Health Informatics Meets eHealth
G. Schreier and D. Hayn (Eds.)

doi:10.3233/978-1-61499-858-7-132

Development of a Protocol for Automated Glucose Measurement Transmission Used in Clinical Decision Support Systems Based on the Continua Design Guidelines

Markus MEYER[a], Klaus DONSA[a,1], Thomas TRUSKALLER[a], Matthias FROHNER[b], Birgit POHN[b], Alexander FELFERNIG[c], Frank SINNER[a] and Thomas PIEBER[a,d]
[a]*HEALTH - JOANNEUM RESEARCH Forschungsgesellschaft mbH, Graz, Austria*
[b]*University of Applied Sciences Technikum Wien, Vienna, Austria*
[c]*Graz University of Technology, Graz, Austria*
[d]*Medical University of Graz, Graz, Austria*

Abstract Background: A fast and accurate data transmission from glucose meter to clinical decision support systems (CDSSs) is crucial for the management of type 2 diabetes mellitus since almost all therapeutic interventions are derived from glucose measurements. Objectives: Aim was to develop a prototype of an automated glucose measurement transmission protocol based on the Continua Design Guidelines and to embed the protocol into a CDSS used by healthcare professionals. Methods: A literature and market research was performed to analyze the state-of-the-art and thereupon develop, integrate and validate an automated glucose measurement transmission protocol in an iterative process. Results: Findings from literature and market research guided towards the development of a standardized glucose measurement transmission protocol using a middleware. The interface description to communicate with the glucose meter was illustrated and embedded into a CDSS. Conclusion: A prototype of an interoperable transmission of glucose measurements was developed and implemented in a CDSS presenting a promising way to reduce medication errors and improve user satisfaction.

Keywords. Mobile Health, Standardization, Clinical Decision Support Systems, Type 2 Diabetes Mellitus, Medication Errors.

1. Introduction

425 million people are suffering from diabetes mellitus worldwide and 58 million people in Europe with around 90% of type 2 diabetes mellitus (T2DM) according to recent estimates of the International Diabetes Federation (IDF) [1]. Glucose measurements and medication administration are important components of T2DM therapy.

Each patient needs a different amount of insulin which depends on many internal and external factors. General Practitioners (GPs) need comprehensive diabetes knowledge and experience to set a personalized insulin dosage for a patient by analyzing the logged glucose measurements. Since it is a time-consuming task to identify the cause of every Hypo- and Hyperglycemia, GPs can usually only focus on the most recent ones. A clinical decision support system (CDSS) can analyze large datasets of measurements

[1] Corresponding Author: Klaus Donsa, HEALTH - JOANNEUM RESEARCH Forschungsgesellschaft mbH, Neue Stiftingtalstraße 2, 8010 Graz, E-Mail: healthca@joanneum.at.

in a short time and can therefore assist GPs by suggesting a personalized medication dosage derived from all logged glucose measurements.

GlucoTab® is a CDSS which is already used in hospitals for the therapy of T2DM. Medication dosage suggestions are derived from glucose measurements as well as personalized therapy settings and follow a rule-based algorithm. The algorithm in place frequently updates the therapy settings based on new input data to fit the personal needs of the patient. GlucoTab® is currently operated by healthcare professionals (HCPs), however with the limitation that the glucose measurements are transferred manually into the CDSS.

The most important variable of a rule-based algorithm to calculate insulin dosages is the blood glucose level. A previously performed study [2] showed an error rate of 5% during manual transfer of measured glucose concentrations from the glucose meter in a paper-based workflow and an error rate of 4% in a computerized workflow. The study further revealed an increased probability of a hypoglycemic event following an insulin dosing error (odds ratio 3.1). Severe hypoglycemia is an indicator for poor patient outcomes and higher mortality risk and should therefore be avoided [3]. Preventing errors by the transfer of glucose measurements with an automated transmission protocol can therefore reduce the mortality rate.

Almost all therapeutic actions are derived from the measured glucose concentrations and therefore an accurate transmission of glucose measurements to other health-related devices such as CDSSs is desirable. Aim was the development of a prototype of an automated glucose measurement transmission protocol based on the Continua Design Guidelines. The protocol will be embedded into a mobile CDSS which will be used by healthcare professionals for the treatment of T2DM patients in the home care setting.

2. Methods

We performed a structured literature and market research on measurement transmission protocols to retrieve state-of-the-art implementations and to develop a prototype of an automated glucose measurement transmission protocol.

2.1. Literature and market research

The query “IEEE 11073 (Medical OR Health) Device” was used to search for publications about protocols, systems and devices which use the personal health device communication standard as defined by ISO/IEEE 11073. The query is applied to IEEE Xplore, ACM and PubMed Digital Library with a total of 99 distinct results. Based on title and abstract, 57 publications were identified as non-relevant for the research because they did not comprise the topic of a personal health device. Titles and abstracts of the 42 remaining relevant publications were examined and rated on a scale from 1 to 10 according to their relevance. This resulted in 21 relevant papers with a ranking of 5 or higher.

We used the google search engine and google play store to identify the state-of-the-art of glucose meters and smartphone applications related to automated measurement transmissions. Glucose meters are categorized by their data transport type (Bluetooth/ZigBee/USB/NFC) and whether they are Continua certified or not.

Table 1. Glucose meters, data transport and standardization status.

Glucose Meter	Data Transport	Continua Certified
Accu-Chek® Guide	Bluetooth/USB	Yes
Accu-Chek® Instant	Bluetooth/USB	Yes
Contour® Next/Plus ONE	Bluetooth/USB	Yes
FORA® D40	Bluetooth/USB	Yes
Accu-Chek® Active	USB	Yes
Accu-Chek® Mobile	USB	Yes
Accu-Chek® Aviva/Performa Insight	USB	Yes
Abbott FreeStyle Libre	NFC	No
Accu-Chek® Aviva/Performa Connect	Bluetooth/USB	No
AgaMatrix Jazz Wireless 2	Bluetooth	No
Beurer GL 50 evo	Bluetooth/USB	No
BodyTel® GlucoTel	Bluetooth	No
Dexcom G5	Bluetooth	No
FORA® TN'G / TN'G Voice	Bluetooth	No
GlucoMen Areo / Areo 2K	Bluetooth/NFC/USB	No
MediTouch® 2 connect	Bluetooth/USB	No
Medtronic Enlite® Sensor	Bluetooth	No
OneTouch Verio Flex®	Bluetooth/USB	No

Applications are categorized by features like reminders and bolus calculators, as well as whether they are using a standardized or a proprietary communication protocol.

2.2. Development of a prototype of an automated glucose measurement transmission protocol

Results from the literature and market research were the basis for the development of an automated glucose measurement transmission protocol from glucose meters to CDSSs. Literature research highlighted the benefits of standardized communication protocols which confirmed the development following the Continua Design Guidelines. Market research revealed a lack of glucose meters using a standardized communication protocol and was resolved by a middleware for the communication with glucose meters which can be extended to translate non-standardized messages into standardized messages.

The system was designed to transfer the measurements from an Accu-Chek® Guide glucose meter via Bluetooth Low Energy to a middleware running on Android. The middleware shall then provide an interface to other applications and allow them to receive and read measured glucose concentrations. The CDSS GlucoTab® implements the interface to the middleware and is thereby able to make therapy decisions from the sensor readings in real-time.

3. Results

Results from literature and market research were used as basis for development of a standardized glucose measurement transmission protocol using an extendable middleware to allow the support of a broad range of glucose meters.

3.1. Literature and market research

Market research revealed that at least 18 glucose meters which can transfer a measured glucose value to another device for further examination exist. However, only 7 out of the

18 listed devices use the standardized ISO/IEEE 11073-20601 PHD exchange protocol [4] and ISO/IEEE 11073-10417 glucose meter device specialization [5], as suggested by the Continua Design Guidelines (Table 1). Moreover only 4 of them support a wireless Bluetooth communication which increases usability in a mobile healthcare setting.

Market research on Android applications which are used to receive measurement values from a glucose meter showed a lack of standardization likewise in software applications and in personal health devices. Four out of 12 listed applications support the standardized protocol as defined by the Continua Design Guidelines (Table 2). Market research revealed further that most applications can only receive, store and visualize the measurement values, but they neither help the user with the medication dosage calculation nor with reminders for glucose measurements or medication administration.

Accu-Chek® Connect and mySugr provide a bolus calculator. The application thereby suggests an insulin dosage for a meal, based on carbohydrates, measured blood glucose and some personalized therapy settings, such as the amount of insulin needed per gram carbohydrate. GlucoTab® takes this approach one step further and manages the entire diabetes therapy. The application tells the user when and how often a glucose measurement should be performed and calculates an appropriate medication dosage several times per day.

3.2. Development of a prototype of an automated glucose measurement transmission protocol

The developed glucose measurement transmission protocol was designed and implemented according to the Continua Design Guidelines [6]. These guidelines define, beside other things, what has to be considered when implementing a Bluetooth Low Energy interface between a personal health device (the Accu-Chek® glucose meter) and a personal health gateway (the tablet running GlucoTab®). This specification is strongly aligned with the specification from the Bluetooth Special Interest Group. An end use application of the protocol was embedded into GlucoTab® (Figure 1).

GlucoTab® is installed together with a middleware on the used tablet. The middleware was implemented as a background service (not having an own graphical user interface) and provides the needed functionalities to connect and communicate with the used Accu-Chek® glucose meter on the one and GlucoTab® on the other hand.

Table 2. Feature, protocol and user comparison of diabetes related android applications.

Application	Logbook	Medication Calculator	Therapy Adjustment	Reminder	Continua Protocol	User
GlucoTab®	Yes	Yes	Yes	Yes	Yes	HCP
mySugr	Yes	Yes	No	Yes	Yes	P
Accu-Chek® Connect	Yes	Yes	No	No	Yes	P
Contour® Diabetes	Yes	No	No	Yes	Yes	P
AgaMatrix Diabetes Manager	Yes	No	No	Yes	No	P
Beurer HealthManager	Yes	No	No	No	No	P
BodyTel Blutzucker	Yes	No	No	No	No	P
Glucolog Lite/Mobile	Yes	No	No	No	No	P
iFORA Diabetes Manager	Yes	No	No	No	No	P
LibreLink	Yes	No	No	No	No	P
OneTouch Reveal®	Yes	No	No	No	No	P
VitaDock+	Yes	No	No	No	No	P

Figure 1. Transmission from Accu-Chek® Guide glucose meter to GlucoTab® CDSS.

Communication between middleware and GlucoTab® were defined through Android Interface Definition Language (AIDL). For the information that is exchanged based on the data objects (Figure 2) stated in the interfaces' definition, further efforts towards standardization were made by using the terminology defined in ISO/IEEE 11073-10417[5], i.e. the terms and/or code as stated in this standard were used to identify the measured parameters and meta data. Following this standard, information like measuring the glucose concentration based on an capillary whole-blood sample or meta information like that measurement has been taken pre-prandial was coded as the integer values 23112 and 29260 respectively.

The middleware, acting as a glucose meter manager, implements an IGlucoseMeterManager interface (Figure 3) and handles communication with the glucose meter as well as with GlucoTab®. Android's build-in platform support for BLE, which is available since Android 4.3, is used to read the services provided by a remote BLE device.

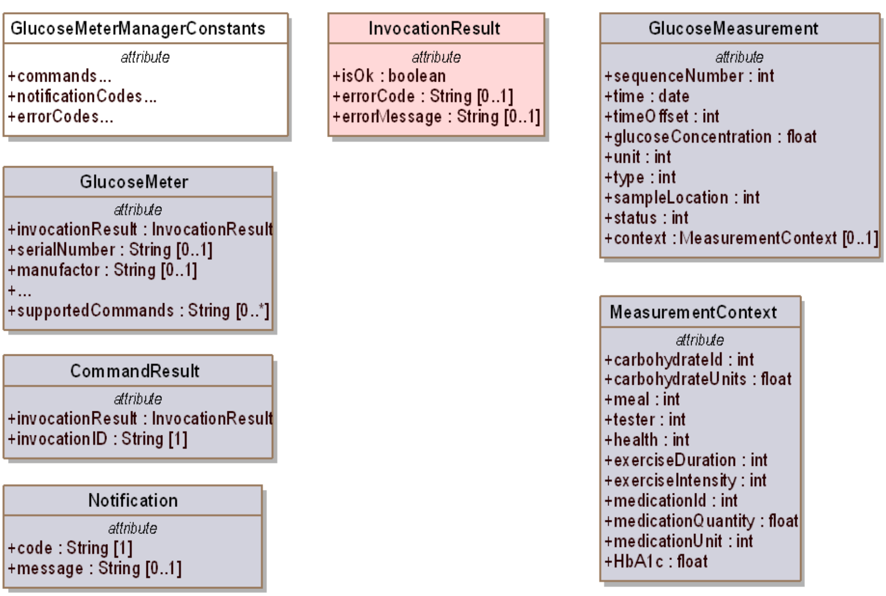

Figure 2. Data objects exchanged by middleware and GlucoTab®.

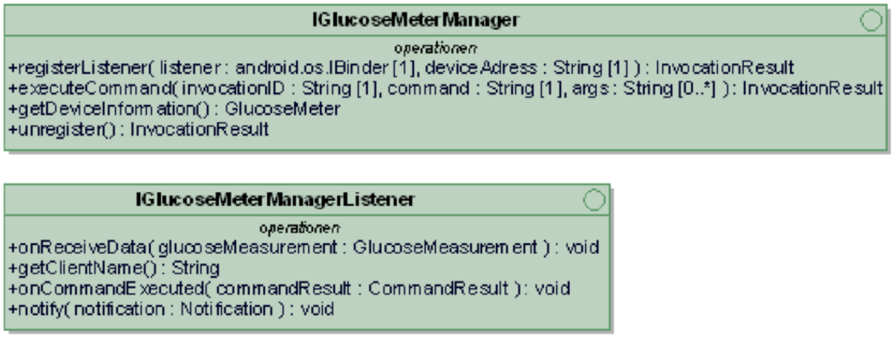

Figure 3. AIDL interface definition between middleware and GlucoTab®.

GlucoTab® implements the IGlucoseMeterManagerListener interface and registers as listener at the middleware by calling the registerListener method. This method holds the unique MAC address of the Bluetooth device to which the connection should be established. After the middleware has established the connection the “Record Access Control Point” service characteristic is used to query actively for stored values. This method also enables the listener to delete stored measurement values on the glucose meter. Methods of the IGlucoseMeterManager interface return a lightweight InvocationResult object to identify errors and supply error details with an error code and a short error message.

The GlucoseMeter class returned by the getDeviceInformation method contains general information about a connected glucose meter and additionally provides information about supported commands by the health device. GlucoseMeasurement is used to provide general information of a glucose measurement, such as the date and time and the glucose concentration. MeasurementContext can be used to give further details about a glucose measurement, such as exercise, meal and medication information related to the measurement when supported by the used blood glucose meter.

4. Discussion

Literature and market research substantiate the need for standardization in communication protocols used by personal health devices. As mentioned in [7-15], a standardized communication protocol for personal health devices enables a seamless plug and play compatibility of various sensors from different manufacturers. However, as mentioned by [8,11,13,15], manufacturers use their own software and communication protocols, building proprietary solutions that can only work alone or inside a single-vendor system. Proprietary protocol solutions eliminate the communication between devices of different manufacturers, leading to an interoperability problem.

One reason for the lack of standardization is the gap between current regulations as well as health policies of medical devices and stakeholders manufacturing the personal health technology. Insufficient or over regulation of health standards can both significantly delay the market adoption [12]. A further reason is the vast amount of pages in standard documents that need to be observed [13] and the overly complex design of the protocols [16]. Nevertheless, advantages of a standardized protocol are the interoperability of devices from different manufacturers, lower healthcare costs and a better patient treatment [11-13]. Moreover, there are tools and frameworks provided to help overcome the difficulties of implementing a standardized communication protocol [13,17].

This article presents a standardized implementation of an automated glucose measurement transmission protocol from glucose meters to the CDSS GlucoTab®. By following the Continua Design Guidelines, future Continua certified glucose meters will be able to communicate out of the box with the presented implementation. Beside the implemented feature to query data using the "Record Access Control Point" characteristic another approach would be to have the data transferred automatically using the indication service, as described by the "Glucose Measurements" service characteristic specification [18]. Concerning the different possibilities how to acquire the data from the Bluetooth device, initiated by the device versus initiated by the middleware or GlucoTab®, at this point in time the decision was made for the latter.

At the first glance an automatic transfer of the data seems more desirable, but for the workflow of HCPs it seems more usable when they can actively pull the values. Therefore the "Record Access Control Point" service characteristic has been implemented and used to get and to delete data from the Bluetooth device. However, another possible way for the same user experience would be that the middleware stores and forwards the data received from the glucose meter. This approach has the disadvantage that data might end up in the middleware and might not be requested from GlucoTab®.

By embedding the automated glucose measurement transmission protocol into GlucoTab® and thereby eliminating the risk of miscopied or misread glucose measurement values, the treatment of T2DM patients by healthcare professionals was further improved. After measuring the glucose concentration of a patient, the value will automatically be transmitted to GlucoTab®. The clinical decision support system can immediately feed the measured value into an algorithm to calculate an adapted medication dosage based on the current glucose level.

Further research including a summative usability assessment of the automated transmission protocol using GlucoTab® in a working environment with healthcare professionals is already planned.

In conclusion a prototype of an automated glucose measurement transmission protocol was developed and embedded into GlucoTab®. Since the glucose measurement is the source of the algorithm behind GlucoTab® a reliable and automated transmission of this data helps to reduce medication errors and to assist HCPs on routine tasks.

References

[1] I. D. Federation, IDF Diabetes Atlas, Eighth edition 2017, 8th ed. 2017.

[2] K. Donsa et al., "Impact of errors in paper-based and computerized diabetes management with decision support for hospitalized patients with type 2 diabetes. A post-hoc analysis of a before and after study," Int. J. Med. Inform., vol. published, no. http://dx.doi.org/10.1016/j.ijmedinf.2016.03.007, 2016.

[3] A. K. Lee et al., "The Association of Severe Hypoglycemia With Incident Cardiovascular Events and Mortality in Adults With Type 2 Diabetes.," Diabetes Care, vol. 41, no. 1, pp. 104–111, Jan. 2018.

[4] IEEE 11073 Committee, IEEE 20601 - Health informatics—Personal health device communication: Application profile — Optimized Exchange Protocol, vol. 2014. 2014.

[5] I. 11073TM S. Committee, "IEEE 11073-10417-2015 - Health informatics -- Personal health device communication Part 10417: Device Specialization -- Glucose Meter." p. 78, 2015.

[6] Personal Connected Health Alliance, "H.811 Personal Health Devices Interface Design Guidelines," p. 114, 2016.

[7] H. S. Park, H. Cho, and H. S. Kim, "Development of cell phone application for blood glucose self-monitoring based on ISO/IEEE 11073 and HL7 CCD," Healthc. Inform. Res., vol. 21, no. 2, pp. 83–94, 2015.
[8] J. H. Lim, C. Park, and S. J. Park, "Home healthcare settop-box for senior chronic care using ISO/IEEE 11073 PHD standard," 2010 Annu. Int. Conf. IEEE Eng. Med. Biol. Soc. EMBC'10, pp. 216–219, 2010.
[9] M. Clarke, S. Member, J. De Folter, C. Palmer, and V. Verma, "Building Point of Care Health Technologies on the," pp. 16–18, 2013.
[10] A. Aragüés et al., "Trends and challenges of the emerging technologies toward interoperability and standardization in e-health communications," IEEE Commun. Mag., vol. 49, no. 11, pp. 182–188, 2011.
[11] I. Martińez et al., "Standard-based middleware platform for medical sensor networks and u-health," Proc. - Int. Conf. Comput. Commun. Networks, ICCCN, pp. 714–719, 2008.
[12] D. Zhong, M. J. Kirwan, and X. Duan, "Regulatory barriers blocking standardization of interoperability," J. Med. Internet Res., vol. 15, no. 7, 2013.
[13] J. H. Lim, C. Park, S. J. Park, and K. C. Lee, "ISO/IEEE 11073 PHD message generation toolkit to standardize healthcare device," Proc. Annu. Int. Conf. IEEE Eng. Med. Biol. Soc. EMBS, pp. 1161–1164, 2011.
[14] H. L. Li, Z. Bin Duan, J. Z. Cui, and Z. W. Chen, "A design of general medical data adapter based on ISO/IEEE 11073 standards," 2015 12th Int. Comput. Conf. Wavelet Act. Media Technol. Inf. Process. ICCWAMTIP 2015, pp. 404–407, 2016.
[15] J. C. Nam, W. K. Seo, J. S. Bae, and Y. Z. Cho, "Design and development of a u-Health system based on the ISO/IEEE 11073 PHD standards," 17th Asia-Pacific Conf. Commun. APCC 2011, no. October, pp. 789–793, 2011.
[16] M. Clarke, J. de Folter, V. Verma, and H. Gokalp, "Interoperable End-to-End Remote Patient Monitoring Platform based on IEEE 11073 PHD and ZigBee Health Care Profile," IEEE Trans. Biomed. Eng., vol. 1, no. c, 2017.
[17] L. Yu, Y. Lei, R. N. Kacker, D. R. Kuhn, R. D. Sriram, and K. Brady, "A general conformance testing framework for IEEE 11073 PHD's communication model," Proc. 6th Int. Conf. PErvasive Technol. Relat. to Assist. Environ. - PETRA '13, pp. 1–8, 2013.
[18] B. SIG, "Bluetooth GATT Characteristic: Glucose Measurement," 2012. [Online]. Available: https://www.bluetooth.com/specifications/gatt/viewer?attributeXmlFile=org.bluetooth.characteristic.glucose_measurement.xml. [Accessed: 25-Jan-2018].