DESIGN, ANALYSIS AND CONSTRUCTION OF A SIMPLE PULSE DUPLICATOR SYSTEM

Taha Yaseen Khalaf

Department of Biomedical Engineering¹

Omar Hussein⊠ Department of Automated Manufacturing Engineering¹ omar.hussein@kecbu.uobaghdad.edu.iq

Ahmed Yaseen Khalaf AL-Tarboolee

College of Biotechnology Al-Nahrain University Baghdad – Jadriya, Iraq, 10070

¹Al-Khwarizmi College of Engineering University of Baghdad Baghdad – Jadrya, Iraq, 10070

⊠Corresponding author

Abstract

One of the most important human diseases that need to be considered in terms of development of the medical engineering devices is cardiovascular disease which is a significant cause of death globally recently. Valvular heart disease is normally treated by restoring or altering heart valves with an artificial one. But the new prosthetic valve designs necessitate testing for durability estimate and failure method. It is significant to simulate the circulation system by the building of a pulse duplicator system. This study is stated by clarifying the parameter and implementation steps of the pulse duplicator system in which the different researchers have utilized the system and tried to explain the design steps of using this system without going into the system design by steps or what are the main part of this system and how can be implemented, tested, and developed individually.

In this design, a DC motor produces, through a hydraulic piston, a flow pulse to the left ventricle chamber model, which is linked with two interchangeable prosthetic heart valves. The computer is used to control and process data from volumetric flow rate and image. The findings show that the linear displacement, the velocity of the piston and the linear acceleration regularly become significant particularly and follows a sinusoidal wave shape during one cycle, when (crank length/connecting rod length) value is equal 0.2 or less. Several sets of measured flow rate readings were obtained by using flow meter sensor YF-S201, results after calibration showed the error rate falls within permissible limits.

Keywords: interchangeable prosthetic heart valves, left and right ventricle chamber.

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1. Introduction

Medical engineering devices are considered as a significant impact on the development of medical healthcare nowadays [1]. It helps clinicians and doctors by providing an accurate examination of different people and different medical diseases [2–4]. It is essential to examine and test humans and make an integrated picture of the disease condition before initiating any medical procedure to ensure the accuracy and safety of the patients' condition. On the point of Human diseases, which are different, and various, and each case has different parameters and conditions, one of the most important human diseases that needs to be considered in terms of medical engineering devices which is cardiovascular disease. As it is known that cardiovascular disease is a significant cause of death globally in recent years. It is the biggest killer for people in the United States, accounting for nearly 1 of every 3 deaths [5, 6]. Cardiac diseases are commonly caused due to heart valve disturbance, which is recognized as a Valvular heart disease.

Valvular heart disease is normally treated by restoring or altering heart valves with an artificial one. But the new prosthetic valve designs necessitate testing for durability estimate and failure method [7]. Therefore, the Food and Drug Administration (FDA) proposes that all new valve designs

undergo important testing as identified by ISO 5840:1, which comprises durability testing and Pulsatile testing [4, 8]. To do that, it is significant to simulate the circulation system by the building of a pulse duplicator system (also known as a mock circulatory system).

A definition of the Pulse duplicator system as presented in the study stated in reference [9, 10] where it has detailed that it's a mechanical apparatus which designed to duplicate the flow waves and pressure according to the cardiovascular physiology, as well as, it can be defined as stated in [11] which a system used to simulate the job of the human heart by creating physiological cardiac conditions to evaluate the performance of total artificial hearts, ventricular assist devices, artificial heart valves and other cardiovascular apparatus. Several design of the pulse duplicator system which have introduced in the study that elaborated in [12, 13] in which it supplies a steady flow during the heart valves test, while a pulse duplicator device for pulsatile fluid flow as stated in [14], can be formed up of only 2-part Wind Kessel model fitting only to circulation system. Since this system focused on the fluid flow in its objectives and did not show the steps and procedure of the design of this system.

Also, a system which has stated in [10] it introduces a more basic mock circulatory system which is composed of a pre-load chamber to produce a constant fluid flow and a mechanical valve to change the pressure drop. As this system has not taken into consideration the pulse duplicator system design in detail. Currently, two types of pulse duplicator systems are introduced in which is used for research and the other for commercial purposes. Research regarding the pulse duplicator systems is limited by the rotation of knowledge and shortage of quality while commercial pulse duplicator systems are distinguished by their flexibility to approval with the progressing in heart valve field and the ability in testing new artificial valve designs [5].

Interrogation of the process of simple pulse duplicator system design is considered a pivotal factor for researchers nowadays. Many trends have been evolved in terms of pulse duplicator system design in which all previous research is dealt on a design of simple pule duplicator system that is used for a specific application and solution to a particular problem, but no detailed design has been provided for accurate readings that could be used by other researchers.

The first presented cardiovascular stimulation device that used to keep the heart beating artificially after isolated from animals by using the oxygenated solution. This model is the first scientific research tool that has developed our knowledge of anatomy and physiology. The second attempt cardiovascular simulation was performed in the mid-1950s, by using the human heart after the death which was activated by hydraulic pumps [15], as this model represents the first pulse duplicator device, which was its main goal to simulate the appropriate hemodynamic activity to test the artificial heart valve, but the study has not addressed the detailed design and what are the parameters of this system.

Also, a primitive pulse duplicator device, later perfected in 1955 as mentioned in [15] to test the flow across the heart valve. The last form inspired another group to build a mechanical pulse duplicator by using a cam-follower system to simulate a waveform of ventricular pressure.

Following, in 1966 researchers in their studies which stated in [16] have noticed the presence of various pulses of backflow in ball valve closure during the work of the pulse duplicator system, and these trends have not go in deep the process of simple pulse duplicator and depends only on the development of specific part in this system and the overall design has not explained clearly.

Moreover, studies with simulations of pulsing flow in the artificial heart are very significant as stated in [14], in which it to provides the results of great significance in the scientific and clinical field. As these studies are continued in the development of using such system to study state of art to calculate the flow circulation and check the valve performance without providing any detailed steps of this system design which increase the needs to investigate in this part.

Study in [17] shows the evolution of various projects in the pulse duplicator units, such as «Vi-vitro», «Sheffield», «Aachen» and «Yoganathan FDA system» pulse duplicator. Previously, the research was concerned with the accurate modeling of the anatomical form of the heart.

Despite all achieved attempts through previous research, which included the use of a simple pulse duplicator system for multiple purposes, details and steps of the system design were not addressed.

Besides, researchers which have developed their research in terms of pulse duplicator system as stated in [18] which stated the utilization of external pulse duplicator for Cardiac valvular

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process but they did not elaborated the detailed design of the system, as their research has considered a specific part of the overall system.

Further, the utilizing of pulse duplicator system has mentioned in this study [19] which it has employed to calibrate a numerical model without going into details, steps, and implementation of the proposed system.

Additionally, a design of pulse duplicator has been introduced in term of obtaining a durable and efficient system for measuring the volume flow rate across a valve as stated in [20], however, the pule duplicator system design was not addressed in detail.

A study, which has developed in [21], has addressed the use of simple pulse duplicator system to show the benefit of using dynamic system in system tuning of pulse duplicator but also it has not referred to the detailed design of pulse duplicator system in which it can be useful for other researchers.

Also, a study which elaborated in [22] has used aortic – left ventricular model to make a simulation of the ventricular pressure and make a whole impression regarding the behavior of the proposed valve. Work steps are identified but authors do not address the detailed steps of the used system which was the pulse duplicator system.

The aim of this study is stated by investigating the overall the design of a simple, pule duplicator system; explore the accuracy of measurement in the volume flow rate across the valve and verify the extracted practical and calculated measurement.

2. Materials and methods

2.1. Pump Design

One of the most significant main elements when creating a pulse duplicator is a design of a pulsatile flow device corresponding to physiological flow circumstances. There are different designs of pumps that have been suggested specially to supply a pulsatile flow depending on the mechanical structure of the pump, such as slider-crank, Scotch Yoke, Cam with return mechanism, Cam with internal profile, bellows, piston, diaphragm, and roller pump. All these types contain a mechanical conversion system and motor, as well as a hydraulic conversion system [17]. Some kinds of pumps are more effective than others, therefore, this study focused on only one type of design that has been suggested which is called slider-crank.

2. 1. 1. Design and kinematic analysis of slider-crank mechanisms

The slider-crank mechanism is widely used in reciprocating piston engines [21]. Because it is submitted many advantages [23], such as a good linearization displacement of the rotating shaft with minimum friction and wear effects, as well as it allows for the control of the volumetric flow by adjustment of the motor speed, this will allow the researcher to be more precise in the simulating as long as the motor can be controlled suitably [24]. It is consists of a rotary part called a crank that is connected with a slider part (piston) by the rigid shaft called connecting rod [25, 26], as shown in **Fig. 1**.

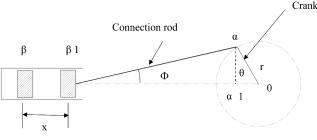


Fig. 1. Slider – crank mechanism

Fig. 2 illustrates the new experimental test pump designed to simulate a pulsed left ventricle, where the crank, connecting rod, and piston mentioned previously are clearly shown.

A large problem in slider crank design is coordinating the output and input movement, because any change in all or one connects lengths influences on the performance of the device [27, 28]. Thus, the first step in slider crank design is kinematic coordinating of components that is followed up by analysis. The coordinating task concentrates on how to detect the dimensions of the slidercrank which appropriate to the required movement characteristics without any problems [29].

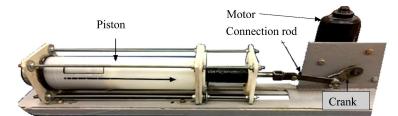


Fig. 2. Experimental pump

Kinematics of the slider-cranking mechanism is expressed by preparing mathematical formula without joint clearances. Either kinematic analysis, it includes determination of linear velocity, linear displacement, linear acceleration of piston, angular acceleration, angular velocity, and angular displacement of connecting rod [30]. It is supposed that the crankshaft rotates at a fixed angular velocity [31]:

- displacement of piston:

$$x = {}^{\beta}O - {}^{\beta}O,$$
$$x = {}^{\beta}O - ({}^{\beta}_{1}\alpha_{1} + \alpha_{1}O).$$
$$x = (1+r) - (l\cos\phi + r\cos\phi).$$

Where x is represented the Linear displacement of the piston, r = Crank length, I = Connect-ing rod length, $\phi = \text{The angle of obliquity of the connecting rod, and } \theta = \text{Input angle of crank and}$:

$$\cos\phi = \sqrt{1 - \sin^2\phi} = \sqrt{1 - \frac{r^2 \sin^2\theta}{l^2}},$$
$$x = (l+r) - \left[l \times \sqrt{1 - \frac{\sin^2\theta}{(l/r)^2}} + r\cos\theta\right].$$

By using the binomial theorem:

$$\sqrt{1 - \frac{\sin^2 \theta}{\left(1/r\right)^2}} = 1 - \left(\frac{\sin^2 \theta}{2\left(1/r\right)^2}\right),$$
$$x = r + \frac{r^2}{21}\sin^2 \theta - r\cos \theta.$$

Where $2\sin^2\theta = 1 - \cos 2\theta$,

$$x \approx \left[r + \frac{r^2}{41} \right] - r \left[\cos \theta + \frac{r}{41} \cos 2\theta \right]; \tag{1}$$

- velocity of piston.

To determine the velocity of the piston at the instant, let's differentiate x with regard to time:

$$v = \frac{dx}{dt} = \frac{dx}{d\theta}\frac{d\theta}{dt} = w\frac{dx}{d\theta}.$$

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Where v is the velocity of the piston, and is the angular velocity of piston (rad/s):

$$v \approx wr \left[\sin \theta + \frac{r}{1} \sin 2\theta \right]; \tag{2}$$

- linear acceleration of piston.

To determine the acceleration of the piston, velocity has been differentiating as stated in [32] concerning time as:

$$a = \frac{dV}{dt} = \frac{dV}{dt}\frac{d\theta}{dt} = w\frac{dV}{d\theta}$$

where a is the acceleration of the piston is calculated using (3):

$$a \approx w^2 r \left[\cos \theta + \frac{r}{1} \cos 2\theta \right]. \tag{3}$$

Also, the inertia force of piston can be obtained using (4):

$$F_i = M_{piston} \times w^2 r \left[\cos \theta + \frac{r}{1} \cos 2\theta \right], \tag{4}$$

where F_i is the inertia force of the piston.

2.1.2. The proposed motor

The full design of the pump requires the electric motor to convert electrical current into mechanical power. Therefore, in this research the DC motor which shown in **Fig. 3** was chosen to accomplish this task.

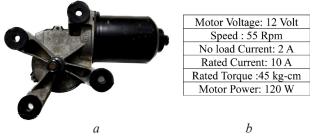


Fig. 3. Motor: a – utilized motor; b – motor specification

It is consists of a magnet DC motor with a gearbox developed to get a constant torque over a wide speeds range from 25 rpm up to about 250 rpm to appropriate the application requirements, a DC motor regulator can be used with this motor if variable output speed control is requested [33].

2. 2. Left ventricular, atrial and compliance chamber design

The left ventricle chamber is a transparent acrylic tank always filled with pressurized water simulates physiological conditions for the heart and the walls have a thickness of 18 mm. A set of metallic screws and silicon material was used to fix the parts and to prevent the leakage of water during the work. The left ventricle chamber represents the main node of the pulse duplicator system loop. It contains three holes as follows, the first to introduce the pulsatile flow from the pump, the second to return the mitral flow, and the third is to push the flow pulse through the aortic valve. The dimensions of the ventricle chamber are represented in **Fig. 4**.

Both atrial and compliance chamber have the same dimensions and the thickness of walls 10 mm that is made from acrylic material.

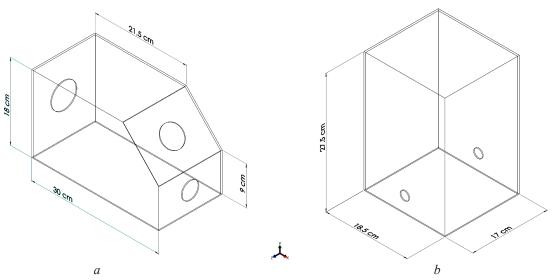


Fig. 4. Champers: a – atrial chamber; b – compliance chamber

2.3. Flowmeter

One of the most common ways to measure the liquid flow rate is YF-S201. Flowmeter sensor YF-S201 is an instrument used to find out the values of the fluid flow when a flow passes through a constant cross-section area, and it has proved to be an excellent device to measure the flow of water. A water flow sensor is formed from the plastic structure, open impeller, and a Hall Effect sensor that is used to detect the nearness of magnetic field [31–34].

The most significant part of the flow meter sensor is the impeller kind, because the impeller speed is proportional to its flow rate. The impeller blades contain tiny particles of the magnets at their ends and, there is a hall-effect magnetic sensor on the other side of the plastic tube that can measure how many spins that impeller has made through the plastic wall, as shown in **Fig. 5**.



Fig. 5. Flowmeter sensor

When the liquid flows across the sensor, it makes the impeller to rotate and hence the rotation of the impeller will create a magnetic field effect on the coil existing in the plastic tube of flow [35]. The magnetic field will be converted by Hall Effect into pulse signal with frequency values in range 16Hz (at 2 L/min) to 90.2 Hz (at 12 L/min) and with percent an error range ± 10 % [36]. After that, the resultant pulses will be converted into flow rates by using a software program for microcontroller Arduino kit and they are displayed by LCD [37].

The pulse signal is a simple square wave so it's quite easy to log and convert into liters per minute by applying equation (5) [38]:

Pulse frequency
$$(Hz) = 7.5 * \text{flow rate} \frac{L}{\text{Min}}$$
. (5)

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In which it is formulated and employed to calculate the pulse frequency based on the flow rate which is in Litter/meter.

2. 4. Prototype of valves

The mitral and atrial valves are employed in the pulse duplicator system, which are responsible for the unidirectional flow into the left ventricle it has represented as shown in **Fig. 6**.

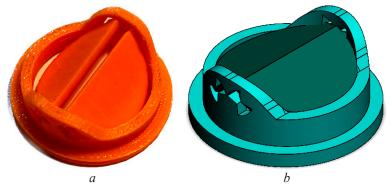


Fig. 6. Valve: a – mitral valve; b – atrial valve

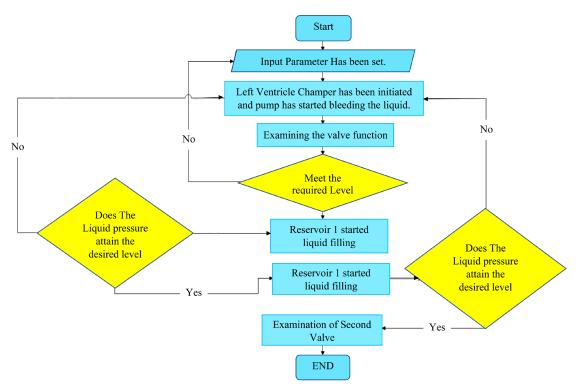
The above two types of artificial heart valves have been employed and used in the pulse duplicator system in which they were printed using a 3D printers and equipped to simulate the shape of leaflet valve.

2. 5. Description of the Pulse Duplicator System

In this experimental research, the details, parts, and the features of the pulse duplicator system is described to picture shown in **Fig. 7**. A pulse duplicator system tester synthetic heart valve simulating heart and blood circulation. It consists of the following parts: a left ventricle chamber with two uni-directional valves (control and test valves), pump, compliance chamber, flow meter, pressure measuring devices, and camera to observe the movement of the valve. The pulsatile flow is achieved by periodic movement of a pump, which is fitted outside a left ventricle chamber. The piston of the pump is periodically pushed by DC motor to produce the pumping movement of the left ventricle.



Fig. 7. Pulse duplicator system



The overall system function steps are illustrated as shown in Fig. 8.

Fig. 8. Pulse duplicator overall steps

Where the process and work principle will be as follow:

- employing the pump to bleed the fluid in the chamber of the left ventricle to pass through the valve;

- the state of art for valve function has been examined using a flow meter sensor and camera which is connected to a controller to check the valve function;

- the main part of the fluid is pumped out to pass through the flow sensor, where readings are gathered through the controller to check the pressure has attained the desired level as shown in **Fig. 9**;

- the liquid continues to pass and stabilize in the first and second compliance chambers, in which pressures are balanced within the entire system through the presence of controlled pressure sensors;

 in case the reservoir Pressure doesn't attain the desired level which it represents the human blood pressure, then the controller reprocess the pump pumping rate until reaching the desired level of liquid pressure;

- after that, the liquid is bled out from the second chamber to return to the chamber of the left ventricle after passing through a valve, in which the function of the valve is examined through flow meter sensor and camera which is connected to a controller to check the valve function.



Fig. 9. Measured data of the valve flow

2. 6. Experimental data

The first step towards achieving the successful design of the pump is to know some important geometric characteristics as listed in **Table 1**.

Table 1

40 mm
76, 96, 116, 136, 156 & 196
80
80

In which Crank Length, connecting rod length, motor speed and Strok are listed which are used to solve equations (1)-(3).

3. Results and discussion

3. 1. Pulse duplicator system outcomes

The variations of linear displacement, velocity, and linear acceleration of the piston against the required crank angle of one cycle of the crankshaft for several lengths of connecting rod have explained, with remaining a length of crank is a constant 7 [39]. In **Fig. 10**, the data follows up a sinusoidal wave shape, and the symmetry of the scheme makes it obvious that there is not an abnormality between the slider and the turning center of the crank (point O) [40]. The linear displacement of piston is defined as the limited value between zero and complete one stroke (2r). This definition corresponds to the diagram in **Fig. 4**. So, notes show that the one stroke of the slider is almost equal 80 mm, and the crank completes one cycle and the slider moves back and forth once in 0.75 s.

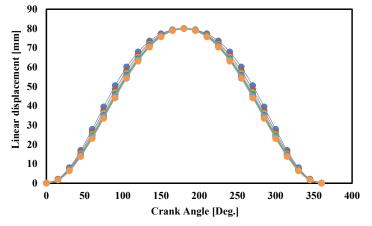


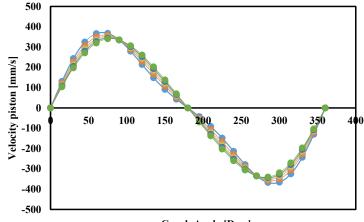
Fig. 10. Linear displacement as a function of crank angle

Fig. 11 shows the velocity of piston calculated for 80 rpm.

As it can be observed, the shapes of the calculated velocities of the piston are very completely matching [39]. This is a reasonable result of the assumption that the torque of the mass of the dynamic model is fixed.

In **Fig. 12**, the solid curves indicate the motion achieved by dominating the torque to the crank. It should be noted that none is identical to sinusoidal shape except for the last curve [39, 41].

Plotting shows that the maximum linear acceleration occurs at $\theta = 0$ and the assessing gives a response of 3370–4260 mm/s. If the length of the connecting rod is large in comparison to the length of the crank (in other words when (r/l) value is less than 0.2), the movement becomes similar to sinusoidal shape, to illustrate this, when the connecting rod length increased from 76 to 196 mm. The linear acceleration is now approximately sinusoidal [42]. But if the opposite then the movement becomes no uniform.



Crank Angle [Deg.]

Fig. 11. Velocity piston as a function of crank angle

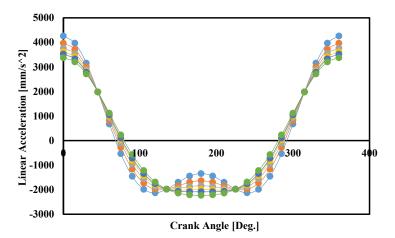


Fig. 12. Linear acceleration as a function of crank angle

3. 2. Flow meter measurements accuracy

Process of calibration and assessment of the flow meter in which it shows that it can be achieved independently of the rest of the pulse duplicator system. So, in this section, the method of calibration that used to validate the accuracy and overall performance of the YF-S201 flow meters sensor as a complete system after calibration will be explained.

Results of the performance obtained with the use of the YF-S201 flow rate sensor has shown in **Fig. 13**. Where it can be seen that with an increase in Reynold's number, the flow rate of water will also increase [43]. With the knowledge that the increase or decrease of the water flow through the sensor depends on the flow rate of the water main source. One can see that the recorded results differ from the calculated predictions by very small value due to the supply flow rate is not well regulated, which leads to accumulating errors and inaccuracies in the values. The results for this sensor showed that the flow is laminar for a flow rate lower than 1 L/min, turbulent for a flow rate higher than 2.1 L/min and transient for the flow rate between 1–2.1 L/min, which can be observed in intersection region for the recorded and calculated flow rate.

In order, to ensure the validity of the performance to the flow meter sensor, it must be mentioned that a general rule that any increase in recorded flow rate must be offset by the same increase in calculated flow rate, regardless to the difference in values of recorded and calculated flow rates obtained, which can be observed in **Fig. 14** [43].

The impeller blades of the flow meter sensor contain tiny particles of the magnets at their ends, when the fluid moves through the flow sensor, the flowing fluid creates a torque on the impeller blades which makes the impeller is spinning and hence this rotate will creating a magnetic field around the blades. The magnetic field of these tiny magnets is detected by the flowmeter detector located near the wheel, and it begins to output electrical pulses. These pulses are then counted by the electronic flow controller. The frequencies of these pulses are directly proportional to the rotation speed of the blades as shown in **Fig. 15** [44], therefore, to the flow rate of the liquid.

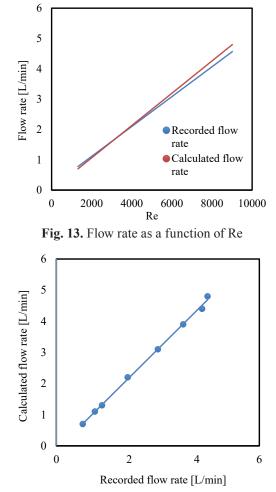
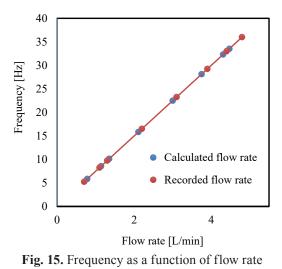


Fig. 14. Calculated flow rate as a function of the recorded flow rate



As a result of all these steps, when the fluid flow rate increases, more pulses are generated.

3. 3. Measurement validity

Experiments' result after calibration of the flow meter sensor have clarified in **Table 2**, it is observed that the error is near 3.5 % or below, except one value, but the gathered data are realistic for the several reasons.

Table 2

Flow	meter	sensor	Calibration

Calculated flow rate [L/min]	Recorded flow rate [L/min]	Error [%]
0.78	0.7	10.25 %
1.14	1.1	3.50 %
1.35	1.3	3.70 %
2.11	2.2	-4.26 %
3	3.1	-3.33 %
3.75	3.9	-5.40 %
4.308	4.4	-2.13 %
4.47	4.8	-7.38 %

The first reason is the dealing with an open system, it is possible for air to be introduced into the system during entry of the liquid causing the formation of bubbles, these bubbles can create unstable flow readings. The second reason is the irregular distributions of flow velocity, which maybe lead to large measurement errors. So, it can be drawn that the tests to prove the efficiency of the flow meter was satisfactory and the values the instrument recorded nearly identical to the reality [43].

As it appeared from the above Table 2.

This will bring attention that the proposed system design has gained accuracy in terms of measurement, which can be employed for any future work to solve such related problems and employed to test the valves to measure the flow rate.

3. 4. Discussion of simple pulse duplicator system measurement

A handiness in terms of design and implementation processes of the pulse duplicator system has been shown in this article in which, other researcher can easily follow the steps of the proposed design of a simple pulse duplicator. As well as the ingenuity of the design, this system shows reliability in terms of measurement as its proven through the comparison in terms of measured data mathematically and practically, as well as output measurement of the flow meter in terms of measuring the flow.

Also, it seems from the gathered information that the obtained result are fit with the required output that considered a necessary parameters for the pulse duplicator system.

Comparison in terms of flow rate measurement [L/min], it obviously showed the less difference in terms of calculated and measured flow rate as well as less error rate in which reasons beyond this have been identified in the section of Measurement validity. As the gathered data of the flow meter measurement for the system practically and mathematically has showed that there is a convergence of values resulting from the accuracy of the design, which contributes effectively to the use of the system **Fig. 13–15** shows the accuracy of measurements, where the measured data are fit with gathered measurement mathematically.

As the comparison of the gathered data from the proposed system can be made only with the mathematical calculation of sensor flow as the current system is available with the absence of the detailed design.

Studying and analyzing the characteristics of kinematic behavior of the slider-cranking mechanism of the pump without clearance by utilizing the traditional method which is clearly demonstrated in the proportional relationship between the stroke and crank. In addition, when checking the calculated data of the linear displacement, velocity, and linear acceleration of the slider-cranking against the crank angle, researcher can conclude that the data follows up a sinusoidal

wave shape except the linear acceleration when (r/l) value is more than 0.2. The flow meter sensor measures the liquid flow rate and it gives an indication of whether the flow through the value is laminar or turbulent.

For each part of the proposed system design, the accuracy in terms of measurement is introduced which shows the efficient and durable systems stated in **Table 2** where the sensor introduced less error rate in terms of measured and calculated data. Some limitations are identified in which this system is not examined practically with real valve, but it works as a simulation to measure the flow rate across the valve. A real experiment will be conducted in the future in which it can prove the efficient use of such system as a disadvantage has been recorded with utilizing this system for valve function examination in which it needs to have a bio environment to make sure that these valves are working with a suiTable bio environment.

4. Conclusions

Ease of implementation and design of the device, as well as ease of use and installation anywhere. Most of the parts of the system are available and cheap and can be used anywhere. The accuracy of the measurements and their applicability to theoretical results and values show the effectiveness of the system for use and reliance on it by other researchers as a reference for them in solving related problems. The findings show that the linear displacement, the velocity of the piston and the linear acceleration regularly become significant particularly and follows a sinusoidal wave shape during one cycle, when (crank length/connecting rod length) value is equal 0.2 or less. The percentage of error resulting from the use of the device is very small, and any problem that researchers may face in the future can be overcome.

Conflict of interest

The authors declare that they have no conflict of interest in relation to this research, whether financial, personal, authorship or otherwise, that could affect the research and its results presented in this paper.

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Data availability

Manuscript has no associated data.

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