# Miniature Emergency Ventilator

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# Background Miniature In-line Respirator

## Current Ventilators

- Bulky for transport/storage space

- Limited availability

- Require advanced training

- Require electricity

- Require service/maintenance

- Expensive

# Background Miniature In-line Respirator

## Ventilator properties

- Requires only  Compressed gas
- Pressure-cycled
- Fixed settings
- Low-cost
- 3-D printing-scalable production
- No moving parts
- Minimal training
- Compact 2.4 cm by 7.4 cm; 13 g
- Reliable
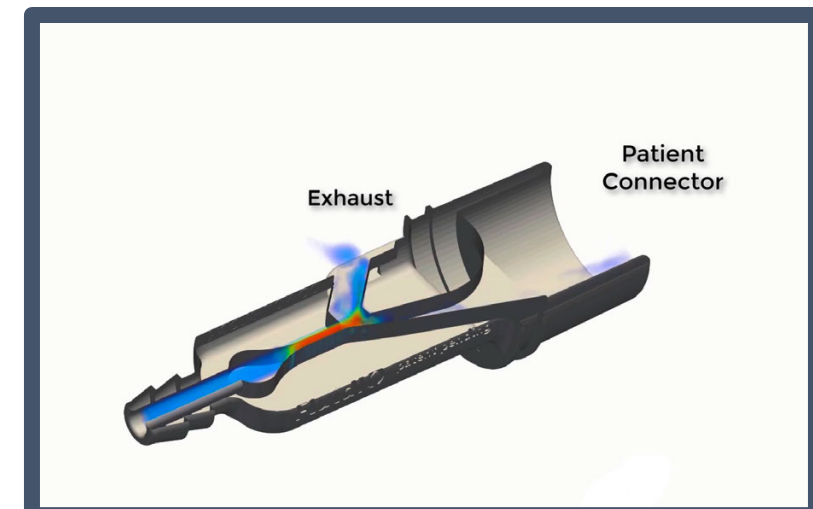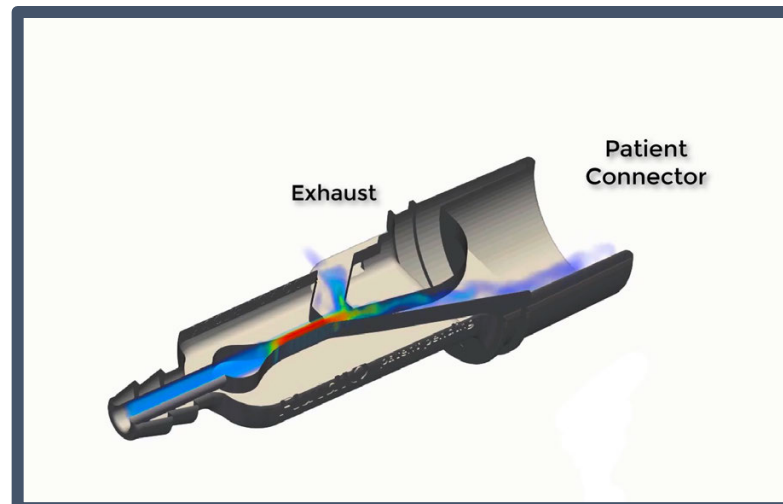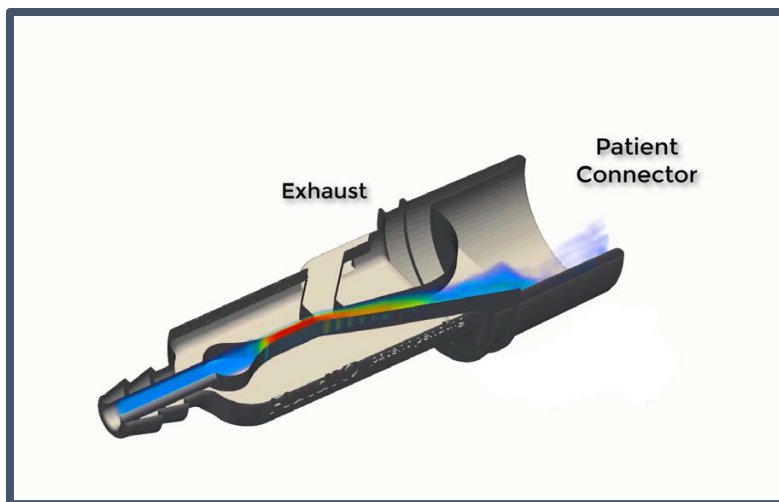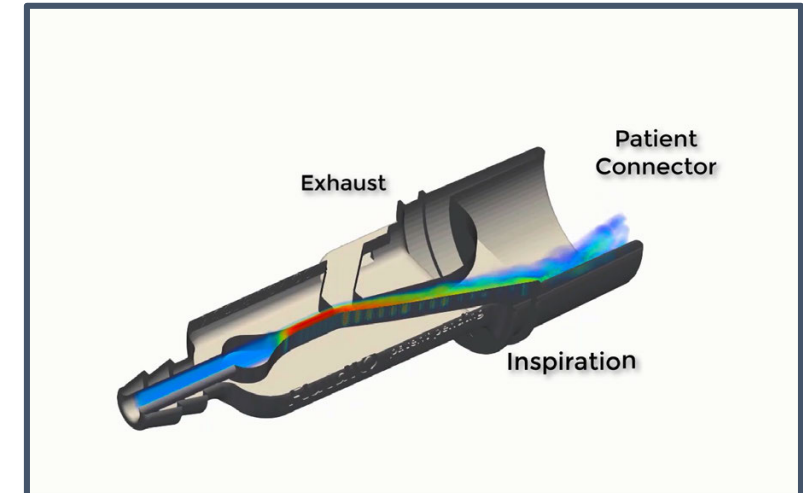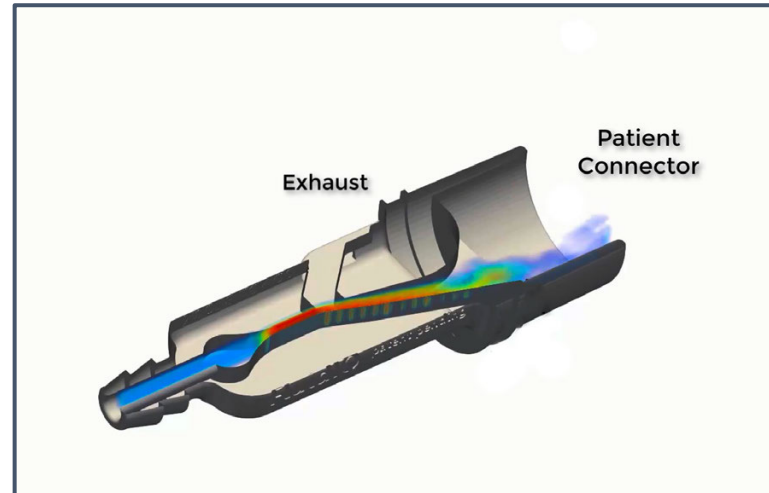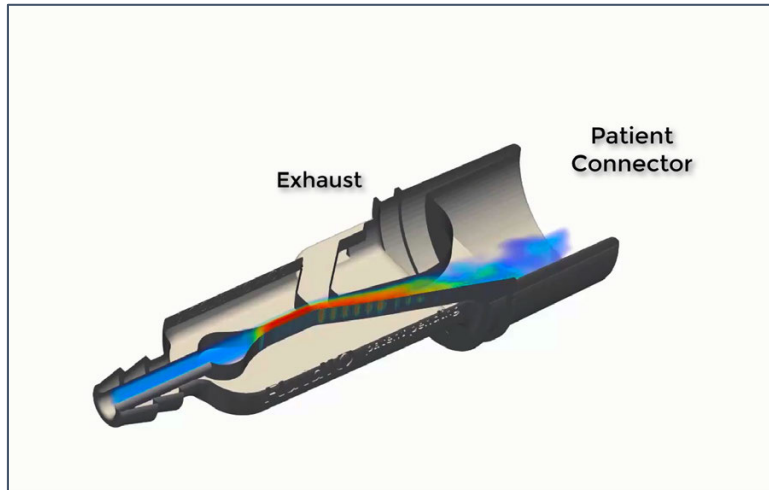- Based on technology developed by Diamond Laboratories for the U.S. Army



## Proposed applications

- Pandemic (long shelf life)
- Underserved countries in need of low-cost ventilators requiring minimal training
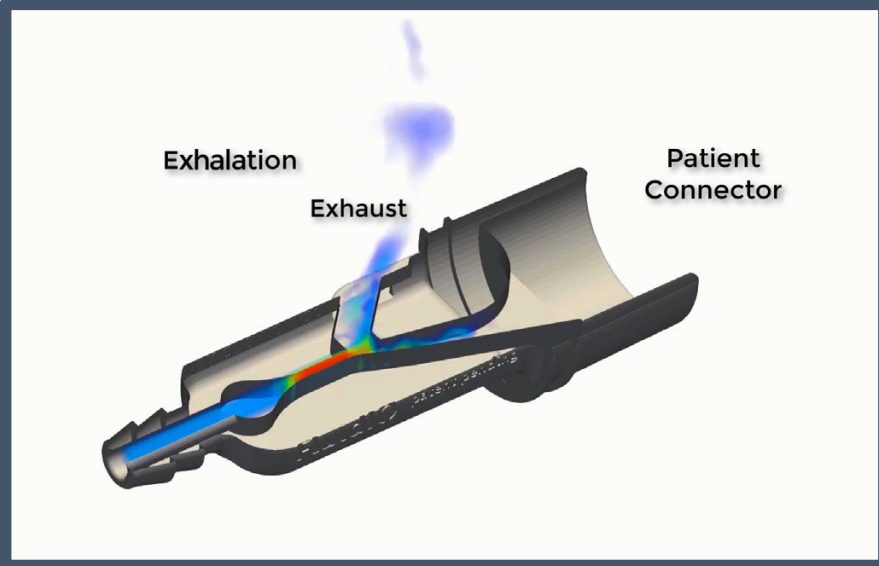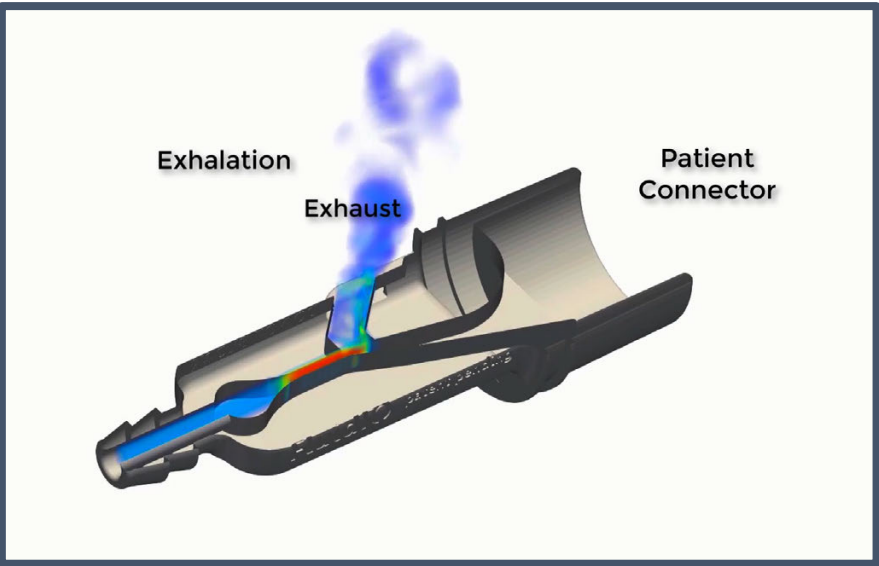- Emergency hands-free transport
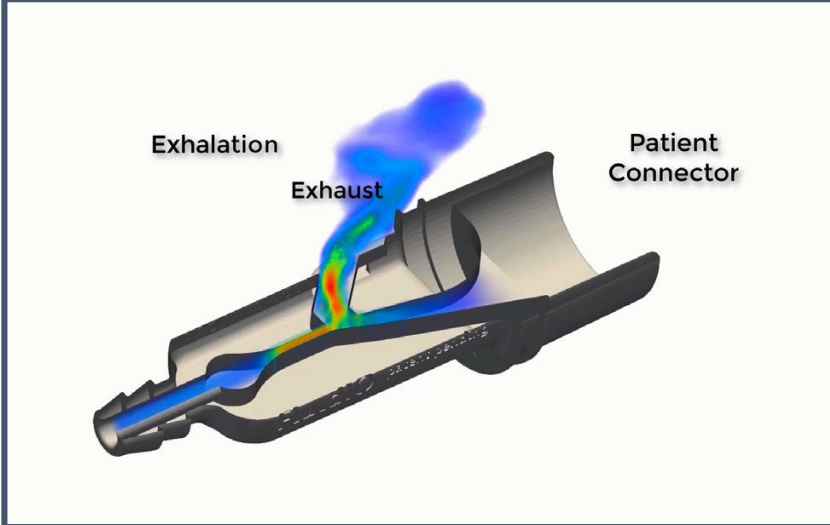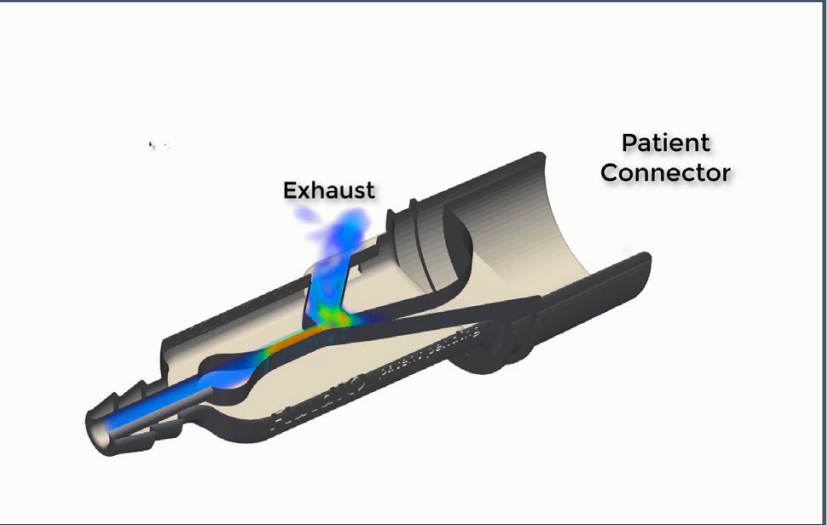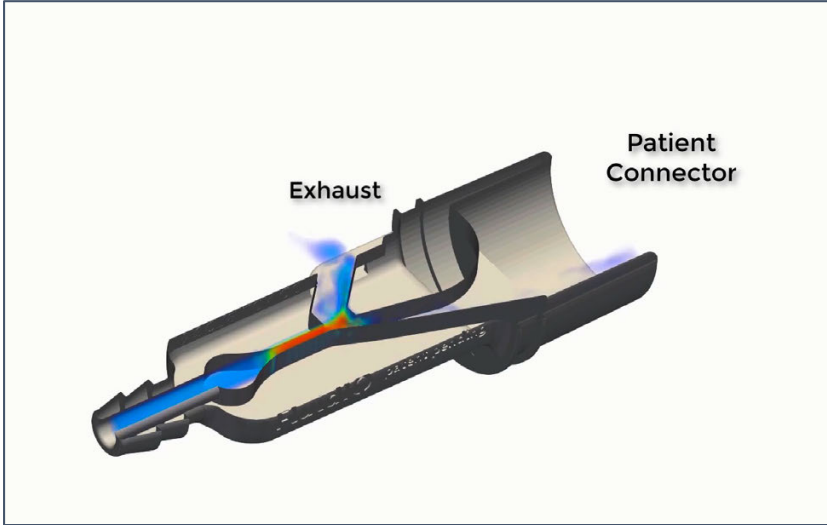- Military medicine

# Background Miniature In-line Respirator- Mechanism of action
## *Inspiration*

# Background Miniature In-line Respirator-Mechanism of action
## *Exhalation*

# Background Miniature In-line Respirator

- In vitro modeling
- Pre-clinical work to date - animal studies in pig (Science Translational Medicine, 2022)

# Design

- Developed by fluidIQ in response to pandemic, beginning winter 2020

- Simple: pressure cycled with no moving parts or manual adjustments

- Currently 3 models, each targeting a specific range of lung injury associated with mild (green), moderate (yellow), and severe (red) lung disease



| Model | Injury level | Compliance (mL/cm $H_2O$) | Resistance (cm $H_2O$/L/s) | PIP (cm $H_2O$) | PEEP (cm $H_2O$) | ΔP (cm $H_2O$) | O₂ Flow (L/min) | I:E | RR (bpm) | $\dot{V}$ (L/min) |
|---|---|---|---|---|---|---|---|---|---|---|
| Green | Mild | 50 | 5 | 16 | 6 | 10 | 25 | 1:2 | 14 | 8.3 |
| **Yellow** | **Moderate** | **38** | **10** | **22** | **10** | **12** | **25** | **1:2** | **16** | **8.3** |
| Red | Severe | 25 | 15 | 28 | 14 | 14 | 25 | 1:1.8 | 22 | 9.0 |

# Pressure Cycled Device—Inspiration

- Inspiration is a stable flow pattern

- When fixed peak airway pressure is reached, ventilator switches to expiration

- Ventilator reverts to inflow when fixed end airway pressure is reached
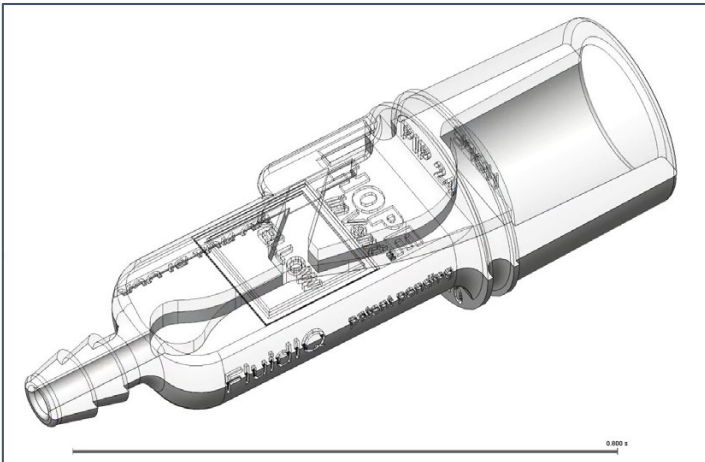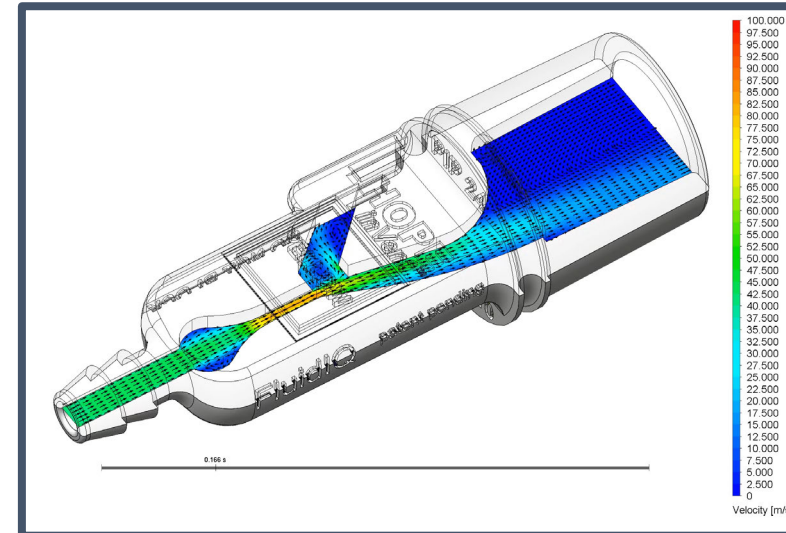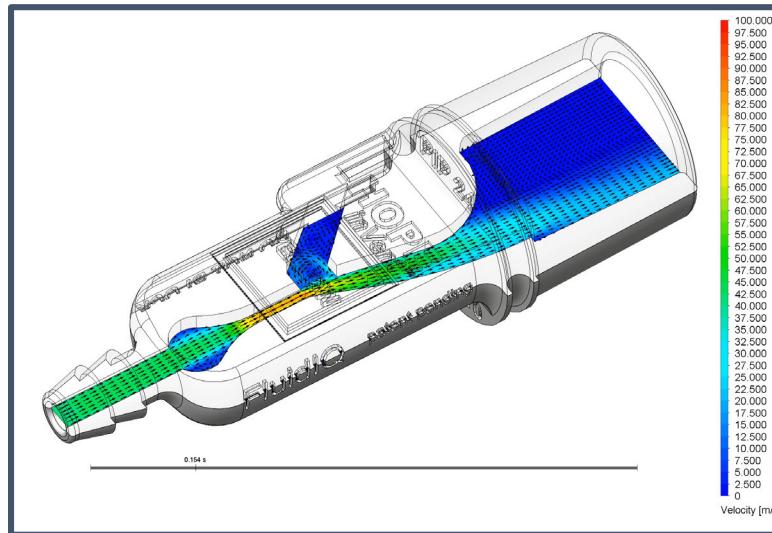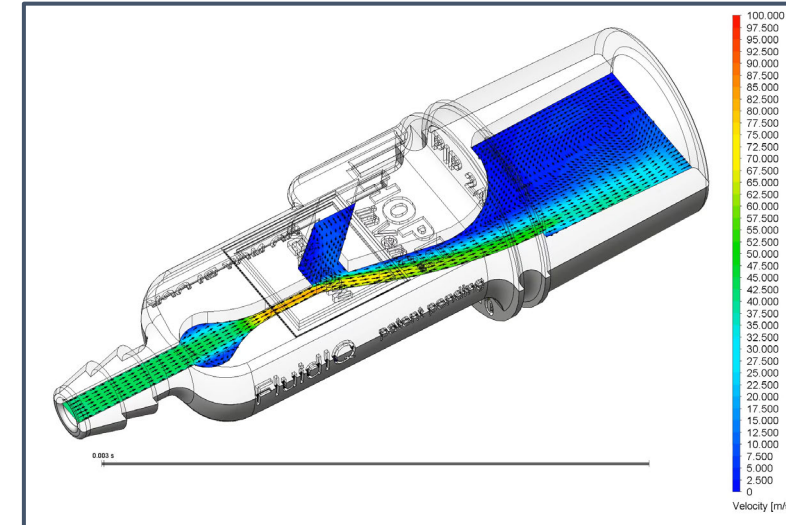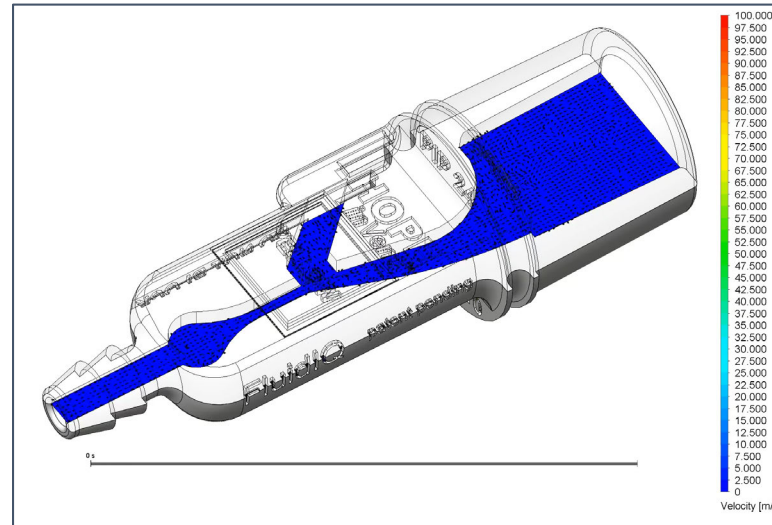
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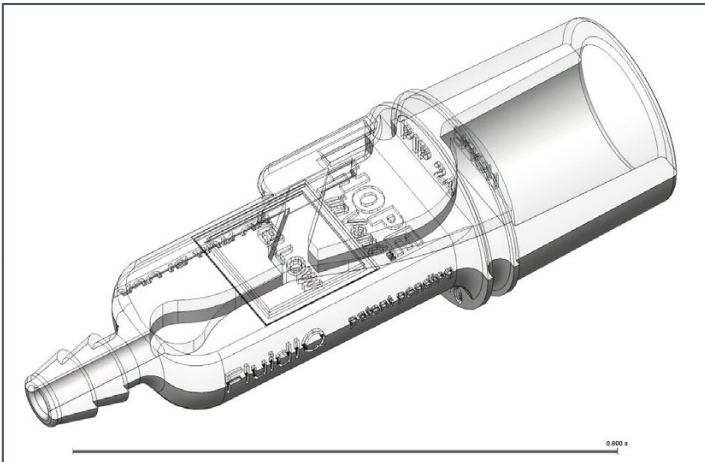
# Bench Testing

- Lung ventilation test system
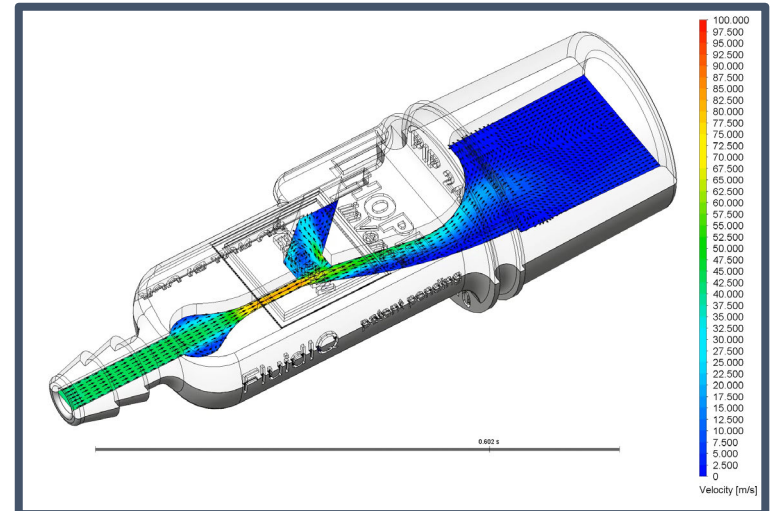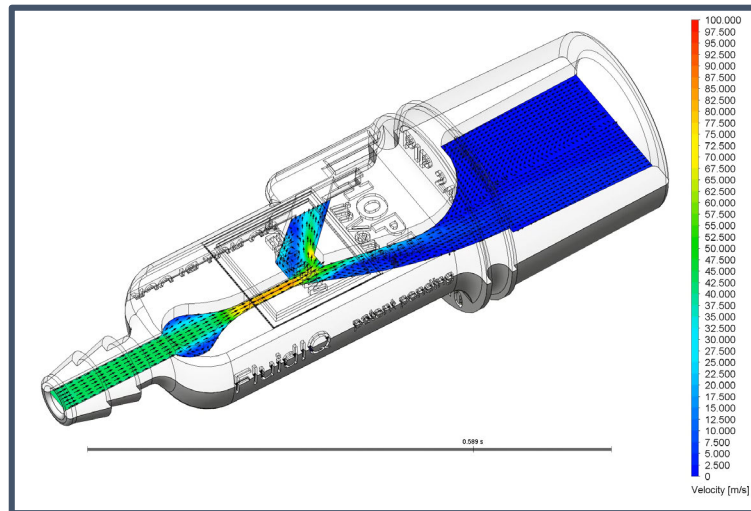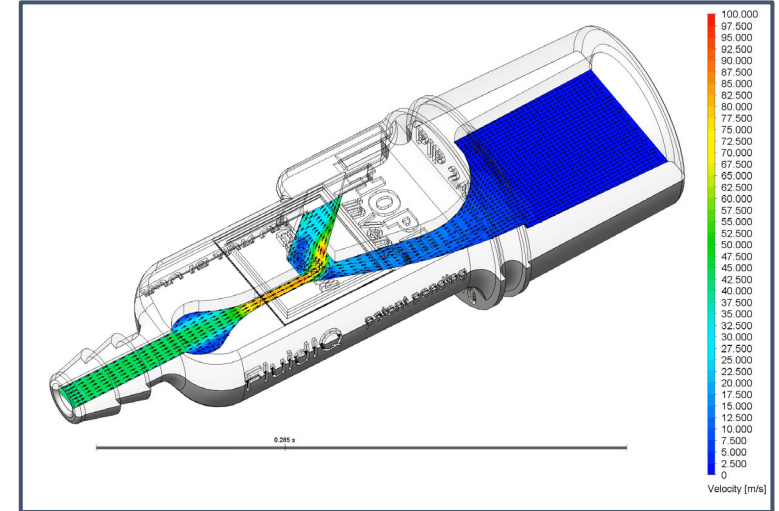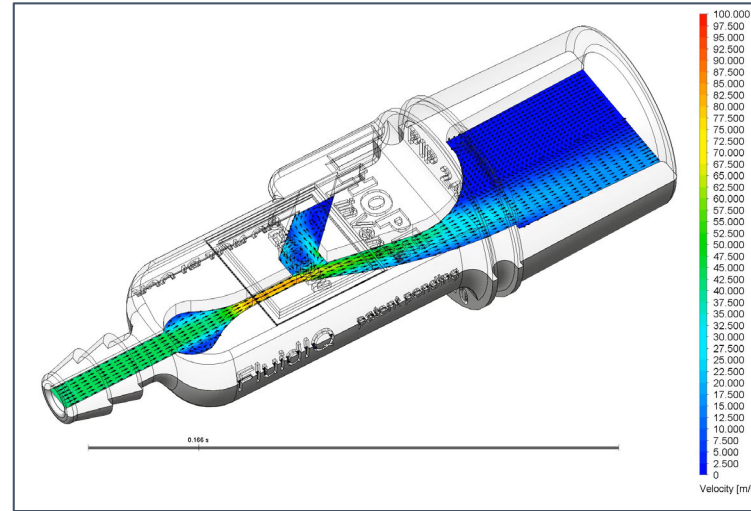- Simulated three fixed lung conditions: mild, moderate, and severe injury
- Tested ventilators against all 3 conditions: 2,250 breaths
- Performed well for mild and moderate injury

# Animal Testing

- Domestic swine up to 86 kg

- Arterial blood gasses, ventilation parameters with each ventilator model

- No difference in blood gasses on anesthesia ventilator vs test ventilator in normal animals

- Lung injury: administered detergent into the lungs

- Oxygen saturation on the ventilators was normal with or without injury

- Green and yellow ventilators adequately supported ventilation in mild/moderate injury

- Severe lung injury exceeded the operating parameters of the red ventilator
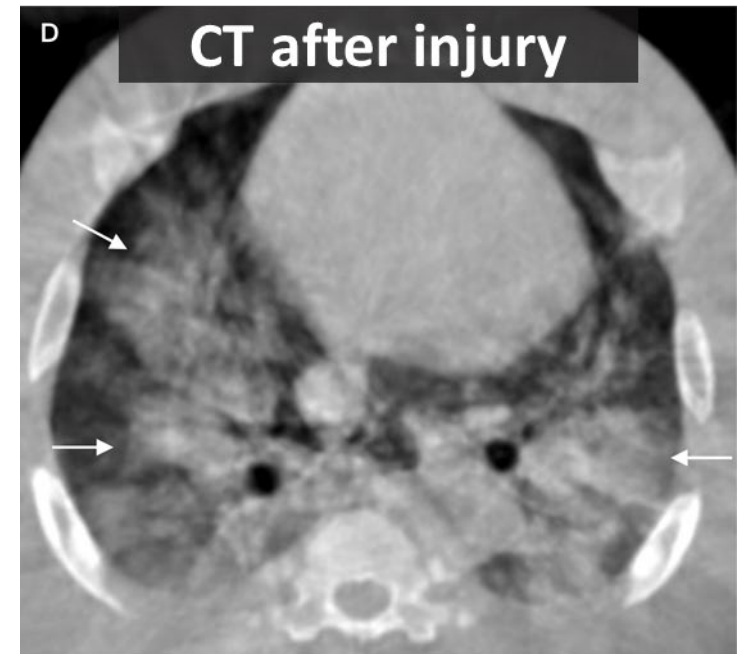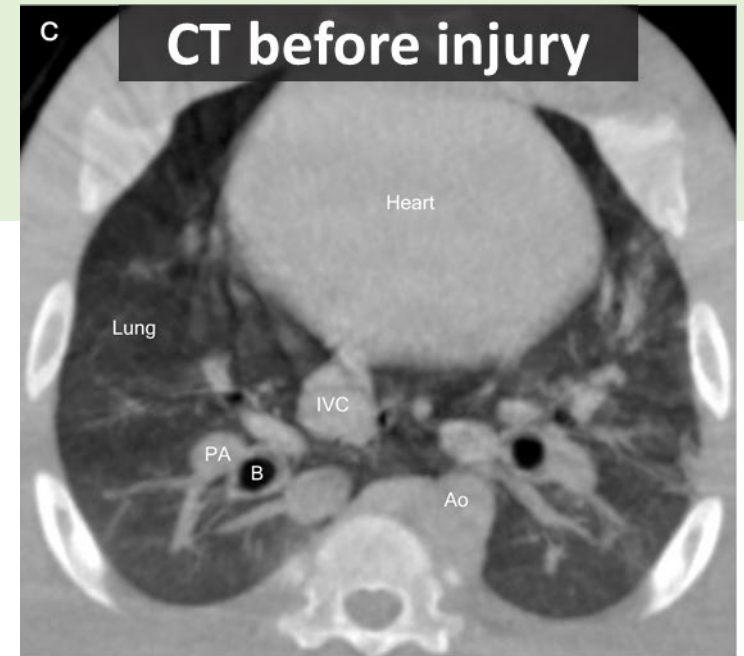
# Clinical Study Design

**Submitted to FDA**

- IDE application

- First in Human Study

**Study Design**

- Phase-I Clinical Trial

- Participants recruited from OR patient population

**Hypothesis**

- The miniature respirator will adequately ventilate patients during recovery from surgical procedures

# Study Summary

## Objectives

- Miniature respirator ventilates within acceptable range.
- Miniature respirator performs as designed.

## Study intervention

- Support patient at the end of a surgical procedure

## Recruiting up to 33 participants

- Referral from surgeons who have patients 18 and older requiring mechanical ventilation for a planned surgical procedure at NIH

# Data Collection in Study

**Safety Data**

- Adverse Event Monitoring (CTCAE)
- Adequacy of ventilation

**Assessment Measures**

- Respiratory parameters ($CO_2$, O2 saturation, TV, PEEP, PAP)
- Respiratory questionnaire
- History and Physical

# Investigator List

**Principal investigator:**

Andrew Mannes, MD

**Collaborators:**

- Bill Pritchard, MD
- Ning Miao, MD
- Kevin Driscoll, PhD
- Tracy Williams, RN
- Allison Manolo, BA

- John Karanian, PhD
- Brad Wood, MD
- Brian Walsh, PhD
- Brian Froelke, MD