



Wright Fit: A Novel Ambulatory Compression Therapy Device for Chronic Venous Insufficiency



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Executive Summary

In the United States, approximately 7 million people are affected by chronic venous insufficiency (CVI)¹. CVI results when the peripheral venous system is impaired, resulting in painful swelling, venous ulcers, and cutaneous abnormalities in the extremities². Traditional compression devices, which consist of heavy pumps and bulky sleeves, completely immobilize patients during treatment, decreasing quality of life and ability to work¹. To address this problem, our team has partnered with Wright Therapy to develop the Wright Fit, a novel ambulatory pneumatic compression therapy device that will apply gradient pressure to the legs to treat CVI without immobilizing the user. The estimated manufacturing cost of the Wright Fit is \$360, allowing it to sell for a competitive price. The Wright Fit would be ideal for patients with mild to medium cases of CVI who require treatment in a home clinical setting and want to maintain an active lifestyle.

Problem & Clinical Need

Chronic Venous Insufficiency

- Effects about 20% of men and 40% of women by age 50, or about 7 million people in the US³
- Occurs when the peripheral venous system is impaired by trauma, thrombosis, venous obstruction, or muscle and vein valve failure²
- Causes painful swelling, venous ulcers, varicose veins, and cutaneous abnormalities in the extremities (Figure 1)



Figure 1: CVI clinical manifestations. A) varicose veins B) hyperpigmentation C) venous ulcer²



Figure 2: Current Wright Therapy product: Wright 51+⁴

Compression Therapy

- Effective treatment for CVI
- Devices provide active pressure that forces fluid from the extremities towards the direction of the heart, reducing swelling and promoting healing of ulcers and cutaneous abnormalities²
- Strict daily treatment regimens required to prevent worsening of symptoms¹
- Current products limit patients to a bed or chair for treatment sessions that can last up to 4 hours¹ (Figure 2)

Market Analysis

Market Size

- \$1.16 Billion US Market⁵
- Only 40% is active compression⁵

Market Segmentation

- Market segmented by disease severity and clinical setting
- Wright Fit intended for mild to medium CVI treatment in a home setting
- Elderly patients are the target demographic

Competitor Analysis

- Only one ambulatory compression device on the market - the ACTouch by Tactile Medical
- Bulky device that hinders ease and discrete use, could lower patient compliance



Figure 3: Tactile Medical's ACTouch⁶

Description of Design

Wright Fit: Compression Sleeve

- Features an adjustable, compact sleeve comprised of three compression chambers (Figure 4)
- Angular pattern to better direct pressure up the leg
- Three Velcro straps to adjust to patient calf size
- Chambers heat-sealed to prevent pressure leaks
- Flame retardant fabric
- Small, compact 1/8" bonded tubing
- Provides gradient compression to the ankle and calf regions without hindering user movement
 - Distal chambers with higher pressures, proximal chambers with lower pressure



Figure 4: The compression sleeve for Wright Fit

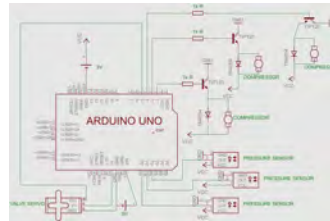


Figure 5: Electronic schematic of the Wright Fit control system

Wright Fit: Control System

- Arduino microcontroller (Figure 5)
- 3 miniature compressors connected to 3 transistors that can be turned on via a digital signal
- Servo can be signaled to turn on/off the valve
- Analog pressure sensors allow precise control of chamber pressure
- Diodes ensure no backward-flow of current
- Replaceable batteries
- Encased in acrylic laser cut box
 - On/off button (user controlled)

Wright Fit: User Experience

- Ambulatory
- Flexible placement of control box
 - Dimensions: 8" x 4" x 2 1/8"
 - Black Velcro elastic strap allows adjustability and unhindered mobility
 - Can be placed around waist or upper leg (Figures 6 and 8)
- Uses conventional store-bought batteries
- Comfortable fit
- Available in small, medium, and large sleeve sizes

Wright Fit: Testing

- Inflation time: ~15 seconds
- Rest time: ~10 seconds
- Deflation time: ~1 seconds
- Pressure of chambers range between 40-60 mmHg, obtained from inline pressure sensors (Figure 7)

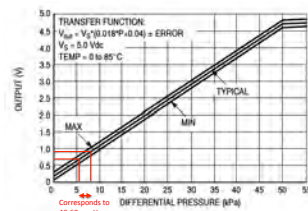


Figure 7: Pressure mapping of sensors



Figure 6: Final prototype on team member Adam Costanza



Figure 8: Final prototype of the Wright Fit (left); control box (right)

Proof of Functionality

Active Compression vs. Passive Compression

- Trends show intermittent pneumatic compression more useful than passive compression (typically evidenced in compression socks)⁷
- Hemodynamic effects in active compression provide favorable environment to wound healing, removes edema, and improves oxygen transport⁸
- In studies, active compression decreased treatment time from 3 months (passive compression) to 20 days, decreasing overall cost⁸
- Higher healing rates are experienced for active compression
- Gradient compression is a relatively novel frontier, but positive trends in a few case studies show promising results in comparison to sustained pneumatic compression⁹

Manufacturing

Low Cost Production:

- \$360 per device
- Microcontroller most expensive component
 - Could minimize cost by bulk purchasing

Assembly Line Manufacturing

- Utilize standard manufacturing procedures to limit waste
 - 3 full time employees
- \$245,000 total manufacturing employee salary¹⁰

Profit Margins

- Retail device for \$1,000
- Roughly \$600 profit per device

Regulatory Pathway & Reimbursement

FDA Regulatory Pathway:

- Class II medical device¹¹
 - Code CFR 870.5800
- 501(k) submission required
 - Minimal risk, similar to predicate devices
 - Differs from existing products in its technical characteristics

Medicare/Medicaid Reimbursement

- Reimbursed in full when requirements met
 - Existing venous ulcer failing to heal within 6 months prior to compression therapy¹²
 - Trial period of 4 weeks required
- Prescriptions may be filled without reimbursement¹³
 - Social Security Act §1861(s)(6)
 - High upfront cost to patients

Veterans Association Reimbursement

- Must fulfill requirement set forth in the Buy American Act¹⁴
 - 50% of manufactured parts must be made in the US

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