Criteria	VII: INSTITUTIONAL VALUES AND BEST PRACTICES
Key Indicator – 7.2	BEST PRACTICES
Metric 7.2.1	Describe two best practices successfully implemented by the Institution as per NAAC format provided in the Manual.
BEST PRACTICE - I	

Title of the Practice: Innovative research on contemporary societal needs

I. OBJECTIVES

The Indo-American Artificial Heart Program is a philanthropic research program, bringing together the medical and engineering fraternities towards building a low-cost left ventricular assist device; a centrifugal blood pump for cardiovascular support. The IAAHP is in collaboration of various organizations, including CBIT, SHARE INDIA, SNIST, KITSW, AIG Hospitals, Laxven Systems and esteemed foreign organizations and universities including University of Pittsburgh, Cornell University and Vadovations. A commercially available LVAD called Centrimag was used as a standard and inspiration for the design and development of the prototypes. Following are the key objectives of the research program;

- Design and development of magnetically levitated extracorporeal blood pump (centrifugal pump) for LVAD and ECMO settings.
- Rapid prototyping using various 3-D printing techniques like FDM and SLA.
- In-vitro hydrodynamic and hemolysis testing of the prototype.
- Injection molding of pump casing and impeller and its design inspection.
- Development of an automated gluing process for the assembly of pump casing.
- Hydrodynamic and in-vitro biocompatibility testing.
- In-vivo testing on sheep.
- Human trials.

II. CONTEXTUAL FEATURES AND CHALLENGING ISSUES

- Almost 30 prototypes of the centrifugal pump were designed and 3D-printed. Magnetically coupled and magnetically levitated impellers were designed. Various blade angles and number of blades were considered during the initial stages of research.
- Adopting computational methods using ANSYS Workbench for fluid flow analysis.

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- Procurement of suitable magnets for the impeller.
- Setting up of a mock circulatory loop, for hydrodynamic and hemolysis testing of the 3d printed prototypes, which replicated the human circulatory system giving a flow rate of 5.0 lpm and pressure head of 120mmHg.
- Incorporating and learning medical terminologies and in-vitro clinical trials for establishing biocompatibility standards.
- Search for a suitable industry for the manufacture of injection moulded pump parts.
- Selection and procurement of an appropriate biocompatible adhesive for joining the pump top and bottom casing.
- Establishing a semi-automated set up for dispensing the adhesive along the pump casing.
- Training the surgeons for animal trials using commercially available pumps and finally animal trials using the manufactured pump.

I. DESCRIPTION

Various versions of the pump were designed using SolidWorks and computational analysis was done using ANSYS Workbench. The pump is designed to deliver a flowrate of 5.0 LPM and a pressure head of 120 mmHg for LVAD setting and 500 mmHg for ECMO setting. SLA 3D printer was used for rapid prototyping.

3D Printed pump bottom casing

The CAD models of the pump parts were sent to a manufacturing facility in Hyderabad. The material used for the pump components is Poly Carbonate (PC). A die was machined as per the designs for pump casing and impeller. The injection molded parts were inspected for dimensional and design accuracy and surface roughness. Design changes and modifications were noted and executed.

Polycarbonate injection-moulded pump casing and impeller were joined using various types of adhesives, manually using a syringe and later with a 3D-Printer robotic arm. The Hyrel 3D printer uses interchangeable heads attached to a stepper motor with a syringe, to print the desired object. The CAD model of the glue path was generated in SolidWorks, and converted to 3D Printer compatible STL file. This file was opened in the Hyrel 3D printer software ‘Repetrel’. Repetrel was used to make adjustments, calibration and control the print with G-Codes.

Pump Fixtures: In order to place the pump bottom casing on top of the printer bed, and to a join the top casing after adding the glue, top and bottom casing fixtures were modelled and 3D printed using ABS material. The fixtures ensured proper alignment of the injected glue with the glue path on the bottom casing and also precision while placing the top casing on the bottom one.

Dymax 1201(viscosity=8000cP), a biocompatible UV curable adhesive was selected to glue the pump casings together. This is blue in color and turns clear upon UV curing. It was cured under UV light in the ‘Form Cure’ UV equipment (wavelength=405nm). The pump casing was further modified to a tongue and groove arrangement. UV curable glue was injected in the groove of the bottom casing and top casing with the tongue was added on top. The casing was designed in a way that the excess glue did not spill inside the casing and instead came out. The pump casing was 3D printed in an SLA printer for trials. The glue was successfully added and the top casing attached with the robotic arm without any spill inside. The glue was UV cured using Form Cure UV equipment.

Glue added to clear 3D printed pump and cured in UV chamber

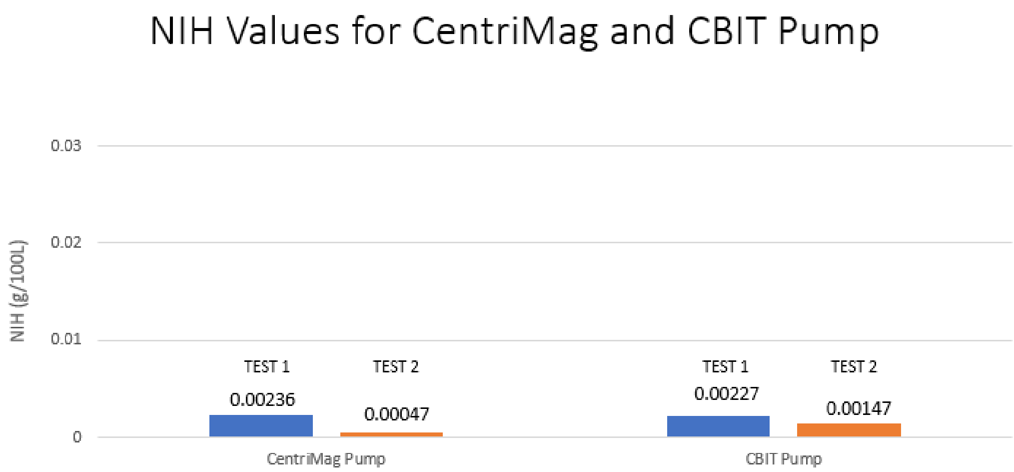
Hydrodynamic Testing of Glued Casing**:** All the glued pumps were tested in the mock loop setup for 4 hours. There was no evident leakage in any pump throughout the test. The test parameters were;

i. Flow rate= 5.0 LPM
ii. Differential Pressure for LVAD setting=110 mmHg
iii. Differential Pressure for ECMO setting= 500 mmHg

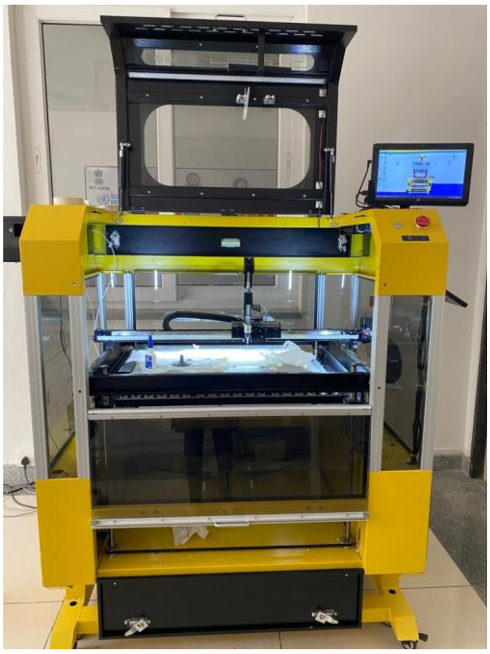
Hydrodynamic Testing

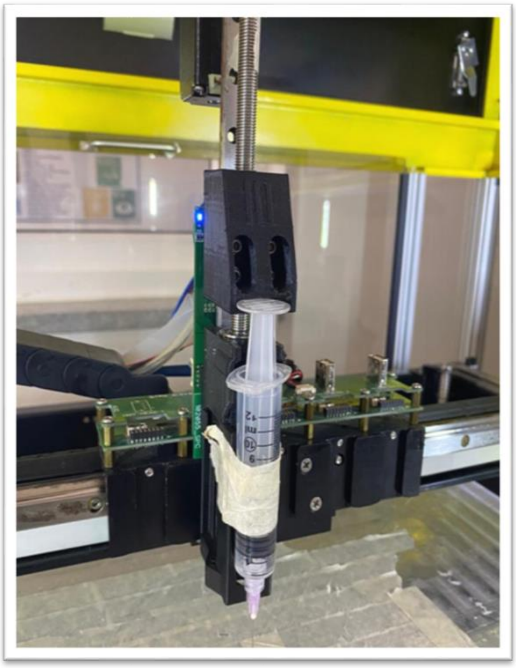
II. EVIDENCE OF SUCCESS

- Hydrodynamic tests showed good results as the flow rate achieved was 5.0 lpm and pressure head was about 120mmHg, which replicated the left ventricle function of the heart.
- Hemolysis tests were performed on the standard Centrimag pump and 3D-printed prototype. The normalized index of hemolysis was calculated and the prototype achieved NIH very close to the Centrimag.

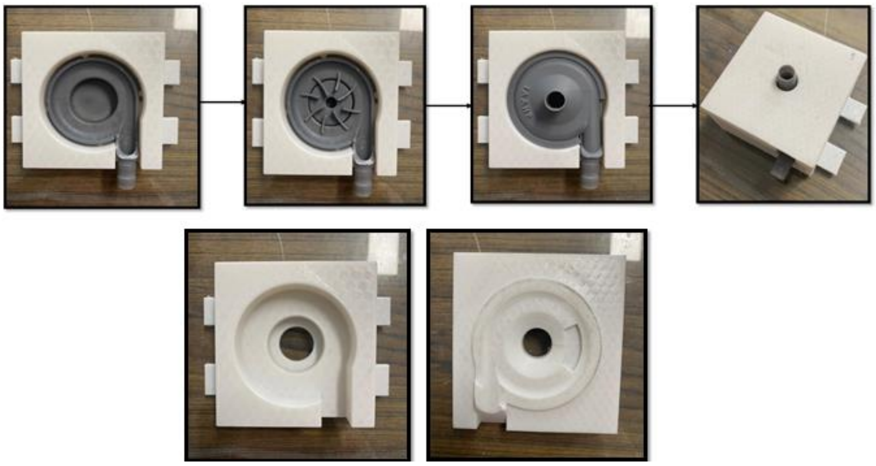


- The Hyrel 3D printer, as shown in the figure below, in CBIT was successfully used as a glue dispensing robotic arm. The G-Codes were modified as per the glueing path and the pump top and bottom casing were assembled. The fixtures for the pump were also 3D printed.

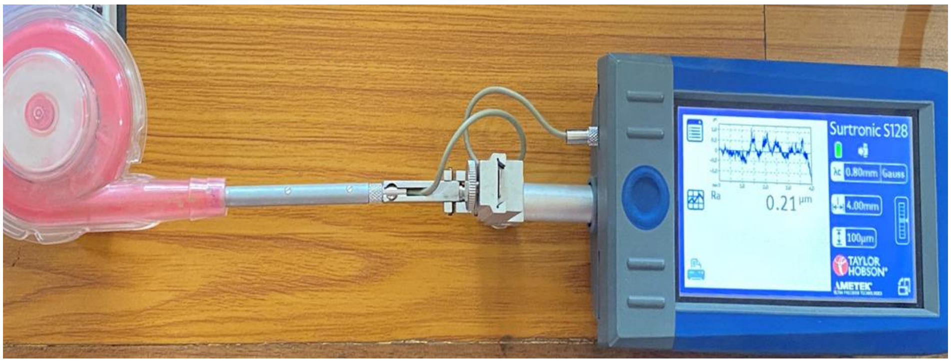




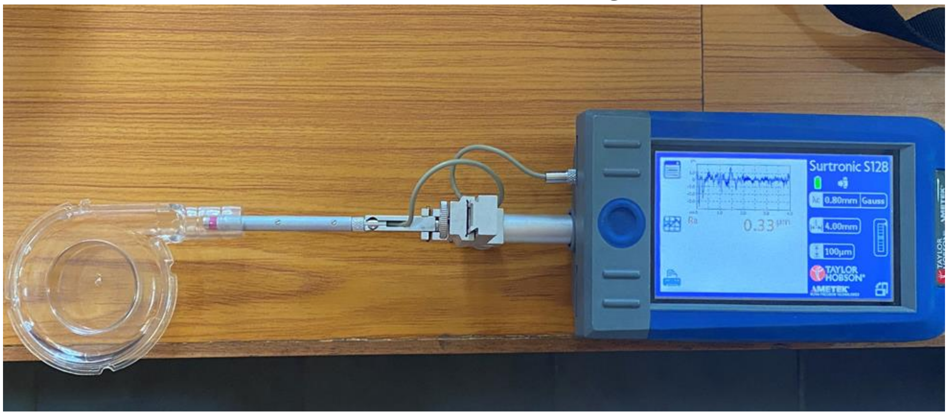
PUMP TOP AND BOTTOM CASING FIXTURES FOR GLUING



- The initial injection moulded parts were successfully manufactured at a facility in Hyderabad. For the initial testing and trials, these pumps were effective with a good surface finish. The surface roughness value (Ra) for Centrimag (control) = 0.21 microns and Ra for injection moulded pump = 0.33 microns

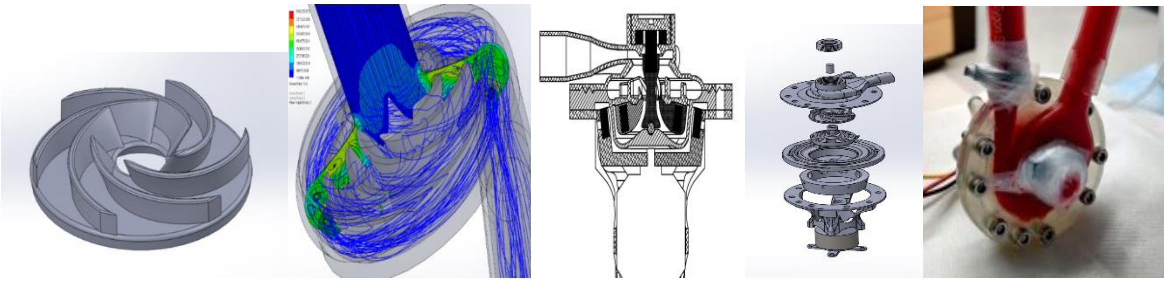


Ra=0.21 for Centrimag

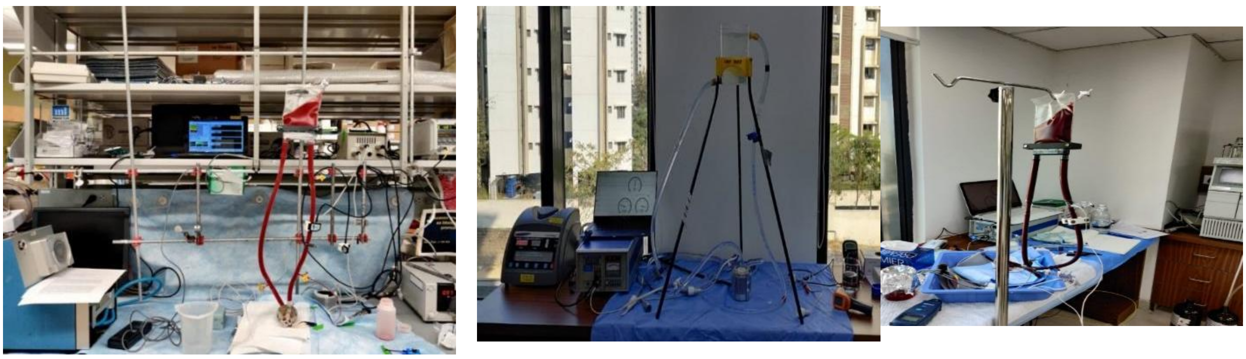


Ra=0.33 for Injection Moulded Pump

- The role of CBIT in the project is to develop a blood pump so that it runs continuously for a long time reliably inducing minimum possible shear stresses. The pump is designed and developed. The pump is tested with human blood. Animal testing is also completed. Once clinical testing is over, the product can be marketed.

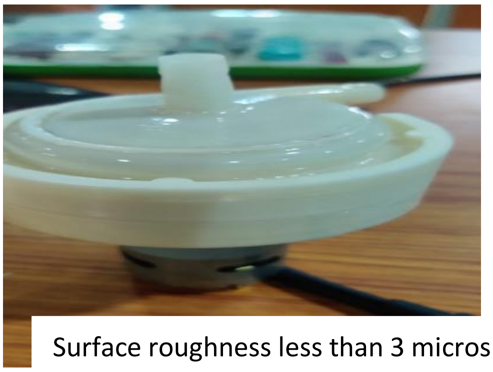


Mono Pivot Bearing Blood Pump Design, Simulation and Prototype



Mock loop and hemolysis setup at AIG Hospital Hyderabad and Hemolysis experiment on prototypes with human blood.

In Vivo experiment on sheep, conducted 4 cardiac Support experiments and Cardio-pulomonary support on sheep at Palamur Bio Sciences Lab.4th study on sheep was conducted on 4th Sept, 2021



Surface roughness less than 3 micros achieved in 3D printed Prototype – with ABS material and post processing techniques.

III. PROBLEMS ENCOUNTERED AND RESOURCES REQUIRED

- The glueing is currently semi-automated. For mass production, a fully automated system needs to be developed. A robotic arm for the pick and place of the pump casing on the fixture would be essential.
- Flood-curing UV equipment for the adhesive that would cure multiple parts in a short time would be needed for the mass production stage.
- Further biocompatibility tests such as von Willebrand factor and ring thrombosis need to be incorporated. Development of adequate protocols and research for these tests are ongoing. Certain chemicals and reagents need to be procured for these tests.
- A more sophisticated manufacturing facility for the pump parts is needed for better precision, accuracy and medical grade standards.
- Motor development for the pump is currently ongoing with a facility named Laxven Systems. Appropriate sensors for magnets need to be selected for their production.

VI. THE TEAM

Our Team of Engineering Experts

Chaitanya Bharathi Institute of Technology

- **Dr. P. Ravinder Reddy**
  Principal CBIT,
  Professor Of Mechanical Engineering Dept, CBIT

Sreenidhi Institute of Science and Technology

- **Sadia Alvi**
  Assistant Professor
  Mechanical Engineering Dept, SNIST

University of Pittsburgh

- **Rugveda Thanneeru**
  PhD Scholar, University of Pittsburgh

KITS, Warangal

- **Dr. Saikumar Gadakary**
  Assistant Professor
  Mechanical Engineering Dept, KITS Warangal
- **Dr. Ganesh Kumar Gampa**

Our Team of Medical Experts

SHARE India, University of Pittsburgh

- **Dr. P.S. Reddy, MD**
  Professor Of Medicine, University of Pittsburgh, USA
  Chairman SHARE/ MediCiti Institute of Medical Sciences, India

Palamuru Biosciences Pvt. Ltd.

- **Dr. D.C. Sharma**
  Head - Technical Operations
  Medical Research Institute for Devices Assessment (MRIDA)
  Palamur Biosciences Private Limited

AIG Hospitals

- **Dr. Sukesh Kumar Reddy,**
  CT surgeon, AIG Hospital,
- **Dr. Naresh,**
  CT surgeon, AIG hospital
- **Dr. Ramakrishna Reddy,**
  Cardiac Anesthesiologist AIG hospital

Hemolytic test at Dr Kameneva's Lab in University of Pittsburgh Medical Center

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