DEVELOPMENT OF LOW-COST CLINICAL BLOOD PRESSURE DATA RECORDING UNIT WITH HIGH SAMPLING RATE

PENGEMBANGAN ALAT PEREKAM DATA TEKANAN DARAH SECARA KLINIS DENGAN LAJU SAMPLING TINGGI DAN BERBIAYA RENDAH

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ABSTRACT

This paper discusses the improvement of blood pressure recording unit in sampling rate and cost efficiency from the previous recorder using Arduino and PLX-DAQ. In order to increase the sampling rate, the NI-myDAQ device and LabVIEW program were used. The recording unit was able to record the blood pressure samples with the sampling rate 200000 samples/second which complies with the ISO/TS 81060-5 : 2019 with relatively low-cost. However, further development in recording Korotkoff sounds, determining systolic, diastolic, and mean arterial blood pressures are required.

Keywords: blood pressure, recording unit, ISO/TS 81060-5, sampling rate, low-cost

ABSTRAK

Paper ini menjelaskan terkait dengan perkembangan alat perekam sinyal tekanan darah dengan laju sampling yang tinggi dan biaya yang efisien dibandingkan dengan alat perekam sebelumnya yang menggunakan Arduino dan PLX-DAQ. Untuk meningkatkan laju sampling, NI-myDAQ dan perangkat lunak LabVIEW digunakan dalam penelitian ini. Alat perekam yang dikembangkan dalam penelitian ini mampu mencatat sampel tekanan darah dengan laju sampling 200000 sampel tiap detik sehingga memenuhi persyaratan ISO/TS 81060-5 : 2019 dengan biaya murah. Namun demikian, perlu dikembangkan lebih lanjut untuk fitur perekaman sinyal suara Korotkoff, serta penentuan tekanan darah sistolik, diastolik, dan tekanan arteri rata-rata.

Kata Kunci: *tekanan darah, alat perekam, ISO/TS 81060-5, laju sampling, biaya murah*

1. INTRODUCTION

Mercury sphygmomanometer was the prominent device that doctor used to measure blood pressure (BP). However, according to Regulation of the Minister of Health of the Republic Indonesia Number 41 of 2019 about "Elimination and Withdrawal of Mercury-containing Medical Device in the Medical Facility Services", any medical devices that contain mercury are prohibited because of its characteristics are toxic to human and the precursor Minamata disease (Muthia Septanti et al., 2022).

For this reason, all medical departments are using automated non-invasive sphygmomanometer as substitute of the mercury sphygmomanometer, with the use of oscillometric method (Park & Park, 2019). However, this automated non-invasive sphygmomanometer is less accurate than the mercury sphygmomanometer, since it mostly uses its proprietary algorithm to determine the systolic and diastolic blood pressure from the air pressure oscillation (Nitzan et al., 2017). Therefore, to ensure reliable blood pressure measurement using automated non-invasive sphygmomanometer, performance test is required such as accuracy test, repeatability for blood pressure indication, air leakage, etc.

Up to now, there are some of non-invasive blood pressure (NIBP) calibrators that are used to calibrate the automated sphygmomanometer such as fluke biomedical with NIBP analyzer BP-Pump 2 and Cufflink NIBP Simulator (Han Wook Song et al., 2008; Doh et al., 2015; Celler et al., 2018). However, these devices are not clinically traceable since they did not generate real biosignals of the human but oscillations with the shape of sine waves, to test the automated oscillometric BP devices (Ughi & Dewanto, 2018). The availability of it is also very few due to its high cost (Santoso et al., 2017).

In order to generate real biosignals of human, human blood pressure signals are required by the blood pressure simulator to perform clinically traceable repeatability test of the automated non-invasive intermittent sphygmomanometer, as describes in Figure 1. Seeing this problem, recording unit is used to record the human blood pressure signal as database. However, there are not much publication regarding the development of recording unit for clinical human blood pressure data acquisition. Thus, this paper discuss the development of the recording unit as well as the calibration results of the pressure sensor used, and how the recording unit is utilized to perform clinical human

blood pressue signals data acquisition for blood pressure signals database.

2. LITERATURE REVIEW

Repeatability of automated intermittent sphygmomanometer is important to produce reliable blood pressure measurement. Therefore, repeatability test on the device must be done. the procedure to perform repeatability test are as follows (Riedel et al., 2011):

1. Acquisition of oscillometric blood-pressure data from human subjects with a specifically developed recording unit.
2. Preparation of a simulator database containing all oscillometric data together with clinical reference values obtained by auscultation.
3. Processing the recorded raw data to obtain the model signal to be output by the simulator.
4. Simulation, i.e., application of the model signal to the sphygmomanometer under test.

Recording blood pressure is one of the important aspects for repeatability test of the automated sphygmomanometer. Therefore, the recording unit performance must be reliable. According to ISO/TS 81060-5 : 2019; the recording unit performance must be in accordance with the following specification:

1. Pressure measurement accuracy of $\leq \pm$ 0.3 mmHg ($\leq \pm$ 0.04 kPa);
2. Pressure range $\leq$ 500 mmHg, (or up to 330 mmHg (44.0 kPa));
3. Time base accuracy of $\leq \pm$ 0.2 s;
4. Recording time $\geq$ 60 s;
5. Analog to digital converter $\geq$ 12 bit;
6. Sampling rate $\geq$ 100 samples/s

These specific requirements are needed to create reliable blood pressure signals database. One of the important aspects is sampling rate. Samples that are taken during recording may affect the graph of the blood pressure signals. Therefore, the more samples are taken the smoother and more precise the blood pressure graph will be due to graph linear regression. Consequently, the repeatability test of the automated sphygmomanometer may affected.

3. METHOD

3.1 Arduino-based Recording Unit

The preceding recording unit developed by SNSU-BSN consists of Arduino as a microprocessor, ADS1115 as the 16-bit analog to digital converter, and MPX4115AP as the pressure sensor, as describes in Figure 2.

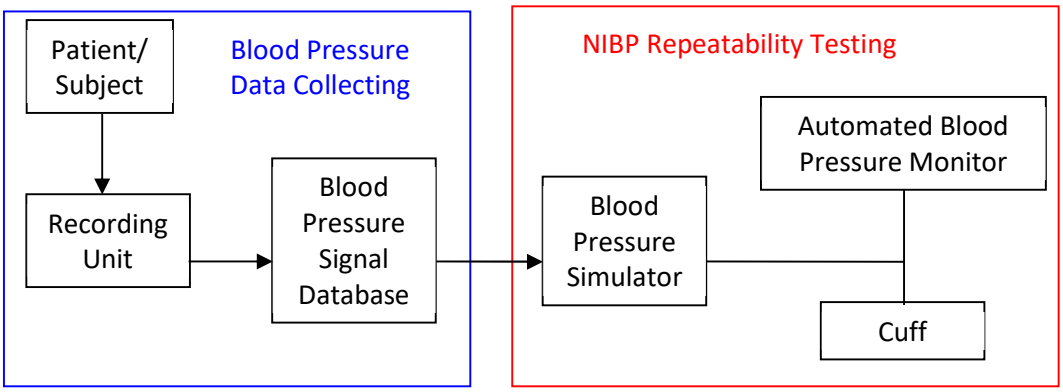

Figure 1. The use of recording unit for blood pressure simulator signal database

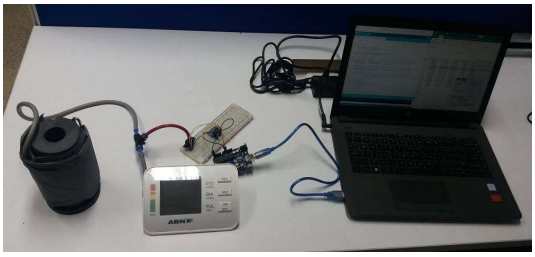

Figure 2. The arrangement of recording unit using Arduino

To record blood pressure samples, a data acquisition program, Parallax Data Acquisition tool (PLX-DAQ), was used. This is an add-in software for Microsoft Excel that acquires data from microcontrollers and convert the numbers into columns as they arrive (Sreenivas Rao & Shivakumar, 2020). However, the data acquisition results did not complied with the ISO/TS 81060-5 : 2019 requirements. As illustrated in Figure 3, the sampling rate was approximately 21 samples/second. This may occur due to the long sampling route from the ADC, Arduino, PLX-DAQ, and finally Excel.

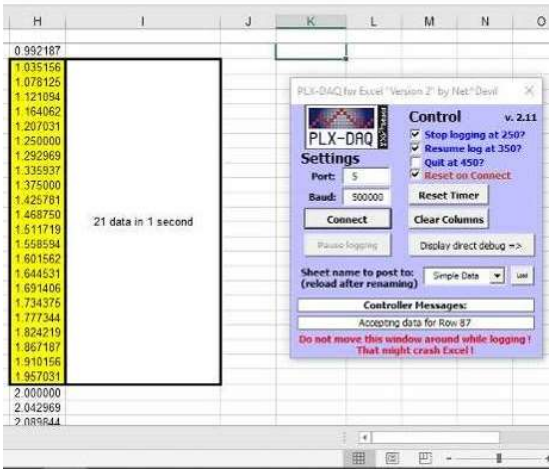

Figure 3. The PLX-DAQ sampling rate

3.2. NI-myDAQ based recording unit

Alternative way, to increase the sampling rate of the recording unit for automated sphygmomanometer is using NI-myDAQ [12]. The pressure sensor and the microphone were connected to the 5 volts as the power supply. The output voltage of each components was connected to the analog input of the NI-myDAQ. The arrangement was shown in Figure 4.

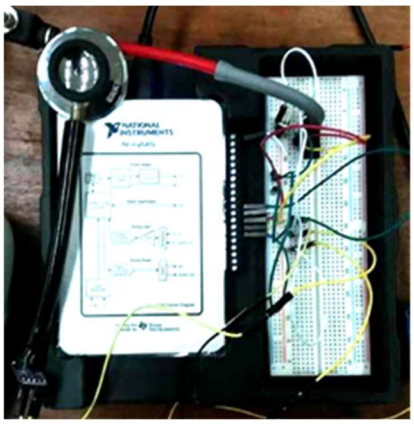

Figure 4. The arrangement of recording unit NI-myDAQ based

The microphone (MAX9814) was attached with the stethoscope chest piece. This enables the microphone to record the human Korotkoff sounds. Korotkoff sounds aid in determining pulse rate, systolic and diastolic blood pressure.

The MPX4115AP pressure sensor was replaced with MPX5100GP because the pressure range of the MPX4115AP (15-115 kPa absolute pressure) is not in accordance with the ISO/TS 81060-5 : 2019. While MPX5100GP has pressure range (0-100 kPa gauge pressure) which complied with ISO/TS 81060-5 : 2019.

With this configuration the sampling rate was up to 100 samples in 2000 Hz. In other words, the NI-myDAQ was able to record 200000 samples/seconds which surpass the ISO/TS 81060-5 : 2019 specification.

LabVIEW was used to program the NI-myDAQ device. LabVIEW uses a graphical programming approach to visualize every aspect of the hardware configuration, measurement data, and debugging. The visualization helps to integrate measurement hardware for example NI-myDAQ to develop data analysis, represent graph and etc.

To program the NI-myDAQ, the DAQ Assisstant was used to input the samples into the LabVIEW. Then, samples were separated between pressure signals and Korotkoff sounds signals. For the pressure, the formula block was used to convert the voltage into pressure in mmHg unit. The formula can be retrieved from the calibration process. The filter blocks were used to observe the oscillation of both the pressure and the Korotkoff sounds samples. Afterwards, all the processed samples were shown in graph and indicator. Write to Measurement file block was used to record all the processed samples (pressure and Korotkoff sounds) with respects to time in .lvm format. This format can be observed in Microsoft excel or notepad. This process are shown in Figure 5.

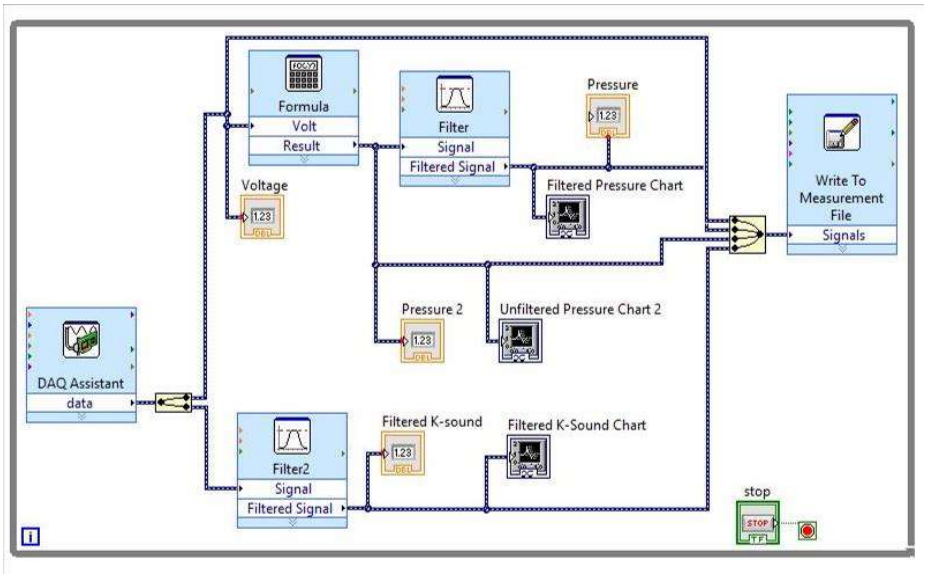

Figure 5. The LabVIEW block diagram of recording unit

The calibration of pressure sensors, MPX5100GP, was performed to acknowledge:

- The correlation between the output voltage from the pressure sensor with the applied reference pressure from the pressure balance.
- Pressure reading error of the pressure sensor with respect to the reference pressure value
- Measurement of uncertainty value

To perform the calibration, the recording unit was set as shown in Figure 6. The recording unit is connected to the volume pressure controller. Volume pressure controller was used to control the volume pressure inside the AMH piston gauge. By controlling the volume pressure, the piston gauge height can be adjusted in its reference mid-float position of 0.0 mm in order to minimize head correction effect and yield accurate pressure reference result.

The method used to calibrate the pressure sensor was the SNSU-BSN Work Instruction I.MM.3.04.2 : Calibration Procedure for Pressure Measuring Devices (PMD) (DKD-R 6-1 : 03/2014), which refers to the international calibration guideline DKD-R 6-1:2014 (PTB, 2014). Although the pressure sensor has the accuracy of 2.5%, however the calibration is performed by using the calibration sequence A of the DKD-R 6-1:2014 as follows:

- 3 cycles (sequence A with additional 1 cycle to check the reproducibility).
- 11 points (0, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100 kPa) increasing and decreasing pressure

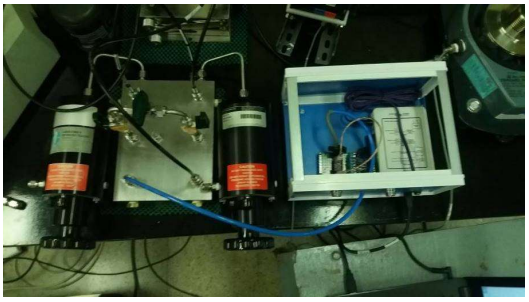

Figure 6. Recording unit calibration set-up in SNSU-BSN pressure laboratory

The mean reference pressure value were determine from the pressure generated by the pressure balance formula in Eq. 1 with corresponding factors that affect the pressure value such as mass, gravitation, area effectivity of piston cylinder assembly, thermal expansion coefficient (Júnior et al., 2015). All of the physical factors are also calibrated according to the each of unit standard.

$$p = \frac{\sum_{i=1}^{n} m_i.g}{A_{(0,20)}.(1+\lambda.p_n)(1+\alpha.(t-t_r))} \text{.....[1]}$$

With P is the pressure generated by the Pressure Balance (Pa), m_i is mass of the weight loaded on the piston (kg), g is the local gravity acceleration (9.78137 m/s^2), $A_{0.20}$ is the effective area of piston-cylinder assembly at null pressure and reference temperature of 20°C (m^2), λ is the distortion coefficient of piston-cylinder (Pa), P_N is the nominal pressure (Pa), α is the thermal expansion coefficient (°C^{-1}), t is the temperature of piston-cylinder (°C), and t_r is the reference temperature (20 °C).

4. RESULTS AND DISCUSSION

4.1 Pressure Sensor Calibration

The correlation between voltage with the reference pressure is illustrated in Figure 7. From the graph, the R^2 is equal to 1 signifies the data is almost linear to the regression line.

The voltage output from the MPX5100GP pressure sensor were directly proportional with the reference pressure generated by the pressure balance. Therefore, the linear regression formula obtained from the graph is used to convert the voltage from the pressure sensor into pressure value in LabVIEW formula block. Thus, the converted pressure regression from its corresponding output voltage can be seen in Table 1.

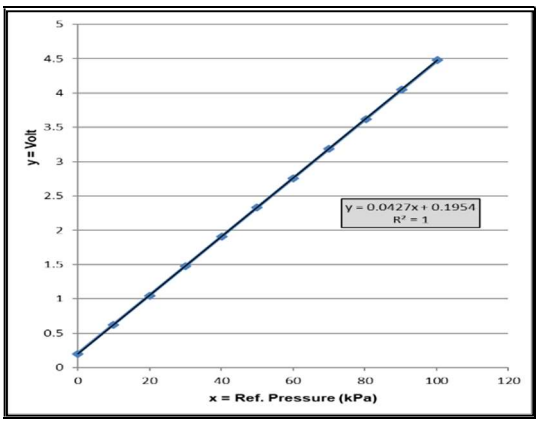

Figure 7. Correlation between voltage with reference pressure graph

The pressure measurement uncertainty of the recording unit is evaluated according to JCGM 100:2008 and DKD-R 6-1:2014. The uncertainty values are expressed in maximum of 2 significant number, as shown in Table 2.

Table 1. The average value from 3 measurement cycles

No	Nominal Pressure (kPa)	Mean Ref. Pressure (kPa)	Volt	Pressure Regression (kPa)
1	0	0	0.1979	0.05793
2	10	9.95424	0.6206	9.95713
3	20	20.01091	1.0481	19.96950
4	30	30.02609	1.4755	29.97867
5	40	40.08276	1.9052	40.04190
6	50	50.00202	2.3293	49.97516
7	60	60.01019	2.7566	59.98228
8	70	70.07387	3.1869	70.05921
9	80	80.26433	3.6216	80.23948
10	90	90.27257	4.0488	90.24315
11	100	100.33625	4.4782	100.30047

Table 2. Uncertainty at 100kPa

Uncertainty Source	Unit	Dist.	U	Divisor	DOF v_i	Std. Uncert ui	Sens. Coeff ci	$(c_i.u_i)^2$	$(c_i.u_i)^4/vi$
Standard	kPa	Norm.	4.5E-03	2	60	2.3E-03	-1	5.1E-06	4.4E-13
Temp.piston	ºC	Rect	5.0E-01	1.73	50	2.9E-01	-0.001	6.8E-08	9.1E-17
Gravity	m/s^2	Rect	4.9E-05	1.73	50	2.8E-05	10.22	8.3E-08	1.4E-16
Thermal exp.	$ºC^{-1}$	Rect	9.0E-07	1.73	50	5.2E-07	11	3.3E-11	2.1E-23
Head corr.	m	Rect	5.0E-03	1.73	50	2.9E-03	0.11	1.0E-07	2.0E-16
Resolution	kPa	Rect	1.0E-04	3.46	50	2.9E-05	1	8.3E-10	1.4E-20
Zero dev.	kPa	Rect	2.3E-02	3.46	50	6.6E-03	1	4.4E-05	3.8E-11
Repeatability	kPa	Rect	1.0E-01	3.46	50	3.0E-02	1	8.9E-04	1.6E-08
Reproduce.	kPa	Rect	6.5E-02	3.46	50	1.9E-02	1	3.5E-04	2.4E-09
Hysteresis	kPa	Rect	4.0E-02	3.46	50	1.2E-02	1	1.3E-04	3.5E-10
Sums								1.4E-03	1.9E-08
Combined uncertainty, uc								0.03770	
Effective degree of freedom, veff								107.87	
Covered factor for CL = 95%								1.98	
Expanded unc, *U* (unit)								0.075	

Factors that influences the uncertainty are piston temperature, gravity, piston thermal expansion, delta density, head correction, resolution, zero deviation, repeatability, reproducibility, and hysteresis. The highest contribution was repeatability of the pressure sensor.

4.2 Blood Pressure Signal Acquisition

The results of blood pressure signal data acquisition by using the developed recording unit can be seen in Figure 8 – Figure 10. In LabVIEW, the graph can be shown in front panel window as illustrated by Figure 8 - Figure 10. The data was in form of number that can be represented in graph. This database is used for the blood pressure simulation for automated sphygmomanometer repeatability test.

Figure 8 describes the graph of the recorded pressure in unit of mmHg with respect to time. The pressure oscillation is observed to acknowledge the pulse rate by calculating the standard deviation from the oscillation peak, as shown in Figure 9. It is also used to determine the mean arterial pressure.

In Figure 10, the Korotkoff sounds were recorded to detect the systolic and diastolic blood pressure more accurate.

However, the noise from surrounding sounds were still recorded. The Korotkoff sounds from the audio channel Therefore, further research on the Korotkoff sounds recording is required.

Variety range of blood pressure samples were taken to observe the performance of the recording unit to record blood pressure from the representative hypertension, normal, and hypotension, as shown in Figure 11 – Figure 13. The systolic and diastolic blood pressure value was obtained from the automated sphygmomanometer (ABN™ DU-120). For the Mean Arterial Pressure (MAP), the value was calculated from 1/3 of systolic blood pressure added with 2/3 of diastolic blood pressure (Dewanto et al., 2016) (Darwongso et al., 2019).

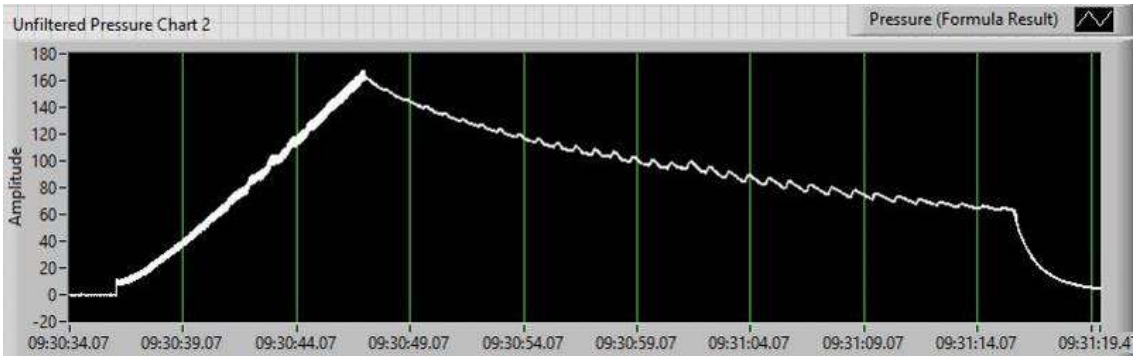

Figure 8. Recorded blood pressure signal graph in mmHg with respect to the elapsed time

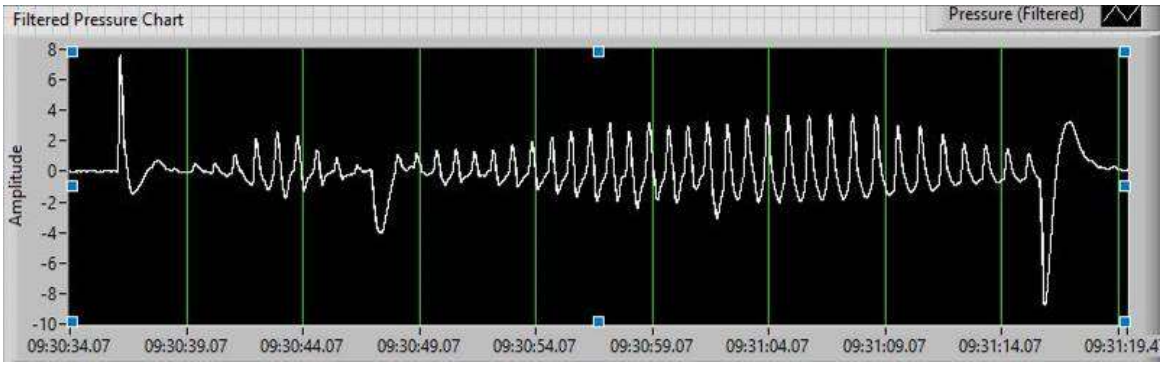

Figure 9. The recorded blood pressure signal oscillation graph expression of Figure 8

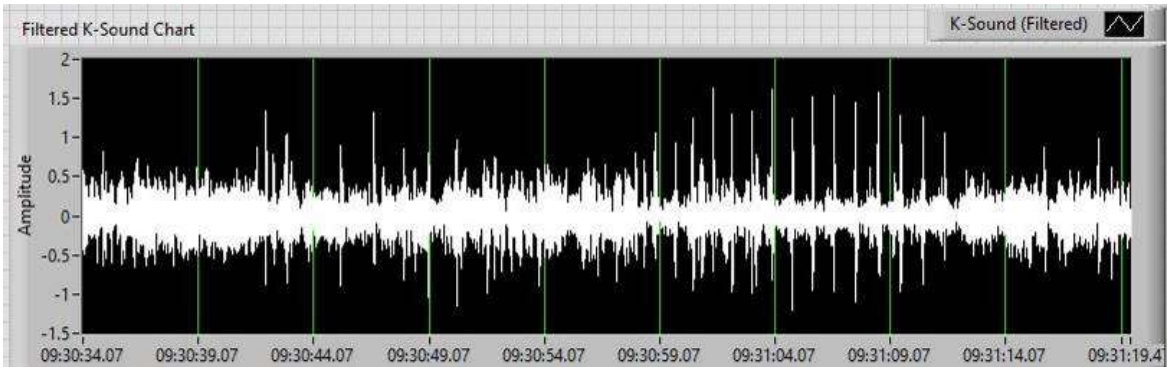

Figure 10. The recorded Korotkoff sounds from the blood pressure signal in Figure 8

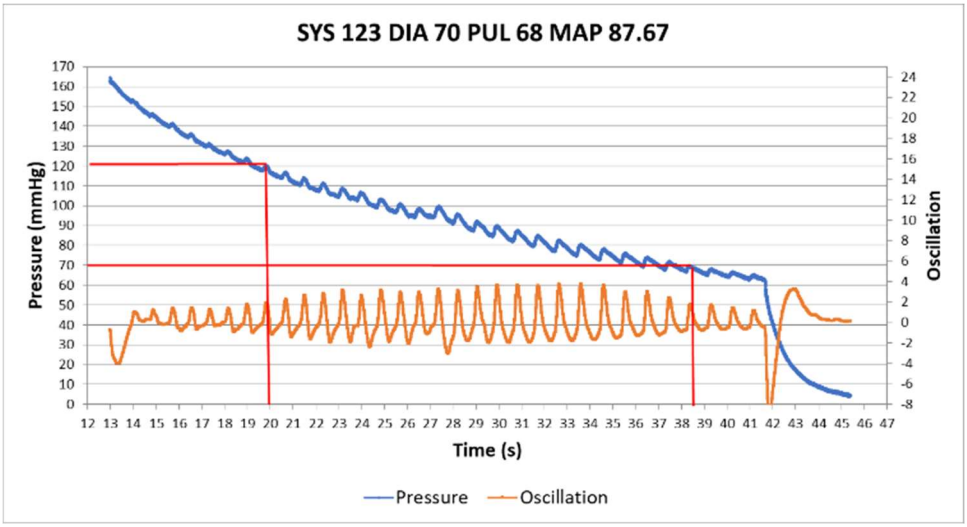

Figure 11. The Normal blood pressure graph

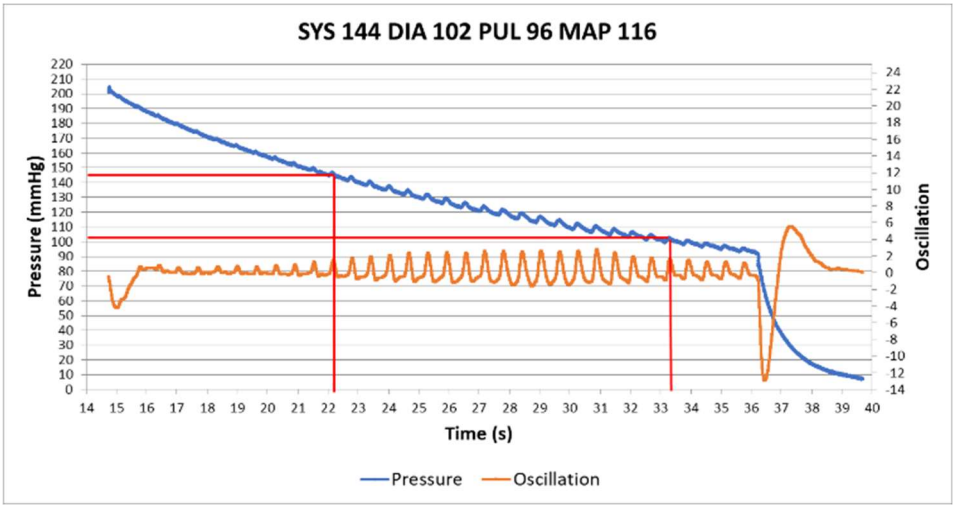

Figure 12. The hypertension blood pressure graph

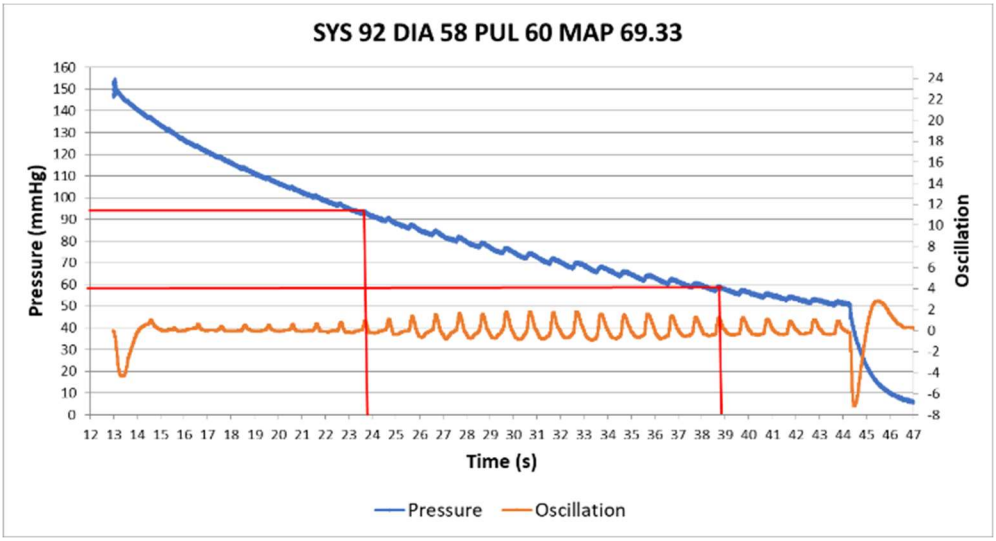

Figure 13. The hypotension blood pressure graph

Table 3. List of hardware cost

Item	Specification	Approx. Price (IDR)
Pressure sensor MPX5100GP	Pressure Range 0-100 kPa Gauge, Accuracy 2.5%, Response time 1.0 ms	365,000
ABN™ DU-120	Pressure Range 0-300 mmHg, Dual 30 Measurement Memory	400,000
NI myDAQ	ADC 16-bit, max. sampling rate 200kS/s, time resolution 10 ns, 2 channels Analog Input and Analog Output, 8 Digital IO, Integrated DMM (V, A, Ohm), Power Supply +5 V and +/-15 V	4,000,000
ERKA Stethoscope	Dual-membrane, chromium-plated brass chest-piece, standard 15° inclined binurals	377,000
TOTAL		5,142,000

From Table 3, the approximation cost of recording unit NI MyDAQ based is lower than the price of the fluke biomedical NIBP analyzer BP-Pump 2 which is IDR 101,616,000.00 (Santoso & Ughi, 2017). Therefore, the low-cost recording unit in this paper is economically proven.

5. CONCLUSION

The recording unit that has been developed in this paper is working properly and has been carried out properly. The calibration result and specification of the recording unit which one of the requirements is high sampling rate has complied with the ISO/TS 81060-5 : 2019. In addition, the low-cost recording unit is proven as well. However, several drawbacks such as the air pump and deflator should not controlled by the automated sphygmomanometer, the poorly quality of the digital stethoscope and unable to connect the audio channel with the analog input channel in order to record the Korotkoff sounds. Therefore, further research and development in the hardware (data acquisition device or microprocessor) and software (data acquisition software) are necessary.

6. ACKNOWLEDGEMENTS

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