11073
Device Profile Tooling
May 2016
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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)
This shows only the classes defined by the standard. There are ~350 classifiers total in the DIM 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 ~440 classes specific to the application.
The Model is the Standard

Why?

- Computable

- 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 artifact. Lots of work the first time you do it and every time you build a new plugin.

- Keep the standard ‘pure’ vs. supporting the functionality that artifacts require.
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
- JSON meta-information
Workflow (Simplified)

- MagicDraw
  - Create / Edit UML
  - Prometheus Plug-ins

- Plug-in Products
  - Ruby implementation of UML
  - GUI specification for interaction with modeled entities
  - Relational Database Schema
  - JSON that be parsed into a Java implementation of the UML

- Integrated Web Applications
  - Device Profiling Tool
    - Device Profiles
      - Rosetta Containment XML
      - Rosetta Containment Conformance Report (HTML)
      - XML Schema
  - Model Manager
    - UML Model (Objects Only / No Diagrams)
  - Document Creation Tool
    - PDF of Standard
      - Formatted ASN.1

- Hand written code
Device Profile Editor
Existing Capabilities 1/3

- 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
Device Profile Editor
Existing Capabilities 2/3

- 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.
Device Profile Editor
Existing Capabilities 3/3

● 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).
New Features

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

Upload Rosetta Containment XML

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">
    <md refId="MDC_DEV_SAMPLE_MHDR"><mref refId="MDC_DEV_SAMPLE_CHAN">
      <channel refId="MDC_DEV_SAMPLE_TYPE"/>
      <numeric refId="MDC_SAMPLE_TYPE"/>
    </channel>
    </md>
  </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</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</code>, <code>&lt;alert_monitor&gt;</code></td>
</tr>
<tr>
<td>AlertScanner</td>
<td><code>&lt;alertscanner</code>, <code>&lt;alert_scanner&gt;</code></td>
</tr>
<tr>
<td>AlertStatus</td>
<td><code>&lt;alertstatus</code>, <code>&lt;alert_status&gt;</code></td>
</tr>
<tr>
<td>Ancillary</td>
<td><code>&lt;ancillary&gt;</code></td>
</tr>
<tr>
<td>BCC</td>
<td><code>&lt;bcc&gt;</code></td>
</tr>
<tr>
<td>Battery</td>
<td><code>&lt;battery&gt;</code></td>
</tr>
<tr>
<td>Channel</td>
<td><code>&lt;channel</code>, <code>&lt;c</code>, <code>&lt;chan&gt;</code></td>
</tr>
<tr>
<td>Clock</td>
<td><code>&lt;clock&gt;</code></td>
</tr>
<tr>
<td>ComplexMetric</td>
<td><code>&lt;complexmetric</code>, <code>&lt;complex_metric&gt;</code></td>
</tr>
<tr>
<td>ContextScanner</td>
<td><code>&lt;contextscanner</code>, <code>&lt;context_scanner&gt;</code></td>
</tr>
<tr>
<td>DCC</td>
<td><code>&lt;dcc&gt;</code></td>
</tr>
<tr>
<td>DeviceInterface</td>
<td><code>&lt;deviceinterface</code>, <code>&lt;device_interface&gt;</code></td>
</tr>
</tbody>
</table>


HTML Rossetta Containment Report

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

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</tr>
</thead>
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<td>Alert</td>
<td>&lt;alert&gt;</td>
</tr>
<tr>
<td>AlertMonitor</td>
<td>&lt;alertmonitor&gt;, &lt;alert_monitor&gt;</td>
</tr>
<tr>
<td>AlertScanner</td>
<td>&lt;alertscanner&gt;, &lt;alert_scanner&gt;</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>
    <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>
  </single_bed_mds>
</RCH>
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?
FY2016 Remaining Goals 1/2

- Finish implementation of r/w permissions in web application
- Improve integration with RTMMS web service
- 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
FY2016 Remaining Goals 2/2

- User documentation / help for device profiling application
- Move from Alpha to Beta testing to release
- Deploy to NIST server
- Resolve critical issues on “Revisions & Comments”
- Release Device Profiling app for general use
- Generate camera ready IEEE standard in MS Word
- Conformance statements from the profile editor
dim3.prometheuscomputing.com

user: dim
password: 11073
End of Presentation
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
Questions? Comments?

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API Example

```ruby
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_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:

{"referenceId":"MDC_AREA_BODY_SURF_ACTUAL","termCode":188744,"systematicName":null,"commonTerm":"Patient body surface area","acronym":null,"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":null,"units":null
},
},
},
{"referenceId":"pump-stopped-transitioning","updateDate":"Nov 7, 2014 4:29:22 PM","status":"PROPOSED","type":null,"sources":null
},
{"referenceId":"_UOM_CONC_GAS","type":"UNITGROUP","sources":null,"units":null
},
{"referenceId":"_MDC_ATTR_AL_COND_DELETED","type":"ENUMGROUP","sources":null,"enums":null
}

* New features in bold.