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Proportional integral derivative-based aneroid sphygmomanometer testing method

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ABSTRACT

One of the parameters to be tested on the sphygmomanometer is the deflection of the dial. The testing method based on the standard uses manual air pressure to increase the pressure so that the dial is pointed to the desired pressure. This paper proposed an automatic testing method using a proportional-integral-derivative (PID) controller based on arduino to control the pressure. The result shows that the system is not suitable to use. The process capability index at each given setpoint is less than 1. This low cost proposed testing method still needs to be improved and could become an alternative solution for laboratory testing of the sphygmomanometer.

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1. INTRODUCTION

Measuring blood pressure (BP) is commonly used to diagnose a patient condition, whether at a low or high level of BP. This procedure is the only way to diagnose hypertension, as most people with high blood pressure have no symptoms [1]-[3]. In Indonesia, there were 23.7 % of 1.7 million deaths by hypertension in 2016 [4]. Therefore, regular BP checking is needed by home monitoring or consulting the doctor [5]. Nowadays, users use an aneroid and/or automatic or digital sphygmomanometer to measure the BP of the patient. These measuring devices are recently replacing mercury sphygmomanometers, [6]-[8] and assume they are reliable, even if they are not tested every day [9].

Many technical errors might occur during the use of the equipment and influence the reading of routine indirect BP measurements [8]. In order to minimize the error, users also need to verify it before they use it for measurement. Users should always beware of the safety and health of the patients in their hands, and they are responsible for employing the medical device for the intended indications only. Hence, it is essential to ensure the performance and accuracy of medical equipment in the health industry [10]. However, Indonesia’s lack of testing laboratory infrastructure becomes one of the challenges to creating and developing testing methods and tools that can help the laboratory or the industry increase its product performance.

SNI ISO 81060-1.2009, an Indonesian national standard that adopts the same number of the ISO and BS EN [11], has stated the requirement and testing method for non-invasive sphygmomanometer, especially in clause 7.1 the pressure indicating means. The testing method applied to the sphygmomanometer is the interpretation of the diagram and the procedure based on the standard guidance. This requirement is applied for the aneroid spygmomanometer, especially for the dial of the sphygmomanometer.

The tool to test this requirement has already existed [12], [13]. However, the testing method still has lack on it. It could be used only for one input, and started it over from the beginning for another input pressure. Therefore, in this research, we proposed the testing method which could be used and ended the test after all the required setpoint is inputed to the system, until the process finished and a low cost. The previous study has shown that the automated testing method can be accepted compared to the manual [14]. Thus, the automated testing method will be developed using a PID control system based on arduino uno R3. The main advantages of arduino include fast processing, support for the microcontroller, easy interfacing with a computer, cheap, and the system is using an open-source platform [15]-[17]. The control gain, gain proporsional (K_p), gain integral (K_i), and gain derivatif (K_d), are determined using the oldest direct-type, simple, and well-known engineering method, Ziegler-Nichols [18]-[22].

The proportional integral derivative (PID) controller is a generic control loop feedback mechanism widely used in industrial control systems [23], [24]. For over eight decades, control loop designers preferred the PID controllers for their outstanding ability to eliminate the control error using the integrator, their ability to improve the performance using the "trend" of the controlled variable through the derivative channel, for many other benefits [25], [26] and this controller concept was used to improve the on-off controller. Those are why this controller is chosen to optimize the existing testing method. The development process of this method will be described briefly in each section of this paper, and for the last section, we concluded this proposed method.

2. METHOD

The method of this research is based on an experiment. First, we will explain the testing method according to the standard. The standard states that the aneroid sphygmomanometer testing method for pressure indicating means is simple. It consists of a calibrated reference manometer with a maximum error of 0,8 mmHg, in Figure 1, a rigid metal vessel with a capacity of 500 ml ± 5% as a replacement of the cuff of the sphygmomanometer, a pressure generator, and the non-automated or the aneroid sphygmomanometer to be tested. Those components are set up as the testing method, and the procedure follows the equipment under test (EUT). The testing method design is based on the standard.

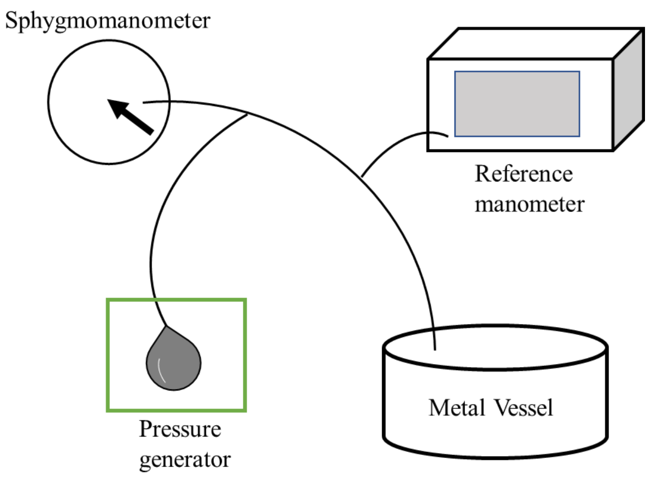


Figure 1. Sphygmomanometer testing system

The testing method will be optimized by modifying the manual pressure generator using the electric pump generator. The pressure outlet will be controlled as the standard requirement. Figure 1 shows the sphygmomanometer testing system based on the standard. The pressure generator stated in the standard will be replaced by the pressure generator of the control system. This replacement aimed to make the testing method enable to be used for the sequence input by increasing the pressure gradually from low to high, the possible input pressure range is 30 mmHg, as the interpretation of the standard requirement, which is not more than 50 mmHg.

2.1. Pressure generator control system (PGCS)

The main point of this paper is to develop the PGCS with a low-cost instrument and local content component. There is no fixed explanation of the pressure generator we should use to generate pressure during the test; however, if we follow the standard by using a manual pressure generator, it takes a long time to do the test. Thus, we will describe how we built the PGCS and the component we used in this part. The green box in Figure 2 is the component of the proposed testing method.

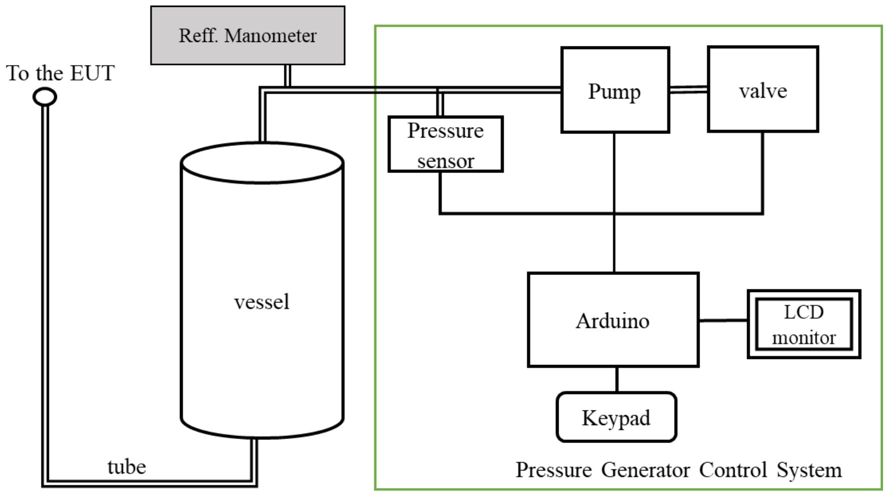


Figure 2. The proposed testing method

2.1.1. Arduino

The arduino is used as a control for the pressure system. It is easy to use for beginners and advanced users with low-cost scientific instruments [27]. In this project, we use the arduino uno. Arduino is preferred in this work for its availability, simplicity, low cost, its easy programing and re-program [28].

2.1.2. Pump

The pump is used to increase and decrease the pressure in the system. This system uses direct current (DC) electric mini-pump powered by 6 Volt (V) DC. Rolling pumps type P53C01R from Oken Seiko [29] contain multiple diaphragms to minimize the pulsation, noiseless operation, long life, and high pressure. It is simple and easy to implement using multiple cylinders per motor. These pumps feature very high flow and high compression pressure up to 80 kPa compared to their sizes. Their discharge valve construction (hat valve) enables silent operation, with which the noise level is maintained low from no-load to maximum pressure conditions.

2.1.3. Pressure sensor

The pressure sensor reads the pressure value, converts it to voltage, and sends this voltage to the analog input of arduino. We use sensor MPX5050GP from NXP semiconductors [30] powered by 5 V DC power to read 50 kPa (375 mmHg) pressure. We use this sensor type because it is suitable with a sphygmomanometer that usually uses 300 mmHg.

2.1.4. PID tuning

In this paper, the PID controller will control the pump, and we use the Ziegler-Nichols (Z-N) method to tune the PID. The Z-N will be used to obtain the gain based on the S-shaped reaction curve of the system for the tunning. The two constants, the delay time (L) and the time constant (T), can be characterized. Those constants are determined by drawing a tangent line at the inflexion point of the curve and defining the intersections of the tangent line with the time axis and the steady-state level line K. The L and T constants will be used to calculate the control gain by the rules in Table 1.

Figure 3. shows the S-shaped step input response of the proposed testing method. The constants are then calculated based on the input response of the L and T values. The result of the gain for each constant controller are K = 14.08, K_i = 0.28, and K_d = 0.07. The constant value of the controller will be used as the tuning parameter and written into the arduino as the control unit of the pressure generator system.

Table 1. The Ziegler-Nichols method tuning rules

Controller	K	K_i	K_d
P	T/L	-	-
PI	0.9(T/L)	3L	-
PID	1.2(T/L)	2L	0.5L

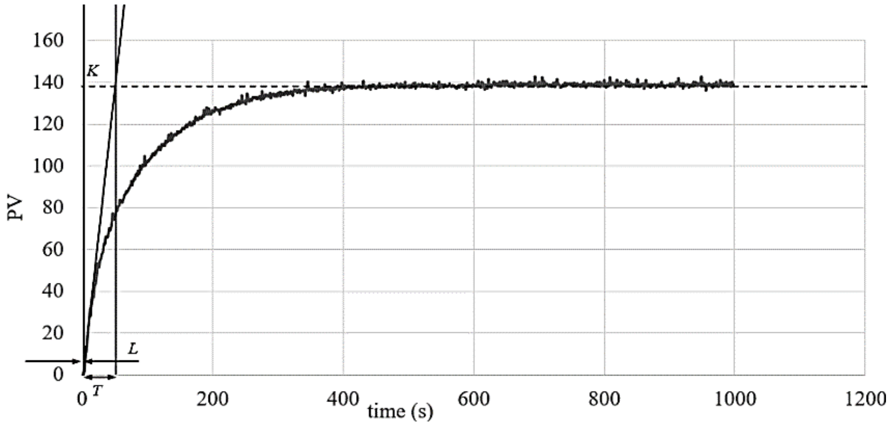


Figure 3. S-shaped step input response curve

2.1.5. Testing method

The next step is how to initiate the setpoint pressure, the flowchart is shown in Figure 4. The prototype of the system is shown in Figure 5, keypad number is used to input the setpoint value shown on the LCD monitor. The input pressure can be inputted at once after the previous process is ended. The input pressure in this testing is started from 30 mmHg to 300 mmHg. The electronic component in the red box is powered by a power supply. The pressure sensor will read the pressure level in the pipeline, and the microcontroller (arduino) records this value. If the pressure value is lower than the setting value of the driver, the control pump will increase the pressure. On the contrary, the valve will decrease the pressure if the pressure is higher than the setting value. A cylinder tube is used to stabilize the pressure. The sphygmomanometer dial as EUT is connected to this cylinder.

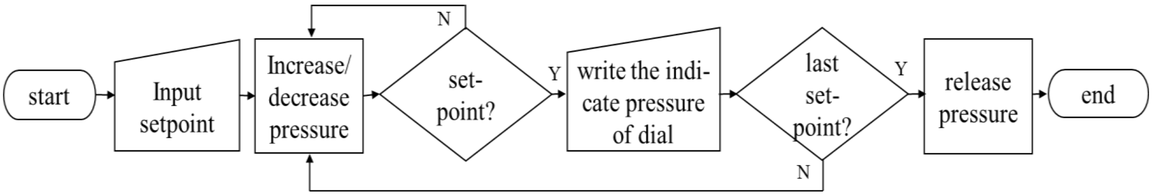


Figure 4. Flowchart of the proposed system

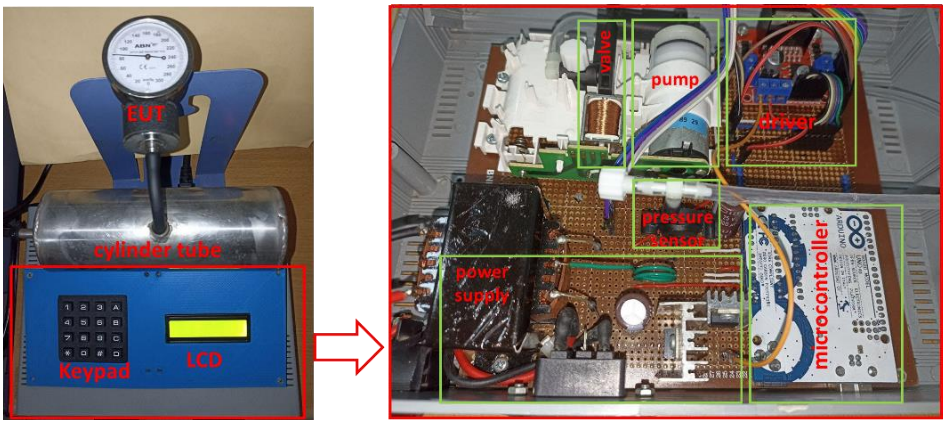


Figure 5. Prototype and the component of the system

3. RESULTS AND DISCUSSIONS

In this section, we are focused on the tuning result of the system. The response system of the proposed testing method with the PID constant gain controller from the Ziegler-Nichols tuning method is shown in Figure 6, with setpoint 120. It shows that the system is not stable; it produces ripples. The response system can reach the given setpoint before producing the ripple at 156.5 seconds, and the error is 0.01 mmHg.

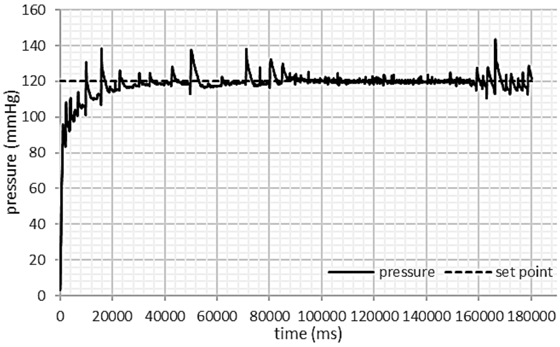
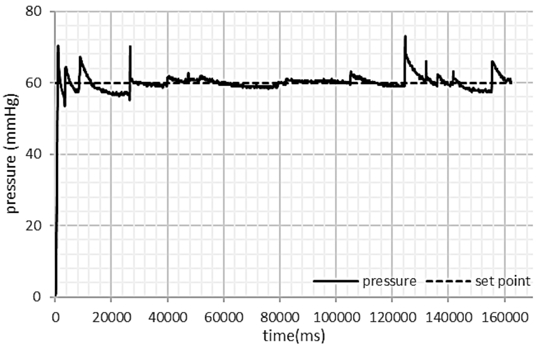


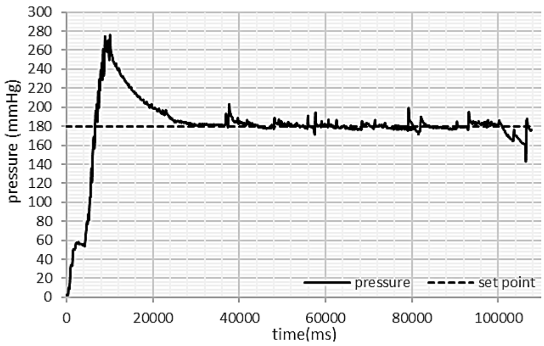
Figure 6. Response system of the proposed method with setpoint 120 mmHg

With setpoint 60 mmHg and 180 mmHg in Figures 7, the proposed method performance shows the same behavior as the setpoint 120 mmHg. The system is not stable, which is one of the PID controller problems [26]. The controller's K_p, K_i, and K_d values will affect the system's transient response. When the K_p value is large enough, the closed-loop system becomes unstable. Moreover, further examination shows that if K_i is smaller than 0.6, the closed-loop system will not be stable [31]. In this paper, the K_i value is under 0.6, which might be one reason.

Figure 7(a) at set point 60 mmHg, considering at the low pressure set point, before the system start to stable, it has ripple. Figure 7(b). shows that the system produces an overshoot, and this high overshoot is the characteristic of the Z-N tuning. That is why the proposed testing method needs to be optimized by another method to make the system more stable and not produce too high maximum overshoot. The other possible cause is the pump, where based on the characteristic, the noise starts to increase at 150 mmHg.



(a)



(b)

Figure 7. Response system of the proposed method at setpoint (a) 60 mmHg (b) 180 mmHg

Based on the tuning and the response system of the proposed testing method, 25 times measurements are conducted at ten setpoints and shown in Figure 8. This measurement aims to determine the system's capability and detect the conformance of equipment performance to the specifications by calculating the process capability index [32]. The (1) is used to calculate the value.

$$Cp = \frac{UCL-LCL}{6\sigma} \quad (1)$$

$$UCL = set\ point + 0.4\ mmHg \quad (2)$$

$$LCL = set\ point - 0.4\ mmHg \quad (3)$$

Where Cp is process capability index, UCL is upper control limit, LCL is lower control limit, σ is the standard deviation, and 0.4 is the tolerance value. The calculation result is shown in Table 2.

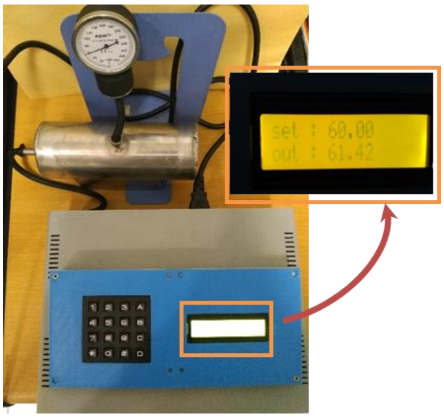


Figure 8. Proses capability index measurement set up

Table 2. Cp calculation result

$Set\ point\ (mmHg)$	Mean	Standard deviation	Cp
30	32.74	3.15	0.042
60	62.59	3.32	0.040
90	91.02	5.18	0.026
120	121.87	6.45	0.021
150	149.24	4.94	0.027
180	16.62	6.36	0.021
210	209.51	6.09	0.022
240	239.41	5.81	0.023
270	267.73	4.85	0.027
300	296.60	5.17	0.026

The processing capability of the proposed testing method based on the calculation for the overall given setpoint is less than 1. This value means that the proposed testing method is not suitable. At the low-value setpoint (30 mmHg to 120 mmHg), the average value during testing is above the setpoint, it is 1.02 mmHg to 2.74 mmHg. However, on the high-value setpoint (180 mmHg to 300 mmHg), the average value is below the set point, it is 0.49 mmHg to 3.4 mmHg. Therefore, this proposed testing method needs to be improved.

4. CONCLUSION

Based on the result, the proposed method of sphygmomanometer testing using PID is not stable at a particular second after the steady-state condition. Moreover, based on the process capability index of the proposed testing method, it is not suitable to use. The Cp at each given setpoint is less than 1. Nevertheless, the proposed method can become an alternative solution to the testing laboratory for sphygmomanometer testing since it is low cost. Considering sphygmomanometer testing in the manufacture becomes a priority in terms of increasing the product quality, this proposed method still needs to be improved by optimizing the PID control system or simulating it using software as comparison, so that the system process capability index will increase.

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