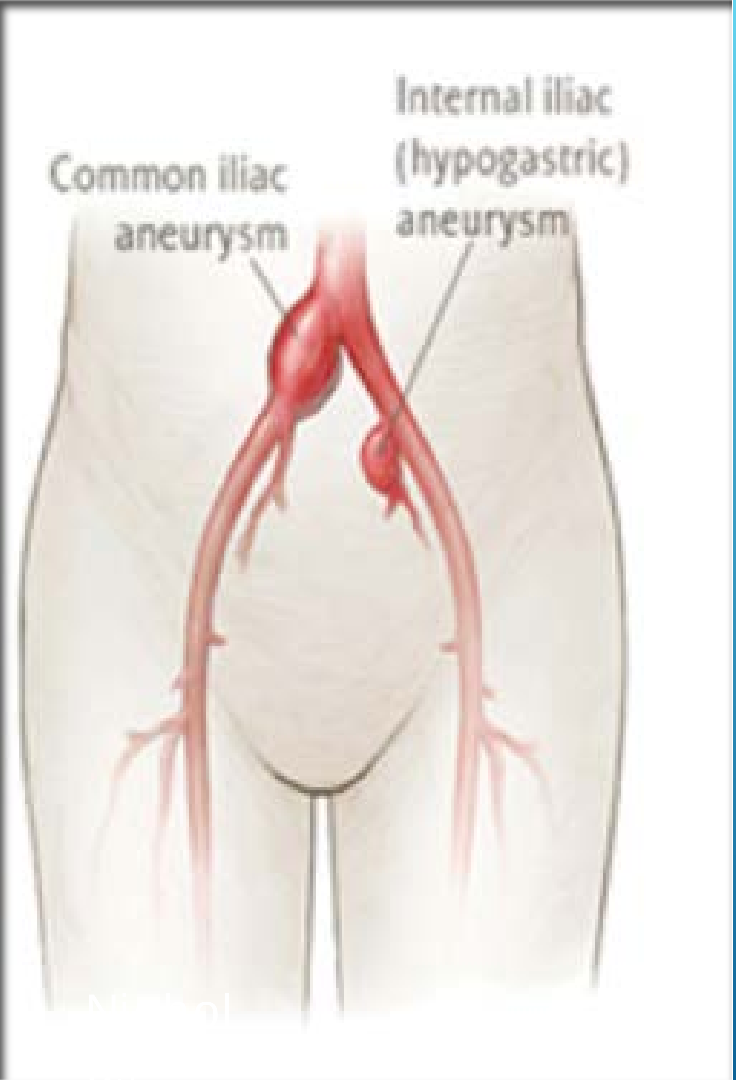


W.L. GORE ILIAC BIFURCATION ANEURYSM MODEL CONCEPT GENERATION AND EVALUATION

Chadrick Jennings - Document Manager

Michael Seth Mabes - Website Developer

Nicholas Norris - Treasurer

Noah Wick - Project Manager

[1]

PROJECT DESCRIPTION

ILIAC BIFURCATION ANEURYSM MODEL

- What it is : We are modeling an aneurysm in one of the common iliacs, and modeling the surrounding vasculature for development of medical devices.

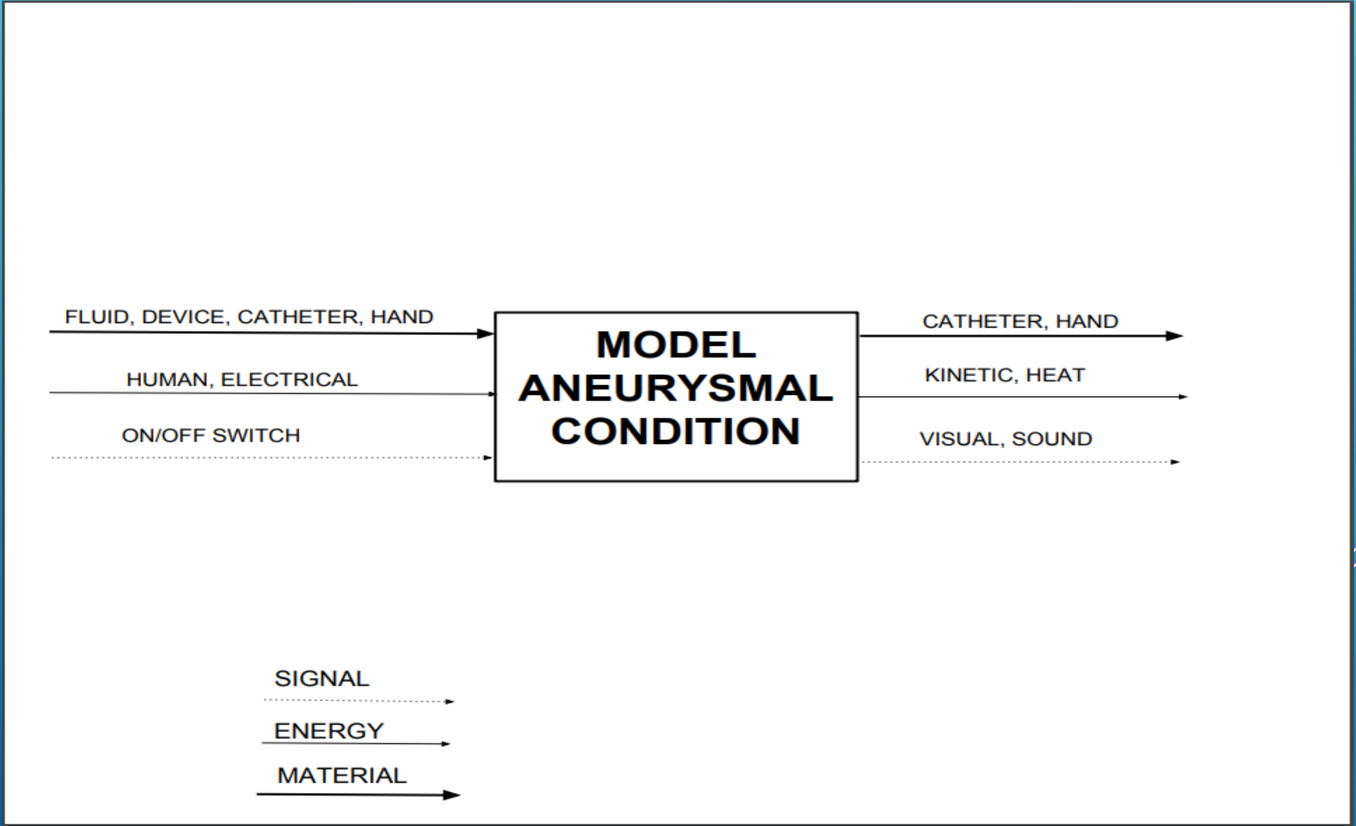
- Who it is :
  - Client - W.L. Gore and Associates
    - William Reilly
  - Faculty Advisor - Dr.Tim Becker

[2]

- Why it is : This project is geared to give real world experience while working towards a meaningful goal. The team is attempting to extend human life, test W.L. Gore stents, and learn from the Gore mentor team.

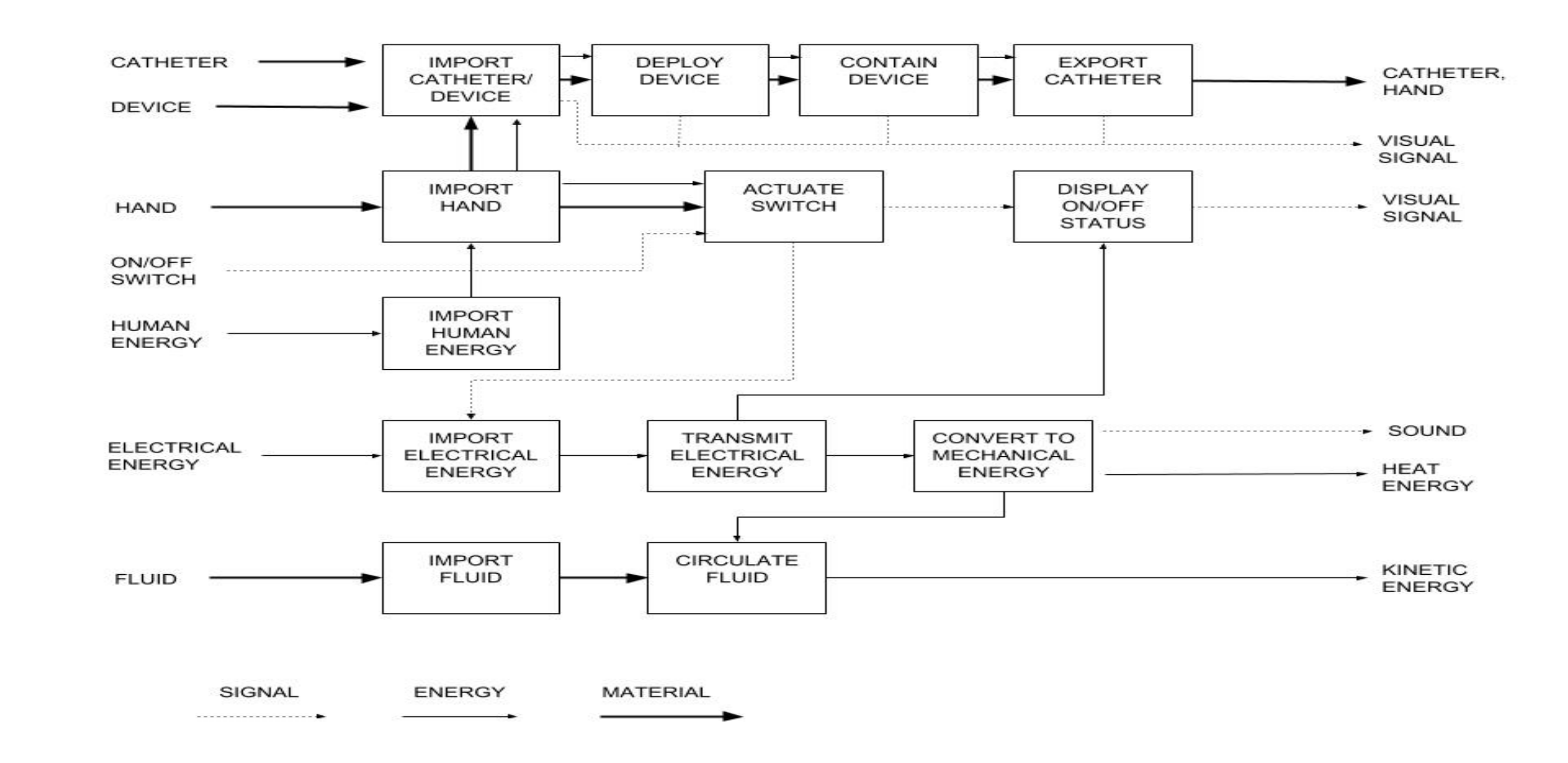
Nicholas

BLACK BOX MODEL



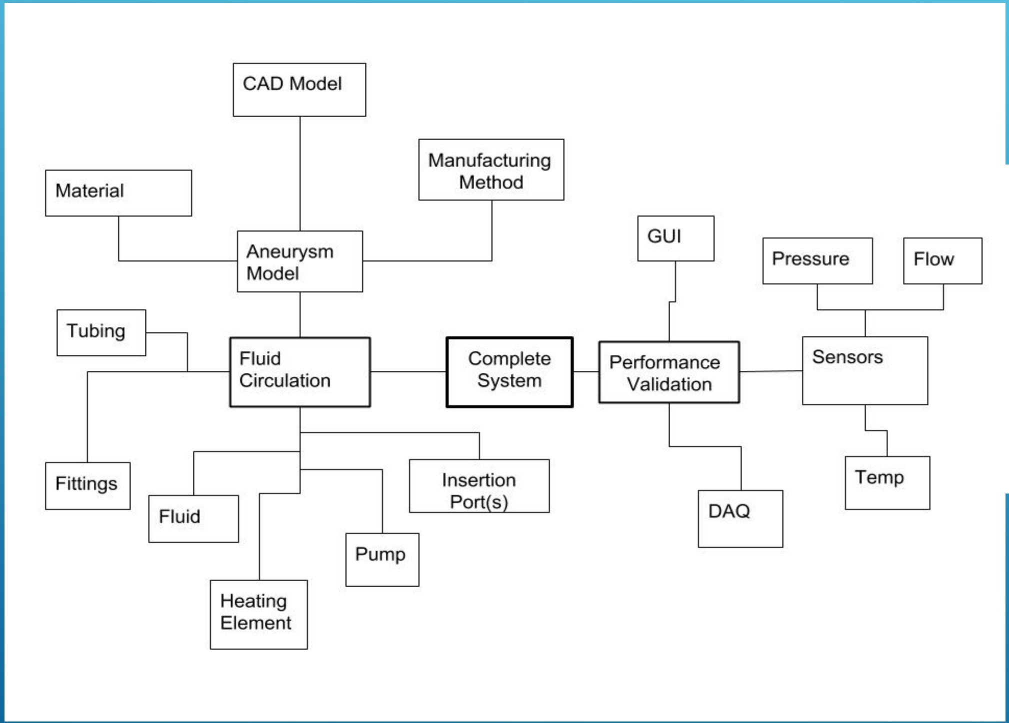
Nicholas

FUNCTIONAL DECOMPOSITION



Noah

DESIGN TREE



Overall Requirements:

1. Safe per ANSI, OSHA, or other related safety standards.
2. Design system to mimic anatomical fluid flow conditions (recommended but not limited to):
   - Flow Rate
   - Pressure
3. Develop, justify, and characterize the following attributes (recommended but not limited to):
   - Aneurysm Durometer
   - Aneurysm Compliance
   - Aneurysm Length
   - Aneurysm Thickness
   - Degree of arotic vessel growth (Creep)
4. Allow Visualization of device deployment
5. Document Repeatable Manufacturing Processes
6. Desired but not required: A Graphic User Interface (GUI)

Noah

CONCEPT GENERATION

MATERIALS

Model Materials

- Silicone
  - 15, 30, 40 Shore A Durometer
- Polyurethane
  - 45 Shore A Durometer
- Hydro Gel
  - PVA

Mold Materials

- Aluminum
- Silicone
  - Platinum Based
    - 45 Shore A Durometer
    - 60 Shore A Durometer
  - Tin Based
    - 10 Shore A Durometer
    - 25 Shore A Durometer

Noah

SENSORS

Flow Sensors

- Adafruit Liquid Flow Meter
  - Pinwheel Turbine System
  - Lowest Cost
- STEMiNC Ultrasonic Flow Sensor
  - Ultrasonic Technology
- Dwyer Series SFI-800 Transmitter
  - Pinwheel Turbine System
  - Highest Accuracy

Pressure Sensors

- Autex Pressure Transducer
  - Lowest Cost
- Dwyer Series 628CR Transmitter
  - Very High Accuracy
- Barksdale Series 600 Transducer
  - Same as Dwyer, but more durable

Chad

GRAPHIC USER INTERFACE (GUI)

- Arduino
  - Lowest cost
  - 2 group member is familiar
  - Capable of interfacing with the most sensors
- LabView
  - Most expensive option
  - 2 group members are familiar
  - Software aids in sensor calibration
  - Easiest to interface sensors

- Raspberry Pi
  - Only option that provides a take away GUI
  - Has to have an analog to digital converter to use some sensors.
  - No one is familiar with Python

Nicholas

PUMPS

- Peristaltic
  - Low cost
  - Reliable
  - Pulsatile
- Piston
  - Most expensive
  - Adjustable wave form
  - Closest to anatomical heart flow

- Continuous Flow Pump
  - Lowest cost
  - Reliable
  - Static simulation of heart

Seth

DESIGN #1: BASE MODEL

Material

-30 shore A silicone model

Casting Method

-Silicon mold for wax core

-Low melt wax core

-Silicone outer mold

Pump

-Custom built pulsatile pump

-Room temperature DI water

GUI

-Lab View GUI

Justification

Two members of the team have experience or knowledge pertaining to LabView, therefore, the GUI is reasonable.

Silicone has a high working temperature range, so it can be reasoned that the temperature of the fluid won't affect flow conditions inside of model. [3]

Chad

DESIGN #2: DELUXE MODEL

Material

-Polyurethane model

Casting Method

-Silicon mold for wax core

-Low melt wax core

-Aluminum outer mold

Pump

-Off the shelf pulsatile pump

-Temperature Control

-DI water for working fluid

Gui

-Full take away GUI with Raspberry Pi

BOE Calculation Volume of Bifurcation

Right iliac volume: 16.5*60.85 = 1004.19 mm^3
Left iliac Volume: 16.5*58.4 = 963 mm^3
Aortic Volume: 25.5*152= 3825 mm^3

Total minimum volume: 5843.79 mm^3

Seth

DESIGN #3: SR4 MODEL

Material

-Hydro Gel model

Casting Method

-Silicon inner and outer molds

-low melt wax core

Pump

-Aquarium sub pump

-Temperature Control

-Blood mimicking fluid

GUI

-Arduino

BOE Calculation

Needed pump outlet diameter

Q = VA   .000111 = pi/4 0.0165 * V   V= 0.0085 m/s

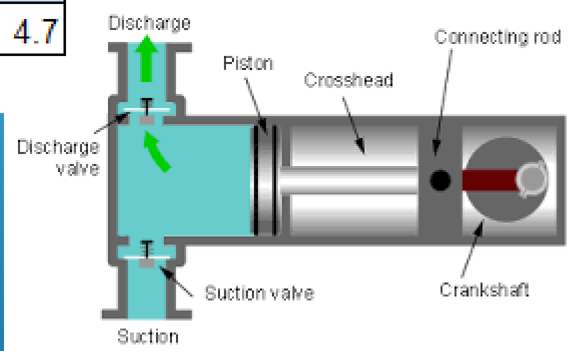
Seth

CONCEPT EVALUATION OF SUBSYSTEMS

PUMPS DECISION MATRIX

Pumps							
Criteria	Weight	Peristaltic		Piston		Constant flow	
Availability	0.3	3	0.9	1	0.3	5	1.5
Meets CN	0.3	3	0.9	5	1.5	5	1.5
Pulsatile	0.2	3	0.6	5	1	1	0.2
Maintenance	0.1	4	0.4	3	0.3	5	0.5
Cost	0.2	3	0.6	1	0.2	5	1
Totals		16	3.4	15	3.3	21	4.7

[5]



[6]

[4]

Seth

MOLD MAKING

0]

[11]

[12]

[13]

Seth

MANUFACTURING DECISION MATRIX

Raw Score
Weighted Score
Weighted Total

Manufacturing							
Criteria	Weight	Aluminum mold		Silicone mold		Silicone wrapping	
Surface Finish	0.3	2	0.6	5	1.5	3	0.9
Consistency	0.3	5	1.5	5	1.5	2	0.6
Shrinkage	0.2	1	0.2	5	1	4	0.8
Time	0.1	4	0.4	5	0.5	2	0.2
Cost	0.2	5	1	4	0.8	3	0.6
Totals		17	3.7	24	5.3	14	3.1

Seth

MATERIALS DECISION MATRIX

Design		Datum		Design 1		Design 2	
Criteria	Weight	Silicone		Polyurethane		Hydrogel	
Availability	0.3	5	1.5	4	1.2	1	0.3
Cost	0.2	5	1	4	0.8	2	0.4
Properties	0.1	5	0.5	4	0.4	5	0.5
Transparency	0.2	3	0.6	5	1	4	0.8
Ease of Mfg.	0.2	4	0.8	5	1	3	0.6
Totals		22	4.4	22	4.4	15	2.6

CRs

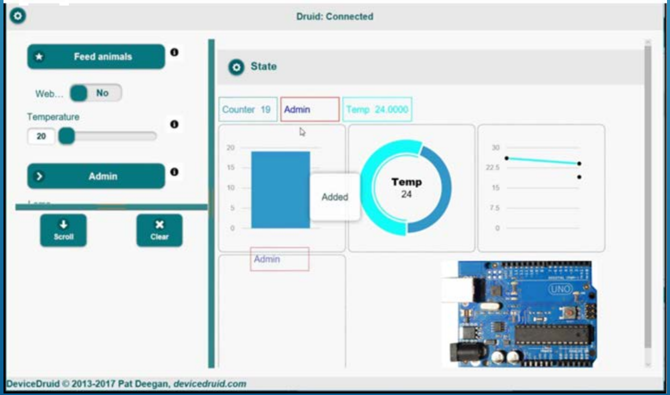
4. Match Aneurysm Mechanical Properties	7
5. Match Aneurysm Geometry	9
6. Transparent Material	9
7. Replicable Manufacturing Process	9

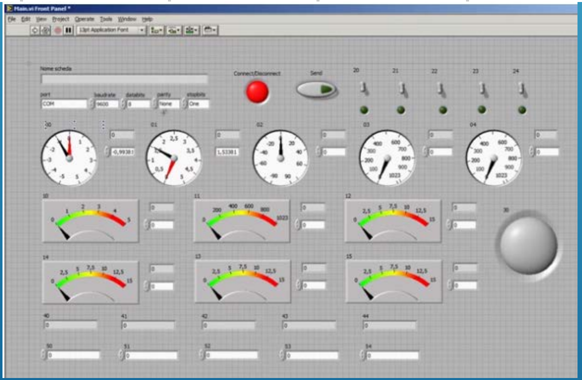
Noah

GUI DECISION MATRIX

Design		Datum		Design 1		Design 2	
Criteria	Weight	Arduino		LabView		Raspberry Pi	
Feasibility	0.2	3	0.6	4	0.8	2	0.4
Cost	0.3	5	1.5	2	0.6	3	0.9
Available Sensors	0.2	4	0.8	3	0.6	2	0.4
Time to Learn Language	0.1	3	0.3	4	0.4	1	0.1
Ease of use	0.2	3	0.6	5	1	3	0.6
Totals		18	3.8	18	3.4	11	2.4

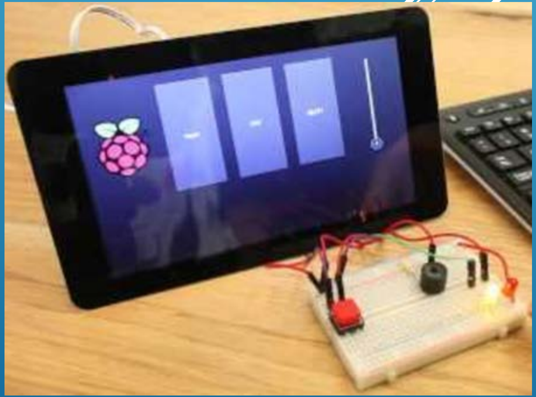
[7]





[8]

[9]



Nicholas

SENSORS DECISION MATRIX

Pressure Transducer Decision Matrix									
Criteria	Weight	Datum (Pressure Gage)		Concept 1 (Autex)		Concept 2 (Dwyer)		Concept 3 (Barksdale)	
Cost	0.2	5	1	5	1	2	0.4	2	0.4
Max Pressure	0.1	3	0.3	5	0.5	5	0.5	5	0.5
Accuracy	0.3	2	0.6	3	0.9	4	1.2	5	1.5
Installation	0.2	4	0.8	3	0.6	4	0.8	4	0.8
Compatibility	0.2	1	0.2	4	0.8	4	0.8	4	0.8
Totals:			2.9		3.8		3.7		4

Flow Meter Deciosion Matrix							
Criteria	Weight	Datum (Adafruit)		Concept 1 (STEMiNC)		Concept 2 (Dwyer)	
Cost	0.1	5	0.5	5	0.5	2	0.2
Accuracy	0.3	2	0.6	3	0.9	5	1.5
Max Fow Rate	0.2	3	0.6	4	0.8	5	1
Max Pressure	0.2	3	0.6	5	1	5	1
Installation	0.1	4	0.4	2	0.2	4	0.4
Compatibility	0.1	4	0.4	3	0.3	4	0.4
Totals:			3.1		3.7		4.5

Chad

CONCEPT SELECTED

Materials:

- 45 shore A polyurethane model
- 45 shore A platinum silicone molds

Casting:

- Silicone molds for exterior and interior
- Lost wax method for hollow core

Pump:

- Continuous Flow Pump

Sensors:

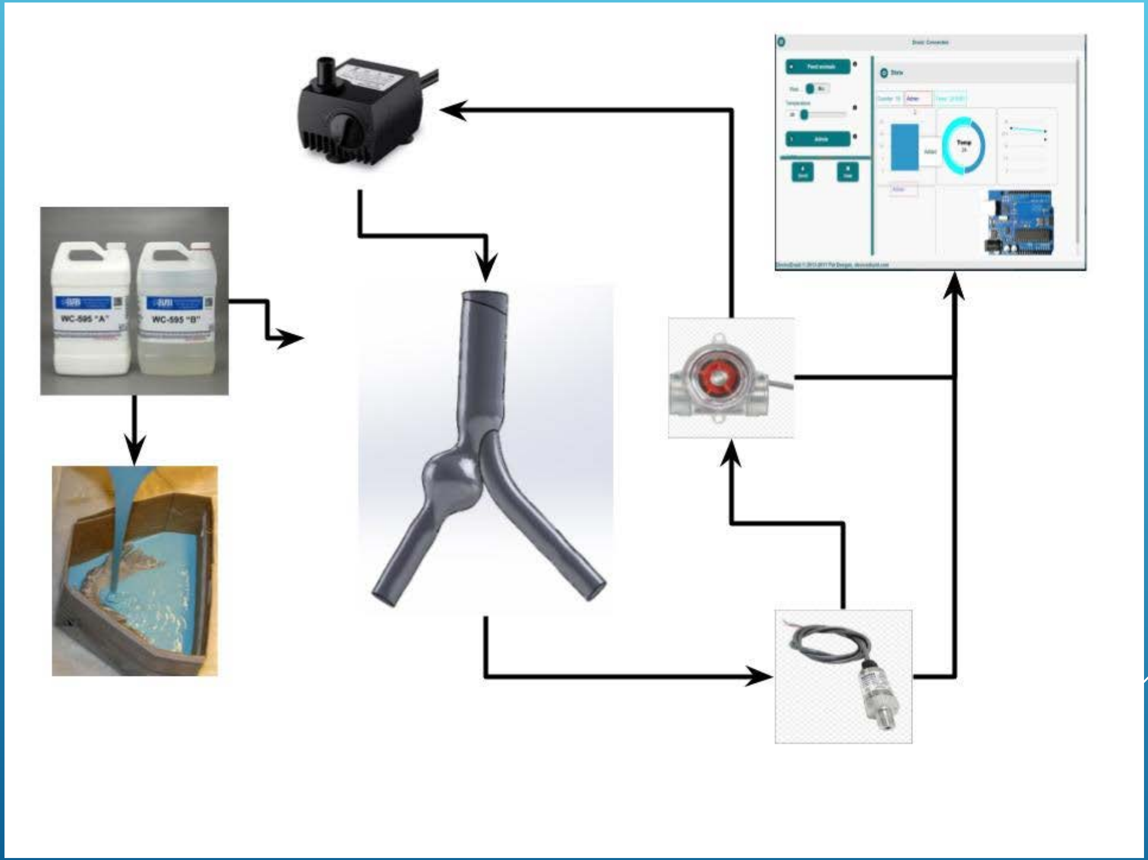
- Barksdale Series 600 Pressure Transducer
- Dwyer Series SFI-800 Flow Meter

GUI:

- Arduino data collection
- Device Druid GUI

Chad

CONCEPT SELECTED (CAD)



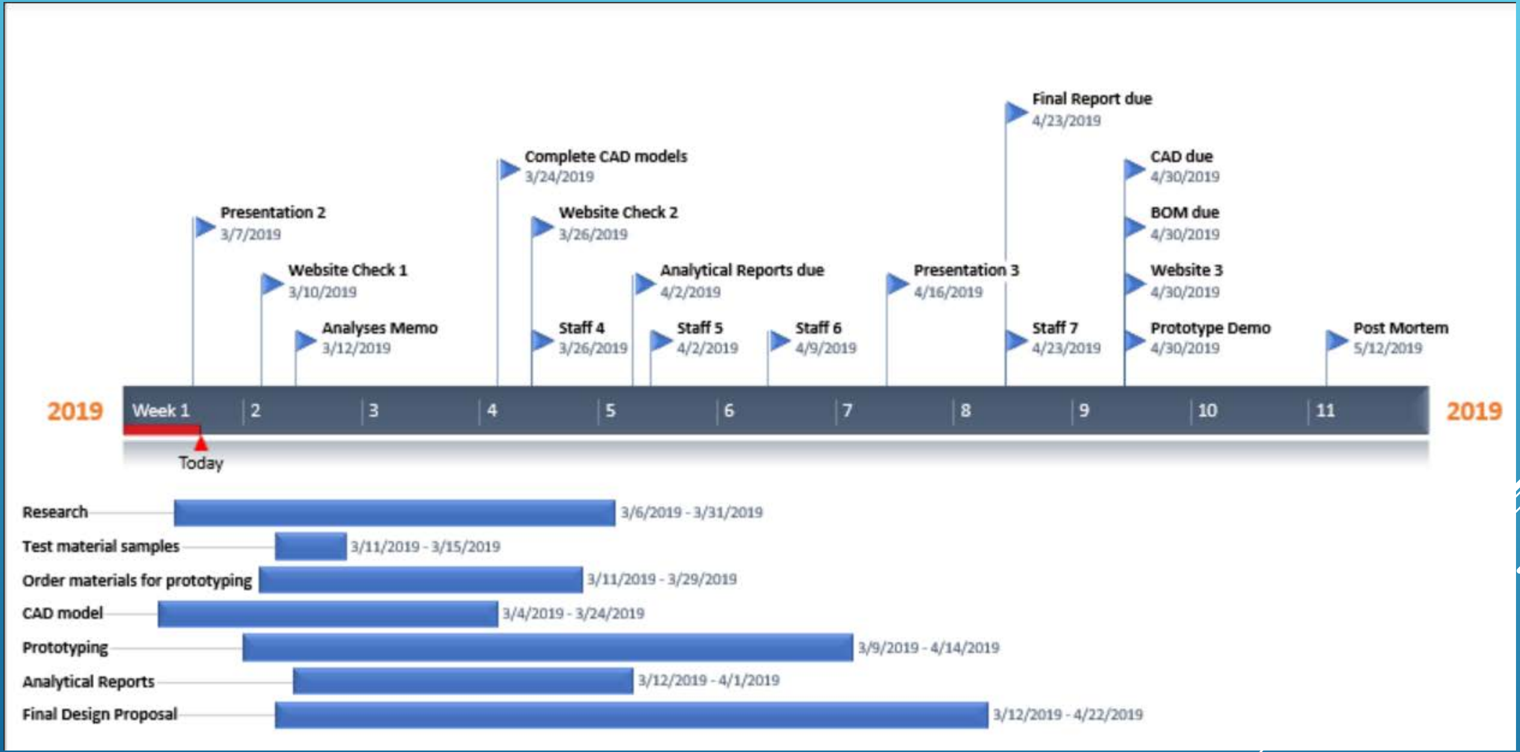
Chad

SCHEDULE AND BUDGET

Budget for Gore Capstone Thus Far			
	Budget	$3,000	
Current list of items	Expected needs	Cost	Rational and Comments
Arduino UNO R3		$35.00	Arduino for GUI
Silicone Tubing		$0.00	Donated from Client
	Aquarium Pump	$12.50	Prototyping
	3D printing	$15.00	prototyping
Polyurethane samples		$0.00	Donated for testing from a manufacturer
	Flow Sensor	$30.00	GUI or some visual reading
	Pressure Sensor	$50.00	GUI or Pressure Gauge (relatively same price)
	Silicone (2 Gallons)	$230.00	For making the wax core mold and vascular mold
	Polyurethane (1 Gallon)	$135.00	For making casts of the vasculature
	Wax	$40.00	For Lost Wax Casting
	Peristaltic Pump	$100.00	could be piston pump. Price can vary
	Frame for Model	$100.00	This is still in descussion: pegboard, cart, CAD?
	Pressure Chamber	$150.00	For degassing of molds and casts
	3D printing	$100.00	For aneurysm model
	Shipping	$100.00	In case shipping is expensive
	Poster	$100.00	For the most shiney poster
Cost		$1,197.50	
Current Budget Remaining for Unknown Expense		$1,802.50	

Nicholas

SCHEDULE



Noah

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APPENDIX A: QFD

Customer Requirement	Weight	Engineering Requirement	Mean Flow Rate in left iliac (ml/s)	Mean Flow Rate in right iliac (ml/s)	Aortic Pressure systolic/diastolic (mmHg)	Surface Roughness (micrometers)	Hardness (shore OO)	Shear Modulus (kPa)	Wall thickness	Aneurysm Diameter	Aneurysm Length (mm)	Creep (mm/year)	See-Through Model (binary)	Fluid Temperature (C)	Weight of entire system (kg)	Total Cost ($)	Diameter of distal Aorta	Diameter of Left Iliac	Diameter of right iliac	Radius of Curvature at Right Junction (mm)	Radius of Curvature at Left Junction (mm)	Length from iliac to catheter insertion point	Take Off Angle of Right common iliac in coronal plane (	Take Off Angle of Left common iliac in coronal plane (d	Take off angle of iliacs in saggital plane (degrees)			
1. Safe per ANSI/OSHA	10			1	3			1	1					1	1													
2. Easy to Move	3								1						9	1												
3. Mimic Anatomical Flow Conditions	8			9	9				1					1		3	9	9	9	3	3	3	3	3				
4. Match Aneurysm Mechanical Properties	7						9	9		9	9	9		1		3	3	3	3	3	3	3	3	3				
5. Match Aneurysm Geometry	9								9		9																	
6. Transparent Material	9												9			1												
7. Replicable Manufacturing Process	9															3												
8. Displays Pressure	5				9									1		3												
9. Displays Flow Rate	5			9										1		3												
10. Stable Base	4			3											3	1												
11. Displays Aneurysm Volume Change	3															3												
Absolute Technical Importance (ATI)																												
Relative Technical Importance (RTI)																												
Target ER values			94	111	141/68		41	175	2	35	27	2.9	Y/N	37	23	##	26	17	17	35	51		29	14	15			
Tolerances of Ers											4.1		n/a			200	6.5	8.5	8.5									
Testing Procedure (TP#)																												