Design and Fabrication of a Pulse Duplicator Capable of Replicating the TAVR Procedure

Ben Holland[1], Ebrahim Tajik[1], Hossein Ravanbakhsh [1]

[1] Department of Biomedical Engineering, The University of Akron, Akron, OH, 44325 USA

Introduction

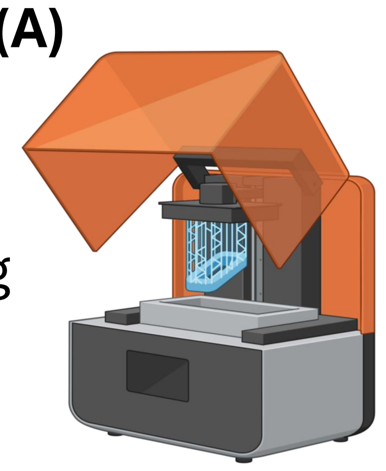
A **pulse duplicator** benchtop testing system evaluates the hemodynamic performance of novel artificial heart valve designs. There is a need for a low-cost pulse duplicator with an intuitive interface.

We designed a low-cost benchtop pulse duplicator that complies with **ISO-5840**[1], using three-dimensional (3D) printed parts, custom circuitry, and Python code.

METHODS

- SolidWorks models were created, and 3D printed.
- Thermoplastic molding was used to make airtight pockets.
- A custom PCB was designed, ordered, and soldered.

(A)



(B)

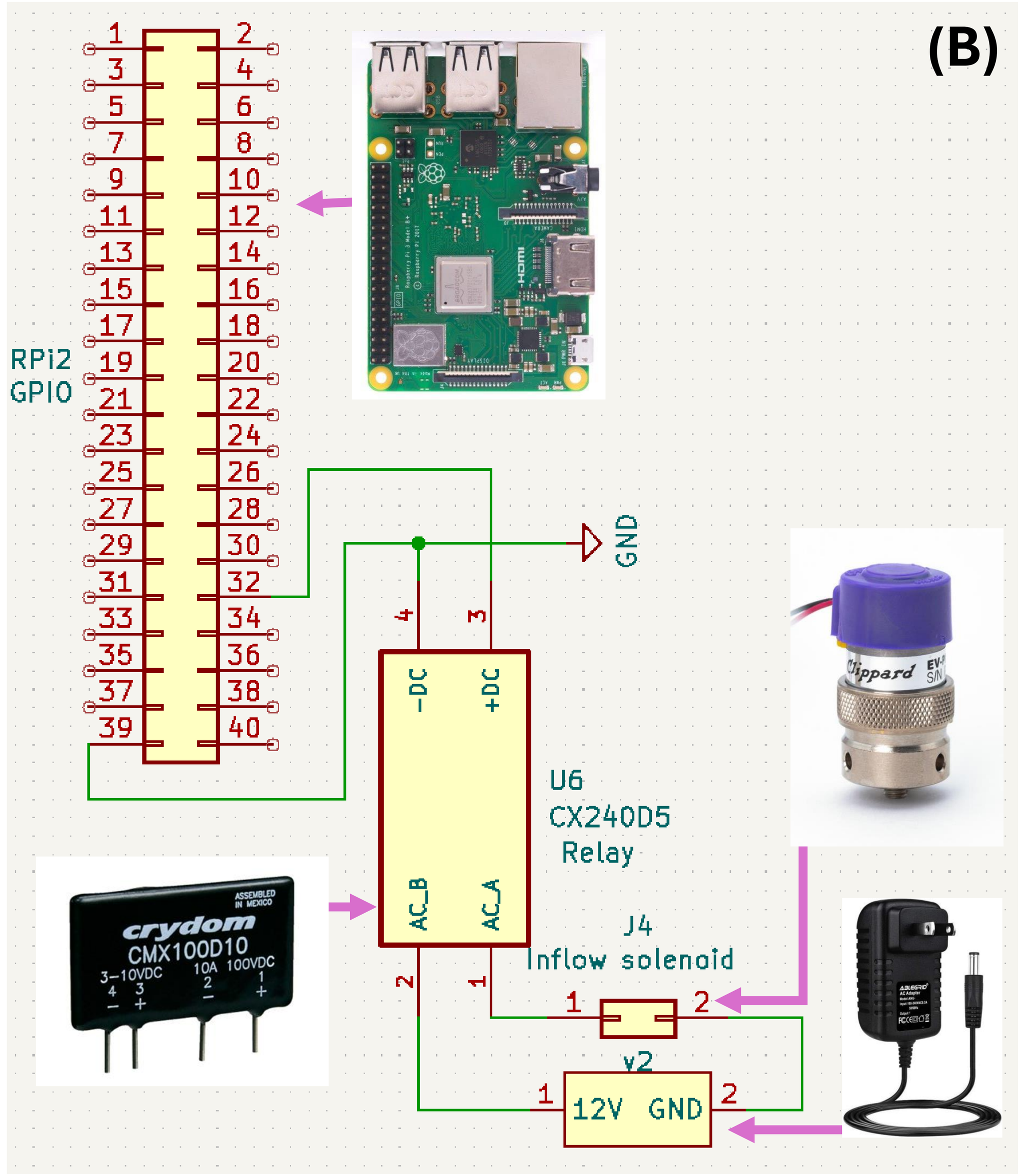


Figure 1. A) An LCD printer, used to print different parts. B) A circuit diagram for one of the airflow valves.

RESULTS

Figure 2. The printed heart structure.

Left ventricle and atrium 3D model created and printed using 80A flexible resin.

TPU sheets molded into airtight pockets, then attached to tubing. Four pockets applied pneumatic pressure on the heart, stimulating systole. When inflated, a pressure of 200mmHg created. This method was developed by Rosalia et al.[2]

Figure 3. Two of the four inflatable pockets.

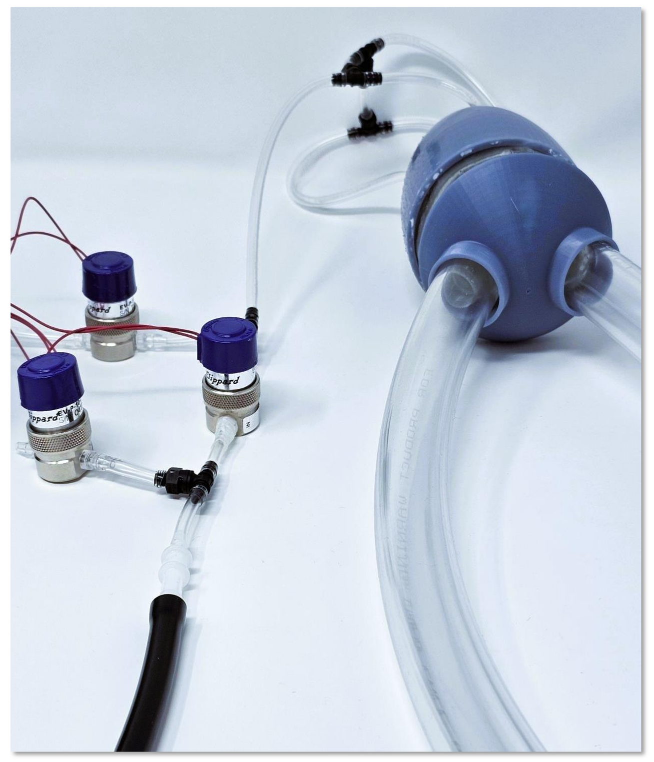


Figure 4. The air valves, used for systole and diastole.

Three solenoid valves attached to tubing from airflow supply, wired to the pins of a Raspberry Pi. Valves programmed to open and close to mimic the cardiac cycle. Cycle rate adjustable from 30 bpm–220 bpm.

Heart structure attached to model blood vessels. Two artificial valves (aortic and mitral) added. Pressure sensors and a flow rate sensor placed at four locations gather data, which was visually displayed. A compliance chamber models blood vessel compliance.

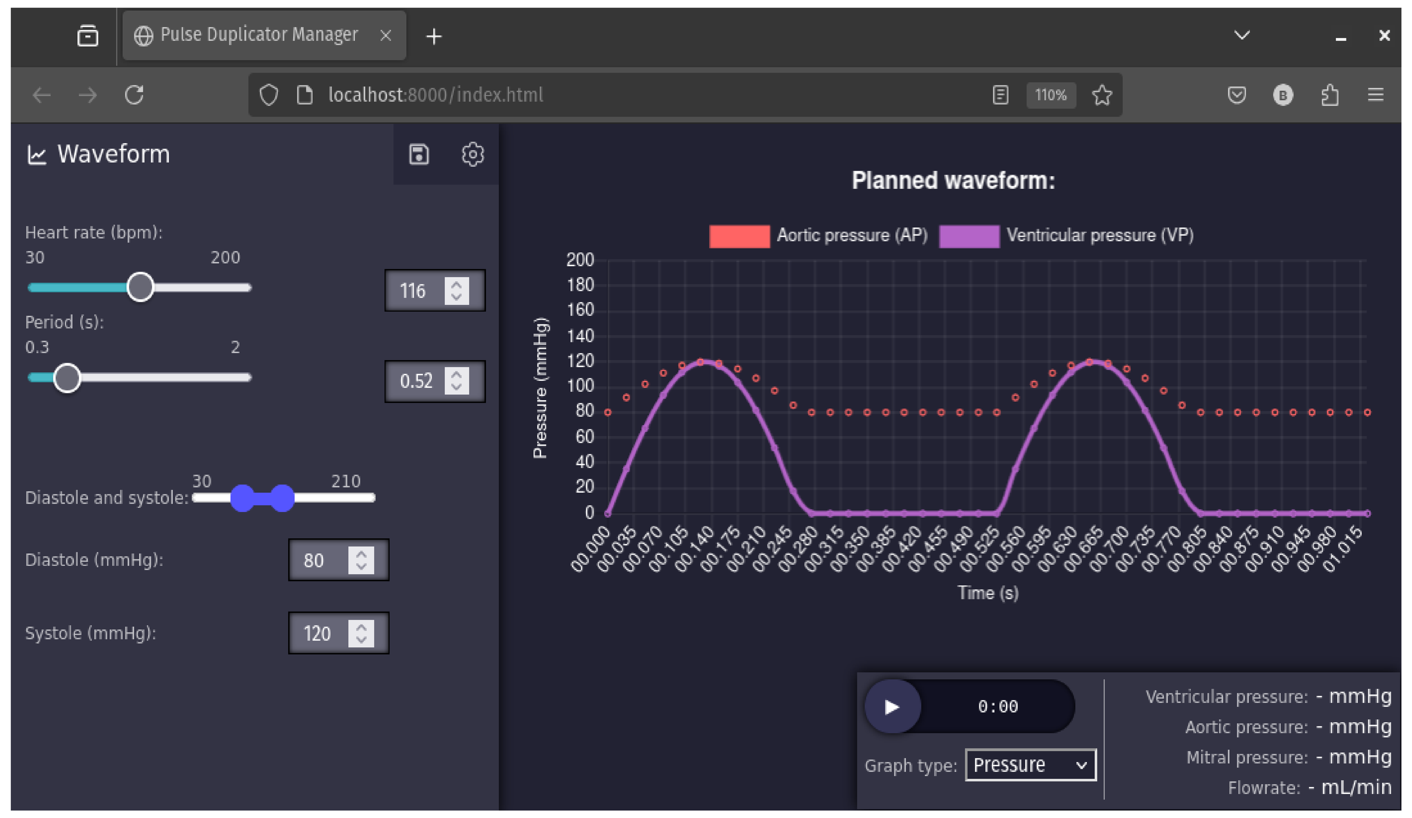


Figure 5. The pulse duplicator software interface.

Software interface created with JS and Python to control behavior and prediction waveform. Live data can be collected and graphed. Data can be exported as a graph or .csv file. The system is capable of ISO-5480 compliant performance.

Table 1. The pulse duplicator's ISO-5840 compliant capabilities.

Pulse Duplicator Capabilities	
Heart rate	30 – 200bpm
Output	3 – 15 L/min
Flow volume	25 – 100 mL
Normal Blood Pressure	120/70 mmHg
Hypotension	80/40 mmHg
Hypertension	210/120 mmHg

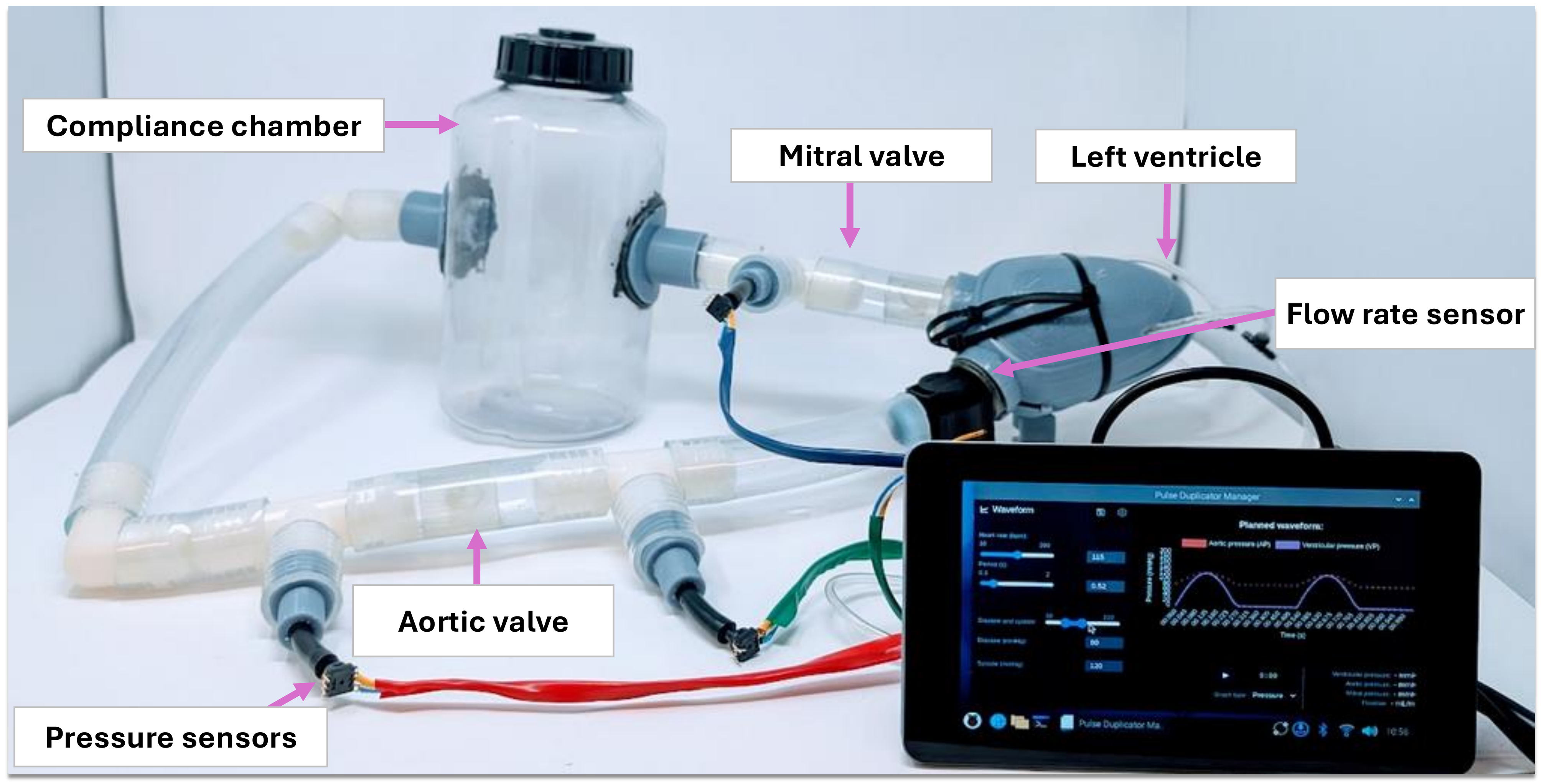


Figure 6. The full hemodynamic simulation setup and system control.

CONCLUSION

This system complies with ISO-5840 for testing 3D printed heart valves. Total cost of fabrication is approximately $3,000, lower than current commercial options. The system controls and data display are novel and will be available as open-source software.

We will also buy commercial artificial heart valves with known in-vivo data, including the St. Jude Masters series, and compare that data with the results when used in our system.

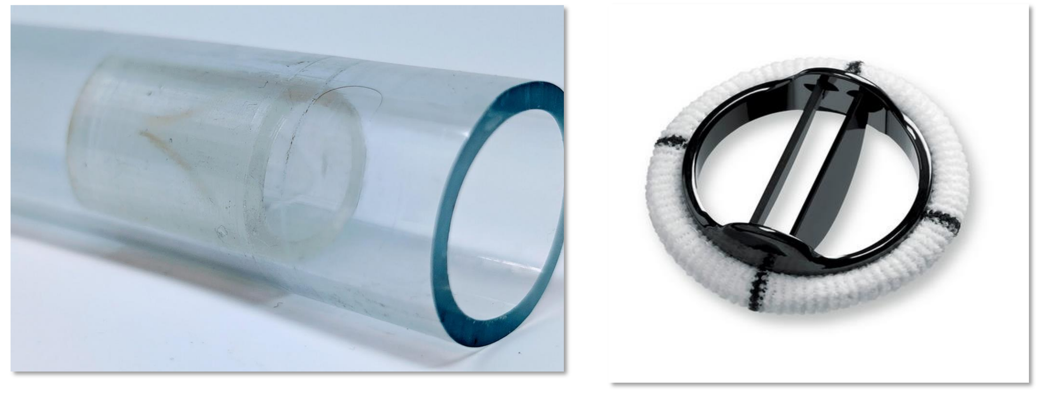


Figure 7. Left: A 3D printed heart valve. Right: A mechanical valve from the St. Jude Masters series. Photo courtesy of St. Jude Medical.

We plan to add to simulate more blood vessels, to model transcatheter aortic valve replacement (TAVR). We will also add bioreactor elements, to test novel cell-laden valve designs.

REFERENCES

[1]ISO 5840-1:2021: Cardiovascular implants — Cardiac valve prostheses, International Organization for Standardization, Geneva, Switzerland.

[2]Luca Rosalia *et al.*, Soft robotic patient-specific hydrodynamic model of aortic stenosis and ventricular remodeling. Sci. Robot. 8 (2023). DOI: 10.1126/scirobotics.ade2184

ACKNOWLEDGEMENTS

H.R. acknowledges The University of Akron's Startup Fund, FRC grant, and the Firestone Research Initiative Award.