

Requirements on the Physical Side of Cyber-Physical Systems

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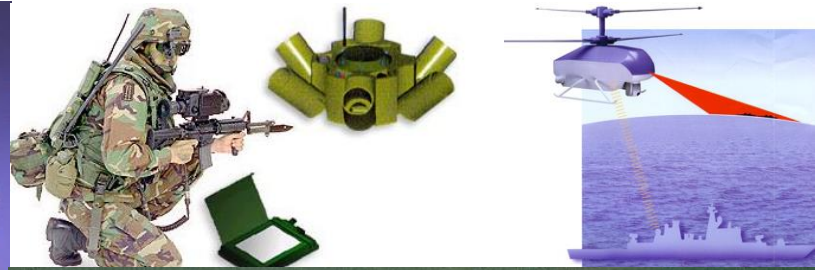
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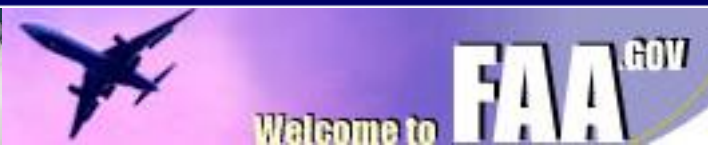
Software Engineering Center

Critical Systems

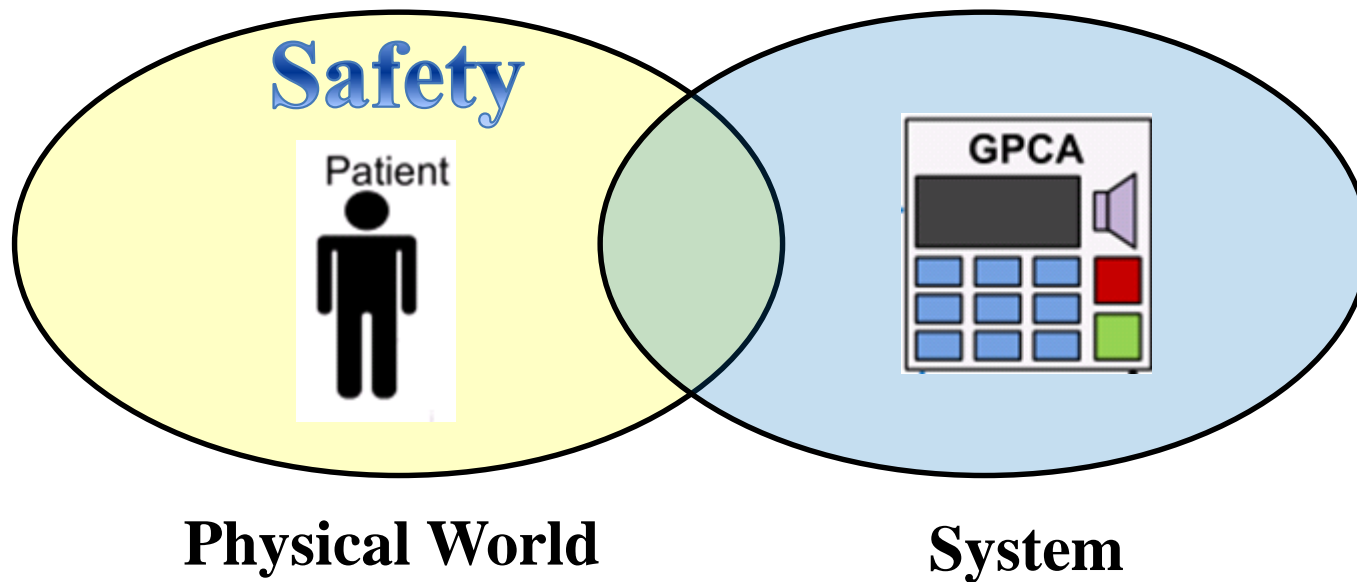


FDA

U.S. Food and Drug Administration

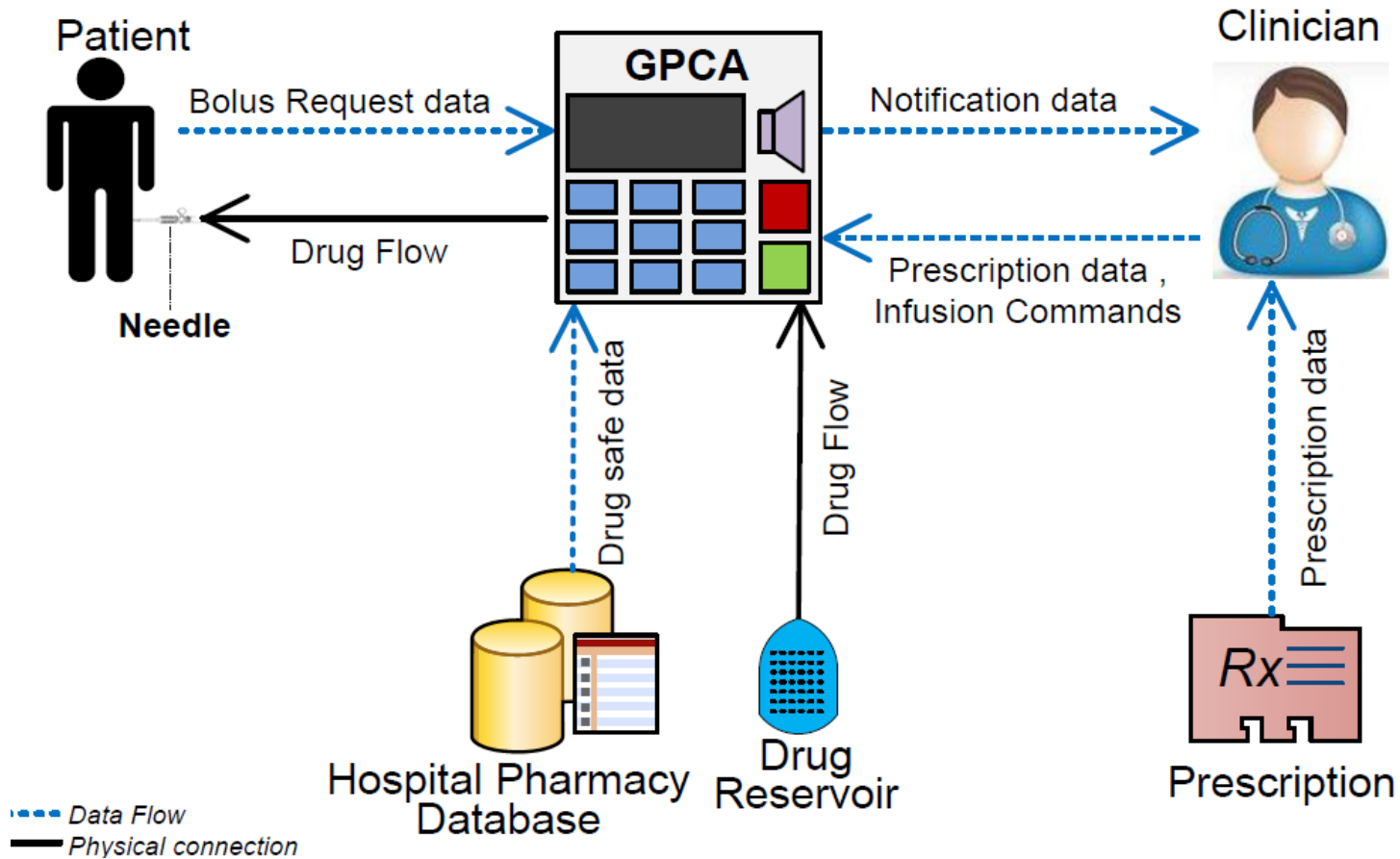


Assurance

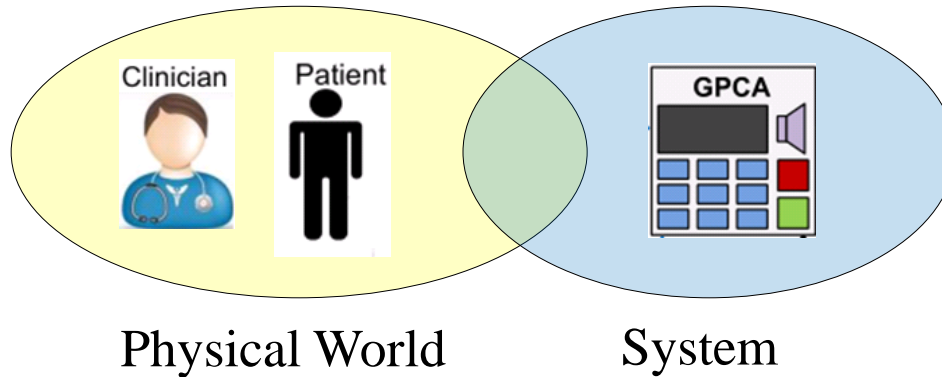


Patient Controlled Analgesia Pump

Hospital



Argument for No Under-Infusion(1)



No Under-
Infusion

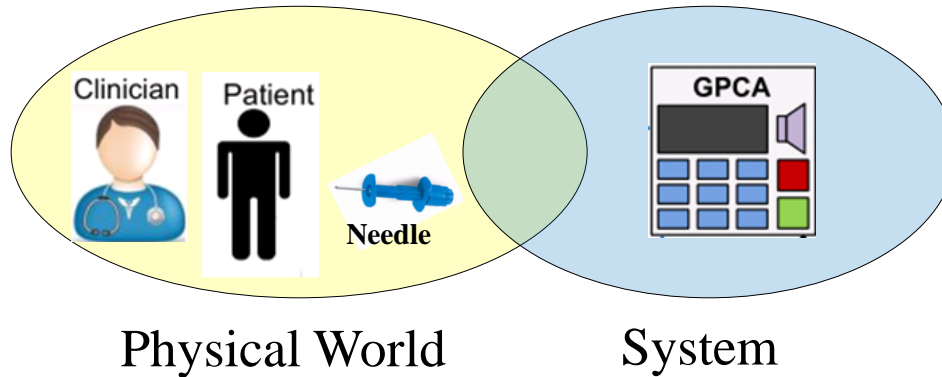
because

Device always delivers the drug **through the needle** at the programmed rate $\pm 5\%$.

Given

The clinician connects the device to the patient as per instructions and enters the prescribed rate accurately.

Argument for No Under-Infusion(2)



Device always delivers the drug **through the hose** at the programmed rate $\pm 5\%$.

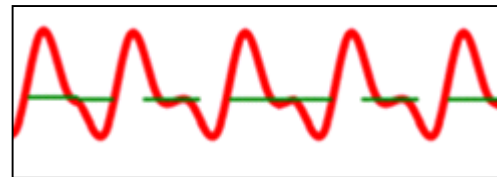
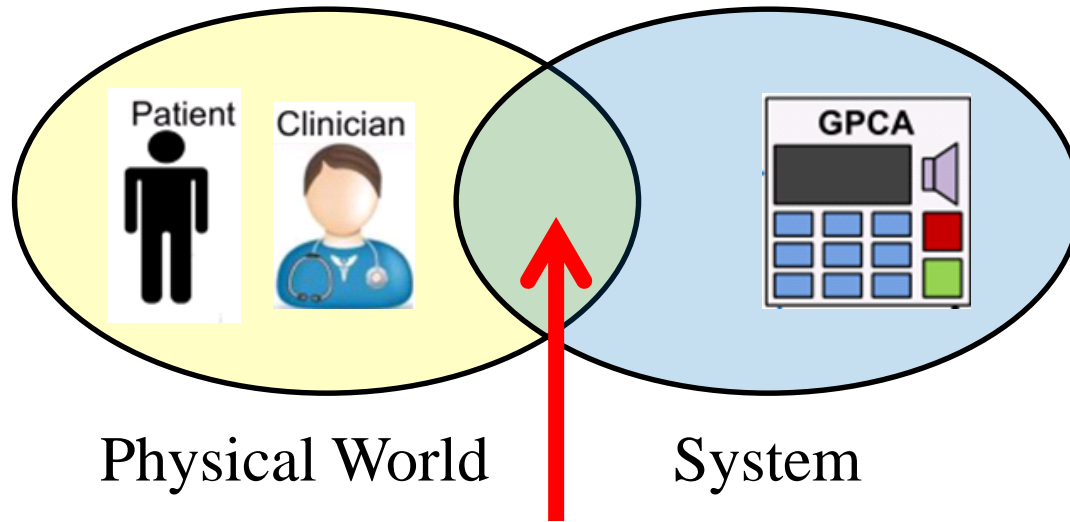
No Under-Infusion

because

Given

The clinician **connects the hose to the needle** as per instructions, clinician ensures that needle is inserted appropriately into the patient and enters the prescribed rate accurately.

Continuous Quantities



Flow rate of drug

Three Immediate Challenges

- Appropriately “scoping” the requirements
 - Where is the system boundary?
- Writing requirements over the continuous and continual nature of (most) critical systems
 - How much do we need to capture?
- Providing the trace-links needed for assurance
 - What links and how many are needed?

Challenge 1 : System Scope

“Patient-requested bolus shall not be delivered more often than a prescribed number of minutes...”

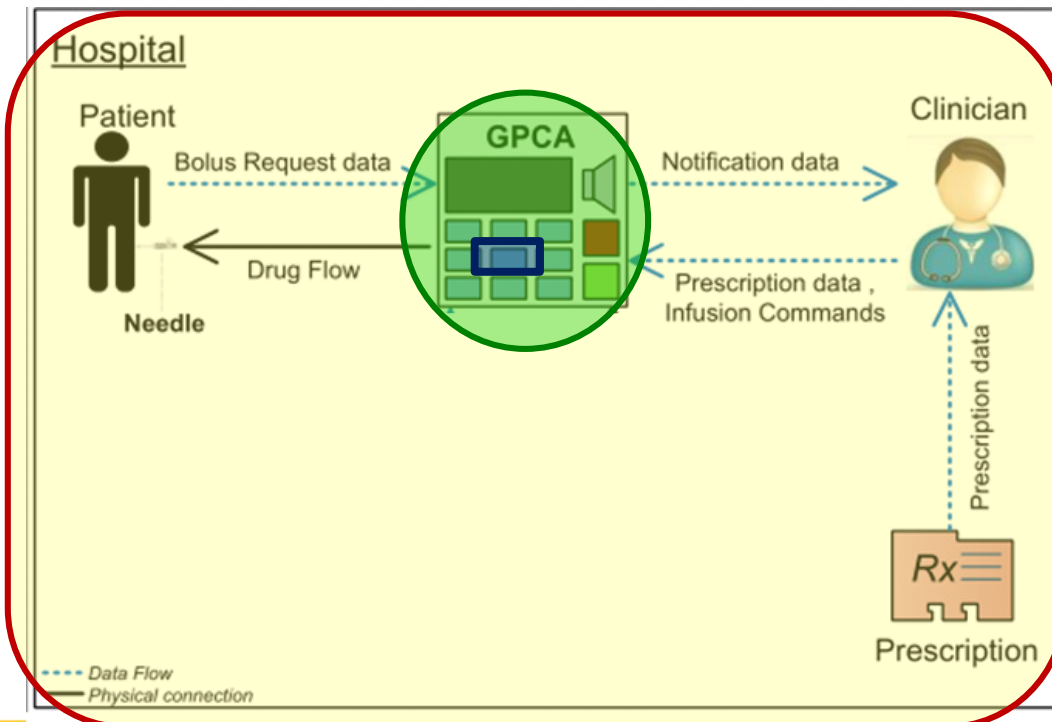
“An upstream occlusion alarm shall be triggered if the system senses an upstream occlusion.”

“When the option to suspend the pump is selected, the current pump stroke shall be completed prior to suspending the pump.”

“Scoping” Requirements

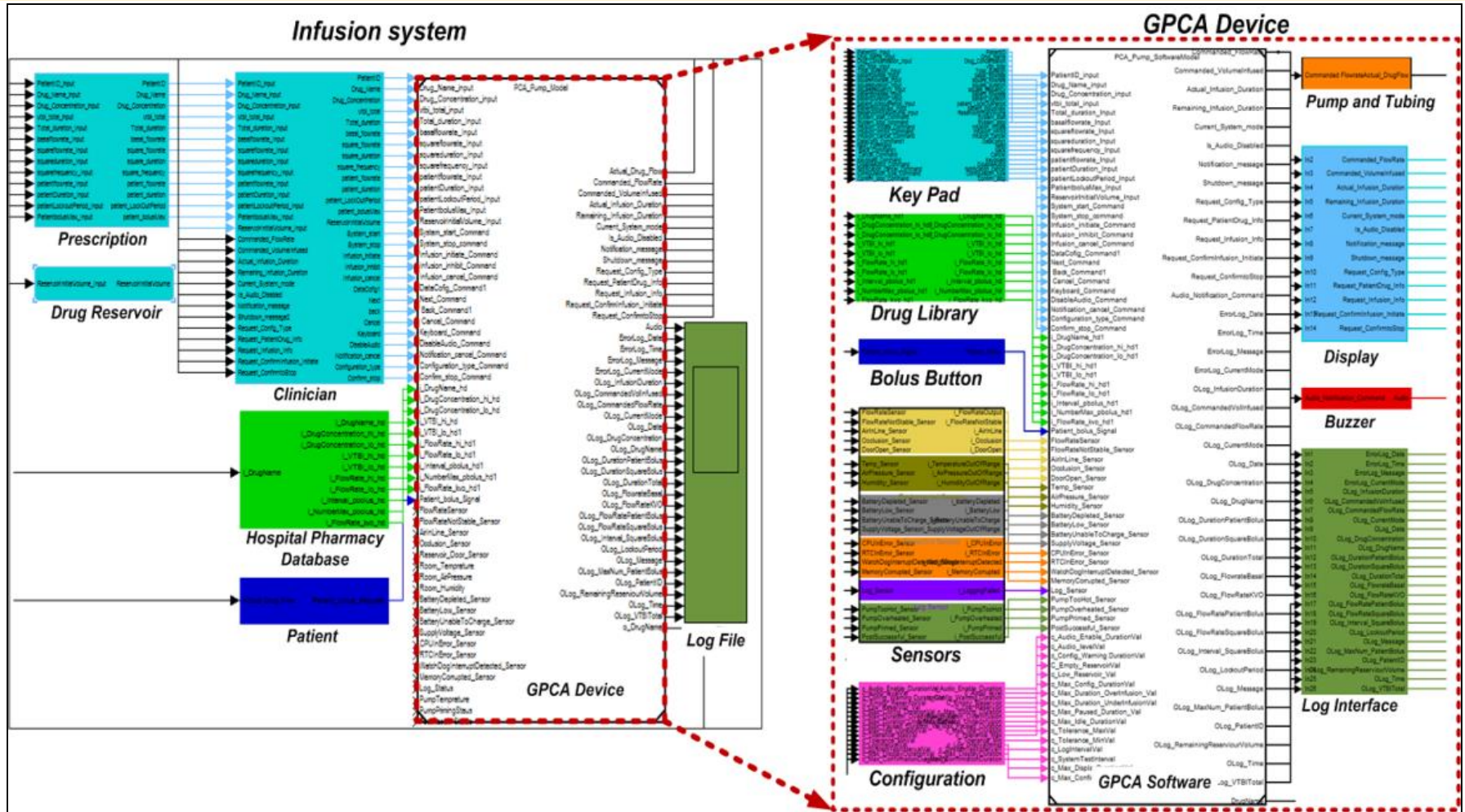
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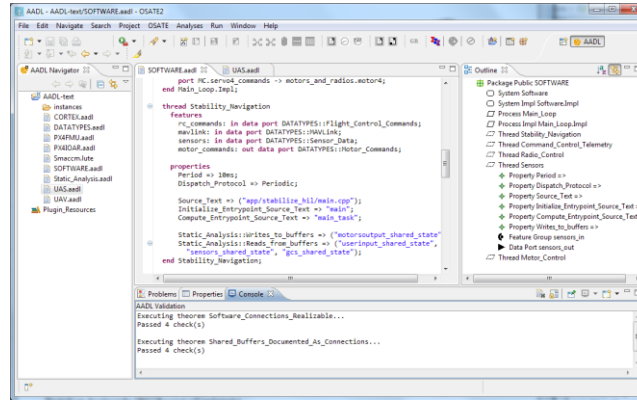
Aid—Architectural Modes



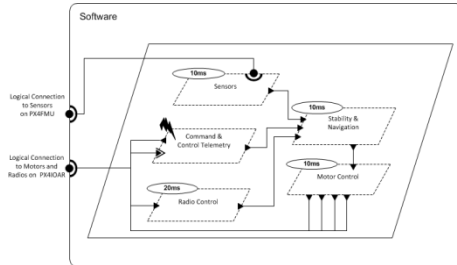
Common Tools: Formal Methods Workbench

OSATE

Trusted
Build



Architecture Models



Architecture Translation



seL4
eChronos

Resolute

Assurance Case

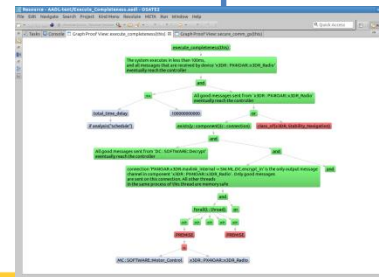
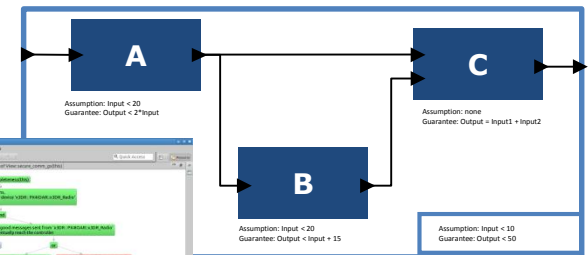
AGREE

Behavioral Analysis

Sute

Structural
Analysis

Architecture Analysis



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Challenge 2: The Physical Side



Typical Requirements

“When the driver requests the cruise control to resume, the cruise control shall be engaged and bring the vehicle’s speed to the target speed.”

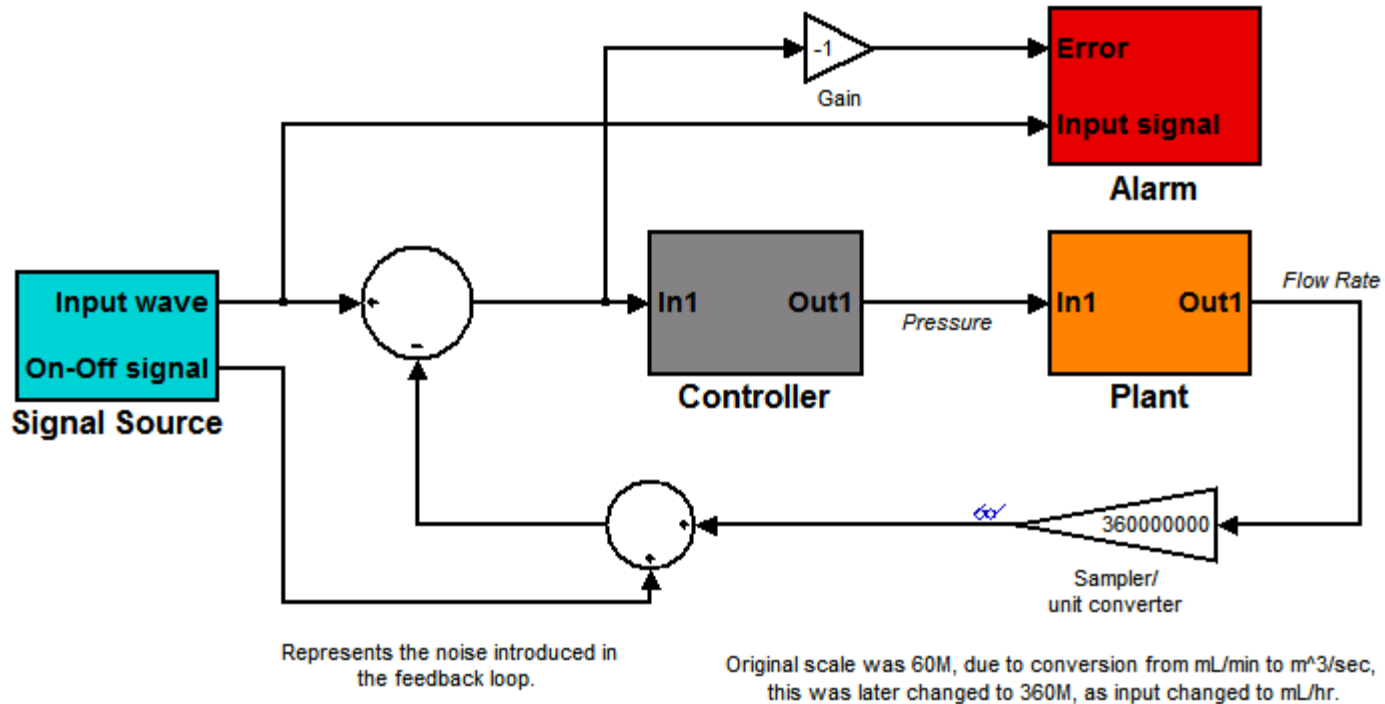
“A patient bolus dose shall be given when requested by the patient.”

More Typical Requirements

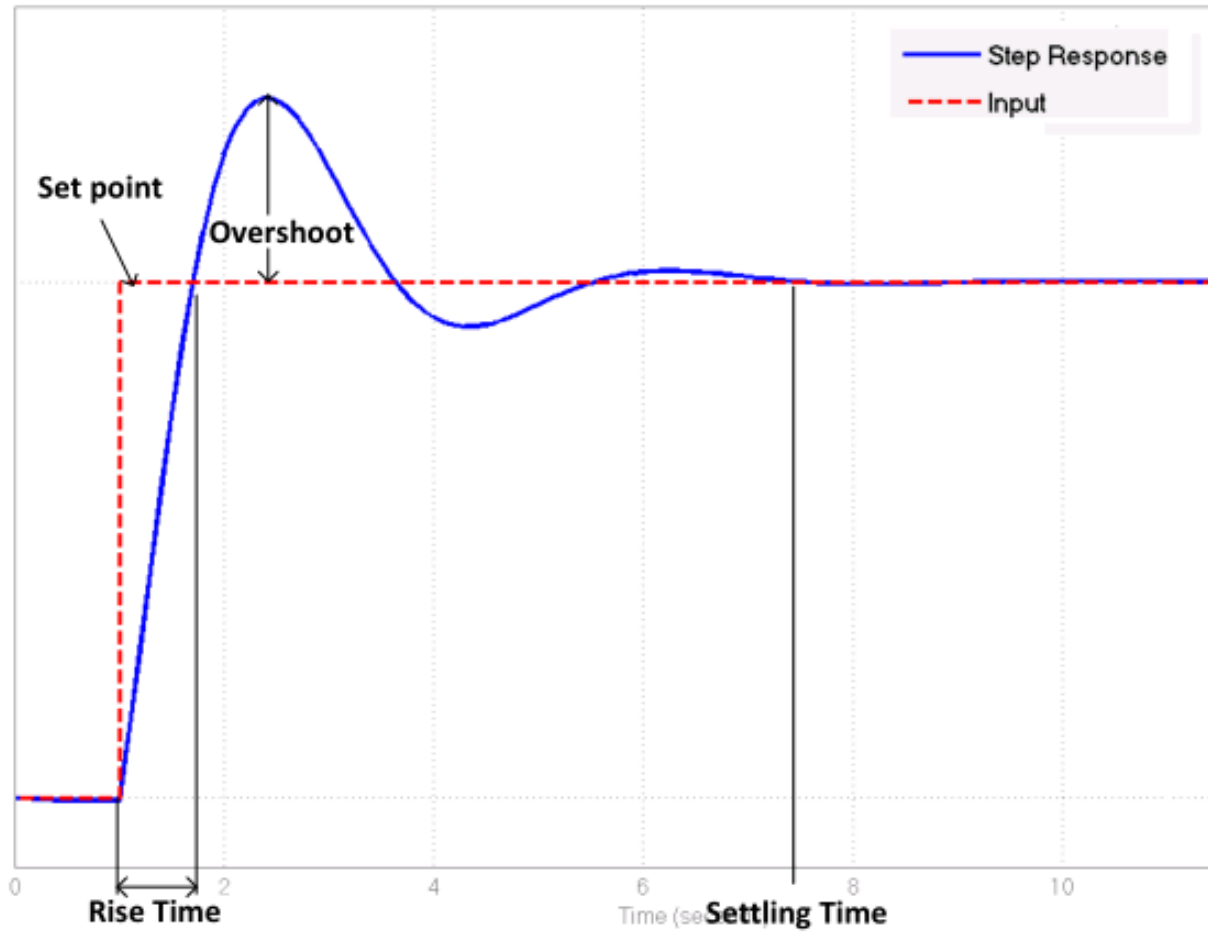
“The actual speed of the vehicle must be within $\pm 5\%$ of the target speed.”

“The actual flow-rate must be within $\pm 5\%$ of the target flow-rate.”

Aid—System Models



Step Response



Initial Classification

- Accuracy
- Rise Time and Drop Time
- Rate of Change
- Overshoot (maximum deviation)
- Settling Time
- Cumulative Error

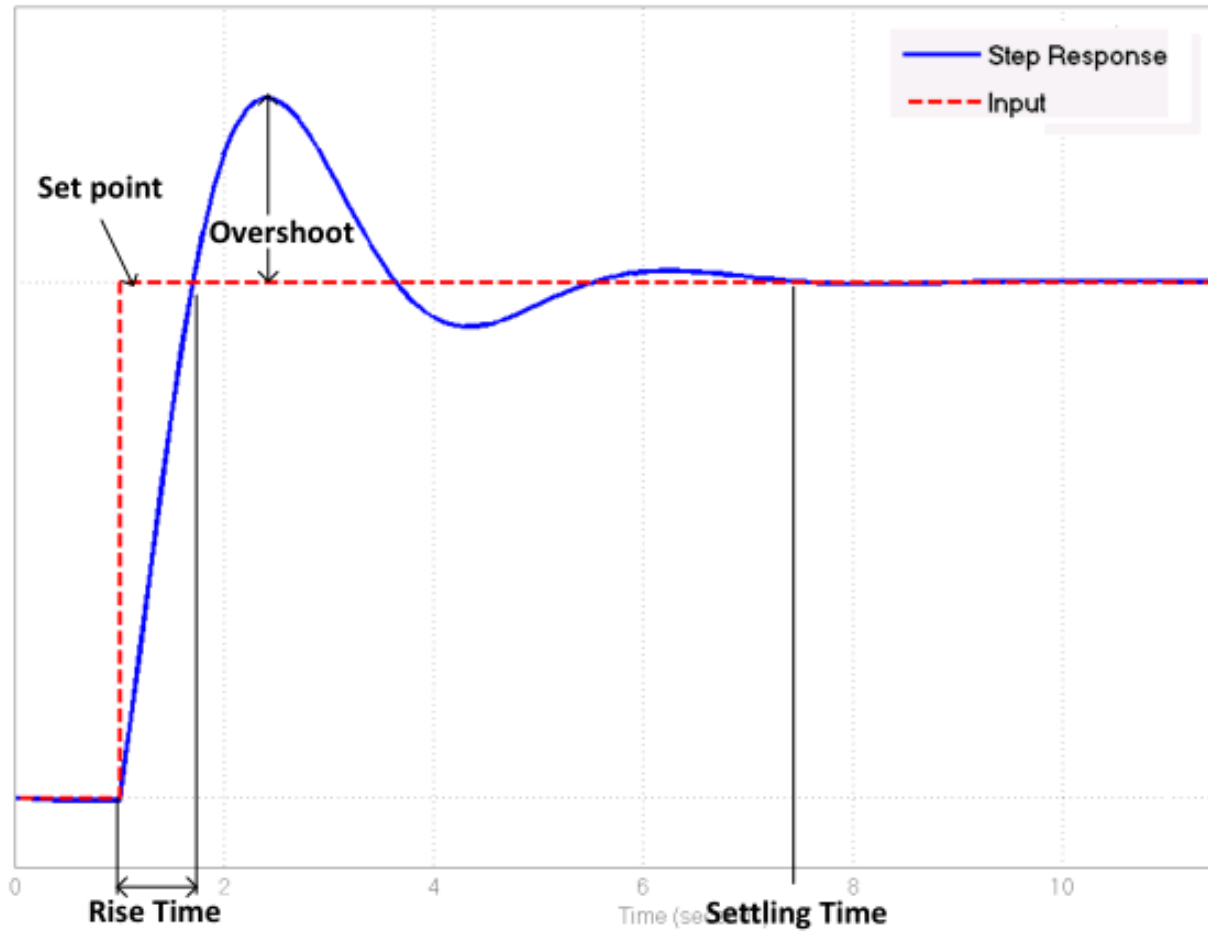
Accuracy

*“The actual flow-rate (f) during normal operation shall be within $\pm 5\%$ of the target flow-rate (tfr):
 $0.95 \cdot tfr \leq f \leq 1.05 \cdot tfr$.”*

Rise Time

“The duration between the time at which a new target flow-rate (tfr) is commanded and the time at which the actual flow-rate (f) reaches within $\pm 5\%$ of the target flow rate shall be less than 1.0 s.”

Step Response



Rate of Change

“The rate of change in the actual flow-rate (f) shall not exceed 0.5 ml/s^2 : $\dot{f} \leq 0.5 \text{ ml/s}^2$.”

Overshoot

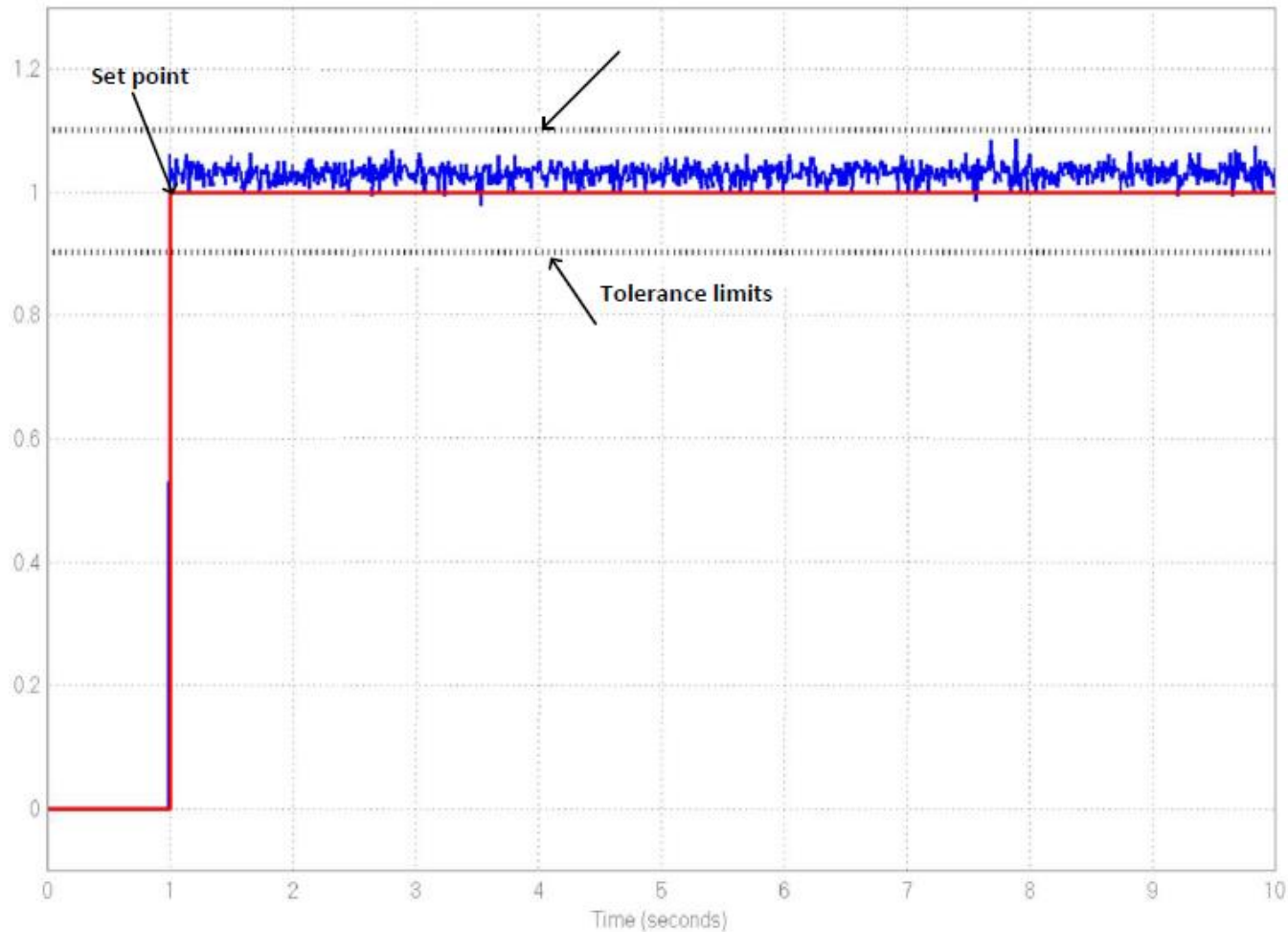
“The actual flow-rate (f) shall never exceed 10% of the target flow-rate (tfr): $f \leq tfr + 10\%$.”

“The actual flow-rate (f) shall never exceed 10 ml/h: $f \leq 10 \text{ ml/h}$.”

Settling Time

“The time between when a new target flow-rate (tfr) is commanded and the time the actual flow rate (f) settles shall be less than 1.2 s.”

Cumulative Error



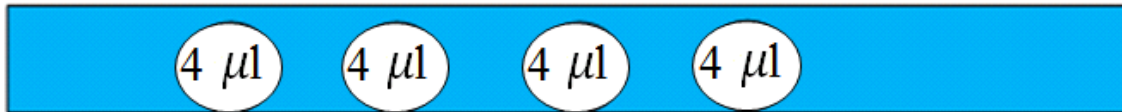
Cumulative Error

“The actual volume infused over a time interval of δ cannot exceed the commanded volume to be infused by more than 0.1 ml:

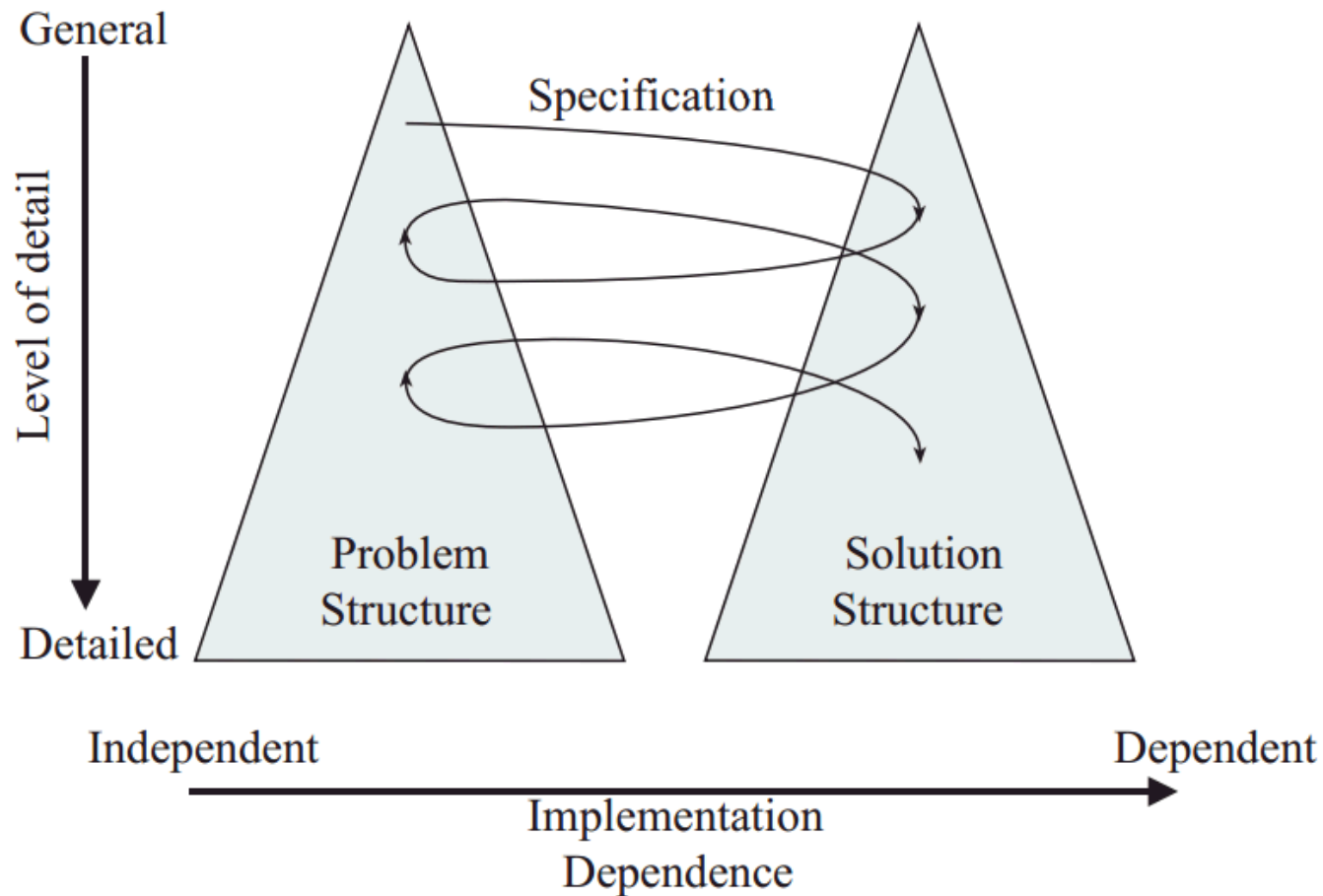
$$\int_t^{t+\delta} f dt \leq \int_t^{t+\delta} tfr dt + 0.1 \text{ ml.}”$$

Cumulative Error

“An **air-in-line alarm** shall be triggered if **air bubbles larger than $5\ \mu\text{l}$** are passing through the delivery hose.”



“Twin Peaks” Model by Bashar Nuseibeh



Summary

- Well defined component boundaries essential
 - Good requirements
 - Compositional assurance
- Bring control concerns to the requirements domain
 - Codify “good enough”
- How much is really needed?
- How to define and constrain acceptable mode-switching behavior?



Thank You



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Discussion

