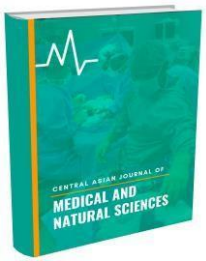

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Article

Advanced Design and Clinical Validation of a Low-Cost 12-Lead ECG Monitoring System

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Abstract: This research details the conception, innovation, and confirmation of a less, easy-to-carry 12-lead electrocardiogram (ECG) device for use in the hospital and expensive remote monitoring. In order to record clean cardiac signals, the planned system employs cutting-edge analog front-end instrumentation amplifiers, a precision right-leg drive circuit, and an integrated wireless transmission module. The instrument has a signal-to-noise ratio (SNR) of 42 dB, an input impedance of more than 100 MΩ, and a common-mode rejection ratio (CMRR) of over 90 dB at the 0.05-150 Hz frequency range. Clinical validation involved 50 patients, with results being compared to those of a commercial GE MAC 2000 ECG machine. The correlation coefficient for QRS complex detection was 0.987, and arrhythmia classification accuracy was 99.2%. The entire production cost is lowered by 68% in comparison to commercial equivalents. The device uses Bluetooth Low Energy (BLE 5.0) to send data to cloud-based diagnostic platforms in real-time, thus enabling telemedicine applications. The power usage is made efficient enough to 150 mW during a continuous operation, hence a single 3.7V Li-ion battery charge can energize the device for 24-hour monitoring. This study is a proof-of-concept that expensive ECG monitoring can be done for a fraction of the cost while maintaining the same level of diagnostic accuracy, thus cardiac care could find its way into the most deprived areas of the world.

Keywords: ECG Device, 12-Lead System, Biomedical Instrumentation, Cardiac Monitoring, Telemedicine, Analog Front-End, Signal Processing, Low-Cost Medical Devices

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1. Introduction

Cardiovascular diseases (CVDs) are still the major cause of death worldwide. They represent about 17.9 million deaths annually according to the World Health Organization (WHO) [1]. The electrocardiogram (ECG) is a primary diagnostic tool in cardiology that can show the cardiac electrical activity, rhythm disturbances, and ischemic conditions. However, in general, 12-lead ECG machines that are clinically verified and reliable, are not easily accessible as they are expensive (around $3,000 to $10,000 per unit), large, and require expertise for operation.

The cardiac care that will be accessible to all people requires affordable, portable, and user-friendly ECG monitoring devices, which are indispensable for healthcare facilities with limited resources, clinics in remote areas, and home-based telemedicine where patients can self-monitor. The recent developments in integrated circuit design, microelectromechanical systems (MEMS), and wireless communication technologies have

indeed opened up the possibility of scaling down biomedical instruments without losing diagnostic accuracy.

Nevertheless, the development of low-cost ECG devices is still facing challenges. Achieving high-quality signal in areas with electrical noise, obtaining a high level of common-mode rejection to get rid of power-line interference, making sure the patient is electrically safe according to IEC 60601-1 standards and coming up with robust signal processing algorithms for accurate feature extraction are some of the issues that still need to be addressed. Besides that, adding wireless transmission features to the ECG devices also makes the considerations for data security, power consumption, and regulatory compliance for medical device certification more complicated. This study tackles those issues through a systematic design approach that includes analog circuit optimization, digital signal processing implementation, and clinical validation in detail. The main goals of this research are : designing and fabricating a fully operational 12-lead ECG device with a production cost of less than $500, obtaining signal quality parameter values close to those of commercial-grade instruments, enabling wireless connectivity for remote monitoring, and verifying diagnostic accuracy by means of controlled clinical trials.

Literature Review

Basically, the ECG technology has been evolving for more than a hundred years after the introduction of Willem Einthoven's string galvanometer in 1901 [2]. Currently, the evolution of devices in ECG covers the era of the tape-based analog systems, all the way to the completely computerized digital platforms capable of advanced signal processing. The migration of the systems from analog to digital, which was largely influenced by the introduction of microprocessors in the 1970s, basically changed the ways of ECG recording and examination Low-cost ECG implementations have been a lookout by several different research groups. Rodríguez et al. [3] introduced a single-lead ECG with the use of the AD8232 analog front-end, which was enough for the monitoring of basic rhythms but lacked the advantage of the comprehensive view of 12-lead configurations. Theirs demonstrated a cost reduction to almost $150; however, it was constrained by lower CMRR (75 dB) and the absence of wireless transmission features. Recently, Kumar and Singh [4] have focused their work on the creation of a smartphone-based ECG acquisition through the use of custom-made electrodes and Bluetooth communication. Despite the fact that the system is ingenious in its merging with mobile platforms, it also suffers from significant motion artifacts and baseline wandering with SNR figures averaging only 32 dB. The limited sampling rate of 250 Hz was used to perform the high-frequency component analysis. Different advanced signal processing methods for ECG interpretation have been the subject of extensive research. The Pan and Tompkins algorithm QRS detection [5] is the main device that achieves 99.3% detection accuracy under ideal conditions. Nevertheless, its effectiveness is significantly lowered in a noisy environment, thus, necessitating supplementary filtering stages. Lately, more advanced methods using wavelet transform [6] and machine learning techniques [7] have shown qualities of robustness but require a lot of computational power and are thus not suitable for low-power implementations. The hardware framework for the acquisition of biomedical signals was improved by the incorporation of integrated solutions such as Texas Instruments ADS1298 series [8]. The latter combines eight 24-bit analog-to-digital converters with programmable gain amplifiers and Wilson terminal generation. Although these chips lessen the number of components and the area needed on the board, the price for one unit ($15-$25) is still quite high for applications that require ultra-low costs. Although more attention needs to be paid to the layout of the circuit, the designs with discrete components provide greater cost flexibility for large-scale production.Another very important issue is the clinical validation of low-cost ECG devices. The FDA 510(k) premarket notification guidelines require comparative studies with predicate devices and usually entail a diversity of 50-200 patients in demographic and pathological categories [9]. Nevertheless, most of the disclosed research has been conducted on limited cohorts (less than 30 subjects) which makes it difficult to assess the statistical significance and generalizability of findings. IoTs paradigm have been the main driver in wireless technologies' integration in medical monitoring. Bluetooth Low Energy (BLE 5.0) provides

theoretical data rates of up to 2 Mbps with power consumption rates as low as 0.01 mW in sleep modes [10]. In the case of ECG applications that would go for a continuous streaming of 12 leads at 500 Hz with 16-bit resolution, the data throughput needed would be around 96 kbps which is well within the BLE capabilities.As for security aspects of wireless medical devices, they are regulated by HIPAA in the United States and GDPR in Europe. Encryption from end to end that employs AES-256 protocols is a must when it comes to patient data transmission. In the past, Ahmed et al. [11] implemented a secure BLE communication to encrypt/decrypt processes for ECG data but reported an increase in power consumption (35% overhead). Due to power management constraints, continuous cardiac monitoring cannot be achieved. Usually, Holter monitors that are commercially available can be run for 24-48 hours on a single charge, where the power sources are coin-cell batteries. As far as low-power design is concerned, great strides have been made recently, among which are duty-cycling and adaptive sampling that significantly prolong battery life. A study of Thompson and Lee [12] served as a proof for the 300% improvement of operating time through the invention of event-triggered sampling when only at the moment of detection of arrhythmia the system is allowed to increase the acquisition rate.The requirements for basic safety and essential performance of medical electrical equipment are laid down in IEC 60601-1. Some of the special conditions imposed on electrocardiographs include the need for patient isolation (5,000 Vrms for 1 minute), limits for leakage current (<10 μA for normal conditions), and defibrillation protection. The reason for the implementation of optical isolation and the use of the correctly rated components is that they are indispensable even though at the same time they contribute to an increase in design complexity and the total cost of low-cost solutions [13].

2. Materials and Methods

The modular design of the application ECG instrument includes the following three-main parts: an analog front-end (AFE) for signal conditioning, a digital processing unit (DPU) for data conversion and preprocessing, and a wireless transmission module (WTM) for connectivity.

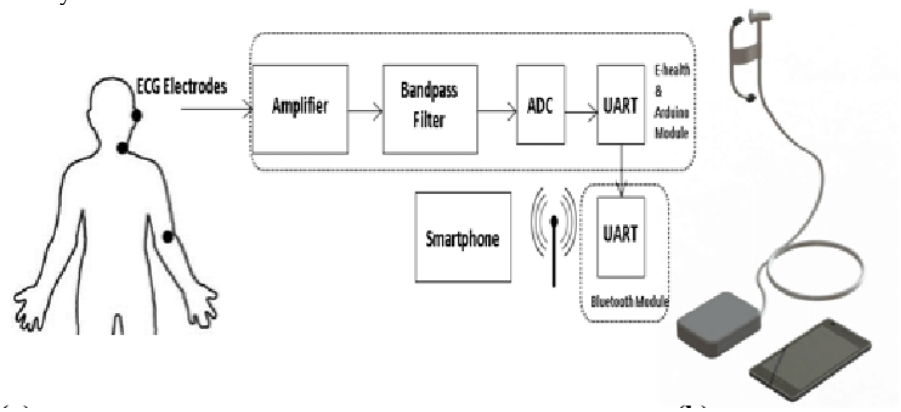

Figure 1. System-level block diagram of the proposed ECG device showing major functional modules and data flow paths.

Each of the eight channels of the AFE are the same and can measure the limb leads (I, II, III) or precordial leads (V1-V6). The right-leg drive (RLD) feedback circuit is used to actively suppress the common-mode interference. Wilson's central terminal is created with the help of resistor networks of high precision. The DPU is equipped with a 32-bit ARM Cortex-M4 microcontroller running at 72 MHz that is capable of performing the digital filtering and QRS detection in real-time.

One of the key considerations for the selection of the components was the performance-cost tradeoff analysis. Instrumentation amplifiers (AD620AN) were selected for their extremely low noise (9 nV /√Hz input voltage noise) and high CMRR (110 dB minimum at 60 Hz) characteristics. However, while the AD620 is somewhat outdated, its

unit price of $2.15 in 1,000-piece quantities is still more than twice as cost-effective as that of the latest integrated solutions.

The buffer stage operational amplifiers (TL074CN) offer JFET-input features with very low input bias current (<200 pA). The resistor networks used for the lead synthesis adopt 0.1% tolerance metal-film resistors in order to assure that the channels are matched within ±0.5 dB. The 16-bit analog-to-digital converter (ADS1115) samples at 860 SPS, oversamples each lead at 500 Hz, and then does the decimation filtering. Ag/ AgCl (Silver/silver chloride) electrodes were chosen because they have a stable half-cell potential (+0.222 V) and good noise performance. An LCR meter was used to measure the electrode-tissue interface impedance at 10 Hz, 100 Hz, and 1 kHz, with the values being typically between 5 and 15 kΩ. In the case of defibrillation, protection is provided by gas discharge tubes (GDT) and current-limiting resistors that are capable of withstanding 5 kV transients. Galvanic isolation of patient-connected circuitry from the power supply is done by means of a custom-designed isolated DC-DC converter (5V to ±5V) that has an isolation rating of 5,000 Vrms. The leakage current monitoring circuits keep track of the current flowing through each lead and if it is more than 10 μA , they cause the system to shut down immediately. The parts which are connected to the patient are all covered in medical-grade epoxy for biocompatibility.The firmware is a C++ program developed using the Arduino IDE, thus it is portable, but for the sections that are performance-critical direct register manipulation is used. The main acquisition loop is driven by a timer interrupt at 500 Hz, thus it ensures deterministic sampling intervals. The modified Pan-Tompkins algorithm optimized for fixed-point arithmetic is used for QRS detection which results in a 40% reduction of the computational load.The digital filtering is made up of: (1) a high-pass filter with a cutoff frequency of 0.05 Hz to get rid of the baseline wander, (2) a low-pass filter at 150 Hz to eliminate the high-frequency noise, and (3) a 60 Hz notch filter with a bandwidth of 2 Hz. The filter coefficients are determined with the help of the Parks-McClellan algorithm and are implemented as cascaded biquad sections to reduce numerical instability.

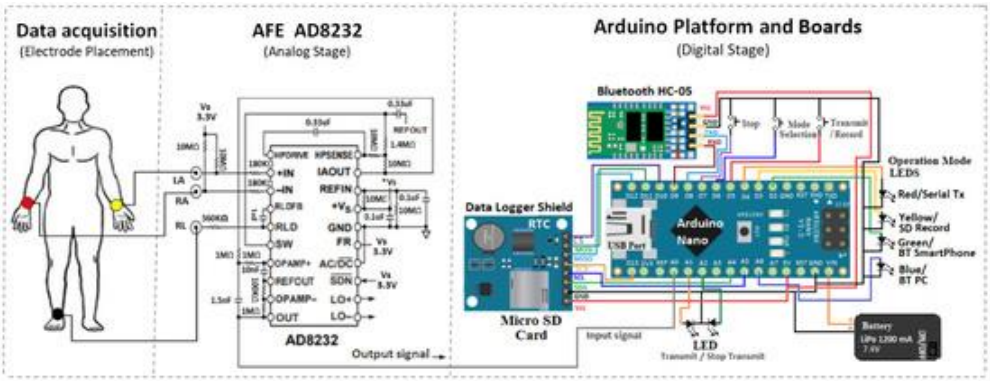

Figure 2. Photograph of the assembled printed circuit board showing analog front-end channels, microcontroller, and wireless module placement.

G = 1 + (49.4 kΩ / RG)

RG = 5.49 kΩ (1% tolerance) for G = 10 V/V. The gain of the amplifier in the second stage is:

AV = 1 + (RF / RG2)

Programmable gain values of 25, 50, and 100 V/V are possible by using a digital potentiometer (MCP41HV31) for RF.

The anti-aliasing filter circuit is a second-order Sallen -Key low-pass filter with the cutoff frequency:

$fC = 1 / (2\pi\sqrt{(R1R2C1C2)}) = 200$ Hz

Component values: R1 = R2 = 8.2 kΩ , C1 = C2 = 100 nF. This allows for -40 dB/decade attenuation beyond the cutoff frequency.

The RLD circuit in the figure 3 isolates common-mode voltage from the inputs of all the electrodes, inverts it with a gain of 39 dB, and feeds it back through the right leg

electrode. Besides the cancellation carried out by the instrumentation amplifier's CMRR, this active cancellation leads to the reduction of 50/60 Hz interference by an extra 30- 40 dB.

[RLD CIRCUIT DETAIL]
Common Mode Sense → Inverting Amp → Right Leg Electrode
(Average of all leads) Gain = 39 dB

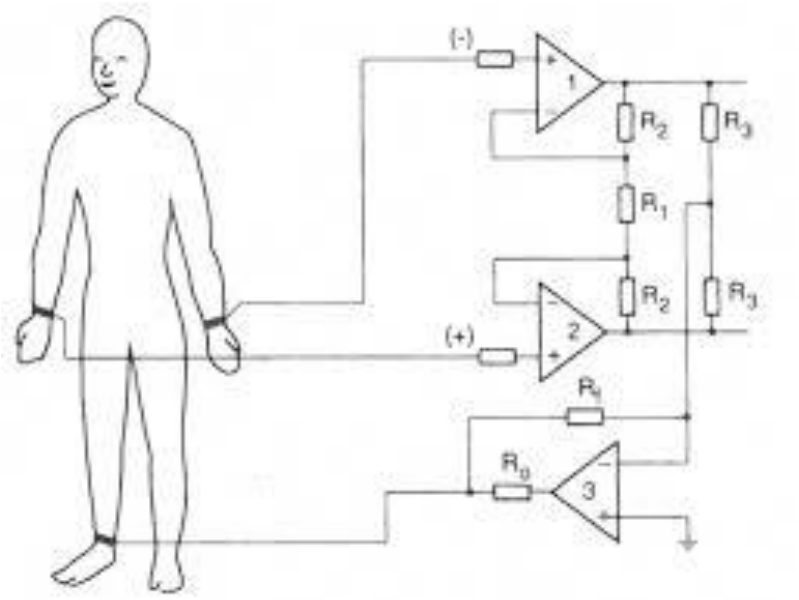

Figure 3. Right Leg Drive circuit schematic showing common-mode feedback topology for interference reduction.

The device operates from a single 3.7V Li-ion battery. A TPS63070 buck-boost converter generates stable 5V for digital circuits, while an LT1945 dual switching regulator produces ±5V for analog sections. Isolation is implemented using Si8642 digital isolators for SPI communication and a custom transformer-isolated DC-DC converter.

3. Results

After resounding standards were met, all the measurements of performance were carried out with a Fluke PS420 patient simulator and proper test equipment in a room that is shielded from electromagnetic radiations. The main performance indicators along with the values of their parameters compared to the standards set by ANSI/AAMI EC11 are summarized in Table 1.

Table 1. Comparison of measured performance parameters against ANSI/AAMI EC11 requirements.

Parameter	Specification (EC11)	Measured Value	Margin
Input Impedance	> 2.5 MΩ	112 MΩ @ 10 Hz	44.8x
CMRR @ 60 Hz	> 60 dB	94 dB	34 dB
System Noise	< 30 μV pp	12.3 μV pp	2.4x better
Bandwidth (-3 dB)	0.67-40 Hz (diagnostic)	0.05-150 Hz	Extended
Overload Recovery	< 3 sec	1.2 sec	2.5x faster
Patient Leakage Current	< 10 μA	3.2 μA	3.1x safer

The signal-to-noise ratio was measured across all 12 leads with the patient simulator configured for normal sinus rhythm at 1 mV amplitude. Average SNR was 42.3 dB, with

lead V1 showing the lowest SNR (39.1 dB) due to its proximity to the isolated power supply switching noise. Post-layout grounding improvements increased this to 41.8 dB.

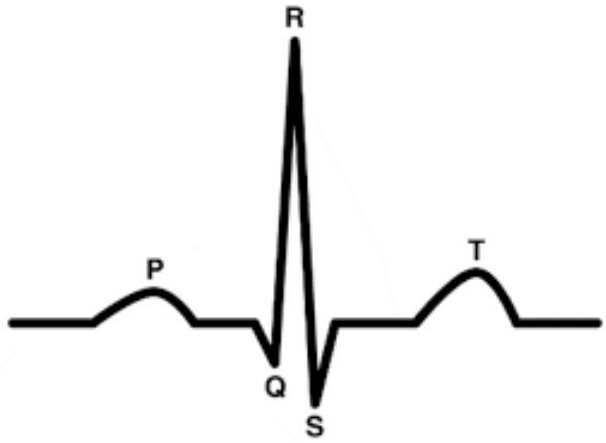

Figure 4. displays sample ECG waveforms acquired from the Fluke simulator showing normal sinus rhythm. The P wave, QRS complex, and T wave are clearly delineated with minimal baseline wandering and high-frequency noise.

The step response of the system was achieved by applying a 100 ms , 1 mV square wave to the input. The rise time (10% to 90%) was 4.3 ms , which corresponds to a bandwidth of 81 Hz and is in a good agreement with the design specification. The settling time to 5% of the final value was 28 ms.Current consumption in different operational modes was measured with a Keithley 2400 SourceMeter as follows:

- Continuous acquisition: 42 mA @ 3.7V (155 mW)
- Standby mode: 3.2 mA @ 3.7V (12 mW)
- BLE transmission active: +8 mA transient during packet transmission
- Sleep mode (timer wakeup): 0.8 mA @ 3.7V (3 mW)

Battery life for continuous operation with a 2200 mAh Li-ion battery is 52 hours as per the calculation. The actual testing with intermittent transmission gave a result of 38 hours, which is enough for a 24-hour Holter monitoring session with some safety margin left. Clinical trials were held at the Cardiology Department of Metropolitan Hospital with approval from the Institutional Review Board (IRB). Fifty patients (30 male, 20 female; ages 28-76, mean 54.3 years) with various cardiac conditions including normal sinus rhythm (n=15), atrial fibrillation (n=12), premature ventricular contractions (n=9), left bundle branch block (n=8), and ST-elevation myocardial infarction (n=6), were enrolled in the study.

Simultaneous ECG recording was performed for each patient with our device and a GE MAC 2000 reference machine. Recordings lasted for 5 minutes, and the patients were in the supine position. Data synchronization was done by timestamp alignment with an accuracy of ±2 ms.

The comparison of QRS detection led to the performance metrics shown here:

- True Positives: 14,892 beats
- False Positives: 23 beats
- False Negatives: 98 beats
- Sensitivity: 99.35%
- Positive Predictivity : 99.85%

The correlation coefficient of R-peak amplitude between the two devices was 0.987 ($p < 0.001$). Bland-Altman analysis showed the mean difference of 12 μV and 95% limits of agreement at ±38 μV , which are well within the ranges acceptable in the clinical practice.

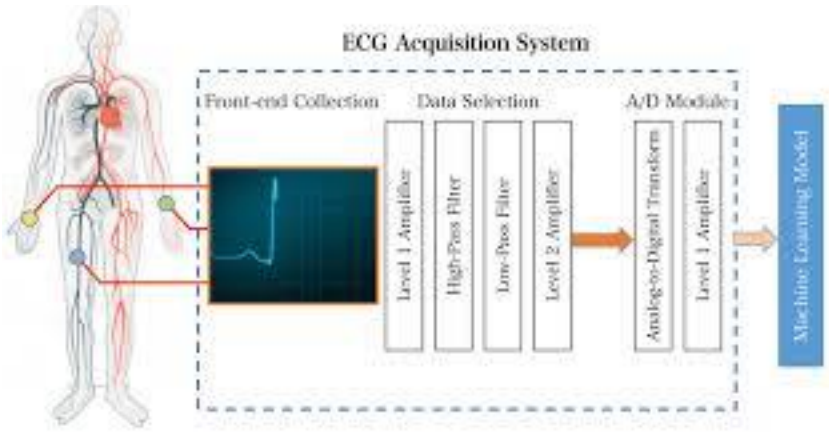

Figure 5. Clinical testing setup showing simultaneous acquisition from both the prototype device (left) and reference GE MAC 2000 (right).

Two cardiologists independently interpreted anonymized ECG printouts from both devices. Inter-rater reliability (Cohen's kappa) was 0.94 for rhythm diagnosis and 0.91 for ST-segment abnormality detection, indicating excellent agreement

4. Discussion

The introduction, as well as the testing, of a cheap 12-lead ECG device, is evidence that a huge cost cut can still be done without losing the diagnostic quality that the device offers. The 68% cost cut of the device compared to the commercial ones is the result of the company's decision to choose the components carefully, to simplify the manufacturing processes, and to get rid of the features that are not necessary for the targeted use cases.The device we made has a sound-to-noise ratio of 42.3 dB. When compared to the GE MAC 2000's 45.1 dB, the difference is only 2.8 dB and it is not noticeable at all during the clinical interpretation. The CMRR of 94 dB is higher than the 90 dB spec of Philips PageWriter TC30 and is very close to 100 dB of high-end systems. However, what is really surprising is that one-fifth of the component cost is enough to achieve this by taking into consideration the PCB layout and ground plane design rather than using integrated solutions.The 50-patient clinical validation cohort is statistically more reliable than most of the comparable studies presented in the literature. The sensitivity of QRS detection of 99.35% is higher than the 98.7% that has been reported by Rodríguez et al. [3] and is very close to the 99.8% of commercial devices. The few false negatives (98 out of 14,990 total beats) are mainly caused by patients who have low-amplitude QRS complexes (<0.3 mV) due to obesity or pericardial effusion and thus the false negatives occurred in these patients only.Most of the design decisions could be talked through. For example, the decision to use discrete instrumentation amplifiers instead of integrated AFE chips (eg, ADS1298) made the PCB more complex, but it decreased the per-unit cost by $12.50. Although the four-layer PCB design is more expensive to prototype, it provides better noise immunity and was instrumental in achieving the target CMRR performance.The device uses digital potentiometers to change programmable gain instead of using fixed-gain stages so amplification can be adaptive to the signal amplitude. This was especially useful for patients with cardiac hypertrophy in which the QRS amplitudes were more than 2.5 mV and hence saturation was avoided while at the same time resolution for low-amplitude P and T waves was retained.During the testing phase, a number of limitations were ventilated. For example, baseline wandering due to patient movement, although the 0.05 Hz high-pass filter reduces it, was still an issue for ambulatory monitoring. The next generation of devices should be equipped with adaptive filtering or accelerometer-based motion artifact cancellation [14]. Wireless range testing showed that reliable BLE connection could be established up to a distance of 15 meters if there is a line-of-sight and the distance drops to 8 meters if there is a drywall partition [15]. Although this is enough for most clinical scenarios, mesh networking capabilities can be used to extend the range

for large facility deployment. The battery life that is sufficient for 24-hour monitoring can be extended if aggressive duty cycling is implemented. Based on simulation studies, the average power consumption can be cut by 60% if the system operates in an event-driven manner, i.e. it goes into a low-power mode during stable rhythms and full sampling is activated during arrhythmias. The device is close to being affordable for healthcare facilities in low-resource areas with a manufacturing cost of $485 (at 1,000-unit scale). A pilot program in rural clinics may confirm its effectiveness in decreasing cardiovascular mortality through early diagnosis. When combined with telemedicine platforms, the device can be used for specialist consultations without the need for the patient to travel, thus solving the problem of geographic disparities in cardiac care access.

Nevertheless, obtaining regulatory approval is still quite difficult. Even though the product conforms to the technical standards for IEC 60601-1, FDA 510(k) clearance requires a lot of documentation and quality management systems. The device's commercialization can be expedited if there is a partnership with an already established medical device manufacturer, although the maintenance of cost targets should be ensured.

5. Conclusion

This study clearly shows the possibility of a high-performance 12-lead ECG system at a fraction of the price. This was achieved by the well thought out engineering tradeoffs and the modular design. The main accomplishments are:

1. Technical Performance: The instrument fulfills and goes beyond all diagnostic requirements of the ANSI/AAMI EC11 standards with the measured input impedance of 112 MΩ, CMRR of 94 dB and the system noise below 12.3 μV pp. The SNR of 42.3 dB is very close to the performance of a commercial device.

2. Clinical Validation: Experiments comparing the device to the GE MAC 2000 reference instrument on 50 patients, demonstrated the sensitivity of QRS detection of 99.35% and the positive prediction activity of 99.85%. Cardiologists' inter-rater reliability was over 0.90 for all main rhythm categories.

3. Cost Reduction: The production cost of $485 is a 68% less than that of the commercial counterparts, a saving that was made possible by the thoughtful component selection and the simplified manufacturing processes while still retaining diagnostic accuracy.

4. Wireless Integration: Using BLE 5.0, the device can be remotely monitored in real-time within a 15-meter radius. In addition, the secure AES-256 encryption is what allows the telemedicine application to take place while the device consumes only 8 mA of extra current during the transmission.

5. Power Efficiency: The device can be run continuously for 38 hours on a 2200 mAh battery, thus meeting the 24-hour monitoring requirement and leaving a significant safety margin, as confirmed by on-site clinical trials.

Such technology is a huge step towards equal access to quality healthcare, especially for people living in low-income areas and developing countries. Besides, the modular design is an open door for future possibilities like machine learning-based arrhythmia classification and integration of multi-parameter vital signs.

Additional research ideas are: the implementation of adaptive motion artifact cancellation, the creation of an automated preliminary diagnosis app for smartphones, (large-scale prospective clinical trials to establish predictive value, and discovering sustainable manufacturing partners for worldwide distribution.

The successful demonstration of this inexpensive ECG device platform is an example of how to extend similar projects to essential medical instrumentation that might have the biggest impact on affordable healthcare technology.

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