

A novel fetal Doppler calibrator: enhancing the precision of fetal heart rate monitoring

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ABSTRACT

The congenital heart disease is associated with abnormal brain development in the womb of pregnant women where fetuses with congenital heart disease are at higher risk of miscarriage compared to the general population. Fetal and neonatal risk identification and assessment are essential for comprehensive risk stratification after diagnosis of congenital heart disease. This study aims to improve the accuracy of Doppler fetal measurements in the diagnosis of congenital heart disease risk with calibrators. This study used an experiment of a calibrator with four push buttons embedded to increase and decrease the beat per minute (BPM) value by comparing the BPM value of the Doppler fetal. The measurement was carried out by comparing the values of the calibrator and the Doppler fetal with units and tens of BPM. Statistical analysis used the paired sample T-Test. The measurement obtained a significant p-value of <0.05 with 95% CI. Furthermore, this calibrator does not have a difference in accuracy level with a Doppler fetal. This states that the calibrator has the feasibility to calibrate the fetal Doppler in the fetal heart examination service for pregnant women. This study has the prospect of improving the technology with the embedding of the internet of things (IoT).

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1. INTRODUCTION

Fetal growth retardation (FGR) is an indicator of abnormal intrauterine growth associated with high fetal mortality, postnatal complications in newborns, and long-term sequelae in adulthood [1]. One of the causes of delayed fetal growth and development is the existence of problems with congenital heart disease, that congenital heart disease (CHD) is the most common congenital abnormality in live births, with a prevalence of 3 to 8 out of 1,000 newborns [2]. Moreover, coronary heart disease problems begin in the early stages of fetal heart development and involve improper formation of ventricles, arteries, and valves [3]. In addition, CHD can affect a wide range of fetal health problems with an incidence rate of 1.0-1.2%. The occurrence of this disability begins in the early stages of development and can lead to critical health problems. Coronary heart disease problems begin in the early stages of fetal heart development and involve improper formation of ventricles, arteries, and valves. In addition, CHD can affect a wide range of fetal health problems with an incidence rate of 1.0-1.2%. The occurrence of this disability begins in the early stages of development and can lead to critical health problems [4].

Furthermore, CHD is associated with abnormal brain development in the womb. Small brain volume and abnormal cortical folds can be detected at 25-30 weeks of gestation [5]. Fetal circulatory disorders can directly interfere with brain development by reducing the substrate (e.g., glucose, oxygen, and other nutrients) available to the brain [6]. The severity of neonatal morbidity may occur depending on the level of neonatal prematurity, the presence of fetal-maternal Doppler anomalies, and birth weight. Advances in postnatal care have reduced mortality substantially, especially for infants with severe CHD [7]. The results of epidemiological studies of congenital heart disease reported in different countries vary and increase with better diagnostic capabilities. This was reported in the results of last year's annual review, 1970-2017, which described the prevalence of congenital heart disease, confirming 9.4 children per year worldwide, 1000 live births, including Indonesia. About 300,000 of these cases are classified as severe congenital heart disease that usually requires a gradual surgery to survive. The incidence of congenital heart defects in Indonesia is estimated to reach 43,200 out of 4.8 million live births (9:1000 live births) per year [8]. Although congenital heart defects, such as mild abnormalities at birth, may not be known for weeks, months, or years, and may even be discovered later in life after reaching adulthood. Many children with congenital heart disease go undiagnosed, and some cases become more severe, leading to life-threatening conditions, organ damage, pulmonary hypertension, and infections (e.g., infective endocarditis, sepsis). Screening and observation checks within 24 hours before discharge from the hospital in newborns and at 6 weeks of age for signs of congenital heart disease are early detection strategies carried out in health care for all infants [9].

The normal value of fetal heart rate is 120–160 bpm per minute. However, the frequency of the heart rate can exceed 160 beats per minute, which can be caused by various factors. The device that detects the fetal heart rate is called a fetal Doppler, where the tool used must display an accurate bpm so that there are no errors in the fetal examination. The fetal heart rate can be assessed using Doppler ultrasound, which is the standard method that can assess the degree of health of the fetus. Fetal heart examination using fetal Doppler is more convenient for pregnant women [10]. If there is an error in the examination, it can result in various factors, including fetal hypoxia, anemia, and so on. Fetal Doppler is one of the medical devices that is an asset that directly improves the quality of life of pregnant women and their fetuses. If the continuous use of fetal Doppler allows for differences or bias in values that can lead to misdiagnosis and fatal risks in patients [11]. Medical equipment (fetal Dopplers) requires calibration, maintenance, repair, user training, and deactivation activities are usually managed by technicians. Medical equipment requires scheduled and unscheduled maintenance during its lifetime [12]. Moreover, fetal Dopplers need to be calibrated in order to determine whether they are suitable for use on patients or not. The calibration function ensures and monitors whether the instrument is still accurate or functioning properly, and finds out how much deviation from the instrument [13].

In previous research, there have been several studies that have made fetal Doppler simulations for the detection of congenital heart defects. One of his studies involves increasing beat per minute (BPM) from 60 to 240 by increasing 30 with selenium instead of heart rate. Then design and build a Doppler fetal calibrator with an LCD display using Arduino Uno [14]. Furthermore, there is research on the design of a mini-Doppler detector system for heart rate control. There is a Doppler fetal calibrator with a microcontroller base that embeds a stethoscope sensor and a condenser mic amplifier, whose data results are shown on an LCD screen with a BPM indicator. Another study specifically looked at the effect of heart rate value on duty cycle in testing Arduino-based fetal simulators. The results found that the average error in the fetal simulator was 0.082 bpm, which has high stability accuracy [15]. In the explanation above, there is no calibrator that can measure the Doppler fetal from the smallest measurement of unity or decimal bpm. The authors have developed a calibrator for the fetal Doppler of these findings. In addition, this calibrator can be a solution to improve the accuracy or precision of fetal heart rate measurement results.

2. METHOD

This study used several stages to carry out the implementation of this technological novelty, which is described below:

2.1. Research methodology

This research is carried out in collaboration and the development of methodologies to develop prototypes. The research process is carried out through stages, including: literature review, prototype design, creating a prototype, integrated system, testing the prototype, result evaluation, and conclusion based on the analysis of the results, as described in Figure 1. All stages are revealed in detail at each stage.

2.2. Literature review

Based on the prototype work system in this study, the literature review is the most important thing to find a comprehensive review of relevant research and the existing literature. A literature review will reveal

research that is linked to previous research on the same topic. The discovery of the results of the literature review will serve as the basis for the development and innovation of the prototype work system made in this research. The literature review study covers various aspects of the basic way the prototype system works. These aspects are related to microcontrollers, electricity, programming, solenoids, setting beat per minute (BPM) additions and subtractions. Furthermore, a literature study is conducted on relevant literature in the field of calibrator of fetal Doppler calibration, especially focusing on the pocket fetal Doppler or digital fetal Doppler.

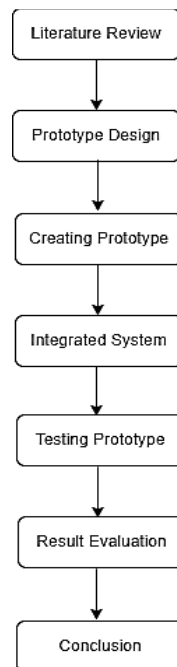


Figure 1. Research methodology

2.3. Prototype design and creating a prototype

At this stage, it is a stage to design the way the prototype electrical system works with the microcontroller. This is explained in Figure 2 with the design of the block diagram prototype. In Figure 2, it is stated that the block diagram has four push buttons to increase and decrease the BPM of the calibrator with tens and unit indicators. Furthermore, the solenoid has a role as a substitute for the fetal heart that beats according to its BPM setting. Then, the OLED displays the amount of the BPM setting where the solenoid beat is adjusted in speed according to the value of the magnitude in the OLED. The microcontroller is used to manage the prototype work system as a data processing motherboard, and so on. The working system of the prototype is explained in more detail in Figure 3, where the wiring prototype shows how the calibrator of the fetal Doppler works.

In Figure 3, it says that the wiring prototype shows the relationship between its components to form the calibrator working system. All push buttons are connected directly to the solenoid to give commands to beat like a fetal heart in the womb of a pregnant woman. Also, the push button is connected to the microcontroller to process and send data to be displayed on the OLED. The final design of the prototype is shown in Figure 4.

The prototype design is made with stainless steel as the main frame of the box, where the frame is wrapped in acrylic. The outer display features four push buttons to adjust the amount of BPM displayed on the OLED. The transducer probe hole is made circular to fit the size of the pocket fetal Doppler. The contents of the prototype box are the place where the electronic components are embedded with the power bank as a storage and supply of electrical energy. This prototype is also a portable and mobile calibrator for calibrating fetal Dopplers. So, this prototype is easy for users to use. This study used the C language in the microcontroller with Arduino IDE in Figure 5. Then, in this prototype, four push buttons were used to increase or decrease the BPM setting when the prototype calibrated a fetal Doppler. Meanwhile, the switch of this prototype is at the bottom to stop or continue.

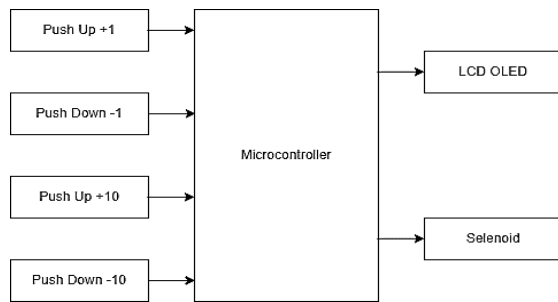


Figure 2. Block diagram of the prototype calibrator

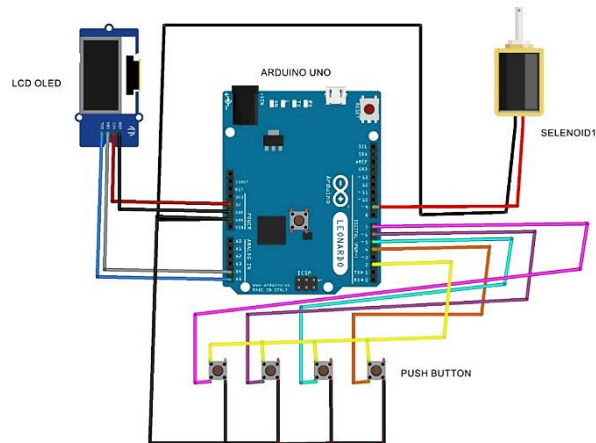


Figure 3. Wiring of the prototype



Figure 4. Design of the prototype

2.4. Integrated system

At this stage is the prototype workflow to calibrate the Doppler fetal from start to finish. This system is described in Figure 6. In Figure 6, it is explained that the initial process of the user must turn on the prototype power supply to distribute their electrical energy. Next, the user sets the BPM amount to provide the solenoid speed where the BPM value is also displayed on the OLED. Then, the user puts the transducer probe in the prototype hole to measure the amount of BPM value from the calibrator. The BPM amount of the Doppler fetal with a calibrator is recorded for analysis of its significance level. After the measurement, the user can press the power button to turn off the power of the prototype's electrical energy. Furthermore, the development part of this prototype is a calibration monitoring system with internet of things technology to see the level of accuracy of BPM settings with the results of fetal Doppler measurements.

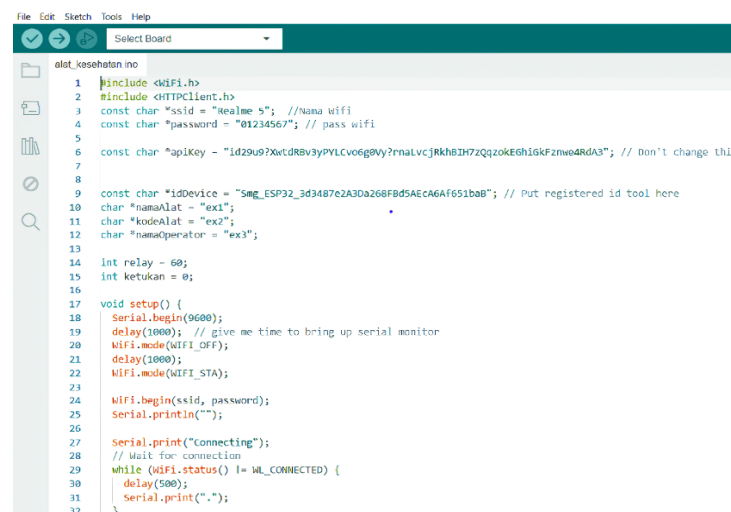


Figure 5. Programming language

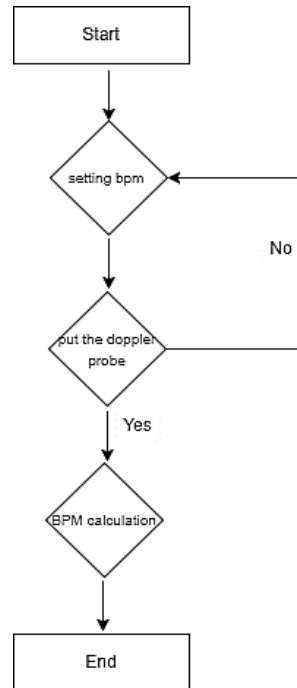


Figure 6. Flow chart of an integrated system

3. RESULTS AND DISCUSSION

This prototype was experimented with a pocket fetal Doppler, where this fetal Doppler has criteria, including: fetal Doppler with uncalibrated conditions. The results of the experiment with this prototype are described in Table 1. The experiment was carried out with two indicators, where the experiment used the tens indicator and the BPM unit. In Table 1, it is shown that the measurement indicator results from the Doppler fetal are obtained with a difference of one BPM in each experiment. The experiment used a Doppler fetal that was still uncalibrated. The results of the data normality test found that the data had a normal distribution with a significance value of $p > 0.05$, more precisely 0.085. These results are described in Table 2.

Furthermore, the data was analyzed to see the significance of the feasibility results of the calibration of the Doppler fetal with this calibrator. In the statistical analysis, the paired sample T test was used, where the data showed the significance of the $p < 0.05$ result. The results of the analysis are explained in Tables 3 and 4 related to the statistical analysis. In addition, the fetal Doppler feasibility is very good to support health services with this calibrator prototype.

Table 1. Results of the calibration

Parameter BPM	Setting a standard calibrator	Average tool reading fetal Doppler
Tens	60	59
	70	69
	80	79
	90	89
	100	99
	110	109
	120	119
	130	129
	140	139
	150	149
	160	159
Unit	61	60
	62	61
	63	62
	64	63
	65	64
	66	65
	67	66
	68	67
	69	68
	70	69
	71	70

Table 2. Test of normality

Variable	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Result of fetal Doppler	0.066	40	.200*	0.956	40	0.085
	0.066	40	.200*	0.956	40	0.085
	0.066	40	.200*	0.956	40	0.085
	0.066	40	.200*	0.956	40	0.085

Table 3. Experiment with tens of bpm

Variable	P-value	Mean difference	RP (95% CI)	
			Lower	Upper
Tens of BPM	.000	280.000	240.54	319.46
calibrator				
Result of fetal Doppler	.000	279.000	239.54	318.46

Table 4. Experiment with unit of BPM

Variable	P-Value	Mean difference	95% CI of the Difference	
			Lower	Upper
Unit of BPM	.000	74.500	71.21	77.79
calibrator				
Results of fetal Doppler	.000	73.500	70.21	76.79

In the measurement results, significant results have been obtained that the calibrator can work well in calibrating the Doppler fetal. The data stated that each measurement experiment received a correction of only one BPM of the entire measurement. The results of this measurement are an indicator of the feasibility of fetal Doppler in examining the fetal heart in pregnant women. Previous studies have stated that to guarantee accurate, reliable, and safe findings and reports in the treatment and diagnosis process, safety and performance testing is necessary as part of an efficient calibration procedure. Calibration has several benefits which are briefly listed as follows [16]:

- Accuracy and precision: The accuracy of medical equipment has a direct influence on the quality of patient care. Inaccurate measurements can lead to misdiagnosis, incorrect treatment, and negative effects.
- Patient safety: Proper calibration of medical equipment is essential for patient safety. Inaccurate readings can result in incorrect dosage, delays in essential treatments, or unnecessary surgery.
- Diagnostic accuracy: Calibration ensures that diagnostic devices provide consistent and precise results, allowing healthcare professionals to make timely and accurate diagnoses.
- Efficacy of treatment: Calibration ensures accurate dosage and treatment, leading to increased efficacy of the therapy.
- Disease monitoring and management: Calibration of this device is essential for properly tracking the progression of the disease and adjusting the treatment program, thereby improving the patient's treatment outcomes.

Furthermore, the measurement results also obtained a $p < 0.05$ value, where the results indicated a significant result for the fetal Doppler feasibility after being calibrated with this calibrator. Calibrated medical equipment provides accurate data and measurements, allowing healthcare practitioners to make informed decisions and provide optimal care to patients [17]. Failure to calibrate medical equipment can result in inaccurate readings, misdiagnosis, improper prescribing, and even life-threatening errors. This is because calibration improves the efficiency and cost-effectiveness of the healthcare system by eliminating the need to repeat tests and treatments due to incorrect findings [18]. Medical equipment plays an important role in improving the efficacy and quality of healthcare services. For the healthcare industry, whether it's hospitals or medical device manufacturers, nothing is more important than patient safety. In recent years, more and more patients are experiencing adverse outcomes related to medical equipment [19].

This calibrator has a technique to calibrate the Doppler fetal, where the recommended calibration technique has several advantages [20]. Based on other medical equipment calibration studies, this technique includes an accurate digital sampling approach to measure various ECG waveforms, such as square, triangular, and normal sine. Second, real-time characterization of differential amplifiers can reduce errors [21]. Every medical equipment requires calibration, maintenance, repair, user training, and decommissioning activities are usually managed by technicians. Medical equipment requires scheduled and unscheduled maintenance throughout its lifetime, including fetal Doppler [22]. Moreover, doctors rely heavily on clinical data to determine the patient's dosage. Inaccurate results can lead to improper recipes. Patients can trust practitioners and healthcare organizations if they know that the technology used is reliable [23]. Another research revealed that calibration of each health work unit must carry out proper measurement and estimation of orientation. A medical device will no longer meet the stated accuracy limit standards if the characteristics of using an integrated sensor may change over a long period or in variable temperatures, and recalibration activities are required [24].

This calibrator can help resolve the fetal Doppler feasibility before it is used by the doctor to examine the patient. Steps to ensure the feasibility of medical devices at health providers that are in accordance with service standards, safety, benefits, security, benefits, and quality requirements, need to be calibrated [25]. Consequently, many health devices only assess trends and need calibration, including the fetal Doppler. In addition, medical devices are calibrated to improve the efficiency and cost-effectiveness of maintenance and healthcare systems by minimizing the need for repetitive tests and procedures due to inaccurate results. Patients can have confidence regarding the feasibility of the medical devices used in their treatment and care [26].

4. CONCLUSION

The results of this study state that the calibrator can calibrate well on the Doppler fetal, where the evidence is that the p-value is significant. Next, the fetal Doppler obtains the accuracy and precision of BPM measurements from the calibrator. Then, a prototype of this tool can be developed with an intelligent system to record all the calibration data from each Doppler fetal.

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AUTHOR CONTRIBUTIONS STATEMENT

This journal uses the Contributor Roles Taxonomy (CRediT) to recognize individual author contributions, reduce authorship disputes, and facilitate collaboration.

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C : **C**onceptualization

M : **M**ethodology

So : **S**oftware

Va : **V**alidation

Fo : **F**ormal analysis

I : **I**nvestigation

R : **R**esources

D : **D**ata Curation

O : Writing - **O**riginal Draft

E : Writing - Review & **E**editing

Vi : **V**isualization

Su : **S**upervision

P : **P**roject administration

Fu : **F**unding acquisition

CONFLICT OF INTEREST STATEMENT

The authors assure that there are no financial or personal relationships that could be considered as conflicting interests or that may have had an impact on the results or interpretations of this study. We confirm that the research was carried out independently, free from any outside influences. The authors have no affiliations, biases, or professional connections that could create any potential conflicts. There are no political, religious, or ideological influences, nor any academic or intellectual disagreements, that could have affected the research process or its outcomes. This study was conducted purely to contribute to scientific knowledge and understanding, with no external party exerting influence over its design, analysis, or conclusions. The authors state that they have no conflict of interest concerning this research.

DATA AVAILABILITY

The authors confirm that the data backing the conclusions of this study are publicly available and can be accessed directly through the article. All pertinent datasets, including the core data, statistical analysis, and additional materials, are integrated into the publication to ensure transparency and reproducibility. This enables other researchers to thoroughly verify the study's findings and methods. By making this data available, we aim to promote open science and provide the scientific community with the opportunity to build on the work presented here. Beyond the data within the article, any further information needed to understand the study's results, such as raw data or additional analyses, can be requested from the corresponding author. This ensures knowledge sharing and supports ongoing research in this field. Making such data available is key to enhancing the credibility of scientific research and encouraging interdisciplinary collaboration. By ensuring the data is readily accessible, the authors invite more thorough examination, replication, and further development of this research by others. We believe that this openness not only strengthens the validity of our findings but also contributes to the broader scientific conversation, laying the groundwork for future exploration in related areas.




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