NIST
Medical Device Communication Testing
Semantic interoperability of Medical Devices

Test Tool Update
Joint HL7 HCD & IEEE 11073 @ San Antonio, TX

John J. Garguilo
National Institute of Standards and Technology
17 January 2017 – San Antonio, Texas
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NIST MDC Testing Staff

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- **Nicolas Crouzier** (Contractor-Dakota) + Ismail Mellouli (GR)
  - RTMMS,
  - HL7 V2 Tools

- **Michael Faughn, Jan Wittenber** (Contractors - *Prometheus Computing, LLC* w/ Art Griesser)
  - DIM Modeling + “DIM Editor/Medical Device Profiler”

- Note: As part of US Federal Government, all NIST work products are freely and publically available
Key Discussion Topics

- Work Area & Status Updates
- HL7 V2 IHE-PCD Tooling Status & Updates
- DIM Editor work updates, tool review, discussion topics
Conformance Tooling Suite

- HL7 V2 (2.6) IHE-PCD Validation Tools
- Rosetta Terminology Mapping Management System (RTMMS) [https://rtmms.nist.gov](https://rtmms.nist.gov)
- DIM Work - ‘DIM Editor/Profiler’ and ISO/IEEE 11073 UML Model
  - Development Tool: [dim.prometheuscomputing.com](http://dim.prometheuscomputing.com)
- NIST HL7 V2 Portal: [http://hl7v2tools.nist.gov/portal/#/tools](http://hl7v2tools.nist.gov/portal/#/tools)
  - IGAMT – Implementation Guide Authoring Management Tool
  - TCAMT – Test Case Authoring Management Tool
Work Areas & Status Updates

**HL7 V2 (2.6) IHE-PCD Validation Tools**

- IHE-PCD Pre-Connectathon, “Isolated Environment”

- IHE-PCD Connectathon, “Instance Environment”

- Enhancements to Pre-Connectathon, Connectathon Tools to support IHE-PCD Cycle 11; mainly CPs

- **Key test events**
  - Supported IHE-Europe Connectathon (April 2016)
  - Supported IHE-Korea Connectathon (Aug 2016)
  - Supported IHE-Japan Connectathon (Sept 2016)
  - Cycle 11 - CP updates coded for 2016-17 (mainly from IHE-PCD);
    → Presently: Fall/Winter ’16-’17 Pre-Connectathon + Virtual Testing
    → **Next week** - January 23-27 2017 Connectathon
  - IHE Europe – May 2017
  - (New) IHE Australia – August 2017
2016-17 IHE-PCD Pre-Connectathon Tool: Cycle 11 Status, continued

- **141** existing User Accounts (as of 16 January 2017)
  - Contributing Orgs, SDO (leads/Co-chairs), Reviewers
  - In total since tool made publically available (2011)

Recorded or stored by NIST tool registered user

- **Cycle 11**: 14 Users, 95 Tests Executed/Stored
  - 13 Unique Companies
- **Cycle 10**: 17 Users, 124 Tests Executed/Stored
- **Cycle 9**: 17 Users, 106 Tests Executed/Stored
  - Recorded or stored by NIST tool registered user
- **Cycle 8**: 22 Users, 115 Tests Executed/Stored
- **Cycle 1-7**: 42 Users, 99 Tests Executed/Stored*
  - *Cycles 1-7 not all test were stored in tool – 99 tests are primarily from cycle 7
Work Areas & Status Updates

2016-17 IHE-PCD Pre+Connectathon Tool: Cycle 11 Status

• IHE-PCD: NIST “Isolated Environment” Test Tools
  – HL7 V2.6
  – Supports 8 Integration Profiles (number of test cases, some duplicated amongst actors)
    • DEC – Device Enterprise Communication (10)
      – SPD – Filter (4)
      – POI – Pulse Ox (3)
    • PIV – Patient Infusion Verification (9)
    • IPEC – Infusion Pump Event Communication (6)
    • IDCO – Implantable Device Cardiac Observation (4)
    • ACM – Alert Communication Management (2)
    • RDQ – Retrospective Data Query (1)
    • MEMDMC – Device Management Communication (1)
    • MEMLS – Location Services (1)
    • OMS, RTLS/CMS, Security white papers/WGs

• 64 Test Cases {31 Unique} (across all ‘Actors’)
Rosetta Terminology Mapping Management System (*RTMMS*)
ISO/IEEE 11073-10101

- **RTMMS Deployment Update and service status**
  - 10101b Work underway, 10101c (future TBD)
  - 10101a added + harmonized co-constraints (e.g., units, enums, body sites): 240 new terms added winter 2015/16! 358 LOINC mappings to MDC terms
  - IEEE Agreement to make available the “Works” (5 key nomenclature attributes)
  - Latest numbers…
RTMMS by the numbers; as of 17 January 2017 (@San Antonio WG Mtgs)

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Terms being or to-be vetted
(“Term Approval” tab for ‘SDO’ user)

- “Proposed Terms”: 185
- “Ready Terms Table”: 79
- “Mapped Terms”: 79
- “Proposed Units”: 188
- “Proposed Enumerations”: 178
• ISO/IEEE 11073 ‘Domain Information Model Editor’ -> “DIM Editor”
  – Progress/Update/Status (Michael Faughn)
  – UML Defined 11073-10201 DIM basis for tooling
  – Issues list (actively/weekly addressing and resolving)
    » Tool continues to improve performance and usability
  – DIM Editor tool – Medical Device subject matter experts wanted!
  – Auto producing ISO/IEEE documentation (to meet SDO’s templates)
    • No major hurdles – from IEEE and w/ document generation
    • Michael provided a sample – Kathryn B. circulated w/in IEEE and accepted
  – Continue weekly TCons (Thursdays @ 2 pm Eastern) – all welcome!

❖ Michael returns from travel in February 2017
Work Areas & Status Updates
Implementation Guide and Test Case Tools

http://hl7v2tools.nist.gov/portal/#/tools

- IGAMT – Implementation Guide Authoring Management Tool
- TCAMT – Test Case Authoring Management Tool
  - *Currently being used for MU domains* (e.g., Lab, Immunization, Syndromic Surveillance)…
  - *Development work underway on IHE-PCD HL7 V2 Messages:*
    - PCD-01 (ORU^R01) + PCD-03 (RGV^R015)…
  - *Initial Goal: Develop first version of IG for PCD-01 (TF Vol. II)*
    - Focus on IHE-PCD TF Vol. II/III (+ IHE-PCD test cases in TCAMT)
    - Base device profiles
  - *Contributing to CAsC ‘Virtual Machine’* (conformity Assessment ISO 17025)
    - TCAMT focus on relatively small number of CAsC Identified Test Cases (presently from IHE-PCD, cycle 10)
  - *Begin producing IGs for device baseline profiles/specializations*
• Underlying ‘Framework’: HL7 profile → IGAMT → TCAMT → Tool
  – “Resource Bundle” generated to automatically update tool instance
  – Developed initial version of PCD-01 (ORU^R01, ACK^R01) and PCD-03
    (RGV^O15, ACK^O15)… additional constructs (e.g., support of “conditionals”
    such as OBX-2 [Value Type] and OBX-5 [Observation Value] in development)
  – Initial Goal: Develop first version of IG for PCD-01 (TF Vol. II)
    • Focus on IHE-PCD TF Vol. II/III
    • Continue to grow IGs for Volume IIIs (Device Specializations)
• New Conformance Book just released by publisher

• Authors:
  – Rob Snelick (NIST)
  – Frank Oemig (HL7 – Germany)
  – CGIT HL7 WG co-chairs

• Available through Springer (order form at HL7 Registration Desk)
Yes!

Conformance *IS Hard Work*

- 700+ pages
- ~3 inches thick
- Good educational source
- HL7 (v2) focus
Meetings + Activities: past, on-going and future

• Weekly “DPI” Meetings on Thursdays @ 2pm (w/ Jan Wittenber)
• Joint HL7 HCD / IEEE 11073 WG Mtgs., San Antonio, TX
• IHE North American Connectathon, Cleveland (23-27 Jan 2017)
  – NIST Connectathon Tool used for static validation
    – John G., Nicolas C., Ismail M., and Sandra Martinez serving as test monitors
    – John G. to participated (“Staff”) in IHE’s education series (“Connectathon 101”)  
      – presented session on how PCD tests…
    – NIST’s IHE-PCD V2 Tool Tutorial
      (recorded fall 2015 for cycle 10 – on IHE wiki)
• HIMSS’17 – Orlando (Feb.2017)
• NIST supporting IHE CaSC effort by providing PCD tooling
  – Validation tooling to be part of CaSC “Virtual Machine”
• Next IHE-PCD F2F: Next: Spring 2017 (location TBD)
  – Most recent, Boca Raton (Oct 2016)
2017 Work Plans

• IHE-PCD Cycle 12 (2017-18)
  – New HL7 V2 Tooling framework (same functionality and execution)
    ➢ Generate tooling from resource bundle (files output from IGAMT and TCAMT)
  – Test Cases/demographics reviewed – used as basis for tooling 2017-18
  – CPs as introduced + requirements added into tooling
    (see PCD wiki: http://wiki.ihe.net/index.php?title=PCD_CP_grid)
  – Consider ACM WCTP validation service (from TF Vol 2)
  – Continue to support IHE (Inter)National Test Events
  – Roadmap of activities updated… see PCD wiki
RTMMS Technology Update
(Coming soon – Winter/Spring ’17)
• Updating tool (interface and dBase)
• ‘AngularJS’ for the front end (user interface).
• ‘Node.js’ for the backend and MongoDB for the NoSQL database.

Terminology Additions Continuing…
• 10101a (~240 terms) + co-constraints

Informational Update
• MDC / LOINC mappings view (i.e., tab in interface)
  – 358 mappings, more coming… added as provide to NIST
2017 Work Plans

• DIM Editor/Profiler 11073-10201
  → Build library of template ‘Device Specializations
  → Complete PHD capabilities
  → Deploy on NIST server

• Near term work:
  – PHD profile functionality working as well as PCD profiles
  – Address the performance issues
  – Freeze features

• Next Steps (after freeze)
  – Generate camera ready IEEE standard in MS Word
  – Redesign application for reusable profiles
  – Resolve critical issues on “Revisions & Comments”
  – See Michael Faughn’s slides
• DoF Validation Service
  – Evaluating and researching FHIR validation services
Thank You or your attention 😊

- Questions
- Discussion
HL7 V2.6 Validation Tooling
IHE-PCD Pre-Connectathon Cycle 11

Semantic interoperability of Medical Devices

Test Tool Update
Joint HL7/IEEE 11073 Healthcare Devices Working Group

National Institute of Standards and Technology
17 January, 2017 – San Antonio, Texas
Contact: john.garguilo@nist.gov, 301-975-5248
Testing Environments

• **Instance Testing**
  – Conformance (e.g., against HL7 2.x or CDA)
    • Test object conforms to specification on which it is based
    • IHE Model: ~Virtual and Pre-Connectathon
    • NIST IHE-PCD v2 Message Validation Test Tool

• **Isolated System Testing**
  – Includes *Instance Testing* Activities
  – Protocol Conformance
  – Functional Behavior Conformance
    • Features and operational behavior correspond to specifications
    • IHE Model: ~Virtual and Pre-Connectathon
    • NIST IHE-PCD v2 Test Tool

• **Peer-to-Peer System Testing**
  – Includes *Isolated System Testing* Activities
  – Interoperability Testing
    • Testing complete application environment
    • May include interacting with Database, using Network Communications, or interacting with other hardware, applications, or systems if appropriate
    • IHE Model: ~Connectathon
The NIST V2 (2.6) Tools perform the following validation:

- Syntax and Semantic Content Validation
  - Against HL7 conformance profile
  - Against IHE-PCD Technical Frameworks/Supplements constraints (e.g., PCD-01: ORU^R01, Communicate Device Data)
  - Against HL7 and/or user [local] provided tables
    - Example of user provided table is RTM for Ref_IDs, Units, body sites, etc.
  - Against ‘validation context’, including specific values
    - Defined in XML (e.g., specific test case values)
NIST V2 HL7 IHE-PCD Test Tool: Operational Process

INTERACTION/REPORTS

MANUAL OR AUTOMATED SUT

END-USER (VENDOR)

Web Application Interface

MESSAGES (TEST OBJECTS)

NIST IHE-PCD HL7 v2/v3 TEST TOOL

(System UNDER TEST (SUT)

STIMULUS OR RESPONSE (MESSAGES)

NIST IHE-PCD HL7 v2/v3 TEST TOOL

(web application protocol currently only MLLP)

SPECIFICATIONS
(test material that defines test assertions)

V3 – Future Work
• Cycle 11 - Test Cases/demographics reviewed – used as basis for tooling at 2017 NA Connectathon

• IHE-PCD F2F Meetings
  – Oct 10-14, 2016 @ Boca Raton, Fl.
  – April 18-22, 2016 @ San Diego, Ca
  – Oct 20-23, 2015 @ Philips in Boca Raton, Fl.
  – Apr 27 – May 1, 2015 @ San Diego, Ca

• IHE-PCD Cycle 11 Pre-Connectathon

• CPs documented and submitted (see PCD wiki)
  – All Cycle 11 CPs (to date) received and processed: [http://wiki.ihe.net/index.php?title=PCD_CP_grid](http://wiki.ihe.net/index.php?title=PCD_CP_grid)

• Roadmap of activities updated… see PCD wiki
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HL7 V2 Tool Updates – New/In Progress

☑ Various test cases corrections (messages examples, validation contexts…) – Update to reflect updated TF

☑ IPEC containment tree validation tested; integrated into tooling as of Cycle 9 (summer 2014)

☑ Pre-Connectathon tool, fixed test case scenarios and validation files for DOC-DOR-DOF test cases.


☑ Limit of 999 for HD-2 length error on MSH-3
  – Should be 199 with total length of 277 for combined length of components
  – Updated TF-2 table (page 140, table C.6-1, second component (999) to 199)

☑ Updated tool to fix error on OBX-3 validation
  69986^MDC_DEV_PUMP_INFUS_VMD^MDC
HL7 V2 Tool Updates, continued

PRE and Connectathon tools:

✓ [PRE & CON] Validate EUI-64 and/or DNS (MSH-4)
✓ [PRE] Re-engineered overall the way tests are represented and processed in the system. This makes testing more stable and faster, allows the potential for dynamic testing (i.e. testing against values vendors enter at launch of test).
✓ [PRE] Every validation artifact is now stored in a database thus allowing faster updates.
✓ [PRE] ‘Admin’ User type can create test case “live”, in future similar functionality could be added (fully or partially) for all users.
✓ [PRE] Accept ‘Ack’ now generated and sent as appropriate (Previously, some ‘Acks’ were not sent at all when certain errors occurred in the inbound message)
HL7 V2 Tool Updates, continued

- Better and faster profile viewer
- Added MEMLS and MEMDMC profiles and basic test recently for Cycle 9 (1 test case each)
- Nomenclature update for ACM
- Updated POI tests and profiles
- Updated DOC-DOF tests
- Better log system for admin to help with user issues
- Some fixes in user interface for browser compatibility and logging issues
Rosetta Terminology Mapping Management System - RTMMS

Semantic interoperability of Medical Devices

Test Tool Update
Joint HL7/IEEE 11073 Healthcare Devices Working Group

National Institute of Standards and Technology
20 September, 2016 – Baltimore, Maryland

Contact: john.garguilo@nist.gov, 301-975-5248
RTMMS Overview

• A web application* that allows vendors and reviewers access, retrieval, and reporting of Rosetta Tables over the internet in conformance to IHE-PCD RTM Profile

• An electronic resource/tool providing the capability of saving data in xml format (as defined by RTM Profile)

• Aids the harmonization process by:
  – Identifying missing terms
  – Automatic generation of the “Harmonized Rosetta Table”
  – Providing latest up-to-date view of hRTM table

• Facilitates the proposal of New Terms to IEEE 11073 Nomenclature standard

• Facilitates Conformance Tooling
  – Message verification and conformance (syntax and semantics)
  – Leading to interoperability…
  – *developed by and currently hosted at NIST
  – Integrated with ICSGenerator Tool (hRTM also imported into DIM Editor)
Rosetta Terminology Mapping Data Base

- Rosetta Table
  - Maps vendor supported observations, units and enumerations to ISO/IEEE x73 nomenclature

- Units Table
  - Defines allowed units-of-measure
  - Defines groups of related units-of-measure

- Enumerations Table
  - Defines groups of enumerated values

- hRTM Table
  - Generated from the original Rosetta X73 Nomenclature DB

X73 Nomenclature DB

- Linked to RTMMS Security DB - Stores users information
RTMMS Key Features

- Access to NIST IEEE 11073 Nomenclature database
  - Appendix A terms (from ISO/IEEE 11073 10101: Nomenclature)
  - Appendix B terms (from ISO/IEEE 11073 10101: Nomenclature)
  - IDCO terms (ISO/IEEE 11073-10301 – implantable device cardiac)
  - aECG (annotated Electrocardiography)
  - PHD terms (personal health domain)

- Access to RTM database
- Ability to propose terms in Rosetta
- hRTM, units, and enumeration downloadable in XML format
- User registration
  - Email confirmation, approval process… controlled through ‘admin’
- Filtering based on regular expressions
- Rosetta validation against hRTM
- Management capabilities for SDO users
  - Integrated w/ ICSGenerator / exported to ‘DIM Editor’
• General user
  – Views Rosetta Tables
• Reviewer
  – Participates in discussions
• Contributing Organizations
  – Vendor/Contributer ‘sandbox’
  – Modifies Vendor Rosetta Table
  – Suggests new terms
  – Modifies Units and Enumerations Table
• SDO (Standard Development Organization)
  – Modifies Units and Enumerations Table
  – Register new terms
• Admin
  – Manages User Accounts
HL7 V2 Tool Updates, RTMMS

✔ Moved to secure server, new address: https://rtmms.nist.gov
✔ Added timestamp to terms for latest update
✔ Added term standard table field (i.e., table in x73 Standard) and populated values for available terms
✔ Added API for ‘My Device’
✔ Updated some terms and corresponding co-constraints that were missing
✔ Fixes in UI and a small performance tweak
RTMMS by the numbers; as of 20 September 2016 @ Baltimore

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Terms being or to-be vetted

- “Proposed Terms”: 185
- “Ready Terms Table”: 83
- “Mapped Terms”: 79
- “Proposed Units”: 195
- “Proposed Enumerations”: 178
RTMMS Terminology Access and Views

✅ Agreement finalized between IEEE and NIST (Dec 2012, Sep. 2014)
  • Allows users free and public access of terminology attributes that were formally ‘pay-for’ via the NIST tool
  • The “Works”

Definition of the “Works” [from IEEE/NIST Agreement]

The following data items within the approved standards, existing and future versions, currently designated as:

1 – IEEE 11073-10xxx
2 – IEEE 11073-20xxx

Limited to the following data items within, currently designated as:

1 – Ref ID
2 – Code
3 – Description
4 – Systematic Name
5 – Common Term – added to agreement in Sept. 2014 (worked w/ Kathryn Bennett/IEEE to amend)

• Banner page updated on tool
RTMMS Primary Updates – Signed Agreement 12/20/12

For IEEE:
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WHEREFOR, the signatories below, having signed this License Agreement, attest as to having the authority to enter into this Agreement and, agree to comply with all of the terms and conditions, covenants and obligations contained herein.

Licensor

[Signature]

Konstantinos Karachalios
Name

Managing Director, IEEE-SA
Title

20 Dec 2012
Date

Licensee

[Signature]

Ram D. Sriram
Name

Division Chief
Title

12.20.12
Date
Project Web site: [www.nist.gov/medicaldevices](http://www.nist.gov/medicaldevices)

**NIST HL7 V2 Test Tooling Web sites:**


**NIST Medical Device Terminology Service:**


**DIM Work - ‘DIM Editor’ and UML Model**

- Development Tool: [dim3.prometheuscomputing.com](http://dim3.prometheuscomputing.com)

**NIST Implementation Conformance Statement Generator (*ICSGenerator*): (no longer supported)**

- [http://hit-testing.nist.gov/medicaldevices/ICSGenerator/ics_download.html](http://hit-testing.nist.gov/medicaldevices/ICSGenerator/ics_download.html)
Domain Information Model
UML / DIM Editor, Progress Update

Semantic interoperability of Medical Devices

Test Tool Update – Michael Faughn
Prometheus Computing

Joint HL7/IEEE 11073 Healthcare Devices Working Group

National Institute of Standards and Technology
20 September 2016 – Baltimore, Maryland
11073
Device Profile Tooling
January 2017
Michael Faughn
Prometheus Computing LLC
DIM UML development

- Initial UML model programmatically derived from 11073-10201:2004 in early 2012
- Work on applications begun FY 2013
- Manual revisions performed
- Supporting models integrated
  - IEEE11073:10101 Nomenclature (RTMMS)
  - IEEE11073:20101 (ASN.1 Simple Types)
  - Device Profiles
  - Metamodel (represents 10201 UML in web applications)
  - Printed Standard
  - Conformance Statements (work in progress)
DIM UML development

- Supporting models integrated
  - **IEEE11073:20601 Personal Health Devices**
  - IEEE11073:10101 Nomenclature (RTMMS)
  - IEEE11073:20101 (ASN.1 Simple Types)
  - Device Profiles - **Significant Extensions Imminent**
  - Metamodel (represents 10201 UML in web applications)
  - Printed Standard
  - Conformance Statements (work in progress)
This shows only the classes defined by the standard. There are ~350 classifiers total in the 10201 DIM model. There are 110 classifiers in the PHD model. The Device Profiling application relies on several other supporting models (MetaInformation, Nomenclature, DeviceProfile, etc.) that interact with the DIM model. The Device Profiling application implements ~550 classes specific to the application.
The Model is the Standard

Why?

● Computable

● Facilitates manage....

● Artifacts programmatically derived from a common source help to ensure harmonization.
  ● Printed Standard
  ● Software tools (Device Profiling, Validation, ...)
  ● XML Schema
  ● Conformance Statements
UML to Artifacts: Challenges

- UML (or UML tools) has trouble expressing some constructs in a convenient way
  - Class instance variables
  - BNF (i.e. ASN.1)
  - BIT STRING

- Each UML element type used has to be implemented for each builder plugin that produces an end product. Lots of work the first time you do it and every time you build a new FIXME plugin e.g. (plugin that produces web app, standard, xml, etc.). replace the word ‘plugin’

- Keep the standard ‘pure’ vs. supporting the functionality that artifacts require.
Published PHD UML

Figure 4—Personal health device—DIM
Programmatically Derived / Generated From UML

- Device Profile Editor web application
  - ~ 3,000 lines of in-memory code per classifier
- XML Schema
- ASN.1
- Relational database schema
- Rich Ruby API for interacting with DIM objects
- .docx
Existing Device Profiles

**PCD**
- Pulse Oximeter
- Infusion Pump
- Vital Signs Monitor
- Ventilator
- Dialysis Machine
- Microenvironment (Incubator)

**PHD**
- Pulse Oximeter
Best Practices for Device Specialization Development

- Maintain terminology and containment structure independently.
- Every term in a list of terms and every node in a containment tree must include a RefID.
- Content over format.
  - Massaging content into a format appropriate for upload into RTMMS and/or the Device Profile Editor is not terribly difficult. Application developers can assist you.
- For information about adding terms to RTMMS see the README files at: IEEE 11073 Downloads
  - Note: The Device Profile Editor will not push terms into RTMMS for you.
(more) Best Practices for Device Specialization Development

Beta testers (most of whom are named Jan Wittenber) have found that it is easier to build device containment trees in XML rather than in the web application. They have leveraged a round-trip, iterative process of editing XML, uploading the XML to the web application to produce a new device profile, making a few edits and spot checks using the application, and downloading updated XML from the application.
Device Profile Editor
Existing Features 1/4

- Assemble DIM objects into device profile containment trees.
  - Composition constrained by the standard
  - View the containment tree
- Allow creation of Normative (11073-103xx) and User Defined device profiles.
- Use any device profile as a template for a new device profile via cloning
  - Entire containment tree must be cloned

Items in blue applicable to profiles for both 11073:10201 and 11073:20601. Otherwise the item applies only to 11073:10201 profiles.
Device Profile Editor
Existing Features 2/4

- Allow user to view metadata about DIM classes and attributes (i.e. what is found in the paper standard)
- Associate device profile elements with terms from RTMMS.
- Fetch new and updated terms from RTMMS.

Items in blue applicable to profiles for both 11073:10201 and 11073:20601. Otherwise the item applies only to 11073:10201 profiles.
Device Profile Editor
Existing Features 3/4

- Summary XML (Rosetta Containment Hierarchy) representation of a device profile
- Detailed HTML report of containment and terminology
- Comprehensive representation of Device Profile in XML
- Comprehensive representation of Device Profile in JSON (same info as XML, different format).

Items in blue applicable to profiles for both 11073:10201 and 11073:20601. Otherwise the item applies only to 11073:10201 profiles.

Items in magenta have suffered a minor regression and need to be fixed.
Device Profile Editor
Existing Features 4/4

- Create Device Profile by uploading XML
  - Original file is stored
  - (Non)Conformance messages provided during upload
- Synchronized Rosetta Containment XML input and output formats for round-trip capable workflow
- HTML Rosetta report
- UI/UX improvements
  - Prevent user from doing harm
  - Reduction of clutter and confusion
- Inclusion of UCUM units in application
- Visual cues provide conformance information
- Support for the use of terms not found in RTMMS
**Upload XML Device Profile**

**Profile Name** My Medical Device

**Profile Type** User Defined

Choose File Glucose_Meter_10416.xml

**Upload RCH XML**

**Example XML**

```xml
<?xml version="1.0" encoding="UTF-8"?>
<RCH>
  <mds refid="MDC_DEV_SAMPLE_MDS">
    <vmd refid="MDC_DEV_SAMPLE_VMD">
      <channel refid="MDC_DEV_SAMPLE_CHAN">
        <enumeration refid="MDC_SAMPLE_TYPE"/>
        <numeric refid="MDC_SAMPLE_SETTING"/>
      </channel>
    </vmd>
  </mds>
</RCH>
```

**Valid XML Tags**

<table>
<thead>
<tr>
<th>Class</th>
<th>Tags (preferred listed first)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ActivateOperation</td>
<td><code>&lt;activateoperation&gt;</code>, <code>&lt;activate_operation&gt;</code></td>
</tr>
<tr>
<td>Alert</td>
<td><code>&lt;alert&gt;</code></td>
</tr>
<tr>
<td>AlertMonitor</td>
<td><code>&lt;alertmonitor&gt;</code>, <code>&lt;alert_monitor&gt;</code></td>
</tr>
<tr>
<td>AlertScanner</td>
<td><code>&lt;alertscanner&gt;</code>, <code>&lt;alert_scanner&gt;</code></td>
</tr>
</tbody>
</table>
<RCH name="VS_Mon-version: 3a; date: 2016-04-14T16-jw2" description="This is a simplistic Vital Signs Monitor profile." owner="Jan W." type="Agent" date="2016-05-09 11:56:08" dim_version="2016" nomenclature_version="2015-10-24 13:08:54 -0400">
  <single_bed_mds refid="MDC_DEV_SYS_VS_MDS" card="1">
    <vmd refid="MDC_DEV_PLETH_VMD" card="1">
      <channel refid="MDC_DEV_PLETH_CHAN" card="1">
        <real_time_sample_array refid="MDC_PULS_OXIM_PLETH" card="1"/>
        <numeric refid="MDC_SAT_02_VEN" card="1"/>
      </channel>
      <channel refid="MDC_DEV_PULS_CHAN" card="1">
        <numeric refid="MDC_PLETH_PULS_RATE" card="1"/>
      </channel>
    </vmd>
  </single_bed_mds>
  <vmd refid="MDC_DEV_ECG_VMD" card="1">
    <channel refid="MDC_DEV_CARD_RATE_CHAN" card="1">
      <numeric refid="MDC_ECG_CARD_BEAT_RATE" card="1"/>
    </channel>
    <channel refid="MDC_DEV_ECG_CHAN" card="1">
      <real_time_sample_array refid="MDC_ECG_ELEC_POTL_I" card="1"/>
    </channel>
  </vmd>
  <vmd refid="MDC_DEV_ANALY_RESP_RATE_VMD" card="1">
    <channel refid="MDC_DEV_ANALY_RESP_RATE_CHAN" card="1">
      <numeric refid="NEW_MEASUREMENT_TYPE" card="1"/>
    </channel>
  </vmd>
</RCH>
Create Device Profile by uploading tables using dotted notation (TSV)

● Original file is will be stored
● Metric types must be guessed at in some cases
● PHD profiles gain support
Newest Features

- PHD almost at feature parity with PCD profiles
- The application is significantly (~10X) faster / more responsive.
- UCUM Units browsable from home page
Profile created by hand
Immediate Goals

- PHD profile functionality working as well as PCD profiles -- only minor loose ends to clean up now
- Freeze features and tidy up the current code base
Next Steps (after The Freeze)

- Produce camera ready IEEE standard in MS Word
  - Adjust structure of .docx output as needed for inclusion in Word file.
- Reimplement device profiles to be modular, flexible, and reusable.
- Resolve critical issues on “Revisions & Comments”
- Create user guide and training materials
Device Profile Redesign

- Device components (e.g. VMDs, Channels) become reusable and shareable across multiple containing profiles
- A change to one component will propagate to all occurrences
- Choices (any of, one of) within normative profiles
- Ad-hoc groupings of metrics
More Goals

● Finish implementation of r/w permissions in web application
● Improve integration with RTMMS
  ● Report new terms, etc.
● Comprehensive audit of updated DIM model / application with respect to 11073:10201© 2004
● Easier access to metadata and information from the DIM standard for device profile users
More Goals (cont.)

- Deploy to NIST server
- Release Device Profiling app for general use
- Conformance statements from the profile editor
dim.prometheuscomputing.com

For login details contact:

dim@prometheuscomputing.com
End of Presentation

Questions? Comments?
dim@prometheuscomputing.com
Deleted Scenes
Questions

- How Handle Duplicate Profile Names?
- Preferred XML tag format?
- Level of error tolerance in XML upload?
- Can ‘proposed tokens’ be lumped in with proposed types?
- Can we hide unused attributes?
- Types of profiles? Normative, User-Defined, more?
- Can we get rid of the old websites?
- What should I work on next?
- other stuff?
Alpha / Beta Testing

- Create base/normative profiles
- Create device profiles from cloned normative profiles
- Use output XML and provide feedback
- Use XML schema as input to C4MI tools
API Example

p = MyDevice::PCDProfile.create(name: "Infusion", intended_use: 'Normative (11073)', purpose: 'Demonstration')

mds = DIM::System::SinglePatientMDS.create(name: "Infusion Pump MDS")

mds.set_ref_id "MDC_DEV_PUMP_INFUS_MDS"

p.profileroot = mds

p.save

v = DIM::Medical::VMD.create(name: "Infusion Pump VMD")

v.set_ref_id "MDC_DEV_PUMP_INFUS_VMD"

mds.vmds_add v

mds.save

delivery_ch = DIM::Medical::Channel.create(:name => "Delivery Channel")

delivery_ch.set_ref_id "MDC_DEV_PUMP_INFUS_CHAN_DELIVERY"
API in REPL

main 003(0) > DIM::Medical::VMD.first

=> #<DIM::Medical::VMD @values={:id=>1, :class_reserved_id=>nil, :name_binding_id=>nil, :ref_id=>5818, :ext_obj_relations_id=>nil, :ext_obj_relations_class=>nil, :label_string_id=>nil, :label_string_class=>nil, :type_id=>nil, :locale_id=>nil, :locale_class=>nil, :alertoralertstatus_id=>nil, :alertoralertstatus_class=>nil, :position_id=>nil, :position_class=>nil, :compatibility_id_dim_id=>nil, :compatibility_id_dim_class=>nil, :operating_hours_id=>nil, :operating_hours_class=>nil, :operation_cycles_id=>nil, :operation_cycles_class=>nil, :instance_number_id=>nil, :vmd_model_id=>nil, :vmd_status=>nil, :measurement_principle=>nil}>

main 011(0) > DIM::Medical::VMD.attributes.keys #=> [:vmd_status, :measurement_principle]

main 012(0) > DIM::Medical::VMD.associations.keys

Examples from RTMMS web service created by Nicolas Crouzier @ NIST:

```json
[{
  "referenceId": "MDC_AREA_BODY_SURF_ACTUAL",
  "termCode": 188744,
  "systematicName": "Area | Actual | BodySurface | Body",
  "commonTerm": "Patient body surface area",
  "acronym": "",
  "termDescription": "The actual body surface area of the patient, calculated from patient actual weight and patient actual length.",
  "updateDate": "Oct 31, 2014 4:03:33 PM",
  "status": "APPROVED",
  "type": "METRIC",
  "sources": ["HRTM", "RTM"],
  "units": ["MDC_DIM_SQ_X_M"]
},
{
  "referenceId": "MDC_ATTR_AL_COND",
  "termCode": 68012,
  "systematicName": "",
  "commonTerm": "",
  "acronym": "",
  "termDescription": "",
  "updateDate": "Dec 17, 2014 5:49:55 PM",
  "status": "APPROVED",
  "type": "ENUMERATION",
  "sources": ["HRTM", "RTM"],
  "enums": ["MDC_EVT_SYRINGE_PATIENT_PRESSURE",
             "MDC_EVT_SYRINGE_PLUNGER_POSITION",
             "MDC_EVT_SYRINGE_FLANGE_POSITION",
             "MDC_EVT_SYRINGE_BARREL_CAPTURE",
             "MDC_EVT_SYRINGE_PRESSURE_DISC_POSITION",
             "MDC_EVT_SYRINGE_END_OF_TRAVEL",
             "MDC_EVT_SYRINGE_EMPTY",
             "MDC_EVT_PCA_DOOR_UNLOCKED",
             "MDC_EVT_PCA_HANDSET_DETACHED",
             "MDC_EVT_PCA_MAX_LIMIT",
             "MDC_EVT_PCA_PAUSED"]
},
{
  "referenceId": "MDC_EVT_STANDBY_WARN",
  "termCode": 258048,
  "systematicName": "",
  "commonTerm": "",
  "acronym": "",
  "termDescription": "",
  "updateDate": "Nov 7, 2014 4:24:18 PM",
  "status": "APPROVED",
  "type": "LITERAL",
  "sources": ["RTM"]
},
{
  "referenceId": "pump-stopped-transitioning",
  "updateDate": "Nov 7, 2014 4:29:22 PM",
  "status": "PROPOSED",
  "type": "TOKEN",
  "sources": ["RTM"]
},
{
  "referenceId": "_UOM_CONC_GAS",
  "type": "UNITGROUP",
  "sources": ["RTM"],
  "units": ["MDC_DIM_PERCENT", "MDC_DIM_VOL_PERCENT", "MDC_DIM_KILO_PASCAL", "MDC_DIM_MMHG"]
},
{
  "referenceId": "_MDC_ATTR_AL_COND_DELETED",
  "type": "ENUMGROUP",
  "sources": ["RTM"],
  "enums": ["MDC_EVT_SYRINGE_NUT_ENGAGED",
            "MDC_EVT_SYRINGE_PATIENT_PRESSURE_ALARM",
            "MDC_EVT_SYRINGE_PRESSURE_DISC",
            "MDC_EVT_SYRINGE_FLANGE",
            "MDC_EVT_SYRINGE_LEVER"]
}]
```

* New features in bold.