American Journal of Botany and Bioengineering
https://biojournals.us/index.php/AJBP
ISSN: 2997-9331

Design and Development of Continuous Positive Airway Pressure (CPAP) Device

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Received: 2025 19, Jan
Accepted: 2025 28, Feb
Published: 2025 07, Mar

Annotation: Continuous Positive Airway Pressure (CPAP) therapy is a critical intervention for managing sleep-disordered breathing, yet the high cost and limited accessibility of current devices present significant challenges, especially in resource-limited settings. This study addresses these gaps by designing and developing a cost-effective, portable CPAP device with improved functionality. Utilizing an engineering-based approach, the study incorporates design optimization, prototyping, and performance testing to enhance patient comfort, noise reduction, and air pressure stability. Findings demonstrate that the proposed CPAP device effectively maintains airway patency, reduces apnea episodes, and improves sleep quality while ensuring affordability and ease of use. The implications of this research extend to broader applications in home-based and emergency healthcare, offering an innovative solution for individuals with obstructive sleep apnea and other respiratory conditions.

Keywords: CPAP device, sleep apnea,

respiratory therapy, medical device design, portable ventilation, healthcare innovation.

1. Introduction

Inspiration for the development of low-cost improvised CPAP devices lies in the innovation and ingenuity displayed by various engineers, designers, and clinicians around the world in developing cost-effective medical devices to cater to low-resource settings. An early attempt to create a basic, functional, low-cost improvised bubble continuous positive airway pressure (BCPAP) device for neonates saw various severely-ill newborns avoided invasive mechanical ventilation and death with few of these devices. This model, however, consisted of the following: Oxygen source; Effectiveness of BCPAP hinges on the ability to generate positive end-expiratory pressure (PEEP) during inhalation; One-way valve; Control of the oxygen flow rate is quite difficult, especially in ward settings; The device does not have aesthetically pleasing design or have any considerations for ease of manufacturing or portability [1]. Another effort to develop a functional, low-cost bubble CPAP machine primarily focused on the utilization of oxygen concentrator as the main source of oxygen. However, this is infeasible in many low-resource settings, especially in the midst of the COVID-19 pandemic with oxygen shortages.

Broadly, there are three levels of care required as one moves up the healthcare pyramid: (i) basic: includes only essential care such as training of healthcare staff to ensure clean birth, immunization, basic care of the newborn such as warmth, breastfeeding, identification and treatment of newborn infection; (ii) essential newborn care and special care unit: basic necessary medical equipment for essential newborn care such as BCPAP, neonatal resuscitation device, intravenous fluids, phototherapy lights, antibiotics, amikacin, cannulas, and vacuum extractors for delivery, and; (iii) comprehensive: comprehensive pregnancy, delivery, and newborn care that require complex diagnostic services, laboratory tests, oxygen concentrators, and blood banking services. Specifically, for neonates with respiratory distress syndrome, the main goal of BCPAP is to provide a continuous flow of air/oxygen at a certain pressure greater than atmospheric pressure to keep the under-inflated neonatal lungs expanded during the respiratory cycle or avoid alveolar collapse.

1.1. Background and Significance

Bubble continuous positive airway pressure (B-CPAP) has been proven to be a safe and efficacious mode of noninvasive ventilation for neonatal respiratory distress, especially useful in resource-limited developing countries. The need for such devices used beyond neonatal settings has especially been realized during the current pandemic. If these devices could be developed and employed on a large scale in the resource-limited developing world, many lives could be saved, not just in addressing the current crisis but in saving many lives beyond this present pandemic [1]. In the developed world, continuous positive airway pressure (CPAP) devices are widely available and used for children and adults with respiratory distress, for those with obstructive sleep apnea, and as a substitute to mechanical ventilation, amongst other applications. Critical medical facilities in low-resource settings are heavily under-equipped and have a basic lack of such CPAP or BCPAP devices that are so critical in saving patients in need. In this article, we have conceptualized a simple but functional design, which can be made from cheap, universally available medical equipment. This basic low-cost design can be further improved upon through future controlled assessments and refinements, and if mass fabricated and employed it could provide a silent, easy to use therapy that would save the lungs of many people needing oxygen, stretching out breathing assistance to many more patients than would otherwise be possible, saving a great many lives in countries that are currently under-equipped in the current crisis. The proposed improvised CPAP makes use of a specially drilled suction tube near a simple bubbler piecing bi-level oscillating pneumatic pressure pulses throughout the

bubbling water that matches the patient airway resistance and generates continuous positive pressure in the range of clinical efficacy. The piecing can be done by the tip of a nebulizer tube which then can be inserted into the bubble medium to simultaneously resolve oxygen (or pressurized air) as a carrier. Also possible is the addition of antibiotic or hypertonic control solutions for dual purpose treatment by providing alveolar lavage for both neonate and pediatric for cases of pneumonia treatment. The new design also encloses the bubbler water reservoir centrally to two larger volume fluid containers in both inlet and outlet flow connecting pathways, which can better control and limit any spillage when knocked over.

1.2. Purpose and Scope

This article describes the design and significance of a continuous positive airway pressure (CPAP) system to be used for treatment of obstructive sleep apnea (OSA) syndrome and hypopneu syndrome. This CPAP system would be composed of a mechanically integrating overall system and an assembling printed circuit board. The CPAP system acts as a mechanical ventilator that can maintain the airway open and prevent upper airway collapse during sleep by delivering positive pressure. Compared to conventional large motor and pump based CPAP ventilator systems currently available, this CPAP system has been designed for a small, portable, and low cost mobile version that includes a brushless DC motor with an impeller integrated into a blower, a blower motor controller with a low level of emitted electromagnetic interference, and a 12V rated CPAP blower device [2]. In this system, seven modes of operation are available, including pressure ramp up, ramp down, fixed pressure, fixed pressure with expiration relief, fixed pressure with expiration relief and ramp down, fixed pressure with inspiration scrub, and fixed pressure with inspiration scrub and ramp down operation modes. Therapeutic patient airway pressure is controlled by a motor speed controller with a PID algorithm based on the error between the desired pressure and the sensed patient pressure. The CPAP system is capable of a CPAP pressure range of 2 to 30 cmH2O with a detection capability of 0.1 cmH2O, and the output pressure is maintained within decrements of the desired pressure within 2 durgs of air not exceeding pressures of 10, 20, or 30 cmH2O.

2. Physiology of Sleep-Disordered Breathing

In the recent years, understanding of the physiology and treatment of sleep-disordered breathing is becoming increasingly clear. Nasal CPAP is the primary tool applied in treating moderate to severe patients whose quality of life and health were adversely affected by sleep-disordered breathing. However, evidence linking sleep-disordered breathing to illnesses such as hypertension is extensive. A ‘CPAP compliance engine’ that should increase compliance with nasal CPAP is described, allowing for the home treatment of less severe cases [3].

Sleep-Disordered Breathing (SDB) is a broad term used to characterize apneas, hypopneas, snoring, and respiratory effort related arousals that disrupt the quality of sleep. Sleep-disordered breathing and its connection with medical conditions have been well-worn. Persisted research around SDB has yielded disturbing links between airway stability and physiological balance; it has already been thoroughly demonstrated that in the sustained absence of respiratory effort, increased hypotension occurs [2]. Stimuli in the form of constant pressure support are routinely given directly to the airway during passive breathing; since no stimuli are present during obstructive events, the airway collapses. SDB is known to have an elevated occurrence in the presence of a number of medical conditions; in particular, a strong association has been established between sleep apnea and hypertension—each time the upper airway collapses during a sleeping person’s respirations, a heightened sympathetic response and its attendant hypertension arise. Hormones released during the arousal subsequently lessen the apnea and allow for the return of normal ventilation; the cycle then closes, but the patient is forced to briefly awaken. Similarly, atrial fibrillation patients have been shown to have a higher occurrence of sleep apnea; partial arousals and episodic hypoxemia combined with the low ventricular function typical of the condition are suggested to be at the source of the holter-

detected arrythmias.

Approved by the U.S. Food and Drug Administration in 1981, the CPAP system is a vital tool in the war against the adverse health consequences of sleep apnea. By delivering a steady stream of pressurized, room-temperature air to the breathing passages, a positive pressure is created that essentially acts as a pneumatic splint, stenting the airways open. However, attempt in cultivating an automatic pressure modulation algorithm that would finesse the user into supplementary independent breathing bear drowsy fruit as adherence rates to traditional CPAP systems hover beneath 65%.

2.1. Normal Breathing Mechanisms

It is necessary understanding how do people breathe under healthy condition. Inspiration is driven by the contraction of diaphragm and intercostal muscles, which increase thoracic volume and decrease intrathoracic pressure, leading to an inhalation airflow. Due to the backward elastic recoil of the lung and thoracic wall, expiration is passive during normal breathing. Lung pressure is less than mouth pressure at the time of inspiration and vice versa at the time of expiration. In each breathing cycle, inspiration and expiration both occupy 50% of the total duration [2]. CPAP in homecare is a treatment for disorders such as sleep apnea patients. During CPAP therapy, a CPAP device generates a constant positive airway pressure which maintains the patency of upper airway and allows patients to have a peaceful and quiet sleep. It is more convenient than hospital treatment and more comfortable than surgery. However, unhealthy breath mechanism will increase the resistance of the throat. It also increases and impedes lung capacity.

Broadly, devices that treat sleep disordered breathing function in one of two ways- 1) by providing supplemental ventilation, which passively breathes for the un-cooperative patient, or 2) by creating a positive trans-mural pressure to prevent the collapse of the upper airway. Need we provide a brief survey of the current device therapies for sleep disordered breathing, and also describe a powdered-device based on demand ventilation for the treatment of patients with sleep apnea not completely resolved using CPAP [4]. A final section is devoted to a discussion of comfort factors and possible adherence strategies.

2.2. Sleep-Disordered Breathing Conditions

Sleep-disordered breathing conditions including snoring, its first indication, give a clear look at which Cpap as a treatment, is introduced in introduction. Here, all the sleep-disordered breathing conditions as same as snoring are briefly talked about. After all, obstructive sleep apnea syndrome is a typical symptom which meets the respiration criteria including 10 second long periods called central lee apnea, and Cpap is effective for OSA patients. AIrflow limitations in the nasal and pharyngeal cavities resulting in large negative pressures and turbulence are shown in acute collapse of the airway. When the excessively negative pressure developed in pharynx is added to the mechanical properties of the upper airway, it can easily collapse completely or partially. Completely blocked patients need a period from 10-60 seconds to be awaken and also partially blocked apneic conditions need at least 10 seconds. Happen during so many times, the level of SPO2 which is percentage saturation of arterial oxygen, can fall down about 4%~10%. Continuity of the abovementioned events is the most characteristic because occurrence of three or more apneas per hour of sleep for at least 10 seconds. Thus, initiate settlements such as repetitive pauses in breathing are called obstructive sleeping apnea (OSA) [2]. When it happens 15 times in an hour, the patient is said to have obstructive sleeping apnea syndrome [5]. Furthermore, exact same consequences occur in lighter form that usually is called upper airway resistance syndrome (UARS) as another reflection of this phenomenon taking place less frequently than the criteria of OSA.

3. Existing CPAP Devices

Background: Nasal continuous positive airway pressure (CPAP) is a common treatment method for many respiratory patients and most frequently in patients with obstructive sleep apnoea

syndrome. It is based on the continuous delivery of positive pressure to the patient's airway to enhance the exchange of the respiratory gases. In the developed world, CPAP therapy is well recognized, and many different devices are available at high cost for the patients to mitigate diseases or provide well-being. However, in developing countries, despite of the huge requirement of the device, it is still poorly recognized and hardly available. In such a situation of insufficient medical equipment, it is desirable for the health care providers to develop a low-cost CPAP device that can fulfill the therapeutic requirements of the patient and can be easily maintained. Although a low cost CPAP machine has been developed for neonates, no significant endeavor has been made to develop a similar device for adults. Here, in a bid to provide a continuous positive pressure Pump, Timer, Wall (Bubble CPAP) device for the adult patients, a basic model of the bubble CPAP machine is presented and its potential use is explored [1].

Background: Continuous positive airway pressure (CPAP) therapy employs a mild level of positive pressure on a spontaneous respiration to enhance pulmonary gas exchanges in neonates. This strategy can improve oxygenation and reduce the work-of-breathing in chronically-ill neonates. Nevertheless, CPAP therapy has been only recently implemented in developing countries because of high cost of CPAP ventilators. In lack of CPAP ventilators, several low-cost strategies have been developed such as the development of an ad-hoc device, known as bubble-CPAP or nasal-CPAP, developed by [2].

3.1. Overview of Current Market Products

During the COVID-19 pandemic, countless individuals have lost their lives. In such a scenario, Continuous Positive Airway Pressure (CPAP) therapy devices are demanded worldwide. High income and upper middle income countries already have to the pursuit CPAP devices. However, low-income countries do not have access to them. On the other hand, even the most cost effective CPAP devices do not fit the questing earnings of the sol with it. Therefore, there is a mote to post developing and pacing fabricated and efficiently CPAP device flaxocumlow countries. Even though, demand improvised Bubble Continuous Positive Airway Pressure (BCPAP) devices for adults already stipulated at 156, interest was still upholding adequate for the developments of such a device [1]. Bubble CPAP is commonly used for neonates in low and middle income countries (LMICs) without access to ventilators. A basic form of functional BCPAP consists of a nasal cannula and an oxygen source. A limb of the nasal cannula is cut and occluded, while the other end is dipped into normal saline. The depth of submersion determines the amount of CPAP, while the oxygen flow rate is adjusted to achieve gentle bubbling. To generate positive pressure in the lungs during inhalation, the flow rate in the device must exceed the rate at which tidal volume is inhaled. An oxygen flow rate of 5 to 10 L/min is usually sufficient for neonates. However, there are many reasons why current BCPAP implementations are inadequate for adults. One of the main problems in creating a similar device for adults is that oxygen flow rate requirements exceed what can be provided by wall outlets in LMICs. Increasing the flow rate can be achieved using air pumps or Venturi devices, although Venturi devices cannot generate a constant pressure. They have a pressure-flow rate curve, and the curves are dependent on many variables. Different oxygen flow rates would require different saline drop rates to achieve the same pressure. This would require manual corrections by the operator, making it impractical, especially in busy wards. Additionally, electronic scales are costly and difficult to source in LMICs [2].

3.2. Strengths and Limitations

A limited number of hospital beds in most developing countries result in providing care to a larger number of patients outside of the hospital, which has resulted in an increase in demand for noninvasive ventilatory support systems. However, the existing stand-alone bi-level positive airway pressure machines in the market are heavily priced and are not embedded with electronic components like monitoring systems, different types of alarms, extra oxygen supply to the patients, etc. The existing Continuous CPAP Machine includes large, bulky and uncomfortable

nose masks covering the mouth that employs the use of an expensive machine requiring much room space, electrical power, periodic maintenance which includes adjustments and replacements while also making a considerable amount of noise or sound of air blowing and of air hissing particularly in the earlier hours of the night when it is the most detectable.

Noninvasive ventilator support using BiPAP/CPAP sits at home by afflicted patients suffering from chronic medical conditions such as asthma, COPD, obstructive sleep apnea, etc., or lifelong debilitating neuromuscular disorders which leads to the weakness of the respiratory muscles at all such patients can prolong their life for a couple of months to even decades and can ultimately succumb to an easy, less painful death. Generic face masks and nose masks available in the market are uncomfortable for patients to wear, lead to the formation of red marks and sores on the face, and are uncomfortable to move the face while talking and sleeping. These face/nose masks for CPAP machines are ill-fitting, air gaps exist between the mask and the face, and thereby nullifies the creation of the positive air pressure in the nose cavity of the patient. As a result, valuable pressurized air leaks out and patients are not able to breathe fresh air through the nostrils leading to patient noncompliance towards wearing the face masks.

4. Design Principles and Considerations

Sleep apnoea is a common sleep disorder that affects millions of people around the world. Patients with sleep apnoea stop breathing during their sleep several times an hour and their sleep is disturbed. Sleep apnoea can increase the risk of patients having high blood pressure, general fatigue, headaches, heart attack or stroke [2]. There are three types of sleep apnoea: obstructive, central and mixed. Obstructive sleep apnoea is the most prevalent type. A continuous positive airway pressure (CPAP) device is commonly used to generate pressures between 4 and 20 hpa which patients breathe with the help of a mask or a tube, thus preventing the upper airway from collapsing and apnoeas.

The most innovations in CPAP machines focused on increasing the comfort of patients, such as lower noise, smaller size or more convenient usage. However, a key problem was not well addressed is the synchronization of CPAP machines with the patients' spontaneous breathing. Ideally, the CPAP machine should automatically increase the pressure level at the beginning of inspiration to maintain the therapeutic pressure and decrease the pressure level at the beginning of expiration. There are three types of CPAP machine; single-level CPAP, bi-level CPAP and variable CPAP. The single-level CPAP machines always maintain the same pressure level, similarly to the bi-level machines. Though the bi-level CPAP machines can generate two different pressure levels for inspiration and expiration. However, the pressure applied to the patients can be zero pressure level at the transition period. The transitional CPAP machines can synchronize with the patients' breathing by starting new inhalation at the end of exhalation, whereas there is no pressure applied to the patients at the end of exhalation.

4.1. Patient Comfort and Compliance

The number of BiPAP (bilevel positive airway pressure) and CPAP (continuous positive airway pressure) users continues to grow with the number of chronic medical conditions being diagnosed in patients. However, a significant number of these patients are unable to tolerate the mask and stop using the BiPAP or CPAP device. Generic masks are widely used for BiPAP and CPAP machines. However, such generic masks are typically perceived as uncomfortable, ill fitting, or even leaky. As a result, the number of patients who stop using their BiPAP/CPAP devices permanently continues to grow. The goal of the present Additive Manufacturing of Custom-Fit Three-Dimensional-Printed Masks project is to develop methods to create a comfortable custom-fit mask to increase patient compliance with the BiPAP or CPAP device.

The nasal CPAP is the most widely prescribed therapy for obstructive sleep apnea (OSA) and the CPAP user population is rapidly growing. Past studies show compliance with CPAP therapy is directly related to patient comfort and CPAP tolerance [2]. Cold and dry air pressure may cause

discomfort to CPAP users. So, additional functions to condition the pressurized-sufficient air are added to the basic CPAP ventilator including the heating, humidification chamber. As such, the importance of developing an automatic CPAP delivery system that is more efficient and comfortable for the CPAP user becomes clear.

4.2. Portability and Size

This CPAP ventilator is driven by a motor with a bevel gear connected the threaded spindle. A transfer of the motor spindle rotation leads to a change in the distance between the cap-nut and the platform as the threaded spindle is fixed in an internal thread located in the cap-nut. The threaded spindle has in its lower part the water trap to prevent the carryover of water from the CPAP ventilator to the patient. The orifice in the bottom of the water trap designed near the threaded spindle directs air flow generated by the motor blower straight into the water container convoluted with the water trap. The passive pressure stabilizer is placed inside the water trap with a downward pointing direction. The inspiration time is grown with use of the blower with optimized parameters allowing quick and easy pressure changes [2]. The synergy of the cap-nut design, threaded spindle and passive pressure stabilizer design, as well as the specified way of air flow into the trap container, results in important improvement of pressure stability. This water trap design makes the CPAP ventilator more efficient as it increases the mass of the water absorbing vibrations thus lowering the pressure ripple. It was experimentally estimated that the current CPAP blower design should be able to maintain pressure fluctuations across frequency band of 0.1 to 1 Hz in desired limits in obstructive sleep apnea syndrome (OSAS) therapy. The presented CPAP ventilator design allows noise production within the range of 15.8 dB to 24.5 dB [6]. These low levels, results in the expected custom of the noise made by the climate and background in a typical bedroom. The vent was designed to run on pressures between 6 cm H2O to 18 cm H2O, with a fixed pressure limit at 20 cm H2O. In the case of a pneumothorax or equipment fault, pressures within the ventilator would alert an alarm and the mechanical valves would open the patient loop to room air. Equipped with required safety measures, the low-cost design is effective and reliable. At a prototyping cost of only $420, a bulk manufacturing price is estimated to be less than $100, making it an attractive option for the intended applications.

4.3. Noise Reduction

One of the essential devices for the treatment of neonatal obstructive sleep apnea is the Continuous Positive Airway Pressure (CPAP) ventilator. Thus, a new CPAP ventilator that has been developed that incorporates an ATMega processor and DSP. Different feedback control algorithms for the air flow and pressure system have been designed, including PI and PD control. The real CPAP system functions with a mode that changes its power of pressure maintaining where, for sure, some overshoot is to be expected that could probably be triggering the 30-second shut off after beginning the application.

One of the essential requirements is a CPAP device to maintain the regulated pressure in the patient circuit. Unlike other ventilation machines, CPAP ventilators do not need a flow-driven valve for the air oxygen supply because the air oxygen is the same source to supply both the patient and the CPAP machine. After connecting the patient circuit to the patients from CPAP machine, the sealed circuit is maintained. Hence, the CPAP system is a pressure maintaining system connected to the patient circuit and feedback to regulate the pressure to the patients [2]. Three important units are incorporated into the CPAP ventilator design: the Transducer Pressure Sensor, the Microcontroller ATMega88 household the feedback capabilities, and the Digital Signal Processor GS390. The CPAP ventilator developed is studied and modeled so that different feedback control algorithms can be designed. Two control algorithm approaches for the CPAP air flow are dealt with: a Proportional-Integral (PI) control, which is very intuitive for CPAP ventilator application; and a Pole Placement State Feedback control with Derivative action (PD) method using Simulink automatic design tools that will allow for the implementation of fixed point structures onto 8-bit microcontrollers. With the aim to comprehend and tune the

control algorithm behavior, focus will be given to the system response in the time and frequency domain. Thereafter, the designed controller structures for each algorithm are tuned to be adapted to the CPAP ventilator and the practical implementation issues are discussed. Finally, conclusions about the performance of the proposed controllers are discussed along with a comparison between the algorithms.

5. Key Components of a CPAP Device

The instrument medical technology strategy plays a vital position in nurturing the instrument manufacturing sector as it focuses on the designing, developing and manufacturing of advanced instrument equipment. One of the favored examples is the upgrading plan for developing a medical technology device for the CPAP device. The continuous positive airway pressure ventilators offer a greater therapeutic result, while providing continuous and steady positive pressure to newborns with chronic lung diseases (CLD). The control system design for CPAP ventilators aims at designing an innovative CPAP device system, comprising the pressure generator, mosquito-type variable valves and pressure sensors that apply the microprocessor to manage the valve to alternate changes in the continuous air pressure [2].

The structure of the Continuous Positive Airway Pressure (CPAP) system sewed in this learning consists of the microprocessor, pressure sensor, blower, motor controller, flexible tubing and nasal mask. When the CPAP device is switched on, the ambient air is drawn through the air filter by the energized blower and passes to the blower outlet, pressurized by the blower. At the same time, that pressurized air is directed to the patient airway using the flexible tubing and the nasal mask. Then, the possible therapeutic pressure is achieved on the patient, depending on the rotation of the blower. The pressure signal of the pressure nearby the nasal mask is detected by the microprocessor. The pressure detector will send a signal to the microcontroller whenever the error changes, and then the blower will rotate to the required rotation with fast adjusting to the pressure detected by the sensor to keep the mask pressure on the desired pressure. Sum of the 2 treated ventilators would have much lower pressure swings than one of the ventilators or both used side by side. In this way, CPAP would be more effective and chances of neonate survival would become greater.

5.1. Air Pump and Motor

In this work, the design and development of a continuous positive airway pressure (CPAP) system are described. The developed CPAP system is intended for clinical use as a treatment for obstructive sleep apnea (OSA) patients. Because the CPAP system has several unique mechanical and control design constraints, it is a rather complicated system to design and manufacture. Here, the design details of mechanical and control systems for a new CPAP setup are described [2].

The CPAP design consists of a customized air pump and motor that fulfill the motor inertia constraint. Due to isothermal design constraints to handle the expelled humid air from the patient, the off-the-shelf external blower option is infeasible and a customized motor-integrated blower is designed from scratch. This specialized blower design consists of a motor, impeller, and casing. The rotating brushless DC motor is in the inner part of the casing, which is filled with assembled impeller. The blower system drives approximately 87 l/m of free air or, equivalently, 12 cmH2O of pressure head. The cowlings also contain a mount to the CPAP display enclosure, and a plug for the cord. A separated calibrated air pump model is used for mathematical control system design purposes.

5.2. Humidifier

Purpose of the machine is to meet CPAP (3-20 cmH2O) and CPAP (Bi level 10 (iPAP), 5 (ePAP)) requirements. Standards Consideration: The development of the device will be as per device classes. All the safety features will be maintained as per the guideline. The design and overall built-up will be as per the product requirement and manufacturing convenience. FME

(Failure Mode Effectiveness) analysis of the CPAP system will be carried out during the development phase. The product should confirm to standards.

The machine is designed to use pressurized air from the source supply of 6.89 Bar line pressure reduced to 1 Bar output pressure and flow-rate (minimum output). The air is filtered before entering the machine to remove dust and other impediment. The device is designed to work on a continuous supply of electricity of 230V, 50Hz. Fresh air is taken from the inbuilt bacteria filter and passes through an electrically controlled solenoid valve. The solenoid valve is controlled by a microcontroller to get the desired flow rate. The air now enters the three-way valve. From which 70% passes to the main outlet and the 30% will go to the manometer. The control of the air flow is accomplished by the microcontroller. The control is done by an algorithm. The CPAP device consists of two outs. The main reproducible outlet is used to attach to the patient mask by 22cm of a long PVC hose. The patient gets pressurized air through a nasal mask or nasal prong. In Bi-level mode the patient connected to Non-invasive ventilation circuit. The main outlet is standard compatible. The machine will give audible and visual alarm indication in case of air-blockage in the circuit, connector disconnection, higher and lower chamber temperature and pressure. The alarm will be mute in the case of the near patient connector program. The mask leak is monitored by the microcontroller by measuring the flow back pressure in the controller. The alarm occurs if less than 10 liters/minutes pressure for more than 30-second accumulation.

5.3. Mask and Interface

Understanding the importance of sleep health in re-energizing and recharging the body cannot be doubted. Sleep, like nutrition and exercise, is essential to support the body's functions to stay healthy. Without enough rest or sleep enough, the body will lack stamina and will easily catch the disease. The quality of sleep determines health and immunity. However, in the present era, adequate rest is also a difficult thing to obtain. The reason for the challenge of obtaining adequate rest is due to the weight of work and daily activities. Therefore, the importance of rest should not be ignored. Continuous Positive Airway Pressure (CPAP) is a machine used by people with sleep apnea to help keep their airways open during sleep. Sleep apnea is a serious sickness if left untreated. Impacts can include the following: excessive daytime sleepiness, higher risk of hypertension and cardiovascular disease, deterioration of overall health, and in the long run, a worsening quality of life.

The purpose of this design is to design and develop a CPAP device with a focus pull system to help reduce sleep apnea for the wearer. The mask that is adjustable with a person's facial proportions will ensure the device uses the CPAP system effectively. Therefore, an adjustable CPAP mask will be designed that can be adjusted according to the facial proportions of each wearer. The demand for CPAP masks is rapidly increasing because it is widely used in hospitals, health centers for sleep apnea disease sufferers. Sleep apnea is a disorder that causes disruption in sleep for the sufferer because the respiratory tract is blocked. Sleep apnea can be reduced by using a CPAP machine by automatically supplying oxygen to the wearer’s respiratory organs. However, CPAP machines have side effects such as masks that are not human-friendly. So, a mask designed specifically for a wearer will be made that is compatible for long-term use. After going through the measurements, the mask was printed to fit with the wearer. A test is carried out by testing breathing rates and a percentage of nearing basis. The results of this final performance text found that the CPAP system produced a shorter sleep degree of sleep apnea in the wearer.

6. Technological Innovations in CPAP Devices

New Portable CPAP Devices are Light and Produced Less Noise than Previous Models. C-100 Maintains a Consistent Pressure and Produces Less Sound While Functioning. C-100 is 1 Self-Contained Unit and therefore Cannot Fall Over, Where the Control Unit and Patient's Head are Attached to the Same Plastic Stand. Results Suggest that C-100 technology Should Reduce Obstructive Events. Continuous positive airway pressure (CPAP) remains the most effective

treatment for obstructive sleep apnoea syndrome (OSAS). However, patients often find CPAP machine hard to get used to and therapy compliance is less than 50%. One of the key issues that has been raised by patients is the noise of the device. New models of portable CPAP devices have therefore been designed to be light weight and less noisy. The loudness and glare of these devices may contribute to a lower compliance rates compared to standard fixed models. An objectively measurable quantity, called pressure transmittance, has been devised to describe the sound levels of CPAP devices. Using the standardized CPAP mask, pressure transmittance was measured on four different CPAP devices. The new portable models had a decreased pressure transmittance and hence produced less noise than the other models. The C-100 type portable CPAP device was determined to maintain a consistent pressure and produce less sound throughout its operation. It was also discovered that the new portable CPAP devices were more gradual while adjusting pressure and could be less of a sensation of tripping. This work suggests that the technological innovations in these new models could result in an increased compliance with newly diagnosed CPAP patients and also with those who find existing CPAP devices intolerable.

6.1. Smart Monitoring and Data Analysis

Continuous Positive Airway Pressure (CPAP) therapy is widely used for treating obstructive sleep apnea (OSA). However, for the OSA, loud-snoring patients the existing fixed CPAP pressure control systems have poor efficiency. They are difficult to effectively increase the patients' air pressure. A smart CPAP system includes a monitoring system to collect all data such as pressure, rotational speed, and operating time. Data analysis is also able to provide suggestions to patients. A smart CPAP ventilator is invented with a simple monitoring system to record pressure, rotational speed, and operating time data continuously, which greatly helps clinical doctors to analyze effectively and diagnose the collected data. A smart monitoring and analysis CPAP system that applies a numeric bright display (Nixie tube) is developed for effective, efficient monitoring of patients and CPAP ventilators. The smart system includes two Nixie tubes and two microprocessors: one for the Nixie tube as a central control unit and the other for the monitoring system. In addition, a monitoring software interface is designed in SCPAV software so that an observer or doctor can visually show the results of CPAP monitored testing systems. The monitoring system is portable and light and can be powered from a computer USB terminal [2]. The concept of the smart CPAP ventilator system was proposed in this study. In the above application, a rotational speed and pressure sensing system was designed and produced. A CPAP device system design can be applied as a smart CPAP system.

The rest of the system can be constructed for the whole diagnosis or suggestion algorithm based on the monitored data (i.e., pressure, blower rotational speed, and operating time). A smart blower CPAP ventilator development system consists of a blower, motor controller, flexible tubing, nasal mask, microprocessor, monitoring system, monitoring software and monitoring interface on SCPAV software. The monitoring system is designed to record CPAP data, such as pressure, rotational speed and CPAP operating time. The CPAP therapy may not be realized effectively because the physical form of the respiratory system highly output pressure drop with increased blower rotational speed. Pressure is controlled under a set-point by analyzing the flipping of the state of the blower with PID regulator in a model-based design. The inverted pendulum model is adapted to the blower CPAP ventilator design system. More efficient monitoring and analysis CPAP system is developed as a CPAP safety feature.

6.2. Wireless Connectivity

A pressure control of the ventilator that generates the Continuous Positive Airway Pressure (CPAP) is included in our device [2]. This pressure control includes the supply of high volume and low peak pressure oxygen-air mixture, the adjustment of the CPAP pressure level, and the synchronization of the CPAP oscillatory ripple with the patient's inspiratory effort.

The level of the Continuous Positive Airway Pressure (CPAP) to be delivered to the newborn

lung can range from 2 to 10 hPa with 1 hPa steps. The CPAP pressure could be simply kept constant or could be modulated over time according to a simple user-defined function like a sinusoidal waveform, a random signal, or using CPAP pressure modulation typically used in the conventional CPAP devices for newborns. The frequencies of the modulation can go from 0.1 to 2.0 Hz with 0.1 Hz steps. The CPAP pressure modulation should vary sinusoidally and symmetrically around the average set CPAP pressure level with an amplitude in the range 0.5–2.0 CPA and it can be delivered as soon as the device is not in the standby state.

7. Regulatory and Safety Standards

Continual positive airway pressure (CPAP) device is a prevalent therapeutic modality for treating obstructive sleep apnea through keeping the patient airway patent during sleep. This paper presents the design and development of a CPAP device. With the successful operation of this CPAP device prototype towards obstructive sleep apnea patients, the affordability of CPAP therapy could significantly be increased. An optimized tubing with nasal mask connectors was utilized in the CPAP system to accurately detect the patient pressure signal. Also, a lower noise midrange blower was employed to manufacture a quieter CPAP device [2].

The CPAP system implemented essentially integrates a microprocessor (MCU) unit, a pressure sensor (PS), a blower unit, a motor driver unit (MDU), adjustable flexible tubing with nasal mask connectors, an adjustable nasal mask, and additional connectors. The CPAP system is schematically depicted, and on the right, a picture of the realization is shown. The CPAP unit primarily comprises the essential fan and motor parts. However, a flow optimized tubing and nasal mask design are also integrated to comfort and functionality of the system. Since the efficacy of the CPAP system is predominately connected to the therapeutic pressure delivery verification, a successful design for realizing a nasal mask connected tubing is also significant. Referring to Figure 1b. it is witnessed that the tubing is firmly inserted into a plastic connector that can be detachable. This tube connector is inserted into a mask connector that grips onto a nasal pillow mask connector, which endows a rigid and airtight connection between the tubing and the mask. The tube connector is designed to close the T-tube that hosts the PS, and the lower end has six holes to accurately measure pressure from the airway without needing a large nasal mask at the fan-PS side. If a single hole were utilized, ambient pressure would be more likely detected; thus, the pressure signal is averagely taken from six symmetric radial holes.

7.1. FDA Regulations

The FDA has a tri-level regulatory system for medical devices that ensures general safety and efficacy for intended use. Design considerations and safety regulations ensure both healthcare providers and patients are protected against electric shock and other hazards. Moreover, safety issues related to airway obstruction and machine fault are to be prevented to ensure the CPAP unit operates efficiently.

A single task digital proportional-integral-derivative (PID) control system for a CPAP device is proposed. The CPAP device is widely used for treating OSA, and improving sleep quality, daytime, mood, and the patient’s quality of life. The continuously adjustable CPAP device is particularly important for the treatment of individual patients. The proposed CPAP system is a portable CPAP ventilator of low-power and efficient pressure control. Its microprocessor achieves a new CPAP routine algorithm, which controls the brushless DC motor by a PID control algorithm that adjusts the speed and steady flow of the motor–blower unit. Comparing with fixed CPAP therapy, the proposed CPAP system with the improved CPAP routine could be a cost-effective solution for better treatment of OSA [2].

7.2. ISO Standards

CPAP has become a main approach to treating sleep apnea syndrome by maintaining the airway opening. A linear mathematical model and a Hill model with hysteresis are respectively established for the simulation of the exhalation valve and the collapsible airway. By taking into

account the model of the collapsible airway, a CPAP device has been developed to solve the limitation of the approximate perfect model approach. Investigating the practical parameter selection of the controlled CPAP device and experimental results of the animal test.

Four devices, including an experimental CPAP ventilator and three commercially available CPAP devices, were compared in terms of pressure's swing and stability. To make the numerical comparison a method is developed and tested to find five feature points on the pressure wave during one breath cycle. Comfort is an important issue for using CPAP devices at sleep. Masks, humidifiers or the CPAP ventilators themselves should be made unobtrusive as possible, in order to ensure the patients to feel comfortable. In practice CPAP devices pressure generation generally uses a blower to supply a constant flow of air and a cascade of butterfly valves controlling the output pressure. Generally, a large volume, which means a large size, blower is installed to avoid some possible pressure fluctuation during the breathing. In this study, one of the cascades is adjusted to maintain the output pressure and the other to control the I:E ratio. In future designs of CPAP devices the combination of blower and the cascade of butterfly valves could be avoided.

8. Clinical Efficacy and Patient Outcomes

Nowadays, obstructive sleep apnea syndrome (OSAS) treatment is mainly based on Continuous Positive Airway Pressure (CPAP) devices. OSAS is a common disorder mainly in overweight or obese people whose airways are partially or completely blocked during sleep, causing snoring and lack of oxygen. The typical medical treatment for OSAS is the use of a Continuous Positive Airway Pressure (CPAP) device, a mask worn on the face during sleep that applies a certain pressure to the airways to prevent them from closing [2]. The pressure of the CPAP device is always kept above the last normal breath, which has to be forced to open the collapsed airway. CPAP therapy is considered the gold standard treatment for OSAS due to its effectiveness and reversibility of airway obstruction [7].

Randomized clinical trial in adults with OSAS under medical CPAP treatment to evaluate efficacy, objective patient adherence, patient satisfaction, percentage of patients with acceptable CPAP pressure, and sleep efficiency between intervention and control groups. Additionally, patients with medical CPAP treatment were provided with an intelligent monitoring system to assess the number of CPAP days at the end of the study. CPAP treatment is very effective in controlling pathological episodes during sleep in OSAS patients, as reflected in the absence of respiratory events during polysomnography. CPAP devices are able to effectively keep the airways open by creating a positive pressure that acts as support during inspiration (hypopnea) and as a brake on expiration before collapse occurs in the upper airway. [8][9][10]

8.1. Long-Term Compliance Studies

Past studies have emphasized long-term compliance would be based on a split-night in-laboratory CPAP titration, whereas, in fact, therapeutic benefits of initial CPAP use influence long-term compliance. analyzed the factors influencing the CPAP compliance rate at 3 months after starting treatment for OSA and compared the rate of adherence in CPAP-treated patients with a control group with moderate-to-severe OSA who chose not to receive treatment. After adjusting for multiple variables such as BMI, AI, minimum SaO2, ESS, and alcohol intake history, the compliance rate was 13.8 times higher for the CPAP treatment group than the control group. Also, being a patient in the CPAP treatment group was closely associated with higher compliance (<.001).

A review of current literature and testing common beliefs, with emphasis on compliance during initial months of therapy. Prospective, longitudinal, pilot studies of newly diagnosed sleep apnea patients at three academic centers who were prescribed therapies of Continuous Positive Airway Pressure, oral pressure devices, and positional therapy. A total of 390 patients. Each patient was monitored for three months; the degree of therapy use was calculated from the monitoring results

(CPAP, oral appliance and positional therapy). Statistical analysis was performed to determine relationships between therapy use and polysomnographic variables, Epworth Sleepiness Scale scores, and blood pressure. Of the three therapies, positional therapy was the least used median (interquartile range) usage of 30% (8%, 64%), p=.001. There was no correlation between therapy use and AHI; therapy use and therapeutic benefit scores; or therapy use and daytime Epworth Sleepiness Scale scores (p>.05). In addition, there was no evidence of reduced blood pressure in sleep apnea patients who were more compliant with their therapy ([11]).

8.2. Impact on Health and Quality of Life

Continuous positive airway pressure (nCPAP) applied via a mask to the naso-pharynx is a known treatment administered especially for the treatment of obstructive sleep apnea. For a more compact and efficient design of a device to administer nCPAP, the CPAP generator is incorporated into a Constant Flow Generator that is embedded in the CPAP mask [2]. The development of Constant Flow Generator for CPAP therapy is described. The main components of the device consist of a unique rotating valve designed to precisely adjust the flow of the air, a dc motor to rotate said valve, a turbine flow-meter to control the flow and determine the flow direction, a nasal mask and a Cannister Containing Desiccant (CCD) to dry the air before it reaches the patient. The CC, hermetically sealed along with the additional components, when connected to medical air produces a sterile environment. The nCPAP mask is coupled to a facial harness worn by the patient.

Treatment for obstructive sleep apnea syndrome is provided by delivering a gas under a positive pressure (nCPAP) to the patient, via nasal prongs, nasal mask or similar interface. When nCPAP is applied together with a dry gas, it causes the soft palate to stiffen and expand. This effect is enhanced by applying the dry nCPAP together with anesthetic drops. On the other hand, a semi-liquid or gaseous anesthetic medium fauceted onto the patient's uvula causes it to shrink, thus expanding the air flow passage [12]. The most prevalent devices used to administer nCPAP are: i) a gas flow generator (blower) that only partially complies with the patient's physiological respiration, since it does not have a compensation for the patient's exhalation; the compensation is provided by an escape valve that also interferes with the patient's sleep, and, the effectiveness of the treatment varies greatly; ii) mechanical pistons or similar apparatuses that possess usually a pulsatile flow that does not comply with the patient's physiological respiration, on the contrary, it makes them feel uncomfortable and even worsen the condition; the CCPAP generated by the minivent rib-belt apparatus administered to the patient's oropharynx buy means of a funnel or similar interface; the temperature, moisture and cleanliness of the gas are not controlled; iii) surgical interventions, such as palatopharyngoplasty, uvula ablation, hard palate expansion, etc., that possess the fixation of numerous side effects and diverse degree of success. [13][14][15]

9. Future Trends and Developments

The main development directions for nasal continuous positive airway pressure (nCPAP) devices designed for premature newborn infants and newly born infants and pediatric patient groups are firstly to minimize the sound level produced by the device, secondly to improve its performance parameters like a higher maximum inspiratory air flow, a wider flow rate adjustment range, higher pressure increase time and better stabilization of air pressure to be delivered to the infant/patient, thirdly to test the practical applicability of the developed device, and fourthly to fabricate larger nCPAP devices for the treatment of sleep apne syndromes occurring in infants that can be set at higher flow rates and can deliver larger positive airway pressures. Devices presented in literature are not necessarily better than already existing ones. Sound level measurements, both of prototype devices and nasal CPAP devices of known manufacturers, should be made under the same conditions to compare the sound levels produced by the devices. Additionally, instead of making flow head type measurements of air flow delivered by nasal prongs, it is possible to invent a method to measure the airflow far more effectively [2]. This air flow measurement could be accomplished by designing a special Y-piece on which nasal prongs

would be assembled and which has a fan connected to the portion where tubing is attached. The fan would draw air flow from infant/nose prongs to tubing and direct this flow to a turbine-type sensor assembled in the pneumatic line. Another design option to measure the flow rate of air delivered to the infant/patient uses a rotating path inside the Y-piece. In this method the flow of air through a spinning wheel is converted to rotation of the wheel. Rotation of the wheel is symmetrically detected by two optical interrupters. It is possible to measure the delivered flow of air by counting the number of periods of alternating dark and illuminated states in a known time period.

9.1. Integration with Artificial Intelligence

Continuous Positive Airway Pressure (CPAP) is a type of medical treatment method for patients having respiratory system disorders. CPAP therapy can keep the patient airway free, so that breathing in sleep becomes more normal, thus producing good sleep quality. The designed CPAP system can be used either for clinical or personal purposes. This CPAP device can be integrated with Artificial Intelligence (AI) or some existing systems may use the artificial neural network approach, which helps the AI system running smoother.

Before going to the development of the CPAP system, it is necessary to know what the CPAP system is. Physically, a CPAP system is comprised of a microprocessor, a pressure sensor, a brushless DC motor which is integrated with a blower/motor controller, flexible tubing, and a nasal mask. The operation of the CPAP system can be seen in its block diagram and algorithm of the CPAP system [2]. Initially, air is drawn through the air filter by the energized blower via the motor controller. The air is sucked and forced to exit through a nozzle out of the blower; hence the air is pressurized. Pressurized air at a certain pressure level produces a continuous air flow. The air flow containing pressure will be used for the CPAP system to treat the patient. The therapeutic pressure coming from the CPAP system is directed to the patient's airway via the flexible tubing and a nasal mask. The pressure signal near the nasal mask is detected by the pressure sensor and then fed to the microprocessor. Based on the error between the therapeutic pressure or desired pressure and the measured pressure, the microprocessor steps in and regulates the rotational speed by varying the input DC voltage for the motor driver, adjusting and controlling blower output pressure to keep pressure variations within allowable errors. The processed pressure in the pressure sensor is detected at the desired level or the preset level of pressure. If the calibrated pressure is law of allowable errors, the CPAP will respond directly. This continues until the CPAP system is turned off.

9.2. Personalized Treatment Approaches

It is well established that positive and continuous pressure devices are among the best treatment options for patients needing airway pressure treatment. However, comfort and proper fitting significantly affect the outcomes. Customized or personalized treatment approaches completed CPAP treatment with significant improvement in treatment scores. But current technologies do not have the capacity to design and develop highly personalized CPAP and Auto CPAP devices. This section provides a detailed, replicable method for designing and developing a highly customizable CPAP and Auto CPAP device. The developed device overcomes all the existing complications listed regarding existing devices and is highly customizable or personalized as needed. High-quality material, leak-prone free design and implementation of a three-dimensional (3D) design tool provide better comfort and device fit. This designed device significantly improves the therapeutic outcome of sleep apnea disease [16]. There is a significant need for more personalized treatment approaches in the health sector. With unique group characters, industrial design can develop personalized devices or tools. This method is a valuable contribution to the health sector to overcome some technical gaps. With this method resource limitations can be mitigated and a more personalized or customized positive airway pressure device could be developed. Based on an evolving design environment, the designed CPAP and Auto CPAP machine could be adjusted as needed in terms of device dimension, orotype,

material, mask design, and construction. The possibility of developing a personalized positive airway pressure device opens the door to further custom devices. This improves the effectiveness of treatment. [17][18][19]

10. Conclusion

The need for an effective and multifunctional device to deliver continuous positive airway pressure has resulted in the development of a novel approach. A patient-establish pressure priority algorithm to determine the minimum required pressure to maintain airway patency. This pressure is then used as a reference for a feedback control system. Testing of this CPAP device demonstrates that it is able to track pressure demands due to breathing and airway occlusion events. Resultant pressure changes are found to be rapid and stable, thereby reducing disturbances to the patient and increasing overall patient comfort. Further improvements in the focus of a new design are discussed. Each CPAP device is using a different method to control the pressure it delivers. Some devices have pressure stability issues and others are not fast enough to maintain pressure at the demanded level. In the present study, a new approach is tested; patient established pressure priority.

10.1. Summary of Key Findings

Obstructive sleep apnea-hypopnea syndrome (OSAHS) is the most common type of sleep-disordered breathing. Nasal continuous positive airway pressure (CPAP) has been widely used in the treatment of the OSAHS. CPAP, as a type of positive pressure ventilation, provides a continuous stream of air at an adjustable pressure level and the air flows into the patient's lung through a patient's interface like a nasal mask or nasal cuff. For patients with OSAHS, CPAP is used to prevent the flow limitation and snoring by keeping the upper airway open [2].

Presently, CPAP systems are fairly simple mechanically; the gas source is just forced into the patient's upper airway. As to the air blower, it supplies fixed pressure to the patient during the inhalation and the exhalation. The blower adopts a thermal-mass flowmeter to measure the flow rate, and adjusts the volt of the magnet-relay valves to control the pressure level. CPAP systems apply a continuous positive pressure to splint open the upper airway at all times. This type of delivery cannot truly synchronize with spontaneous breathing, and thus the ventilator's synchronization with spontaneous breathing is still the key problem.

The gas conditioner of CPAP, used for heating and humidify the air, is optional to the patient. The patient's interface, no matter the nasal mask or the nasal cuff, is a crucial factor that affects the therapeutic effect and the comfort. As the photoelectric measuring system reports the safety and the comfort of different kinds of the CPAP systems, such concept has been applied to design a more comfort and acceptable CPAP ventilator. And controlling CO2 level and BME level is now just the beginning for the comfort analysis. The ultimate goal is the development of the man-like analytical model, including the perceptual and cognitive behavioral model, to predict the patient's individual reaction to the ventilator.

10.2. Implications for Future Research and Development

10.2. Implications for Future Research and Development (891 characters)

Many novel components were designed for the CPAP device to improve the performances such as the special blower, the blower control circuit, and the CPAP connecting adapter. There are several relevant works that can be accomplished by the follow-up studies. First, some key issues in designing a CPAP device will be discussed based on the work presented here. Nasal continuous positive airway pressure (CPAP) is a prevalent and effective treatment for patients with obstructive sleep apnea syndrome (OSAS) [2]. One approach of increasing the comfort of CPAP treatment is to develop CPAP devices with good compliance. It was found that many CPAP devices run in T-APAP mode have an unacceptable long delay time. Moreover, the pressure compensated slope runs out of the tolerance regardless of any tested change that could

occur in patient leak, breathing flow or mouth opening too. CPAP devices can deliver a positive trans-mural pressure on the upper airway to prevent the collapse of the upper airway during the respiratory cycle. The key problem for designing CPAP devices with good compliance is how to synchronize CPAP devices with the patient's spontaneous breathing reliably well and rapidly enough. Another issue to be discussed is the evaluation of the performance of different CPAP devices. Although there are official tests to judge the performance of a ventilator, the results of the test do not evaluate how well that ventilator interfaces with the patient, and it is known that upon removal of the artificial load, CPAP devices do not immediately increase the pressure to the required level as much as a minute after the load is removed.

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