

Tuff-Huff: Active Cycle of Breathing Computer Game for Children

Pallavi Nair, Robert Piston, Kenneth Yan, Wendy Shung, Pojung Chen, Allison Kator

Conrad M. Zapanta Ph.D., James F. Antaki Ph.D., Joseph Pilewski M.D., Rebecca Muntich, Daniel Weiner M.D.

Executive Summary

Problem: Existing breathing therapies are time-consuming and require third-party assistance. Also, an element of fun and motivation are lacking.

Solution: A fun and easy computer game to guide children ages 3-5 through the Active Cycle of Breathing Technique

Competition: Existing therapies which require a visit to the clinic, or potential cure to Cystic Fibrosis or other pulmonary disease

Differentiation: Novel computer game that uses technology to make therapy easier

Technical Feasibility: Working proof of concept

Regulatory and Reimbursement: 510k premarket notification, Class II medical device

Sales and Marketing: targeted at children 3-5 with lung disease

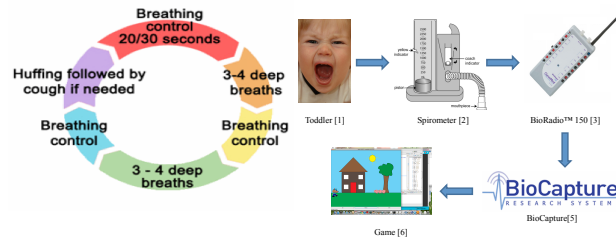


Figure 1. The Active Cycle of Breathing

Figure 2. Design prototype to obtain

Is it Novel?

Our project is novel because there are no other software products that accomplish our goal of assisting patients with pulmonary diseases. We developed a software game to guide children through the active cycle of breathing with a fun twist. This incentive motivates children to complete their therapy thoroughly.

Estimation of Product Costs

Item	Cost
BioCapture Research System	\$5990
Transducer cable	\$299
Vernier spirometer	\$199
Replaceable mouthpieces	\$10 pkg of 30
Microbial filter	\$30 pkg of 10
Nose clips	\$10 pkg of 10
TOTAL	\$6538

Problem and Clinical Need

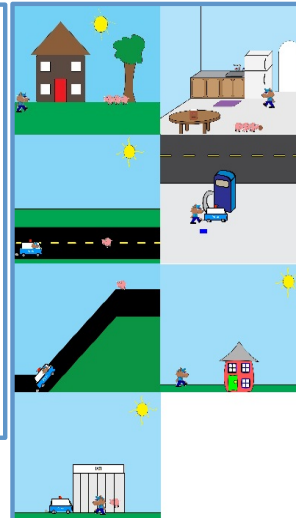
A common symptom for pulmonary diseases is excess mucus in the lungs. However, existing treatments for lung disease are tedious and time consuming. This is especially true for children, who must be instructed by their parents or a therapist. For parents of children with pulmonary disease, they must spend incredible amounts of time assisting their children with breathing therapy. A need exists to make therapy easier for parents of children with lung disease. One current breathing therapy is called the Active Cycle Breathing Technique, but involves the patient being instructed to breathe different amounts and speeds in order to loosen mucus in the lungs.

Market

Besides the Active Cycle Breathing Technique, other therapies exist to address excess mucous, such as manual chest physical therapy and a forced expiration technique. Furthermore, there are some oscillating devices that help remove mucus such as the Flutter and Acapella devices. The high frequency chest wall oscillation (HFCWO) vest is an inflatable therapy vest with high frequency chest compression that vibrate patient's airway walls to loosen the built-up mucus. However, most of these therapies are extremely time consuming.

Description of Design

The computer game will guide the patient through the breathing control, deep breathing, and huff cough steps. The game also customizes the breath threshold flowrates for each child to account for differences in breathing ability among patients, which is dependent on the breathing disorder and its severity. Initial measurements of peak expiratory flow and forced vital capacity will be measured to establish a baseline. The game will also include a feedback mechanism to ensure effectiveness by monitoring the patients' breath flowrates. The game will not progress if a step in the active breathing cycle is not met.



Anticipated Regulatory Pathway

Our product is similar to preexisting instruments in the immunology panel for pulmonary related devices and the anesthesiology panel for gas flow spirometers. While these devices are Class I devices, our is expected to be a Class II device subject to special controls to ensure reliability of the package. We will pursue a 510K premarket notification.

Future Work

- Future work for this project includes:
- Submitting a revised IRB to receive approval to test our game on children
 - Changing our recorded volts into a flow rate and volume so that we may record these data
 - Incorporating a calibration breath/huff at the beginning of the game so that the therapy is customized for each patient.
 - Integrate the game into a LabVIEW application