Automated Healthcare Device to Provide Non-Invasive Therapy to Treat Deep Vein Thrombosis using BLE Connectivity

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Abstract— **A blood clot in a vein deep beneath the skin causes Deep Vein Thrombosis (DVT), a medical disease. It is often treated by boosting blood flow in the veins of the affected limb. Therefore, it is necessary to focus on a device which is small and efficient circuitry to make it portable and implementable. In this study, an Automated Test Equipment (ATE) is built to do system testing of Deep Vein Thrombosis (DVT) healthcare equipment in order to confirm its functioning and collect data from it, using Microcontroller CYBLE which is a low power Bluetooth component in the device. The test begins with the installation of a mobile application that uses the Bluetooth Low Energy (BLE) protocol to communicate with the ATE. The testing system then opens the Device Under Test (DUT). A servo motor is used by ATE to start the gadget. The pressure values can now be manually entered by the physiotherapist as per the requirement of the patient. On the basis of our study, our device best works for hypotensive patients under the guidance of a physiotherapist. Therefore, our device is an alternative to the existing technology which can maintain medical-distancing.**

Keywords—Automated Test Equipment (ATE); Deep Vein Thrombosis (DVT); Bluetooth Low Energy (BLE); Device Under Test (DUT)

I. INTRODUCTION

Deep Vein Thrombosis (DVT) is the most prevalent form of venous thrombosis, and if left unchecked, it can lead to Pulmonary Embolism (PE) and fatality. When a blood clot (thrombus) forms in one or more of your body's deep veins, typically in your legs, DVT develops. A thrombus can develop spontaneously or as a consequence of clinical situations such as surgery, trauma, or prolonged bed rest. DVT can be diagnosed by various methods such as imaging techniques which include ultrasonography or venography, D-dimer test, and Magnetic Resonance Imaging (MRI) [14]. One of the effective treatments in general patients could be prophylaxis with low-dose anticoagulants such as heparin or warfarin followed by Vitamin-K antagonists. However, using anticoagulants in neurosurgical patients could be problematic as it leads to serious bleeding [6]. Other invasive treatments include administration of thrombolytic directly into the clot or insertion of the filter into vena cava in the abdominal region. Invasive treatments will always be accompanied by side effects. Hence, the best way of treating DVT would be using non-invasive methods such as the usage of compression stockings [11][12] that reduce the chance of blood pooling and forming a clot [1][8]. The major drawbacks with the present non-invasive therapies to treat DVT are: The patient must devote time exclusively for the treatment and these stockings are one time use as they are customized products which depend upon the circumference of the calf of the DVT patient. In this paper, we have discussed a device that follows bio-mimicking to provide continuous compressions to the injured limb. The device is compact and portable making it compliant for DVT patients traveling for a longer duration and not able to take physiotherapy in the clinical environment [2][9]. A mobile application that communicates with the device provides the ease to set the inflation and deflation pressure values when the device is placed in the sole of the patients' shoe as shown in fig. 1. Working model of the proposed system is discussed in section 2, hardware components inside the device is discussed in section 3, Device communication with the mobile app is explained in section 4, conclusion and results obtained are covered in sections 5 & 6 respectively.

Fig. 1. Device is in-built in the sole of the shoe

II. WORKING MODEL

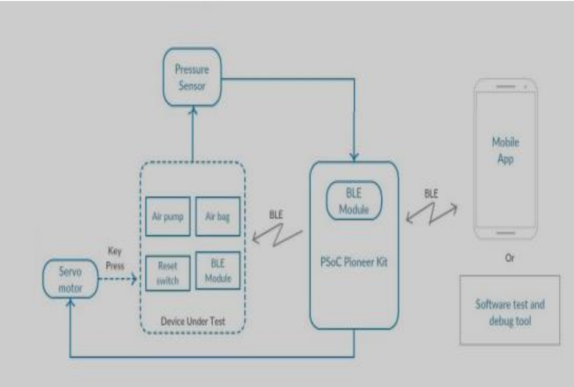

Fig. 2. Block diagram

The block diagram consists of the following (fig. 2.):
1. It consists of a PSoC 4 pioneer kit with ARM Cortex M0 controller
2. A BLE module.
3. Pressure sensor
4. A Mobile app called CySmart provided by Cypress Semiconductors.

The PSoC (Programmable system-on-chip) Creator is a software that assists us in running the application in the mobile app. The PSoC generates two files: APK and HEX files. The APK file is to run the mobile app whereas the HEX file is for the device. PSoC can be easily configured for Bluetooth communication as well.

BLE operates over the 2.4 GHz ISM band. It is a low-power wireless technology that enables devices to communicate with one another.

The working of the block diagram is summarized below:

- The smartphone application is used to start the test. The test system must be configured as a server, while the mobile app must be configured as a client.
- As soon as the device is turned on, the motor will start pumping air into the airbag thereby inflating it. The airbag should inflate at a certain pressure. Now the test system is configured as a client whereas the mobile app is considered as a server, and transmitting pressure values to the DUT via the BLE protocol.
- Now, the pressure sensor that is being used takes the values accordingly. The airbag pressure level becomes equal to the pre-set pressure value, the motor will stop pumping and the solenoid valve closes, preventing the escape of air from the airbag. This is called hold time.
- Post which the solenoid valve opens allowing escape of air from the airbag causing deflation, and the cycle continues.
- The pressure values are collected for 10 cycles of 20 seconds each.
- Repeat the above steps for different pressure readings.
- Notifying the mobile app of the analyzed data. This entails switching the BLE mode of the test system from client to server.

III. COMPONENTS REQUIRED

Portable medical devices have transformed people's ability to track and assess their health and well-being. These devices can provide continuous and non-invasive monitoring of health parameters and real-time updates to healthcare providers.

In order to make the device compact, a multi-layered PCB is used. They have high capacity and better speeds due to their innate electrical properties. The higher density of assembly and reduction in the number of connectors used, facilitates simple construction and reduces the weight of the device. We have made use of 0402 smd type package components to reduce the form factor as much as possible.

The hardware components (Fig.3) used here are: -

- Microcontroller-CYBLE: Bluetooth Low Energy (BLE) can communicate over short distances of 100m.
- ADP5062: Digital input/output USB interfaces
- MMA8653FC: A 3-axis, low power 10-bit digital accelerometer
- MP3V5050GC6U: Pressure sensor
- ADP151: Linear voltage regulator
- DRV8839: Dual half H- bridge driver IC which drives maximum of 1.8A current.
- AT24C04: EEPROM data storage.

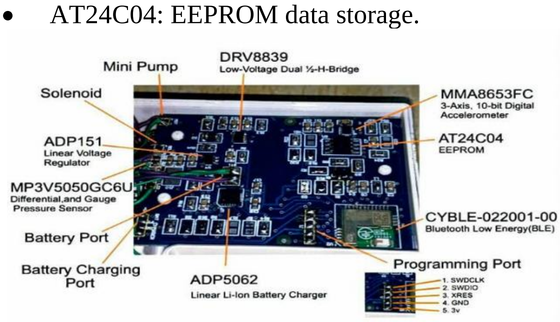

Fig. 3. Circuitry

IV. SOFTWARE IMPLEMENTATION

CySmart is a Bluetooth Low Energy application developed in collaboration with Cypress Semiconductor and Infineon Technologies (fig. 4). Any BLE chip will work with CySmart. In general, it's an app that uses Bluetooth Technology to connect to an embedded system. This app is available for both Android and iOS devices. The CySmart Android app can be used with any BLE products including BLE development kits from Cypress like the following ones:
1. CY8CKIT-042-BLE-A PSoC® 4 BLE Pioneer Kit
2. CY8CKIT-062-BLE PSoC® 6 BLE Pioneer Kit

3. WICED BT Kits

Fig. 4. CySmart app

Device Communication with Mobile App

Steps to establish a communication between the device and the mobile app are as follows:

1. Firstly, the device (STVD_B) is powered up and is connected with the mobile app via Bluetooth.
2. Then there's a feature called Generic Attribute Profile (GATT), that specifies how two Bluetooth Low Energy devices exchange data using concepts like Services and Characteristics.
3. Services are used to divide data into logic entities that contain specific data chunks termed as Characteristics.
4. Characteristics consist of 15 ports to control and communicate with the device.
5. Currently, we have used only 5 ports in our device namely,
Port f1: This port is used to set inflation pressure of the air bag (fig.5).
Port f6: This port is used to turn the device ON and OFF using 1 and 0 as its controls respectively (fig.6).
Port fb: This port is used to set the hold time of the air bag (fig.7).
Port fd: This port is used to describe the battery condition (fig.8).
Port ff: This port informs the user about the number of cycles the device has undergone (fig. 9).

Fig. 5. Port f1

Fig. 6. Port f6

Fig. 7. Port fb

Fig. 8. Port fd

Fig. 9. Port ff

V. RESULT

Hospitals now routinely use intermittent pneumatic compression devices to prevent DVT. The differential pressure at the limits produces discomfort to the patient (between the ankle and the knee) since the stocking only applies pressure to a certain section of the leg. The device demonstrated in this study improves blood flow by imitating the natural muscular contractions in airbag placed on the wounded limb. The user can control the airbag inflation pressure via a smartphone app using BLE protocol. After that, the airbag cycles through inflation and deflation.
For each pressure value, there are two sets of data samples, each with 50 readings —80mmHg as a minimum
Maximum pressure: 200 mmHg
The number of cycles is ten, each lasting 20 seconds.
3.3 V is the voltage of the battery (Li-ion battery)

VI. CONCLUSION

The purpose of this research is to make the lives of DVT patients easier by reducing the number of hospital visits and also facilitating comfortable long-distance travels. The method employed in this study includes the collection of pressure values and their application to improve production efficiency. There is no need for human intervention because the entire treatment method is automated. Furthermore, the complete automation process reduces the treatment costs as an adjustable airbag is used unlike in thromboembolic stockings which needed to be replaced with variation in DVT levels. The results showed that our proposed technique was both efficient and effective. If enhanced further, our method could help in post invasive treatment care of people suffering from DVT ensuring medical distancing.

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