

## Senior Design Project Data Sheet

Project #	Project Name	Project Track	Project Family
14026	Portable Emergency Ventilator	Biomedical Systems and Technologies Track	Medical Device P13026, P13027
Start Term	Team Guide	Project Sponsor	Doc. Revision
Fall 2013	Edward Hanzlik	Jeff Gutterman Dr. Roman Press Mary Murphy	2

### Project Description

#### **Project Background:**

A Portable Emergency Ventilator (PEV) is a device that can provide positive pressure ventilation to a person who is incapable of breathing on their own. In the early 1990s, a PEV device known as the Mediresp-III was developed by Jeff Gutterman and Dr. Roman Press. Nearly two decades later, Rochester Institute of Technology adopted the project and Multidisciplinary Senior Design Team 13026 was assigned the task of updating the device. Currently, a third revision is under development by team 13027 in order to enhance the features of the Mediresp-IV. Hence, as the technology for this device continues to develop there exists a growing need for test data that validates the functionality of the PEV prototypes. Specifically, the team assigned the task will acquire a test system capable of measuring the functionality of the PEV and focus their efforts on data acquisition.

#### **Problem Statement:**

Develop a process for testing and recording flow rates, pressure levels, and oxygen concentration while providing a way to make adjustments to tidal volume, residual lung volume, lung compliance, and airway resistance that will simulate the human respiratory system under both normal conditions and conditions of disease.

#### **Objectives/Scope:**

1. Acquire a test fixture that will validate the functionality of a PEV and develop a process for testing the device
2. Record and measure test data on the first and second revisions of Mediresp-IV
3. Testing will cover neonatal up to adult patients at room temperature (24°C)

#### **Expected Project Benefits:**

- Provide measurements and data for UUT's
- Prove or disprove that prototypes are meeting standards
- Provide comprehensive data on the functionality of the prototypes including error rates
- Develop team's engineering knowledge.

#### **Core Team Members:**

- Kristeen Yee– Project Manager (IE)
- Michael Allocco (ME)
- Danielle Koch (ME)
- Andrew Miller (ME)
- Soham Chakraborty (EE)
- Leslie Havens (EE)
- Stephanie Zambito (EE)

#### **Deliverables:**

- Test process that incorporates the pulmonary system
- Recorded measurements and test data to support product to market of the PEV

### Strategy & Approach

#### **Assumptions & Constraints:**

1. Team must first understand how ventilation is performed and how the respiratory system works.
2. Team knowledge of the current PEV device and how it operates is critical.
3. Team must learn how typical ventilator testers operate.
4. Team will focus on design issues necessary for meeting engineering requirements and customer needs.
5. Testing will comply with FDA 510k and follow standards for breathing machines (ANSI Z79.7), adult and infant lung care (ISO 5469:1967), and ventilators for use in critical care (ASTM F 1100-90).
6. Proposed budget: \$1,000.

#### **Issues & Risks:**

- This project is a new area of study for members on the team, which limits knowledge and experience.
- Acquisition of a ventilator tester may be difficult and will require adjustments to schedule.
- Relying on third party for testing (i.e., owner of ventilator tester and hospitals) may lead to unaddressed concerns.