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DESIGN AND IMPLEMENTATION OF A MOBILE DIABETES MANAGEMENT SYSTEM

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This paper describes a universal Mobile Diabetes Management and Internetworking System - MDMIS. The MDMIS system aims to improve diabetes control by providing a portable, secure and ubiquitous diabetes management service for both diabetics and medical providers.

MDMIS is composed of a medical control centre, patient stations, physician stations, medical administration stations, and system maintenance stations. A patient station collects blood glucose measurements autonomously from a Bluetooth empowered glucose meter and transmits the data to the medical centre via internetworking communications. The medical centre of the system provides powerful services to both patients and physicians, such as updating user information and medication plans, side-effects reporting, blood glucose analysis and alarming, and medicines management. These services can be accessible by patients and physicians through a simple interface from variable devices powered by different operating systems. The security issues of MDMIS are also addressed briefly.

Key words: Disease management, Bluetooth, m-Health, Security, Software Portability
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1 Introduction

Diabetes is a chronic, progressive disease that affects 1.8 million people in UK [1], and more than 194 million worldwide [2]. The cost is high. According to the World Health Organization (WHO), it is estimated that about 2.5-5% of annual health budgets are spent on diabetes-related illnesses 2. Diabetes cannot yet be cured, but it often can be managed through proper medical care, diet, and regular exercise. Research studies have shown that many complications of diabetes can be prevented or delayed through effective management [3].

With the advantages of emerging mobile wireless technologies, a m-health [4] system can give diabetics and medical personnel a closer link without consideration of their locations. Recently several systems have been developed to manage diabetes via mobile technologies. For example, Ferrer-Roca used short message service (SMS) to transmit the blood glucose levels and body weight to the server [5]. In the DAILY project [6], a wireless, portable system was designed to send the measured data to the server. In addition, a computer game was implemented in the DAILY system to motivate the youngsters to adhere to the management. Another similar system which can transmit and process the data via a mobile phone is e-San [7]. DiabetesMobil [8] improved the analysis and visualization of the acquired data, by graphical illustrations and statistical evaluations. However, most of these studies

without clear classification of different level of users, without flexible medication protocol management; or without completely wireless data access.

In this paper, a system for general diabetes management, namely Mobile Diabetes Management and Internetworking System (MDMIS) is presented. The MDMIS system provides a mobile environment to access the diabetes management service for diabetics and healthcare personnel. It offers a wireless solution via Bluetooth and GPRS. The advantages of the system can be summarized as follows:

1) Autonomous data acquisition and transmission of blood glucose data: The measurements are called from the sensor and sent to the medical centre without the intervention of the patient.

2) Mobile and interactive access. MDMIS allows all the end users access the system via wireless or wired connection anytime and anywhere.

3) Flexible interface and operational modalities.

4) Intelligent update of medical treatment plan and online update of medication protocols: A medical practitioner or supervisor can manually change patients' therapeutic plans. In addition, the MDMIS is capable of detecting a patient's current blood sugar status, automatically changing the medical treatment plan according to medication rules defined in a health information database, recording the change and informing the patient via email or SMS. The MDMIS also provides real-time update of the medical treatment protocol for those users who have the priority.

5) Secure access: MDMIS has applied several measures to provide a secure connection between system users and the medical control centre.

The remainder of this paper describes how the MDMIS system provides these features.

2 System Design and Implementation

The MDMIS system aims to give users a mobile environment and a broad access to diabetes management. The users are divided into four categories: diabetic, physician, medical administrator and system maintainer. Accordingly, the system design and implementation of MDMIS arises from the duties of these users.

An internet based software architecture has been applied to ensure users' location independency. The MDMIS system is composed of a medical control centre and clients. A medical control centre consists of a master station and a health information database. It is located at a hospital site with broadband access to the Internet. If there are a large number of users, there can be several medical sub-centres connected to one main control centre.

The master station processes all requests from MDMIS clients and stores health related information in the health information database. A master station is a web server. Apache Tomcat [9], Java Servlet [10] and XML [11] technologies have been applied to implement the functions on master stations to support access from a WAP phone, smart phone, PDA or a PC.

The MDMIS clients can be anywhere in the world, mobile or stationary, from which the end users can access the MDMIS system. They are divided by their owners' role into patient stations, physician stations, medical administration stations and system maintenance stations. Thousands of users or more may exist in this system. The client stations access the services which are provided by a master station.

The system architecture for MDMIS is shown in Figure 1.

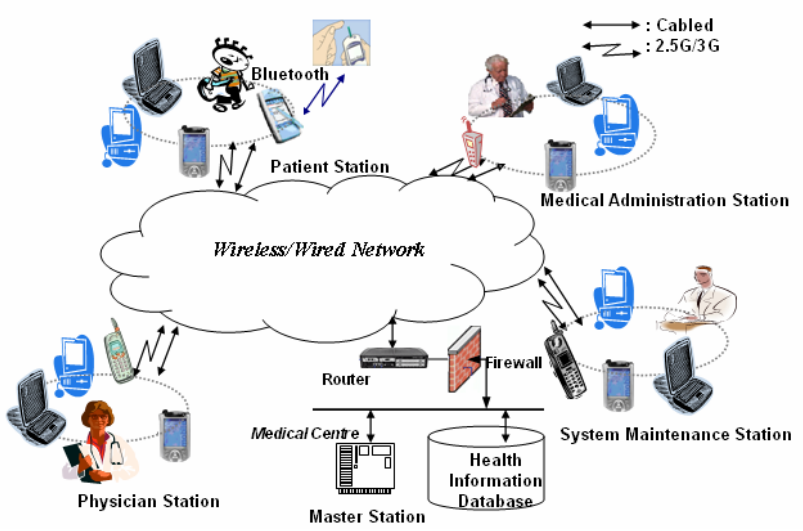

Figure 1. System architecture of the MDMIS

2.1 Master Station

The software on the master station consists of a broker, a registrar, a data accessing module, and an intelligent data processing module.

The broker is responsible for:

-Accepting the requests from different types of client stations;

-Verifying the requested service types;

-Passing the information to the registrar and intelligent data processing module;

-Wrapping the messages for responses from different type of browsers and sending the messages back to the requesting 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, processes data request, searches database 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. An intelligent data processing module handles further service request process from the remote clients, and saves the information to the health information database. Furthermore, it provides MDMIS clients analysis tools to assist users analysing patients' health situation and making decisions.

Figure 2 shows the data flow in the medical control centre. The digit within the brackets on the diagram shows the 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, the broker will identify the type of client station, and send relative user information for authentication to the registrar residing on the master station. The registrar queries the health information database via the DAM to get the user validation and identification information. If the registrar finds that the account does not exist in the health information

database or the account is not qualified for this operation, further operations will be refused. Otherwise the registrar will alert the intelligent data processing module for further operations and notify the broker. The broker sends other operational information to the intelligent data processing module to request a data analysis result. The intelligent data processing module will query data through DAM, analyze data and produce results, and send them back to the broker. The broker wraps this information to suit the client's type and returns the message to the client.

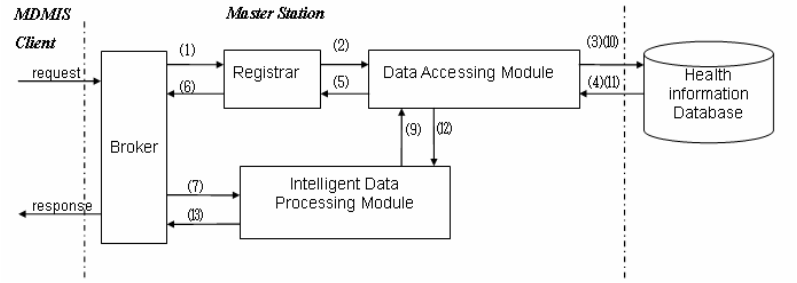

Figure 2. Data flow of a client request

2.2 System Functions

The master station provides many functions for access from the clients, including:

1) User management

Users may manage their own information, including date of birth, contact information, residence, etc., and change their passwords. MDMIS can tell a user's role from the user's ID (Identification) that he/she provided from the first login. Except for a patient, other management operations involve creating or deleting a user, or updating an existing user's information and password. Physicians can manage a patient's account information; medical administrators can manage physicians' accounts, while the system maintainer can manage medical administrators' user information. All these operations will be recorded for later query.

2) Time segment definition

MDMIS can save the measurement record automatically in the health information database according to the patient's time segment definition. MDMIS provides a default time segment definition. However, every patient may set a time segment definition to define which time period is best for the blood glucose to be measured according to his or her living style. Every time before the measurements are received from a patient station, the intelligent data processing module will compare the patient's time segment to save the reading to the corresponding record. This function can only be reached by a physician or a patient role.

3) Medication management

Users of MDMIS other than system maintainers may check patients' historical mediation records. Patients can only view their own records. Physicians and medical administrators can review and change patients' medications if they feel there is a need. This operation will be saved to the database, and a notification will be sent to the patient concerned via an email or a short message.

4) Side-effects report

A patient can report side-effects caused by a change of medication. Side-effects include anorexia, nausea, vomiting, constipation, diarrhoea, abdominal pain and metallic taste. The physicians and medical administrator can record a side-effect in the health information database for a patient. After a side-effect report the medication can revert to the previous prescription. An email or a short message about the change will be sent to the patient. If the side effects are caused by a first prescription, the patient will be notified to stop taking the medication. An email or a short message will be sent to the responsible physician to request a new prescription for the patient.

5) HBGM Analysis

Home blood glucose measurement (HBGM) is an important and proven step towards good glycaemic control [12]. HBGM consists of fasting, pre-prandial (pre-lunch, pre-evening meal) and pre-bedtime (4 finger-stick recordings) performed on three days each week.

For this application, metformin is used as the therapy method as metformin may reduce the incidence of diabetes in persons at high risk [13].

6) Medicine management

A medical administrator can manage the available medicine information for diabetes treatment. This can include insertion, deletion or updating the information, such as name, method (oral or injection), units etc.

7) Check measurement records

The MDMIS system provides a variety of means for users to check their own or other patients' measurement records according to their roles. These records can be shown as tables, trend curve graphs, point density graphs or pie charts. In addition statistics (including amount of normal data, out of range, reading times at different time periods) are shown.

8) Medication protocol management

Medical administrators can define, update or delete information on medication protocols. These include the medicine name, taken steps, dose, taken time etc.

9) Operation tracking

MDMIS users can check their historic operation records by operation type and operation date. However, none of them can change the existing operation records.

2.3 MDMIS Information Database

The MDMIS information database of the system is located at the medical control centre. It stores health related information, including all users' operation records and account information, medication rules, medications, measurement records, etc. This database should be reliable and be able to deal with concurrent users' requests.

Oracle 9i release 2 has been chosen for the development of the MDMIS database system. This provides a powerful database for secure, reliable, high capacity Internet applications. The health information database has been designed and installed on a windows XP server. It has been configured as a standard edition with optimised transaction processing. Due to the significance of health information, a database backup mechanism has been introduced to help system restoration. An incremental backup will be implemented every midnight. A full backup will happen every weekend

because the load on the master station is then at its lightest. Therefore the MDMIS system has a secure database which can be recovered with the lowest data loss even after system disasters.

2.4 Patient Station

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

Autonomous data collection and transmission to the medical control centre has been implemented in MDMIS. Data acquisition can be implemented via a cabled connection between PC and a glucometer or wirelessly between a smart glucometer and a mobile phone. In this case, Bluetooth technology is adopted to send the patient's glucose value wirelessly to a patient station, besides a cable connection solution.

A diagram showing data acquisition and transmission via Bluetooth is shown in Figure 3.

For a case study, MediSense Optium was chosen as the glucometer, and ConnectBlue cB-SPA32i as the Bluetooth adapter. At this stage, these two devices combine together to make a Bluetooth glucometer, as shown in Figure 4. The Sony Ericsson P800 was chosen as the patient station. Bluetooth data acquisition software was developed and installed on the P800.

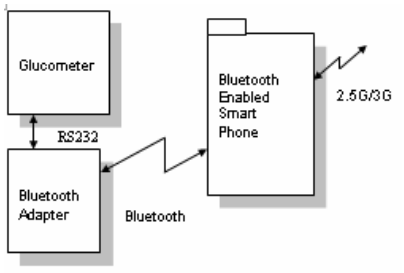

Figure 3 Bluetooth/Wireless connectivity of the MDMIS system

Figure 4 Bluetooth glucose meter

The first time a patient sends his measurement records to the medical centre, he needs to identify the sensor that will be the data source. The software can give a list of available Bluetooth devices.

Once a sensor is specified, its Bluetooth address will be saved at the local patient station as the identification for a default address. Next time if the sensor is the same device, this step can be ignored. The data communication protocol for the glucose meter is a serial handshaking protocol and the data exchange is in ASCII format and it is the patient station initiates the query procedure. The actual reading begins only after the patient station receives acknowledgement and the meter gets acknowledgement. The data length of a measurement record is from 26 bytes to 31 bytes, depending on the size of measurement. MDMIS will check the patient station's identification before a patient can submit data to the medical control centre. A dialog prompts the user for his or her ID and password for verification. This account information is sent to the medical control centre for validation. If it is not valid, the patient station will not be able to send measurements to the medical centre. Otherwise, the account information will be stored to avoid the repetition of the operation. Now the patient station is ready to collect and send the data from the sensor to the medical control centre. Figure 5 shows data received from a glucometer.

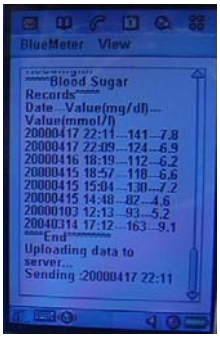

Figure 5 Sample of received data from glucose sensor

Before sending data to the medical control centre, the data acquisition software will perform an initial data processing to obtain the real measurement record, and arrange the measurement in a fixed data format with only measurement time and measured glucose value. This initial data processing reduces the data quantity for transmission and eases the burden of data processing at the centre side. At the medical control centre, the software on the master station (see figure 2) will first verify the integrity of the received data, classify the time period of this measurement, save the record to the health information database, and analyze if it is out of normal rage. If it is, according to the medication rules defined in the health information system, it will query the last several days' records to make a revision on the patient's treatment when there is a need. An email and short message will be sent back with the suggestion for patient's instant view. Meanwhile, the suggestion information will also be sent out to the responsible physician.

Besides data acquisition and transmission, the patient station also allows patients to manage their personal information, review statistical results and check historic treatment records.

2.5 Physician Station

Physicians can choose available computing devices to remotely manage patients' account information, inquire and analyse the patients' history and current situation, manage patients' medical

treatment scheme, and give suggestions to the patients. A physician station can be a mobile, such as handset, PDA, laptop, or stationary terminal, desktop PC.

2.6 Medical Administration Station

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

2.7 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.

3. Portability and Security Issues

3.1 Portability

The MDMIS system provides universal access. The portability of MDMIS has been ensured by applying the following technologies:

1) XML technology XML (eXtensible Markup Language) has been chosen to make the system content portable. XML is an industry-standard, system-independent way of representing data. XML schemes provide means to define data structure, information content and semantics. Combined with XSL language (eXtensible Stylesheet Language), the data content can be translated into corresponding HTML, XHTML and WML languages according to the type of access device.

2) Java technology Java programs are interpreted by a Java Virtual Machine (Java VM) during running. This means that any computer system with the Java VM installed can run a Java program regardless of the computer system on which the application was originally developed [10]. Java Servlet technology has been applied on the medical control centre.

3.2 Security of Medical Data Transfer

As healthcare information is usually private and critical, any health information system must have consideration of security issues to keep data confidentiality and data integrity. Data confidentiality refers to the process of ensuring that only the entities which are allowed to access the data can access it in a usable format.

Data integrity is for validity of data [14]. It can be broken in a number of ways: such as introduced errors when the data is entered to the system or transferred from one computing device to another, software bugs, viruses, hardware failures, or same messages are distributed at different time.

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

1) Authentication, authorization 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 users; Access control is that only those with valid and authorization

users or systems are allowed to access the specific functions or resources of the system. Authentication, authorization and access control are the considerations of data confidentiality or privacy.

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

Every time a user accesses the service from MDMIS, the system will verify the user's identification to check his account's validity. If it is a valid user, the system will also check the user's rights on each operation. Meanwhile, only the functions with a MDMIS user's privilege range are listed. MDMIS user management provides the functionalities to grant 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 level of access rights for specific kinds 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 1 User Roles

In Table 1, there are four roles created corresponding to the different users. They have strictly limited access to specific database tables or views according to their particular role.

2) Prevention of invalid input

The validity of some inputs will be checked in MDMIS before further data analysis. If a wrong data input is attempted, the warning message will be prompted to the users along with the correct format or interpretation of the data.

3) Security of data transmission.

MDMIS adopted SSL for secure data transmission. SSL is an abbreviation for Secure Sockets Layer and is now the "de facto standard for providing secure ecommerce transactions over the Web." [15] The SSL protocol 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, data is protected from eves-dropping.

4) Database Backup

The database backup scheme was designed 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 backed into backup set.

- Incremental backup. This is a method that only modified data blocks are backed.

Both an incremental backup and full backup scheme have been implemented to MDMIS database to minimise the risk of data damage in case of hardware or software failure. Two scheduled tasks for the MDMIS database are defined: the incremental backup will be performed every midnight and the full backup will be performed every Saturday shortly after the incremental backup. Midnight was chosen because at that time there are few data queries to MDMIS database, and therefore the lightest data load.

5) 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 change medical information.

Furthermore, whenever there is a critical change on patient's information, such as a modification of medication, the information will be sent to the patient through an email or a short message. Hence patients are aware of the change.

6) Firewall

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

4. Results

MDMIS (mobile diabetes management system) was first tested in the laboratory on a simulation software Openwave SDK 6.2.2 [16]. The performance of the system was also tested successfully on various types of mobile equipment, such as Sony Ericsson P800 (a smart phone), Nokia 3100, IPAQ h5450 (PDA), Microsoft Internet Explorer 6.0, Netscape Navigator 7.1, Mozilla Firefox 1.0. The access speed is acceptable with the responses arriving within 6 seconds by GPRS.

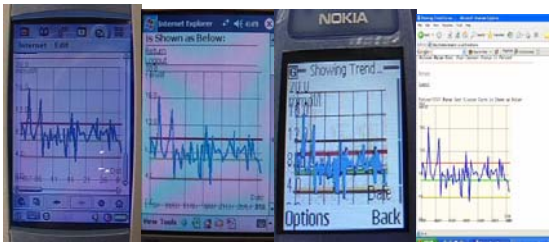

Figure 6 Curve graph for measurement records

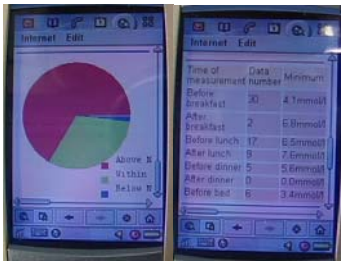

Figure 7 Statistics of Measurements

Figure 6 displays the blood glucose measurements graphically for an easy overview for the measurements of patient (User ID 333) between 01/07/2003 and 01/08/2003 from variable devices, Sony Ericsson P800, a PDA -IPAQ H5450, Nokia 3100 and a PC (from left to right respectively). The results were statistically analysed. The numerical display and pie chart display are shown in Figure 7. From the results, the patient and physician will have an indication of the patient's condition. Ongoing work is being undertaken to test the system in hospitals with a larger patient population.

5. Conclusion

In this paper, a mobile diabetes management system is presented. Wireless connectivity and relevant database development of the system are also described. The relevant experimental and test results of the system have shown the successful implementation of a GPRS wireless diabetes management system.

The presented architecture can be adopted for other mobile chronic disease management such as asthma, cardiac disease and COPD (chronic obstructive pulmonary disease).

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