

HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

NIST Medical Device Communication Testing

Semantic interoperability of Medical Devices

HIT Test Tool Update

Joint HL7/IEEE 11073 Healthcare Devices Working Group

National Institute of Standards and Technology

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Content Topics

- *HL7 V2 (2.6) IHE-PCD Validation Tools*
 - Cycle 7 – 2012-13; Fall Pre-Connectathon, Virtual Testing, January/February 2013 Connectathon, HIMSS13
- Rosetta Terminology Mapping Management System (*RTMMS*) Overview
 - RTMMS Deployment Update and service status
 - User Membership Protocol / pending IEEE decision
- *ICSGenerator*
 - Implementation Conformance Statement Generator
 - Device Profile/Specialization
- ISO/IEEE 11073 ‘*Domain Information Model Editor*’
 - UML Defined x73 DIM
 - Provides DIM Objects
 - Art Griesser + Jun Ho Shin (“Shin”) [see presentation]

NIST MDC Testing Project Web Sites

- **Project Web site:** www.nist.gov/medicaldevices
- **NIST HL7 V2 Test Tooling Web sites:**
 - **IHE-PCD Pre-Connectathon:**
<http://hit-testing.nist.gov:13100/PCD-HL7WebPreCon/>
 - **IHE-PCD Connectathon:**
<http://hit-testing.nist.gov:13100/PCD-HL7WebCon/>
- **NIST Medical Device Terminology Service:**
 - **Rosetta Terminology Mapping Management System (RTMMS):**
<http://hit-testing.nist.gov:13110/rtmms/>
- **NIST Implementation Conformance Statement Generator (ICSGenerator):**
 - http://hit-testing.nist.gov/medicaldevices/ICSGenerator/ics_download.html

IHE-PCD 2012 Pre-Connectathon + Connectathon

NIST Testing Support

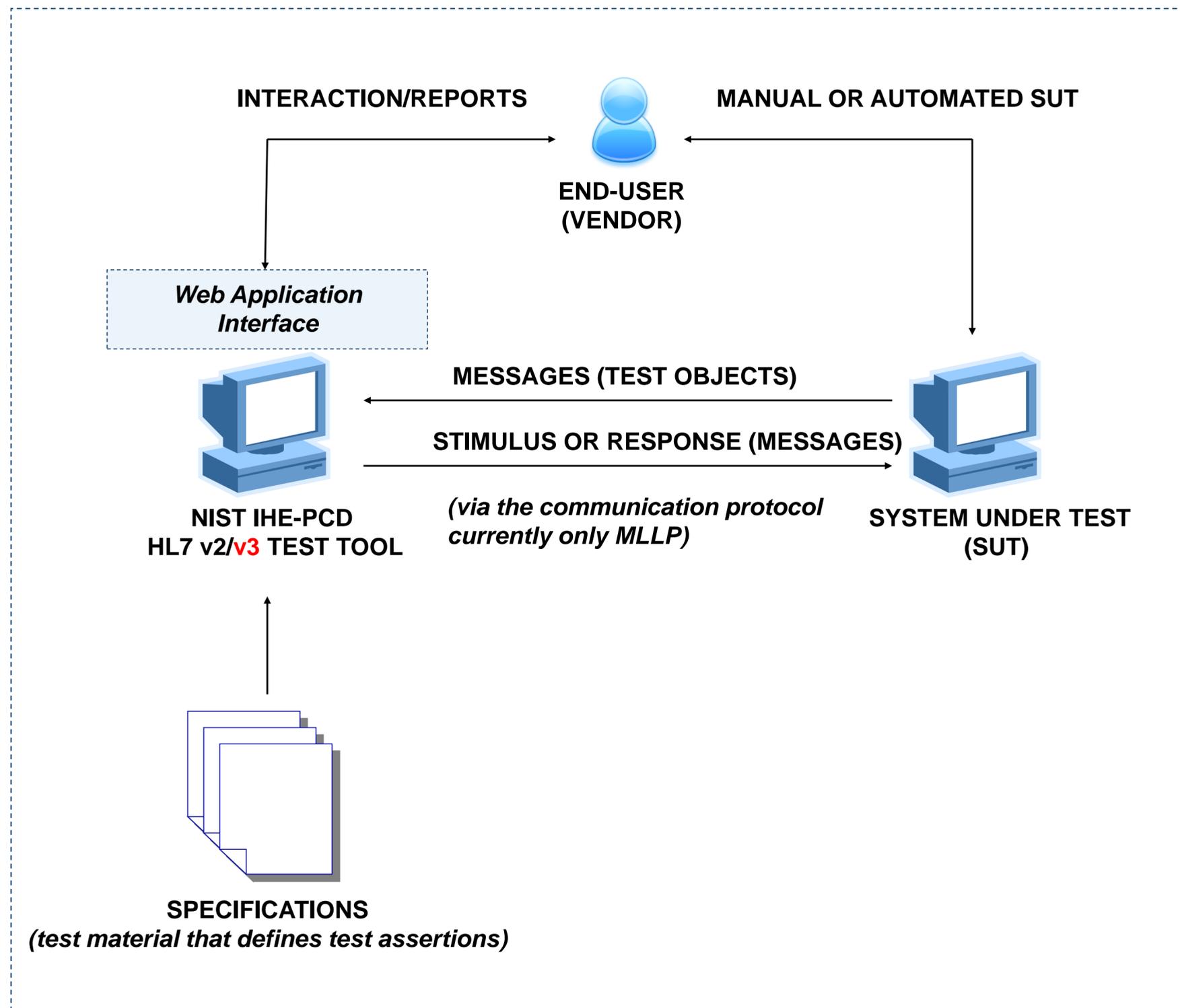
The NIST V2 (2.6) Tools perform the following validation:

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

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*

NIST V2 HL7 IHE-PCD Test Tool: Operational Process



V3 – Future Work

IHE-PCD Pre-Connectathon 'Isolated Environment' Tool

<http://hit-testing.nist.gov:13100/PCD-HL7WebPreCon/>

IHE-PCD Pre-Connectathon Test Tool

Welcome, Guest | Register | Log in

NIST HL7 V2 Tools

Overview | Execute Test | User Account | Documentation | Features | Contact us

Run | Result

Select an actor to view the list of available Test Cases

HL7 Version v2 Actors

<input type="radio"/>	Gazelle ID	IHE DEC Reporter
<input type="radio"/>	60001	IHE DEC Reporter
		IHE DEC Consumer
		IHE DEC Filter
		IHE PIV Programmer
		IHE PIV Consumer
		IHE ACM Reporter
		IHE ACM Manager
		IHE IDCO Reporter
		IHE IDCO Consumer
		IHE IPEC Reporter
		IHE IPEC Consumer

Patient(DOR_SUT)



Date Created: 11-24-08 | Date Updated: 09/07/2012 04:26 PM
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IHE-PCD Connectathon 2012 Test Tool

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NIST HL7 V2 Tools

[Home](#) [Test Case Index](#) [Message Validation](#) [Patient Demographics *Beta*](#)

[Validate](#) [Report](#) [View Errors](#) [Parse Message](#) [Configure](#)

➔ **Select the IHE profile, the actor and the transaction corresponding to the message to validate (required)**

IHE Profile

DEC
DEC-PHD
DEC-SPD Option (Grouped Test)
DEC-SPD Standalone
PIV
ACM
IPEC
IDCO

Sending Actor

DOR
DOC

Transaction

PCD-01 (ORU^R01^ORU_R01)

➔ **Select the test case corresponding to the message to validate (required)**

Test Case

DEC_DOR_DOC_One_Patient
NIST_DEC_DOR_Standalone_DOF_DOC_

Step

1

Test Case Description

NIST Id: DEC_DOR_DOC_One_Patient

Gazelle Id:

Title:

NIST Pre-Connectathon + Connectathon: Test Case Updates Cycle 7

	IHE Profile	Test Case Title	Description		
1	DEC	NIST DEC DOR DOF DOC Patient Demographics Table2010927	Step 1	PCD-01 (ORU^R01^ORU_R01)	DOR sends data for patient in table 2010927
			Step 2	ACK (ACK^R01^ACK)	DOC responds with ACK message (MSA-1 = "AA")
2	DEC	NIST DEC DOR DOF DOC One to One Communication	Step 1	PCD-01 (ORU^R01^ORU_R01)	DOR sends data for patient Albert Hon (MRN: HO2009001, DOB: Jan.1 1961, Location: HO Surgery, OR-1, Sex: M, Mother's Maiden Name: Adams). At least 4 parameters for each type of device are sent. Patient's data is not validated
			Step 2	ACK (ACK^R01^ACK)	DOC responds with ACK message (MSA-1 = "AA")
			Step 3	PCD-01 (ORU^R01^ORU_R01)	DOR sends data for patient Charles Hon (MRN: HO2009002, DOB: Feb.1 1961, Location: HO Surgery, OR-2, Sex: M, Mother's Maiden Name: Brooks). At least 4 parameters for each type of device are sent. Patient's data is validated
			Step 4	ACK (ACK^R01^ACK)	DOC responds with ACK message (MSA-1 = "AA")
3	DEC SPD Option	NIST DEC SPD By Location	Step 1	PCD-02 (QSB^Z02^QSB_Q16)	DOC sends subscription to DOF requesting patients in the ICU
			Step 2	ACK (ACK^Q16^ACK)	DOF sends ACK to DOC
			Step 3	PCD-01 (ORU^R01^ORU_R01)	DOR sends data for patient Amy Hon (MRN HO2009003) in ICU to DOF
			Step 4	ACK (ORU^R01^ORU_R01)	DOF sends ACK to DOR
			Step 5	PCD-01 (ORU^R01^ORU_R01)	DOF sends received data for patient Amy Hon to DOC
			Step 6	ACK (ORU^R01^ORU_R01)	DOC sends ACK to DOF
			Step 7	PCD-01 (ORU^R01^ORU_R01)	DOR sends data for patient Albert Hon (MRN HO2009001) in OR to DOF
			Step 8	ACK (ORU^R01^ORU_R01)	DOF sends ACK to DOR. DOF does not forward the message to DOC.

About Rosetta

Current version of Rosetta in RTMMS :**3q**

The Rosetta Terminology Mapping uses three primary tables that define and constrain the semantic content of IHE PCD messages. The three tables are:

[Rosetta](#) The Rosetta table contains the observation identifiers, units-of-measure and enumerations that vendors currently support on their gateways and how they plan to map these to the ISO/IEEE 11073-10101 nomenclature and its extensions.

[Units](#) This table defines all the allowed units-of-measure and normative mapping between the ISO/IEEE 11073-10101 units-of-measure (by Reference IDs and numeric codes) and the equivalent UCUM term(s). It also defines groups of related units-of-measure, such as units used for drug dose, concentration, etc. that are referenced by the primary Rosetta table. It also specifies the dimensionality of each unit-of-measure to ensure that all the units associated with an observation identifier are consistent. The units table includes additional information required for publication in ISO/IEEE 11073-10101 standard so that all of the units-of-measure information can be updated and maintained in a single repository.

[Enums](#) This table defines groups of enumerated values (either token strings or as IEEE Reference IDs and numeric codes) that are referenced from the main 'Rosetta' table.

Other tables:

[hRTM](#) The Harmonized Rosetta table contains terms agreed upon during the harmonization process. This table is automatically generated from the Rosetta table.

[Groups](#) An informative table that defines the groups that reference identifiers may belong to, as an aid to sorting and organizing them.

RTMSS - Deployment Status

- RTMMS went live on May 1, 2012.
 - <http://hit-testing.nist.gov:13110/rtmms/>
- Beta-Test version was available from mid January – April 2012
 - any data/change was not committed (i.e., discarded)
- Beta version of RTMMS was available for ~2 months to a select few (~15) individuals of varying roles (e.g., vendor, SDO, Admin)
 - NIST received feedback on functionality, capability, usability, and interface and subsequently updated the on-line RTMMS
- NIST continues to work out IEEE membership issues w/ IEEE
 - Full presentation and proposal made to IEEE by NIST in Dec 2011
 - Presentation and Q&A session with IEEE ‘systems people’
 - Kathryn Bennett (IEEE) indicated IEEE-SA Senior Management agreed to RTMMS DIM + Nomenclature freely available ☺ (June 2012)
 - IEEE formal announcement pending – likely final approval soon! (Sept 2012)

RTMSS - Deployment Plan – Going Forward

- RTMMS becomes the “master” version going forward
- [Today] RTMMS is now available to various user types and domain groups (e.g., IHE-PCD members) and select others (but only if IEEE members)
 - If interested in obtaining an RTMMS system id and password
 - Go to Web Applications (URL below) and request an account
 - <http://hit-testing.nist.gov:13110/rtmms/>
 - NIST will perform the appropriate background checks
 - Typically same day turn-around
 - If/Once approved (vetted with IEEE) - NIST will provide a corresponding email with approved account information.

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

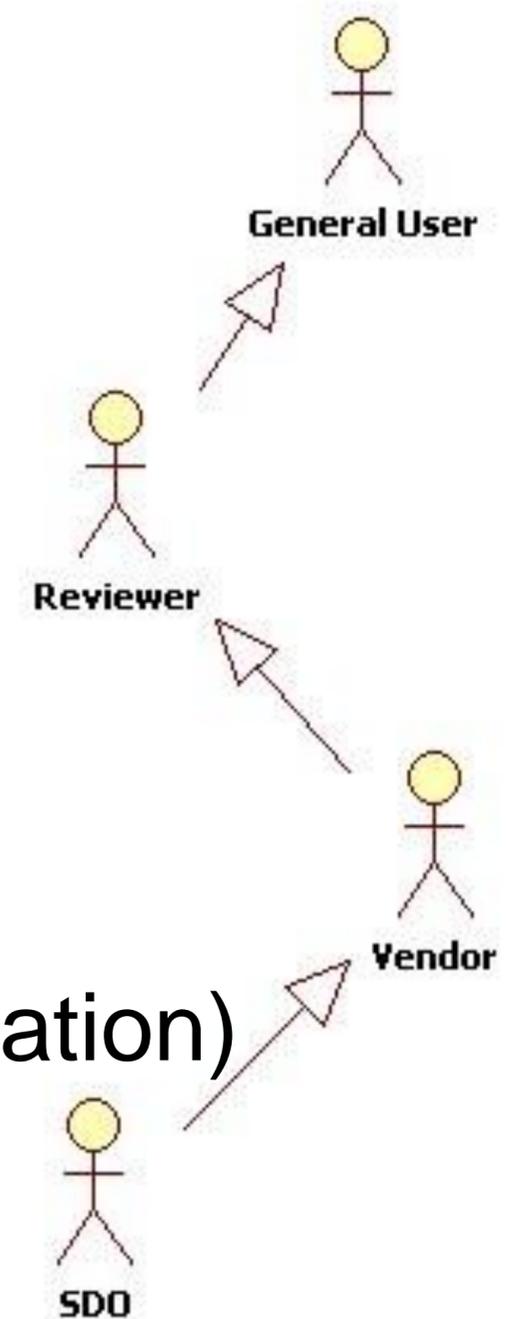
X73 Nomenclature DB

Security DB - Stores users information

- 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 download-able 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*

RTMMS Users

- General user
 - Views Rosetta Tables
- Reviewer
 - Participates in discussions
- Vendor (includes Organizations)
 - Vendor ‘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



- Synching membership from IEEE to NIST (issue may go away in June)
- IEEE copyright issues
 - Against NIST Policy to maintain proprietary data or public displaying of copyrighted information...
- Long-term – who owns and maintains RTMMS
- Maintenance issues...
- Hosting/Server issues...
- Access control issues...
- Integration of SNOMED-CT Terms
 - Expertise needed – mappings provide equivalence between SNOMED CT/x73 (e.g., Norman Jones IHTSDO)
- Integration of LOINC Terms
 - Mapping must be provided by experts (e.g., Clem McDonald – NLM)

RTMMS Updates

- Updates and focus on Rosetta term after search (results)
- Allow user to download only the current terms / Clearer label for download buttons
- New/better format for xml download
- Better icons for enumeration group/ unit groups
- Focus on edited term after edit or new comment
- Vendors can create group in group panel
- Allow group sorting
- Duplicate Rosetta term button
- Use of views for "quick" SQL queries
- Add project on Hudson server (eliminates NIST firewall issues)
- Major code cleanup / doc

RTMMS Updates (Continued)

- From Last Time (May 2012, Vancouver WG Mtgs.)
- Vendors can now propose units and enumerations
- Fixed interface glitches found during testing period
- Rosetta terms can now have multiple groups
- Mouse-over help on table headers
- Improved PDF reports for x73
- Wrapped text in x73 tables
- Global search in x73 tab
- SDOs can now create/propose a Rosetta term
- Improved new account request process
- RTMMS is now compatible with IE7, although it works best with Firefox, Chrome or Safari
- Updated user's guide

RTMMS Functionality Demo

- Viewing the RTM Tables (all user types)
- Mapping X73 and UCUM units (SDO)
- Mapping a Term (Vendor and SDO)
- Proposing new terms (Vendor and SDO)
- Term Review (SDO, Vendors and Reviewers)
- Term approval (SDO)

http://www.youtube.com/watch?v=rP_Tsb6wIF8&hd=1

- Model Devices in compliance with the X73 DIM, capturing;
 - object relationship (containment)
 - object attributes, behavior and notifications
 - Objects and parameters term codes from hRTM and X73 Nomenclature
 - Device profile generated in XML in compliance to the DIM schema
- Generates Implementation Conformance Statements (device supported features) in a tabular and XML format.
 - General ICS
 - Service Support ICS
 - Transport ICS
 - DIM MOC ICS
 - MOC Attribute ICS
 - MOC Behavior ICS
 - MOC Notification ICS
- Uses an embedded DIM database originated from the DIM Schema
- Provides access to IEEE 11073 nomenclature, hRTM and Rosetta (proposed terms)
- Generates a PDF file that includes only object containment and parameters.
- Generates simplified version of the device profile (xml)

ICSGenerator Status

- In this year, we have been challenged by three major problems,
 - Data Synchronization
 - Quick Delivery
 - Private Owned Terms
- Several improvements and new functionality (focus areas):
 - New Model for ICSGenerator
 - More outputs (Device Profiles [DP] in XML, and device reports in PDF file)
 - Integration of Rosetta proposed terms and associated Unit/Enumeration
 - Web based API including terminology search engine
 - DP database
 - Object level and term level cardinality
 - Misc (security, UML diagram, cache, UI, OBX)

ICSGenerator Status

- From Last Time/WG Mtgs (Vancouver)
- Object cardinality support
- Access to RTMMS Rosetta “proposed terms” including units and enumerations
 - Connecting to NIST RTMMS web service
- Automatic generation of device profile in PDF format
- “compound numeric” support
- Dbase lookup (X73 nomenclature, DIM and hRTM)
- In the process of developing a web application

PCD-01 Infusion Pump - Vol2 (Annex D)

The screenshot shows the ICS Generator application window. The left pane displays a tree view of DIM elements under '1.1.1.1 Source [Channel]', with '1.1.1.1 Set Fluid Delivery Rate [Numeric]' selected. The right pane shows the configuration for this element, including fields for Object Name, Reference id, Object Code, Clause, Reference ID, Term Code, Display name, and Description. A table at the bottom of the right pane shows DIM and UOM details.

DIM	UOM_MDC	UOM_UCUM	Term Code
L3T-1	MDC_DIM_MILLI_L...	mL/h	4:3122

Access to
MDDbase(x73
, hRTM and
Rosetta)

ICSGenerator XML Profile content

ICSGenerator XML PCD-01 Infusion Pump Profile

```
<Numeric>
  <OBJECT_NAME Label="">Numeric</OBJECT_NAME>
  <OBJECT_ID>MDC_MOC_VMO_METRIC_NU</OBJECT_ID>
  <TERM_CODE>6</TERM_CODE>
  <Reference>clause 7.3.5</Reference>
  <MOC_COMMENT/>
  <MOC_RESTRICTIONS/>
  <MOC_TYPE_ID>MDC_FLOW_FLUID_PUMP</MOC_TYPE_ID>
  <MOC_TYPE_TERM_CODE>26712</MOC_TYPE_TERM_CODE>
  <Attribute_Info>
    <Label-String attrGrpId="MDC_ATTR_GRP_VMO_DYN" attrGrpName="VMO
      <ATTRIBUTE_NAME>Label-String</ATTRIBUTE_NAME>
      <ATTRIBUTE_ID>MDC_ATTR_ID_LABEL_STRING</ATTRIBUTE_ID>
      <ATTRIBUTE_TYPE>OCTET STRING</ATTRIBUTE_TYPE>
      <TERM_CODE>2343</TERM_CODE>
```

- The ICSGenerator profile contains:
 - All the objects involved
 - object attributes
 - Behavior and Notifications
 - Object term codes
 - Containment
 - Units and enumerations

Channel: Delivery

Name	Term Code	Units	Values
Total Current Rate	MDC_FLOW_FLUID_PUMP (26712)	MDC_DIM_MILLI_L_PER_HR (4::3122)/	
Total Volume Infused	MDC_VOL_INFUS_ACTUAL_TOTAL (26876)	N/A	
Operational Status	MDC_PUMP_STAT (53436)		pump-status-ready/pump-status-infusing/pump-status-paused/pump-status-kvo/pump-status-delayed/pump-status-standby/pump-status-vtbi-complete/pump-status-off/pump-status-priming/
Operational Mode	MDC_PUMP_MODE (53432)		pump-mode-nominal/pump-mode-drug-dosing/pump-mode-ramp-taper/pump-mode-multi-step/pump-mode-multi-dosing/pump-mode-bolus/pump-mode-loading-dose/pump-mode-multi-channel/pump-mode-pca/pump-mode-continuous/pump-mode-pca-and-continuous/pump-mode-piggyback/pump-mode-concurrent/

Channel: Source

Name	Term Code	Units	Values
Set Fluid Delivery Rate	MDC_FLOW_FLUID_PUMP (26712)	MDC_DIM_MILLI_L_PER_HR (4::3122)/	
Remaining VTBI	MDC_VOL_FLUID_TBI_REMAIN (26800)	MDC_DIM_MILLI_L (4::1618)/	
Duration	MDC_TIME_PD_REMAIN (26844)	MDC_DIM_MIN (4::2208)/	
Drug Dose Rate	MDC_FLOW_DRUG_DELIV (26732)	MDC_DIM_MILLI_L_PER_HR (4::3122)/	
Volume Infused	MDC_VOL_FLUID_DELIV (26792)	MDC_DIM_MILLI_L (4::1618)/	
Drug Label	MDC_DRUG_NAME_TYPE (53258)		

Containment Tree

Simple MDS: Infusion Pump	MDC_DEV_PUMP_INFUS_MDS (4449)
VMD: Infusion Pump	MDC_DEV_PUMP_INFUS_VMD (4450)
Channel: Source	MDC_DEV_PUMP_INFUS_CHAN_SOURCE (61441)
Channel: Delivery	MDC_DEV_PUMP_INFUS_CHAN_DELIVERY (61442)

REFID	OBX-4	Comments
MDC_DEV_PUMP_INFUS_MDS	1	
MDC_DEV_PUMP_INFUS_VMD	1.1	
MDC_DEV_PUMP_INFUS_CHAN_SOURCE	1.1.1	
MDC_FLOW_FLUID_PUMP	1.1.1.1	
MDC_VOL_FLUID_TBI_REMAIN	1.1.1.2	
MDC_TIME_PD_REMAIN	1.1.1.3	
MDC_FLOW_DRUG_DELIV	1.1.1.4	
MDC_VOL_FLUID_DELIV	1.1.1.5	
MDC_DRUG_NAME_TYPE	1.1.1.6	
MDC_DEV_PUMP_INFUS_CHAN_DELIVERY	1.1.2	
MDC_FLOW_FLUID_PUMP	1.1.2.1	
MDC_VOL_INFUS_ACTUAL_TOTAL	1.1.2.2	
MDC_PUMP_STAT	1.1.2.3	
MDC_PUMP_MODE	1.1.2.4	

MD Semantic Dbase “Look-up”

File Device Specialization Help

Builder Database Conformance Statements

ISO/IEEE 11073 Nomenclature ISO/IEEE 11073 DIM Harmonized Rosetta

ISO/IEEE 11073 Nomenclature

Reference ID	Term Code
MDC_MOC_VMO	1:1
MDC_MOC_VMO_VMD	1:2
MDC_MOC_VMO_CHAN	1:3
MDC_MOC_VMO_METRIC	1:4
MDC_MOC_VMO_METRIC_ENUM	1:5
MDC_MOC_VMO_METRIC_NU	1:6
MDC_MOC_VMO_METRIC_SA	1:7
MDC_MOC_VMO_METRIC_SA_D	1:8
MDC_MOC_VMO_METRIC_SA_RT	1:9
MDC_MOC_VMO_METRIC_SA_T	1:10
MDC_MOC_SCAN	1:16
MDC_MOC_SCAN_CFG	1:17
MDC_MOC_SCAN_CFG_EPI	1:18
MDC_MOC_SCAN_CFG_PERI	1:19
MDC_MOC_SCAN_CFG_PERI_FAST	1:20
MDC_MOC_SCAN_UCFG	1:21
MDC_MOC_SCAN_UCFG_ALSTAT	1:22
MDC_MOC_SCAN_UCFG_CTXT	1:23
MDC_MOC_SCAN_UCFG_OP	1:24

Reference ID search

Physiological Monitor – “Compound Numeric”

The screenshot shows the ICS Generator software interface. The left pane displays a hierarchical tree of physiological monitor components, with '1.1.1.1.1 Systolic [Numeric]' selected. The main panel shows the configuration for this DIM, including ISO/IEEE 11073:10201 DIM Details and Term Details. A text box in the Comment field contains the text: "MDC_DIM_C M_H2O", unit used in Vol3 is not in hRTM. At the bottom, a table lists DIMs and their associated UOMs.

ISO/IEEE 11073:10201 DIM Details

- Object Name: Numeric
- Reference Id: MDC_MOC_VMO_METRIC_NU
- Object Code: 6
- Clause: clause 7.3.5

Term Details

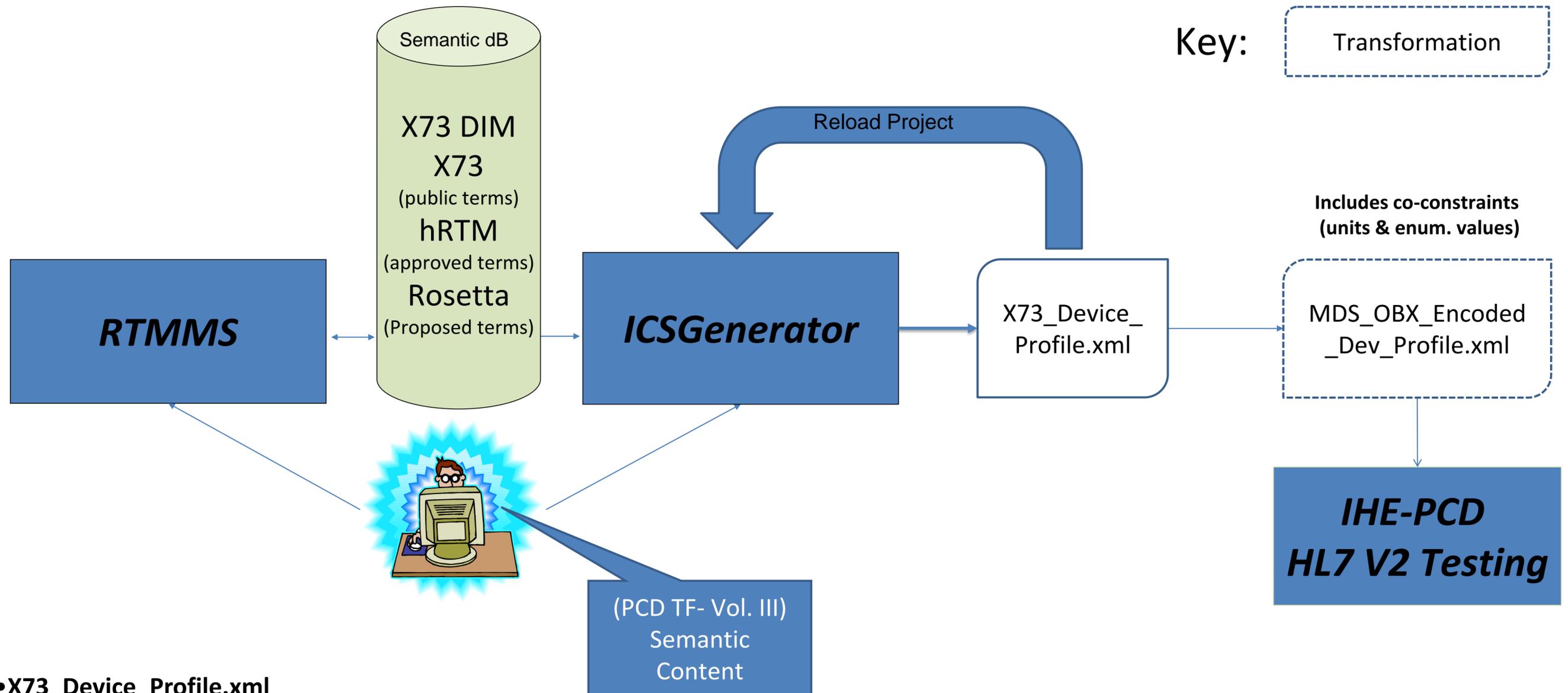
- Reference Id: MDC_PRESS_BLD_ART_ABP_SYS
- Term Code: 2:18965
- Display name: Systolic
- Description:

Comment

"MDC_DIM_C M_H2O", unit used in Vol3 is not in hRTM

DIM	UOM_MDC	UOM_UCUM	Term Code
LMT-2L-2	MDC_DIM_MMHG	mm[Hg]	4:3872
LMT-2L-2	MDC_DIM_KILO_PASCAL	kPa	4:3843

ICSGenerator and IHE-PCD V&V testing artifacts



•X73_Device_Profile.xml

- Main testing artifact, this file will be transformed to an **HL7 OBX encoded** file. ICSGenerator OBX encoded X73 device profile,

•MDS_OBX_Encoded_Device_Profile.xml includes:

- OBX-2(data types) → could develop for partial data type testing
- OBX-3 (OBX-3.1= <term code> ,OBX-3.2= <refid> and OBX-3.3="MDC")
- OBX-4 (containment), dotted notation
- OBX-5 (enumeration values) – **ICSGenerator access to hRTM**
- OBX-6(units) – **ICSGenerator access to hRTM**
- OBX-7(value range) if provided
- Cardinality at object level ???
- Attribute, behavior and notification information could also be added as a mapping to OBX segment is defined.

Thank YOU! For your attention

- DIM Work w/ Art and Shin...(reference associated slide set)
- Discussion?