

DESIGN OF A BREATHING SIMULATOR GENERATING ADULT AND PEDIATRIC PATTERNS

by



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DESIGN OF A BREATHING SIMULATOR GENERATING ADULT AND PEDIATRIC PATTERNS

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ACADEMIC ETHICS AND INTEGRITY STATEMENT

I, Senad Tüzünoğlu, hereby certify that I am aware of the Academic Ethics and Integrity Policy issued by the Council of Higher Education (YÖK) and I fully acknowledge all the consequences due to its violation by plagiarism or any other way.

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ABSTRACT

DESIGN OF A BREATHING SIMULATOR GENERATING ADULT AND PEDIATRIC PATTERNS

In this thesis, a mechanical breathing simulator is developed, constructed, tested and calibrated for the experimental use of medical devices such as nasal drug products, nebulizers and inhalers. The aim of the simulator is to protect users from inhaling hazardous materials, and also performance of the simulator is not affected by the users' breathing conditions. In order to increase reliability, the simulator has different flow pattern capabilities to match different devices. The design of the simulator uses a mechanical air piston, which is air thigh, controlled by a program for creating different types of volume-flow diagrams in order to be applicable for different breath patterns. Volume control, sine flow and sine volume breath patterns are programmed and the user can choose any of them with the desired volume for each. These flow patterns can provide relative comparison of individual respirators by measuring the performance under the same breathing conditions, which gives better results for repeatability. The calibration and testing of the simulator has completed by connecting to a flow measuring device in lab. The tests are done to measure the volume error between input volumes set by user and output volumes provided by the simulator. Also respiratory rates, inhalation time, exhalation time and inhalation to exhalation ratios are measured. Test results showed that the simulator for volume; gives minimum 0,04 % error and maximum 3,52% error respectively, also for the respiratory rate minimum 0,67 % error and maximum 5,44% error was calculated . Also a test was completed according to EN 13544 to measure aerosol output of Omron A3 nebulizer. Aerosol output of nebulizer was measured as 0,25 ml. The study showed that, the simulator can be used for testing nebulizers, CPAP devices and also inhalers and nasal drug products.

Keywords: Breath, Simulator, Volume, Flow, Breath Pattern, Nebulizer, CPAP.

ÖZET

YETİŞKİN VE ÇOCUK SOLUNUM MODELLEYEN SOLUNUM SİMÜLATÖR TASARIMI

Bu tezde, mekanik olarak yapay solunum simülatörü tasarlanmış, üretilmiş ve solunan ilaçların, nebulizatör ve inhaler testi için kalibre edilmiştir. Bu sayede test aşamasında kullanıcılar zararlı olabilecek kimyasalların solunumu önlenmiştir. Ayrıca kullanıcıların farklı solunumlarından kaynaklanabilecek ölçüm değerleri de önlenmiş olacaktır. Simülatörün güvenirliği ve uygulanabilirliğini artırmak amacıyla farklı solunum parametre ve programlamaları da eklenmiştir. Simülatörün başlıca farkı tasarımdadır. Elektronik devre ve yazılımla kontrol edilen step motor yardımıyla lineer hareket eden hava piston elde edilmiştir. Bu hava pistonuyla, değişik hava üfleme kapasiteleri olma amacıyla farklı varyasyonlar tasarlanmıştır; bunlar da; hacim kontrollü, sinüs akış ve sinüs hacimli solunum türleridir. Cihaz belli sayıda döngüyü tamamlayıp ölçüm için beklemeye geçmektedir. Simülatörün kalibrasyonu tamamlanmış ve bu da biyomedikal laboratuvarındaki akış kontrol cihazıyla test edilmiştir. Simülatör, laboratuvar ortamında testlere tabi tutulmuştur. Öncelikli testler cihaza, giriş yapılan hacim ile cihazın verdiği hacimlerin karşılaştırılması olmuştur. Bu ölçümler Fluke VT mobile test ile yapılmıştır. Ayrıca akış grafikleri de karşılaştırılmıştır. Giriş yapılan hacim ile çıkışı olan hacim arasında en az %0,2 hata tespit edilmiş, en fazla da %5,7 hata tespit edilmiştir. Ayrıca simülatör ile Omron A3 nebulizatör EN 13544 Annex CC2'ye göre test edilmiş ve 0,25 ml aerosol çıktıları ölçülmüştür. Bu değer Omron A3 kullanım kılavuzundaki 0,5 aerosol çıktısında daha düşük ölçülmüştür. Tezin sonucu olarak simülatör EN 13544'deki tüm testleri yapabilecek kapasitededir.

Anahtar Sözcükler: Solunum, Simülatör, Hacim, Akış, Cihaz Modları, Nebulizatör, CPAP.

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LIST OF SYMBOLS

e_{BPM}	Breath per Minute Error
e_v	Volume Error
V_{max}	Maximum Volume-Air Chamber Capacity



LIST OF ABBREVIATIONS

Ast P	Assist Pressure
Baro P	Barometric Pressure
BF	Base Flow
BPM	Breath Per Minute
COMP	Compliance
CPAP	Continuous Positive Airway Pressure
ERV	Expiratory Reserve Volume
FRC	Functional Residual Capacity
IC	Inspiratory Capacity
IE	Inspiratory Time to Expiratory Time Ratio
IPP	Inspiratory Pause Pressure
IRV	Inspiratory Reserve Volume
LCD	Liquid Crystal Display
LPM	Liter Per Minute
MAP	Mean Airway Pressure
Min P	Minimum Airway Pressure
MV	Minute Volume
O2	Oxygen Percent
PEEP	Positive-End Expiratory Pressure
PEF	Peak Expiratory Flow
PIF	Peak Inspiratory Flow
PIP	Peak Inspiratory Pressure
RR	Respiratory Rate
RV	Residual Volume
Te	Expiratory Time
Ti	Inspiratory Time
TLC	Total Lung Capacity
TV	Tidal Volume

VC

Vital capacity



1. INTRODUCTION

1.1 Human Breathing

In human breathing, inhaling occurs as a result of expanding of the chest cavity by contracting the intercostal muscles and diaphragm. The diaphragm moves downwards and flattens and the intercostal muscles move the rib cage upwards and out. The increase in size causes to decrease in the internal air pressure and as a result air from the outside rushes into the lungs and equalize the pressures [1].

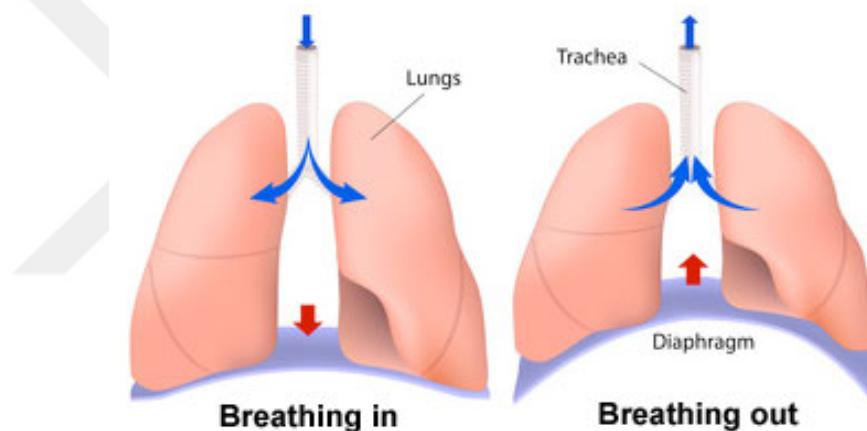


Figure 1.1 Diaphragm movements for breathing in and out [1].

The exhale occurs when the intercostal muscles and diaphragm relax and return to their resting positions. The volume of the thoracic cavity reduces, thereby the pressure increases and the air is pushed out of the lungs.

The respiratory center controls the breathing rate at which we inhale and exhale. When inspiratory nerves increase firing, inspiration occurs and when the impulses stop exhalation occurs.

Our lungs have a protection system from excess inspiration due to stretch and the protection receptors within the bronchi and bronchioles send impulses to the Medulla Oblongata when stimulated.

Chemoreceptors controls the breathing rate within the main arteries and monitors the

levels of Oxygen and Carbon Dioxide within the blood. When oxygen saturation decreases, ventilation accelerates the volume of Oxygen inspired.

When Carbon Dioxide level increases, carbonic acid is released into the blood, as a result Hydrogen ions (H^+) forms. An increased level of H^+ in the blood increases ventilation rates. This also happens when lactic acid is released into the blood after high-intensity exercise.

Respiration is controlled by the autonomic nervous system, which consists of two branches, the sympathetic nervous system and the parasympathetic nervous system [2].

At rest, we inhale approximately 500 ml of air per breath and 15 breaths per minute. The tidal volume is volume of air we breathe in or out per breath, the minute ventilation is volume of air we breathe in or out per minute.

The minute ventilation is calculated as; tidal volume \times respiratory rate = (7.5 l/min). Normal TV is 500 ml, normal RR is 15 breaths per minute, inspiration takes 1-1.5 seconds, normal exhalation takes 1-1.5 seconds and followed by a pause for 1-2 seconds [3].

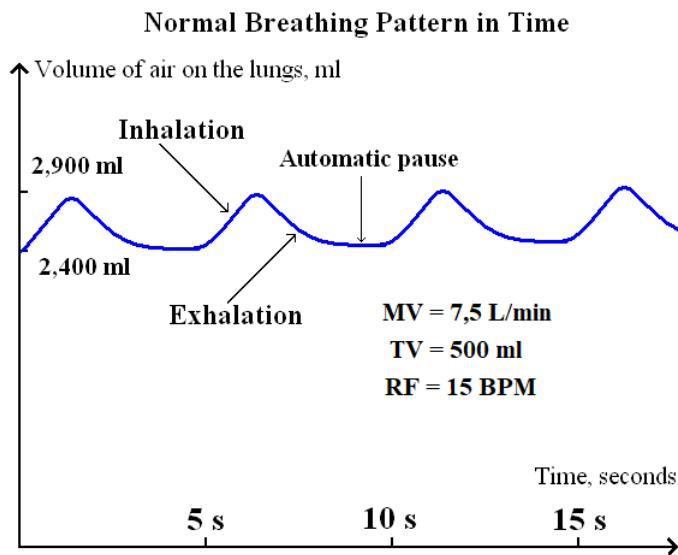


Figure 1.2 Time course of a Normal breathing pattern [3].

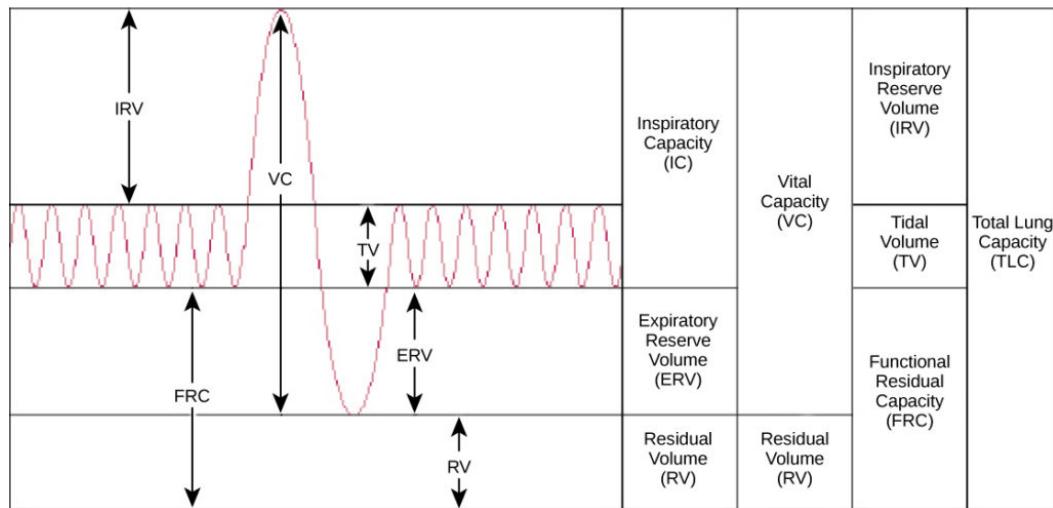


Figure 1.3 Human lung volumes and capacities [3].

- Tidal volume (TV) is the amount of air inhaled during a normal breath
- Expiratory reserve volume (ERV) is the amount of air that can be exhaled after a normal exhalation
- Inspiratory reserve volume (IRV) is the amount of air that can be further inhaled after a normal inhalation
- Residual volume (RV) is the air left in the lungs after a forced exhalation
- Vital capacity (VC) is the maximum amount of air can be moved in or out of the lungs in a single respiratory
- Inspiratory capacity (IC) is the volume of air that can be inhaled in addition to a normal exhalation
- Functional residual capacity (FRC) is the volume of air remaining after a normal exhalation
- Total lung capacity (TLC) is the total volume of air in the lungs after a maximal inspiration

Table 1.1
Human Lung Volumes and Capacities [3].

Volume/Capacity	Volume (liters)	Equations
Tidal volume (TV)	0.5	—
Expiratory reserve volume (ERV)	1.2	—
Inspiratory reserve volume (IRV)	3.1	—
Residual volume (RV)	1.2	—
Vital capacity (VC)	4.8	ERV+TV+IRV
Inspiratory capacity (IC)	3.6	TV+IRV
Functional residual capacity (FRC)	2.4	ERV+RV
Total lung capacity (TLC)	6.0	RV+ERV+TV+IRV

1.2 Breathing Simulation

Breathing Simulators are instruments that generate an inhalation and/or exhalation profile that mimics that of a human subject, have become a routine feature of orally inhaled product testing to replace existing constant flow conditions with breathing profiles more representative of conditions *in vivo*.

Table 1.2
Breathing Simulators Comparison Data.

	Si-Plan 625 [4]	Ingmar Medical ASL 5000 [5]	Copley BRS3000 [6]	Michigan BSM [7]	The Breath Simulator (Thesis)
Maximum TV	6250 ml	60000 ml	5000 ml	2000 ml	5000 ml
Minimum TV	100 ml	2 ml	500 ml	50 ml	50 ml
Minimum BPM	5	3	0	1	1
Maximum BPM	60	150	Defined by acceleration limit	60	60
Maximum MV	375 LPM	280 LPM		120 LPM	250 LPM
Minimum MV	0.5 LPM	0.5 LPM	0.5 LPM	0.05 LPM	0.5 LPM
Height	585 mm	425 mm	850 mm	622 mm	450 mm
Width	370 mm	315 mm	800 mm	483 mm	220 mm
Depth	370 mm	219 mm	400 mm	350 mm	220 mm
Weight	55 kg	10 Kg		15 kg	19 kg

Si-Plan 625 is driven by a servo-pneumatic actuator. Ingmar Medical ASL 5000 and Copley BRS3000 uses a servo motor similar to our design to generate the air flow. Michigan Instruments Breathing Simulator is a separate module that is attached to a test lung.

The advantage of the breath simulator is the low cost and its simplicity in the design when compared with Ingmar and Copley.

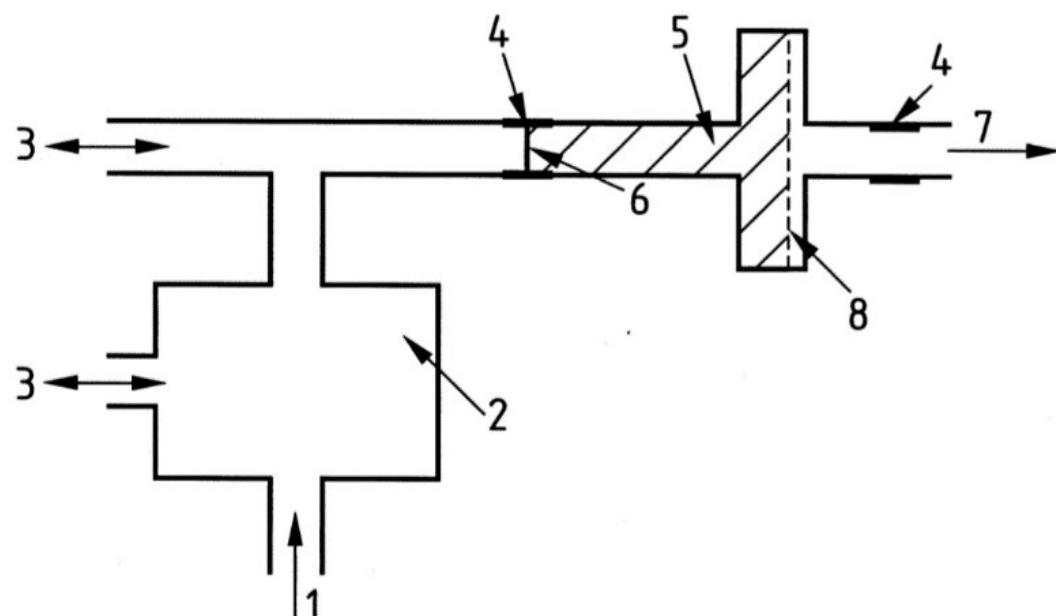
1.3 Applications of Breathing Simulator

1.3.1 Typical Uses

Breath Simulators are used in testing orally inhaled and nasal drug products, nebulizers, dry powder inhalers and CPAP machines, to generate in vivo flow patterns

and breathing conditions for infant, child and adult.

The European standard EN 13544-1:2007 Respiratory therapy equipment - Part 1: Nebulizing systems and their components is concerned with testing of the nebulizer system by measuring the aerosol output rate, the aerosol output and particle sizing, by connecting it to a sine pump which simulates the respiratory flow. The test equipment shown in the Figure 1.4.



Key

- | | |
|--|---------------------------------|
| 1 Recommended driving gas flows | 5 Dead Space |
| 2 Nebulizer Filled with 1 % sodium flouride soluiton | 6 Patient interface |
| 3 Entrained air | 7 Sine pump |
| 4 Dismountable connectors | 8 Collection filter for aerosol |

Figure 1.4 Human lung volumes and capacities [8].

With dry powder inhalers the measurement set up will be as shown in Figure 1.5.

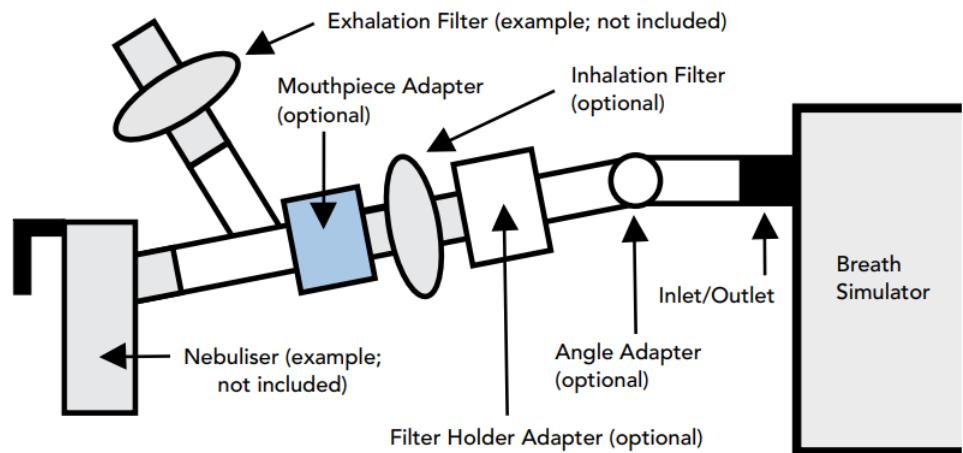


Figure 1.5 Dry Powder Application [8].

The sine pump mimics a respiratory cycle with a frequency of 15 BPM; I/E = 1/1 and TV of 500 ml measured at the output of the filter; Test methods for the aerosol output rate, the aerosol output and for particle sizing [9].

Similarly, EN 80601 standard describes the test method for Stability of dynamic airway pressure accuracy (short-term accuracy) of CPAP machine.

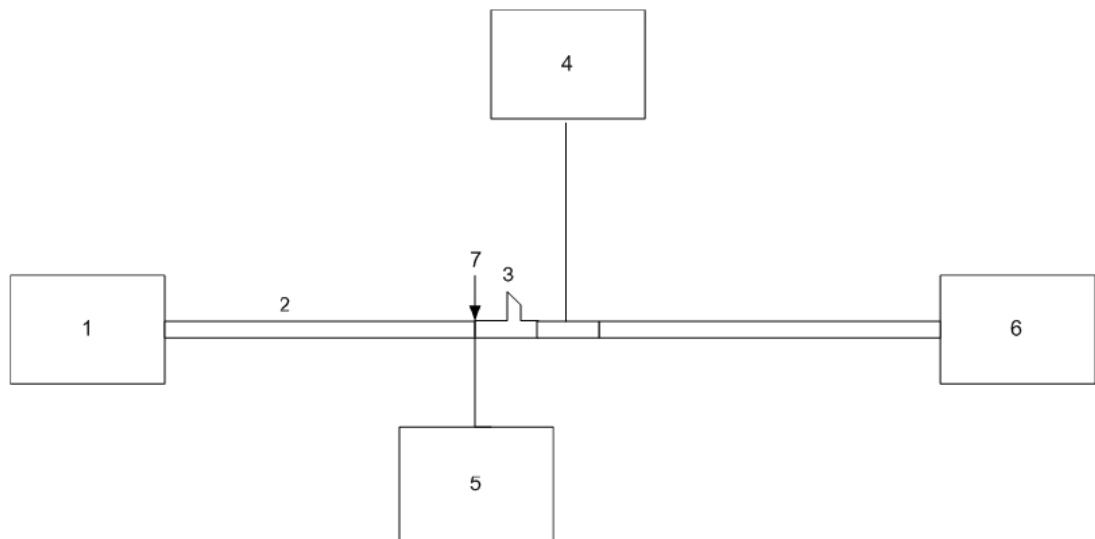


Figure 1.6 Test set-up for dynamic airway pressure accuracy in normal use [9].

Key

- 1 – Sleep apnoea breathing therapy equipment
- 2 – Breathing gas pathway
- 3 – Standard resistance
- 4 – Flow meter
- 5 – Pressure-measuring device
- 6 – Pump that produces a sinusoidal cycle
- 7 – Patient-connection port

2. DESIGN OF THE SIMULATOR

During inhalation and exhalation phases of breathing positive and negative pressures are created in the lungs, the pressure changes are the most critical parameters in the design of the breathing simulator. Similarly; intensive care unit ventilators, they create positive air pressure in the device so the air can leave but they cannot create negative pressure, so the main difference between the ventilator and breath simulator is the negative pressure phase.

The design of the simulator is based on the working principle of the pneumatic air cylinders. The pneumatic cylinder guides a piston in a cylindrical metal piece that moves inside along a straight line. The air is converted into mechanical energy in the cylinder by expansion. The gas is compressed in the cylinder of the compressor to increase the pressure. The pneumatic cylinder is composed of a cylinder, an end cover, a piston, a piston rod and a seal. The piston is lubricated by the oil mist in the compressed air when the cylinder operates [10].

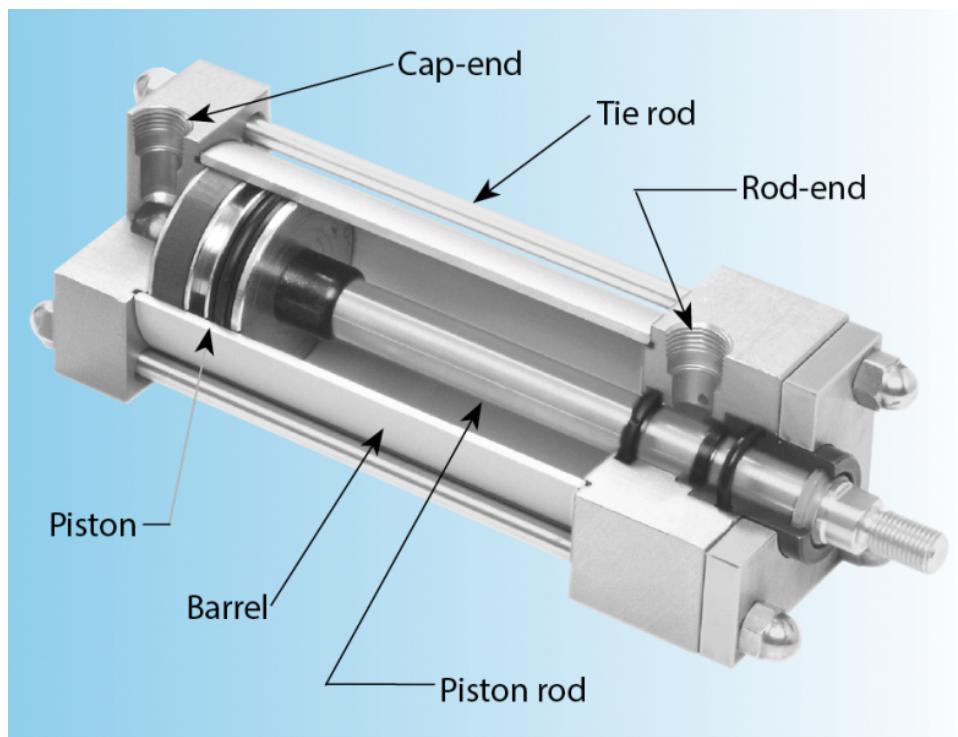


Figure 2.1 The Pneumatic Cylinder [10].

The piston rod, moves forward when the compressed air enters from the cap end and the rod moves backward when the compressed air enters from the rod end. By using this movement principle instead of compressed air When a negative pressure is created in the cap the piston rod moves backward. But in actual mechanical design, the piston is activated with a step motor and linear ball bearing system in order to create negative and positive pressures.

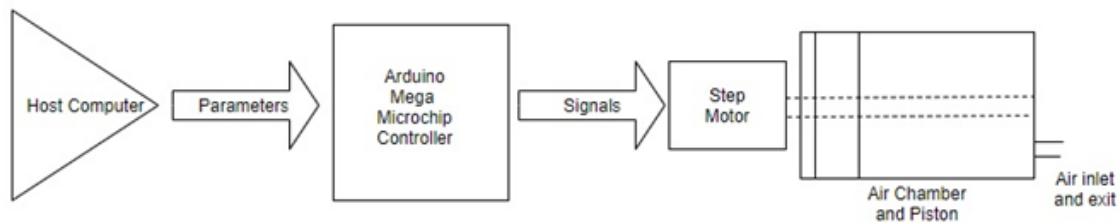


Figure 2.2 The Breathing Simulator Diagram.

The device consists of the following components;

- (i) Air piston with a diameter of 160 mm
- (ii) Ball screw bearing with a lead of 5 mm
- (iii) Tube-Air chamber with a volume of 5 liters
- (iv)] Air exit with diameter of 22 mm
- (v) Connecting rods
- (vi) Sliding rods
- (vii) Air thigh seals
- (viii) Step motor 5,2 Nm Torque
- (ix) Arduino Mega Micro controller
- (x) Keypad
- (xi) Step Motor Driver
- (xii) Power Supply

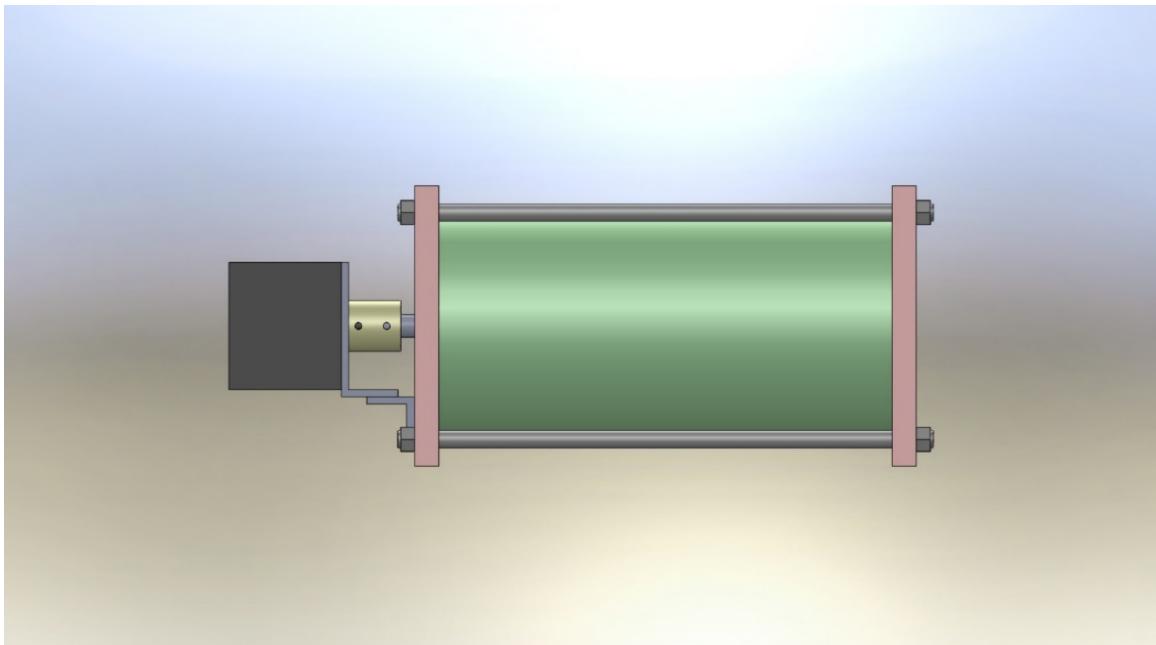


Figure 2.3 Breath Simulator Design.

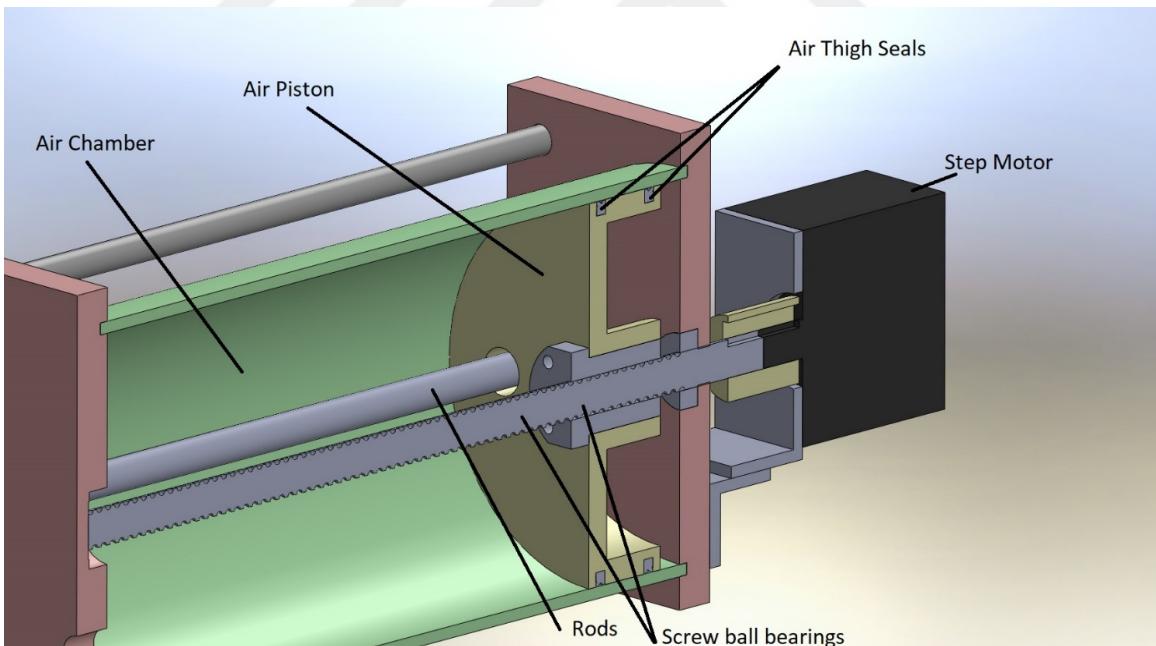


Figure 2.4 Inside The Chamber.

The largest possible vital capacity of 4.8 liters in adults is subject to considerable variation between individuals. However, this does not necessarily reflect the typical volume inhaled during with a pulmonary drug delivery device [11].

For cigarette testing, the International Standards Organization define a single puff volume of 35mL and experimental data have shown that cigarette smokers can typically inhale between 40 and 90ml [11],[12].

For devices such as passive dry powder inhalers, the United States Pharmacopeia guidelines for measuring emitted dosage define an inhaled volume as 4 liters. To accommodate this wide variation and to provide some margin of flexibility, a maximum volume for inhalation of 5 liters for the test rig has been chosen [12]. The piston diameter is 160 mm and the stroke of the piston is 250 mm. Maximum air that can be inhaled or exhaled can be calculated from;

$$V_{max} = \pi r^2 l \quad (2.1)$$

giving $V_{max} = 5,024$ liters.



Figure 2.5 Ball screw bearing system [12].

The piston is motioned by a ball screw bearing system. The lead for the screw is 5mm. There are two rods to control the piston in linear angle. The volume change for one full revolution of the motor is calculated from;

$$\Delta_v = Lead \cdot A \quad (2.2)$$

Therefore, for one revolution of the motor a volume change of 0,1 ℓ is obtained. For the system to be air tight, two seals are placed on the piston. The flow rate of the system is calculated from;

$$Q = A \cdot V \quad (2.3)$$

Where; Q is flow rate (ℓ/s), A is the internal area of the pipe or channel (m^2), V is velocity of the liquid (m/s) The step motor has a maximum rotational capacity of 1200 rpm. Since the lead for screw is 5mm, the maximum linear velocity is 100 mm/s. From Eq. 2.3, Qmax is 120,6 LPM.

Normal breathing flow rate is 18 LPM, and for testing pharmaceutical devices flow rate is 60 LPM. The Qmax 120,6 LPM therefore meets the requirements.

Arduino Mega controls the whole system. A software is written for the simulator.

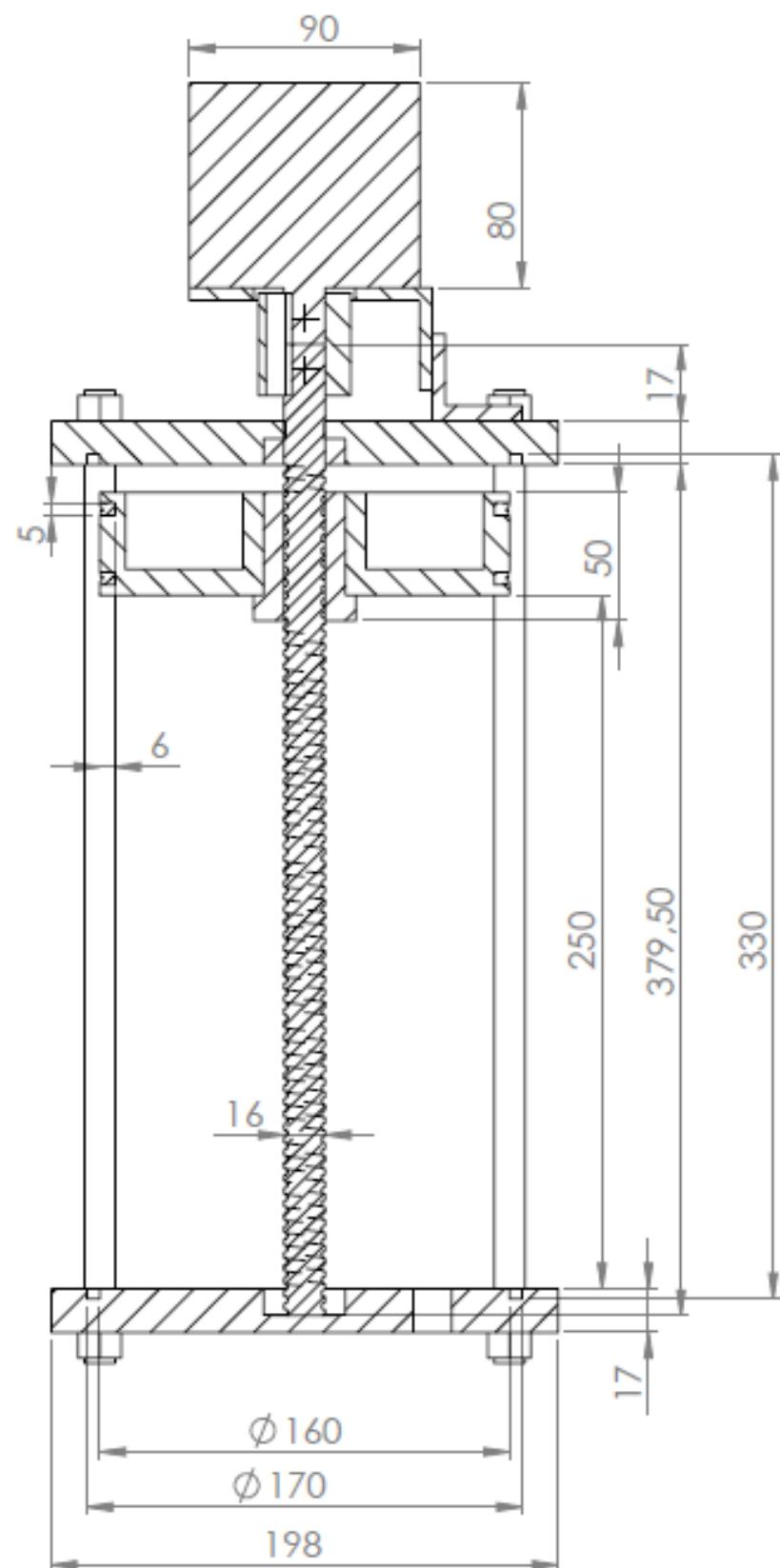


Figure 2.6 The Technical Drawing of The Breathing Simulator.



Figure 2.7 The Breathing Simulator.

A keypad and a LCD screen provides the user interface to control the air pattern and the volume input.



Figure 2.8 The Control Panel.

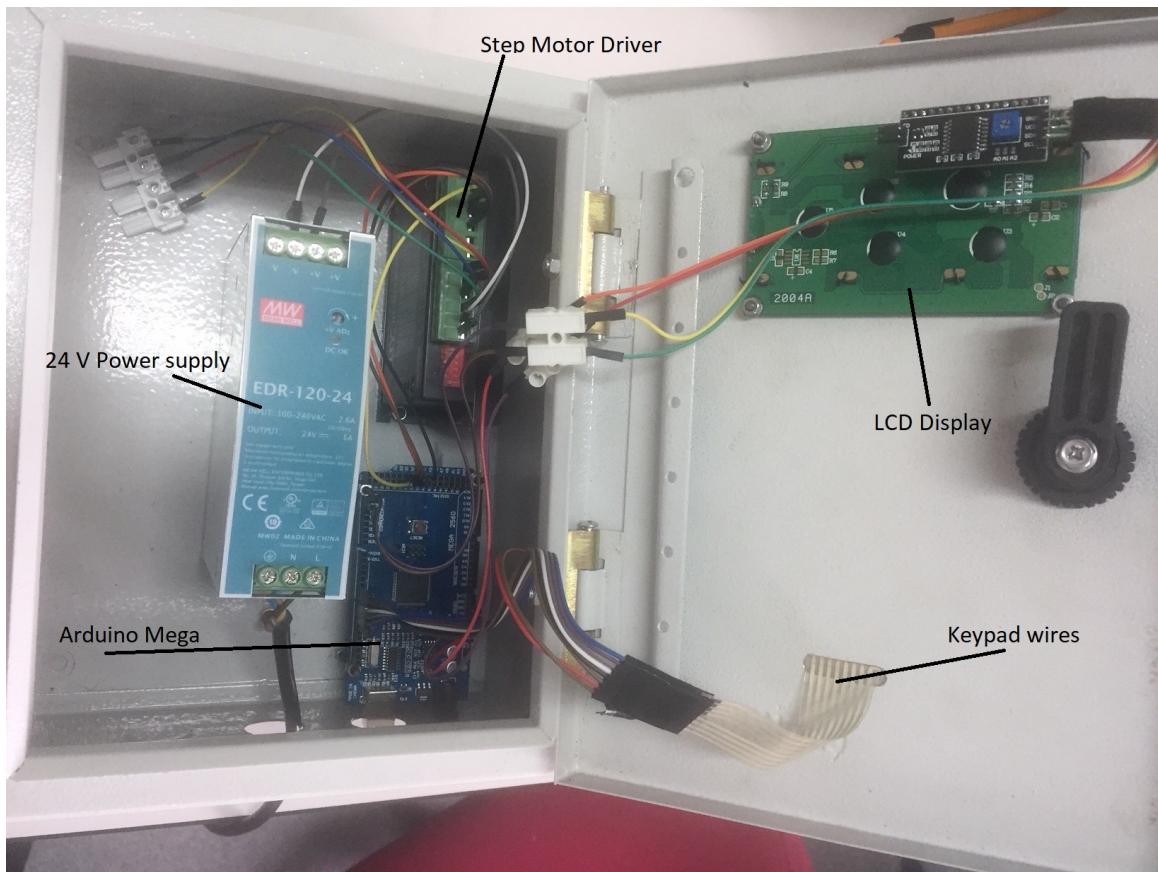


Figure 2.9 The Inside View of the Control Panel.

2.1 User Interface

The device is simple and easy to use with three different air flow modes, namely The Volume control Breathing mode, the sine volume mode and the sine flow mode. The user chooses the mode by pressing A, B or C on the keypad and then the simulator asks for the volume to be entered from 50 ml to 1000 ml. For each mode of operation the simulator completes 5 full cycles for the given volume and then stops with two options, the first option is to repeat for another 5 cycles under the same conditions, or to go back and reset the conditions and make a new choice for the mode. The simulator is set for respiratory rates according to EN standard 80601;

Table 2.1
Respiratory Rate Values for Volumes.

Volumes	Setted Respiratory Rate
50 ml	50 BPM
500 ml	15 BPM
1000 ml	10 BPM

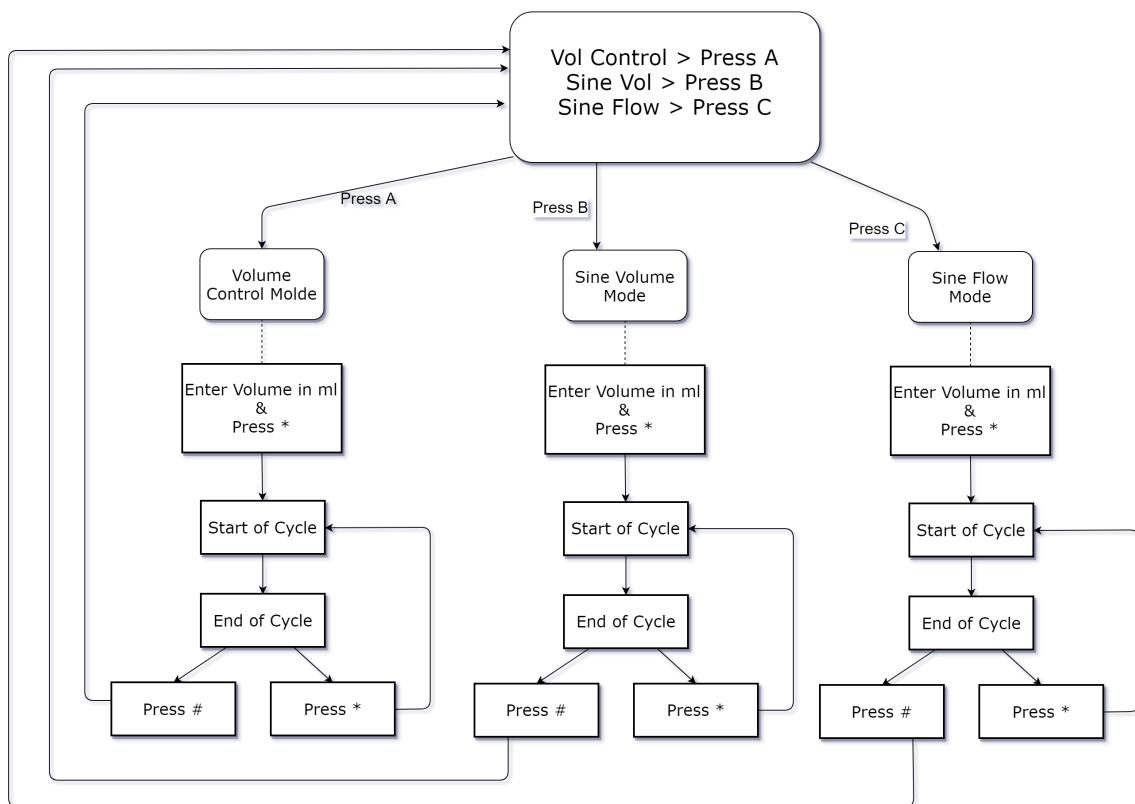


Figure 2.10 User Interface.

2.1.1 Volume Control Breathing Mode

The breathing simulator has three different modes and the volume control mode is the first one of them. The volume control mode, when triggered it gives a linear volume increase for inhalation and exponential volume decrease for exhalation. To achieve a linear volume change, constant flow during inhalation is applied and to achieve exponential volume change for the exhalation, the flow decays exponentially.

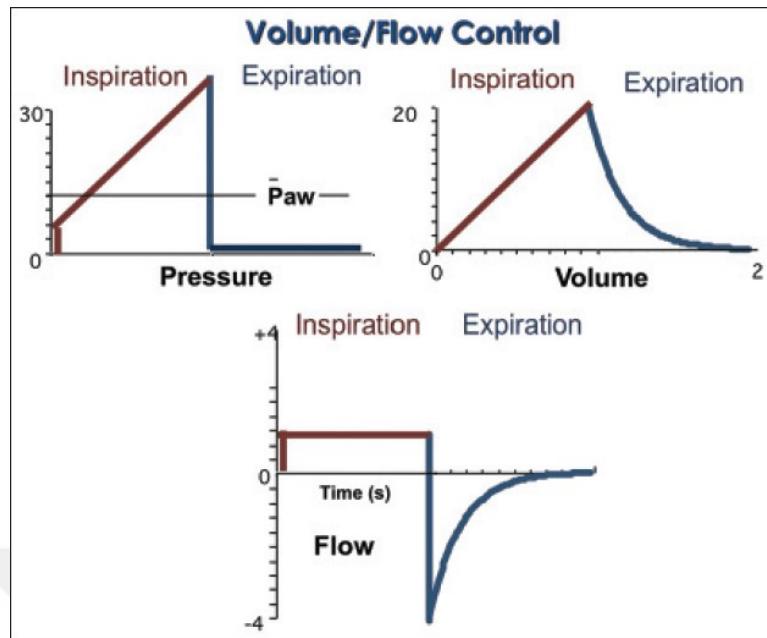


Figure 2.11 Volume control mode graphs [13].

2.1.2 Sine Volume Mode

The second mode of the simulator is the sine volume mode. The simulator gives sine volume profile for both inhalation and exhalation. Flow linearly increases until the required volume reaches and then linearly falls down to zero. For exhalation, the flow again linearly increases in the opposite direction for suction until it reaches the required volume and then linearly drops to zero.

2.1.3 Sine Flow Mode

The third mode of the simulator is the sine flow mode. The simulator gives the sine flow for inhalation and exhalation.

3. PERFORMANCE MEASUREMENTS



Figure 3.1 Instrumentation for Testing the Breathing Patterns.

To measure the performance of the simulator, a test lung is connected to air exit of the simulator. Three different volumes were chosen for each mode of operation of the simulator, namely 50 ml, 500 ml and 1000 ml. For each mode and each volume, 5 cycles we completed to calculate mean of the volumes, respiratory rates and their standard deviations. There datas are shown on Table 3.2.

Table 3.1
Lists of Tests Completed.

	Mode of the Simulator	Input Volume
1	Volume control Mode	50 ml
2	Volume control Mode	500 ml
3	Volume control Mode	1000 ml
4	Sine Volume Mode	50 ml
5	Sine Volume Mode	500 ml
6	Sine Volume Mode	1000 ml
7	Sine Flow Mode	50 ml
8	Sine Flow Mode	500 ml
9	Sine Flow Mode	1000 ml

Also according to the European standard EN 13544-1:2007 Respiratory therapy equipment, aerosol output of the nebulizer (Omron A3) was measured .

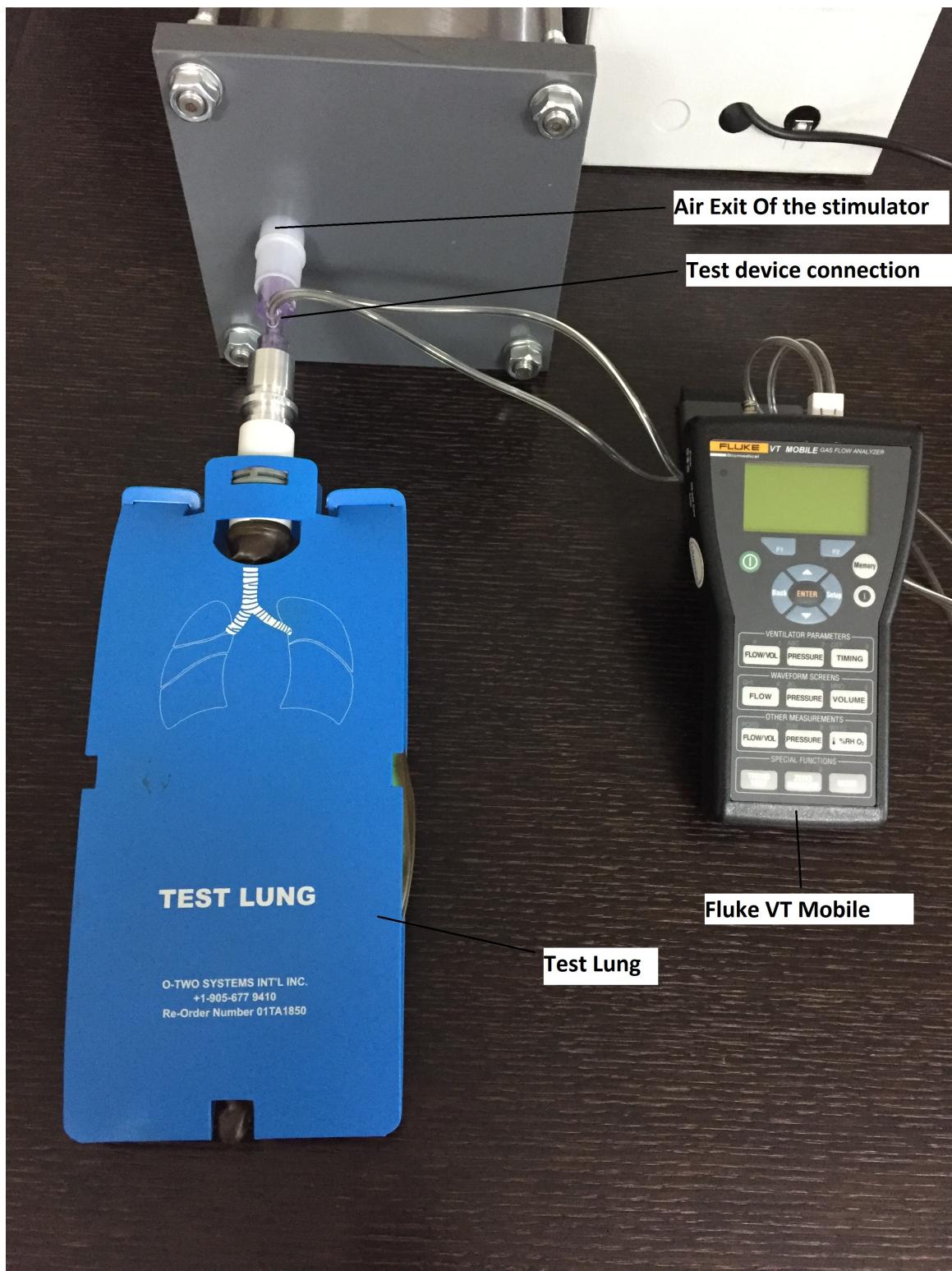


Figure 3.2 Test Set-up for Performance Measurements.

3.1 Volume Control Breathing Mode Test Results

3.1.1 Volume Control Breathing Mode With 50 ml Volume

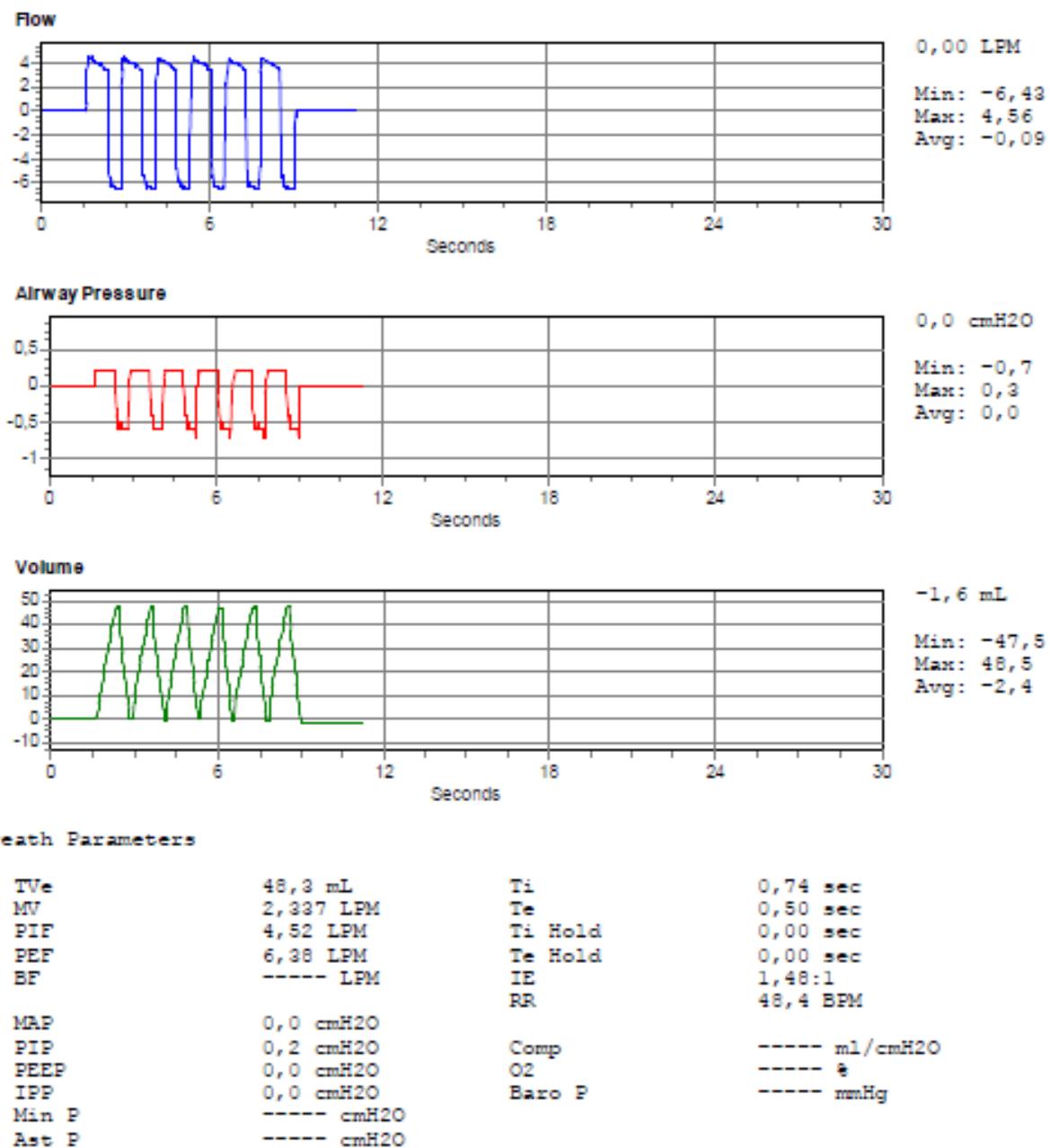


Figure 3.3 Output Wave forms for the Volume Control Breathing Mode for an Input Volume of 50 ml.

3.1.2 Volume Control Breathing Mode With 500 ml Volume

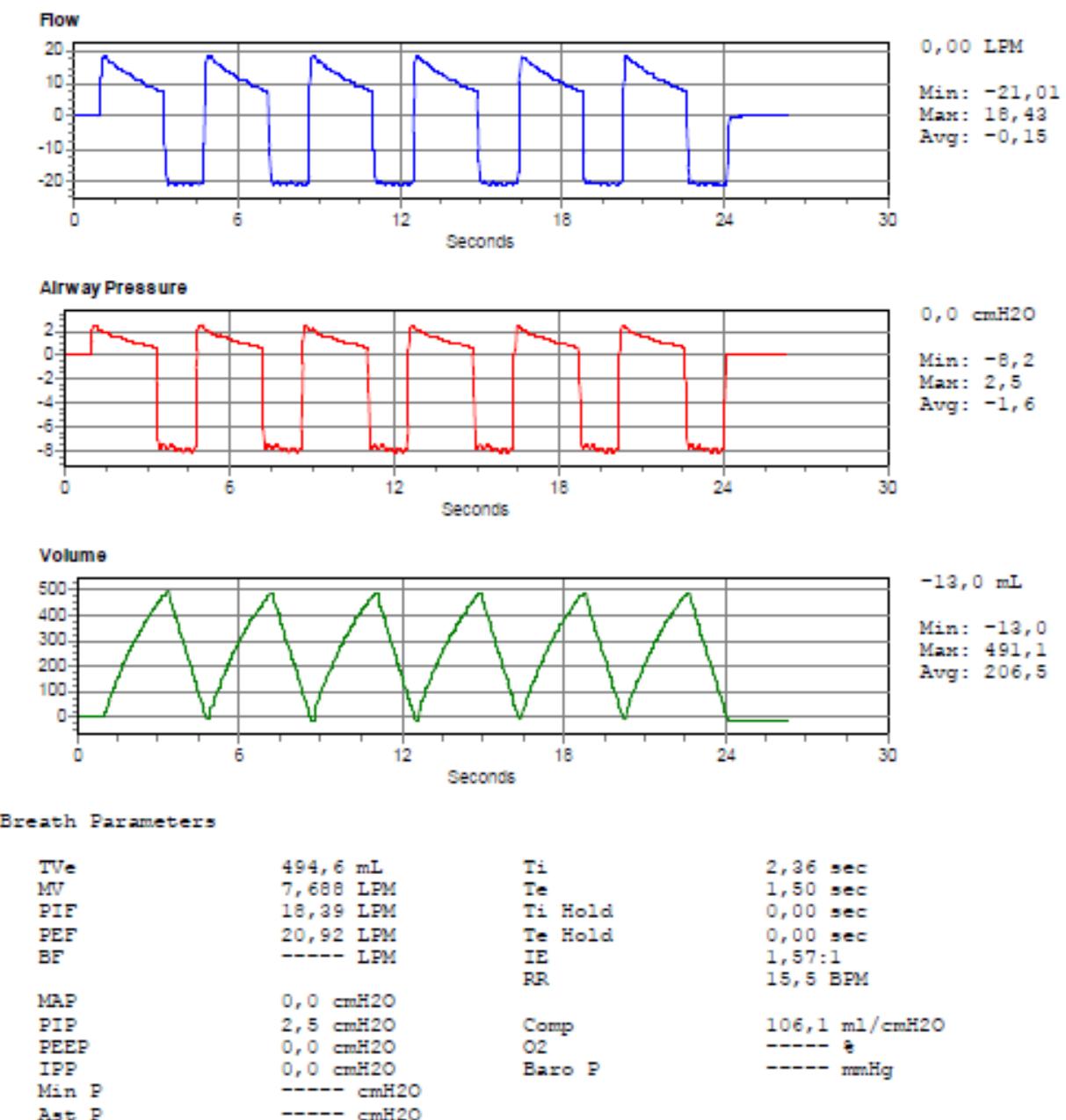


Figure 3.4 Output Wave forms for the Volume Control Breathing Mode for an Input Volume of 500 ml.

3.1.3 Volume Control Breathing Mode With 1000 ml Volume

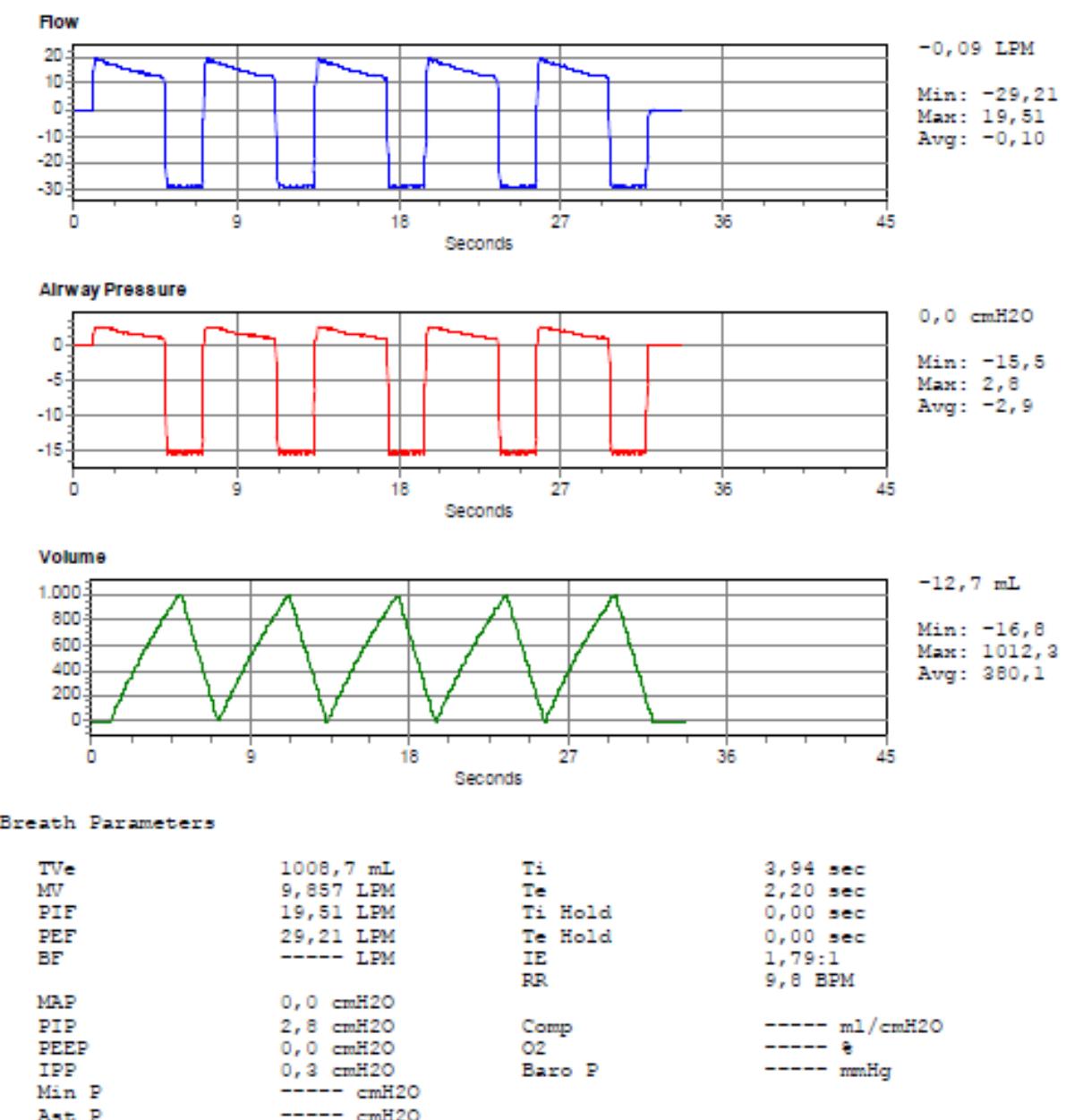


Figure 3.5 Output Wave forms for the Volume Control Breathing Mode for an Input Volume of 1000 ml.

3.2 Sine Volume Mode Test Results

3.2.1 Sine Volume Mode With 50 ml Volume

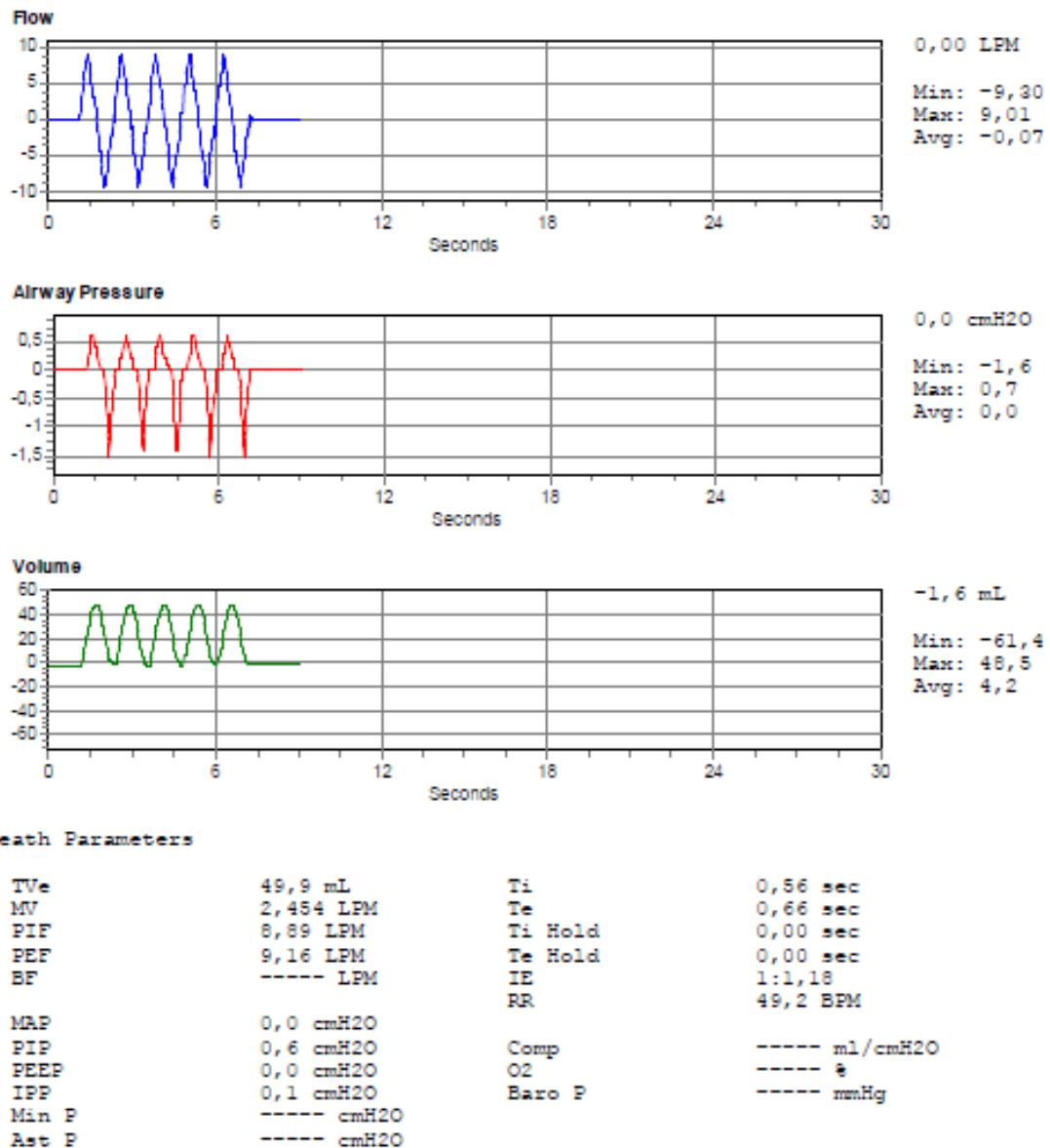


Figure 3.6 Output Wave forms for the Sine Volume Mode for an Input Volume of 50 ml.

3.2.2 Sine Volume Mode With 500 ml Volume

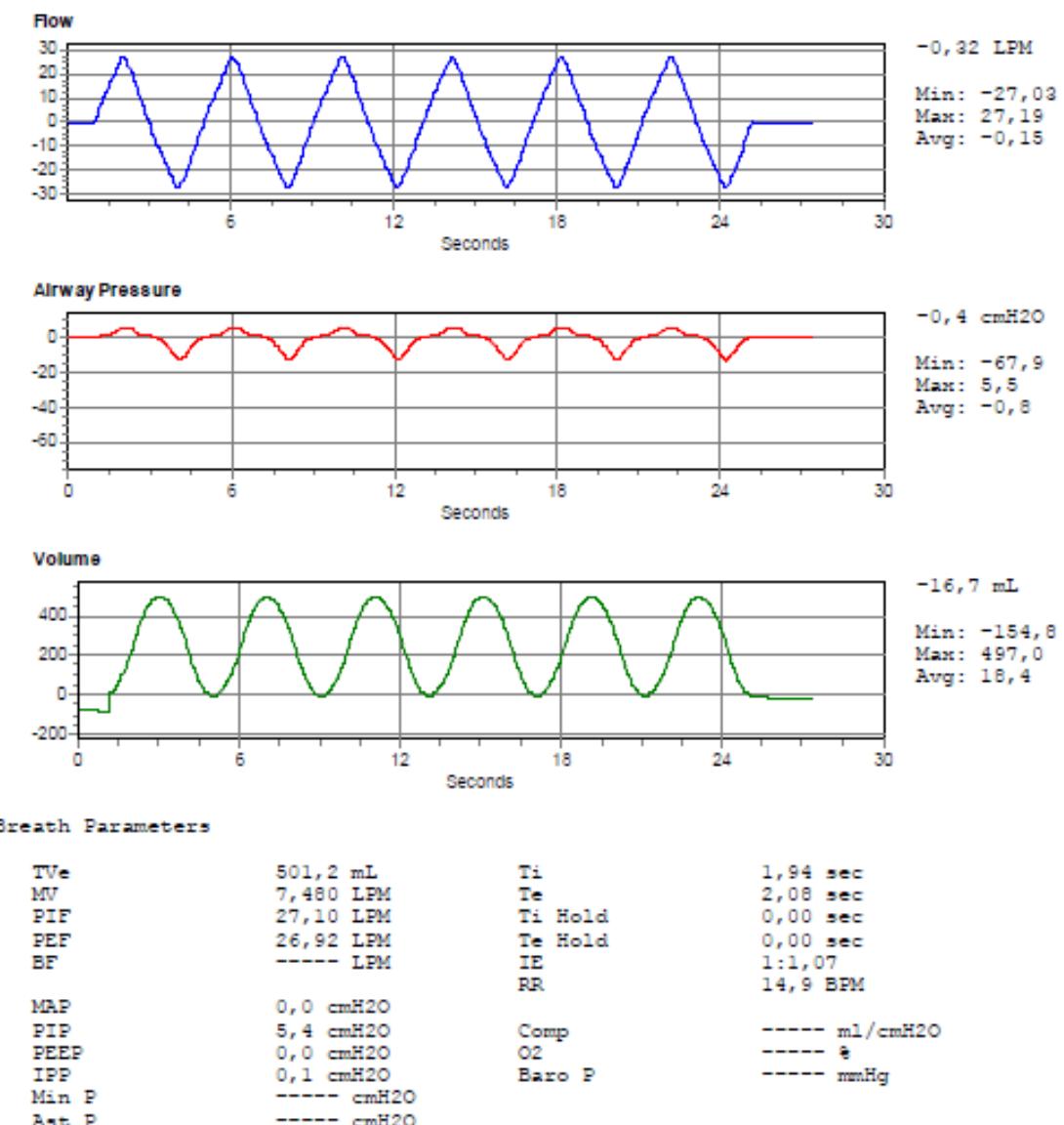


Figure 3.7 Output Wave forms for the Sine Volume Mode for an Input Volume of 500 ml.

3.2.3 Sine Volume Mode With 1000 ml Volume

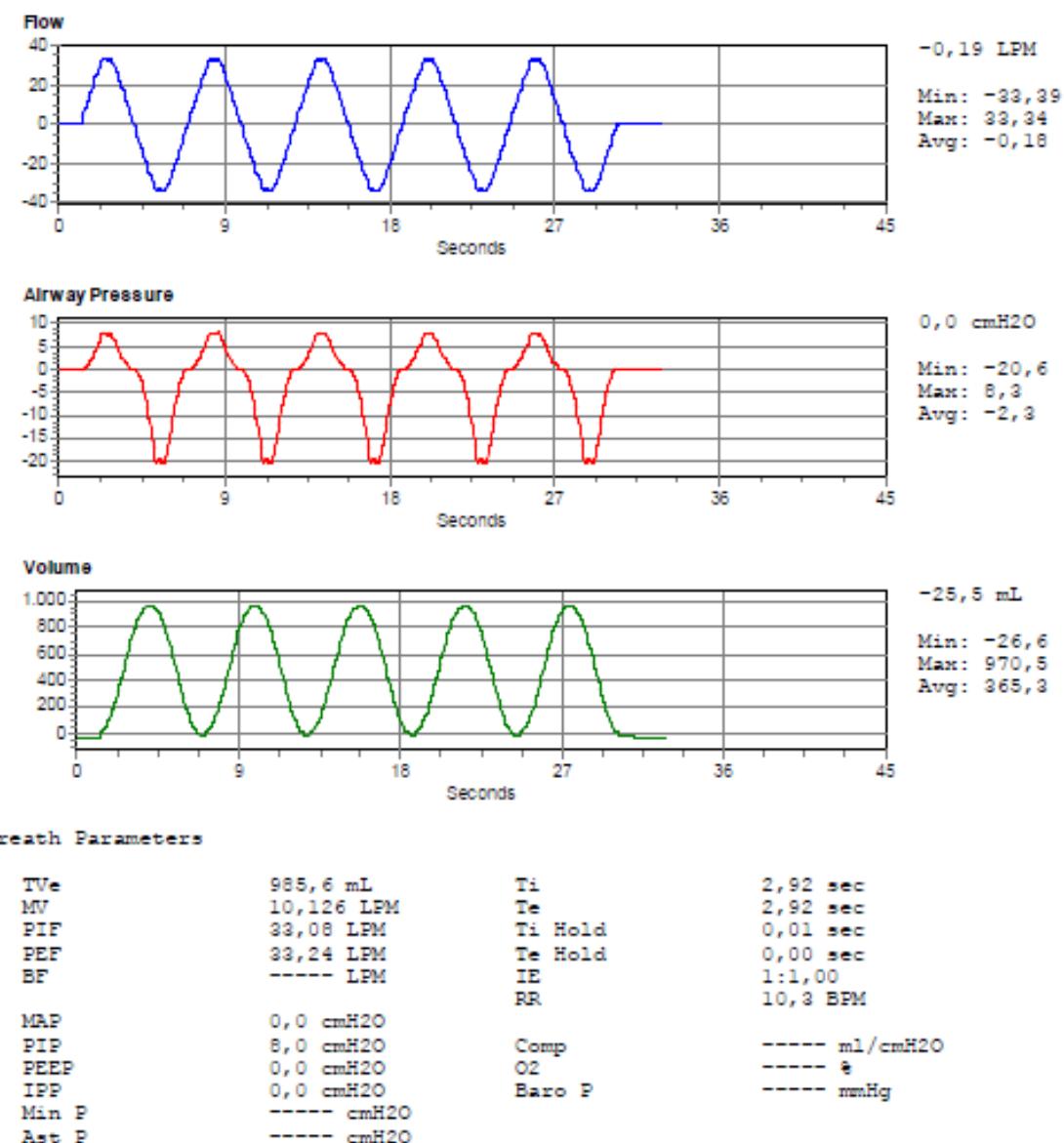


Figure 3.8 Output Wave forms for the Sine Volume Mode for an Input Volume of 1000 ml.

3.3 Sinus Flow Mode Test Results

3.3.1 Sine Flow Mode With 50 ml Volume

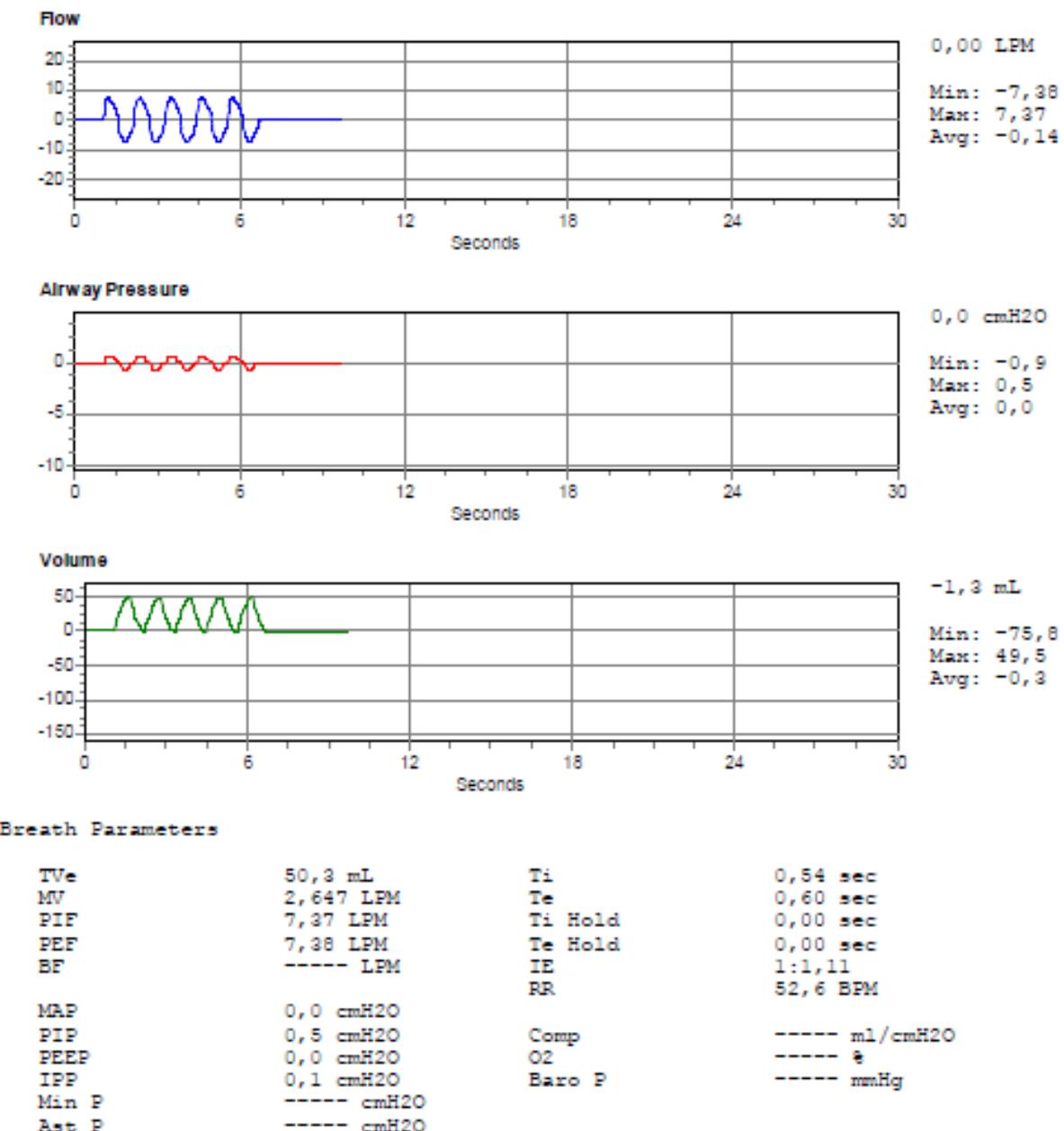


Figure 3.9 Output Wave forms for the Sine Flow Mode for an Input Volume of 50 ml.

3.3.2 Sine Flow Mode With 500 ml Volume

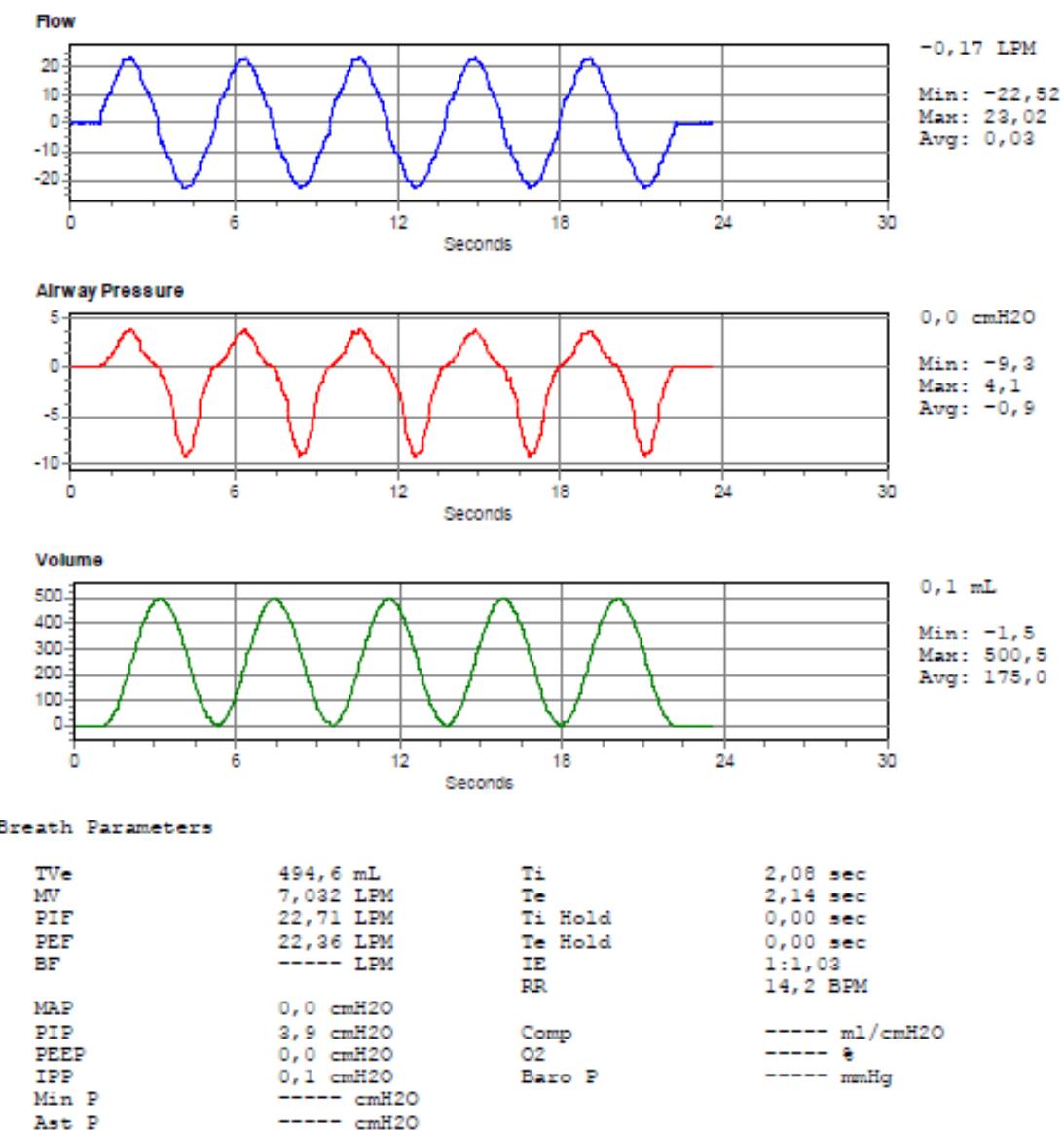


Figure 3.10 Output Wave forms for the Sine Flow Mode for an Input Volume of 500 ml.

3.3.3 Sine Flow Mode With 1000 ml Volume

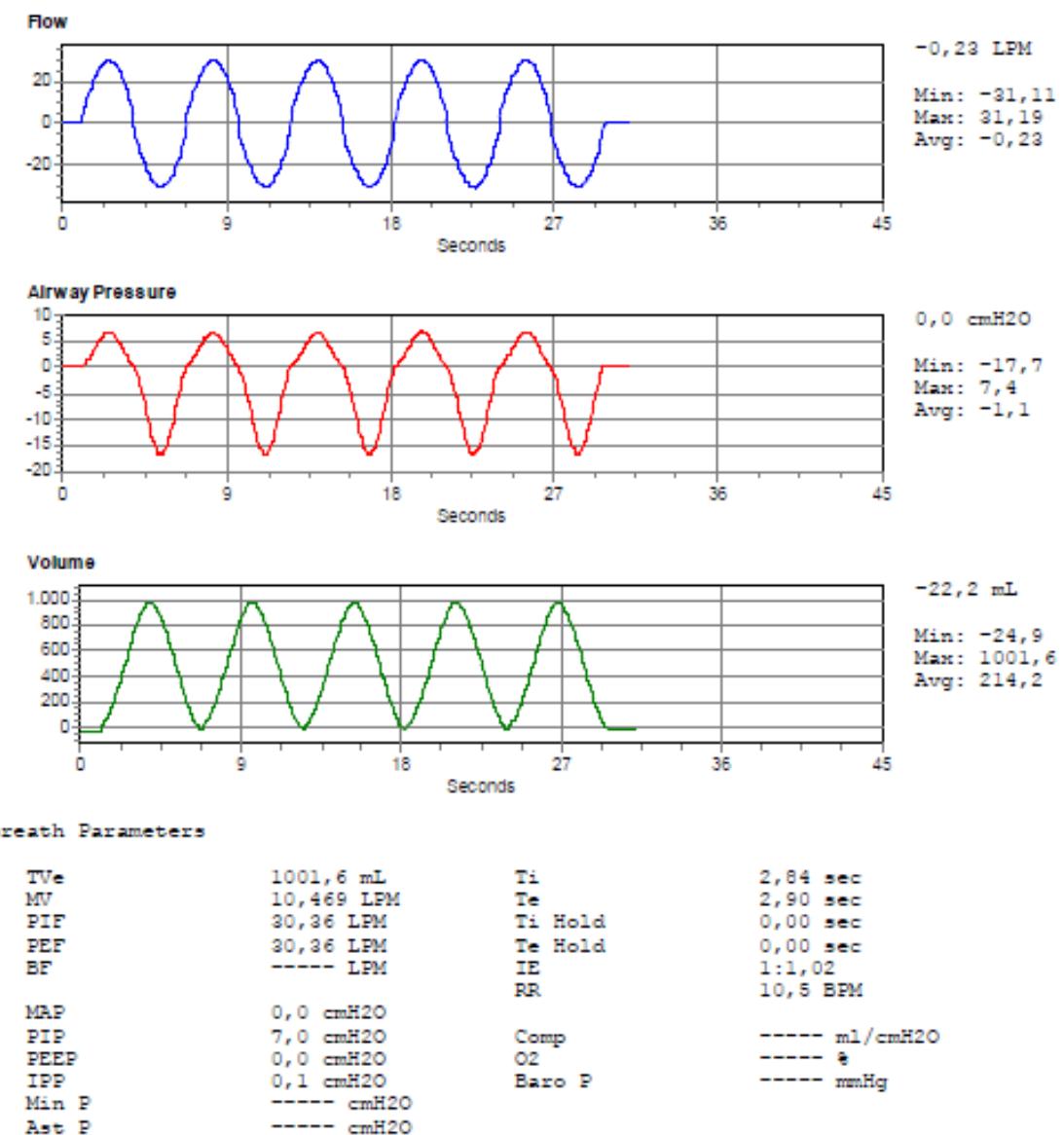


Figure 3.11 Output Wave forms for the Sine Flow Mode for an Input Volume of 1000 ml.

Table 3.2
Table of Input, Set and Calculated Parameters.

Input Parameters		Set Parameters	Calculated Parameters		
Mode	Input Volume	Respiratory Rate	Paramaters	Te	I:E
Volume Control Breathing Mode	50 ml	50 BPM	0,72 sec	0,48 sec	1,5
Volume Control Breathing Mode	500 ml	15 BPM	2,4 sec	1,6 sec	1,5
Volume Control Breathing Mode	1000 ml	10 BPM	3,6 sec	2,4 sec	1,5
Sine Volume Mode	50 ml	50 BPM	0,6 sec	0,6 sec	1
Sine Volume Mode	500 ml	15 BPM	2 sec	2 sec	1
Sine Volume Mode	1000 ml	10 BPM	3 sec	3 sec	1
Sine Flow Mode	50 ml	50 BPM	0,6 sec	0,6 sec	1
Sine Flow Mode	500 ml	15 BPM	2 sec	2 sec	1
Sine Flow Mode	1000 ml	10 BPM	3 sec	3 sec	1

Table 3.3
Table of Measured Parameters.

Measured Parameters									
	TV	RR	Ti	Te	I:E	PIF	PEF	PIP	PEP
Mean Values	48,24	48,56	0,74	0,50	1,47	4,44	6,38	0,30	0,70
SD	0,47	0,36	0,01	0,00	0,00	0,06	0,03	0,00	0,05
Mean Values	496,26	15,50	2,35	1,51	1,55	18,46	20,99	2,54	0,70
SD	1,45	0,00	0,01	0,01	1,00	0,10	0,05	0,05	0,05
Mean Values	1007,58	9,72	3,96	2,20	1,80	19,40	29,13	2,82	0,70
SD	2,79	0,04	0,01	0,00	0,00	0,20	0,06	0,04	0,00
Mean Values	49,80	48,56	0,58	0,66	0,88	8,85	9,16	0,70	0,70
SD	0,17	0,88	0,03	0,01	3,16	0,03	0,03	0,00	0,00
Mean Values	500,38	14,90	1,95	2,07	0,94	27,04	26,86	5,50	0,70
SD	2,30	0,00	0,03	0,03	0,88	0,12	0,04	0,00	0,00
Mean Values	985,10	10,30	2,93	2,91	1,01	33,20	33,21	8,24	0,70
SD	0,51	0,00	0,01	0,01	1,00	0,14	0,02	0,09	0,04
Mean Values	49,98	52,72	0,54	0,60	0,89	7,35	7,34	0,46	0,70
SD	0,33	0,27	0,01	0,00	0,00	0,06	0,03	0,05	0,00
Mean Values	495,72	14,20	2,09	2,13	0,98	22,66	22,34	4,10	0,70
SD	1,23	0,00	0,01	0,01	1,00	0,09	0,04	0,00	0,04
Mean Values	999,64	10,50	2,84	2,89	0,98	30,25	30,23	7,40	0,70
SD	2,40	0,00	0,00	0,01	0,00	0,20	0,16	0,00	0,13

Table 3.4
Table of Relative Errors.

Mode	Set Volumes	Relative Measurement Error in Volume	Relative Measurement Error in Respiratory Rate	Relative Measurement Error in Ti	Relative Measurement Error in Te	Relative Measurement Error in I:E
Volume Control Breathing Mode	50 ml	3,52%	2,88%	-2,22%	-4,17%	1,87%
Volume Control Breathing Mode	500 ml	0,75%	-3,33%	2,17%	5,50%	-3,53%
Volume Control Breathing Mode	1000 ml	-0,76%	2,80%	-7,33%	8,33%	-17,09%
Sine Volume Mode	50 ml	0,40%	2,88%	3,33%	-9,33%	11,59%
Sine Volume Mode	500 ml	-0,08%	0,67%	2,40%	-3,60%	5,79%
Sine Volume Mode	1000 ml	1,49%	-3,00%	2,40%	3,07%	-0,69%
Sine Flow Mode	50 ml	0,04%	-5,44%	6,00%	0,00%	6,00%
Sine Flow Mode	500 ml	0,86%	5,33%	-4,60%	-6,60%	1,88%
Sine Flow Mode	1000 ml	0,04%	-5,00%	5,33%	3,73%	1,66%

3.4 Nebulizer Measurement for Aerosol Output Test

The breath simulator is used for testing the nebulizer by Omron A3. Ventolin nebulles are used and the Ventolin nebulles contain 2,5 mg of salbutamol salute in 2,5 ml sterile saline solution. The experiments are done with 500 ml tidal volume using the sine flow control mode until nebulization at the output ceases.



Figure 3.12 Test apparatus for testing the nebulizer output.

Table 3.5
Omron A3 Nebulizer Specifications [14].

Nebulization Rate	0.5 ml/min (by weight loss)
Aerosol Output	0.5 ml (2,5 ml, 1%NaF)
Aerosol Output Rate	0.1 ml/min (2,5 ml, 1%NaF)

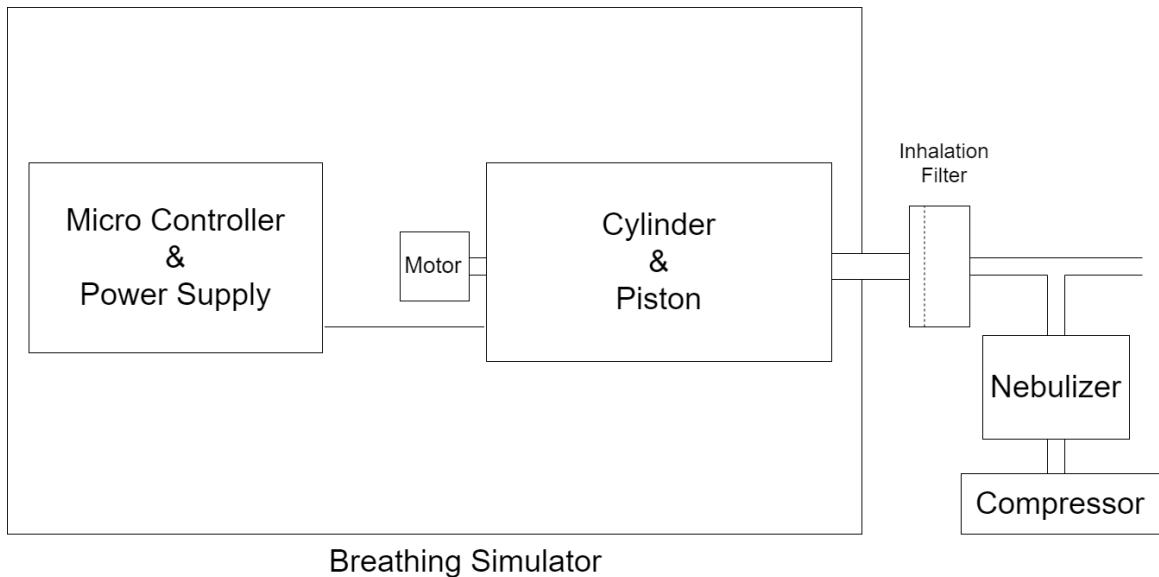


Figure 3.13 Inhalation control filter diagram.

The experiment was carried out for testing The Nebulizer (Omron, A3) with the designed breath simulator according to EN13544 ANNEX CC2. 2,5 mg Ventolin Nebules was nebulized until nebulization completely ceased with Sine flow mode ,500 TV and 15 BPM and the data shown on Table 3.4.

Table 3.6
Inhalation Filtered Experiment Results.

Nebulizer weight when empty	14,6545 g
Nebulizer weight when full	17,1840 g
Nebulizer weight at the end	16,0896 g
Inhalation Filter weight at the beginning	26,1833 g
Inhalation Filter weight at the end	26,4340 g

The Omron Nebulizer; nebulized 1,0944 g of Ventolin Nebule in 7 minutes. 0,2507 g of Ventolin measured on inhalation filter.

$$26,4340 - 26,1833 = 0,2507g \quad (3.1)$$

According to specifications of Omron A3; the aerosol output of 2,5 mg Ventolin Nebules at the end of 7 minutes should be seen around 0,5 ml but according to our test results it was 0,25 ml [14].



4. DISCUSSION

The breath simulator is simple, easy to use and more economical compared to existing simulators.

The simulator is tested with Fluke VT Mobile test device for each one of the three modes; volume control mode, sine flow mode and sine volume mode. The tests are completed for input volume and output volume comparison and control of the graphs for modes. Also a test for a nebulizer is completed. The test was to measure aerosol output of Omron A3 nebulizer according to EN 13544 Annex CC2. According to Omron A3 datasheet, the aerosol output is 0,5 ml but 0,25 ml was measured according to test in lab.

The EN 13544 standard has other tests for nebulizers in Annex CC1 and Annex CC2. These tests measure aerosol output rate, particle sizing. These tests could be conducted furthermore. Also for the EN 80601-2-70 Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment standard the breathing simulator can be used for testing.

5. CONCLUSION

This study shows that; human breathing pattern can be obtained by a breath simulator. The simulator can be used for testing medical devices such as nebulizers, also for laboratory measurements.

The simulator can work in three different modes, volume control mode, sine volume mode and sine flow mode. The modes are tested for three different volume parameters; 50 ml, 500 ml and 1000 ml. Within those volume parameters, minimum error values are obtained in volume control mode.

Also, the nebulizer (Omron, A3) is tested for output rate. The weights of inhalation and the exhalation filters are measured before and after tests and compared for the output rate of the nebulizer.

APPENDIX A. THE STEP MOTOR OF THE SYSTEM

A.1 Nema 34 Step Motor



General specifications:

Step Accuracy	±5%
Resistance Accuracy	±10%
Inductance Accuracy	±20%
Temperature Rise	80°C MAX.
Ambient Temperature Range	-20°C ~ +50°C
Storage Temperature Range	-30°C ~ +60°C
Insulation Resistance	100M Ω MIN. 500V DC
Dielectric Strength	820VAC , 1s, 3mA
Radial Play	0.02mm MAX. (450g Load)
End Play	0.08mm MAX. (450g Load)
Max. radial force	220N
Max. axial force	60N

Electrical Specifications:											
Series Model	Old P/N	Motor Length (mm)	Rated Current (A)	Phase Resistance (ohm)	Phase Inductance (mH)	Holding Torque (N.m Min)		Detent Torque (N.cm Max)	Rotor Inertia (g.cm²)	Lead Wire (No.)	Motor Weight (kg)
						Unipolar	Bipolar				
34H2A8850	34HS8802	78	5.0	0.5	1.8	3.0	4.2	6.5	1050	8	2.0

Figure A.1 Nema 34 Step Motor [15].

APPENDIX B. THE MICROCONTROLLER OF THE SYSTEM

B.1 Arduino Mega



Figure B.1 Arduino Mega Microcontroller [16].

The Arduino Mega 2560 is a microcontroller board based on the ATmega2560. It has 54 digital input/output pins (of which 15 can be used as PWM outputs), 16 analog inputs, 4 UARTs (hardware serial ports), a 16 MHz crystal oscillator, a USB connection, a power jack, an ICSP header, and a reset button. It contains everything needed to support the microcontroller; simply connect it to a computer with a USB cable or power it with a AC-to-DC adapter or battery to get started. The Mega 2560 board is compatible with most shields designed for the Uno and the former boards Duemilanove or Diecimila

Table B.1
Arduino Mega Specifications [16].

Microcontroller	ATmega2560
Operating Voltage	5V
Input Voltage (recommended)	7-12V
Input Voltage (limit)	6-20V
Digital I/O Pins	54 (of which 15 provide PWM output)
Analog Input Pins	16
DC Current per I/O Pin	20 mA
DC Current for 3.3V Pin	50 mA
Flash Memory	256 KB of which 8 KB used by bootloader
SRAM	8 KB
EEPROM	4 KB
Clock Speed	16 MHz
LED-BUILTIN	13
Length	101.52 mm
Width	53.3 mm
Weight	37 g

APPENDIX C. CODE FOR THE MICROCONTROLLER

C.1 Source Code

```
#include <math.h>
#include <stdio.h>
#include <Wire.h>
#include <LiquidCrystal-I2C.h>
#include <Keypad.h>
#include <AccelStepper.h>
#include <Stepper.h>

// Define a stepper and the pins it will use
AccelStepper stepper(4,32,34,36,38); // Defaults to AccelStepper::FULL4WIRE (4
pins) on 2, 3, 4, 5
Stepper stepper1(200,32,34,36,38);

const byte rows = 4;
const byte cols = 4;
char keys[rows][cols] = {
{'1','2','3','A'},
{'4','5','6','B'},
{'7','8','9','C'},
 {'*','0','#','D'}
};

const int stepPin = 38;
const int stepmin = 36;
const int dirPin = 34;
```

```
const int dirmin = 32;

const int e = 5 ; // cycle size
//const int k1,k2,k3,k4,k5,k6;
char KEY2,KEY3,KEY4,KEY5,KEY6;

float const k = 8.2 ; //calibration constant for volume
float b,volume;
float a = 0 ;
float forward;
float backward;
byte rowPins[rows] = 11,10,9,8;
byte colPins[cols] = 7,6,5,4;

char customKey;

long second = 0;
double total = 0;

#define trigPin 51
#define echoPin 50

float MX, ACC,r1;

float duration, distance1, distance2;

Keypad customKeypad = Keypad(makeKeymap(keys), rowPins, colPins, rows, cols);
```

```
{  
Serial.begin(9600);  
  
lcd.init(); // initialize the lcd  
lcd.init(); // Print a message to the LCD.  
lcd.backlight();  
lcd.setCursor(3,0);  
lcd.begin(16,2);  
lcd.noAutoscroll();  
  
stepper.setMaxSpeed(2500);  
stepper.setAcceleration(10000);  
stepper.setSpeed(2000);  
  
pinMode(stepPin,OUTPUT);  
pinMode(dirPin,OUTPUT);  
  
pinMode(stepmin,OUTPUT);  
digitalWrite(stepmin,LOW);  
pinMode(dirmin,OUTPUT);  
digitalWrite(dirmin,LOW);  
Serial.begin(9600);  
  
pinMode(echoPin, INPUT);  
}  
void initLCDKeys()  
{
```

```
LiquidCrystal-I2C lcd(0x27,20,4); // set the LCD address to 0x27 for a 16 chars
and 2 line display
void setup()
```

```
lcd.init();
for (int i = 0; i < sizeof(rowPins); i++)
pinMode(rowPins[i],OUTPUT);
for (int i = 0; i < sizeof(colPins); i++)
{
pinMode(colPins[i],INPUT);
digitalWrite(colPins[i],LOW);
}
}
void loop(){
```

S:

```
long first = 0;
initLCDKeys();
delay(50);
lcd.print("Vol Control>press A");
lcd.setCursor(0,1);
lcd.print("Sine vol > press B");
lcd.setCursor(0,2);
lcd.print("Sine flow > press C");
lcd.setCursor(0,3);
lcd.print("Maintanece > press D");
delay(500);
customKeypad.setDebounceTime(20);
char key = customKeypad.waitForKey();

if (key == 'A') {
```

```
lcd.init();
lcd.setCursor(0,0);
lcd.print("Enter Volume in (ml)");
lcd.setCursor(0,1);
lcd.print("Then Press *");

customKey = customKeypad.waitForKey();
switch(customKey)
{
    case '0' ... '9':
        first = first * 10 + (customKey - '0');
        lcd.setCursor(0,2);
        lcd.print(customKey);
        //Serial.print (first);
        customKey = customKeypad.waitForKey();
        switch(customKey)
        {
            case '0' ... '9':
                first = first * 10 + (customKey - '0');
                lcd.print(customKey);
                customKey = customKeypad.waitForKey();
                switch(customKey)
                {
                    case '0' ... '9':
                        first = first * 10 + (customKey - '0');
                        lcd.print(customKey);
                        //Serial.print (first);
                        customKey = customKeypad.waitForKey();
                        switch(customKey)

                            case '0' ... '9':
```

```
first = first * 10 + (customKey - '0');
lcd.print(customKey);
Serial.print (first);
customKey = customKeypad.waitForKey();
switch(customKey)

case '0' ... '9':
first = first * 10 + (customKey - '0');
lcd.print(customKey);
Serial.print (first);
customKey = customKeypad.waitForKey();
case '*':
lcd.setCursor(0,3);
lcd.print(first);
Serial.print(first);
volume=first;
break;
}
case '*':
lcd.setCursor(0,3);
lcd.print(first);
Serial.print(first);
volume=first;
break;
}
case '*':
lcd.setCursor(0,3);
lcd.print(first);
Serial.print(first);
volume=first;
break;
}
```

```

case '*':
lcd.setCursor(0,3);
lcd.print(first);
break;
}
}
A:
if(0 < volume && volume > 5000)
for(int i = 0 ; ; i++)

```

```

float const k = 2.2;
int y = 450;
int c = 750;

```

```

//_____
//_____
b = volume * k ;
int s1 =1200 / volume;

```

```

Serial.println (b);
Serial.println (volume);
Serial.println (k);
// Enables the motor to move in a particular directio

```

```

digitalWrite(dirPin,HIGH); // Enables the motor to move in a particular direction
for(int x = 0; x <10 ; x++) {
digitalWrite(stepPin,HIGH);
delayMicroseconds(650);
digitalWrite(stepPin,LOW);
delayMicroseconds(650);
}

```

```
for(int x = 10 ; x < 50 ; x++) {  
    digitalWrite(stepPin,HIGH);  
    delayMicroseconds(450);  
    digitalWrite(stepPin,LOW);  
    delayMicroseconds(450);  
}  
for(int x = 50 ; x < (b-10) ; x++) {  
    digitalWrite(stepPin,HIGH);  
    delayMicroseconds(y);  
    digitalWrite(stepPin,LOW);  
    delayMicroseconds(y);  
    y = y+s1 ;  
}  
for(int x = 0 ; x > 10 ; x++) {  
    digitalWrite(stepPin,HIGH);  
    delayMicroseconds(y);  
    digitalWrite(stepPin,LOW);  
    delayMicroseconds(y);  
    y = y+100 ;  
}  
delay(25); // second delay  
digitalWrite(dirPin,LOW); //Changes the rotations direction  
  
for(int x =0; x < 100 ; x++) {  
    digitalWrite(stepPin,HIGH);  
    delayMicroseconds(c);  
    digitalWrite(stepPin,LOW);  
    delayMicroseconds(c);  
    c = c-2 ;  
}  
for(int x = 100; x < (b-100) ; x++) {  
    digitalWrite(stepPin,HIGH);
```

```
delayMicroseconds(c);
digitalWrite(stepPin,LOW);
delayMicroseconds(c);
}
for(int x = 0; x < 100 ; x++) {
digitalWrite(stepPin,HIGH);
delayMicroseconds(c);
digitalWrite(stepPin,LOW);
delayMicroseconds(c);
c = c+2 ;
}
delay(25); // One second delay
```

```
if (i == e){
lcd.init();
lcd.setCursor(0,0);
lcd.print("Repeat Cycle Press *");
lcd.setCursor(0,1);
lcd.print("Reset Press #");
customKey = customKeypad.waitForKey();
switch(customKey)
{
case '*':
goto A;
case '#':
goto S;
}
}
}
}
else{
```

```
lcd.init();
lcd.setCursor(0,0);
lcd.print ("Wrong Volume");
lcd.setCursor(0,1);
lcd.print("Reset Press #");
lcd.setCursor(0,2);
lcd.print("Enter Volume | 5000");
customKey = customKeypad.waitForKey();
switch(customKey)
{
    case '#':
        goto S;
}
}
```

```
if (key == 'B'){
    lcd.init();
    lcd.setCursor(0,0);
    lcd.print("Enter Volume in (ml)");
    lcd.setCursor(0,1);
    lcd.print("Then Press **");

    customKey = customKeypad.waitForKey();
    switch(customKey)
    {
        case '0' ... '9':
            first = first * 10 + (customKey - '0');
            lcd.setCursor(0,2);
            lcd.print(customKey);
    }
}
```

```
//Serial.print (first);  
customKey = customKeypad.waitForKey();  
switch(customKey)  
{  
case '0' ... '9':  
    first = first * 10 + (customKey - '0');  
    lcd.print(customKey);  
    customKey = customKeypad.waitForKey();  
    switch(customKey)  
{  
    case '0' ... '9':  
        first = first * 10 + (customKey - '0');  
        lcd.print(customKey);  
        Serial.print (first);  
        customKey = customKeypad.waitForKey();  
        switch(customKey)  
{  
        case '0' ... '9':  
            first = first * 10 + (customKey - '0');  
            lcd.print(customKey);  
            Serial.print (first);  
            customKey = customKeypad.waitForKey();  
            case '*':  
                lcd.setCursor(0,3);  
                lcd.print(first);  
            }  
        }  
    }  
}
```

```
Serial.print(first);
volume=first;
break;
}
case '*':
lcd.setCursor(0,3);
lcd.print(first);
Serial.print(first);
volume=first;
break;
}
case '*':
lcd.setCursor(0,3);
lcd.print(first);
Serial.print(first);
volume=first;
break;
}
case '*':
lcd.setCursor(0,3);
lcd.print(first);
break;
}
}
B:
if(0 < volume && volume < 5000){
for(int i = 0 ; ; i++)
```

```
    float k = 8.6;
    float y=0;
    float c=0;
```

```
//-----
```

```
// Measure the response from the HC-SR04 Echo Pin
```

```
// duration = pulseIn(echoPin, HIGH);
```

```
// Determine distance from duration
```

```
// Use 343 metres per second as speed of sound
```

```
//distance1 = (duration / 2) * 0.0343;
```

```
//Serial.print (distance1);
```

```
//-----
```

```
b = volume * k ;
```

```
stepper.setMaxSpeed(20000);
```

```
stepper.setAcceleration(-(8*volume));
```

```
stepper.runToNewPosition(-b);
```

```
stepper.setMaxSpeed(20000);
```

```
stepper.setAcceleration(-(8*volume));
```

```
stepper.runToNewPosition(0);
```

```
//-----
```

```
// Measure the response from the HC-SR04 Echo Pin
```

```
//duration = pulseIn(echoPin, HIGH);
```

```
// Determine distance from duration
```

```
// Use 343 metres per second as speed of sound
```

```
//distance2 = (duration / 2) * 0.0343;  
//Serial.print (distance2);  
//—————  
//if ((distance1 - 0.5) < distance2 && distance2 > (distance1 + 0.5)){  
// ;  
//}  
//else  
//{  
// exit(0);  
//}  
if (i == e){  
lcd.init();  
lcd.setCursor(0,0);  
lcd.print("Repeat Cycle Press *");  
lcd.setCursor(0,1);  
lcd.print("Reset Press #");  
customKey = customKeypad.waitForKey();  
switch(customKey)  
{  
case '*':  
    goto B;  
case '#':  
    goto S;  
}  
}  
}  
}  
}  
}  
}  
else{  
lcd.init();  
lcd.setCursor(0,0);
```

```
lcd.print ( "Wrong Volume");
lcd.setCursor(0,1);
lcd.print("Reset Press #");
lcd.setCursor(0,2);
lcd.print("REnter Volume < 5000");
customKey = customKeypad.waitForKey();
switch(customKey)
{
case '#':
goto S;
}
}
}
if (key == 'D'){
D:
lcd.init();
lcd.setCursor(0,0);
lcd.print("Pist. Fwd Press A");
lcd.setCursor(0,1);
lcd.print("Pist. Bwd Press B");
lcd.setCursor(0,2);
lcd.print("To Exit Press 0");

customKey = customKeypad.waitForKey();
switch(customKey)
{
case 'A':
stepper1.setSpeed(600);
stepper1.step(-3200);
goto D;
case 'B':
stepper1.setSpeed(600);
```

```
stepper1.step(3200);
```

```
goto D;
```

```
case '0':
```

```
goto S;
```

```
}
```

```
}
```



APPENDIX D. FLUKE VT MOBILE GAS FLOW ANALYZER

D.1 Overview



Figure D.1 Fluke VT Mobile [17].

VT MOBILE is a compact and portable general-purpose gas-flow analyzer designed to meet the needs of the traveling technician or engineer. This versatile tool evaluates performance of a wide variety of medical gas-flow/pressure devices and measures 16 ventilator parameters.

The base unit measures high- and low-flow ranges, volume, pressure, and oxygen concentration. Additionally, the temperature and relative humidity option can be ordered separately to ensure the most accurate gas-flow measurements.

VT MOBILE can be purchased with the ACCU LUNG portable, precision simulation lung, or other precision and non-precision simulation lungs, each of which can also be purchased separately [17].

D.2 Features of VT Mobile

- Bidirectional flow (high- and low-flow ranges), volume, vacuum, pressure, and oxygen-concentration measurements
- 16 ventilator parameter measurements
- Trending and statistical analysis of all measured values
- Onboard graphical display
- Portable and compact
- RS232 for computer control
- Memory for storing results
- VT for Windows PC software
- Optional sensor assembly for temperature and humidity measurements

Table D.1
Fluke VT Mobile Specifications [17].

Technical Specifications		
Display	64 x 128 pixels, reflective LCD, blue on yellow	
Operational Modes	Standalone without any PC software or with the VT for Windows PC software.	
Gas Types	Air, N2, N2O, CO2, O2, N2O bal O2, N2 bal O2	
Battery Power Supply	Maximum Over-Voltage:	15 V dc
	Input Voltage Range:	9 V dc
	Power Consumption:	<70 mA
	Battery Life:	>7 hours
External Power Supply	Maximum Over-Voltage:	264 V ac
	Input Voltage Range:	100 V ac to 240 V ac
	Input Frequency Range:	50/60 Hz
	Output Voltage:	12 V to 15 V
	Output Current:	1.2 A
	Fuse Rating:	N/A
Low-Pressure Port	Maximum Applied Pressure:	5 psi
	Operating Pressure (Differential):	- 20 cmH2O to 120 cmH2O
	Operating Pressure (Common-Mode):	N/A
	Span Accuracy:	+ 2 % of reading or 1.5 mmHg
	Frequency Response:	>10 Hz
	Resolution:	0.1 mmHg
	Sample Rate:	100 Hz
	Fittings:	Flow connector with 2 tubes "T" connected to a single Luer fitting
	Note:	No fluid may be applied to port

Table D.2
Fluke VT Mobile Specifications (Cont.) [17].

High-Pressure Port	Maximum Applied Pressure:	125 psi
	Operating Pressure:	- 2 psi to 100 psi
	Span Accuracy:	+ 2 % of reading or +
	Frequency Response:	>10 Hz
	Resolution:	0.1 psi
	Sample Rate:	100 Hz
	Fittings:	Single port, Luer lock, stainless steel
	Note:	No fluid may be applied to port
Airway Pressure	Maximum Applied Pressure:	5 psi
	Operating Pressure:	- 20 cmH ₂ O to 120 cmH ₂ O
	Span Accuracy:	+ 2 % of reading or + 0.5 cmH ₂ O
	Frequency Response:	>25 Hz
	Resolution:	0.1 cmH ₂ O
	Sample Rate:	100 Hz
	Fittings:	Internally connected to flow-sensor pressure lines
High-Flow Port	Maximum Flow Rate (absolute value):	200 lpm
	Operating Flow Range:	+/- 200 lpm
	Accuracy:	+/- 3 % of reading or +/- 2 % of range
	Floor for Absolute Accuracy:	25 lpm
	Resolution:	0.01 lpm
	Frequency Response:	>25 Hz or t10-90 <40 ms
	Sample Rate:	100 Hz
	Dynamic Resistance:	<2 cmH ₂ O @ 60 lpm
	Low-Flow Dropout:	2.5 lpm
	Breath-Detect Threshold:	4 lpm
	Volume Range:	>+/- 60 l
	Tidal Volume Accuracy:	+/- 3 % of reading or +/- 20 ml, whichever is greater
	Fittings:	15 mm OD/ID, 1:40 conical male

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