A Novel Magnetically Levitated Axial Flow Left Ventricular Assist Device

Steven Day

Dept. of Mechanical Engineering
Rochester Institute of Technology

steven.day@rit.edu

NEW MAGNETICALLY SUSPENDED LEV-VAD

Bioengineering Research Partnership: 1RO1 HL 077085-01A1
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Don B. Olsen, DVM - Principle Investigator
S. Durrant - Executive Administrator
Utah Artificial Heart Institute, Salt Lake City, Utah

Steven W. Day, PhD – Research & Design Lead
Rochester Institute of Technology, Rochester, NY

Ronald W. Kipp, BS - Engineering Coordinator
R K Engineering, Willow Street, PA

Joe Imlach, PhD - Magnetic Fields and Bearing Design
Innovative Concepts in Engineering, Anchorage, AK

Paul A. Nolte, BS - Device Manufacturing
Flowserve Corp., Nashville, TN

Scope of current NIH funded project

Design

Bench-top component testing

Full prototypes

Acute and chronic animal implants

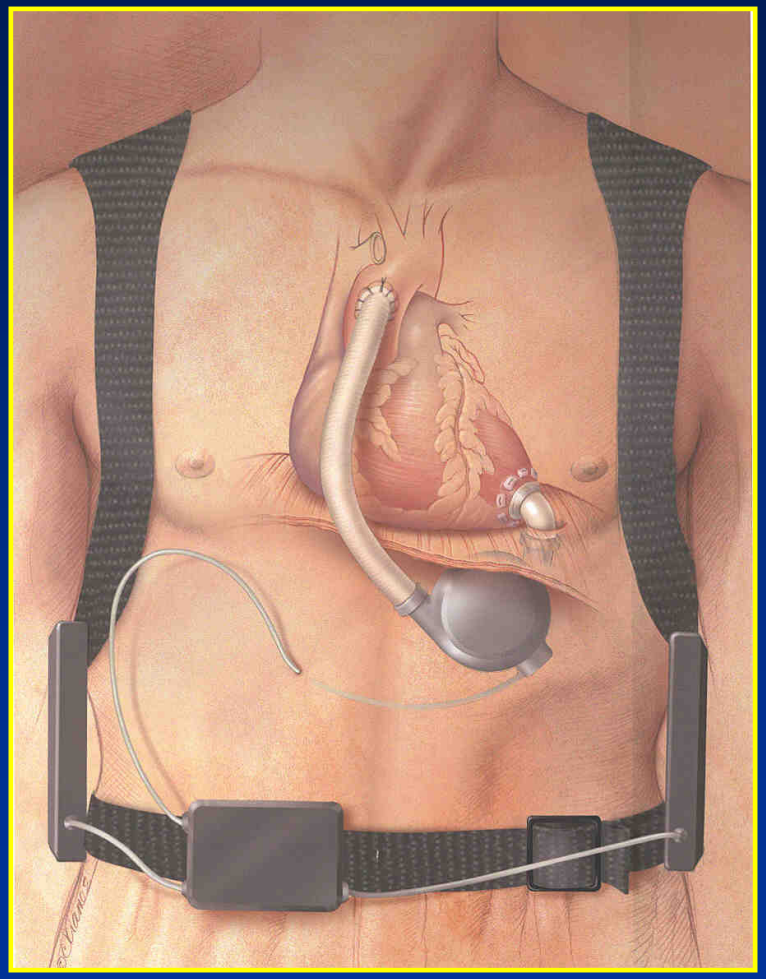
Investigational Device Exemption (IDE) Application

Motivation

- ~ 5,000,000 people in US with congestive heart failure
  - *Over 550,000 new cases of heart failure will be diagnosed in the next year.*
  - *responsible for more hospitalizations than all forms of cancer combined.*
- <2,500 transplants available per year
  - *2,016 and 2,127 heart transplants were performed in the United States in 2004 and 2005, respectively.*
- Many patients would benefit from a mechanical device:
  - Short term – *'bridge-to transplant' (BTT)*
  - Long term – *'destination therapy'*

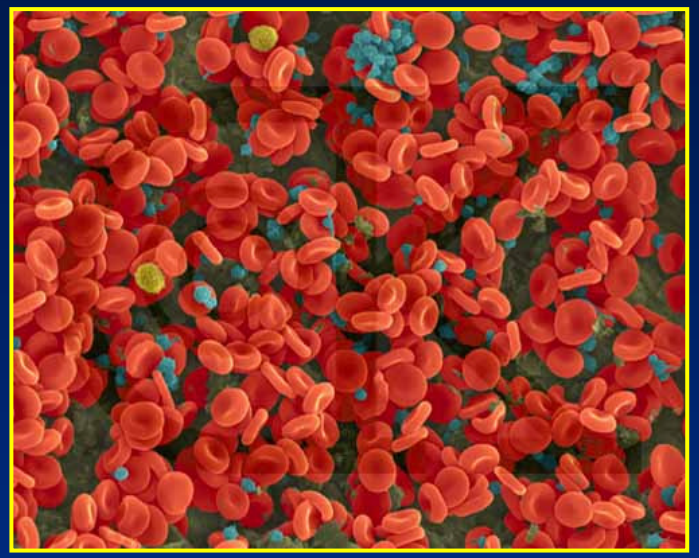
Left Ventricular Assist Device (LVAD)

- Pump assists native heart
- Proven **short-term** effectiveness
- Current devices have limited design life due to **biocompatibility**
  - Degradation of the artificial material
    Mechanical Wear
  - Blood damage caused by the device
    Hemolysis & Thrombosis
- Need for a **long-term** implant
  - Mechanical design life of 10+ years
  - Negligible effect on blood



Blood Damage

- Hemolysis
  - Red Blood cell membrane is torn, releasing cell contents
  - Caused by shear stress



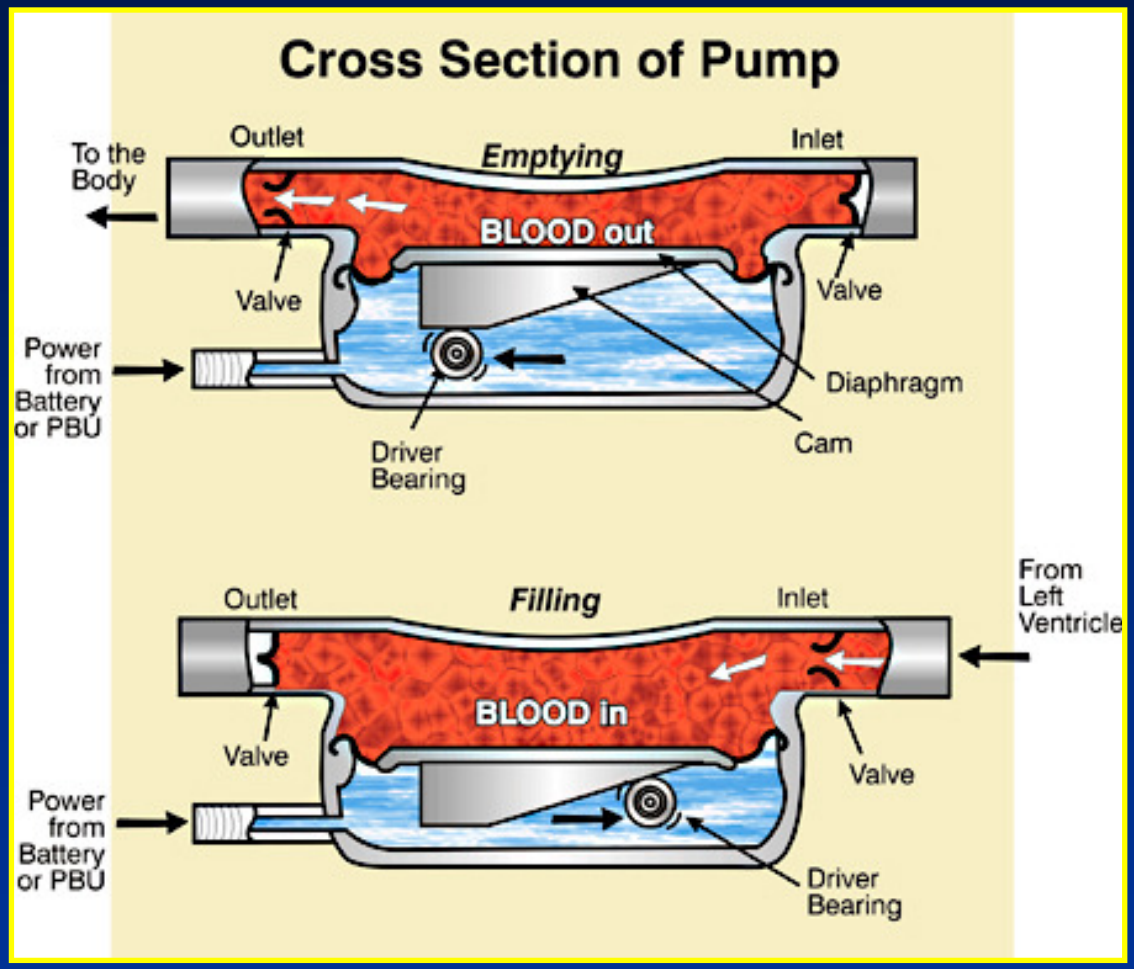
- Thrombosis
  - Chemical and physical clotting cascade creates thrombus (clot)
  - Thrombus may detach and clog arteries
  - Encouraged by (among other things) turbulence, recirculation, stagnation

Evaluation and Prediction of Blood Damage

- Turbulent flow, shear, and stagnation are unavoidable
- **Theory**, **empiricism**, and **Computational Fluid Dynamics (CFD) a**ll have limitations in this miniature pump

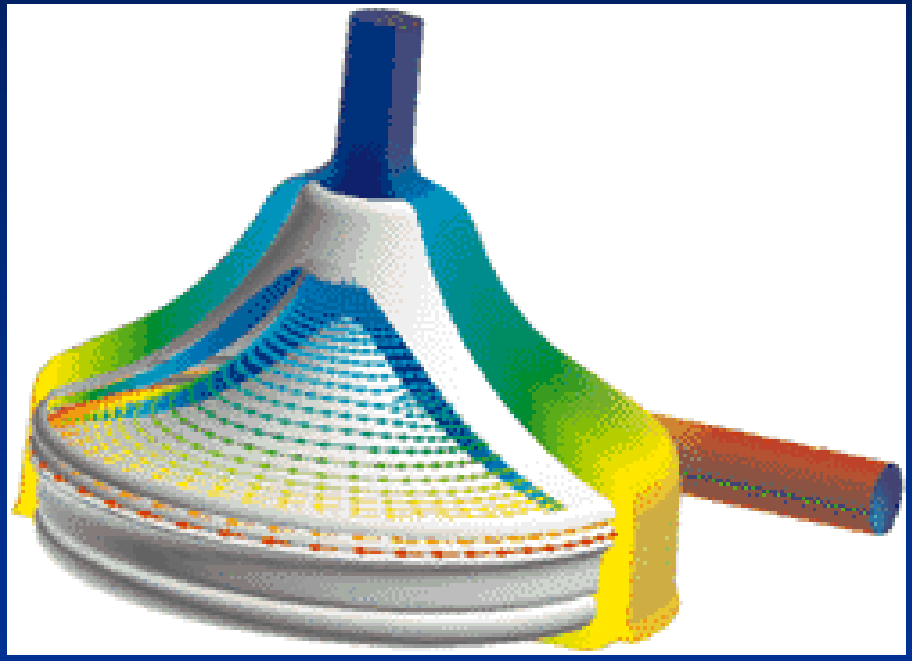
Quantitative modeling and measurement of flow are required

History - "1st generation" LVADs



HeartMate™ LVAS - Thoratec

History - “2nd generation” LVADs
Rotary Pumps



Medtronic Biomedicus pump

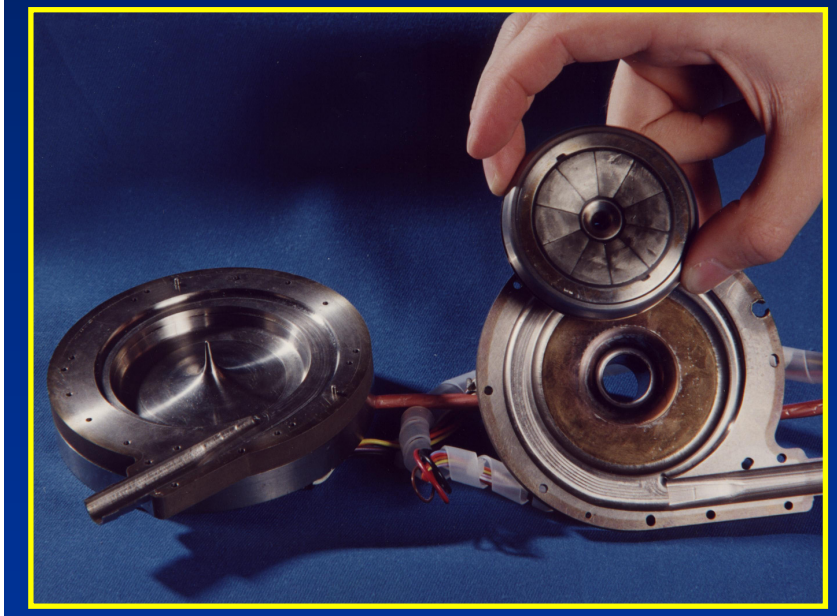
Magnetically Suspended Rotary Blood Pumps

Requirements

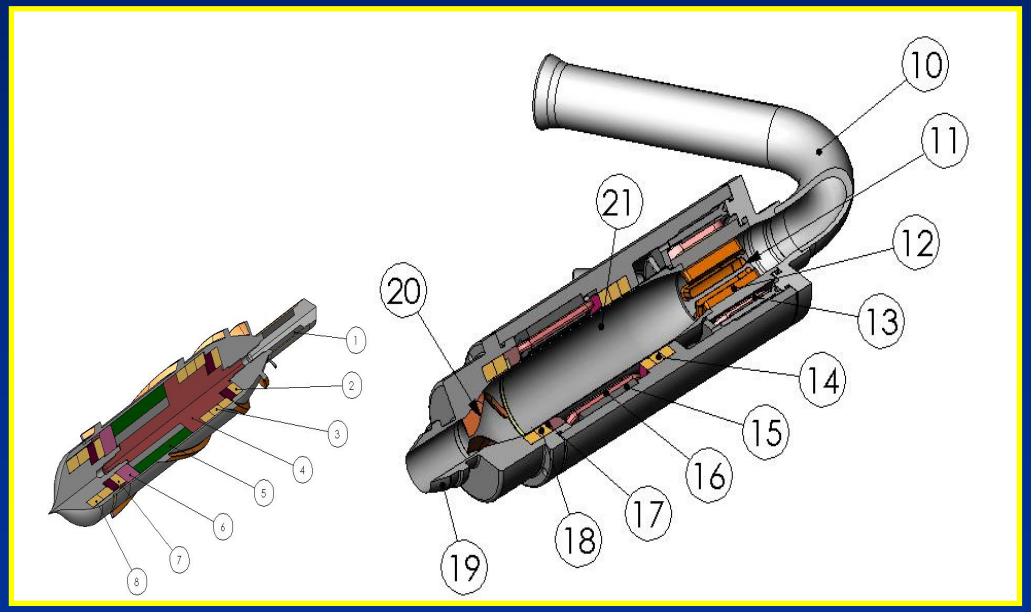
- Long design life
- Negligible blood damage

Characteristics

- Fewer parts, no flexible materials, no moving contacting surfaces
- No valves, unobstructed pathway, and large clearances

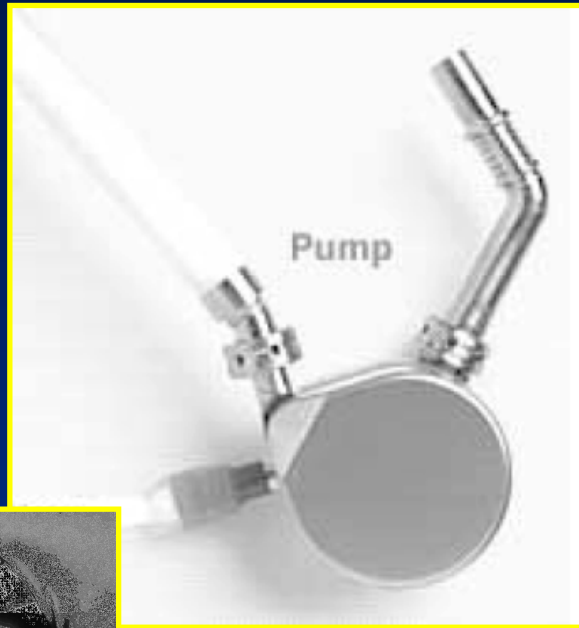


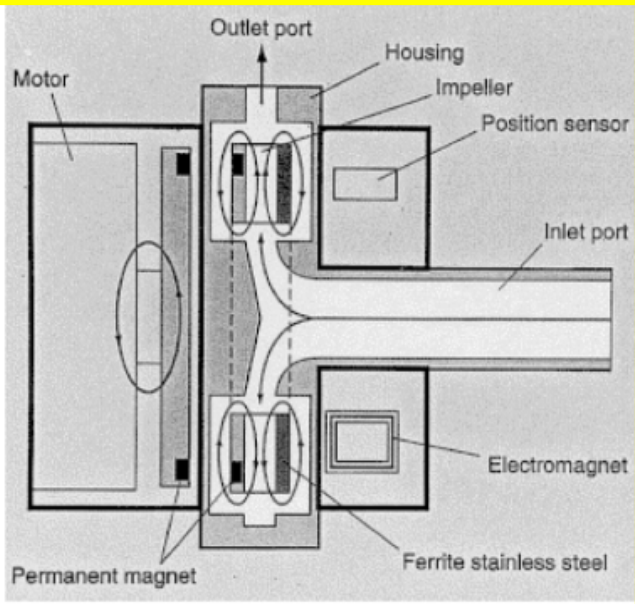
CF4 – implanted in 5+ humans
Licensed to MedQuest Products, Inc.
Currently WorldHeart Levacor VAD

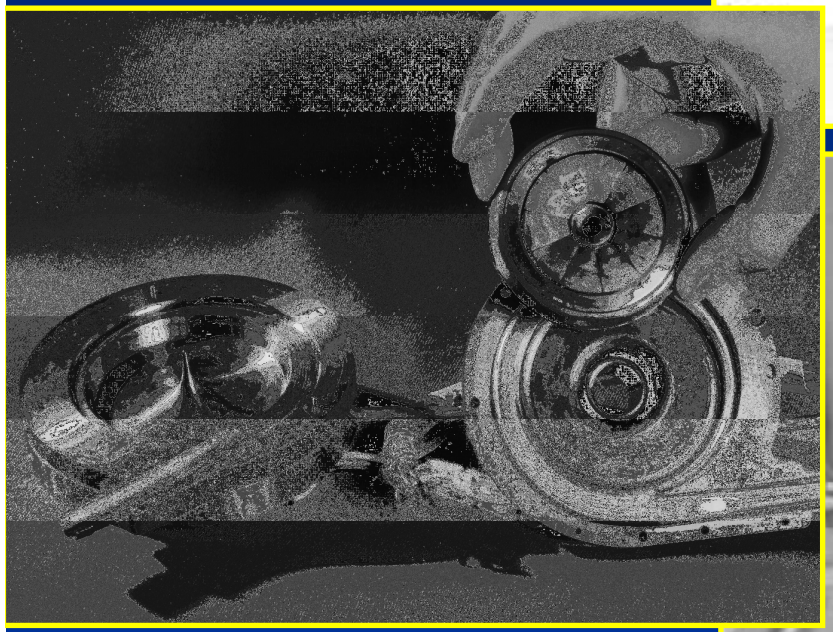


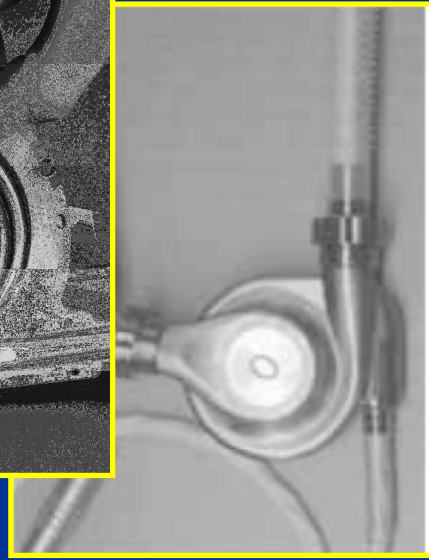
LEV-VAD1
Initial design under this BRP

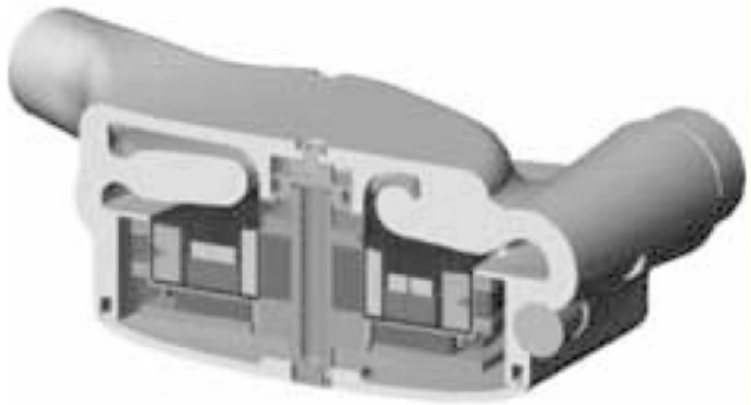
Centrifugal Flow Pumps



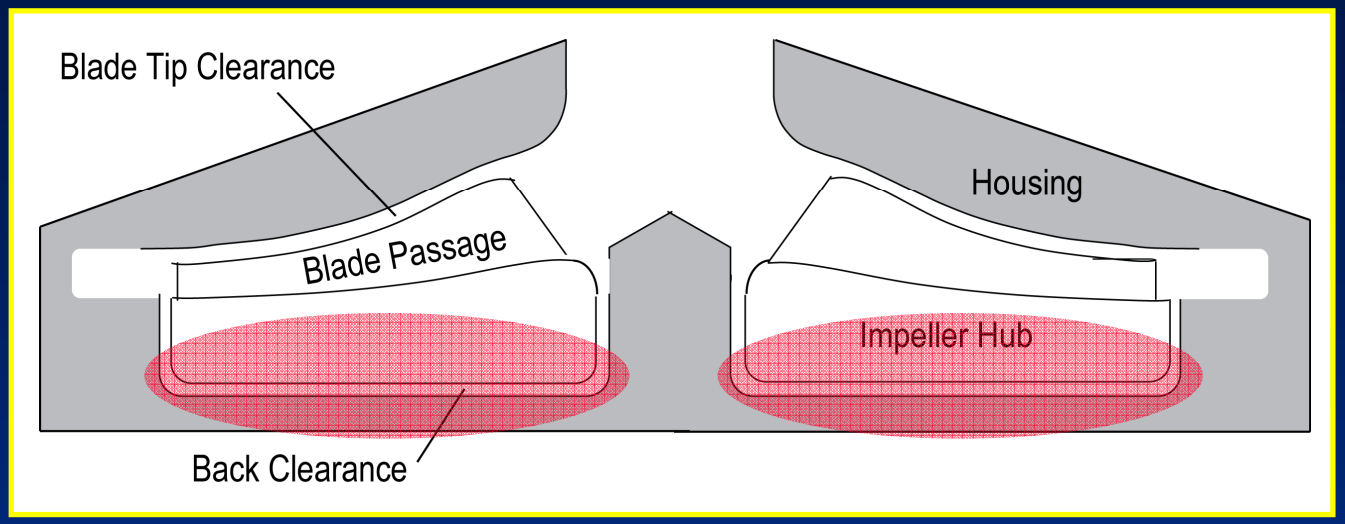




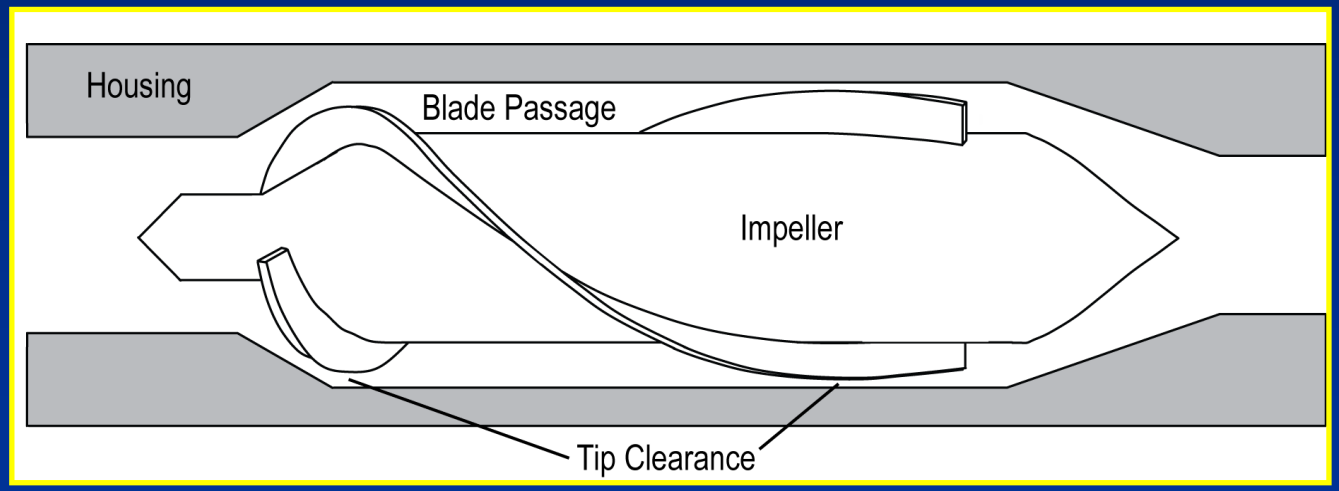




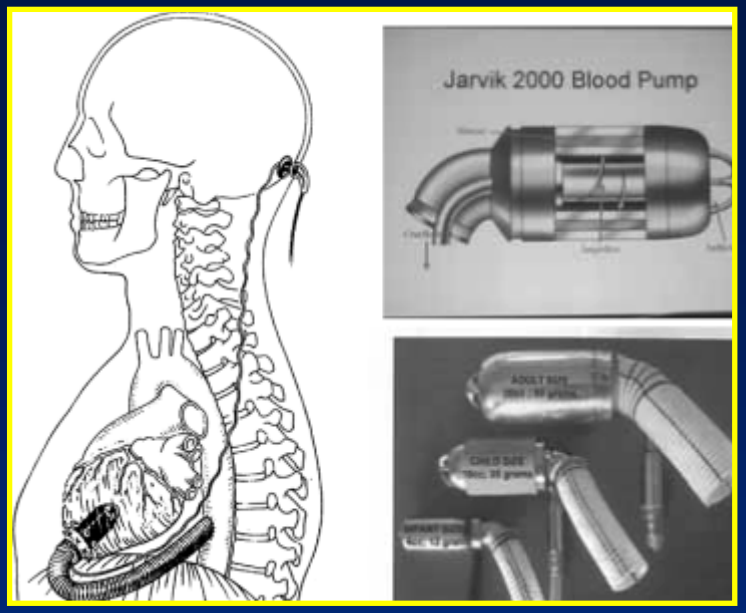
Centrifugal



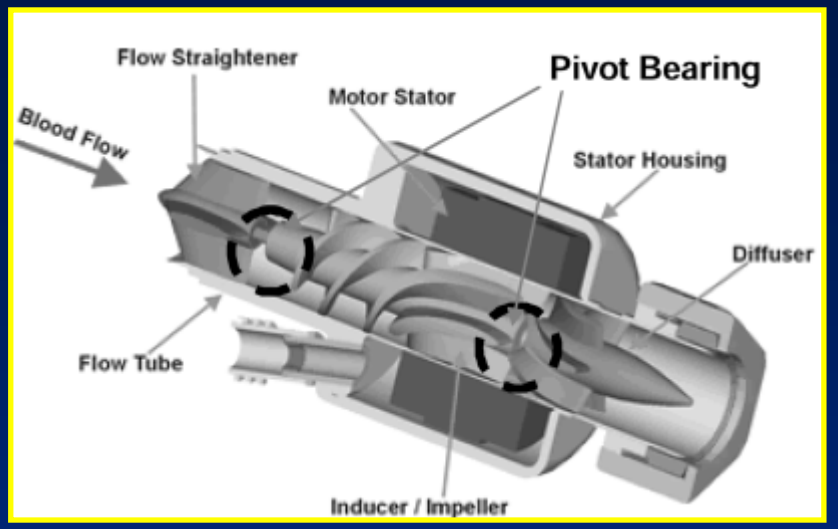
Axial



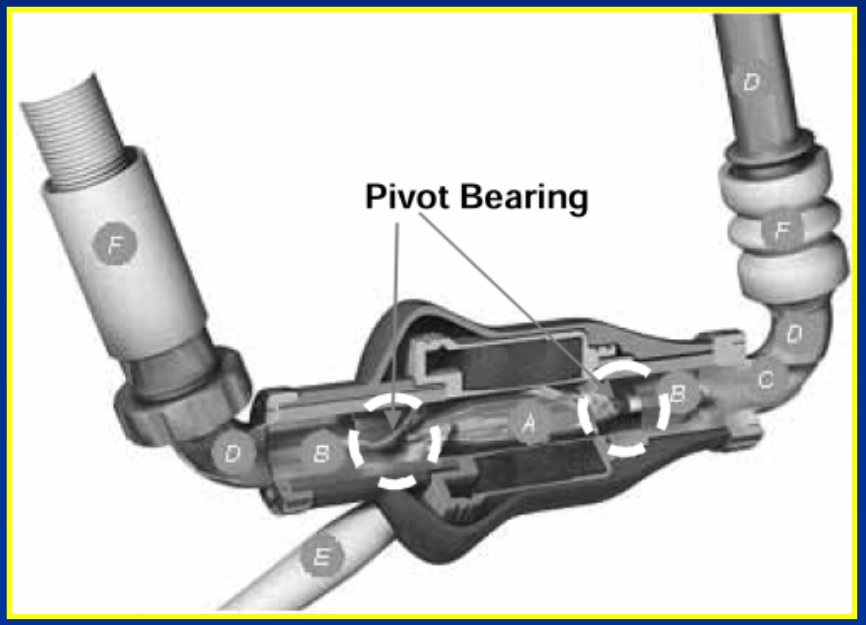
Axial Flow Pumps



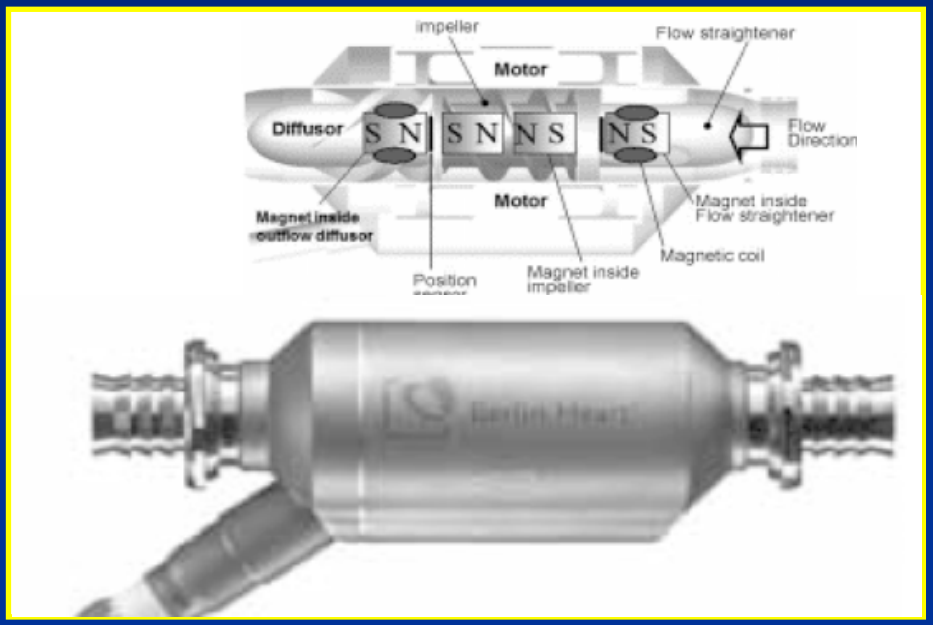
Jarvik



Micromed/DeBakey

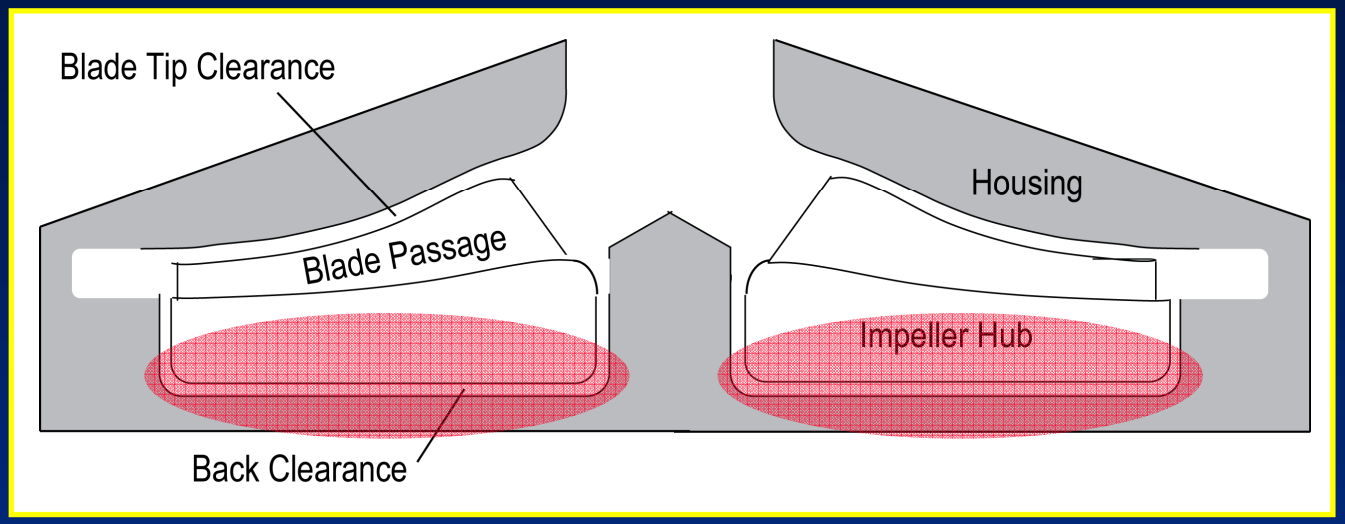


Thoratec

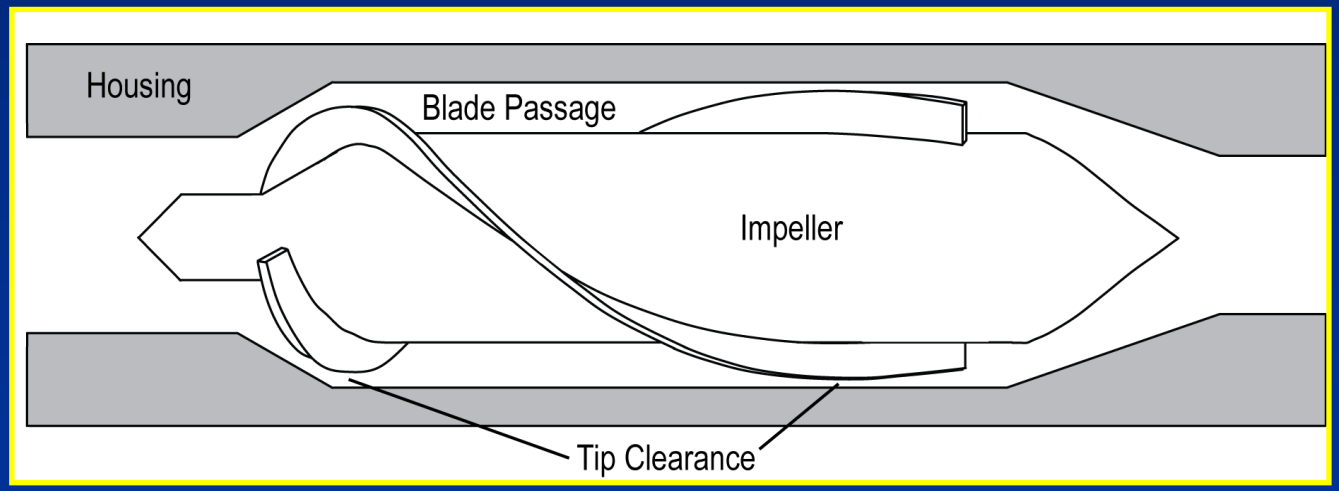


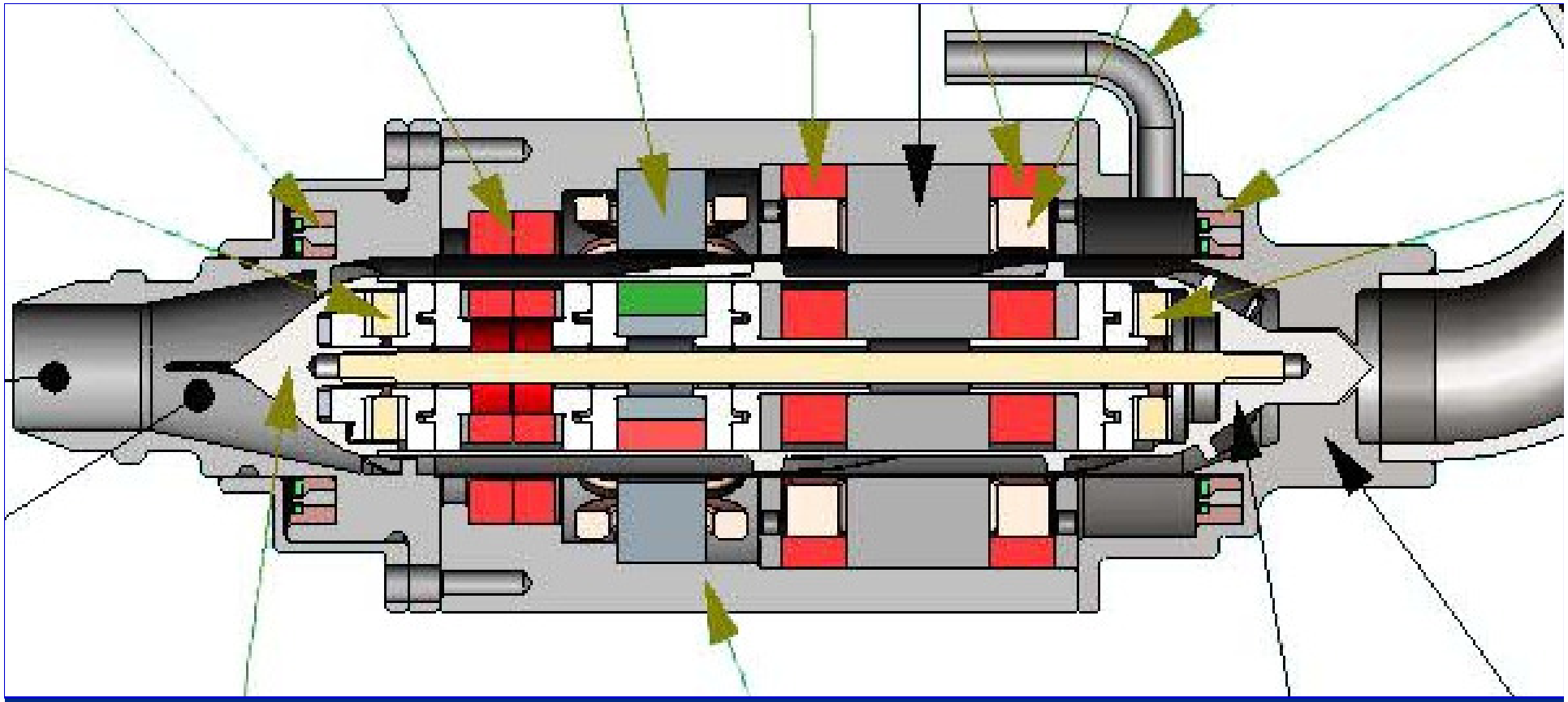
Berlin Heart

Centrifugal



Axial





LEV-VAD2
Current design

Sub-Systems

Fluid System

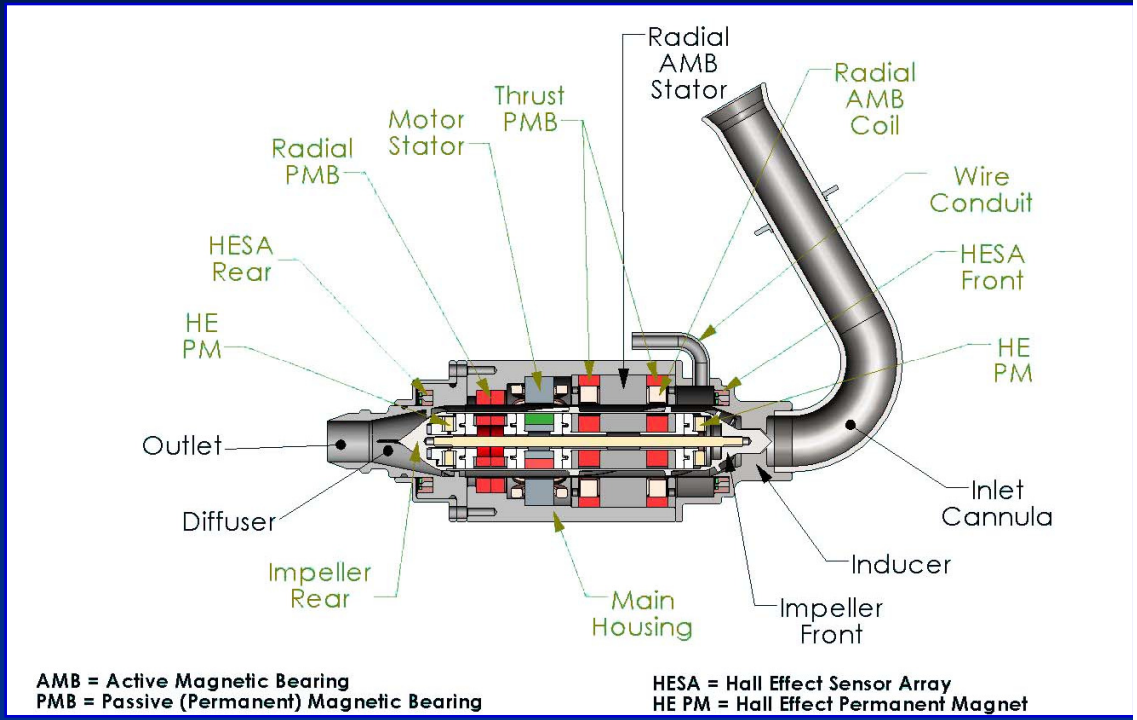
Pumping Performance,
Blood damage

Magnetic System

Bearing, Motor, Sensing

Peripheral systems

Physiological Control,
Cannula, Patient interface,
Power, Monitoring



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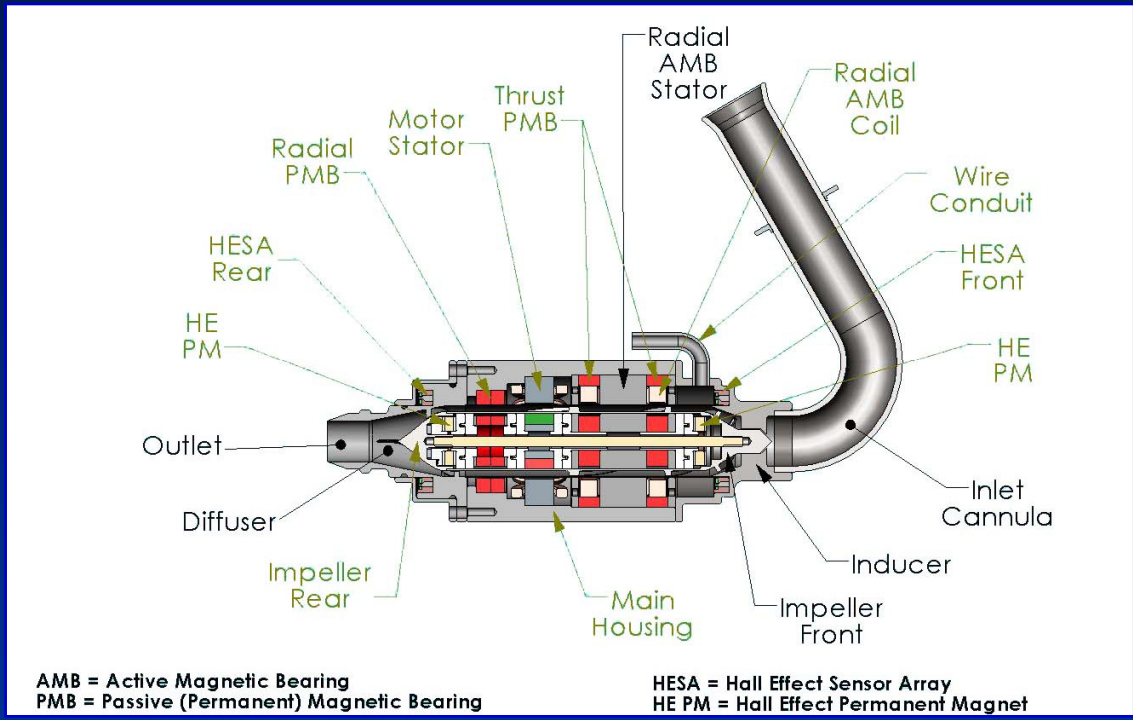
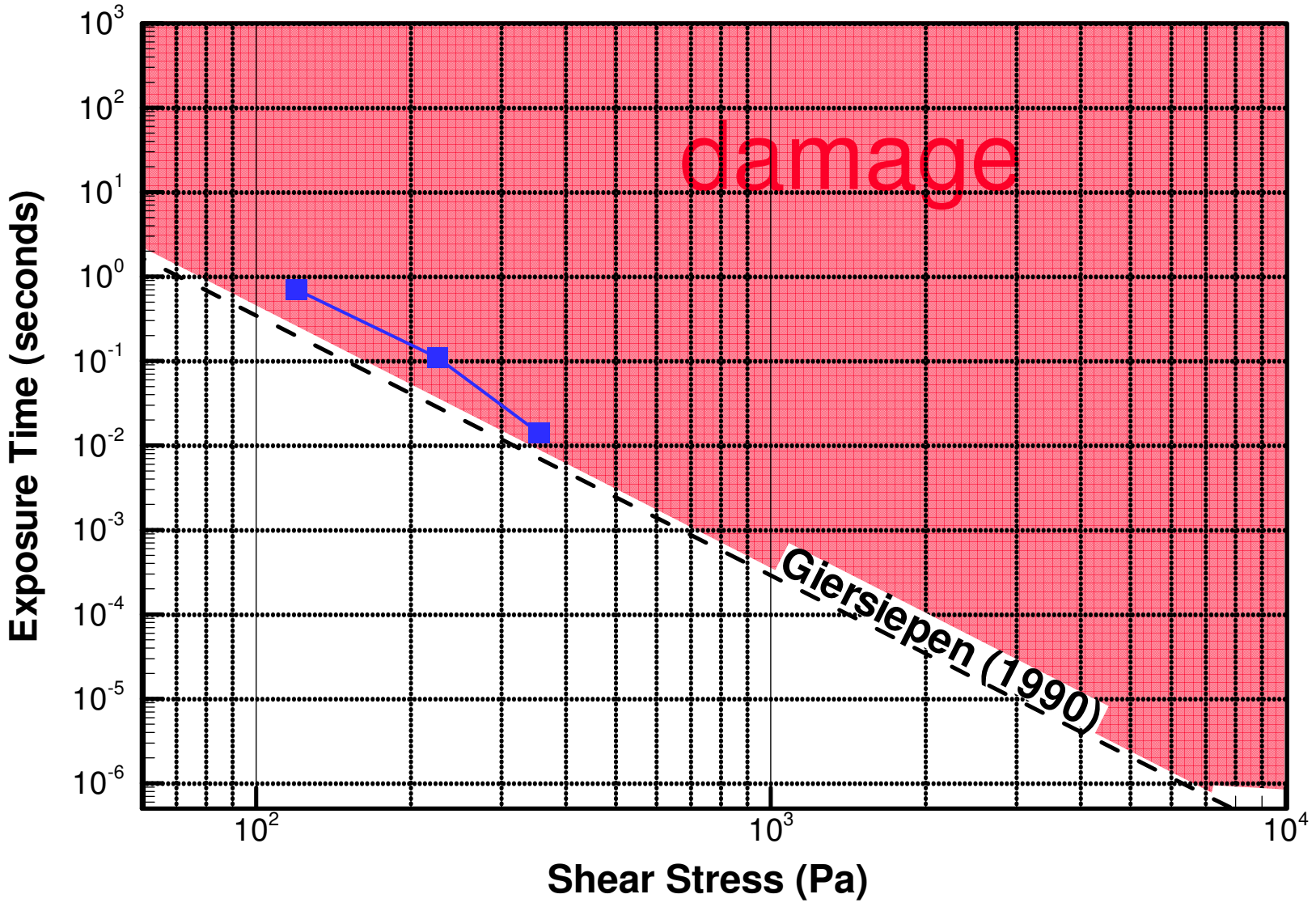
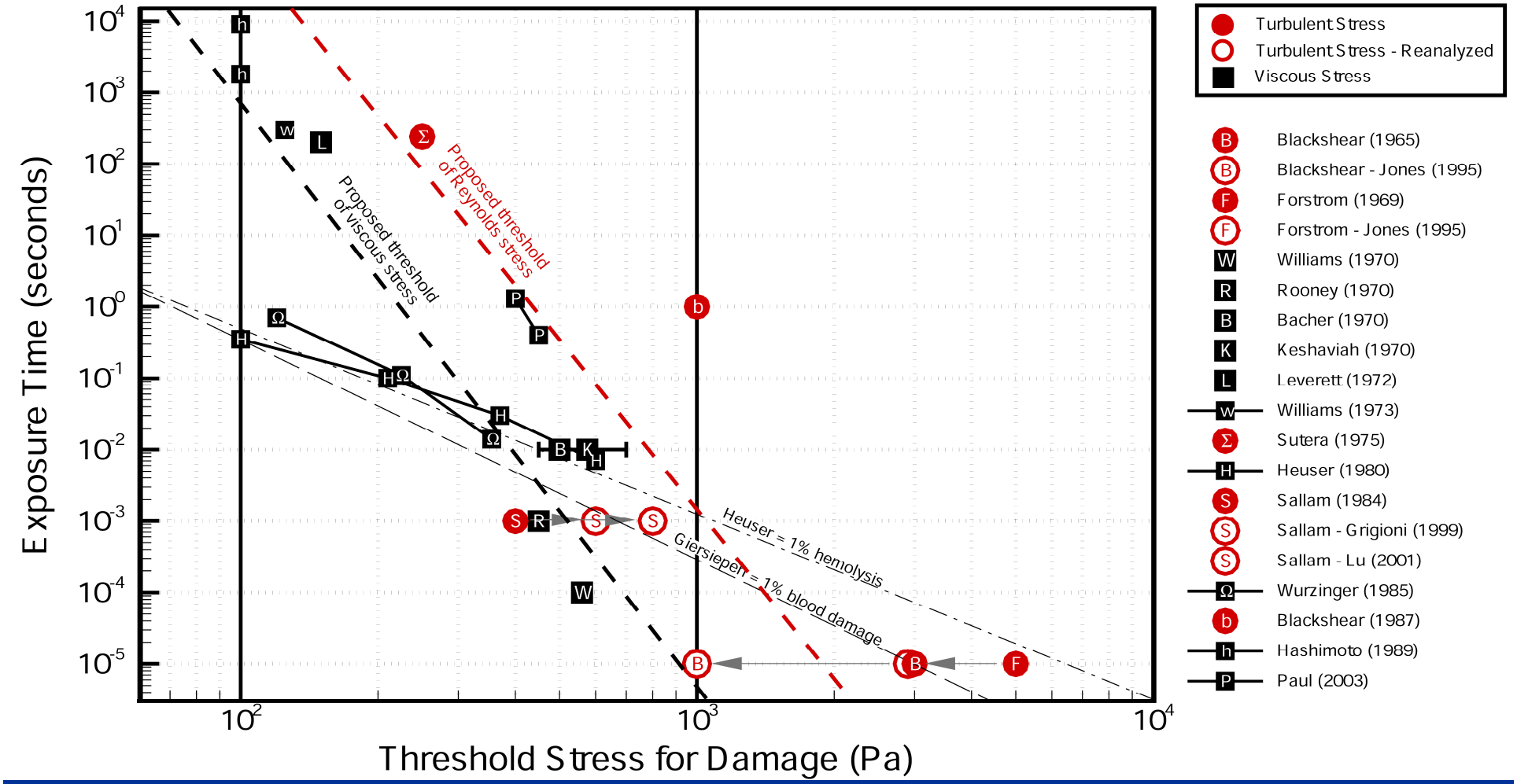


LEV-VAD2
Current design

Hemolysis Thresholds

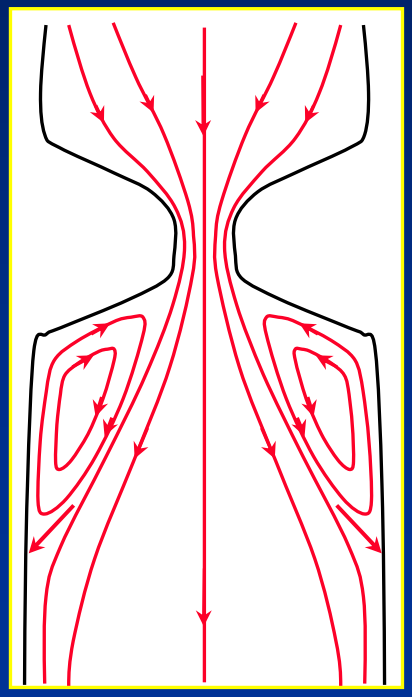


Hemolysis Thresholds



Thrombosis

- Chemical and physical cascade creates thrombus (blood clot)
  - activation
  - amplification
  - adhesion
- Encouraged by fluid dynamics (among other factors)

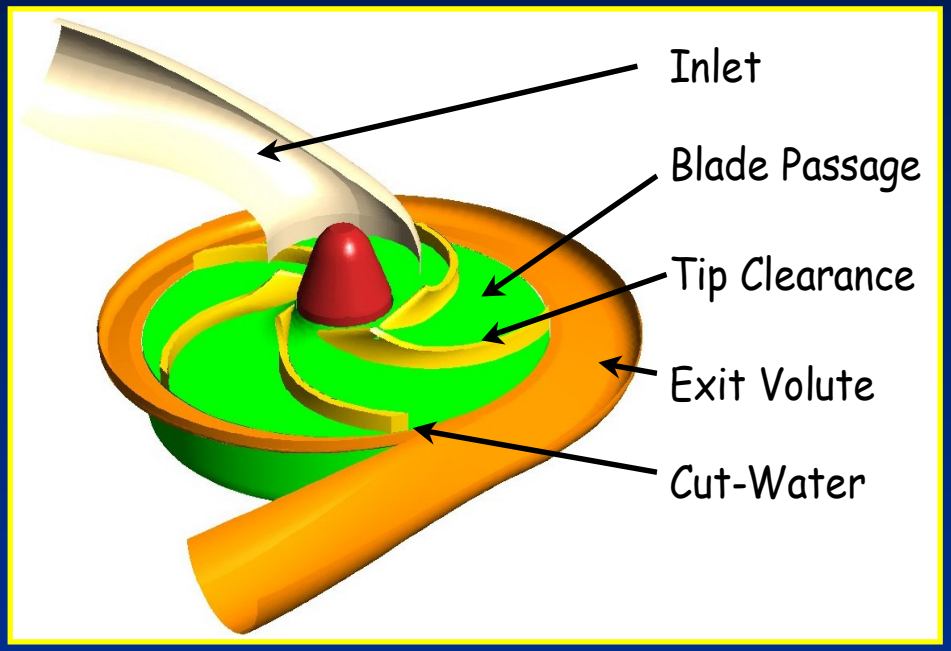


1. High Shear → platelet activation

2. Recirculation → amplification

3. Stagnation → adhesion

Fluid Mechanics Contribute to Blood Damage



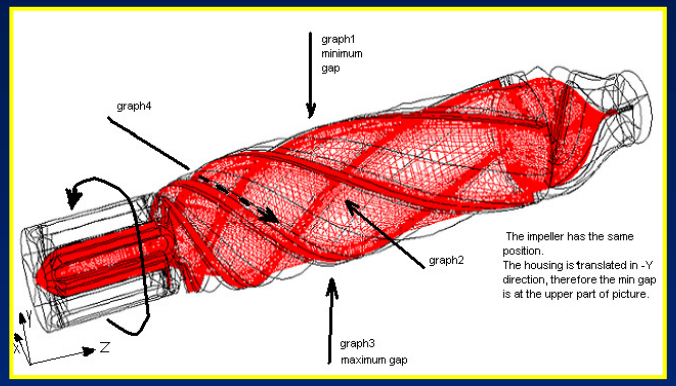
- Regions of turbulent flow, shear, and stagnation are unavoidable
- Must be designed to minimize blood damage

  Avoid stagnation while maintaining acceptable stress levels

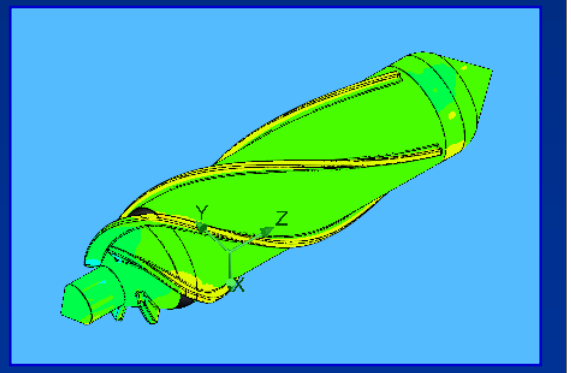
- Design requires reliable techniques to predict and measure the flow

Computational Fluid Dynamics - CFD

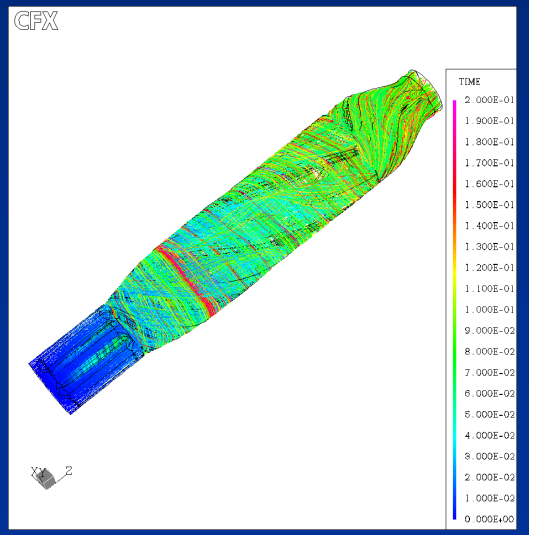
- Commercial fluid solvers used for full 3-d Reynolds averaged Navier-Stokes equations.
  - Steady flow simulations using the frozen-rotor assumption and k-e or k-w turbulence model.
- Outflow pressure vs. flow curves determined over a range of rotational speeds.
- Used extensively in the design of blood pumps
- Limited accuracy:
  - Turbulence modeling
  - Rotating frames of reference
  - Limited grid resolution – 3D
- Results **must** be verified with experiments



forces

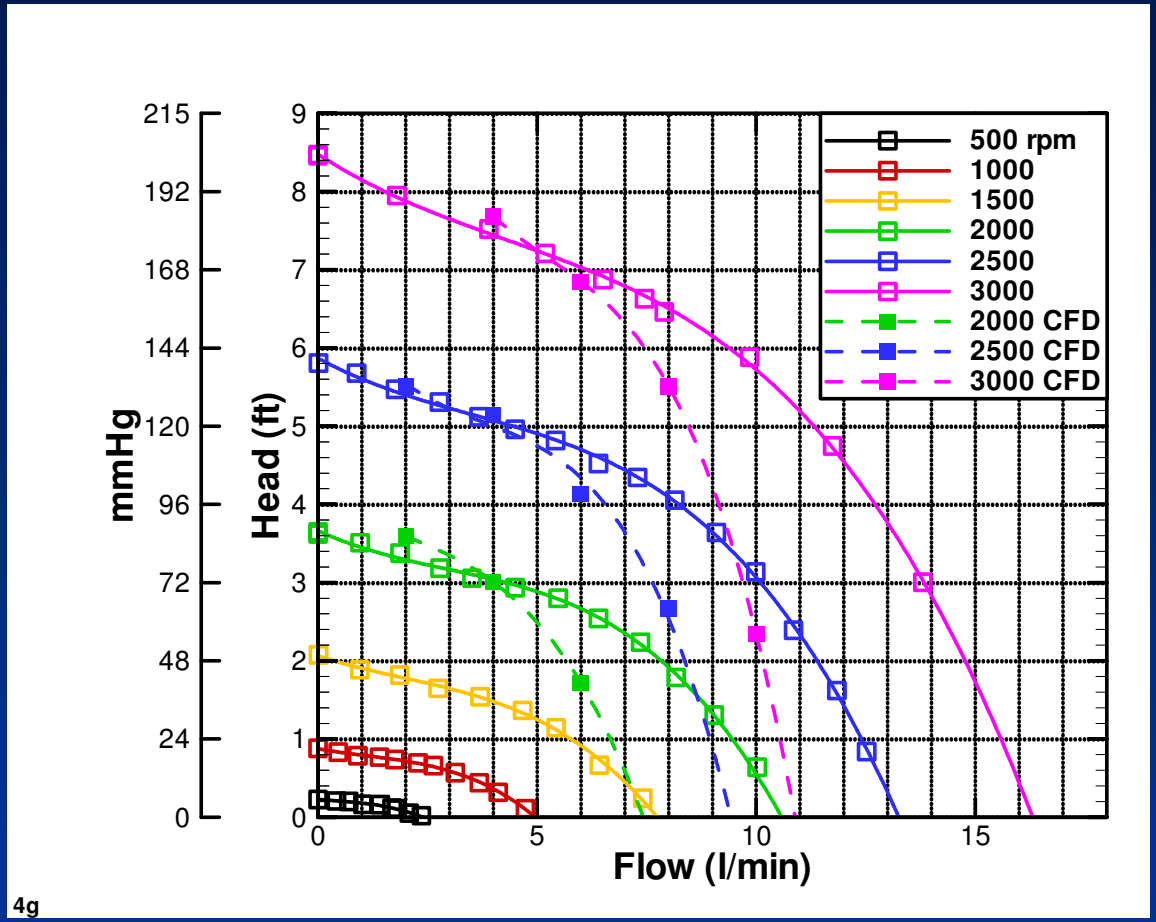


stress



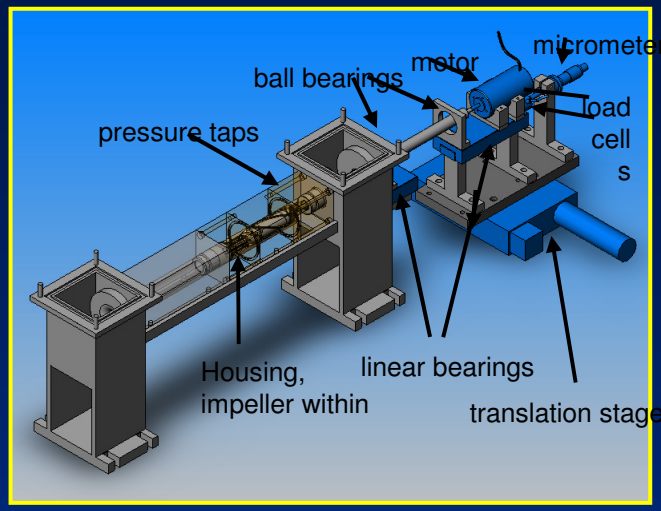
cell trajectories

Comparison of Experiment to CFD with k-ε and frozen rotor

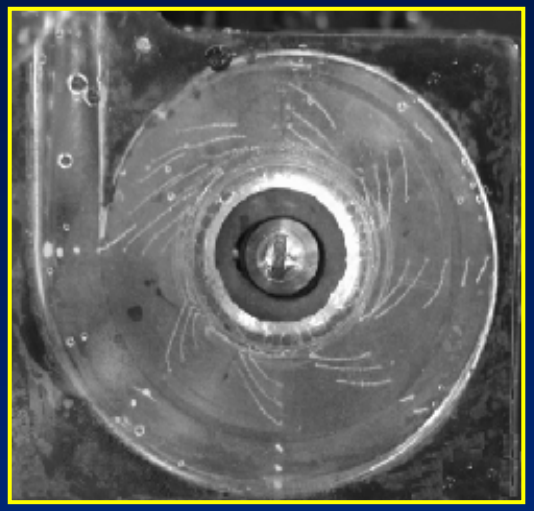


- Accurate near design point
- Under-prediction at high flow

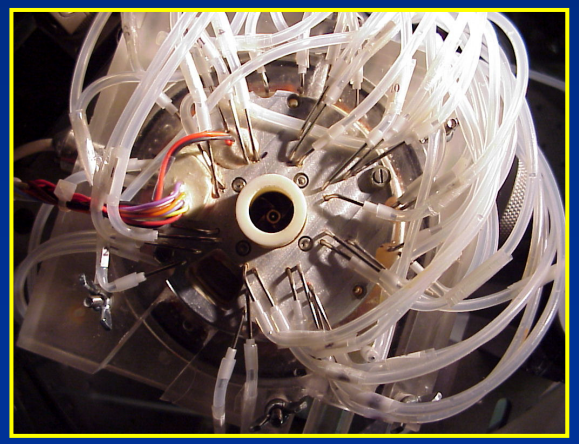
Experimental



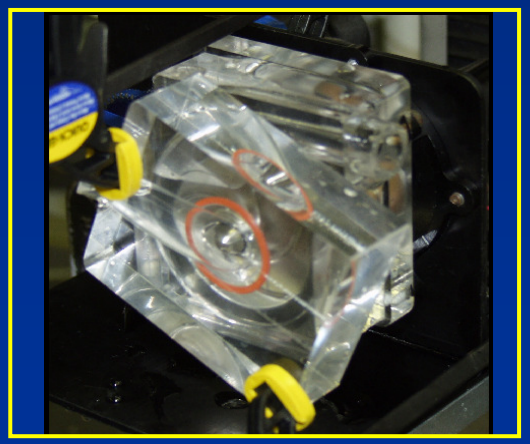
Forces and torques on impeller



Oil streaking for wall shear stress

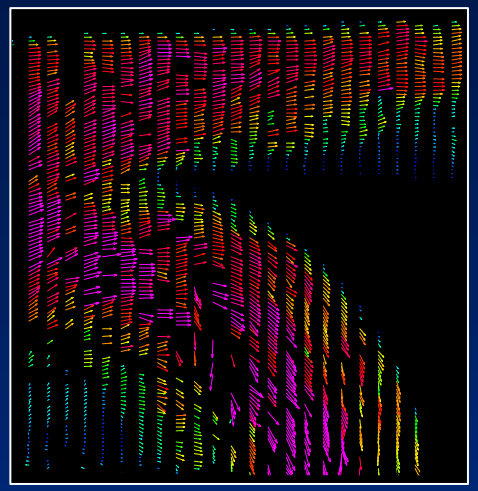


Pressure

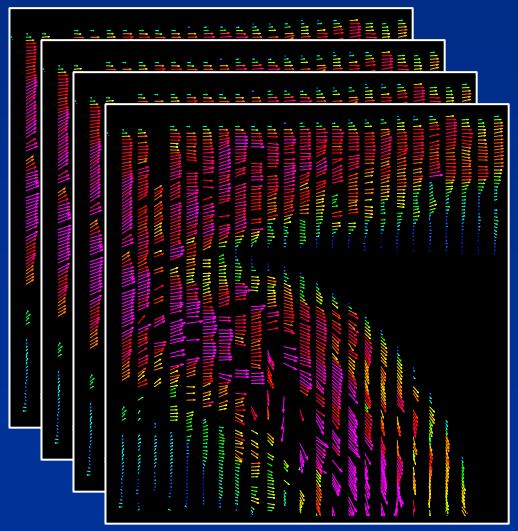


Flow visualization and Velocimetry (PIV)

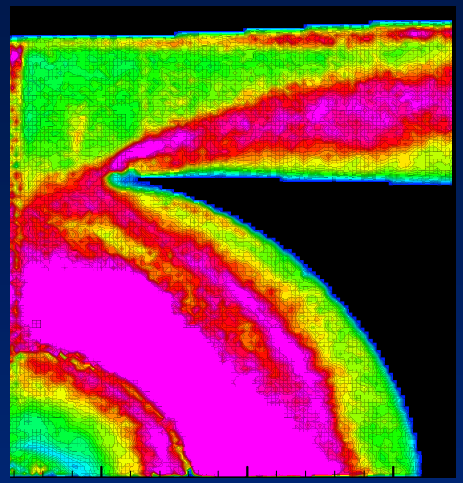
Instantaneous Measurement



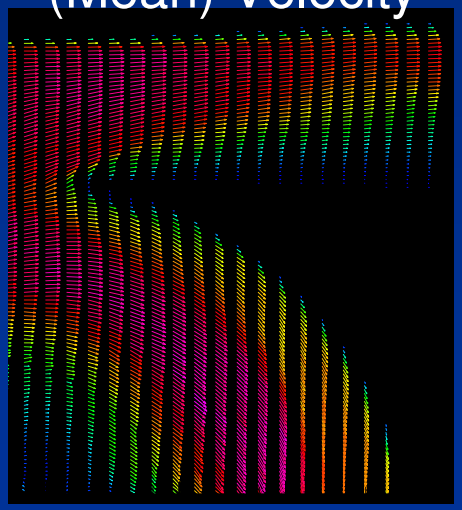
Series of Instantaneous Measurements



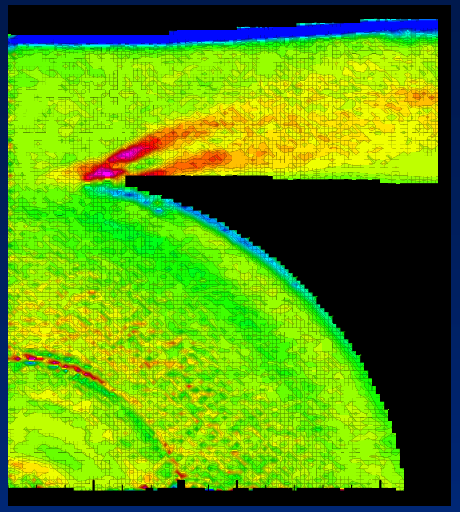
Turbulence Statistics



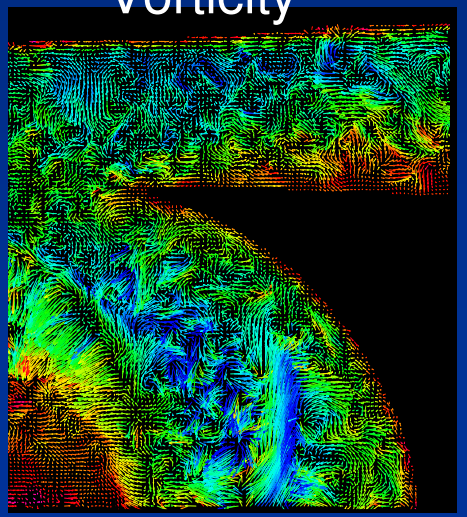
Time Averaged (Mean) Velocity



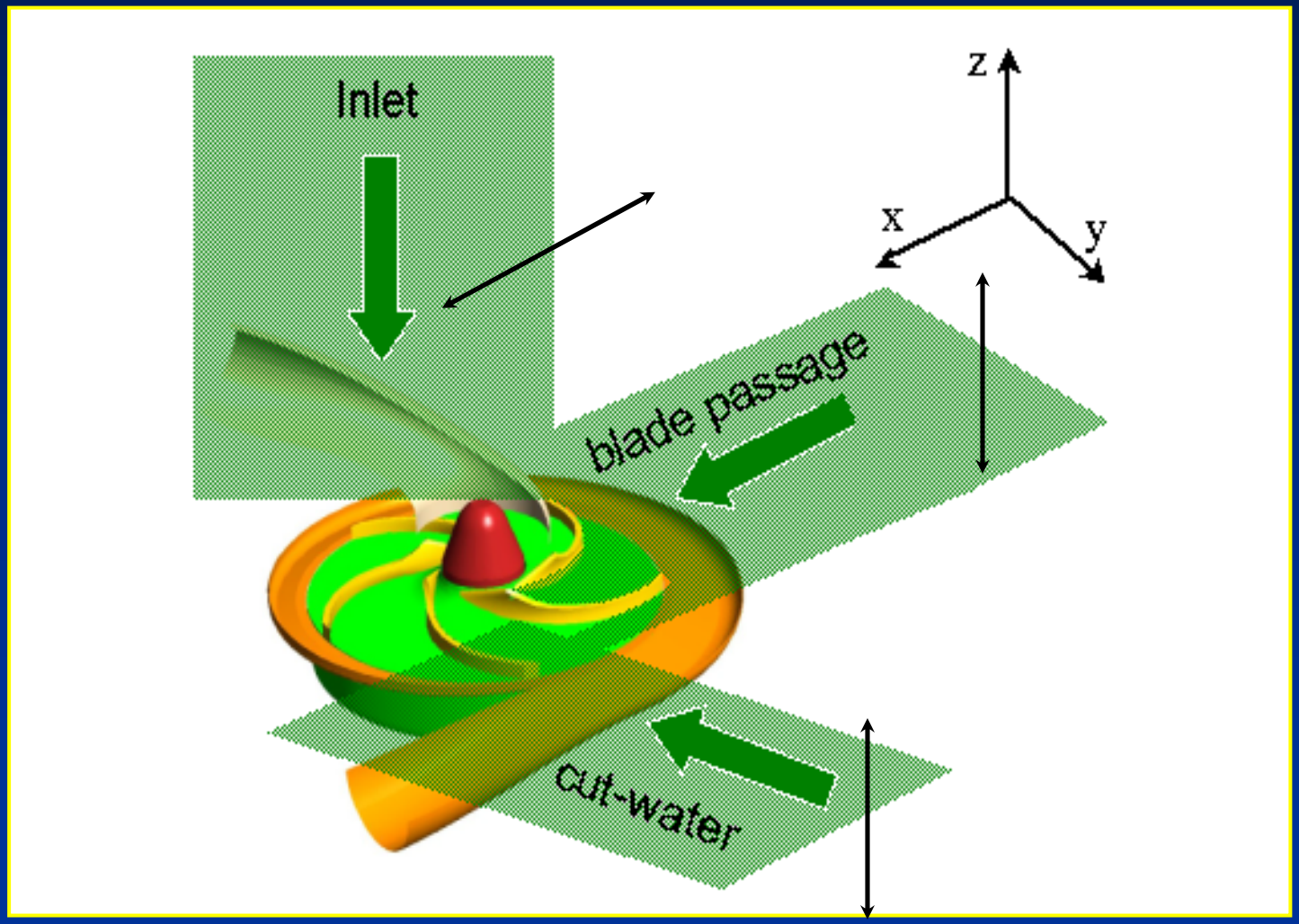
Spatial Derivatives
Viscous Shear Stress



Vorticity



PIV Measurements within the Blood Pump



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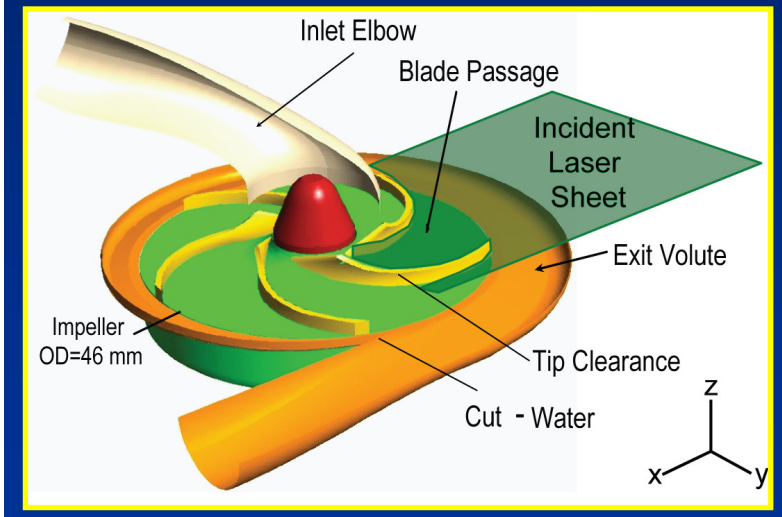
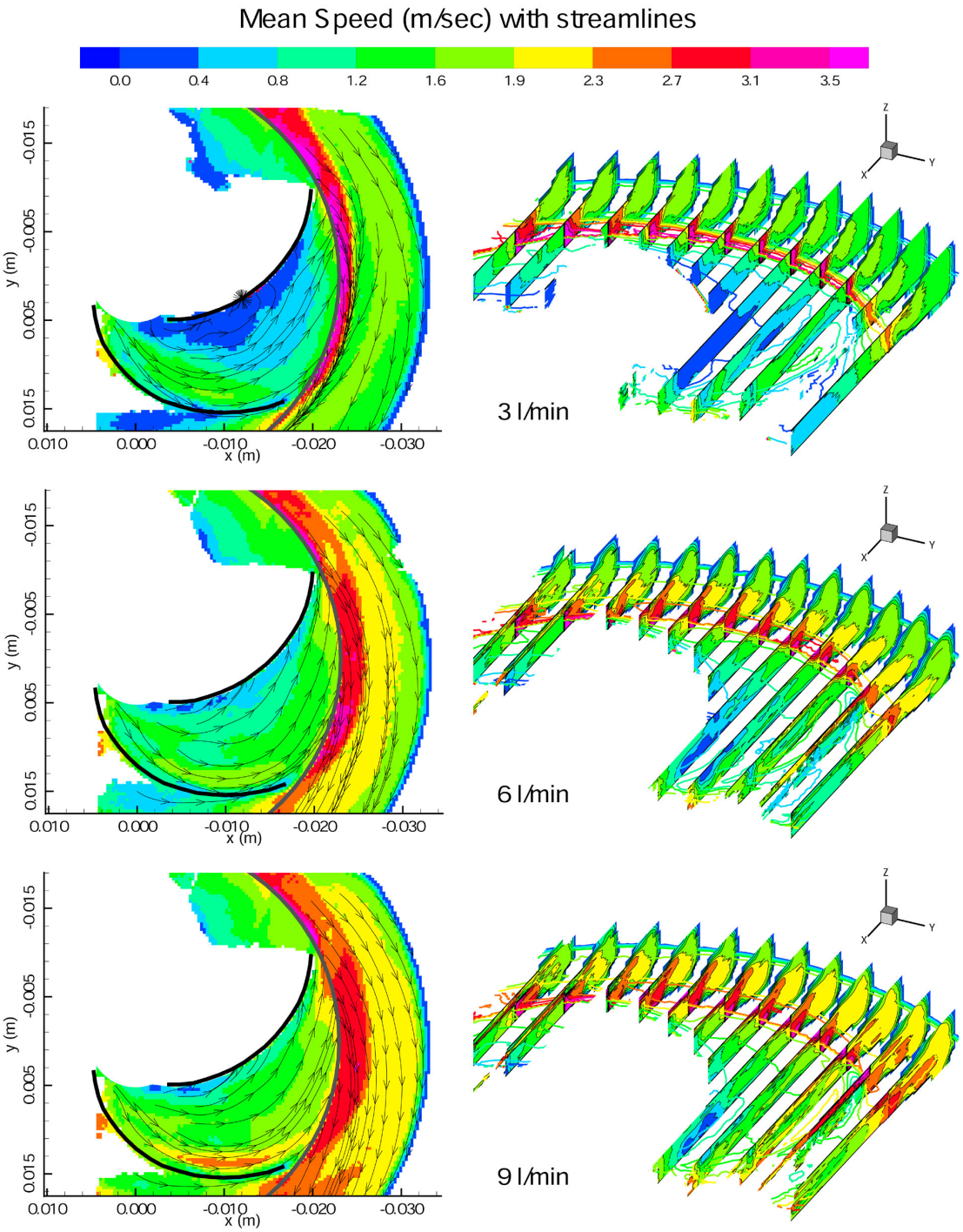
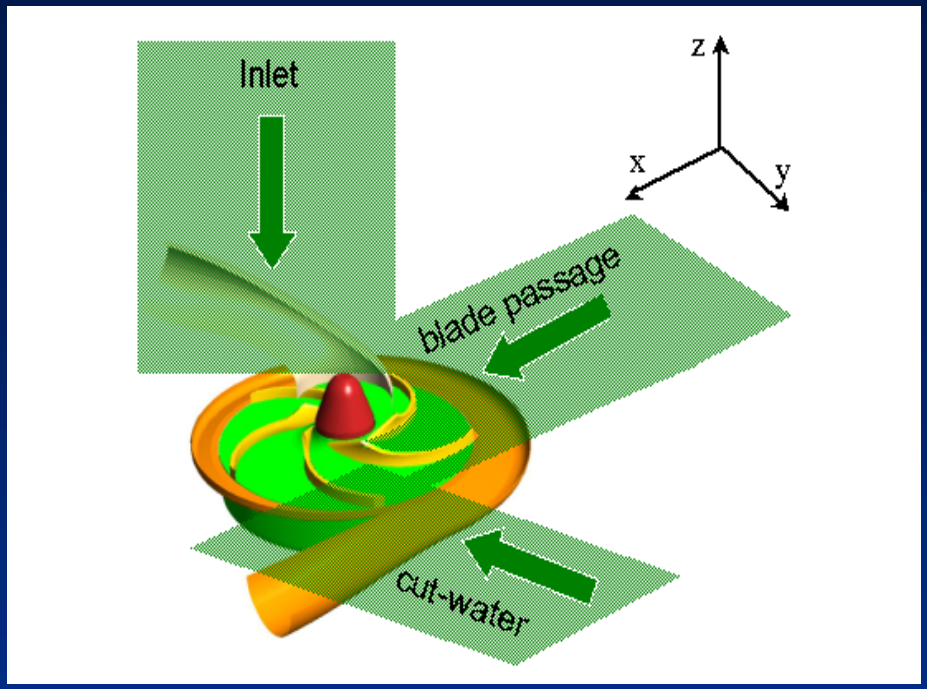
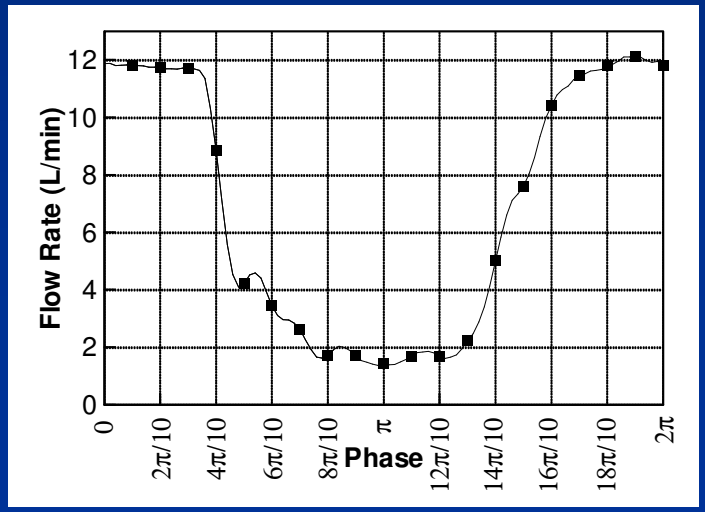
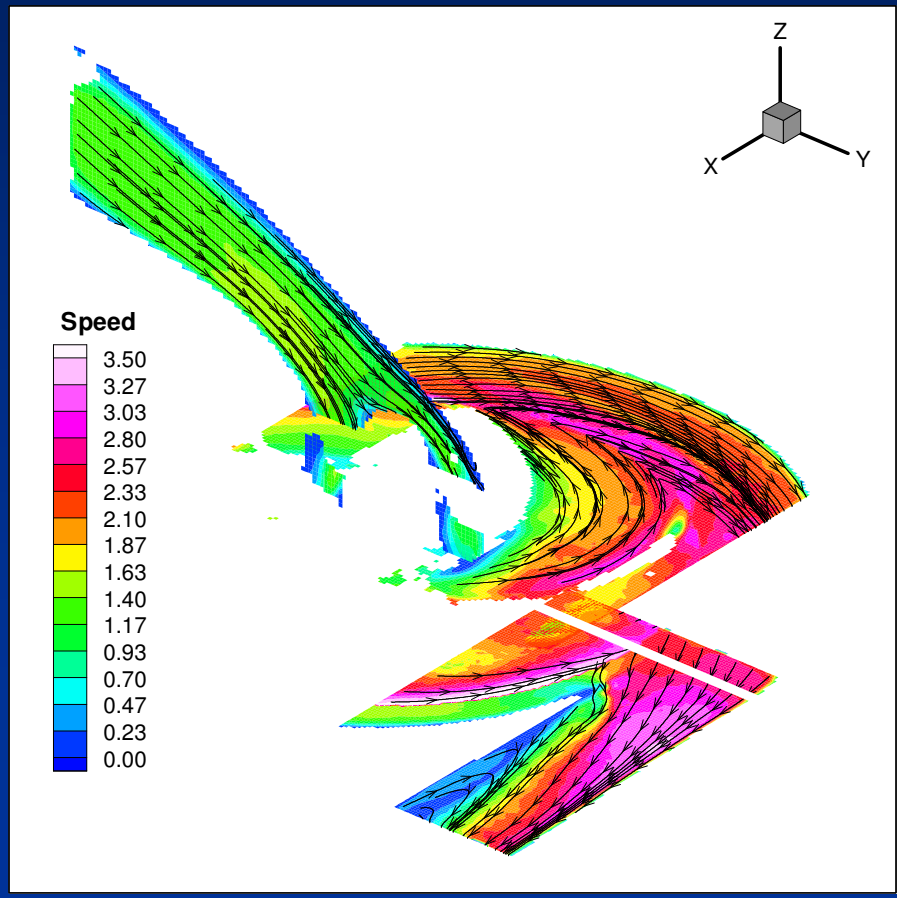




Transient Flow During Heartbeat







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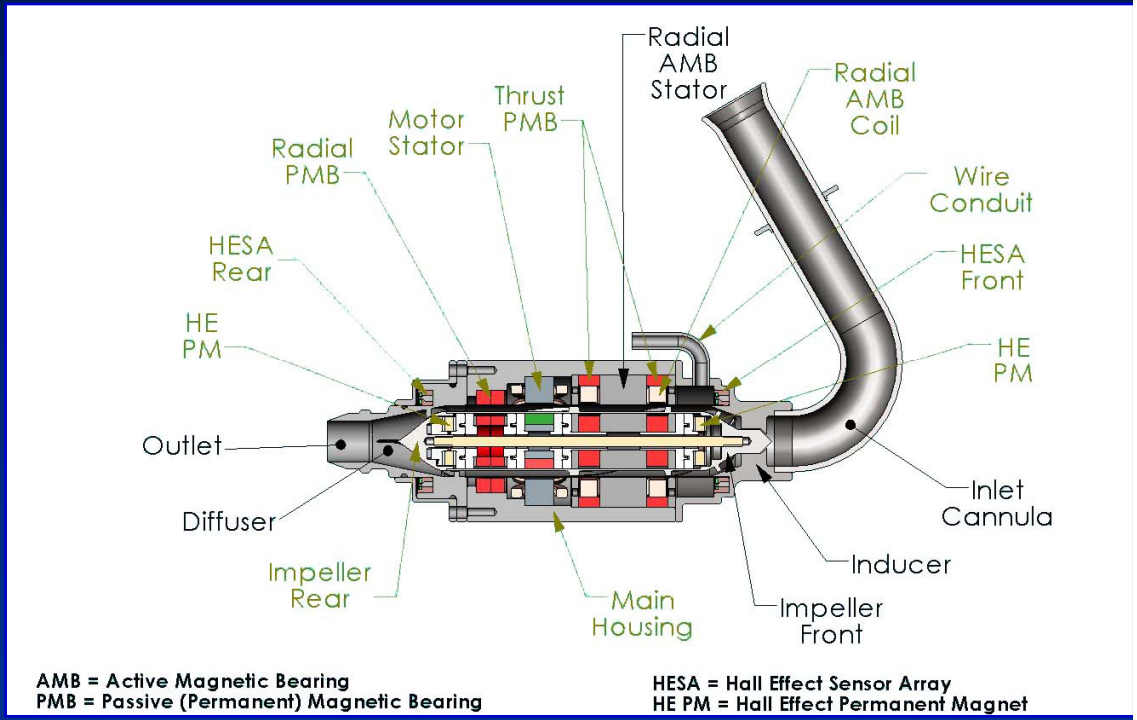
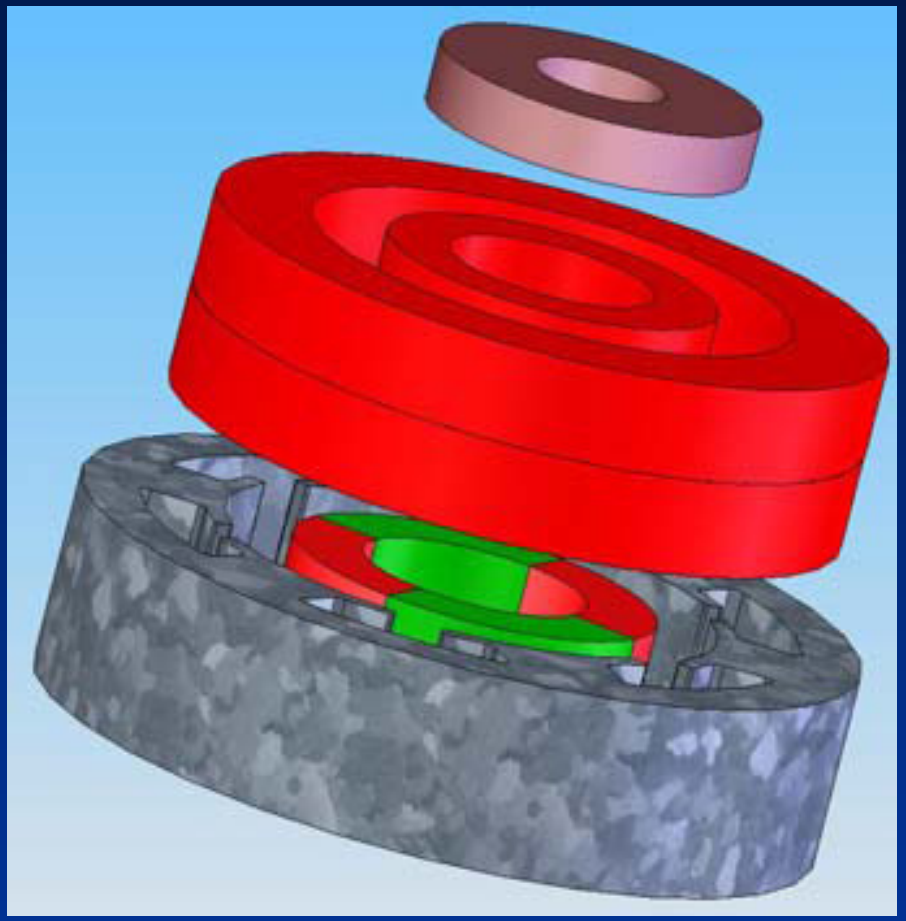
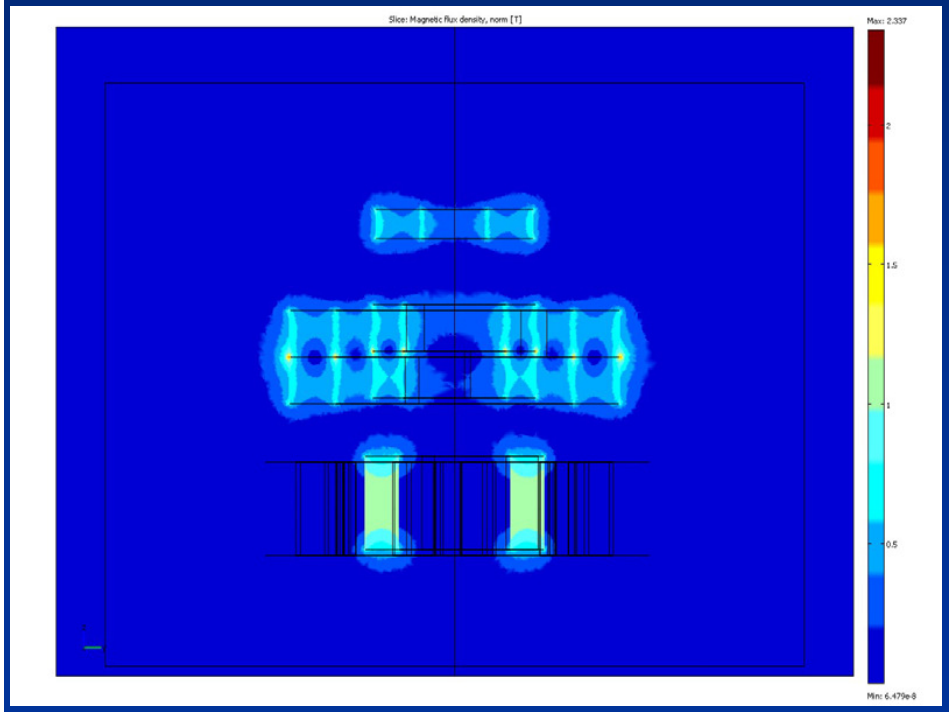


LEV-VAD2
Current design

Magnetic Finite Element Analysis

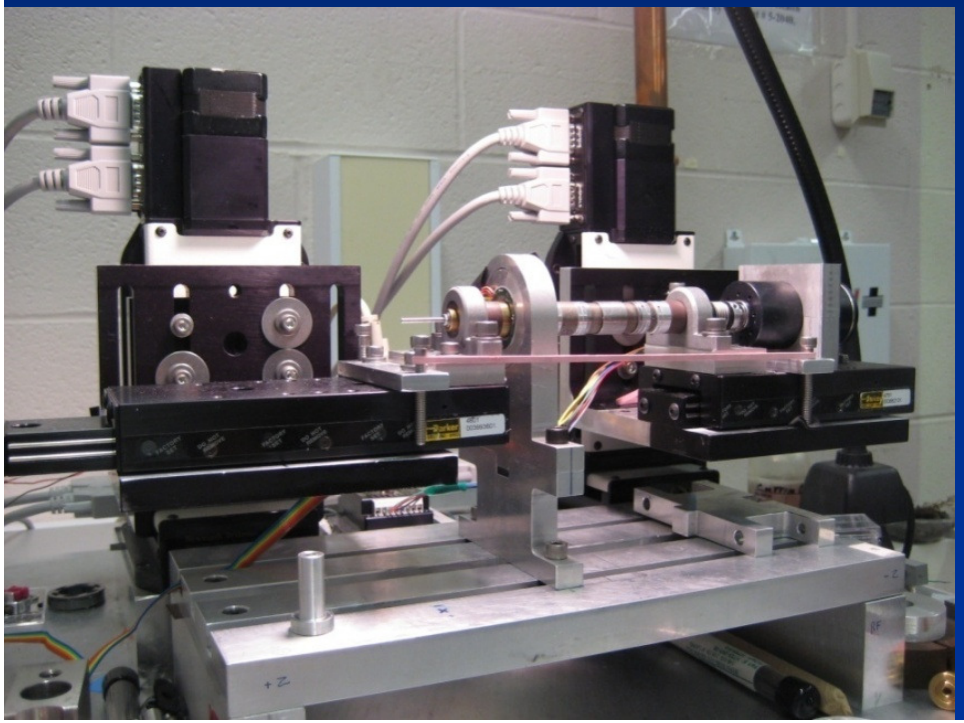
- Determine magnetic fields and resulting magnetic forces
- Used for individual components and interactions of neighboring magnets

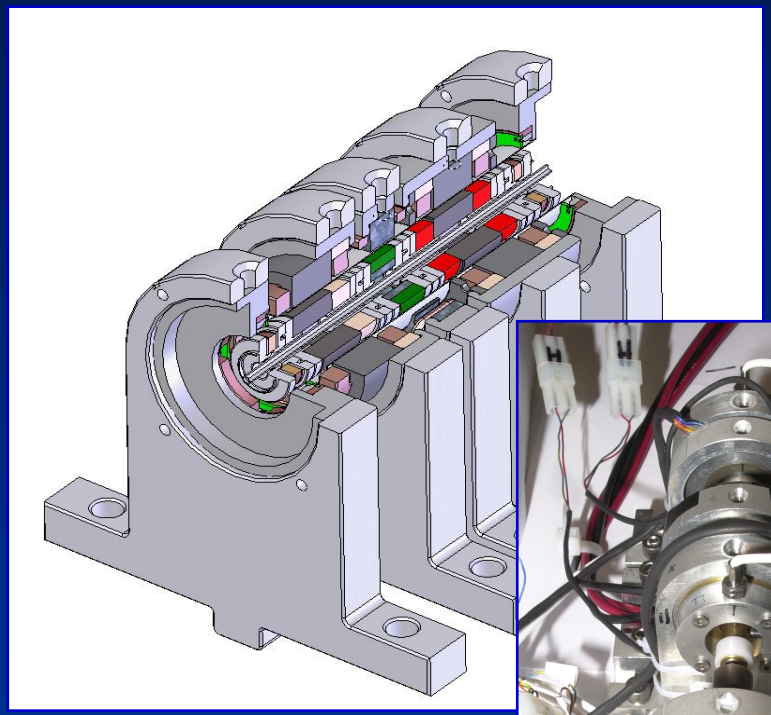


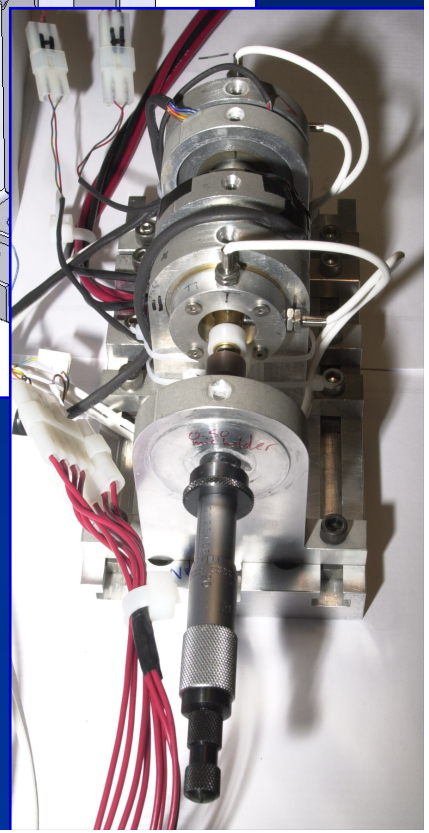


Magnetic Suspension Benchtop Testing

- All magnetic components can be located and held independently
- Useful for characterizing combined effect of individual magnets
- Development and testing of control laws







Sub-Systems

Fluid System

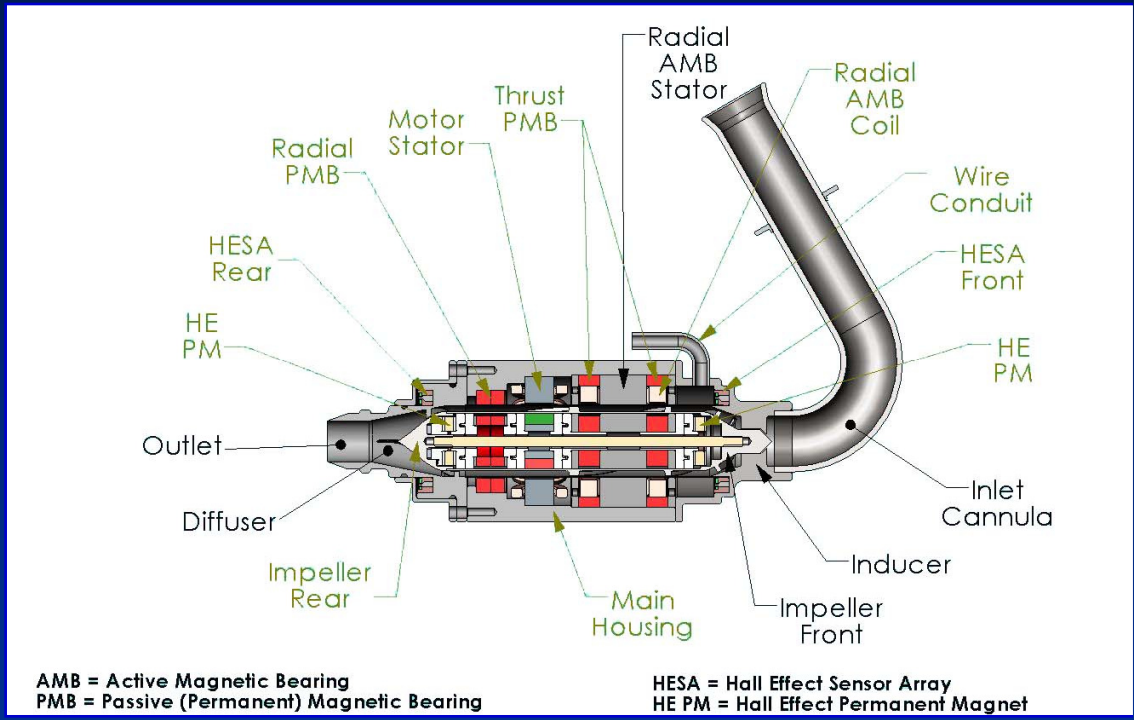
Pumping Performance,
Blood damage

Magnetic System

Bearing, Motor, Sensing

Peripheral systems

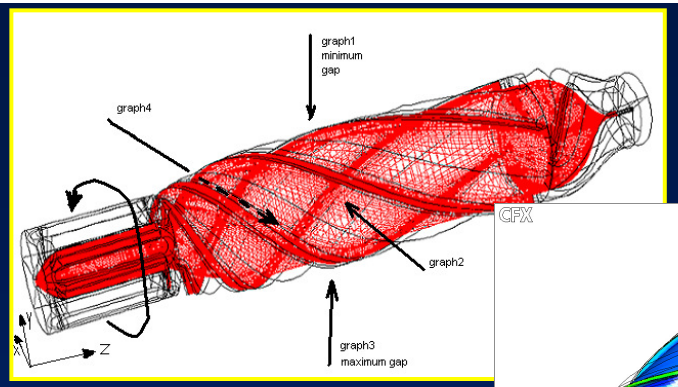
Physiological Control,
Cannula, Patient interface,
Power, Monitoring

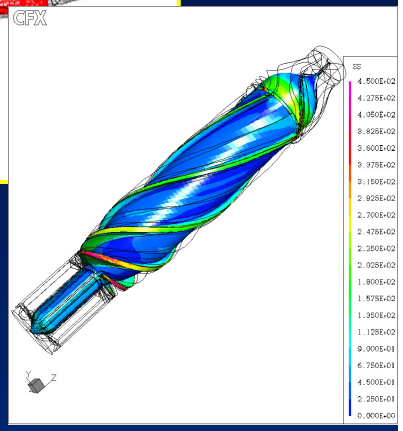


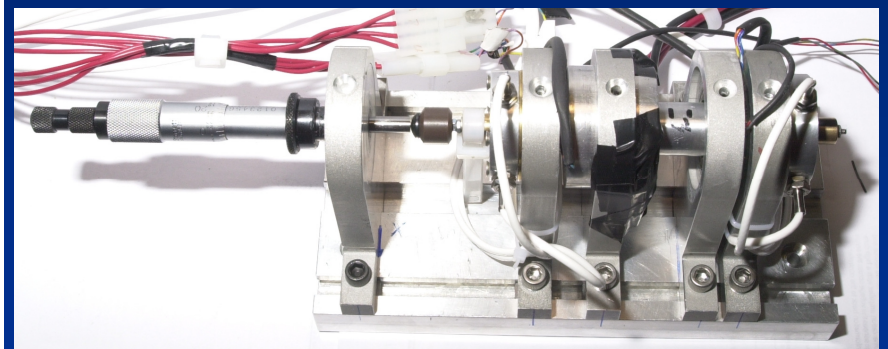
LEV-VAD2
Current design

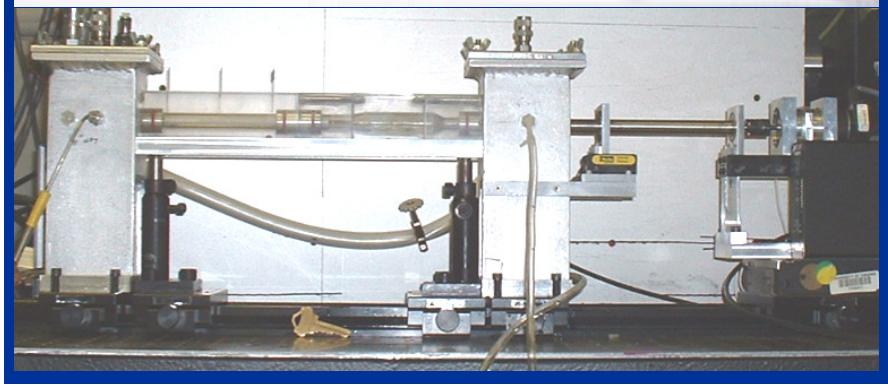
Progress and Plans

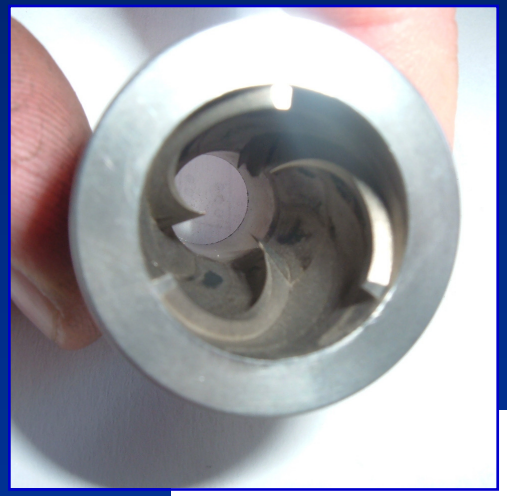
- ✓ Paper design
- ✓ Computational modeling of subsystems
- ✓ Demonstration of manufacturability
- ✓ Bench-top validation of fluidic and magnetic subsystems
- ✓ Optimization of subsystems
- ✓ Prototype of complete pump
- ❑ Blood Testing
- ❑ Animal Testing











Current & Future Work

Investigation of Underlying Physics & Methodological

- Applying linked CFD & thrombosis models to pumps
- Effects of turbulence on red cells lysis and platelet activation
- Individual cell tracking
- Continued validation and refinement of computational methods
- Methods for measuring shear stress in pump

Design

- Design revision and optimization of current axial flow pump.
- Simplified designs that are smaller, cheaper, more efficient, manufacturable, etc.
- Other blood handling devices: catheters, stents, lungs, kidneys, etc.

RIT Team

Co-op students

Scott Carlson

Josh vanHook

Nick Babin

Tim Seibert

Aaron Burger

Jamil Ali

Faculty

John Wellin

Ag Crassidis

Tuhin Das

Graduate Students

Amy Slevar

Tom Fountain

Carlos Cheek

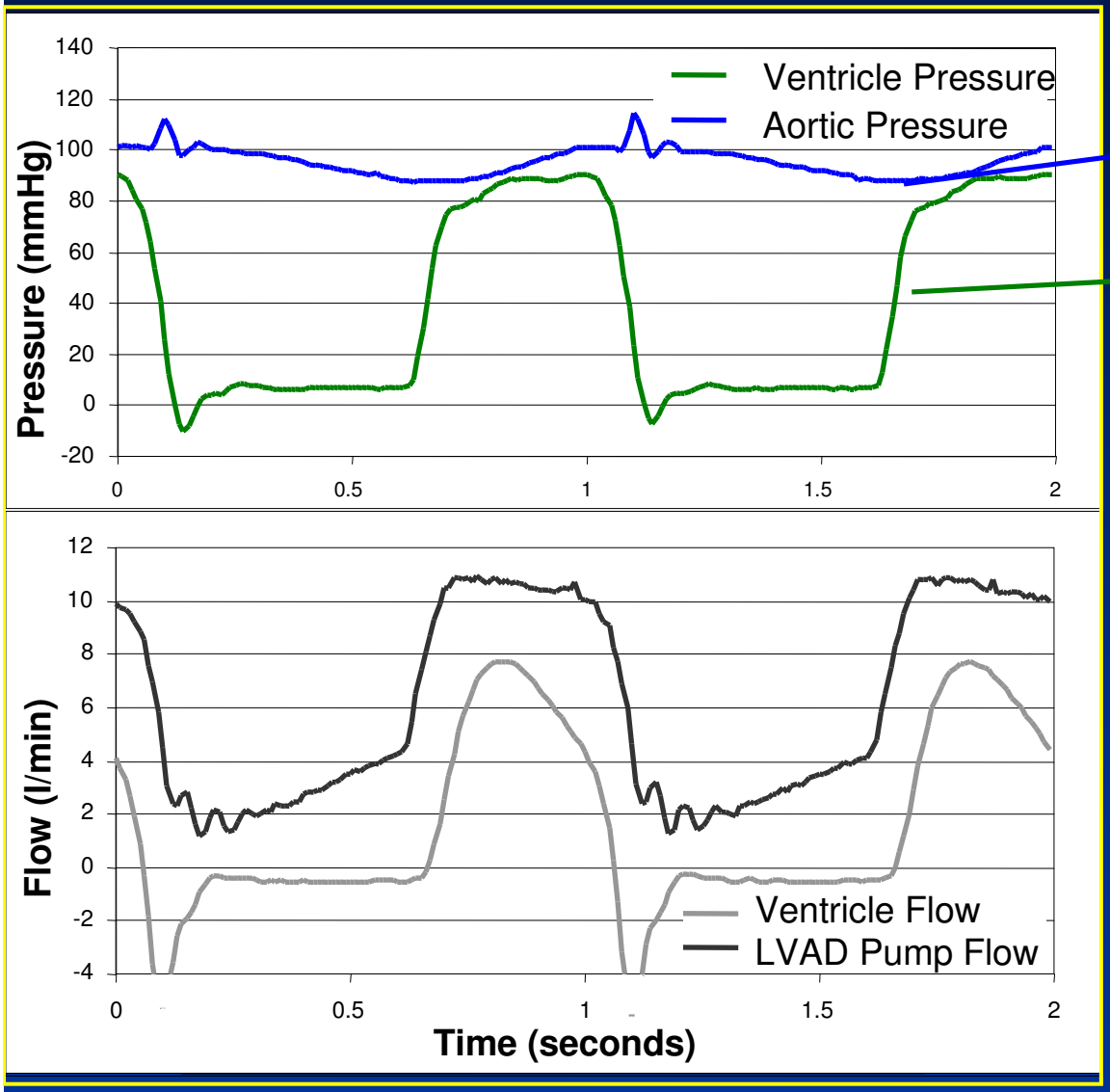
Dave Gomez

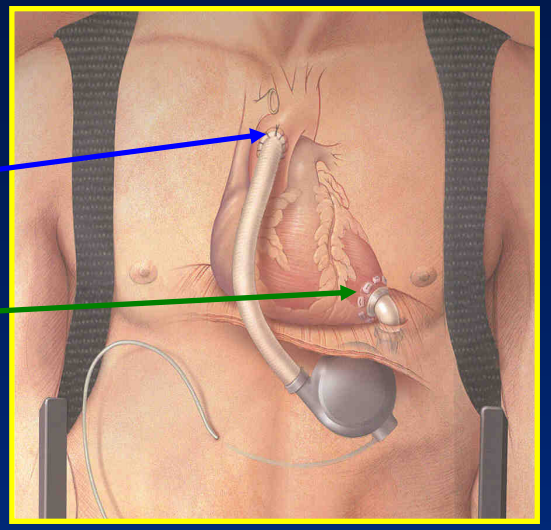
Jim Cezo

Aditi Khare

Questions?

Measured Physiological Flow Conditions





- Continuous pump speed ≠ constant flow
- Need for measurements at:
  - ‘design’
  - off-design
  - pulsatile flow rates