Interoperability of Wearable Cuffless BP Measuring Devices

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Abstract—**While a traditional cuff-based Blood Pressure (BP) measuring device can only take a snap shot of BP, real-time and continuous measurement of BP without an occluding cuff is preferred which usually use the pulse transit time (PTT) in combination with other physiological parameters to estimate or track BP over a certain period of time after an initial calibration. This article discusses some perspectives of interoperability of wearable medical devices, based on IEEE P1708 draft standard that focuses on the objective performance evaluation of wearable cuffless BP measuring devices. The ISO/IEEE 11073 family of standards, supporting the plug-and play feature, is intended to enable medical devices to interconnect and interoperate with other medical devices and with computerized healthcare information systems in a manner suitable for the clinical environment. In this paper, the possible adoption of ISO/IEEE 11073 for the interoperability of wearable cuffless BP devices is proposed. In the consideration of the difference of the continuous and cuffless BP measuring methods from the conventional ones, the existing device specialization standards of ISO/IEEE 11073 cannot be directly followed when designing the cuffless BP device. Specifically, this paper discusses how the domain information model (DIM), in which vital sign information is abstracted as objects, is used to structure the information about the device and that generated from the device. Though attention should also be paid to adopt the communication standards for other parts for the communication system, applying communication standards that enable plug-and-play feature allows achieving the interoperability of different cuffless BP measuring devices with possible different configurations.**

I. INTRODUCTION

Hypertension, also known as raised blood pressure (BP), has been long recognized as a global public health issue, contributing to the burden of heart disease, stroke and kidney failure and premature mortality and disability [1]. Of nearly 17 million deaths a year caused by the cardiovascular disease (CVD), which is the first killer worldwide, complications of hypertension account for more than the half [1].

The BP measurement is fundamental for the prevention, prediction, diagnosis, and treatment of hypertension [2]. While a cuff-based BP measuring device can only take a snap shot of BP, continuous and real-time measurement of BP without an occluding cuff is preferred for the ambulatory, clinical, home remote monitoring of patients with CVDs in ubiquitous healthcare application. Continuous and cuffless BP measuring methods can usually be implemented using pulse transit time (PTT), which is a time period taken for the pulse wave to travel along the artery and arrive at the periphery, in combinations with other physiological parameters to estimate or track BP over a certain period of time after an initial [3, 4]. A practical test was carried on 85 subjects to evaluate this noninvasive and wearable BP measuring method [3]. The results are comparative to AMMI standards, which suggest that the cuff-less technology has great potential to be developed into wearable devices for BP monitoring [3].

Since the working principle of cuffless BP measuring device is different from the ones with cuffs, its operation method, error distribution and analysis, result evaluation, and calibration procedure are not totally conformed to the existing standards for conventional sphygmomanometers [5]. Therefore, IEEE P1708 draft standard for wearable cuffless BP measuring devices was proposed aiming at "providing guidelines for manufacturers to qualify and validate their products, potential purchasers or users to evaluate and select prospective products, and health care professionals to understand the manufacturing practices on wearable BP devices [6]". While the draft standard IEEE P1708 is mainly focusing on their objective performance evaluation, ISO/IEEE 11073 family of standards can be referred to in order to improve the interoperability of the cuffless BP measuring devices.

IEEE/ISO 11073 Personal Health Devices (PHD) Standards is a set of standards that specify nomenclature, domain models, service models, communication models and implementing models for medical device communication. The primary goals of the standards are to "provide real-time plug-and-play interoperability for patient connected medical devices and facilitate the efficient exchange of vital signs and medical device data, acquired at the point-of-care, in all health care environments [7]". Not long ago in November 2013, the U.S. Food and Drug Administration (FDA) recognized the IEEE 11073 PHD family of standards for medical-device communication [8], which acknowledged their usability to enhance interoperability of medical devices. By applying these standards to cuffless BP measuring devices with good performance ensured by IEEE P1708, interoperability can be improved not only to enhance the automatic connectivity of the wearable cuffless BP devices with other medical devices but also to reduce gaps and errors across the spectrum of healthcare system.

II. THE IMPORTANCE OF INTEROPERABILITY FOR CUFFLESS BP DEVICE

The design for wearable medical devices should consider their miniaturization, intelligence, networking, digitalization and standardization (MINDS) [9]. Aiming at miniaturization,

This work is supported in part by the National Basic Research 973 Program (NO. 2010CB732606), and the Guangdong Innovation Research Team Fund for Low-cost Healthcare Technologies in China.

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978-1-4244-7929-0/14/$26.00 ©2014 IEEE

measuring BP without an inflatable cuff is a big step forward. In addition, benefiting from advancement in materials, ultrathin and flexible sensors can be designed to collect physiological parameters [10], which make a promise for measuring BP based on PTT-related modeling by a sheet-thin sensor attached to the skin. But at the same time, the capabilities of the devices are limited to some degree, such as restricted process abilities and storage, small battery, fixed configuration. Therefore, by applying communication standards, the processing and storage task can be transferred from the terminal device to the manager with the architecture of mobile health (m-health) [11]. This is especially helpful to wearable cuffless BP measuring device because it requires more computing power to estimate BP using PTT-related parameters and more storage space for continuous BP data compared to the conventional snap-shot measuring methods.

In order to make better sense for CVDs predication and diagnosis, BP should be used combining with the accurate-correct understanding of the context data generating from other user terminals besides the cuffless BP measuring device. For example, an elevated BP can be normal under some circumstances (i.e. the user performs some physical activity) or can be anomalous if the patient is sleeping. In addition, a patient may be connected to one or more vital signs monitors which are required to work coordinately [12], like a cuffless watch-type BP measuring for the day time [13] and a bedside monitoring BP [14] at night. Thus, a stable and reliable communication mode allowing plug-and-play and wireless connections for the interactions between medical devices contributes to higher efficiency and effectiveness of seamless healthcare delivery [15].

In fact, IEEE 11073 PHD Standards has already defined several device specialization standards which give detailed communication directions for a certain type of medical device, including IEEE 11073 Part 10407: Device specialization — Blood pressure monitor [16]. However, IEEE 11073 Part 10407 alone is not enough for the cuffless BP measuring devices because they estimate BP through a model with multiple physiological parameters instead of conventional snapshot BP measuring method. For example, IEEE 11073 Part 10407, the metric object for BP is treated a numeric one, so the standard is not adequate to BP measurements taken by a continuous measuring method. Therefore, this paper will base on the existing device specialization standards of IEEE 11073 to depict the models of the cufless BP device for communication to enhance its interoperability.

III. DOMAIN INFORMATION MODEL (DIM) FOR CUFFLESS BP MEASURING DEVICE

The ISO/IEEE 11073 family is based on object-oriented systems that specify the structure of communicated information in form of managed object, as well as the events and services that are supported by each object [17]. An object-oriented model represents the relevant information (i.e., data) and functions (e.g., device controls) encountered in the problem domain of medical device communication, including measurement information, contextual data, device control methods, and other relevant aspects [17]. In this way, data and methods in the information objects can be accessed and manipulated using an object access service protocol and the elements contained in the model can be implemented by different technologies.

The entities like the vital sings communicating in the domain of the cuffless BP measuring device are abstracted as a set of objects with their attributes, and their methods in the DIM. Vital signs information objects that are defined in this standard encompass digitized biosignals that include direct and derived, quantitative and qualitative measurements, technical and medical alarms, and control settings [17]. These objects and their attributes represent the elements that control behavior and report on the status of the agent and data that an agent can communicate to a manager. The DIM proposed in IEEE 11073 Part 10407 is shown as in Figure 1. The DIM applies to conventional BP measuring devices, which just take BP reading discontinuously.

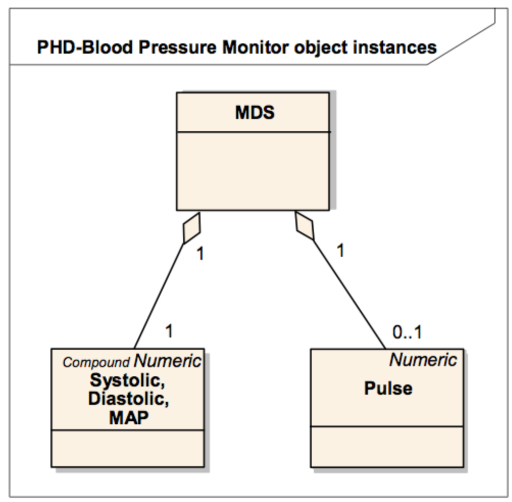

Figure 1. DIM of BP monitor in IEEE 11073-10407 [16]

Figure 2 is the DIM of cuffless BP measuring device. The Single Medical Device System (MDS) object is an abstraction of a device with only a single purpose, thus containing only a Virtual Medical Device (VMD). The cuffless BP measuring device here is assumed to be of a single intention to just measure BP, though in real applications it can also measure other physiological parameters like heart rate, SpO2, breathing rate and body temperature and so on. The outlined rhombus represents an aggregation relationship. Channel object in this model groups together physiological measurement data and data derived from these data which all deal with one thing. In most measuring principles of the cuffless BP measuring device, it utilizes ECG waveform and PPG waveform to calculate the PTT. Actually only one lead ECG signal is enough for comparison with PPG signal to get PTT samples. An initial calibration is performed to acquire a BP measurement using convention method and its corresponding PTT. Through an algorithm based on a model showing their correlation relationship and incorporating other physic and physiologic factors like arterial vascular properties and the subject's activities state, BP can be tracked over a certain period of

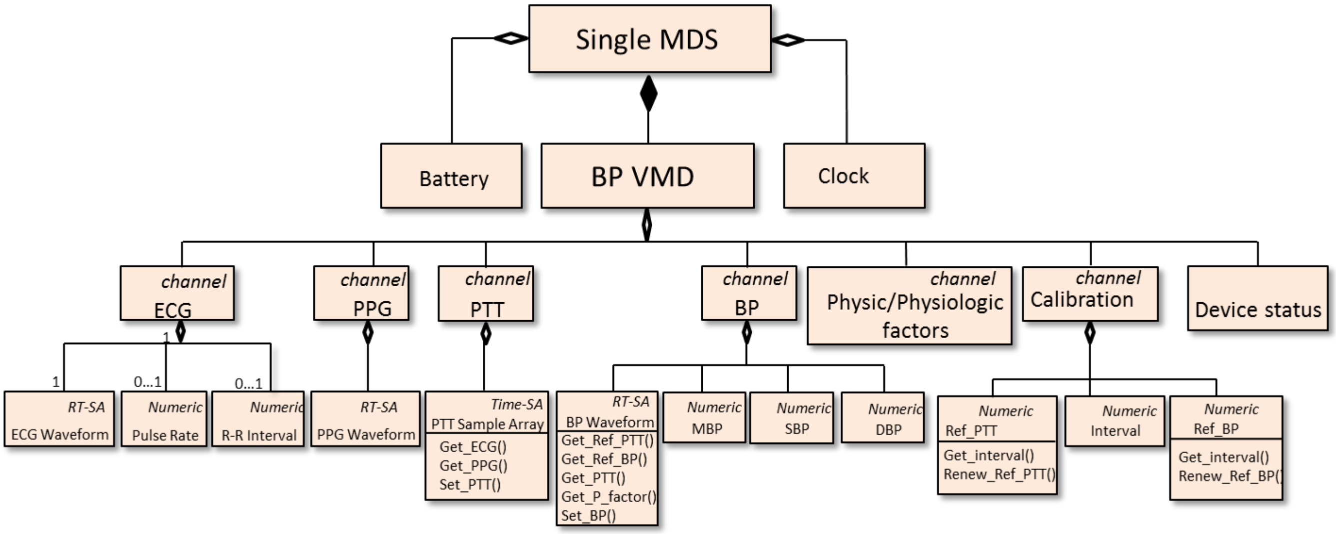

Figure 2. DIM of the wearable cuffless BP measuring device.

time. After the interval that is set according to the device properties and patient status, the calibration is carried out again and renews the reference BP and PTT for the next measuring period. As for calibration intervals, it may vary from one wearable BP measuring device to another incorporating multiple factors [18]. The device status enumeration object informs the user of events related to the device, such as ECG lead signal loss or low battery [17].

IV. Discussion

As above-mentioned, the specificity of the model for BP device results from the adoption of a different measuring method by incorporating multiple parameters to estimate BP from the conventional ones. Based on the working principles of the cuffless BP measuring device, this paper has described the design of DIM in which information are organized as objects to be communicated for interoperability.

In addition, conceptual communicating systems architecture is presented in Figure 3 where objects in DIM are treated as managed objects [17]. The applications use services provided by Common Medical Device Information Service Element (CMDISE) and Association Control Service Element (ACSE) [17]. The managed objects in the DIM can only be directly available to management (i.e., access) services from CMDISE which enables exchange of information, like retrieving object attribute value and so on [17]. The services are mapped to messages defined by the Common Medical Device Information Protocol (CMDIP). The ACSE offers services to establish logical connections between medical service systems. It can provide service primitives for requesting and accepting an association, releasing an association and accepting the release, association abort in case of a failure [17]. For the lower communication layers, data can be transmitted via different communication methods like Wi-Fi, Bluetooth and so on.

In summary, in the consideration of the difference of the continuous and cuffless BP measuring method from the conventional ones, the existing device specialization

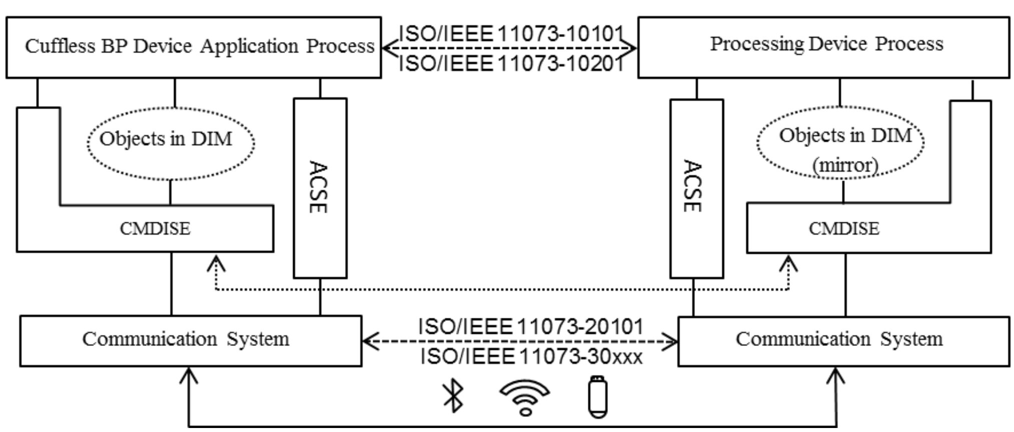

Figure 3. Conceptual Communicating Systems Architecture for Cuffless BP Measuring Device(*adapted from* [17])

standards cannot be directly followed for designing the cuffless BP device. This paper has described the object composition of the DIM to show the structure of the information generating from and relating to the wearable cuffless medical device. For future work, the model can be referred for designing the communication module of the wearable BP measuring device, thus enhancing its interoperability. And attention should also be paid other than this part when using the communication standards. When the cuffless BP measuring devices are equipped with a plug-and-play feature, the detection, configuration and communication between the devices can automatically proceed after users make the connection, which make the point-of-care medical system run properly and automatically even if there are replacements of medical devices.

ACKNOWLEDGMENT

This work is supported in part by the National Basic Research 973 Program (NO. 2010CB732606), and the Guangdong Innovation Research Team Fund for Low-cost Healthcare Technologies in China.

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