1-27-2016

Design and Implementation of Continua Compliant Wireless Medical Gateway

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By

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A Thesis
Submitted to the Faculty of Graduate Studies
through the Department of **Electrical and Computer Engineering**
in Partial Fulfillment of the Requirements for
the Degree of **Master of Applied Science**
at the University of Windsor

Windsor, Ontario, Canada

2015

Design and Implementation of Continua Compliant Wireless Medical Gateway

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ABSTRACT

Collecting data from various medical devices associated with a patient at one location and sending it to a caregiver at another location in an integrated format is a challenge in telehealth systems. This challenge comes from following factors. First, these medical devices are not equipped with long range communication technologies. Second, medical devices from different manufacturers lack interoperability. Third, communication time is inconsistent. In order to address above challenges, a Continua compliant Wireless Medical Gateway (WMG) is designed and implemented in this research using various hardware components such as BeagleBone Black, Stollmann adapter and Unison Real-Time OS (RTOS). Being complaint to Continua enables interoperability between medical devices from different manufacturers. The selected hardware and software provide easy interface for data transfer over long range. The prototype has been tested extensively using various scenarios to calculate the total communication time, delay consistency and data accuracy. The results show the consistent deviation in communication time for WMG.

DEDICATION

To my Parents,

Pran Ballab Saha and Babuli Rani Saha

For raising me to believe that everything was possible

&

To my Brother, Robin Saha and my Husband, Prosanjit Paul

For encouraging me to make everything possible

ACKNOWLEDGEMENTS

I would like to extend my deepest gratitude to my supervisor, Dr. Kemal Tepe, for his consistent support and guidance throughout the research. I have truly enjoyed working with him and I consider myself very fortunate to have got this opportunity. I would like to thank my committee members, Dr. Z. Pasek and Dr. Mitra Mirhassani, for their valuable input and guidance throughout the research process. I would like to extend my gratitude to my fellow laboratory members Dr. Brajendra Kumar Singh, Ms. Saneeha Ahmed, Mr. Jeremy Coulter, Dr. Kazi Atiqur Rahman, Mr. Gorge Pelington, Mr. Michael Mati and Mr. Sanam Mehta for their constant involvement and valuable feedback. Finally, I wish to extend a special thank you to my loving family, especially my parents for always being there and believing in me. At last but not the least I would like to thank my husband for always supporting me in all my decisions and tolerating me during this research.

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LIST OF ABBREVIATIONS

APDU	Application Packet Data Unit
BT	Bluetooth
BPM	Blood Pressure Monitor
BT-HDP	BlueTooth Health Device Profile
BT SIG	BlueTooth Special Interest Group
CCON	Communication between Continua to BPM
CESL	Continua Enabling Software Library
CWMG	Communication between WMG and BPM
E2E	End-to-End
ECG	ElectroCardioGram
GAP	Generic Access Profile
GUI	Graphical User Interface
HRN	Health Record Network
IDE	Integrated Development Environment
IEEE	Institute of Electrical and Electronics Engineers
LAN	Local Area Network

MD	Medical Device
MED WG	Medical Device Working Group
OS	Operating System
OPE	Optimized Exchange Protocol
PAN	Personal Area Network
PDH	Personal Health Device
RTOS	Real-Time Operating System
SDP	Service Discovery Protocol
TAN	Touch Area Network
WMG	Wireless Medical Gateway
WAN	Wide Area Network
WBAN	Wireless Body Area Network
WLAN	Wireless Local Area Network

1. INTRODUCTION

Health care is an expensive affair. The cost of healthcare is expected to increase from the current $500 billion per year to $685 billion per year by 2020 in North America [1]. It is estimated that, spending on the treatment of heart diseases, stroke and diabetes will increase by $9 billion in North America alone [2]. Due to environmental and lifestyle factors, large number of people are becoming vulnerable to different types of chronic diseases like, cardiovascular diseases, respiratory diseases, neurological diseases and diabetes etc [3]. Technology has been playing vital role in healthcare to enable the practitioners offer efficient patient care. The recent developments in information and communication technologies have increased the degree of connectivity between people using smart devices. These technology advancements can help the healthcare practitioners offer cheaper, faster and more efficient care. A World Health Organization (WHO) report, estimates that the usage of various technology driven healthcare approaches will result in savings of $1 billion over the next 10 years [2]. One of such approaches is personal telehealth systems. Personal telehealth systems, including remote patient monitoring and management, can facilitate caregiver to effectively deliver high-quality healthcare service at lesser cost. However, telehealth systems depend on a large number of medical devices installed at both the patient's and health caregiver's end. A growing number of manufacturers are producing different types of medical devices for telehealth system. But majority of these devices lack ability to interoperate with devices of other manufacturers and can communicate or transmit data - only to vendor specific software applications. So, handling information from various medical devices becomes a challenge for healthcare practitioner. In addition to lack of interoperability, existing systems have limited connectivity and inconsistent delays. For example, to know the Blood Pressure (BP) of patient, who is getting an extended care from home, need trained people or professional's involvement.

To overcome these limitations, a long range multi-hop communication with various types of medical devices with consistent delays is needed. The Wireless Medical Gateway (WMG) presented in this thesis is one such implementation devised to overcome the limitations associated interoperability, connectivity and delay consistency.

The WMG is designed to allow plug-n-play connectivity to the patients monitoring devices. The WMG can collect medical data wirelessly from various health parameter measurement devices and transmit the data over the internet. For data communication, Continua Health Alliance (Continua) specified standard protocol is implemented in the WMG. This protocol ensures the interoperability between various medical devices following the same standard.

The WMG provides multi-hop and long range communication with shorter consistent delay for transmitting Continua compliant medical data. Also the plug-n-play connectivity and less complex hardware design ensure that any general user can operate the gateway with minimal knowledge of Bluetooth connectivity.

1.1 Problem Statement

Collecting data from various medical devices associated with a patient at one location and sending this data to a caregiver at another location in an integrated format is a challenge.

This challenge comes from following requirements. First, quite often, these medical devices are not equipped with long range communication technologies. Second, each of these medical devices come with its own user interface to display the acquired data, hence, a mechanism is needed to combine the data from various medical devices associated with one patient and forward it to the concerned system through internet. Third, as any medical data is crucial for monitoring the patient's health, maintaining the delay consistency is a must while forwarding medical data. Finally, now-a-days, increasing numbers of medical devices are designed with Continua health alliance guidelines for communication. Hence, any solution to the above problem should also be compliant to continua guidelines.

1.2 Thesis Contribution

In order to collect data from various continua compliant medical devices, a continua compliant medical gateway is designed and implemented in this research. Specifically, the designed gateway supports Ethernet communication to send data over the internet. This gateway is tested with continua compliant blood pressure monitor devices. As this test device was working on Bluetooth (BT) technology with Bluetooth Health Device Profile (HDP), the whole HDP code is implemented in C language in the WMG. The collected data from blood pressure monitoring device is sent over the internet using Ethernet interface of the gateway. The gateway is designed such that it is completely compliant to continua guidelines for communication.

1.3 Background

Communication gateways for medical data are becoming popular to form a network of ubiquitous medical devices. In medical applications, slightly corrupted or delayed data may cause serious issues. Therefore, the medical gateway has to ensure some desired characteristics such as correctness of received data, low delay, delay consistency and plug-n-play capability. Hence, a ubiquitously communicable solution is necessary to collect data within a short delay.

1.4 Gateway Design Requirements

The Continua compliant medical gateway has three major design requirements; (1) data communication with consistent delay (2) correctness of received data with respect to sent data and (3) conformance to Continua guidelines. A software module called Bluetooth Continua Communication (BT-CC) module has been developed for implementing the Continua guideline in WMG. This module plays a crucial role to enable the Continua compliant BT communication in the gateway. The BeagleBone Black (BBB) has been chosen as a development platform for WMG. It is chosen for its high computational power compared to its compact size. BBB provides high performance through the ARM cortex A8 processor [9], 5 high speed I/O ports, built-in antennae, separate data and instruction memories and high speed RAM.

1.5 Thesis Organization

This thesis is organized into 5 chapters. The Chapter 1 (this chapter), explains the problem statement and contribution of this thesis towards the solution. The related work in the field of automated healthcare systems, communication technologies for health data collection, existing communication gateways and their limitations are discussed in Chapter 2. The major challenges faced during the development of WMG, design requirements, model of proposed prototype and major assumptions and limitations are provided in Chapter 3. The performance analysis of the system for verifying the timing, delay consistency and error in received data packets has been illustrated in Chapter 4. The conclusion and future works are provided in Chapter 5.

2. RELATED WORK

2.1 Introduction

Using the developments in networking and communication technology, many systems [7], [8], [11], [12], [13], [14], [15], [16] are proposed to handle the transmission of health data from patient to care giver. Most of these systems are built with a custom hardware and unique design [7], [8], [11], [12], [13], [14], [15], and [16]. For instance, [8] and [15] use Power over Ethernet (PoE) (for lower power consumption) and ZigBee based multi-hop communication to transfer data. A three layer application based medical information network model with customized network interface, application and operating system is proposed in [7]. All these systems provide communication between the medical device or sensor and receiving end. However, all these systems have inconsistent delay [11], inaccuracy [12], [13] and complex non-interoperable design [8], [14], [15], [16]. This chapter explains what Continua is and why it is important for the medical devices and gateways to be compliant to Continua standards. Then, this chapter discusses the existing gateway systems, their components and limitations.

2.2 Continua

The Continua Health Alliance, normally referred as "Continua" is an international non-profit group and the leading organization convening global technology industry to develop end-to-end, plug-and-play connectivity for personal connected health. Continua's Design Guidelines based on global industry standards and test tools enable more efficient, standardized development and create new market opportunities for interoperable personal health devices and services used to collect and relay vital health information. Continua is a pioneer in establishing standards-based guidelines and security for connected health technologies such as smart phones, sensors, remote monitoring devices, tablets and gateways, as well as networked and cloud solutions [1][11] . This guideline is based on IEEE 11073- Personal Health Device (PHD) communication standards and Health Device Profile (HDP) [18]. This guideline of continua provides acknowledgement based packet transmission which ensures the reliable data transmission for any Continua certified devices. Continua, through its product certification program, certify the medical devices with a recognizable logo signifying interoperability with other certified products [17]. The guideline is divided into multiple clauses for implementing a medical device which can be certified by the Continua [49]. The applicable clauses for a specific device implementation have to be chosen by the developer.

The clauses 1 to 5 of continua guideline provide background information such as definition, supported interfaces and terminology necessary to understand the specifications. Then, clause 6 provides the E2E system architecture, device components which have been followed in this project. This clause also defines the security requirements such as authentication protocol and integrity checks implemented in the BT-CC module of the gateway. Additionally, this clause describes topologies and compatibility requirements that have been considers in the implementation of BT-CC module. The clause 7 of the continua guideline in called the "Common PAN Interface design guideline" which provides the guidelines for data layer that are common to all BT devices. This section of the guideline is followed during the implementation of WMG.

The applicable standards are selected for the individual layers for following the guideline. These standards are IEEE 11073-20601: Optimized Exchange Protocol (OEP) [18] and Bluetooth Health Device Profile. This IEEE 11073-20601 protocol acts as a bridge between devices. The sub clause of 7, "The compatibility clause" defines the semantics of command and messages to establish communication of WMG with various kinds of MDs. In this research a Blood Pressure Monitor (BPM) is the MD and the device specific requirements "-10407: Blood Pressure Monitor" have been followed from IEEE 11073. The BT-CC module has been developed mainly based on the clause 6 and 7. The BT-CC module uses HDP massage communication to determine channel formation and management. The hand shaking procedure, channel establishment, is based on the clause 7 of Continua guideline. Clause 8 of the guideline is about the Touch Area Network (TAN) interfaces, which is not in the scope of this research work. At last, the important device information (e.g. manufacturer name, model number, serial number, system ID) that needs to be exchanged during channel establishment process which is explained in clause 9.

2.2.1 IEEE 11073 Standard

IEEE 11073 is a set of standards that specify nomenclature, an abstract data model, a service model and transport specifications for interoperable devices [13], [18], [19]. The specifications have 12 parts; 10101-Nomenclature, 10201- Domain information model, 10408- Device specialization (Thermometer), 10407- Device specialization (BPM), 20601- Optimized Exchanged Protocol (OEP) and others, under the general title "Health informatics — Personal health device" [21]. The OEP specifies the definition of the application layer services, commands, agent configuration information, data format and data exchange procedure between agents and managers [13], [21]. Implementation of this protocol allows the connection management to support any type of agent. In the proposed system, the agent is the medical device and manager is the WMG. Implementation of this connection oriented protocol provides reliable communication to any system. This protocol uses acknowledgement based packet transmission and handshake based data channel formation. This protocol specifies the threshold for delay in data communication, which is up to 3s. This threshold is the timeout for data channel mentioned in the standard. This implies a maximum allowable delay of 3s in communication.

Another important aspect of IEEE 11073 is device specific services for various types of medical devices. According to IEEE 11073 all medical devices are classified as either agents or managers based on their services. The BPM has been chosen as the agent for the experiments done in this research.

2.2.2 Health Device Profile

Bluetooth is vastly used as a near-distance wireless technology in many applications and is very suitable for many medical device applications. Until 2008, the Bluetooth systems for medical application used proprietary implementations and data format. In most cases applications that run on top of the Serial Port Profile (SPP) were used. Such systems are – if they don´t come from one supplier – non-interoperable. Since the implementation is customized for just one vendor and/or device, data exchange between such systems is often difficult. Even Bluetooth interoperability with PC´s using different Bluetooth stack versions from different vendors is hard to achieve. To solve such issues, in 2008, the Bluetooth SIG released the Bluetooth HDP [26]. The BT-HDP supports a variety of in-home medical applications. The most typical use cases are portable sensors like oxygen saturation data transmitters, blood glucose level meters and blood pressure meters that transmit the measurements to a monitoring system [12]. BT- HDP provides a wireless discovery method to determine device-type and supported data-type. BT-HDP uses the handshaking procedure for data and control channel establishment, link maintenance and retransmission of erroneous packets [12]. Other advantages of HDP are flexible data channel configuration, clock synchronization and resource optimization for constrained devices.

2.3 Components and Services of Existing Gateway

Medical connectivity involves data transfer between an agent and manager. Medical devices connectivity can be wired or wireless such as Bluetooth, Bluetooth low-energy, Wi-Fi etc. In terms of energy efficiency, accessibility, remote communication and independency; wireless devices are better than wired solutions. Most of the recent medical devices can communicate wirelessly. However, these wireless technologies support only near-distance communication and can’t connect to internet directly. To be able to transfer the medical data to a care giver who’s at different location, connectivity to internet is needed and that can be achieved through a gateway. These gateways are sometime referenced as aggregation manager or medical device hub. Selection of appropriate technology and implementation procedure is a crucial consideration for medical gateways as the applications are inherently delay intolerant and require accurate data.

The available medical gateway systems can be classified into two categories

1) Systems that are using single embedded application.

2) Systems that are using an embedded application developed on operating system.

2.3.1 Systems with Embedded Application

Systems working as medical gateways with embedded application are discussed in [8], [15], and [28]. In [14], [16], [21] [29], [28] designs have been explained which works with the modification of the hardware or software of a mobile phone to use it as gateway.

In [8], the design and implementation of a two-fold Dual Radio ZigBee Homecare Gateway (DRZHG) has been proposed. Important features of the gateway are low latency, highly accurate telehealth service and zero configurations. This system has a ZigBee transceiver connected to a 32 bit Micro Controller Unit (MCU) through Universal Asynchronous Receiver/Transmitter (UART) interface. Here, the MCU processes the data and interacts with different communication interfaces for medical data collection. The ZigBee has lower data transmission rate and long transmission distance than Wi-Fi and Bluetooth [29]. The majority of Continua certified medical devices are communicating using Bluetooth and Bluetooth Low Energy (BTLE), which can't be supported by the proposed solution. Also, this system will need a ZigBee node for each medical device and this system is not continua compliant so, lacks interoperability.

The gateway designs explained in [15] and [28] are focused on energy efficiency and scalability at a low cost with massive ubiquitous deployment. The paper [18] shows the benefits of a Power over Ethernet (PoE) enabled medical gateway, where the data and power are combined into a single cable. The literature [28] has mainly focused on low costing middleware for collecting data from various medical devices (MD). The system is built on Microchip 8 bit MCU, PIC 18F67J94 which has inbuilt USB interface, LCD support, 128KB memory and 3862 Bytes RAM including 4 UARTs. UART modules are configured for enabling BT, Ethernet and GPRS. The gateway proposed in [18] has limited communication ability with Continua certified medical device.

The three systems discussed above along with [16], [17], [19], [20] have specific hardware and embedded software application and don't use any operating system. The OS generally hides the hardware details from the application programmers and provides multitasking, threading, scheduling which are usually help in rapid development, scalability and maintenance of the application. The systems proposed in [19], [16], [17] have designs where mobile phones are integrated into the system. These systems need installing specific application on mobile phones to achieve data transaction. Also, to communicate with these gateways, a specific model of medical sensors or medical device is needed, which does not, ensures the plug-n-play facility.

2.3.2 Systems with General Operating System

The gateway systems proposed in [7], [26], and [27] are built on general operating systems. In [6] an Android-based smart mobile phone has been used as health-care gateway. The main mechanism of this type of gateway is- collecting data from medical or body sensors via classic Bluetooth and transfer them to the server or central system via GPRS or cellular technology. These designs ensure that, the gateways are capable of sending raw data using low power consumption and very small packets loss. The gateway's application is built on OS to handle multiple tasks and leverage other features of OS. However, these technologies do not ensure interoperability and bounded delay for data communication. In order to create a complete and vast medical device network, multiple pre-programmed mobile phones are needed, which is a big restriction in industrializing these design architectures.

A patient centric health monitoring system has been developed by the author of [30]. A quite complicated architecture has been proposed to provide solution to the health monitoring systems. A wireless body area network has been created by developing various body sensors which are attached in patient body. Communication has been enabled in the body sensor using ZigBee and Bluetooth. To communicate with body sensors, a personal server has been created by employing mobile phone networks or WLAN to reach internet. Security has been ensured by storing patient authentication information in personal server cross checked by the sensors before sending patient data. Some software modules are running on IAS/ISMP and Tmote sky platforms for personal server and sensor node. It uses TinyOS environment for backend applications. This system is very stable because of operating system. But the personal server has some limitations, like its communication is only bounded with specified sensors and it is not ensuring any interoperability among various medical sensors from other vendors.

Literature [17] and [31] only explain about ensuring the security during data communication. Thus, in [17], a security policy delivery system called MOPS has been developed. The MOPS is security application layer of a medical information network model. Whereas, the stable secured communication technology have been developed using SUSE Linux 9.2 FTP Version [31] for central system. It ensures partial stability and secure medical data transfer through the application. The research on this system is based upon the development of a CGI script to create a secure communication link between

HTTP server and middleware of a medical network. These systems do not ensure interoperability and guaranteed timing.

2.4 Summary

This chapter gave an introduction to Continua and importance of being complaint to continua standards. Also, it discussed systems architecture and features of some existing medical gateways and their design limitations. How the usage of continua standards and BT HDP can help in developing a gateway system to overcome the discussed limitations was discussed here.

3. RESEARCH WORK

3.1 Introduction

The Wireless Medical Gateway proposed in this research is designed to meet the following end goals.

1. The WMG shall be able to connect to internet so that the medical data can be transferred between the patients and health care practitioner who are geographically separated. Internet is the right medium for such long distance communications due to its ubiquitous availability and increasing reliability.

2. The WMG shall be able to seamlessly connect to Continua certified; Bluetooth enabled medical devices without any changes to the system.

3. A consistent delay is maintained in the data transfer between the MD and the gateway.

The following subsections will explain how the WMG is designed and implemented throughout my M.A.Sc. studies as my research work.

3.2 The Telehealth System with WMG

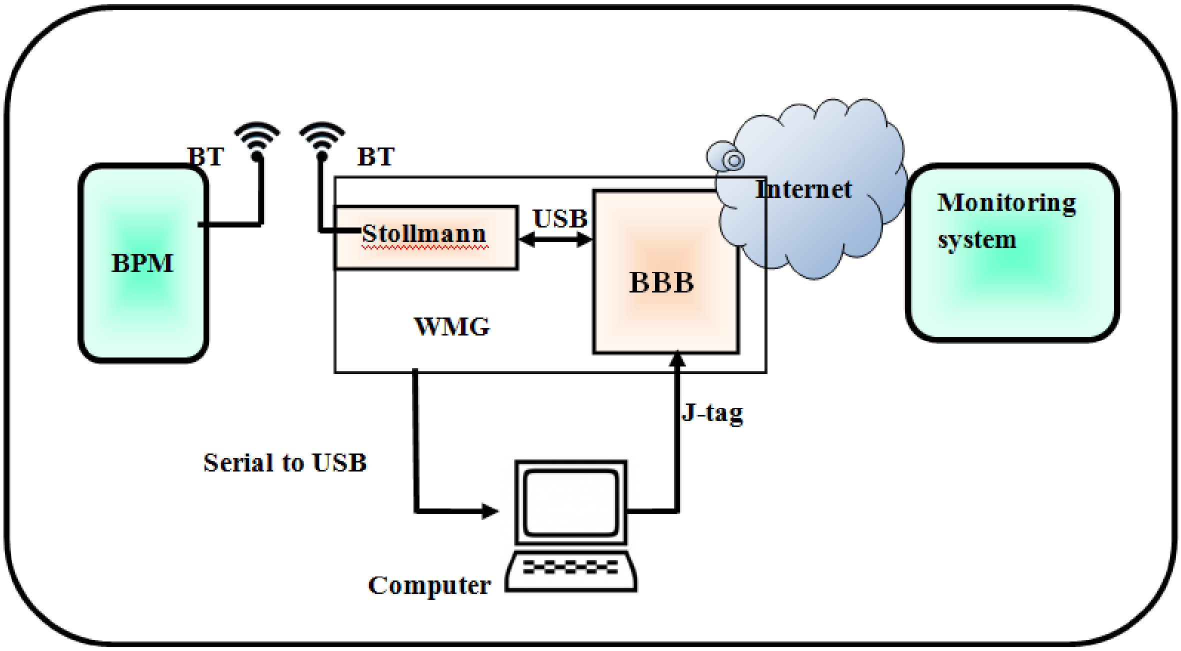

Figure 1: Hardware Configuration and Connection

Different subsystems of the telehealth system with the WMG and connectivity between them are shown in Figure 1. The WMG subsystem is designed to connect continua compliant MDs like BPM through Bluetooth interface to the internet by using the Ethernet interface. Any monitoring system capable of connecting to internet can receive the data by connecting to the WMG. The WMG also connects to the host computer system through serial and J-tag interfaces. Any monitoring system application running on the host computer can receive the medical data over the serial interface. The J-tag interface is used to load the software on the WMG.

3.3 Dataflow of WMG Based System

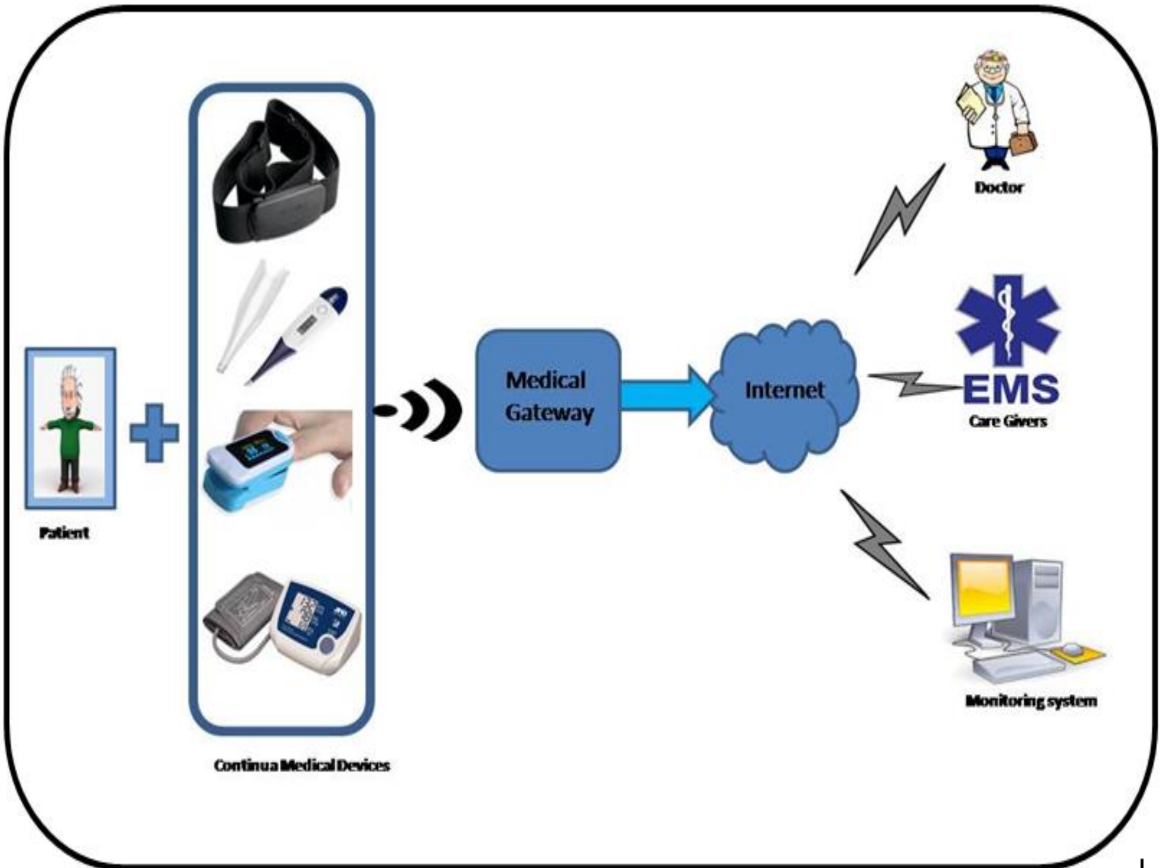

Figure 2: The Dataflow of WMG Based System

The Figure 2 explains the data flow in the telehealth system with the designed WMG. The medical data or patient's health data is collected from various Continua certified MDs. The WMG forward the data to the end receiver with an Ethernet connection. At the end point, the user can accrue the data from internet in various ways like an automated email service, an emergency SMS service, a monitoring system in website, a server, or a monitoring system mobile device.

3.4 The Design Methodology of WMG

The design of proposed WMG is carried out in two phases

(1) The hardware configuration

(2) The development of the software

3.4.1The hardware configuration

The Figure 3: Block Diagram of Medical Gateway shows different components of the designed WMG. The BeagleBone Black (BBB) hardware has been chosen as the base development board for this implementation. In order to add the BT interface to the BBB, a BT-HDP based adapter is used. This adapter is connected to BBB through a USB interface. This adapter is manufactured by Stollmann Inc, and from now on it will be referenced as "Stollmann adapter" throughout this thesis. Through the Stollmann adapter, the BBB can connect to the Blood Pressure Monitor (BPM) to receive the data read from human body. A LAN cable is connected in the Ethernet port of the BBB. The BBB has a surface soldered J-tag header to load the binary image of software on to BBB. The BBB has a serial interface and can be connected to any host system though a serial to USB converter. The WMG is powered with 5V DC adapter.

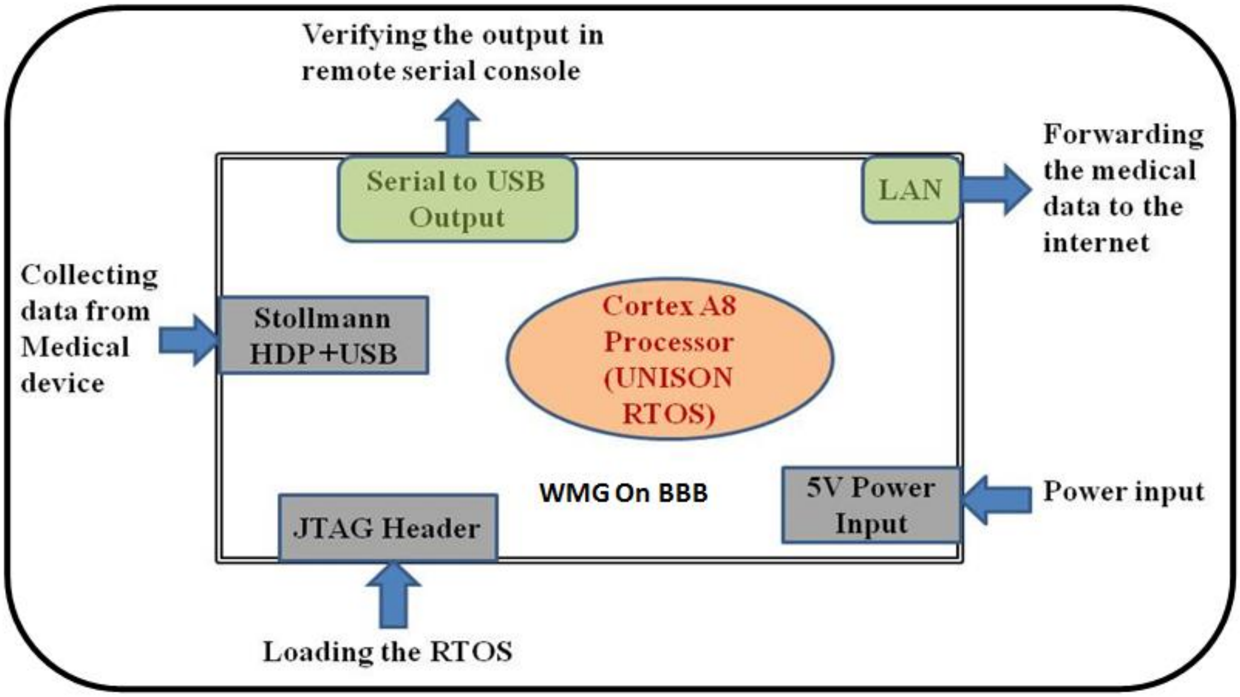

Figure 3: Block Diagram of Medical Gateway

3.4.1.1 BeagleBone Black (BBB)

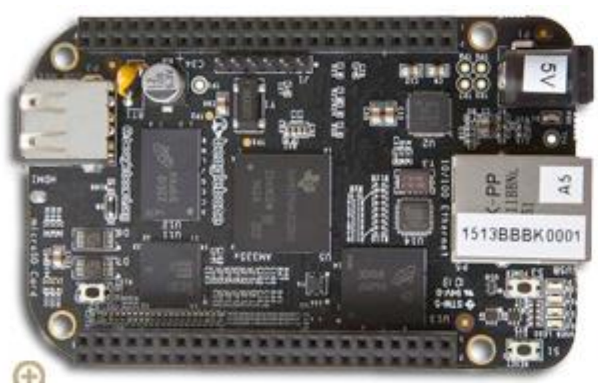

Figure 4**: BeagleBone Black [39]**

BBB is a miniaturized energy efficient computer with high computational capabilities [39]. BBB has open source libraries and low cost development platform, which was appealing in selection as the implementation platform for this prototyping effort. BBB is built with a TI-Sitara AM335x ARM Cortex-A8 processor, has 512MB DDR3 SDRAM, 4GB ROM with 8-bit embedded multi-media card, Ethernet, USB, HDMI, UART and mini USB interfaces [40]. The BBB is powered with 5V DC. This board comes with open source UNIX based operating system called Angstrom and supports other UNIX based OSs [41]. However, because of the research was collaboration between an industrial partner and our research lab, real-time Unison OS had to be ported to the BBB and used as the OS in WMG implementation.

3.4.1.2 Stollmann Adapter

Figure 5: Stollmann Adapter

Stollmann is a Germany based company which has been developing serial and USB BT adapters and standard modules since 1999. Stollmann has a proprietary BT adapter, which can be used to add Health Device Profile (HDP) and Serial Port Profile (SPP) functionality to any PC with a standard USB slot [47]. By using this adapter a HDP based communication can be established between the WMG and any Continua certified MD. The Stollmann adapter uses Continua specified Local Transport Protocol (LTP) to communicate with MDs.

3.4.2 Software Components and Configurations

Following are the software components that are used in the implementation of WMG software.

1. The Unison Real Time Operating System (RTOS)
2. The BT-CC module
3. The Internet Communication Module

3.4.2.1 Real Time Operating System

RTOS is an operating system which processes real-time application data without buffering delays [34]. RTOS guarantees a certain application execution capability within a specified time constraint. How an RTOS meets the deadline determines whether it's hard RTOS or soft RTOS.

In this research Unison RTOS is used since the project was collaboration with Rowebots Inc. Unison is ultra tiny Linux and POSIX compatible embedded RTOS and is developed and maintained by RoweBots. It supports many general purpose microcontrollers (MCUs), digital signal processors (DSPs), FPGAs, microprocessors (MPUs) and digital signal controllers (DSCs) [37]. Unison ensures multitasking and threads scheduling by employing round robin scheduling method, pre-emptive dynamic multithreading and cooperative multi threading and poison pill approach for thread termination. Unison also uses Interrupt Service Routines (ISR) to handle hardware interrupt requested by the processors [36].

3.4.2.2The BT-CC module

The BT-CC module through Stollmann adapter, manages the complete HDP message communication between WMG and MD. The BT-CC module has been developed by following the guideline provided by Continua and satisfies the OEP and "Device specification" sections of the IEEE 11073 standard. The BT- CC consists of one read and one write function. The read function receives and interprets the signal sent by MD through Stollmann and the write function reply back with the response signal according to the request. The BT-CC module is developed inside the main thread of the Unison RTOS which has the highest priority among all threads. This ensures the timely execution and real time behavior of the BT-CC module.

This module is responsible for carrying out all BT communication steps such as channel formation, channel management, packet formation, connection management and data transfer. The channel formation and management guideline has been followed from the standard for managing the data communication. The module ensures acknowledgement based data transmission and performs handshaking procedure for channel establishment. The packet formation procedure does a CRC check to ensure the payload is error free. Any payload data that do not pass this CRC check will be dropped by the system before it can reach to the user end. So, the user does not receive any erroneous data packet. To initiate the communication, a command is generated from WMG to MD. The response to this command includes data channel request, security verification, radio link request, profile connection request etc. Various steps are involved in formation of the connection which are discussed in the sections 3.5 and 3.6

3.4.2.3 The Internet Communication Module

The Internet Communication module of the WMG software is responsible for forwarding the received medical data from BPM to the remote server at the healthcare provider's end over the internet. The medical data to be sent over internet is formed by extracting 4 bytes from 100+ data bytes received from BPM over the BT-CC communication. These 4 data bytes are packed into an IPV4 packet as payload which is accessible to the remote server using HTTP protocol. An html web page is designed on the healthcare provider's end to display this received data on the web based GUI.

3.5 Development Tools

The development of WMG software has been done on Code Composer Studio (CCS). The CCS is an Integrated Development Environment (IDE) for TI's microcontroller and embedded processors [42]. CCS includes C/C++ compiler, source code editor, project build environment, debugger and profiler. It offers different features for various development boards. By combining the advantages of the eclipse software framework and advanced embedded debug capabilities, CCS is a good platform for embedded systems software development. In this research a number of selective modules of RTOS have been combined using CCS under one project. The build output of the project is ".out" file which is a binary image of the Unison RTOS with BT-CC and Ethernet modules [43]. The ".out" file is placed in the 'debug' folder and the J-tag loader loads the file into BBB.

3.6 Channel Formation and Management:

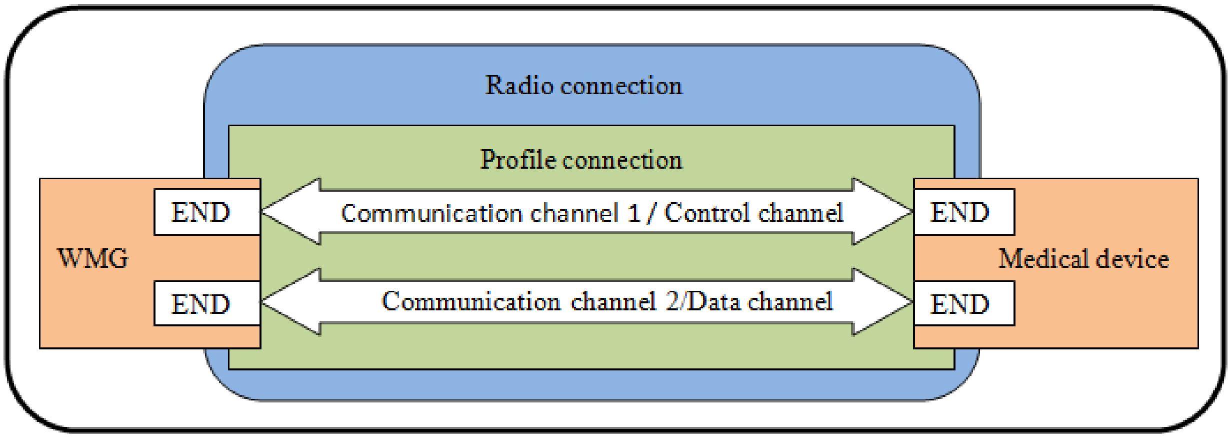

Figure 6: Channel Formation Management.

The connection management of the BT-CC module is explained in Figure 6. The communication is initiated by requesting the radio connection with the nearby Continua certified device. The radio connection is created using frequency hopping. Once the radio connection is established the BT profile is obtained from the device. After verifying the BT profile, WMG establishes the profile connection. The profile connection enables BT-CC on WMG to select appropriate connection management and signal handling procedure. Later the WMG creates the communication channel 1. This channel is used for exchanging initial information like device name, device id, device type, BT address. The successful formation of this channel allows secure communication between MD to WMG. This channel is also called as control channel. At this stage, the BT-CC waits for the request from MD to open a data channel. The data channel is also known as communication channel 2 and is managed by the BT-CC. the secure transmission is initiated by WMG. After the data transmission is complete, the BT-CC closes the data channel to end the communication.

This entire communication is complaint to the Continua guidelines for BT-CC. The BT-CC is implemented as a Finite State Machine (FSM) and HDP connection management sequence.

3.6.1 Finite Sate Machine:

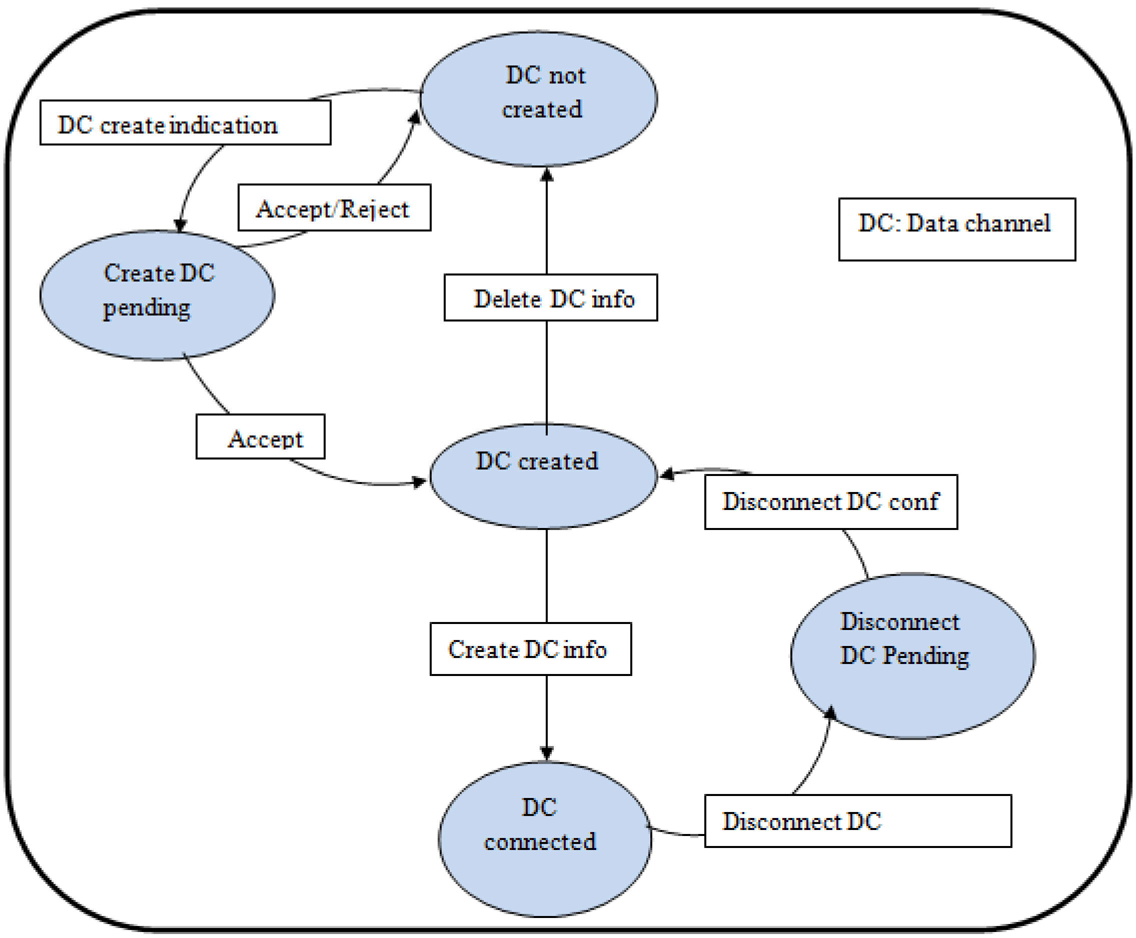

Figure 7: The FSM for HDP Connection

Figure 7 illustrates the states of the FSM implemented in HDP connection establishment. This diagram shows the successful HDP connection but does not consider the HDP reconnect functionality. Some initial information is exchanged at the starting of the BT communication between WMG and MD. The signaling for each MD is separately handled by the FSM. A signaling mechanism for HDP connection has been created using this State diagram.

3.6.2 HDP Connection Management

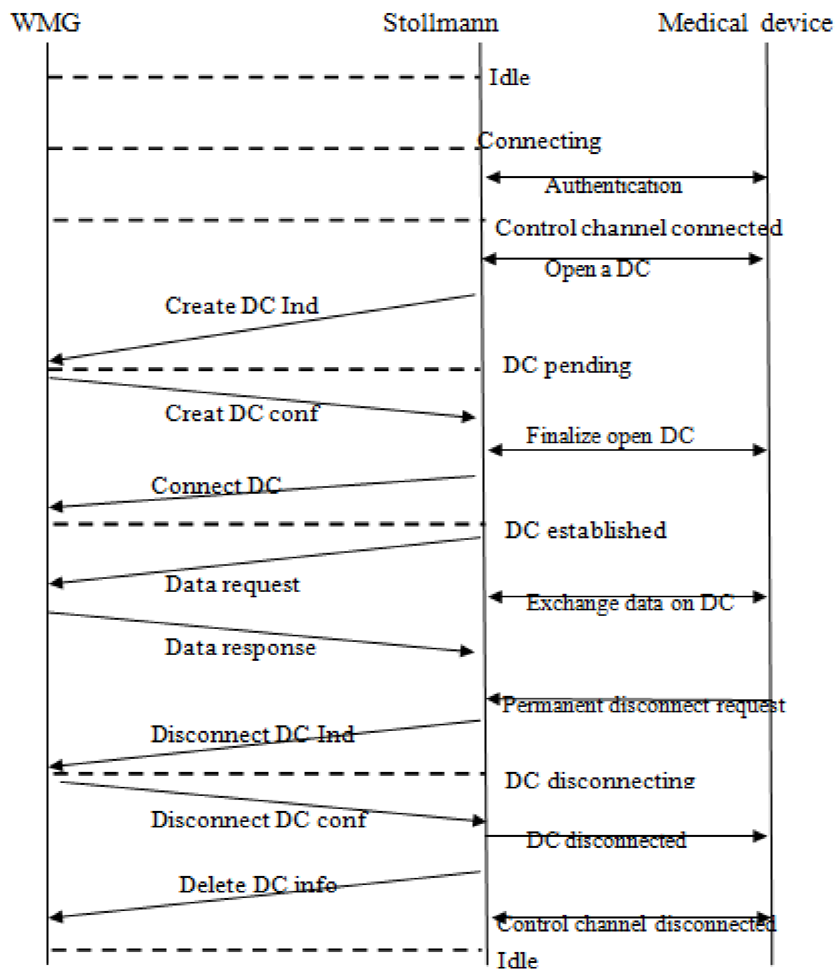

Figure 8: HDP Message Communication

Figure 8 illustrates the signaling mechanism for handling the incoming connection implemented in the communication protocol between WMG and the MD. Initially, both

WMG and MD are in the idle state. Later the WMG issues command to MD and enter into the connect state. In the connected state, authentication parameters are exchanged. After completing the authentication a control channel is established. On this channel the initial parameters such as device type, BT id, device ID, timing information and profile identifiers are exchanged and Create Data Channel Request is sent by the MD. The WMG opens the channel and receives Connect Data Channel Response from MD. At this point, the data channel is established. When the data is available in the MD, it sends Data Request to the WMG. After receiving the data request WMG starts receiving the data from MD via Stollmann. When the complete data is received an acknowledgement is sent by WMG to MD. After receiving this acknowledgement from WMG, the MD issues the disconnect request. WMG disconnects the data channel and sends the disconnect confirmation massage. Then WMG enter into the disconnected state. Meanwhile MD requests WMG to delete the data channel information for the device and MD closes the control channel.

3.7 Continua Compliant Packets Formation

The packet formation procedure is implemented by following IEEE 11073 standards. The BT-CC HDP packet consists of cmd, copmsk, lp, P1, P2, P3, payload fields. The cmd is a 1 byte field which defines command type. The copmsk is defined as ‘cmd optional parameter mask’. Copmsk is a 1 byte field which specifies the optional parameter for the command given in the cmd field. ‘lp’ is 2 byte field which defines the length of the packet. The P1, P2, P3 are optional parameters whose values depend upon the payload. The payload is appended at the end of the packet and may occupy up to 64 kilo bytes (kB). This payload forms the application data packet unit (APDU) of HDP. Although

Segmentation And Reassembly (SAR) mechanism is provided in the standard the realization of segmentation and reassembling is left to the developers.

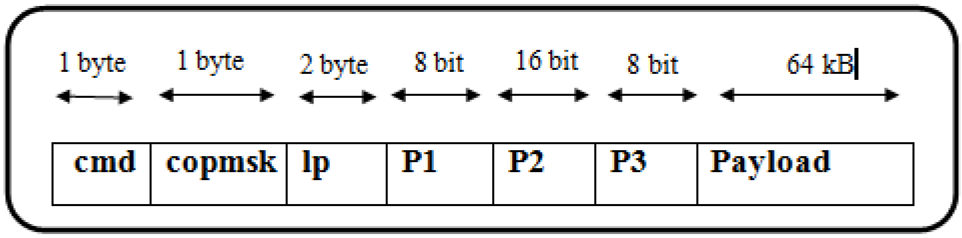

Figure 9: Packet Structure of HDP

3.8 Summary

A Continua compliant WMG that is capable of communicating with any Continua certified MD has been developed and implemented in this research. The design methodology for developing the WMG prototype has been explained in this chapter. A detailed description of required hardware and software components of WMG has been given in this chapter. The data flow of the full medical network using this WMG is also explained. Detailed development procedure of BT-CC communication module has been explained to allow other researchers to re-create a WMG prototype successfully.

4. TESTING AND RESULT ANALYSIS

4.1 Introduction

In this section, the delay consistency of end-to-end communication between BPM and the designed WMG is measured and analyzed. The timely receiving of medical data at the care givers end is very important. If the medical data is delayed then giving timely services to the patient in emergency may not be possible.

In order to determine and compare delay in the end-to-end communication time of WMG, two test setups are used. In one setup, as shown in Figure 11, the BPM sends the measured BP values to WMG over Bluetooth. This communication between BPM and WMG is denoted as CWMG in this thesis. The WMG then forwards the data to the global internet. In another setup, as shown in Figure 10, the BPM sends the data over Bluetooth to a PC application called Continua manager. The Continua manager application is developed and maintained by the Continua health alliance. In this thesis the communication between BPM and Continua Manager is denoted as CCON.

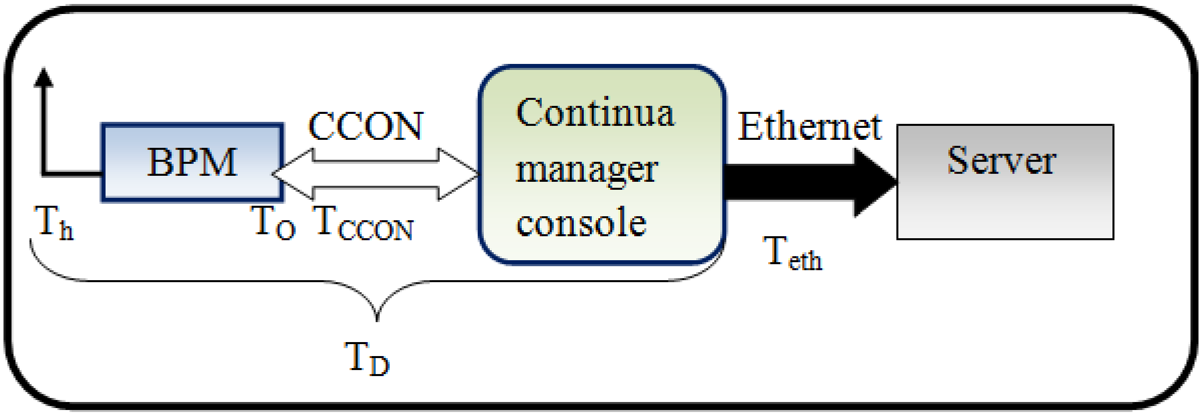

Figure 10: Test-bed for Measuring CCON time

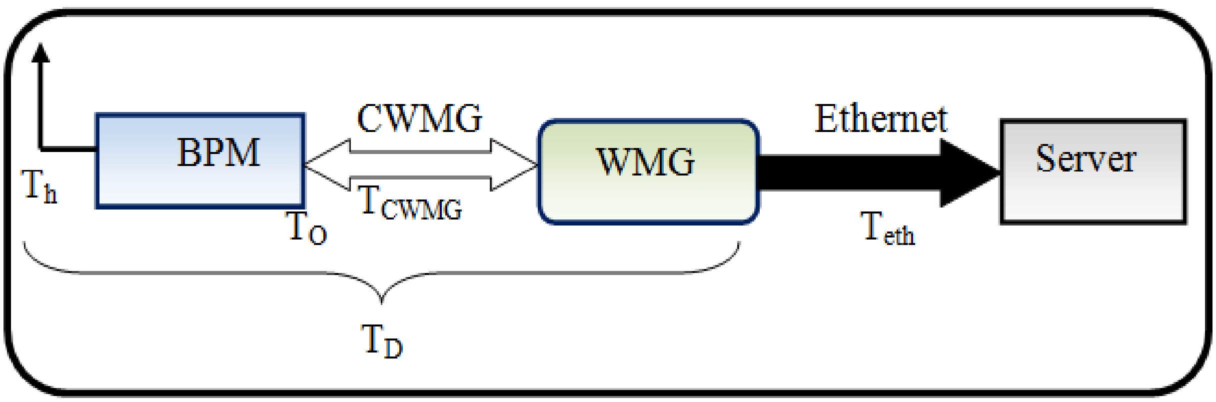

Figure 11: Test-bed for Measuring CWMG time.

4.2 Test Scenarios

The data transfer sequence between BPM and Continua Manager or the designed WMG has following steps. Here, steps are explained with respect to the designed WMG. Same steps are applicable for connecting to Continua Manager. The Figure 12 shows how the test scenarios are designed and steps involved in the data transfer.

1. When the designed WMG is powered up, it waits for the BPM to become visible as Bluetooth device.

2. When the Bluetooth device is powered up, it becomes visible to the WMG.

3. The user selects the BPM device on the WMG for data transfer. At this stage, messages are exchanged between the BPM and the designed WMG for authentication, pairing and establishment of the connection. This time is represented as 'data channel establishment' delay.

4. Once the connection is established, the BPM measures the data (Data Collection) and transfer the data (Data Transmission) to the WMG.

5. The designed WMG receives data and display it on the serial terminal and forward it to the global internet on request.

In Test Scenario 1, the time is measured from the time BPM is powered up until receiving data on the serial terminal. In Test Scenario 2, the data channel establishment delay is excluded from the measurements.

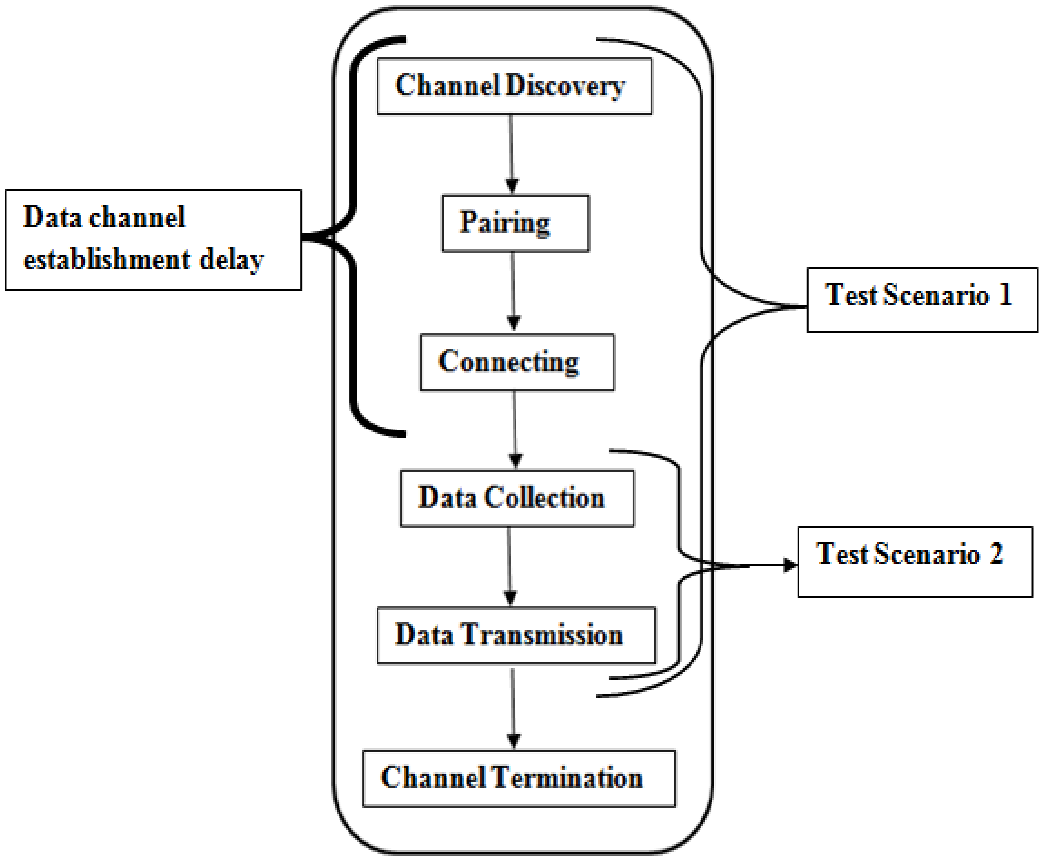

Figure 12: The Data Establishment Delay

4.3 Test Cases

Multiple test cases are executed to measure the accuracy of medical data and delay consistency in communication. The accuracy is measured through comparison of received data with sent data. The CCON time is compared with the CWMG time to measure performance of WMG. In the first case, the CCON time and CWMG time are measured with data channel establishment delay. In the second case the data channel establishment delay is excluded from measurement. For each scenario 25 observations are taken and the second scenario is repeated for 3 different users. The Ethernet interface is the exit interface to forward the data to global internet. However, the Ethernet delay is not considered in these measurements and it's assumed to be constant as given in [38].

The Continua certified BPM developed by A&D medical is used as MD in all these test cases. The measurements are taken on real people.

4.3.1 Test Case 1: CCON with data channel establishment delay

Objective of this test case is to measure the total time needed for taking one set of reading using BPM and Continua Manger. The test setup as shown in Figure 10 is used for running this test case. The Continua Manager is running on PC and communicating to BPM through the Stollmann adapter. The PC is connected to internet. As shown in Figure 10, the total communication time includes 4 parameters, namely, data channel establishment delay (T_H), observation delay (T_O), BPM to Continua Manager communication time (T_{CCON}) and Ethernet delay (T_{eth}).

Procedure:

Step 1: Start the Continua Manager tool and connect it with BPM using the setup discussed in Appendix A.

Step 2: Power up the BPM. Let the Continua Manager discover the nearby BT devices.

Step 3: Once the BPM is discovered by the Continua Manager, tool sends the pairing and connection request to BPM. There is a delay from the time when pairing request is made until the BPM completes the connection and states "END" on the screen

Step 4: Now, attach the BPM cuff to the patient’s arm. Press the "start" button of the BPM to let the BPM measure blood pressure data. Wait till the BPM inflates the cuff and release the air pressure to calculate the upper bound (Systolic) and lower bound

(Diastolic) blood pressure and pulse of the user. This is another source of the delay. This delay is called "observation delay" and can vary from user to user on the basis of physical conditions of the user.

Step 5: Once the blood pressure is measured, the BPM forwards the data to the Continua manager. This process is automatic and only involves the transmission delay of the medium, which is negligible. The installation and user instructions for Continua manager and Tera-term are explained in the appendices.

Various delay times explained in the above steps were measured using a separate timer application.

4.3.2 Test Case 2: CWMG with data channel establishment delay

Objective of this test case is to measure the total time needed for taking one set of reading using BPM and WMG. The test setup as shown in Figure 11 is used for running this test case. As shown in Figure 11, the total communication time includes 4 parameters namely data channel establishment delay (T_H), observation delay (T_O), BPM to WMG communication time (T_{CWMG}) and Ethernet delay (T_{eth})

Procedure:

Step 1: Connect the Stollmann adapter to the WMG. Make the j-tag connection between the WMG and the PC where WMG software binary is available. Connect the serial port on WMG to the USB port of PC through a USB to serial converter. Load the WMG software using the CCS IDE.

Step 2: Power up the BPM. The designed WMG will connect with the BPM by sending the pairing and connection request. When the connection is established after data channel establishment delay, the "END" will be displayed on the BPM screen.

Step 3: Now, attach the BPM cuff to the patient’s arm. Press the "start" button of the BPM to let the BPM measure blood pressure data. Wait till the BPM inflates the cuff and release the air pressure to calculate the upper bound (Systolic) and lower bound (Diastolic) blood pressure and pulse of the user. .

Step 4: Once the blood pressure is measured, the BPM forwards the data to the designed WMG. The WMG displays the received medical data on the Tera-term. The Tera-term is an open source terminal application that can be used to send and receive data over serial port connection

The total communication delay is calculated using the following equations;

$T_D = T_H + T_{CCON}$ ---------------- (1)

$T_D = T_H + T_{CWMG}$ --------------- (2)

4.3.3 Test Case 3: CCON without Data Channel Establishment Delay

Objective of this test case is to measure the total time needed for taking one set of reading from BPM on Continua Manger but without the data channel delay. The same setup and procedure as used for test case 1 is used for this test. Only difference is that, the time is measured after the BPM and Continua Manager connection is established up to receiving data on the Continua Manager.

4.3.4 Test Case 4: CWMG without Data Channel Establishment Delay

Objective of this test case is to measure the total time needed for taking one set of reading from BPM on the designed WMG, but without the data channel delay. The same setup and procedure as used for test case 2 is used for this test. Only difference is that, the time is measured after the BPM and WMG connection is established up to receiving data on the Tera-term.

4.3.5 Test Case 5: CWMG and CCON for Different Users without Data Channel Establishment Delay

Objective of this test case is to measure the data transfer time for different users. To do this, the test cases 3 and 4 are repeated for 3 different users. The reason for selecting test cases 3 and 4 is that, the data channel establishment delay doesn’t vary from user to user and hence, doesn’t need to be measured. In this experiment, two female users aged 34 and 27, one male user aged 25 have gone through the test procedure.

4.4 Result Analysis

4.4.1 Result Analysis of Test Case 1 and Test Case 2

The Figure 13 shows comparison of total time T_D measured for CCON and CWMG in test cases 1 and 2.

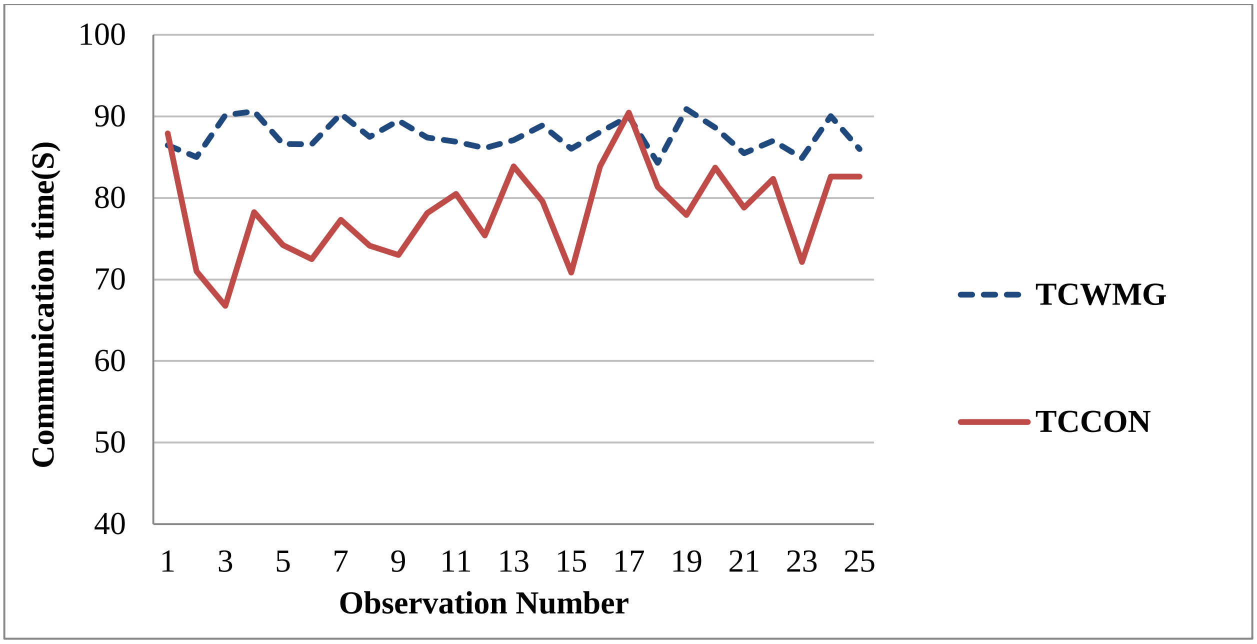

Figure 13: CCON time and CWMG Time with Data Channel Establishment Delay

It is observed that the average CWMG $T_{D\ is}$ higher as compared to the CCON T_D. However, the difference in the means of T_D (CWMG) and T_D (CCON) is less than 10 seconds. The deviation in T_D (CCON) is about ±5.6127s but the deviation in T_D (CWMG) is ±1.928s. This illustrates that, the maximum deviation in T_D (CWMG) is 3.856s whereas the maximum deviation in T_D (CCON) is 11.22s. This implies a better delay consistency of the designed WMG in data transfer. The total communication time T_D includes the data channel establishment delay during which no medical data is transferred. The delay consistency of communication without the data channel establishment delay is illustrated in the next section.

4.4.2 Result Analysis of Test Case 3 and Test Case 4

The Figure14 shows comparison of data transfer times T_{CCON} and T_{CWMG} measured in test cases 3 and 4.

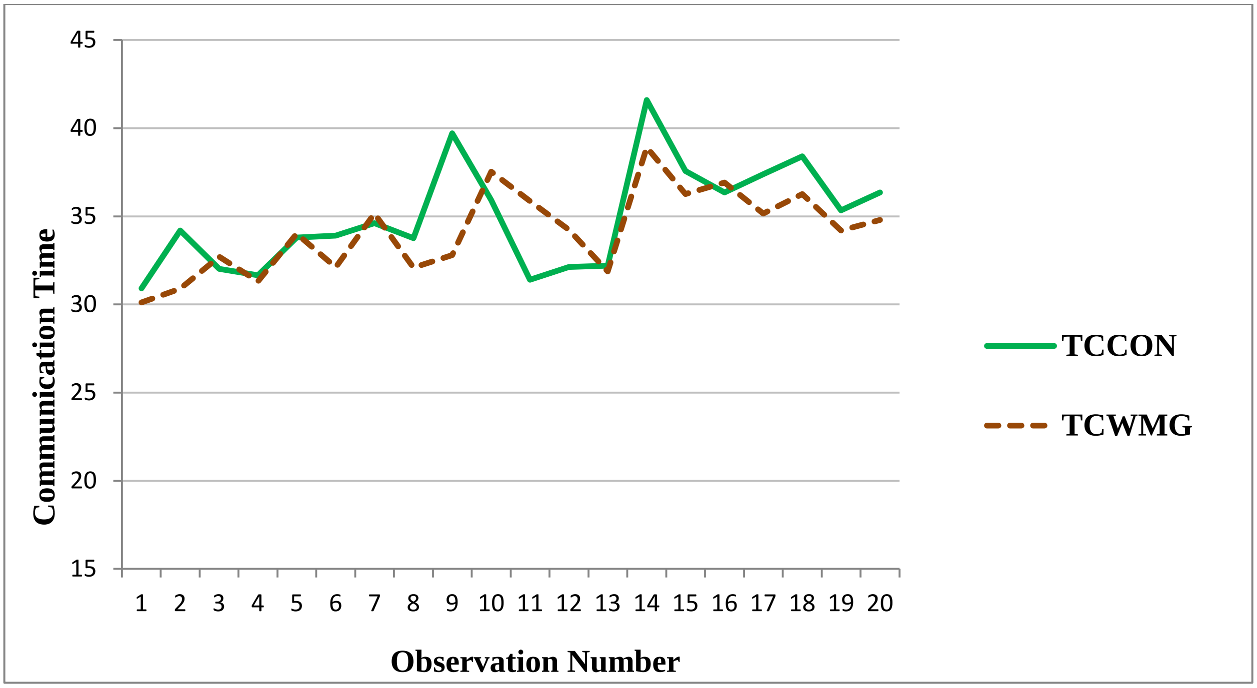

Figure14: The Comparison of CCON Time and CWMG time without Data Channel Establishment Delay

It is observed that the difference in the means of T_{CWMG} and T_{CCON} is 0.7965s. The deviation in T_{CCON} time is about ±2.86854s and the deviation in T_{CWMG} time is ±2.32934s. This illustrates that the maximum deviation in T_{CWMG} is 4.64879s whereas the maximum deviation in T_{CCON} is 5.73707s.

4.4.3 Result Analysis of Test Case 5:

The results of the test case 5 are plotted in Figure 15 and Figure 16. The measurement time varies from user to user based on their arm size. So, plotting total communication time for different users in one graph to get an even distribution is difficult. So, in this plot, ‘deviation from mean’ for a given user for 5 observations is plotted.

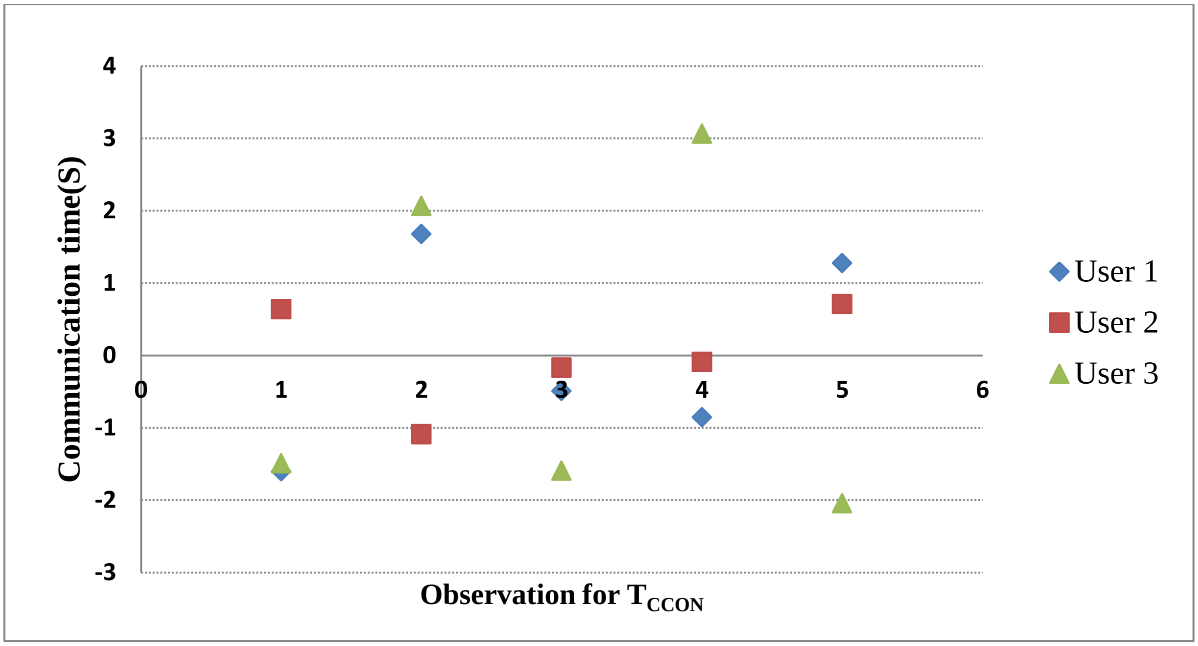

Figure 15 User to User CCON time without Data Channel Establishment Delay

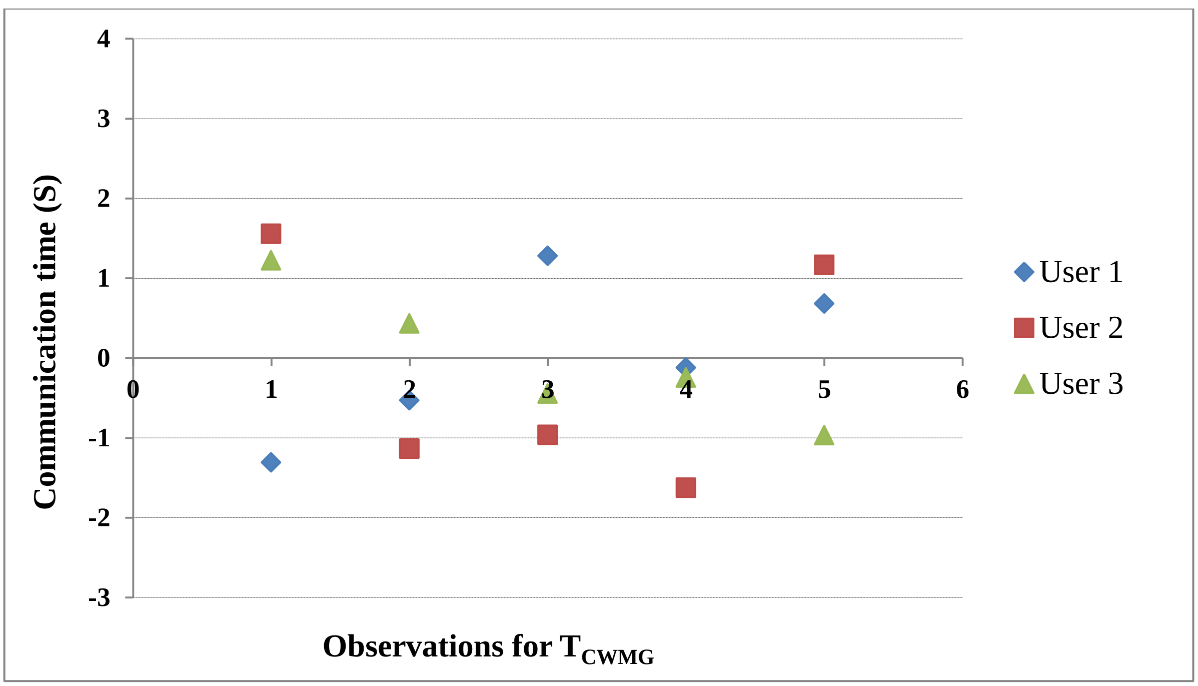

Figure 16: User to User CWMG time without Data Channel Establishment Delay

Suppose, the recorded communication time for an observation i is x_i and the mean of communication time for 5 observations is $\overline{x}$. Then deviation from mean is computed as $y_i = x_i - \overline{x}$.

It is demonstrated in Figure15 and Figure 16, that T_{CCON} has higher variation among the readings as compared to T_{CWMG}. The maximum variation in CWMG is for user 2 and T_{CWMG} is 3.18s. Whereas the maximum variation in CCON is for user 3 and T_{CCON} is 5.11s. As discussed earlier in the result analysis of test cases 3 and 4, the standard deviation for T_{CCON} is about ±2.86854s and the deviation in T_{CWMG} is ±2.32934s. This shows that the designed WMG can operate at narrow delay margins consistently.

4.4.4 Analyzing Accuracy in Data Transfer

In table 1, a comparison of data as read on BPM against the data received on the designed WMG is shown. The BPM shows the data in decimal. The WMG shows the data on the terminal in hexadecimal. For easier comparison, the data received on the WMG is converted to decimal.

Observation	**Sent Data (Decimal)**	**Received Data (Hex)**	**Received Data (Decimal)**
1	Systolic: 114 Diastolic: 78 Pulse/Min: 88	Systolic: 72 Diastolic: 4E Pulse/Min:58	Systolic: 114 Diastolic: 78 Pulse/Min: 88
2	Systolic: 115 Diastolic: 75 Pulse/Min: 78	Systolic: 73 Diastolic: 48 Pulse/Min:4E	Systolic: 115 Diastolic: 75 Pulse/Min: 78
3	Systolic: 114 Diastolic: 80	Systolic: 72 Diastolic: 50	Systolic: 114 Diastolic: 80

	Pulse/Min:76	Pulse/Min: 4C	Pulse/Min: 76
4	Systolic: 114 Diastolic: 80 Pulse/Min: 76	Systolic: 72 Diastolic: 50 Pulse/Min: 4C	Systolic: 114 Diastolic: 80 Pulse/Min: 4C
5	Systolic: 114 Diastolic: 82 Pulse/Min: 79	Systolic: 72 Diastolic: 52 Pulse/Min: 4F	Systolic: 114 Diastolic: 82 Pulse/Min: 79
6	Systolic: 114 Diastolic: 79 Pulse/Min: 79	Systolic: 72 Diastolic: 4F Pulse/Min:4F	Systolic: 114 Diastolic: 79 Pulse/Min: 79

Table 1: The Comparison between receive data and sent data

The comparison in table 1 shows, that there is no discrepancy between received data and sent data. This proves that the data transfer is 100% accurate.

4.5 Summary

The various testing scenarios for the designed WMG and their results analysis has been provided in this chapter. Test case results show that the deviation in the communication delay is very minimal and thus the designed WMG has a very good delay consistency while maintaining the 100% accuracy in the data receiving. A comparison of different communication times against the communication time of Continua Manager has also been shown in this chapter.

5. CONCLUSION

The Wireless Medical Gateway (WMG) designed and implemented in this thesis, meets all the design goals. It can connect to Bluetooth enabled Continua complaint medical devices and communicate with them with consistent communication delay. Being continua compliant, it is readily interoperable with medical devices from different manufacturers who follow the same guidelines. Through various test cases and their results analysis, it is observed that the communication time variation is ± 2.33 seconds and this variation is consistent across the users of different body physics. It can connect to the internet through an Ethernet interface and successfully send the medical data to remote server. Through various measurements it is observed that medical data is always received at the WMG without any error.

Establishing the initial communication between the designed WMG and Continua compliant medical device has been challenging, primarily because of abstractness in the Stollmann adapter functionality and non-availability of tools to sniff over-the-air Bluetooth communication. Because of these challenges, Local Transport Protocol (LTP) interface library could not be developed for BT-CC communication. Now, that good information on BT-CC communication is available in this thesis, development of the LTP library can be taken up as extension and future work. Adding the connectivity with medical devices with low power Bluetooth (BTLE) and ZigBee interfaces can be taken up as future development.

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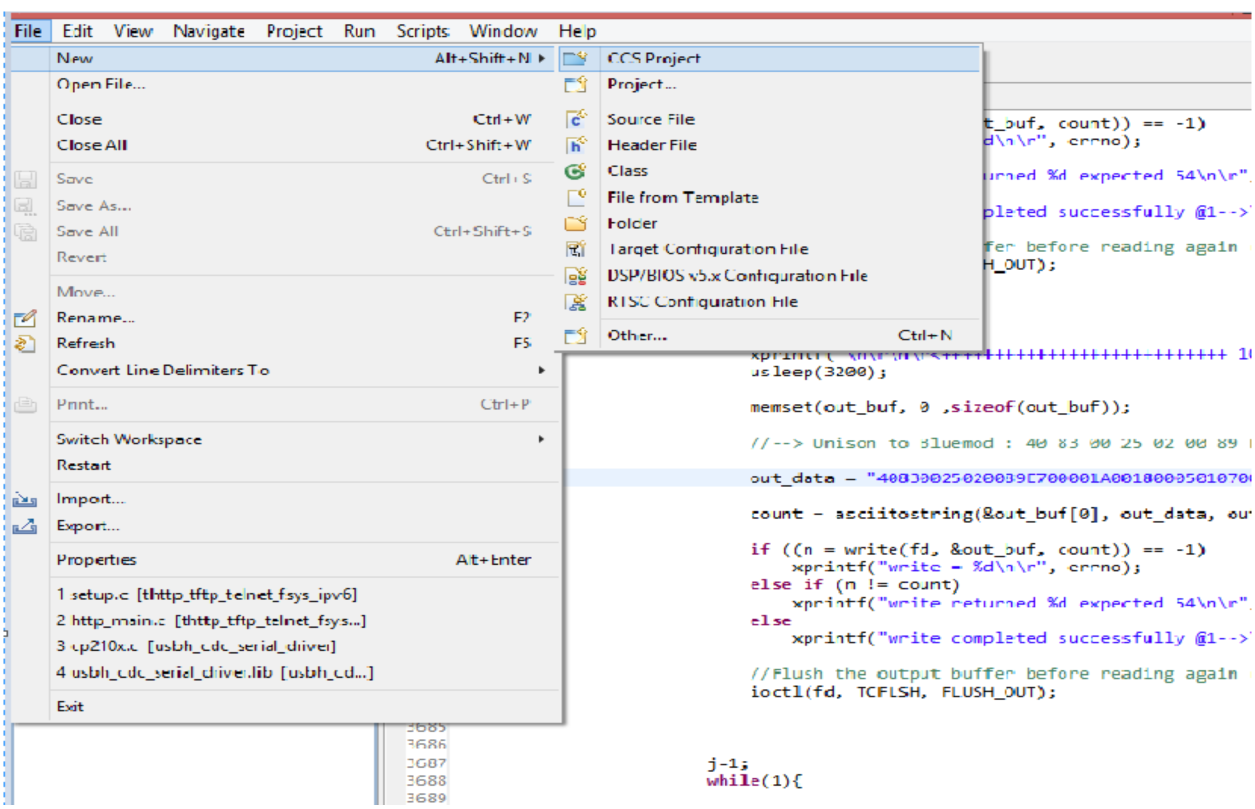
APPENDIX

A. Code Composer Studio Setup and Working

- Download the **offline installer** for CCS 5.5.x for windows.
- After extracting the CSS 5.5.x_Win32.zip file browse for the executable file called "CSS_setup _5.5.x.exe".
- Now right click on the file and choose "Properties". Open the compatibility tab check "Run this program in compatibility mode for:" and then select "Windows 7" in the subsequently enabled drop down menu. Click apply and then ok.
- Temporarily disable any active virus scanning software and firewalls.
- Right click on css"_setup_5.5.x and choose "Run as administrator".



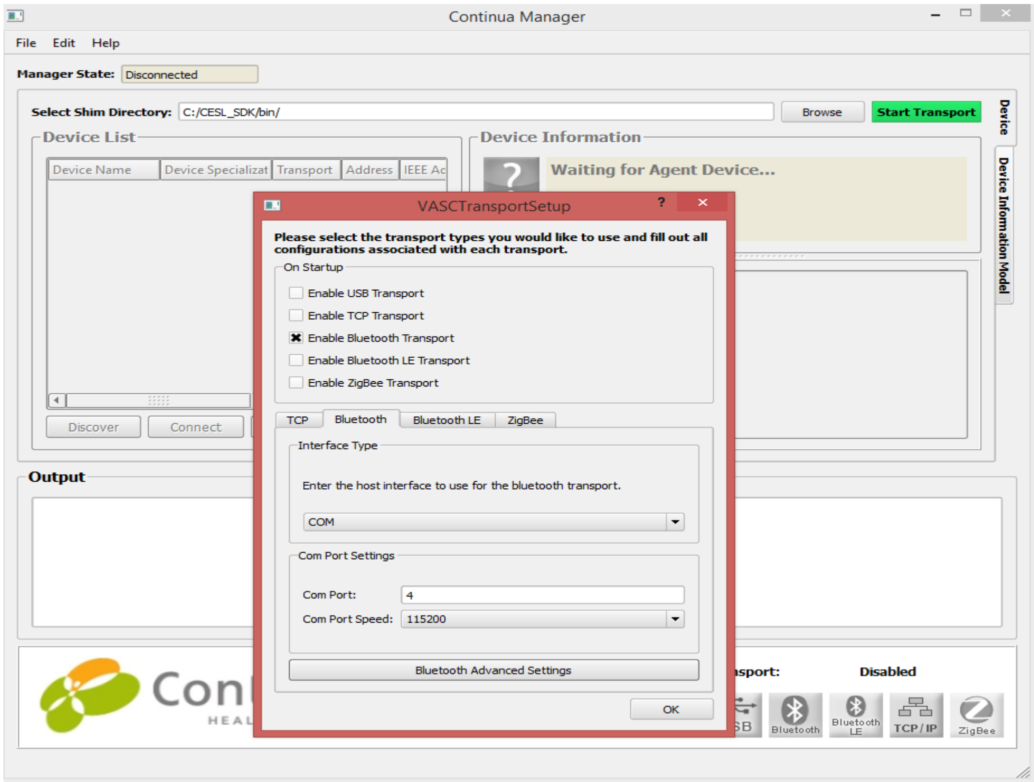
- Now tailor the installation process to suit your system requirements. In this research for "Processor Support", install "Sitara AMxxx processor". On the "Components" install all Texas Instruments related options like "TI ARM Complier Tools" and "TI Simulators" as well as the "GCC ARM Compiler Tools". Finally under the "Emulators" options, "XDS100 Class Emulator Support" needs to select.
- Now after you start CCS; go to "New" in “File” drop down menu and select “CCS Project".
- Then import the OS modules inside the project explorer.
- Then run the project following building and debugging the project. Before running the process The WGM has to be connected with system and powered externally.

B. Continua Manager Setup and Working

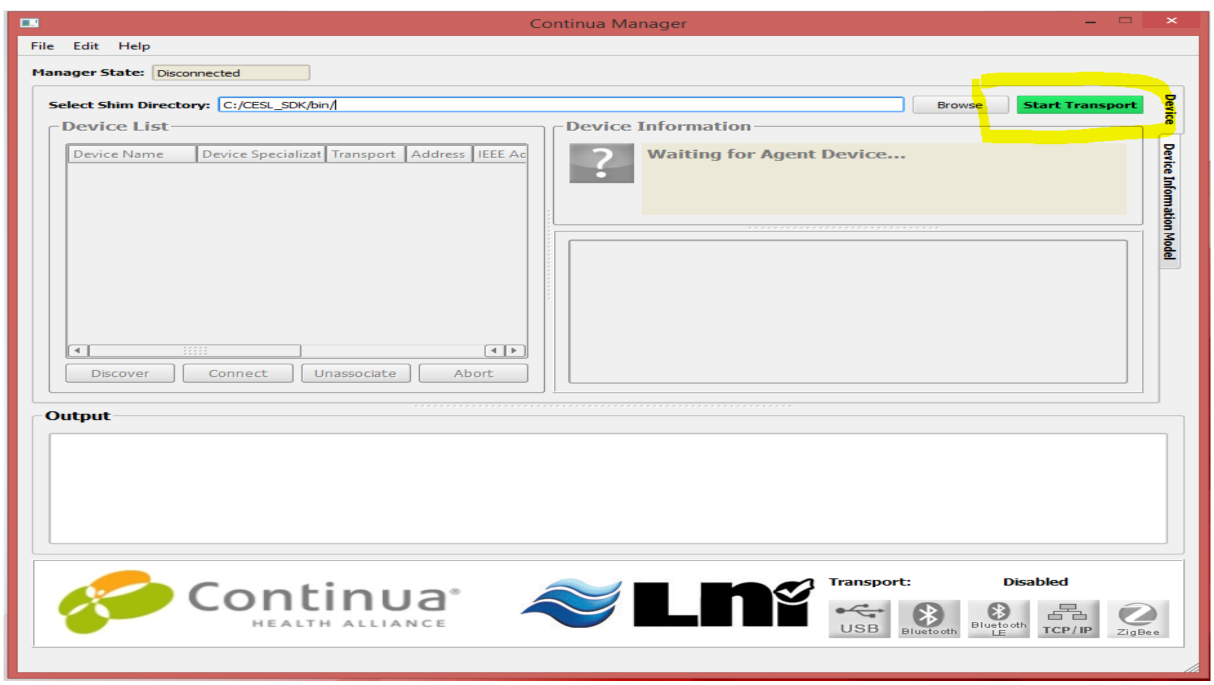
- Continua Manager setup file is provided by the Continua alliance after taking membership.
- Any organization can become a member of continua at this address, by paying a membership fee of $1000.

"http://www.continuaalliance.org/about-the-alliance/join"

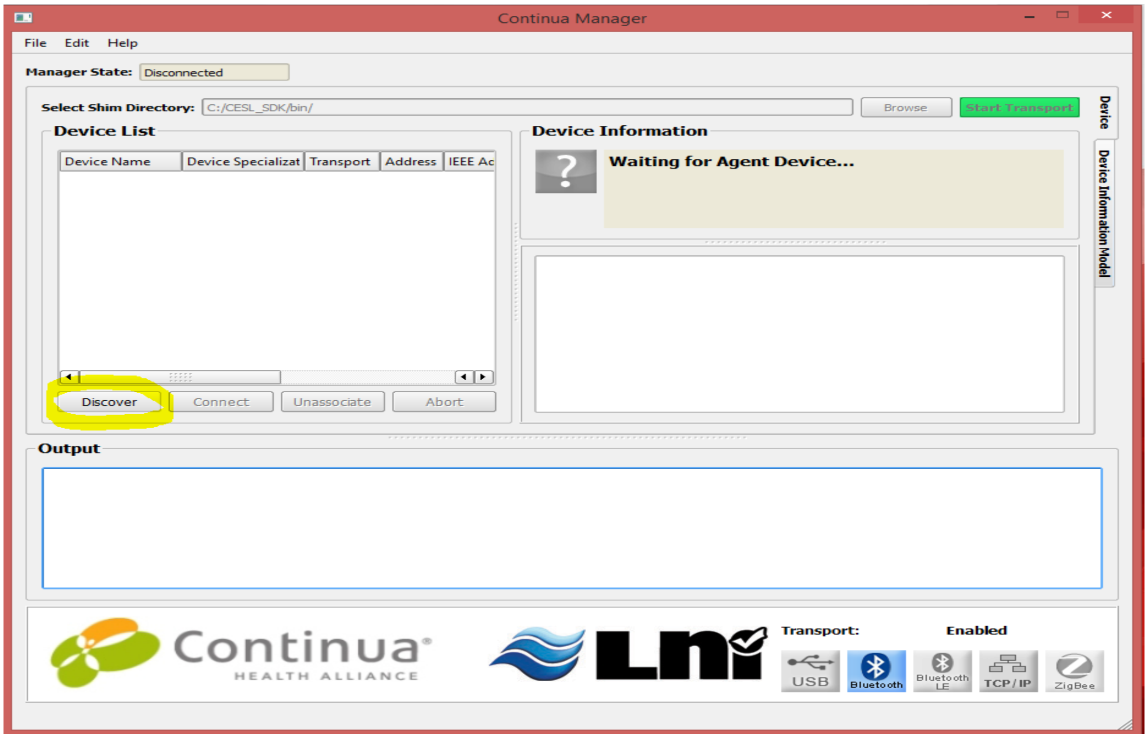
- Continua alliance provides a file called CESL_v4.0_Relese_to_Members
- An installation file called CESL_SDK_4.0.msi will be there in the folder.
- Install the CESL_SDK file in desired location, preferably, in C drive.
- Then open the location of installation find "ContinuaManagerGUI.exe" application and install it.
- After opening the continua manager first enable the Transport type as shown in the image below. This option is available in the “Edit” drop down menu.



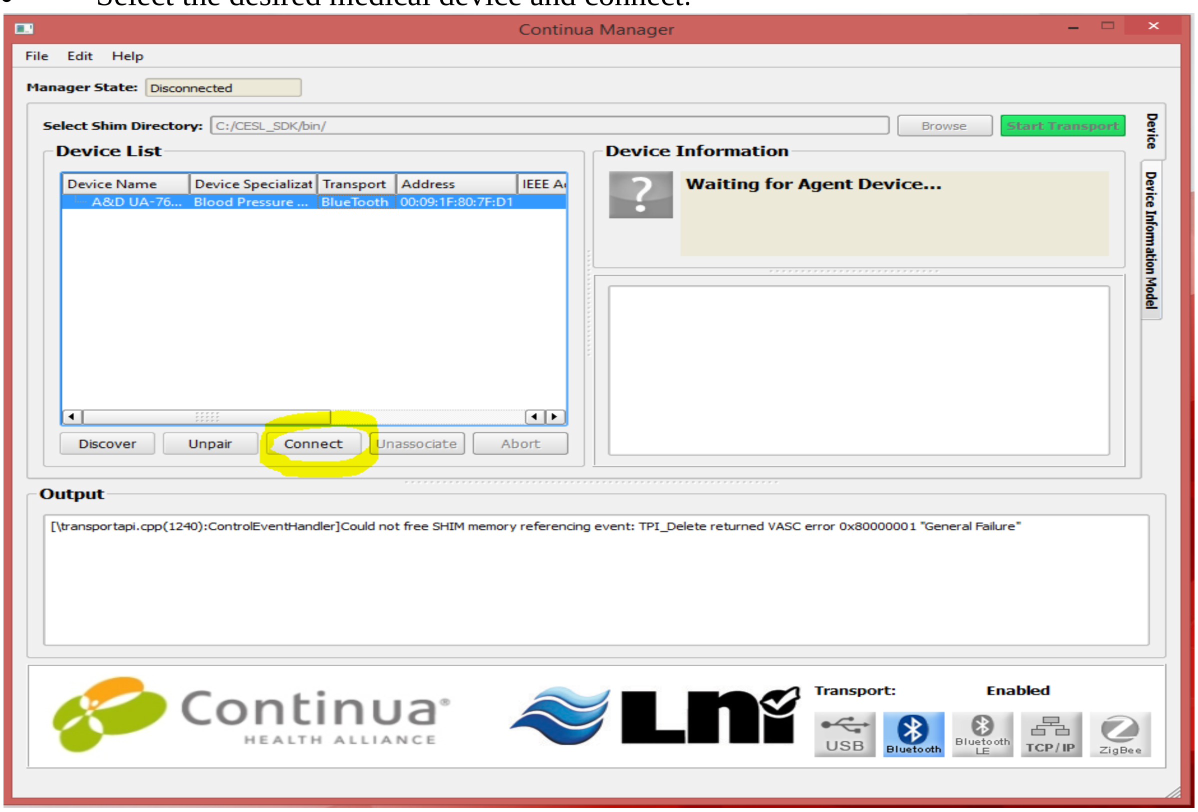
- Click "Start transport" to start the communication.



- The click discovers to discover the Continua certified medical device nearby.



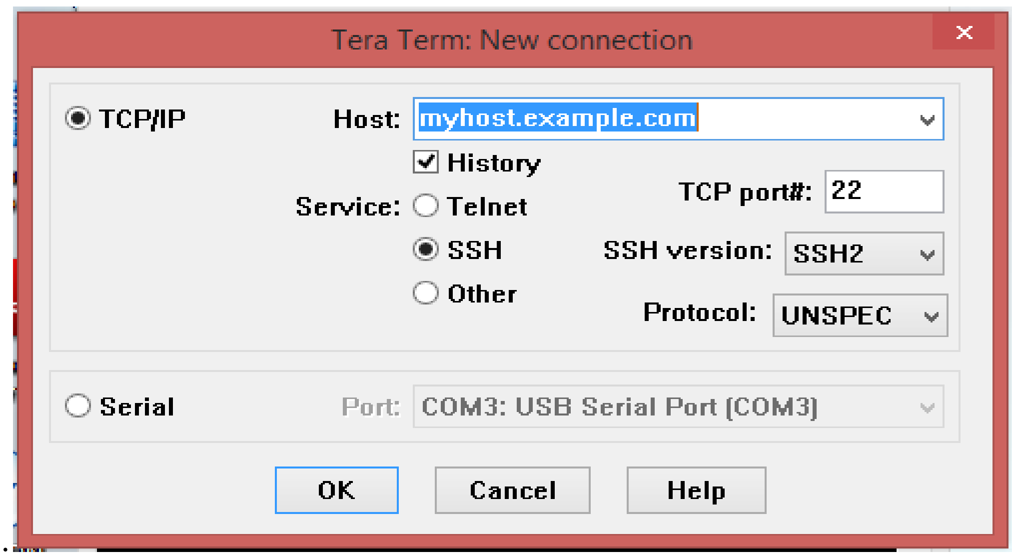
- Select the desired medical device and connect.



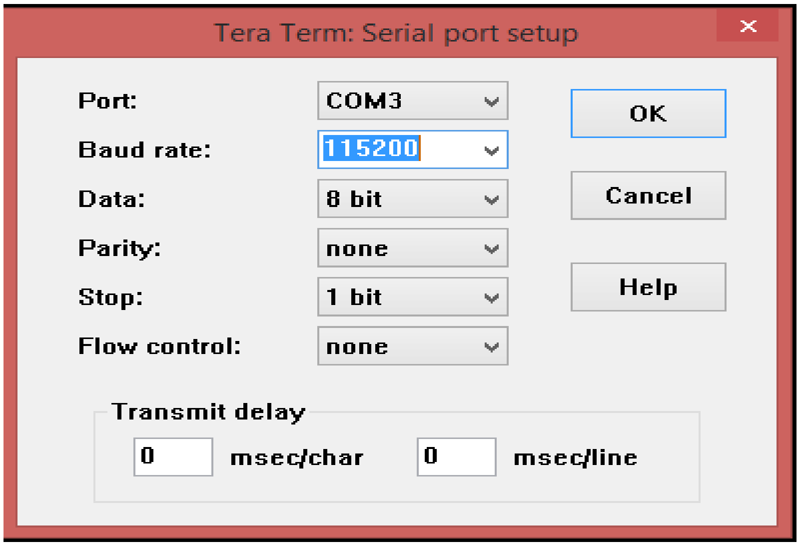
- Now Blood Pressure Monitor can be started to take the data from human body.

C. Teraterm Setup and Working

- Download from http://download.cnet.com/Tera-Term/3000-20432_4-75766675.html
- Double click ttermp23.exe and unpack it into C:\TEMP\tterm
- Double click C:\TEMP\tterm\setup.exe and install
- Make a shortcut to C:\Program Files\ttermpro\ttsh.exe for your start-up menu, desktop or both.
- Now after starting the tera-tem a dialogue box will pop-up, cancel it.



- Then open the ‘Serial’ option from the ‘Setup’ drop down menu. Put the configuration as shown in the figure below.
- Use comport number in which the WMG in connected to your PC. In this case, it is COM3. Press Ok.



Now you are connected to the WMG.

VITA AUCTORIS

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