IEEE 11073 – MDC
Domain Analysis Model (DAM) –
Infusor

Introduction and Contents

- This document is intended to serve as a domain model[1] to support computable definition, particularly using UML[2] methodology, to be used in IEEE 11073-series standards[3] in conjunction with renewal of base (aka "Classic") standards, generally term the Medical Device Data Language (MDDL)

- In general, this amounts to a framework ("Model of Models"; see p.3)

- Content models are structured, as follows:
  - (p. 4) Topological
    - PoC and Enterprise distribution of supervisory and automatic feedback control
  - (pp. 5-8) Device model
    - (p. 5) Functional; Information models
    - (p. 6) Domain Info Model (DIM) (LVP context)
      - (p. 7) Metrological – flows; Max. Entropy Framework (MEF)
      - (p. 8) Behavioral model - alerts (PCA context)

Notes: [1] For UML background, see http://en.wikipedia.org/wiki/Unified_Modeling_Language.
[2] For HL7 DAM/DCM definition, see http://wiki.hl7.org/index.php?title=Domain_Analysis_Model and http://wiki.hl7.org/index.php?title=Detailed_Clinical_Models
.   [3] ISO/IEEE 11073-101xx (Nomenclature, -102xx (DIM), -103xx & -104xx device specializations, -20xxx (MDAP), and -3xxxx (Transports).

MDC Pt. Infusion DAM – Framework (Model of Models)

Clinical Use Context: Control/Flow Model

Functionality generally involves supervisory (semi-automatic) feedback control and data acquisition (SCADA) for results observation, distributed between Enterprise and PoC topological levels.

Application Context : Device Model

Top: **Functional model**
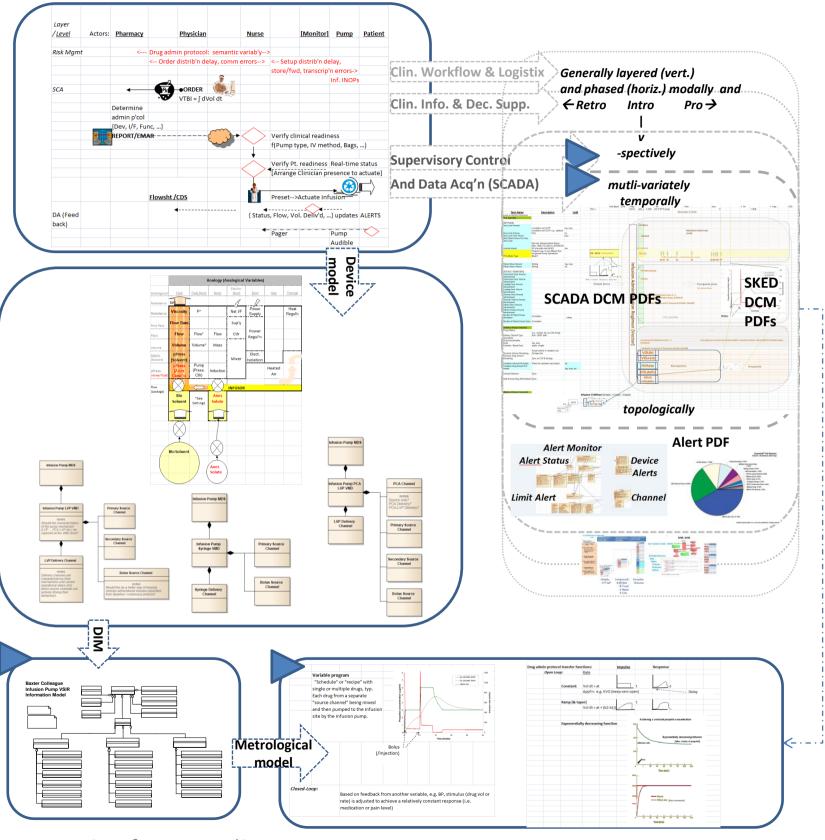
Bottom: **Domain Info Model (DIM)**
(Ctree) variations among Large Volume (LVP), Syringe, and Pt. Controlled Analgesic (PCA) Pump types.
→ **Metrological, Alert models**

SCADA. MEDical DEVices, in terms of key info contributors, are largely structurally organized sets [/clusters] of Metrical abstractions [/instances]), chiefly NUMeric and ENUMational. Most pertain to regularly OBServed physioclogical variables, some remotely controllable, and others to infrastructural configuration and status. Physiological observations and controls are typically "modally" related due to the device facilitating medical diagnostic and therapeutic functions.

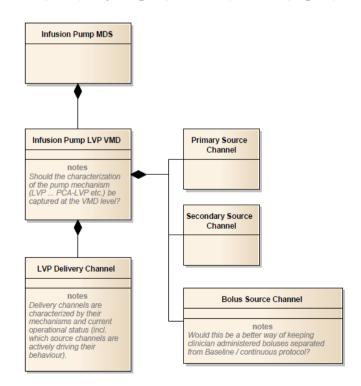# MDC Pt. Infusion DAM – Distributed, semi-automatic control topology

Layer /Level	Actors:	Pharmacy	Physician	Nurse	[Monitor]	Pump	Patient
Risk Mgmt			<--- Drug admin protocol: semantic variab'y-->				
			<-- Order distrib'n delay, comm errors-->	<-- Setup distrib'n delay, store/fwd, transcrip'n errors->			
					Inf. INOPs		
SCA			●ORDER VTBI = ∫ dVol dt				
		Determine admin p'col {Dev, I/F, Func, …} REPORT/EMAR		Verify clinical readiness f(Pump type, IV method, Bags, …)			
				Verify Pt. readiness Real-time status [Arrange Clinician presence to actuate]			
		Flowsht /CDS		Preset-->Actuate infusion			
DA (Feed back)				{ Status, Flow, Vol. Deliv'd, …} updates ALERTS			
				Pager		Pump Audible	

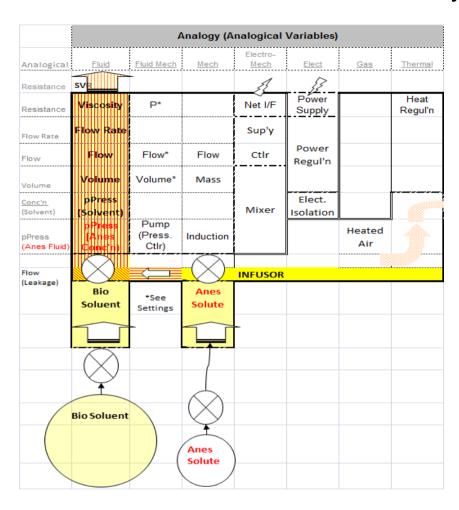See "**Metrological**" model for flow characteristics

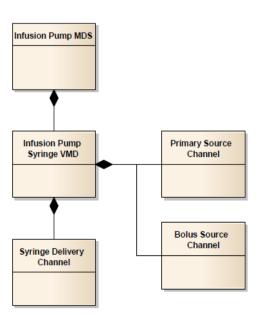# MDC Pt. Infusion DAM – Device functional and information object models
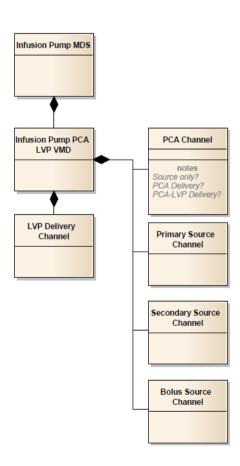
Device functional topology

Information object topology
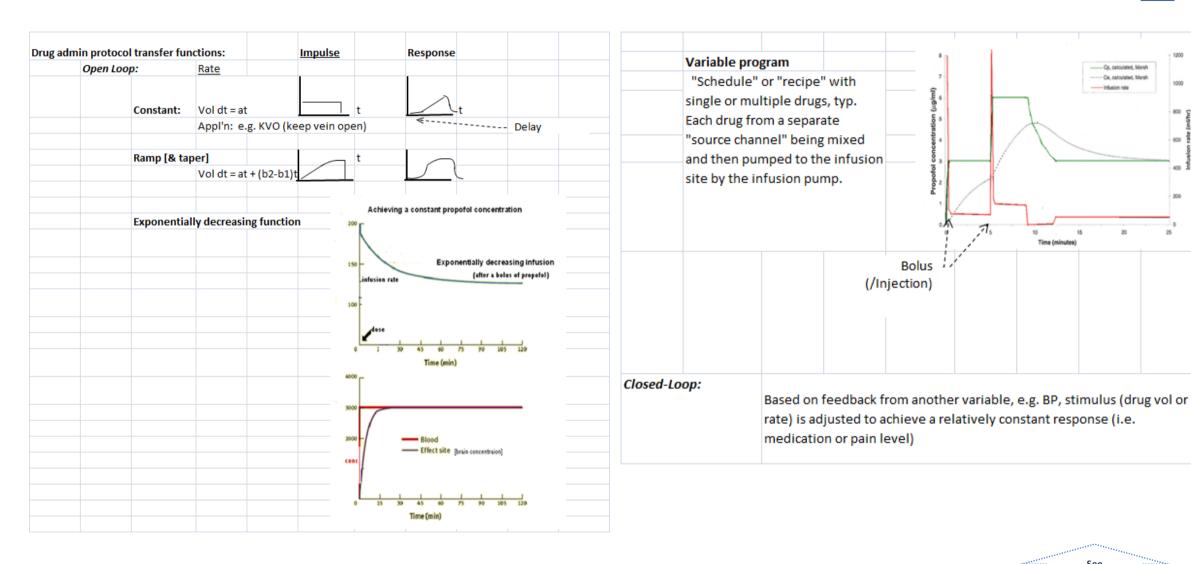LVP (left), Syringe (middle), PCA (right)

See "**DIM**" for detail.

Flow patterns represented as concurrent transfer functions.

Drug admin protocol transfer functions:

Open Loop: Rate   Impulse   Response

Constant: Vol dt = at

Appl'n: e.g. KVO (keep vein open)   — Delay

Ramp [& taper]

Vol dt = at + (b2-b1)t

Exponentially decreasing function

Achieving a constant propofol concentration

Exponentially decreasing infusion
(after a bolus of propofol)

infusion rate

dose

Time (min)

Blood
Effect site [brain concentraion]

conc

Time (min)

Variable program

"Schedule" or "recipe" with single or multiple drugs, typ. Each drug from a separate "source channel" being mixed and then pumped to the infusion site by the infusion pump.

Bolus
(/Injection)

Closed-Loop:

Based on feedback from another variable, e.g. BP, stimulus (drug vol or rate) is adjusted to achieve a relatively constant response (i.e. medication or pain level)
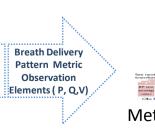
Note: This is the VENT MODE structure but could be modified to "Modal Volumetric Fluid Delivery ["Adjunct" ➔ Adaptive (/"Smart")

Detailed Clinical Model (DCM) Focus: Vent Mode

See 11073-10303-G0 Vent specialization Guide

Vent Mode Term Reference ID (semantic string)								Max # BT's	
Modal	**Volumetric**			**Breath Delivery**				**Prim.**	**+Sec.**
Mode Group	(CHOICE)			BT	_Adjunct (SEQ OF CHOICE)			Gobal Const.	@ MG&BT
MG	VC	VCvt	vt	[CHOICE]	_CND (Conditional)	_ATC	_AFC	_Other	Exp [Lo]	Insp [Hi]

Breath Delivery Pattern Metric Observation Elements (P, Q,V)

See
Health Care Device
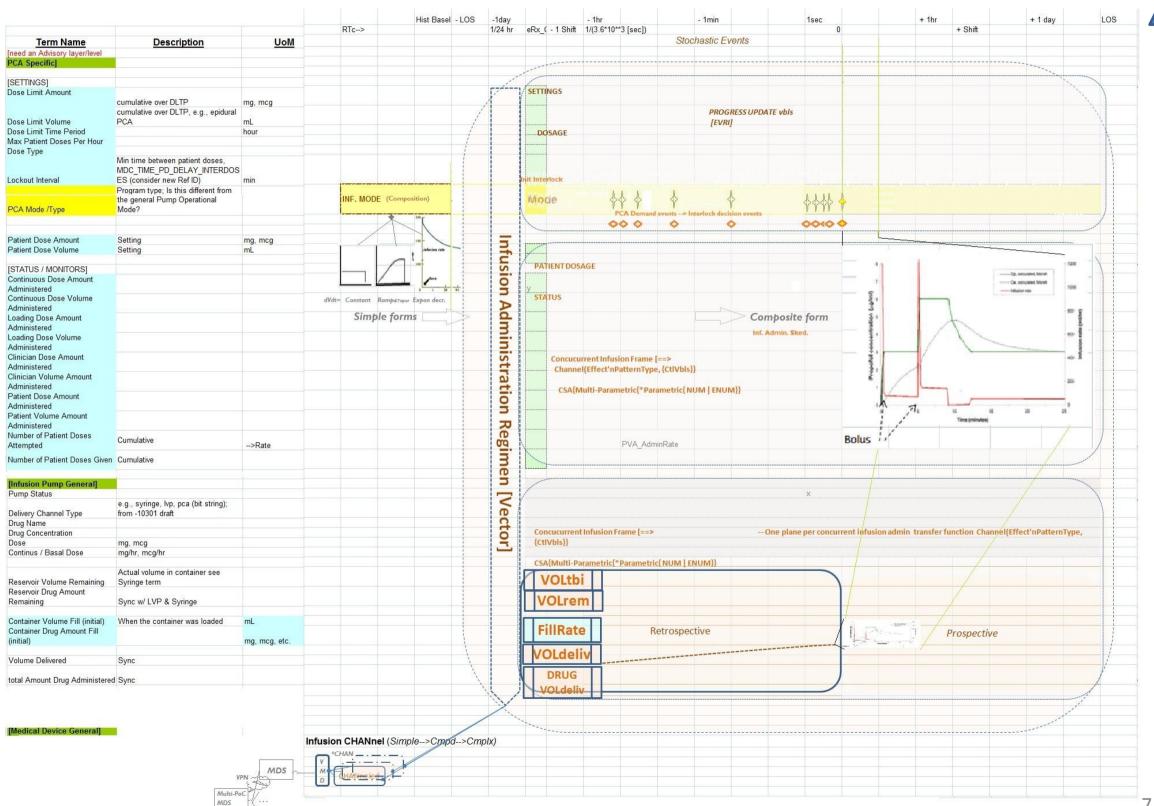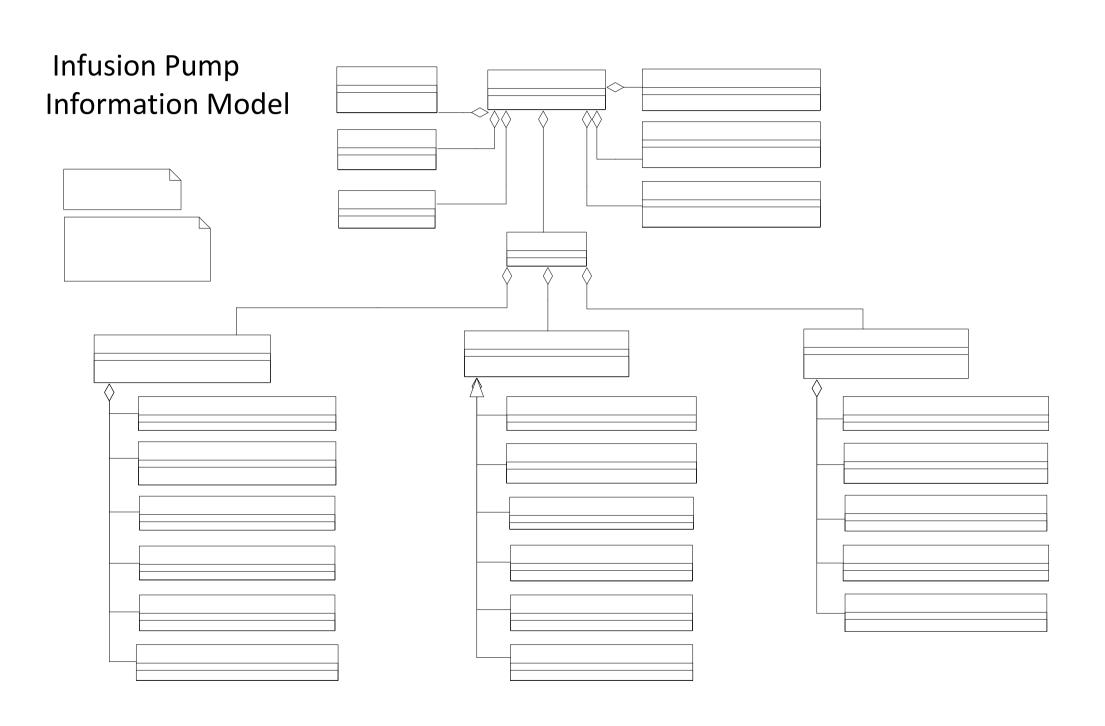Results reporting
CDA/XML Format

Metric observation value forms

MDC Pt. Infusion DAM – Behavioral model - MEF (Max. Entropy Framework)

PCA Infusion administration regimen characterized @ maximum entropy formalism (MEF).
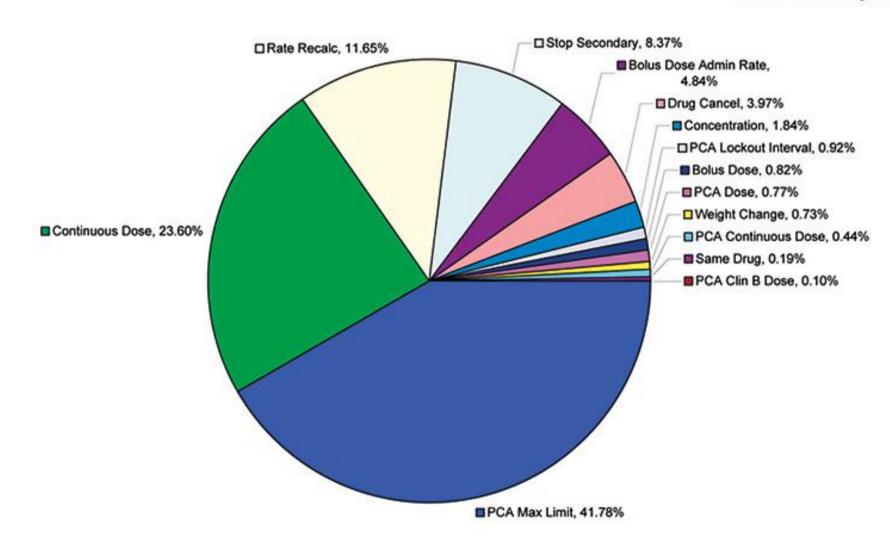
Infusion Pump
Information Model

Alert type characterization (PCA).

Guardrails® CQI Reporter
Chart 5: All Alerts by Alert Type

Rate Recalc, 11.65%
Continuous Dose, 23.60%
Stop Secondary, 8.37%
Bolus Dose Admin Rate, 4.84%
Drug Cancel, 3.97%
Concentration, 1.84%
PCA Lockout Interval, 0.92%
Bolus Dose, 0.82%
PCA Dose, 0.77%
Weight Change, 0.73%
PCA Continuous Dose, 0.44%
Same Drug, 0.19%
PCA Clin B Dose, 0.10%
PCA Max Limit, 41.78%

http://www.psqh.com/janfeb07/smartpumps.html