THE PORTABLE VENTILATOR TESTER

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ABSTRACT

The ventilators are the lifesaving equipment for helping the patients who cannot breathe properly or when they cannot breathe on their own. The ventilator is often used during surgery and for recovering from surgery or used when having difficulty breathing on your own. Ventilator accuracy is important. Maintaining a ventilator effectively at all times is also necessary. Therefore, the development of a ventilator tester to verify the operation of the ventilator was proposed. The cost of a prototype is much lower than the commercial device. The designed ventilator tester is based on the principle of calibration graph relationship between flow sensor and pressure sensor with standard flow rate and measured standard pressure measured by the flow rate and pressure standard calibrator respectively. The designed ventilator tester consists of 3 main components: 1) The input part: consists of standard flow rate and pressure value, flow meter sensor SENSIRION SFM3000 and pressure sensor MPS20N0040D-S, 2) The processing unit: comprising of ESP-32 microcontrollers, programmed with C language, 3) Display part with an HMI display: which can display the parameter of the ventilator with values of Tidal Volume, Respiration Rate, I: E Ratio, Peak Inspiratory Flow, Peak Inspiratory Pressure and Positive End Expiratory Pressure. The results of the performance test for measuring the value of Tidal Volume, Respiration Rate, I: E Ratio, Peak Inspiratory Flow, Peak Inspiration Pressure and Positive End Expiratory Pressure compared with the Gas Flow Analyzer showed that the average percentage of error of the six parameters were acceptable according to the testing procedures and standard for medical measuring devices, Department of Medical Sciences, Ministry of Public Health, Thailand and were 6.19%, 2.37%, 7.46%, 3.39%, 0.97%, and 2.54%, respectively. The proposed prototype cost is 6500 Baht.

Keywords: ventilator, ventilator tester.

1. INTRODUCTION

Respiratory activity is an involuntary and life-sustaining function in humans[1]. The patient, on the other hand, needs breathing aid, such as during surgical operations involving general anesthesia or due to respiratory insufficiency. There are two types of medical ventilation such as mechanical ventilation and noninvasive ventilation. For mechanical ventilation, mechanical ventilators were necessary. In the severe case of a covid-19 pandemic, the virus cause damage to the lungs. The patient's SpO_2 level drop and hard to able breathe. The ventilator was used to alleviate these by push air into the lung to increase the oxygen level. However, although a ventilator is useful for treating patients some risks need to be watched. In particular, the measurements such as pressure and flow rate used in the ventilator system must be accurate following the accuracy of the respirator. The most significant dynamic parameters, like Tidal Volume (TV), Respiration Rate (RR), I: E Ratio, Peak Inspiratory Flow (PIF), Peak Inspiration Pressure (PIP), and Positive End Expiratory Pressure (PEEP) are also needed to consider.

Belforte et al. [1] proposed a model of a fully pneumatic gas-fueled variable volume control ventilator, as well as two types of ventilator analyzers that replicate the breathing capacity and resistance of babies, children, and adults. Control and monitoring of all respiratory parameters are possible with custom-developed software. All prototypes performed admirably, proving those novel breathing mechanisms and testers are feasible.

Zhang et al. [2] developed a Ventilator Tester Calibration Equipment that is fully integrated. A traceable platform is being developed for the calibration or verification of ventilator testers, which includes calibration modules for both static and dynamic parameters including gas flow rate and static pressure. However, the most important dynamic parameters are still being established, such as tidal duration, airway peak pressure, PEEP, and oxygen concentration.

In this paper, a proposed prototype of the portable ventilator tester for verifying the operation on the ventilator was designed and constructed for verification the operation of the ventilator by measure parameters: pressure, volume, flow rate, using a microcontroller to process and show results with HMI display. The prototype is small in size and measures multiple parameters by use flow and pressure. In the experiment, the parameter of the ventilator was set to test the performance in real conditions under the testing procedures for medical measuring devices Department of Medical Sciences, Ministry of Public Health, Thailand.

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2. BASIC CONCEPT

This paper consists of four basic concepts that relate to the prototype: ventilator parameter, flow measurement, pressure measurement, volume measurement, the procedure for verifying the operation, and accuracy of ventilation controls and indicators.

2.1 Ventilator parameter

The basic essential features of a ventilator should be as follows

1. The inspiratory pressure connected to the patient's respiratory tract should be adjusted from 5-30 cm. water that makes a pressure difference enough to push the air pass through the lungs without harm to the air sacs, lungs.
2. The duration of the inhalation period should be adjusted between 0.5-2 seconds and the duration of the exhalation period should be adjusted to be between 1-5 seconds. The proportion of inhalation and exhalation time should be adjusted so that the ratio of I: E is 1: 1.5 to 1: 2.5.
3. The respiratory rate should be adjusted from 6-40 times/minute.
4. The volume of the inhaled air should be measured every breath cycle.
5. The airflow rate can be adjusted up to 60 l / min.

The experiment will follow the above setting. The relationship of volume, flow rate, and pressure according to time can get basic parameters of the ventilator as Tidal Volume (TV), Respiration rate, I : E ratio, PIF, PIP, and PEEP. Each parameter can determine from Figure 1.

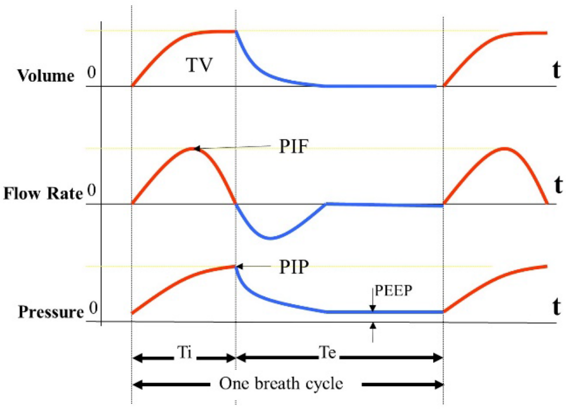


Figure 1. The volume /time, Flow rate/Time, and Pressure/ time graph during the breath cycle and the related parameter were shown in the graph.

2.1 Flow measurement

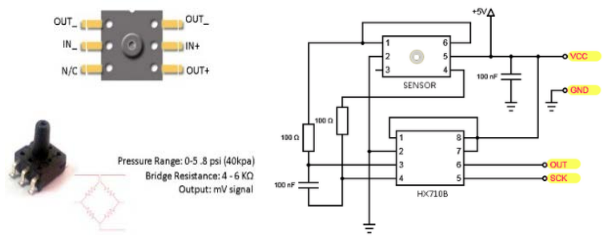
This research includes sensors for measuring inhalation, exhalation, and proximal flow, as well as gas mixing in ventilation and anesthesia applications. The Sensirion's flow platform SFM3xxx [3] was chosen. They accurately measure the flow rates of air and other non-corrosive gases in both directions since this sensor is fully calibrated and temperature compensated. They're also remarkable for having a low-pressure drop and fast signal processing. It's a digital flow meter that works well in high-volume applications. Because of the flow channel's nature, the sensor part has a very low-pressure drop, making it ideal for medical ventilation and respiration applications. A silicon sensor chip SF05 is used in the flow meter, which includes an amplifier, A/D converter, EEPROM memory, digital signal processing circuitry, and interface, as well as a thermal mass flow sensor element. The SFM3000 has a digital 2-wire I2C interface and runs on a 5 Volt supply voltage. Internally linearized and temperature compensated measurement results are obtained.

The following formula must be used to transform the calculated flow into [lpm]:

$$volume\ flow\ rate\ [lpm] = \frac{measured\ value - offset\ flow}{scale\ factor\ flow} \quad (1)$$

2.2 Pressure measurement

The pressure measurement in this study is the electronic pressure measurement base. The Wheatstone bridge and amplifier are used to measure the pressure. Pressure sensor MPS20N0040D-S [4] has the measuring range :0-5 .8 psi (40kpa) within the ventilator range 0-100 cmH2O as shown in Figure 2 (a). The HX710B chip is intended to interface directly with a bridge sensor in weighing scales and industrial control applications. When a 5V reference voltage is connected to the VREF pin, the input low-noise amplifier (PGA) has a fixed gain of 128, corresponding to a full-scale differential input voltage of 20mV. The system clock is provided by the on-chip oscillator, which does not require any external components. Figure 2 (b) is the schematic diagram of the HX710B module and pressure sensor. The pressure sensor module's measurement range is noted as 0-5.8 psi. When the psi unit is converted to the SI unit Pascal (PA), the pressure sensor's measurement range is 0-40 kpa.



(a) (b)

Figure 2. (a) Pressure sensor MPS20N0040D-S (b) The circuit diagram of pressure measurement [5]

2.3 Volume measurement

The volume of airflow can calculate from volume flow rate and time with the formula below

$$volume = volume\ flow\ rate\ [lpm] x\ time \tag{2}$$

2.4 The procedure for verifying the operation and accuracy of ventilation controls and indicators

Attaching the ventilator to a lung simulator or ventilator tester and comparing calculated values to settings on the ventilator was a common technique for inspecting the operation and accuracy of ventilation controls and indicators. The research was done according to the manufacturer's guidelines for proper ventilator settings to ensure proper operation and accuracy. According to the J. Tobey Clark et al. [6] and Testing Procedures for Medical Measuring Devices (Ventilator) [7], the calculated values should usually be within 10%. The tidal volume as determined by the volume monitor should be registered. If the ventilator fails to breathe circuit compliance, measure circuit compliance and apply it to the total volume at the exhalation's outlet. If the ventilator does not have breathing circuit compliance, measure circuit compliance and multiply it by the total volume at the exhalation valve or PEEP valve's outlet, if necessary. The delivered tidal volume can also be estimated by measuring the test lung and breathing circuit compliance (C) by the peak inspiratory pressure (PIP) (V = C PIP). Deliver a fixed volume (same volume as the ventilator) to the breathing circuit and test lung with a large syringe, and record the resulting change in pressure at the inlet of the test lung to determine compliance. The compliance is calculated by dividing the supplied volume by the recorded pressure. The volume estimated should be within 10% of the tidal volume set. Keep track of the number of breaths that take in a minute. Confirm that the calculated rate is within 1 breath/min of the set rate (high set rates can be 2 breaths/min). Enable the spontaneous breath indicator by triggering the test lung, and make sure the respiratory rate monitor is set to spontaneous breaths.

3. PROTOTYPE DESIGN

The prototype was designed and divided into 4 parts which are the power supply unit, processing unit, heating unit, and temperature measurement unit. The diagram of the prototype design is shown as follows:

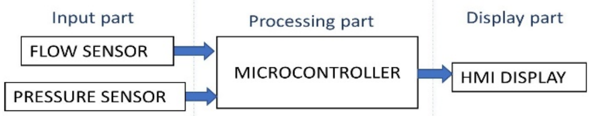


Figure 3. Diagram of the ventilator tester prototype

According to Figure 3, the system starts from the input part which is composed of the flow sensor, and the pressure sensor was mainly used to detect airflow rate and pressure as shown in Figure 4. For the flow sensor, we choose flow meter sensor SENSIRION SFM3000 which is a medical-grade sensor with a flow rate range ±200 l/min. The accuracy and sensitivity of the flow sensor are ± 0.05 slm and < 0.05 slm respectively. The MPS20N0040D-S pressure sensor was chosen to measure pressure. The pressure measurement range 0- 100 cmH_2O. The accuracy of the pressure sensor was 0.25% FS. The processing unit is used to get and calculate the related parameter from the sensing unit. The esp32 [8] was used as a microcontroller in this part because of it feature can support future development. The display unit uses the 3.2" Human Machine Interface (nx4024k032) [9] display to display all related parameters. The overall circuit use in the designed prototype was shown in Figure 5.

(a) Sensirion SFM3000 flow sensor (b) MPS20N0040D-S pressure sensor

Figure 4. The sensor used in this prototype

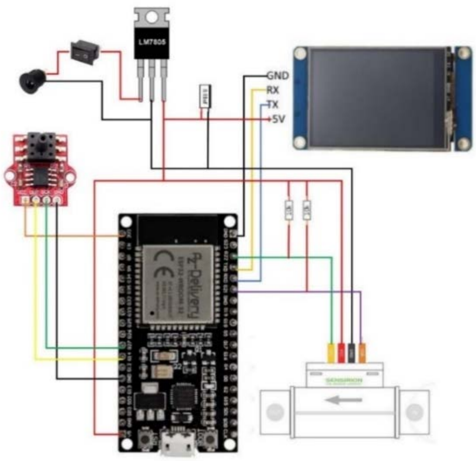


Figure 5. The overall circuit use in the designed prototype.

The display design uses Nextion Editor software for the HMI GUI development. The operation of the HMI display when press button A of the first page the display will change to all parameter page Figure 6(b). When the B button was pressed, the display will change to the pressure data page (Figure 6 (c)). If the B button was pressed the display will change to the volume data page (Figure 6 (e)). If the D button was pressed the display will change to the flow data page (Figure 6 (c)). Case the E button was pressed the display will change to the all-parameter page (Figure 6 (b)).

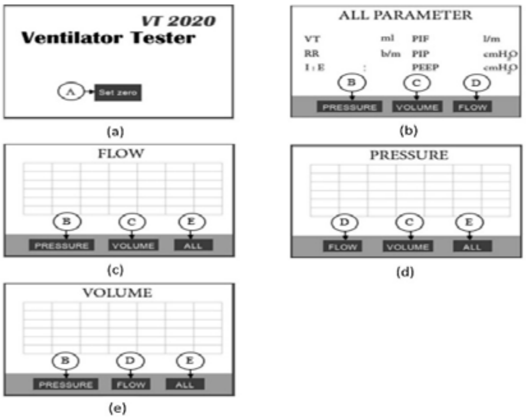


Figure 6. The display design (a) the 1st page when power on, (b) the all-parameter page, (c) the flow data page, (d) the pressure data page, and (e) the volume data page.

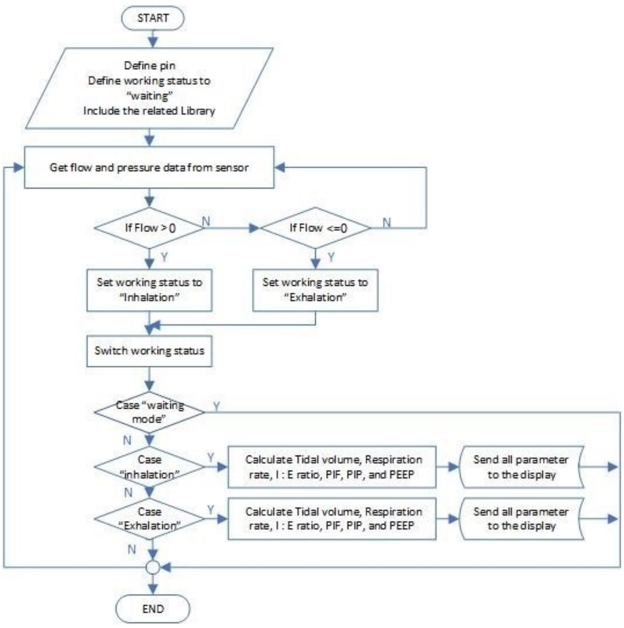


Figure 7. The processing flow chart

The flow chart, according to Figure 7, was started at the defined related pin, library, and working status. Then the pressure and flow data were included. The flow was used to consider inhalation or exhalation case for I:E ratio calculation. When the flow rate was positive it was considered as inhalation, and when the flow rate was negative it was considered as exhalation as shown in Figure 1. Volume data was calculated from flow data and time. While tidal volume was a maximum volume got from the maximum volume data array in one breath cycle. Respiratory rate calculated from the time of one breathing cycle. PIF was got from the maximum value of flow array data in one breathing cycle. PIP was got from the maximum value of pressure array data in one breathing cycle. PEEP was got from the pressure data during the end exhalation period.

The case design and prototype of the ventilator tester is shown in Figure 8 and 9. As shown in Figures 8 (b) and (c), the straight pipe connectors were designed using SolidWorks software and printed using a 3D printer (c).

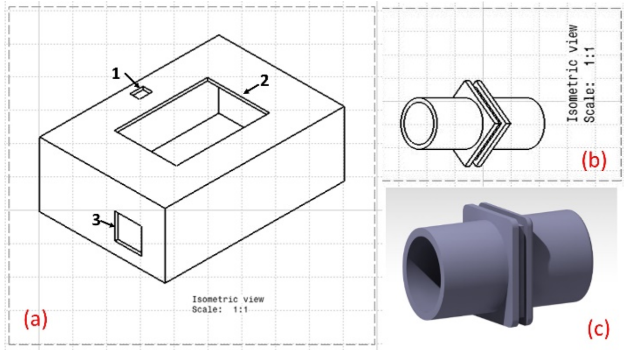


Figure 8. (a) the case design when (1) the on-off switch (2) the HMI display and (3) the straight pipe connectors to a ventilator, (b) the connector design, (c) the 3D connector.

Figure 9. The ventilator tester prototype

The prototype of the ventilator tester was intended to be compact, and it can connect to the ventilator using both sizes of connectors, as shown in Figure 9. The dimension of the designed prototype is 15x10x5.5 cm.

Furthermore, the prototype was created with only one switch for simple operation. The prototype starts up automatically and changes the data view by pressing a button on the HMI display.

4. EXPERIMENTS

Before using each sensor, the sensor needs to adjust the measurement by using the equation of the calibration curve from the standard equipment. The pressure equation was determined from the designed device data to compare with the calibrated digital pressure gauge with the setting pressure during 10-100 cmH_2O for 9 steps with 10 cmH_2O per step. The standard digital pressure gauge used in this process is the brand Additel model Digital Pressure Gauges 681. The flow equation was determined from the designed device data to compare with the standard device VT MOBILE Gas Flow Analyzer. with the flow setting during 10-60 lite per minute(l/m) for 9 steps with 5 l/m per step. The calibration equations were used for the processing unit. The procedure was set as shown in Figure 10.

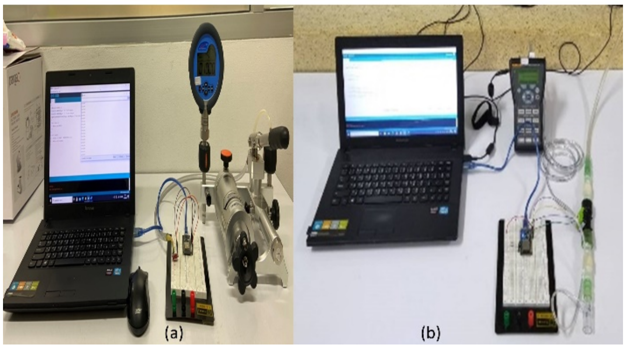


Figure 10. The calibration of (a) pressure and (b) flow sensors compared with the standard equipment.

The prototype of the ventilator tester was tested to evaluate its performance. The experiment condition was set as shown in Figure 10 with temperature condition 25-30ºC. The experiment was set according to Figure 11.

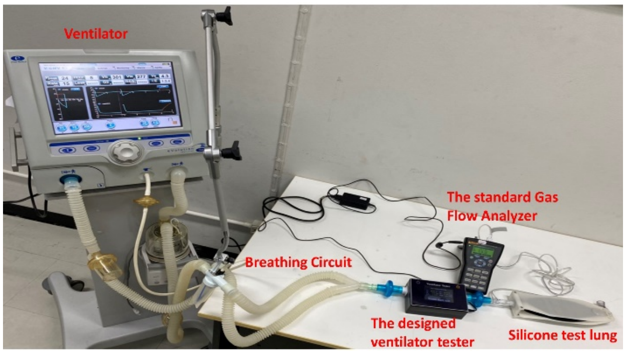


Figure 11. The experiment setting

The procedure of testing starts from connecting the ventilator to the breathing circuit, the designed device, and the gas flow analyzer in serial. Then adjust the ventilator's parameter as define. After that, read the designed device parameter compared with the parameter from the standard device. The accuracy of the prototype can be determined by the percentage error calculated in equation 3. Finally, repeat the above step with the other parameter until cover all parameters.

$$Percentage\ Error = \frac{|E-S|}{S} \times 100\% \qquad (3)$$

where S is a standard physical quantity

E is the physical quantity as same as S.

The statistical analysis of this research uses average ($\bar{X}$) and standard deviation (δ) when N is the number of measurements and X_i data of measurement. Therefore, $\bar{X}$ can be determined from equation (4).

$$\bar{X} = \frac{\sum X_i}{N} \qquad (4)$$

The sample standard deviation (δ) can inform the accuracy of measurement. If the sample standard deviation has a low value, the measured information has high accuracy. The sample standard deviation can be found by using equation (5).

$$\delta = \sqrt{\frac{\sum(X_i-\bar{X})^2}{N-1}} \qquad (5)$$

5. RESULTS

The result can be divided into three sections which are the calibration curve of sensor data and the standard device. Next is the result to verify the efficiency of the proposed prototype test on the eVolution 3e ventilator compared with the standard device VT MOBILE Gas Flow Analyzer. The considered parameters were Tidal Volume, Respiration Rate, I: E Ratio, PIF, PIP, PEEP, and I:E time.

5.1 The calibration curves of a sensor for pressure measurement and flow measurement

According to the experiment in Figure 10, the calibration equation for flow measurement was determined as shown in equation (6). The least-square error technique was used with MATLAB to find the relation curve and equation of the flow sensor data compared with the standard flow meter VT MOBILE Gas Flow Analyzer.

Flow Rate(l/m) = 0.8604×(sensor data) + 0.0264 (6)

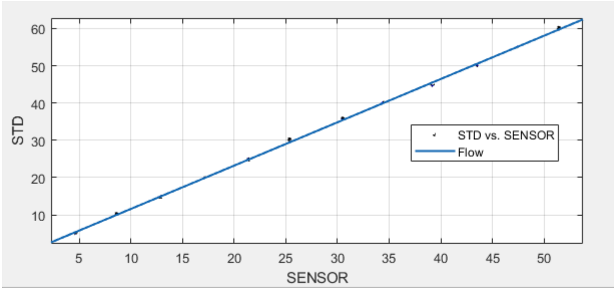


Figure 12. The relation graph of the flow sensor data compared with the standard flow meter

Pressure (cmH_2O) = 35.69 × (Result) + 8918 (7)

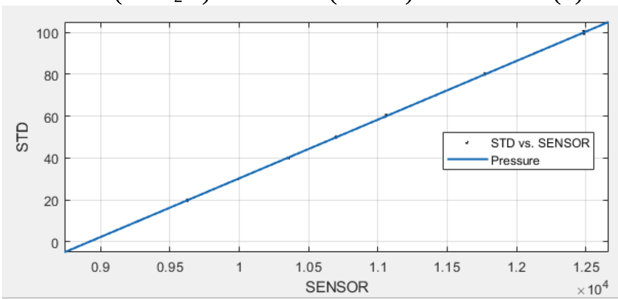


Figure 13. The relation of the pressure sensor data compared with the standard digital pressure gauge

The display was designed according to figure 6, the operation was shown in figure 14. When switch was turn on, the display shows in figure 14(a). When the set zero button was pressed, the display will change to all parameter page figure 14(b). After connect and set the ventilator finish, the display shows the parameter value as figure 14(c). The user can switch to monitor graphical of flow, volume and pressure by press the below button of the page as shown in figure 14 (d), (e), and (f) respectively.

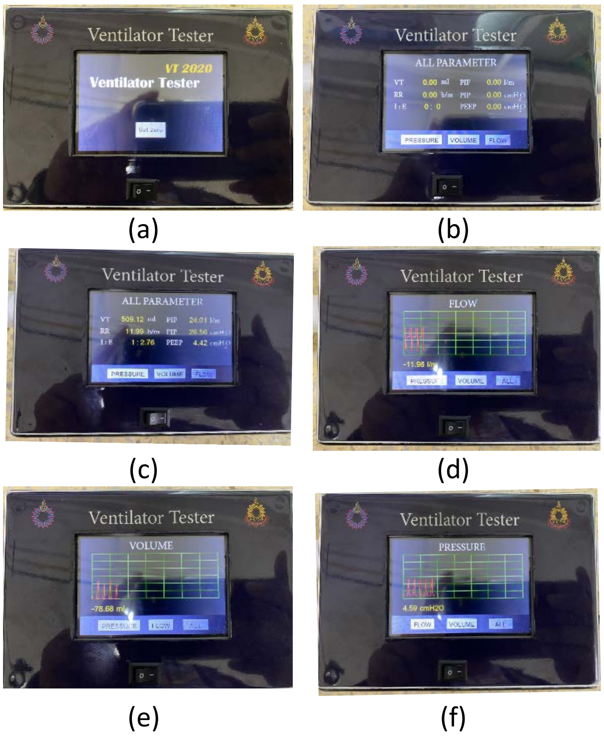


Figure 14. The display result (a) the 1st page when power on, (b) the all-parameter page without data, (c) the all-parameter page with data, (d) the graphical of flow data page, (e) the graphical of pressure data page, and f) the graphical of volume data page.

In this section, the experiment was set according to Testing Procedures for Medical Measuring Devices (Ventilator) [10]. The results of the proposed prototype parameter reading compare to the standard device VT MOBILE Gas Flow Analyzer for the ventilator variable setting like tidal volume, respiratory rate, PIF, PIP, and PEEP. The testing for each parameter was done 10 times for each parameter setting. The average, standard variation, and percentage error were calculated and shown in Table 1. The time duration of inhalation and exhalation which related to I:E ratio were measured 10 times. The average, standard variation of inhalation and exhalation time from the designed device and the standard device and the percentage error were calculated and shown in Table 2.

6. DISCUSSION

The development of a portable ventilator tester used for verification of the operation of the ventilator in parameters like tidal volume, respiratory rate, PIF, PIP, PEEP, and Inhalation time and exhalation time was meet the objective.

According to Figures 9, 11, and 12, the prototype used the calibration equation for flow and pressure measurement.

Table 1: The accuracy of the parameter reading from the standard device and the prototype device

Ventilator variable setting	the standard device		the prototype device		% Error
	average	SD	average	SD	
Tidal Volume					
300 ml	284.70	1.34	306.94	5.92	7.81
500 ml	473.01	1.01	497.88	2.66	5.26
800 ml	747.66	1.04	788.80	4.89	5.50
Respiratory Rate					
10 bpm	10.02	0.04	9.99	0.02	0.27
20 bpm	20.00	0.00	19.84	0.02	0.79
30 bpm	30.00	0.00	30.42	1.88	1.40
PIF					
20 l/m	21.05	0.13	21.07	0.20	0.10
40 l/m	40.18	0.07	41.28	0.20	2.74
60 l/m	60.51	0.37	63.92	0.43	6.14
PIP					
10 cmH_2O	9.80	0.00	9.91	0.01	1.16
20 cmH_2O	19.30	0.00	19.29	0.04	0.04
40 cmH_2O	39.80	0.00	39.15	0.24	1.63
PEEP					
5 cmH_2O	3.10	0.00	3.24	0.02	4.61
10 cmH_2O	9.10	0.00	9.33	0.01	2.52
15 cmH_2O	14.00	0.00	14.07	0.04	0.48

Table 2: The accuracy of the inhalation and exhalation time duration reading from the standard device and the prototype device

I:E	Standard device				Designed device				%error	
	avg		SD		avg		SD			
	Ti	Te	Ti	Te	Ti	Te	Ti	Te	Ti	Te
1:1	2.46	2.53	0.01	0.01	2.43	2.51	0.01	0.11	1.26	0.71
1:2	1.26	2.48	0.01	0.01	1.24	2.45	0.07	0.07	1.35	1.13
1:3	1.26	3.74	0.01	0.01	1.24	3.73	0.07	0.12	1.04	0.11

when Ti is the inhalation time(sec) and
Te is the exhalation time (sec).

From table 1, the percentage error of all parameters was less than 10 % which was acceptable according to the testing procedures and the standard for medical measuring devices [10].

The error of tidal volume was maximum at 300 ml in the ventilator setting and the error was decreased when the tidal volume was increased, while the other parameters had no significant error. These results may cause the volume to be calculated from flow rate and time which is not directly from the sensor as the other parameter.

The proposed prototype cost is 6,500 Baht. The designed prototype is compact with dimensions 15x10x5.5 cm. as shown in figure 9. There is only one switch for turn on the device. The prototype starts to measure all parameters automatically and the HMI display was used for display graphical and numeric data shown in figure 14. Moreover, it was designed to use both the ventilator and standard device.

7. CONCLUSION

This research designs and develops of portable ventilator tester to verify the operation of the ventilator by using the sensor and microcontroller principle. The device was designed to have low cost, portable, user friendly, and work automatically. The experiment was compared the parameter read from the prototype with the standard device. The measured parameter was according to the testing procedures and standards for medical measuring devices[10]. The result shows that the percentage error of the prototype was acceptable according to the standard. In the future development, the design device needs to be improved to send data to record on cloud or database reduce the user error on the recording.

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