



# Development of Helmet-Patient Interface for Non-Invasive Ventilation



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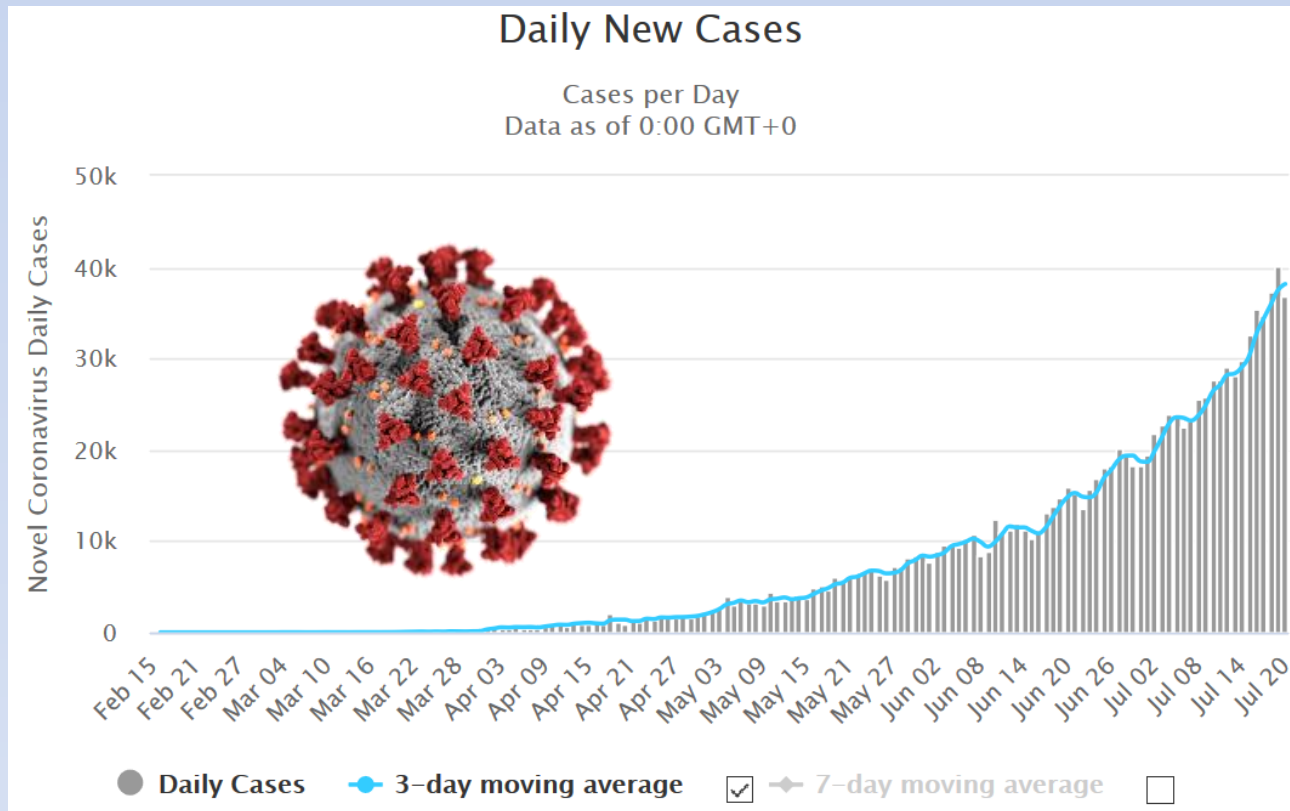


# Outline

- Need for non-Invasive ventilation (NIV) in COVID-19
- Product highlights and key features
- Engineering Innovations
- In-laboratory mechanical testing on mannequin
- Path to deployment with COVID-19 patients
- Summary



# Need for Non-Invasive Ventilation in COVID-19 in India



- Unprecedented health crisis in India
- Graph still exponential with 12.4 lakhs cases and 29,861 deaths (8 am July 23 )

- COVID-19 causes respiratory distress
- ~5% of the infected patients need oxygenation and ~2% need ventilator support
- High-flow Nasal Canula is conventionally used for oxygenation
- *A helmet patient interface (HPI) which delivers oxygen-rich air at a constant positive airway pressure (CPAP) is very effective way of oxygenation for COVID-19 Hypoxia patients*
- The effectiveness of this NIV helmet with COVID-19 patients has been reported from Europe



# Strong Case for Helmet Patient Interface

Esquinas Rodriguez et al. *Critical Care* 2013, 17:223  
<http://ccforum.com/content/17/2/223>



## REVIEW

### Clinical review: helmet and non-invasive mechanical ventilation in critically ill patients

Antonio M Esquinas Rodriguez<sup>1\*</sup>, Peter J Papadacos<sup>2</sup>, Michele Carron<sup>3</sup>, Roberto Cosentini<sup>4</sup> and Davide Chiumello<sup>5</sup>

- Clinical review of 152 studies establishes efficacy of helmet-based NIV
- NIV with helmet reduces CO<sub>2</sub> rebreathing and ventilator asynchrony
- Review concludes *“NIV delivered by helmet could be safe alternative to the face mask in patients with acute respiratory failure”*



*Helmet used in Italy with CPAP*

## Suggested key points

- Long duration NIV
- Skin lesions
- Air leaks in masks/Mask intolerance
- Avoid CPAP via Mechanical Ventilator
- 50% higher PEEP with helmets as compared to masks

*J Cardiothorac Vasc Anesth.* 2020 May 8

doi: [10.1053/j.jvca.2020.04.060](https://doi.org/10.1053/j.jvca.2020.04.060) [Epub ahead of print]

PMCID: PMC7205670

PMID: [32540245](https://pubmed.ncbi.nlm.nih.gov/32540245/)

### Role of Helmet-Delivered Noninvasive Pressure Support Ventilation in COVID-19 Patients

[Richard J. Ing](#), MBBCh, FCA (SA),\*<sup>†</sup> [Corey Bills](#), MD, MPH,<sup>†‡</sup> [Glenn Merritt](#), MD,<sup>§¶</sup> [Rosalia Ragusa](#), MD,<sup>||</sup> [Ross M. Bremner](#), MD,<sup>#</sup> and [Francesco Bellia](#), MD\*\*





# Helmet Patient Interface (HPI) Non-invasive Ventilation (NIV) for Hypoxia

## INDUSTRY-ACADEMIA COLLABORATION

## HPI SPECIFICATIONS

- Continuous Air/O<sub>2</sub> delivery
- Adjustable flowrate: 15 – 60 LPM
- FiO<sub>2</sub> between 21% (Air) to 100% (Pure O<sub>2</sub>)
- Adjustable expiratory pressure : 5 – 20 cm H<sub>2</sub>O
- *HPI works with CPAP device, wall oxygen-air supply, or any commercial ventilator*



Continuous Positive Air  
Pressure-Helmet  
Patient Interface  
(CPAP-HPI)  
is a *ready-to-use device*

Studies have found *non-invasive ventilation to be extremely effective* based on objective parameters of pulmonary mechanics, biochemistry and final treatment outcomes\*



# Key Features and Benefits

- **Benefits for the Patient**

- Ventilation asynchrony is not present, minimizes claustrophobia, avoids pain and sense of suffocation
- No nasal cannula or intubation, no headgear to tighten, no irritation → Comfort for a longer period
- Spacious with a clear view all around
- Patient can speak, listen, drink, wear glasses while being treated



Manometer



Catheter Port

- **Patient Management**

- Due to completely sealed and “zero leakage”, *protects associated health workers*
- As patient is more comfortable, treatment is continued without breaks associated with intubation, mask pressures, nebulized drug therapy etc.
- **LARGE ACCESS PORT:** For easy care - drink, facial cleaning, expectorate
- **SEALED CATHETER PORT:** Provides access for drug delivery, sensors, liquid intakes
- The upper portion is easily removable



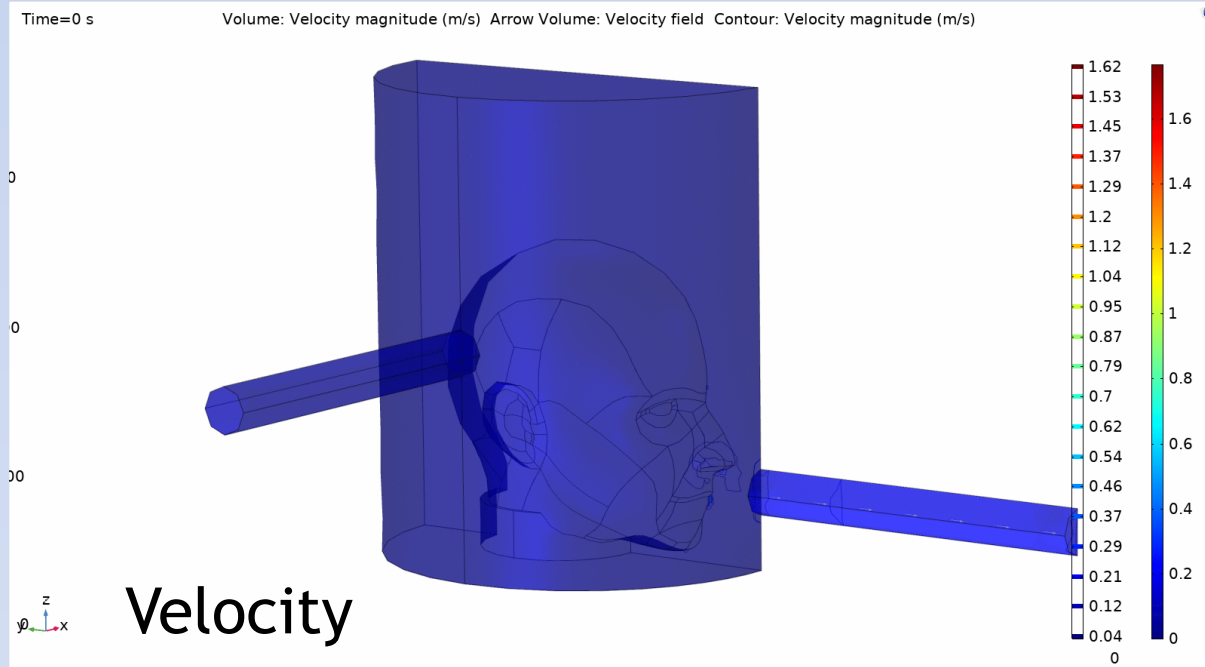
Anti Asphyxia Valve

- **Safety Features and Alarms**

- Anti-asphyxia valve and pressure relief valves
- The HEPA filter ensures patient exhales pathogen-free air for safety of health workers
- **AUDIO-VISUAL ALARMS:** Low Pressure/High Pressure/Battery Fault/Low Battery/Battery Charge Indicator
- Separate flow meters for oxygen and total flow/FiO2 calculator (On CPAP device)

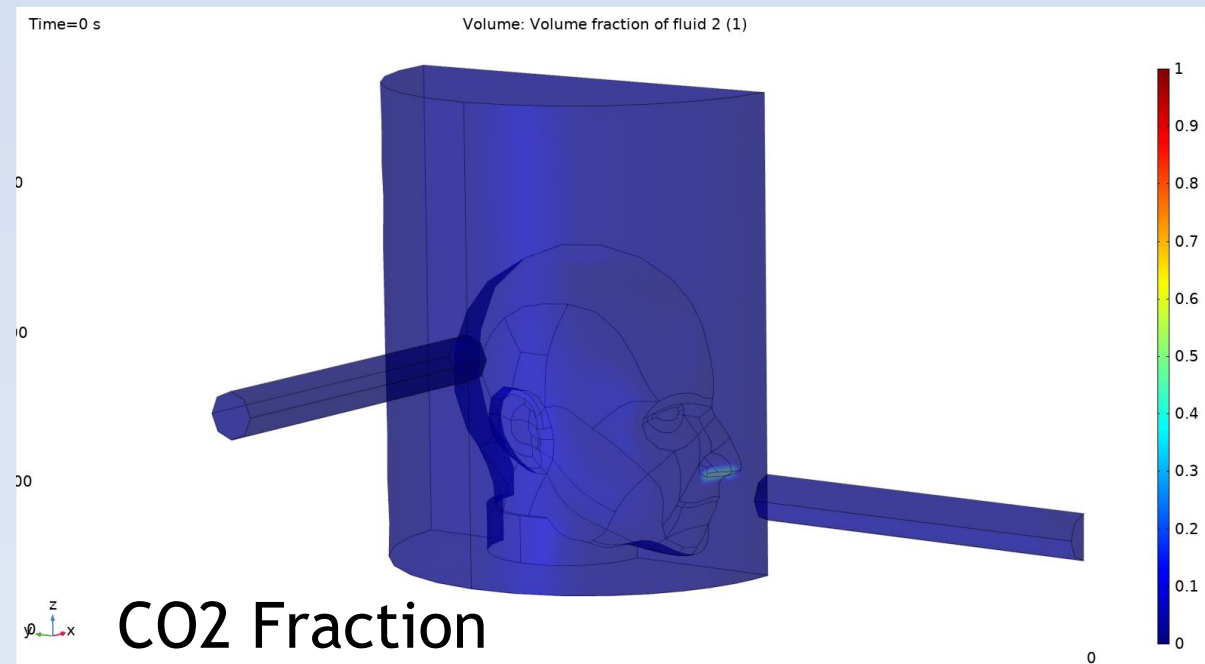


# Engineering Innovation

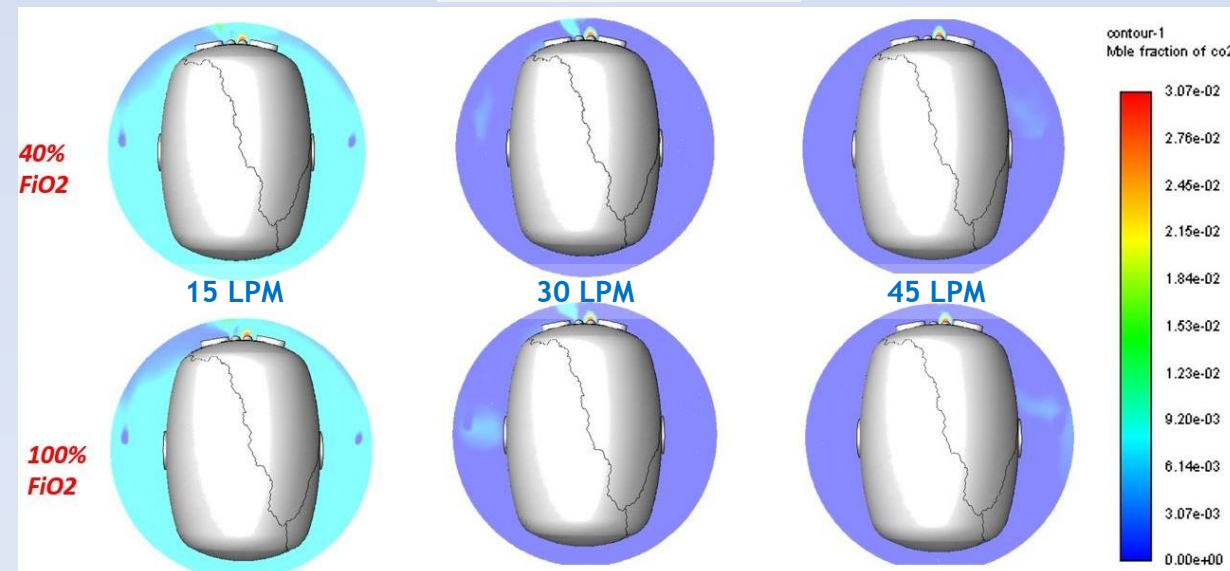


## Computational Fluid Dynamics (CFD)

- CFD analysis provides a streamlined flow of air/oxygen under different flow rate conditions.
- Inlet/Outlet locations optimized for minimum CO<sub>2</sub> rebreathing and maximum oxygenation



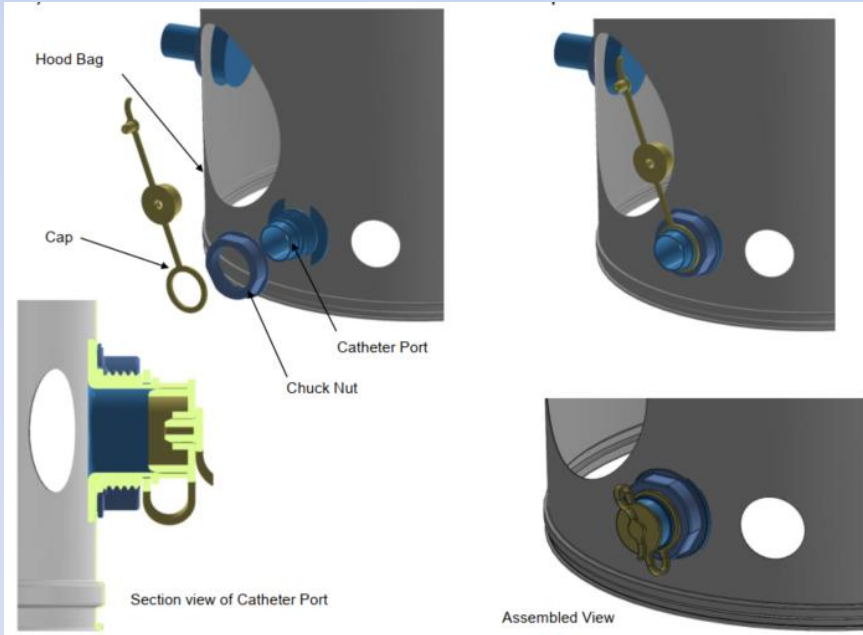
### CO<sub>2</sub> MOLE FRACTION





# Engineering Innovation

## Design Iterations for Improved Ergonomics and Patient Comfort

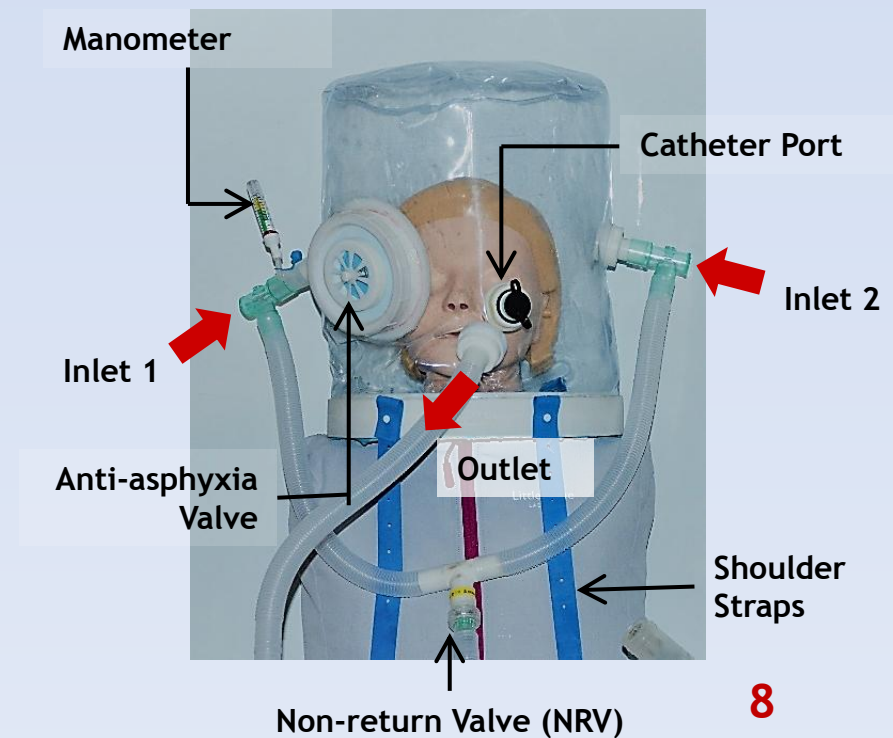
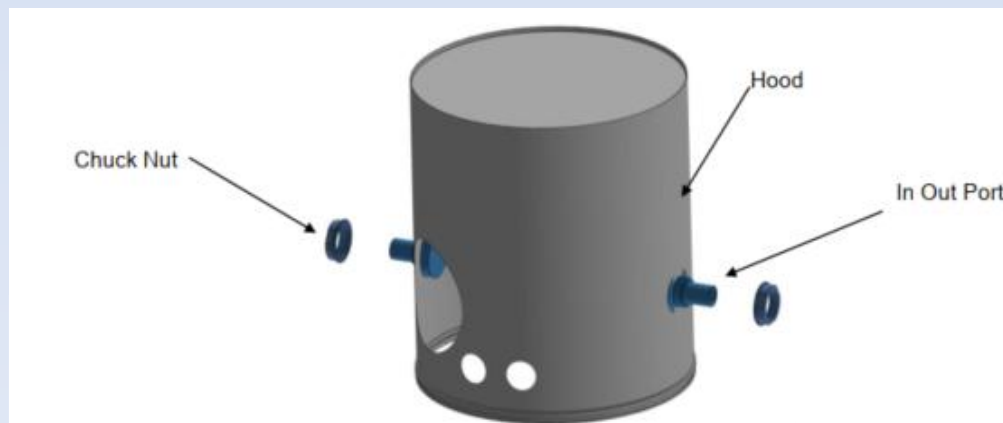


Large access ports and catheter ports for quick access



Neck ring with cushion and neck seal added to provide comfort and reduce leakage

Two inlets near ears and one outlet in front of the nose to improve flow





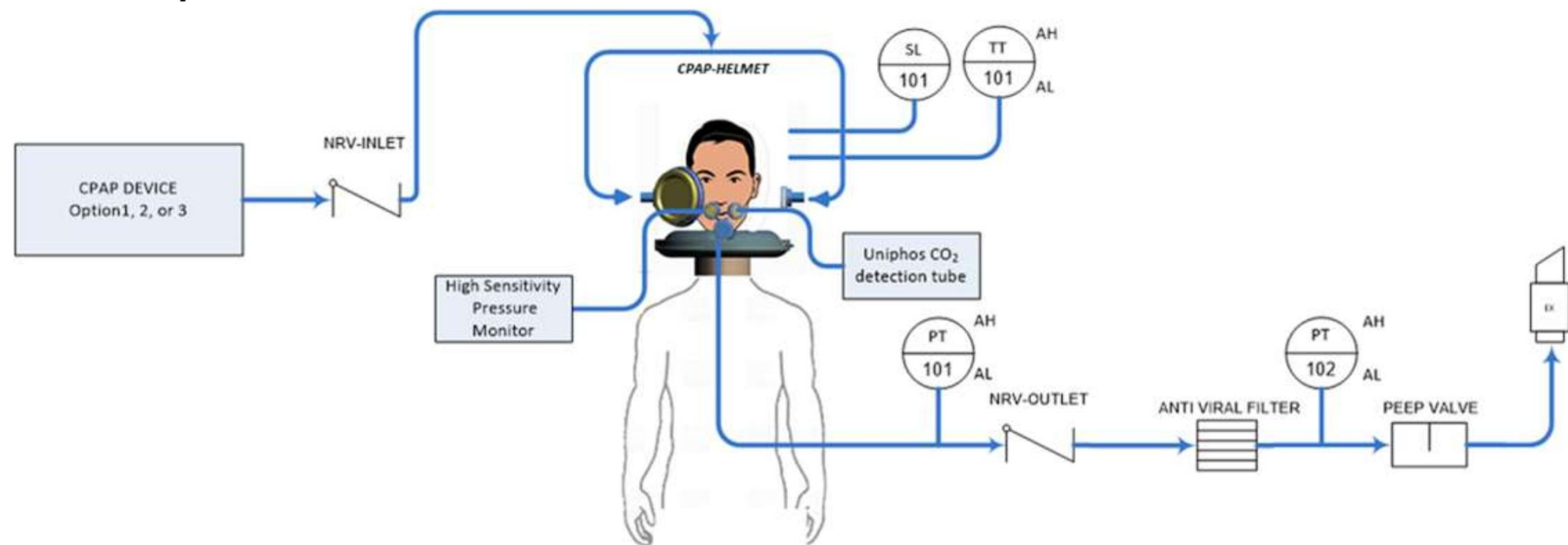


# System Verification and Validation

## Test protocols designed to verify the functioning of the device

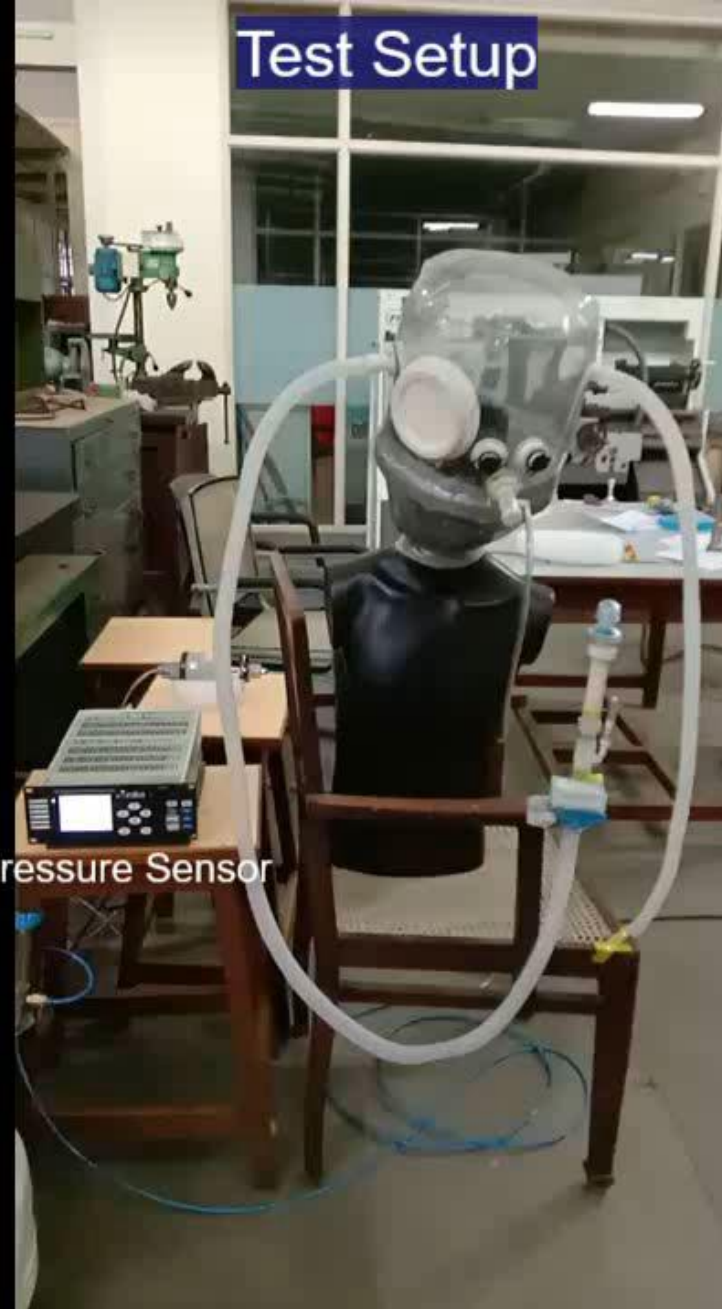
- Integrity, leakage and pressure hold test (up to 30 cm H<sub>2</sub>O pressure)
- Flow and pressure drop test (up to 40 LPM flow)
- PEEP pressure hold test (up to 40 LPM flow, 20 cm H<sub>2</sub>O pressure)
- High flow mode test (up to 60 LPM)
- Helmet fitment, fogging, and noise level test (on mannequin)
- Safety interlock check

### Test Setup:





# System Verification and Validation





# Final Design





# Path to Deployment: 2-Stage Clinical Studies

## Stage I: Healthy Participants

- No history of respiratory disorder (preferred age < 35 years)
- In collaboration with IIT Bombay Hospital
- Following issues will be studied
  - Noise harshness assessment
  - Discomfort due to retinal pressure
  - Assessment of helmet ergonomics
  - CO<sub>2</sub> concentration in the helmet

## Stage II: COVID-19 Patients

- COVID 19 induced Hypoxia (preferred age > 35 years)
- In collaboration with Tata Memorial Hospital
- Following issues will be studied
  - SpO<sub>2</sub> measurement
  - Arterial Blood Gas (ABG) /Blood chemistry
  - Noise harshness assessment
  - Discomfort due to retinal pressure
  - Assessment of helmet ergonomics





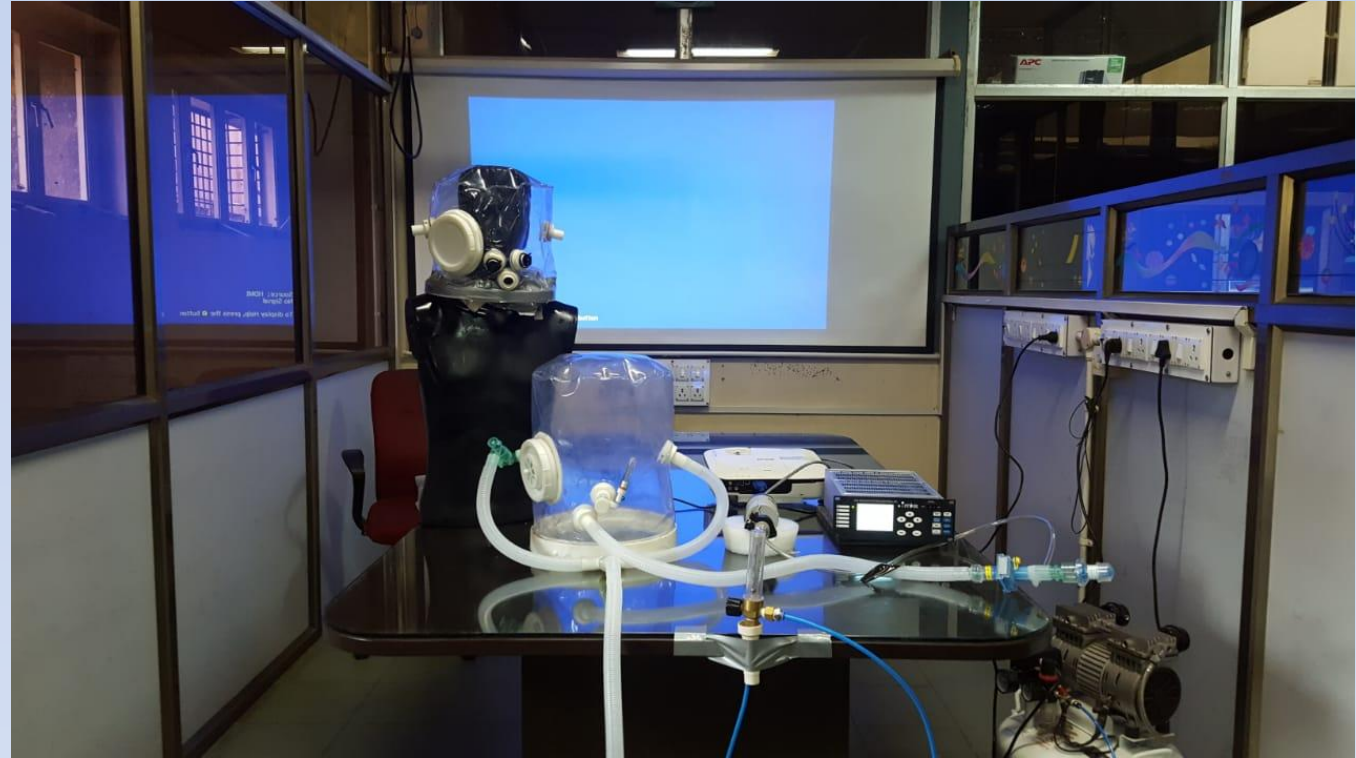
# Path to Deployment: Status

- The Helmet Patient Interface has been engineered for optimal performance and has been manufactured to design specifications
- It has been tested comprehensively for mechanical integrity and flow performance in the lab
- IIT Ethics committee suggestions received for Stage I clinical studies at IIT Bombay Hospital
- Plan to conduct Stage I studies before August 15
- Stage II studies at Tata Memorial Hospital will be conducted after the data is analyzed from Stage I
- Partners on-board with capability to scale up. An excellent example of Industry-Academia Collaboration



# Acknowledgements

- Machine Tools Lab Students & Staff
  - Chaitanya Vundru, Bhargavi Ankamreddy, Arun Nayar, Vasudevan Nayar and Vishwas Kevale
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- IIT Hospital
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- InnAccel
  - Mr. Vijayarajan
- Dr. Satish Deopujari



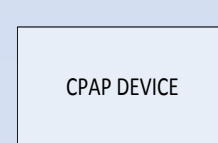


# Extra Slide

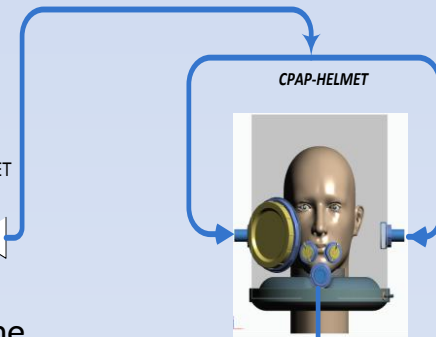
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- Expiratory pressure in range 5-20 cm H<sub>2</sub>O

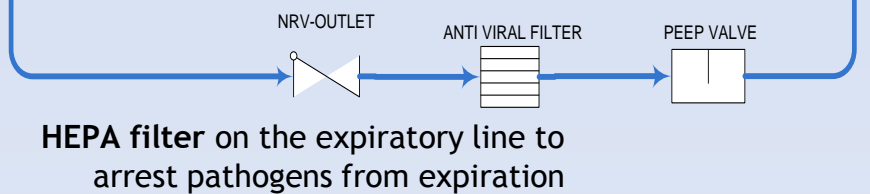
## SYSTEM SCHEMATIC



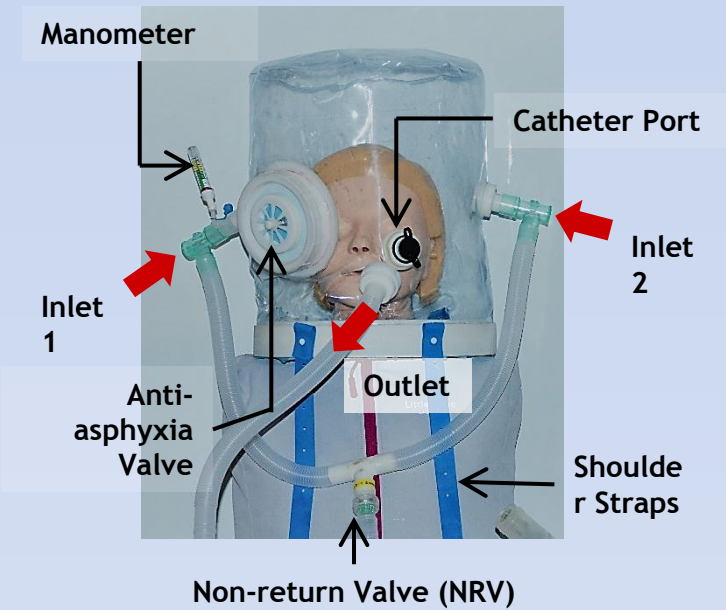
CPAP device provides the continuous flow at positive pressure and is attached to the inlet NRV.



Adjustable PEEP valve maintains the positive pressure as desired by doctors, the set positive pressure is indicated on the manometer on HPI.



HEPA filter on the expiratory line to arrest pathogens from expiration



Anti Asphyxia Valve



Catheter Port



Manometer