

HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

NIST Medical Device Communication Testing

Semantic interoperability of Medical Devices

Test Tool Update

Joint HL7/IEEE 11073 Healthcare Devices Working Group

National Institute of Standards and Technology

15 January, 2013 – Phoenix, Arizona

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

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- Julien Deshayes (Guest Researcher) – HL7 V2 Tools
- Nicolas Crouzier (GR) - RTMMS
- Jing Gao (GR) – ICSSGenerator
- Art Griesser (*Prometheus Computing*) – DIM Modeling

Discussion Topics

- *HL7 V2 (2.6) IHE-PCD Validation Tools*
 - Cycle 7 – 2012-13; Fall/Winter Pre-Connectathon [completed] + Virtual Testing, January/February 2013 Connectathon, March 2013 HIMSS13
 - IHE-PCD Pre-Connectathon, “Isolated Environment”
 - IHE-PCD Connectathon, “Instance Environment”
- Rosetta Terminology Mapping Management System (*RTMMS*) Overview
 - RTMMS Deployment Update and service status
 - IEEE Agreement to make available the “Works”
- ISO/IEEE 11073 ‘*Domain Information Model Editor*’
 - Proposed Roadmap
 - UML Defined x73 DIM, Provides DIM Objects
 - Art Griesser: issues/questions worked on via Tooling and Standards weekly WG

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HL7 V2.6 Validation Tooling IHE-PCD Pre-Connectathon Cycle 7

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2012-12 IHE-PCD Pre-Connectathon Status

- IHE-PCD: NIST “Isolated Environment” Test Tools required
 - HL7 V2.6
 - Supports 6 Integration Profiles
 - DEC – Device Enterprise Communication (9)
 - SPD – Filter (4)
 - POI – Pulse Ox (3)
 - PIV – Patient Infusion Verification (7)
 - IPEC – Infusion Pump Event Communication (6)
 - IDCO – Implantable Device Cardiac Observation (4)
 - ACM – Alarm Communication Management (1)
 - RDQ – Retrospective Data Query (1)
- 28 Test Cases
- 60+ existing User Accounts
 - In total since tool made available

IHE-PCD 2012/13 Pre-Connectathon + Connectathon

NIST Testing Support

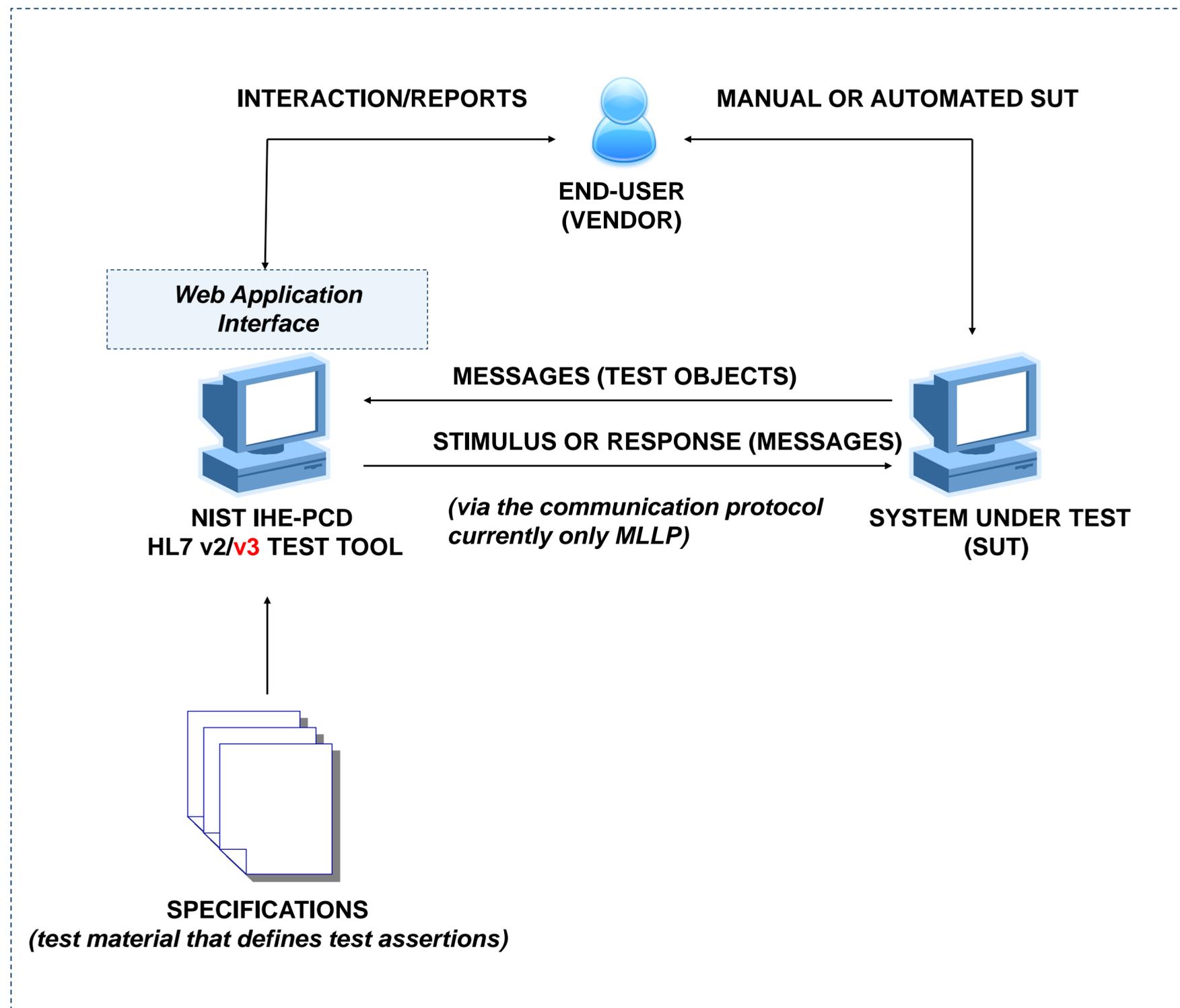
The NIST V2 (2.6) Tools perform the following validation:

- 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 Cycle 7 2012-13 Pre-Connectathon Test Result Statistics – Organizations and Tests Executed

- Total Organizations (by User Accounts): 19
 - Total Organizations (by *unique Company Name): 14
- *Org No. followed by dash indicates more than one account from same organization in following slide

Registered (stored) at NIST site (over Pre-Con 2012-13 cycle)

- Total number of Tests Executed: 82
- Total Number of Tests Passed: 81
- Total Number of Tests Failed: 1

IHE-PCD Cycle 7 2012-13 Pre-Connectathon Test Result Statistics – by Actor

Organization running DEC Reporter: 16

Organization running DEC Consumer: 1 (1 Test Case) – OZ Systems

Organization running DEC Filter: 1 (1 Test Case) – B Braun

Organization running PIV Programmer: 0

Organization running PIV Consumer: 5

Organization running ACM Reporter: 6

Organization running ACM Manager: 1 (1 Test Case) – Philips Medical

Organization running IDCO Reporter: 0

Organization running IDCO Consumer: 0

Organization running IPEC Reporter: 4

Organization running IPEC Consumer: 0

Organization running RDQ Reporter: 0

Organization running RDQ Consumer: 0

Organizations running DEC Option POI: 1 (3 Test Cases) - Massimo

2012-13 IHE-PCD Pre-Connectathon Results, 1 of 3

Org No.	Organization	Result	Integration Profile/Actor
1-1	GE (Yang)	1 Pass	DEC Reporter
1-2	GE Healthcare (Flanders)	1 Pass	DEC Reporter
2	B Braun (Engelbert)	1 Pass 4 Pass 4 Pass 1 Pass 6 Pass	DEC Report DEC Filter PIV Consumer ACM Reporter IPEC Reporter
3	True Process, Inc (Anggara)	1 Pass 5 Pass	DEC Reporter PIV Consumer
4	Carefusion (Lunde)	1 Pass 5 Pass 3 Pass/1 Fail	DEC Reporter PIV Consumer IPEC Reporter

2012-13 IHE-PCD Pre-Connectathon Results, 2 of 3

Org No.	Organization	Result	Integration Profile/Actor
5-1	Philips Medical (Gold)	1 Pass	ACM Manager
5-2	Philips Healthcare (Rhoads)	1 Pass	DEC Reporter
5-3	Philips Healthcare (K, Raja)	1 Pass	DEC Reporter
5-4	Philips Healthcare (Shekhar)	1 Pass	DEC Reporter
6-1	West Health Institute (Mellott)	1 Pass	ACM Reporter
6-2	WHI (West Health Institute)	1 Pass 1 Pass 6 Pass	DEC Reporter ACM Reporter IPEC Reporter

2012-13 IHE-PCD Pre-Connectathon Results, 3 of 3

Org No.	Organization	Result	Integration Profile/Actor
7	Nuvon (Neto)	1 Pass 1 Pass	DEC Reporter ACM Reporter
8	Baxter (Yang)	1 Pass 4 Pass	DEC Reporter PIV Consumer
9	Hospira (Walton)	1 Pass 5 Pass 1 Pass 6 Pass	DEC Reporter PIV Consumer ACM Reporter IPEC Reporter
10	Mindray (Fuchs)	1 Pass	DEC Reporter
11	OZ Systems (Kunte)	1 Pass 5 Pass	DEC Reporter DEC Consumer
12	Masimo Corp. (Housel)	4 Pass	DEC Reporter
13	Medtronic Inc. (Stomberg)	4 Pass	DEC Reporter
14	Baxter (Cuti)	1 Pass	ACM Reporter

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Rosetta Terminology Mapping Management System - RTMMS

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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

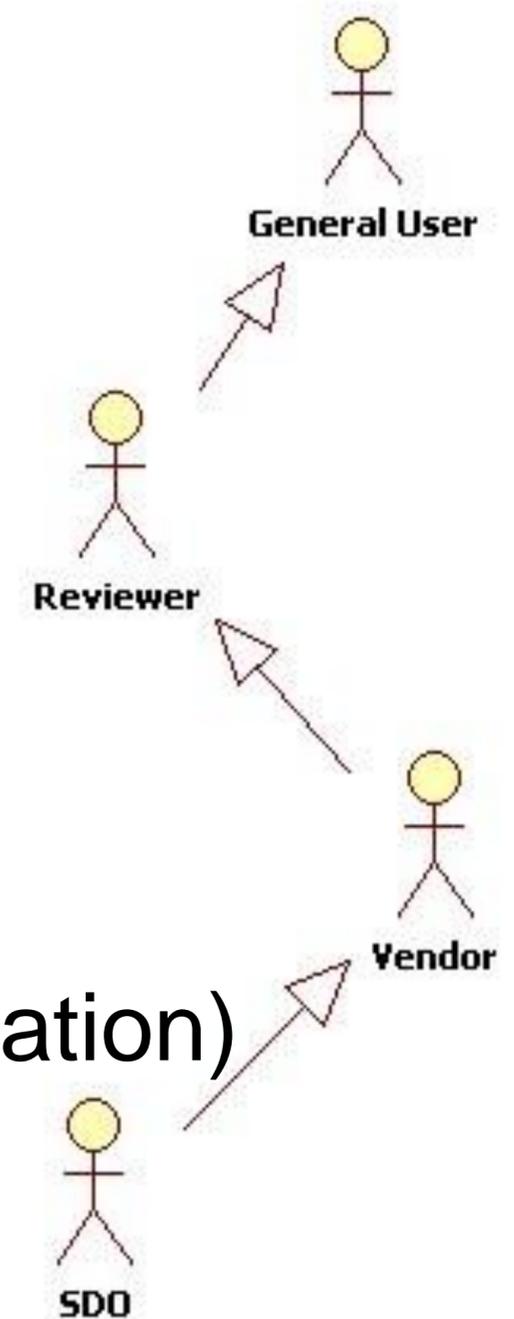
Security DB - Stores users information

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 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 / exported to ‘DIM Editor’*

RTMMS Users

- 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



RTMMS (as of 15 January 2013)

- 605 hRTM terms
- 34 Contributing Organizations now Registered!

Contributing Organization		
CO ID	Suffix	CO Name
DocBox-Inc	DOCBOX	DocBox Inc
Draeger		Draeger-Siemens
Editorial-pss		Editorial additions (Paul Schluter)
Editorial-RTMV		
Elbrys-Networks	ELBRYIS	Elbrys Networks
EPIC	EPIC	EPIC
Eversolve	EVERSOLVE	Eversolve
Fresenius	FRE	Fresenius
GE_Aware	GE	GE (Aware Gateway)
HL7-Hellas	HL7HELLAS	HL7 Hellas
Hospira	HSP	Hospira
IEEE	IEEE	ISO/IEEE 11073-10101 and its extensions
IHE PCD Infusion Pump Work ...	IHEPCDINF	IHE PCD Infusion Pump Work Group
LiveData		LiveData
Mindray	MR	Mindray
Nuvon		Nuvon
OSD_MIL	OSDMIL	OSD MIL
Philips		Philips Healthcare
Shoulders_Corporation	SCO	Shoulders Corporation
Siemens	SI	Siemens
Smiths Medical	SM	Smiths Medical
Spacelabs		Spacelabs Healthcare
STYK		
True Process Inc	TPI	True Process Inc.
VA	VA	Veterans Affairs
VIASYS		Cardinal VIASYS
WelchAllyn		Welch Allyn
West_Health	WH	West Health Institute

RTMMS Primary Updates

- ✓ Agreement finalized between IEEE and NIST (Dec 2012)
 - 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

- ✓ Revised "term approval" Functionality

Revised “term approval” tables/tab

“New proposed terms” tab (205 rows)

Re-groups all the newly proposed terms with “MDCX_” prefix

The ‘Assign REFID’ button allows to change the *REFID* from an “MDCX_” term to a “MDC_term” (or anything else)

RTM Management Service
In partnership with NIST

sdo (SDO) | User Guide | Preferences | Logout

Home | Contributing Organizations Rosetta | Rosetta | hRTM | Units | Enumerations | Groups | Contributing Organizations X73 | Term Approval

New proposed terms | Ready to review terms | Mapped terms | Approved terms | Proposed units | Proposed enumerations

Proposed Terms Table

Assign REFID | Download | Search

Group	REFID	Standard Tbl	CF_CODE10	DIM	UOM_MDC	UOM_UCUM	CF_UC
CVS_HEMO_CALC_...	MDCX_			L 1 1 L3 ...	MDC_DIM_MILLI_L_PER_M_SQ	MDC_...	mL/m2 % {unitle...
GASDLV	MDCX_AIRWAY_PRESS_COMPENSATION_ENA...						
CNS_EEG	MDCX_ALARM_LIMIT_EXCEEDED						
DS-IP-SYR DS-IP-PC...	MDCX_ATTR_EVT_COND						
GASDLV	MDCX_AUDIO_ALARM_VOLUME_SETTING			[Bel]	MDC_DIM_DECIBEL	dB dB[10.nV]	26:
GASDLV	MDCX_AUDIO_BATT_VOLUME_SETTING			[Bel]	MDC_DIM_DECIBEL	dB dB[10.nV]	26:
GASDLV	MDCX_AWAY_CO2_ET_AVG_PERIOD_SETTING			1	MDC_DIM_BREATH	{breath}	26:
GASDLV	MDCX_BI_PHASE_TIME_HIGH_PSV_SETTING						
GASDLV	MDCX_BI_PHASE_TIME_HIGH_SETTING				MDC_DIM_SEC	s	26:
GASDLV	MDCX_BI_PHASE_TIME_HIGH_TRANS_SYNC_P...			1	MDC_DIM_PERCENT	%	26:

Page 1 of 5 | Displaying terms 1 - 50 of 205

Term Approval, cont.

- “Ready to review terms” tab (220 rows):
 - Terms with MDC_ prefix and null or 0 term code
 - The ‘Register’ button allows to register a term (define a Block, partition, code, systematic name etc...) to the x73 database

RTM Management Service
In partnership with NIST

sdo (SDO) User Guide | Preferences | Logout

Home Contributing Organizations Rosetta Rosetta hRTM Units Enumerations Groups Contributing Organizations X73 Term Approval

New proposed terms **Ready to review terms** Mapped terms Approved terms Proposed units Proposed enumerations

Ready Terms Table

Register Download Search

Group	REFID	Standard Tbl	CF_CODE10	DIM	UOM_MDC	UOM_UCUM	CF_UC
CVS_HEMO_CALC	MDC_ACCELERATION_INDEX	Hemo-msmt	0				
INFANT_INCUBATO...	MDC_ATTR_PT_WEIGHT_LAST	ECG-lead	0		MDC_DIM_G	g	26
GASMON_AR	MDC_AWAY_AR	Resp-msmt	0	L3L-3 LM...	MDC_DIM_VOL_PERCENT MDC_DIM_...	%{vol} kPa mm[Hg]	26
GASMON_AR	MDC_AWAY_AR_EXP	Resp-msmt	0	L3L-3 LM...	MDC_DIM_VOL_PERCENT MDC_DIM_...	%{vol} kPa mm[Hg]	26
GASMON_AR	MDC_AWAY_AR_INSP	Resp-msmt	0	L3L-3 LM...	MDC_DIM_VOL_PERCENT MDC_DIM_...	%{vol} kPa mm[Hg]	26
GASMON_HE	MDC_AWAY_HE	Resp-msmt	0	L3L-3 LM...	MDC_DIM_VOL_PERCENT MDC_DIM_...	%{vol} kPa mm[Hg]	26
GASMON_HE	MDC_AWAY_HE_EXP	Resp-msmt	0	L3L-3 LM...	MDC_DIM_VOL_PERCENT MDC_DIM_...	%{vol} kPa mm[Hg]	26
GASMON_HE	MDC_AWAY_HE_INSP	Resp-msmt	0	L3L-3 LM...	MDC_DIM_VOL_PERCENT MDC_DIM_...	%{vol} kPa mm[Hg]	26
GASMON_N2	MDC_AWAY_N2_EXP	Resp-msmt	0	L3L-3 LM...	MDC_DIM_VOL_PERCENT MDC_DIM_...	%{vol} kPa mm[Hg]	26
BLD_CHM_ART	MDC_BASE_EXCESS_BLD_ART_INDEX?						

Page 1 of 5 Displaying terms 1 - 50 of 220

- ✓ These processed terms would become / be added to the harmonized Rosetta terms (hRTM) upon approval by SDO user and balloting

RTMMS Updates, cont.

- User can now download an HTML version of:
 - “hRTM”
 - “New proposed terms”
 - “New proposed terms” table,
 - Note: hope is users find this version to be easier to work with when working outside the tool
- “Standard Table”
 - A new column “Standard table” is now present in all Rosetta, hRTM and review tables -
 - Provides association of the term with corresponding table in the base standard
 - Only the terms given by Jan W. (275) REFIDs are currently linked
 - NIST can add more if community provides the/additional mapped terms.

Domain Information Model UML / DIM Editor, Proposed Roadmap

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Contact: Arthur Griesser <a.griesser@prometheuscomputing.com>

How Should Road Map be Built?

- Suggested process
 - First figure out where we want to go (goals)
 - Then figure out how to get there
- Suggested principles
 - Get fundamental artifacts fast
 - Prove one implementation strategy fast
 - Iterative improvement
 - Basic functionality first, frills next, 'pretty' last
 - Rigorously OO
 - Add additional implementations

Goals

- Widespread use of standard
 - Clear, easy implementation
 - Machine interpretable artifacts
 - Artifacts in multiple forms, for multiple technologies
 - Self consistent, few if any conflicts
 - All artifacts derived from one fundamental source
 - Useful, meets user needs (use cases as tests)
 - Compliance tests
 - Interoperability tests

Progress I

- Made UML model from DIM standard
- Made XML Schema from UML model of DIM
- Made web-based editor for DIM data
- Added to DIM UML and web app:
 - RTMMS data
 - Conformance statements
 - Meta-information
- Demonstrated an example (non-DIM) standard derived from a model

Progress II

- Created interface for DIM section 8
- Finished testing framework document
- Injected additional metainformation into UML
 - Encoding values, clause numbers & titles, name binding, registered as, description, update type, attribute id
- Discussed semantics of DIM groups
- Discussed ASN.1 representation of inheritance
- Generated JSON and YAML files of meta-info

Next Steps

- Understand ASN.1 generation requirements
- Derive ASN.1 syntax programmatically
- Extract normative text, with formatting
- UML model elements associated with normative text
- Programmatically generated IEEE compliant standard
- Add containment tree browser to DIM GUI
- Executable use cases
- Review ASN.1/UML/XML mapping
- Generate HL7 messages
- Review & improve models
- Encoded versions of schema

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