senSWELL

BMEN 3151 *Medical Device Practicum*

Paul Novara, Rahema Rashid, Nichole Torgerson
Advisor: Prof. Steven Saliterman

Clinical Problem

Congestive heart failure (CHF) occurs when the heart fails to pump blood adequately and is present in 1-2 million adults in the US. The diagnosis is difficult to be accurate specifically in women and in overweight patients. Causes for congestive heart failure include disease, high blood pressure, damage to heart valves and heart muscle, inflammation, and congenital heart defects. These factors lead to the heart stiffening and becoming weaker. As a result, fluid builds up in the lungs and throughout the body because the ventricles are not able to pump the blood efficiently enough for the blood to be able to return, so the blood pools in the veins. This causes a lack of oxygenation delivered to all other organs and tissues, leading to numerous complications such as shortness of breath, fatigue, water retention, and abnormal heart rhythm. Treatment options include a left-ventricular assist device (LVAD), coronary artery stents, and improved diet.

CHF has other societal effects such as high healthcare costs, depression and anxiety, and $10.6 billion of lost productivity (lost future earnings of person who will die from CHF).

Needs Statement

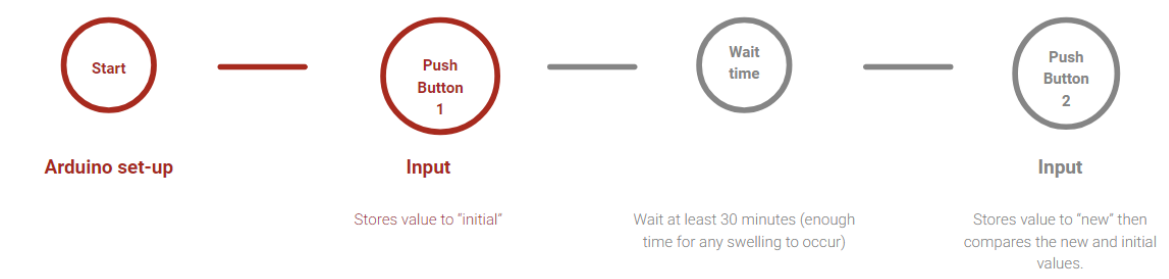
"High-risk heart failure candidates need a way to be alerted of a potential catastrophic event because constant monitoring by a doctor is not feasible."

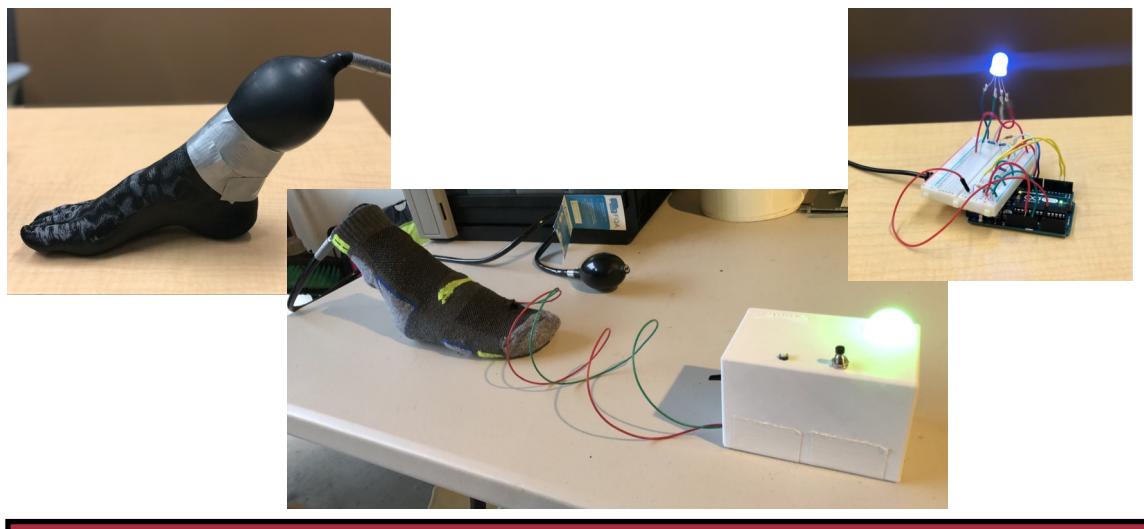
Market Analysis

According to NCBI, fluid accumulation, or edema, is responsible for multiple numbers of hospital visits. Congestions can lead to over 20 liters of fluid (20 kg of excess weight). This device targets people that are high-risk for congestive heart failure. Over half of heart failure patients exhibit peripheral edema, so this device has the potential for success. Most devices on market involve treating edema, not monitoring it. Many edema-monitoring devices still in their prototype or clinical trials stages. A device similar to the senSwell is the Edemeter, which continuously monitors fluid retention using a flex sensor placed around an ankle cuff, and sends this data to a Bluetooth device. Our device differs in that it is placed in a sock, which is more flexible than an ankle cuff, so it measures swelling more accurately.

Medical Device Solution

In clinical settings, CHF leg edema may be detected by pressing a finger on the skin over the lower tibia for several seconds, and then palpating the amount of indentation. Swelling is lowest upon arising from sleep in the morning and increases throughout the day; however, increasing circumference and longer bounce time can indicate a worsening heart condition. We designed a sock that detects the different levels of edema in the lower extremities and gives a warning to the patient of the severity of the edema by color changes in an LED. In our prototype, the sock uses a flex sensor to measure the amount of swelling. The sensor's resistance varies based on the degree of the flexion of the sensor, which in turn is correlated with leg circumference. Resistance is relayed to and processed by an Arduino Uno microcontroller, which changes the color of the LED. Enhancements to this design include Bluetooth connectivity to the Arduino or to a smart device, continuous readings, audible or visual alarms, and developing sock inserts.





Team Photo