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DEVELOPMENT AND EXTENSION OF A MODULAR, JAVA-BASED, 2ND GENERATION ISO/IEEE 11073 MANAGER FRAMEWORK

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Abstract

For the purpose of establishing interoperability between personal health devices, the industry standard ISO/IEEE 11073 was developed and is being adopted by the Continua Health Alliance. Our core research area is the evaluation of interoperability standards in the field of medical devices in order to transfer data between medical systems in clinical settings. An ISO/IEEE 11073 compliant "manager" software was developed, which is needed to communicate with Personal Health Devices – referred to as "agents"(for example: blood pressure monitor, pulse oximeter). The developed "Healthy Interoperability Framework" (HIOFW) contains the ISO/IEEE 11073 compliant manager and modules to extend the capabilities of the HIOFW with IHE functionalities. The compliance with Continua certified products is another feature of the HIOFW. Communication can take place on the agent side via TCP/IP, USB and Bluetooth, on the other end of the communication line, modules can be included to export data using HL7 CDA, IHE XDS and to store data into database systems.

Keywords – ISO/IEEE 11073, IHE, Framework, CDA, HL7

1. Introduction

In the near future we can expect an increasing need for telemedicine and especially for the possibility to check the health status of many persons in an even shorter time than is now possible for hospitals and general practitioners. A new market is emerging, which will reach full operation in the next years [6]. The increasing number of chronic diseases like COPD, diabetes and cardiovascular diseases will need treatment in many different ways. Existing IT systems for healthcare are not fully capable to provide all the upcoming requirements and functionalities which users will be asking for. Improved telemedicine capabilities of IT systems can therefore help to maintain the same high level of service in the health sector that we are used to now, and hopefully improve it, by introducing new possibilities to help chronically ill people to improve their conditions. Our approach is to give users and care providers the possibility to gain more control over their health data, through the

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usage of our software. The Healthy Interoperability Framework (HIOFW) developed in this project can handle data from many different kinds of medical devices, designed for personal usage. For exactly this purpose the ISO/IEEE 11073 standard defines medical devices as "agents" and software which is capable of dealing with data from these devices as "managers". Typical agents are e.g. Blood pressure monitors, pulse oximeters. A typical manager might be installed on a PC, PDA or Smartphone. The HIOFW is also capable of analyzing the data which is being sent to it via TCP/IP, Bluetooth or USB through the integration of dedicated modules. The HIOFW is designed for usecases involving data collection from agents, analysis and integration into hospital information systems and other medical information systems. Wherever possible the data interchange needs to be maintained via internationally accepted standards like ISO/IEEE 11073, HL7 CDA and IHE profiles so that standardized and legacy systems in hospitals and other information systems, databases, or electronic health records can access and process the data in a flexible way and vendor independently. The first implementations of ISO/IEEE 11073 agents and managers at the University of Applied Sciences Technikum Wien took place in the year 2008, at that time a console program, transmitting temperature and weight values in a standardized format, written in ANSI C, and a knee-bend simulator (GUI in MatLab) were developed. In 2009 the console program was extended in C# and several functions, which are defined by the ISO/IEEE 11073 standard like persistent metric store and functions which are not defined by the standard like database storage options, were added to the functionalities of the developed agent/manager solution [3]. Since summer 2009 there was a huge effort to make the derived software platform independent by changing to a Java development environment. The current HIOFW is being designed to be adaptable for future extensions [4]. In a typical use case a person with a chronic disease always has an overview about his/her current health data. Hence, there is a need for devices which can transfer data in a standardized way so that flexible systems can be assembled easily from available components. A person with a cardiovascular disease could buy a weighting scale and a blood pressure monitor and combine these two devices with a software which is capable of dealing with both kind of devices. The standardization of the data makes it irrelevant which kind of device is sending the data, as long as it is conform to the standard. Afterwards, the data can be analyzed through specialized modules which can be even developed by multiple independent vendors. The overall aim of this approach is to be able to have a timely and complete overview of the medical data of a person, to provide detailed analysis options and to possibly generate hints on how to solve medical issues, to avoid further hospitalization - a definite benefit for the patient and also for the medical system.

2. Methods

The current version of the HIOFW is being developed in Java and is intended to be executable on PC, server and mobile platforms. Functions and features from former prototypes were added and extended. A complete new architecture for data handling within the HIOFW was established with the main focus on extensibility and modularity as shown in *Figure 1*. Each "module" is working independently within the framework. Modules may be inserted, removed and configured at runtime into the framework via plug and play. For example the X73 manager module is capable of handling ISO/IEEE 11073 data packets. For the exchange of data between the modules a new data structure called "data container" was created. The "kernel" of the HIOFW is the controller-module which is dealing with the automatic registration of each module after it has been installed in the HIOFW via plug and play. The controller is also in charge for the correct handling of the data container within the HIOFW between the exchanging modules.

The instances of the data container are being generated by the controller-module and exchanged through an interchange procedure across the whole HIOFW. Inside the container (see *Figure 1*), the

data is being held as ISO/IEEE 11073 data packets and in a refined way in plain text, extended with demographic information for an advanced usage with HL7 and other exporting modules.

Typically our HIOFW would run on a PC and take measurements from medical devices and store the data to a server sided repository. Some parts of the HIOFW could also run as an agent on Smartphones. The Smartphone platforms were explored for their interoperability capabilities through the development of agent simulating applications. On the iPhone an Objective C application was developed and deployed to generate ISO/IEEE 11073 data packets and to exchange these with the HIOFW. The Android platform was tested with a Java application in a similar way by exchanging data packets with the HIOFW.

There are two subprojects within our research project, maintained by students at the University of Applied Sciences Technikum Wien, Department of Biomedical Engineering. One of the projects is dealing with the design and implementation of hardware which is capable to interact with the HIOFW over Bluetooth, this hardware is also equipped with RFID technology to support the use-case of temperature measurement.

The second subproject is dealing with ambient assisted living [5], therefore with the sensorial assessment of movement data and the automatic analysis of behaviour patterns to facilitate the recognition of emergency situations for elderly people to allow a longer residence in their home environments.

3. Results

The 2010 Java HIOFW is capable of dealing with Continua Alliance [1] certified devices/agents via USB and Bluetooth. Other ISO/IEEE 11073 device agents have also the possibility to connect to the HIOFW via TCP/IP and Bluetooth. When an agent wants to connect to the HIOFW, the appropriate module for the desired communication line is being activated. The data packet communication takes place and the data container is being forwarded to the destination module.

On the other end of the communication line are the export modules which are capable of communicating HL7 CDA to hospital information systems or to ELGA. For other EHRs the IHE XDS is also part of the features of the newly derived HIOFW and also the database connections are well defined in an extended data structure.

The HIOFW has also functions to maintain audit trail and logging the data streams for security reasons.

4. Discussion

The diversity of systems in the health environment is very high and it is definitely a big challenge to introduce novel technology like the ISO/IEEE 11073 standard into clinical practice on a wider scale. Nevertheless it is absolutely mandatory to promote and develop standards to improve the quality of medical data interchange.

As a result of the work in this project until now the current data model of the HIOFW, i.e. the “data-container”, is functioning very reliable, this was verified through the connection of Continua certified standard devices to interchange data with our HIOFW. With slight adaptations it could

even serve as a possible pattern for a standard to deal with ISO/IEEE 11073 data within software products (modules).

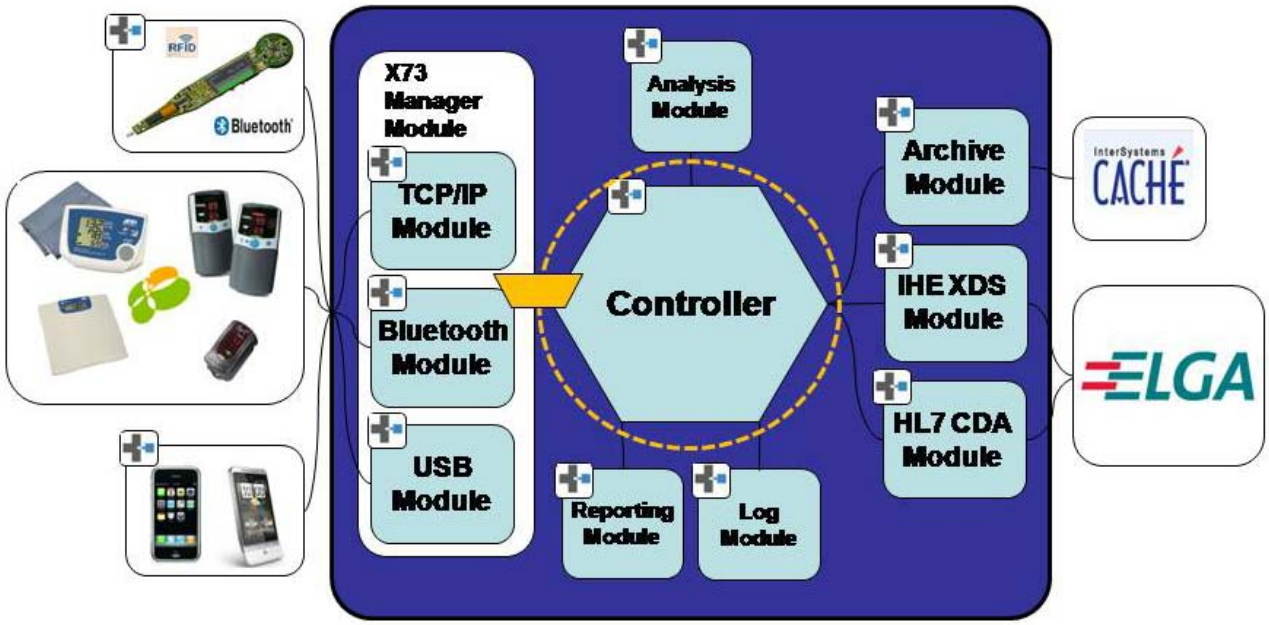

Figure 1: The Healthy Interoperability Framework, HIOFW (marked in blue), Data Container (orange figure), schematic circulation path of data container (orange dotted line), agent devices on the left, databases and electronic health records on the right

To safeguard the process of getting from individual pilot projects to industry projects a variety of different devices need to be available on the market. Only then individual and adaptive systems can be set up for several usecases. Individual consumers and developers need to be able to choose between different devices according to their needs and requirements. Until now the availability of Continua certified devices is limited to 5 device types. There is evidence that further devices will be certified soon, and some of them will reach the market in 2010. However device availability is still a limiting factor at this point in time.

The availability of a certification process by the Continua Health Alliance for newly developed devices is in itself a very valuable asset. It provides a means for users and developers to assure that a given device is indeed conformant to the standards, and that the resulting data can therefore be communicated and further processed with high reliability and low effort.

Not only the devices need to be available on the market but also vendor systems need to implement new services out of the distinct configurations of the medical devices. This is the key niche for our HIOFW: We intend to supply the industry with a software solution that helps to deal with incoming device data, for analyzing, storage and forwarding it to legacy and EHR systems - in a standardized format. Potential users of the HIOFW do not need to navigate the deeper technical details of the underlying standards. This functionality is already implemented as a software module within the HIOFW. Users of the HIOFW only needed to identify a service they want to offer to their customers, and add the necessary modules into the HIOFW. Modules can be provided by ourselves and also by partners.

In the coming year 2010 the initial development phase will be closed and a first version of the HIOFW will be released end of Q2 2010. Currently cooperation projects are in the planning phase, so that a dedicated application oriented development phase will follow in the second half of 2010. The first use cases are for management of chronical conditions in residential and mobile care organizations, for example chronic heart failure and diabetes. Great effort is also spent to actively contribute to building up a network of medical experts, industry, SMEs and other organizations. This network intends to further encourage the application of telemonitoring technologies in clinical practice by providing guidance on medical processes, quality indicators, legal issues, business models and cost-benefit considerations for this area.

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