Medical Device Communication: A Standards-based Conformance Testing Approach

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Abstract
NIST researchers are collaborating with medical device experts to facilitate the development and adoption of standards for medical device communications throughout the healthcare enterprise as well as integrating it into the electronic health record. We have developed test tools and corresponding electronic representation of an international standard's information model that provides several important capabilities leading toward device interoperability. We describe a conformance testing approach which allows users to abstractly define devices via device profiles and implementation conformance statements. This information and tooling is subsequently used to provide syntactic and semantic validation of medical device messages according to medical device communication standard ISO/IEEE 11073.

Keywords: Conformance; Interoperability; Medical Device Communications; Testing Approach; XML; XML Schema.

1 Introduction

The reality that medical devices need to communicate with tens, if not hundreds, of other devices of varying makes, models, and modalities have large market and substantial healthcare implications. Acute point-of-care settings such as a hospital's intensive care unit, a patient's bedside, or personal telehealth location require each class of medical device to use the same terminology and data organization to seamlessly and reliably communicate physiological data. Healthcare communication standards that address plug-and-play medical device interoperability are critical.

NIST researchers are collaborating with medical device experts to facilitate the development and adoption of standards for medical device communications throughout the healthcare enterprise as well as integrating it into the electronic health record. We have developed test tools and corresponding electronic representation of an international standard's information model that provides several important capabilities leading toward device interoperability.

Conformance testing is a key step leading to, although not guaranteeing, interoperability[1]. Conformance test methodologies are presented which provide the medical device industry with tools to ensure that critical devices correctly implement the medical device standards. Correct implementation of standards lead to plug-and-play devices thereby allowing clinicians to focus more on the patient and less on the devices. The ability to reliably and effectively integrate data from a broad range of point-of-care devices will ultimately lead to a reduction in medical errors and the associated loss of life.

Central to our approach is an electronic data representation of the Standard's information model and tools derived from that electronic representation. This approach enables medical devices, through tooling, to be abstractly defined and validation of messages exchanged between actual device implementations. Further, by use of this tooling, devices can be specialized to meet particular implementation profiles that address specific workflow or use cases. Defining and applying constraints enables more thorough conformance testing thus leading to greater levels of interoperability assurance.

2 Medical Device Communication Standard

The ISO/IEEE 11073 Health Informatics – Point of Care Medical Device Communication standard (x73) defines a set of information objects and functions needed for medical device communication. Such a standard was developed to address the critical need of enabling medical devices to share physiologic data between devices and computerized healthcare information systems. Two primary parts of this standard used in our approach pertain to the *Domain Information Model* (DIM)[2] and *Nomenclature*[3]. The DIM provides the objects and object relationships necessary to abstractly define a device. It defines the overall set of information objects as well as the attributes, methods, and access functions which are abstractions of real-world entities in the domain of medical devices and device communication. Nomenclature defines terminology and codes used across classes of medical devices.

3 DIM XML Schema

We developed a DIM XML[4] Schema[5] (*XSchema*) which is an XML language (or metagrammar) for defining the syntactic structure and semantics of the XML document representing the x73 DIM. The *XSchema* supports the x73 DIM primary requirements of providing a detailed specification. An XML schema was selected as the technology employed to enable information modeling

capabilities while maintaining the integrity of the structure and vocabulary. The ***XSchema*** was created as a foundational component for developing the conformance test tools described below. The ***XSchema*** allows the use of information objects defined in the DIM in an automated fashion and is used to validate conformance claims set to address conformance requirements.

Features implemented in the ***XSchema*** to satisfy the requirements identified in the x73 standard include capabilities to:

- Represent common data types,
- Ensure DIM object definition (attributes, behaviors and notifications),
- Ensure containment association,
- Represent attributes/notification/behavior inheritance,
- Ensure object cardinality,
- Ensure term codes (Managed Objects, attributes, behaviors and notifications), and
- Allow for future extensions of the model.

NIST developed a tool based on the x73 DIM using the ***XSchema*** to provide the capabilities necessary to assure that manufacturers are defining the information required by the x73 standard. Furthermore, vendors may adopt this public domain XML schema to contribute to their own implementation development goals. Adoption of the schema into a vendor implementation information model maintains integrity of the structure and vocabulary as defined by the x73 standard.

4   Conformance Tools

Our ***ICSGenerator*** tool[6][7] enables users to produce XML *device specializations* that are a form of *device profiling*. Device specializations may be constrained (to the value level) to address more specific conformance testing. The ***ICSGenerator*** tool provides users an easy to use interface to shape, while maintaining compliance to, the Standard's information model by adding and/or removing objects; including the object's attributes, behavior, and notifications. The abstract representation of a device is created by a user, validated by the tool against the ***XSchema***, and saved in XML format. The resultant XML files therefore abstractly define a device which is x73 DIM compliant described using the x73 standard's nomenclature.

Users attempt to provide specific details about their device by issuing an Implementation Conformance Statement (ICS). The ICS is a form of data sheet that discloses details of a specific implementation and specifies which features are provided. The ICS provides a consistent means to describe device features spanning manufacturers or various makes and models. ICSs can effectively narrow the scope of device interfaces by defining supported features thus leading to a reduction (and ultimately elimination) of the need to

have unique interfaces for each connecting or communicating device. The ***ICSGenerator*** tool enables the user to easily produce automatically formatted ICSs that meet the requirements set in the conformance section of the x73 standard. Conformance statements, produced by device manufacturers and implementers, provide an effective way to increase the likelihood of communicating data correctly. Such statements, typically produced prior to actual communication, have utility as an early stage interoperability function.
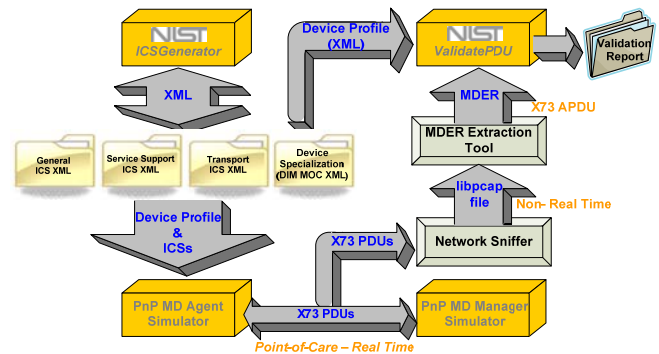

Figure 1: Medical Device Conformance Test Tooling Process Flow

Figure 1 (top left portion) shows ***ICSGenerator***'s output of several produced ICS statements ('General', 'Service Support', and 'Transport') and an XML device specialization (or profile).

The ***ICSGenerator*** also enables users to load and compare (previously saved) device profiles, generate object diagrams (i.e., UML[8] class diagrams of the derived profile), and automatically generate partial HL7[9] observation reporting segments (i.e., HL7 OBX-2 through OBX-7 segments).

We developed a second tool that validates exchanged medical device messages encoded according to the x73 standard. Syntax (i.e., the message structure) and low-level semantics (i.e., the message is within the constraints of the device profile produced by the ***ICSGenerator*** tool) are validated by our ***ValidatePDU*** tool[10].

The ***ValidatePDU*** test tool validates basic syntax and structure of medical device message protocol data units (PDUs) being exchanged. Information format is initially defined using a medical device data language in an abstract syntax, i.e., Abstract Syntax Notation One (ASN.1[11]). This information is then mapped to, and interchanged through, a transfer syntax, e.g., basic encoding rules (BER) and/or medical device encoding rules (MDER), typically for efficiency in the form of integers. We created a library that provides the encode/decode services to parse and validate the message exchanged. The library services were developed allowing for decoding of MDER/BER encoded

messages. The NIST *ValidatePDU* tool flags incorrect syntax and data type errors and produces a resultant validation report.

4.1   Medical Device Message Testing Approach

The *ICSGenerator* tool-generated device profile described above may also be used to configure devices. Configuration is typically performed on medical devices acting in an "agent" or "server" role. After association is established, the configuration information is propagated to medical devices acting in a "manager" or "client" role. General network sniffers are used to capture x73 encoded information, or messages, exchanged as PDUs. The application layer data is parsed out of the data stream to obtain APDUs (Application layer PDUs). The APDUs are encoded using a specific notation based on MDER and contain the medical device data we are interested in evaluating. The APDUs are input into the *ValidatePDU* tool and parsed to determine if the message exchanged has x73-compliant structure.

A second use of the *ICSGenerator* tool generated profile is to validate that the message being evaluated has content or semantics that meet attribute constraints defined by the user in the profile. The *ValidatePDU* tool highlights any syntax and object-level discrepancies and generates resultant validation reports.

Figure 1 shows the described process flow of using the *ICSGenerator* tool generated XML device profile and syntactic and semantic validation of x73 PDUs by the *ValidatePDU* tool.

5   Conclusions

Our approach of applying tools, based on an XML schema derived directly from the information model and nomenclature of the x73 standard, increases test comprehensiveness and quality and supports conformance testing leading to interoperability. Ultimately, these tools aid medical device manufacturers in achieving the primary goals established by the family of x73 Standards 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.

In addition to the approach presented above this methodology also provides invaluable feedback into the standards developing organizations as the information model is applied and implemented. Addressing issues or discrepancies as discovered through such tooling lead to comprehensive and correct standards which subsequently may enter the marketplace more rapidly. Correcting discovered errors or inconsistencies in the Standards and tooling greatly reduce, or eliminate, the chance of errors being propagated throughout manufacturer implementations. Additionally, the tools become more complete and correct as issues are discovered using this approach. Furthermore, by simply updating the XML Schema and configuration files, the *ICSGenerator* tool stays in compliance. Saved device profiles (output from *ICSGenerator* and complying or validated against a prior version of the Standard [schema]) can be reloaded into the tool and re-evaluated to ensure compliance to the most recently approved version.

Currently, within the personal health device domain, new normative additions to the x73 Standard are being proposed[12][13][14][15][16][17][18][19][20] and produced to address and optimize additional devices (for device specializations including pulse oximeter, blood pressure monitor, thermometer, glucose, cardiovascular and strength fitness, and independent living hub). The proposed information model in those additions can be modeled using our tooling - thus leading to more accurate standards prior to being approved and used. Thus more accurate and consistent implementations are made available further increasing the likelihood of interoperable solutions.

NIST also continues to actively participate with the on-going work of the Integrating the Healthcare Enterprise - Patient Care Device (IHE-PCD) domain and IEEE Personal Health Device working groups. This work strives to advance x73-based device information into HL7 observation messaging formats as well as enhance the tooling described above to meet industry conformance testing needs. The XSchema described has been accepted to become a normative part of the x73 standard (*P11073-10202 – Standard for Health informatics – Point-of-care medical device communication – Domain information model (DIM) – XML schema format*).

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