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Research Article

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An Automated Jet Nebulizer with Dynamic Flow Regulation

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Abstract—

Purpose

The present study is focused on designing an automated jet nebulizer that possesses the capability of dynamic flow regulation. In the case of existing equipment, a high fraction of the aerosol is lost to the atmosphere through the vent, during the exhalation phase of respiration. Specifically, 50% of the volume of aerosol generated, is wasted. Desired effects of nebulization may not achieve by neglecting this poor administration technique. There may be adverse effects like bronchospasm, and exposure to high drug concentrations.

Methods

The proposed nebulizer is composed of two modes as “Compressed Air” mode and “Oxygen Therapy” mode. The automated triggering from one mode to another will be dependent upon the percentage of oxygen saturation of the patient, monitored from the SpO₂ sensor. The compressed airflow will be delivered to the patient according to his or her minute ventilation, derived with the aid of a temperature sensor-based algorithm.

Results

The compressor circuitry controller ensures that the patient receives compressed air as per the flow rate decided by the system. At the end of the drug delivery, if the liquid level sensor detects the absence of medication within the nebulizer chamber, the nebulization process will be terminated.

Conclusions

The dynamic regulation of the motor speed with respect to the minute ventilation was accomplished successfully. A laminar flow was obtained from the outlet of the compressor towards the nebulizer tubing, and a turbulent flow was obtained within the chamber, as expected. No excessive turbulent flows or rotational flow patterns were detected. The result could certainly lead to the improvements of the existing nebulizers.

Keywords: Jet nebulizer, Proportional Integral Derivative controller, Inhalation therapy, Computational fluid dynamics

INTRODUCTION

A considerable percentage of the population suffers from respiratory diseases such as asthma and COPD. As per WHO statistics, 235 million people are affected with asthma, and 64 million people are affected with COPD while millions of others suffer from other unidentified chronic respiratory diseases (Hubbard, 2006). Nebulizers that atomize medication are widely used in aerosolized inhalation therapy for such respiratory diseases.

A nebulizer is a device that functions by converting drugs which are in liquid form into a wet mist, more specifically, aerosols of a size that can be inhaled by the lower respiratory tract. (Ari, 2014), (Hess,2000). There are three main types of nebulizers in clinical practice such as Jet nebulizers, Ultrasonic nebulizers and Mesh nebulizers. Jet nebulizers use compressed gas to make the aerosol.

Two important factors which determine the delivery of the drugs to the effect site are molecular weight and the particle size. Droplets size more than 20 μm collects in tubing or in upper airways if not baffled out and droplets of 5 μm fall out in trachea. Between 1-5 μm will reach lower airways. 1 μm particles are likely to deposit in alveoli while particles smaller than this are very stable and may move in and out during respiration rather than being deposited at the site of action.

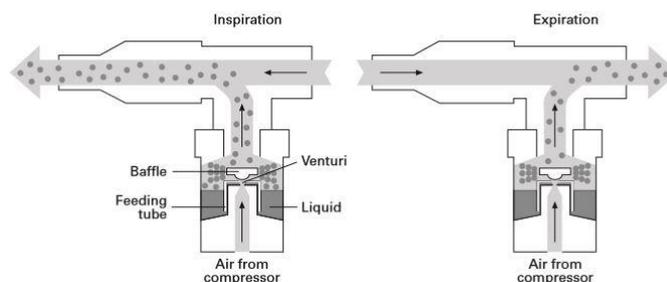


Figure 1: Conventional Nebulizer Design (O'Callaghan & Barry , 1997)

In spite of the introduction of lightweight and portable devices like metered-dose inhalers, dry powder inhalers, the popularity of the nebulizers have not diminished due to their simplicity and the ability to be frequently used in inhalation therapy for infants, small children, and the elderly (Rau & Hess,2009; Clay,1987). It is considered advantageous because it has the ability to aerosolize several drug solutions, drug mixtures and it can be useful in treating debilitated or distressed patients (Rau & Hess,2009) and drug delivery is not affected by coordination of respiration and technique of use. Inhalers are more dependent on technique of use which is not practical in patients whom respiration is severely affected like in acute severe or life-threatening asthma.

However, most of the conventional nebulizers fall short of desired preferences. One of the issues with the current nebulizers is that they deliver inadequate volume of aerosolized drugs to the patient. According to research (O’Callaghan & Barry,1997; Chatburn & McPeck,2007; Volsko et al, 2014), conventional nebulizers (Fig.1) are considered highly inefficient due to the high wastage of aerosol. The efficacy and the quality of the aerosol generated by a jet nebulizer are a product of the design of the device and the drug formulation (Bisgaard et al, 2001). It was mentioned that the driving gas flow rate, the ratio of liquid to gas flow, characteristics of the compressor have an impact on the size of the droplets produced by a nebulizer (Hess,2000; O’Callaghan & Barry,1997; Kendrick et al ,1997; Mittal et al,2010). In addition to that, controlling the relative humidity within the airflow between the nebulization source and patient can be achieved by simply controlling the flow rates in the system (Haddrell et al,2014). Furthermore, patient factors such as breathing rate also have an effect on drug delivery. In the case of a continuously operating compressor, a high fraction of the aerosol is lost to the atmosphere through the vent, if the patient may not inhale faster enough (Brun et al ,2000). Specifically, 50% of the volume of aerosol generated, is wasted during exhalation (O’Callaghan & Barry,1997).

As for the existing research on improving the conventional nebulizers, (Yardimci,2011), has developed a microcontroller-based jet nebulizer, in which the compressor is controlled using the fuzzy logic system, for domiciliary use. However, the inhalation profile which is an important factor hasn’t been considered when regulating the compressor. In addition to that, (Ivanova & Glazova,2015), have conducted research on enhancing the performance of the ultrasonic nebulizer, through the incorporation of an indicator that registers time, duration of an asthma attack, and dosage. The study has been limited to children who are suffering from bronchial asthma.

One of the reasons behind the inability of conventional devices to deliver the entire dosage, as mentioned in the literature, is the fact that the driving gas flow is unidirectional and constant in contrast to the breathing pattern, which is bidirectional and variable. In order to address these issues, the proposed research is specifically focused on the regulation of the dynamic flow of the compressor in sync with the inhalation profile of the patient. The proposed design employed the use of a digital temperature sensor for monitoring the respiration rate during nebulization. How the temperature sensors could be incorporated in detecting respiration rate was studied with the help of the conceptual model stated (Gupta & Qudsi,2013). For the purpose of regulating the compressed air flow, the proposed research takes an approach in employing an Arduino based proportional integral derivative (PID) control system. PID control is one of the most widely used dynamic control techniques in industrial applications (Paz,2001). It involves the use of a feedback controller, which changes the output based on the sensed/ observed result as shown in Fig. 2. The process variable of a given setpoint is measured by the sensor, which in turn is compared to the setpoint (desired output), in order to determine the error. The error signal is used to find out the controller output, which is delivered to the actuator. The difference between the process variable and setpoint is the error (Knospe,2006). Here the integral time (T_i) and derivative time (T_d) refers to the time constants which are required to acquire the manipulated variable using the integral action and derivative action respectively.

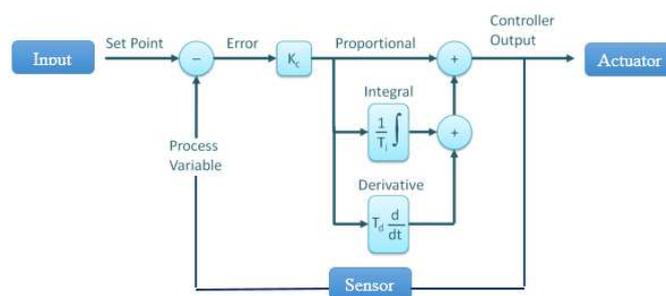


Figure 2: The Schematic of a PID Controller [17]

The present error is taken into account by the proportional term. Integral response takes all the errors, which are present in the system, from the starting point to a particular point of time in the process. The derivative response is proportional to the rate of change in the process variable (Theopaga,2014).

During nebulization with bronchodilators like salbutamol, there is a possibility of desaturation due to worsening of ventilation perfusion mismatching. So it is advisable to provide oxygen during this procedure, so use of “oxygen therapy mode” prevent this adverse reaction while nebulization.

METHODS

A. The Approach and Information Gathering

After conducting market analysis on existing products, and a literature survey, the research problem was identified. Furthermore, information regarding nebulization was gathered during the visitation of the National Hospital for Respiratory Diseases, located at Welisara, Sri Lanka.

B. The Conceptual Design and Hardware Components

Conceptual design of the proposed nebulizer is presented in Fig. 3. The conceptual design was carried out to achieve two modes namely, *Compressed Air Mode* and *Oxygen Therapy Mode*. Oxygen Therapy Mode is triggered or selected, depending on the percentage of oxygen saturation (94% is the threshold) of the patient being nebulized and the clinical requirements because at most times addition of oxygen is beneficial though rarely it may exacerbate respiratory failure in severe COPD patients. The temperature sensor monitors the temperature difference which occurs during inhalation and exhalation. Hence, breathing count will be determined which will be converted to a volumetric breathing rate. The SpO₂ circuit monitors the percentage of oxygen saturation percent in arterial blood. An initial set flow rate will be given to the diaphragm pump through the controlling unit of the nebulizer. The airflow sensor monitors whether the diaphragm pump is operating in that given flowrate. The airflow sensor readings will be taken up by the controlling unit. If there is some error present between the desired flow rate and the sensed flowrate, it will be altered by the PID function through the variation of the voltage fed to the motor controller through pulse width modulation. This process continues only if the oxygen saturation percentage is within the required range. If the oxygen saturation percentage of the patient, lowers than the specified limit, Oxygen Therapy Mode is triggered. Triggering of the Oxygen Therapy Mode will cause oxygen therapy to be delivered via the opening and closing of the specific solenoid valves which will be done through the controlling unit. The non-contact liquid level sensor monitors the level of the medication in liquid form. Once it detects that no liquid is present within the nebulizer chamber, the process of nebulization will be terminated.

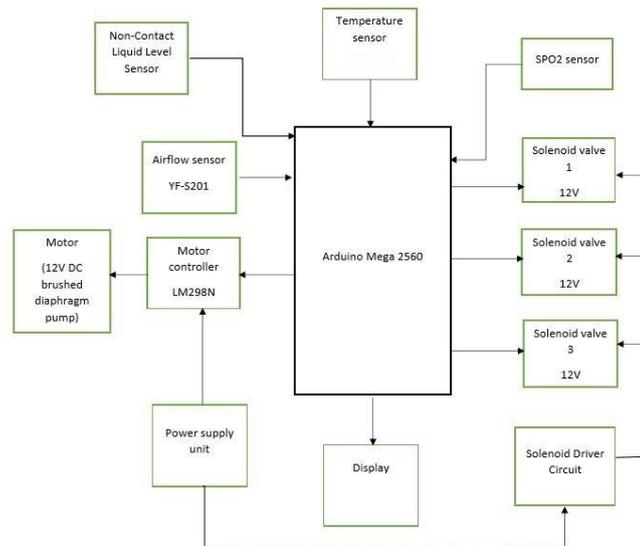


Figure 3: Conceptual Design of the Proposed Nebulizer

The sensing elements used for nebulizer design include, one wire DS18B20 temperature sensor for monitoring the temperature of inhaled air and exhaled air. It has the capability of reading temperatures to a resolution of 0.0625 °C. In addition to that, the YF-S201 airflow sensor was used for monitoring the compressed air flow rate. It consists of an integrated magnetic hall sensor that outputs an electrical pulse with every revolution. A non-contact liquid level sensor was used to achieve non-contact liquid level detection. The actuators used for the proposed nebulizer include a micro diaphragm pump (Fig. 4) and L298N motor controller. The micro diaphragm pump is basically composed of a DC brushed motor. The rotational movement of the motor is converted into oscillating movement by an eccentric. It is connected through a connecting rod to a diaphragm, which moves up and down its central point. The elastic diaphragm in conjunction with an inlet and outlet valve generates a pumping action. The particular pump can be mounted in any position and can deliver a flow rate up to 11 l/min.



Figure 4: DC Micro Diaphragm Pump

Arduino Mega 2560 microcontroller reads the signals obtained from the relevant sensors, makes logical decisions such as comparing the sensed signals with the desired signals, and finally transmits the necessary PWM signals to the actuators.

C. Designing the 3D Model of the Nebulizer

The dimensions were determined by referring to the service manuals of conventional nebulizers and altering those dimensions according to the requirements of the proposed equipment. The 3D model of the design was created with the aid of the SOLIDWORKS software and depicted in Fig. 5.



Figure 5: 3D Model of the Proposed Nebulizer

The 3D model of the interior of the nebulizer was designed using SOLIDWORKS Software and presented in Fig.6. The dimensions of every single component were studied thoroughly prior to designing it. Medical standards and guidelines were followed while doing so. Here the volume of the pump is equal to (88mm x 65mm x 40.5mm). The inlet and outlet diameters can be stated as, 3.4mm and 6.5mm respectively. The airflow sensor is connected to the outlet of the pump and the tubing is connected to the outlet of the airflow sensor. The nebulizer tubing is connected to the nebulizer chamber and the mask is attached to the nebulizer chamber. The mask, nebulizer chamber and nebulizer tubing were drawn as per the dimensions of the pre-existing nebulizers.

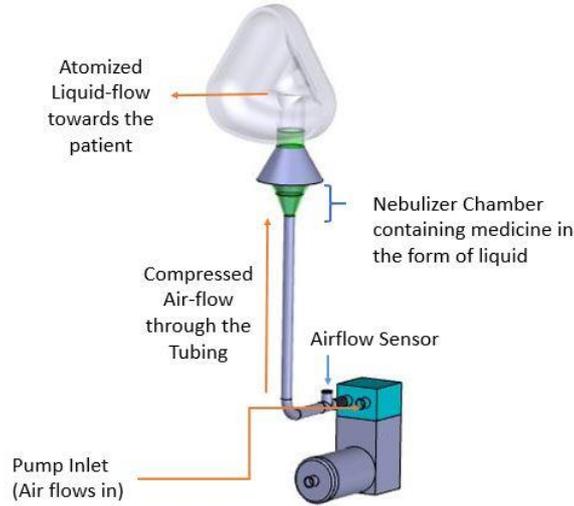


Figure 6: 3D Model of the Pump Assembly

D. Analysis of the Safety Requirements & Circuitry Designing

Each subsystem of the overall system is part of an integrated safety system. The system software can manage routine error handling and communicate the system state to the user. For example, the airflow sensor in combination with the PID function integrated within the controlling unit ensures that the patient doesn't receive an airflow of higher flowrate than the desired flow rate. In addition to that, the device is of un-obtrusive and non-invasive type.

The circuit was designed using the "schematic capture" feature of the Proteus Design Suite. The power supply was designed in such a way that it converts 230V AC to a 12V DC supply for powering up the motor controller the three solenoid driver circuits, furthermore a 5V DC supply for powering the display unit. The 12V and 5V requirements were fulfilled by the use of a 12V regulator (7812) and a 5V regulator (7805) respectively. The required components were selected from the proteus library whilst referring to their datasheets. The components were placed on the workspace. The components were routed to the Arduino as necessary.

E. Monitoring of the Minute ventilation and Dynamic Flow Regulation of the Compressor

The temperature value is read through the analogue input. The temperature value is then matched with the immediately previous value, to see if the value reaches a maximum and minimum. If the value of temperature increases and suddenly decreases, or vice versa, a peak is reached. The peak could be either positive or negative. On either of these peaks, a count is set as a value, so that the order can be checked to measure the time gap between two adjacent crests and trough. Then this particular time difference is used to derive the breathing rate of the patient.

As the controller gets the flow rate set by the user, simultaneously the airflow sensor starts monitoring the airflow given by the diaphragm pump. The flowrate entered by the user and the current flow rate are compared and the difference is calculated as error and in accordance with that, the PWM signal given to the L298N IC for driving motor through Arduino Mega2560 is varied. The two pins are used as output for the motor driving and the enable pin in the motor driver is supplied by the PWM signals from the Arduino. By supplying high to the enable (ENA) pin on the L298N, the motor driver provides the 12V supply to the motor, so by varying the signal to the enable pin, the motor speed will be varied. As shown in the above circuit diagram, ENA is connected to pin 11 of the Arduino, which serves as one of the output pins for the PWM function. The difference is counted as an error and from there onwards, PID calculation starts in the program. As for the next step, in determining the values of proportional, integral, and derivative errors.

F. Performance Evaluation of the Nebulizer

1) *Assessing the Nebulizer Motor Performance*: The motor function is a vital factor for the performance of the proposed nebulizer. Therefore, the motor control circuit was simulated using Matlab & Simulink (R2016b) software as per the experimental setup given in Fig.7.

Since the PID control was to be applied for the DC brushed motor integrated within the micro diaphragm pump, the transfer function of the motor was chosen accordingly.

$$G(s) = \frac{\omega_n^2}{s^2 + 2\zeta\omega_n s + \omega_n^2} \quad (1)$$

The above general equation describes the behaviour of a typical second-order function with no zeros. Here ζ and ω_n are damping ratios and the natural frequency respectively. The PID controller block was created within the Controller subsystem and the output of the PID controller was connected to the input of the pump motor. The PID controller block output is a weighted sum and the weights are the proportional, integral, and derivative gain parameters. Then the inputs from the temperature sensor were added to the motor controlling circuitry. The MATLAB function contains the program for how the pump speed has to be varied according to the volumetric breathing rates of the patient. The pump speed has to be varied between 10 l/min, 8 l/min, and 6 l/min with the change of the volumetric breathing rate of the patient.

PID controller was tuned automatically with the aid of the Control System Toolbox. The goals of the motor controlling circuit were to achieve a settling time of less than 5 seconds and to get a zero steady-state error to the step reference input.

2) *Circuitry Simulation and Experimental Analysis:* The circuitry simulation was run on Proteus 8.0 software. In a way of checking the Arduino program for errors, and specifically, to check the functioning of the breath rate monitoring coding, an experimental setup was built using the hardware components mentioned in Section II-B. However, due to the unavailability of the diaphragm pump, in place of it, a normal DC motor was used. The DC motor was checked for the RPM values corresponding to the flowrates of the pump.



Figure 7: Experimental Setup for Assessing the Motor Function

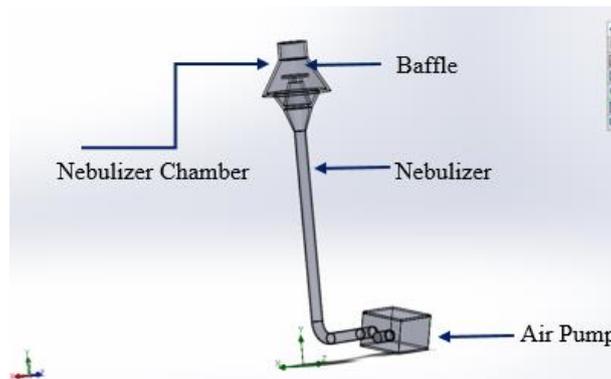


Figure 8: Domain Created on SOLIDWORKS

3) *CFD Simulation of the Compressed Airflow:* In order to incorporate design considerations into a prototype device consistent with project goals, an iterative design process was implemented. For this purpose, Computational Fluid Dynamics simulation was performed on the conceptual device solid models as depicted in Fig.8 and Fig. 9. SOLIDWORKS Flow Simulation and ANSYS Fluent software were utilized.

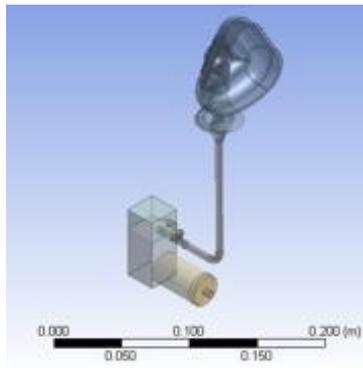


Figure 9: Domain Created on ANSYS Fluent

The values given in Table 1 were entered under the properties option of the two software.

TABLE 1
PARAMETER CHARACTERIZATION

Parameter	Value
Velocity	1.02 m/s, 1.36 m/s, 1.7 m/s
Flowrate	6 l/min, 8 l/min, 10 l/min
Pressure	101 325 Pa
Fluid Type	Normal Air

RESULTS AND DISCUSSION

A) PID Controller Simulation

Since PID tuning is an iterative process, obtaining gain values using automated tuning of the linearized model and testing the entire Simulink model via simulation were carried out a few times till the desired results were obtained. After performing a series of simulations and comparing them using Simulink, the most appropriate system response was chosen. Thus, Fig. 10, denotes the response of the entire closed-loop system. It fulfills the design requirements. With the change of the volumetric breathing rates, the flowrates of the pump change smoothly without any unrealistic spikes, in a settling time of 2.63 seconds. There's only a slight difference between the control input and the measured output.

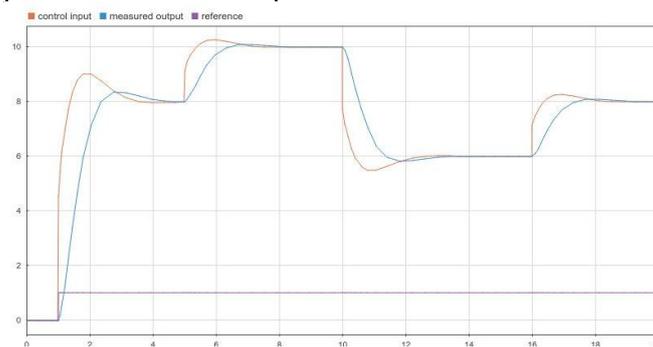


Figure 10: Closed Loop System Response (Flowrate vs Time)

B) Circuitry Simulation and Experimental Analysis

Due to the complexity of the circuitry, it was hard to simulate the entire circuit on Proteus software. Therefore, two errors were encountered as: “[SPICE] transient GMIN stepping at time=2.19633e-006” and “Simulation is not running in real-time due to excessive CPU load”. However, when the power supply-motor controller circuit was simulated separately, correct voltage values were displayed on the DC voltmeters. The terminal voltages of the motor were shown 12V as well. Thus there were no errors in the power supply nor with the motor controller circuitry.

All the components that were used in the experimental setup functioned according to the uploaded program. The DC motor speed was regulated as per the rpm values specified in the Arduino program. The respiratory monitoring coding functioned successfully. The DS18B20 temperature sensor was able to detect the small fluctuations of temperature between inhalation and exhalation. This particular experiment suggested that there were no shortcomings in the coding.

C) CFD Simulations

1) *Flow Simulation:* The simulation was turbulent and laminar and time-independent with air as the fluid. Therefore, the airflow through the pump assembly was modelled and assessed using the flow trajectories generated as a result. At the pump, a turbulent flow was to be observed as depicted in Fig.11.

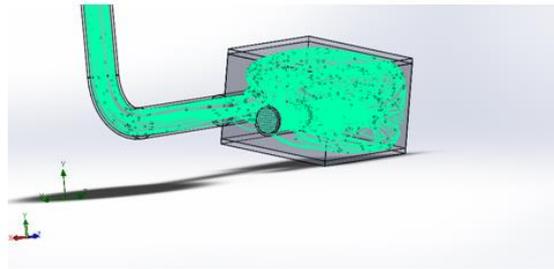


Figure 11: Flow Trajectories within the Pump

The flow generated from the outlet of the pump towards the nebulizer tubing shows the characteristics of laminar flow. The flow was steady. In addition to that, the flow of air through the nebulizer tubing was also examined to be uniform and laminar without any excessive turbulent flow or rotational flow pattern as depicted in Fig. 12. The presence of a rotational flow pattern is considered unacceptable because it imposes a restriction at recruiting drug particles and dispersing them through the mask and dispositioning them within the airways.

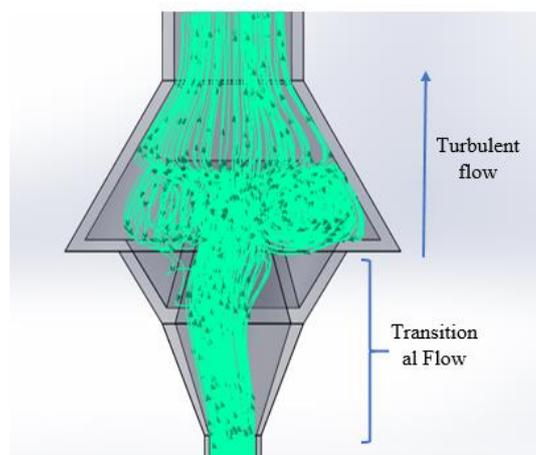


Figure 12: Flow Trajectories within the Nebulizer Tubing

Within the nebulizer chamber, pressurized atomization air is discharged from an orifice, and is directed against baffles, which causes the air to flow with swirling turbulence over the orifice. The turbulent swirling flow of the atomization air is what causes the droplets to decrease in size. The flow path of the aerosol through the nebulizer chamber towards the mask shows a rapid change of directions to facilitate condensation of any large droplets in the aerosol as presented in Fig. 13.

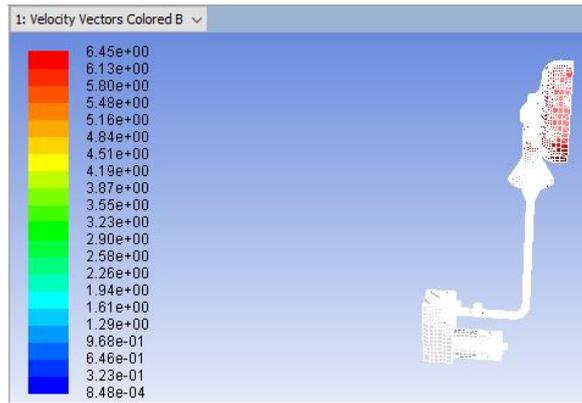


Figure 13: Flow Trajectories within Nebulizer Chamber

2) *Simulation of Velocity Distribution:* The graphical representation of the velocity distribution within the pump assembly is shown in Fig. 14. The velocity variation within the mask is denoted in red colour. In addition to the velocity variation, an energy convergence occurs within the domain. However, there were few difficulties encountered whilst using ANSYS, one of them was the inability of sectioning the pump assembly to analyze the flow rates at different parts of the assembly. Even after adding a boundary to the SOLIDWORKS model, it was unable to section the pump assembly and analyze the flow rates at different regions.

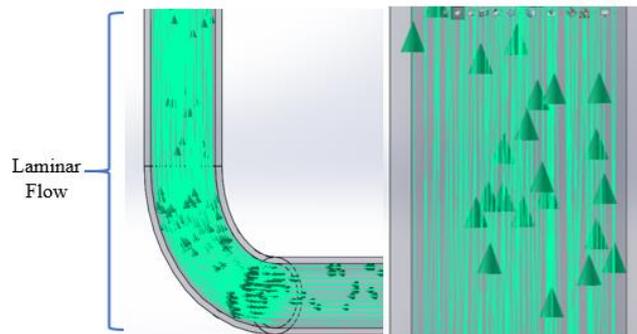


Figure 14: The Velocity Distribution within the Pump Assembly

CONCLUSION

Nebulizers is one of the oldest methods of delivering aerosolized drugs to the respiratory tract, mostly where it might become the primary site of action. Though this is widely used in hospital and home setting there are major draw backs. With newer technologies and various fundamental process have improved its performance and suitability to use with numerous drug formulations. Though MDI and Dry powder inhalers can be used to deliver drugs to respiratory tract it can never replace the nebulizer because patients who are critically ill, poor co-ordination techniques, young children, and many others may fail to use these effectively.

Insufficient drug delivery to effect site and wastage of the administrated drug dose is a major draw back in current clinical practice, where patient do not show the desired response. This particular issue is addressed by the current research. Patients have a bidirectional air flow during inspiration and expiration while conventional nebulizer has a unidirectional flow throughout the operational time. In the first phase of the research, the development of the temperature sensor-based algorithm for volumetric breathing rate detection, and the implementation of the compressor control circuitry (PID) were completed successfully where drug was delivered only during the inspiratory phase of respiration. By this we were able to reduce the drug wastage by nearly fifty percent. All the objectives were met. The simulation results obtained from Simulink validated the performance of the PID control unit. In addition to that, the results gained from the physical simulations carried out on SOLIDWORKS and ANSYS Fluent 16, were satisfactory. No substantial amount of turbulent flow or rotational flows were detected, within the device and this will help the delivery of the drug more distally with a cone front laminar flow.

Detecting the drug levels in nebulizing chamber will prevent continuous work up for the machine and also in situations where back to back nebulization (or continuous inhaled drug delivery) is required like in life threatening asthma treatment plan can be continued without interruption by detecting absent drug levels in the chamber.

Oxygen therapy mode where identifying patients desaturation and adding up of oxygen is a very important factor where patient can be already hypoxic or ventilation – perfusion mismatch which occur during the therapy especially in Asthma patients but may disadvantageous in severe COPD patients where this can increase partial pressure of carbon dioxide and exacerbate the respiratory failure.

In future developments of the model, addition of a method where each phase of breath, inhalation and exhalation identification may help to optimize the drug delivery in a bi-directional flow in a respiratory distressed patient where breathing pattern can be variable. But possibility of using volume and pressure change is difficult especially in open systems other than in closed breathing circuits like in invasively ventilated patients.

FUTURE WORK

As per the Section VIII of FDA regulations, in-vitro testing is required, prior to completing the product development. For this purpose, techniques like laser scattering or cascade impactor will be incorporated to actually determine, the size of the respirable droplet produced by the nebulizer and the amount of drug deposition (FDA, 2017). In addition to that, the device will be tested for the available drug types.

DECLARATION

All the authors mentioned in the manuscript have agreed for authorship, read and approved the manuscript, and given consent for submission and subsequent publication of the manuscript.

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Figures

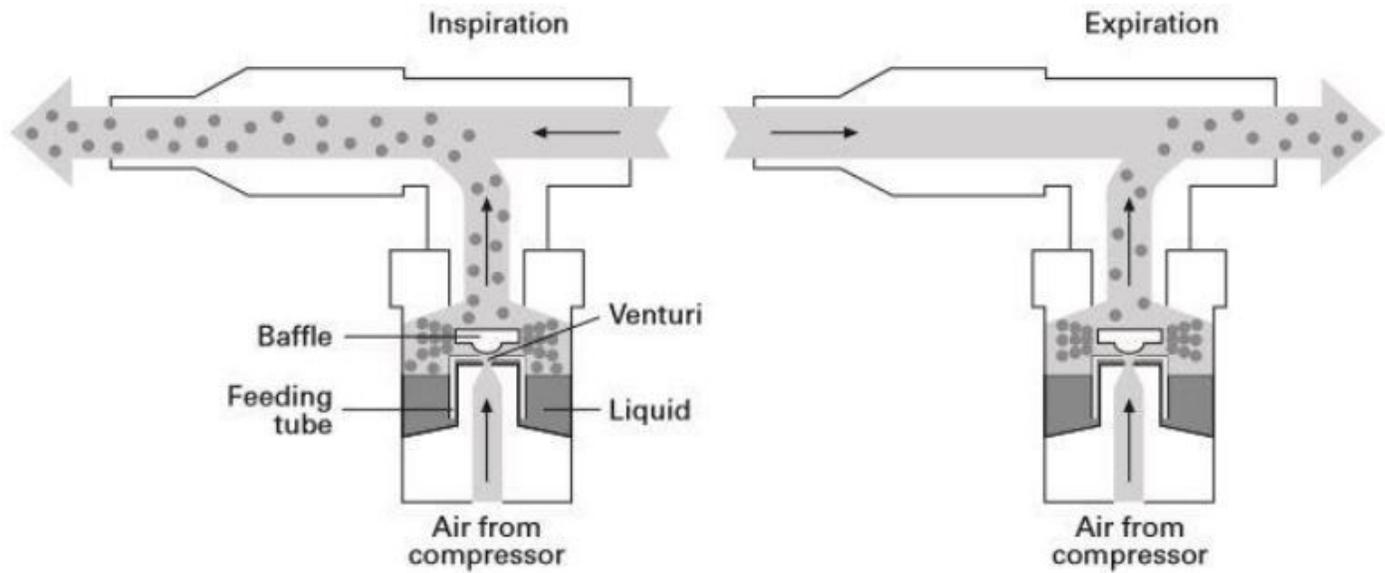


Figure 1

Conventional Nebulizer Design (O'Callaghan & Barry , 1997)

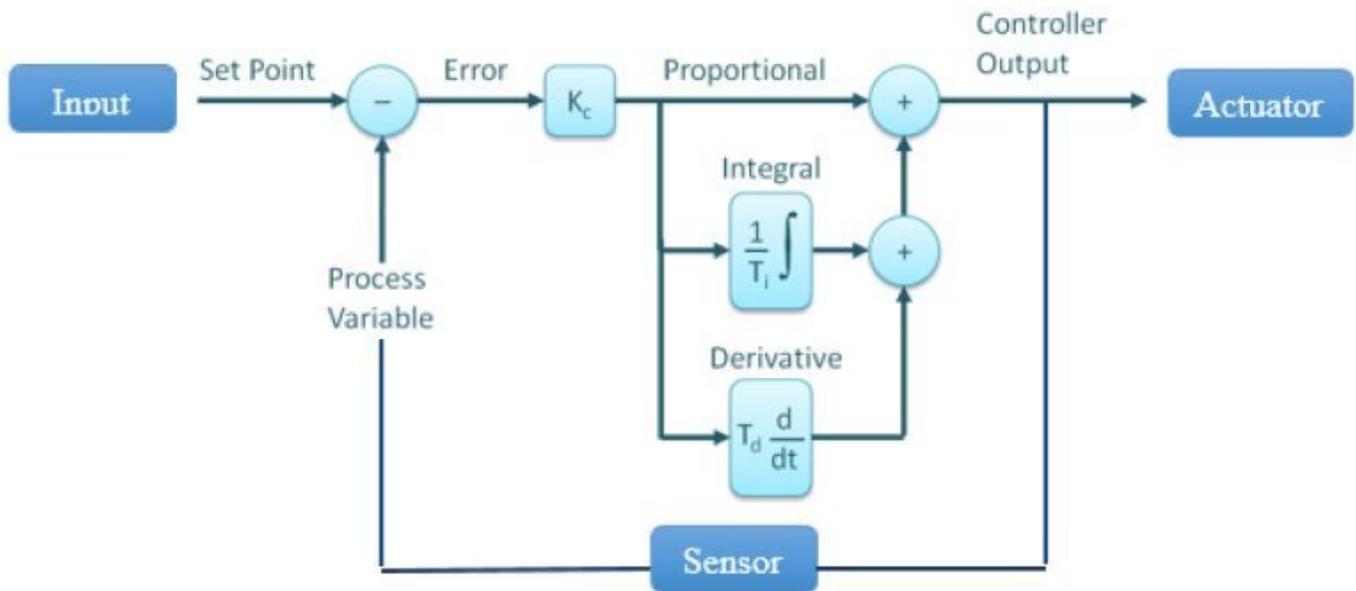


Figure 2

The Schematic of a PID Controller [17]

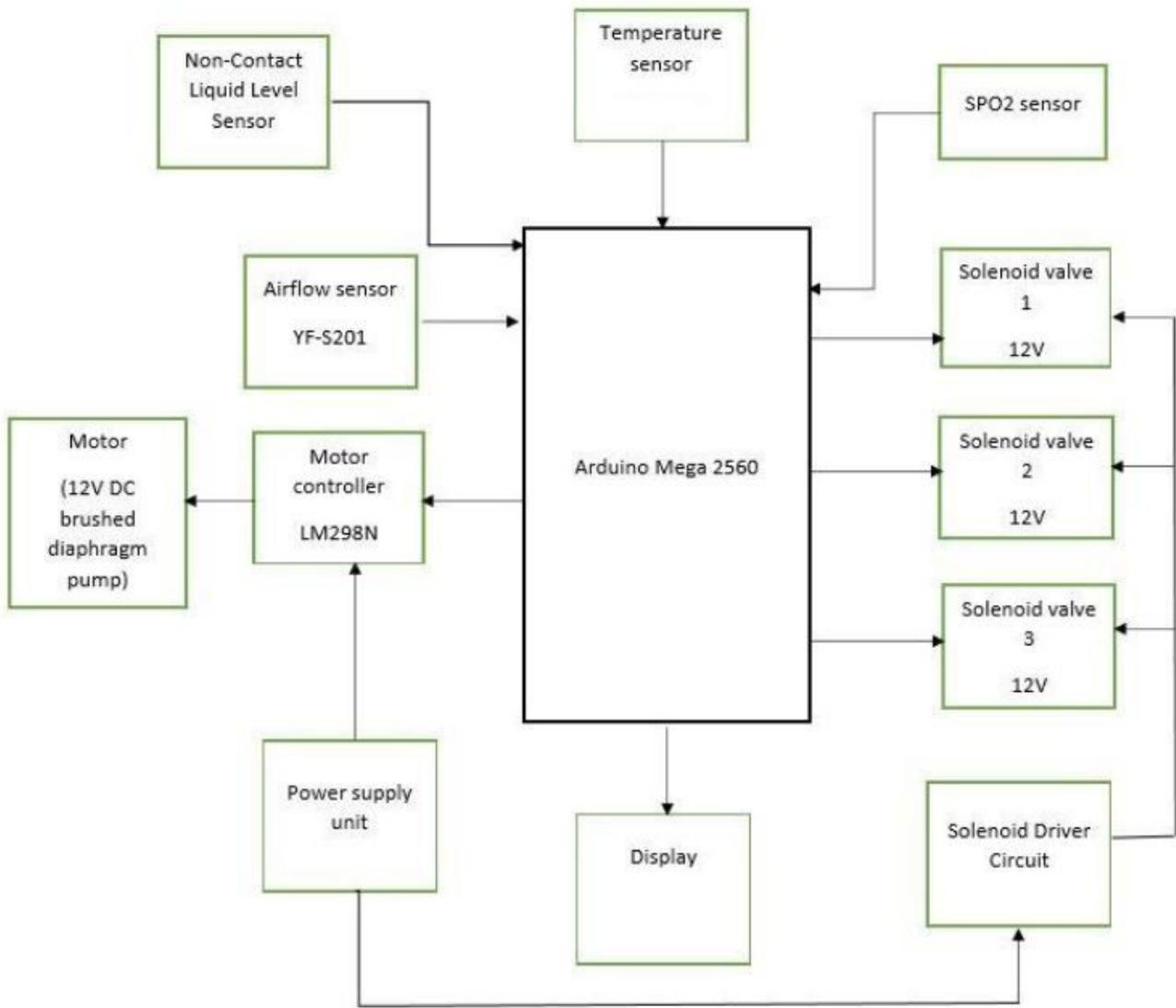


Figure 3

Conceptual Design of the Proposed Nebulizer



Figure 4

DC Micro Diaphragm Pump



Figure 5

3D Model of the Proposed Nebulizer

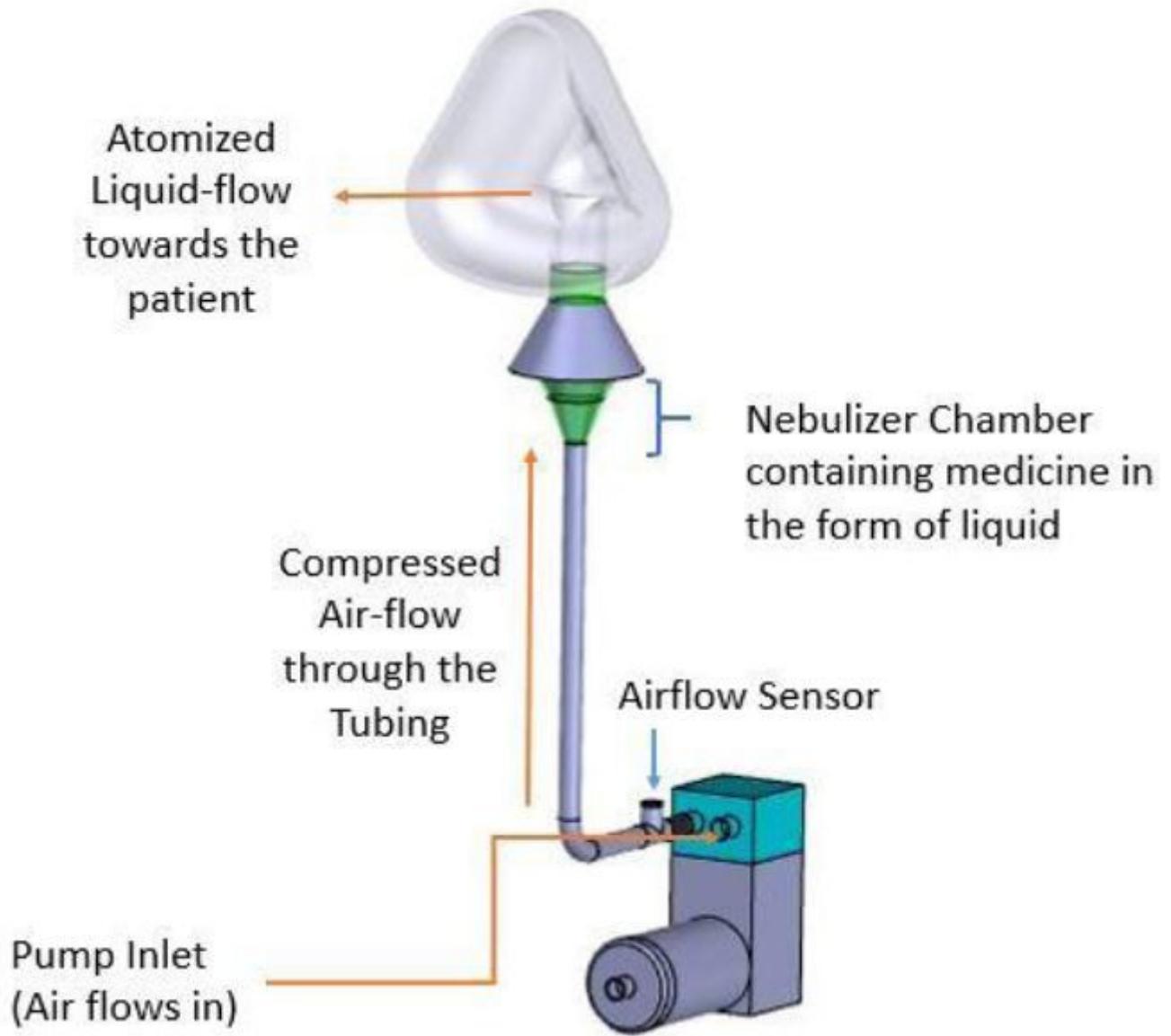


Figure 6

3D Model of the Pump Assembly



Figure 7

Experimental Setup for Assessing the Motor Function

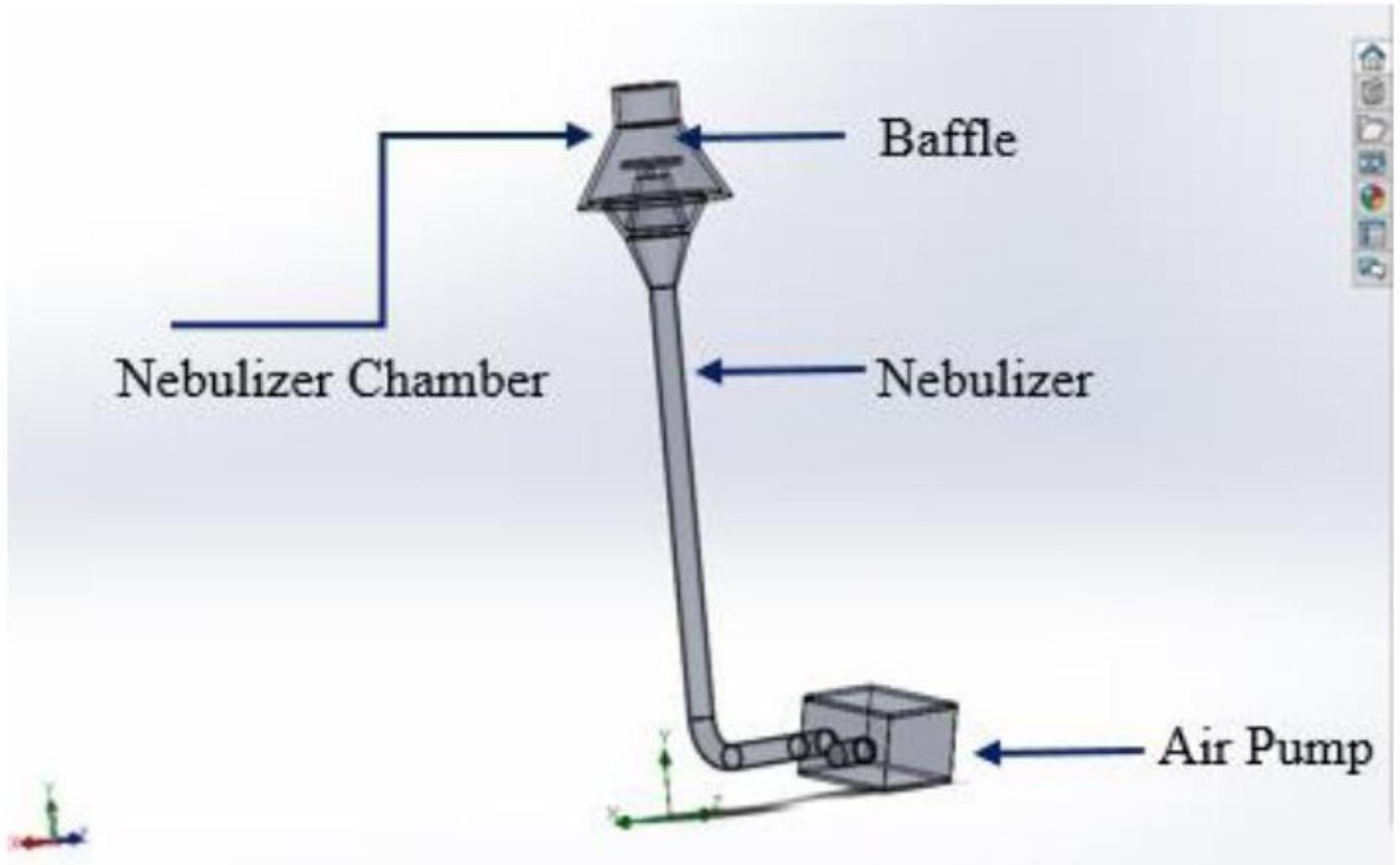


Figure 8

Domain Created on SOLIDWORKS

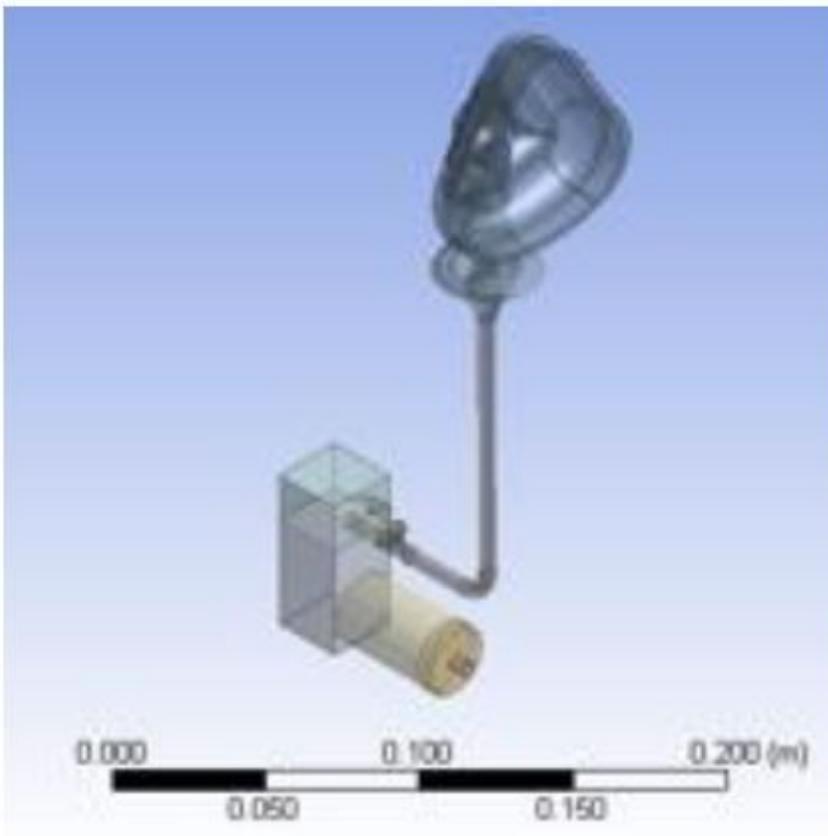


Figure 9

Domain Created on ANSYS Fluent

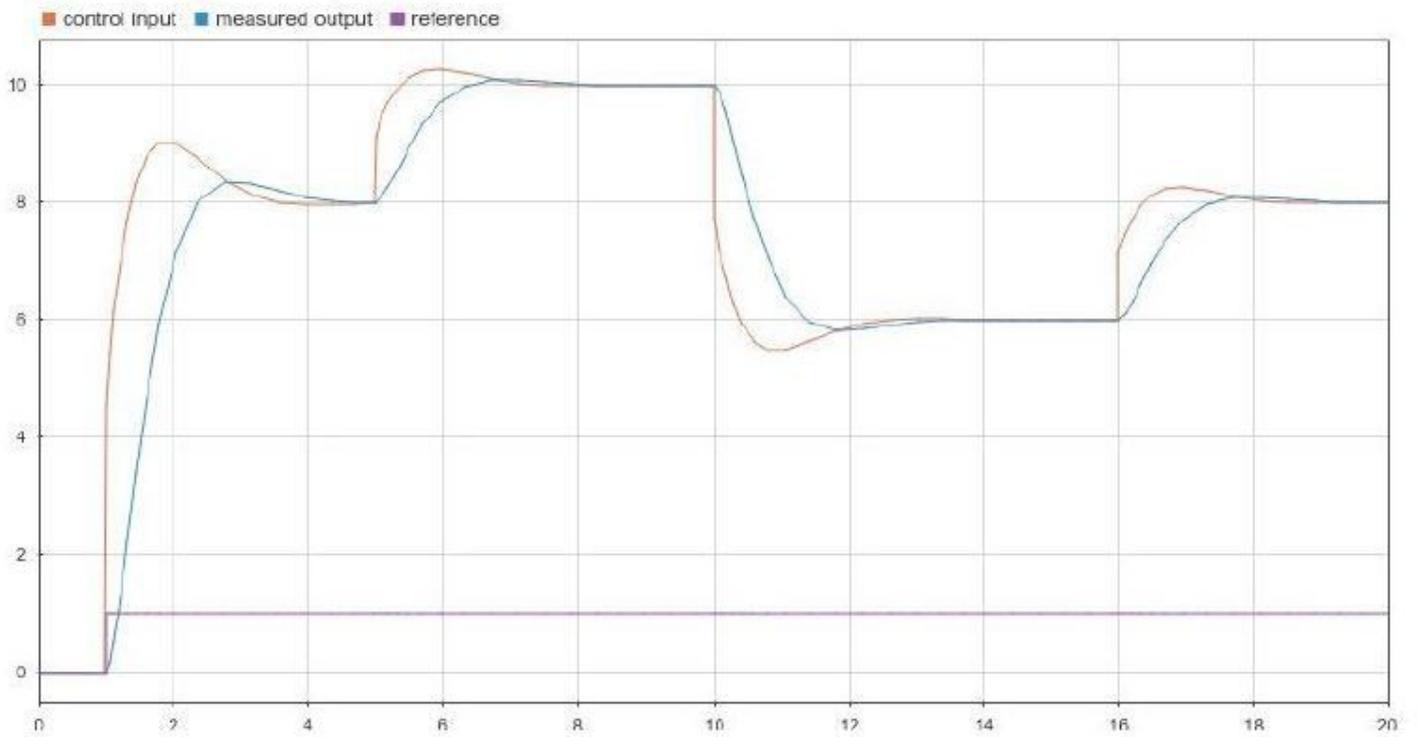


Figure 10

Closed Loop System Response (Flowrate vs Time)

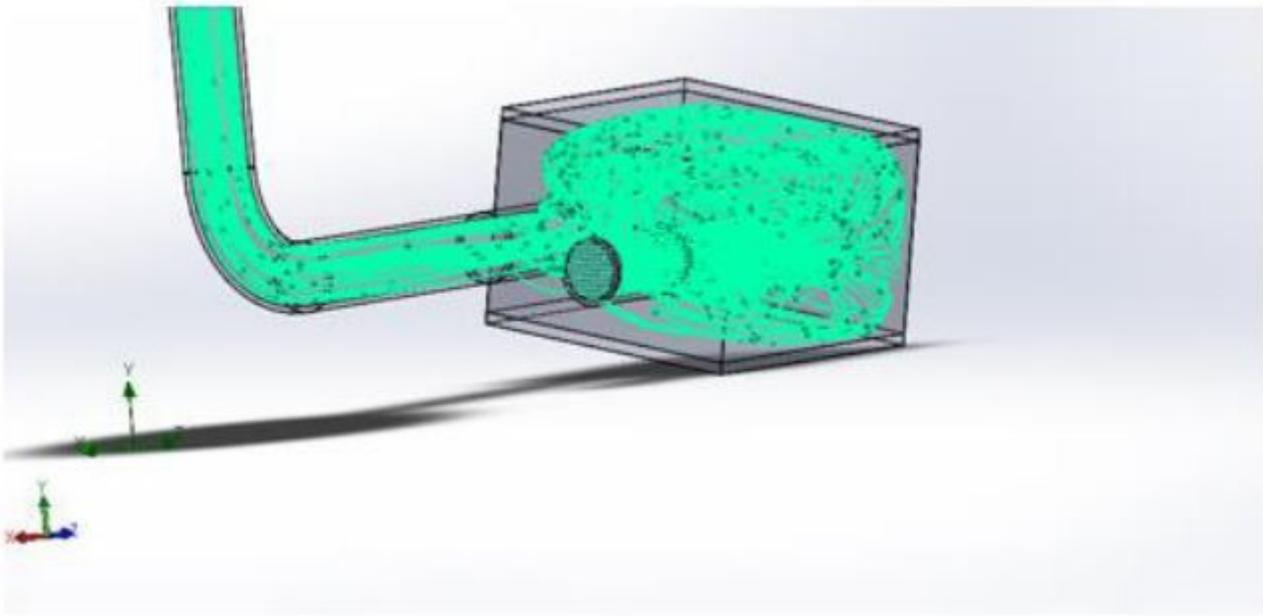


Figure 11

Flow Trajectories within the Pump

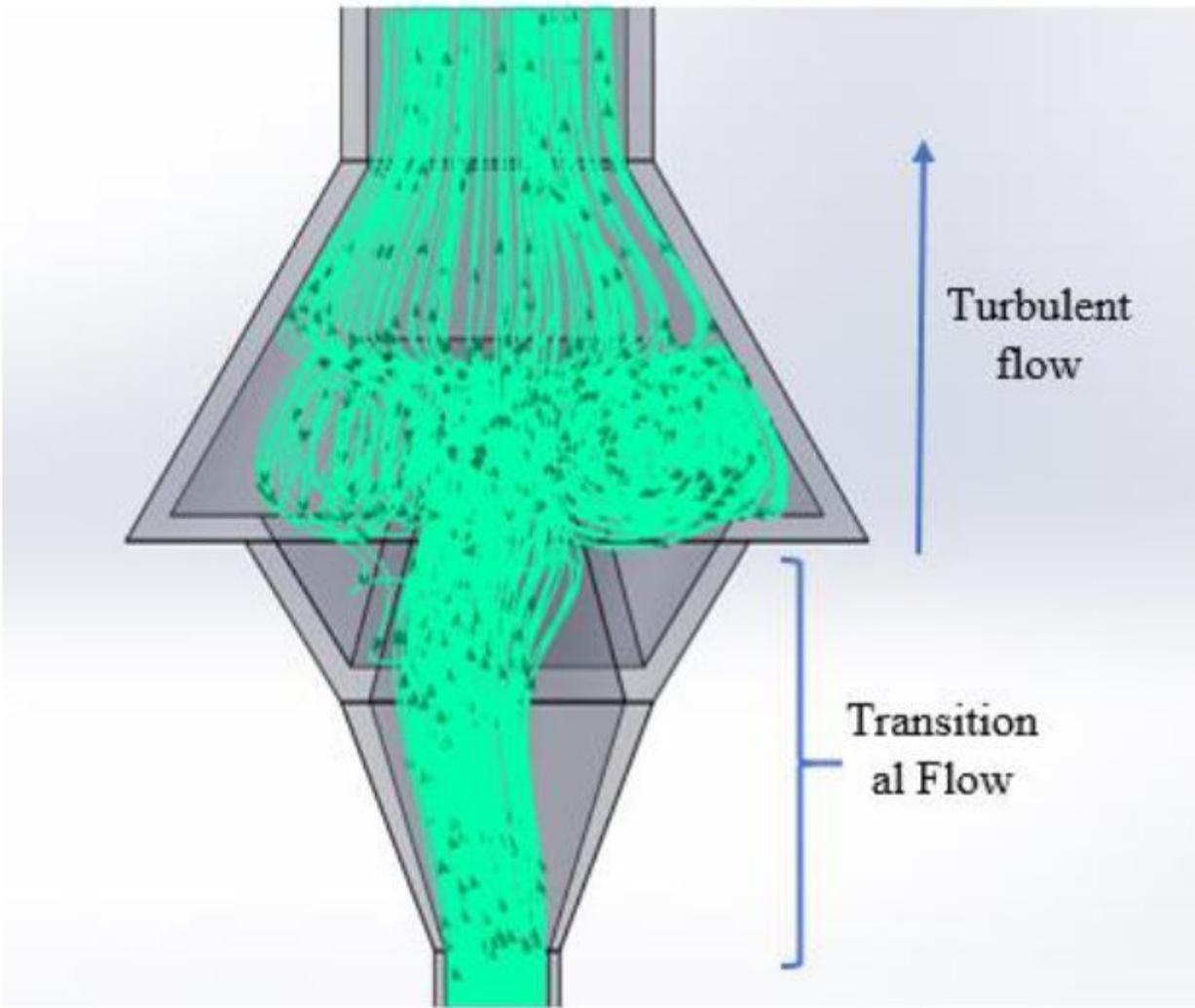


Figure 12

Flow Trajectories within the Nebulizer Tubing

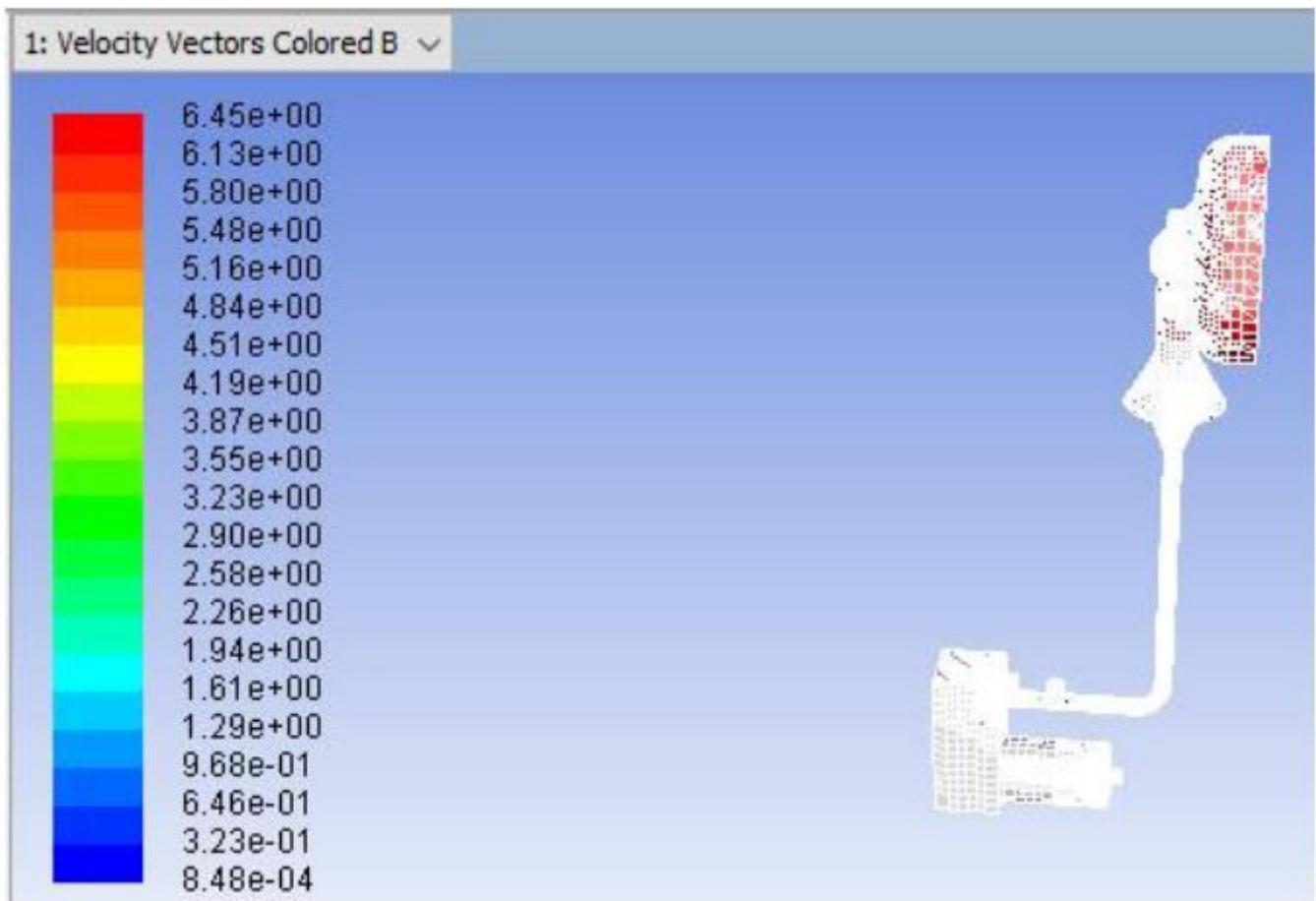


Figure 13

Flow Trajectories within Nebulizer Chamber

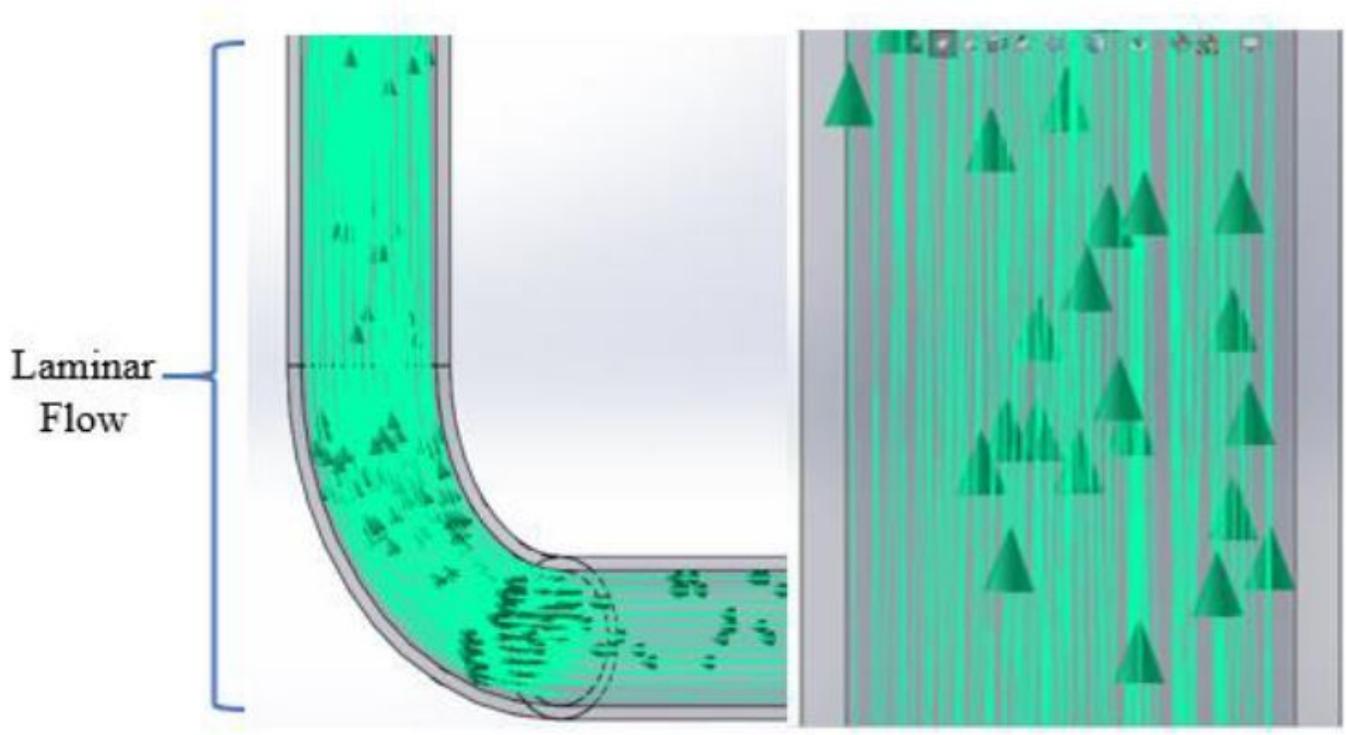


Figure 14

The Velocity Distribution within the Pump Assembly