



# Breasy Incentive Spirometer

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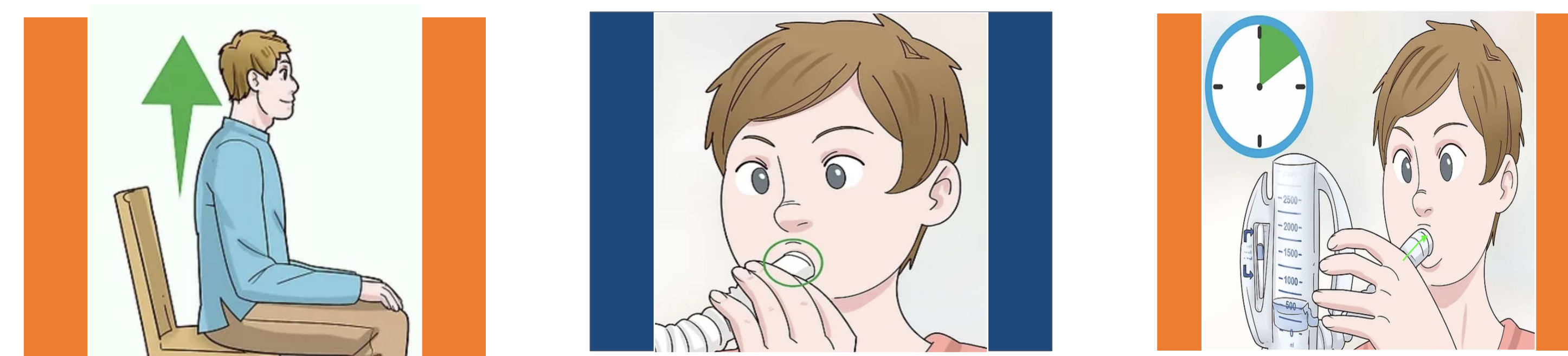


## Problem

**Incentive Spirometers** are most often used to assist in the treatment of asthma, chronic obstructive pulmonary disease (COPD), chronic bronchitis, and emphysema as well as following major chest or abdominal surgery, to lower the risk of postoperative pneumonia and atelectasis<sup>1</sup>.



Figure 1. Image demonstrating incorrect usage of an incentive spirometer<sup>2</sup>.



The non-intuitive design has led to misuse of the spirometer by patients who instinctively think to exhale into the device, which leads to low patient compliance and possible negative downstream effects on recovery.

The Breasy Incentive Spirometer project seeks to redesign an incentive spirometer to allow for easier and more intuitive use, with the downstream effect for potential increase in prevention, diagnosis, and treatment of respiratory conditions as well as postoperative pulmonary complications.

## Standards

**ISO 26782:2009** The standard for respiratory equipment, specifically spirometers intended for the measurement of time forced expired volumes, this standard will be used to ensure the device is functioning correctly with accurate output readings.

**Section 201(h) of the Food, Drug, and Cosmetic Act** classifies Incentive Spirometers as Class II medical devices, following guidelines as moderate risk device, eligible for 510(k) review and can be submitted for accredited review.

**ISO14971:2019** This standard outlines the hazards associated with medical devices In context of the Breasy Incentive Spirometer risks include, but are not limited to, durability of the device, device sanitation, and data and system security.

## Design Criteria

	Incentive Spirometer Needs	Design Requirements
This Semester	Intuitive Design	Device Training < 5 Minutes
	Positive Reinforcement Of Proper Usage	50% Decrease In Improper Usage
	Disposable	100% Recyclable Materials
	Cost Effective	~\$13 - \$20
Future	Increase Device Usage By Patient	Alarm   Bluetooth Connectivity
	Quantitative Readout	Cost Effective Digital Output < \$50

## Prototype Iterations

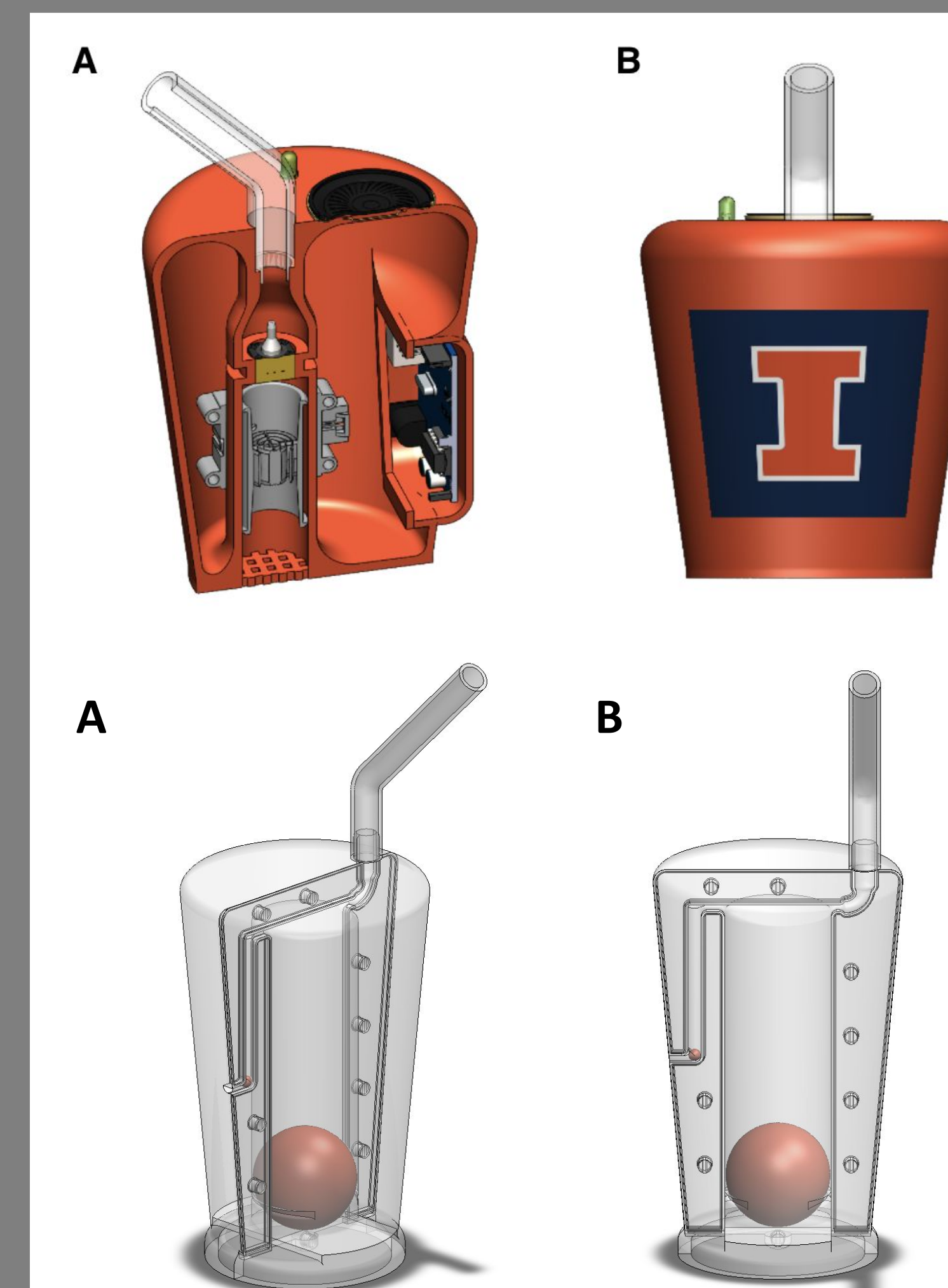


Figure 2. Digital Design Iteration 2 for Breasy Incentive Spirometer.

A) Isometric cross-sectional view of Digital Design Iteration 2, displaying each internal mounting feature for key individual electronic components, and a hashed input slot. B) Front profile view of Digital Design Iteration 2 with Illinois branding.

Figure 3. Analog Design Iteration 4 for Breasy Incentive Spirometer.

A) Isometric profile view of Analog Design Iteration 4, featuring revised new mechanical volume and flow rate indicators, integrated into a 2-piece modular assembly. B) Front profile view of Design Iteration 4.

## Design Stages

- 01 The first phase involved thorough background research, literature and patent review, and observations via interviews with doctors & nurses.
- 02 The first problem solutions began to be generated, such as the possibility of a manual / label or a complete redesign of the device.
- 03 Decision to move forward with the, "Breasy Incentive Spirometer" digital concept and began incorporating key electronic components.
- 04 Design of two different CAD design iterations incorporating several components such as an arduino, speaker, and digital display.
- 05 Decision to move forward with an analog design by sponsor, making the device more feasible for the hospital setting and market price.
- 06 Design of five different analog CAD design iterations and rapid prototyping of the 4<sup>th</sup> and 5<sup>th</sup> Iterations via 3D-Printing.

## Optimized Design & Physical Prototype

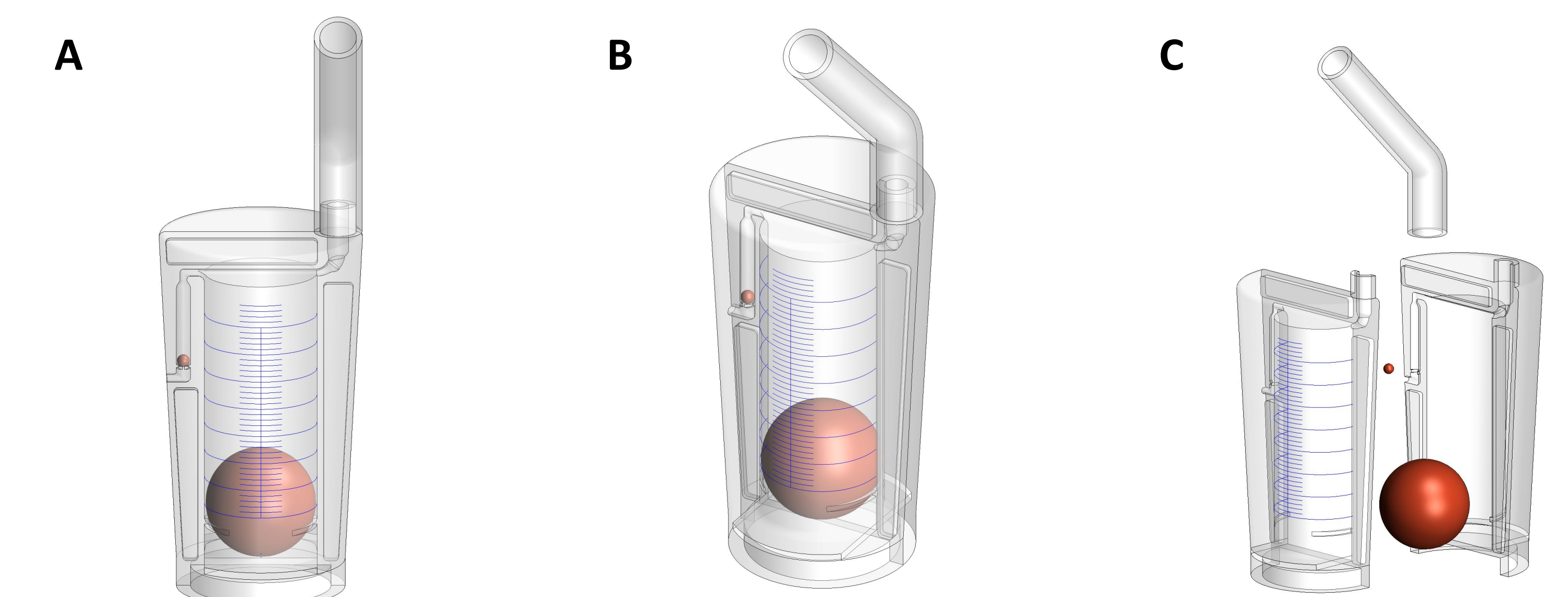


Figure 4. Analog Design Iteration 5 for Breasy Incentive Spirometer. A) Front profile view. B) Isometric profile view. C) Exploded view of CAD

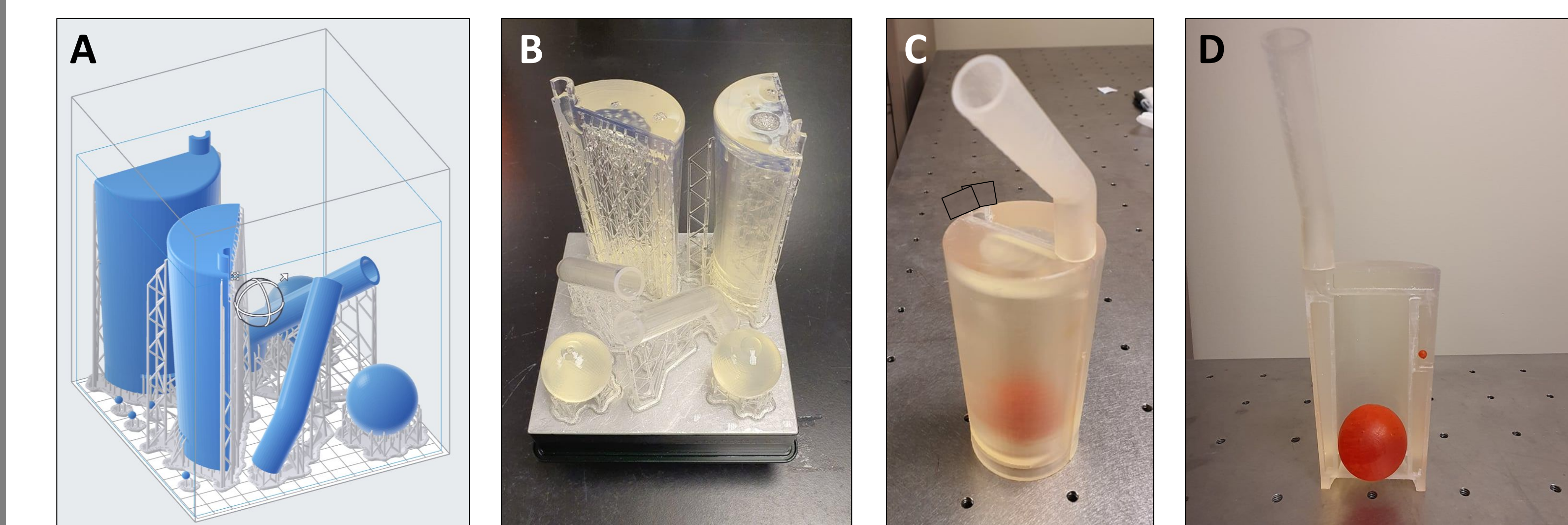


Figure 5. 2<sup>nd</sup> 3D-Printed-Prototype of the Breasy Incentive Spirometer.

A) SLA rapid prototyping setup at 75% scale. B) Pre-processed printed components. C) Isometric profile view of post-processed assembly. D) Front profile cross-sectional view.

## Future Directions

- Immediate next steps include printing another prototype at true scale, using semi-clear PLA material that is recyclable and biodegradable "under the specific conditions of industrial composting".
- Redefine design via incorporation of positive reinforcement - research addition of a Kazoo or consider a different method to complete the design requirement of a 50% decrease in improper patient usage.
- Calibration of volume and flow rate quantification, incorporation of measurement indication marks, and perform efficacy and accuracy testing of the 2nd 3D-Printed-Prototype. Evaluate effectiveness of new design.

## Citations & Acknowledgements

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