Development and characterization of a system for measuring and analyzing the frequency response of transducers used in the ventilation of neonates and premature infants

S G M Santiago[1,2], D G Valério[2], J H Angelo[1], R Romano[1] and H T Moriya[2]

[1] Laboratory of Final Uses and Energy Management, Energy Center, Institute for Technological Research, São Paulo, 05508-901, Brazil
[2] Biomedical Engineering Laboratory, University of Sao Paulo, São Paulo, 05508-010, Brazil

saragm@ipt.br

Abstract. Intensive care equipment in premature neonates need specific pulmonary ventilation settings, due to their unique lung compliance and resistance, so as to avoid hyperventilation with large tidal volumes (VT) that can lead to lung injury. Thus, high-frequency ventilation has emerged as a strategy for newborns and preterm infants since it uses a volume below dead space at extremely high frequencies (between 5 and 15 Hz; 300-900 cycles/min), making it possible to obtain higher mean pressures in the airway with minimal volumetric variation in the alveolus. Lung ventilators need to be tested to assess their functioning and essential performance, and in Brazil the ISO IEC 80601-2-12:2020 standard describes the required performance tests with parameter tables for compliance, resistance, tidal volume, respiratory rate and pressure that simulate the ventilation characteristics of a newborn baby. The analysis of the frequency response of the sensors that make up the pulmonary ventilation system is important in the design and development phase of the medical equipment industry, and for this purpose a device that generates a sinusoidal signal for the frequency range of interest in ventilation therapy for premature neonates was developed. This system has a load that simulates the resistance and compliance parameters described in the regulatory standard. The device was characterized in terms of its linearity and frequency response, in order to enable evaluation of the ventilator transducers in respiratory rates, compliance parameters and pulmonary resistances that simulate a premature neonate.

1. Introduction

Intensive care medicine is essential for the treatment of critically ill patients. It requires quick decisions and difficult procedures from its professionals, such as intubation to ensure the ventilation of patients with oxygenation difficulties, for example. In this routine, it is crucial for the success of patient care,

that inconsistencies in the measurements made by its sensors are avoided, as they impair its essential performance. [1]

In hospitals, in neonatal intensive care units, lung ventilators that support newborns with respiratory failure have particular settings for this volume range, and it is known that the harm of hyperventilation in neonates with large tidal volumes (VT) can lead to lung injury by alveolar overdistension, in addition to the release of cytokines that contribute to the inflammatory process of tissues. [2]

As lung ventilators are essential components in a patient's recovery, these medical devices need to be tested to assess their functioning. In Brazil, the ISO IEC 80601-2-12:2020 standard describes the required performance tests for lung ventilators. One of these tests evaluates the equipment's deliveries in volume and pressure controlled ventilation by means of test scenarios, in which resistance and static compliance values are defined with an acceptable tolerance of 10%. These parameters are adjusted in a lung simulator, usually consisting of bellows and springs, these adjustments allow simulating lung conditions for different age groups, including neonates. Lung ventilators have their requirements evaluated by commercially available ventilation analyzers with the necessary requirements to meet the standard. [3]

High-frequency ventilation has emerged as an interesting ventilatory strategy for newborns and premature infants, as it uses a volume below dead space at extremely high frequencies (between 5 and 15 Hz; 300-900 cycles/min), thus making it possible to obtain higher mean pressures in the airway, but with minimal volumetric variation in the alveolus. [4]

The analysis of the frequency response of the transducers used in pulmonary ventilators is an important step in the design and development phase at the medical products industry, therefore, it was noted the need to develop instrumentation capable of evaluating and homologating the transducer components of the ventilators in terms of their response to the entire frequency range provided by the standard and the high-frequency range used in treatment therapies for preterm infants and neonates, allowing the best choice by the manufacturer in the product development phase.

This study presents a prototype under development for these analyzes and the characterization of output parameters.

2. Methodology

2.1. Materials

A Linear Variable Differential Transducer (LVDT) (244-0000, TRANSTEK, USA) was used to measure the volume delivered by the piston in the developed device, since it presents a high resolution, high linearity and almost zero friction in the piston. The LVDT with DC output was coupled to the linear actuator.

In order to receive the position signal from the LVDT, an AD/DA converter (USB6008, National Instruments, USA) was used. This AD/DA converter can receive at its input a voltage from -10V to +10V and is able to output a sinusoidal signal with amplitude between 0 and 5V. As in the project negative voltages will also be applied at the input of the linear actuator, it is necessary to add a subtractor in the signal conditioning circuit, which will be described below.

The control routine for the device was developed in a virtual instrumentation environment (LabView, National Instruments, USA), due to compatibility with the AD/DA converter used, and the control output will also be transmitted to the AD/DA converter.

To activate the linear actuator, it is necessary to use a current driver circuit, which will feed a linear actuator responsible for moving a piston that has been removed from a small animal ventilator (flexiVent, SCIREQ, Canada). This actuator consists of a solenoid, so that the application of a positive voltage at its input generates a movement in one direction, and the application of a negative voltage generates a movement in the opposite direction.

2.2. Methods

In the construction of the device the LVDT piston was coupled to the linear actuator, so that it measures its position. The transducer LVDT output was taken to the AD/DA converter, which in turn sent the signal to a computer. In addition, a control routine was developed in which it is possible to define the desired amplitude and frequency for a sinusoidal movement of the linear actuator. From the input of these parameters, the developed routine generates an output to the AD/DA converter, which transmits it to the linear actuator conditioner and driver circuit, which generates its motor movement, as shown in Figures 1 and 2.

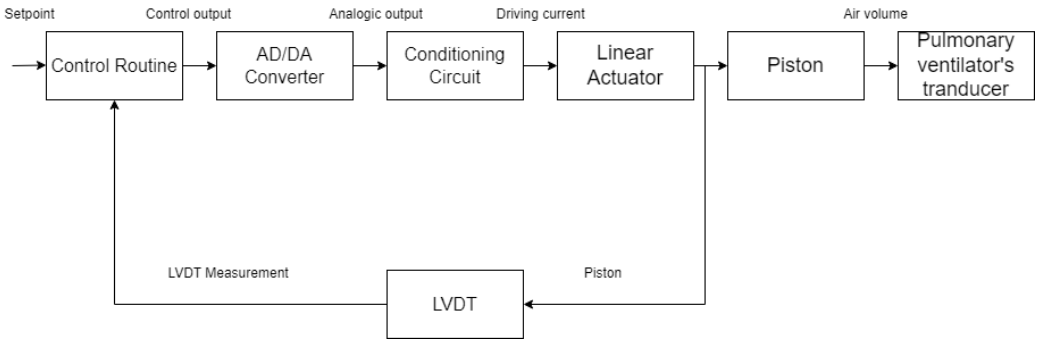

Figure 1. System's schematic

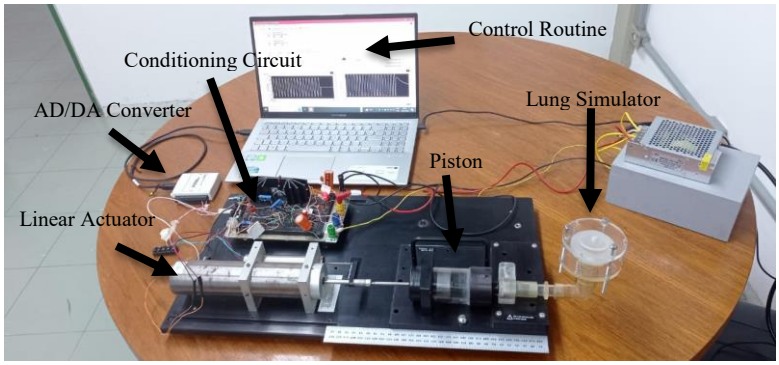

Figure 2. Measure System

From this assembly, it was necessary to test and characterize the system with the developed control routine, in order to evaluate its performance and adjust the control parameters. The analyses were performed either with the system open or with the lung simulator as load at the output.

As the total length of the tube is 10 cm, the plunger was centered at 5 cm. The variation in tension read by the LVDT and the time taken to carry out the course were acquired and the distance that the plunger traveled was measured in cm. For this, the initial position in the middle of the tube was considered 0 and steps of 0.5V; 1.0V; 1.5V; 2.0V were applied at the circuit input. In this way, the LVDT proportionality constant was calculated.

To evaluate the frequency response of the developed system, the proportional, integral and derivative gain of the PID controller were set to 1.00, 0.01 and 0.00, respectively. In addition, the error margin was specified at 0.05V. These values were chosen after tests to determine the best control parameters for the desired performance. For the no-load system, the desired amplitude was readjusted by a factor of 1/f, multiplied by the total voltage excursion used. This was done after testing the response time of the linear actuator, where it was possible to verify that it was not able to travel the total distance for frequencies greater than 10 Hz.

A similar measurement was performed with the developed load in the system's outlet, this load consists of a lung simulator built using a bellows and a set of springs, as shown in Figure 3. The lung simulator was characterized with an average compliance of approximately 0.5mL/hPa, simulating the lowest compliance described by the standard. [5] Due to limitations of neonatal lung simulator volume, the maximum amplitude applied was 1V. Then, with the increase of frequency, for those where the system output saturated and was not able to follow the specified sinusoid, the applied amplitude was decreased by 0.1V until the system operated out of saturation.

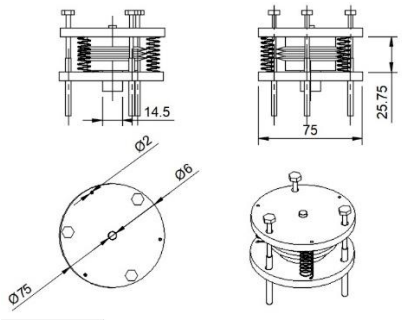

Figure 3. Lung Simulator [5]

3. Results

3.1. Device's control routine

The developed virtual instrument aims to enable the control of a linear actuator in a sinusoid motion (Control Routine in Figure 4). The developed control method consists of a PID controller with an automatic cascade adjustment, so that the input of the system is adjusted by a second loop, which allows a higher accuracy in the specified amplitude at the output. Hence, it is necessary to specify an error margin, which determines the upper and lower thresholds of action of the PID control, so that the second loop adjusts automatically the input when the system is outside of the specified error margin. The schematic of the control system can be seen in Figure 4.

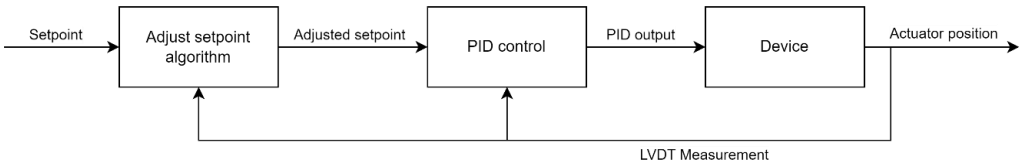

Figure 4. Control System Schematic

Thus, the front panel of the developed control system can be visualized in Figure 5. In this panel, it is possible to specify the sampling frequency of the output signal, as well as the desired parameters of the sinusoidal signal, such as frequency, peak amplitude and an offset. In addition, one must specify the error margin for activation of the cascade setpoint adjustment algorithm. Finally, one can change and adjust the control parameters of the PID system. It is indicated in red in Figure 5 which are the parameters chosen by the operator.

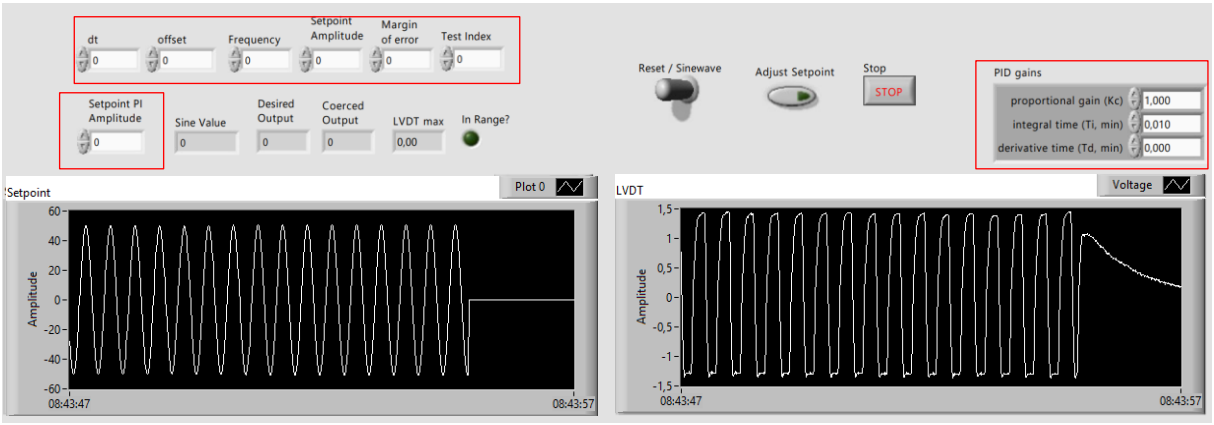

Figure 5. Virtual instrument interface

3.2. Device's hardware

The hardware works as a current driver for the linear actuator, implemented through a subtractor circuit that decreases the received signal by 2V, since the AD/DA converter is only capable of producing positive voltages at its output.

After performing initial control tests, it was observed that the AD/DA converter was saturating for any proportional gain applied, since it has 5V as output limitation. Therefore, a proportional gain equal to 2 was added to the conditioning circuit, by means of a signal multiplier.

The circuit can be subdivided into three sections, A, B and C, as shown in Figure 6. In part A, it is possible to observe the power driver, which consists of a class B amplifier. Part B shows the voltage gain of 2 installed in hardware, while part C shows the 2V subtractor. In particular, section C.1 has a circuit with a potentiometer that sets the subtraction voltage at 2V.

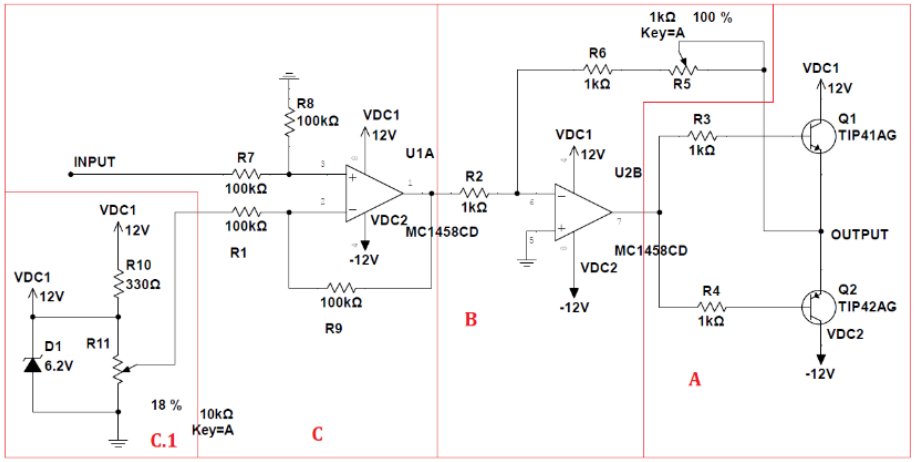

Figure 6. Conditioning Circuit

3.3. LVDT Characterization

System's output noise with zero input was evaluated and the maximum magnitude for the measured noise was equal to 0.025V.

In Table 1, one can visualize the results of the application of steps in the input of the linear actuator. Through the initial analysis of the component, it was possible to verify that at the end of the linear plunger the voltage read is 5.8V. Thus, since the piston has a total length of 10 cm, the LVDT proportionality constant is 1.16 V/cm, when adopting its center as the point of reference.

Table 1. Response of the linear actuator in the application of steps with different voltage values.

Applied voltage (V)	Voltage difference (V)	Travelled Distance (cm)
0.5	5.8	5.07
1.0	5.9	5.09
1.5	5.8	5.01
2.0	5.8	5.04

3.4. System's characterization – Frequency response with no load

In Table 2, it is possible to observe the setpoint amplitude for each frequency. In addition, one can see the obtained output for the respective frequency and the linear gain.

Table 2. Setpoint, adjust by the cascaded control and output in test without load.

Frequency (Hz)	Setpoint (V)	Output (V)	Relative Error	Linear Gain
5	1.00	1.02	-0.02	1.02
6	0.83	0.84	-0.01	1.01
7	0.71	0.70	0.01	0.99
8	0.63	0.63	0.00	1.00
9	0.56	0.56	0.00	1.00
10	0.50	0.48	0.04	0.96
11	0.45	0.44	0.02	0.98
12	0.42	0.40	0.05	0.95
13	0.38	0.34	0.11	0.89
14	0.36	0.33	0.08	0.92
15	0.33	0.32	0.03	0.97

3.5. System's characterization – Frequency response with load

In Table 3, it is possible to observe the setpoint amplitude for each frequency and the adjust made by the cascaded portion of the control system. In addition, one can see the obtained output for the respective frequency and the linear gain was shown.

Table 3. Setpoint, adjust by the cascaded control and output in test with load.

Frequency (Hz)	Setpoint (V)	Output (V)	Relative Error	Linear Gain
5	1.0	0.96	0.04	0.96
6	1.0	0.97	0.03	0.97

7	1.0	0.97	0.03	0.97
8	1.0	0.88	0.12	0.88
9	0.9	0.77	0.14	0.86
10	0.8	0.67	0.16	0.84
11	0.7	0.65	0.07	0.93
12	0.7	0.57	0.19	0.81
13	0.6	0.56	0.07	0.93
14	0.6	0.45	0.25	0.75
15	0.5	0.47	0.06	0.94

4. Discussion

As it can be observed in the analysis of the frequency response with no load, the developed system adjusted the input amplitude, using the PID control with cascaded setpoint adjustment, so that a peak voltage close to the desired one could be measured at the LVDT output. The linear gain varied between the limits 0.89 and 1.02, which was a satisfactory performance for the application of the instrument.

In the frequency response with load, it was necessary to make manual adjustments in the amplitude so that the system delivers the maximum possible volume to the lung without being lost due to saturation of the output. With this adjustment, it was possible to have the system gain above 0.75.

5. Conclusion

The results obtained in the system characterization tests show that it was possible to reach a 15 Hz frequency with the built device and linear behavior for the evaluated frequencies. Additionally, the control system was able to adjust the output when the load was introduced, maintaining the linearity trend for lower frequencies. For higher frequencies, there is still a need for manual adjustment of the system parameters, but as it is a prototype in the development phase, the results are considered satisfactory.

For future work, it is intended to evaluate commercial sensors with known technical specifications so as to analyze their behavior in conditions that simulate ventilation in neonates and premature infants.

6. References

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