A MOBILE DIABETES MANAGEMENT AND INTERNETWORKING SYSTEM

Ying Zou

A THESIS SUBMITTED IN PARTIAL FULLFILLMENT OF
THE REQUIREMENTS OF KINGSTON UNIVERSITY
FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

Faculty of Computing, Information Systems and Mathematics
Kingston University

Submitted: December, 2005

To my husband Bin and my son Naxin

Acknowledgement

First and foremost, I would like to express my sincere and deep gratitude to my supervisor – Prof. Robert S. H. Istepanian. I will always be grateful for his continuous advice and diligent supervision of this work.

I would like also to acknowledge the support of Orange, UK for the funding and the provision of mobile network facilities for this study.

I would also like to thank Faculty of Computing, Information Systems and Mathematics, Kingston University for providing me with this opportunity to fulfill this research, especially to Prof. Timothy Ellis, Dean of the faculty, for his support and suggestions.

I have had the pleasure of being a member of MINT Centre and MOMED group. Especially thanks for the support from Dr. Henry Wang. Thanks also for the friendship and encouragement from Mr. Tom Geake, Ms. Nada Philip, Mr. Ala Sungoor, Mr. Salem Garawi, Dr. David Wertheim and Mr. Nilesh Prag in the group.

I am grateful to Prof. Yonghua Song for his support at the beginning of project. I appreciate the advice of Dr. Janet Cole on thesis writing, Ms. Bee Tang who has provided invaluable administration guidance and support throughout this research.

My appreciation also goes to Dr. Steve Bain from Birmingham Heartland Hospital, Dr. Kenneth Earle and Ms. Diane Harry from St. George's Hospital, for their kind medical suggestions and help for the clinical trial.

This thesis could not have been accomplished without the love from my husband - Bin Wang and my son- Naxin and the love from my parents, my sister and my brothers. Thanks for their support.

Finally, I would like to thank all of those who have helped me and showed their support. They are always in my mind and with my best wishes.

Abstract

Diabetes is a chronic, progressive disease that affects 1.8 million people in UK, and more than 194 million worldwide. It is currently ranked amongst the leading causes of chronic disease related death because of the occurrence of its life threatening complications.

This thesis presents the design, implementation and evaluation of a mobile diabetes management and internetworking system (MDMIS). The system is based on Bluetooth and GPRS wireless communication technologies and provides an improved ubiquitous diabetes management service to both the diabetes sufferers and medical doctors.

The MDMIS consists of modular suites of medical control centre, patient stations, physician stations, medical administration stations, and system maintenance stations. A patient station acquires the blood glucose measurement autonomously from a Bluetooth enabled glucose meter and transmits the data to a tailored MDMIS administration system via a GPRS wireless communications link. The medical centre of the system provides the relevant management services to both patients and physicians, such as updating user information and medication plans, side-effects reporting, analysis and alarming of blood glucose measurements, together with medical management procedures. These tasks can be accessible by patients and medics through a simple interface from various devices powered by different operating systems. The security issues of MDMIS are addressed briefly. The prototype of the system has been tested successfully. The system performance analysis of these tests is also presented in this study.

The thesis also addresses the interoperability issues between mobile chronic disease management system and medical devices for universal mobile healthcare applications. An architectural framework to improve interoperability for m-health applications is presented and discussed. This architecture has been initially implemented successfully on the MDMIS system.

Table of Contents

Glossary

ACK : Acknowledge
ACL : Asynchronous Connection-Less
APN : Access Point Name
ARC Group : Advanced Research Committee
ASCII : American Standard Code for Information Interchange
AuC : Authorisation Centre
BD_ADDR : Bluetooth device address
BSSGP : Base Station System GPRS Protocol
BTS : Base Transceiver Station
CDC : Connected Device Configuration
cHTML : Compact HTML
CLDC : Connected Limited Device Configuration
CLI : Common Language Infrastructure
CLR : Common Language Runtime
CRC : Cyclic Redundancy Check
CS : Coding Schemes
CVD : Cardiovascular Disease
DAM : Data Accessing Module
DCCT : Diabetes Control and Complications Trial
DECT : Digital Enhanced Cordless Telecommunications
DH : Data High
DLL : Dynamic Link Library
DM : Data Medium
DSMN : Diabetes Self-Management Network
DTD : Document Type Definition
DUNP : Dial-up Networking Profile
DUNP : Dial-up Networking Profile
EJB : Enterprise JavaBeans
EOD : Early Onset type-2 Diabetes
EOT : End of Text
EPR : Electronic Patient Records
ERD : Entity-Relationship Diagram
ETSI : European Telecommunications Standards Institute
FEC : Forward Error Correction
FTP : File Transfer Profile
GAP : Generic Access Profile
GGSN : Gateway GPRS Support Node
GMSC : Gateway Mobile Switching Centre
GOEP : Generic Object Exchange Profile
GPRS : General Packet Radio Service
GSM : Global System for Mobile
GTP : GPRS Tunnelling Protocol
HBGM : Home Blood Glucose Measurements
HDML : Handheld Devices Markup Languages
HIPERLAN : HIgh PErformance Radio LAN
HiSWANa : High Speed Wireless Access Network

HLR : Home Location Register
HomeRF :Home Radio Frequency
HTML : HyperText Markup Language
HTTP : Hypertext Transfer Protocol
HV Packet : High-rate voice packet
ID : IDentification
IDDM : Insulin Dependent Diabetes Mellitus
IDF : International Diabetes Federation
IEEE : Institute of Electrical and Electronics Engineers
IETF : The Internet Engineering Task Force
ISM : Industrial, Scientific, and Medical
J2EE : Java 2 Platform, Enterprise Edition
J2ME : Java2 Micro Edition
Java VM : Java Virtual Machine
JDBC : Java Database Connectivity
JMS : Java Message Service
JPEG : Joint Photographic Experts Group
JSP : JavaServer Pages
L2CAP : Logical Link control and Adaptation protocol
LAP : Lower Address Part
LC : Baseband Link Controller
LLC : Logical Link Control
LMP : Link Manager Protocol (LMP)
MAC : Media Access Control
MAP : Mobile Application Part
MDMIS : Mobile Diabetes Management and Internetworking System
MFE : Medical Front End
MIDD : Maternally Inherited Diabetes and Deafness
MIDP : Mobile Information Device Profile
MIME : Multipurpose Internet Mail Extensions
MMAC : Multimedia Mobile Access Communication
MMS : Medical Master Station
MODY : Maturity Onset Diabetes of the Young
MRTU : Medical Remote Terminal Units
MS : Maintainer Station, Mobile Station
MSC : Mobile Switching Centre
MVC : Model-View-Controller
NAP : Non-significant Address Part
NHS : National Health Service
NICE : National Institute for Health and Clinical Excellence
NIDDK : American National Institute of Diabetes and Digestive and Kidney Diseases
NIDDM : Non-Insulin Dependent Diabetes Mellitus
NSF : National Service Framework
OBEX : Object Exchange
OEM : Original Equipment Manufacturer
OPP : Object Push Profile
PCU : Packet Control Unit
PDA : Personal Digital Assistant
PDCH : Packet Data Channel
PDP : Packet Data Protocol
PNG : Portable Network Graphics

PPP : Point-to-Point Protocol
QoS : Quality of Service
RDBMS : Relational Database Management System
RFCOMM : Radio Frequency Communications
RLC : Radio Link Control
RTT : Round-trip Time
SCO : Synchronous Connection-Oriented
SDAP : Service Discover Application Profile
SDP : Service Discovery Protocol
SGSN : Serving GPRS Support Node
SIP : Session Initiation Protocol
SNDCP : Sub-Network Dependent Convergence Protocol
SOAP : Simple Object Access Protocol
SPA : Serial Port Adaptor
SPP : Serial Port Profile
SQL : Standard Query Language
SRW : Short-range Wireless
SSL : Secure Socket Layer
STX : Start of Text
TBF : Temporary Block Flow
TCP/UDP/IP : Transfer Control Protocol/User Datagram Protocol/Internet Protocol
TCS BIN : Telephony Control protocol Binary
TDMA : Time Division Multiple Access
UAP : Upper Address Part
UDDI : Universal Description Discovery and Integration
UI : User Interface
UKPDS : United Kingdom Prospective Diabetes Study
UMTS : Universal Mobile Telecommunications System
UWB : Ultra Wideband
W3C : World Wide Web Consortium
WAE : Wireless Application Environment
WAP : Wireless Application Protocol
WHO : World Health Organization
WLAN : Wireless Local Area Network
WML : Wireless Markup Language
WSDL : Web Service Definition Language
WPAN : Wireless Personal Area Network
XHTML : Extensible Hypertext Markup Language
XML : Extensible Markup Language
XSL : Extensible Stylesheet Language

List of Tables

List of Figures

Chapter 1

Introduction

Diabetes is a serious chronic disease with potentially devastating complications. There are at least 2.8 % of the world's population with diabetes; this Figure is likely to more than double by 2030 [1]. The ever-growing population of diabetes translates to enormous amounts on the healthcare costs and healthcare personnel time that need to be expended in order to treat the patients effectively and timely. In the UK, the NHS spends around 5% of its budget (about £10 million a day) treating diabetes related diseases [2]. A study estimated that by 2011 NHS spending on diabetes will rise to ten percent [2].

Diabetes is currently ranked amongst the leading causes of chronic disease related death. Mortality rates are up to five times higher for people with diabetes [3] . According to the National Service Framework for Diabetes (NSF) Standards document (2001), life expectancy is reduced on average by more than 20 years for Type 1 diabetes and up to ten years for Type 2 diabetes [4].

Fortunately, research studies have shown that many complications of diabetes can be prevented or delayed through effective management, which means that effective therapy, life-style intervention and interactive disease management can delay the onset of diabetes complications, thus reducing relevant cost escalation [1] [2] [5] [6] [7].

Recent years have witnessed numerous 'wired-telemedicine' follow-up solutions and studies for diabetic care. These studies represented an initial and major drive for patient centred care and showed significant benefits to the management of this major chronic disease.

With new and emerging technologies in mobile telecommunications and handheld computers, it is envisaged that a considerable qualitative and quantitative improvement can be achieved for an effective and timely diagnosis and treatment of diabetes patients, with a subsequent improvement in cost effectiveness and management of the available resources.

The research of the Mobile Diabetes Management Internetworking System (MDMIS) is to exploit mobile computing concepts to provide improved diabetes management and to empower diabetes patients.

This chapter presents the research's motivation, aims, objectives and general structure of the thesis.

1.1 Motivation of the Research

1.1.1 Introduction to Diabetes

Diabetes is a chronic and progressive disease; it is characterized by a raised blood glucose level. Diabetes comprises a group of disorders. It is the result of a lack of the hormone insulin and/or an ineffectiveness of the insulin produced. Insulin is a hormone produced by the pancreas; it is in the blood to ensure that glucose obtained from food can be utilized by the body [4]. The deficiency of insulin leads to an increased concentration of glucose in the blood, which may damage tissues in the body. High levels of glucose in the blood may cause medical complications [8].

The criteria for the diagnosis of diabetes are shown as in the following Figure:

WHO Diagnosis criteria for diabetes

1. Symptoms of diabetes plus casual venous plasma glucose not less than 11.1 mmol/l.
2. Fasting plasma glucose not less than 7.0 mmol/l or whole blood not less than 6.1 mmol/l.
3. 2 hour plasma glucose not less than 11.1 mmol/l during oral glucose tolerance test using 75g glucose load.

In the absence of symptoms, these criteria should be confirmed by repeat testing on a different day. If the fasting or random values are not diagnostic, the 2 hour value post-glucose load should be used.

Note:

Fasting plasma glucose < 6.1mmol/l – Normal
Fasting plasma 7.0 mmol< glucose ≤ 6.1mmol/l – Impaired fasting blood glucose
Fasting plasma glucose ≥ 7.0mmol/l – Provisional diagnosis of diabetes; the diagnosis must be confirmed.

The typical symptoms of diabetes include polyuria, polydipsia and unexplained weight loss.
Fasting is defined as no recent calorie intake for at least 8 hours.
Casual is defined as any time of day without regard to time since last meal.

Source: Diabetes Care 1997;20:1183-1195

Figure 1. WHO Diagnosis Criteria for Diabetes

1.1.2 Diabetes diagnostic categories

The WHO classification system has divided diabetes into three major types of diabetes, type 1 diabetes, type 2 diabetes and gestational diabetes. This categorization is mainly based on the etiology of diabetes [10].

(i) Type 1 Diabetes

A. Definition

Type 1 diabetes is formerly known as insulin-dependent diabetes mellitus (IDDM), immune-mediated or juvenile-onset diabetes.

People with type 1 diabetes are usually unable to produce insulin because the insulin-producing cells (β-cells) have been destroyed by the body's immune system [4]. Scientists do not know what exactly causes type 1 diabetes, but they believe that auto-immune, genetic and environmental factors are involved [11].

B. Symptoms

The typical symptoms of type 1 diabetes are excessive secretion of urine, thirst, weight loss and tiredness [12].

C. Prevention and treatment

Type 1 diabetes is treated by insulin injections, diet and regular exercise [13].

D. Prevalence

This type of diabetes usually appears before the age of 40, it develops more commonly in children, youth and young adults [13].

IDF (International Diabetes Federation) estimates that more than 17 million people worldwide have type 1 diabetes. According to news release from Diabetes UK, there are approximately 350,000 people with Type 1 diabetes in the UK [11].

(ii) Type 2 Diabetes

A. Definition

Type 2 diabetes, formerly named Non-Insulin-Dependent Diabetes Mellitus (NIDDM), results from the body's inability to respond properly to the action of insulin produced by the pancreas.

B. Symptoms

The possible symptoms may be tiredness, frequent urination, increased thirst, weight loss, blurred vision and frequent infections.

C. Prevention and Treatment

People with Type 2 diabetes need to adjust their diet and their lifestyle. Some patients need to take tablets and/or insulin to achieve control of their blood glucose level [13].

Type 2 diabetes can be delayed or even prevented by prompting a balanced diet and physical activity [8] [9].

D. Prevalence

Type 2 Diabetes occurs most frequently in adults, but is being increasing significantly in adolescents as well. It is much more common and accounts for around 90% of all diabetes cases worldwide [15]. In the UK, over 1.5 million people (about 85% of total diabetics) have type 2 diabetes; it also indicates the number of people with undiagnosed Type 2 diabetes are estimated to be between 765,000 and one million [2].

(iii) Gestational diabetes

Gestational diabetes is associated with pregnancy and symptoms usually disappear after the birth. If a woman has gestational diabetes, she will have a higher risk of developing one of the main types of diabetes later in life.

Studies have also identified new variants of the disease, which have resulted in major changes in the classical classification and understanding of diabetes, these including the new variants of Maturity Onset Diabetes of the Young (MODY), Early Onset type-2 Diabetes (EOD) and Maternally Inherited Diabetes and Deafness (MIDD) and other types [14].

1.1.3 The importance of diabetes management

The importance of diabetes management can be justified by the following issues:

(i) Increasing Onset of Diabetes

According to Diabetes UK's report, Diabetes affects 1.8 million people(about 3% of the total population) in UK [16], over 60 million people in the enlarged Europe EU [17], and more than 194 million worldwide [5] [10]. Moreover, the findings from Wilds, Sarah etc. indicate the number of people with diabetes has been increasing, "due to population growth, ageing, urbanization, and increasing prevalence of obesity and physical inactivity"[15]. This report also presents that the estimated number of diabetes sufferers worldwide would be increased from 171 million (2.8% of total population) in 2000 to 366 million (4.4% of total population) in 2030.

(ii) Diabetes Is a Life-threatening Condition

Furthermore, diabetes is a major cause of death; every year 5% deaths (3.2 million) are attributable to Diabetes in the world [18]. Diabetes itself doesn't threat a life, but people with long-term diabetes may suffer complications which affect eyes, kidneys, nerves or major arteries. These complications put diabetics' lives at risk.

Diabetes seriously affects patients' life age because of complications, and surveys have shown that:

--About 80% people with diabetes will die from Cardiovascular Disease (CVD) [2][19].

-- The rate of lower limb amputations in people with diabetes is 15 to 40 times higher than in those people without diabetes [19].

-- People with diabetes have two to four times the risk of developing atherosclerosis compared to people without diabetes [19].

-- Nephropathy (kidney disease) causes long-term high blood glucose levels that may damage small blood vessels. Kidney disease is a major cause of kidney failure and death.

(iii) Diabetes As a Costly Disease

A. High spending of health providers or organizations for diabetes

The spending by health providers or organization on diabetes and its compliments are huge. According to the World Health Organization (WHO), it is estimated that about 2.5-15% of annual health budgets from different countries is spent on diabetes-related illnesses [20]. In the United Kingdom, "around 5% of total NHS resources and up to 10% of hospital in-patient resources are used for the care of people with diabetes" [4]. Another study shows U.S. health expenditures for the health care components totaled $160 billion out of $865 billion was incurred by people with diabetes [21]. Furthermore, recent research also shows "The management of diabetic complications (microvascular and macrovascular) increased NHS costs by over 500 percent compared with patients without complications" [22] .

B. Cost from diabetes individuals and their families

Not only the diabetics and their families spend time or money on medical care and medicines for diabetes, but the affected individual may suffer a painful and inconvenience life.

Table 1 shows the direct and indirect cost incurred by diabetes and diabetes complications.

Direct costs	Indirect costs
• Preventive services; • Diagnosis; • Treatment; • In patient care; • GP consultations; • GP prescriptions; • Diabetes clinics; • Specialist diabetes nurses; • Long-term residential and nursing care;	• Loss of working days and/or productive output due to illness, disability or death • Reduced quality of life.

Table 1. Direct and Indirect Cost Incurred by Diabetes [23]

(iv) Shortage of Specialist Nursing Staff

Another well-known fact is that the shortage of specialist nursing staffs and lack of bedding in NHS urges an effective and intelligent diabetes management to reduce medical human resourse spending.

Conducted on behalf of Diabetes UK and The Royal College of Physicians (2001), the Diabetes Medical Manpower Survey shows that existing staffing levels fall far below recommended targets. It also points that only about 20 percent health authorities in England and Wales currently have the recommended number of consultants. It is already proving difficult filling existing consultant posts due to a lack of suitable applicants [24].

(v) Effective Diabetes Management can Reduce Diabetes Complications

Diabetes cannot be cured; nevertheless, it often can be managed with proper medical care, diet, and regular exercise. Researches have shown that many complications of diabetes can be prevented or delayed through effective management; a full and healthy life is possible with diabetes [1].

In 1993, A clinical study - DCCT (Diabetes Control and Complications Trial), which was conducted by American National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) conclusively demonstrated that lowering blood glucose to near-normal levels decreases the risk of both the development and the progression of complications in people with Type 1 diabetes: 76% reduced risk on eye disease, 50% reduced risk on kidney disease and 60% reduced risk on nerve disease [5].

In 1998, the results of the UKPDS (United Kingdom Prospective Diabetes Study) have given convincing evidence that life threatening complications in people with Type 2 diabetes can be significantly reduced by appropriate treatment [6]. It shows "any improvement in blood glucose or blood pressure levels will help to reduce the risk of complications". The study also indicated "People with diabetes taking insulin injections will also often require dosage increases over time to maintain glycaemic control". Furthermore, it also shows intensive blood glucose control in patients with type 2 diabetes significantly increased treatment costs but substantially reduced the cost of complications and increased the time free of complications [7].

1.2 Mobility & Diabetes Management Issues

1.2.1 Potential of Mobile Users

It is well known that mobile technologies bring people a roaming environment to access their desired services. In another words, anywhere and anytime, users have the freedom to travel but keep in contact and being contacted from the benefit of mobile technologies.

Moreover, mobility reduces manual errors and costs. Data can be transmitted electronically and automatically without intermediate papers work.

Nowadays, with mobility in people's life style and with the convenience of mobile technology innovations, mobile devices have become many peoples' daily necessity.

According to an ARC group survey, there is a sharp increase in mobile data user penetration in recent years for Europe, USA and Japan, and a double global increase from 1999 to 2005 (see Figure 2). The mobile data includes access to data via cell phones, PDAs and interactive pagers.[25]

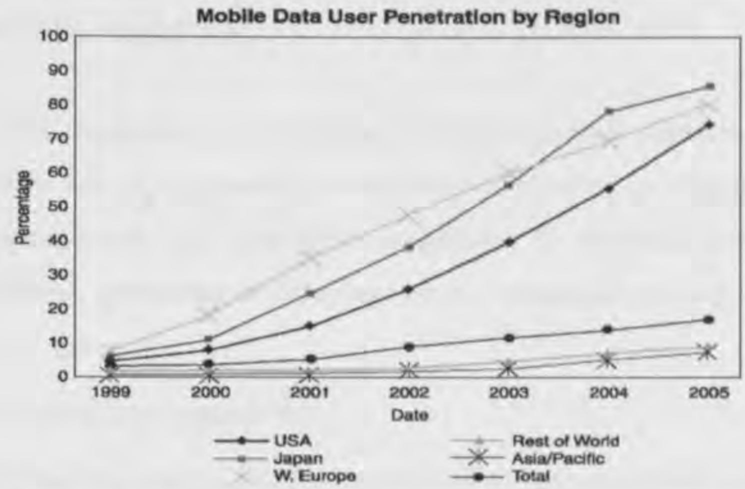


Figure 2. Mobile Data User Penetration by Region. Source: ARC Group [25][26]

1.2.2 From wired telemedicine to m-health

Telemedicine is defined as "The use of electronic information and communications technology to provide and support healthcare when distance separates participants." [27] . The communication means of it can be telephone, fax or computers. Since the first telepsychiatry practise was set up in late 1950s using two-way interactive television [28], the concept of telemedicine has been more than 40 years.

To date, the applications on telemedicine have spanned the areas of emergency healthcare, hospital information system to home monitoring.

M-Health is described as 'emerging mobile communication and network technologies for healthcare' [29]. This concept represents the evolution of e-health systems from traditional desktop 'telemedicine' platforms to wireless and mobile configurations. Current and emerging developments in wireless communications integrated with developments in pervasive and wearable technologies will have a radical impact on future healthcare delivery systems.

The recent clinical trials of the Diabetes Self-Management Network (DSMN) in Canada have shown that using the amalgamated technologies of handheld computing and web technologies would provide both effective cost saving and efficient patient care mechanisms [32]. However, there is no system yet in the UK that has adopted such a system.

The application of m-health technologies in diabetes management is critical and important. These technologies can link diabetes patients and their health care providers anytime and anywhere, and provide significant cost effective and efficient health care.

1.3 Aims of this research

The aim of this research is to develop an integrated mobile diabetes management system for diabetes care. Consequently, the system will provide a roaming environment for diabetes management and intelligent suggestions to patients, thus to achieve alleviating symptoms, preventing or delaying diabetes complications and improving the quality of patients' life.

The specific aims of this research are:

- To design and implement a prototype mobile diabetes management system.
- To study short-range Bluetooth and cellular GPRS connectivity issues to offer both patients and medical doctors a roaming environment for diabetes management.
- To facilitate digital patient records and a diabetes database in mobile environments.
- To provide an instant medical messaging service to alert and inform mechanisms diabetic patients of the necessary medication, along with wellbeing reminders.
- To develop an interoperability structure to improve the system's flexibility.

1.4 Thesis Contributions

The major contributions of this thesis are summarized as follows:

(1) Propose of a scaleble and portable framework for diabetes meanagement which is also suitable for other chronic disease management because of their common features.

(2) Design and development of a new Mobile Diabetes Management and Internetworking System (MDMIS). This system empowers both patients and medical doctors with a roaming environment for diabetes management by utilizing emerging wireless technologies.

(3) The implementation of the wireless data acquisition parts of the system. These include the Bluetooth short range wireless connectivity between the medical sensor device (source of blood glucose measurement records) and the GPRS mobile cellular network.

(4) The study and design of a wireless interoperability system that allows the universal

interface between commercially available medical sensing devices and relevant mobile terminals.

(5) Preliminary implementation of an interoperability structure for MDMIS.

(6) Preliminary testing of the system and performance evaluation to validate the proposed design architecture of MDMIS.

1.5 The structure of thesis

Chapter 2 includes an extensive literature review of relevant projects on remote diabetes managements systems. The future research trend of diabetes management is proposed. The aim of the chapter is to present the relevant background study of this research.

Chapter 3 involves the design concept of MDMIS and the internetworking structure of the system.

Chapter 4 details the choice of glucose meter, relative handsets and Bluetooth application development schemes used for MDMIS implementation together with the relevant wireless data acquisition and connectivity system.

Chapter 5 includes details of the design and implementation issues of the management platform and relevant database sub-system.

Chapter 6 details the preliminary laboratory tests and performance validation issues of the system.

Chapter 7 presents a software architecture for an interoperability for chronic disease management and its preliminary implementation on MDMIS.

Chapter 8 concludes the work and addresses the possible future research directions in this area.

Chapter 2

Mobile Diabetes Management Systems
A Literature Review

2.1 Introduction

This chapter explores the background research of mobile diabetes management and examines previous and ongoing research and study directions in this emerging area.

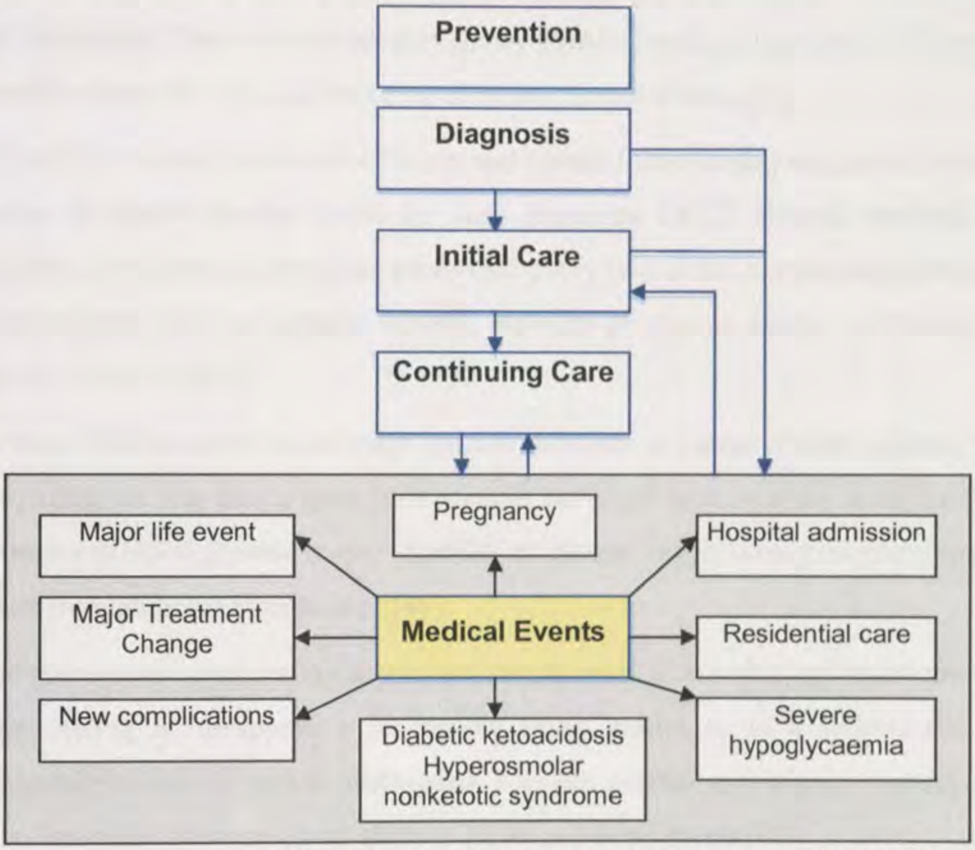
The chapter introduces diabetes managements at first, and then explores early telemedical approaches in diabetes management. The review details previous and ongoing wireless diabetes management technologies. It also compares different approaches and does an analysis of the advantages and shortcomings of each of these methods reviewed.

2.2 Diabetes Management

According to National Service Framework for Diabetes: Standards (2001) [4], the management of diabetes includes diagnosis, making care plan, clinical care, care during admission to hospital, patient education on diabetes self-management, management of diabetic emergencies, detection and management of long-term complications.Therefore, diabetes management is a long-term and complicate healthcare process that requires ubiquitous systems for improved care and better disease management procedures.

During the prevention stage, the major objectivity of management is to reduce the risk in the development of type 2 diabetes. The purpose of diagnosis is to identify the diabetes when there are signs of diabetes, thus the further management scheme can be made to reduce the risk of development of complications as soon as possible for a better outcome. Once the diabetes is diagnosed, the patient will be provided with personalised care program, education information about diabetes management. At the continuing care stage, the management is more about prevention and management of diabetes complications.

Figure 3 shows the general approach and procedures of diabetes prevention and management [4].



Source from: National Service Framework for Diabetes: Standard (2001)

Figure 3. General scheme for the prevention and diabetes management procedures

As the majority of diabetes care is self-care, home monitoring is essential for diabetes self-management in order to enable the patient to get appropriate treatment or lifestyle choices. The key for a patient to right control diabetes is to maintain his or her blood glucose levels at as near normal levels as possible. The only way to be accurately assessed and to be taken action is by monitoring blood glucose levels regularly. It is clear that extensive cost will be saved from self diabetes management through saving time and money on transport. On the other side, because of the reduced frequency of support needed from health providers, hospital admissions and further treatment by helping prevent those devastating complications are potentially decreased.

Haemoglobin is the substance in the blood that carries oxygen within red blood cells. The glucose sticks to the haemoglobin, which is 'glycosylated haemoglobin', also called haemoglobin A1C or HbA1C. By measuring the HbA1C, we can tell how high the blood glucose has been on average over the last 8-12 weeks [36]. The result is given in a percentage (%); the more glucose in the blood, the higher haemoglobin A1C or HbA1C will be present in the blood. A low Figure indicates that the blood glucose level is being controlled well [37]. A normal non-diabetic HbA1C is 3.5-5.5% (this varies between different hospitals). There is evidence that shows HbA1c levels of less than 7.0% could significantly reduce the risk of developing diabetic complications. [38]

NHS NICE (National Institute for Health and Clinical Excellence) suggested clinical monitoring of blood glucose levels by high precision DCCT-aligned methods of haemoglobin A1c (HbA1c) should be performed every two to six months depending on the achieved level of blood glucose control; stability of glucose control or change in medication regime [39][40].

However, HbA1c is only an average glucose indicator to assess overall control. For example, a diabetic may have a good HbA1c result but could have poor day to day control with extremes in blood glucose levels. "Stability of glucose levels is only measurable and achievable through home monitoring" [41].

Blood glucose and urine testing enable self-care in order to maintain optimum control. But urine testing is unsupportive for people using insulin or in a serious risk of hypoglycaemia because it cannot distinguish between normal and hypoglycaemia and there is a time delay between blood glucose levels and urine levels [41].

"The key to achieving optimal diabetes control is regular blood glucose measurement accompanied by a clear understanding of the diurnal profiles so obtained. The optimal insulin regimen can then be devised" [13]. "Self-tests are usually done before meals and/or at bedtime."[43] [44]

American Diabetes Associations also points out "Blood glucose checking is one of the best tools for keeping diabetes in control. Frequent testing and good record-keeping give you, your child, and the health care team the most accurate possible picture of her diabetes control."[45] Also, they emphasis the importance of the "records keeping", "The only way your health care team can make the right changes is if you hand them the real numbers." [43]

2.2.1 Unit of Blood Glucose Measurement

There are two main different units for describing blood glucose level: milligrams per deciliter (mg/dl) by weight and micromoles per liter (mmol/l) by molecular count. The conversion factor between these two units depends on the molecular weight of the substance in question.

The mg/dl (milligrams/deciliter) is the traditional unit for measuring blood glucose. The mmol/l (millimoles/liter) is the designated system international (SI) unit and the international standard unit for measuring glucose in blood. The mmol/l expression is used everywhere except in the United States. In the United Kingdom, mg/dl is applied as unit for measuring the blood glucose level. For patient convenience, we provide the conversion between the two measurement units.

The following table (Table 2) shows formulas for the conversion of mmol/l and mg/dl.

Conversion	Formula
From mmol/l to mg/dl	1 mg/dl = 1mmol/l * 18
From mg/dl to mmol/l	1mmol/l = 1mg/dl ÷ 18* or 1mmol/l = 1mg/dl * 0.055 * The result is rounded to a decimal place.

Table 2. Conversion Table of Blood Glucose Measurement Units

2.2.2 Measurement Range of Blood Glucose Level

The NICE guideline for type 1 diabetes management suggests the control target should be set "a pre-prandial blood glucose level of 4.0–7.0 mmol/l and a post-prandial blood glucose level of less than 9.0 mmol/l" [42]. The suggestions from some clinical experts are, " a 12-hour profile can be measured on a single day from time to time, taking recordings before meals (four times a day), one to two hours after meals (three times a day) and at bedtime"[12].

For type 2, the NICE guideline suggests the optimal frequency of self-monitoring should be based on the characteristics of individual blood glucose control, treatment regime and personal life style [42].

While Diabetes UK suggests people to set the blood glucose target at 4-7 mmol/l before meals (preprandial) and at no higher than 10 mmol/l two hours after meals (postprandial) [38].

Table 3 shows the normal range of blood glucose level for management objectivity (following the guideline from NHS Direct), the normal level is between 4 and 7 mmol/l before meals, and less than 10 mmol/l two hours after meals.

Time of Glucose Measurement	Normal Glucose range	
	mmol/l	mg/dl
Pre-meal or pre-bed	4.0 – 7.0	72 – 126
Two hours after meal	4.0 – 10.0	72 – 180

Table 3. Typical Glucose Measurements for Diabetes Management [38][46]

2.3 Diabetes Management and Telemedicine

It is evident that telemedicine can provide a better and more efficient diabetes management for patients. Recent clinical research projects have shown that regular recall and review of people with diabetes can improve the quality of diabetes care and subsequent outcomes for people with diabetes [4]. It also shows drops in glycohemoglobin were observed by applying the telecommunications technology [47] [48] [49].

In summary, the impact of telemedicine on diabetes management can be concluded as the following:

(i) Telemedicine Enhances Patients' Self-efficacy in Managing Diabetes [50].

Self-efficacy is defined as people's beliefs about their capabilities to produce designated levels of performance that exercise influence over events that affect their lives [51]. Telemedicine enhances patients' sense of control, awareness of current health status, increase self-confidence in disease control. A patient's strong self-efficacy may lead to a successful diabetes management, as he could utilize the available knowledge to change his behavior for an optimal control.

(ii) Telemedicine Increases Interactions Between Patients and Medics.

By applying telemedicine on diabetes management, patients can access more frequently the medical advice from the medical provider. Otherwise, consultation with medical doctors can only happen during clinical visits or medical home visits. With emerging science technologies, it also is possible that the communication between patients and medics can happen without the consideration of patients' geographical location.

(iii) Telemedicine Reduces the Transportation Costs and the Costs of Further Complications with Diabetes.

The quality of care can be improved because patients can be more closely monitored; thus an efficient diabetes control may be achieved, and the quality of life can be maintained with decreased complications. Furthermore, the financial and time expenses for clinical visits are saved.

(iv) Telemedicine Provides Timely Medication and Suggestions Because of a Frequent Communication.

The increased frequency of medical information exchange will allow the medical personnel to have a better understanding the current health status of the patients, find the problems and provide quicker therapeutic remedies.

2.4 Review on Mobile Diabetes Management Systems

We review recent research works in the area of mobile diabetes management with the following objectives:

- To provide a comprehensive review in the area and understand existing projects on diabetes management and mobility;
- To provide a detailed analysis and critical review of these systems.
- To assess these systems against the design and development architecture of the MDMIS system presented in this thesis.

The search strategy of the literature on past and ongoing diabetes management systems is carried out by searching for projects or researches news, reports on the Internet through Google[1], major conference or journal papers published by IEEE with IEEE Xplorer[2], EMBASE[3], Mary Ann Liebert, Inc. Publishers[4], Telemedicine information exchange[5] – which provides a bibliographic database of telemedicine literature, and Entrez PubMed [52]. PubMed is a service of the National Library of Medicine, USA, which includes over 15 million citations of biomedical articles back to the 1950's.

[1] http://www.google.com

[2] http://ieeexplore.ieee.org/Xplore/guesthome.jsp

[3] http://www.sciencedirect.com/science/search/database/embase

[4] http://www.liebertonline.com/

[5] http://tie.telemed.org/

We restricted the scope of the review period from January 1990 to May 2005 as most of the new developments in this area are within this period. The regional range spans from UK, Europe to worldwide. Key words used for the search are: "telemedicine, e-health, telecare, mobile, healthcare, chronic disease management, Diabetes, Glycaemic Control". The reason of including "chronic disease management" in the key words for searching is to find more extensive research methods for the study.

The further selection procedures of searched conference and journal papers were as following: first, the title and abstract of the paper was read to decide if the full text of the paper should be studied; if it is related to our research, the complete paper was read and examined.

A report from Kalorama Information (2002) [53] shows, "the global market for diabetes products, particularly new therapeutics and monitoring products, is a large and growing one." There are three reasons for this trend: (1) a rapidly increasing patient population, (2) excessive unmet needs, particularly on therapeutics, (3) advances in biomedical technology [53].

For that reason, it is not surprising that there have been a large number of projects on diabetes management.

2.4.1 Recent Studies on Diabetes Management

Generally, we divide these studies into the following four categories:

(i) Traditional Clinical Diabetes Management Systems

Although there are clinical studies reported or commercially available diabetes management systems, still, the dominant clinical practice for long-term care is that patients visit their prospective clinics every 2 to 6 months. The visit involves a discussion of their diabetes management and any problems encountered together with a review of their normal paper diary of blood sugar readings and insulin doses. The meeting of the visit is usually over in less than 15 minutes. Apart from these visits, patients are largely left on their own to measure their blood sugars, manage medications, and manage various lifestyle issues such as diet, exercise and weight. Apparently, these diabetes management procedures are too complex for those patients without poor education background.

(ii) Standalone Management or Telephone Follow-up Systems

Most manufacturers of glucose meters or medical devices provide standalone PC interface with the meter. Generally, the management software runs on a PC, although some are combined with a PDA device. In these systems, the blood sugar level measurements are stored in a glucose meter, and software is accessed by a patient only when he wants to view his measurements records. This type of management usually aims to help prospective patients to view and analyse their own blood glucose level records. Some applications provide aid tools for physicians to make decisions for their patients. However, all these systems lack the simple interactivity between the patients and the physicians and the necessary solutions of ubiquitous diabetes management.

Some examples of such systems are: OneTouch™ Diabetes Management software [54], Abbott Diabetes Care's Freestyle blood glucose monitoring systems and precision blood glucose monitoring systems [55] , Accu-Chek compass diabetes care software [56]. Generally, the data connection between the meter and PC are via RS-232 or Infrared.

There are also other standalone management systems, such as Glucose Manager (2001, USA) [57], Diabetes tracker blood glucose meter data management system (2001, Canada) [58], Overlook software, Inc.'s DiaTrends (USA)[59] (1998- present, USA) , etc.

Some telephone follow-up from the medical centres which enables medical consultation with patients via telephone calls, are also reported in [60][61].

(iii) Online and Wired Diabetes Management Systems

Online and wired diabetes management systems enable physicians or other diabetes care providers to analyse the diabetics' cases. Some systems even provide functionalities for patients to access the systems. In general, the commercial systems provide an RS232 link between a glucose meter and a PC. Usually the relevant medical data or measurements are input to the system by the medical care providers during patients' visits directly or by patients on a PC.

A typical commercial project of this type is DiabetEASE (Canada) [62], launched at 2000. DiabetEASE is a web-based health monitoring system to track daily glucose levels and to support insulin planning for diabetics with several types of glucose meters. However, there is no decision support from medical providers.

T-IDDM (Telematic Management of Insulin Dependent Diabetes Mellitus) [63] [64], was developed from 1996 to 1998, funded by the European Commission. It aims to improve IDDM (Type 1) diabetics' disease management. T-IDDM is composed of a patient unit (PU) and a medical unit (MU). The MU and PU are connected through public telephone networks. PU and MU can work independently. The T-IDDM system provides decision support tools to assist physicians in choosing an appropriate treatment protocol; it also provides data management and retrieval services.

C-Monitor (EU Funded, 2001-2003) [65] is another example. The system includes three main function units: namely doctor unit, patient unit and a database server to monitor patients' compliance. The C-Monitor system is PC-based, and the doctors are able to provide appropriate treatment for patients.

Another typical system to check and analysis the compliance of patients includes the AARDEX's MEMS ® [66]. The system collects the real-time data from the patient's monitor, transfers and stores the data in a database. Reports can be displayed and printed accordingly afterwards.

Other reported commercial systems, such as ProWellness [67], DiabCarnet [68] , etc, are all of a similar design.

In general, these systems share a generic diabetes management architecture, shown in Figure 4. The system is usually composed of a medical server, PC-based patient units and PC-based physician units. A medical server deals with data processing and data request from PC-based patient units and physician's units. The medical data in these systems is usually fed to the system manually by a patient on his/her computing terminal. The interaction between the patient and physician is limited.

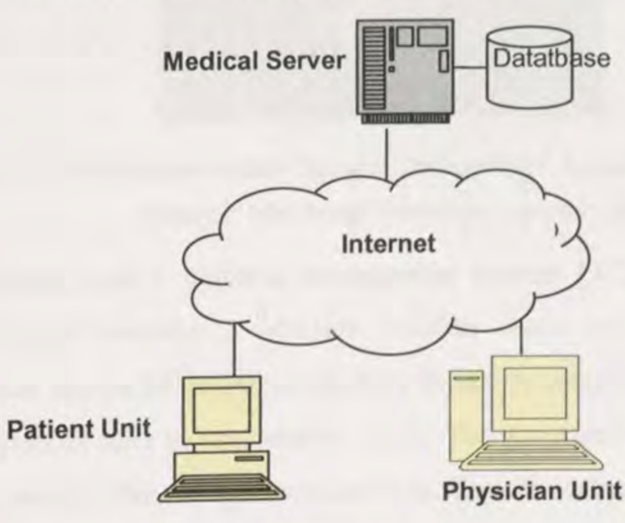


Figure 4. Typical system architecture for Internet based diabetes management system

(iv) Wireless Diabetes Management Systems

In recent years, with advances in wireless communication systems, wireless diabetes management systems have become the most popular and effective category of overall chronic disease management system. An example of research work and system is M2DM (Multi-Access Services for telematic Management of Diabetes Mellitus) [69] [70], funded by the Europe IST (Information Society Technologies) programme, from 2000 to 2003. The purpose of M2DM is to provide patients and medical professionals multi-access services for supporting diabetes shared care by using different access methods. The services are provided by applying a Multi-Access Server (MAS). M2DM is with a web-based architecturem, which enables users to access the system from different types of devices, such as WAP terminals.

MediCompass Mobile [71] is a commercial available product of co-operation between BT (UK) and iMetrikus company (a US-based healthcare company), from 1999 to date. The MediCompass Mobile allows patients and the healthcare team to share information and communicate through a PDA or an internet-enabled phone. MediCompass allows patients to upload the blood glucose data via a wired, then a wireless link. Figure 5 shows this system [71].

Figure 5. MediCompass Mobile Diabetes Management System - Data Acquisition Unit (Source: http://www.imetrikus.com/prod_MM.asp)

E-San is another type 1 diabetes management system [72], developed by a UK company –E-San, it provides a wireless solution based on GPRS mobile phone technology. E-San applys Bluetooth technology for short-range connectivity and is able to upload the glucose data to the remote server. The graphical analysis result is then returned to the patient after the system's analysis. The clinical professionals are able to contact the patient via the mobile to identify concerns and problems for medications. Figure 6 shows a patient terminal of the E-San system. A similar system with this functionality is VIE-DIAB [73].

Figure 6. E-San Blood Glucose Acquisition [72]

INCA project (Intelligent Control Assistant for Diabetes) (2003), was designed to provide type 1 diabetics a care environment with optimum convenience and user-friendliness. Based on intensive monitoring of the blood glucose level, the system aims to change automatic insulin dose by applying mobile communication technologies. [74]

2.4.2 Summary and Conclusions

After extensive study, we can summarise relevant telemedical diabetes management systems reported from 1990 to 2005 as shown in table 4.

Study Name	Project	Population	Description
Horan (1990) [75]	DISC	Type 1	Management of blood glucose data to improve self-care and glycmic control; provides computer-based diabetes education information. Data is entered to a database.
Billiard (1991) [76]		Type 1	Blood glucose analysis based on transmitted results (Telephone network)
Shultz (1991)[47] [77]		Not specified	Patients' data are sent via modem weekly for the reference of health care providers
Ahring (1992) [78]		Type 1	Transfer of data via Modem and telephone counseling
Marrero (1995) [79]		Type 1	Transmits self-monitoring blood glucose data to the hospital via modem every 2 weeks, GP makes telephone calls with patients in response.
Allucca (1996) [80]	DIANET	Type 1	Unrestricted analysis of blood glucose data transmitted provided at a 2-weekly clinic.
Meneghini(1998) [81] [82]	ECM	Type 1 and 2	A voice-interactive system, remote patients can access system through a touch-tone telephone.
Alaoui (1998) [83]		Type 1	Uses an electronic device to gather blood glucose levels, and transmits the data electronically to their physician through telephone line.
Edmonds (1998) [84]		Not specified	Uses telephone to transmit data to a central database for a summary. Without therapeutic support.
Bellazzi (1998) [85]	TIDDM	Type 1	Downloads data through PC via Internet or PSTN
Salzseider (1999) [86]	TeleDIAB		A networked solution, transmission of blood glucose data with interactive advisory programme

Biermann (2000) [87]		Type 1	Telephone advice given by clinician in response to transmitted blood glucose readings through telephone line.
Piette (2000) [88]	ATDM		Patients receives usual care and bi-weekly ATDM calls with telephone follow-up by a diabetes nurse educator.
Liesenfeld (2000) [48]		Type 1	Transfers the data via modem and individual telephone consultations.
Frost (2000) [89]	Carelink	Type 1	Transmission of blood glucose results via a PC through telephone line and advice on insulin dose by phone.
Gómez (2001) [90]	DIABTel	Type 1	Data exchange between patient unit (for patients) and, Medical workstation (for nurses and physicians) through internet.
Reichlin(2002) [91] [92]	MOBIUS		A mobile chronic disease management platform.
Bellazzi (2003) [93]	M2DM		A mobile environment between patients and doctors.
Chase (2003) [49]	DCCT (Trial)	Type 1	Data transfer every two weeks through modem.
Horn (2003) [73]	Vie-DIAB	Type 1	Uses mobile phone and internet services with a special visualization method for the last 4 weeks of medical measurements.
Hernando (2003) [74]	INCA	Type 1	Automatically adjusts insulin dosage according to the data transmitted. With GPRS support.
(2003) [94]	e-San	Type1	Automatic data transmission via Bluetooth, mobile solution
Vahatalo (2004) [95]		Type 1	Blood glucose data entered by patient onto a mobile phone with subsequent transmission. Doctors send comments as text messages back to patients phone once a week.
(2004) [96] Commercial available	Doc@home		The core is an intelligent device for patients to browse and collect medical data

Table 4. Summary of Telemedicine Based Diabetes Management Systems

Figure 7 shows the evolution time line of the development of diabetes management system within the last 15 years. These systems span from early basic management infrastructure to present ubiquitous wireless systems.

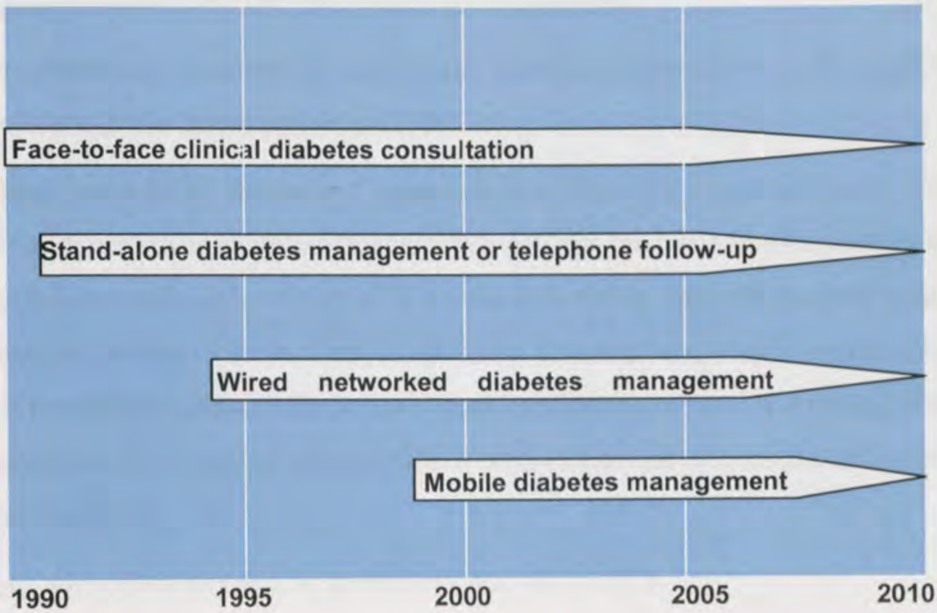


Figure 7. Timeline of Current & Future Diabetes Management Systems (1990-2010)

From the above review, the following issues are addressed in conjunction of the current system design and development:

(i) Networked Solution for Diabetes Management

With the fact of that patients and medical care providers are always geographically separated, most systems addressed in the literature are Internet-based management architectures. This internet connectivity shares two major common factors that improve the diabetes care management procedures:

(1) Data-sharing

With an Internet-based structure, the patients' data can be stored for further analysis. This reduces data repetition and increasement of the safety of data storage. Efficient usage of the relevant medical data leads to an improved medical service as medical doctors can examine patients' real-time or abundant historical medical measurements and describe proper medications without the need to a face-to-face consult with the patient.

(2) Global access and connectivity

It is well known that Internet enables patients and medical care providers to access the system globally. Therefore, patients and medical providers can be "connected" without limitation of their physical locations.

(ii) Wireless Connectivity and Medical Data Acquisition

(1) The advances in wireless technology can provide an alternative to the traditional paper based data to electronic patient records

Traditional paper-based disease management procedures have several shortcomings: first, this introduces the possibility of errors while patients read data from a meter; second, it is costly and inconvenient, because it is a time consuming work for users to read and write, reread and rewrite to the medical database for data analysis, which is inevitably not convenient for patients; at last, effecicany of data ananlysis is rebated from these isolated paper records. Hence, it calls for expenditure of commercial communication technologies within next few years.

(2) From wired data acquisition to wireless data acquisition

Wireless data acquisition to the medical centre for a physician's analysis is becoming demanding, in view of the fact that short-range wireless technology (Infrared, Bluetooth etc.) has been so popular and has been successfully applied in some medical scenarios.

However, most of these studies only addressed type 1 diabetes care and not for a hybrid management of both diabetes types; without clear classification of different levels of users; incomplete wireless data access and without interoperability issues addressed (see Table 4).

Therefore, in this thesis, we address the following issues regarding to the design and development of the MDMIS system:

(1) Universal access and wireless connectivity. MDMIS is designed to provide ubiquitous and wireless access to medical data acquisition and management services. It is important for the medical data to be collected from relevant sensors wirelessly and sent to the medical centre without much intervention by the patient.

(2) Division of user groups. The users of MDMIS need to be divided into different group for security and implicity of the system.

(3) Empowerment of patients. MDMIS is designed to provide proper analysis tools for patient to aware his/her disease progress and management details.

(4) Intelligent update of medical treatment plan: A medical practitioner or healthcare providers (specialist nurses) can change their patients' therapeutic plans according to their medical data sent. It is critical for instantly updating patients' medication plan along

with a significant change of patient medical status.

(5) Online update of medication protocol: MDMIS is designed to allow real-time update of patients' medical treatment protocol for those users who have relevant priority.

(6) Simple user interface: The system is designed with a simple interface for user operation. There are three benefits from this: first, a simple user interface will allow easier access and operation for users; second, users are given a uniform access interface despite of the size and display capabilities of the equipment; finally, the amount of data to be transmitted is reduced, which alleviates network traffic and decreases users' cost on network usage.

(7) Interoperability with different commercial medical sensor devices. With the increasing population of users, the interoperability between various commercial medical devices and the management system has become an important matter to consider. A solution for this has been proposed within this thesis.

Chapter 3

MDMIS System Design

3.1 Introduction

This chapter presents the design issues of the **M**obile **D**iabetes **M**anagement and **I**nternetworking **S**ystem (MDMIS). The requirements analysis of MDMIS, choice of mobile & IP communication technologies used for the system design and the detailed system architecture for MDMIS and relative design concepts are described respectively.

3.2 System Features and Specifications

From the objectivities of MDMIS which has been described in Chapter 1 and literature of mobile diabetes management systems, we can see that a typical scenario for the medical specialist to give new medication to the patient can be summarized in Figure 8.

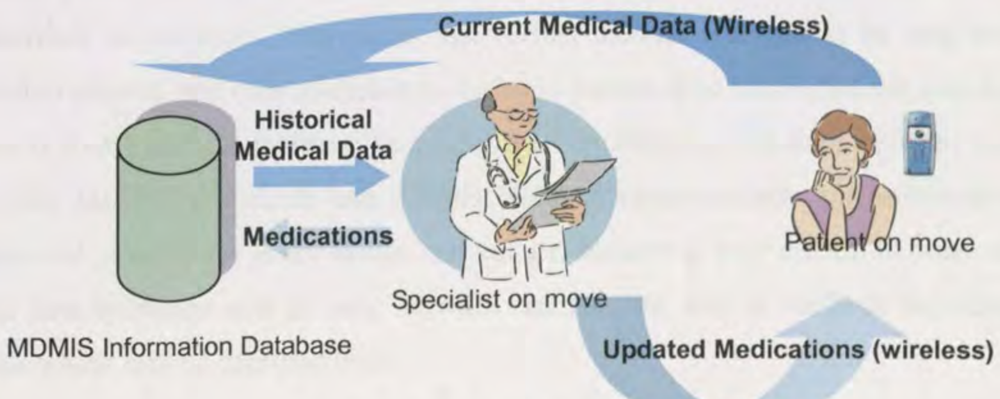


Figure 8. A Data flow Scenario of MDMIS

Based the above diagram, we can outline the major specifications for MDMIS as following:

(i) Mobility for Patients

One of the major objectives of MDMIS is to empower diabetes patients, which means decreasing the inconvenience and cost of frequent clinical medical meetings with medical doctors, maintianing the quality of life and improving diabetes management. To achieve this, MDMIS supplies a roaming environment for patients to send their medical measurements to MDMIS and obtain instant diabetes management services.

(ii) Mobility for Doctors or Physicians

The advantages of mobility also apply to medical doctors or physicians, who are then able to offer their medication suggestions to their patients not only within their clinical offices but also on move.

(iii) Intelligent Medical Decision Tool

To ease the shortage of medical staffs, MDMIS also provides intelligent medical decision making assistance tool for diabetes management to reduce the manual intervention of the medical doctors. This provides automatic medication suggestions according to current medical condition of patients.

(iv) System Scalability

MDMIS should also consider system scalability to allow flexible amount of users accessing simultaneously.

(v) Data Security and Privacy

MDMIS aims to empower patients and doctors on diabetes management, but on the same time it must ensure not putting patients' health at risk by any incorret medical electronic information. This means that correct medical data has to be sent from the reliable sources and only available to the right person, also these medical data must be kept in a safe place to maintain data integrity. Furthermore, with the fact of the mobility for the MDMIS's patients and doctors, medical measurements and information are delivered globally for users' access and update, security is very critical in order to keep safe data exchange and privacy. MDMIS has adopted several methods regarding this issue which will be decribed later.

3.3 MDMIS Wireless Connectivity

A medical sensor are always with very restricted data transmission ability because of the device itself's limited memory storage and low power supply. One practical solution for a medical sensor sending acquired medical measurement to a remote medical provider for medical analysis is by applying emerging smart phone tehcnology and combining both suitable short-range and celluar wireless communication technologies.

3.3.1 Connectivity Requirement of MDMIS

MDMIS aims to provide wireless connection for data acquisition, the wireless connectivity requirements of MDMIS are:

- Short–range wireless connectivity between a medical sensor and a mobile phone (terminal).
- Long-range wireless connectivity of a mobile terminal and a remote medical centre (hospital).

3.3.2 Short-range Wireless Technology for MDMIS

Short-range wireless (SRW) technology refers to a technology that enables wireless data networking across distances of up to a few hundred metres [97].

SRW technologies provide cordless connections among mobile devices such as cell phones, headsets, PDAs, laptop computers, digital cameras, audio and video players, and sensors such as health monitoring devices. SRW can also allow users wirelessly to access a host of new services provided by in-building LANs and their wired Internet connections [98].

SRW includes two general categories: WPAN (Wireless Personal Area Network) and WLAN (Wireless Local Area Network) technologies. WLANs enable mobile users to connect to a local area network (LAN) through a wireless (radio) connection. Radio is currently most useful transmission media for WLAN because of the optical links' limitation of line-of-sight paths. The major standards of WLAN are IEEE 802.11 series, ETSI (European Telecommunications Standards Institute) HIPERLAN (HIgh PErformance Radio LAN) and MMAC (Multimedia Mobile Access Communication) HiSWANa (High Speed Wireless Access Network) [99].

Wireless Personal Area Network technology emphasises on low cost and low power consumption instead of range and peak speed. WPAN technology includes Bluetooth, UWB, Zigbee, Home RF etc.

All the short-range wireless technologies share the following common features:

- Unlicensed frequency bands. Most of them use ISM (Industrial, Scientific, and Medical) frequency bands.

- Local coverage. Generally it is limited to about 100 metres transmit distance.

WLAN is always used in an office environment to ensure quicker data transmission, although with higher power consumption. The problem with WLAN is that a fast data transmission speed and wider coverage is off set by high power consumption and a complex configuration. It is apparent that WLAN is not suitable for MDMIS, which demands lower power consumption and a simple configuration. WPAN is for the communication of devices within a personal operation space, with the benefit of relative lower power consumption and lower cost. Furthermore, WPAN supports ad hoc networking, which supports a flexible and rapid networking style. Hence, the WPAN technology is suitable to be applied for of the MDMIS data acquisition between a medical sensors and a mobile terminal.

Currently, there are several WPAN technologies available: IEEE 802.15 series, HomeRF, InfraRed, DECT (Digital Enhanced Cordless Telecommunications) et al.

Market Name Standard	Bluetooth™ 802.15.1	ZigBee™ 802.15.4	802.15.3	HomeRF	InfraRed
Application Focus	Cable Replacement	Monitoring & Control	Multimedia Data Communication	Home LAN	Line-of-sight device networking
Power Consumption	Low	Very low	Low	Medium	Low
Bandwidth	720kbps	20 – 250kbps	22,33,44,55Mbps	11Mbps	Up to 4Mbps
Transmission Range (meters)	10(class 3) 100(class 1)	1 - 100+	30-50m	50m	1m
Success Metrics	Cost, Convenience, Extensive manufacturers support	Reliability, Power, Cost	Very High Data Rate	High Data Rate	Cost, Power

Table 5. Comparison of WPAN technologies [100] [101]

Table 5 shows the comparison of major WPAN technologies. We can see that 802.15.3 and HomeRF can be used for video data communication with a high data speed, but this feature also means a higher power consumption. In MDMIS scenario, the data to be transmitted is only text data rather than huge volumn of voice or video data.

Infrared [102] is mature and with low cost and low power utilization, and there have been several commercially available infrared glucose meters. However, its optical communication media made its connection directional, which means the two devices must line up with each other to exchange data. This is generally inconvenient for patients to obtain a data link between a phone and a medical sensor.

Zigbee [103] seems the best solution for our application because of its feature of low power consumption. Zigbee is used for text data transmit for its low data speed. From the beginning, Zigbee was poised as a sensor standard, thus it has a very flexible networking ability [104]. The very low power consumption of Zigbee is attractive (the battery can last for years), thus it is economical for MDMIS.

However, Zigbee is a relatively new technology. The first specification was only released in December 2004 [105]. This means that there are quite few electronic manufacturers who support Zigbee technology. In this situation, Zigbee is exempt of our consideration for MDMIS.

Bluetooth® [106], named after the 10th Century Danish King Harold Bluetooth, refers to an open specification for a technology to enable short-range wireless voice and data communications anywhere in the world [107]. Bluetooth was developed by a group of electronics manufacturers that allows electronic equipment, from computers and cell phones to keyboards and headphones, to make inter-connections without wires or cables. It operates at a frequency of 2.4 GHz, supports one data channel, and up to three voice channels. Data can be exchanged at a rate of approximately 720 kpbs. In 2002, IEEE approved the IEEE 802.15.1 standard for wireless personal area networks adapted from the Bluetooth specification, which gave Bluetooth greater validity and support in the market. [108]

Bluetooth devices can interact with each other in several ways:

(i) Piconet. A piconet is any such Bluetooth network with one master and one or more slaves. In this case, the channel (and bandwidth) is shared among all the devices in the piconet. A master determines hopping sequence. The slaves synchronize with the master. There can be up to seven active slaves in a Piconet. It supports ad hoc networking to enable a fast network establishment. Once a Piconet has been formed it can be added to at any time by new devices joining, and active members can leave as required without affecting the Piconet. A diagram showing the Piconet topology and data exchange is depicted in Figure 9.

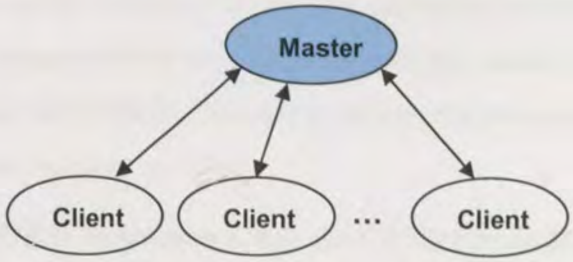


Figure 9. General Bluetooth Piconet Architecture

(ii) Scatternet. Two or more Piconets join together and form a Scatternet. One of the node functions as a bridging unit between the Piconets. A diagram of the Scatternet topology and data exchange is shown as Figure 10.

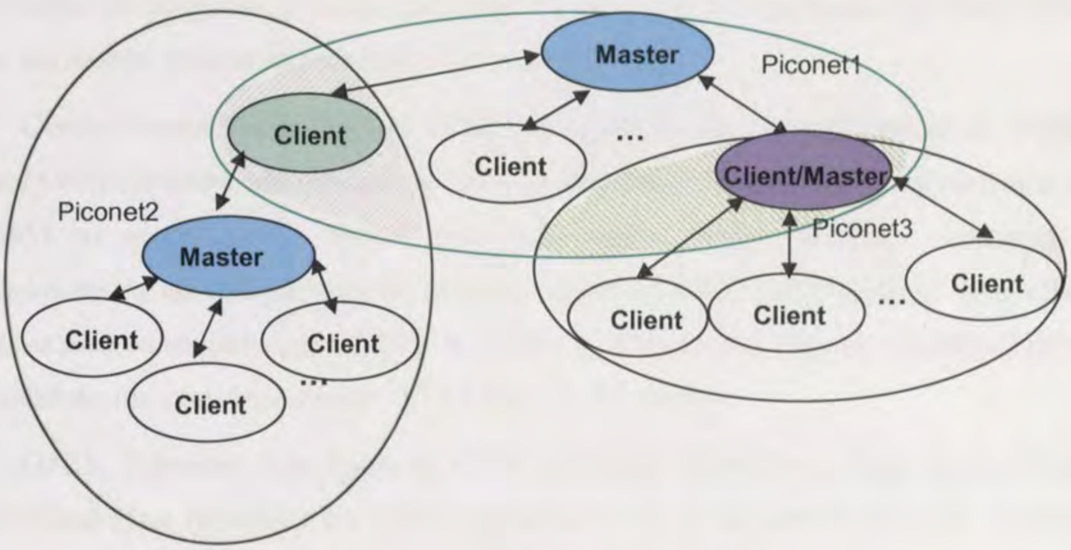


Figure 10. General Bluetooth Scatternet Architecture

Bluetooth applies four connection states for an efficient power management:

(i) Active Mode. The unit actively participates on the radio channel. Active slaves listen in the master-to-slave slots for packets and the master schedules data transmission.

(ii) Hold Mode. The hold mode is typically entered when there is no need to send data for a relatively long time. It is a low-power sleep mode.

(iii) Park Mode. When a slave does not need to participate on the piconet channel, it can enter the park mode, which is a low-power mode with very little activity in the slave.

(iv) Sniff Mode. The unit stays synchronised in the Piconet but polls periodically to save power consumption.

Low power consumption of Bluetooth is suitable for embedded devices. We chose

Bluetooth technology as the wireless link for data acquisition in the MDMIS system. As the connection only happens between a mobile phone and medical devices, the piconet networking was chosen for MDMIS. The mobile phone operates as a master device, while the medical devices act as client devices.

3.3.3 MDMIS GPRS Wireless Link and Connectivity

With the growth in demand for mobile internet access and services, the evolution of wireless telecommunication technologies has expanded from 2G, 2.5 G to 3G, which is represented by Global System for Mobile (GSM), GPRS (General Packet Radio Service) and Universal Mobile Telecommunications System (UMTS). The speed and quality of data service has been improved progressively. Compared to UMTS, GPRS has the benefit of larger coverage and extensively available models of mobile terminals. We chose GPRS as the mobile cellular service bearer for MDMIS.

General Packet Radio Services (GPRS) is a specification for data transfer on TDMA and GSM networks, also known as 2.5G, i.e. between 2G and 3G. It is an evolution on GSM to accommodate packet data transmission, which involves overlaying a packet-based air interface on the existing circuit switched GSM network, thus offers faster data transmission then GSM. It utilizes up to eight 9.05 kbps or 13.4 kbps TDMA timeslots, for a total bandwidth of 72.4 kbps or 107.2 kbps.

GPRS, Enhanced Data-Rates for GSM Evolution (EDGE) and High Speed Circuit Switched Data (HSCSD) are often referred as 2.5G. Compared to HSCSD, GPRS is packet-based, GPRS is the more cost effective for mobile Internet use, and users only need pay according to the amount of data sent or received. [109]

Furthermore, GPRS provides fast and easy data access to different services. The registration or connection to the GPRS network can be performed automatically at power on if the GPRS network is available, so there is a fast connection setup with minimal delays.

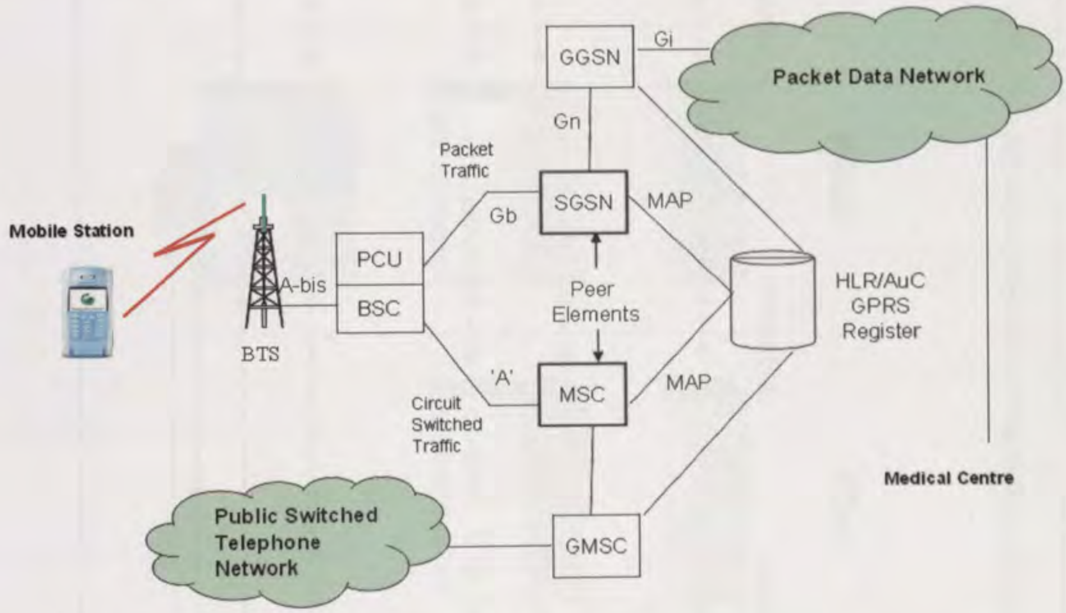
(i) GPRS Network Structure

GPRS introduces several new network elements and interfaces to the base of architecture of GSM: [109]

- **GGSN** (Gateway GPRS Support Node) acts as a gateway between the GPRS network and Packet Data Network (IP, X.25), it also maintains routing information to tunnel the PDU to the SGSNs.

- **SGSN** (Serving GPRS Support Node) keeps track of individual mobile stations' location and performs security functions and access control. The SGSN is connected to the base station system with frame relay connection.

- **PCU** (Packet Control Unit) manages and controls radio-related operations, compresses and decompresses frames. It is logically associated with a BSC (Base Station Controller) and lies between a BTS (Base Transceiver Station) and a SGSN.



BTS: Base Transceiver Station — BSC: Base Station Controller

MSC: Mobile Switching Centre — GMSC: Gateway Mobile Switching Centre

SGSN: Serving GPRS Support Node — GGSN: Gateway GPRS Support Node

HLR: Home Location Register — AuC: Authorisation Centre

PCU: Packet Control Unit — MAP: Mobile Application Part (a protocol)

Figure 11. GPRS Data Link and Connectivity of MDMIS

The block diagram of the GPRS connectivity for MDMIS is shown in Figure 11. A mobile station can be a device with a patient or a medical doctor to access MDMIS services. If a mobile station makes a voice call, it goes through the GSM circuit-switched network, while a mobile station communicates with a medical centre via GPRS For data query.

(ii) GPRS Protocol Stack

GPRS is a packet switched technology based on GSM. The GPRS protocol stack provides a bearer service from a data network to a GPRS protocol stack terminal. Figure 12 shows the GPRS protocol stack between mobile station and application service.

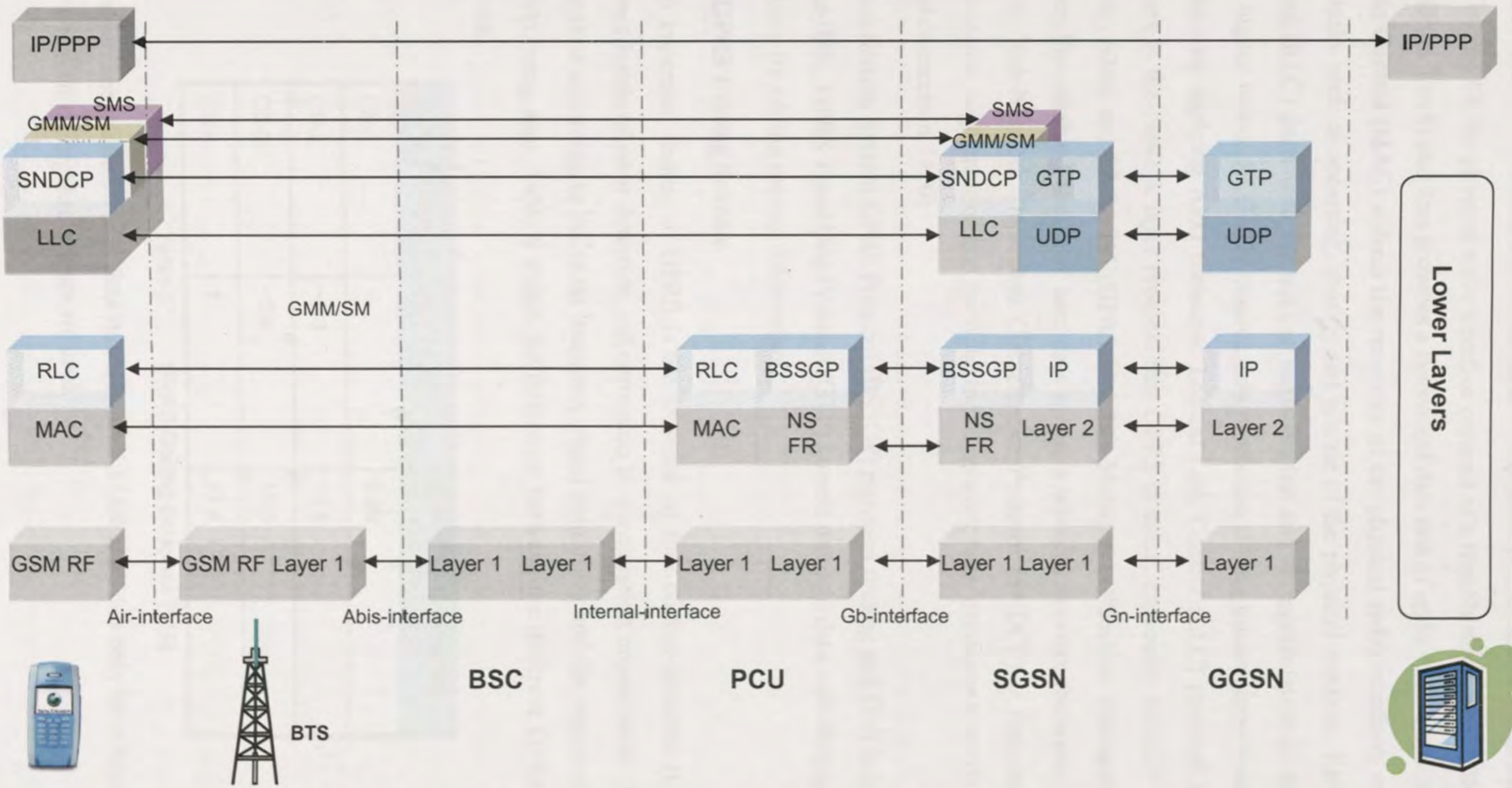


Figure 12. GPRS Protocol Stack between Mobile Station and Application Service[110][111]

In Figure 12, the physical radio interface consists of a flexible number of TDMA time slots (from 1 to 8) and thus provides a theoretical data rate of up to 171.2 kbps. A Media Access Control (MAC) utilizes the resources of the physical radio interface, and deals with tasks such as accessing, sharing and release of the physical medium. Radio Link Control (RLC) deals with the tasks of segmentation and de-segmentation of data units from higher layers. RLC also ensures data protection during transmission over the air interface by applying ARQ measures. Logical Link Control (LLC) protocol provides services to the network layer protocol that GPRS is using, especially SNDCP for data transfer, SMS and GMM/SM (GPRS Mobility Management/Session Management). It ensures the reliable transfer of user data across a wireless network (between MS and SGSN). Sub-Network Dependent Convergence Protocol (SNDCP) is responsible for compression, segmentation and multiplexing of network layer messages towards a single virtual connection. [110]

Base Station System GPRS Protocol (BSSGP) provides routing and QoS information for the BSS. GPRS Tunnelling Protocol (GTP) tunnels protocol data units through the IP backbone by adding routing information.

(iii) GPRS Coding Scheme

An important feature of GPRS is the presence of four coding schemes (CS) with different levels of error detection and correction to transmission impairments. The CSs are applied according to the radio frequency signal conditions and the requirements for the data being sent. Table 6 shows the difference between the different GPRS coding schemes.

Coding Scheme	Code Rate	User data rate(kbps) (1 time slot)
CS-1	½	9.05
CS-2	~2/3	13.4
CS-3	~3/4	15.6
CS-4	1	21.4

Table 6. GPRS Coding Schemes [110]

We can see the theoretical data throughput of 171.2 kbps can only be achieved with CS-4 when all the eight time slots are used.

(iv) GPRS Multislot Classes

GPRS multislot classes are product dependant, and determine the maximum achievable data rates in both uplink and downlink directions. A multislot class is expressed as **x+y, z**. The x represents number of downlink time slots, y represents number of uplink time slots, and z represents maximum number of slots used simultaneously. For example, if a mobile phone is with configuration of multislot **class 10 (4+2, 5)**, that means the mobile phone supports 4 downloading (up to 53.6 kbps) and 1 uploading (up to 13.4 kbps) with CS-2, or 3 downloading and 2 uploading (3+2=5) with maximum 5 active time slots at the same time. Please refer to [112] for the details of multislot classes.

(v) GPRS Mobile Station Classes

According to their ability of supporting simultaneous voice and data, GPRS mobile stations can also be divided to Class A, Class B and Class C. A Class A mobile phone supports both simultaneous voice (via GSM) and data transmission (via GPRS). Class B handsets support voice and packet data, but not at the same time. Class C mobile phones can handle packet data only or they can be set manually to handle one or the other.

(vi) GPRS Data Exchanges

Before a mobile patient or physician station can exchange data with the remote medical centre, it must request attachment or register to a SGSN by sending its identification. The SGSN verifies whether the user is authorized and authenticated for the data service by checking the HLR (Home Location Register), if the user is, it constructs an updated location message and registers this message at the HLR, and sends back the reply to the mobile station. This procedure can happen as soon as a mobile station is switched on. If a mobile station is attached to a GPRS network, prior to sending and receiving data, it must activate a PDP (Packet Data Protocol) context by sending a PDP request to SGSN. The PDP context is used for packet routing and transfer purposes inside a GPRS network, it contains the type of network the PDP used (for instance, X25, IP...), PDP Addresses of the terminal (x.121, IP), IP Addresses of the SGSN where the subscriber is located, the access point to the service network used (NSAPI) and the QoS (Quality of Service). The SGSN chooses a GGSN based on information provided by the MS and other configurations and requests the GGSN to create a context for the MS. The GGSN allocates an IP address for the mobile station, creates a PDP context for the MS and sends this information to the SGSN, the SGSN informs the MS that a PDP context is created [113]. Now the data can be transferred between the MS and the medical centre.

The MS can detach a PDP context by sending a PDP context deactivate request to the SGSN, the procedure is the opposite to PDP context activation.

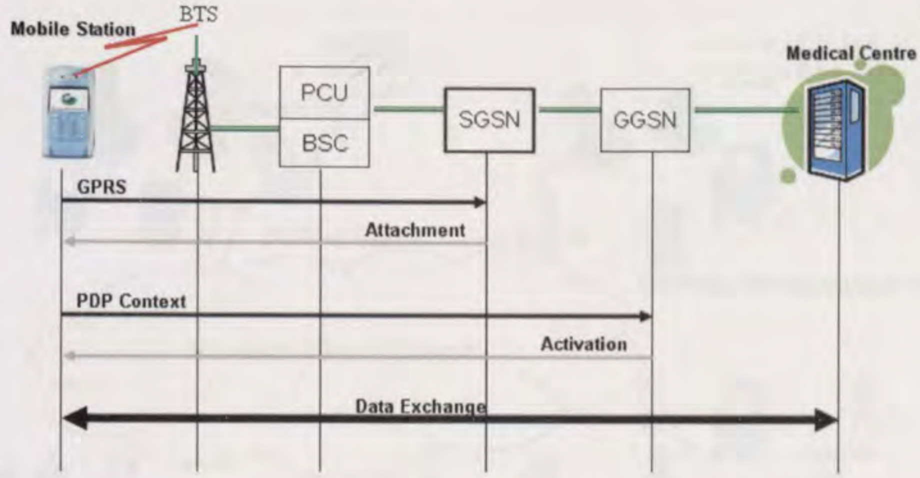


Figure 13. GPRS Data Exchange between a MS and Medical Centre (initiated by the MS)

3.4 System Design and Architecture of MDMIS

As discussed earlier, MDMIS is designed to provide a flexible mobile diabetes management environment for patients. The users of MDMIS are divided into the following categories:

(i) Patients. Patients are the source of the medical data for the analysis. Also they need to browse and get medical advice.

(ii) Physicians. Physicians are to provide medical advice for patients according to the information that patients supply.

(iii) Medical Administrators. A medical administrator is a "super" physician. To have a secure medical environment, we limit the general physician's priority only to browse, analysis and provide medical suggestions to patients, but allow medical administrators to manage the medical protocols and available treatments.

(iv) System Maintainers. A system maintainer is not allowed to browse patient's medical information, or make medical decisions due to privacy and ethical constraints. But he can maintain the health information database, browse various users' operation records, or add geographical information for general usage, such as updated address or new road names.

The functionalities of MDMIS are thus designed in a flexible way according to different types of users' requirements.

The general system architecture of MDMIS is shown in Figure 14.

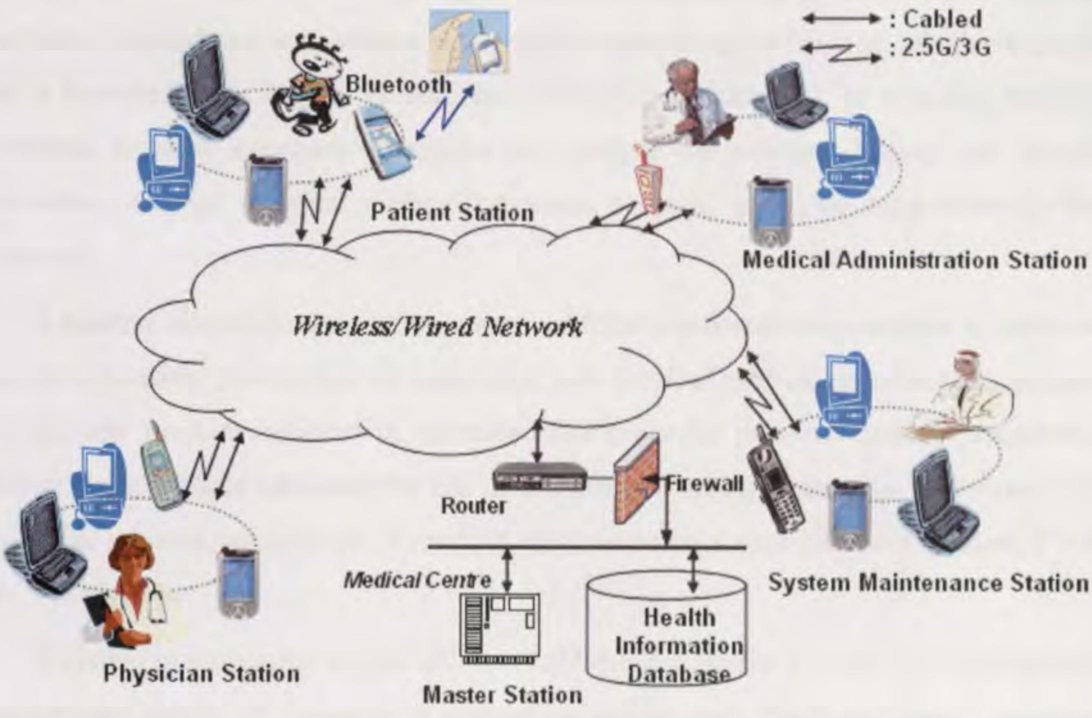


Figure 14. System Architecture of MDMIS

We can see MDMIS is composed by patient stations, medical administration stations, physician stations, system maintenance stations and a medical control centre.

A medical control centre consists of a master station and a health information database or MDMIS information database. It resides in a hospital with broadband access to the Internet. If there are large numbers of users, there can be several sub medical control centres to balance the load of the requests.

A master station processes all requests from MDMIS clients and stores health related information in the health information database. A MDMIS database stores health-related information, including all users' operation records and account information, medication protocols, medications, measurement records, etc. This database is required to be reliable and able to deal with large amount of concurrent users' requests.

A patient station is a data acquisition terminal as well as an operation portal. It captures a patient's blood glucose measurements through Bluetooth and sends these data to a remote medical control centre. Moreover, patients should be able to update their account information; inspect their historical medical records, which includes their measurements and treatments; and report recent side-effects. A patient station can be a PC, laptop, mobile phone, or PDA.

A physician station is a computing device for a MDMIS physician to access MDMIS services. A physicians may choose any available computing device, a mobile device, such as a handset, PDA, laptop, or stationary terminal, desktop PC, to remotely manage patients' account information, inquire and analyze the patients' history and current situation, manage patients' medical treatment scheme, and give suggestions to the patients.

A medical administration station allows a MDMIS medical administrator to create or update available information on medicines, edit medical medication protocols, manage physicians' account information, intervene and supervise patients' therapy procedures. However, a medical administrator has no authority to manage any other user except for patients' account information. A medical administration station can be a handset, PDA, PC, or a laptop.

A system maintenance station allows a MDMIS maintainer to carry out maintenance procedures locally or remotely. A system maintainer may check any users' operation records, manage medical administrator's account, or check system operation status.

Chapter 4

Design and Implementation of MDMIS Wireless Data Acquisition and Processing System

4.1 Introduction

The emphasis of this chapter is on software design and implementation issues of the MDMIS data acquisition system. The wireless connectivity of the data acquisition system is based on Bluetooth and GPRS technologies.

The aim of data acquisition system of MDMIS is to acquire medical data wirelessly from a medical sensor and forwarding this information to remote medical care providers for further medical analysis and disease management via GPRS network.

4.2 Overview of MDMIS's Wireless Medical Data Acquisition System

The functionality of the MDMIS data acquisition subsystem is to transmit the electronic medical data (blood glucose measurement) of a patient to the remote data centre and to provide the patient appropriate prompt medical suggestions ubiquitously. Figure 15 shows the schematic diagram of the wireless data acquisition system of MDMIS.

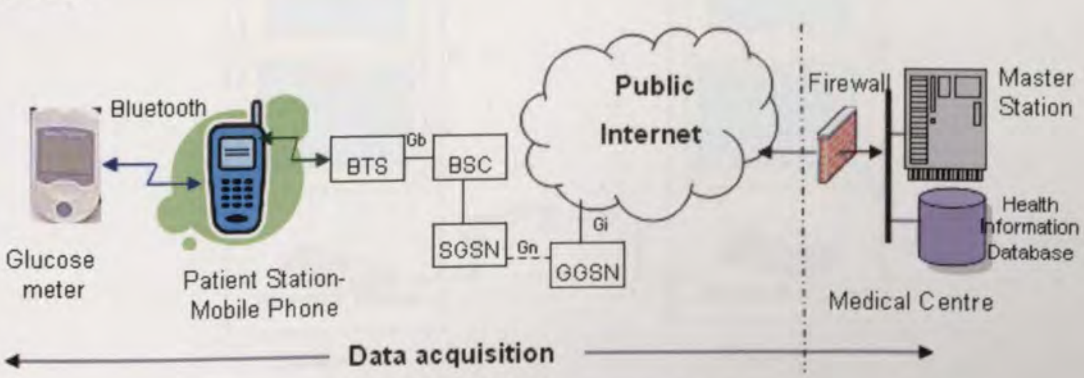


Figure 15. Schematic Diagram of Wireless Data Acquisition of MDMIS

As we presented in Chapter 3, in MDMIS, Bluetooth communication technology is applied on short-range data exchange (in this case, point-to-point networking – between a meter and a mobile phone). GPRS technology is used for the mobile link between a mobile phone and a remote medical centre. Therefore, the major design and implementation issues of the MDMIS wireless data acquisition system are summarised as follows:

- A short-range Bluetooth connectivity between a medical sensor (Glucose meter) and a GPRS-enabled mobile phone (patient station) ;
- Adaquate data processing before the medical data is sent to the medical centre;
- Mobile cellular data transmission between a patient station and a medical centre.

4.3 Design of Bluetooth Connectivity for MDMIS

MDMIS uses Bluetooth connectivity for its front-end medical data link, in this section, we discuss the communication issues relevant to such short-range connectivity for completeness. Further details on Bluetooth architecture and protocols can be found in [114] [115].

To communicate via Bluetooth, the relative devices need to have a Bluetooth communication module. A Bluetooth communication module provides a Bluetooth protocol stack, which ranges from the physical layer to the upper RFCOMM layer. It may also have a application software to implement advanced functionality for Bluetooth communication. Figure 16 shows the Bluetooth link between two devices.

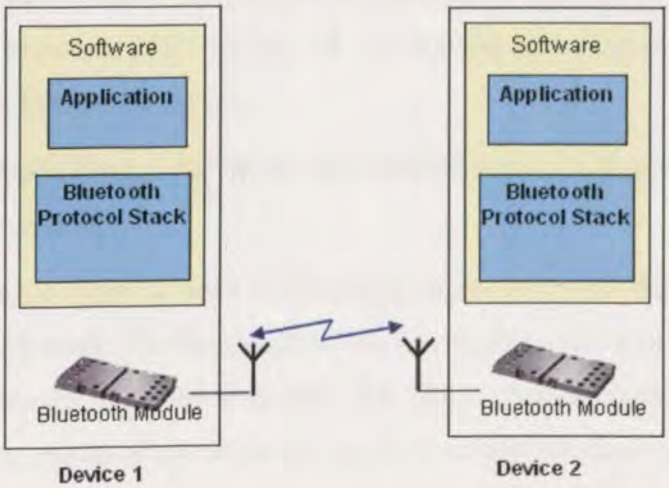


Figure 16. Bluetooth Enabled Short-range Communication

4.3.1 Introduction to Bluetooth protocol stack

The general layout of the Bluetooth protocol stack is shown in Figure 17.

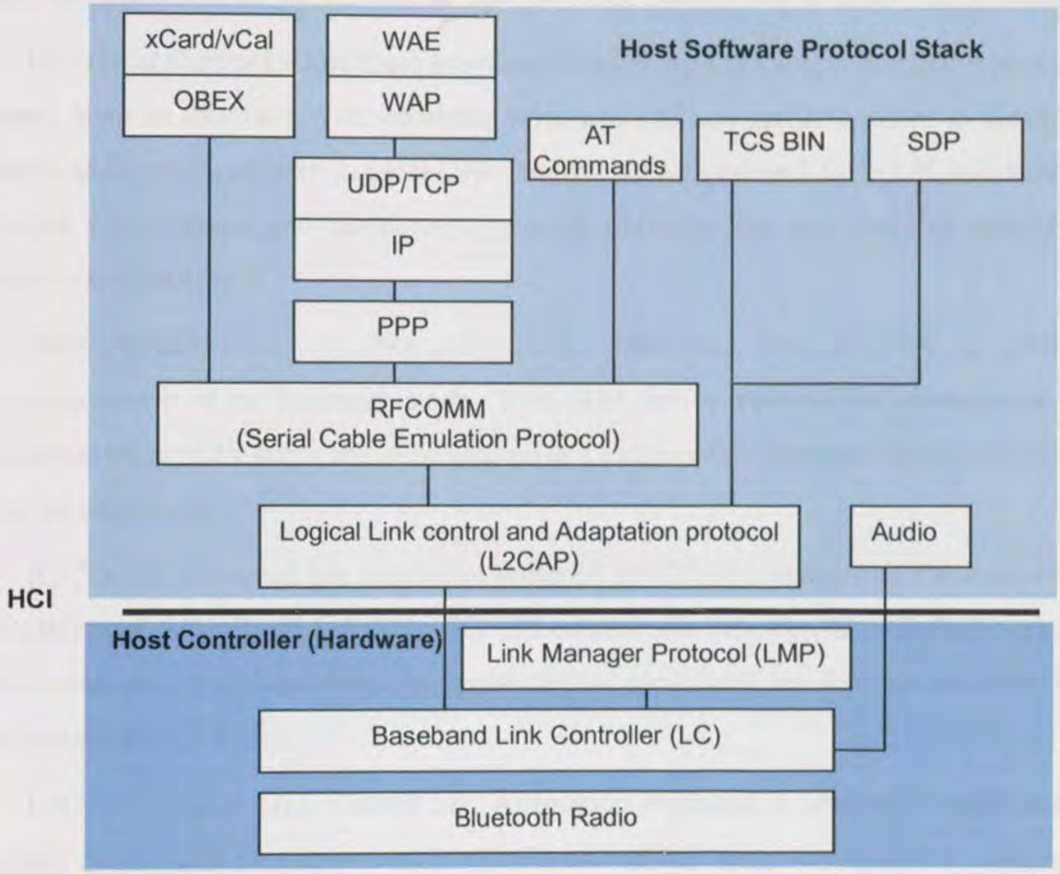


Figure 17. Bluetooth Protocol Stack [114] [115]

According to the purpose, including whether Bluetooth SIG has been involved to specify the protocols, the Bluetooth protocol stack can be divided into 4 layers: Bluetooth core protocols (Baseband, LMP, L2CAP, SDP), cable replacement protocols (RFCOMM), telephony Control protocols (TCS binary, AT commands) and adopted protocols (PPP, UDP/TCP/IP, WAP, OBEX etc.) [114].

The Bluetooth Radio layer is the lowest layer, which defines the specifications of the Bluetooth transceiver device.

The Baseband is the physical layer of Bluetooth. It lies on top of the Bluetooth radio layer in the Bluetooth stack. The Baseband protocol is implemented as a Link Controller. The Baseband manages physical channels and links, frequency-hopping sequence selection and timing, modes of operation and medium access functions etc.

The Link Manager (LM) carries out link setup, authentication, link configuration and other protocols. It discovers other remote LMs and communicates with them via the Link Manager Protocol (LMP). The Link Manager Protocol essentially consists of a number of PDUs (Protocol Data Units), which are sent from one device to another, determined by the AM_ADDR in the packet header. LM PDUs are always sent as single-slot packets.

HCI (Host Controller Interface) interfaces directly with the host controller, it provides upper layer an interface to the baseband layer and link manger, and access to hardware status and control registers. Logical Link Control and Adaptation Layer (L2CAP) handles packet segmentation and reassembly, protocol multiplexing, and provides quality of service information.

SDP (Service Discovery Protocol) handles publishing and discovery of services running on top of the Bluetooth stack. With SDP, device information, services and the characteristics of the services can be queried and a connection between Bluetooth devices can be established.

RFCOMM is a serial line emulation protocol. RFCOMM simulates a standard serial (COM) port. The protocol emulates RS 232 control and data signals over the Bluetooth baseband, providing both transport capabilities for upper level services that use serial line as transport mechanism.

L2CAP (Logical Link Control and Adaptation Protocol) is above the baseband, it adapts upper layer protocols over the baseband. L2CAP supports channel multiplexing and conveys the quality of service information. It also provides flow control and handles packet segmentation and reassembly operations. L2CAP is defined for ACL (Asynchronous Connection-Less) links, which means the Bluetooth data applications use L2CAP to communicate with the baseband.

TCS Binary or TCS BIN (Telephony Control protocol– Binary) is a bit-oriented protocol. It defines the call control signaling for the establishment of speech and data calls between Bluetooth devices. It also defines mobility management procedures for handling groups of Bluetooth TCS devices.

Telephone Control – AT commands, controls the modem and the mobile phone commands.

PPP (Point-to-Point Protocol) is a protocol that allow TCP/IP suite of TCP/IP to run over a serial connection.

TCP/UDP/IP (Transfer Control Protocol/User Datagram Protocol/Internet Protocol) are defined by IETF, mainly for usage on internet

OBEX (IrOBEX) is a session protocol to exchange objects in a simple and spontaneous way. OBEX provides a model for representing objects and operations. It also defines a folder-listing object for browsing the contents of folders on remote device.

WAP (Wireless Application Protocol) is a standard for applications that use wireless communication to accessing online services from a mobile phone simple.

vCard & vCalendar are specifications developed by the versit consortium. The specifications define the format of an electronic business card and personal calendar entries and secheduling information. Bluetooth SIG adopts vCard and vCalendar to help the exchange of personal information.

4.3.2 Bluetooth Profile and MDMIS Implementation

To ensure interoperability and consistency between different Bluetooth-enabled devices, the purpose of designing Bluetooth profiles is to to ensure the relevant devices which claim specific capabilities can interoperate together. A Bluetooth profile is a specification that defines the minimum requirements that a Bluetooth device must support in a specific usage scenario. A Bluetooth profile can be described as a vertical slice through the protocol stack. These are two types of profiles [116].

(1) Conforming profiles

GAP (Generic Access Profile) defines the usage of low-layers of the Bluetooth protocol stack. It is fundamental for all the Bluetooth application.

Service Discover Application Profile (SDAP) describes a specific application and usage of SDP, the availability and user interface aspects of service of service discovery.

Generic Object Exchange Profile (GOEP) defines the OBEX, SPP and GAP interoperability requirements and OBEX capabilities for file transfers, object push and synchronization.

Serial Port Profile (SPP) defines the RFCOMM., L2CAP, SDP and lower layer interoperability requirement and capabilities for serial cable emulation.

(2) Interoperability profiles

Dial-up Networking Profile (DUNP) defines the interoperability requirements for dialling and control capability that allows a device as a dial-up device.

Object Push Profile (OPP) defines the user interface requirements use of OBEX and SDP, and the object push feature.

File Transfer Profile (FTP) defines the user interface requirements and interoperability and use of GOEP, OBEX and SDP.

LAN access profile defines how Bluetooth-enabled devices can access the services of a LAN using PPP and shows how the same PPP mechanisms are used to form a network consisting of two Bluetooth-enabled devices.

For the MDMIS application scenario, it is possible to apply SPP, DUNP or LAN access profile for the usage of data exchange.

The scenarios covered by the DUNP profile are the following [115]:

- Usage of a cellular phone or modem by a computer as a wireless modem for connecting to a dial-up internet access server or using other dial-up services.
- Usage of a cellular phone or modem by a computer to receive data calls.

In MDMIS, the Bluetooth link is used for data exchange between an embedded device and a cell phone. Apparently, DUNP is not appropriate for this scenario.

The LAN access profile defines how PPP networking supported in following situations:

- LAN access for a single device or multiple devices.
- PC to PC (using PPP networking over serial cable emulation).

Similar as DUNP, the usage situation of the LAN access profile is not suitable for the implementation of MDMIS. Furthermore, nearly all the Bluetooth-eanabled cell phones do not support LAN access profile.

The scenario covered by Serial Port Profile (SPP) deals with legacy applications using Bluetooth as a cable replacement through a virtual serial port abstraction. Since it is a conforming profile, basically, all the Bluetooth-enabled phones support this profile; furthermore, most of medical sensors support serial port communication. Therefore, SPP is selected to be followed for the implementation of MDMIS.

To transmit the relevant data from a medical sensor (Glucose meter in this case) through a GPRS mobile phone to a remote medical centre, the Bluetooth communication modules are required on both sides, that means both devices should support at least part of the Bluetooth protocol stack. In addition, it requires that data acquisition software for data control to be developed on either side.

Currently, a commercially available Bluetooth-enabled mobile phone already has a Bluetooth communication module; while there is not a Bluetooth-enabled glucose meter on the market. Furthermore, developing a fully integrated Bluetooth glucose meter has the following drawbacks:

- A brand new Bluetooth glucose meter means choice of Bluetooth chip, Biochemical chip (for calculating the blood glucose level), PCB design and printing, hardware and clinical test. Particularly, an extremely stringent safety requirement is compulsory for medical usage. These procedures are inevitably time-consuming.
- A new Bluetooth product must be certificated by Bluetooth SIG for further commercial usage. This procedure is also time-consuming and may cause huge financial cost implications.

Therefore, the realistic option for this study is choosing a commercially available Bluetooth module to link a popular glucose meter with data output functionality and developing a compatible data collection and data transmission software on the cell phone side.

There are two development schemes for data collection and transmission in MDMIS. A data acquisition software beyond the SPP profile can be developed (1) on a Bluetooth-enabled glucose meter and on a mobile phone, or (2) on a Bluetooth embedded mobile phone since most integrated glucose sensors already have data communication abilities. Choosing the first method will limit choice of Bluetooth communication modules and further research on the glucose sensor is required. Therefore, we chose developing additional data acquisition software on a GPRS-enabled Bluetooth mobile phone.

Based on the above analysis, the following detailed steps were followed to develop the wireless data acquisition system of MDMIS:

(1) Selection of an appropriate blood glucose sensor that has data interface with external devices.

(2) Selection of a suitable Bluetooth adapter to enable a glucose meter's Bluetooth connectivity.

(3) Study of the data communication protocol of the blood glucose sensor to ensure correct data initiation and data exchange between the sensor and a mobile phone.

(4) Selection of an appropriate Bluetooth enabled mobile phone model to be supplied by Orange UK. The mobile phone will act as a data gateway, and is responsible for collecting medical data from the glucose sensor and sending the information for further medical reviews via a GPRS network.

(5) Development of a relevant software on a mobile phone to capture and process a patient's blood glucose measurements and send the relative data to the remote medical centre.

4.4 Blood Glucose Sensor - Medisense Optium Glucose Meter

The general criteria for the choice of a blood glucose sensor can be summarized as follows:

- The glucose sensor must be adopted and recommended within UK NHS system.
- User popularity should also be considered.
- The meter must retain an external data exchange interface. This means the device must allow other technologies to be able to read data within it.

According to the statistics for the West Midlands (Birmingham) NHS region [117], the top five blood glucose test strips used within the NHS in that region are shown in Table 7.

Rank	Strip type
1	Active (Reagent) Strips
2	MediSense G2 (Reagent) Strips
3	Advantage II (Reagent) Strips
4	MediSense Optium(Reagent) Strips
5	One Touch (Reagent) Strips

Table 7. Top 5 Blood Glucose Test Strips Used in West Midlands NHS Regions

MediSense Optium glucose sensor model (shown in Figure 18) was selected to collect patients' blood glucose measurements for this study. As Table 7 shows, The MediSense Optium product is a popular blood glucose sensor in that NHS region and throughout the UK as well; it also has an external data exchange interface; furthermore, the diabetes specialist we are in co-operation with for this research recommended this glucose sensor.

The MediSense Optium blood glucose sensor is a product of Abbott Laboratories [118]. The theory of its measurement procedure is as follows: When a blood sample is applied to the blood glucose electrodes, glucose in the blood reacts with the chemicals on the electrode; this reaction produces a small electrical current; the current is measured and calculated to get the blood glucose measurement; the blood glucose level is displayed by the sensor.

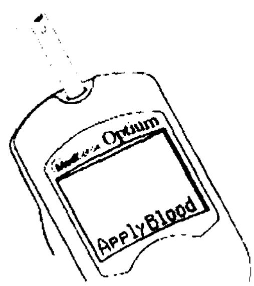


Figure 18. MediSense Optium Blood Glucose Meter [118]

(i) MediSense Optium Glucose Meter Serial Communication Setting

The MediSense Optium supports serial data transfer. Serial data transfer refers to transmitting data one bit at a time.

MediSense Optium serial communication setting is assigned as follows (Table 8):

Bits per second: 9600
Data bits: 8
Parity: None
Stop bits: 1
Flow control: None

Table 8. Medisense Optium serial communication setting [119]

(ii) MediSense Optium Glucose Meter Communication Protocol

The time sequence of the MediSense Optium glucose meter communication protocol for data exchange is shown in Figure 19.

Basically the protocol is based on a hand-shaking serial communication model. Once a communication channel is set up, a receiver (a mobile phone) can query the current status of the sensor (a MediSense Optium glucose sensor) by sending "READ_STATUS" to a transmitter (the glucose sensor) and remain waiting for response (an "ACK" message). If the reciever doesn't receive response from the sensor after a specific time, it will keep sending the same command -"READ_STATUS" to ensure that the sensor is ready. The sensor will send back "ACK" if it is ready to accept further commands. The receiver may send command "ID" to get the sensor's product ID which was allocated by manufacturer; command "GET_METER" to get existing glucose measurement records from the sensor.

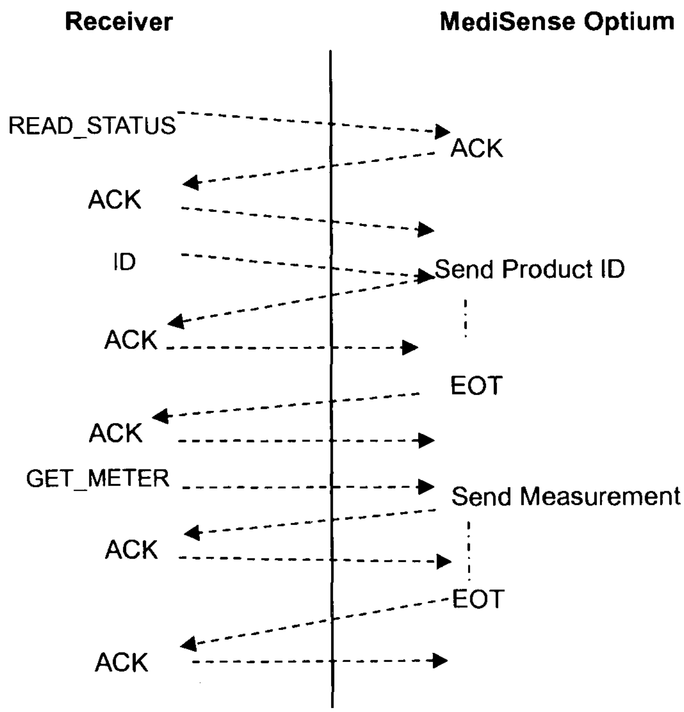


Figure 19. Time sequence of the glucose meter communication protocol

4.5 Bluetooth Connectivity Module

As we mentioned in section 4.3.2, we follow the SPP profile to implement the Bluetooth connectivity between a mobile phone and a sensor. The connectBlue Serial Port Adaptor (SPA 32i) from connectBlue (a supplier of Bluetooth solutions) [120]was selected as the Bluetooth communication module for this study.

Figure 20. The connectBlue SPA 32i Serial Port Adaptor [120]

The connectBlue SPA 32i serial port adaptor is a product which allows a device with a

RS232/422/485 port to wireless communication with other devices via Bluetooth. It supports Bluetooth Serial Port Profile, Dial-up Networking Profile and LAN-access Profile.

The technical specification of connectBlue SPA 32i is shown in Table 9 [119]:

Output Power: 20dbm(>100m)
Power Supply: 5V
Serial Interface: Baud rate from 900 bps – 921.6 kbps ,Flow Control: CTS/RTS or None
Serial Connector: Male DSUB-9pins
Wireless MultiDrop Multipoint: 7 slaves
Antenna: Internal
Dimensions(mm): 63*80.2*25.7

Table 9. connectBlue SPA 32i Technical Specification

connectBlue also provides small size and power saving OEM Bluetooth adapter chips in the same product line. It will be very valuable for the development of future fully integrated medical sensors.

The connectBlue bluetooth serial adapter is configured as a Bluetooth communication module for the Medisense Optium sensor device. To provide a successful communication channel, this Bluetooth Module for COM (serial port) needs to be configured following the communication configuration of the MediSense Optium glucose meter (Table 8).

Since it is a point-point connection between a mobile phone and a glucose meter in MDMIS, the network topology of this application is Piconet. After successful pairing, it is the mobile phone acting as the master device as it controls the connection with the glucose meter. The Bluetooth serial adapter is also configured as "discoverable" for service discovery and accepting incoming connections.

4.6 Mobile Phone and GPRS Network Issues

The low cost of Bluetooth's wireless communication chips has led to a large number of Bluetooth-enabled mobile phones available; therefore, it is feasible to choose a Bluetooth-enabled mobile phone for MDMIS development. As stated earlier in Chapter 3, the GPRS service is applied for long-range wireless connection, thus the mobile phone needs to support GPRS communication technology at the same time. We also require uploading the data acquisition program into the mobile phone;, the mobile phone should also have a good software supporting environment.

We selected Sony Ericsson P800 (figure 21) for the MDMIS development.

Figure 21. Sony Ericsson P800

The Sony Ericsson P800, integrated with combined WAP and Web browser, supports the following Bluetooth profiles:

- Generic Access Profile,
- Serial Port Profile
- Generic Object Exchange Profile
- Dial-up Networking Profile
- Object Push Profile
- Headset Profile

General	Processor: ARM 9 OS: Symbian OS v7.0 Weight: 158g with flip Size: 117 x 59 x 27mm User storage: 12 Mb Antenna: Build in
Additional storage	Memory Stick Due, up to 128 Mb supported
Screen	Display resolution: 208 x320 pixels (40 x 61 mm) Colour depth: 4096 (12 bit)
Third party application support	C++, PersonalJava, J2ME CLDC 1.0/MIDP
Local connectivity	Cable Infrared (up to 115.2 kbps) Bluetooth
GPRS connectivity	Multi-slot class 8 (Slots: 4+1) Coding scheme: CS-1, CS-2,CS-3, CS-4 Downlink rate: Up to 53.6 kbps (CS-2) Uplink rate: Up to 13.4 kbps (CS-2)

Table 10. Some specifications of Sony Ericsson P800 [121]

The Bluetooth communication distance of Sony Ericsson P800 is up to about 10 metres

(33 feet) and support Bluetooth specification version 1.1. Some technical specifications of Sony Ericsson P800 are listed in Table 10.

Sony Ericsson P800 has a screen size suitable for patients accessing the MDMIS system. With the support of Bluetooth Serial Profile, the mobile phone is able to communicate with the glucose sensor to collect a patient's blood glucose measurements.

4.6.1 The Orange GPRS Network in UK

The GPRS network used for MDMIS is Orange UK GPRS network because Orange UK funded this research.

Orange UK is one of the biggest mobile service providers in the United Kingdom. Independent research by AIRCOM International indicated that Orange has the largest integrated 3G/GPRS network for business in the UK. Orange covers 99% of UK population and has also extended GPRS roaming for UK subscribers to 74 countries [122]. Figure 22 shows the Orange UK network coverage [123].

Figure 22. Orange UK network coverage in UK[123]

4.6.2 GPRS Configuration

Before being able to transmitting data via GPRS on a mobile phone, GPRS configuration must be carried out on a mobile phone.

To enable GPRS data transmission for MDMIS, the configuration for Orange Access Point Name (APN) on the mobile phone must be set. A APN is a name which is logically linked to a GGSN. The APN identifies the service or network to which a user can connect from a GGSN in a GPRS network. The syntax of the APN corresponds to a fully qualified domain name [124]. According to the APN from a mobile station, a SGSN can perform a DNS query to find out the corresponding GGSN during PDP context activation. As we discussed in Chapter 3, GGSN converts the GPRS packets coming from the SGSN into the appropriate PDP format and sends them out to the relevant packet data network. In the other direction, PDP addresses of incoming data packets are converted to the GSM address of the destination user. The readdressed packets are sent to the responsible SGSN. Therefore, the communication channel can be built and a patient's medical information can be sent to a remote medical centre and remote medical suggestions can be received at a patient station.

There are two APNs of Orange GPRS connections available, which are "orangewap" for Orange WAP GPRS and "orangegprs" for Internet GPRS. Orange WAP GPRS is for the mobile phone to browse WAP pages only. We set "orangegprs" for MDMIS for internet connection usage.

4.7 Software Implementation of MDMIS Data Acquisition

The main objectives of the data acquisition software can be summarized as follows:

- To communicate with a medical sensor – MediSense Optium sensor;
- To acquire accurate medical measurement data – blood sugar level records;
- To pre-process and send this medical information to a remote MDMIS health information database;
- To get feed back of medical suggestions from a medical doctor.

A schematic diagram for prototype for MDMIS data acquisition is depicted in Figure 23.

Figure 23. MDMIS Data Acquisition and Processing System

The communication cable between a glucose meter and the Bluetooth adapter is a special serial cable, which is available from Abbott Laboratory along with the MediSense Optium sensor. The origin of the data (Blood glucose level measurement) is within the glucose meter. With presence of Bluetooth serial adapter, a mobile phone is able to acquire the medical data, pre-process it, and send the blood glucose measurements via GPRS to the remote medical centre. Software in the master station processes and stores the incoming data to the MDMIS health information database (see section 5.4). If the software analyse that a measurement is out of range, a text message will be sent to the mobile phone for the patient's attention.

4.7.1 Bluetooth Serial Port Profile (SPP)

The SPP profile is a transport protocol profile that defines the fundamental operations necessary to establish RFCOMM communications between two peer devices. The SPP describes how to use the Bluetooth protocols to establish a virtual serial connection.

The protocols used by the SPP are depicted in Figure 24.

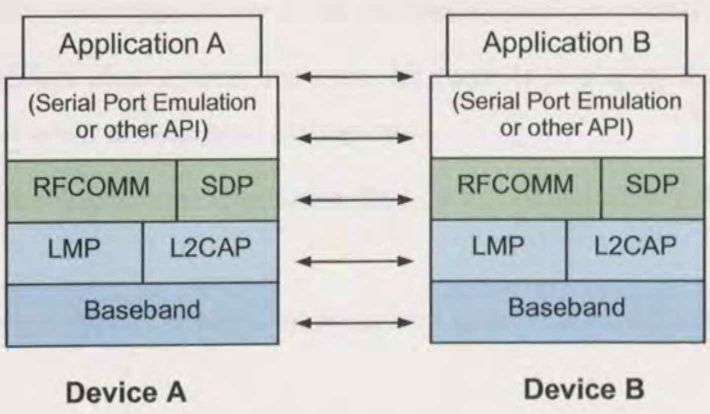


Figure 24. Protocols involved in SPP

The scenario covered by this profile is setting up virtual serial ports (or equivalent) between two Bluetooth-enabled devices and connecting them to emulate a serial cable between the two devices. Legacy applications can run on either device, using the virtual serial port as if there were a real serial cable connection.

There are no fixed Master-Slave roles for execution of the SPP. The user data, modem control signals and configuration commands are transported by RFCOMM.

4.7.2 Bluetooth Software Development

(i) UIQ Programming Model

The development of a Bluetooth application for a Sony Ericsson P800 mobile phone requires a Symbian OS development environment. Symbian OS v7.0 comes with an advanced, object-oriented application framework, and supports UIQ, which provides a UI (User Interface) framework and APIs (Application Program Interface) for handheld devices. The UIQ application framework provides a Model-View-Controller (MVC) model that separates the user interface from the application logic (model). [125]

This UIQ framework requires four objects to be defined: an application, a document, an application UI, and one or more application views, corresponding to following four classes:

(1) Application class identifies the application's property and creates the document object associated with this application.

(2) Document class represents the data model of the application and provides the application's data and methods to save the information and close down the application.

(3) User interface class creates and owns UI controls to display the application data and provides for event or command management.

(4) View class displays the application data on screen and allows the user to interact with it.

Figure 25 shows the UIQ's MVC model as well as the relationships between these four classes.

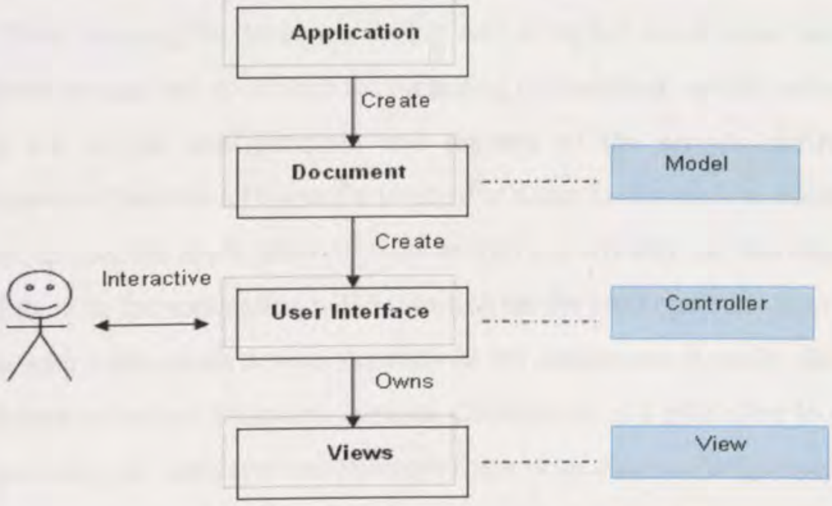


Figure 25. Generic UIQ's MVC Model

(ii) Bluetooth APIs

Symbian OS development environment provided the following Bluetooth APIs for the Bluetooth enabled application development:

Bluetooth Socket API. Bluetooth Sockets encapsulates access to L2CAP and RFCOMM through a TCP/IP-like sockets interface. The purpose of Bluetooth Sockets is to discover other Bluetooth devices, read and write data over Bluetooth. The Bluetooth Sockets API supports communication over both the L2CAP and RFCOMM layers.

Bluetooth Service Discovery Database is a registry of local Bluetooth services that enables remote Bluetooth service to discover. Bluetooth Service Discovery Database API provides an interface that allows Bluetooth service records and their attributes to be added, deleted, and updated.

Bluetooth Service Discovery Agent allows Bluetooth applications to discover the services that are available on a remote device and those services' attributes. Bluetooth Service Discovery Database and Service Discovery Agent are the APIs for usage of the Bluetooth SDP.

Bluetooth Security Manager enables Bluetooth services to set security requirements for incoming connections. Security settings are whether authentication, authorization, and/or encryption are required or not.

Bluetooth UI defines a method to use the Notification Services API, with a device selection plug-in to discover nearby devices and prompt the user to select a remote device to connect to.

Figure 26 describes the Bluetooth operations that a Bluetooth application needs to implement. Prior to using the Bluetooth socket API, a socket server must be initialized, and an application must set up service for incoming connections, which includes setting the security and access configuration, and registry of the service. After this, the application needs to discover a Bluetooth device that a user is desirable to communication, if it finds one device, the application requires to find out whether the relevant service is available. If there is, the application will be waiting for the coming connection or activate a connection with a Bluetooth device. As soon as the connection is made, data could be exchanged between the two Bluetooth devices. Cleaning up is a procedure to un-register the service and close all open connections once there is no data exchange needed.

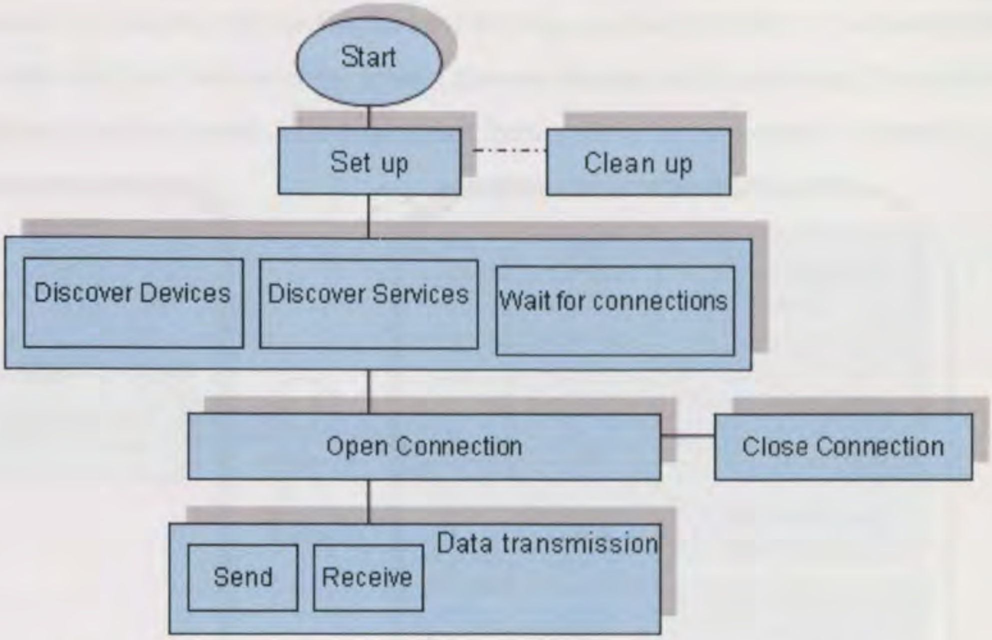


Figure 26. Procedures of Building Bluetooth Data Communications [125]

4.7.3 Software Design and Implementation of 'BlueReader'

"BlueReader" is the name of a data acquisition software designed by us for the Sony Ericsson P800 mobile phone and dedicated for MDMIS.

Sony Ericsson P800 supports variable programming languages: C++, PersonalJava (pjava), J2ME MIDP or Visual Basic. C++ is a compiled language; the applications run faster and have a faster startup time than those written in pJava, J2ME or Visual Basic, moreover, applications written in C++ have the most direct access to hardware and functions of the phone [126]. Therefore, we chose C++ for MDMIS's data acquisition for Bluetooth and GPRS connection in this study.

The MDMIS data acquisition system from a patient's perspective is to ease of communication between a patient's sensor and remote medical centre. On a patient side, the related data acquisition activities involve two devices: a glucose meter and a mobile phone. The principal operation on a glucose sensor is measuring a patient's blood glucose level manually, while the major functions are to be designed on the mobile phone. Operations on a mobile phone could be: (1) specifying a medical device from which data is to be collected; (2) pairing with this equipment to ensure the other party trusts the further Bluetooth connection; (3) inputting user account information for remote master station to verify the patient's ID; (4) manually input data to be transmitted to the remote medical database; (5) initiating reading data from the glucose meter and delivering data to the database, (6) stopping the reading activity during a reading process; (7) reviewing the original data that has been received from a glucose sensor; or (8) receiving the medical advice from a medical centre. These activities from a patient are depicted in Figure 27.

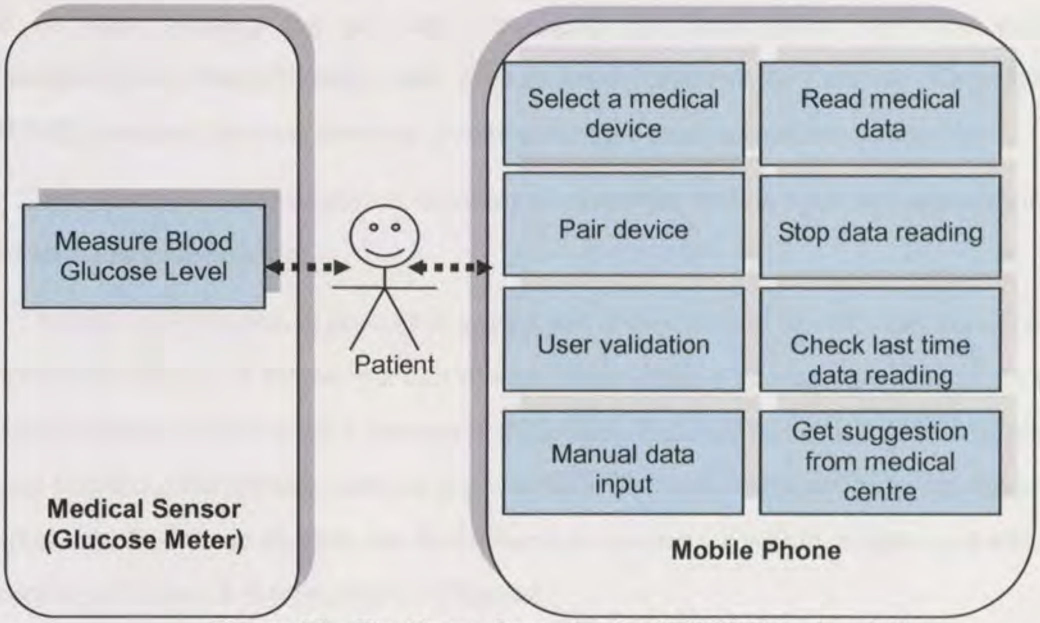


Figure 27. The Usage Scenarios for MDMIS Data Acquisition

Prior to presenting the detailed design and implementation of MDMIS data acquisition software - the BlueReader, we introduce two concepts:

(1) Synchronous and asynchronous

There are two types of services of function calls that can be performed, either synchronously or asynchronously. A synchronous service is the usual pattern for function calls, in which, the function returns while the service request has been performed either successfully or has failed with an error code.

An asynchronous service requested by a function call may complete later after the function call. Completion of the service is indicated by a signal. The request is been pending between the issue of the request and the signal. During this period, the requesting program can do other processing or it can wait. The operating system wakes up the program when there is a signal on completion of its pending requests.

In a multiprocessing system, user programs can do other things while waiting for a specific events, for example, keyboard input, pointer input, completion of an I/O request, timer events etc. These events and the services associated with them are provided by asynchronous service providers (a thread or process). This means, a function calls an asynchronous service, a asynchronous service provider informs the requester through a signalling mechanism that the requested service has actually completed.

In the MDMIS data acquisition system, the system requires to response to other user input (such as cancelling the reading procedure) during reading data from a glucose meter. To do data reading, the program also needs to detect other services, such as communication channel ready, data prepare ready and end of data etc. Therefore, in MDMIS, reading the measurement data is processed as an asynchronous service.

The important issues related to asynchronous service and on MDMIS data acquisition software are as following:

Thread and process. A process is a program; it can contain one or more conceptually concurrent threads. A thread is a unit of execution within a process. Every process has a primary thread created when a process is initialised. A thread can create, suspend, resume, panic and kill other threads, subject to protection. Data can be passed between threads no matter whether those threads are in different processes or within a same process. The interface of a thread is provided by RThread.

A **Semaphore** is for restricting of the number of simultaneous users on a shared resource. Threads can request access to a resource (decrementing the semaphore), and can signal that they have finished using a resource (incrementing the semaphore). A thread that requests access to a busy resource is put in a waiting state. A semaphore maintains a FIFO queue of waiting threads for a resource. When another thread increments a semaphore, the first thread in this queue is resumed. The semaphore handle is provided by RSemaphore.

An **active object** is an encapsulation of behaviors involved in making requests to an asynchronous service provider and handling the completion of those requests. It also encapsulates the functions that a service provider's request and cancels the function which handles the completion of those requests.

An **active scheduler** encapsulates a wait loop to use multiple asynchronous services. Together with the Active objects, this scheme provides a system of non pre-emptive multi-processing which runs on a single thread.

(2) Client/Server framework

Client/server framework is usually chosen to provide services on the management of shared system resources; asynchronous services or protection offered by running in a separate process from clients.

A server defines an interface that a client uses to request specific services. A server and a client communicates each other with a message-passing protocol. The client and server programs run in different threads and so do not directly access each other's address space.

Several concepts are introduced in Symbian Client/Server programming: Server, Session, Sub-session, and Message.

A **Server** is responsible for handling requests from client threads, forwarding the requests to s relevant server side client session, and the creation of server-side client sessions as a result of requests for connection from client threads. The server interface is provided by CServer.

A **Session** is the communication channel between a client and a server. The base client-side session interface is provided by `RSessionBase`. The communication from a client with the server is channeled through this interface's implementation. The corresponding server-side session interface is provided by `CSession`. Its base class - `CSharableSession` also provides the support needed for a session to be sharable by all threads within a single process.

A **Sub-session** presents an efficient refinement of a session when a client requires multiple simultaneous uses of a server. The base-client side sub-session interface is provided by `RSubSessionBase`. An implementation that derives from this defines the functions that to be exposed to clients. A server implements a corresponding sub-session class based on `CObject`.

A **Message** is a data structure passed between client and server. The interface of a message is provided by `RMessage`. A message consists of the type of client request, and four data parameters. Messages representing client requests are encapsulated in Client-side session and sub-session interfaces. Server-side sessions and sub-sessions can read client data from messages, and write data back to the client.

The MDMIS data acquisition software – BlueReader consists of a Server and a Client with a Client/Server framework.

The BlueReader Server provides the background services instead of a user interface. It provides connection to a glucose meter and gathers a patient's blood glucose measurement, which includes measurements and test time. The BlueReader Client follows the MVC model. It provides user interfaces, requesting data reading, selecting and pairing medical device, simulating data to be sent to a remote medical centre.

The final installation version of the BlueReader server is a .dll (Dynamic Link Library) file, while the BlueReader client is an installable .sis file. A schematic diagram showing the BlueReader software framework is shown in Figure 28.

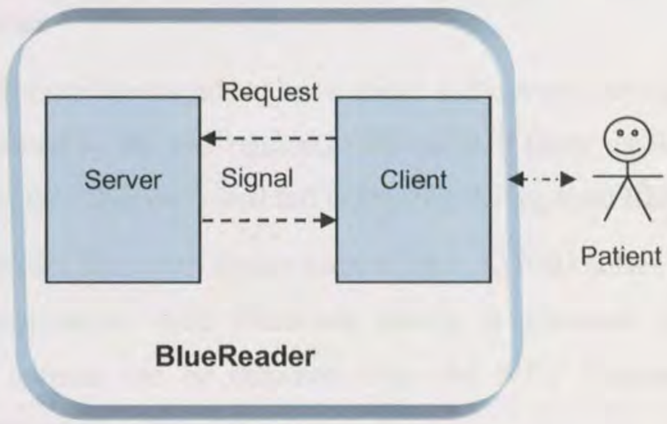


Figure 28. BlueReader Software Framework

The implementation and debug of BlueReader is achieved under the Symbian UIQ environment on a Windows XP PC platform.

(i) BlueReader Client

In this section we describe the design and implementation of the functions of BlueReader Client.

The BlueReader Client of the BlueReader provides user interface, which allows a patient to enter data, send commands and receive messages to and from the BlueReader server.

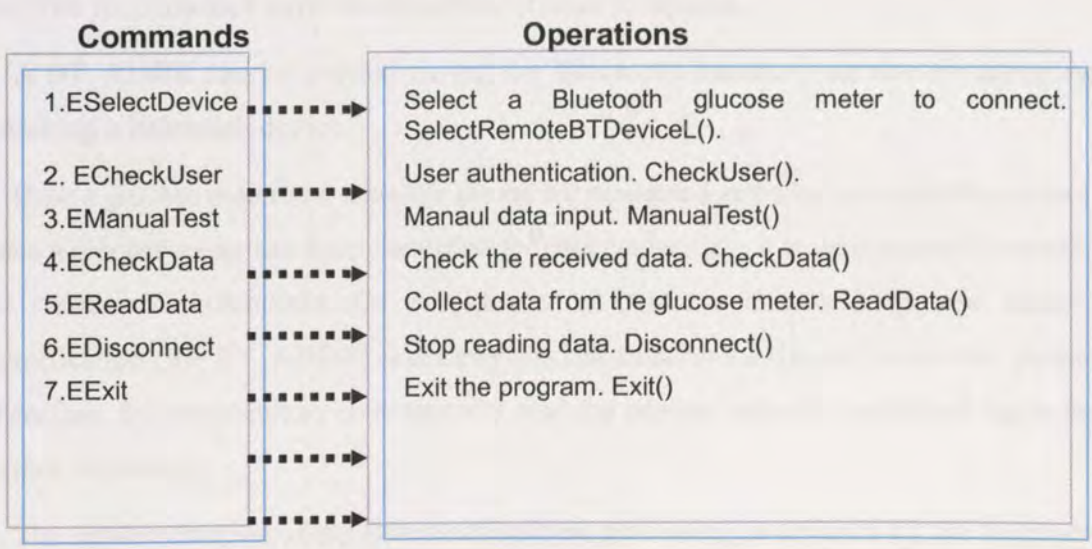


Figure 29. Schematic of functions of BlueReader Client

Figure 29 shows the mapping table of commands and operations of BlueReader Client.

(1) Specify a Bluetooth Glucose Meter

To acquire data from a glucose meter, the BlueReader must know the data source for building a connection channel. Hence the primary idea is to get the identification of a relevant glucose meter.

Generally, a device can be recognized by its name. A Bluetooth device name can be up to 248 bytes and named by the user randomly. However, if there are Bluetooth devices with the same name, the other party will fail to identify the required Bluetooth device.

The introduction of a Bluetooth device address (BD_ADDR) solves this problem. In the Bluetooth specification, each Bluetooth device is allocated a unique 48-bit BD_ADDR. This address can be obtained from the IEEE Registration Authority (http://standards.ieee.org/regauth/oui/).

The BD_ADDR is divided into the following three fields:

- LAP (Lower Address Part) field: consisting of 24 bits;
- UAP (Upper Address Part) field: consisting of 8 bits;
- NAP (Non-significant Address Part) field: consisting of 16 bits.

The LAP and UAP forms the significant part of the BD_ADDR. A BD_ADDR can be any value, except the 64 reserved LAP values (0x9E8B00-0x9E8B3F) for general and dedicated inquires one. One reserved LAP address (0x9E8B33) is for general inquiry and used regardless of the contents of UAP and NAP. The remaining 63 LAPs are reserved for dedicated inquires of specific classes of devices.

A BT_ADDR can be queried during the Bluetooth discovery service by activating searching a Bluetooth device.

Both a glucose meter and a mobile phone are possessed and used by a specific patient. Once a glucose meter has been identified for data connection, it is unnecessary to specify the device a second time. So our idea is to obtain a Bluetooth glucose meter's identification (the BT_ADDR) and store this information locally on the mobile phone. Therefore, the program can automatically read the address without querying it again for further connection.

The implementation of the Bluetooth address processing is obtained by the function-SelectRemoteBTDeviceL(). Within this function, the program first activates a dialogue instance derived from CQBTUISelectDialog by using the method LaunchSingleSelectDialogLD(). If a patient has chosen a Bluetooth glucose sensor from the available Bluetooth devices list, the address can be obtained by an object instance of TBTDevAddr. The program writes this address into a file "BlueMeter_devAddr.txt" which is saved in the local mobile phone. When building the next connection, the address can be acquired by reading the file.

(2) User authentication

For system security consideration (for example, excluding further data processing from unknown or illegal sources), it is compulsory to validate a user's identity before he/she can submit his/her medical measurements to a remote medical centre. However, the patient may feel it unacceptable to enter his/her user information every time. Furthermore, the mobile phone is always with them. A measure is therefore considered to save time and simplify user authentication during the design and implementation of the BlueReader.

Figure 30 shows the data flow of user authentication. The execution of the CheckUser() method prompts a dialogue for a user to input his/her user account information (user id and password) for verification. A feedback from the remote master station will be sent back to the BlueReader and shown on the mobile phone's screen to indicate valid or invalid user information. If it is a valid account information, the user id and password will be written to a local file stored within the mobile phone. Even if there is user information already, the program still will overwrite the file with the new data.

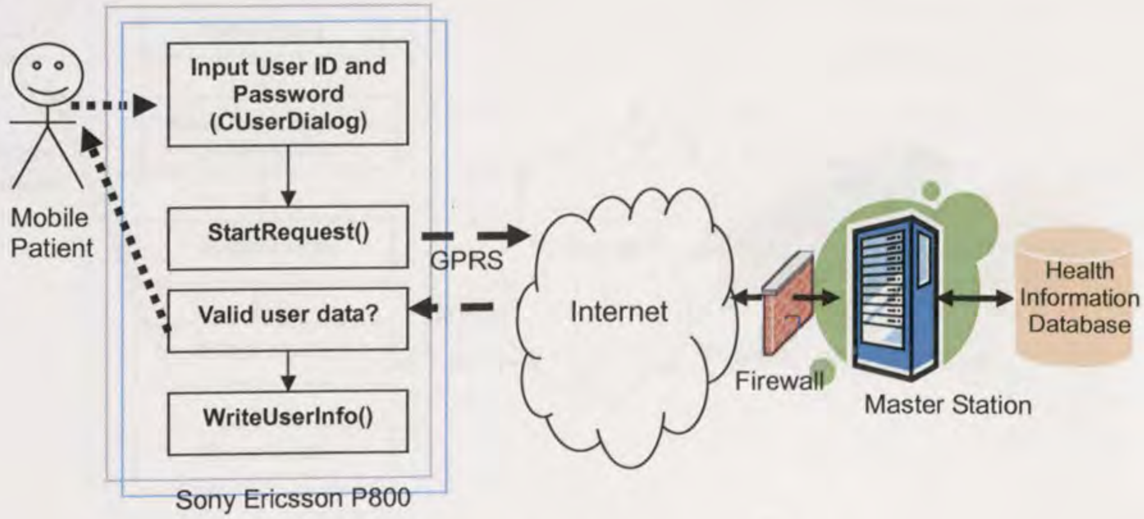


Figure 30. User Authentication Data Flow

(3) Manually input blood glucose data

This function is designed with two objectives:

- For a patient to manually input medical measurement data;
- For test usage.

During this operation, a dialog is prompted to ask a patient to input blood glucose level in either "mmol/l" or "mg/dl" unit, and measurement time (the default is the current time). The data will be converted to "mmol/l" if it is in "mg/gl" by following the formula as described in section 2.2.1 in chapter 2. All the data provided by a patient are verified to ensure they are in the correct format before being sent to the medical centre. This information will be further analyzed in the master station and saved to MDMIS accordingly. If the measurement is found to be out of the recommended range, or the patient's medication needs to be changed, a warning message will be sent back directly to the patient's mobile phone and an e-mail message of details will also be sent to the patient. Otherwise, the returned message to the patient is simply the notification "data was saved". A summary of this procedure is depicted in Figure 31.

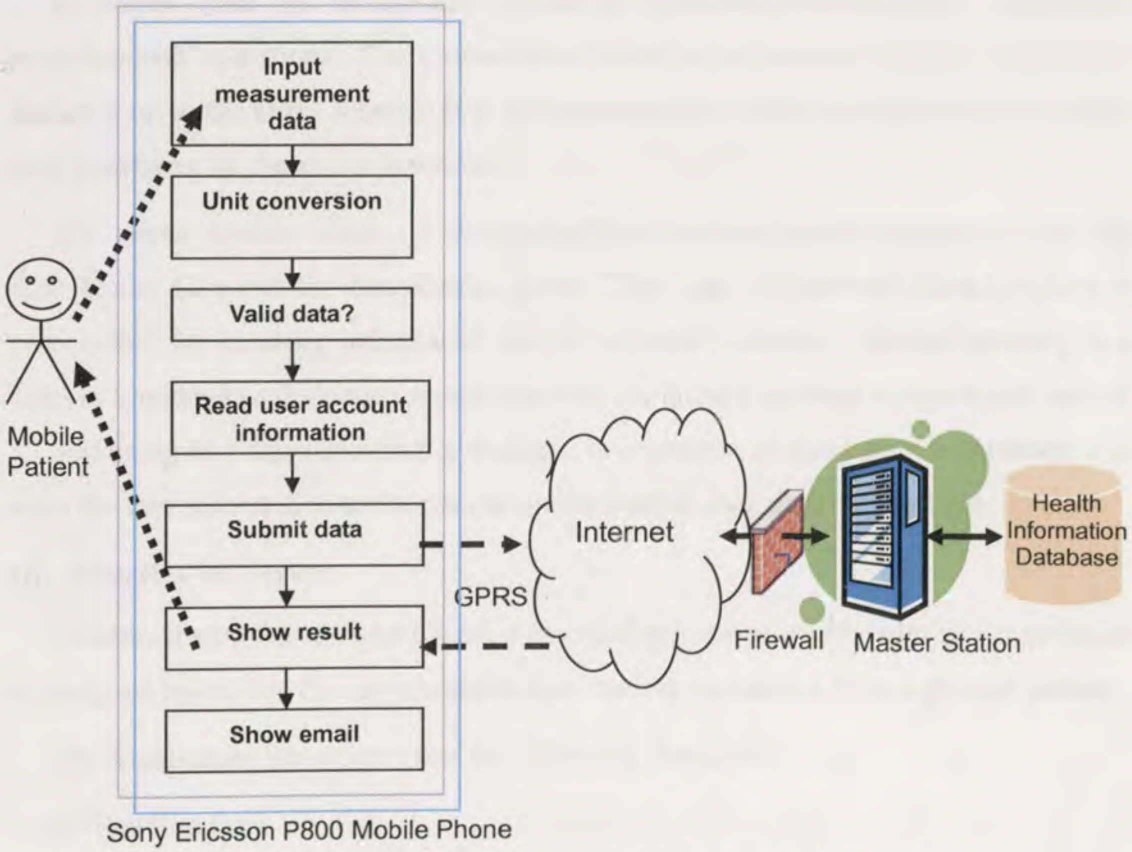


Figure 31. Summary of Manual Data Test Procedure

(4) Check received data from a glucose meter

The latest received original datagram from a glucose meter is saved as a file in a local mobile phone and can be read. This function is reserved for debugging the data reading. The patient can also review these data anytime afterwards. The earlier received data was overwritten with the recent data received by the program and was not archived because of the limited storage space of the mobile phone.

(5) Reading data and disconnecting a communication channel

The BlueReader Client sends commands of reading and disconnecting to the BlueReader Server. These two functions are implemented by the BlueReader Server and will be discussed in the following subsections.

(6) Exit the procedure

This function involves checking the reading status, closing Bluetooth connection if there is an existing Bluetooth link, clearing the stack, and termination of the BlueReader program.

(7) Class Implementation

A major class in BlueReader Client is CBlueMeterClientAppUi supporting asynchronous operations. The CBlueMeterClientAppUi handles the user's input and passes it on to the client session. It is also responsible for the implementation of all the user interfaces for the above functions.

The client session class - CBlueMeterClientSession sends commands from the BlueReader Client to the BlueReader server. The class CBlueMeterClientAppView is responsible for showing information on the terminal's screen. CManualInputDlg is a class to implement a dialogue for user manually inputting a medical measurement record. CUserDialog is a class in which a dialogue is prompted to input user information and send the user information to the remote master station once data is submitted.

(ii) BlueReader Server

Combined with BlueReader Client, a essential activity of BlueReader server software is designed to provide the asynchronous data reading operations from a glucose sensor.

The BlueReader Server provides the following functions:

(1) Reading Data

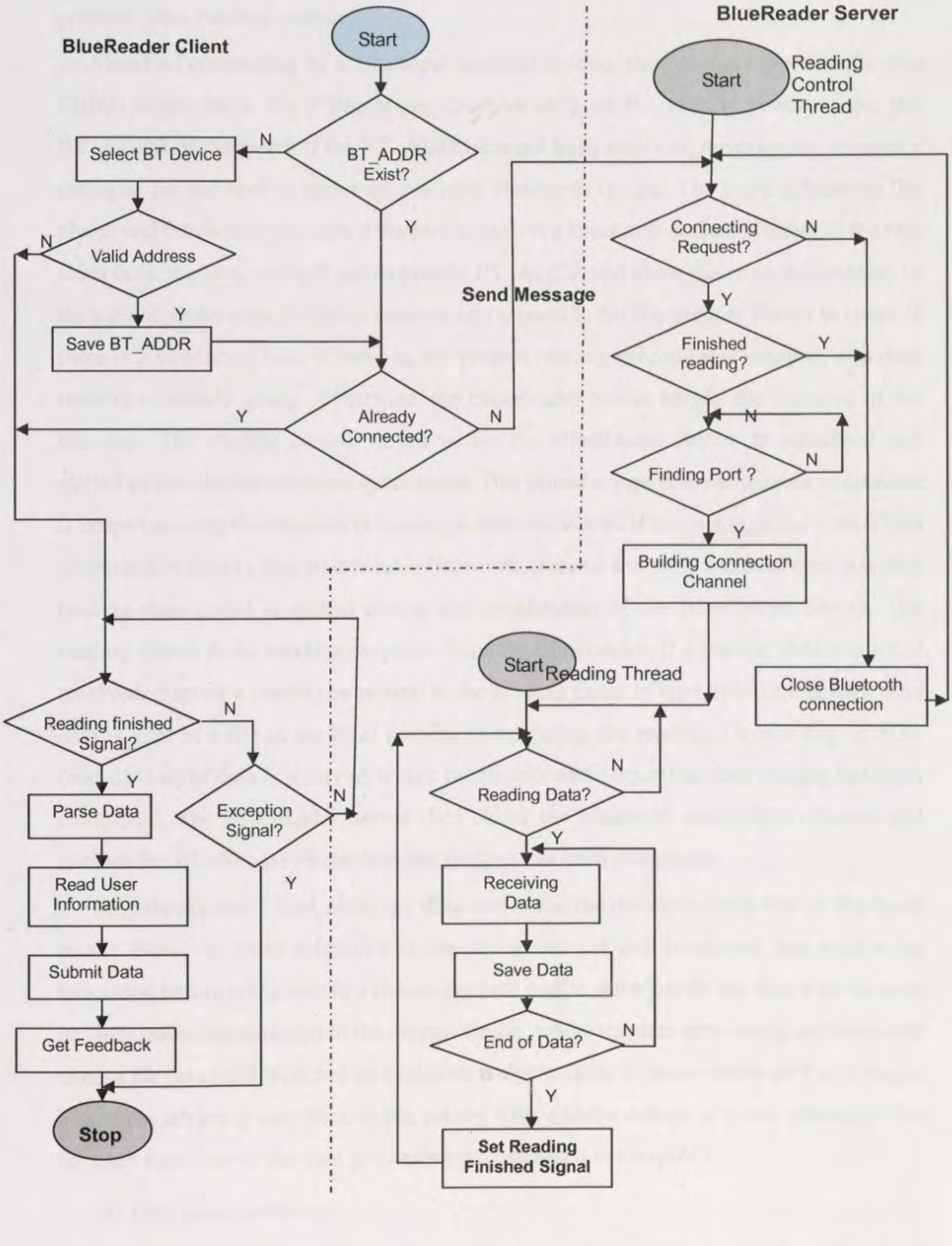


Figure 32. Data Flow of Reading Medical Data

The procedure of reading data from a glucose meter on a mobile phone in the

BlueReader is shown in Figure 32. The reading data procedure is initiated after a patient pressed "data reading" menu.

Ahead of connecting to a Bluetooth medical device, the program (the BlueReader Client) looks for a file ("BlueMeter_devAddr.txt") on the mobile phone to get the BT_ADDR of the meter. If the BT_ADDR has not been archived, the program prompts a dialogue for the user to select an available Bluetooth device. The pairing between the phone and the device preceeds if the patient selects a Bluetooth device. If either of the two sides fails, the program will get an invalid BT_ADDR and show the error information to the patient. Otherwise, it sends a reading data request to the BlueReader Server to check if there is a connected link. If there is, the present reading procedure is stopped, as a data reading is already going. Otherwise, the BlueReader Server checks the category of the message. The reading control thread within the BlueReader Server is initialised and started as soon as the whole program starts. This thread supports asynchronous operations. It keeps handling the requests or messages from the client. If the message is a connection command, it tries to find an available Bluetooth channel and build a connection. Another reading data thread is started during the initialisation of the BlueReader Server. The reading thread is for handling requests from the BlueReader. If a reading data request is received, it sends a reading command to the glucose meter to start transmitting data. The data is kept in a file in the local mobile phone during the reading. Once a flag of EOT (end-of-text) of data is received, it tells the BlueReader Server that data reading has been completed. The BlueReader Server then closes the Bluetooth connection channel and notifies the BlueReader client that data reading has been completed.

The BlueReader Client reads the data and saves the data to a local file on the local phone. However, these original data are coarse and not well-formatted, and need to be processed before being sent to a remote medical centre. Afterwards, the data with the user account information is sent to the master station, where the data-processing software will checks for data validation and do a relative analysis. If the measurements are out of range, a medical advice is sent back to the patient with a text message or email message. The detailed functions of the data processing are discussed in Chapter 5.

(2) Data pre-processing

Since the original data acquired from a blood glucose meter maybe incorrectly formatted or even invalid, it is necessary to process these data before being submitted to the remote centre (the MDMIS master station).

There are two benefits of data pre-processing:

First, the amount of data to be transmitted is decreased because the unuseful data is filtered and discarded. This reduces the data flow over the wireless network and the cost of data transmission.

Second, the pre-processing alleviates the load on the remote master station. The measurements are converted to a uniformed measurement unit (mmol/l) before being sent. Data is processed by following a specific data format: ("userid@userpassword@yyyyMMdd hh:mm measurement"). The master station only needs to process the data strictly conforming to this format.

Accordingly, a data processing consists of three steps: selection of the useful data, conversion of measurement unit and data formatting. The original data packet is put in a file by the BlueReader server on the mobile phone after a successful data reading.

For example, an original data packets for measurement records from the glucose meter are as in Figure 33:

*..**(STX)**D8...007.1.20040318.15:36.00630..*
*A4...**101**.1.20040314.17:12.00163..*
*98...**206**.1.20040314.17:00.01..*
*02...**306**.1.20041112.17:00.02..*
*01...**407**.1.20041112.16:57.00318..*
*A8...**507**.1.20041112.16:56.00318..**(EOT)**..*

Figure 33. Data packet received from the glucose meter

The necessary data processing to get the useful data is as follows:

(a) Selection of useful data. The STX is an ASCII control character, means "Start of Text", while the EOT means "End of Text". The text paragraph between two signs is the measurement records. Each line in this text paragraph represents a record. However, only "***A4...101.1.20040314.17:12.00163..***" is a valid record, since its verification byte(the eighth byte) is "1". "***20040314.17:12***" is a time when the patient measured his/her blood glucose level. The "163" is a glucose measurement. The "**.**"in the Figure 33 is an ASCII control character.

(b) Unit conversion. The measurement uploaded to the BlueReader software is in "mg/dl". However, in UK clinics, the unit of "mmol/l" is adopted to measure blood glucose level. A conversion is made from "mg/dl" to "mmol/l" as the original data is in "mg/dl" on the glucose sensor.

(c) Data formatting. In this scenario, the BlueReader software sends a uniformed data "20040314 17:12 9.1" to the medical control centre after formatting the original data - "*A4...101.1.20040314.17:12.00163..*".

The data flow of the BlueReader data processing is shown in Figure 34.

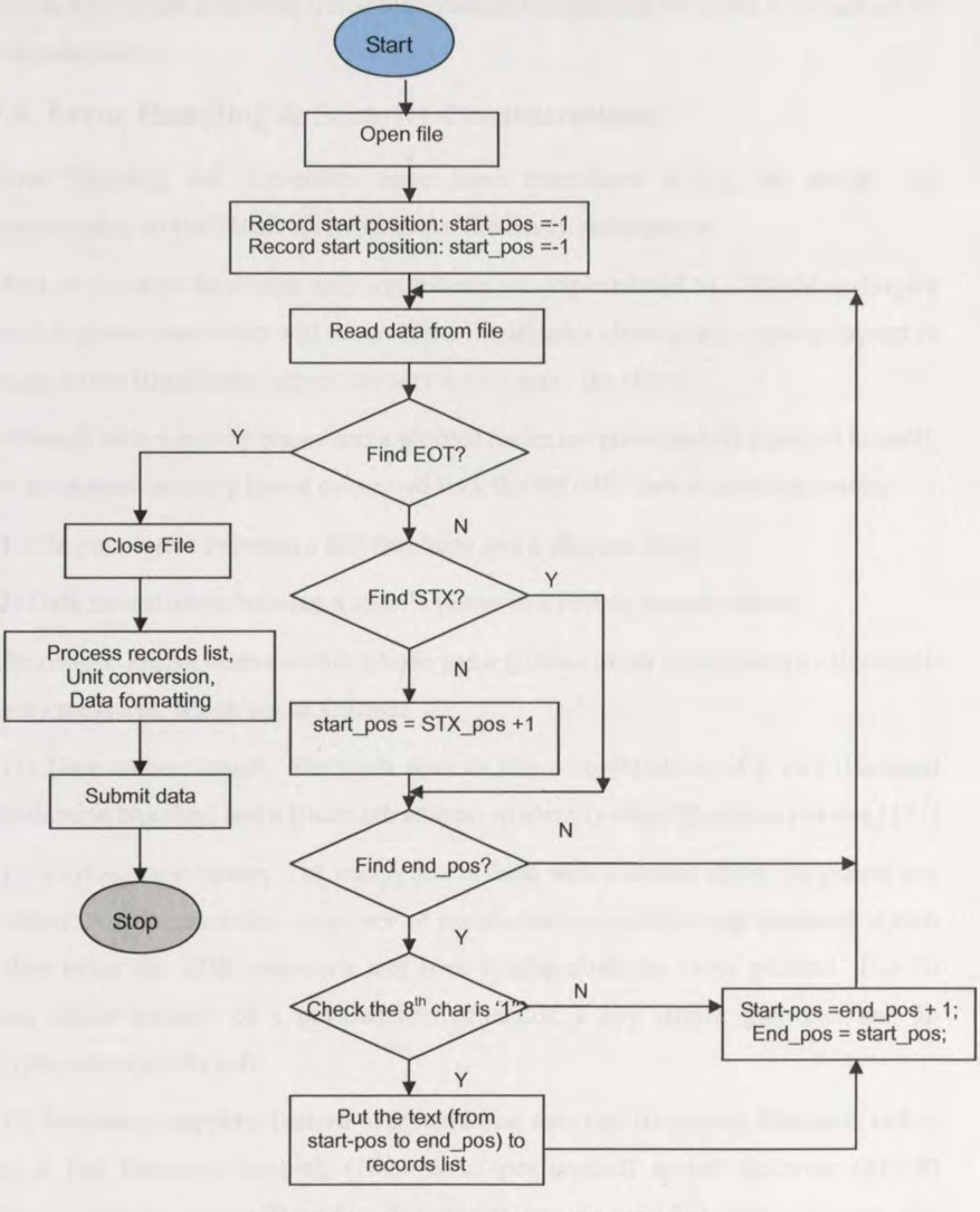


Figure 34. Data Processing of BlueReader

(4) Class Implementation

A major class for the BlueReader server is CBlueMeterServer. It handles all the requests from the BlueReader Client, passes the requests to the engine if necessary, and provides services to the client. CBlueMeterEngine sets up and handles Bluetooth connection with a glucose sensor. CRFCOMMServiceFinder performs a port searching for a Bluetooth connection. CBlueReader handles the reading operations from Bluetooth socket and saves the data read. CBlueMeterSession dispatches the client messages to the BlueReader server.

4.7.4 Error Handling & Security Considerations

Error handling and prevention have been considered during the design and implementation of the BlueReader client and the BlueReader server.

Most of the error handlings and preventions are implemented in CBlueMeterEngine since it is where most errors will occur. If the BlueReader client sends a wrong request or message to the BlueReader server, the server will panic the client.

Although both a mobile phone and a glucose meter are possessed by a patient himself, there are several security issues concerned with the MDMIS data acquisition system:

(1) The connection between a mobile phone and a glucose meter.

(2) Data transmission between a mobile phone to a remote master station.

The connection between a mobile phone and a glucose meter is enhanced by Bluetooth security measures, which are as follows:

(1) User authentication. Bluetooth devices use a combination of a PIN (Personal Identification Number) and a Bluetooth address to identify other Bluetooth devices.[127]

(2) Payloads encryption. The encryption is done with a stream cipher E0 (secret key algorithm), which generates a sequence of pseudorandom numbers and combines it with the data using the XOR operatoris and is re-synchronized for every payload. The E0 stream cipher consists of a payload key generator, a key stream generator and an encryption/decryption part.

(3) Frequency hopping. Instead of transmitting over one frequency, Bluetooth radios using a fast frequency-hopping (1600 times per second) spread spectrum (FHSS) technique, jumping among 79 random frequencies within a specified range, allowing only synchronized receivers to access to the transmitted data.

Data transmission from the BlueReader to the remote MDMIS master station is ensured by the BlueReader software itself with the following measures:

(1) User authentication. Any submitted data to the master station is combined with a user identification and a user password. The data-processing software at the master station side will analysis and any measurement without correct user information will not further processed and be saved in the MDMIS health information database.

(2) Data transmission. The data submitted to the master station is through a SSL secure transmission channel to ensure a secure data transmission.

4.8 Summary

In this chapter, we have presented the detailed design and implementation of the wireless data acquisition system of MDMIS. The Bluetooth connectivity and development of the system has been described, together with the relevant GPRS connectivity issues.The communication protocol of the medical sensor is also described.

Chapter 5

Design of MDMIS Software System

5.1 Introduction

In this chapter, we address the software issues for the management and internetworking of MDMIS. We present in the next section the usage scenario analysis. Section 5.3 describes the selection of development languages and the software architecture for MDMIS. The design of the MDMIS health information database is presented in section 5.4. We describe the design and implementation of services provided by the master station in section 5.5, while the MDMIS functions that can be accessed from client stations are described in section 5.6. Finally, system mobility and security issues of MDMIS are discussed in section 5.7.

5.2 Usage Scenario Analysis

As explained in section 3.4, the flexible architecture design of MDMIS is based on the user requirements of the system. The users of MDMIS are categorized as Patients, Medical Administrators, Physicians, and System Maintainers. After consulted with medical doctors and diabetics, we clarify the major usage scenarios for MDMIS users as follows:

- **User Management.** Each user should be able to manage their own account information, including date of birth, contact information, residence address, etc., and change their passwords. Some kinds of users may have the privilege to manage multiple users' account.

- **Definition of time segment.** Long-term diabetes monitoring requires examining the pre-prandial, pre-bed and post meal blood glucose level of a patient. Yet, every patient has his/her own life style, a same measurement time may be taken before a breakfast by a patient, but after a breakfact by another one. Hence, MDMIS needs to adaptively detect what time the measurement was taken. Both patients and medical doctors should be able to define the relevant time segment.

- **Check measurement records**. Patients should be able to browse their previous measurements for good understanding of their present diabetes situation. Tools should be provided for analysing the patients' measurements, thus to assist the relative physicians or doctors make medical decisions.

- **Browse medication history records and medication management.** Patients may want to check their medication history to be aware of their therapy situation. Medical doctors may browse patients' medication records and be able to change the medication for a specific patient.

- **Side-effects report.** Changeing the medication of a patient may lead to side-effects. Patients should be able to report the side-effects. Physicians can also help a patient to build the side-effects record.

- **Automatical medication correction.** In MDMIS, tools are provided to help automatically change a medication according to a patient's recent glucose measurements.

- **Medicine management.** Physicians or doctors may manage or check relative electronic information of available medicines for diabetes therapy.

- **Medication protocols management.** The specified medical doctors should be manage the medication protocols which are the basis of changing medications.

- **Operation tracking.** Significant operations may be recorded for later review. The operations can then be reviewed to examine the users' activities.

- **Diabetes education information.** It has been well known that diabetes self-education plays a significant role in diabetes self-management, the system should be able to provide such information to help patients improve their knowledge on diabetes management.

5.3 Software Tools and Languages

In this section, we describe the choice of the relevant software tools and programming languages used for the development of the MDMIS system.

5.3.1 Wireless Programming Options for Mobile Devices

There are several programming options for wireless devices, which are summarised as follows:

(i) WAP (Wireless Application Protocol) and WML (Wireless Markup Language)

"The WAP is a de-facto world standard for the presentation and delivery of wireless information and telephony services on mobile phones and other wireless terminals." [128] The WAP specification defines a architecture and a set of protocols for implementation of wireless Internet access. WAP communications involve three major component types: WAP-enabled mobile device, WAP gateway and Web server. A WAP gateway is designed to do "translation" between WAP to HTTP (Hypertext Transfer Protocol), which allows the transfer and viewing of information in web transactions. It accepts requests from a WAP -enabled mobile device, and converts WAP content to HTTP content to request the service from a relative web server. The web server processes the request and sends the information back to a WAP gateway with HTTP, the WAP gateway translates the content back to WAP and sends it to the requested mobile device.

WML is the language used to create pages displayed in a WAP browser. It is inherited from HTML but based on XML.

(ii) HDML (Handheld devices markup languages)

HDML was among the first programming languages for small and handheld devices. It is similar to HTML (Hypertext Markup Language), but HTML is not effective for those devices with small screens. HDML can only be viewed on mobile phones with Openwave browsers. The evolution of it is WML (Wireless Markup Language).

(iii) I-mode and Compact HTML (cHTML)

I-mode has been developed by a Japanese wireless Internet access provider - NTT DoCoMo. The operation mechanism of the i-mode service is similar to WAP. The markup language used in i-mode is compact HTML (cHTML, a subset of HTML). I-mode service is available mainly in Japan.

(iv) Java 2 Micro Edition (J2ME) and java

With the benefit of the Java technology, J2ME can be deployed on various consumer devices. J2ME provides an application environment for wireless or embedded devices. The J2ME architecture comprises configurations, profiles, and optional packages for developing applications. There are two types of J2ME configurations: the Connected Limited Device Configuration (CLDC) and the Connected Device Configuration (CDC). A profile is a set of higher-level APIs that further define the application's life-cycle model, the user interface, and access to device-specific properties. The Mobile Information Device Profile (MIDP) provides a complete Java application environment for cell phones and other devices with similar capabilities by combining with CLDC. Java is J2ME's programming language. [129]

(v) Extensible Hypertext Markup Language (XHTML) Basic

The World Wide Web Consortium (W3C) has defined XHTML as the latest version of HTML, and XHTML will gradually replace HTML. XHTML is a family of document types and modules that reproduce, subset, and extend HTML 4. The motivation for XHTML Basic is to provide an XHTML document type that can be shared across various devices [130].

5.3.2 Software architecture for MDMIS

MDMIS uses a three-tier software architecture as shown in Figure 35.

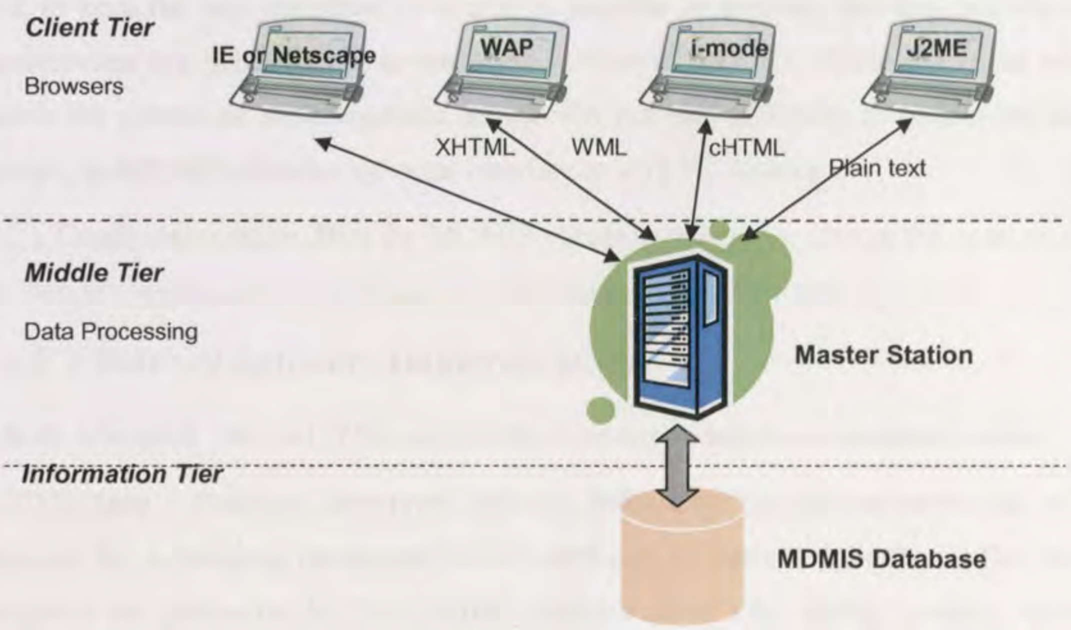


Figure 35. Software Architecture of MDMIS

The information tier is the MDMIS health information database, which provides the storage and retrieval of the medical information and user accounts.

The middle tier is an information processing tier. It processes remote clients' requests and interacts with the MDMIS health information database; furthermore, it marks up the response and sends contents of the result back to variable clients with a different content rendered accordingly across heterogeneous environments.

The client tier consists of four client types: Internet Browsers, WAP browsers, i-mode and J2ME. Microsoft Internet Explorer, Netscape, Firefox, etc. can display XHTML content, the WAP browsers can show WML content, a I-Mode terminal can show cHTML content, while J2ME can show content in plain text. In fact, the majority of J2ME-enabled handheld devices with the Internet connection support also have browsers for browsing XHTML context.

A web-powered solution has been applied in the implementation of MDMIS for providing a reliable, scalable, and highly available system on diabetes management.

The advantages of this software architecture are:

(1) Ease of deployment. MDMIS can be deployed without any additional or further client-side configuration. Update of the MDMIS services is straightforward as the changes can be made only on a server-master station.

(2) Simple user interface. We considered different backgrounds of MDMIS users, and seek to keep the user interfaces as simple as possible to decrease the data quantity of transmission and help users to access the functions of MDMIS efficiently. Users who access the system on their handheld device will not find difficulty to understand and operate, as MDMIS provides a similar interface as on a PC desktop.

(3) Timely data update. Data for MDMIS clients to access are always the latest as all the data are stored and any data query is performed at the server side.

5.3.3 Choice of Software Implementation

Both Microsoft .Net and J2EE support the three-tier architecture mentioned earlier.

J2EE (Java 2 Platform, Enterprise Edition), defined by Sun Microsystems Inc, is a standard for developing component-based multi-tier enterprise applications. The Java programs are interpreted by Java Virtual Machine (Java VM) during running, which means that any computer system with the Java VM installed can run a Java program regardless of the system on which the application was originally developed [131]. J2EE can work on any platform with a compliant Java VM and a compliant set of required platform services (EJB container, JMS service, etc.) [132]. All the specifications that define J2EE are published and reviewed publicly, and there are numerous vendors offer compliant products and development environments.

.NET is the Microsoft web services strategy and integrated across the Microsoft platform to quickly build, deploy, manage, and apply the connected and security-enhanced solutions with web services. [133] The Common Language Runtime (CLR) is Microsoft's commercial implementation of the Common Language Infrastructure (CLI) specification, which is a standard for creating development and execution environments in which languages and libraries can work together seamlessly.

A comparison of J2EE and .Net is shown in Table 11. [134]

Feature	J2EE	.NET
Type of technology	Standard	Product
Middleware Vendors	30+	Microsoft
Interpreter	JRE	CLR
Dynamic Web Pages	Servlet/JSP	ASP.NET
Middle-Tier Components	EJB	.NET Managed Components
Database access	JDBC SQL/J	ADO.NET
SOAP, WSDL, UDDI	Yes	Yes
Implicit middleware (load-balancing, etc)	Yes	Yes

Table 11. Comparison of J2EE and .NET

We choose J2EE Servlet technology for the web-service solution of MDMIS. Servlet is a Java technology based web component and is managed by a servlet container. Servlets are the platform-independent Java classes that can be loaded dynamically and run by a Java-enabled web server. A servlet container contains and manages servlets through their life. It is a part of a web server or an application server that provides the network services over which requests and responses are sent, decodes Multipurpose Internet Mail Extensions (MIME) based requests, and formats MIME-based responses. A servlet container can be built into a host web server, or installed as an add-on component to a Web Server via that server's native extension API. All servlet containers must support HTTP protocol. [135]

Apache Tomcat [136] was chosen as the servlet container as well as the web server for MDMIS. Apache Tomcat is open-source servlet container and is used in the official Reference Implementation for the Java Servlet and JavaServer Pages (JSP) technologies.

5.3.4 Extensible Markup Language (XML)

XML has been a widely supported open technology for data exchange. It was developed in 1996 by the XML Working Group under the auspices of the World Wide Web Consortium (W3C) [137]. XML describes a group of data objects called XML documents and partially describes the behavior of computer programs which process them. XML documents consist of entities (storage units). All the entities are with content and are identified by entity name(except for the document entity and the external DTD subset). A XML begins with a document entity or "Root". A software module - XML processor is used to read XML documents and provide access to their content and structure with technologies such as the Extensible Stylesheet Language (XSL) [138].

XSL is a family of W3C recommendations for defining XML document transformation and presentation. XSL includes 3 sections: The XSL Transformation (XSLT) is a language for transforming XML; the XML Path Language (XPath), an expression language used by XSLT to access or refer to parts of an XML document; and XSL Formatting Objects (XSL-FO), an XML vocabulary for specifying formatting semantics.

The key advantage of XML is the portability. The data content and the format of expression are separate, which means the data can be published to different media.

We applied XML and XSL technology for the data exchange between the MDMIS clients and the MDMIS master station to improve system's portability. Information content are carried through XML, combined with the XSL language, and can be translated to corresponding HTML, XHTML and WML languages according to the type of the relevant client.

5.4 Design of MDMIS Health Information Database

We chose Oracle 9i as the database management system for MDMIS health information data management. The Oracle DBMS (DataBase Management System) is a world-famous, comprehensive database solution. It provides unique portability across all major platforms, and ensures that the applications will run without modification even on a changed platform. Another advantage of Oracle9i is the scalability. Oracle 9i Real Application Clusters is self-tuning and adapts to the changing nature of the database workload by dynamically shifting database resources across the cluster servers for optimal performance.[139]

The database interface between the MDMIS services and the MDMIS database is Java Database Connectivity (JDBC). JDBC is a java API for java programs to execute SQL statements. This allows java programs to interact with any SQL-compliant database. For MDMIS, the data access interface of JDBC is adopted for programming, which means any other relational database system which supports JDBC can also be the database systems for MDMIS health information data storage and management.

We chose the Oracle enterprise edition for MDMIS solution to support potential large numbers of users' concurrent access. During the installation, we tuned Oracle to "optimised transaction processing" for a fast and efficient processing of SQL statements of the Oracle database server.

Although the medical rule of deciding whether or not a blood glucose measurement is out of range could be designed and stored in the database, we did not consider this way. The justification for this can be summarised: the rule has been fixed to specific data and it will not be changed; the relevant data processing time is reduced by directly reading data from memory instead of from a database. The measurement range of blood glucose level for diabetes management is presented in Table 3 (Chapter 2).

5.4.1 Terminologies about Relational Database

Oracle 9i is a Relational Database Management System (RDBMS). A relational database is a database in which data are viewed as a collection of linked tables.

A **table** is a set of data arranged in rows and columns. It contains data about a specific entity type. An entity is synonymous with a table. An entity type is a class of real word objects or concepts with common properties, such as students, appointments. Each column represents a specific attribute (or property) of the table's entity type, for example, age of students. Each row represents a unique entity type, for example a specific student or appointment.

A **relationship** is an association established between common columns in two tables. A relationship can be:

(1) One-to-one (1:1): each row in table A can have at most one matching row in table B, and each row in table B can have at most one matching row in table A.

(2) One-to-many (1:n): each row in table A can have zero or more matching rows in

table B, but each row in table B has only one matching row in table A.

(3) Many-to-many(m:n): each row in table A can have zero or more matching rows in table B, and each row in table B can have many matching rows in table A.

A **primary key** is a field or a combination of fields, the data of which is the unique identification for a record within the table. A **foreign key** is a field that is not the primary key of a table, but is a primary key of another table.

Entity-Relationship Diagrams (ERDs) demonstrate the logical structure of a database graphically. An ERD represents the structural contents (columns) in tables in a database. Additionally, an ERD includes schematic representations of various types of relationships between entities, plus primary and foreign keys.

5.4.2 MDMIS Health Information Database

The MDMIS health information database is located in a medical centre and can be deployed in the same LAN as the master station or the mobile MDMIS web server.

The design of the MDMIS database follows the procedures below:

- Clarify the data requirement of the MDMIS system to specify data tables and relationships.
- Normalise database to eliminate data reduncancies and enforce data integrity. The process of normalisation is reducing a specific collection of relations to a more desirable form by complying with "Normal Form"s.

The MDMIS database consists of four types of data to meet the specific medical data requirement of MDMIS:

- User data;
- Medication protocols;
- Medical records;
- Operations records.

These four types of information are all related with each other in the MDMIS database. For example, medical records are related to user account data, from a patient's medical record, the detailed account information of the patient can be acquired through the relationship between the user tables and the medical records tables.

5.4.3 Data Structure of User Data

The ERD (Entity – Relationships Diagram) of user data is shown in Figure 36. In a ERD, each block represents a table. On each block of every table, the top row shows the table's name, the fields are shown in the middle; the bottom row shows the primary key of the table. A relationship is represented by a labelled link between the both tables. For instance, a "1:x" link represents a one-to-many relationship between the linked tables.

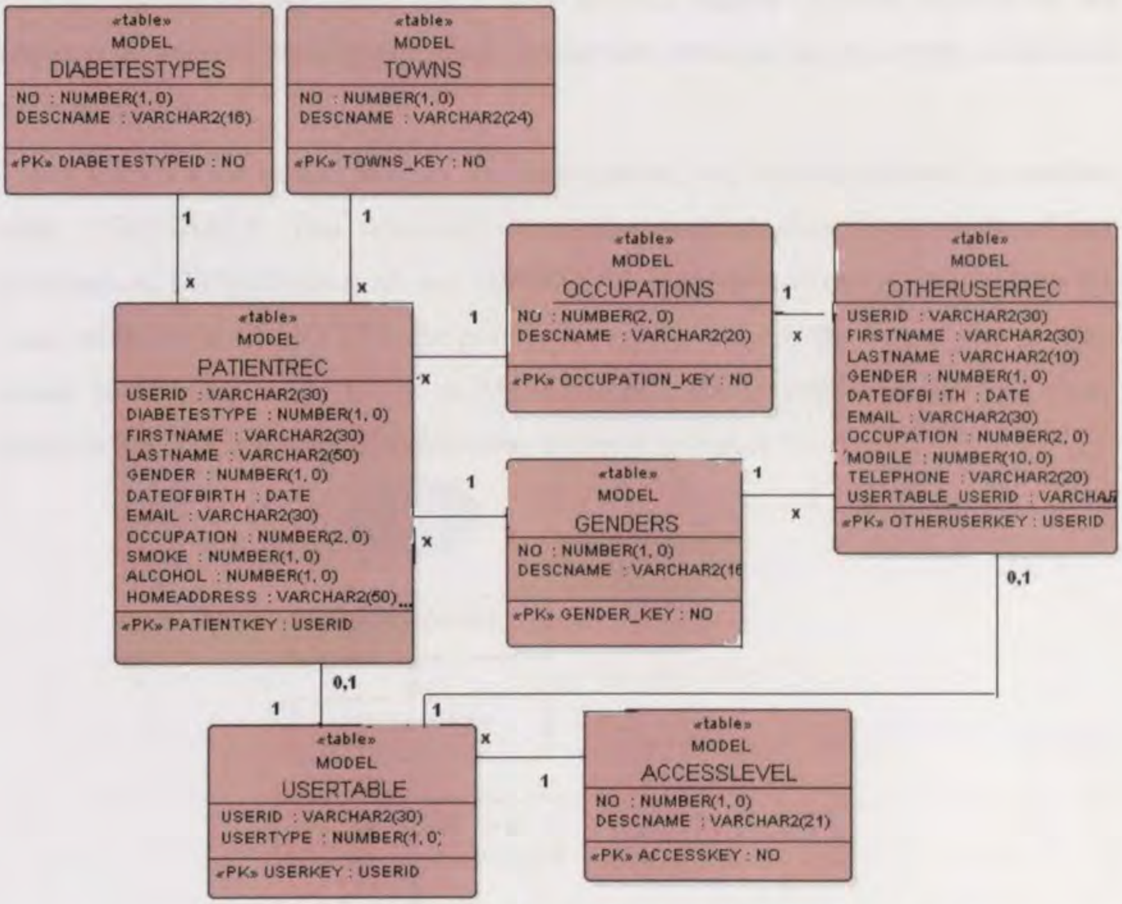


Figure 36. Entity-Relationship Diagram of MDMIS User Data

To save database storage space and avoid data redundancy (database normalisation), we designed the enumerator data in reference tables which only contains a serial number field NO (an integer with 1 or 2 digits) and a description field DESCNAME (string). The referring data table only needs to store the index number of the field. For example, the table OCCUPATION is an enumerator table. It has two fields: NO and DESCNAME. In the table OTHERUSERREC (other users records), the real data of the OCCUPATION field are the digits which are the corresponding field of field NO in table OCCUPATION. This relationship is expressed by a foreign key: the field OCCUPATION in the table OTHERUSERREC, which is not the primary key of OTHERUSERREC, but the primary key of the table OCCUPATIONS.

The user data of MDMIS consists of all types of users' account information. We divided the data structures of the user data into two types: (1) patients' user accounts, the table PATIENTREC (patient records) is designed to store these information; (2) other users's accounts, which includes physicians, medical administrators and system maintainers, they are all stored in the same user information table - OTHERUSERREC. This division is for the reason that a more detailed patients' account information are required for analysis while a shared and simpler data struction for other types of MDMIS users is enough.

However, for the convenience of the data retrieval, we created a shared information table: USERTABLE. This table only stores the common data of all kinds of user information: USERID (user id) and USERTYPE (role type of user). By querying the value of the field USERTYPE, the program is able to acquire the further user account details in OTHERUSERREC or in PATIENTREC. The procedure of querying these tables to find a user's account information is shown in Figure 37.

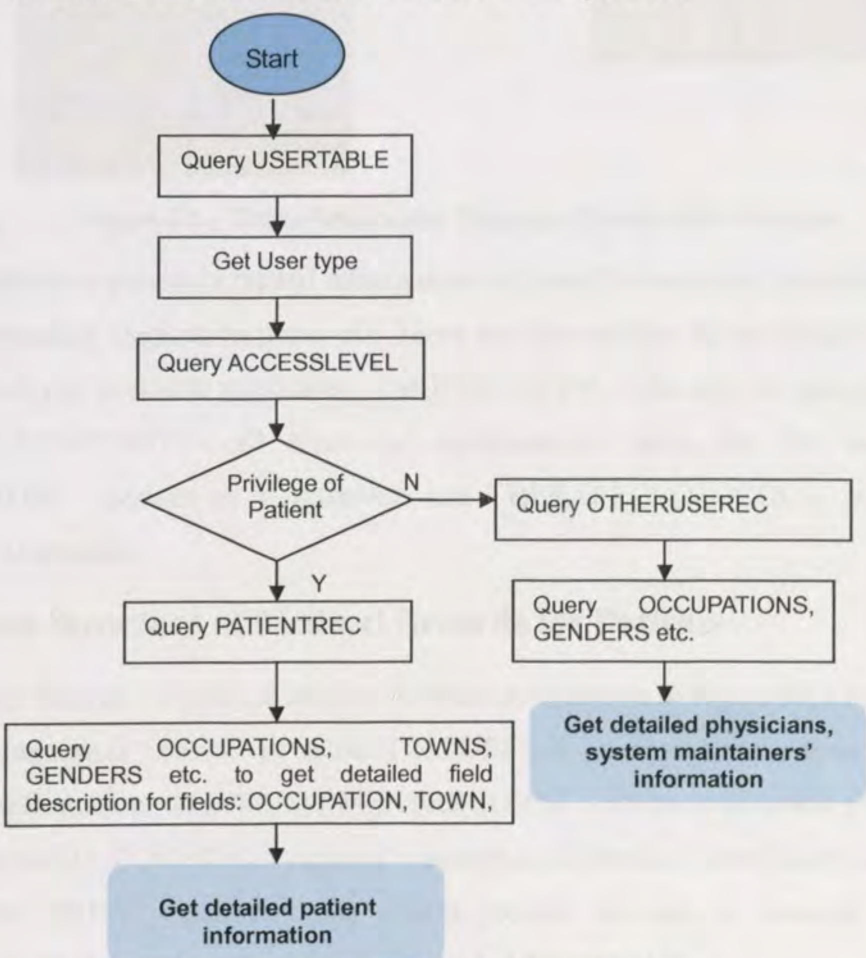


Figure 37. User Data Retrieval Procedure

5.4.4 Data Structure of the Medication Protocols

The ER diagram of medication protocols is shown in Figure 38.

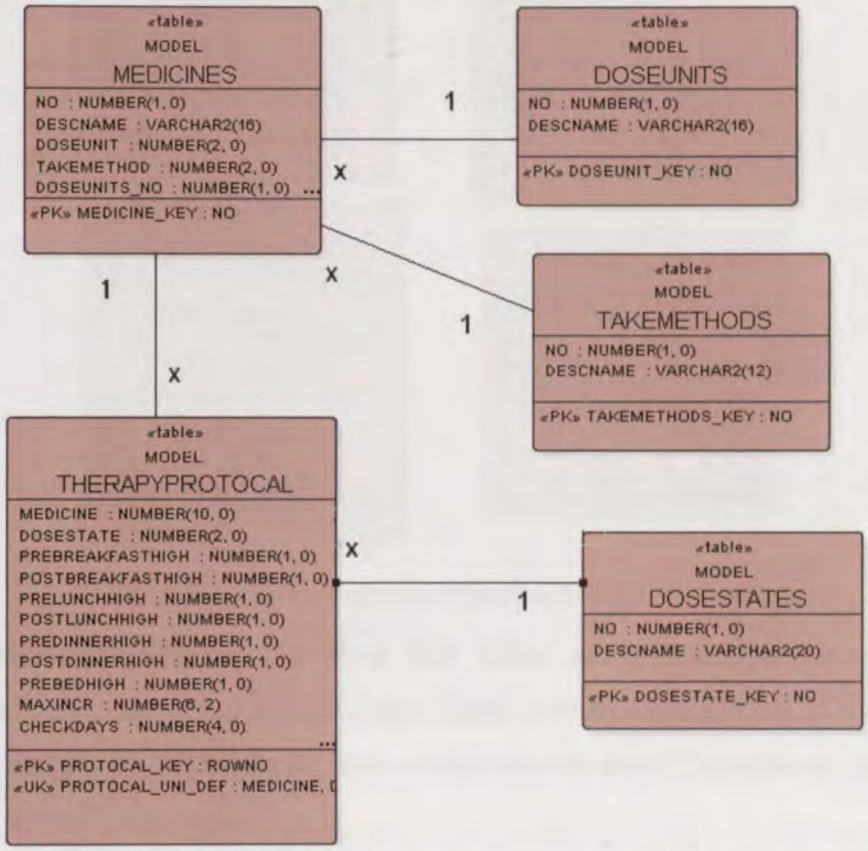


Figure 38. Entity-Relationship Diagram of Medication Protocols

The medication protocols related information includes the medicines information and the corresponding medication protocols. There are five relative tables: MEDICINES – details of all the available medicines, TAKEMETHODS – the way to administer the medicine, DOSEUNITS –all kinds of measurement units for the medicines, DOSESTATES – periods of a treatment, and THERAPYPROTOCOL – medication protocols information.

5.4.5 Data Structure of Medical Records for Patients

The entity diagram of medical records for patients is shown in Figure 39. The medical records information consists of table TIMEDEFINE - measurement time segment definition information, table TREADMENTRECORDS – all the medication records for patients, table GLUCOSEREC – patients' blood glucose measurement records, and table SIDEEFFECTSREC – patients' side effects records because of changes in their medications. All these tables are related with table USERTABLE.

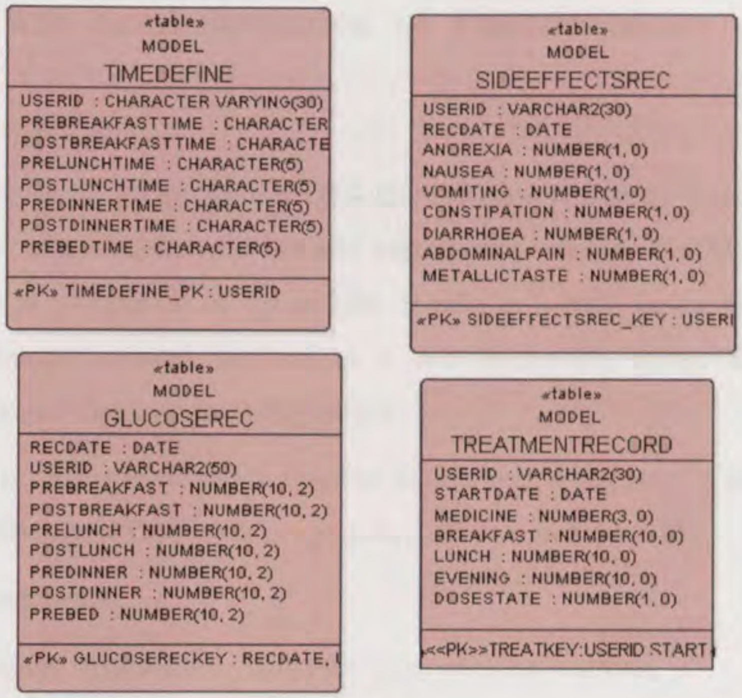


Figure 39. Entity Diagram of Medical Records Information

The fields of USERID in all these four tables are the foreign key of table USERTABLE, the relationship between table USERTABLE and each table of this type is 1:x (one to many). We didn't depict their relationships in the ER diagram to avoid the redundancy with the Figure 36.

5.4.6 Data Structure of Operations Records

The operation records are data about users' activities, with a data structure of combined time tags and user information for all kinds of operation events: login or logout the system, user account operations or a medication change.

The ERD of user operation records is shown in Figure 40. The information of operations records involve table OPERATIONS and table USERLOGS. Table OPERATIONS stores the operation type, and table USERLOGS stores the operation records of all MDMIS users.

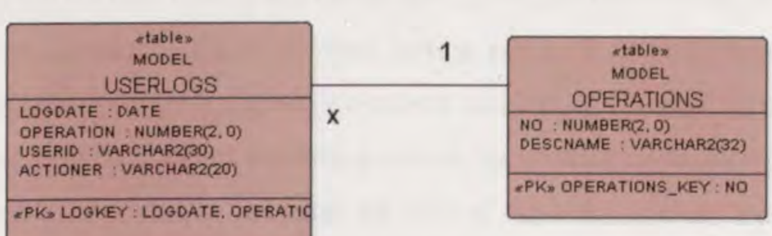


Figure 40. Entity-Relationship Diagram of Operation Records

5.5 Design and Implementation of Functionalities of Master Station

As show in Figure 14, MDMIS consists of a master station, patient stations, physician stations, medical administrator stations and system maintainers. The MDMIS master station is a critical component in the system. It acts as a web server, publishing the diabetes management services, as well as a data processing agent, accepting and analyzing the requests from other client stations.

The software on the master station consists of a broker, a registrar, a data accessing module, and an intelligent data processing module (shown in Figure 41).

A broker is responsible for:

- Accepting the requests from different types of client stations;
- Verifying the requested service types;
- Passing the data to the registrar and intelligent data processing module;
- Wrapping the content of response according to the type of the browser where the request was made and sending the information back to the client stations.

A **registrar** is responsible for providing authorisation, authentication and access control services. A **data accessing module** (DAM) interacts with the MDMIS health information database, verify the requested service type, and returns the data to the registrar or the intelligent data processing module. Only the DAM has direct access to the MDMIS health information database in MDMIS. An **intelligent data processing module** handles further data processing for the requests from remote clients, and saves the corresponding data to the MDMIS database. Furthermore, it is the data processing module provides the MDMIS clients analysis tools to assist examining patients' health situation and making decisions.

Figure 41 shows the data flow in the master. A digit within the brackets of the diagram represents a step number. A MDMIS client station can be a patient station, physician station, medical administrator's station or a system maintainer's station. At the beginning of the data flow, a MDMIS client requests access to the system, on receiving the request, the Broker in the master station identifies the type of the client station, and clarifies the user information for the authentication on the Registrar. The Registrar queries the

MDMIS health information database via the DAM. If the Registrar finds that the account does not exist in the database, the password is not valid, or the account is not qualified for the operation that he requested, further operations will be refused. Otherwise the Registrar notifies the broker, and the DAM is initialised for further operations. The broker sends other request information to the intelligent data processing module to get a data analysis result. The intelligent data processing module querys data through DAM, does analysis, sents the analysis result back to the Broker. The Broker wraps this information to suit the client's type and returns the wrapped message to the client that made the requrest.

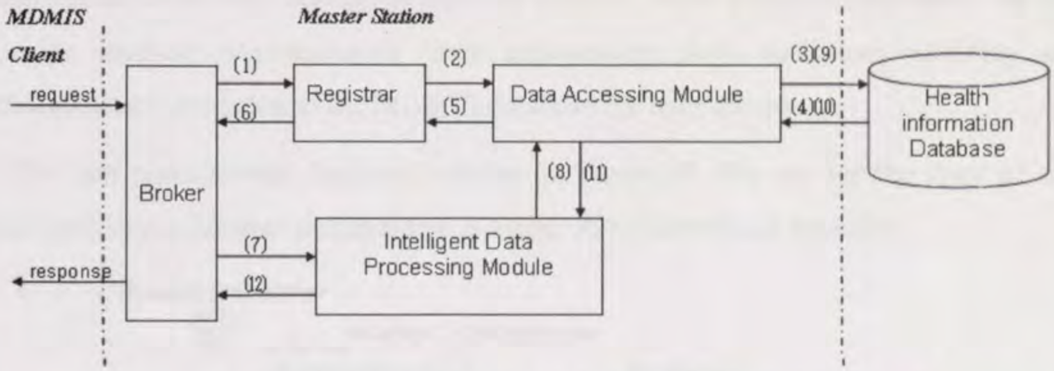


Figure 41. Data flow for processing MDMIS client's request

5.5.1 Management and Internetworking Functionalities

We design the functionality by following suggestions from medical doctors. The diabetes management and internetworking services provided by the cooperation of the above modules through web service publishing on the master station are shown in Figure 42.

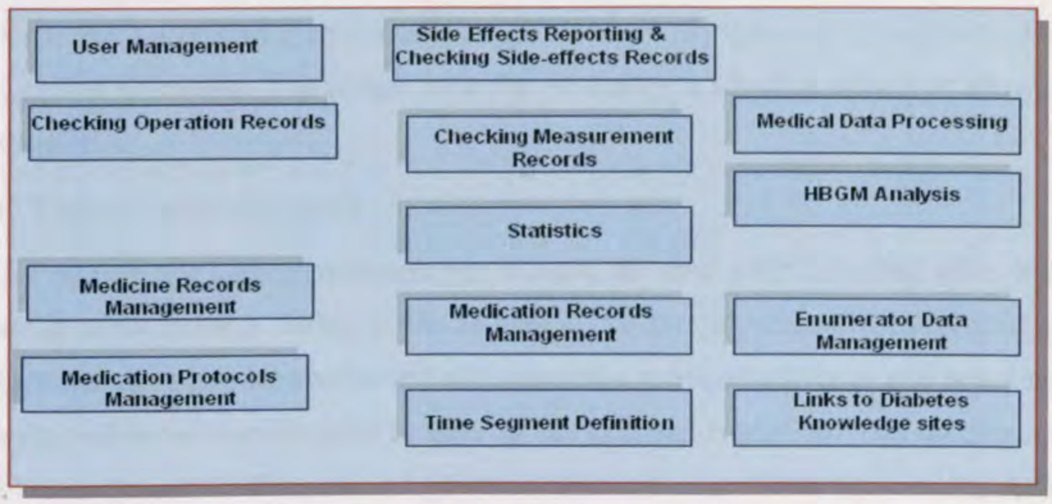


Figure 42. Functionalities Provided by Master Station

(i) User Management

All the MDMIS users can manage their own account information, including date of birth, contact details, residence address, etc., and change their passwords. MDMIS can tell a user's role from the user's ID (identification) provided by a login page on the beginning of accessing the system. User management follows a restricted access control rule for data safety, different role of user has a different priviliage on user management. Except for a patient, other management operations involve creating, deleting or updating an existing user's information and password beside the management of self's account. Furthermore, physicians can only manage patient's account information; medical administrators can only manage physicians' account, while a system maintainer can only manage medical administrators' user information. Any operation involving user management is recorded to the MDMIS database for later review.

The user management diagram is shown in Figure 43. We can see the grant of each role's privileges for user management is based on a hierarchical structure.

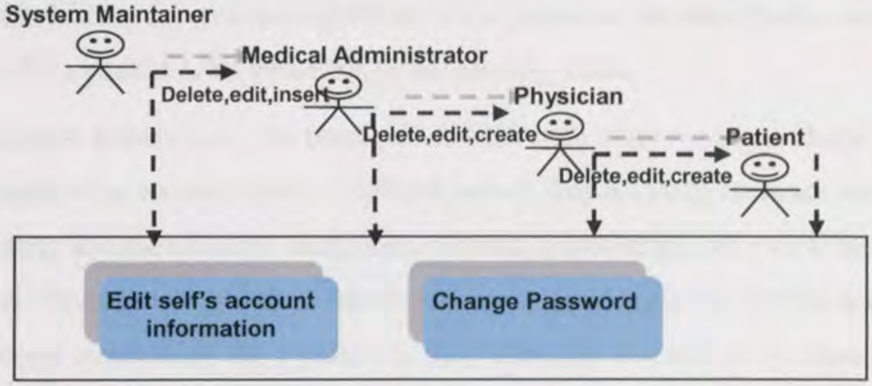


Figure 43. Operation hierarchical diagram of user management

Each user's password is created or changed automatically with a format of mixed digits and mixed characters. The source code for generating a user's password is shown in Appendix A.

(ii) Time Segment Definition

Along with the glucose measurement records, the time when a patient takes blood glucose measurements during a day is critical for the physician's medical analysis. Whether or not a glucose level is within the expected management range also depends on the time when the measurement is taken as the different benchlines with the time (see Table 3 in Chapter 2). Continuous high blood glucose measurements may result a change of a patient's medication. As we see in section 2.2, on diabetes management, a day can be divided into the following segments: "pre-breakfast", "post breakfast", "pre-lunch", "post lunch", "pre-dinner", "post dinner" and "pre-bed". However, due to individual's own life style, each patient may have his/her own time segment definition which determines the time period when blood glucose measurement are taken. This function allows a physician or a patient to define and manage patients' or his/her time segment definition. If a patient's time segment definition are not predefined in the database, a default time segment definition will be applied for this patient.

Following this rule, once the system receives a measurement record with a time tag, the intelligent Data Processing Module will compares the time agaist the defined time segment for the patient, and saves the reading correctly to the corresponding time period. Therefore, MDMIS is able to save the patients' measurement records automatically into the health information database.

(iii) Medication History Records Management

Medication history records are significant for a physician to make further medication change and for a patient to be aware his or her therapy status.

Except system maintainers, the users of MDMIS with other roles can check patients' historical medication records during a defined period. Any MDMIS users are not allowed to edit or delete anyone's history medication records; a patient can only view his/her own medications. Nevertheless, medical administrators or physicians can review and change the most recent medication for a patient if they conclude it needs to be changed. This changed medication is treated as a new medication record as all the medication records are time-tagged. This operation will also be logged into the MDMIS database, and a notification of this change will be sent to the relavent patient via an email. A message will also be sent to the patient's corresponding physician for further review.

(iv) Side-effects Reporting and Checking Historical Side-effects Records

In MDMIS, a patient can report side-effects caused by a changed medication. Side-effects include anorexia, nausea, vomiting, constipation, diarrhea, abdominal pain and metallic taste according to the document provided by the diabetes specialists (see Appendix B).

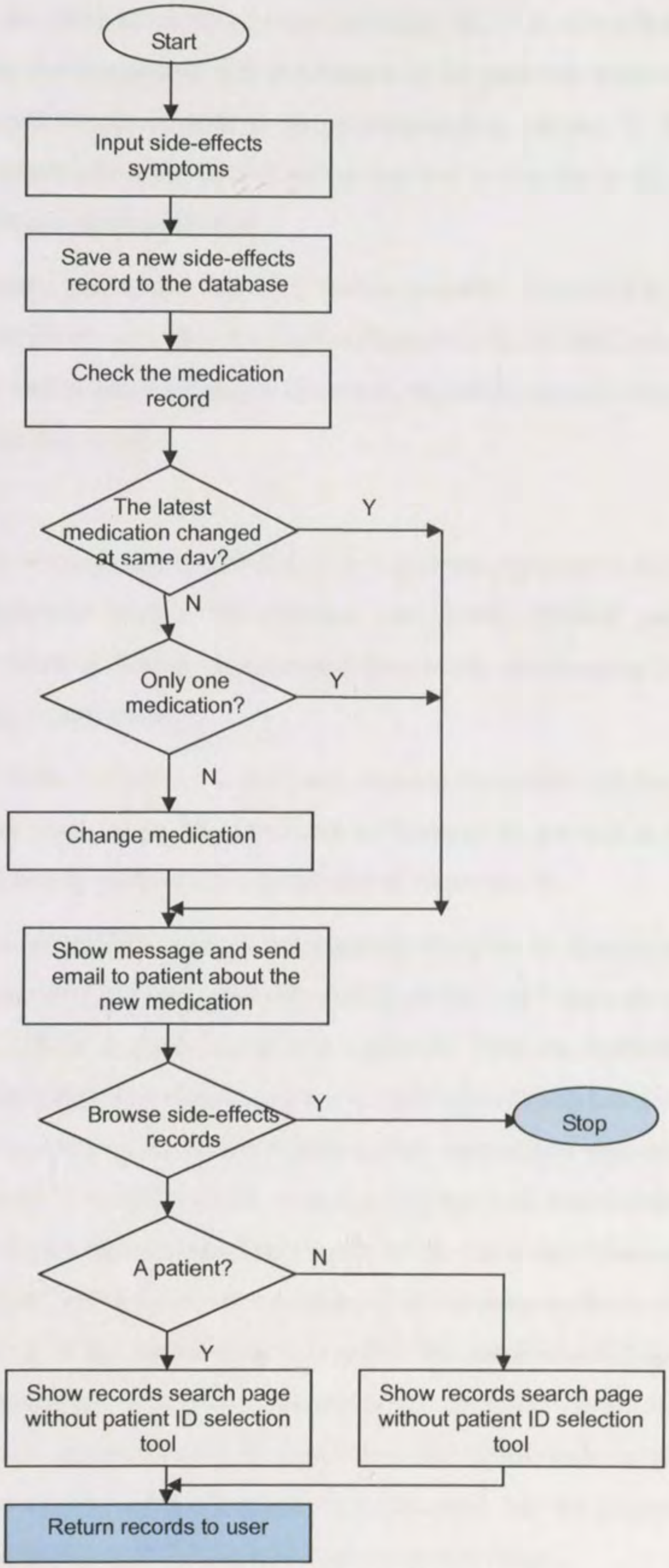


Figure 44. Data Flow of Reporting Side-effects

Figure 44 shows the data flow of reporting a side-effect. A physician or a medical administrator can do this for a patient if he/she receives such an oral report from the patient. According to the medical protocol (see Appendix B), if a side-effects case is reported, the medication for this patient will be changed to the previous medication. An email about the changed details is sent to the corresponding patient. If the recent medication is the first prescription, the patient will is notified to stop the medication and seek medical advices from a medical doctor.

Medical administrators, physicians can also review patients' historical side-effects records, a patient can only browse his/her own side-effects records. MDMIS provides the users a powerful query tool to assist the query. However, any of the users could not make any change on these existing records.

(v) HBGM Analysis

Home Blood Glucose Measurements (HBGM) is an important and proven step towards achieving a good glycaemic control for diabetes care [140]. HBGM performs 4 fingerstick recordings taken at fasting, pre-prandial (pre-lunch, pre-evening meal) and pre-bedtime on three days each week.

For the study of MDMIS, metformin is used as a therapy medication by the diabetes specialists as metformin may reduce the incidence of diabetes in persons at high risk [141]. The detailed metformin medication is addressed in Appendix B.

The HBGM analysis in MDMIS aims to intelligently examine or change a specific patient's medication according to their measurements up to the last 7 days on a specific date. The procedure of HBGM analysis is shown in Figure 45. First, the software checks whether a patient did check their blood glucose level at least twice during the last week. If there is only one or no record existing in the database, that means there was not enough data for analysis, the medication will keep the same, the software will stop further HGBM analysis. Otherwise, it checks the measurement records of the latest day. The message of "the measurements are fine" will be given to the patient if all the measurements are within the range. Otherwise none of the measurements is within the recommanded range, it is also not necessary to change the medication. Otherwise, the software checks if there are previous measurements out of range within the last 7 days and labels each corresponding time periods. If it is, the current medication will be maintained, but the patient will be noticed that his/her measurements at that time are out of normal range.

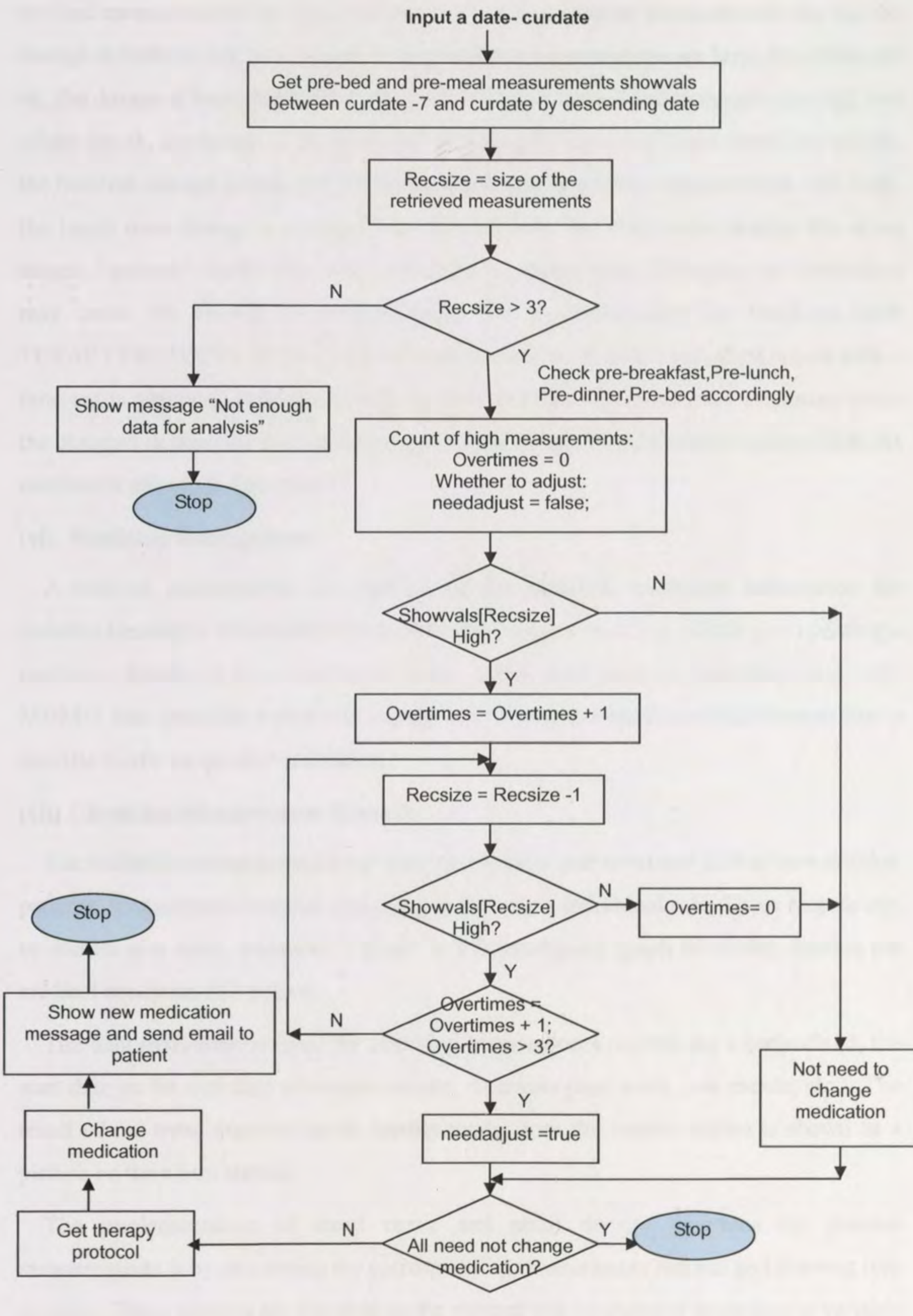


Figure 45. Data Flow of HBGM Analysis

Otherwise, according the medication rules (see Appendix B), if the pre-breakfast or pre-bed measurements are high, but pre-lunch and pre-dinner measurements are ok, the dosage at bedtime will be changed; if the pre-lunch measurements are high, but others are ok, the dosage at breakfast will be changed; if the pre-dinner measurements are high, but others are ok, the dosage at the lunch will be changed; if pre-bed or pre-breakfast is high, the bedtime dosage is changed; if the pre-lunch and pre-dinner measurements are high, the lunch time dosage is changed. In this situation, the Metformin therapy has three stages. A patient's medication status can show the dosage stage. Changing the medication may cause the change of dosage stage; this is implemented by checking table TERAPYPROTOCOL to find the medication protocol. A new medication record with a time-tag is generated and inserted into the MDMIS database at last, and a message about the changed details will be sent to the patient via E-mail. Partial source codes of HBGM analysis is shown in Appendix C.

(vi) Medicine Management

A medical administrator can manage all the available medicines information for diabetes treatment. The medicine management includes inserting, deleting or updating a medicine details, such as medicine name, taken style (oral or injection), units etc. MDMIS also provides a powerful search tool to help the medical administrators find a specific medicine quicker and easier.

(vii) Checking Measurement Records

The MDMIS system provides variable means for a user to review his/her own or other patients' measurement records according to the user's individual role. These records can be shown as a table, trend curve graph or a point density graph to vividly express the medical condition of a patient.

The data (parameters) input for checking measurement records are a patient's id, the start date or the end date of measurements, durations (one week, one month, etc.). The result of the trend curve or point density made from the master station is shown as a picture on the client station.

The implementation of trend curve and point density diagrams for glucose measurements is by processing the corresponding measurement records and drawing into pictures. These pictures are dynamic as the content will be changed according to variable inputted query parameters. As we stated before, the picture type is also varied with the type of the client station. For example, it will be a ".wbmp" file on a WAP phone while on any other terminal, the picture file is in ".jpg" format (see Figure 57).

The graph of trend curve and point density diagram for different measurement period (Pre-breakfast, post-breakfast, pre-lunch, post-lunch, pre-dinner, post-dinner or pre-bed) can be shown selectively or as a whole.

The majority of the data processing module for showing measurements in a trend curve or point density graph is to situate the display range and calculate a coordination of the measurement projected on the graph. The difference between a point density graph and a curve graph on expressing measurements are that the former one emphasises on each individual measurement, while the latter one connects the measurements together with straignt lines. The schematic diagram and equations for drawing the coordinate of measurements is shown in Appendix D.

(viii)Statistics

The statistics information of a patient's blood glucose measurements are shown both in a table and as a pie chart during a time period. The statistic of the blood glucose measurements during specific time period consists of the following information:

- Total number of the measurements;
- Total number of the measurements within the normal range;
- Total number of the measurements above the normal range;
- Total number of the measurements below the normal range;
- The maximum measurement;
- The minimum measurement;

An additional pie chart (see Figure 55) shown the percentage of normal measurements and abnormal measurements (including above the normal and below the normal) of a patient.

Showing a pie chart graph is different from showing data in a table. This function is implemented on the master station in two parts: first, the statistic information about the amount of data which are within normal, above normal and below normal are calculated; second, the coordinates of the pie chart are determined and calculated, the result of the first step is drawn in the graph and so is its legend. The graph is also transmitted as a picture files (in .wbmp format for WAP phones, in .jpg format for other devices).

(ix) Medication Protocol management

Along with a data query tool, only a medical administrator can define, update or delete information of medication protocols. The information of a medication protocol includes the medicine name, steps taken, dose, taken time, etc. Any operation on medication protocol management is logged in the MDMIS database.

(x) Checking Operation Records

Every significant operation is recorded as soon as the operation is completed. MDMIS users can check their previous operation records by operation type or operation date. However, none of them can change any existing operation record.

(xi) Medical Data Processing

In chapter 4, we have mentioned that after a patient station gathered a patient's blood glucose level from his/her glucose meter, it transmits the measurement to the remote master station. The master station analyses the data and returns the analysis result to the patient.

Figure 46 shows the procedure of medical data processing. The data submitted from a patient station combines both the patient's user identity information and his/her blood glucose measurement record. Both the information is required for analysis by the data processing module on the master station. According to the time segment definition of the patient, the module calculates the measuring time and examine if the glucose level is out of the medical suggested range. If it is, a message of indicating that the data has been saved successfully will be sent back to the patient station via the broker. Otherwise, an HBGM analysis will be started to examine whether a change of medication is needed. If there is a change, and a warning message is sent back to the patient station, and an e-mail with the details of the new medication are also sent to the patient.

(xii) Enumerator Data Management

As we presented in the previous section, several enumerator tables are designed for saving data storage space within the MDMIS database. Certain users can manage these data, for example, a system maintainer can manage occupation information in the table OCCUPATIONS, add add more occupations or delete an improper occupation description.

(xiii)Links to Diabetes Knowledge Sites

MDMIS provides some useful links to common diabetes education websites, such as

Diabetes UK website, www.diabetesuk.org, and International Diabetes Federation's website, www.idf.org .

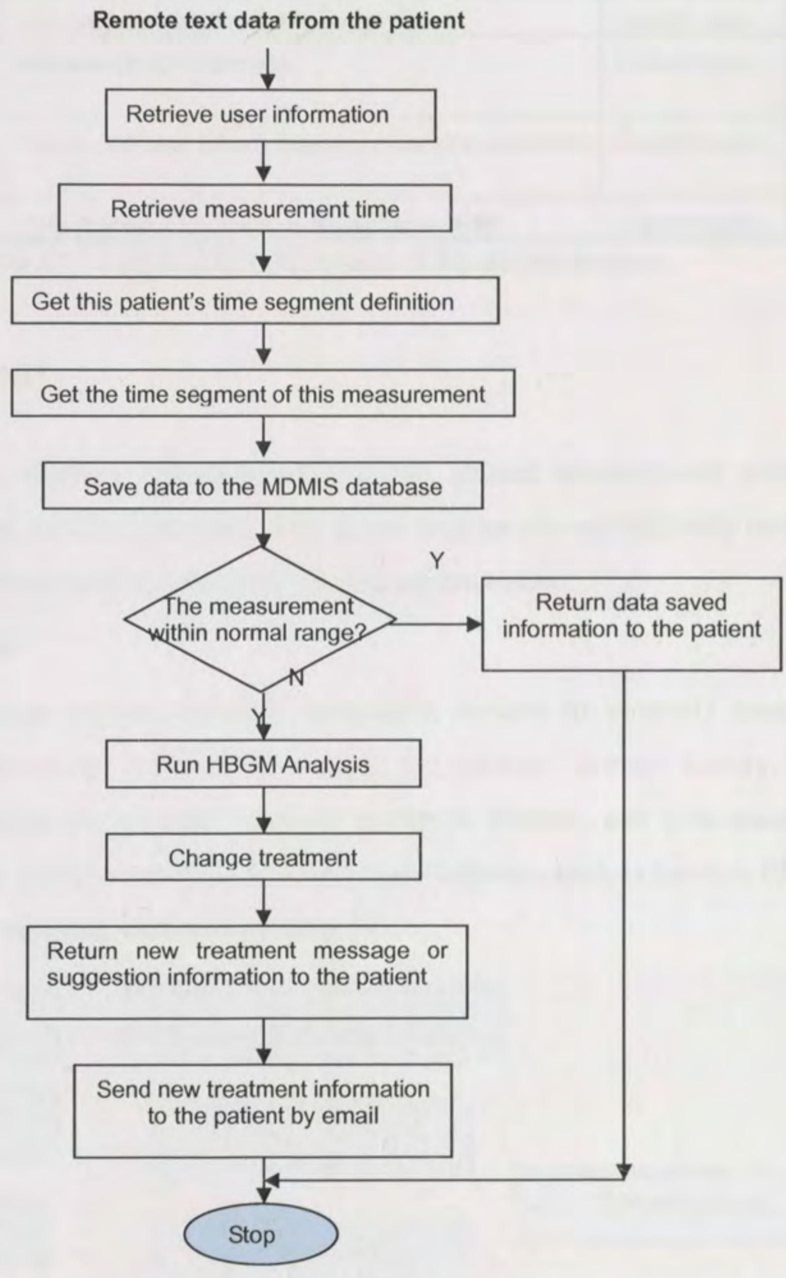


Figure 46. Data Flow of Measurement Data Processing

5.5.2 Error Handling

The MDMIS system detects the errors that may occur during user operation. In this scenario, the latest operation is terminated and the error messages is shown on the corresponding MDMIS client station.

Some examples of such messages are shown in table 12:

Cause	Message Content	Redirect Page
Can't find User ID	User ID or Password error	Login page
Password error	User ID or Password error	Login page
Send message error	Message are failed to sent to user ***	Current page
Database connection error	Database connection error	Current page
Not enough privilege to do the operation	You do not have the privilege to proceed this operation	Current page
Data format error	Data format of *** is error, please follow:####	Current page

Table 12. Typical Error Messages of the MDMIS System

5.6 Client Stations

Physician stations, medical administrator stations, patient stations and system maintainer stations are all client stations. The client stations request MDMIS master stations for services of diabetes management via internet browsers.

(i) Physician Station

Physicians can choose various available computing devices to remotely manage patients' account information, inquire and analyse the patients' disease history and current situation, manage the patients' medical treatment scheme, and give medical suggestions to patients. A physician station can be a mobile device, such as handset, PDA, laptop, or a stationary terminal, such as a desktop PC.

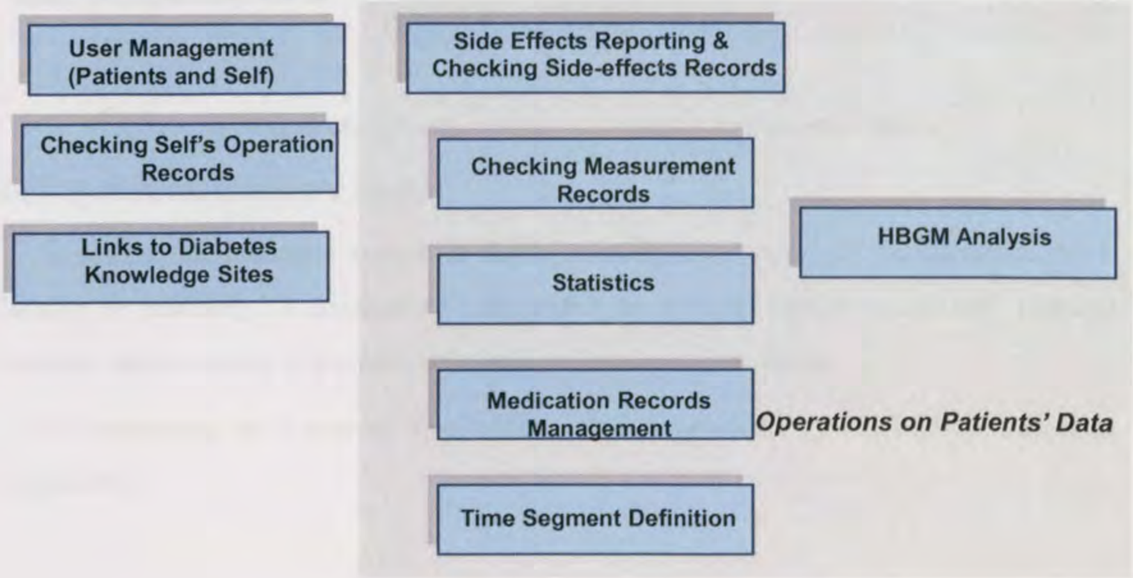


Figure 47. Functionalities of Physician Station

Figure 47 shows operations on a physician station. Services provided to a physician station by MDMIS include: patients' account management, check or change patients' treatment plan, check or report patients' side-effects, check patients' measurements records, HBGM analysis, operation records query etc.

(ii) Medical Administration Station

A medical administration station is for a medical administrator to create or update available medication information, update medication protocols, manage physicians' account information, intervene and supervise a patient's therapy procedure. However, a medical administrator has no authority to manage any other users except the physicians account information. A medical administration station can be a handset, PDA, PC, or a laptop.

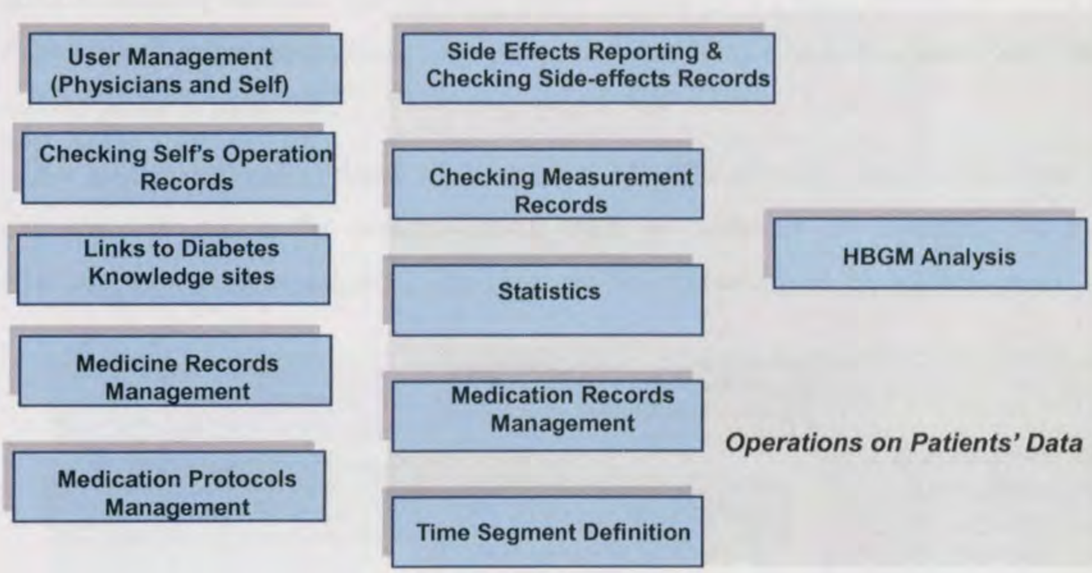


Figure 48. Functionalities of Medical Administration Station

(iii) System Maintenance Station

A system maintenance station is for a maintainer to carry out maintenance work locally or remotely. A maintainer may check any users' operation records, manage medical administrator's account, or check system operation status.

The operation on a system maintenance station provided by MDMIS is shown in Figure 49.

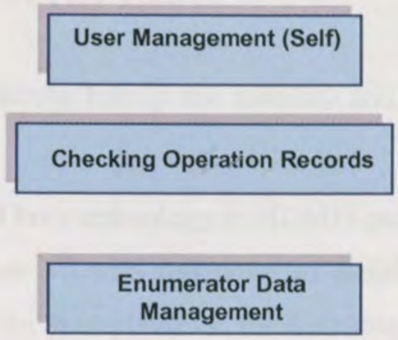


Figure 49. Functionalities of System Maintenance Station

(iv) Patient Station

A patient station is for a patient to review his/her disease status with various mobile or fixed computing devices. The MDMIS functionalities on a patient station are listed in Figure 50. For data acquisition, only the patient station of a Sony Ericsson P800/P900 mobile phone is adaptable.

For all the medically related client stations, MDMIS provides some useful links of diabetes information for self-evaluation, such as websites of Diabetes UK and NHShttp://www.diabetesuk.org/. The links can be accessed by all the MDMIS users.

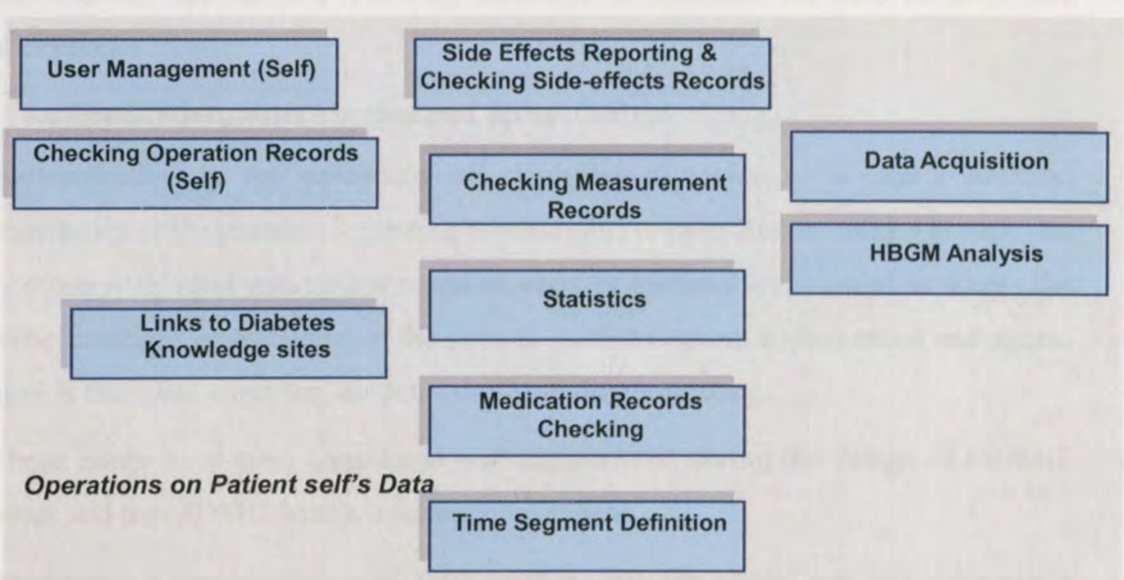


Figure 50. Functionalities of Patient Station

5.7 Mobility & Security Issues

In this section, we describe briefly the mobility and security issues of the MDMIS software system.

The usage of XML and Java technology in MDMIS provides a suitable and compatible solution for user to access MDMIS functions on variable mobile devices (see section 5.3.3 and section 5.3.4). An example of xsl file formatting the XML data and expressing HBGM analysis result is shown in Appendix F.

It is well known that the healthcare information is always private and critical; any health information system must have consideration of security issues to maintain data confidentiality and data integrity.

Data confidentiality refers to the process of ensuring that only the entities which are allowed to access can access the data in a usable format [142]. Data integrity is in terms of the validity of data. The data integrity may be broken under the errors are introduced when data is entered, data transferring from one computing device to another; software bugs, virus; hardware failures; or same messages are distributed at different time. [143]

MDMIS has applied the following measures to maintain the data integrity and confidentiality:

(i) Authentication, authorisation and access control

Authentication is the procedure of validating a device or a user's identity; Authorization is the process of granting access rights to user; Access control is such that only those with valid and authorization of users or systems are allowed to access the specific functions or resources of the system. Authentication, authorization and access control is therefore important for data confidentiality or privacy.

These issues have been considered and implemented during the design of MDMIS services and the MDMIS health information database.

Every time a user accesses a MDMIS service, first, the system will check the user's identification (user id and password) and examine his/her account's validity. If it is a valid user, the system will also check if the user has the right to access this operation. Only the functions with a MDMIS user's privilege range are listed. MDMIS user management provides the functionality to grant a user's privilege to access MDMIS other services.

We have also considered the access control issues within MDMIS health information database. Database views were created and granted to different levels of access rights for specific kind of users or user roles.

Role Name	Description
A_PATIENT	A role of a patient or request from a patient station
A_PHYSICIAN	A role of a physician or request from a physician station
A_MEDICALADMINISTRATOR	A role of a medical administrator or request from a medical administrator station
A_SYSTEMMAINTAINER	A role of a system maintainer or request from a system maintainer station

Table 13. User Roles

In Table 13, there are four roles created corresponding to different users. They have strictly limited access to specific database tables or views.

For example, a view of SELFINFO_GLUCOSEREC was created. The view only contains the current user data; a SQL statement to create this view is shown in Table 14. The operations of select, insert, delete, and edit are granted to users with a role of A_PATIENT. The role of A_PATIENT has no right to access the original table: GLUCOSEREC. Therefore, data confidentiality of blood glucose level records is ensured in MDMIS health information database.

```
CREATE VIEW or REPLACE VIEW
SELFINFO_GLUCOSEREC //view name
AS
SELECT * FROM GLUCOSEREC WHERE USERID = User
```

Table 14. SQL Statement for View: SELFINOF_GLUCOSEREC

(ii) Prevention of invalid input.

The validity of some inputs will be checked in MDMIS before further data analysis. The correct format or interpreting of data will be shown to the users within the error message prompt after an attempt to input wrong data.

(iii) Security on data transmission.

MDMIS adopted SSL for security on data transmission. SSL is an abbreviation for Secure Sockets Layer "and is now the de facto standard for providing secure e-commerce transactions over the Web." [144]. The protocol SSL aims to provide a secure connection between communication parties by using encryption of data to be transmitted.

A SSL transaction consists of two stages: handshaking and data transfer. Handshaking between the client and server is to use a public key encryption algorithm to calculate private key parameters. During data transfer, both parties use a private key to encrypt and decrypt the data transmissions. Hence, both the server and client encrypt all the traffic before sending out data, so that data is protected from eves-dropping.

MDMIS supports SSL to ensure data transmission security between client stations and the master station by adding SSL support to Apache Tomcat web service. URLs that require an SSL connection start with *https://*.

This procedure of adding SSL to Apache Tomcat is to:

- Prepare the certificate keystore. This can be done either by importing an existing certificate into the `JKS` or `PKCS12` format keystores or creating a new keystore containing a single self-signed certificate using a command keytool.
- Edit the Tomcat configuration file to configure the secure socket.
- Test to check the SSL connection works.

(iv) Database Backup

We designed and implemented a database backup scheme for recovery after system disasters with the lowest damage in case of system failure.

There are two types of backup for Oracle 9i databases.

- Full backup. This is a method that all the data will be stored into a backup set.
- Incremental backup. This is a method that only modified data blocks are backup.

Both an incremental backup and full backup scheme have been implemented to MDMIS database to keep the data damage to a minimum in the case of hardware or software failure. Two scheduled tasks for MDMIS database are defined: an incremental backup will be performed every midnight; a full backup will be performed every Saturday shortly after the incremental backup. Choosing a backup at midnight is because at that moment there are few data queries to the MDMIS database, therefore there is the lightest data load.

(v) Operation recording and message notification

An important operation will be recorded with a time tag, such as login, logout, insert, update user account information or a change of medical information.

Furthermore, whenever there is a critical change in a patient's information, such as modified medication, the information will be sent to the patient through an e-mail or a short message. Hence patients are aware of the change (see Figure 55).

(vi) Firewall

A firewall and antivirus software - VirusScan Enterprise 7.0.1 [145] has been installed and deployed to secure the master station and the MDMIS health information database from unauthorized access and virus.

5.8 Summary

In this chapter, we presented details of the design and implementation of the MDMIS software and database. The chapter explains the data structures of the MDMIS database system; it also details the relevant modules and their functionality within a mobile environment. The chapter also outlines security issues relevant to the software design of the system.

Chapter 6

System Enhancement – Interoperability

Further to the implementation of MDMIS, this chapter addresses the interoperability issues between the medical sensing devices and general m-health systems. An architectural framework to improve the interoperability of m-health applications and the initial implementation on MDMIS are presented in this chapter.

6.1 Interoperability in M-health Systems

Interoperability means "The ability of hardware and software on multiple computers manufactured by different vendors to communicate with one another." [155]

With the new application of emerging medical and computing technologies on healthcare products and the possibility of changing patients' medications, it is a common phenomenon that patients add medical sensors or devices in a m-health system. However, the introduction of the new device may result in failure of appropriate communication between an existing wireless data acquisition system and an updated medical device. Consequently, a proper remote medical decision for a patient may not be made as the lacking of relevant medical measurements or information. Any new medical device must maintain proper communication channel between patients and medical doctors within the healthcare delivery chain.

Currently, all the m-health systems share the concept of sharing medical data in a wireless environment to improve disease management. However, none of an existing m-health system supplies an interoperability solution to provide "plug-and-play" mechanism for variable medical sensors or equipments that can offer ease of use on a patient side. Furthermore, there is not a specific architecture addressed on interoperability issues for existing medical devices and wireless communication system.

Without electronic capture of medical data and events, it is not possible to do sophisticated medical data analyses. The more medical information from a patient is provided to medical doctors, the more suitable prescription may be made for the patient.

Nevertheless, with the involvement of vast end users and the competitive commercial environment, upgrading, altering a medical device or sensor, or introducing a new equipment may happen in the whole m-health system from time to time, here and there. Therefore, interoperability between a management application and medical devices becomes a significant issue to measure m-health system's practicability.

There have been efforts on standardising medical devices communication to improve interoperability, for instance, IEEE 1073.

However, to date, there are very few m-health or telemedicine systems which are IEEE 1073 compliant. The main reasons for this can be summarised as the following: (1) the standard itself - IEEE 1073 is in continuous revise; (2) there are existing large amount of medical equipments which do not comply with IEEE 1073 ; (3) genereally, the upgraded products or medical devices are still not IEEE 1073 compliant as it may still need a significant change on its data interface design; (4) as "medical devices must adhere to all relevant patient and user safety regulations", the commercialize of a new medical device from research is time-consuming.

6.2 System Architecture with Enhanced Interoperability for Mobile Chronic Disease Management

In this section, we present a general architecture for a mobile chronic disease management system with enhanced interoperability consideration between medical sensors and a management system. The proposed architecture is shown in Figure 51.

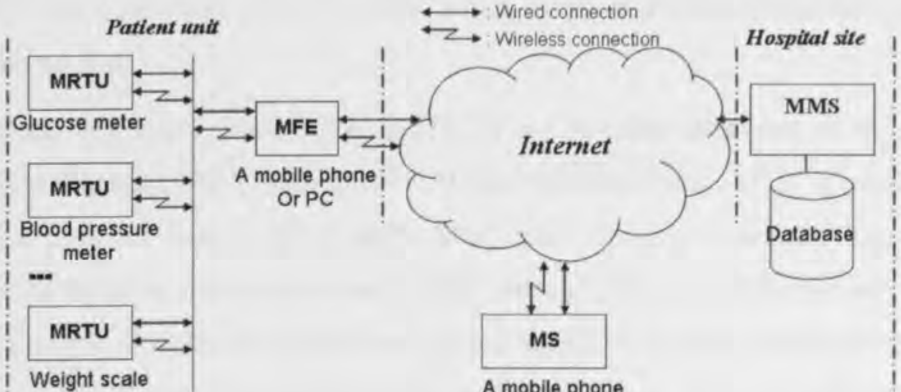


Figure 51. System Architecture of Mobile Disease Management with Enhanced Interoperability Considerations

The major components of a m-health system with interoperability considerations are (i) *M*edical *M*aster *S*tation (MMS), (ii) system *M*aintainer *S*tations (MS), (iii) *P*atient *S*tations (PS) which includes *M*edical *F*ront *E*nd (MFE) and *M*edical *R*emote *T*erminal *U*nits (MRTU). This division is according to each component's functionality of the enhanced system.

(i) Medical Remoter Terminal Unit - MRTU

A MRTU is a medical device or sensor. It can take one or several medical measurements related to a patient's health. For example, a glucose meter to take glucose measurements, a blood pressure meter to take blood pressure, or a weight scale to take weight. A MRTU may also be a medical controller, such as an infusion pump with automatically adjusted dose. A MRTU is always with a patient, it may be located in a patient's home or a hospital's ward. A MRTU is the source of the electronic data records in a m-health system.

To exchange data with an external system, all the relative medical sensors or devices should have a data output interface. In this case, the interface is regarding to the ability of communication with a MFE.

(ii) Medical Front End - MFE

A MFE is a data acquisition unit as well as a computing device. Putting a MFE in the middle of MRTUs and a MMS, is for the reason that a MRTU always has very limited communication ability with a remote system. As a middle data-relay station, a MFE not only can send control commands to a MRTU and collect measurements of a MRTU, but also can do initial data processing and send the information to a remote MMS. A MFE and a MRTU are connected over a data link, which maybe a wireless (Bluetooth, Zigbee, etc.) or a wired link.

A MFE can be a smart phone, PDA or a PC. It can be either stationary or mobile. All data going to a remote MMS from a MRTU with a patient is via a MFE. Therefore, the information received from a MFE on a MMS can identify a patient since a user authentication must be made whenever a MFE intends to access MMS to keep system secure. Therefore, an m-health system can tell the source of medical information even a patient is using different equipment as MFE at different time. In an m-health system, a patient may possess several medical sensors for variant monitoring objectives. A patient can also access other management services of the system on a MFE.

(iii) System Maintainer Station – MS

A MS is a computing device for a system maintainer to do maintenance work locally or remotely. Whenever a computing device (a mobile phone, a PDA or a PC) running maintenance work, this equipment is called a MS.

(iv) Medical Master Station - MMS

A MMS is located at a hospital or a clinical site, it accepts the data submission or request, and does major data processing and analysis work. A MMS is connected with a secure medical database for further data storage and analysis. The database stores all the medical related information of an m-health system.

In a m-health system, the communications between MFE and MMS is via Internet through wired or wireless connection.

6.3 Interoperability Design Issues

In a system described in Figure 51, a MFE needs to acquire various medical measurements from sensing devices and provide medical doctors or specialist nurses the information for a clinical diagnosis. For a MFE to collect those data electronically, a proper data communication protocol for a MRTU must be available on the MFE. A varied MRTU may lead to a failed MFE data call as the previous specific communication protocol may become invalid. A new communication protocol is required at these different scenarios: when (1) a MFE is swapped, for example, from a PC to a cell phone, different ways for communication maybe involved because of changing of connection type; (2) a MRTU is altered, because there is a significant product upgrading or it comes from another manufacturer; (3) A new MRTU is added, which includes upgrading or an enhanced monitoring.

With the fact of that a MFE might be a mobile computing device with limited data storage, it is not practical to save all the possible communication protocols for all the MRTUs with a patient on one MFE. Moreover, providing a protocol information is isolated from the whole m-health system, a specific communication protocol for a MRTU must be updated for every individual MFE each time even there is a small change.

A scheme of sharing communication protocols information on the MMS side to improve the interoperability between a MFE and MRTUs is proposed in this study. A database with all the data communication protocols for variable kinds of MRTUs needs to be designed. In this case, A MFE only needs to query a relative protocol if it could not find an appropriate protocol locally for the connection with a MRTU. Once the MFE gets the protocol data, it can then save locally until there is change on it. This benefits data sharing, data reliability and flexibility of communication. A data flow for a successful data call with a MRTU on a MFE is show in Figure 52.

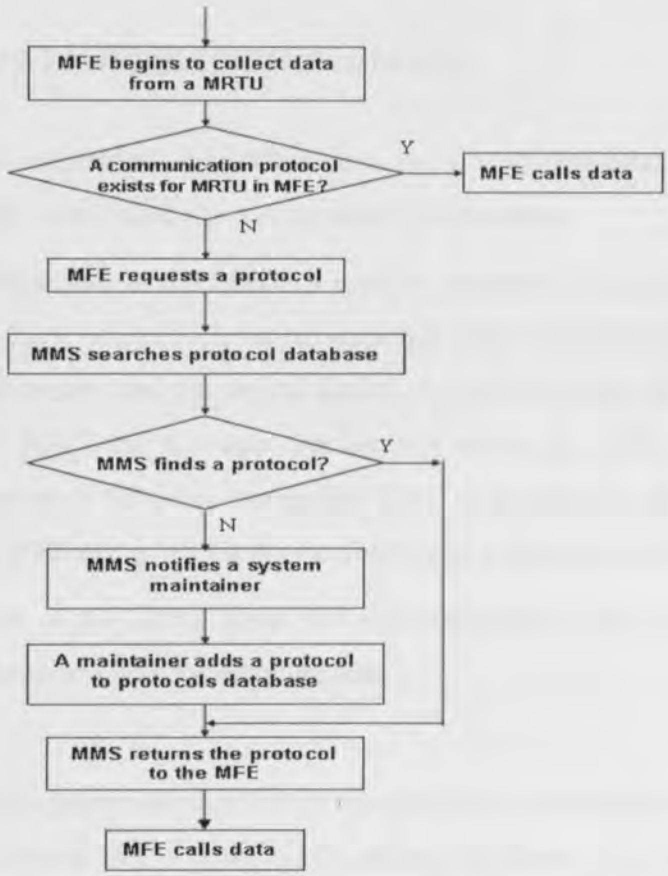


Figure 52. Data flow for a data call from MFE to MRTU

Whenever a patient adds, alters or upgrades a medical device, if a MFE fails to interoperate with a MRTU, it will prompt a dialog for user to input the relative information of the MRTU (a medical device) and send a query statement to a remote MMS for an appropriate communication protocol. A query statement mainly includes a medical device's type, its manufacture, connection category, the MFE's model etc. Accordingly, the MMS will query the communication protocols database and return a suitable protocol to MFE.

If a relavant protocol is not present in the database, the MMS will send an alert message to a corresponding system maintainer to indicate that a specific protocol should be added for a model of MRTU and a model of MFE. Once the system maintainer receives this notice, he can add the data communication protocol to the protocols database remotely or locally, and sends a message to the MMS that the protocol is ready to be queried. Afterwards, the MMS will send this protocol to the previous MFE, the MFE receives the protocol, stores the information locally and restarts to gather data of the MRTU.

6.4 Preliminary MDMIS Implementation

This proposed interoperability model has been initially implemented and tested on MDMIS for enhanced mobile diabetes management functionality.

To apply this architecture to the MDMIS system, we need to map these concepts described in section 6.2 to MDMIS. A patient station is MFE as it acts as a middle relay between the medical sensors and the master station. A medical sensor is a MRTU, The master station is the MMS and a system maintenance station is a MS. Similar as the previous implementation of MDMIS, we applied XML technology on the protocol data exchange between a MFE and a MS for the flexibility and portability of XML.

A brief description of the issues about the interoperability issues tailored for the MDMIS system is described here for completeness.

(i) Routines

There are three major operations in MDMIS relevant to the interoperability. These are: A MFE querying a protocol from a MMS, a MS adding a protocol, and a MMS returning a protocol to a MFE.

(ii) MFE Queries a Protocol from MMS

Whenever a new MRTU is introduced, a MFE lost a communication protocol, or a changed model of a MFE, a MFE needs to send a request message to MMS for a data communication protocol. An example XML file (for a user "Joanne" is requesting MMS for a protocol between a glucose meter – specifically "*MediSense Optium*" and Sony Ericsson P800) is shown in Figure (1), Appendix G.

(iii) Add a Protocol to the Protocol Database

This happens when a system maintainer adds a new communication protocol to the m-health system. The data will be sent from a MS to the MMS and saved into the protocol database. An example XML file for a system maintainer adds communication protocol is shown in Figure (2), Appendix G.

(iv) MMS Returns a Protocol to MFE

The MMS searches the communication protocols database to find a suitable protocol as requested and sends the protocol back to a MFE. The MFE receives the new protocol and saves this information locally for next data query with the same medical sensor. An example XML file that the MMS sends back the appropriate protocol to a MFE is shown in Figure (3), Appendix G.

6.5 Preliminary Results

This architecture has been applied in MDMIS to improve the interoperability of the system. We designed several other tables on current MDMIS health information database system (see section 5.4) for this implementation of interoperability. The MDMIS database provides a powerful data storage for a secure, reliable, high capacity Internet m-health system. The tables include communication protocols table, a medical sensors table, a patient information table and a protocol status table.

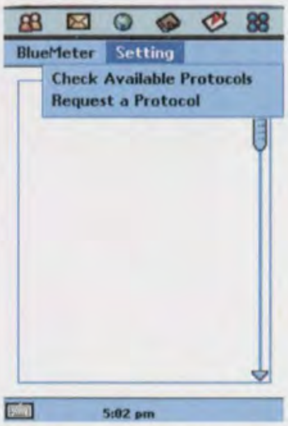
A medical sensors table stores models information for the variable medical sensors which are being used in the MDMIS, which includes model no. of each medical sensor, the manufacturer, measurement catagory, data ouput interfaces etc. A patient information table is about a user's general information, such as name, address, disease and contact information etc (see section 5.4.3).

A protocol status table is a quick index for the availability status of a data communication protocol. There are three types of status: existed, requested or deleted. Every time after a query from a MFE received, the MMS will first query protocol status table. If this protocol exists, the MMS will search the communication protocols table and return the medical protocol to the MFE or MS.

The data communication tables are divided into several types according to theire connection types: Serial communications table, Bluetooth communications table or USB communications table. This division is because of the different requirement of connection parameters for different communications types. We implemented further functions for interoperability issues on the current MDMIS data acquisition software – BlueReader (see Chapter 3).

The software test has been made on a Sony Ericsson P800 mobile phone. The outputs of the test on a Sony Ericsson P800 mobile phone simulator are shown in Figure 53. In Figure 53 (A), a patient requests a communication protocol to the MMS on a MFE. A dialog is prompted to ask the user to input the manufacturer and model information of a specific MRTU. Figure 53 (B) shows available operations of a MFE's on the communication protocols. The software can show all the available protocol in the local MFE, or request a new protocol from MMS. Figure 53 (C) shows all the operations that are related with data connection with MRTUs. The interface for a MS entering communication protocol parameters to the MMS is shown in Figure 53 (D) (Bluetooth SPP).

(A) Requesting a data protocol from P800



(B) Requesting a data protocol from P800

(C) Bluetooth Meter Operation Menu

(D) Adding a protocol to the protocols database

Figure 53. Operations on Communication Protocols

6.6 Summary

This chapter addresses enhanced issues and proposes a general architecture on improving the interoperability between the mobile health management system and the medical sensing devices. We also presented the preliminary implementation of this achitecture on MDMIS in this chapter.

Chapter 7

Preliminary Evaluation and Performance Analysis

7.1 Introduction

This chapter presents the preliminary test results of the MDMIS system, together with the result of the system's mobile performance analysis. The following sections address respectively the preliminary laboratory and clinical test results; the performance evaluation of the MDMIS system over short-range connectivity (Bluetooth) and the MDMIS end-to-end performance over GPRS connections.

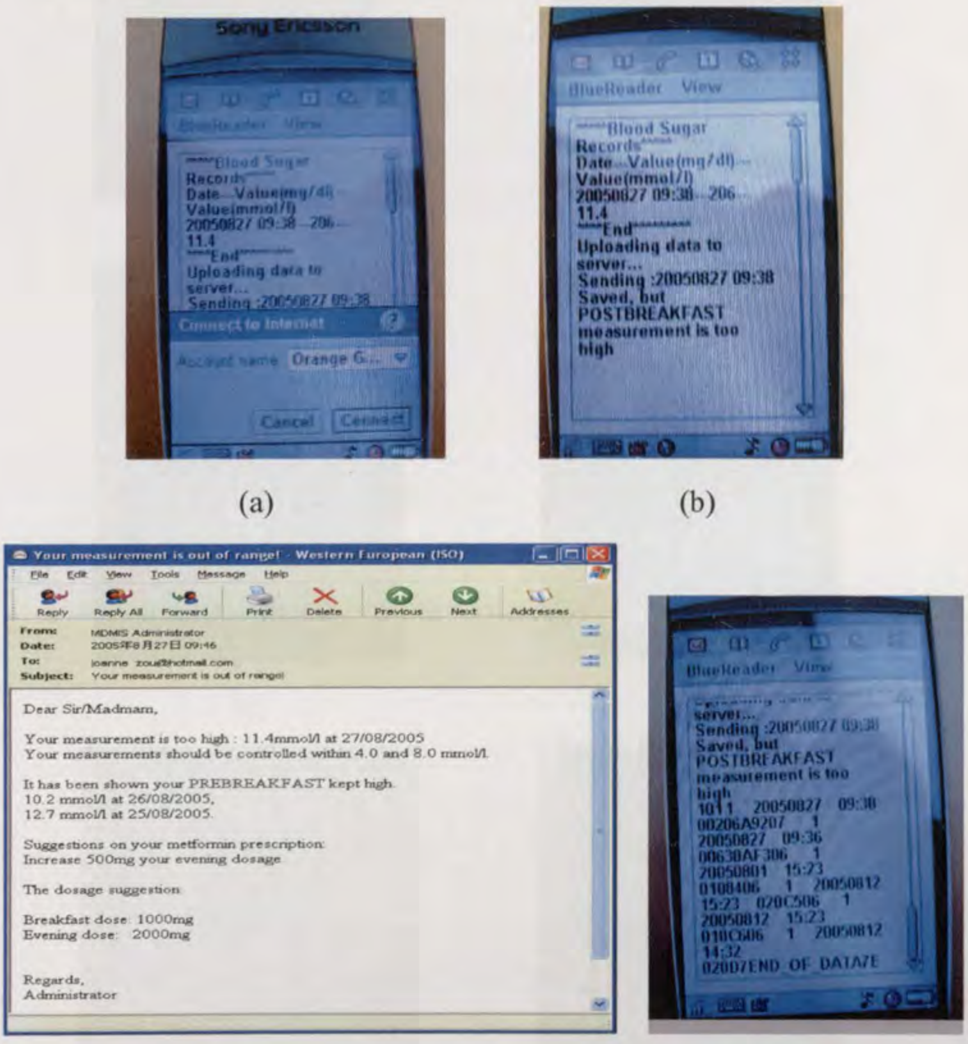
7.2 Preliminary Results

In this section, we describe the test results of the functions of MDMIS. The MDMIS system has been tested both in a laboratory and in an anonymous diabetes patient environment, the services of MDMIS was accessed on variable devices during the test. The test result shows the MDMIS system performs successfully in different mobility scenarios.

Figure 54. Sample Measurement Display on the MediSense Optium Glucose Meter

Figure 54 shows a sample reading from an anonymous diabetes patient who volunteered to use the system. Figure 55 shows the snapshots of the data acquisition procedures of the MDMIS BlueReader during the tests. Figure 55(a) shows that the BlueReader initiated a GPRS connection to send the acquired data to the MDMIS master station after blood glucose level was collected from the MediSense Optium glucose meter.

Figure 55(b) shows the feedback from the MDMIS master station on a patient's mobile terminal after the measurement was submi. The patient's sample measurement was taken before a breakfast, as its value (11.4 mmol/l) was out of recommended range (4-7mmol/l), we can see the feedback said "POSTBREAKFAST measurement is too high". In addition, an HBGM analysis on the master station had been carried out during processing the measurement due to the high blood glucose value, the analysis changed the patient's medication by following a medication protocol and addressed with an email sent back to the patient (as described in section 5.5). The email message is shown in Figure 55(c). The original coarse data received from the sensor can be reviewed; a sample of the data is shown in Figure 55(d).



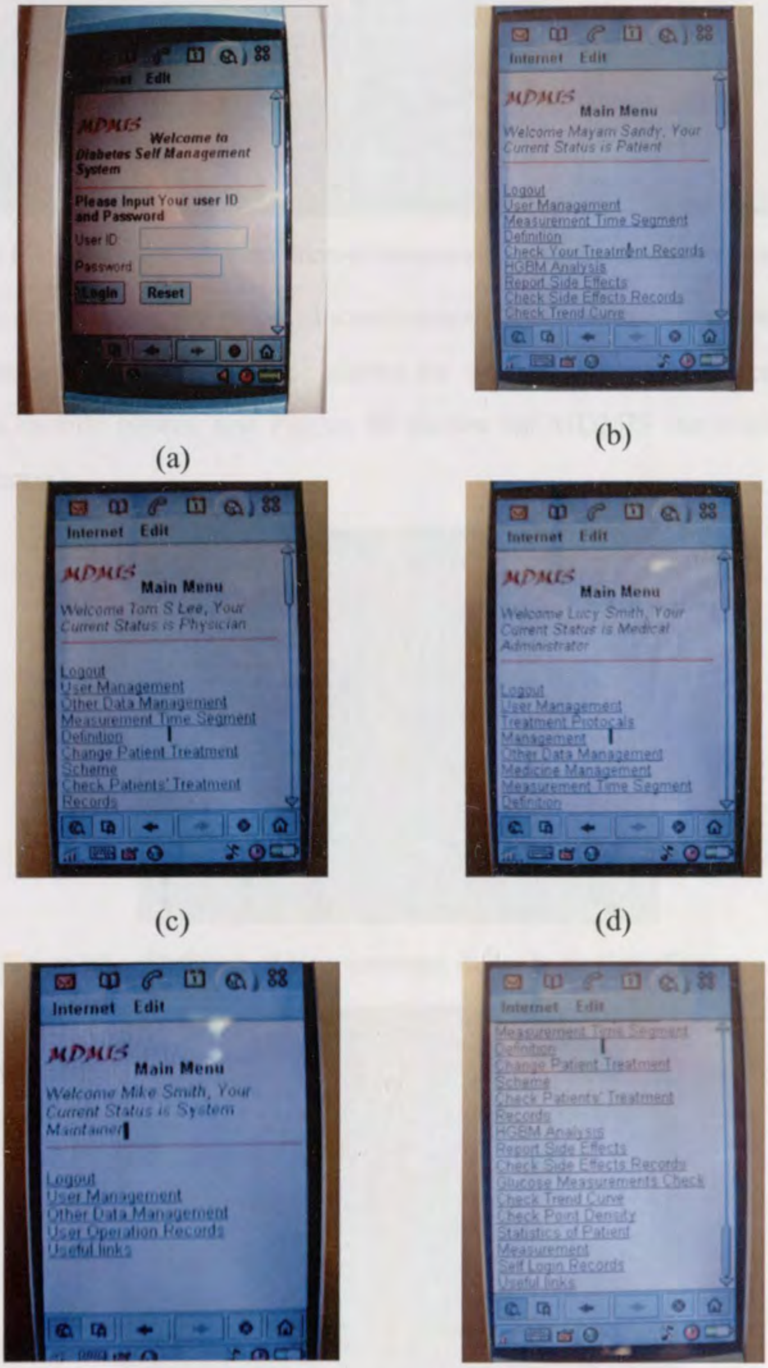
(a) (b)

(c) (d)

Figure 55. Snapshots from Data Acquisition Procedures of a MDMIS' Patient Station

Figure 56 shows the login page and the different functions list of MDMIS from the mobile data management perspective. The MDMIS user login page is shown in Figure

56(a) The MDMIS system shows different services to different users as different authorization is allocated according to the present user's role. The functions for MDMIS users to choose are shown as a menu list in Figure 56(b) to a patient, in Figure 56(c) to a physician, in Figure 56(d) to a medical administrator and in Figure 56(e) to a system maintainer. Figure 56(f) shows further information on the functionalities of the MDMIS system.



(a) (b)

(c) (d)

(e) (f)

Figure 56. MDMIS Login and Functionalities List Pages

Figure 57 shows the results of the medical measurement records shown from a browser on different mobile terminals used in this test (Sony Ericsson P800, HP IPAQ H5450, Nokia 3100) and from a PC Internet Explorer.

Figure 57. Graphical Presentation of Measurement Records from Variable Devices

In MDMIS, statistics on the blood glucose measurement records can also be made for patients and medics' review. Figure 58 shows the statistics of measurements on a Sony Ericsson P800 mobile phone, and Figure 59 shows the MDMIS statistics results on a Nokia 3100 phone.

Figure 58. Statistics of Measurement Records on Sony Ericsson P800

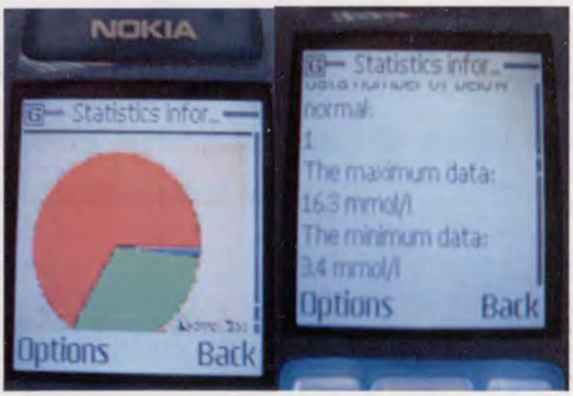


Figure 59. Statistics of Measurement Records on Nokia 3100

Appendix E shows more snapshots of MDMIS functionalities. Further tests on the system show the MDMIS system operated successfully on variable mobile devices (Sony Ericsson P800, Nokia 3100 mobile phone and HP IPAQ H5450 PDA) as well as on a Laptop or a PC.

From the feedback from the relative patients and nurse who has experienced the test (Appendix H shows the questionnaires of the study) shows that they all admitted that the system improved the management efficiency and the patients felt an increased consciousness on her diabetes management.

7.3 Performance Analysis of MDMIS Bluetooth Connectivity

In this section, we present the analysis result of the MDMIS's performance over Bluetooh from the perspective of connection time, data rate and response time parameters.

A research laboratory (7.5 x 8.5 metres) was utilized to serve as an experimental environment for evaluating the Bluetooth performance of MDMIS. An IEEE 802.11 access point within the university campus was about 50 meters away. As presented in Chapter 4, the Bluetooth connection happens between a Sony Ericsson P800 handset and a Bluetooth-enabled glucose sensor - the connectBlue Serial Port Adaptor (SPA 32i). A diagram of the experimental set-up is shown in Figure 60.

Figure 60. MDMIS Experimental Set-up Test for the Bluetooth Connection Evaluation

To quantify the MDMIS performance over Bluetooth, there are several main performance metrics to be considered as following:

(i) Connection Times

Before the two Bluetooth devices can be connected, the synchronization procedures between the transmitter and the receiver must be carried out. There are inquiry procedure and paging procedure to perform the synchronization. An inquiry procedure enables a

Bluetooth device to discover which devices are in range, finds the address and determines the clock of the device. A paging procedure will follow the inquiry procedure to form the link. It can take up to 10 seconds to establish a Bluetooth link. Table 15 shows the experimental statistics of connection times to build an active Bluetooth link.[146]

Operation	Minimum Time (sec)	Average Time (sec)	Maximum Time (sec)
Inquiry	0.00125	3-5	10.24-30.72
Paging	0.0025	1.28	2.56
Total	0.00375	4.28-6.28	12.8 - 33.28

Table 15. Connection Times to Build an Active Bluetooth Link

We evaluate the connection establishment time of the MDMIS data acquisition system between the start of an inquiry to the start of the data transmission, as the data begins to be transmitted as soon as the connection was successfully built. This duration includes time spending on the inquiry procedure and the paging procedure. In order to determine the effect of distance on the performance of Bluetooth connectivity, the test process was repeated at four different separation distances for <1, 3, 6, and 9 meters respectively. The time is counted by the software – "BlueReader" on the patient station (Sony Ericsson P800).

We evaluated 10 trials continuously for each distance: the start time (when the user presses "Read data" menu item in BlueReader) and the end time of building the connection for each test were recorded (when a prompt information "Start Reading" is shown to the user) for each trial. The maximum, minimum and mean durations were calculated afterwards accordingly.

Table 16 shows the experimental result of this test. The Bluetooth communication establishment time within the BlueReader is less than 30 seconds for the next successful connection.

The Bluetooth connection setup time in the BlueReader is composed by:

- Reading the Bluetooth address for the glucose meter;
- Prompting information to users;
- Bluetooth inquiry time;
- A 5 seconds inquiry halt time after a failure to find the device;
- Bluetooth paging time.

These results indicate that the Bluetooth connection setup time (in seconds) of the BlueReader is within a acceptable range for typical mobile users.

Distance	Mean Connection Setup Time (Seconds)	Maximum Connection Setup Time (Seconds)	Minimum Connection Setup Time (Seconds)
<1m	10.561	17.15	8.34
3m	11.087	17.69	8.40
6m	12.602	18.34	8.53
9m	15.378	27.11	8.56

Table 16. BlueReader Bluetooth Connection Setup Time

Table 16 also demonstrates the impact of the geographical distance between the two Bluetooth devices on the connection setup time. The statistics of net connection setup time were calculated and these are shown in Table 17:

Distance	Maximum Connection Setup Time (Seconds)	Net Maximum Connection Setup Time(Seconds)	Minimum Connection Setup Time (Seconds)	Net Minimum Connection Setup Time(Seconds)
<1m	17.15	6.15	8.34	3.34
3m	17.69	6.69	8.40	3.40
6m	18.34	7.34	8.53	3.53
9m	27.11	9.11	8.56	3.56

Table 17. BlueReader Bluetooth Net Connection Setup Time

These results show that the Bluetooth connection setting-up time is within the extensive statistical range presented in Table 15.

(ii) Data Reading Duration

The data reading duration of the MDMIS data acquisition system is affected by Bluetooth data rate and packet delay aspects.

There are two Bluetooth link types: Synchronous Connection-Oriented (SCO) and Asynchronous Connection-Less (ACL) links [146]. An SCO link provides a symmetric, point-to-point link between a master and a slave. It reserves the slots and provides a circuit-switched connection where data are regularly exchanged. The SCO packets are normally used for voice transmission and are never retransmitted. A master can support up to three SCO links to the same or to different slaves. A master sends SCO packets regularly at a rate of 64 kbit/s. There are 3 types of SCO High-rate voice packets (HV1, HV2 and HV3) with different levels of protection (Forward Error Correction) and DV packet which is combined data-voice packet. No Cyclic Redundancy Check (CRC) is used on all the SCO voice packets except the data field in a DV packet.

The ACL links are used for carrying asynchronous data. An ACL link is a point-to-multipoint link between a master and all the active slaves participating within a piconet. There is no slot reservation for an ACL link. The ACL link provides a packet-switched connection where data are exchanged sporadically. The traffic over the ACL link is scheduled by a master. For most ACL packets, CRC is used to ensure data integrity. Each received packet is checked for errors. Thus delays are on slot in duration and only lost packets need to be retransmitted. The maximum data rate for ACL link is 721 kbps in one direction and 57.6 kbps in the reverse direction. This is obtained by using an unprotected 5-slot packet. ACL packets can be either Data Medium (DM) or Data High (DH) type. The DH packets can achieve higher rate by using less error correction.

Table 18 shows typical maximum data rates of the Bluetooth ACL Packets [146].

ACL packet type	Payload Header (Bytes)	User Payload (Bytes)	FEC	CRC	Symmetric Max Data Rate (kbps)	Asymmetric Max Data Rate (kbps)	
						Forward	Reverse
DM1	1	0-17	2/3	Yes	108.8	108.8	108.8
DH1	1	0-27	0	Yes	172.8	172.8	172.8
DM3	2	0-120	2/3	Yes	258.1	387.2	54.4
DH3	2	0-180	0	Yes	390.4	585.6	86.4
DM5	2	0-224	2/3	Yes	286.7	477.8	36.3
DH5	2	0-338	0	Yes	433.9	723.2	57.6

Table 18. Bluetooth ACL Packet Maximum Data Rates [146]

As CRC is used for reliability of transmission of ACL packets, each packet carries a header with an acknowledgement bit. The device uses the acknowledgement bit to indicate whether the last packet it received was good or corrupted. If an acknowledgement bit is set to indicate a corrupted packet, when the other device receives this packet, the corrupted packet will be retransmitted until an indication that the packet was received correctly is received. Therefore, the connection delays are caused.

To check the efficiency of the data reading procedure, we made comparision among reading variable amouts of records: 5 records, 22 records, 58 records and 110 records respectively from a MediSense Optium glucose sensor on a Sony Ericsson P800 handset. The data length of a record is from 26 bytes to 31bytes, depending on the size of measurement. The result is shown in Table 19.

Number of Measurements	Mean Reading Time (Seconds)
5	0.98
22	2.83
58	6.52
110	10.27

Table 19. Duration of Reading Blood Glucose Measurement over Bluetooth

From these experiments and user acceptabilty, we conclude that the data reading of the MDMIS BlueReader via Bluetooth is effective for acquiring timely medical measurements between a Bluetooth-enabled sensor and a mobile GPRS terminal.

7.4 MDMIS Network Performance Analysis over GPRS

In this section, we present the result of MDMIS' performance analysis over GPRS network. The end-to-end performance of the MDMIS system over GPRS is measured in the following aspects:

(i) Data Throughput

GPRS provides logical channels – Packet Data Channel (PDCH) for data transfer. As the available radio resources are shared between GPRS and GSM logical channels, GPRS has a variable channel capacity. GPRS uses up to 8 timeslots for uplink and downlink data transmission. According to the radio resource conditions and QoS requirement, different coding scheme with different level of error detection and correction are adopted in GPRS for the data transmission. The amounts of data of one timeslot are decided by the coding scheme (Section 3.3.3). Theoretically, the maximum date rate can reach 171.2kbps. However, this is reduced in practice. One reason is that most of GPRS network operators only deployed CS1 and CS2 coding schemes [147]. Other major aspects affecting the GPRS data throughput include: (1) the GPRS modem or GPRS mobile terminal which decides the maximum number of time-slots supported; (2) the number of the concurrent users and data packets size affect the throughput as the GPRS users potentially share the same bandwidth; (3) radio conditions and interference: the achievable data rate over GPRS can vary with the radio environment; (4) for web applications, the browser's behaviour also plays a substantial aspect on page downloading times over GPRS [148].

(ii) Packet Loss and Packet Delay

GPRS ensures the integrity of received data through the implementation of two reliable modes of operation: RLC acknowledged and LLC acknowledged. The RLC acknowledged mode is used by default to ensure the data transfer to or from the MS is reliable. The LLC acknowledged mode is optional in GPRS. The protocol ensures that an LLC frames are received reliably, thus the higher level layer protocols (such as IP) rarely experience non-congestive losses, but packet losses happen due to the mobility management such as handoff and routing area updates [149].

Latency is the time taken for the data packets to pass through the GPRS bearer; it is normally measured as a RTT (Round-Trip Time). The latency mainly comes from: (1) time-varying quality of the radio link, a sudden change in the link quality may lead to a burst of transmission errors and data retransmissions; (2) handoff delay when users are transferred to other base stations and transmission interruptions. [150]

The Round-trip Time (RTT) of a TCP segment is the time that takes a segment to reach the receiver and return to the sender with the generated acknowledgment message. [151]. RTT is the average time spent in transit when a client and server exchange the SYN (synchronize sequence numbers flag) and its corresponding ACK (acknowledge flag). The measurement of RTT is fundamental to TCP's timeout and retransmission. It is an indicator of transit delay that is independent of data size. RTT reflects the total delay of the forward and backward paths between hosts [152]. As described earlier in chapter 5, MDMIS is a web-based system; the lower level communication protocol for MDMIS is TCP. It is well known that "TCP is a connection-oriented, end-to-end reliable protocol", the lost packet will be retransmitted to ensure the reliability [153]. Furthermore, MDMIS is not image or video critical application, hence, the quantitative analysis of packet loss will not be considered in this situation.

All of the data throughput, packet loss and packet delay of the GPRS network affect the service response time of a GPRS application. High data throughput, low packet loss and packet delay produce a relative better service response time.

(iii) MDMIS End-to-End Performance Evaluation over GPRS

The MDMIS end-to-end performance over GPRS is examined by measuring the following measurements: service response time, data throughput and RTT (as the connection protocol is based on TCP/IP). Ethereal was selected as the network performance analyzer [154]. The schematic diagram of test bed set-up for the performance measurements is shown in Figure 61. In this diagram, the connected thicker lines represent the end-to-end data transmission route (between a MDMIS mobile terminal and the MDMIS master station).

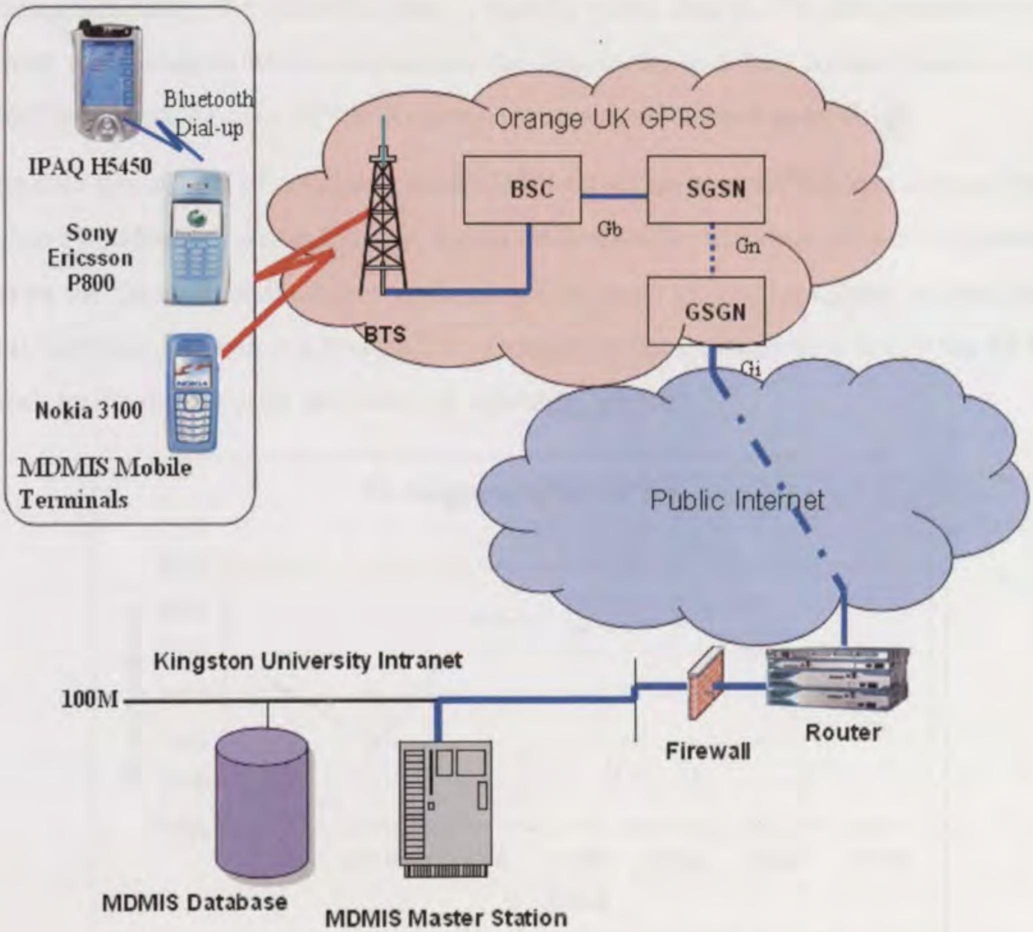


Figure 61. GPRS Test Set-up for Performance Evaluation of MDMIS

The GPRS connection network in this test was provided by the mobile service provider - Orange UK. A dynamic IP address is allocated by Orange GPRS service provider each time after a valid PDP context activation request was initiated (please refer to section 3.3 for details). The Orange GPRS network is connected with public internet via a GGSN. The MDMIS master station and health information database are located within Kingston University's 100M high speed intranet which is connected with outside internet.

We planned data accessing to and from MDMIS via a Sony Ericsson P800 at different daily time periods: namely 7:00, 9:30, 11:40, 14:40, 16:40, 20:30 and 23:50. We did not consider the time period between 0:00 and 6:00 as we thought it was unlikely that users to access the MDMIS services during these early hours. The user operations involved all the possible MDMIS functions by changing user roles. We found the length of data packet during each transmission was from 60 bytes - RST (reset packet) to 1334 bytes - data packet.

During accessing the MDMIS from a mobile client station, the data packets were gathered with Ethereal while transmitting the data in the real-time mode to analyze the network performance over GPRS. Response time was calculated accordingly.

The data throughput of accessing the MDMIS functions over GPRS on a using a Sony Ericsson P800 handset was calculated during different time periods is shown in Figure 62. It shows the throughput fluctuates with time. The range of the throughput during these tests is between 7.3 kbps and 8 kbps. The variation in the throughput is due to the GPRS network traffic during peak and off-peak operating periods.

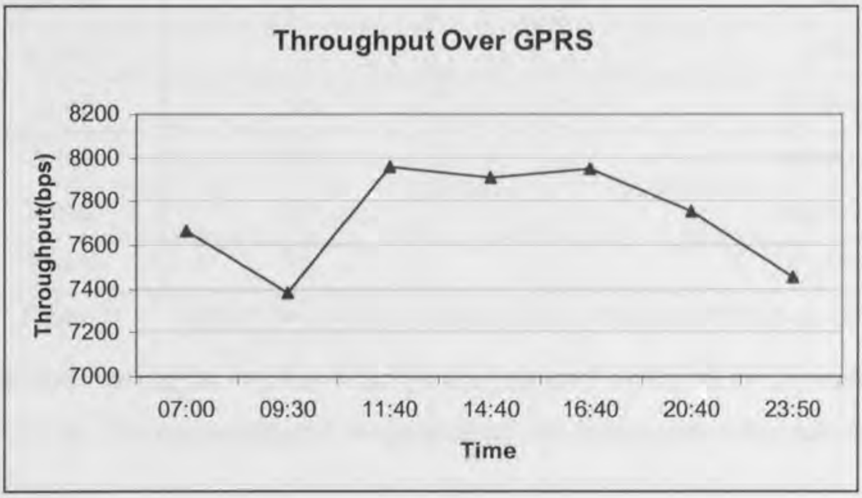


Figure 62. Mean Throughput Measurements Using Sony Ericsson P800 Mobile Terminal over GPRS

The Round-trip Time (RTT) is calculated by measuring the time interval between a SYN request and the corresponding ACK signal recieved. Figure 63 shows the average RTT over the GPRS network between a Sony Ericsson P800 and the MDMIS master station. We can see the range of RTT is from 0.8s to 1.2s in this study.

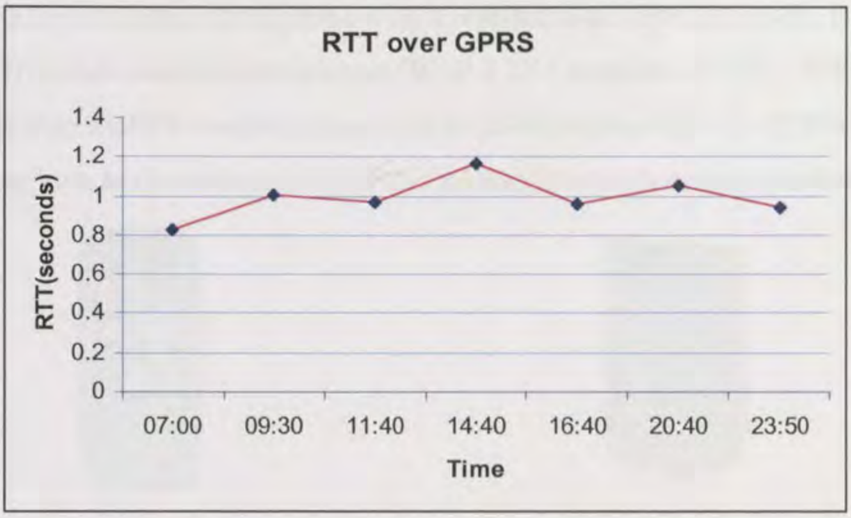


Figure 63. RTT Variations between a Sony Ericsson P800 and the MDMIS Master Station

Table 20 shows the system response time of accessing the MDMIS management functionalities on a Sony Ericsson P800 handset during a day. The result indicates that most responses can be made within 6 seconds.

Access Time	Maximum Duration(seconds)	Minimum Duration(seconds)	Frequency of Events(below 6s)
07:00	26	3	92.26%
09:30	30	2	87.42%
11:40	19	3	94%
14:40	21	3	91.60%
16:40	18	2	89.47%
20:40	15	3	90.50%
23:40	16	3	93.73%

Table 20. MDMIS Response Time from Sony Ericsson P800 over GPRS

We also found the longest waiting time for the response of the MDMIS master station during the day is 30s (returning the measurements in trend curve format) on a Sony Ericsson P800 mobile client station, which happened at 9:30 in the morning while the lowest data throughput happened (Figure 62).

Two other mobile devices: Nokia 3100 mobile phone (Figure 64) and a PDA -HP IPAQ H5450 (Figure 65) from different manufacturers were selected to check the impact of variable mobile devices on the system performance. Data packets to and from different mobile devices were caught at the same time period: 11:40 during the day.

Nokia 3100 is a tri-band GSM phone with a resolution of 128*128 pixels. It supports 4096 (12 bits) colours and wireless internet (WAP 1.2.1 / supports xHTML, JPEG, PNG). Nokia 3100 is also a GPRS enabled phone with multi-slots class 6 (3+2). HP IPAQ H5450 Pocket PC supports both wireless LAN (802.11b) and Bluetooth communications.

Figure 64. Nokia 3100

Figure 65. HP IPAQ H5450 Pocket PC

Figure 66 shows the comparison of the MDMIS end-to-end throughput over GPRS from Nokia 3100, HP IPAQ H5450 and Sony Ericsson P800 mobile terminals during the daytime test period. We found Nokia 3100 has a higher throughput (approx. 13 kbps). This result demonstrates that the throughput varies with the device's GPRS multi-slot class (Section 3.3.3) (the multi-slot class of Sony Ericsson P800 is class 8(1+4), while Nokia 3100's is class 6 (3+2)).

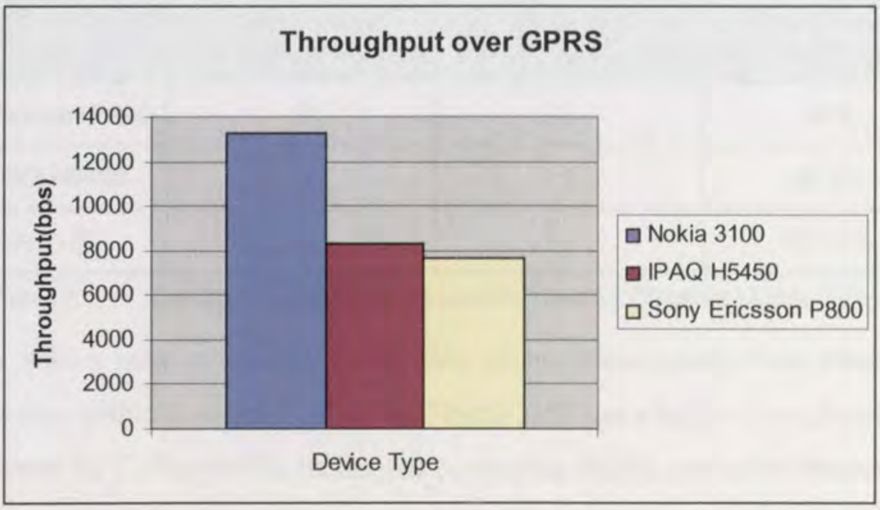


Figure 66. Comparative Performance of Average Throughput from Different Mobile Terminals

Comparative RTTs between variable mobile devices and the MDMIS master station are calculated and shown in Figure 67. We can see the packet delay between a Nokia 3100 mobile phone and the MDMIS master station is comparatively the smallest.

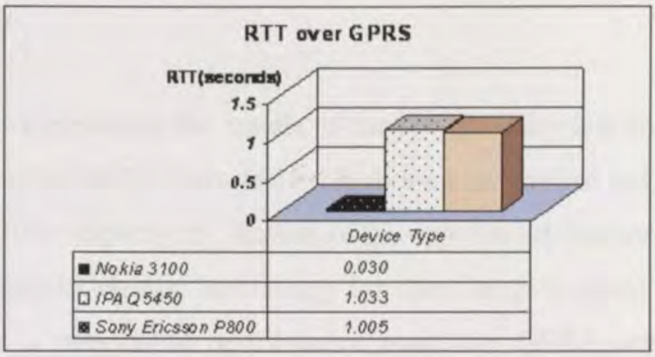


Figure 67. Average RTT between variable devices and the MDMIS Master Station

We also examined the variable service response time of accessing MDMIS services on these variable mobile terminals. The time counting was started as soon as the user clicked the relative function item and stopped as soon as the full content of service page was returned. Statistics of all the response time was performed separately; the maximum and minimum response time was calculated accordingly.

A comparison of MDMIS response time among different mobile devices (Sony Ericsson P800, Nokia 3100 and HP IPAQ H5450) is shown in Table 21 during daytime testing.

Device Type	Maximum Duration(seconds)	Minimum Duration(seconds)	Frequency of Events(below 6s)
Sony Ericsson P800	19	3	94%
HP IPAQ H5450	12	2	96.2%
Nokia 3100	31	4	82.36%

Table 21. Comparative MDMIS Response Time for Different Mobile Terminals

Table 21 shows most system response time where access made from other mobile terminals is also within 6 seconds. Although Nokia 3100 has a higher throughput (Figure 66) and a lower RTT (Figure 67), its limited computing ability and cache memory cause much slower access (82.36% of all the response time below 6 seconds) to the MDMIS system than on the other two mobile devices.

We also examined the response time on a PC which is connected to Internet over ADSL (outside of Kingston University). We found all the response times are within 3 seconds.

7.5 Summary

In this chapter, we presented the results of the functionality test and an experimental performance study of MDMIS. Tests and evaluations were carried out via live Bluetooth and GPRS connectivity respectively. Results of the experiment demonstrate: 1) Bluetooth connectivity is a feasible wireless technology for short-range medical data transmission; 2) MDMIS shows a reasonable performance over live GPRS network while users accessing the system on different mobile terminals.

Chapter 8

Conclusions and Future Work

8.1 Conclusions

This study aims to alleviate diabetes symptoms, prevent or delay the complications and improve the quality of patients' life by providing an intelligent mobile diabetes management system – MDMIS for diabetes sufferers and medical care providers. We designed, implemented and evaluated a Bluetooth data acquisition system to capture medical data wirelessly and the abundant MDMIS diabetes management services provided by MDMIS. The MDMIS system can be accessed remotely over GPRS on variable mobile equipments. In summary, the thesis presented the following research objectives and issues:

(i) Comprehensive Study and Review of Diabetes Management System

A comprehensive background study for this research has been carried out to understand the procedure of traditional and current diabetes management by searching and studying extensive documents from NHS diabetes framework, National Institute for Health and Clinical Excellence, and other sources cited in the thesis.

A comprehensive review on state of art of remote diabetes management systems was conducted. This review involves studying past and existing diabetes related telemedicine research projects, and examining each system' advantages and shortcomings.

From this study, we drew these conclusions: (1) checking blood glucose level regularly is very important to keep diabetes in control; (2) current and future e-health systems are towarding mobile and networking solutions; (3) the interoperability is an important issue to measure a system's flexibility and practicability.

(ii) Design and Implementation of a Prototype System for Mobile Diabetes Management

We have proposed in this thesis a complete system for mobile diabetes management, which includes mobility modules together with relevant software and hardware options of the mobile terminals and sensor connectivity.

Emerging Bluetooth and GPRS wireless technologies are adopted in MDMIS. Bluetooth is a short-range wireless technology with the advantage of low power consumption and availability of extensive chips from many manufactures. GPRS is a specification for data transfer on TDMA and GSM networks. It is a packet-based, cost effective, and with better coverage than UMTS in the UK, hence is suitable for this study.

The MDMIS system has a scalable, three-tiers and J2EE compliant software architecture, which supports a portable deployment and flexible user interface. We adopted XML and Java technology to MDMIS implementation, this enables the users to access the MDMIS system on variable mobile devices.

MDMIS is composed by several integrated modular units: patient stations, medical administration stations, physician stations, system maintenance stations and medical control centre. The medical control centre consists of a master station and a MDMIS health information database. Generally it resides in a hospital with broadband access to the Internet. A secure MDMIS health information database was designed and set up. It is an Oracle database and stores health related information, which includes all the MDMIS users' operation records and accounts information, medication protocols, patients' medications and medical measurement records, etc. The master station processes all requests from other MDMIS stations (clients), analyses and stores health related information into the health information database.

The access of variable MDMIS functions is restricted according to the individual user's role. There are four user roles designed in MDMIS: patient, physician, medical administrator and system maintainer. A patient station is a mobile data acquisition terminal as well as an operation portal for diabetes patient. A special Bluetooth data acquisition system (BlueReader) for MDMIS patient station was designed and implemented. The BlueReader was developed in Symbian OS environment. It is able to read the blood glucose measurements from an off-shelf medical sensor by complying with the Bluetooth SPP profile. The other functionalities of the BlueReader are pre-processing, sending the data to the medical centre and displaying the feedback or the medical suggestions from the remote medical centre to the patient. Furthermore, on a patient station, a patient can update his account information; examine his historical medical records, or report recent side-effects to the system. Physician stations are the computing devices for MDMIS physicians or other relevant medical doctors accessing patients' data. Physicians can remotely manage patients' accounts information, inquire, analyze the patients' medical situation and manage patients' medications. A MDMIS medical administrator can manage the relevant medication protocols, manages physicians' account information, intervene and supervise patient's therapy procedures on a mobile medical administration station. A system maintenance station represents a MDMIS maintainer and is designed to carry out maintenance procedures locally or remotely. The medical analysis functions of the system have been designed and implemented by strictly following the relevant medical rules of diabetes management.

An instant medical messaging service was designed for alerting and informing the diabetic patients with necessary medications and wellbeing reminders. The relevant security issues regarding MDMIS were also discussed in this thesis.

The MDMIS system can also be referenced by other chronic disease management systems because of the similar characters in long-term disease management.

(iii) Enhancement of the Interoperability

An improved interoperability structure for mobile chronic disease management was introduced. This mechanism provides an innovative concept of flexible devices interfacing within m-health systems.

The principle of this architecture concerns the compatible data acquisition from variable medical devices. To get data from a medical device on computing equipment, a data acquisition software must have an appropriate communicate protocol to communicate with the medical device. With the fact of limited data storage capability of mobile equipments and the possibility of introducing new medical devices within the system, it is not appropriate and efficient to keep all the protocols for each possible individual medical device on one data acquisition equipment, furthermore, even the equipment itself maybe vary each time. Therefore, it may lead to a failure of electronical medical data collection if a system is restricted to adapte only one or several medical devices. In this thesis, we proposed a scheme in which the data communication protocols are shared among all the users. These protocols are stored in the health information database within a medical centre and maintained by system maintainers; only a required protocol needs to be downloaded and stored locally on a data acquisition unit. This design reduces the storage space of protocols and always keeps up-to-date protocols on variable data acquisition devices, consequently the interoperability of the relavant system is improved. This scheme has been premilinarily implemented on to the MDMIS system.

(iv) Preliminary Clinical Test and Performance Evaluation

The thesis also presents the preliminary test and performance evaluation of the wireless functionalities of the MDMIS system in both laboratory and sample patient environments.

A diabetes patient and nurse have volunteered using the MDMIS system and the survey shows both of them were satisfied with the flexible and extensive services of MDMIS. We evaluated the syste performance of MDMIS over Bluetooth and GPRS connectivity respectively. Performance of MDMIS data acquisition system - BlueReader has been examined by measuring the Bluetooth connection establishment time and duration of reading medical measurement over Bluetooth between a Sony Ericsson P800 smart phone and a MediSense Optium blood glucose meter. The test process was repeated 10 times at four different separation distances for <1, 3, 6, and 9 meters respectively, we found the net connection establishment time was between 3.34 seconds to 9.11 seconds, this result demonstrates the impact of the geographical distance between the two Bluetooth devices on the connection setup time. We made a comparison among reading variable amounts of medical measurement records: 5, 22, 58, 110 measurements to examine the duration over Bluetooth. The experiment result shows the average time of reading 5 records is 0.98 seconds, this proves the Bluetooth connectivity is suitable for short-range medical data transmission.

To examine the MDMIS system performance over GPRS, we chose Sony Ericsson P800 mobile phone and accessed the MDMIS system at different time during a day; the corresponding data packets were caught by a data packet analyser software; data throughput and RTT were calculated afterwards. We also compared the end-to-end performance of MDMIS over GPRS on variable devices: a Nokia 3100 headset, a Sony Ericsson P800 smart phone and a Compaq IPAQ H5450 PDA. The experiment results show the performance of MDMIS over GPRS is affected by the radio condition and the mobile device. We also found that all the service response time of MDMIS were within 30 seconds, most of responses can be made within 6 seconds on these mobile devices. This demonstrates the performance of MDMIS over live GPRS network is acceptable when a user is accessing the system on a mobile phone.

8.2 Future work

The area of mobile chronic disease management is considered as an emerging field of modern healthcare. Advanced technologies can be utilized to enhance the performance and ubiquity of such systems. In this section, we propose some future research directions and emerging technologies that can provide such enhanced characteristics and combine with the current MDMIS system.

The following are summary of some of the suggestions for future work of such system:

(i) An integrated Bluetooth enabled non-invasive medical glucose sensor

During the initial clinical tests, the patients still were using the traditional "off the shelf" invasive blood glucose measurement device. Inevitably, improved and non-invasive glucose meter will be an appropriate replacement. GlucoWatch G2 Biographer is such option. However, the integration of such sensor with wireless communication ability needs further research efforts and clinical validation studies compared to traditional blood glucose sensor.

(ii) Mobile Agents Enhanced Multiple Chronic Diseases Management

People with diabetes are vulnerable to a variety of complications, such as obesity and high blood pressure. A fully intelligent and integrated multiple chronic diseases management system is demanding to achieve more effective management. Mobile agents technology is seen as a perfect technology option for such intelligent mobile disease management.

Mobile agents are specific programs that can migrate from host to host in a network, at times and to places of their own choosing [156] [157]. They can encapsulate protocols, work remotely, asynchronously and even disconnected from a network. Mobile agents technology has the advantages on reducing network load and overcoming network latency especially on relatively unreliable mobile environment. The concept of mobile agent technology on diabetes management has been proposed in [158]. Nevertheless, further research on the integration of mobile agents technology with MDMIS functionality are necessary.

(iii) SIP Based Mobile Disease Management

SIP is a part of the IETF (The Internet Engineering Task Force) standards process. The SIP technology is used to establish, change and terminate multimedia sessions between one or more users in an IP-based network [159] [160].

The application of SIP on chronic disease management will enhance interaction between patients and medical personals because of its feature of session control.

Further research on our MDMIS will aim to broaden the current architecture and management to integrate SIP functionality for an effective management of the communication between patients and medical doctors.

(iv) Clinical Studies for Medical Validation of MDMIS

Further wider clinical studies on such emerging mobile chronic disease management systems are also required as part of future research work. These studies are important if not crucial for implementation and deployment of such systems within the NHS and to provide larger m-health services within the current primary care diabetes services.

References

[1] World Health Organization (2004), Diabetes Action now booklet - Diabetes Action Now: An Initiative of the World Health Orgnanization and International Diabetes Federation [online]. Available at: <http://www.who.int/diabetes/actionnow/en/DANbooklet.pdf>.

[2] Diabetes UK (2004), *Diabetes in the UK 2004, a Report from Diabetes UK* [online]. Available at: <http://www.diabetes.org.uk/infocentre/ reports/in_the_UK_2004.doc>.

[3] Yuen, P (2004), *The Compendium of Health Statistics*, 16th ed. Office of Health and Economics. Whitehall, London.

[4] Department of Health (2001), *National service framework for diabetes: Standards* [online], Available at: <http://www.publications.doh.gov.uk/nsf/diabetes/>.

[5] NIDDK website (2001), *Diabetes control and complications trial* [online]. Available at: <http://diabetes.niddk.nih.gov/dm/pubs/control/#study>.

[6] Diabetes UK website (1999), *UKPDS–Implications for the care of people with Type 2 diabetes* [online]. Available at: <http://www.diabetes.org.uk/infocentre/state/type2.htm#ref2>.

[7] Gray A, Raikou M, McGuire A, Fenn P, Stevens R, Cull C, et al.(2000), Cost Effectiveness of an Intensive Blood Glucose Policy in Patients with Type 2 Diabetes: Economic Analysis Alongside Randomised Controlled Trial. *BMJ* 320, 1373–1378.

[8] International Diabetes Federation (2003), What is Diabetes? [Online]. Available at: http://www.idf.org/home/index.cfm?node=2.

[9] Diabetes UK (2005), Reducing your familiy's risk of type 2, *Balance*, May-June, 66-67.

[10] Reinauer H, Home PD, Kanagasabapahy AS, Heuck CC (World Health Organization document, 2002), Laboratory Diagnosis and Monitoring of Diabetes Mellitus [online]. Available at: <http://whqlibdoc.who.int/hq/2002/9241590483.pdf>.

[11] Juvenile Diabetes Research Foundation (2004), *About type 1 diabetes* [online], Available at: < http://www.jdrf.org.uk/cgi-bin/cms/FileLib/JDRF%20About%20Type1.pdf>.

[12] Diabetes UK website (2005), *What are the symptoms of diabetes* [online], http://www.diabetesuk.co.uk/diabetes/sympt.htm.

[13] Watkins, P.J.(2003), *ABC of Diabetes*, 5th ed. London, BMJ Publishing Group Ltd.

[14] Rehman, H.U.(2000), Diabetes mellitus in the young, *Royal Society of Medicine* 94(2), 65-7.

[15] Wild S., Sicree R., Roglic J., King H., Green A.(2004), Global Prevalence of Diabetes-Estimates for the year 2000 and projections for 2030, *Diabetes Care* 27(5), 1047-1053.

[16] Diabetes UK (2004). *News Archive - Diabetes numbers leap to 1.8 million people in the UK* [online]. Available at: < http://www.diabetes.org.uk/news/oct04/statistics.htm>.

[17] Hall, M., Felton, A., Hirst, M. (2004), *"Enabling Good Health for all"- A reflection process for a new EU Health Strategy,* IDF Europe. Available at: <http://europa.eu.int/comm/health/ph_overview/Documents/refl/ev20041015_co_127_en.pdf>.

[18] World Health Organization (2005), Global Strategy on Diet, Health Activity and Health [Online]. Available at: <http://www.who.int/dietphysicalactivity/publications/facts/diabetes/en/>.

[19] International Diabetes Federation (2005), *Fact sheets- Diabetes and cardiovascular disease (CVD)* [online]. Available at: <http://www.idf.org/home/index.cfm?node=1158>.

[20] World Health Organization (2002), *Diabetes: the cost of diabetes, Fact sheet 236.* Available at: <http://www.who.int/mediacentre/factsheets/fs236/en/>.

[21] Hogan P, Dall T, Nikolov P (2003), Economic costs of diabetes in the US in 2002, *Diabetes Care* 26(3), 917-32.

[22] The Pharmaceutical Journal- Clinical Pharmacy (2000), Study counts cost of diabetes complications, *The Pharmaceutical Journal* 264, 429, Available at: <http://www.pjonline.com/Editorial/20000318/clinical/diabetescomplication.html>.

[23] Diabetes UK (2001), Fact Sheet: No 3- Diabetes: Cost and complications [Online]. Available at:http://www.diabetes.org.uk/infocentre/fact/fact3.htm.

[24] Diabetes UK/RCP (2001), *Endocrinology-Diabetes Medical Manpower Survey* [online], Available at: <http://www.diabetes.org.uk/infocentre/reports/manpower2001.pdf>.

[25] ARC Group (2000), Mobile Data User Penetration by Region - Table 3.2. *Content & Applications for the Wireless Internet—Worldwide Market Analysis & Strategic Outlook 2000-2005.*

[26] Evans, D. N. (2001), *Business Agility: Strategies for Gaining Competitive Advantage through Mobile Business Solutions*- Figure 2.2, Financial Times Prentice Hall.

[27] Pattichis, C. S., Kyriacou E., Voskarides S., and Istepanian, R.S.H. (2002), Wireless Telemedicine Systems: An Overview, *IEEE Antennas and Propagation* 44(2), 143-153.

[28] Doolittle, G.C. and David Cook (2000), Telemedicine, in Davidson, L. P. (eds.), *Healthcare Information Systems*, Auerbach Publications, pp. 453-468.

[29] Istepanian, R. S. H., Jovanov E. and Zhang Y.T.(2004), Guest Editorial Introduction to the Special Section on M-Health: Beyond Seamless Mobility and Global Wireless Health-Care Connectivity, *IEEE Transactions on Information Technology in Biomedicine* 8(4), 405-411.

[30] Istepanian, R S. H. and Lacal, J. (2003), 'Emerging Mobile Communication Technologies for Health: Some Imperative notes on m-health', *Proceedings of the 25th. Annual International Conference of the IEEE Engineering in Medicine and Biology*, Cancun Mexico, September 17-21, 2003, pp1414-1416.

[31] 3G News (2001), *What is 3G?* [online], Available at: <http://www.3gnewsroom.com/html/what_is_3g/index.shtml>.

[32] Istepanian, R.S.H. and Tseng, A. (2001), Diabetes management using advanced mobile technologies for cost-effective, real-time patient monitoring, *Proceeding of the 3rd Int. Conference in the Delivery of Care – E-Health; a Future Prospective*, E Carson, F, Harvey and Mike Hughes (Eds.), City University, London, April 4-6, 2001, pp. 139-143.

[33] International Diabetes Federation (2003), *Facts and Figures, Did you know?* [online]. Available at: <http://www.idf.org/home/index.cfm?unode=3B96906B-C026-2FD3-87B73F80BC22682A>.

[34] Department of Health, UK, (2004), *National service framework for diabetes: One year on* [online], Available at: <http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4079281&chk=QbeAKX>.

[35] Medical Research Council, UK (2002), *Current and Future Research on Diabetes, A Review for the Department of Health and the Medical Research Council* [online]. Available at:

<http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4091473&chk=OWqO5q>.

[36] Diabetic Retinopathy (2005), *What is HbA1c?* [Online], Available at: <http://medweb.bham.ac.uk/easdec/prevention/what_is_the_hba1c.htm#hba>.

[37] The Royal College of General Practitioners, Effective Clinical Practice Unit, University of Sheffield (2002), *Clinical Guidelines for Type 2 Diabetes: Management of blood glucose* [Online]. Available at:< http://www.nice.org.uk/page.aspx?o=38551>.

[38] Diabetes UK (2002), *Blood glucose targets* [Online]. Available at: <http://www.diabetes.org.uk/infocentre/inform/targets.htm>.

[39] National Institute for Health and Clinical Excellence (2004), *National Clinical guideline for diagnosis and management in primary and secondary care – Type 1 Diabetes in Adults*. Available at:< http://www.nice.org.uk/page.aspx?o=213575>.

[40] The royal college of general practitioners, Diabetes UK, The royal college of physicians and the royal college of nursing (2002), *Clinical Guideline for Type 2 Diabetes-Management of Blood Glucose*. Available at: <http://www.nice.org.uk/page.aspx?o=36882>.

[41] Diabetes UK (2003), *Home monitoring blood glucose levels* [Online]. Available at: <http://www.diabetes.org.uk/infocentre/state/monitoring.htm>.

[42] NICE Guidelines (2004), *CG015 Type 1 Diabetes: Diagnosis and Management of Type 1 Diabetes in Adults* [Online]. Available at: <http://www.nice.org.uk/page.aspx?o=213575>.

[43] American Diabetes Association (2003), *Brochure- Record Keeping* [Online]. Available at: <http://www.diabetes.org/uedocuments/DiabetesRecordkeeping.pdf>.

[44] National Diabetes Education Program USA (2002), *Brochure - If You Have Diabetes, Know Blood Sugar Numbers* [Online]. Available at:< http://www.ndep.nih.gov/diabetes/pubs/KnowNumbers_Eng.pdf>

[45] American Diabetes Association (2005), *Brochure- Checking Blood Glucose* [Online]. Available at: <http://www.diabetes.org/for-parents-and-kids/diabetes-care/CheckingBG.jsp>.

[46] NHS Direct (2004), *NHS Direct Online Health Encyclopaedia –Diabetes: Treatment* [Online]. Available at: http://www.nhsdirect.nhs.uk/he.asp?articleID=128&LinkID=2535.

[47] Shultz EK, Bauman A, Hayward M, Rodbard D, Holzman R.(1991), Improved diabetic prognosis following telecommunication and graphical processing of diabetic data. *Proceedings of the Annual Symposium on Computer Applications in Medical Care*, November, Washington DC, pp 53–57.

[48] Liesenfeld B, Renner R, Neese M, Hepp KD. (2000), Telemedical Care Reduces Hypoglycemias and Improves Glycemic Control in Children and Adolescents with Type 1 Diabetes, *Diabetes Technology & Therapeutics* 2(4), 561-567.

[49] Chase HP, Pearson JA, Wightman C, Roberts MD, Oderberg AD, Garg SK.(2003), Modem transmission of glucose values reduces the costs and need for clinic visits. *Diabetes Care* 26, 1475.

[50] Po,Y.M.(2000), Telemedicine to improve patients' self-efficacy in managing diabetes, *Journal of Telemedicine and Telecare* 6(5), 263–267.

[51] Bandura, A.(1997), *Self-efficacy: The exercise of control*, New York, W.H. Freeman.

[52] Entres PubMed, Search Engine. Available at : <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed>

[53] Kalorama Information (2002), *Diabetes and Diabetic Complications: Major World Markets* [Online]. Available at: <http://www.marketresearch.com/map/prod/696493.html>.

[54] LifeScan UK (2005), *OneTouch™ Diabetes Management Software* [Online]. Available at: <http://www.lifescaneurope.com/uk/products/otdms/software/>.

[55] Abbott Diabetes Care (2005), *Products page* [Online]. Available at: <http://www.diabeteshealthconnection.com/products/index.aspx>.

[56] Roche Diagnostics (2005), *Accu-Chek Compass* [Online]. Available At: < http://www.accu-chek.co.uk/gb/rewrite/content/en_GB/3.5:60/article/ACCM_general_article_47.htm>.

[57] Glucose Manger (2001). Available at: <http://www.proaxis.com/~rwi/glumgr.htm>.

[58] DIAsoft (2002), *Diabetes tracker blood glucose meter data management system* [Online]. Available at: <http://www.prihar.com/diasoft/default.htm>.

[59] Overlook Software(2005), *DiaTrends Software* [Online]. Available at: <http://overlooksoftware.com/index.aspx>.

[60] Allen D. (1997), Telephone follow up for older people discharged from A&E. *Nursing Standard* 11(46), 34-37.

[61] Poncia H. D. M., Ryan J. and Carver M. (2000), Next day telephone follow up of the elderly: a needs assessment and critical incident monitoring tool for the accident and emergency department, *The Emergency Medicine Journal 17*, 337-340.

[62] DiabetEASE (2005). Available at: <http://www.diabetease.com> .

[63] Bellazzi R, Larizza C, Montani S, Riva A, Stefanelli M, d'Annunzio G, Lorini R, Gomez EJ, Hernando E, Brugues E, Cermeno J, Corcoy R, de Leiva A, Cobelli C, Nucci G, Del Prato S, Maran A, Kilkki E, Tuominen J.(2002), A telemedicine support for diabetes management: the T-IDDM project, *Computer Methods and Programs in Biomedicine* 69(2),147-161.

[64] T-IDDM Project (2005). Available at: <http://aim.unipv.it/projects/tiddm> .

[65] Wang, X.H. and Istepanian, R.S.H. (2003), A Web Based Service for Patients Compliance to Disease Treatment, *Proceedings of the 25th. Annual International Conference of the IEEE Engineering in Medicine and Biology*, pp.1417-1420.

[66] AARDEX (2005). Available at: <http://www.aardex.ch>.

[67] ProWellness chronical disease management system (2005). Available at: <http://www.prowellness.com>.

[68] Diabcarnet (2005). Available at: <http://www.diabcarnet.com>.

[69] M2DM Project. Available at: <http://aim.unipv.it/projects/m2dm/index.html>.

[70] Bellazzi R., Carson E.R., Cobelli C., Hernando E., Gomez E.J., Nabih-Kamel-Boulos M., Rendschmidt T., Roudsari A.V. (2001), Merging telemedicine with knowledge management: the M2DM project, Proceedings of the 23rd Annual EMBS International Conference, Vol 4, pp. 4117 – 4120.

[71] MediCompass (2005). Available at: <http://www.medicompass.com/>.

[72] E-San (2005). Available at: < http://www.e-san.co.uk/ >.

[73] Horn W., Rami B., Schober E.(2003), VIE-DIAB: A Support Program for Telemedical Glycaemic Control. AIME 2003, 350-354.

[74] Hernando ME, Gomez EJ, Gili A, Gomez M, Garcia G, del Pozo F.(2004), New trends in diabetes management: mobile telemedicine closed-loop system, *Studies in Health Technology and Informatics* 105, 70-79.

[75] Horan PP, Yarborough MC, Besigel G, Carlson DR (1990). Computer-assisted self-control of diabetes by adolescents. *Diabetes Educator* 16(3), 205-211.

[76] Billiard A, Rohmer V, Roques MA, Joseph MG, Suraniti S, Giraud P *et al.* (1991),Telematic transmission of computerized blood glucose profiles for IDDM patients. *Diabetes Care* 14, 130–134.

[77] Shultz EK, Bauman A, Hayward M, Holzman R (1992). Improved care of patients with diabetes through telecommunications. *Annals of the New York Academy of Sciences* 670(1), 141–145.

[78] Ahring KK, Joyce C, Ahring JPK, Farid NR (1992). Telephone modem access improves diabetes control in those with insulin-requiring diabetes. *Diabetes Care*; 15: 971–975.

[79] Marrero DG, Vandagriff JL, Kronz K, Fineberg NS, Golden MP,Gray D *et al.* (1995), Using telecommunication technology to manage children with diabetes: the Computer-Linked Outpatient Clinic (CLOC) Study. *Diabetes Educator* 21, 313–319.

[80] Fallucca F, Di Biase N, Sabbatini A, Borrello E, Sciullo E, Napoli A.(1996), Telemedicine in the treatment of diabetic pregnancy. *Pract Diabetes Int* 13, 115–118.

[81] Albisser AM, Harris RI, Sakkal S, Parson ID, Chao SC.(1996), Diabetes intervention in the information age. *Med Inform (Lond)* 21(4), 297–316.

[82] Meneghini LF, Albisser AM, Goldberg RB, Mintz DH. (1998), An electronic case manager for diabetes Control. *Diabetes Care* 21: 591–596.

[83] Alaoui A, Clement S, Khanafer N, Collman J, Levine B, Mun SK.(1998), Diabetes home monitoring project. *Proceedings of the Pacific Medical Technology Symposium*, Honolulu: 258–261.

[84] Edmonds M, Bauer M, Osborn S, Lutfiyya H, Mahon J, Doig G *et al.* (1998), Using the Vista 350 telephone to communicate the results of home monitoring of diabetes mellitus to a central database and to provide feedback. *Int J Med Informat* 51, 117–125.

[85] Bellazzi R, Larizza C, Montani S, Riva A, Stefanelli M, d'Annunzio G *et al.* (2002), A telemedicine support for diabetes management: The TIDDM project. *Comput Meth Programs Biomed* 69, 147–161.

[86] Salzsieder E, Boltz H, Ramirez JC, Rutscher A, Fischer U, Koenig Ch. (1999), Telematics in diabetes care: application of an advisory program based on routinely monitored self-control data. *Diabetologia* 42: A54.

[87] Biermann E, Dietrich W, Rihl J, Standl E. (2002), Are there time and cost savings by using telemanagement for patients on intensified insulin therapy? A randomised controlled trial. *Comput Meth Programs Biomed* 69, 137–146.

[88] Piette JD, Weinberger M. (2000), Automated Telephone Calls Improve Outcomes in Patients with Diabetes, *Journal of Science of Communications* 7(4), 11-12.

[89] Frost D, Beischer W. (2000), Telemedicine in the management of pregnancy in type 1 diabetic women. *Diabetes Care* 23, 863–864.

[90] Gómez EJ, Hernando ME, Garcìa A, del Pozo F, Cermeno J,Corcoy R *et al.* (2002), Telemedicine as a tool for intensive management of diabetes: the DIABTel experience. *Computer Methods and Programs in Biomedicine* 69, 163–177.

[91] Versweyveld L. (2002), MOEBIUS Mobile Extranet platform allows telemonitoring of patients with chronic disease, *Virtual Medical Worlds*, May 2002 [Online]. Available at: <http://www.hoise.com/vmw/02/articles/vmw/LV-VM-05-02-15.html>.

[92] MOEBIUS Project. Available at: <http://www.ist-moebius.net>.

[93] Bellazzi R, Arcelloni M, Bensa G, Blankenfeld H, Brugues E, Carson E, et al. (2003), Design, methods, and evaluation directions of a multi-access service for the management of diabetes mellitus patients. *Diabetes Technol Ther.* 5(4), 621-629.

[94] E-San (2004), *e-Sans type 1 diabetes trial sponsered by the Vodafone Group Foundation* [Online]. Available at: <http://www.e-san.co.uk/>.

[95] Vähätalo MA, Virtamo HE, Viikari JS, Rönnemaa T (2004), Cellular phone transferred self blood glucose monitoring: prerequisites for positive outcomes. *Pract Diabetes Int* 21, 192–194.

[96] Doc@HOME (2005). Available at: <http://www.docobo.co.uk>.

[97] Leeper, D.G. (2001), A long-term view of short-range wireless, *Computer* 34(6), 39 – 44.

[98] O'Driscoll G. (2000), *Essential Guide to Home Networking Technologies, The.* 1th ed. Prentice Hall PTR.

[99] Yeh J., Chen J.; Lee C. (2003), WLAN standards, *IEEE Potentials* 22(4), 16 – 22.

[100]InformIT Network (2001), *Bluetooth and Other Wireless Technologies* [Online]. Available at: <http://www.informit.com/articles/printerfriendly.asp?p=24265>.

[101]Bluetooth Alliance Website (2003), *Bluetooth is Booming: Report* [Online]. Available at: < https://www.bluetooth.org/admin/bluetooth2/news/story.php?storyid=7>.

[102]Infrared Data Association Website (2005). Available at: <http://www.irda.org>.

[103]Zigbee Alliance Website (2005). Available at: <http://www.zigbee.org>.

[104]Patrick Kinney (2003), *ZigBee Technology: Wireless Control that Simply Works* [Online], Available at: <http://www.zigbee.org/imwp/idms/popups/pop_download.asp?contentID=5162 >.

[105]Zigbee Alliance Website (2005), *ZigBee Alliance Finalizes Specification* [Online]. Available at: <http://www.zigbee.org/imwp/idms/popups/pop_download.asp?contentID=5534>.

[106]Bluetooth Alliance Website (2005). Available at: <http://www.bluetooth.org>.

[107]Miller B.A., Bisdikian C. (2000) *Bluetooth Revealed*, Prentice Hall PTR.

[108]IEEE Standards Website (2002), *IEEE approves IEEE 802.15.1 standard for wireless personal area networks adapted from the Bluetooth specification* [Online]. Available at: <http://standards.ieee.org/announcements/802151app.html>.

[109]Bates, R.J.(2002), *GPRS: General Packet Radio Service*, The McGraw-Hill Companies.

[110]INACON (1999), Training material - *GPRS – From A-Z V4.5* [Online]. Available at: <http://www.inacon.de/index.php>.

[111]Karam ,J., Peignot, E., Abou A.M.(2002), *GPRS/EDGE* [Online]. Available at: <http://dessr2m.adm-eu.uvsq.fr/gprs-edge.pdf>.

[112]INACON (2001), Training material - *GPRS - Signaling & Protocol Analysis / The Core Network V2.1*[Online]. Available at: <http://www.inacon.de/index.php>.

[113]Chen, Y., Lin, Y. (2005), IP Connectivity for Gateway GPRS Support Node, *IEEE Wireless Communications* 12(1), 37-46.

[114]Mettala R. (1999), Bluetooth Protocol Architecture, *Bluetooth white paper* [Online]. Available at: <http://www.bluetooth.org>.

[115]Bluetooth SIG (2001), Bluetooth Specification 1.1 Volume 2 –Profiles [Online]. Available at: <http://www.bluetooth.org>.

[116]Microsoft website, *Platform builder for windows CE 5.0 - Bluetooth Profiles* [Online]. Available at: <http://msdn.microsoft.com/library/default.asp?url=/library/en-us/wcecomm5/html/wce50conBluetoothProfiles.asp>.

[117]NHS Birmingham Heartland Hospital (2002), *Top 5 Blood Glucose Test Strips in West Midlands NHS regions*.

[118]Abbott Laboratories (2000), *MediSense Optium User's Guide.*

[119]ConnectBlue AB (2003), *OEM Serial Port Adapter™ 2nd Generation Electrical & Mechanical Datasheet* [Online]. Available at: <http://www.connectblue.com/files/spa2_documentation/cb_oem_serial_port_adapter_gen2_e_m_datasheet_1_5.pdf>.

[120]ConnectBlue AB Website (2005), *connectBlue - your complete Bluetooth Provider*[Online]. Available at: <http://www.connectblue.com/> .

[121]Sony Ericsson Mobile Communications AB (2003), White paper-P800/P802.

[122]Orange UK, *Orange Business - Why Orange?* [Online]. Available at: <http://www.orange.co.uk/business/corporate/whyorange/index_nonflash.html>.

[123]Orange UK, Orange Business – Global Network – UK Coverage [Online]. Available at: <http://coverage.orange.co.uk/business/corporate/uk/UKCoverageSearch.htm>.

[124]Wasserman, M. (Ed.) (2002), *RFC 3314: Recommendations for IPv6 in Third Generation Partnership Project (3GPP) Standards* [Online]. Available at: <http://tools.ietf.org/tools/rfcmarkup/rfcmarkup.cgi?rfc=3314>.

[125]Sony Ericsson Communications AB (2003), *Bluetooth C++ Application Development for Sony Ericsson P800 and P900* [Online]. Available at: <http://www.sonyericsson.com>

[126]Sony Ericsson Communications AB (2004), Developers' training material: *Developing Applications for the Sony Ericsson P800/P900.*

[127]Bluetooth SIG Security Expert Group (2002), *Bluetooth Security White Paper* [Online]. Available at: < http://www.bluetooth.com/upload/24Security_Paper.PDF >.

[128]WAP Forum (2000), *Wireless Application Protocol White Paper* [Online]. Available at: <http://www.wapforum.org/what/WAP_white_pages.pdf >.

[129]Sun Developer Network (2004), *Java Technology: Java 2 Platform, J2ME* [Online]. Available at: <http://java.sun.com/j2me/ >.

[130]The World Wireless Web Consortium (2000), *XHTML Basic* [Online], Available at: http://www.w3.org/TR/xhtml-basic .

[131]Sun Java Technology (2005). Available at: <http://java.sun.com>.

[132]Sun Developer Network (2005), Java *Technology, Java 2 Platform, Enterprise Edition* [Online], Available at: <http://java.sun.com/j2ee/index.jsp>.

[133]Microsoft .NET (2005), *What Is .NET?* [Online]. Available at: <http://www.microsoft.com/net/Basics.mspx >.

[134]Vawter C., Roman E. (2001), *J2EE vs. Microsoft.NET: A comparison of building XML-based web services* [Online]. Available at: <http://www.theserverside.com/articles/article.tss?l=J2EE-vs-DOTNET >.

[135]Coward D., Yoshida Y. (2003), *Java Servlet Specification Version 2.4* [Online]. Available at: <http://java.sun.com/products/servlet/index.jsp> .

[136]Apache Jakarta Tomcat (2005). Available at: <http://jakarta.apache.org/tomcat/>.

[137]W3C (2004), *Extensible Markup Language (XML) 1.0 (Third Edition)* [Online]. Available at: < http://www.w3.org/TR/2004/REC-xml-20040204/>.

[138]W3C(2005), *The Extensible Stylesheet Language Family (XSL)* [Online]. Available at: <http://www.w3.org/Style/XSL/>.

[139]Oracle white paper (2002), *Oracle 9i Database Summary* [Online]. Available at: <http://www.oracle.com/technology/products/oracle9i/pdf/Oracle9i_Database_summary.pdf>.

[140]Tieszen K.L., Haque S., New J.(2000), Evaluation of patients' preferences for an alternate site glucose testing system, *Diabetes*.

[141]Knowler W.C., Barrett-Conner E., Fowler S.E., Hammanm R.F., Lachin J.M. E.A., Nathan D.M. - Diabetes Prevention Program Research Group (2002), Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin, *The New England Journal of Medicine*, 346(6), 393-403.

[142]Kaeo, M. (1999), *Designing Network Security*, Cisco Press.

[143]Wells, A. (2004), *Oracle 9i Fundamentals I Exam Cram™ 2 (Exam 1Z0-031)*, Que.

[144]Chou, W. (2002), Inside SSL: the secure sockets layer protocol, *IT Professional* , 47-52.

[145]McAfee Website (2004), Available at: <http://www.mcafee.com>.

[146]Bray, J. (Tech. Ed.), Senese, B., McNutt, G., Munday, B., Kammer, D. (2002), *Bluetooth Devloper's Guide: The Short Range Interconnect Solution*. Syngress Publishing, Inc. MA, USA.

[147]Sanders,G., Thorens, L., Reisky, M., Rulik, O., Deylitz, S. (2003), *GPRS Networks*, John Wiley & Sons, Ltd.

[148]Chakravorty, R., Pratt, I. (2002), Performance Issues with General Packet Radio Service, Journal of Communications and Networks, 4(2).

[149]Chew, K.; Tafazolli, R. (2002), Performance analysis for GPRS with prioritized and non-prioritized mobility management procedures, *3G Mobile Communication Technologies, 2002. Third International Conference on (Conf. Publ. No. 489)*, 544 – 549.

[150]Klein, T.E.; Leung, K.K.; Parkinson, R.; Samuel, L.G. (2004), Avoiding Spurious TCP Timeouts in Wireless Networks by Delay Injection, *IEEE Proceedings – Global Telecommunications Conference 2004*. 2754-2759.

[151]Aikat, J., Kaur, J., Smith F. D., Jeffay K.(2003), Variability in TCP Roundtrip Times, Proceeding of IMC '03, Florida, USA.

[152]Zeitoun, A. Jamjoom, H. El-Gendy, M. (2002), Scalable Parallel-Access for Mirrored Servers, *Proceedings of IASTED International Conference on Applied Informatics*, February 2002.

[153]Postel, J. (ed.) (1981), *RFC793- Transmission Control Protocol.*

[154]Ethereal: A Network Protocol Analyzer, Available at: <http://www.ethereal.com>.

[155]Held, G. (1998), *Dictionary of Communications Technology: Terms, Definitions and Abbreviations, Wiley,* John Wiley & Sons Ltd.

[156]Kotz, D. and Gray (1999), R. S. Mobile Agents and the Future of the Internet , *ACM Operating Systems Review,* 33(3), pp. 7-13.

[157]Milojicic, D. (1999), Trend Wars - Mobile agent applications, *IEEE Concurrency [see also IEEE Parallel & Distributed Technology]*, 7(3), pp. 80-90.

[158]Li, M., Istepanian, R.S.H. (2003), 3G Network Oriented Mobile Agents for Intelligent Diabetes Management: A Conceptual Model, *Proc. of the 4th Annual IEEE Conference on Information Technology Applications in Biomedicine*, pp.31-34.

[159]Rosenberg, J., Schulzrinne, H., Camarillo, G., Johnston, A., Peterson, J., Sparks R., Handley M., Schooler, E., "SIP: Session Initiation Protocol", *The Internet Engineering Task Force,* RFC 3261, June 2002, http://www.ietf.org/rfc/rfc3261.txt.

[160]Arabshian K., Schulzrinne, H. (2003), A SIP -based Medical Event Monitoring System, *5th International Workshop on Enterprise Networking and Computing in Healthcare Industry*, Healthcom, pp.66-70.

Author's Publications and Award

Conference Publications

1. Zou Y., Istepanian R.S.H, Huang W., Performance Evaluation of a GPRS/Bluetooth Enabled Diabetes Management System, *3rd International Conference on Advances in Medical, Signal and Information Processing (MEDSIP)*, Glasgow, UK. 17-19 July, 2006 (accepted).

2. Zou Y., Istepanian R.S.H., Architecture for interoperability of Medical Data Interfaces in M-Health system, *Second Middle East Conference on Healthcare Informatics (MECHCI 2005)*, Dubai, 9-10 April, 2005.

3. Zou Y., Istepanian R.S.H., Bain S. C., Ibidun K., Pervasive Diabetes Management and Internetworking System **(poster)**, *Telemed 04*. London, UK, 29-30 November, 2004.

4. Zou Y., Istepanian R.S.H., Bain S. C., Policy Driven Mobile Agents for Ubiquitous Medical Diagnosis Assistant system, *Proceedings-IDEAS Workshop on Medical Information Systems:The Digital Hospitcal*, IEEE Computer Society, Beiing, China, 1-3 September, pp.3-7, 2004.

5. Zou Y., Wang X., Istepanian R.S.H., Philip N., Bluetooth Connectivity Issues on Mhealth application, Proceedings of International Symposium on Wireless Personal Multimedia Communications - *WPMC'05*, Aalborg, Denmark, 18-22 September, pp.1003-1006, 2005.

Journal Publications

1. Zou Y., Istepanian R. S. H., Wang X., Geake T., Design and Implementation of a Universal Diabetes Management System, *Journal of Mobile Multimedia, 1(6)*, pp.273-284, *2006.*

Award

1. Commendation for the posters representations on research away day, Faculty of Technology, Kingston University, London, 14 Nov 14, 2003.

Appendix A - Source Code for Generating Random Password

```
String generatePassword(int length)
{
    Random random;
    byte[] bstr;
    StringBuffer strBuffer;
    random=new Random();
    bstr=new byte[length];
    strBuffer=new StringBuffer(length);
    for(int i=0;i<length;++i)     strBuffer.append('9');
    random.nextBytes(b);
    for(int i=0;i<bstr.length;++i)
    {
        int b=this.bstr[i];
        if(b<0) b=-b;
        b=0x30+(b&0x3f);
        char c=(char)b;
     strBuffer.setCharAt(i,Character.isLetterOrDigit(c)?c:'z');
        //if the char is not a digit or a letter, then repace it with letter 'z'
  }
    return strBuffer.toString();
}
```

Appendix B - Tablet Medication (Metformin)

Use of metformin in tablet-naïve patients who have sub-optimal glycaemic control despite attempts at diet and exercise.

Aim is to use patient monitoring of:

*Glycaemic control

*Side-effects

To allow rapid upwards titration of metformin

Sub-optimal control is: HbA1c >7%

Home blood glucose analysis (HBGM) >8 mmol/l

HBGM is fasting, pre-prandial (pre-lunch, pre-evening meal) and pre-bedtime (4 fingerstick recordings) performed on three days each week. Results transmitted automatically by monitor and telephone link-up.

Targets are: HbA1c <7% but this is a level which will be assessed in clinic since it requires a venous blood sample, rather than a fingertstick blood glucose.

*HBGM 4-8 mmol/l. Never lower. 8 or less 80% of the time

*No side-effects

Patients should be suitable in terms of not having known contra-indications to metformin

Hepatic impairment Check liver function tests should be normal

Renal impairment Check creatinine should be less than 150 micromol/l

Previous ketoacidosis Patients should be type 2 diabetics

Predisposition to lactic acidosis

Absence of Severe dehydration

Severe infection

Shock, trauma

Heart failure

Respiratory failure

Recent myocardial infarction

Severe peripheral vascular disease

Aalcohol dependency

Use of x-ray contrast media

Pregnancy and breast-feeding

Prescribing clinician should note concurrent medications that may interact with metformin and acknowledge these:

ACE Inhibitors hypoglycaemic effect possibly enhanced

Aminoglutethimide hypoglycaemic effect possibly reduced

Anabolic Steroids hypoglycaemic effect possibly enhanced

Cimetidine increased plasma-metformin concentration

Corticosteroids hypoglycaemic effect possibly reduced

Diazoxide	hypoglycaemic effect reduced
Diuretics, Loop	antagonism of hypoglycaemic effect
Diuretics, Thiazide	antagonism of hypoglycaemic effect
Ketotifen	depressed thrombocyte count with concomitant use
Lithium	hypoglycaemic effect possibly reduced
MAOIs	enhanced hypoglycaemic effect
Octreotide	hypoglycaemic effect possibly enhanced
Oestrogens	antagonism of hypoglycaemic effect (not HRT)
Progestogens	antagonism of hypoglycaemic effect (not HRT)
Testosterone	hypoglycaemic effect possibly enhanced

Dose: initially 500 mg with breakfast for at least 1 week then 500 mg with breakfast and evening meal for at least 1 week then 500 mg with breakfast, lunch and evening meal

The weekly increase in medication by 500mg to maximum of 3000 g in three divided doses.

Dose to be increased depends on which glucose levels are highest:

If all >8 mmol/l then continue breakfast, evening meal, lunchtime sequence.

If bedtime and/or pre- breakfast high & others OK then increase evening dose

If pre-lunch high & others OK, increase breakfast dose

If pre-evening high & others OK, increase lunchtime dose

Side-effects are as follows: anorexia, nausea, vomiting, constipation, diarrhoea, abdominal pain, metallic taste

If side-effects develop then patient should go back to previous dose of metformin and remain on this for 2 weeks, then try increase again. If side-effects recur then stop increases at this point.

Hypoglycaemia should not occur when patients are on metformin monotherapy.

Using this protocol, all patients will be in one of three categories within three months (when clinic review occurs)

Optimal diabetic control

Maximal metformin dose without optimal control

Maximal tolerated dose of metformin

--If all >8 mmol/l then continue breakfast, evening meal, lunchtime sequence.

--If bedtime and/or pre- breakfast high & others OK then increase evening dose.

--If pre-lunch high & others OK, increase breakfast dose.

--If pre-evening high & others OK, increase lunchtime dose.

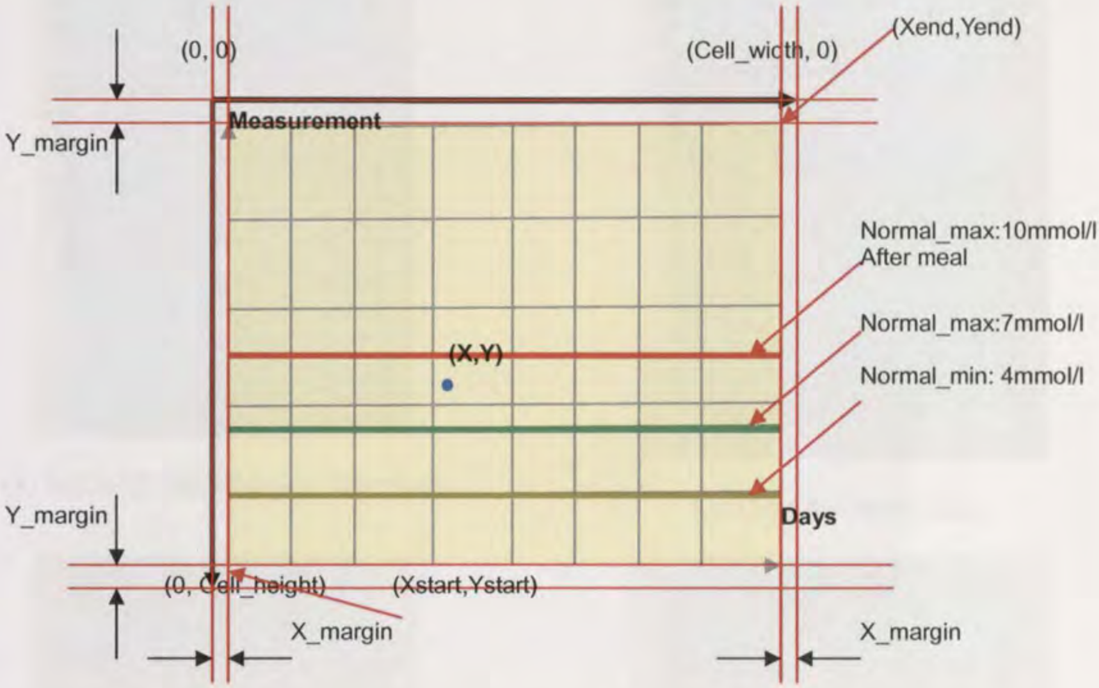
Source: British National Formulary, Available at: <http://www.bnf.org>

Appendix C - HBGM Analysis Source Code (partial)

```
int recsize = showvals.size(); //Measurement records length
if(showvals.size()>2)
{
        boolean[] needadjust = new boolean[showtime.length];
        for(int k = 0 ;k < showtime.length; k++)
        {
            suggestinfo[k] = "Please follow the physician's recommandation!";
            //information to be given to the patient
            needadjust[k] = false; //indication that if the dose should be changed
            float[] showval = new float[7]; //measurements record
            float currentval; //current measurement
            boolean mostrecent = true;
            float recentval = -1 ;
            boolean needcheck = false; //indication that if the dose should be changed
            int i ;
            int overtimes = 0; //how many measurements are high during the last 7 days.
            //IF THE LATEST ONE IS NORMAL, THEN WE NEED CHECK AGAIN.
            for(i = recsize-1; i >= 0; i--)
            {
                showval = (float[])showvals.elementAt(i);
                currentval = showval[k];
    //if the most recent day the value is ok, then need adjust is false,you can pass by this check;
                if(currentval >= 4.0 && currentval <= 8.0)
                {
                    if(!needcheck)  break;
                }
                else if(currentval> 8.0)
                {
                    if(!needcheck)
                        needcheck = true;
                    overtimes = overtimes + 1;
                }
                else
                {
                    //ignore
                }
            }
            if(!needcheck)
            {
                overtimes = 0;
                for(i = recsize-1; i >= 0; i--)
                {
                    showval = (float[])showvals.elementAt(i);
                    currentval = showval[k];
                    if(currentval> 8.0) overtimes = overtimes + 1;
                }

                if(overtimes> 0)
                    suggestinfo[k] = "Your recent record is ok, but there are several
measurements on " + showtime[k] + " too high!";
                else
                    suggestinfo[k] = "The " + showtime[k] + " measurement records are fine!";

            }
            else if(needcheck && overtimes > 3)
                //need adjust the treatment;
                needadjust[k] = true;
            else
                //need check but overtimes < 3
                suggestinfo[k] = "Please notice your dietary and check your "+ showtime[k] +
```

```
"blood glucose every day";
                }
          }
          else
          {
                errinfo = "There are too few measurements to carry on HBGM Analysis, At least two days'
measurements are required";
                logInfo(errinfo);
                return false;
          }

          //Dose to be increased depends on which glucose levels are highest:
          //If all >8 mmol/l then continue breakfast, evening meal, lunchtime sequence.
          //If bedtime and/or pre- breakfast high & others OK then increase evening dose
          // If pre-lunch high & others OK, increase breakfast dose
          // If pre-evening high & others OK, increase lunchtime dose
          return true;
   }
```

Appendix D - Schematic diagram and equations for drawing the coordinates of measurements



X axis expresses the measurement value (from 0 mmol/l to 20 mmol/l);
Y axis represents the measurement time.

Equations:

Xstart = X_margin; Ystart = Cell_height – Y_margin;

Xend = Cell_width – X_margin; Yend = Y_margin;

Xcoeff = (Xend – Xstart) / (Start_hour – End_hour); Ycoeff = (Ystart – Yend) / 20;

X = (Curhour – Start_hour) * Xcoeff; Y = Ystart – Curval * Ycoeff.

Definitions:

Cell_width: Total width of the picture; Cell_height: Total height of the picture;

X_margin: Horizontal margin between the graph with the edge of the cell;

Y_margin: Vertical margin between the graph with the edge of the cell;

Start_hour: The start date in hours;

End_hour: the end date in hours;

Xcoeff: the coefficient of axis X, it represents how much the hours passed per unit of X;

Ycoeff: the coefficient of axis Y, it represents the value of the blood glucose level per unit of Y.

Xstart: the origin of X in pixels. Ystart: the origin of Y in pixels;

Xend: the maximum of X in pixels. Yend: the maximum of Y in pixels;

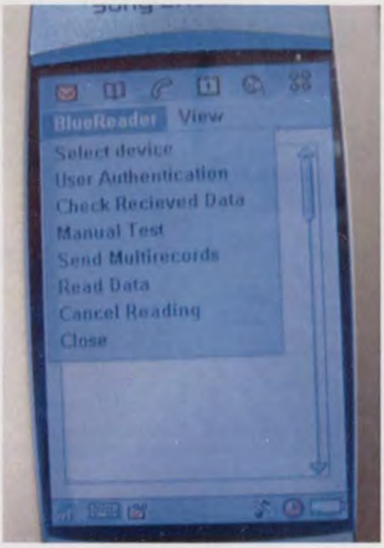
Origin: (Xstart, Ystart).

X, Y : current location of the measurement record.

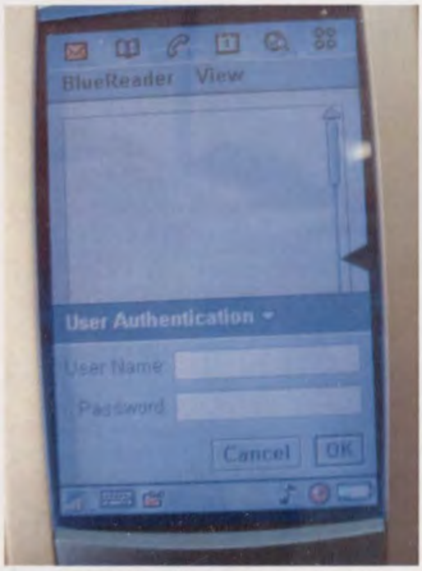
Curhour: the time when the measurement was taken in hours;

Curval; the measurement value.

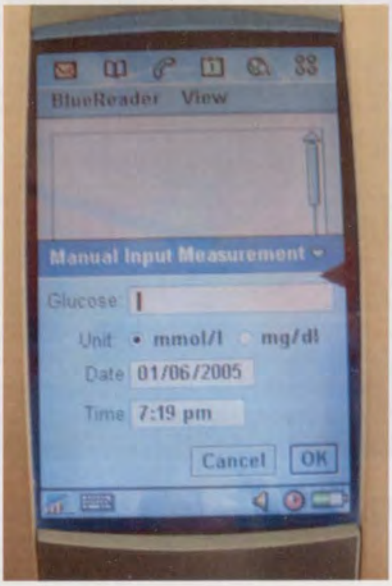
Appendix E - Snapshots of MDMIS Functionalities



(1) MDMIS BlueReader functions



(2) User Authentication



(3) Manual Measurement Data Input

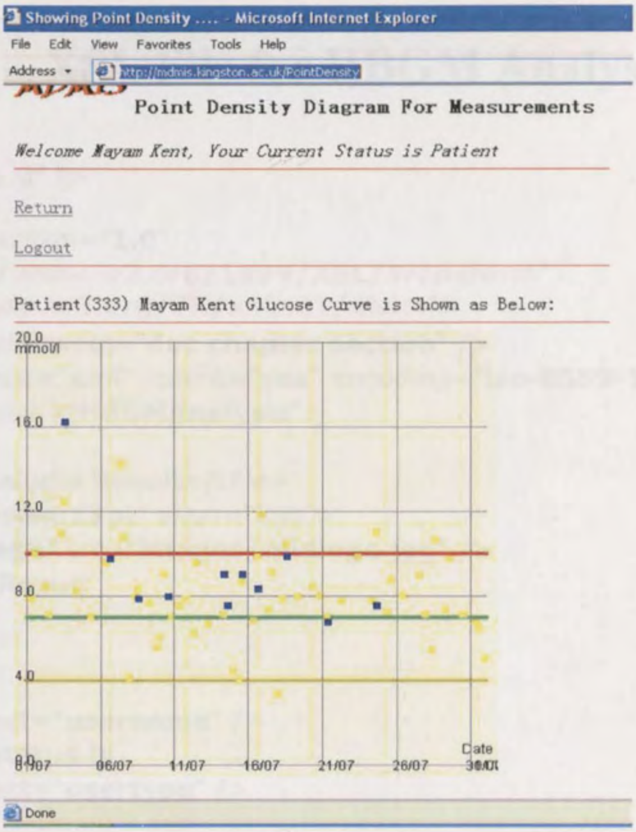
(4) Time Segment Definition

(5) HBGM analysis

(6) Data management

(7) Function list on Nokia 3100

(8) Report Side Effects on Nokia 3100



(9) Point Density of Glucose Measurements

Appendix F – XSL File for HBGM Analysis Result

```
<?xml version="1.0" ?>

- <xsl:stylesheet version="1.0"
xmlns:xsl="http://www.w3.org/1999/XSL/Transform"
xmlns="http://www.w3.org/TR/xhtml1/strict">
  <xsl:strip-space elements="doc chapter section" />
  <xsl:output method="xml" indent="yes" encoding="iso-8859-1" />
- <xsl:template match="HBGMAnalysis">
- <html>
  <title>HBGM Analysis Result</title>
- <h3 style="font-size:11pt" align="left">
  <img name="image" src="images/midlogo.jpg" />
  HBGM Analysis Result
  </h3>
- <em>
  Welcome
  <xsl:value-of select="username" />
  , Your Current Status is
  <xsl:value-of select="usertype" />
  </em>
  <hr size="1" align="left" width="50%" style="border:#FF6633;
background-color:#FF6633" />
- <body link="#000000" vlink="#666666" alink="#ff8c00">
- <br>
  <a href="./ProjectServlet">Return</a>
  </br>
- <br>
  <a href="./Welcome">Logout</a>
  </br>
  <hr size="1" align="left" width="30%" style="border:#FF6633;
background-color:#FF6633" />
  The measurements for
  <xsl:value-of select="patientid" />
  (from
  <xsl:value-of select="startdate" />
  to
  <xsl:value-of select="enddate" />
  ):
  <br />
- <table border="2" bordercolor="orange">
- <tr bgcolor="#f5deb3" align="center">
- <xsl:for-each select="measurelabels">
- <td size="50">
  <xsl:value-of select="measurelabel" />
  </td>
  </xsl:for-each>
  </tr>
- <xsl:for-each select="measurelist/measures">
```

```
- <tr align="center">
- <xsl:for-each select="ameasure">
- <td>
  <xsl:if test="measureval=''">-</xsl:if>
  <xsl:value-of select="measureval" />
  </td>
  </xsl:for-each>
  </tr>
  </xsl:for-each>
  </table>
- <strong>
  <xsl:value-of select="msginfo" />
  </strong>
  <hr size="1" align="left" width="50%" style="border:#FF6633;
background-color:#FF6633" />
  Treatment records are as following:
  <br />
- <table border="2" bordercolor="orange">
- <tr bgcolor="#f5deb3" align="center">
- <xsl:for-each select="fieldlabels">
- <td size="50">
  <xsl:value-of select="fieldlabel" />
  </td>
  </xsl:for-each>
  </tr>
- <xsl:for-each select="recordslist/records">
- <tr align="center">
- <xsl:for-each select="record">
- <td>
  <xsl:if test="recordval=''">-</xsl:if>
  <xsl:value-of select="recordval" />
  </td>
  </xsl:for-each>
  </tr>
  </xsl:for-each>
  </table>
  </body>
  </html>
  </xsl:template>
  </xsl:stylesheet>
```

Appendix G – XML Files on Communication Protocols Operations

```
<msgptl>
    <cmd>
        request
    </cmd>
    <userinfo>
        <username>
            Joanne
        </username>
        <password>
            Kingston
        </password>
        <fetype>
            SonyEricsson P800
        </fetype>
    </userinfo>
    <sensorinfo>
        <manufacturer>
            Abbott Laboratories
        </manufacturer>
        <model>
            MediSense Optium
        </model>
        ...
    </sensorinfo>
</msgptl>
```

(1) XML file for requesting a protocol

```
<msgptl>
    <cmd>
        Submit
    </cmd>
    <userinfo>
        <username>
            Paul
        </username>
        <password>
            Kingston
        </password>
    </userinfo>
    <sensorinfo>
        <manufacturer>
            Abbott Laboratories
        </manufacturer>
        <model>
            MediSense Optium
        </model>
    </sensorinfo>
    <protocol>
        <datainterface>
            Bluetooth SPP
        </datainterface>
        <configuration>
            ...
        </configuration>
        <parameters>
            ....
        </parameters>
    </protocol>
</msgptl>
```

(2) XML file for adding a new protocol from a MSU

```
<msgptl>
    <cmd>
        protocol
    </cmd>
    <sensorinfo>
        <manufacturer>
            Abbott Laboratories
        </manufacturer>
        <model>
            MediSense Optium
        </model>
    </sensorinfo>
    <protocol>
        <datainterface>
            Bluetooth SPP
        </datainterface>
        <configuration>
            ...
        </configuration>
        <parameters>
            ...
        </parameters>
    </protocol>
</msgptl>
```


(3) XML file for returning a protocol to a MFE from MMS

Appendix H - Questionnaire for Clinical Study of Mobile Diabetes Management System

Questionnaire – patient (Pre-trial)

Date: ____________

1. **What is your ID number for the clinical trial:**

2. **How long have you been diagnosed with diabetes?**

   ☐ Within the last 3 months

   ☐ More than 3 months but less than 1 year

   ☐ More than 1 year but less than 5 years

   ☐ More than 5 years but less than 10 years

   ☐ More than 10 years

3. **What type of diabetes do you have?**

   ☐ Type 1 ☐ Type 2 ☐ Others (Please specify)

4. **Are you:**

   ☐ Female ☐ Male

5. **How old are you?**

   ☐ Under 18 ☐ 19 – 39 ☐ 40-65 ☐ 66 or over

6. **Do you smoke?**

   ☐ Yes ☐ No

7. **Do you drink alcohol?**

   ☐ Yes ☐ No

8. **What is your Ethic group?**

   ☐ White ☐ Asian or Asian British

- ☐ Black or Black British ☐ Chinese or Chinese British
- ☐ Other (Please specify)

9. Do you take any medication for the diabetes?

- ☐ Tablet ☐ Insulin Injection
- ☐ Diet and Exercise ☐ Other (Please specify):

10. How often do you exercise?

- ☐ Never ☐ Every day
- ☐ Every week ☐ Occasionally

11. How much attention do you pay to your food intake?

- ☐ Very much ☐ Not much
- ☐ Fair ☐ Not at all

12. How often do you take your blood sugar measurement?

- ☐ At least twice or more daily ☐ Once daily
- ☐ Not every day, but at least once a week ☐ Occasionally

13. How often do you use a computer?

- ☐ Every week ☐ Every day
- ☐ Seldom ☐ Never

14. Generally, who takes your blood glucose measurement?

- ☐ You ☐ A relative or friend ☐ A nurse

15. What type of glucose meter do you use at the moment?

- ☐ Medisense ☐ ACCU-CHEK
- ☐ Lifescan ☐ Other (Please specify)

16. How easy do you find using this glucose meter?

- ☐ Very easy ☐ Somewhat easy
- ☐ Somewhat difficult ☐ Very difficult

17. What aspects of the current glucose meter need to be improved in your opinion?

☐ Weight, size and colour ☐ Painful during blood collection

☐ Too difficult to operate ☐ Too slow to show the data

18. How often do you review your blood glucose measurement records?

☐ Every week ☐ Every day

☐ Seldom ☐ Never

19. How often do you see a doctor or nurse?

☐ Daily ☐ Weekly ☐ Every month

☐ Every 3 months ☐ Every 6 months or longer

20. How much interested are you in taking part in this study?

☐ Very interested ☐ Interested ☐ Fair

☐ Somewhat ☐ Not at all

21. Why did you decide to take part in this study?

☐ Curiosity ☐ Get more medical advice

☐ Recommended by others ☐ Other (Please specify)

Questionnaire – patient (After-trial)

Date:_____________

1. **What is your ID number for the clinical trial:**

2. **Do you take any medication for the diabetes?**
   - ☐ Tablet ☐ Insulin Injection
   - ☐ Diet and Exercise ☐ Other (Please specify):

3. **How often do you exercise?**
   - ☐ Never ☐ Every day
   - ☐ Every week ☐ Occasionally

4. **How much attention do you pay to your food intake?**
   - ☐ Very much ☐ Not much
   - ☐ Fair ☐ Not at all

5. **Generally, who takes your blood glucose measurement?**
   - ☐ You ☐ A relative or friend ☐ A nurse

6. **What aspects do you think the mobile phone needs to improve?**
   - ☐ Size, colour and weight ☐ Battery life
   - ☐ Functionality

7. **How easy did you find using this glucose meter?**
   - ☐ Very easy ☐ Somewhat easy
   - ☐ Somewhat difficult ☐ Very difficult

8. **How often do you take your blood sugar measurement?**
   - ☐ At least twice or more daily ☐ Once daily
   - ☐ Not every day, but at least once a week ☐ Occasionally

9. **How often do you access the electronic diabetes management system?**

- [ ] Every week
- [ ] Every day
- [ ] Seldom
- [ ] Never

10. How do you find accessing the electronic management system on the mobile phone?

- [ ] Very easy to operate
- [ ] Easy to operate
- [ ] Fair
- [ ] Difficult to operate
- [ ] Very difficult to operate and very slow

11. How do you think of this study to your diabetes management?

- [ ] Very useful
- [ ] Useful
- [ ] Fair
- [ ] Useless
- [ ] Don't know

12. Did you experience system failures during this clinical trial?

- [ ] Frequently
- [ ] Seldom
- [ ] Never

13. Which the following results have this trial caused? (Multi-choices)

- [ ] Better diabetes control
- [ ] Improved self-confidence
- [ ] Improved discipline in glucose measurement
- [ ] Little change on my diabetes control
- [ ] No change
- [ ] Things get worse

14. Comments on this study?

Questionnaire – Medics (Pre-Trial)

Date:_____________

1. **What is your ID for Clinical Trial:**

2. **How long have you been involved with diabetes care?**
   - ☐ Less than 6 months
   - ☐ More than 6 months but less than 2 year
   - ☐ More than 1 year but less than 5 years
   - ☐ More than 5 year but less than 10 years
   - ☐ More than 10 years

3. **What type of diabetes patients do you look after?**

   ☐ Type 1 ☐ Type 2 ☐ Both

4. **What kind of glucose meter are you using for the patients?**

   ☐ Medisense ☐ ACCU-CHEK

   ☐ Lifescan ☐ Other (Please specify)

5. **How easy do you think it is to use?**

   ☐ Very easy ☐ Easy ☐ Fairly

   ☐ Difficult ☐ Very difficult

6. **How often do you use a computer?**

   ☐ Every week ☐ Every day

   ☐ Seldom ☐ Never

7. **Are you interested in being involved in doing this clinical trial?**

   ☐ Very much ☐ Interested

☐ Does not matter ☐ Not at all

8. **In your opinion, how could current diabetes care be improved?**

9. **What advantages do you expect the telehealth system to bring in terms of diabetes management?**

Questionnaire – Medic (After-trial)

Date:______________

1. **What is your ID for the clinical trial:**

2. **How did you think of this study?**

   ☐ Very useful ☐ Useful ☐ Fair

   ☐ Useless ☐ Don't know

3. **How often did you access the electronic diabetes management system?**

   ☐ Every week ☐ Every day

   ☐ Seldom ☐ Never

4. **Did you experience system failures during this clinical trial?**

   ☐ Frequently ☐ Seldom ☐ Never

5. **What do you think needs improvement?**

   ☐ Functionality ☐ Model of mobile phone

   ☐ Model of glucose meter ☐ Speed of accessing the system

6. **Comment**