DESIGN OF A WEARABLE AND PORTABLE NON-INVASIVE EXTERNAL VENTILATOR (NIEV)

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SickKids

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Background

In Fontan circulation, pulmonary blood flow bypasses the heart. Over time, Fontan patients experience elevated pulmonary vascular resistance (PVR) and a reduction in cardiac output (CO), and exercise intolerance. Studies have shown that assisting chest motion during respiration significantly promotes systemic venous return, thereby lowering PVR.

Purpose

Commercially-available ventilators proved to reduce the symptoms of Fontan failure, but they restrict patient mobility and activity levels. The purpose of this project is **to design a wearable and portable ventilator**.

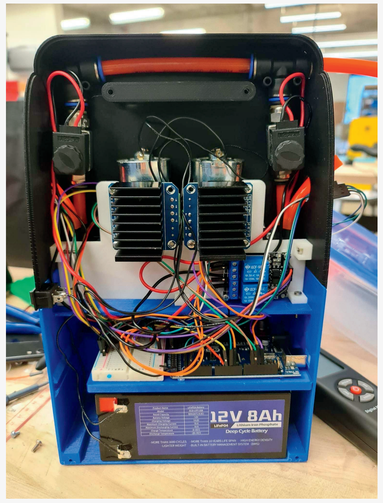
Requirements

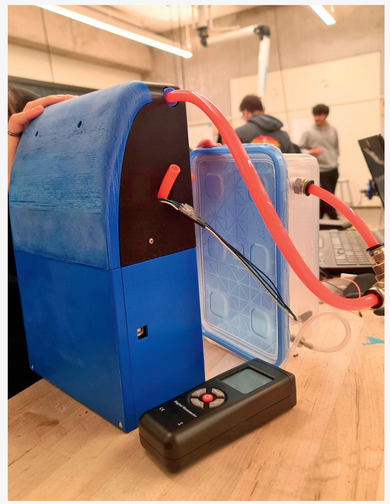
The design assists patient respiration by manipulating pressure around the thoracic area. It must comply with medical device (ISO 13485, 60601-1) and ventilator (ISO 10651) standards.

Design Objectives:
— Portability: weight (5kg), dimensions (56×35×23 cm)
— Effectiveness: range (±60cmH2O), I:E ratio (1:6~6:1)
— User Experience: comfortability, operability
— Durability
— Cost (prototype ~CA$500)

Design

Components for the minimal viable product are selected based on specifications and acquirability. The control and pressure circuit are connected to fit inside the 3D-printed enclosure. Full assembly of the pressure and electronic circuit is followed by testing and debugging of the control system.

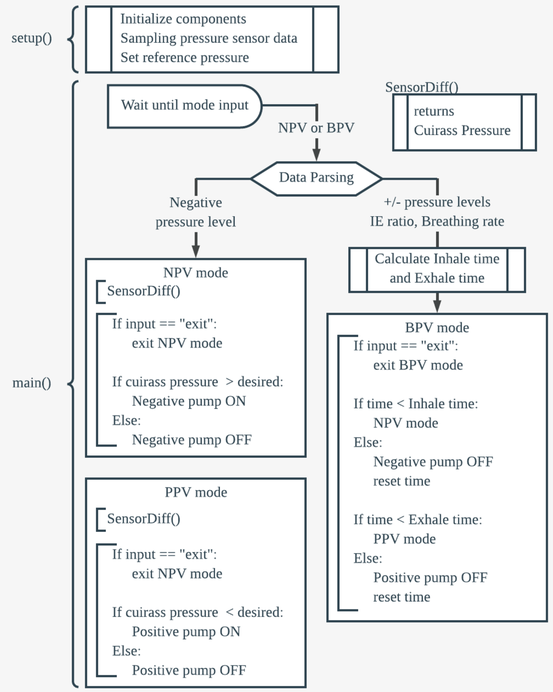




Control Modes:
- *NPV:* Generate constant negative pressure inside the cuirass.
- *BPV:* Alternates negative and positive pressure at specified rate.

Safety Features:
- LED indicators
- Buzzer
- Pressure release valves

Fig: Flowchart of the Control System



Testing

The desired settings were set by the user, and the pressure difference over time was measured with a sensor module inside the cuirass volume.

Table: NPV (-10cmH2O)

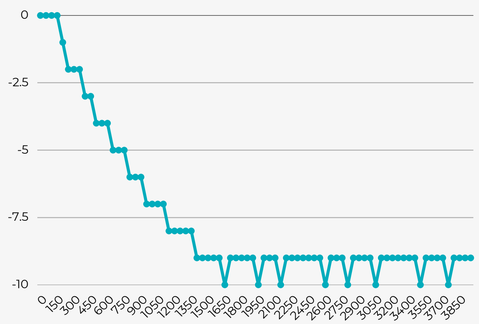
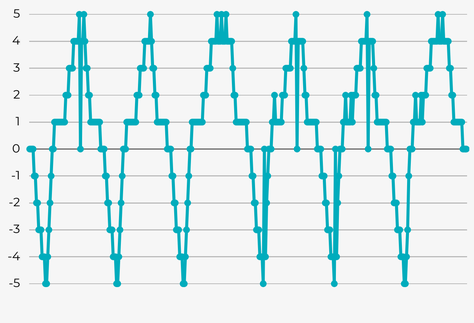


Table: BPV (-/+5cmH2O, IE1:2)



Future Developments

Limitations to the current design:
1. Noise level.
2. Inconsistent performance at extreme pressure and IE parameters.

Next steps and recommendations:
1. Integration of jacket, cuirass, and GUI with the current prototype.
2. Further development of safety features and control modes.
3. Development of medical-grade prototype for testing.

Conclusion

Overall, the design is successfully able to manipulate the pressure within the provisional cuirass. The prototype achieves the objectives set for portability and partially meets the desired effectiveness.

Related Literature

P. Charla et al., "Augmentation of pulmonary blood flow and cardiac output by non-invasive external ventilation late after Fontan palliation", BMJ Journals, 2021.