function Deployment (QFD) as a Tool for UCD

The QFD is an approach of UCD which designers use for matching of the designs to the functional needs of the users. The engineering designers use the QFD approach to meet the physical design to the functional needs of the users as one of the three common approaches. This QFD approach is more or less traditional method for understanding and integrating customer needs into engineering product design (Stefano, Lombardo and Tarantino 2007).

In this QFD approach, customers provide functional requirements (Barone, Lombardo and Tarantino 2007), with real-value weights, (1–7) for example, and the designers use subjective ordinal-value weights, for example (1, 3, 9), to match users functional requirements to physical design elements. Hence, the designers use simple calculations to combine weights and choose design elements and use these design elements to create a new design (see also Figure 3.3).

The engineering designers have used the QFD approach, with some degree of success, since the 1960s (Smith *et al*., 2012). However, the QFD approach is inherently inaccurate (Kannan 2008; (Ling C., Hwang W. and Salvendy G. 2007) because, customers use subjective, inaccurate weights to rank requirements and designers also use subjective, inaccurate weights to match requirements to design elements (Ling C., Hwang W. and Salvendy G. 2007) (Ling *et al*., 2007). Designers combine the weights to choose design elements. The new design may not match requirements. The combination of UCD approach with the QFD as a tool has verified to be effective to increase the quality of a design research at the early stages in a research work on automotive development process (Di Bucchianico 2019). According to this author, the results coming from QFD matrix provide a detail and measurable evaluation about user needs, which often report subjective points of view.

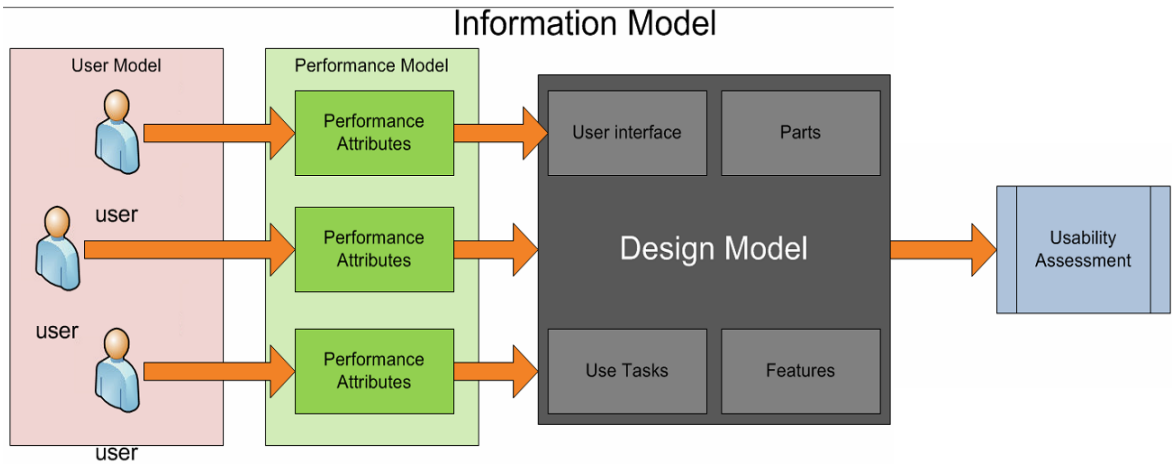

Figure 3.3: Information model of QFD/UCD (Smith et al., 2012).

3.7.2 Conjoint analysis (CA) Approach

The conjoint analysis (CA) approach is the other approach of UCD which is used for matching physical designs to user rankings (Barone, Lombardo and Tarantino 2007). The CA approach is a well-established tool especially in marketing research for translating customer needs and outlooks into product characteristics. Conversely, customers are still demanding and expecting more satisfaction and realization of their emotions and psychological needs (Stefano, Lombardo and Tarantino 2007) and thus, the engineering designers must place strong emphasis on capturing and integrating these features into product design process for that matter. This approach, similar to QFD, is more or less traditional method for understanding and integrating customer needs into engineering product design (Stefano, Lombardo and Tarantino 2007). The CA is also a useful tool within a KE project going to be discussed below.

3.7.3 Kansei Engineering (KE) Approach

The other approach of UCD used by engineering designers is the Kansei Engineering (KE) approach to match physical designs to emotional needs (Nagamachi *et al*., 1995). The KE approach is a design philosophy that takes into account customer perceptions and emotions as well by implementing multi-disciplinary approach (Stefano, Lombardo and Tarantino 2007). Due to conventionality of QFD and CA, KE which is part of emotional design is new approach of UCD developed and integrated into product design processes in order to analyse the affective sphere of customers. This approach is gaining substantial interest in more of academic and industrial research (Stefano, Lombardo and Tarantino 2007).

3.8. Principles of User-Centered Design

There are four activities set as requirements by ISO standard 9241-210 in which Human-Centered Design is used instead of User-Centered design (Ritter, Baxter and Churchill 2014.). These requirements were previously known as recommendations which are listed below:

- The first one is understanding and specifying the perspective of use (users, tasks, environments).
- Identifying the user needs in sufficient detail to drive the design.
- Making design solutions that meet these needs.
- Performing user-centered assessments of these design solutions and modifying the design to take into account the results.

In 1985, it was recommended that there could be three principles of UCD (Gould and Lewis 1985) as discussed below.

3.8.1. Early and Continual Focus on Users Tasks

First of all who the users are and the cognitive, behavioural, anthropometric, and attitudinal characteristics of the users need to be studied before the designing activity is started. In line with these, studying the nature of the work expected to be accomplished in part is also important (Gould and Lewis 1985). Article by (Dabbs, et al. 2009) also stated that understanding the patient-users, their characteristics, and the health-related tasks to be performed are the product development team's primary concerns.

3.8.2. Empirical Measurement of Usability

The second important principle of UCD recommended in a previous study (Gould and Lewis 1985) is that, early in the design process, the proposed users should actually use simulations and prototypes to perform real work, and their performance and reactions should be observed, recorded and analysed. The factors that contribute to overall usability and how each may be measured during usability testing sessions should be measured empirically and frequently throughout the design process (Dabbs, et al. 2009, Hagedorn, Krishnamurty and Grosse 2016).

3.9. The Iterative Approach of UCD and QFD Principles

This is a principle of UCD whereby the system including simulated, prototyped, and real are modified, tested, modified again, tested again, and the cycle is repeated again and again (Gould

and Lewis 1985). According to these authors, when problems are found in user testing, they must be fixed. This statement is to mean that the design must be iterative which further imply that a cycle of design, test and measure, and redesign, repeated as often as necessary must be always there. All the principles of UCD including this interactive design require looping back to earlier stages so that design occurs in iterative cycles of assessing-designing-testing analyzing-refining-testing-analyzing-refining (Dabbs, et al. 2009). Generally, UCD is a way to identify the real needs, feedbacks and behaviours of users as they interact with the system over the course of its design iterations until users consider it usable and functional.

The QFD method includes eight steps (CLIVE, PATRICK and and ELIZABETH 2014, AHMADI 2014, QFD 2019), which are listed as follows:

1) Identify the customers;
2) Determine the customers' requirements;
3) Determine relative importance of the requirements;
4) Identify and evaluate the competition;
5) Generate engineering specifications;
6) set up technical targets for the product;
7) Set engineering specification targets and importance, and
8) Identify relationships between engineering specifications.

The detail of the quality function deployment steps are explained one by one as following.

Step 1 - Identifying the customers

To enable the investigation of the customer needs and to understand the problems, the first step is to determine who the customers are. Both internal and external customers i.e. customers inside and outside the organization, must be considered. In many cases there is more than one customer group.

Step 2 - Determining the customers' requirements

The next step is to determine what the customers want. The information regarding customer requirements should be collected from the customers themselves and there are different ways of doing so, e.g. observations or surveys. The better the customer's needs are understood and documented, the better the developers will be able to address them and make informed decisions. Information from customers can be analysed, clarified and translated into so called

"need statements". Personal values are suppressed and the raw data is interpreted into concrete statements describing customers' needs.

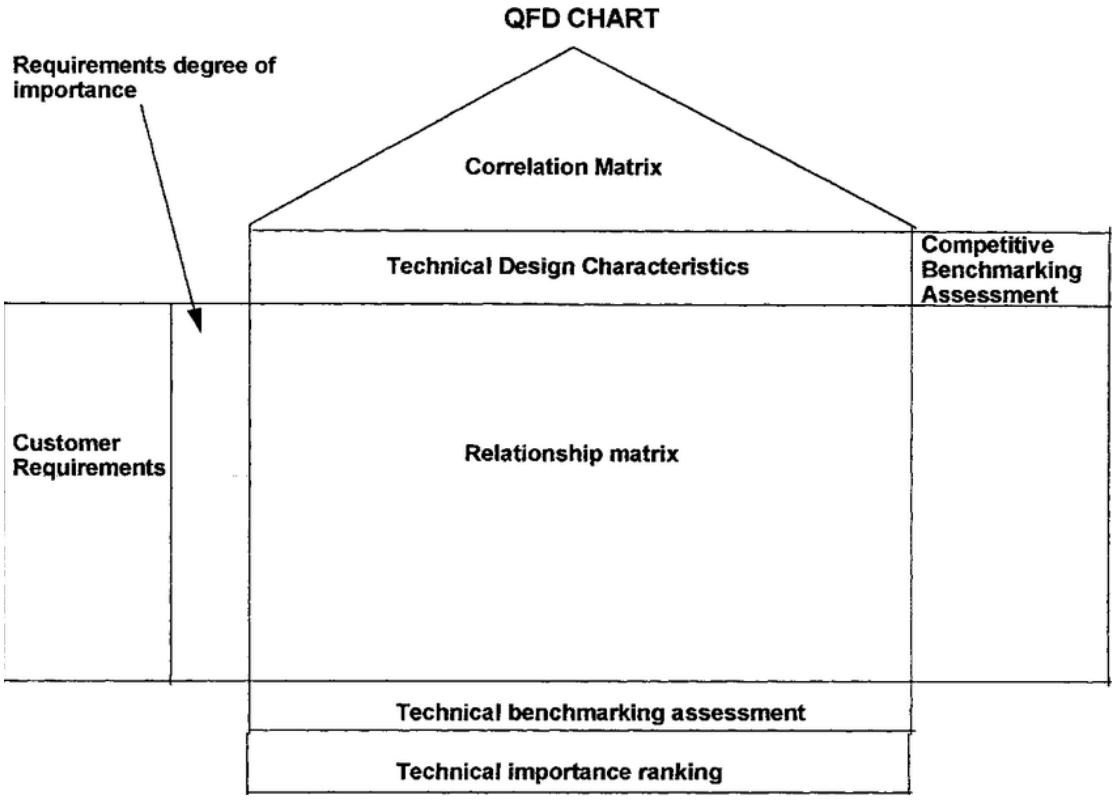

Figure 3.4: An elementary abstraction of a House of Quality (HoQ) that displays and relates Customers' interests, design attributes, measures, targets, and current products *(CLIVE, PATRICK and and ELIZABETH 2014, Srivastava 2011).*

During the implementation of each step, a matrix called the house of quality (HoQ) is successively filled out. The numbers in each "room" of the HoQ refer to the eight steps of the QFD processes and are specified in Figure 3.4 above.

Step 3 - Determining relative importance of the requirements

Step three of the process is to evaluate and rank the identified customer requirements. The requirements are weighted after importance and this hierarchy will later guide decision-making and indicate how much resources should be allocated to each requirement. There are different ranking methods, e.g. rating the requirements on a scale of 1 to 5. Some requirements are crucial for the functioning of the product and are not included in the weighting.

Step 4 - Identifying and evaluating the competition

The next step is to study how satisfied the customer is now, i.e. determining the competition's ability to meet the customers' requirements. This step raises awareness regarding existing solutions and improvement possibilities. Each existing product is assessed and the requirements are rated on a scale from 1 to 5 for each existing product. The rates represent the following:

1. The product does not meet the requirement at all.
2. The product meets the requirement slightly.
3. The product meets the requirement somewhat.
4. The product meets the requirement mostly.
5. The product fulfils the requirement completely.

Step 5 - Generating engineering specifications

The customers' requirements, the 'what's' are need to be translated into technical requirements. These engineering specifications should be measurable parameters so that the engineers will be able to know if the system satisfies the customer. One customer requirement can have several technical translations. The requirements should also be marked with the symbol "↑" or "↓", to tell the direction of improvements of requirements.

Step 6 - Setting up technical targets for the product

In this step the engineering specifications are related to the customer requirements. The relationships are graded according to numbers, as follows:

9 = strong relationship
3 = medium relationship
1 = weak relationship
Blank = no relationship at all

Step 7 - Setting engineering specification targets and importance

The inferior part of the HoQ is filled out in this step. The specifications importance is calculated to know how much effort should be devoted to the specification. Next, the competitions products are compared and measured relative to the engineering specifications. Now the specification initial targets for the project can be developed. This establishes a basis for further product development and design.

Step 8 - Identifying relationships between engineering specifications

The roof of the HoQ shows the relationships between the engineering specifications. The engineering specifications can be dependent on each other and this is noted in the roof section with a "+" if the specifications have a positive effect on each other and a "−" if it is negative. The strong positive represented by "⊕" and strong negative by "⊖".

Finally, the real HoQ matrix for the QFD design was created. In order to generate the HoQ, EdrawMax 10.0.6 version software was utilized. The EdrawMax (a.k.a EdrawSoft.com) software is the all-in-one diagramming tool that serves many purposes. It can provide workspace for creating many diagram platforms including UML (Unified Modelling Language) diagrams, flowcharts, fishbone diagrams and many more. Generally, the software accelerates understanding and drive innovation in multiple forms (Edraw 2020). The result of the HoQ has been shown in Figure 4.1.

3.10. Ideation

An ideation is the most important part at the beginning of design projects so that many ideas are generated, from which best solutions to be selected depending on the scenarios and feasibility issues. To do so, brainstorming is a good mechanism. The aim of the method is to explore a large number of ideas. Brainstorming may be the most creative and open-ended activity of the project. This task can be useful for people working in a group but also for individual projects.

There are four factors that are relevant for the concept generation process:

- Criticism and judgment should be suspended during concept generation. Judgmental thinking should be converted into suggestions for alternative concepts.
- Generation of a large number of ideas increases the likelihood of completely exploring the solution space. Each idea has shown to act as a stimulus for other ideas, so a large number of ideas further stimulate the generation of even more ideas.
- Ideas that may seem infeasible are actually valuable and should be welcomed. Infeasible ideas can often be improved and most importantly they stretch the boundaries of the solution space and encourage the group/individuals to think in a new way.
- Abundant sketching surfaces should be provided since text and verbal language may be an inefficient and difficult tool when reasoning ideas.

3.11. System Development

The system architecture is the result of all the processed data and formulated system technical requirements. In the QFD-based methodology for UCD system design, the users' needs (collected from target users through the semi-structured interviews and/or questionnaires) and the mapped functionalities (derived from the technological parameters and categories via the brainstorming of experts) form selected functionalities. The selected functionalities and the technological parameters, at the end, form the system technical requirements. From these system technical requirements, the final system architecture was derived.

Figure 3.5 presents the system block diagram for the proposed neonatal airflow resuscitation device in this thesis. The major components of the design include a stepper motor, Ambu/self-inflating bag and Arduino Uno micro controller. Feedback readings and actions are displayed with LCD indication and buzz sounds.

1. If the BR of the patient is below normal level, the nurse will set on the needed value of BR and the machine will automatically start to inflate with the help of a stepper motor.

2. If the BR of the neonate under resuscitation is >=100, stop chest compression and continue bagging.

3. If the neonate starts breathing by itself, stop bagging and switch to CPAP and continue monitoring for the next 5 minutes for improvements and follow APGAR value recordings. Normally, if the APGAR value is below 7 out of 10, then it needs close monitoring for improvement.

4. The machine will monitor the infant's gas flow rate, breathing rate, temperature and humidity, heart rate and SPO2 value, and the pressure through which the flow moves. All the parametric values will be displayed on the LCD. The gas flow sensor monitors the amount of gas flow rate moving to the infant in ml/s. The heart rate and PSO2 sensors will monitor the amount of beat per minutes and the oxygen saturation of the infants in bpm and %, respectively. The amount of pressure (in CmH_2O) through which the gas flow will be measured by the pressure sensor and it will monitor safe air flow pressure to the infants.

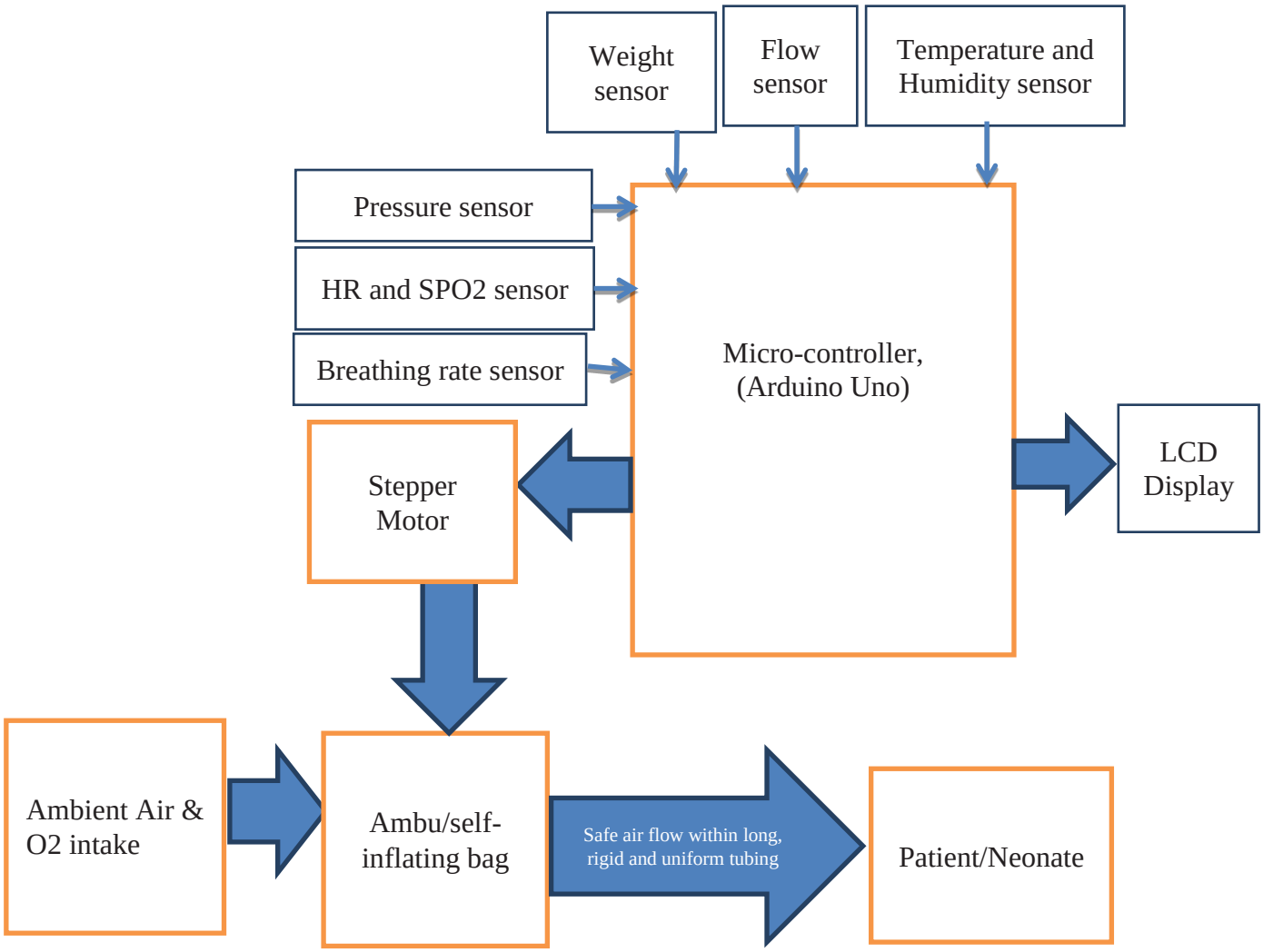

Figure 3.5: The system block diagram

Figure 3.5 above depicts the proposed system block diagram. The microcontroller, Arduino Uno, will control all the functioning of the system. It will control the stepper motors backward and forward rotation speed based on the pre-settled standard breathing rate. The motor controls the SIB compression distance and inflate appropriate amount of flow based on the tidal volume reading. Specific tidal volume for each neonate is calculated from respective infant weights. Constant and controlled air flow and pressure is needed to flow to the neonate. This enables a safe air to flow from BVM to the infant or neonate. The controlled air flow and pressure will protect the infants' lung from damage/harm.

3.12. Materials

Different materials used to control parameters under the study so that the manual squeezing actions of human hand replaced by automatic and regulated action of the developed system. All the materials specifications incorporated in the design process were explained below in detail in this section.

3.12.1. Ambu SIB and Mask

Selection of right size of Ambu SIB and mask size is important for performing genuine resuscitation. Figure 3.6 depicts a neonatal Ambu bag with reservoir and pop-off valve.

Figure 3.6: Neonatal Ambu Bag with reservoir and pop-off valve

Table 3.1 below presents the WHO standard bag sizes for different neonatal weights. From the table it can be seen that for the majority infant size, up to 80 mL of air is needed to compress into the lung, which only takes less than one third of the total volume of 250 ml. Studies show that mask leak usually has a range of 45±20%. It has been found that smaller self-inflating bags reduce the incidence of over tidal volumes and produce greater guideline-consistent results for cardiac arrest patients (Nehme and Boyel 2009).

Table 3.1: Neonatal resuscitation bag with mask specifications prepared by WHO to request tenders *(WHO 2016).*

Product	**Neonatal resuscitation bag with masks specifications**
Key resuscitation bag features	• Size: 200-320 ml • For full term babies, preterm and low-weight infants less than 5kg • Reusable and Self-inflating • Portable and Motor operated and hand operated or both • Ventilation can be done either by oxygen or ambient air • Made of silicone or other materials specified in ISO10651-4 or equivalent • Intake valve with optional nipple for O2 tubing, material made of polycarbonate/ polysulfone or any other material fulfilling ISO 10651-4 or equivalent.
Mask features	• Size 0 for preterm and low-weight babies, round type, outer diameter 35–50 mm • Size 1 for term baby, round type, outer diameter 50–65 mm • Translucent • Fulfilling ISO 10993-1:2009; ISO 10993-5:2009; ISO 10993-10:2010 or USP Class V (or equivalents)
Bundling instructions	• Resuscitator bag and masks supplied as a complete set along with the following: • Non-rebreathing patient valve with a pressure limiting valve so that the airway pressure does not exceed 4.5 kPa (45 cmH2O) and can generate an airway pressure of at least 3 kPa (30 cmH2 O)
Materials	• All parts manufactured from high-strength, long-life materials that require no special maintenance or storage conditions and comply with national standards • The mask is made of silicone rubber or any material fulfilling ISO 10993-1:2009; ISO 10993-5:2009; ISO 10993-10:2010 or equivalent or USP Class V • The bag is made of silicone and valve of polycarbonate/polysulfone or any materials fulfilling ISO10651-4 or equivalent.

3.12.2. Arduino Uno Board

The Arduino microcontroller is an easy to use yet powerful single board computer that has gained considerable traction in the hobby and professional market. The Arduino Uno is a microcontroller board based on the ATmega328 (datasheet). It has 14 digital input/output pins (of which 6 can be used as PWM outputs), 6 analog inputs, a 16 MHz ceramic resonator, a USB connection, a power jack, an ICSP header, and a reset button. It contains everything needed to support the microcontroller; simply connect it to a computer with a USB cable or power it with an AC-to-DC adapter or battery to get started. It is an open-source physical computing platform based on a simple microcontroller board, and a development environment

for writing software for the board. An important feature of the Arduino is that you can create a control program on the host PC, download it to the Arduino and it will run automatically. Remove the USB cable connection to the PC, and the program will still run from the top each time you push the reset button (Allen 2012)**.** Arduino is composed of two major parts: the Arduino board, which is the piece of hardware you work on when you build your objects; and the Arduino IDE, the piece of software you run on your computer. You use the IDE to create a sketch (a little computer program) that you upload to the Arduino board. The sketch tells the board what to do.

Not too long ago, working on hardware meant building circuits from scratch, using hundreds of different components with strange names like resistor, capacitor, inductor, transistor, and so on. Every circuit was "wired" to do one specific application, and making changes required you to cut wires, solder connections, and more. With the appearance of digital technologies and microprocessors, these functions, which were once implemented with wires, were replaced by software programs.

The Arduino board is a small microcontroller board, which is a small circuit (the board) that contains a whole computer on a small chip (the microcontroller). You see a black chip with 28 "legs"—that chip is the ATmega328, the heart of the board. Here is an explanation of what every element of the board does:

- **14 Digital IO pins** (pins 0–13): These can be inputs or outputs, which is specified by the sketch you create in the IDE.
- **6 Analogue In pins** (pins 0–5): These dedicated analogue input pins take analogue values (i.e., voltage readings from a sensor) and convert them into a number between 0 and 1023.

6 Analogue Out pins (pins 3, 5, 6, 9, 10, and 11): These are actually six of the digital pins that can be reprogrammed for analogue output using the sketch you create in the IDE. The board can be powered from your computer's USB port, most USB chargers, or an AC adapter (9 volts recommended, 2.1mm barrel tip, and centre positive). If there is no power supply plugged into the power socket, the power will come from the USB board, but as soon as you plug a power supply, the board will automatically use it (Mohd 2011)**.** So, in this project the microcontroller of Arduino (ATmega328, brain of Arduino) plays a major role in monitoring the needed parameter and order the GSM as to send necessary messages to the concerned station.

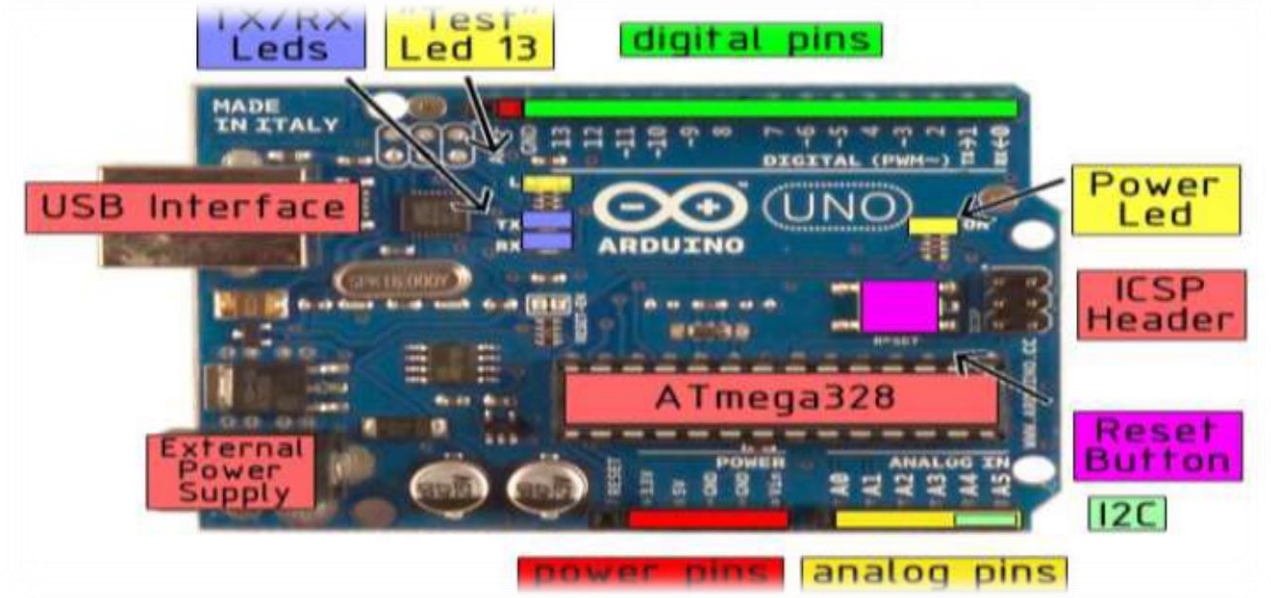

Figure 3.7: The Arduino Uno R3

Table 3.2 Technical specification for Arduino Uno

Technical Specifications	
Microcontroller	ATmega328
Operating Voltage	5V
Supply Voltage (recommended)	7-12V
Digital I/O Pins	14 (of which 6 provide PWM output)
Analog Input Pins	6
DC Current per I/O Pin	40 mA
DC Current for 3.3V Pin	50 mA
Flash Memory	32 KB (ATmega328) of which 0.5 KB used by boot loader
SRAM	2 KB (ATmega328)
EEPROM	1 KB (ATmega328)
Clock Speed	16 Hz

3.12.3. Bipolar Stepper Motor

This small hybrid bipolar stepping motor has a 1.8° step angle (200 steps/revolution). Each phase draws 600 mA at 3.9 V, allowing for a holding torque of 180 g-cm (2.5 oz-in). The motor

has four color-coded wires terminated with bare leads: black and green connect to one coil; red and blue connect to the other. These leads connect to the stepper motor through a removable JST-ZHR-5 connector.

Figure 3.8: Bipolar stepper polar

The motor can be controlled by a pair of suitable H-bridges (one for each coil), but we recommend using a bipolar stepper motor driver or one of our Tic Stepper Motor Controllers. In particular, the Tics make control easy because they support six different interfaces (USB, TTL serial, I²C, RC, analog voltages, and quadrature encoder) and are configurable over USB with our free configuration utility. Our 4 mm universal mounting hub can be used to mount objects on the stepper motor's 4 mm-diameter output shaft.

Table 3.3: Technical specification for Stepper Motor

Technical Specifications	
Size	20 mm square × 30 mm, not including the shaft (NEMA 8)
Weight	60 g (2 Oz)
Shaft diameter	4 mm "D"
Steps per revolution	200
Current rating	600 mA per coil
Voltage rating	3.9 V
Resistance	6.5 Ω per coil
Holding torque	180 g-cm (2.5 oz-in)
Inductance	1.7 mH per coil
Lead length	30 cm (12″)
Output shaft	supported by two ball bearings

3.12.4. MAX30100 Pulse Oximeter

The sensor (show in Figure below) is an integrated pulse oximetry and heart-rate monitor sensor solution. It combines two LED's, a photo detector, optimized optics, and low-noise analog signal processing to detect pulse and heart-rate signals. It operates from 1.8V and 3.3V power supplies and can be powered down through software with negligible standby current, permitting the power supply to remain connected at all times.

Features

Consumes very low power

Ultra –low shutdown current (0.7µA)

Fast data output capacity

Figure 3.9: MAX30100 pulse oximeter and heart-rate sensor

The device has two LEDs, one emitting red light, another emitting infrared light. For pulse rate, only the infrared light is needed. Both the red light and infrared light is used to measure oxygen levels in the blood. When the heart pumps blood, there is an increase in oxygenated blood as a result of having more blood. As the heart relaxes, the volume of oxygenated blood also decreases. By knowing the time between the increase and decrease of oxygenated blood, the pulse rate is determined. It turns out, oxygenated blood absorbs more infrared light and passes more red light while deoxygenated blood absorbs red light and passes more infrared light. This is the main function of the MAX30100: it reads the absorption levels for both light sources and stored them in a buffer that can be read via I2C. MAX30100 Pulse Oximeter Sensor has been interfaced with Arduino on simulation. The circuit diagram and connection is given in figure below. The Vin pin of MAX30100 has been connected to Arduino 5V or 3.3V pin, GND to GND. Moreover, the I2C Pin, SCL & SDA of MAX30100 to A5 & A4 of Arduino.

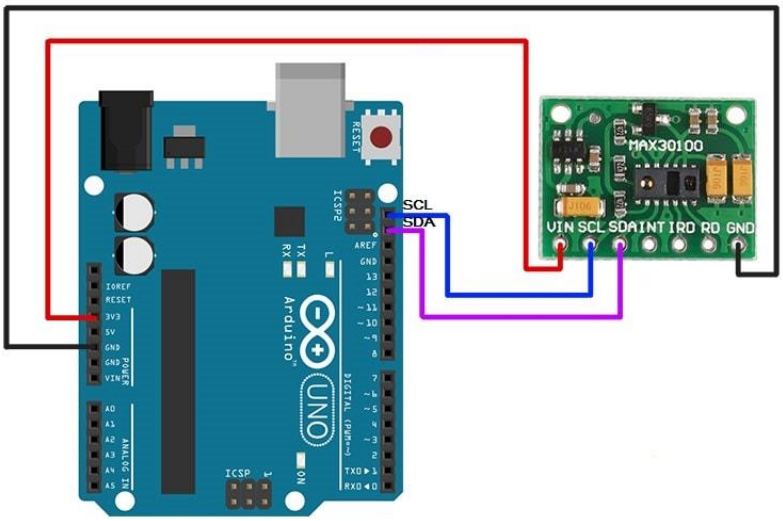

Figure 3.10: MAX30100 pulse oximeter interface with Arduino on simulation

(***Source***: *https://bit.ly/3imNPv6)*

The nasal/mouth airflow sensor is a device used to measure the breathing rate in a patient in need of respiratory help or person. This device consists of a flexible thread which fits behind the ears, and a set of two prongs which are placed in the nostrils. Breathing is measured by these prongs. The specifically designed cannula/holder allows the thermocouple sensor to be placed in the optimal position to accurately sense the oral/nasal thermal airflow changes as well as the nasal temperature air. It is comfortable, adjustable and easy to install.

Figure 3.11: Breathing rate sensor (Source: https://bit.ly/3bCMoat)

3.12.5. DHT22 Unit (Digital humidity and temperature sensor)

The DHT22 is the low-cost digital humidity and temperature sensor. It utilizes a capacitor based humidity sensor combined with a temperature sensor component to measure the

surrounding air. The output of the sensor is a digital signal that is to be transferred to appropriate data pin.

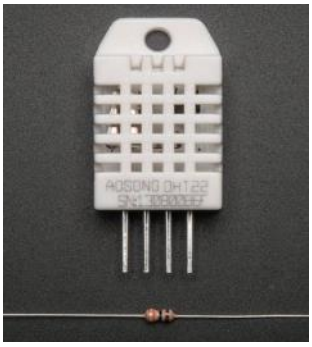

Figure 3.12*:* DHT22 Sensor

This sensor is perfect and accurate with working in a broad range of humidity and temperature (Jayalaxmi and Pritviraj 2014)**.**

Table 3.4: Technical specification for DHT22 Sensor

Model	DHT22/AM2302
Power supply	3.3-6V DC
Output signal	Digital signal via 1-wire bus
Operating range	Humidity 0-100%RH;
Accuracy	Humidity +-2%RH (Max +-5%RH);
Temperature	<+-0.5Celsius
Resolution or sensitivity	Humidity 0.1%RH;
Temperature sensitivity	0.1 ^{o}c
Repeatability	Humidity +-1%RH; Temperature +-0.2Celsius
Humidity hysteresis	+-0.3%RH

3.12.6. Alphanumeric LCD display (20 x 4)

This an intelligent dot matrix display is employed for very broad applications such as very small size computers (palmtop), photo copier machines, cellphones, medical devices and other

Figure 3.13: LCD display

equipment. It has a capability to display 224 different sorts of characters and symbols and normally powered by 5V voltage supply source**.** (Jayalaxmi and Pritviraj 2014)

A typical LCD display consists of 16 pins that control various features of the screen. A table that shows the pins and describes each function can be seen in table 3.4 below**.** The Arduino microcontroller can output voltages of either 5 V or 3.3 V, so the LCD can be powered by wiring VSS and VDD to the ground and 5 V pins on the microcontroller. It is possible to adjust the contrast of the screen by wiring a variable resistor to V0 located at pin 3 on the screen. The RS, R/W, and E pins are wired to pins 12, ground, and 11 respectively on the Arduino. The LCD 5 screen can operate in both 8-but mode and 4-bit. For this application note only 4-bit mode will be discussed, as it requires fewer pins and is generally easier to use.

Table 3.5 Pin out of a typical LCD screen

Pin No.	**Symbol**	**Function**
1	VSS	Ground
2	VDD	Power Supply
3	V0	Power Supply for LCD
4	RS	Select Display Data (“H”) or instructions(“L”)
5	R/W	Read or Write Select Signal
6	E	Read or Write Enable Signal
7	DB0	Display Data Signal
8	DB1	
9	DB2	
10	DB3	
11	DB4	
12	DB5	
13	DB6	
14	DB7	
15	LED- (K)	For Back ground light for LCD as –ve
16	LED+ (A)	For Back ground light for LCD as +ve

To interface with the LCD in 4-bit mode the Arduino only needs to be connected to pins DB4-DB7, which will connected to digital output pins 5-2 respectively. Pins 15 and 16 on the LCD screen are used to power a backlight in the screen. This makes text displayed in the screen

easier to read in poorly lit environments and is optional. In order to power the backlight pin 15 should be connected to ground while pin 16 should be connected to the 5 V output of the Arduino. To power the Arduino a 9 V battery can be connected to the VIN and ground pins on the Arduino. If such power source is available the Arduino can be powered by using its USB connection with a computer (Moghavvemi and S.Tan 2005). Figure below shows what the final wiring scheme should look like after all connections are made.

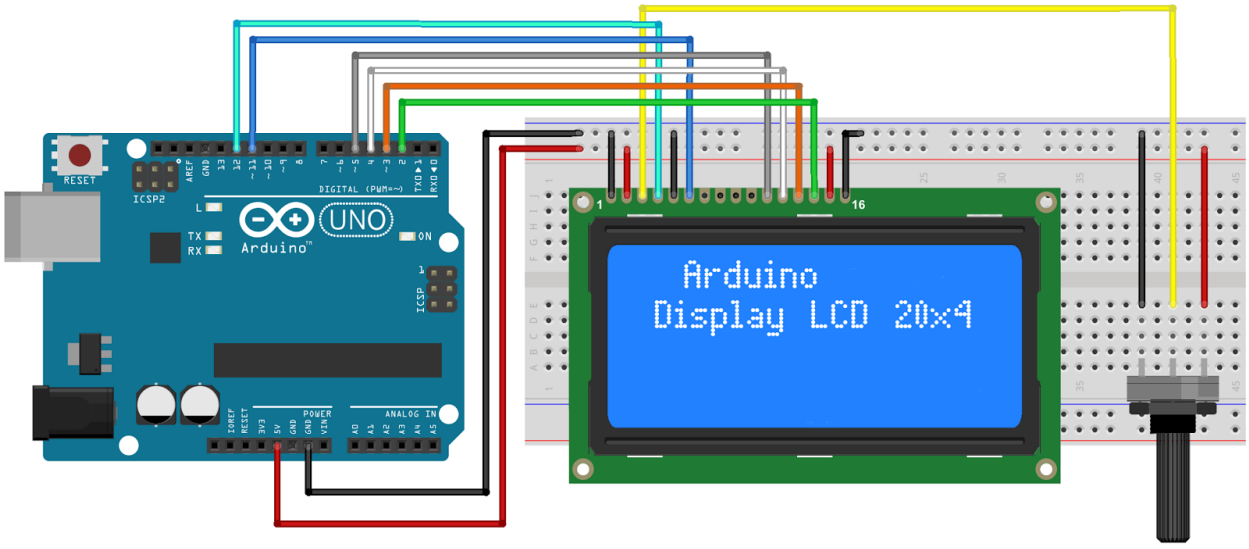

Figure 3.14: Wiring schematic for LCD-Arduino interfacing.

(Source: https://bit.ly/35IGT6k)

3.12.7. Weight sensor

Arduino Weight Measurement using Load Cell and HX711 Module

Load cell is transducer which transforms force or pressure into electrical output**.** Magnitude of this electrical output is directly proportion to the force being applied. Load cells have strain gauge, which deforms when pressure is applied on it. And then strain gauge generates electrical signal on deformation as its effective resistance changes on deformation. A load cell usually consists of four strain gauges in a Wheatstone bridge configuration. Load cell comes in various ranges like 5kg, 10kg, and 100kg and more, here we have used Load cell, which can weight up to 40kg.

Figure 3.15: Weight sensor

The electrical signals generated by Load cell is in few millivolts, so they need to be further amplify by some amplifier and hence HX711 Weighing Sensor comes into picture. HX711 Weighing Sensor Module has HX711 chip, which is a 24 high precision A/D converter. HX711 has two analog input channels and we can get gain up to 128 by programming these channels. So HX711 module amplifies the low electric output of Load cells and then this amplified and digitally converted signal is fed into the Arduino to derive the weight.

3.12.8. Pressure sensor

The sensor used here (i.e., SPD005G) is a gauge type sensor. There are actually four sensing elements inside the SPD005G and they are arranged like a Wheatstone bridge. The sensing range of SPD005G is 0 – 0.350 x 105 Pa (i.e.; 0 – 14.50 psi). The internal schematic and pin out of an SPD005G pressure sensor is shown below.

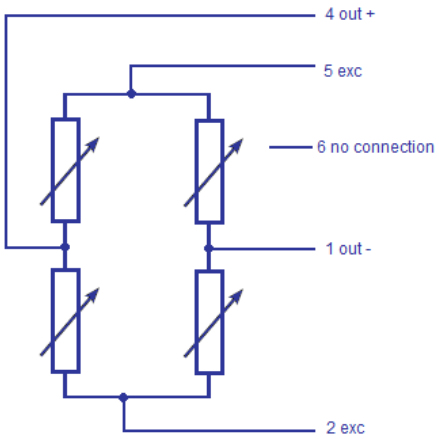

Figure 3.16: Pressure sensor

3.13. Mathematical Flow Model in Part of NOVENT™

The mathematical modelling is mostly to show the flow profile in the vertical tube which was attached to the tip of the Ambu to normalize the flow before it reaches the mouth/nose of neonate and/or mask. In the fluid dynamics, the fluid flow can form parabolic velocity profile in which the pressure drop along the flow direction is constant and there is no acceleration i.e., there is no velocity change. The region in the pipe where the velocity profile gets its parabolic and constant velocity is called fully developed flow region. To get this shape, there should be enough entrance length (XE) (Waite and Fine 2007, Najmi and Shah 2016). See also Figure 4.6.

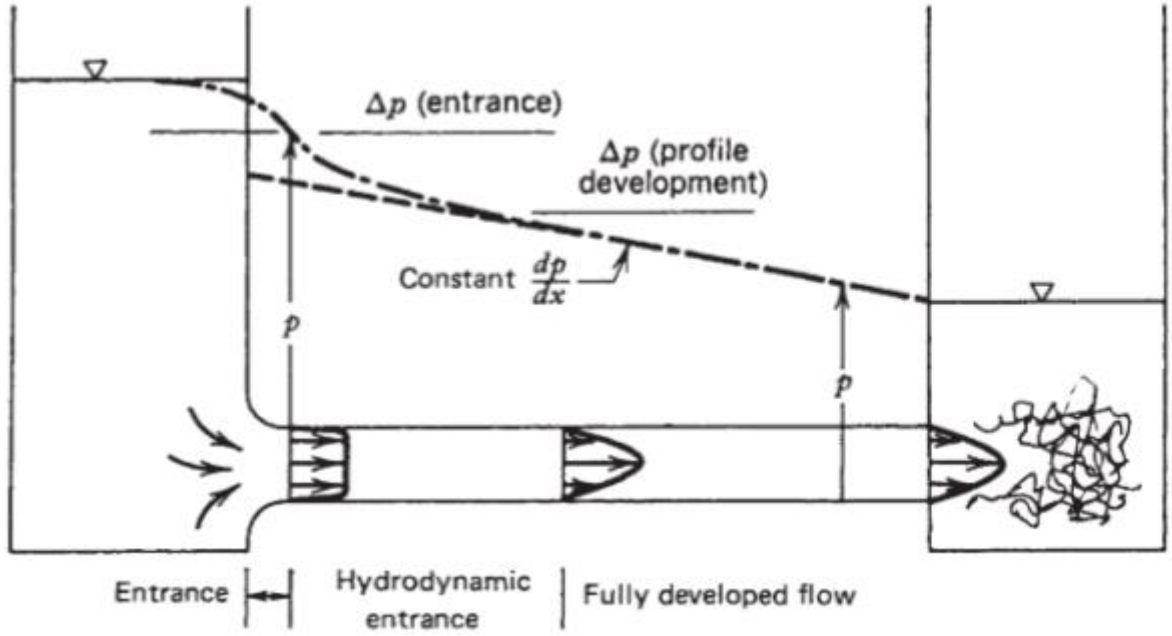

Figure 3.17 Entrance region and fully developed flow in a tube (Najmi and Shah 2016).

According to the proposed neonatal airflow resuscitation design, the mathematical model needs to be setup between the developed system and the neonates. So far, many works have been performed regarding the fluid flow mathematical modelling in different materials by different scholars. These works applied to human respiratory system modelling, especially by classifying the anatomy of the respiration systems to upper and lower parts and/or by dividing into different grades. By standing on the novel works of these scholars, the current thesis study presented with the mathematical representation of the air/oxygen flow in the rigid, long and constant cross sectional area tube. This starts from the internal chamber of the squeezed self-inflating bag to the designed circular tube (with uniform local cross-sectional area) and then to

the mask covering both mouth and nostrils, finally to the neonate's lung. Gas flow is very complex event which needs extra knowledge advancements to be well understood.

Unlike liquids, gases are known as compressible fluids as they can change their volume under applied pressure. However, we can consider the gases to be incompressible in our case because there is no significant pressure applied to change their volume considerably, i.e., the density is constant. This comes from slow and calculated compressing pressure (driving force) of the motor on the SIB. Solving gas/fluid flow analytically is impossible in the real world. That is why different scholars took some assumptions and ignore facts to explain some aspects of the flow. Some of them assume that flow is inviscid (ideal), which in fact fluid flow is real. The nonlinear second order partial differential equation, Navier-Stokes equation was requested to be solved analytically. But, no one could do that so far. As in computational fluid dynamics (CFD), scholars apply some equations by suppressing some situations by assumptions. In this study, different fluid flow equations have been employed to describe the flow regime between Ambu and mask. According to (Tracy, et al. 2019) the relationship between distance of bag squeezing, tidal volume and airway pressure were examined by using automated two–armed robotic mechanism by simulated standard hand compressions in the distances ranges of SIB.

The present study tried to model the flow that takes place between the designed transitional tubing at the exit tip of the Ambu bag and the nose and/or mouth of the neonate being treated (mask). We can characterize this flow and control its pressure, velocity and volumetric flow rate of the fluid (ambient air and/or Oxygen in our case) by changing the dimensional parameters of the tubing and its alignment with respect to the ground. The pressure and speed by which the SIB is compressed also determines the safety status of inflation gas to the neonate. We can classify this model into different categories. Flow model in the squeezed Ambu, and flow model in the rigid, cylindrical and smooth pipe with length L and diameter D. As mentioned above, flow model developed by Tracy et al. for bag compression in the precise distance ranges depicted that only half of the 20 models were safe to use for resuscitating infants (Tracy, et al. 2019).

The main point in this regard is pertaining the amount of flow passing to the neonate per minute (flow rate), velocity with which it is flowing and pressure that originate from the squeezing of the SIB and flow under the guidance of unidirectional valves which directs flow to take place in the forward and desired direction. Other point is the extent and speed by which the bag gets

squeezed by the applied pressure. The third point is the relationship between pressure, mass flow rate and velocity of the flowing fluid along with systems dimensions.

The amount of air filled in the Ambu SIB determines the maximum air reaching the lung of the patients. Thus, neonate standard Ambu selection is mandatory to safely resuscitate new-born patients. However, the selecting right volume alone cannot decide amount of flow and pressure with which it reaches the lungs, but also squeezing speed, percentage of total volume squeezed, leakage conditions, dead space along the course of the flow and length of the path to reach target place, alveoli (gas exchange area). For example, let's take the standard and average Ambu size of 250ml. If about 50% of this Ambu is squeezed to resuscitate an infant of a specific weight, we can calculate the tidal volume of this flow. The 50% of 250ml is 125ml and if one calculates by using average 45% mask leakage, the net tidal volume becomes 125 times 55% which equals 68.75mL per breathe. This tidal volume can cause over ventilation for a neonate and cause lung damage. The following fluid flow equations can well describe the gas flow profile in the proposed design solution for the safe neonatal resuscitator. In this case, Eulerian description of flow is used. Unless identified explicitly, velocity in this description is average (mean velocity) of the flowing fluid mass in the direction of flow.

3.13.1. Poiseuille Law

Jean-Marie Poiseuille and empirically derived this law in 1838. This law describes steady, laminar, incompressible, and viscous flow of a Newtonian fluid in a rigid, cylindrical tube of constant cross section, which was published by Poiseuille in 1940 (Waite and Fine 2007). It explained velocity of moving fluid tube as a function of the tube radius to calculate the total flow rate.

$$V = \frac{1}{4\mu}\frac{dP}{dx}[r^2 - R^2] \quad \text{(4.1)}$$

where, *V* is velocity, *dP/dx* is differential pressure gradient along the direction of flow, μ is dynamic viscosity, *r* is differential radius and *R* is radius of the tube.

This parabolic velocity profile (flow profile) is for flow in the long, rigid and cylindrical tube. There are five assumptions to get this velocity profile: i) the flow is steady; ii) the flow is in the fully developed flow region in long tube with constant cross section; iii) Viscosity is constant (Newtonian fluid); iv) No slip boundary conditions, and v) Flow is laminar.

By taking the boundary condition, we can calculate the maximum velocity. At radius *r=0,* i.e., the centreline of the tube, the velocity of the flowing fluid is maximal. Thus Equation (4.1) becomes:

$$V_{max} = \frac{1}{4\mu}\frac{dP}{dx}[-R^2] \quad \text{..... (4.2)}$$

Furthermore, the velocity as a function of radius can be written in the following form after incorporating equation (4.2) in equation (4.1) and rearrangements:

$$V = V_{\max}\,[1 - r^2/R^2] \quad \text{..... (4.3)}$$

where, R is the tube radius, r is differential radius, V_{max} is maximum velocity or the centreline velocity of the velocity profile. Since this expression is about laminar pipe flow, it is assumed that the flow in only one direction (i.e., in forward direction along the pressure gradient). From the concept of viscosity and no slip condition, the velocity of the flowing fluid in the tube is zero at the wall of the tube and maximal in the centreline.

The velocity profile can also be rewritten as a function of average velocity (V_{av}) as:

$$V = 2V_{\text{av}}\left[1 - \frac{r^2}{R^2}\right] \quad \text{..... (4.4)}$$

Equation (4.4) uses average velocity, which is half of $V_{max.}$ Using average velocity is preferred expression in the fluid flow model as expressed by Eulerian flow description (Waite and Fine 2007). Here, a velocity of a single molecule of fluid is of no interest, but the overall velocity of molecules which are applying internal frictions to nearby streamlines due to intermolecular cohesive forces and no slip condition.

To match this mathematical model with the current design, there are some issues to be considered. First of all, the flow of fluid moving in the tube cannot be steady always. Secondly, flow condition in the region of fully developed region cannot be applicable to flow in the entire flow regime. Thirdly, flow cannot be laminar always. Hence, in case of the turbulent flow of moving fluid it is more intricate to find analytical solutions. Many researchers have been trying to find it as in Navier-stokes equation of fluid flow. One of the well-known expression of velocity flow profile for turbulent flow is power law velocity profile expression (equation 4.5) below:

$$V = V_{max}\left[1 - \frac{r^2}{R^2}\right]^{\frac{1}{n}} \quad \text{..... (4.5)}$$

where *n* is a coefficient which is a function of the Reynolds number.

From the above mentioned velocity profile expressed with tube radius and constant pressure drop along the direction of flow, the volumetric flow rate was formulated and defined as:

$$Q = -\frac{\pi R^4}{8\mu}\frac{dP}{dx} \quad \text{(4.6)}$$

where *Q* is volumetric flow rate, *R* is internal radius of tube, *dP/dx* is differential pressure drop along direction of flow and μ is dynamic viscosity constant. Volumetric flow rate is directly proportional to the four power of the radius of the tube and pressure drop. Here, to get the positive flow rate because in fact flow rate should be positive, the *dP/dx* term should be negative as the pressure drops along the direction of flow streamline.

3.13.2. Bernoulli's Equation (BE)

For some flows, it is possible to neglect the viscosity and focus on the pressure changes along a streamline, which is a line drawn through the flow field in a direction that is tangential to the velocity field. The Bernoulli equation can be used to investigate the relationship between pressures and velocities for such an ideal, incompressible flow along a streamline. This is particularly useful in situations with converging flows. Because the Bernoulli equation does not take frictional losses into account, it is not appropriate to apply the Bernoulli equation to the flow through long constant–cross section pipes, as described by Poiseuilli's law. The following restrictions apply to the BE.

- Flow is inviscid, there are no viscous drag forces;
- Heat conduction is not possible for an inviscid flow;
- The fluid is incompressible;
- The flow is steady (velocity pattern constant);
- The paths travelled by small sections of the fluid are well defined;
- Implicitly uses the Euler equations of motion (fluid flow description which makes use of velocity field and flow fields).

The equation, named after the Swiss mathematician, physicist, and physician, Daniel Bernoulli, is written as

$$P1 + \frac{1}{2}\rho V1^2 + \rho g z1 = P2 + \frac{1}{2}\rho V2^2 + \rho g z2 \quad \text{(4.7)}$$

where *P1* and *P2* are pressures at points 1 and 2, *V1* and *V2* are velocities at points 1 and 2 and *z1* and *z2* are heights at points 1 and 2.

3.13.3. Navier-Stokes Equations

The Navier–Stokes equations are nonlinear, second-order partial differential equations and they are considered to be the governing differential equations of motion for incompressible, Newtonian fluids (Waite and Fine 2007).

Conservation of mass: $div(V) = \nabla . \mathrm{V} = 0$

$$\frac{\partial u}{\partial x} + \frac{\partial v}{\partial y} + \frac{\partial \omega}{\partial z} = 0 \quad \text{(4.8)}$$

Navier-Stokes Equation:

$$\frac{D\,\mathrm{V}}{Dt} = \frac{\partial \mathrm{V}}{\partial t} + (\mathrm{V}.\nabla)\mathrm{V} = -\frac{1}{\rho}\nabla \mathrm{P} + \mathrm{v}\nabla^2 \mathrm{V} \quad \text{(4.9)}$$

where ρ is fluid density, $\frac{DV}{Dt}$ is material derivative of velocity vector, and ∇P is pressure gradient. Hence, the Navier-Stokes equation for flowing fluid in the (x, y, z) coordinates is:

$$\frac{\partial u}{\partial t} + u\frac{\partial u}{\partial x} + v\frac{\partial u}{\partial y} + \omega\frac{\partial u}{\partial z} = -\frac{1}{\rho}\frac{\partial \mathrm{P}}{\partial x} + \mathrm{v}\left(\frac{\partial^2 u}{\partial x^2} + \frac{\partial^2 u}{\partial y^2} + \frac{\partial^2 u}{\partial z^2}\right) \quad \text{(4.10)}$$

$$\frac{\partial v}{\partial t} + u\frac{\partial v}{\partial x} + v\frac{\partial v}{\partial y} + \omega\frac{\partial v}{\partial z} = -\frac{1}{\rho}\frac{\partial \mathrm{P}}{\partial y} + \mathrm{v}\left(\frac{\partial^2 v}{\partial x^2} + \frac{\partial^2 v}{\partial y^2} + \frac{\partial^2 v}{\partial z^2}\right) \quad \text{(4.11)}$$

$$\frac{\partial \omega}{\partial t} + u\frac{\partial \omega}{\partial x} + v\frac{\partial u}{\partial y} + \omega\frac{\partial \omega}{\partial z} = -\frac{1}{\rho}\frac{\partial \mathrm{P}}{\partial z} + \mathrm{v}\left(\frac{\partial^2 \omega}{\partial x^2} + \frac{\partial^2 \omega}{\partial y^2} + \frac{\partial^2 \omega}{\partial z^2}\right) \quad \text{(4.12)}$$

where ν is the kinematic viscosity, which is μ/ρ. This equation represents the mathematical expression of velocity profile of flowing fluid in the spatial coordinates (x, y and z) and with varying time. Specially for fluid moving with flow conditions other than laminar flow, there is movement in the other two coordinates because of formation of vortices and eddying. Thus, the fluid can move in the y and z directions while moving in the forward, x direction in case the fluid is flowing in the horizontal direction. Even though the significant amount of motion takes place along the direction of the driving force (pressure gradient), there are movements also in the direction of 2nd and 3rd plane coordinates. That is why velocity profile of the flow depends on the partial differential equations of the x, y and z along with time change. For laminar fluid flow, we cannot detect the crossing over of the streamlines, and formation of vortices as in turbulent flow. When it comes to fluid flow in circular cylindrical tube with cylindrical coordinates (r, θ, z) there would be radial movement of flow while moving in the forward direction. Considering incompressible and isothermal Newtonian flow with a velocity field of: $V = (u_r, u_\theta, u_z)$ cylinderical flow of fluid can be expressed as:

Incompressible continuity equation $\frac{1}{r}\partial\left(\frac{ru_r}{\partial r}\right)+\frac{1}{r}\partial\left(\frac{u_\theta}{\partial\theta}\right)+\frac{\partial u_z}{\partial z}=0$ ……..… (4.13)

The r, θ *and* z components of the cylindrical coordinates of flow of Navier-Stokes equation:

$$\frac{\partial u_r}{\partial t}+u_r\frac{\partial u_r}{\partial r}+\frac{u_\theta}{r}\frac{\partial u_r}{\partial\theta}-\frac{u^2{}_\theta}{r}+u_z\frac{\partial u_r}{\partial z}=-\frac{1}{\rho}\frac{\partial P}{\partial r}+g_r+v\left[\frac{1}{r}\frac{\partial}{\partial r}\left(r\frac{\partial u_r}{\partial r}\right)-\frac{u_r}{r^2}+\frac{1}{r^2}\frac{\partial^2 u_r}{\partial\theta^2}-\frac{2}{r^2}\frac{\partial u_\theta}{\partial\theta}+\frac{\partial^2 u_r}{\partial z^2}\right]$$ ……..…… (4.14)

$$\frac{\partial u_\theta}{\partial t}+u_r\frac{\partial u_\theta}{\partial r}+\frac{u_\theta}{r}\frac{\partial u_\theta}{\partial\theta}+\frac{u_r u_\theta}{r}+u_z\frac{\partial u_\theta}{\partial z}=-\frac{1}{\rho r}\frac{\partial P}{\partial\theta}+g_\theta+v\left[\frac{1}{r}\frac{\partial}{\partial r}\left(r\frac{\partial u_\theta}{\partial r}\right)-\frac{u_\theta}{r^2}+\frac{1}{r^2}\frac{\partial^2 u_\theta}{\partial\theta^2}+\frac{2}{r^2}\frac{\partial u_r}{\partial\theta}+\frac{\partial^2 u_\theta}{\partial z^2}\right]$$ …….. (4.15)

$$\frac{\partial u_z}{\partial t}+u_r\frac{\partial u_z}{\partial r}+\frac{u_\theta}{r}\frac{\partial u_z}{\partial\theta}+u_z\frac{\partial u_z}{\partial z}=-\frac{1}{\rho}\frac{\partial P}{\partial z}+g_z+v\left[\frac{1}{r}\frac{\partial}{\partial r}\left(r\frac{\partial u_z}{\partial r}\right)+\frac{1}{r^2}\frac{\partial^2 u_z}{\partial\theta^2}+\frac{\partial^2 u_z}{\partial z^2}\right]$$ ……..…… (4.16)

where $u_r$is the radial component of velocity, $u_\theta$is the azimuthal component and u_z is the velocity component in the direction along tube, ρ is density, μ is dynamic viscosity.

3.14. Safety Profiles of the Neonatal Resuscitator

Safety is important concern for all reusable medical equipment. Reuse of medical equipment is a multi-stage process that involves cleaning, sterilization and/or disinfection of the equipment. The designed resuscitator should appropriately pass through all these stages to ensure the safety of the patients and the caregivers. All the pneumatic parts of the device which have direct contact with airflow and face mask should be regularly and carefully reprocessed immediately after each use. First the device and all its accessories should be dismantled carefully and all surfaces must be cleaned using clean gauze or cloth for removing debris that could hinder successful sterilization. All relevant accessories should be rinsed in hot soapy water and dried, and a further sterilization should follow to attain high level disinfection. Sterilization can be done by using steam autoclave at temperature of 121^{o}C (for 30 minutes) or 132^{o}C (for 4 minutes). Other option is applying high level disinfection using heat-based method (boiling and steaming) and chemical-based method (chlorine solution 0.5% and activated glutaraldehyde 2.4%) by total immersion for a minimum for 20 minutes. Rinsing in hot clean water and drying after high level disinfection is important to remove chemical residues. Finally, the device must be reassembled and stored for further use.

CHAPTER FOUR

RESULTS AND DISCUSSION

The results from the different phases and methods implemented are presented and described in this section. Materials concerning the semi-structured interviews mentioned in this section is found in Appendix A.

4.1. Quality Function Deployment

The overall results obtained from the QFD/UCD should be restated in this section as what have been done can be revealed in this way. Bringing the approaches and deal with the results achieved through the lengthy and repetitive method is important to know how the QFD works and help in design decision making. The final result of the QFD matrix is illustrated in figure 4.1. The results from each step of the QFD method will be further described in detail as follows.

Step 1- Identify the customers

In this case the customers significant for this study were identified as the healthcare professionals working at Jimma University Medical Centre in neonatal ICU (NICU), paediatrics ICU (PICU), labour and delivery ward, adult ICU and biomedical engineering unit in the hospital. Accordingly, the following customers were identified and interviewed:

1. X1 - Male medical doctor and paediatric specialist who worked for 11 years in the healthcare.
2. X2 - Male medical doctor working in NICU who has more than four years of experience in healthcare and neonatal resuscitation and CPR.
3. X3 - Female neonatologist nurse who has been working in JUMC Neonatal ICU department and an expert in critical neonate resuscitation and oxygenation for 8 years.
4. X4 - Male Neonatologist nurse who have outstanding experience in resuscitation and bagging using Ambu bag for 5 years.
5. X5 - Male labour and delivery ward head and midwifery nurse at JUMC for the last 7 years.
6. X6 - Male midwife who has been working in the department of CS side delivery ward and has experience in resuscitating neonates immediately after birth.

7. X7 - Female nurse working in the department of surgical adult ICU for the last 3 years and has been working in the ward with the team to recover whenever a patient needs resuscitation and bagging.
8. X8 - Male senior biomedical engineering expert and department head for 4 years and working in maintenance team both on preventive and corrective maintenance.
9. X9 - Male biomedical service engineer working at JUMC centre for biomedical engineering.
10. X10 - Male nurse head at paediatric ICU for more than 8 years in JUMC who has great experience of helping babies breathe and CPR
11. X11 - Male paediatric intensivist medical doctor who has been working at JUMC for the last 5 years and has very vast knowledge on paediatrics and neonates.
12. X12 - Male biomedical service engineer in the centre for biomedical engineering in JUMC.

Step 2 - Determine the customers' requirements

The interview results from the participants were in good agreement with each other and indicated an evident demand for a new product with improved quality, functionality and usability. The answers from the interviews can be found in Appendix B. The experienced problems will be described in this section to provide an understanding of the current situation and highlight the problem areas. The described problems were analysed, clarified and translated into the following need statements:

4. Functionality
    - Operates at pressure of 30-45cmH_2O
    - Delivers 5-8ml per kg of neonates
    - Easy to control flow rate
    - Detect and prevent leakage
5. Structure
    - Fits with standard mask size
    - Easily fits to neonates positioning and bed alignment
6. Usability
    - Easily usable by one staff
    - Reusable bag and mask
7. Safety
    - Safely provides air for neonates
    - Cheap

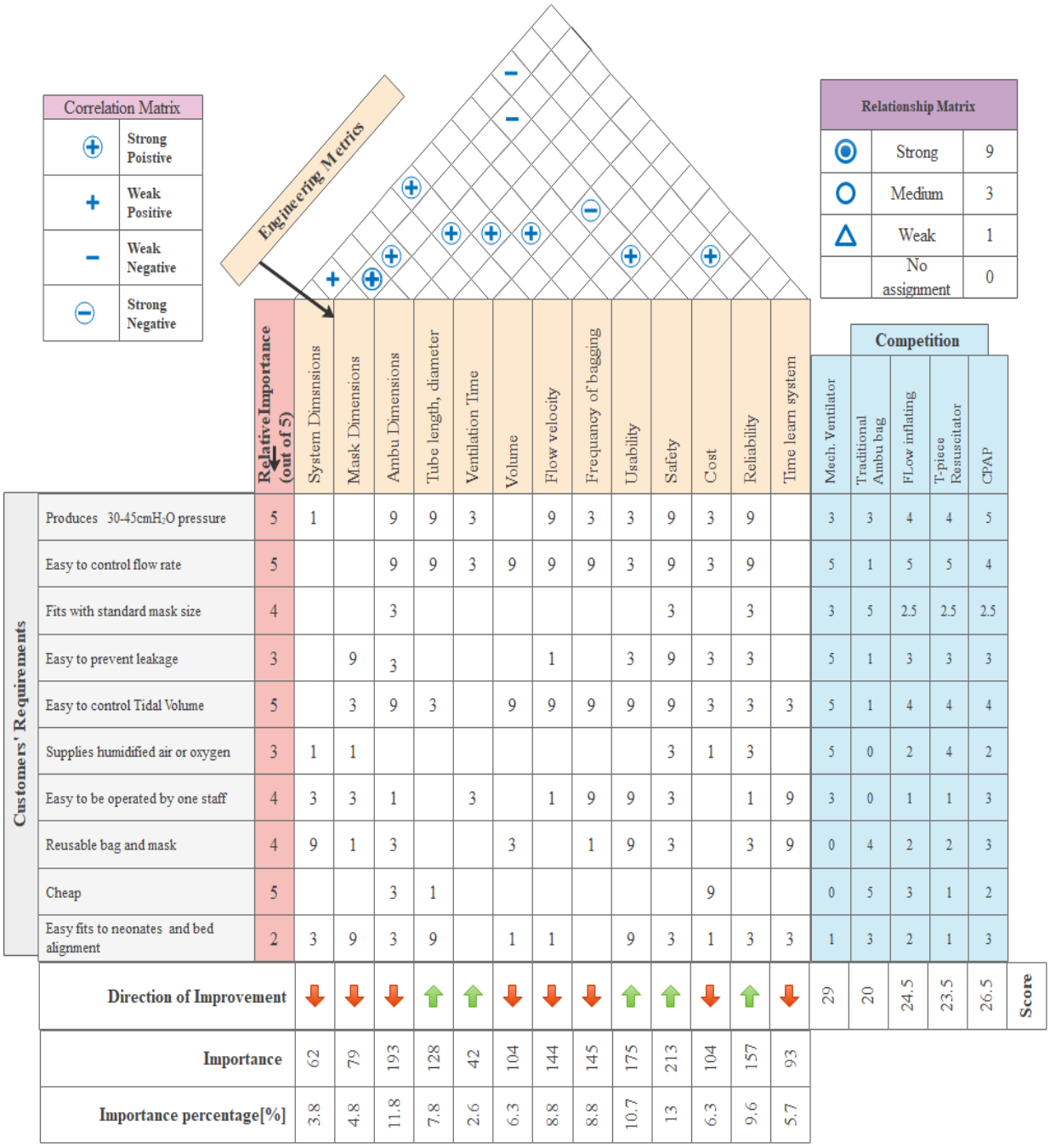

Figure 4.1: The result summary from the QFD/HoQ matrix developed step by step using EdrawMax 10.0.6 version.

Step 3 - Determine the relative importance of the requirements

The interview participants were contacted and consulted for the ranking process of the requirements. They rated the requirements on a scale of 1 to 5. The results from the different participants were in good agreement with each other so the average for each requirement was calculated and used in the QFD matrix.

Step 4 - Identify and evaluate the competition

For the competitive analysis, different literature study was conducted and available traditional Ambu bags were used. The Google searching engine was used for finding all available products on the market online. Different combinations of the following words were searched: resuscitation, inflation, ventilation, airflow, safe flow, neonatal, oxygenation, respiration, Ambu and mask. The available products presented for competition can be used for different purposes or have the same functionality with that of SIBs. The existing technologies identified for competition were included in evaluation and depicted in Figure 4.1 on the right column in the HoQ matrix. These were listed as:

1. Mechanical ventilator
2. Traditional SIB
3. Flow-inflating bag
4. T-piece Resuscitator
5. CPAP

Step 5 - Generate engineering specifications

The following engineering specifications were generated: ·

- System dimensions
- Mask dimensions
- Ambu dimensions
- Ventilation time
- Volume
- Flow Velocity
- Frequency of bagging
- Usability
- Safety
- Cost
- Reliability
- Time to learn system

Step 6 - Set up technical targets for the product

The results of the engineering specifications in relation to the customer requirements can be found in the centre of the QFD matrix on Figure 4.1.

Step 7 - Set engineering specification targets and importance

The result of the calculation of the specification importance is presented below, in descending order.

1. Safety
2. Ambu Dimensions
3. Usability
4. Reliability

5. Frequency of bagging
6. Flow velocity
7. Tube length, diameter
8. Volume
9. Cost
10. Time to learn system
11. Mask dimensions
12. System dimensions
13. Ventilation time

Step 8 - Identify relationships between engineering specifications

Three negative relationships between the engineering specifications were found and nine positives (for details see the roof of the house of quality on Figure 4.1).

4.2. Geometric Modelling

As depicted on Figure 4.2, the 3D view of the proposed design solution was developed by using a CAD software.

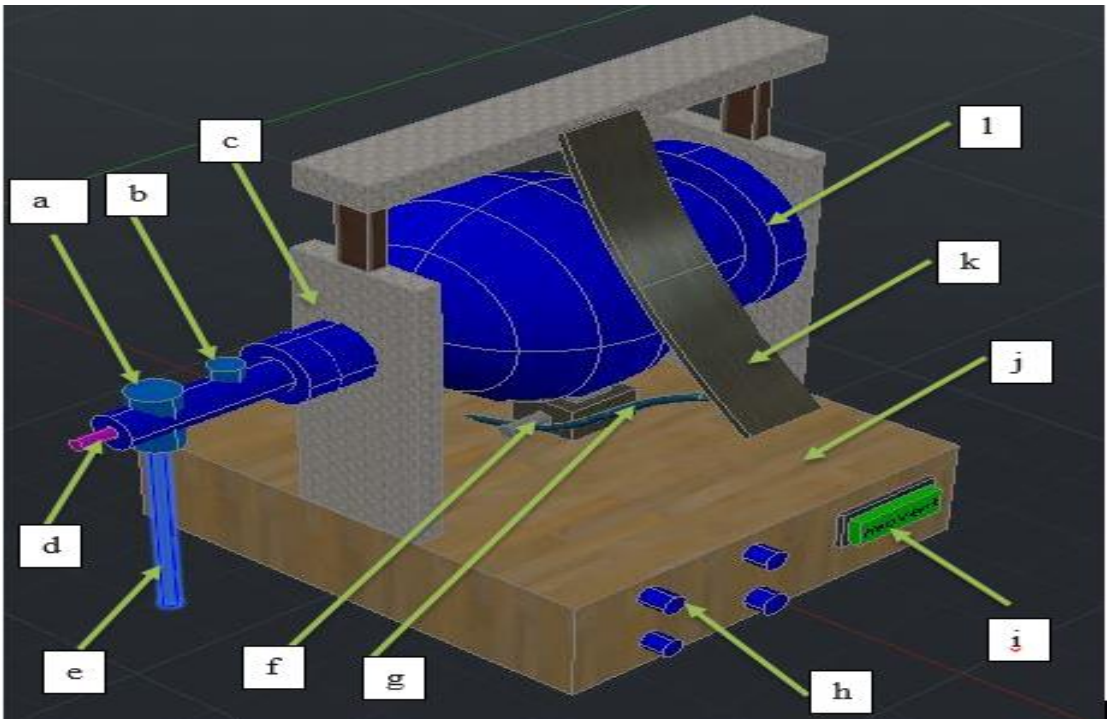

Figure 4.2: The CAD geometrical model of the system: a) manometer, b) pop-off valve, c) stand, d) exhaust, e) flow normalizing tube, f) stepper motor, g) connector cable, h) adjustment buttons, i) display, j) control panel, k) squeezer, and l) Ambu bag.

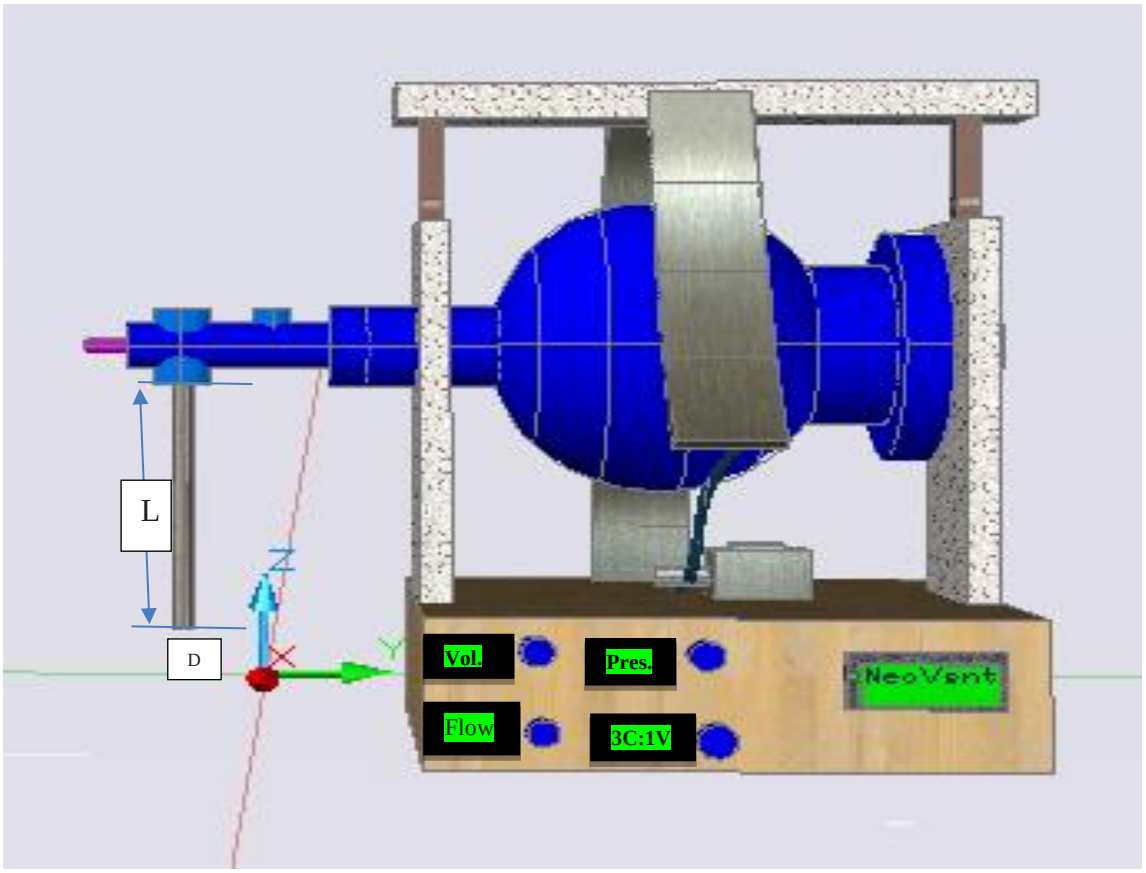

Figure 4.3: The NEOVENT™ control buttons and LCD display

As shown on Figure 4.3, the vertical, circular, long enough, rigid and uniform cross-sectional pipe added at the tip of the Ambu is to normalize and pass steady flow to the neonates. At the sufficient entrance length which is greater than its diameter, pressure drops constantly along the direction flow in the pipe. Figure 4.4 presents the proposed design viewed from four different directions.

The average standard self-inflating bag (Ambu) with the volume of 250ml was selected. It has barometer for pressure indication and pop-off valve to prevent over pressurizing the neonates, which gets relief once the pressure in the systems exceeds 45cmH_2O. The problem is there are only 2 SIBs with these features in JUMC to treat neonates in three rooms, which contains up to 17 neonates each, for the treatments. And the nurses and neonatologists do not use these devices appropriately during the procedures, which can result in negative outcomes for the patients. When we use the proposed device, such problems will not happen as everything was calculated and designed by considering the situations of the staff and each physical parameters were adjusted with the features of the system design. After inserting the infant's weight either

manually or automatically by reading from balance sensor, even if the staff may not well trained, s/he cannot inflate the patient beyond standard ranges.

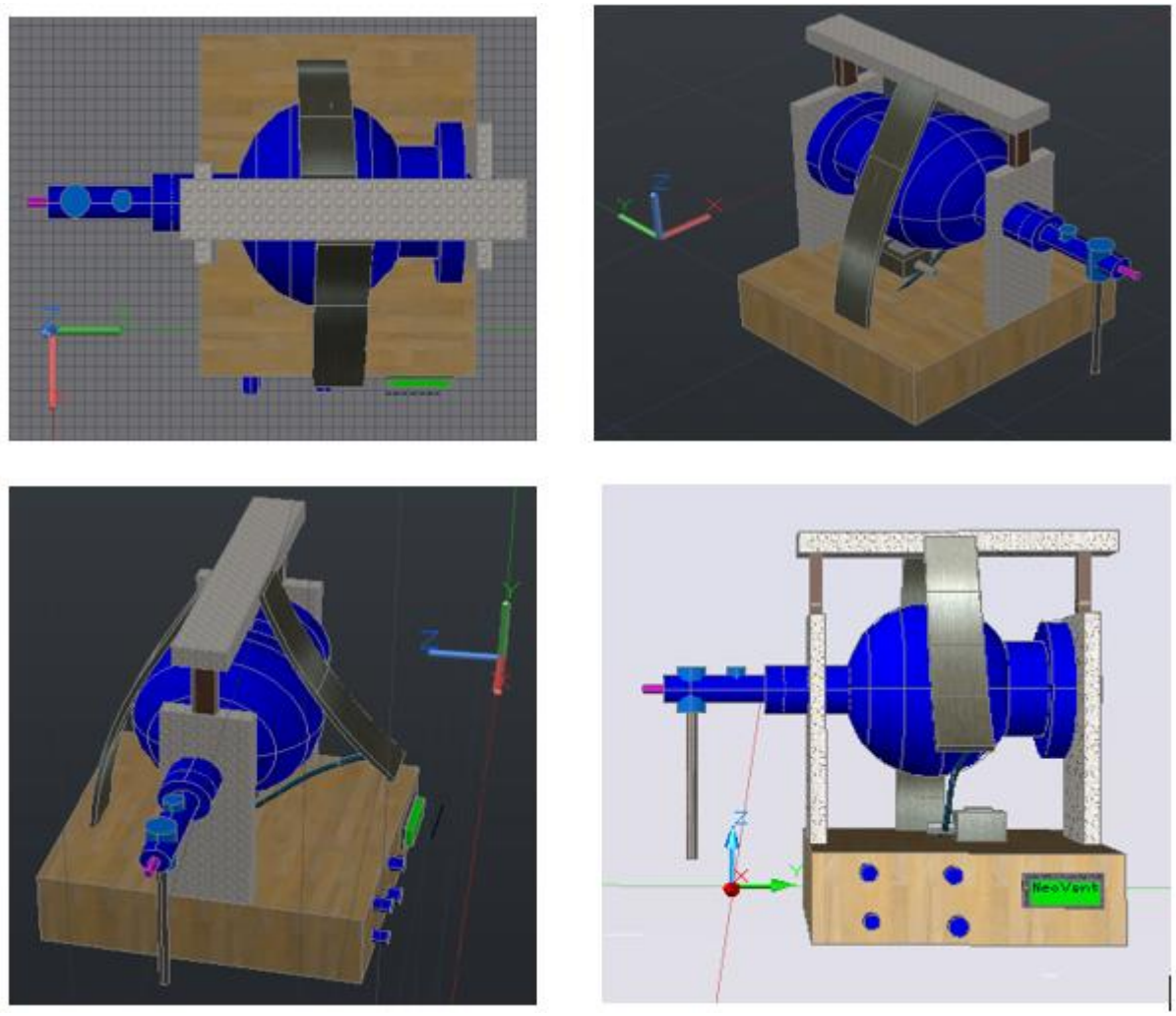

Figure 4.4: The design solution view from different angles

The general purpose of the current thesis work was to design a neonatal resuscitation device with improved features and modifications that simplified the hospital staffs' work and consequently could improve patient outcomes. The QFD approach was chosen because it was industrially proven to be beneficial and could be effectively realized with the given resources and time. QFD clarified the current solutions and their weaknesses and facilitated the development of a design that met the customer requirements. The method described the design problem systematically and formed the basis for the development of an improved design. User involvement was an essential and significant part of the QFD method and thus to this thesis project. The results from the QFD method indicated an evident demand for an improved product. During the second step of the QFD method, several comprehensive interviews were

conducted and served as the main fact collection method of this thesis. Several previous reports have emphasized the importance of using manual resuscitator to do CPR for neonates. However they also have shown that many of the safety issues, standard and usability issues undermines the products value (WHO 2016).

This fact was verified during the interviews and observations period at JUMC in the NICU ward. The safety issue is very significant and horrifying event when it comes to seeing the bleeding noticed through nose and mouth of neonates under CPRs, from which anyone can predict the immediate infant death. The other painful experience was on reporting. No one claims exactly why that specific infant died since everyone reports that the cause of death is the underline disease.

To mitigate these problems, the following two conditions must be shortly fulfilled: either having well equipped system and easily usable tool kits for CPRing infants or having well trained and committed professionals who can alleviate these problems by utilizing the limited resources and who can work under stressful conditions of the hospital wards. Treating neonatal patients by itself is very difficult task because of many reasons. The first one is that it is a tiresome task as the caregiver on duty handles alone many neonates the whole night or full day. The condition in JUMC, for example, reveals that one medical intern works in a ward full of more than a dozen critical neonates (up to 17 neonates in some cases). S/he should take vital signs of all infants frequently on a regular basis. As it was exposed during the deep observations, two to three hours pass before s/he reaches each infant. However, most of neonatal patients need critical follow up every 30 minutes. The other thing is they have no training on how to appropriately and safely resuscitate critical neonates. What they do is just putting the available BVM on face of a victim and flushing air in by looking at chest rise. Resuscitation doesn't mean just pushing air into the lungs of neonates (WHO 2016, LeCroy, CRTT and EMT 2014), but is a very delicate procedure which needs thoughtful training. The condition can be the same or even worse in the other developing countries. If not done carefully, it is a dangerous procedure to the life of immature lung and under developed cardiovascular system. The outcomes of such CPR procedures were clear- enormous bleeding that result in fatalities. The core requirement of the UCD approach is understanding users more than they understood themselves. The other critical and utmost important issue is understanding context of use and the environment through which the product functions. All the customer requirements were addressed in the final result; however, the results from the QFD indicated how much

effort and time should be devoted to each requirement. Since safety was the highest rated engineering specification, a lot of time and effort was dedicated to solutions that could affect the safety of the system positively.

4.3. Electrical System Simulations

The electrical system design was simulated using proteus 8 software. As shown in Figure 4.5, Arduino Uno, Stepper motor, temperature and humidity sensor (DHT22), breathing sensor (analogue simulation), weight sensor, SPO2 and heart rate sensor, pressure and flow sensors were used to simulate the design. All sensor readings are displayed on the liquid crystal display (LCD) of SIZE 20x4. Due to increasing number of the parameters controlled, the LCD has not displayed all the values at single shoot, therefore the reading values automatically scrolled on LCD to display the unseen parametric readings. Rotation of the stepper motor to inflate the Ambu bag depends on the breathing rate and TV value set by the care giver/nurse. For the simulation shown in Figure 4.5, the motor rotates in order to provide a breathing rate of 63 BPM. In addition to this, assuming that the weight of the neonate reading is 4kg, a tidal volume of 23 mL provided to the infant; which is based WHO standard mentioned in Table 4.1.

Table 4.1 Ambu SIB sizes standard along with neonatal weights (WHO 2016)

	Maximum	Majority (97%)
Infant weight	Less than 7kg	2.4-4.5kg
Optimum tidal volume	28-56mL	10-36mL
Average	42mL	23mL
Stroke volume needed with 45% leakage	63-126mL	22-80mL
Average	95mL	51mL

The other sensors will monitor the infants health condition based the analogue value received from the neonate. The temperature and humidity sensors, which will be attached on the inhalation circuit (tubing), will monitor the temperature and humidity value of the inhaled gas in degree Celsius and percentage, respectively. The SPO_2 and heart rate are measured in % and beat per minutes, respectively. Likewise, the pressure and flow rate of the air passing to the infant are monitored by cmH2O and ml/breath, respectively. Specific tidal volume for each

neonate is calculated from respective infant weights. By doing so, neonates under resuscitation progress will not be harmed by overinflating and/or low inflation.

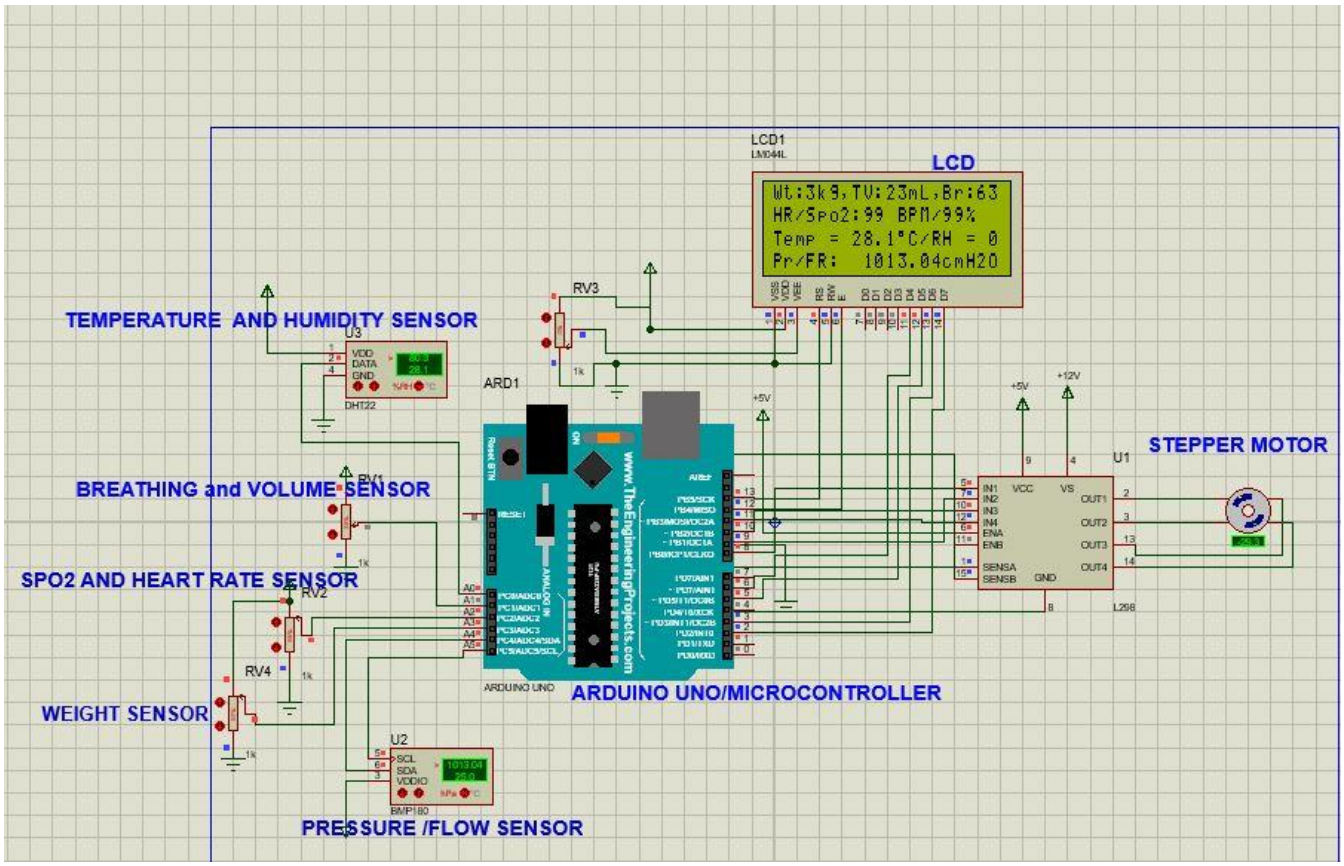

Figure 4.5: Electrical simulation for Arduino based stepper motor controller.

4.4. The Research Limitations

Involving the users in the development process had much importance. However, parts of the collected data through the semi-structured interviews and observations, and then the analysis made then must be considered as subjective. The results obtained from the assessment of the collected data are partially dependent on the users' knowledge, experience and skills. In some cases it is difficult to know exactly whether a problem with the apparatus derives from the poor user knowledge or from the device itself. Nevertheless, most of the errors, uncertainty and unreliability are due to inappropriate designs for user interaction by considering the users' conditions and context of use. The study is based on the selected users' understanding, but the ambition has been to dependably take into account this limitation. The compensation consisted of an open approach to negative results and an endeavour to cover a wide range of the participants' experiences. Therefore, further research is needed in some cases to explore and

include objectively measurable issues. All the interviewees' responses on the same question are almost the same and agree with each other pertaining requirements for a new technologies and approaches to alleviate the issues. Furthermore, most issues they raised regarding the mask size, Ambu size and parameters to be controlled are overlapped with that indicated by the WHO (WHO 2016). The other limitation with this study is that it only involved small samples from a single hospital and it might not exactly represent the whole issues and experiences with the same device being used by different personnel in the different environment and context of use. In spite of the market analysis made from the performed research, data obtained from the interview can be based on the devices used by the participants and the environment in which they had used. As a result of this, large study sample and participants from different hospitals and health facilities should be included to improve the study validation and product quality.

CHAPTER FIVE

CONCLUSION AND RECOMMENDATIONS

5.1. Conclusion

The results from the research and situational analysis indicated an apparent demand for a new product with improved quality, functionality and usability. The QFD-based UCD approach clarified the existing solutions and their drawbacks and supported the development of a new design that met the user requirements. All the customer requirements along with context of use were addressed in the final design solution results. In this case as in all engineering design solutions, safety was the highest rated engineering specification. Therefore, a lot of effort was dedicated to part of the solutions that could affect the safety of the system positively. The presented design solution can meet the customer needs and wants that has potential to improve the user experience. For instance, controlling tidal volume depending on the weights of neonates is vital feature of the design because it decides appropriate amount to be inflated to the respective patients. This was done by calculating distance of Ambu SIB to be compressed as shown on the simulation presented in this study. When the distance by which Ambu SIB squeezed increases, the tidal volume of ventilation increases proportionally. By doing so, the design can hopefully solve the problems of volutrauma (due to high TV) and brain damage (because of low TV and unsustained ventilation). The other important feature of the design is controlling pressure. This can be done by controlling speed and force by which the automated stepper motor squeeze the Ambu SIB. Volumetric flow rate is another parameter that should be controlled to perform safe resuscitation. According to CFD and concept of continuity equations, pressure and velocity of flowing fluid are inversely proportional. When the local cross-sectional area of the pipe is varying, the pressure and velocity of the flowing fluid is varying oppositely to compensate one another to fulfil the law of conservation of mass. As shown in the Poiseuilli's law, the flow rate (Q) is directly proportional to fourth power of the radius of the tube and pressure drop along the direction of viscous flow. This indicated that flow rate can be controlled by varying internal diameter of the circular pipe.

The final design solution is considered more reliable, safer and efficient than the existing technologies for neonatal resuscitation. Though the final design solution met the engineering specifications identified, however, the limitations mentioned in the previous chapter need extra considerations and further researches. Thus, before launching and manufacturing this product,

advanced researches around the area should be carried out. Testing and validating the final product are crucial to guarantee safety of patients.

5.2. Recommendations and Future Works

A new design of optimal neonatal resuscitator device can benefit infants mostly, and also hospital staff for ease of work burdens. An easily usable, safe and reliable neonatal resuscitation device lead to minimum complications during and after procedure, decrease the morbidity and mortality of the neonates, reduces hospital treatment costs and increase the confidence of the surrounding community to get treatment for their new-borns at the healthcare settings. Although the final design solution is hopefully reliable, sustainable and safe, new technology may come with unpredicted risks and issues. Consequently, a solid risk analysis and extra consideration should be performed for justification of the potential benefits over the potential risks. Medical device regulatory bodies and relevant directives should be consulted before manufacturing and using the life-saving device. Generally, further safety issues, choice of best materials, risk and cost analysis and performing research from national perspective for requirements identification and context of use of the Ethiopian health professionals should be deeply considered before manufacturing a new product. The manufactured device should be validated from relevant perspectives and get national accreditation from national regulatory bodies and also conform international safety regulations for life saving medical equipment.

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APPENDIX A - INTERVIEWS

Interview questions for nurses/doctors

Personal data

1. What is your name and what department are you working on?
2. What is your position?
3. How long have you worked in health care?

Use

1. What resuscitation (air delivering) devices do you use in your department?
2. When do you use them?
3. What profession are those who use the system?
4. Is a person responsible for the system?
5. What factors determine the use of the system?
6. What gas used for the system?
7. Is it always in the emergency room?

Functionality

1. Which gas do you use most often? When do you use oxygen reservoir?
2. How often do you squeeze the device with different mask size? Is there a warning for squeezes?
3. What should you consider? What are the risks? Infection Risk?
4. Do high pressure and volume are major risks? How dangerous are they?
5. If there is no system for regulation of the volume and pressure?
   . How do you know volume of flow?
   . How do you regulate pressure?
   . How do you regulate flow rate?
6. How do you clean the system?
7. Do you use always three mask sizes?

Evaluation

1. If there is hyperventilation or high pressure, how do you know?
2. How do you control the optimal respiration rate?
3. What other possible problems do you see with the system?
4. If you used different systems, which do you prefer?
5. Do you see any opportunities for improvement?
6. What factors might facilitate your Job?

……..Thank you very much, indeed

Interview questions for the biomedical engineers

Personal data

1. What is your name and what department are you working on?
2. What is your position?

Use

1. What plenum performing maintenance work on?
2. How often is the maintenance of this product?
3. How do maintenance to?
4. What is your experience of working with the plenum?
5. What problems are common during maintenance work?

Evaluation

1. How is it to clean?
2. Are there any difficulties or unnecessary elements in the maintenance of this product?
3. What nurses say about the system, what they complained about?
4. What do you think about an automatic solution?
5. What factors might make your job easier?
6. What opportunities for improvement do you see?

……..Thank you very much, indeed

APPENDIX B - SUMMARY OF THE INTERVIEW RESULTS

The summary of the semi-structured interviews performed in the departments of NICU, PICU, ICU, labour ward and centre of BME at JUMC are listed below. These identified problems are

- No way to control pressure of flow
- No way to control volumetric flow rate
- No way to control volume (Tidal volume, Tv)
- Lack of appropriate mask and bag size
- Lack of sufficient resuscitation tool kits
- Lack of staff training(staff assigned to the NICU and PICU wards randomly, without training how to do neonatal resuscitation)
- Difficult to know occurrence of hyperventilation
- Problem of pneumothorax occurrence
- Amount of flow, sustainability and continuity of flow depends on the experience and commitment of the operator and vulnerable to the operator error
- Respiration rate depends on manual counting down by users
- Luckily nasal and oral bleeding happen during or after bagging (also perceived during observation)
- Lack of feedback mechanism during resuscitation
- High death rate of resuscitated neonates(less than 10% positive outcomes)|
- The leakage problems and no leakage detection mechanism
- Deciding that inflation by only chest rise observation, which is susceptible to chest rise-low inflation error which will result in negative patient response/outcome
- There is no machine for CPR and the procedure needs need body fitness (from adult ICU interviewees)

APPENDIX C - THE ELECTRICAL SIMULATION ARDUINO CODE

```
/* Stepper Motor Control */
#include <LiquidCrystal.h>
#include <Stepper.h>
#include "DHT.h"
#include <SFE_BMP180.h>
#include <Wire.h>

// We need to create an SFE_BMP180 object, here called "pressure":

SFE_BMP180 pressure;

double baseline; // baseline pressure
//
//SCROLLING THE PARAMETRIC READING TO THE LEFT
int Li         = 20;
int Lii        = 0;
//int Ri         = -1;
//int Rii        = -1;

//END SCROLLING

//#define DHTPIN 2
int DHTPIN = A0;
// Digital pin connected to the DHT sensor
// Feather HUZZAH ESP8266 note: use pins 3, 4, 5, 12, 13 or 14 --
// Pin 15 can work but DHT must be disconnected during program upload.

// uncomment whatever type we're using!
//#define DHTTYPE DHT11   // DHT 11
#define DHTTYPE DHT22   // DHT 22 (AM2302), AM2321
DHT dht(DHTPIN, DHTTYPE);
char temperature[]  = "Temp = 00.0 C";
char humidity[]     = "RH = 00.0 %";


int B  = A1;// Breathing rate and volume (tidal volume)  sensor pin
int SPO2 = A2;//spo2 and Heart rate sensor pin
int W = A3;// weight sensor pin
int previous = 0;
// initialize the library by associating any needed LCD interface pin
// with the arduino pin number it is connected to
const int rs = 13, en = 12, d4 = 6, d5 = 5, d6 = 3, d7 = 2;
LiquidCrystal lcd(rs, en, d4, d5, d6, d7);

const int stepsPerRevolution = 90;
// change this to fit the number of steps per revolution
// for motor
// initialize the stepper library on pins 8 through 11:
Stepper myStepper(stepsPerRevolution, 8, 9, 10, 11);

void setup() {


  lcd.begin(20, 4);
  pinMode(DHTPIN, INPUT);
  pinMode(B , INPUT);
  pinMode(SPO2, INPUT);
  pinMode(W, INPUT);

  // Initialize the sensor (it is important to get calibration values stored on the device).

  if (pressure.begin())
    Serial.println("BMP180 init success");

  else
  {
    // oops!, see the comments at the top of this sketch for the proper connections.

    Serial.println("BMP180 init fail (disconnected?)\n\n");
    while(1); // Pause forever.
  }
     baseline = getPressure();
```

```
  Serial.print("baseline pressure: ");
  Serial.print(baseline);
  Serial.println(" cmH2O");

   // set the speed of the motor at 400 rpm:
   myStepper.setSpeed(400);
   // initialize the serial port:
   Serial.begin(9600);
// set up the LCD's number of columns and
rows:
   lcd.begin(20, 4);
   dht.begin();
}

void loop() {
  //get the sensor value
   // Wait a few seconds between
measurements.
  delay(200);
// Read humidity
  int RH = dht.readHumidity() * 10;
  //Read temperature in degree Celsius
  int Temp = dht.readTemperature() * 10;

  // Check if any reads failed and exit early
(to try again)
  if (isnan(RH) || isnan(Temp)) {
    lcd.clear();
    lcd.setCursor(5, 0);
    lcd.print("Error");
    return;
  }
 if(Temp < 0){
    temperature[6] = '-';
    Temp = abs(Temp);
  }
  else
    temperature[6] = ' ';
  temperature[7]   = (Temp / 100) % 10  +
48;
  temperature[8]   = (Temp / 10)  % 10  +
48;
  temperature[10]  =  Temp % 10 + 48;
  temperature[11]  = 223;        // Degree
symbol ( °)
  if(RH >= 1000)
    humidity[6]    = '1';
  else
    humidity[6]    = ' ';
  humidity[7]      = (RH / 100) % 10 + 48;
  humidity[8]      = (RH / 10) % 10 + 48;
  humidity[10]     =  RH % 10 + 48;

  B = analogRead(A1);
  int BR = 100 - (B/10.2); //Breathing rate
for simulation
  int TV = B/10.2; // tidal volume; it is
depends on the infants weight
  SPO2 = analogRead (A2);
  SPO2 = 100 - (SPO2/10.2);
  int HR = 100 - (SPO2/10.2);// SPO2=
HR; //Using the SPO2 pin for HR; just for
Analog demonstration
  W= analogRead(A3);//W= weight in Kg
  W= 100 - (W/10.2)+1;
  if(W >=2.4 && W<=4.5){
    TV = 23;
  }
  else if (W >4.5 && W <7){
    TV = 42;
  }
  else{
    TV = W*7;
  }
  //lcd.clear();

  lcd.setCursor(0,0);

  //lcd.println("BR/Wgt/TV:");

lcd.println(Scroll_LCD_Left("Wt:"+(Strin
g)W+"kg" ","+"TV:"+(String)TV+"mL"
","+"Br:"+(String)BR+"BPM"));
  lcd.setCursor(0,1);
  lcd.println("HR/Spo2:"+(String)HR+"
BPM" + "/"+(String)HR+"%");
  lcd.setCursor(0,2);
  lcd.print((String)temperature+
"/"+(String)humidity);
  lcd.setCursor(0,3);
  lcd.println("Pr/FR:");

lcd.print((String)baseline+"cmH2O"+"/"+(
String)(baseline-100)+"ml/sec");

  //move the number of steps equal to the
change in the sensor reading
    // step one revolution in one direction:
//   Serial.println("clockwise");
    myStepper.step(BR-previous);
```

```
   delay(100);
   // step one revolution in the other
direction:
  // Serial.println("counterclockwise");
   myStepper.step(-(BR-previous));
   delay(100);

   // remember the previuos value of the
sensor
   //previous = BR;
}

///
double getPressure()
{
  char status;
  double T,P,p0,a;

  // we must first get a temperature
measurement to perform a pressure
reading.

  // Start a temperature measurement:
  // If request is successful, the number of
ms to wait is returned.
  // If request is unsuccessful, 0 is returned.

  status = pressure.startTemperature();
  if (status != 0)
  {
    // Wait for the measurement to
complete:

    delay(status);

    status = pressure.getTemperature(T);
    if (status != 0)
    {
      status = pressure.startPressure(3);
      if (status != 0)
      {
        // Wait for the measurement to
complete:
        delay (status);

        status = pressure.getPressure(P,T);
        if (status != 0)
        {
          return (P);
        }
        else Serial.println("error retrieving
pressure measurement\n");
      }
      else Serial.println("error starting
pressure measurement\n");
    }
    else Serial.println("error retrieving
temperature measurement\n");
  }
  else Serial.println("error starting
temperature measurement\n");
}
String Scroll_LCD_Left(String
StrDisplay){
  String result;
  String StrProcess = "                " +
StrDisplay + "                ";
  result = StrProcess.substring(Li,Lii);
  Li++;
  Lii++;
  if (Li>StrProcess.length()){
    Li=20;
    Lii=0;
  }
  return result;
}
void Clear_Scroll_LCD_Left(){
  Li=20;
  Lii=0;
}

//// "If we cannot help neonates breathe, at least we should not

////harm them"- Copyright © 2021, Gamada Abara


////END!
```