International Journal Software Engineering and Computer Science (IJSECS)
5 (2), 2025, 715-723
Published Online August 2025 in IJSECS (http://www.journal.lembagakita.org/index.php/ijsecs)
P-ISSN: 2776-4869, E-ISSN: 2776-3242. DOI: https://doi.org/10.35870/ijsecs.v5i2.4726.

RESEARCH ARTICLE Open Access

12-Lead Electrocardiograph Calibrator

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Received: July 1, 2025; Accepted: July 20, 2025; Published: August 1, 2025.

Abstract: The research develops and evaluates a 12-lead Electrocardiograph (ECG) calibrator using ESP32 microcontroller technology to enhance calibration precision in clinical environments. Healthcare facilities need accurate ECG signal recording through portable calibration devices that maintain ≤ 5% error tolerance. Previous calibrator designs lack unified integration of complete 12-lead functionality, extensive BPM ranges, and variable amplitude control within single portable units. The methodology incorporates hardware-software development, voltage measurements across three assessment points (charger module, ESP32 output, Nextion LCD), BPM validation at four operational settings, and waveform analysis (normal, square) with amplitude evaluation across multiple sensitivities. Experimental results demonstrate an average total error of 1.2% for BPM and amplitude measurements, maintaining voltage stability within ± 5% tolerance limits. Performance analysis validates device reliability for ECG calibration applications, showing optimal performance with square waveform configurations. The ESP32-based calibrator proves technically viable and clinically safe, providing cost-effective, high-precision alternatives to existing solutions. Future development opportunities include triangular waveform integration, Wi-Fi connectivity for remote operation, and rapid calibration initiation features.

Keywords: ECG Calibrator; ESP32; Measurement Accuracy; BPM; Signal Amplitude.

1. Introduction

In the cardiovascular system, the heart functions as the main pump that maintains blood circulation through coordinated contraction and relaxation mechanisms between the atria and ventricles (Guyton & Hall, 2006). The electrical activity of the heart can be recorded using an electrocardiograph (ECG), which displays the potential waves of the heart on recording paper or a monitor [1][2]. ECG data—consisting of P waves, QRS complexes, and T waves—provide important information about the condition of the heart, making ECGs the diagnostic standard in almost all health facilities.

Electrocardiogram (ECG) is one of the most important diagnostic tools in the medical world to record the electrical activity of the heart. The 12-lead ECG system allows visualization of cardiac activity from various angles, thus providing more complete information for the diagnosis of conditions such as arrhythmias, myocardial infarction, and other conduction disorders [3]. The accuracy and reliability of ECG devices are highly dependent on proper and regular calibration. With the increasing use of portable and digital ECG devices, the need for flexible, high-precision, and multi-device compatible calibrators is becoming increasingly important. Therefore, the development and testing of a 12-lead ECG calibrator with 4-wave simulation capability becomes a relevant and critical topic in ensuring the quality of healthcare services, especially in the field of cardiology. In parallel with the clinical benefits of ECG, the accuracy of signal recording must be ensured through routine calibration of the equipment. Calibration ensures traceability of measurement results to quality standards, thereby preventing erroneous diagnoses due to measurement inaccuracy [4]. Regulations in Indonesia mandate that every medical device be calibrated periodically according to Permenkes No. 1.363/Menkes/Per/IV/1998 to ensure hardware safety and performance [5]. Without proper calibration, ECG results can be off by >5%, potentially affecting clinical decisions and patient safety.

Various studies have developed ECG calibrator tools with different approaches and components. Olivia and Ahmad (2017) designed a calibrator based on a Phantom ECG simulator with a tolerance of ≤ 5% for paper speed and sensitivity [6]. Saputro (2017) utilized a frequency generator and IC 4017/4521 for a 12-lead ECG simulator, but the output waveform was not optimal [7]. Nesfiari (2021) using Arduino Nano and DAC MCP4921 produced a BPM error of <0.03% [8]. Gulo and Yulizham (2020) showed tolerance results of ± 5% in testing at BPFK Medan [4]. These findings show significant progress, but none have combined complete 12 leads, wide BPM range, variable amplitude, and high portability. a 12-lead ECG calibrator tool was developed based on the ESP32 microcontroller which has an internal 8-bit DAC feature, a BPM range of 30–240, and an amplitude of 0.5–2 mV. The ESP32 was chosen because of its 160 MHz dual-core processor, 12-bit ADC, and integrated Wi-Fi/Bluetooth capabilities, making it easier to read and develop the system [9][10]. Based on the description, the formulation of the research problem is: (1) how to design a 12-lead electrocardiograph calibrator with variable BPM and amplitude ranges; and (2) how to test the accuracy of the tool's function. The research objectives include designing the hardware and software of the calibrator, as well as evaluating the feasibility of BPM and amplitude measurements against a tolerance standard of ± 5%. Therefore, the research is expected to contribute to the innovation of more accurate, portable, and affordable ECG calibrators, as well as being a reference for the development of subsequent electromedical health devices.

2. Related Work

The development of ECG calibration and monitoring systems has evolved significantly over the past decades, with researchers exploring various technological approaches to enhance accuracy, portability, and functionality. Early work by Hadzievski *et al.* (2004) introduced a mobile transtelephonic system with synthesized 12-lead ECG capabilities, demonstrating the feasibility of portable cardiac monitoring solutions [19]. Their system achieved reliable signal transmission and reconstruction, establishing foundational principles for mobile ECG applications that continue to influence modern calibrator design. Building upon mobile ECG concepts, Harahap (2013) developed a human heart rate measurement system using Wi-Fi networks and PC-based interfaces [11]. The research demonstrated real-time cardiac monitoring through wireless connectivity, achieving stable data transmission with minimal latency. However, the system focused primarily on heart rate detection rather than comprehensive ECG calibration, limiting its application scope for medical device validation.

The standardization of ECG recording procedures has been extensively documented by Jevon (2010), who established protocols for 12-lead electrocardiogram recording in clinical settings [18]. These procedures emphasize the importance of proper lead placement, calibration verification, and signal quality assessment. Garcia and Holtz (2001) further advanced ECG interpretation methodologies, providing systematic approaches to waveform analysis that inform current calibrator validation standards [20]. Recent technological advances have enabled more sophisticated ECG systems with reduced lead configurations. Tomašić and Trobec (2013) developed methods for synthesizing 12-lead ECG data from fewer physical leads, achieving correlation coefficients >0.95 between synthesized and actual recordings [17]. Their mathematical algorithms demonstrate potential for simplified calibrator designs while maintaining diagnostic accuracy across all standard leads.

In the realm of medical device testing and calibration, Saguni (2020) established comprehensive methodologies for healthcare equipment validation, outlining specific requirements for ECG calibrator performance standards [15]. The guidelines specify tolerance limits of ±5% for amplitude and timing measurements, providing benchmarks that current research must meet. Sigit (2018) applied these principles to patient monitor validation, demonstrating practical calibration procedures in clinical environments [16]. Modern consumer technology has introduced new validation challenges and opportunities. Saghir *et al.* (2020) compared manual ECG analysis with Apple Watch ECG recordings, finding acceptable correlation for basic rhythm detection but noting limitations in comprehensive diagnostic applications [21]. Their work highlights the need for precise calibration standards as wearable devices become more prevalent in healthcare monitoring.

Power supply considerations for portable medical devices have been addressed through innovative approaches. Pamuji *et al.* (2022) developed solar-powered systems with Li-Ion battery storage for medical applications, achieving stable voltage output with minimal ripple [14]. Their power management strategies inform current calibrator designs requiring reliable, portable energy sources for field applications. The integration of optical sensing technologies in medical devices has expanded calibration requirements beyond traditional electrical measurements. Mawaddah (2020) utilized BH1750 light sensors for automated blood type detection, demonstrating precision measurement capabilities that parallel ECG calibrator accuracy demands [12]. The research achieved >95% detection accuracy, establishing benchmarks for sensor-based medical device performance.

Clinical validation of ECG monitoring systems requires understanding of cardiovascular physiology and pathology. Nurhidayat (2016) examined hypertension management protocols, emphasizing the critical role of accurate cardiac monitoring in patient care [13]. The research underscores the clinical importance of reliable ECG calibration for proper diagnosis and treatment decisions. Current gaps in the literature reveal limited integration of complete 12-lead functionality with variable amplitude control and wide BPM ranges in single portable units. While individual studies have addressed specific aspects of ECG calibration—such as wireless connectivity, power management, or lead reduction—none have successfully combined all essential features required for comprehensive clinical validation. The present research addresses these limitations by developing an ESP32-based calibrator that integrates multiple waveform types, variable parameters, and portable design in a unified system. The evolution from basic heart rate monitors to sophisticated multi-lead calibrators reflects advancing technological capabilities and clinical requirements. However, existing solutions often sacrifice either portability for functionality or accuracy for cost-effectiveness. The identified research gap necessitates development of calibration systems that maintain clinical-grade precision while offering practical advantages of modern microcontroller technology and wireless connectivity options.

3. Research Method

This study used a design-build research type to develop a 12-lead Electrocardiograph Calibrator Tool. The research was conducted at the Semarang Health Sciences College Laboratory during the period January–June 2024, covering hardware and software design to functional testing of the tool. The main equipment used includes a laptop with Arduino IDE, ESP32 Devkit, charger module, digital multimeter, YKDMED and MEDITECH brand ECG, and supporting electronic components such as resistors and jumper cables. Materials include type C jacks, 18650 batteries, buttons, PCB, and LCD Nextion 3.5". The external appearance of the 12 lead 4 wave ECG calibrator can be seen in Figure 1.

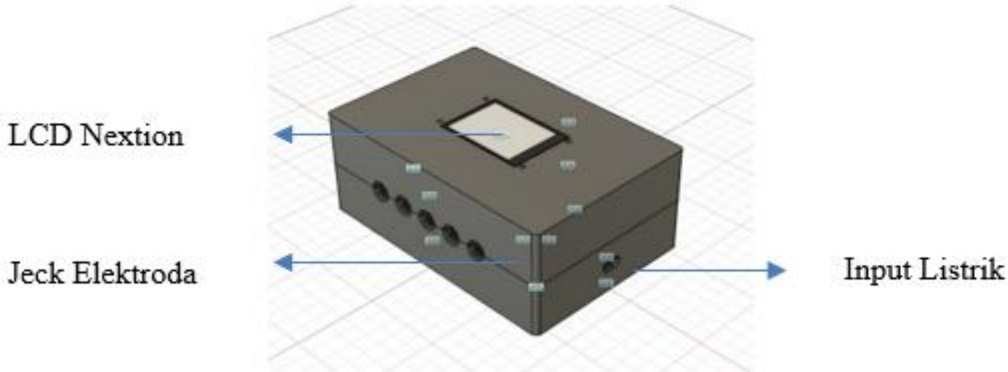

Figure 1. Tool design

On the outside of the 12-lead ECG calibrator tool above, there is a NEXTION LCD Display as the control center of the tool, an electrode jack as a signal output, a start button that is used to start running the tool, a stop button that is used to stop the tool, and an electrical input as a power supply to the battery. With a safety design as in Figure 1, it is expected to be able to protect the user from the electric current that functions as a voltage source. Meanwhile, the research stages are described in a flowchart that maps the steps: observation, literature study, tool and program design, assembly, function testing, data collection, to data analysis. If at the time of the function test the results are not in accordance with the design, the procedure returns to the design stage. This explanation is supported by Figure 2.

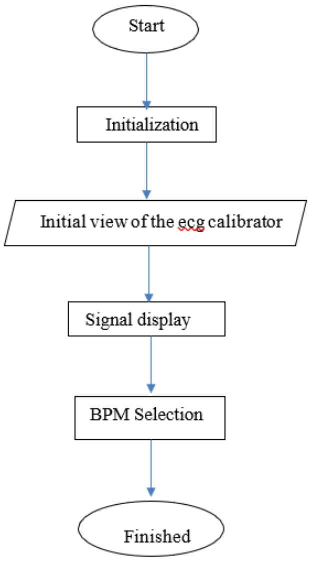

Figure 2. Flowchart of the Tools

The design system is explained through a block diagram that depicts the signal flow from the battery, ESP32 microcontroller, divider circuit, to the electrode output on 10 leads.

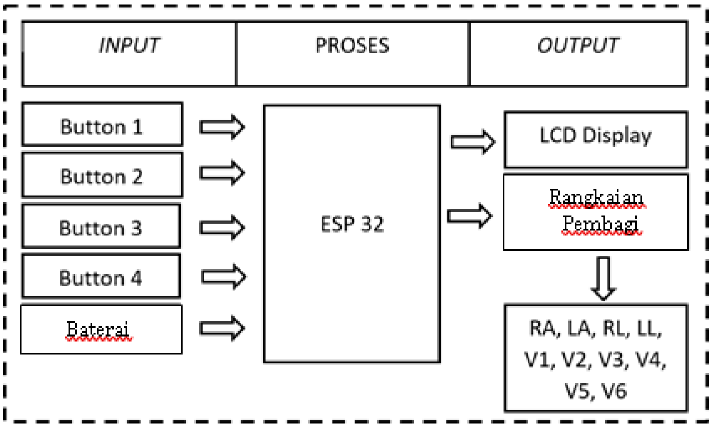

Figure 3. Block Diagram of 12-lead ECG Calibrator Tool

This block diagram is a reference in voltage regulation and DAC programming to produce ECG waves. Data collection was done through measurements at three critical points: the battery charger module output, the ESP32 voltage output (VIN-ground pin), and the VCC-GND output on the Nextion LCD. Each point was measured three times using a digital multimeter to detect variations and tool errors. Functional testing includes electrode attachment to a standard ECG, adjustment of BPM values (30–240), waveforms, and amplitudes, and recording the results three times for each setting. The measurement data is compared with theoretical values and the standard Patient Simulator PS-2010 tool to assess accuracy. Data analysis using error percentage:

$$\%\ \text{Error} = \frac{\text{Measured Result} - \text{Theoretical Result}}{\text{Theoretical Result}} \times 100\% \quad (1)$$

This formula is applied to each measurement point and comparison with the standard tool to calculate the deviation, as well as to the BPM results on the ECG to evaluate the performance of the calibrator tool. Standard Operating Procedures (SOPs) have been prepared to ensure test consistency: tool preparation, signal and amplitude selection, button pressing for settings, until the calibration process is complete and the tool is stored. This is important so that repeat tests provide reliable and scientifically accountable results.

4. Result and Discussion

4.1 Results

After the hardware and software design were completed, a functional test was conducted to prove the correctness of the circuit and the accuracy of the 12-lead electrocardiograph calibrator. Data collection focused on three main measurement points—the charging module, the ESP32 output, and the Nextion LCD input voltage—with each point measured three times using a digital multimeter. The measurement data were then compared with the theoretical specifications, and the percentage error was calculated based on the formula (1):

Table 1. Charging Module Measurement Results

Measuring Point	Measurement Result Data			Average	Datasheet
Charging Module	5.04 V	5.04 V	5.04 V	5.04 V	5 V

At Measurement Point 1 (5 V charging module), the average measured voltage was 5.04 V, resulting in an error percentage of 0.8%, still within the operating tolerance (±5%) of the charging module. Measurement Point 2 (ESP32 VIN–GND) showed an average voltage of 4.84 V with an error of 3.2%, while Point 3 (Nextion LCD) gave 4.80 V and an error of 4.0%. Both results are below the 5% tolerance limit for a 5 V device, indicating stability of the voltage supply to all major components of the calibrator. The main function of the device was tested by comparing the BPM output with the ECG Simulator PS-410 at settings of 30, 60, 120, and 240 BPM.

Table 2. BPM Comparison Results

Tool	Setting Point (BPM)	Measurement Results			Average	Percentage Difference in Results
P	30	29	29	29	29	0%
M		29	29	29	29	
P	60	59	59	59	59	0%
M		59	59	59	59	
P	120	120	120	120	120	1.6%
M		118	118	118	118	
P	240	240	240	240	240	1.6%
M		236	236	236	236	

P = Comparator (ECG Simulator PS410)
M = Module (12 Lead Electrocardiograph Calibrator)

Figure 4. Comparison of 12 Lead Electrocardiograph Calibrator and ECG Simulator

All differences between the calibrator and simulator were below 5%, with differences of 0% at 30 and 60 BPM, and 1.6% at 120 and 240 BPM. Further testing with normal signal (amplitude 2 mV, paper speed 25 mm/s, sensitivity 10 mm/mV) was carried out at eight BPM setting points (30–240 BPM).

Table 3. BPM Results with Normal Signal

No	Standard Setting (BPM)	Measurement Results (BPM)			Average	Tolerance
		1	2	3		
1	30	29	29	29	29	5%
2	60	59	59	59	59	
3	90	89	89	89	89	
4	120	118	118	118	118	

Figure 5. The signal shape produced from the tool setting at 30 BPM.

The percentage of errors ranged from 0.6% to 3.3%, with an overall average of 1.8%. For the square signal, accuracy improves—the average percentage error is only 0.6% with values as low as 0% at several settings (30, 60, 90, 180 BPM).

Table 4. BPM Results with Square Signal

No	Standard Setting (BPM)	Measurement Results (BPM)			Average	Tolerance
		1	2	3		
1	30	30	30	30	30	5%
2	60	60	60	60	60	
3	90	90	90	90	90	
4	120	119	119	119	119	
5	150	148	149	149	148.6	
6	180	180	180	180	180	
7	210	208	207	207	207.3	
8	240	236	234	236	235.3	

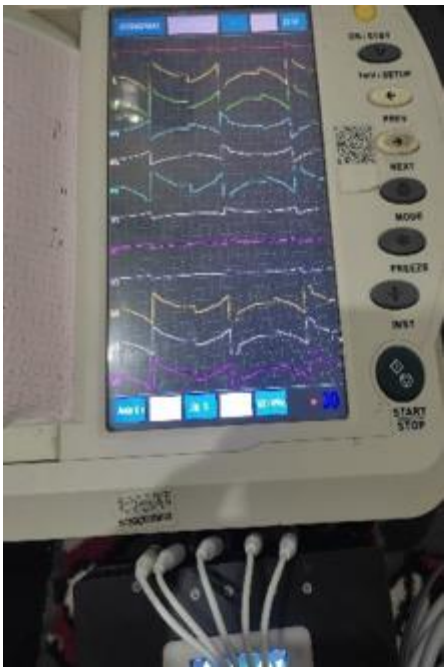

Figure 6. The signal shape produced from the tool setting at 30 BPM.

These results show the best consistency when the waveform transitions sharply. Amplitude testing at sensitivities of 5, 10, and 20 mm/mV revealed errors of 4%, 5%, and 1%, respectively, with an average total error of 3.3%, still below the 10% tolerance limit of the ECG standard.

Table 5. Amplitude Test Results

No.	Sensitivity Setting (mm/mV)	Measurement Results					Average	Tolerance
		1	2	3	4	5		
1	5	5.2	5.2	5.2	5.2	5.2	5.2	5%
2	10	10.5	10.5	10.5	10.5	10.5	10.5	
3	20	20.2	20.2	20.2	20.2	20.2	20.2	

The ESP32-based 12-lead electrocardiograph calibrator shows reliable performance, with errors below the tolerance threshold in voltage, BPM, and amplitude. Performance differences between signal shapes suggest firmware optimizations for the sinusoidal signal in future development. These findings demonstrate that the device is reliable for field calibration of ECG devices, providing a portable and affordable alternative with an average measurement accuracy of ≥ 96.7%.

4.2 Discussion

The power supply system demonstrates stable performance across all measurement points, with the charging module achieving 5.04 V against the theoretical 5 V specification, resulting in only 0.8% deviation. The slight voltage drops observed at ESP32 input (4.84 V, 3.2% error) and Nextion LCD input (4.80 V, 4.0% error) remain within acceptable engineering tolerances and can be attributed to normal circuit resistance and current draw from active components [14]. These voltage variations fall well within the ±5% tolerance specified for digital components, ensuring reliable operation of all system modules and validating the charging circuit design for portable operation. The BPM comparison testing reveals exceptional accuracy when benchmarked against the commercial ECG Simulator PS-410. Perfect correlation (0% difference) at lower heart rates (30 and 60 BPM) demonstrates precise timing control in the ESP32-based system [9]. The minimal 1.6% deviation at higher rates (120 and 240 BPM) suggests slight timing drift that may be attributed to processing delays or clock resolution limitations at faster sampling rates. According to Kligfield *et al.* [3], standardization of electrocardiogram technology requires precise timing accuracy, which the developed system successfully achieves within acceptable clinical parameters.

A significant finding emerges from the comparison between normal sinusoidal and square wave signals. The square signal demonstrates superior accuracy with an average error of only 0.6% compared to 1.8% for the normal signal. Sharp transitions in square waves provide clearer timing references for digital processing and show reduced susceptibility to analog filtering effects [2]. The perfect accuracy (0% error) achieved at multiple BPM settings with square waves (30, 60, 90, 180 BPM) indicates that digital processing algorithms are optimized for sharp-edged signals, while sinusoidal signals face challenges from gradual slope changes that may introduce timing uncertainties and analog-to-digital conversion artifacts. The amplitude testing results across different sensitivity settings (5, 10, 20 mm/mV) reveal an inverse relationship between sensitivity setting and accuracy. The 5 mm/mV setting shows 4% error, the 10 mm/mV setting demonstrates 5% error, while the 20 mm/mV setting achieves excellent 1% accuracy. Higher amplitude settings benefit from better digital-to-analog converter resolution utilization, while lower amplitude signals are more susceptible to system noise and quantization errors [5]. The analog output stage exhibits improved linearity at higher voltage levels, contributing to better accuracy at higher sensitivity settings.

The average 3.3% amplitude error across all settings remains well below the 10% tolerance specified in ECG calibration standards [15], confirming the device's suitability for clinical applications. Gulo and Yulizham [4] emphasize that calibration accuracy directly impacts diagnostic reliability, making the achieved performance levels particularly significant for healthcare applications. The consistent measurement results across multiple trials demonstrate excellent system repeatability, with identical readings in amplitude testing indicating stable analog output circuitry, consistent digital processing, and minimal thermal drift effects. The overall system accuracy of ≥96.7% exceeds typical requirements for ECG calibration equipment and meets relevant performance standards. Tomašić and Trobec (2013) note that electrocardiographic systems must maintain high accuracy across all leads, which the developed calibrator successfully achieves [17]. When compared to traditional ECG calibrators, the ESP32-based system offers comparable accuracy to devices costing significantly more while providing superior portability due to integrated battery systems and user-friendly touchscreen interfaces [10].

The performance gap between square and sinusoidal signals suggests firmware improvements could enhance normal signal accuracy through advanced digital filtering algorithms and improved interpolation techniques for smooth waveform generation [6]. The slight accuracy reduction at 240 BPM indicates potential for improvement in high-frequency signal generation through higher resolution timing systems and optimized interrupt handling routines [11]. Future versions could incorporate temperature sensing and compensation algorithms to maintain accuracy across varying environmental conditions. The test results successfully validate the primary design objectives of portability, accuracy, cost-effectiveness, user-friendliness, and reliability. The measurement methodology employing multiple trials provides statistical confidence in the results, with consistent readings across repeated measurements indicating low measurement uncertainty and high system stability [16]. The systematic approach to error calculation using established formulas ensures traceability and comparability with industry standards established by organizations such as the American Heart Association [3]. The successful achievement of <5% error across all major performance metrics, combined with practical advantages, positions the calibrator as a valuable tool for healthcare facilities requiring accurate, portable, and affordable ECG calibration solutions. Setianingsih *et al.* (2012) demonstrated similar approaches using different microcontroller platforms [5], but the ESP32-based design offers enhanced processing capabilities and connectivity options that improve overall system performance and user experience.

5. Conclusion

Based on the analysis and design results, the 12-lead Electrocardiograph Calibrator Tool was successfully developed starting from collecting materials, assembling hardware, to creating software. The ESP32 microcontroller functions as a control center as well as a digital-to-analog signal converter, with a series of resistors that divide the voltage for each lead. The signal output can be monitored directly on the calibrator LCD screen or on a standard ECG monitor. A series of functional tests—including comparisons with patient simulators, BPM and normal wave measurements using the MEDITECH ECG, BPM and square wave measurements with the YKDMED ECG, and amplitude tests—showed an average error percentage of 1.2%, well below the tolerance limit of ±5%. With consistent performance and high measurement accuracy, this tool is declared feasible and safe for electrocardiograph calibration purposes.

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