

Seizure detection using a wearable electrocardiography device with smartphone integration: A feasibility study

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Abstract—

Background: Detection of focal epileptic seizures during activities of daily living has potentially important benefits, from robust and objective seizure reporting, to life-saving precautionary measures by notifying the patients themselves, family members or caregivers in a timely manner.

Objective: This study aims to evaluate the feasibility of a wearable seizure detection system based on ECG with continuous Bluetooth streaming to a smartphone.

Methods: Testing of parameters such as battery consumption, signal quality and comfort were performed. A SWOT analysis was performed to systematically evaluate factors essential for making the necessary system architecture decisions. A proof of concept for exporting an existing seizure detection algorithm from LabVIEW to an executable file was carried out, to investigate whether this is a viable alternative to translating the algorithm to another programming language.

Results: The battery life proved sufficient for one day of use, no significant noise or instabilities were found when analyzing the signal quality and the comfort of wearing the ECG device for long-term monitoring was satisfactory. The proof of concept proved to successfully export a LabVIEW program to an executable file, which was imported and run in a console application.

Conclusion: The proposed system is well-suited to function as basis for an upcoming development project, which will aim to implement the system as a research setup.

Index Terms—seizure detection, focal seizure, telemonitoring

I. INTRODUCTION

A. Background

Epilepsy is one of the most common neurological disorders in the world, with a prevalence between 5.8 and 15.4 per 1000 citizens depending on the country [1]. WHO estimates around 50 million people worldwide are actively living with epilepsy, of which 70 % could live seizure-free, if properly diagnosed and treated [2]. This leaves an estimated 30 % of people with epilepsy untreatable, and obliged to live with unpredictable symptoms, such as seizures, which can be life-threatening, especially when unattended [3].

Detection of focal epileptic seizures (FS) is a growing research area, with many wearable devices used in recent papers. Today, several wearable devices for detecting seizures

are commercially available [4], but these primarily focus on generalized tonic-clonic seizures (GTCS), or focal onset seizures (FOS) with motor features. Wearable devices for detecting focal seizures without convulsion are not yet available to patients.

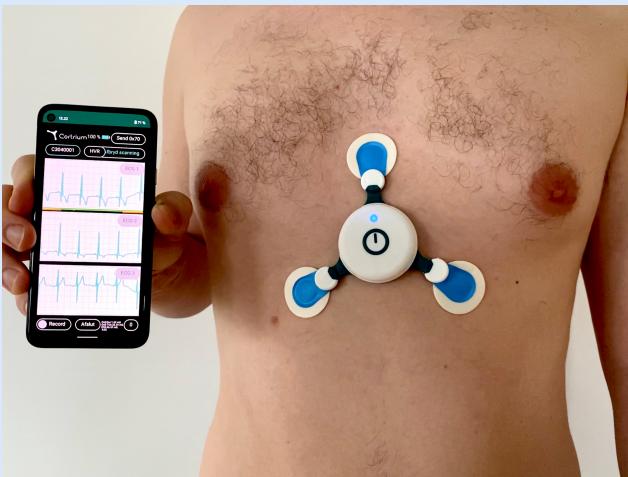
Devices with this capability would help quantify the seizure burden to patients with focal epilepsy, as they would provide objective data on the number of seizures the patient has. This would provide caregivers with an insight into how well the patient responds to medication plans over time, and mitigate the well-known challenge of under-reporting epileptic seizures [5].

For the patient group living with FOS, an alarm in the early stages of a seizure could reduce the response time before caregivers or family members arrive to attend the patient during the tonic-clonic phase. Further, it could warn the patient about an impending seizure, and potentially dangerous activities such as driving or operating heavy machinery can be discontinued.

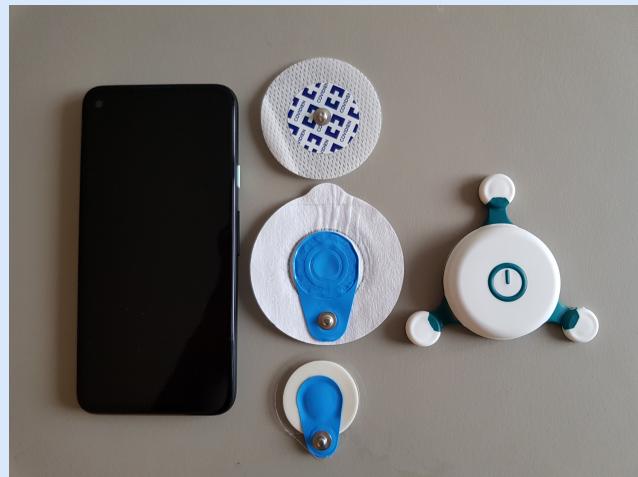
Ongoing research in epileptic seizure detection has shown heart rate variability as a biomarker for detecting focal seizures in the preictal and early ictal phase of the seizure [6]. As a result, a detection algorithm has been developed by researchers at Aarhus University Hospital [7], which can potentially be implemented in a wearable seizure detection system. However, such a system is required to function in a daily life situation, thus a number of factors related to this must be explored.

B. Objective

The aim of this study is to investigate the feasibility of a wearable seizure detection system based on noninvasive ECG. Factors crucial for real-world use, such as comfort, battery life and signal quality will be tested. However, the described system is primarily intended as a tool for use by researchers, and not as a commercial product.



(a) System in operation



(b) The three different size electrodes tested

Figure 1: Test setup. Cortrium C3⁺, smartphone and electrodes.

For this study, the CE approved and commercially available Cortrium C3⁺ Holter Monitor was used for capturing ECG data, and streaming this via Bluetooth Low Energy (BLE) to an Android smartphone. The C3⁺ device captures 3-lead ECG data in 256 Hz (24 bit), but for the purpose of this study, only a single lead is necessary. The data is saved locally on the C3⁺ device, as well as on the smartphone, which facilitates the comparison of the two signals to evaluate the reliability of the Bluetooth streamed signal. The smartphone is a new Google Pixel 4a, which was not connected to a mobile data network or WIFI during testing.

II. MATERIALS AND METHODS

A. Proof of concept

The already existing implementation of the seizure detection algorithm, along with an R-peak detection algorithm by the researchers at Aarhus University Hospital [7], was written in the programming language LabVIEW. As a proof of concept, it was investigated, whether it is possible to export LabVIEW programs (*VI*s) as an executable file. This will enable the algorithms to run stand-alone, which is particularly relevant to set design the system, such that the detection algorithm runs on a server. Additionally, it will prevent the need for translation of the algorithms to another programming language, which would consequently complicate the opportunity to continue improvement of the algorithm, by the researchers who originally developed it using LabVIEW.

B. SWOT analysis

To evaluate the strengths, weaknesses, opportunities and threats of the proposed system in a systematic way, a SWOT analysis has been conducted [8]. This analysis is devised in the light of the conducted tests (see section II-C), and on the basis of the system architecture draft. A subsequent test is carried out to elucidate the character of the weakness' and threats to improve the architecture based on these findings.

C. Test setup

The C3⁺ device is worn for several long-term recordings, continuously streaming the signal to a smartphone via Blue-

tooth. Each recording ends when either the smartphone or the C3⁺ device is out of power. During the recordings, the ECG signal is saved on the C3⁺'s internal storage, as well as on the smartphone.

During the long-term recordings, all activities of the subject wearing the system were noted down along with a timestamp. This allowed for finding specific activities, and match these against artefacts in the recorded signal.

All long-term recordings were recorded from one male subject. A short test was performed on a female subject, primarily to assess the comfort of wearing the C3⁺ device under a bra. It was furthermore confirmed, whether the signal amplitude was sufficient, as the location of the electrodes are often placed in a less desirable location on females.

The test parameters are divided into three main parts: 1) Power consumption, 2) Signal quality, 3) Comfort and practicalities.

The power consumption is tested on both the smartphone and C3⁺ device, to assess the adequacy for real-world use, where a battery life of at least 18 hours is necessary.

The signal quality is tested to assess the significance of the noise in the signal captured by the smartphone. To do this, the signal captured locally on the C3⁺ device serves as the golden standard, and is used for comparison with the signal captured by the smartphone. Quantitatively, the signals are compared by running an existing R-peak detection algorithm against both signals. The most optimal procedure would be to run the seizure detection algorithm on the same epileptic

seizure recorded on the phone and C3⁺ device respectively, but since we are only able to capture ECG data from healthy subjects in this study, running an R-peak detection algorithm is adequate. Qualitatively, the two signals are compared by plotting corresponding parts for visual inspection to reveal any significant differences. As the signal recorded on the smartphone, and the one recorded on the C3⁺ devices does not start at the exact same time, two corresponding parts are isolated by finding distinct features in the full signal, and selecting a number of samples around this feature. This results in a number of samples from the C3⁺ and smartphone respectively, which match up accurately, as seen in figure 2.

A qualitative test of comfort and practical challenges was performed by using a variety of electrodes for the C3⁺ device during long-term monitoring. This is done to evaluate the discomfort experienced while wearing the device during activities of daily living.

D. System architecture

For illustrating the system architecture, a deployment diagram of the Unified Modelling Language (UML) 2.5.1 standard was used [9]. The specific system architecture is chosen based on the results from the SWOT analysis, and the practical test of the system.

III. RESULTS

A. Proof of concept

A small LabVIEW program was coded, to which the input is an integer, and the output is the same integer incremented by 1. It was exported as a .exe-file, and imported in a working C# console application. This indicates that it is likely possible to include the seizure detection algorithm in a similar pipeline, allowing the algorithm to run on a server.

B. SWOT analysis

1) *Strengths*: The system does not consist of embedded software deployed to the ECG device. This results in a loose architecture, enabling the ECG device to be exchanged for another model than the one used for this study with relative ease. This contributes to future-proofing the system, as it is expected smartphones and ECG-devices will improve across parameters, such as battery life and comfort, with future generations. The loose architecture also makes the system independent of specific smartphone and ECG-device manufacturers.

The intended user of the system will most likely already be carrying a smartphone daily. By basing the system on a device, which the user is already accustomed to carrying around during activities of daily living, there is a greater chance of a high patient compliance.

2) *Weaknesses*: Placing the algorithm on the ECG-device itself, would be the most optimal solution in terms of battery consumption, as this would result in the lowest possible amount of data streaming. Since the system in this study is intended to have the algorithm running on a smartphone device and server, it results in increased draining of the battery for both the smartphone and ECG-device. This is primarily due to

the need for continuous ECG-signal streaming from the device to the smartphone.

Another weakness can be related to the placement of the seizure detection algorithm on a server. This could cause a delay between the seizure being recorded, and the system alerting about the seizure.

Furthermore, the C3⁺ device needs to be charged daily, when continuously streaming the signal via Bluetooth. Since charging is currently not possible while wearing the device, it entails the need for two devices for each patient, if it is to be worn both day and night.

3) *Opportunities*: Avoiding to place any software specific for this system directly on the C3⁺ device, will make the system independent of any specific ECG monitor. Since the seizure detection algorithm only needs a single lead ECG, it is possible a future system would involve a much smaller and more comfortable ECG device.

To improve on the battery life of the smartphone, a possible extension to the system could include placing a gateway in the patient's home. In this way, the ECG device could seamlessly switch between streaming the signal to the smartphone and the gateway, depending on whether the gateway is within range.

4) *Threats*: In the proposed system, the C3⁺ is intended to be worn 24 hours a day, which could pose issues with patient compliance. The choice of electrodes are crucial to the comfort, and individual patients will likely have preferences towards specific electrodes. This entails an adaption phase, in which the patient tests different electrodes, which may result in rashes and discourage the patient from wearing the ECG device.

C. Test results

1) *Power consumption*: A total of 4 long-term recordings with complete exhaustion of the C3⁺ device battery were performed. As seen in table I, the longest battery life was achieved in the first recording. This recording mostly consisted of being inside, with the exception of a run outside. The other three recordings, which lasted notably shorter, all included a significant amount of time walking outside. Please refer to the enclosed appendices for the full detailed journals that were kept during the long-term recordings.

Table I: long-term recordings

Start date	Total duration	Phone battery left
25/11-2020	40 hours	11 %
28/11-2020	24 hours	49 %
04/12-2020	25 hours	51 %
05/12-2020	24 hours	51 %

2) *Signal quality*: The signal is evaluated qualitatively by visual inspection of the filtered signal from the phone and C3⁺ device respectively. This is done in selected parts of the recorded signal from the long-term monitoring, where the signal is expected to be the most exposed to noise, and thus the signal recorded by the phone will deviate the most from the signal recorded by the C3⁺ device.

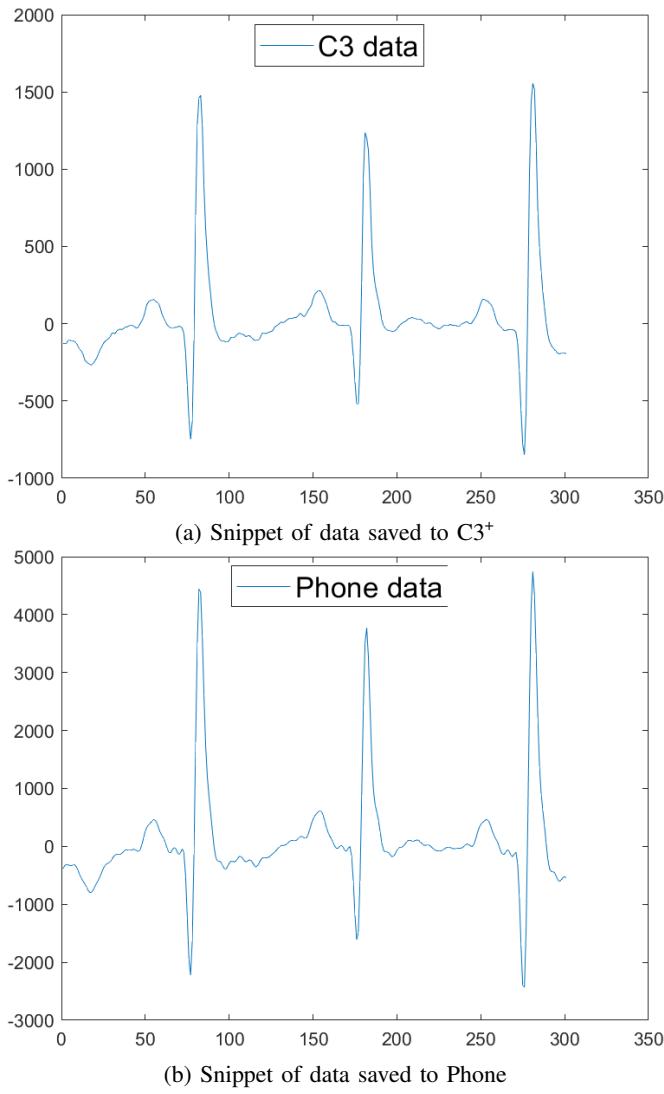


Figure 2: Qualitative comparison of signal quality. This specific part of the signal was captured during a run.

Figure 2 shows a small section of the exact same part of the ECG signal stored on the C3⁺ (a) and the smartphone (b) respectively. It can be observed that the two signals are almost identical, and the small deviations are presumably due to differences in the filtering of the signal. Evaluation of additional selected parts of the signal showed a similar tendency.

The signal is also evaluated quantitatively by comparing the output of the R-peak detection algorithm. This algorithm showed no differences in output between the Bluetooth stream signal saved to the smartphone and the signal saved to the internal storage of the C3⁺ monitor.

3) Comfort and practicality: The type and size of the electrodes are crucial to the level of comfort experienced when wearing the C3⁺ device. It has proven to be the smallest electrodes that appeared to have the highest overall comfort for long-term monitoring.

Table II shows the electrodes that were tested along with a comfort score from 1 to 3, where 3 is the best comfort. In the table, they appear corresponding to the order in figure 1b.

Table II: Electrodes tested

Manufacturer	Model name	Relative comfort score
Covidien/Kendall	H99SG	2
Ambu	BlueSensor VL	1
Ambu	BlueSensor P	3

With the H99SG from Covidien/Kendall, it was generally difficult to obtain a sufficient signal amplitude, without scrubbing the skin with a piece of cloth prior to applying the electrodes. In addition, they had a tendency of falling off when moving the chest region, as they are relatively inflexible. The BlueSensor VL from Ambu were easy to apply and obtain a sufficient amplitude. However, an intolerable itch generally developed after 10 hours. This is presumably due to the large area covered by the adhesive. The BlueSensor P from Ambu were equally easy to apply and obtain a sufficient amplitude. They have a much smaller area of adhesive, compared to the other electrodes. These were comfortable to wear for long periods.

The comfort was briefly tested on a female subject using the Ambu BlueSensor P electrodes. This showed no discomfort, and easy placement of the electrodes and device while wearing a bra. However, the electrodes need to be located slightly lower on the chest region due to the underwire. In this location, it was confirmed that the amplitude of the streamed signal was still sufficient.

D. System architecture

Figure 3 shows the entire system architecture, but only the area within the dotted lines is included in the practical test in this feasibility study. The rest of the diagram is the proposed system for upcoming development.

The C3⁺ device connects to the smartphone using Bluetooth Low Energy. On the smartphone, an R-peak detection algorithm continuously analyzes the streamed signal. For this study, the app running on the phone was provided by Cortrium.

The smartphone communicates with a server at Aarhus University using HTTPS, preferably with HL7 FHIR, where the seizure detection algorithm analyzes the streamed signal. If the algorithm running on the server detects a seizure, an alert is sent to the patient smartphone, and any connected relative or caregiver devices.

A database for storing patient information and events is connected to the database. This might be used by caregivers and personal physicians to monitor the events and access relevant data to e.g. analyze the progression of seizures.

Note the diagram on figure 3 only illustrates a draft architecture, and is likely to change as a result of further design iterations in a future project.

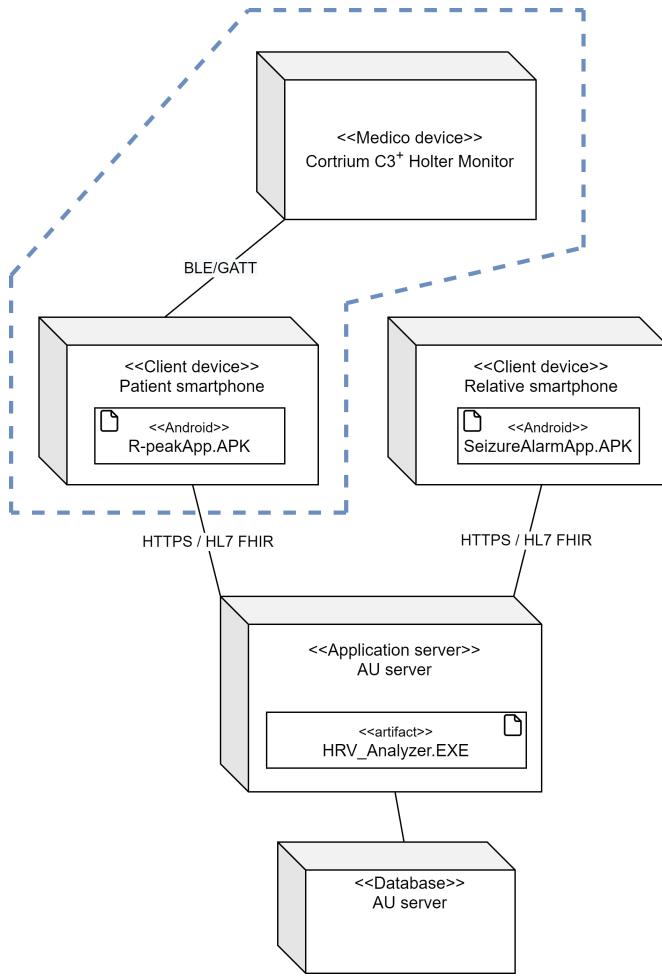


Figure 3: UML Deployment diagram - System architecture

IV. DISCUSSION

A. Power consumption

When the ECG-signal is streamed to the phone, the only processing is the filtering and saving of the signal. Therefore, the smartphone will likely consume a larger amount of power, when an R-peak detection algorithm is implemented for continuous data processing, as it is intended according to the architecture diagram on figure 3. Also, the smartphone was brand new, and not connected to WIFI or mobile data networks during any of the tests. This has undoubtedly contributed to the low power consumption. In a real-world scenario, the patient's own smartphone would be used instead, which will likely result in the battery draining at a significantly higher rate than indicated in this study. However, when the C3⁺ ran out of battery, the phone had around half of its charge left in 3/4 recordings, meaning there is some allowance for additional consumption by the smartphone.

The battery life of the C3⁺ device was possibly affected by the range of activities conducted during the recordings. The majority of the 40-hour recording were spent inside, meaning outdoor activities are presumably more likely to drain

the battery faster. It is suspected that the device increases the Bluetooth signal amplitude when outdoors, to reach a sufficient level for streaming the signal to the smartphone. When indoors, the signal will reflect off nearby surfaces, thus the amplitude is sufficient when relatively low.

B. System architecture

A design decision mentioned in the SWOT analysis, is to embed the detection algorithm directly on the ECG device. This would result in less power consumption, as the signal would not need to be continuously streamed to the smartphone. However, the main drawback of such a design solution, is that the system would be tightly connected to the specific ECG monitor, on which the detection algorithm is embedded. In a future situation, there might be multiple ECG devices to choose from, and the specific device may depend on patient preference and other factors. The result from keeping the detection algorithm on either a server or a smartphone app makes the architecture loosely coupled, facilitating greater flexibility for using different ECG devices.

Another point mentioned in the SWOT analysis is the possibility of extending the architecture with a gateway situated in the patient's home. This would increase the battery life of the smartphone, as the ECG monitor would switch to using the gateway, whenever available.

C. Signal quality

One of the methods used to evaluate the signal quality, is to visually inspect parts of the smartphone- and C3⁺-signal, after they have been aligned in such a way that every sample matches, as seen in figure 2. This has only been done on a few small parts of each long-term recording, as it is time consuming to extract and align parts of the signals. With additional resources, it would be possible to conduct more inspections, leading to a greater evidence base.

Additional quantitative parameters would also be relevant to investigate, such as the signal-to-noise ratio for the signal recorded by the smartphone..

The data was only gathered from a single male subject. To further improve the data basis, additional subjects could be included. The best case scenario would be to record multiple epileptic seizures, and compare the performance of the seizure detection algorithm using the signal recorded by the smartphone and the C3⁺ respectively.

V. CONCLUSION

In this feasibility study, a proposed system consisting of a wearable ECG device and a smartphone for the automatic detection of epileptic seizures underwent preliminary testing and analysis. The results show the system to be well-suited to function as basis for an upcoming development project, which will aim to implement the entire system as a research setup.

VI. APPENDICES

Appendix 1: Long-term ECG monitoring journal

ACKNOWLEDGMENT

Thanks to Cortrium for sponsoring a C3⁺ Holter Monitor for use in this project and further research.

CONFLICTS OF INTEREST

There are no conflicts of interest to declare. Cortrium Aps sponsored a C3⁺ Holter Monitor for use in the project, but were not involved in the planning and execution.

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