

ISO/IEEE 11073 Personal Health Devices (PHD) Standards Tutorial

**ISO/IEEE 11073 Personal
Health Device Work Group**

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Agenda

- Background
- Base Standard Tutorial (ISO/IEEE Std 11073-20601)
- Device Specializations Tutorial (ISO/IEEE 11073-104zz)
- Tool Support
- Summary
- Questions (feel free to ask while we go too)

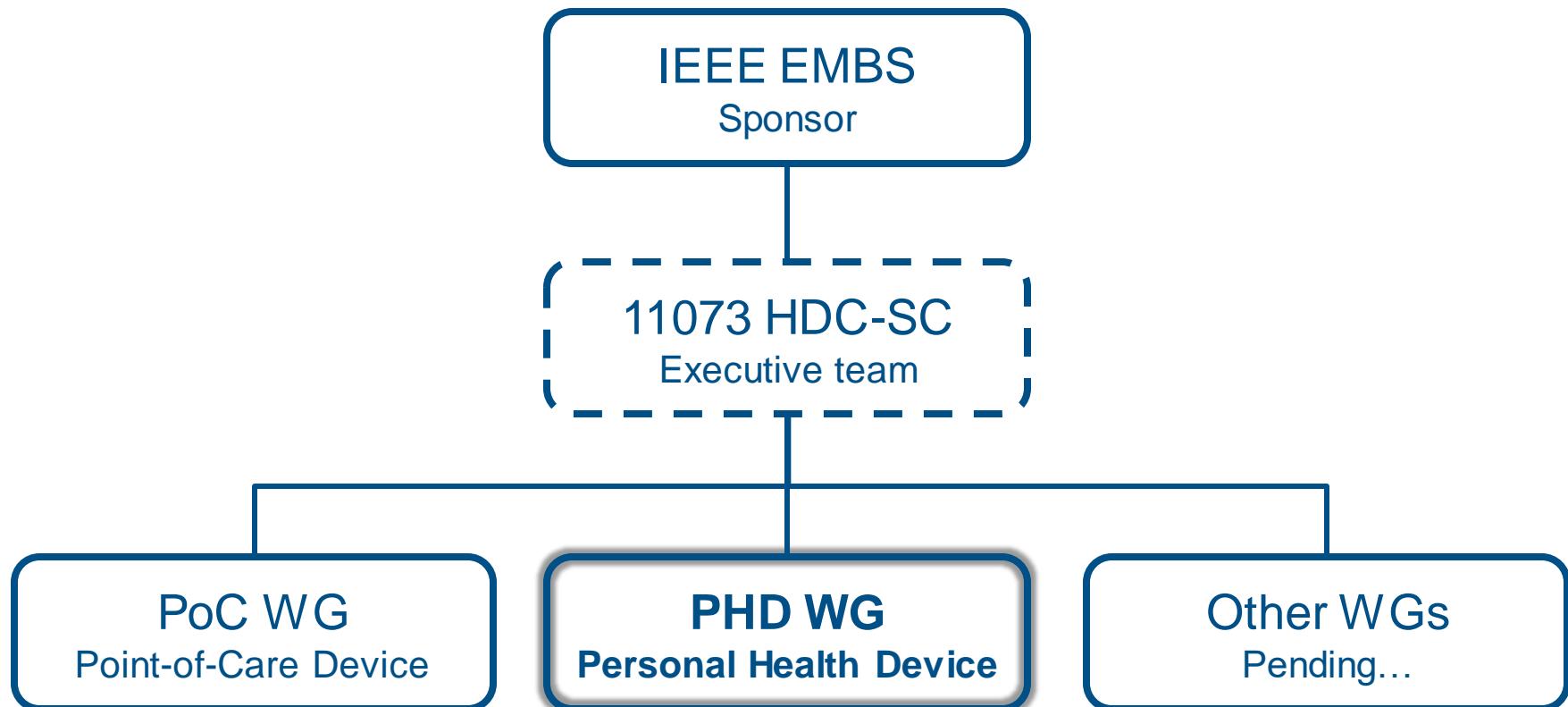
IEEE Standards Association (IEEE-SA)

- IEEE-SA is a respected international SDO
 - Widely-accepted P&P
 - Open participation
 - Low cost for membership
 - Easy access to standards
- ISO-IEEE Cooperation Agreement
 - ISO/IEEE Partner Standards Development Organization (PSDO)
 - ISO/TC 204 - Intelligent Transportation Systems
 - **ISO/TC 215 - Health Informatics**
 - ISO/IEC JTC 1

IEEE 11073

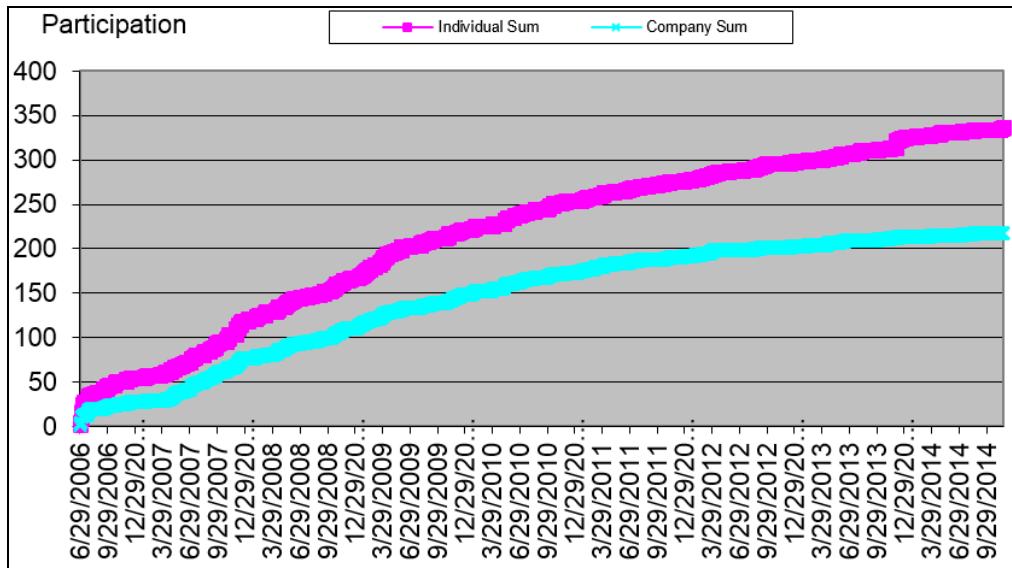
Healthcare Device Communications

Standards Committee (HDC-SC) 2015-



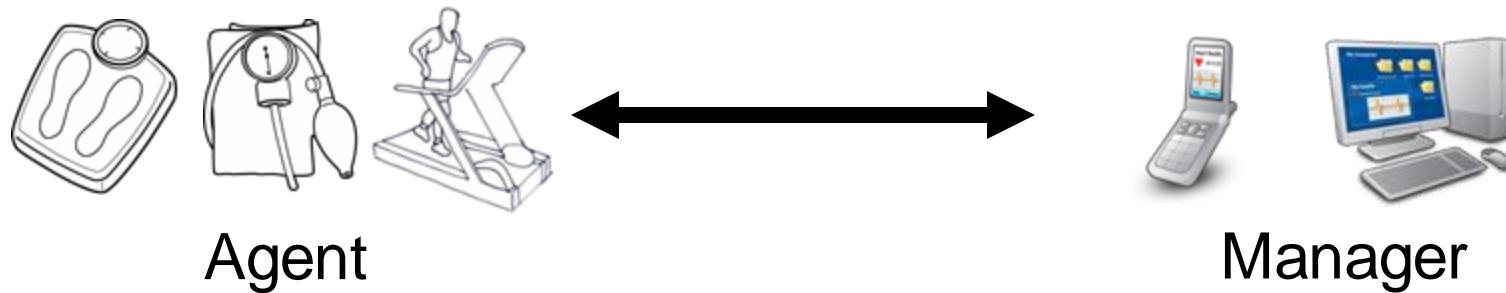
Membership of 11073-PHD WG

- Established at 2006; 337 members; 217 entities
- Weekly conference calls (Thu 8:15 AM Pacific T)
- Face to face meetings 2 ~ 3 / year
- International involvement in the Work Group



53 % North America
25 % Europe
22 % Asia & Pacific

11073-PHD's focus



- Exchange Protocol + Device Specializations
 - Domain Information Model
 - Service Model
 - Communication Model
 - Device-specific information
- Supported domains
 - Disease Mgmt (DM), Health&Fitness (HF), Aging Independence (AI)

Background: Device Capabilities

- Agents typically have:
 - Limited capabilities (RAM, ROM, CPU)
 - Connection to a single Manager
 - Limited power resource (small battery)
 - Low cost (consumer device)
 - Fixed configurations (data type and format does not change)
 - Intermittent connections (disconnect when inactive)

- Managers typically have:
 - Richer capabilities (RAM, ROM, CPU)
 - Connections to multiple Agents
 - Wall power or larger batteries

Background: Guiding Principles

- ❑ Exchange protocol:
 - Places more burden on Managers than Agents
 - Supports multiple data types (episodic, streaming, store and forward)
 - Designed to be transport portable (Bluetooth, USB, etc.)
 - Optimizes data exchange
 - Enables efficient reconnections
 - Targets personal health in home and mobile environments

Background: Personal Health Device Standards Overview

-00103 Overview

Device Specializations

-10404	-10407	-10408	-10415	-10417	-10441	-10442	-10471	...
Pulse Oximeter	Blood Pressure	Thermo- meter	Weighing Scale	Glucose	Cardio	Strength	Activity Data	

-20601 Optimized Exchange Protocol

Communication Protocols

Serial	IrDA	Bluetooth	USB	ZigBee	NFC
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OSI

Layers 5-7

Layers 1-4

Completed Standards (21)

- IEEE Std 11073-10404 Dev specialization – Pulse oximeter
- IEEE Std 11073-10406 Dev specialization – Basic ECG
- IEEE Std 11073-10407 Dev specialization – Blood pressure monitor
- IEEE Std 11073-10408 Dev specialization – Thermometer
- IEEE Std 11073-10415 Dev specialization – Weighing scale
- IEEE Std 11073-10417 Dev specialization – Glucose meter + Revision
- IEEE Std 11073-10418 Dev specialization – INR (blood coagulation)
- IEEE Std 11073-10420 Dev specialization – Body composition analyzer
- IEEE Std 11073-10421 Dev specialization – Peak flow
- IEEE Std 11073-10424 Dev specialization – SABTE
- IEEE Std 11073-10425 Dev specialization – CGM

- IEEE Std 11073-10441 Dev specialization – Cardiovascular + Revision
- IEEE Std 11073-10442 Dev specialization – Strength fitness equip

- IEEE Std 11073-10471 Dev specialization – Activity hub
- IEEE Std 11073-10472 Dev specialization – Medication monitor

- IEEE Std 11073-20601 Optimized exchange protocol + Amend + Revision
- IEEE Std 11073-00103 Guide for Health informatics - Personal health device communication - Overview

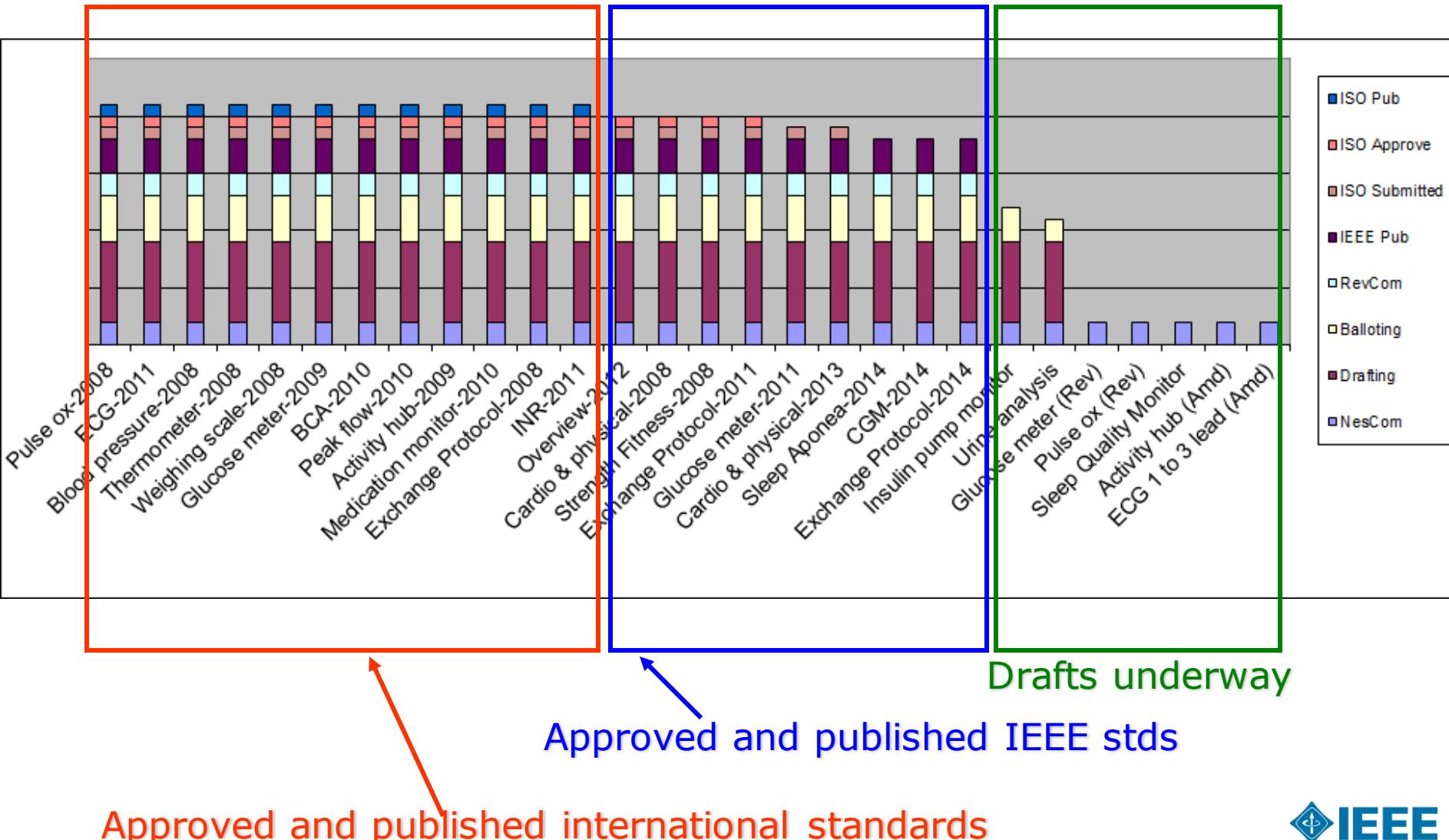
Projects Underway (15)

- IEEE P11073-20601 Optimized exchange protocol (Corrigenda + **Revision**)
- IEEE P11073-10419 Dev specialization – Insulin pump
- IEEE P11073-10422 Dev specialization – Urine analyzer
- IEEE P11073-10423 Dev specialization – Sleep Quality Monitor
- IEEE P11073-10425 Dev specialization – Continuous Glucose Meter (Revision)
- IEEE P11073-10417 Dev specialization – Glucose meter (Revision)
- IEEE P11073-10404 Dev specialization – Pulse oximeter (Amendment)
- IEEE P11073-10406a Dev specialization – Basic ECG (Amendment)
- IEEE P11073-10471a Dev specialization – AI Living Hub (Amendment)
- IEEE P11073-10407 Dev specialization – Blood Pressure Monitor (Amendment)
- IEEE P11073-10408 Dev specialization – Thermometer (Amendment)
- IEEE P11073-10415 Dev specialization – Weighing Scale (Amendment)
- IEEE P11073-10420 Dev specialization – Body composition analyzer (Amendment)
- IEEE P11073-10418-Cor Dev specialization – INR monitor (Corrigenda)

Adoption Path

- ❑ IEEE → ISO TC215 → CEN TC251
- ❑ IEEE → PCHA → ITU SG16
- ❑ IEEE → FDA Recognized Consensus Standards
- ❑ Harmonized or coordinated with NCCLS/CLSI, HL7, IHE, IEC SC-62A, ISO TC121 and NIST

Progress of each standard



Approved and published international standards

Step by Step

- ❑ WG Membership: 11073-PHD WG
- ❑ Ballot Group Membership: IEEE-SA, Individual

- ❑ Engagement (use case, tiger team)
- ❑ Draft the (Project Authorization Request) PAR
- ❑ PAR Submission/Approval (NesCom) -- 3~4 opportunities per year
- ❑ **Draft the standard (pre-ballot)** -- usually 8~16 months for new standard
- ❑ Forming the Ballot Group -- ≥ 30 days
- ❑ MEC Review -- 30 days
- ❑ Initial Ballot -- ≥ 30 days
- ❑ Re-circulations (0 *) -- ≥ 10 days (criteria higher than IEEE default)
- ❑ **RevCom Submission**/Approval -- 3~4 submission deadlines per year
- ❑ IEEE proof editing process -- 1 ~ 2 months
- ❑ Published

- ❑ **Total:** 1.5 ~ 2.5 years (typical)

ISO/IEEE 11073 Personal Health Devices Tutorial – Part I – Base Standard

Slides Created by

Douglas P. Bogia, Brian Reinhold and Malcolm Clark

on behalf of the

ISO/IEEE 11073 Personal Health Device Work Group

June 13th, 2012

Agenda

- ❑ Background
- ❑ Base Standard Tutorial (ISO/IEEE Std 11073-20601)
- ❑ Device Specializations Tutorial (ISO/IEEE 11073-104zz)
- ❑ Tool Support
- ❑ Summary
- ❑ Questions (feel free to ask while we go too)

20601 Devices: Agent

Takes measurements (has the sensor)

Simple (minimal hardware requirements)

Highly specialized (does just one thing)

Server device (that's weird)



20601 Devices: Manager

Receives measurements from agent

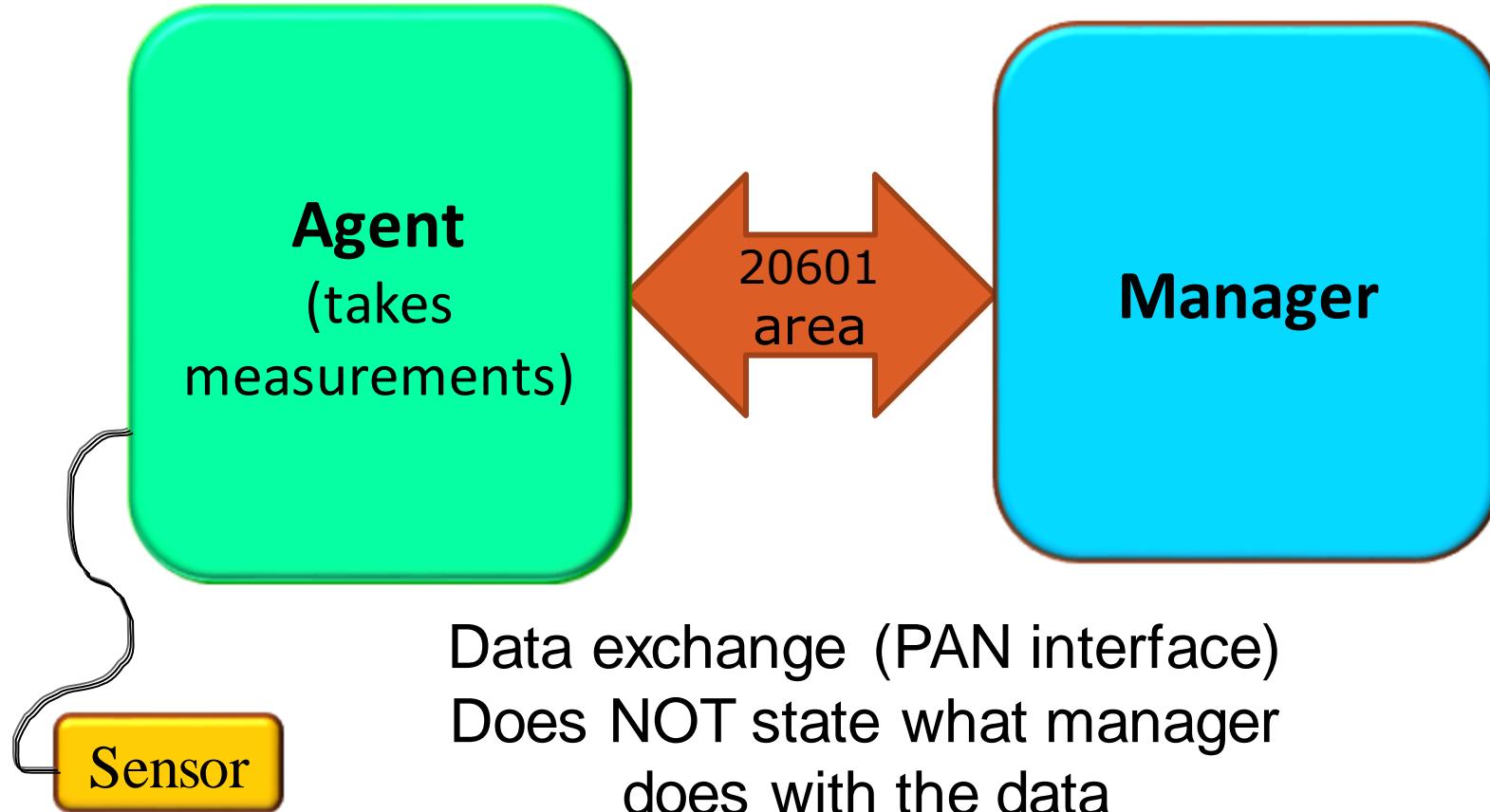
Higher end device (more horsepower)

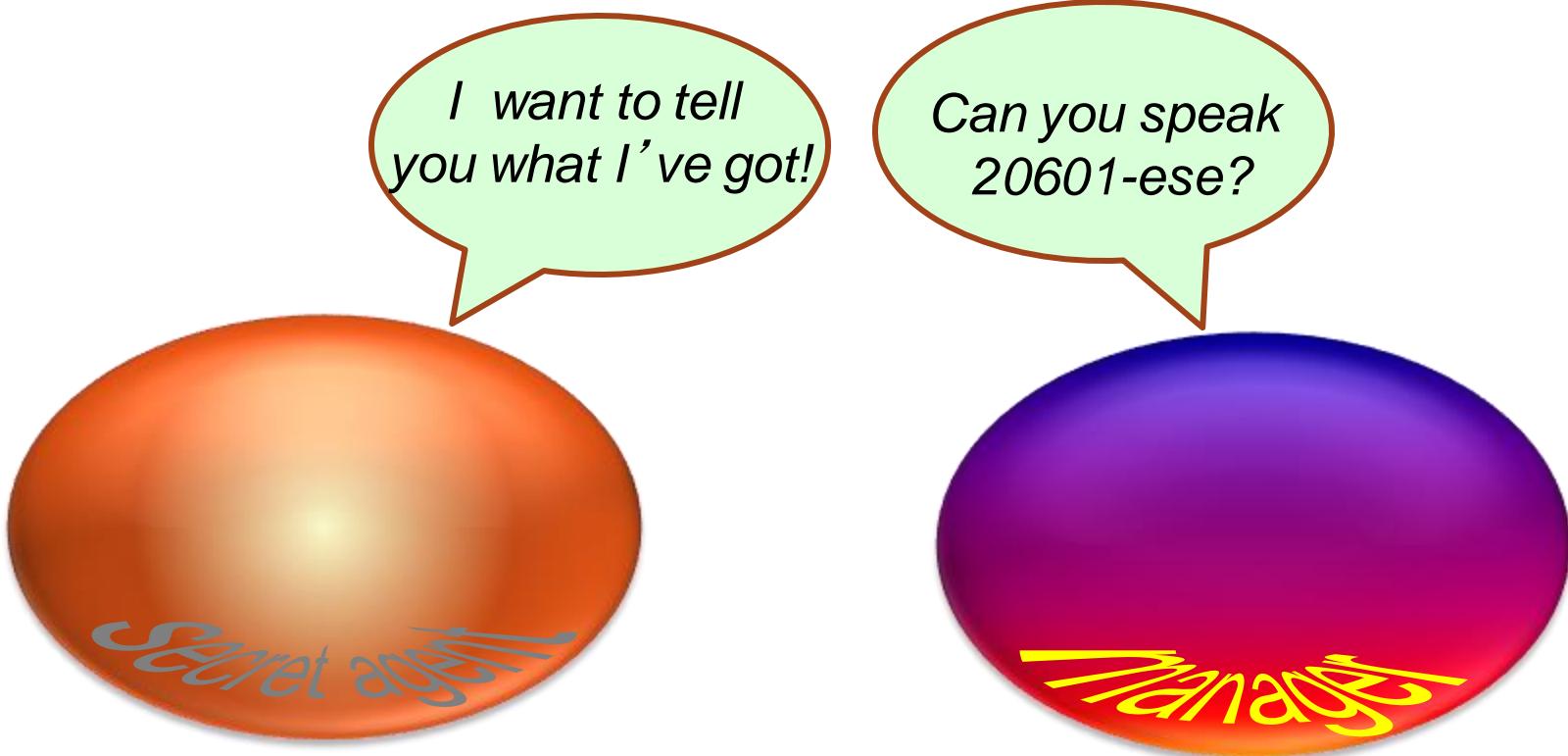
Usually generic (handles many agents)

Client device ... (this is weird, too)



20601 Coverage





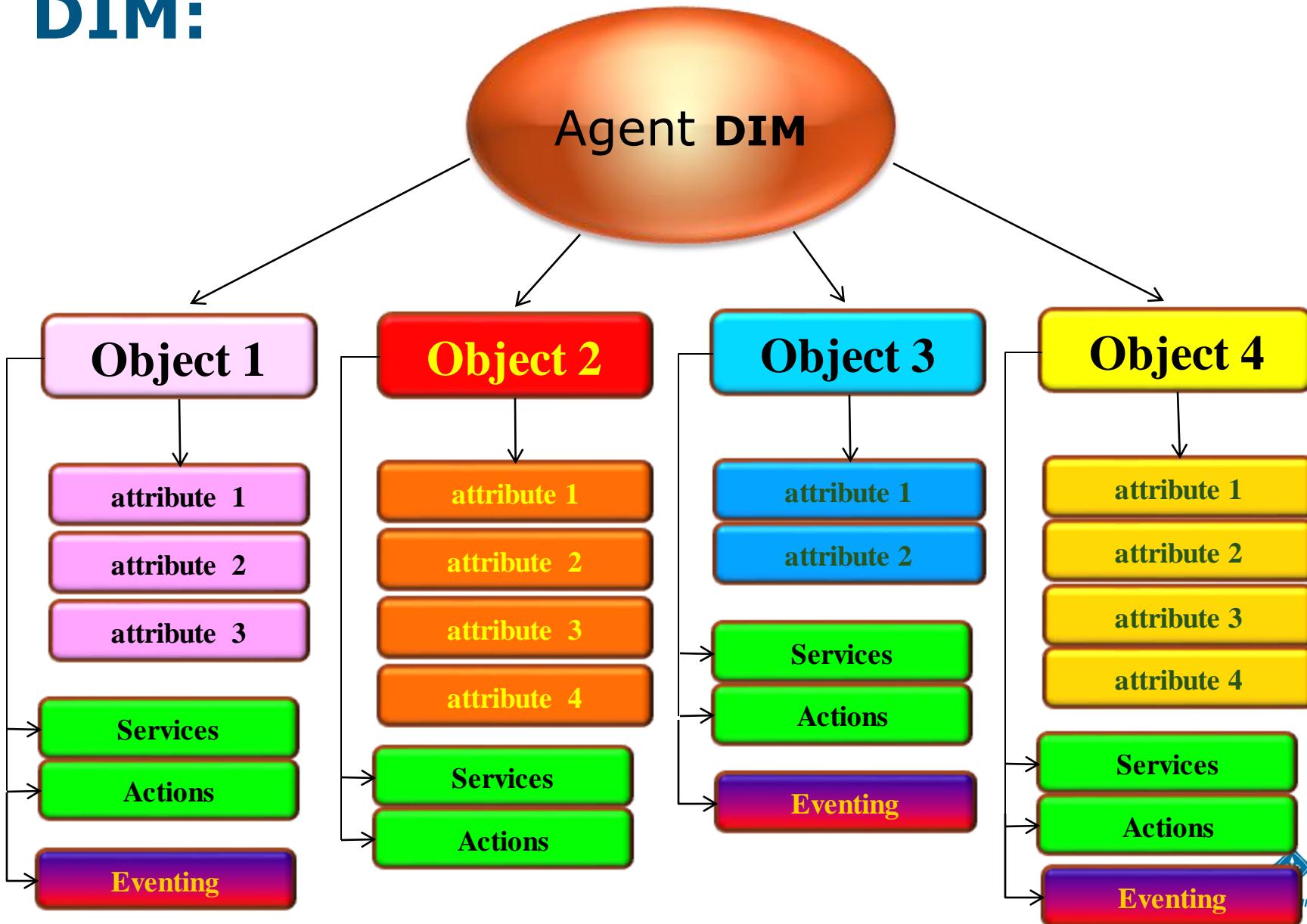
1. Need to structure the information

DomainInformationModel (DIM)

2. Need to get the information to peer

ApplicationProtocolDataUnit (APDU)

DIM:



20601-' Objects' describe items

MDS Object

Agent's bureaucratic
and system information,
must have

Metric object k

Describes a
measurement
weight, status,
waveform
***optional* (hah!)**

Scanner object m

(eventing formatter and organizer)
optional

PM-Store object n :

Agent's hard disk
optional

Sensor

Agent has “Objects” to describe its features

Metric Objects

Metric objects

Numeric

Describes a measurement that is typically a number:
weight, pulse, BP, SpO₂

RealTime- SampleArray

Describes measurements that are periodic and streaming; typically waveforms

Enumeration

Describes a measurement that is typically one of a known set of values (status, threshold, bit)

Scanner Objects

Scanner objects

Episodic Scanner

Organizes the data from one or more (metric) objects for sending to the manager

Periodic Scanner

Organizes the data from one or more (metric) objects describing periodic measurements for sending to the manager

!! Manager can turn these things on and off !!

PM Store Objects and Segments

PM-Store object

Like a directory on a hard disk

Like a file in the directory

Episodic PM Segment m

Stores non-periodic (metric) data

Another file in the directory

Periodic PM Segment n

Stores periodic (metric) data

!! In 20601, Segments are second class objects!!

Attributes describe objects

Has an ID (nomenclature code)

Value has a structure

Structure is described by ASN1:

Some are simple scalars (BasicNuObservedValue)

Some are complex structures (RegCertDataList)

AttributeValueMap attribute

ID = 2645 (MDC_ATTR_ATTRIBUTE_VAL_MAP)

ASN1 struct:

AttrValMap ::= **SEQUENCE OF**
AttrValMapEntry

AttrValMapEntry ::= **SEQUENCE**
{
 attribute-id OID-Type,
 attribute-len INT-U16
}

Attributes are classed as Static, Dynamic, or Observational

Static:

The value of the attribute does not change.

Dynamic:

The value of the attribute may change.

Observational:

The value of the attribute is only valid until it or another attribute changes.

MDS Attributes

MDS Object

Handle attribute = 0 always*

LEGAL ATTRIBUTES

System ID attribute*

System Model attribute*

Production Specification attribute

RegCertDataList attribute

INFORMATIONAL ATTRIBUTES

Power Status attribute

Battery Level attribute

Remaining Battery Time attribute

TIME ATTRIBUTES (AGENT CLOCK)

MdsTimeInfo attribute

Date and Time attribute

Relative Time attribute

Hi-res relative time attribute

Base offset Time attribute

CONFIGURATION ATTRIBUTES

Dev Configuration ID attribute*

System Type / Spec List attribute*

Confirm Timeout attribute

Attribute Value Map attribute

Common Metric Attributes

Metric Object

Handle attribute = x*

MEASUREMENT DESCIBERS

TYPE attribute*

Unit Code attribute

Metric Spec Small attribute*

Supplemental Types attribute

Measurement Status attribute

Metric Structure Small attribute

Metric Id attribute

Metric Id List attribute

Metric Id Partition attribute

TIME ATTRIBUTES

Measurement active period attribute

Absolute Time Stamp attribute

Relative Time Stamp attribute

Hi-res relative time stamp attribute

Base offset Time Stamp attribute

HELPER ATTRIBUTES

Unit Label string attribute

Label String attribute

Source Handle Reference attribute

Attribute Value Map attribute

Metric Numeric Attributes

Attributes that make the Numeric Obj

Basic Nu Observed Value attribute

Simple Nu Observed Value attribute

Compound Basic Nu Obs Val attribute

Compound Simp Nu Obs Value attribute

Nu Observed Value attribute

Compound Nu Observed Value attribute

Accuracy attribute

One and
only one
of these
shall be
used.

Pulse Ox SpO₂ Numeric

SpO₂

TYPE = {MDC_PART_SCADA, MDC_PULS_OXIM_SAT_O2}

Metric Spec Small = mss-avail-stored-data, mss-acc-agent-initiated

Unit Code = MDC_DIM_PERCENT

**Attribute Value Map = MDC_ATTR_NU_VAL_OBS_BASIC,
MDC_ATTR_TIME_STAMP_ABS***

Basic Nu Observed Value = x

Absolute Time Stamp = t^*

** time stamp not in pulse ox standard configuration*

Metric RT-SA Attributes

Attributes that make the RT-SA Obj

Sample Period attribute*

Scale and Range Spec attribute*

Sa-Spec attribute*

Simple Sa Obs Value attribute*

Pulse Ox Pleth Wave RT-SA

Pleth Wave

TYPE = {MDC_PART_SCADA, MDC_PULS_OXIM_PLETH}

Metric Spec Small = mss-acc-agent-initiated

Unit Code = MDC_DIM_DIMLESS

Attribute Value Map = MDC_ATTR_SIMP_SA_OBS_VAL

Sample Period attribute = p

Scale and Range Spec attribute $y = mx + b$

Sa-Spec attribute (8, 16, 32 bit, etc)

Simple Sa Obs Value attribute = Σx

Metric Enumeration Attributes

Attributes that make the Enum Obj

Enum Obs Val Simp OID attribute

Enum Obs Val Simp Bit Str attribute

Enum Obs Val Basic Bit Str attribute

Enum Obs Val Simp Str attribute

Enum Obs Val Basic Str attribute

Enum ObservedValue attribute

Enum Obs Val Partition attribute

One and
only one
of these
shall be
used.

Pulse Ox Pulsatile Occ Enum

Pulsatile Occurrence

TYPE = {MDC_PART_SCADA, MDC_TRIG}

Metric Spec Small = mss-acc-agent-initiated

Source Handle Reference = Pleth Wave Object Handle

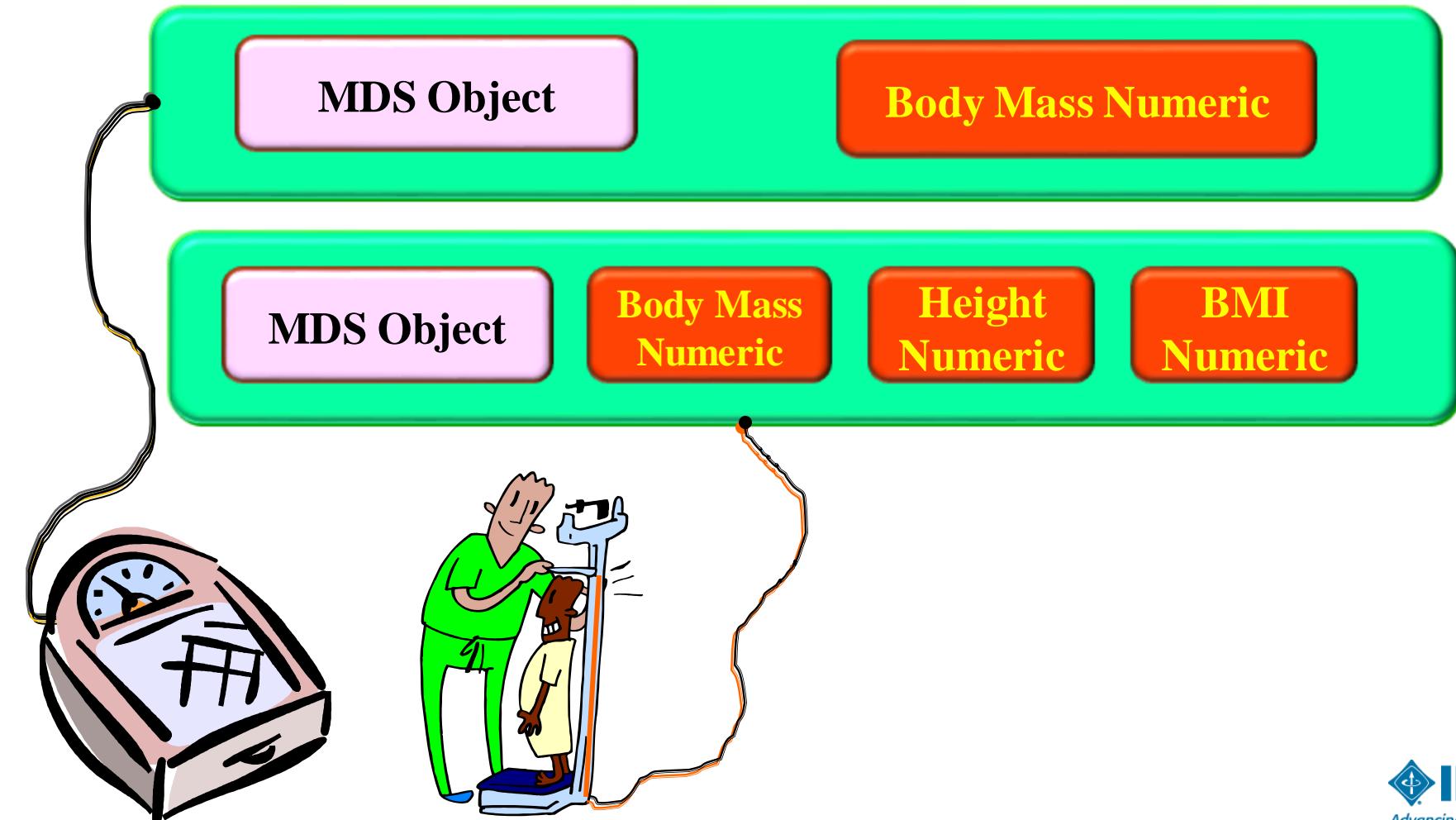
Attribute Value Map =
MDC_ATTR_ENUM_OBS_VAL_SIMP_OID,
MDC_ATTR_TIME_STAMP_ABS

Enum Obs Val Simp OID = one of:
MDC_TRIG_BEAT
MDC_TRIG_BEAT_MAX_INRUSH
MDC_METRIC_NOS

Scanner and PM Store Attributes

Yes, Scanners, PM Stores, and PM Segments have attributes. Putting aside for the time being!

Weigh Scale Agent DIMs



Pulse Ox Agent DIMs

MDS Object

SpO₂ Numeric

Pulse Rate
Numeric

MDS Object

SpO₂
Numeric

Pulse Rate
Numeric

PlethWav
eRT-SA

Periodic Scanner: SpO₂
Pulse Rate PlethWave

Pulsatile
Occurrence Enum

PM-Store 1

PM-Store 2

SpO₂
Segment

Pulse Rate
Segment

Pulsatile
Segment

20601 Jargon:

Agent *Configuration*

the set of *non-MDS objects* and *non observational attributes*

Configurations are assigned Ids

Configurations can be memorized by a Manager

Standard configurations

Extended configurations

An agent may have several configurations

Rules: Standard Configurations

Standard Configuration: A DIM where all non-MDS objects and non-observational attribute values are pre-specified in a document.

Standard Configuration ID: A number from 1 to 0x3FFF.

Corollary 1: A standard config with ID ‘ x ’ is the same on all agents regardless of manufacturer.

Corollary 2: A manager does not need to *ever* ask for an agent’s configuration if it is a standard configuration.

Rules: Extended Configurations

Extended Configuration: A DIM where all non-MDS objects and non-observational attribute values are NOT pre-specified in a document.

Extended Configuration ID: A number from 0x4000 to 0x7FFF.

Rule 1: An extended config with ID ‘ x ’ may be different on agents with different system IDs.

Rule 2: An extended config with ID ‘ x ’ must be the same for an agent with a given system ID *for a given manager*.

Corollary 1: The same configuration on an agent with a given system ID does NOT have to use the same config id ‘ x ’ . (*Must be a good reason!*)

Rules: All Configurations

Rule 1: An agent shall send a config report containing its configuration if a manager asks for it (AARE accepted-unknown-config).

Rule 2: An agent can add attributes or change attribute values while in the operating state.

Rule 3: An agent may NOT add objects while in the operating state.

Corollary 1: Any changes and / or attribute additions to a configuration of ID 'x' are lost upon re-association with the same config ID 'x' .

Corollary 2: The MDS is NOT part of the configuration

Corollary 3: The MDS can be different every time a manager associates with the same agent with the same config ID

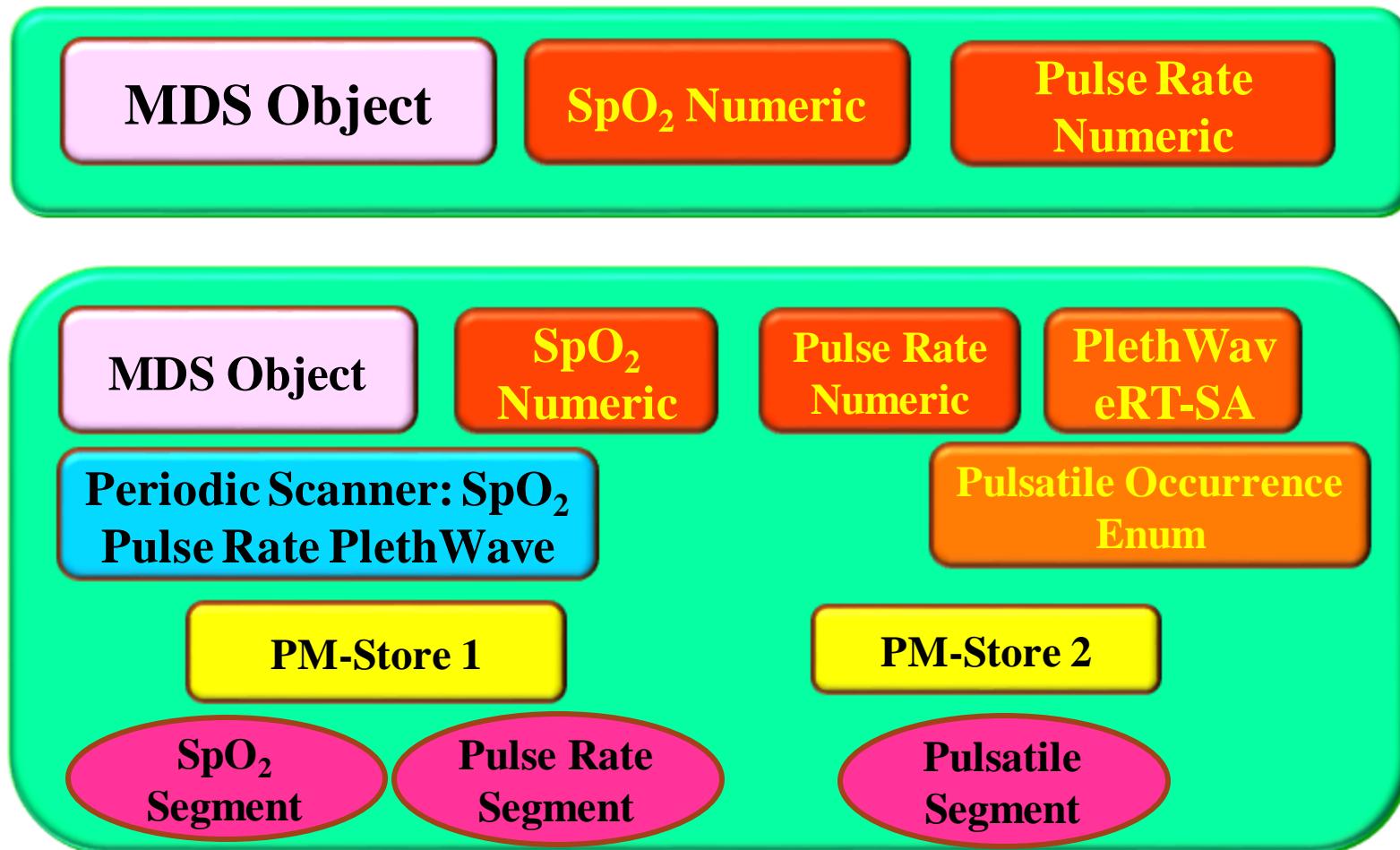
20601, Continua, Specializations

20601 is the ‘base’ standard

Continua places restrictions on 20601

Specializations place restrictions on
objects/attributes

So what makes up the following agents' configuration?



This device conforms to a specialization

MDS Object

SpO₂ Numeric

Pulse Rate
Numeric

This device does not or it is two!

MDS Object

SpO₂ Numeric

Pulse Rate
Numeric

Temperature
Numeric

Object Services and Actions

Operations that can be done on object by *manager*

Services are operations on attributes

GET service ‘gets’ attribute values

SET service sets attribute values

Actions are operations that perform a task

Set Time, MDS Data Request,

Get Segment Info, Clear Segment

Object Services and Actions

MDS Object

GET service*

SetTime

SetBOTime

MDSDataRequest

Metric objects

No services

No Actions

Scanner object

SET service on 1 attribute*

No actions

PM-Store object

GET service*

GetSegmentInfo*

ClearSegment

TrigSegmentDataXfer*

Sensors

*required by 20601

Object Eventing

Events are done by *Agent*
contain measurement
data
contain *configuration*

Events are *only* done by THREE agent objects
MDS (sends agent-initiated or manager-initiated events)
Scanner (sends buffered or unbuffered agent-initiated events)
PM Store (data segment events)

Getting Data from Agent to Manager

Three Steps:

Transport Technology Handshaking

(The transports shall be assumed to work)

20601
Handshaking
Data Exchange

These two stages
require **APDUs**
and the **State
Machine**

APDUs (ASN1 TLV packets)

Association Request (AARQ)* *cause state change

Association Response (AARE)*

Association Release Request (RLRQ)*

Association Release Response (RLRE)*

Abort (ABRT)*

Presentation Apdu (PRST)

Config Report* SET service request

Config Response* SET service response

GET service request Action requests

GET service response Action responses

Scan Event reports Scan Event Confirmations

Data Segment Events Data Segment Confirmations

State Machine

Agent

Unassociated

Associating

Sending Config

Waiting Approval

Operating **data exchange**

Disassociating

Manager

Unassociated

Associating

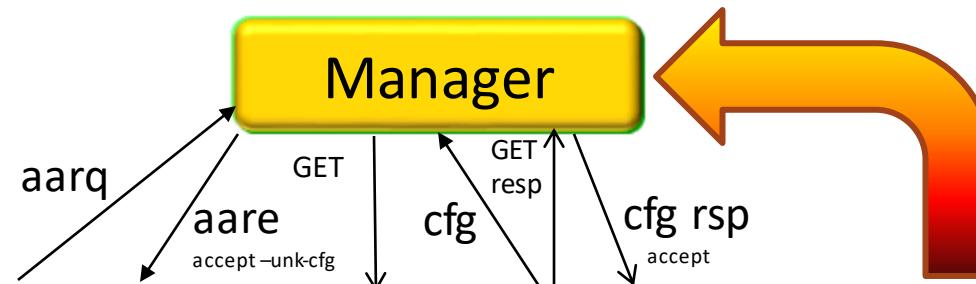
Waiting Config

Checking Config

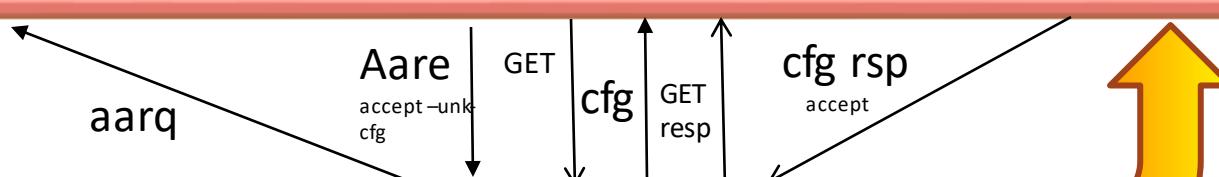
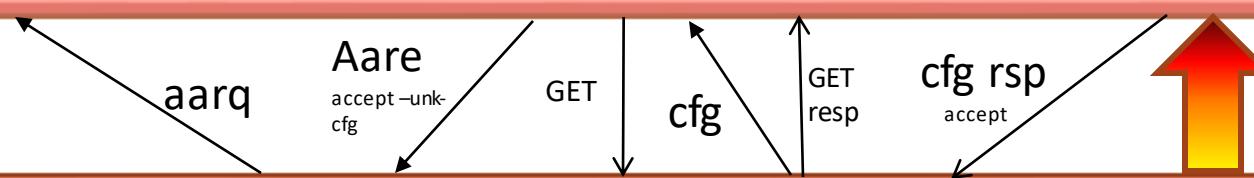
Operating

Disassociating

20601 Handshaking



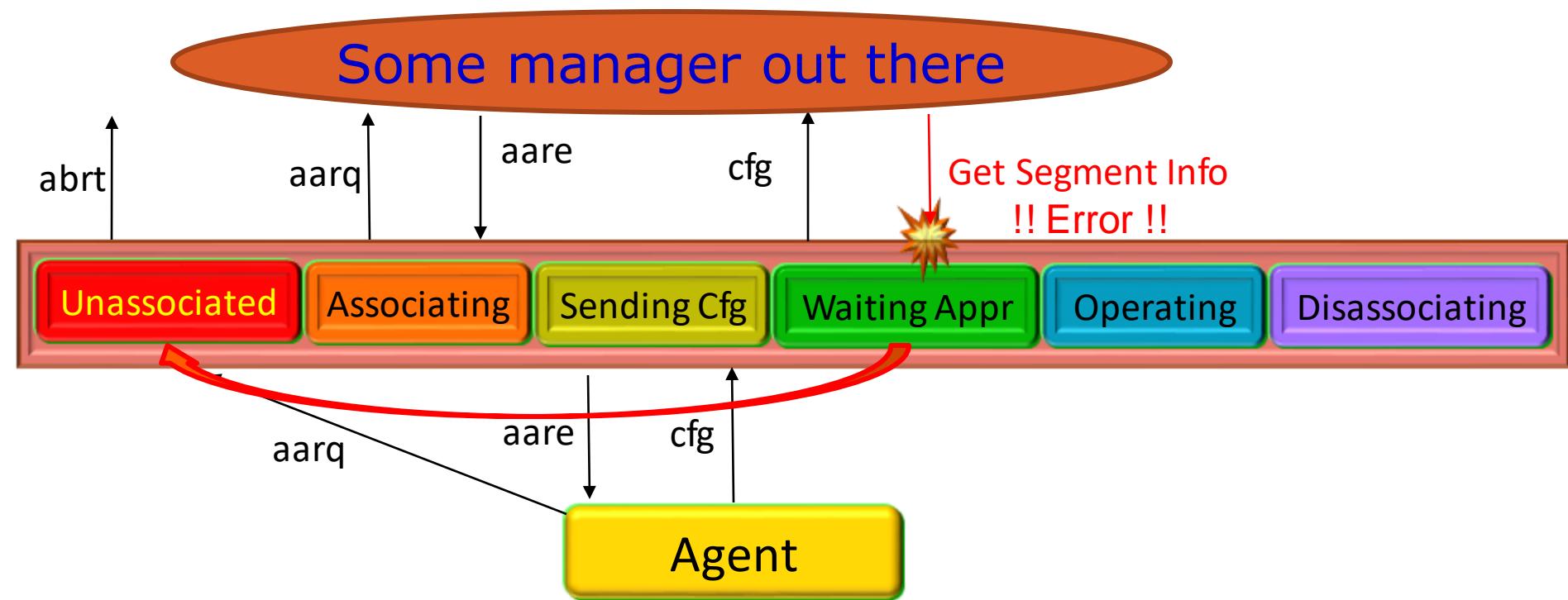
Data Flow!!



Weird! the server starts it!!

Agent

State Machine Filter



Association Request (AARQ)

Offers the following to the Manager:

association version (only one)
protocol versions
nomenclature versions
encoding versions (MDER)
functional units offerings
data request modes supported
system id
configuration id

manager checks if it can do this
manager picks one
manager picks one
manager picks one (MDER)
manager picks one or none
manager checks if it can do any
do I like this manufacturer?
can I support this configuration?

Responses: AARE rejected *:

We are done!

accepted-unknown-config: *Need more info!*

accepted: *I know you, we can go to work.*

Need More Info: Config Report

Gives the following to the Manager:

Config Id (repeats that of AARQ)

Number of Non MDS objects

For each Object:

Class of the object

Handle of the object

Number of attributes in the object

For each attribute:

Attribute ID

Attribute value

Config Responses: unsupported config: *Give me another if you have one!*

unknown standard config: *Give me another OR give me config!*

accepted: *Okay, I can do this, we can go to work.*

Give me another:

Agent offers a second config report for a different configuration (if it has one)

Agent sends an Association Release Request (RLRQ) if it has no more

Config Cycle:

For n = 1 to number of configurations:

Agent sends Config Report (sending config – waiting approval)

Manager responds unsupported config (checking config – waiting config)

Agent sends RLRQ with reason ‘no-more-configurations’

Manager sends RLRE

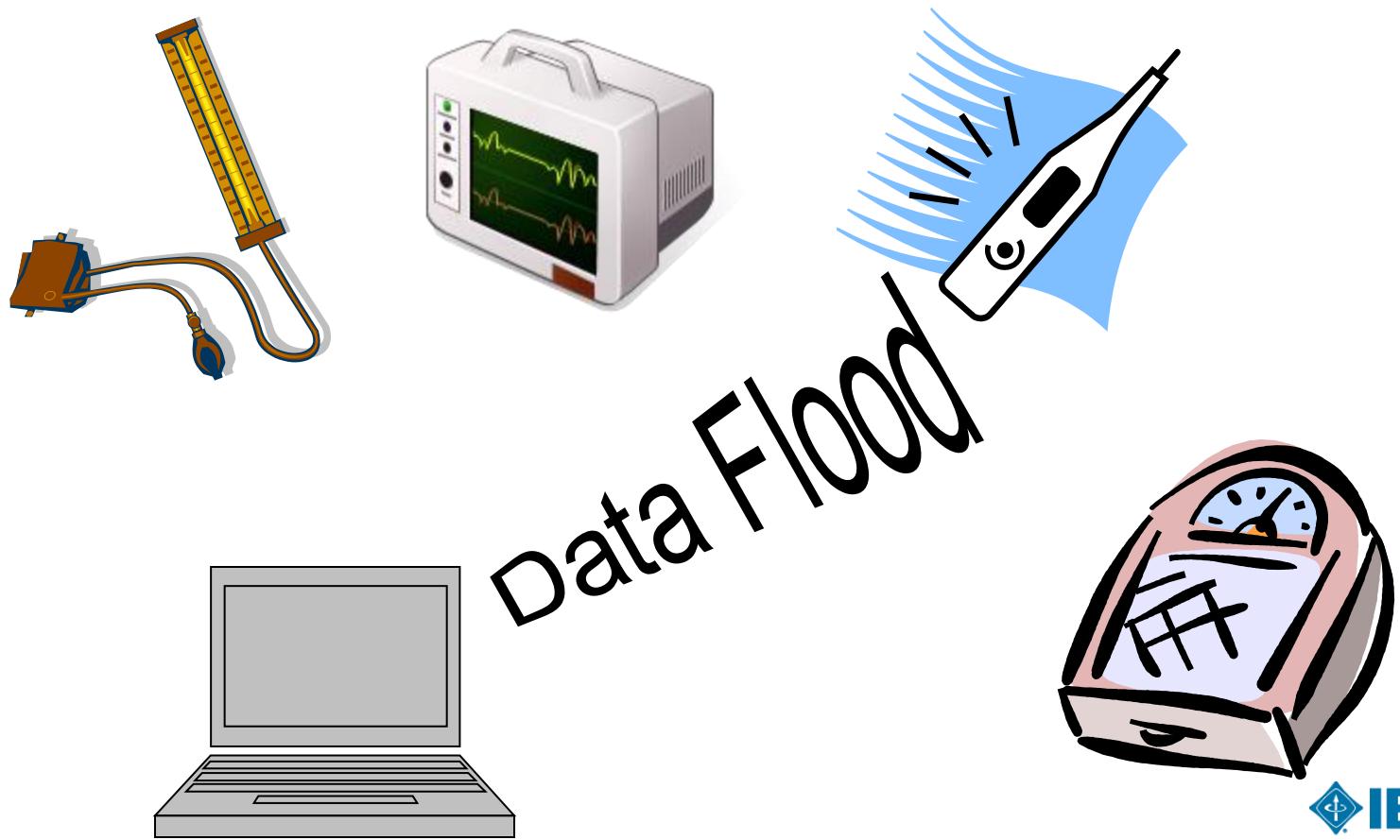
I know you: Direct to operating

The manager knows the configuration:

- **Have associated with this agent before and saved the config**
- **Looked up the configuration in a book (standard config)**

OPERATIONAL STATE !!

(after all that configuration work)



Messages from Manager

GET service: Gets attribute information

SET service: Sets attribute values

ACTION: Set Time

ACTION: Set Base Offset Time

ACTION: Get PM Segment Info

ACTION: Trigger PM Segment Data Transfer

ACTION: Clear PM Segments

Messages from Agent

Scan Event Reports: Measurement Data!!

Data Segment Events (upon request) from PM Store

Tidbits about Scan Event Reports

Can only be sent during the operating state

Contain **zero** or more Observation Scans

Can be agent-initiated by the MDS

Observation Scans contain the DATA

Can be manager-initiated** (deprecated?)

Observation Scans contain one or more attribute updates
(Attribute Change Sets)

Can be agent-initiated by Scanners

Can be sent confirmed or unconfirmed

All agent-initiated scan events have same data-request-id 0xF000

Have a scan-report-number for each data-request-id

PUT IT ALL TO WORK



Scan event report with
Observation scan

object handle 1
nu-obs-val-simp 60.7
2010-08-22 3:34:12

To WAN

Device: Weigh Scale
System ID: 0xfeedabeedeadbeef
Body Mass: **60.7** kilograms
Time: **Aug 22 2010 at 3:34:12 AM**

!! Atomic
Update !!
combine with config info

MANAGER

Agent sys ID: 0xFeedabeedeadbeef

Agent config ID: 0x5DC

Copy of Agent Configuration

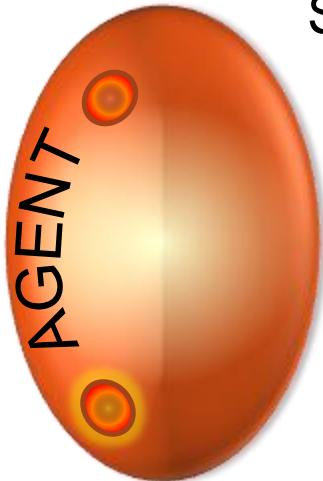
Body Mass Object

- Handle: 1
- TYPE: MDC_MASS_BODY_ACTUAL
- Unit Code: MDC_DIM_KILO_G
- MetricSpecSmall: agent-init, aperiodic, intermittent, temp-data
- Attribute Value Map:

MDC_ATTR_NU_OBS_VAL_SIMP,
MDC_ATTR_TIME_STAMP_ABS

**Now Examine the Role of
Static, Dynamic, or
Observational
Attributes**

DYNAMIC UPDATE



Scan event report with
Observation scan

object handle 1
unit-code `MDC_DIM_LB`

!! No measurement !!
Device: Weigh Scale
System ID: 0xfeedabeedeadbeef
Body Mass: **60.7** pounds
Time: **Aug 22 2010 at 3:34:12 AM**

**!! Still Atomic
Update !!**

combine with config info

MANAGER

Agent sys ID: `0xFeedabeedeadbeef`
Agent config ID: `0x5DC`

Copy of Agent Configuration

Body Mass Object

- Handle: `1`
- TYPE: `MDC_MASS_BODY_ACTUAL`
- Unit Code: `_D1LO_G`
- MetricSpecSmall: `agent-init, aperiodic, intermittent, temp-data`

Attribute Value Map:

`MDC_ATTR_NU_OBS_VAL_SIMP,`
`MDC_ATTR_TIME_STAMP_ABS`

NEW MEASUREMENT



Scan event report with
Observation scan

object handle 1
nu-obs-val-simp 160.4
2010-08-22 9:40:14

To WAN

Device: Weigh Scale
System ID: 0xfeedabedeadbeef
Body Mass: **160.4** pounds
Time: **Aug 22 2010 at 9:40:14 AM**

!! Atomic
Update !!
combine with config info

MANAGER

Agent sys ID: 0xFeedabedeadbeef
Agent config ID: 0x5DC

Copy of Agent Configuration

Body Mass Object

- Handle: 1
- TYPE: MDC_MASS_BODY_ACTUAL
- Unit Code: MDC_DIM_LB
- MetricSpecSmall: agent-init, aperiodic,

intermittent,
temp-data

Attribute Value Map:

MDC_ATTR_NU_OBS_VAL_SIMP,
MDC_ATTR_TIME_STAMP_ABS

NOW THIS!!



Scan event report with
Observation scan

object handle 1
nu-obs-val-simp 180.7

To WAN

Device: Weigh Scale
System ID: 0xfeedabedeadbeef
Body Mass: **180.7** pounds
Time: **Manager's time**

!! Atomic
Update !!
combine with config info

MANAGER

Agent sys ID: 0xFeedabedeadbeef

Agent config ID: 0x5DC

Copy of Agent Configuration

Body Mass Object

- Handle: 1
- TYPE: MDC_MASS_BODY_ACTUAL
- Unit Code: MDC_DIM_LB
- MetricSpecSmall: agent-init, aperiodic, intermittent, temp-data

Attribute Value Map:

MDC_ATTR_NU_OBS_VAL_SIM
MDC_ATTR_TIME_STAMP_ABS

The 20601 Traps

- **The required optional GET**
- **The MetricSpecSmall ‘setting’ and observational-to-dynamic conversion**
- **MDS Data Request action**
- **Manager-initiated, scanners, agent data-request-id, and MetricSpecSmall mgr-init**
- **Scanners DON’ T scan!**
- **Can’ t negotiate specialization versions**
- **Protocol version error in specializations**
- **Communication and Service model inseparability**
- **Parse and Ignore (why ASN1 is so cool)**
- **PM segment entry map header miss (no parse and ignore)**
- **Error conditions**
 - No more Rorj
 - PM Store/Segment actions

Nu är det klart

ISO/IEEE 11073 Personal Health Devices Tutorial – Part II – Device Specializations

Slides Created by

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on behalf of the

ISO/IEEE 11073 Personal Health Device Work Group

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Agenda

- Background
- Base Standard Tutorial (ISO/IEEE Std 11073-20601)
- Device Specializations Tutorial (ISO/IEEE 11073-104zz)
 - Background and concepts
 - Overview of completed and drafting device specializations
 - Detailed example 1: 11073-10425 Continuous Glucose Monitor
 - Detailed example 2: 11073-10419 Insulin Pump
- Tool Support
- Summary
- Questions (feel free to ask while we go too)

Background: Why Device Specializations?

- ❑ 11073-20601 provides a generic framework (base protocol) for semantic interoperability
- ❑ In order to build interoperable devices, specific domain information model instantiations and nomenclature codes need to be standardized (*Linguistic analogy*: 11073-20601 defines the grammar and 11073-104zz defines the vocabulary needed for a certain topic)

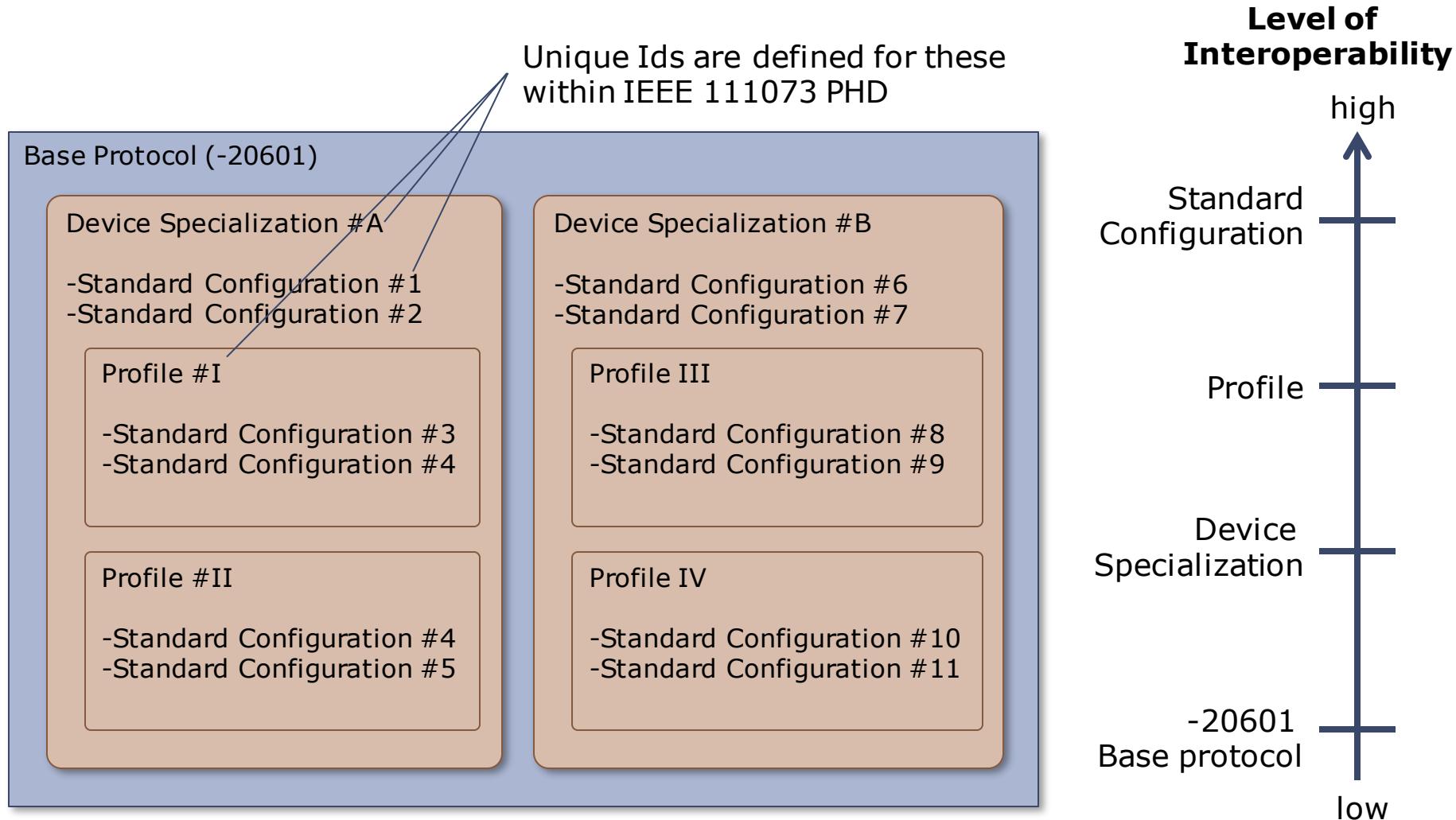
Device Specialization Standards

- ❑ Increase the likelihood of interoperability by defining specific objects, attributes, nomenclature ids, and services for particular device types
- ❑ Narrow down options:
 - Define mandatory objects and attributes for the agent's configuration (Note that all objects in - 20601 are optional, except the MDS)
 - Define mandatory elements of the service and communication model
- ❑ Some Device Specializations describe broad categories of devices types, other have a narrow focus
- ❑ Some Device Specializations define Profiles and Standard Configurations for further increasing interoperability

Profiles of Device Specializations

- Defined within a Device Specialization, which typically covers a broad category or distinct set of device types
- Set further constraints on those objects, attributes, and service, that are defined optional in a Device Specializations
- Define common objects that are useful to particular device types
- Not intended to extend the set of objects, attributes, and services, that are defined in a Device Specialization

Specializations, Profiles, and Configurations



Example: IEEE 11073-10406 Basic ECG (1-3 lead)

Base Protocol (-20601)

-10406 Basic ECG (1-3 lead)
MDC_DEV_SPEC_PROFILE_ECG

Heart rate profile
MDC_DEV_SUB_SPEC_PROFILE_HR

-Standard Configuration **0x0258**

Simple ECG profile
MDC_DEV_SUB_SPEC_PROFILE_ECG

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 - Detailed example 1: 11073-10406 Basic ECG (1-3 lead)
 - Detailed example 2: 11073-10417 Glucose meter
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Tabular Device Specialization Overview

Device Spec	Title	Specified Objects				Comments	
		Numeric	Real-Time Sample Array	Enumeration	PM-Store		
Scanner	Store						
11073-104zz	<Title of Device Specialization >	Mandatory Object (Optional object)	Mandatory Object (Optional object)	Mandatory Object (Optional object)	Y/-	Y/-	

Disease Management (1/3)

Device Spec	Title	Specified Objects				Comments	
		Numeric	Real-Time Sample Array	Enumeration	Scanner	PM-Store	
11073-10404	Pulse oximeter	SpO2 Pulse rate (Pulsatile quality)	(Plethysmogram)	(Device annunciation) (Pulsatile occurrence) (Pulsatile characteristics)	Y	Y	• 1 x standard configuration for episodic mode
11073-10406	Basic ECG (1-3 lead)	Heart rate (R-R interval)	(ECG waveform)	(Device status) (Context data trigger)	Y	Y	• Heart Rate profile • 1 x standard configuration
		(Heart rate) (R-R interval)	ECG waveform				• Simple ECG profile
11073-10407	Blood pressure monitor	Systolic Diastolic MAP (Pulse)	–	–	–	–	• Uses Compound Numeric for Systolic, Diastolic, MAP • 1 x standard configuration
11073-10408	Thermometer	Body Temperature	–	–	–	–	• 1 x standard configuration
P11073-10413	Respiration rate monitor	Respiration rate (Absent breath)	(Waveform)	(Device status)	Y	Y	• In early drafting state, subject to change
11073-10415	Weighing scale	Body weight (Body height) (Body mass index)	–	–	–	–	• 1 x standard configuration
11073-10417	Glucose meter	Glucose (Context exercise) (Context carbohydrates) (Context medication) (HbA1c)	–	(Device annunciation) (Context health) (Context meal) (Context tester) (Context sample location)	–	Y	• 1 x standard configuration • Two use case: home use and carrying to doctor's office

Disease Management (2/3)

Device Spec	Title	Specified Objects					Comments
		Numeric	Real-Time Sample Array	Enumeration	Scanner	PM-Store	
11073-10418	INR monitor	INR (Prothrombin time) (Quick value) (ISI) (Control calibration) (INR target level) (Current med level) (New med level)	–	(Device status) (Device alarms) (Context tester) (Batch code)	–	Y	<ul style="list-style-type: none"> • Measures blood coagulation ability • 2 x standard configurations defined
P11073-10419	Insulin pump	Basal delivery Bolus delivery (Basal rate) (Basal rate profile) (Total daily dose) (Basal delivery adjustment)	–	(Active profile) (Operational state) (Notification)	–	Y	<ul style="list-style-type: none"> • In bolting state, subject to change • 1 x standard configuration
11073-10420	Body composition analyzer	Body fat Body height Body weight (Fat free mass) (Soft lean mass) (Body water) (Body mass index)	–	–	–	–	• 1 x standard configuration
11073-10421	Peak expiratory flow monitor	PEF FEV1 Personal best (FEV6)	–	(Reading status)	–	–	<ul style="list-style-type: none"> • Measures peak expiratory flow and forced expiratory flow after 1 and 6 secs • 1 x standard configuration

Disease Management (3/3)

Device Spec	Title	Specified Objects					Comments
		Numeric	Real-Time Sample Array	Enumeration	Scanner	PM-Store	
P11073-10422	Urine analyzer	<to be defined>	<to be defined>	<to be defined>	<>	<>	• No draft available yet
P11073-10423	Sleep quality monitor	<to be defined>	<to be defined>	<to be defined>	<>	<>	• No draft available yet
11073-10424	Sleep apnea breathing therapy equipment	Duration of flow generation Device mode set Therapy mode set (too many to list)	(Airflow waveform) (Therapy pressure waveform) (Leakage waveform)	(too many to list)	Y	Y	
11073-10425	Continuous glucose monitor	Glucose (Sensor Calibration) (Sensor run-time) (Glucose sampling interval) (Glucose trend) (Patient low/high thresholds) (Device hypo/hyper thresholds) (Glucose rate of change thresholds)	–	(PHD DM status) (CGM status)	–	Y	• Measures glucose concentration • 1 x standard configuration

Health and Fitness (1/2)

Device Spec	Title	Specified Objects				Comments	
		Numeric	Real-Time Sample Array	Enumeration	PM-Store		
11073-10441	Cardiovascular fitness and activity monitor	(Age) (Altitude) (Altitude gain) (Altitude loss) (Ascent time and distance) (Body weight) (Breathing rate) (Cadence) (Calories ingested) (Carbohydrate calories ingested) (Descent time and distance) (Distance) (Energy expected) (Heart rate) (Height) (Incline) (Intensity) (Latitude) (Longitude) (Power) (Resistance) (Slope) (Speed) (Stride length) (Sustained physical activity threshold) (User max heart rate)	–	Session (Sub-session) (Activity time) (Program identifier)	–	–	<ul style="list-style-type: none"> General model for many types of cardio devices Support for episodic mode 26 Numeric objects defined No standard configurations defined

Health and Fitness (2/2)

Device Spec	Title	Specified Objects					
		Numeric	Real-Time Sample Array	Enumeration	Scanner	PM-Store	Comments
P11073-10441 Revision	Cardiovascular fitness and activity monitor	See 11073-10441 and additionally: (PIM) (RMS) (TAT) (TAT threshold) (Estimated weight loss)	(3D_Acceleration_X) (3D_Acceleration_Y) (3D_Acceleration_Z) (3D_Acceleration_X Pitch) (3D_Acceleration_Y Roll) (3D_Acceleration_Z Yaw) (3D_Acceleration_Z with gravity offset)	See 11073-10441 and additionally: (Sub-session-start-indicator)	Y	Y	<ul style="list-style-type: none"> In balloting state, subject to change Adds real-time reporting Adds three profiles: <ul style="list-style-type: none"> Step counter Activity monitor Actigraphy monitor Adds several Numeric objects and RT-SA objects Adds PM-Store and Scanner support Adds 3 x standard configurations RMS = root mean squared ZCM = zero crossing mode PIM = proportional integral mode TAT = time above threshold
11073-10442	Strength fitness equipment	(Resistance) (Repetition) (Repetition count)	-	Set (Exercise laterality) (Exercise grip) (Exercise position) (Exercise movement)	-	-	<ul style="list-style-type: none"> General model for many types of strength building equipment No standard configurations defined

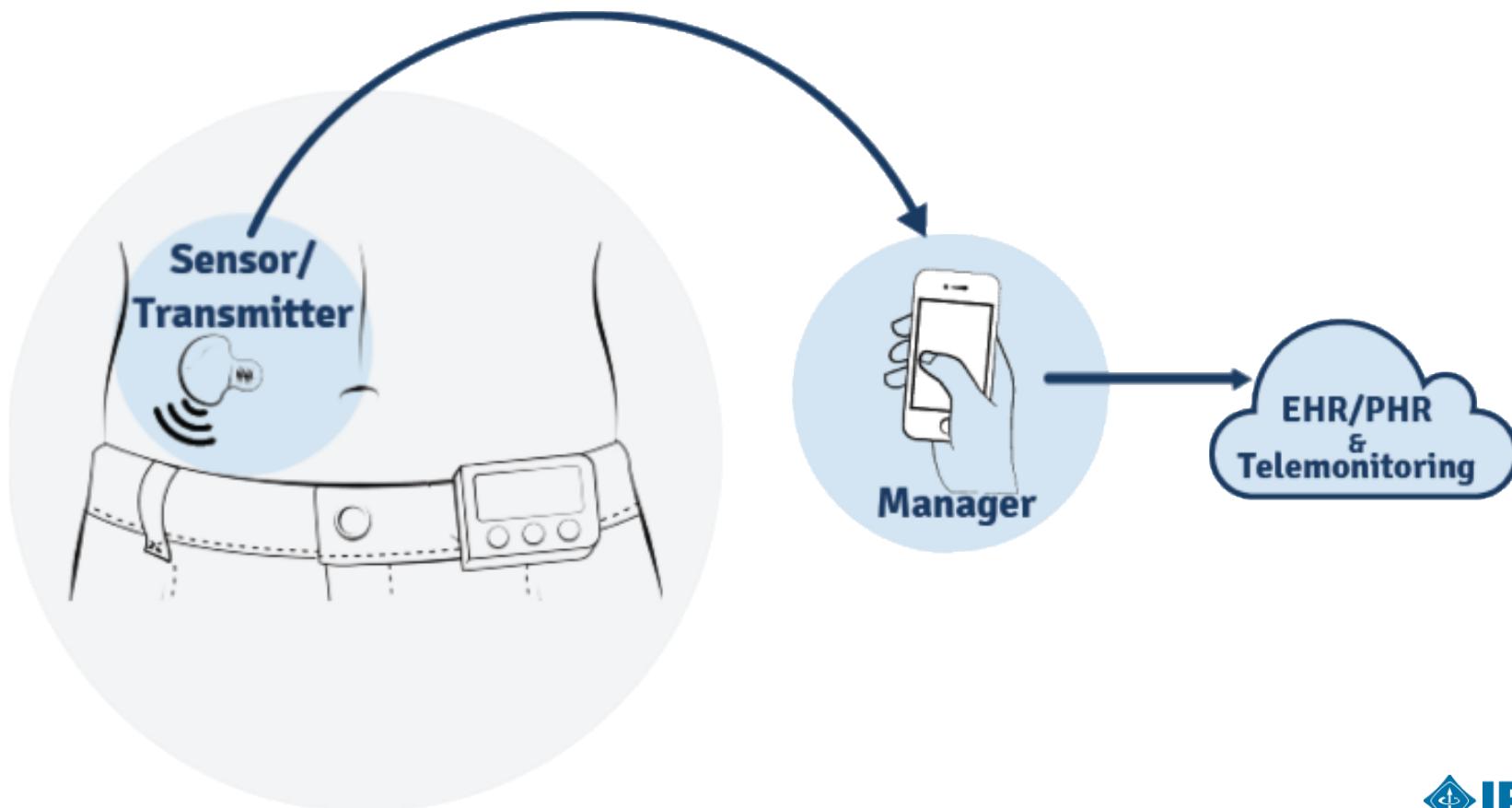
Independent Living (Aging Independently)

Device Spec	Title	Specified Objects					Comments
		Numeric	Real-Time Sample Array	Enumeration	PM-Store	Scanner	
11073-10471	Independent living activity hub	–	–	(CO sensor) (Contact closure sensor) (Enuresis sensor) (Fall sensor) (Gas sensor) (Medication dosage) (Motion sensor) (PERS sensor) (Property exit sensor) (Smoke sensor) (Switch sensor) (Temperature sensor) (Usage sensor) (Water sensor)	–	–	• General model for different home sensor devices • No standard configurations defined
11073-10472	Medication monitor	Fixed medication dispensed {XOR} Variable medication dispensed	–	(Status reported) (User feedback)	–	Y	• Measures dispensing of medication • 4 x standard configurations defined

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 - **Detailed example 2: 11073-10419 Insulin Pump**
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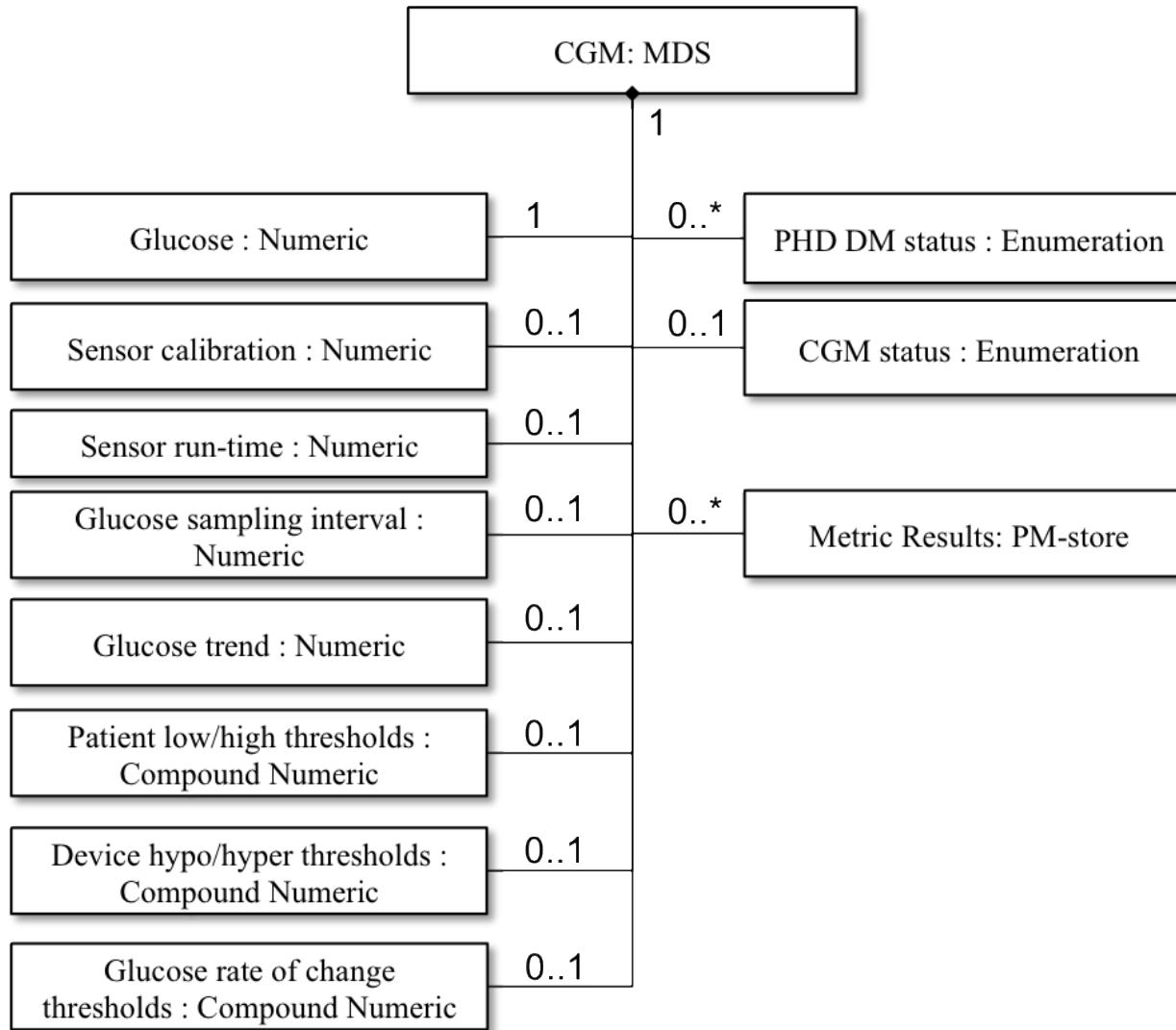
Continuous Glucose Monitor introduction



ISO/IEEE Std 11073-10425 Continuous Glucose Monitor (CGM)

- -10425 Standard was published in late-2014
- One Standard Configurations defined.
 - Supports the glucose numeric object.
- Extended Configurations can include optional objects.
- Uses nomenclature from -10101 and adds new terms for CGM.
- Support for periodic mode.
- Measurement data transfer is either agent-initiated or PM-Store. (Scanner objects are not required by this standard)

ISO/IEEE Std 11073-10419 Continuous Glucose Monitor



CGM Standard Configuration

- Common continuous glucose monitor, interstitial fluid, subcutaneous tissue.
- Numeric class is instantiated to create a Glucose object.

Glucose		Numeric
Handle	= 1	
Type	= MDC_CONC_GLU_ISF	
Supplemental Type	= MDC_CTXT_GLU_SAMPLELOCATION_SUBCUTANEOUS	
Metric-Spec-Small	= 0xC042 (available intermediate, available stored, agent initiated, calculation)	
Unit-Code	= MDC_DIM_MILLI_G_PER_DL	
Attribute-Value-Map	= {MDC_ATTR_NU_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_BO}	
Base-Offset-Timestamp	= (date and time of the glucose measurement)	
Basic-Nu-Observed-Value	= 104 mg/dL	

CGM Extended Configuration

- Must include the Glucose object and may include one or more of the optional numeric and enumeration objects.
- Numeric objects include...
 - Glucose (mandatory)
 - Sensor Calibration (periodic calibration of the sensor is required for most CGMs)
 - Sensor run-time (embedded sensors only last for a period of days)
 - Glucose sampling interval (time between glucose samples)
- Compound Numeric Objects
 - Patient high/low thresholds (indicates patient glucose goals)
 - Device hypo/hyper thresholds (indicates hypoglycemia hyperglycemia levels)
 - Glucose rate of change thresholds (indicates patient change in glucose goals)

CGM Extended Configuration

- Enumeration objects include...
 - PHD DM Status (General disease management status object with common bit definitions across all specializations)
 - CGM Status (CGM specific status bits)

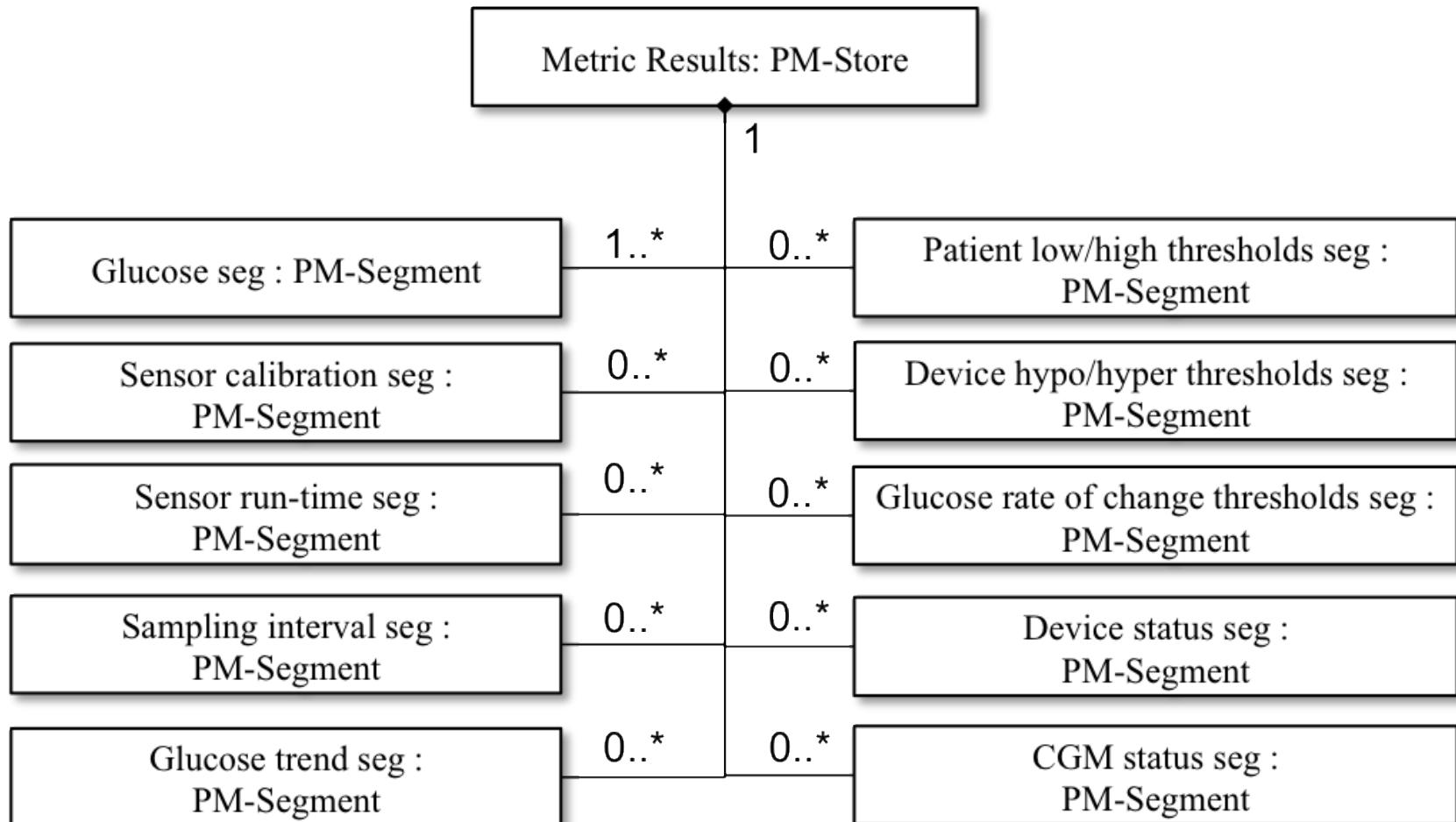
CGM Extended Configuration – Example of Compound Numeric object

<i>Compound Numeric</i>	
Patient low/high threshold	
Handle	= assigned by the implementation, cannot be zero
Type	= MDC_CONC_GLU_PATIENT_THRESHOLDS_LOW_HIGH
Metric-Spec-Small	= (mss-avail-stored-data mss-upd-aperiodic mss-acc-agent-initiated mss-cat-setting mss-cat-manual)
Metric-Structure-Small	= ms-struct-compound-fix
Metric-Id-List	= MDC_CONC_GLU_PATIENT_THRESHOLD_LOW then MDC_CONC_GLU_PATIENT_THRESHOLD_HIGH
Unit-Code	= MDC_DIM_MILLI_G_PER_DL or MDC_DIM_MILLI_MOLE_PER_L
Base-Offset-Timestamp	= (date and time of the patient low/high entry)
Compound-Basic-Nu-Observed-Value	= { 4 mmol/l, 7 mmol/l }

CGM PM-Store

- PM-store is only used in Extended configurations.
- Measurements, thresholds and status entries are correlated by time stamps.
- PM-segment entries could be periodic or episodic.

CGM PM-Store model



CGM PM-Segment Example Layout

Glucose seg : PM-Segment

PM-Segment Attributes

PM-Segment-Entry-Map

...

Fixed-Segment-Data

<i>Entry 1</i>	SegmentEntryHeader(opt)	Glucose Concentration measurement value	Base-offset time stamp of the measurement
<i>Entry 2</i>	SegmentEntryHeader(opt)	Glucose Concentration measurement value	Base-offset time stamp of the measurement
:			
<i>Entry 3</i>	SegmentEntryHeader(opt)	Glucose Concentration measurement value	Base-offset time stamp of the measurement
<i>Entry n</i>	SegmentEntryHeader(opt)	Glucose Concentration measurement value	Base-offset time stamp of the measurement

CGM PM-Store

How is the measurement data retrieved?

- Transfer of measurement data is manager-initiated.
- The manager must retrieve information about the instantiated PM-segments using the Get-Segment-Info method.
- The manager initiates transfer of the data entries stored in the PM-segment objects using the Trig-Segment-Data-Xfer method.
 - The manager can retrieve all segments, individual segments, or segments by time range.

If supported by the agent, a manager may delete the data entries in the PM-segments.

APDU Example

0xE7 0x00	APDU CHOICE Type (PrstApdu)
0x00 0x50	CHOICE.length = 80
0x00 0x4E	OCTET STRING.length = 78
0x00 0x02	invoke-id = 2 (start of DataApdu. MDER encoded.)
0x01 0x01	<u>CHOICE</u> (Remote Operation Invoke Confirmed Event Report)
0x00 0x48	CHOICE.length = 72
0x00 0x00	obj-handle = 0 (MDS object)
0xFF 0xFF 0xFF 0xFF	event-time (set to 0xFFFFFFFF if RelativeTime is not supported)
0x0D 0x1C	event-type = MDC_NOTI_CONFIG
0x00 0x3E	event-info.length = 62 (start of ConfigReport)
0x09 0xC4	config-report-id (Dev-Configuration-Id value)
0x00 0x01	config-obj-list.count = 1 Measurement object will be “announced”
0x00 0x38	config-obj-list.length = 56
0x00 0x06	obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x01	obj-handle = 1 (→ 1 st Measurement is glucose)
0x00 0x05	attributes.count = 5
0x00 0x30	attributes.length = 48
0x09 0x2F	attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04	attribute-value.length = 4
0x00 0x02 0x71 0xD4	MDC_PART_SCADA MDC_CONC_GLU_ISF
0x0A 0x61	attribute-id = MDC_ATTR_SUPPLEMENTAL_TYPES
0x00 0x08	attribute-value.length = 8
0x00 0x01	SupplementalTypeList.count = 1
0x00 0x04	SupplementalTypeList.length = 4
0x00 0x80 0x72 0x39	MDC_PART_PHD_DM
0x0A 0x46	MDC_CTXT_GLU_SAMPLELOCATION_SUBCUTANEOUS
	attribute-id = MDC_ATTR_METRIC_SPEC_SMALL

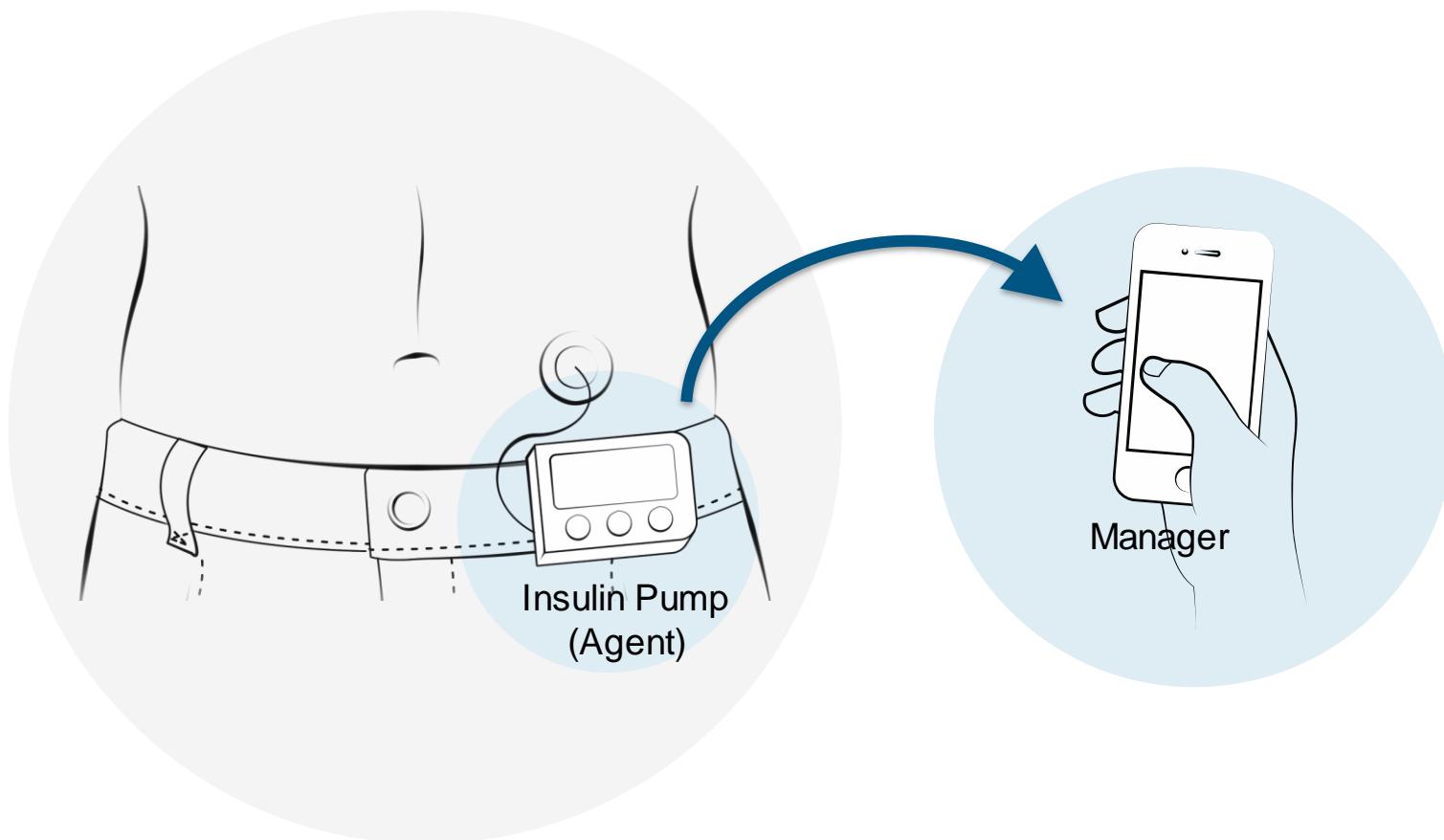
APDU Example (continued)

0x00 0x02	attribute-value.length = 2
0xC0 0x42	mss-avail-intermittent, mss-avail-stored-data, mss-acc-agent-initiated, <u>mss-cat-calculation</u>
0x09 0x96	attribute-id = MDC_ATTR_UNIT_CODE
0x00 0x02	attribute-value.length = 2
0x08 0x52	MDC_DIM_MILLI_G_PER_DL
0x0A 0x55	attribute-id = MDC_ATTR_ATTRIBUTE_VALUE_MAP
0x00 0x0C	attribute-value.length = 12
0x00 0x02	AttrValMap.count = 2
0x00 0x08	AttrValMap.length = 8
0x0A 0x4C 0x00 0x02	MDC_ATTR_NU_VAL_OBS_BASIC value length = 2
0x0A 0x82 0x00 0x08	MDC_ATTR_TIME_STAMP_BO value length = 8

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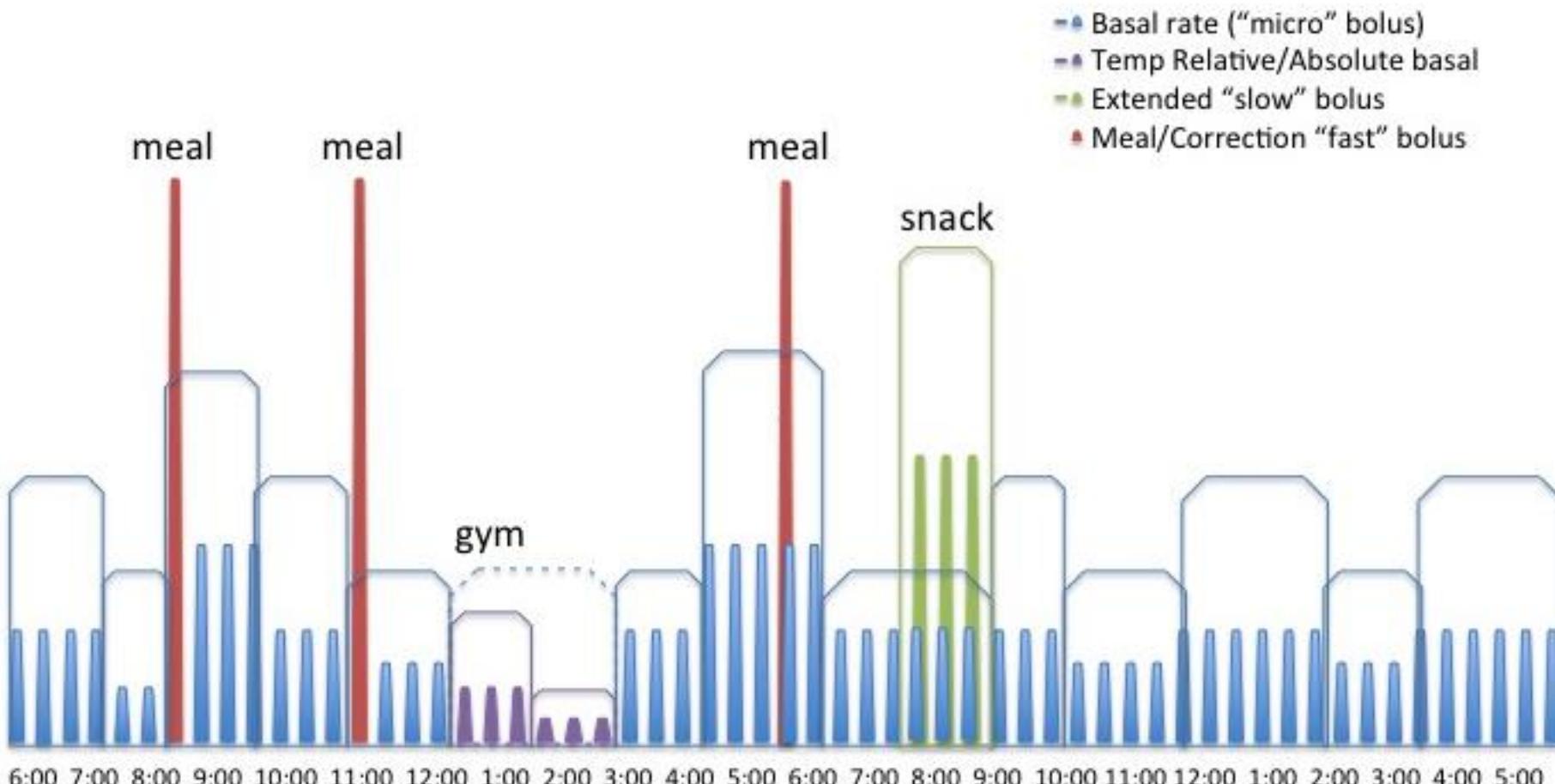
Insulin Pump introduction



Insulin Pump introduction

- a device that administers insulin (hormone to regulate glucose levels)
- primarily used in the Continuous Subcutaneous Insulin Infusion (CSII) therapy of type 1 diabetes mellitus
- Insulin pump therapy therefore differentiates between basal insulin and bolus insulin.
 - Basal insulin, sometimes also referred to as “background” insulin. Insulin pumps continuously administer insulin at a given rate depending on the fluctuating need throughout the day.
 - Bolus insulin compensates for an increased need for insulin induced by food intake. Insulin pumps can deliver through a fast bolus (over a very short period), extended bolus (longer period), or as a multi-wave bolus (combination of short and long periods).

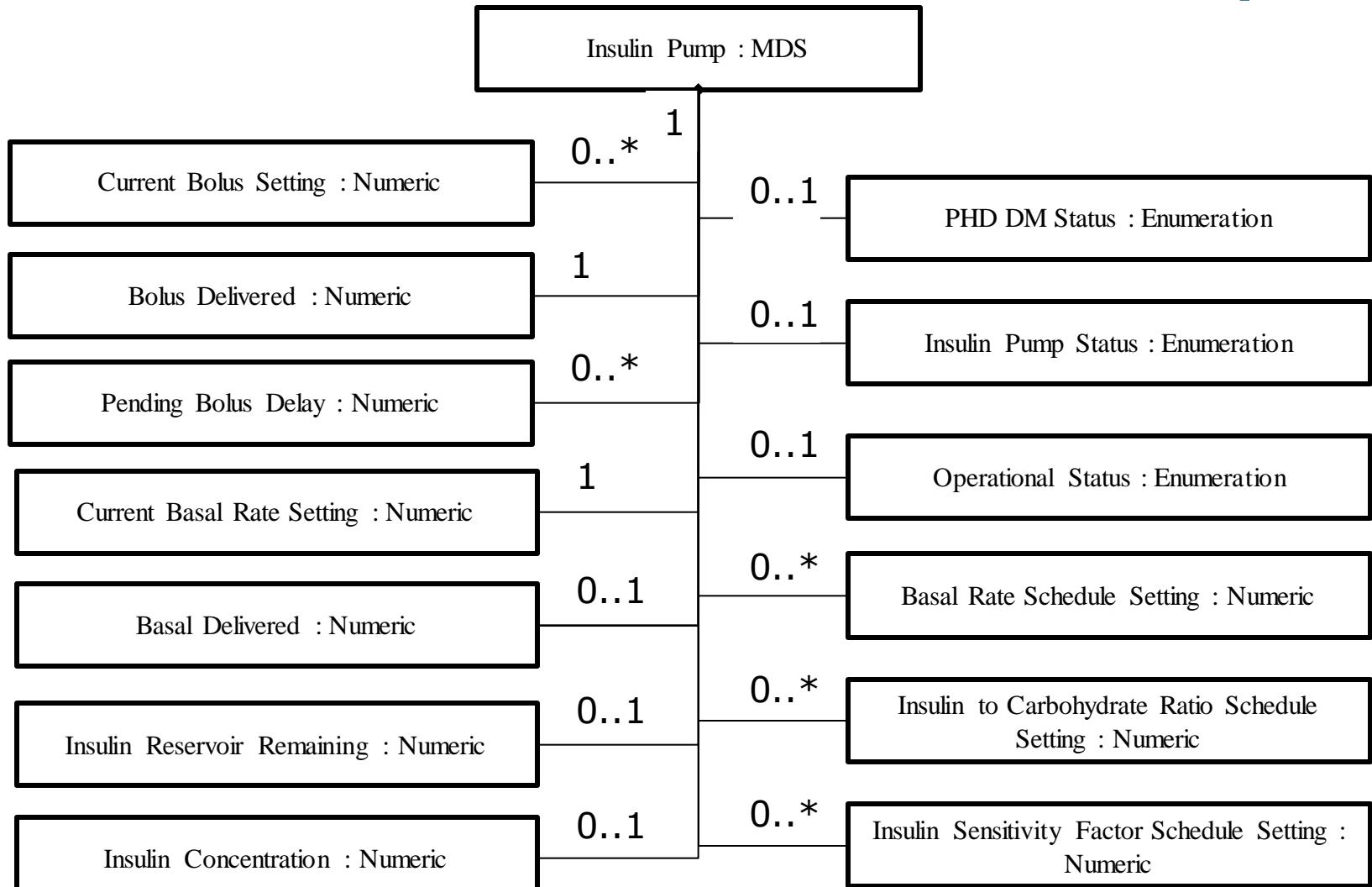
Total Daily Insulin Delivery



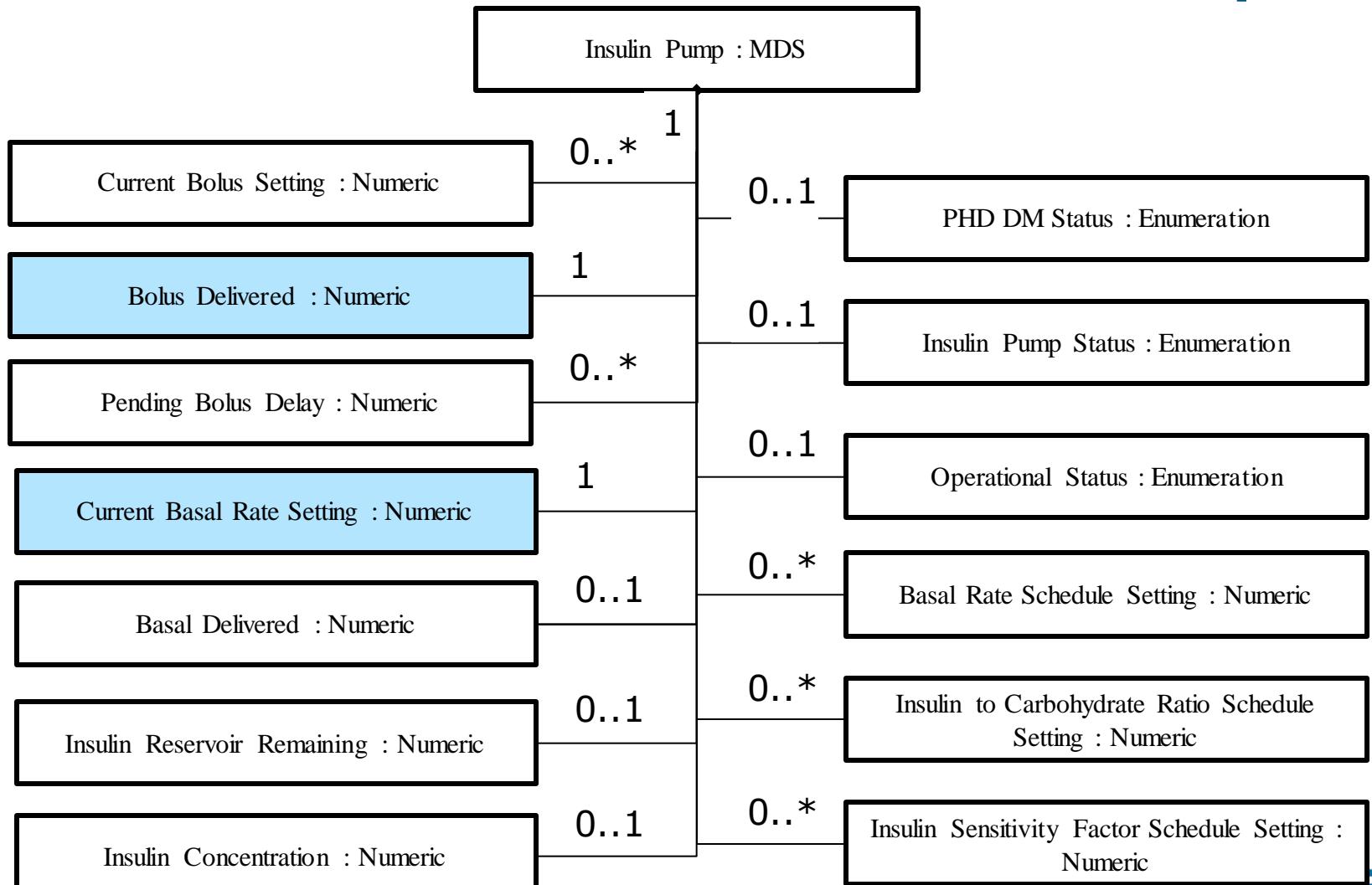
ISO/IEEE Std 11073-10419 Insulin Pump

- -10419 Standard balloting September 2014
- One Standard Configurations defined.
 - Supports the bolus delivered and current basal rate setting numeric objects.
- Extended Configurations can include optional objects.
- Uses nomenclature from -10101 and adds new terms for Insulin Pump.
- Measurement data transfer is either agent-initiated or PM-Store. (Scanner objects are not required by this standard)
- New Schedule Class object to represent settings (i.e 24 hour Basal Profiles)

ISO/IEEE Std 11073-10419 Insulin Pump



ISO/IEEE Std 11073-10419 Insulin Pump



Insulin Pump Standard Configuration

Dev-Configuration-Id = 0x076C

- ❑ Object 1: Bolus Delivered
- ❑ Object 2: Current Basal Rate Setting

Bolus Delivered		<i>Numeric</i>
Handle	= 1	
Type	= MDC_INS_BOLUS	
Supplemental Type List	= MDC_INS_BOLUS_FAST, MDC_INS_BOLUS_MEAL	
Metric-Spec-Small	= mss-acc-agent-initiated	
Unit-Code	= MDC_DIM_INTL_UNIT	
Attribute-Value-Map	= {MDC_ATTR_NU_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_BO}	
Base-Offset-Time-Stamp	= (date and time of the bolus delivered)	
Basic-Nu-Observed-Value	= 1.2 IU	

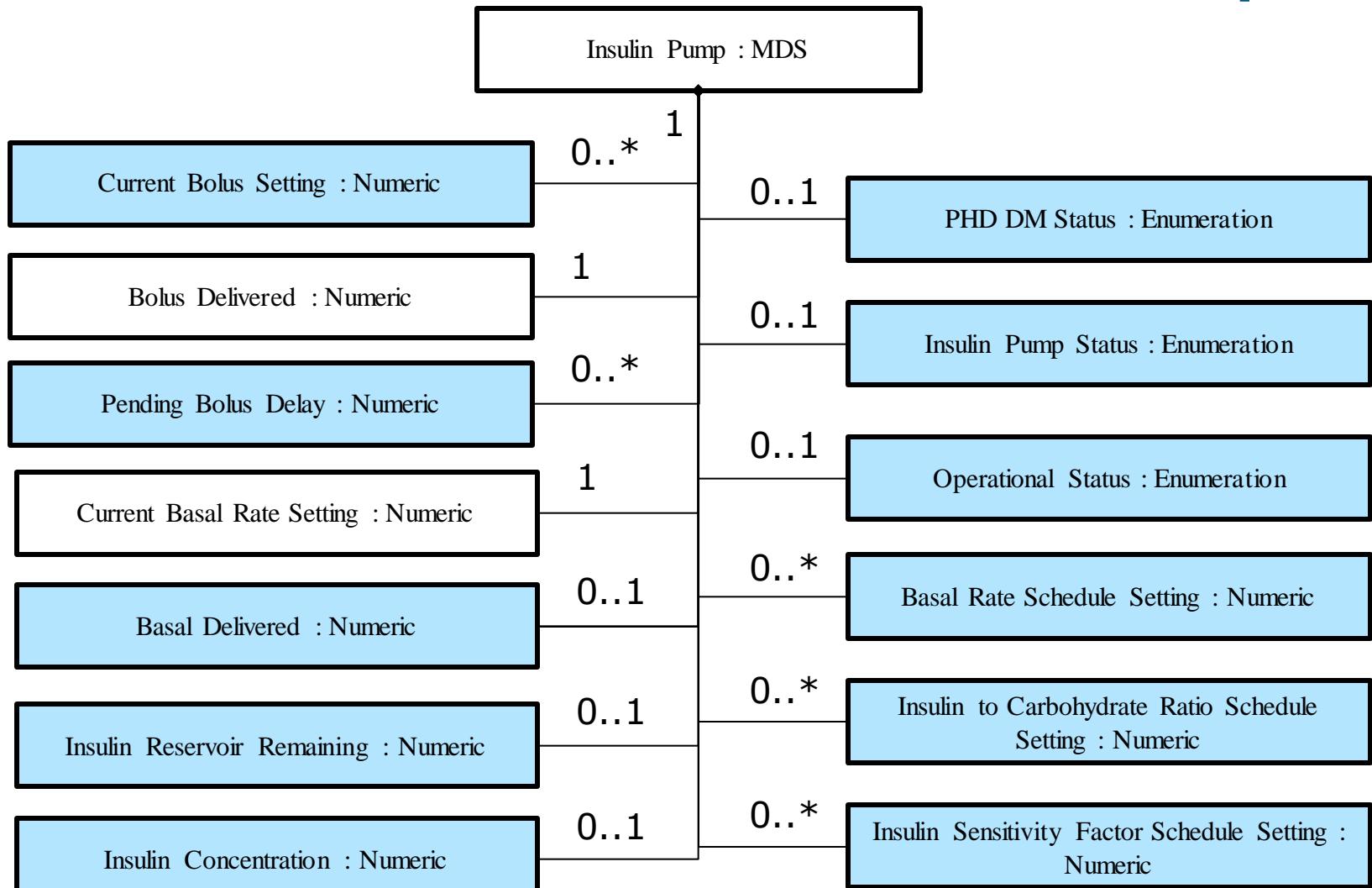
Insulin Pump Standard Configuration

Dev-Configuration-Id = 0x076C

- ❑ Object 1: Bolus Delivered
- ❑ Object 2: Current Basal Rate Setting

Current Basal Rate Setting		Numeric
Handle	= 2	
Type	= MDC_INS_BASAL_RATE_SETTING	
Supplemental Type List	= MDC_INS_BASAL_PRGM	
Metric-Spec-Small	= mss-cat-setting	
Metric-ID	= MDC_INS_BASAL_REMOTE	
Unit-Code	= MDC_DIM_INTL_UNIT_PER_HR	
Attribute-Value-Map	= {MDC_ATTR_NU_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_BO}	
Base-Offset-Time-Stamp	= (date and time of the current basal rate setting)	
Basic-Nu-Observed-Value	= 2.3 IU/hr	

ISO/IEEE Std 11073-10419 Insulin Pump



Insulin Pump Extended Configuration

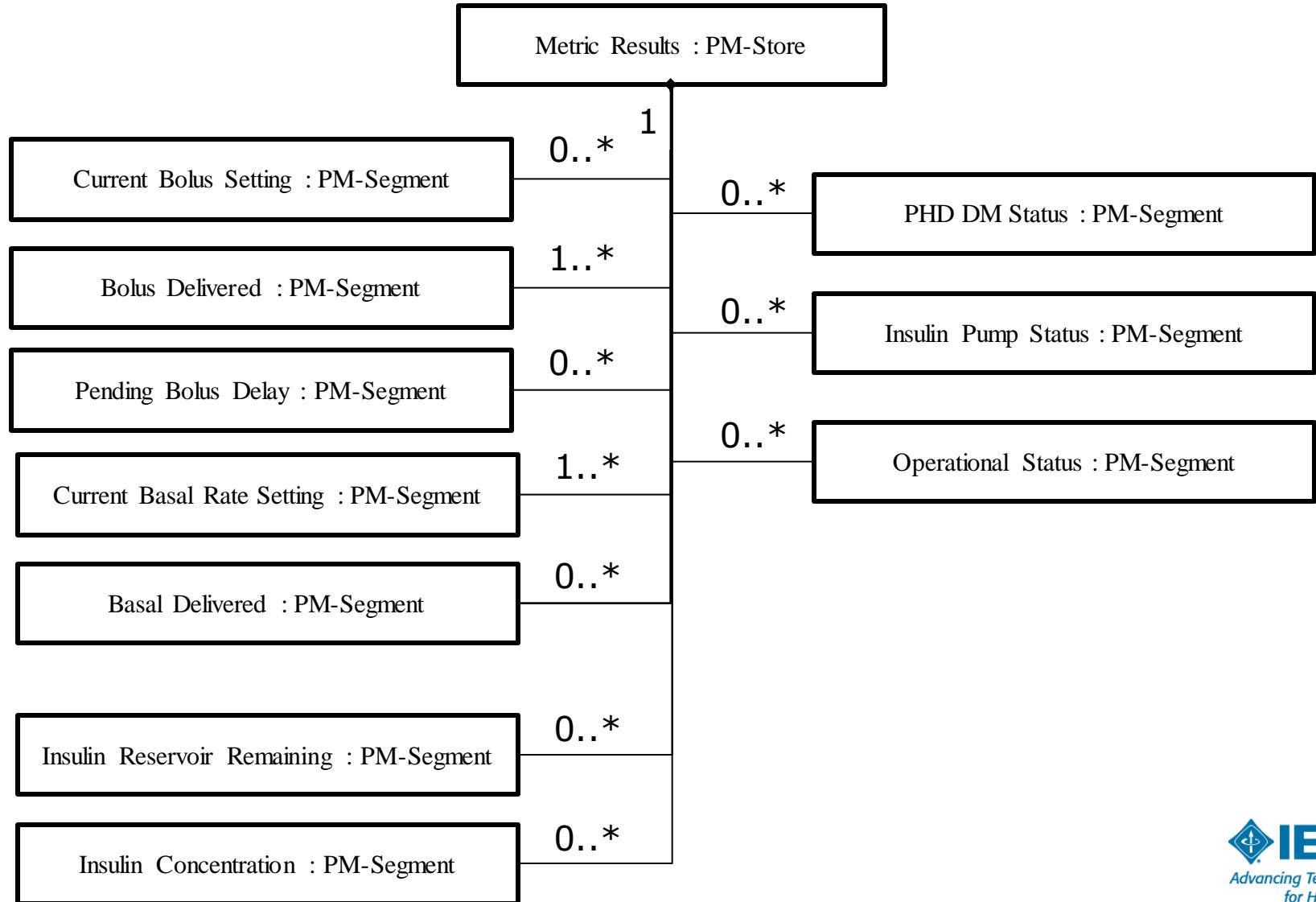
– Example of an Enumeration object

<i>Enumeration</i>	
Operational Status	
Handle	= assigned by the implementation, cannot be zero
Type	= MDC_INS_PUMP_OP_STAT
Metric-Spec-Small	= mss-avail-intermittent
Attribute-Value-Map	= {MDC_ATTR_ENUM_OBS_VAL_BASIC_BIT_STR, then MDC_ATTR_TIME_STAMP_BO}
Absolute-Time-Sstamp	= (date and time of the operational state)
Enum-Observed-Value-Basic-Bit-Str	= insulin-device-op-ready, insulin-device-therapy-run

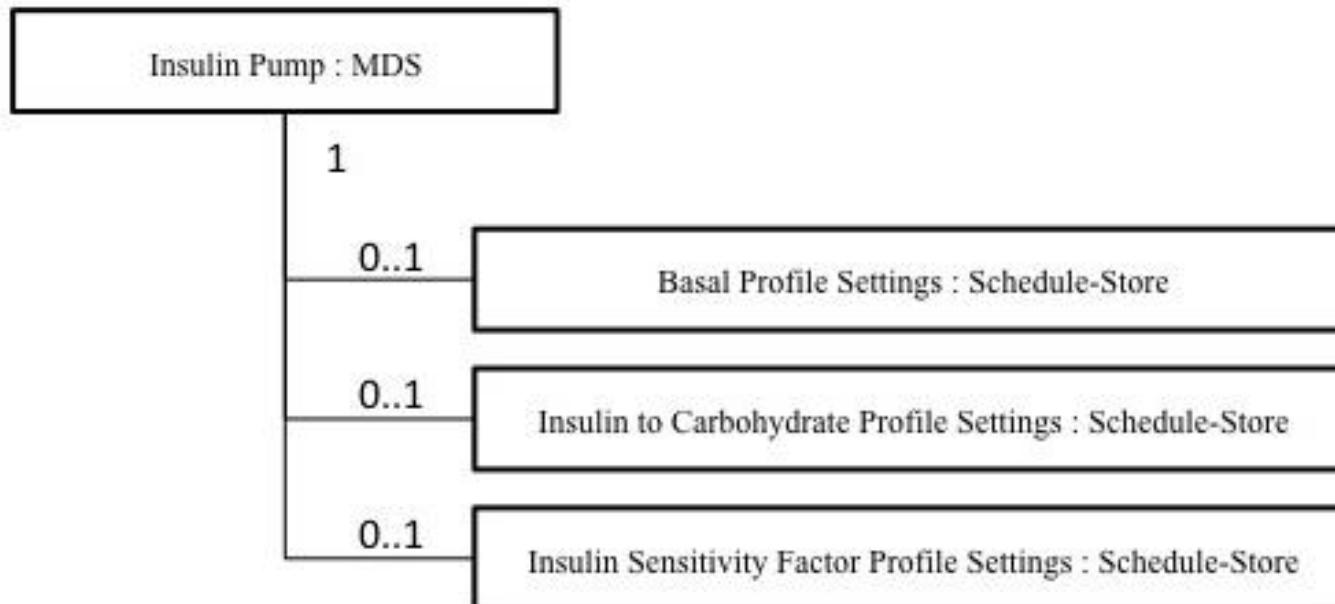
Insulin Pump PM-Store

- PM-store is only used in Extended configurations.
- If PM-store is implemented, the use of agent-initiated measurement data transmission shall be disabled.
- All measurement and context segments are episodic.
- User-session measurement and context entries are correlated by identical time stamps.

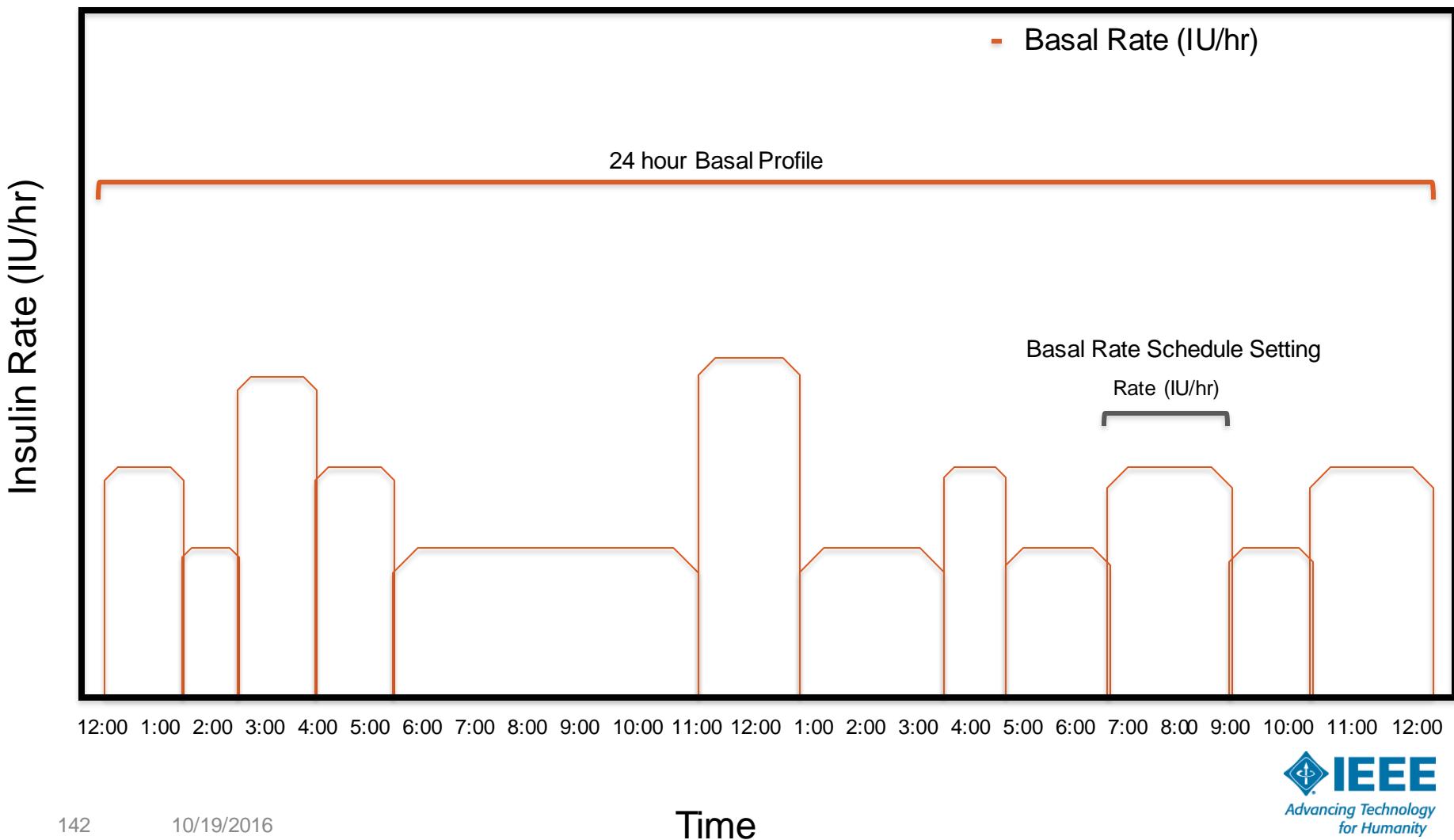
Insulin Pump PM-Store model



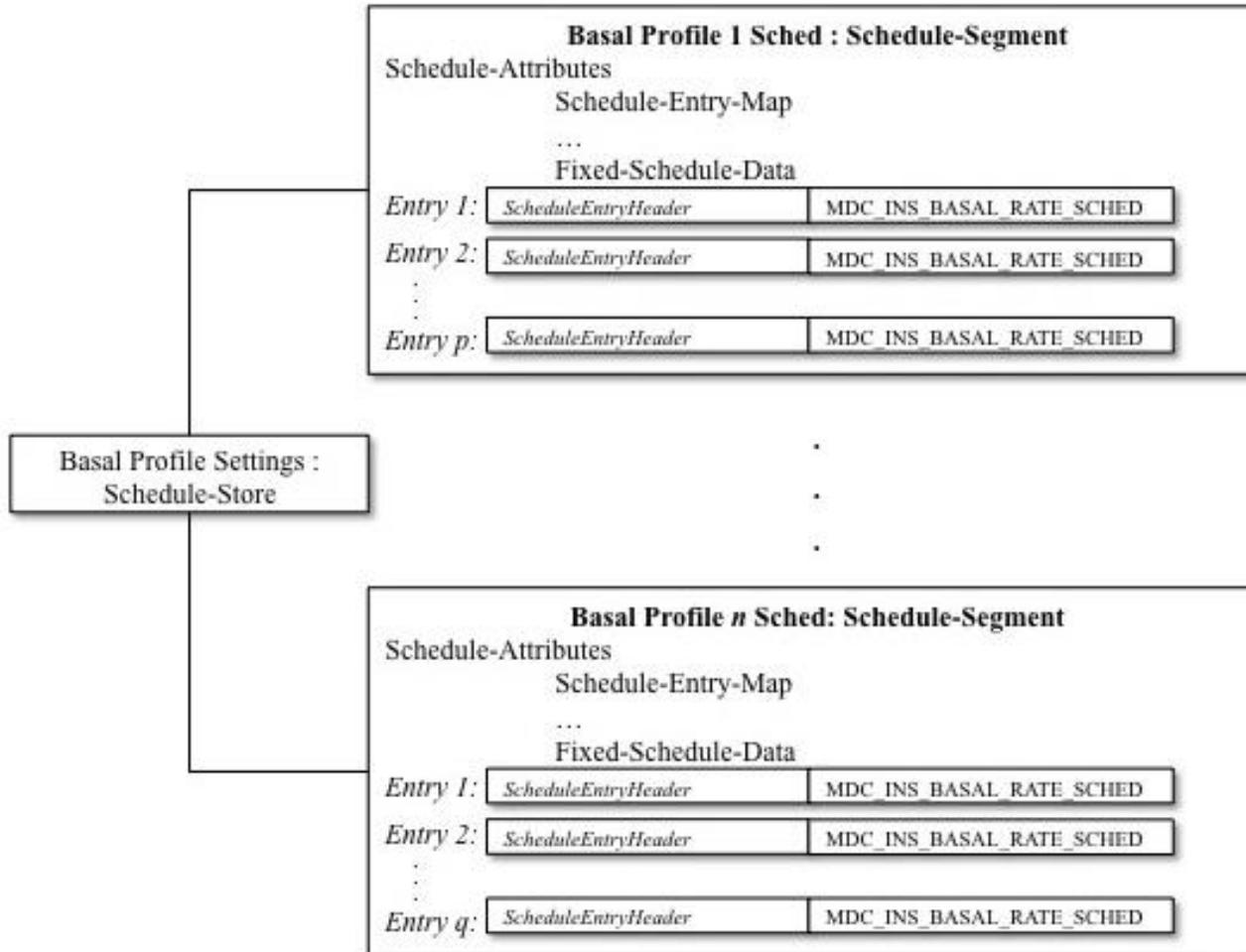
Insulin Pump Schedule class - NEW!



Basal Profile Setting : Schedule



Basal Profile Setting : Schedule-Segment



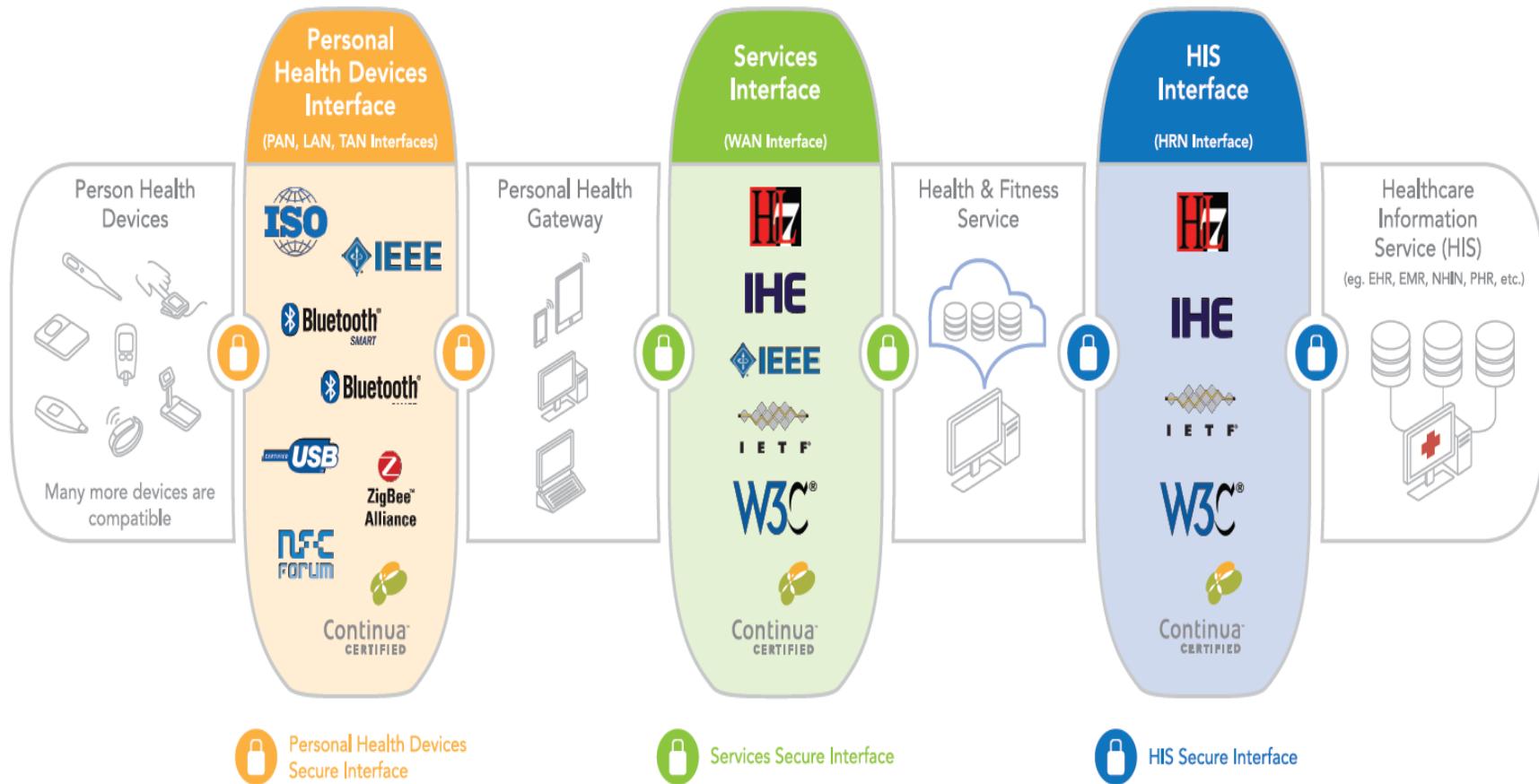
Summary Device Specializations

- ❑ Narrows a broad framework to a specific application
- ❑ Enable interoperability for each device type
- ❑ Profile concept allows for profiling particular device types within broad ‘container-like’ device specializations

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Continua Tools Coverage

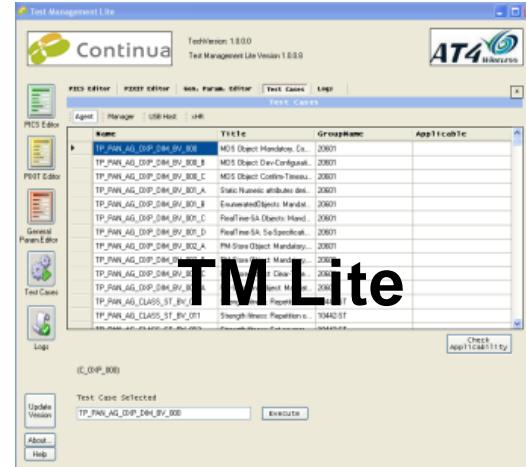


Development and Testing Tools

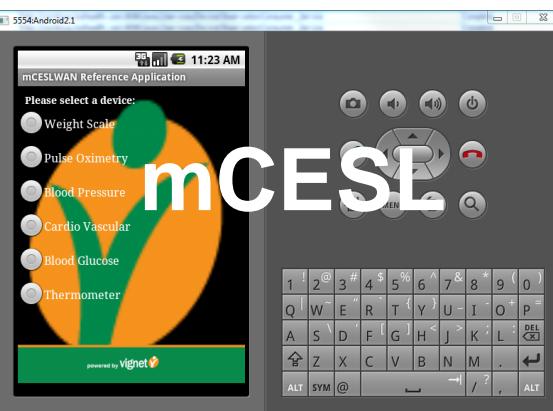
All Software is Free to Continua Members!



PC based , transport hardware, sold separately

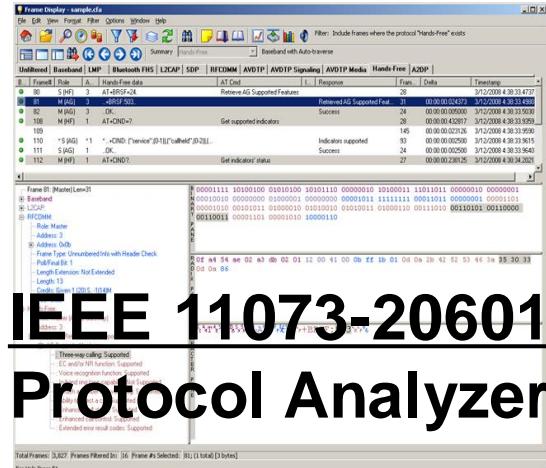


PC based , transport hardware, sold separately



Android 4.0 based (HDP) application plus code
Phone sold separately

TM Lite

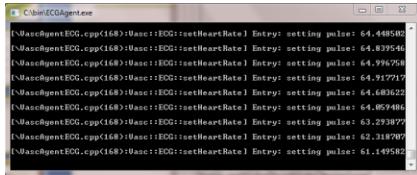


IEEE 11073-20601
Protocol Analyzer

PC based analyzer, No hardw are interface required

CESL Simulators Connect to any Continua Device

Agent Simulator



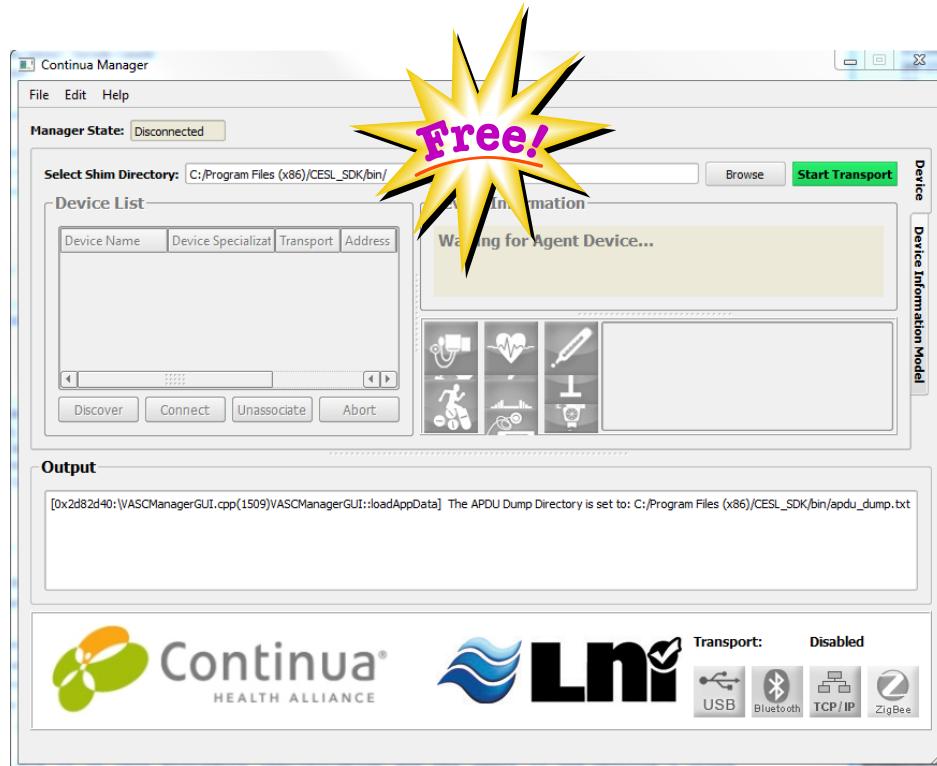
Manager Simulator



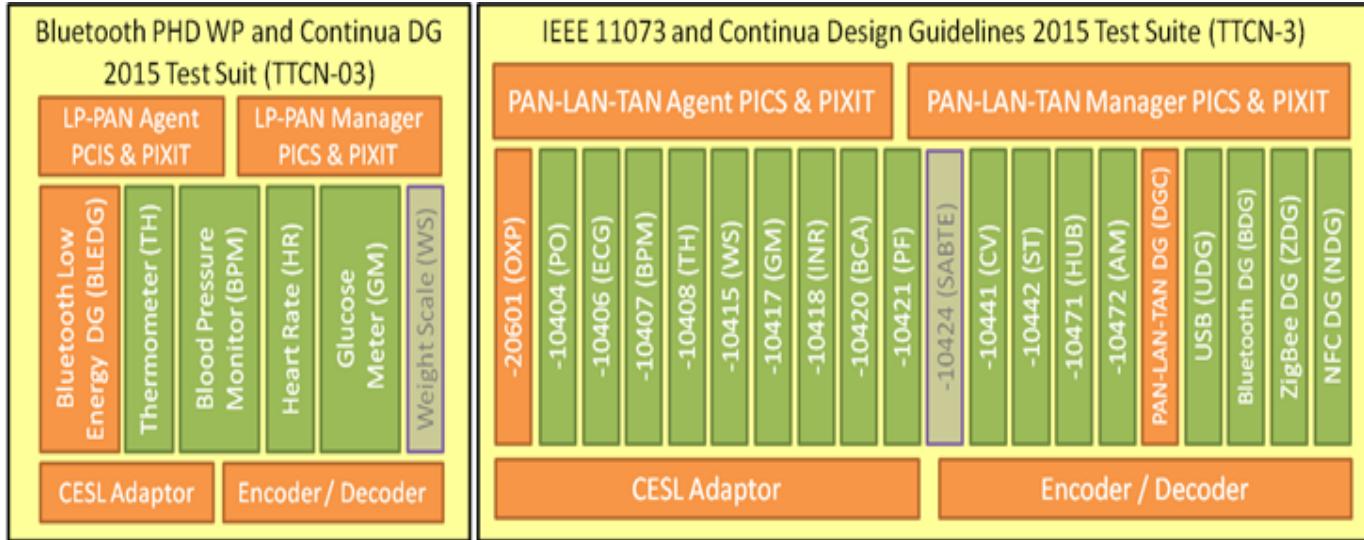
- Easy
 - Fast
 - Cost-effective

CESL: Plug in to Development

- Enhances development speed, cost-effectiveness
- Covers all Continua device specializations & transports
- \$1M+ of Code, free to members
 - Create reference implementation
 - Test against real devices
 - Run demos
- CESL Package
 - Device Agent & Mgr. Simulators
 - Reference source code
 - Software Development Kit (SDK)

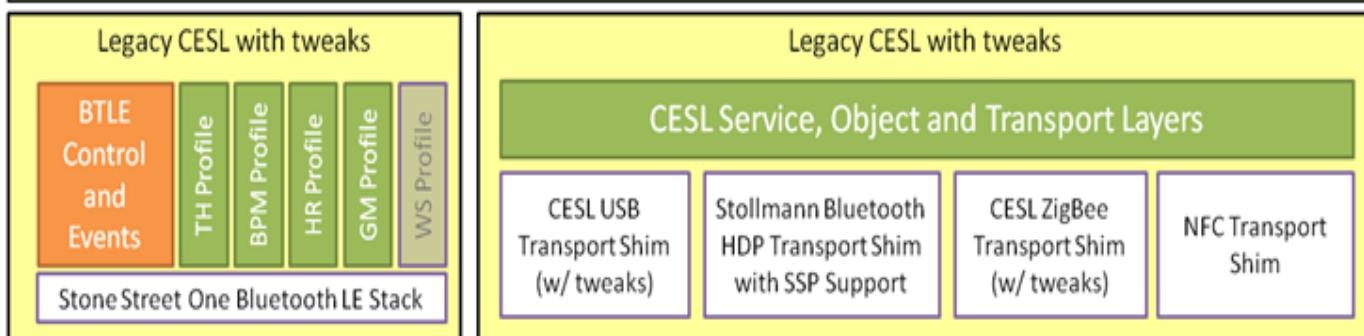


Test Tool Support



HW/SW module already included in Test Tool. It does not require modification

SW module already included in Test Tool. It requires modification or add new functionality to verify the updates from Continua DG2013



SW module already included in Test Tool. It might require modification or add new functionality to verify the updates from Continua DG2013



PAN-LAN-TAN Compliance Framework – CDG 2015

IEEE 11073

PHD Communication

-104xx Device Specializations

-10404 Pulse Oximeter	-10406 Basic ECG (1-3 Lead)	-10408 Thermometer	-10415 Weighing Scale	-10417 Glucose Meter	-10418 INR Monitor	-10419 Insulin Pump	-10420 Body Composition Analyzer	-10421 Peak Expiratory Flow Monitor	-10424 Sleep Apnea Breathing Therapy Equipment	-10425 Continuous Glucose Monitor	-10441 Cardiovascular Fitness and Activity Monitor	-10442 Strength Fitness Equipment	-10471 Independent Living Activity Hub	-10472 Medication Monitor
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-20601 Optimized Exchange Protocol

Bluetooth HD
Profile

USB PHD Class

ZigBee HC
Profile

NFC PHD Class

Bluetooth 2.1

USB 2.0

ZigBee

NFC

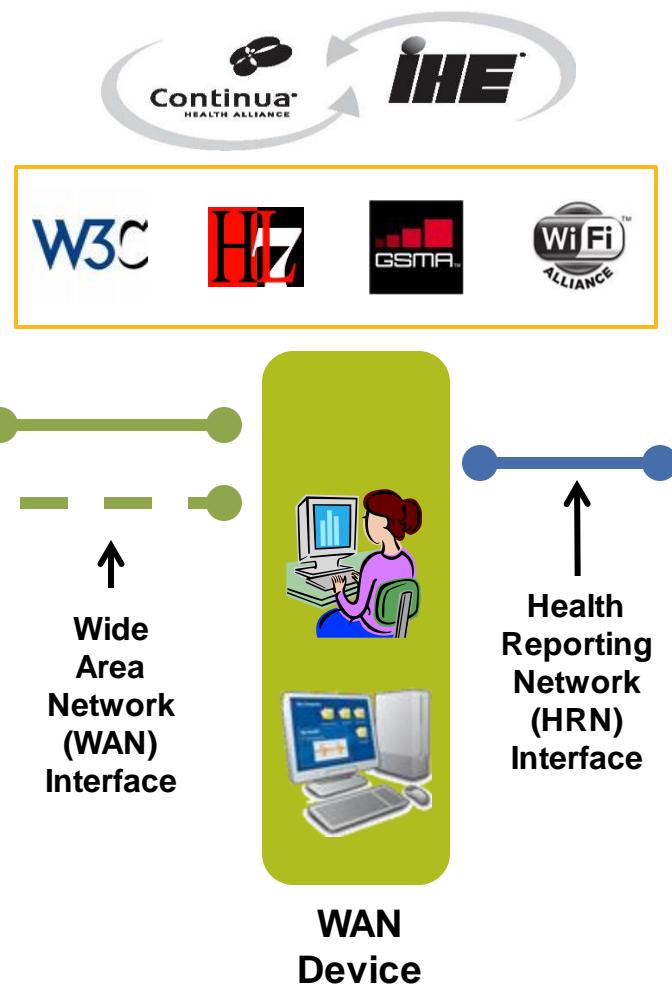
Bluetooth LE
Device
Profiles

Thermometer	Heart Rate	Blood Pressure	Weight Scale	Glucose Meter	Continuous Glucose Monitoring	Pulse Oximeter
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Bluetooth LE
Attribute Profile

More and More Added Each Year

CESL Goal = Complete Code for Continua E2E Architecture



10 Continua Test Labs



North America

AT4 Wireless, Virginia, US

Europe

AT4 Wireless, Malaga, Spain
UL, Hampshire, UK
Sharp, Berkshire, UK

Asia

TMC, Beijing, China
Allion, Tokyo, Japan
TTA, Gyeonggi-do, S. Korea
Allion, Taipei, Taiwan
AT4 Wireless, Taipei, Taiwan
SGS, Gyeonggi-do, S. Korea

Questions

