

The Medical Device Digital Engineering Thread

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PTC Engineering Fellow
MBSE Specialist

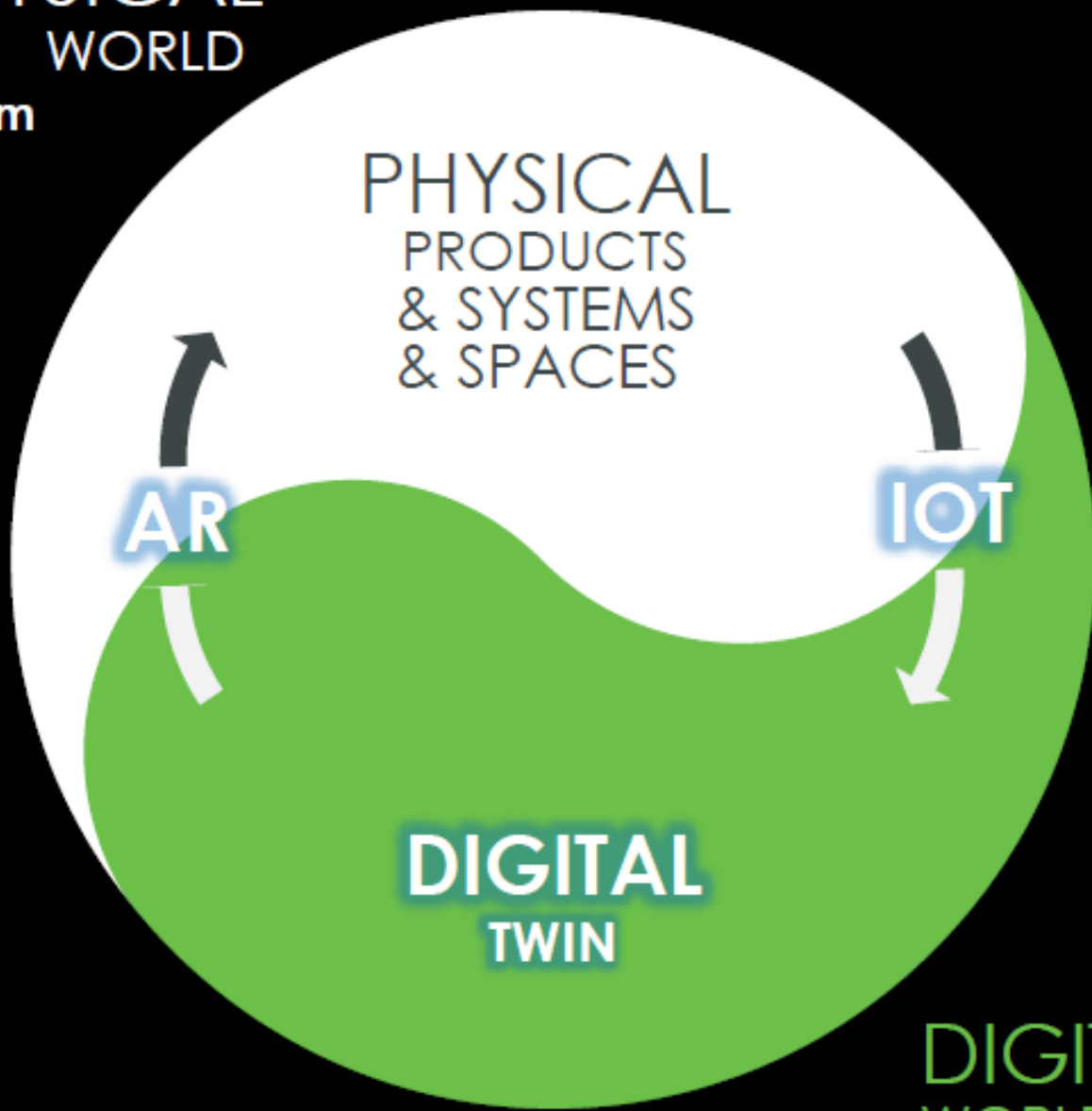


PHYSICAL WORLD

Industrial Innovation Platform

>\$100M Revenue
 > 50% Bookings Growth FY16
 1,200 End Customers
 250 OEMs/Resellers
 Ecosystem of SI's, partners

- IoT & ANALYTICS | thingworx®
- AUGMENTED REALITY | vuforia™
- INDUSTRIAL CONNECTIVITY | kepware®



PHYSICAL
PRODUCTS
& SYSTEMS
& SPACES

AR

IOT

DIGITAL
TWIN

DIGITAL
WORLD

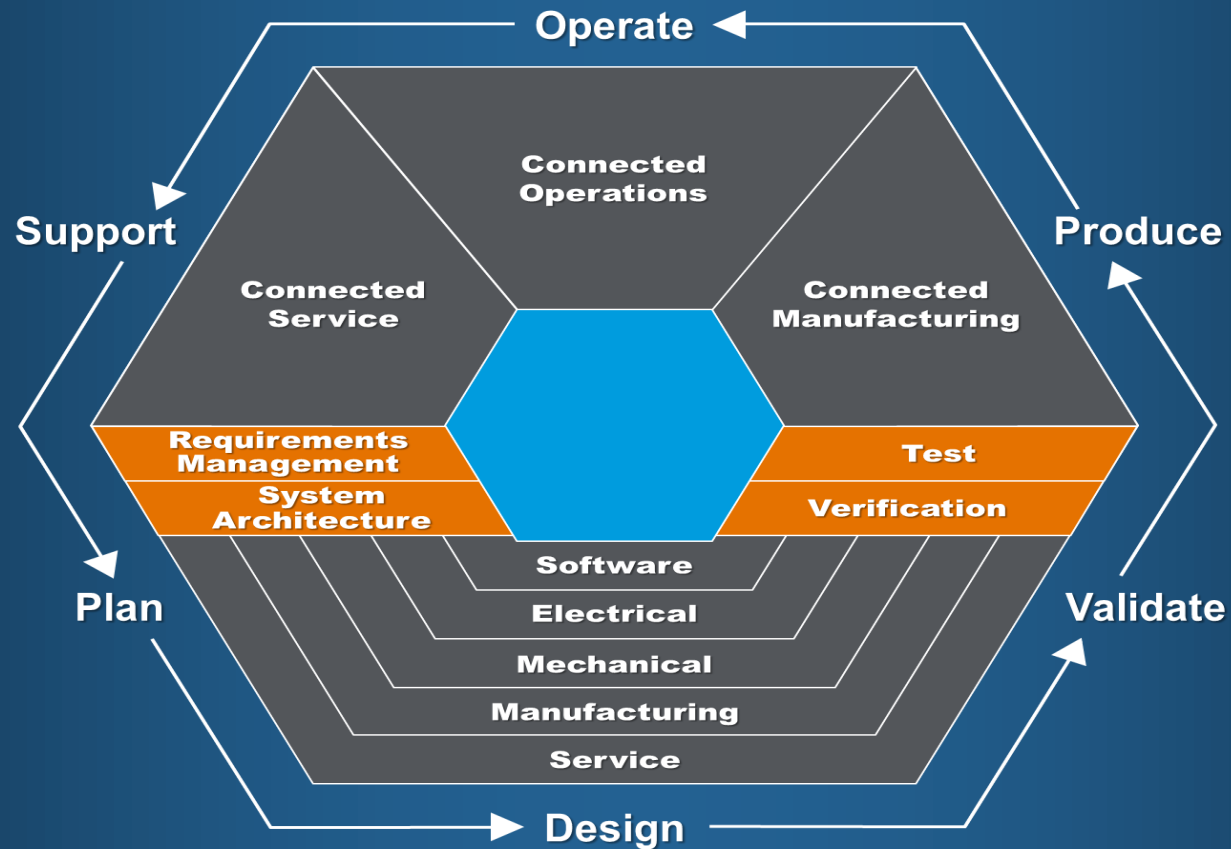
PLM Solutions

>\$1B Revenue
 10% Bookings Growth FY16
 28,000 End Customers
 70% Direct Sales
 30% VARs (~400)
 Ecosystem of SI's, partners

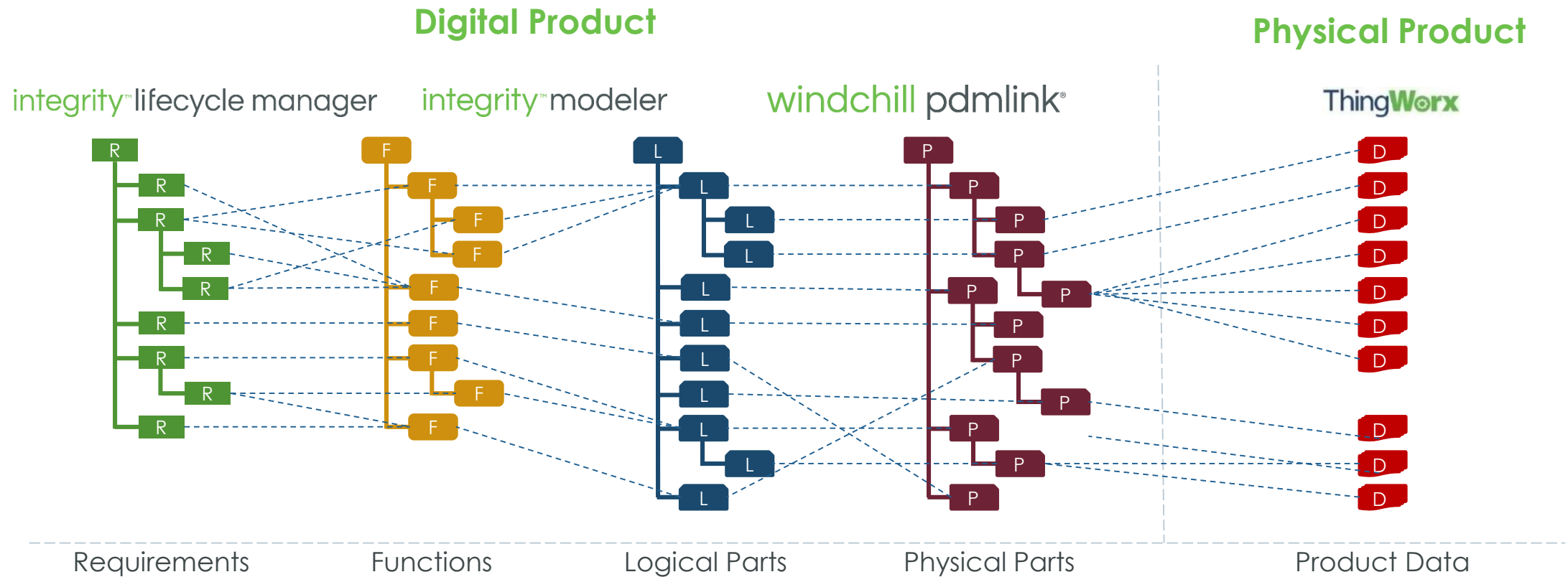
- CAD | creo®
- PLM | windchill®
- ALM | integrity®
- SLM | servigistics®

- Systems Engineering requires a multidisciplinary approach:
 - At all levels of the architecture
 - Throughout the development lifecycle
- Smart
 - Enables quantitative and qualitative analysis
 - FMEA, Risk, Safety, Human Factors, PLM, Mechanical Engineering, Electrical Engineering, etc.
 - Data driven rather than diagram driven or document driven
- Connected
 - To virtual teams
 - As part of an integrated tool chain
 - Providing data when and where it is needed
 - Supporting openness as well as security
- Standards-Based
 - SysML, UML, UAF, DoDAF, OSLC, RAS, REST, etc.

A **holistic, multi-disciplinary** and collaborative approach to designing and maintaining **complex** systems throughout the systems lifecycle.



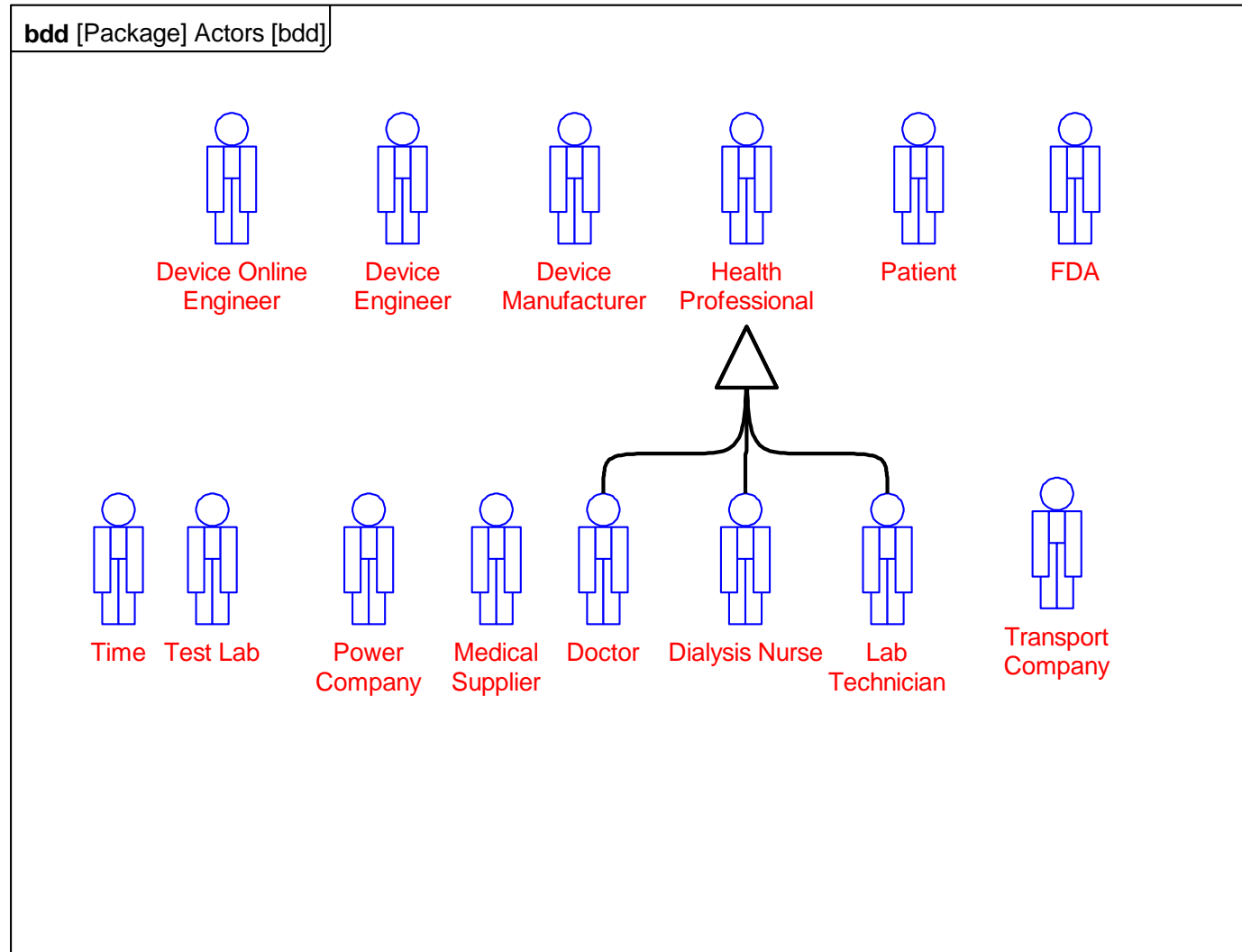
DIGITAL PRODUCT TRACEABILITY



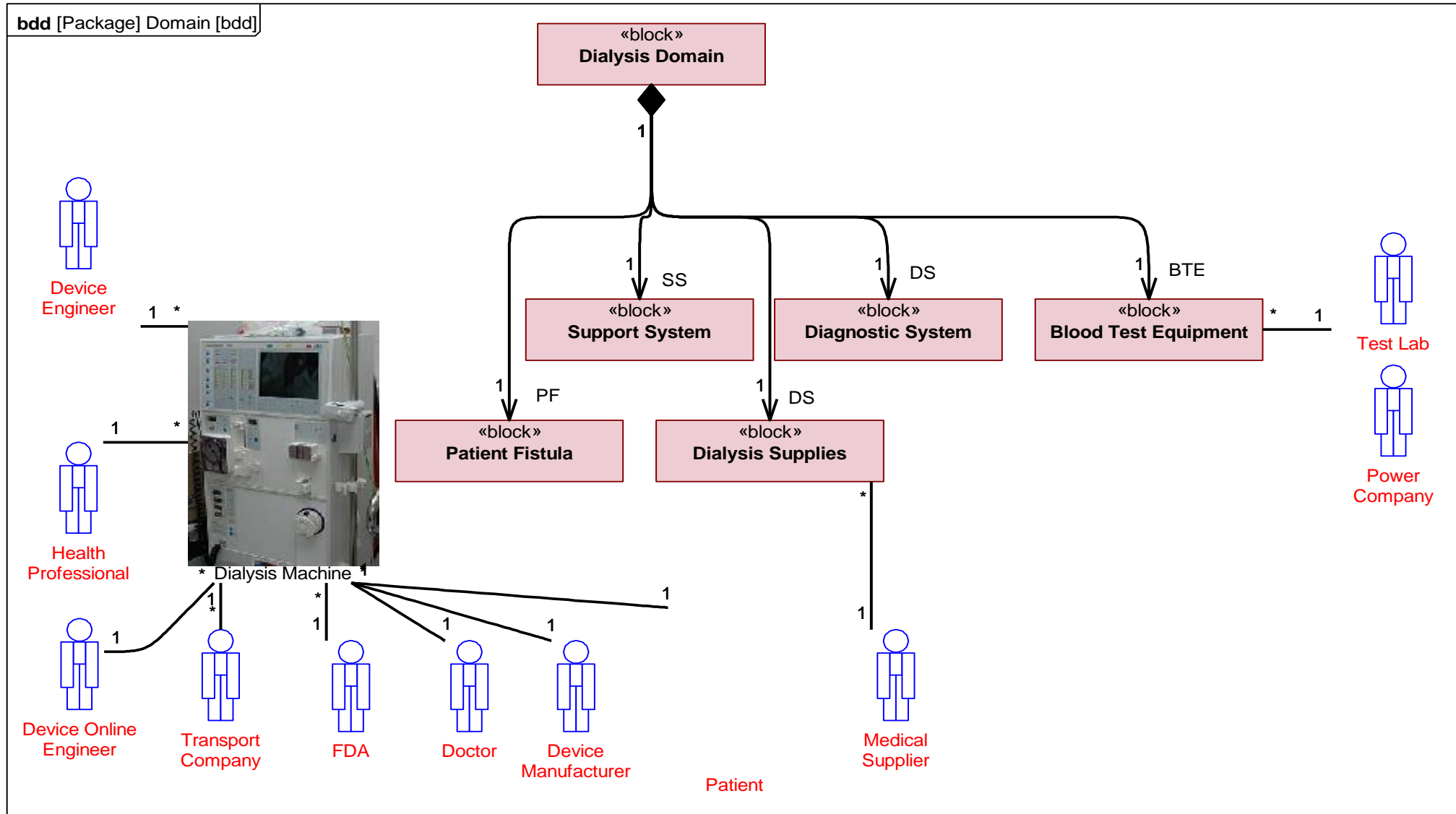
Requirements.....'satisfied by' System Functions.....'allocated to' Logical Parts...
... 'implemented by' Physical Parts.....'sending & receiving' real world data

DEVELOPING A DIALYSIS MACHINE

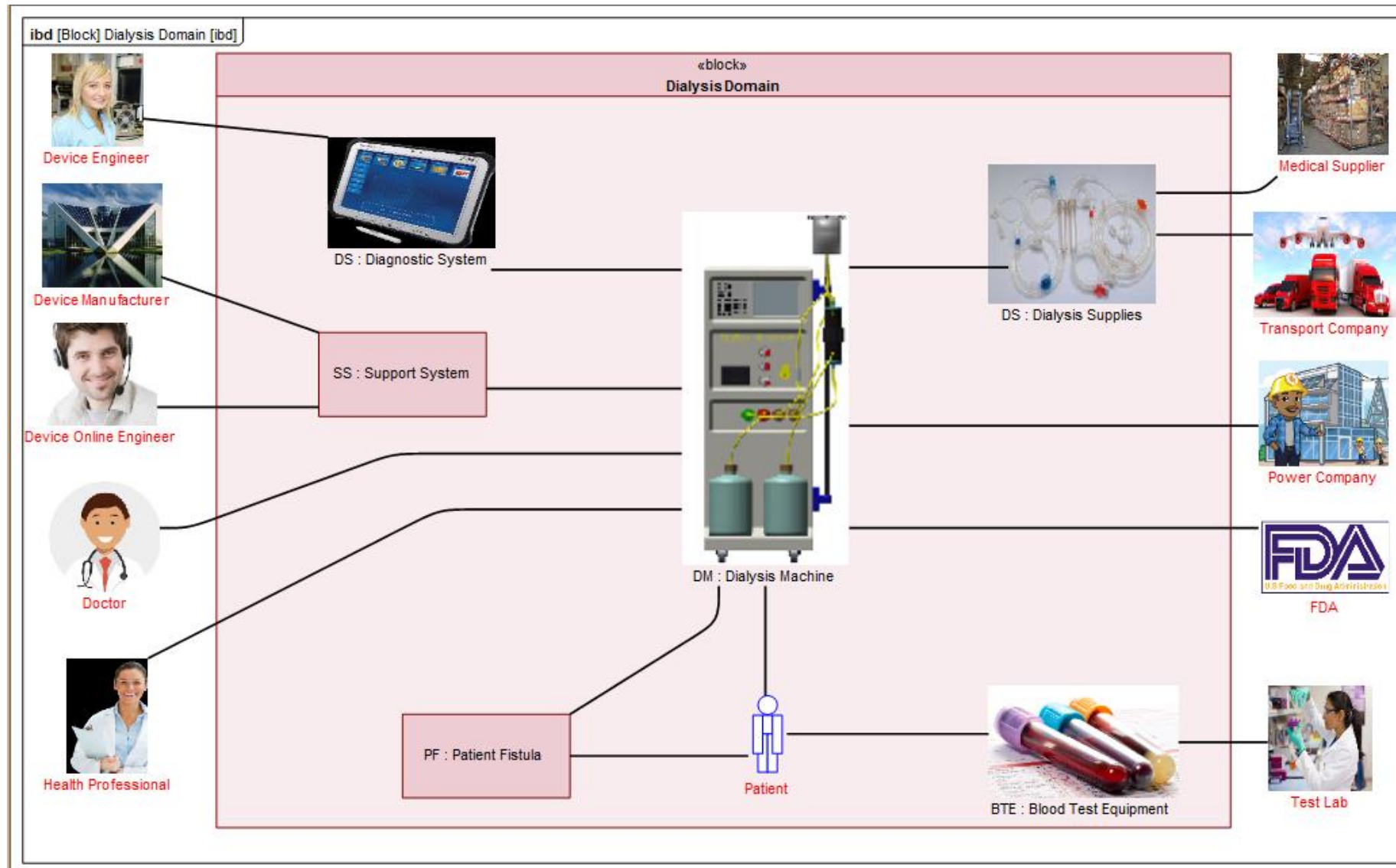
STAKEHOLDER IDENTIFICATION



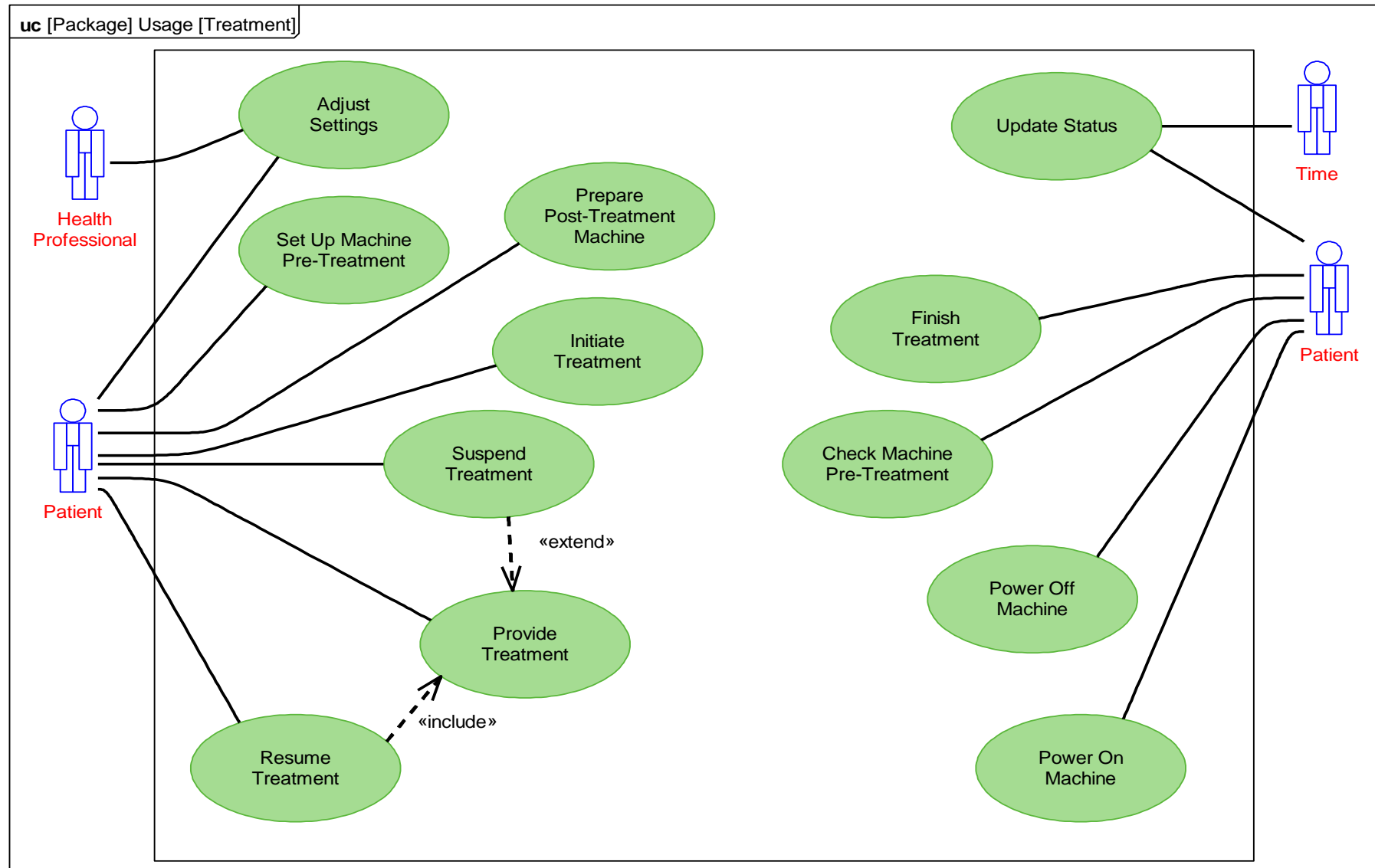
SYSTEM CONTEXT BREAKDOWN



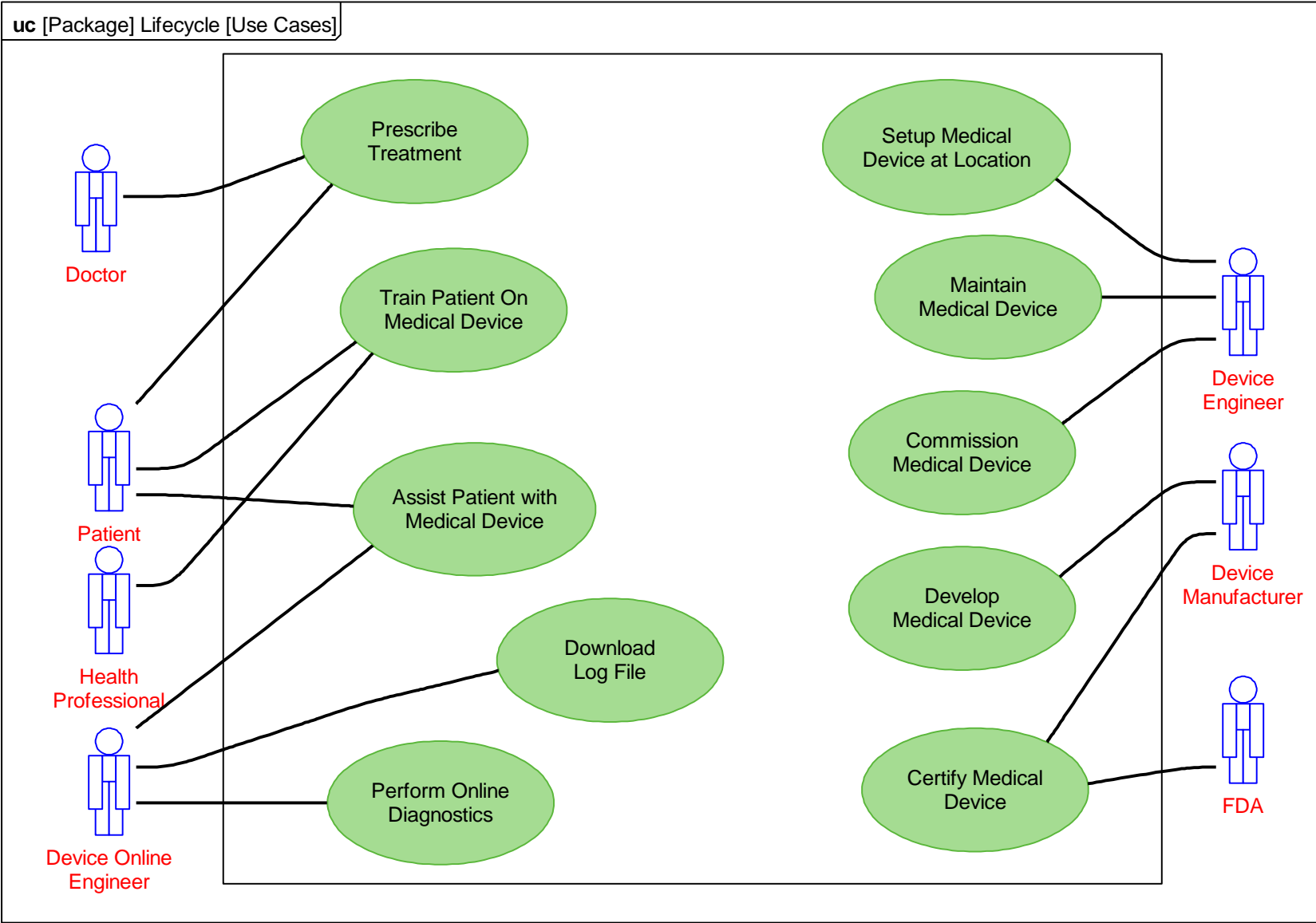
SYSTEM CONTEXT



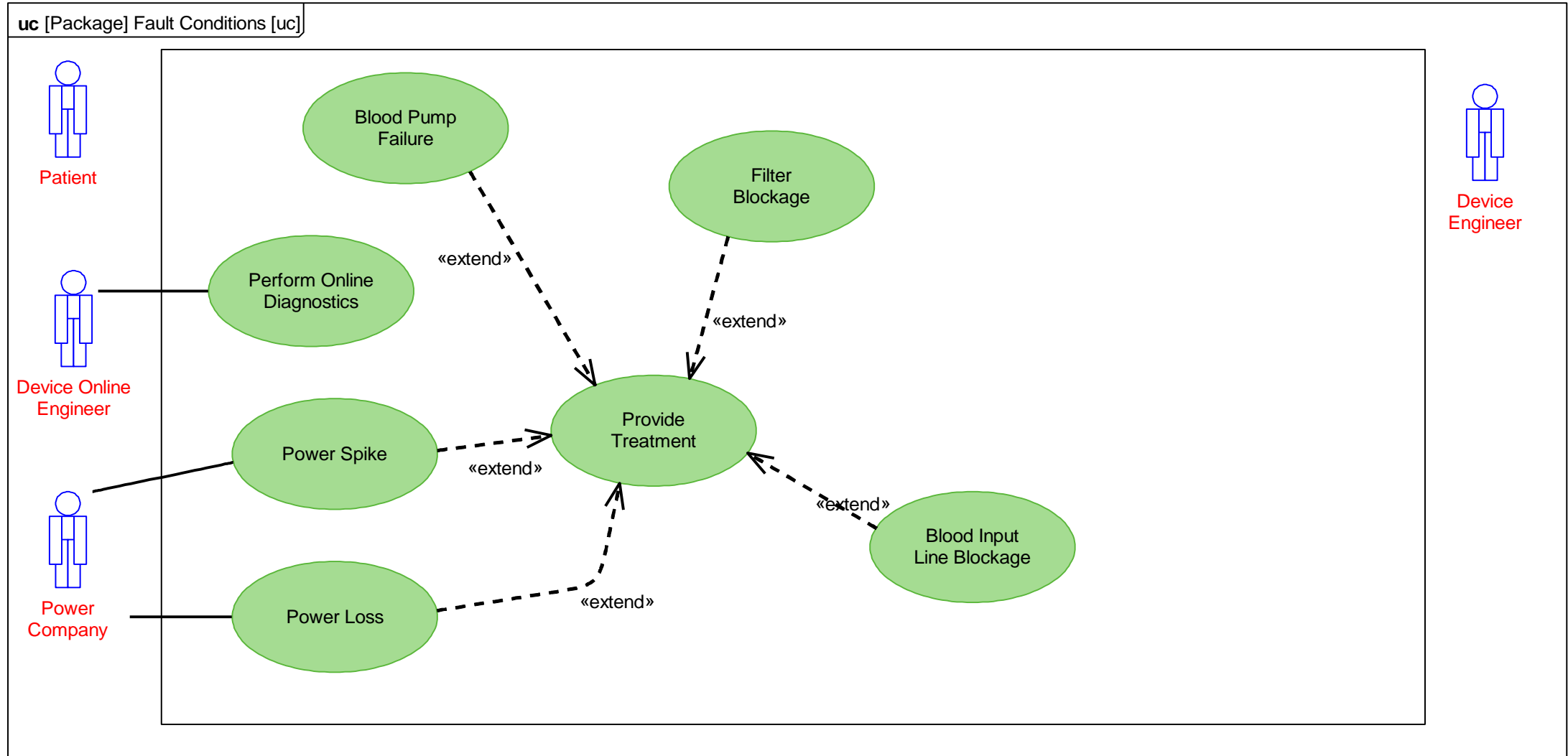
SYSTEM TREATMENT USE CASES



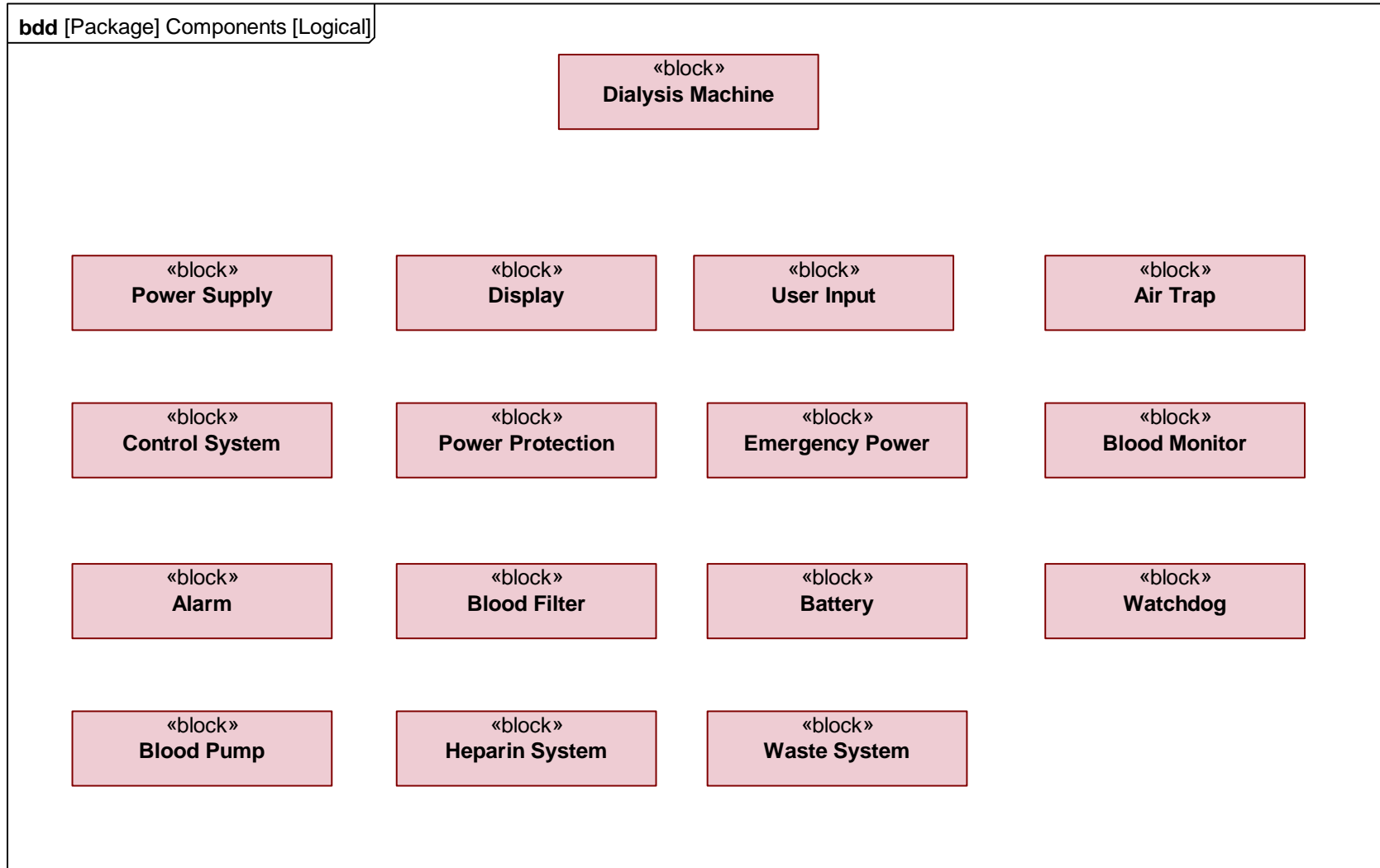
LIFECYCLE USE CASES



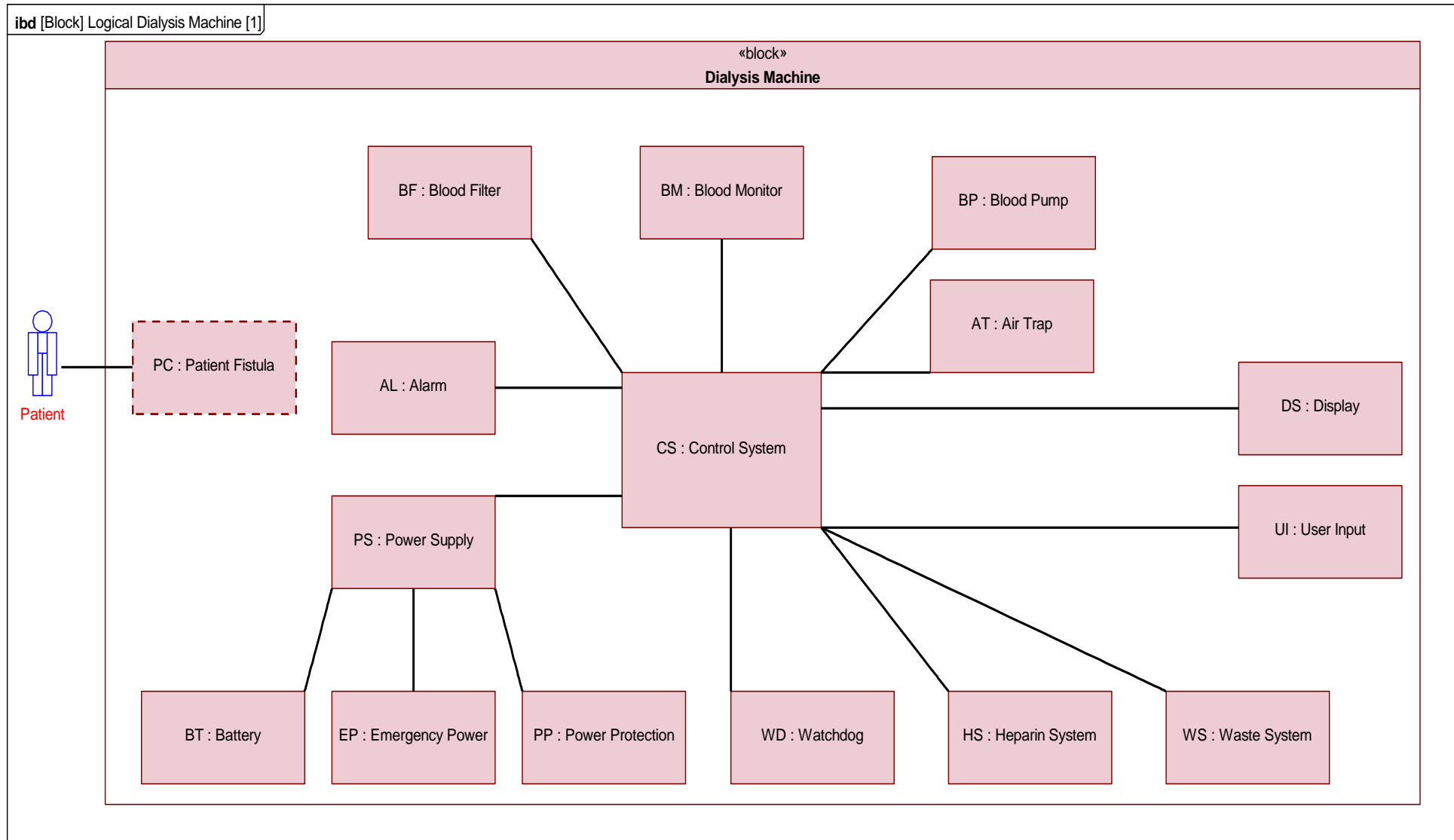
FAULT CONDITION USE CASES



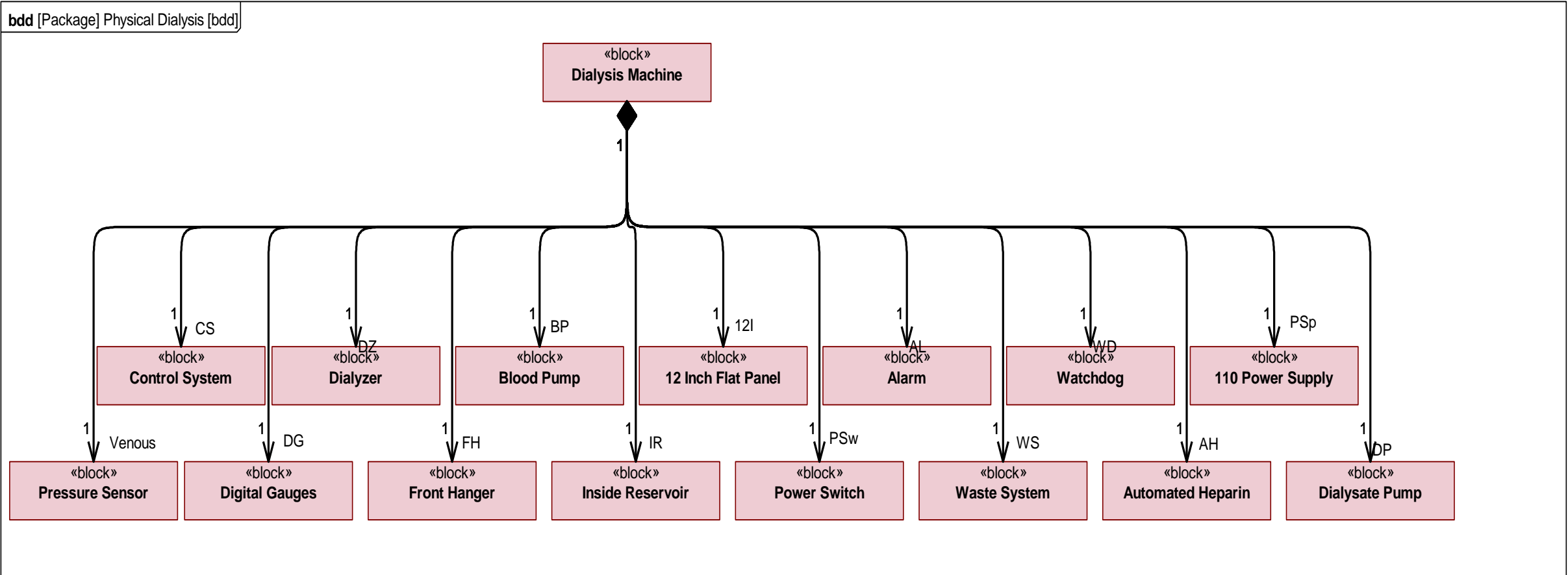
LOGICAL DIALYSIS MACHINE LOGICAL SYSTEMS



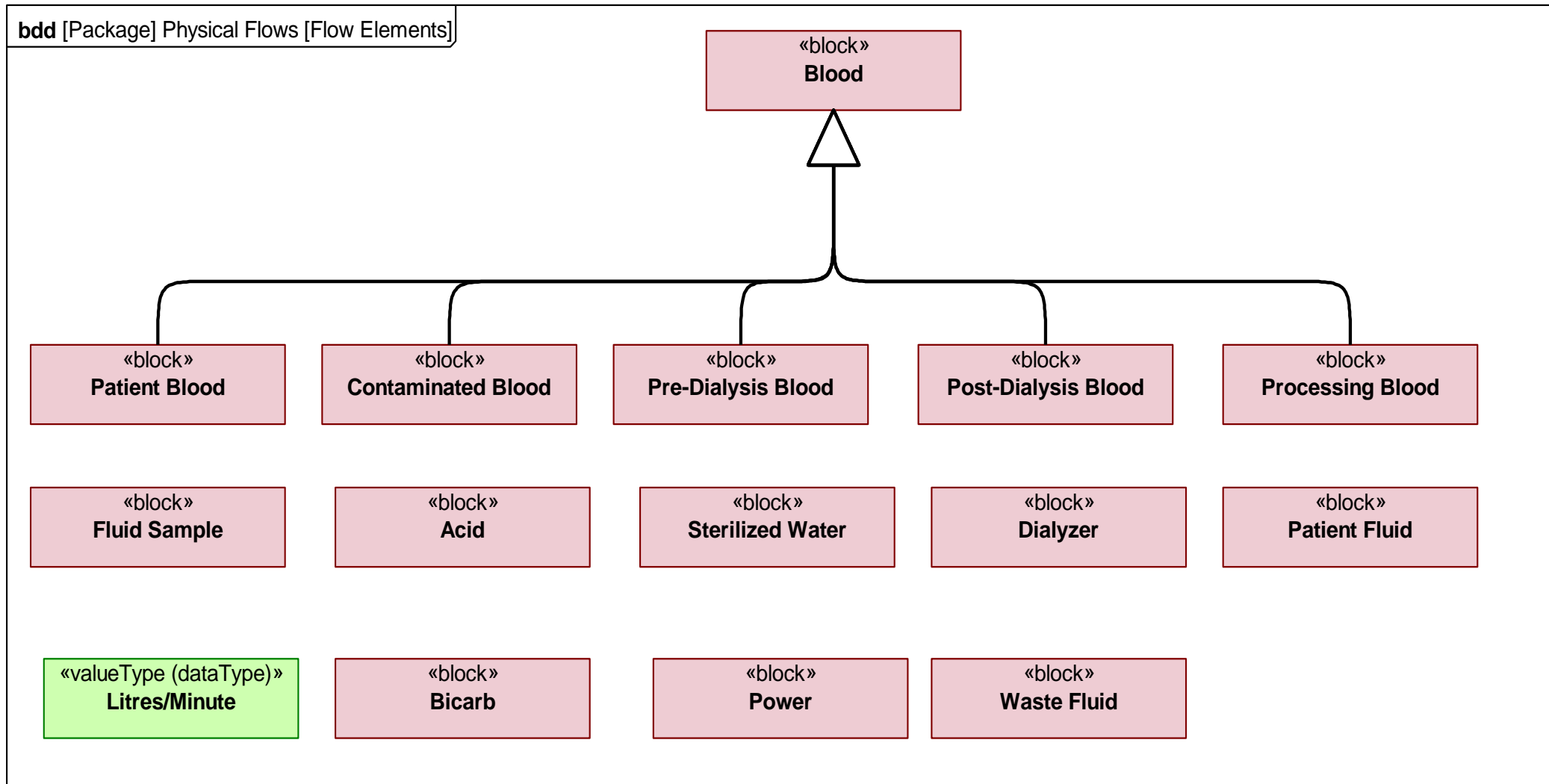
DIALYSIS LOGICAL ARCHITECTURE



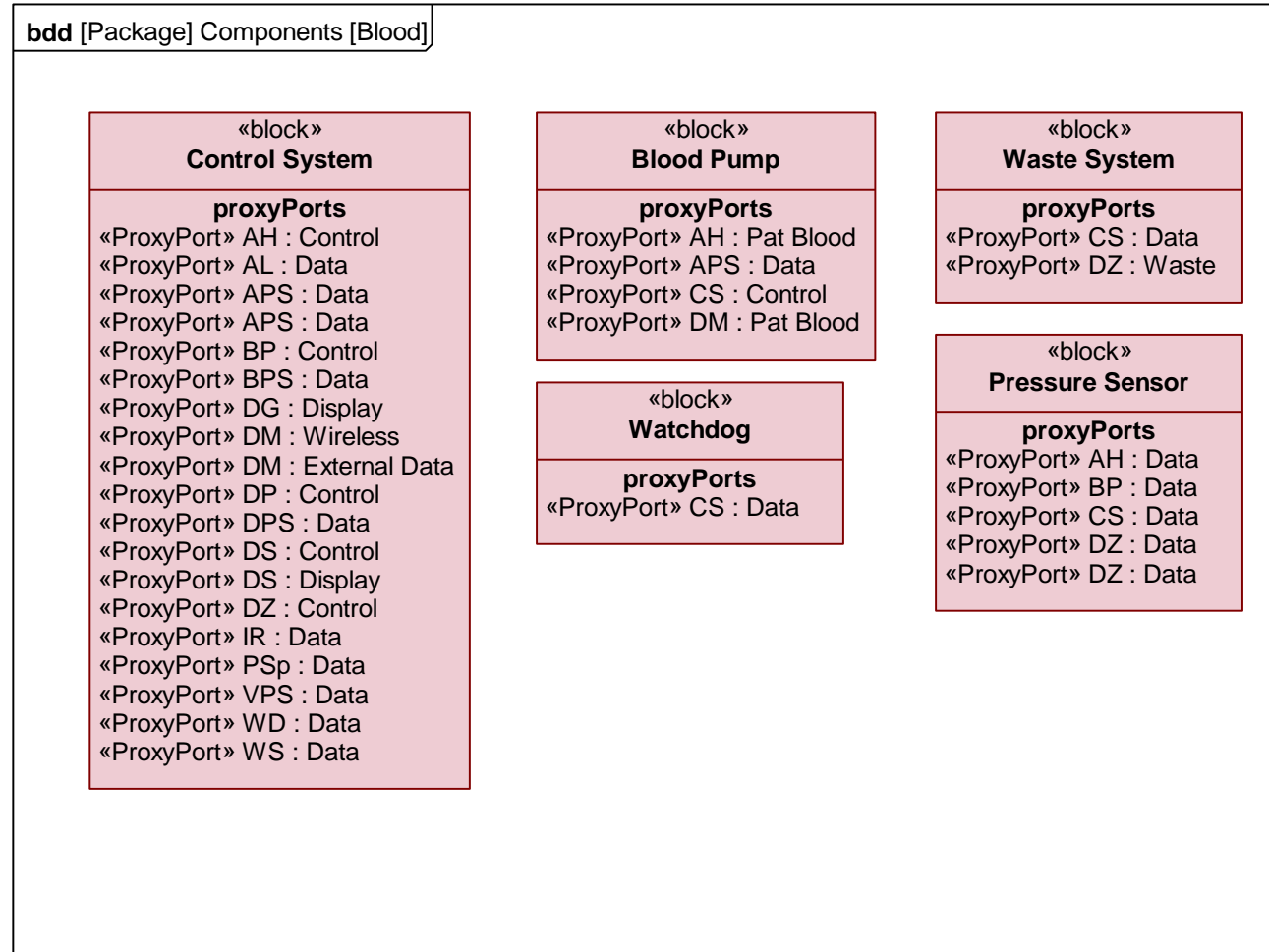
DIALYSIS PHYSICAL ARCHITECTURE



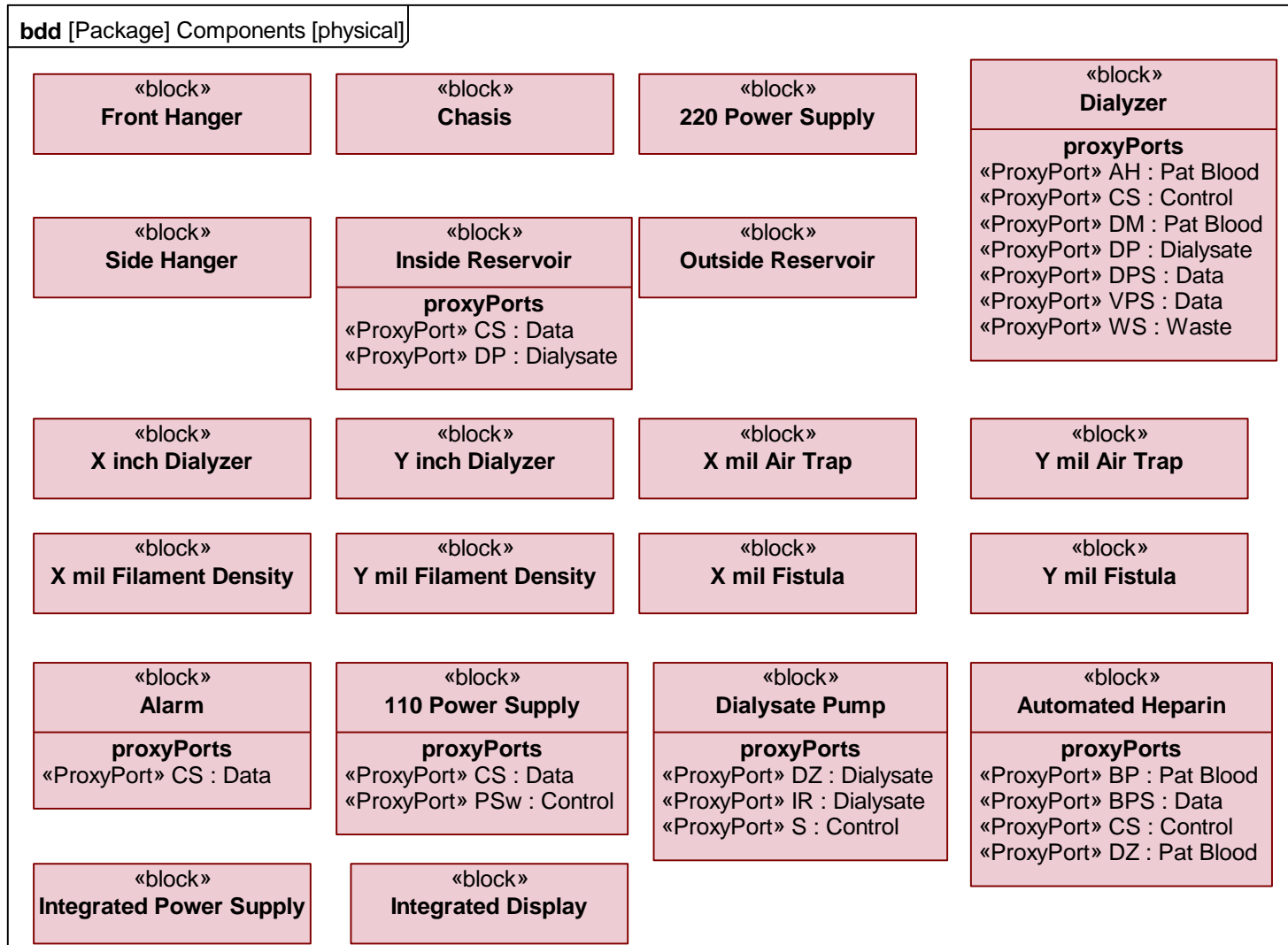
SYSTEM FLOW ELEMENTS



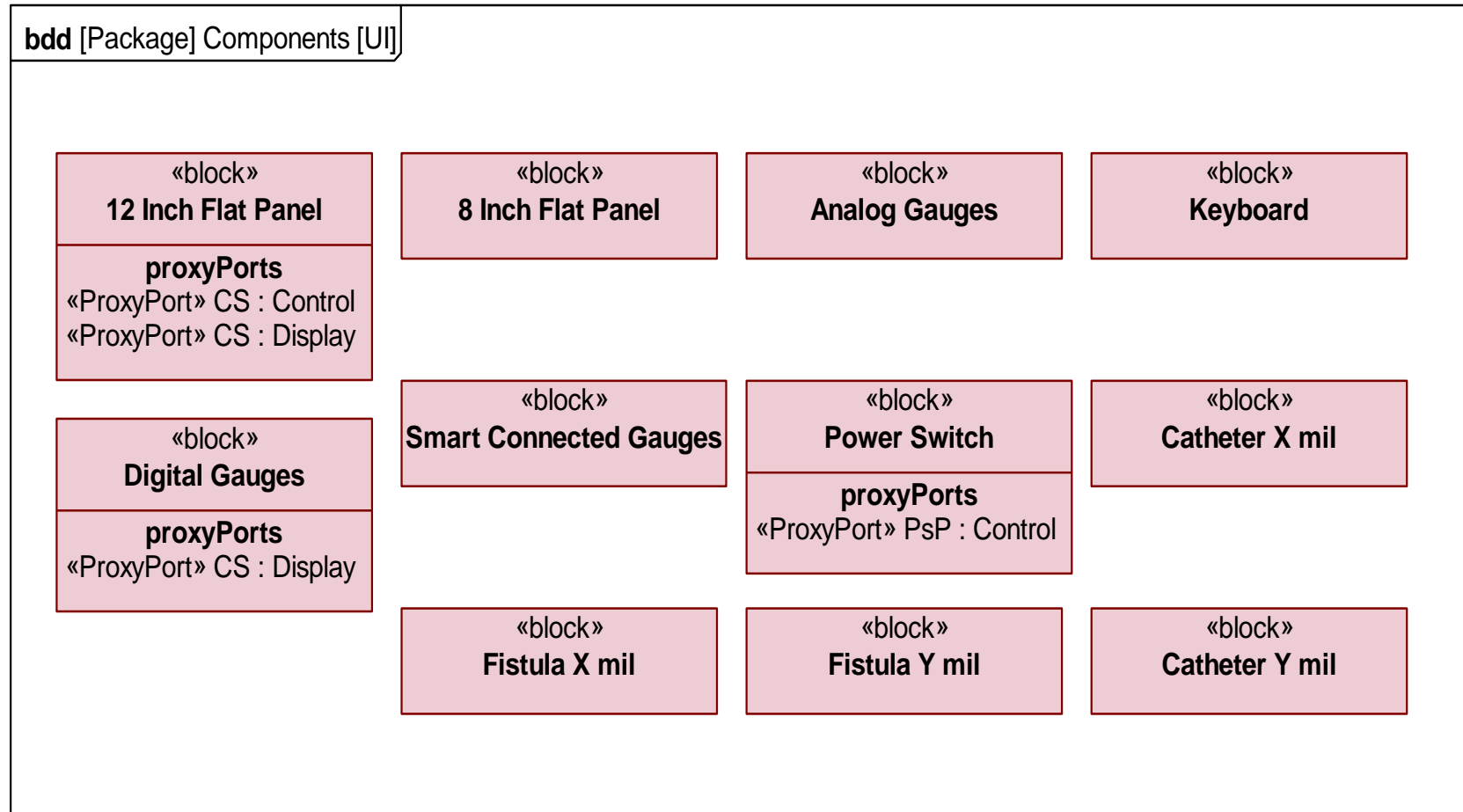
SYSTEM COMPONENTS (BLOOD)



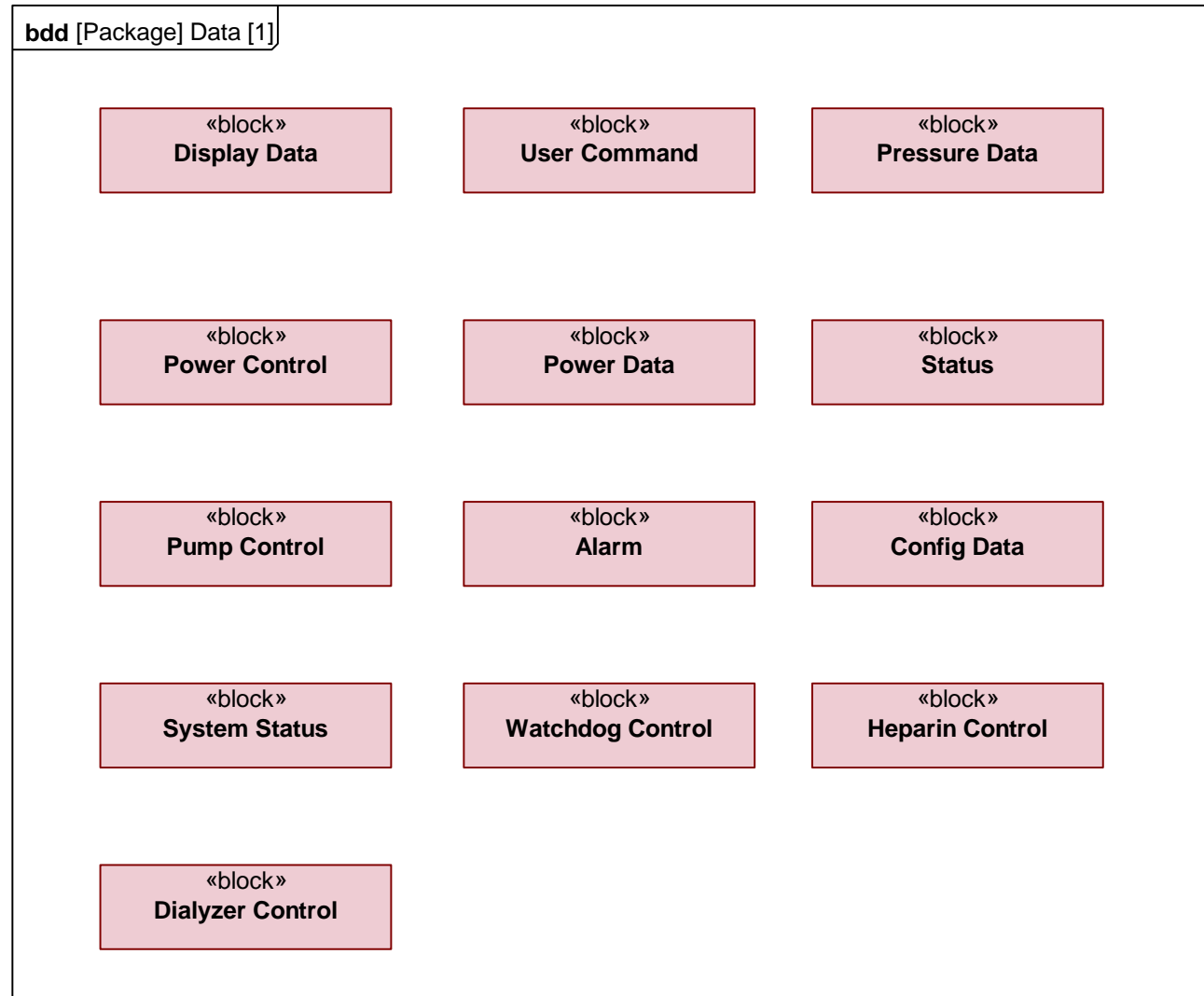
PHYSICAL COMPONENTS



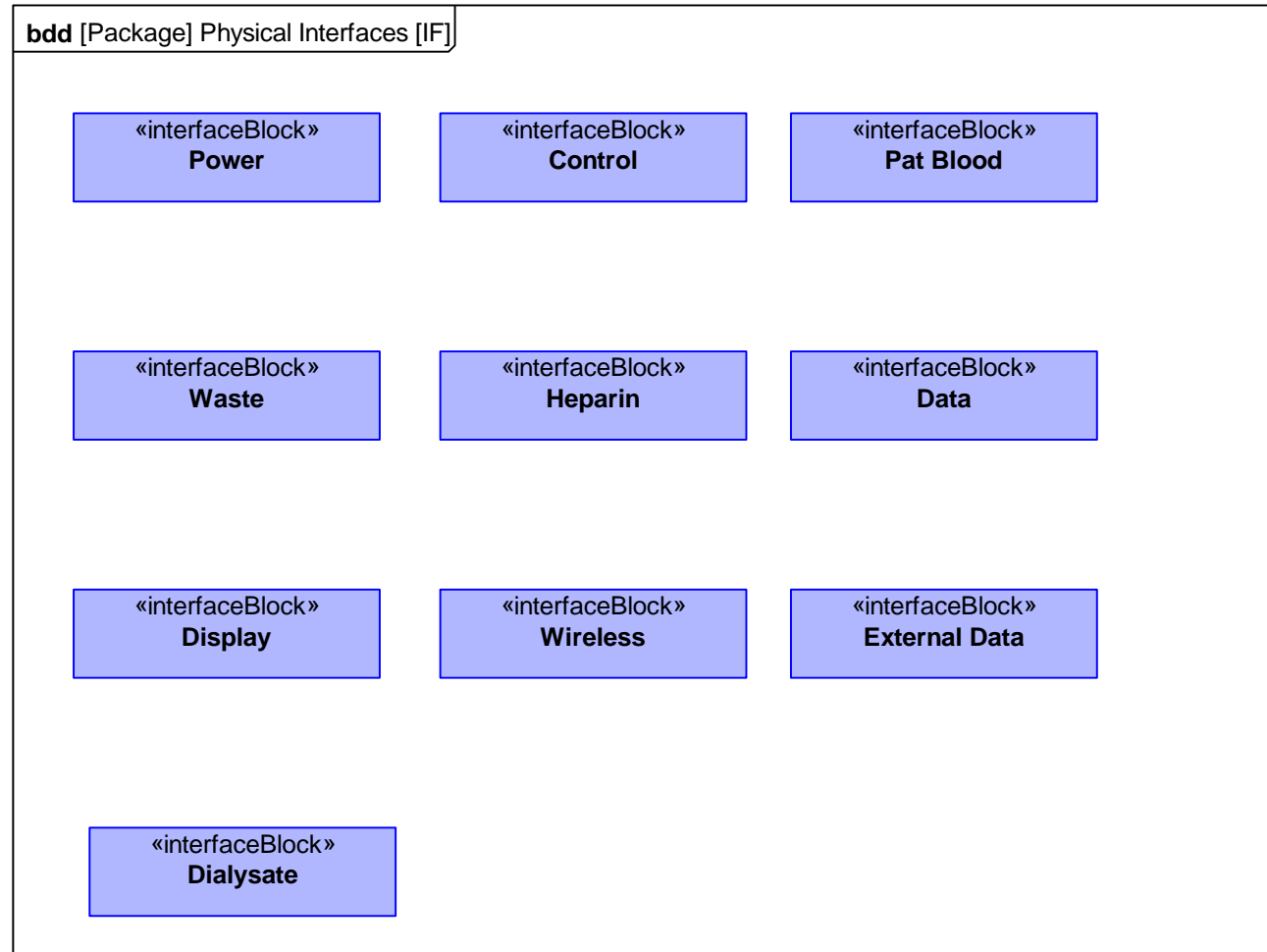
UI COMPONENTS



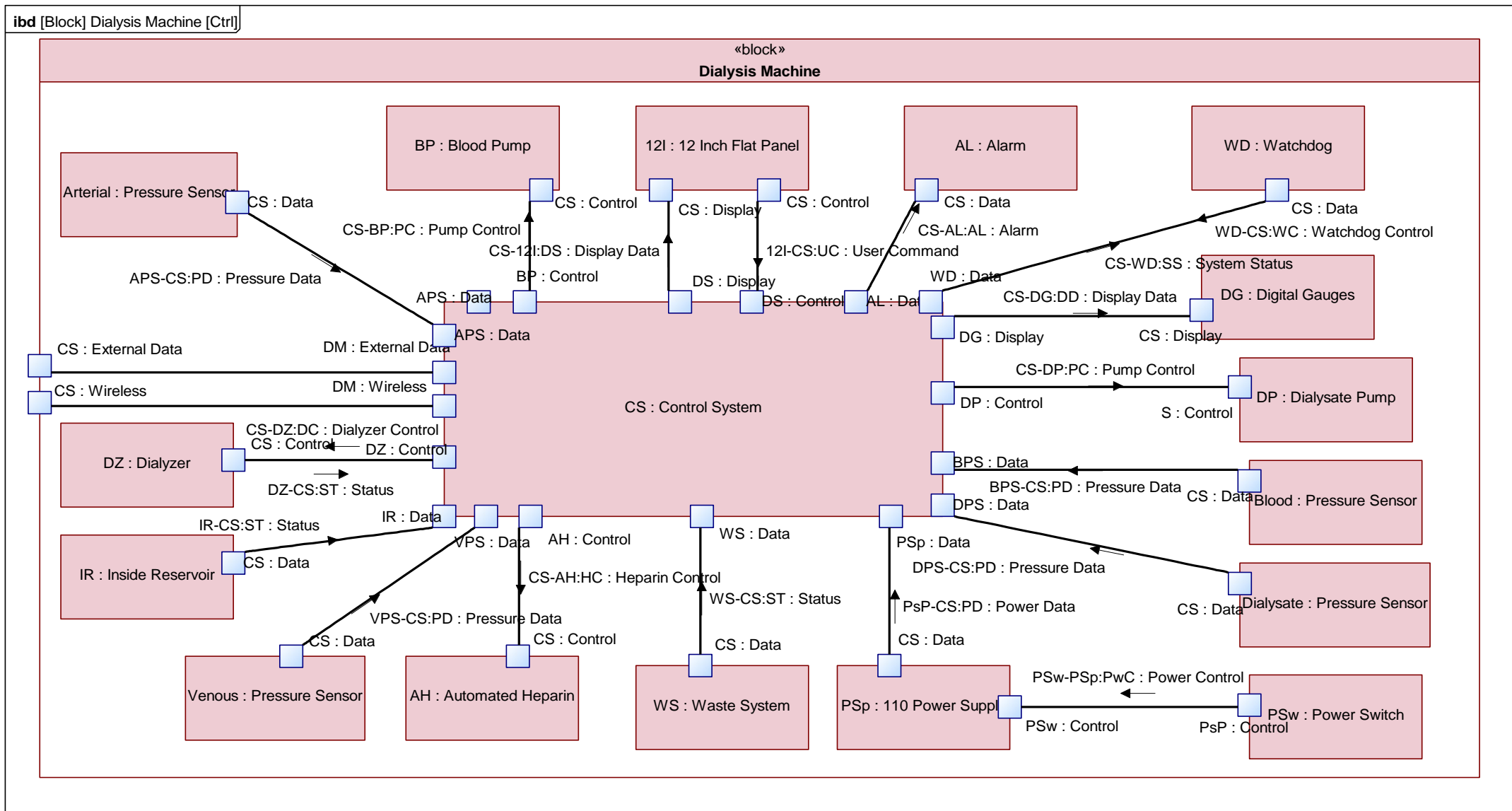
DATA FLOW ELEMENTS



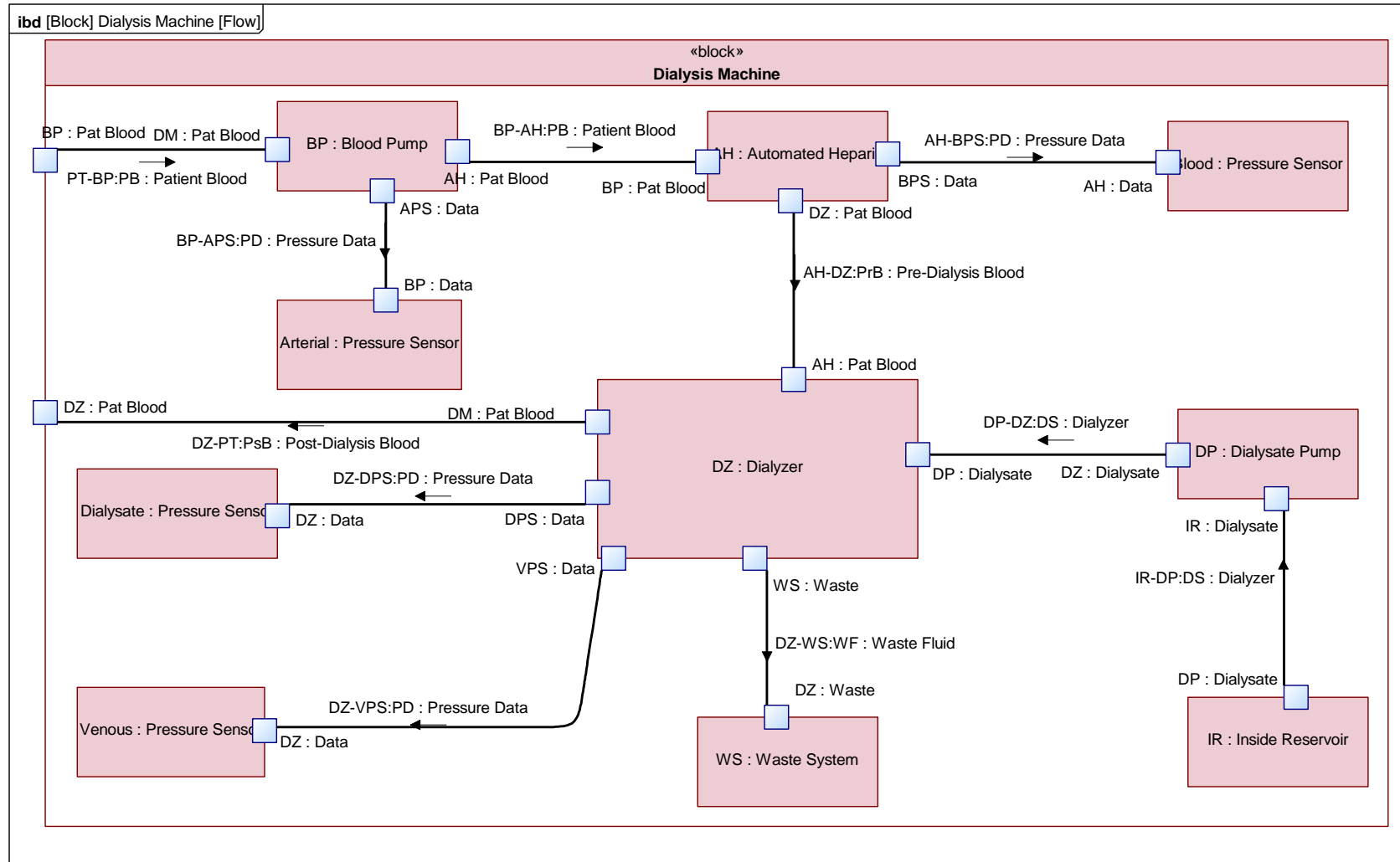
SYSTEM INTERFACES



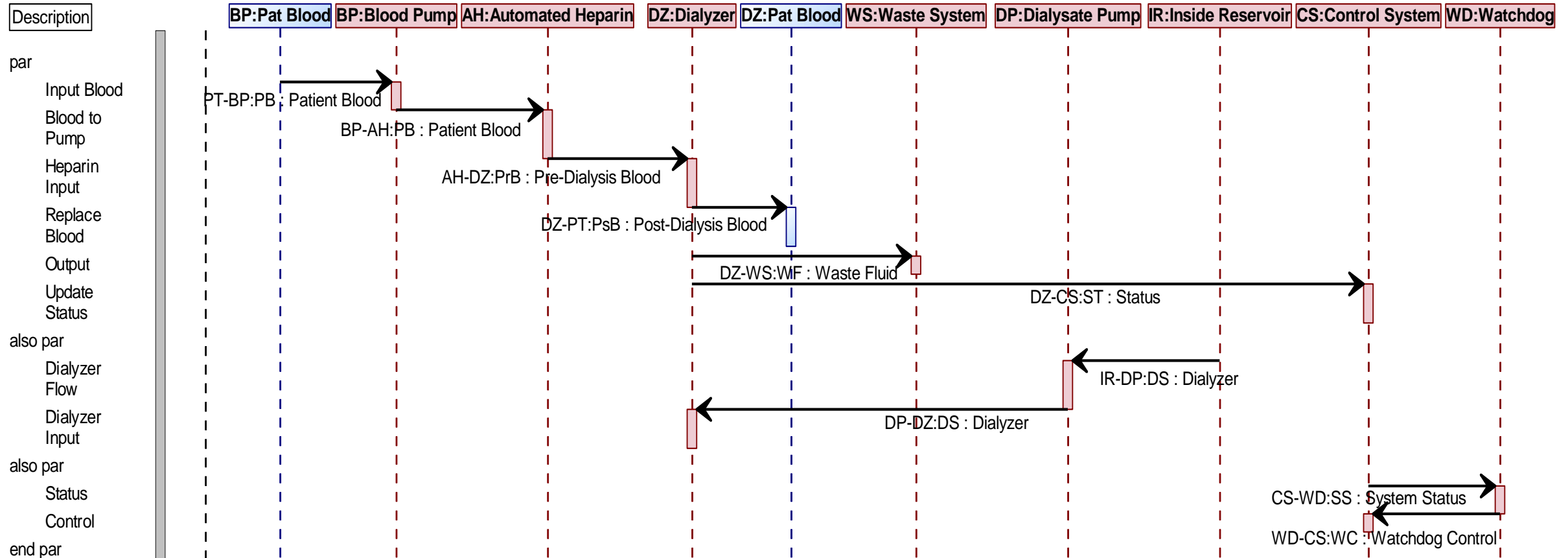
DIALYSIS MACHINE CONTROL SYSTEMS



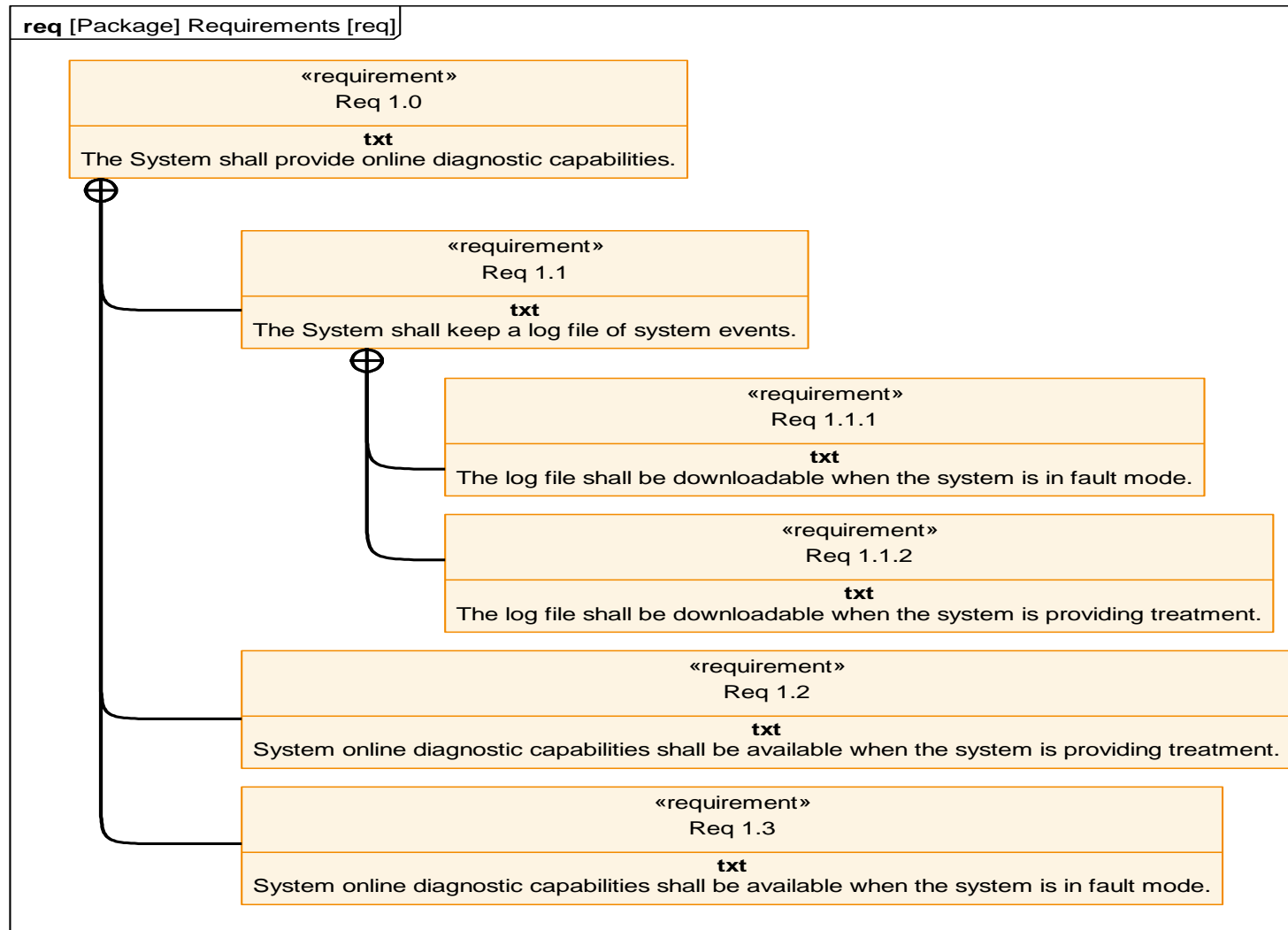
DIALYSIS PHYSICAL FLOWS



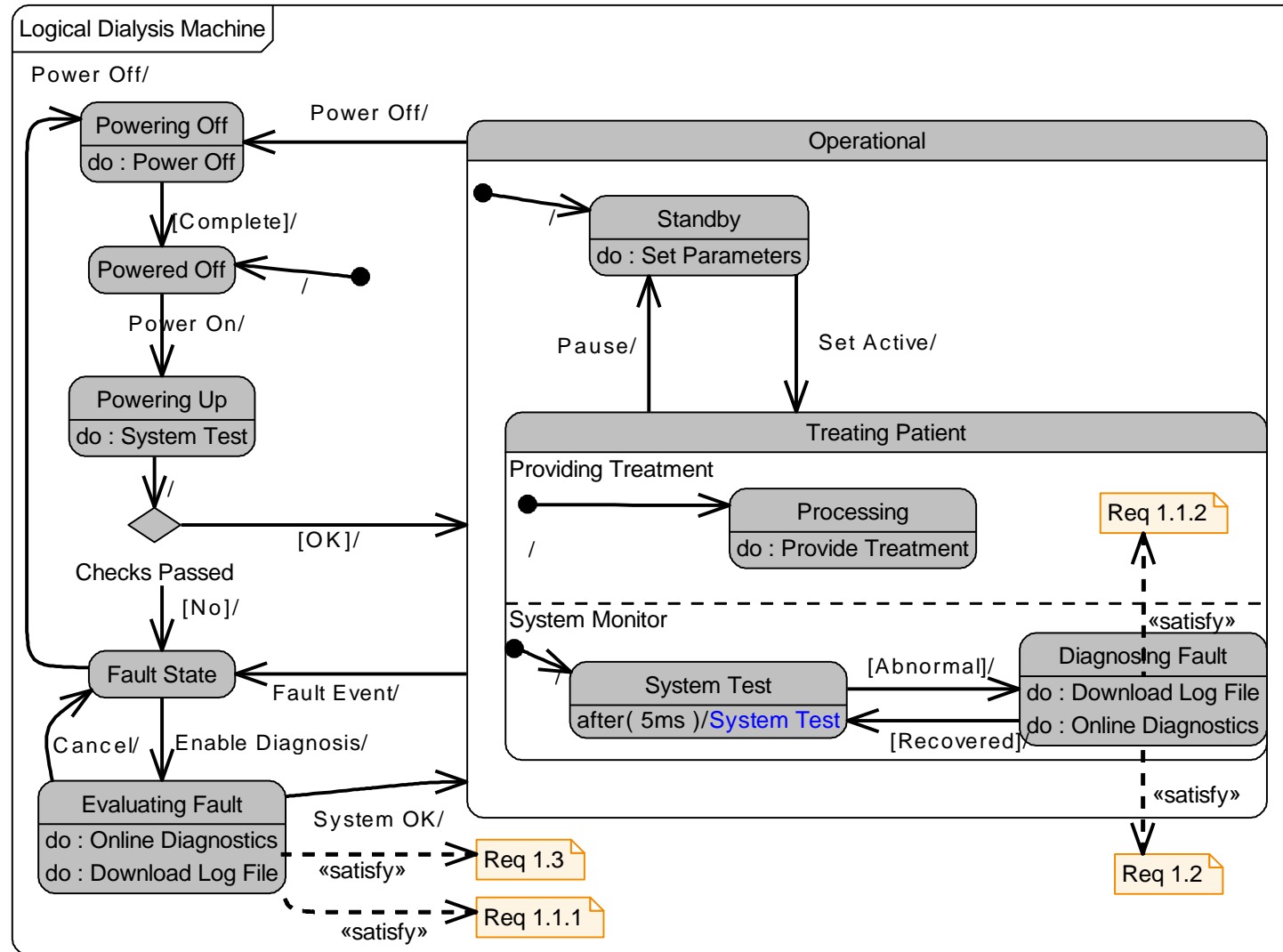
SYSTEM INTERACTIONS



SYSTEM REQUIREMENTS (EXTRACT)



SYSTEM OPERATIONAL STATES



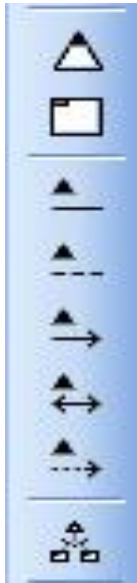
[Package] Requirements [tbl]

Type: Requirement Table (rt)

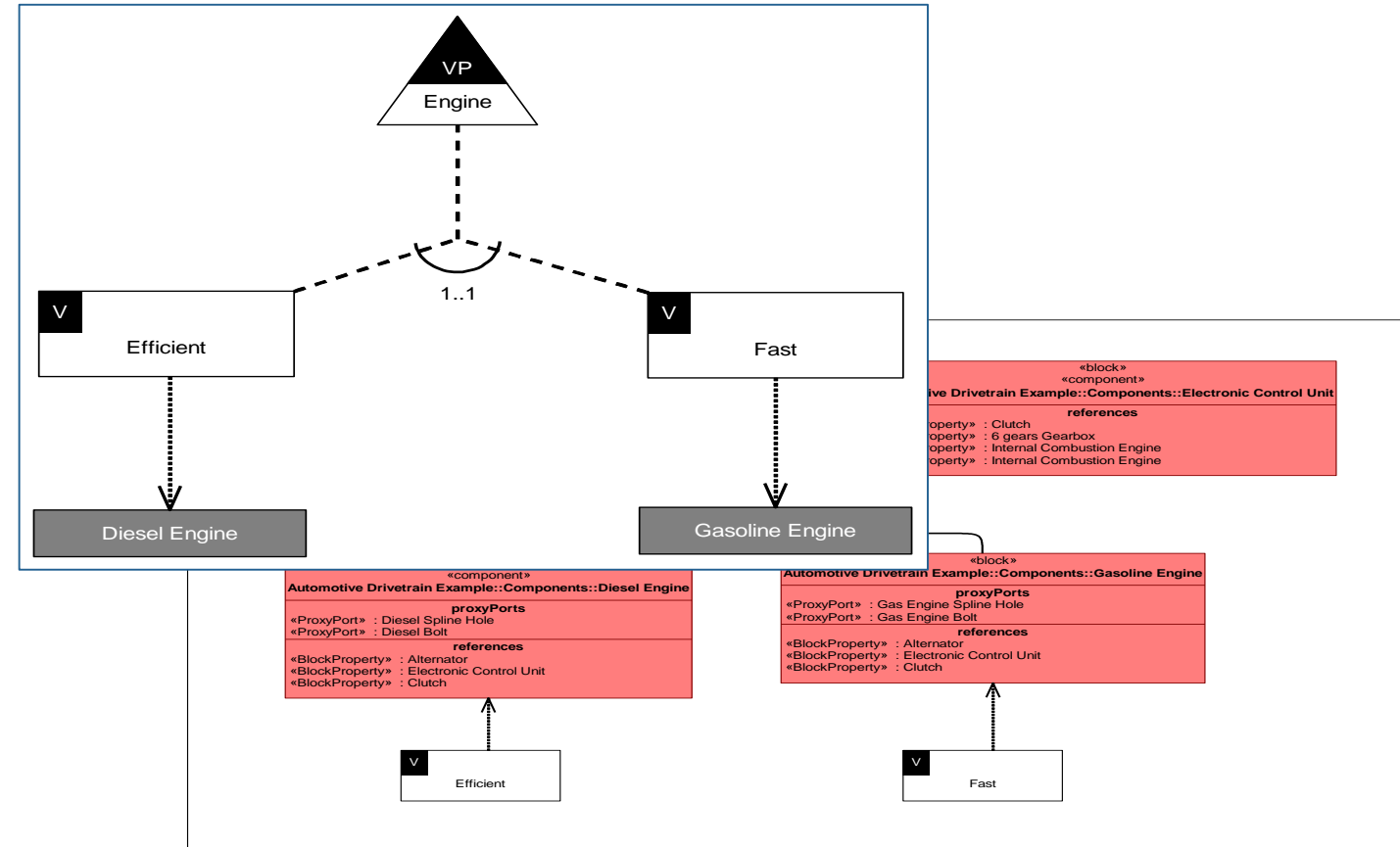
Description:

| Name | txt | satisfiedBy | refinedBy |
|-----------|--|---|---|
| Req 1.0 | The System shall provide online diagnostic capabilities. | | «Use Case» Perform Online Diagnostics |
| Req 1.1 | The System shall keep a log file of system events. | | |
| Req 1.2 | System online diagnostic capabilities shall be available when the system is providing treatment. | «Activity» Online Diagnostics | |
| Req 1.3 | System online diagnostic capabilities shall be available when the system is in fault mode. | «Activity» Online Diagnostics | |
| Req 1.1.1 | The log file shall be downloadable when the system is in fault mode. | «Activity» Download Log File | |
| Req 1.1.2 | The log file shall be downloadable when the system is providing treatment. | «Activity» Download Log File | |

- Variant Diagram
- Variation on all Diagrams
- Simple Notation



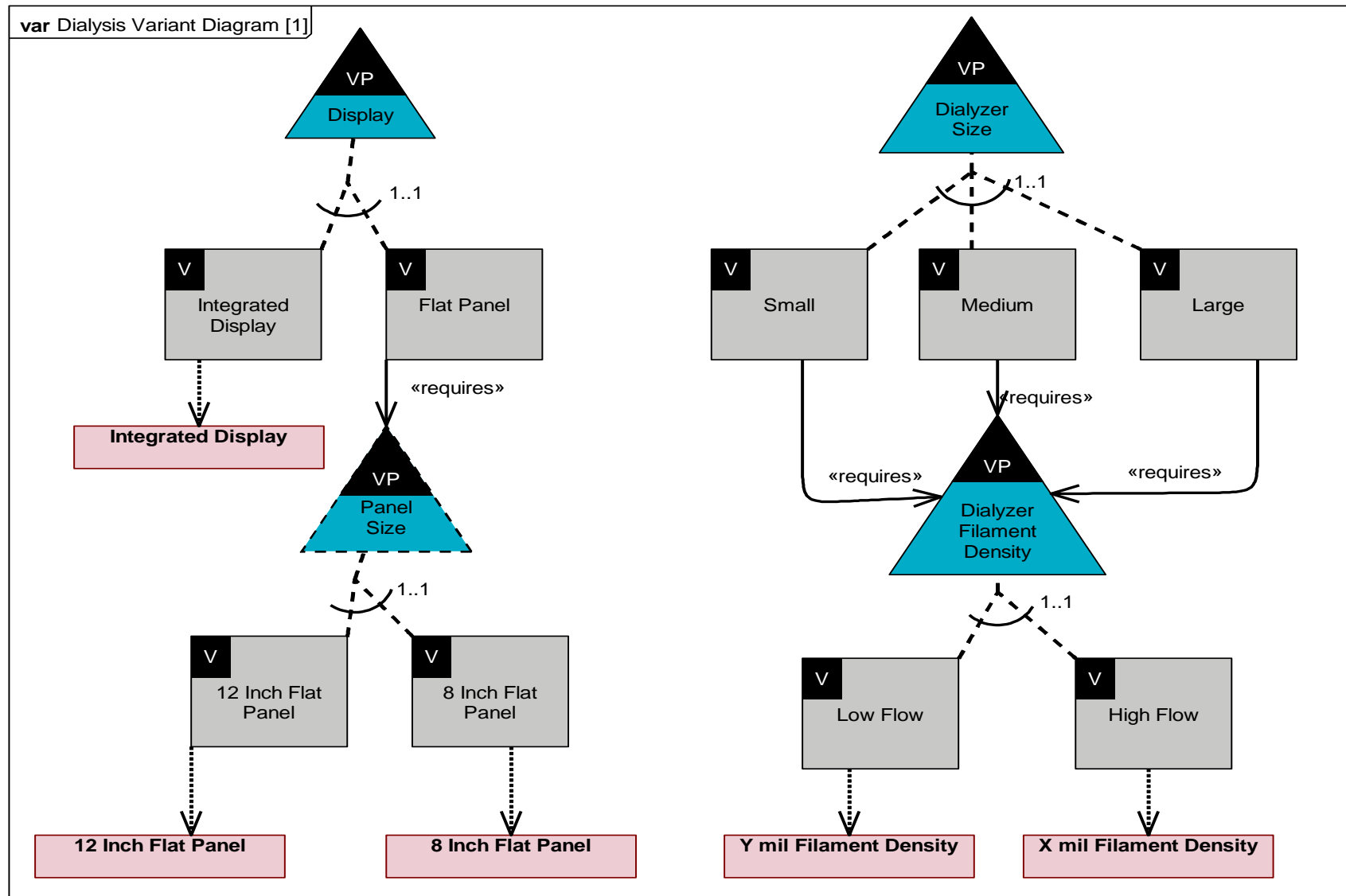
- Variation Point
- Variant
- Variability Dependency
 - Mandatory/Optional
- Requires Dependency
- Excludes Dependency
- Artifact Dependency
- Alternate Choice



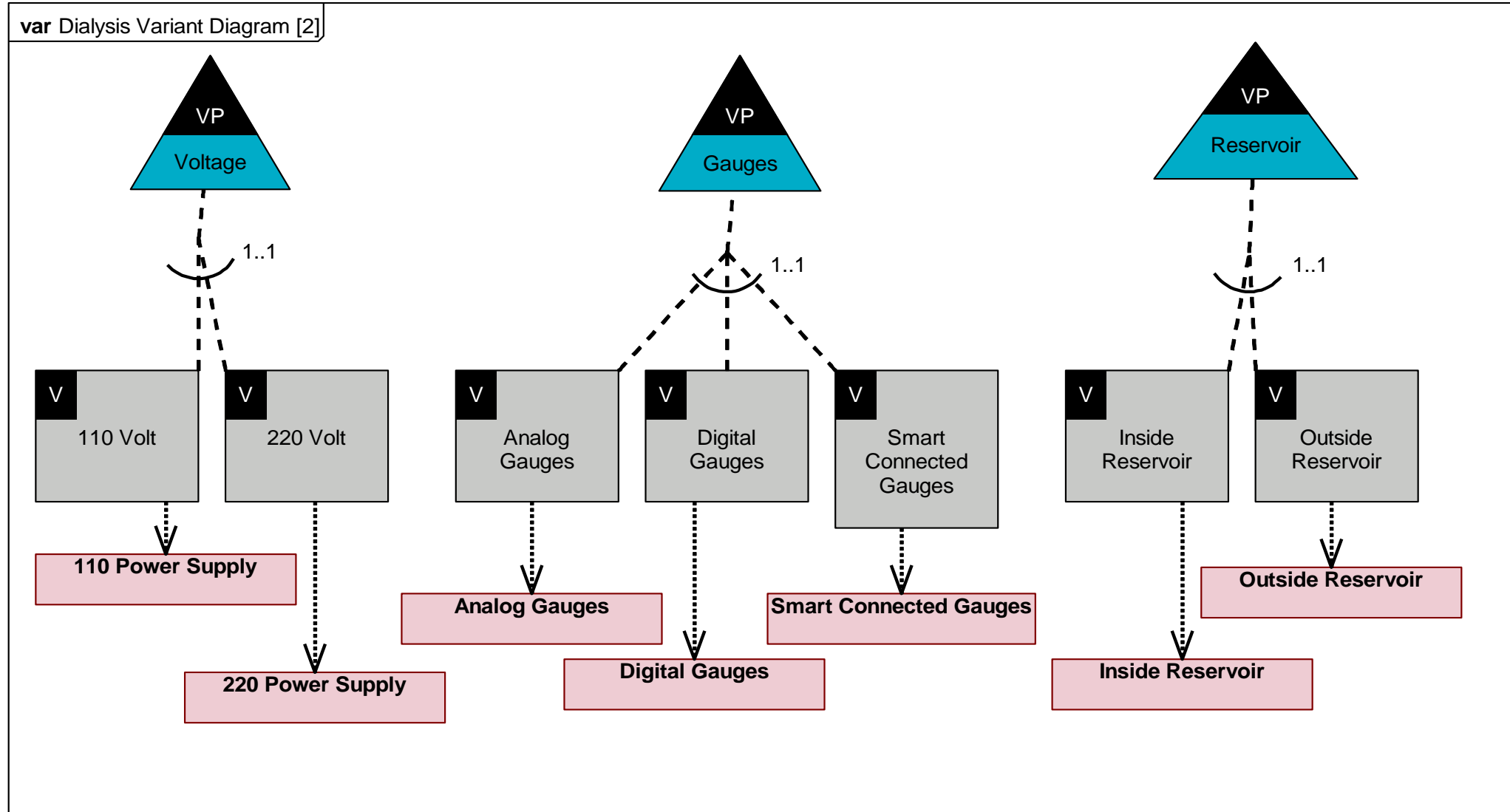
■ OVM

PALUNO, The Ruhr Institute of Software Technology
 Software Product Line Engineering (Pohl et al - Springer 2005)

SYSTEM VARIABILITY



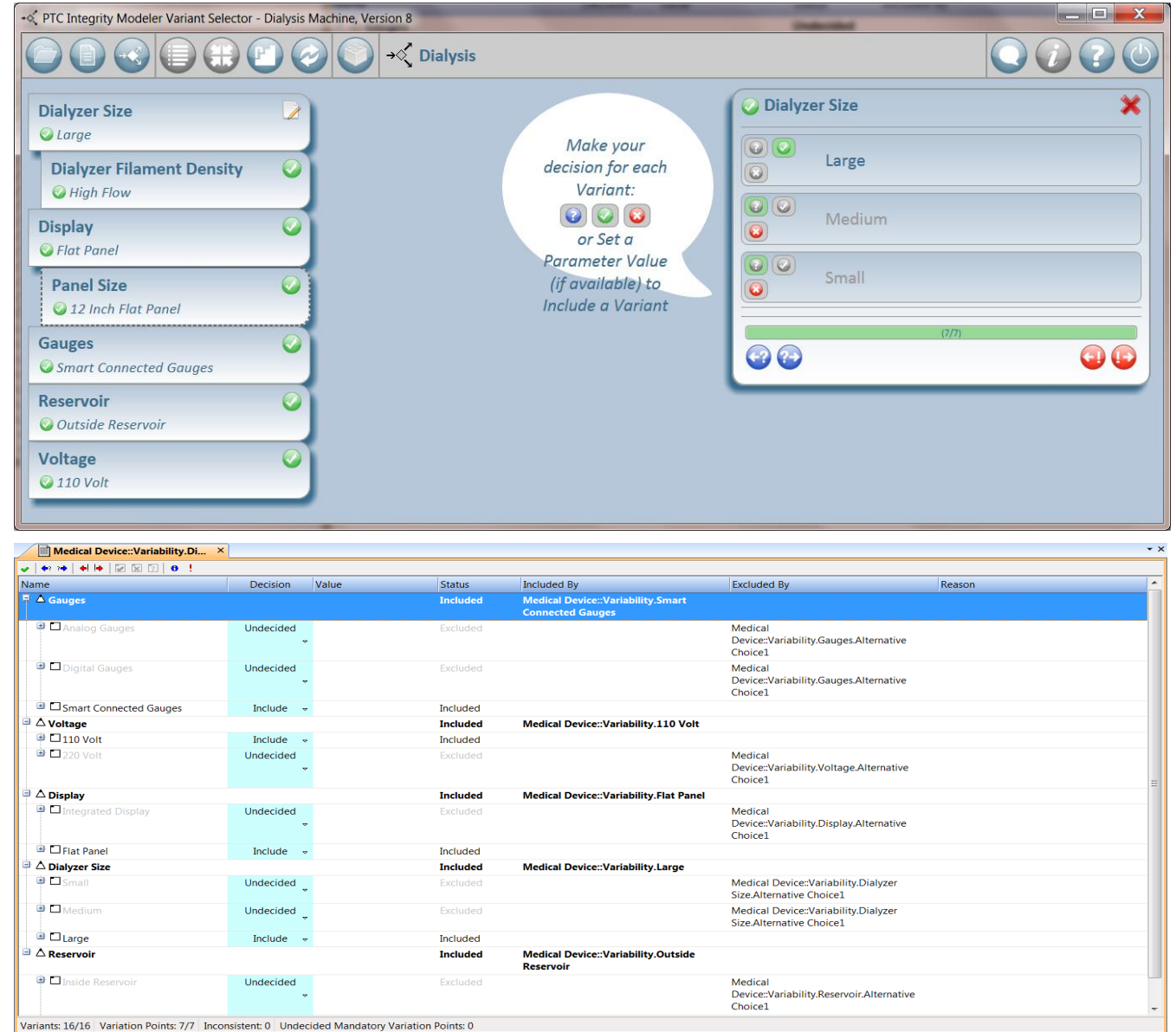
SYSTEM VARIABILITY



VARIANT SELECTION

- Variant Selector
Browser User Interface
External Variation Points Only
Jump to Next Decision/Problem
Progress Bar
- Decision Set Editor
Variant Debug
External & Internal
Variation Points
Jump to Next Decision/Problem

■ Both Edit the Same Decision Sets



The screenshot displays the PTC Integrity Modeler Variant Selector interface for a Dialysis Machine. The top window shows a list of decision sets on the left and a detailed view of the 'Dialyzer Size' decision on the right. A callout bubble instructs the user: "Make your decision for each Variant: or Set a Parameter Value (if available) to Include a Variant". The bottom window shows a table of variation points.

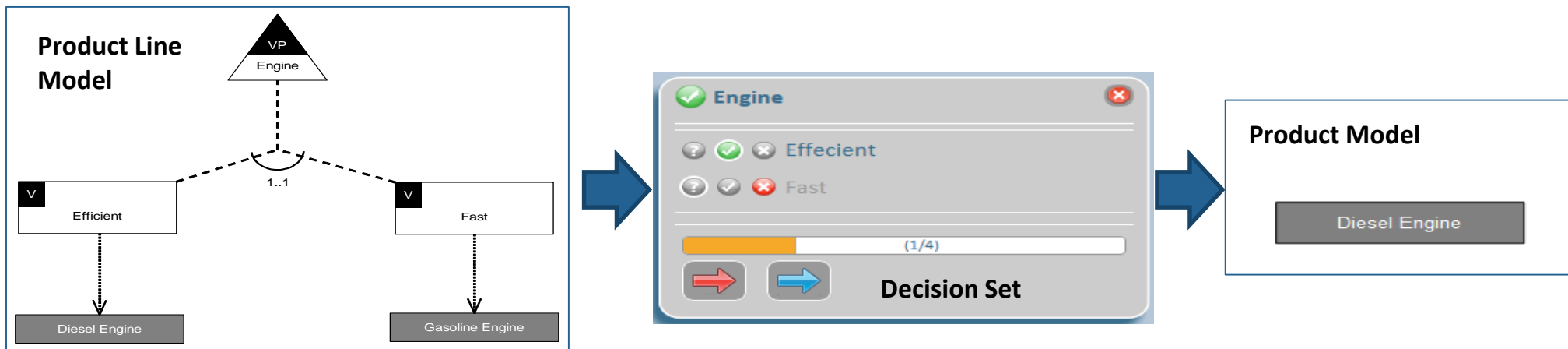
| Name | Decision | Value | Status | Included By | Excluded By | Reason |
|--------------------------|-----------|-------|----------|--|---|--------|
| ▲ Gauges | | | Included | Medical Device::Variability.Smart Connected Gauges | | |
| □ Analog Gauges | Undecided | | Excluded | | Medical Device::Variability.Gauges.Alternative Choice1 | |
| □ Digital Gauges | Undecided | | Excluded | | Medical Device::Variability.Gauges.Alternative Choice1 | |
| □ Smart Connected Gauges | Include | | Included | | | |
| ▲ Voltage | | | Included | Medical Device::Variability.110 Volt | | |
| □ 110 Volt | Include | | Included | | | |
| □ 220 Volt | Undecided | | Excluded | | Medical Device::Variability.Voltage.Alternative Choice1 | |
| ▲ Display | | | Included | Medical Device::Variability.Flat Panel | | |
| □ Integrated Display | Undecided | | Excluded | | Medical Device::Variability.Display.Alternative Choice1 | |
| □ Flat Panel | Include | | Included | | | |
| ▲ Dialyzer Size | | | Included | Medical Device::Variability.Large | | |
| □ Small | Undecided | | Excluded | | Medical Device::Variability.Dialyzer Size.Alternative Choice1 | |
| □ Medium | Undecided | | Excluded | | Medical Device::Variability.Dialyzer Size.Alternative Choice1 | |
| □ Large | Include | | Included | | | |
| ▲ Reservoir | | | Included | Medical Device::Variability.Outside Reservoir | | |
| □ Inside Reservoir | Undecided | | Excluded | | Medical Device::Variability.Reservoir.Alternative Choice1 | |

Variants: 16/16 | Variation Points: 7/7 | Inconsistent: 0 | Undecided Mandatory Variation Points: 0

- Auto-Create Product Models

Applies Variability Decisions

Unnecessary Variation Points, Variants & Base Model Artefacts Removed

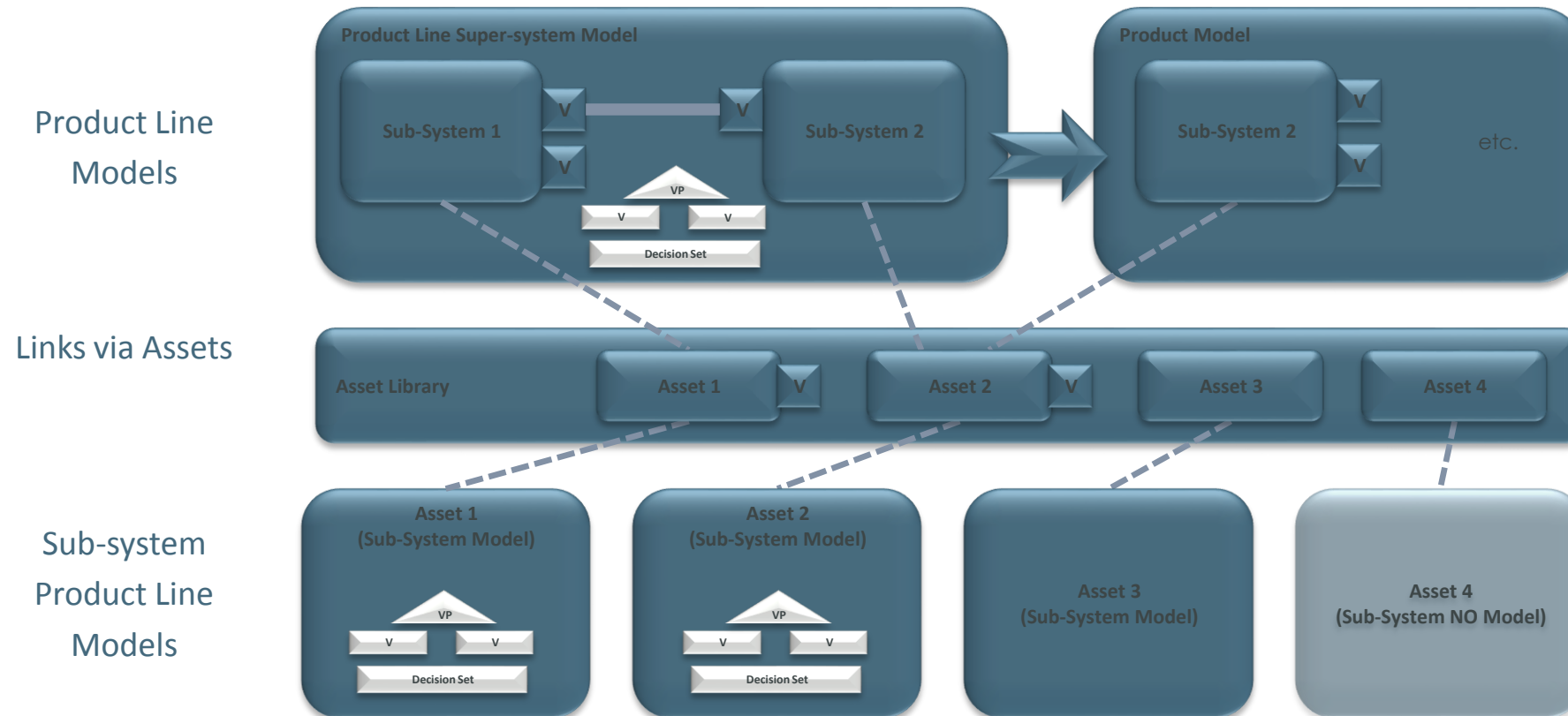


- Creates New Product Model Branch, Original Product Line Model Retained

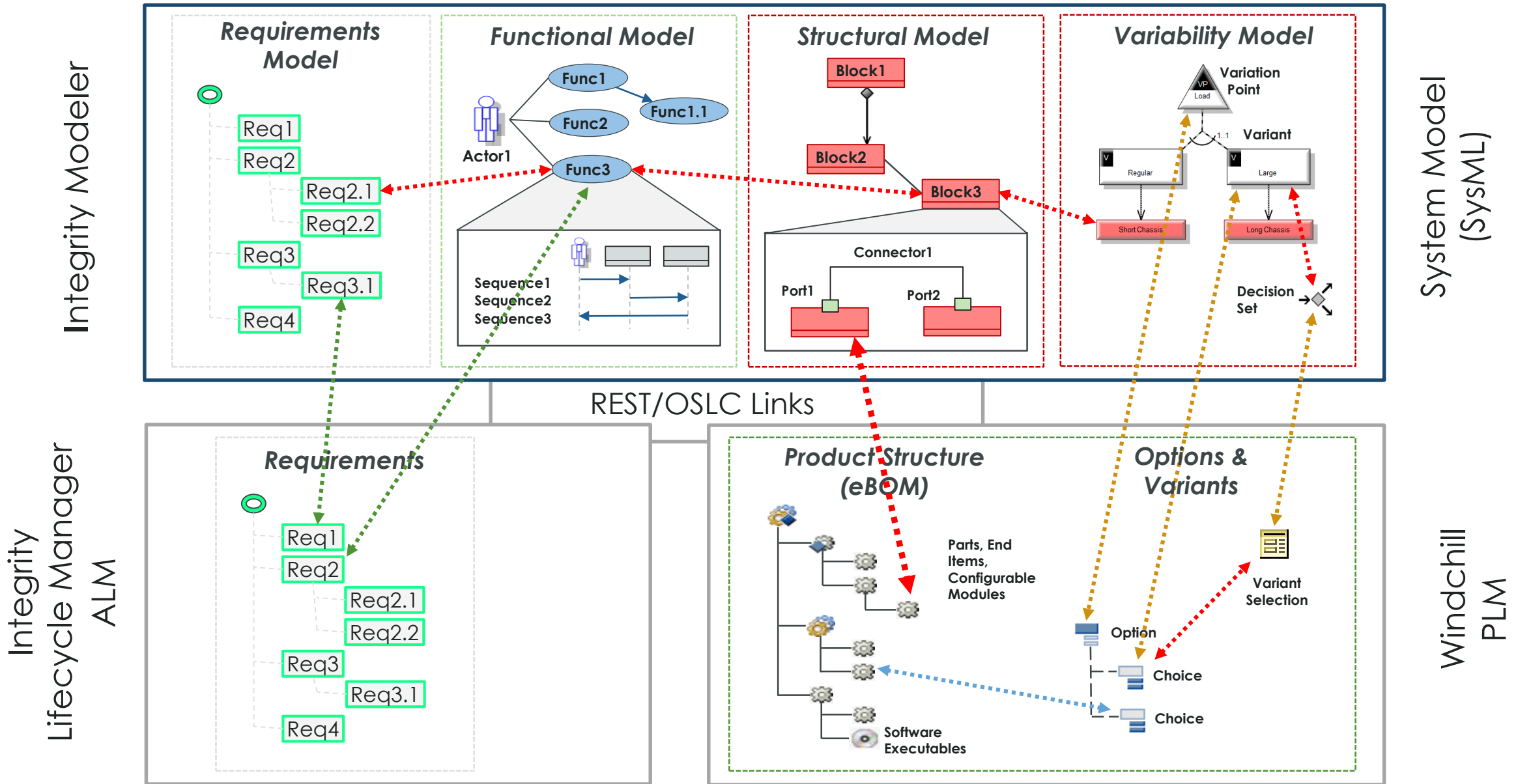
- Product Model suitable for Trade Studies, Simulation, Documentation & Generation

MODEL- BASED PRODUCT LINE ENGINEERING

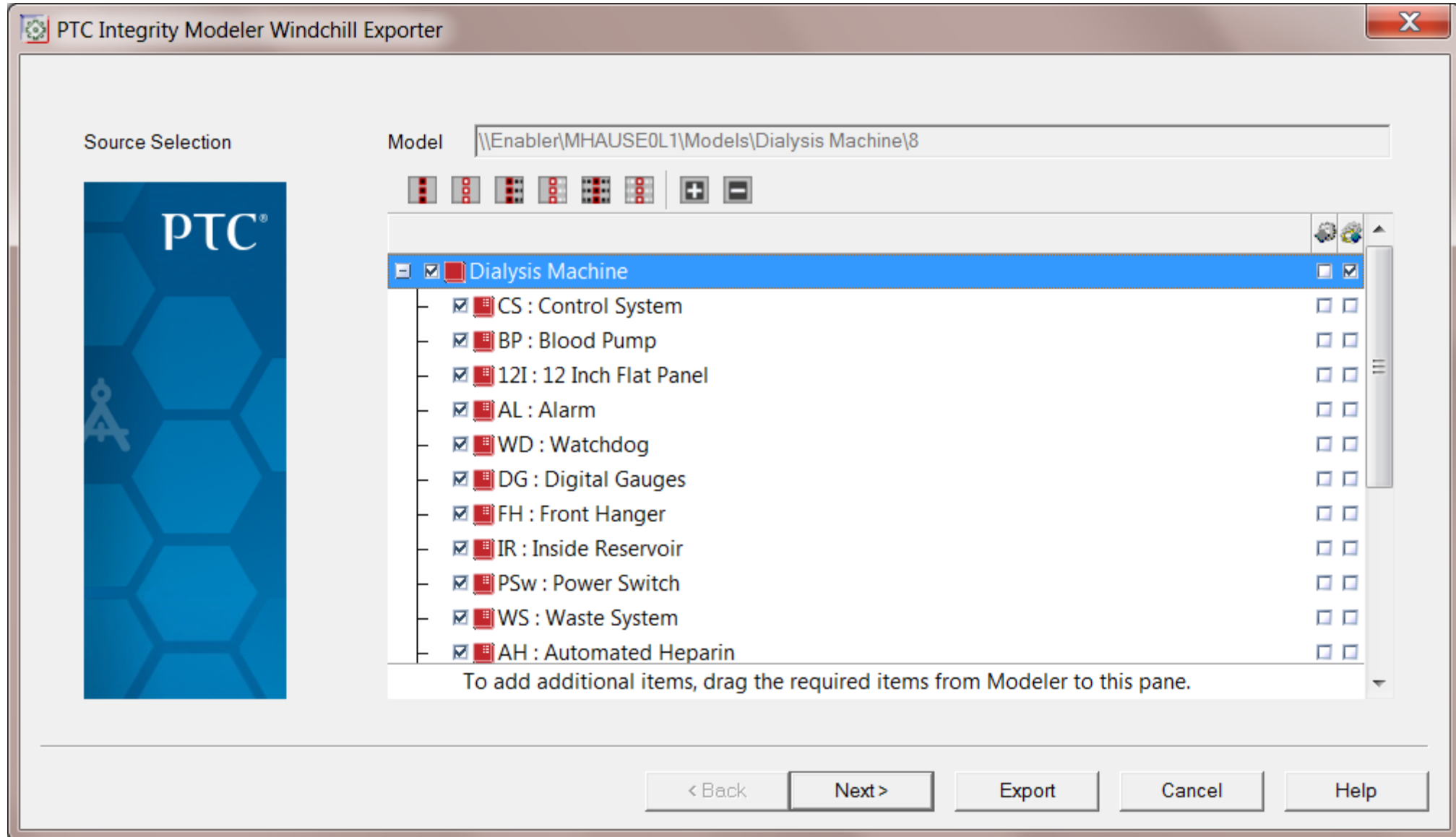
- Integrated MBSE, Modular Design & Variability Modeling = Model-based Product Line Engineering
- Uses the OMG Reusable Asset Specification (RAS)



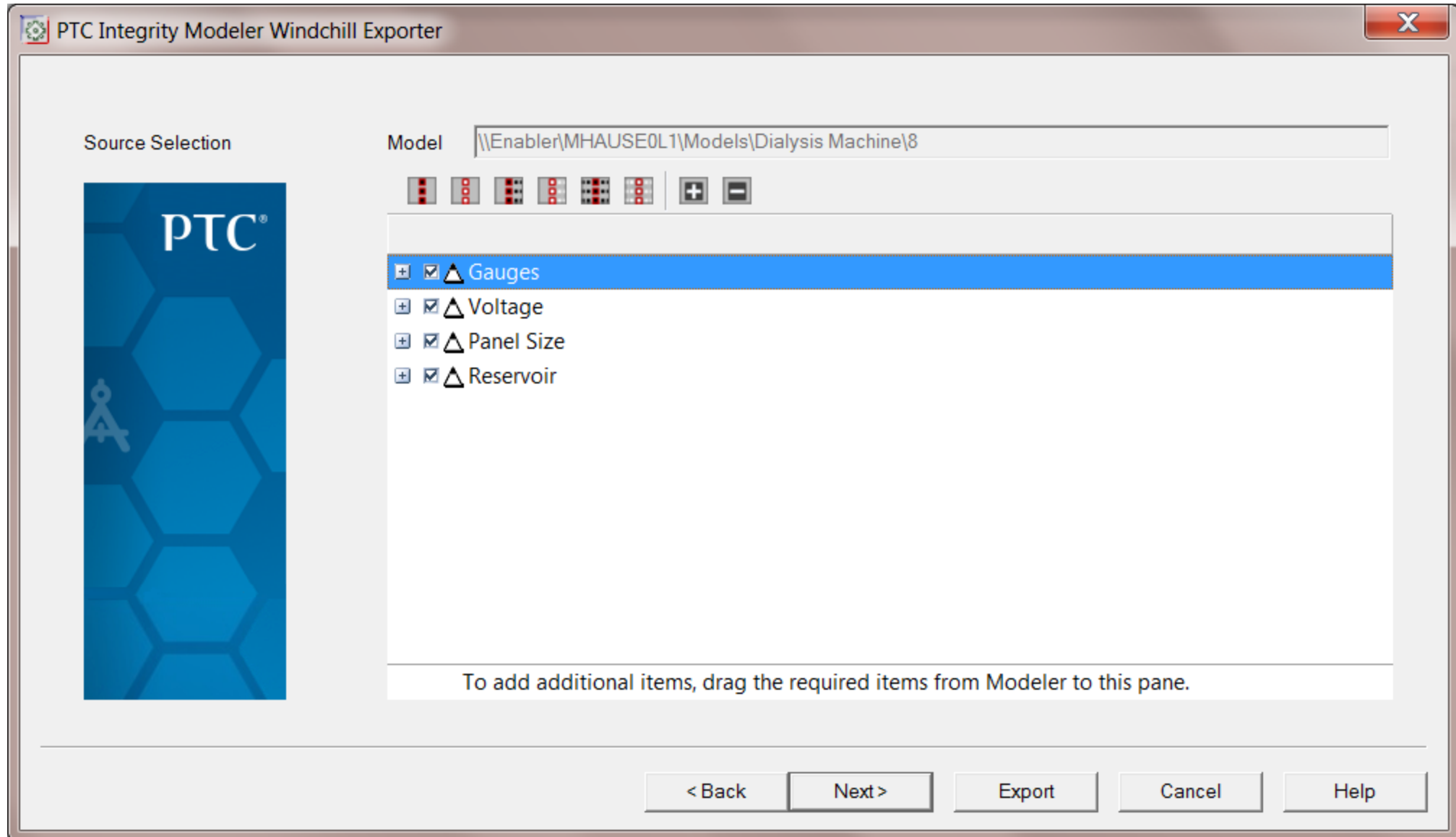
MBSE, ALM & PLM DIGITAL PRODUCT TRACEABILITY



SELECTING THE SYSML TO WINDCHILL TRACE ELEMENTS




SYSTEM VARIABILITY



EXPORT LOG

PTC Integrity Modeler Windchill Exporter

Export Log



```
0055 Exporting WTPart 'Waste System'
0056 Exporting WTPartUsageLink between WTPart 'Dialysis Machine' and WTPart 'Waste System (WS)'
0057 Exporting WTPart 'Automated Heparin'
0058 Exporting WTPartUsageLink between WTPart 'Dialysis Machine' and WTPart 'Automated Heparin (/
0059 Exporting WTPart '110 Power Supply'
0060 Exporting WTPartUsageLink between WTPart 'Dialysis Machine' and WTPart '110 Power Supply (P:
0061 Exporting ChoiceMappableChoiceLink for Choice '110 Volt' - WTPart '110 Power Supply'
0062 Exporting WTPart 'Pressure Sensor'
0063 Exporting WTPartUsageLink between WTPart 'Dialysis Machine' and WTPart 'Pressure Sensor (Ven
0064 Exporting WTPart 'Dialysate Pump'
0065 Exporting WTPartUsageLink between WTPart 'Dialysis Machine' and WTPart 'Dialysate Pump (DP)'
0066 Exporting WTPart 'Dialyzer'
0067 Exporting WTPartUsageLink between WTPart 'Dialysis Machine' and WTPart 'Dialyzer (DZ)'
0068 Exporting WTPartUsageLink between WTPart 'Dialysis Machine' and WTPart 'Pressure Sensor (Arte
0069 Exporting WTPartUsageLink between WTPart 'Dialysis Machine' and WTPart 'Pressure Sensor (Bloc
0070 Exporting WTPartUsageLink between WTPart 'Dialysis Machine' and WTPart 'Pressure Sensor (Dial
0071 Compressing XML files to 'C:\temp\WCE7B06.jar'
0072 Updating Tracelink file 'C:\temp\WCETracelinks.xml'
0073 -- Export Complete --
```

< Back Next > Exit Cancel Help

WINDCHILL BOM OF SYSML ELEMENTS



All Types Search ... Quick Links

Products > Dialysis Machine, OEM > Import from IM

Part - 00077, Dialysis Machine, OEM, A.1

Details Structure Related Objects Changes History Where Used Traceability AML/AVL Product Analytics UDI Submissions Substitutes/Alternates/Supersedes Replacement Connected Quality

Editing: Insert Existing, Remove, Insert New, Edit
Check Out/In: Check Out, Revise, Check In, My Checkouts
Clipboard: Paste, Copy
Viewing: Show, Views, Hide, Display
New/Add To: New, Add to
Filter: Current Filter, Set Path Filter, Edit Filter, Saved Filters, Disable Path Filter
Tools: Compare, Open in
Service: Generate
Reports: Reports, Export

Find in Structure: All, Advanced

| Identity | Version | Role_Name | Assigned Item Expressions | Assigned Us... |
|-------------------------------------|---------|-----------|------------------------------------|----------------|
| 00077, Dialysis Machine, OEM, A.1 | A.1 | | | |
| 00078, Control System, OEM, A.1 | A.1 | CS | | |
| 00079, Blood Pump, OEM, A.1 | A.1 | BP | | |
| 00080, 12 Inch Flat Panel, OEM, A.1 | A.1 | 12I | Panel Size = "12 Inch Flat Panel"; | |
| 00081, Alarm, OEM, A.1 | A.1 | AL | | |
| 00082, Watchdog, OEM, A.1 | A.1 | WD | | |
| 00083, Digital Gauges, OEM, A.1 | A.1 | DG | Gauges = "Digital Gauges"; | |
| 00084, Front Hanger, OEM, A.1 | A.1 | FH | | |
| 00085, Inside Reservoir, OEM, A.1 | A.1 | IR | Reservoir = "Inside Reservoir"; | |
| 00086, Power Switch, OEM, A.1 | A.1 | PSw | | |
| 00087, Waste System, OEM, A.1 | A.1 | WS | | |
| 00088, Automated Heparin, OEM, A.1 | A.1 | AH | | |
| 00089, 110 Power Supply, OEM, A.1 | A.1 | PSp | Voltage = "110 Volt"; | |
| 00090, Pressure Sensor, OEM, A.1 | A.1 | Venous | | |
| 00090, Pressure Sensor, OEM, A.1 | A.1 | Blood | | |
| 00090, Pressure Sensor, OEM, A.1 | A.1 | Dialysate | | |
| 00090, Pressure Sensor, OEM, A.1 | A.1 | Arterial | | |
| 00091, Dialysate Pump, OEM, A.1 | A.1 | DP | | |
| 00092, Dialyzer, OEM, A.1 | A.1 | DZ | | |

Attributes Uses Supersedes Occurrences Classification Visualization

Part Attributes
Thumbnail:
Number: 00077

Edit Filter

Configuration Specification Spatial Filter Option Filter Attribute Filter Path Filter

Option Set - Dialysis Machine(8), A.1 Standard Disable Rule Checking:

Design Option

All Options (4 objects)

| Name | Choices | Group |
|------------|---------|-------|
| Gauges | | |
| Panel Size | | |
| Reservoir | | |
| Voltage | | |

M00008, Gauges

- Analog Gauges, ()
- Digital Gauges, ()
- Smart Connected Gauges, ()

*Indicates required field

OK Cancel

WINDCHILL TO MODELER LINKS



Product - Dialysis Machine, OEM

- Details
- Option Pool
- Option Sets x
- Product Families

Dialysis Machine (14 objects)

| Identity ↑ | Description |
|-----------------------------|-------------|
| Dialysis Machine, OEM | |
| M00008, Gauges | |
| M00016, Analog Gauges | |
| M00017, Digital Gauges | |
| M00018, Smart Connected ... | |
| M00009, Voltage | |
| M00019, 110 Volt | |
| M00020, 220 Volt | |
| M00010, Panel Size | |
| M00021, 12 Inch Flat Panel | |
| M00022, 8 Inch Flat Panel | |
| M00011, Reservoir | |
| M00023, Inside Reservoir | |
| M00024, Outside Reservoir | |

(0 objects selected)

- Design Option
- Conditional Rules
- Include Rules
- Exclude Rules
- Enable Rules
- Expression Aliases

Options (4 objects)

| Name ↑ | Description | Required | Single Selection | Choices |
|------------|-------------|----------|------------------|---|
| Gauges | | Yes | Yes | Analog Gauges, Digital Gauges, Smart Connected Gauges |
| Panel Size | | No | Yes | 12 Inch Flat Panel, 8 Inch Flat Panel |
| Reservoir | | Yes | Yes | Inside Reservoir, Outside Reservoir |
| Voltage | | Yes | Yes | 110 Volt, 220 Volt |

(0 objects selected)

WINDCHILL TO REQUIREMENTS LINKS IN ILM

PTC.ManageTraces.IntegrityRequirementsMashup - Mozilla Firefox
icenterv05.ptc.com:8084/Thingworx/Runtime/index.html#mashup=PTC.ManageTraces.IntegrityRequirementsMashup&resourceSoftType=com.ptc.tir.RequirementResource&bomData=undefined&dc

PTC® Navigate™ Manage Traces

icenterv05 Document 485 Requirement text filter Filter Trace Satisfy Apply

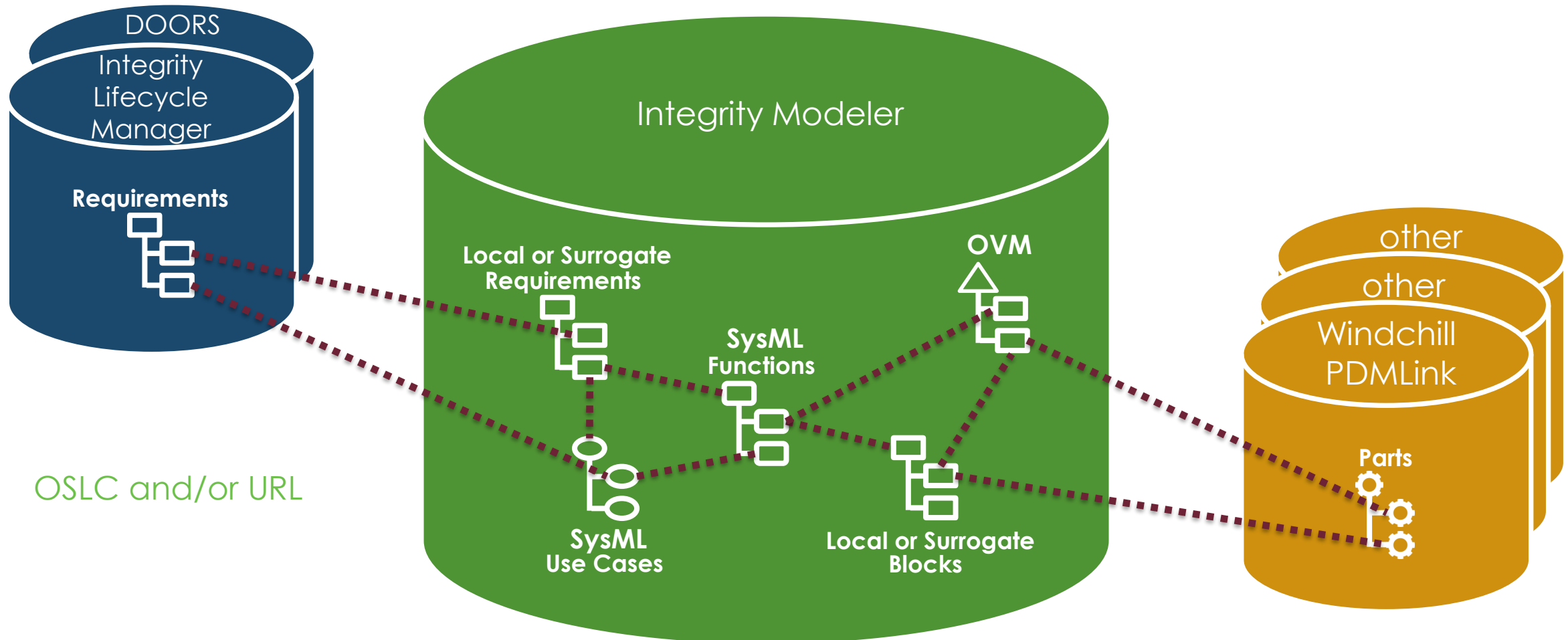
| Id | Category | Description |
|-----|----------------------|---------------------------------|
| 487 | Heading | Introduction |
| 489 | Comment | This document is in response 1 |
| 491 | Heading | System Requirements |
| 497 | Heading | Waterproof Requirements |
| 499 | Business Requirement | In order to adhere to safety re |
| 501 | System Requirement | Because of base waterproof pr |
| 511 | Heading | Time Zone Requirements |
| 513 | System Requirement | All time zones must run of the |
| 515 | System Requirement | When one time zone time is cl |
| 517 | Heading | Timer Requirements |
| 519 | System Requirement | The timer must have a user in |
| 521 | System Requirement | For the Timer feature, the cou |
| 523 | Heading | Chronometer Requirements |
| 525 | System Requirement | The chronometer must have a |
| 527 | System Requirement | For the chronometer, the cour |
| 493 | Heading | Synchronization Requirements |
| 503 | System Requirement | Must be accurate to within 1 s |
| 505 | System Requirement | Must have a mechanism for cc |
| 507 | System Requirement | Must use the client API for the |

| Number | Name | Version |
|-----------------|---------------------------------------|--------------|
| NWR DTS01951339 | NWR DIALYSIS THERAPY SYSTA.8 (Design) | |
| 0000000109 | NWR Dialysis Design | A.6 (Design) |
| 0000000058 | Is_901151_01_item2.prt | A.2 (Design) |
| 0000000004 | NW_Door | A.3 (Design) |
| 0000000011 | Venous Pressure Monitor | A.4 (Design) |
| 0000000007 | Dialyzer_Bracket | A.2 (Design) |
| 0000000101 | wheel_tente.prt | B.1 (Design) |
| 0000000092 | Drip_Arm_Bracket | A.2 (Design) |
| 0000000021 | Container_Assembly | A.3 (Design) |
| 0000000108 | Arterial Pressure Monitor | A.5 (Design) |
| 0000000071 | Screen | A.2 (Design) |
| 0000000022 | Tool Tray | A.2 (Design) |
| 0000000086 | Drip_Arm | A.2 (Design) |
| 0000000105 | POWER SUPPLY ASM | A.3 (Design) |
| 0000000026 | Drip_Arm2 | A.2 (Design) |
| 0000000056 | Dialyzer | B.1 (Design) |
| 0000000081 | Drug_Bag | A.3 (Design) |
| 0000000075 | NWR CamClamp | A.2 (Design) |
| 0000000072 | Blood_Lines | A.3 (Design) |

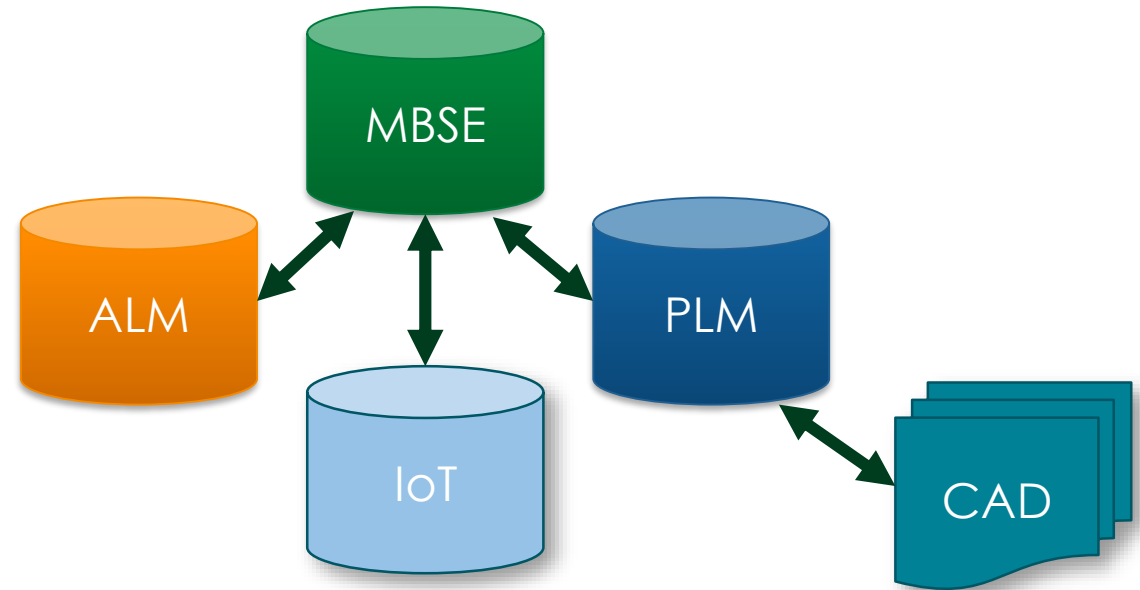
Start | Part - NWR DTS... | PTC.ManageTr... | ServerManager... | MethodServer-2... | EN | 2:27 PM

INTEGRITY MODELER – MBSE TRACE HUB

External Traces & Model Surrogates with Visual Model Trace Links

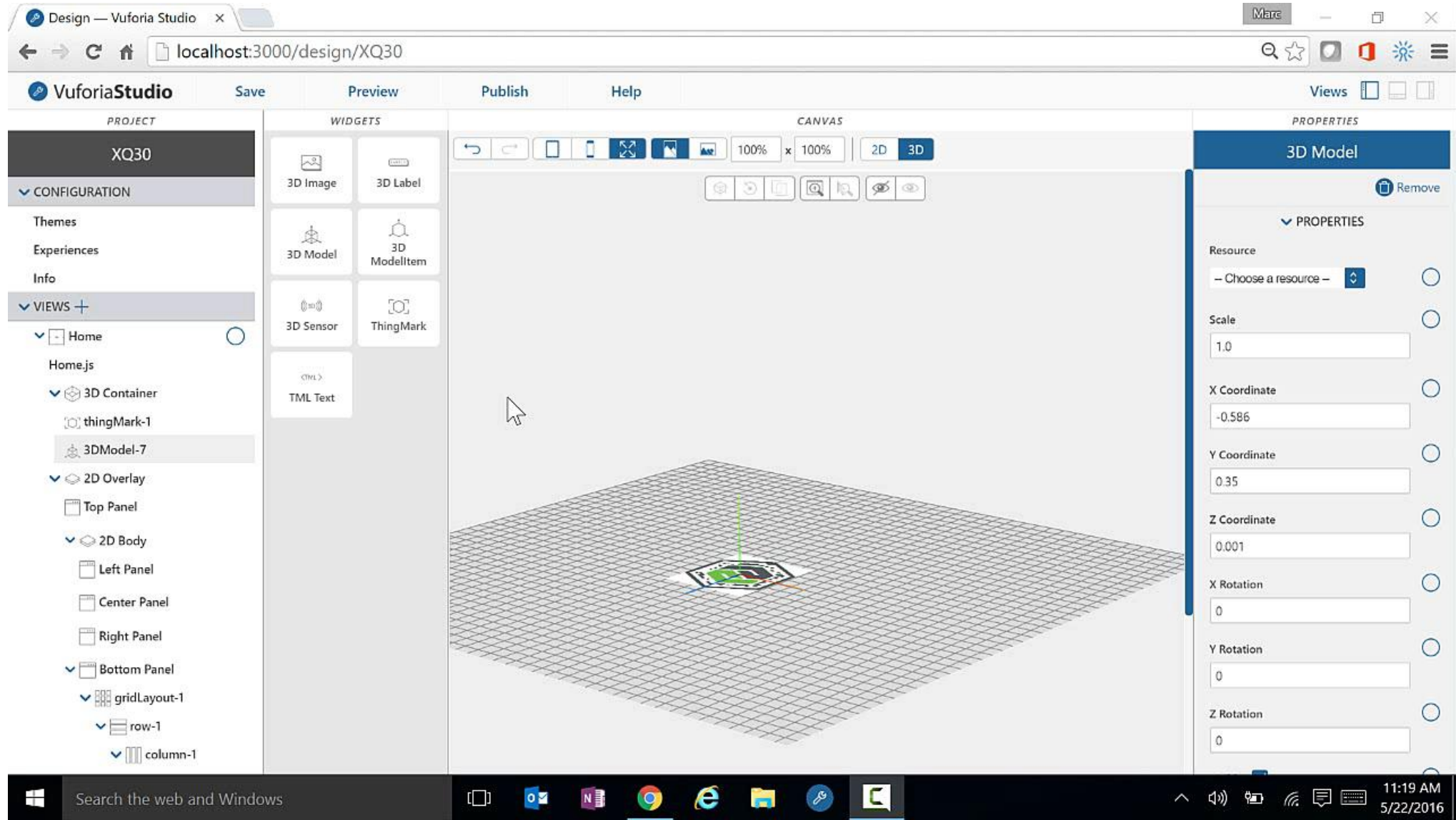


- Integrity Modeler 8.5 provides a range of new capabilities that enable product engineering toolchain and system of record integrations
- By integrating the entire toolchain and supporting end-to-end product development processes, Integrity Modeler 8.5 is able to perform the role of an information, or MBSE hub.

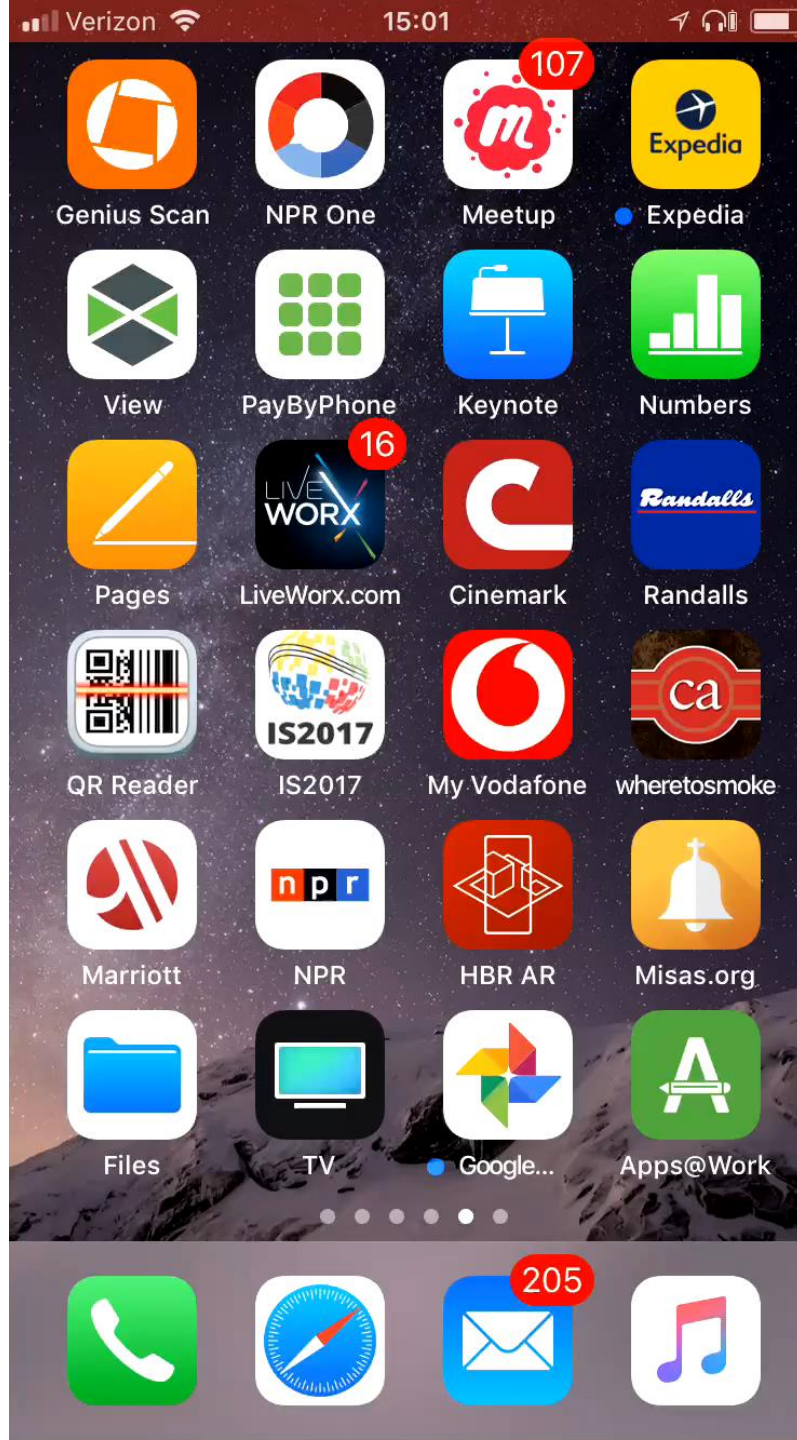


This ensures product development data across the systems engineering, product engineering and software engineering domains is connected and product development engineers can easily view all the relevant and related information they need regardless of the system in which it resides.

WHAT IF YOU COULD CREATE AND USE AUGMENTED REALITY EXPERIENCES IN LESS THAN A MINUTE? ... WITH YOUR ENGINEERING DATA?



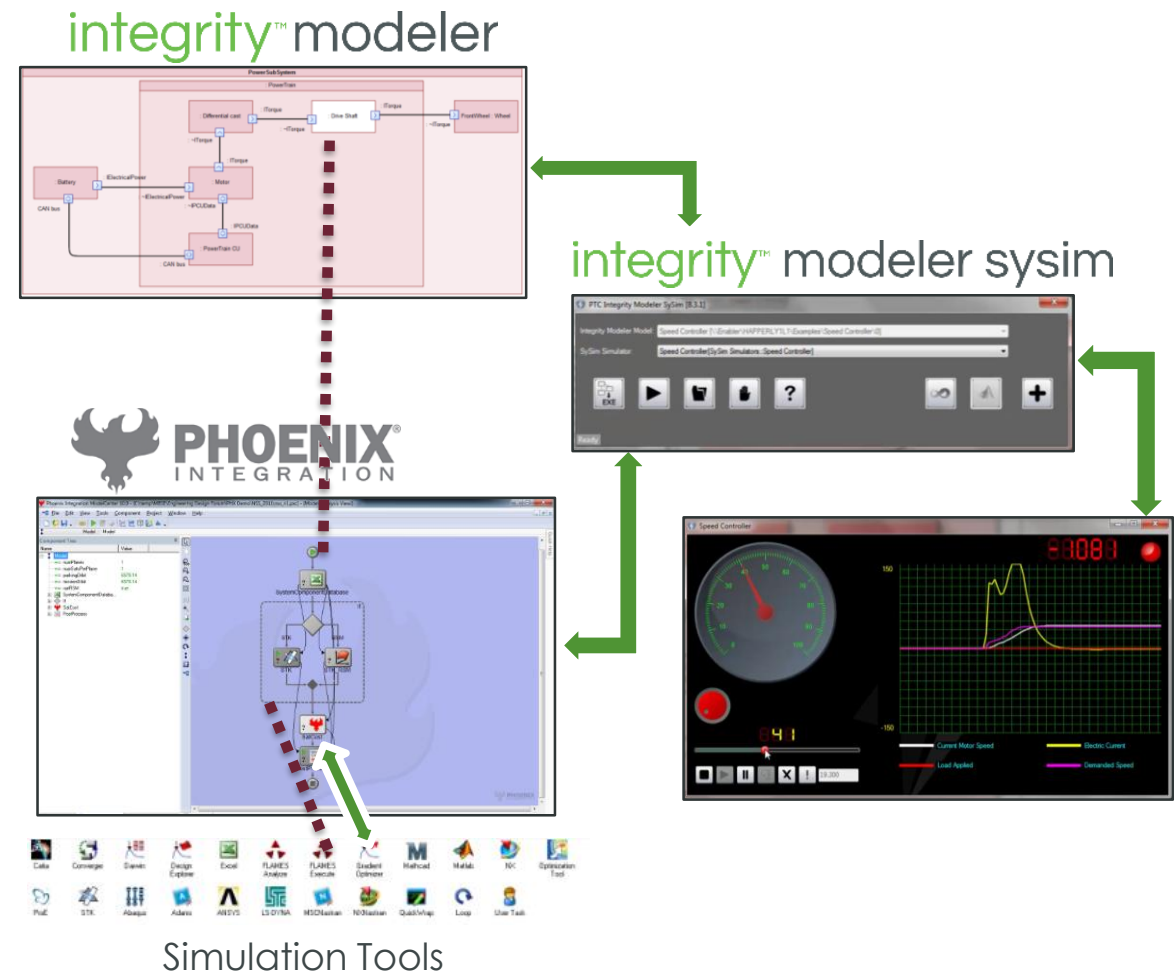
AN AUGMENTED REALITY VIEW OF THE DIALYSIS MACHINE



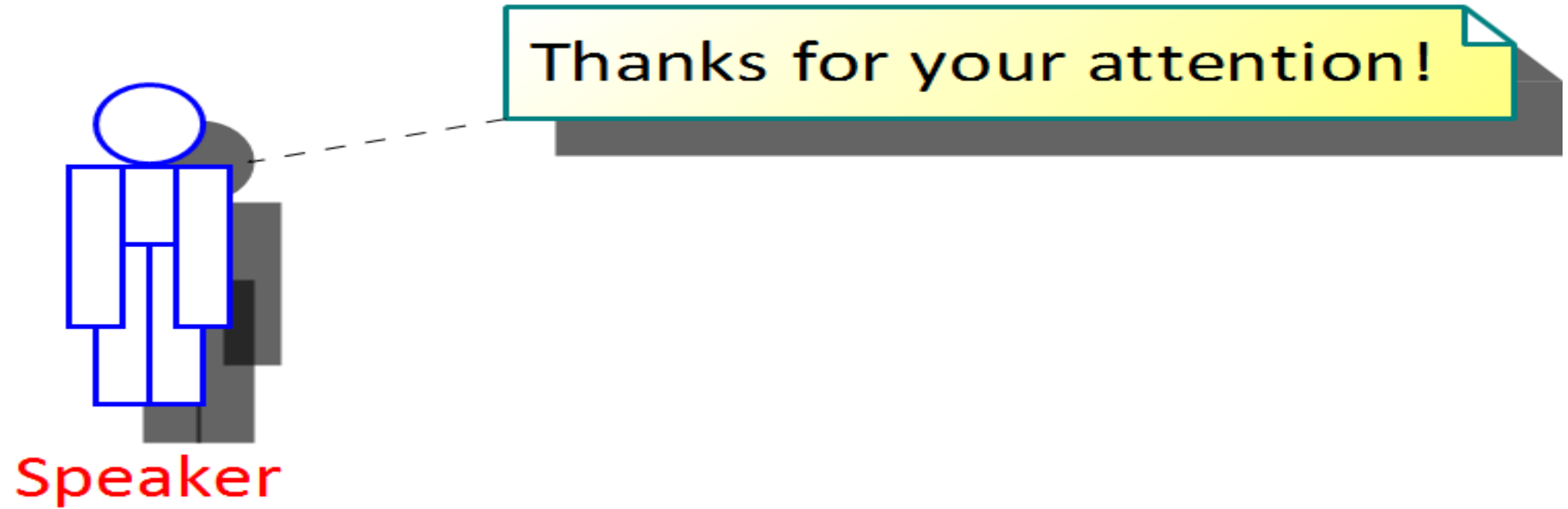
INTEGRITY MODELER 9.0 (1)

Co-simulation with 3rd Party Tools

- Integrity Modeler & SySim integration with Phoenix Integration's Model Center
 - Simulation Units linked to Blocks
 - Model Center Simulation Units
 - Model Center Simulation Workflows
 - Access to 200+ Simulation Tools
 - SySim Co-simulation
 - Model-drive, multi-scenario simulation
 - Visual simulation
 - Live or Batch Parameter Input



Planned for Sept 2018



THE DIGITAL ENGINEERING JOURNEY



Thank you for attending!
Share your experiences at #HWGSEC

