P08025 – LVAD Durability Test Machine

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P08025 – LVAD Durability Test Machine

Background Information

LVAD (Left Ventricular Assist Device)

Provides Congestive Heart Failure Patients with a high quality of life while waiting for a heart transplant (Bridge to Transplant)

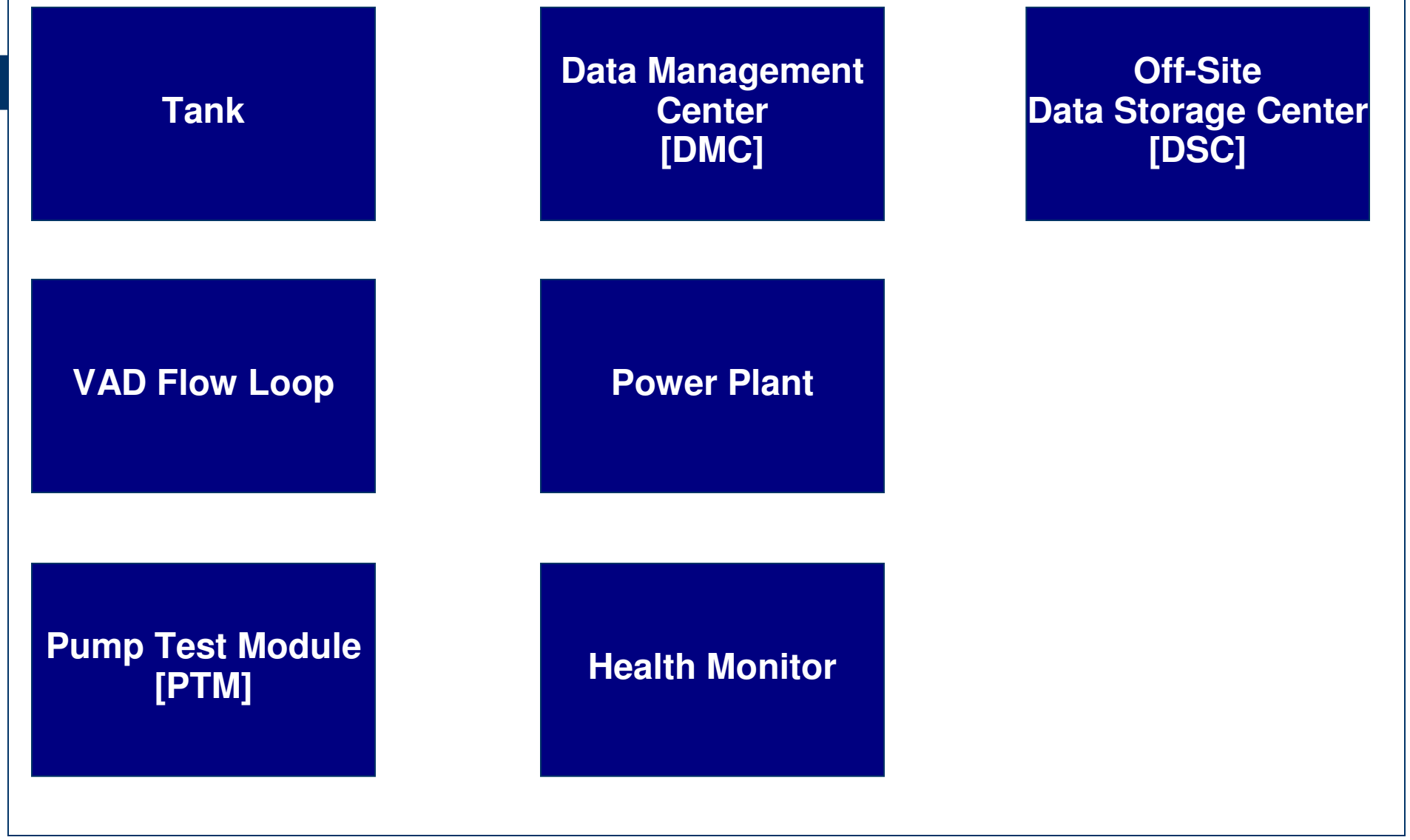
The LVAD-R2 is currently being developed at the Rochester Institute of Technology

CARNA is a tool to gain FDA Approval for an Investigational Device Exemption (IDE), which will allow the LVAD-R2 to enter Clinical Human Trials.

P08025: CARNA High Level Customer Needs

- Probability of Failure < 2% over 2 years
- Will run for 2 years uninterrupted with the following exceptions
  - Critical Signals may be lost for 24 hours (with proof of VAD normal operation)
  - Non-Critical Signals may be lost for 72 hours
- Will Allow Multi-Unit Connection and Operation (10 VAD Units)
- Will measure the LVADR2 Performance
- Will Analyze data to detect faults and early warning signs of VAD
- Will Safely Store VAD Data
- Will Provide Remote and Local Access to the Data

P08025: CARNA Sub-System Breakdown



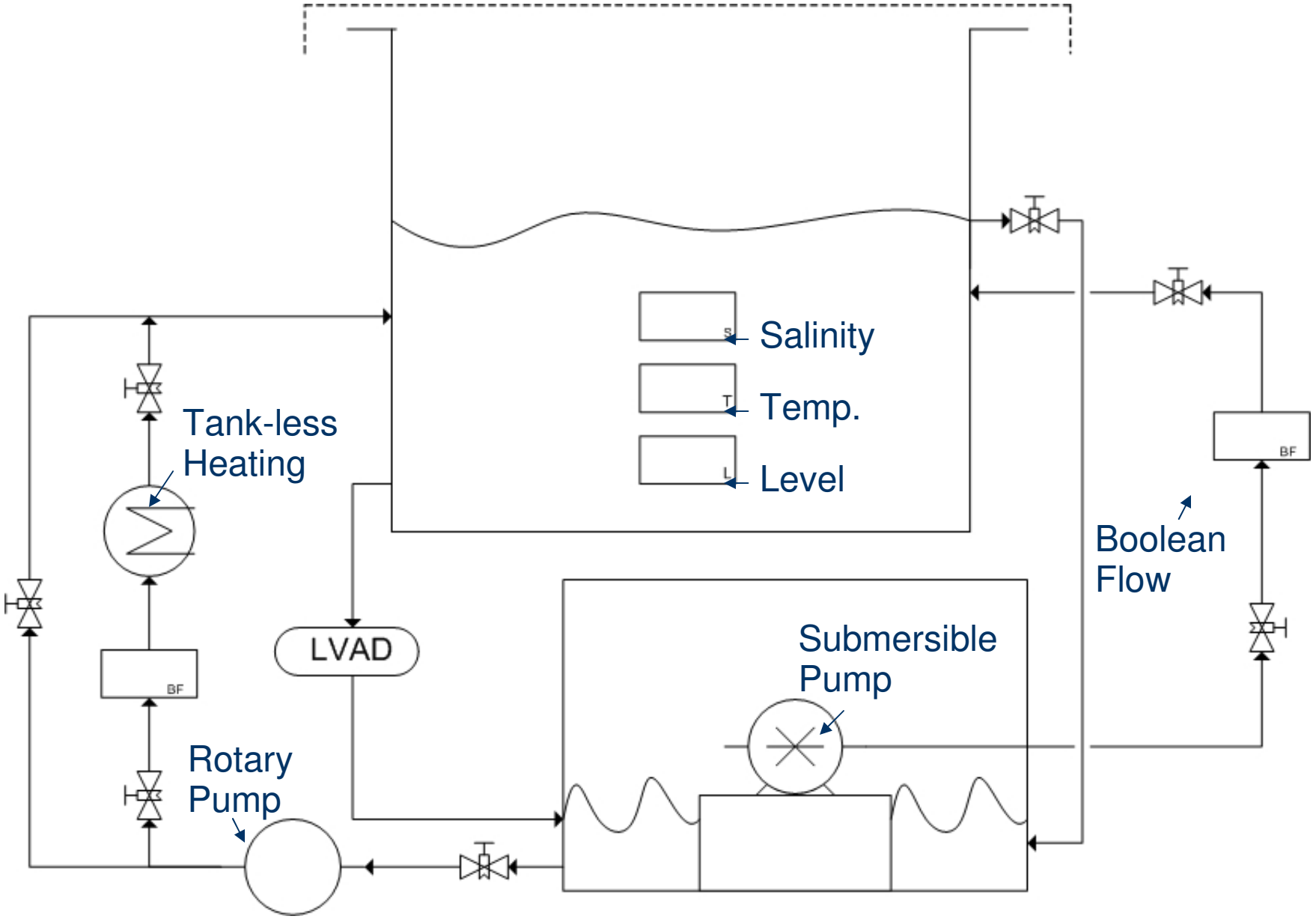
P08025: CARNA Current State of Design

- Design meets all customer needs, with some caveats:
  - Two year continuous run time assumes a constant supply of uninterrupted power
  - Health monitor will not be incorporated into project at this time
    - Detect early warning signs of pump and CARNA & alert users
- Design meets engineering specifications
  - Same caveats apply to health monitor specifications
- Initial project budget of $4,000 underestimated due to robustness and complexity of subsystems
  - Current projected cost of $12,225
- Mitigations
  - Projects not being tackled this term (e.g. power plant, health monitor) will be spec'd out for future Senior Design work, current possibility of 3 design projects.

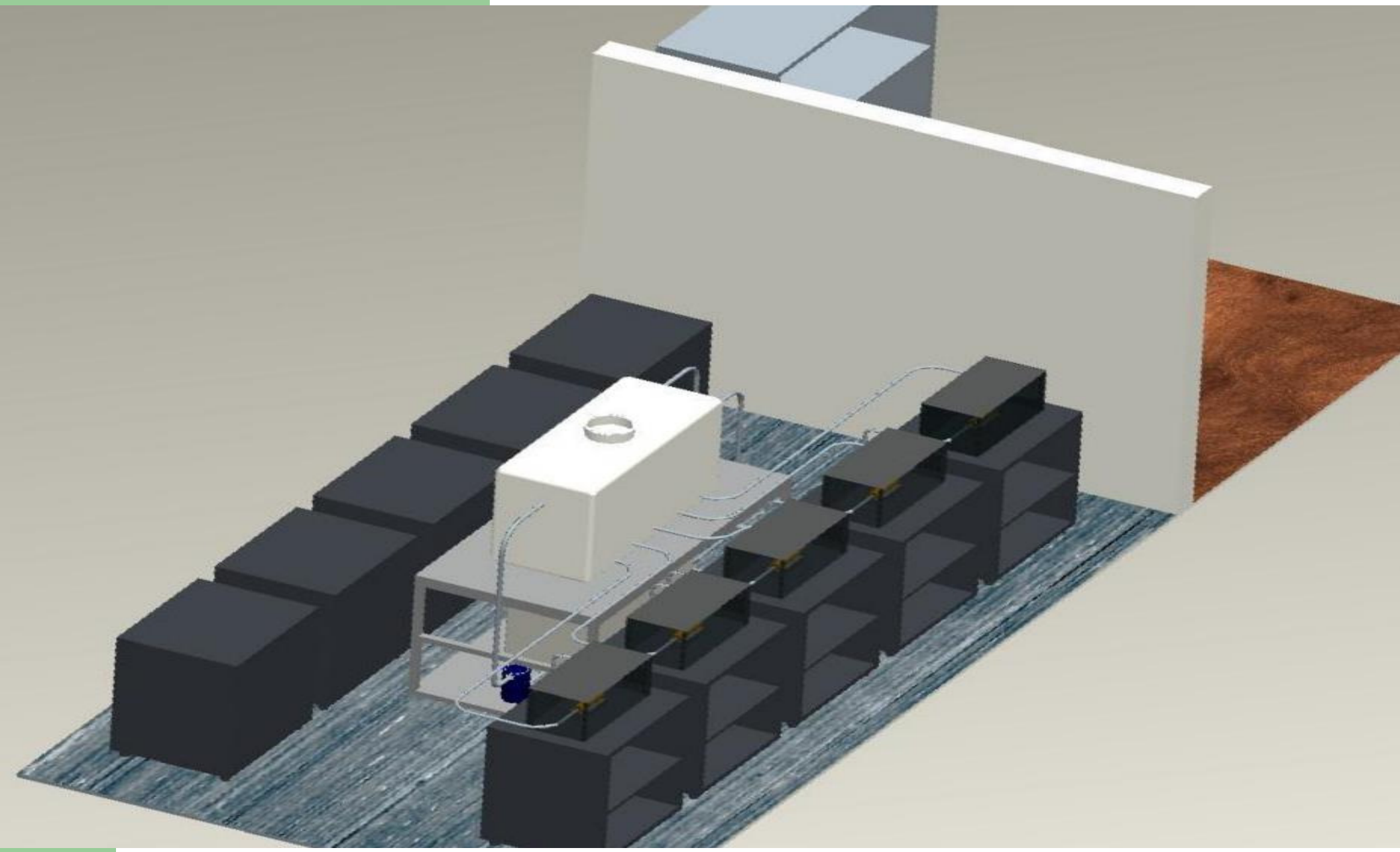
Selected Concept - TANK System

- Need two tanks to generate pressure needs
  - Head tank to control pressure at LVAD inlet
  - Sump tank to drain to atmospheric pressure
- Non-interrupting maintenance
  - Replace heater without loss in flow
  - Planned Maintenance of primary and secondary return flows
- Single fault tolerant
  - Primary pump fails
  - Level sensor detects change in tank height
  - Backup sump pump activated

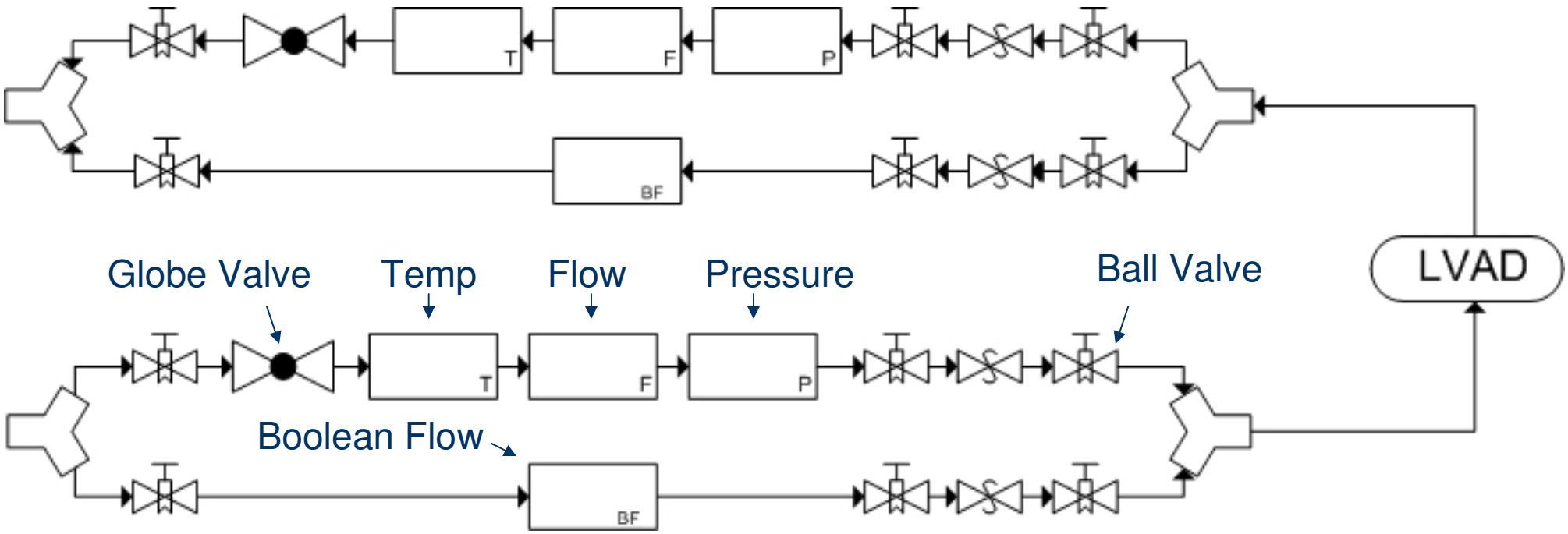
Selected Concept - TANK System



Project CARNA - System Layout

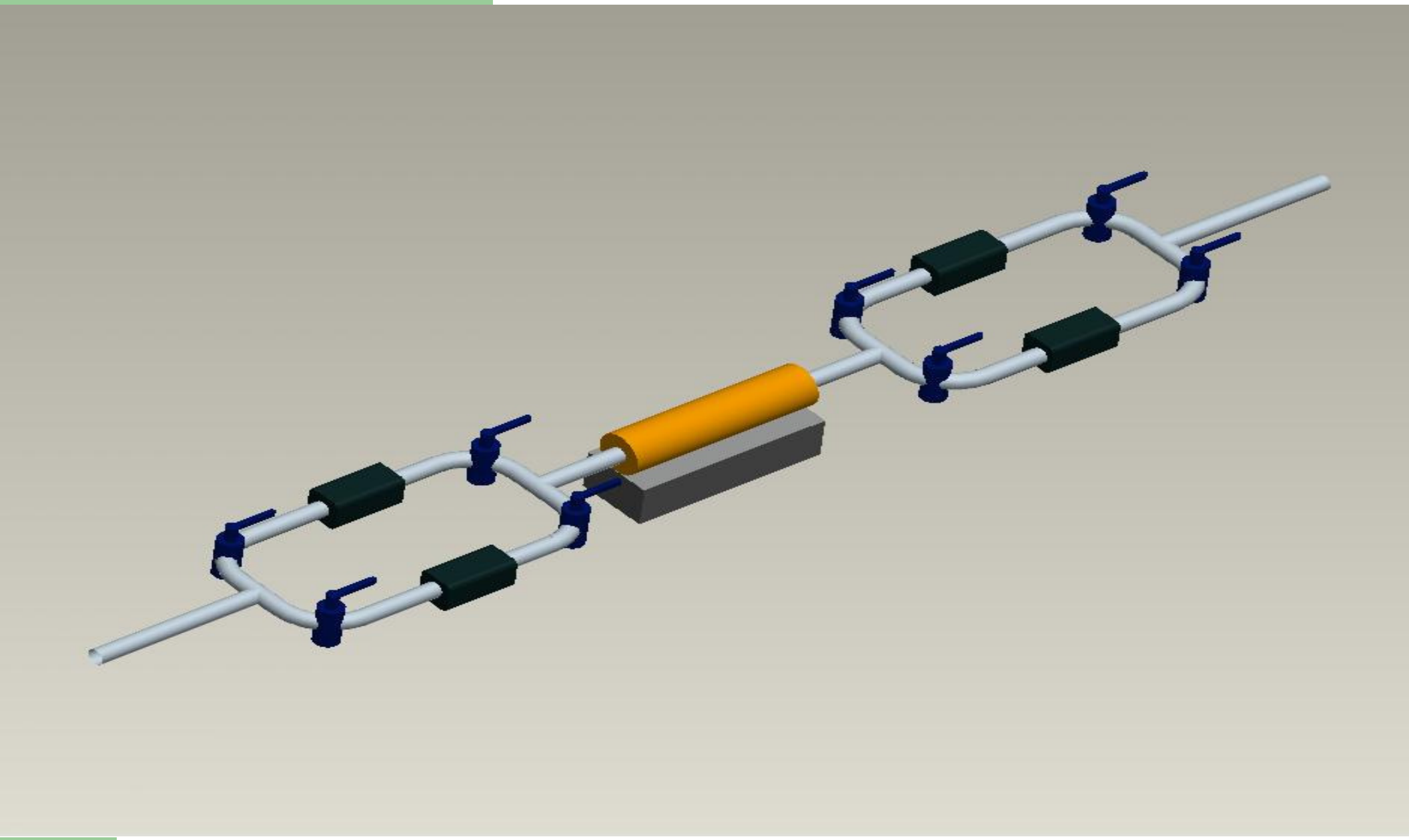


Selected Concept - VAD Flow Loop System



- Non-interrupting maintenance
  - Replace failed Sensors or Valves (Fail-safe Open)
  - Planned Maintenance [Swap and Re-Validate sensors]
- Interchangeable parts
  - Fast, easy change out

Selected Concept - VAD Flow Loop System

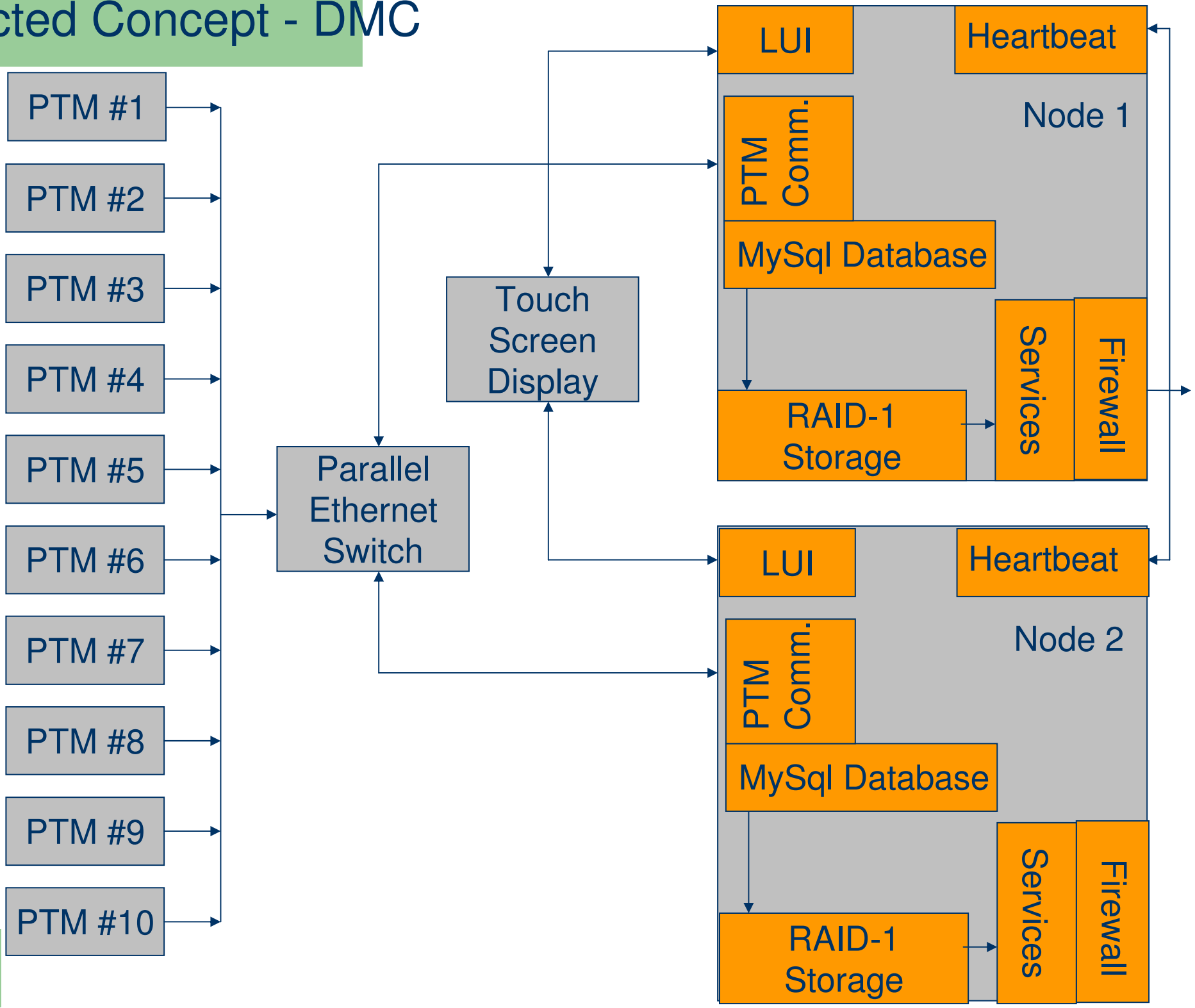


Selected Concept – Data Management Center [DMC]

- Two Redundant PC's with Linux OS
  - Receive Data from PTM via Ethernet
  - Analyze and Store Data
  - Make Data Available Remotely

- In addition, the DMC will do the following:
  - Provide a Local User Interface
    - Real-Time Performance and Statistics
    - VAD Flow Loop Configuration
    - Trouble-Shooting / Repair Procedures
  - Communicate with the Health Monitor

Selected Concept - DMC

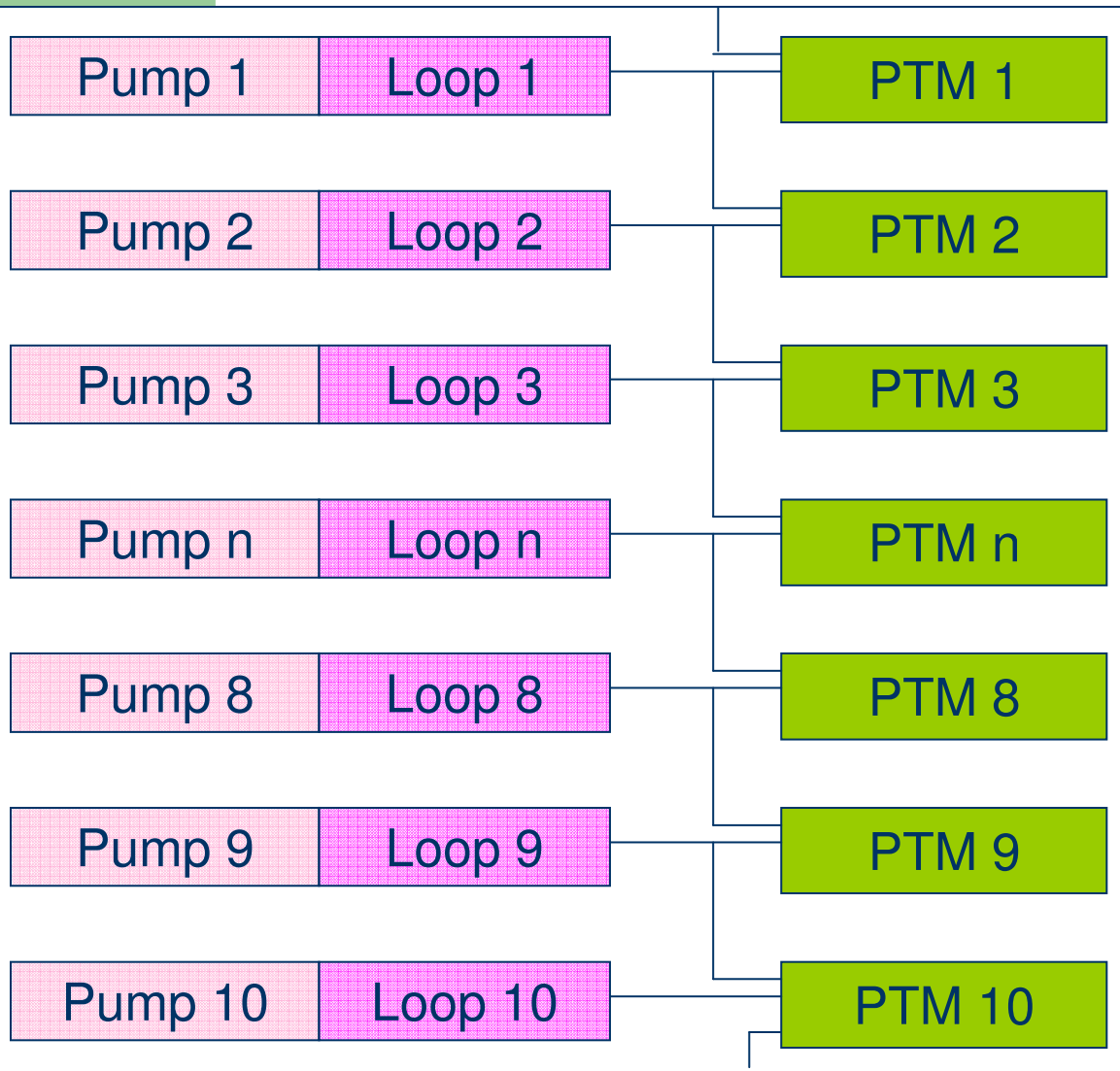


Selected Concept – Pump Test Module [PTM]

- PC with National Instruments RTOS and DAQ Hardware will measure all signals from the VAD and the VAD Flow Loop.

- In addition, PTM will do the following:
  - Receive control messages from the DMC
  - Store the data locally
  - Send the data to the DMC through Ethernet
  - Communicate with the Health Monitor
  - Measure adjacent VAD and VAD Flow Loops

Selected Concept – Pump Test Module [PTM]



Single Fault Tolerance

If one PTM unit fails, ALL pump signals are still measured.

Pseudo Double Fault Tolerance

If 2 non-adjacent PTM units fail, ALL pump signals are still measured.

P08025: CARNA Identified Risks

- Project Size
- Proving Reliability
- Software
- Analog Data Acquisition

Project Size

- Attempt to do too much
- Larger Budget → Bigger Failure

Solution:

- Renegotiated customer needs
- Asking: Is it necessary?

Proving Reliability

- Testing
- MTBF and Reliability Statistics

Solution:

- Continuing to Research Statistical Methods
- Shifting Resources

Software

- Size and Complexity
- National Instruments RTOS

Solution:

- Flowcharting Software
- Researching RTOS
- Acquire Development Hardware Soon

Analog Data Acquisition

- Noise
- Large Quantity of Collected Data

Solution:

- Industry Standard – National Instruments
- Plan to Experiment and Optimize

P08025: MSD II Project Schedule Milestones

- Dec 3: Begin Software Development
- Dec 10: Design finalized and all components purchased
- Jan 4: Completion of loop assembly
- Jan 5: Begin initial testing phase and incorporating electronics
- Feb 2: Run continuous test and continue Software Development
- Feb 15: Documentation finalized: technical paper, poster, design history file
- Feb 29: MSDII Final Design Review

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Our Audience

THANK YOU!