Intelligent wirelessly powered pacemaker

Jaouaher Belgacem
Electronic Engineering Department,
Hochschule of Hamm-Lippstadt
Lippstadt, Germany
jaouaher.belgacem@stud.hshl.de

***Abstract*— The implantation process of traditional pacemakers is complicated. However, the replacement surgery is more exhausting for the patient since it needs to be done periodically. Furthermore, the process itself is problematic as it may cause a damage to the heart because of retrieving the leads.**

The patients that they are treated with traditional pacemakers are limited in their daily lives in terms of practicing some sport activities, eating specific food, drinking alcohol and the list is long as they suffer from breath shortage and continuous feelings of fatigue that is caused by the working mechanism of these pacemakers. Moreover, the device itself is sensitive to various disturbances such as being exposed to any king of radiation that leads to serious consequences.

Despite of the advanced technologies of new released pacemakers, the patient has no access to monitor or to control the device themselves. The recent pacemakers' improvements were made to help doctors to monitor and check the heart performance from a distance where the patients are involved only in reading the data and sending it use specific devices.

In this paper, we discuss our concept of a smart and wireless pacemaker, that could be powered via a wireless and portable radio-frequency device, and both devices could be monitored by the patient through a mobile application. Our main goal behind this project is to assure that bradycardia patients can live their lives as normal as possible. The second goal is to enable the patients to control the simple functionalities of the system and monitor the heart performance themselves under the supervision of the doctors.

Keywords—leadless pacemaker, smart pacemaker, wireless power, implantable medical device.

I. Introduction

Technology has solved a tremendous number of complicated health challenges which have made a big impact on human lives. As the medical fields have improved a lot after the invention of intelligent and autonomous machines that made doctors' mission more efficient and more effective. However, the technology has exceeded our expectations with the microchips that can be implanted inside of human bodies. As a result, in the recent few years, we noticed that the number of implanted devices has grown exponentially and nowadays, we are talking about implantable medical microchips of a size range between 1 to 5mm.

The heart is one of the most complicated and critical organs to treat as it is responsible to pump the blood to the rest of the body. One of the most common heart problems that cardiologists need to treat is a sudden low heartbeat rate which is named in the medical field as bradycardia. The pacemakers were invented as a lifelong treatment for this disease and around 50 years ago, doctors started to implant leads-based pacemakers that generate a fixed rate of electrical signals to support the heart in case of a detection of a low heart rate. However, these types of pacemakers can cause health problems in the long term.

After various clinical studies, scientists have invented implantable wirelessly powered pacemakers [1][2] to replace the traditional pacemakers, these new versions of pacemakers were invented to avoid the critical replacement process of leads-based pacemakers. However, leadless pacemakers still can cause heart problems in the future and that's why scientists have invented smart pacemakers. These pacemakers can protect the heart from further diseases by providing an automatic regulation of the heartbeat rate depending on the mental and physical demands of the patient [3].

II. Concept

A. Components

The system is composed of three different parts:

- Implantable pacemaker on chip

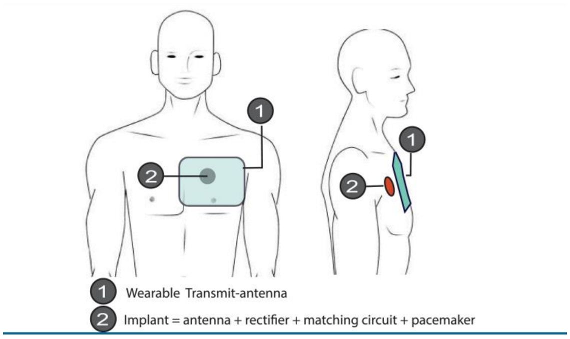

Fig.1 Number 2 indicated the implanted chip and number two is the placement of the RF power source [1]

As shown in the picture this pacemaker can be charged from distance where the patient needs to place the power source directly on the chest, in parallel to the implanted pacemaker. Studies proved that the wireless charging in this case is effective if the distance between the pacemaker and the RF power source is less than 2cm [2].

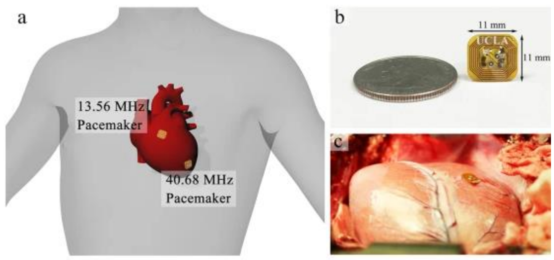

Fig.2 An example of a pacemaker on-chip [9]

The implantable chip fixed in the heart through planting the two pins inside, these pins are responsible for delivering the generated electrical signals by the pacemaker to the heart.

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- Portable/Rechargeable RF power source

Fig.3 wireless RF power supplier [4]

This figure shows how the RF power source is designed. The device is easy and practical to use. It is composed of two buttons, the button is the top-center is for switching on/off the device and the top left button can be pressed to activate/deactivate the Bluetooth module so the device can receive and send data to the monitoring system. Finally, the RF power source includes two LEDs to indicate the battery level.

- Mobile Application

Fig.4 Control system via mobile application [4]

The mobile application represents the control system where the patient can use it to monitor the pacemaker and the RF power source in an offline mode via Bluetooth and to send/receive data.

B. *Functioning mechanism*

The implanted chip is responsible for detecting abnormal heart rate and adjusting it by generating an electrical signals and transmitting them to the heart via the injected pins. In this process a couple of components are involved such as the sinoatrial node that is used to detect a low heartbeat rate is [1] and in this case the heart needs an urgent support to get back to normal rate again. Furthermore, the proposed pacemaker can determine mental and physical demands with the help of the accelerometer sensor and metabolic sensor. These sensors are used to detect accurately the amount of the needed increase of the heart rate with respect to the performed activities by the patient [10]. To charge the pacemaker, the patient needs only to place the RF power source on the chest and press the button that sends low radio-frequency (< 9GHZ) signals to the pacemaker [2]. The RX antenna receives these signals and transmit them to the RF-DC rectifier. The rectifier converts the RF power to a DC power that is transmitted to the battery and the capacitor to store it. For manipulating, these components we need a power management unit (PMU).

The PMU switches on and off the CMOS switches to enable the battery or the capacitor to store power again. This unit monitor the voltage on the storage capacitor [2] continuously. Another fundamental component in our concept is the microcontroller. Its main functionality is to receive data from the sensors and transmit them to the PMU, which stimulates the pacing circuit to generate the needed number of electrical signals.

The microcontroller can transfer and receive data to the mobile application offline through the established Bluetooth communication in the parts of the system. As a result, the patient can see the levels of the batteries, receive alarms in case of urgent problems occurred in the pacemaker, and receive periodic reports about the heart performance. In case the battery levels are low the patient can choose which one to charge first.

Moreover, the mobile application enables the patient to transfer the reports to hospitals or doctors. It can also give the patient the ability to notify the doctor or the hospital in case of emergency. However, if a critical problem occurred and there is no interaction from the patient about the sent alarms from the pacemaker, the system will automatically notify the hospital and send the location of the patient if the mobile phone has internet, if not, then a trusted contact will receive an emergency SMS.

The patient is required to check continuously the alarms as well as making sure of recharging the RF power source and the pacemaker's batteries, where the minimum level of charge in the main battery must be over 30%.

III. Designing of the Concept

A. *Requirements*

- The chip size is between 8-10mm maximum.
- Microcontrollers are low power based.
- The capacitor storage is 10uF [2].
- PMU is ultra-low power based.
- RF band of frequency is smaller than 9GHZ [2].
- The RF power source needs to be in the same size of a standard mobile phone.
- The system should switch to safe mode in case of a defect in the main microcontroller of the pacemaker.
- The system should be able to switch internal power sources in case of discharge.
- The Bluetooth modules needs to be low power based.
- The microcontroller should respond to all the requests in milliseconds
- The PMU should function independently from the microcontroller.
- The communication must be established in real-time a without any delays.
- The batteries should last for a long period of time.

B. *Models*

In this section, we used two UML diagrams and one SysML diagram to model the different aspects of the system's mechanism. The UML diagram are used to explain the concept of the control system which is mainly the mobile application, and the requirement diagram is dedicated for representing the requirements of the pacemaker.

1) Use case diagram

a) Patient with bradycardia

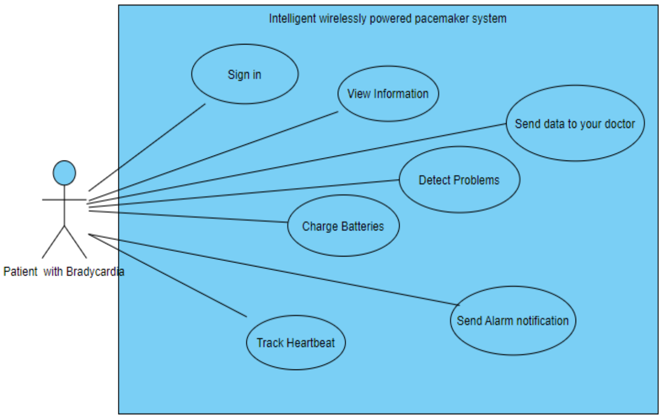

Fig.5 The patient's use case diagram with the main functions

This is the use case of the patient where we represent the main use cases of the control system. As we mentioned previously the mobile application gives the user the ability to monitor and control the pacemaker and the RF power source. To access these functionalities the user needs to successfully sign-in to the system.

- *Use Cases for monitoring the system*
  - Track Heartbeat
  - View information
  - Detect problems
- *Use Cases for controlling the system*
  - Charge Batteries
  - Send data to your doctor
  - Send alarm notification

b) Doctor

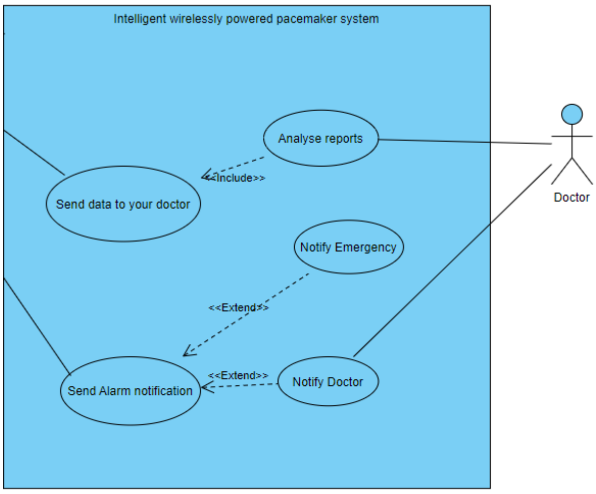

Fig.6 The use case diagram of the doctor

The Doctor can analyze heart performance reports once the user sends them. Besides, the system enables the doctor to receive alarms in case of a critical health problem or a problem in the device.

2) Activity diagram

The activity diagram represents the behaviour of the mobile application and the different parallel functions that the user can perform. The user is always required to sign in first to commit any task.

- Charging the battery

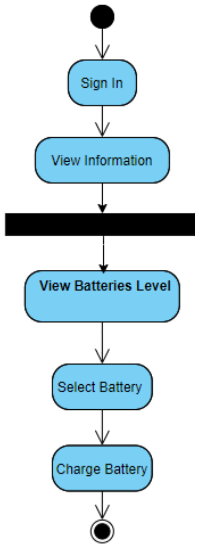

Fig.7 Activity sequence of Charging the battery functionality

To charge a battery, the user needs to select one of the two batteries because the system is designed to allow only battery to store power at a specific point of time,

- Sending heart performance reports to a second party

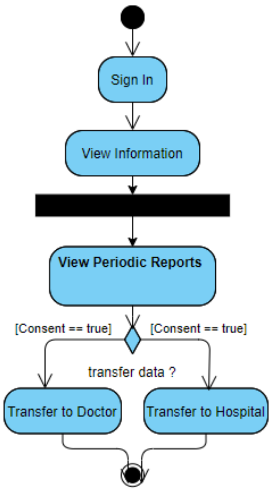

Fig.8 Activity sequence of the signing-in function

The system generates periodic reports about the heart performance, the device performance as well as detailed reports of occurred problems in the system's functionality. These reports can be stored in the mobile phone or in the cloud. The patient needs to give a consent first to transfer to the doctor or/and hospital.

- Update the profile data

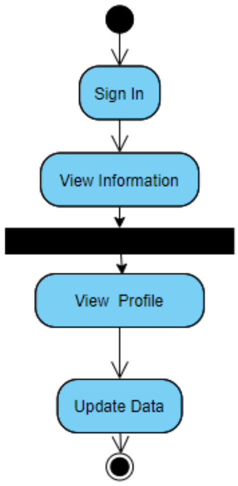

Fig.9 Activity sequence of the updating profile data function

The patient needs to create a profile that includes general health information such as the blood group, allergies, and other diseases so, in case of emergency, doctors can have an overview of the important data of the patient to speed up the checking-up process. The user can update the profile when it is needed.

- Receive and send an Alarm notification

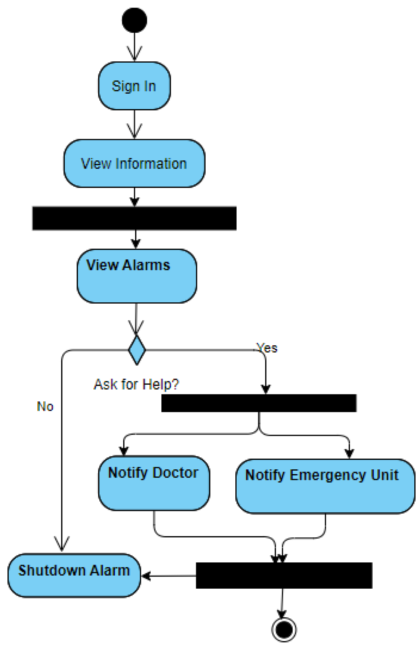

Fig.10 Activity sequence of the sending alarm's functionality

The system sends alarms to the user through the mobile application. The sent alarms are generated by the RF power source, to remind the user to recharge the device and by the pacemaker to notify the user to recharge batteries or to report a problem in the device. As a result, the user can decide to shut down the alarms if they are regular reminders or to notify the doctors and/or the hospital if the patient noticed a serious problem in the heart rate or if a problem occurred in the any part of the system.

3) Requirement Diagram

1) Functional requirements

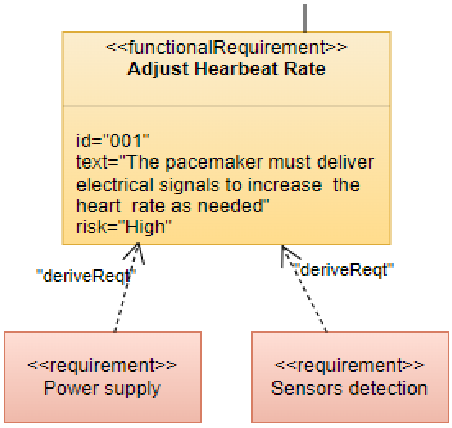

Fig.11 Requirement diagram of Adjust heartbeat rate functionality

The main functionality of the pacemaker is adjusting the heartbeat rate by generating electrical signals to support the heart. However, this function depends on the internal power sources that enables the pacing circuit to generate a responsive rate of signals according to the detected movement/vibration of the body by the sensors.

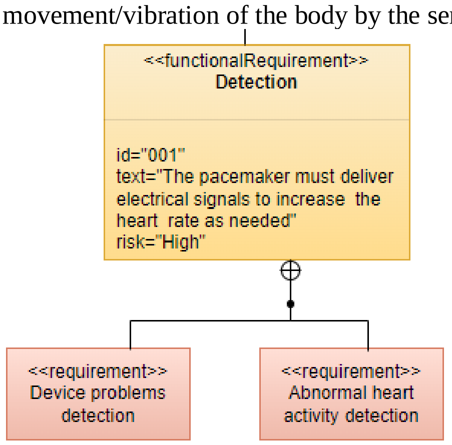

Fig.12 Requirement diagram of the detection functionality

The second requirement is the detection of abnormal heartbeat rate and of problems in the functionality of the pacemaker.

2) Safety requirement

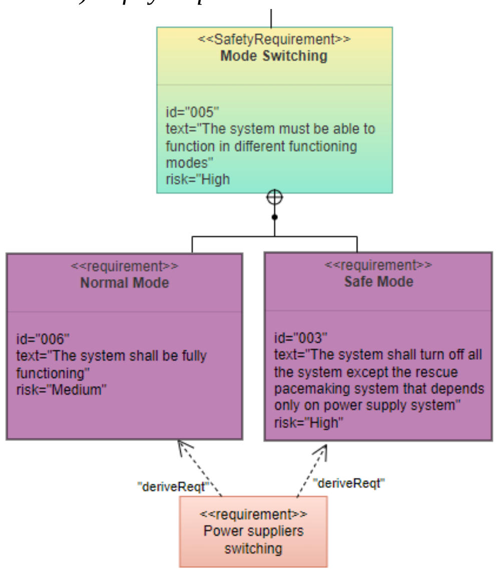

Fig.13 Requirement diagram of mode switching functionality

The system supports two modes, the normal mode where all the parts of the pacemaker are enabled. However, the safe mode consists of disabling the smart block.

3) Performance requirement

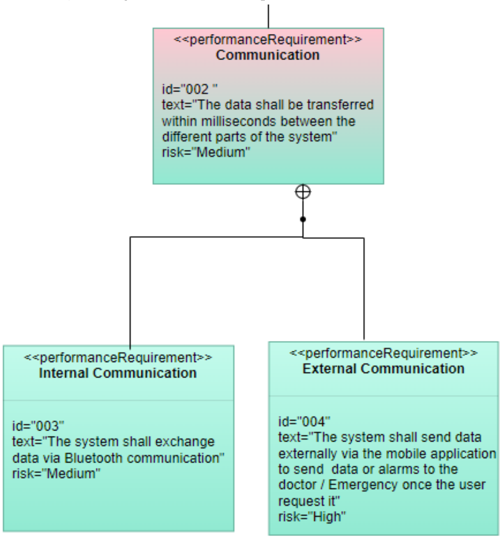

Fig.14 Requirement diagram of the communication functionality

Communication is a fundamental requirement as it ensures an effective and efficient functional system. It is required to be established externally, which means between the different parts of the system that are the pacemaker, the power source, and the mobile application to guarantee data exchange. An internal communication is also needed between the microcontroller and the PMU in order to synchronize the internal blocks.

C. Hardware

For the hardware part, the on-chip pacemaker needs to be customized, therefore the hardware platform for this part is ASIC. All the components are low power consumption-based. As a result, the used microcontroller for the RF power source is low battery-based to reduce the recharging frequency.

1) Implantable pacemaker

1) The fundamental components of the pacemaker

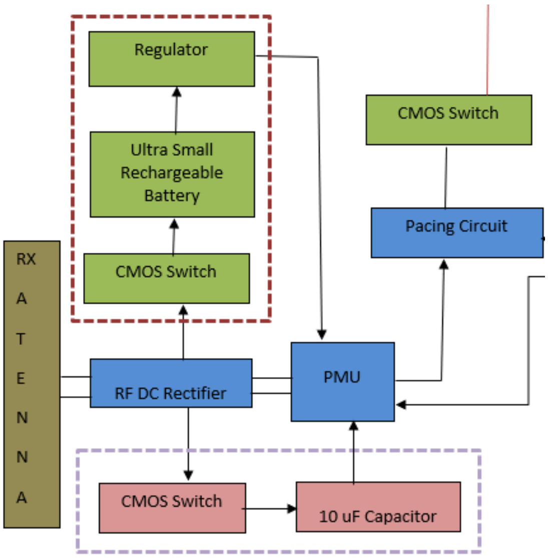

Fig.15 Hardware model of the fundamental blocks of the pacemaker

This is the base of the pacemaker, where the RX antenna receives radio frequency signals from the external RF power source and the rectifier transfers the dc power to be stored in the capacitor or the battery.
The power management unit enables one of them or both to store energy by sending signals to CMOS switches, then it enables the pacing circuit to generate pulse signals from internal power sources.

2) The smart block of the pacemaker

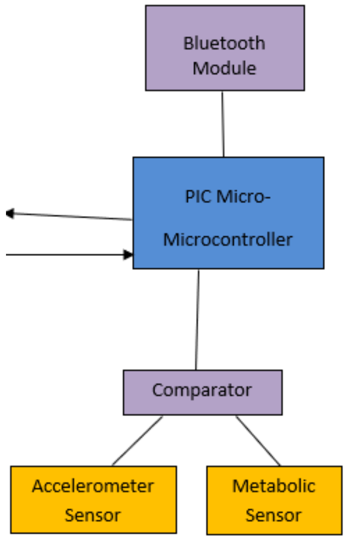

Fig.16 Hardware model of the intelligence block of the pacemaker

This block is responsible for the smart part of the pacemaker, as it improves the pulse rate by adjusting it to the physical and mental efforts made by the patient. Both, the metabolic sensor, and the accelerometer sensor provide the information to the microcontroller, that transfers the exact rate needed to the pacing circuit.

- The accelerometer detects body movements in concerning to physical activity [7].
- The metabolic sensor detects both mental and physical activities like mental stress and sport activities for example. It describes the correlation of the heart rate to metabolic needs according to the age, weight, and sex of the patients [8].

2) RF power supplier components

This device is a standard component since, it needs to be researchable, convert power from RF to DC and transmit data via a Bluetooth module.

- Microcontroller: MSP430FR5969 16bit, this model is an ultra-low-power microcontroller, and it includes a non-volatile memory

Fig.17 The model of low power microcontroller [6]

- DC to RF power converter

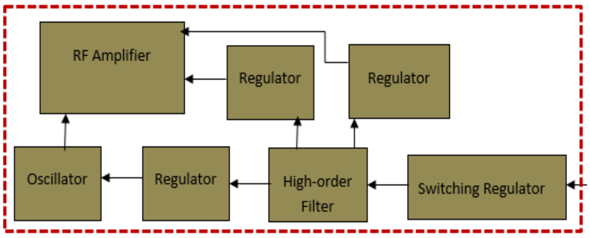

Fig.18 DC to RF power converter internal components

- PAN1780(nRF52840), this model of a Bluetooth module needs low Energy.


Fig.19 A low-power Bluetooth module [5]

D. *Critical-based parts of the system*

1) *Redundancy*

a) *Redundant Batteries*

Since the pacemaker is a delicate device and a problem in its functionalities may lead to dangerous health consequences or at an unfortunate situation which is the death of the patient. The pacemaker can stop from working for several of reasons, one of them is a dead battery. This component is fundamental in all types of pacemakers as it is responsible for delivering power to all the blocks of the pacemaker to operate. As a result, we thought about implementing two batteries. One of them is the capacitor, that represents the primary power source of the system and an extra ultra-small rechargeable battery as a secondary source of power.

b) *Redundant sensors*

One of the main functionalities of this system is to provide a responsive rate of electrical signals instead of a fixed one and that's the main reason behind replacing traditional pacemakers with intelligent versions.

Providing the heart with a slightly increased or decreased single rates can cause multiple of other heart diseases in a long term. Therefore, an accurate signal rate is a must in our system so for more precision, we used two types of sensors both detect physical/mental activities in correlation with heart rate.

c) *Redunadant microcontrollers*

The Power Management Unit (PMU) is a type of microcontroller that is responsible for monitoring the power status of different components, and it can disable and enable components [2]. The second microcontroller is our pic microcontroller which is mainly used for the intelligent part of the system.

2) *Safety aspect:*

Our system can switch to the safe mode in case the main microcontroller encountered a problem. Therefore, it is going to be disabled immediately and our pacemaker will act like a traditional pacemaker, that generates a pulse signal to support the heart in case of a detected low heart rate in order to ensure the pacing functionality. For this mode, we need only to have one internal power source, PMU, and the pacing circuit.

3) *Reliability aspect:*

This aspect is represented in our system by including a comparator. That is used to compare the inputs provided by the sensors and then, to produce an accurate output in case they are too different.

The PMU is the second aspect of reliability as it assigns the power to activate specific components of the system for a well-determined duration of time.

E. *User Interface*

One of the most important parts of our system is the mobile application as it gives the patient a direct control of the pacemaker. In this part, we represent the user interfaces of the different mobile application's functions. We choose "Click for Heartbeat" as a name for it.

1) *Sign in*

Fig.20 Sign-in interface

The mobile application can be connected only to one pacemaker device so the patient needs to register first using his/her health insurance security ID number and the device ID of the pacemaker.

2) *Home*

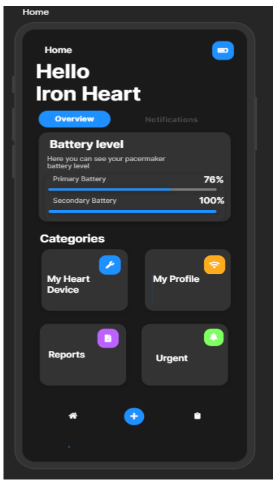

Fig.21 Home interface

Here the user can see all the important information such as battery level and the different categories of the application.

3) My heart Device

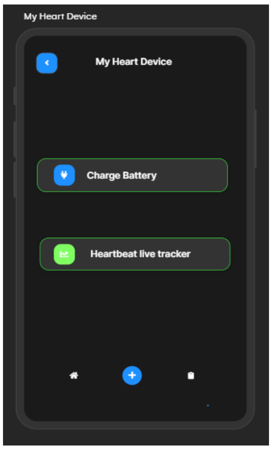

Fig.22 My heart device interface

In this part of the application, the user can track the heartbeats in real-time and charge the batteries of the implantable pacemaker.

4) Charge Battery

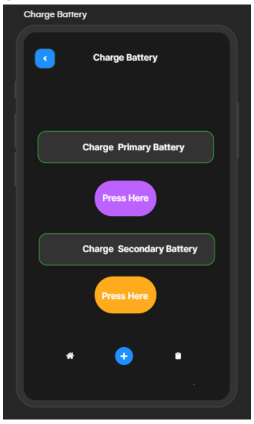

Fig.23 Charge battery interface

The user can choose which battery to charge first by pressing on the related icon of the battery.

5) Urgent

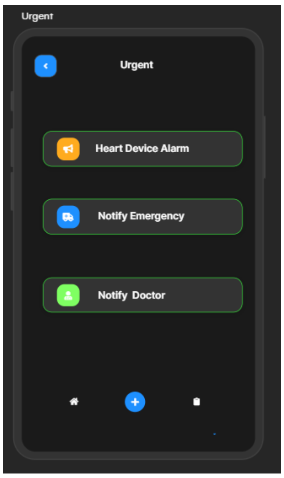

Fig.24 Urgent interface

The user can receive alarms from the pacemaker and send notifying alarms to the hospital or/and doctor in urgent cases.

The mobile application, have a deadline for reaction time concerning the alarms. In a scenario where the patient did not register any activity or reaction according to a detected problem in the system, the mobile application can notify a second person and the decision is made according to the type of alarms. A trusted contact defined by the patient, can be notified in case of a regular alarm such as a low-battery level in the primary or/and the secondary batteries. However, in case of detecting serious problems in the device or/and a heart problem that requires an external professional interference, the doctor and/or the hospital will be automatically and autonomously alarmed through the mobile application.

IV. Discussion

This paper discussed a concept of a system that is composed of an intelligent pacemaker and a portable RF power source. The pacemaker is our main device which can be powered wirelessly using a portable and rechargeable RF power source. The patient can monitor both devices by using the mobile application.

This system has solved mainly all the mentioned problems as it combines permanent implantable pacemaker, wireless powering system and involving the patient in controlling and monitoring the devices.

Throughout the lectures and exercises, we implemented a redundant architecture and developed a safety mode for the system. Moreover, the requirements have been redefined based on the discussions and feedback that we had during the exercise sessions. The lectures helped us to define which part of the system must be ASIC and which part needs to be standard IC and according to the professor’s explanation, we decided to have the implantable pacemaker as an ASIC circuit, and the RF power source as a standard IC. The last lecture clarified how to decide which integrated circuits is suitable for which use cases. For the pacemaker we decided to use a microcontroller instead of an FPGA. The reason behind this decision is that the SRAM of the FPGA is sensible toward external disturbances such as radiation. However, the powering mechanism of our pacemaker is based on radio-frequency.

V. Conclusion

We proposed a concept of an intelligent wirelessly powered pacemaker controlled through a mobile application and powered by an RF portable power source.

The main goal of this system is to improve the life quality of the bradycardia patients. With the implemented mechanism that produces a responsive rate our system helps patients to avoid further heart diseases and heart failure in the future [3]. The second point is to develop a one-time implantable device that is easy to use and monitor to avoid the side effects of pacemaker replacement. Although, this concept overcomes the other pacemakers’ limitations and problems and helps to avoid further health complications in the future, it is limited in terms of supporting the heart in case of heart failure. We are looking forward to a develop a pacemaker that supports a rhythmic compression of the heart to restore normal heartbeat without any medical or human interference.

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