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 and the process may cause damage to the heart by retrieving the leads. Furthermore, patients with traditional pacemakers are limited in terms of physical activities. As they suffer from breath shortage and continuous feelings of fatigue.**

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

I. Introduction

Technology has solved complicated problems and it has a big impact on human life, especially in the medical field. In the recent few years, the number of implanted devices has grown exponentially. Nowadays, we are talking about implantable heart medical microchips of a size range between 1-5mm.

After numerous clinical studies, scientists have invented implantable wirelessly powered pacemakers [1][2] to replace the leads-based pacemakers to avoid the exhausting replacement process and to give patients more life quality. Furthermore, smart pacemakers protect the heart from further damage by providing an automatic regulation of the heartbeat rate depending on the mental and physical demands of the patient. failure [3]. However, the proposed pacemakers keep patients from controlling and monitoring their medical devices themselves.

In this paper, we propose a concept of a smart wirelessly powered pacemaker with a portable and rechargeable RF power source that can be monitored with the help of a mobile application.

II. Concept

A. Components

The system is composed of three different parts:

- Implantable pacemaker on chip

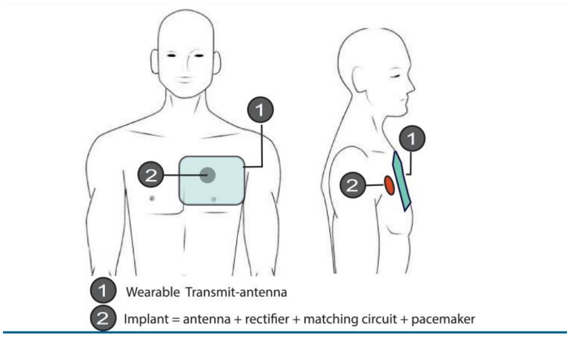

Fig.1 Number 2 indicated the implanted chip and number two is the placement of the RF power source [1]

As shown in the picture, the patient needs to place the power source directly on the chest, in parallel to the heart. Studies proved that the charging is possible if the distance between the RX antenna on-chip and the RF power source is less than 2cm [2].

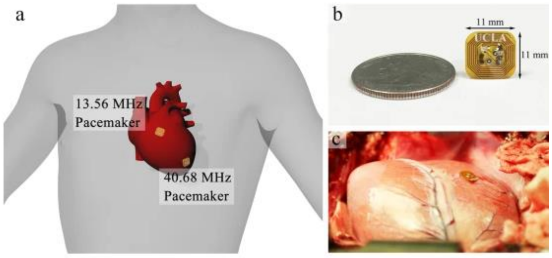

Fig.2 An example of a pacemaker on-chip [9]

The implantable chip fixed in the heart through 2 pins that are responsible for delivering the generated pulse signals to the heart.

- Portable/Rechargeable RF power source

Fig.3 wireless RF power supplier [4]

This figure shows how the RF power source is designed, so the patient can turn it on through the bottom in the top. The battery level of this device is indicated via LEDs. To activate the Bluetooth for transferring data, the patient needs to press a side button.

- Mobile Application

Fig.4 Control system via mobile application [4]

Through the mobile application, the patient can monitor the pacemaker and the RF power source offline and send/receive data.

B. *Functioning mechanism*

The implanted chip is responsible for detecting abnormal heart rate and adjusting it by generating a stimulation pulse signal and transmitting it to the heart via the injected pins. The pacemaker can determine mental and physical demands with the help of the accelerometer sensor to accurately increase the heart rate when it is needed [10]. To charge the pacemaker, the patient needs only to place the RF power supplier on the chest and press the button that sends low radio-frequency (< 9GHZ) signals to the pacemaker [2]. The RX antenna receives these signals, the RF-DC rectifier converts the RF power to a DC power that is stored in the battery and the capacitor store it. The power management unit (PMU) switches on and off the CMOS switches to enable the battery of the capacitor to charge again, so the PMU continuously monitor the voltage on the storage capacitor [2]. The microcontroller receives information from the sensors and transmits it to the PMU. Which stimulates the pacing circuit to generate pulse signals.

The microcontroller can transfer and receive data to the mobile application offline through Bluetooth communication. The patient can see the levels of the batteries, receive alarms in case of urgent problems from the pacemaker, and receive periodic reports about the performance. In case the battery levels are low the patient can choose which one to charge. The mobile application enables the patient to transfer the reports to hospitals or doctors. The mobile application gives the patient the ability to notify the doctor or the hospital in case of emergency and sends the location once the mobile phone is connected to the internet. In case of the absence of response of the patient to critical alarms, the mobile application automatically sends a notification to the hospital.

The patient needs to charge the RF power supplier first to charge the pacemaker. The RF power source can transfer data with the mobile application through a Bluetooth communication module. The RF power is converted from DC power inside of this device.

III. Designing of the Concept

A. *Requirements*

- The chip size is 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 supplier needs to be the 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

B. *Models*

In this paper, we represent two UML diagrams and one SysML diagram.

1) Use case diagram

a) Patient with bradycardia

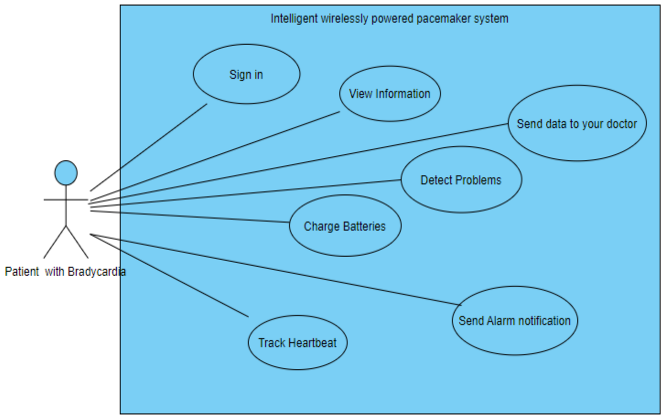

Fig.5 The patient's use case diagram with the main functions

This is the use case of the patient that presents the main cases of the system. The system gives the user the ability to monitor and control the system through the mobile application once the sign-in step is successfully done.

- *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

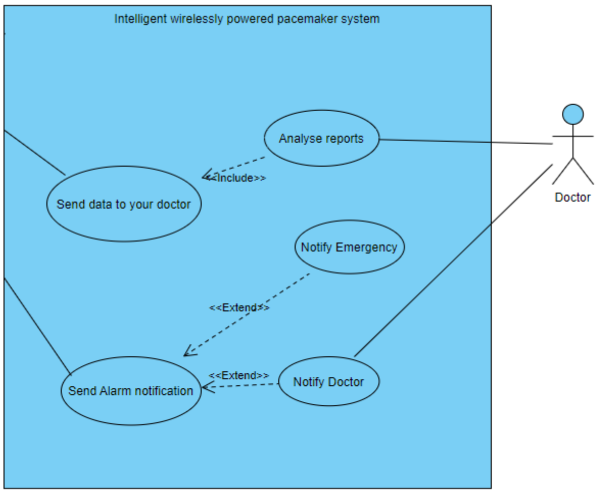

Fig.6 The use case diagram of the doctor

The Doctor can analyze heart performance reports after 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 actions that the user can execute. The user needs to sign in first to commit any task.

- Charging the battery

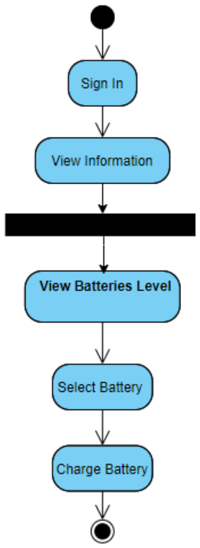

Fig.7 Activity sequence of Charging the battery functionality

To charge a battery, the user needs to select one of the two batteries.

- Sending heart performance reports to a second party

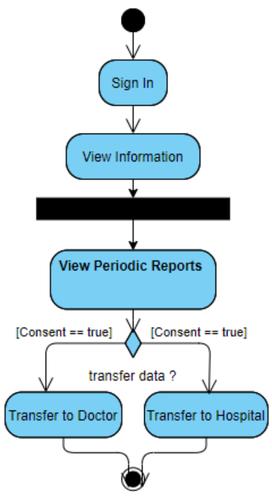

Fig.8 Activity sequence of the signing-in function

The system generates periodic reports about the heart performance and the device performance, that the patient can transfer to the doctor or/and hospital after giving his/her consent.

- Update the profile data

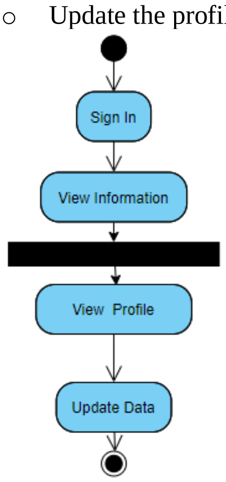

Fig.9 Activity sequence of the updating profile data function

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. The user can update the profile when it is needed.

- Receive and send an Alarm notification

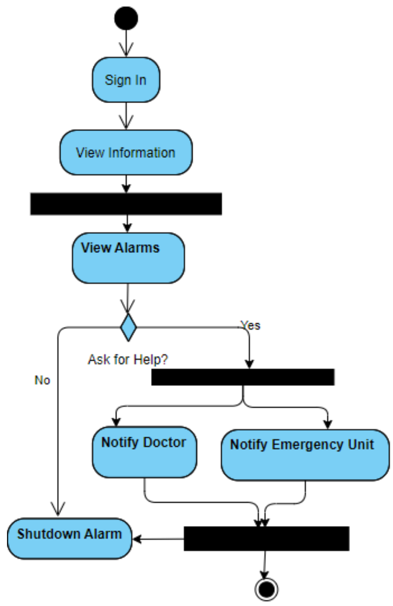

Fig.10 Activity sequence of the sending alarm's functionality

The system sends alarms to the user through the mobile application. The alarms are sent from the RF power source, to remind the user to recharge it and from 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 reminders or to notify the doctors and/or the hospital if the patient needs help.

3) Requirement Diagram

1) Functional requirements

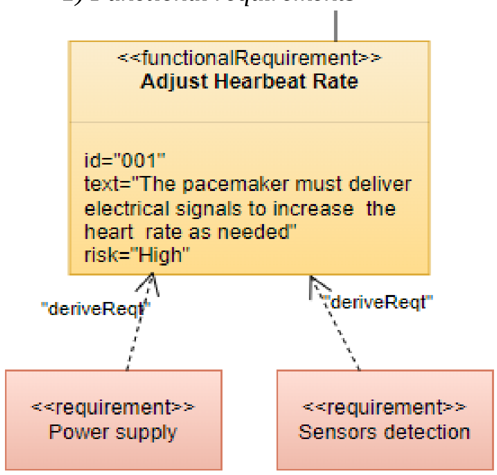

Fig.11 Requirement diagram of Adjust heartbeat rate functionality

The main functionality of the pacemaker is adjusting the heartbeat rate by generating pulse signals to support the heart. However, this function depends on the internal power supply that enables the pacing circuit to generate pulse signals and the output of the sensors to support a responsive rate.

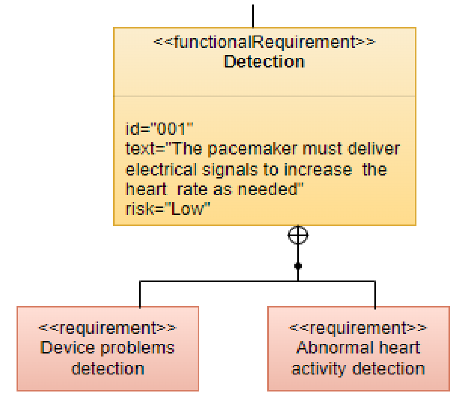

Fig.12 Requirement diagram of the detection functionality

The second requirement is detecting abnormal heart activity and mainly low heart rate and detecting defects in the device itself.

2) Safety requirement

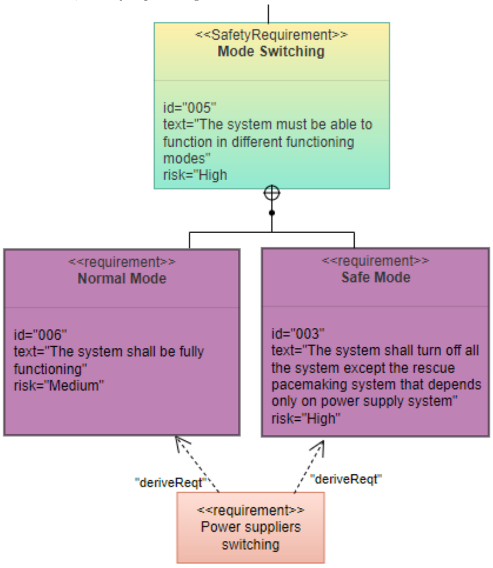

Fig.13 Requirement diagram of mode switching functionality

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

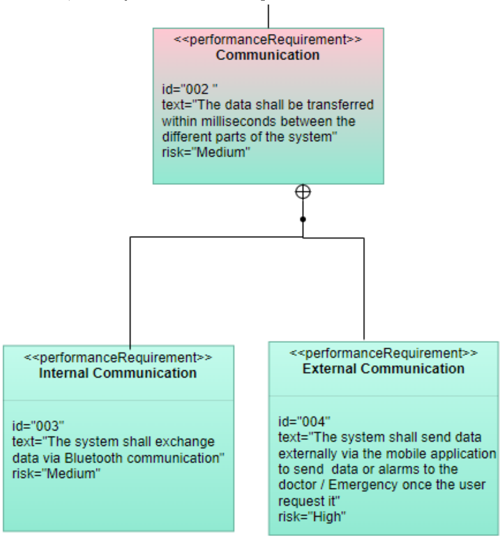

Fig.14 Requirement diagram of the communication functionality

Communication is required externally, that means between the different parts of the system to guarantee data exchange and internally between the microcontroller and the PMU.

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

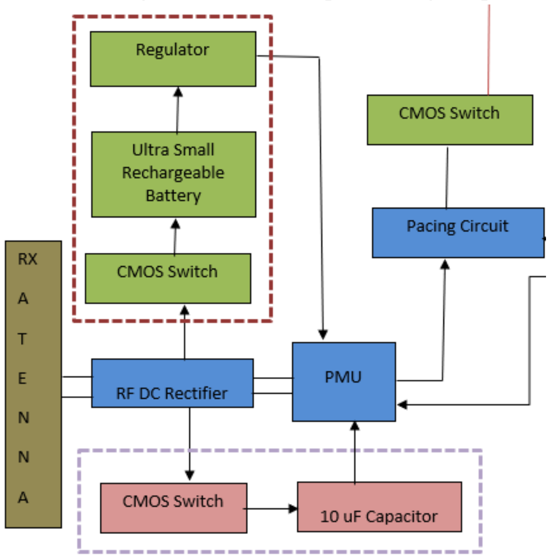

Fig.15 Hardware model of the fundamental blocks of the pacemaker

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

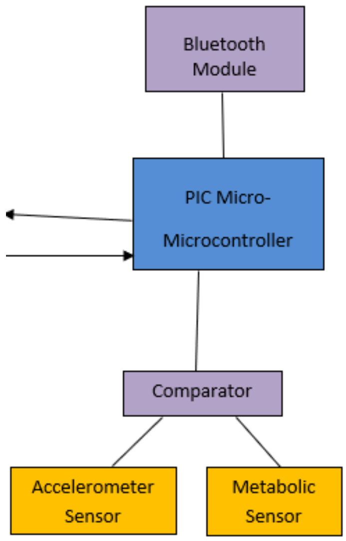

Fig.16 Hardware model of the intelligence block of the pacemaker

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

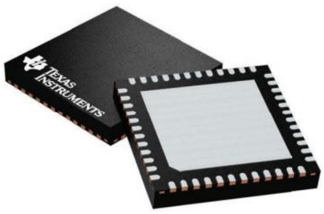

Fig.17 The model of low power microcontroller [6]

- DC to RF power converter

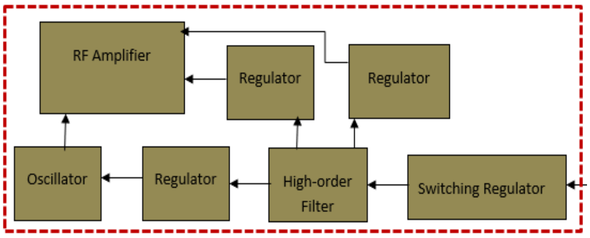

Fig.18 DC to RF power converter internal components

- Bluetooth module PAN1780(nRF52840), as it 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 a big health problem for the patient and the patient can lose his/her life. As the battery is one of the most critical parts of our system. We implemented two batteries one of them is represented as a capacitor that stores power as a primary internal power source, and a secondary ultra-small rechargeable battery.

b) Redundant sensors

One of the main functionalities is this system is to provide a responsive rate instead of a fixed rate which is what traditional pacemakers provide. For more precision, we used two types of sensors both detect 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. 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, it 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 a low heart rate is detected. To provide the pacing functionality. As a result, we need only one internal power source, PMU, and the pacing circuit.

3) Reliability aspect:

We included a comparator, for the used sensors to have an accurate responsive pulse rate.
The PMU is the second aspect of reliability as it assigns the activated components for a specific duration of time.

E. *User Interface*

One of the important parts of our system is the mobile application as it gives the patient direct control of the pacemaker. In this part, we represent the user interface of our mobile application “Click for Heartbeat”

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 ID number of the pacemaker.

2) Home

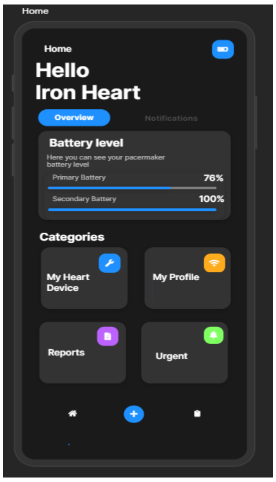

Fig.21 Home interface

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

3) My heart Device

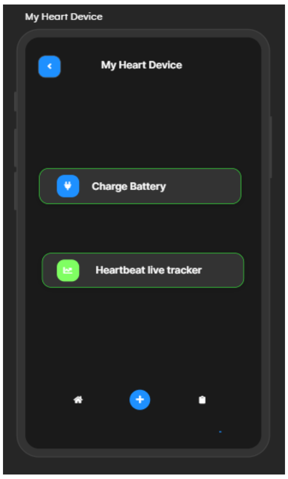

Fig.22 My heart device interface

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

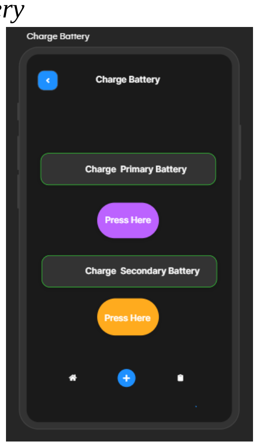

Fig.23 Charge battery interface

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

5) Urgent

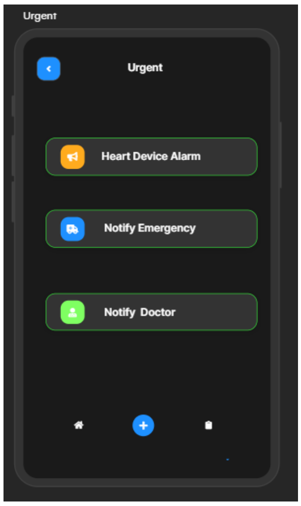

Fig.24 Urgent interface

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 reacting with the alarms, it depends on the detected problem, the mobile application can notify a trusted contact in case a low-battery level in both, the primary and the secondary battery. However, in case of detecting a serious problem in the device or a heart problem that requires an external help, the doctor and the hospital will be automatically alarmed.

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 rechargeable RF power source. The patient can monitor both, the implantable pacemaker and the RF power source by using our mobile application.

The system solves the discussed problems as it provides a leadless pacemaker that can be charged with portable RF power, and it gives the patient the to monitor and control the pacemaker independently.

Throughout the lectures and exercises, we implemented a redundant architecture and developed a safety mode for the system. Moreover, the requirements are redefined based on the discussion that we had during the exercise session and the supervisors’ feedback. The last lectures helped us to define which part of the system must be ASIC and which part needs to be standard IC. As a result, we decided to have the implantable pacemaker as an ASIC, regarding the requirements and we choose to include a microcontroller instead of an FPGA. The SRAM in the FPGA is sensible toward external disturbances such as radiation and our powering system is based on Radio-frequency can affect it.

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 is to improve the life quality of the bradycardia patients through a smart pacemaker that supports a responsive rate. Moreover, the responsive rate functionality helps patients to avoid further heart diseases and heart failure [3]. As a result, the users will be able to practice activities freely. 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. However, the support given by this device is limited in terms of supporting the heart in case of heart failure.

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