Proposal of an HRV Measurement and Analysis System in Comparison to Available Products

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Abstract— There is no question the world is filled with health monitoring devices that rely on Heart Rate Variability (HRV) measurement and analysis to conclude health state. Most of these devices are marketed for sport or stress monitoring instead of health to bypass some of the restrictions of the Food and Drug Administration (FDA. This paper conducts a comparison between the available devices; this comparison is based on the device capabilities. As a result, a new HRV measurement and analysis product is proposed to address the shortcomings of those devices and refocus the interest on instantaneous, continuous and secure monitoring as opposed to the current focus on sampling rate and resolution. The novelty of the proposed product is in the secure communication of between the device and the analyzing server where it relies on cellular networks (3G) or Wi-Fi for data transmission, it is also meant to meet the FDA regulations presented in the introduction. The importance of this discussion is manifested in the possibilities that could be realized with refocusing the devices and reprioritizing the specifications.

***Keywords* — eHealth products, mHealth, FDA regulations, HRV, HRV analysis, HRV measurement.**

I. INTRODUCTION

With the tremendous growth of technology and the fast pace of life, the need for instant information became a necessity of everyday aspect. One of these aspects is health; the world is obsessed with monitoring vital signs and sharing results instantly. This has opened the door widely for competition in the technology market and specifically among biomedical companies. Nowadays there are many off-shelf solutions for wireless health monitoring purposes than cosmetic products. One of the most targeted vital sign is heart signal and mainly those that are based on Heart Rate Variability (HRV) measurement and analysis. With such devices, targeted group varies from children to elderly people and athletes. Due to strict Federal Food and Drugs Administration (FDA) regulations on medical devices, most of the biomedical companies market their devices for sports, stress management and such. This is a real possibility for those products that do not properly implement wireless technology or whose systems aren't tested rigorously. Nevertheless, these devices are still required to meet certain criteria that are less complicated yet compelling, because no company wants to release a product that does not meet performance or reliability requirements. Raising safety concerns is not in the interest of any company. Taking this into account, here are some of the key requirements [1]

1) Security: It is critical to design safeguards against unauthorized access to hospital networks or the disclosure of sensitive patient/user data. Protecting the confidentiality of patient/user data in transit and ensuring that the data is not tampered with or corrupted is vital to product success and patent security.
2) Interoperability: One of the main drivers for adding wireless technology to medical devices is so they can share data with other wireless devices, peripherals, and networks. For a device to succeed in the market, it must interoperate reliably with multiple vendor solutions.
3) Reliability: Wireless solutions must be robust and designed to work well regardless of the circumstances of the environments. This is especially important for medical devices where poor wireless performance can impact health and safety. Dropped connections, timeouts, and data retransmission caused by external factors are critical for many medical applications and all should be considered in the design phase.
4) Future proofing: Solutions must employ an architecture that will continue to work or can be upgraded to accommodate newly adopted wireless technology and standards. Companies need to anticipate future changes to wireless infrastructure, like the cellular network or hospital/home Wi-Fi access points. Infrastructure planning demands flexibility for future capabilities.
5) Wireless coexistence: In the era of wireless technology, it is very common for a wireless device to be used in the presence of other wireless devices and equipment. Many devices even operate in the same frequency bands. It is the designer's responsibility to understand the environment of the user, consider other wireless technologies that may be present, and evaluate their impact on the designed medical device. This is important to avoid potential interference and performance issues. A variety of lab and field tests must be performed to detect and mitigate wireless coexistence problems.
6) Wireless safety: When wireless devices are operated near the human body, body tissue absorbs some energy from the transmitted signal. For high-power wireless devices, this poses several safety concerns. To prevent hazardous radiation levels, the FCC and other international regulatory bodies have defined radiation limits and test

procedures to measure the amount of energy absorbed by the human body from wireless devices. These limits need to be considered in wireless product development and are especially important for implantable and body-worn medical devices. [2]

7) International considerations: This is important for going global. Differences in wireless technology, spectrum allocation, and transmit power limitations imposed by foreign regulatory bodies may impose unique design requirements on the radio and antenna and should be thoroughly evaluated early in the product development cycle.

These were few requirements for wireless medical devices, meeting those requirements is not impossible. All it takes is proper preparation and planning and companies can efficiently align themselves with the FDA's current guidance, emerging market trends, and superior product performance.

This paper discusses and compares available HRV measurement devices and analysis systems in today's market. The comparison is based on the device capabilities and it takes into account the FDA regulations. As a result, a new HRV measurement and analysis product is proposed.

II. Comparison between available products

The comparison is solely based on the technical specifications that are available to the public, namely: Sampling rate, data exchange, device purpose, data resolution, battery life, and data analysis method. The FDA regulations are taken into account when applicable.

A. Technical Specifications

The manufacturers of these devices have shared these specifications with the public [3,4,5,6,7,8,9]. To keep the focus on the specifications and not the reputation of the manufacturers those names were not used in the text and the devices are referred to with numbers from 1 - 6.

Table I Comparison between selected HRV measurement devices

	Device (1)	Device (2)	Device (3)	Device (4.1)	Device (4.2)	Device (5)	Device (6)
Analysis Software	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Battery life (Hours)	144	36	504	Wired	~50	120	14
Sampling Rate (Hz)	12.5	100 - 1024	128	1024	50	8000	256
Storage Capacity (Hours)	480	36	504	-	-	120	150+
Resolution (bit)	8	8 -10	8	14	19	16	-
Availability	Public	Public	Public	Public	Public	Public	Public
Usage	Sport	Clinical	Clinical	Health pro	Health pro	All	Research
Data exchange	USB	USB	USB	USB	Bluetooth	Bluetooth	Bluetooth

B. Discussion

There is no question the available devices satisfy their purposes well enough to be successful in the market. But each device has favored one of the discussed aspects over the others to be able to deliver what's promised. For instance, it is obvious that the battery life was extended in the expenses of the sampling rate and the resolution of the recorded signal.

Looking at table 5, device (1) has long battery life and storage capacity, and reasonable sampling rate that is good enough for tracking sport health. As opposed to device (2) that has high sampling rate to make it suitable for clinical use, yet the battery life is very low compared to others. On the other hand, device (3)

Among these devices, device (5) seems to have it all; it has long life battery, high sampling rate and high resolution of the recorded signal. This makes device (5) the best HRV measurement and analysis product available in the market now based on the selection criteria shown in table 5.

There is a common drawback between these devices, which is the data exchange that is based on either USB cables or Bluetooth. Both methods are considered limiting to the whereabouts of the user, and that's where the proposed device will shine.

III. Proposed Product

Looking at the available devices, we can see that none of these devices is limitless when it comes to the data exchange. Even those with Bluetooth data exchange are limited to the maximum Bluetooth coverage distance between the device and the PC.

A. Why Another Product?

The novelty of the proposed device (product) is to find a good balance between the aspects discussed in table 5 without having to favor one over the other. The main addition in this product is its ability to exchange the data wirelessly; over Wi-Fi or cellular networks.

This product will be targeting both clinical and free use; the proposed HRV measurement and analysis product is a complete solution for continuous and instantaneous monitoring. It is a real telemedicine system.

Based on the discussed devices, the below details are the proposed enhancement to build a better solution.

B. Technical Details

The proposed product is thought to have the following:

- Built in 3G SIM card and Wi-Fi modem.
- ECG sampling rate of 600 Hz
- Resolution of 8 bits
- Battery life (with Wi-Fi on) 6.5 hours
- Battery life (with 3G on) 3 hours
- Storage capacity of 6 hours

C. Features

- Option to upload in Wi-Fi coverage only
- Authentication enabled access to the Analysis Software
- Analysis Software: Product X has a secured server for data storage per user and friendly User Interface to visualize the results'

D. How to achieve this?

The novelty of this device is to offer continuous measuring and instantaneous analysis, by uploading the data wirelessly to the analyzing server over 3G or Wi-Fi connections. This is possible by integrating SIM card and Wi-Fi modems in the device.

It is known that 3G drain the battery of mobile device especially when the signal is poor or fluctuating. Not to mention that 3G connection is continuously on while Wi-Fi (in smart devices) uses less power when idle and only spikes when it is searching for an access point. In this device, the proposed device will be using the connection algorithm used in iPhone, which guarantee battery life of 3 – 6 hours. The use case is very similar to the "health" app developed by Apple (starting from the 8th version of Apple mobile operating system iOS 8) and the battery life was optimized for that.

The device will also use ECG sampling rate of 600 Hz, which is relatively low compared to the discussed devices; this sampling rate is sufficient to analyze HRV. A study [10] conducted in 2008 by Ziemssen, Gasch, and Ruediger where they recorded 46 ECG signals of 23 persons using the original ECG sampling rate of 500 Hz and simulated sampling frequencies of 200 and 100 Hz. The study showed that there are no statistically significant differences in baroreflex sensitivity and frequency bands ranging from VLF and HF using 100 Hz instead of 500 Hz, except for UHF band (>0.40 Hz). The only case that required higher sampling rate (500 Hz) was when there is pathologically decreased variability of RR interval, and as a try to cover all cases, the sampling rate of 600 Hz was selected and also to compete with the available devices in this aspect. This sampling rate will cover all frequency bands ranging from ULF, VLF, and HF. It will also make it possible to maintain the promised battery life.

The device will have an internal memory that could be wiped manually, this memory. The ECG signal has the resolution of 8 bits per sample and 600 samples per second; this means the size of each signal 4800 bits. The device is meant to save up to 6 hours of records locally, for this it will have a memory of 256 KB.

E. Security

Security of the data transmission is very sensitive especially for medical information. Therefore, the data will be encrypted before it is sent. The proposed device will encrypt packets using RSA public key encryption and Optimal Asymmetric Padding (OAEP). Combining RSA with OAEP adds an element of randomness, which converts deterministic scheme of RSA to a probabilistic scheme. The client-server communication will use secure communication Secure Socket Layer/Transport Layer Security (SSL/TLS), used ciphers and algorithms are determined by the underlying system and through the SSL/TLS handshake. Commonly this is based on RSA & Advanced Encryption Standard (AES). On the server side, HTTPS will be enabled. This should give sufficient security. The data will be stored in MySQL database

F. Price Estimate

Considering the offered features along with the 3G SIM card and Wi-Fi modems and the offered memory size, the price of this device is expected to be in the range of 490€– 500€. This estimation is in comparison to the market price and the corresponding device features.

IV. Conclusion

To serve the main purpose of HRV measuring and analysis products that is instant and continuous monitoring of the heart condition, the available features had to be revised. As well as the technical specifications that focused on Sample rate despite the low significance it adds. The proposed device solves the discussed issues by refocusing the on significant features and relying on long-range secure communication based on cellular networks or Wi-Fi. This makes an instantaneous and continuous monitoring possible and it takes the HRV measurement and analysis products a step closer to be fully approved by the FDA.

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