Sudan University of Science and Technology

College of Graduate Studies

Simulation of Mechanical Ventilator Using Simscape Fluids Gas Library

محاكاة جهاز التنفس الصناعي بإستخدام مكتبة سيمسكيب للموائع الغازات

A thesis submitted in Partial Fulfillment of the Requirements of MSc Award Degree in Biomedical Engineering

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بسم الله الرحمن الرحيم

(وَلَولا فَضْلُ اللهِ عَلَيكَ وَرَحْمَتُهُ لَهَمتْ طَائِفَةٌ مِنْهُمْ أَنْ يُضِلُّوك وَمَا يُضِلُّونَ إلا أَنْفُسَهُمْ وَمَا يَضُرُّونَكَ مِنْ شَيْءٍ
وَأَنْزَلَ اللهُ عَلَيكَ الكِتَابَ وَ الحِكْمَةَ وَعَلَمَكَ مَا لَمْ تَعْلَمْ وَكَانَ فَضْلُ اللهِ عَلَيكَ عَظِيماً)

صدق الله العظيم

(سورة النساء الآية 113)

DEDICATION

I dedicate this work to my family and many friends. A special feeling of gratitude to my parents, Prof. Alnazier Osman whose words of encouragement and push for tenacity rings in my ears, and to my dear fiancée.

ACKNOWLEDGEMENT

I would like to give thanks to Allah for guiding my steps throughout this study, and for granting me more knowledge.

I am deeply grateful to Prof. Alnazier Osman for overwhelming me with his wisdom, and to provide me with his insistent efforts to lead me to the right path.

Also, I can’t describe my honest gratitude to my parents for dedicating me their lovely support.

المستخلص

جهاز التنفس الصناعي عبارة عن جهاز يستبدل كليا أو جزئيا الجهود التي يتحتم على الجسم القيام بها لدفع الهواء إلى الرئة ومنها, وهو جهاز مهم لأولئك الذين لا يستطيعون التنفس بكفاءة.

فيروس كورونا المستجد 2019 زاد الحاجة عالميا لأجهزة التنفس الصناعي لأجل مساعدة المرضى الذين يعانون من متلازمة الضائقة التنفسية الحادة والتي تعتبر العرض الأكثر شيوعا للفيروس.

المشروع يقترح ويقدم نموذج جهاز تنفس صناعي حجمي التحكم مدمج مع نموذج للجهاز التنفسي, كلا النموذجين قابلين للتعديل ويسمحان للمستخدم بمحاكاة تصميمه بدقة, وتقييم أداء التصميم عند إستخدامه مع عدة ظروف تنفسية.

تم إستخدام ماتلاب\سيميولنك مكتبة الموائع (الغازات) لمحاكاة ثلاثة حالات مختلفة مرتبطة بنموذج جهاز تنفس صناعي حجمي التحكم, تم إستخلاص نتائج موجتي معدل التدفق والضغط وتمت مقارنتهما بالموجات المثالية لمعدل التدفق والضغط, وأظهر النموذج تشابها كبيرا.

المشروع يقدم حلولا مناسبة لمشاكل معقدة مثل, تعقيد أجهزة التنفس الصناعي, التكلفة المرتفعة للأجهزة التجارية, الحاجة لتصاميم المصادر المفتوحة التي تحد من التكاليف, وإختبار هذه التصاميم دون تهديد للحياة.

Abstract

A mechanical ventilator is a machine which completely substitute the efforts the body most produce to move air into, and out of the lung, it is an essential device for those who can’t breathe sufficiently.

COVID-19 increases the need for mechanical ventilators worldwide in order to help patients who suffers from acute respiratory distress syndrome as the most common symptom.

This project suggests and presents a volume control mechanical ventilator model integrated with respiratory system model, both models are adjustable and allow the user to simulate his design accurately and assessing it is performance with multiple patients’ respiratory system conditions.

MATLAB\Simulink fluids(gas library) was used to simulate three different cases coupled with VCV mode adjustable model of mechanical ventilator, and the results of the flow rate and pressure waveforms were extracted and compared against ideal waveforms of flow rate and pressure, and they showed great similarity.

The system provides proper solutions for difficult problems such as mechanical ventilator complexity, high costs of commercial designs, the need of open source designs which cut the costs, and assessment of these designs without jeopardizing human lives.

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CHAPTER ONE

INTRODUCTION

1.1 General View

A mechanical ventilator is an automatic machine designed to provide all or part of the work the body must produce to move gas into and out of the lungs. The act of moving air into and out of the lung is called breathing, or more formally ventilation [1].

Biomedical engineers design these machines, which vary slightly in components, but serve the same purpose and have the same general principles.

The corona virus pandemic increases the need of mechanical ventilators all over the world. Researchers, and engineers everywhere intense their efforts, to response to the shortage of ventilators. Lots of designs implemented and huge amount of researches have been published.

Simulation is an important concept in order to design ventilators and assess their performance.

1.2 problem Statement

Worldwide shortage of ventilators, which help COVID19 patients who suffer acute respiratory distress syndrome and the risk of evaluate new designs that could have many problems directly on critical cases, which could cause harm to those patients.

1.3 General Aim

Design a precise simulation template that includes all essential components of atypical mechanical ventilator, which simplifies the process of designing, assessing performance without threatening patients’ lives.

1.4 Specific Objectives

1- Implement SIMULINK model template of mechanical ventilator.

2- Simulate respiratory system and coupling the two models to each other.

3- Test the overall model with different operation’s modes, different components’ geometrical dimensions, and different respiratory conditions.

4- Compare the model results with ideal waveforms of mechanical ventilators.

1.5 Research Methods

1- Implement pneumatic scheme of a typical ventilator including all essential components.

2- Convert the pneumatic scheme into a simulation model, which substitute pneumatic components with their equivalent SIMULINK blocks, using (Simscape fluids “gas” library).

A- Simulink is a MATLAB-based graphical programming environment for modeling simulating and analyzing multi domain dynamical systems .It has many libraries to build many types of models.

B- MATLAB and Simulink since version 2019(Simscape fluids “gas” library) allows simulating most pneumatic components required to build ventilator .older versions have many limitations.

3- Build patient respiratory system mathematical model, including airways and lung model which represents lung compliance, and trachea model using Simulink.

4- Couple the pneumatic Simulink model of ventilator with the Simulink model of lung and airways.

5- Adjust pneumatic components geometrically, ventilation parameters, lung and airways conditions, then extract and record the output of the sysem.

1.6 Thesis layout

Chapter two includes general knowledge about mechanical ventilators, their types and classifications, their operation modes, pneumatic scheme, and the benefits of simulation in the field of designing medical equipment.

Chapter three discusses researches related to this work, chapter four introduces the methods that will be followed, chapter five shows the results extracted from simulation template and discusses their characteristics, and the similarity between results and ideal waveforms of mechanical ventilators.

Chapter six represents the conclusion, and the recommendations.

CHAPTER TWO
THEORETICAL BACKGROUND

2.1 Mechanical ventilation

Mechanical ventilation is an important treatment which is usually utilized to ventilate patients who cannot breathe adequately on their own [2].

Mechanical ventilators, which are often also called respirators, are used to artificially ventilate the lungs of patients who are unable to naturally breathe from the atmosphere [3].

In almost 100 years of development, many mechanical ventilators with different designs have been developed [3].

The very early devices used bellows that were manually operated to inflate the lungs. Today's respirators employ an array of sophisticated components such as microprocessors, fast response servo valves, and precision transducers to perform the task of ventilating the lungs [3].

The changes in the design of ventilators have come about as the result of improvements in engineering the ventilator components and the advent of new therapy modes by clinicians [3].

A large variety of ventilators are now available for short-term treatment of acute respiratory problems as well as long-term therapy for chronic respiratory conditions [3].

It is reasonable to broadly classify today's ventilators into two groups. The first and indeed the largest group encompasses the intensive care respirators used primarily in hospitals to support patients following certain surgical procedures or assist patients with acute respiratory disorders. The second group includes less complicated machines that are primarily used at home to treat patients with chronic respiratory disorders [3].

The level of engineering design and sophistication for the intensive care ventilators is higher than the ventilators used for chronic treatment. However, many of the engineering concepts employed in designing intensive care ventilators can also be applied in the simpler chronic care units [3].

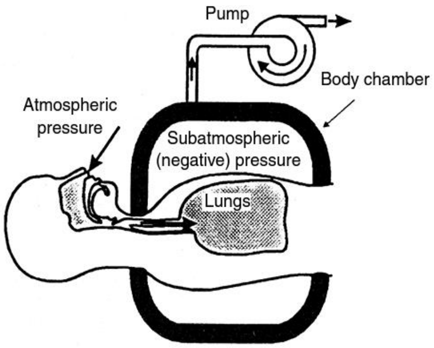

Figure (2.1) Simplified illustration of negative pressure ventilator [3].

At the beginning, the designers of mechanical ventilators realized that the main task of a respirator was to ventilate the lungs in a manner as close to natural respiration as possible. Since natural inspiration is a result of negative pressure in the pleural cavity generated by distention of the diaphragm, designers initially developed ventilators that created the same effect. These ventilators are called negative-pressure ventilators [3].

However, more modern ventilators use pressures greater than atmospheric pressures to ventilate the lungs; they are known as positive-pressure ventilators [3].

2.1.1 Negative pressure ventilators

In this design, the flow of air to the lungs is created by generating a negative pressure around the patient’s thoracic cage [3].

The negative pressure moves the thoracic walls outward expanding the intra-thoracic volume and dropping the pressure inside the lungs. The pressure gradient between the atmosphere and the lungs causes the flow of atmospheric air into the lungs [3].

The inspiratory and expiratory phases of the respiration are controlled by cycling the pressure inside the body chamber between a sub-atmospheric level (inspiration) and the atmospheric level (exhalation). Flow of the breath out of the lungs during exhalation is caused by the recoil of thoracic muscles. Although it may appear that the negative pressure respirator incorporates the same principles as natural respiration, the engineering implementation of this concept has not been very successful [3].

A major difficulty has been in the design of a chamber for creating negative pressure around the thoracic walls. One approach has been to make the chamber large enough to house the entire body with the exception of the head and neck [3].

Using foam rubber around the patient’s neck, one can seal the chamber and generate a negative pressure inside the chamber. This design configuration, commonly known as the iron lung, was tried back in the 1920s and proved to be deficient in several aspects. The main drawback was that the negative pressure generated inside the chamber was applied to the chest as well as the abdominal wall, thus creating a venous blood pool in the abdomen and reducing cardiac output [3].

More recent designs have tried to restrict the application of the negative pressure to the chest walls by designing a chamber that goes only around the chest. However, this has not been successful because obtaining a seal around the chest wall is difficult [3].

Negative-pressure ventilators also made the patient less accessible for patient care and monitoring. Further, synchronization of the machine cycle with the patient’s effort has been difficult and they are also typically noisy and bulky. These deficiencies of the negative-pressure ventilators have led to the development of the positive-pressure ventilators [3].

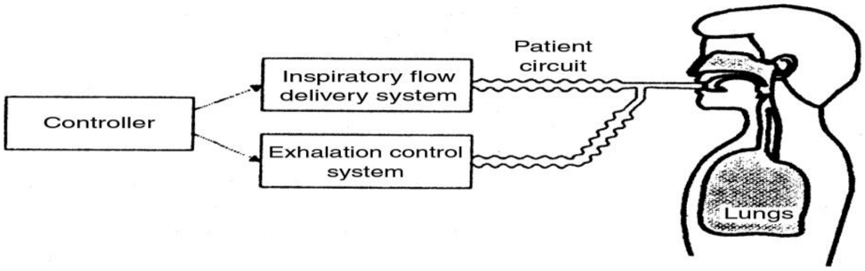

Figure (2.2) The functional blocks of a positive-pressure ventilator [3].

2.1.2 Positive pressure ventilators

Positive-pressure ventilators generate the inspiratory flow by applying a positive pressure (greater than the atmospheric pressure) to the airways [3].

During inspiration, the inspiratory flow delivery system creates a positive pressure in the tubes connected to the patient airway, called patient circuit, and the exhalation control system closes a valve at the outlet of the tubing to the atmosphere. When the ventilator switches to exhalation, the inspiratory flow delivery system stops the positive pressure and the exhalation system opens the valve to allow the patient’s exhaled breath to flow to the atmosphere. The use of a positive pressure gradient in creating the flow allows treatment of patients with high lung resistance and low compliance. As a result, positive-pressure ventilators have been very successful in treating a variety of breathing disorders and have become more popular than negative-pressure ventilators [3].

Positive-pressure ventilators have been employed to treat patients ranging from neonates to adults. Due to anatomical differences between various patient populations, the ventilators and their modes of treating infants are different than those for adults. Nonetheless, their fundamental design principles are similar and adult ventilators comprise a larger percentage of ventilators manufactured and used in clinics. Therefore, the emphasis here is on the description of adult positive-pressure ventilators. Also, the concepts presented will be illustrated using a microprocessor-based design example, as almost all modern ventilators use microprocessor instrumentation [3].

2.2 Ventilation modes

Since the advent of respirators, clinicians have devised a variety of strategies to ventilate the lungs based on patient conditions. For instance, some patients need the respirator to completely take over the task of ventilating their lungs. In this case, the ventilator operates in mandatory mode and delivers mandatory breaths. On the other hand, some patients are able to initiate a breath and breathe on their own, but may need oxygen-enriched air flow or slightly elevated airway pressure. When a ventilator assists a patient who is capable of demanding a breath, the ventilator delivers spontaneous breaths and operates in spontaneous mode [3].

In many cases, it is first necessary to treat the patient with mandatory ventilation and as the patient’s condition improves spontaneous ventilation is introduced; it is used primarily to wean the patient from mandatory breathing [3].

2.2.1 Mandatory ventilation

Designers of adult ventilators have employed two rather distinct approaches for delivering mandatory breaths: volume controlled ventilation and pressure controlled ventilation [3]. Volume controlled ventilation, which presently is more popular, refers to delivering a specified tidal volume to the patient during the inspiratory phase. Pressure controlled ventilation, however, refers to raising the airway pressure to a level, set by the therapist, during the inspiratory phase of each breath. Regardless of the type, a ventilator operating in mandatory mode must control all aspects of breathing such as tidal volume, respiration rate, inspiratory flow pattern, and oxygen concentration of the breath. This is often labeled as controlled mandatory ventilation (CMV) [3].

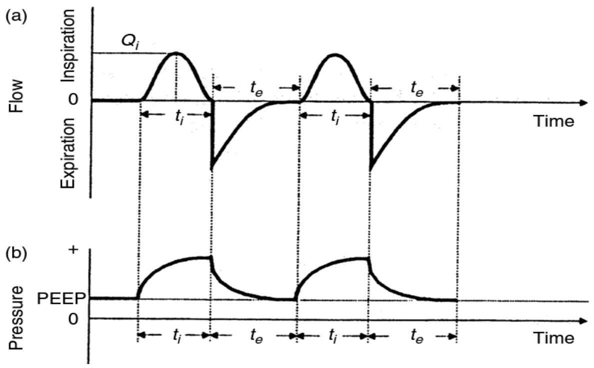

Figure (2.3) (a) Inspiratory flow for a controlled mandatory volume controlled ventilation breath.(b) Airway pressure resulting from the breath delivery with a non-zero PEEP [3].

Figure (2.3) shows the flow and pressure waveforms for a volume controlled ventilation (CMV) [3]. In this illustration, the inspiratory flow waveform is chosen to be a half sine wave. In Figure (2.3) (a) ti is the inspiration duration, te is the exhalation period, and Qi is the amplitude of inspiratory flow [3].

The ventilator delivers a tidal volume equal to the area under the flow waveform in Figure (2.3) (a) at regular intervals (ti + te) set by the therapist [3]. The resulting pressure waveform is shown in Figure (2.3) (b) [3]. It is noted that during volume controlled ventilation, the ventilator delivers the same volume irrespective of the patient’s respiratory mechanics [3]. However, the resulting pressure waveform such as the one shown in Figure (2.3) (b) will be different among patients [3]. Of course, for safety purposes, the ventilator limits the maximum applied airway pressure according to the therapist’s setting. As can be seen in Figure (2.3) (b), the airway pressure at the end of exhalation may not end at atmospheric pressure (zero gauge) [3]. The positive end expiratory pressure (PEEP) is sometimes used to keep the alveoli from collapsing during expiration. In other cases, the expiration pressure is allowed to return to the atmospheric level [3].

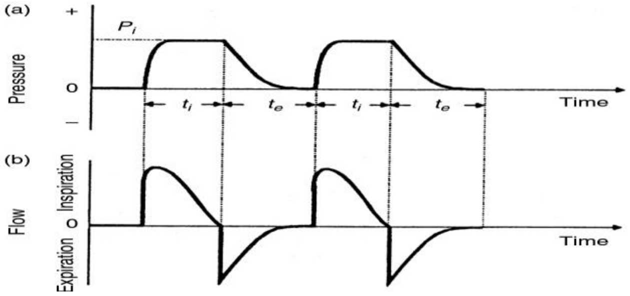

Figure (2.4) (a) Inspiratory pressure pattern for a controlled mandatory pressure controlled ventilation breath.(b) Airway flow pattern resulting from the breath delivery. Note that PEEP is zero [3].

Figure (2.4) (a) shows a plot of the pressure and flow during mandatory pressure controlled ventilation [3]. In this case, the respirator raises and maintains the airway pressure at the desired level independent of patient airway compliance and resistance [3]. The level of pressure during inspiration, Pi, is set by the therapist. While the ventilator maintains the same pressure trajectory for patients with different respiratory resistance and compliance, the resulting flow trajectory, shown in Figure (2.4) (b), will depend on the respiratory mechanics of each patient [3].

Volume controlled ventilators, which are more common. Further, in a microprocessor-based ventilator, the mechanism for delivering mandatory volume and pressure controlled ventilation has many similar main components [3]. The primary difference lies in the control algorithms governing the delivery of breaths to the patient [3].

Table (2.1) volume controlled and pressure controlled comparison of the ventilators [11].

Volume Controlled Ventilator (VCV)	Pressure Controlled Ventilator (PCV)
In VCV type instruments, all modes are independent of peak airway pressure (PAP) and plateau pressure (PP), system designed to provide constant tidal volume VT distribution.	In PCV types instruments, regardless of distributed VT, fixed peak airway pressure (PAP) and plateau pressure (PP) are provided.
The inspiratory flow rate is constant.	The inspiratory flow rate is variable.
Inspiration current shape is square.	Inspiratory flow pattern is exponentially slowing down.
Tidal volume is constant.	Tidal volume is variable.
The pressure is variable.	Airway pressure is variable.

2.2.2 Spontaneous ventilation

An important phase in providing respiratory therapy to a recovering pulmonary patient is weaning the patient from the respirator [3]. As the patient recovers and gains the ability to breathe independently, the ventilator must allow the patient to initiate a breath and control the breath rate, flow rate, and the tidal volume. Ideally, when a respirator is functioning in the spontaneous mode, it should let the patient take breaths with the same ease as breathing from the atmosphere [3]. This, however, is difficult to achieve because the respirator does not have an infinite gas supply or an instantaneous response [3].

In practice, the patient generally has to exert more effort to breathe spontaneously on a respirator than from the atmosphere. However, patient effort is reduced as the ventilator response speed increases [3].

Spontaneous ventilation is often used in conjunction with mandatory ventilation since the patient may still need breaths that are delivered entirely by the ventilator [3].

Alternatively, when a patient can breathe completely on his own but needs oxygen-enriched breath or elevated airway pressure, spontaneous ventilation alone may be used [3].

As in the case of mandatory ventilation, several modes of spontaneous ventilation have been devised by therapists. Two of the most important and popular spontaneous breath delivery modes are described below [3].

Continuous Positive Airway Pressure (CPAP) in Spontaneous Mode

In this mode, the ventilator maintains a positive pressure at the airway as the patient attempts to inspire [3].

Figure (2.5) illustrates a typical airway pressure waveform during CPAP breath delivery. The therapist sets the sensitivity level lower than PEEP. When the patient attempts to breathe, the pressure drops below the sensitivity level and the ventilator responds by supplying breathable gases to raise the pressure back to the PEEP level [3].

Typically, the PEEP and sensitivity levels are selected such that the patient will be impelled to exert effort to breathe independently [3].

As in the case of the mandatory mode, when the patient exhales the ventilator shuts off the flow of gas and opens the exhalation valve to allow the exhaled gases to flow into the atmosphere [3].

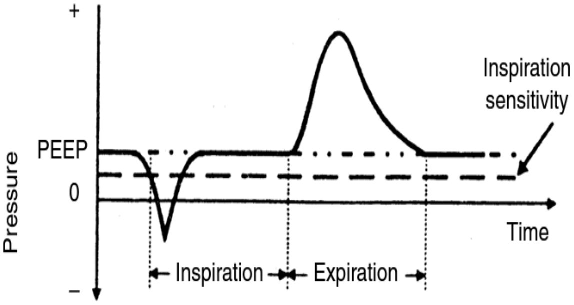

Figure (2.5) Airway pressure during a CPAP spontaneous breath delivery [3].

Pressure Support in Spontaneous Mode

This mode is similar to the CPAP mode with the exception that during the inspiration the ventilator attempts to maintain the patient airway pressure at a level above PEEP [3].

In fact, CPAP may be considered a special case of pressure support ventilation in which the support level is fixed at the atmospheric level [3].

Figure (2.6) shows a typical airway pressure waveform during the delivery of a pressure support breath [3].

In this mode, when the patient's airway pressure drops below the therapist-set sensitivity line, the ventilator inspiratory breath delivery system raises the airway pressure to the pressure support level (>PEEP), selected by the therapist [3]. The ventilator stops the flow of breathable gases when the patient starts to exhale and controls the exhalation valve to achieve the set PEEP level [3].

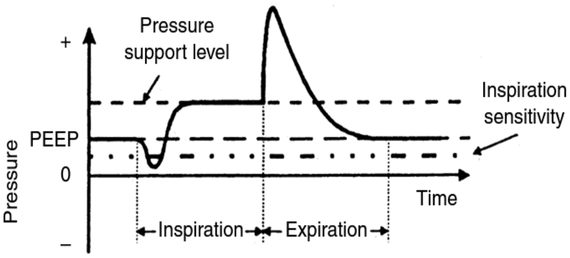

Figure (2.6) Airway pressure during a pressure support spontaneous breath delivery [3].

2.3 Pneumatic components of mechanical ventilator

Figure (2.7) shows pneumatic functional scheme which includes essential components of an ICU ventilator, beginning with compressed air and o2 sources (0), then filters to remove impurities (1), check valves (2) to avoid reverse flow , reducing valves which reduce sources pressure (3) , and pressure sensors to sense the amount of pressure after reduction (4) are important, air and O2 metering valves responsible of controlling gas mixture FIO2 are essential (5),(6),then a tank(7) used for blending air and O2 with the desired FIO2 which already adjusted using metering valves, an O2 sensor (8) to measure the value of FIO2 inside the tank and send feedback signal to controller if measured value isn’t equal to the desired value, tank relief valve (9) to relief over pressure inside the tank, then (10) a filter to protect the next inspiratory valve against infection, inspiratory valve (11) to deliver gases to patient with required flow, pressure and FIO2, pressure relief valve(12) to avoid uncontrolled pressure increase downstream the patient, and safety valve(13) which is normally open and allows patient to breath in case of standby or malfunctioning, these valves (12) and (13) remain closed during normal operation of ventilator, pressure sensor(14) to measure pressure at this point of the circuit, humidifier and/or heat exchanger(15) can optionally be used to control the humidity or temperature of inhaled gas mixture, (16) a flow sensor placed close to patient’s mouth in order to measure the flow rate inspired and expired by the patient [4].

The last part consists of pressure sensor (17) , an optional additional filter (18) , expiratory valve(19) which used for both adjusting the minimum pressure in the patient circuit , and regulate the expiratory flow of gases to external environment and check valve (20) to avoid reverse flow in the expiratory circuit[4].

Some medical treatments need the patient to be provided with medicine in the form of aerosol, when this additional function is activated, the directional on/off valve (21) is opened. Afterwards, the compressor (22) increases the pressure of the gas taken from the tank, which can enter a nebulizer jar (23) to blend with the medicine to be supplied to the patient [4]. This method has the advantage of not disrupting the air/oxygen ratio of the gas that delivered to the patient [4].

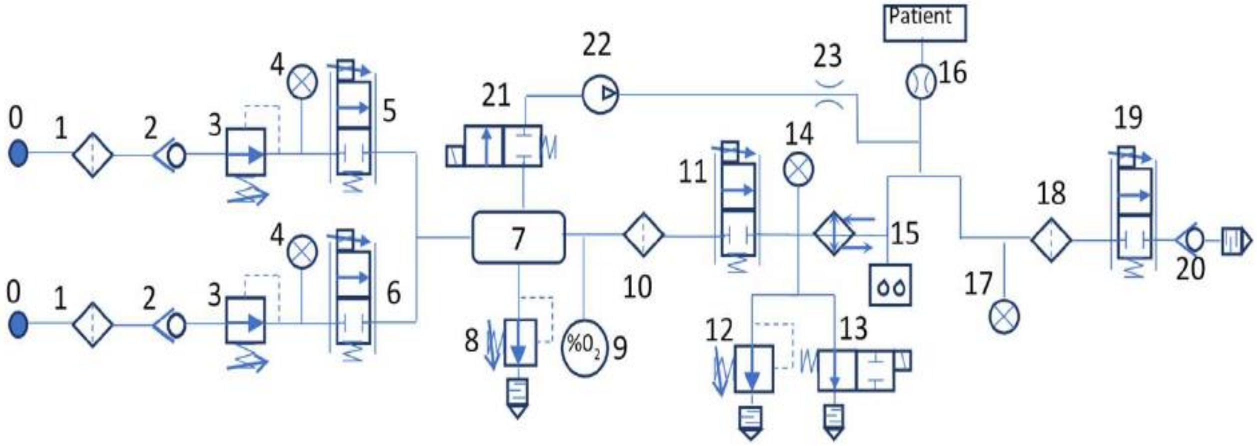

Figure (2.7) Pneumatic scheme of an ICU ventilator with ISO symbols [4].

2.4 Simulation in the Manufacturing of Medical Devices

Operational efficiency is commonly measured in terms of overall equipment efficiency (OEE) [5]. It is a combination of availability, performance, and quality to produce consistent and repeatable metrics of business performance [5]. Manufacturing efficiency in the medical device industry is already lower than the manufacturing average [5]. It has been observed that medical device plant OEE levels below 50% are not uncommon while automobile and semiconductor manufacturers often have OEE levels of 85% or higher [5]. This suggests that there are recoverable plant capacities which are essentially untapped [5]. Simulation analysis is a very powerful tool which can help to exploit these untapped capacities and offer much more and if this technology is ignored, it can prove to be very costly in the long run [5].

In recent years the medical device industry has been apprehensive in adopting simulation technology but if manufacturers want to remain competitive in 21st century they cannot afford to ignore this powerful approach [5]. The industry is well positioned to embrace the technology and can leverage key ingredients from existing systems [5].

CHAPTER THREE
LITERATURE REVIEW

One of the rare positive consequences of COVID19 pandemic is the international unity in order to find solutions that help humanity facing the international challenge.

This unity took the shape of cooperation in the field of medicine and technology; biomedical engineering has been playing a vital role in the battle against the pandemic.

Many designs of mechanical ventilators were published, and minimum specifications of rapidly manufactured ventilators that are acceptable to help acute respiratory distress syndrome patients were defined. Simulation and modeling as useful tools for designing and assessing the new designs were used.

In this chapter provides the most important works which were done to simulate mechanical ventilators during last few years.

Medicine and healthcare products regulatory agency in UK, (2020), published minimal acceptable specifications of ventilators that could be used in UK during the pandemic [6].

It includes the modes of ventilation (mandatory or spontaneous), (volume control or pressure control) that are required, and the ranges of ventilation parameters like tidal volume, positive end expiratory pressure, respiratory rate or frequency, and inspiratory to expiratory ratio, peak and plateau pressures[6].

This guideline is very important because it relied on clinical experiments that were done in UK when pandemic hit violently in Britain which is known as one of the most affected countries [6].

It is important too because this research will follow these specifications.

Jaber M *et al*. (2020), using MATLAB\Simulink designed mathematical model of lung and ventilator [7].

Pressure wave of pressure controlled ventilation (PCV) was produced using equations that define all important variables in PCV mode, such as positive end expiratory pressure (PEEP), airway pressure (PAW), inspiratory time, expiratory time, and respiratory rate (RR) for healthy patient, and unhealthy patient [7].

The pressure wave then used as an input to either single or double compartmental model that represent lungs compliance and airway resistance using capacitors and resistors respectively[7].

The volume and flow waves' affection by changing the pressure input wave was displayed by the overall model, and volume\pressure loop also extracted [7].

The main disadvantage noticed is that the work represents the lung model as an electric model, while the respiratory system is a pneumatic system [7].

Yashurun T *et al.* (2020), designed an emergency ventilator that helps patients, who are capable of autonomous breathing but need pressure support, and some assistance to keep acceptable oxygen saturation levels [8].

The ventilator consists of input branch that mixes air and O2 from central gas supplies of the hospital, and output branch controlled by control system [8].

The ventilator design includes pneumatic components that simulated using MATLAB\Simulink Simscape Gas library, and the lung model simulated using translational mechanical converter consists of spring represents lung compliance, a damper represents airway resistance, and air force represents the induced pressure of patient's muscles [8].

The model allows adjusting vital parameters include PEEP, RR, assessing the design by showing the output waves of pressure, volume, and flow for healthy patients, and for those who suffer from acute respiratory distress syndrome ARDS due to their infection with COVID 19.Lung compliance and airway resistance are also adjustable [8].

The model represents an emergency ventilator for crises circumstances, not an ICU ventilator that capable to assist patients for months, and which has multiple respiratory modes convenient for many conditions [8].

Tamburanno P *et al*. (2020), designed adjustable model which could be used as template for manufacturing ICU ventilators [4].

The Pneumatic schemes of several commercial mechanical ventilators, were used to design an accurate ventilator model, that could be used for both design new ventilators, and assessing their performance [4].

MATLAB\Simulink Simiscape fluids (gas) library was used to translate pneumatic scheme to equivalent Simulink blocks, the ventilator pneumatic scheme composed of gas sources, filters, pressure reducing valves, air and oxygen metering valves, which can be directional proportional valves, or servo valves, tank to mix air and O2, pressure and flow sensors, pressure relief valves and safety valves, inspiratory valve and expiratory valve, humidifier and heat exchanger, nebulizer can be added optionally for patients who need medications in aerosol form. Considering the control system the control variable could be volume, or pressure [4].

The patient respiratory system was modeled as translational mechanical converter that simulates lungs, and composed of piston moves inside a cylinder, and spring which resists this displacement; all of the above represent lung compliance that varies among patients, pressure loss in the trachea is the other part of simulating patients’ respiratory system [4].

The ventilator model coupled with patient respiratory system model, allows the user to modify pneumatic scheme to fit with his design, changes patients respiratory system conditions. Precise assessment of ventilator performance was done using the model [4].

It could be considered almost the perfect ventilation model, unless that every possible component and safety feature were included in the work, that makes the process of manufacturing very expensive and difficult for many countries [4].another disadvantage is that the only mode is the (VCV), while (PCV) require changes of pressure controller [4].

Giri J *et al.* (2021), presented a simplified design of mechanical ventilator as an attempt to reduce cost of manufacturing [9].

The block diagram was simplified to only two proportional valves that adjust desired value of FIO2, pressure regulators adjust the pressure of gas mixture, two solenoid valves to control inspiratory and expiratory phases respectively, three pressure sensors aim to measure and display pressure values after regulation, before inspiration, and after expiration, two flow sensor to monitor and display the flow rate to and from the patient [9].

Simulation code using MATLAB/Simulink was introduced as well, all functional components were introduced, the ventilation parameters like PEEP, RR, I:E ratio, VT, flow rate were included with their clinical ranges[9].

Patient’s lung was simulated as translational mechanical converter allows simulation of multiple condition and diseases. The output waves of pressure, volume, and flow were extracted using Simulink block (scope), the results were found are similar to those of commercial mechanical ventilators [9].

The paper discussed the use of artificial intelligence to assist therapists to set the adequate parameters fit with a specific patient’s conditions, or further more completely replaces the human supervision [9].

The paper introduced and discussed several cost reduction techniques like AI that replace expensive therapists, simplified pneumatic components. Modeling and simulation provide precise assessment of the design without threatening human lives.

The work only introduced (VCV) and (PCV) modes, and it could be more enhanced adding more ventilation modes [9].

Table (3.1) Literature reviews summary

Authors	Date of publication	Paper	Summary
MHRA.	2020	[6]	It defines the minimal acceptable specifications of ventilators includes operation modes, parameter ranges such as PEEP, tidal volume. The paper is very useful and it guides this work.
Jaber M *et al.*	2020	[7]	Introduce PCV model of ventilator and lungs, the model lacks reliability due to the electric simulation of lungs.
Yashurun T *et al.*	2020	[8]	Introduce simulation and prototype ventilator for those who are capable of autonomous breathing but need O2 enrich gas flow The model and prototype are limited to crises circumstances and can’t be considered as an ICU ventilator.
Tamburanno P *et al.*	2020	[4]	Almost the perfect model of an ICU ventilator, the only disadvantage is that it includes every possible feature involved in the commercial ventilators, which increases costs. The most fruitful work that gives knowledge and inspires this work.
Giri J *et al.*	2021	[9]	The work simplifies the mechanical ventilator circuit diagram and offers many creative solutions to reduce costs, suggests substitution the expensive medical supervision with an AI supervision , but it remains just wishes with no illustrations in the paper

CHAPTER FOUR

RESEARCH METHOD

The Simulink template design was done by performing four stages as follow:

At first the pneumatic scheme of a typical ICU ventilator was clarified showing its functional components, and then it was used to derive the Simulink code that substitutes each essential component in the pneumatic scheme.

The code was performed using MATLAB\Simulink 2020 (Simscape fluids”gas library”), the older versions before 2019 have many limitations related to accuracy of the model, and lots of blocks weren’t found.

The second part of the template which represents patient’s respiratory system was performed using (translational mechanical converter block), after this the two models were linked together, modifications showed the template flexibility to interpret several scenarios were done , whether they are related to ventilator design or patient’s conditions.

A.Stage1:-

4.1 pneumatic scheme of mechanical ventilator

Mechanical ventilators are complex devices that composed of many pneumatic components such as valves, regulators, filters and many others.

At the beginning ventilator doesn’t generate gas or concentrate it from an ambient air like oxygen concentrator, so it need gas supplies either hospital central gas supply (1) ends beside ventilator with schrader sockets that provide medical gases that varies between 2 to 7 bar, or cylinders which are more expensive, and need external pressure regulators between the gas cylinder and the ventilator.

Most ventilators work with medical oxygen and medical air, they have filters to remove impurities(2), water traps to remove humidity that could harm electronic ports inside the devices, then the check valves(3) to prevent reverse flow.

Another part of ventilator circuit starts with pressure reducing valves(4) or regulators that reduce the pressure of the supplies to less than 500 mbar, pressure sensor to show the amount of regulators output(5), after reduction the most important components of mechanical ventilator are metering valves of air(6)and oxygen(7) , they have adjustable opening degree that can be controlled by the signal sent from microcontroller, and these opening degrees of air\oxygen metering valves determine the oxygen percentage in the inspiratory flow delivered to the patient FIO2.

A tank (8) that mixes air\oxygen is needed with an oxygen sensor (10) send its output to the microcontroller that modifies its signal which adjusts the opening degree of air\oxygen metering valves, to prevent pressure buildup within the tank a pressure relief valve (9) is required, to prevent contamination particles from reaching downstream inspiratory valve an additional filter (11) could be added.

An inspiratory valve (12) that monitors and controls the output flow is then applied to the circuit, pressure relief valve (13), and safety valve (14) represent essential safety feature that allows patient to breath in the case of malfunction.

For measuring the pressure at this point of the circuit, an additional pressure sensor is useful (15).

To control the temperature and humidity of the output flow an optional humidifier\heat exchanger (16) is required.

Flow sensor (17) that measures the actual amount of flow inspired and expired is essential.

The last part of the circuit is the expiratory valve (20) which controls the PEEP (positive end expiratory pressure).The PEEP is important to protect patient’s lung from collapsing at the end of expiration.

Pressure sensor (18) that detects the PEEP and alerts the microcontroller to adjusts the opening degree of expiratory valve, and regulates the output flow to the atmosphere, an additional filter (19) is required to prevent infections, check valve (21) to prevent the exhaled gas reverse flow

Figure (4.1) shows the pneumatic circuit of a typical ventilator

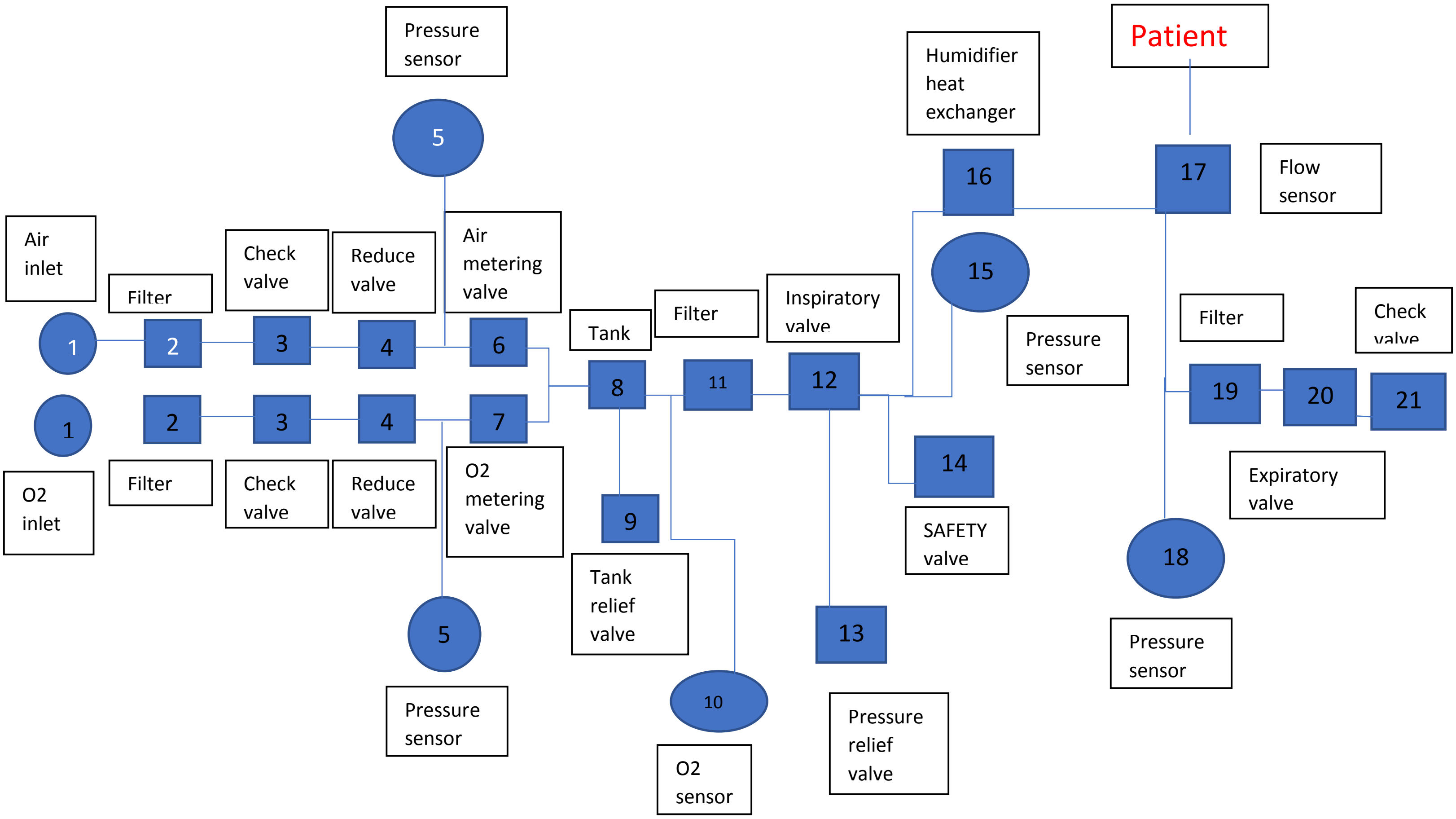

Figure (4.1) Pneumatic scheme of a typical ventilator.

B.Stage2:

4.2 SIMULINK blocks translation of the pneumatic scheme:

Simscape fluids (gas) library included in MATLAB\Simulink provides simulation blocks that simulate the same properties of the pneumatic components of a typical ventilator.

The gas properties of the model was simulated using gas properties block, only one gas properties can be defined; so the O2 percentage in the gas mixture was fixed, gas properties block allows user to choose among three states of gas: real gas, perfect gas, semi perfect gas.

The air and oxygen sources (1) were simulated using pressure source block; it provides constant pressure at the outlet no matter the flow fluctuations.

Check valve block was used to represent the check valves (3), and the minimum upstream pressure required to open the valve (cracking pressure) was defined.

The process of pressure reduction (4) was done using pressure reducing valve block, and the amount of reduction was controlled using block properties.

Pressure-temperature sensor block was used to monitor the downstream pressure of the pressure reducing valve as pressure sensors (5).

Variable orifice ISO 6358 and was used to simulate air and oxygen metering valves (6) and (7), the valve represents an orifice, valve, or a restriction, it models pressure loss from port A to port B depending on the control signal at port L, the valve has an opening fraction between 0 (valve closed) and 1(valve fully open).The valve properties could be set by sonic conductance, flow coefficient, or restriction area, although the gas critical pressure ratio should be defined as well.

The tank (8) was reproduced using constant volume chamber block, the volume must be defined, the pressure inside the tank could be calculated by volume, temperature, and the mass of the gas inside the chamber, the block has 1 inlet at port A, 1 outlet at port B connected to the inspiratory valve, the temperature inside the tank can be defined.

The inspiratory valve(12) was simulated using 2-way directional valve block , gas properties can be defined using sonic conductance, flow coefficient, or restriction area of the inspiratory valve, the valve opens the connection between ports A and B proportionally depends on control signal at port S.

The pressure relief valve (13) simulated by pressure relief valve block, it remains closed as long as the upstream pressure is less than the defined maximum pressure.

Safety valve (14) simulated using 2-way directional valve block controlled by the control signal where 0 closes the valve and 1opens it.

The pipe block used to represent pressure drop in the circuit due to humidifier and\or heat exchanger (16) connection, the proper length and diameter should be defined.

Flow sensor (17) was simulated as volumetric flow rate sensor block in order to measure the flow rate inspired, and expired by the patient.

Pressure and temperature sensor block was used to simulate pressure sensor (18) that measures the pressure at this point of the circuit.

Expiratory valve (20) was simulated using the 2-way directional valve block that mentioned above.

Finally check valve block was used to simulate check valve (21) that prevent the back flow.

C.Stage3:-

4.3 Simulation of patient’s respiratory system

Translational mechanical converter block namely “piston moving inside a cylinder” was used to simulate the lung; it was connected in series with spring block that represent lung compliance.

The lung compliance is the lung volume change divided by the lung pressure change.

$C=\Delta V/\Delta P$

Where

$C \equiv$ lung compliance

$\Delta V \equiv$ volume change

$\Delta P \equiv$ pressure change

The lung compliance could be represented by choosing the proper values for spring stiffness and piston area.

$\Delta P= k\ \Delta X/A = k\ \Delta V/A$

Where

$K \equiv$ spring stiffness

$\Delta x \equiv$ piston displacement

$\Delta V \equiv$ cylinder volume

$A \equiv$ piston area

Then

$C= A/k$

So if we fix the piston area we can get the desired value of compliance by changing the spring stiffness

The initial compression of the piston X0 could be computed by considering the minimum pressure in the airways (PEEP) which occurring in the end of expiration or the beginning of inspiration

$X0=A/k\ (PEEP)$

The dead volume of the cylinder

$V0= A(X0)$

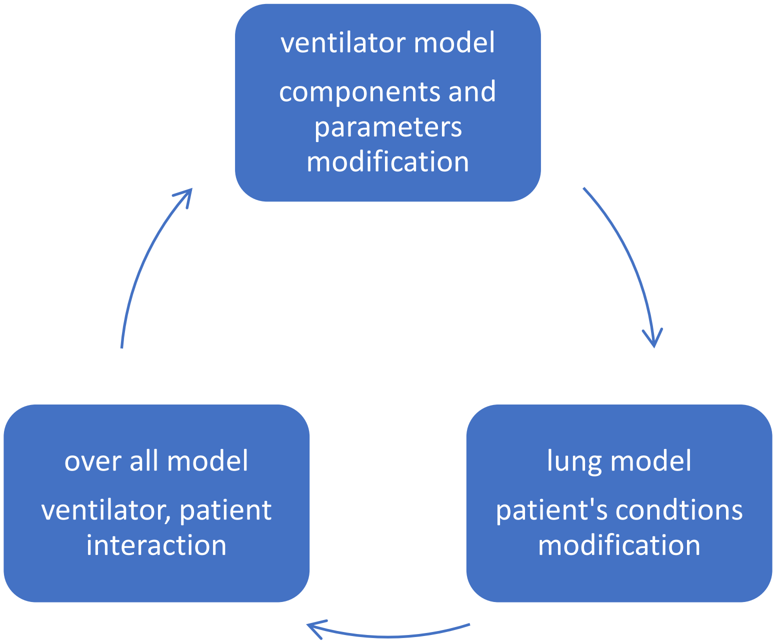

Figure (4.2) Overall model of lung and ventilator interaction.

D.stage4:-

4.4 The overall model

The overall model was derived by combining the ventilator template design with patient's respiratory system model.

Respiratory system model was represented as a subsystem connected in series with the ventilator model.

Modifications related to respiratory rate, PEEP, patient's conditions, and other variables were done.

The results of the modifications were extracted and discussed deeply in the next chapter.

The system was tested for three patients with different lung compliances (patient1, C=0.04L/m bar), (patient2, C=0.0333L/m bar), (patient3, C=0.05L/m bar).

The ventilator's parameters used in the simulation are clarified in table (4.1).

The ventilator adjustable variables such as:

Inspiratory time, inspiratory pause, expiratory time, tidal volume, positive end expiratory pressure, and inspiratory flow rate, and the patients' respiratory system conditions (the lung compliance, and pressure losses in the trachea) are clarified in table (4.2).

Table (4.1) Operating and geometrical parameters of the ventilator

Parameter	Value
Operation mode	VCV
Triggering	Ventilator
FIO2	20.9%
Specific gas constant	287.1 J(Kg K)
Supply pressure	2000 mbar
Critical pressure ratio (b value)	0.53
Pressure downstream of pressure reducing valves	300 mbar
Cracking pressure of the check valves	1 mbar
Cracking pressure of pressure relief valve	80 mbar
Sonic conductance of air metering valve, O2 metering valve , inspiratory valve, and expiratory valve	10 l/s/bar
Opening offset of the inspiratory and expiratory valves	-10%
Tank volume	5 l
Tank temperature	293 k
Length and diameter of humidifier+ heat exchanger(pressure drop)	0.5 m x 0.01m2
Heat exchanger temperature	300 k

Table (4.2) The ventilator adjustable variables and patient's conditions

Parameter	Value(patient1)	Value(patient2)	Value(patient3)
Lung compliance(c) (l/mbar)	0.04	0.0333	0.05l
Pressure losses in the trachea	5 mbar at 25 l/min	5 mbar at 25 l/min	5 mbar at 25 l/min
Inspiratory time (s)	1.2	1.2	1
Pause time (s)	0.4	0.4	0.2
Expiratory time (s)	2.4	2.4	2
Tidal volume (l)	0.5	0.5	0.5
Inspiratory flow rate (l/min)	25	25	30
Positive end expiratory pressure (PEEP) (mbar)	5	5	10

The parameters entered in the subsystem (respiratory system) to obtain the right values of lung compliance, and pressure losses in the trachea are clarified in table (4.3).

Table (4.3) The translational mechanical converter parameters

Parameter	Patient(1)	Patient(2)	Patient(3)
Piston area (A) m^2	0.01	0.01	0.01
Spring stiffness(k) N/m	250	300	200
Spring pre-compression(x0) M	0.0200	0.0166	0.0500
Cylinder dead volume(v0) L	0.2000	0.1660	0.5000
Sonic conductance required for pressure loss in the trachea l/s/bar	3	3	3

CHAPTER FIVE
RESULTS and DISCUSSION

5.1 The graphs of the pressure and the flow

According to table (4.2) the (PEEP) value is 5 mbar and the corresponding compliance is equal to 0.04 l/mbar, figure (5.1) shows that the minimum pressure is equal to PEEP, the breathe time is equal to 4 seconds, 2.4 seconds for expiration phase, while inspiration phase is equal to 1.2 seconds, because the I:E ratio is 1:2 , the inspiratory pause is 0.4 seconds which is equal to the remaining period of the breath cycle.

The time axis applied is equal to 50 seconds including approximately 12.5 breath cycles.

P peak is equal to 22 mbar.

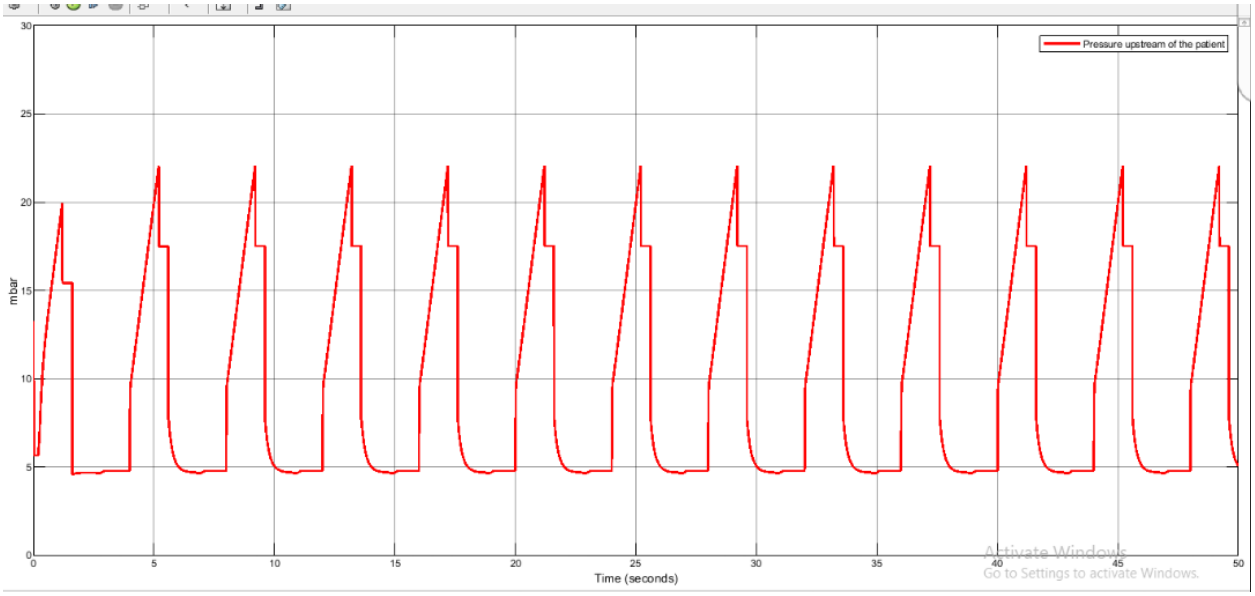

Figure (5.1) Pressure upstream patient (1).

Table (4.2) set 25 l/minute as the inspiration flow rate, and figure (5.2) shows this clearly, the inspiratory pause that equal to 0.4 seconds is also clear, in contrast to the pressure wave that always remains positive and its minimum value is equal to PEEP, the flow wave swings between positive and negative values due to inspiration and expiration phases respectively.

The maximum expiratory flow which has a negative value refers to the opposite direction of the flow is equal to -37 l/minute, it affected with the lung compliance that is for patient (1) is equal to 0.04 l/mbar, the compliance value is the lung elasticity that indicates how much the volume changes due to the change of the pressure, more lung compliance leads to more negative value of the expiratory flow required to return the lung to its original volume.

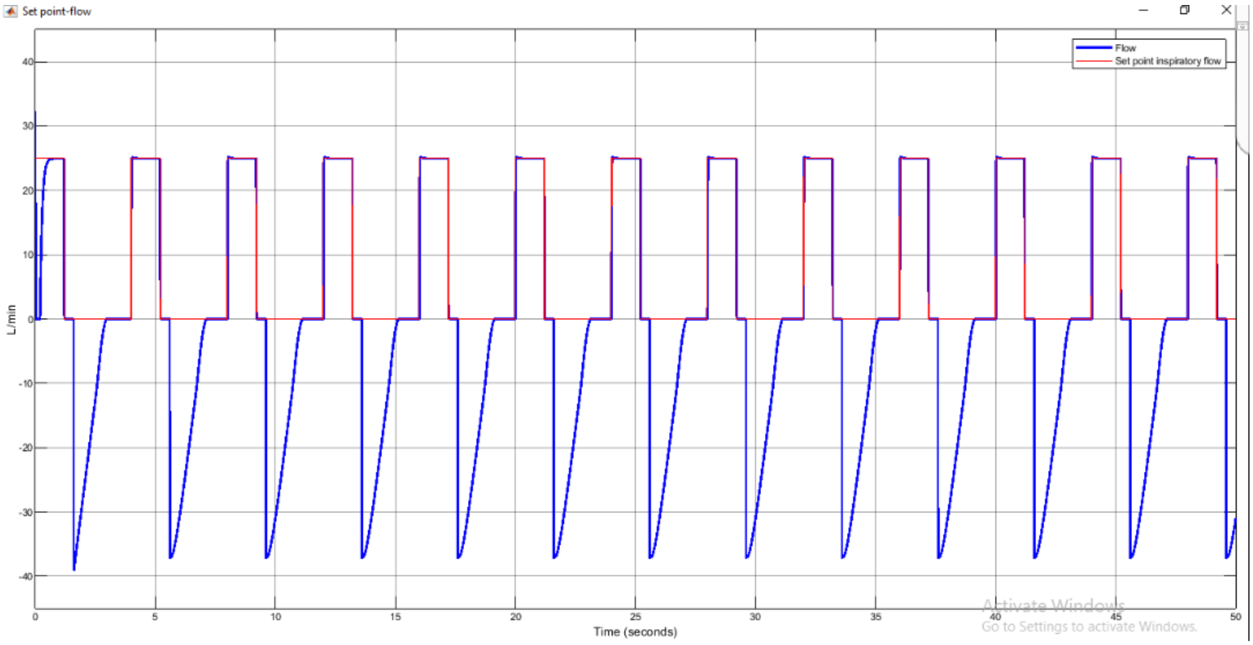

Figure (5.2) Flow rate to (>0), and from (<0) patient (1).

In contrast to patient (1) the lung compliance of patient 2 equal 0.0333 l/mbar, the P peak during inspiration phase changes to 24 mbar, this means that the less lung compliance leads to greater peak pressure, regardless of the other parameters which are equal for two patients.

This is because there is to types of pressure appears during inspiration , trans airway pressure resulted from airways friction with gas molecules of inspiratory flow PTA = RAW * inspiratory flow rate, the second type is the alveolar pressure or static pressure or plateau pressure PA = PPLATEAU = VT/C

The peak inspiratory pressure PIP = PTA + PPLATEAU, compliance is clearly reversely proportional to plateau pressure, and so to the peak inspiratory pressure [12].

Figure (5.3) shows that the compliance decreasing raises the peak inspiratory pressure as well as the plateau pressure

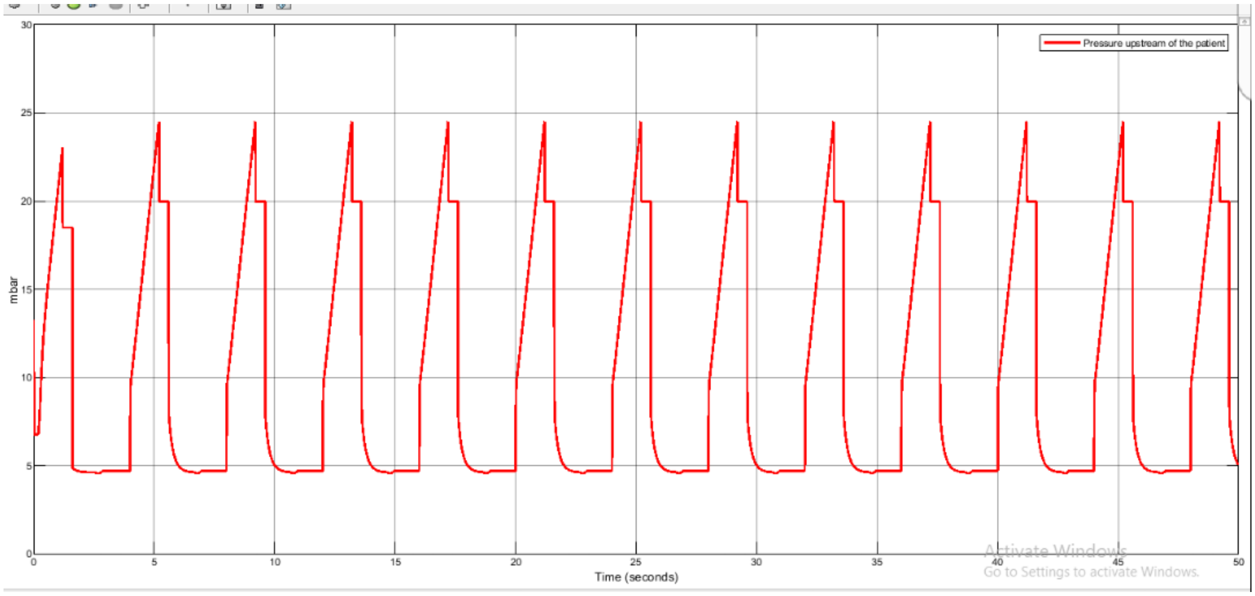

Figure (5.3) Pressure upstream patient (2).

The inspiratory flow rate of patient (2) is equal to that of patient (1) 25 l/minute, while the lesser amount of lung compliance produces higher negative value of expiratory flow rate equal -41 l/minute for patient (2) in contrast to -37 l/minute for patient (1).

Figure (5.4) shows the influence of decreasing the compliance on the expiratory flow rate.

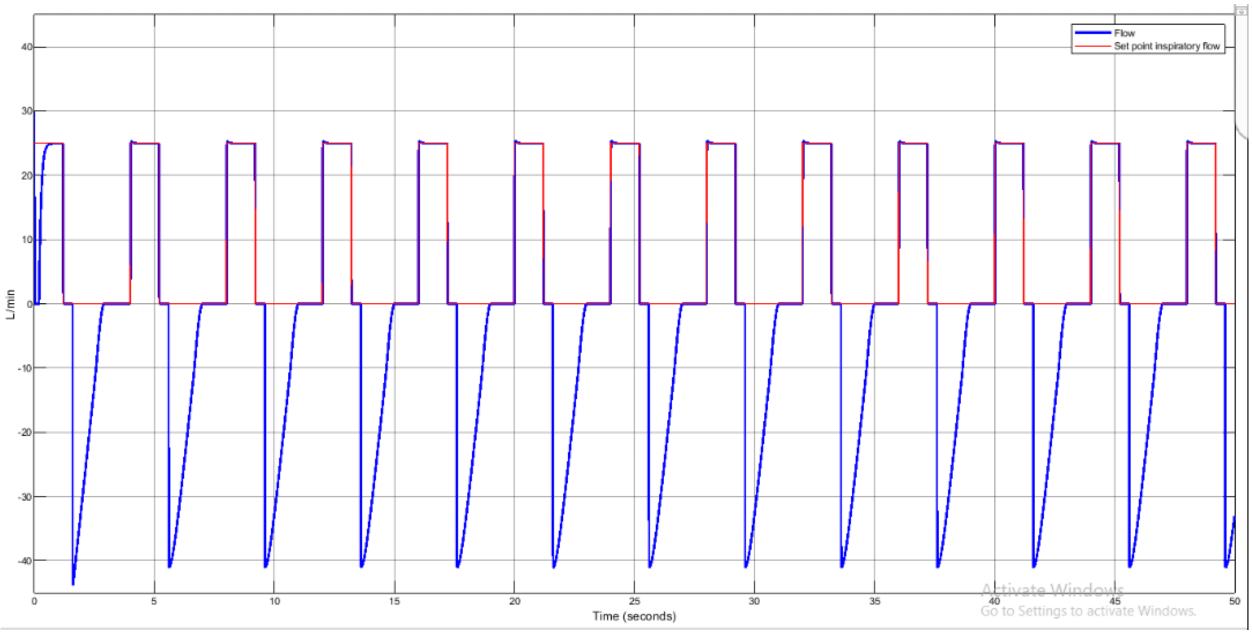

Figure (5.4) Flow rate to (>0), and from (<0) patient (2).

Patient (3) has many different parameters than those of patients (1) and (2), the whole breath period is equal to 3.2 seconds, so the simulation time of 50 seconds shows approximately 15.625 breath cycles, inspiratory time is equal to 1 second, expiratory time equal 2 seconds, inspiratory pause equal 0.2 seconds.

The PEEP value is equal 10 mbar, compliance is equal 0.05 l/mbar, the peak pressure equal 26 mbar which is the greatest value of the three patients, but this result is affected with higher PEEP value.

Figure (5.5) shows all changes.

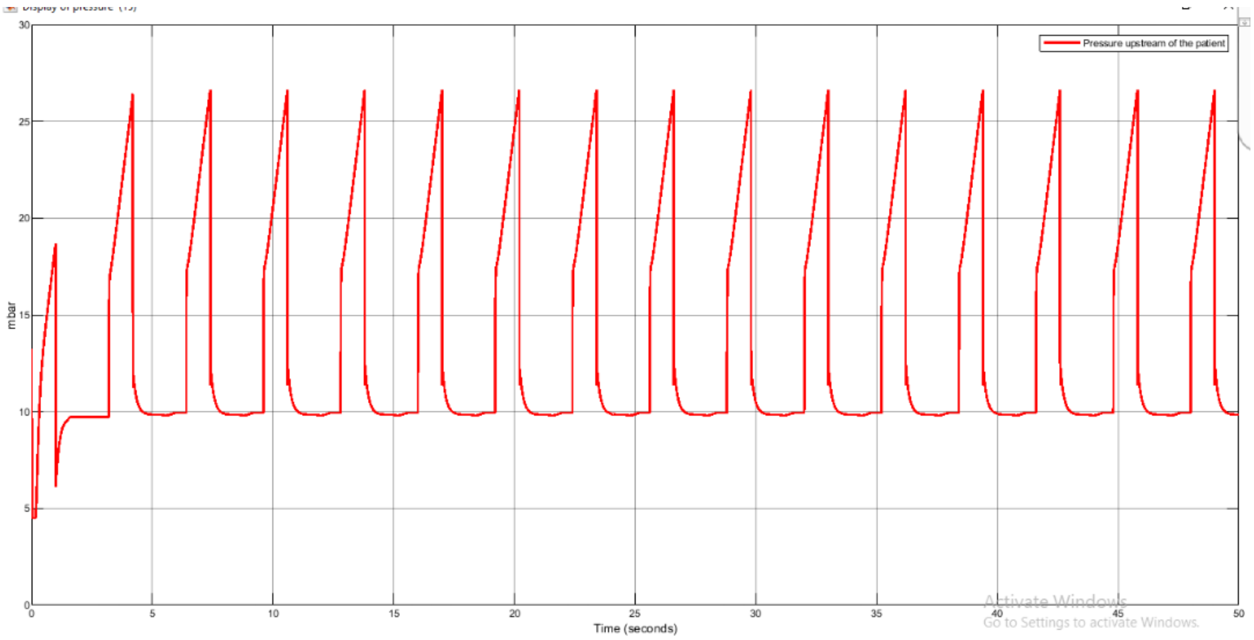

Figure (5.5) Pressure upstream patient (3).

Figure (5.6) shows the inspiratory flow rate changes to 30 l/minute, the negative value of the expiratory flow rate is equal to -33 l/minute due to high lung compliance of patient (3).

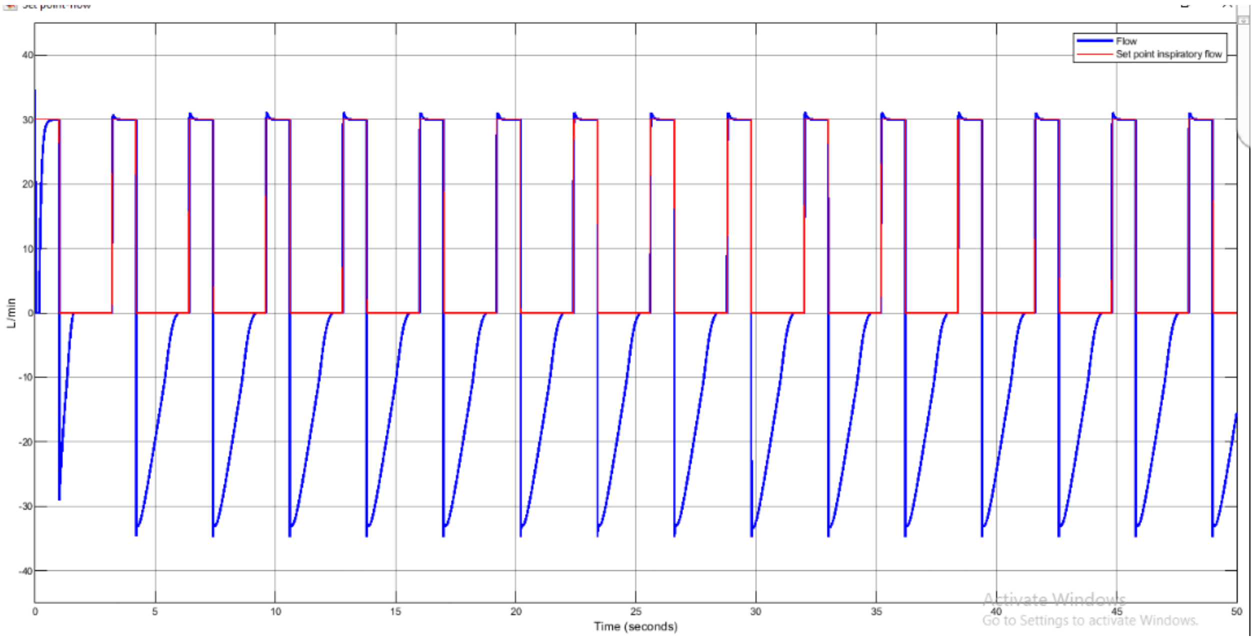

Figure (5.6) Flow rate to (>0), and from (<0) patient (3).

5.2 Ideal pressure and flow graphs versus the model graphs

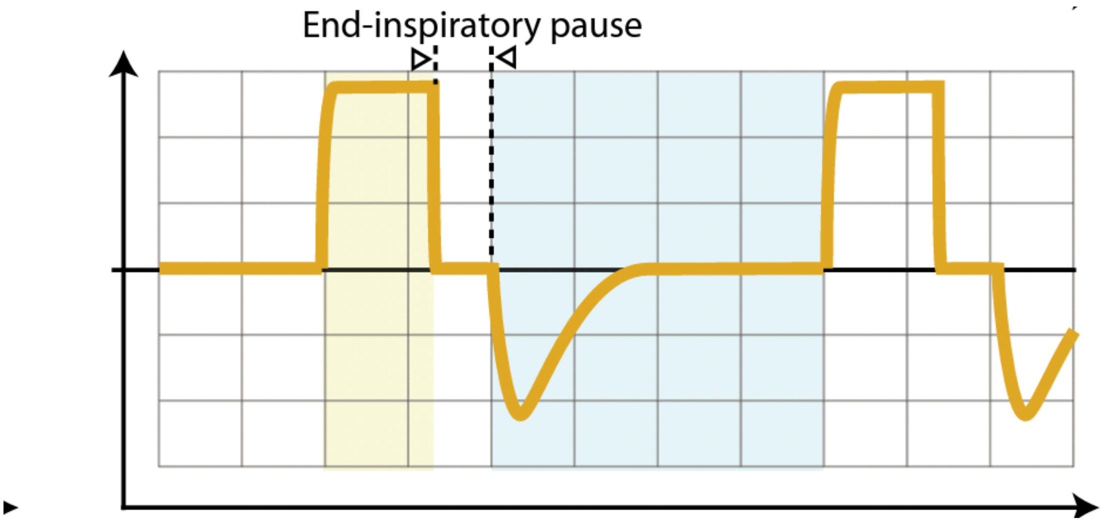

Figure (5.7) ideal flow waveform of VCV with an inspiratory pause [10].

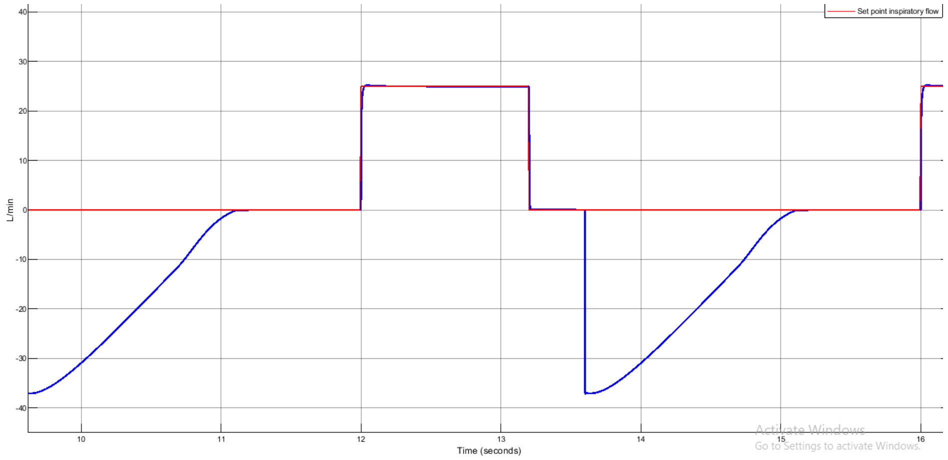

Figure (5.8) Enlarged flow rate waveform, inspired (>0) and expired (<0) by patient (1).

Both figures show the characteristics of volume controlled ventilation waveform with end inspiratory pause, the flow stopped before inspiratory time elapsed, and the exhalation valve remained closed, this helps to build up the plateau pressure within the lung, before initiating the expiratory phase by opening the exhalation valve.

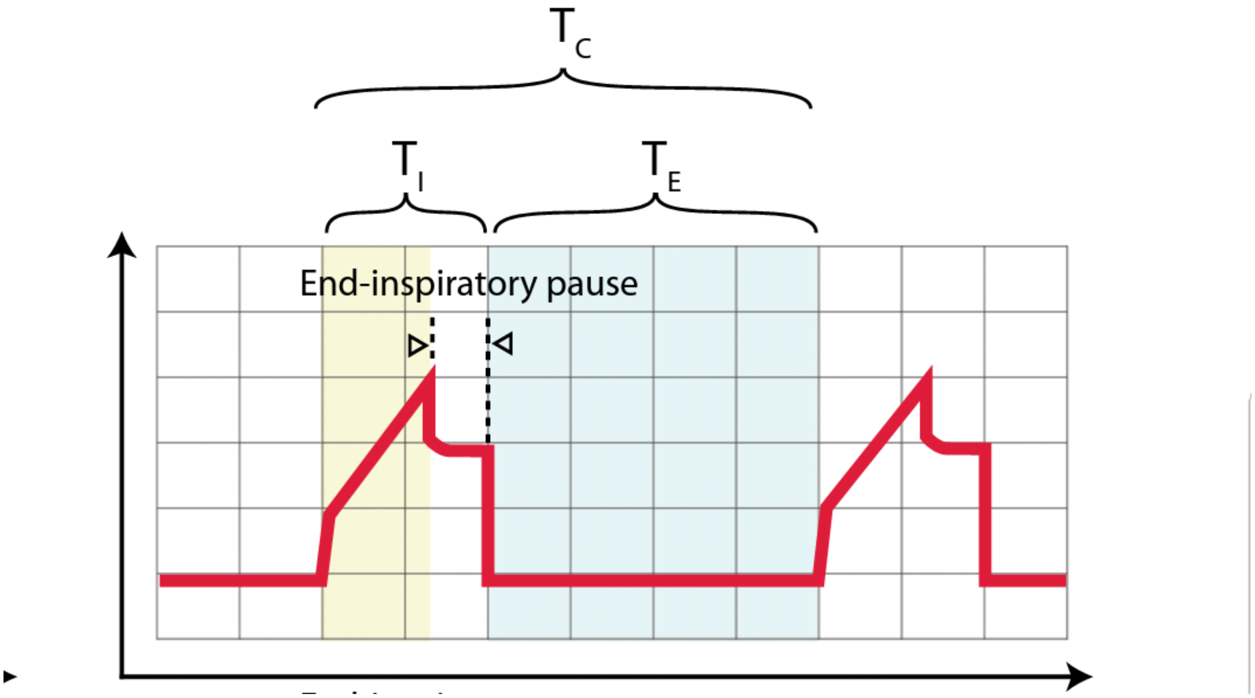

Figure (5.9) ideal pressure waveform of VCV with an inspiratory pause [10].

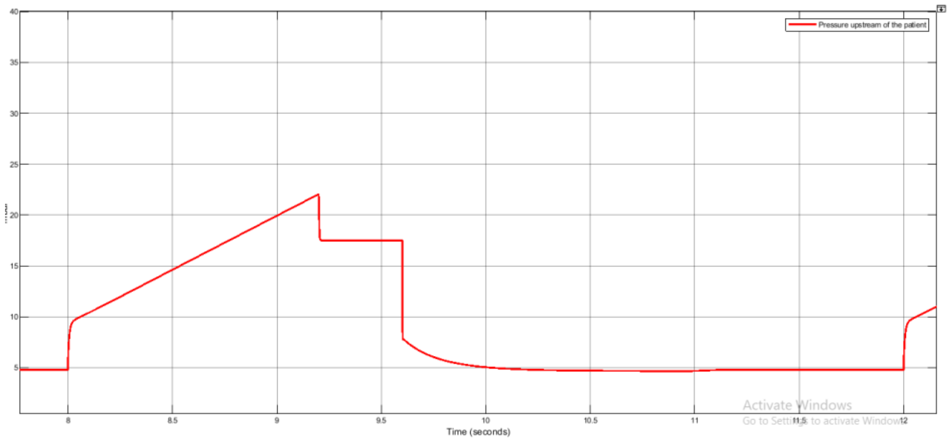

Figure (5.10) Enlarged airways pressure waveform of patient (1).

Both figures of the ideal and the model, show the breath phases clearly, and the airways pressures, the PEEP is clear, and so is the peak inspiratory pressure, the plateau pressure or static pressure is the pressure appears at the end inspiratory pause period as shown in the figures above

Figures (5.7), (5.8), and (5.9), (5.10) shows the model consistency, by comparing the results extracted from it with ideal results.

CHAPTER SIX

CONCLUSION and RECOMMENDATION

6.1 Conclusion

Covid-19 increases the demand on medical ventilators worldwide, many challenges facing manufacturing of medical ventilators such as the complexity of these devices, high cost required in order to build them, difficulty of assessing their performance because their faults could probably cause harm to the patients.

The project presents solution to overcome these challenges, it shows simulation template that simulates typical ICU ventilator connected with respiratory system model, both models allow modifications to meet engineers designing requirements, and precise prediction of multiple scenarios of ventilator/patient interaction, the model is very flexible in term of adding new components, adjusting existing, and modify patients' respiratory system condition.

Development in MATLAB/Simulink libraries in the last few years provides accurate Simulink blocks that represent each pneumatic component of mechanical ventilator, the older versions only provide electrical models in order to simulate a pneumatic system, which limits the design applicability, and reduces its worth.

Waveforms of flow rate, airways pressure were extracted and compared with ideal waveforms and the model was found very consistent.

The patients' conditions were modified and shown for three different patients and the results found were agreed with references.

The project depends on recent researches and papers have been published since covid-19 has been started, one of the most valuable papers which model relied on is (RMVS) by MHRA [6], the work introduced the minimal acceptable specification for rapidly manufactured ICU ventilators, it identified important ranges of the essential parameters that the design should stick to.

6.1 Recommendations

1. Accurate FIO2 adjustment should be performed if newer MATLAB/Simulink versions allow entering more than one gas specific constant at gas properties block.

2. Gas metering valves are simulated using variable orifice ISO 6358 blocks which constrict it is function of controlling FIO2 and should be replaced with two ways directional valves if previous problem solved.

3. The model only simulates VCV mode, further improvements on pressure PID controller could be done in order to simulate PCV mode.

4. More than three patients' examples could be considered in future works.

5. Better tuning of PID initial conditions may lead to better first pressure and flow waveforms consistency with subsequent waveforms.

6. Better consideration of airways resistance rather than only respiratory system compliance should lead to more accuracy and reliability of the model.

7- Produce a prototype design based on the Simulink model should be considered.

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