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A portable ECG for recording and flexible development of algorithms and stress detection

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Abstract

Cardiovascular diseases are directly or indirectly responsible for up to 38.5% of all deaths in Germany and thus represent the most frequent cause of death. At present, heart diseases are mainly discovered by chance during routine visits to the doctor or when acute symptoms occur. However, there is no practical method to proactively detect diseases or abnormalities of the heart in the daily environment and to take preventive measures for the person concerned. Long-term ECG devices, as currently used by physicians, are simply too expensive, impractical, and not widely available for everyday use. This work aims to develop an ECG device suitable for everyday use that can be worn directly on the body. For this purpose, an already existing hardware platform will be analyzed, and the corresponding potential for improvement will be identified. A precise picture of the existing data quality is obtained by metrological examination, and corresponding requirements are defined. Based on these identified optimization potentials, a new ECG device is developed. The revised ECG device is characterized by a high integration density and combines all components directly on one board except the battery and the ECG electrodes. The compact design allows the device to be attached directly to the chest. An integrated microcontroller allows digital signal processing without the need for an additional computer. Central features of the evaluation are a peak detection for detecting R-peaks and a calculation of the current heart rate based on the RR interval. To ensure the validity of the detected R-peaks, a model of the anatomical conditions is used. Thus, unrealistic RR-intervals can be excluded. The wireless interface allows continuous transmission of the calculated heart rate. Following the development of hardware and software, the results are verified, and appropriate conclusions about the data quality are drawn. As a result, a very compact and wearable ECG device with different wireless technologies, data storage, and evaluation of RR intervals was developed. Some tests yielded runtimes up to 24 hours with wireless Lan activated and streaming.

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1. Introduction

Cardiovascular diseases are directly or indirectly responsible for up to 38.5 % of all deaths in Germany [1] and are the first cause of morbidity and mortality in Europa and America [2, 3]. In the procedure of demographic change within Germany, this problem will become even more severe. Cardiovascular diseases are mainly discovered late or sometimes even too late during routine tests by the doctor. However, the patient must always act on his own because a qualified electrocardiogram does not belong to a standard check during regular visits to the doctor.

At present, there is no proper way of proactively detecting diseases and abnormalities of the heart that can be used in everyday life and observing them adequately in the further course of the disease. Corresponding long-term electrocardiograph (ECG) devices, such as those currently used by doctors, can at best be used in the acute phase, i.e., after the initial diagnosis, at short notice [4]. For everyday life, these devices are too unwieldy, expensive, and not available in sufficient numbers. Another problem is the low acceptance of such devices by the public. Another major problem in our society is the factor of stress. According to a German Stress Study 2016, over 60% of the people surveyed feel 'frequently' or 'sometimes' stressed. [5] Stress is a term that is not precisely defined, but it is mainly associated with high levels of psychological tension, which is often faced over a long period. High tension has a direct effect on heart rate and blood pressure. In this case, whether a person is in stress after a stressful event or whether it is just a subjective sensation, it can mainly be determined only by close monitoring of the heart.

The effects mentioned above on pulse and blood pressure harm the body over a more extended period and can have serious long-term consequences [6, 7, 8]. Since the primary goal of the project is to provide a highly integrated, comfortable, and mobile solution for the acquisition, recording, and transmission of ECG signals, it is necessary to use different storage and data transmission options. For storing the data, a micro SD card was chosen because it can be easily changed and read, and also it offers high data storage capacity. Bluetooth, WiFi, and mobile internet were used for data transmission to enable different operation modes depending on available resources. The developed device has to be wearable, comfortable, and ready to be used every day. For this, a wise energy management is required.

The analog signal processing is done directly on the module to avoid external sources of errors and to obtain consistent signals. All the required electronic components for power management and signal processing were placed directly on the Search Results

Web results Printed circuit board (PCB) and shielded from external influences. The only exceptions are the Lithium Polymer battery, micro SD card, and two ECG electrodes. The analog ECG signal is directly digitalized by a high-resolution, low noise ADC and transmitted to the microcontroller through the bus system. Depending on the operation mode, the module is able to store the raw ECG signals on a micro SD card, and after processing, it transmits the current heart rate and ECG wirelessly to an external evaluation device, for example, to a mobile phone. When storing the data on the SD card, the data is stored in an easy-to-manage file to enable efficient further processing of the raw data.

The main features of the system are the long life of the battery and user-friendly handling. The system is intended to be as comfortable as possible to wear, and therefore, it needs rounded edges to avoid the risk of injury. Standard parts are used to ensure a long-term supply of components only.

In general, another important objective is the cost factor. To be able to use the device in practice, the approximate costs without the reusable microcontroller should not exceed 20 € per unit.

2. State of the Art

Currently, more and more mobile health devices are becoming available on the market. These are mainly aimed for the curious end-users, who want to inform themselves about their current health condition just out of personal interest.

Most of these devices set up the recorded measurement data only for graphic visualization for the end-user, and very few provide a proper insight into the actual raw data, and even fewer provide an option to store the raw data.

The electrocardiogram (ECG) describes the electric characteristics of the heart muscle. The ECG is the most common and accessible tool to monitor the heart and to diagnose heart-related diseases. ECG devices can be classified in stationary and portable systems. Stationary ECGs are designed for hospitals; they are equipped with a display and provide a very high level of accuracy. They are usually used for monitoring non-mobile patients. Portable systems are smaller and are used for monitoring patients outside the hospital. The portable systems are mostly used for monitoring the heart during physical activity or monitoring elderly patients in a non-clinical environment. The main challenges for mobile systems are size, data processing, energy consumption, wearability, memory, real-time visualizing, and connectivity.

In the field of mobile ECG devices, there are mainly two types of use cases. On the one hand, professional or medical long-term ECG devices, such as those used by cardiologists, and on the other hand, non-medical devices for interested persons, which provide only an overview of data and some visualization of it. Very often, these consumer devices do not offer any possibility to extract the unprocessed raw data; other access to this data has to be purchased additionally. Mobile ECG systems or holders that run on batteries and can record data for more extended periods, but they usually have very high power consumption. Due to the limited capacity and size of the batteries, they have to be charged or replaced periodically¹. Many commercial non-medical solutions only record short time frames on demand to extend the battery lifetime. This solution is frequently used for monitoring physical activity [9, 10].

A comparison of the options for communicating wireless and extracting data from the devices shows differences between commercial and healthcare products. Several newer ECG Monitors offer local area network (LAN) and Wireless connectivity². However, the data can only be accessed with exclusively compatible software. Newer Holter ECGs also offers Bluetooth for the download of the data what is mainly done by docking or a cable with the use of dedicated software to read the data. In Table 1 we give a very general overview of different mobile ECG devices and an ECG monitor. This is a small subset of available devices, and it does not intend to give a complete overview of all the available devices. In general, all mobile professional ECGs with any kind of wireless connectivity or storage capability present very similar characteristics and are more or less homogenous.

There were no significant differences in runtime or storage. On the contrary, development systems are much more miscellaneous. The focus was set on the recent development of wireless wearable systems with low energy requirements. As we can see in this subset of ECG devices, the difference between the professional solutions and the development solutions are mainly that development system versions are mostly designed for the transmission and visualization of live streams. The data (stream) in the development system is usually stored after the data was sent to an external storing device like a smartphone, an embedded system, or a PC. Those systems are, in general, not intended to store internally more than a few seconds of the data, but they offer different connectivity options. Medical solutions do store larger amounts of data in internal memory, but usually, the access to the raw data is limited, and the extraction of the data is only possible with proprietary software. Physical sizes and battery capacity, as well as operating time, spread widely between professional and development versions, but obviously, professional systems tend to have longer operating times.

In the last years, there appeared a handful of new devices that are adapted to particular use cases like [11]

Currently, only very few ECG devices provide access to raw data for research and stress studies [12, 13] at an acceptable price. An example of such kind of device that does not require any cables or external electrodes, and that can store data in an unstandardized format on the internal memory is [14].

We defined the criteria for the development of our system as follows. The system had to be wearable, able to store a large amount of data (over a week), have minimal energy consumption, be able to interact with different end devices like smartphone and computer trough different wireless technologies, and expansibility allowing to add new functionalities and implement different algorithms for detection of ECG. The system should unify the advantages of

¹ Technical Specifications DOC1246084/1212 GE Healthcare

² Technical Specifications 4522 962 98661 * NOV 2013 Philips PageWriter TC70 cardiograph

professional medical devices and development systems. Currently, the system supports various data transfer protocols like Bluetooth, LoRa, and Wireless LAN and also enables to store the data on an SD card.

Table 1. A subset of ECG Devices

Device	Connectivity	Storage on device	Memory size	Battery	Approximate Operation time	Size in mm	Property software
Cardio Mem CM 3000-12BT	Bluetooth	Flash card	Up to2GB	AA	48-96h	108x86x22	proprietary
Cardio Mem Cm 4000B	Bluetooth, USB	SD Card Fixed	1 GB (AA	48-120h	65x108x16,5	proprietary
DigiTrax XT Recorder	USB	Flash	512 MB	AAA	7 days	91,44x55,88x19,05	proprietary
SEER 100	Bluetooth	Internal Flash		1 AAA	7 days	70 x 63 x 18	proprietary
DR300	Bluetooth	Internal Flash	512 MB (aprox. 25 MB * 14 days)	1 AA	14 days	86 x 60 x 20	proprietary
Bio2Bit	BLE	External	NONE	592 mWH	20h	68.6x53.4	open
System 5	BLE	External	NONE			30x30x30	open
System 2	Bluetooth	External	NONE				open
System 3	Bluetooth	External	NONE				open
System 2	BLE	External	NONE	3,6V	7 Days		open
System 1	Bluetooth	External	NONE	AA	11-25h	20x45x5	open

3. Methodology

3.1. System overview

The proposed system is divided into three main modules: the first is an analog module, the second module is responsible for digitalization and processing of ECG signals, and the third module is for sending, saving, and storing ECG data. The current system only requires approximately 100 mA at full operation with additional functionality (i.e., LEDs) disabled. The system should have an approximate operating time of 5 days. Achieving better results is possible by improving the programming and the capacity of the battery pack. Table 2 shows the technical characteristics of the developed ECG.

The ECG analog modules are realized in hardware to increase performance and simplicity. It is in charge of amplifying and filtering the signal. The second component obtains the analog amplified signal from the first module, digitalizes and processes it, and prepares the data for storage or wired transmission. The third module stores the data on the micro SD cards and sends it through one of the available wireless technologies. The developed PCB has two connectors for electrodes compatible with most wet and dry electrodes pads, as seen in Fig.1 b. The third electrode as a reference electrode is also available and can be connected with a wire.

The form of the PCB has round corners and borders to increase safety and wearability. The size and some of the characteristics can be seen in Table 2. The PCB can be designed more compact, but this size was chosen due to the average size of a human sternum. The module for data processing is placed under the processing board because the analog module is very sensitive to contact and pressure. It is designed so to get better insulation and mechanical protection from external influences. Each module or subsection has a customized and buffered power supply that reduces the influences and errors. Fig. 2 shows us a very simplified operation of the prototype and an application that visualizes the ECG graphically.

Table 2. ECG Characteristic

Device	Connectivity	Storage on device	Memory size	Resolution	Battery	Approximate Operation time	Size in mm	Property software
WearECG v.00	Bluetooth SixFox WiFi LoRa	SD Card	32 GB	16 Bit	LiPo INR18650-35E 3500mAh	35 to 116 h	75x42	Plane Text Simple text file

3.2. Analog module

The main problem during the development and design of an ECG is the noise caused by the amplification. Due to the low source signal, a strong amplification is needed. For this application, we decided to use a INA321 and a OPA336 from Texas Instruments. The filter frequency of the system is 0.04Hz for the high pass and 40Hz for the low pass. This is how we can reduce any external noise sources.

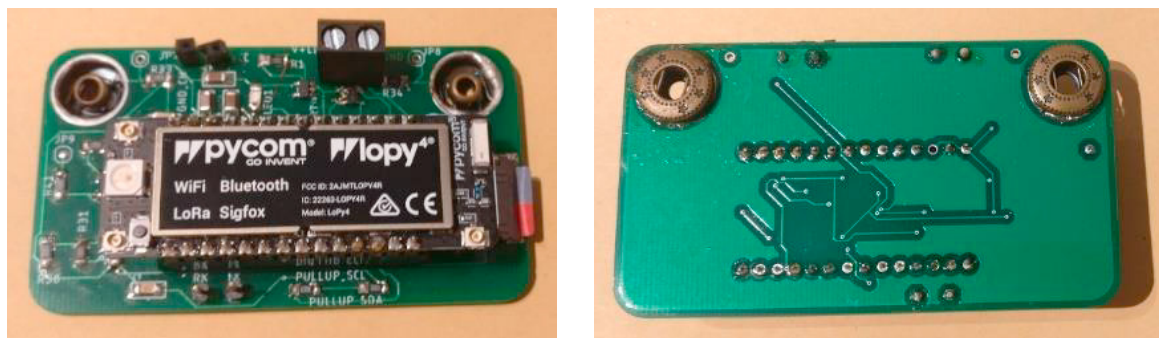


Fig. 1. (a) Top Side ECG; (b) bottom side ECG

3.3. Digitalization and algorithmic processing

In this module, we use an analog-to-digital converter ADS1115 by Texas instruments. An advantage of this ADC is the configurable sample rate that can be set up to 860 samples per second, the low power consumption of 150 μ A, 16 Bit resolution, and the integrated amplifier. The data is read using an Inter-Integrated Circuit (I2C) bus. The microcontroller reads the data from the analog to digital converter (ADC) at an interval of 0.01 sec (100Hz). After the data is read from the ADC the RR intervals are calculated using the integrated real-time clock of the microcontroller. A peak detection algorithm detects whether the acquired value is an R-wave. Because of the high sampling rate of the ADC, some thresholds and windows have to be used. First, a threshold should be between 0,15V and 0,21V. All values under this threshold will not be considered as a possible R-peak. Second, if a peak was detected and to avoid a misdetection, a waiting window of 20 samples is applied. If this threshold is not applied, a misdetection of up to 20 peaks per R wave may occur. Heart rates above 180 beats per minute (bpm) are not to be expected in healthy humans; therefore, only frequencies below 180 bpm are considered as plausible heart rates. All the detected heart rates, which represent frequencies above 180 bpm or more than three heartbeats per second (RR interval shorter than 333ms), are discarded. The actual RR-interval represents an average of the last 10 peaks.

3.4. Data storage and broadcasting

After RR intervals are calculated, and the data is read from the ADC, the data has to be stored and sent. Due to speed limitation with the SD card interface caused by the implementation, a maximal speed of 60 Hz is reached. As

storage format for the current data a tab-separated file was used. When measurement begins, a new file with a timestamp is generated. In the file, the current-voltage, the calculated RR interval, and the sampling time are stored.

If a WLAN connection is available, the microcontroller tries to establish a connection to a socket server. If Bluetooth is available, the data is broadcasted through Bluetooth low energy (BLE). Using one of the available connections and a server that listens for incoming connections, the data can be sorted in a database. This could be done using a program or a mobile application.

3.5. Power consumption

The prototype integrates two energy management functionalities: (1) power regulators with buffering capacitors for each component of the system. (2) battery management functionality enables for recharging.

The prototype uses the Texas Instrument LM3671 buck converter for regulating the system tension to 3,3 V. This tension is chosen due to the I2C commination and compatibility with the microcontroller. Like this, level shifters to ensure safe communication between different components are not required, and the overall power consumption can be reduced. The LM3671 is optimized for usage with LiPo batteries.

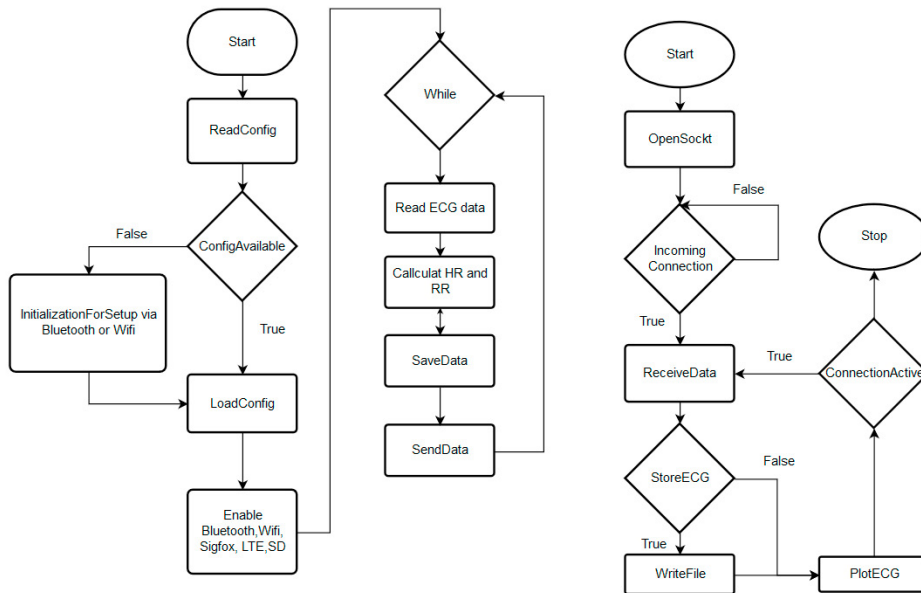


Fig. 2. (a) Flowchart Initialization and data write, (b) client that stores and visualizes ECG.

For charging and managing the LiPo battery, the controller MCP73831 from Microchip is used. 4,2 V was chosen as a charging voltage. The module offers a programmable charging current from 15 to 500 mA, thermal regulation for safe charging, and it only requires a minimal set of additional components as a capacitor for smoothing the voltage and resistance to select the programmable charging current.

4. Results

A prototype with the characteristics, as shown in Table. 2 was developed, as seen in Fig 1. The system consists of two modules. The first one is the PCB with the ECG amplification and ADC. On the same PCB, there are placed the power sources, battery management, and the SD card slot. The second part of the system is the development board that can be stacked on the ECG module. The prototype uses a lithium-ion battery with 3500mAh. The module is fixed with two standard electrodes over the chest. For the tests, the prototype was placed above the sternum in the area

between the 5th and 6th ribs. A comparison between the operation with two and with three electrodes, as shown in Fig.3 and Fig. 4 showed that the operation with two electrodes has a good signal quality that it can be used for stress research.

The prototype was tested while the test person was lying on the back and during mild physical activity. In both cases, the QRS components and the R-peak were good detectable. Several 15-minutes-long tests were made, during which we compared the heart rate that was calculated with the prototype and the obtained heart rate from Xiaomi Mi Band 3. The Xiaomi Mi Band measures the heart rate using pulse oximetry. Measuring the heart rate using pulse oximetry is not recommended for heart rates over 150 beats per minute [15]. The results obtained from both devices had an average variation of 3 heartbeats per second.

Some runtime test was also performed with a 400mAh and a 2400mAh LiPo batteries. Approximate runtime of 4h to 24h could be reached if the system is streaming the data via Wireless Lan. Batteries with a higher capacity as 2400 mAh are not recommended due to the weight.

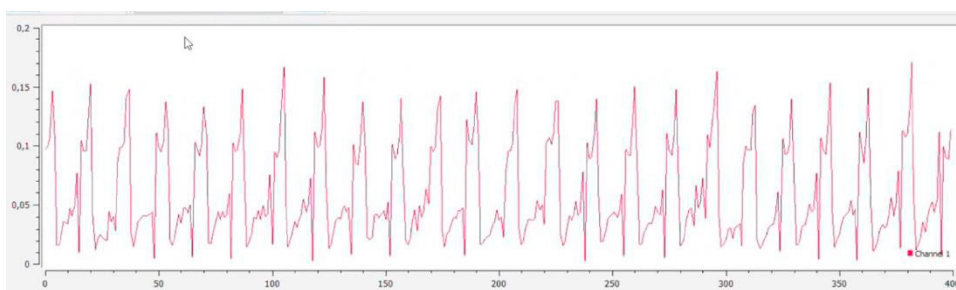


Fig. 3. Measurement with two electrode

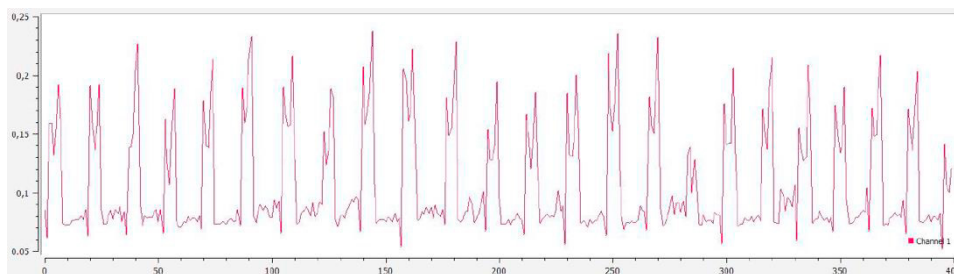


Fig. 4. Measurements with 3 electrodes

5. Conclusion

In this paper, we presented a design of a mobile ECG system with multi communication abilities, such as Wireless Lan, Bluetooth, Sixfox, etc. that also offer an option of storing the ECG data on an internal micro SD card. The mobile ECG is able to detect, record, and send the data to an external program for visualization and configuration. The main challenges as size, data processing, storing, energy consumption, wearability, memory, real-time visualizing, and connectivity were fulfilled. An additional advantage is the low cost of approximately 50€ for the complete system.

Future studies and comparison with professional and consumer devices will be carried out to validate the correctness of the data. Furthermore, different processing algorithms will be analyzed and implemented on the microcontroller to reduce the power requirement of the system.

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