

No-Touch Wireless Transfer of Blood Glucose Sensor Data

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INTRODUCTION

Systems for self-management of chronic and lifestyle-related diseases are attracting growing interest. This is due to both the increase in prevalence and the technical progress within sensors, wireless communications and personal terminals in the form of powerful programmable mobile phones with integrated short-range communication transceivers. The number of cases of diabetes worldwide in the year 2007 is estimated at 246 million [1]. The same source anticipates that the number of people with diabetes will nearly double by 2025. There are two main types of diabetes. Type 2 diabetes accounts for about 92% of all instances. Nearly all the remaining cases are Type 1 and require continuous medication with insulin. For both types, tight control of blood glucose is important in reducing long-term diabetes complications. For the USA alone, direct medical and indirect expenditures attributable to diabetes in 2002 were estimated at \$132 billion [2], of which a high proportion was caused by complications due to unsuccessful management of blood glucose levels.

In particular, typical situations in which children with diabetes need help from a distance for blood glucose regulation are: home alone, at school, leisure activities, visiting friends, overnight visits, and weekend trips without their parents. The development of sensors that collect medical information by monitoring physiological parameters is progressing rapidly, but with limited results in the form of new and better products for patients. This is especially true for patient-operated blood glucose monitors (BGM), a field our research group has followed closely during the last six years through several projects, e.g. [3],[4],[5]. Few new BGMs are released each year, and no models have so far fully utilized the new advances within communication technology and mobile phone technology. Wireless communication technology has made dramatic progress in recent years, with the emergence of standards such as Bluetooth, ZigBee, WiFi, and others. In spite of this, few of the widely used sensor types such as blood pressure and blood coagulation measuring systems, asthma PIF monitors or BGMs are interfaced wirelessly to a management system.

In designing a system for easy transfer of patient-centric sensor data, one has to choose between setting up communication via an existing personal terminal such as a mobile phone and building the transceiver unit into the sensor system. A personal terminal enables more alternatives, depending on the terminal design. More advanced mobile phones are emerging rapidly, and are considered good candidates for patient terminals in patient-centric systems used for disease management.

Our solution for wireless transfer is based on both a short-range communication adapter connected with the blood glucose monitor, and a mobile phone for long-range communication of the data. The paper presents the technology and concepts behind a system for fully automatic transfer of blood glucose data from a commercial available BGM, utilizing the *Bluetooth* and *GSM* communication standards, and the possibilities that mobile phones offer as patient terminals. The concept has been implemented in 17 clinically functioning units, and tested on real users for four months. The user group comprised children with Type 1 diabetes and their parents, and the user reactions have been reported elsewhere [6]. Typical feedback from the parents included: "I think this is an incredibly good way of following up the blood glucose measurements for one's child", "with this system we as parents have got more responsibility, but all in all the system is a good thing", "we would like to use such a system on a daily basis", "Especially when we parents had to be apart from the child, this system was very reassuring".

BACKGROUND

Even though our selected patient group comprises children and adolescents with Type 1 diabetes, who have a particularly great need for communication and support from their relatives, there is a general trend towards and increased demand for solutions that support disease self-management, also referred to as "ambient assisted living" [7]. Until now, the majority of self-management systems for achieving better blood glucose control have required the patient to type the blood glucose value into a terminal, typically a mobile phone, PDA or PC, e.g. [8],[9]. This is often perceived as a tiresome process and seldom has the potential to be used on a regular basis. Although about half of all the personal

blood glucose monitors do have an interface for directly communicating data, applications utilizing the interfaces suffer from functionality that is too complex for most patients to use. Of these meters with an interface, almost all are based on wired RS232 communication, with a few using IR. The majority of systems that utilize the interface are designed for physical connection with a PC. Recently, systems for mobile communication of blood glucose data have appeared, e.g. GlucoMON [10], T+ Diabetes [11] and Polymap Polytel [12].

Common to all patient-operated blood glucose monitors today is that the measurement is done invasively. For most monitors the measuring procedure involves the following steps: 1) Insert a measurement strip into the monitor; 2) Use a lancet to puncture one of the fingers, see Fig. 1; 3) Squeeze a small drop of blood out of the finger and apply it to the measurement strip; and 4) Wait approximately 5 seconds for the blood glucose value to appear on the LCD of the meter, and remove the strip.

The GlucoMON system is a long-range wireless data transfer system, based on Diabetech's long-range wireless network. A long-range radio transmitter is attached as a "jacket" to the serial port (RS232) of the blood glucose meter. The system requires the user to detach the meter from its jacket (serial-port adapter), measure the blood glucose level, and replace it in the jacket to initiate an automatic transfer of the blood glucose data. Alerts may be sent to e-mail systems, cell phones and pagers. The system is primarily intended for children with Type 1 diabetes.



Fig. 1. Measuring blood glucose, using a lancet to puncture the finger.

The T+ Diabetes system is based on short-range communication between a serial Bluetooth cradle connected with the blood glucose meter and a mobile phone. A Java program installed on the mobile phone enables GPRS transfer of the measurements (and optionally nutrition, insulin, illness and physical activity data) to a secure web server. At any time, the data can be examined both from the Java program on the phone and on a Web page. Optionally, a clinician can monitor the patient data on the web page. The primary user group for this system is young adults (18 years and older). The user must initiate the transfer of blood glucose values and other data manually via the phone's menu, and must manually switch on the power of the Bluetooth cradle.

The authors have not been able to gain sufficient information about, or test, the Polymap Polytel system yet, but it appears to be easy to use, like the "no-touch" concept presented in this article.

Since 2001, the Norwegian Centre for Telemedicine (NST) has run projects using diabetes with the parameter blood glucose as a case for new self-management tools. The main challenges throughout this period have been finding a suitable short-range communication protocol, managing the power consumption issue, and developing software and hardware enabling wireless transfer of blood glucose data with no-touch operation. In 2002 we demonstrated a system for wireless and automatic transfer of blood glucose data, but this required manual (one-touch) initiation [3]. The system was based on the blood glucose meter Dex from Bayer, the Bluetooth Serial Port Adapter from connectBlue AB and the mobile phone Siemens SX45. After aiming to design a fully automatic version, in early 2003 we managed to implement a no-touch system, i.e. a system that did not require any technical skills or any user intervention. The system was based on the OneTouch Ultra blood glucose monitor, a miniaturized version of the Bluetooth serial port adapter from connectBlue, and the mobile phone Nokia 7650.

METHODS

User Needs and User Involvement

Prior to the user intervention we designed questionnaires and obtained feedback both from the children with diabetes and from their parents (two different questionnaires). Two of the project team members have Type 1 diabetes, and their experiences and views were helpful during the design period. One of these team members had the prototype connected to his regular blood glucose monitor for half a year - using it 5-10 times a day before the main intervention. This was valuable both for adjusting the final design and in debugging

software and hardware. In addition, we assigned one of the 15 children as a superuser, letting him use the prototype for one month, and received feedback from his experience. After this last user test, the application was finalized on the basis of the feedback, and the whole cohort was offered a four-month trial. We cooperated both with the diabetes nurse and with the specialist at the department of pediatrics at the local hospital in order to achieve an intervention that was as smooth as possible.

The intervention took place from October 2003 to February 2004. The children and their parents were told to use the system as the primary blood glucose measurement device. All of the children had to change to the designated mobile phone and nearly all had to change blood glucose monitor as well. The parents did not need to change their mobile phone. Using the system as their primary BGM meant that they brought it with them to school, leisure activities, sleepovers with friends, and weekend trips; they also used it when they were home alone. They were told that when they were home together with their parents at weekends they could unplug the Bluetooth serial port adapter, but should otherwise keep it active. This option was allowed to avoid possible irritation over unnecessary SMS messages. No changes in the relationship with the health care system or other disease management routines were required.

Design Methods

Wireless transfer of blood glucose values may be achieved in several ways; two of these are used in the two products [10] and [11]. None of these or any other documented systems known to us utilizes a "no-touch" transfer of data, i.e. a system that does not require users to perform any actions in addition to those normally involved in measuring blood glucose levels. The methods and requirements for achieving our no-touch system, presented in Fig. 2, are described below.



Fig. 2. Overall architecture of the no-touch wireless system for blood glucose transfer.

Choice of Blood Glucose Monitor

The blood glucose monitors used in a system for wireless data transfer must have a communication interface and be able to store blood glucose values measured previously, in case communication fails. Many of the BGMs do fulfill these requirements, but not all monitors have open data communication protocols like the BGM from LifeScan [13]. Another requirement, which is fulfilled much more rarely, is that it must be possible to use the monitor for measurements simultaneously with preparation of the communication interface for data transfer. In most cases this means that the RS-232 cable has to be plugged into the monitor while the measurement is performed. For most BGMs this is impossible, either because the RS232 port is the same as the measurement-strip port or because the monitor is physically switched into communication mode when the RS232 plug is inserted. The OneTouch Ultra meter from LifeScan Inc. [14] enables this, which may also be the reason that GlucoMON and the T+ Diabetes system use this meter.

Choice of Long-Range Communication Unit

The overall aim of our concept is to wirelessly transfer blood glucose data over a long range from patients, wherever they are, to caregivers. With access to the blood glucose data (value, date and time) through a cable and communication protocol, there are mainly two choices. The first choice is to build a long-range communication unit into or attached to the blood glucose measurement system. The GlucoMON system [10] has chosen this solution, requiring a somewhat larger BGM supply case for the necessary electronics. The second choice is to transfer the data via a short-range communication unit to an external long-range communication unit. This may sound like a more complex solution, but as a large percentage of the user group already wears such a unit in the form of a mobile phone, this may be an advantageous option. In our user group of 15 children aged 9 to 15, there were 14 who owned a mobile phone prior to the intervention. Another important reason for choosing a mobile phone as the long-range communication unit is that the phone provides a verbal communication channel at the same time. The users can then use the same terminal for emergency calls and disease support from relatives or health care personnel. GSM coverage worldwide is very good, and GSM is the fastest growing communications technology, with over 2.8 billion subscribers [15]. The main requirements for such an external communication unit are thus that it is programmable and features a short-range communication transceiver. The Nokia 7650 mobile phone fulfilled all our requirements and proved to be a suitable terminal for our purpose. To access both

the Bluetooth and GSM/SMS protocols on the phone, it was necessary to program the unit using C++. The Nokia 7650 terminal runs the Symbian OS, Series 60 application framework, on which the application for blood glucose transfer was run. This involves handling incoming blood glucose values from the BGM via Bluetooth, checking which data has been sent out earlier, and sending new data out to one or two recipients as SMS.

Choice of Short-Range Communication Unit

Some blood glucose monitors enable data transfer using IR, but this requires aligning the monitor with the receiver to avoid disturbance of the communication signal, and the propagation distance is shorter. Bluetooth was therefore found superior and chosen as the wireless communication standard for our system. Bluetooth is so far the only short-range communication standard that is widely implemented on mobile phones, and this was also a reason for our choice. Power consumption is an essential issue for increasing compliance in an application that is intended for use as a daily tool for people with a chronic disease. Fine-tuning of the communication modes of the Bluetooth unit made our short-range communication unit acceptable for the four-month clinical trial. The chosen unit forming the basis of the blood glucose serial port adapter was the CB-OEMSPA13i-02 Bluetooth unit from connectBlue [16]. In addition, electronics were built for interfacing the RS232 port, battery, and power handling. Fig. 3 displays the interface card (on top), Bluetooth unit (beneath) and battery. Each Bluetooth unit was paired with the accompanying mobile phone, and accessed through the Nokia 7650's Bluetooth Serial Port Profile. The chosen Bluetooth serial port adapter model supported "short-range" communication, implying coverage of 10 meters (radius). This means that the mobile phone could be placed in the child's rucksack at school or even further from the BGM system, and still allows the system to work. For example, a child with diabetes can measure her blood glucose at school and transfer the reading to her parents, without operating or paying any attention to the phone lying in the rucksack.

Interconnecting the System Elements

Our aim of designing a system that did not need any additional actions from the user was achieved by letting the interface card (Fig. 3, marked "5") power up the Bluetooth serial port adapter when it senses a "power down signal" from the blood glucose meter. The meter is powered down either when the user removes the blood glucose test strip after a measurement or two minutes after a measurement is performed due to an automatic power-down function at the BGM (i.e. when the user forgets to remove the test strip). To take into account the fact that blood glucose testing may fail, requiring the user to repeat the test, the interface card was set to power the Bluetooth transceiver for a period of three minutes (using the IC timer: 7555CU). Special efforts were made to find methods for reducing the power consumption. The electronics were powered by a 3.6 volt lithium battery (SAFT model LS14500, size AA), with a 2250 mAh nominal capacity. The daily power consumed is 3 minutes multiplied by the number of times the blood glucose is measured each day, typically five times. The software application in the user's mobile phone was set to constantly listen for Bluetooth activity, since glucose metering may take place at any time. The software application does not increase the phone's power consumption, but keeping the phone's Bluetooth transmitter switched on does.

All measurements stored in the memory of the BGM are transferred at each Bluetooth connection, to ensure that no measurements that have not been transferred are lost. With a baud rate of 9600, transferring all 150 measurements only takes a few seconds. The software application running on the mobile phone keeps track of the last measurement value sent and the time of transfer. If the system failed to send some earlier measurements, for example because the blood glucose monitor was too far from the mobile phone (> 10 meters), the application sends all the unsent measurements in batches of five SMS messages (due to the 160-character limit for each SMS). The current value measured is however given priority and always sent first as a stand-alone SMS (see Fig. 4).



Fig. 3. Inside view of the blood glucose Bluetooth serial port adapter (battery has AA size).



Fig. 4. Example of SMS appearing at the recipient's mobile phone. It reads: "Last blood glucose value: 5.7 (mmol/l). Date: 05.05.2004. Time: 10:23". The message may be sent to any GSM-enabled mobile phone.

RESULTS

No-Touch System

The main result of our attempt to design a no-touch system for wireless transfer of patient-measured blood glucose data is the conclusion that this is definitely achievable. The growth of the short-range communication standard Bluetooth holds much of the credit for the accomplishment of this goal. In addition, the open communication protocol and the other necessary BGM requirements that only the OneTouch Ultra BGM, and recently also the OneTouch Ultra 2, seem to fulfill made this no-touch system possible. The main finding from the clinical four-month trial was that when the system was free of problems such as power failure, cable instability and electronics instability, the users perceived it as a very helpful tool.

Power Capacity

The measured power consumption of the Bluetooth adapter in hibernation mode was 0.08 mA and in communication mode less than 65 mA. Assuming average use of the system to be five times a day, the battery of 2250 mAh capacity should theoretically last more than 123 days, in ideal conditions. The finding from the four-month trial (120 days) was that about half of the batteries lasted the whole period. The power consumption of the blood glucose monitor itself was also increased due to the three-minute longer power-on periods after each measurement. However, only a few of the monitors needed replacement of the battery (CR2032, button size) during the trial. Enabling Bluetooth on the mobile phone also increases the phone's power consumption. For users who only

used the phone functionality a couple of times each day in addition to the wireless blood glucose data transfer function, the battery lasted approximately three days. The users were encouraged to charge the phone each evening, causing no troubles for the average user who followed this recommendation. However, some users used the phone a great deal, and one of these even turned off the Bluetooth transceiver via the phone's menus to extend the life of the battery. The result was of course no communication with the blood glucose Bluetooth adapter, and this "user error" was discovered through a phone call to the project leader.

Flexibility

The system works independently of geographic location, including foreign countries as long as there is GSM coverage and the phone number(s) of the SMS recipient(s) are written with a country code (e.g. +47 for Norway). Normally the recipient's number(s) are entered only once, but this was made easy to change from the menu in the phone's software application. The systems also transfer blood glucose data even while the user is speaking on the mobile phone. This enables a parent to call his child with diabetes and ask her to measure the glucose value. He can receive the result by SMS and can discuss possible action, all during the phone conversation.

Error Rates

The users experienced some situations in which the system did not transfer the blood glucose data. The design decision to cut power to the Bluetooth adapter three minutes after the BGM had shut down was probably the biggest cause of these errors. When two (or more) consecutive measurements are performed, the shutdown may occur in the middle of a transmission. Another reason for errors in data transmission was a low battery level in either the blood glucose monitor or the Bluetooth serial port adapter. Due to the limited resources available to refine the prototype, it was unfortunately not possible to eliminate technical problems during the test period. Of the prototypes, 27 % functioned perfectly without any problems, 60 % had minor problems which were corrected through simple instructions to the user, and 13 % had major problems.

Reference Application

The developed system was designated as a "reference application" for the Bluetooth serial port vendor connectBlue AB [17]. Bluetooth SIG exhibited it as a Business Case Study on their web page [18], and as a reference eHealth application during a marketing tour in Asia during the autumn of 2004 and Europe in the spring of 2005.

Consequent Projects and Concepts

The no-touch wireless blood glucose transfer concept has so far generated four subsequent projects and concepts. The first project involves wireless transfer of the blood glucose value directly into the electronic health record (EHR) system. Through the "Wireless Health and Care" project, it was demonstrated that we could send blood glucose data into the "DIPS" EHR system [19]. The second spin-off concept involves using blood glucose data as an indicator for epidemic disease outbreaks, based on the fact that infectious diseases increase the blood glucose level [20]. This idea assumes a wide propagation of the no-touch system, where all data is transferred to a central database. The third concept entails combining this no-touch system with an analogous no-touch system for wireless transfer of physical activity and an easy-to-use function for recording nutrition data in an electronic diabetes diary [21]. This is now an ongoing activity in the form of a PhD project, lasting until 2009. The fourth project, "Better Use of Blood Glucose Measurements" aims to utilize the many measurements that people with diabetes record. This may be done by building further on the wireless "no-touch" data transfer concept presented here.

DISCUSSION

There are still no good solutions for either implantable blood-glucose sensors or non-invasive blood glucose sensors. This means that blood glucose is still being measured invasively, puncturing the skin with a needle and applying blood to a blood-glucose meter. *Glucowatch*, a watch that can read the blood glucose value each 10 minutes non-invasively, is a promising product, but is too inaccurate and cumbersome in use to be a reliable and non-obtrusive alternative [22]. This leaves us at this stage with semi-automatic solutions such as the GlucoMON [10], T+ Diabetes [11] and our prototype, which require the patient to perform the blood glucose measurement, but transfer the data more or less automatically either to a medical care provider's database or to an individual support team or person. Rational use of the data from such systems may lead to improved glycaemic control, and thus enhanced health [8],[23] and lower medical expenditures.

The concept of transferring the data directly into the EHR as demonstrated in [19] seems tempting, but also has many implications. A situation in which health care personnel have such an amount of data available prior to or during patient consultations will clearly be beneficial if the data are used in the right way. There may also be a vast medical research potential if these data are made available in databases for data mining and refined analysis.

Among the more critical considerations is the question of whether health care professionals could then be held responsible for those medical complications that patients themselves cause due to unhealthy management of their blood glucose level. Health care professionals would then have detailed information throughout the often long-term progression of the medical complications, and might be judged for not taking action in time. Another consideration is that it might become an unmanageable burden for health care personnel to act upon this vast amount of data in any case, due to the prevalence of diabetes in the population (typically at least 5%). Ownership of the data and the database may be open to debate, especially since in this case it is the patients themselves who both acquire the data and transfer it into the database. A fear often expressed by this patient group is that insurance companies may get hold of the data and subsequently increase premiums because blood glucose control is not optimal. Similarly, there are concerns that medical personnel may refuse to support renewal of the patient's driving licence or other licences if they misinterpret (or correctly interpret) the patient's blood glucose data. Not least, there are many other psychological implications related to patients' awareness that they are constantly being monitored by health care.

It is also obvious to suggest building on the concept described to develop a two-way disease management system between the patient and health care personnel. A typical concept might be to let health care personnel interact with the patient, suggesting changes in factors essential for diabetes management such as medication, nutrition, and physical activity. Possibly the strongest argument against this is that it would require considerable effort from a number of medical personnel. Another consideration is that patients who have lived for many years with diabetes often know more about how to handle difficult disease-related situations than physicians and nurses. It might also be tempting to suggest a two-way system that provides feedback on the basis of algorithms and routines implemented in software, but there is a risk that providing clinical advice in this way could have harmful or even fatal consequences. An example might be that a high blood glucose value triggers an automatically generated message to inject more insulin. The algorithms must then take into account both physical activity and nutrition, since both influence the blood glucose level. This is not straightforward, however, because activity and food intake after the insulin injection will also influence the resulting blood glucose value. A value that is too low may cause unconsciousness and, in the worst case, death. Although less likely, a value that is too

high may have the same outcome.

The system presented demonstrates the feasibility of setting up a truly no-touch system using mostly standard components. The trial also demonstrated several weaknesses in the system that should be taken into account in future systems. One of the main weaknesses is that it is dependent on a specific mobile phone model. A future system could be based on Java instead of C++. The software application could then be downloadable via GPRS/3G, like the T+ Diabetes@ [11] system. Thus, until all mobile phones have a common short-range communication transceiver such as Bluetooth, and interpret the same code (e.g. Java), choosing the "right" terminal will be an issue. Using the communication standard ZigBee instead of Bluetooth on mobile phones could reduce power consumption to a third, considerably enhancing user compliance. Even though Bluetooth has become the main short-range communication standard on mobile phones today (besides IR, which is less flexible), the well-known power consumption problem perhaps requires a transition to another communication standard for such sensor systems. ZigBee, Wibree and other specially designed radio frequency communication solutions optimized for low power consumption are good candidates, but are embedded in few mobile phones so far. Building a long-range communication transmitter into the BGM system as in the GlucoMON [10] solves the terminal issue, but provides the user with a one-way communication tool instead of a two-way tool. Depending on the user group and the individual needs, either of these two approaches may be helpful in designing future variants of such tools, and could also be used for diseases other than diabetes.

The solution presented is an example of a totally stand-alone system, which does not involve any health personnel. The communication is solely between the patient and the relatives and the frequency of use is decided by the patient herself. Besides the hardware expenses, the solution transfer cost is only related to the number of measurements performed per day, which equals the number of SMS messages sent per day. The most widely used Norwegian mobile phone operator typically charges 0.08 EUR / 0.10 USD per SMS, giving the intervention group with an average use of five measurements per day a daily cost of 0.40 EUR / 0.50 USD. Since the intervention group was given the option to unplug the Bluetooth serial port adapter during weekends and other periods when the children were together with their parents all the time, they could reduce this cost. As a cost-reducing option, we considered sending the blood glucose

values every second time the user had measured, or only when there were unhealthy values. This option was rejected because the system would not give the parents the reassurance of knowing that their child is actually measuring the values NOW and that the blood glucose value is acceptable or unacceptable NOW. Future systems should be context-sensitive, sensing the presence of the recipient(s) and only sending data when it is rational to do so. We suggest that this concept may provide a valuable tool for monitoring health parameters in other conditions as well, for example, asthma and cardiac arrhythmia.

CONCLUSION

The system described is the only no-touch transfer system for blood glucose data which our research group has found documented and subjected to a clinical trial. As children with Type 1 diabetes and their parents face rigorous procedures for blood glucose monitoring and regulation, they welcome new ways of providing disease management as presented in our intervention [6]. Both the system presented and other mobile telecommunication systems [9],[10],[11] show potential as an aid for families' self-management of diabetes. According to the review by Raju et al. [23], there are few studies involving mobile phones and even mobile computers in health care. In a thorough literature search and data analysis from 2004, the authors of the review found only two studies involving mobile phones in the category for "recording and transfer of patient data". This indicates a potential for more focus on research and development of such systems. The current aim of our research group is to design similar concepts and conduct research on eHealth tools for patients. Natural extensions are solutions for recording of physical activity and nutrition, integrated into a complete system as in [21]. Many of the parents from this project's intervention study [6] concluded: "If it's not automatic, forget it", and this statement will guide our future work within this field.

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