Chapter

Low-cost Approaches to Follow-up Cardiac Patients in Low-Income Countries using Public Data Networks

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Abstract

The main characteristics of three approaches to cardiac care using public data networks are presented. All efforts were addressed to get minimum-cost solutions for low-budget public health systems. The first solution was developed to follow-up arrhythmic patients between medical consultations, setting a more closed patient-physician relationship, and a daily recording of cardiac rhythm changes. It is based on a personal battery-powered device for one-channel ECG recording, minimizing electrode setting and operation complexity. An ECG recording taken daily allows a detailed analysis anytime without the patient's traveling to a health institution. A second solution was aimed at monitoring high-risk cardiac patients. A 24-h portable device capable of monitoring heart rate and sudden falls, typically associated with cardiac syncope, was developed. When any cardiac event or fall is detected, an urgent message is sent to relatives and the medical emergency care system asking for help. The third system implemented is oriented to the study of different cardiac parameters in people who suffer from heart disease or in those who are prone to suffering from it. Twelve-lead ECG is recorded periodically by each patient and trend graphics reflect ECG parameters strongly associated with cardiac disturbances, such as sudden death and ischemia. This approach allows the detection of the first troubling electrocardiographic deviations, making possible early medical intervention.

Keywords: telemedicine, cardiac home care, ECG processing, cardiac syncope identification, arrhythmia analysis, cardiac disturbance predictors

1. Introduction

For decades, heart disease has been the leading cause of death worldwide, according to periodic reports from the World Health Organization (WHO) [1, 2]. The high consumption of so-called junk food, sedentary lifestyle, smoking, and other conditions have driven humankind to this situation. Some years ago, heart disease as the leading cause of death was strongly associated with high-income countries, but nowadays it has been extended to medium and low-income countries, displacing infectious-contagious diseases. In poor countries, the situation becomes even more critical since their economies do not have sufficient resources to face the cost of therapies, medical devices, and high-qualified physicians to cover the population, so the public health system falls into crisis frequently.

The resting electrocardiogram (ECG) is worldwide the leading test to detect cardiac disorders; more than 100 million of ECGs are indicated in the United States annually [3]. For any surgery procedure, it is mandatory to check the cardiovascular status previously and for the rest ECG is the ideal test, since it is noninvasive, easy to perform, and highly standardized, offering significant information about the cardiovascular system status. Its interpretation is supported by more than 100 years of accumulated knowledge [4].

Devices and methods for automatic ECG acquisition and processing have greatly evolved, making it possible for this technology to be used efficiently after minimal training. In fact, several systems have been developed combining this kind of devices with public data networks, web applications, and the proper procedures allowing the implementation of telecardiology services [5–7]. However, new solutions emerge continuously because each region and country have needed a customizing process according to local requirements.

The authors of this chapter have developed solutions that provide health services aimed at the care of heart diseases, but these approaches could be extended to other chronic diseases. The solutions presented have the following in common:

- They are focused on the treatment of cardiac patients.
- Combine the use of public data networks with medical devices for personal or home use.
- They minimize the operating cost of the solution without sacrificing high performance and quality standards.

The authors hope the discussed topics will motivate other specialists to contribute to the continuous improvement of public health services, mainly in low-income countries that suffer from the most critical situations.

2. Follow-up of persons suffering from cardiac arrhythmia

Cardiac arrhythmia is a chronic disease, so persons suffering must visit their cardiologist periodically to check their condition and the medical treatment effectiveness; this is the traditional approach to follow-up persons suffering from chronic disease. The main disadvantage is that changes and disorders occurring between a visit to the cardiologist and the next one never been recorded or known by the cardiologist. Suddenly, no evidence of why the patient got worse after a visit to the cardiologist and died inexplicably, and this is a non-infrequent situation.

The proposal of the authors solves the described situation. The patients are trained to use a portable medical device and are able to acquire and transmit a one-channel ECG, enough for cardiac rhythm analysis purposes. The digital ECG is uploaded to a website in order to be processed, stored, and reviewed at any time by the cardiologist in charge of the studied person. This specialist indicates the frequency of ECG acquisition, maybe 2 or 3 days, and trend charts are generated with the data extracted from the stored signals. This approach provides an easy way to know what changes in the cardiac rhythm take place day by day, contributing to a very close patient-cardiologist relationship. Dynamically, medical treatment can be changed when an abnormal situation is detected. All the process contributes to minimize patient's discomfort and agglomerations at hospital centers since visits to cardiologist can be reduced.

2.1 The proposed solution

The proposed system enables ECG recording several times per day, so the patient's condition can be analyzed with a detailing level impossible to get with the traditional approach. Any change can be studied from its first manifestations. Another feature to remark on is the possibility to make changes in the medical treatment dynamically, only with a phone call after analyzing the ECGs stored in the system's database. In addition, by reducing the frequency of visits to the cardiologist, patients improve their comfort and agglomerations in hospitals are reduced.

The development of the proposed system was divided into three parts as follows:

- The ECG recorder: A portable medical device to acquire one-channel ECG and transfer digital samples using a Bluetooth channel.

- The Android terminal: An Android-based application to receive the digital ECG transmitted from the ECG recorder, store and upload it to the analysis station when connectivity is available.

- The analysis station: A web application to store, analyze, and display the ECGs and the information associated with them.

Each part will be explained in detail below. The proposed solution can be viewed as a three-layer system. A first layer for the acquisition of the ECG with the developed portable device, a second layer is based on an Android application to guarantee connectivity with the web, data integrity, and a third layer, the web level, where the transferred ECGs are stored and processed. The web application provides complementary tools to help cardiologists to study the evolution of each patient. A representation of the proposed solution is shown in **Figure 1**.

2.1.1 The ECG recorder

A battery-powered medical device was developed to digitize a bipolar ECG lead; the authors recommend to attach the electrodes as it was defined for lead II from the standard 12-lead ECG because it is the best approach to study cardiac rhythm disturbances.

The ECG recorder was designed as a low-cost solution, so commercial electronic components were used instead of ASIC, FPGA, and so on. However, surface montage electronic components were combined with a multilayer print circuit design to reduce the device size and improve its reliability. The ECG recorder description can be divided as follows:

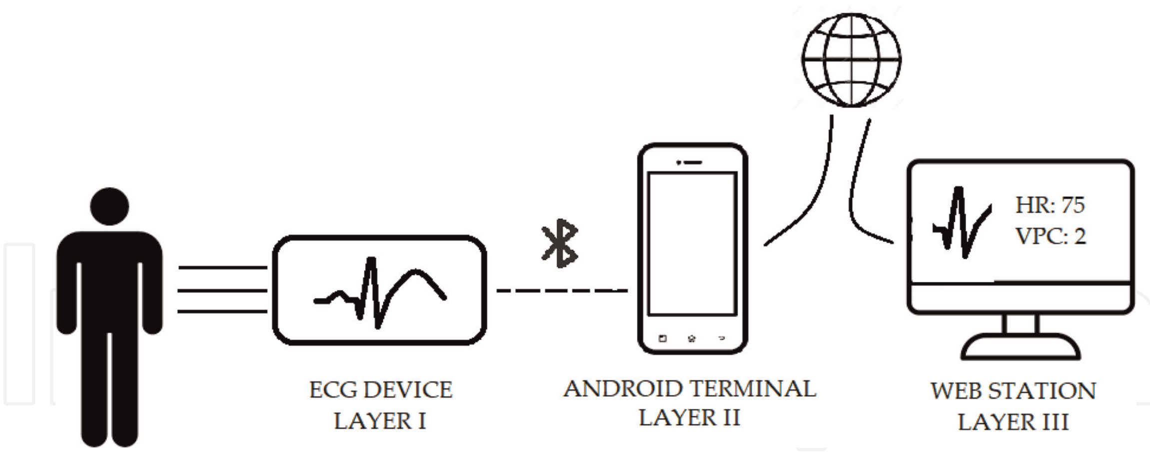

Figure 1.
The proposed three-layer system.

- The ECG amplifier: A low-noise one-channel ECG amplifier was designed to digitize a bipolar ECG lead characterized by its low power consumption. The amplifier design is based on the OPA4236 operational amplifier and the micro power single-supply INA826 instrumentation amplifier to get a very low power consumption, below 10 μA. The bandwidth is limited between 0.5 and 40 Hz to improve the signal quality and to keep the main ECG frequency components.

- The central processing unit: The MSP430F5529 microcontroller from Texas Instruments was selected as "the heart" of the ECG recorder; it is in charge of the control of the device functioning and all the computing tasks. This microcontroller is an ultralow-power component with a 16-bit RISC architecture and high-level integration. Several peripherals, such as serial ports, interrupt controllers, timers, memory, and A/D converter, are integrated into a single chip.

- The Bluetooth block: The first version was developed with the LMX9838 Bluetooth serial port module because it was mentioned as a standard by several electronic component manufacturers when the use of Bluetooth became widespread. This module is too expensive for our purpose, so a cheaper alternative was selected, it was the RN4678 module. This component provides a friendly and reliable solution for Bluetooth communication; the host communicates with the RN4678 sending commands interpreted and executed by a Bluetooth stack in charge of wireless bidirectional communication.

- The power unit: Two AAA NiMH batteries supply the required isolated voltage for the planned autonomy. A battery-charging circuit was not included to simplify the device and reduce its dimension, so batteries should be charged in any commercial charging station. A better solution will be a lithium polymer battery, not available in the market at the time when the design was developed.

ECG samples are acquired automatically when the ECG recorder is turned on; the sampling frequency always is set to 250 Hz. Bluetooth protocol is used to transmit digital samples to a mobile phone. Additional information about pacemaker spikes and electrode contact is transmitted too. A circuit for pacemaker spike identification was included in the ECG amplifiers; spike detection is based on signal slope analysis. Another circuit was designed to detect poor contact between the electrodes and the patient's skin; this process is very important because only one signal is available and its quality is very important for the intended use (**Figure 2**).

ECG samples, pacemaker information, and electrode status are packed and sent with a sync byte. The receiving, called the Android terminal (an app running on an Android-based mobile telephone) can identify the start of each packet and extract the information bits corresponding to ECG samples, electrode status, and pacemaker spike detection. ECG strip duration is set according to the study to be performed; a typical duration could be 3 min. When ECG transmission is finished, the MSP430F5529 microcontroller goes to "sleep mode" in order to minimize energy consumption. Only hardware interrupts generated by the keypad or the timer are able to wake the microcontroller.

2.1.2 The android terminal

This android application was programmed in Java language, but several other options are available nowadays; the same happens with the programming framework. The best choice of these items will strongly depend on the programmer's skills and will be determinant to shorten or delay the time to get the final solution.

The main features of this part of the proposed solution are the following:

- Device pairing: It is a mandatory process to set the Bluetooth link between the ECG recorder and the Android telephone. It is set for one time unless hardware changes or fails. It started with the mobile telephone.

- Bluetooth communication: The hardware components selected are fully compatible with this wireless communication standard, so a reliable channel is implemented. A user-level protocol was defined by the authors to guarantee a continuous data flow. ECG samples are transferred by blocks and information about electrode status and presence of pacemaker spikes is added. Control commands are included as head and tail for each block, contributing to easy synchronization.

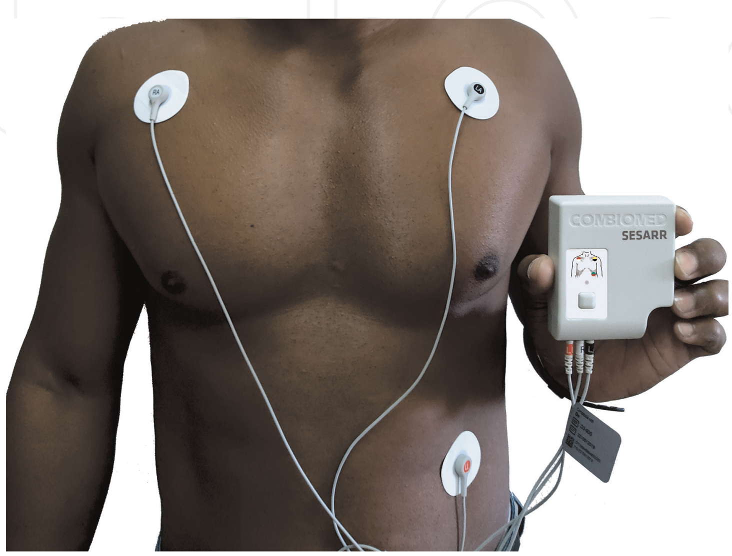

Figure 2.
The ECG recorder prototype.

- Database operations: MySQL was the database engine selected because of its compatibility with the SQL standard and its simplicity. The database to implement is not heavy or complex, so the selection is proper for the intended use. Addition, sorting, and querying are the most common operations in this application. The access is controlled by a password mechanism.

- ECG uploading: This feature considers that noncontinuous connectivity is a real possibility; accordingly, the proposed solution has been designed thinking in poor countries' conditions, where public communication networks are not as stable as the same service in First World countries. ECGs received from the recorder are stored in the Android terminal's database as a backup and are uploaded when connectivity is available using a secure HTTP protocol. The uploading process includes an encryption algorithm to avoid unauthorized personal data publication since it is mandatory in telemedicine systems [8].

2.1.3 The analysis station

This web application is the main part of the proposed solution because it enables cardiologists to analyze the status of any patient based on the collection of all signals captured by the ECG recorders and powerful graphic tools. Several parameters are computed as a complement of the stored digital ECG. A simple SQL database was implemented to store all general data, ECGs, and parameters. Tables and graphics are available to analyze the evolution of any patient, so cardiologists can evaluate the effectiveness of the drug treatment and make any necessary changes. Cardiologists' comments and treatment changes are stored in the database too. In summary, the analysis station provides the following features:

- User access control: A username and password mechanism are implemented to set a one-to-one relationship between cardiologists and their patients. Each cardiologist reviews ECG associated with his/her patients only.

- Trend charts of different electrocardiographic parameters: This kind of graphics represents parameter changes versus time, so cardiologist can observe when dangerous situations start their clinical manifestation. For instance, isolated heart rate changes are not dangerous, but it is so different when the change is observed continuously.

- Reports: Any table of graphics can be printed or stored as a PDF file. It is so useful to discuss any complex situation with other specialists or to create patient paper files.

- Export results: It is implemented to allow interoperability with other digital systems.

A simple way to appreciate the advantages of the proposed solution is the following example: A cardiologist instructs a patient to capture three ECGs daily with the ECG recorder (morning, afternoon, and night). After a month, the cardiologist has 90 ECGs of the specific patient and he/she can analyze in detail how it is influencing medical treatment in the disease studied. Following the traditional method of visits to the specialist, so much valuable information would never be accumulated. This is why it is said that the proposed system allows a much closer doctor-patient relationship.

Digital ECGs are processed at the analysis station to facilitate future software updating tasks. It is easier to update the web application only than to update each of the ECG recorder devices connected to the system or the Android app linked to each one.

2.1.4 ECG processing

ECG processing starts with digital filtering to remove or attenuate spurious signals. A FIR (finite impulse response) moving average filter proposed by Ligtenberg and Murat [8] was implemented. It was used by the authors in previous projects with good results; an attractive characteristic is that the filter is based on integer arithmetic only. The mathematical expression of the proposed filter is as follows:

$$y(k) = \frac{1}{K^2} \sum_{m=k-K+1}^{k} \sum_{n=m-K+1}^{m} x(n) - \frac{1}{L^2} \sum_{m=k-L+1}^{k} \sum_{n=m-L+1}^{m} x(n) \qquad (1)$$

where x(n) is the input signal, y(k) is the output filtered signal, K, L are filter constants strongly associated with cut-off frequencies.

The authors have implemented a QRS complex detection based on an energy collector and two thresholds. The energy function is easy to implement because it is based on integer arithmetic; it is an important feature because the same function can be used for real time and offline applications with similar performances.

The energy function is defined as the sum of the squared differences of the samples corresponding to a preestablished time window previous to the studied sample. The windows width is set to 150 ms taking into count the width of ventricular beats which are prone to durations over 120 ms. Eq. (2) corresponds to the described energy collector.

$$y(k) = \frac{1}{N} \sum_{n=k-N+1}^{k} [x(n) - x(n-1)]^2 \qquad (2)$$

where x(n) is the input signal, y(k) is the energy function.

The energy function is combined with two thresholds. The first one is used to detect high-energy peaks and the second threshold is applied to a rough onset and offset identification for each QRS complex. R waves are identified as the wave including the most positive peaks within each QRS complex, so a peak detection algorithm is applied after the onset and offset events were detected.

RR intervals are computed after the identification of all R wave's peaks as the difference between two consecutive peaks. Each cardiac beat is classified as premature or not premature according to their previous RR interval duration. An ECG strip is classified as "arrhythmic" if more than 10% of QRS detected gets into this classification. This percentage should be defined at the Android terminal setup and cardiologists can be modified according to the patients.

The information associated with each digital ECG is stored in a temporary database and uploaded to a sHTTP server. The temporary mobile telephone database can be very useful when public data network is out of service for a prolonged period due to natural disasters, army conflicts, and similar situations. When public data networks are not available, ECG can be reviewed in a limited framework.

The system operation can be summarized as follows:

1. Patients are enrolled in the system. Each patient receives the user guide, the ECG recorder (including patient cable and electrodes), and the Android terminal is installed on his phone.

2. The cardiologist explains to the patient his/her role in the system and an ECG strip is acquired as patient training.

3. The patient prepares his skin, by means of a light cleaning, and attaches the electrodes in the appropriate positions to acquire lead II unless the cardiologist indicates another configuration of electrodes.

4. The incoming digital ECG is filtered; the QRS complexes are detected and classified; and heart rate and ectopic beat rate are computed. All data are stored in a database and uploaded to sHTTP server.

5. The analysis station checks the sHTTP server periodically looking for new ECG data files. When new files are detected, all the uploaded information is into a database.

6. The cardiologists log in to the analysis station to study any patient. Each cardiologist can study his patients only. Arrhythmic evolution is analyzed and the treatment is corrected if necessary.

2.2 Results and discussion

Five ECG recorder prototypes have been tested according to the IEC 60601-2-47 standard and all results were successful. The proposed device is not a pure ambulatory medical device, but the IEC 60601-2-47 standard is suitable for its evaluation. Some of the most highlighted results are shown in **Table 1**.

The proposed device is safe for patients, according to the test results, following the IEC 60601-2-47 standard requirements.

The android terminal application was fully tested. The Bluetooth communication was checked with 200 simulated 3 min ECG strips with different heart rates: 60, 80, 120, and 150 beats per minute. These strips were acquired with three ECG recorders wireless connected to a mobile phone running the proposed Android terminal. This

Test	Result
Dynamic input range	5 mV
Input impedance	Greater than 2.5 MΩ
Maximum DC input level	320 mV
Internal noise	Less than 25 μV
Patient auxiliary current	Less than 0.01 mA
Setting time	Less than 3 s
Common mode reject ratio	Greater than 90 dB
IEC 60601-1 classification	Class I, BF type

Table 1.
Some results from technical tests.

test passed without errors, and the signals received by the Android terminal were identical to the original simulated ECGs. Also, the communication process was never aborted by errors.

The digital filter performance has been published in previous papers, so the authors do not consider necessary new evaluation [9]. A similar situation happens with the QRS detection process based on the previous experiences of the authors [9, 10]. Nevertheless, the authors considered it useful for the readers to show the performance when the algorithm was tested with the MIT-BIH arrhythmia database; results are shown in **Table 2**.

Thus, the performance of the QRS complex detection algorithm is enough for the intended use. The MIT-BIH arrhythmia database is a golden reference to test this kind of algorithm.

All the features of the proposed Android terminal have been tested with a significant amount of ECG strips. The performance of the implemented Bluetooth link has

Record	QRS	Detected	Sensitivity (%)	Record	QRS	Detected	Sensitivity (%)
100	2273	2273	100.00	201	1963	1960	99.85
101	1863	1861	99.89	202	2136	2127	99.58
102	2187	2160	98.77	203	2980	2963	99.43
103	2084	2084	100.00	205	2656	2624	98.80
104	2229	2220	99.60	207	1860	1833	98.55
105	2572	2549	99.11	208	2955	2933	99.26
106	2027	2007	99.01	209	3005	2996	99.70
107	2137	2120	99.20	210	2650	2631	99.28
108	1762	1741	98.81	212	2748	2746	99.93
109	2532	2507	99.01	213	3251	3220	99.05
111	2124	2111	99.39	214	2262	2241	99.07
112	2539	2538	99.96	215	3363	3360	99.91
113	1795	1794	99.94	217	2208	2177	98.60
114	1877	1860	99.09	219	2154	2136	99.16
115	1953	1951	99.90	220	2048	2046	99.90
116	2412	2398	99.42	221	2427	2407	99.18
117	1535	1520	99.02	222	2483	2466	99.32
118	2278	2253	98.90	223	2605	2581	99.08
119	1987	1981	99.70	228	2053	2018	98.30
121	1863	1861	99.89	230	2256	2253	99.87
122	2476	2475	99.96	231	1571	1568	99.81
123	1518	1516	99.87	232	1780	1772	99.55
124	1619	1592	98.33	233	3079	3036	98.60
200	2601	2576	99.04	234	2753	2750	99.89

Table 2.
Results with 12 ECG strips from MIT-BIH database.

been stable; no user-level errors have been detected. QRS complex detection algorithm was tested with MIT-BIH arrhythmia database, an international standard for this purpose, and the sensitivity was high, this result is enough for the intended use.

As has been seen, a full version of the proposed solution has been tested with satisfactory results. The ECG recorder safety meets the requirements set by the IEC 60601-1 standard for this kind of medical technology. The functioning of the system has been tested in stressing conditions without failures, demonstrating the robustness of the proposed solution.

The proposed system looks like a useful tool to study arrhythmic patient progression using existing data networks, mainly mobile telephone networks. Other chronic diseases can be studied following the same philosophy.

3. Cardiac monitoring of high-risk persons

Those persons who are subjected to high stress as part of their daily activities and do not have healthy lifestyle habits are prone to suffer from serious and sudden cardiovascular disorders, whose main manifestations are high blood pressure, malignant cardiac arrhythmia events, and acute myocardial infarctions. This kind of person needs continuous cardiac monitoring to detect dangerous changes since their beginning. Implanted cardiac loop recorders could be a solution for persons suffering from this situation, but these devices and the associated surgery procedure are expensive [11]. Besides, the risk associated with any surgery is always present.

An alternative without surgical risk and much cheaper would be the development of a device capable of monitoring the heart rhythm and transferring the digital signal to a remote central station when any dangerous change is detected from the analyzed person. For this data transfer, the existing public mobile data network in the country would be useful. The authors of this chapter focused their efforts on this kind of solution and present a proposal.

3.1 Proposal for out-of-hospital cardiac monitoring

We have developed a cardiac telemonitoring system as part of a larger telecardiology system with other final applications. The proposed system is composed of connected two parts using the mobile data network:

- ECG recorder: It is a small battery-powered device able to acquire and process one ECG channel in real time. When a dangerous event is detected, an ECG strip is transferred to the response central station and the device waits for instructions for the analyzed person about what to do. Several different indications can be sent, “relax and wait for an ambulance,” “relax and send an ECG strip in 10 min” or person’s intervention is not required because the process starts due to a false positive alarm.

- Response central station: A set of personal computers are connected as a local network linked to the public mobile data network to keep available to receive any request from the recorders integrated into the proposed system. A group of medical specialists is in charge of responding to incoming requests. When a help request is received, the ECG strip, some electrocardiographic parameters, and GPS location are displayed on a personal computer screen and an acoustic message is activated. A specialist analyzes the information and send the proper response, all the process (arriving time, delay to response, and specialist in charge) is stored in a database because this information is useful to optimize the system's performance. The response central station works together with the available ambulances to assign the closest one to the person who requires it.

The target of the ECG recorder design was to minimize the cost without decreasing its reliability. Besides, the device should be user-friendly, safe, and resistant to mechanical impacts. The device is composed of the following blocks:

- The ECG amplifier: It is a two-channel ECG amplifier characterized by its low power consumption, measured below 10 μA. The LT1496 operational amplifier and the micro power single-supply INA321 instrumentation amplifier are the main components of the proposed amplifier. The bandwidth is limited between 1 and 30 Hz in order to improve the signal quality and to keep the ECG frequency components associated with the intended use. The second ECG channel is used as a backup because electrode failures are common in long-term ambulatory ECG monitoring devices, so the channel with the best signal-to-noise ratio is used to extract cardiac rhythm information.

- The processing unit: The MSP430F149 microcontroller from Texas Instrument was selected as the processing unit. It is an ultralow-power and a highly integrated microcontroller with a 16-bit RISC architecture. Several peripherals, such as serial ports, timers, memory, and A/D converter, and an interrupt request controller, are integrated into a single chip. Also, a very large collection of application notes and examples of applications with this microcontroller are available, making easy its use in new products.

- The wireless communication module: The SIM928A module was selected for this purpose; it is a module that integrates into a single container GSM/GPRS and GPS standards. The mobile phone section is GSM/GPRS type and can operate in the most common bands. In terms of connectivity, this module has two UARTs for serial communication and also integrates TCP/IP functionality and extended AT commands to manage it. Its compact dimensions (30 × 30 × 3 mm), allow to develop very compact devices, such as trackers.

- The display unit: The LCD display used is the model GF5123FBWBF from crystal clear technology; its graphic resolution is 128 × 64 dots. The intended use is to show several data as part of the user interface and to check signal quality using its graphic capabilities. Also, messages from the response central station are displayed if patient cooperation is required.

- The keypad: Setup data is introduced using this soft-touch keypad. It is composed of five keys and is water-protected to avoid damage caused by spilled liquids.

- The power unit: The required isolated voltage is supplied by two NiMH batteries, which are recharged in a charging station when the device is not in use. It is recommended to move to lithium polymer technology to increase the device's autonomy (**Figure 3**).

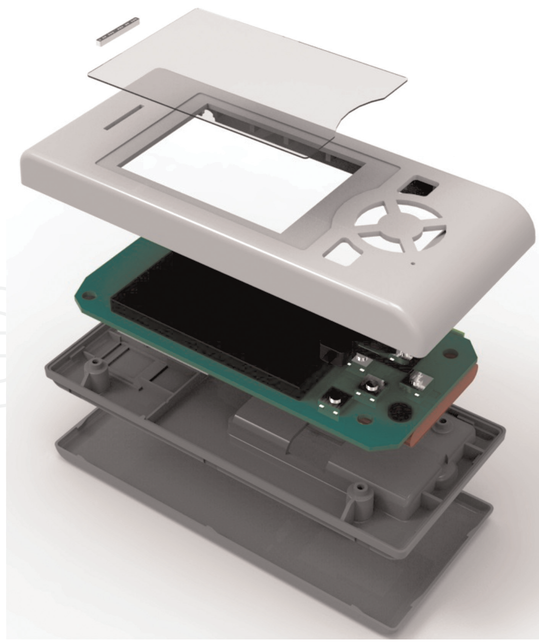

Figure 3.
Representation of the ECG recorder design.

The electronic design of the ECG recorder was made on a single printed circuit board; the LCD display and the GSM modem are connected to this board using board-to-board connectors. This design approach is robust against severe mechanical impacts and guarantees continuous functioning.

Two bipolar ECG leads are analyzed in real time to detect dangerous events, such as severe cardiac rhythm disturbances and pronounced ST-segment deviations. Since the cardiac patient's conditions are known a priori, the location of the electrodes can be adjusted to capture the ST-segment deviation in a given plane. It should not be forgotten that the heart is a three-dimensional organ and ST-segment deviations can manifest differently in different planes. However, the heart rhythm is unique and can be observed in the same way in any lead, although lead II is preferred due to its coincidence with the ventricular depolarization main vector. The ECG analysis algorithm can be divided as follows: ECG acquisition, QRS-complex detection, QRS-complex classification, ST-segment deviation measurement, and communication.

ECG samples are acquired from two bipolar channels simultaneously using s sampling rate of 250 Hz, enough according to the sampling theorem [12]. A single channel could seem enough, but a second channel is used as a backup because it is known electrode contact is prone to failures in long-term ambulatory monitoring systems, so a good approach is to acquire two channels and select for cardiac rhythm analysis the one with the best signal-to-noise ratio. Also, the two channels provide a better approach to the ST-segment deviation analysis.

The digital ECG is smoothed using a Hanning filter and the energy function is computed sample-by-sample for each channel according to Eq. (2) previously shown.

The QRS-complex detection process is based on the energy collector function computing and two thresholds. The first one is set as 20% of the maximum value of energy and it is used to identify high-energy signal segments. It is known that QRS complexes are integrated by high-energy components. The second threshold is used to set a rough identification of the onset and offset for each QRS complex; it is set as 5% of the maximum energy value. The position of these events is refined using a derivative function and each QRS complex width is computed; the QRS complex candidates should reach a minimum duration (30 ms). The mean RR interval duration is updated when a new QRS complex is detected because its previous RR interval is calculated. A baseline estimation for each QRS complex is set as the mean value of the samples associated with 20 ms before the complex onset. The average heart rate is updated every 10 s.

The proposed system is focused on long-term real-time ambulatory monitoring, a much more complex scenario than the first explained system. This is the reason for introducing a change in the energy function. Instead of using a simple signal slope calculation, the authors introduce the Teager operator as the basis to obtain the signal energy.

The Teager operator is a nonlinear operator that mainly shows the frequency and instantaneous changes of the signal amplitude and is very sensitive to subtle changes. Although the Teager operator was first proposed for modeling nonlinear speech signals, it was later widely applied in ECG and EEG research [13]. Its expression is as follows:

$$TO(x[n]) = x^2[n] - (x[n-1] * x[n+1]) \tag{3}$$

where TO is the Teager operator, x[n] is the input signal.

Once the QRS complexes have been detected, they are classified to group them as normal (NB), premature (PB), and unclassified. This process is important for the measurement of ST-segment deviation, it is only measured in normal complexes, and for calculating the premature beats rate, which can alert about serious ventricular disorders. To facilitate the execution of these tasks in real time, the criteria to be used must be simple without losing effectiveness. The defined criteria were the following:

- A normal beat must be preceded by an RR interval whose duration is greater than 80% of the average duration of previously measured intervals of this type and less than 110% of it.

- The width of a normal QRS complex has to be greater than 85% of the average value of this variable for the previously detected complexes and less than 110% of it.

- A premature beat must be aberrant and its duration must be greater than 120% of the average value of this parameter for the previously detected QRS complexes.

- The RR interval preceding a premature beat (PB) must be short and this concept is expressed as 80% of the average duration of the previously measured RR intervals.

- The duration of RR interval previous to a premature beat (PB) must be less than 80% of the average duration of this interval.

The premature beats rate is updated every 10 s. Unclassified beats are not studied.

The ST-segment deviation is defined as the difference in voltage between the sample place 80 ms after the QRS complex onset and the baseline estimation for the studied complex (**Figure 4**).

When the ECG recorder is turned on and configured, a first information block is transmitted to the response central station in order to open a patient profile. This block includes the following information:

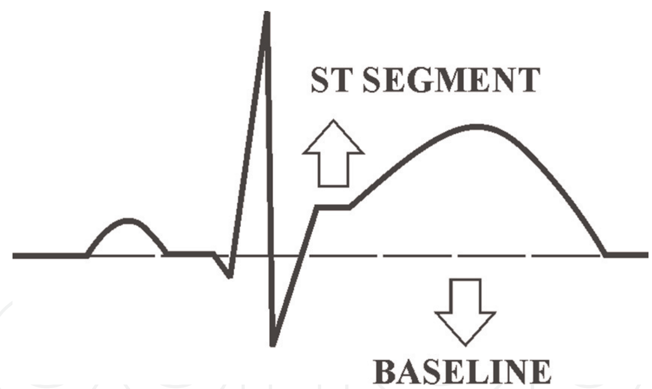

Figure 4.
ST-segment deviation.

- Device identification
- Sampling rate
- Amplitude resolution
- Channel quantity
- Studied variables (ST-segment deviation, heart rate, etc.) and their normality limits

The response central station responds with a block known as "echo block." If the ECG recorder requesting to be recognized is correctly identified, an echo block identical to the one sent by the ECG recorder is transmitted. If an error occurs and the ECG recorder is not properly identified, the response central station does not send a response block. The ECG recorder tries the connection three times before reporting the error on its screen so that the specialized personnel can take some action to solve this technical problem.

Since the ECG recorder is turned on; it will analyze the ECG in real time to transmit signal segments to the TCS when any electrocardiographic event reflecting a dangerous condition is detected or when the studied subject decides to send an ECG segment because he is feeling discomfort. Also, ECG segments can be sent periodically if the device is configured for this purpose.

Dangerous events that can be identified by the ECG recorder are marked tachycardia and bradycardia, high premature beats rate, and significant ST-segment deviations. The information is transmitted in blocks composed of a header that identifies the type of block, a body that contains the ECG samples, and a tail containing a checksum code to validate data integrity.

An identification block is sent to start the communication with the TCS. The transmitted ECG strip could be split into several signal blocks and, in the end, a final block is transmitted, including the block quantity transmitted. The ECG recorder will wait for an answer, which will be displayed if patient's cooperation is required.

3.2 Implementation results

Five ECG recorder prototypes were manufactured and tested.

The developed real time ECG processing method has been tested with 25 min ECGs, including eight ECGs with premature beats, from a Holter system. The signals were analyzed by two highly-qualified cardiologists with more than 20 year of experience in analyzing ECG strips. They were helped by a Windows application, developed by the authors of this document, which allowed them to carry out an exhaustive analysis of the digitized ECGs. These cardiologists were not aware of the method outcomes in order to perform a blind evaluation. The opinions and conclusions of the specialists were the golden rule to test the method. The evaluation results can be summarized in **Table 3**.

As can be seen in **Table 3**, all the QRS complexes present in the analyzed signals were detected. This result is remarkable because it is the basis for reliable ECG analysis.

It should not be forgotten that all processing is done in real time on a battery-powered device, so a vital requirement is low power consumption to ensure the expected runtime. For this reason, a trade-off between the simplicity of the rules for classifying QRS complexes and their effectiveness must also be achieved. Complex calculations imply high energy consumption.

The set rules for the QRS complexes classification are simple, and based on low-complexity computational operations. Despite this, they have demonstrated high effectiveness with more than 96% of identified premature complexes. Only a small number of normal QRS complexes were misclassified, but this flaw does not affect the intended use of this solution. The main objective is the early detection of cardiac events associated with ventricular disorders and the results obtained are satisfactory. It should be noted that a premature QRS complex was never considered normal, although some of them were identified as unclassified beats (UB).

The ST-measurement algorithm was not evaluated because it was not implemented for the ECG recorder's first version. However, the algorithm was implemented in order to evaluate the real-time performance of the proposed method.

Communication with the response central station was set under the following conditions: more than two premature beats in 10 s; heart rate value over 100 beat per second (bpm) or heart rate value below 60 bpm.

To test the communication process, 40 ECG strips were transferred and these operations were always successful. The signals received at the response central station were compared, sample by sample, with the originally transmitted signal. A graphic program was used for this test and remarkable differences were not observed. Also, communication never was unexpectedly, and the received signals were not corrupted by noise or distortions. These results confirm that the communication process was effective.

The proposed system seems a useful monitoring tool for patients prone to suffer sudden heart attacks. Also, it could be useful for long-term ECG studies.

Test	Result
QRS complexes studied	7268
QRS complexes detected	7268 (100%)
Normal QRS complexes	6993
Normal QRS well-classified	6830 (97.67%)
Ventricular QRS complexes	275
Ventricular QRS well-classified	266 (96.73%)

Table 3.
Global results of the proposed method for real time ECG analysis.

4. A tool for primary and secondary cardiac disease prevention in the community

It is internationally recognized that all public health systems should focus their efforts and resources on the prevention of chronic diseases, giving top priority to health services related to this purpose [14]. In the particular case of heart disease, the leading cause of death worldwide, the international scientific community accepts that there are certain electrocardiographic parameters strongly related to the prediction of severe cardiac disorders. Based on this criterion, it is proposed that if these parameters are long-term studied; it is possible to predict cardiovascular system complications and take therapeutic actions before they manifest.

Early detection of heart disease ensures that medical treatment is less aggressive and more effective than if the disease progresses to more advanced stages. This is the reason why several multidisciplinary groups of researchers are working to develop tools and strategies for the primary and secondary prevention of heart disease. Primary prevention means medical attention for people who are prone to develop heart disease because of their lifestyle or genetic facts, even before they get sick. These people must learn to improve their lifestyle (eliminating tobacco, proper nutrition, fitness, etc.), but it is also feasible to study them periodically to identify any change toward morbidity from its first manifestations. When a person has already had a heart attack, the medical procedure is to enter that person into a cardiac rehabilitation program. Secondary prevention focuses on inducing healthy lifestyles and regular screening for any early signs of another attack. The study of the evolution of different electrocardiographic parameters can contribute decisively to avoiding a new heart attack.

Resting ECG is an inexpensive cardiac test that provides valuable information for implementing the approaches described above.

The aim of this section is to present and discuss a system designed for the implementation of primary and secondary prevention of heart disease in the community. The periodic study of a group of electrocardiographic parameters is intended to evaluate their evolution and thus predict the onset of severe cardiac disorders. This study is focused on subjects who have already had a heart attack or who are prone to one.

4.1 How to help prevent cardiac diseases?

The proposed system is composed of two main elements: a portable device for rest ECG acquisition, henceforth, recorder and Windows-compatible software, called a. The designer team's aim was a low-cost device able to get a high-quality rest ECG and ready to be used anywhere, without special requirements. Besides, the proposed system will be addressed to the community and the neighborhood, so it should be friendly for the users, the family doctors, and nurses or paramedics.

4.2 The recorder

These recorders are based on an ARM9 microprocessor operating at a frequency of 400 MHz; they have the following features:

- Graphic LCD with touch screen interface

- Soft keypad

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- USB interface
- Embedded modem with TCP/IP stack
- Eight-channel ECG amplifier
- SD memory
- NiMH battery-pack
- Medical grade's power supply

The described hardware is enough for the intended use, but the cost could be reduced using alternatives available in the single-board computer market currently.

The multichannel ECG amplifier is dedicated to acquire and adequate the electrocardiographic signals generated by the patient. These analog signals are converted to digital values at a sampling rate of 500 Hz [12] (**Figure 5**).

The main features of the ECG multichannel amplifier are described below. An analog bandpass filter was implemented to limit the frequency spectrum of the signals between 0.05 and 100 Hz according to the requirements of the IEC 60601-2-25 standard. Each amplifier channel is protected against defibrillator discharge with 10 kΩ resistors. A classic right leg circuit for improved common mode rejection ratio was included as part of the amplifier [3]. Pacemaker spike detection is based on lead II; the signal at the output of the corresponding instrumentation amplifier is used to detect the spikes; and this signal is connected to the input of a filter capable of generating a pulse every time a spike is detected, while the rest of the time it has a zero as output.

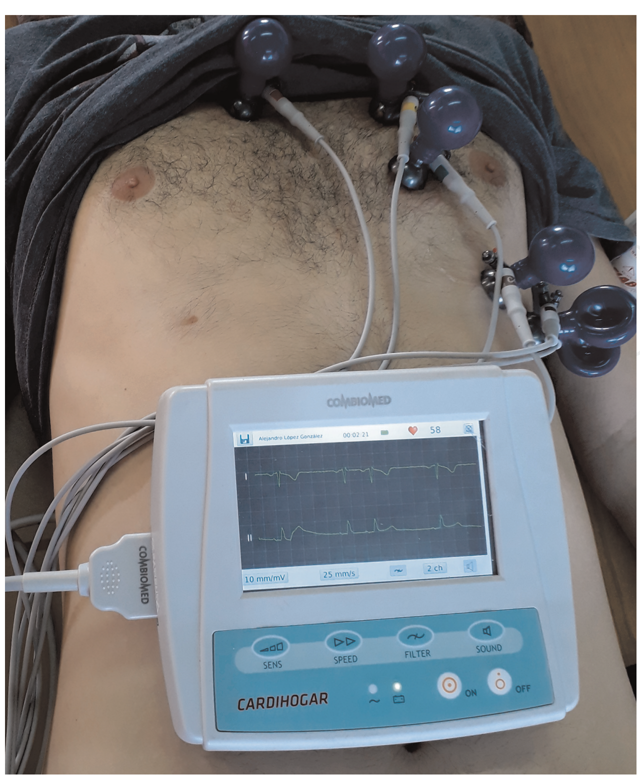

Figure 5.
View of the ECG recorder.

Another circuit called "trace recovery" is implemented to minimize the required time to recover the reference level when an electrode contact fails and any amplifier is saturated.

The eight independent leads (I, II, V1, V2, V3, V4, V5, and V6) are simultaneously digitized at a rate of 500 Hz with a 12-bit A/D converter; the LSB value is 3.15 microvolts. Leads III, aVR, aVL, and aVF are not implemented in the ECG amplifier because they can be derived from classical expressions when leads I and II are acquired simultaneously.

When signals from the eight channels have been acquired, two digital filters are applied. A notch filter is used to reject the 60 Hz component and a moving average type FIR filter is used to improve signal quality, minimizing noise and removing baseline wandering.

QRS complexes are detected in real time to calculate the heart rate when the ECG is acquired. A function of spatial velocity (FSV) is the basis for this process. This auxiliary function makes so easy to identify the signal segments associated with the QRS complexes [4].

$$FSV(k) = \sum_{i=1}^{C} [x(i,\ k) - x(i,\ k-1)]^2 \tag{4}$$

where FSV(k) is the Function of spatial velocity, x(i, k) is the ECG sample for lead i, C is the number of simultaneous leads.

As it is classic in the resting ECG devices, the electrocardiographic signals are acquired for 10 s and subsequently processed to extract the value of all the variables studied, more than 220 variables in each signal studied. However, the ECG is acquired without specifying when it will be analyzed; the operator is the one who decides when he wants the last 10 s of the ECG to be analyzed. While this process is going on, before it is analyzed in ECG, the device keeps calculating the heart rate in real time and updating its value on the screen every 10 s.

When the operator presses the proper button to start the ECG analysis, the signal acquisition process stops, and the ECG is analyzed automatically. More than 220 variables are calculated, and the process takes about 3 s. All this information is stored on the device. Computed variables can be grouped as follows:

- Amplitude and duration of P, P′, Q, R, S, R', and T waves.
- ST-segment deviation at the J point, the middle, and the end of the segment.
- PR, QT, and QRS interval widths.
- QT interval spatial dispersion.
- Corrected QT interval.
- Time of ventricular activation.

The recorder works as a data logger. For each ECG acquired, the recorder stores general patient data, the ECG (12 leads for 10 s), and measurements in internal memory where it maintains a database. This information is encrypted to guarantee its confidentiality. Data can be transferred to a computer using a USB connection.

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Data and signals are displayed on the recorder's screen; it is a liquid crystal display (LCD) with a resolution of 800 × 600 pixels and colors. This peripheral greatly facilitates the interface with the operator. A flat, soft-key keyboard complements the operator interface while making cleanup easy.

In an emergency, the recorders can be connected to a telecardiology system to request specialized help. The recorder can send a digital ECG and receive guidance on the actions to take on the patient suffering from dangerous disturbances. The integrated modem is used to establish the connection using the traditional telephone network or using a TCP/IP stack.

4.3 The analyzer

The analyzer is a Windows application running on a personal computer with sufficient resources to store all information associated with each patient enrolled in the proposed system. **Figure 6** shows an ECG from a patient and a list, on the left extreme of the screen, of the acquired ECGs. The system language is configured as Spanish. Other languages may also be incorporated.

The physicians use a graphical interface to evaluate patient ECGs; they can see the ECG one by one or they can study the trend of different parameters and thus detect the first signs of a heart disorder. Also, they can upload complex ECGs to a web application, called "The Expert," looking for a second specialized opinion before taking decisions. The parameters studied are:

- Cornell and Sokolow Indexes: These indices are strongly associated with ventricular hypertrophy. They are computed for each ECG and their trend is represented in a proper chart. The aim of the long-term analysis of these indices is the early detection of a ventricular dilation process because this process appears at the beginning of ventricular hypertrophy. Medical intervention at the beginning of this ventricular disturbance could delay its negative effects or even avoid them.

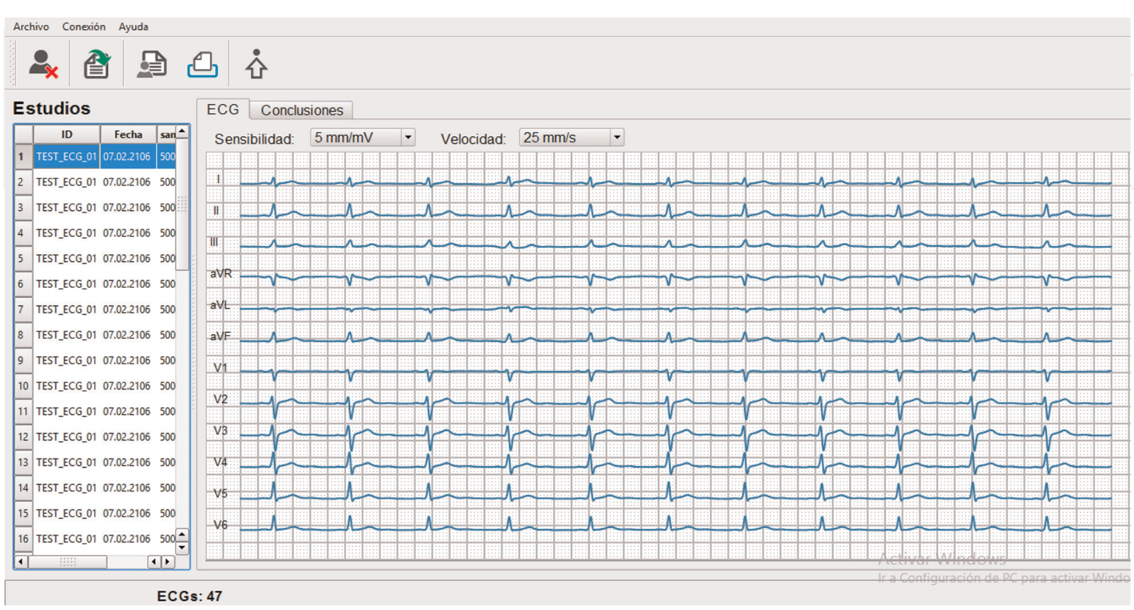

Figure 6.
ECG from a patient enrolled in the proposed system.

- QT interval spatial dispersion: Reported as an indicator to predict the onset of malignant arrhythmias [15]. Its analysis is a powerful surveillance tool for persons suffering from ventricular arrhythmias. A long-term study of QT interval dispersion for a patient could alert the family doctor about a forthcoming dangerous ventricular arrhythmic event; this kind of cardiac disturbance can provoke death or major cardiac damage. The proper analysis of the QT interval spatial dispersion using a trend chart constructed with big ECG data is a powerful tool for health services focused on cardiac care.

- Selvester scoring: This punctuation system assigns points according to criteria based on the amplitude and duration of waves of the QRS complexes. The accumulated points are proportional to the heart area damaged by a heart attack; it has been tested by taking autopsy data as a reference [16].

The proposed system studies the trend of the parameters mentioned above. Isolated values can be affected by different factors, while the tendency of a collection of values will indicate its behavior over time. All data associated with each study is displayed on the same screen to facilitate the analysis without continuous window changing.

4.4 Results and discussion

Five prototypes have been manufactured and tested; they have successfully passed parametric tests and electrical safety tests established in IEC 60601-2-25 for rest ECG devices with automatic wave measurement capabilities. Some of the main results of these tests, from the hardware point of view, are summarized in **Table 4**; it is impossible to show all of them because of the available space for the present document.

The obtained results meet the IEC 60601-1-25 requirements, so it is possible to affirm that the implemented electronic design solutions used in this device have been effective and according to the state-of-the-art. The software developed for ECG processing has been evaluated with CSE and CTS databases according to the same IEC standard [2]. For all studied variables, the maximum permissible error in measuring an ECG event has not been exceeded. Some of the results are shown in **Table 5**.

The QRS-detection algorithm was full-effective, and all the QRS complexes present in the analyzed ECGs were identified; all these signals are from the CTS and CSE databases, considered as an international standard. This result is very promising,

Parameter	Result
Frequency response	0.05–100 Hz
Accuracy and stability of the sensitivity	Less than ±5%
Intrinsic channel noise	Less than 30 μV
Common mode rejection ratio	Greater than 90 dB
Patient auxiliary current	Less than 50 μA
Permanent leakage current	Less than 300 μA
Classification according to IEC	Class 1, type CF

Table 4.
Main results of parametric tests.

Interval	Mean error (ms)	Standard Deviation (ms)
P wave	7.02	6.73
PQ interval	6.88	6.91
QRS complex	4.02	5.48
QT interval	8.17	5.12

Table 5.
Mean differences and standard deviations for global intervals on analytical ECGs.

although it can change a little under extreme-noisy conditions, so it is strongly recommended to take care to minimize noise presence.

When the accuracy of amplitude measurements within the QRS complex was analyzed, automatic measurements never deviated from the reference more than 25 microvolts for amplitudes lower than 500 microvolts or higher than 5% for amplitudes greater than 500 microvolts. This behavior meets the IEC standard requirements.

The full system has also been preliminarily tested with simulated signals and volunteers. The performance has been stable and there were no recorders out of order, software malfunctions, or unexpected errors. The proposed system has been completed with satisfactory results. All the IEC tests have passed successfully.

The analyzer works properly and is a friendly application. Five experienced cardiologists confirmed this criterion after several work sessions. By combining the available analysis tools and data, cardiologists can get new results unreachable using the traditional approaches. The proposed system seems a useful tool for cardiac disease prevention approach at the community level.

5. Final considerations

The three solutions described in this chapter are aimed at caring for subjects suffering from or prone to cardiac disorders. Two of these solutions are based on medical devices for personal use and the third is a system for the care of subjects in the community, in the environment in which they carry out their daily activities, based on the standard 12-lead ECG. In all solutions, public data networks are used to exchange information without requiring special services, so the cost is minimized for this concept.

Chronic diseases were associated with countries with high industrial development, while low-income countries were more linked with non-chronic diseases, such as dengue, diarrhea, and others. This situation has changed in recent years because of several factors and chronic diseases have reached an equal impact on all countries, regardless of their economic development. The great difference lies in the economic resources available to implement public health policies, while in developed countries the necessary resources are available, the health systems of underdeveloped countries are unable to serve the entire population due to their economic and financial limitations. The use of telemedicine, based on public data networks, can be a powerful tool to expand health services to everyone.

Table 6 summarizes some of the characteristics of the proposed solutions, showing the elements they have in common and their differences.

It should be noted that the three solutions have been developed in full adherence to the safety and performance requirements established in the IEC standards

Solution	Intended use	Basic standard	ECG channels	Basic operation mode
1	Arrhythmia follow-up	IEC 60601-2-47	1	Off-line
2	Ambulatory monitoring	IEC 60601-2-47	2	Real time
3	Disturbance prediction	IEC 60601-2-25	8	Off-line

Table 6.
Main characteristics of the proposed solutions.

(International Electrotechnical Commission), accepted as international standards and compatible with other similar institutions, such as FDA (Food and Drug Administration) and Japanese regulatory documents. Another aspect to highlight is the multidisciplinary teamwork for the development of the proposed solutions. The scientific level required for this software, mechanical, and electronic solutions was combined with the theoretical knowledge and practical experience of high-qualified cardiologists with more than 20 years dedicated to clinical services in their specialty, who provided valuable criteria for the implementation of the necessary features and for the evaluation of the proposed systems in real conditions of use.

One-channel and two-channel devices were developed to analyze cardiac rhythm disturbances; one solution focused on following up arrhythmic disease and the other for real time surveillance purposes to detect dangerous events immediately. The third solution was developed to predict arrhythmic and non-arrhythmic disorders, so the standard 12-lead ECG is the basis for this task. Several cardiac disorders involve spatial structures and the 12-lead standard ECG is the best noninvasive approach for their analysis.

The three proposed solutions are viable in low-income countries and therefore can be extended to countries with better economic standards. Electronic designs are based on commercial components that are available in the international electronic market; this facilitates manufacturing and after-sales service, guaranteeing the sustainability of the systems.

The two solutions based on portable devices are easy to use for the subjects that require their use. Today, there is a great disposition of most human beings to use portable technology because of the impact of mobile telephony that is part of our lives. The proposed portable devices were designed to minimize their size in order to avoid discomfort and their operation requires minimal user intervention. The third solution proposes the approach of the standard resting ECG to the community to assess the trend of different parameters strongly associated with dangerous cardiac disorders. In this case, the electrocardiographic test is the traditional 12-lead ECG, so its acceptance by the subjects studied is a fact.

The three proposed solutions offer health services that do not exist or are very difficult to implement traditional methods of care for patients suffering from heart disease. It is typical for a subject suffering from cardiac arrhythmias to visit the cardiologist periodically, for instance, it could be every 3 months, but it is impossible to know what happens between two visits while the solution proposed by the authors allows to evaluate the cardiovascular system changes day by day. The second solution proposes a way to keep people with high cardiac risk due to stress or suffering from some cardiac disorder under cardiovascular surveillance. This is also very difficult to achieve in low-income countries, although in developed countries there are more compact solutions than the one proposed, although they are also more expensive.

6. Conclusions

The solutions described in this chapter are examples of simple systems to provide effective tools for cardiac disease analysis and monitoring. The approaches discussed are feasible for other chronic diseases, such as diabetes, arterial blood pressure disturbances, and respiratory diseases. The common element is the measuring of the main parameter characterizing the analyzed disease with a medical device easy to use at home. This element combined with the use of public data networks is the basis for this kind of solution.

The greatest effort has always been aimed at achieving, at a minimum cost, solutions that meet the highest current safety and quality standards.

The proposed systems have been developed and tested under real conditions without any exceptional resources. A public data network of a poor country was the support for all tests and the results were satisfactory.

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Conflict of Interest

The authors guarantee that there is no conflict of interest with the information published in this document.

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