A STANDARD-BASED MOBILE AND WIRELESS VITAL SIGNS MONITORING SYSTEM

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Abstract

This paper presents an implementation of the European standard VITAL —now ISO/IEEE/CEN 11073—, whose main purpose is the representation and exchange of vital signs. More specifically, we have developed an implementation of the CEN/TS 14271 pre-standard, which deals with the off-line communications and provides the specification for an universal File Exchange Format (FEF) for vital signs. As an application and to evaluate our implementation, we have developed a prototype for glucose measurement, making use of wireless techniques and off-the-shelf handheld devices. The prototype consists of an agent —monitoring system on the diabetic patient site— and a manager - diagnosis system on the hospital site. The agent is composed of a glucometer, a GSM/GPRS mobile phone, and a Personal Digital Assistant (PDA) which stores acquired data in a FEF file and transmits it via File Transfer Protocol (FTP). The wireless communication between the devices is carried out through Bluetooth technology. The manager is composed of an FTP server, and a mobile phone. Our prototype provides a solution to satisfy the main requirements of point-of-care vital signs monitoring systems, i.e. interoperability, mobility and portability.

Introduction

The significant progress of telecommunications technologies has made it possible to achieve substantial advances in medical devices. Even though physicians' work has been significantly eased and patients' comfort improved (Bashshur, 2002), the problem of communicating devices still remains, as major manufacturers tend to develop their own proprietary protocols (Anagnostaki et al., 2002). It has therefore appeared necessary to devise some basic rules for data exchange between different medical devices and management elements. Several standardization attempts have been made. On the one hand, the Committee for European Normalization TC251 Working Group IV —CEN, Health Informatics - Technology for Interoperability— defined a standard called VITAL ("CEN/TC 251 Health Informatics") and, on the other hand, IEEE —Medical Device Communications— defined the set of standards IEEE 1073 ("IEEE 1073 Medical Device Communication").

Over the last few years, there has been an international harmonization in the area of medical device communications standardization, joining both groups' efforts under ISO TC215 WG2.1 —Health Informatics - Messaging & Communications - Devices. The obtained standards, named ISO/IEEE/CEN 11073, have been developed in close coordination with other standards development organizations including HL7, DICOM, NCCLS and the ANSI Health Informatics Standards Board (HISB) and Medical Devices Standards Board (MDSB).

Despite these important initiatives, standard-based monitoring systems are still very rare. In this paper we present an implementation of the VITAL standard for different medical devices, and more specifically the part concerned with offline data exchange. Furthermore, we have developed a mobile and wireless prototype for blood glucose levels measurement making use of our implementation.

Materials and Methods

The following subsections describe the proposed implementation of the FEF specification, and the development of our glucose measurement prototype.

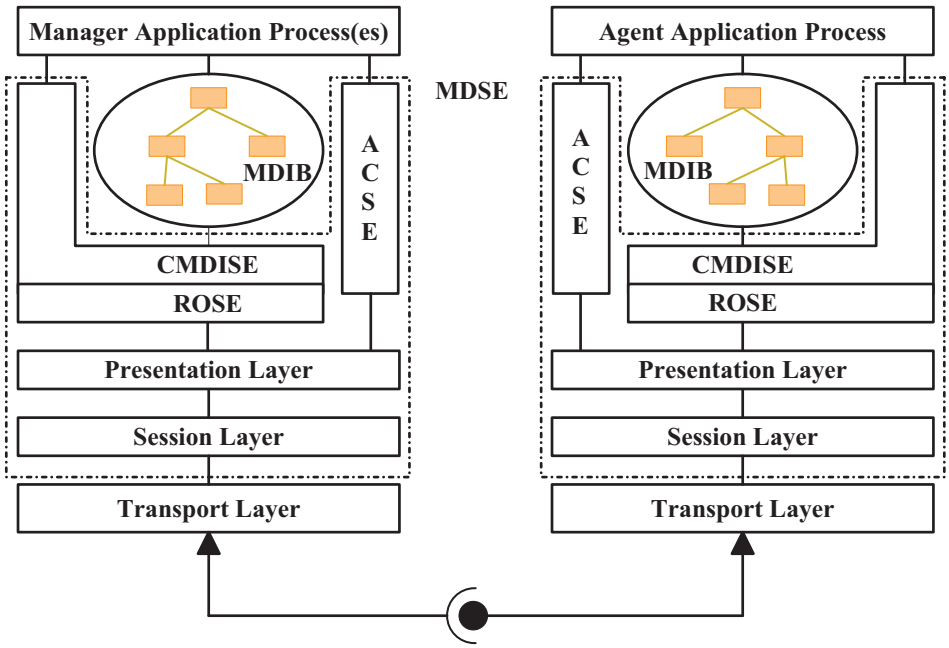
A Brief Overview on VITAL Standard

VITAL is particularly focused on the application, presentation, and session layers of the ISO/OSI seven layer system management model. Its principal goal is to provide both a plug-and-play connectivity, and a ”shared” representation for every medical device. As a result, a Manager-Agent structure —see Figure 1— is defined consisting of the following main elements (“UNE-ENV 13734”;”UNE-ENV 13735”):

- The Medical Data Information Base (MDIB) is an object-oriented database which contains a structured collection of managed medical objects, representing the vital signs information provided by a particular medical device.
- The Association Control Service Element (ACSE), as a standard protocol, provides the set of methods for establishing logical connections between medical device systems.
- The Common Medical Device Information Service Element (CMDISE) offers access services to data stored in the database.
- The Remote Operation Service Element (ROSE) provides basic services used by the CMDISE to invoke remote operations.

The last three elements are, respectively, adaptations of ISO-model ACSE, CMIP and ROSE layers for vital signs data exchange standardization and, along with a minor modification of presentation and session layers, conform the Medical Device Service Element (MDSE) —the upper layer communications stack.

Figure 1: VITAL Manager-Agent structure.



The above-described structure allows an on-line standard messages exchange between medical devices. In addition, VITAL offers the possibility of exchanging off-line only a particular set of the information stored in the database. This feature is defined by the pre-standard CEN/TS 14271 (“prENV 14271”), which provides the specification for an universal FEF within the domain of health care, containing demographic and administrative data, as well as medical information.

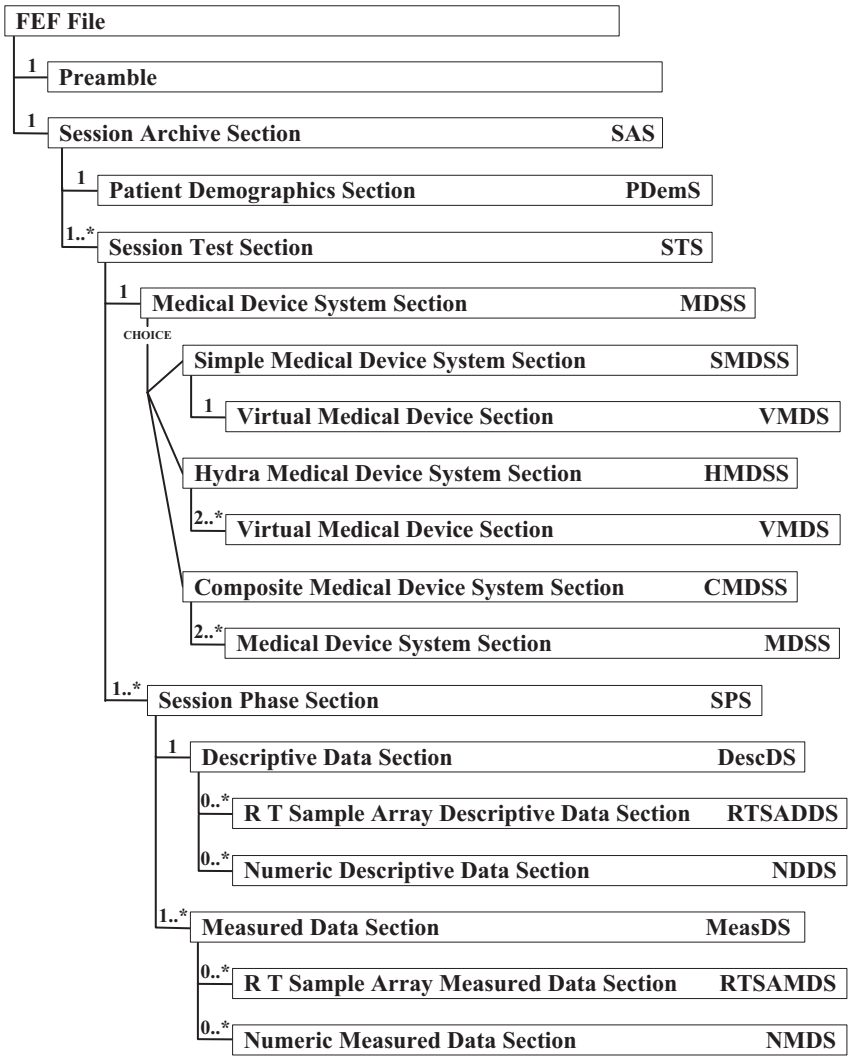
The File Exchange Format (FEF)

The FEF implementation proposed in this paper takes into account both mandatory and signal type-specific objects for supporting the following set of medical devices typically required by the users: glucometer, electrocardiograph —up to 12 leads—, oxygen saturation monitor and blood pressure meter.

Since FEF contains information from the MDIB of VITAL, it was essential to build a database for extracting and recording the required data. For this purpose, C++ language has been chosen to comply with VITAL proposal of building an object-oriented database. However, this suggestion is not mandatory, and the database could be implemented using other programming techniques.

The diagram in Figure 2 presents the objects structure of the implemented FEF with their cardinality denoted by the left-side numbers. The implemented code can act both as manager and as agent. Considering that objects for a specific type of data formats —arrays and numerics— have been implemented, our system is capable of encoding/decoding FEF files for these signal types.

Figure 2: Structure of the implemented FEF.



prENV 14271 specification defines the objects and basic types using an abstract syntax, and recommends to take into consideration abstract syntax notation one (ASN.1) for their implementation (Larmouth, 1999). Given that this notation specifies data-structures at a high level of abstraction, is internationally standardized and vendor-platform-language independent, it allows the programmer to select the preferred or more appropriate language.

We have implemented every ASN.1 type as a C++ class composed of attributes and methods, which provide the interface for managing the object.

ASN.1 offers diverse encoding rules for data representation purposes, but FEF specification proposes the use of those known as Basic Encoding Rules (BER) ("X.690"). These rules encode all data types into Tag-Length-Value triples (TLV), where the tag identifies the element being encoded, the length represents the number of bytes of the encoded data and, finally, the value is either a simple type value —primitive— or a complex one —constructed— composed of more TLV triples.

Mobile Prototype

The following scenario is considered: a non-critical but chronic patient, diabetic for instance, should visit an expert periodically for a control; however he is also required to travel frequently due to his occupation, giving therefore rise to ubiquity problems. This situation could be solved by considering the telecommunications advances, the recent wireless technologies, the expansion of a new generation of mobile devices and, the efforts made in vital signs data exchange standardization.

As a specific response to the presented scenario, we have developed a mobile prototype for blood glucose level measurement purposes consisting of an agent and a manager making use of our FEF implementation.

Agent. The agent —see Figure 3— is composed of a glucometer, a PDA and a mobile telephone. It performs as follows:

- The data acquired by the patient glucometer are sent to the Pocket PC through Bluetooth connectivity.
- Once the data have been received, the standard-based algorithm encodes those data and records them into FEF.
- The standard file is then sent to a health care centre via GSM Bluetooth-modem for data interpretation.

Figure 3: Agent side prototype.

The application, named *GlucoSend*, is intended to be easy to use for novice users. As a first step, the user should provide some information necessary to establish the communication with the health care centre, such as patient name, connection to be used for transmission purposes, IP address where the data should be sent to, etc. If the configuration sequence fails, it will be presented again in the next execution. Once the system has been configured successfully, the user only needs to turn on the glucometer and the mobile telephone. A progress bar on the PDA screen notifies the user of the whole process status.

Manager. To complete the transfer operation, there must be a manager on the health care centre site. The manager is composed of a PC equipped with a Bluetooth-modem and an FTP-server, with essentially the role of:

- receiving the standard file transmitted by the agent,
- decoding the information, and
- visualizing the received information for its interpretation.

The application, named *GlucoView,* displays the incoming FEF data —managed by the FTP server— to the physician on the PC screen. When an event requires immediate attention, alarms and warning messages are activated to alert the physician. The incoming FEF data are recorded and can be retrieved for later diagnosis, reviews, non-critical data exchange, patient demographic information retrieval, etc.

Results

The prototype described previously has been tested and evaluated considering three important user requirements: mobility, usability and performance. The mobility of the agent, evaluated in relation to size and weight, obtained high satisfaction thanks to the choice of a compact and lightweight PDA-based solution. The usability was estimated by easy operation and easy monitoring, which proved to be satisfying, even though a short introduction of the system to the user was necessary. Regarding the performance, the wireless data transmission test reveals no error in the real time vital sign transmission from the mobile unit to the management unit. The management unit receives the data and adequately displays the patient´s information.

Discussion

As a response to the presented scenario and as a solution to interoperability, a prototype for blood glucose levels measurement has been developed adding plain graphical interfaces to the FEF implementation —which has been designed to act both as manager and as agent. The agent has been developed over a mobile platform offering the patient full mobility facilities. In addition, the employed Bluetooth technology facilitates devices management, avoiding wires.

As mentioned previously, our FEF implementation is intended to support a specific set of medical devices —glucometer, electrocardiograph, oxygen saturation monitor and blood pressure meter—. Other monitoring systems could therefore easily be developed in a similar way to the one presented in this paper. Moreover, our development might also easily be applied to other devices provided that their signals could be stored in any of the implemented types.

While developing the prototype some technical issues arose such as controlling the Bluetooth communications programmatically. Given that the Pocket PC 2002 platform SDK does not allow this control, we solved this issue making use of the Bluetooth software included in our handheld machine. This implies that the application would have to be modified if it had to be installed on a different handheld.

Despite our efforts to keep the applications as easy-to-use as possible, some specific technical data are still required, for example an IP address. It is therefore necessary to ensure that the user knows these data and how to use them.

For the FEF transmission, GSM technology and FTP have been used. The main disadvantages of using GSM are the long connection time and low data transmission speed, and they could be improved by means of GSM/GPRS or UMTS technologies. Security is also an important issue, and could be addressed using Secure File Transfer Protocol (SFTP).

Conclusions

While the rapid evolution of telecommunications has allowed drastic advances in healthcare, some communication problems between medical devices —and even between hospitals— still arise and could be solved by means of standardization.

However most of the medical devices are today based on proprietary solutions and standardisation will not be achieved rapidly. As an alternative, we propose the use of off-the-shelf or widely used equipments as mediators. Our solution has proved to satisfy to the main requirements of today's medical devices: ease-of-use and interoperability.

To conclude, we emphasize that interoperability in telemedicine is required, not only at low —medical devices data exchange— but also at higher levels —hospitals data exchange—, only then shall we see medical information communications, and consequent improvements in practice and safety of healthcare.

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