Tripolar LV Volume Sensor For Rotary Blood Pumps

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LVADvancements

UTSA Engineering and Integrated Design

ABSTRACT

The purpose of this project is to modify a commercial LVAD device through the implementation of a four electrode configuration with the intention of monitoring instantaneous cardiac output.

The Incorporated Shell Wire Sensor is an implantable sensor designed to measure real-time left-ventricular volume.

Its purpose is to complement Left-ventricular assist devices (LVAD's) in self-regulation and provide self-weaning protocols as cardiac output (CO) regulates healing patients.

The implantable device achieves this by utilizing a system of electrodes that can translate complex admittance generated by the heart into volume readings.

STATEMENT OF PURPOSE

Need statement: *There is a need for less invasive continuous measurement of native cardiac output on rotary heart pumps.*

Subset need: *The need to make the current design less invasive within the confines of stenting procedures involved in rotary heart pumps.*

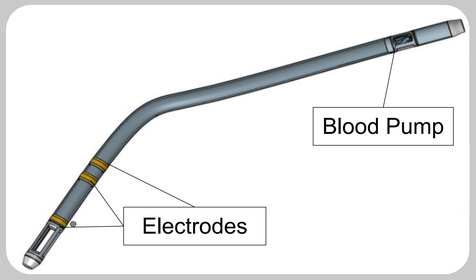
OBJECTIVES

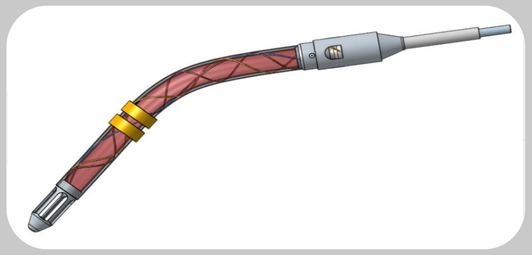
- To increase Cardiac Output
- To obtain real time Cardiac Output readings
- To give the pump the ability to self wean

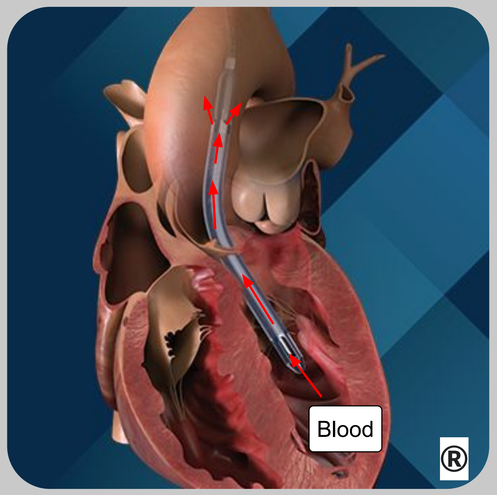
CUSTOMER REQUIREMENTS

Patient Requirements	Affordable	**Physician Requirements**	CO Readings
	Less Invasive		Flexible Cannula
	Minimal Revisions		
	Longer implantation times		Blood compatible

PROPOSED DESIGN







HOUSE OF QUALITY

		Importance Rating 1=low, 5=high ↓	% of Importance ↓
Physician Req.	Affordability	4	13%
	Less Invasiveness	4	13%
	Ease of Use	3	9%
	Longer Implantation times	1	4%
	Minimized revisions	3	9%
Patient Req.	CO readings	5	15%
	Material Flexibility	4	13%
	Biocompatibility (No clotting)	5	15%
	Can be used as an emergency procedure	3	9%

Most Important requirements

	Correlated Importance 1=low, 5=high ↓	% of Importance ↓
Flexible Cannula	2.4	11%
Biocompatible Polymers and Alloys	3.1	14%
Real time CO readings	4	18%
Ability to pump blood	3.2	15%
Dual interface to translate data	2.8	13%
No exposed wiring	3.6	16%
Sensors solderend into pump	2.7	13%

Most Important Technical Specs

DESIGN ANALYSIS

How does our design meet the most important needs and requirements?

- **Our design builds upon an existing blood pump**
  - Keeps blood flowing on failing hearts
- **Our design provides real time cardiac volume readings**

How do we achieve this?

- Tripolar plethysmography
  - Uses current sensing electrodes to translate blood impedance into volume readings.
- **Our design is compliant with FDA standards**
  - Exposed wiring is the main problem with current prototypes, our design would not have this problem.
  - Biocompatible materials and soldering would be utilized throughout the manufacturing process.

RISK ANALYSIS

After analyzing and listing all components with their respective function and connections using FMEA, it was deducted that the design possess the following major potential hazards: part breakage and chipping, especially electrodes, and exposed wiring. To reduce the risk created by these very possible hazards, strict assembly processes would need to be followed such as proper soldering and gluing of each part.

COST BREAKDOWN

Materials/Parts	Source	Cost
Impella 5.5	Abiomed	~$25,000 USD
Implantable Electrode Wiring	Cooner Wire Co.	$20-$100 USD depending on wire quality
Implantable Electrodes	Johnson Matthey Chemical Company	$11.345 USD per unit
Total Material Cost		**~$25,100 USD**
Total SD1 Cost		**~$1,300 USD**

CONCLUSIONS

- Tri-polar plethysmography would provide real time Cardiac Output readings
- Shell can be engineered based on existing Impella components
- Would meet FDA standards for implantable devices in humans

TEAM MEMBERS & MENTORS

Team Members

- Richard Avila
- Jonathan Blades
- Guillermo Ramirez
- Luis Alan Díaz Sanmartin

Mentors

- Drew Nolen, UT Health Biomedical Engineering Researcher.
- Dr. Jonathan Valvano, Ph.D, UT Austin Electrical Engineering professor.
- Dr. Marc Feldman, M.D. , UT Health professor of medicine, cardiac surgeon.

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