HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

NIST
Medical Device Communication Testing

Semantic interoperability of Medical Devices

HIT Test Tool Update

National Institute of Standards and Technology

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- Julien Deshayes (Guest Researcher) – HL7 V2 Tools
- Nicolas Crouzier(GR) - RTMMS
- Jing Gao (GR) - ICSGenerator

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**

Content Topics

- RTMMS Deployment Update and Status
  – User Membership Protocol
- Rosetta Terminology Mapping Management System (**RTMMS**) Overview
- RTMMS & ICSGenerator - **IHE-PCD V&V Testing**

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 considering making the access to RTMMS freely available ☺
    - IEEE requested June 2012 stakeholders' meeting – likely final approval

RTMSS - Deployment Plan – Going Forward

- RTMMS becomes the “master” version going forward
- 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 and account
    - **http://hit-testing.nist.gov:13110/rtmms/**
  - NIST will perform the appropriate background checks
    - Initially there may be a 3-5 business day turn-around
    - If approved (vetted with IEEE) - NIST will provide a corresponding email with approved account information.

RTMSS - Deployment Plan (continued)

- NIST has in parallel performed initial evaluation ISO/IEEE 11073 “SDO Database”
  - Created, owned, and used by Jan Wittenberg (Philips Healthcare) as IEEE x73 Upper Layer Chair
    - Tool used for moving to x73-10101 V2
  - NIST/x73 Co-chairs working on a procedure to integrate RTMMS data with Jan W’s/x73 database and enable additions to the standard vetted through the x73 ballot process.
- RTMMS X73 dBase has 5604 terms vs. 3803 terms in SDO dBase (+1801)
- There are 208 terms (RefIDs) not present in NIST database.

- Overall there are (≈ 236 terms) terms in our database that are not in Jan’s SDO dBase.

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

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

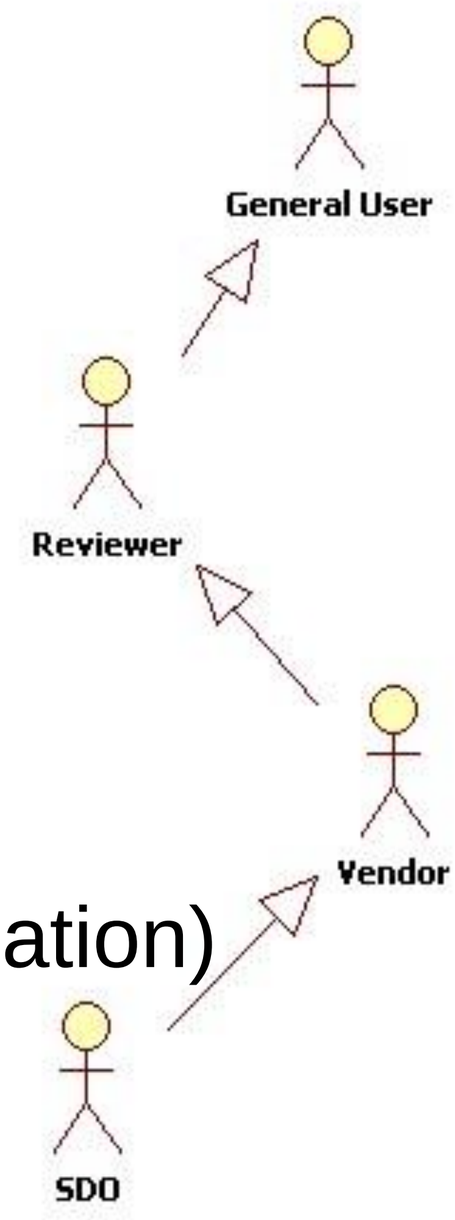
RTMMS Features

- 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 proposed 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



Issues / Key Work Items

- 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 exerts (e.g., Clem McDonald – NLM)

Issues / Key Work Items

- Term review/approval process to date - not yet finalized
  - If approved, would this require a new type of user “RTM/ICE” that will approve terms with RTMP|ICEP status?

code^REFID	<Status>	Description
V#^MDC*VV*_	-	Vendor ‘private term’, vendor Partition MDCGE_PART_* and vendor MDCGE_ REFID *Vendor uses assigned V# for MDCVV_PART_* partition (upper 16-bits) and assigns lower 16-bit code.*
↓		
V#^MDC*VV*_	RTMP | ICEP	Vendor ‘private term’ that is later proposed by RTM or ICE for ‘elevation’ to MDC_ term. *If MDC_ term approved later on, it can be declared as a ‘preferred’ Rosetta synonym with vendor private term.*
↓		
0^MDC_	RTMP | ICEP	0^**MDC_*refid*** that is **proposed** for further consideration by RTM or ICE teams. *Comparison with existing IEEE 11073 REFIDs should be done **before** submitting them for RTM or ICE review.*
↓		
0^MDC_	RTMA | ICEA	0^**MDC_*refid*** that has been **approved** by RTM or ICE **for final consideration** by IEEE General Committee. *This includes a thorough vetting against existing, proposed and private terms; suitable for Connectathon testing.*
↓		
0^MDC_	IEEEA	0^**MDC_*refid*** that has been **approved by IEEE GC for #^MDC_ status**. *All that needs to be done is assign the CF_CODE10 numeric identifier (partition and CODE_10 value).*
↓		
#^MDC_	don’t care	Term that has been approved by IEEE GC and has an assigned numeric code.

Issues / Key Work Items

- If the term review/approval process is approved then,
  - A list of suffix for each vendors (the *VV* in MDC*VV*_) must be provided.
  - Are there rules for these/such suffixes? (e.g., max length, case, who decides new suffixes..)

Vendor id	Suffix
AMS-Consulting	AMS
BBraun_PL	
Breakthrough Solutions Foundry	BSF
Capsule	
Cerner	CERN
DocBox-Inc	DocBox
Draeger	
Editorial-pss	
Editorial-RTMV	
EPIC	EPIC
GE_Aware	GE
Hospira	HSP
IEEE	IEEE
IHE PCD Infusion Pump Work Group	IHEPCDINF
LiveData	
Mindray	MR
Nuvon	
Philips	
Spacelabs	
STYK	
VIASYS	
WelchAllyn	

RTMMS Updates

- 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_Tsb6wlF8&hd=1

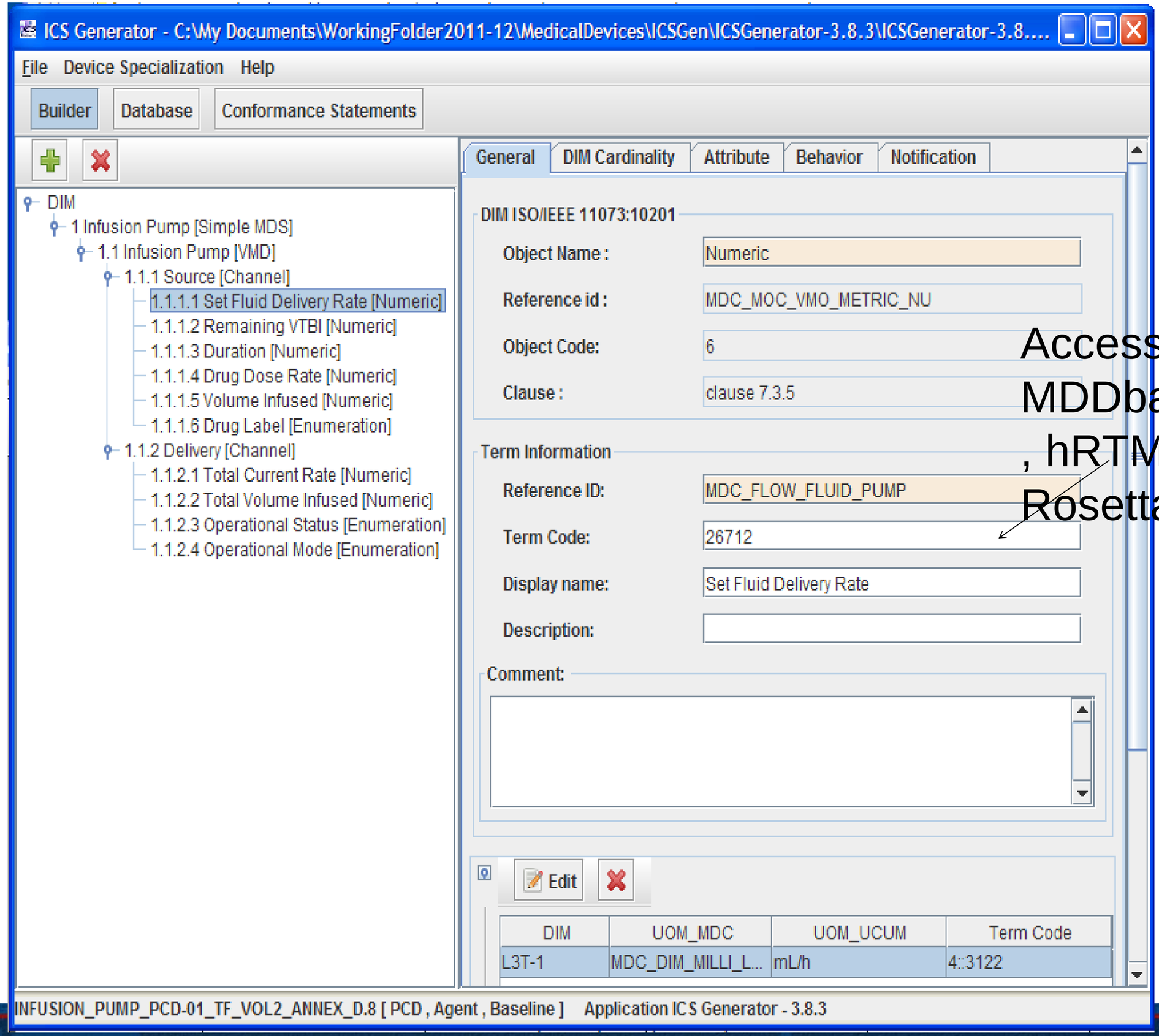
ICSGenerator Overview

- 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

- 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)



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

PDF generated from the Infusion Pump Device profile

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/

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)

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)		

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”

ICS Generator - C:\My Documents\WorkingFolder2011-12\MedicalDevices\ICSGen\ICSGenerator-3.8.5-pre-sp\ICSGenerator-3.8.5-pre-sp\Physiol...

File Device Specialization Help

Builder | Database | Conformance Statements

- Profile (Overview)
  - 1 Physiological Monitor [Hydra MDS]
    - 1.1 Blood Pressure [VMD]
      - 1.1.1 Invasive BP [Channel]
        - 1.1.1.1 Arterial Blood Pressure [Compo
          - 1.1.1.1.1 Systolic [Numeric]
          - 1.1.1.1.2 Diastolic [Numeric]
          - 1.1.1.1.3 Mean [Numeric]
        - 1.1.1.2 Wedge Pressure [Numeric]
      - 1.1.2 Non-Invasive BP [Channel]
        - 1.1.2.1 Non-Invasive Blood Pressure [C
          - 1.1.2.1.1 Systolic [Numeric]
          - 1.1.2.1.2 Diastolic [Numeric]
          - 1.1.2.1.3 Numeric
        - 1.1.2.2 Cuff Pressure [Numeric]
      - 1.1.3 Pulse Rate BP [Channel]
        - 1.1.3.1 Pulse Rate [Numeric]
    - 1.2 Temperature [VMD]
      - 1.2.1 Temperature [Channel]
        - 1.2.1.1 Body Temp [Numeric]
        - 1.2.1.2 Skin Temp [Numeric]
        - 1.2.1.3 Core Temp [Numeric]
    - 1.3 Pulse-Oximeter [VMD]
      - 1.3.1 Pulse-Ox [Channel]
      - 1.3.2 Pulse Rate Ox [Channel]
    - 1.4 ECG Monitor [VMD]
      - 1.4.1 ECG [Channel]
      - 1.4.2 ECG Resp [Channel]
      - 1.4.3 Heart Rate [Channel]
      - 1.4.4 Arrhythmia [Channel]
      - 1.4.5 Ischemia [Channel]
      - 1.4.6 ECG Measurements [Channel]
    - 1.5 Cardiac Output [VMD]
      - 1.5.1 Continuous CO [Channel]

General | DIM Cardinality | Attribute | Behavior | Notification

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

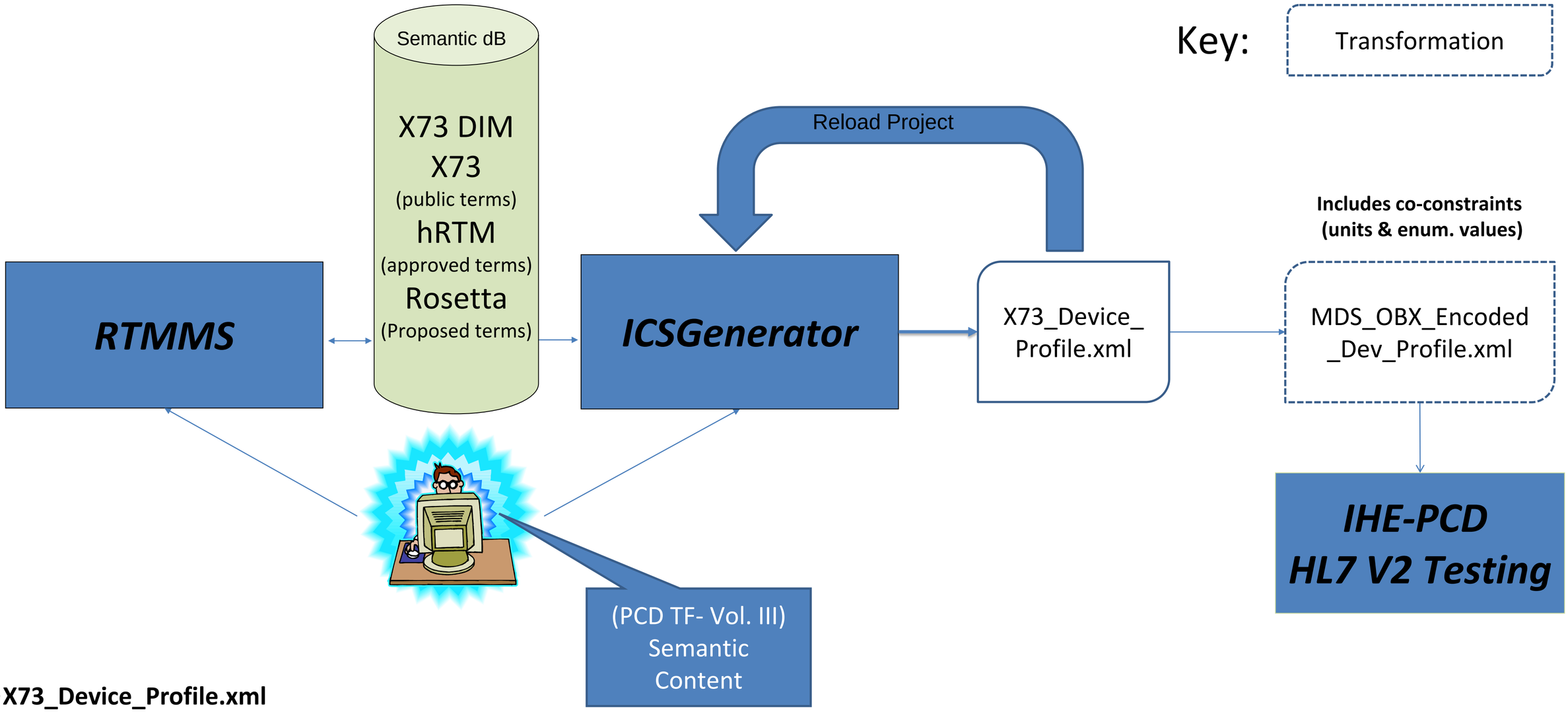
“MDC_DIM_CM_H2O “, unit used in Vol3 is not in hRTM

Edit

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

Application ICS Generator - 3.8.5

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 if there is a mapping to OBX segment.

Thank YOU! For your attention

- Discussion?