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

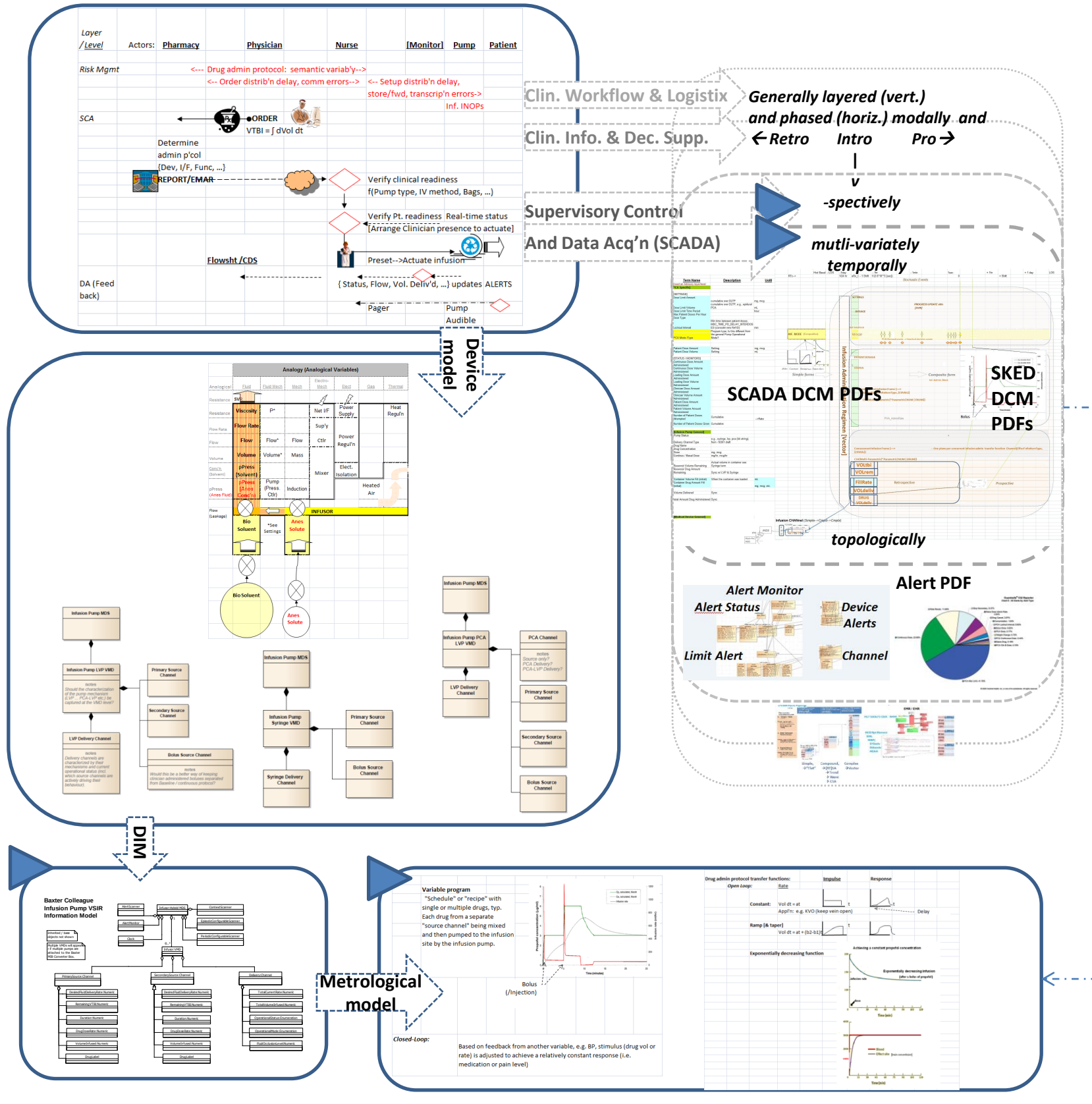
Top: **Functional model**

Bottom: **Domain Info Model (DIM)**

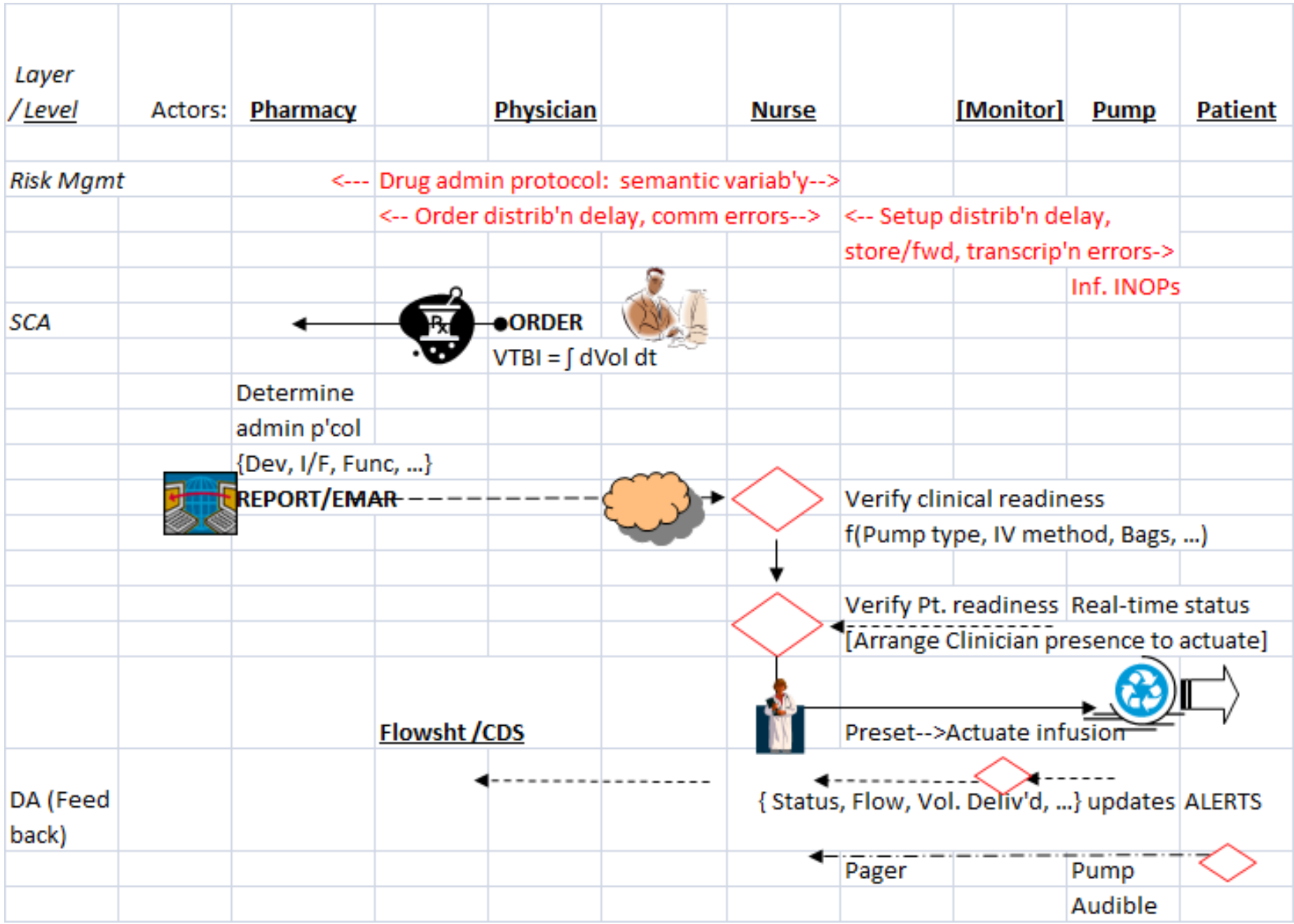
(Ctree) variations among Large Volume (LVP), Syringe, and Pt. Controlled Analgesic (PCA) Pump types .

→ **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.



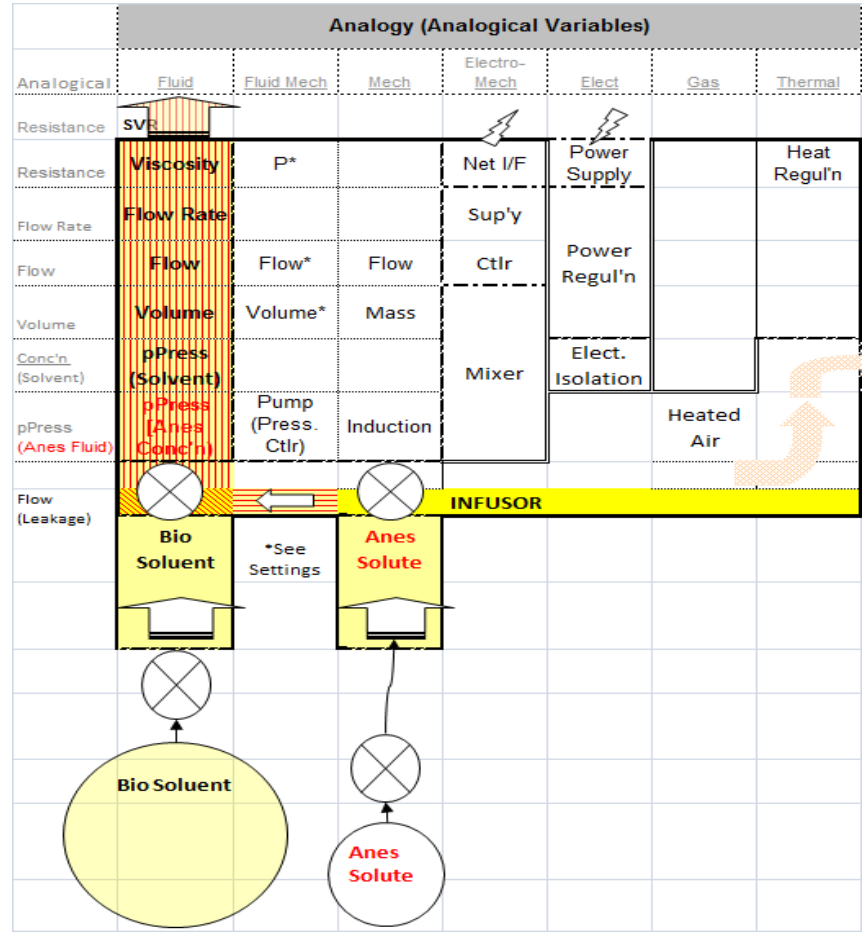
MDC Pt. Infusion DAM – Distributed, semi-automatic control topology



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

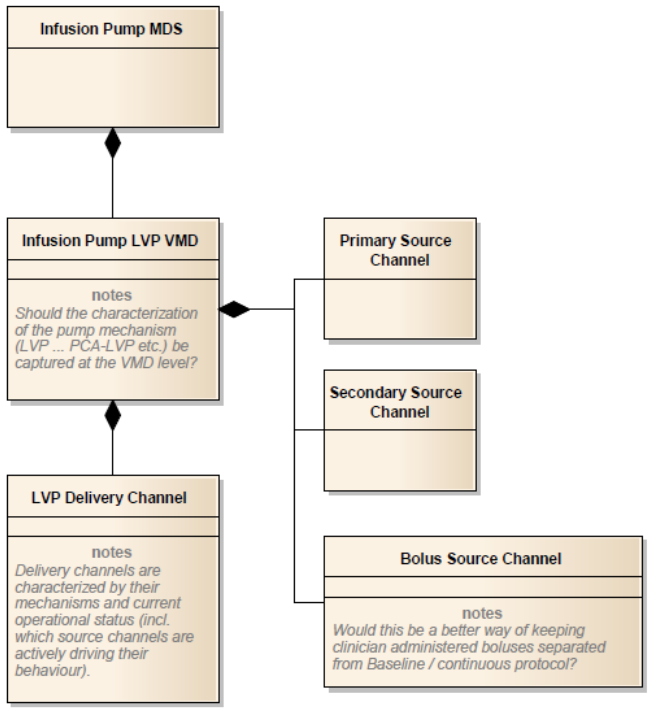
MDC Pt. Infusion DAM – Device functional and information object models

Device functional topology

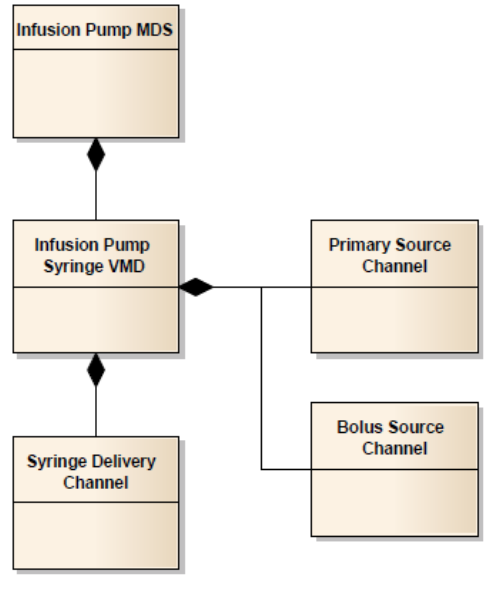


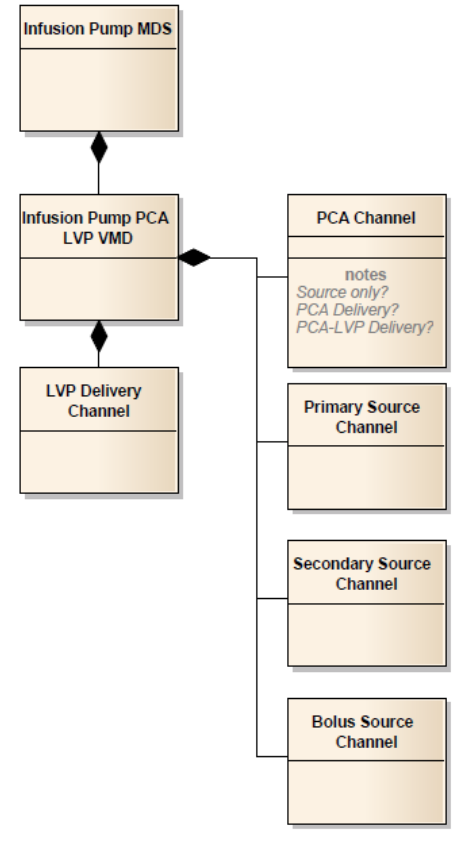
Information object topology

LVP (left), Syringe (middle), PCA (right)



See "**DIM**" for detail.

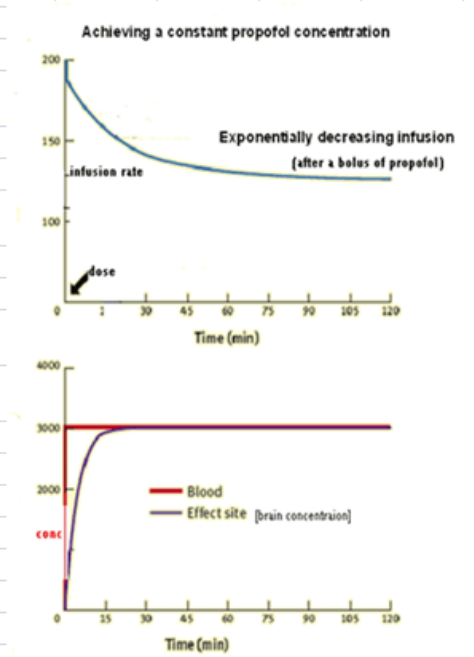




MDC Pt. Infusion DAM – Metrological Model

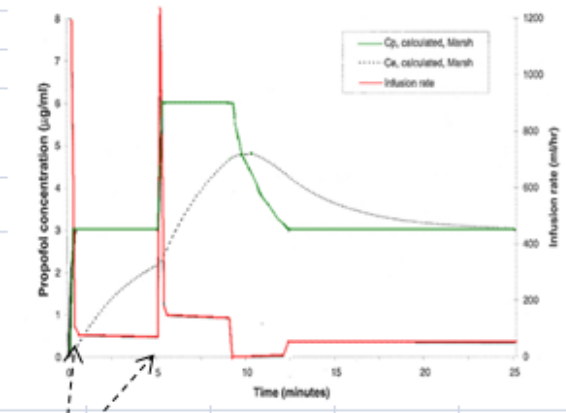
Flow patterns represented as concurrent transfer functions.

Drug admin protocol transfer functions:		Impulse	Response
Open Loop:	Rate		
Constant:	Vol dt = at	t	t
	Appl'n: e.g. KVO (keep vein open)		Delay
Ramp [& taper]	Vol dt = at + (b2-b1)t	t	
Exponentially decreasing function			



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")

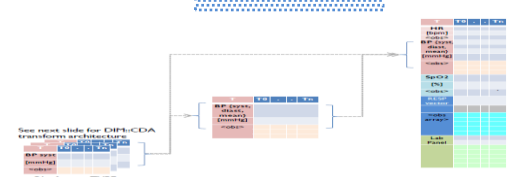
Detailed Clinical Model (DCM) Focus: Vent Mode

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 MG	(CHOICE)			BT	_Adjunct (SEQ OF CHOICE)			Gobal Const.	@ MG&BT
	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

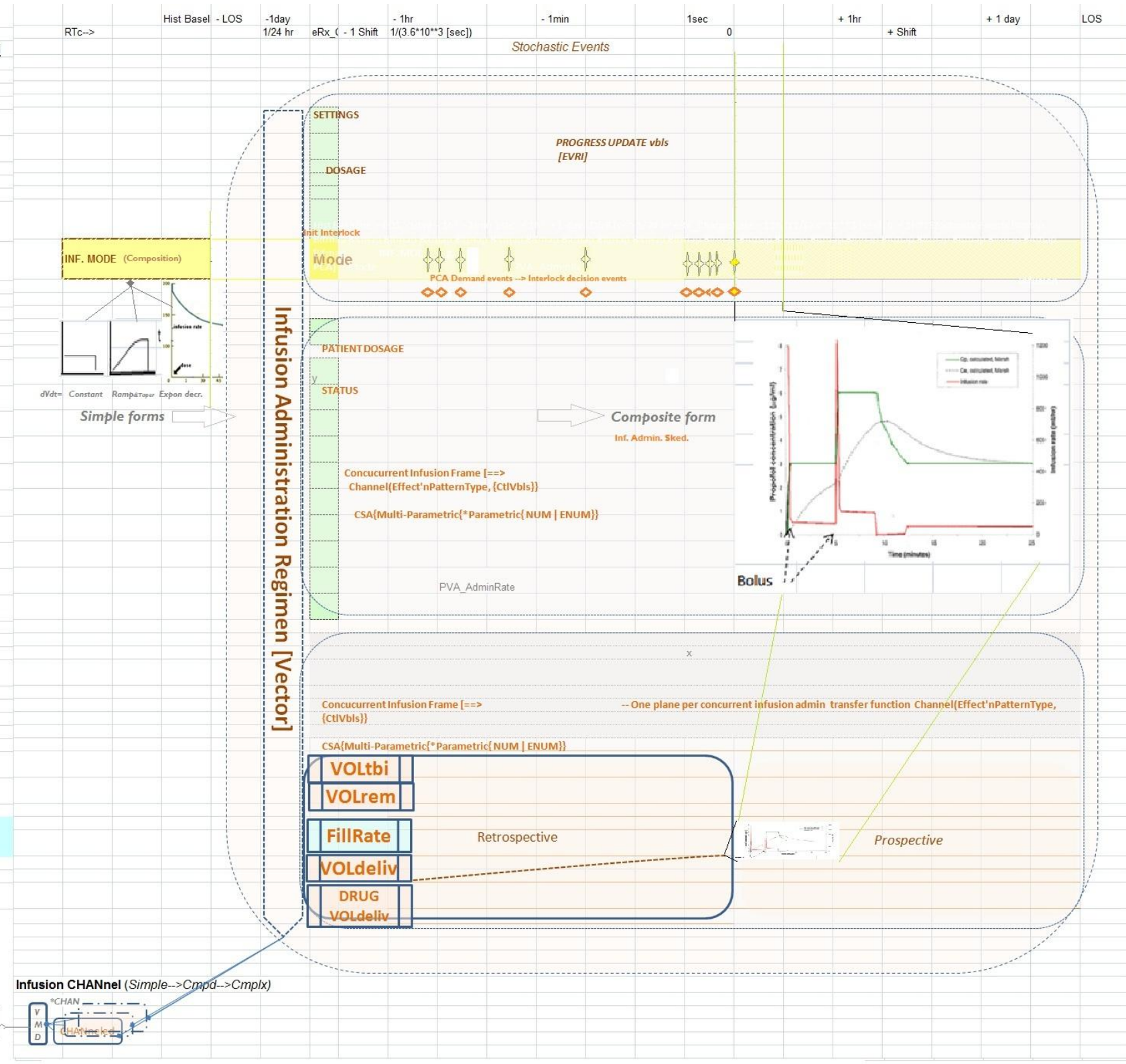


Metric observation value forms

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

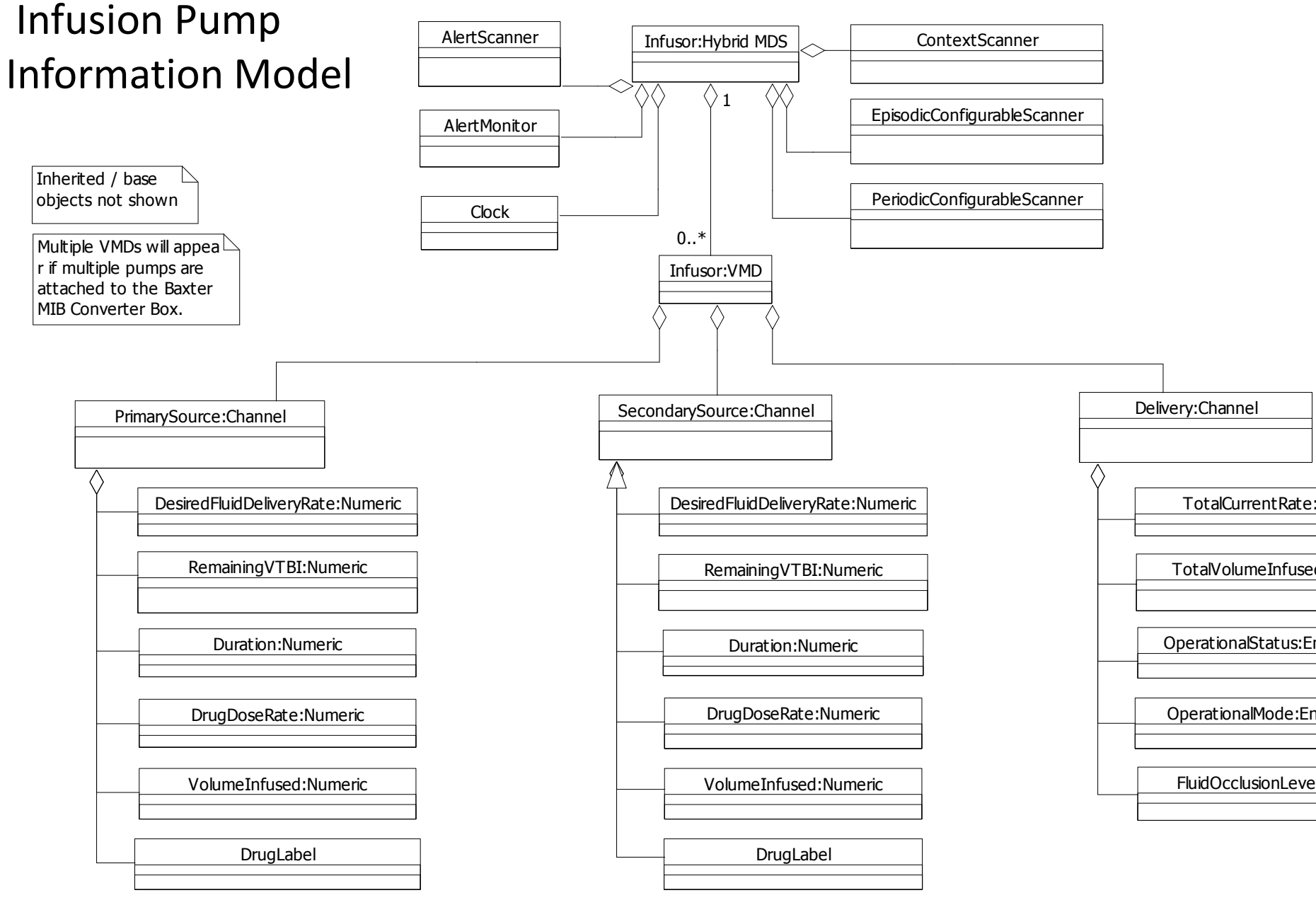
PCA Infusion administration regimen characterized @ maximum entropy formalism (MEF).

Term Name	Description	UoM
[need an Advisory layer/level		
PCA Specific]		
[SETTINGS]		
Dose Limit Amount	cumulative over DLTP	mg, mcg
Dose Limit Volume	cumulative over DLTP, e.g., epidural PCA	mL
Dose Limit Time Period		hour
Max Patient Doses Per Hour		
Dose Type		
Lockout Interval	Min time between patient doses, MDC_TIME_PD_DELAY_INTERDOSES (consider new Ref ID)	min
PCA Mode /Type	Program type; Is this different from the general Pump Operational Mode?	
Patient Dose Amount	Setting	mg, mcg
Patient Dose Volume	Setting	mL
[STATUS / MONITORS]		
Continuous Dose Amount Administered		
Continuous Dose Volume Administered		
Loading Dose Amount Administered		
Loading Dose Volume Administered		
Clinician Dose Amount Administered		
Clinician Volume Amount Administered		
Patient Dose Amount Administered		
Patient Volume Amount Administered		
Number of Patient Doses Attempted	Cumulative	-->Rate
Number of Patient Doses Given	Cumulative	
[Infusion Pump General]		
Pump Status		
Delivery Channel Type	e.g., syringe, lvp, pca (bit string); from -10301 draft	
Drug Name		
Drug Concentration		
Dose	mg, mcg	
Continus / Basal Dose	mg/hr, mcg/hr	
Reservoir Volume Remaining	Actual volume in container see Syringe term	
Reservoir Drug Amount Remaining	Sync w/ LVP & Syringe	
Container Volume Fill (initial)	When the container was loaded	mL
Container Drug Amount Fill (initial)		mg, mcg, etc.
Volume Delivered	Sync	
total Amount Drug Administered	Sync	
[Medical Device General]		

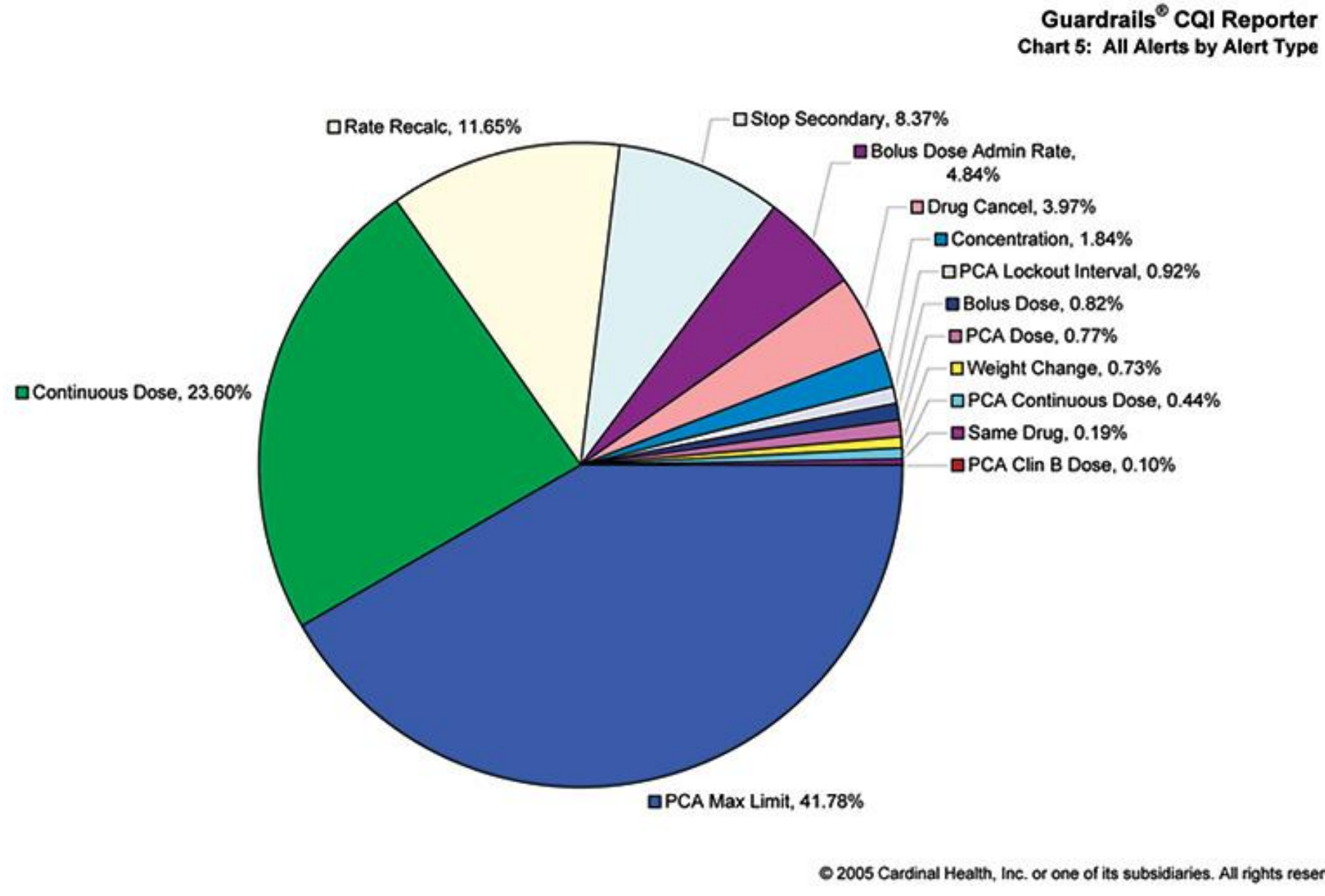


MDC Pt. Infusion DAM – Domain Information Model (LVP context)

Infusion Pump Information Model



Alert type characterization (PCA).



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