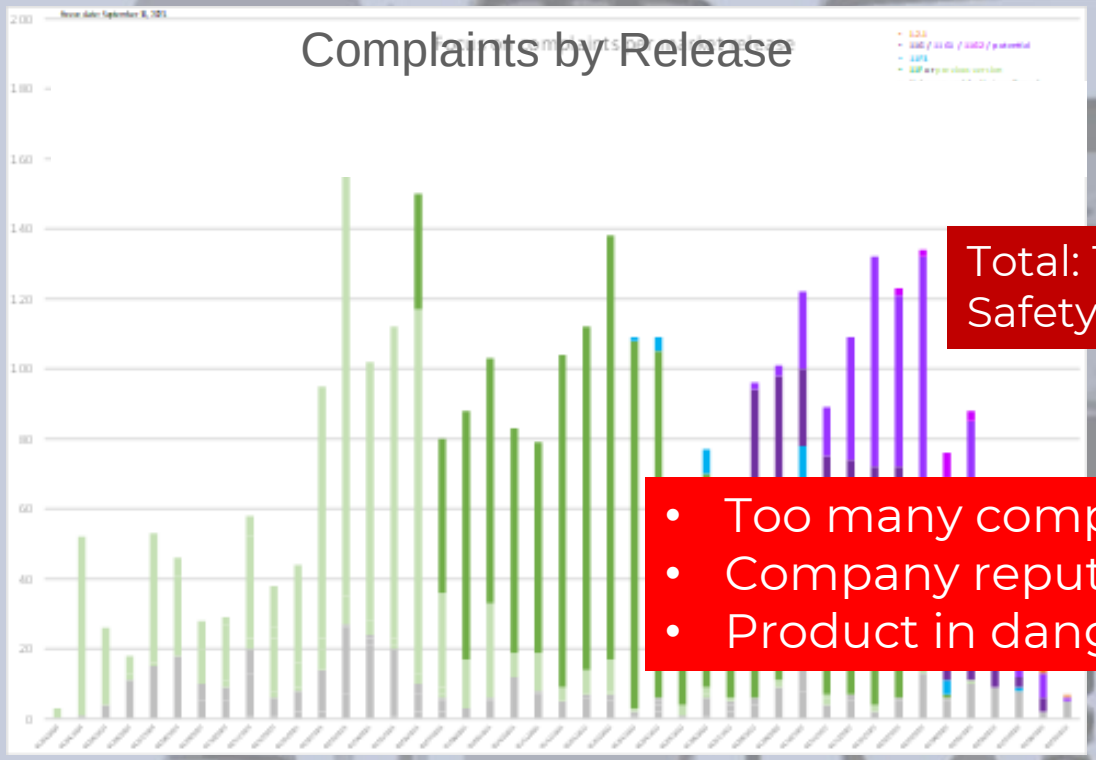
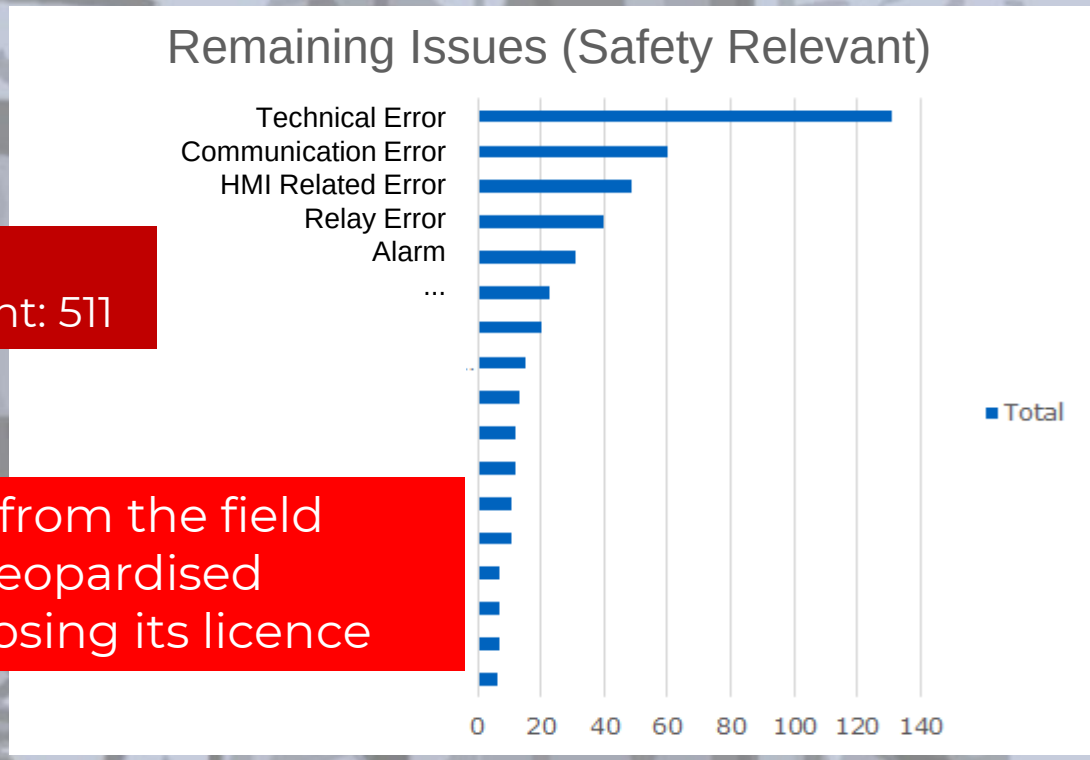
A STORY EXPERIENCED
Effective Requirements Elicitation

For an existing Infusion Pump Alarm System

European Market Leader IV-Pumps



Total: 1428
Safety Relevant: 511



- Too many complaints from the field
- Company reputation jeopardised
- Product in danger of losing its licence

→ Customer REQs Review
→ Architecture Review

Systematic REQs Elicitation

Some Definitions

- *Requirements Elicitation* is the practice of researching and discovering the Requirements of a System from users, customers, and other stakeholders.

  [Ramos and Kurts, 1997]

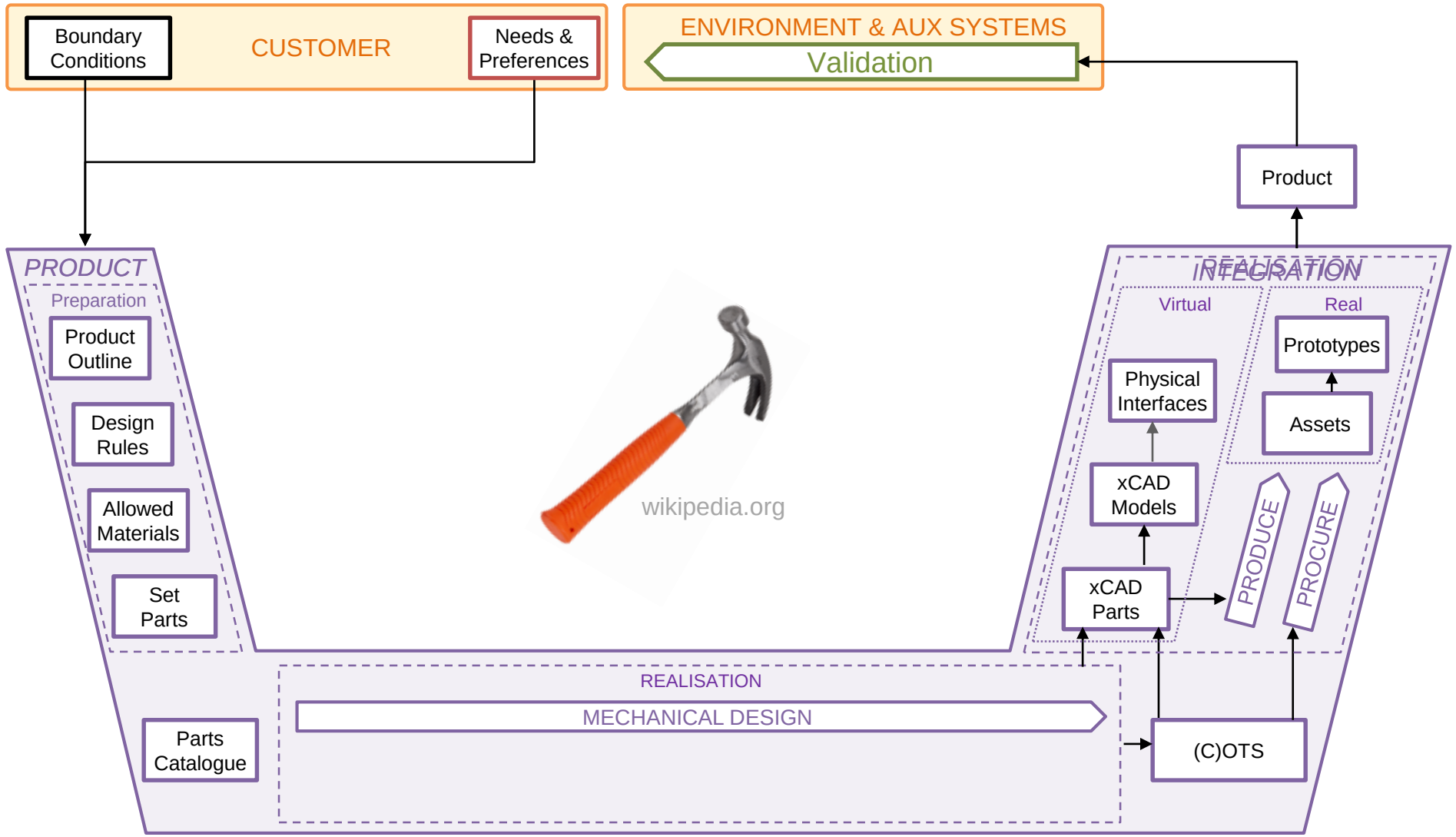
- *Requirement Elicitation* goes beyond simply collecting information - it involves collaboration, communication, and critical thinking. Techniques such as interviews, workshops, surveys, and observation are used to extract both explicit and implicit requirements.

  [theknowledgeacademy, 2025]

- ***Effective REQs Elicitation*** employs *Systems Thinking (Systematic and Systemic)* to aid perspective analysis and to define a logical process and structure in which to record and maintain the information and relationships elicited.

Product Development

Realising a simple product …

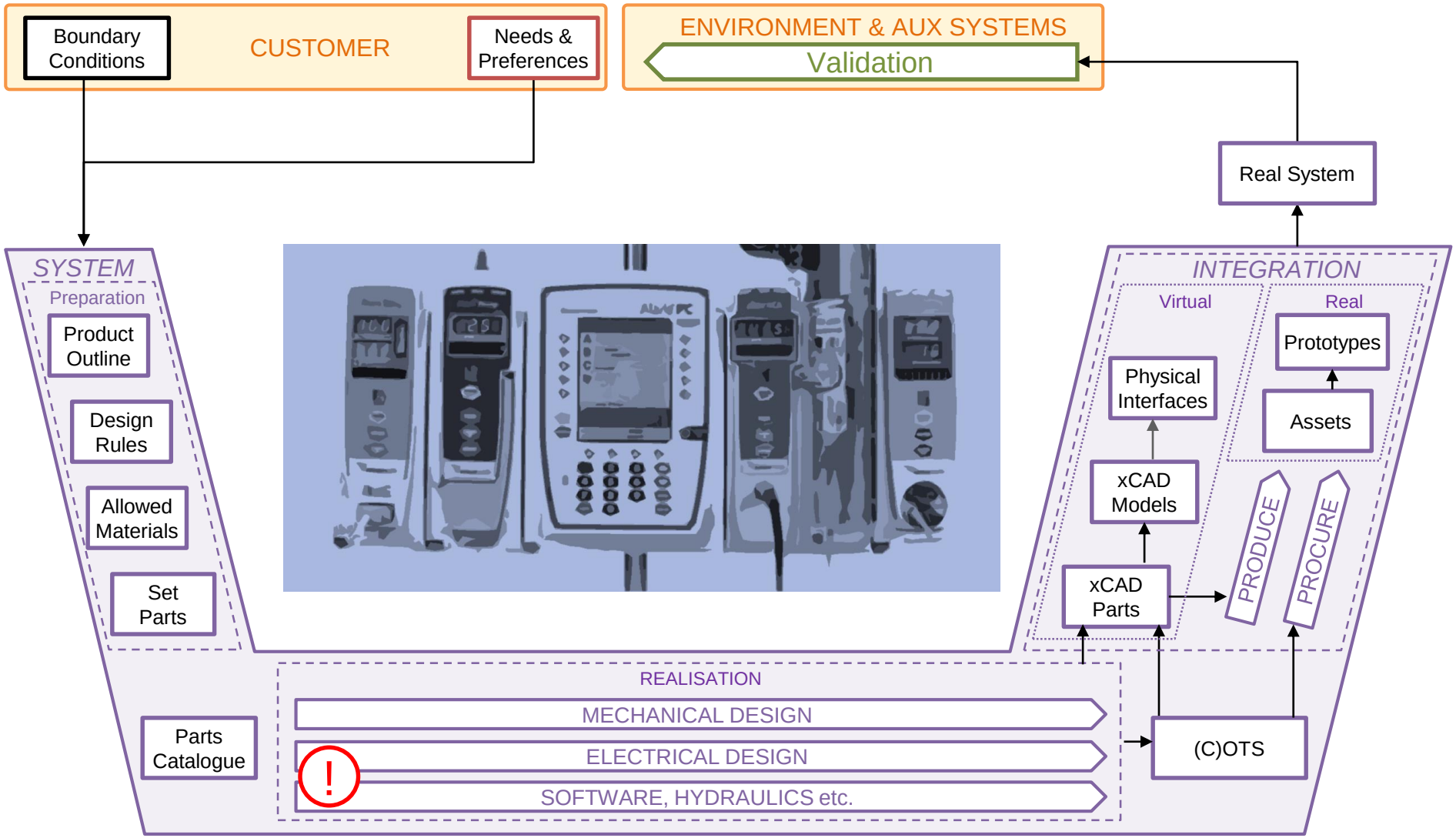


[Mechanical] Product:

- Has a Physical Architecture
- Respects all Constraints
- Yields all (visible) Physical IF

Product vs System

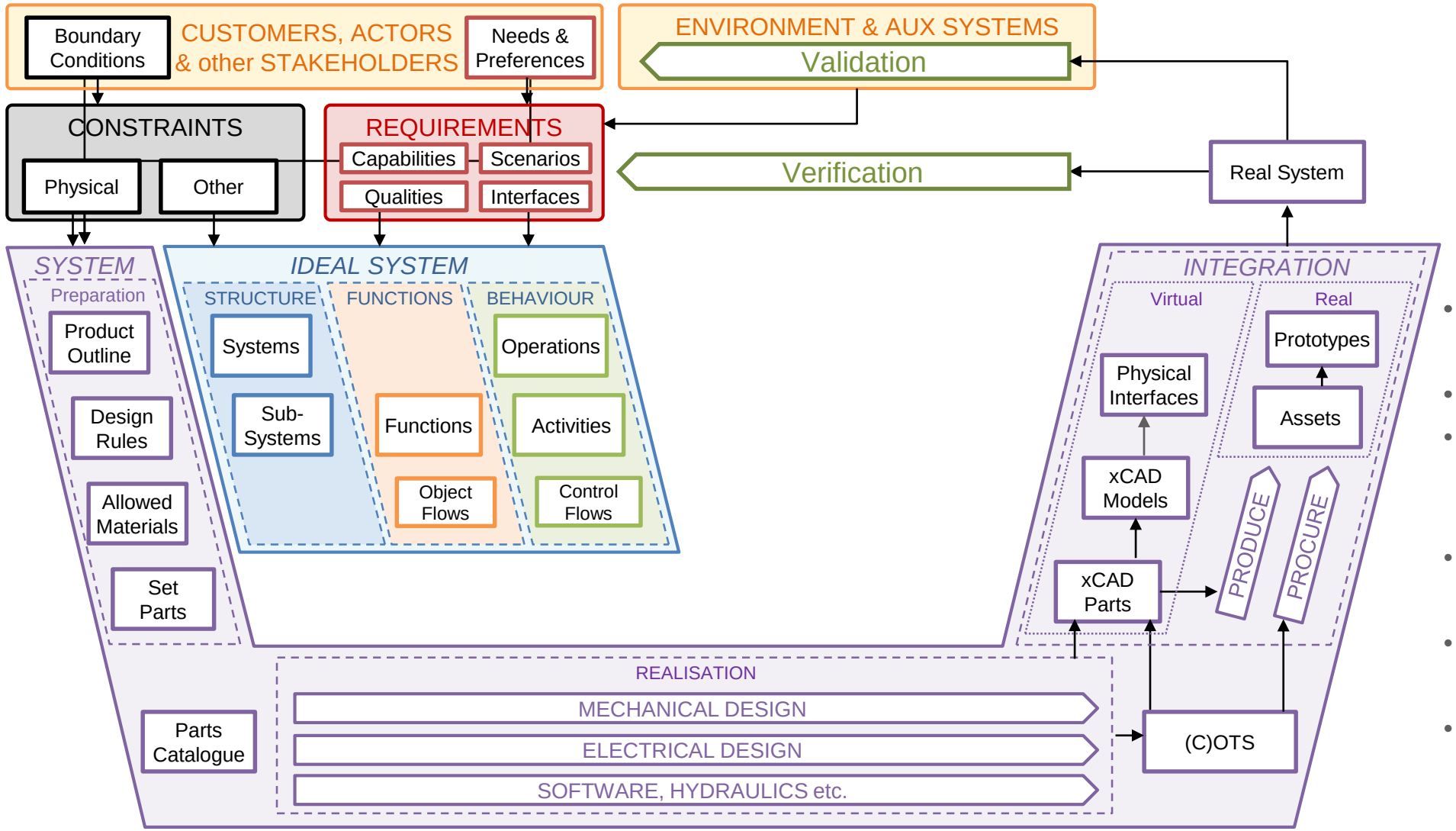
… and if it's not that simple?



Key Points

1. There is a fundamental difference between the hammer (simple product) and an IV Pump (system)!
2. The *challenge* developing safe, reliable and sustainable IV Pumps requires Systems Engineering & Architecting
3. The challenge's complexity must not penetrate the SOI boundary to allow for an elegant solution.
4. This requires a systematic and effective Requirements Elicitation process!

System Development



Ideal vs Real System

- Strict Separation of Ideal and physical System Perspectives
- All Modelled as Architectures
- Requires Structured Input!

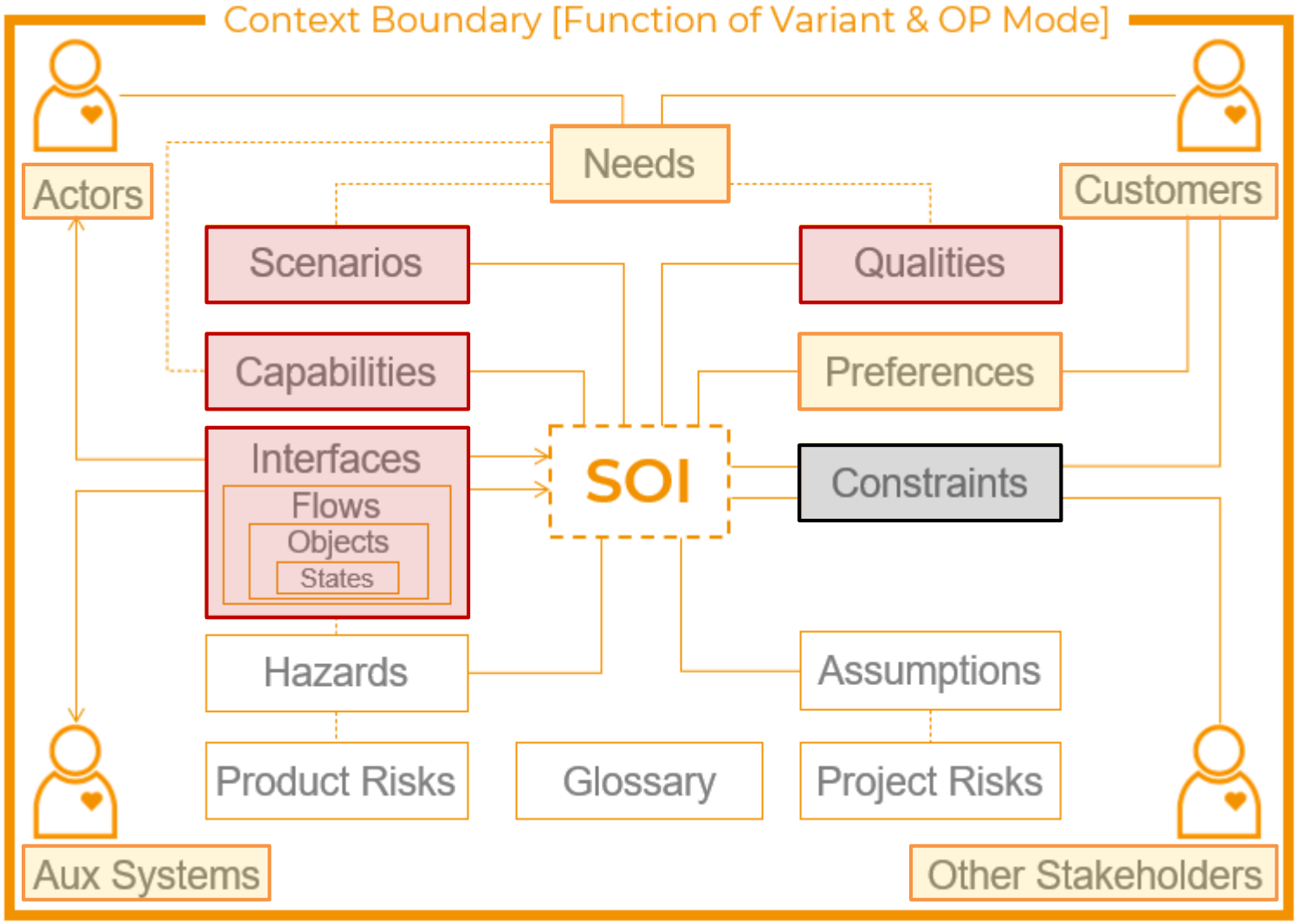
Customer Requirements

- Provide the Input for both, the Ideal and the Real System
- Dynamic Model supporting active Change Management!
- Are developed in a Systematic and Structured way as to not overlook or forget salient REQs

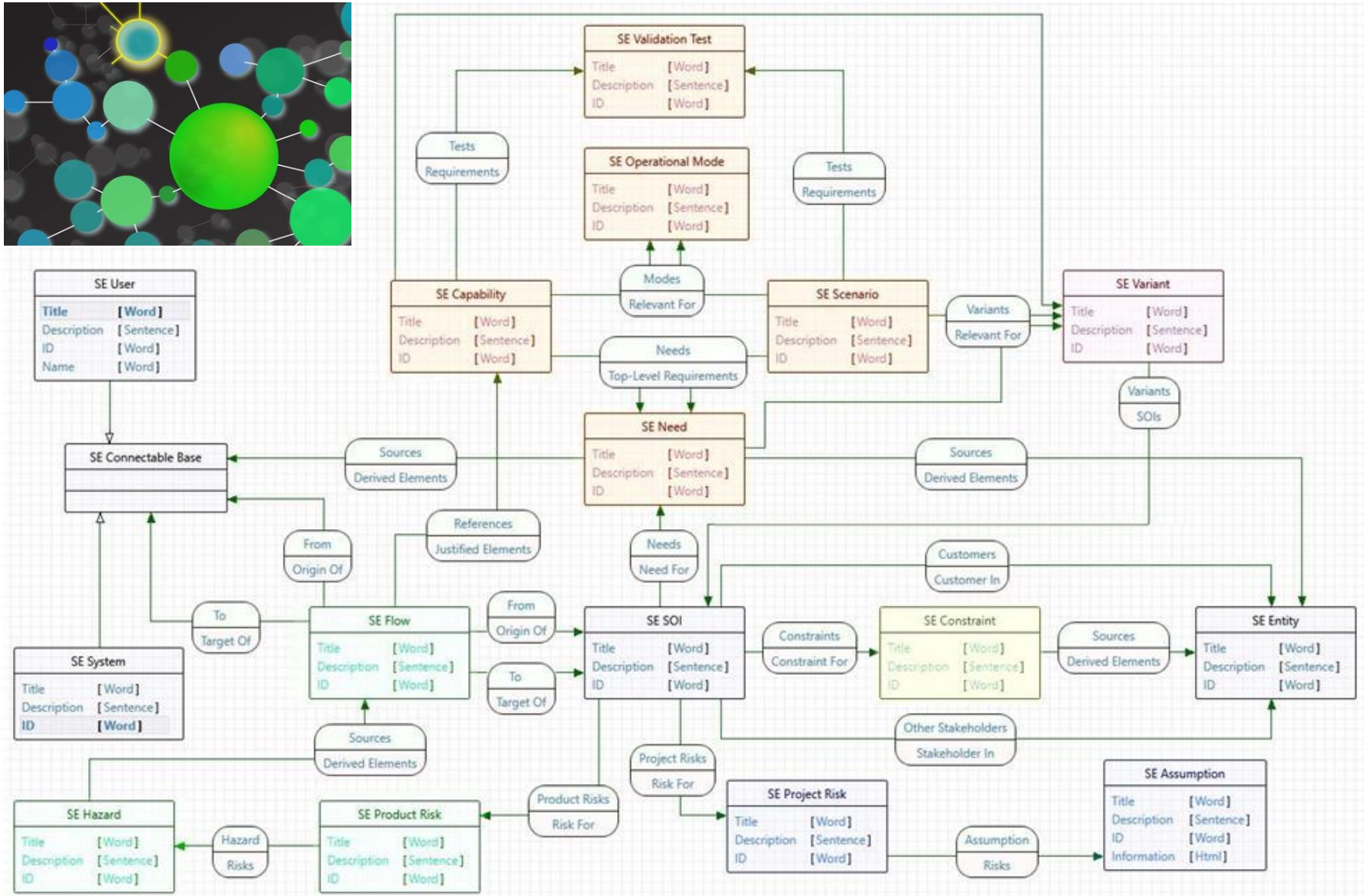
Elicitation Model

- Define Variants & Operational Modes
  Focussing on one particular combination at a time yields more insightful analyses
- Identify Stakeholders
  - Customers (Needs & Constraints)
  - Actors (Needs & Interfaces)
  - Aux Systems (Only Interfaces)
  - Other STKs (Only Constraints)
- Formalise Needs as "testable…"
  - … Capabilities
  - … Scenarios
  - … Qualities ("so called –Ilities")
- Analyse Object Flows & Hazards
  - Control Signals
  - Information
  - Energy
  - Matter

Boxes are Registers
The information within are Data Items



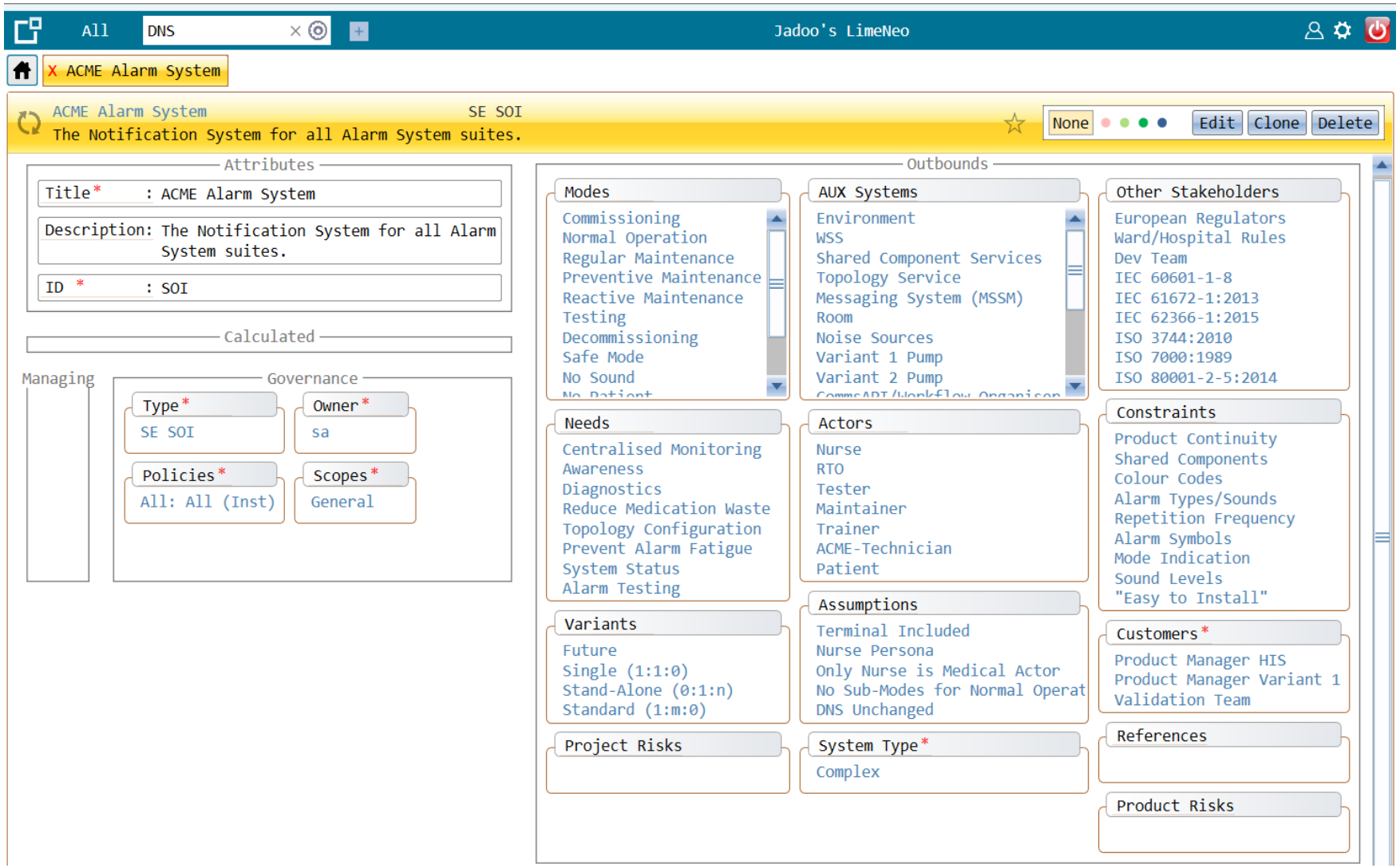
SOI Context Data Model



Key Features

- Nodes and Edges represent Items and Relationships, respectively.
- The semantics of all items/artefacts (including their bi-directional Relationships) are strictly defined
- Model is by definition consistent and allows for high levels of reuse
- Full & immediate traceability along multi-dimensional Relationships fostering trust in impact analysis
- Aids modelling & communication thus improving efficiency and reducing human errors
- Robust and reliable basis for high levels of automation, e.g. for rule-based document generation

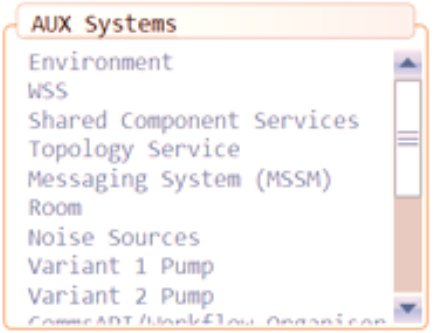
Modelling Tool: LIME

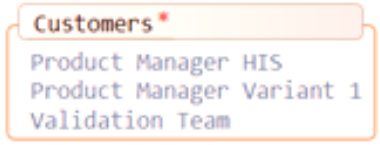


Key Points

- 1 : 1 Representation of the data model where an Item “owns” Attributes (data that only exists because the item does) and so-called “outbound” Relationship to other, pre-existing items, that are also Properties of this Item (e.g. an Item of *City* as part of an *Address*)
- Secondary information (e.g. a grand-parent or age of a person) is calculated in real-time (as the parent of a parent or the current date minus their date-of-birth), to avoid duplication, manual up-keep and wrong/out-dated information)
- Meta-Data (Title and Description) are calculated to avoid redundancy
- Ad-hoc reporting on user level
- Spreadsheet-like (bulk) editing even of complex information

Stakeholders





Customers

ID	Title	Description	Type
CM-01	PMH	Product Manager HIS, provides the needs and applicable constraints.	Internal
CM-02	PMP	Product Manager PUMP (but NOT for ALARM SYSTEM). Insight into French "hospital world".	Internal
CM-03	VST	The visualisation Team are responsible for the Validation; partly in the role of a Customer.	Internal

Actors

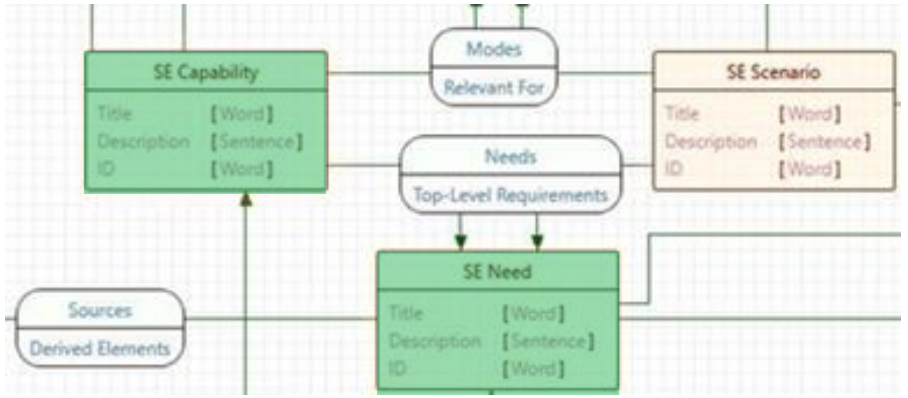
ID	Title	Description	Type
AC-01	Nurse	A professional who cares for the sick or infirm. Here: in the context of a hospital ICU ward.	Primary
AC-02	RTO	Responsible Technical Operator, i.e. a manager (IT or Clinical) in a hospital	Secondary
AC-03	Tester	A member of the V&V Team	Secondary
AC-04	Maintainer	A trained person who can do regular and reactive Maintenance.	Secondary

Other STKs

ID	Title	Description	Type	Filter
SH-02	Ward/Hospital Rules	There might be rules depending on Ward (type) Hospital type, country etc.	Potentially Negotiable	Alarm
SH-03	Dev Team	Possibly limiting the potential options of realisation (imperfect knowledge)	Full Control	Alarm
SH-04	IEC 60601-1-8	International Standard for Medical Electrical Equipment	Non-Negotiable	Alarm
SH-05	IEC 61672-1:2013	Electroacoustics – Sound level meters – Part 1: Specifications	Non-Negotiable	Alarm

Capabilities: Needs & Response Matrix

ID	Title	Description	Modes	Actors	Variants
ND-02	Awareness	As a nurse I need to react to any important change in patient or equipment condition. I therefore want to be alerted to and clearly identify any alarm condition that requires my immediate or prompt response.	OM-02 OM-08	AC-01	All
ND-06	Prevent Alarm Fatigue	As a nurse I need to stay calm and prevent Alarm Fatigue by Anticipating and Preventing Alarms, even in challenging situation with a complex set of active alarm conditions in my ward. I therefore want to be in control of the notifications, their frequency and intensity, and be able to overrule/mute or snooze them.	OM-02 OM-08	AC-02	All
ND-07	System Status				
ND-08	Alarm Testing				

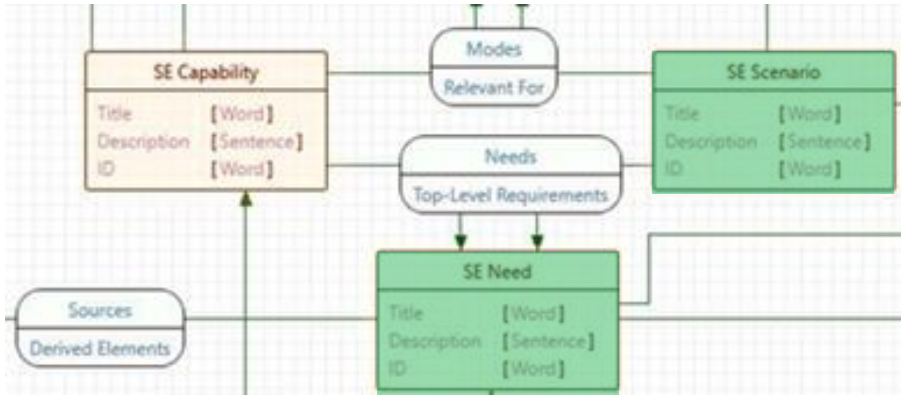


Pump State	Trigger	Alarm Condition	Other	Visual	Audio
Empty	Occlusion (HI)	Active	No	Technical Error	Beep
Empty	EOI (MD)	Active	No	Technical Error	Beep
Loading	Occlusion (HI)	Active	No	Technical Error	Beep
Loading	EOI (MD)	Active	No	Technical Error	Beep
Loaded (not running)	Occlusio				
Loaded (not running)	Occlusio				
Loaded (not running)	Occlusio				
Loaded (not running)	Occlusio				
Loaded (not running)	EOI (MD)				
Loaded (not running)	EOI (MD)				
Loaded (not running)	EOI (MD)				
Loaded (not running)	EOI (MD)				
Running	Occlusio				
Running	Occlusio				
Running	Occlusio				

ID	Title	Description	Modes	Needs	Variants
CP-16	Process Alarm Conditions	The Capability to clearly pick-up, identify and interpret any Alarm Condition from its source including source and additional information and to display the corresponding Visual and accompany it with the correct Audio Alarm Notification.	OM-01	ND-02	All
CP-17	Allow Customisation	The Capability to allow Users to be in control of the notifications, their frequency and intensity, and be able to overrule/mute or snooze them.	OM-01	ND-06	All
CP-18	Self-Diagnostics	The Capability to "self-diagnose" and display the current state of the whole System, i.e. from Source to Communicator to anticipate False Positive as well as False Negative Alarms.	OM-01	ND-07	All
CP-19	Testing	The Capability to allow a Tester to inspect the System behaviour for a set of standard correct and deliberately wrong Alarm Conditions.	OM-03 OM-04	ND-08	All
CP-20	Intelligence	The Capability to interpret, prioritize, and aggregate a collection of simultaneously occurring Alarm Conditions into the Corresponding Alarm Notifications (Visual and Audio)	OM-01	ND-02	All

Scenario Elicitation: Factor Analysis

ID	Title	Description	Modes	Actors	Variants
ND-02	Awareness	As a nurse I need to react to any important change in patient or equipment condition. I therefore want to be alerted to and clearly identify any alarm condition that requires my immediate or prompt response.	OM-02 OM-08	AC-01	All
ND-06	Prevent Alarm Fatigue	As a nurse I need to stay calm and prevent Alarm Fatigue by Anticipating and Preventing Alarms, even in challenging situation with a complex set of active alarm conditions in my ward. I therefore want to be in control of the notifications, their frequency and intensity, and be able to overrule/mute or snooze them.	OM-02 OM-08	AC-02	All
ND-07	System S				
ND-08	Alarm Te				



NURSE

Position		Condition		Skill	
N-P-1	Outside Room	N-C-1	Calm	N-S-1	Experienced
N-P-2	Inside, 4m distance	N-C-2	Tired	N-S-2	Training
N-P-3	Inside, 1m distance	N-C-3	Stressed	N-S-3	Supply

ROOM

People		Light		Sound		Mood	
R-P-1	Empty	R-L-1	Artificial	R-S-1	Quiet	R-M-1	Calm
R-P-2	Only Necessary	R-L-2	Daylight	R-S-2	Normal	R-M-2	Normal
R-P-3	Too Many	R-L-3	Direct Sun	R-S-3	Noisy	R-M-3	Hectic
		R-L-4	Darkness				

SYSTEM

Mode		State	
S-M-1	Testing	S-S-1	Normal
S-M-2	Commissioning	S-S-2	Faulty
S-M-3	Normal Operation	S-S-3	Audio Off
S-M-4	"Safe Mode"		

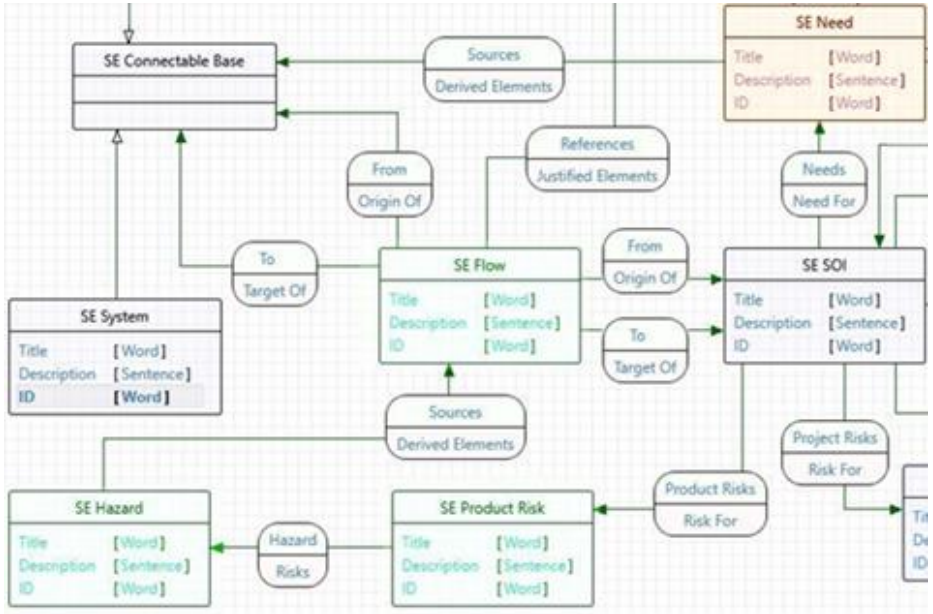
PUMP/COMBOX/THERAPY MANAGER

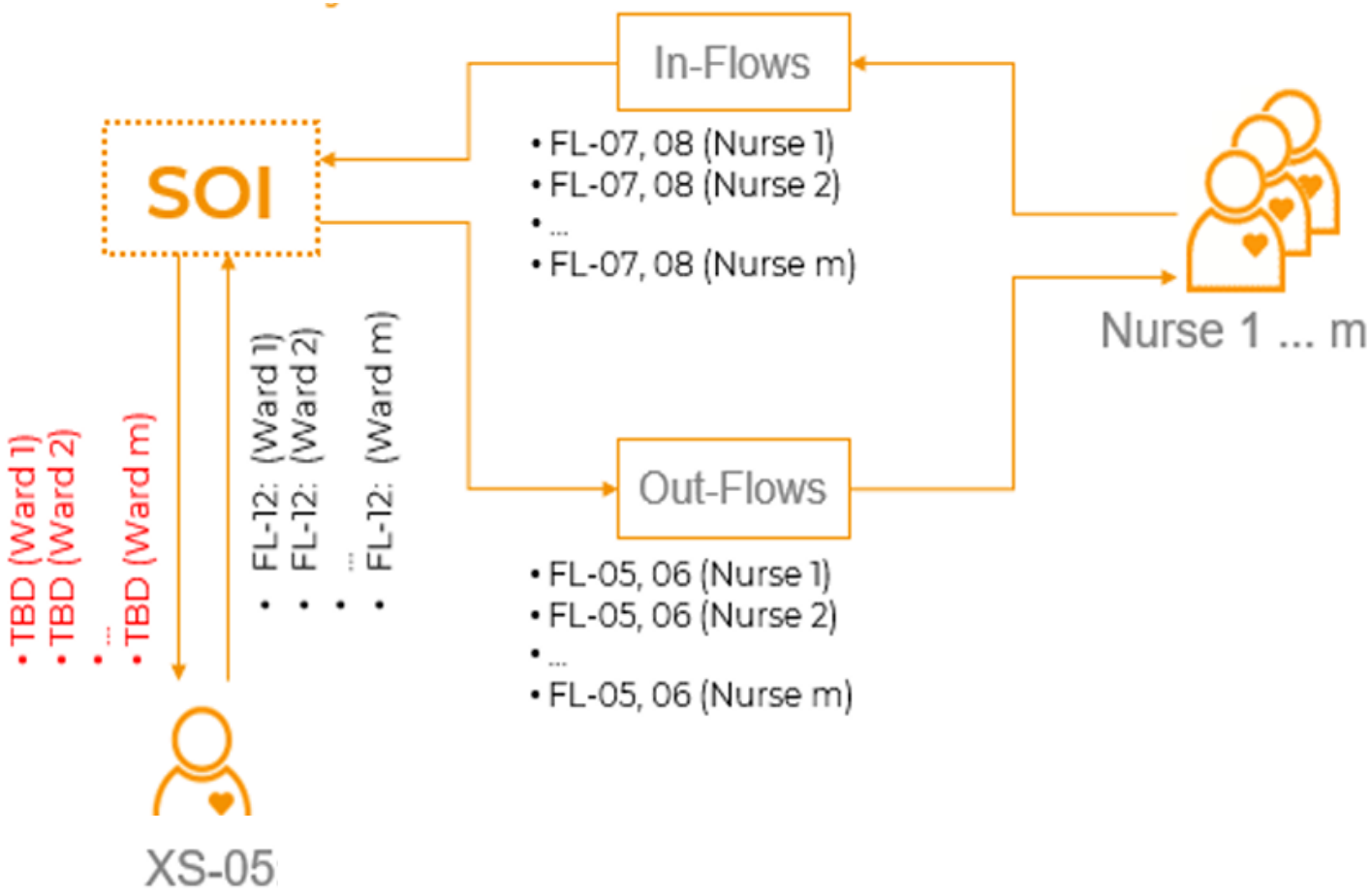
Alarm Condition(s)		Type		Max. Priority	
A-C-1	Single	A-T-1	New	A-P-1	Low
A-C-2	Multiple from same Station	A-T-2	Latched	A-P-2	Med

ID	Title	Description	Modes	Needs	Variants
SC-07	N:P2,C3,S2 | R:P2,L2,S3,M2 | A:C3,T1,P3 | S:M3,S1	- Training Nurse is in the Room (daylight, noisy) with 1 other nurse, ca 3m from Communicator, when 3 Alarm Conditions occur from 2 stations. - System aggregates the 2 Alarms from the same Stations, Displays all Visual Alarms at Source Location incl. Alarm Information and sounds the corresponding Audio Alarms - Nurse accepts Responsibility - Nurse mutes lower Priority Alarms - System displays that it is in "Mute" - Nurse identifies Source of Alarm - Nurse resolves Source Condition - Nurse "unmutes" the System and acts on remaining alarms	OM-02	ND-02 ND-06	All

Interface Elicitation: Flow Analysis

Visualisation Only





User Requirements Document

Semi-Auto-Generated

User Requirements Document (URD)

ACME “PUMP-ALARM SYSTEM-Notification-Features” (Alarms)

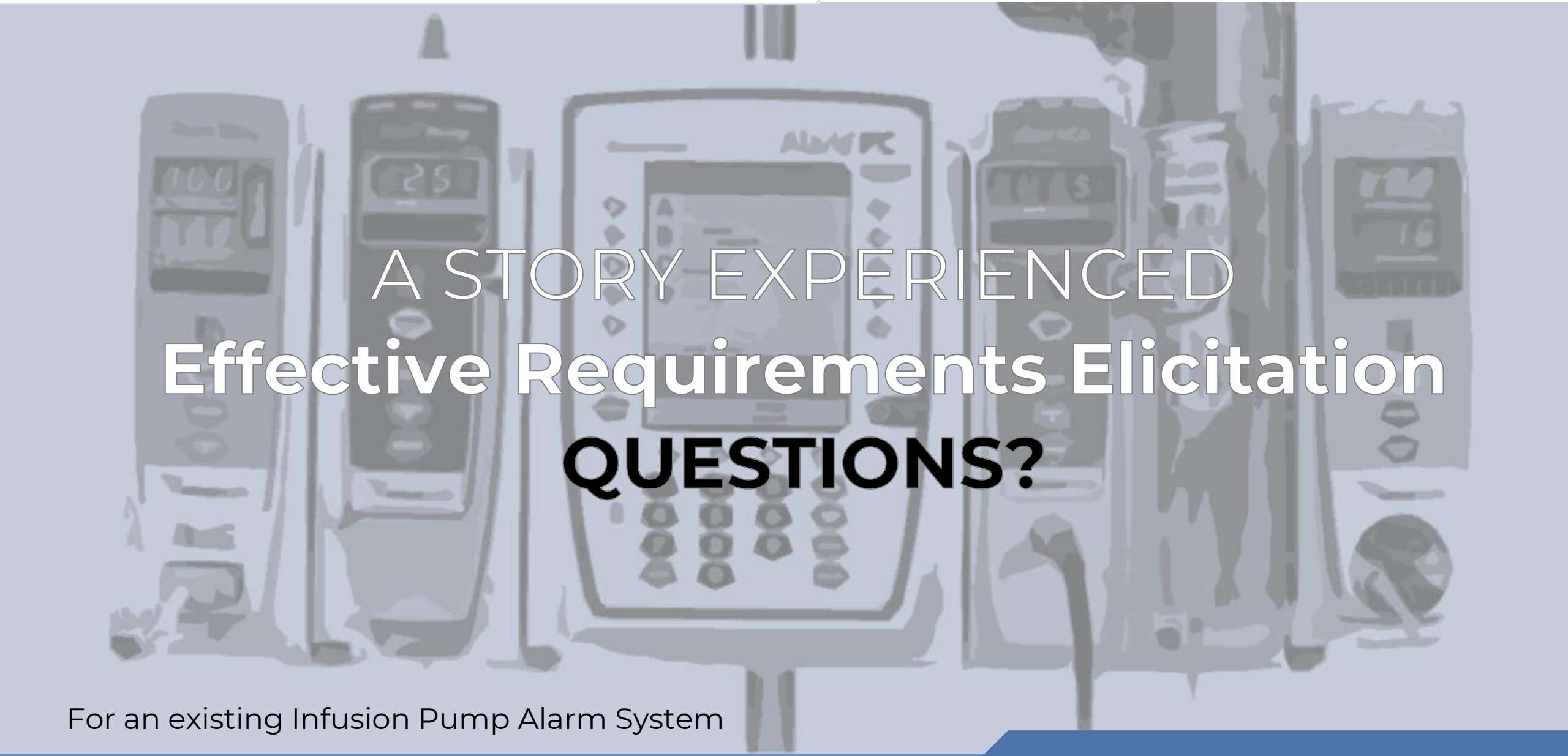
NOTE: This document serves as an example of how to derive a URD from the information captured in the Context Diagrams’ registers. The User Requirements covered by this document have been developed based on the clear understanding that it is only for illustration purposes. From the actual SOI covering the whole of the next generation ACME Infusion System, aka “PUMP”, only 2 of the ALARM SYSTEM related Alarm Features - namely “Occlusion” and “End-of-Infusion” - have been used to show the information traceability from Context Analysis to URD (See Response Matrix).

1) Introduction

ALARM SYSTEM is the name given to a set of Capabilities of the ACME Infusion System covering the relay of infusion status information and bed-side alarms from the beds to a remote display and sound unit. While the aim is to relay the infusion status as closely as possible to its original content, the Alarm Conditions raised by a pump shall be relayed in form of a notification that can be prioritised, aggregated, and muted or snoozed.

CONCLUSIONS

- It has been shown how to systematically derive a **User Requirements Document** from the information captured in the Context Diagrams' registers.
- The actual SOI is covering the whole of the next generation ACME Infusion System, aka "PUMP", only 2 of the ALARM SYSTEM related Alarm Features have been used to show the process of the **Structured Context Analysis**
- The approach using a **Semantic Graph & Fractal Information Tool** results in zero-redundancy and low error levels (which are typically quickly recognised & corrected).
- User can **Export all Information from each of the Registers,** including "hidden", i.e. related secondary information, to an RE tool or spreadsheet software of choice.
- A **Generic Data Model** was used for Context Analysis & Diagram Development
- The **Full Traceability** from Context Analysis to URD has been demonstrated
- The User can semi-automatically **Generate all Required Documentation**, e.g. the URD, from each of the registers including "hidden", i.e. related secondary information



A STORY EXPERIENCED
Effective Requirements Elicitation
QUESTIONS?

For an existing Infusion Pump Alarm System