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ISO/IEEE 11073 PHD Message Generation Toolkit to Standardize Healthcare Device

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Abstract—**As senior population increases, various healthcare devices and services are developed such as fall detection device, home hypertension management service, and etc. However, to vitalize healthcare devices and services market, standardization for interoperability between device and service must precede. To achieve the standardization goal, the IEEE 11073 Personal Health Device (PHD) group has been standardized many healthcare devices, but until now there are few devices compatible with the PHD standard. One of main reasons is that it isn't easy for device manufactures to implement standard communication module by analyzing standard documents of over 600 pages. In this paper, we propose a standard message generation toolkit to easily standardize existing non-standard healthcare devices. The proposed toolkit generates standard PHD messages using inputted device information, and the generated messages are adapted to the device with the standard state machine file. For the experiments, we develop a reference H/W, and test the proposed toolkit with three healthcare devices: blood pressure, weighting scale, and glucose meter. The proposed toolkit has an advantage that even if the user doesn't know the standard in detail, the user can easily standardize the non-standard healthcare devices.**

I. Introduction

In aging society, the population of seniors and number of chronic disease patients are increased [1-2]. And, to effectively care these patients, many researches on healthcare devices and services are actively studied. For example, there are new devices such as fall-detection device to detect the fall situation of a senior, ECG device to detect an abnormal ECG signal, insulin-pump device to help diabetes patients, and etc [3-4]. And, using these devices, many healthcare services are developed such as well-being support service, home hypertension management service, and etc.

However, to extend usability of new devices and services, there is a problem should be solved, which is a standard compatibility. Until now, many healthcare device companies use their own data protocols. Therefore, they can't provide interoperability with devices of other companies. That is, to get a hypertension management service of a company, a user has to use a blood pressure device of that company. And because each healthcare device such as glucose meter and blood pressure device on the market has different and unknown data protocols, when a company wants to develop a glucose management service, the company also has to develop every component devices of its own. After all, such incompatibilities make it more difficult to grow healthcare markets, and it makes the standard more significant.

Recently, ISO/IEEE 11073 Personal Health Device (PHD) standards are established, and define communication protocols between healthcare devices and a health gateway [5-7]. However, currently there are few devices compatible with the PHD standards. The reasons are as follows: firstly, it has been short time since the PHD standards are established. And secondly, it isn't easy to understand and implement the PHD standards for healthcare device companies that have no standardization experience. To develop a standard healthcare device, they should read standard documents of over 600 pages carefully and analyze them. And, they need to develop an encoding/decoding scheme, ASN.1 data structures, communication messages, state machine modules, and etc., and it will take a long development time. Therefore, a new standardization method is needed to convert non-standard devices to standard-compatible devices more easily.

In this paper, we propose a PHD message generation toolkit to easily standardize existing healthcare devices. If a user inputs target device information to the proposed message generation GUI, the toolkit automatically generates the standard messages. And, the generated messages are adapted to the target device with the standard state machine file. Through this process, the target machine becomes a PHD standard compatible device. For the experiments, we develop a reference H/W, and test the proposed toolkit with three healthcare devices of blood pressure, weighting scale, and glucose meter. The proposed toolkit has an advantage that even if the user doesn't know the standard in detail, the user can easily set the device information, automatically generate the standard messages, and easily adapt the standard messages to the device.

This paper is organized as follows. The ISO/IEEE 11073 PHD standard is reviewed in section 2, and in section 3, the proposed toolkit is explained in detail. In section 4, we show the experiments of the device standardization. And then, we conclude the proposed toolkit in section 5.

II. ISO/IEEE 11073 PHD

ISO/IEEE 11073 PHD is the communication protocol standard between personal health device and healthcare

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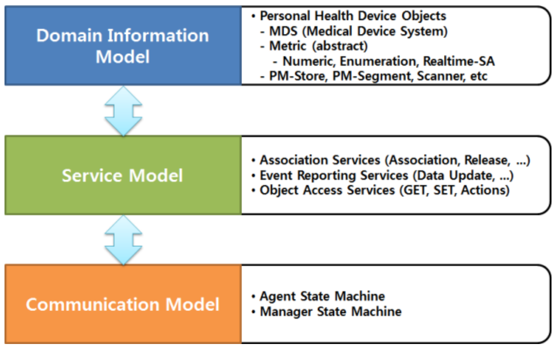

Fig. 1. The structure of 11073 PHD Standards

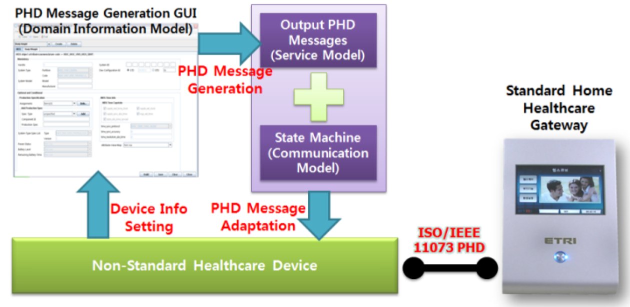

Fig. 2. The architecture of the proposed PHD message generation toolkit

gateway [8]. Usually, a personal health device (agent) is used in home and mobile environment, and has small size and low performance capacities of CPU, RAM, battery, and etc. Contrastively, a gateway (manager) such as Smart-Phone, PC, and etc., has high performance capacities than the device. Therefore, the standard is designed to put more burdens on the manager than an agent. The manager should process various devices and configurations, but an agent can select and use only one configuration to send measurement data.

The 11073 PHD standards are composed of Domain Information Model (DIM), Service Model, and Communication Model. The relationships of these models are shown in Fig. 1 [8].

Firstly, DIM represents information structures for health devices. The DIM has an object-oriented structure, and represents the device information using objects such as Medical Device System (MDS), Metric, Numeric, Enumeration, and etc.

The MDS object represents unique information of a device such as device manufacture, version, device type, and etc. All healthcare devices should have only one the MDS object.

The Metric object is an abstract class to represent measurement data of healthcare devices. It has Numeric, Enumeration, and RealTime-SampleArray (RT-SA) child objects. The Numeric object represents a numerical data. It has attributes such as measurement value, time, and value type, which indicate weight, temperature, and etc. The Enumeration is an object for event data such as device status change (i.e. measurement finish, measurement error, and etc.), fall detection, an irregular heartbeat, and etc. The RT-SA object represents waveform data such as ECG signal. It has waveform related attributes such as sample array, array size, count, scale/range variables, and etc. Generally, these objects are most widely used to standardize healthcare devices.

Secondly, the service model defines functions of device and gateway for standard communication. In the PHD standard, a function is defined as a message. More specifically, the service model defines standard communication messages such as association messages, device configuration report messages, GET and SET messages, measurement data update messages, release messages, and etc.

Lastly, the communication model is a message sequence protocol between device and gateway. The model defines state machines for device and gateway, and the device and gateway communicate messages according to each state machine.

Using these 3 models, the PHD standard defines communication method between a device and a gateway. The 11073-20601 base standard, named of *optimized exchange protocol*, defines these 3 models [8]. And additionally, there are 11073-104zz device specialization standards for specific type of devices such as blood pressure, glucose meter, pulse oximeter, and etc [9]. Currently, there are about 10 device specialization standards.

III. PHD Message Generation Toolkit

In this section, we explain a non-standard healthcare device standardization method using the proposed PHD message generation toolkit. The overall architecture of the standardization method is shown in Fig. 2. The proposed toolkit is composed of three phases of device information setting, PHD message generation, and message adaptation. And, each phase is corresponded to PHD domain information model, service model, and communication model, respectively.

A. Device Information Setting

A user inputs target device information to the PHD message generation GUI, then output PHD messages are generated for standard communication. An example of PHD message generation GUI is depicted in Fig. 3. The GUI is designed according to the DIM of PHD standard.

The usage scenario of the message generation GUI is as follows: firstly, a user selects a device specialization standard for the target device such as 11073-10415 *Weighing scale* standard. Then, the message generation GUI automatically adds measurement objects of the standard configuration. If the target device has additional measurement data, the user manually adds the correspondence measurement objects to the object list. And then, a user sets the device information to the MDS and measurement objects. The object setting GUI is composed of 3 parts of mandatory part, optional (conditional) part, and measurement data transmission part. In the mandatory part, there are object handle, measurement data type, unit, and etc., and in the optional (conditional) part, there are label string, accuracy, and etc. In the measurement data transmission part, a user selects a transmission format between fixed format and variable format. In the case of the fixed format transmission, a user defines transmission format

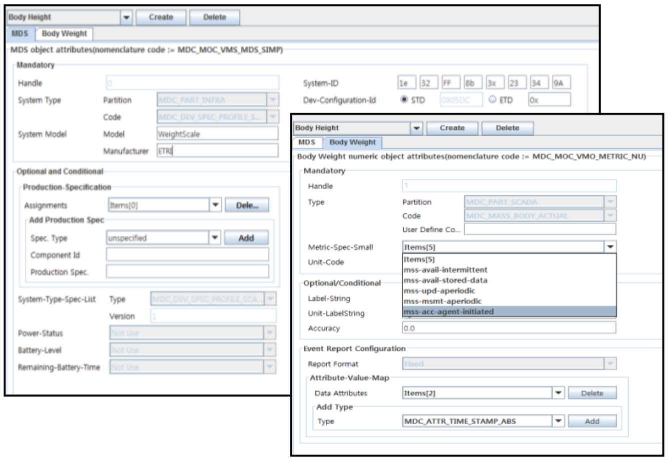

Fig. 3. Screenshots of PHD Message Generation GUI; left screenshot is a MDS object GUI and right screenshot is a Body Weight object GUI.

```
unsigned char report_request_hex_data[] = {0xE7,0x00,0x00,0x2A,
    0x00,0x28,0x12,0x36,0x01,0x01,0x00,0x22,0x00,0x00,0x00,0x00,
    0x00,0x00,0x0D,0x1D,0x00,0x18,0xF0,0x00,0x00,0x00,0x00,0x01
    ,0x00,0x10,0x00,0x01,0x00,0x0C,0xFF,0x00,0x01,0x72,0x20,0x07
    ,0x12,0x06,0x12,0x10,0x00,0x00};
unsigned char report_request_changeValue_1_attribute_1_code[] =
    {0x0A,0x56}; // MDC_ATTR_NU_VAL_OBS_SIMP
int report_request_changeValue_1_attribute_1_startPos = 34;
int report_request_changeValue_1_attribute_1_size = 4;
unsigned char report_request_changeValue_1_attribute_2_code[] =
    {0x09,0x90}; // MDC_ATTR_TIME_STAMP_ABS
int report_request_changeValue_1_attribute_2_startPos = 38;
int report_request_changeValue_1_attribute_2_size = 8;
int report_request_invokeId_startPos = 7;
int report_request_invokeId_size = 2;
int report_request_hex_length = 46;
```

Fig. 4. Sample of PHD messages generation of a weighting scale

by adding measurement attributes of the object.

For example, if a target device is a weighting scale, a user selects the 11073-10415 *Weighting Scale* device specialization [9]. As default, the MDS and Body Weight objects are added into the object list. If the target device can measure a BMI data, a user can add a Body Mass Index object, which is defined in the 10415 PHD standards. In the MDS object, a user inputs the device information of handle, system-id, type, device model, manufacture, configuration id, and etc. as mandatory information. And, as optional (conditional) information, it is needed serial number, h/w and s/w revision, time capacity, battery and etc. And then, a user inputs the Body Weight object information such as handle, object type, specification, unit-code, and other additional information. And, a user additionally inputs the measurement data transmission part of the Body Weight object. Commonly, it is most widely used that the fixed format transmission type, composed of measurement value and absolute time.

B. PHD Message Generation

The message generation GUI generates PHD message, which is defined in the service model of PHD standard. And, it supports template-based PHD message. That is, if there is a dynamically changeable value such as measurement data, the output message marks it as a dynamic range to support changing values in the device adaptation phase.

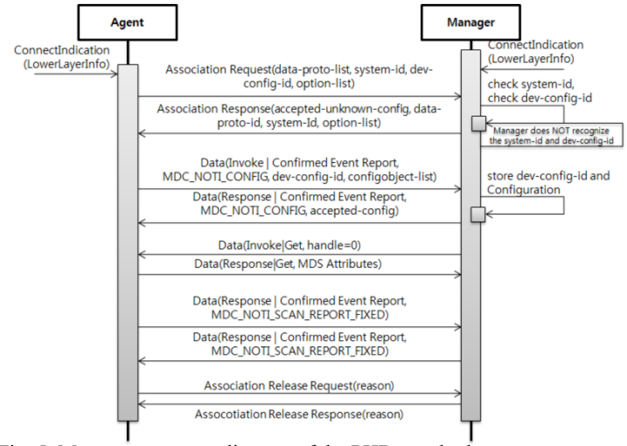

Fig. 5. Message sequence diagram of the PHD standard

The output PHD message is generated as a "c" source file format. It is composed of two variable types of *byte array* and *int*. The *byte array* variables represent PHD message body, which is a result of MDER (medical device encoding rules) [8]. And, *int* variables represent position and length of dynamic ranges such as measurement time and data, invoke-id, and etc. Fig. 4 shows the sample output PHD messages of the weighting scale of the previous section.

The generated PHD message covers all required messages for the standard communication. That is, it includes Association Services Messages (association request, release request, response, and abort messages), Event Reporting Services Messages (measurement data transmission, configuration, and response messages) and Object Access Services Messages (GET, SET, and Action messages). This approach makes the message adaptation module to be more independent with the message generation results.

C. PHD Message Adaptation

In this section, we describe a PHD message adaptation method for the target device, and this phase corresponds to the communication model of PHD standard.

To communicate with the standard gateway, a state machine of the PHD Communication Model is required. The proposed standardization toolkit provides master agent state machine file of the PHD standard. The master state machine file builds with the generated PHD message c file, and generates executable standardization file.

Fig. 5 shows a message sequence diagram of the PHD agent state machine. It operates in order of Association, Configuration, GET MDS, Data Update Event Report, and Release messages. Note that, the state machine sends the generated PHD messages, and analyzes OK or NOT-OK response using the generated PHD messages, as well. And, if there is a dynamic range of the source file, a modification of the state machine source code is required. For example, to adapt a real measurement data into the PHD message, a PHD message replacement code is required.

The measured health data which is transferred to the healthcare gateway is stored to the healthcare database and used for the healthcare services.

Fig. 6. Pictures of reference H/W

IV. Experiments

In this section, we describe non-standard device standardization experiments using the proposed toolkit. As experiment devices, we use 3 devices of weight scale, blood pressure, and glucose meter. All these devices are retail products, and we can't modify the hardware firmware of the retail devices. Therefore, we make a reference H/W to test the toolkit output. And, we generate PHD messages for each target device using the message generation GUI. Then, we build an executable file using the master state machine and the generated PHD message, and writing the executable file to the reference H/W ROM. Finally, we connect the non-standard health device and the reference H/W, and test it with the standard healthcare gateway. Based on these experiments, we verify the effectiveness of the proposed standardization toolkit.

A. Reference H/W

To connect with many different healthcare devices, the reference H/W is developed for general purpose. More specifically, it uses ATMega 1280V processor, and provides 14-pin connector for device connection, rom-writing port, debug port, and etc. And, to provide standard Bluetooth communication, it uses a Bluetooth module for HDP (Health Device Profile) [10]. The size is 6cm * 3.5cm. The picture of the reference H/W is shown in Fig. 6.

B. Home Healthcare Gateway

We use the standard home healthcare gateway for the compatibility testing of the proposed toolkit. The gateway is shown in the right side of the Fig. 2 [11]. It is compatible with the -20601 and -104zz PHD standards and continua guideline. It provides Bluetooth HDP and USB PHDC (Personal Health Device Class) communication-layer protocol [10],[12].

The gateway collects health records using the 11073 PHD standards, stores the records to the database, and visualizes the health records using the Senior GUI like Fig. 7 (b).

C. Standardization Example

To get a measurement data from the experimental devices, the 14-pin connector of the reference H/W is wired with devices. As health devices, A&D weigh scale (*UC-321PBT*), A&D blood pressure monitor (*UA-767PBT*), and glucose meter of All-Medicus (*AGM-3000*) are used.

The experimental result is shown in Fig. 7. The devices are standardized using the proposed message generation toolkit, and send standard health data to the gateway. The Fig. 7 (a), (c) and (d) show connection of reference H/W with the experiments devices, and Fig. 7 (b) shows the gateway GUI for measurement data transmitted through the proposed toolkit and reference H/W [11].

Fig. 7. Standardization of 3 healthcare devices using the proposed toolkit: (a) is a blood pressure monitor standardization, (b) is a measurement GUI result of the home health gateway, (c) is a weight scale standardization, and (d) is a glucose meter standardization.

V. Conclusion

In this paper, we propose a PHD message generation toolkit to standardize healthcare devices. It is compliant with Continua guideline. The proposed toolkit provides a GUI to easily set the target device information, and automatically generates template-based PHD standard messages. And, to support PHD communication model, it provides master state machine file. That is, the proposed toolkit can easily standardize healthcare devices without deep understanding of the PHD standards.

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