
APPLYING THE ISO/IEEE 11073 STANDARDS TO WEARABLE HOME HEALTH MONITORING SYSTEMS

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Yao J, Warren S. Applying the ISO/IEEE 11073 standards to wearable home health monitoring systems.

J Clin Monit Comput 2005; 19: 427–436

ABSTRACT. Objective. The goal of this effort was to investigate the feasibility of applying the ISO/IEEE 11073 (a.k.a. X73) standards, originally intended for bedside monitoring in hospital environments, to wearable, multi-sensor monitoring systems designed for home healthcare. **Methods.** The X73 upper-layer sub-standards (i.e., nomenclature specification, domain information model, application profiles, and vital sign device descriptions) were adopted and implemented on microcontroller-based sensor hardware to provide plug-and-play medical components. Three types of system elements (base stations, data loggers, and sensor units) perform the functionality required in this standards-based home health monitoring system and communicate using Bluetooth wireless modules. The base station incorporates a LabVIEW interface running on a personal computer. Each data logger and sensor unit is implemented on a microcontroller-driven embedded platform. Sensor units include wearable sensors (e.g., electrocardiograph, pulse oximeter) and nearby sensors (e.g., weight scale, ambient environment sensors). **Results.** The standards-based prototype system with an open architecture achieves plug-and-play performance suitable for a home environment. Each wireless element in the body/home area network can automatically detect other nearby devices, associate with them, and exchange data with them as appropriate. **Conclusions.** With minor modifications, the X73 standards can be successfully applied to wearable, wireless, point-of-care systems in the home.

KEY WORDS. Bluetooth, home health care, ISO/IEEE 11073 standards, plug-and-play interoperability, wearable embedded platform, wireless, X73.

INTRODUCTION

In 1982, researchers from academia and industry recognized the benefits that plug-and-play features would provide to medical devices used in hospital wards and operating rooms [1, 2]. They worked jointly to develop IEEE 1073 (a.k.a. the Medical Information Bus) [1–13], recently renamed ISO/IEEE 11073 (a.k.a. X73), a set of standards that specify nomenclature, an abstract data model, a service model, and transport specifications for interoperable bedside devices. 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 [14].” Significant progress in X73 development has been made in the two decades since the committee was formed [1, 2, 15–19]. Four sub-standards have been recently approved by IEEE [20] following the approval of the first sub-standard in 2000.

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Received 10 March 2005. Accepted for publication 30 June 2005.

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While this technical progress has been achieved with a goal of implementing the standard in acute care environments, little has been done to implement plug-and-play features into home healthcare equipment, where plug-and-play capabilities are more important due to (a) the variety of relevant system configurations, (b) an anticipated lack of professional caregiver assistance, and (c) the limited ability of the average patient to work with technology tools. The movement toward continuous monitoring systems (e.g., with wireless and wearable elements) further imposes a need for low-power, embedded, plug-and-play systems that utilize interoperability standards.

This project investigates the feasibility of applying the X73 standards to home health care environments and explores the technical issues regarding this migration, specifically when these applications incorporate wearable point-of-care technology designed for continuous monitoring. When the authors were researching candidates for medical information representation/exchange standards, the Chair of the X73 standards committee noted that “(although) the home health and community computing communications environment is different from that of intensive care units or emergency rescue,” the ISO/IEEE 11073 standard should be able to migrate to this application area because “the basic semantics of the devices remain the same [21]”. He also anticipated that a primary benefit of this work would be “extending the standards into some new areas that best demonstrate this class of devices and communication use cases [21]”. This extension to home care, when compared with hospital scenarios, includes applying the X73 standard to devices that (a) need to be wearable, (b) require more frequent association and release, (c) use off-the-shelf wireless communication technology (in this case, Bluetooth [22]), and (d) incorporate low-power, microcontroller-driven embedded platforms.

BACKGROUND

ISO/IEEE 11073 (X73) overview

The X73 standards define medical devices using the conceptual model shown in Figure 1, where system application processes use services (i.e., association control services and medical device information services) to establish associations with other devices and to access managed objects in the Medical Data Information Base (MDIB), which resides locally or on a remote device. Within this conceptual model, the X73 standards define a family of sub-standards that map to the full seven-layer ISO/OSI (International Standards Organization/ Open System Interconnect) model [23, 24]. Table 1 illustrates the relation-

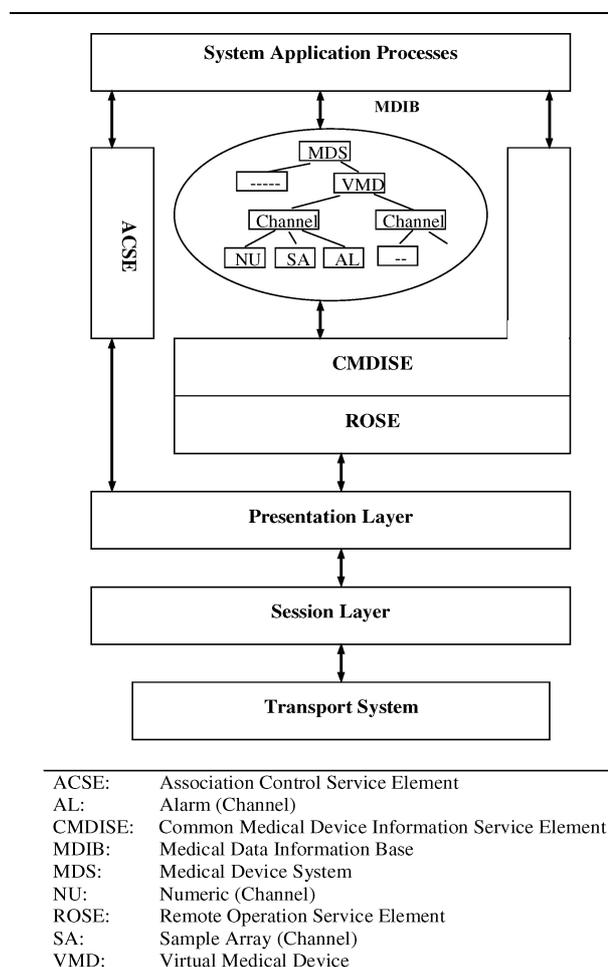


Fig. 1. Conceptual model for an X73-compliant medical device (adapted from [11]).

ship between the OSI reference model and the corresponding X73 sub-standards.

The X73 Application Profile (AP), sub-standard 11073-102xx [4], specifies protocols and services relevant to the upper three layers of the OSI model. In the Application layer, the ISO/IEEE 11073-10xxx sub-standards define a Medical Device Data Language (MDDL) which primarily consists of a nomenclature definition (11073-10101) [11], a domain information model (DIM) (11070-10201) [13], and specifications for general (11073-10300) and specialized (11073-1030x) medical devices [6, 8]. The nomenclature definition includes a data dictionary with unique terms and concepts needed for existing point-of-care medical devices and their data communications. The DIM defines a general, objected-oriented model to organize information and identify services.

The Transport Profile (TP, sub-standard 11073-30xxx) [5, 9, 12], defines protocols and services for connection and

Table 1. Relationship between the ISO/OSI layers and the X73 sub-standards

OSI layers	ISO/IEEE 11073 standards
Application	ISO/IEEE 11073-10xxx: Medical Device Data Language (MDDL) ISO/IEEE 11073-10101 MDDL Nomenclature ISO/IEEE 11073-10201 Domain Information Model ISO/IEEE 11073-1030x Device Specializations ISO/IEEE 11073-20xxx: Medical Device Application Profile
Presentation	In ISO/IEEE 11073-20101
Session	In ISO/IEEE 11073-20101
Transport	ISO/IEEE 11073-30xxx: Transport Profile
Network	ISO/IEEE 11073-30xxx: Transport Profile
Data link	ISO/IEEE 11073-30xxx: Transport Profile
Physical	IEEE 1073.4.1 Physical Layer; Cable-Connected Mode (Withdrawn)

message transport using existing IEEE standards. (Note: The IEEE P1073.4 sub-standard [10], which addressed the physical layer, was withdrawn in 2000.) Two sets of transport systems are defined in X73: cable-connected and wireless. The latter adopts the stack from the Infrared Data Association (IrDA) [25]. The AP and TP sub-standards are defined to be independent from one another. Therefore, the upper-layer sub-standards can work with transport systems other than those defined in the original X73 standard.

Two X73 devices communicate according to the agent-manager model in ISO system management. For example, an infusion pump (agent) may communicate with a bedside care system (manager) to which it is connected. A device can be an agent, a manager, or both, depending upon how the system is configured. An agent provides information in the form of medical objects; a manager interprets and acts upon this information. An agent and a manager use a device communication controller (DCC) and a bedside communication controller (BCC), respectively, to control dynamic behaviors in response to remote messages.

X73 optimizations driven by acute care needs

The X73 standards rely on existing international standards when possible. However, elements of both the lower and upper layers are optimized for acute care applications in

bedside environments [2]. Optimizations on the cable-connected transport profiles include multiple data rates, encoding methods, and clock acquisition. For example, instead of defining a single data rate for all applications, the standards support five data rates (9.6 kilobits per second (kbps), 19.2 kbps, 38.4 kbps, 57.6 kbps, and 115.2 kbps) to accommodate applications with different bandwidth requirements.

The upper layers, based directly on the ISO standards, increase overhead automatically because the ISO standards define features that are not needed by medical applications. After considering feedback from device manufacturers, the ISO/IEEE 11073 Committee simplified the X73 standards, which were too complicated and inefficient, in the following ways [2]. First, in 1994, X73 adopted the mOSI (“minimal OSI”), a subset of the OSI standards most often needed by implementers. With mOSI, 95% of the necessary application tasks can be accomplished, while overhead is reduced to 5% relative to the original X73 specification. The second upper-layer optimization was the design of its own encoding rules: the MDER (Medical Device Encoding Rules). The MDER supports encoding/decoding of “canned” messages: pre-encoded protocol data unit (PDU) templates with fixed length, where fields to be updated are located at known offsets. During run time, PDU encoding simply requires updating these field values. Additionally, the upper layers were simplified by use of the ISO “Scanner” object, which sets up message context conventions so that later messages can be much smaller in size.

Design considerations: Ambulatory home health care versus bedside care

Table 2 compares representative design considerations for an ambulatory home health monitoring system with those for a bedside monitoring system. These are roughly grouped by usage requirements (the upper portion of the table) and technical requirements (the lower portion of the table).

First, it is crucial to consider human factors when addressing usage requirements in the home. Home users consist of an extremely wide range of individuals: elderly residents, chronic patients of any age, pregnant women, high-risk infants, rehabilitation patients, and so forth. These individuals vary significantly in their ability to operate new devices, and most users will want their health monitored in such a way that they can continue to participate in normal daily activities such as shopping, mild exercise, and social gatherings. Additionally, these patients cannot assume that they will have immediate access to professional caregiver assistance when questions arise regarding device installation, operation, or troubleshooting.

Table 2. *Requirements comparison: home health monitoring versus bedside monitoring*

	Home health monitoring	Bedside monitoring
Usage Requirements		
Users	Elderly, chronic, wounded/ rehabilitation, or prenatal patients; infants	Seriously ill, chronic, rehabilitation, or maternity patients; patients with major injuries
Activity	Normal daily routine	Laying in bed
Measurements	Medical/non-medical, activity, and environment	Medical
Duration	Short term to long term (days to years)	Acute care (<30 days by definition)
Professional assistance	Not generally available	Available
Security	Required	Required
Technical Requirements		
Sensor/Device Mobility	Wearable or nearby	Stationary
Connection	Wireless	Primarily cable-connected
Size	Small	Desktop or smaller
Weight	Very light	Moderate to heavy
Power source	Battery	Wall outlet
Data exchange	Store-and-forward or streaming	Real-time upload
Computational capability	Limited	Available
Reconfiguration	Highly dynamic and frequent	Dynamic
Affordability	Critical	Less important
Human-machine interface	Easy to use, simple	More sophisticated

Continuous monitoring enables trend analysis and helps caregivers identify intermittent or infrequent symptoms. In many cases, continuous data collection both day and night is desired, and this continuous monitoring could last days, weeks, or even years. Moreover, clinical professionals can interpret the health status of a patient more appropriately if they have knowledge of patient activity and the conditions within which continuous data are acquired. Point-of-care monitoring devices from the home should be wearable (or nearby) and easily accessible. Nearby devices include ambient temperature sensors, weight scales, and activity monitors (e.g., floor sensors and drawer sensors). Devices that inhibit users' activities are unacceptable. Wearable devices must be wireless, low power, unobtrusive, and light. Furthermore, wearable devices are typically less computationally powerful than standard desktop devices and offer limited user interaction. These wearable devices should also be able to acquire and store health information prior to uploading these data for further processing and display. In other words, their fundamental mode of operation should be store-and-forward.

Finally, as mentioned earlier, access to professional assistance cannot be assumed in a home environment. This means that users must set up devices and execute device functionality themselves. Additionally, these systems will need to be configured dynamically. In some cases, differ-

ent family members may need different device configurations. A given user may need to reconfigure their devices periodically (e.g., prior to a bath, before bedtime, or before/after exercise). Therefore, ease of use is arguably more relevant in a home than in a hospital. Less required human intervention will result in greater product acceptance by users. To make this happen, devices must associate with each other without prior knowledge of one another's existence: devices should be able to announce their existence and introduce themselves to other devices, or devices should be able to discover nearby devices and obtain their device descriptions prior to connecting to them. These features are often referred to as "plug-and-play," which also implies little or no setup, system scalability, reconfigurability, and interoperability of products from different vendors.

To maintain the integrity of health information acquired in the home and to preserve patient confidentiality, point-of-care systems must incorporate security mechanisms such as user authentication and data encryption. Like plug-and-play features, the presence of security features will increase user acceptance of new technology. Vendor competition at the device level (which is facilitated by plug-and-play design) should help to lower device costs, further increasing patient acceptance and offering even lower costs due to economies of scale.

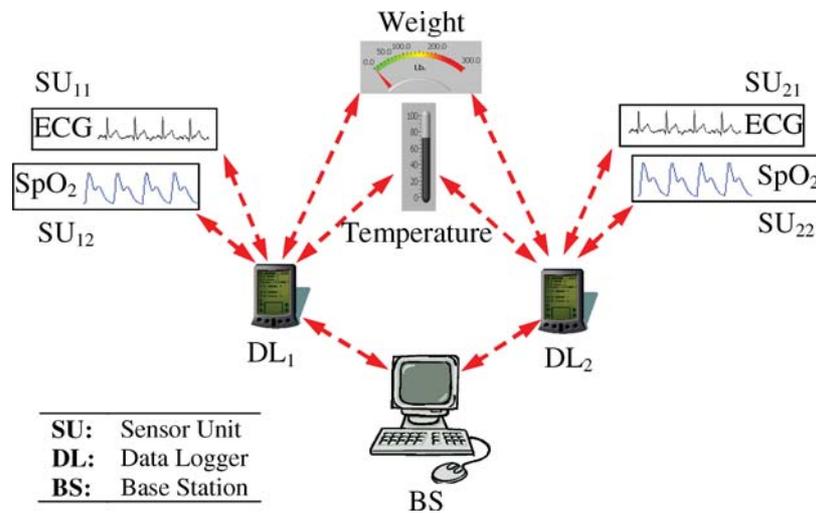


Fig. 2. Layout of a health monitoring system constructed with X73 components.

METHODS¹

As noted earlier, the goal of this effort was to develop a collection of wearable point-of-care components that continuously acquire, store, and upload physiologic and environmental data in a home care setting [26]. Home health monitoring tasks can be addressed by collections of components in three categories: (1) Sensor Units (SUs) – wearable or nearby devices that acquire physiologic information or other relevant information; (2) Data Loggers (DLs) – mobile devices that store a significant amount of user data before uploading these data to a monitoring station; and (3) Base Stations (BSs) – terminals that receive, process, display, store, and forward data uploaded by data loggers, primarily to remote clients over the Internet. A collection of these devices addresses the conceptual requirements in Table 1. Sensor units represent two classes of devices: wearable sensors that are owned by a single individual and nearby sensors (e.g., a weight scale, blood pressure cuff, or ambient temperature sensor) that can be shared by multiple users.

Figure 2 illustrates a system constructed with components from these three categories. A BS is installed in a living area. Each user wears a DL that associates with one or more SUs. The SUs upload their data to their respective DL, which in turn uploads these data to a BS. The number of DLs associated with a BS and the number of SUs associated with a DL are both scalable.

¹Work addressed in this paper that involves human subjects has been approved by the Human Studies Board at Kansas State University under protocols #2211 and #2686. Original approval was received on April 30, 2001, and the most recent approval, based on continuing review, was received November 4, 2004.

To accomplish plug-and-play behavior and interoperability between devices from different manufacturers, devices in the three categories are designed using the conceptual model in Figure 1. Within the context of the X73 standards, an SU is an agent that uses a DCC to control its transport system. A BS is a manager which interacts with its transport system through a BCC. A DL, working as both an agent and a manager, uses both a DCC and a BCC to communicate with its SUs and BS, respectively.

The system developed for this project follows the X73 upper-layer standards (ISO/IEEE 11073.1 and 11073.2) when possible. Upper-layer design considerations for devices in different categories relate to three areas: (1) managed objects in the MDIB, (2) application processes, and (3) communication controllers. The lower layers, as required by the use cases noted earlier, must embody a wireless transport system. The system developed here does not adopt the IrDA stack as defined in the standards, however, because infrared light is not well suited for ambulatory home care devices: (a) infrared transmission is directional and sensitive to light interference, (b) the transmission range (1 m) defined by IrDA is too short to be practical, and (c) the IrDA stack does not support point-to-multipoint connections. Bluetooth, a wireless communication protocol adapted from IrDA for radio-frequency (RF) data transmission, is instead used to provide lower-level connectivity and network maintenance. This new wireless technology is consistent with the power and functionality requirements in Table 1 and suits the application because of its transmission ranges (10 cm–100 m), interference immunity (it uses the frequency hopping spread spectrum technique), and protocols that support both point-to-point and point-to-multipoint communications.

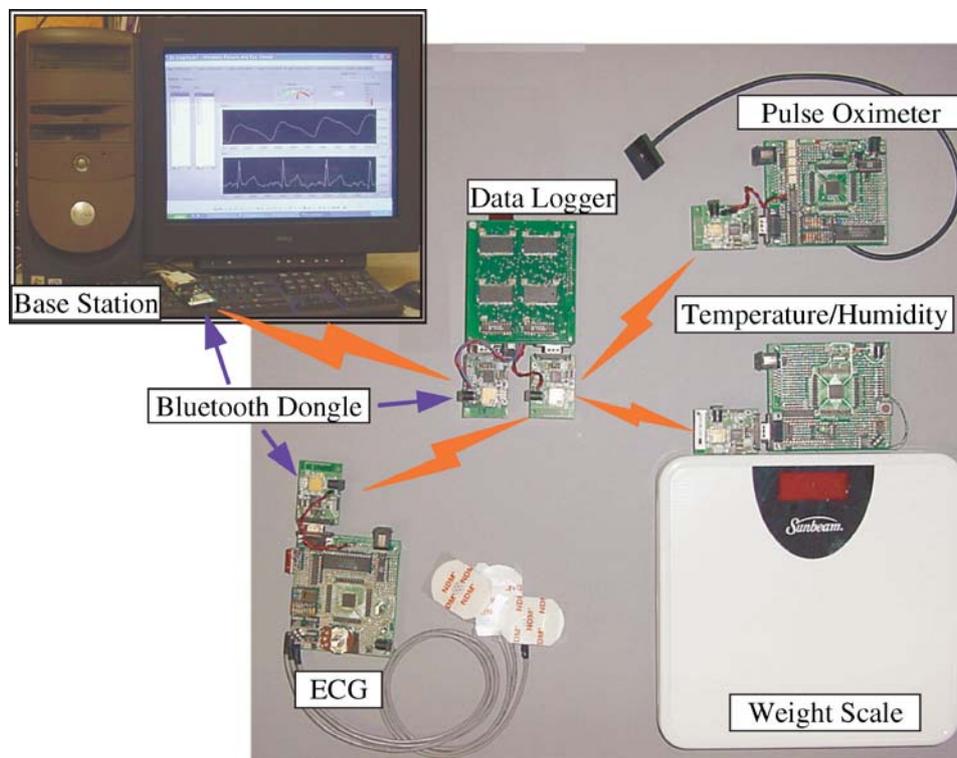


Fig. 3. Demonstration units for the three-tier home healthcare system.

Figure 3 illustrates the demonstration units, where the BS is implemented on a personal computer running LabVIEW. DLs and SUs are implemented on feature-rich PIC18F8720 microcontroller development boards to address the requirements of low power, small size, light weight, wearability, and low cost. BrightCom Callisto® II Bluetooth modules are employed; each BS and SU has a Bluetooth module, and each DL has two Bluetooth modules for communication with the BS and SUs, respectively. The microcontrollers and the personal computer interact with their respective Bluetooth modules over RS-232 serial ports.

RESULTS

X73-compliant components using Bluetooth wireless modules were constructed for this project. These components include a base station implemented on a personal computer, a data logger, and three sensor units: (1) a wearable, reflectance-mode pulse oximeter, (2) a wearable, 3-lead electrocardiograph, and (3) a weight scale (i.e., nearby sensor) that also has the ability to measure ambient temperature and humidity (refer to Figure 3). These components can form a health monitoring system dynamically. Because

of the system’s open architecture, devices can be added to the existing system as required. Bluetooth modules handle device detection, facilitate device connection, and maintain each link. Once a link exists, the device upper layers use it to continue the process of X73 association, configuration, and data operation between a given agent and manager. At the BS and DL levels, the X73 manager (Bluetooth master) moderates the dynamic configuration of its agents; it queries for new devices and decides which agents may connect. The system demonstrates plug-and-play performance: no manual setup is required, and the system is scalable. All interdevice interactions are automatic; none require human intervention.

Figure 4 shows two oscilloscope printouts that depict the interactions between a data logger and a pulse oximeter sensor. The process starts with a Bluetooth inquiry and connection, which is followed by X73 association and configuration. Once the association is established, periodic data uploads ensue. The waveforms in the upper picture illustrate the whole process, whereas the zoomed-in middle picture displays the details of the Bluetooth connection and the X73 procedures. Figure 5 illustrates the panels of the LabVIEW interface that track device connections/disconnections and present data acquired by the wearable and nearby sensors.

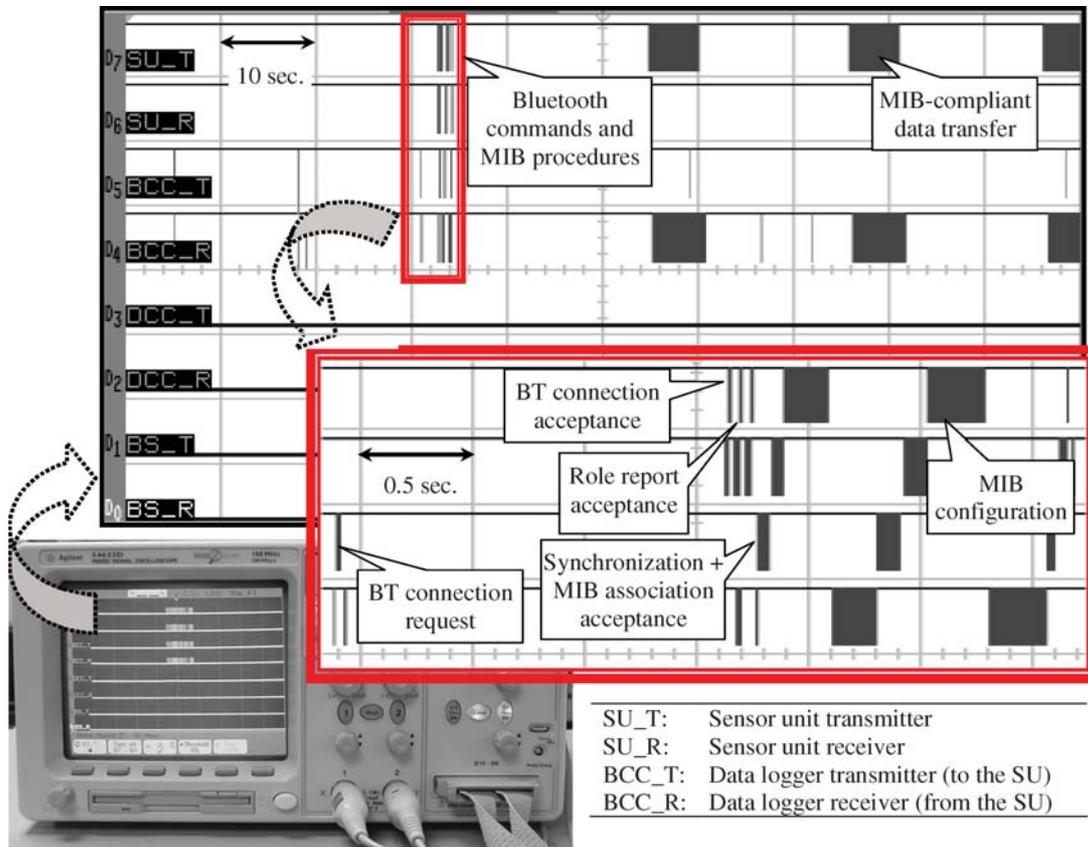


Fig. 4. Oscilloscope screens illustrating interactions between a sensor unit and a data logger, including Bluetooth (BT) commands, X73 associations, and data uploads.

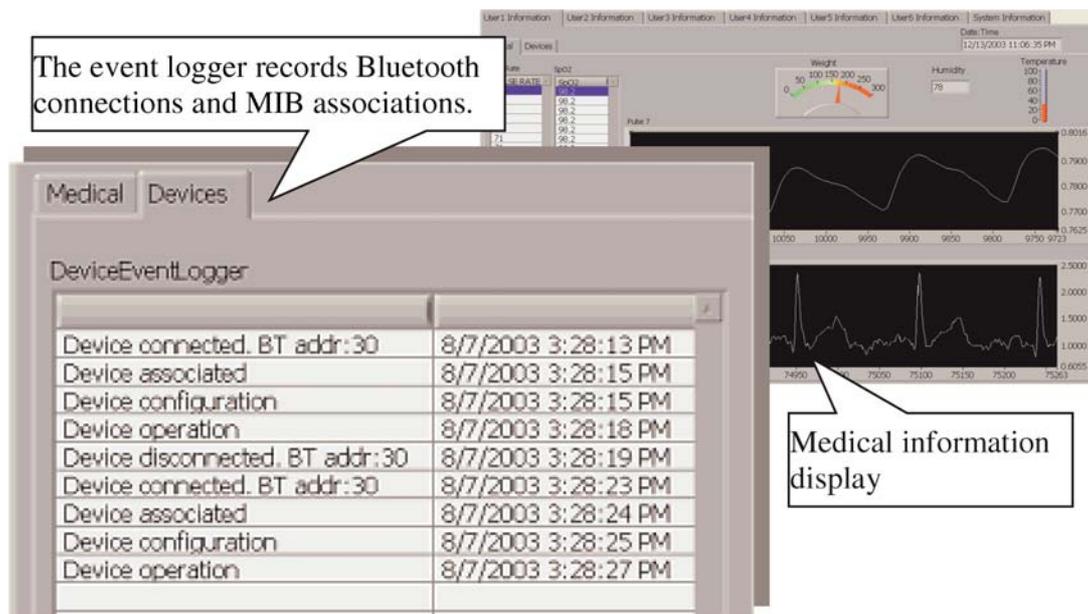


Fig. 5. A LabVIEW interface tracks device connections and displays sensor data.

In addition to these plug-and-play features, the system architecture, local storage, and wearable units allow a user to leave the range of the base station for up to 14 hours without data loss, which greatly improves patient mobility and is an important criterion for user acceptance of this new technology.

DISCUSSION

This effort demonstrates that the X73 upper layers, working with Bluetooth, can be successfully applied to home health monitoring systems that incorporate both wearable and nearby devices. Most of the X73 elements (the nomenclature, domain information model, syntax communication model, and services) map well to home healthcare systems that utilize embedded components. A monitoring system assembled from these components exhibits scalability, interoperability, and other plug-and-play features. However, this effort also identified limitations of the X73 standards when applied to ambulatory point-of-care environments. The primary limitations are driven by the following factors:

- A. microcontroller resource limits (e.g. memory, computational capability, and supporting tools),
- B. Bluetooth wireless transport,
- C. the three-tier system architecture, and
- D. store-and-forward data uploads.

The following paragraphs discuss the combined effects of these issues in more detail.

Simplification and service combination

When implementing the X73 standards on a microcontroller-based system, Factor A (microcontroller resource limits) requires the merging of layers and the combination of services. Traditional standardization via the ISO/OSI reference model partitions functionality into multiple layers and organizes services into groups. In the OSI model, service access is performed layer-by-layer, which requires nested function calls and consequently wastes clock cycles. An implementation that exactly follows this methodology is straightforward. However, service access increases run time and requires additional memory and battery power. In the implementation described here, functions are no longer layered and services are no longer grouped as in the ISO standards. Instead, a single collection of functions handles all the tasks defined in the upper-three layers, avoiding verbose layer-by-layer service calls.

Non object-oriented programming

The X73 standards were originally defined with an object-oriented programming (OOP) paradigm. While systematically documenting and organizing the medical domain entities as hierarchical objects is preferable, the OOP approach requires considerable hardware and software resources that are difficult for microcontroller-based systems to supply: as a result of factor A, OOP becomes impractical. A non-OOP implementation like the one utilized here must find alternative means to provide native OOP operations such as object inheritance and encapsulation. Moreover, this raises issues of system reconfigurability, which requires dynamic object creation/deletion in two scenarios: (1) when an agent creates or deletes objects (as required by its manager), and (2) when a manager changes its configuration (instantiates or destroys objects) to support dynamic association and release with its agents. The latter scenario speaks to an open system's scalability.

Static versus dynamic encoding/decoding

Again, because of factor A, designers should optimize computational functionality whenever possible. X73's "canned" messages (PDU templates with fixed lengths and changeable fields at fixed offsets) help to reduce the number of required computations for encoding and decoding. Most PDU templates are fully pre-encoded and saved in the program memory. During run time encoding, the processor copies the necessary template and modifies the changeable fields. Likewise, the decoder identifies the PDU by its first couple of bytes and extracts its data without fully parsing the message. This static encoding/decoding is, in fact, a major part of the function simplification process described earlier: the encoding/decoding of all three layers is completed once rather than layer by layer. Note that there are instances when PDUs cannot be fully statically pre-encoded. A DL's Context-Scanner-Creation-Event PDU has to be encoded during run time: the number and types of devices associated with the DL vary, and the PDU should report this dynamic configuration to a BS.

Packet length

Packet length, usually not an issue for data communication between cable-connected devices, becomes a concern due to factors B, C, and D. Bluetooth data transmission and reception occur in time slots of 625 milliseconds between two consecutive frequency hops. The maximum payload, limited by this time slot, is 339 bytes using Bluetooth's DH5 mode. This is inconvenient for two important reasons:

1. Due to factor D, the amount of stored data could be several megabytes, which far exceeds Bluetooth's maximum payload. Consequently, these data must be segmented and stored in small fragments at the onset (i.e., in the Application layer), even though the X73 object PM_Store [11] can store larger data blocks.
2. Most PDUs for setting up connections and associations fit into a single Bluetooth packet. However, a DL's Context-Scanner-Creation-Event PDU, which reports the DL's associated agents, could exceed the maximum length when multiple agents are connected.

In these cases, it is desirable for the X73 Session layer, which currently allows concatenation, to support PDU segmentation and reassembly so that big data blocks can be segmented into multiple smaller packets as required by Bluetooth.

Device synchronization

Factor D, store-and-forward data exchange, requires time stamps on data sets so that proper timelines are maintained for identifying adverse events. Device synchronization is required because multiple types of sensor data may contribute to state-of-health interpretation. However, clocks do not run on these embedded devices (Factor A). Additionally, frequent connections and disconnections due to Factor C complicate device synchronization. Finally, transmission time uncertainty due to wireless communication (Factor B) requires a specialized synchronization algorithm. In this implementation, device synchronization is utilized when a manager decides to continue interactions with an agent after a role check. In this instance, a DL obtains the time reference from its BS and sends this reference to its agents using the Simple Network Time Protocol as specified in the X73 transport profiles. Expedited services are preferred to minimize synchronization latency.

Device role

Due to Factor B (where a Bluetooth master can detect and connect to any slave device) and Factor C (where a BS is supposed to talk only with DLs but not SUs), a type of device role check must be defined to prevent undesirable interactions. Moreover, devices with different owners or devices designed for other application environments should not normally be allowed to exchange data for security reasons. Future X73 efforts should address the issue of checking the role of the connected device to deter-

mine whether to continue further communication. This role check would ideally be part of the *Association* stage, but in this implementation the role check occurs *after* a successful association since role checking rules of this nature are not supported in the current X73 standards.

Non-medical measurements

Non-medical measurements, while not directly related to the factors noted previously, are important elements of a well designed point-of-care system. Measurements like room temperature, barometric pressure, and humidity can help care providers to better understand and control a user's living environment. Non-medical sensors like gyroscopes and accelerometers can help to monitor patient gait and activity for applications such as fitness assessment and rehabilitation monitoring. Additionally, sensors embedded in the environment (e.g., strain gauges in the floor and switches on drawers, doors, etc.) can provide information about an individual's whereabouts and daily activities that can be correlated with physiological parameters to assess state of health. The inclusion of non-medical measurements would enrich the X73 nomenclature and domain information model; these parameters should be addressed by the committee in future revisions to the X73 standards.

CONCLUSION

Because of its focus on interoperability and its reliance on other industry sub-standards, the ISO/IEEE 11073 standards are well suited to the design of plug-and-play components that utilize Bluetooth as the transport system, where both wearable and nearby sensors provide state-of-health parameters. The X73 standards' nomenclature, domain information model, and application profiles should also be able to work with other emerging wireless communication technologies such as Wi-Fi (802.11b) [27] and ZigBee [28]. This issue is currently being addressed by the ISO/IEEE 11073-00101 Health Informatics Committee [29].

The ISO/IEEE 11073 standards committee is strongly encouraged to pursue adjustments to the X73 standards that facilitate their use in home environments. Additionally, the X73 committee should address changes to the standards that accommodate the needs of ambulatory monitoring systems: (a) incorporation of both wearable and nearby devices, (b) inclusion of most often used 'non-medical' sensors, and (c) efficient mechanisms that support time synchronization between wireless devices.

The authors wish to thank Mr. Todd Cooper, the Chair of the ISO/IEEE 11073 General Committee, for his invaluable consultation and for sample code he provided for this research. We also acknowledge Ryan Schmitz's contribution to the ECG and weight scale hardware. This work was supported by the National Science Foundation under grant BES-0093916. Any opinions, findings, and conclusions or recommendations expressed in this material are those of the authors and do not necessarily reflect the views of the NSF.

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