

# IHE-PCD ISO/IEEE 11073, and NIST

NIST Medical Device Connectivity Test Tooling

IHE-PCD/IEEE WG Meetings (F2F @ Berkley, California) May 4, 2010





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- Jing Gao (GR)

**Project Web site:** 

www.nist.gov/medicaldevices

Semantic Interoperability of Medical Devices





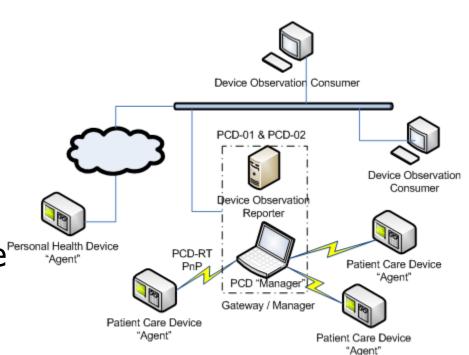
# Topics

- Areas being addressed by Test Tooling Effort
- HIT Test Infrastructure
  - Conformance testing across various test environments
- IHE-PCD HL7 Message Verification
  - Using Profiles (constraints  $\rightarrow$  assertions)
- IHE-PCD Tooling (2010 cycle 4) & going forward...(2010-11 cycle 5)
- ISO/IEEE 11073 Tooling
  - RTMMS
  - ICSGenerator





- Medical Device Standards Work
  - Device and Enterprise-level
- Integrating Health Enterprise - Patient Care Devices (IHE-PCD)
  - Enterprise-level
- Personal Health Devices
  - Personal Tele-health-level
  - Facilitate the efficient exchange of medical device Personal Health Device and vital signs data throughout the HC enterprise
    - Test Research Methods
    - Conformance → Interoperability (based on Standards)
    - Ultimately: Real-time plugand-play interoperability



**Medical Device Communication** 



#### NIST Test Effort



#### **IHE-PCD** Testing

#### **IHE-PCD Testing – Key Objectives**

- Increase test comprehensiveness & quality
- Support both conformance & interoperability testing
- Support for pre- & virtual- connectathons, actual connectathon & enable year round testing
- Remain in alignment with IHE-PCD integration profile development road map
- Establish single framework for PCD covering increasing complexity and technologies over next 5 years
- Coordinate with IHE "Gazelle Project" and NIST's HIT Test Infrastructure
- Generate work products that companies can use in their regulatory submissions





#### **IHE-PCD** Testing

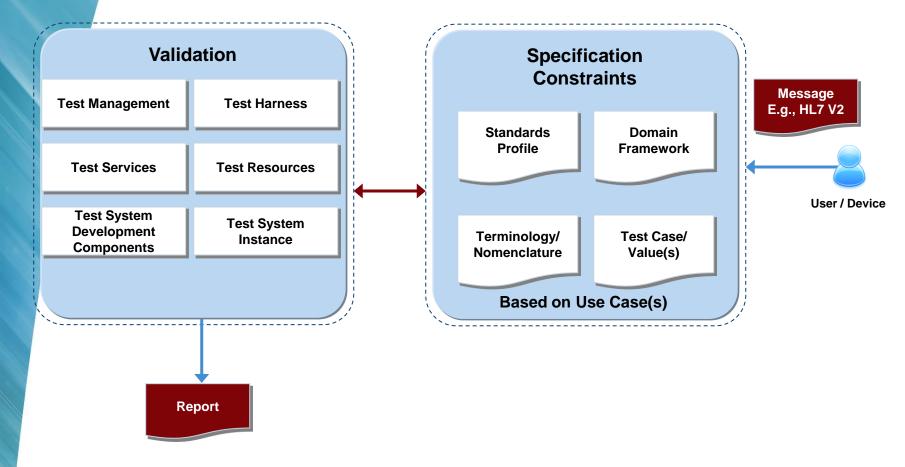
#### **IHE-PCD Testing – Key Ingredients**

- Well Defined Integration Profiles
  - Technical Framework
  - Supplements
- Unambiguous Standards
- Test Guidelines
- Test Plans
  - Test Scenarios, Actors, Transactions, Validation Criteria
- Test Artifacts, including:
  - HL7 Profile(s) (and eventually x73 Device Specializations?)
  - Repositories
  - Nomenclature (e.g., RTM)
  - Value Tables (e.g., HL7, units, local, etc.), Default and Sample Values
- Test Cases





#### Conformance Testing: Using 'Profiles' to Advance Rigorous Testing

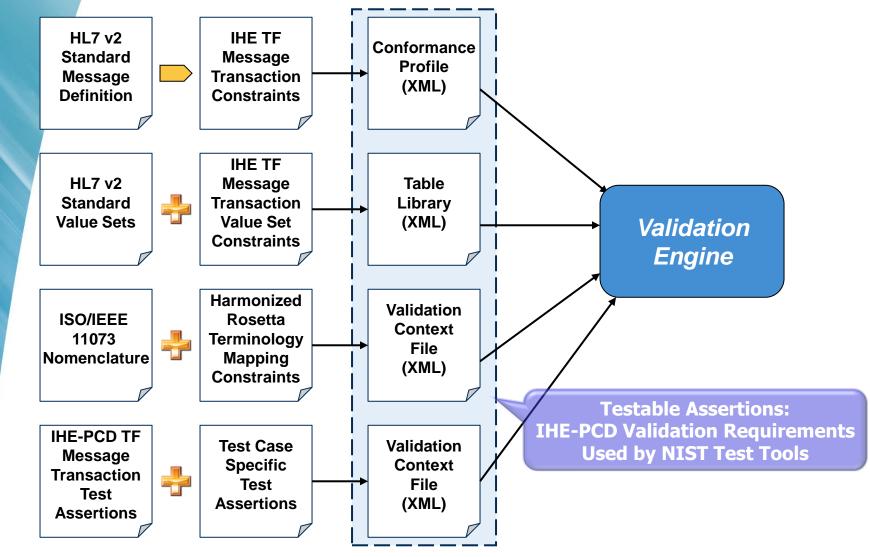


Patient Care Devices (PCD)





#### Validation Operational Process: Origin of Test Assertions



Patient Care Devices (PCD)





#### NIST V2 Testing Tools and Services Testing Validation Types

- Validation against 'failure types':
  - **VERSION\*:** The version in the message and in the profile should match.
  - MESSAGE\_STRUCTURE\_ID\*: The message type (MSH.9 element) in the profile and in the message should match.
  - MESSAGE\_STRUCTURE: The message should have a valid message structure (correct usage, correct cardinality, and correct element name).
  - USAGE: R elements should be present; X elements should not be present in the message.
  - CARDINALITY: Elements should be present at least the minimum times and at most the maximum times specified in the profile. It should also take into account the usage of the element (X element with a minimum of 4 should not be present in the message).
  - LENGTH: The value of the element should have a length equal or less than the value specified in the profile.
  - DATATYPE: For the datatype NM, DT, DTM, SI and TM, the value of the element should match the regular expression defined in the standard.
  - DATA: The value of the element should match a constant specified in the profile, a value set specified in a table, a value or a regular expression specified in the message validation context.
  - MESSAGE\_VALIDATION\_CONTEXT\*: This is a user input error when the location specified in the message validation context can't be found in the message.
  - TABLE\_NOT\_FOUND\*: This is a user input when a table can't be found in the table files (TableProfileDocument).
  - **AMBIGUOUS\_PROFILE\*:** The profile should not be ambiguous.





#### Test Environment Message Validation NIST V2 Testing Tools: IHE-PCD

- Validation of IHE-PCD message(s) and corresponding HL7 Profile(s)
- Syntax and Semantic Content Validation
  - Against HL7 V2 message (e.g., PCD-01)
    - Message structure (e.g., MSH,PID,PV1,OBR,NTE,{{OBX},OBX,OBX,OBX,...})
  - Against HL7 profile
    - (Msg\_type^Event\_type^ e.g., ORU^R01^...)
  - Against HL7 and/or user 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)





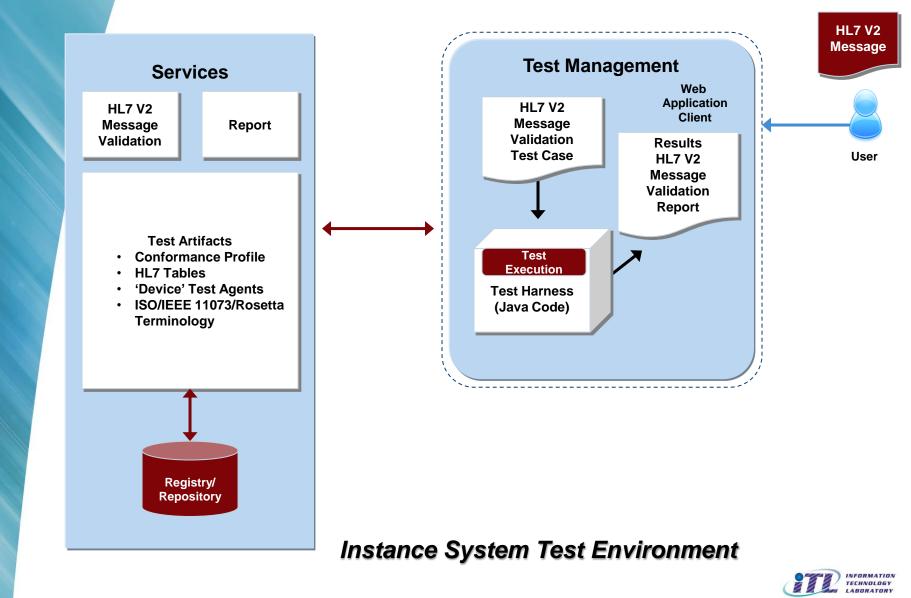
## **Test Environments**

- Instance Testing
  - Conformance (e.g., against HL7 V2.x or CDA)
    - Implementation conforms to Spec. on which it is based
- Isolated System Testing
  - Includes Instance Testing Activities
  - Protocol Conformance
  - Functional Behavior Conformance
    - Features and Operational behavior correspond to Specs.
- Peer-to-Peer System Testing
  - Includes Isolated System Testing Activities
  - Interoperability Testing
    - Testing complete application environment
    - May include interacting w/ Database, using Network Communications, or interacting w/ other hardware, apps, or systems if appropriate





#### Conformance Testing of an HL7 V2 Message





## **Test Environments**

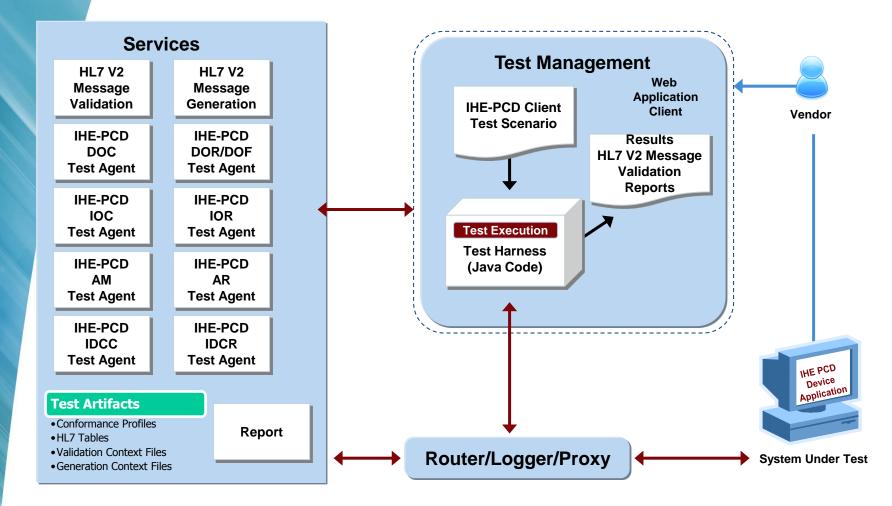
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#### NIST HIT Test Infrastructure





#### IHE-PCD Testing using a Web Application Client



Isolated System Test Environment

INFORMATION TECHNOLOGY LABORATORY





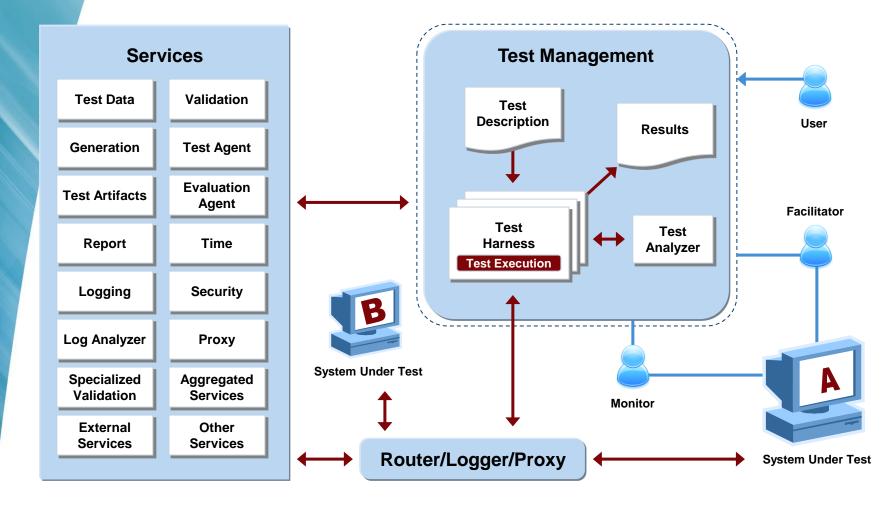
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#### A Framework for Building Test Systems—an SOA Approach



#### Peer-to-Peer Test Environment





#### NIST'S IHE-PCD HL7 V2 TOOLS IHE-PCD Pre-Connectathon Tool

#### http://xreg2.nist.gov:8080/PCD-HL7Web/

Select the IHE profile, the ac IHE Profile	tor, the transaction and the Sending Actor	e test case corresponding to the mo Transaction	essage to validate (required) Pre-Connectathon Test Case
DEC PIV ACM DEC SPD option IDCO	DOR	PCD-01 (ORU_R01)	60001 (Message 1) 60002 (Message 1) 60003 (Message 1) 60004 (Message 1) 60005 (Message 1) 60006 (Message 1) 60007 (Message 1) 60009 (Message 1) 60009 (Message 1) 60010 (Message 1) 60041 (Message 1)
Select the message to validation	ate (required)	<u>×</u>	<u>v</u>
O Browse for a message:			Browse
or Paste a message:			



## NIST's IHE-PCD HL7 V2 Tools

#### **IHE-PCD** Connectathon Tool

http://xreg2.nist.gov:8080/PCD-HL7WebCon/

ome Message Valida	ation				
<u>alidate</u> Report Viev	w Errors Parse Message	Configure			
Select the IHE profil	le, the actor, the transactic	on and the test case correspondi	ing to the message to valida	te (required)	
IHE Profile	Sending Actor	Transaction	Connectathon Test Case	Step	
DEC	IOP	PCD-03 (RGV_015)	PIV_Test_Patient_D	1	~
PIV ACM	IOC		PIV_IOP_IOC_Exces PIV_Multiple_Pumps	3 5	
DEC SPD option			PIV_IOP_IOC_Two_	7	
IDCO			PIV_IOP_IOC_Comm	63	
	2	*	3		4
Select the message	to validate (required)				
Browse for a mess	sage		Browse.		
Oor Paste a messag	171 J				
or r doto a mooodg	,				
Load Message					
Start Validation					
Validate					
T diff di di t di					



# ISO/IEEE 11073 – How Are We Involved?

- MDC Standards development
  - ISO/IEEE 11073 Point-of-care Medical Device Communication
  - Co-chair new normative chapter addition provides NIST developed electronic information model
  - Assist development of more complete and correct specifications prior to balloting
  - Work with SDOs (testing perspective), clinicians, clinical engineers
- Device Communication Test Tooling
  - XML Schema of the ISO/IEEE 11073 Domain Information Model
  - ICSGenerator Tool
    - Produces standard-compliant device profiles and specializations
    - Generates Implementation Conformance Statements
  - ValidatePDU Tool
    - Provides message syntax and semantic validation
  - Java Class Library (of standard's syntax notation)
    - Implementable-code of abstract types defined in standard
    - Coder (encodes and decodes APDUs/messages)
  - 'Rosetta' Terminology Management System
    - Standardized terminology across MD manufacturers





#### Rosetta Terminology Mapping Management System (RTMMS)

National Institute of Standards and Technology (NIST)

MARIA CHERKAOUI, John Garguilo, Sandra Martinez April 2010



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# NIST Tooling To Support RTM Process (\*Championed by Paul Schluter [GE Healthcare])

What is RTMMS?

- A web application that allows vendors and reviewers access, retrieval, and reporting of Rosetta Tables over the internet in conformance to RTM
- The tool provides the capability of saving the data in the XML format as defined by RTM
- Aid in The harmonization process by:
  - Identifying missing terms
  - Facilitate the proposal of new terms
  - Facilitate discussion of the proposed term
  - Automatic generation of the "Harmonized Rosetta Table"
- Database/XML Server initially prototyped and located at NIST
- A web service/tool used as part of SDO's ballot / approval process





#### NIST Tooling To Support RTM Process

# What is RTMMS? (Continued)

- Facilitate Conformance Tooling
  - Message verification and conformance
  - Leading to interoperability...



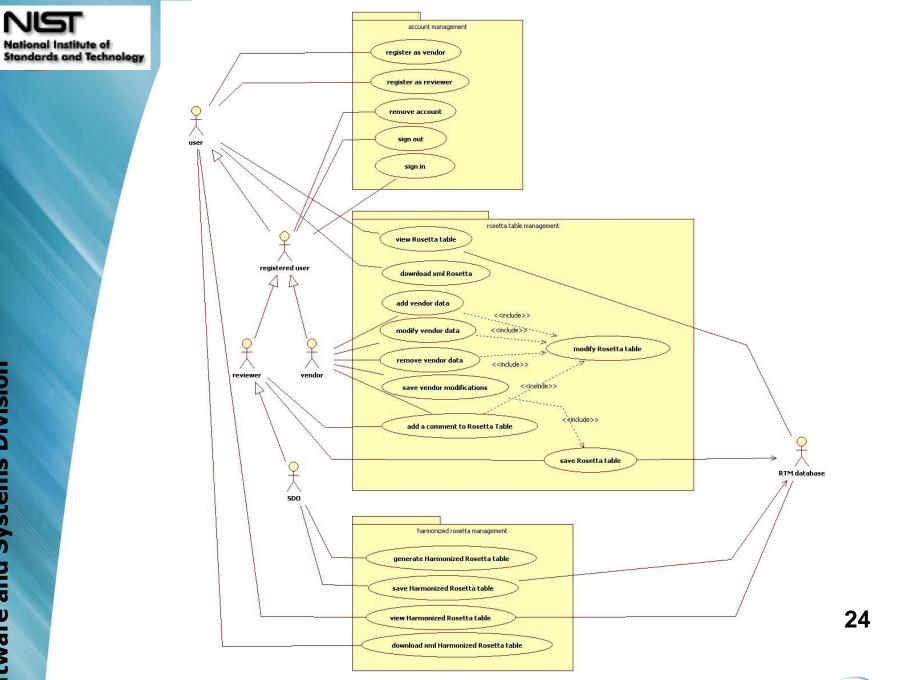


# RTMMS vs. RTM Excel process

#### • For Vendors

- Facilitate input of entries by vendors
  - Tooltips providing supplementary information
  - Available Interface to lookup values from the database
  - Automatic completion of codes
  - Validation of required content
- Reduce errors made by vendors while submitting entries
- For Reviewers and SDO
  - Facilitate the generation of the Harmonized Rosetta
  - Help the review process of Rosetta entries
    - Highlighting discussed entries
    - Highlighting proposed REFIDs
    - Adequate interface to view discussions and add comments
- For all users
  - Rosetta data available to everyone any time
  - Provide XML version of tables
    - All XSLT transformations can still be used

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# **RTMMS Roles**

- "Non-registered User"
  - Able to download RTM (latest approved version)
- "Vendor" (Registered)
  - Able to view, edit and propose vendor terms (only for vendor they are registered with)
- "Reviewer" (Registered)
  - Able to view all vendor terms and make annotations (discussion points)
- "Expert Reviewer" (Registered and approved by SDO)
  - Technical expert (e.g., Jan Wittenber (Phillips) and Paul Schluter (GE)) who can view and comment on all vendor terms
  - Expert has the ability to generalize term to overall specification
- "SDO" (Standards Development Organization approved official)
  - Authority to approve/decline new or edited term proposed by vendor
  - Approval based on SDO ballet rules
  - Considers working group and especially 'Expert Reviewer' input
  - Usually chair/co-chair of standards body and or working group
- "Administrator" (Approved by 'SDO')
  - Provides administrative support to database
  - Generates and provides new user account information (user name and password), delete accounts, etc.



#### Database

- Models RTM data and relationships
- Uses x73 Nomenclature database
  - REFIDs
  - Term codes
  - Partition numbers
  - (New terms added as approved/normative additions to standard)
- Stores RTM data
  - Rosetta table
  - Units and Unit Groups
  - Enumerations and Enumeration Groups
  - hRTM table
  - (New terms proposed may be missing from x73 Nomenclature Database)

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#### Available Features of RTMMS

- Features based on the Rosetta Supplement
  - Units table management
  - Unit groups management
  - Rosetta table management
  - Handling uncertain REFIDs
  - Automatic generation of the Harmonized Rosetta
    - Need additional requirements
  - XML Rosetta download
- User oriented features
  - User management module (Implemented user (roles) and privileges)
  - Columns filtering
  - REFIDs lookup in database
  - Group lookup in database
  - Units and Enumerations lookup in database
  - Term codes completion from database
  - Saving browsing history
  - User registration





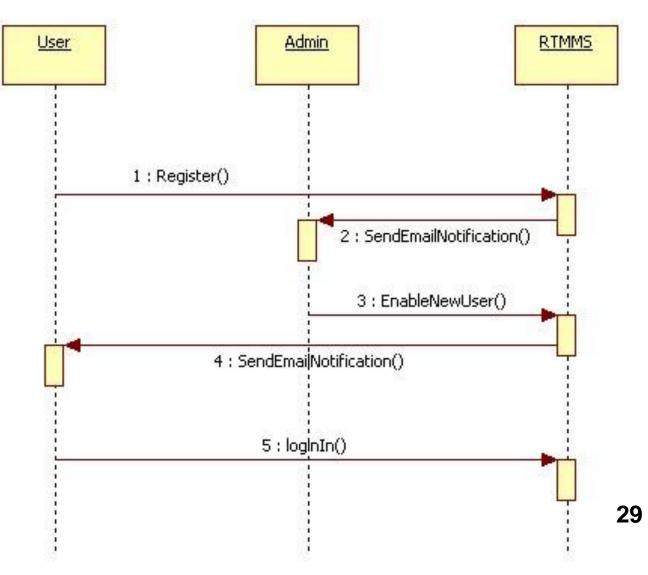
# Features of RTMMS (continued)

- RTMMS Architecture improvements
- New Features (enhancements from May 2009 WG meetings)
  - New x73 Nomenclature
    - Terms in both annexes A and B.
    - IDC Nomenclature
  - Highlighted New Terms in Rosetta, Units and Enumerations Tables
  - Added Interface for selecting REFID from x73 Nomenclature database
  - Added Interface to propose New Terms
  - Added New Term View for SDO users
  - Implement Rosetta validation against H-Rosetta
  - Enhanced registration process.
    - Email confirmation, approval...
  - Added Admin Type of users to manage users and enable new users
  - XML Units Download
  - Added ranking capabilities to assess probability of valid terms in the Rosetta table
    - Scale from 1 to 10
  - Include column filtering based on regular expressions





#### User Registration









#### Units Table

Unit Groups						
Dimension:	lect dimension	¥ X				
Download Table 🛛 🗐	Discussion					
UOM_MDC_REFID	UOM_UCUM	CODE10	Symbol	Description	Discussion	
MDC_DIM_NOS	{unknown}	0	?	«Unspecified»		^
MDC_DIM_DIMLESS		512	-	«dimensionless»		
MDC_DIM_BOOLEAN	1 (unitless)		1/0	«boolean»	(2009-03-06): Must be 1 (t	rue)
MDC_DIM_X_BEL	в		в	Β	(2009-03-06): 6432 for Be	?
MDC_DIM_DECI_BEL	dB		dB	Decibel	(2009-03-06): 6432+16=64	48 1
MDC_DIM_DECIBEL	dB	6432	DB	Decibel	(2009-03-06): DEPRECATE	?
MDC_DIM_X_BEL_MV	B[m∨]		B(mV)	bel millivolt	(2009-03-06): (new code)	for
MDC_DIM_DECI_BEL_MV	dB[m∨]		dB(mV)	decibel millivolt	(2009-03-06): (new code)	+16
MDC_DIM_PERCENT	%	544	%	10-2 (percent)		
MDC_DIM_PARTS_PER_10	_TO [ppth]	576	Ppht	10-3 (part(s) per thous	and)	
MDC_DIM_PARTS_PER_10	_TO [ppm]	608	Ppm	10-6 (part(s) per million	)	
MDC_DIM_PARTS_PER_10	LTO 10*-910^-9	640		10-9 (part(s) per milliaro	1)	
MDC_DIM_PARTS_PER_10	_TO 10*-1210^-12	672	Ppb	10-12 (part(s) per billior	1)	
MDC_DIM_PARTS_PER_10	_TO_10*-1510^-15		Ppt	10-18 (part(s) per trillior	ו)	
MDC_DIM_ANG_DEG	deg	736	Degree	angle degree		
MDC_DIM_ANG_RAD	rad	768	Rad	angle radian		
MDC_DIM_X_G_PER_G	g/g	800	g g-1	«magnitude» gram(s) pe	er gram	
MDC DIM O DER KO	alia	027	a ka 4	veropetudov exoprio) or	or kiloon	<u>×</u>





## **Enumeration Groups Table**

Enumeration groups						
_ENUM_GROUP			GroupDescription			
 _MDC_ATTR_AL_COND			Alarm Condition			1
MDC_PUMP_MODE			Operational Mode			
_MDC_PUMP_STAT			Operational Status			
_BODY_SITE_NBP_BP			Body Site - BP			
_BODY_SITE_HR			Body Site - HR			
BODY_SITE_TEMP			Body Site - Temperat	ure		
BODY_SITE_SPO2			Body Site - SpO2			
BODY_SITE_EEG_EX			Body Site - EEG			
_BODY_SITE_EEG			Body Site - EEG			
MDC BREATH DHASE						2
Contained enums						
ENUM_VALUE_TOKEN	ENUM_VALUE_REFID	PART	CODE10	VendorDescription	Discussion	
	MDC_UPEXT_ARM_UPPER_L	-		Left Upper Arm		
	MDC_UPEXT_ARM_UPPER_F	2		Right Upper Arm		
	MDC_LOEXT_LEG_L			Left Leg		
	MDC_LOEXT_LEG_R			Right Leg		





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# Edit Entry Form

Entry Information	Vendor Discussion General Discussion	Units/Enumera	itions	
Group:	CVS_HEMO_NBP	has units	🔘 has enumerations	
- 🔺 Term informati	on	UOM_MDC_REFID	UOM_UCUM	
REFID:	MDC_PRESS_BLD_NONINV_SYS			
🔲 is uncertain REF.		MDC_DIM_MMHG	mm[Hg]	
PART:	2			
CODE10:	18949	i		
CF_CODE10:	150021	i		
Vendor parame Description: DisplayName:	Non-invasive blood pressure (systolic)			
Vendor_UOM:	mmHg/kPa			
Vendor_Status:	SC			
- Vendor_Sort:	170			





## Add Comment Dialog

All Rosetta Ta	ble												
Vendor Disc	cussion 🛛 🗐	General Di	scussion	🔚 Download Table									
Group	REFID	PART		CF_CODE1 Vendor_ID	Description	DisplayName	Vendor_UOM	UOM_MDC	UOM_IEEE	Enum_Values	Vend	Venc Ger	ne
INFUS	MDC_VOL_F	EL 2	Add New	Comment Dialog	Totel Volume Infi	I						•	^
CNS_EEG	MDC_EMG_E	ELE 2	Discuss	sion							F	•	
CNS_EEG	MDCX_		2009-0:	)3-06;							F	•	
CVS_HEMO_IB	H MDC_PRESS	5_8 2	Aspect	t dB relative to 0.000:	L ( <u>uV</u> )^2						F	•	
CVS_HEMO_IB	MDC_PRESS	S_8 2									F	•	
CVS_HEMO_IB	H MDC_PRESS	G_8 2	John, 2	2009-4-21:							F	•	
CVS_HEMO_IB	MDC_PRESS	_В 2	Comm	ient							F	•	
CVS_HEMO_C	( MDC_OUTPU	JT_									F	•	
CVS_HEMO_C	C MDCX_										F	•	
CVS HEMO C			New Co	omment							F		~
🛛 🗐 🗐 Page	e 1 of 5		Name:							Display	ing top	oics 1 - 25 o	f 114
Group: CNS_			John										
PART:	<		New Co	omment:									
CODE10: DisplayNam	e: AMP												
Vendor_UON Vendor_Sta	M: dB												
Vendor_Sor	t:			omment									
Enum_Value				omment						J			
								Save	Cancel				

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#### Rosetta Table

Rosetta Table	-													
🔳 Vendor Dis	cussion 🛛 🔳 Ge	eneral Di	iscussion	🔂 Downlo	ad Table									
Group	REFID	PART	CODE10	CF_CODE1	Vendor_ID	Description	DisplayName	Vendor_UOM	UOM_MDC	UOM_UCUM	Enum_Values	Vend	Venc	Gene
CVS_ECG_ST	MDC_ECG_AMF	2	768	131840	Philips	ST generic label	ST	mm	MDC_DIM_MILL	mm mV		s		-
CVS_ECG_ST	MDC_ECG_AM			<b>.</b>	Philips	ST lead I	ST-I	mm	MDC_DIM_MILL	mm m∨		s		
CVS_ECG_ST	MDC_ECG_AM				Philips	ST lead II	ST-II	mm	MDC_DIM_MILL	mm mV		s		
CVS_ECG_ST	MDC_ECG_AN				Philips	ST lead V1	ST-V1	mm	MDC_DIM_MILL	mm mV		s		
CVS_ECG_ST	MDC_ECG_AN				Philips	ST lead V2	ST-V2	mm	MDC_DIM_MILL	mm m∨		s		
CVS_ECG_ST	MDC_ECG_AN				Philips	ST lead V3	ST-V3	mm	MDC_DIM_MILL	mm m∨		s		
CVS_ECG_ST	MDC_ECG_AN				Philips	ST lead V4	ST-V4	mm	MDC_DIM_MILL	mm m∨		s		
CVS_ECG_ST	MDC_ECG_AN				Philips	ST lead V5	ST-V5	mm	MDC_DIM_MILL	mm m∨		s		
CVS ECG ST	MDC ECG AN				Philips	ST lead V6	ST-V6	mm	MDC DIM MILL	mm m∨		s		
🚺 🖣 Page	e 1 🛛 of 46 🛛 🕨		2								Displayin	ig topic	s 1 - 25	5 of 1148
_	ECG_ST _ <i>ECG_AMPL_ST_1</i>						-	_Discussion _Discussion						2
PART: CODE10: DisplayNam Vendor_UON Vendor_Sta Vendor_Sor	<b>M:</b> mm <b>tus:</b> S													Ē
Description:														
UOM_MDC_	REFID UOM_L	JCUM												

MOC DTM MILLT M

<

mm

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#### User Management Table

User Management				
🥥 Edit  😧 Remove				
User Name	Email	Туре	Vendor	Enabled
john	john@nist.com	Vendor		false
sandra	sandra@nist.gov	Vendor	IEEE	true
admin	mcherk@nist.gov	Admin		true
maria	mcherk@nist.gov	Vendor	IEEE	true
sdo	mcherk@nist.gov	SDO		true





# REFID Selection Dialog (1/3)

Ferm Selection Wizard	
REFIDs are defined in ISO/IEEE 11073 Nomenclature Standard. New REFIDs st	ting with MDCX_ can be proposed
Select REFID from ISO/IEEE 11073 Nomenclature Standard	
Propose new REFID starting with MDCX_	
Enter New REFID 👻	
Back	Done



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# REFID Selection Dialog (2/3)

#### **Term Selection Wizard**

Select a partition from table then click on Next button to view terms from the Nomenclature.

Block	Block Name	Block Description	Partition Name	Partition Description	
🗆 Bloc	k ID: 1 (8 Item	s)			^
1	MDC_PART_OB	Object Infrastr.	ACT	Description Action	=
1	MDC_PART_OB	Object Infrastr.	AL-STAT	Description Alert Object ID	-
1	MDC_PART_OB	Object Infrastr.	ATTR/GROUP	Description Attribute Group	-
1	MDC_PART_OB	Object Infrastr.	ATTRs	Description Attribute	
1	MDC_PART_OB	Object Infrastr.	MD-Gen	Description Medical Device - Generic	
1	MDC_PART_OB	Object Infrastr.	MOC/BASE	Description Object	
1	MDC_PART_OB	Object Infrastr.	NOTI	Description Notification	
1	MDC_PART_OB	Object Infrastr.	PMS	Description Persistent Metric Store Object ID	
🗆 Bloc	k ID: 2 (10 Iter	ns)			
2	MDC_PART_SC	SCADA(Physio IDs)	BLD CHEM	Description Blood/Fluid Chemistry	
2	MDC_PART_SC	SCADA(Physio IDs)	ECG-LEADS	Description ECG Lead	~
Back				Done N	lext



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# REFID Selection Dialog (3/3)

Select term from	n table.		
Term Code	Part	REFID	
1	1	MDC_MOC_VMO	
2	1	MDC_MOC_VMO_VMD	
3	1	MDC_MOC_VMO_CHAN	
4	1	MDC_MOC_VMO_METRIC	
5	1	MDC_MOC_VMO_METRIC_ENUM	
6	1	MDC_MOC_VMO_METRIC_NU	
7	1	MDC_MOC_VMO_METRIC_SA	
8	1	MDC_MOC_VMO_METRIC_SA_D	
9	1	MDC_MOC_VMO_METRIC_SA_RT	
10	1	MDC_MOC_VMO_METRIC_SA_T	
16	1	MDC_MOC_SCAN	
17	1	MDC_MOC_SCAN_CFG	
18	1	MDC MOC SCAN CEG EPI	

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#### New Terms Table

New Terms Table					
Vendor Discuss	sion 🛛 😑 General Discussion				
Group	REFID	Vendor_ID	Description	DisplayName	Vendor_St: Vendor_Di: General_Di
CVS_ECG_ST	MDC_ECG_AMPL_ST_1	Philips	ST lead I	ST-I	S
CVS_ECG_ST	MDC_ECG_AMPL_ST_#	Philips	ST lead II	ST-II	S
CVS_ECG_ST	MDC_ECG_AMPL_ST_V1	Philips	ST lead V1	ST-V1	S
CVS_ECG_ST	MDC_ECG_AMPL_ST_V2	Philips	ST lead V2	ST-V2	S
CVS_ECG_ST	MDC_ECG_AMPL_ST_V3	Philips	ST lead V3	ST-V3	S
CVS_ECG_ST	MDC_ECG_AMPL_ST_V4	Philips	ST lead V4	ST-V4	S
CVS_ECG_ST	MDC_ECG_AMPL_ST_V5	Philips	ST lead V5	ST-V5	S
CVS_ECG_ST	MDC_ECG_AMPL_ST_V6	Philips	ST lead V6	ST-V6	S
CVS_ECG_ST	MDC_ECG_AMPL_ST_III	Philips	ST lead III	ST-III	S
CVS_ECG_ST	MDC_ECG_AMPL_ST_AVR	Philips	ST lead aVR	ST-aVR	S
CVS_ECG_ST	MDC_ECG_AMPL_ST_AVL	Philips	ST lead aVL	ST-aVL	S

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Group: CVS\_ECG\_ST REFID: *MDC\_ECG\_AMPL\_ST\_V1* DisplayName: ST-V1 Vendor Status: S

Vendor\_Status: 5 Description: ST lead V1 Vendor\_Discussion

General\_Discussion

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## **Next Steps**

- Features based on the Rosetta Supplement
  - Incorporate "Enumerations" management capabilities
  - Add "containedBy", "contains" and "External\_Sites" to the interface
  - Ability to edit Harmonized Rosetta table and save changes
- User oriented features
  - Implement "change trailing" capabilities
    - To identify occurred changes, time they were made, users who made them...
  - Incorporate enhanced X73 Nomenclature database
    - Includes Systematic name, description...
  - Automate generation of the "Harmonized Rosetta Table"
  - Adding new user role "Expert (or Technical) Reviewer"
- Continue discussion of approving and adding normalized terminology to IEEE x73
  - Build on April 23 Discussion (w/ Jan, Paul, Melvin, Todd, John R, others?)



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## ICSGenerator Capabilities

Generates Implementation Conformance Statements (ICSs)

- Required in conformance section (10) of DIM x73 document
- Ensures common format for ICS generation
- Builds Device Profile (XML)
  - Generates an electronic (XML) version of device data model based strictly on the IEEE x73 DIM
  - Includes private or manufacturer-specific extensions
- Provides validation against DIM Schema
  - A device data model generated using this tool can be validated against an updated version of the DIM XSchema
- Provides high level semantic interoperability
  - Ensures correct containment relationship and terminology at the object class and related attribute, notification, and behavior level
  - Compare Device ICSs
    - Device ICSs comparison capability aids in identifying *potential interoperability issues*
- Generates HL7 OBX Segments
- Generates Device UML Diagram





#### Tooling Status ICSGenerator

- Interface update:
  - Make list of attributes visible for selected MOC in the right pane.
    - The value and unit are not included in this enhancement, but will be included when Rosetta dbase is incorporated.
  - Added status bar to show the nature of medical device profile.
  - Added a direct tooling accessibility tool bar.
  - Added a tree panel tool bar to aid in managing and operating ICSGenerator modeling capabilities. (also available when right clicking the objects in the tree)
- Incorporated the x73 Nomenclature Dbase
  - Added drop down menu for any text box where the data could be extracted from the database.
    - Infrastructure terms (e.g., object & attribute names)
    - Object Type ID (if not in hRTM)
    - Object Class
  - Term code auto-filled when object type is available from dbase.
  - The drop down include auto completion and keyword searching, no case sensitive.
  - ICSGenerator does not depend on dbase installation, it access the data from and XML file that contains the data from the x73 Nomenclature Dbase.





Tooling Status ICSGenerator

#### Status (cont.)

- Added a drop down to allow user to change the attribute status when the status is not "mandatory".
- Initial implementation of RCH (Rosetta Containment Hierarchy).
- Code restructuring to improve maintainability, expandability and performance.
- Fixed bugs
  - Label not fully displayed on Jtree.
  - Attribute update panel hanging when removing attributes and adding the changes.





## Tooling Status/Next Steps ICSGenerator

- Incorporate Rosetta Dbase.
  - Object Type, unit code, metric id (?)- in Nu-Observed-Value value type
- Finalize implementation of RCH.
  - Implementing OBXV and derived OBX-4
- Value display enhancement
- Add information description to tabs
- Provide initial guidance on the right panel when stating ICSGenerator
- Update PHD specialization profiles





# Summary / Discussion

- Develop "Conformance Test" WG for this cycle
  - Bi-weekly, meet w/ individual Integration Profile Groups
  - Update test cases
  - Update/Continue work on Test Plans / Conformance Guide
- Develop Test Agents across Integration Profile Actors
  - Continue work on TF and Supplements
  - Further define 'scenarios' (message transaction sequences)
- RTMMS
  - Continue discussion of approving and adding normalized terminology to IEEE x73
  - Build on April 23 Discussion (w/ Jan, Paul, Melvin, Todd, John R, others?)
  - Add two columns to support mapping to ITSDO work (w/ Jan)
- ICSGenerator
  - Start developing IHE-PCD Device 'specializations' for devices across various IHE-PCD Integration Profiles
- Explore OHT work (w/ Ioana, David Carlson)
  - <u>http://mdht.projects.openhealthtools.org</u>
- Questions? / Discussion...
- Thank-you!

