

# Innovating with MBSE - Medical Device Example

**Tony Komar**  
Siemens  
MBSE Evangelist  
@LinkedIn

**12/10/2020**

## My history with Capella.

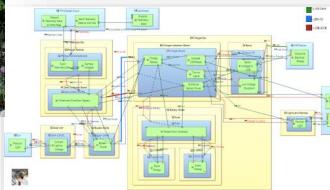
2017 Introduced to Capella, by a customer.



Shortly after I built my first model....



Solar Charger



2018 Siemens and OBEO announced partnership and product based on Capella



2019 coached middle school students on Capella

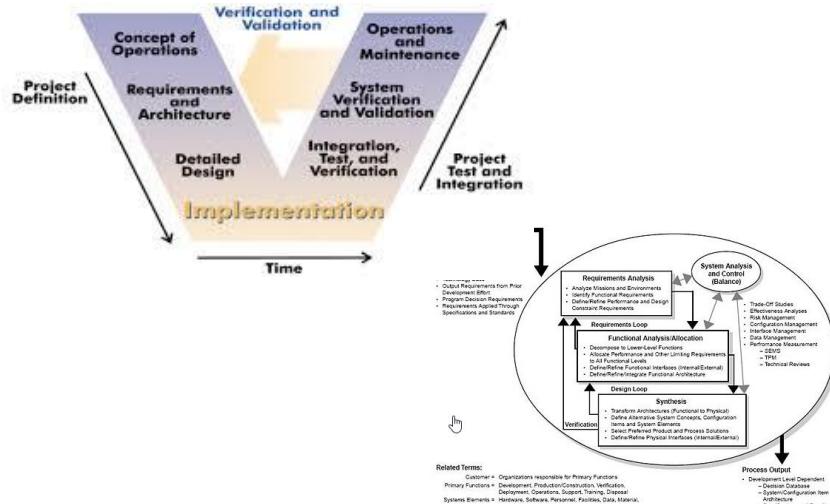
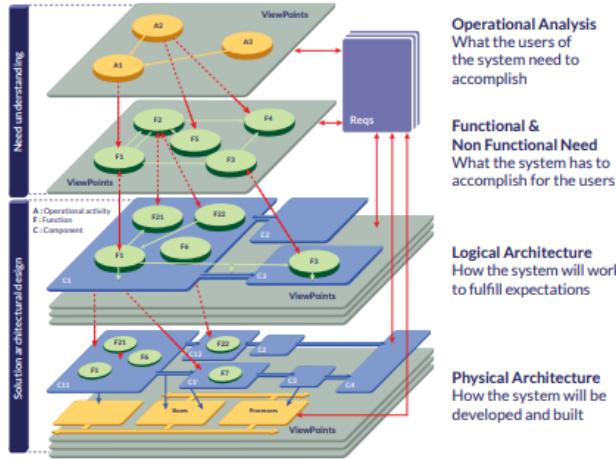


2019-20 Introduce SMW/Capella to over dozen companies of various industries.

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# One of my biggest challenges: How do you introduce Capella?

## Model Based System Engineering



Do you really have to understand 50+ years System Engineering knowledge to appreciate Capella?

There must be an easier way?

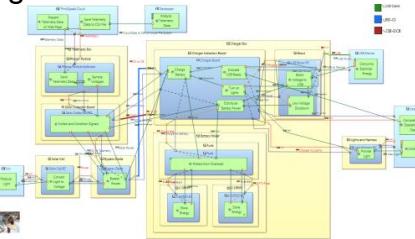
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# My answer: Capella is a tool for Innovation

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Solar Charger



Diabetic Care System

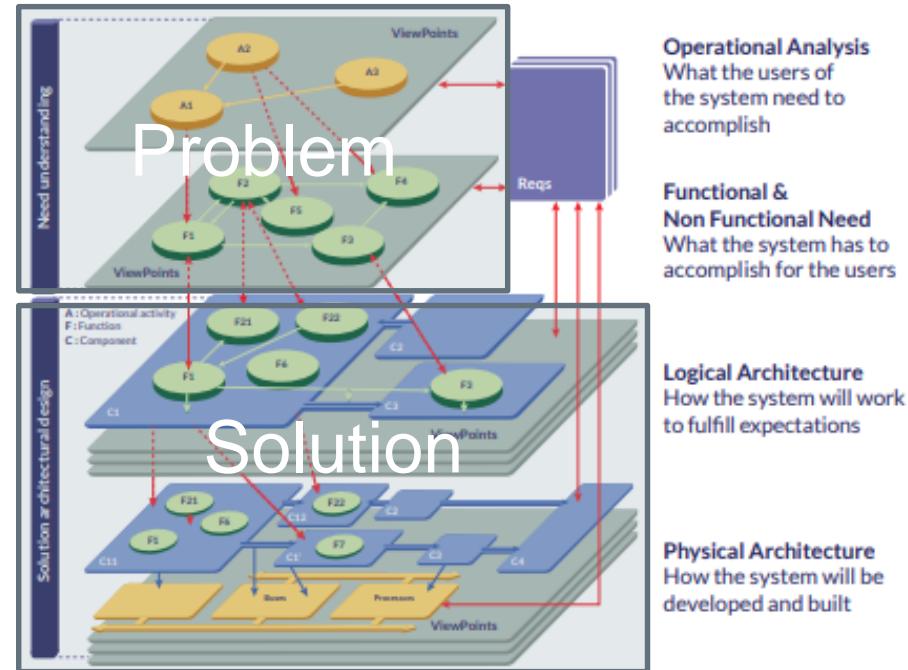
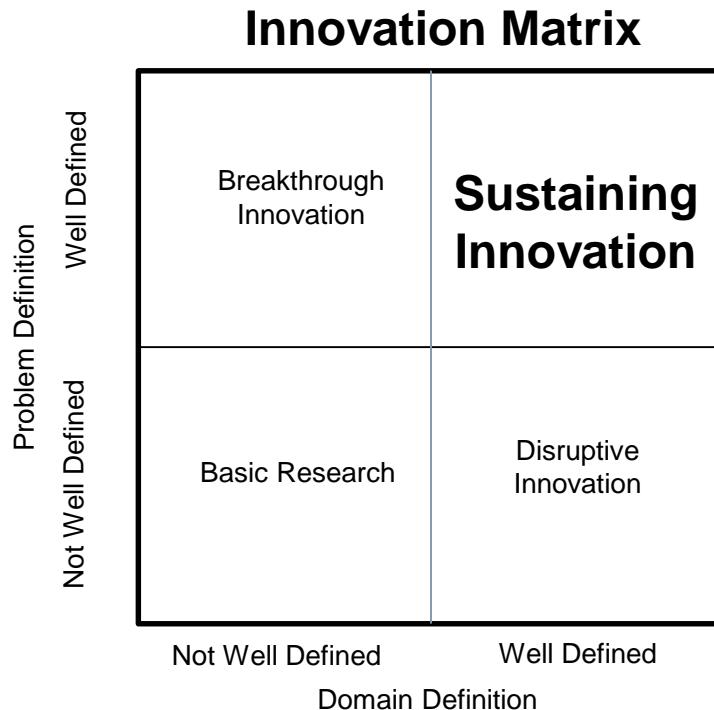


Agriculture Mission Planning System of System



Innovation

**My argument is that Innovation is goal of all companies and Capella can aid in delivering that goal.**



# This Case Study on MBSE Originated from FDA request to Siemens

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FDA – Siemens “Digitalization” event  
March 3-5, 2020 at MxD  
“The Art of the Possible”



15 FDA Leaders (CDRH & ORA) attended

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Page 8

**FDA Request:**  
Can we work on a real use case together, starting with Production Twin?



PB560

Siemens Digital Industries Software

## Medtronic PB560 Ventilator

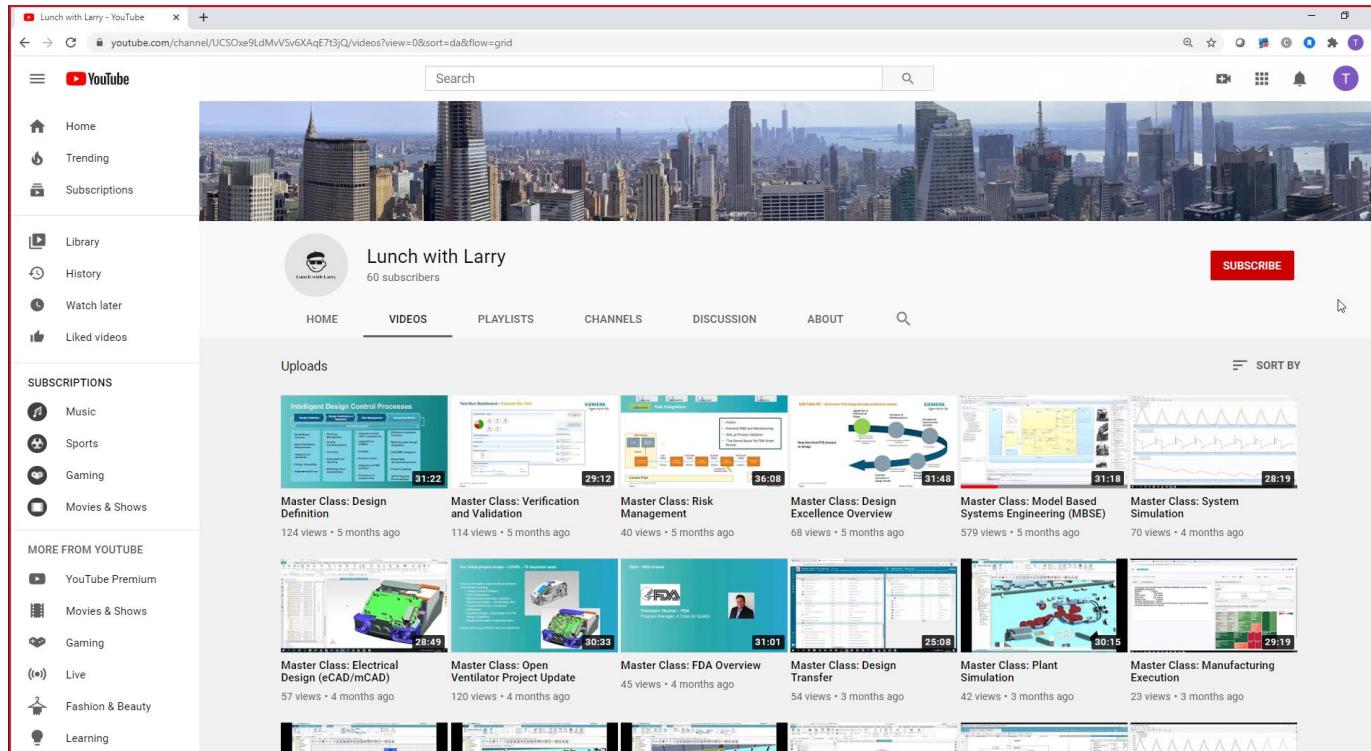
- 1) Intelligent Design Control**
  - Requirements, V&V & Risk Management
- 2) Design Excellence - Product Digital Twin**
  - Model Based Systems Engineering (MBSE)
  - ECAD and MCAD Design
  - Product Performance
- 3) Operational Excellence - Production Digital Twin**
  - Design Transfer (eBOM/mBOM, BOP)
  - Plant and process simulation
  - Production execution
- 4) Post-market Surveillance – Performance Digital Twin**
  - Requirements/Performance
- 5) Closed-Loop Quality**
  - NCR investigation/CAPA



<https://www.medtronic.com/us-en/e/open-files.html>

# The effort has led to a Design Excellence Series led by my associate Laurence Sampson

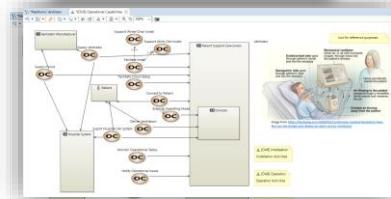
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# Effort began by developing the model of a Ventilator in Siemens System Modeling Workbench/Capella

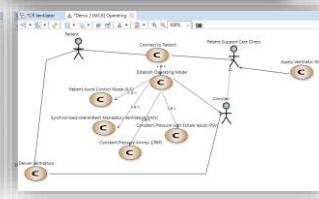
## Operational Analysis

Define Stakeholders Needs



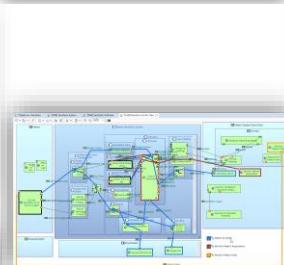
## System Analysis

Formalize System Requirements



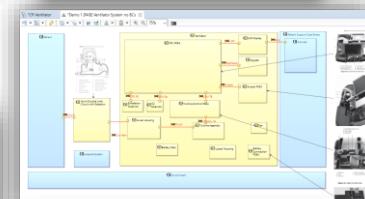
## Logical Architecture

Develop System Architectural Design



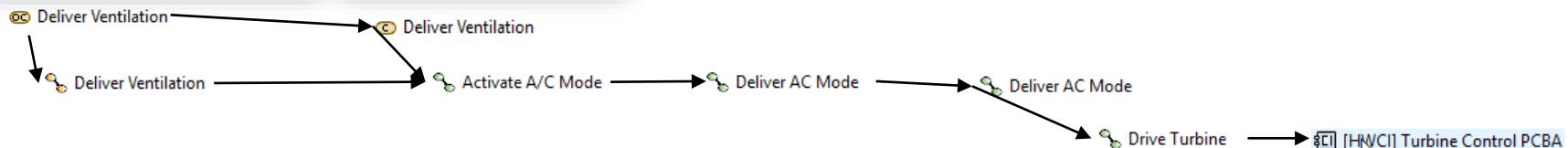
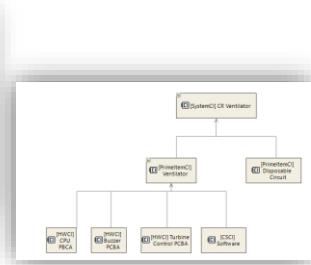
## Physical Architecture

Develop System Architectural Design



## EPBS

Formalize Components Requirements



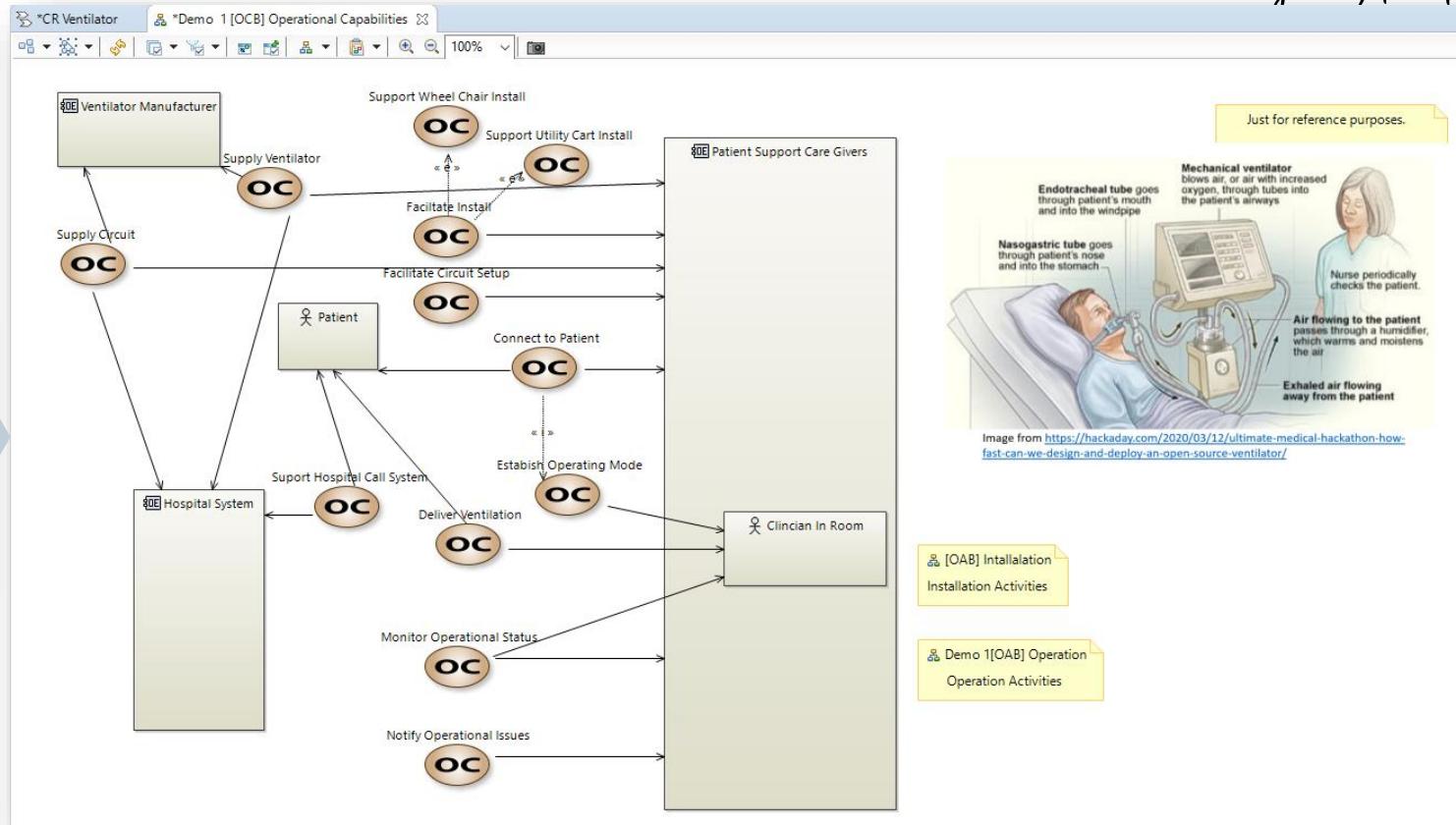
# Ventilator – Operational Capability Diagram

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## Operational Analysis

Define Stakeholders Needs

## User Manual

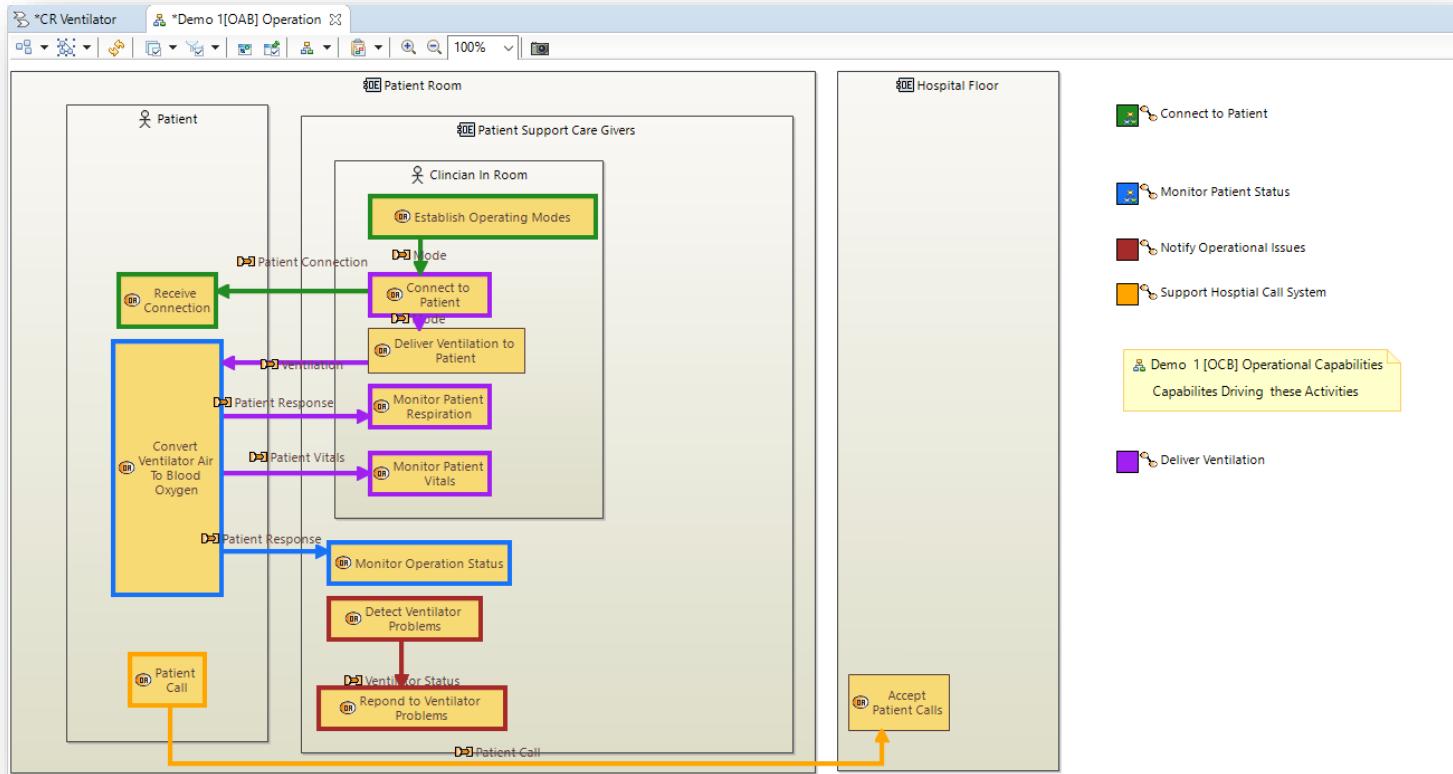
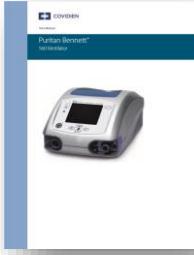


# Ventilator – Operational Activity

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## Operational Analysis Define Stakeholders Needs

## User Manual



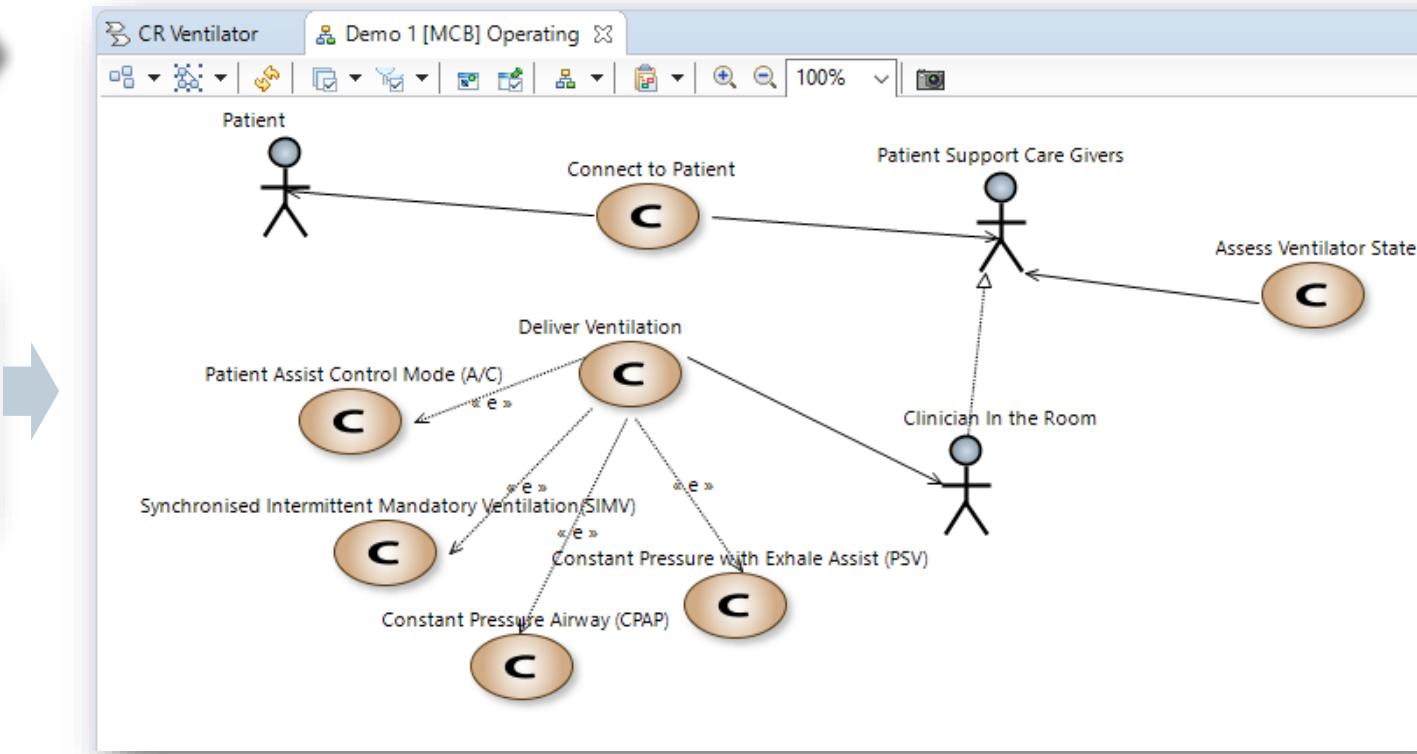
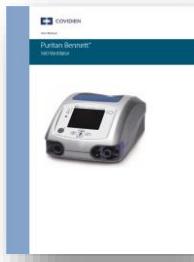
# Ventilator – System Mission Capability Diagram

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## System Analysis

Formalize System Requirements

## User Manual



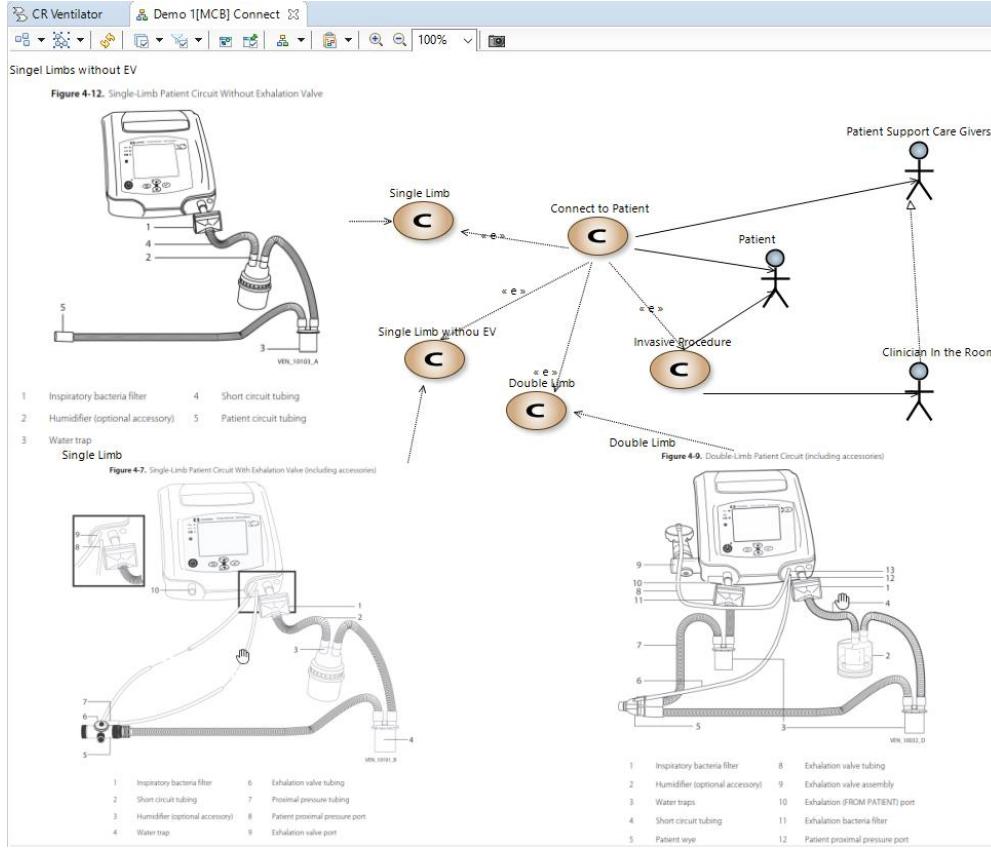
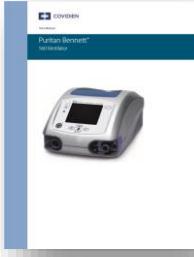
# Ventilator – System Mission Capability Diagram - Connect

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## System Analysis

Formalize System Requirements

## User Manual



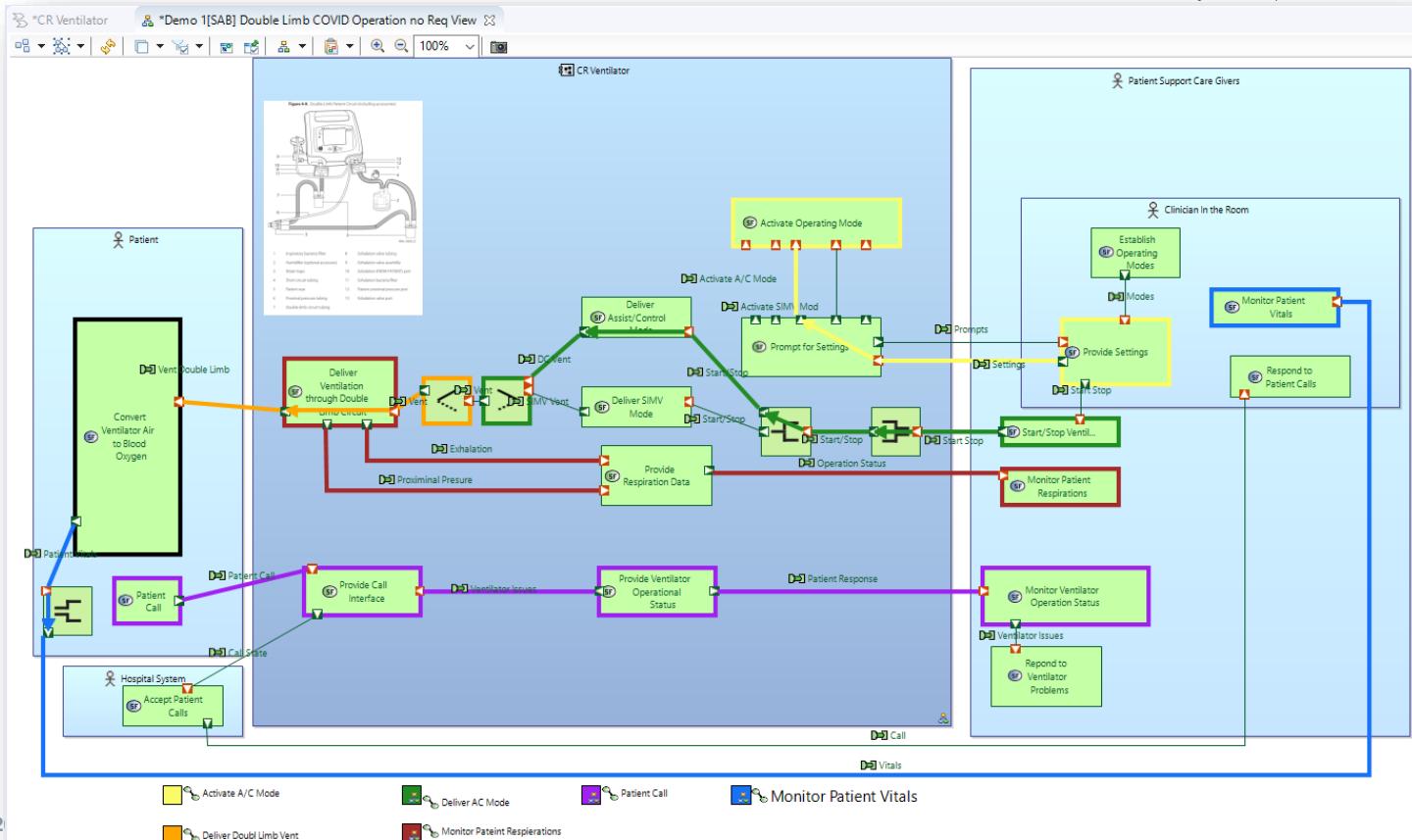
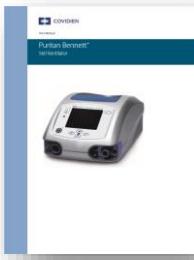
# Ventilator – System Analysis Diagram

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## System Analysis

Formalize System Requirements

## User Manual



# Ventilator – Requirements into Teamcenter Requirements

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## System Analysis

Formalize System Requirements

## Product Requirement Document



Teamcenter - 048381/A1-Medtronic PB560 Product Requirements

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Medtronics PB560 Product Requirements > 9 VENTILATION MODES AND OPERATION STATES >

Revision: Global (Latest Working) Date: Today Units: All Units Variant: 048381/A1-Medtronics PB560 Product Requirements Expansion: No Rule Owner: Tony Kumar (tks) Date Modified: 15-Jun-2020 Release Status: Type: Requirement Spec

Architecture Documentation Overview Parameters Where Used Attachments History Relations Collaboration Reports

Element Name ID Revision Revision Nar Medtronics P

Medtronics PB560 Product Requirements

1 No Title

2 1 INTRODUCTION

3 MARKETING PERSPECTIVES

4 REFERENCES

5 GENERAL PRODUCT REQUIREMENTS

5.1 PHYSICAL

5.2 MOUNTING, PORTABILITY, AND STABILITY

5.3 CLEANER AND SOLVENT RESISTANCE

5.4 OPERATING NOISE / SOUND LEVELS

6 COMPONENT REQUIREMENTS

7 EXTERNAL INTERFACES

8 SELF TEST

9 VENTILATION MODES AND OPERATION STATES

10 VENTILATION PERFORMANCE REQUIREMENTS

11 DISPLAYED PATIENT DATA MONITORING PERFORMANCE

12 OPERATOR INTERFACE REQUIREMENTS

13 FEATURES AND CAPABILITIES

14 DATA LOG THROUGH VENTILATOR INTERFACE

15 ASSOCIATED PC SOFTWARE

16 POWER SUPPLIES

17 USER/CLINICIAN MANUAL

18 CLINICAL SOFTWARE MANUAL REQUIREMENTS

19 SERVICING MANUAL TOPICS REQUIREMENTS

20 DEVICE LABELING

21 PRODUCT TRACEABILITY

22 SUPPORTED LANGUAGES

23 SYSTEM COMPONENTS

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048381 A Medtronics P

048428 A No Title

048414 A 1 INTRODUC

048474 A MARKETING I

048433 A REFERENCES

048384 A GENERAL PR

048418 A PHYSICAL

048435 A MOUNTING

REQ-003232 A CLEANER ANI

REQ-003401 A OPERATING N

048460 A COMPONENT

048467 A EXTERNAL IN

048439 A SELF TEST

048432 A VENTILATION

048442 A VENTILATION

048437 A DISPLAYED PR

048478 A OPERATOR IN

REQ-003203 A FEATURES AN

048440 A ASSOCIATED

048396 A POWER SUPP

048470 A USER/CLINI

048484 A CLINICAL SO

048458 A SERVICING M

048431 A DEVICE LABE

048390 A PRODUCT TR

REQ-003378 A SUPPORTED L

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**9.1.4.6 REQ-003447-Priority Alarm**  
The ventilator shall include a high priority alarm when the ventilation is stopped using the ventilation ON/OFF key. This alarm shall be set in the setup or preference menu and can be turned off.

**9.1.5.0 048422-VALVE OR CALIBRATED LEAKAGE CONFIGURATIONS AND DETECTION**

**9.1.5.1 REQ-003471-Compatible with valve and calibrated leakage**  
The ventilator shall be compatible with both valve and calibrated leakage configuration (vented mask). The modes and settings will be then restricted according to the settings section requirements.

**9.1.5.2 REQ-003163-Detect circuit**  
The ventilator shall include a detection of the patient circuit configuration at the launch of ventilation. It shall detect the presence of the exhalation valve or if no exhalation valve is present (non-invasive configuration with calibrated leakages or leakage configuration). A symbol will be displayed when the valve is detected and the same symbol will be crossed out when no valve is detected. In standby, the ventilator will keep the configuration detected during the previous ventilation period.

**9.1.6.0 048452-SERVICE STATE**

**9.1.6.1 REQ-003298-Service States**  
The ventilator shall provide a 'Service State' which shall allow the maintenance and the check-up of ventilator system service functions.

**9.1.6.2 REQ-003416-Entry of service state**  
The System shall enable to reach the "Service State" when the ventilator has been powered down with inactive ventilation only and when powering on the device and with key press on AUDIO PAUSED. This shall prevent the operator to get in the "Service State" unintentionally. There shall be no other way than the one above to get in the "Service State".

**9.1.6.3 REQ-003249-Exit service state**  
Once in "Service State" the only way to exit is to power down the device. No switch from "Service State" to other states (Active ventilation State or Ventilation Stand-By State), or from other states to "Service State", shall be allowed.

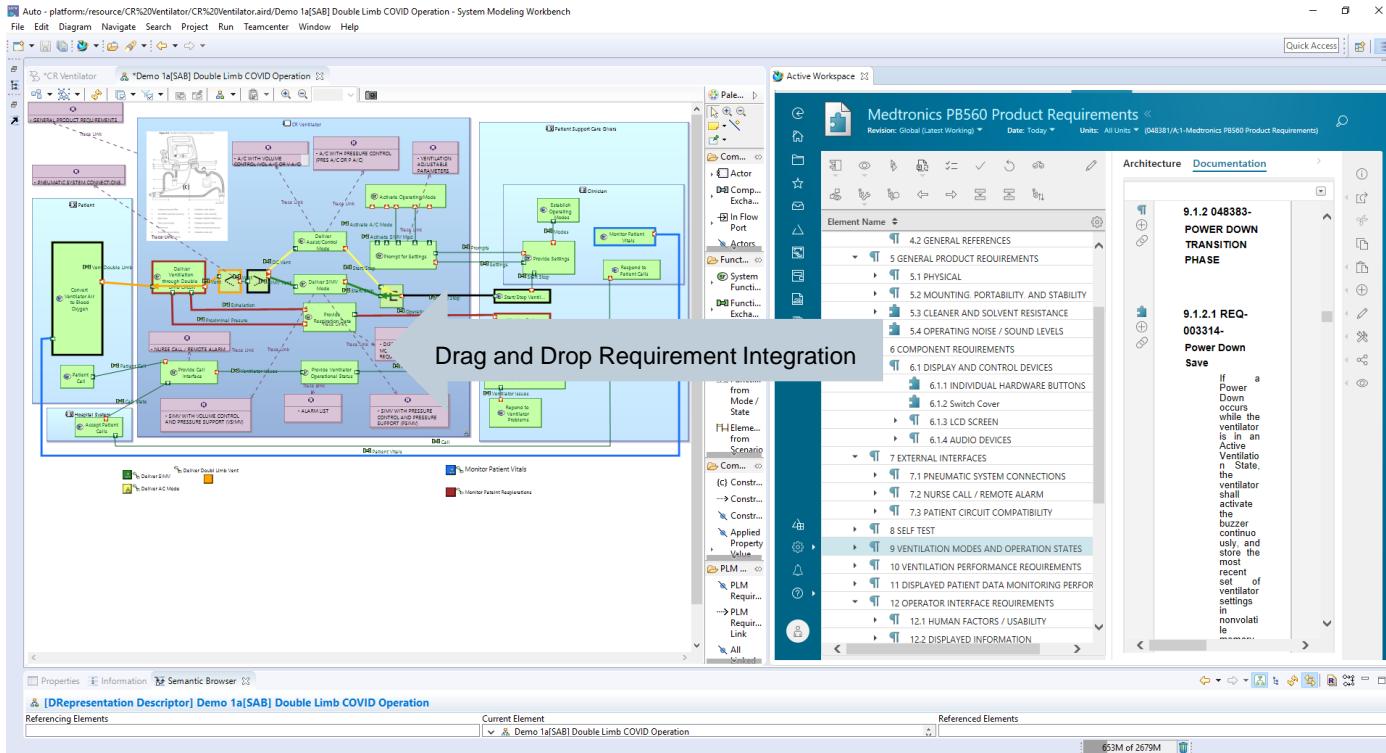
**9.2 048476-OPERATIONAL VENTILATION MODE**

# Ventilator – System Analysis Diagram with Requirements

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## System Analysis Formalize System Requirements

## Product Requirement Document



# Ventilator – System Analysis Diagram

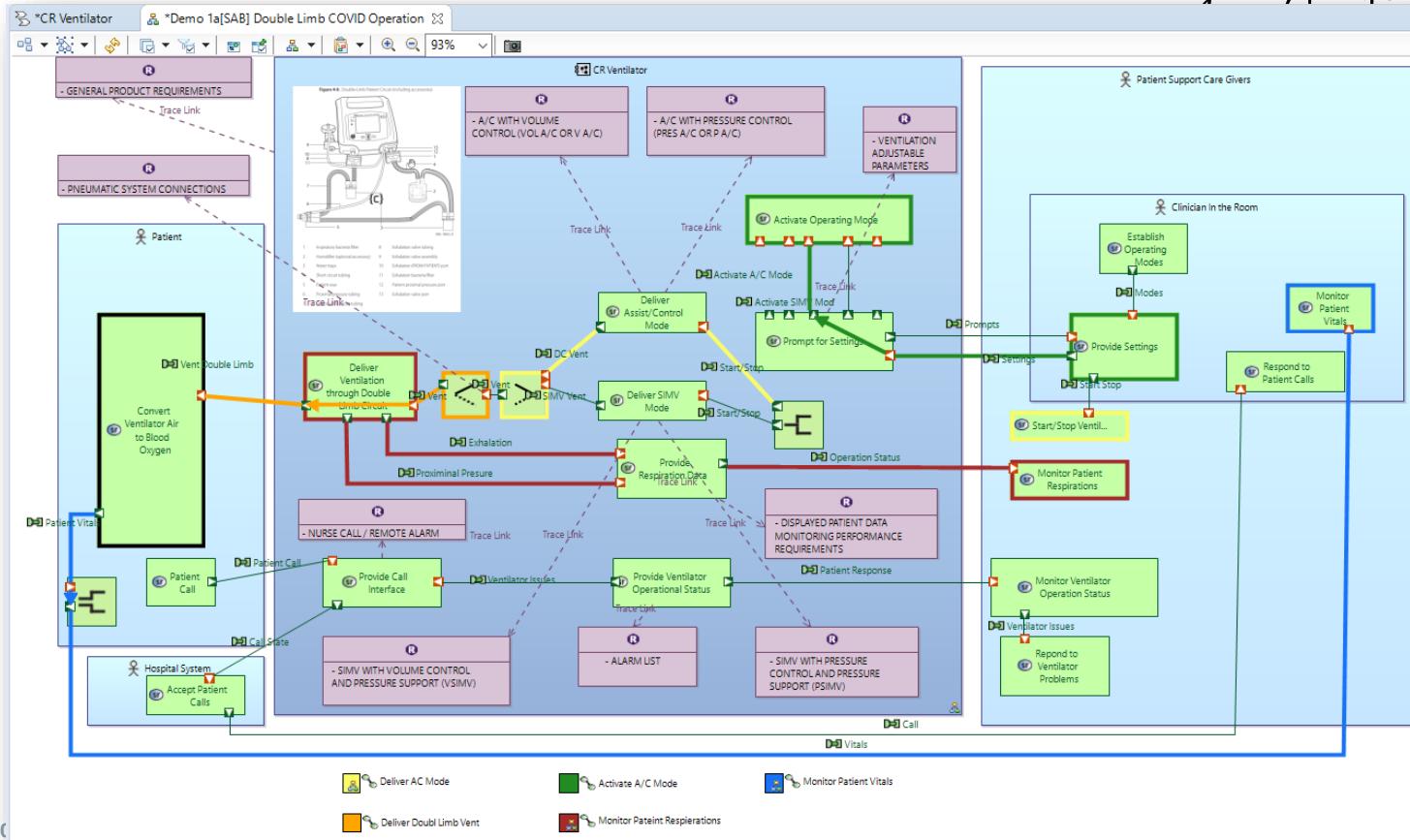
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## System Analysis

Formalize System Requirements

## Product Requirement Document

PRODUCT REQUIREMENTS DOCUMENT  
PB566-509



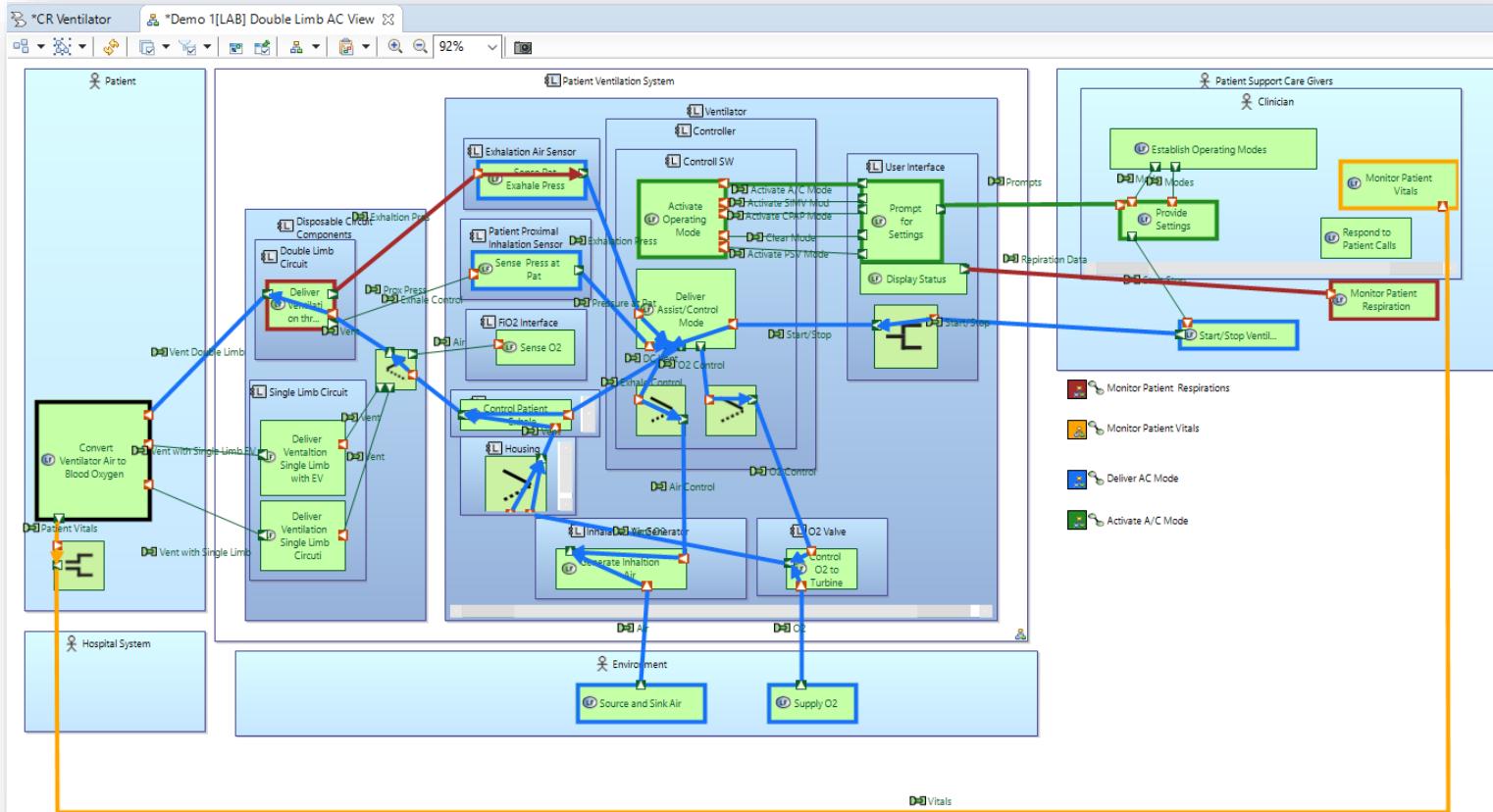
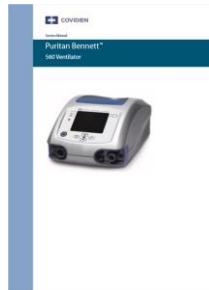
# Ventilator – Logical Analysis Diagram

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## Logical Architecture

Develop System Architectural Design

## Service Manual

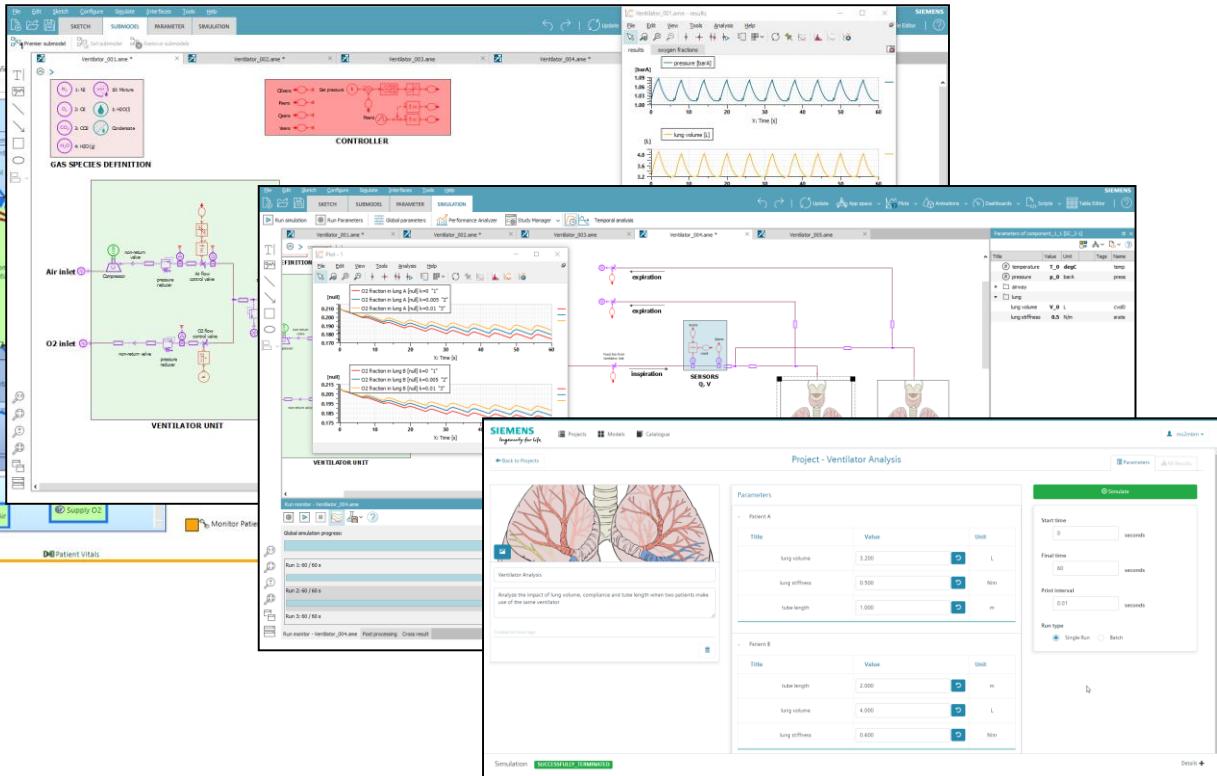
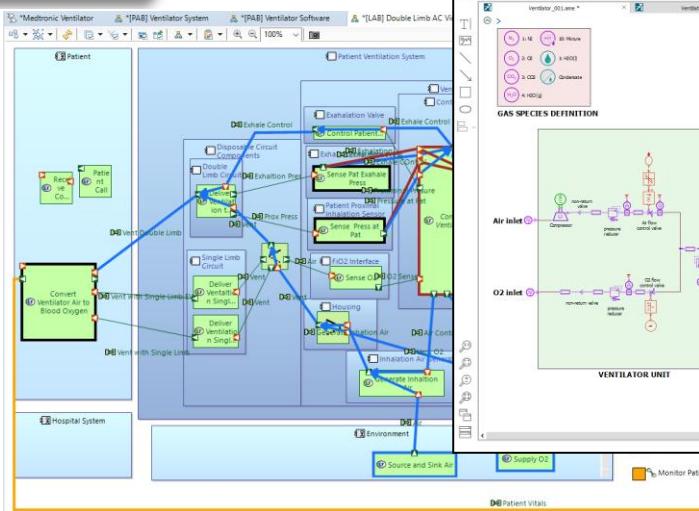


# Logical Architecture is a usable blue print for simulation with tools **SIEMENS** like Siemens Simcenter Amesim

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## Logical Architecture

Develop System Architectural Design

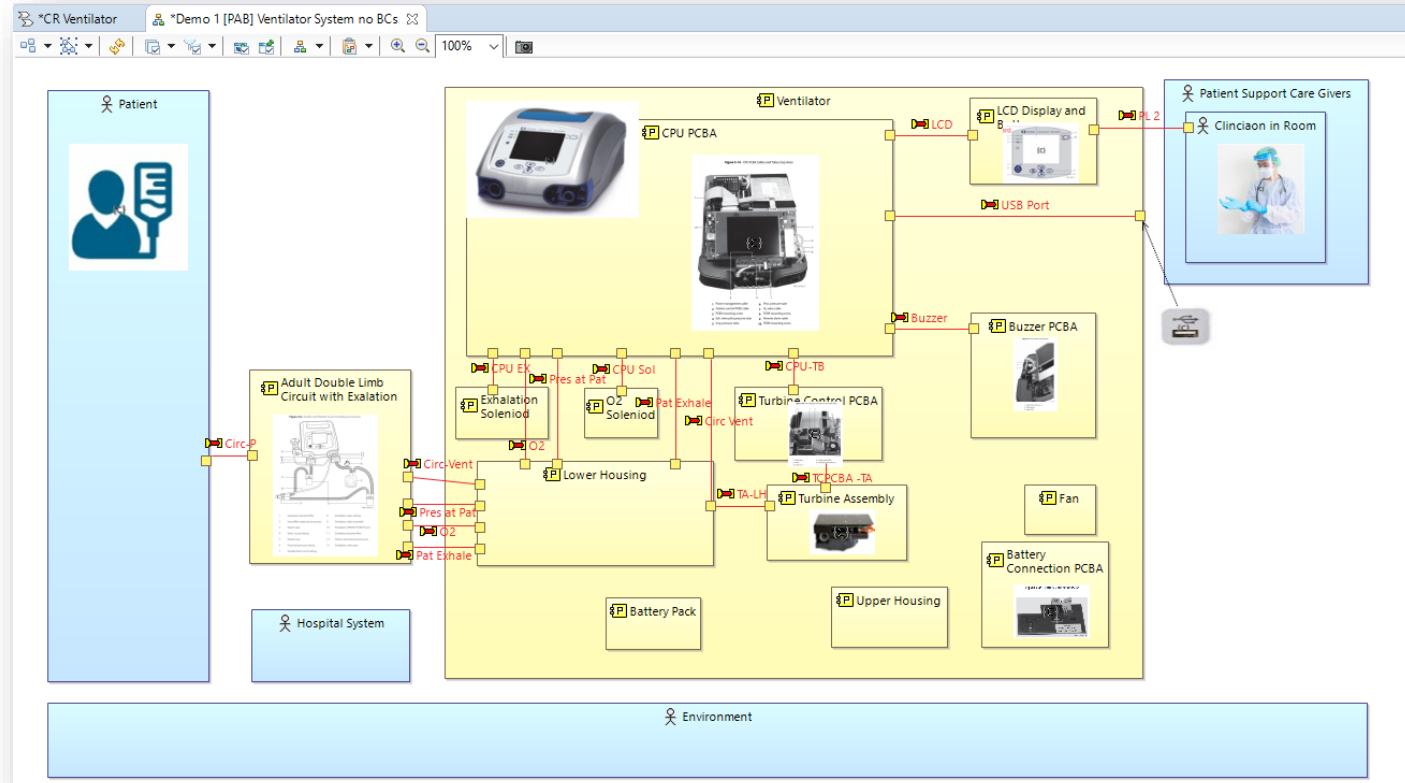


# Ventilator – Physical Analysis Diagram

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**Physical Architecture**  
Develop System Architectural Design

Service Manual

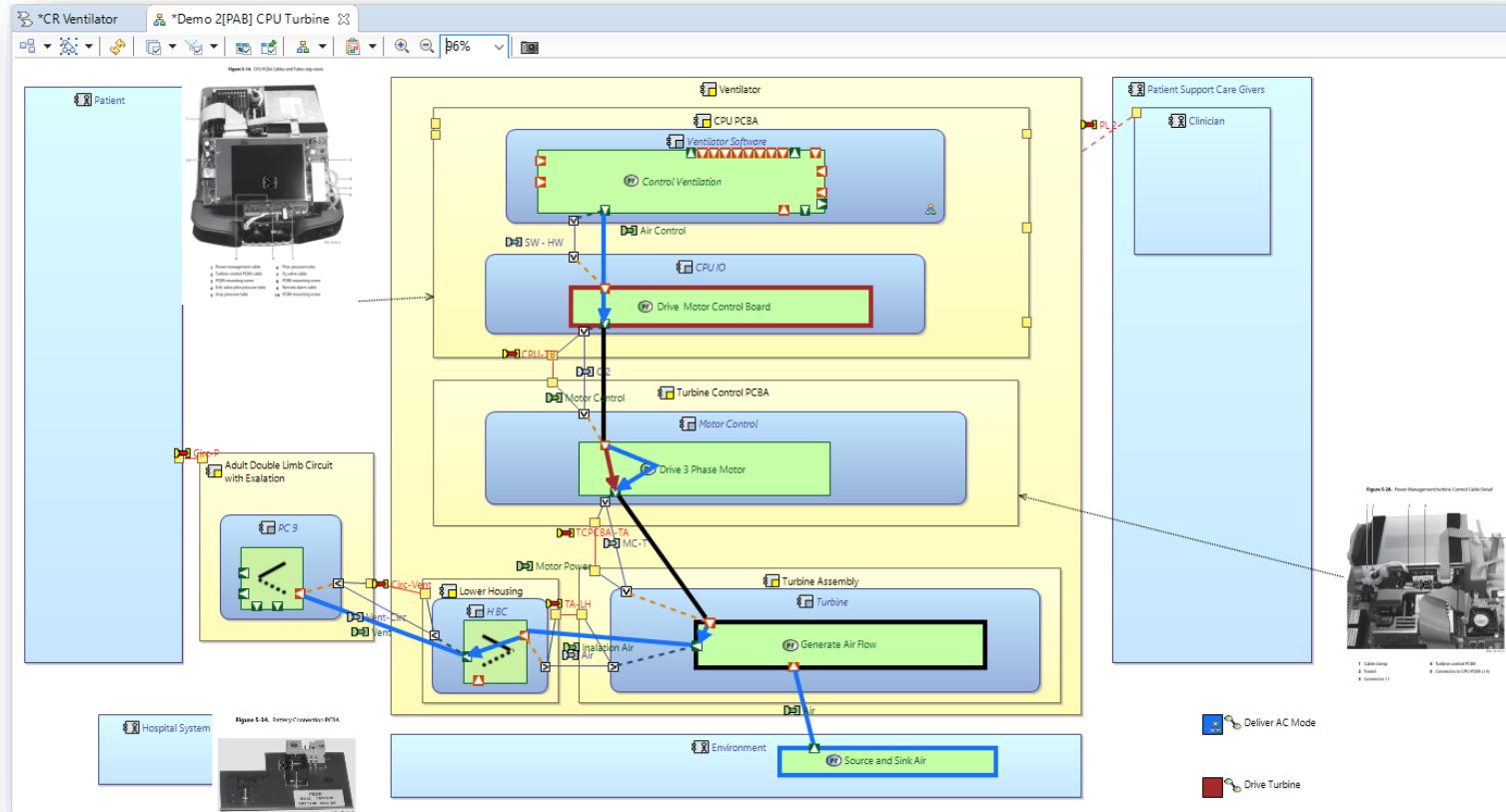


# Ventilator – Physical Analysis Diagram

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**Physical Architecture**  
Develop System Architectural Design

Service Manual

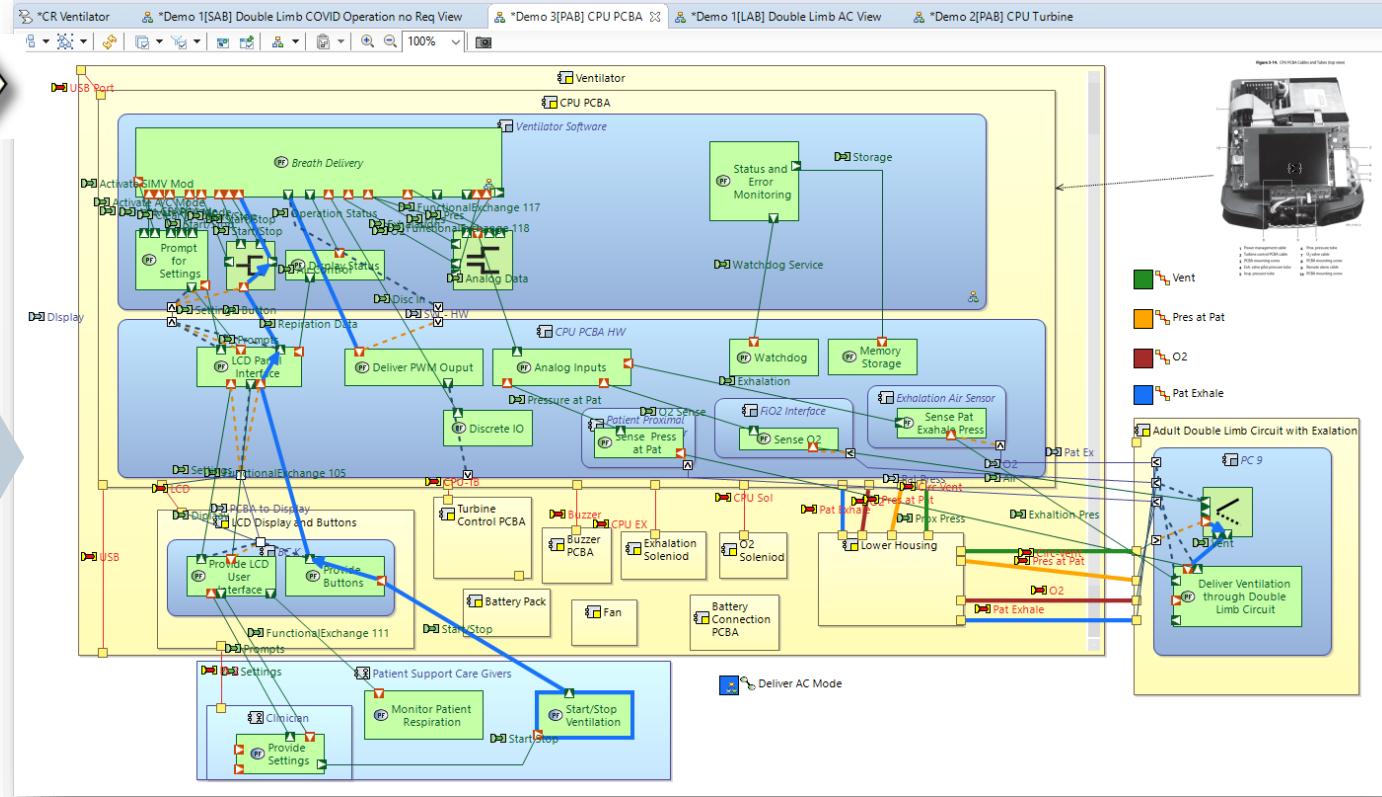


# Ventilator – Physical Analysis Diagram

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**Physical Architecture**  
Develop System Architectural Design

Service Manual



Legend for Figure 9-14: Cables and Tubes Log View

- Green line: Vent
- Orange line: Pres at Pat
- Red line: O2
- Blue line: Pat Exhale

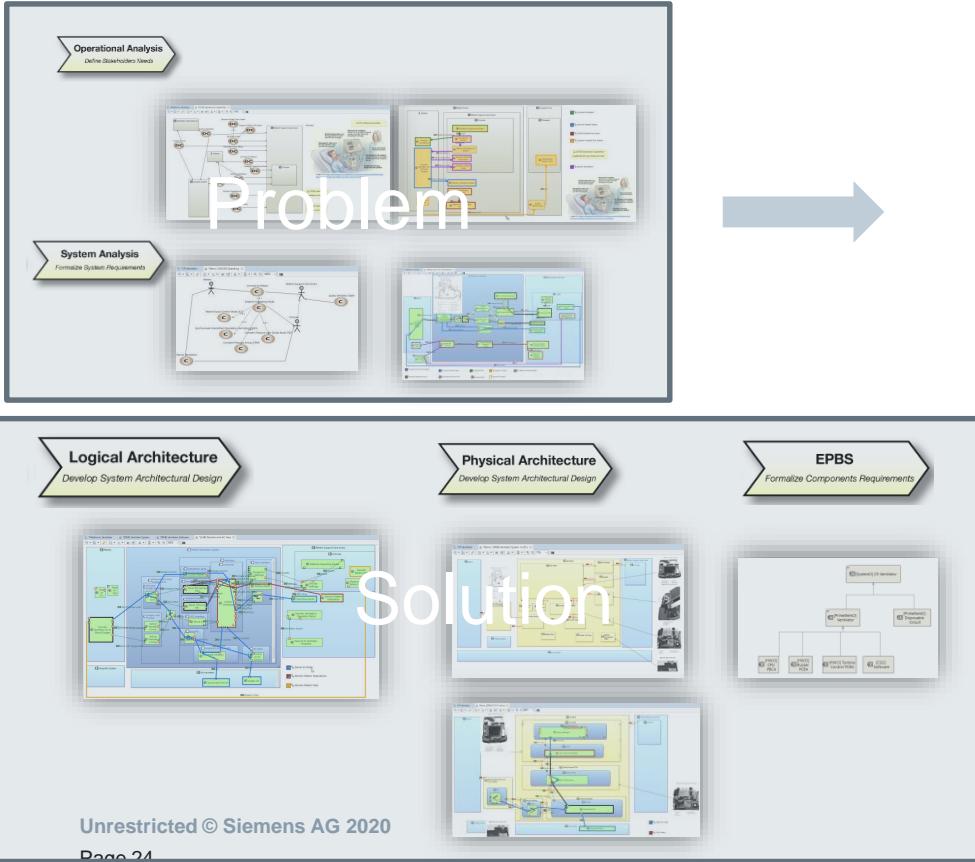
Information can then be published in Siemens Teamcenter PLM system and be viewed by wider audience.

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The screenshot displays the Siemens Teamcenter PLM system interface, specifically the System Modeling Workbench, for the CR Ventilator project. The left side shows the Project Explorer and various workspace tabs like Operational Analysis, System Requirements, Logical Architecture, and Physical Architecture. The central and right sections show the detailed structure of the CR Ventilator system, including its components, requirements, and relationships. A large, complex system architecture diagram is visible on the right, illustrating the internal components and their interactions. The Siemens logo is prominently displayed at the bottom right of the interface.

We understood the problem, we understood the solution.

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Problem Definition  
Not Well Defined

## Innovation Matrix

	Breakthrough Innovation	<b>Sustaining Innovation</b>
Not Well Defined	Basic Research	Disruptive Innovation

Not Well Defined  
Well Defined  
Domain Definition

Where is the innovation?

We needed a idea, and that led us to...

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## Wayne Memorial Hospital



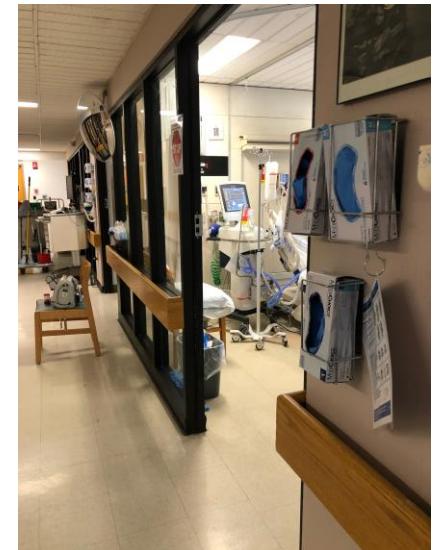
Jeff Franco – Respiratory Therapist

[www.wmh.org](http://www.wmh.org)

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**COVID-19 has introduced new problems**



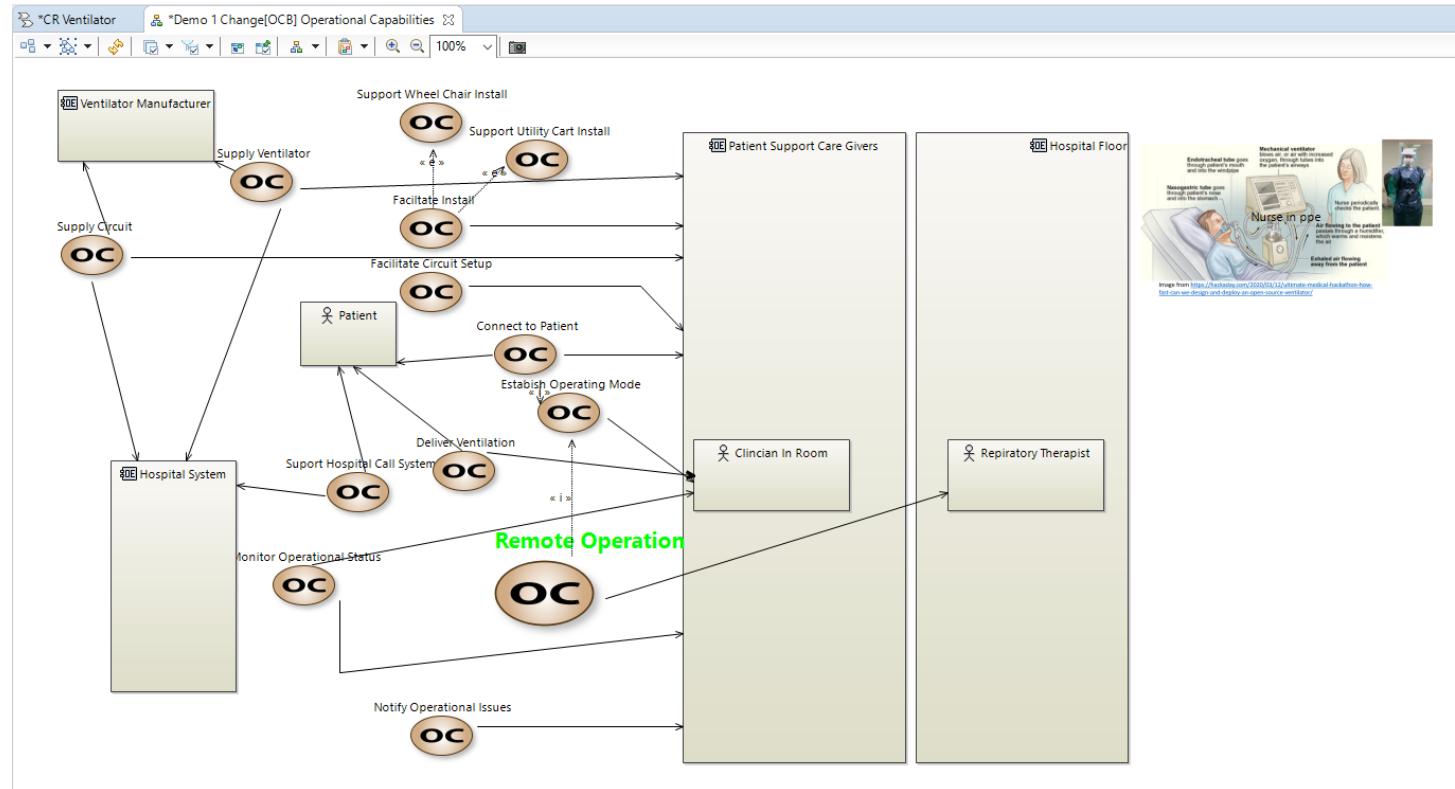
Siemens DI SW

# Ventilator – Operational Activity – Incorporating Remote Operation



## Operational Analysis

Define Stakeholders Needs

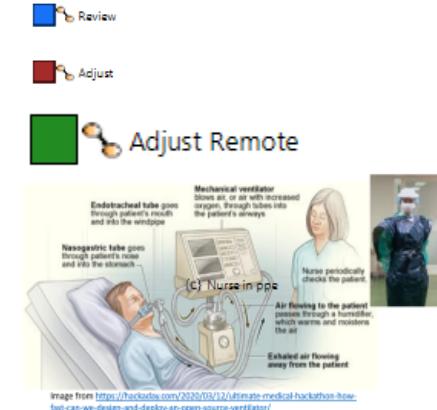
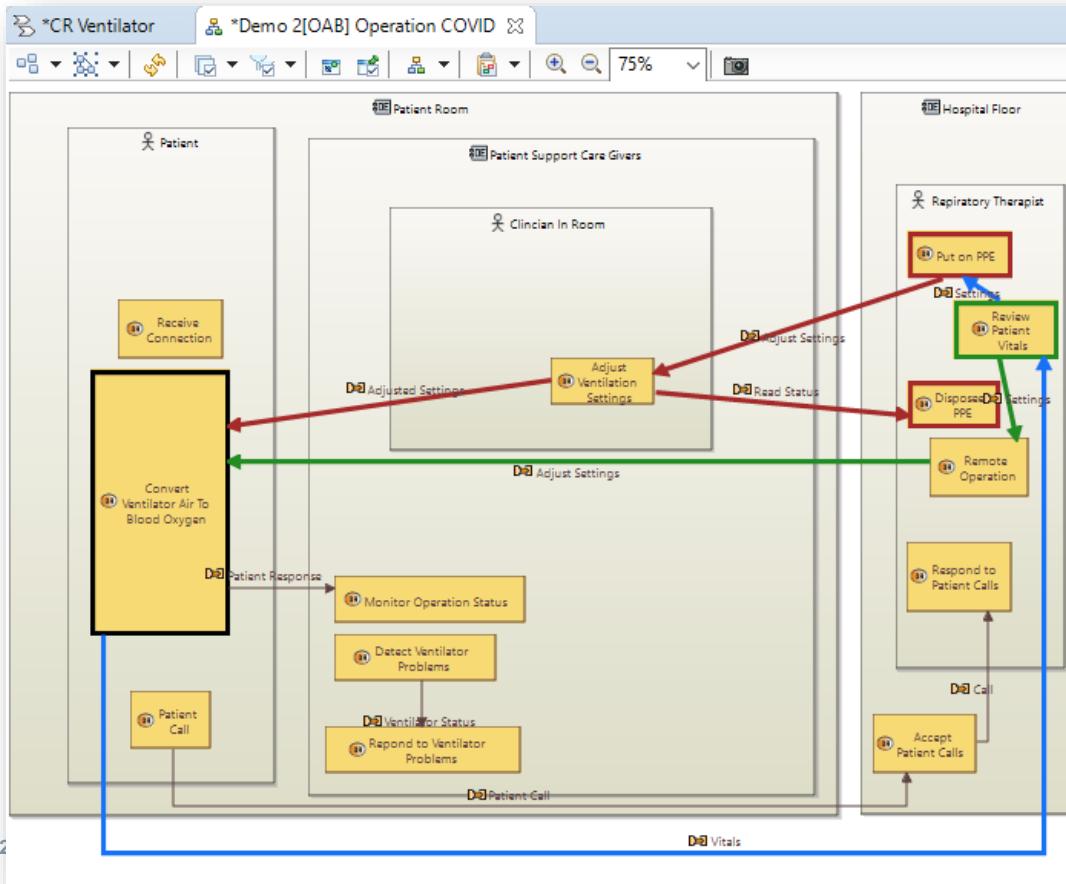


# Ventilator – Operational Activity – Adjust Ventilator Operational Processes

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Operational Analysis  
Define Stakeholders Needs

Remote Operation

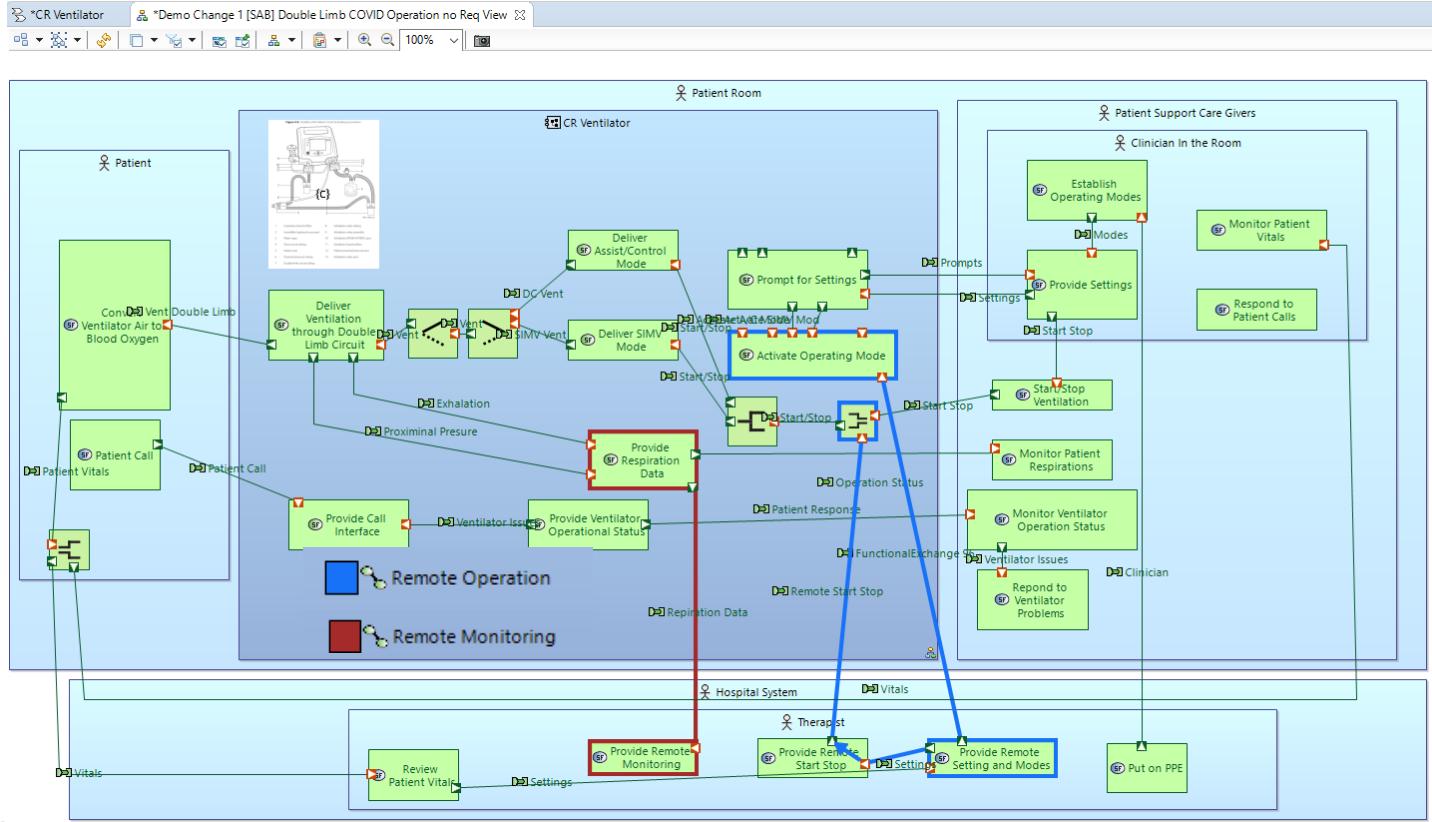
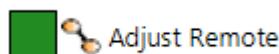


# Ventilator – System Analysis – Remote Operation and Remote Monitoring Functional Chains

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## System Analysis

Formalize System Requirements



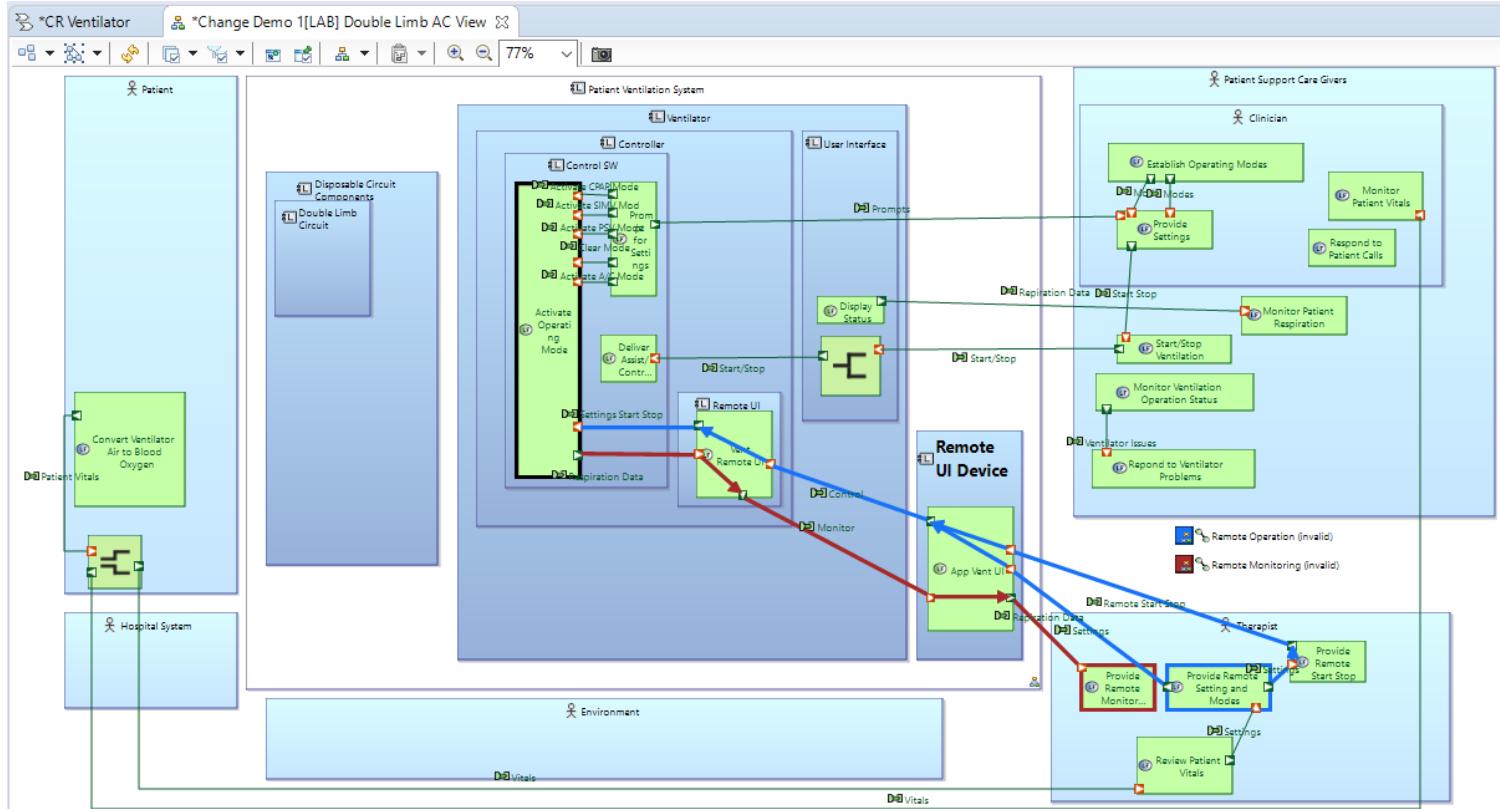
# Ventilator – Logical Analysis Diagram – Explore Concept to deliver Remote Operation and Remote Monitoring

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## Logical Architecture

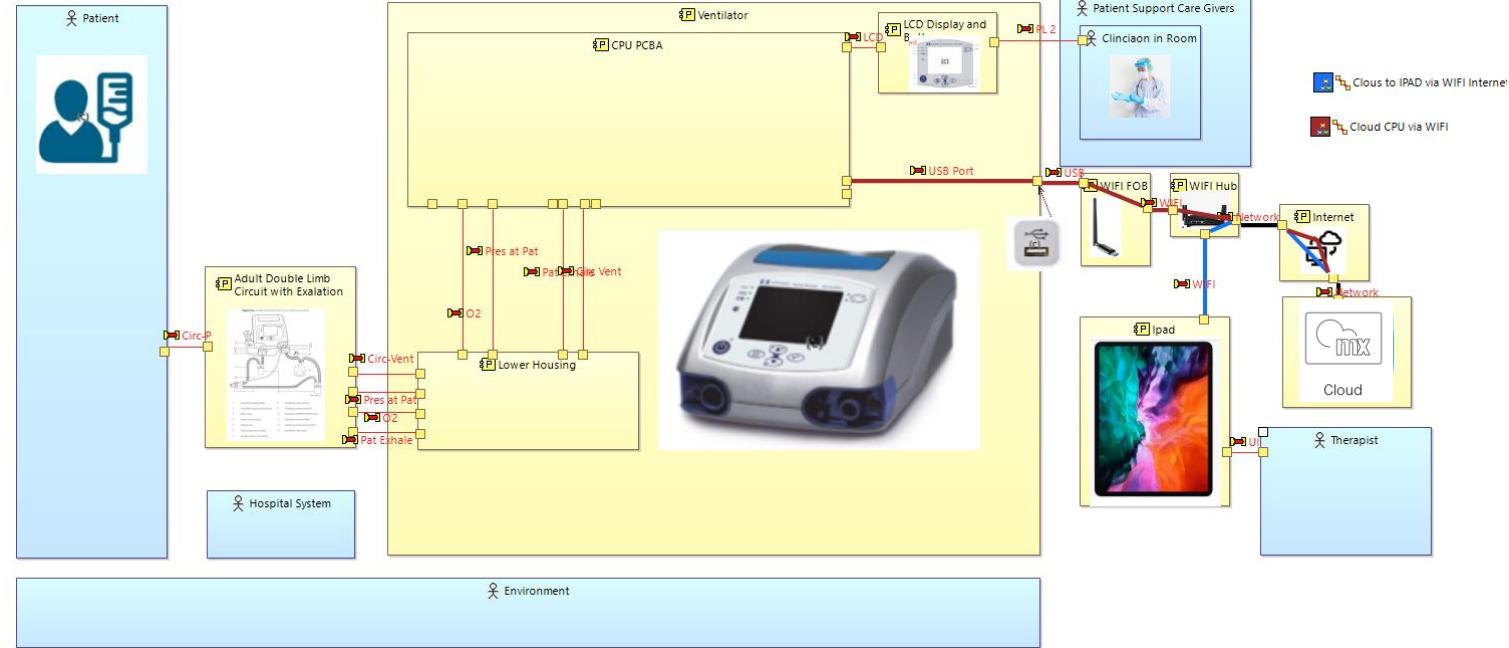
Develop System Architectural Design

- █ Remote Operation
- █ Remote Monitoring



# Ventilator – Physical Analysis Diagram – Made some decisions on **SIEMENS** implementation

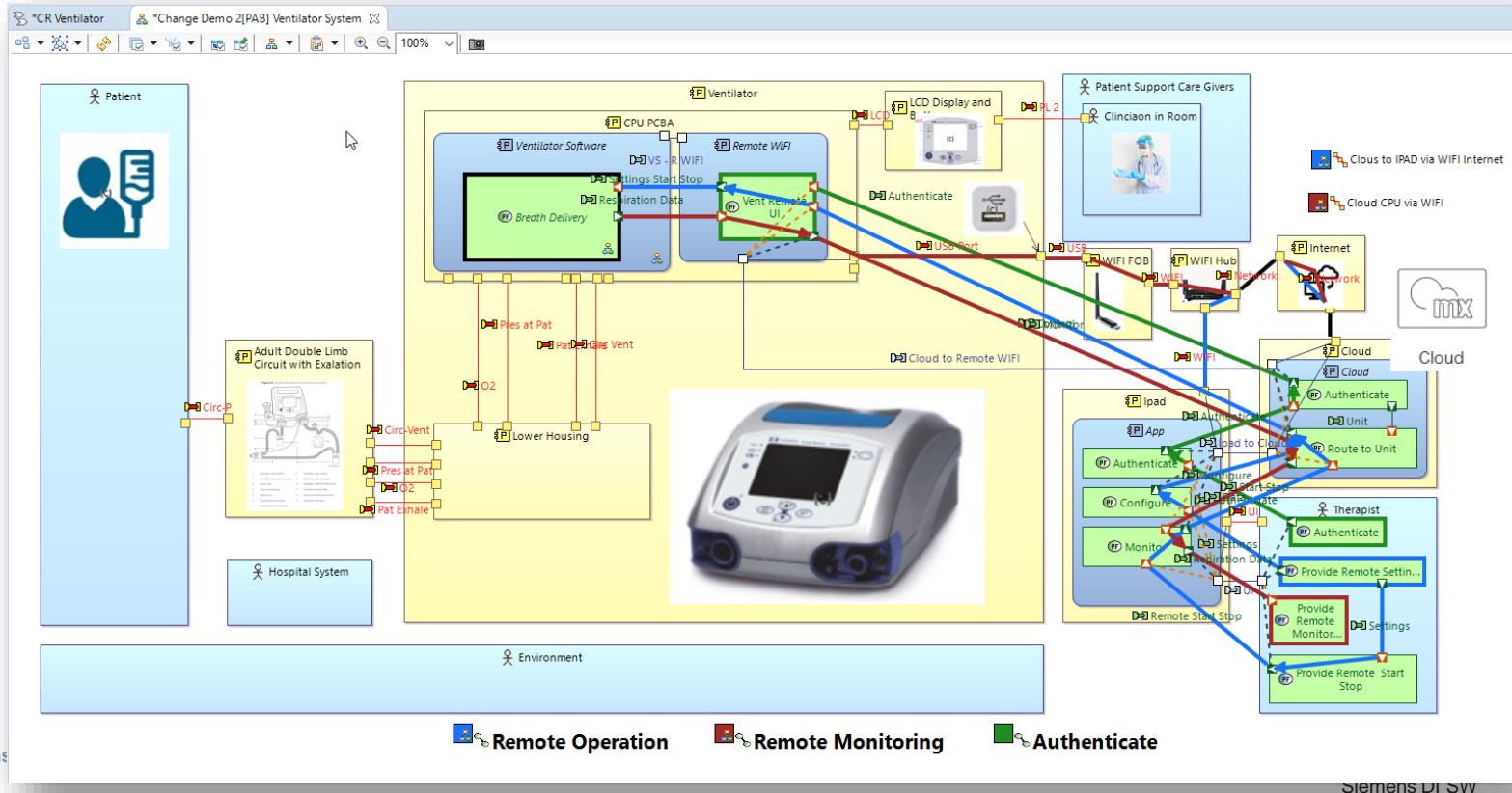
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# Ventilator – Physical Analysis Diagram – Allocated functions to the implemented components

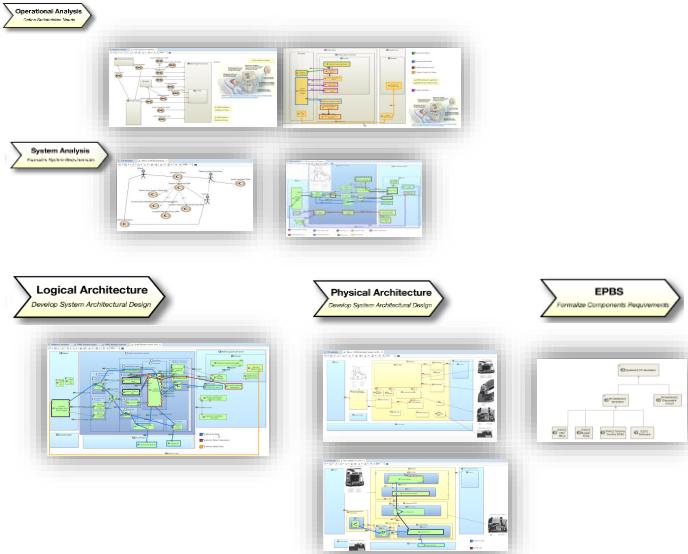
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Physical Architecture  
Develop System Architectural Design



# Capella is a tool for Innovation

Assists in understanding a problem and design

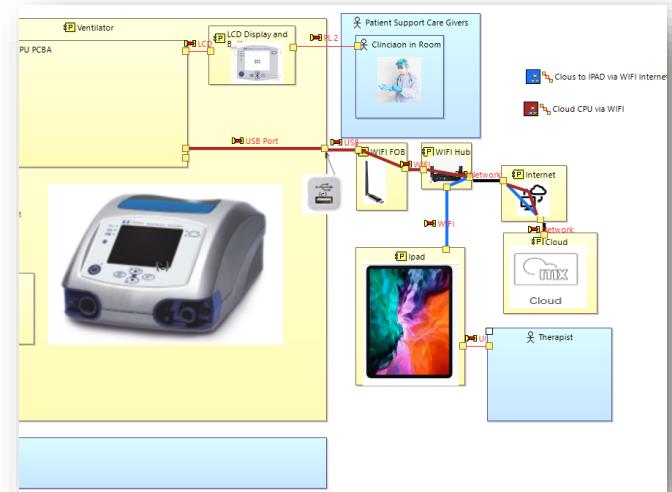


It uncovers a gaps in understanding



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## Innovative Solution



# Hopes for today's presentation



- You will be able to promote Capella as a tool for innovation
  - It allows you to develop an understanding of the problem you can share with others.
  - Provides a means to help you methodically develop a solution that will lay blueprint for design.
- The model I shared can bring forth new solutions
  - May this case study help fill some gaps



# Thank you

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## Tony Komar

MBSE Evangelists

Senior Solution Architect

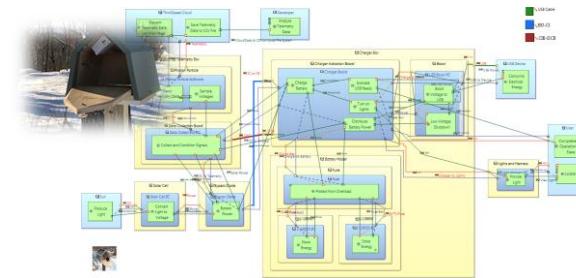
[tony.Komar@siemens.com](mailto:tony.Komar@siemens.com)

<https://www.linkedin.com/in/tony-komar/>

## Autonomous Missioning Planning



## Solar Charger



## Diabetic Care System



#CapellaDays



Please wait a few seconds before  
we automatically bring you to the **next session:**

Successful Capella Landing on a CNES Operational Use-Case

Artal / Magellum

*If you want to keep talking with the speakers of this talk, you will have to come back to this session by opening the Capella Days agenda menu in the top left-hand corner*