Simulation and Validation of FiO_2 Mechanism in Ventilator

A Thesis

Submitted by

HARIIKUMAR S

For the award of the degree of

MASTER OF TECHNOLOGY in CLINICAL ENGINEERING

Jointly offered by

IIT MADRAS CMC VELLORE SCTIMST

INDIAN INSTITUTE OF TECHNOLOGY MADRAS &

CHRISTIAN MEDICAL COLLEGE, VELLORE &

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY, TRIVANDRUM

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THESIS CERTIFICATE

This is to certify that the thesis titled "**Simulation and Validation of FiO_2 Mechanism in Ventilators**" being submitted by **Harikumar S** to SCTIMST Trivandrum, for the award of the degree of **Master of Technology in Clinical Engineering** jointly offered by IIT Madras, CMC Vellore and SCTIMST Trivandrum, is a bonafide record of the research work done by him under my supervision. The contents of this thesis, in full or in parts, have not been submitted to any other Institute or University for the award of any degree or diploma.

The research work had been carried out at Sree Chitra Tirunal Institute of Medical Sciences and Technology, Trivandrum.

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Abstract

The Ventilators demand has been on the rise due to the covid-19 pandemic. SARS-CoV-2, the virus causing the pandemic, has severe symptoms affecting the respiratory system, i.e., SARS- Severe Acute Respiratory Syndrome, causing difficulty in breathing and a drop in oxygen percentage of the blood. There was a sudden increase in the need for the ventilator to manage the breathing issues of the patients. As ventilators are very costly, innovations in design and manufacturing are essential to reduce the cost. Hence in order to address the issue, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, under the Department of Science and Technology Govt of India, one of the pioneers in medical devices development, took responsibility for developing low-cost portable indigenous ventilators. One of the critical innovations provided in the ventilator is implementing an affordable and easy to manufacture FiO_2 mechanism. The rationale behind the design process was to implement a FiO_2 mechanism with proven biocompatible surface materials and interaction with airway circuits with artificial materials are made nil or minimum. Thus the time, effort, and cost of development shall be reduced to a great extent.

The idea behind the project is to validate the novel low-cost FiO_2 controlling mechanism using simulation. The mechanism used to control the FiO_2 involve the squeezing of input gas tubes using a stepper motor. The simulation of the FiO_2 mechanism, as it involves both fluid flow and structural changes, the flow analysis, and structural analysis are done independently. The tube area is used as a common parameter between flow analysis and structural analysis. A relationship between FiO_2 and clamp displacement of the stepper motor is established. The experimentation of the squeezing mechanism is conducted with similar boundary conditions. The FiO_2 values are obtained by using an oxygen sensor in the experiment. The experiment results and simulation results are compared, and error calculations are computed to validate the mechanism to be implemented in the low-cost portable ventilator.

Keywords: Ventilator, FiO_2, simulation, flow analysis, structural analysis, Validation

Abbreviations

VCV	Volume Control Ventilation
PCV	Pressure Control Ventilation
SIMV	Synchronous Intermittent Mandatory Ventilation
PRVC	Pressure Regulated Volume Control
CPAP	Continuous Positive Airway Pressure
APRV	Airway Pressure Release Ventilation
FiO_2	Fraction of Inspired Oxygen
SpO_2	Saturation of Peripheral oxygen
SaO_2	Saturation of Arterial Oxygen

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Chapter I

Introduction

The physiology of the respiratory system involves the coordination of multiple organs. With injuries, ailments, or age, the respiratory system may get weakened or perform inefficiently. The development in technology has paved the way to come out of such conditions and heal the respiratory system with the help of an artificial respirator or ventilator. The purpose of ventilators is to support or recreate the breathing of the patient. In this chapter, we shall understand the respiratory physiology and anatomy, the various respiratory failures, detailed view on the ventilator, history of positive pressure ventilators, parts, terms, modes, types, effects of the ventilator, shall also have a brief understanding of FiO_2.

1.1. Respiratory Physiology and Anatomy

Respiration is the process that facilitates the exchange of gases on a cellular level; it involves the intake of oxygen and removal of carbon-dioxide. [1] The anatomy of respiration consists of the trachea, lungs, pleural cavity, chest cage, muscles of respiration, nerves, and respiratory center. Figure 1.1 shows the detailed image of various parts of the human body participating in the respiratory process. The respiratory process can be controlled by both the voluntary and involuntary parts of the brain. It switches the control depending on the action performed. Breathing is a complex motor task that needs to be coordinated while we eat, speak, sing, run, and even during sleep.

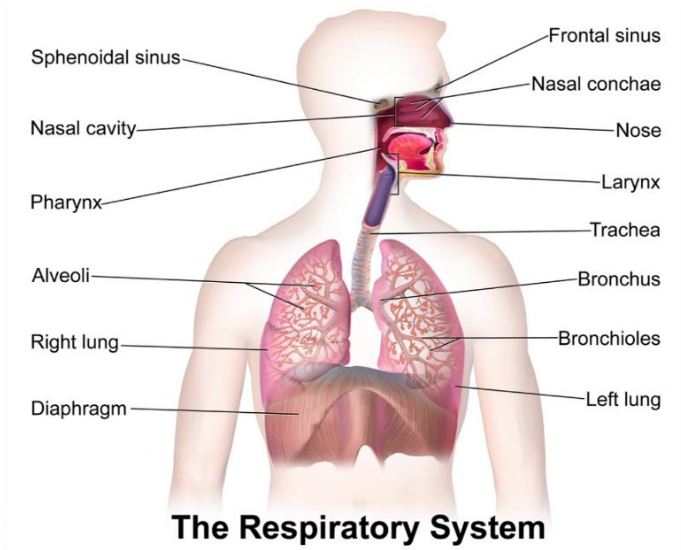


Figure 1.1: The parts of the Respiratory System [16]

Respiration is a multiple-step process. The processes are ventilation, perfusion, diffusion, transport of gases, cellular respiration. Ventilation is the process of breathing in and breathing out the air. Perfusion is the process through which the deoxygenated blood is taken through the lungs and then back to the heart. Diffusion is the mechanism through which the gas exchange happens from alveolar sacs and capillaries due to the partial pressure difference. The transportation of gases refers to the pumping of blood to every single cell in the body. Cellular Respiration is the process through which the system absorbs oxygen, and the hemoglobin is replaced with CO_2. [1]

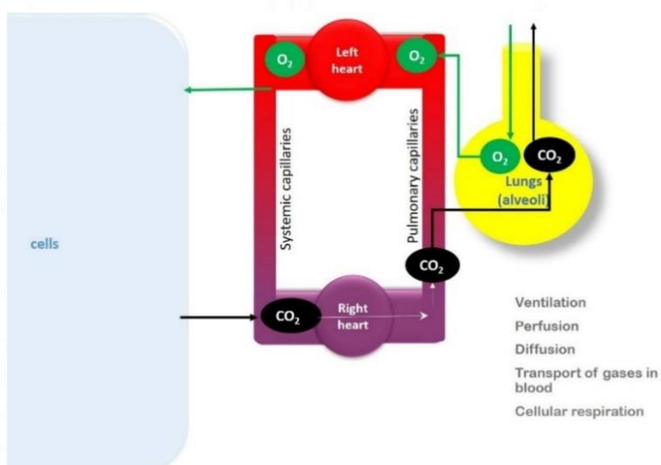


Figure 1.2: Multiple processes in Respiration [16]

The seamless functioning of the respiratory system depends on the efficient coordination of the respiratory center, sensory input system, respiratory muscles, and lungs**.** The neural control center works collectively to regulate inspiration and expiration. Mechanoreceptors, Metaboreceptors, and peripheral and central chemoreceptors are sensory input systems that work with other components of the respiratory response system to regulate breathing. Information from neuronal and sensory input signal system to the diaphragm and other respiratory muscles to control the mechanical aspects of respiration. [1]

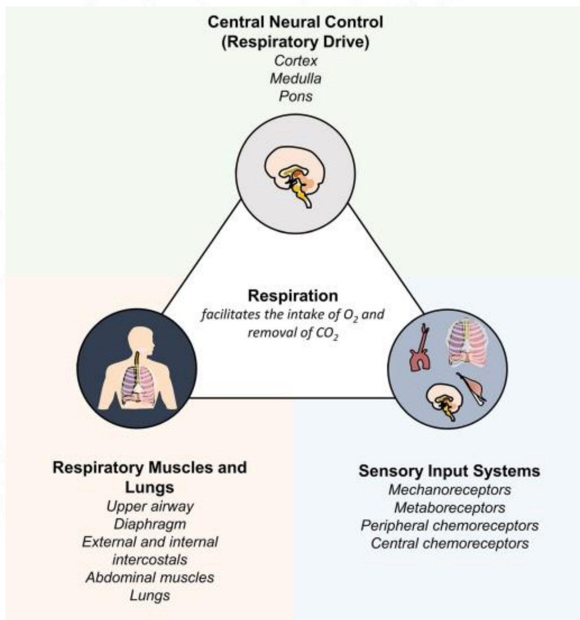


Figure 1.3: Respiratory Synchronization. [1]

The respiratory process is under the control of the respiratory center of the brain. The Nerve impulses sent to the muscle allow the muscles to contract and create the space for the pleural cavity to expand. A negative pressure is created within the lungs as it expands. The negative pressure facilitates the atmospheric air to enter the lungs through the airways**.**

Ventilation

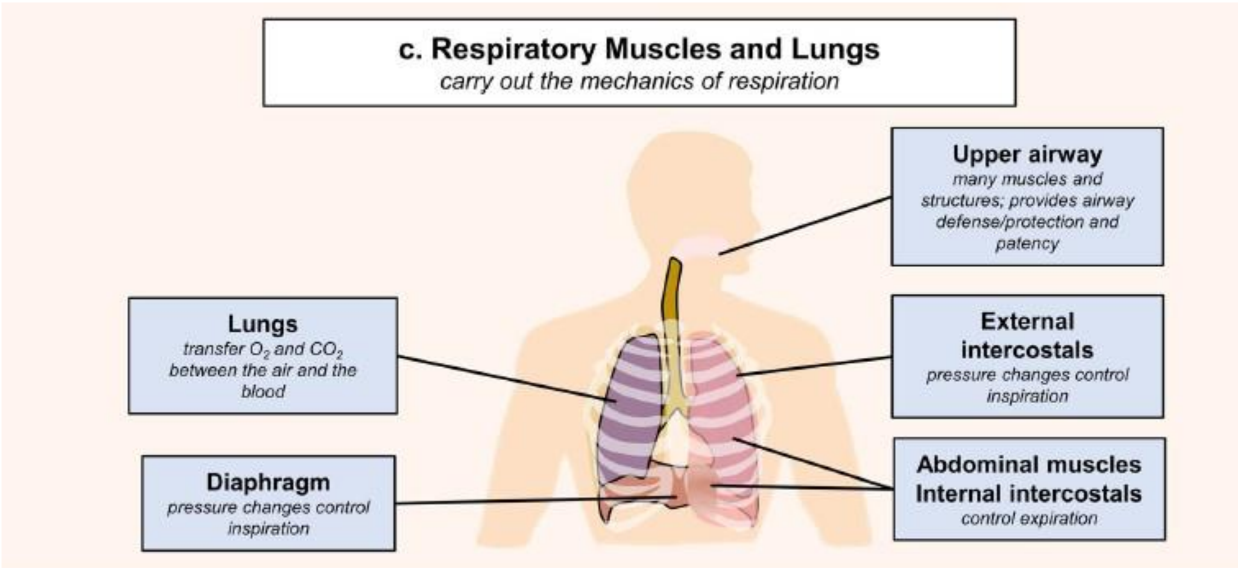


Figure 1.4: Muscles aiding respiratory process [1]

Breathing or ventilation refers to the inhalation and exhalation of air. The muscles participating in the inspiration activity are the diaphragm and external intercostals. While the exhalation process doesn't require any active involvement of muscles, it happens through the relaxation of inspiratory muscles. But in forced expiration, the abdominal and internal intercostals muscles aid the act. In case of respiratory failure, it can be easily addressed during the ventilation process. The processes shall be explained in detail in the ventilator chapter.

1.2. Respiratory Failure

Respiratory failure is the inability of the respiratory system to maintain the oxygenation, ventilation, or metabolic requirement of the patient. It leads to the rise in carbon dioxide level and decrease in the oxygen level in the blood, also varying the pH of the blood and considered to be a grave condition. Respiratory failure is classified with the arterial partial pressure of O_2 and CO_2 into type 1 and type 2. [2]

Hypoxemic Failure

Hypoxemic failure (Type-1) occurs due to oxygenation failure, i.e., the respiratory system fails to maintain satisfactory levels of oxygen in the arterial blood. Most of the abnormalities will improve with the administration of supplemental oxygen. In this type, the gas exchange is affected at the alveolar-capillary membrane; it is referred to as oxygenation failure. It is indicated by $PaO_2 < 60$mmHg; the $PaCO_2$ level may be normal or abnormal.

Hypercapnia Failure

Acute hypercapnic (Type-2) respiratory failure occurs when a patient arterial blood gas reveals acute respiratory acidemia with a $PaCO_2$ of greater than 50 mm Hg. The $PaCO_2 > 50$mmHg, the PaO_2 level normal or abnormal.

Respiratory failure may be due to malfunctioning of the brain, spinal cord, neuromuscular disorders, thorax and pleura, upper airway disorders, or lower airway disorders.

Brain Injury

The malfunctioning of the brain due to any head injury or any diseases affects the respiratory system. Cerebral malignancy, Central Alveolar hypoventilation, Drug overdose are few clinical conditions.

Spinal Cord Injury

The cervical part of the spinal cord is responsible for respiratory activity. Any injury at or above the cervical part may lead to the following conditions Amyotrophic lateral sclerosis, Cervical cordotomy, Guillain-Barré syndrome, Poliomyelitis, Spinal cord trauma, etc.

Neuromuscular Disorder

CNS causes due to depression of the neural drive to breath as in cases of overdose of a narcotic and sedative. Respiratory muscle and chest wall weakness as in cases of Guillian-Barre syndrome and myasthenia gravis.

Upper and lower airways obstruction

Due to various causes as cases of exacerbation of chronic obstructive pulmonary diseases and acute severe bronchial asthma, Atelectasis, bronchitis. [2]

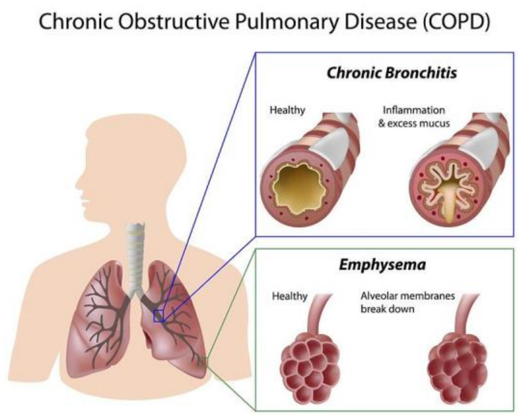


Figure 1.5. COPD diseases [22]

1.3. Ventilator

A ventilator is a device that supports or recreates breathing by pumping air into the pump. It can also be called an artificial respirator. The ventilators are life-saving devices used in case of respiratory failure due to any disorder. They are chiefly used in Intensive Care Units, home care, anesthesiology. The development in ventilators evolved rapidly over the years, starting from negative pressure ventilators to the positive pressure smart ventilators currently available. The evolution of positive pressure ventilators is discussed below.

1st Generation

The first positive pressure invasive ventilator was featured in the 1940s by Morch and Emerson. It only offered volume-control ventilation mode. With these first-generation ICU ventilators, patient-triggered ventilation was not feasible. There were no monitors, no alarms, and no special settings on this ventilator. A secondary instrument was used to count the respiratory rate and estimate the tidal volume. [3]

Figure 1.6: Morch ventilator, Emerson post-operative ventilator. [3]

2nd Generation

The 2nd generation ventilator has inbuilt mechanisms to measure parameters such as the respiratory rate, pressure, flow rate in the ventilators. The majority of these devices in this category controlled tidal volume and respiratory rate along with the patient-triggered inspiration [3]. However, volume control ventilation was still the only mode of operation. Basic warnings such as high pressure, high rate, and low tidal volume were also included in this category of ventilators for the first time. Below, figure 1.7 shows the puritan bennet ventilator. [3]

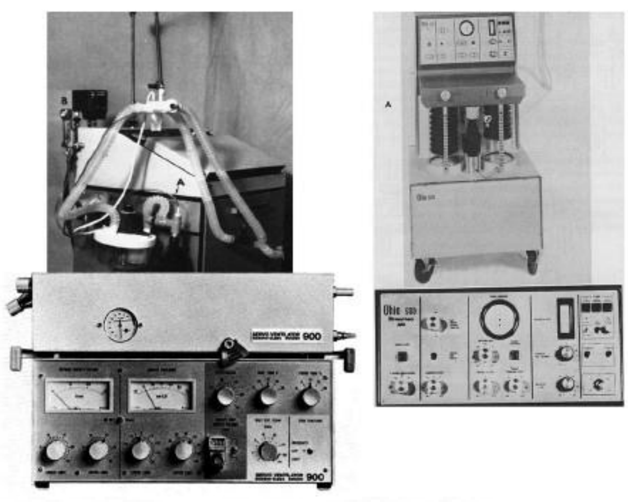


Figure 1.7. Puritan Bennet MA-1, Ohio 560 [3]

3rd Generation

In the 1980s to the 1990s, the ventilator was equipped with microprocessor control. The most significant feature shared by all of these generations of ventilators. This was a watershed moment in the history of mechanical ventilators because it opened the door to almost every method of gas distribution and monitoring. Furthermore, gas distribution systems have been greatly improved. Compared to previous generations of mechanical ventilators, these ventilators were significantly more receptive to patient demand. [3]

Figure 1.8. Puritan Bennet 7200. [3]

4th Generation

The latest generation of ICU ventilators is the most complex and flexible mechanical ventilators ever produced. There has been a significant rise in the number of ventilators of all forms currently. However, the most distinguishing feature of the current ventilators is the plethora of modes of ventilation.

Figure 1.9. Puritan Bennett 840, CareFusion Avea, Maquet Servo-i.

1.3.1. Parts of Ventilator

A ventilator is a complicated device with several components. The proper functionality of the ventilator depends on the quality and standards of each of the components. The Figure 1.8. shows the parts of the ventilator. The ventilator operates on a power supply, gas supply, pressure generator. It has various pressure, flow, and volume sensors for the trigger mechanism. The other parts in the ventilator are the breathing circuit, valves and for safety purposes, filters and alarms are used.

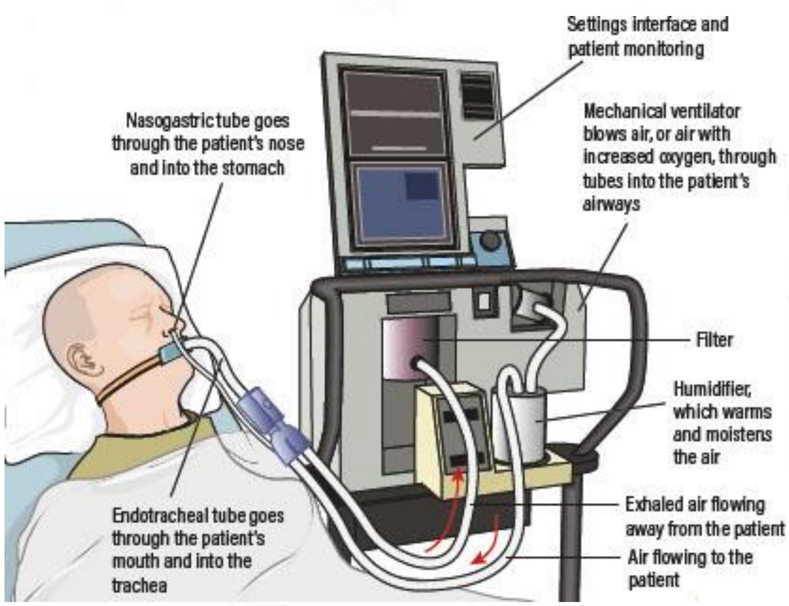


Figure 1.10. Parts of Ventilator [24]

SENSORS

The ventilator uses a variety of sensors for its functionality. They are designed to help control pressure, airflow, temperature, and humidity.

Pressure Sensors

The pressure sensors are designed to measure the pressure of air and oxygen pressure to and from the patient so that the pressure doesn’t exceed the desired level. Stable, accurate, easy to use sensors are used in the ventilators.

Figure 1.11: Pressure sensor [16]

Air Flow sensors

The airflow sensors are designed to measure the flow of air and oxygen. It is used to deliver the set volume of the gas mixture to the patient. The total mixture that is delivered to the patient is also measured and displayed on the ventilator display. It can also identify the patient breathing, which is used as a trigger mechanism in many ventilator modes. [4]

Figure 1.12: Flow sensor [4]

Thermistors Sensing Elements

Warm, moist air provides a more comfortable breathing environment for the patient and may decrease sore throats caused by cold, dry air. The temperature of the air delivery system is frequently monitored and regulated to ensure that the necessary amount of warmth in the air stream. The sensors are meant to monitor and control the air temperature and are inserted directly into the air stream. [4]

FILTERS

Filters in mechanical breathing systems are made to collect pathogens and particles with sizes ranging from 0.1 to 10 microns. A SARS-CoV-2 virus has a diameter of 0.06 to 0.14 µm, whereas a hepatitis C virus has a diameter of 0.03 µm. The filters in ventilators are just as crucial as any other component. They serve a variety of functions, including protecting the patient from microorganisms and dust particles. Second, they protect the ventilator from damage caused by particles coming into the system. Lastly, they also act as protection to the operating staff and doctors working around it, as it filters out the bacterial or any other pathogen flow in the patient circuit from the patient's exhalation.

The gas supplied to the patient may be contaminated by multiple possible agents:

- Non-sterile water, condensing in the pipes
- Dust from gas supply pipes
- Bacteria from non-sterile wall faucets and pipes

- Dust from the soda lime canister

HEPA filters

HEPA is the acronym for “high-efficiency particulate air [filter]”**.** It is a pleated type air filter. It can remove 99.97% of dust, mold bacteria, and any air-borne particles with a size of 0.3 microns. The diameter specification of 0.3 microns refers to the worst case; the most penetrating particle size . Particles either larger or smaller are trapped with even higher efficiency.

Filter placement

Ideally, two filters should be used and changed with every patient's use. The Expiratory filter is placed between the machine and the expiratory limb of the ventilator circuit. The patient filter is placed between the Wye connector of the circuit and the patient. Placing filters at these locations protects against contamination of the circuit as well as the machine.

Alarms

Ventilators are life-critical devices; alarms are an inevitable part of the functioning of the ventilators. Various parameters trigger the ventilator alarm. The alarm type can be classified as check for Dislodgement, Obstruction of ETT through mucus plugs or by patient bitting on the tube, Pneumothorax, Equipment malfunction, and Stacked Breaths or patient-ventilator dyssynchrony.

1. High Peak Pressure
   The rise in pressure may have occurred due to the increase in resistance of ETT or distal bronchus narrowing in diameter and requiring higher pressures for pumping the same air.
2. Low Peak Pressure
   The ventilator shall alert when the pressure drops beyond the set pressure or minimum limit, it may be due to leakage generally. Please check the
3. Hypoxia
   Suppose the SaO_2 levels drop, generally caused by dead-space ventilation or poor perfusion. Consider an Intra-cardiac shunt, pulmonary embolism, AV- fistula, hypovolemia, shock states.

GAS SUPPLY

Most hospitals use a wall gas supply for the operation of ventilators. In general, the gas supply can be one of the following. For transport and emergency ventilator, a turbine type is used

- Piped wall (or cylinder) air and oxygen
- Piped cylinder oxygen and room air
- Room air only

PRESSURE REGULATOR

A pressure regulator is a device that reduces high input pressure to a controllable output pressure to control the pressure of liquids or gases. They also act to maintain a steady output pressure even when the inlet pressure fluctuates. It's an important part of ventilators since it regulates and reduces the pressure coming in from wall pipes or cylinders to the device's operating pressure. The working pressure of the ventilator is 0-25 cm H2O.

Figure 1.13: Pressure Regulator [8]

1.3.2. Terms of Ventilation

The ventilator involves a myriad of components and multiple functionalities[5]. The following terms and definitions will enhance the understanding of ventilator and ventilation processes.

Airway pressure

The pressure at the airway opening measured relative to atmospheric pressure during mechanical ventilation.

Assisted breath

A breath during which all or part of inspiratory (or expiratory) flow is generated by the ventilator doing work on the patient. In simple terms, if the airway pressure rises above end expiratory pressure during inspiration, the breath is assisted

Blower

A blower is a machine for generating relatively large flow of gas as the direct ventilator output with a relatively moderate increase of pressure. Blowers are used on home care and transport ventilators.

Compliance

A mechanical property of a structure such as the respiratory system; a parameter of a lung model, or setting of a lung simulator; defined as the ratio of the change in volume to the associated change in the pressure difference across the system. The normal value is 200 ml/cmH_2O for adults.

Compressor

A compressor is a machine for moving a relatively low flow of gas to a storage container at a higher level of pressure. Compressors are generally found on intensive care ventilators, whereas blowers are used on home care and transport ventilators. Compressors are typically larger and consume more electrical power than blowers, hence the use of the latter on small, portable devices.

Driving pressure

The pressure causing delivery of the tidal volume during pressure control modes. The range of pressure used in ventilator is 0-25 cm H_2O, up to maximum of 40 cm H_2O.

Breathing circuit

It is the system of tubing connecting the patient to the ventilator, which carry the air to and from the patient.

Inspiratory flow

The flow into the airway opening during the inspiratory time. By convention, inspiratory flow is in the positive direction (above zero) in graphs.

Inspiratory flow time

The period from the start of inspiratory flow to the instant when inspiratory flow stops.

Expiratory flow time

The period from the start of expiratory flow to the instant when expiratory flow stops. By convention, expiratory flow is in the negative direction (below zero) in graphs.

Expiratory time

The period from the start of expiratory flow to the start of inspiratory flow; expiratory time equals expiratory flow time plus expiratory pause time.

Tidal Volume

The volume of gas, inhaled or exhaled during a breath. The value is 7ml/kg, for an adult weighing 70 kgs it is around 500ml.

Pressure Support

The name of a mode using a set-point targeting scheme in which all breaths are pressure or flow triggered, pressure targeted, and flow cycled.

PEEP

Positive end expiratory pressure; the value of trans-respiratory system pressure at end expiration. Its value ranges from 5-20 mmHg.

Resistance

A mechanical property of a structure such as the respiratory system; a parameter of a lung model, or setting of a lung simulator; defined as the ratio of the change in the pressure difference across the system to the associated change in flow. [5]

Secondary breaths

Spontaneous breaths during Intermittent Mandatory Ventilation (IMV).

Sensitivity

The sensitivity setting of the ventilator is a threshold value for the trigger variable which, when met, starts inspiration. In other words, the sensitivity is the amount the trigger variable must change to start inspiratory flow. Sensitivity is sometimes used to refer to the cycle threshold. [5]

Trigger

The stimulus to start the inspiratory time. [5]

Time triggering

The starting of inspiratory flow due to a preset time interval. The most common example is a preset ventilator frequency. [5]

Pressure triggering

The starting of inspiratory flow due to a patient inspiratory effort that generates an airway pressure drop below end-expiratory pressure larger than a preset threshold (ie, the trigger sensitivity setting). [5]

Flow triggering

The starting of inspiratory flow due to a patient inspiratory effort that generates inspiratory flow above a preset threshold. [5]

Machine triggering

Starting inspiratory flow based on a signal (usually time) from the ventilator, independent of a patient trigger signal. Examples include triggering based on a preset frequency (which sets the ventilatory period), or based on preset minimum minute ventilation (determined by tidal volume divided by the ventilatory period). If a signal from the patient (indicating an inspiratory effort) occurs within a synchronization window, the start of inspiration is defined as a machine trigger event that begins a mandatory breath. [5]

Patient Triggering

Starting inspiration based on a patient signal occurring in a trigger window, independent of a machine trigger signal. The signal is related to one of the patient determined components of the equation of motion Common examples of patient trigger variables are airway pressure drop below baseline and inspiratory flow due to patient effort. [5]

Work of breathing

The general definition of work is the integral of pressure with respect to volume during an assisted inspiration. There are two general components of work related to mechanical ventilation. One kind is the work performed by the ventilator on the patient, which is reflected by a positive change in airway pressure above baseline during inspiration. [5]

1.3.3. Modes of Ventilation

The mode of ventilation is the method or the way in which a breath is delivered by altering or changing the available variables. A ventilator mode can also be defined as a set of operating characteristics that control the manner in which a ventilator functions.

The various modes of ventilation are:

1. Volume Control Ventilation
2. Pressure Control Ventilation
3. Assist Control Ventilation
4. Synchronous Intermittent Mandatory Ventilation
5. Pressure Regulated Volume Control
6. Airway Pressure Regulatory Ventilation

Each ventilator mode is elaborated below

Volume Control Ventilation

In Volume control ventilation, the volume of gas mixture given to the patient for each breath is controlled. By setting a fixed volume, it is ensured that the patient is receiving a stable minute volume, the specified tidal volume given is achieved at the least possible pressure. In this method, as there is no upper limit set for the pressure, resistance in the breathing circuit might cause high pressure leading to barotrauma or similar conditions. The graph below shows that the specified volume is given by constant flow rate during the inhalation time, and a drop in flow rate indicates the exhalation period. The graph shows the rise in volume parallel to the flow and pressure throughout the inspiration.

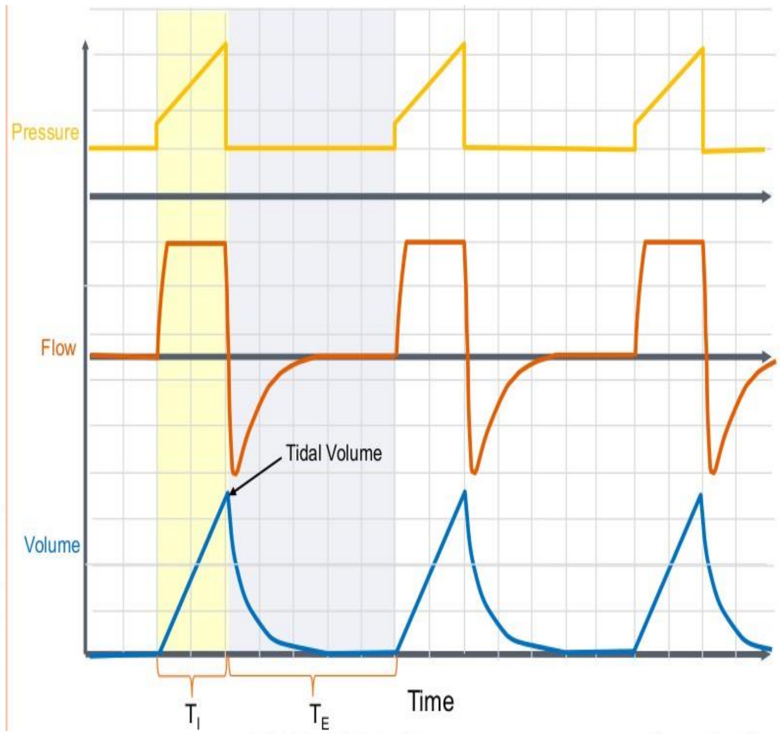


Figure1.14 Volume Control Ventilation [11]

Pressure Control Ventilation

In pressure control ventilation mode, the pressure at which the gas mixture is delivered into the lungs is specified. The volume and flow are variable, depending on the compliance and resistance of the lungs. The pressure control ventilation increases the mean airway pressure and also the duration of alveolar recruitment. The work of breathing is reduced, and patient comfort is increased compared to VCV. There is high flow initially during the inspiratory phase, as shown in the graph. As the volume is not controlled, lungs with high compliance may have the risk of volutrauma.

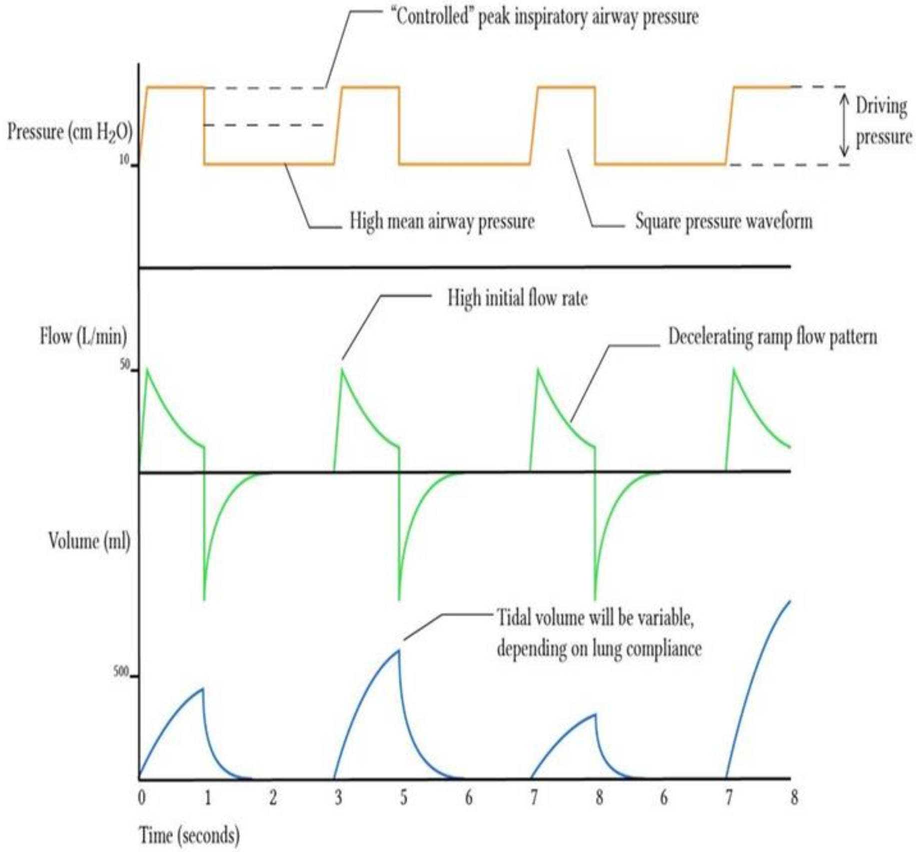


Figure 1.15. Pressure Control Ventilation. [11]

Assist Control Ventilation

In assist control ventilation, the patient can initiate each mechanical breath. Thus, the patient is ventilated synchronously with his spontaneous breathing effort in assisted ventilation. Thus, assist controlled ventilation combines mandatory and assist breaths that can be either volume control or pressure control, or dual control.

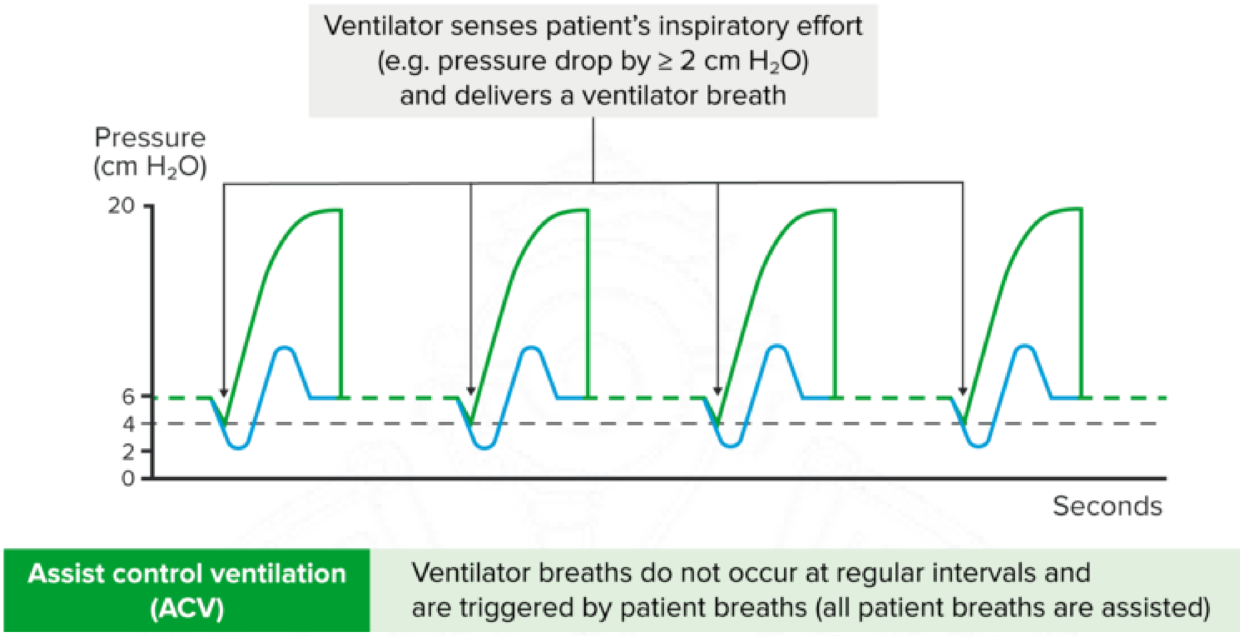


Figure 1.16. Assist Control Ventilation [13]

Synchronized Intermittent Mandatory Ventilation (SIMV)

In SIMV, ventilation can happen in three different ways. It can be time-triggered completely under that control of ventilator or patient triggered breath assisted or patient triggered but unassisted. In Synchronized intermittent mandatory ventilation (SIMV), the ventilator will deliver a mandatory (set) number of breaths with a set volume while at the same time allowing spontaneous breaths. Spontaneous breaths are delivered when the airway pressure drops below the end-expiratory pressure (trigger). Synchronized intermittent mandatory ventilation is typically used to help wean patients from the ventilator. One concern when using SIMV is that it can result in an increased work of breathing. One way to counteract this is by adding pressure support to the SIMV.

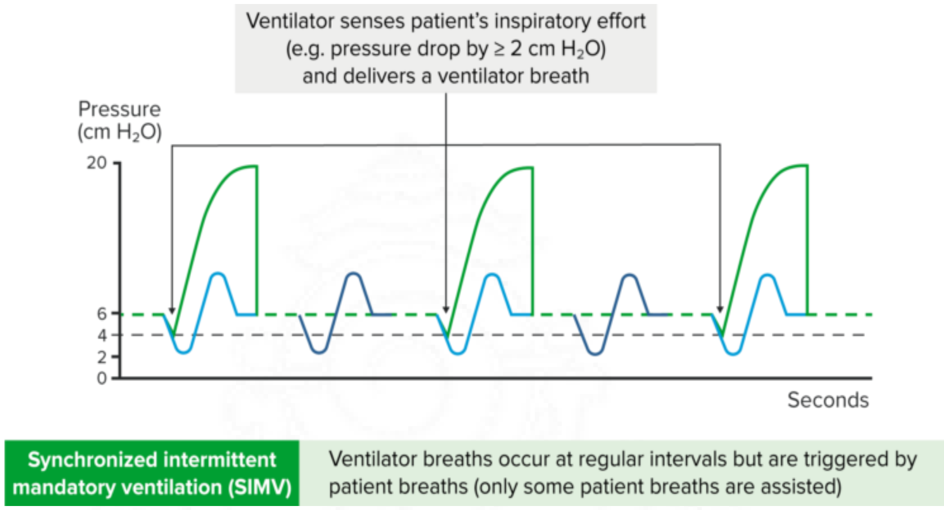


Figure 1.17. Synchronous Intermittent Mandatory Ventilation [13]

Pressure Regulated Volume Controlled Ventilation (PRVC)

Pressure-regulated volume control (PRVC) is a mode of ventilation in which the ventilator attempts to achieve set tidal volume at the lowest possible airway pressure. PRVC gives you the clinical benefits of both volume control and pressure control ventilation, i.e., volume guarantee and ventilation with low inspiratory pressure but at the same time takes away the major disadvantage of both modes. PRVC avoids the need for sedation and its effects on circulation.

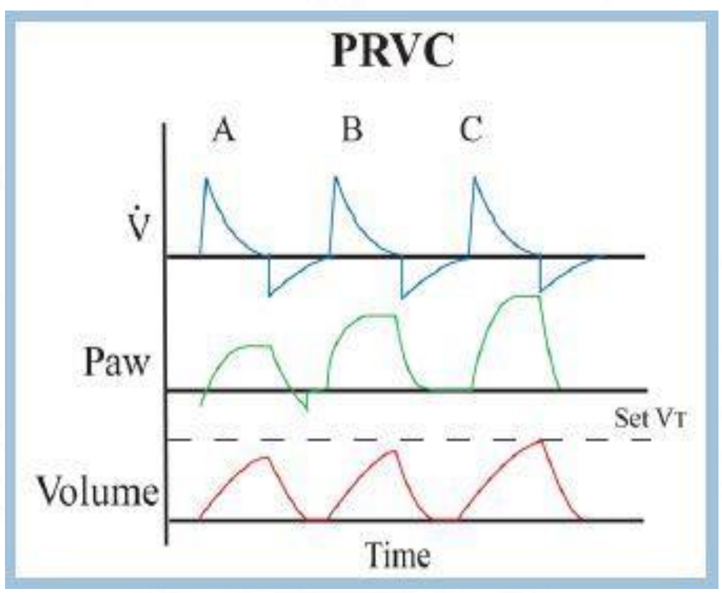


Figure 1.18. Pressure Regulatory Volume Control Ventilation [13]

Airway Pressure Release Ventilation

In Airway Pressure Release Ventilation, a continuous positive airway pressure (CPAP) is applied for a prolonged time to maintain adequate lung volume and alveolar recruitment with a time cycled release phase to a lower set of pressure for a short time or release time where most of the ventilation or CO_2 removal occurs. Airway pressure release ventilation (APRV) is a pressure control mode of mechanical ventilation that utilizes an inverse ratio ventilation strategy.

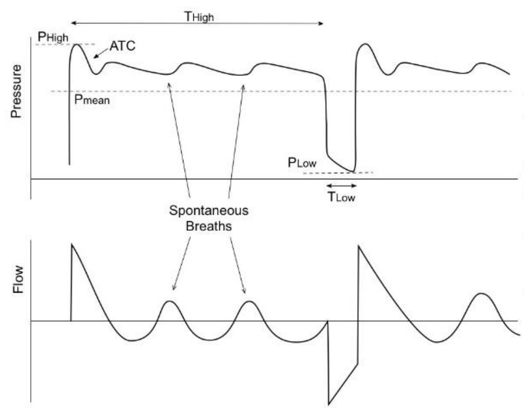


Figure 1.19. Airway Pressure Release Ventilation [12]

1.3.4. Applications of ventilator

A ventilator helps to recover from various conditions affecting the respiratory system. A few clinical conditions are:

1) In anesthesia
2) Home care in hypoventilated patients
3) Emergency medicine
4) Intensive care medicine

During any surgery requiring general anesthesia, the ventilator is necessary. The ventilator is also necessary after surgery as the patient may not be able to breathe immediately. The COPD, covid-19, Neuromuscular diseases.

1.3.5. Effects of Ventilator

In the case of acute sickness, mechanical breathing is a necessary medical intervention. However, there is a significant concern connected with using a ventilator. A few issues related to ventilators are listed below.

Intubation Related Complications

For mechanical ventilation, critically ill patients usually require endo- or nasotracheal or tracheostomy intubation. Intubation is associated with danger, including difficult intubation, laryngospasm, bronchospasm, and airway blockage; tube obstruction or occlusion; erroneous tube insertion, tube dislodgement; aspiration; and local damage to the thorax, dentition, pharynx, larynx, and trachea; hematoma formation; tracheal stenosis or necrosis; upper respiratory tract infection including sinusitis; tracheobronchitis and, VAP. [9]

Ventilator Induced Lung Injury (VILI)

VILI is caused by four basic pathophysiologic mechanisms: atelectrauma, barotrauma, volutrauma, and biotrauma.

Atelectrauma

High-shear forces open and seal recruitable atelectatic lung units, causing atelectrauma. At the interface of air boluses and collapsed recruited airways, shear stress and mechanical damage arise.

Barotrauma

High lung inflation pressure causes barotrauma in mechanically ventilated patients, which leads to high trans-pulmonary pressure, localized lung over-distension, and air leakage. As a result, careful inflation pressure control is a method for limiting lung distension and preventing barotrauma. As a result of over-distension, excessive inflation pressures can cause alveolar rupture, pneumothorax, pneumo-mediastinum, and subcutaneous emphysema, all of which are forms of barotrauma or air leakage. [9]

Volutrauma

Alveolar over-distension causes volutrauma. Alveolar epithelial strain is caused by mechanical hyperinflation, which causes lipids to be mobilized to the alveolar plasma membrane for cell repair. The surface area of cells is successfully increased, and the plasma membrane is prevented from rupturing. Under conditions of growing cell tension, these protective systems may be gradually exhausted, resulting in cellular detachment from the plasma membrane. [9]

Biotrauma

Mechanical injury to the lungs can cause an inflammatory reaction that can be harmful, a condition known as "biotrauma". Biotrauma is caused by the activation of harmful cytokines and other inflammatory mediators not only in sick and normal lung regions but also in other organs, resulting in multi-organ dysfunction and increased mortality. [9]

1.3.6. Types of ventilator

Based on Actuator

Centralized gas supply

Most of the hospital ventilators work based on the gas supplied from a centralized pressure system. The working pressure range of the wall pipe is from 350- 400 KPa. They are regulated by a pressure regulator before giving input to the ventilator.

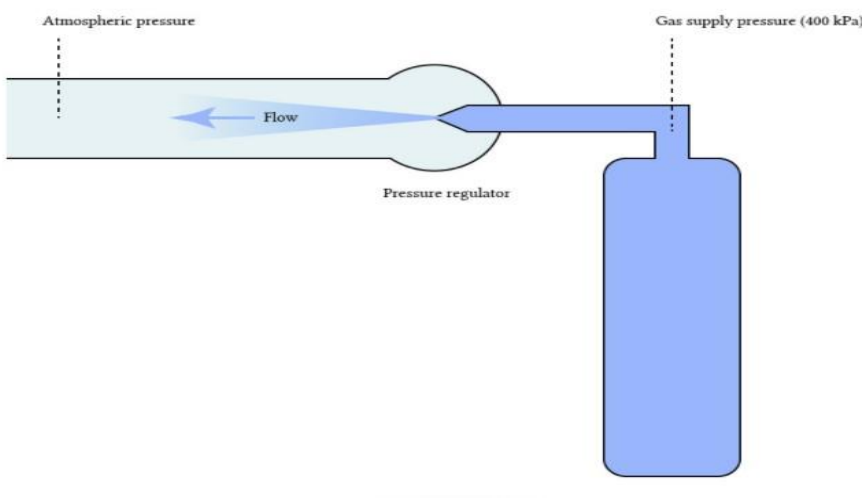


Figure 1.20. Wall gas supply to ventilator [10]

Turbine type

Ventilators can use special devices incorporated inside the system to generate the required pressure. For example, the blower of the turbine or centrifugal type can generate a modest pressure of 2psi, which is still about 140 cm H_2O. As the human requirement is less than 40 cm H_2O, it can be highly efficient in creating portable ventilators.

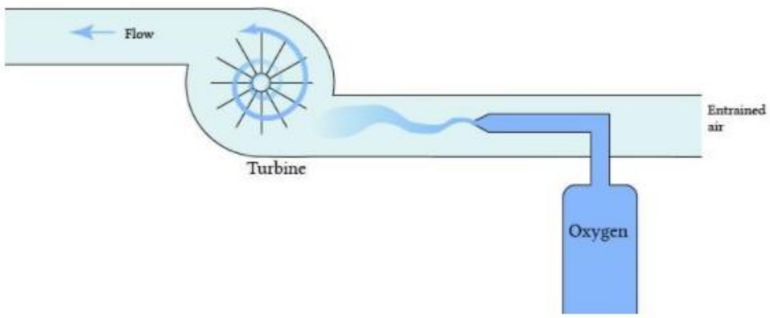


Figure 1.21: turbine type compressor [10]

Piston Type

A rigid chamber, the volume of which is mechanically manipulated to generate inspiratory flow, is used, a plunger pulls and pushes the fresh gas mixture inside the cylinder.

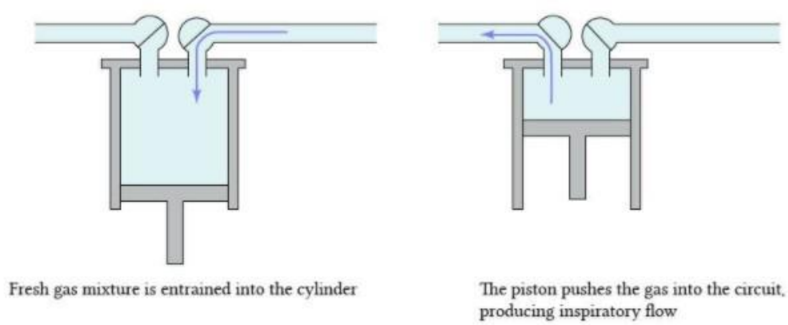


Figure 1.22: Piston actuator [10]

Bellows Type

The “bellows” is a flexible accordion-like reservoir which stores the gas mixture which you intent do inflate your patient with. By applying external pressure to this reservoir, inspiratory flow is generated. There are numerous ways of applying this external pressure (by a lever, a motor, a weight using gravity, etc) but by far the most popular appears to be the pressure of a second gas circuit. [105]

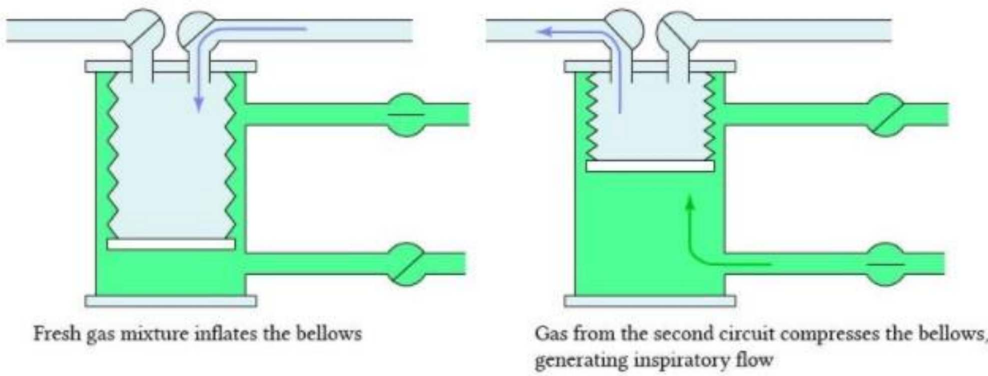


Figure 1.23. Bellows Actuator [10]

Based on usage

Based on the usage, the ventilators are classified majorly into the following types:

ICU Ventilator

The ICU ventilators are sophisticated, with various ventilator operating modes, the trigger sensitivity, flow capabilities are high to treat patients under critical condition.

Figure 1.24: ICU ventilator [18]

Transport Ventilator

The transport ventilator is designed to be compact, uses a turbine-type actuator to generate the pressure and flow. The essential pressure and flow rate are easily achieved with the ventilator. It generally operates on a few ventilator modes only.

Figure 1.25: Transport Ventilator [18]

Neonatal Ventilator

The neonatal ventilator is specially designed to handle higher respiratory rates. The normal range of infant breathing rate is 20-30 breaths per minute(bpm). For diagnosis, it generally increases.

Figure 1.26 Neonatal [15]

Homecare Ventilator

The homecare ventilator is designed in a cost-effective manner. It doesn't have the requirement of multiple ventilator modes. It uses a blower or turbine-type actuator to generate the pressure and flow rate. The oxygen input is given to stored oxygen from cylinders.

Figure 1.27: Homecare Ventilator [18]

1.4. Fraction of Inspired Oxygen

FiO_2 is the concentration of oxygen in the gas mixture delivered to the patient. The proportion of inspired oxygen in the gas mixture at room air is 21%, implying that the FiO_2 at room air is 21%. In Medical treatment and emergencies, the requirement of FiO_2 is much higher than 21% and goes up to 100%.

1.4.1. Significance of FiO_2 Management

Clinical Significance

The fraction of inspired Oxygen, FiO_2, estimates the oxygen content a person inhales and is thus involved in gas exchange at the alveolar level. Understanding oxygen delivery and interpreting FiO_2 values are imperative for the proper treatment of patients with hypoxemia. Hypoxemia under critical conditions can cause mortality. When oxygen consumption and supply are mismatched, cell damage and death occur. The key is recognizing the cause and, thus, the appropriate route of treatment. [14]

FiO_2 Administration

The appropriate FiO_2 delivery depends on the etiology of hypoxemia:

1. Hypoventilation
2. V/Q mismatching
3. Shunt

To reduce surgical site infections, the World Health Organization and the US Centers for Disease Control recently advised the use of 0.8 FIO_2 in all adult surgical patients having general anesthesia. [21]

The Delivery of Oxygen given to the patients is not standardized. The physician has certain parameters as references based on which the decision on the FiO_2 % shall be taken. One important parameter is saturation of arterial oxygen (SaO_2) level, and also the Carrico index. Carrico Index is the ratio of arterial Partial pressure of oxygen to the Fraction of Inspired Oxygen. [14]

Risk Associated with High FiO_2

The administration of high FiO_2 value may lead to the following conditions:

Potent Cellular Toxins - the oxygen-free radicals created at high PaO_2, superoxide, hydroxyl & hydrogen peroxide, singlet O_2 are different forms. They cause cellular Injury, Inflammation, Oedema, pulmonary Fibrosis.

Absorption Atelectasis- a high volume of O_2 in the alveolar volume can cause the sudden collapse of the alveoli.

Chronic Hypercapnia - the body loses its potential to sense excess CO_2, leading to slow accumulation.

Decreased Cardiac Output- increased peripheral vascular resistance in congestive heart failure leading to reduced cardiac output. [14]

1.4.2. Gas Blender

The inspiratory gas flow is always a gas mixture. A gas blender of some type is needed to combine the gases. The gas blender is normally a chamber with proportional valves that regulate the flow of air and oxygen, respectively. Typically, these valves are connected in such a way that their openings are related to one another, such that opening one valve to 100% of the desired flow rate closes the other valve completely. This type of setup is called a proportional valve, and it's used in almost all ICU ventilators. [14]

Figure 1.28. Gas Blender [11]

Chapter II

Project Objective

The SARS CoV-2 has managed to spread to every part of the world. The medical infrastructure of most countries struggled to encounter this unprecedented situation. The demand for ventilators has seen an exponential rise in the market due to the covid-19. The total spreading had crossed over 100 million, and the casualties are more than 3 million. Most countries have been affected by the 1st wave of the covid-19 pandemic, and some countries fear the 3^{rd} wave. One of the severe symptoms of covid-19 is SARS(Severe Acute Respiratory Syndrome). In such cases, the patient would need assistance for breathing; the ventilators can provide that. Patients with underlying lung disease may develop respiratory failure under various challenges and should be supported by mechanical ventilators. These are machines that mechanically assist patients in inspiring and exhaling, allowing the exchange of oxygen and carbon dioxide to occur in the lungs; this is called artificial respiration. Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, under the Department of Science and Technology Govt of India, one of the pioneers in medical devices development, took responsibility for developing low-cost portable indigenous ventilators.

The ventilator is a low-cost portable type ICU ventilator that works based on a turbine actuator to produce the necessary pressure and flow, as shown in Fig 2.1. The settings on the machine provide controls for various parameters of the ventilator. In the Novel FiO_2 mechanism we have overcome the major difficulties faced with the conventional FiO_2 mechanism. It needs rigorous testing to validate the performance, especially the biocompatibility tests. Since the validation process consumes a lot of time and effort, the development and manufacturing of ventilator within a short time is not possible during a pandemic. Hence, the rationale behind the design process was to implement a FiO_2 mechanism with proven biocompatible surface materials and interaction with airway circuits with artificial materials are made nil or minimum. Thus the time, effort, and cost of development shall be reduced to a great extent.

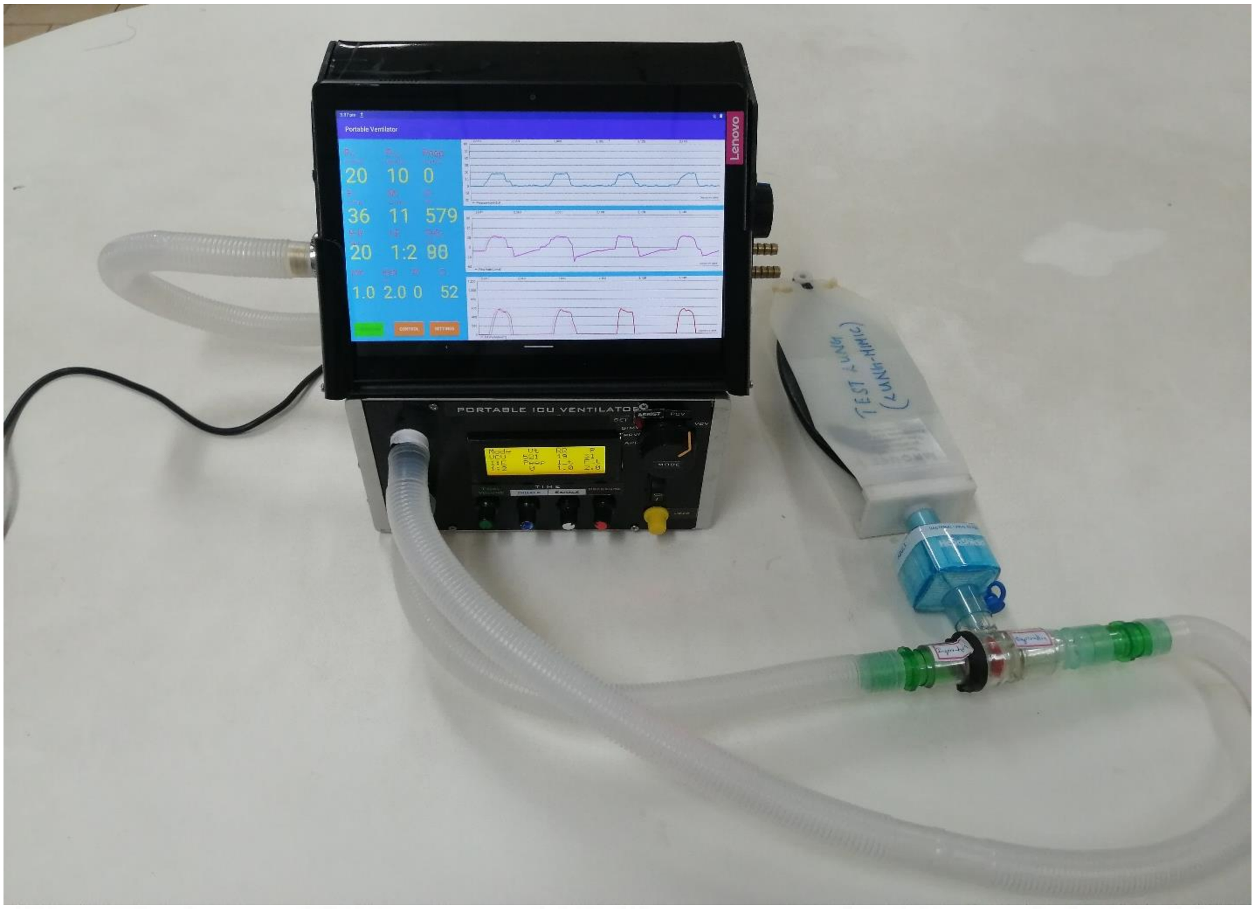


Figure 2.1 The Chitra Portable Ventilator

The concept diagram of the mechanism is shown in Figure 2.2. Conventionally, to obtain varying FiO_2 in the range of 21% to 100%, the flow rates of air and oxygen need to be controlled. In the Chitra Portable Ventilator, the mechanism involves using two stepper motors attached to pusher plates to squeeze the air and oxygen tubes to control the flow rate of both the air and oxygen given to the patient to obtain different FiO_2. The air and oxygen are passed through two tubes provided in the ventilator. They are joined with the help of a y-connector. The squeezing varies based on the FiO_2 set by the physician. The stepper motor is controlled with a driver circuit and a microcontroller such as Arduino board.

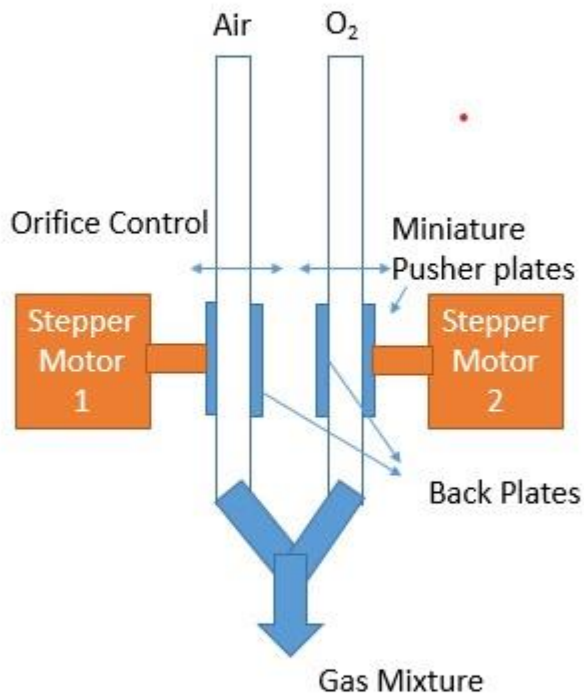


Figure 2.2 The FiO_2 Mechanism in Chitra Ventilator

The position of the pusher plates are changed as per the demand using a suitable algorithm in the microcontroller. The change in squeezing of the tube, changes the resistance offered to the flow, thus producing different velocities of the fluid. The various velocities creates different flowrates of the fluid which intrun changes the concentration of the oxygen in the air. Thus it has become necessary to find relationship between the squeezed areas or position of the pusher plates to flowrates to caliberate the device for clinical usagea.

2.1. Objectives

The objective of the project is to validate the novel FiO_2 mechanism used in Chitra ventilators using a two-step approach. In the first approach, the geometry of the FiO_2 mechanism is created using suitable CAD software and simulation of the fluid flow will be carried out to find out the velocities of the fluid flow for different areas of squeezing. CAD models for different areas of squeezing and position of the pusher plates shall be prepared and simulated using suitable software for structural analysis and fluid flow analysis. From the simulation, a relationship between the areas of the plate, the position of the pusher plates to FiO_2 shall be developed. The change in the FiO_2 with the squeezing area shall be studied properly to provide feedback on the improvement of the mechanism.

In the second approach, an experimental setup of the same dimension and materials will be set up with pusher plates which can be manually adjusted. The experimental setup will be tested for different area ratios and positions to obtain the flow rates of fluid flow through it. Using the obtained flowrates, FiO_2 shall be computed with an analytical method. The results obtained through simulation and experiments shall be compared to validate the mechanism.

2.2. Application

The mechanism can bring cost reduction both in the production and testing of the lung ventilator. The novel mechanism can lead to the development of homecare and portable ventilators in a rapid and affordable manner during pandemic times. Based on the reaction time and reliability, it can be used in ICU ventilators also.

Chapter III

Methodology

In this chapter, the approach adopted to simulate the mechanism, the various dimensioning implemented in the device, challenges in the flow analysis, and structural analysis in low-cost FiO_2 controlling mechanism of Chita portable ventilator is explained. The methodology adopted for obtaining the project objectives is described in detail.

3.1. FiO_2 Control Mechanism in Chitra Portable Ventilator

The FiO_2 mechanism used in the Chitra Portable Ventilator is shown in figure 3.1. The ventilator takes air and oxygen as input. The gases pass through the medical-grade PVC tubes and get mixed with the help of a y-connector. The mechanism involves stepper motors to squeeze the tubes to control the air and oxygen flow rate. The squeezing varies based on the FiO_2 set by the physician. The stepper motor is controlled with a driver circuit and an Arduino board.

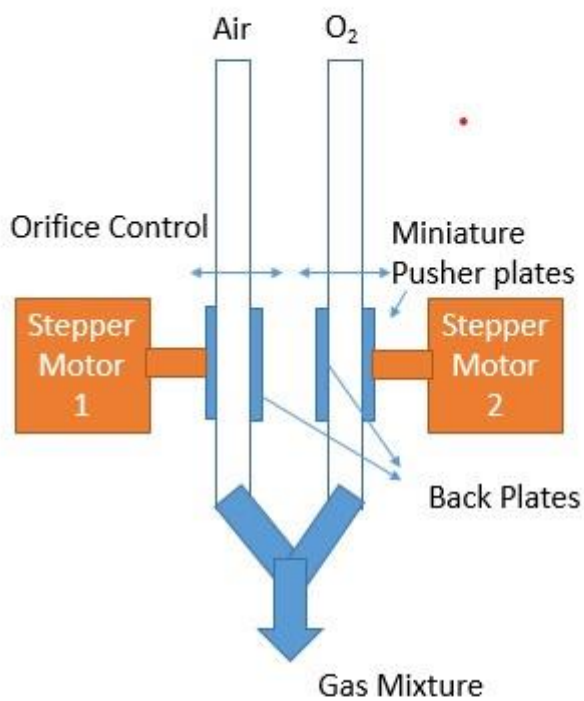


Figure 3.1 The FiO_2 Mechanism

3.2. Simulation of FiO_2 Mechanism

Simulation Modelling allows us to solve real-world problems safely, quickly, and efficiently. It can create a hypothetical situation and obtain results in the least possible time. The cost and time saved are immense. The interpretation of the result is simple to understand. It is vastly used across industries and in the medical field as well. The simulation allows to perform both structural and flow analysis in the FiO_2 mechanism. The simulation modeling provides valuable solutions by giving clear insights into complex systems. Hence, in this project, the validation of the FiO_2 mechanism and the calculating the correlation between the area ratio of fluid-carrying tubes is performed by simulating the fluid domain and conducting structural analysis.

3.2.1. Approach

With the literature survey and basic understanding of the ventilator requirements, usage, and other aspects, the dimensions are recorded to perform the simulation. Simulation is used to extract the data to control the operating parameters of the ventilator. The objective of the simulation is to determine the flow changes in the tube due to the structural changes occurring. The incorporation of flow analysis within structural analysis can be called the multi-physics model or fluid-structural interaction(FSI). The mechanism can be simulated either through a multi-physics model or two-step simulation processes where the flow analysis and structural analysis are done separately. The multi-physics model is challenging as it involves the results of structural analysis to be imported into flow analysis and vice-versa. Some software can solve multi-physics problems with certain limitations.

The multi-physics model of the mechanism on running in ANSYS didn't show promising results as the data transfer between structural and fluid analysis lead to a lot of errors. The same simulation on performing in COMSOL as well. It has shown reliable results in multi-physics problems with axis-symmetry, where it initially solves the problem as 2D and able to extrapolate the results in the region. The problem statement solved in the project is not axis-symmetry. Hence we adopt the 2 step process. The structural and flow analyses are done independently.

3.2.2. 3D Modelling

The simulation of the FiO_2 Mechanism was done with the help of commercially available CREO 6.0 and ANSYS 19.0 software. The CREO allows creating the models that we would like to work upon or get analyzed. It is equipped with multiple special tools to create intricate shapes and measure irregular surface area. Taking the initial dimensions of the setup that is to be used in the ventilator, the CAD modeling was done as shown in Figure 3.3.

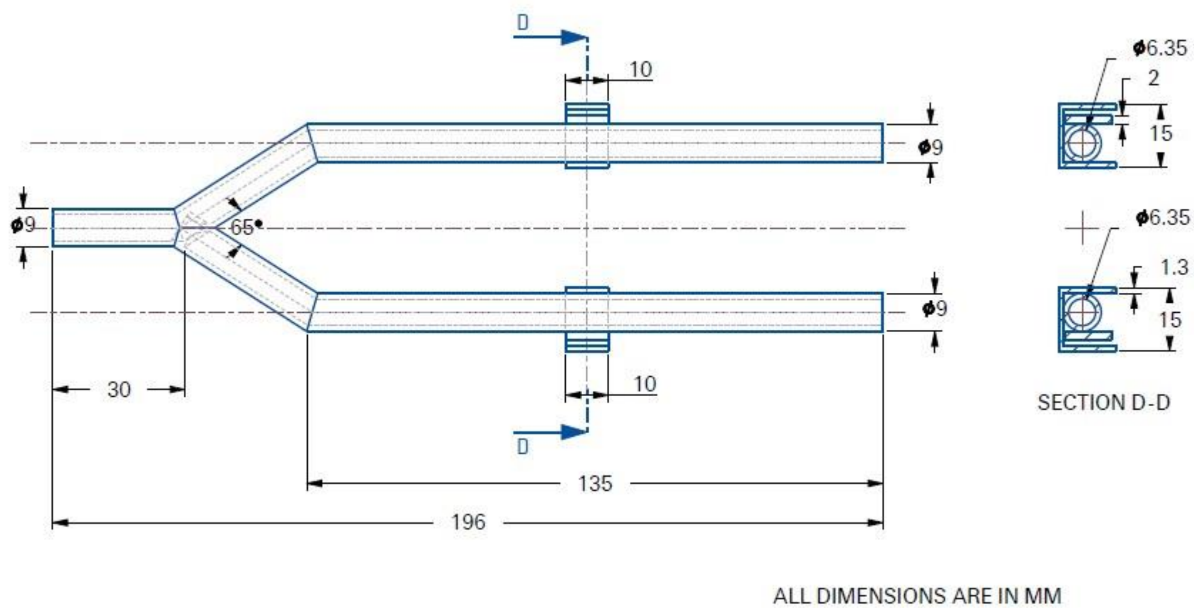


Figure 3.2. Dimensions of the FiO_2 Mechanism

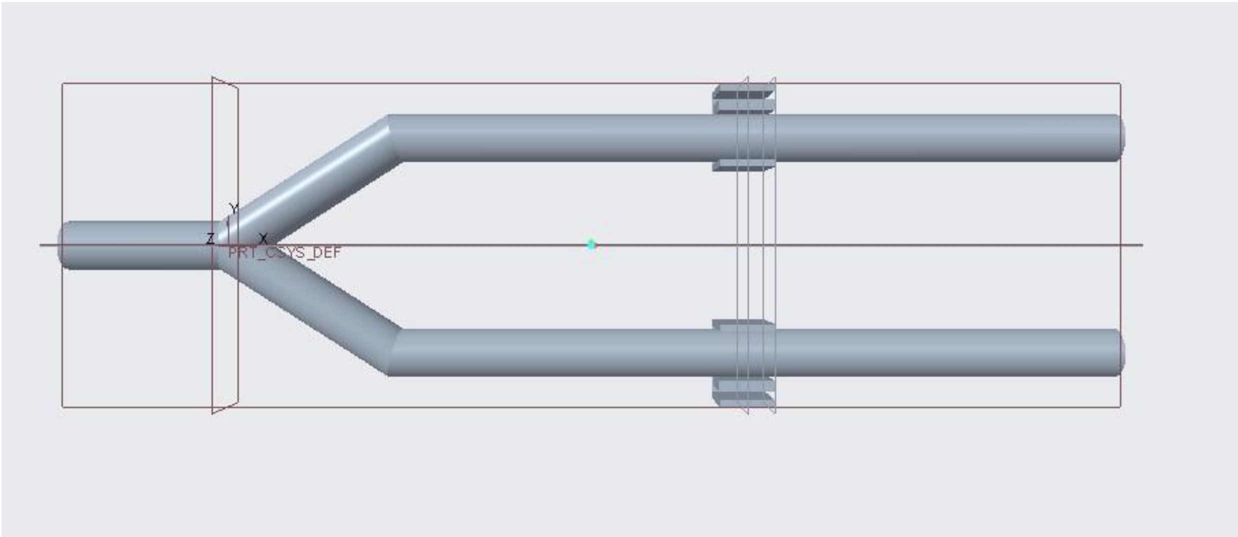


Figure 3.3. The CREO model of the FiO_2 Mechanism.

Figure 3.2 & 3.3 gives the dimensions of the mechanism and the CREO model that helps to visualize the mechanism and overall design.

Fluid Models

The flow analysis using ANSYS-CFX requires the 3D models of the fluid domain to work with the defined boundary conditions. The approach is to model the fluid domain with squeezed area to identify the flow rate. To model the fluid domain, the area of squeezing needs to be chosen. The oxygen and air tube area vary with the movement of the clamps. The variation of air tube area and oxygen tube area is inversely proportional. Assuming a 10% increment in oxygen area and a 10% decrement in air tube area, the simulation is done to cover all FiO_2 ranges possible with the current mechanism. Table 3.1 shows the size variations in the tube. At maximum clamp displacement, there is still a 12% opening of the gas tube area, which is calculated using structural analysis. Hence the least area considered is 3.85 mm^2.

Table 3.1. Area variation in Oxygen and Air tube

S.No.	O_2 Area(A1) (mm^2)	% O_2 tube opening	Air Area (A2) (mm^2)	% Air tube opening
1	3.85	12	31.67	100
2	3.85	12	28.50	90
3	6.33	20	25.34	80
4	9.50	30	22.17	70
5	12.67	40	19.00	60
6	15.84	50	15.84	50
7	19.00	60	12.67	40
8	22.17	70	9.50	30
9	25.34	80	6.33	20
10	28.50	90	3.85	12
11	31.67	100	3.85	12

Variation in the area is chosen for the percentage of FiO_2 to vary in the clinically required range from 21 % to 100%. The CAD models of the selected area, as listed in table 3.1. are designed in PTC CREO 6.0.The drawing of fluid domain based on which all other models with area variations is generated is shown in figure 3.4.

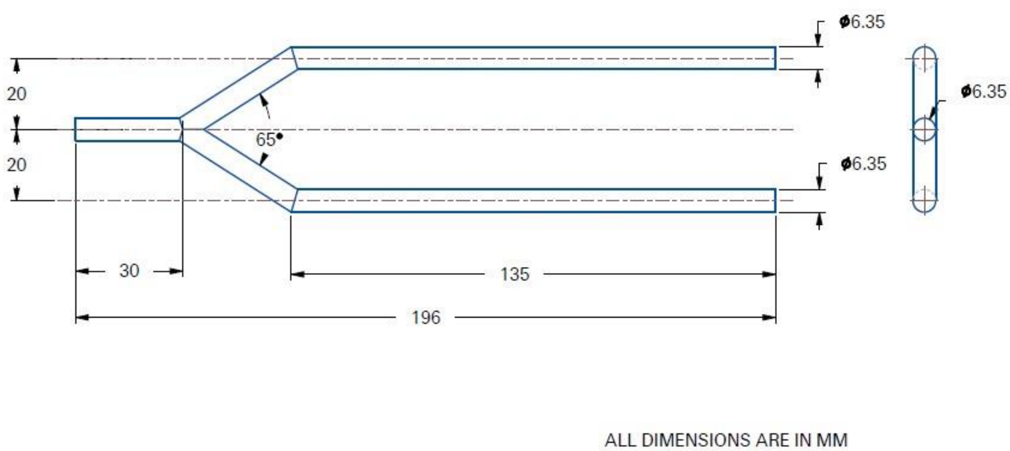


Figure 3.4. Fluid Domain

Figure 3.5 is used to understand the flow analysis better, where the oxygen flows in the upper tube and the air in the lower tube for all the models discussed in the 3D modeling section as listed in table 3.1. The mixture of the gases obtained at the output of the Y-connector is delivered to the patient through a blower. The variation in the area is achieved through a squeezing mechanism.

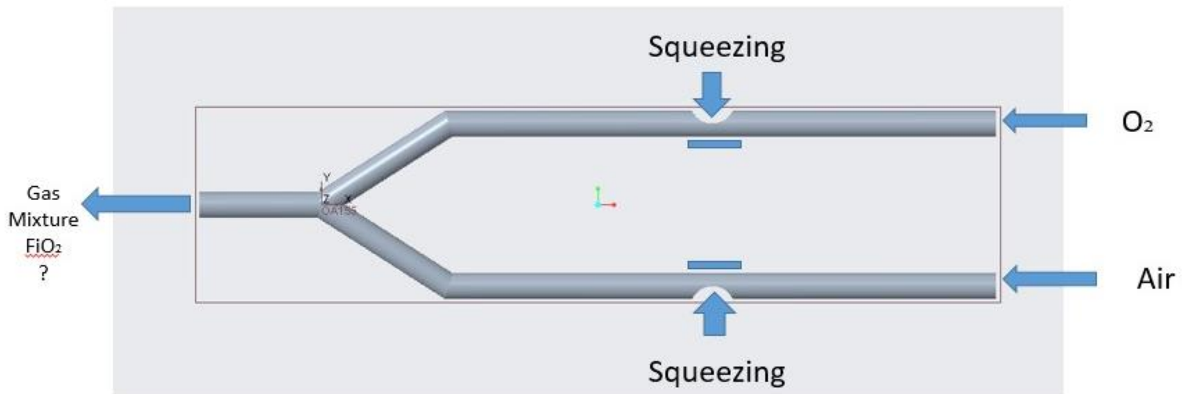


Figure 3.5: Flow Diagram

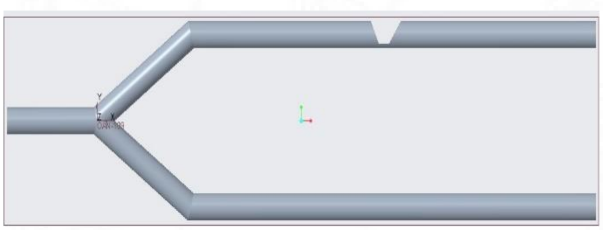


Figure 3.5.1: 12% O_2 and 100% Air

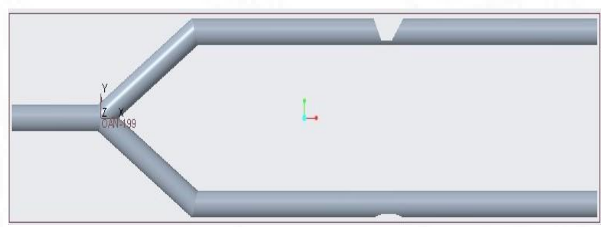


Figure 3.5.2: 12% O_2 and 90% Air

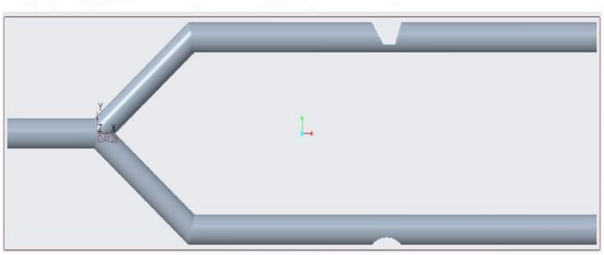


Figure 3.5.3: 20% O_2 and 80% Air

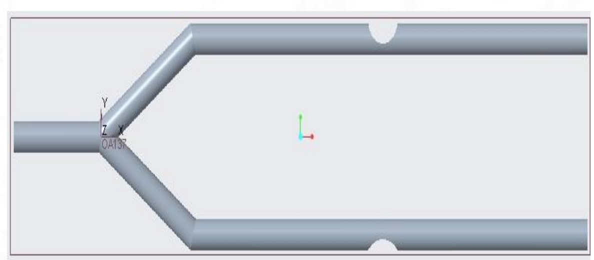


Figure 3.5.4: 30% O_2 and 70% Air

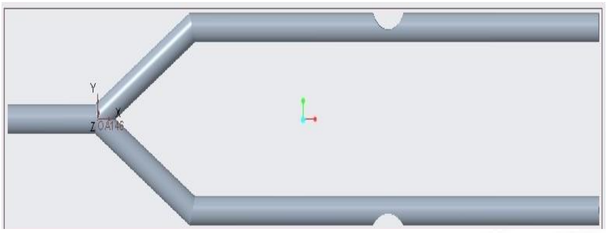


Figure 3.5.5: 40% O_2 and 60% Air

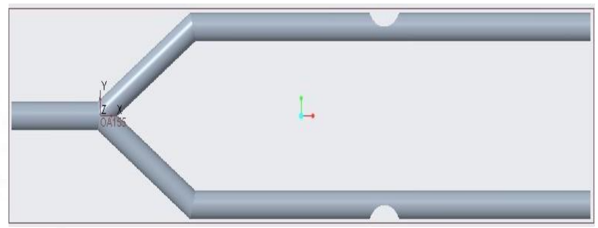


Figure 3.5.6: 50% O_2 and 50% Air

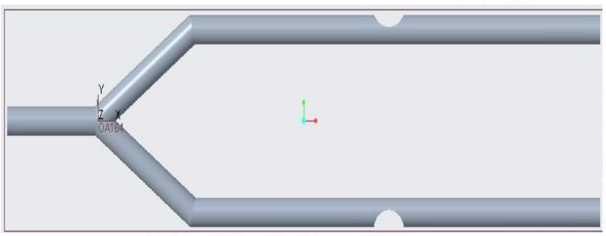


Figure 3.5.5: 60% O_2 and 40% Air

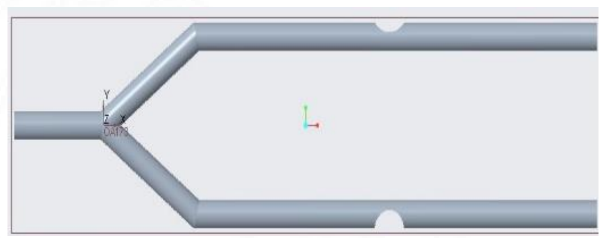


Figure 3.5.6: 70% O_2 and 30% Air

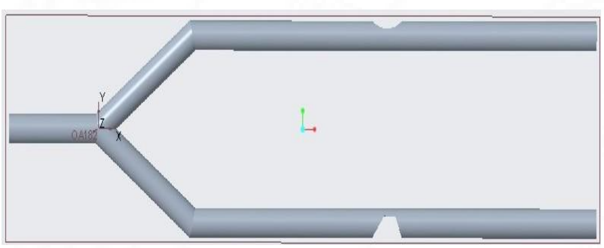


Figure 3.5.6: 80% O_2 and 20% Air

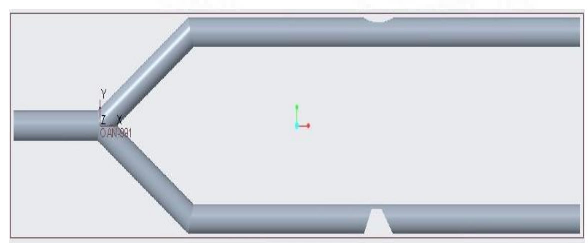


Figure 3.5.6: 90% O_2 and 12% Air

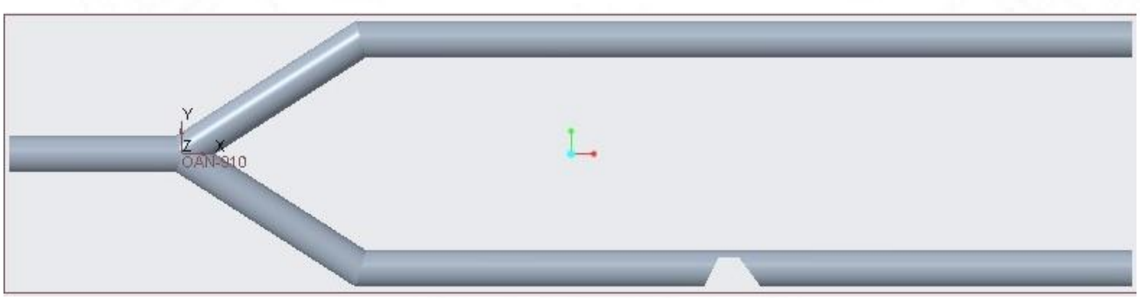


Figure 3.5.11: 100 % O_2 and 12 % Air

3.2.3. Flow Analysis

The objective of the flow analysis is to determine the flow rate of air and oxygen for the change in the squeezed area. The difference in the area due to pipe squeezing was made by drawing the 3D models of the fluid domain, as shown in figures 3.5.1 to 3.5.11. The squeezed models area is mentioned in table 3.1. The inner volume of the tubing makes the fluid domain.

The type of flow has to be classified by determining the Reynolds number, to perform the simulation.

Reynolds Number

Reynolds number is the ratio of inertial forces to viscous forces. The Reynolds number is a dimensionless number used to categorize the fluid systems in which the effect of viscosity is essential in controlling the velocities or the flow pattern of a fluid. [23]

Reynolds Number calculation requires the properties of the fluid flowing.

In ventilators, there is a mixing of air and oxygen. As the air density is 1.225 kg/ m^3 and the oxygen density is 1.429 kg/m^3, the density difference is only 0.204 kg/m^3. As ventilators are operated with higher oxygen volume in clinical conditions and the minor difference in density, it can be assumed that the impact of consideration of oxygen instead of the air-oxygen mixture is negligible in the simulation results. Hence the simulation is run considering the fluid as oxygen to replicate close conditions.

The fluid properties of oxygen are as follows

Density: 1.429 kg/m^3

Specific heat capacity: 0.918 KJ/Kg/K

Dynamic Viscosity: 2.018 x 10^(-5) Pas or 0.2018 centiPoise,

Formula for Reynold's number

$$Re = \frac{\rho V D}{\mu} \qquad \text{.......(1)}$$

The velocity of the fluid flowing in the ventilator is needed to compute the Reynolds number.

The velocity is calculated considering the peak flow of the ventilator i.e., 60 Lpm. In general, the velocity is higher than the specified peak flow within the gas tubes, but if the flow is turbulent for the least velocity, then the flow shall be turbulent for any higher velocity.

For Q = 60 Lpm

Then the flow rate is Q = 100 x 10^(-5) m^3/s

Q=AV= 100 x 10^(-5) m^3/s, where A= 31.67mm^2

Hence V = 31.575 m/s,

D= 6.35mm, ρ= 1.429 kg/ m^3 , μ = 2.018 x 10^(-5) Pas

$$Re = \frac{\rho V D}{\mu}$$

Using equation no (1) and substituting the values for the density, viscosity, diameter, and velocity of the fluid, the Reynolds number for the geometry is computed to be **14201.** In order to classify the type of flow within the geometry as either laminar or turbulent, a comparison of the calculated Reynolds number is made with the critical Reynolds number for a pipe flow which is 2300. The Reynolds number for the flow within the geometry is much higher than the critical Reynolds number. The flow is classified as a turbulent flow for the simulation studies.

Mesh Independent Studies

The simulation works based on the division of the model into a finite number of elements and applying the equations at every element. The element size determines the accuracy of the result; by reducing the size of the element, the results get more accurate. But the disadvantage with the finer element size is the high simulation time and computational resources. To determine the optimum element size, the simulation is run with different element sizes maintaining the same boundary conditions. The variation in the results are calculated. If the value variation is less than 5%, the particular element size is selected.

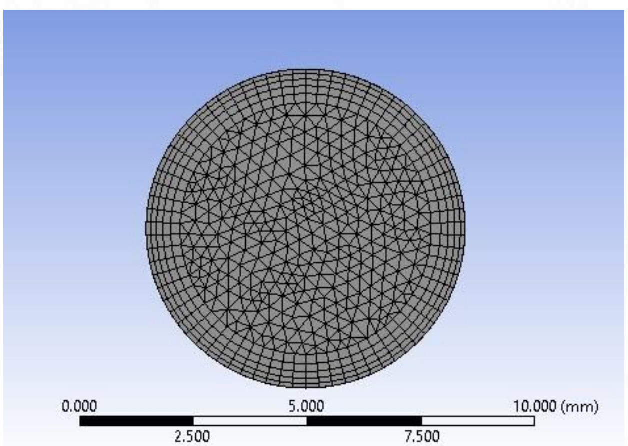
Table 3.2: Mesh Independent studies for Flow analysis

S.No	Elemental Size	O_2 (A1) (mm^2)	Air(A2) (mm^2)	Average Velocity (m/s)	O_2 Velocity (m/s)	O_2 Flowrate (m^3/s)	Air Velocity (m/s)	Air Flowrate (m^3/s)	Peak Flow (m^3/s)	FiO_2 %
1	0.3	19.22	19.22	102.75	51.46	118.84	51.46	118.82	237.26	60.60
2	0.5	19.22	19.22	102.84	51.67	119.32	51.53	118.99	237.47	60.77

In order to perform the mesh independence studies, the flow domain is meshed with different element sizes using ANSYS CFX inbuilt settings. Table 3.2. show the parameters determined from the simulation for element sizes 0.3mm and 0.5mm. The difference in average velocity values, oxygen velocity, and FiO_2 is minimal. Therefore, the error is less than 1% between 0.3mm mesh size and 0.5mm mesh size, and 0.5 mm element size is considered for meshing in the project.

Table 3.3: Variation in Mesh Independent Studies

S. No.	Parameter	Variation Value %
1	Average Velocity	0.08
2	Oxygen Velocity	0.4
3	FiO_2	0.28



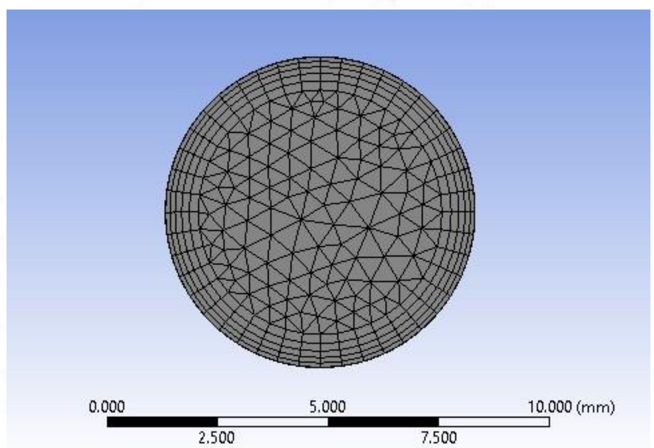


Figure 3.6: shows the cross-section of the meshing with 0.3mm and 0.5mm respectively.

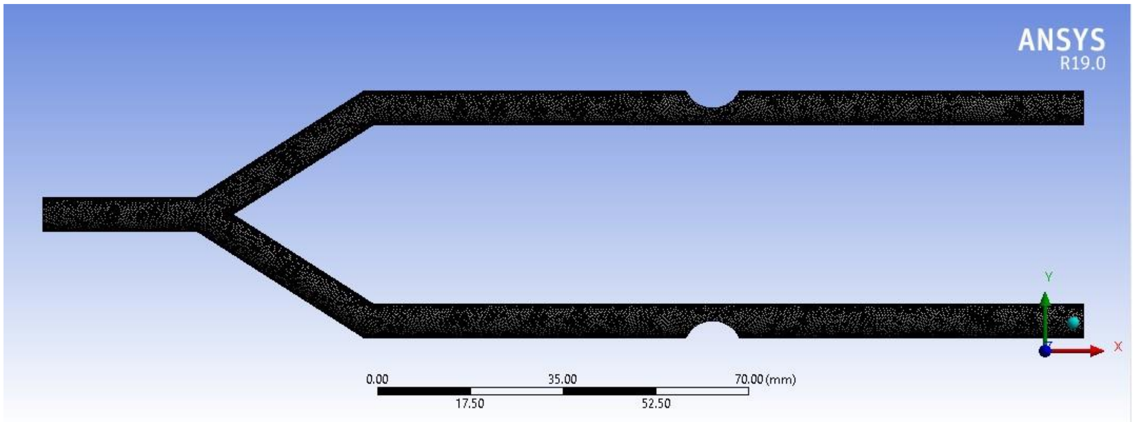


Figure 3.7. The body sizing meshing 0.5mm of 50% opening of air and O_2.

ANSYS-CFX

In ANSYS 19.0, Fluid Flow (CFX) method is used to simulate the fluid flow.

The simulation procedure is as follows:

1) Import the geometry
2) Edit the Mesh file, choose Body Sizing meshing, give the element size as 0.5mm. Give prism layers using the inflation option. The first layer thickness of 0.1mm, total of five layers and growth rate of 1.2 is used. The Inlet and Outlet sections are also named.
3) Edit the Setup file; give the boundary conditions as 20 KPa and 10 KPa pressure respectively for inlet and outlet. Choose turbulence k-Epsilon Fluid model to run the simulation.
4) Update the solution, and wait for the computation to finish.
5) Edit the Results.

After the solution is updated, a few CFD-post processing steps are done to extract the results. Streamline with at least 500 points from the inlet is taken to study the velocity and the flow distribution. Contour is used to plot the pressure gradient and Yplus values.

The results are recorded in an excel sheet. Our interest lies in the flow velocity to determine the flow rate. Since we define the pressure as boundary conditions recording the pressure won't be of any help. The velocity of the fluid in the upper and lower tube has to be obtained just after the squeezing. So, separate planes are created in each tube. In the function calculator, the average area method gives the velocity at the chosen plane. The planes are created using three points method, and the area of the plane is specified to prevent overlapping with another tube. The x-axis coordinates are the same for all planes created in different models to make sure velocity is measured at a particular section for comparison.

The velocity streamlines results of 11 cross-sections are shown in the below Figures 3.8 to 3.18.

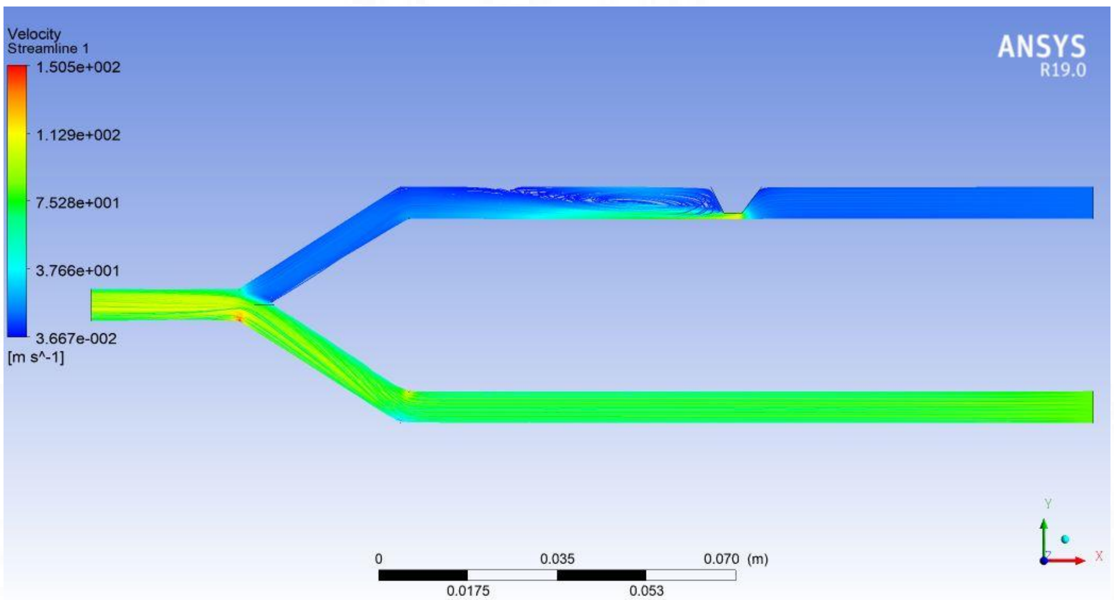


Figure 3.8. 12 % opening of oxygen tube and 100% opening of the air tube

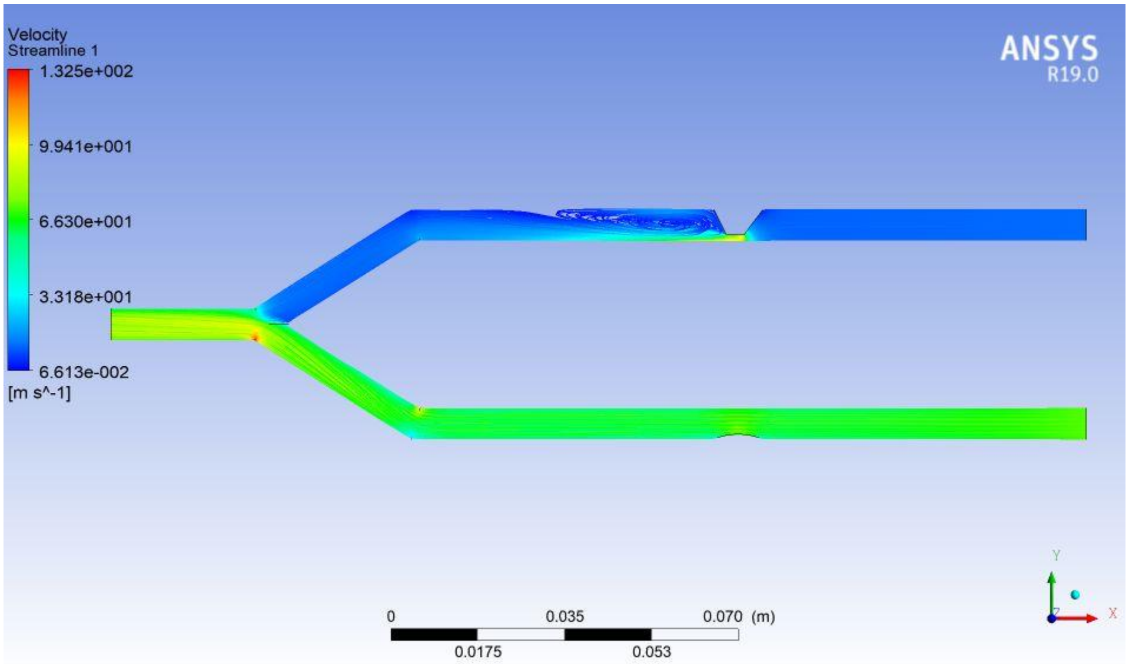


Figure 3.9: 12 % opening of oxygen tube and 90 % opening of the air tube

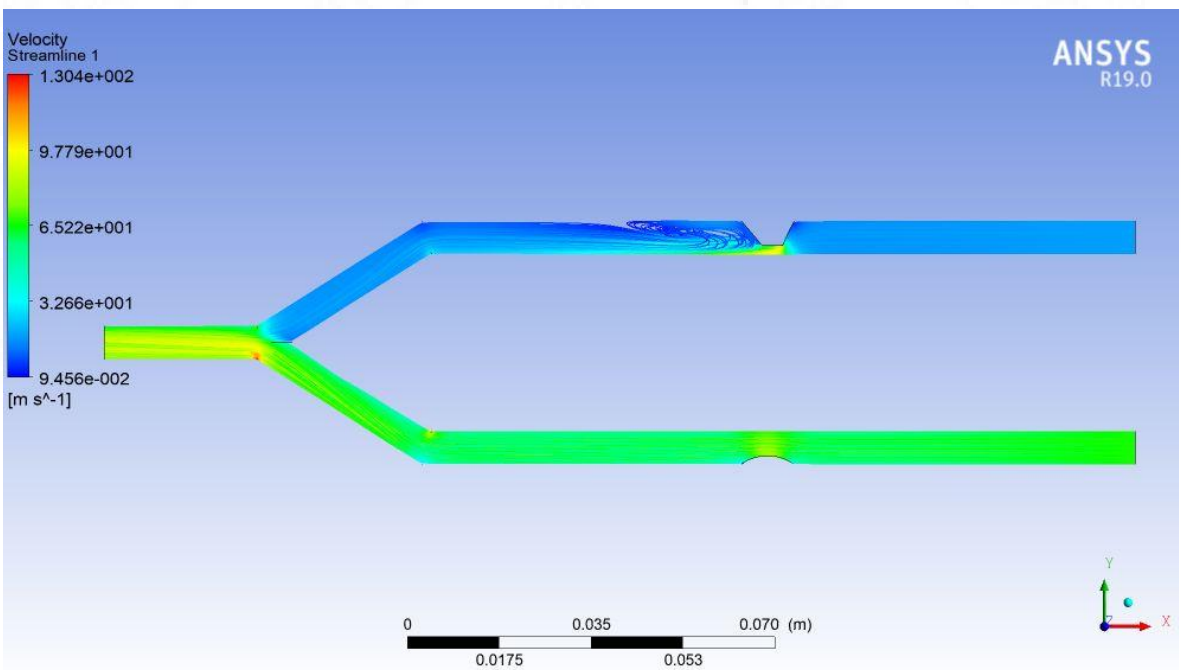


Figure 3.10: 20 % opening of oxygen tube and 80 % opening of the air tube

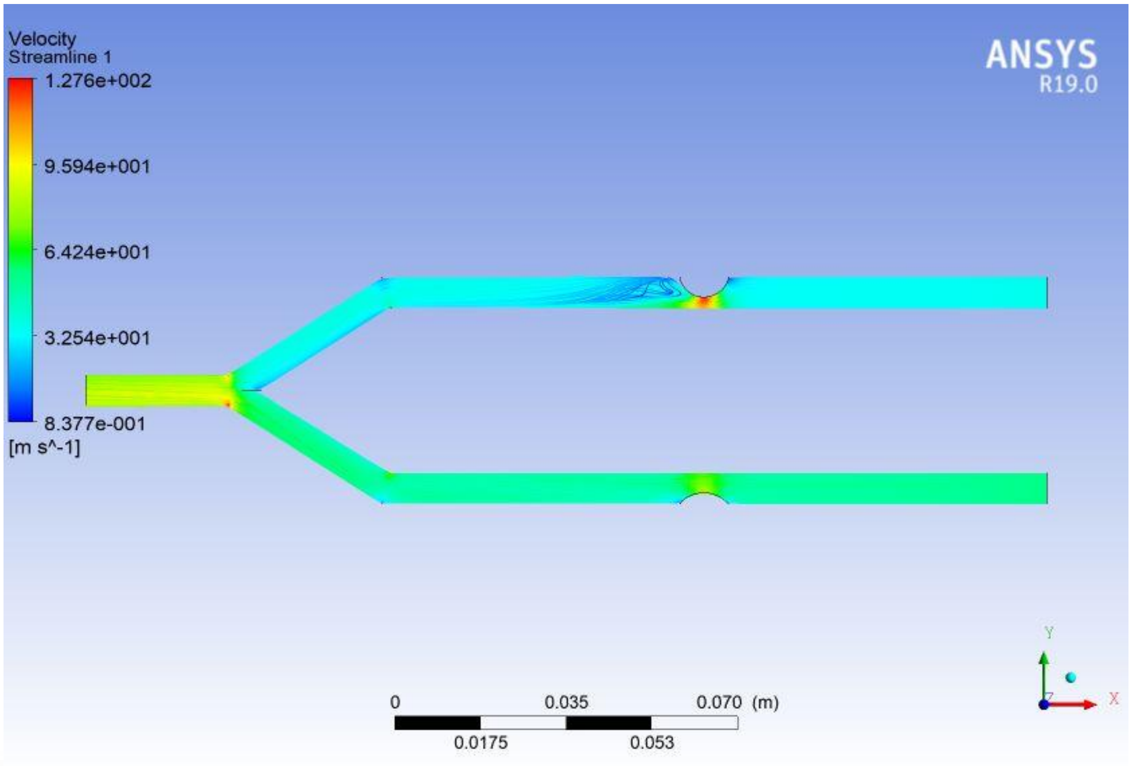


Figure 3.11: 30 % opening of oxygen tube and 70 % opening of the air tube

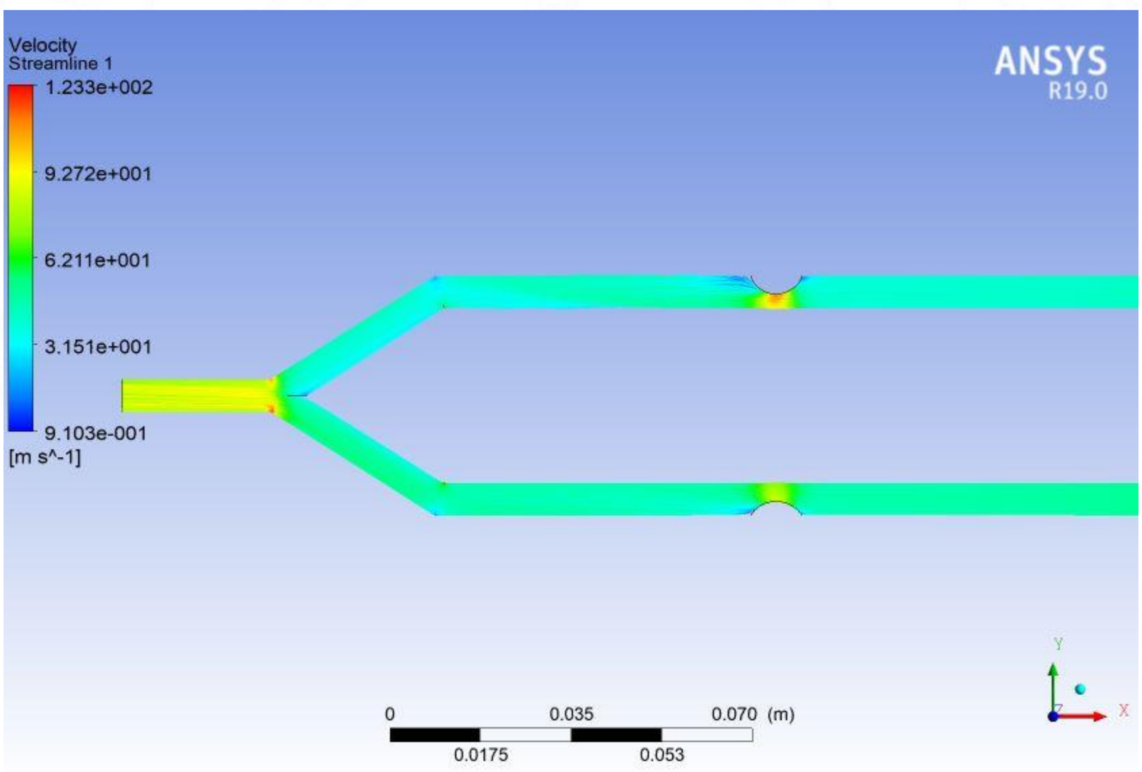


Figure 3.12: 40 % opening of oxygen tube and 60 % opening of the air tube

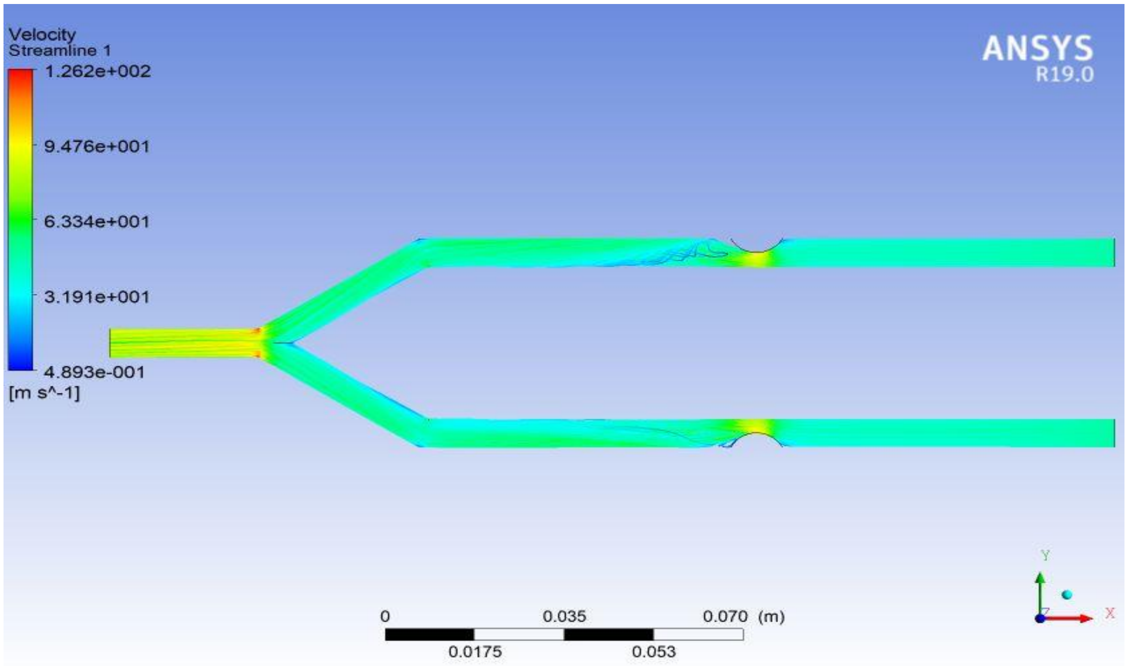


Figure 3.13: 50 % opening of oxygen tube and 50 % opening of the air tube

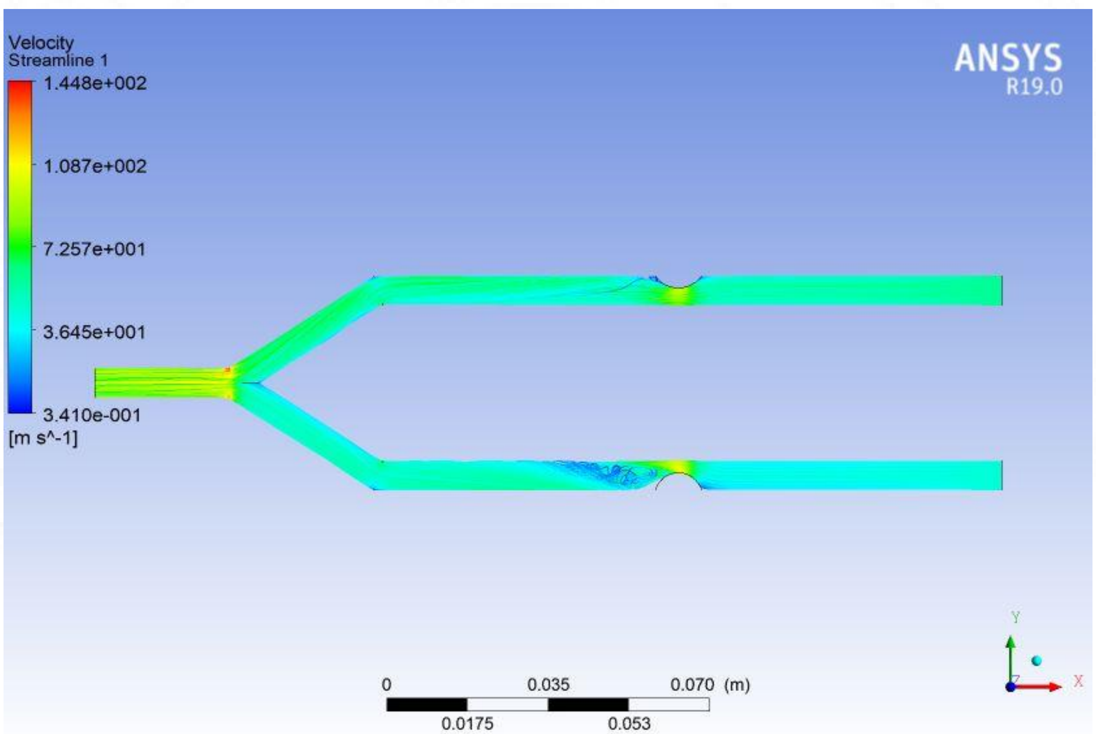


Figure 3.14: 60 % opening of oxygen tube and 40 % opening of the air tube

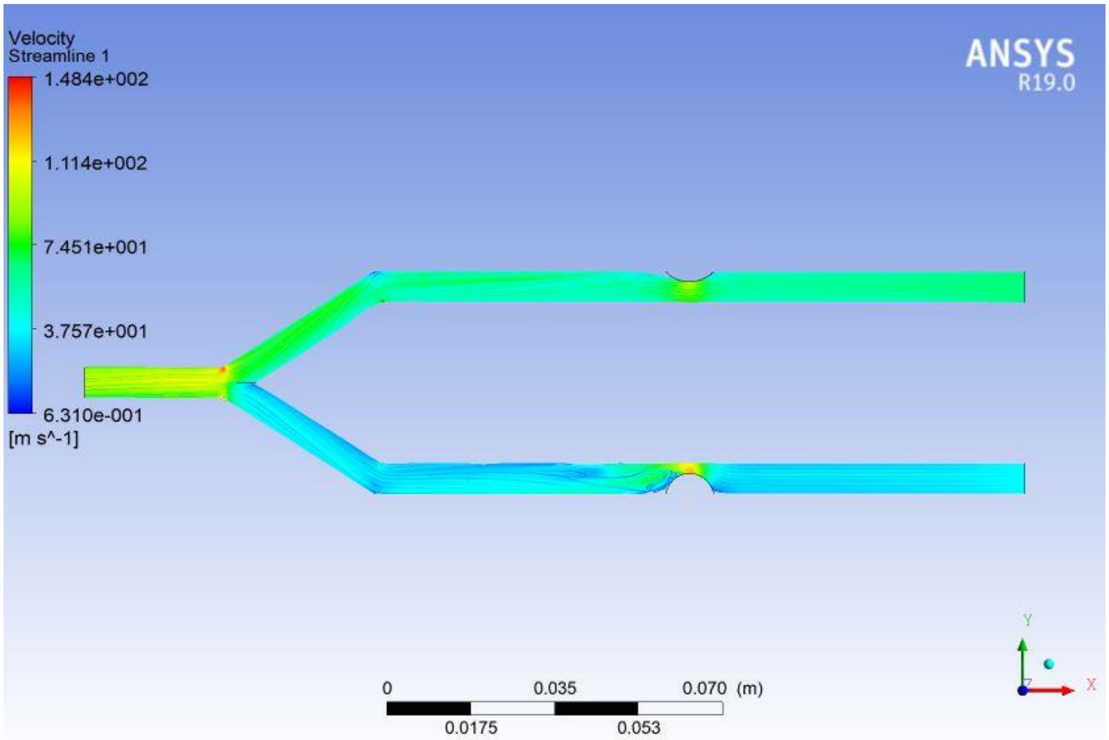


Figure 3.15: 70 % opening of oxygen tube and 30 % opening of the air tube

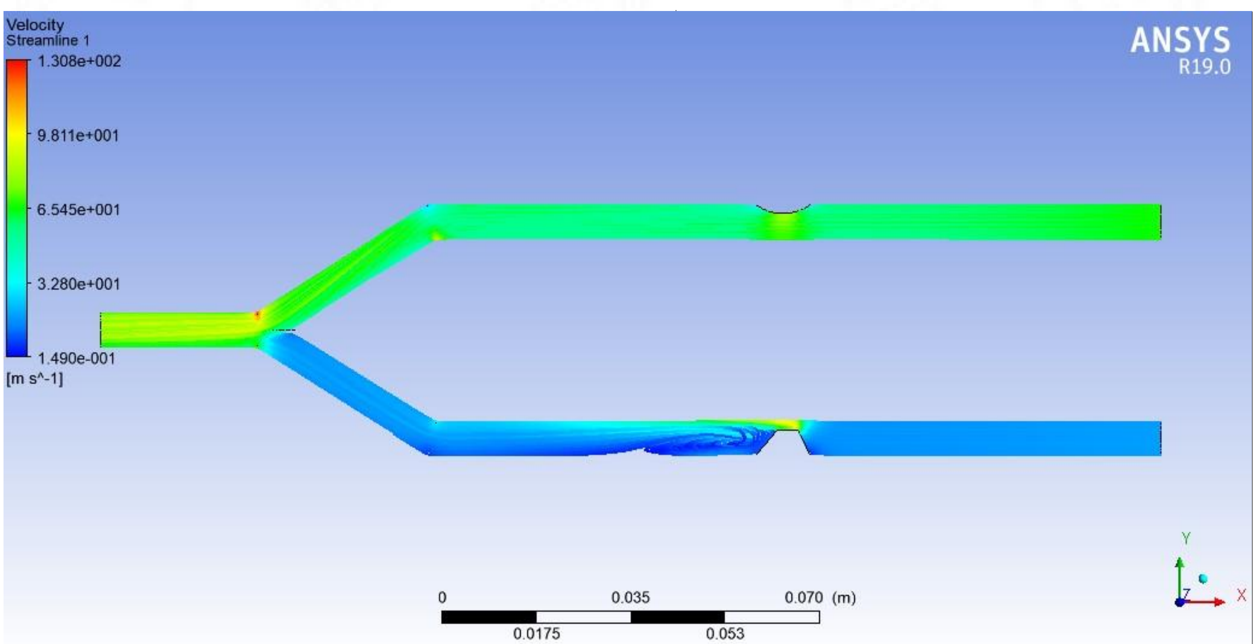


Figure 3.16: 80 % opening of oxygen tube and 20 % opening of the air tube

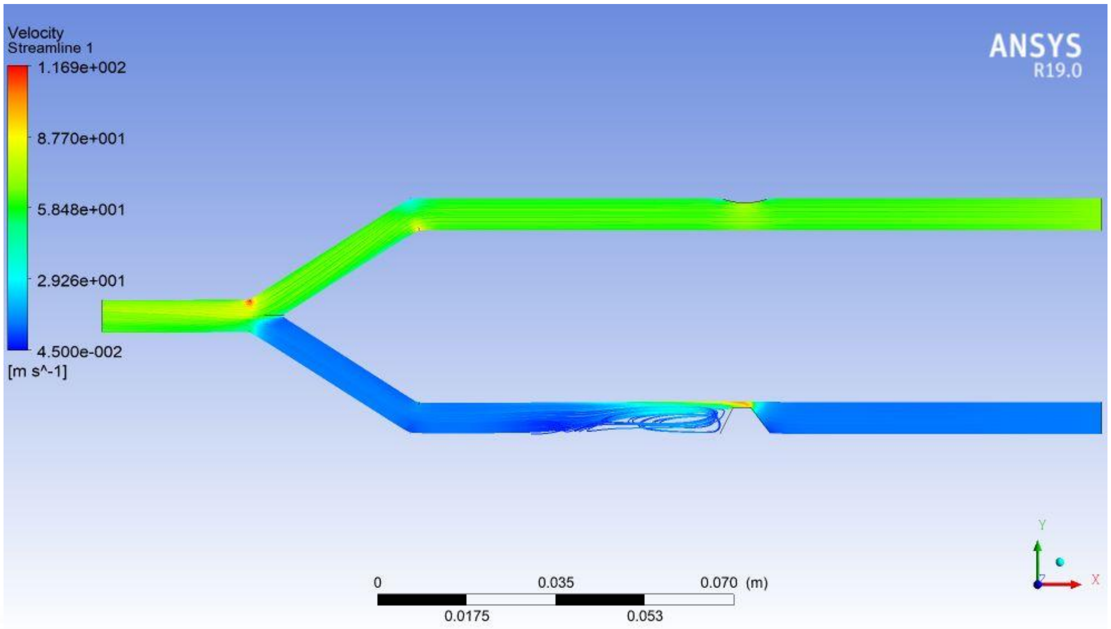


Figure 3.17: 90 % opening of oxygen tube and 12 % opening of the air tube

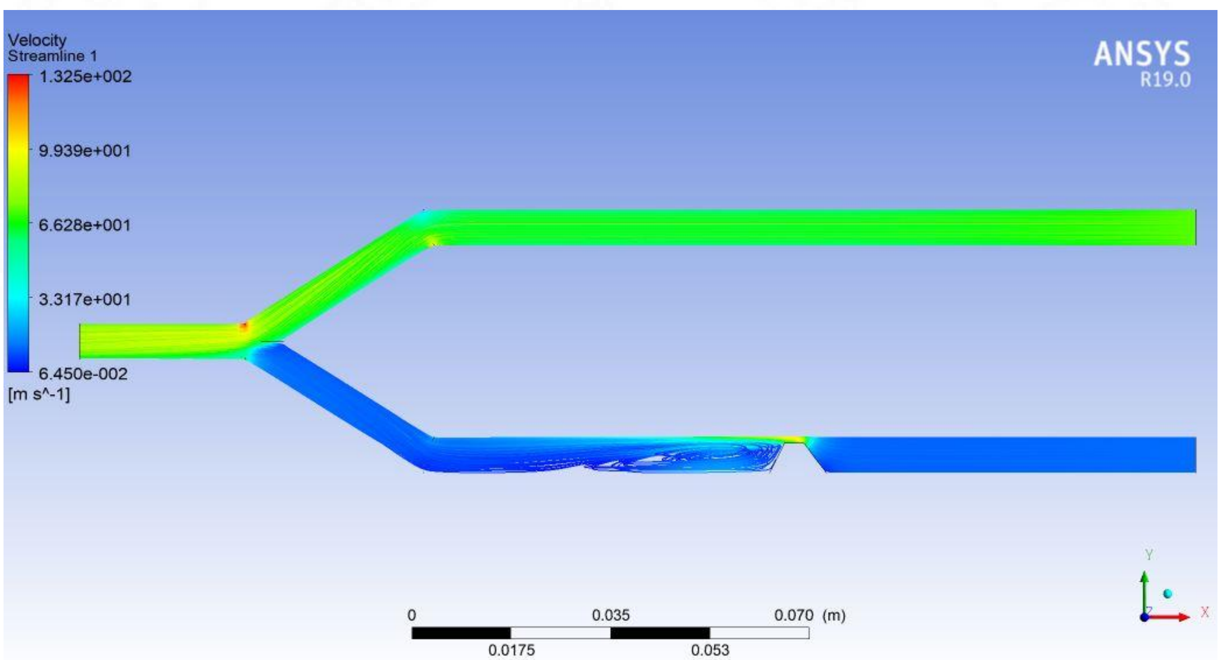


Figure 3.18: 100 % opening of oxygen tube and 12 % opening of the air tube

Simulation Results

From the simulation for the defined boundary condition of inlet 20KPa and outlet 10KPa, the flow velocity of the oxygen, air, and gas mixture is obtained for 11 different variations in the area of the oxygen and the air tube. The relation between FiO_2 % and area ratio is desired. Area ratio is defined as the ratio of oxygen area opening to the air area opening.

The simulation results such as oxygen and airflow velocity, as well as average velocity of the gas mixture are recorded as shown in the table 3.4. As the area of oxygen increases, the oxygen flow velocity continuously increases.

Table 3.4: The flow analysis data is shown in the table.

S.No.	O_2 Area (A1) (mm^2)	Air Area (A2) (mm^2)	Area Ratio (A1/A2)	Average Velocity (m/s)	O_2 Velocity (m/s)	Air Velocity (m/s)
1	3.85	31.67	0.12	94.95	12.61	82.36
2	3.85	28.5	0.14	83.41	11.21	82.05
3	6.33	25.34	0.25	84.96	18.03	66.9
4	9.5	22.17	0.43	91.39	36.11	55.28
5	12.67	19	0.67	93.1	42.43	50
6	15.84	15.84	1	96.26	48.23	48.29
7	19	12.67	1.5	104.74	59.54	45.63
8	22.17	9.5	2.33	102.84	65.6	37.3
9	25.34	6.33	4	85.11	67.03	18.54
10	28.5	3.85	7.4	78.37	67.2	11.35
11	31.67	3.85	8.23	83.72	72.49	11.23

Using the simulation results as shown in the above tables, The FiO_2 values are calculated using equation no. [6].

The FiO_2 was calculated with the help of empirical relations. [6]

FiO_2 = ((O_2 flow + (airflow*0.21))/peak flow)

Table 3.5. FiO_2 Calculation

S.No.	O_2 Area (A1) (mm^2)	Air Area(A2) (mm^2)	Area Ratio (A1/A2)	O_2 Flowrate (lpm)	Air Flowrate (lpm)	Peak Flowrate (lpm)	FiO_2 %
1	3.85	31.67	0.12	23.97	156.50	180.42	31.50
2	3.85	28.50	0.14	21.30	155.91	158.50	34.10
3	6.33	25.34	0.25	34.26	127.12	161.43	37.76
4	9.50	22.17	0.43	68.61	105.05	173.66	52.21
5	12.67	19.00	0.67	80.63	95.01	176.91	56.85
6	15.84	15.84	1.00	91.65	91.76	182.92	60.64
7	19.00	12.67	1.50	113.15	86.70	199.03	66.00
8	22.17	9.50	2.33	124.66	70.88	195.42	71.41
9	25.34	6.33	4.00	127.37	35.23	161.72	83.33
10	28.50	3.85	7.40	127.69	21.57	148.92	88.79
11	31.67	3.85	8.23	137.74	21.34	159.08	89.40

The relationship between the area ratio and the FiO_2 is plotted as shown in figure 3.19. As seen in the graph, the FiO_2 consistently increases with the increase in the area ratio as the oxygen flow increase and the airflow reduces.

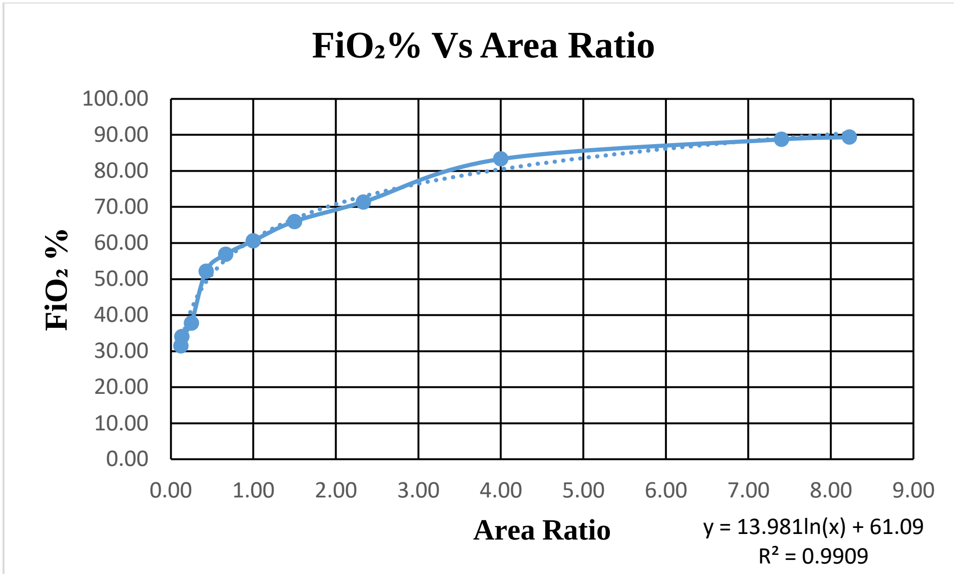


Figure 3.19: The FiO_2 characteristic curve

The area ratio ranges from 0.12 and goes up to 8.23, with the minimum and maximum areas of 3.85 and 31.67 mm2. A logarithmic curve is plotted to determine the equation of the curve. The curve is congruent with the original curve. The curve has an R-value of 0.9909. The FiO_2 for the set area can be calculated using the above equation.

As the area changes with the amount of squeezing done by the stepper motor, the variation in the area with deformation are studied with structural analysis.

3.2.4. Structural Analysis

In the structural analysis, variations in the tube area to the linear actuation of the stepper motor controlled by the micro-controller are studied. The model used for the structural analysis has a few modifications to minimize the simulation time without compromising the desired results. The changes in the model are done such that it has a minimum area of the tube, and all the moving components are included. Only one tube is squeezed in the analysis, and the tube length is reduced to 60 mm, with the squeezing happening at the center. The changes made on the model chosen for structural analysis are such that there is no distortion with the real-time squeezing of the tube. The deformation of the clamping plate varies from 0 to 6.35 mm. Due to the elasticity of the pipe, the deformation may increase slightly in real-time squeezing with can also be incorporated in the simulation.

Materials

The material used for the tubing is medical-grade PVC.

The properties of the PVC material used:

Density = 1400 kg/m3

Poisson's ratio= 0.4

Young's Modulus= 3275 MPa

The clamp material is structural steel:

Density = 7850 kg/m3

Poisson's Ratio=0.3

Young's Modulus= 200 GPa

The CAD model used for Structural analysis

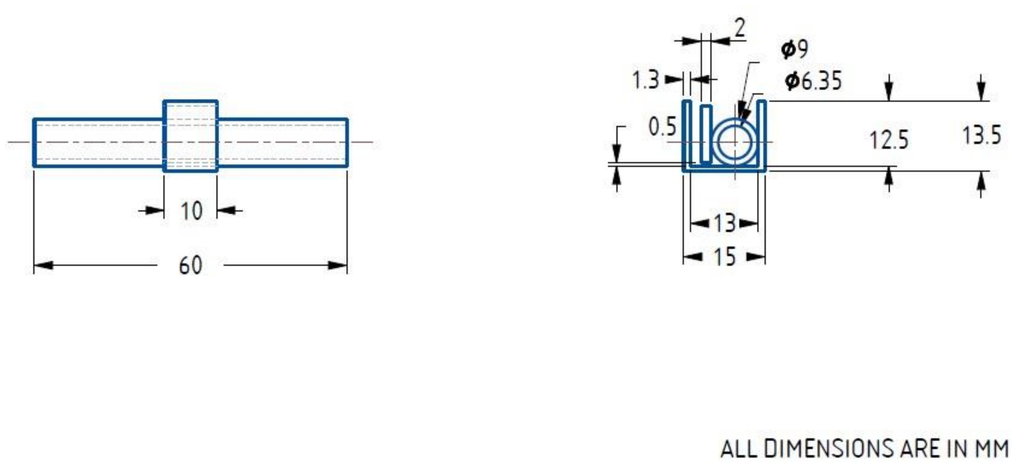


Figure 3.20: The Drawing of the model used for structural analysis.

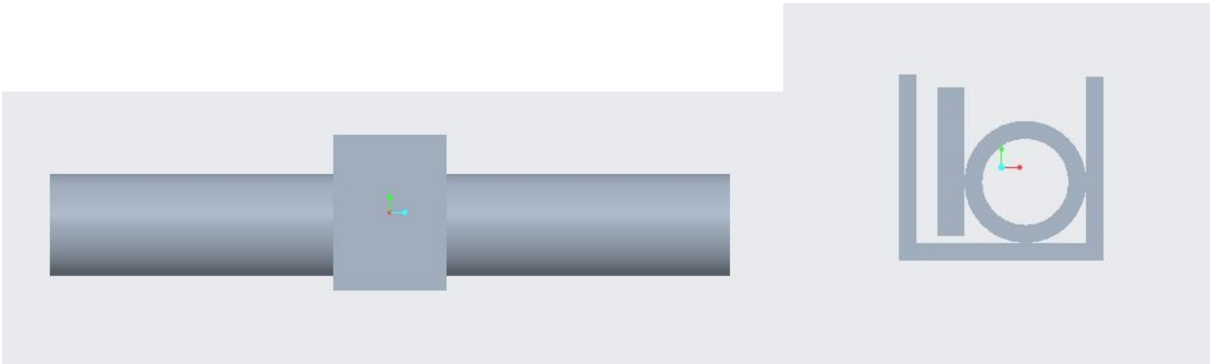


Figure 3.21: CAD model used for structural analysis.

Mesh Independent Studies

The mesh independent studies are explained in the flow analysis part. The process is repeated for the structural analysis to identify the optimum element size for calculating the area.

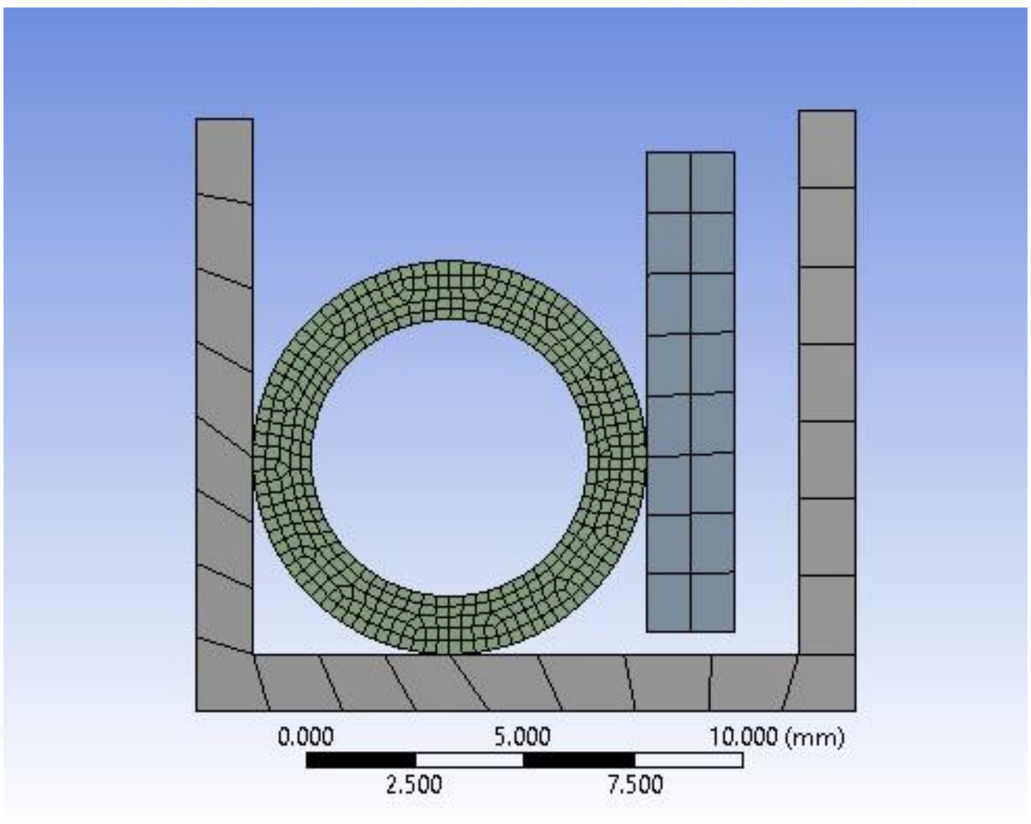


Figure 3.22: Meshing of the tube with 0.3 mm element size.

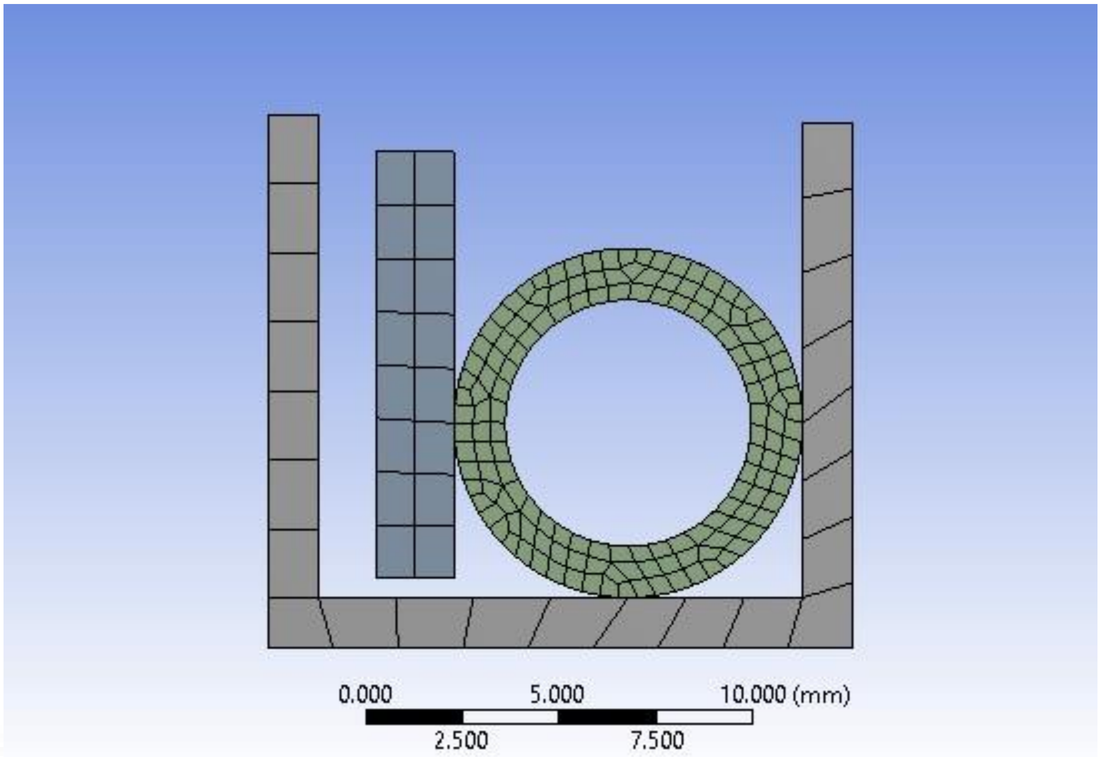


Figure 3.23: Meshing of the tube with element size 0.5 mm.

Figure 3.22 & 3.23 shows the pipe cross-section with the meshing of 0.3 mm and 0.5 mm, respectively. The element size is not of concern for the squeezing plates. As the region of interest is the area variation that depends on the tube's physical properties only. The unnecessary plate meshing shall increase the simulation time.

Table 3.6. Mesh Independent studies for structural analysis

S.No.	Element Size	Clamp Displacement(mm)	Imported Area (mm2)	Actual Area(mm2)
1	0.3	4	11.97	18.53
2	0.5	4	11.76	18.20

Table 3.4. shows the change in values due to the element size. The area variation is found to be 0.33 mm. The error percentage in area calculation is computed and found to be 1.46%. As the error percentage is less than 5%, the element size 0.5mm is chosen for simulation.

Images of structural Deformation

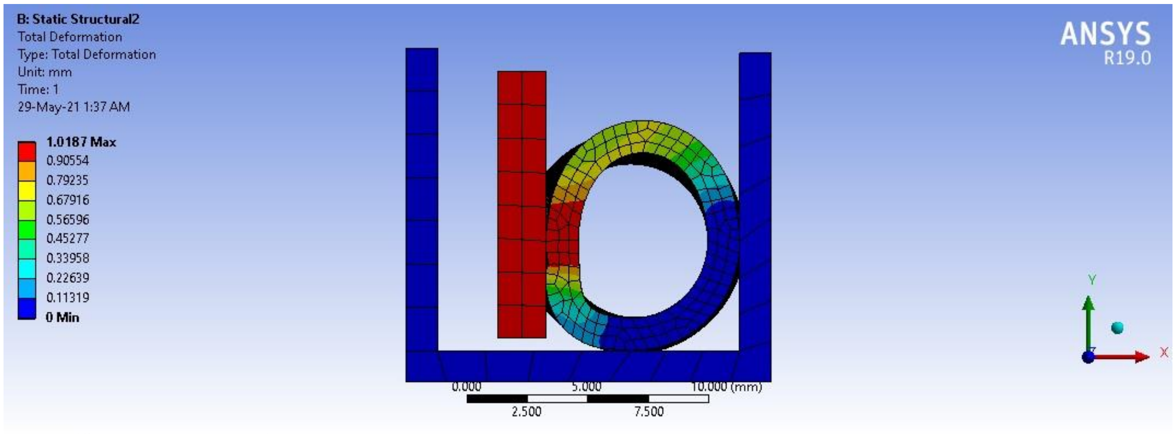


Figure 3.24: Structural deformation of the tube with clamp displacement of 1mm.

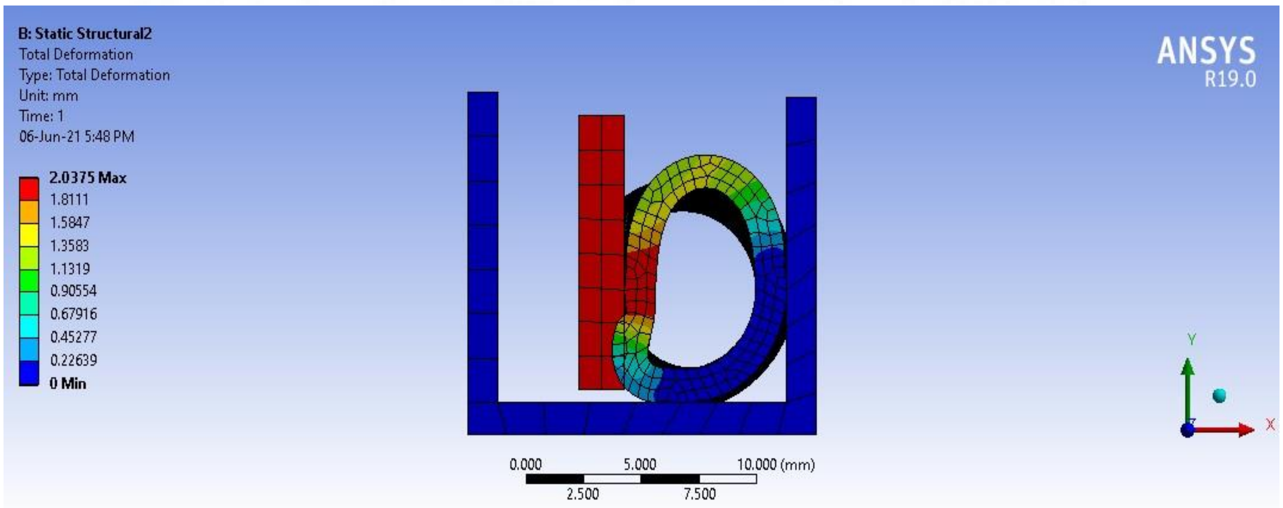


Figure 3.25: Structural deformation of the tube with clamp displacement of 2mm.

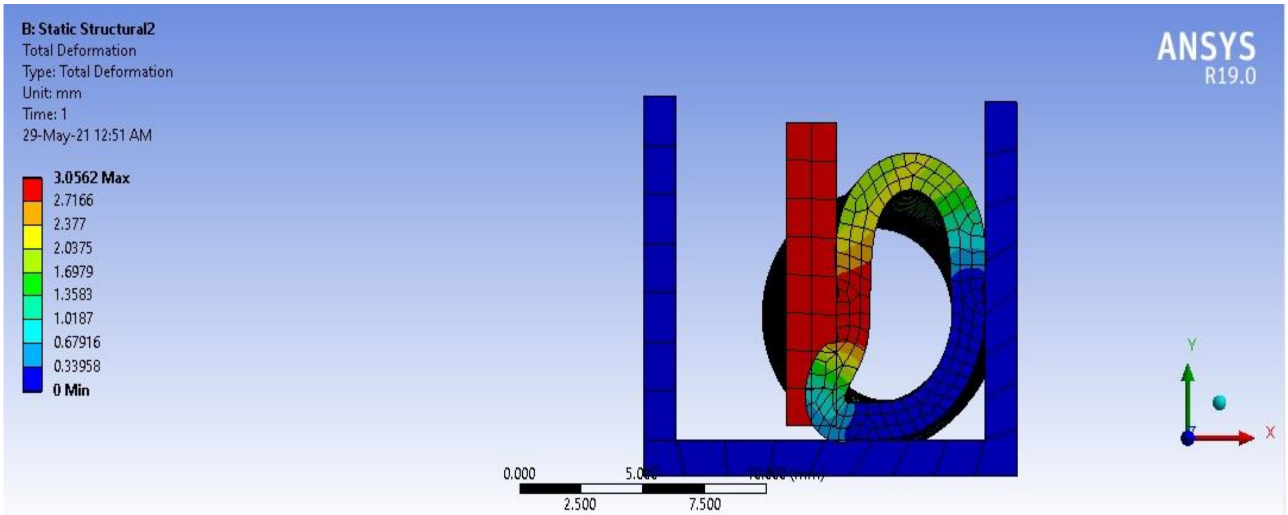


Figure 3.26: Structural deformation of the tube with clamp displacement of 3mm.

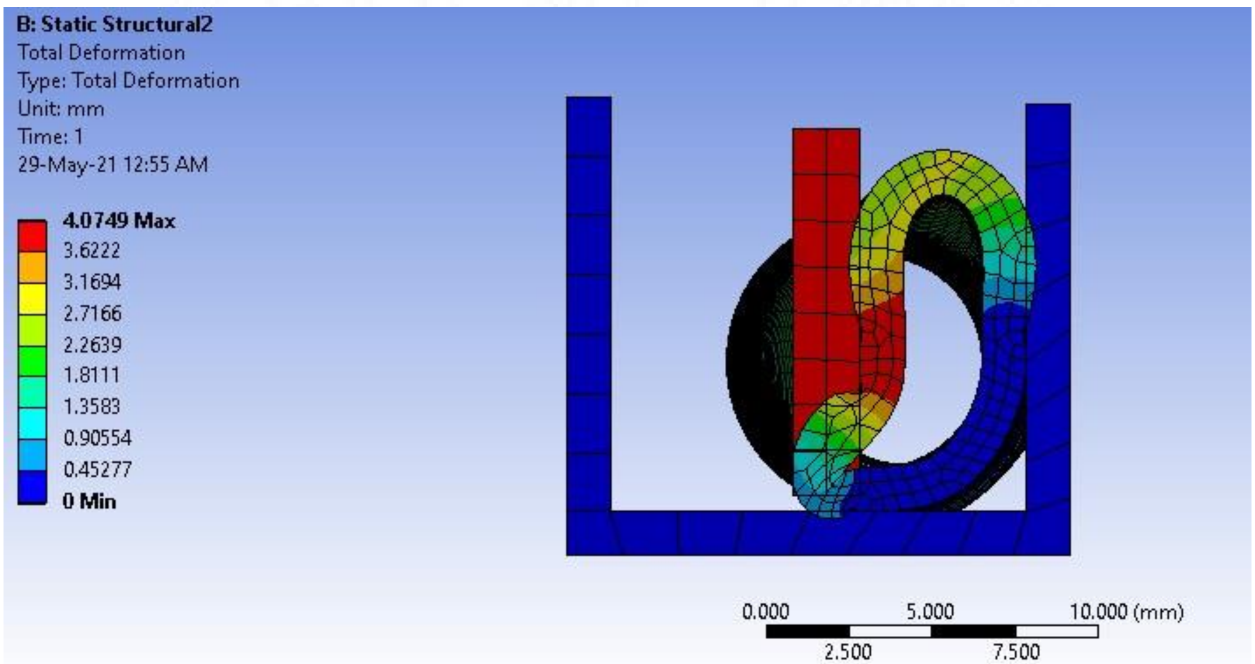


Figure 3.27: Structural deformation of the tube with clamp displacementof 4 mm.

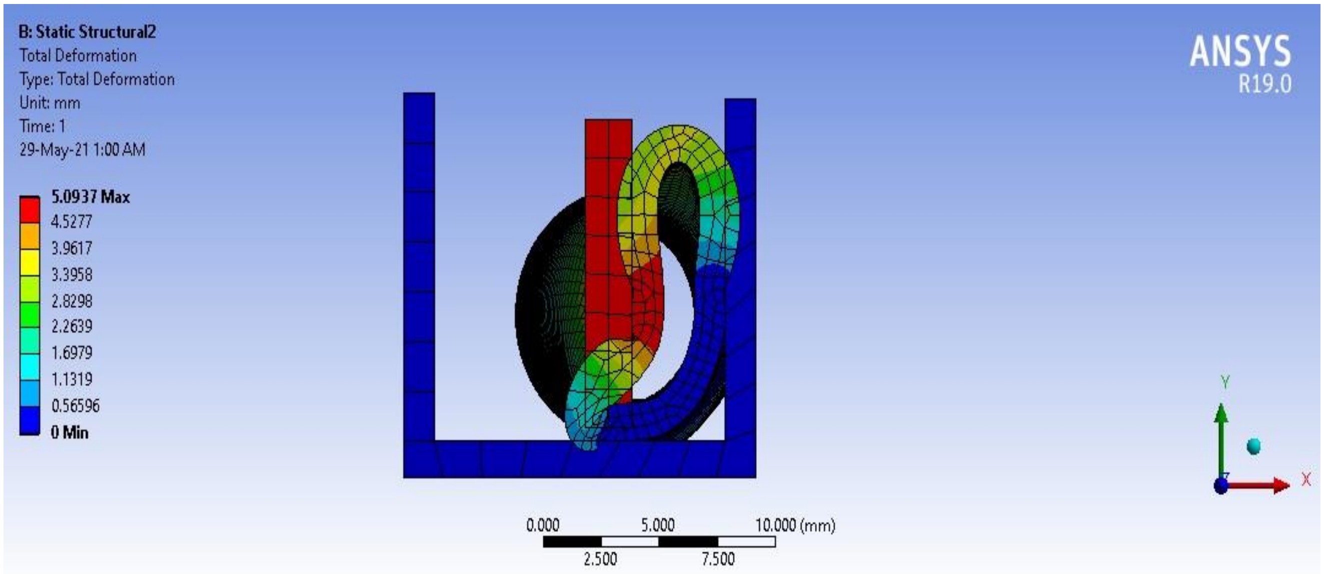


Figure 3.28: Structural Deformation of the tube with clamp displacement of 5mm.

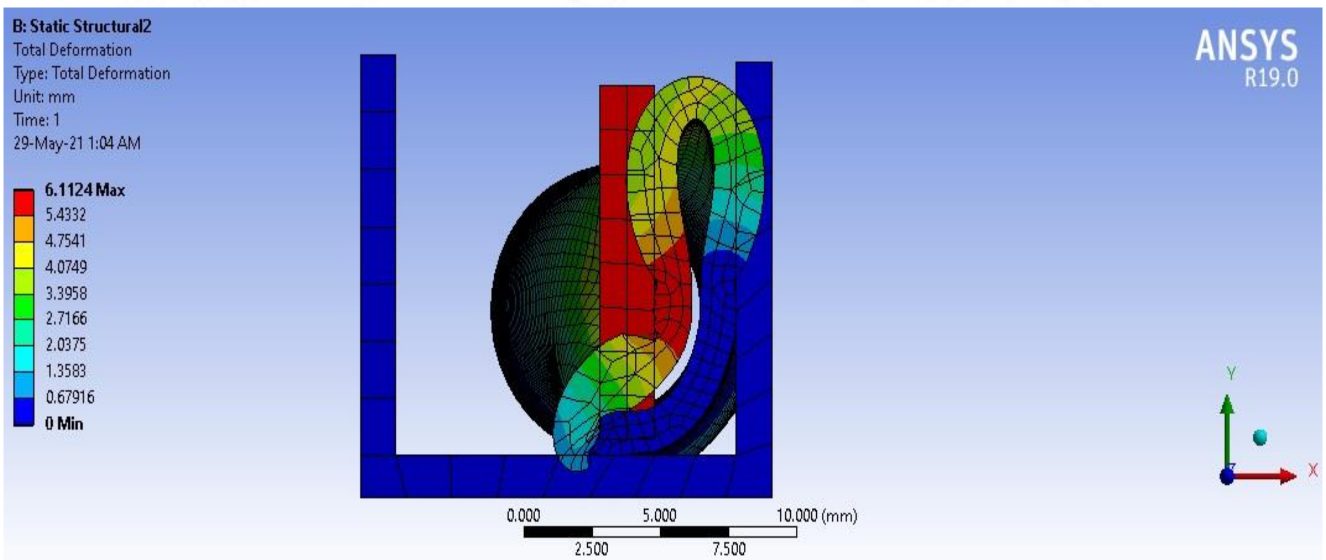


Figure 3.29: Structural deformation of the tube with clamp displacement of 6mm.

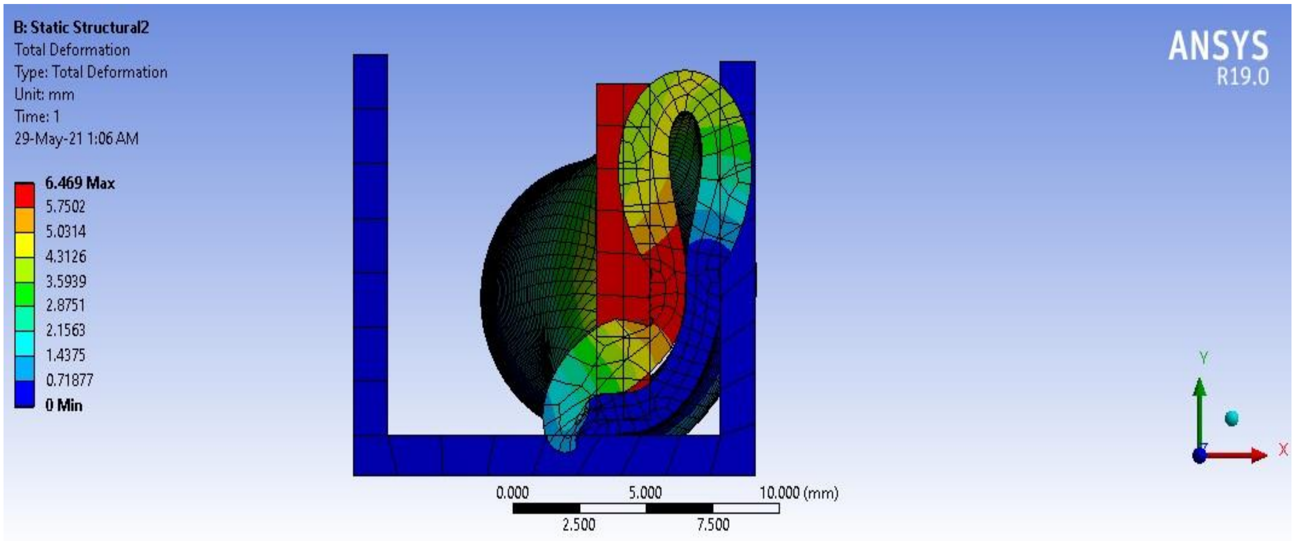


Figure 3.30: Structural Deformation of the tube with clamp displacement of 6.35mm.

After the simulation is done in the structural analysis, few post-processing processes are performed on the deformed models. The structural analysis results in ANSYS is exported as STL files to calculate the change in the area of the opening at the section where squeezing happens. The deformed tube is imported into CREO software for the same.

A dimensional change occurs due to importing of STL files from ANSYS to CREO. So, in the imported models, the area cannot be determined directly. However, the area obtained will be in the range of 10^(-3)mm^2.

The following procedure is followed to calculate the variation in the area for different squeezing.

1) While exporting the STL file from ANSYS, make sure you do it in true scale, and take a section at the mid-point of the squeezing plates.
2) Open the STL file in CREO, Create a plane using a three-point method, draw a cross-section closely following the inner diameter of the squeezed tubing.
3) After completing the sketch, extrude it, and determine the area of the cross-section using the‘Measure’ tool.

To calculate the actual area, the imported area determined in CREO for the unsqueezed tube area is recorded, which is supposed to be equal to the maximum area of the tube opening i.e.

31.67mm^{2}·(diameter 6.35mm), but the value shown in the CREO is 20.46 x 10^(-3). Based on this, a scale of error in the imported area is calculated as **1.55 x 10^(3)**. The other area values are determined using the error scale if the imported area is known, as shown in table 3.5.

Simulation Results

Table 3.5 shows the values obtained through the simulation for the area variations in the tube for a given deformation. The squeezing of the tube with the mechanism deployed in the ventilator is simulated. The minimum area possible with the mechanism is 3.85 mm^2 for a clamp displacement of 6.35 mm. For the tube to get closed completely, the way of squeezing has to be changed. The actual area value is calculated by the method mentioned above.

Table 3.7 Structural Analysis tabulation

S.No.	Clamp Displacement(mm)	Imported Area x 10^(-3) mm^2	Actual Area(mm^2)
1	0	20.46	31.67
2	1	19.04	29.47
3	1.5	18.17	28.13
4	2	17.13	26.52
5	2.5	16.02	24.79
6	3	14.72	22.78
7	3.5	13.25	20.51
8	4	11.76	18.20
9	4.5	9.89	15.31
10	5	8.02	12.42
11	5.5	6.08	9.42
12	6	4.07	6.30
13	6.35	2.50	3.85

The graph was plotted with the simulation data as shown in figure 3.31. With the help of the polynomial equation, the deformation that has to be given to the squeezing plate for a certain area setting can be determined. The polynomial equation has a prefect fit with the R^2 value of 0.9966. The R^2 value can be chosen from the more options section of the trend line in the excel sheet.

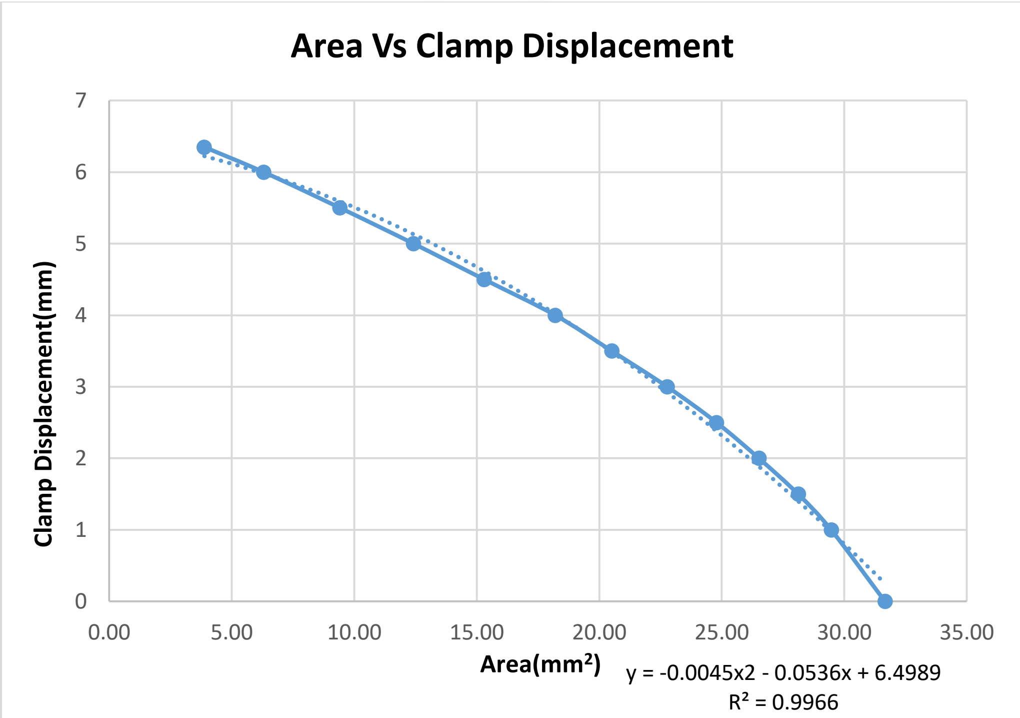


Figure 3.31: Relationship between change is clamp displacement and area.

$$y = -0.0045x^2 - 0.0536x + 6.4989$$

Initially, the FiO_2 values for the corresponding area are determined using the results from the flow analysis in the previous section. The above equation from graph figure 3.31 gives the relationship between the change in area for the clamp displacement. It helps to calculate the deformation of the clamp required to set the oxygen and air tube area as used in the flow analysis to achieve a certain FiO_2. A relationship between FiO_2 and deformation of the clamp is established indirectly from the flow analysis and structural analysis, as shown in table 3.6.

In table 3.6, The clamp plate on the oxygen side is at the maximum displacement(D1) initially, and the clamp plate on the air-side is at 0mm(D2). As the displacement(D2) of the clamp plate on the air-side increases, the air tube is squeezed, and the oxygen tubing is released from squeezing. There is no equation relating D1 and D2 as the change in the area at lower clamp displacement, and higher clamp displacement is different. But they are inversely proportional.

Table 3.8. Relationship between Clamp displacement and FiO_2 %

S. No.	**O_2 Area (mm^2)**	**O_2 Area %**	**Displacement D1(mm)**	**Air Area (mm^2)**	**Air Area %**	**Displacement D2(mm)**	**FiO_2 %**
1	3.85	12	6.35	31.67	100	0.00	31.50
2	3.85	12	6.35	28.50	90	1.32	34.10
3	6.33	20	5.98	25.34	80	2.25	37.76
4	9.50	30	5.58	22.17	70	3.10	52.21
5	12.67	40	5.10	19.00	60	3.86	56.85
6	15.84	50	4.52	15.84	50	4.52	60.64
7	19.00	60	3.86	12.67	40	5.10	66.00
8	22.17	70	3.10	9.50	30	5.58	71.41
9	25.34	80	2.25	6.33	20	5.98	83.33
10	28.50	90	1.32	3.85	12	6.35	88.79
11	31.67	100	0	3.85	12	6.35	89.40

Figure 3.32 shows the graph between displacement(D2) at the air tube clamp and the FiO_2. The air-side clamp displacement is used for better understanding as it varies from 0 to 6.35 the FiO_2 % varies from 21 to 100 %. The FiO_2 characteristic curve rises continuously with an increase in clamp displacement (D2) of the air tube. A polynomial trend line was plotted in the graph, the equation obtained is used to calculate the FiO_2 % for a given deformation of the clamp. The polynomial line has an R^2 value of 0.9821, which signifies the agreement of the curve with the original curve.

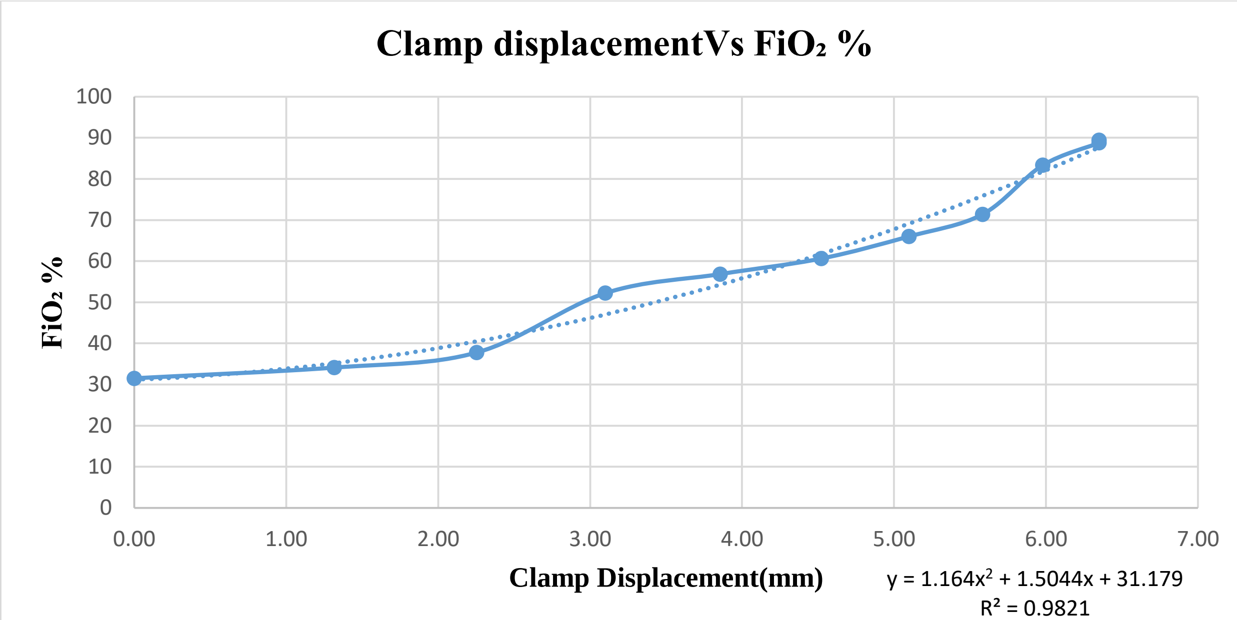


Figure 3.32: The Clamp displacement vs FiO_2 % relationship is shown in the graph

$$y = 1.164x^2+1.5044x+31.179$$

Chapter IV

Experimentation

4.1. Introduction

The objective of the experiment is to evaluate the FiO_2 of the gas mixture obtained from the mixing of air and oxygen supplied through a squeezed tube for various settings of the displacement. The components used for the experiment are an oxygen sensor, PVC tubes, Screw Clamps, connector, air compressor, oxygen cylinder, vernier caliper, etc. The experimental setup is made similar to the tubing in the ventilator.

4.2. Experimental setup

The experimental setup is shown in figure 4.1. The oxygen and air tubing length is equal to the tube length in the Chitra ventilator design. The tube is squeezed with screw clamps. A y-connector is used to mix air and oxygen. Then, it is passed through the oxygen sensor, and let out to the atmosphere. An Air compressor is used for the air supply. The oxygen is supplied through the oxygen cylinder; both the gases are set at 20KPa.

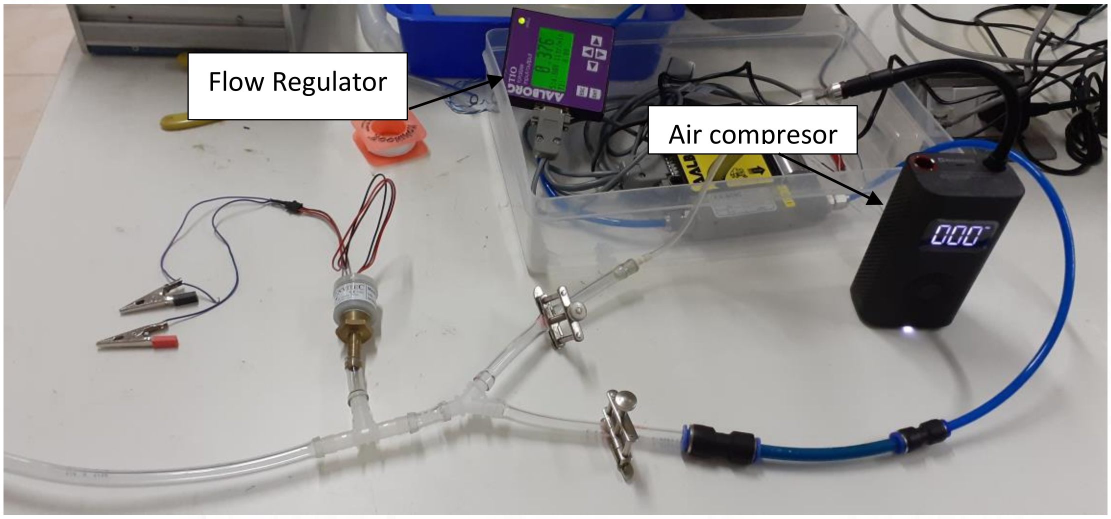


Figure 4.1: Experimental Setup

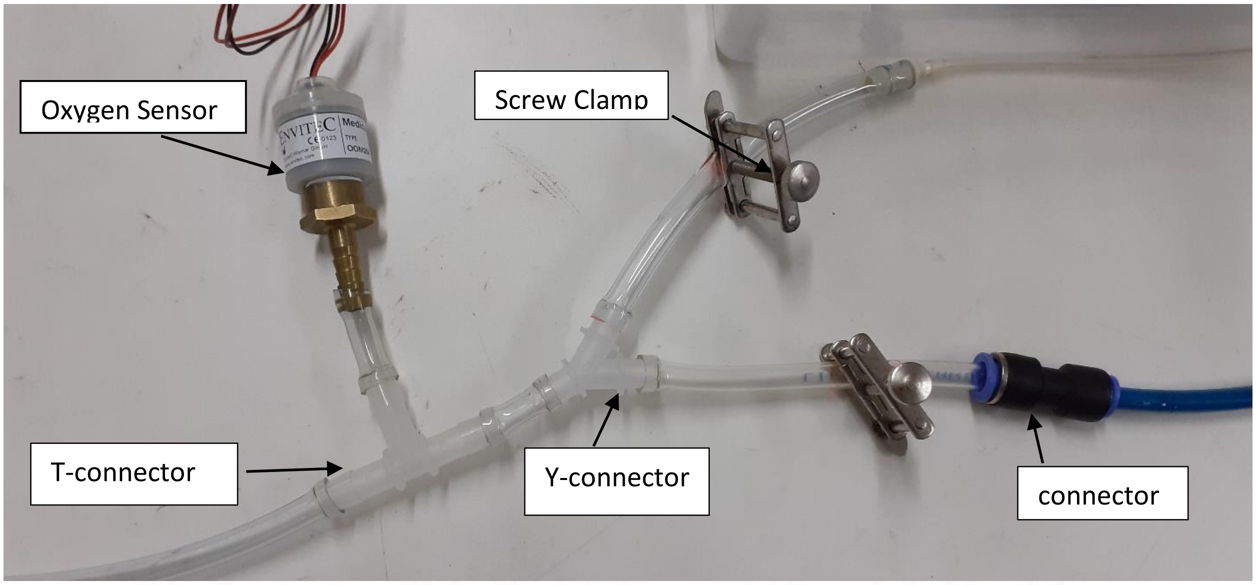


Figure 4.2. The gas flow section- experimental setup

Components

The various components used for the experiment consists of

1) FiO_2 sensor
2) Medical Oxygen Cylinder fitted with flow regulator
3) Medical oxygen tubings
4) Screw clamp (20mm movement)
5) Quick couplers to connect the medical oxygen tubing to the experiment set up.

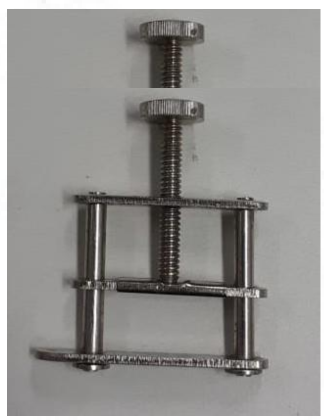
The components listed are shown in figure 4.3

2.

1.

3.

4.



5.

Figure 4.3: Components of Experiment

FiO_2 Sensor Calibration

The FiO_2 sensor is assumed to be linearly calibrated. Multiple experiments are conducted to calibrate the sensor with room air and 100% oxygen as shown in table 4.1. The average value for 21% FiO_2 and 100% FiO_2 is calculated as 11mv and 60mV, respectively. Figure 4.4. gives the graph between voltage and FiO_2. From the graph, the relationship between oxygen FiO_2 value and the voltage output of the sensor is found to be

$FiO_2\%$ = 1.6122 * sensor voltage + 3.2653

Table 4.1: Sensor Calibration

S.No.	FiO_2 %	Sensor Output (mV)	Sensor Output (mV)	Sensor Output (mV)	Average O/P (mV)
1	21	11	11	11	11
2	100	60	60	60	60

The Figure 4.4. show the graph of linear calibration of the sensor. It is adopted due to the limitations in experimentation.

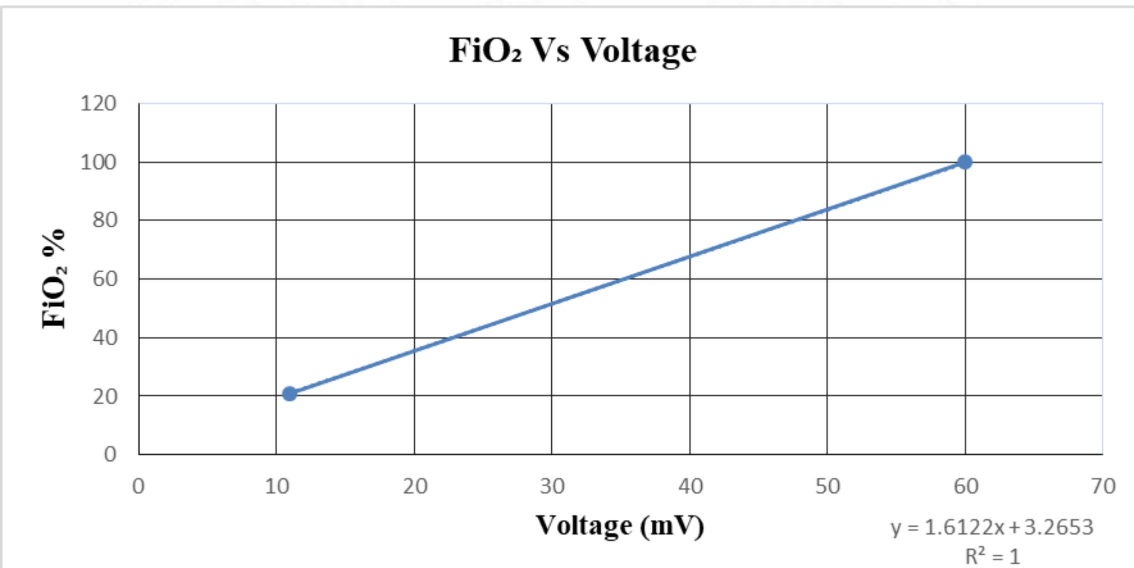


Figure 4.4: Calibration of the Sensor

4.3. Experiment

The following conditions are to be checked prior to the beginning of the experiment.

1) It should be made sure that the fluid circuit is complete from the inlet to the exhaust.

2) The input air and oxygen are both operated at a pressure of 20 KPa.

3) The squeezing is done with the help of a screw clamp at 70mm from the inlet of the tube.

In the experiment, the squeezing of the air tube is changed by an increment of 1mm, and the oxygen tube is changed with a decrement of 1mm, as shown in table 4.2. The experiment began with the oxygen tube completely occluded with the screw clamp and the air completely open and inserted in the screw clamp. The oxygen and air flow should be continuously supplied, and the change in voltage values from the oxygen sensor is measured using a multimeter. The sensor requires a response time of 12s. Every reading is recorded after waiting for 12s in a particular squeezed state of the air and oxygen tube.

4.4. Experiment Results

In the experiment, the change in voltage(mV) values of the oxygen sensor for the squeezing given through the screw clamp is recorded as shown in table 4.2.

Table 4.2. The experimental results

S.No.	Displacement (D1)(mm)	O_2 Area (mm^2)	Displacement (D2)(mm)	Air Area (mm^2)	Sensor Output-1(mV)	Sensor Output-2(mV)	Sensor Output-3(mV)	Average (mV)	FiO_2 %
1	6.35	0.00	0	31.67	12	12	12	12.00	22.61
2	5.35	11.90	1	30.48	35.00	38.00	34.00	35.67	60.77
3	4.35	17.31	2	28.59	38.00	40.00	37.00	38.33	65.07
4	3.35	21.99	3	25.71	43.00	44.00	44.00	43.67	73.66
5	2.35	25.71	4	21.99	44.00	45.00	45.00	44.67	75.28
6	1.35	28.59	5	17.31	46.00	48.00	48.00	47.33	79.58
7	0.35	30.48	6	11.90	49.00	51.00	49.00	49.67	83.34
8	0	31.67	6.35	0	52.00	53.00	52.00	52.33	87.64

The Figure 4.4 & 4.5 are showing the relation of clamp displacement with the FiO_2 % and voltage of the sensor respectively. The graphs are similar as the FiO_2 varies linearly to the voltage. The FiO_2 value rises with the increase in clamp displacement of the air tube.

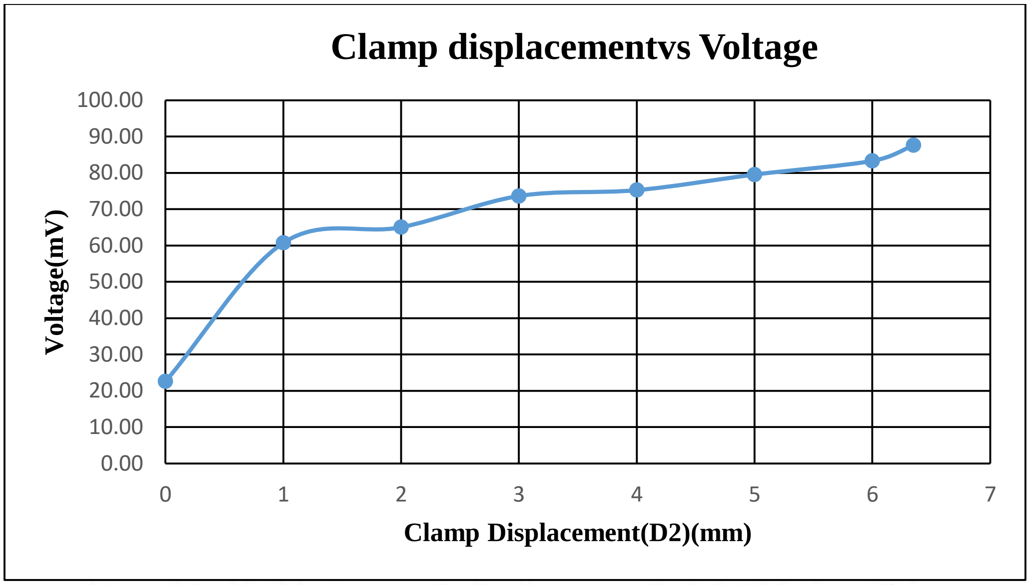


Figure 4.4: Displacement(D2) Vs Voltage Curve

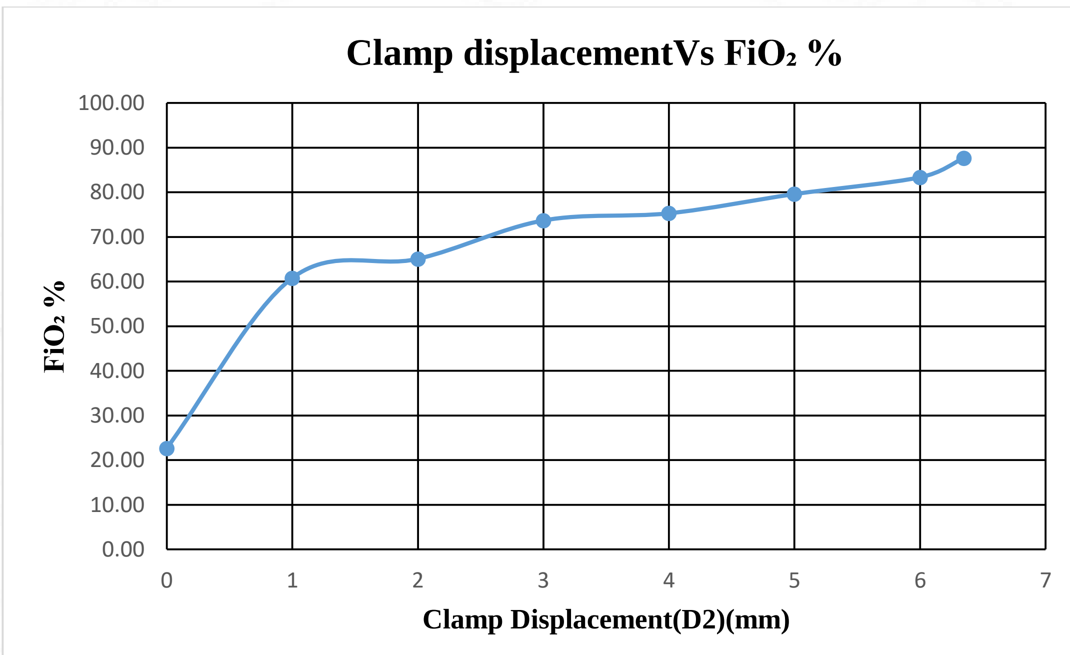


Figure 4.5: Clamp displacement(D2) Vs FiO_2 curve

For better understanding variation of FiO_2 with linear clamp displacement of 0-6.35mm. There is a release of the oxygen tube for the corresponding occlusion of air tube, they are related with the equation D1= 6.35-D2, D1 is the clamp displacement in the oxygen side. In the experiment, the method of squeezing done is different from the method adopted in the ventilator. Hence there is a change in the way the area varies. In the experiment, 100% occlusion of the air tube is achieved, whereas there is an opening of 12% even at maximum squeezing in the ventilator.

4.5. Conclusion

From the experiment, the FiO_2 value for the corresponding deformation of the air and oxygen tube is obtained. As the oxygen flow increases, the output of the oxygen sensor was rising, giving a clear indication of the rise in FiO_2 %. It can also be concluded that the clamp displacement in the range of 0-6.35 mm is suitable for achieving the range of FiO_2 21-100 %.

Chapter V

Results and Conclusion

In this chapter, the experimental and simulation results are analyzed and explained. The FiO_2 value was related to the area in the flow analysis and the displacement with the structural analysis, respectively. The various conclusions obtained from the results at different stages of the project along with the major conclusions, are also mentioned in this chapter.

5.1. Results

Flow Analysis Results

The flow analysis result was able to establish a relation between the area ratio and the FiO_2 value. It began with the Classification of the flow with the Reynolds number. The simulation on the gas mixing part of the Chitra ventilator computed the flow velocities for all the area variations adopted in the ventilator. The recording of the flow velocity at three different regions, as mentioned in chapter 3, gave the velocity of the oxygen, air, and the peak flow of the gas mixture. From the flow velocity data, the flow rate of the oxygen, air, and the peak flow is computed as the area of the tube is known. The FiO_2 calculation is made with the empirical relation mentioned in chapter 3.2.3, from the flow rate values obtained through the simulation as shown in table 5.1

Table 5.1. FiO_2 Calculation

S.No.	O_2 Area (A1) (mm^2)	Air Area(A2) (mm^2)	Area Ratio (A1/A2)	O_2 Flow rate (lpm)	Air Flow rate (Lpm)	Peak Flow rate (Lpm)	FiO_2 %
1	3.85	31.67	0.12	23.97	156.50	180.42	31.50
2	3.85	28.50	0.14	21.30	155.91	158.50	34.10
3	6.33	25.34	0.25	34.26	127.12	161.43	37.76
4	9.50	22.17	0.43	68.61	105.05	173.66	52.21
5	12.67	19.00	0.67	80.63	95.01	176.91	56.85
6	15.84	15.84	1.00	91.65	91.76	182.92	60.64
7	19.00	12.67	1.50	113.15	86.70	199.03	66.00
8	22.17	9.50	2.33	124.66	70.88	195.42	71.41
9	25.34	6.33	4.00	127.37	35.23	161.72	83.33
10	28.50	3.85	7.40	127.69	21.57	148.92	88.79
11	31.67	3.85	8.23	137.74	21.34	159.08	89.40

From the above data in table 5.1, we have plotted the graph between FiO_2 and Area ratio as shown in figure 5.1. A logarithmic curve is generated in the graph with an R^2 value of 0.9909, indicating close agreement with the actual curve.

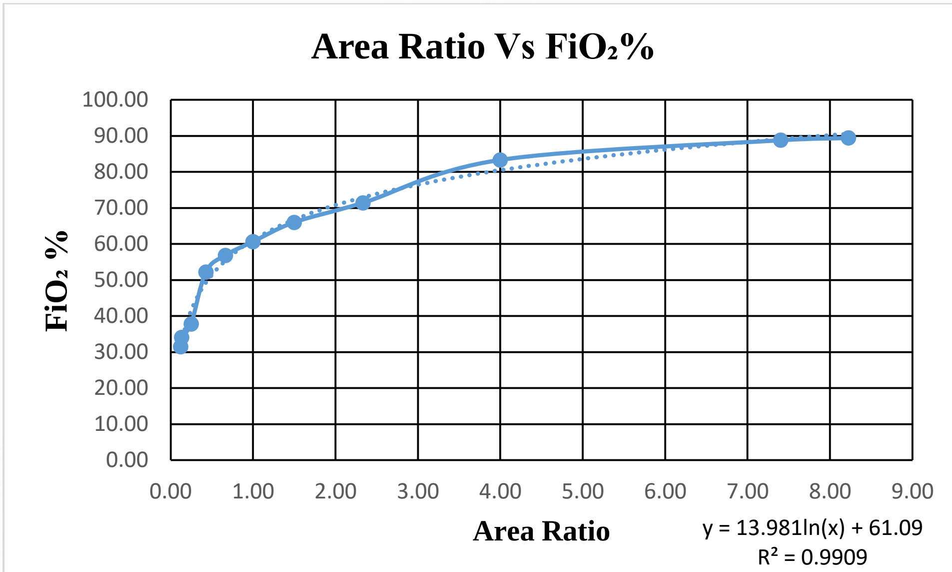


Figure 5.1: Relation between FiO_2 and Area Ratio.

Structural Analysis Results

The structural analysis determined the variations in the area for the linear squeezing, as shown in the table. The variation in the area is non-linear. Initially, the change in area for 1mm movement is much less than the change in area for 1mm movement at the end of the displacement.

Table 5.2. Structural Analysis Results

S.No.	Clamp Displacement(mm)	Actual Area(mm^2)
1	0	31.67
2	1	29.47
3	1.5	28.13
4	2	26.52
5	2.5	24.79
6	3	22.78
7	3.5	20.51
8	4	18.20
9	4.5	15.31
10	5	12.42
11	5.5	9.42
12	6	6.30
13	6.35	3.87

The Figure 5.2. gives the plot between displacement and Area of the squeezed tube. A polynomial curve is aligned with the actual curve with R^2 value of 0.9966. So, the equation can be safely used for determining the displacement required for any area value. Except the extreme values, that may differ slightly if gone by the equation, i.e. for 31.67mm^2, if show a 0.29mm of movement is needed.

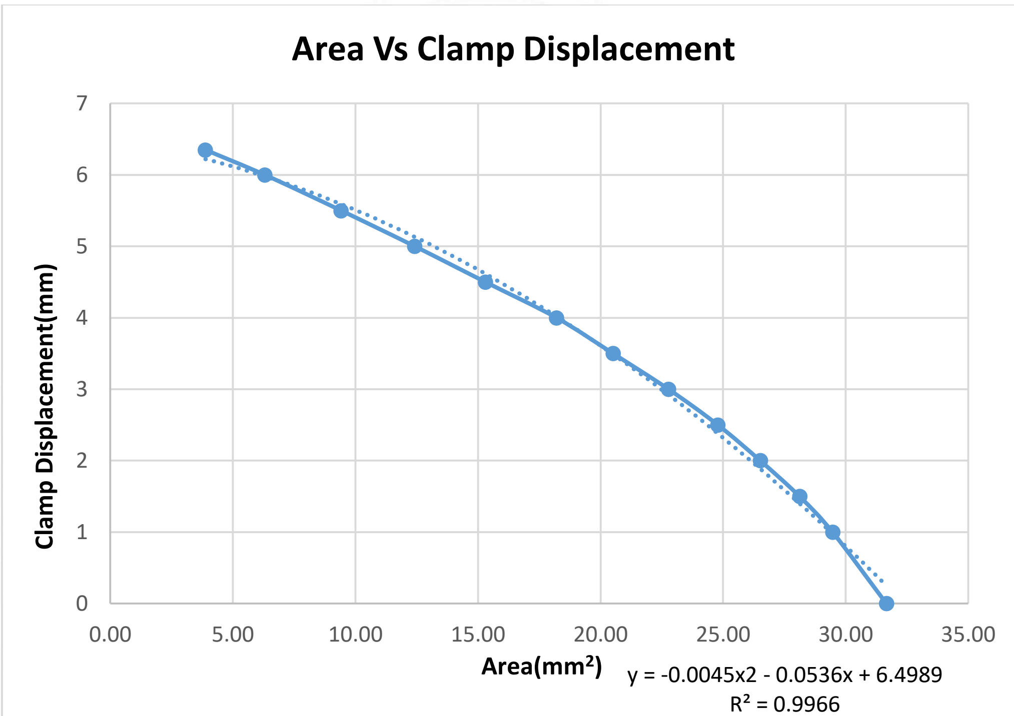


Figure 5.2. Relation between displacement and area of the squeezed tube.

$$\mathbf{y = -0.0045x^2 - 0.0536x + 6.4989} \qquad \ldots\ldots(2)$$

The flow analysis has been done assuming a steady increase in the oxygen tube and vice versa in the air tube. To determine the displacement at which the assumed area is achieved is done with the help of the above equation (2). For the extreme values 31.67 mm^2 and 3.85 mm^2, the displacement value is taken from table 5.2. The flow analysis results are related to the structural analysis results in table 5.3. The FiO_2 values at a given area are already calculated, and the displacement needed to set the area is determined through the structural analysis. Hence a relation between FiO_2 and displacement is established through the area.

Table 5.3. Relation between displacement and FiO_2

S. No.	O_2 Area (mm^2)	O_2 Area %	Displacement D1(mm)	Air Area (mm^2)	Air Area %	Displacement D2(mm)	FiO_2 %
1	3.85	12	6.35	31.67	100	0.00	31.50
2	3.85	12	6.35	28.50	90	1.32	34.10
3	6.33	20	5.98	25.34	80	2.25	37.76
4	9.50	30	5.58	22.17	70	3.10	52.21
5	12.67	40	5.10	19.00	60	3.86	56.85
6	15.84	50	4.52	15.84	50	4.52	60.64
7	19.00	60	3.86	12.67	40	5.10	66.00
8	22.17	70	3.10	9.50	30	5.58	71.41
9	25.34	80	2.25	6.33	20	5.98	83.33
10	28.50	90	1.32	3.85	12	6.35	88.79
11	31.67	100	0	3.85	12	6.35	89.40

The Figure 5.4. gives the graph plotted between Displacement and FiO_2 %, the change in FiO_2 value for the given displacement through the stepper motor can be calculated with the equation (3), which coincidence with the actual curve with a congruence value of 0.9821.

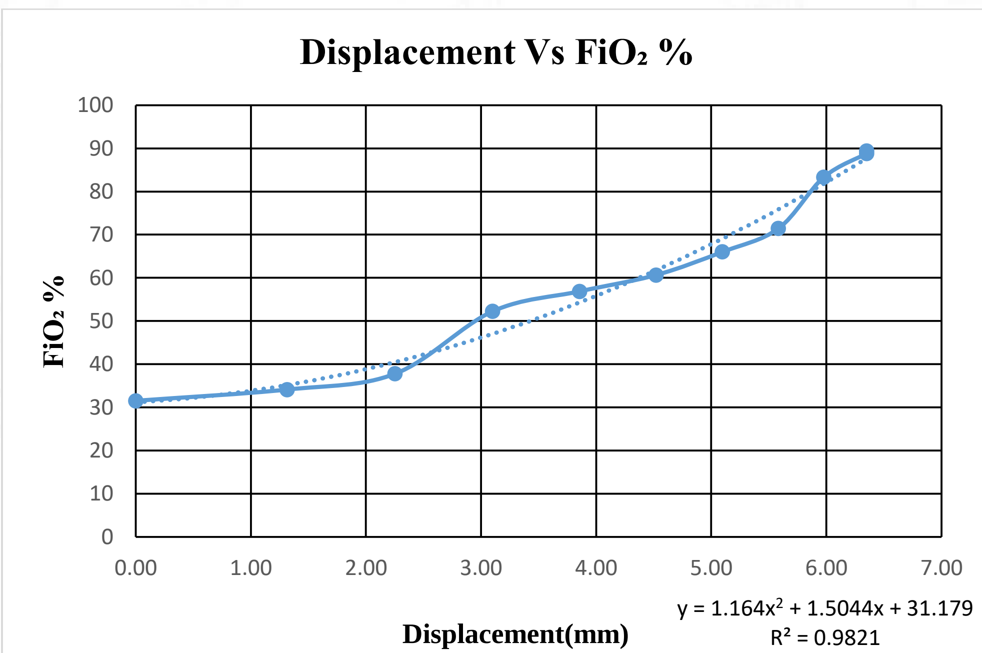


Figure 5.3. Displacement vs FiO_2 graph

$$y = 1.164x^2 + 1.5044x + 31.179 \quad \ldots\ldots(3)$$

The initial change in FiO_2 is very low, but after 2mm displacement, the FiO_2 values have a higher increment till the maximum displacement, as shown in figure 5.4. The graph can also be understood better with the area displacement graph as the initial displacement has a minimum change in the area which is reflected in the FiO_2 value.

Experimental Results

In the experiment, the FiO_2 results were derived from the oxygen sensor output for the variations in the area controlled by the displacement of the screw clamp. We have observed a steady rise in the FiO_2 values as the displacement (D2) on the air increases, as shown in Table 5.4. The increase in D2 implies the decrease in displacement on the oxygen side (D1), i.e. as the air area decreases, the oxygen area increases.

Table 5.4. Experimental Results

S.No.	**Displacement (D2)(mm)**	**Sensor Output-1(mV)**	**Sensor Output-2(mV)**	**Sensor Output-3(mV)**	**Average (mV)**	**FiO_2 %**
1	0	12	12	12	12.00	22.61
2	1	35.00	38.00	34.00	35.67	60.77
3	2	38.00	40.00	37.00	38.33	65.07
4	3	43.00	44.00	44.00	43.67	73.66
5	4	44.00	45.00	45.00	44.67	75.28
6	5	46.00	48.00	48.00	47.33	79.58
7	6	49.00	51.00	49.00	49.67	83.34
8	6.35	52.00	53.00	52.00	52.33	87.64

Figure 5.5.show the graph between FiO_2 and displacement, the initial rise in FiO_2 value is very high, and gradually the slope decreases. The FiO_2 values are calculated with the help of linear calibration of the sensor.

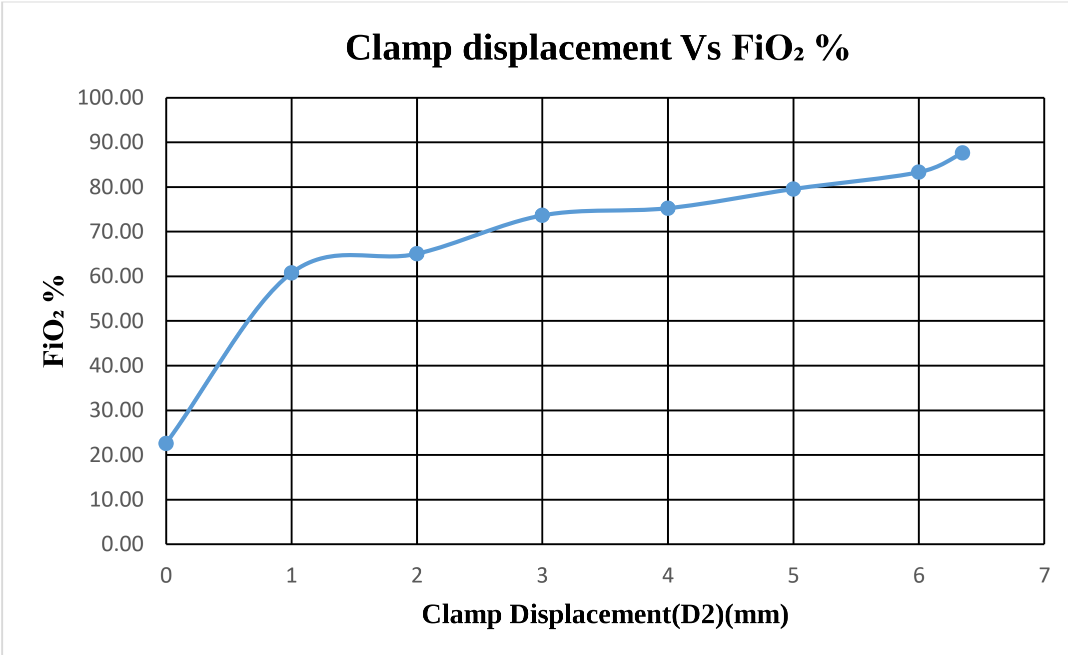


Figure 5.4. Experimental Relation between Displacement Vs. FiO_2

Validation

The simulation results have to be validated to implement it in the device. The experiment results and simulation results are compared with the plotting as shown in the figure 5.6.

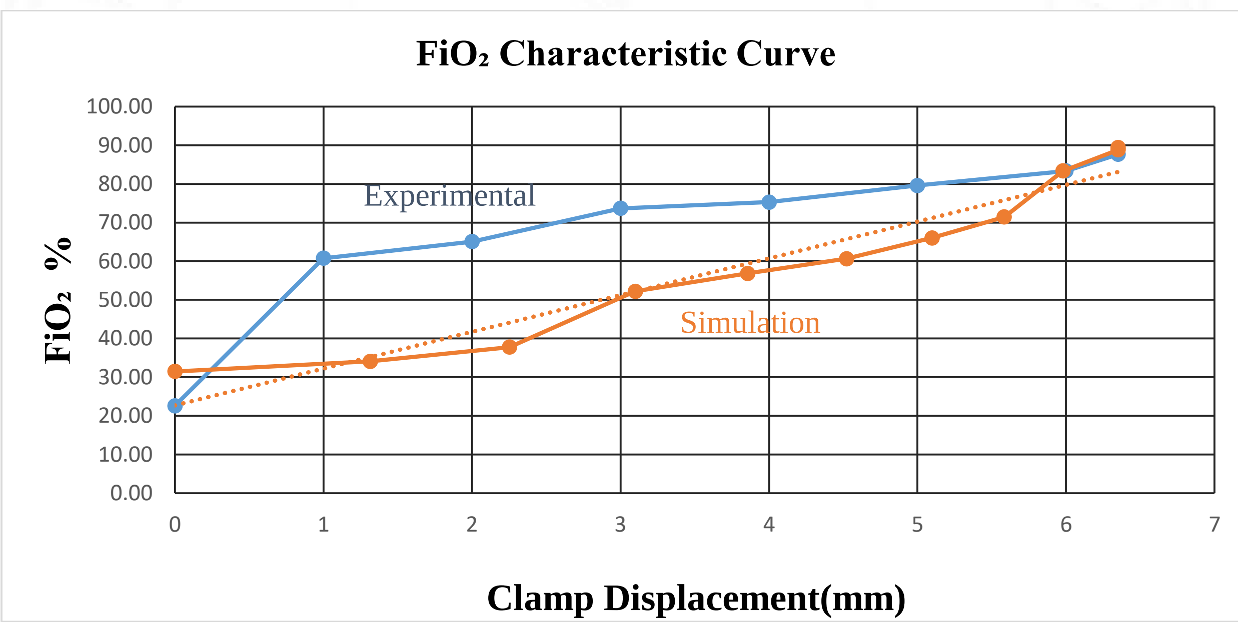


Figure 5.5. Comparison between experiment and simulation.

The Figure 5.6. show the relationship of Displacement and FiO_2 in experiment and simulation. The displacement here indicates the linear movement happening in the air tube, as mentioned in previous tabulations. The experimental values start with a lower FiO_2 value than simulation as 100 % occlusion of the oxygen tubing is possible in the experiment. But in simulation, the least area taken is 12%, as the squeezing mechanism in the ventilator had that limitation. The FiO_2 values of 1mm and 2mm displacement are quite high for the experiment. The variation in the area for 1mm releasing of the screw clamp produces a significant change in oxygen tube area, allowing high flow. The oxygen supply used in the experiment is continuous, but the air supply is intermittent due to limitations with the compressor. The erratic air supply is significantly reflected at high airflow and reduces as the air tube is occluded. The simulation and experimental curves converge from the clamp displacement of 3mm, i.e., as the oxygen flow increases, the FiO_2 is aligning with simulation FiO_2. At 6 mm and 6.35 mm clamp displacement, the error percent is 1.5 % and 0.03 %.

Error in FiO_2 calculation.

In table 5.5., the difference in FiO_2 values from the simulation and experiment is calculated. The error % is computed comparing the difference with simulation FiO_2.

Table 5.5. Error Calculation in Simulation and Experiment.

S.No	Displacement	Simulation FiO_2 %	Experimental FiO_2%	FiO_2 Difference	Error %
1	0	31.18	22.61	-8.57	-27.48
2	1	33.85	60.77	26.92	79.54
3	2	38.84	65.07	26.23	67.52
4	3	46.17	73.66	27.49	59.55
5	4	55.82	75.28	19.46	34.86
6	5	67.80	79.58	11.78	17.37
7	6	82.11	83.34	1.23	1.50
8	6.35	87.67	87.64	-0.03	-0.03

Figure 5.7. shows the corresponding error in FiO_2 in the experiment compared with the simulation FiO_2. The simulation values have a low error percent at higher FiO_2 values; the reason behind the higher error percent in the lower range of FiO_2 is attributed to the inconsistent supply of air. The way of squeezing in simulation is different from the way of squeezing in the experiment, which also contributed to the error. The shortage in oxygen due to the covid situation further reduced the possibility to optimize the oxygen sensor through the trial and error method.

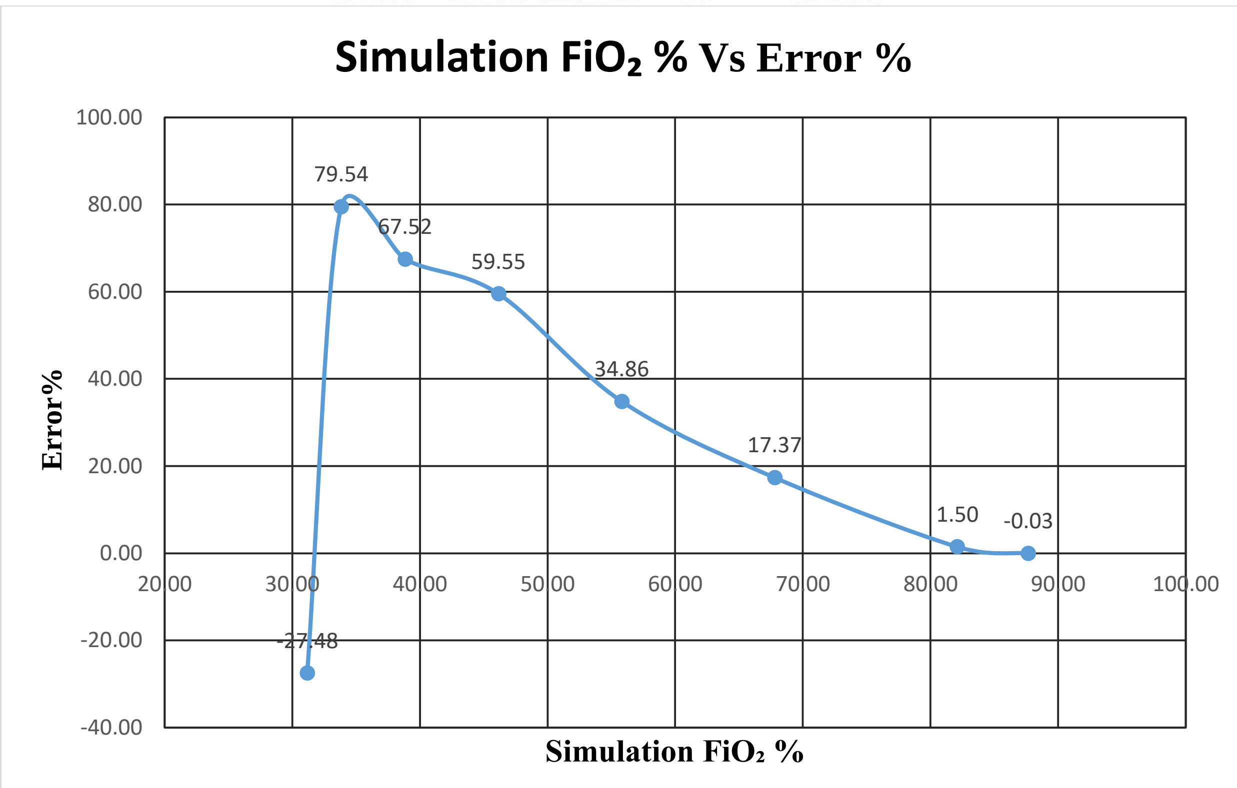


Figure 5.6. Error in FiO_2 Calculation.

Figure 5.8 gives the relationship between clamp displacement and error%. The clamp displacement indicates the clamp squeezing in the air tube. The percentage of error has one spike at 1mm and reduces continuously after 1mm. The error values are minimum at 6 mm and 6.35 mm.

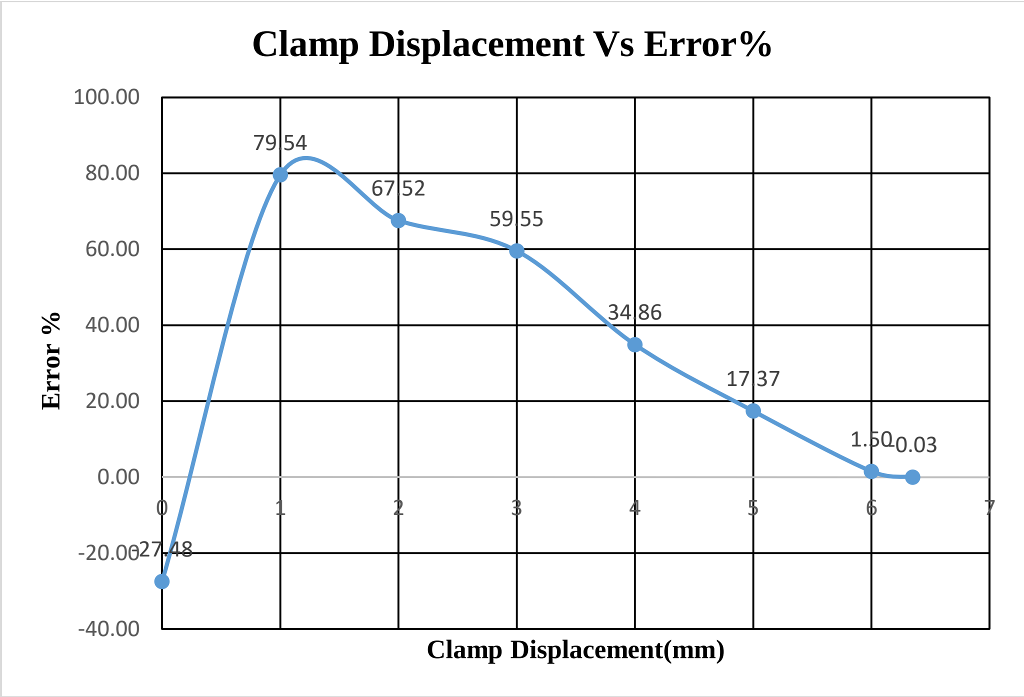


Figure 5.7. Relationship between Clamp Displacement and Error %

As the experimental results are showing close values at a higher percentage of FiO_2, the improvement in experiment condition will have better congruence with the simulation results. Thus the equation obtained from the simulation can be adopted in the design of the Chitra ventilator for the regulation of the percentage of FiO_2 %. In a practical case, the clinician or operator will be setting the required FiO_2 in the ventilator. The algorithm in the ventilator computes the necessary clamp displacement to be provided for the squeezing of the air and oxygen tube for a set FiO_2. A graph is plotted with the obtained FiO_2 in X axis and clamp displacement in the Y axis to determine a relationship between FiO_2 and clamp displacement Figure 5.9. A polynomial equation with an R^2 value of 0.9739 is fitted in the curve. Through this graph, an equation for displacement is obtained.

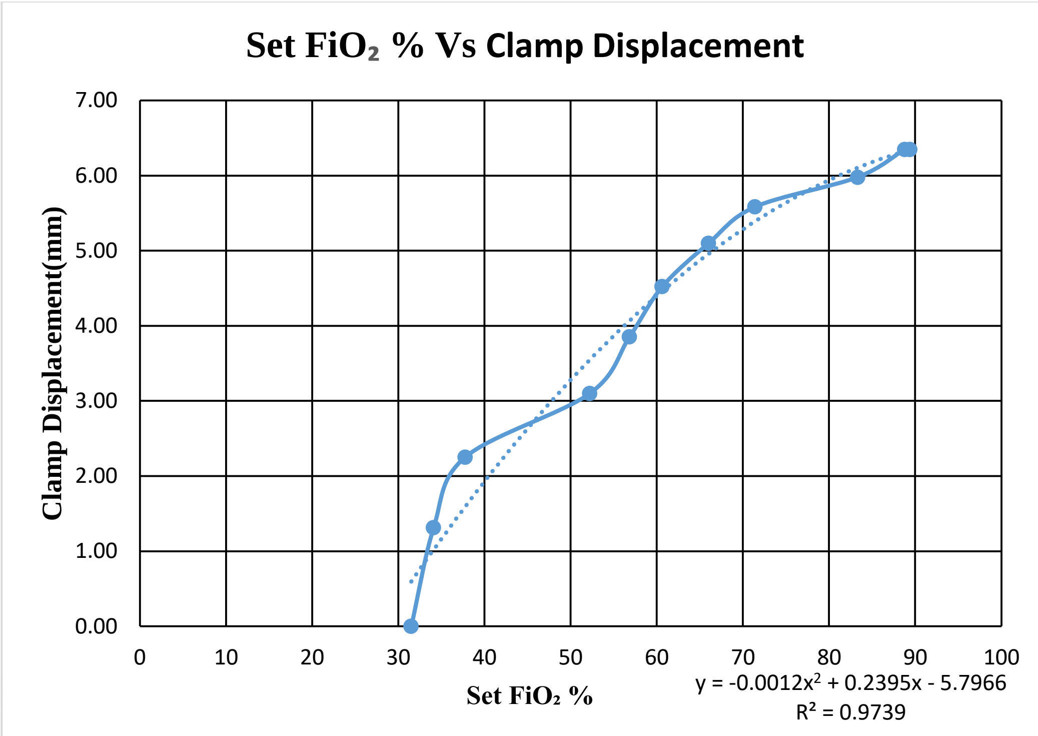


Figure 5.8: The graph shows the relationship between displacement and FiO_2 %.

For determining the displacement value that has to be given to the stepper motor through the microcontroller, the equation obtained from the graph is shown below.

$$\mathbf{y = -0.0012x^2 + 0.2395x - 5.7966}$$

5.2. Conclusion

The process of validation of the FiO_2 mechanism in the Chitra ventilator is conducted in various steps. The various checkpoints in the project were to simulate the FiO_2 mechanism and establish a relation between displacement and FiO_2.

The approach used to simplify the multi-physics model into two separate individual problem statements, i.e., the flow analysis and structural analysis, has helped to arrive at the results in a quick and reliable manner.

The boundary conditions needed for the flow analysis signify the drop in pressure in the breathing circuit. The safe pressure limits within which the ventilator should be operated and the flow required is also taken into account.

The simulation is done under few assumptions. The fluid assumed is oxygen in the flow analysis. The relation between the area ratio and FiO_2 is obtained from the flow analysis, with the flow velocities for the change in the area directly derived from the post-processing. The FiO_2 values can be obtained from the empirical relation as the flow velocities of oxygen and airflow rate are computed.

In the structural analysis results, the relationship between displacement and area ratio was plotted. With the area as a common parameter, the flow analysis and structural analysis results are combined, and a relation between the change in FiO_2 for the clamp displacement in the air tubing is established.

The validation of the FiO_2 obtained from the simulation is done with experimentation. From the experiment, the FiO_2 value for the corresponding deformation of the air and oxygen tube is obtained. As the oxygen flow increases, the output of the oxygen sensor was rising, giving a clear indication of the rise in FiO_2 %. The linear movement of the squeezing plate of air and oxygen is inversely related. The current increment of displacement in the squeezing plate is suitable for achieving percentages of FiO_2 from 21 to 100 %.

The experimental results had a high error percentage in the lower range of FiO_2, but the error is significantly reduced in the higher range of FiO_2.

The convergence of the graph with simulation and experiment percentages of FiO_2 against displacement for the higher values of FiO_2 suggests simulation data is reliable to be used in the device. The improvement in the experiment condition will have better congruence with the simulation results. The equation obtained from simulation results can be adopted in the design of the Chitra ventilator for the regulation of the percentages of FiO_2, considering few conditions.

The relationship established between the displacement and FiO_2, with the FiO_2 as independent variable in the graph, is the one of the major outcomes the project has aimed. The equation can be directly used to find the displacement for the corresponding FiO_2.

5.3. Future Work

The effort in this project is a beginning in the design of a novel FiO_2 regulating mechanism. The mechanism shows signs of effective, low-cost operation in portable ventilators.

The following changes can guide to optimum design in the project,

1) The experimentation optimization, with standard air supply with control on low range pressure, e.g., 20KPa.
2) The oxygen sensor has to be calibrated with a gas blender.
3) The experimentation and simulation shall have the same method of squeezing.
4) The multi-physics models are evolving. If a reliable platform is available, the simulation can be made in the multi-physics model, which would provide more accurate results.
5) The relation between the linear clamp displacement through the stepper motor for a given voltage needs to be established. Then, the FiO_2 and voltage relation can be derived, as the clamp displacement and FiO_2 are already specified in the project. This result shall be directly used in the algorithm to regulate the FiO_2.

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