

# Innovating with MBSE - Medical Device Example

**Tony Komar**  
Siemens  
MBSE Evangelist  
@LinkedIn

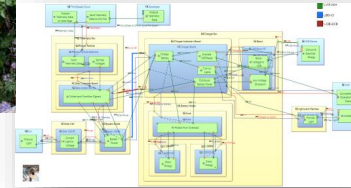
**12/10/2020**

# My history with Capella.

2017 Introduced to Capella, by a customer.



Solar Charger



Shortly after I built my first model....

2018 Siemens and OBEO announced partnership and product based on Capella



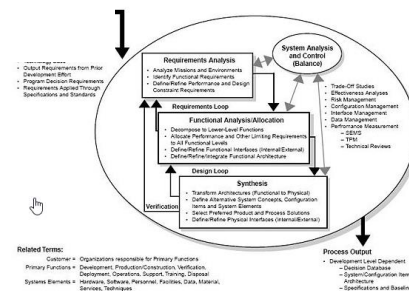
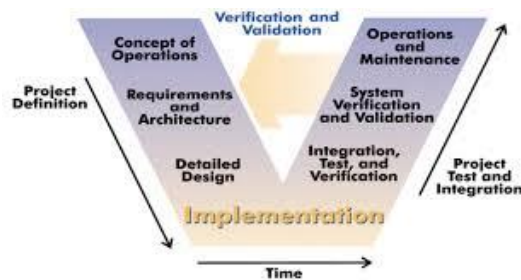
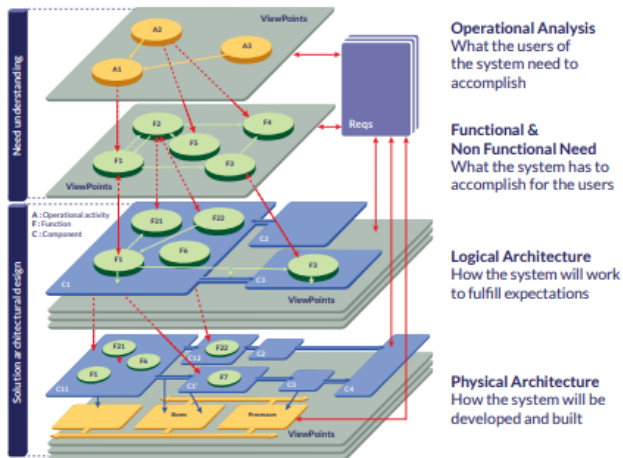
2019 coached middle school students on Capella



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

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

## Model Based System Engineering



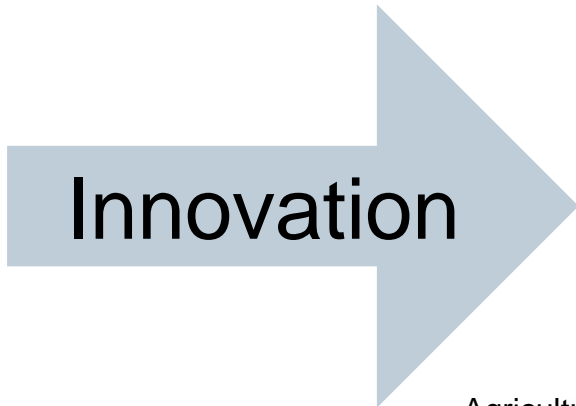
Do you really have to understand 50+ years System Engineering knowledge to appreciate Capella?

There must be an easier way?

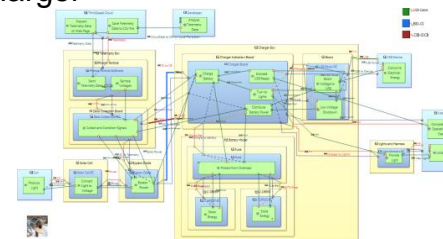
**SIEMENS**  
*Ingenuity for life*



# My answer: Capella is a tool for Innovation



Solar Charger



Diabetic Care System



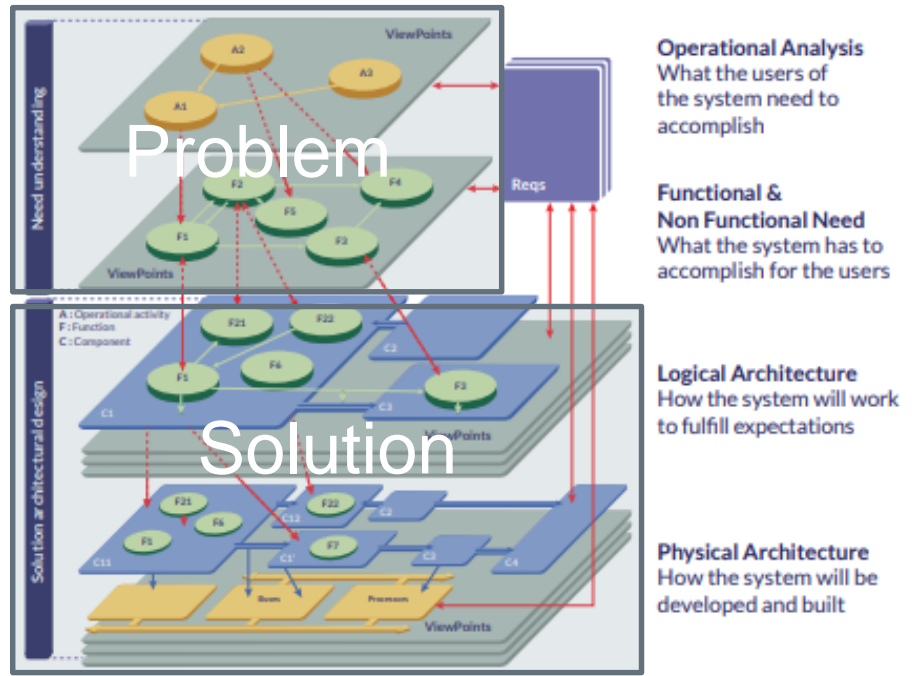
Agriculture Mission Planning System of System



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

**Innovation Matrix**

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





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

## FDA – Siemens “Digitalization” event

March 3-5, 2020 at MxD

“The Art of the Possible”



15 FDA Leaders (CDRH & ORA) attended

Unrestricted © Siemens 2020

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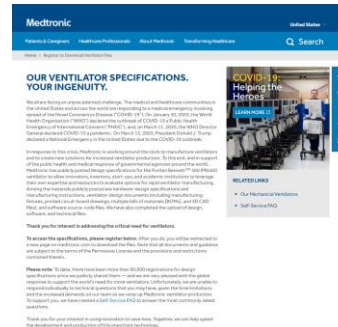
### FDA Request:

Can we work on a real use case together, starting with Production Twin?



PB560

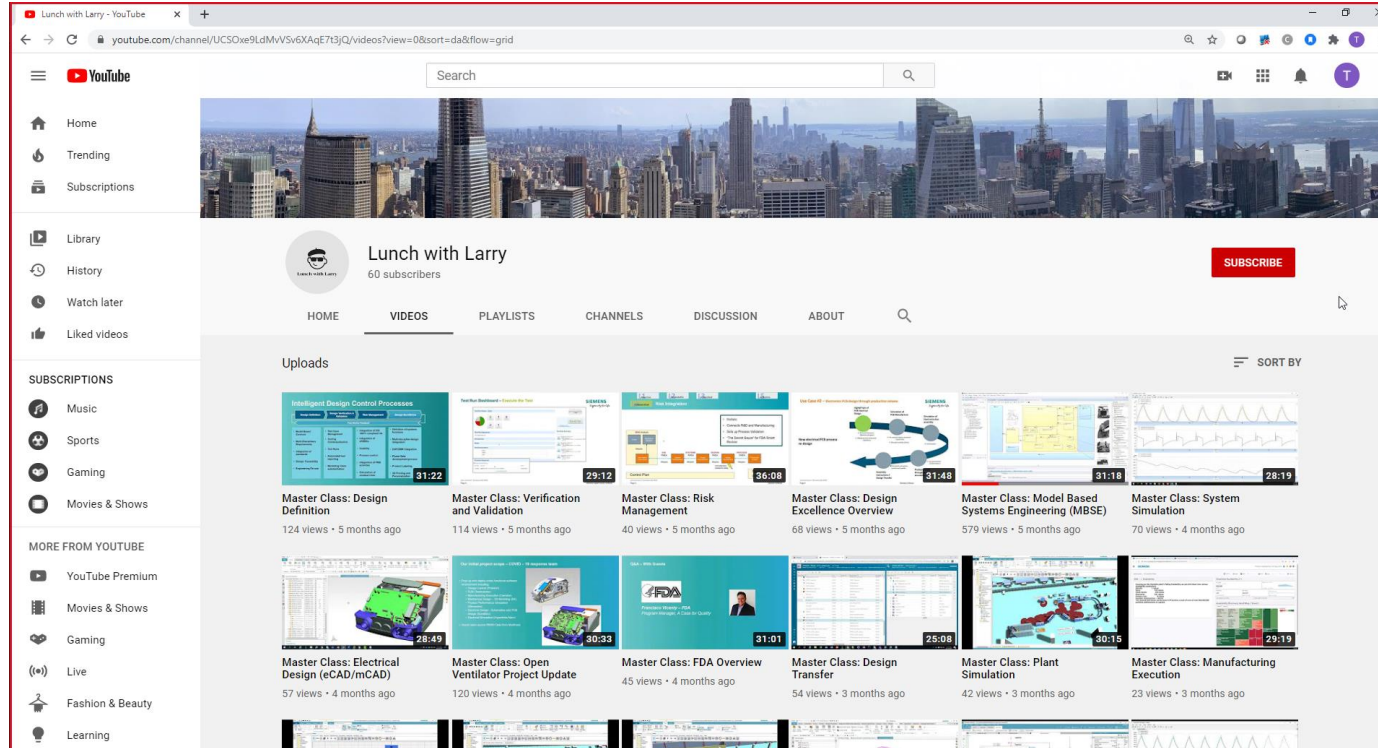
Siemens Digital Industries Software



## Medtronic PB560 Ventilator

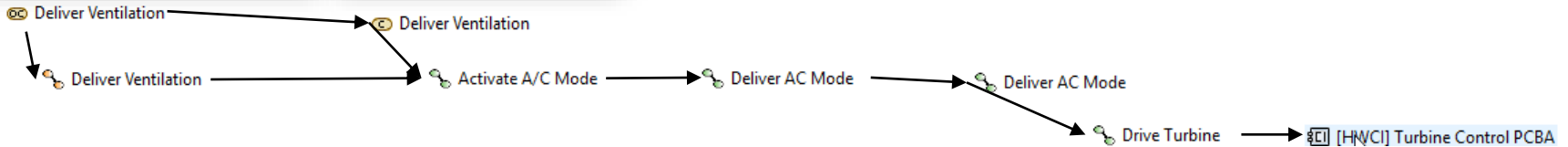
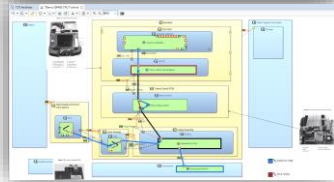
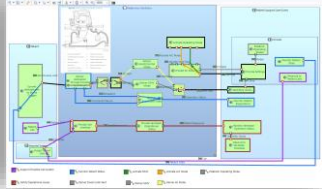
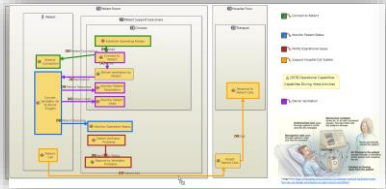
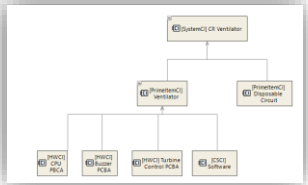
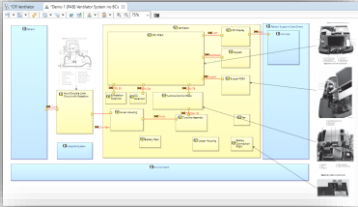
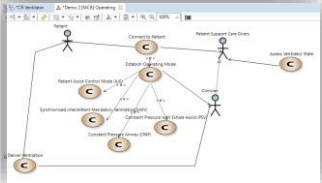
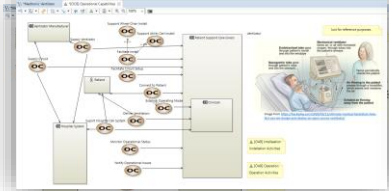
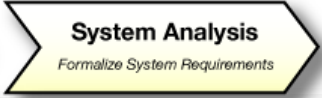
- 1) **Intelligent Design Control**
  - Requirements, V&V & Risk Management
- 2) **Design Excellence - Product Digital Twin**
  - Model Based Systems Engineering (MBSE)
  - ECAD and MCAD Design
  - Product Performance
- 3) **Operational Excellence - Production Digital Twin**
  - Design Transfer (eBOM/mbBOM,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

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





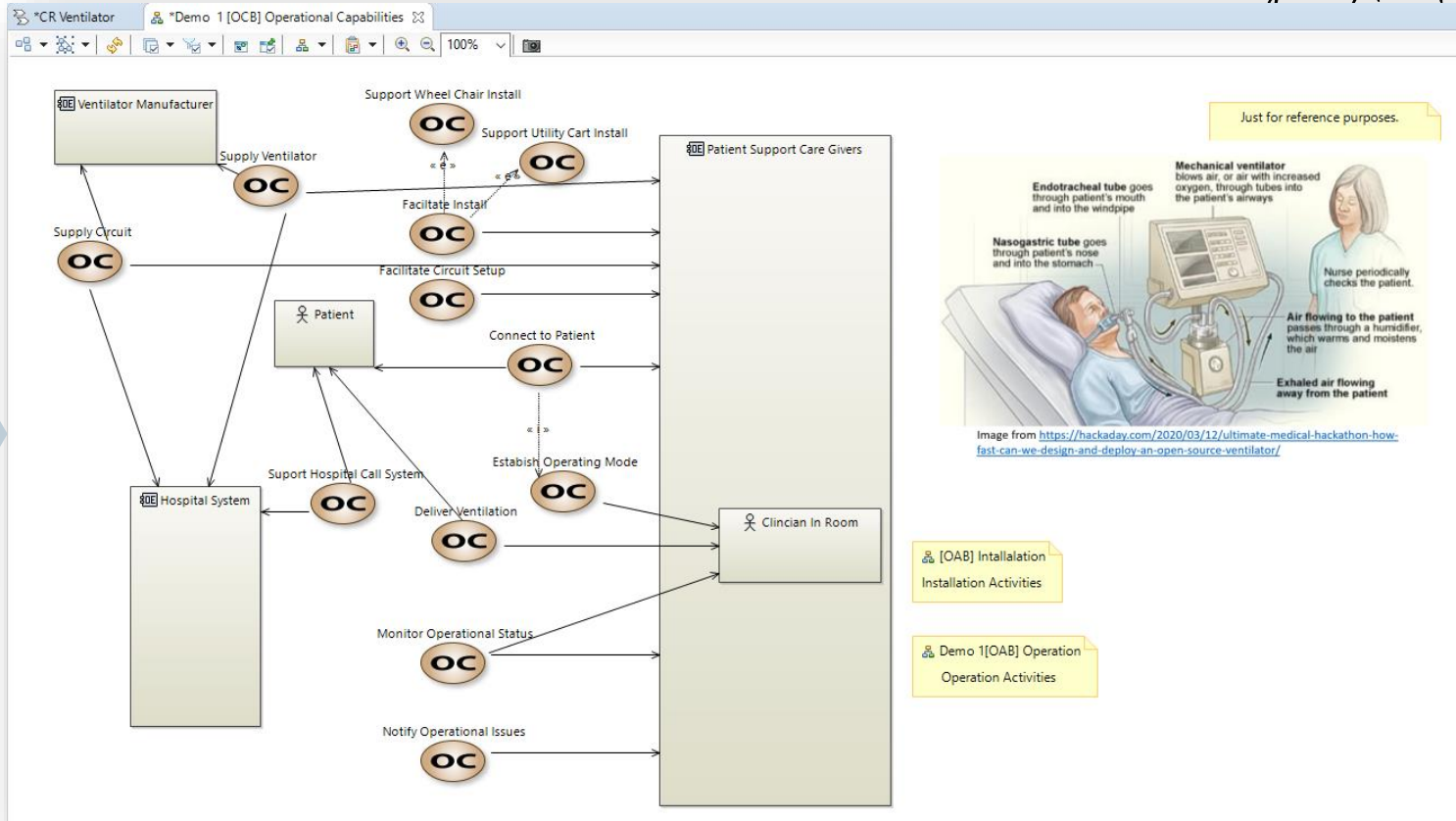
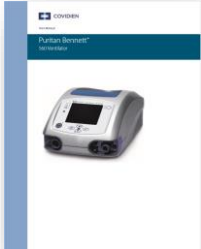
# Effort began by developing the model of a Ventilator in Siemens System Modeling Workbench/Capella



# Ventilator – Operational Capability Diagram

**Operational Analysis**  
Define Stakeholders Needs

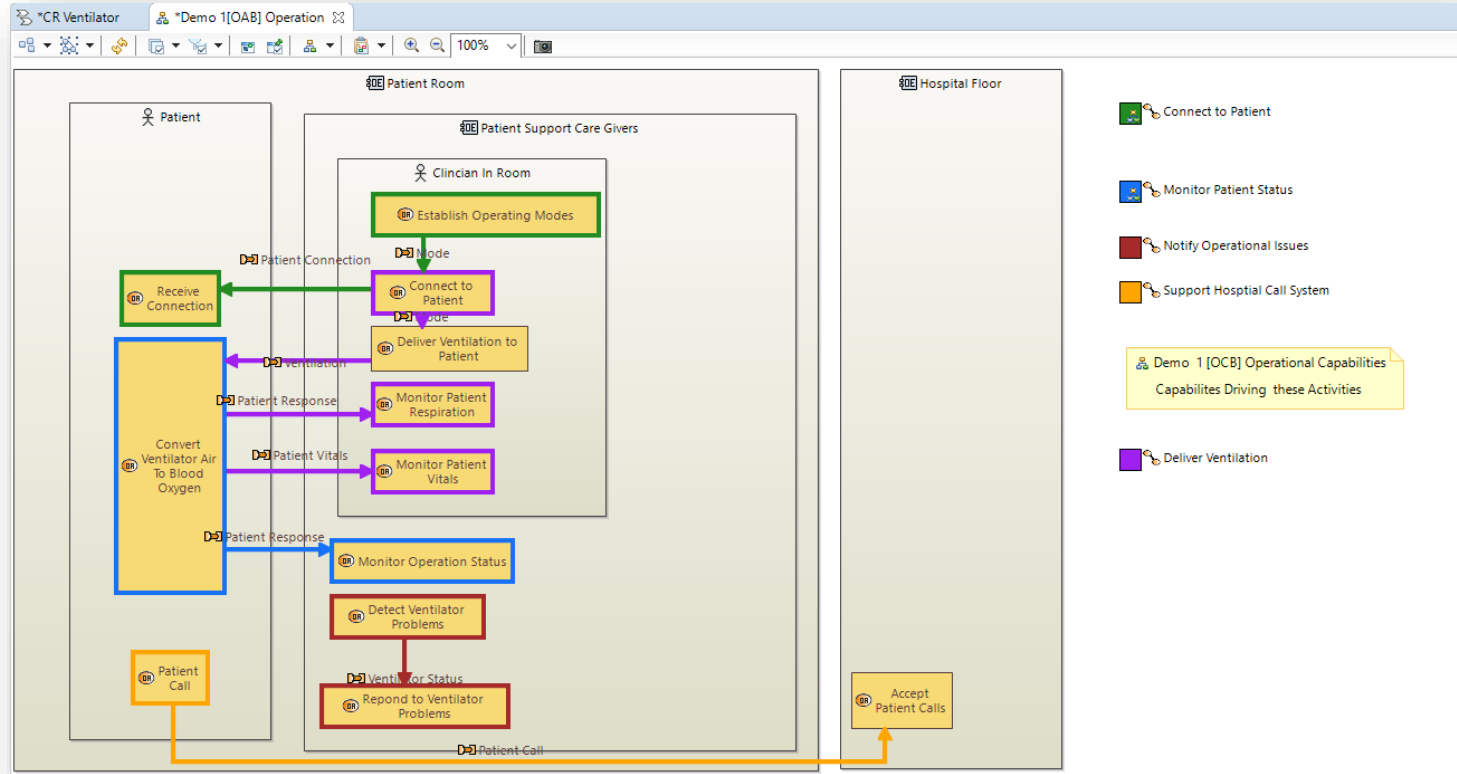
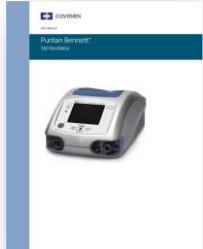
**User Manual**



# Ventilator – Operational Activity

**Operational Analysis**  
Define Stakeholders Needs

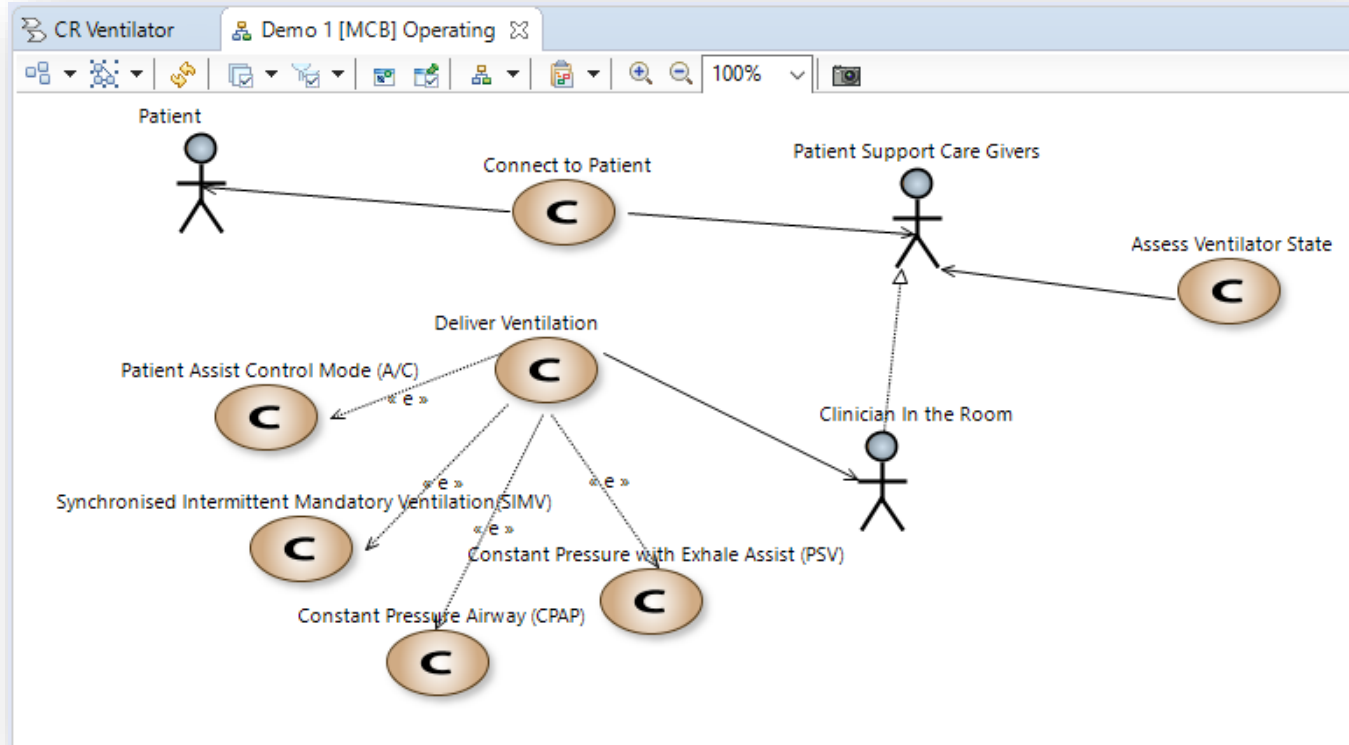
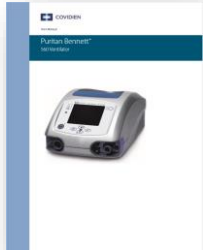
User Manual



# Ventilator – System Mission Capability Diagram

**System Analysis**  
Formalize System Requirements

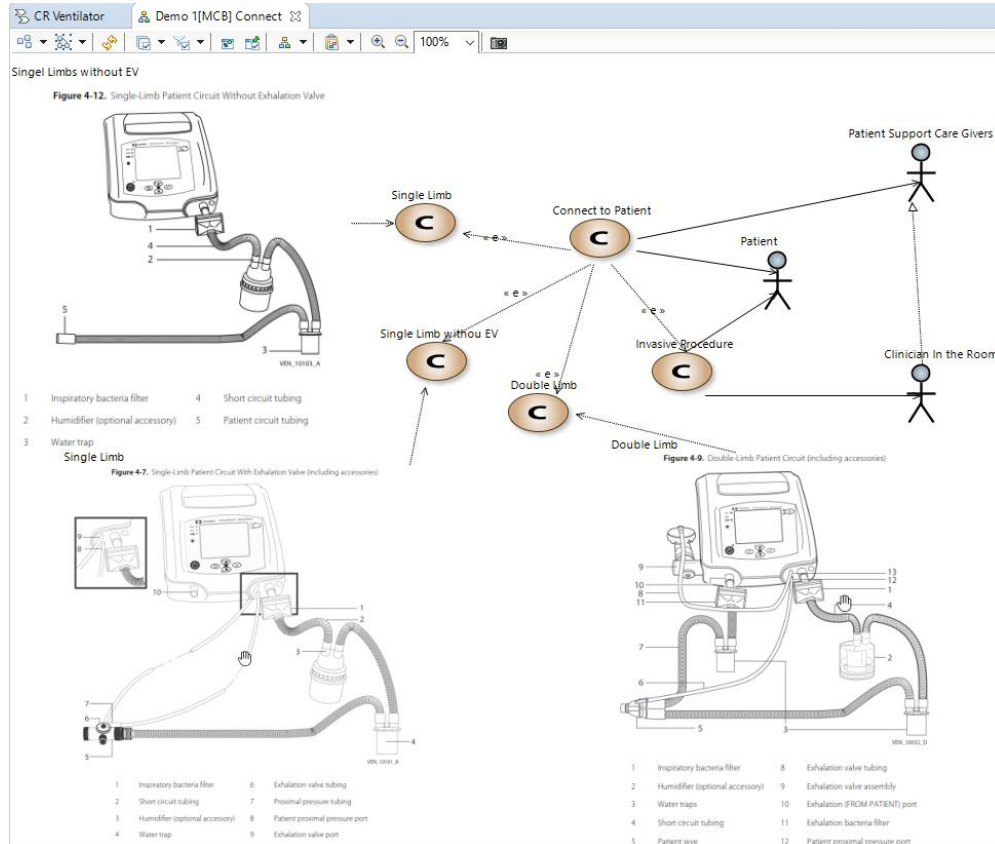
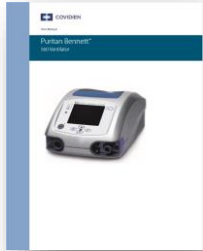
User Manual



# Ventilator – System Mission Capability Diagram - Connect

**System Analysis**  
Formalize System Requirements

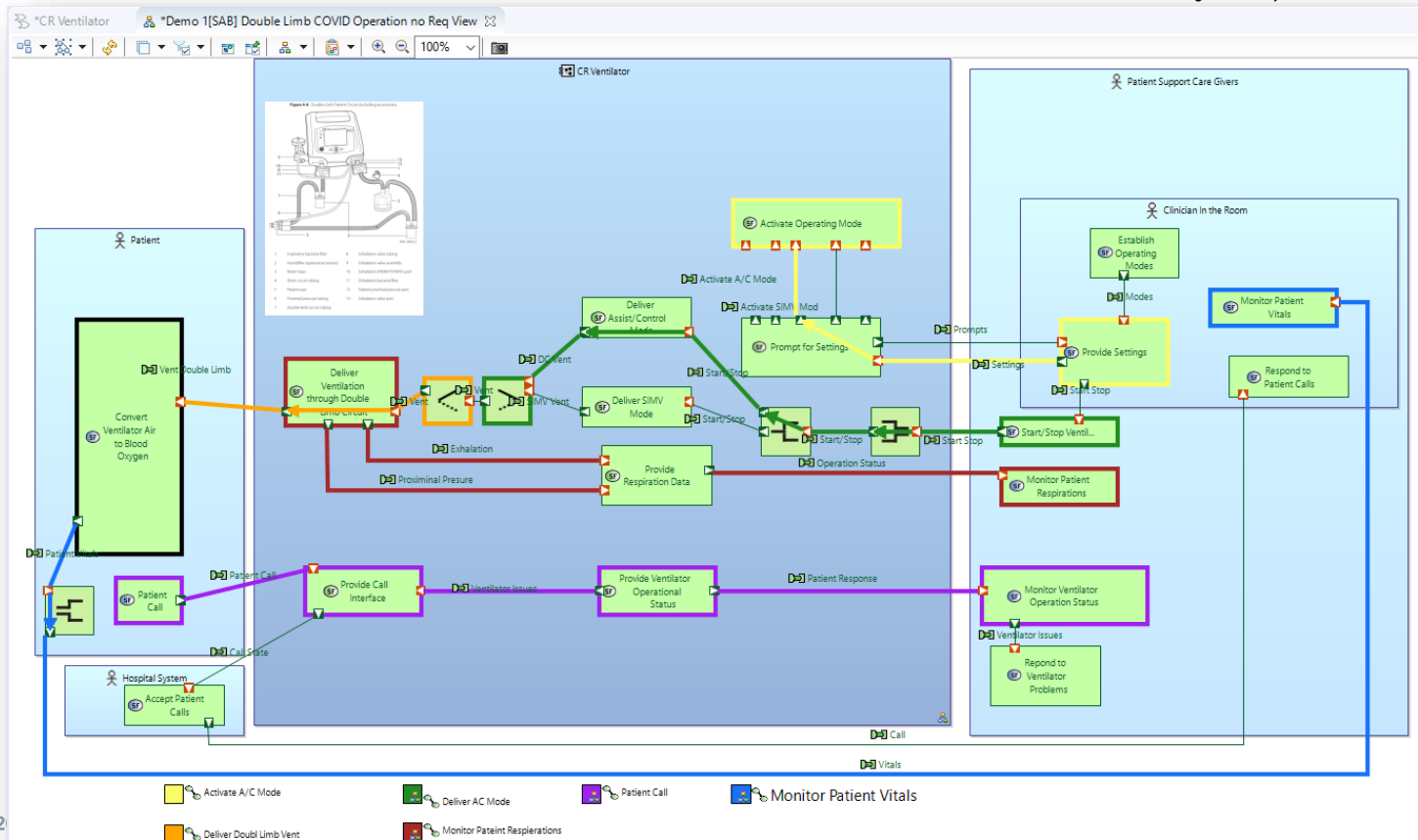
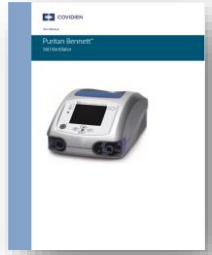
User Manual



# Ventilator – System Analysis Diagram

**System Analysis**  
Formalize System Requirements

User Manual



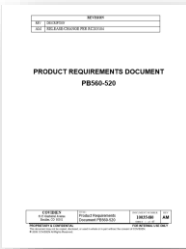


# Ventilator – Requirements into Teamcenter Requirements



**System Analysis**  
Formalize System Requirements

Product Requirement Document



Element Name	ID	Revision	Revision Na
Medtronics PB560 Product Requirements	048381	A	Medtronics P
1 No Title	048426	A	No Title
2.1 INTRODUCTION	048414	A	1 INTRODUC
3 MARKETING PERSPECTIVES	048474	A	MARKETING P
4 REFERENCES	048433	A	REFERENCES
5 GENERAL PRODUCT REQUIREMENTS	048384	A	GENERAL PRO
5.1 PHYSICAL	048416	A	PHYSICAL
5.2 MOUNTING, PORTABILITY, AND STABILITY	048455	A	MOUNTING, I
5.3 CLEANER AND SOLVENT RESISTANCE	REQ-003322	A	CLEANER AND
5.4 OPERATING NOISE / SOUND LEVELS	REQ-003401	A	OPERATING N
6 COMPONENT REQUIREMENTS	048480	A	COMPONENT
7 EXTERNAL INTERFACES	048467	A	EXTERNAL IN
8 SELF TEST	048439	A	SELF TEST
9 VENTILATION MODES AND OPERATION STATES	048432	A	VENTILATION
10 VENTILATION PERFORMANCE REQUIREMENTS	048442	A	VENTILATION
11 DISPLAYED PATIENT DATA MONITORING PERFORMANCE	048437	A	DISPLAYED P
12 OPERATOR INTERFACE REQUIREMENTS	048478	A	OPERATOR IN
13 FEATURES AND CA	12 OPERATOR INTERFACE REQUIREMENTS	A	FEATURES AN
14 DATA LOG THROUGH VENTILATOR INTERFACE	REQ-0033203	A	DATA LOG TH
15 ASSOCIATED PC SOFTWARE	048440	A	ASSOCIATED
16 POWER SUPPLIES	048396	A	POWER SUPP
17 USER/CLINICIAN MANUAL	048470	A	USER/CLINIC
18 CLINICAL SOFTWARE MANUAL REQUIREMENTS	048484	A	CLINICAL SOF
19 SERVICING MANUAL TOPICS REQUIREMENTS	048456	A	SERVICING M
20 DEVICE LABELING	048431	A	DEVICE LABEL
21 PRODUCT TRACEABILITY	048390	A	PRODUCT TR
22 SUPPORTED LANGUAGES	REQ-003378	A	SUPPORTED L
23 SYSTEM COMPONENTS			

**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 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 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 a key press on AUDIO PAUSED. This shall prevent the operator to get in the "Service State" unintentionally. There shall be no other way that the one above to get in the "Service State".

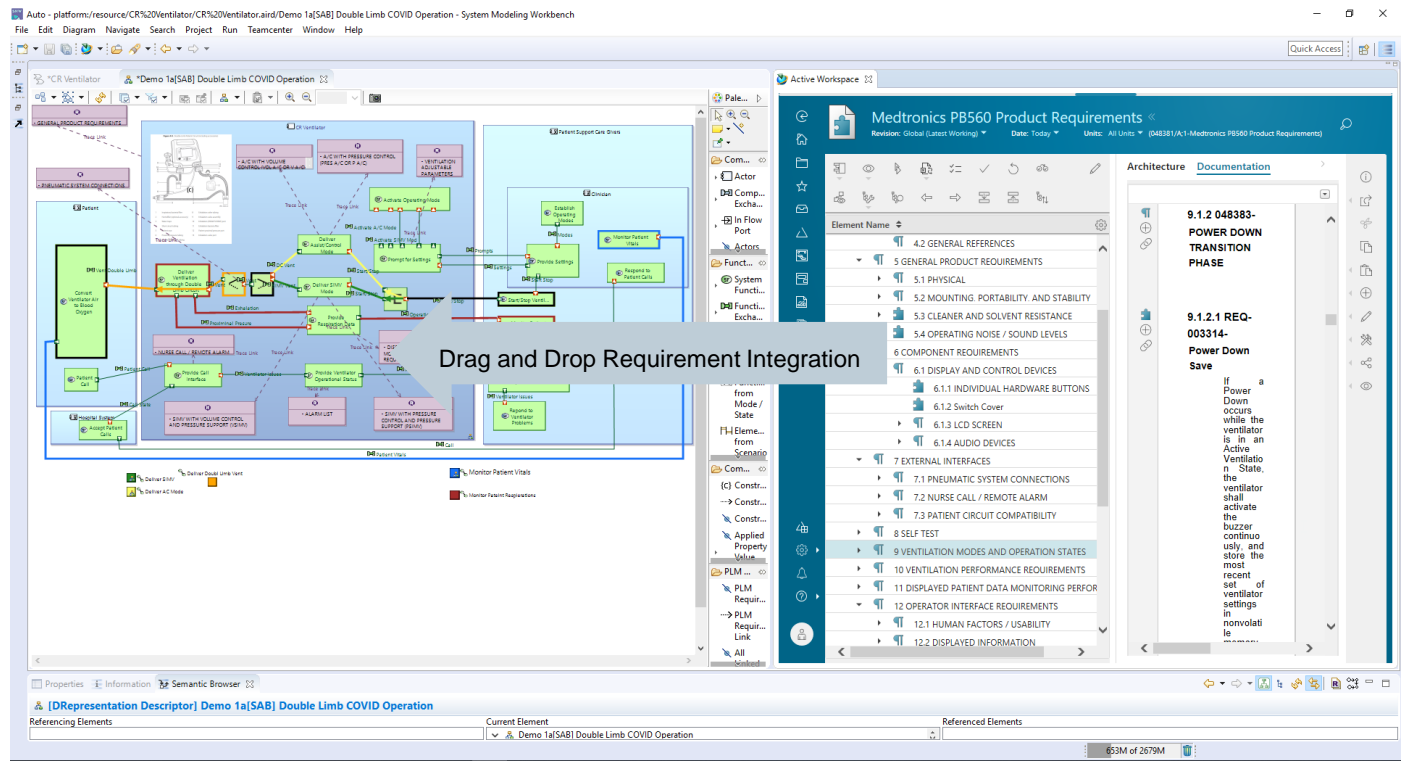
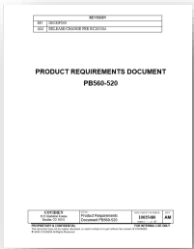
**9.1.6.3 REQ-003249-Exit service state**  
Once in "Service State" the only way to exit is to power down the device. No switch from "Service State" to other states (Active ventilation State or Ventilation Stand-By State), or from other states to "Service State", shall be allowed.

**9.2 048476-OPERATIONAL VENTILATION MODE**

# Ventilator – System Analysis Diagram with Requirements

**System Analysis**  
Formalize System Requirements

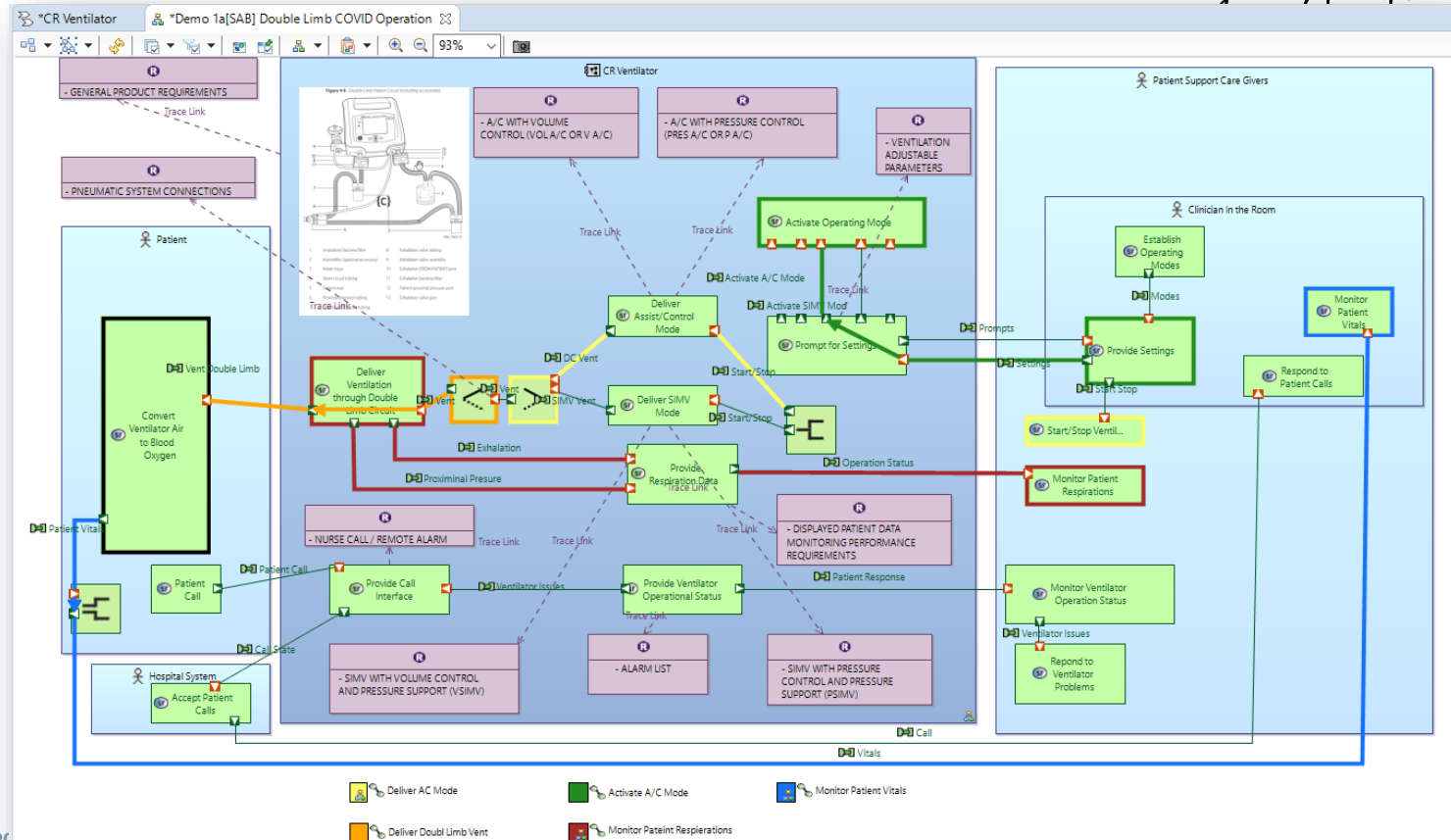
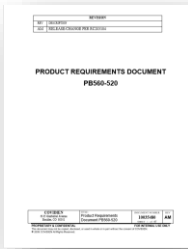
Product Requirement Document



# Ventilator – System Analysis Diagram

**System Analysis**  
Formalize System Requirements

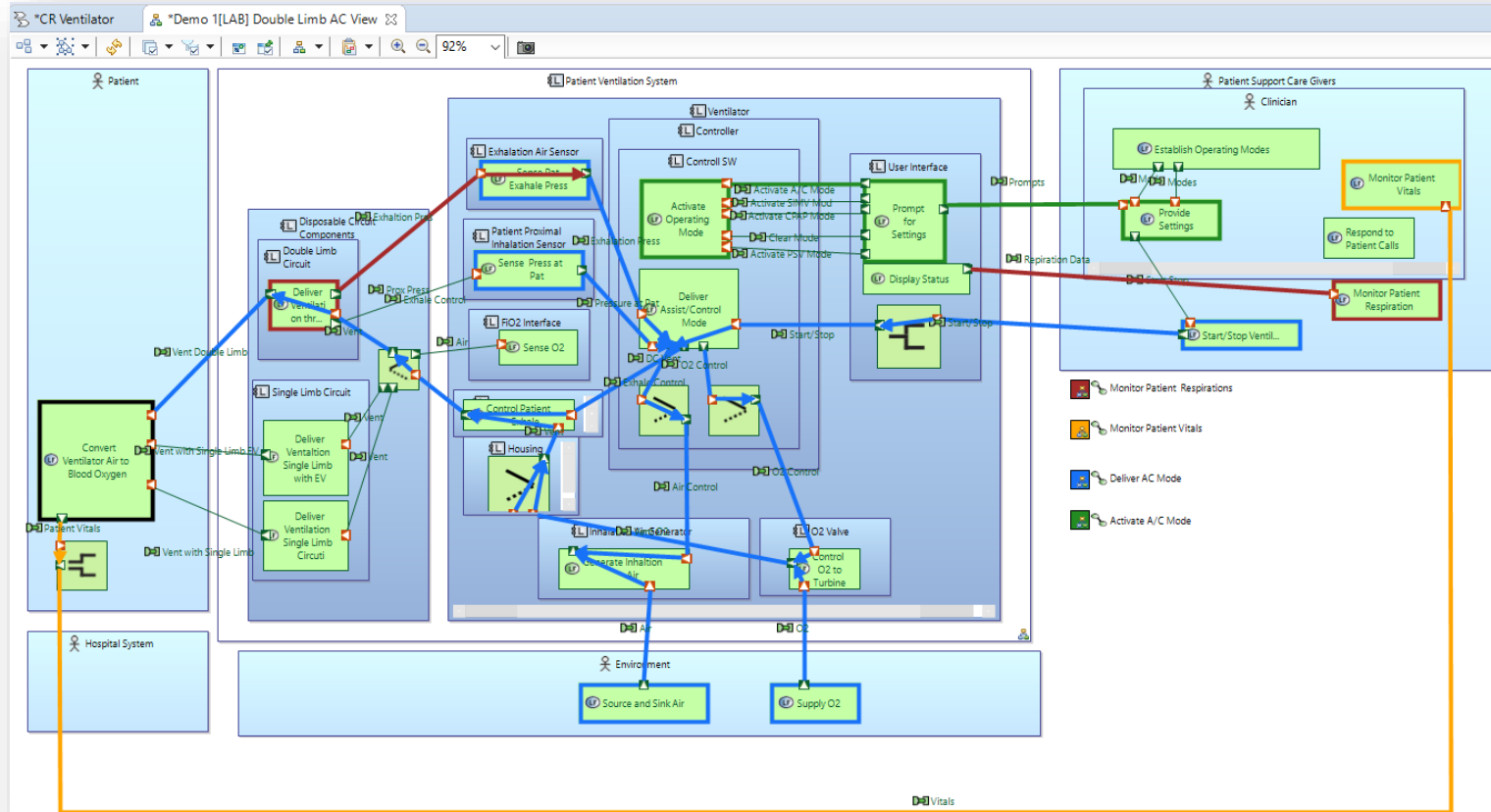
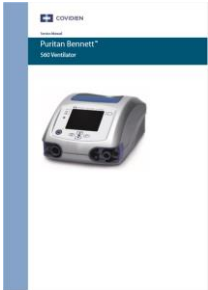
Product Requirement Document



# Ventilator – Logical Analysis Diagram

**Logical Architecture**  
Develop System Architectural Design

Service Manual



# Logical Architecture is a usable blue print for simulation with tools **SIEMENS** Ingenuity for life

**Logical Architecture**  
Develop System Architectural Design

The image displays a complex simulation environment for a ventilator system. It includes a high-level logical architecture diagram on the left, a central controller and ventilator unit diagram, and several simulation windows showing data plots and parameter settings. The simulation windows show graphs for oxygen fraction and lung volume over time, and a table of parameters for Patient A and Patient B.

Parameter	Value	Unit
lung volume	3.200	L
lung stiffness	0.500	N/m
tube length	1.000	m

Parameter	Value	Unit
tube length	2.000	m
lung volume	4.000	L
lung stiffness	0.600	N/m

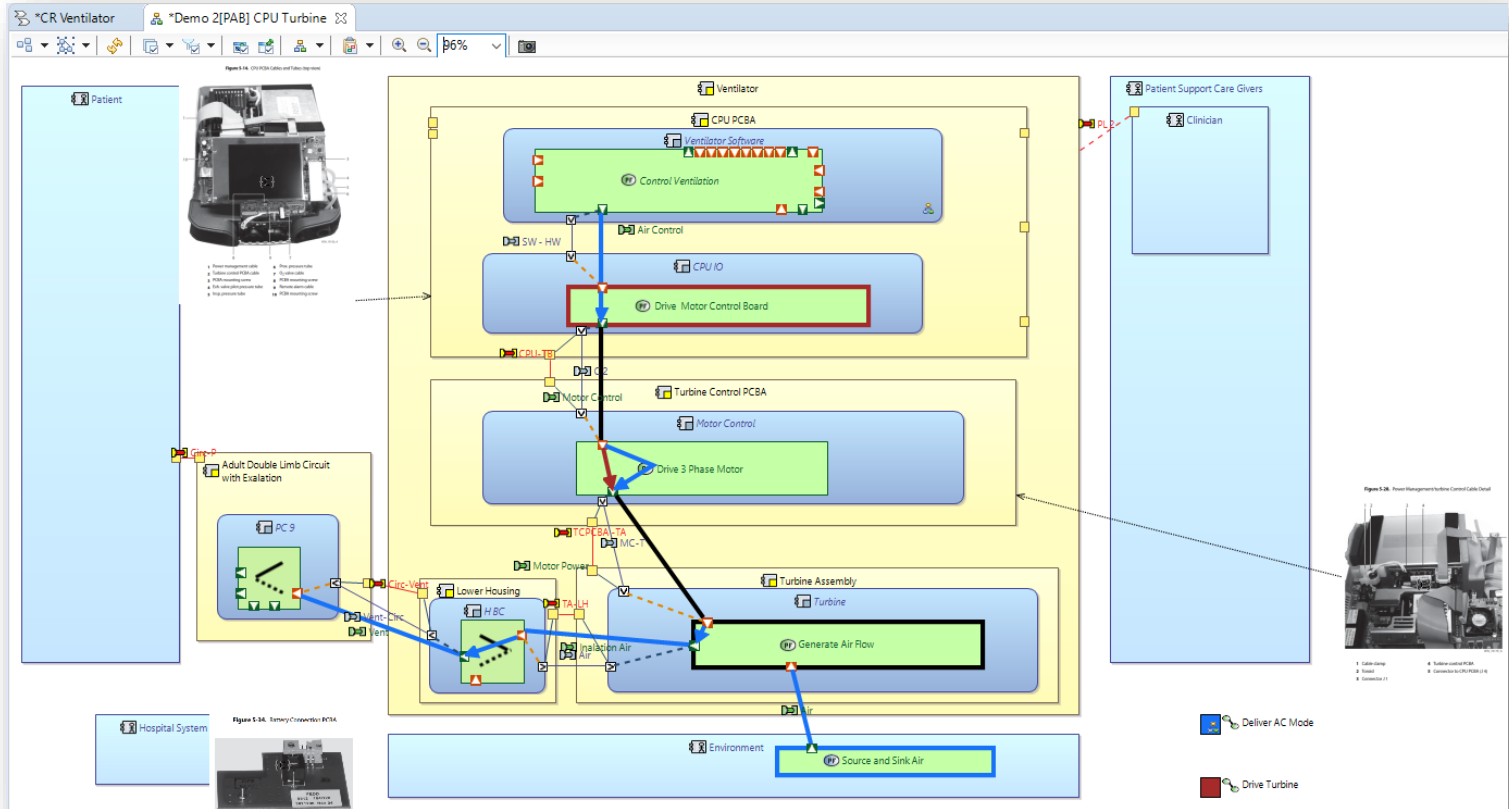




# Ventilator – Physical Analysis Diagram

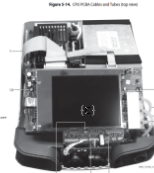
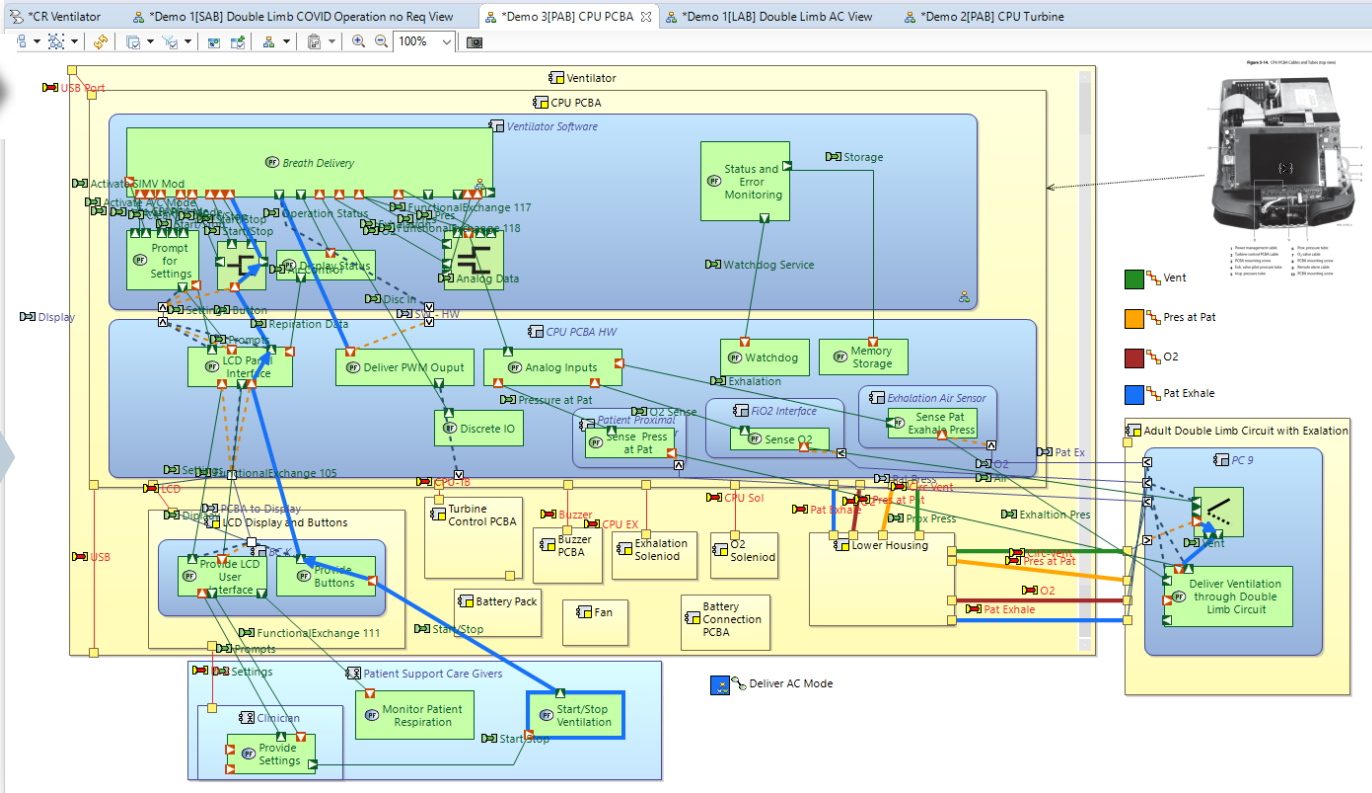
**Physical Architecture**  
Develop System Architectural Design

Service Manual



# Ventilator – Physical Analysis Diagram

**Physical Architecture**  
Develop System Architectural Design

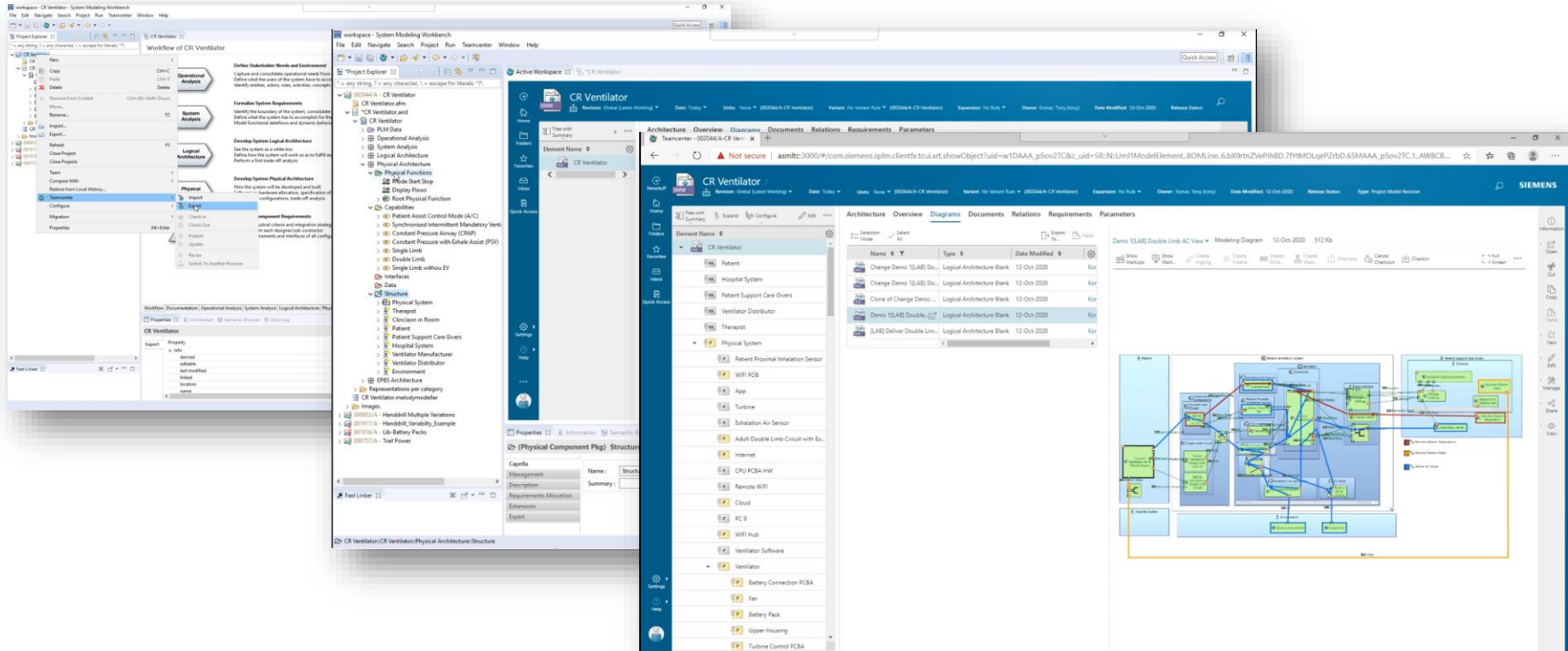


Service Manual

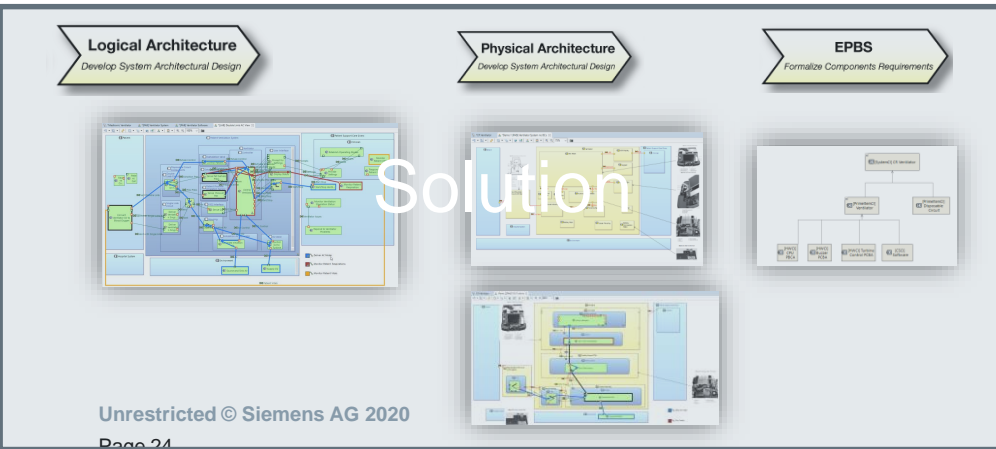
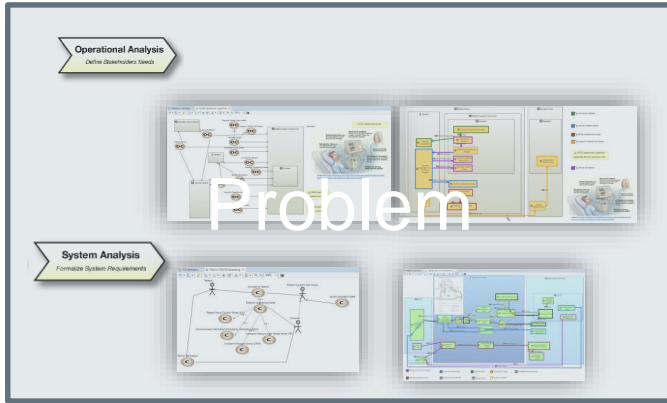


# Information can then be published in Siemens Teamcenter PLM system and be viewed by wider audience.

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*Ingenuity for life*



We understood the problem, we understood the solution.



Problem Definition

Not Well Defined    Well Defined

Breakthrough Innovation	Sustaining Innovation
Basic Research	Disruptive Innovation

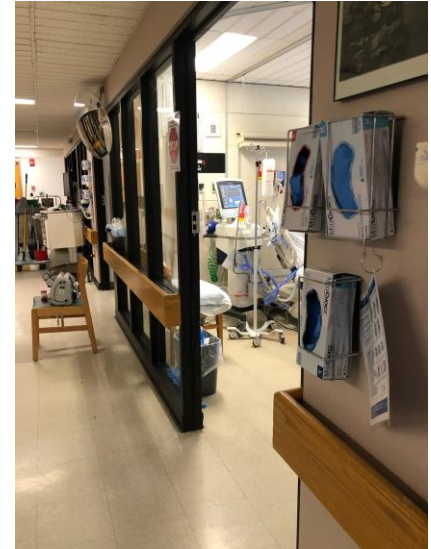
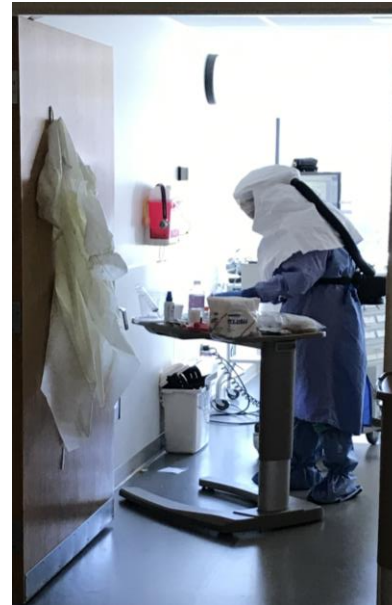
Not Well Defined    Well Defined  
Domain Definition



**Where is the innovation?**

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

Wayne Memorial Hospital



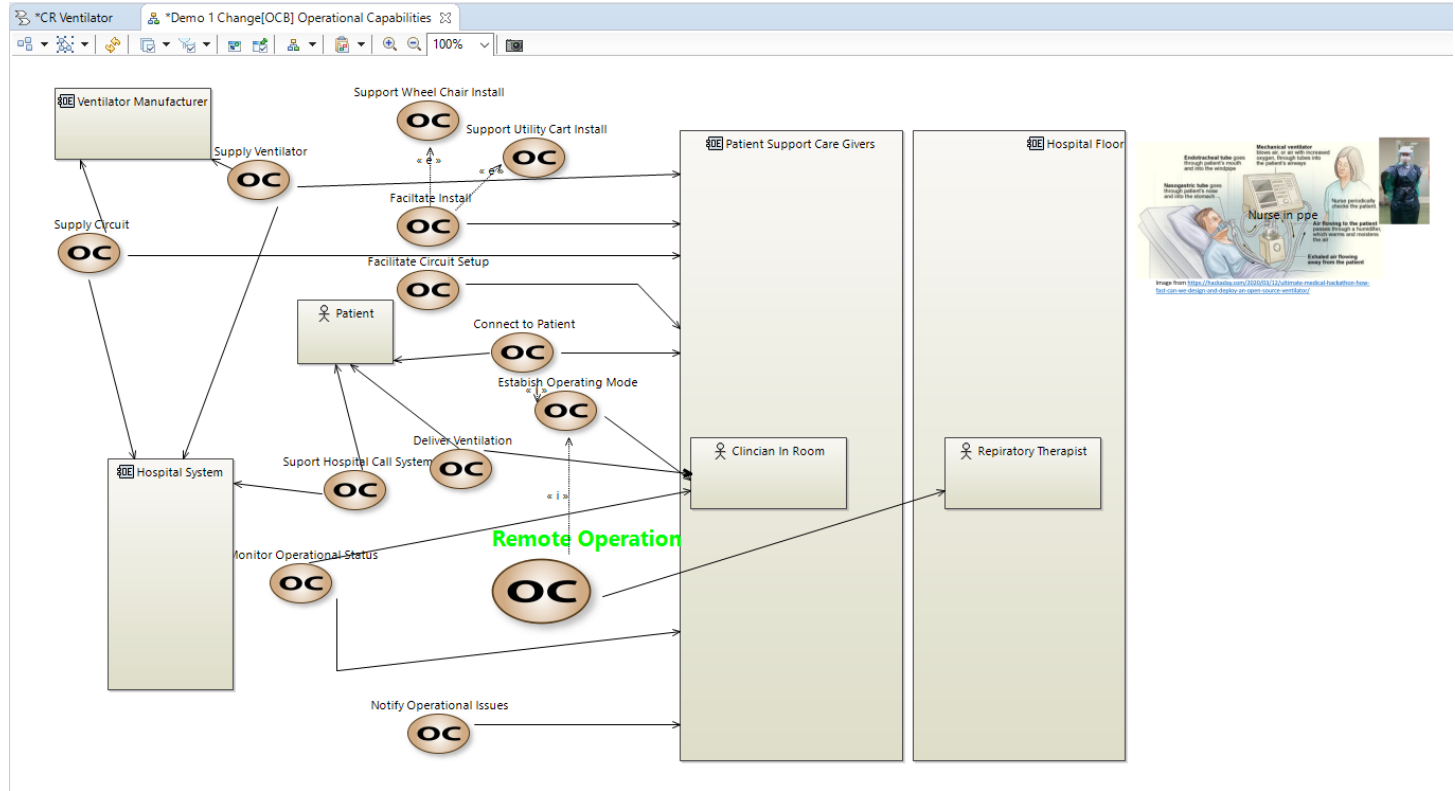
Jeff Franco – Respiratory Therapist

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

**COVID-19 has introduced new problems**

# Ventilator – Operational Activity – Incorporating Remote Operation **SIEMENS** Ingenuity for life

**Operational Analysis**  
Define Stakeholders Needs

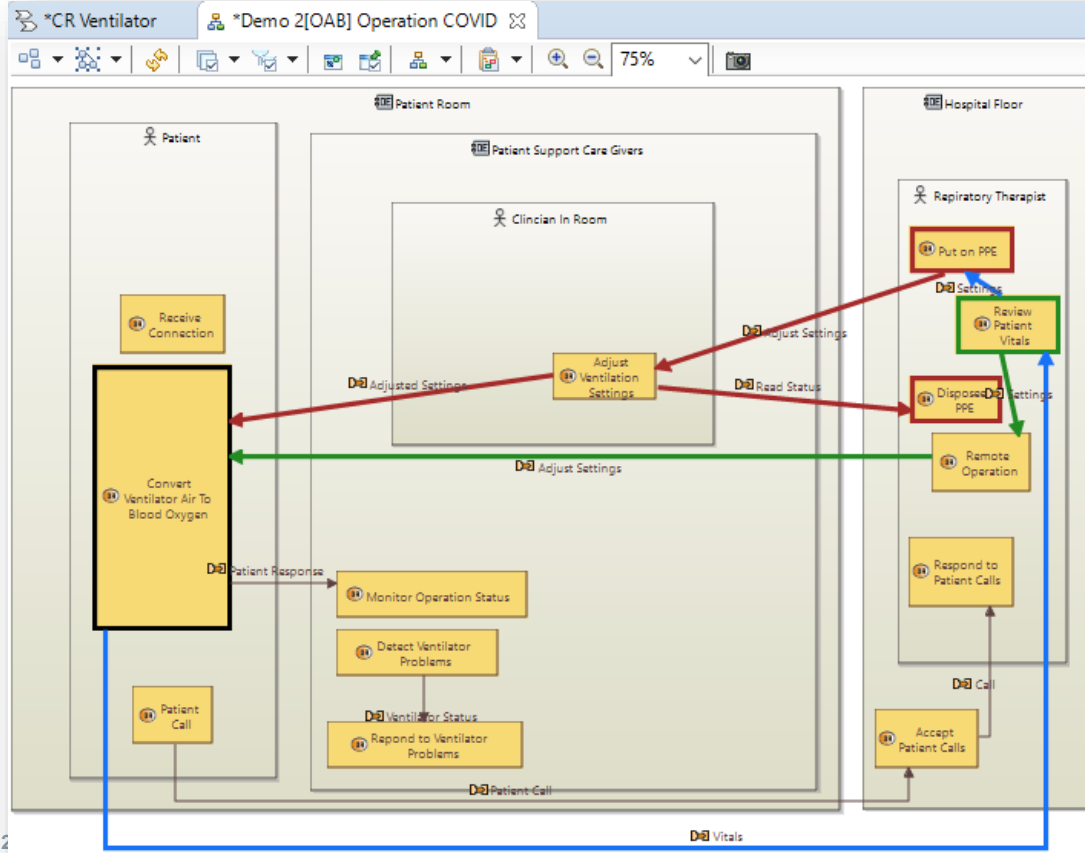




# Ventilator – Operational Activity – Adjust Ventilator Operational Processes

**Operational Analysis**  
Define Stakeholders Needs

Remote Operation



**Legend:**

- Review
- Adjust
- Adjust Remote

Endotracheal tube goes through patient's mouth and into the windpipe

Nasogastric tube goes through patient's nose and into the stomach

Mechanical ventilator Sucks air or air with increased oxygen, through tubes into the patient's airways

(C) Nurse in ppe

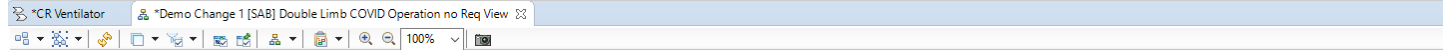
Air flowing to the patient passes through a humidifier, which warms and moistens the air

Exhaled air flowing away from the patient

Nurse periodically checks the patient

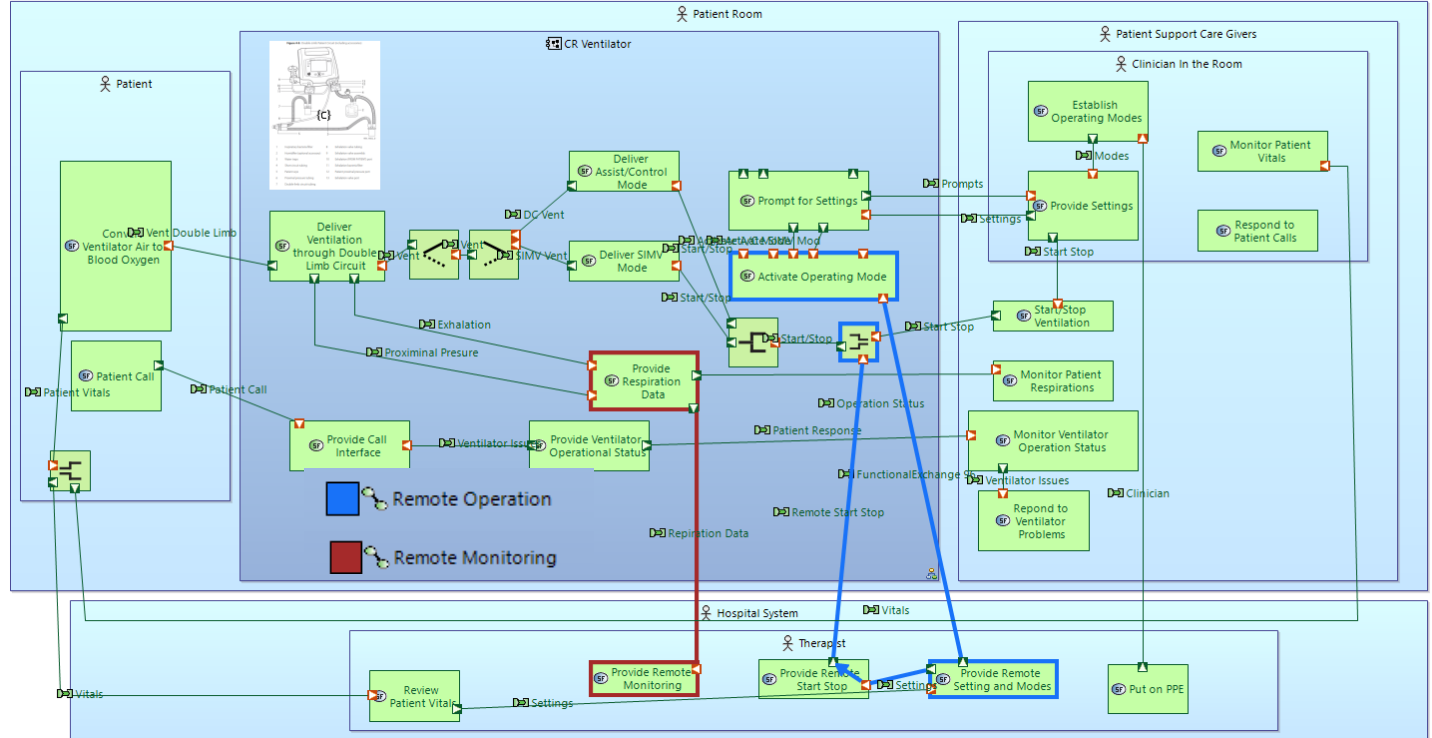
Image from <https://hackaday.com/2020/03/12/dtmm-ase-medical-hackathon-how-fair-can-we-design-and-deploy-an-open-source-ventilator/>

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



## System Analysis

Formalize System Requirements

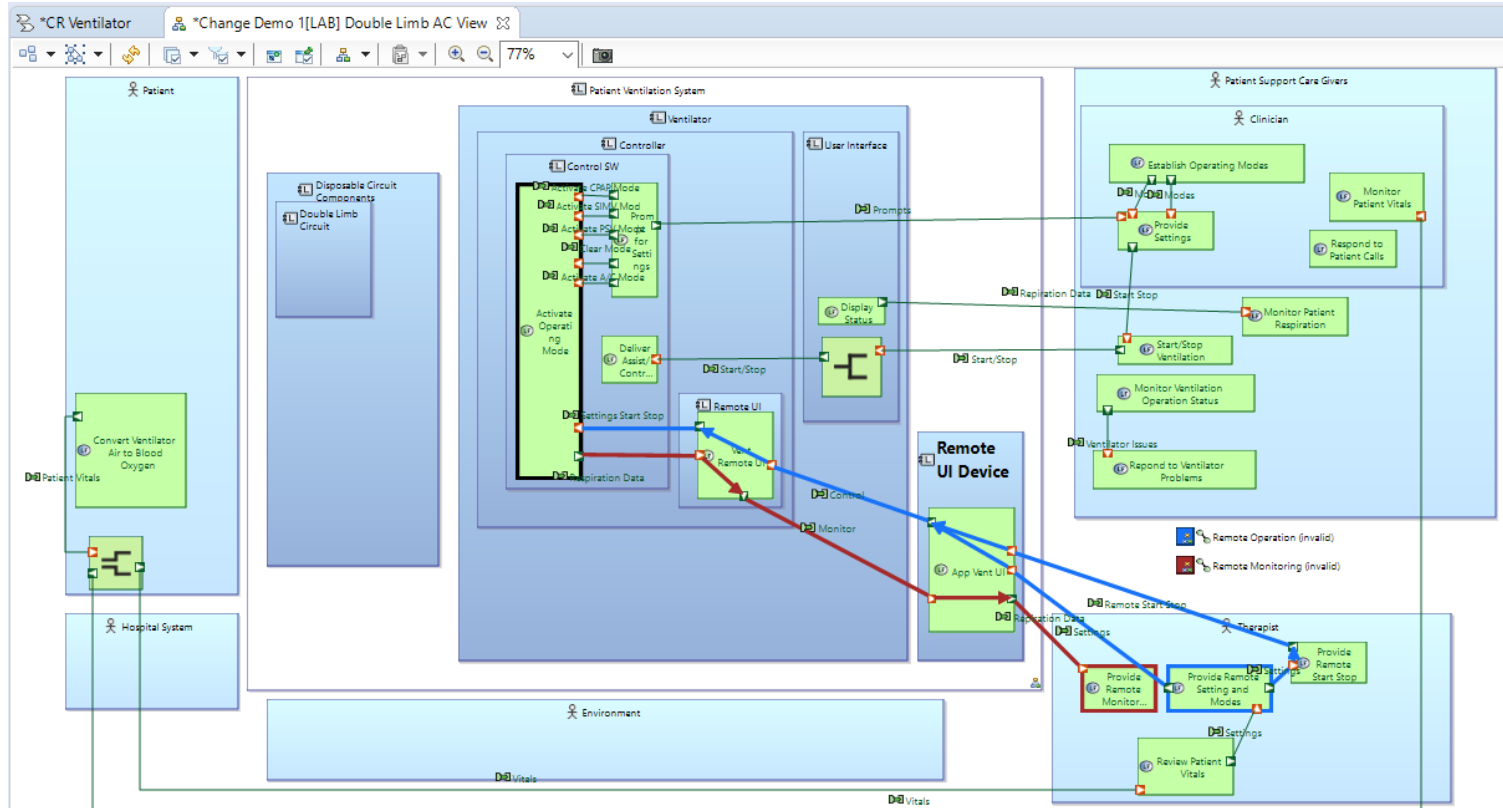


Adjust Remote



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

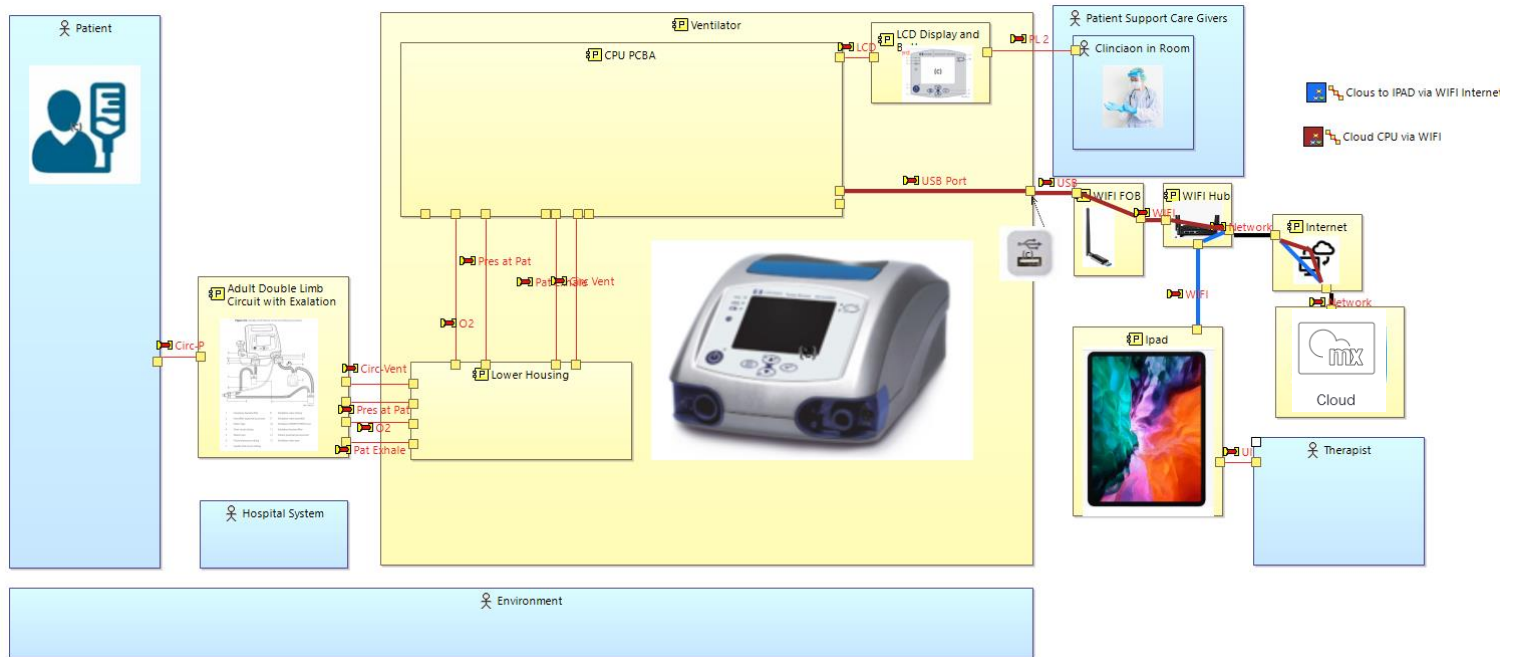
**Logical Architecture**  
Develop System Architectural Design



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

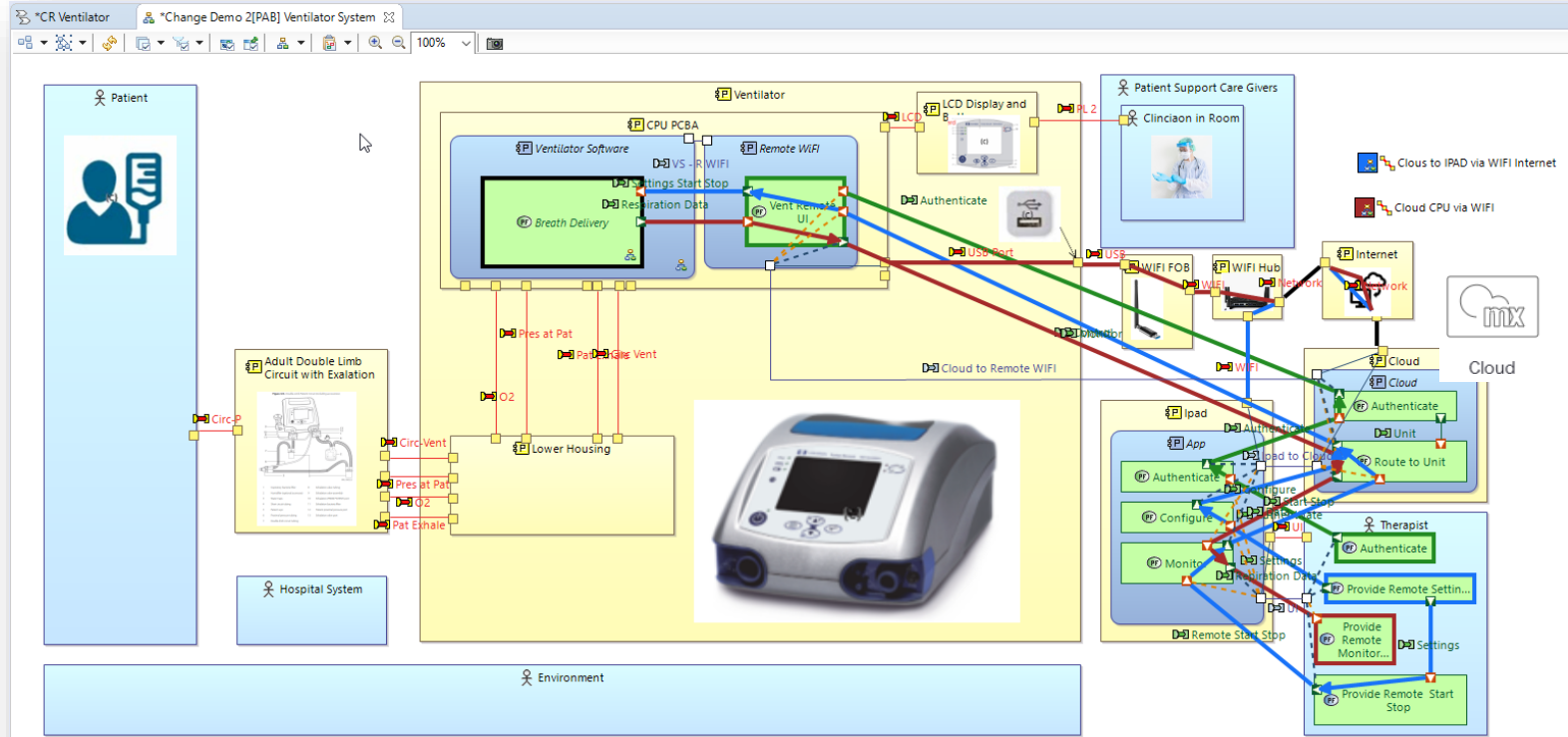
*Ingenuity for life*

**Physical Architecture**  
Develop System Architectural Design



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

**Physical Architecture**  
Develop System Architectural Design



Remote Operation  
Remote Monitoring



Remote Operation    Remote Monitoring    Authenticate

# Capella is a tool for Innovation

Assists in understanding a problem and design

It uncovers a gaps  
In understanding

Innovative Solution

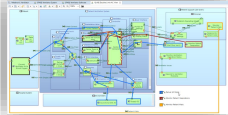
Operational Analysis  
Understand the problem



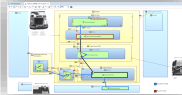
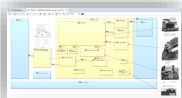
System Analysis  
Parameterize System Requirements



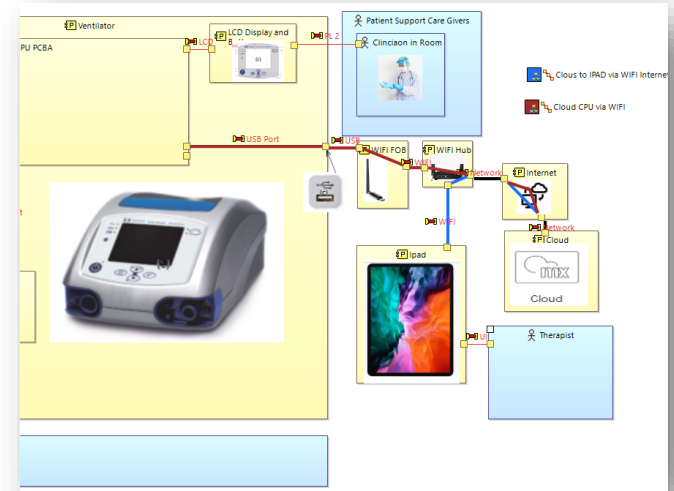
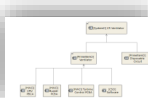
Logical Architecture  
Develop System Architectural Design



Physical Architecture  
Develop System Architectural Design



EPBS  
Formalize Component Requirements





# 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 other.
  - 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

## Tony Komar

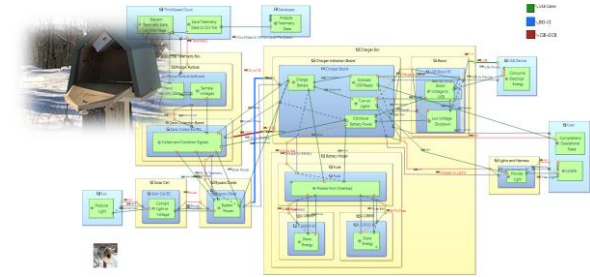
MBSE Evangelists

Senior Solution Architect

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

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

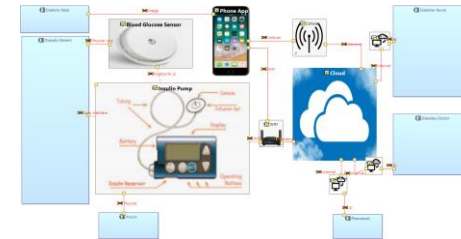
## Solar Charger



## Autonomous Missioning Planning



## 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 / Magellium

*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*