Business aspects

Project #36
Software development for a wireless ECG

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Information page

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Summary

In the western world, there is a shift in demographics, with an aging population. The higher age, combined with obesity, the risk of cardiovascular diseases is growing. The measuring of electrical bio signals, like an electrocardiogram (ECG) is important to spot early symptoms and see a specialist in case of a suspicion. Even though the equipment should not be used for diagnosis, providing an affordable and easy to use tool enables self-checks and possible early recognition of arising problems. If in doubt, contact your specialist. This device is not a medical device in its performance must not be treated as one.

In educational programs related to ECG, a hands-on experience will improve the teaching and deepen the understanding. Furthermore, in third world countries, this can be an alternative .... really? we are not making a medical device...

Our product provides real time monitoring with aid of the PC software. In addition, an introduction to ECG for non-medical users is available.

Our product is developed for educational purposes, and as such, all documentation and software is available. Furthermore, as this will not be used in medical application, the performance and regulatory requirements are lighter. Using a certified radio module enables us access to Europe, North America and Japan. For other regions, depending on the market size the radio approvals can be applied for later.

Business idea

Our product is a wireless ECG monitoring system. The product consists of a portable hardware device, a computer software. On top of these we also have an optional mobile phone application, that can be used to monitor the live ECG data. The product is only meant for self-monitoring and shall not be used for diagnosis. If the ECG shows any irregularities, the customer should contact their physician.

The developed device is wireless and uses Bluetooth Low Energy (BLE) to communicate with the paired host device. We use three industry standard electrodes to acquire the measurements from the subject. The data is then send over the BLE to the paired host device to be analysed. The software filters out the data and presents it back to the user.

Our main clientele consists of the elderly population of above the age of 65. Elderly homes and care centres are considered as possible business partners.

We also hope that universities and educators (e.g. nursing schools) will be interested of our product taking in to account the competitive pricing and the thorough documentation. The product is designed in such a way that features like signal filtering can be taken off, so that a more noisy and distorted signal can be presented, and filtering methods can be applied to clean it up. This will improve the understanding of the signals and improve the students understanding of signal vs noise.

The design must be robust and affordable. In addition, the device should be reliable, easy and safe to use.
Product/service

The provided product consists of a hardware unit and a PC/mobile software for using the hardware. With the system the customer is able to gather data from his/her heart functioning, present it graphically, and store it for later analysis. Cost-effective yet still accurate solution for displaying, collecting and storing ECG datum would also benefit the healthcare education in developing countries, where accessibility to more expensive systems are limited.

The hardware unit communicates wirelessly through Bluetooth Low Energy (BLE). It is powered by two rechargeable AAA-batteries. The measurement unit is connected to the patient with disposable adhesive electrodes, which can be replaced afterwards with reusable ones if so desired. There are three electrode connections to the body: right arm, left arm, and left foot. The system is designed so that no matter what, the measurement unit can’t be connected to any external power outlets while still connected to a person.

The computer software is compatible with GNU+Linux, macOS and Windows platforms. The system requirements for it are very minimal as the software utilises just the platforms Bluetooth adapter and writes and plots data. The UI of the desktop software consists of the three ECG graphs, graph axis controls, the measurement session control, the measurement unit handling controls, and status updates of the system. Everything needed to measure ECG successfully from start to finish will be accessible straight from the User Interface.

The mobile software utilizes the same properties as the pc software, and it is free to download from the Apple APP Store and the Google Play Store. From the mobile app and data cannot be exported, and the measurement time for one measurement session is limited to 15 minutes, but otherwise the app provides the exact same functions than the desktop app.

Market situation and competitors’ analysis

Since the ECG market is quite large, the competition for customers is huge. Since we are not in the market for medical ECG:s we want to stand out from the market by offering a reasonably priced ECG for commercial and educational use.

The Medical ECG market was valued at 4,516 Million in 2016 and is expected to rise to 6,637 Million in 2023. Since cardiovascular disease has become a common health problem, the market for informational devices about heart condition for not only hospitals but also the average consumer has been growing steadily. Furthermore, the technological advancement in handheld and portable devices have also boosted the ECG market. However, since ECG have become more common, the market has become more saturated, which has hindered the growth.

(source: https://www.alliedmarketresearch.com/electrocardiograph-ECG-market)

The ECG devices are categorized into resting ECG, stress ECG and holter monitors. Holter monitors are also categorized into wired and wireless holter monitors.

Since these estimates only give a market share of the medical devices, we don’t know the market size of commercial non-medical devices such as Omegawave, BioPack and Qardiocore to name a few. Since there are many commercial ECG, a breakthrough in a market like this is hard. Our plan is to develop a product that has not only a fair price for a robust and reliable ECG for the average consumer, but a product that can offer a educational hands-on experience for students and nursing school.
A few competitors are mentioned below and offer an insight in the current market. Omegawave offers a complete sports integrated solution, which uses the ECG as a conditioning tool for sports teams and individual athletes. The ECG measurement data aims to indicate the athletes’ current fitness level and avoid overtraining based on the measurement. The software itself is a subscription-based service that, apart from the measurement, offers individual training plans and digital training. The price for a device and a one-month subscription is 215 euros. If the customer wants to keep using the software, it is going to cost a lot more. (source: https://www.omegawave.com/)

Qardiocore offers an hybrid between a medical device and a sports tracker. The device includes heart rate measurement, ECG measurement, activity tracking, skin temperature measurement and respiratory rate. The data can also be shared to your personal doctor to be evaluated and checked. Therefore, doctor appointments doesn’t need to be had as often, since the data can be sent directly to a database. The price for the product is a one-time payment of 449 dollars, with the software offered for free. (source: https://www.getqardio.com/qardiocore-wearable-ecg-ekg-monitor-iphone/)

BioPack offers an educational set which includes many varieties of modules with varying sensors and devices. The price of the base module is 7 100 euros which supports 16 channels. With the ECG module of either wireless, which costs 2 500 euros, or with wires, which costs 1 000 euros. Since the product is used in research and education, the quality and price is high.

In terms of the competitors mentioned, every single one costs more than the intended price we want to offer. In terms of the market, the Omegawave is concentrated on a completely different market than us. The educational and research ECG offered by BioPack is complex and overpriced for only ECG measurements and in case of offering a hands-on experience for a reasonable price, we could deliver that. Lastly, the Qardiocore offers a multipurpose ECG and sports tracker device for average consumers with a reasonable price tag for the device. Since we are targeting the same consumers, it is crucial to offer a cheaper and simpler ECG device and skip the sports tracking feature to specialize in the ECG measurement.

**Value Proposition canvas**
The value proposition canvas introduces a plan for our business idea and plan for our product.
**Intellectual property**

The components used to build the measurement device are not bound by any usage limitations by their manufacturers.

We have acknowledged and read component manufacturers’ *terms of sale and use* and there are no sections that would limit our business. As we are developing the device ourselves there are no intellectual property that is in danger of being infringed.

The libraries used for the software development are all open source and licensed under the MIT License, which allows the usage of such software for commercial products.

**Product development and technology**

As the real outcome for the project is a learning tool for students, our approach is with open documentation and available source code too, so that the device will improve the understanding, and can be continuously developed further, in both hardware and software. Because of the occasional use, the powering with primary (non-rechargeable) AAA batteries was chosen, so that the device will comply with safety requirements and will be ready to use at once, instead of having discharged batteries regularly and then require time to charge before use.

When transforming the design into a commercial product, at first, the documentation and software should be hidden. Furthermore, the design should be improved in such a way that the input stage is filtered better, as in the educational model some noise is a wanted part of the signal chain. The shape of the product is affected by the choice of the component sizes as well as the selected power source. A rechargeable battery would be implemented for sustainability reasons, and a more appealing form factor would be utilized. By adding the charging circuitry, it is possible and wanted to connect a power source to the device, and it must be ensured that the device cannot be connected to the person at the same time (e.g. use the same connector for electrodes and charging). A more standard interface for the electrodes would be used.

**Conformance**

As this device is not intended for the medical market, the regulatory requirements are lighter. Despite that, this is a radio product, so it must conform to regional radio standards, as well as electrical safety. The radio module complies with the European Radio Equipment Directive (RED) (2014/53/EU) and has pre-approval for FCC, Canada and Japan. For radio devices, safety regulations are mandatory too. Of course compliance with RoHS is mandatory.

Here is a list of applicable standards and directives

**Safety:**

International: IEC 60950-1

**Radio**

Europe: EN 300 328 V2.1.1

EN 301 489-1 V.2.2.0
In order for the product to fulfil the requirements, a couple of design decisions were made early on. For once, using a certified radio module does reduce the risk and time to market, in the regions where the certification has been granted and also ensures a high probability of passing local regulations in other potential markets.

For compliance with safety regulations, the same connector that is used for the electrodes will be used for charging the batteries. In this way, it is not possible for the user to be connected to the electrodes and a charger.

**SWOT-analysis**

In this chapter we introduce a SWOT-analysis of our product.

**Strengths**

- **Price**
  - our system provides high performance without the multi-thousand price tag
- **Ease of use**
  - the system initialization and its use are designed to be intuitive and reliable
- **Wireless and portable**
  - rigid and compact form-factor and the wireless connection allows flexibility in different use cases
  - the price/quality ratio is convenient for educational use
  - the system provides option to alter the filtering of the data so that the electrical factors can be really experimented
  - the data is as accurate and precise as the current medical devices provide
  - low price allows the purchase of several units, so the experiment and breaking of one unit is extremely budget-friendly
- **Measurement data export as an industrial standard file (.edf) and also a standard data file (.csv)**
  - The .edf file can be sent to medical professional for analysis, which could provide early warnings that could have otherwise been left unnoticed
  - the .csv file allows more flexible use of 3rd party analysis tools, for example Matlab.

**Weaknesses**

- Although the device is highly accurate and provides health-related data, it is not qualified specifically as a medical devices
  - the standardization would decimate the price-advantage this product has, as the medical certificates are highly priced.
- **Closed code of software limits the educational benefits**
  - the software side of ECG will be unreachable with our product, which reduces the computer-science approach of education
Hardware is not proprietary
- the system is built with several ready-made free to use parts, making the productization of the system quite difficult

Opportunities
- High educational value and competitive price/quality ratio poses business opportunities in the healthcare education markets in the developing countries
  - suitable for practising the ECG measurement while the medical-grade devices are used in real healthcare situations
- improving the general health and heart wellbeing awareness
  - more people can afford to acquire a unit and monitor their health
- Rapidly aging population and increasing risks of cardiovascular disease
  - more people are at risk of getting dysfunctions in their heart, so more affordable yet suggestive heart monitoring solution will be needed
- in-app advertising possibilities in the mobile app
  - while using the mobile software the customer could get advertisements of local (public or private) hospitals or health centres for health examinations

Threats
- Getting name and market shares would be difficult at start, as the older and bigger companies have highly optimized sales network and connections
  - their brand status will definitely be at higher point as ours, also
- regulatory changes especially in the RF electronics
  - changes of regulations may force critical changes of the overall design of the system, which may cause unexpected costs, production shutdown or even product recalls
- our “newcomer” position in this somewhat conservative market
  - our product doesn’t have the amount of references as the bigger companies may have
  - the beginning after product launch would be highly critical for the success of our brand

Critical success factors
The price that the customer has to pay is relatively minimal compared to the quality the product provides. The multiple use cases this product covers is high, making this extremely flexible for different purposes.

Risk factors and analysis
- customer doesn’t have Bluetooth connectivity in his/her computer
  - The need for Bluetooth capability is highly emphasized while advertising the product
- Customer has limited access to disposable batteries and/or adhesive ECG electrodes
  - our Sales Unit will provide those parts for a reasonable price
Supplement: Distribution of work and learning outcomes

The work was split among the whole group so that everyone had 2 parts, which were also similar to the presentation to optimize the effort. One challenge is the switch between a commercial product and the actual outcome of our project.