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Executive Summary

Every year, 2,500 babies in the United States are born with Cystic Fibrosis. Children who have been diagnosed with this disease are recommended to perform daily breathing therapies, which are arduous, boring, and often painful. In a market expected to exceed \$896 million by 2015, current treatments have failed to make performing these therapies more comfortable and entertaining for the child. We have developed a video game for children ages 3-8 years old, which uses the child's breath as a controller to play a number of mini games while guiding the child through different parts of the Active Cycle Breathing Therapy.

Clinical Need

- Cystic fibrosis causes excess mucus in lungs which can lead to chronic lung infections, extreme pneumonia, and even death.
- Mucus must be expelled in order to prevent build up.
- The Active Cycle of Breathing Technique (ACBT) is one of multiple techniques used for mucus expulsion.
- ACBT, while effective, is not recommended for children under 8 because of its complex and tedious nature. It is usually performed daily for 20-40 minutes a day.
- Children need motivation and incentive to successfully perform ACBT, which can be provided through a video game.

Description of Market

Target Market: The device targets parents of children 3-8 with Cystic Fibrosis. In addition, hospitals and respiratory clinics may also consider acquiring the device since the mask is interchangeable.

Market Size: Currently there are about 70,000 CF patients worldwide.

- 2,500 new cases in the US annually
- 50% of CF patients are under 18 years old [1]
- CF market in the US expected to exceed \$896 million by 2015 [2]

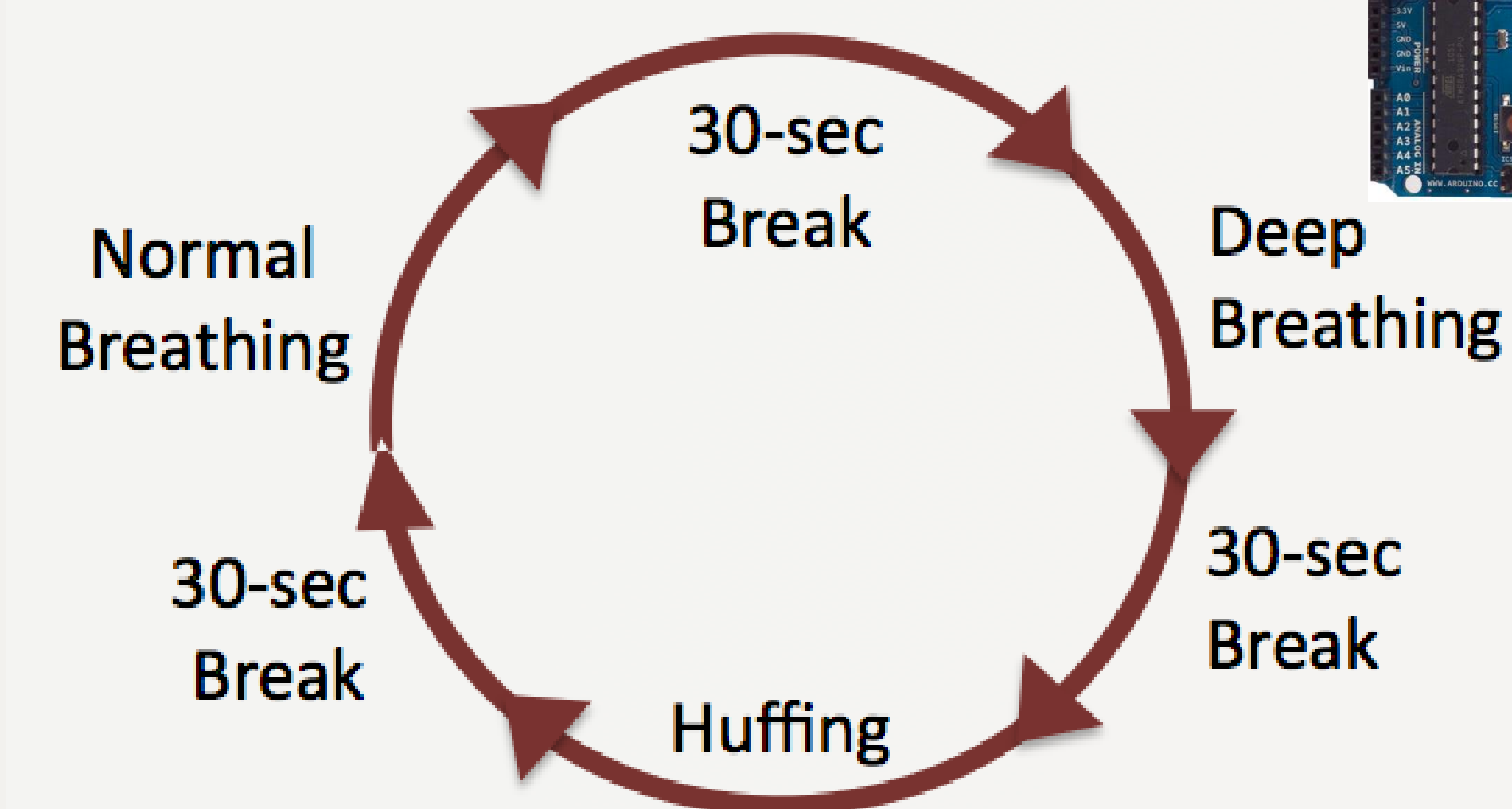
Competition/alternative devices: Currently, there are two known video games in the market designed for children with CF. However, they both involve the Positive Expiratory Pressure (PEP) method.

Description of Design

DESIGN AND FUNCTION: TURNING A BREATHING CYCLE INTO A VIDEO GAME!

The system is designed to accommodate any user. The system can be calibrated by the maximum exhalation pressure of any user before the game begins. Once set, the maximum pressure serves as a reference point for the rest of the breathing exercises.

The game runs as a time-based cyclic exercise regimen that changes every 30 seconds. In each section, the user is asked to exercise a different style of breathing. The different breathing exercises are recommended for active-cycle breathing techniques normally taught to patients with cystic fibrosis.



Once the video game is complete, the full active-cycle breathing regimen is complete as well. The full cycle enables users to expel mucus and expand their breathing capacity.

The game can be repeated as many times as recommended by a respiratory therapist or as is comfortable for the user.

NEXT STEPS

Implementing a feedback mechanism and a real-time data flow analysis.

Implementing a scoring system for users to have affirmation and increase motivation to complete the game.

MAIN COMPONENTS

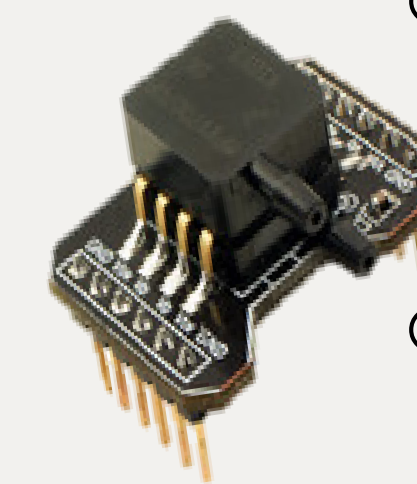
Modern Devices Wind Sensor

- Determines the presence of wind via dual-heated copper elements and convection.
- Varies voltage based on wind and sends signal to microcontroller



Honeywell Differential Pressure Sensor

- Determines the difference in pressure from atmospheric pressure
- Determines both negative and positive pressure
- Varies voltage based on signal strength and sends signal to microcontroller

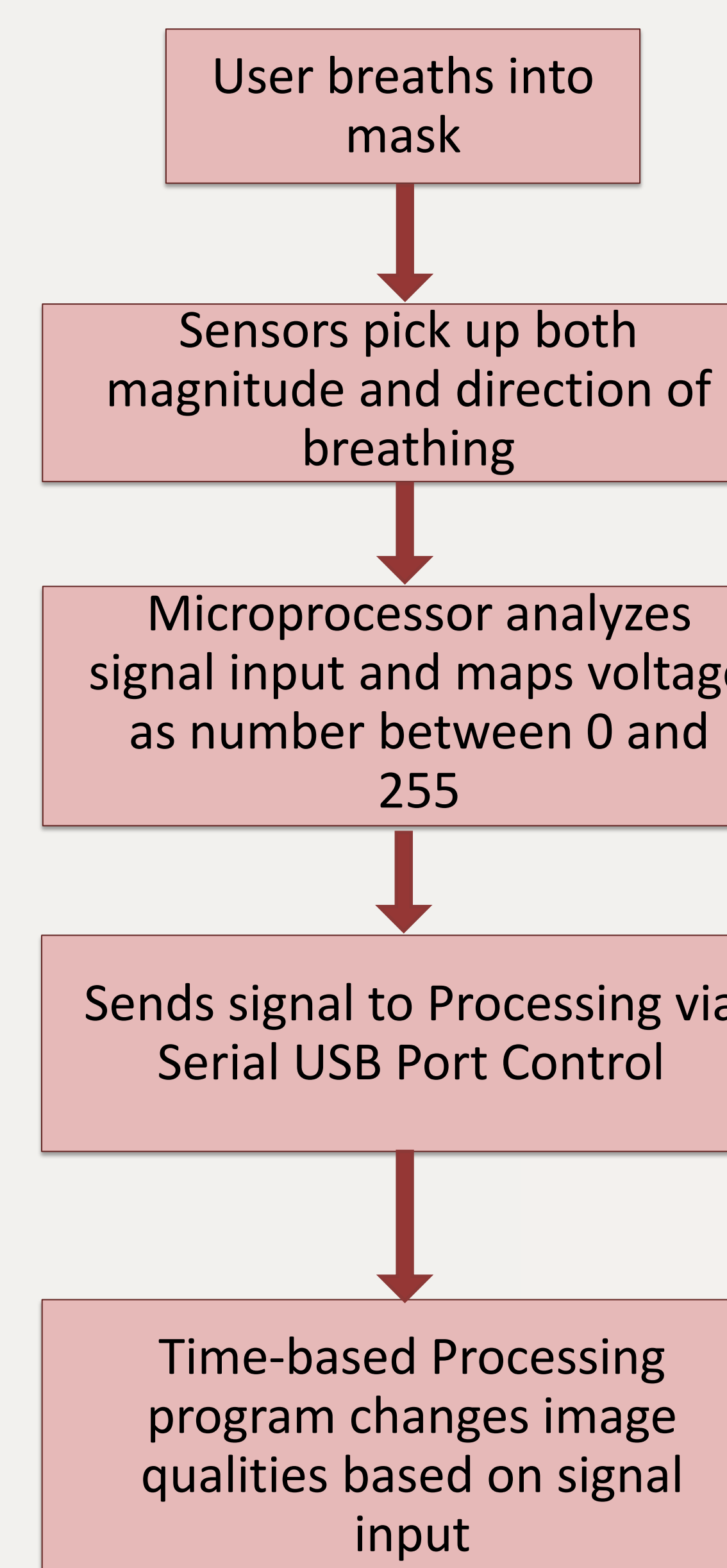


Micro-controller (Arduino Uno)

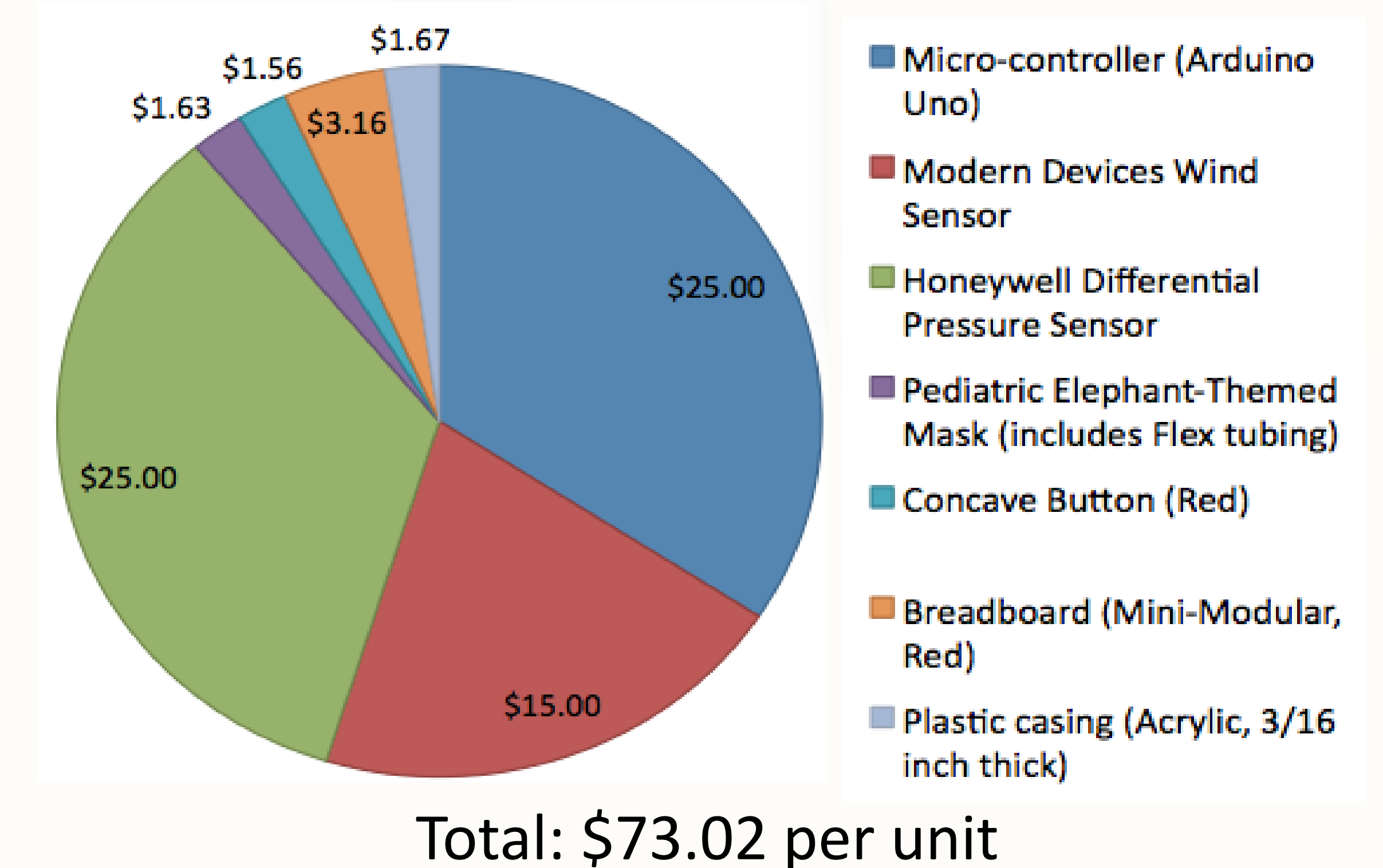
- Obtains the input from the wind sensor and pressure sensor via varying voltage
- Translates voltage reading to changes in breath from user



SYSTEM DATA FLOW



Estimated Cost



Anticipated Regulatory Pathway

- 510(k): other similar airway clearance devices exist
- Acapella and the Vest Airway Clearance System are both 510(k), Class II
- These similar devices are not gamified. However, Able-X, a gamified stroke rehabilitation aid, was approved through the 510(k) regulatory pathway. Able-X uses a wireless handheld controller that transmits data to the user's computer, allowing the patient to complete therapeutic exercise games.

Acknowledgements

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References

- [1] Kaneshiro, Neil K. "Cystic Fibrosis." PubMed Health. U.S. National Library of Medicine, 16 May 2016. Web. 14 Dec. 2012.
- [2] "US Cystic Fibrosis Market to Exceed \$896 Million by 2015, According to New Report by Global Industry Analysts, Inc." PRWeb. Vocus, 10 June 2010. Web. 14 Dec. 2012. <http://www.prweb.com/releases/Cystic_fibrosis/pulmozyme/prweb4112824.htm>.
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