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Performance Comparison of Domestically Produced and Imported Fetal Doppler Simulators

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ABSTRACT Fetal Doppler is an ultrasonic wave-based medical device used to detect and monitor fetal heartbeat. This device is widely used in maternal and child health practices, both in hospitals and other health facilities. However, there have been few studies comparing the quality and accuracy of domestically produced Fetal Doppler devices with foreign products. This study aims to compare the measurement performance between domestically and foreign-produced Fetal Doppler Simulators with variations in bpm settings of 60, 90, 120, 150, 180, and 210. The measurement data were analyzed using statistical methods in the form of averages, standard deviations, correction values,% Error, and Accuracy. Tests were conducted on five fetal doppler units with two different simulators for five consecutive days. The results of the analysis showed no significant difference between the two. The average accuracy value of the foreign-produced simulator was 99.73%, while the domestic production was 99.71%. This shows that the domestically produced simulator has competitive performance and is worthy of being used as an alternative medical device.

INDEX TERMS Fetal Doppler, Fetal Doppler Simulator, Domestic Production, Foreign Production

I. INTRODUCTION

Fetal Doppler is a tool used to examine and monitor the fetal heart rate in the womb of pregnant women. This tool is useful for checking whether the fetus is growing normally, which is indicated by the rhythm of the fetal heart rate. [1]. The accuracy of this tool in displaying BPM values is an important factor because examination errors can result in various factors, including fetal hypoxia, anemia, and others. For this reason, it is necessary to calibrate the fetal Doppler tool to determine whether or not the tool is suitable for use. According to the Regulation of the Minister of Health of the Republic of Indonesia (Permenkes RI) No. 54 of 2015 concerning testing and calibration of medical devices, it states that medical devices used in health service facilities must be tested or calibrated periodically, at least once a year. [2].

The calibration tool or calibrator used to test the suitability of the fetal doppler is called a fetal doppler simulator. The Fetal Doppler Simulator is a tool used to simulate the fetal heartbeat per minute with several setting options. The working principle of this tool is to produce a heartbeat pulse with several value options that can be set. In a previous study, entitled "Analysis of the Influence of Media on Fetal Simulators on Calibration Results" Researchers analyzed the influence of the media used by the fetal simulator on its calibration results using the "After Only Design" method, namely the author only looked at the BPM results, with the control group, Fetal Doppler as a comparison. In the results of his research, the researcher concluded that the results of BPM measurements using a fetal doppler simulator with oil and water media on three fetal doppler devices and one sound level meter unit showed that the difference in media did not affect the calibration results, but the provision of more or less media volume This affects the loudness of the tapping sound produced by the fetal Doppler simulator. [3].

Field observations show that the use of fetal doppler at the Banten Province Labkesda UPTD is one of the most popular services, so it is necessary to procure additional fetal doppler calibrators to ensure the suitability and quality of the device. Referring to the Decree of the Minister of Health of The Republic of Indonesia Number HK.01.07/MENKES/1258/2022 concerning the substitution of imported medical devices with domestic medical devices in the electronic health sectoral catalog [4], the Banten Province Labkesda UPTD is in line with encouraging this program where the procurement of fetal doppler simulators has used domestically produced devices or TKDN to substitute or replace imported products in meeting its needs.

Currently, the government is increasing the strategy of increasing domestic products (PDN) for medical devices, one of which is by paying attention to regulations that support domestic medical devices, purchasing through the E-Catalog, and increasing the promotion of domestic medical devices to increase awareness among health workers. However, the main problem in substituting domestically produced medical devices with foreign production is the limited availability of medical-grade raw materials on the market. This means that further development is still needed, especially for medical devices with medium to high technology.

Therefore, the habit of using imported products still requires time and evidence that can state that these domestic products can compete and can replace imported products that are widely circulated in the market, this is due to differences in quality and the components used.

Based on the background above, to find out the differences between tools produced domestically or by TKDN with foreign production, the author is interested in submitting a study

A. Appeal Test

The activity of comparing calibrators with other calibrators is known as interlaboratory comparison (ILC) if carried out systematically between laboratories. [5]. If carried out in one laboratory to evaluate the consistency of the tool, it is called "internal comparison" or "intracomparison". To determine the accuracy and precision of domestic and foreign fetal Doppler simulators in measurements, in addition to calibration, a comparative test is also carried out. The comparative test was followed by 5 (five) fetal dopplers with different specifications and brands. The results of the comparative test can be used as a basis for evaluating the implementation of measurements and analysis that have been carried out to improve calibration performance. [2].

B. Fetal Doppler

Fetal Doppler in Fig. 1 is a diagnostic tool that can be used to detect the baby's heartbeat in the womb. [4]. Fetal Doppler uses sound waves to listen to the fetal heartbeat and is very useful for detecting fetal health conditions, which also use non-invasive methods, so that they are safe to use [2]. Fetal Doppler has similarities with a fetal stethoscope, but in fetal Doppler, the output produced is electronic audio that can be heard by people other than the operator, including pregnant women who are being examined. [6].

Figure 1. **Fetal Doppler [12]**

The parts of the fetal Doppler device, as shown in Fig. 1, consist of the following. [7]:

1. Probe: The part used to attach to the pregnant woman's stomach to detect the fetal heartbeat.
2. Speaker or audio output: The part that produces the sound of the fetal heartbeat to be heard by the operator.
3. LCD: The part that displays fetal heartbeat information, such as heartbeat frequency.
4. Control buttons: The part used to adjust and operate the device, such as the power button and the button to adjust the volume.
5. Battery: Some Fetal Dopplers use batteries as a power source.

The working principle of the Fetal Doppler is as follows. [3].

a. Transmits ultrasound waves with a frequency of around 2 or 3 MHz, as seen in Fig.2.

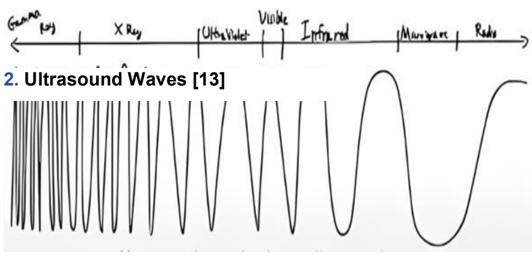

Figure 2. **Ultrasound Waves [13]**

b. Then receives the waves back after being reflected by the heartbeat activity of the fetus,
c. The part that sends and receives ultrasound waves on the fetal doppler is called a transducer The activity of sending and receiving ultrasound waves is then processed into sound signals and heartbeat values per minute (Beats per Minute, BPM)

The way the fetal doppler works uses the Doppler effect to simulate the sound of the fetal heartbeat [8]. Fetal doppler transmits ultrasonic waves to the pregnant woman's stomach with a gel as a medium, which will then be received back by the sensor on the device and converted into sound. The ultrasonic waves are transmitted through a probe that functions as a transducer [6]. The fetal heartbeat is an indicator in pregnancy examinations to detect the condition of the baby in the womb, so that the fetal doppler device used must display an accurate BPM so that there are no errors in the fetal examination [4]. Therefore, calibration needs to be carried out to determine whether the tool used displays accurate results and is suitable for use in examination.

C. Calibration

The definition of calibration according to ISO/IEC Guide 17025:2005 and the Vocabulary of International Mentrology (VIM) is an activity that forms a relationship between the values indicated by a measuring instrument or measurement system, or the values represented by a measuring material, with known values related to the measured quantity under certain conditions. In other words, calibration can be interpreted as an activity carried out to determine the truth of the values produced by measuring instruments and measuring materials by comparing them to measuring standards to match the standard quantities used with a certain accuracy. [9].

Regulation of the Minister of Health of the Republic of Indonesia (Permenkes RI) No. 54 of 2015 concerning Testing and Calibration of Medical Devices states that equipment used for diagnostic, therapeutic, rehabilitation and medical research purposes needs to be tested or calibrated to ensure the availability of medical devices according to service standards, quality requirements, safety, benefits, safety and suitability for use. [5]. Calibration is done by comparing the values read by a device with a measuring instrument called a simulator or calibrator. Medical devices that have been calibrated will receive:

a. Testing and Calibration Results, namely a written statement stating that the medical device is fit for use or not fit for use based on the results of testing and calibration
b. Certificate, namely a written or printed guarantee given/issued by an accredited testing and calibration institution/laboratory/institution to state the suitability of testing and calibration.
c. Label, namely any form of writing and/or image printed and attached to a medical device to provide information on suitability/unsuitability.

A simulator is a tool used as a learning medium that has the same form and function as the original tool [10]. A calibrator is an instrument used as a reference whose measurement results will be compared with other instruments. A calibrator is a measurement standard used in calibration. [11]. The tool used to test the accuracy of the fetal Doppler is the fetal Doppler simulator.

D. Fetal Doppler Simulator

Fetal doppler used to detect and display fetal heart rate in the womb of pregnant women requires a device that functions properly, and the accuracy of the examination is ensured by the desired provisions. [12]. Medical devices are instruments, apparatus, machines, tools, and/or implants, in vitro reagents, calibrators, software, materials, or materials used singly or in combination, for humans with one or more purposes. [13]. Medical devices that are directly related to humans and involve life must be calibrated to ensure and monitor whether they are still accurate or functioning properly, and to determine how much deviation from the device. Accuracy can be seen from good and correct calibration, therefore, it is necessary to carry out periodic calibration according to existing regulations. Fetal Doppler calibration can be done with a fetal Doppler simulator that works as a substitute for the fetal heart rate. The selection for BPM (Beats Per Minute) is usually set at 60, 90, 120, 150, 180, 210 bpm. [2].

E. Domestically Produced Fetal Simulator

The fetal doppler simulator tool used to test the suitability of the fetal doppler tool is the ERSA brand fetal doppler simulator as shown in Fig. 3. The ERSA fetal simulator type FD-01 [14] It is a domestic calibrator tool. According to the Regulation of the Minister of Industry, domestic products are goods that are designed, built and engineered, and produced by companies that produce in Indonesia, which allows the production process to use imported raw materials or components. The domestic component level, or TKDN, is the amount of domestic components used in the production of an item. Domestic components in goods are the use of raw materials, design, and engineering that contain elements of manufacturing, assembly, and completion of the work that originate from and are carried out domestically [15].

Figure 1. Domestically Produced Fetal Simulator [14]

The domestically produced fetal doppler simulator has a choice of heart rate parameters that can be used from 30 to 210 bpm with an increase of 30 bpm. How to use it is also very easy. The first step that needs to be done is to turn on the domestically produced fetal doppler simulator, then select the heart rate to be measured. Apply the necessary gel to the part used for the probe. Turn on the fetal doppler to be calibrated and place the probe on the part to measure. The sound of the Doppler pulse will be heard, and the fetal Doppler unit's heart rate indicator will display the heart rate according to what has been set.

F. Fetal Simulator Overseas Production

The fetal doppler simulator as shown in Fig. 4 produced abroad is a fetal monitor simulator that simulates fetal and pregnant mother ECG and uterine activity. This calibrator simulates several fetal parameters, including twins, to train users on how to recognize normal and abnormal responses. The heart rate simulator produces fetal heartbeat sounds to test the fetal Doppler cable and transducer. The choice of heart rate parameters that can be used ranges from 30 to 240 bpm with an increase of 30 bpm. How to use this calibrator is to turn on the fetal doppler simulator produced abroad and connect the mechanical fetal heart to the port. After that, determine the heart rate to be measured. Apply enough gel to the simulation point. Place the fetal doppler ultrasound transducer on the simulation point, facing upwards. [14].

Figure 2. Fetal Simulator Overseas Production [15]

The difference between the two fetal doppler simulators is in the part for placing the probe or transducer. In the domestic fetal doppler simulator, the transducer is placed on the same device, while in the foreign fetal doppler simulator, the probe or transducer is placed on the mechanical fetal heart, which is a different device used to set its parameters. In addition, there is also a difference in the choice of heart rate; in the domestic fetal doppler simulator, it starts from 30 to 210 bpm, while the foreign fetal doppler simulator starts from 30 to 240 bpm.

II. RESEARCH METHODS

A. RESEARCH DESIGN

In this study, measurements will be carried out by taking data on 5 fetal doppler units with 5 measurements on each different fetal doppler, with 1 domestically produced fetal doppler simulator unit and 1 foreign-produced fetal doppler simulator unit. The author will conduct a comparative test of the results of the Fetal Doppler test using a domestically produced Fetal Doppler Simulator and a foreign-produced Fetal Doppler Simulator by setting the same heart rate on each Fetal Doppler Simulator. The data collection process uses quantitative data collection methods and determines the data measurement scale in the form of a nominal scale until the interpretation is carried out by comparing the measurement results with existing standards.

B. CONCEPTUAL FRAMEWORK

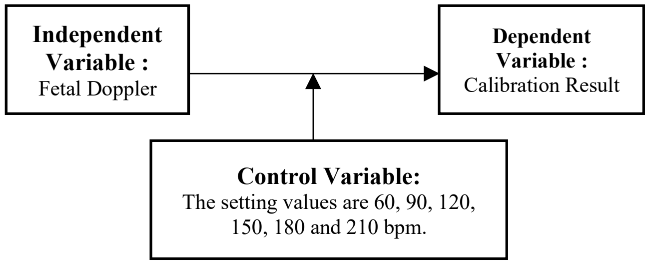

Figure 3. Conceptual Framework

Fig. 5 shows the conceptual framework in this study, that can be explained as:

1) *Independent Variable*: In this study, the independent variable in this study is the Fetal Doppler device. This refers to the five different brands of fetal Doppler used in the calibration performance test. Each device may have different levels of sensitivity, detection mechanisms, and display systems, which could potentially affect the measurement results. The use of multiple brands is intended to evaluate the consistency and reliability of the fetal Doppler simulator across a representative range of clinical instruments.
2) *Dependent Variable*: In this study, the dependent variable is the calibration result obtained from the fetal Doppler device when tested using the simulator. The calibration result is expressed in beats per minute (BPM) readings displayed by the fetal Doppler, and is analyzed for its accuracy compared to the set BPM values generated by the fetal Doppler simulator. This variable reflects the effectiveness of the simulator in providing consistent and correct output for fetal Doppler calibration.
3) *Control Variable*: The control variable in this study is the setting value of the heart rate programmed on the fetal Doppler simulator. These settings were maintained consistently across all test conditions to ensure fair comparison. The specific BPM settings used in this research were: 60 BPM, 90 BPM, 120 BPM, 150 BPM, 180 BPM, and 210 BPM. By standardizing these values, the study aims to isolate the effect of the independent variable and ensure that variations in results are not due to changes in simulator output.

C. DATA COLLECTION TECHNIQUES AND RESEARCH INSTRUMENTS

1. Data Collection Techniques

In this study, the data collection method that will be carried out by the author is primary data collection and documentation. The author will use primary data to measure heart rate on 5 (five) fetal dopplers using a domestically produced fetal doppler simulator and a foreign-produced fetal doppler simulator. In this study, the heart rate setting was set at 60, 90, 120, 150, 180, 210 BPM. In one data collection, 5 (five) measurements were taken to determine the average of the heart rate measurements. The results of these measurements will be processed and analyzed.

The test begins with fetal doppler A being given a 60 BPM heart rate simulation by a domestically produced fetal doppler simulator 6 (6) times, with the same fetal doppler unit. The domestically produced fetal doppler simulator is replaced with a foreign-produced fetal doppler simulator, and the same test is carried out. Repeat the test using fetal doppler A with a periodic heart rate rhythm of up to 210 BPM with an increase of 30 BPM, then take the data. The next step is to test using fetal doppler B, C, D, to E with the same treatment as fetal doppler A. After the test data is obtained, process the data to determine the accuracy and precision of the fetal doppler simulator. Next, a conclusion will be obtained from the data comparison.

2. RESEARCH INSTRUMENTS

The research instruments used in this study consisted of a fetal doppler simulator (domestically and internationally produced), five fetal doppler devices, an analytical balance, and a thermohygrometer. Each device was identified by brand, model, serial number, room location, and test date.

Room conditions (temperature and humidity) were measured at the beginning and end of each test session using a calibrated thermohygrometer. Environmental conditions were maintained within 25°C ± 5°C and 55% ± 20% RH, by calibration standards.

Before testing, all fetal Doppler units underwent a visual and functional inspection covering the device casing, probe cables, control buttons, and display indicators. This ensured the devices were physically intact and operational before calibration was performed.

C. DATA ANALYSIS TECHNIQUES AND METHODS OF DATA PRESENTATION

In this study, the data analysis and presentation techniques used by the author include the calculation of mean value, correction error, and percentage error. These methods were applied to evaluate the calibration results of fetal Doppler devices using simulators at various BPM settings.

1. Mean Value ($\bar{x}$)

The mean value represents the arithmetic average of the BPM values displayed by the fetal doppler across repeated trials for each test setting. It is calculated to evaluate the central tendency of the measurement data and serves as a basis for further error and accuracy analysis. By reducing random fluctuations through repeated measurements, the mean value provides a more stable representation of each device's performance at a specific BPM setting.

Calculating the Mean Value ($\bar{x}$) from the distribution of all random data values obtained from measurements:

$$\bar{x} = \frac{\Sigma x}{n} \qquad \text{...................(1)}$$

With :

x = Mean value of measurement

Σx = Number of measurement values ($x_1 + x_2 + x_3 \ldots$)

n = The number of measurements

2. Correction Value

The correction value is calculated as the absolute difference between the mean BPM value recorded by the fetal doppler and the nominal value set on the simulator. This metric reflects the deviation of the device's output from the true standard, regardless of direction (positive or negative). It is crucial for identifying systematic bias in measurement.

$$|error| = \bar{x} - \text{nilai setting} \qquad \text{....................(2)}$$

With :
|error| = absolute measurement error value
x = average measurement value
Setting value = applied setting value

3. Percentage Error (%)

To normalize the correction error and enable comparison across different BPM settings, the percentage error is computed. This parameter expresses the deviation as a proportion of the reference value and is particularly useful for assessing relative performance when dealing with multiple calibration points.

Calculate the error value in percentage form.

$$\text{Percentage } Error = \frac{|error|}{nilai\ setting} \times 100\% \quad \text{.........(3)}$$

With :
Percentage Error = percentage of error
|error| = absolute measurement error value
Setting value = applied setting value

4. Accuracy Percentage (%)

The level of measurement accuracy is obtained by subtracting the percentage error from 100%. This value quantifies the closeness of the measured result to the true value and serves as a critical indicator for assessing whether the fetal Doppler device meets calibration standards.

Calculate the accuracy value in percentage form.

Accuracy = 100% - deviation

Description:
Accuracy = percentage of measurement
Deviation = percentage of measurement deviation

Each measurement series, conducted at BPM settings of 60, 90, 120, 150, 180, and 210, was analyzed using the above techniques to determine the overall calibration performance of the fetal doppler device. Comparisons were made between results obtained using domestic and foreign simulators, allowing the researcher to identify consistency, reliability, and deviation trends across brands and environments.

III. RESULTS AND EXPLANATION

To evaluate the performance of both domestic and foreign fetal Doppler simulators, calibration measurements were conducted over five consecutive days. The tests were performed at six preset BPM values, and the output from each Doppler device was recorded, analyzed, and compared. The following tables summarize the results, including the mean BPM values, correction errors, percentage errors, and accuracy percentages for each simulator across all days of testing. The results are shown in Table 1. Table 2, Table 3, and Table 4.

TABLE I
RESULT OF MEASUREMENT ON DAY 1

Fetal Doppler Simulator	Set Point (BPM)	Mean Value	Correction	% Error	% Accuracy
Domestic	60	60	0	0.00%	100.00%
Domestic	90	90	0	0.00%	100.00%
Domestic	120	120	0	0.00%	100.00%
Domestic	150	149	1	0.67%	99.33%
Domestic	180	178	2	1.11%	98.89%
Domestic	210	212	2	0.95%	99.05%
Foreign	60	60	0	0.00%	100.00%
Foreign	90	90	0	0.00%	100.00%
Foreign	120	120	0	0.00%	100.00%
Foreign	150	150	0	0.00%	100.00%
Foreign	180	180	0	0.00%	100.00%
Foreign	210	210	0	0.00%	100.00%

TABLE 2
RESULT OF MEASUREMENT ON DAY 2

Fetal Doppler Simulator	Set Point (BPM)	Mean Value	Correction	% Error	% Accuracy
Domestic	60	60	0	0.00%	100.00%
Domestic	90	90	0	0.00%	100.00%
Domestic	120	120	0	0.00%	100.00%
Domestic	150	149	1	0.67%	99.33%
Domestic	180	178	2	1.11%	98.89%
Domestic	210	212	2	0.95%	99.05%
Foreign	60	60	0	0.00%	100.00%
Foreign	90	90	0	0.00%	100.00%
Foreign	120	120	0	0.00%	100.00%
Foreign	150	150	0	0.00%	100.00%
Foreign	180	180	0	0.00%	100.00%
Foreign	210	210	0	0.00%	100.00%

TABLE 3
RESULT OF MEASUREMENT ON DAY 3

Fetal Doppler Simulator	Set Point (BPM)	Mean Value	Correction	% Error	% Accuracy
Domestic	60	60	0	0.00%	100.00%
Domestic	90	90	0	0.00%	100.00%
Domestic	120	120	0	0.00%	100.00%
Domestic	150	149	1	0.67%	99.33%
Domestic	180	178	2	1.11%	98.89%
Domestic	210	212	2	0.95%	99.05%
Foreign	60	60	0	0.00%	100.00%
Foreign	90	90	0	0.00%	100.00%
Foreign	120	120	0	0.00%	100.00%
Foreign	150	150	0	0.00%	100.00%
Foreign	180	180	0	0.00%	100.00%
Foreign	210	210	0	0.00%	100.00%

TABLE 4
RESULT OF MEASUREMENT ON DAY 4

Fetal Doppler Simulator	Set Point (BPM)	Mean Value	Correction	% Error	% Accuracy
Domestic	60	60	0	0.00%	100.00%
Domestic	90	90	0	0.00%	100.00%
Domestic	120	120	0	0.00%	100.00%
Domestic	150	149	1	0.67%	99.33%
Domestic	180	178	2	1.11%	98.89%
Domestic	210	212	2	0.95%	99.05%
Foreign	60	60	0	0.00%	100.00%
Foreign	90	90	0	0.00%	100.00%
Foreign	120	120	0	0.00%	100.00%
Foreign	150	150	0	0.00%	100.00%
Foreign	180	180	0	0.00%	100.00%
Foreign	210	210	0	0.00%	100.00%

TABLE 5
RESULT OF MEASUREMENT ON DAY 5

Fetal Doppler Simulator	Set Point (BPM)	Mean Value	Correction	% Error	% Accuracy
Domestic	60	60	0	0.00%	100.00%
Domestic	90	90	0	0.00%	100.00%
Domestic	120	120	0	0.00%	100.00%
Domestic	150	149	1	0.67%	99.33%
Domestic	180	178	2	1.11%	98.89%
Domestic	210	212	2	0.95%	99.05%
Foreign	60	60	0	0.00%	100.00%
Foreign	90	90	0	0.00%	100.00%
Foreign	120	120	0	0.00%	100.00%
Foreign	150	150	0	0.00%	100.00%
Foreign	180	180	0	0.00%	100.00%
Foreign	210	210	0	0.00%	100.00%

From Table 1. Table 2, Table 3, and Table 4. It can be concluded that the calibration of fetal Doppler devices was carried out over five consecutive days using two types of simulators: one domestically manufactured and one imported. The BPM setpoints used during the tests were 60, 90, 120, 150, 180, and 210. For each setting, the mean value, correction error, percentage error, and percentage accuracy were calculated to assess the performance of each simulator.

The results showed that the foreign-made simulator consistently produced 100% accuracy across all BPM settings on all five days, with no correction error recorded. This indicates that the foreign simulator output was highly stable and aligned exactly with the intended setpoints throughout the testing period.

In contrast, the domestically produced simulator also demonstrated high performance, particularly at lower BPM settings (60, 90, and 120), where it achieved 100% accuracy consistently across all five days. Minor deviations were observed at higher BPM values (150, 180, and 210), where the mean readings showed a correction of 1–2 BPM. The highest percentage error recorded was 1.11% at 180 BPM, corresponding to an accuracy of 98.89%, which remains within the acceptable tolerance range of ±5% as defined by calibration standards.

The consistency in the domestic simulator's performance across the five days suggests that the observed deviations are not due to instability or random errors, but are likely systematic and reproducible. These minor discrepancies, although statistically insignificant, could be addressed through internal adjustment or firmware optimization in future device iterations.

Overall, both simulators were found to be highly reliable and effective in producing accurate calibration signals for fetal Doppler devices. The results validate the potential of the domestically manufactured simulator to serve as a feasible alternative to imported devices, particularly in supporting local content policies and reducing reliance on foreign medical technology.

Table 6 presents the daily accuracy results of five fetal Doppler devices when tested using the domestically produced fetal Doppler simulator over five consecutive days. The devices tested include various models commonly found in clinical practice. The accuracy values were calculated based on the percentage deviation from the simulator's set BPM values. This analysis aims to assess the consistency and reliability of the simulator in delivering accurate signals across different Doppler brands. The final column summarizes the average accuracy of each device throughout the testing period.

TABLE 6
Accuracy Calculation of the Domestically Produced Fetal Doppler Simulator

Fetal Doppler	Day 1	Day 2	Day 3	Day 4	Day 5	Total Accuracy
Elitech Sonotrax B	99.53%	99.60%	99.60%	99.40%	99.50%	99.53%
Elitech Sonotrax Pro	99.62%	99.60%	99.60%	99.60%	99.70%	99.62%
Bistos BT 200L	100%	100%	100%	100%	100%	100.00%
VCOMIN	99.86%	99.90%	99.90%	100%	99.90%	99.91%
Bistos BT 220C	99.54%	99.50%	99.50%	99.50%	99.50%	99.51%

TABEL 7
Accuracy Calculation of Foreign-Produced Fetal Doppler Simulator

Fetal Doppler	**Hari Kesatu**	**Hari Kedua**	**Hari Ketiga**	**Hari Keempat**	**Hari Kelima**	**Akurasi Total**
Elitech type Sonotrax B	99,69%	99,70%	99,60%	99,70%	99,60%	99,66%
Elitech type Sonotrax Pro	99,59%	99,60%	99,60%	99,60%	99,60%	99,60%
Bistos tipe BT 200L	99,65%	99,70%	99,50%	99,40%	99,50%	99,55%
VCOMIN	99,81%	99,80%	99,80%	99,90%	99,90%	99,84%
Bistos tipe BT 220C	100%	100%	100%	100%	100%	100,00%

It can be seen from Tables 6 and Table 7 that the percentage value of total accuracy of the five Fetal Doppler units using Fetal Doppler Simulators produced domestically and abroad. In the table, it can be concluded that the accuracy of both is almost 100%, but there is a significant difference between the Bistos Type 200L Brand and the Bistos Type 220C Brand.

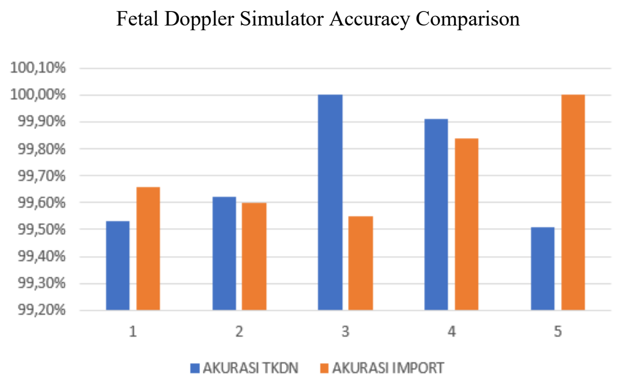

FIGURE 6. Fetal Doppler Simulator Accuracy Comparison

The linear equation obtained from each micropipette size and room temperature yielded a positive constant value, showing the independent variable's positive effect (temperature). If the independent variable (temperature) increases or is greater, the dependent variable (micropipette calibration results) will decrease in value.

Fig. 6 shows a comparison diagram of the percentage value of the measurement results accuracy of five different brands of fetal doppler units measured using domestic and foreign fetal doppler simulators with measuring instrument setting points on the fetal doppler simulator of 60 bpm, 90 bpm, 120 bpm, 150 bpm, 180 bpm and 210 bpm. The graph shows that the Elitech and VCOMIN brands have accuracy values with differences that are not too significant when using both fetal doppler simulators.

However, in the Bistos BT 200L and Bistos 220C brands, there is a significant difference in the measurement results, from the calculation results it can be seen that the difference value in the Bistos BT 200L brand is ± 0.45% where the measurement using a domestically produced fetal doppler simulator is higher while the difference in the Bistos BT 220C brand is ± 0.49% where the measurement using a foreign-produced fetal doppler simulator produces higher accuracy. However, if we conclude testing these five fetal doppler brands, there is no significant difference in the domestic and foreign-produced fetal doppler simulators, this can be shown in Table 8.

TABEL 8
Fetal Doppler Simulator Accuracy Calculation Table

Unit Under Test	Akurasi Fetal Doopler Simulator Produksi Dalam Negeri	Akurasi Fetal Doppler Simulator Produksi Luar Negeri
Elitech Tipe Sonotrax B	99,53%	99,66%
Elitech Tipe Sonotrax Pro	99,62%	99,60%
Bistos Tipe BT 200L	100%	99,55%
VCOMIN	99,91%	99,84%
Bistos Tipe BT 220C	99,51%	100%
% Rata - rata Keakurasian Total	**99,71%**	**99,73%**

IV. CONCLUSIONS

Based on the data collection and analysis described in the previous section, it can be concluded that the use of both domestically and internationally produced fetal Doppler simulators across five different fetal Doppler brands did not result in any significant difference in calibration outcomes. Both types of simulators demonstrated reliable performance and were able to produce consistent measurement results.

The comparison shows that the foreign-made Fetal Doppler Simulator achieved a slightly higher average accuracy (99.73%) compared to the domestically produced simulator (99.71%). However, this difference is minimal and remains well within acceptable calibration standards. These results indicate that domestically manufactured simulators can serve as effective alternatives in clinical practice, supporting national initiatives to increase the use of locally produced medical equipment.

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